Jenny®

Instructions for Use

reddot award 2016
winner

DESIGN AWARD 2015

Manufacturer

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CE 2797

TABLE OF CONTENTS

1 Introduction

These **Jenny®** *Instructions for Use* provide basic information on operating and troubleshooting the Jenny®. Before using the Jenny® thoroughly read this manual. For the latest version of the **Jenny®** *Instructions for Use* please visit our website:

http://www.mswestfalia.com

or contact your local *MS Westfalia* partner.

For detailed information on how to service please carefully read the **Jenny®** *Service Manual*, which can be found on the above-mentioned website, or be provided by your local partner.

Table 1-1. Instructions for Use Versions of the Jenny®.

Issue	Date	Instruction for Use version	Software version
1	04/04/2017	EN V1.0	1.0
2	22/01/2019	EN V2.0	2.0
3	15/07/2019	EN V2.0	2.0

2 Safety notice

This chapter contains the main safety notices (warnings, cautions and notes) an operator needs to take in account when using the Jenny®.

2.1 Safety symbols and messages used in this user manual

The definitions of the safety symbols and warnings are listed in the following table.

Table 2-1. Safety symbol definitions

Symbol	Description
WARNING:	Indicates a potentially hazardous situation that could result in death, injury or adverse outcomes to the patient or the user and/or substantial damage to the environment.
CAUTION:	Indicates a potentially hazardous situation that could result in moderate injury to the patient or the user and/or moderate damage to the environment. It may also be used to alert against device related problems, such as device malfunction, failure, damage and other material damages. Maybe used to alert against unsafe practices.
NOTE:	Indicates additional guidelines or information that should be followed for a proper device installation, operation or service.

2.2 General safety remarks

The following are general warnings and cautions relevant to a safe operation of the device. Additional module specific warnings, cautions and notes are found next to the corresponding instructions in this document.

WARNING:

Read this user manual thoroughly before proceeding with the installation, connection and operation of the device.

WARNING:

Make sure that only trained qualified medical personnel uses the equipment to administer treatment in order to avoid the possibility of physical injury to the patient or to the operator.

 **WARNING:**

Do not use the equipment if it has a malfunction. Replace the device or the corresponding module and have the malfunctioning unit repaired by authorized trained service technicians.

 **WARNING:**

The equipment, in all product configurations, is restricted to be used with one patient at a time.

2.3 Safety during transport, installation and maintenance

 **WARNING:**

Internal parts of the equipment shall not be serviced or maintained while using the equipment with a patient.

 **WARNING:**

Only internal MS Westfalia staff trained for the maintenance of this equipment shall conduct reparations or maintenance.

 **WARNING:**

Make sure that the preventive maintenance procedures described in this manual are performed correctly in the intervals specified.

 **WARNING:**

Do not install the equipment adjacent or stacked with other equipment.

 **WARNING:**

During installation, do not place the equipment or its accessories close to anything that would block or reduce the performance of:

- The air inlet in the Ventilator Module
- The gas inlets in the Ventilator Module
- The exhaust port and expiration valve in the Ventilator Module
- The sound speakers in the Docking Station
- The alarm LEDs in the Docking Station

WARNING:

During installation, do not position the equipment in a way that makes it difficult:

- To disconnect the patient from the equipment in any of its configurations
- To exchange the operational battery
- To access the defibrillation paddles

WARNING:

During operation, do not place the equipment or its accessories close to anything that would cover, block or reduce the performance of:

- The air inlet in the Ventilator Module
- The gas inlets in the Ventilator Module
- The exhaust port and expiration valve in the Ventilator Module
- The sound speakers in the Docking Station
- The alarm LEDs in the Docking Station

WARNING:

For a safe operation, mount the equipment only to the wall mounts, transportation frames or trolleys supplied by MS Westfalia.

CAUTION:

To prevent possible equipment damage, make sure that all modules are removed from the Docking Station while transporting the device from one location to another when the device is not put into operation.

CAUTION:

Remove the operational and reserve batteries before having the device transported in a vehicle. Observe the local regulation about transportation of Lithium-ion batteries.

2.4 Electrical safety

WARNING:

To guarantee the protection of the equipment, patient and operator(s) against effects of a cardiac defibrillator discharge, use only the cables and accessories approved for use with the equipment listed in this user manual .

WARNING:

Do not operate or store the device in the vicinity of strong electromagnetic fields, such as MR imaging equipment.

2.5 Fire and other hazards

WARNING:

Do not operate the device in the vicinity of flammable anesthetic gases or any other flammable substance. Placing the device in an oxygen-rich environment could increase the risk of fire due to accelerated combustibility.

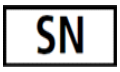
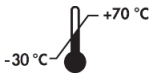
WARNING:

Do not operate the device in the vicinity of explosive substances.

2.6 General symbols description

Table 2-2 describes the symbols printed on labels and packaging. For additional symbols printed on the Docking Station, batteries or modules refer to chapter 4.

Symbol	Description
Symbols on labels	
	Manufacturer
	Date of manufacture
	CAUTION! Consult accompanying documents for safety-relevant information
	Consult Instructions for Use for complete information
	The device meets the requirements for electrical protection Class II

Symbol	Description
	Defibrillation-proof type BF applied part
	Defibrillation-proof type CF applied part
	Disposal per European Directive 2002/96/EC or WEEE (Waste Electrical and Electronic Equipment)
IP54	Protected against dust and splashing water
	Serial number
CE 2797	CE Marking of Conformity, Notified Body 2797, BSI
Symbols on packaging	
	Single use only. DO NOT REUSE
	Storage Temperature range: - 10 … to …+ 50 °C

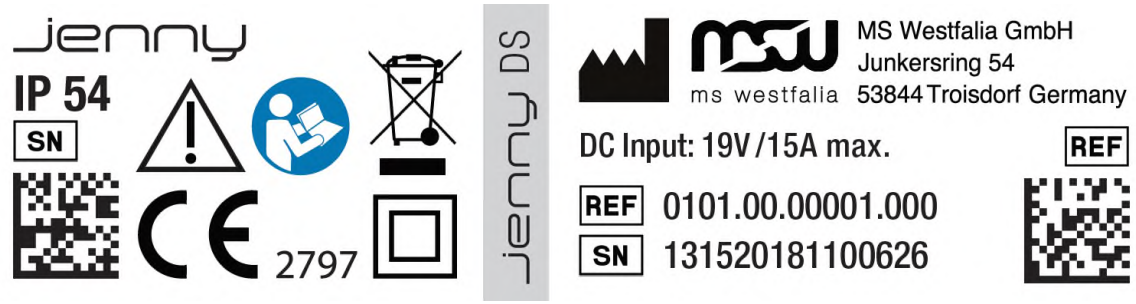


Figure 2-1: Docking Station Label

Figure 2-2: Ventilator Module Label

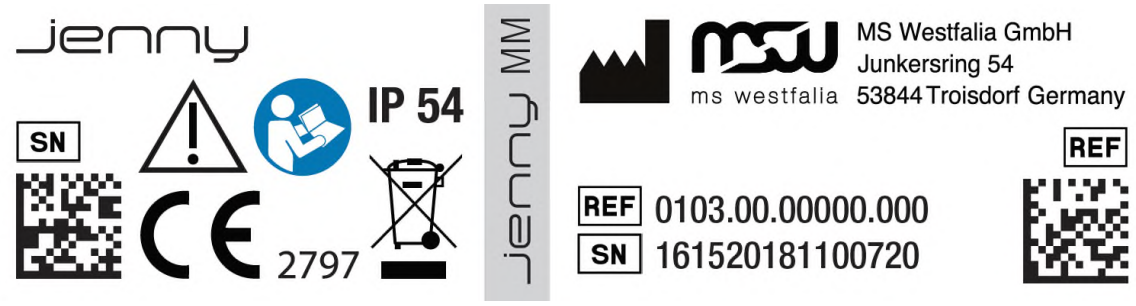


Figure 2-3: Monitoring Module Label

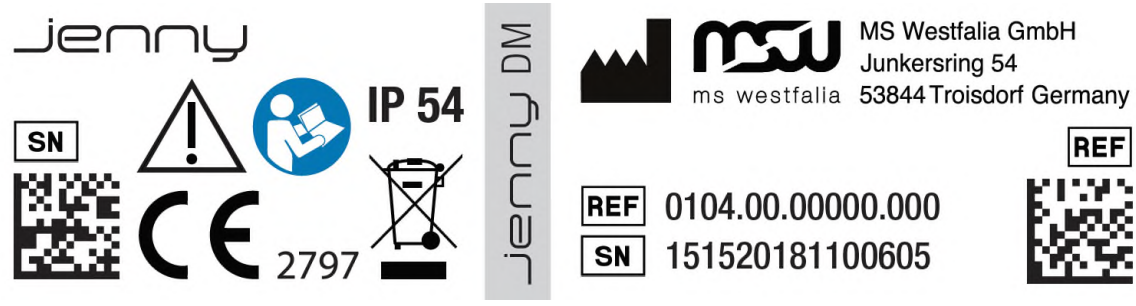


Figure 2-4: Defibrillation Module Label

3 Electromagnetic Compatibility

WARNING:

Operation of the equipment below the specified minimum amplitude of patient physiological signals for certain functions may cause innacurate results.

WARNING:

The use of accessories, transducers or cables other than specified in this manual may result in increased emissions or decreased immunity of the Jenny® equipment.

WARNING:

The use of Jenny® accessories, transducers or cables with other medical devices or medical systems may result in increased emissions or decreased immunity of the medical devices or medical systems.

The Jenny® complies with the requirements for IEC 60601-1-2:2007 on electromagnetic immunity.

The operator should be aware of possible radio frequency interference if portable and RF devices are operated near the devices.

The equipment requires special precautions to be taken regarding EMC and must be installed and put into service per the EMC information provided in section 9.6

4 Product Overview

Jenny® is a mobile, modular intensive care station. Its function includes ventilation, monitoring and defibrillation.

Jenny consists of:

- the Docking Station (DS)
- 3 modules –Ventilation Module (VM), Monitoring Module (MM) and Defibrillation Module (DM)
- Additional components –Transport Frame (TF), Wall Mount hospital (WMH), Transport Wall Mount for ambulance car (TWM), Trolley (TR), and Docking arm for Hospital (DAH).

The areas of application are:

- Pre-clinical - outside hospitals or clinics, or any other medical service facility.
- Inter-clinical - during transport to and from a medical service facility (ambulance car, helicopter).
- Intra-clinical - during transport inside a medical service facility.
- Intensive care unit
- Emergency care - in emergency service facilities dedicated other to out-of-hospital acute medical care, transport to definitive care, and other medical transport.
- Routine medical care - in routine medical care facilities including but not limited to primary center hospitals, secondary center hospitals, tertiary care hospitals, clinics, and clinical facilities.

Table 1. Configuration management for the use cases

Use case	Environment	Required components
1	Pre-clinical	Transport Frame (TF)
2	Inter-clinical	Transport Frame (TF) Transport Wall mount (TWM)
3	Intra-clinical	Transport Frame (TF)
4	Intensive Care Unit	Wall mount hospital (WMH) Docking arm hospital (DAH) Trolley (TR)
5	Emergency care	Wall mount hospital (WMH) Docking arm hospital (DAH) Trolley (TR)
6	Routine medical care	Wall mount hospital (WMH) Docking arm hospital (DAH) Trolley (TR)

NOTE:

The serial number or the IFU version number from which on an airborne usage of the Jenny system is possible will be communicated in a separate announcement document to customer.

4.1 Intended use

Jenny system is a mobile, modular, medical device. Its functionality includes vital parameter monitoring, ventilation and defibrillation in stationary and transport use (only with TF and TWM). The intended use of each module is described in the corresponding chapter.

Patient population:

- Adults
- Children
- Neonates

Operator information:

- The operator is responsible for selecting the appropriate:
  - Accessories
  - Single use parts
  - Module settings
  - Alarm settings for each patient

4.1.1 Docking Station

The Docking Station is intended for the operation and control of the connected modules.

The Docking Station functions as:

- Graphical user interface
- Alarm system
- Power supply
- Telemetry
- Data storage

Patient population: N/A.

4.1.2 Ventilation module

The Ventilation Module is intended for adults, children, infants, term and preterm neonates (minimum body weight 300 g) who require respiratory support or mechanical ventilation. The Ventilation Module is intended to provide long-term invasive and non-invasive continuous positive pressure ventilation, high-flow and low-flow oxygen

therapy, inspiratory nebulization of pharmaceuticals under ventilation and monitoring capnography ($EtCO_2$) under direct supervision of a trained physician.

4.1.3 Patient monitoring module

The Monitoring Module is intended for monitoring the following physiological parameters and direct supervision of a trained physician:

- Diagnostic support (HES®) and non-diagnostic ECG and related printouts
- Arrhythmia detection
- Automatic ST segment analysis
- Respiratory Rate
- Masimo Rainbow SET® Pulse Oximetry Parameters: SpO2, PR, PI and Pulse CO-Oximetry Parameters: SpHb, SpCO, SpMet, SpOC, PVI, ORI Capnography (EtCO2)
- Four-channel Invasive Blood Pressure (IBP) : Invasive Blood Pressure (IBP), Central Venous Pressure (CVP), Intracranial Pressure (ICP)
- Non-Invasive Blood Pressure (NIBP)
- Two-channel Temperature

The diagnostic ECG (HES®) printout is supporting but not replacing the diagnosis by a physician.

Arrhythmia detection and ST Segment Analysis are intended for adults and pediatric patients only.

The arrhythmia detection is not intended for atrial fibrillation and/or flutter.

WARNING:

The pulse CO-oximeter parameters (Masimo Rainbow ® parameter set) should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

The pulse CO-oximeter is not an apnea monitor.

The pulse CO-oximeter should not be used for arrhythmia analysis.

4.1.4 Defibrillation module

The defibrillation module is intended for the termination of ventricular fibrillation (VF) and pulse absent ventricular tachycardia (VT).

The defibrillation module provides the following modes of operation:

1. Automated External Defibrillation (AED)
2. Manual defibrillation
3. Cardioversion

4. Non-invasive pacing

The AED mode is intended for patients from the age of 1 year and adults who are unresponsive, not breathing and pulseless, using adult-sized pads. For children from the age of 1 year to 8 years, it must be used with pediatric pads, if available.

The manual defibrillation is intended for patients who are pulseless and unresponsive.

The cardioversion mode is intended to revert unstable supraventricular tachyarrhythmia, unstable atrial fibrillation, unstable atrial flutter, and unstable monomorphic (regular) VT.

The non-invasive pacing mode is intended to revert bradycardia, bradyarrhytmia, and symptomatic heart blocks (clearly dependent on physician's decision).

Operator information:

- The AED mode is intended for use by responders with BLS training and qualification
- The Defibrillation, Cardioversion and Non-Invasive Pacing modes are intended for use by responders with ACLS training and qualification, or other physician authorized by emergency medical response program.

4.2 Contraindications

Jenny is not intended for use in a home care environment.

Jenny is not intended for use in presence of strong electromagnetic fields, MRI environments, hyperbaric chambers and explosive or flammable environments.

4.2.1 Ventilator Module

Positive pressure ventilation is contraindicated in the presence of untreated pneumothorax; application decision can only be made by an experienced physician.

Positive pressure ventilation via turbine has physical limitations on neonatal patients being transported in helicopters; application decision can only be made by an experienced physician.

Positive pressure ventilation needs to be paused during analysis phase and shock application in AED mode.

Positive pressure ventilation might be paused during analysis phase and shock application in manual and pacer mode.

Noninvasive ventilation (NIV) is contraindicated in the following situations:

- Inability to protect airway
- Facial or brain injury

- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Gastric distension
- Intolerance of the selected interface (e.g. mask, helmet, prongs)
- Untreated pneumothorax
- Severe bullous lung disease
- Patients requiring mechanical ventilation and intubation
- Patients with inability for spontaneous breathing

An application decision towards NIV can only be made by an experienced clinician.

High Flow Oxygen Therapy is contraindicated in the following situations:

- Dehydration
- Hemodynamic instability
- Airway obstruction, including blocked nasal passages/choanal atresia
- Facial or nasopharyngeal trauma (including skull base fracture)
- Nasopharyngeal or cranial surgery
- Epistaxis
- Cerebrospinal fluid leak
- Untreated pneumothorax
- Severe bullous lung disease

4.2.2 Monitoring Module

The NIBP monitoring is contraindicated in patients with sickle-cell disease or any condition where skin damage has occurred or is expected.

4.2.3 Defibrillator Module

The AED mode is contraindicated in the following scenarios:

- Neonates
- Patient is conscious
- Patient is breathing
- Patient has a responsive behavior

If any of the above signs of life are present, the device should NOT be used on the patient. The ECG data derived from DM are not intended to be used as source of information for further diagnostic decisions besides defibrillation initiation.

Defibrillation shock initiation is contraindicated for pulseless electrical activity (PEA) and asystole.

The pacing mode is contraindicated in VF/VT/asystole.

The cardioversion mode is contraindicated in Automatic arrhythmias include ectopic atrial tachycardia, multi focal atrial tachycardia (MAT), and junctional tachycardia.

4.3 Product configurations

The following product configurations are possible:

Configuration	Description	Additional instructions
1. Docking station only	No modules attached. No therapeutic, monitoring or diagnostics functions are possible.	In this combination, only system settings and patient data management functions are available
2. Docking station + Ventilator	Therapeutic functions: Ventilation	For a proper device operation, you have insert the ventilator module into the two lower bays *(slots 1&2*)
3. Docking station + Monitor	Patient monitoring functions only	The monitoring module must be inserted into the bottom bay *(slot 1)*
4. Docking station + Defibrillator	AED defibrillation only Manual Defibrillation External Pacemaker	The defibrillator module must be inserted into the bottom bay (*slot 1)*
5. DS + Ventilator + Monitor	Ventilation and patient monitoring	The ventilator module must be inserted into the two lower bays *(slots 1&2). The monitor must be inserted into bay 3.*
6. DS + Ventilator + Defibrillator	Ventilation and AED defibrillation	The ventilator module must be inserted into the two lower bays *(slots 1&2).* The defibrillator module must be inserted into bay 3
7. DS + Monitor + Defibrillator	Patient monitoring and therapeutic function: AED and Manual defibrillation, external Pacemaker.	The monitoring module must be inserted into the bottom bay *(slot 1).* The Defibrillator must be inserted on top of the monitoring module *(slot 2).*
8. DS + Ventilator + Monitor + Defibrillator	Complete configuration	The ventilator module must be inserted into the two lower bays *(1&2)* On top of it the monitor *(slot 3)* and at the top the defibrillator module *(slot 4)*

Table 4-1: Product configurations

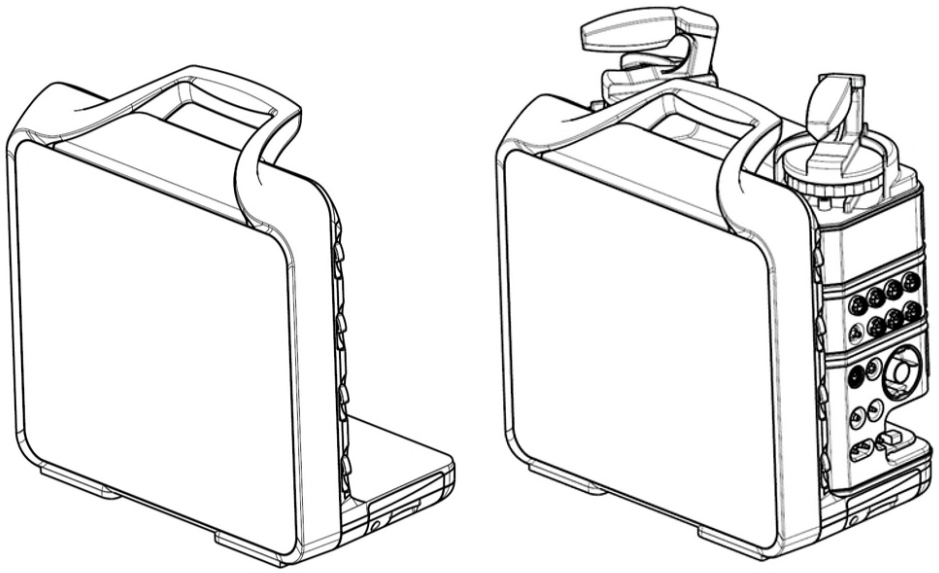


Figure 4-1: Jenny Docking Station and a fully equipped Jenny.

4.4 Physical views

4.4.1 Docking Station

4.4.1.1 Front view

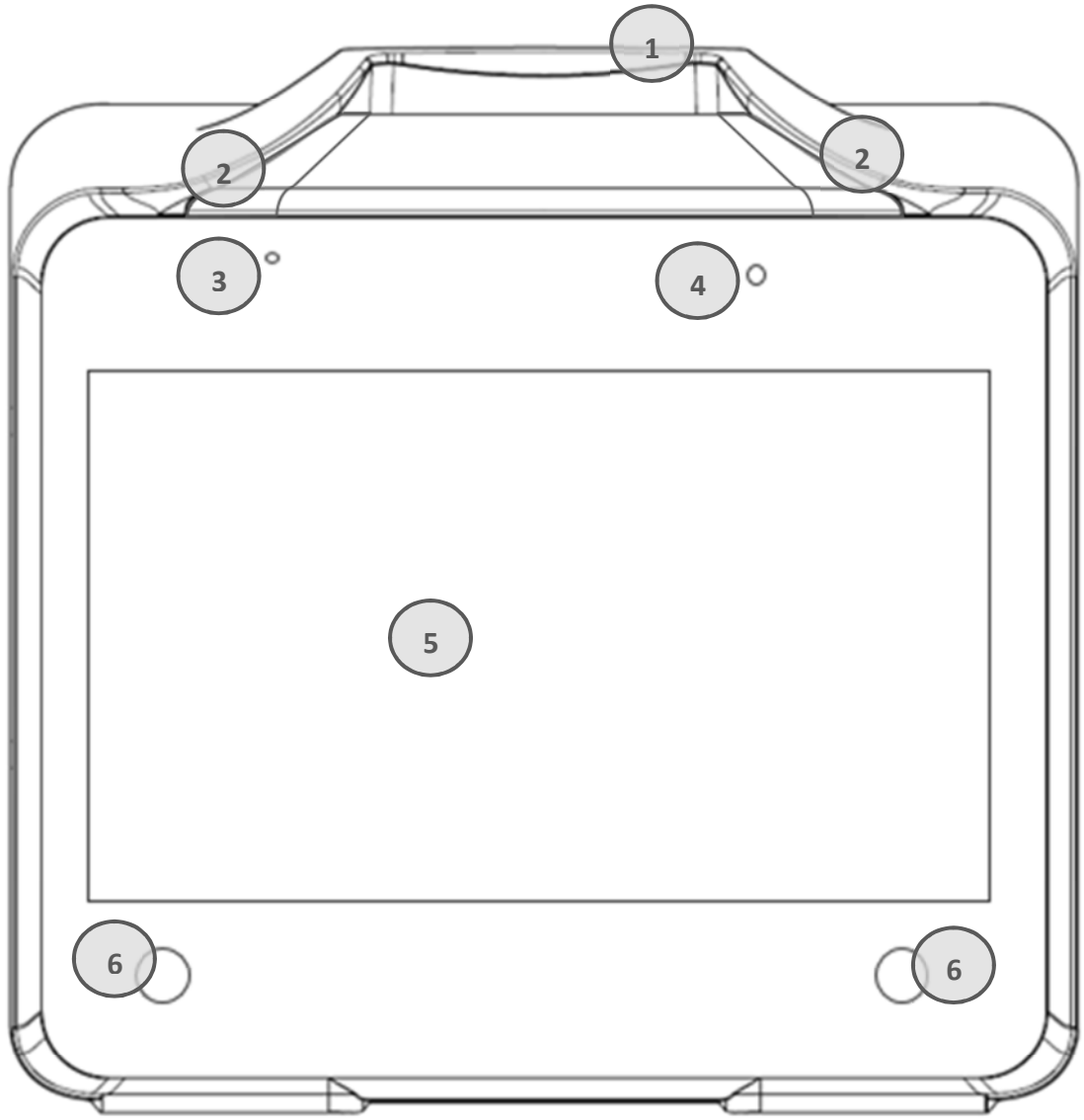


Figure 4-2

1. Handle
2. Alarm LEDs
3. Light Sensor
4. Camera
5. Touchscreen
6. Touch sensors (shock capacitive buttons) with LED lighting

4.4.1.2 Rear view

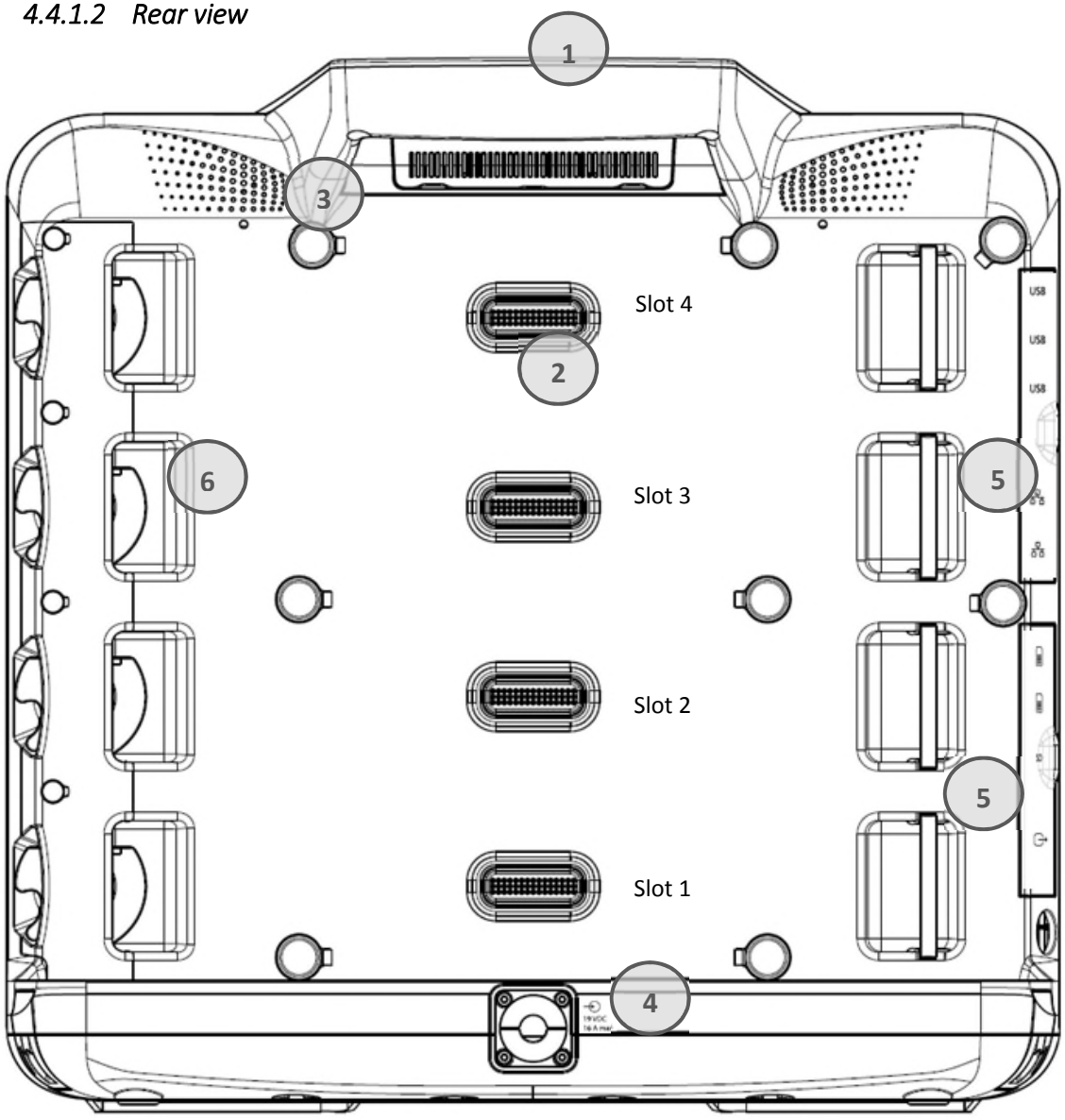


Figure 4-3

1. Handle
2. Module data/power supply connectors (4X)
3. Speakers (2X)
4. RoPD Power socket connector
5. Module-Docking Station female connectors
6. Module locking levers

Each bay consists of:

- A central multi-pin connector: To supply the modules with power and communication with the Docking Station

- Two grooves (female connectors) to mechanically attach the modules to the Docking Station

4.4.1.3 Side views

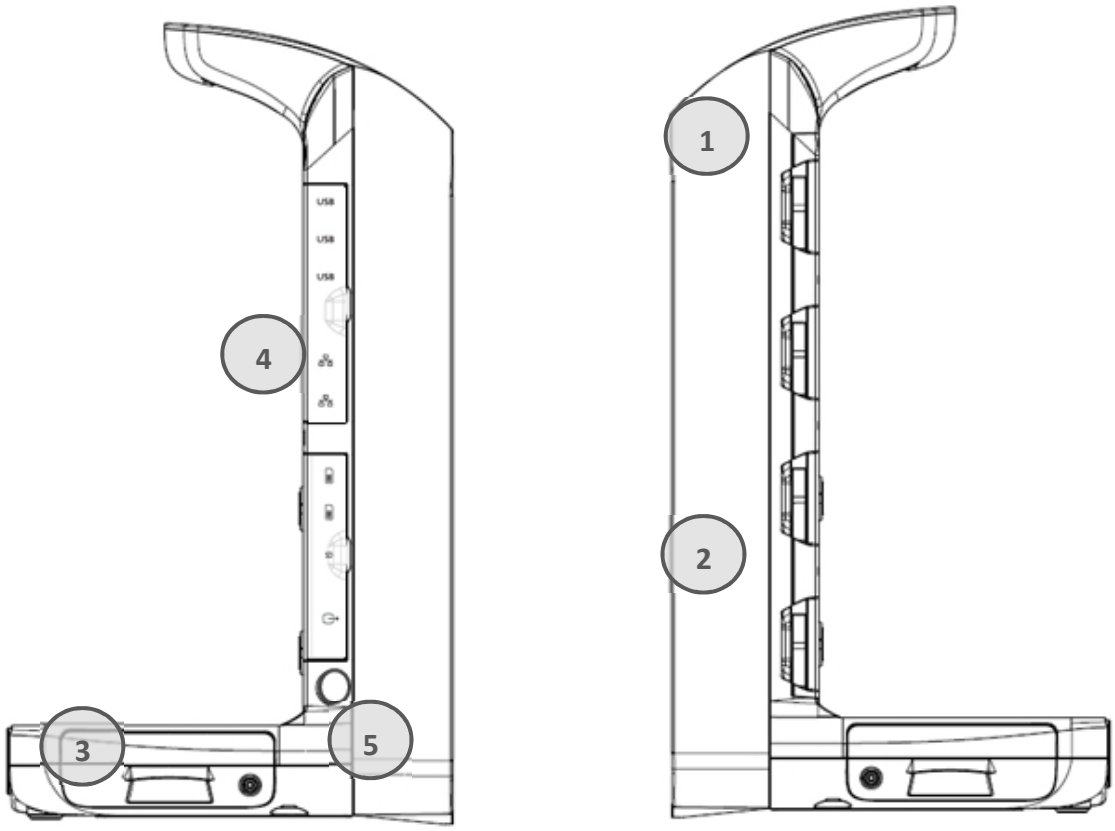


Figure 4-4

1. Handle
2. Module locking levers
3. Battery compartment
4. Connector compartment (SD card, Ethernet, USB)
5. Power ON/OFF button

4.4.1.4 Symbols and abbreviations

Symbol	Description
	Module ejection
	ON/OFF button
SD	SD card slot
	SIM card slot
	LAN connection
USB	USB slot

Table 4-2

4.4.2 Ventilator module (Optional)

4.4.2.1 Front view

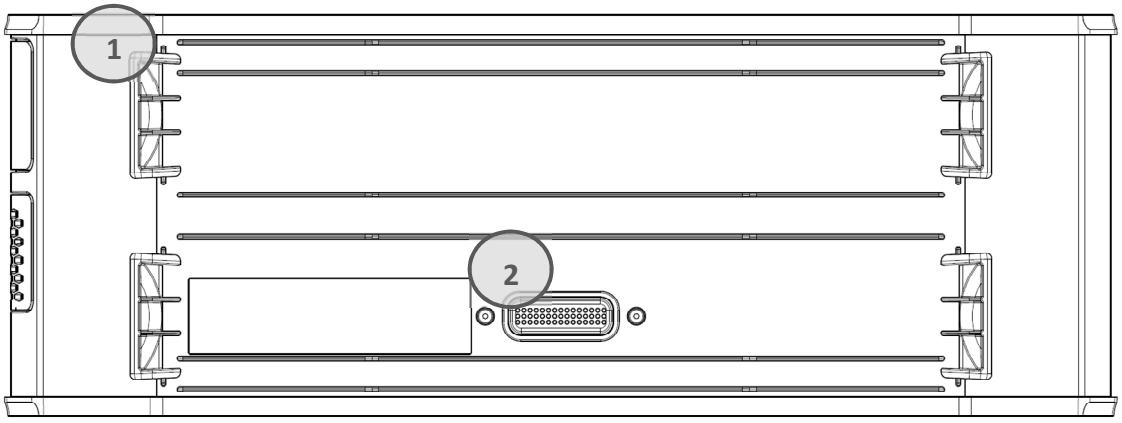


Figure 4-5

1. Module-Docking Station male connectors
2. Module data/power supply connector

4.4.2.2 Left side view

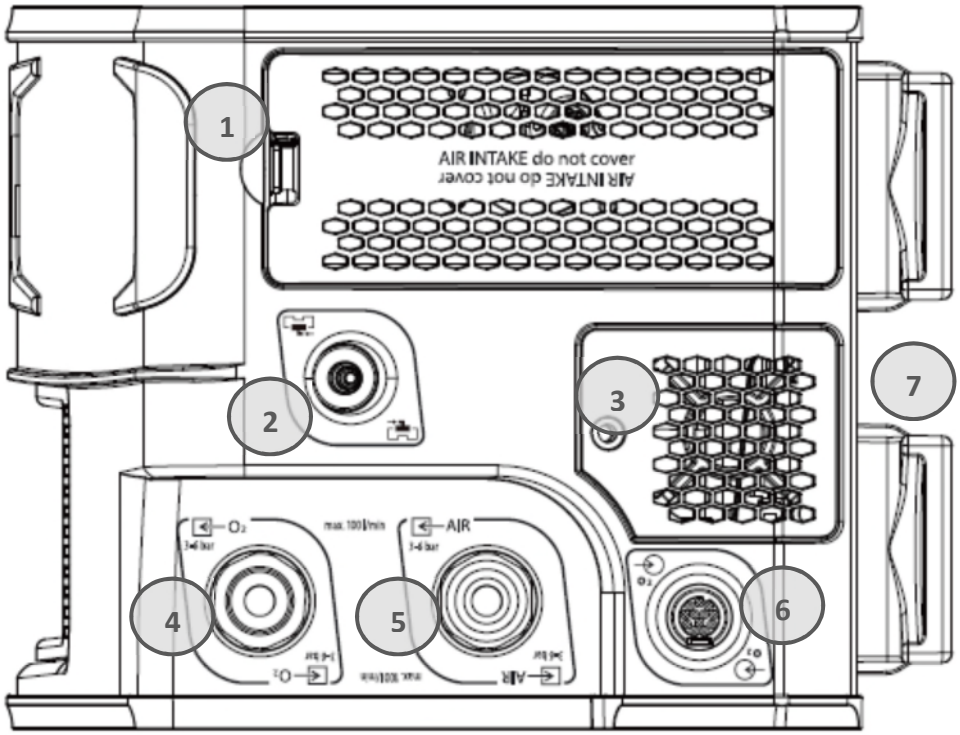


Figure 4-6

1. Air intake filter cover
2. External exhalation valve control port
3. Fan cover
4. Oxygen inlet NIST-connector
5. Air inlet NIST-connector
6. External oxygen sensor connector
7. Module-Docking Station male connectors

4.4.2.3 Right side view

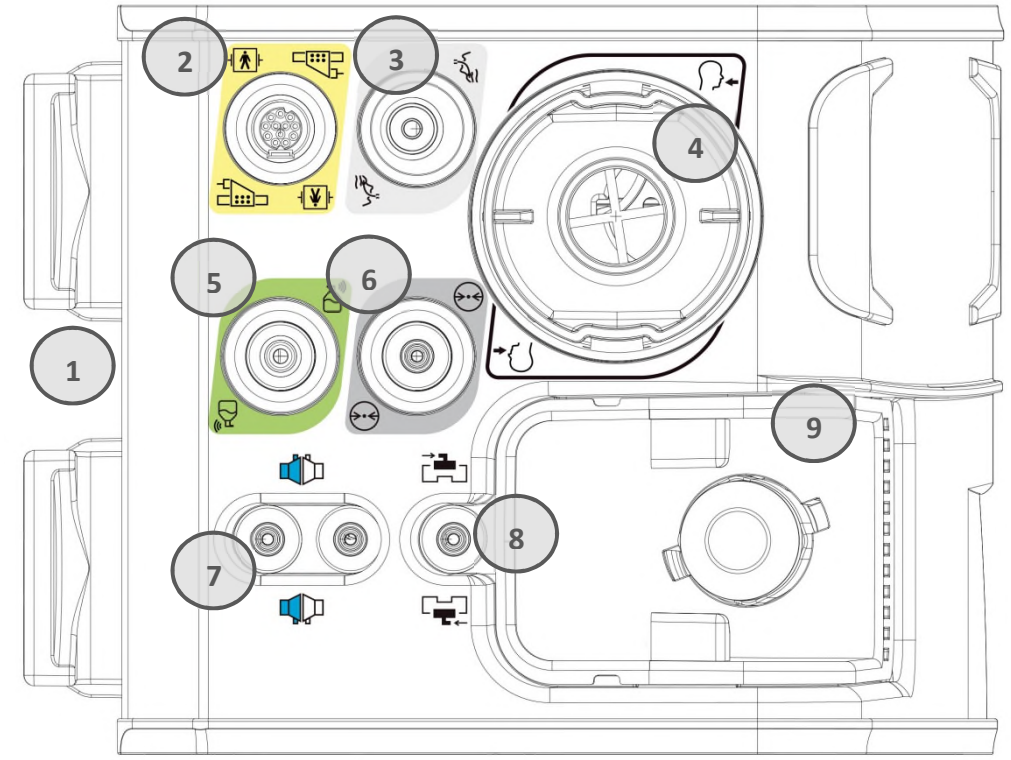


Figure 4-7

1. Module-Docking Station male connectors
2. IRMA™ and ISA™ sensor connection
3. Endotracheal cuff pressure connection
4. Inspiration connection
5. Nebulizer connection
6. Auxiliary pressure port
7. Flow sensor ports
8. Exhalation valve control port
9. Exhalation valve connection and holder

4.4.2.4 Symbols and abbreviations

Symbol	Description
Symbols on the module	
	Consult Instructions for Use for complete information
	Defibrillation-proof type BF applied part

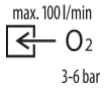
Symbol	Description
	Oxygen inlet
	Air inlet
	External oxygen sensor connection
	Nebulizer connection
	Endotracheal cuff
	Exhalation port
	Inspiration port
	IRMA™ and ISA™ sensor
	Auxiliary pressure
	Patient flow sensor
	Exhalation valve control line
Symbols on accessories packaging	

Table 4-3

4.4.3 Monitoring module (Optional)

4.4.3.1 Front view

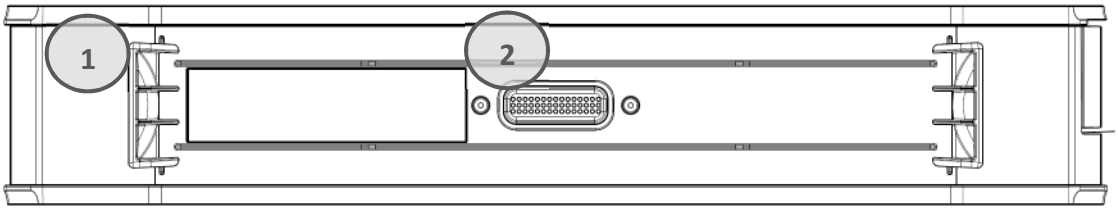


Figure 4-8

1. Module-Docking Station male connectors
2. Module data/power supply connector

4.4.3.2 Left side view

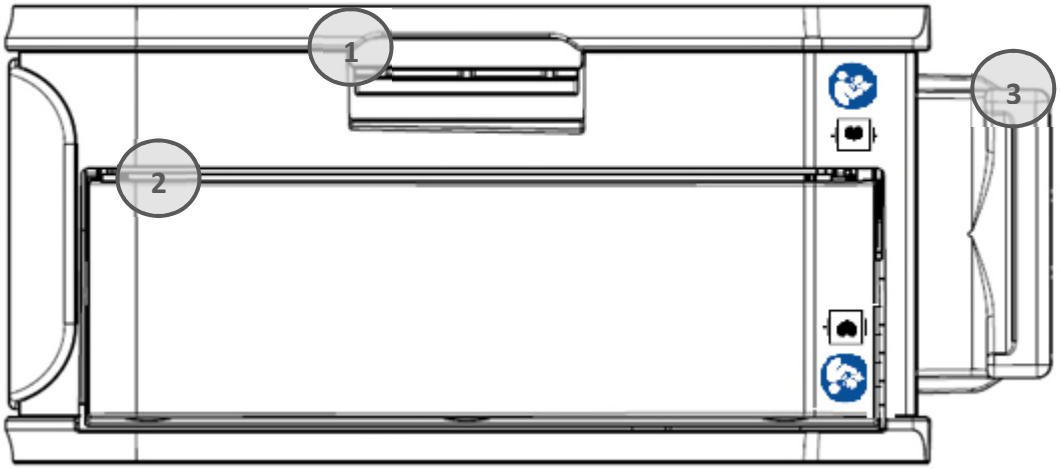


Figure 4-9

1. Printer door handle
2. Printer
3. Module-Docking Station male connectors

4.4.3.3 Right side view

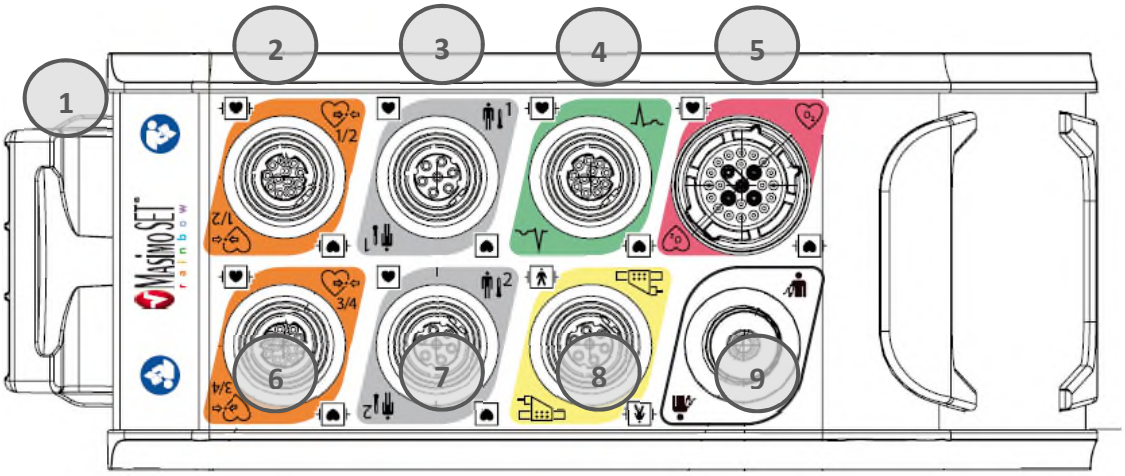


Figure 4-10

1. Module-Docking Station male connectors
2. IBP connector 1
3. Temperature connector 1
4. ECG connector
5. Masimo Rainbow SET ® connector
6. IBP connector 2
7. Temperature connector 2
8. IRMA™ and ISA™ sensor connection
9. NIBP port

4.4.3.4 Symbols and abbreviations

Symbol	Description
Symbols on the module	
	Consult Instructions for Use for complete information
	Defibrillation-proof type CF applied part
	Defibrillation-proof type BF applied part

Symbol	Description
	IRMA™ and ISA™ sensor connection
	ECG connection
	Masimo Rainbow SET® Pulse-CO Oximetry connection
	IBP connection
	NIBP connection
	Temperature 1 connection
	Temperature 2 connection
Symbols on accessories packaging	
	Warning! Use only MS Westfalia GmbH approved monitor cables (ECG, IBP, SpO2, Temp, NIBP, and Capnography) to attain defibrillation protection.

4.4.4 Defibrillator module (Optional)

4.4.4.1 Front view

Paddle Version

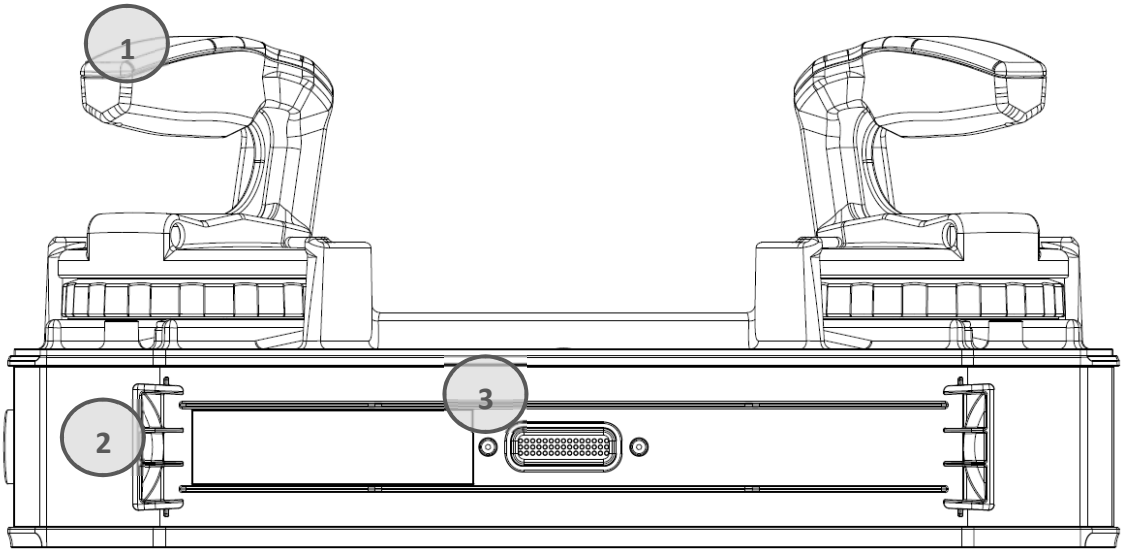


Figure 4-11

1. Defibrillation paddles (optional)
2. Module-Docking Station male connectors
3. Module data/power supply connector

Slim Version

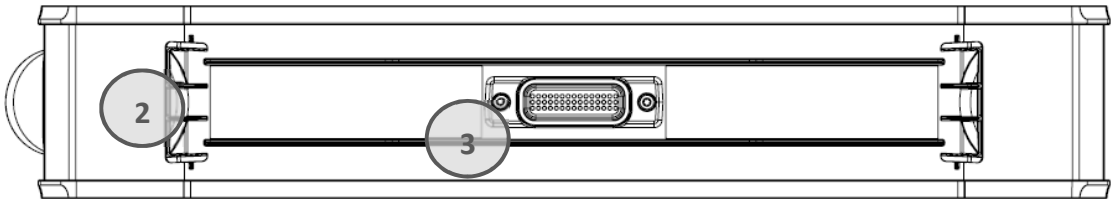


Figure 4-12

4.4.4.2 Left side view

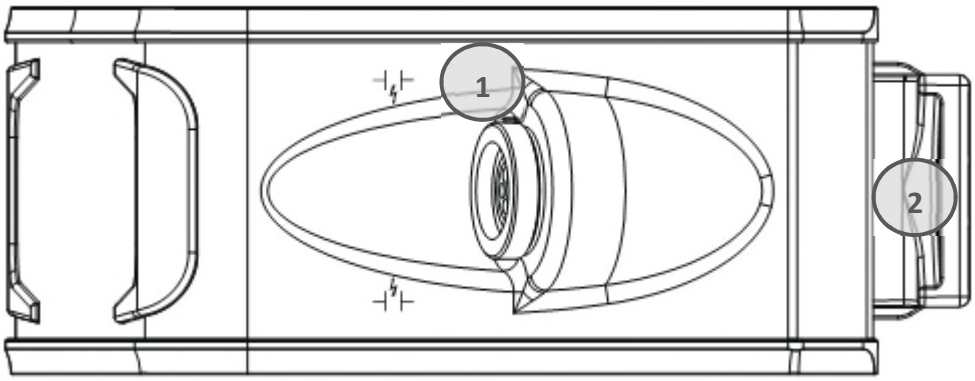
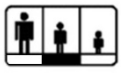


Figure 4-13

1. Electrodes therapy cable connector
2. Module-Docking Station male connectors

4.4.4.3 Symbols and abbreviations

Symbol	Description
Symbols on the module	
	Defibrillation
Symbols on accessories packaging	
	Single use only. DO NOT REUSE
	Expiry date. USE BY
	Lot number. BATCH CODE

Symbol	Description
SN	Serial number
REF	Item reference number. CATALOGUE NUMBER
STERILE	STERILE
	Manufacturing date
	Adult use only. From 8 years and/or 25 kg
	Pediatric use only.
	Neonatal use only.

4.5 Graphical user interface (GUI)

4.5.1 Overview

The user interaction with the device is mainly taking place through the touchscreen. The display on the touchscreen will change per the module configuration installed and to the function being performed.

CAUTION:

Do not use any sharp object on the display. Use only your fingertips to operate the touchscreen.

4.5.1.1 Display in Stand-by: Home Screen

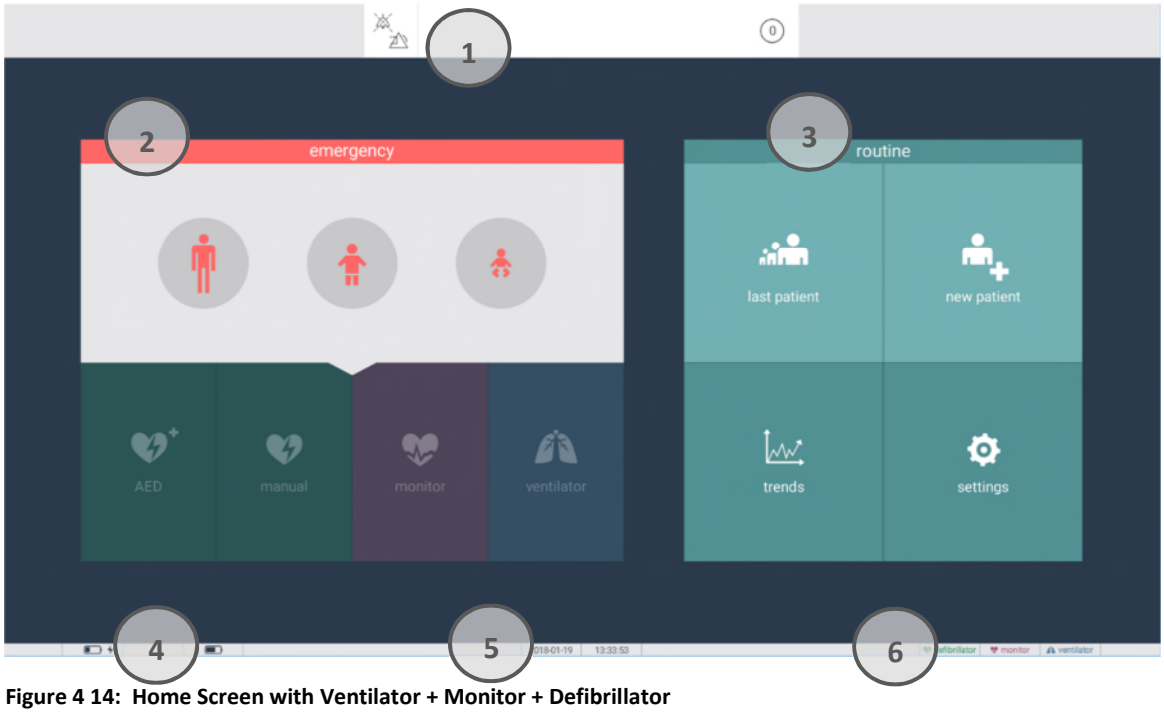


Figure 4 14: Home Screen with Ventilator + Monitor + Defibrillator

1. Alarm bar
2. Emergency area
3. Routine area
4. Operational battery, Mains & Reserve battery charge indicator
5. Time and date
6. Device configuration information

The Home Screen (Figure 4-14) is displayed in the following cases:

- After device power on.
- After the operation of all running modules has been stopped.
- After pressing the 'home' button in an intermediate configuration screen.

From the Home Screen, you can:

- Start an emergency therapy and/or vital parameter patient monitoring
- Start a therapy and/or patient monitoring with a new patient
- Resume a therapy with last patient settings
- Admit a new patient
- Visualize and modify patient data
- Adjust system settings
- Run system tests and calibrations

The Home Screen is divided into two separate conceptual areas:

- Emergency area *(Figure 4-15, item 1)*: organizes the access to emergency use regarding ventilation, monitoring and/or defibrillation. First select the patient area, then select the module and mode.

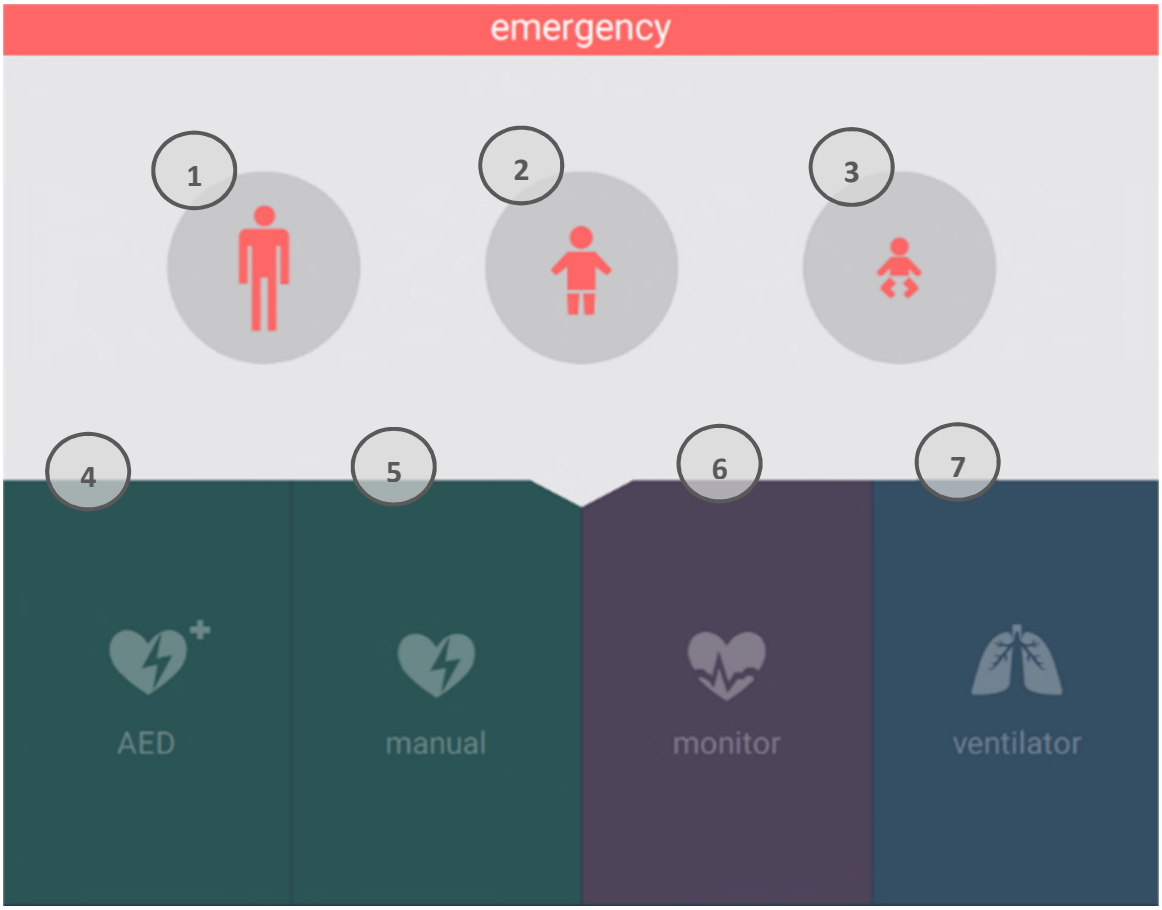


Figure 4-15: Home Screen Emergency Area

1. Adult patient settings
2. Pediatric patient settings
3. Neonatal patient settings
4. AED defibrillator mode
5. Manual defibrillator mode
6. Monitor module
7. Ventilator module

- Routine area *(Figure 4-16, item 2)*: organizes the access to patient data management and the therapy, monitoring and diagnostic functions for intra-hospital use. It also provides access to general system settings and tests.

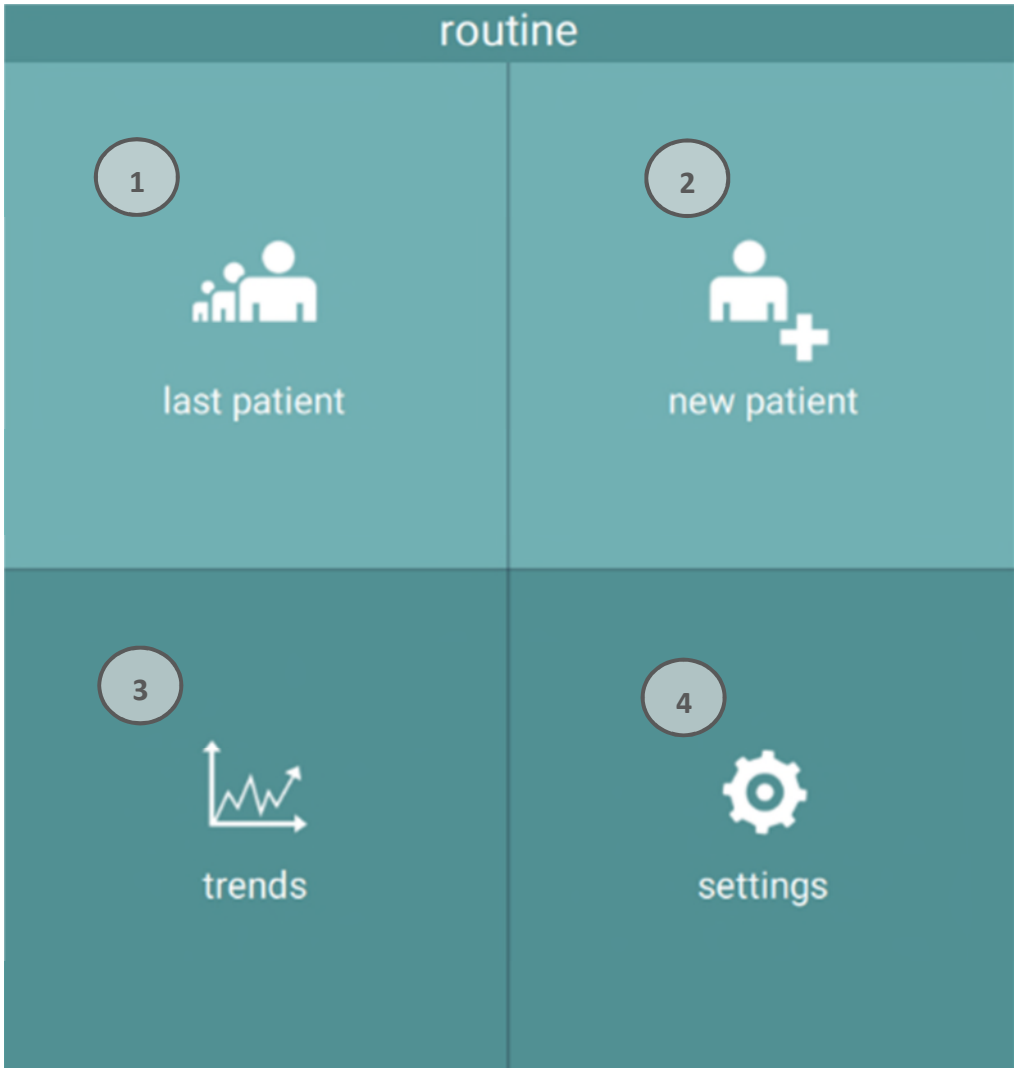
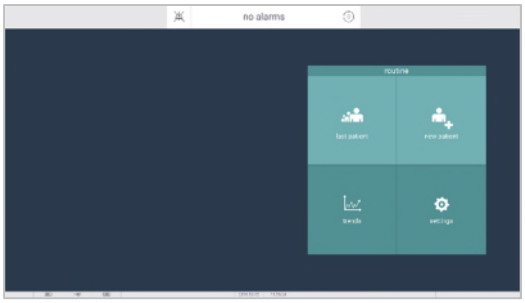
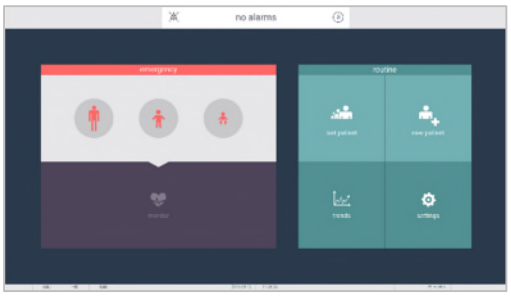


Figure 4-16: Home Screen Routine Area

1. Last patient settings
2. New patient settings
3. Trend data
4. General System Settings

Additionally, the Home Screen displays general system status information in a bar placed at the bottom of the screen: the power status information area displays the current power source (AC or batteries) and the charge status of the reserve and operational batteries *(Figure 4-14, item 4)*. The device configuration status information area lists the modules currently installed in the Docking Station *(Figure 4-14, item 6)*. This bar is visible through all the screens in the GUI.

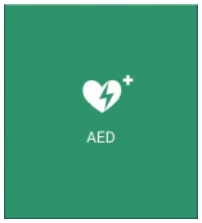
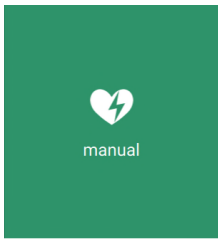
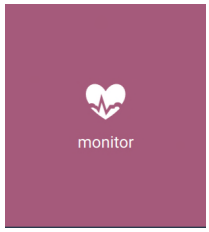
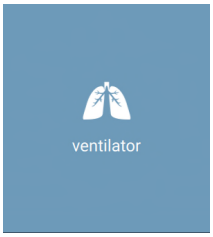
The Home Screen has the following layouts depending on the product configurations described in chapter 4.3:

Configuration	Home Screen
1. Docking station only	
2. Docking station + Ventilator	
3. Docking station + Monitor	
4. Docking station + Defibrillator	

Configuration	Home Screen
5. DS + Ventilator + Monitor	
6. DS + Ventilator + Defibrillator	
7. DS + Monitor + Defibrillator	
8. DS + Ventilator + Monitor + Defibrillator	

Table 4-4: Home Screen layouts

Location	GUI item	Description
Figure 4-15, item 3.		*ADULT emergency button* allows you to select the desired emergency therapy/monitoring immediately with predefined ADULT emergency settings.

Location	GUI item	Description
Figure 4-15, item 3.		*PEDIATRIC emergency button* allows you to select the desired emergency therapy/monitoring immediately with predefined PEDIATRIC emergency settings**.**
Figure 4-15, item 3.		*NEONATAL emergency button* allows you to select the desired emergency therapy/monitoring immediately with predefined NEONATAL emergency settings**.**
Figure 4-15, item 7.		*AED button* allows you to start automated defibrillation therapy immediately. This function is not available for NEONATAL patients.
Figure 4-15, item 7.		*Manual defibrillation button* allows you to start *manual defibrillation* therapy immediately.
Figure 4-15, item 7.		*Monitor button* allows you to admit the patient category selected and start vital monitoring immediately.
Figure 4-15, item 7.		*Ventilation button* allows you to start ventilation therapy immediately.

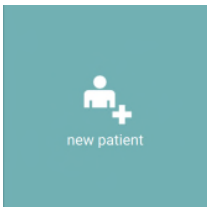
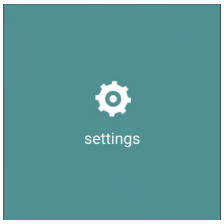
Location	GUI item	Description
Figure 4-16, item 5.		*Last patient button* opens the last patient configuration screen. There, you can visualize and/or modify patient demographic data and start a ventilation therapy and/or vital monitoring with the last patient settings.
Figure 4-16, item 6.		*New patient button* opens the new patient configuration screen. There, you can input patient data and start a ventilation therapy with the default or with proposed initial ventilation settings calculated from the patient data.
Figure 4-16, item 8.		*Trends button* opens the patient trends configuration screen.
Figure 4-16, item 9.		*Settings button* opens the general system settings configuration screen: sound volume, display brightness, languages, units, service mode.

Table 4-5

4.5.1.2 Display during operation: module control panels

The screen layout displayed while the modules are running is divided in three areas:

- Header bar *(Figure 4-17, item 1):* Displays patient information, active modules operating status and alarm messages. It also contains the Alarm silence/reset button and the modules control panel switch.
- Main menu bar *(Figure 4-17, item 2*): Provides access to the GUI functionalities common to all modules (Views, Alarm settings, System settings, Screen lock, Stop modules …).
- The rest of the screen is occupied with the different module control panels.

A module control panel (see ventilation control panel, *Figure 4-17)* is displayed while the corresponding module is running, either immediately after the module has been started or when you select the module in the modules control panel switch.

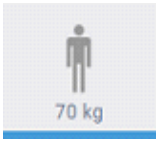
All module control panels have a similar structure:

- A central monitoring area with waveforms and numerical monitored values (*Figure 4-17, items 3 and 4).*
- At the right end, the module specific function bar *(Figure 4-17, item 5).*
- *At the bottom, a panel with specific module controls (Figure 4-17, item 6).*

Figure 4-17: Example. Ventilation control panel

1. Header bar
2. Main menu bar
3. Module monitored values area
4. Module waveforms area
5. Module function bar
6. Module settings bar
7. Current Patient button

Module control

GUI item	Description
	*Current patient button* displays the current patient category and PBW. On pressed, opens the current patient data panel, where you can visualize and modify patient data.
	*Alarm silence/reset button* allows you to silence the currently active alarm sound and/or reset alarms. Displays the remaining silence time during alarm silence. Refer to chapter 6.3.4.3 Alarms for detailed information.

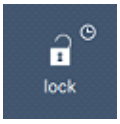
GUI item	Description
	*Alarms bar* displays alarm messages and the number of active alarms. On pressed, displays a list with active alarm messages. Refer to chapter 6.3.4.3 Alarms for detailed information.
	*Modules switch* allows you to switch between module control panels. Refer to chapter 6.3.5 Switching between module control panels for detailed information.
	*Views button* opens the *views* menu. You can select different layouts for the module control panels.
	*Alarms settings button* opens the alarm settings menu. You can visualize a list with all the measurements that have an alarm associated and modify the alarm limits.
	*Trends & log button* opens the trends and logs. You can visualize graphical trends and the alarm/events log
	*Settings button* opens the system settings menu.
	*Screen lock button* on tap and hold locks/unlocks the touch screen.
	*Stop button* opens the stop menu. You can stop currently active modules one by one or stop all modules at once.

Table 4-6

4.5.2 Labels, symbols and abbreviations

4.5.2.1 General

Symbol	Description
ARDS	Acute Respiratory Distress Syndrome
COPD	Chronic Obstructive Pulmonary Disease
PBW	Predicted Body Weight

4.5.2.2 Ventilation modes

Symbol	Description
ABV	Apnea backup ventilation
APRV	Airways Pressure Release Ventilation

Symbol	Description
BILEVEL	Bi-level Ventilation
CPAP	Continuous Positive Airways Pressure
MMV	Mandatory Minute Volume
PC-SIMV	Pressure Controlled – Synchronized Intermittent Mandatory Ventilation
PCV	Pressure Controlled Ventilation
PCV a/c	Pressure assisted/controlled Ventilation
PCVR	Pressure Controlled Volume Regulated
VC-SIMV	Volume Controlled – Synchronized Intermittent Mandatory Ventilation
VCV	Volume Controlled Ventilation
VCV a/c	Volume assisted/controlled Ventilation

4.5.2.3 Ventilation symbols

Symbol	Description
$C20/C_{dyn}$	Compliance ratio
Cdyn	Dynamic compliance
C_{stat}	Static compliance
EtCO2	End-tidal carbon dioxide
F_{air}	Air flow
F_e	Peak expiratory flow
F_i	Peak inspiratory flow
FiO2	Fraction of inspired oxygen
F_{leak}	Leakage flow
HME	Heat and Moisture Exchanger
HPO	High Pressure Oxygen source
I:E	Inspiration to Expiration ratio
LPO	Low Pressure Oxygen source
T_{limit} PS	Maximum inspiratory time in pressure support
MV_e	Expiratory minute volume
$MV_{ie\text{-}spont}$	Spontaneous Expiratory Minute Volume
MV_i	Inspiratory Minute Volume
NIF	Negative Inspiratory Force
NIV	Noninvasive Ventilation
P0.1	Airway occlusion pressure
$P_{ambient}$	Ambient pressure
P_{cuff}	Cuff pressure
PEEP	Positive End Expiratory Pressure
$PEEP_i$	Intrinsic Positive End Expiratory Pressure
P_{limit}	Maximum Allowed Airway Pressure
P_{mean}	Mean airway pressure
P_{min}	Minimum airway pressure
P_{pat}	Patient pressure
P_{peak}	Peak airway pressure
P_{plat}	Plateau pressure
PS	Pressure support
R	Resistance
RR	Respiratory Rate
RSBI	Rapid Swallow Breathing Index
T_{apnea}	Apnea interval
T_e	Expiration time
T_i	Inspiration time
T_{ramp}	Pressure rise time
V_e	Expiratory volume
V_i	Inspiratory volume
V_{leak}	Leakage volume
VT	Tidal volume
V_{limit}	Maximum tidal volume
WOB	Work of Breathing

4.5.2.4 Monitoring symbols

Symbol	Description
ECG	Electrocardiogram
RR	Respiratory Rate
IBP	Invasive blood pressure
NIBP	Non-invasive blood pressure
SpO2	Peripheral oxygen saturation
PR	Pulse rate
PI	Perfusion Index
PVI	Pleth Variability Index
SpHb	Total Haemoglobin
SpMet	Methaemoglobin
SpCO	Carboxyhaemoglobin
SpOC	Oxygen Content
ORI	Oxygen Reserve Index
Temp	Temperature
Print	Printer

4.5.2.5 Defibrillation symbols

Symbol	Description
AED	Automatic External Defibrillator
Bpm	Beats per minute
CPR	Cardiopulmonary resuscitation
mA	Milliampere
Sync	Synchronized defibrillation (cardioversion)

4.5.3 Touch gestures

Action	Description	Used to
Single-tap	Tap quickly with one finger on the item	Navigate through the GUI, operate menus …
Tap and hold	Tap with one finger on the item and hold for at least 1.5 seconds	Lock screen, start maneuver, Activate O2 Flush, Activate nebulizer …
Drag	Move finger over a surface without losing contact	Move through alarm list
Drag and drop	Tap and hold the item and drag it to the desired position. Lift the finger to stop.	Move sliders

5 Installation

5.1 Unpacking

1. Remove the device from the shipping carton and place it in a horizontal surface.
2. Unpack the accessories from their packaging.
3. Check all received goods against the packing list.
4. Visual inspection for signs of shipping damages.
5. Store all packing materials, packing list and invoices.

⚠ **CAUTION:**

Before the first use of the device, you have to clean and/or disinfect the corresponding accessories as described in section 7.5 Cleaning, disinfection and sterilization

5.2 Docking Station

5.2.1 Mechanical functions

Module installation

Inserting and locking

⚠ **CAUTION:**

To guarantee patient and operator safety and a proper operation of the device, only the product configurations listed in chapter 4.3 are allowed.

Rules for the insertion of modules into the Docking Station:

1. Inserting one module into an empty Docking Station:

- Please release the locking mechanism before attaching a module to the Docking Station.
- The module must always be inserted into the bottom bays *(slot 1)*
- The ventilator module must always be inserted into the two lower bays *(slots 1&2)*

2. Inserting additional modules:

- The ventilator module must always be inserted into the two lower bays *(slots 1&2)*
- The modules should be inserted starting from the bottom by, piling up the modules bottom to top and leaving no empty slots between them.
- The jog-dial counters must be closed by two positions after inserting the module.
- The defibrillator module must always be inserted at the top of the modules pile, to facilitate the access to the defibrillation paddles (if available).

CAUTION:

Inserting two or more identical modules is regarded as a misuse and will be alarmed.

Unlocking and removing

Removing modules:

- Switch off the functionality of the module you want to remove.
- Disconnect the module from all cables or circuits that are connected to it.
- Release the locking mechanism to the Docking Station, by turning the jog-dial in counter-clockwise direction, by two positions. For the defibrillator and monitor modules, the locking mechanism consists of one jog-dial. For the ventilator module, the locking mechanism consists of two jog-dials.
- Remove the module.

Other mechanical installations

Transport frame

Refer to the corresponding user manual

Transport wall mount

Refer to the corresponding user manual

Docking Station Arm

Refer to the corresponding user manual

5.2.2 Power supply

The Docking Station can be used with the following power sources:

1. AC mains power supply.

Jenny® can be operated with an AC power between 100 and 240 VAC at 50/60 Hz. The system electrical isolation from mains is made through the external AC/DC adaptor supplied with the equipment (Class II). For further information, refer to the technical specification of the external adaptor in chapter 9.

2. Operational and reserve internal batteries.

Two identical, lithium-ion batteries with a nominal voltage of 14.4 V and a nominal capacity of 86.4 Wh. The operational battery can be replaced any time (hot swappable) without the use of tools. The reserve battery is not accessible to the user, and can only be replaced by a service trained technician. For further information, refer to the technical specification of the batteries in chapter 9.

Please refer to the Accessories Catalogue for further information on batteries.

5.2.2.1 Power supply management

The AC mains power source has the highest priority. A device connected to mains will always be operated with this power supply and the batteries installed in the device will be charged during use.

In absence of mains AC power supply, the power supply switches to the internal operational battery. If the operational battery is absent or significantly depleted (below 5 % of charge), the device switches to the internal reserve battery. When the internal reserve battery is below 20 % of charge, an alarm will be displayed commanding you to connect an alternative power source. If batteries are empty, the device will be powered off.

AC mains	Operational battery	Reserve battery	Jenny® power supply
Yes	Yes (charging)	Yes (charging)	AC mains
Yes	No	Yes (charging)	AC mains
No	Yes (discharging)	Yes	Operational battery
No	No / discharged	Yes (discharging)	Reserve battery

NOTE:

Jenny® is intended to be used with both batteries inserted.

5.2.2.2 Connecting to mains power supply

WARNING:

To avoid the risk of electrical shocks:

- Use only the AC/DC external adaptor with the RoPD™ connector and the AC power cord supplied with the equipment.
- Make sure that the external adaptor and the AC power cord and plugs are in good condition before you connect the equipment.
- For a safer operation, connect the equipment to a grounded, hospital grade AC power outlet.
- In case of doubt about the integrity of the external power earth arrangement, unplug the device from mains and operate it with batteries.
- Do not use extension cables or adapters.
- Do not connect the equipment to a multiple socket outlet (power strip).

WARNING:

For a proper operation, position the equipment in a way that makes it easy to access the AC/DC external adaptor and the AC power cord.

WARNING:

Ensure that the AC power cord is positioned in a way that reduces the possibility of tripping and choking.

To connect to mains:

1. Plug the female RoPD ™ magnetic clip from the external adapter into the male connector in the Docking Station. Note that there is only one correct position (both connectors are mechanically coded). The magnetic force keeps the connection and it is only released if the pulling force is strong enough.
2. Plug the female end of the AC power cord into the external adapter 2 pins male connector.
3. Plug the power plug at the other end of the AC power cord into a properly grounded power outlet. *You can check the status of the AC power supply at the bottom left-hand corner of the display* (Figure 4-14, item 4).

To disconnect from mains:

1. Unplug the AC power cord from the grounded power outlet. To do so, pull the AC power plug gently until it has been completely disconnected from the outlet.

5.2.2.3 Working with the reserve battery

WARNING:

Never leave the device and the patient unattended when the device is battery-powered.

WARNING:

When the device is working with the reserve battery, make sure to connect to an alternative power source (either AC power supply or a fully loaded operational battery) when the device is close to having a loss of power.

WARNING:

Batteries must be carefully handled at all times, to prevent contact with water or dust.

CAUTION:

The reserve battery can only be replaced by trained service personnel. Refer to the service manual for the replacement procedure.

The reserve battery ensures an uninterrupted power supply when mains power supply is not available and no operational battery is powering the device.

The reserve battery can power the device for approx. 2 hours under typical conditions of use.

5.2.2.4 Working with the operational battery

WARNING:

Have the battery periodically checked and replace it in case that you suspect that its performance is reduced.

WARNING:

Risk of fire, explosion or burns:

1. DO NOT short the battery terminals
2. DO NOT incinerate, crush or dissamble
3. DO NOT reverse polarity
4. DO NOT overcharge or over discharge
5. DO NOT operate battery beyond published voltage, current and temperature limits

NOTE:

The system will emit an information signal when any of the batteries has reached its limit of life time expectancy.

To insert the operational battery

1. Orient the battery as shown in the picture above.
2. Place the battery in the battery compartment and push until it clicks. This indicates that the battery is locked inside.
3. The door of the battery compartment must be closed.

NOTE:

The battery can only be properly inserted in one orientation.

To remove the operational battery

1. Pull the slider of the battery ejector. The battery will be ejected.
2. Then pull out the battery until it has been completely released from the battery compartment.

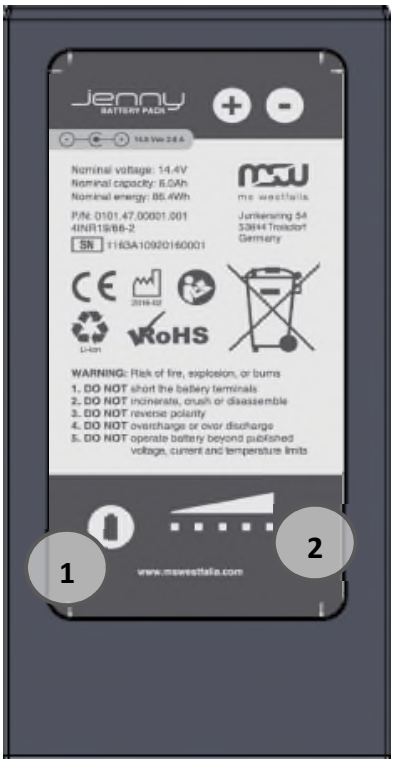
NOTE:

For a safe operation, always insert a fully loaded operational battery.

Checking the charge level

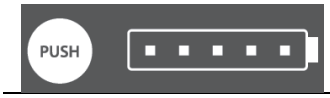
When the battery is inserted, the charge status is displayed in the GUI, operational battery status indicator *(see below).*

You can also check the charge level on the operational battery when the battery is not inserted by pressing the status button (“Push”) on the battery. The current charge level is displayed in the 5-LED layout on the battery.



1. Status button
2. Charge level display

Symbol	Description
CE	CE Marking of Conformity
2016-06	Manufacturing date
	Do not dispose

Symbol	Description
	Lithium Ion Rechargeable Battery
	Safety Warning
	Please read manual
	RoHS complaint
	Battery Status Indicator. Push the 'Push' indicator.
	Battery Serial Number
	Battery contact points ('+' is the cathode-side, '-' is the anode side)

Charging the batteries

Apart from the automatic charge when the batteries are inserted in a Docking Station being supplied with mains as described in 5.2.2.1, the operational battery can be externally charged with the supplementary external charger.

To charge the batteries with the external charger

1. Read the supplementary charger user manual before using it for the first time.
2. Connect the external charger to mains. Check that the red LED power indicator lights up.
3. Connect the battery to the charger.
4. Check that the green indicators in the charger with the charging level.
5. If all 5 indicators blink (error), check integrity of battery (follow the indications above about checking the charge level in the battery).
6. If batteries are ok and error persists, replace the charger.
7. If there are no errors, observe the progress of the charge in the indicator. When a charge level is reached (20%, 40% etc.) the reached progress indicator is steady and the rest blink.
8. When the battery is fully charged, all 5 green LED's are steady illuminated.

5.2.3 Other accessories

Please refer to the Accessories Catalogue.

5.2.4 Alarm management system

WARNING:

Do not silence, deactivate or decrease the volume of any auditory alarm that could compromise patient or operator safety.

The goal of the alarm management system is to alert of conditions that require operator intervention to ensure patient safety. These alarm conditions generate acoustic and optical alarm signals.

The maximum delay in the determination of an alarm condition counted from the moment that the alarm condition first occurs until the corresponding alarm signal is generated is < 10 s.

The acoustic alarm signals are emitted from the speakers in the Docking Station, with a sequence of recognizable tones and a repetition interval matching the alarm priority.

The functionality of the alarm system is tested immediately after start up. First, the buzzer emits two short audible tones and immediately after that, the speakers emit a recognizable sequence of two tones.

Each acoustic alarm generated will be monitored by the device safety system. If an expected alarm tone is not detected (speakers malfunction), the device will generate an alarm and the internal buzzer will begin to sound.

The alarms are optically displayed in the LED layout on top of the front panel in the Docking Station. If an alarm occurs, the LEDs flash with a frequency and a color matching the alarm priority.

In the GUI, alarm messages are displayed on the display *Alarm bar (Figure 4-14, item 1*). Additionally, if the alarm condition is a physiological alarm triggered by a measurement, the measured value field displayed in the module control panel is highlighted with the corresponding alarm priority color.

The operator's position to manage alarms is standing, 1 m away from the touchscreen.

5.2.4.1 Alarm classification

Alarms are classified as:

- *Technical alarms*: Alarms generated by internal components failure in the Docking Station or in the modules or an event or failure in the electrical or pneumatic connections.
- *Non-technical alarms*: Includes the physiological alarms (alarms related to the monitoring of the patient physiological condition) and other alarms or events related to the interaction of the patient with the device.

5.2.4.2 Alarm priority

The alarms are categorized into three degrees of priority regarding the severity and the urgency in the response to the alarm conditions:

Alarm visual indicators

Priority	Alarm lights	Alarm bar
High	Red, flashing	Red
Medium	Yellow, flashing	Yellow
Low	Cyan, steady	Cyan

Alarm audible indicators *(sounds after ISO/IEC 60601-1-8)*

Priority	Alarm sound	Audible tones
High	 C4 C4 C4 - C4 C4	10 tones, repetition every 5 seconds
Medium	 C4 C4 C4	3 tones, repetition every 15 seconds
Low	 C4 C4	2 tones, repetition every 25 seconds

Rules for the generation of alarm signals:

- Multiple simultaneous active alarms with different priorities: The tone of the alarm with the highest priority is generated. The LED lights flash with the color and frequency of the alarm with the highest priority.
- Multiple simultaneous active alarms with the same priority: The tone and lights corresponding with the alarm priority are generated. The behavior is the same as if there was only one alarm with this priority.

5.2.4.3 Latching alarms

Latching alarms will continue to sound and to be displayed in the LEDs and the Alarm bar even after the alarm condition that caused the alarm has ceased. Non-active latched alarms can be deleted pressing the Alarm silence/reset button. All technical alarms are non-latching alarms and all non-technical alarms are latching alarms.

The alarm is greyed out if the alarm cause has ceased.

5.2.4.4 Resettable alarms

Resettable alarms can be deleted by the user on demand, even when the alarm cause is still active. This applies among others to the cable disconnection alarms for patient vital monitoring functions in the monitoring module.

5.2.4.5 Alarm bar

The alarm bar and the Alarm silence/reset button are always visible.

- Active alarms: the alarm bar and button are highlighted with the priority color of the alarm message being displayed

1. Alarm silence/reset button
2. Alarm bar
3. Alarm message
4. Active alarms counter

Rules to display alarm messages in the Alarm bar:

- Multiple active alarms simultaneously with different priorities: The Alarm bar displays the text of the alarm with the highest priority. The alarm counter in the Alarm bar displays the total number of alarms. When the highest priority alarm is cleared, the next highest priority alarm is displayed.
- Multiple active alarms of the same priority: The alarms of the same priority are sorted out with an internal order within the priority. See Alarm messages
- Technical alarms have priority over non-technical alarms.
- If there are multiple active alarms, by tapping on the Alarm bar, the bar is expanded and it displays a list with active alarm messages. Up to twelve active alarm messages are displayed in the expanded Alarm bar, sorted by time of occurrence, with the most recent alarm at the top of the list and with an icon indicating what module generated the alarm:

5.2.4.6 Alarm silence / reset button

The alarm silence / reset button silences active alarm tones and resets latched alarms and resettable alarms.

The alarm tones can be temporarily muted for a maximum period of 2 minutes. The active alarms optical indicators will continue to display the present alarm conditions. If the 2 minutes' period has expired and the alarm condition persists, the corresponding tone will be audible again.

Additionally, the button will reset all latched and all resettable alarms.

It is also possible to perform an alarm *pre-silence* when there are no active alarms and the white 'no alarms' bar is displayed. This is useful when intentionally disconnecting a patient from the device, for example for a suction maneuver during ventilation.

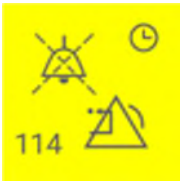
Pre-silence is available for ventilation alarms only. Other alarms will end the audio pause immediately.

To silence alarms:

1. Tap on the Alarm silence/reset button, applying a pressure of at least 2 seconds.

A progress bar will be displayed in the field for Alarm silence/reset button. When completed, a down counter starting from 120 seconds will be displayed, and alarms will silenced.

If there are latched alarms or active resettable alarms, the alarm counter in the Alarm bar is updated and the latched and/or the resettable alarm messages are deleted from the Alarm bar.



To reset alarms:

1. Tap on the Alarm silence/reset button.

The down counter will be deleted, and audible sound the latched and/or the resettable alarm messages will be resumed.

5.2.4.7 Alarm sound volume

WARNING:

The alarm sound volume should be set at a level that allows the operator to distinguish the alarm sound from other background noises.

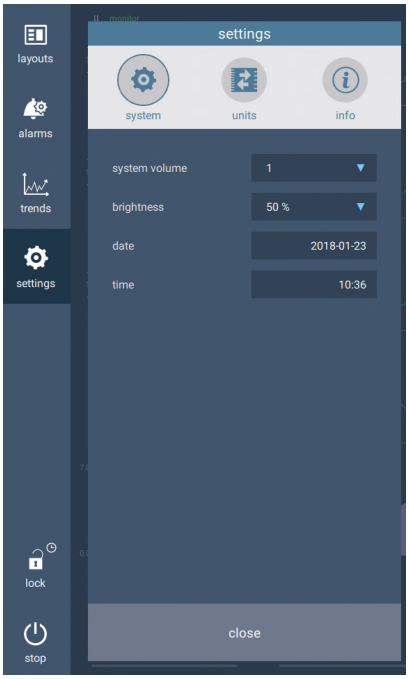
The alarm sound volume is linked to the system sound volume.

The system sound volume ranges from 1 (minimum) to 10 (maximum). Setting the system volume to mute is not possible.

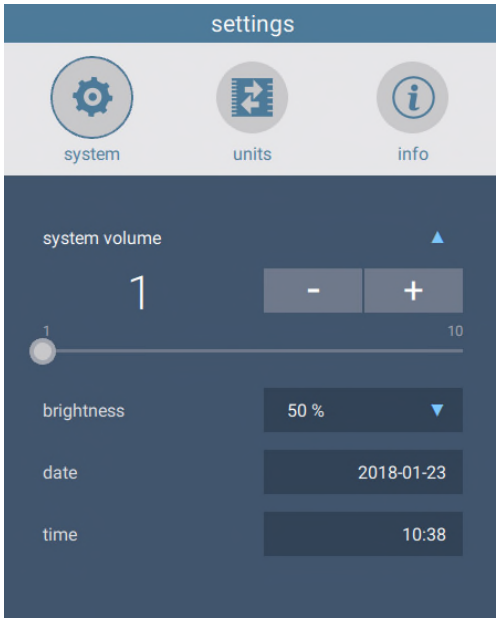
To see the physical specifications of the system sound level, please refer to Docking Station environmental specifications in section 9.1.3

To set alarms sound volume

1. Tap on the 'settings' button on the main menu bar. The system settings menu opens.



Tap on the volume setting to expand the menu



Adjust the system sound volume as desired by dragging the slider or with the adjustment '+' and '-' buttons.

5.2.4.8 Alarm configuration after complete power off

The alarm limits set by the operator are valid if the device is powered on. Alarm limits are reset to factory defaults any time the device power is cycled, independent from the duration of the power interruption.

5.2.4.9 Alarm log

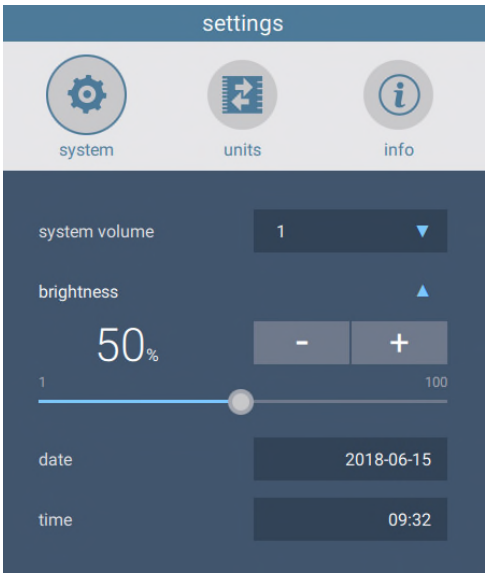
The alarms messages that occur are date and time-stamped and listed in the alarm log. The alarm log is accessible during standby through the Trends button in the Home Screen and during module operation through the Trends button in the main menu bar. An entry is added to the top of the list when a new alarm message occurs. The alarm log entries are displayed if the device is powered on. Log entries are cleared any time the device power is cycled, independent from the duration of the power interruption. The powering down event is not registered in the log.

The log can store up to 100 alarm messages. When the storage capacity is reached, the oldest alarm messages are deleted and the most recent message is added at the top of the list.

5.2.5 Brightness

The brightness of display in the Docking Station can be adjusted manually by the operator, to adapt to different ambient and illumination settings, enhancing visibility.

Adjust the brightness scale as desired by dragging the slider or with the adjustment '+' and '-' buttons.



5.2.6 Connectivity

5.2.6.1 Central Monitoring System (CMS)

The JENNY Docking Station can be used with available Central Monitoring Systems, providing centralized monitoring and critical care management for patients monitored by bedside JENNY devices, via wire or wireless connection.

Wire connection

The Figure 4-4, in the section *4.4.1.3*, describes the position of the connector compartment, where the socket for Ethernet wire socket is located.
The user must plug gently the Ethernet wire to the socket, and follow the instructions for admitting the patient in the CMS.

Wireless connection

The device can connect to available networks via WLAN and NFC technologies. Please refer to the section *9.1.5.4* for the corresponding specifications.

5.2.6.2 Cell-phone connectivity

The JENNY Docking Station can be connected for data storage and transmission with cellular phone technology, via two slots for SIM cards. Please refer to the section *9.1.5.4* for the corresponding specifications.

5.2.6.3 Bluetooth ®

The JENNY Docking Station can be connected for data transmission with Bluetooth ® technology. Please refer to the section *9.1.5.4* for the corresponding specifications.

5.2.6.4 Universal Serial Bus (USB)

WARNING:

The Jenny Docking Station must be connected only with USB devices that are separately isolated.

The JENNY Docking Station can be connected for data storage with USB devices. Please refer to the section *9.1.5.4* for the corresponding specifications.

5.3 Ventilator module (Optional)

5.3.1 Overview

The ventilation module is an electrically powered, electronically controlled pneumatic ventilator. The pneumatic system is designed to provide a compressed air source any time. To achieve this, a dual pneumatic drive system is integrated in the module. It can ventilate the patient with compressed air from an external source (medical pipeline or compressor) and when an external source is not available, an integrated dynamic blower provides compressed air uninterruptedly.

It is electrically powered through the Jenny® Docking Station and it is intended to be used only when inserted and locked to a fully functional Jenny® Docking Station. An internal microprocessor controls the communication with the Docking Station.

WARNING:

The Ventilator Module shall not be used with: Nitric oxide, Helium or Helium mixtures.

5.3.1.1 Oxygen sensors

The ventilator also measures the percentage of oxygen in the gas mixture delivered to the inspiratory breathing circuit. The oxygen sensor is internally mounted at the patient gas output port, after the gas mixing chamber assembly and just before the patient inspiratory filter F4. (Refer to Electro-pneumatic diagram in 9.2.4.1).

NOTE:

The oxygen concentration measured by the sensor may not correspond to the actual oxygen concentration in the gas that the patient finally inspires.

Depending on the configuration of your Jenny® ventilation module, you can have either a galvanic oxygen sensor or a digital paramagnetic oxygen sensor. The paramagnetic sensor delivers a very stable measurement and does not need a frequent calibration.

On the contrary, the galvanic cell needs regular calibration.

The sensors (either paramagnetic or galvanic) are used for independent monitoring of the delivered oxygen and have no influence on the control of the actual oxygen concentration delivered by the ventilator.

WARNING:

Only use a Paramagnetic Oxygen sensor in stationary use.

WARNING:

Do not use the Blower as an air source for respiratory therapy in a gas contaminated environment.

WARNING:

The system may leak 100% oxygen. Risk of explosion!

Additionally, the ventilator is equipped with automatic barometric pressure compensation (this measured pressure is used to correct the oxygen concentration measured by the sensors).

5.3.2 Accessories

WARNING:

Use only certified accessories for the Ventilatior Module.

WARNING:

Do not clean, disinfect or reuse ventilation accessories marked as single use. Doing so may increase the risk of cross-contamination, compromise device functionality and reduce performance.

WARNING:

Do not use sterile-packaged accessories if the packaging has been opened, it is damaged or there are other signs of non-sterility. Disposable articles may not be reprocessed and resterilized.

Please refer to the Accessories Catalogue for a detailed list of available options.

5.3.3 Connecting accessories

WARNING:

Do not invert the ventilation module while ventilating a patient. In case the ventilation was inverted, you must change all disposable accessories for ventilation.

5.3.3.1 Pneumatic connections

Connecting to compressed air

Connection to compressed air is not strictly necessary as the ventilator module can operate with blower alone. However when compressed medical grade air is available (3-6 bar), please connect the NIST hose first to Air Inlet Port of the ventilator module (see Fig 4-5), subsequently connect the other end of hose to the compressed Air supply.

The air supply may be a central hospital supply, a medical compressor or gas bottle.

Connecting to compressed 100% oxygen

Connection to compressed 100% oxygen (3-6 bar) can be performed by connecting the NIST hose first to Oxygen Inlet Port of the ventilator module see Fig 4-6), subsequently connect the other end of the compressed 100% oxygen supply.

The oxygen supply may be a central hospital supply or gas bottle.

Labelling and NIST connectors prevent wrongly connecting the Air and Oxygen supply.

CAUTION:

Air and Oxygen are medical gases; you need to supply via dry, oil free and clean supply systems. Dosage flow and concentration to be adjusted only by trained and authorized medical personal.

5.3.3.2 Ventilation Breathing System

There are different configurations of the breathing circuits compatible with Jenny®. Three basic system configurations are described here.

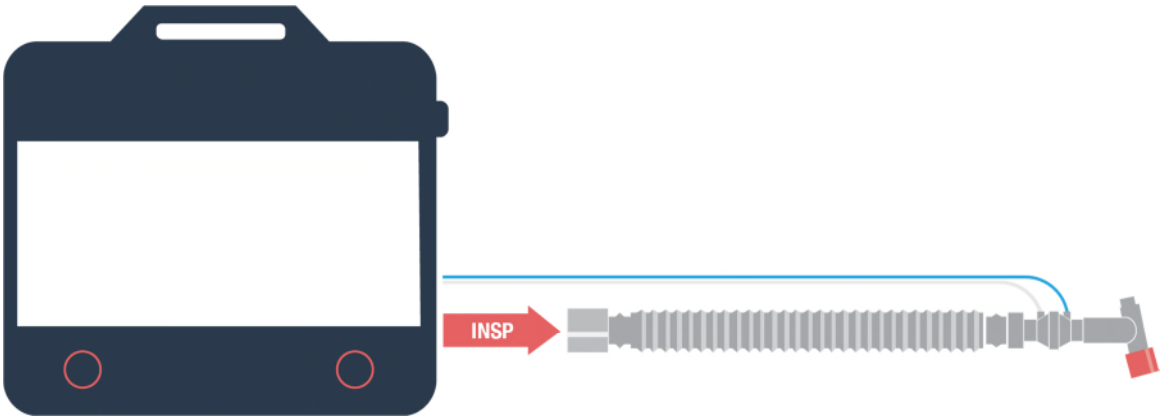
WARNING:

Do not use anti-static or electrically conductive breathing hoses or tubing to prevent an electrostatic discharge to the patient and/or to the operator.

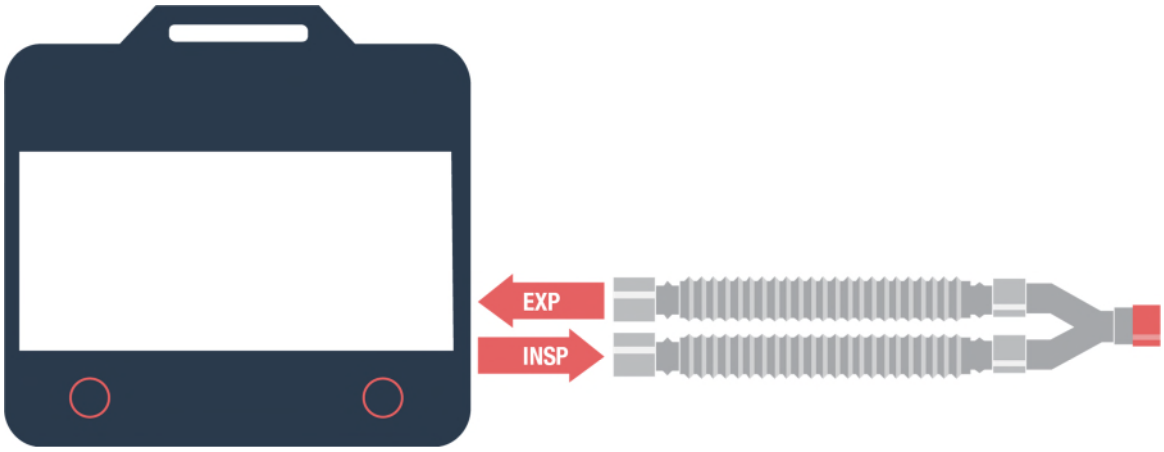
WARNING:

Additional attachements, accessories or sub-assemblies in the breathing circuit can significantly increase the resistance or the dead space and consequently reduce the ventilation performance.

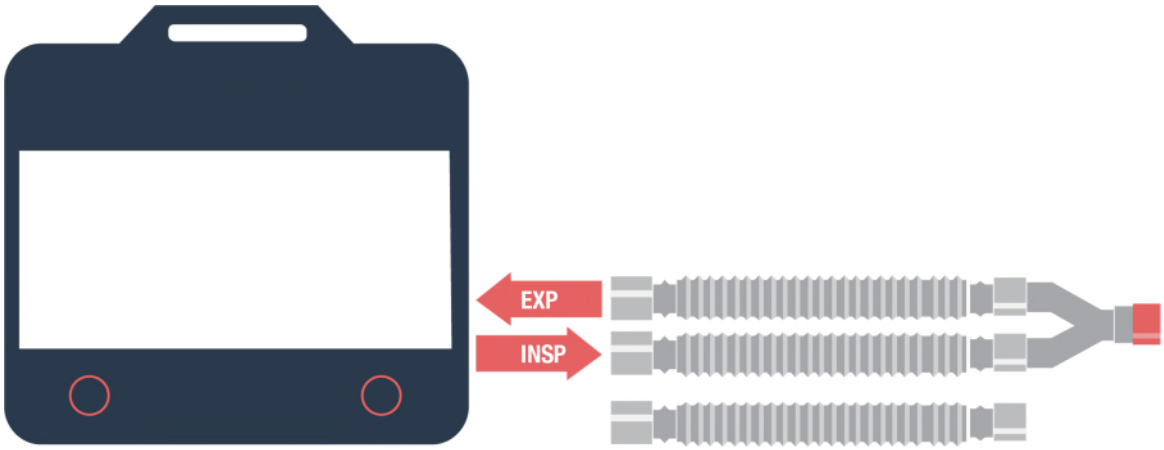
User must strictly observe the correct assembly of breathing circuit.



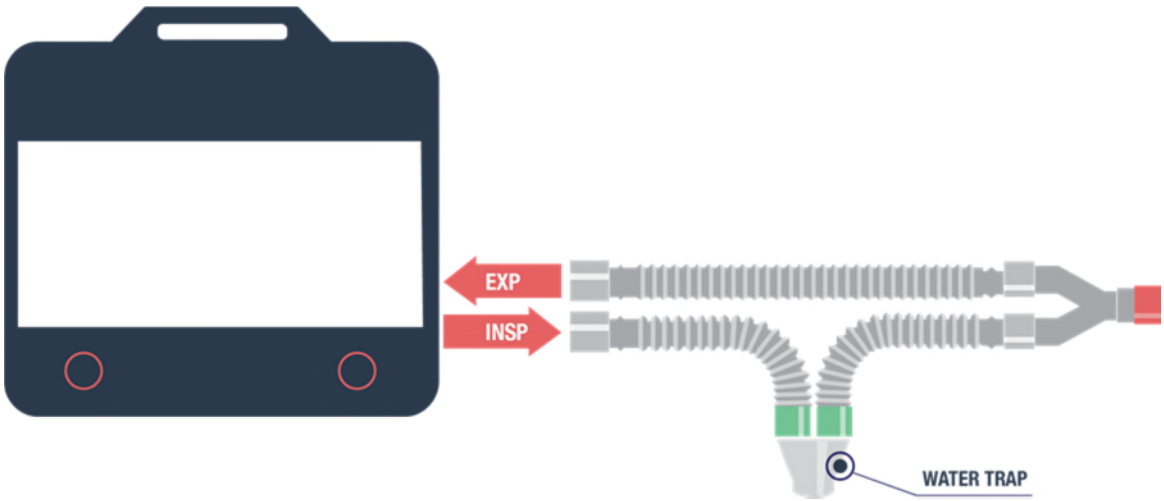
For single-limb breathing circuits with built-in expiration valve - check the connection of pressure line, flow sensor controls lines. Follow the color coding. When using a humidifier – connect additional limb between ventilator and humidification chamber, connect breathing circuit to the other outlet of humidification chamber.



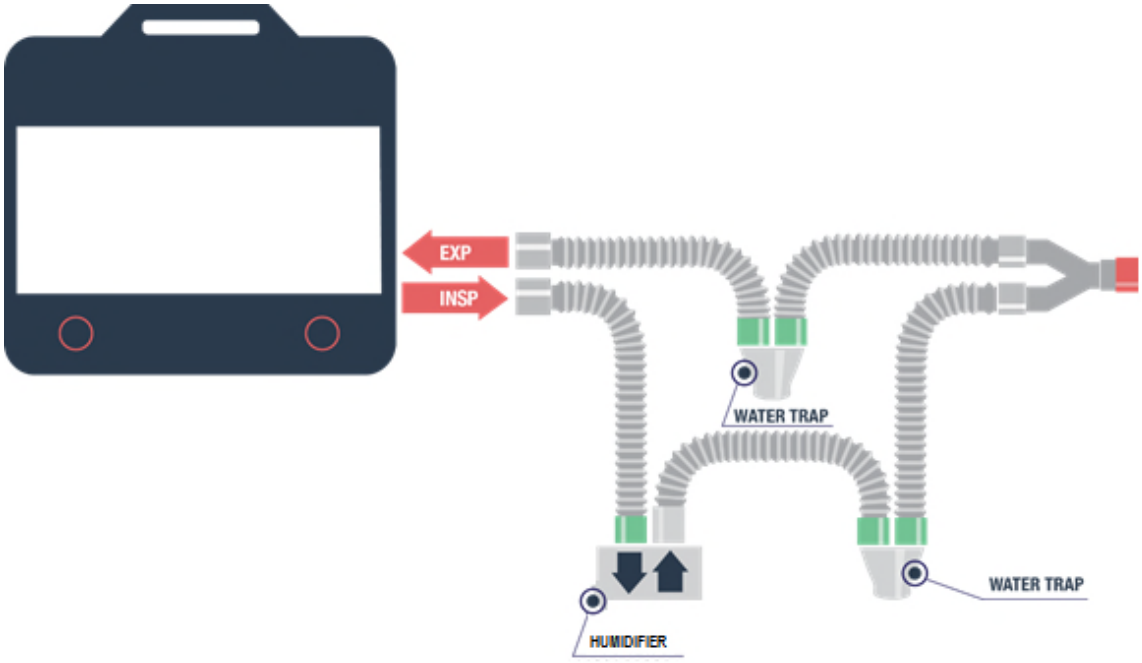
For dual-limb breathing circuits without color coding: connect one hose to inspiration outlet of the ventilator, another one – to the built-in expiration valve. For dual-limb breathing circuits with color coding - follow the assembly instructions from the manufacturer.



When using a humidifier – connect additional limb between ventilator and humidification chamber, connect breathing circuit to the other outlet of humidification chamber.



When using a water trap – insert it to expiration or inspiration hose of the breathing circuit.



When using a humidifier – connect additional limb between ventilator and humidification chamber, connect breathing circuit to the other outlet of humidification chamber.

5.3.3.3 Patient-Ventilator Interfaces

Please refer to the Accessories Catalogue for a detailed list of available options.

When using automatic Tube Compensation (TC) the user must be sure to enter the correct length and diameter of the Endotracheal Tube.

Before using Cuff pressure control, the user must be sure that there is no leak in the cuff, and that the connection between the cuff and the cuff pressure control port is tight. This can be done by gently pressing the small bellow at the connector of the cuff. The cuff pressure on the screen of the Jenny should respond accordingly.

When using an oronasal or total facial mask, the user must select a mask that fits the patient tightly to ensure the patient receives the pressure needed.

When using a helmet, the user must assess the benefits and potential risks associated specifically to the interface (noise level, ear/sinus increased pressure).

When using nasal prongs or masks, the user must assess not only the fitting of the mask or prongs, but also the leakage that might occur due to air escape through the mouth of the patient.

CAUTION:

The following are potential adverse reactions for masks, helmets and nasal prongs:

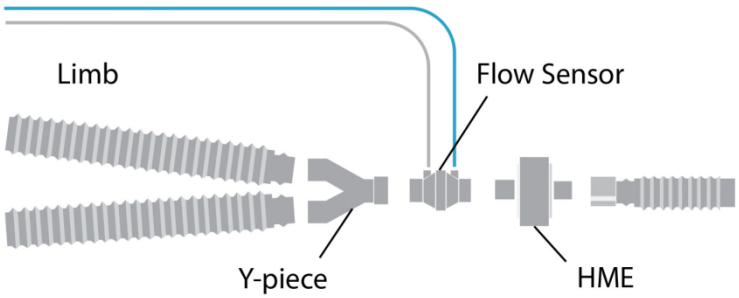
Skin injuries (pressure sores) due to interface
Aspiration
Conjunctivitis
Gastric insufflation
Claustrophobic reaction
Potential hemodynamic instability

NOTE:

If the interface fitting cannot be improved, select an alternative method to deliver the therapy.

5.3.3.4 Proximal (flow) sensor and Heat-Moisture Exchange (HME) filter

To attach the proximal flow sensor, consider that the blue line is closer to the patient. Please be sure to calibrate before use and with the correct calibration equipment.



5.3.3.5 Humidifier

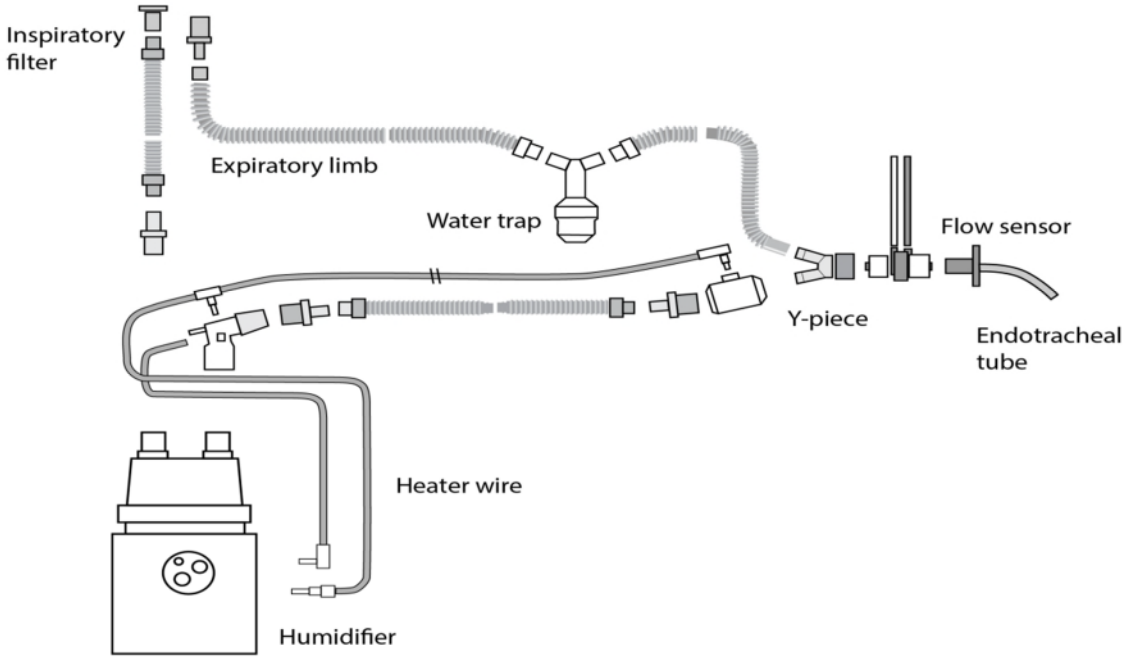
The ventilator module is suitable for use with a humidifier. Please make sure when switching off the ventilator module, or stop the flow to the humidifier to also switch off the humidifier to prevent overheating and over-humidifying gas to the patient.

WARNING:

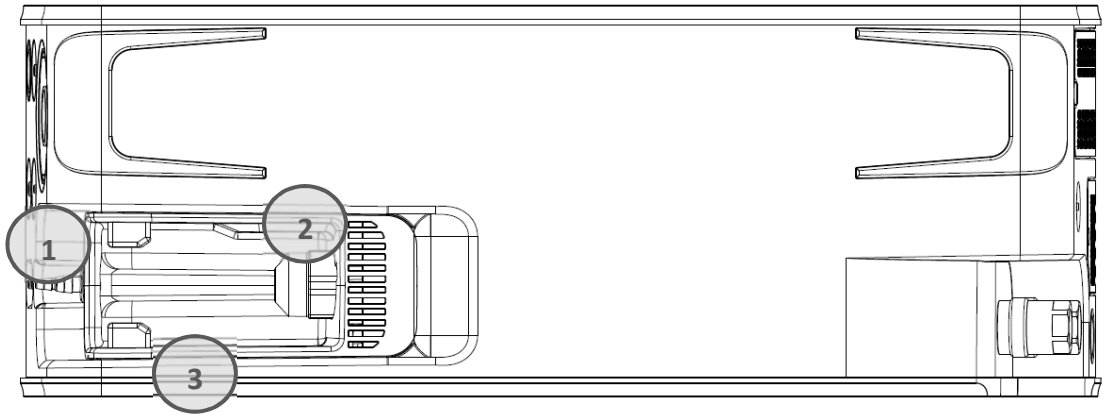
Humidification and nebulization increase the resistance of breathing system filters. Have the breathing system filters regularly checked for increased resistance or blockage.

WARNING:

When using noninvasive ventilation, all circuits are to be actively humidified (heated humidifiers). Heat moisture exchangers (HMEs) are not recommended for use in noninvasive ventilation.

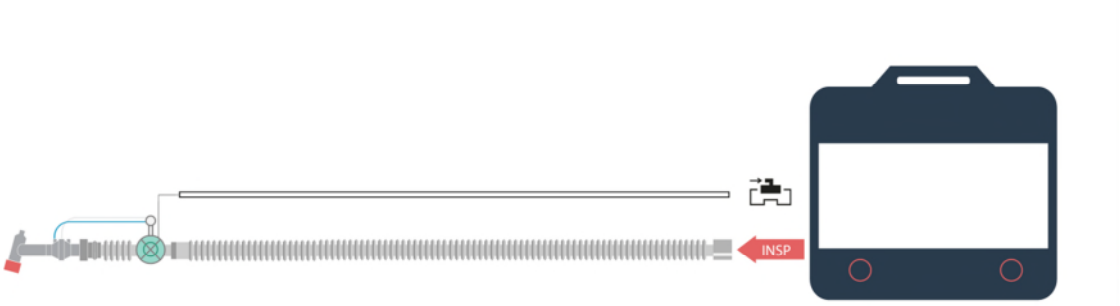


5.3.3.6 Exhalation valve



To insert the first connect the exhalation valve tube to the exhalation valve control port (1). Secondly push back the spring loaded holder (2) and place the exhalation valve such that the exhalation valve rests safely between the spring loaded holder (2) and the exhalation valve brackets (3).

When using single-limb breathing circuits, the expiratory valve must be positioned in the ventilation breathing system as described below. The arrow indicating the direction of the flow must be directed towards the patient. The silicone line must be connected to the Exhalation valve control line.



5.3.3.7 Nebulizer

The ventilator includes an intelligent pneumatic nebulizer that is only activated in the first 75 % of the inspiratory phase and only if the flow to the patient is above 5 L/min. It is not available in “stand by”.

Please note that the additional gas volume applied by the nebulizer (up to 100 mL) can be in the same order of magnitude as small tidal volumes – e.g., neonatal and pediatric patients. Under some circumstances it may be required to reduce the tidal volume.

WARNING:

In neonatal patients, it is advised to use an ultrasound nebulizer.

WARNING:

Before administering any medication via the nebulizer, consult the manufacturer regarding the appropriateness of ultrasonic nebulization for the medication.

WARNING:

Do not use flammable or aerosolized alcohol-based medications in the nebulizer, or use in the presence of flammable anesthetic mixtures. Risk of ignition!

WARNING:

The ventilation accuracy can be affected by the gas added by use of a nebulizer.

WARNING:

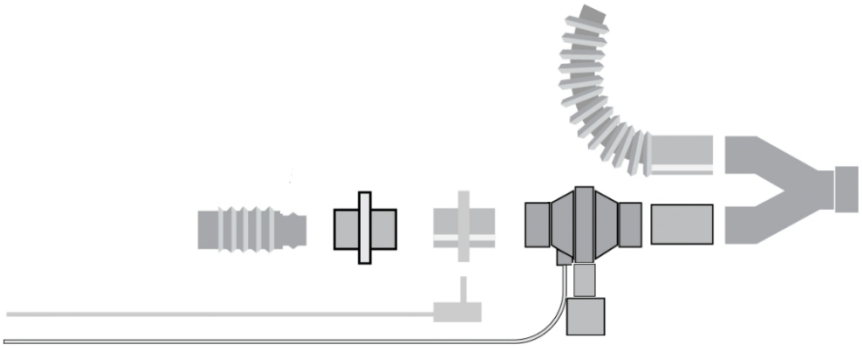
When using the nebulizer, the additional volume is not compensated in volume - controlled modes.

CAUTION:

During nebulization, do not use an HME humidifier in the Y-piece, to ensure that the nebulized medication will be delivered to the patient.

To connect Jet nebulizers

1. Assemble tubing, nebulizer cup, and interface (mask for spontaneously breathing patients or breathing circuit for mechanically ventilated patients).
2. Fill the nebulizer cup with the medication and the solution (according to the institutional protocols and instructions for use of the drug).
3. Connect the nebulizer to a power source.



To connect Ultrasonic nebulizers

WARNING:

• Do not autoclave any component or accessory of the system.

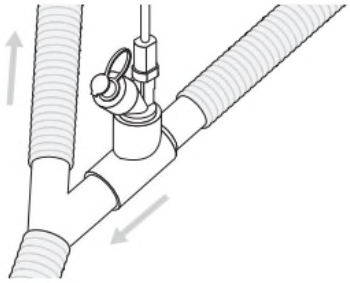
• Do not use a syringe with a needle to add medication.

• While using anesthetic mixtures, the following volatile anesthetic agents are compatible under the stated conditions below (anesthetic agent/maximum percentage/maximum time of exposure):

- Isoflurane / 3.5 % / 12 hours
- Sevoflurane / 8 % / 12 hours
- Desflurane / 10 % / 12 hours

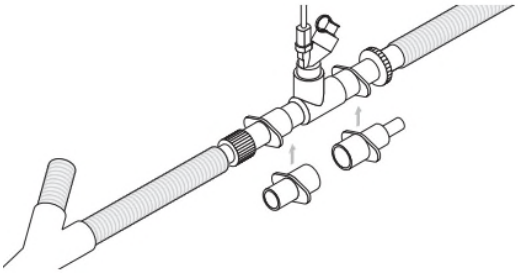
Connection to a Breathing Circuit

1. For 22 mm **adult breathing circuits** connect the nebulizer with an adult T-piece into the inspiratory limb of the breathing circuit before the patient Y-piece.

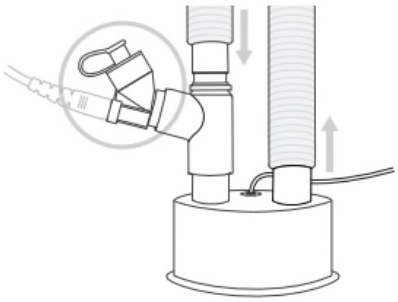


2. For 15 mm **pediatric breathing circuits** connect the nebulizer with the pediatric T-piece into the inspiratory limb of the breathing circuit before the patient Y-piece.

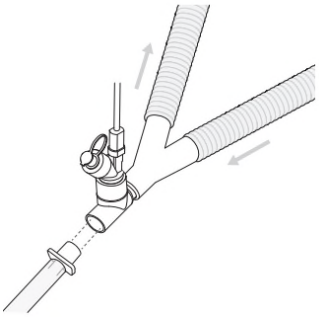
The device can connect to 10 mm pediatric breathing circuits with the 15mm pediatric T-piece and the pediatric adapters. This can be positioned approximately 30 cm back from the patient Y-piece.



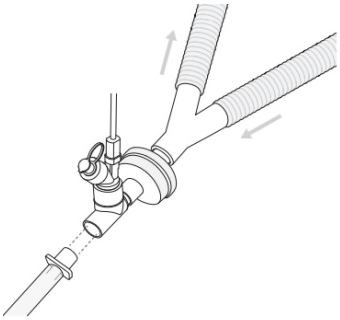
3. The nebulizer can be placed on the dry side of the humidifier as shown. It can be used with a nasal interface in this configuration.



4. The nebulizer can be placed between the wye and endotracheal tube as shown. It can be used with a Heat and Moisture Exchange device (HME) which contains a filter.



5. Only a HME approved for use with a nebulizer should be used in this configuration. Ensure the combination of nebulizer, T-piece and HME volumes is suitable for the tidal volume being delivered.



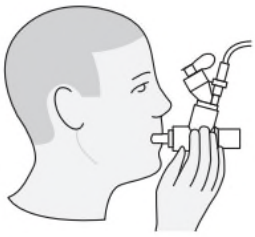
6. Perform a leak test before inserting or removing the nebulizer.

Connection to a Facial Mask

1. When using a mask, connect the vented elbow, mask elbow and mask to the nebulizer by firmly pushing the parts together.
2. Rotate the vented elbow to suit the position of the patient.

Connection to a Mouthpiece

1. The device is compatible with any standard ISO 22mm nebulizer mouthpiece inserted into the adult T-piece.
2. When using a mouthpiece, connect the nebulizer to the T-piece and then connect the T-piece to the mouthpiece by pushing the parts firmly together.

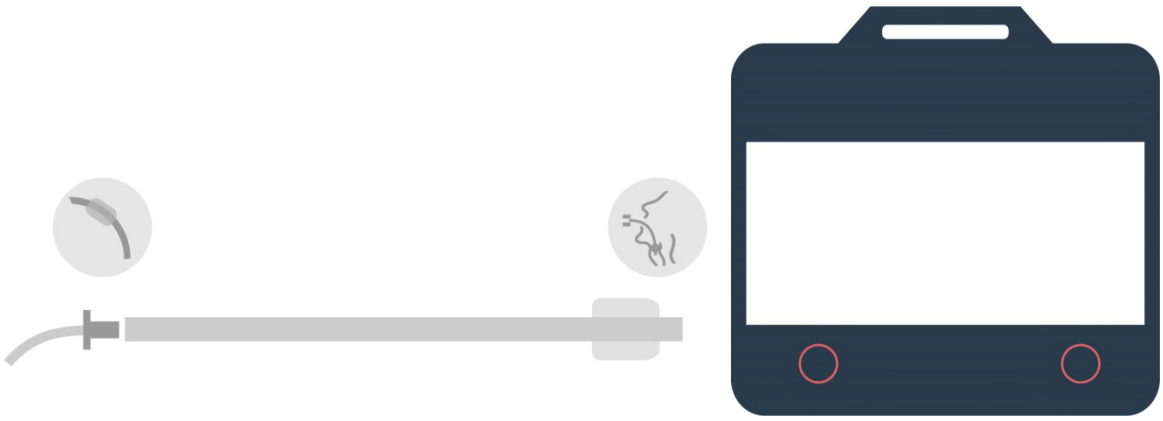


Connection to a Nasal Interface

The nebulizer can be used on/off ventilator with a nasal interface when configured with a humidifier (see figure above).

5.3.3.8 Endotracheal cuff control line

The ventilator is suitable for use with an endotracheal cuff control line. The line must be positioned in the ventilation breathing system as described below.



5.3.4 Patient preparation for ventilation

5.3.4.1 Invasive Ventilation

Before connecting a patient to Jenny® for invasive ventilation therapy:

1. Connect all necessary accessories as described in this user manual.
2. Make sure that the ventilation module is recognized and operative.
3. Select the appropriate patient category.
4. Make sure that the accessories connected are appropriate for the patient category selected.
5. Check that the selected invasive ventilation settings and alarm limits are safe for the patient category selected
6. Run the circuit test.

WARNING:

To avoid physical injury to the patient, never connect a patient to the ventilator before the ventilation module has been recognized by the system and you have selected the appropriate patient category.

NOTE:

For a proper operation, always run the circuit test before connecting a new patient to the ventilator.

5.3.4.2 Non-Invasive Ventilation

Before connecting a patient to Jenny® for noninvasive ventilation therapy:

1. Connect all necessary accessories as described in this user manual.
2. Make sure that the ventilation module is recognized and operative.
3. Select the appropriate patient category.
4. Make sure that the accessories connected are appropriate for the patient category selected.
5. Check that the selected noninvasive ventilation settings and alarm limits are safe for the patient category selected
6. Run the circuit test.

NIV can be applied either via an open single-limb circuit or a closed double-limb circuit.

An open single-limb circuit requires a vented mask with a built-in exhalation port or a non-vented mask and an additional exhalation valve in the circuit to allow carbon dioxide (CO_2) removal. A closed double-limb circuit is used with a non-vented mask and has an exhalation port or filter for CO_2 removal within the system.

The interface itself adds an additional dead space to the system, which can increase CO_2 rebreathing.

WARNING:

Locate the exhalation port, assure its patency and check compatibility of the circuit and interface prior to the start of NIV.

WARNING:

The exhalation port should never be obstructed intentionally (e.g. taping up the holes in the mask) to reduce leakage.

5.3.4.2.1 Selection of the Interface

The operator must assess the characteristics of the patient and the clinical setting, in order to select the appropriate interface for the administration of NIV therapy, accordingly with institutional protocols.

Interface selection for Nonivasive Ventilation					
Setting	**Oronasal mask**	**Total face mask**	**Helmet**	**Nasal mask**	**Nasal prongs**
Acute clinical condition	•	•	•		
Use outside HDU/ICU	•	•		•	•
Claustrophobia				•	•
Likelihood of leakage in acute setting	•			•	•
Nasal patency				•	•
Easiness to expectorate and cough				•	•
Prominent facial anatomy		•	•		•
High level of noise			•		
Contraindication for nasal bridge pressure		•	•		•
High gas flow requirements			•		
Likelihood of eye irritation	•			•	
Easiness to speak			•	•	•

HDU: High-dependence unit

WARNING:

Choosing the inappropriate interface and circuit can lead to CO_2 rebreathing, which can be lethal to the patient.

5.3.4.2.2 Application of the Interface to the Patient

Nasal, oronasal and total face masks

1. Select the appropriate mask type and size, after assessing the characteristics of the patient. Use the measuring tape (when applicable).
2. Inspect the mask prior to each use.
3. Place the mask over the face of the patient and hold it in position.
4. Activate the ventilator immediately after placing the mask over the face of the patient.
5. Adjust the length of the straps to approximately the width of the face.

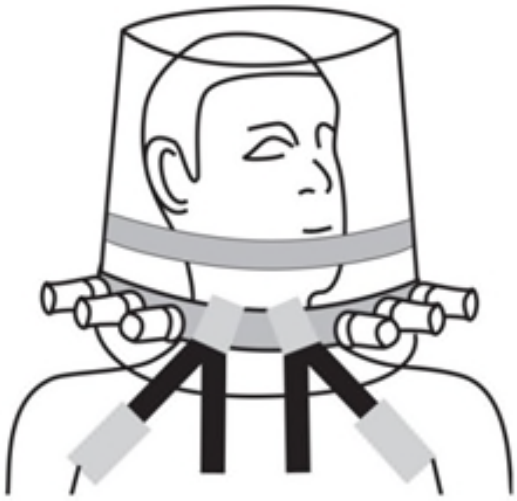
6. Pull the upper strap over the head of the patient with your hand or swivel it around and snap it into its place. Then pull the second strap around the head and attach it to the mask while keeping the mask in position with the other hand.
7. In order to modify the cushion pressure, insert either a pump ball (when provided) or a syringe in the cushion valve, allowing the air volume in the cushion to be increased or decreased and thus, shape the mask to the patient's face contours.
8. If necessary, change the position of the forehead support and forehead pad to eliminate leaks at the bridge of the nose. Nose-bridge leaks must not be decreased by over-tightening the headgear straps.
9. Check the mask carefully for leaks and readjust the shape if necessary.
10. Check the straps for equal tension, making sure they are not too tight.

Oronasal mask

Total facial mask

Helmets

1. Measure the neck size of the patient, to determine the appropriate size of the interface, and where to cut the rubber collar of the interface.
2. Once selected the size, attach the rubber collar of the device to the plastic inner ring of the bag.
3. Attach the inner ring to the transparent hood of the helmet, ensuring a tight seal.
4. Attach the inspiratory and expiratory arms of the breathing circuit to the port sites in the base of the helmet.
5. Set the ventilation parameters for NIV. To improve the synchrony of the patient, adjust the pressure rise time to 50 milliseconds and change the inflow to 50%.
6. Stretch the rubber collar of the helmet, and place over the head of the patient.
7. Once the helmet is fully inflated, attach both of the arms of the patient to the straps, on the front and the back of the helmet, to secure the position of the interface.
8. The helmet must pressurize in seconds.



Nasal prongs

1. Select the appropriate size of the prongs, using the measuring tape.
2. Apply the prongs to the face of the patient, ensuring the appropriate insertion of into the nostrils.
3. Secure the prongs to the head of the patient.

5.3.4.2.3 Troubleshooting

Problem	Possible cause	Proposed remedy
Interface-related pressure ulcers	**General risks** - Sensory impairment - Acute or chronic illness - Hypoxia or very low blood pressure - Extremes of age - Low level of consciousness - Psychological status - Vascular disease - Malnutrition/dehydration - Acute damage or chronic skin condition - History of previous pressure damage - Medication (e.g. analgesia, chronic steroid therapy). **Extrinsic factors** - Closely fitting headgear and over-tightened straps - Poorly fitted masks and headgear - Mechanical forces: pressure, shear or friction from the interface - Allergy to the cushion **Other factors** - Facial edema - Shape and size of nose/face - Time of interface application - Inability to self-manage the mask	Ensuring the skin is clean and dry. Regular pressure relief (ideally every 2–4 h). Use of special mask cushions. Application of dressings to the skin to redistribute pressure. Use of masks with softer cushions (e.g. hydrogel cushions or double spring airfilled cushions, or a combination of both). Adjustable forehead spacer.

Problem	Possible cause	Proposed remedy
Upper airway obstruction	Pushing the lower jaw backwards in the supine position or during rapid eye movement sleep.	Loosen the strap. Refit the mask. Slightly increase the expiratory positive airway pressure.
Mucosal dryness	- Leakage of air through the mouth or around the mask. - Cold, dry air from the ventilator	Add humidifiers, nasal saline/emollients Application of external heated humidifier to the circuit.
Discomfort and/or claustrophobia	- Inappropriate interface selection - Inappropriate ventilator settings - Agitated, poorly collaborative patient	Select carefully the patient Choose correct interface and size. Use of manual mask application (i.e. placing the interface gently over face, holding it in place and starting ventilation; then tighten straps to avoid major air leaks) Careful selection of ventilatory support (i.e. starting with CPAP and adding the lowest PS needed). Optimize ventilatory support (i.e. reduce pressures slightly) Reassure patient Change device (i.e. consider the helmet instead of the face mask) Consider mild sedation
CO_2 rebreathing	- Inappropriate circuit selection - Inappropriate interface selection - Inappropriate ventilator settings	Careful patient selection. Choose correct interface and size. Optimize ventilatory support (i.e. reduce RR, ensure an adequate inspiratory tidal volume, increase the expiratory time, add PEEP≥4 cm H2O). Reduce high end-tidal CO2 (i.e. reduction in caloric intake). Use a two-line ventilator circuit. Use interface with exhalation ports located within the mask. Insert foam rubber to reduce dead space.

Problem	Possible cause	Proposed remedy
Patient-ventilator asynchrony	- Inappropriate circuit selection - Inappropriate interface selection - Inappropriate ventilator settings - Leakage of air or water in the circuit	Careful patient selection Choose correct interface and size. Optimize ventilator support (i.e. increase PS, add PEEP, increase inspiratory flow trigger, and use low respiratory rate for the helmet). Check factors for patient–ventilator dyssynchrony (i.e. air leaks, water in circuit, noise). Consider a reduction in PS to a tidal volume of about 6 ml kg−1.

5.3.4.3 High Flow Oxygen Therapy

The Jenny ® Ventilator can provide High Flow Oxygen Therapy with nasal interfaces (cannulas, prongs or masks) for spontaneously breathing patients. The operator must select the corresponding accessories for each mode.

Mode	Flow Rate	Accessories requirements
Low flow	1 ... 15 L/min	O_2 mask or nasal prong (0.6 L/min). Standard crush resistant safety tube (same for nebulizer). Adapter for the ventilator.
High flow	1 ... 80 L/min	O_2 mask Standard dual, coaxial or single hose system. If an expiration valve is connected, it must be open.

WARNING:

The nasal cannulas and ventilator transition kits are only designed for use with equipment, accessories and spare parts approved by manufacturer. Unauthorized equipment, accessories or spare parts which are used with this product may impair performance of the product or compromise safety (including potentially causing serious patient harm).

WARNING:

Appropriate patient monitoring (e.g., oxygen saturation) must be used at all times. Failure to monitor the patient (e.g., in the event of an interruption to gas flow) may result on serious harm or death.

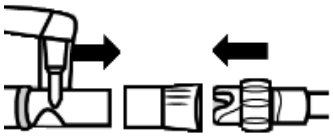
WARNING:

If using supplemental oxygen, keep ignition sources away from the patient.

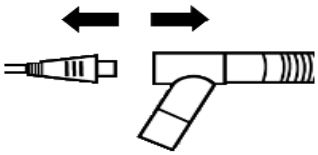
Before connecting a patient to Jenny® for High Flow Nasal Therapy:

1. Connect all necessary accessories as described in this user manual.
2. Make sure that the ventilation module is recognized and operative.
3. Select the appropriate patient category.

4. Select the appropriate accessories (humidifier and breathing circuit) and interface (type and size) for the patient category.
5. Connect the nasal cannula to the adapter and to the inspiratory limb of the ventilator breathing circuit.



6. Connect the system to the ventilator and after following the instructions, ensure that the gas flow through the prongs.
7. Remove and discard the expiratory limb of the circuit. Disconnect the expiratory heater wire adaptor if in use.



8. Check that the settings and alarm limits are safe for the patient selected.

WARNING:

Failure to disconnect the heater wire adaptor from the expiratory limb may increase the risk of fire or burns.

CAUTION:

• Regularly monitor the patient to ensure skin integrity and that the skin underneath the cannula remains dry. A barrier film may be used between the cannula and the patient's upper lip to prevent irritation.

• Do not soak, sterilize or reuse the product. Avoid contact with chemicals, cleaning agents, or hand sanitizers. Secretions on the cannula and the prongs can be removed by gently wiping with a damp cloth.

• Reuse may result in the transmission of infectious substances, interruption to treatment, serious harm or death.

• Do not stretch the cannula on the application; this may cause increased pressure to the patient's skin. If necessary, the cannula may be repositioned.

• Tubing may pose a risk of strangulation or airway restriction.

• Do not used if the product or its packaging has been tampered with.

• Ensure that the patient does not lie on the tubing as it may apply pressure to the patient's ears or face.

• Product only to be used with medical grade gas supplies. The gas supply used with this device may unexpectedly fail to deliver oxygen or flow.

5.3.4.3.1 Selection of the Interface

Select the correct interface for the patient category, patient weight from the options listed in the accessories list in this manual. The recommended nare occlusion is approximately 50%.

Adult Patients

The nasal cannulas are available in the sizes S, M and L. All are compatible with dual-hose circuits for humidifiers.

Pediatric and Neonatal Patients

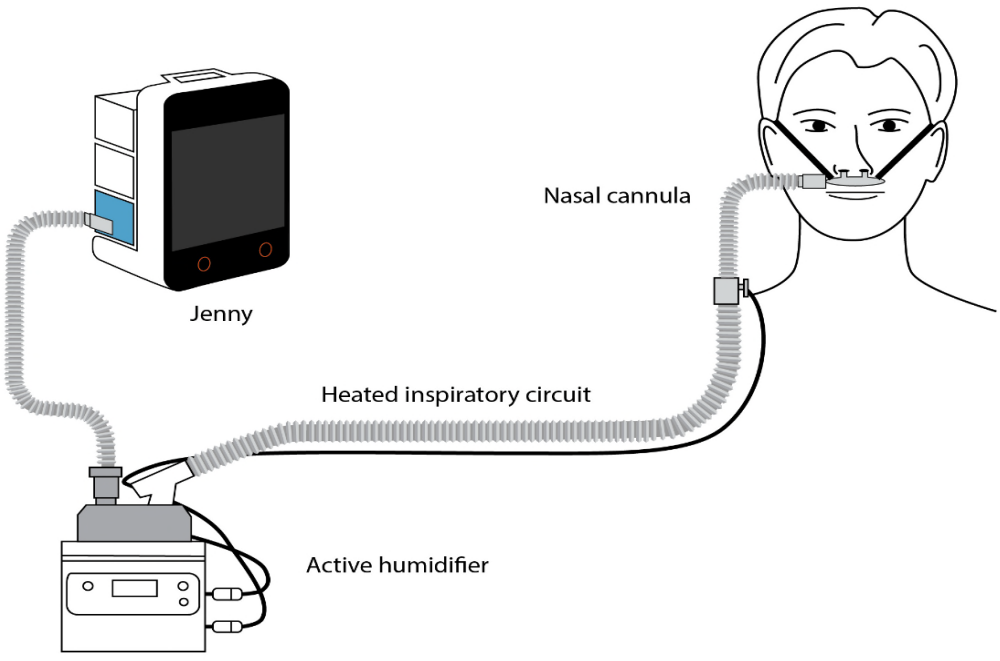
The nasal cannulas are available in 5 sizes, according to the body weight of the patient:

- XS: Patients from 500 g to 2500 g.
- S: Patients from 900 g up to 4000 g.
- M: Patients from 1 kg up to 10 kg.
- L: Patients from 3 kg up to 20 kg.
- XL: Patients from 5 kg up to 30 kg.

The breathing circuits and humidifier must be selected accordingly to the desired therapy (low flow or high flow), as described in the accessories catalogue.

5.3.4.3.2 Assembling the System

The High-Flow Oxygen Therapy requires the connection of a humidifier system to the Ventilator Module, as shown below.



5.3.4.3.3 Application of the Interface to the Patient

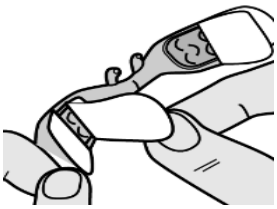
1. Prepare the skin of the patient according to institutional protocols.

Adult patients

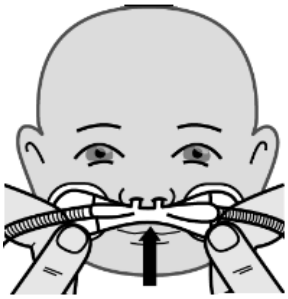
2. Insert the cannula into the nares. Ensure that the cannula bridge rests close to the nose without touching the septum.
3. Adjust the fixation of the cannula to the head of the patient with the straps. Do not allow the straps to press into the ears, eyes or damaged skin.

Pediatric and Neonatal Patients

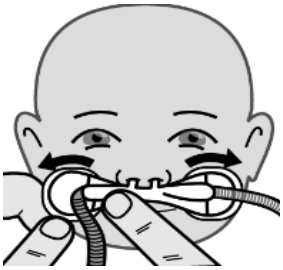
2. Remove the first backing tabs from the wigglepads, avoiding touching the adhesive side.



3. Insert the cannula into the nares. Ensure that the cannula bridge rests close to the nose without touching the septum. Do not stretch the cannula during application. Stick the wigglepads to the cheeks of the patient.



4. Remove the second backing tabs and stick the wigglepads onto the cheeks.



WARNING:

Do not allow the prongs to seal in the nares. Occlusion may result in septal damage or barotrauma.

CAUTION:

- Do not place the wigglepads on the patient's eyes, ears or injured skin.
- Ensure that the cannula is placed directly on the wigglepads. Direct skin contact caused by cannula misalignment may result in skin breakdown.

5.3.5 Neonatal Noninvasive Ventilation (nCPAP)

Before connecting a patient to Jenny® for nCPAP therapy:

1. Connect all necessary accessories as described in this user manual
2. Make sure that the ventilation module is recognized and operative.
3. Select the appropriate patient category.
4. Connect the circuit set to the CPAP driver or the ventilator and the humidifier. If necessary, use the extra connectors. Insert the temperature sensors completely, until the tip reaches the gas flow.
5. Connect the bigger connection of the CPAP generator (Medijet ®) to the inspiratory tube.
6. Put the pressure measurement line into the smaller connection of Medijet® (pressure port) and connect the pressure measurement line to the pressure port of the CPAP driver or ventilator.
7. Close the prong adapter of the Medijet® with a finger and adjust the nCPAP parameters, e.g. the pressure, on the ventilator, e.g. the pressure.
8. Check that the selected ventilation settings and alarm limits are safe for the patient selected.
9. Run the circuit test.

WARNING:

If the packaging of any part or the part itself is damaged, this part cannot be used and must be discarded and disposed of.

Check that the holes of the generator and of the prongs /masks are not blocked. If the openings are not patent, the products in question should not be used.

NOTE:

If all connections are correct and Medijet® is the reason for the failure, discard this Medijet® and dispose of it.

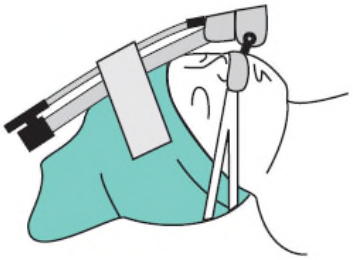
5.3.5.1 Application of the Interface to the Patient

1. Select a prong or mask with the aid of the measuring tape.

2. The prong should be selected such that it is large enough to seal the entire nostril. The prong is placed on the Medijet® generator ensuring that the arched side of the prongs point towards the upper lip of the patient.
3. The mask should be selected such that it fits precisely along the sides of the nostrils. The mask is attached ensuring that it adapts to the shape of the nose.
4. Select a bonnet of the correct size using the measuring tape and the corresponding color coding.

5. The bonnet should be secured firmly enough but without leading to deformation of the head. Remove the separate Velcro strap from the bonnet and put it aside, within easy reach. The bonnet is placed on the head such that the gap between the two fleece parts is centred over the forehead. The bonnet should cover the ears and be pulled down to the nape of the neck. Thread the fixation straps through the loops on the prong or on the mask.
6. Pull the bonnet down to just above the eyebrows of the patient. This simplifies the fixation of Medijet®. Too small bonnets will be followed by a deformation of the head. Too big bonnets cannot guarantee a sufficient fixation of the CPAP generator.
7. Choose the most suitable angle for the Medijet® prong adapter (45° or 60°). If a prong is used, it generally yields the narrower angle; if a mask is used, it generally yields the wider angle.
8. Place the Medifoam foam wedge between the two fleece pieces in the middle of the bonnet. Fit the Medijet® into the round opening of the foam provided.
9. Insert the prong into the nostrils. Maintain a small distance between the nasal septum and the base of the prong. Do not insert the prongs fully into the nostrils. The connector blockshould not touch the nose.
10. When using the mask, ensure that it rests evenly on the skin. The nostrils must be kept clear and should not be displaced by any part of the mask.
11. Using the Velcro strap, secure the Medijet® from above to the fleece pieces of the bonnet. Do not pull the strips too hard. The Medijet® is held primarily by means of

the bonnet and the foam. If the leak is too large, check the selected prong or mask size – pulling the straps more tightly does not by itself solve the problem.



12. Secure the Velcro area of the strap in the area of the ears as an extension of the fixation loops of the prong. Do not pull the straps too tightly; they should only provide the lateral support needed.
13. Ensure that the weight of the tubes does not pull directly on the head of the patient or on the interface. Use cushioning to support the tubes.
14. The inspiration tube should slope away from the patient and the Medijet® so that water condensation does not come into contact with the baby

WARNING:

- Always insert the Medijet® complete into the prongs or masks.
- Do not use cream near the prong, mask or Medijet®, otherwise the prong or mask can slip of the Medijet®.
- Do not re-use the prongs or masks. They are for single patient use only.
- Sterilized and disinfected prongs and masks may harden and cause injury to the patient.

NOTE:

Always use the largest possible prong to avoid leaks and ensure the best possible positioning – the smaller the leak is, the higher and more stable the CPAP pressure is.

NOTE:

The reusable bonnet is equipped with a Velcro closure in which the interface is secured. The tubes are directed behind the head of the patient.

5.4 Monitoring module (Optional)

5.4.1 Overview

The Jenny Monitoring Module provides monitoring, display, diagnostic and alarming of multiple physiological parameters, ranging from basic vital signs monitoring: ECG, Heart rate, SpO_2, Pulse, Temperature, and NIBP through advanced monitoring functions like four invasive blood pressure channels (IBP) and capnography to diagnostic quality monitoring such as 12-lead ECG and detection of arrhythmias and ST elevation myocardial infarction (STEMI).

NOTE:

Arrhythmia detection and ST-analysis functions are not available for neonatal patients.

5.4.2 Accessories

Please refer to the Accessories Catalogue for a detailed list of the available options for every functionality of the Module.

5.4.3 Patient preparation for ECG

WARNING:

- Use only the ECG electrodes and cables provided by manufacturer as specified in this manual. You should use high quality eclectrodes with low polarization and low contact resistance.
- When the electrode polarization voltage is too high, the monitor will indicate that condition with an alarm.
- Before connecting the ECG cables to the monitor, please check the integrity of the lead wires and cables. If in doubt, replace the cables.
- When you are connecting the electrodes patch or the patient cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are completely attached to the patient, to prevent them from contacting conductive parts or earth.
- When conducting defibrillation, you must use only the ECG electrodes and cables supplied by the manufacturer as specified in this manual.
- Do not touch the patient or the ECG cables during defibrillation.
- The monitoring module is protected against defibrillation effect. When applying defibrillator to the patient, the monitor will display transient distorted waveforms. If the right electrodes are used and placed correctly, the display of the monitor will be restored within 10 s. During defibrillation, the chest leads V1-V6 should be removed

and the limb leads RA, LA, RL, LL electrodes should be moved to the side of the limbs.

- When using the monitor with high-frequency electrosurgical units (ESU), to reduce to hazard of burns in the surgical unit neutral electrode, make sure that the electrodes are not located between the surgical site and the electro-surgical unit return electrode
- Interference from instruments near the patient and ESU interference can cause artifacts problems with the display of the ECG wave.
- The monitor cables cannot be directly applied to heart and cannot be used for the measurement of endocardiography.

Skin preparation

WARNING:

Check the patient skin before attaching the electrodes to the skin. Make sure that skin is healthy, without wounds, burns or medical patches. Ensure that skin is dry and clean from oils and ointments. Relocate the electrodes if you observe a skin allergic reaction.

To ensure a good electrode-skin contact

1. Make sure that the skin area is intact.
2. If necessary, shave the excess of hair at the electrode area.
3. Gently scrape skin to remove dead cells using ECG skin preparation paper to improve electrical conductivity.
4. Clean the area with an alcohol pad.
5. Let it dry completely before placing the electrode patch.

CAUTION:

The following are potential complications that can be associated to the use of electrodes:

- Allergic reaction
- Skin hyperpigmentation

5.4.3.1 Placing leads

Simply connect the cable lead clip or snaps to the corresponding electrode button before attaching the electrode to the patient skin.

Color coding for ECG leads

AHA symbol	AHA color	IEC symbol	IEC color	Electrode / Lead Placement
Limb Leads				
RA	White	R	Red	Under the right clavicle, between the shoulder and the elbow
LA	Black	L	Yellow	Under the left clavicle, between the shoulder and the elbow

AHA symbol	AHA color	IEC symbol	IEC color	Electrode / Lead Placement
RL	Green	N	Black	On the right lower abdomen, above the ankle and below the torso
LL	Red	F	Green	On the left lower abdomen, above the ankle and below the torso
Chest Leads				
V1	Red	C1	Red	4th Intercostal space to the right of the sternum
V2	Yellow	C2	Yellow	4th Intercostal space to the left of the sternum
V3	Green	C3	Green	Midway between V2 (C2) and V4 (C4)
V4	Blue	C4	Brown	5th Intercostal space at the midclavicular line
V5	Orange	C5	Black	Anterior axillary line. Same horizontal level as V4 (C4)
V6	Violet	C6	Violet	Midaxillary line. Same horizontal level as V4 (C4) and V5 (C5)

NOTE:

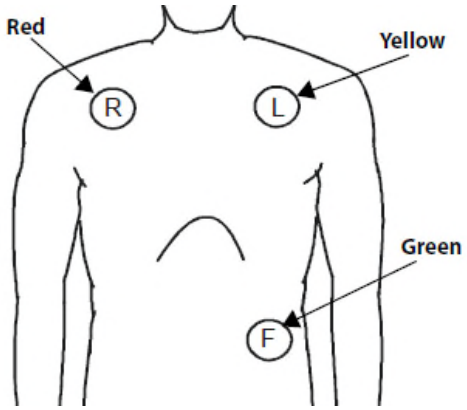
For a 12 Lead resting ECG, it is recommended to put the RA and LA limb electrodes directly on the patient's wrist and RL and LL electrodes a few centimeters above the ankles.

5.4.3.2 Placing electrodes

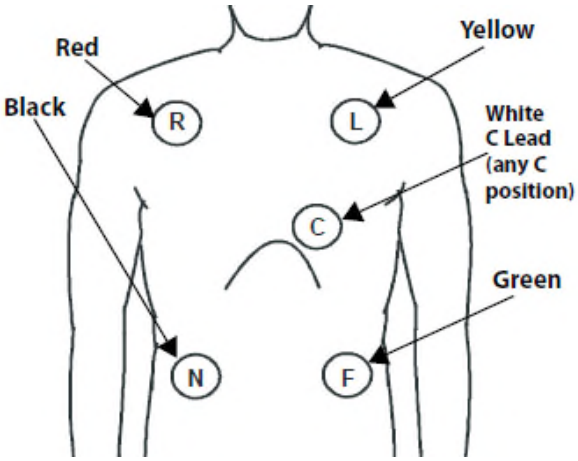
To place the electrodes

1. Follow the previous recommendations for skin preparation
2. Ensure that the patient is relaxed
3. Check the electrodes expiry date at the packaging before applying the electrodes
4. Check integrity of packaging. Discard if compromised
5. Remove the electrodes from the package and check that they are in good condition
6. While placing electrodes for a surgical patient, the type of surgery should be considered, for instance, as to a chest surgery, the chest lead electrodes can be placed at sides or backside of chest.
7. While using a surgical electrotome, in order to reduce the influence of artifacts to ECG waveform, the electrodes can be placed at left and right shoulders, close to left and right sides of abdomen; the chest lead electrodes can be placed at left side of chest midst
8. Please avoid placing the electrode at the upper arms, otherwise the ECG waveform will become very small.

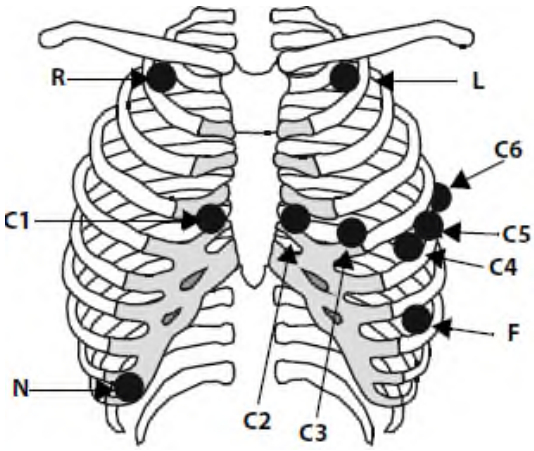
Placing 3-leads



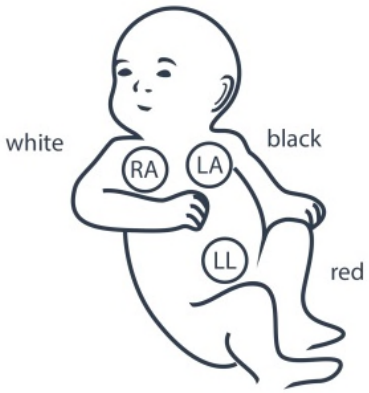
Placing 5-leads



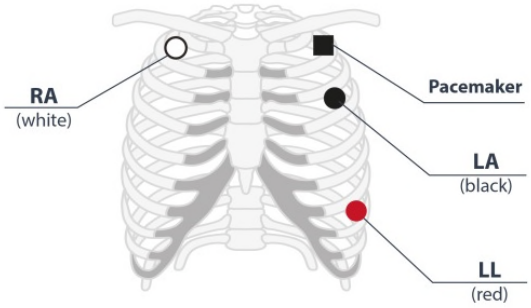
Placing 12-leads



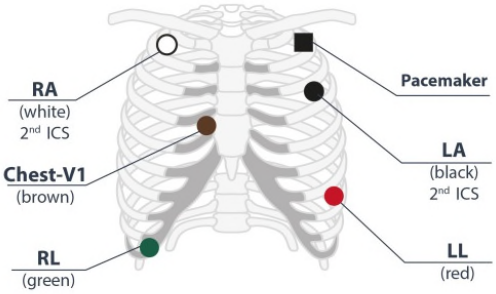
Placing leads in neonates



Placing 3-leads in internally paced patients



Placing 5-leads in internally paced patients



5.4.3.3 Connecting ECG cable to the monitoring module

Plug the ECG cable into the corresponding ECG connector in the monitor module. You can now start monitoring the ECG.

For ECG monitoring and settings adjustments, refer to chapter 6.5.3

5.4.3.4 Troubleshooting

Problem	Possible cause	Proposed remedy
Noisy ECG signal	- Loose electrodes - Dry electrodes - ECG cables/electrodes damaged - ECG cables too close to other electrical equipment - Radio frequency interference	- Check electrodes. Replace if damaged. Moist/add gel to electrodes - Check 50-60 Hz filter - Selected another ECG filter equipment - Route the ECG cables away from other equipment - Stay away from radio frequency emitting equipment

Problem	Possible cause	Proposed remedy
Patient movement. Muscle artifacts in ECG signal	- Inadequate skin preparation - Muscle tremor artifact (nervous, cold or shivering patient) - Poor electrode placement - Seizures or epilepsy	- Check skin preparation - Calm the patient down Release muscular tension, check that limbs are resting - Check electrodes placement - Wait till patient is calmed or hold the limbs during measurement
Too many ECG alarms: HR, Arrhythmias, lead disconnection …	- Loose electrodes - Dry electrodes - Wrong patient category - Wrong alarm limits - Patient nervous, trembling	- Check electrodes - Moist/add gel to electrodes - Check correct patient category is selected - Readjust alarm limits - Calm the patient down Release muscular tension, check that limbs are resting
No ECG waveform	- Gain setting too low - Wrong patient category - Cables and electrodes not properly attached - Damaged cable and/or electrodes	- Check gain setting - Check patient category - Check proper connection to patient and to module - Test cables
Baseline artefacts (Line wander)	- Inadequate skin preparation - Patient nervous, trembling - Patient breathing interference - Electrodes dry or loose - Wrong ECG filter setting	- Check skin preparation - Calm the patient down Release muscular tension, check that limbs are resting - Check electrodes placement - Set ECG filter settings to Monitor
Equipment-related artifacts	- Neuromodulation devices, either transcutaneous or implantable - Diagnostic procedures: Evoked potential monitoring unit, MRI, flexible bronchoscope, sinus endoscope, among others. - Therapeutic procedures: Hemodialysis machine, cardiopulmonary bypass, intravenous fluid warming set, pressure-controlled irrigation pumps, extracorporeal shockwave lithotripsy (ESWL), among others.	- Check 50-60 Hz filter - Selected another ECG filter equipment - Route the ECG cables away from other equipment - Readjust alarm limits - Set ECG filter settings to Monitor

5.4.3.5 ECG Printer

CAUTION:

Use only thermo-sensitive recording paper in order to avoid recording failure, bad-quality record or damage of thermo-sensitive printing head.

Do not pull out the recording paper during an active ECG printout, otherwise the recording meter might be damaged.

Open the ECG paper slot only to replace paper.

NOTE:

The printer paper exhibits a red stripe mark at its edge, which indicates the end of the paper roll. It is recommended to load a new roll of paper as soon as this marking is visible.

To load the ECG recording paper

1. Pull the locking lever of the printer door handle slightly downwards, to unlock the printer flap and open it downwards.
2. Push the paper roll holder on both sides slightly outwards to remove the roll of paper.
3. Insert a new roll of paper into the holder so that the end of the paper has its printed side facing upwards and forwards.
4. Pull the paper forwards over the edge of the printer flap and hold.
5. Push the printer flap upwards and close the printer compartment until the lock is heard to click into place.
6. Make sure that the locking hooks at the printer flap are firmly engaged on both sides.

To clear a ECG recording paper jam

In case of absence of effective ECG printout, or when abnormal noise is evidenced while printing, it is recommended to assess if a paper jam is blocking the ECG printer.

1. Open the ECG door handle.
2. Pull out the recording paper, and cut off the wrinkle part.
3. Load the recording paper once again and close the flap.

5.4.4 Patient preparation for Pulse-CO Oximetry (Optional)

WARNING:

The pulse co-oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

WARNING:

All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise degraded performance and/or patient injury can result.

 **WARNING:**

Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.

 **WARNING:**

Do not start or operate the pulse co-oximeter if it appears or is suspected to be damaged.

 **WARNING:**

Do not place the pulse-oximeter or accessories in any position that might cause it to fall on the patient.

 **WARNING:**

Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide. Risk of explosion!

 **WARNING:**

To ensure safety, avoid stacking multiple devices or placing anything in the device during operation.

 **WARNING:**

Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site as frequently as every (1) hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia. During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis. With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.

 **WARNING:**

Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor. Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.

 **WARNING:**

Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.

WARNING:

Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor, Trendelenburg position). Venous pulsations may cause erroneous low SpO2 readings (e.g. tricuspid value regurgitation, Trendelenburg position).

WARNING:

The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.

WARNING:

The sensor should be free of visible defects, discoloration and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.

WARNING:

Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.

WARNING:

Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.

WARNING:

Do not use the sensor during MRI scanning or in a MRI environment.

WARNING:

Do not adjust, repair, open, disassemble, or modify the device or accessories. Injury to personnel or equipment damage could occur. Return the device for servicing if neccesary.

WARNING:

To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device or sensors in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions as instructed in Chapter 7.

- Do not attempt to clean the device or sensors while monitoring a patient.
- Do not attempt to reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.

 **WARNING:**

- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.
- To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

 **WARNING:**

Interfering substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

 **WARNING:**

SpO2, SpCO, SpMet and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

 **WARNING:**

SpCO readings may not be provided if there are low arterial saturation levels or elevated methemoglobin levels.

 **WARNING:**

Inaccurate SpCO and SpMet readings may be caused by:

- Improper sensor application.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels including altitude induced hypoxemia.
- Elevated total bilirubin levels.
- Motion artifact.

 **WARNING:**

Inaccurate SpO2 readings may be caused by:

- Improper sensor application

- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of bilirubin and/or dyshemoglobin
- Vasospastic disease such as Raynaud's disease
- Peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalasemia, Hbs, Hb*c*, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Birthmark (s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers, etc.
- skin color disorders.

WARNING:

Inaccurate SpHb and SpOC readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO2 or bilirubin levels
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin and/or methemoglobin levels
- Hemoglobinopathies and synthesis disorders such as thalasemia, Hbs, Hb*c*, sickle cell, etc.
- Vasospastic disease such as Raynaud's disease
- Elevated altitude
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

WARNING:

- For reusable finger sensors: The sensor is to be removed and repositioned at least every 4 hours, or sooner if the patient exhibits poor circulation or skin integrity.
- For adhesive finger sensors: The sensor must be checked or changed at least every 8 (eight) hours to ensure adequate adhesion, circulation, skin integrity, and correct optical aligment.
- For reusable tip-clip ear sensors: The sensor must be removed and repositioned to a different monitoring site at least every four (4) hours. Because individual skin conditions and perfusion levels affect the ability of the site to tolerate sensor placement, it may be necessary to move the sensor more frequently.

WARNING:

The probes and probe cable extender listed in the accessories list are designed for use only with Jenny® monitor module.

WARNING:

Use only the accessories listed in this manual for SpO2. The user must verify the compatibility of the sensor and the extension cable with the monitor before the use. Incorrect use may lead to incorrect measurements and patient injury.

WARNING:

High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.

WARNING:

To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.

WARNING:

If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.

WARNING:

The pulse co-oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING:

The pulse co-oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

CAUTION:

Do not place the device where the controls can be changed by the patient.

CAUTION:

Do not place the device on electrical equipment that may affect the device, preventing it from working properly.

CAUTION:

If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If sensor is exposed to the radiation, the reading might be inaccurate or the unit might read zero for the duration of the active radiation period.

CAUTION:

When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION:

To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the device.

CAUTION:

Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed after completing the low SIQ troubleshooting steps listed on this manual.

CAUTION:

The device must be configured to match your local power line frequency to allow for the cancellation of noise introduced by fluorescent light and other sources.

NOTE:

Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

NOTE:

High intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the Pulse CO-Oximeter to obtain vital sign readings.

NOTE:

Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

NOTE:

Additional information specific to the compatible Masimo sensors, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's Directions For Use (DFU).

5.4.4.1 No Implied License Statement

"Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device."

5.4.4.2 Principle of Operation

SpO_2 and Pulse Rate

Pulse oximetry is governed by the principles that oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), and methemoglobin (blood with oxidized hemoglobin content) species differ in their absorption of visible and infrared light. The amount of arterial blood in tissue changes with the pulse (photoplethysmography). Therefore, the amount of light, absorbed by the varying quantities of arterial blood, changes accordingly.

SpCO, SpMet and SpHb

The Masimo Rainbow SET technology uses a multi-length wave sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, blood with oxidized hemoglobin and blood plasma. Once the Masimo Rainbow SET technology receives the signal from the sensor, it calculates the patient's functional oxygen saturation (SpO_2), fractional concentration of carboxyhemoglobin (SpCO), fractional concentration of methemoglobin (SpMet), total hemoglobin concentration (SpHb) and pulse rate.

5.4.4.3 Intended patient categories

The Pulse CO-Oximetry measurements are intended for Adult, Pediatric and Neonatal patients.

5.4.4.4 Selecting the SpO2 sensor

Select the correct sensor for the patient category, patient weight and application site from the compatible sensors listed in the accessories list in this manual.

WARNING:

The Rainbow DCI and DCI-P reusable sensors are contraindicated for use on mobile patients or for prolonged periods of use.

WARNING:

The RD SET TC-I reusable sensor is contraindicated for patients with pierced ears at the measuring site.

NOTE:

The RD SET reusable and disposable sensors provide monitoring for only the following parameters: SpO_2, PR, PI and optional PVI

5.4.4.5 Connecting the SpO2 sensor to the monitoring module

The sensor's instrument connector is attached to an appropriate cable, which is then attached to an instrument equipped with Masimo Rainbow technology and the instrument is turned on.

5.4.4.6 Application

Site Selection

- Always choose a site that is well perfused and will completely cover the sensor's detector window.
- Site should be cleaned of debris and dry prior to sensor placement.

Reusable sensors

DCI: Middle or ring finger
DCI-P: Middle or ring finger, or thumb
TC-I: Ear lobe or pinna

Disposable Sensors

Adult Sensor (>30 kg): The preferred site is the middle or ring finger of non-dominant hand.

Pediatric Sensor (10–50 kg): The preferred site is middle or ring finger of non-dominant hand.

Infant Sensor:

- 3–10 kg: The preferred site is the great toe. Alternatively, the toe next to the great toe, or the thumb can be used.
- 10–20 kg: The preferred site is the middle or ring finger of the non-dominant hand.

Neonatal/Adult Sensor:

- < 3 kg: The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.
- > 40 kg: The preferred site is the middle or ring finger of non-dominant hand.

5.4.4.7 Attaching the SpO2 sensor to the patient

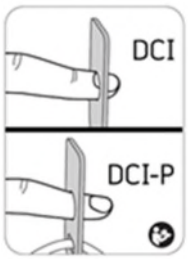
To estimate arterial oxygen saturation in the patient

For reusable finger sensors
Slender Digit Gauge Instructions

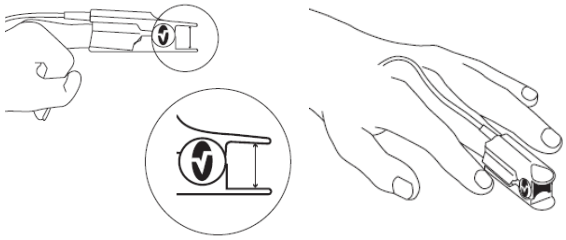
The Slender Digit Gauge on the sensor cable is an aid for selecting an appropriate digit for sensor application (available on sensors capable to measure SpHb).

Use of this gauge is recommended only for patients weighing > 30 kg that have slender digits. Remove the gauge from the digit BEFORE sensor application.

1. It is preferable to start with the ring finger of the non-dominant hand. If this is too slender, select a larger digit. Slide the gauge circle on the digit. If the gauge circle stops at any point of the nail bed before the cuticle, the DCI sensor should be used on that digit.
2. If the gauge slides past the cuticle, the digit is too slender for this sensor. Select a different digit, or use a pediatric/slender digit sensor (DCI-P) on this patient.



3. The medical practitioner selects a site that is well perfused and restricts the patient's movements (generally the ring or middle finger of the non-dominant hand) to apply the sensor.
4. Pressing on the hinged tabs on the sensor, the sensor is placed over the digit so that the patient's finger position corresponds to that of the finger shown on top of the sensor.
5. The marks on the side of the sensor which indicate the location of the sensor light source and detector should approximately align with the back edge of the patient's finger nail. The cable form the sensor will run on top of the patient's hand.
6. The position of the cable is adjusted to prevent entanglement.
   The cable may be taped to the patient's arm for comfort and to further prevent entanglement.



For reusable Tip-Clip ear sensors

1. To improve perfusion to the ear, rub the earlobe vigorously for 25-30 seconds. The ear lobe can also be rubbed with rubefacient cream (10-30% methyl salicylate and 2-10% menthol).
2. Clip the sensor onto the ear lobe or pinna. Orient the cable so that it runs down the neck toward the body. If the RD SET TC-I sensor does not fit properly on the ear, consider using an RD SET disposable sensor or RD SET reusable finger clip on another finger/digit.

CAUTION:

Do not use strong vasodilator creams such as nitroglycerine paste.

Discontinue use of the ear sensor if there is loss of spring tension sufficient enough to allow slippage or movement of the sensor from its proper position on the ear lobe or pinna.

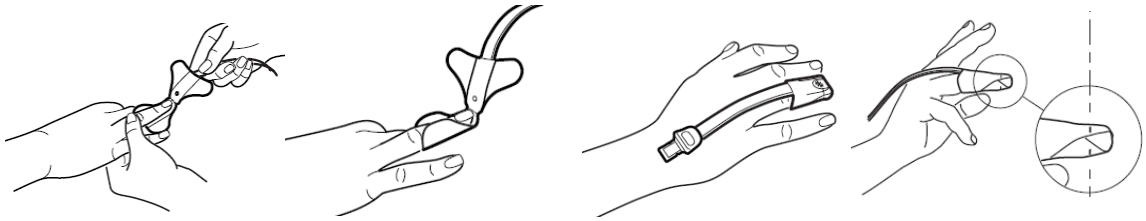
Avoid positioning the patient so that external pressure is applied to the sensor at the measuring site.

For adhesive finger sensors

1. Open the pouch and remove the sensor. Remove the backing from the sensor.

Adt sensor for ADULTS (> 30 kg) and Pdt sensor for PEDIATRICS (10–50 kg)

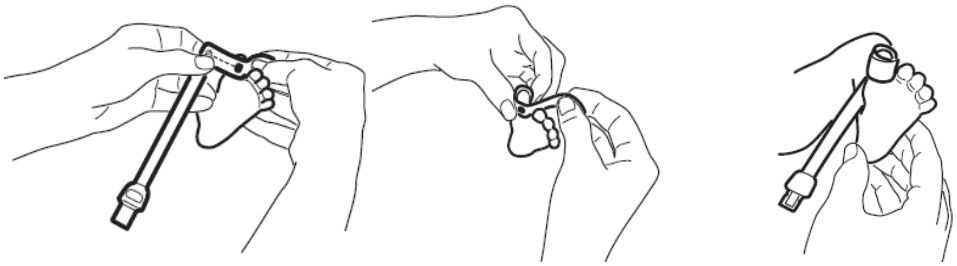
2. Orient the sensor so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the finger outline and detector window (Fig. 1).
3. Press the adhesive wings, one at a time, onto the finger. Complete coverage of the detector window is needed to ensure accurate data (Fig 2).
4. Fold the sensor over the finger with the emitter window (*) positioned over the fingernail. Secure the wings down, one at a time, around the finger (Fig. 3).
5. When properly applied, the emitter and detector should be vertically aligned (the black lines should align). Reposition if necessary (Fig. 4).



1 **2** **3** **4**

Inf sensor for INFANTS (3–10 kg)

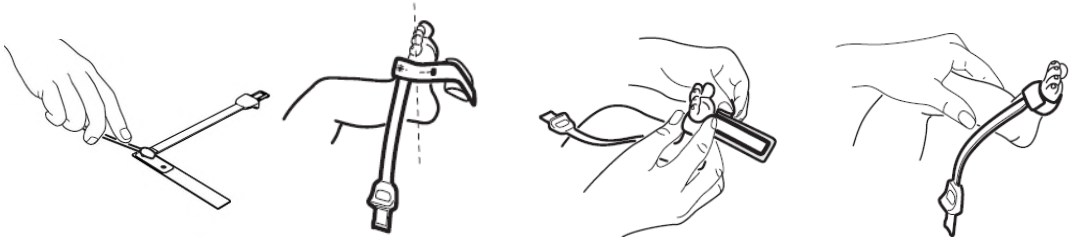
2. Direct the sensor cable so that it runs along the top of the foot. Position the detector on the fleshy pad of the great toe. Alternatively, the toe next to the great toe, or the thumb can be used (not shown) (Fig. 1).
3. Wrap the adhesive wrap around the toe so the emitter is positioned on the nailbed of the great toe. Complete coverage of the detector window is needed to ensure accurate data (Fig. 2).
4. Ensure that the emitter window (*) aligns on the top of the toe directly opposite the detector. Verify correct positioning and reposition if necessary (Fig. 3).



1 **2** **3**

Neo sensor for NEONATES (< 3 kg)

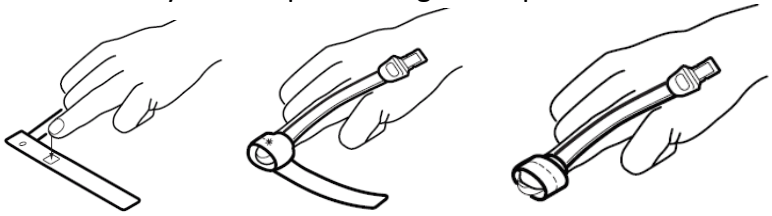
2. For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or gauze (Fig. 1)
3. Direct the sensor cable toward the ankle (or wrist). Apply the sensor around the lateral aspect of the foot (or hand), aligned with the fourth toe (or finger). Complete coverage of the detector window is needed to ensure accurate data (Fig. 2).
4. Wrap the adhesive/foam wrap around the lateral aspect of the foot (or hand) and ensure that the emitter window (*) aligns directly opposite of the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor (Fig. 3).
5. Verify correct positioning and reposition if necessary (Fig. 4).



1 **2** **3** **4**

Neo sensor for ADULTS (> 40 kg) Inf Sensor for INFANTS (10–20 kg)

2. Direct the sensor cable so that it runs along the top of the hand. Position the detector on the fleshy part of the finger. Alternatively, the sensor may also be applied to the toe (not shown) (Fig. 1).
3. Wrap the adhesive wrap around the finger so the emitter window (*) aligns on the top of the finger directly opposite the detector. Complete coverage of the detector window is needed to ensure accurate data (Fig. 2).
4. Check the sensor to verify correct positioning and reposition if necessary (Fig. 3).



1 **2** **3**

Reattachment of adhesive sensors

• The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

• If the adhesive no longer adheres to the skin, use a new sensor.

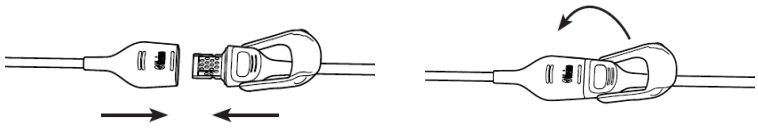
NOTE:

When changing application sites, or reattaching sensor, first disconnect the sensor from the patient cable.

5.4.4.8 Attaching the sensor to the patient cable

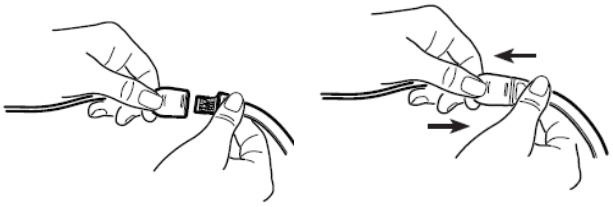
For reusable finger and tip-clip sensors

- Properly orient the sensor connector and insert the sensor connector completely into the patient cable connector.
- Close the protective latch completely.



For disposable sensors

- Orient the sensor's connector tab so that the side with the "shiny" contacts is facing up. Orient the patient cable with the color bar and finger grips facing up. **(Fig. 1)**
- Insert the sensor tab into the patient cable until there is a tactile or audible click of connection **(Fig. 2).**



1 **2**

5.4.5 Patient preparation for Temperature

To measure patient temperature

1. Select the correct type and size of the probe you are going to use regarding the application site and the patient category.
2. Connect the temperature probe cable to the monitor in the corresponding female connector.
3. Apply the probe to the patient.
4. Select the appropriate label in the Temp menu in the user interface. See chapter 6, section *6.5.3.5.*
5. Check the temperature alarm limits: Check that the alarm settings are appropriate for the application site and the patient category.

WARNING:

Disposable Temperature probes must not be re-sterilized or reused.

WARNING:

Make sure you set alarm limits for the correct label. The alarm limits you set are stored for that particular label only. Changing the label may change the alarm limits.

NOTE:

In the current software version the temperature default limits are identical for all temperature application sites.

5.4.6 Patient preparation for IBP

The invasive blood pressure measurement is a direct measurement of the arterial or venous blood pressure. The pressure is measured directly from a catheter inserted into a vein or artery, converted into an electrical signal by a transducer *(with 5uV/V/mmHg sensitivity)* and interpreted and displayed in the GUI by the monitor module. The IBP monitoring function is indicated for measuring arterial, venous and intracranial blood pressures for resting patients in critical care and inner clinical transport.

WARNING:

Defibrillation protection requires use of adapter cables provided by MS Westfalia only as specified in the Accessories Catalogue.

WARNING:

Defibrillation protection is dependent in the type of transducer selected. Only transducers specified in the Accessories catalogued are authorized for use.

WARNING:

Avoid contact with conductive parts of accessories while being connected or applied.

WARNING:

Disposable IBP catheters should not be reused.

WARNING:

When using the monitor with high-frequency electrosurgical units (ESU), to reduce to hazard of burns in the surgical unit neutral electrode, make sure that the transducer and cables are not in contact with ESU devices or cables.

WARNING:

Measurement artifacts are possible with any pressure monitoring device. Do not make changes to patient therapy based solely on the readings obtained from the IBP module. Check that the patient condition is consistent with the readings. Failure to do so could result in inappropiate treatment.

WARNING:

When disposable IBP transducers are applied:

• Do not use a flush device when monitoring intramuscular or intracranial pressures.

• Do not use for left arterial pressure monitoring without air filter between the IBP transducer and the arterial vascular system.

CAUTION:

A blood pressure measurement can be affected by changes in the performance of tubing, transducer or cable a result of ageing and/or environmental conditions.

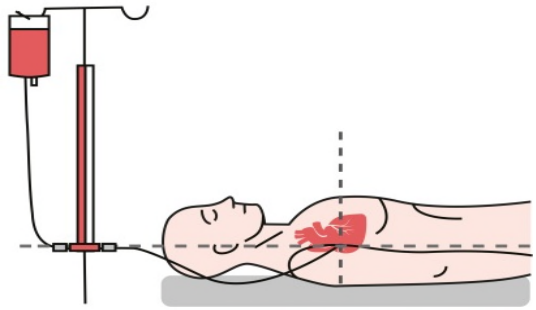
CAUTION:

A blood pressure measurement can be affected by the position of the patient, and the physiological conditions as well as other factors, such as patient movement.

To measure IBP:

1. Plug the IBP cable connector into the *Jenny* IBP input (Figure 4-10, item 2).
2. Prepare the pressure transducer as described in the supplementary instructions delivered with the transducer.

3. Connect the IBP transducer cable connectors you are going to use to the pressure transducer.
4. Prepare the flushing solution (Heparinized sodium chloride solution or 0.9% sodium chloride solution, according to institutional protocols).
5. Flush the system to remove all air from the tubing. Make sure that the transducer and the stopcocks are free of air bubbles
6. Select the proper pressure label in the IBP settings menu. (Refer to section 6.5.3.7)
7. Zero the pressure transducer. (Refer to section 6.5.3.7)
8. Connect the catheter line to the transducer and insert the catheter into the desired measurement point in the patient.
9. Position the pressure measuring side of the transducer at the phlebostatic axis. This is located in the fourth intercostal space and mid axillary line. Indicates the position of the atria and therefore reflects central blood pressure.



10. Make sure that the transducer stopcock and the patient stopcock are turned on. The corresponding IBP curves and numeric should now be visible in the monitor.

NOTE:

For ICP measurements, the position of the IBP transducer must be at the level of the circle of Willis.

- Supine position: The pressure transducer is in line with the Foramen of Monro, which falls at the level of the external auditory meatus of the ear.
- Lateral position: At the mid sagittal line (between the eyebrows).

NOTE:

Do not insert the arterial pressure catheter on a limb that is being used for another medical procedure, such as an IV catheter, NIBP Cuff or SpO_2 sensor.

NOTE:

Zero and flush the pressure line regularly following the corresponding hospital policies.

5.4.6.1 Troubleshooting

Problem	Possible cause	Proposed remedy
No IBP numerical data/waveform	- Cable disconnection - Transducer disconnection - Stopcock closed - Zero calibration was not performed - Improper IBP selection in the menu (Wrong selection, pressure reading is out of range)	- Check cable connection - Check transducer, dome and stopcock - Perform or repeat the zero calibration - Check that the IBP setting corresponds with the invasive channel you are measuring
Pressure waveform damped	- Air bubbles in tubing - Kinked tubing - Catheter incorrectly inserted - Blood entered tubing - Catheter partial occlusion with solids (i.e. clot) - Improper IBP selection (pulsatile instead of no pulsatile, out of range …) - Improper zeroing - Displacement of the position of transducer	- Purge tubing from air - Check tubing - Change catheter position - Check for leakages - Check catheter insertion - Repeat zero calibration - Check position of transducer
Pressure values too low		
Pressure values too high	- Broken transducer - Displacement of the position of transducer	- Check transducer - Check position of transducer
Zero calibration always fails	- Transducer/Stopcock not open to atmosphere	- Check transducer

5.4.6.2 Central Venous Pressure Measurement Troubleshooting

Problem	Possible cause	Proposed remedy
Technical factors	- Position of the patient - Phlebostatic axis - Position of the catheter	- Check position of the patient - Check position of transducer
Physiological factors	- Changes in intrathoracic pressure, (like intraabdominal hypertension, breathing and PEEP in patients with mechanical ventilation) - Changes in central venous volume, cardiac rhythm disturbances, RV compliance and tricuspid valve diseases.	- Check patient status - Check mechanical ventilation parameters

5.4.7 Patient preparation for NIBP

The Jenny Monitoring Module integrates the oscillometry method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. The method of oscillometry indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring the change of the pressure within blood pressure cuff along with the volume

of the arteries and calculates the average pressure. The mean arterial pressure is also calculated.

The NIBP measurement is suitable for use in the presence of electro surgery and during the discharge of a cardiac defibrillator.

The pressure transducer or any applied parts or the NIBP equipment do not provide protective means against burns to the patient when used with HF surgical equipment.

A physician must determine the clinical significance of the NIBP measurement.

 **WARNING:**

- Use only original cuffs and hoses from MS Westfalia as listed in the accessories catalogue.
- Check the patient category before measurement. Incorrect settings may result in some risk for patient safety. High inflation pressure adult setting is not suitable for pediatric and neonatal patients.
- Continuous cuff pressure applied to the patient due to connection hose kinking can lead to blood flow interference and harmful injury (skin, vascular or nerve injury).
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- Applying the cuff over a wound can cause further injury.
- DO NOT attach the cuff to a limb being used for intravascular infusions or arterio-venous shunt, as the cuff inflation can block the infusion, potentially causing injury to the patient
- For patients with known history for breast cancer surgery or axillary surgery/biopsy/radiation, or known history of lymph node-related disease, or lymphedema risk, the cuff should be applied to the opposite arm.
- Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
- Use clinical judgement to decide whether to perform frequent Auto BP easurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- When possible, avoid use of cuff in paretic arm (patients with motor sequel of stroke). The differences in SBP and DBP values are clinically relevant.
- Pressurization of the cuff can temporally cause loss of function of simultaneously used monitoring options on the same limb. If the cuff is applied on the same limb as the pulse oximeter, the SpO2 measurement will be altered when the cuff occludes the brachial artery.

Before measuring NIBP

- The patient should be seated, standing or lying down depending on the procedure being performed. If the patient is seated, he will be comfortably seated with back and arms supported, feet flat on the floor, and legs uncrossed with the middle of the cuff leveled with the right atrium of the heart.
- When lying down, the patient should be in supine position.
- The patient should be relaxed as much as possible and not talking during the complete NIBP measurement procedure
- Once the patient is positioned and before taking the first measurement, a period of at least 5 minutes should elapse to give time for blood pressure stabilization
- Operator position is according with the intended user of Jenny®, standing, in a position in which he can clearly read the screen and have direct access to the patient and the connectors.
- Make sure that the connection tubing (from the cuff to the pneumatic connector in the monitor module) is not kinked, compressed or restricted.

CAUTION:

A blood pressure measurement can be affected by the position of the limb, and his/her physiological condition as well as other factors, such as patient movement.

5.4.7.1 Contraindications

NIBP measurements are not possible with heart rates less than 40 bpm or over 240 bpm or if the patient is connected to a heart-lung machine.

The NIBP module should not be used when the oscillometry pulses can be altered by other devices or techniques such as External Counter Pulsation (ECP) or Intra-Aortic Balloon Pump Counter Pulsation.

The measurement may be inaccurate or impossible in case of:

- Excessive and continuous patient movements
- Not detecting arterial pressure
- Rapid blood pressure changes
- Severe shock or hypothermia with reduced blood flow on the limbs
- Edematous extremity
- Note that the performance of the NIBP measurement can be affected by extreme environmental conditions (temperature, humidity and altitude).

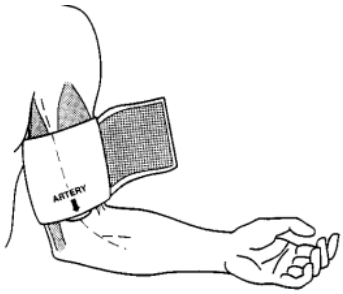
WARNING:

The oscillometric NIBP measurement is not considered as a reliable monitoring method during transport of patients in air medical vehicles.

5.4.7.2 Measuring NIBP

To measure NIBP for the first time:

1. Measure the patient's limb circumference and choose the correct cuff. Use the range lines indicators inside the cuff to determine the correct cuff size to use.
2. Prior identification of artery via palpation, auscultation or ultrasound support is advisable.
3. Wrap the cuff around the arm making sure that the 'ARTERY' and/or 'Φ' markers are aligned over the brachial artery as shown in the figure below. The cuff should fit to the patient's arm for maximum oscillometry signal quality.



4. Once the cuff is applied, connect the patient cuff hose to the corresponding NIBP cuff port in the monitoring module *(Figure 4-10, item 9).* The connector should be easily attached to the port without additional pressure or force. Make sure that the hose is not kinked and that there are no leakages in the connection.
5. Start monitor in Jenny® GUI with the appropriate patient category. (Refer to section 6.5.1)
6. There is a predefined initial inflation pressure for each patient category. If necessary, you can set the initial inflation pressure for the NIBP in the NIBP settings menu (Refer to section 6.5.3.8). This initial inflation pressure will be applied to the patient the first time you perform a NIBP measurement. Once the device has successfully measured NIBP pressures for the first time, for further measurements, the inflation pressure will automatically be adjusted to the last previously measured systolic pressure + 30 mmHg. You can revert this anytime by manually setting a different initial inflation pressure.
7. Select the NIBP measurement mode
8. Proceed as described in the corresponding section for each measurement mode. (Refer to section 6.5.3.8)
9. If any changes in skin color or temperature, or circulation changes in the limb where NIBP is measured appear, rotate urgently the cuff to another location or suspend measurement.

NOTE:

The accuracy of measurement of BP depends on the suitability of the cuff.

5.4.7.3 Measurement modes

The monitor module offers three modes of measuring NIBP:

- Manual: Measurement is triggered by the operator on demand
- Auto: Periodical measurements with an interval set by the operator
- STAT: Rapid series of measurements over a five minutes' period

5.4.7.4 Troubleshooting

Problem	Possible cause	Proposed remedy
Unexpected readings are obtained Dashes "-" are displayed instead of numeric values after a measurement	- Invalid measurement	- Check cuff for tightness. Readjust if necessary - - Try in another limb
Unexpected readings are obtained. Reading is too high or too low	- Wrong cuff size/cuff not in the accessories list - Wrong patient category selected	- Measure patient limb circumference accurately. Change cuff. - Use only approved cuffs listed in the accessories list. - If necessary, use an alternative NIBP. - Select appropriate patient category.
	- Movement Artifact	- Wait till patient is calmed or hold the limb during measure
Unexpected readings are obtained Unable to obtain a measurement	- The patient pressure(s) exceed the software low/high limitation in the device	- Use an alternative NIBP with a wider range

The clinician must be aware of the environmental or operational factors which can affect the performance of the NIBP module:

- Wrong cuff size.
- The cuff is wrapped too tightly around the limb.
- Folding or twisting of the bladder of the cuff.
- Compression or restriction of pressure tubes.

5.5 Defibrillator module (Optional)

WARNING:

Using a defibrillator in the pressence of flammable agents or in an oxygen enriched atmosphere presents explosion and fire hazard.

WARNING:

- Avoid having the device exposed to very low temperatures during storage and transportation prior to use the defibrillator to avoid moisture condensation at the device or its accessories. If neccesary, wait until moisture has been completely vaporized and make sure that paddles contact surface and cables are dry before using the defibrillator.

- Avoid using the defibrillator in a humid environment unless it is absolutely neccesary.

WARNING:

Keep defibrillation electrodes clear of other electrodes or metal parts in contact with the patient.

WARNING:

A maximum of 10 subsequent shocks can be delivered.

WARNING:

For the lifetime of the electrodes please carefully read the package.

WARNING:

For the application method of the electrodes please carefully read the package.

WARNING:

Do not reuse electrodes intended for single use. Use electrodes according to their safety instructions.

WARNING:

Only use approved electrodes. All approved electrodes are biocompatible.

WARNING:

Do not connect defibrillator electrodes before running the selftest.

WARNING:

When the capacitive (shock) buttons are lighting yellow, the device is ready to release a shock. If the buttons are pressed, they will light to “red”. If both buttons are lighting “red” the shock release signal is sent to the Defibrillator.

If the shock buttons do not light up, use another set of pads or use hard paddles. This could also be detected during daily functional test.

WARNING:

If device is used with an implanted pacemaker the displayed analysis results could be wrong.

WARNING:

In patients with implantable medical devices, place the defibrillator electrodes in the recommended position, with a minimal distance of 2.5 cm from any implantable medical device.

WARNING:

Always interrogate the device and confirm the program settings after delivery of cardioversion, defibrillation or external pacing therapies.

WARNING:

Other electrical devices may be impaired after applying a defibrilliation shock.

WARNING:

Do not use another defibrillator when electrodes are attached.

WARNING:

Paddles can not be used in the Slim-Line Defibrilator Module.

WARNING:

Avoid performing defibrillation and/or cardioversion on a metal surface and/or a wet surface without taking appropriate protective measures:

- Use SavePad electrodes with sufficient safety distance to the patient.
- Place the patient on a dry stretcher or non-conductive surface before defibrillation.

WARNING:

In aeromedical vehicles: Before a medical transport, adhesive pads should be attached to patients with high-risk for malignant arrhythmias prior to flight, to reduce likelihood of interference with flight safety controls**.**

CAUTION:

Keep any other ME equipment which has no Defibrillation-proof applied parts disconnected from the patient during defibrillation.

5.5.1 Overview

The Jenny® Defibrillator Module provides the following therapeutic functionalities:

- Semiautomatic external defibrillation (AED)
- Manual defibrillation
- Cardio version
- Non-invasive transcutaneous external pacemaker

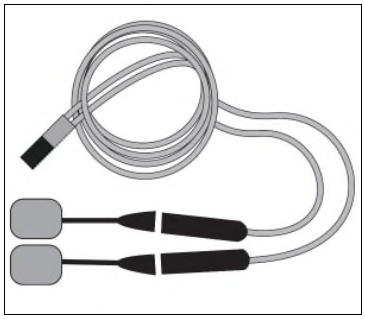
5.5.2 Accessories

Please refer to the Accessories Catalogue for a detailed list of the available options for the Module.

5.5.3 Handling therapy electrodes

5.5.3.1 Electrodes description

Electrodes	Therapy	Patient category	Use limitations
Paddles			
	- AED - Manual defibrillation - Cardioversion - ECG monitoring	- Adult - Pediatric	ECG curve monitoring only. No HR calculation

Electrodes	Therapy	Patient category	Use limitations
SavePads Adult			
	- AED - Manual defibrillation - Cardioversion - Noninvasive pacing - ECG monitoring	- Adult	
SavePads Children			
	- AED - Manual defibrillation - Cardioversion - Noninvasive pacing - ECG monitoring	- Children from 1 to 8 years. - Max. 25 kg	Maximum defibrillation energy **100 J**
Shock spoons (internal paddles)			
	- Manual defibrillation - Cardioversion - ECG monitoring	- Adult - Pediatric - Neonates	Maximum defibrillation energy **50 J**

CAUTION:

Always inspect the electrode cables and handles for possible defects before using them.

5.5.3.2 Paddles

To remove/insert the paddles on their holders

1. Hold the paddles firmly from their handles with both hands
2. Pull the shock paddles away from the defibrillator module
3. To insert the paddles again, push them firmly against the holders until you notice that they are firmly attached to the holders.

NOTE:

The paddle labelled APEX must be placed on the right-hand holder looking from the front panel of the Docking Station. The unlabelled paddle (STERNUM) is to be placed on the left-hand holder.

Pediatric paddles

For pediatric defibrillation, special electrodes with smaller surface must be used. The pediatric paddles are integrated into the adult paddles.

To switch between adult/pediatric electrodes

1. Kindly turn the adult electrodes on both paddles anti-clockwise until the adult conductive cover has been completely detached from the electrodes.

2. To mount the adult paddles again onto the pediatric electrodes kindly turn the adult paddles clockwise until you notice a click. Make sure the adult paddles are fixed tightly, to ensure a perfect contact.

3. Clean the pediatric paddles after use, before re-attaching the adult paddles.

5.5.3.3 SavePads Adult

WARNING:

- Replace the electrodes after 24 hours of contact with the skin during monitoring, after 50 shocks or after 8 hours of continuous pacing (@ 70 mA/ 60 bpm) or after one hour of continuos pacing (140 mA/120 bpm).
- Noninvasive pacing may cause skin irritations and/or burns. Have the underlying skin inspected every 30 minutes of continuous pacing.

WARNING:

Regard the following safety before using the SavePads for adults . These instructions can also be found on each SavePads pouch:

- Do not open until ready for use!
- Do not use if gel is dry or package is broken!
- Do not bend, fold, crush or puncture!
- Remove protective cover before applying to patient!
- Do not touch patient during defibrillation!
- Do not use additional gel on electrodes!
- Inspect the integrity of pouch, electrode and cable prior to use
- Keep defibrillation electrodes clear of other electrodes or metal parts in contact with the patient!

CAUTION:

Misuse or misapplication of any electrode may result in patient burns or inneffective therapy.

NOTE:

Reddening of patient skin is normal after delivery of defibrillation therapy with SavePads.

5.5.3.4 SavePads Mini

WARNING:

- Use only with children less than 8 years of age and less than 25 kg weight
- The maximum energy for defibrillation with children is limited to 100 J

- Replace the electrodes after 8 hours of contact with the skin during monitoring, after 25 shocks or after one our of continuous pacing (@ 70 mA/ 140 bpm)
- Noninvasive pacing may cause skin irritations and/or burns. Have the underlying skin inspected every 30 minutes of continuous pacing.

WARNING:

Regard the following safety before using the SavePads for children . These instructions can also be found on each SavePads pouch:

- Do not open pouch until ready for use!
- Inspect the integrity of pouch, electrode and cable prior to use. Do not use if compromised!
- Do not crush, bend or fold electrodes or store them under heavy objects!
- Do not touch patient during defibrillation!
- Do not use the electrodes if gel is dry!
- Do not use additional gel on electrodes!
- Do not overlap defibrillation electrodes!
- Keep defibrillation electrodes clear of other electrodes or metal parts in contact with the patient!
- If the patient is not being observed during treatment noninvasive pacing is allowed only in FIX-mode!
- Do not discharge hand-held paddles through these electrodes!

5.5.3.5 Spoons (internal paddles)

WARNING:

Patient hazard! Use only sterilised electrodes for internal defibrillation. Note that the electrodes must be sterilised before each use (see section 7.5.3.4)

WARNING:

Inspect the spoons frequently for signs of deterioration such as cracks, crazing or damaged cables. Replace if deterioration is noted.

To insert the spoons on their holders

1. Select the spoons accordingly to the category of the patient.
2. Connect the electrode cable of the spoons to the adapter.

5.5.4 Patient preparation for defibrillation therapy, cardioversion and noninvasive pacing

WARNING:

Do not touch the patient, bed, device or cables during defibrillation.

WARNING:

- When conducting defibrillation, use only the ECG electrodes and cables supplied by the manufacturer as specified in this manual.
- Warn bystanders not to touch the patient or parts in contact with the patient and to keep their distance from liquids in contact with the patient.
- Interference from instruments near the patient and ESU interference can cause artifacts problems with the display of the ECG wave.
- It is strongly recommended to only use self-adhesive pads for defibrillation in oxygen rich environments. Poorly applied paddles can generate sparks that can lead to fire and burns to the patient and/or the operator
- If the patient is under oxygen therapy, take off the mask or nasal prongs and place them at least 1 m away from the patient's chest.
- If the patient is under mechanical ventilation therapy, leave the breathing circuit connected to the tracheal tube. If necessary, replace the mechanical ventilator with a ventilation bag and switch off the ventilator or connect it to a test lung to prevent oxygen rich mixtures being vented into the room.

CAUTION:

Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood or saline and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.

5.5.4.1 Skin preparation

1. After patient examination, remove all clothing from patient chest area, including any piece of jewelry.
2. If necessary, shave or clip the excess of hair at the electrode area.
3. Make sure that the skin area is intact. Avoid placing the electrodes on injured areas.
4. Gently scrape skin to remove dead cells and dirt using a dry towel.
5. If necessary, clean the skin with a moist cloth and dry the skin. Avoid using alcohol.

5.5.4.2 Applying electrodes to the patient

CAUTION:

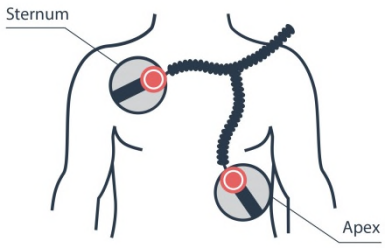
Before applying the paddles or spoons to the patient, apply a coupling agent (high-conductivity gel or gel pads) in sufficient amount to cover completely the metallic surface of the paddles.

CAUTION:

Do not use medical gels or pastes with poor electrical conductivity, such as ultrasound gel.

Paddles position protocol

1. First paddle ('sternum'): To the right of the upper sternum and below the clavicle
2. Second paddle ('apex'): To the left of the nipple in the midaxillary line, centered in the 5th intercostal space, with a vertical orientation in relation to the patient position (not horizontally).
3. Apply the correct force to the paddles (at least 80 N or 8 kg), to ensure appropriate impedance to administer the therapy.

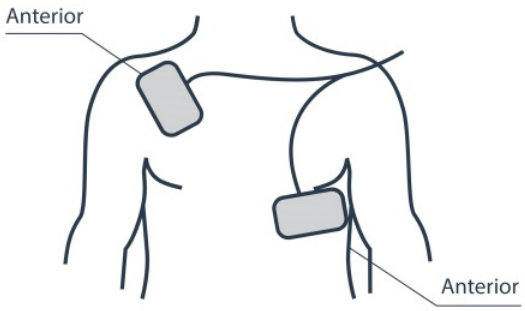


SavePads Adult

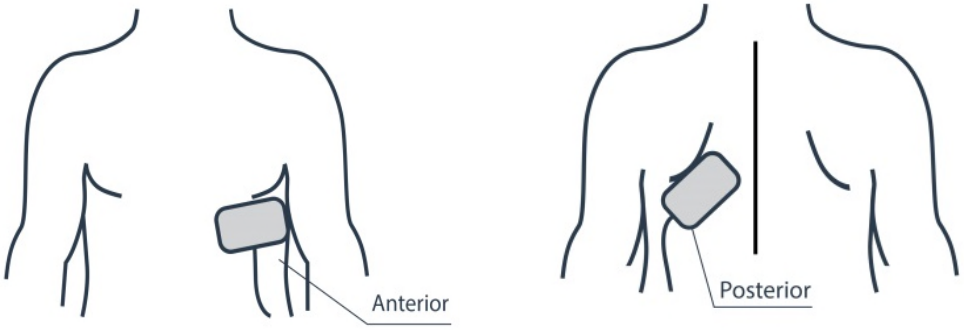
1. Check integrity of electrode packaging and validity of expiry date before using them.
2. Select placement sites on the body per the procedure (Recommended is: Anterior-Anterior for AED and Anterior-Posterior for Manual Defibrillation, cardioversion and pacing).
3. Remove protection cover of electrodes.
4. Apply to patient in accordance with protocol and ensure electrode have good contact with the skin.
5. Press down firmly.

6. Gently scrape skin to remove dead cells and dirt using a dry towel.
7. In obese patients and/or patients with large breasts: Apply the pads in a flat surface. If skin folds, spread the skin to create a flat surface.
8. In thin patients: Apply the pads following the contour of ribs and intercostal spaces, to minimize air gaps and improve contact with the skin.

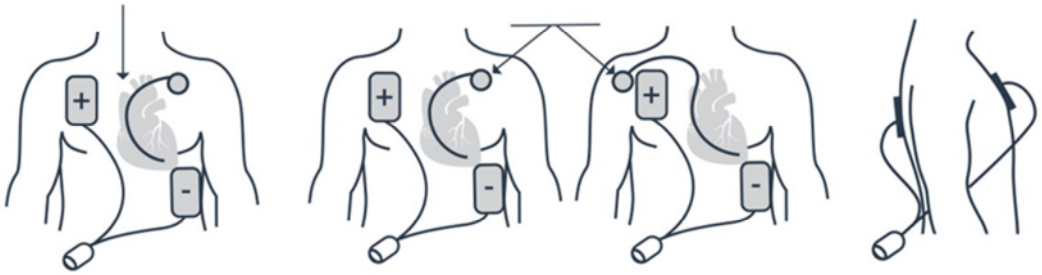
Anterior-Anterior placement site



Anterior-Posterior placement site



Recommended placement sites for patients with implantable medical cardiac devices



SavePads Mini

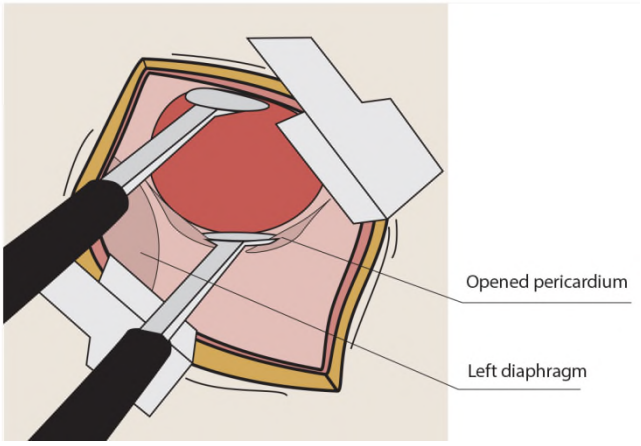
1. Check integrity of electrode packaging and validity of expiry date before using them.
2. Select placement sites on the body per the procedure (Recommended is: Anterior-Anterior for AED and Anterior-Posterior for Manual defibrillation and cardioversion and pacing.
3. Make sure that skin area is clean and dry.
4. Open the electrode pouch at the indicated site.
5. Remove protective electrodes cover.
6. Apply to patient in accordance with protocol. Press down firmly to ensure good contact of the adhesive surface with the skin
7. Connect electrodes cable to the defibrillator module. Continue the Defibrillation procedure.
8. Make sure that the patient category selected in Jenny® is Child (or, if applicable, neonate).
9. Deliver the therapy.

NOTE:

These instructions for use can also be found in every pouch of the SavePads electrodes.

Spoons

1. Check integrity of spoons.
2. Select placement sites (pericardium for adult and pediatric patients; chest for neonatal patients).
3. Position the spoons on the heart, following an anterior-posterior axis.



5.5.4.3 Connecting electrode therapy cable to defibrillation module

The electrode therapy plug to the defibrillation modules is identical for pads and paddles.

To connect the electrode therapy cable:

1. Align the electrode therapy cable plug with the connector in the defibrillation module. The white arrows marker in the electrodes connector must be aligned with the top of the connector in the module
2. Kindly push the electrodes cable plug inside the module until it is completely attached. Confirm the connection by kindly pulling the cable to make sure that the plug is fixed.

5.6 Capnography (Optional)

5.6.1 Overview

WARNING:

Do not operate the IRMA mainstream or the ISA sidestream gas analyzers outside the specified operating environment.

Do not clean, disinfect or reuse the CO_2 airway adapter. Doing so may increase the risk of cross-contamination, compromise the functionality of the device and reduce performance.

NOTE:

The capnography analyzers (both Mainstream and Sidestream) can be connected either to the Ventilator Module or Monitoring Module. The user must select the appropriate module to connect the analyzer, accordingly to the operational needs.

The CO_2 sensor should be connected to the ventilator module as the first option when applying invasive ventilation.

Mainstream CO_2 gas analyzer (IRMA)

The IRMA mainstream gas analyzer is intended to be connected to other medical devices for monitoring of breath rate and CO_2. It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.

WARNING:

- The IRMA probe is intended for use by qualified medical personnel only.
- The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Disposable IRMA Airway Adapters shall not be reused. Reuse of the single use adapter can cause cross infection.
- Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.
- Do not use the IRMA Adult/Pediatric Airway Adapter with infants as the adapter adds 6 ml dead space to the patient circuit.
- Do not use the IRMA Infant airway adapter with adults/pediatrics as this may cause excessive flow resistance.
- Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.

- The IRMA probe is not designed for MRI-environments.
- Do not place the IRMA Airway Adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
- To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.
- Do not use the IRMA Airway Adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.
- Incorrect probe zeroing will result in false gas readings.
- Replace the airway adapter if rainout/condensation occurs inside the airway adapter.
- Use only Masimo manufactured IRMA Airway Adapters.
- The IRMA probe is not intended to be in patient contact.
- If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.
- No modification of this equipment is allowed.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.

The IRMA sensor is equipped with an automatic barometric pressure compensation (the total pressure of gas mixture is estimated measuring the actual atmospheric pressure).

On the screen the end tidal CO_2 concentration will be displayed numeric and by waveform.

The sensor needs some warm-up time to perform at full accuracy. The warm up-time is < 10 seconds.

The adapter is a non-sterile single patient use and available in two sizes, on for adult and pediatric patients and one for infant patients:

Sidestream CO_2 gas analyzer (ISA CO_2)

The ISA CO_2 is a plug-in, low-flow sidestream gas analyzer, designed for routine clinical use in environments that place special demands on the product's ruggedness.

WARNING:

● The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.

● Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

● Do not lift the ISA gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA gas analyzer to fall on the patient.

● Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.

● Use only airway T-adapters with the sampling point in the center of the adapter.

● Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.

● Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.

● Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

● Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

● Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

● The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

● Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.

● Replace the sampling line if the sampling line input connector starts flashing red, or the medical backboard device displays a "Check sampling line" message.

● No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.

● The ISA sidestream gas analyzers are not designed for MRI environments.

● During MRI scanning, ISA must be placed outside the MRI suite.

● Use of high frequency electrosurgical equipment in the vicinity of the ISA/medical backboard device may produce interference and cause incorrect measurements.

● Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.

● Too strong positive or negative pressure in the patient circuit might affect the sample flow.

● Strong scavenging suction pressure might affect the sample flow.

● Exhaust gases should be returned to the patient circuit or to a scavenging system.

● Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.

● Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

● Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.

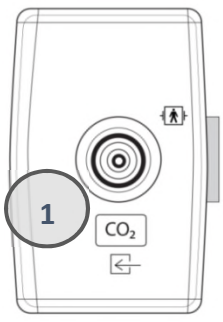
● Do not sterilize or immerse Nomoline Family sampling lines in liquid.

● Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.

● Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the adult/pediatric airway adapter adds 6 ml dead space.

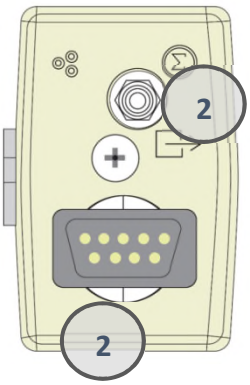
● Do not use the NomoLine Infant/Neonate Airway Adapter Sets for adults/pediatrics as they may cause excessive flow resistance (0.7 ml dead space).

Front view



1. LEGI/Gas inlet

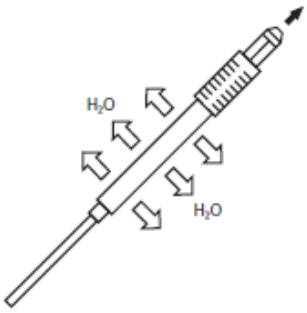
Rear view



2. Gas outlet
3. Communication cable connector

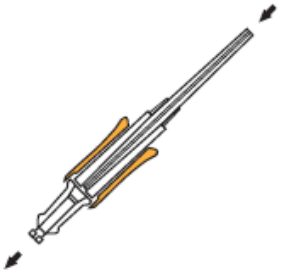
The ISA CO_2 continuously removes a gas sample flow from the respiratory circuit, for example a nasal cannula, a respiratory mask or a Y-piece on an intubated patient. The gas sampled is fed through a Nomoline® sampling line to the gas analyzer. The gas outlet port on the rear side of the ISA analyzer fits gas exhaust external tubing with an inner diameter of 2.4 mm.

The sampling lines are specially designed for 50 ml/min low sample flow applications**.** The lines can be used in all clinical scenarios. The Nomoline ® sampling lines incorporate a water separation system (NO Moisture) section, which removes condensed water. The NOMO section also has a bacteria filter which protects the gas analyzer from water intrusion and cross contamination.



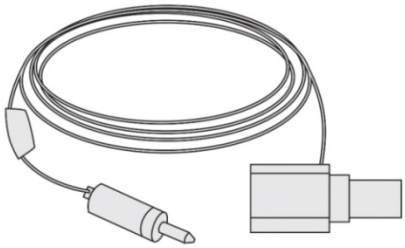
Accordingly to the environmental conditions of use, the operator must select the appropriate sampling line configuration:

- Low Humidity (LH): Sampling lines for short-term applications in low-humidity conditions (Procedural sedation, critical care, sleep lab, EP, EMS, ED, cath lab). Available for intubated and non-intubated patients.

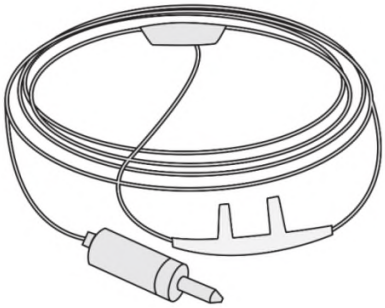


- High Humidity (HH): Sampling lines for long-term applications in high-humidity conditions (OR, EMS, ED). Available for intubated and non-intubated patients.

The Nomoline ® Adapter Set is available as multiple-patient use (disposable) or non-sterile, single-patient use (disposable), and in two sizes, for adult and pediatric patients and one for infant/neonatal patients:



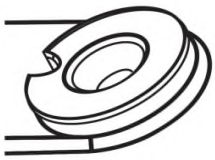
Spontaneously breathing patients could be similarly monitored using a disposable Nomoline ® Nasal CO_2 Cannula or a combination of the multiple-patient use Nomoline ® Adapter and a disposable Nomoline ® Nasal CO_2 Cannula with Luer connector.



NOTE:

See also NomoLine Family Directions For Use.

The ISA analyzer is fitted with a mounting bracket system, making it possible to attach the gas analyzer to different fixtures, e.g., medical-rail systems, C-clamps, IV poles (in use with the ISA Analyzer Clamp Adapter and the ISA Analyzer Modura Holder), or directly to the Jenny ® Docking Station.



5.6.2 Accessories

Please refer to the Accessories Catalogue for a detailed list of the available options.

5.6.3 Patient preparation for capnography

5.6.3.1 Mainstream CO_2 gas analyzer

To monitor CO_2 from the patient

WARNING:

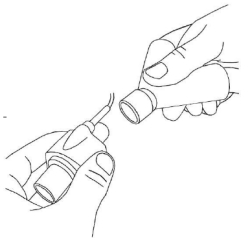
● Do not use the IRMA Adult/Pediatric Airway Adapter with infants as the adapter adds 6 ml dead space to the patient circuit.

● Do not use the IRMA Infant Airway Adapter with adults/pediatrics as this may cause excessive flow resistance.

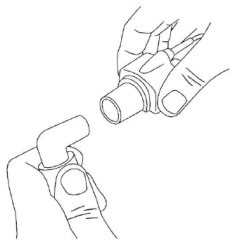
● The IRMA probe is not intended to be in patient contact.

● If for any reason the IRMA probe is in direct contact with any parts of the infant's body, an insulation material shall be placed between the probe and the body.

1. Check gas readings and waveforms in Jenny® GUI before connecting the capnography probe interface cable to the corresponding Jenny® module.
2. Connect the IRMA interface cable to the Jenny® module.
3. Snap the IRMA probe on top of the airway adapter. It will emit a click when properly placed.
4. Perform the zero calibration as explained in 6.7.1
5. When the calibration is successfully finished, connect the 15mm male adapter to the corresponding breathing circuit end piece.



6. Then, connect the other end (15 mm female) to the patient's tube. If you are using a HME filter, place it between the patient tube and the probe.



7. Remember to perform the ventilator circuit test with the IRMA probe snapped on the IRMA airway adapter to have the right volume calculation of the circuit compensation.
8. The sensor and airway adapter should be placed vertically (with the LED pointing upwards) to reduce the possibility due to window contamination.
9. When connecting the probe to a small child, it is important to avoid direct contact with the infant's body due to the elevated surface temperature of the probe.

WARNING:

Replace the airway adapter if rainout/condensation occurs inside the airway adapter.

CAUTION:

Do not apply tension to the probe cable.

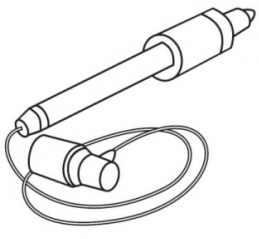
5.6.3.2 Sidestream CO_2 gas analyzer

To connect the ISA CO_2 to the patient

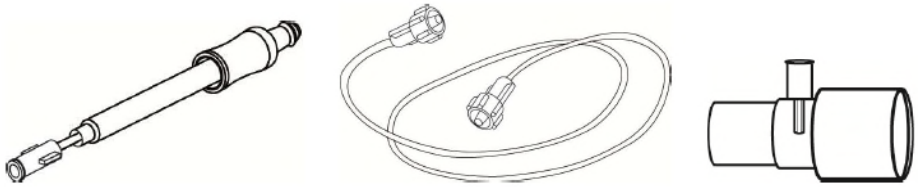
1. Check gas readings and waveforms in Jenny® GUI before connecting the capnography probe interface cable to the corresponding Jenny® module.
2. Connect the ISA CO_2 interface cable to the Jenny® module.

Intubated patients

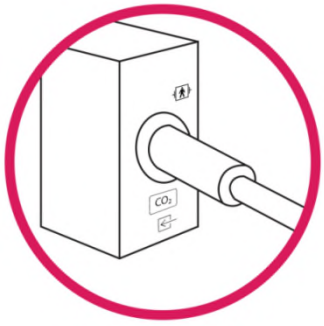
3. Connect the Nomoline® Airway adapter set to the breathing circuit. The Nomoline ® with a male Luer Lock type connector is compatible with any normal configuration that uses a female Luer Lock connector.



4. When connecting to a T-adapter, be sure to use a Masimo® T-adapter that samples gas from the center of the T-adapter.



5. Connect the NOMO section to the Light Emitting Gas Inlet (LEGI) located in the frontal side of the ISA analyzer.



6. Connect the ISA CO_2 interface cable to its corresponding connector in the rear side of the ISA analyzer.
7. Remember to perform the ventilator circuit test with the ISA probe snapped on the ISA airway adapter to have the right volume calculation of the circuit compensation.

Spontaneously breathing patients

3. Apply the Nomoline ® Nasal Cannula to the patient, ensuring proper fit of the hose and correct placement in the nostrils.
4. Connect the NOMO section to the CO_2 port located in the frontal side of the ISA analyzer.
5. Connect the ISA CO_2 interface cable to its corresponding connector in the rear side of the ISA analyzer.

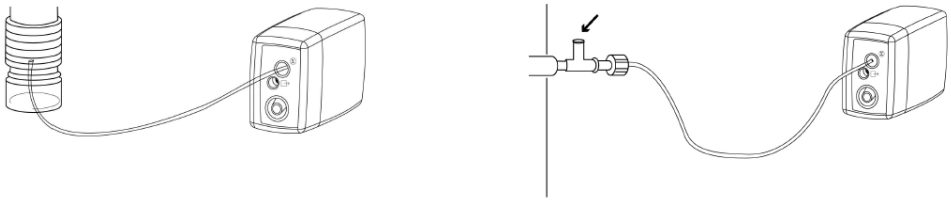
To connect the pneumatic interface

WARNING:

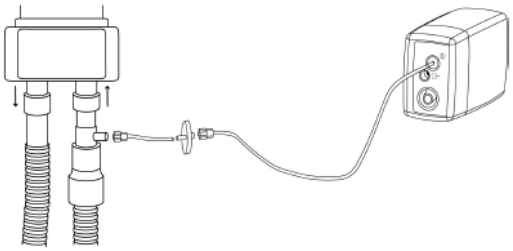
The distal extreme of the exhaust tube must be connected to a scavenging system or to the breathing circuit of the patient, to prevent pollution of the operation room when N_2O and/or other anesthetic agents are being used.

1. Connect the exhaust tube in the port located in the rear side of the ISA analyzer.

2. Connect the distal end of the exhaust tube to scavenge the exhaust gas, either through a ventilator reservoir or directly to a scavenging system. In both cases, a deliberated leakage must be generated, to avoid vacuum in the exhaust tube of the ISA.



3. If returning the gas to the patient's breathing circuit, a bacteria filter should be mounted on the exhaust gas tube of the ISA before connecting it to the expiration limb.

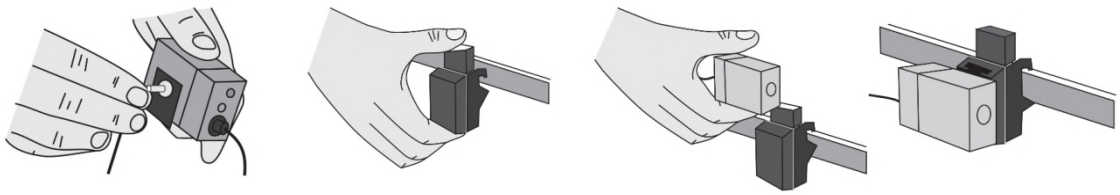


To secure the ISA CO_2 to the mounting interface

CAUTION:

The ISA CO_2 analyzer should be securely mounted in order to avoid the risk of damage to the ISA.

1. Attach the ISA Analyzer Clamp Adapter to the mounting bracket, located in the lateral left side of the ISA Analyzer (Fig. A).
2. Place the ISA Analyzer Modura Holder in the selected fixture: medical rail system, C-clamp or IV-pole (Fig. B).
3. Place the ISA Analyzer with its fixed Clamp Adapter into the Modura Holder. It will emit a click when properly placed (Fig. C and D).



A **B** **C** **D**

6 Operation

6.1 Power on / off

Power on

To power on the Docking Station

1. Press the power on/off button on the left side of the Docking Station for at least 1 second.
2. The operator has to watch the buzzer tone at start up. Two buzzer beeps are emitted, followed by a three beep tone sequence.

WARNING:

To power on the Docking Station for the first time: After insertion of the batteries in the Docking Station, press the power on/off button for at least 15 seconds.

WARNING:

Do not take the device into operation if the buzzer beeps or the alarm pattern is not clearly audible.

3. An automatic system self-test is performed. A startup screen is displayed (see picture):

4. When the system check is finished, the Home Screen is displayed. The startup time takes approximately 15 seconds.

NOTE:

When the ventilator module is installed the self-test may require an additional amount of time after power-on.

When installed after startup, the ventilation module performs an additional preoperational test that lasts a couple of seconds. The progress of the test can be visualized in a pop up window on top of the module configuration information area.

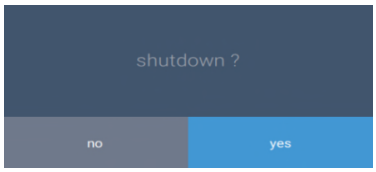
WARNING:

To avoid physical injury to the patient, make sure that the patient is disconnected from the ventilator during the ventilator preoperation test.

Power off

To power off

1. Press the power on/off button on the left side of the Docking Station for at least 1 second.
2. A confirmation menu is displayed in the screen (see picture). You can confirm or cancel the action.



3. On confirmation, the system will be shutdown.

Additionally, there is a forced power off without confirmation which could be used, for example when there is no response from the touch display.

To force power off

1. Press the power on/off button on the left side of the Docking Station and hold it for at least 10 seconds.
2. After this time has elapsed, the system is shutdown.

NOTE:

When the Docking Station is powered off, the buzzer remains active (intermittently) until it enters in sleep mode (completely powered off).

In case of sudden power off

NOTE:

If a sudden power off occurs, the buzzer will beep continuously.

1. Perform the steps described above to force power off. After this time has elapsed, the system should be shutdown. If not, wait for 5 seconds and repeat the procedure.
2. If the system is not shutdown after a second attempt, replace the Docking Station.

6.2 Module handling during operation

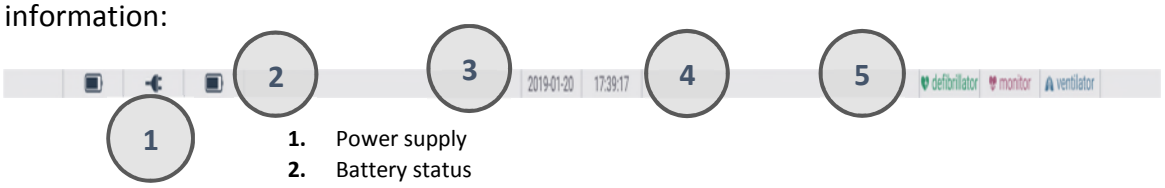
WARNING:

The mechanical disconnection (unlocking) of a module when the module is in operation will be alarmed. For a proper operation and to avoid the risk of physical injury to the patient, stop the module in the corresponding GUI menu before physically disconnecting it from the Docking Station.

6.3 General operation

6.3.1 System status information (Module status, batteries, power supply, time/date)

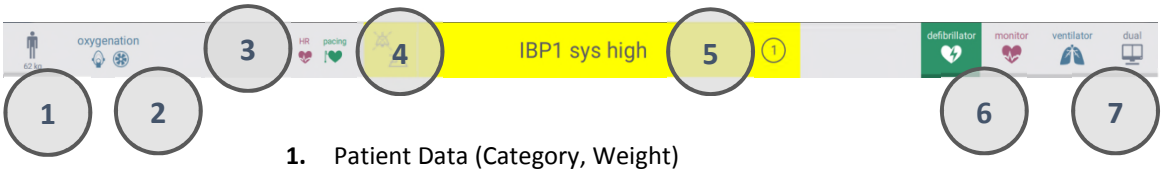
Once the device is powered on, the inferior bar of the screen will display the system information:



1. Power supply
2. Battery status
3. Date
4. Time
5. Module status

6.3.2 Header bar

The superior bar of the screen (Header Bar) will display the following information:



1. Patient Data (Category, Weight)
2. Ventilator Mode and Source
3. Heart Rate
4. Pacer metronome (displayed when active)
5. Alarm bar
6. Module Control Panel
7. Dual Screen Panel

The Module Control Panel is described below in the section *6.3.5.*

6.3.3 Patient data management

You can admit a new patient and enter patient data such as demographics, bed/room, pathologies and other relevant information any time, even when there are no modules installed in the Docking Station.

For the different modules, the availability of certain operating functions and the values of presets will be dependent on the patient data (for example, the ventilation proposed

settings and some ventilation options will depend on the patient category, gender, and predicted body weight (PBW) and respiratory pattern (Lung Pathology).

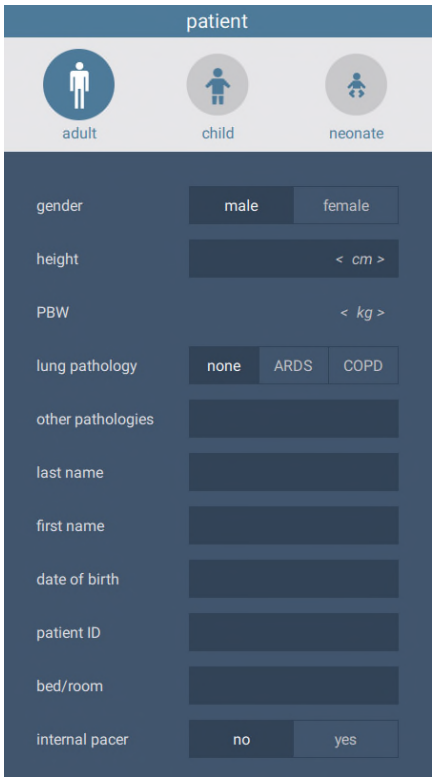
Additionally, you can recall and modify patient data of the last patient admitted in the system either by accessing the 'last patient' screen or by pressing the 'current patient' button on the header bar during module operation.

NOTE:

The system comes with default patient factory settings which allow you to begin a therapy without setting patient data. The default values can be seen in the table below.

To admit a new patient:

1. Press the 'new patient' button in the Home Screen.
2. The 'new patient configuration panel' is displayed at the left end of the screen. Depending on the module configuration, additional configuration panels may be displayed.
3. You can enter or modify patient data, either by choosing a value in a multiple selection field or by tapping on an input field.



NOTE:

For the weight, height and date of birth fields, a numerical keypad is displayed. The numerical keypad displays the allowed value range. For the rest of the data with user input, a complete alphanumerical keyboard will be displayed.

Field	Description	Value Range	Default
Patient category	Selects the patient category	Adult, Child, Neonate	Adult
Gender	Selects the gender of the patient. Only for adult and pediatric patients	Male, Female	Male
Height	Patient's height input. Only for adult and pediatric patients.	See chapter 9.1.5.2	166 cm
Weight	Weight input for a neonatal patient	See chapter 9.1.5.2	3000 g
PBW	Display only. Predicted Body Weight calculation based on patient category, gender and height. If a ventilation module is connected, PBW is used to calculate proposed initial ventilation settings	See chapter 9.1.5.2	Male: 66 kg Female: 57 kg
Lung pathology	You can select three general pathologies: None, Restrictive (e.g., patients with ARDS) and Obstructive (e.g., patients with COPD). If a ventilation module is connected, the lung pathology is used to calculate proposed initial ventilation settings. Available for Adult and Pediatric patients.	None, Obstructive, Restrictive.	None
Other pathologies	Free text field to input additional pathologies up to 20 characters	-	-
Last name	The patient's last name up to 20 characters	-	-
First name	The patient's first name	-	-
Date of birth	The patient's date of birth in YYYY-MM-DD format	From 1900-01-01	-
Patient ID	Unique alphanumeric patient identifier up to 20 characters	-	-
Bed/room	Bed, room or station	-	-
Internal Pacer	Select if the patient has an implanted pacer or not. When a monitoring module is connected, the paced rhythms detection in the ECG monitor will depend on this selection.	Yes, No	No

WARNING:

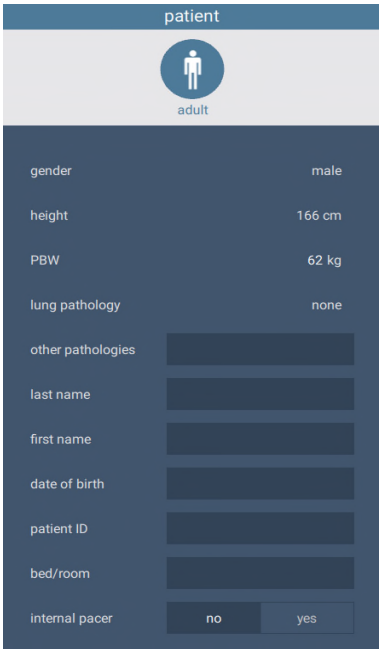
You must set the 'Paced' field accordingly with the patient characteristics during ECG monitoring:

- For a paced patient it must be set to 'Yes'. If it is incorrectly set to 'No', the ECG monitor and the arrhytmia detection could display wrong results and fail to alarm critical patient conditions.
- Respectively, it must be set to 'No' for a non-paced patient.

To recall data from an admitted patient:

1. Press the 'last patient' button in the Home Screen.
2. The 'last patient configuration panel' is displayed at the left end of the screen. Depending on the module configuration, additional configuration panels may be displayed.

3. You can enter or modify patient demographics. Other patient data: patient category, gender, PBW and lung pathology cannot be modified. To modify these fields, a new patient must be admitted.



NOTE:

You can also recall the current patient data during module operation by pressing the 'Current patient' button on the left end of the header bar (Figure 4-17, item 7).

6.3.4 Main menu bar

6.3.4.1 Views

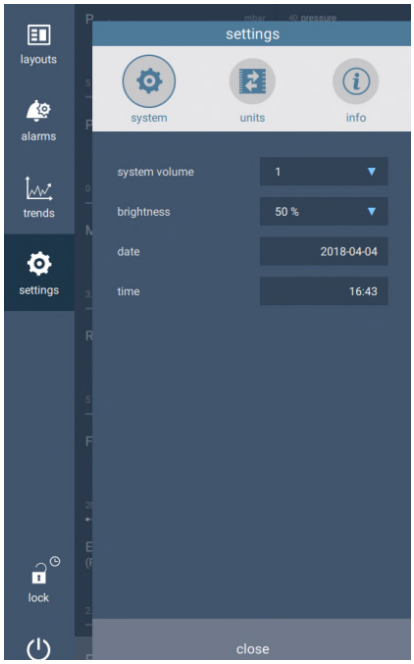
The user can access at all times of operation, and from any functioning module, the main menu bar, located in the left section of the layout.

The Main Menu bar allows the access to:

- Layout Menu: For ventilator and monitor modules (described below in the sections *6.4.2.1* and *6.5.2.1*)
- Alarms Menu
- Trends Menu
- Settings Menu

6.3.4.2 System settings

The System settings menu displays a list with the individual parameters that are either user-selectable or indicate current features of the functioning version.



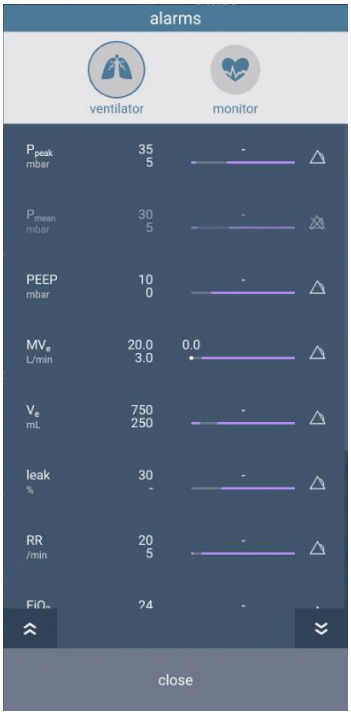
Setting	Description	Value Range	Default
Sound Volume	Sets the volume level of the alarm tones.	1 (low) to 10 in steps of 1	6
Language	Sets the current language in the GUI from the list of languages available	English. See chapter 9.1.5.1	English
Date	Allows you to set the day, month and year displayed in the GUI	YYYY-MM-DD from 2000-01-01	2000-01-01
Time	Allows you to set the hours and minutes of the time displayed in the GUI	Hour: minute From 0:00 to 23:59	00:00
Units	Sets the units used in the GUI from a list of different parameters	See chapter 9.1.5.1	See chapter 9.1.5.1
Info	Displays the Version and serial number for the Docking Station and installed modules.	V. 1.0 – ## Serial Number: ##	-
Service	Access to the Service Menu	-	-

Adjusting system settings

To access the system settings, tap on the *Settings button* in the Main menu bar.

6.3.4.3 Alarms

The alarms settings menu displays a list with the individual thresholds for measured physiological values that have an alarm associated.



In the alarm settings menu, you can perform the following tasks:

To visualize the list of alarm settings:

1. Select the module (Ventilator or Monitor). For the Defibrillator Module, alarms cannot be modified.
2. Scroll down the list. This can be done by dragging in the list or by taping on the up and down arrows at the bottom of the menu.
3. You can visualize the current upper and lower limits of the alarm setting. Additionally, the current measured data is displayed in a graphical bar at the right of the alarm field. The position of the value regarding the upper and lower alarm is updated in each measurement. This gives you estimation on how close the upper and lower alarm limits are adjusted to the current measured value.
4. If an alarm is triggered, the corresponding upper or lower alarm limit in the list will be highlighted in a color matching the alarm priority.

To activate/deactivate the alarm monitoring of a measured value

1. To deactivate an alarm: Tap on the line of the alarm label, to open the parameter control panel. Press the bell button and it will be greyed out. The associated measured parameter will not generate either acoustic or visual alarms.
2. To activate an alarm: Tap on the crossed-out icon of a deactivated alarm. The icon switches to the active alarm icon and the field is no longer greyed out. The associated measurement will generate alarms again.

To restore/auto set all the alarm limits in the list

1. You can restore all the alarm limits in the list back to the default values by pressing the 'restore all' button.
2. You can automatically adjust the upper and lower limits of all the alarm limits in the list to the current value of the parameter by tapping on 'auto set all'.

The auto set of current reading +/- for units or current reading +/ for % are depending on specific alarm ranges. For a detailed description of the alarm values and ranges, please refer to sections *9.2.5.10* (Ventilator Module) and *9.3.5.7* (Monitoring Module).

To set the alarm limits manually

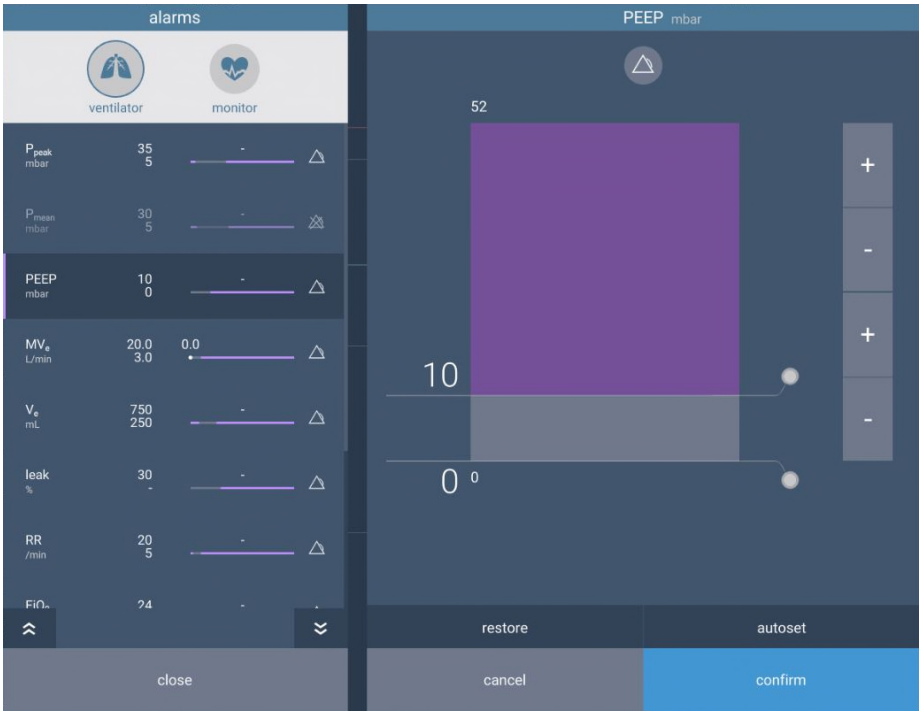
WARNING:

Setting the alarm limits to extreme high or low values, could cause the associated alarm not to activate and thus reduce the efficacy in the monitoring of the patient condition in clinical situations that may require operator intervention.

1. Tap on an alarm field in the list.

An additional control panel opens at the right of the menu.
Tap on the corresponding alarm slider control to adjust upper or lower alarm limits. Alternatively, you can use the + and – buttons.

2. Tap on 'confirm' to apply the changes.



NOTE:

You can restore/autoset each alarm individually in the additional control panel.

NOTE:

You can also recall the control of a specific alarm limit by tapping on the corresponding measurement field in the module control panel.

6.3.4.4 Screen lock

To lock/unlock the screen:

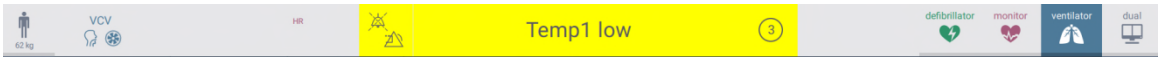
1. Tap and hold the 'screen lock' button on the main menu bar. A progress bar will be displayed on top of the button.
2. When the progress bar is full, the icon will change to indicate that the screen is locked/unlocked.

NOTE:

If you tap at any point on the screen while the screen lock is activated, the screen lock button will be highlighted in yellow to remind you that the screen is locked.

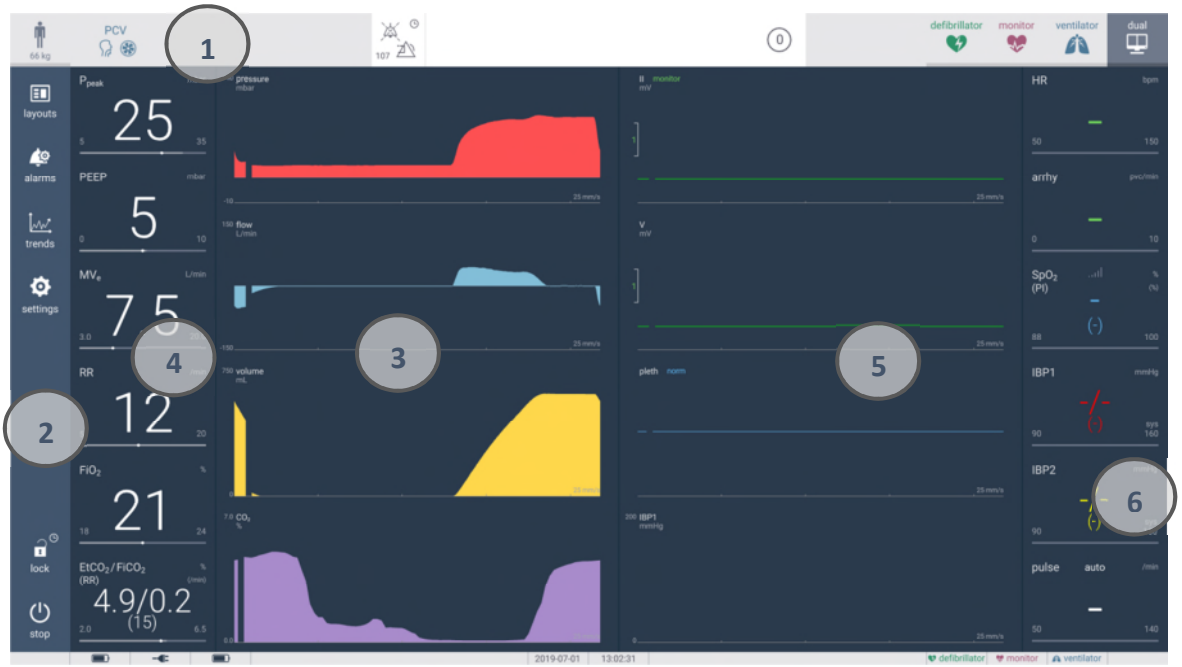
6.3.5 Switching module control panels

The right upper-section of the GUI provides access to the module control panels. The user can obtain access to every module of the Jenny ® at any times of operation, by pressing the corresponding icon. Every icon has a corresponding, identifying color.



6.3.6 The Dual Control Panel

The Jenny ® Docking Station provides a unique functionality, with simultaneous view and control panels for the Ventilator and Monitoring Modules.



1. Header bar
2. Setting configuration bar
3. Ventilator waveform layout
4. Ventilator numeric parameter layout
5. Monitor waveform layout
6. Monitor numeric parameter layout

The settings and alarms for every parameter displayed (waveform or layout) can be promptly accessed from the Dual control panel by pressing on the corresponding field.

The operating process for Ventilator and Monitoring modules will be extensively reviewed in the sections *6.4.2.1* y *6.5.2.1*.

6.3.7 Stopping modules

The Docking Stations allows the user to stop the modules accordingly to the characteristics of the clinical setting. The process will be reviewed in the sections *6.4.3*, *6.5.3* and *6.6.2*.

6.3.8 Connectivity

6.3.8.1 Central Monitoring System

The Jenny Docking Station synchronizes the patient data management with the available Central Monitoring System. The telemetry device can be paired with the monitor at the CMS or at the monitor. For detailed information, please refer to the CMS corresponding instructions for use.

Pairing at the monitor is only possible when the monitor already has a connection to the CMS and the CMS software version allows pairing at the monitor.

WARNING:

• When ECG is being measured with a telemetry device directly connected to the monitor, arrhythmia relearning is initiated, and also when the telemetry device is disconnected.

• Controls on the Telemetry Device (e.g. nurse call) will be inactive when the device is directly connected to the monitor except in the case when the monitor has no network connection and data are transferred via the telemetry device.

Synchronized Settings

The physiological data of the JENNY device that can be displayed on the-CMS include:

Monitoring functions	Waveforms	Numeric Parameters
ECG	2	HR, ST value, PVCs
Plethysmography	1	SpO_2, PR

Monitoring functions	Waveforms	Numeric Parameters
IBP	4	ART, PA, CVP, RAP, ICP, LAP, P1, P2 (only IBP supported by the monitor will be displayed)
CO_2	1	$EtCO_2$, $FiCO_2$
Gas Analysis	4 (CO_2, N_2O, O_2, AA)	$EtCO_2$, FiCO2, EtO_2, FiO_2; EtN_2O, FiN_2O
NIBP	N/A	SBP, DBP, MAP
Temperature	N/A	Temp1, Temp2

The CMS provides also calculation of ventilation parameters, obtained through input of measured parameters of the Ventilator Module.

Input (Measured) Parameters	Output (Calculated) Parameters
FiO2 Percentage fraction of inspired oxygen	Cdyn Compliance dynamic
RR Respiration rate	PAO_2 Partial pressure of oxygen in the alveoli
$PeCO_2$ Partial expiratory carbon dioxide pressure	$AaDO_2$
$PaCO_2$ Partial arterial carbon dioxide pressure	PaO_2/FiO_2 Arterial oxygen tension to inspired oxygen fraction ratio
PaO2 Partial arterial oxygen pressure	$AaDO_2/PaO_2$ Arterial-alveolar oxygen tension difference to Partial arterial oxygen pressure ratio
VT Tidal volume	PaO2/AO2 alveolar to arterial oxygen tension ratio
RQ Respiratory quotient	MV Minute volume
Patm Atmospheric pressure	VD Volume of physiological dead space
Pinsp Peak Inspiratory Pressure	VD/VT Physiological dead space in % tidal volume
PEEP Positive End-Expiratory Pressure	A Alveolar volume

WARNING:

- The operator must be aware that not all the monitoring waveforms and parameters are synchronized with the telemetry system, in order to take the corresponding surveillance measures.
- After changing the ECG source, always check that the settings are appropriate.

For further information, please refer to the CMS corresponding instructions for use.

6.4 Ventilation

6.4.1 Starting ventilation therapy

WARNING:

In case of ventilator failure, the lack of immediate access to an appropriate alternative means of ventilation can result in the death of the patient.

WARNING:

In case of a ventilation failure, make sure that an alternative source of ventilation, such as a self-inflating /manually powered resucitation bag with mask, is always available when using the ventilator.

6.4.1.1 Emergency ventilation

To provide a quick response in critical emergency situations, emergency ventilation can be immediately started with predefined ventilation settings. The proposed ventilation modes and parameter settings were defined following the advice of clinicians and are intended for an average patient population. The tidal volume delivered in the volume controlled modes for adult and pediatric patient is set to 6 ml/kg. For neonates the tidal volume delivered is set to 4-6 ml/kg.

Patient category	**PBW** kg	**Mode**	**Settings**				
			FiO_2 %	**P_{in}** Mbar	**VT** ml	**PEEP** mbar	**RR** /min
Adult	66	**VCV**	21	-	500	5	12
Pediatric	25	**VCV**	21	-	200	5	15
Neonate	3	**PCV**	21	18	-	5	40

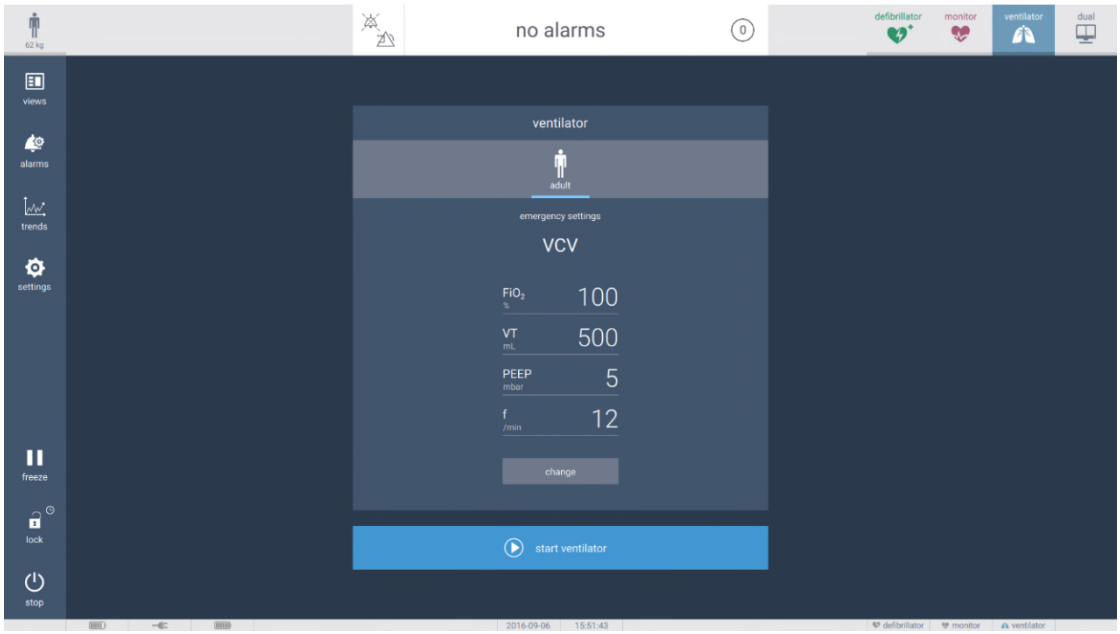
NOTE:

The proposed ventilation settings can be changed before starting the emergency ventilation.

To start emergency ventilation:

1. Select the patient category: Adult, Pediatric or Neonate.
2. Tap on ventilator button
3. An intermediate confirmation screen with the proposed ventilation settings is displayed. Tap on ‘start ventilator’ button to start ventilation with the proposed settings.

Alternatively, you can modify the proposed settings by tapping on the ‘change’ button. This action will take you to the conventional ventilation settings menu.



NOTE:

To cancel the selection and return to the Home Screen, tap on the 'home' button

6.4.1.2 Routine ventilation

To start ventilation with a new patient:

1. Press the 'new patient' button in the *Home Screen*. The *New Patient Configuration Screen* is visible.
2. Select patient category and input additional patient information as described in 6.3.3.
3. If necessary, set the ventilator configuration in *Ventilator* menu (Air and oxygen sources, hose type, humidifier and flow sensor) as explained below.
4. Run the circuit test.
5. If the proposed ventilation settings are appropriate for the patient, connect the ventilation breathing circuit to the patient side. Otherwise, modify the proposed ventilation settings as explained below.
6. Tap on 'start ventilator'

1. New patient configuration panel
2. Ventilator settings panel
3. Ventilator options panel
4. Circuit test button
5. Start ventilator button
6. Home button

To start /resume ventilation with an already admitted patient:

Option A: From the Home Screen

This is the case when all modules are stopped (Jenny® is in standby):

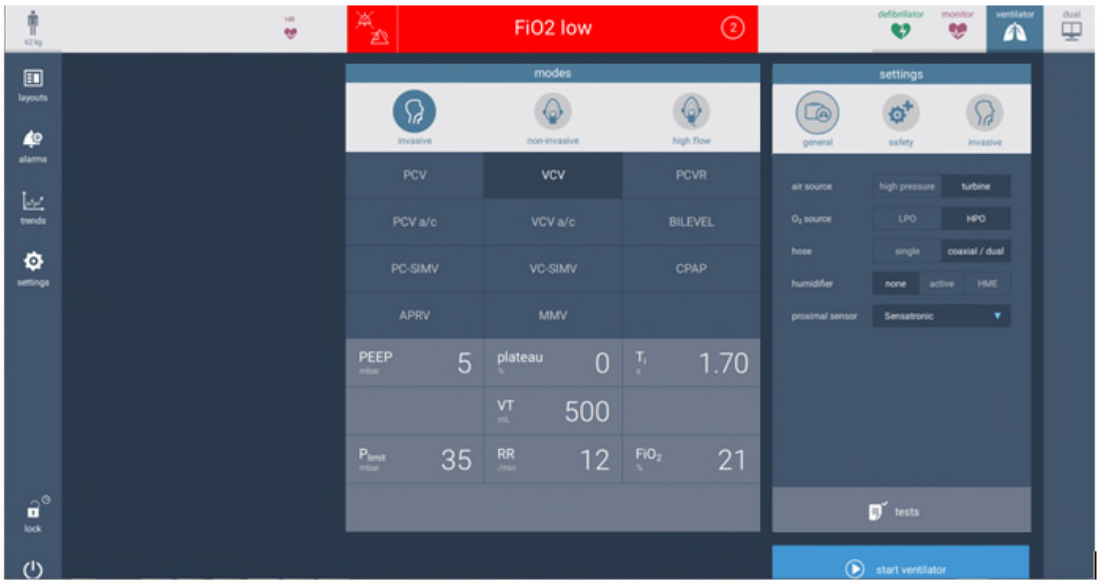
1. Press the 'Last Patient' button in the *Home Screen*. The *Last Patient Configuration Screen* is visible. The last applied patient data is displayed. The ventilation settings must be adjusted.
2. If necessary, set the ventilator configuration in the General menu (Air and Oxygen sources, hose type, humidifier and flow sensor) as explained below.
3. If necessary, run the circuit test.
4. If the proposed ventilation settings are appropriate for the patient, connect the ventilation breathing circuit to the patient side. Otherwise, modify the proposed ventilation settings as explained below.
5. Tap on 'start ventilator'

1. Last patient configuration panel
2. Ventilator settings panel
3. Ventilator options panel
4. Circuit test button
5. Start ventilator button
6. Home button

Option B: From the ventilation control panel

This is the case when ventilator is stopped but other modules are currently running.

1. Press the ‘ventilator’ button on the Modules control panel switch to go to the ventilation control panel. The last applied ventilation settings and options are displayed
2. Proceed as described in Option A.



6.4.1.3 Ventilation settings panel

In the ventilation settings panel, you can

- Select the ventilation modality: Invasive, Non-invasive or Oxygen Therapy.
- Select the ventilation mode from the modes available for the selected patient category and ventilation modality. (See section 6.4.5.1 for availability).
- Visualize and modify the ventilation control settings for the selected ventilation mode.

6.4.1.4 Ventilator modality

To select the ventilation modality

Simply tap to switch between Invasive, Noninvasive ventilation and High Flow Oxygen Therapy.

WARNING:

During non-invasive ventilation (NIV), the actual exhaled volume of the patient can differ from the exhaled volume measured by the ventilator due to leaks around the mask.

6.4.1.5 Ventilation modes

To select a ventilation mode

1. Tap on the desired mode on the mode list. The mode selected will be highlighted and the ventilation control settings for this mode will be displayed at the bottom of the ventilation settings panel. See table below to check the availability of ventilation modes regarding ventilation modality and patient category:

Ventilation Mode	Mode Availability					
	Adult		Pediatric		Neonate	
	Invasive	Non invasive	Invasive	Non invasive	Invasive	Non invasive
Pressure controlled						
PCV	•	•	•	•	•	•
PCV a/c	•	•	•	•	•	
APRV	•	•	•	•	•	•
PRVC	•[1]		•[1]		•[1]	
Volume controlled						
VCV	•		•			
VCV a/c	•		•			
Support modes						
BILEVEL	•	•	•	•	•	•[2]
CPAP	•	•	•	•	•	•[2]
PC-SIMV	•	•	•	•	•	
MMV	•		•			
VC-SIMV	•		•			

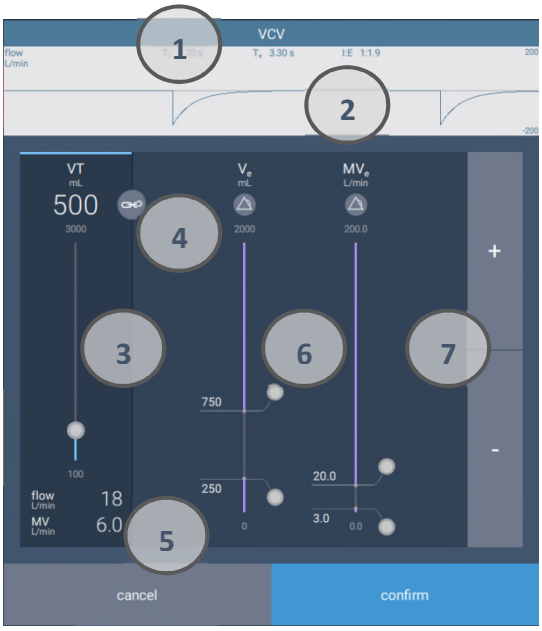
6.4.1.6 Ventilation settings control

The proposed ventilation settings controls for the mode selected are displayed at the bottom of the ventilation settings panel.

To modify ventilation controls

1. Tap on the button with the ventilation control you want to modify.
2. The ventilation control settings panel is displayed. The control setting slider is highlighted (see picture).

[1] Flow sensor must be used, options “pressure only” and “none” not allowed
[2] No pressure support available



1. Ventilation mode
2. Preview curve
3. Ventilation control setting
4. Link/unlink button
5. Related parameters data
6. Related alarms controls
7. Fine adjustment '+' and '-' buttons

3. Simply drag the blue slider control knob and drop when the desired control value is displayed. Alternatively, you can adjust the value with the '+' and '-' buttons.
4. Tap on 'confirm' to apply the changes or tap 'cancel' to close the control settings panel without applying changes.

The control settings panel displays additional helpful information for the adjustment of the selected ventilation control:

- A pre-visualization pressure or flow curve (when the current ventilation mode is pressure and volume controlled, respectively). You can graphically and numerically visualize the changes in the ventilation pattern along with the adjustment of the ventilation control.
- You can visualize, if there are any, the related ventilation controls that change along with the control you are modifying. For example, in the previous figure, the selected control is tidal volume. The related control settings are displayed at the bottom of the slider (Minute Volume and flow).

6.4.1.7 Ventilation mode settings and alarms

You can also visualize alarm limits for monitored values influenced by the control you have selected. *For example, the related alarms for the tidal volume in VCV (as in the previous picture) are 'expiratory Volume', 'expiratory minute volume' and 'inspiratory flow'. In a volume controlled mode, an increase in the control 'tidal volume' will*

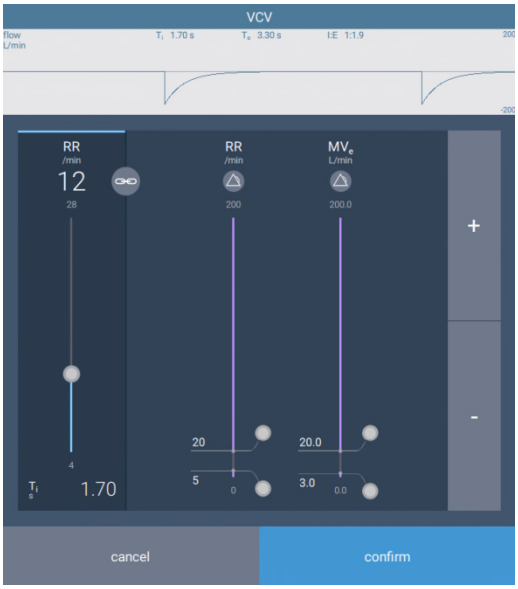
presumably increase the value of the measured expiratory volume. The alarm limits for the measured expiratory volume should be adjusted accordingly.

These related alarms limits are adjusted automatically along with the ventilator control setting. You can activate or deactivate this function by tapping on the Link/unlink button.

Additionally, you can manually activate/deactivate the related alarms and adjust the alarm limits directly from the control settings panel.

To set the related alarm limits manually

1. Tap on the area of the alarm limit you want to modify. The slider control will be highlighted.



2. Tap on the corresponding alarm slider control to adjust upper or lower alarm limits. Alternatively, you can use the *'+'* and *'-'* buttons of the corresponding upper or lower alarm limit.
3. Tap on *'confirm'* to apply the changes or tap 'cancel' to close the control panel without applying changes.

6.4.1.8 Ventilation options panel

In the ventilation options panel you can

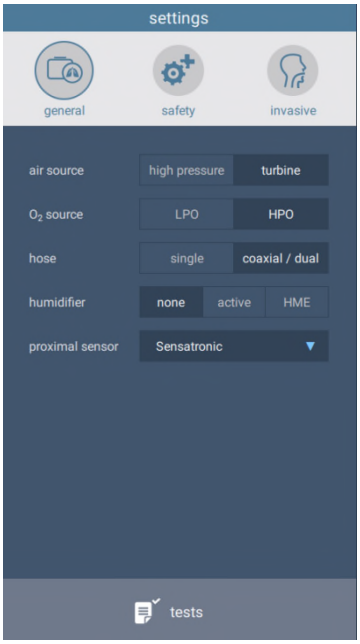
- Configure the pneumatic drive and the gas supply sources for the ventilator.
- Configure the ventilation breathing circuit and its accessories.
- Run the ventilation circuit test.
- Configure additional ventilation options for the ventilation modality and the ventilation mode selected in the ventilation settings panel. See table below to check the availability of ventilation options regarding ventilation modality and patient category.

Ventilation Options	Option Availability					
	Adult		Pediatric		Neonate	
	Invasive	Non-invasive	Invasive	Non-invasive	Invasive	Non-invasive
General	•	•	•	•	•	•
Safety	•	•	•	•	•	•
Trigger[1]	•	•	•	•	•	
Invasive	•		•		•	
Non-invasive		•		•		•

[1] Not available in PCV, VCV, PCVR modes and High flow therapy mode

General settings

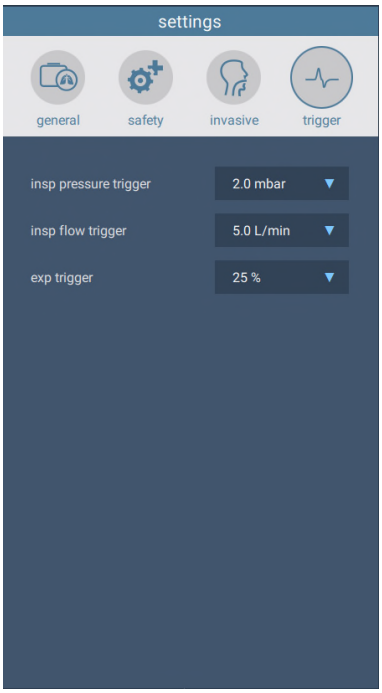
In the *General* button you can configure the pneumatic supply for the ventilation module and the ventilation breathing circuit.



Field	Description	Value Range	Default
Air source	Select the source of the pneumatic ventilator drive	High pressure, turbine	Turbine
Hose	Select the breathing hose system type	Single, coaxial/dual	coaxial/dual
Humidifier	Select the type of humidifier, if any, in the ventilation breathing system	None, active, HME	None
Flow sensor	Select the patient flow sensor from the list of compatible flow sensors	**Adult and Pediatric:** None, Hamilton, Sensatronic, EnviteC, pressure only **Neonates:** None, Hamilton, Respironics, pressure only	**Adult and Pediatric:** Sensatronic **Neonates:** Hamilton
O2 source	Select the type of the connected O2 source.	LPO, HPO	HPO

Trigger

In the trigger menu, you can set the inspiratory trigger sensitivity for modes with spontaneous or assisted breaths and the expiratory trigger sensitivity for modes with spontaneous breaths. For the trigger specifications, refer to ventilation performance specification.

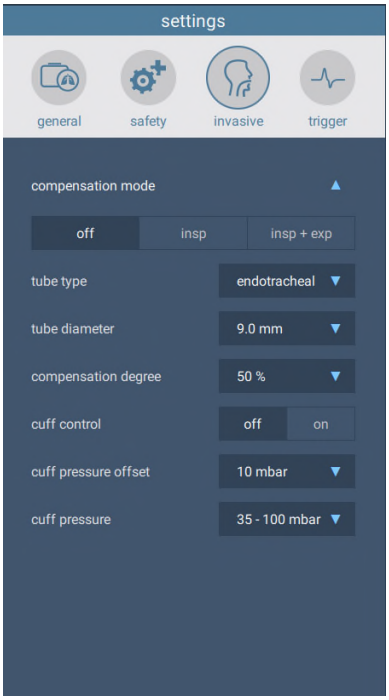


Field	Description	Value Range	Default
Inspiration pressure trigger	Set the sensitivity of the pressure trigger	0.5 to -5 mbar Step: 0.1 mbar	-2.0 mbar
Inspiration flow trigger	Set the sensitivity of the inspiratory flow trigger	0.1 to 20 L/min Step: 0.1 L/min	5.0 L/min

TC (Tube Compensation)

The automatic TC option applies an additional positive pressure to the patient to overcome the additional resistance of the artificial airway during invasive ventilation. This is especially relevant during spontaneous breath delivery to reduce the imposed work of breath and improve the patient synchrony with the ventilator.

When the TC option is active, the calculated tracheal pressure curve is displayed over the airways pressure curve.



Field	Description	Value Range	Default
Compensation mode	Select when is the compensation applied: never, during inspiration only (for example for patients with COPD) or during inspiration and expiration	Off, insp, insp+exp	Off
Tube type	Select the type of tube that is being applied to the patient	Endotracheal, tracheostomy	Endotracheal
Tube diameter	Select the diameter of the endotracheal tube	Adult: 7 -12 mm Child: 4 – 7 mm Neonate: 2 - 4 mm	Adult: 9 mm Child: 6 mm Neonate: 3 mm
Compensation degree	Select to determine the percentage of compensation applied	5 to 50%	50%

Cuff Control

The integrated cuff pressure control provides the operator with continuous monitoring and adjustment for the cuff of endotracheal tubes and cuffed tracheostomy tubes. The monitoring device detects changes in the cuff pressure, and a dedicated, miniaturized pump, increases or decreases the cuff pressure according to the desired parameters, and compensates for leakages.

WARNING:

- AIR or O2 gas supply is required in order to perform an active cuff control.
- Do not connect the tubing to any other device or connector other than to the automatic cuff pressure controller port on the ventilator and to the inflating tube on the tracheal tube or tracheostomy tube.
- Disconnect the automatic cuff controller tubing from the tracheal or tracheostomy tube if the automatic cuff pressure controller is switched off.

- The operator must set the minimum and maximum cuff pressures carefully, in order to avoid tracheal injury, as well as leakage or aspiration of gastric content.
- Check the Cuff Control connections regularly, to avoid bending or kinking of tubes, and incorrect pressure measurements.

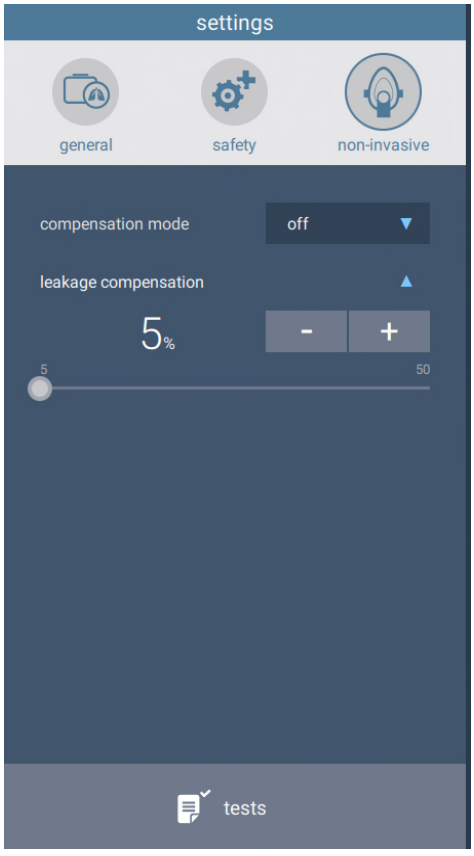
Field	Description	Value Range	Default
Cuff control	Activate / deactivate cuff control	Off, On	Off
Cuff pressure offset	Pressure offset over the airways pressure	0 to 50 mbar Step 1 mbar	10 mbar
Minimum cuff pressure	Minimal pressure that will be applied to the cuff	From 10 mbar	**Adult:** 35 mbar **Pediatric:** 25 mbar **Neonate:** 25 mbar
Maximum cuff pressure	Maximal pressure that will be applied to the cuff	Up to 120 mbar	100 mbar

Leakage compensation

The leakage compensation option is available when Non-invasive ventilation (NIV) is selected for Adult and Pediatric patients. For neonatal patients, it is available for invasive ventilation, since the neonatal endotracheal tubes used with neonates normally are uncuffed and a significant leakage can occur.

WARNING:

In patients with pneumothorax, it is advisable to switch off the leakage compensation to avoid increased airflow consequently to patient pneumothorax.



Field	Description	Value Range	Default
Compensation mode	Set the compensation mode, either manual with a fixed percentage set by you or automatic, with a compensation percentage calculated from the leakage volume	Off, manual, auto	**Invasive (A, P):** Off **Invasive (N):** Auto **NIV (A, P):** Auto **NIV (N):** Off
Compensation degree	Compensation percentage for manual compensation mode	5 to 100 %	5 %

Circuit test

The circuit test is a short test that checks the integrity of the ventilation breathing circuit and performs important adjustments for the proper operation of the ventilator with the patient (especially the calibration of the patient flow sensor).

With the circuit test you can

- Measure the resistance and compliance of the hose system.
- Check the breathing circuit for leakages
- Calibrate the patient flow sensor
- Calibrate the expiration valve

You must run the circuit test when

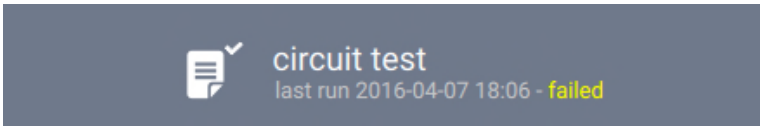
- Connecting a new patient to the ventilator. Before starting ventilation
- Replacing the ventilation breathing system *(hose type)*
- Adding, removing or modifying accessories to the breathing *system (Humidifier, filter, water traps, capnography sensor, etc.)*
- Changing the humidifier type
- Changing the HME filter
- Changing the expiration valve
-

Preparation for the circuit test

WARNING:

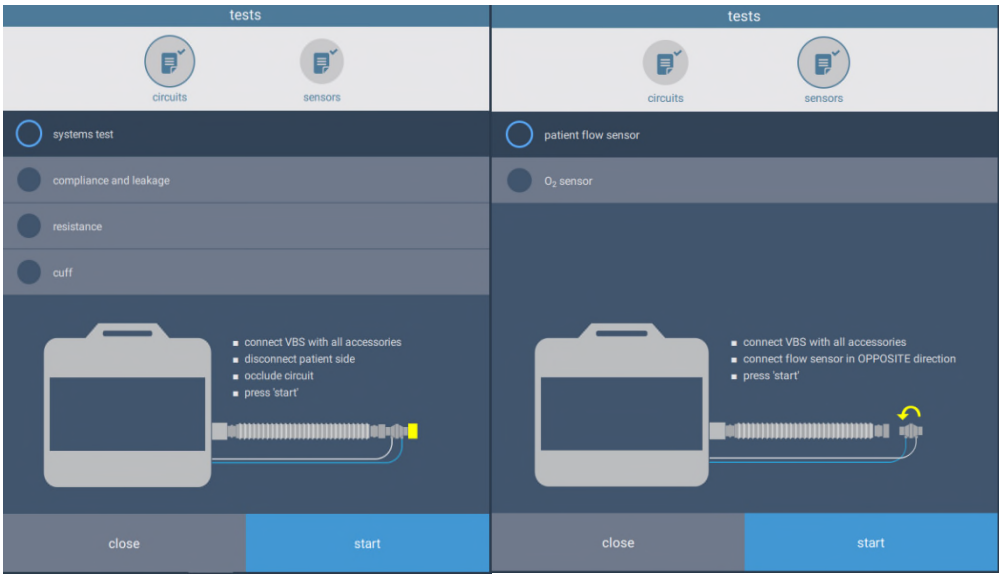
To avoid physical injury to the patient, make sure that the patient is disconnected from the ventilator before running the circuit test.

You can find the circuit test button at the bottom of the ventilation options panel. The circuit test button displays the date and time in which the last circuit test was run. It also displays the result *(passed or failed)* of the test.



To run the circuit test

1. Press the ‘circuit test’ button. The circuit test panel is displayed:



2. Follow the instructions displayed in the screen
3. Make sure that the **patient is disconnected** before starting the test
4. Make sure that the Settings correspond with the breathing system configuration installed (Hose, Humidifier and Flow Sensor type)
5. Keep the patient side of the breathing circuit occluded
6. Press ‘start’

After pressing ‘start’, the test starts automatically. The test performs the following tasks:

Circuits Tests

Field	Description
System	During this test, the patient circuit must be occluded. The following parts are tested: - Oxygen source - Compressed air source - Blower air source - Pressure and safety valves - Expiratory valve - Internal air flow - Internal oxygen flow - Air-source check valve - Cuff source If the test fails, inspect the pressure, safety and expiratory valves, as well as the oxygen, air and cuff sources.

Field	Description
Compliance and leakage	During this test, the patient circuit must be occluded. - First, it estimates the compliance and calculates the compressible volume in the hoses system. - Second, it measures the leakage in the hose system and estimates if it is below the maximum leakage permitted If the test fails, inspect the breathing circuit for leakages, especially in the interfaces (connection to inspiration, expiration valve, flow sensor …)
Resistance	During this test, the patient circuit must be open. Calculates the resistance of the inspiratory limb and estimates if it is below the maximum resistance permitted. If the test fails, inspect the breathing circuit for obstructions.
Cuff	During this test, the cuff control line must be connected to the endotracheal tube. The compressed Air and/or Oxygen source must be available and connected. Checks correct functionality of the cuff related sensor and actuator systems by sending test steering signals and receive measurements. If the test fails, replace the module.

Sensors Tests

Field	Description
Patient flow sensor	- First, the patient flow sensor is calibrated in the expiratory direction. For this, the flow sensor must be connected in the opposite direction and the patient circuit must be open. - Second, the patient flow sensor is calibrated in the inspiratory direction. For this, the flow sensor must be connected in the normal direction. If the calibration fails, retry the circuit test. If it continues to fail, replace the patient flow sensor.
O_2 sensor	During this test, the patient circuit must be occluded. - First, the oxygen sensor must be installed, the device enabled to all its connections, and an oxygen source must be available. - Second, the device delivers the O_2 percentage that is established by the operator. - Estimates the sensor function and resets the calibration point specific to the cell in use. If the test fails, inspect for correct installation of the oxygen sensor and the cable, as well as for O_2 availability. If it continues to fail, replace the O_2 flow sensor.

After each task, the GUI displays the results and moves forward to the next task. If a task fails, the GUI gives you the option to retry the circuit test from the beginning. The test

result data is updated on the 'circuit test' button when the circuit test is run completely *(not when the test is aborted by the user)*.

6.4.2 During ventilation

6.4.2.1 Ventilation control panel

1. Waveform layout
2. Numeric parameter layout
3. Ventilation controls
4. Ventilation function bar

Ventilator waveforms

The monitor waveforms display real-time measurement data in fixed mode, with a moving erase cursor that refreshes the data from left to right. The cursor is running at the configured sweep speed set in the 'advanced' ventilation menu. The sweep speed set is applied to all ventilation waveforms. The ventilation curves are redrawn from left to right when the sweep speed is modified.

The ventilation control panel displays the airways pressure waveform on top of the waveforms stack for all ventilation views.

Numeric parameter layouts

The ventilation numeric layouts display the different measured parameter values.

The numeric layouts for ventilation have the following formats:

- Parameters without alarm:

- Parameters with alarm. **Alarm is on:**

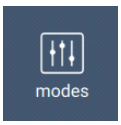
- Parameters with alarm. **Alarm is off:**

1. Parameter name
2. Parameter units of measure
3. Parameter digit value
4. Parameter lower alarm
5. Parameter upper alarm
6. Alarm off

When the parameter displayed has an alarm with adjustable limits, the numeric layout also displays the upper and lower alarm limit and a graphic bar with:

- A white moving dot that represents the current parameter value relative to the upper and lower alarm limits.
- A lighter variable area in the graphic bar that represents the maximum and minimum measured values in the last 5 minutes (mini-trend).

Ventilation controls and indicators

Location	GUI item	Description
		**Modes button**– Opens the ventilation modes menu.

Location	GUI item	Description
		**Maneuvers button**– Opens the maneuvers menu
		**Nebulizer button**– Opens the nebulizer menu
		**O_2 flush button**– On Tap and hold the O_2 flush is activated for 2 minutes.
		**Control button**– Displays the current control value. On tap, opens the control settings menu.

Ventilation control panel views

There are dedicated views with different parameters and curves layouts, which can be accessed from the left tool bar in the main panel view.

Standard layout:

Provides visualization for:

- Pressure, Flow, Volume and $EtCO_2$ curves in real-time display.
- Peak pressure (Ppeak), PEEP, Minute Ventilation (MV), Respiratory Rate (RR), FiO_2 and $EtCO_2$.
- Ventilation Settings: PEEP, VT, Inspiratory Pressure (Pinsp), Plateau Pressure (Pplateau), Inspiratory Time (Tinsp), RR, FiO_2.

- Function bar: Access for Modes, Maneuvers, Sigh, Nebulizer, O_2 flush and Gas Analyzer buttons.

1. Waveform layout
2. Numeric parameters
3. Ventilation controls bar
4. Ventilator functions bar

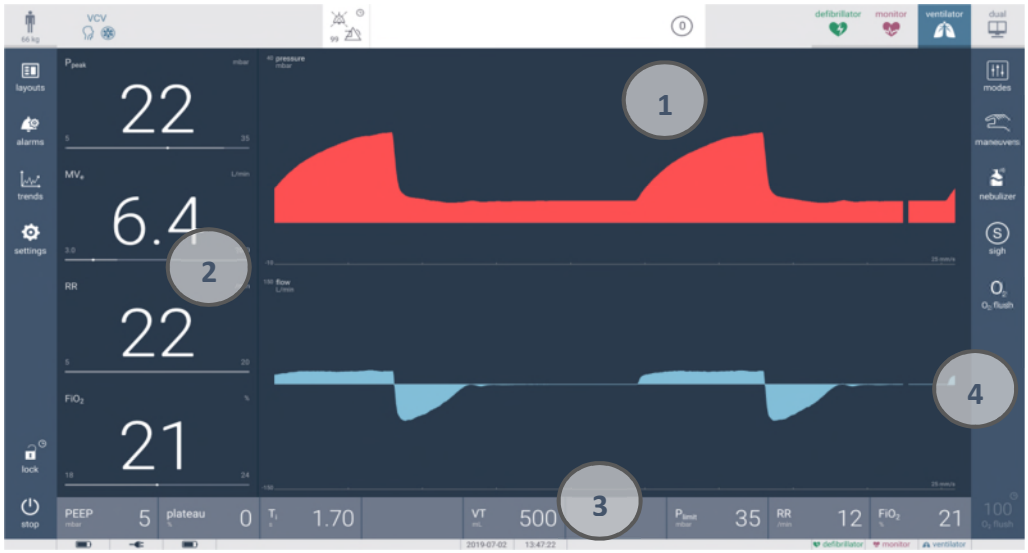
Standard + Loops layout:

Displays, in an additional bar with 3 fields for 3 loops, obtained from calculated and measured respiratory parameters (Volume-Pressure, Flow-Pressure, Flow-Volume).

1. Waveform layout
2. Numeric parameter layout
3. Ventilation controls
4. Ventilation function bar
5. Loop layout

Basic layout

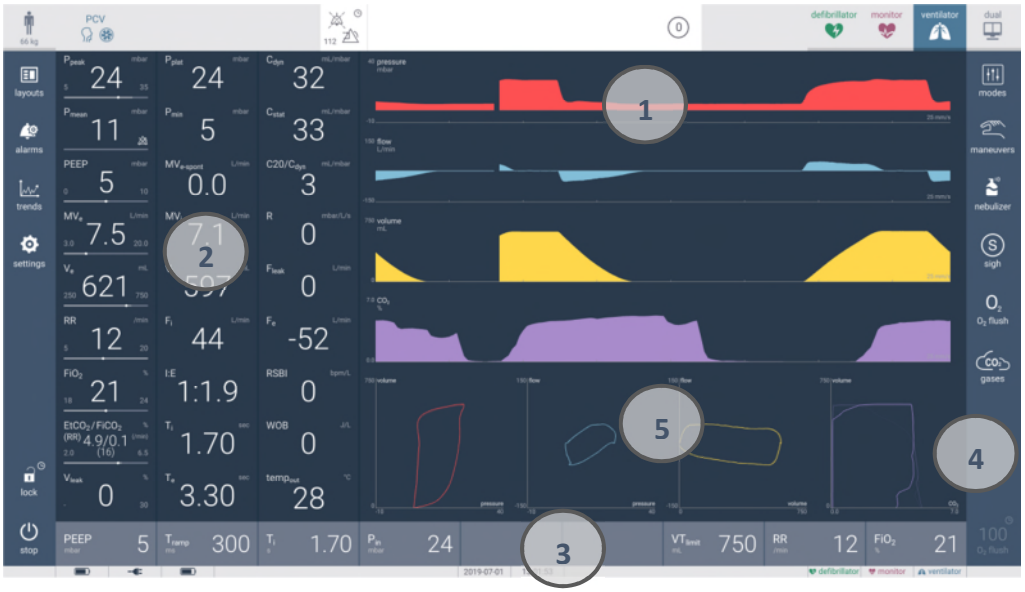
Provides enlarged visualization form 2 waveforms (Pressure and Flow). The $EtCO_2$ waveform and numeric data cannot be visualized in this layout.



1. Waveform layout
2. Numeric parameter layout
3. Ventilation controls
4. Ventilation function bar

Extended layout

This layout includes 2 additional bars, for the visualization of measured and calculated parameters, to assess respiratory mechanics and physiological variables.



1. Waveform layout
2. Numeric parameter layout (described in table below)
3. Ventilation controls
4. Ventilation function bar
5. Loop layout

Numeric parameters description

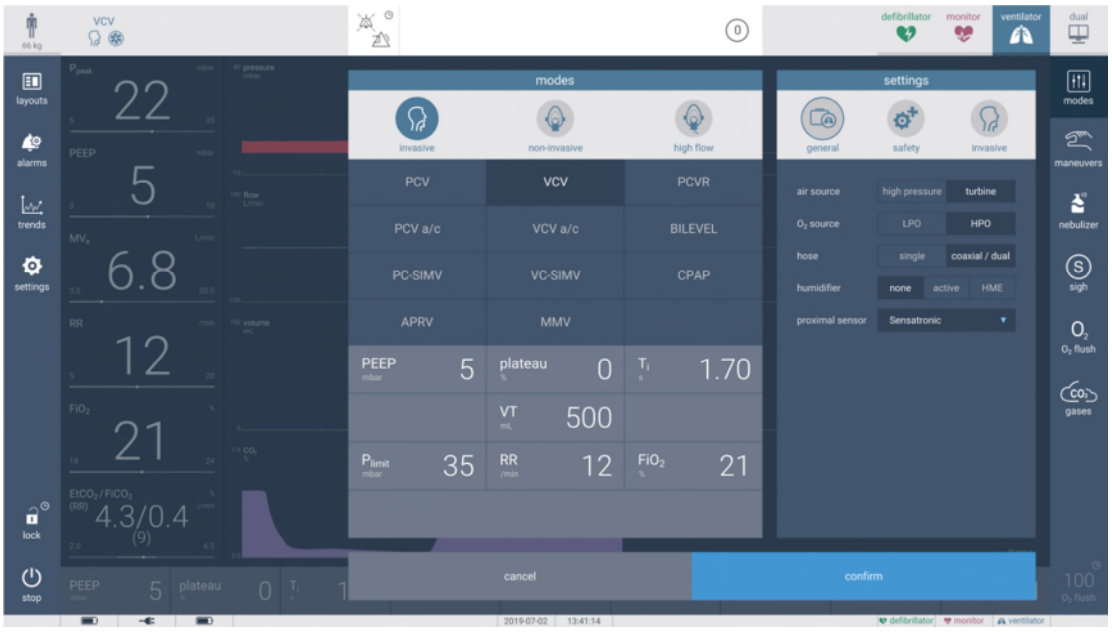
Column 1	Column 2	Column 3
Peak Pressure (Ppeak)	Plateau Pressure (Pplat)	Dynamic Compliance (Cdyn)
Mean Pressure (Pmean)	Minimum Airway Pressure (Pmin)	Static Compliance (Cstat)
Positive End-Expiratory Pressure (PEEP)	Spontaneous-Expiratory Minute Volume (MVe-spont)	Compliance ratio (C20/Cdyn)
Expiratory Minute Volume (MVe)	Inspiratory Minute Volume (MVi)	Resistance (R)
Expiratory Volume (Ve)	Inspiratory Volume (Vi)	Leakage Flow (Fleak)
Respiratory Rate (RR)	Peak Inspiratory Flow (Fi)	Peak expiratory flow (Fe)
Inspired Fraction O_2 (FiO_2)	Inspiration to Expiration Ratio (I:E)	Rapid Swallow Breathing Index (RBSI)
End-tidal Carbon Dioxide ($EtCO_2$)	Inspiration Time (Ti)	Work of Breathing (WOB)
Leakage Volume (Vleak)	Expiration Time (Te)	Temperature (Temp)

6.4.2.2 Changing current mode controls

The controls for ventilator parameters and settings can be modified according to clinical criteria, in two manners:

From the Ventilator Functions menu

1. The operator must press the **Modes** button, accessing the menu for all available Ventilation Modes and Parameters.
2. By pressing the respective field, the modifications of the target parameter can be done.

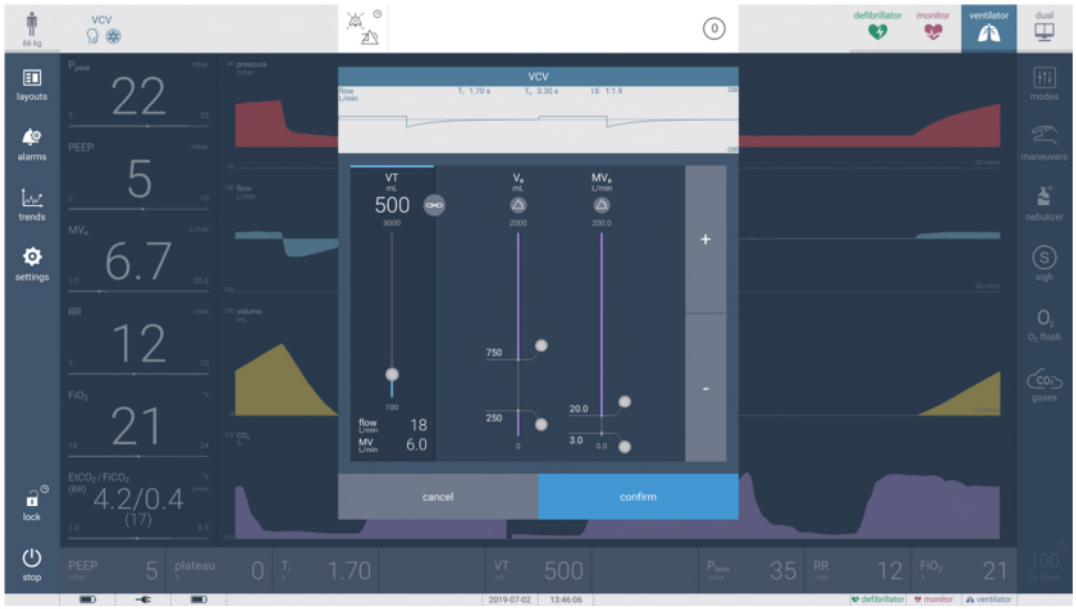


In this screen, it is possible to establish whether the alarm modification for related parameters will be modified in response to the new values, by pressing the link button (**Chain Symbol**).

In the upper segment of the square, the user can assess the modifications of the corresponding waveform (pressure or flow) associated with the target parameter.

From the Ventilator Controls bar

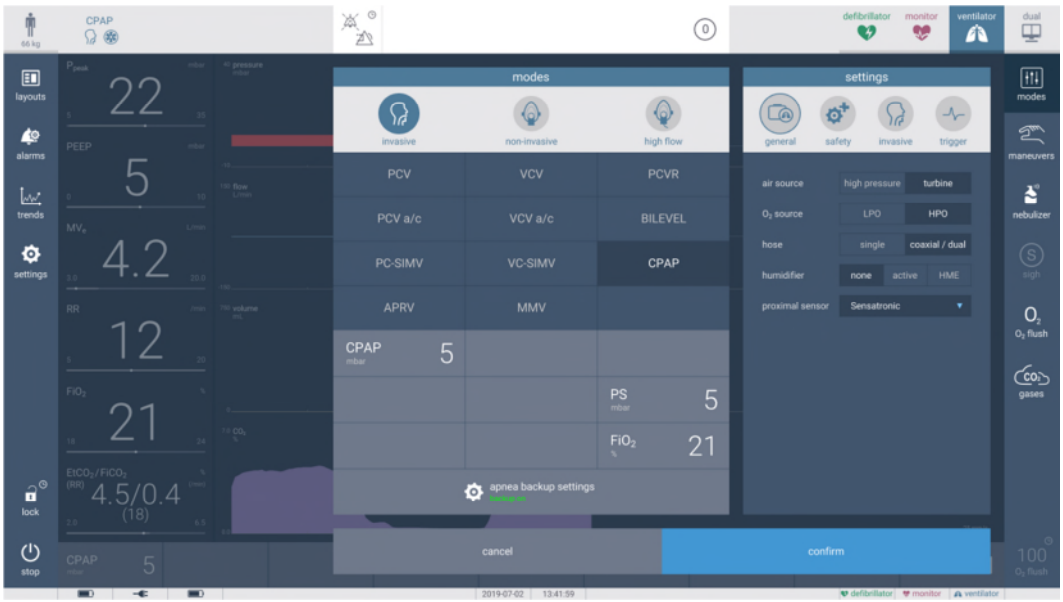
The operator must press the target parameter directly in the lower bar, for all ventilator layouts. The visualization of alarms and waveforms remains similar as in the Ventilator Function menu.



6.4.2.3 Changing ventilation mode

The different ventilation modes are available to the operator from the Ventilator Function menu. By pressing the corresponding option, the default values are visible and accessible to modifications.

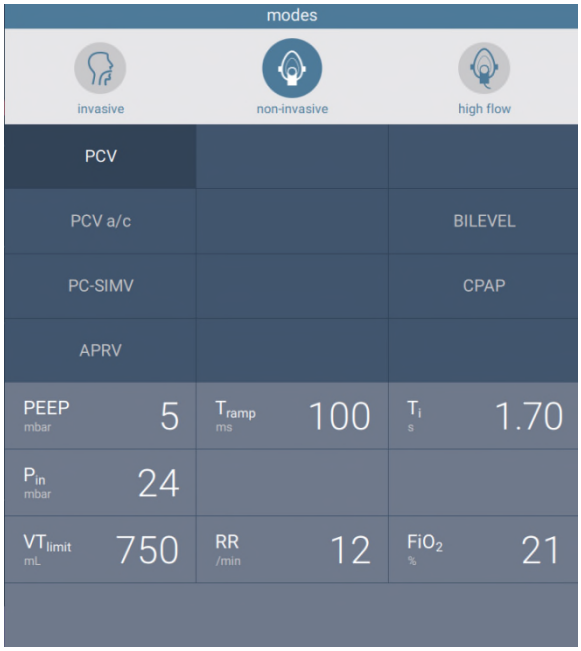
When the desired mode involves spontaneous breathing (e.g., weaning modes), the apnea settings menu is accessible, to provide ventilator support in response to need.



6.4.2.4 Changing ventilation options

The different ventilation options (Invasive, Non Invasive and Oxygen Therapy), are available to the operator from the Ventilator Function menu. By pressing the corresponding icon, the operator can select the desired option.

6.4.2.4.1 Non-Invasive Ventilation (NIV)



The available NIV modes will be displayed, with their respective default settings.

The Settings menu allows the operator to access the NIV specific screen for Leakage compensation.

WARNING:

The patient must remain under close surveillance while receiving NIV therapy, with emphasis on early detection of NIV failure signs:

- Interface intolerance
- Excessive air leaks
- Patient-ventilator asynchrony
- Claustrophobia
- Agitated, poorly collaborative patient

NOTE:

Assessment of mask fit, interface type, head strap tightness, skin integrity of mask contact point, ventilation synchrony and degree of mask leak are to be completed each time the interface is adjusted and at least evey 2 hours, according to the institutional protocols.

WARNING:

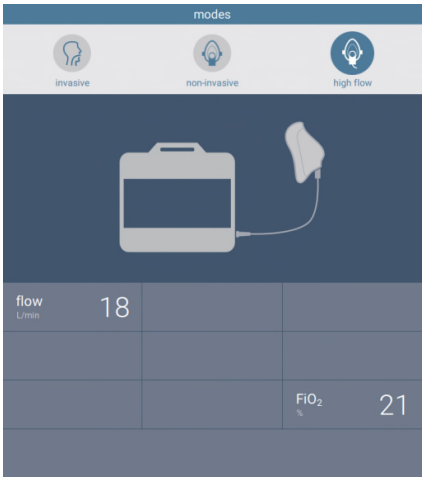
In case of NIV failure, the operator must access promptly the Invasive Ventilation Menu and start the required ventilation support.

Troubleshooting

Problem	Possible cause	Proposed remedy
Leakage of air	Air escapes the circuit due to lack of seal.	- Careful patient selection - Choose correct interface and size - Encourage mouth closure with nasal mask. - Check interface fit - Consider change device - Optimize ventilatory support (i.e. reduce pressures slightly)
Nasal congestion	Inflammatory reaction of the nasal mucosa to the constant flow of cold, dry air.	- Choose correct interface and size - Consider topical and systemic decongestants (i.e. saline solution, emollients, steroids, and antihistaminergics) - Optimize ventilatory support (i.e. reduce pressures slightly) - If using nasal mask, consider switching to facial mask or helmet
Nose/sinus/ear pain	Increased airway pressure	- Choose correct interface and size - Check mask fit, readjust straps - Optimize ventilatory support (i.e. reduce pressures slightly)
Aerophagia and gastric insufflation	Air passage into the digestive tract	- Choose correct interface and size - Optimize ventilatory support (i.e. reduce pressures slightly) - Gastric drainage when appropriate - Consider medication
Vomiting		- Optimize ventilatory support (i.e. reduce pressures slightly) - Consider antiemetics - Gastric drainage when appropriate - Quick-release of straps and remove device if occurs

6.4.2.4.2 High – Flow Oxygen Therapy

The available oxygen therapy options will be displayed, with the respective default settings.

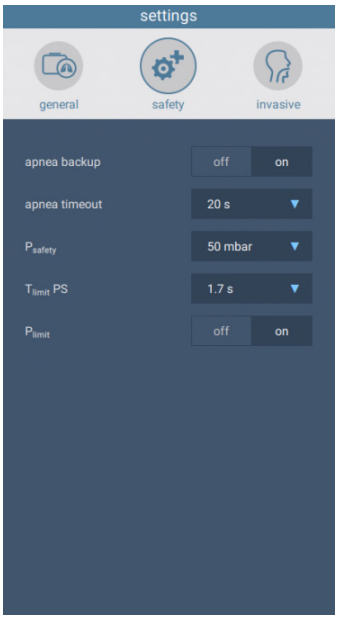


Field	Description	Value Range	Default
Flow	The operator can set the desired oxygen flow according to the clinical situation.	**Adult:** 2 to 80 L/min **Pediatric:** 2 to 80 L/min **Neonate:** 2 to 12 L/min	18 L/min 9 L/min 2 L/min
FiO_2	The operator can set the desired inspired fraction of oxygen, according to the clinical situation.	**Adult:** 21 to 100 % **Pediatric:** 21 to 100% **Neonate:** 21 to 100%	40% 21% 21%

WARNING:

In case of oxygen therapy failure, the operator must access promptly the Invasive Ventilation Menu and start the required ventilation support.

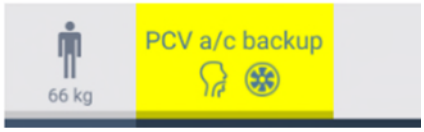
6.4.2.5 Ventilation Safety settings



Field	Description	Value Range	Default
Apnea backup	Sets the time after which, if no patient breath is detected, the ventilator switches to apnea backup ventilation if the mode allows it. Available in BiLevel, CPAP, PC-SIMV, APRV, VC-SIMV, MMV ventilation modes.	Off, On	On

Field	Description	Value Range	Default
Apnea timeout	Sets a timeout to initiate apnea backup.	5 to 60 secs	**Adult:** 20 s **Pediatric:** 15 s **Neonate:** 10 s
Safety pressure (P_{safety})	The **Maximum working pressure** of the ventilator is ensured by the Psafety setting. When this value is reached an Emergency Pressure Release alarm is generated and the pressure is released from the system.	2 to 105 mbar	50 mbar
T_{limit} PS	The operator can set the maximum Inspiratory time during a pressure-supported breath. This more is relevant in Non-invasive ventilation.	**Adult:** 0.5 to 5.0 secs **Pediatric:** 0.5 to 5.0 secs **Neonate:** 0.5 to 2.0 secs	**Adult:** 3 s **Pediatric:** 2 s **Neonate:** 1 s
P_{limit}	The operator can set the maximum allowed peak pressure during a volume-supported breath.	Off, On	On

The Apnea Backup ventilation can be cancelled also, if required, by clicking on the yellow button located in the left section of the Header Bar, where the current running backup ventilation is indicated.



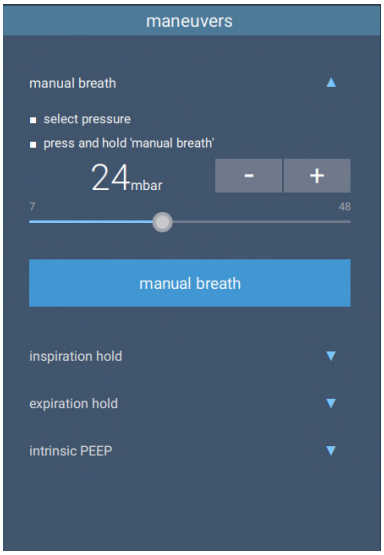
6.4.2.6 Maneuvers

In the Ventilator Functions bar, the user can access all the available maneuvers, both for assessing respiratory mechanics and physiological data, and to assess the respiratory efforts in patients that will undergo weaning from mechanical ventilation.

6.4.2.6.1 Manual Breath

This function allows delivering additional breaths to the patient. It is available in all ventilation modes.

Manual Breath settings



Field	Description	Value Range	Default
Pressure	The operator can set the desired pressure to deliver the manual breath.	**Adult:** 7 to 48 mbar **Pediatric:**7 to 48 mbar **Neonate:**7 to 48 mbar	**Adult:** 24 mbar **Pediatric:** 18 mbar **Neonate:** 18 mbar

6.4.2.6.2 Inspiration Hold

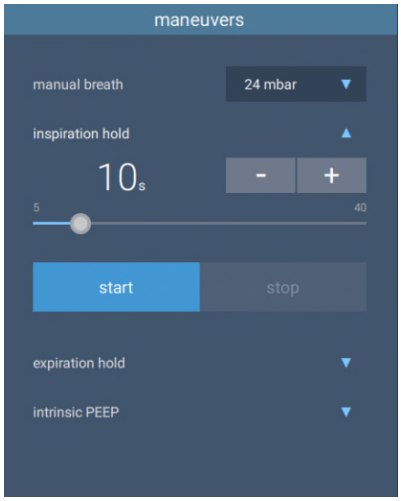
This function will close the inspiratory and expiratory valves for a time fraction (default value: 10 s) at the end of the next inspiratory phase. It is available in all ventilation modes. Its application is suggested for chest X-ray procedures, and to determine plateau pressure and static compliance calculations.

NOTE:

This function should not be repeated when:

- A trigger for spontaneous breath is detected
- A mandatory breath is delivered.

Inspiration Hold settings



Field	Description	Value Range	Default
Time	The operator can set the time to deliver the inspiration hold.	5 to 40 secs	10 secs

If needed, an active maneuver can be immediately suspended. Press Stop.

6.4.2.6.3 Expiration Hold

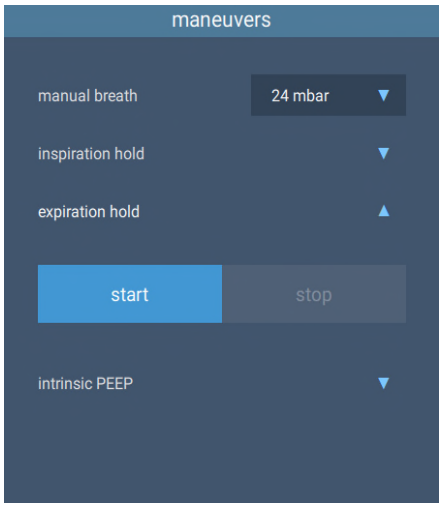
This function will close the inspiratory and expiratory valves at the end of the next expiratory phase. The maneuver is stopped when the user presses the Stop button or when the maximum expiration time of 60 seconds has been passed. It is available in all ventilation modes. Its application is suggested to measure the end expiratory lung pressure and static compliance.

In case of a negative airway pressure originated from patient (under the set PEEP value) or reaching a pressure trigger, the ventilator will end the hold and deliver a breath.

This function should not be repeated when:

- A trigger for spontaneous breath is detected
- A mandatory breath is delivered.

Expiration Hold settings



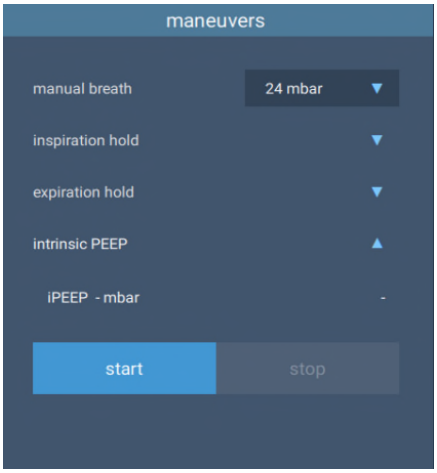
If needed, an active maneuver can be immediately suspended. Press **Stop.**

6.4.2.6.4 Intrinsic PEEP

This function will stop the flow of gas at the end of expiration and measure the airway pressure (when the lung and circuit pressures equilibrate). The value indicates the amount of pressure that remains above the PEEP value.

This function is available in the following ventilation modes: PCV, VCV, PCVR.

Intrinsic PEEP settings



Field	Description	Value Range	Default
Intrinsic PEEP	The operator can measure the amount of pressure that remains above the PEEP value.	-5 to 105 mbar	-

If needed, an active maneuver can be immediately suspended. Press **Stop.**

6.4.2.6.4.1 Troubleshooting

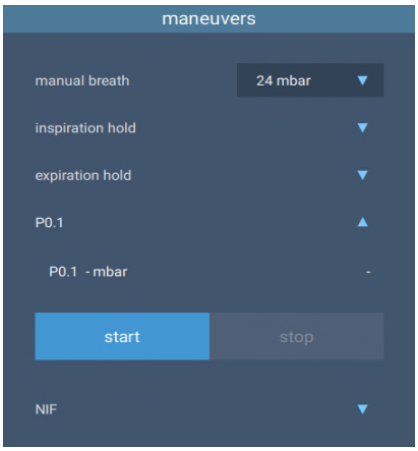
Problem	Possible cause	Proposed remedy
High intrinsic PEEP	**Increased expiratory resistance:** - Bronchospasm, e.g., Asthma, COPD - Narrowed/kinked ETT - Inspissated secretions - Exhalation valves - HME filter **Impaired elastic recoil:** - Emphysema **Increased minute ventilation:** - Inadequate expiratory time	- Treat reversible factors (bronchospasm, secretions, expiratory devices). - Prolong expiratory time (decrease I:E ratio, decrease RR, increase inspiratory flow) - Decrease tidal volume - Measure PEEPi (expiratory hold) - Set exogenous PEEP to ~2/3 PEEPi, this will decrease inspiratory triggering work and improve distribution of inspired gas (others prefer a PEEP of zero, or ZEEP) - If in doubt and dynamic hyperinflation is suspected, disconnect the ETT from the circuit to allow spontaneously exhalation, then reconnect to the ventilator
"-"	- Failure of the expiratory flow curve to reach baseline - Spontaneous breath triggers - Activation of other procedures	- Assess sedation and relaxation of the patient - Repeat the maneuver if necessary

6.4.2.6.5 Airway Occlusion Pressure (P0.1)

This function allows measuring the airway occlusion pressure during the first 0.1 second (100 miliseconds) after beginning an inspiratory effort when the airway is occluded. Its application is suggested to determine the respiratory drive and effort of the patient.

This function is available in the following ventilation modes: PCV a/c, VCV a/c, Bilevel, PC-SIMV, VC-SIMV, CPAP, APRV, MMV.

P0.1 settings



Field	Description	Value Range	Default
P0.1	The operator can measure the airway occlusion pressure in the first 0.1 sec	--105 to 5 mbar	-

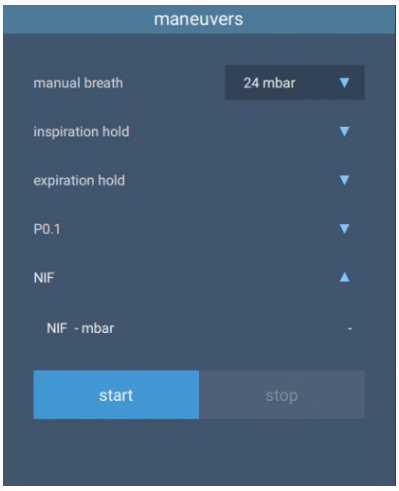
If needed, an active maneuver can be immediately suspended. Press **Stop.**

6.4.2.6.6 Negative Inspiratory Force (NIF)

This function allows measuring the maximal inspiratory effort after previous expiration. Its application is suggested to determine the patient's respiratory muscle strength and reserve.

This function is available in the following ventilation modes: PCV a/c, VCV a/c, Bilevel, PC-SIMV, VC-SIMV, CPAP, APRV, MMV.

NIF settings



Field	Description	Value Range	Default
NIF	The operator can measure the maximal inspiratory effort after a previous expiration	-105 to 5 mbar	-

6.4.2.7 Nebulizer

The Nebulizer function allows delivering aerosolized medication, under medical criteria. This function can be used both manually and automatically.

WARNING:

- Use only the recommended pneumatic nebulizer as listed in the accessories list.
- Use only HME devices approved for use with nebulizers.
- Do not use an expiratory filter or HME between the nebulizer and patient airway during nebulization.
- To ensure adequate delivery of the medication, turn off the heated humidifier during nebulization.
- Do not use the nebulizer without buffer liquid (sterile water); otherwise the ultrasonic generator crystal may break.
- Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.

- To prevent the expiratory valve from sticking due to nebulized medications, use only medications approved for nebulization and regularly check and clean the expiratory valve.
- Ensure that the total combined volume of nebulizer, T-piece and HME is suitable for the tidal volume being delivered and does not increase dead space to the extent that it adversely impacts the ventilatory parameters of the patient.
- Always monitor the resistance to flow and excessive rain-out.
- Condensate can collect and occlude ventilator circuits. Always position ventilator circuits so that fluid condensate drains away from the patient.
- Always connect a bacteria filter to the expiratory inlet of the ventilator. Otherwise the function of the expiratory channel may be degraded.

CAUTION:

The amount of gas administered during nebulization therapy must be accounted in specific patient populations (e.g., pediatric patients).

NOTE:

Gas sampling and CO_2 monitoring are suspended while nebulizer is in use.

To use a jet nebulizer

1. Check that the medication cup is undamaged and firmly in place.
2. Fill the medication cup with the medication and the buffer liquid to the MAX level indicated on the cup.
3. Check frequently the buffer liquid level. Keep the level between MIN and MAX when the nebulizer is operating.
4. Assess the airway pressure during nebulization. Increased airway pressure could result from a clogged filter. Replace the filter if the expiratory resistance increases or after 24 hours of nebulizer use.
5. Check frequently that moisture is being generated in the medication cup.

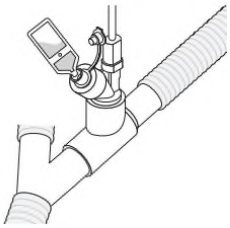
To use an ultrasound nebulizer

WARNING:

- To avoid damage to the nebulizer, do not use a syringe with a needle.
- During use observe for correct functioning of the nebulizer.
- The maximum capacity of the nebulizer is 6 mL.

Intermittent mode

1. Open the plug on the nebulizer.
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer.



3. Close the plug.
4. To start a 30 Minute nebulization cycle, press and release the blue On/Off power button. The green 30 Minute indicator light illuminates to indicate that the 30 Minute nebulization cycle is in progress.
5. To stop the nebulizer at any time, press the On/Off power button. The indicator turns off to indicate that nebulization has stopped.

NOTE:

Medication can be added to the device during nebulization. This does not interrupt nebulization or ventilation.

Continuous mode

The continuous Nebulization Tube Set is an accessory specific to the nebulizer which enables safe continuous infusion of liquid medication for aerosolization.

WARNING:

It is important to ensure that the maximum flow rate through the tube set into the nebulizer must not exceed the output rate of the nebulizer.

• Check for leaks from the system prior to and during use.

• The graduations on the syringe are for indication use only.

• Store at room temperature and use product within labeled shelf life.

• To ensure correct and safe connection between the nebulizer and the medication reservoir, trace the medication tube from the nebulizer back to the medication reservoir to make sure the medication tube is connected to the correct source.

• The recommended syringe pump software setting with the syringe is typically the “BD Plastipak” setting. This must be validated locally before use. Refer to pump manual or manufacturer for guidance. These pumps may also be used in accordance with local hospital or ward policies.

• Ensure that the tethered silicone plug is attached to the device when connecting tube set. • Ensure that the tubing is safely orientated to prevent a trip hazard.

• Rising level of medication in the reservoir may occur if the nebulizer is turned off while the feed system is still on or the nebulizer is not in its recommended orientation.

• The level of the medication in the reservoir of the nebulizer should be periodically monitored to ensure that the fill rate of medication does not exceed the output rate of the nebulizer. A rising level of medication in the reservoir indicates that the fill rate is exceeding the output rate of the nebulizer.

• Replace both the tube set and syringe when changing the type of medication.

• If the syringe needs to be replaced during use (even when empty), turn off the syringe pump and disconnect the nebulizer end of the tube set first. Failure to do this may result in primed medication in the tube flowing into the nebulizer reservoir.

• To avoid spillage of medication when changing the syringe tubing, keep both ends of the tubing at the same height.

• Do not connect the tube set and syringe to non-respiratory equipment.

• Do not clean or sterilize.

• Do not connect to any nebulizer other the one provided.

1. Ensure that the nebulizer is firmly fitted into the T-piece in the breathing circuit.
2. Remove the syringe cap from the medication-filled syringe.
3. Attach the syringe end of the tubing onto the syringe.
4. Prime the tubing until the medication reaches end of tubing.

NOTE:

The tubing priming volume is maximum 3.65 mL.

5. Unplug the tethered silicone plug from the nebulizer, but do not remove it from the nebulizer.
6. Screw the nebulizer end of the tubing onto the top of the nebulizer.
7. Insert the syringe filled with medication into the syringe infusion pump and set the appropriate flow rate (refer to pump manual or manufacturer for guidance).
8. To start a continuous nebulization cycle, press and hold the blue On/Off power button from the off state for at least three seconds. Verify the green, 'continuous nebulization' indicator light is on.
9. Observe nebulizer for correct operation. During continuous nebulization, the nebulizer is on continuously and the medication is nebulized on a drop by drop basis. Nebulization should be visible with regular intermittent pauses. Medication level in the nebulizer reservoir should not rise during use.
10. To stop the nebulizer at any time, press the On/Off power button. The indicator turns off to indicate that nebulization has stopped.

CAUTION:

The recommended input rate of medication into the nebulizer during continuous nebulization is up to a maximum of 12 mL per hour. The upper limit of 12 mL per hour is based on the specifications of the manufacturer for the minimum nebulizer flow rate.

NOTE:

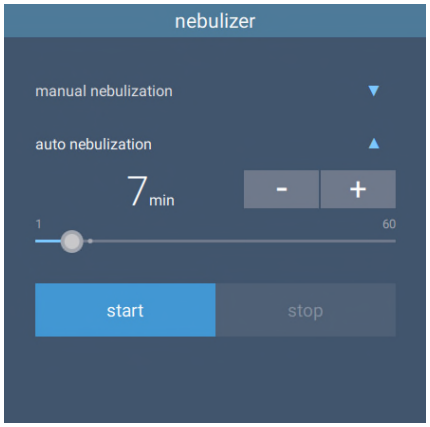
Place the syringe cap on the syringe after it is filled with medication.

Nebulizer settings

Manual nebulization

The operator must press the “Manual nebulization” button to begin the nebulization procedure, and hold it to maintain its duration.

Auto nebulization



Field	Description	Value Range	Default
Time	The operator can set the time for the administration of therapy.	1 to 60 min	10 min

6.4.2.8 Sigh

This function allows delivering breaths, at a regular interval, with a higher-than-normal pressure or volume. The interval can be selected based on medical criteria.

Sigh settings

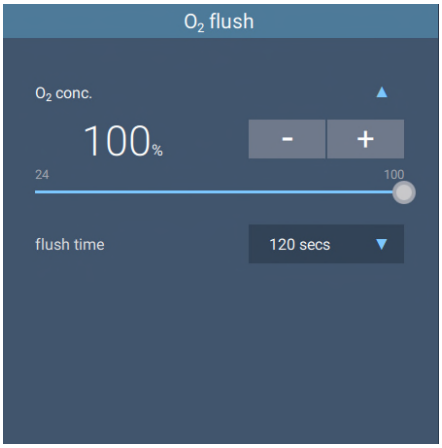
Field	Description	Value Range	Default
Pressure	The operator can set the desired Pressure Offset	0 to 20 mbar	10 mbar
Volume	The operator can set the desired Volume Offset	**Adult:** 0 to 1000 mL **Pediatric:** 0 to 150 mL **Neonate:** 0 to 25 mL	**Adult:** 500 mL **Pediatric:** 50 mL **Neonate:** 10 mL
Interval	The operator can set the desired breathing range	10 to 2000 breaths	100

If needed, an active maneuver can be immediately suspended. Press **Off.**

6.4.2.9 Oxygen Flush

This function allows providing an increased oxygen supply for a specific time, under medical criteria.

Oxygen Flush settings



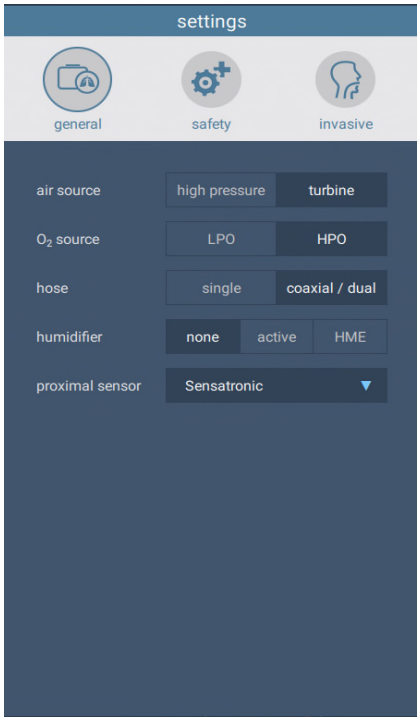
Field	Description	Value Range	Default
O2 concentration	The operator can set the desired oxygen concentration.	21 to 100%	**Adult**: 100% **Pediatric:** 100% **Neonate:** 60%
Flush Time	The operator can set the desired time of administration	30 to 300 secs	120 secs

6.4.2.10 Monitoring Oxygen concentration

Sensor calibration

Depending on the sensor installed in the Jenny® Ventilator module, the operator must perform more frequent calibrations (daily with the galvanic cell) or less frequent (yearly with the paramagnetic cell).

The calibration of the oxygen sensor must be performed prior to initiate ventilation therapy, from the New Patient or Last Patient Screen, in the Tests section. For Emergency Patients, the calibration buttons are not available.



To calibrate the oxygen sensor

1. Tap on the ‘sensors’ button on the ventilator options panel
2. The oxygen sensor calibration menu opens:

3. Connect VBS with all accessories
4. Disconnect patient side
5. Tap on ‘start’ button
6. The calibration takes around 1 minute
7. When the calibration is completed the following screen is displayed:

8. If the calibration was unsuccessful you can retry by tapping on ‘start’ button.
9. If calibration remains unsuccessful, replacement of the oxygen sensor might be indicated. Please refer to the Service Manual.

6.4.2.11 Neonatal Ventilation

The Neonatal Ventilation Menu can only be accessed from the Main Screen, by selecting the appropriate patient group.

For emergency patients, the default body weight that is used 3000 g.

For routine patients, the real body weight must be introduced in the data field.

Accessories selection

The user must select the appropriate accessories for neonatal ventilation mode, including nasal prongs, masks or uncuffed endotracheal tubes, flow sensor and CO_2 adapter.

Ventilation modes

The ventilation modes that are available for neonates are pressure-driven modes. The default setting mode for emergency ventilation is PCV.

The Leakage Compensation function is available for invasive and noninvasive ventilation modes.

NOTE:

The occurrence of leakage in neonatal ventilation can be significant, due to poorly fitting masks and uncuffed endotracheal tubes. The user must check the leakage volume and its correlation with the measured expired VT periodically, and select the leakage compensation accordingly.

The following ventilation modes are available for neonates:

Ventilation Mode	Mode Availability	
	Neonate	
	Invasive	Non invasive
Pressure controlled		
PCV	•	•
PCV a/c	•	
APRV	•	
PRVC	•[1]	
Support modes		
BILEVEL	•	•[2]
CPAP	•	•[2]
PC-SIMV	•	

[1] Flow sensor must be used, options “pressure only” and “none” not allowed
[2] No pressure support available

WARNING:

The apnea Backup Ventilation is not available for Noninvasive Ventilation modes for neonatal patients.

Ventilator controls

There are specific settings that demand further attention and assessment when providing mechanical ventilation to neonates.

Flow trigger

WARNING:

The occurrence of auto triggering is harmful for neonates, and can be due to inappropriately sensitive trigger settings from gas leakage around the endotracheal tube.

The default trigger type for neonatal ventilation is flow triggering. When active, the ventilator will deliver a constant base flow from the inspiratory limb to the expiratory limb, at the end of expiration.

When a significant leakage occurs, and it is higher as the set value for flow trigger, auto triggering can occur. In this case, the user can increase the set value for the flow trigger, to reduce the sensitivity and stop the auto triggering.

Pressure Rise Time (Tramp):

WARNING:

In neonates with compromise of lung expansion (i.e., respiratory distress syndrome), an inappropriately pressure rise time short can increase the risk of barotrauma.

The user must select the appropriate *Tramp* setting accordingly to the patient.

Maximum Inspiratory Time (Max Ti PS):

The maximum inspiratory time is set for spontaneous breaths. This setting provides a backup so inspiration can be terminated. The ventilator will switch over to expiration when the Max Ti is reached.

Inspiratory Time and Expiratory Time (Ti and Te):

The clinician must select the Ti and Te accordingly to the respiratory dynamics of the patient, to avoid incomplete inspiration or expiration.

The Ti can be selected with a stepsize of 0.05 seconds (minimum value of 0.15 seconds).

Maneuvers

WARNING:

In preterm infants, the prolonged exposure to high oxygen concentrations can be associated to irreversible ophthalmological injuries and pulmonary fibrosis.

The O_2 Flush maneuver has a default setting for a duration of 120 secs and an O_2 concentration of 40%.

The Sigh maneuver is not available for neonatal ventilation.

6.4.2.12 Suction

The suction maneuver can be applied to mechanically ventilated patients, either with open or closed suction systems.

WARNING:

To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before suppressing ventilation. You must confirm that no patient is attached before suppressing ventilation.

WARNING:

For open-suction and closed-suction maneuvers: Do not insert the suction catheter through the flow sensor.

Open-Suction Maneuver

To perform an open-suction maneuver with a mechanically ventilated patient, the user must apply the following steps:

1. Prepare the suction accessories according to the respective instructions of use and institutional protocols.
2. Press the alarm silence key.
3. Administer an O_2 enrichment sequence (according to institutional protocols).
4. Disconnect the circuit now at the patient side (Inspiratory Limb or flow sensor).
5. Perform the suction maneuver.
6. Resume ventilation by first reconnecting the patient.

Closed-Suction Maneuver

The closed suctioning technique facilitates continuous mechanical ventilation and oxygenation during the suctioning event. It may prevent tidal recruitment associated with the use of open-suction system in patients at higher risk of desaturation.

It should be considered in patients requiring high FIO_2 and PEEP.

To perform a closed-suction maneuver with a mechanically ventilated patient, the user must apply the following steps:

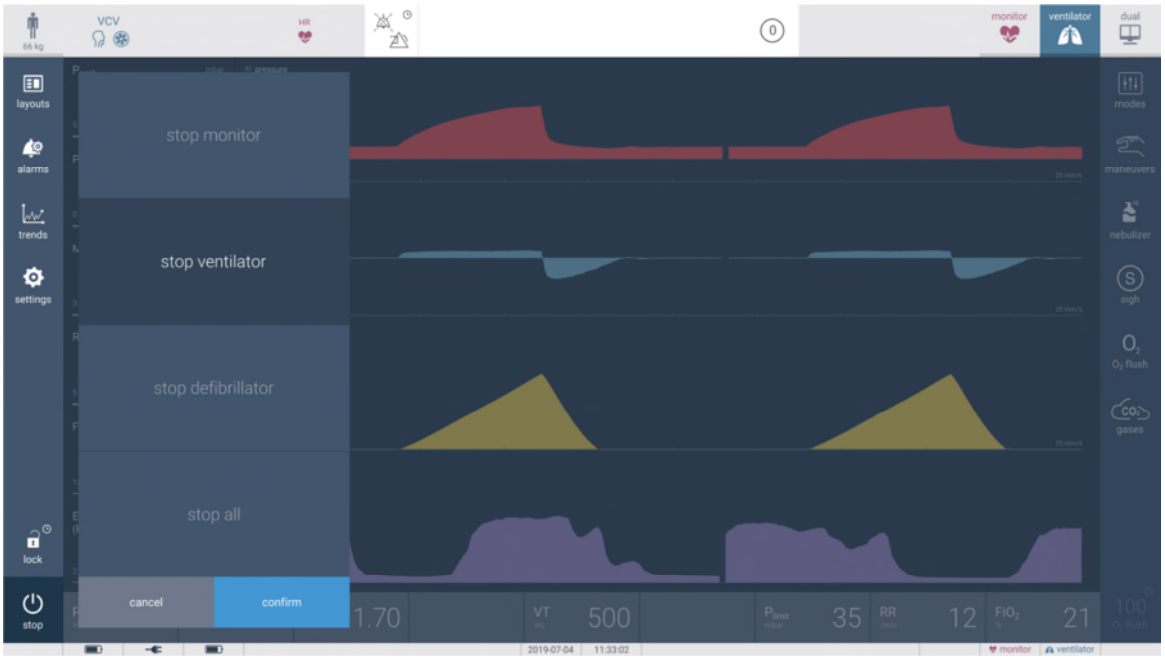
1. Prepare the suction accessories according to the respective instructions of use and institutional protocols.
2. Press the alarm silence key.
3. Administer an O_2 enrichment sequence (according to institutional protocols).
4. Disconnect the circuit now at the patient side (Inspiratory Limb or flow sensor).
5. Connect the thumb valve to the suction tubing, and the other end of the suction tubing to the canister of the suction machine.
6. Attach the patient port side of the elbow to the endotracheal or tracheostomy tube and reconnect the ventilator. If the patient is using both an HME and the ventilator, attach both to the ventilator side of the elbow.
7. Support the elbow connector and tracheostomy tube with one hand, and then grasp the catheter through the sleeve and advance the catheter slowly through the endotracheal or tracheostomy tube.
8. Perform the suction maneuver.
9. Immediately after the suction maneuver finishes, the ventilator settings will be automatically recovered.

6.4.3 Stopping ventilator

The Ventilator Module can be stopped quickly, accessing **the ON/OFF button**, located at the bottom of the left tool bar.

By pressing this button, the options for **Stop** for every module are available. The operator must press **Stop Ventilator** to cease the functions of the module. Ventilation will be stopped after confirmation.

The stopping of a module can be done without interference with the Monitor and Defibrillator Modules.



6.5 Monitoring

6.5.1 Starting patient monitoring

To start patient monitoring, the operator must select the Monitor icon, from the main menu (when initiating the operation of the device), or from the upper-right section of the header bar (when using Ventilator or Defibrillator modules).

6.5.2 During patient monitoring

6.5.2.1 Monitoring control panel

Once the patient is connected with the appropriate electrodes and sensors, the monitor will display the following panel:

1. Waveform layout
2. Numeric parameter layout 1
3. Numeric parameter layout 2
4. Monitor function bar

Monitor waveforms

The monitor waveforms layout displays real-time measurement data in fixed mode, with a moving erase cursor that refreshes the data from left to right. The cursor is running at the configured sweep speed set in the corresponding monitoring parameter settings menu. There can be different sweep speeds for different waveforms.

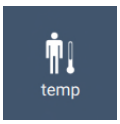
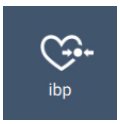
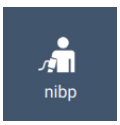
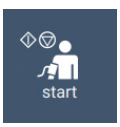
The waveforms for all monitor parameters are redraw from left to right, when a monitoring setting menu is open or a when parameter that affects the display of the waveform is modified.

The monitoring control panel displays the ECG primary lead waveform on top of the waveforms stack for the monitor views.

Numeric parameter layouts

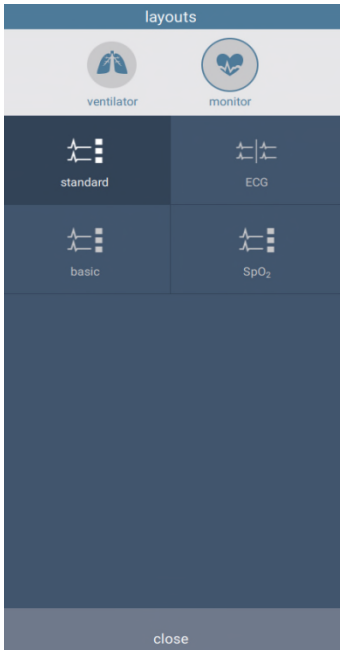
All the numerical parameters from the monitor have an alarm associated. Additionally, the numeric will be displayed in a color corresponding with the waveform color associated with the numeric measurement.

Monitor controls and indicators

Location	GUI item	Description
		**ECG settings button**– Opens the ECG settings menu. You can configure the leads and the visualization of ECG curves
		**Arrhythmia settings button**– Opens the arrhythmia settings menu. You can activate/deactivate the arrhythmia detection and configure what arrhythmias are detected.
		**ST segment analysis button**– Opens the ST analysis menu. You can activate/deactivate the ST segment measurement and set the ISO and ST measurement points with the help of an ECG reference template. NOT AVAILABLE for Neonatal patients
		**SpO_2 settings button**– Opens the SpO_2 configuration menu.
		**Temp settings button**– Opens the temperature configuration menu
		**IBP settings button**– Opens the Invasive Blood Pressure measurement configuration menu
		**NIBP settings button**– Opens the NIBP configuration menu
		**Start/Stop NIBP button**– On single tap you can start/stop the NIBP measurement

Monitoring control panel views

There are dedicated views with different parameters and curves layouts, which can be accessed from the left tool bar in the main panel view.



Standard layout

Provides visualization of parameters for ECG (3 waveforms and 3 fields for numeric parameters), pulse-oximetry (1 waveform and 2 fields for numeric parameters), IBP (2 waveforms and 2 numeric parameters), NIBP and temperature (2 fields for numeric parameters).

1. Waveform layout
2. Numeric parameter layout 1
3. Numeric parameter layout 2
4. Monitor function bar

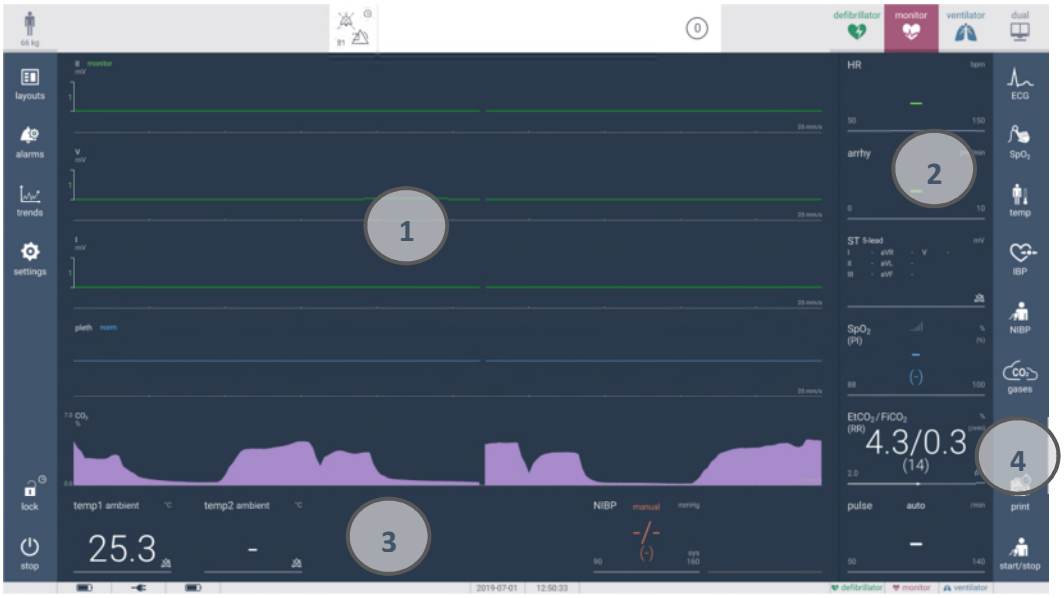
ECG layout

Provides visualization of 7 ECG waveforms (I, II, III, aVR, aVL, aVF, V).

1. Waveform layout
2. Monitor function bar

Basic layout

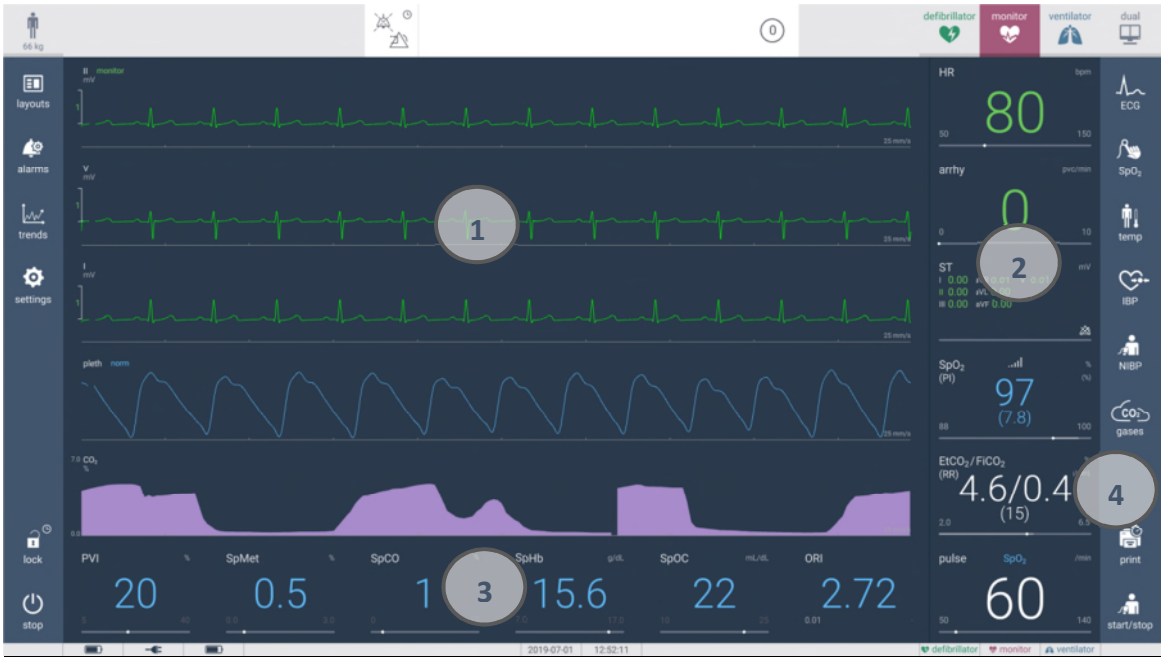
Provides visualization of parameters for ECG (3 waveforms and 3 fields for numeric parameters), pulse-oximetry (1 waveform and 2 fields for numeric parameters), $EtCO_2$ (1 waveform and 1 numeric parameter), NIBP and temperature (2 fields for numeric parameters).



1. Waveform layout
2. Numeric parameter layout 1
3. Numeric parameter layout 2
4. Monitor function bar

SpO2 layout

Provides visualization of parameters for ECG (3 waveforms and 3 fields for numeric parameters), pulse-oximetry (1 plethysmography waveform and 1 fields for numeric parameter), $EtCO_2$ (1 waveform and 1 numeric parameter), 1 numeric field for pulse rare and an inferior bar with visualization of 5 numeric parameters for Masimo ® Optical parameters (described in section 6.5.3.5)



1. Waveform layout
2. Numeric parameter layout 1
3. Masimo ® Optical parameters bar
4. Monitor function bar

6.5.3 Monitoring functions

6.5.3.1 ECG

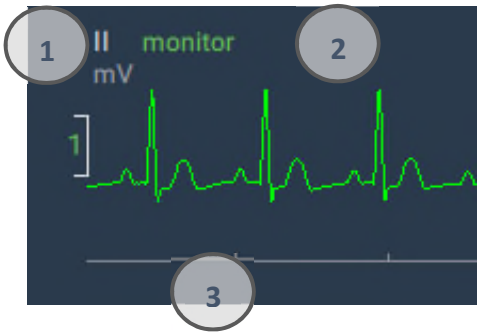
ECG Waveforms

The GUI can display a waveform for each of the ECG-leads being monitored.

Primary lead

The primary lead waveform data is the lead on which the arrhythmia detection algorithm will be applied. Additionally, the ST reference template and the alarm are calculated from the primary lead.

The primary lead waveform displays the following information:



1. Primary lead label
2. ECG filter mode label
3. 1 mV calibration bar (*10 mm/mV for a gain of x1)*
4. ECG primary lead waveform
5. ECG waveform sweep speed

Filter mode

A filter can be applied to the ECG waveforms to reduce interferences. Basically, to reduce the ECG baselines wander due to low frequency power line interference, and to filter high frequency artifacts due to patient movement. The type of filter applied to the ECG-Waveforms is displayed in the primary lead layout:

Filter	Description	Bandwidth
Monitor	Used for conventional ECG monitoring. Filters power line interference and patient movement. Not for diagnose purposes. It is the default filter setting	**0.5 to 40 Hz**
Diagnosis	Used when diagnosis quality is required. The ECG waveforms are displayed unfiltered, so the changes in the waveform are visible. ST analysis is performed only with Diagnosis filter.	**0.05 to 120 Hz**
Surgery	Used in the operation room to reduce artifacts and interference from ESU. It is the filter with the narrowest bandwidth so it may eventually display ECG curves with QRS complex suppression. Not for diagnosis purposes	**1 to 25 Hz**

To change the filter setting, refer to the ECG settings menu.

Paced beat marker

WARNING:

Pacemaker patients' rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarm signals. Keep pacemaker patients under close surveillance. See the Performance Specifications chapter for the monitor module for disclosure of the pacemaker pulse rejection capability of this instrument.

Additionally, when the patient has a pacer and accordingly 'Paced' field of the patient data is set to 'Yes' and the 'Pacer' detection option is activated in the ECG settings

menu, the primary lead waveform displays the detected paced beats. The paced pulses will be marked with a white line on top of the waveform area.

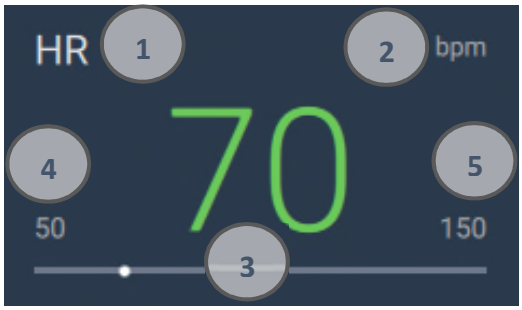
Other leads

Other ECG waveforms can be displayed under the primary lead waveform. They display the following information:

1. Lead label
2. Magnitude *(mV)*
3. ECG lead waveform
4. Erase cursor
5. ECG waveform sweep speed

ECG numeric parameter. Heart rate

The measured heart rate in beats per minute is displayed in a numeric format:



1. Heart rate label
2. Units of measure
3. Heart rate digit value
4. Heart rate lower alarm limit
5. Heart rate upper alarm limit

- The HR displays the heart beat with a resolution of 1 bpm
- If the HR measurement is invalid, '- -' is displayed in the place of the digit value

ECG settings

To display the ECG settings menu

Simply tap on the ECG settings button on top of the Monitor function bar. The ECG menu will be visible.

Field	Description	Value Range	Default
Lead type	Selects the number of leads you want to monitor the patient with	3-lead, 5-lead, 12-lead	5-lead
Primary lead	For the lead configuration selected in lead type, select the primary lead	**3-lead** I, II and III **5-lead** I, II, V, Auto (II) **12-lead** I, II, V1, V2, V3, V4, V5, V6, Auto (II)	3-lead: II 5-lead: Auto 12-lead: Auto
Filter mode	Select the filter applied to ECG waveforms	Monitor, surgery, diagnosis	Monitor
ECG gain	Sets the gain of all the ECG waveforms displayed. The gain can be adjusted automatically by taping on the 'auto size' button.	0.25X, 0.5X, 1X, 2X	1X
Sweep speed	Sets the speed of the erase cursor and the horizontal resolution of all ECG waveforms	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	25 mm/s
Internal pacer	If the patient is registered as paced in the patient data, the 'pacer' option **must** be set to on. The paced rhythms will be displayed on the primary lead waveform	On, Off	Off

Printer function

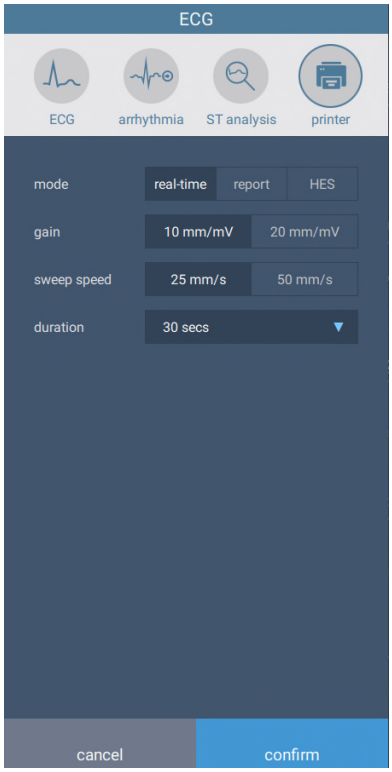
This function allows the operator to obtain a printable report of ECG data from a patient connected to the Jenny Monitoring device.

WARNING:

The ECG printouts do not replace the diagnosis by an experienced physician.

NOTE:

ECG paper may run out while printing.



Field	Description	Value Range	Default
Mode	Selects the ECG report format	Real time, report, HES	Report
Gain	Sets the gain of the ECG waveform displayed	10 mm/mV, 20 mm/mV	10 mm/mV
Sweep speed	Sets the speed of the erase cursor and the horizontal resolution of ECG waveform	25 mm/s, 50 mm/s	25 mm/s
Presentation	Selects the desired presentation of ECG leads in the report. Available when the selected mode is Report.	Standard, Cabrera, HES	Standard
Format	Sets the desired distribution format for ECG leads. Available when the selected mode is Report.	4x3, 6x2	4x3
Duration	Sets the desired duration for the ECG report	2 to 10 secs	5 secs

Real time

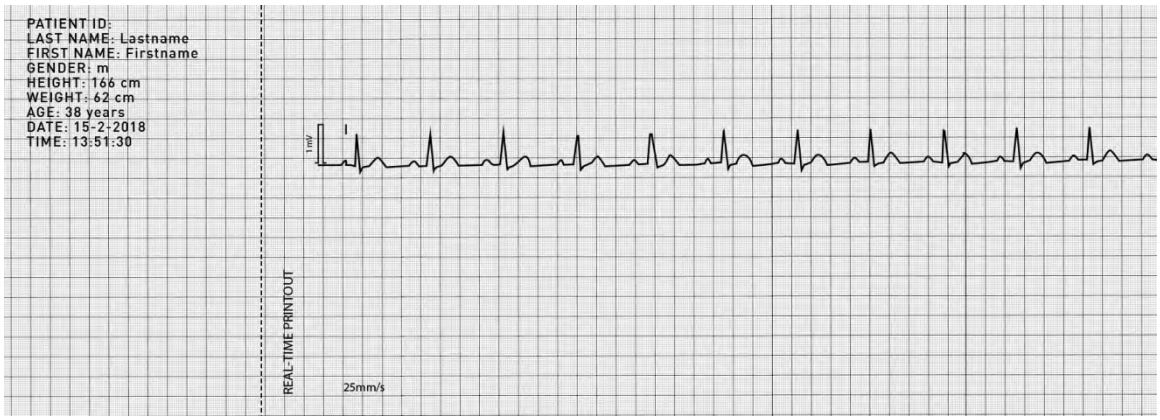
The Real Time printout can be obtained for 3,5 and 12-lead ECG monitoring.

NOTE:

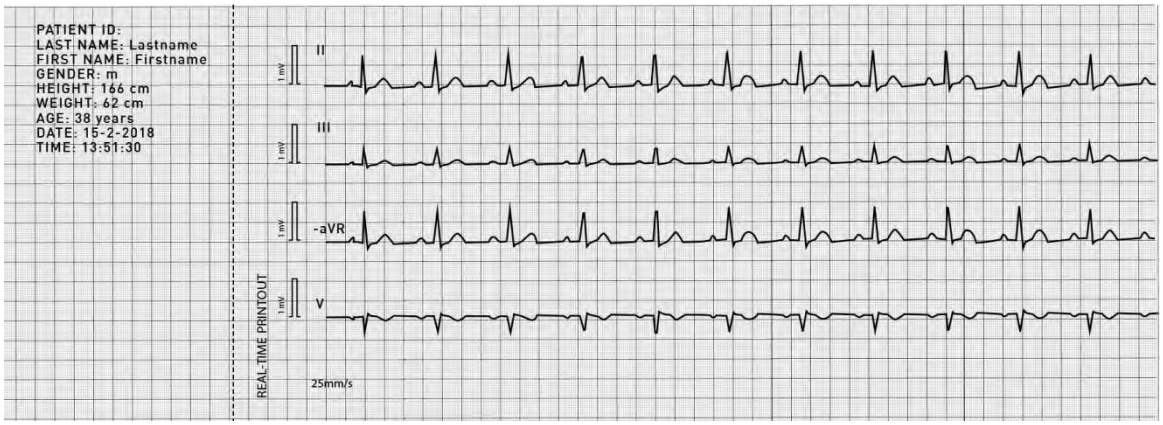
For 3-lead, only the curve for I or II is printed.

In 5-lead and 12-lead modes, only the curves for leads II, III, aVR and V4 are printed.

3-lead



5-lead and 12-lead

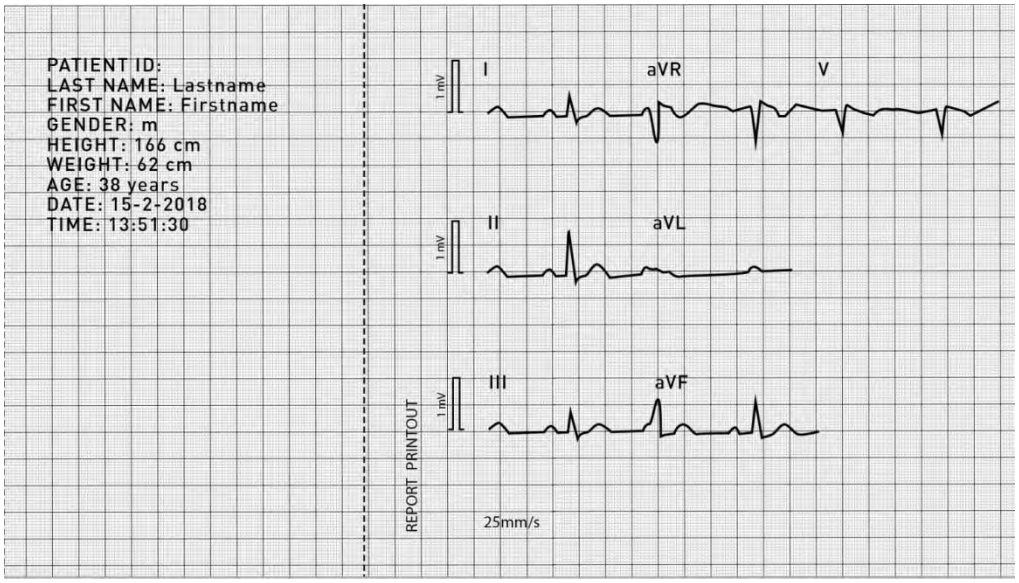


Report

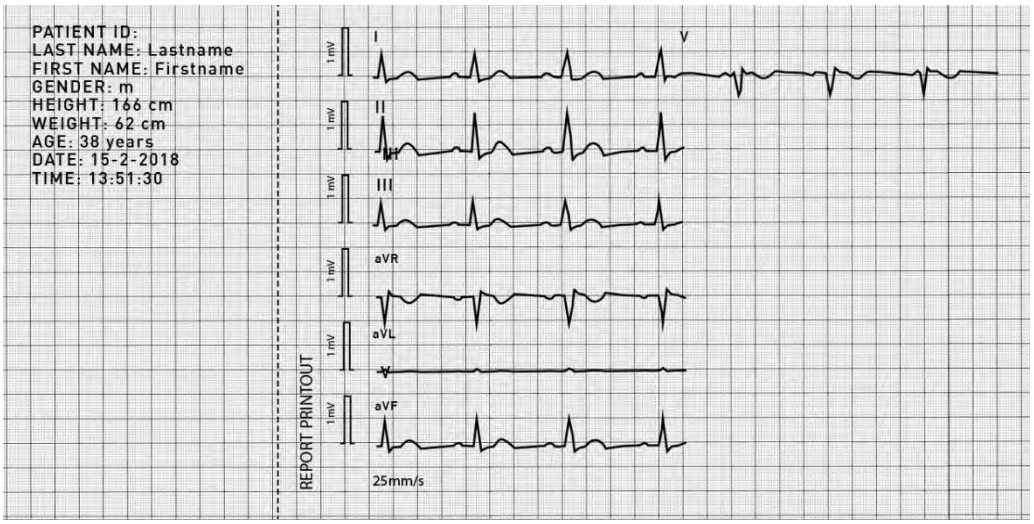
The ECG Report can be obtained and printed in two presentations (Standard and Cabrera), and two formats for the ECG leads (4x3 or 6x2).

Report printouts can be obtained with 5-lead and 12-lead modes.

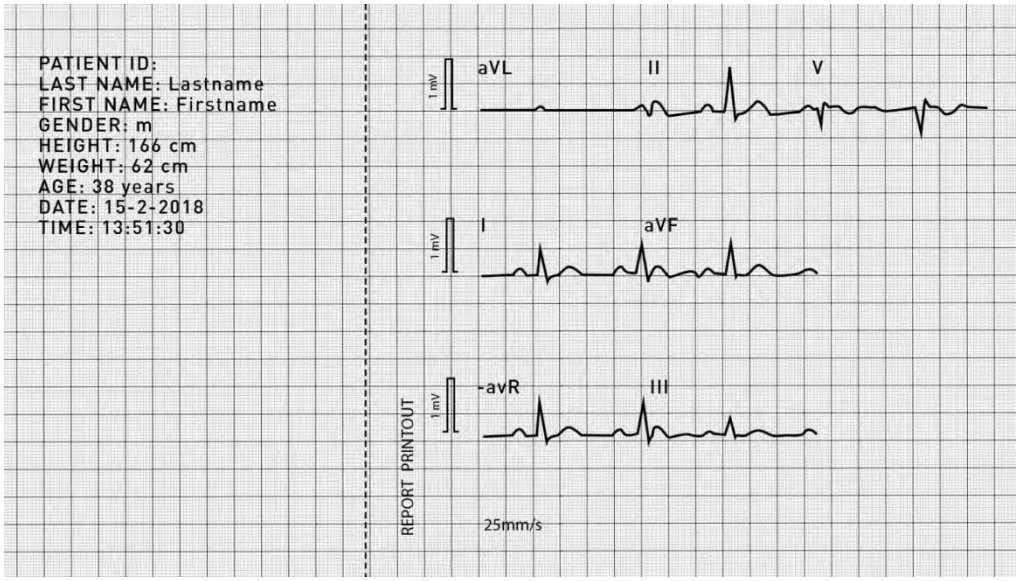
Standard, 4 x 3 (5-lead)



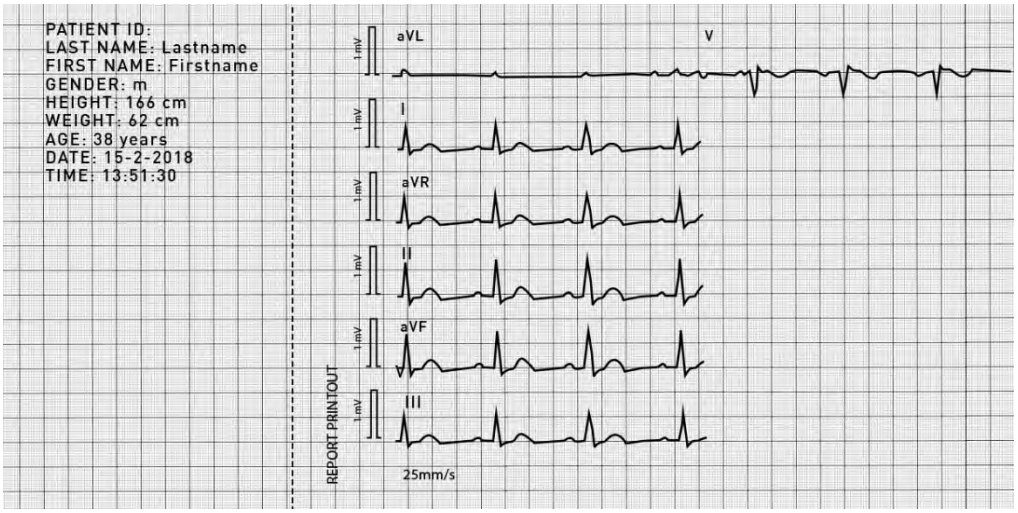
Standard, 6 x 2 (5-lead)



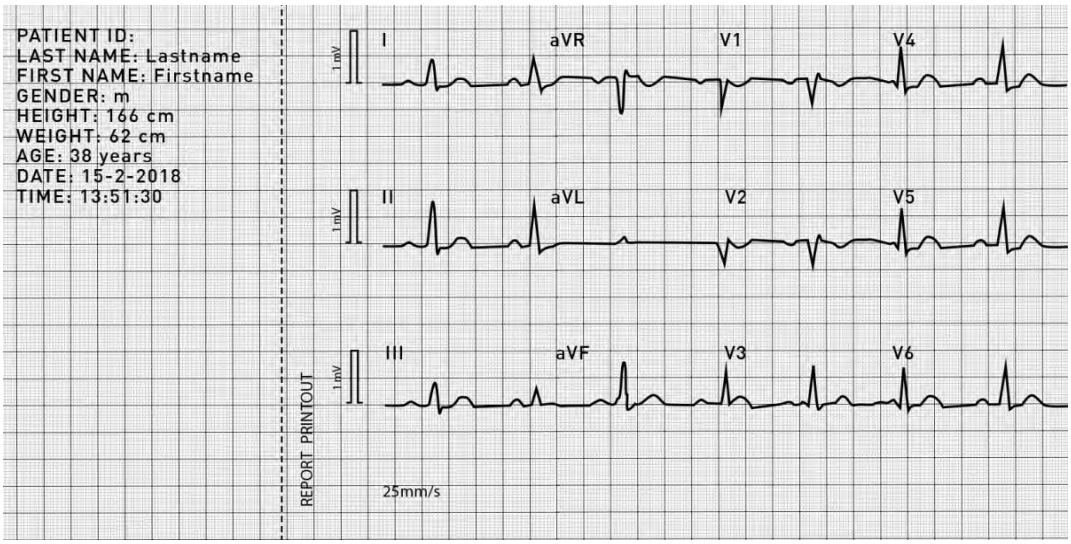
Cabrera, 4 x 3 (5-lead)



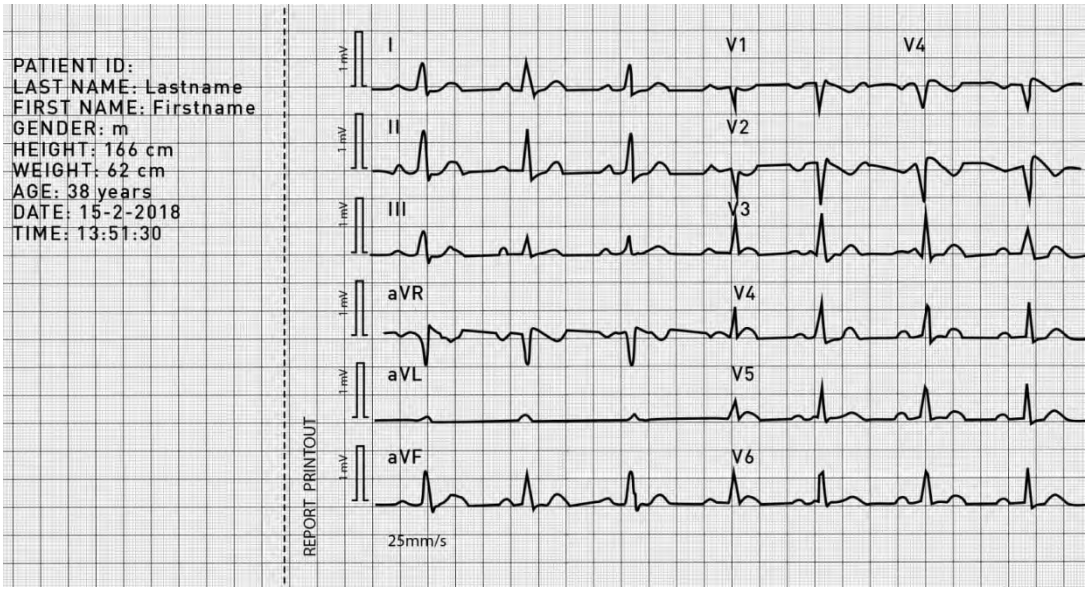
Cabrera, 6 x 2 (5-lead)



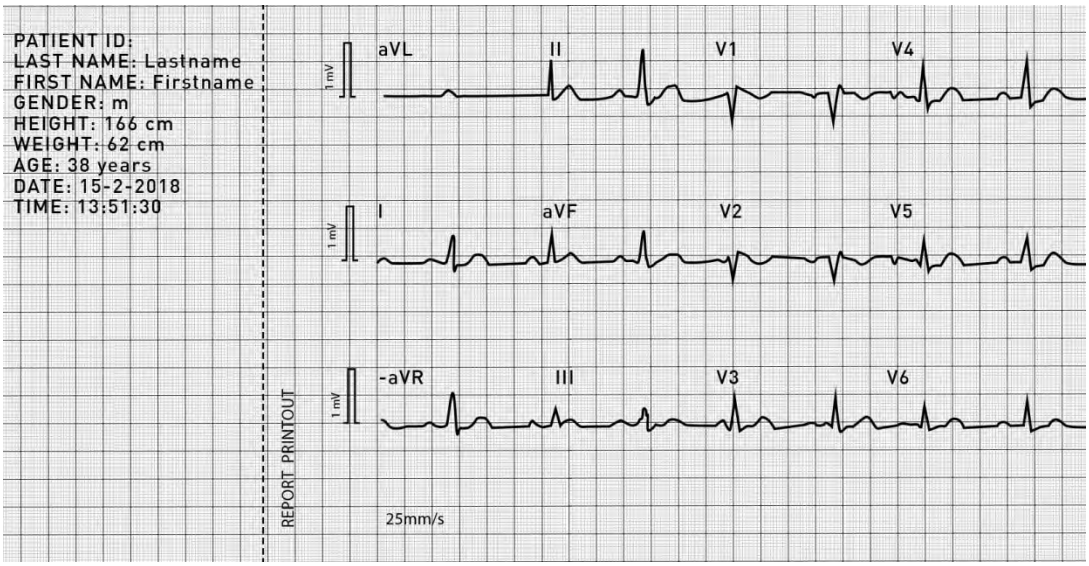
Standard, 4 x 3 (12-lead)



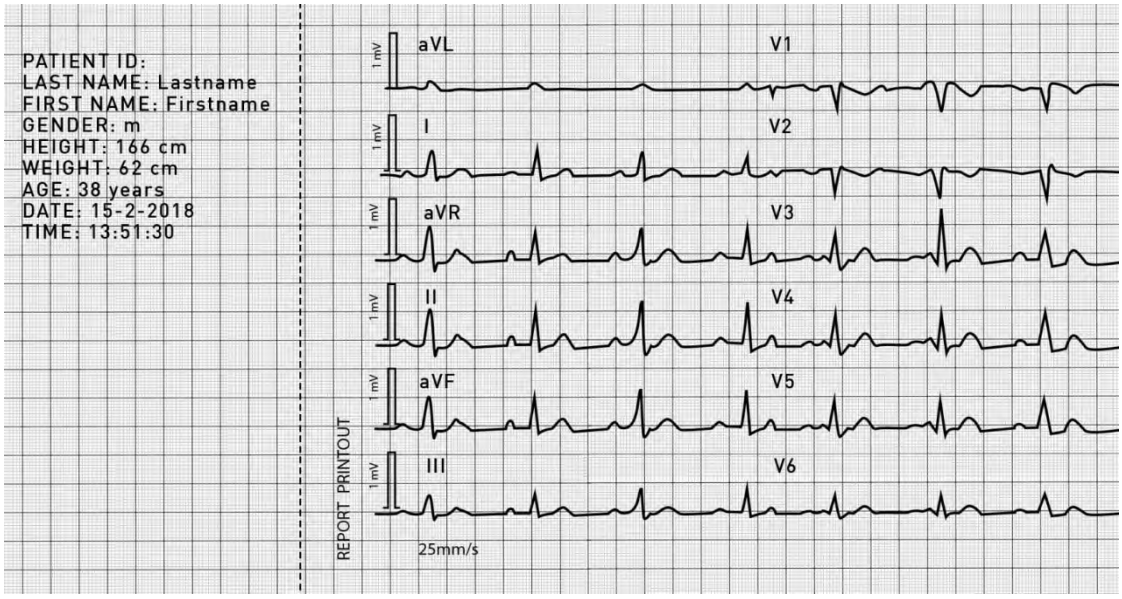
Standard, 6 x 2 (12-lead)



Cabrera, 4 x 3 (12-lead)



Cabrera, 6 x 2 (12-lead)



Hannover ECG System ® (HES)

For each analysis a short report and, on a request, and an extended report with a detailed measurement can be provided.

For pediatric ECGs, the HES® algorithm provides diagnostic indications based on well-known diagnostic tables for pediatric ECGs for a number of ECG parameters. The diagnostic tables are based on age dependent confidence intervals (2% / 98% and 5% and 95%) which were generated from normal pediatric ECGs. There is a distinction between 12 different age classes:

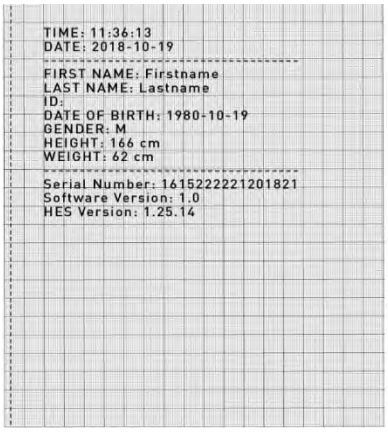
- 0-1 days
- 2-3 days
- 4-7 days
- 8-30 days
- 1-3 months
- 4-6 months
- 7-12 months
- 1-3 years
- 4-5 years
- 6-8 years
- 9-12 years
- 13-16 years

The report is available in 2 configurations:

- Standard: Comprises in 6 pages the following information.
- Basic: Comprises in 5 pages the following information.

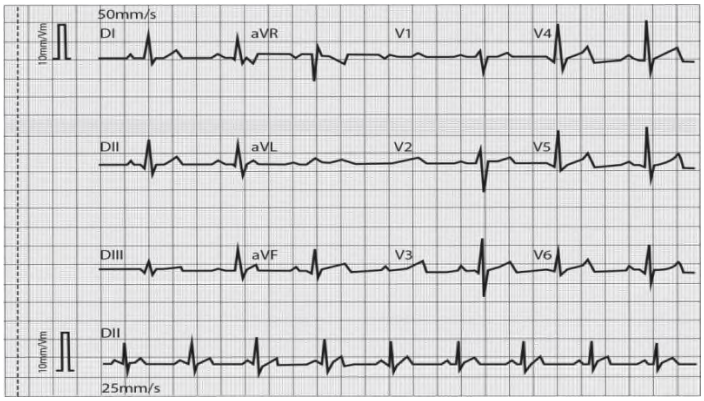
Page 1. Patient Preamble (Basic, Standard)

The report of demographic data, as example the patient ID, ECG number, date of birth, age, recording date and time, and anthropometrical parameters.



Page 2. HES representative curve (Standard)

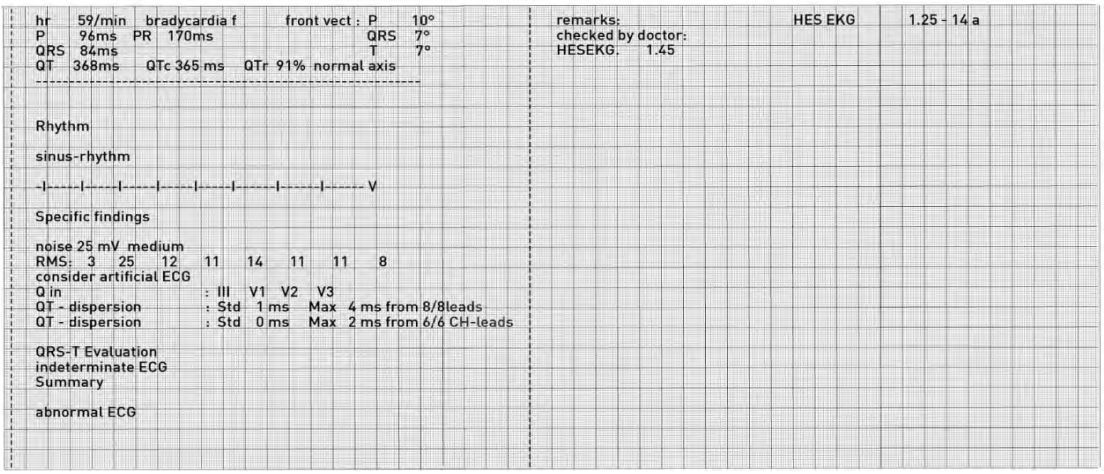
The visualization of the ECG curves to be used for analysis, as well as a 10-seconds II waveform record.



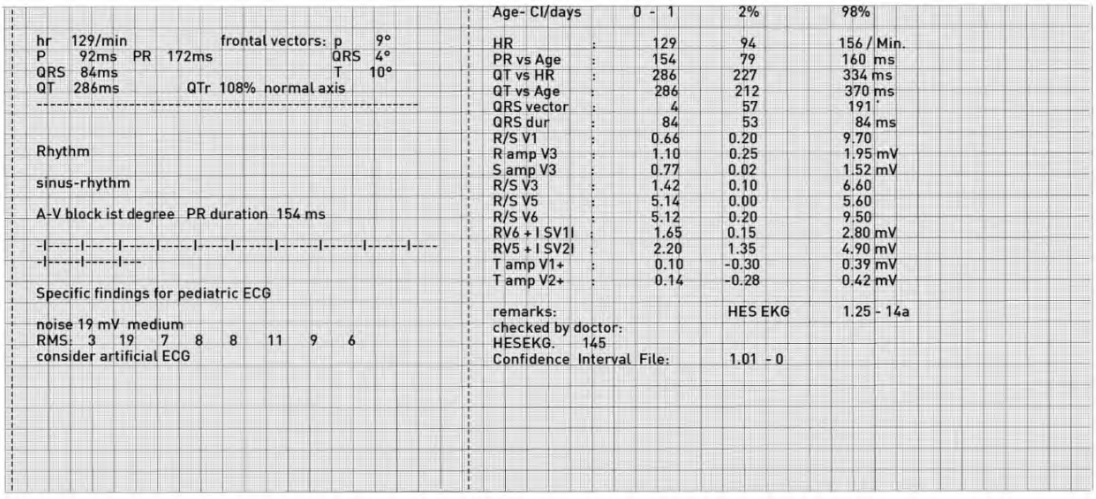
An over reading physician should never confirm a report without having seen and checked the Representative Cycle with its wave recognition points.

Pages 3 and 4. HES Analysis Report – Rhythm Analysis and Interpretation (Basic, Standard)

Adult Patients



Pediatric and Neonatal Patients



hr 129/min frontal vectors: p 9°
P 92ms PR 172ms QRS 4°
QRS 84ms T 10°
QT 286ms QTr 108% normal axis

Rhythm

sinus-rhythm

A-V block ist degree PR duration 154 ms

Specific findings for pediatric ECG

noise 19 mV medium
RMS: 3 19 7 8 8 11 9 6
consider artificial ECG

Age- CI/days	0 - 1	2%	98%	
HR	129	94	156 / Min.	
PR vs Age	154	79	160	ms
QT vs HR	286	227	334	ms
QT vs Age	286	212	370	ms
QRS vector	4	57	191	°
QRS dur	84	53	84	ms
R/S V1	0.66	0.20	9.70	
R amp V3	1.10	0.25	1.95	mV
S amp V3	0.77	0.02	1.52	mV
R/S V3	1.42	0.10	6.60	
R/S V5	5.14	0.00	5.60	
R/S V6	5.12	0.20	9.50	
RV6 + I SV1I	1.65	0.15	2.80	mV
RV5 + I SV2I	2.20	1.35	4.90	mV
T amp V1+	0.10	-0.30	0.39	mV
T amp V2+	0.14	-0.28	0.42	mV

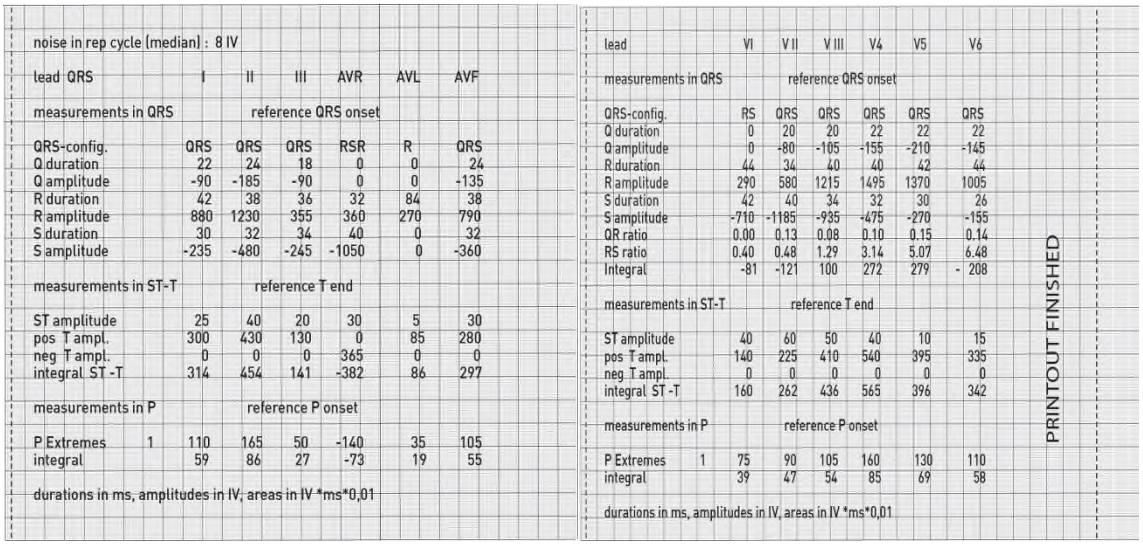
remarks: HES EKG 1.25 - 14a
checked by doctor:
HESEKG. 145
Confidence Interval File: 1.01 - 0

Field	Description
Heart Rate	Beats per minute. If above 100 beats per minute, a specific hint on tachycardia is given.
Characteristic global interval measurements	P-duration, PR-interval, QRS-duration, QT-interval including the heart rate
Intervals	Given in the same section as heart rate since they depend on the heart rate.
Magnitude of frontal vectors	For P-wave, QRS-complex and T-wave. For these vectors also the axis angle within the Cabrera-Circle is given. The QRS axis is additionally "classified" into normal or abnormal
Rhythm statement	Includes classification as sinus rhythm, sinus arrhythmia, absolute arrhythmia, atrial fibrillation, ventricular premature beats, AV block, etc.
Specific findings	Contain figures on noise levels found in the raw data. These figures are qualified as small, medium or high: • Hints with regard to specific abnormalities within the QRS complex, for example, presence of Q waves, reduced R amplitudes, broad S waves, slow QRS-onset or delta waves, ST depression or elevation. • Hints with regard to repolarization abnormalities with a specific classification into endocardial and epicardial type and a grading. • Hints to the "diagnostic path", i.e. the tests which have been analyzed specifically for this ECG.
Specific findings for pediatric ECG	Provides the measured parameter for the ECG, the lower and upper bound for "normal" based on the age dependent confidence intervals: • Heart Rate (HR) • QRS frontal vector • PQ-Interval • QRS duration • QT duration • P amplitude in II • Q amplitudes in III, AVF, V5 und V6 • R amplitudes inAVR, V3r, V1, V2, V4, V5 und V6 • S amplitudes in V3r, V1, V2, V4, V5 und V6 • T amplitudes in V3r, V1, V2, V5 und V6 • R/S amplitudes ratio in V3r, V1, V5 und V6 • R+S amplitudes in V2 und V4 • R amplitude in V5 + S amplitude in V2 • R amplitude in V6 + S amplitude in V1 • VAT (Ventricular Activation Time) in V5 All values which are not in the age dependent confidence interval are marked with a "*". If a value is missing, e.g. if a S-peak is not present, the comparison is omitted.

Field	Description
QRS-T interpretation	Whether the ECG is "Normal" or whether this ECG has been allocated to the group of infarctions or hypertrophies or bundle branch blocks. The extent of these specific findings may vary from ECG to ECG. Some ECGs may exhibit a very "simple" morphology while others may show various deviations in the morphology from normal ECGs.
Remarks / Approved by Doctor	Any user of a computer ECG analysis report should be aware of the fact that the computer printout becomes a medical document only if it has been over-read by a competent physician.

Pages 5 and 6. HES Analysis Report – Numerical Measurements (Basic, Standard)

These pages provide an extensive description of the numerical measurements for waves, intervals and segments in correlation to every lead, as well as its corresponding references for onset and end.



noise in rep cycle (median) : 8 IV

lead QRS	I	II	III	AVR	AVL	AVF
measurements in QRS	reference QRS onset					
QRS-config.	QRS	QRS	QRS	RSR	R	QRS
Q duration	22	24	18	0	0	24
Q amplitude	-90	-185	-90	0	0	-135
R duration	42	38	36	32	84	38
R amplitude	880	1230	355	360	270	790
S duration	30	32	34	40	0	32
S amplitude	-235	-480	-245	-1050	0	-360
measurements in ST-T	reference T end					
ST amplitude	25	40	20	30	5	30
pos T ampl.	300	430	130	0	85	280
neg T ampl.	0	0	0	365	0	0
integral ST-T	314	454	141	-382	86	297
measurements in P	reference P onset					
P Extremes 1	110	165	50	-140	35	105
integral	59	86	27	-73	19	55

durations in ms, amplitudes in IV, areas in IV *ms*0,01

lead	VI	V II	V III	V4	V5	V6
measurements in QRS	reference QRS onset					
QRS-config.	RS	QRS	QRS	QRS	QRS	QRS
Q duration	0	20	20	22	22	22
Q amplitude	0	-80	-105	-155	-210	-145
R duration	44	34	40	40	42	44
R amplitude	290	580	1215	1495	1370	1005
S duration	42	40	34	32	30	26
S amplitude	-710	-1185	-935	-475	-270	-155
QR ratio	0.00	0.13	0.08	0.10	0.15	0.14
RS ratio	0.40	0.48	1.29	3.14	5.07	6.48
Integral	-81	-121	100	272	279	- 208
measurements in ST-T	reference T end					
ST amplitude	40	60	50	40	10	15
pos T ampl.	140	225	410	540	395	335
neg T ampl.	0	0	0	0	0	0
integral ST-T	160	262	436	565	396	342
measurements in P	reference P onset					
P Extremes 1	75	90	105	160	130	110
integral	39	47	54	85	69	58

durations in ms, amplitudes in IV, areas in IV *ms*0,01

PRINTOUT FINISHED

A complete list of Text Printouts and Diagnostic Statements from HES can be found in the Appendix B.

6.5.3.2 Arrhythmia Monitoring

The arrhythmia monitoring provides additional information on the patient condition monitored by the ECG. This includes detection and alarming of lethal arrhythmias (Asystole, Ventricular Fibrillation and Ventricular Tachycardia) and non-lethal arrhythmias, including ectopic beats.

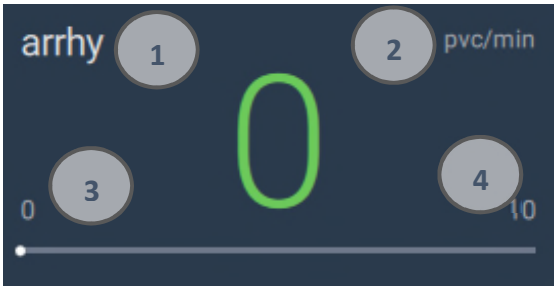
NOTE:

Arrhythmia analysis is intended for adult and pediatric patients only.

The arrhythmia detection has not been validated for neonatal patients.

Arrhythmia numeric parameter. Premature Ventricular Contractions (PVC)

The monitor displays the number of premature ventricular contractions occurring within a minute. When the number of measured PVC in one minute exceeds set counter limit (see arrhythmia settings), an alarm is generated.



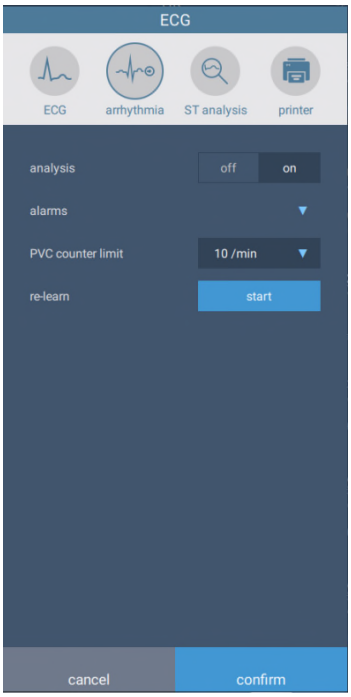
1. Parameter name
2. Parameter units of measure
3. PVC per minute digit value
4. PVC counter limit

Arrhythmia settings

You can configure what arrhythmias are detected in the arrhythmia settings menu.

To display the arrhythmia settings menu

Tap on the arrhythmia button in the Monitor function bar. The arrhythmia menu will be visible.



Field	Description	Value Range	Default
Arrhythmia analysis	Activates/deactivates the alarming of arrhythmia conditions. When arrhythmia analysis is Off, the Asystole, V-Fib and V-Tach arrhythmias are detected and alarmed.	On, Off	On
Arrhythmia alarms	You can activate/deactivate the alarming of alarm conditions individually	See table below	See table below
PVC counter limit	Set the limit of PVCs per minute allowed before an alarm is generated	0 to 30 PVC/min	10
Arrhythmia relearning	Tap on the button to perform a manual relearning for the arrhythmia recognition	-	-

Arrhythmia	Patient type	Alarm priority	Default
Asystole	All	High	On
V-Fib	Non-paced	High	On
V-Tach	Non-paced	High	On
Run PVCs	Non-paced	Medium	Off
Couplet	Non-paced	Medium	Off
Bigeminy	Non-paced	Medium	Off
Trigeminy	Non-paced	Medium	Off
R on T	Non-paced	Medium	Off
VPB	Non-paced	Medium	Off
Tachycardia	All	Medium	Off
Bradycardia	All	Medium	Off
Missed beats	Non-paced	Medium	Off
PNP	Paced	Medium	Off
PNC	Paced	Medium	Off
Noise	All	Medium	Off

Arrhythmia relearning

The Jenny ® Monitoring Module performs an automatic learning process of the arrhythmia analysis after any of the following events:

- The arrhythmia analysis is switched to 'On' in the arrhythmia settings menu.
- The lead type is changed in the ECG settings menu.
- After a lead disconnection, when the lead is reconnected.
- When the primary lead is changed in the ECG settings menu.

Manual relearning

You can also initiate a manual arrhythmia relearning during monitor anytime by pressing the arrhythmia relearning button in the arrhythmia settings menu:

The manual relearning is recommended after one or more of the following cases:

- You have observed clinically questionable arrhythmia alarms
- You observe significant changes in the patient ECG rhythm or ECG waveforms (changes in QRS complex, noise, etc.)
- ECG leads/electrodes have been repositioned
- More than eight hours elapsed after the last relearn

During the relearning process, an information text message 'Arrhythmia relearning' is displayed in the alarm bar.

6.5.3.3 ST segment analysis and monitoring

The Jenny ® Monitoring Module performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations or depressions. The result of the analysis can be displayed in a numeric parameter field. The ST analysis is performed for all the leads available (for the currently selected number of leads) simultaneously. In the

current software version, only the ST analysis from the primary lead has a reference template for the measurement and an alarm associated.

WARNING:

The monitor module provides ST segment variation information only. The clinical significance of the ST segment analysis results must be determined by a trained physician in order to emit a diagnostic. The operator must follow the institutional protocols for ST monitoring.

WARNING:

The ST monitoring should be switched off under the following conditions:

- If the primary lead is too noisy
- If the patient is continuosly ventricularly paced
- If the patient has left bundle branch block and/or right bundle branch block (complete blocks)
- If the patient has clinical history for chronic "scooped" ST segment caused by prolonged digitalis use
- If the patient has a confirmed diagnosis for myopericarditis

WARNING:

ST segment analysis is intended for adult and pediatric patients only. The default setting for ST monitoring in neonatal patient is set to ST analysis: Off

NOTE:

- When using Filter, the bandwidth decrease may reduce accuracy for the ST segment measurements.
- The Monitor filter and the Surgery filter can considerably modify the display of the ECG waveform.
- The ST segment displayed in the waveforms layout may look different from the ST-segment displayed in the ST reference template.

ST numeric parameter

The monitor displays the measured ST value in each lead:

1. ST label with current lead selection
2. ST measurements
3. ST lower alarm limit
4. ST upper alarm limit
5. Primary lead ST current value

The number of ST segments displayed in the ST numeric parameter depends on the number of leads selected in the ECG settings menu: 3-Lead, 5-Lead and 12-Lead. All available ECG leads are analyzed to measure deviations in the ST segment. A positive ST value indicates ST segment elevation. A negative value indicates ST segment depression.

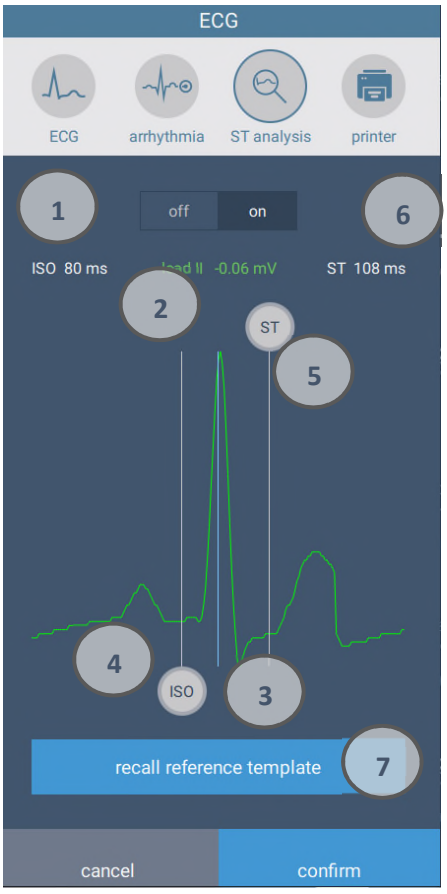
Setting the ST alarm

The ST upper and lower alarm limits are adjusted in the alarm settings menu. The set limit will announce ST alarms for each ST lead being monitored. The white dot displayed in the alarm bar, shows the current value of the ST deviation in the primary lead.

ST settings

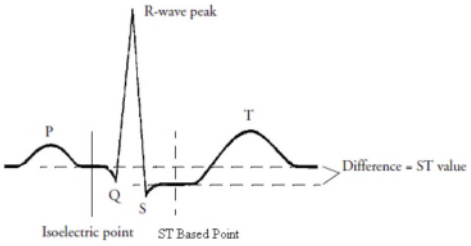
To display the ST settings menu

Tap on the ST analysis button in the Monitor function bar. The menu will be visible:



1. ISO position in milliseconds relative to the R-wave peak
2. Primary lead label with ST deviation in the template
3. Reference QRS template
4. ISO adjustment button
5. ST adjustment button
6. ST position in milliseconds relative the R-wave peak
7. Button to refresh the ECG template

Adjusting the ST point



The ST value in each lead is the vertical difference between the isoelectric point and the ST point, as displayed in the figure above. The isoelectric or ISO point, provides the ECG baseline, and the ST point is the middle point of the ST segment.

In the ST analysis menu, you can adjust the ISO and the ST points by dragging the corresponding round button over the template, aligned with the vertical lines that indicate the position of the points. You can also visualize the absolute distance in millisecond from the R-wave peak (0 milliseconds as reference) and the ST deviation for the current ISO and ST points position in the template.

ST reference template

The reference QRS template can be visualized in the ST settings menu. The QRS template is centered in the R-wave peak and has a total duration of 800 milliseconds. You can adjust the ISO point up to 400 milliseconds. Before the R-wave peak and the ST point up to 400 milliseconds after. There is a single reference template obtained from the primary lead. The template is refreshed with a new wave every 10 seconds or by request pressing the *'recall reference template'* button.

You should adjust the ISO and ST measurement points when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly.

When the ISO adjustment button is moved, the new ST values will be seen immediately after releasing the buttons. Once the ISO adjustment changes, the former ST values will be automatically replaced.

6.5.3.4 Pulse-Oximetry (SpO_2 and Pulse Rate)

The patient's oxygen saturation, perfusion index and pulse rate are monitored by the medical practitioner for any abnormal value or trends.

WARNING:

If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse-co oximeter for proper functioning.

CAUTION:

If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

Oxygen Saturation and Perfusion Index numeric parameters

1. Parameter labels: Oxygen Saturation (SpO_2) and Perfusion Index (PI)
2. Units of measure (for each parameter)
3. Parameters digit value
4. SpO_2 lower alarm limit
5. SpO_2 upper alarm limit
6. Signal strength indicator

Signal IQ (SIQ) interpretation

Number of bars	1	2	3	4	5
Signal strength	Weak	Low	Average	Good	Optimal

CAUTION:

If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

CAUTION:

Change the application site or replace the sensor and/or patient cable when a “Replace sensor” and/or “Replace patient cable”, or a persistent poor signal quality message (such as “Low SIQ”) is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

The SpO_2 numeric displayed in the monitor is the average of the data collected within a specific time (this time is configurable in the SpO_2 settings menu).

The user-selectable averaging feature allows the clinician to select the desired level of visibility to subtle variations in the measured value. Depending on the patient acuity and area of care, shorter averaging times are sometimes preferred (sleep testing) over longer averaging times (telemetry & neonates) and vice-versa. 8-second averaging is generally considered the most common averaging interval and recommended for most patients since it is short enough to provide visibility to subtle desaturations while also being long enough to minimize major changes in SpO2 due to quick, transitory desaturations.

Although averaging times greater than 10 seconds are more likely to reduce visibility to rapid, brief desaturations, this may be desirable in care areas where brief desaturations that do not require clinician intervention occur more often (i.e., NICU). It is also recommended that this be enabled as a “sticky” configuration so as to hold the setting after power cycles

The Perfusion Index is a value that indicates arterial pulse signal strength as the percentage of pulsatile signal to non pulsatile signal. The perfusion index assists clinicians in determining optimal placement of the SpO_2 sensor. This parameter is also useful as a troubleshooting tool by helping a clinician rule out whether a questionable value may be due to low perfusion and/or a low signal to noise condition.

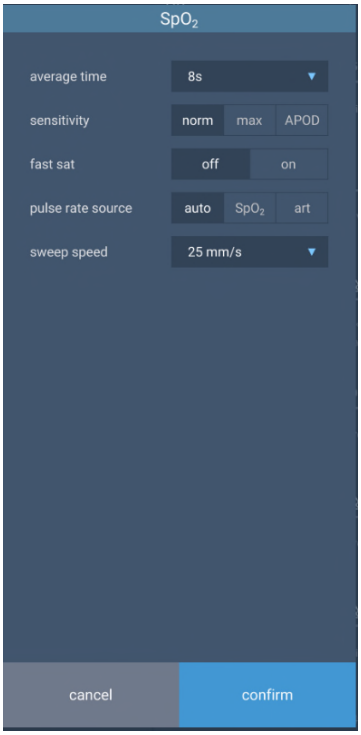
Plethysmography waveform

1. Parameter label
2. Erase cursor
3. Oxygen saturation waveform sweep speed

NOTE:

The pleth waveform is normalized. The amplitude of the pleth curve is independent from the pulse amplitude. It cannot be changed and the maximum amplitude is always set to 100 % saturation.

SpO_2 settings



Field	Description	Value Range	Default
Average time	Allows the clinician to select the desired level of visibility to subtle variations in the measured value.	2-4,4-6, 8, 10, 12 , 14 , 16 secs	8 s
Sensitivity mode	Allows the clinician to adapt the SpO_2 measurement sensitivity to the patient's level of SpO_2 signal strength and quality at the measurement site.	Normal, Adaptive Probe Off Sensor (APOD), Maximum (MAX)	Normal
FastSat	Enables rapid response to, and display of, fast changes in SpO_2 by giving priority to the most recent data.	On, Off	Off
Pulse rate source	Allows the clinician to select the source for measurement of the pulse rate	Auto, SpO2, Arterial (art)	Art
Sweep speed	Sets the speed of the erase cursor and the horizontal resolution of the pleth curve.	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	25 mm/s

CAUTION:

To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the device is used.

The Sensitivity mode can be adapted accordingly to the clinical setting:

- **Normal:** Is the recommended for patients who are experiencing some compromise on blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as the Intensive Care Unit (ICU).
- **Adaptive Probe Off Sensor (APOD):** Is the recommended sensitivity mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.
- **Maximum:** Is recommended for use on patients with weak signals (e.g., high ambient noise and/or patients with very low perfusion) and for use during procedures or when clinician and patient contact is continuous such as in higher acuity settings.

NOTE:

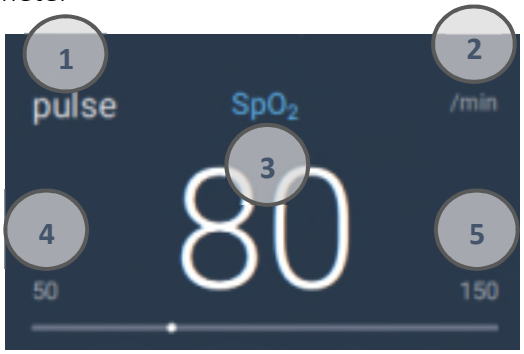
When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration and excessive air movement.

NOTE:

The FastSat™ aids the clinician in clinical settings requiring fast response time, such as those seen with induction, sleep studies and resuscitation.

As a result of the increased fidelity in this mode, FastSat™ is not recommended for routine use as there might be an increase of the frequency of alarms caused by rapid, transitory SpO_2 changes.

Pulse rate numeric parameter



1. Parameter label
2. Units of measure
3. Parameter digit value
4. Pulse rate lower alarm limit
5. Pulse rate upper alarm limit

Pulse CO-Oximetry - Masimo ® Rainbow SET Parameters

The Jenny ® Monitoring Module can display (when the appropriate sensors are connected to the monitor and to the patient, and optional rainbow parameters are enabled) the following optical parameters:

Field	Description	Value Range	Default
PVI Pleth Variability Index	Measure of peripheral perfusion changes secondary to respiration or the PI amplitude over a respiration. Can be closely related to intrathoracic pressure changes.	0 to 100%	-
SpMet Methaemoglobin	Percentage of methaemoglobin within the blood.	0,1 to 99%	-
SpCO Carboxyhaemoglobin	Percentage of carboxyhaemoglobin within the blood.	1 to 99%	-
SpHb Total Haemoglobin	Total haemoglobin concentration in arterial blood.	1 to 24.5 g/dL	-
SpOC Oxygen Content	Non-invasive measurement of the total oxygen content present in the blood. Uses the combination of haemoglobin and oxygen saturation to provide one index that represents the level of oxygen available to be delivered to the tissues.	1 to 34 ml O_2/ dL blood	-
ORI Oxygen Reserve Index	Provides the clinician with an index defining the amount of reserve oxygen in the arterial blood.	0.00 to 1.00	-

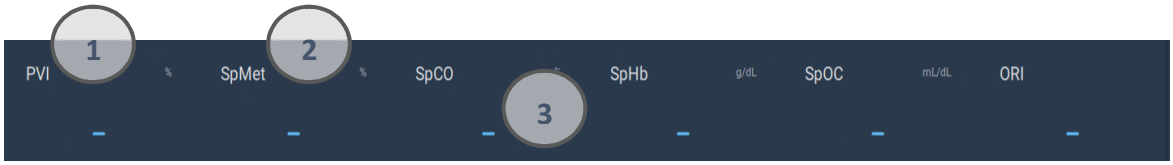
CAUTION:

Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any result exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory devices prior to clinical decision making to completely understand the patient's condition.

Masimo ® Rainbow SET numeric parameters (Optional)

The GUI will display the Masimo ® Rainbow SET optical parameters as a bar in the inferior section of the SpO_2 layout.

If the Rainbow parameter measurement is invalid, the sign '-' is displayed in the place of the corresponding digit value.



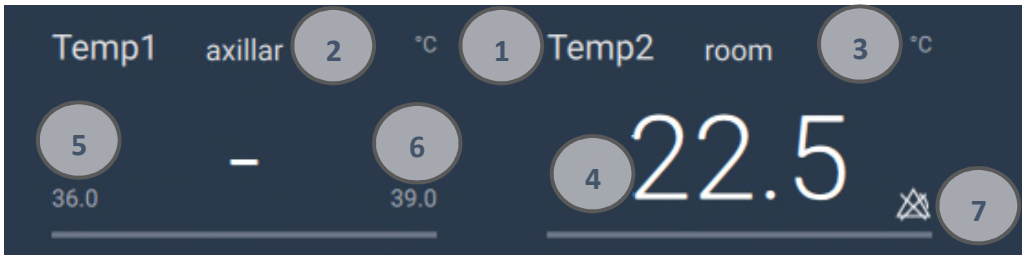
1. Parameter label
2. Units of measure
3. Parameter digit value

If the applied sensor is not appropriate or the license is not acquired, the Rainbow parameter field will appear in grey, indicating that is invalid.

6.5.3.5 Temperature

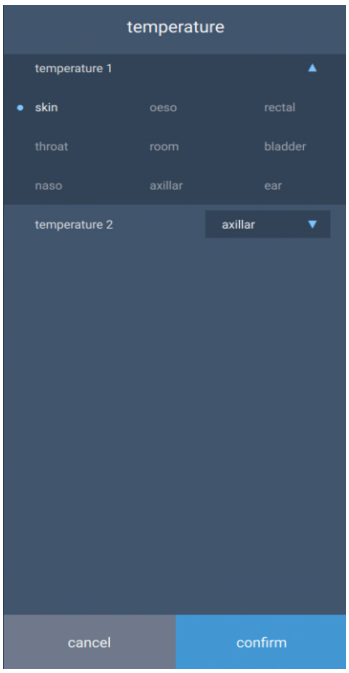
The Jenny Monitoring Module can measure up to *two* temperature numeric parameters simultaneously.

Temperature numeric parameter



1. Temperature field: 1 , 2
2. Parameter label
3. Units of measure
4. Parameter digit value
5. Temperature lower alarm limit
6. Temperature upper alarm limit
7. Alarm off

Temperature settings



Field	Description	Value Range	Default
Temperature 1	Select the site of application for temperature probe.	Skin, Oesophagus, Rectal, Throat, Ambient, Bladder, Nasal, Axillar, Ear	Ambient
Temperature 2	Select the site of application for temperature probe.	Skin, Oesophagus, Rectal, Throat, Ambient, Bladder, Nasal, Axillar, Ear	Ambient

CAUTION:

The self-test of the temperature measurement is performed automatically termly during the monitoring. The test procedure lasts about 1 sec and does not affect the normal measurement of the Temp monitoring.

The Temp sensors and cables should be handled with care. When not in use, the sensor and the cable should be rounded into loose ring shape.

If the ambient temperature is over 15-35 ℃ , the temperature measurement may be inaccurate.

NOTE:

If Temperature to be measured beyond the measurement range for the probe, over measuring range alarm will be displayed on the screen. Check if probe is on the corresponding patient body site, or change it to other site on the patient.

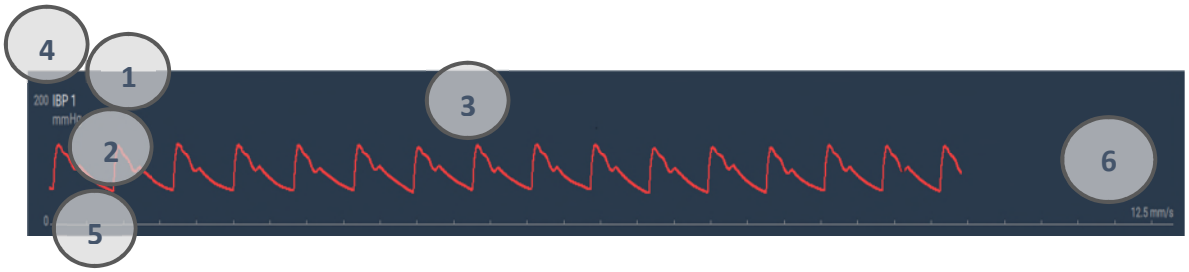
If “Temperature self-check error” is displayed on the screen, it is possibly that something is wrong with the temperature module, the operator should stop using the Temperature function and contact the manufacturer.

The recommended minimum measuring time for temperature is 15 minutes.

6.5.3.6 Invasive blood pressure (IBP)

The *Jenny* monitoring module can measure up to *four* invasive blood pressure channels simultaneously. The blood pressure measurement is suitable for the determination of the invasive blood pressure (e.g. of the arterial, venous or pulmonary and intracranial pressures) within an absolute range of -50 mmHg to 400 mmHg. For each channel, Systolic, Diastolic and Mean pressure are displayed as digits in the corresponding numeric parameter.

IBP Waveforms

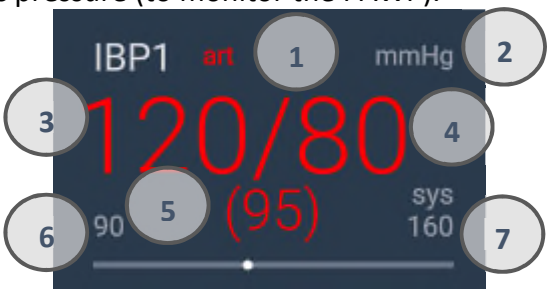


1. IBP label
2. Pressure units
3. IBP waveform
4. Pressure upper range value
5. Pressure lower range value
6. IBP waveform sweep speed

IBP numeric parameter

There are different types of IBP numeric parameters, depending on the measurement channel selected in the IBP settings menu:

- **Pulsatile pressures** (IBP1/2/3/4, Art/RVP/LVP): Format **SYS/DIA (mean)**. The alarm source for these pressures is the systolic pressure. For the Pulmonary artery (PA), the alarm source is the diastolic pressure (to monitor the PAWP).



- **Non-Pulsatile pressures** (CVP/RAP/LAP/ICP): Format **MEAN (sys/dia)**. The alarm source for these pressures is the mean pressure.

1. IBP label
2. Pressure units
3. Systolic pressure digit value
4. Diastolic pressure digit value
5. Mean pressure digit value
6. Alarm source upper alarm
7. Alarm source lower alarm

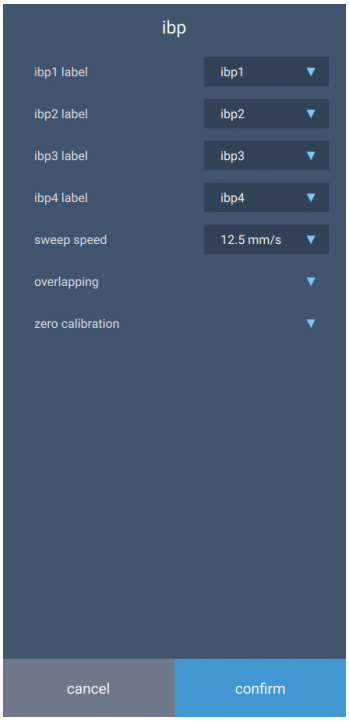
- The IBP numeric displays the invasive blood pressure with a resolution of 1 mmHg.
- If the IBP measurement is invalid, '-' is displayed in the place of the corresponding digit value.

IBP settings

You can configure the IBP channels in the IBP settings menu

To display the IBP settings menu

Tap on the IBP settings button in the Monitor function bar. The IBP settings menu will be visible.



Field	Description	Value Range	Default
IPB_i label *i= 1,2,3,4*	It configures the IBP label for each channel with the description of the vessel where the catheter is inserted. The label uniquely identifies the pressure channel and the GUI will adapt the waveform scale and the alarm limits to the label selected	IBP_i, ART, PA. CVP, RAP, LAP, RVP, LVP ICP.	IPB_i *i= 1,2,3,4*
Sweep speed	Sets the speed of the erase cursor and the horizontal resolution of all IBP waveforms	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	12.5 mm/s

Field	Description	Value Range	Default
Overlapping	It allows the overlapping of two IBP waveforms in the same diagram. It is possible to overlap IBP2 with IBP1 on the IBP1 diagram and/or IBP4 with IBP3 on the IBP3 diagram	IBP1-IBP2, IBP3-IBP4	-
Zero calibration	Opens the zero-calibration dialog for the four channels	See 'Zero calibration'	-

NOTE:

It is recommended to calibrate the IBP every 4 hours.

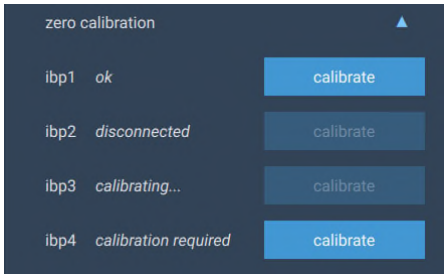
Zero calibration

To avoid inaccuracies in pressure readings, the transducer requires a valid zero value. The transducer must be zeroed per the hospital policies, at least once per day and after any of the following events:

- Before starting any IBP measurements.
- When replacing with a new transducer or tubing.
- When the transducer has been measuring continuously for a period of 4 hours
- When reconnecting the IBP cable to the monitor module after a disconnection.
- You suspect that the monitor pressure readings are not correct.
- When the monitor module is restarted.

To zero the pressure transducer

1. Allow a 5 minutes' warm-up time before calibration of the system.
2. Turn off the stopcock (3-way stopcock) to the patient.
3. Open transducer port to atmosphere.
4. Open the 'zero calibration' function on the IBP settings menu. The transducer status of each IBP lines is displayed. If there is a transducer attached to a line, the button 'calibrate' is available. The status *'calibration required'* informs that the transducer connect was not previously zeroed or that a previous zero calibration was not performed successfully.



5. Press the button for the transducer(s) you want to calibrate. The transducer status information displays *'calibrating…'*
6. After approx. 3 seconds, the zeroing procedure is complete. The status information switches to *'ok'.* The pressure values displayed in the corresponding IBP numeric will approximately display zeros.
7. Once the zero calibration is completed, close the stopcock to atmospheric pressure and turn on the stopcock to the patient.

CAUTION:

During zeroing, the 3-way stopcock near artery needle shall be closed and avoid connecting the artery needle to patient. Ensure that the tubing is free of air.

6.5.3.7 Non-invasive blood pressure (NIBP)

WARNING:

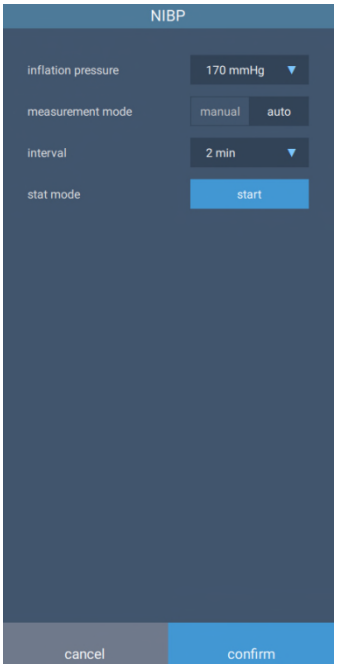
In aeromedical devices: Due to motion and vibration interference, it is recommendable to use an alternative BP measurement method (IBP) for the in-flight monitoring of patients.

The automated sphygmomanometer will automatically be put in neonatal mode when the patient category selected is Neonate.

NIBP settings

To display the NIBP settings menu

Tap on the NIBP button on the Monitor function bar. The menu will be displayed.



Field	Description	Value Range	Default
Inflation pressure	Sets the initial inflation pressure of the first NIBP measurement	**Adult** 100 to 280 mmHg **Pediatric** 100 to 240 mmHg **Neonate** 50 to 140 mmHg	**Adult** 170 mmHg **Pediatric** 130 mmHg **Neonate** 100 mmHg
Measurement mode	Selects the operation mode	Manual, Auto	Manual
Interval	Sets the interval between measurements in auto mode. It is visible only when auto mode is selected	2, 3, 4, 5,0, 15, 30, 60, 90 minutes, 2, 4, 8, 16 hours	2 min
STAT mode	Button to start the STAT mode	-	-

WARNING:

Note that in order to measure NIBP in a neonatal patient, the Neonate patient category must has been selected in the GUI before attempting to measure NIBP in neonates.

To measure NIBP in manual mode

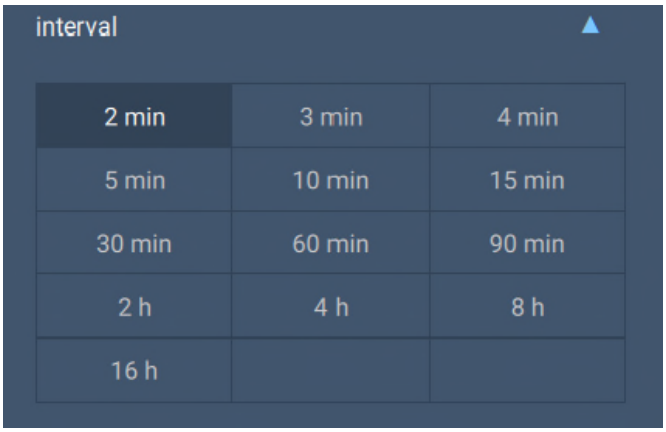
1. Set measurement mode to Manual
2. Tap on the Start/Stop NIBP button on the Monitor function bar. Tapping on the button again while a measurement is in progress will abort the measurement.

WARNING:

If a cuff is going to be positioned on a patient with the intention of performing NIBP measurements for an extended period of time, be sure to regularly check the limb for proper circulation.

To measure NIBP in auto mode

1. Set measurement mode to auto.
2. Set the interval between measurements.



3. To start the auto series of measurement, tap on the Start/Stop NIBP button on the Monitor function bar. A measurement will start immediately. After the completion of the first measurement, the monitor will perform periodical measurements repeated with the interval set in the menu

To measure NIBP in STAT mode

1. Open the NIBP menu and press the start button at the right end of the ‘stat mode’ label

2. The NIBP menu is closed and the STAT measurements start automatically. Only one measurement will be performed.

CAUTION:

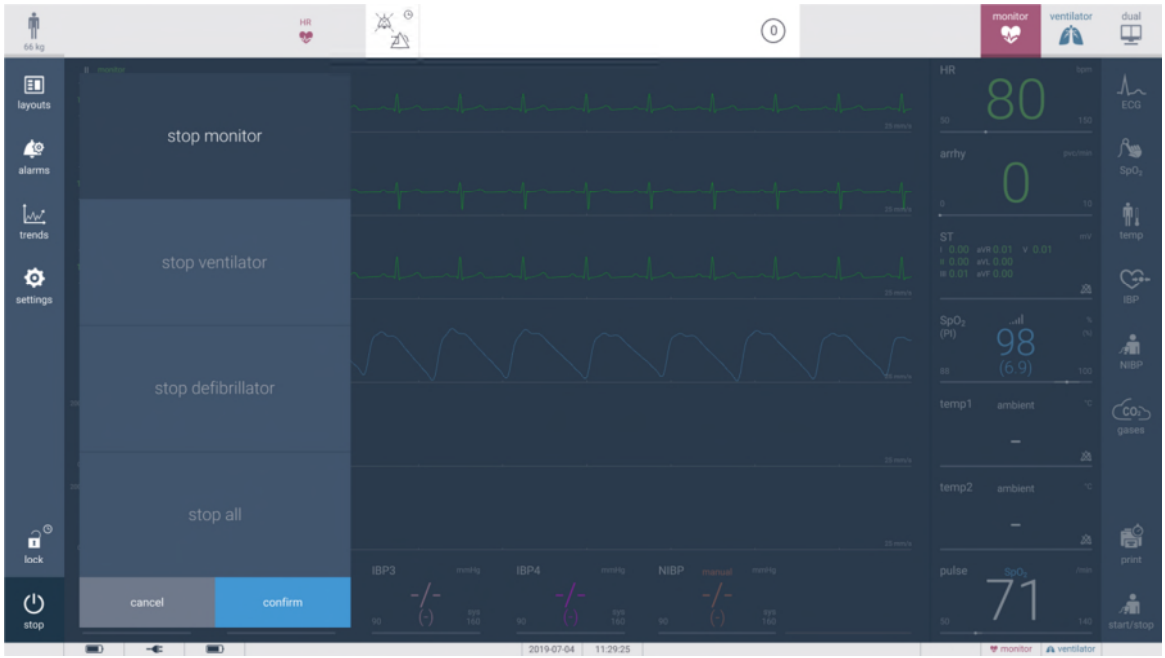
If the cuff position is higher than heart level, the BP reading will be lower, the measured result shall be added 0.75mmHg (0.1kPa) for each centimeter higher; in case the cuff position is lower than heart level, the BP reading will be higher, the measured result shall be deducted 0.75mmHg (0.1kPa) for each centimeter lower.

6.5.4 Stopping monitoring

The Monitor Module can be stopped quickly, accessing **the ON/OFF button**, located at the bottom of the left tool bar.

By pressing this button, the options for **Stop** for every module are available. The operator must press **Stop Monitor** to cease the functions of the module. The Monitoring Module operation will be stopped after confirmation.

The stopping of a module can be done without interference with the Ventilator and Defibrillator Modules.



6.6 Defibrillation

6.6.1 Starting defibrillation therapy

Defibrillation therapy must always be accessible to the user when needed. Since Jenny® is a multifunctional device, the defibrillation therapy is always at your reach with clearly marked controls independent from what other device functionalities are currently running.

The defibrillation function is available after device start-up at the Emergency area selection in the Home Screen.

It is also always available for an already admitted patient while other functionalities are active on the modules control panel switch *(Figure 4-17, item 1).*

The defibrillator module performs a short self-test every time the defibrillator module is switch on. The duration of the self-test is < 5 seconds.

The defibrillator also performs a continuous check of the necessary functions during run time (i.e. the supply voltage ranges). Any detected malfunction that could be potentially dangerous for the user or the patient will set the module is safe status and an alarm will be emitted.

When using adhesive pads or spoons, the defibrillation and cardioversion shocks are delivered either through the shock capacitive buttons, located at the front of the Docking Station; or through the button in the Apex paddle.

In case of non-shockable rhythm while charging the Defibrillator, the“Discharge” button in the GUI allows the device to be discharged, by delivering the shock into an internal resistor. The shock is not delivered to the patient.

WARNING:

- Verify that no one is in contact with monitoring cables, leads, bed rails, or any other potential current pathway prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation.
- All persons in attendance of the patient must be warned to STAND CLEAR prior to defibrillator discharge.
- Do not touch the paddles together during the shock delivery to a patient.

WARNING:

In aeromedical devices: During flight, the notification and approval from the pilot is mandatory before any shock delivery.

6.6.1.1 MANUAL / AED selection

To start emergency defibrillator with a new patient

The emergency defibrillation therapy with a non-admitted patient is available at the Emergency area of the Home Screen.

1. Tap on the patient category: ADULT, PEDIATRIC or NEONATE
2. Select AED or Manual Defibrillation by tapping on the corresponding button on the Emergency panel. The corresponding defibrillator control panel opens.
3. Follow the indications on the screen (AED) or start the therapy manually (Manual defibrillation).

NOTE:

AED is not available for NEONATE patients.

To start defibrillator with an already admitted patient

1. Tap on the 'defibrillator' button on the modules control panel switch.
2. The defibrillator control panel opens. The defibrillator module default mode is AED.
3. If necessary, to interrupt the AED and change to 'Manual defibrillation' or pacer therapy, tap on the corresponding tab on the right end of the defibrillator control panel.

6.6.1.2 AED

WARNING:

- Do not touch, move or transport the patient during ECG rhythm analysis phase. Artifacts could result into delayed or inappropiate therapy.
- It is not recommended to analyze the ECG rhythm obtained through defibrillation paddles. Moving artifacts could result into delayed innapropiate therapy.
- Use SavePads only for AED therapy when possible.
- The AED algorithm and the standard adult paddles and SavePads are intended to be used with patients older than 8 years of age and/or with weight > 25 kg.
- The Jenny® AED algorithm is validated for use in adult patients an pediatric patients (from 1 year of age). In pediatric patients from 1 to 8 years of age, whose weight is < 25 kg, pediatric paddles or SavePads mini must be used and the correct patient category must be selected, so the energy limitation for pediatric patients is activated. If no pediatric electrodes are available, then adult electrodes can be used in case of emergency, as stated in the 2015 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.

- Response to implanted cardiac pacemakers impulses from implanted pacemakers can affect or prevent correct arrhythmia detection. As a result, not all defibrillable rhythms may be detected and shock delivery may not be recommended by the device.
- For patients under 1 year of age, the Jenny® AED functionality is not to be used. Only in extremely rare cases, and if the AED is the only defibrillator available, its use should be considered.

WARNING:

To avoid a misinterpretation of the ECG rhythm analysis results that could lead to a wrong decision about the delivery of defibrillation therapy, it is strongly recommended to briefly pause the ventilator module (when in use) during the analysis phase and shock delivery in AED mode.

To prepare for defibrillation therapy in AED mode

1. Confirm that the patient is in cardiac arrest:
   - Non-responsive.
   - Not breathing.
   - Pulseless.
2. Prepare the skin of the patient as described in 5.5.4.1 (Skin preparation)
3. Apply the corresponding electrodes to the patient as described in 5.5.4.2
4. Connect electrodes cable to the defibrillation module as described in 5.5.4.3

To deliver defibrillation therapy in AED mode

1. Go to the AED screen as described in 6.6.1. If the electrodes are correctly attached to the patient and connected to the defibrillator module, the analysis phase is started automatically.
2. Follow the screen messages and audio voice prompts.

CAUTION:

If the victim has an ICD that is delivering shocks (i.e., the patient's muscles contract in a manner similar to that observed during external defibrillation), allow 30 to 60 seconds for the ICD to complete the treatment cycle before attaching an AED.

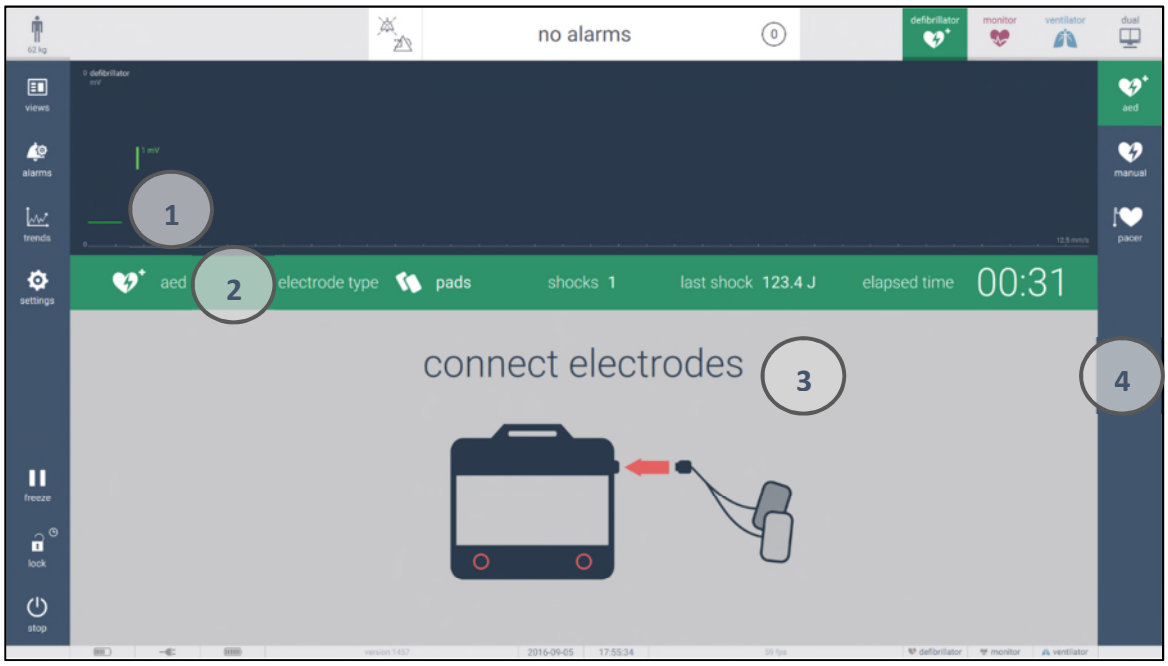
NOTE:

Jenny® AED initiates the rhythm analysis phase automatically after detecting that the electrodes are properly connected to the defibrillator module and have been attached to the patient.

The AED analysis is performed also during the charging of the capacitor, until the shock is released. The incremented shock-counter and the shock energy are displayed.

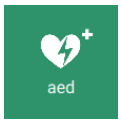
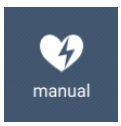
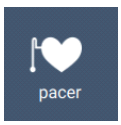
If the ECG rhythm of the patient changes from a shockable to a non-shockable rhythm, the shock will not be delivered (in the GUI: “Energy = 0 Joule” is displayed) and the capacitor will be internally discharged.

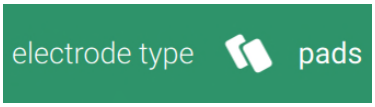
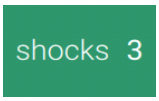
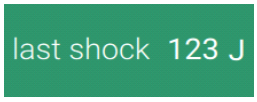
AED screen layout



1. Defibrillation electrodes ECG lead curve
2. AED Status panel
3. AED instructions panel
4. Therapy selection panel

AED controls and indicators

Location	GUI item	Description
		**AED button**– Allows you to switch to AED mode. When AED is selected, the button is highlighted in green
		**Manual defibrillation button**– Allows you to switch to manual defibrillation mode
		**Pacer button**– Allows you to switch to pacing mode

Location	GUI item	Description
		**AED indicator**– Indicates that the current defibrillator mode is AED
		**Electrode type**– Indicates that the electrode type currently connected to the defibrillation module: Paddles, pads, spoon or '-'
		**Shocks**– Indicates that the number of shock delivered during the current session (period in which the defibrillator module has been active). Includes shocks delivered in AED and Manual mode.
		**Last shock**– Indicates the actual energy delivered in the last shock.
		**Elapsed time**– Indicates the duration of the current session in the format mm:ss

AED audio and text messages

AED audio	AED Text
-	connect electrodes
"Attach the electrodes to the bare chest"	apply electrodes
"Analyzing heart rhythm. Stand clear of the patient"	analyzing... stand clear
"Shock required"	shock required
"No shock recommended"	No shock recommended
"Give 30 chest compressions now!"	perform CPR
--	charging
-	shock ready
-	deliver shock
"Shock was delivered"	shock was delivered
"Shock was not delivered"	shock was not delivered

6.6.1.3 Manual defibrillation

WARNING:

To avoid a misinterpretation of the ECG rhythm analysis results that could lead to a wrong decision about the delivery of defibrillation therapy, it is strongly recommended to briefly pause the ventilator module (when in use) during the analysis phase and shock delivery in Manual Defibrillation mode.

To prepare for defibrillation therapy in Manual Defibrillation mode

1. Confirm that the patient is in cardiac arrest (as described in previous section).

2. Prepare the skin of the patient as described in 5.5.4.1 (Skin preparation)
3. Apply the corresponding electrodes to the patient as described in 5.5.4.2
4. Connect electrodes cable to the defibrillation module as described in 5.5.4.3

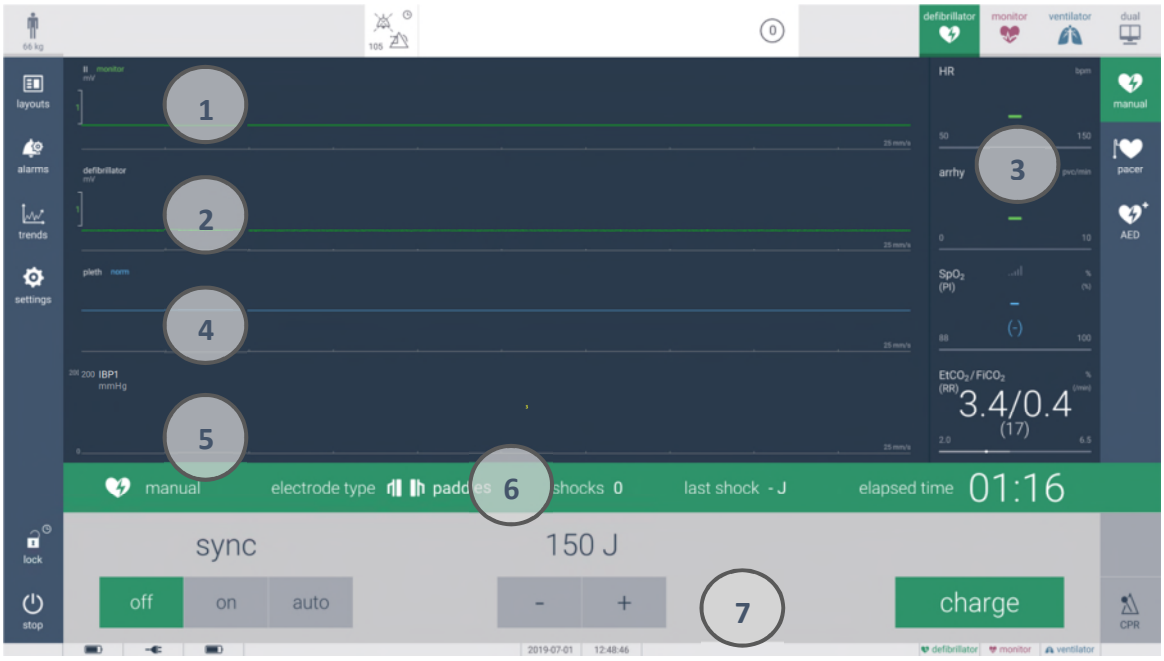
To deliver defibrillation therapy in Manual Defibrillation mode

1. Select Manual Defibrillation
2. Select the desired energy of the unsynchronized shock.
3. Press Charge. In case of using paddles, it is also possible to charge by pressing the Charge button of the *Apex* paddle.
4. Press the button of the paddles or the capacitive buttons in the Docking Station. The incremented shock-counter and the shock energy are displayed.

WARNING:

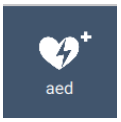
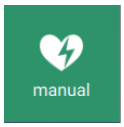
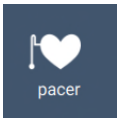
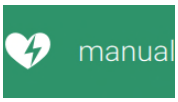
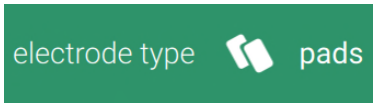
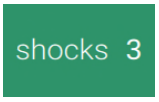
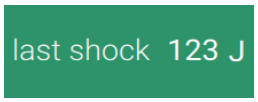
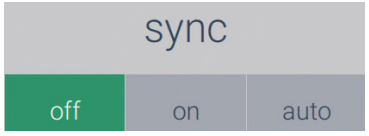
If the patient is receiving mechanical ventilation, it's advised to pause briefly the Ventilator Module to administer the shock. After the shock is delivered, mechanical ventilation can be immediately resumed.

5. After the delivery of the shock, the ECG waveform will resume monitoring and the operator must continue with the CPR procedure according to international guidelines and institutional protocols.
6. The operator can use the Metronome function, to receive audible indication for chest compressions.



1. Primary lead ECG monitor curve
2. Defibrillation electrodes ECG lead curve
3. Numeric parameters field
4. SpO_2 curve
5. IBP curve
6. Manual defibrillation Status panel
7. Manual defibrillation Control panel

Manual defibrillation controls and indicators

GUI item	Description
	**AED button**– Allows you to switch to AED mode.
	**Manual defibrillation button**– Allows you to switch to manual defibrillation mode. When manual mode is selected, the button is highlighted in green
	**Pacer button**– Allows you to switch to pacing mode
	**Manual indicator**– Indicates that the current defibrillator mode is Manual.
	**Electrode type**– Indicates that the electrode type currently connected to the defibrillation module: Paddles, pads, spoon or '-' for no connected paddles
	**Shocks**– Indicates that the number of shock delivered during the current session (period in which the defibrillator module has been active). Includes shocks delivered in AED and Manual mode.
	**Last shock**– Indicates the actual energy delivered in the previously shock.
	**Elapsed time**– Indicates the duration of the current session
	**Synchronized defibrillation switch**– Allows you to activate/deactivate normal and automatic sync modes (Cardioversion)

GUI item	Description
	**Energy selection control**– Allows you to manually select the energy for manual defibrillation therapy.
	**Charge button**– Allows you to charge the capacitor with the energy previously selected
	**Discharge button**– Allows you to discharge the capacitor
	Metronome– Provides audible indication to administer chest compressions accordingly to the current CPR requirements.

Manual defibrillation settings

Field	Description	Value Range	Default
Synchronized defibrillation	You can select if the next defibrillation shock is synchronized or not. Once the selection is made and the defibrillator is charging you cannot modify the sync function. Refer to cardioversion for further information	On, Off, Auto	Off
Energy selection	You can select the amount of energy to be delivered in the shock.	Adult:0.5 to 200 J Pediatric: 0.5 to 100 J Neonatal: 0.5 to 20 J	Adult: 200 J Pediatric: 50 J Neonatal: 5 J

NOTE:

In internally paced patients, use the lowest energy output of external defibrillation equipment that is clinically acceptable.

6.6.1.4 Cardioversion

You can deliver a synchronized shock with Jenny® defibrillator module.

To deliver a synchronized shock

1. Select Manual Defibrillation
2. Tap on the 'On' button on the left end of the control panel. This will set cardioversion on.
3. If R-complexes are detected in the monitored ECG signal, they will be marked with a white small triangle on top of the ECG waveform.

4. Select the energy of the synchronized shock
5. Press charge
6. Press the button of the paddles or the capacitive buttons in the Docking Station. The shock will be delivered synchronized with the detected R-complex.

NOTE:

The maximum delay between the detection of the R-waves and the delivery of the shock is 60 milliseconds.

NOTE:

The sync 'on' state remains:

After the delivery of a synchronized shock
After delivering the shock
When the sync timeout is reached

The sync 'on' state will be reverted to sync 'off':

After switching to another defibrillation mode

Auto-Synchronized Shock

This functionality is available to deliver an autosynchronous shock. The shock shall be delivered synchronously with a R-wave which is detected during an adjustable time period. When no R-wave is detected during this period, an unsynchronized shock is administered.

To deliver an auto-synchronized shock:

1. Select Manual Defibrillation
2. Tap on the 'Auto' button on the left end of the control panel. This will set cardioversion on.

3. If R-complexes are detected in the monitored ECG signal, they will be marked with a white small triangle on top of the ECG waveform.

4. Select the energy of the synchronized shock
5. Press charge
6. Press shock. The shock will be delivered synchronized with the detected R-complex.

NOTE:

The time period in which the device searchs for an R-wave is 1000 milliseconds. After this time expires the capacitor is internally discharged.

6.6.1.5 Pacer

WARNING:

The Pacer therapy mode is not available when Paddles are connected as electrodes.

WARNING:

The Pacer function must not be used near high frequency surgical devices or microwave therapy devices.

WARNING:

Noninvasive pacing therapy can be associated with the following complications:

Failure to capture
Failure to pace
Intolerance (discomfort) due to pain or contraction of local skeletal muscles

To prepare for noninvasive therapy in Pacer mode

1. Confirm that the patient has indication for noninvasive pacing therapy.
2. Prepare the skin of the patient as described in 5.5.4.1 (Skin preparation)
3. Apply the corresponding electrodes to the patient as described in 5.5.4.2
4. Connect electrodes cable to the defibrillation module as described in 5.5.4.3

To deliver noninvasive pacing therapy

1. Select Pacer.
2. Select the desired Pacing Mode.

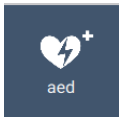
3. Select the desired Current level.
4. Select the heart rate Frequency. With the soft key controls, increase the frequency until heart beat capture can be regularly seen. Once the selected HR is obtained, adjust to the desired frequency for the patient.

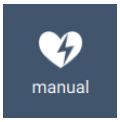
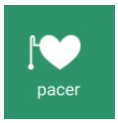
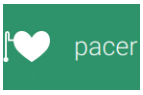
NOTE:

The ECG waveform will display the desired HR, with wide-QRS complexes and a corresponding pulse, indicating the pacer stimulation (only in demand and overdrive mode, not in fixed mode).

5. If the pacing pulse is not followed by a QRS complex, increase the Current level until the stimulation threshold is reached, and the desired frequency is displayed. Once the desired capture is obtained, adjust the Current level to administer the lowest current level possible without compromising the HR.
6. Repeat the steps 4 and 5 as needed to achieve the desired capture.
7. If the capture is unsuccessful, assess the connections of the patient and possible failure causes.

Pacing controls and indicators

GUI item	Description
	**AED button**– Allows you to switch to AED mode.

GUI item	Description
	**Manual defibrillation button**– Allows you to switch to manual defibrillation mode.
	**Pacer button**– Allows you to switch to pacing mode. When Pacer is selected, the button is highlighted in green
	**Pacer indicator**– Indicates that the current defibrillator mode is Pacer
	**Pacing mode switch**– Allows you to select the pacing mode. (Fixed mode as default)
	**Current selection control**– Allows you to manually set the current of the pacing pulses. At start up, the default current is 0 mA.
	**Frequency selection control**– Allows you to manually select the frequency of the pacing pulses.
	**Start button**– Allows you to start the pacing therapy with the previously selected settings.
	**Stop button**– Allows you to pause the pacing therapy. The current settings will be available.

Pacer settings

Field	Description	Value Range	Default
Pacing mode	You can select the modality for the pacing therapy	Fixed, demand, overdrive	Fixed

Field	Description	Value Range	Default
Current [mA]	You can set the current of the pacing impulses	0 to 150 mA	0 mA
Frequency [bpm]	You can set the frequency of the pacing impulses	20 to 150 bpm 20 to 300 bpm (Overdrive mode)	70 bpm

6.6.1.5.1 Troubleshooting

Problem	Possible cause	Proposed remedy
Discomfort	- Nociceptive perception of current delivery - Anxious patient	- Consider analgesia and / or sedation - If using the anterior-posterior pacing electrode placement: consider changing the location of the anterior electrode to the mid-axillary line position.
Failure to capture	- Insufficient current delivery to the myocardium - Altered myocardial contractility: Myocardial ischemia Metabolic disturbances - High transthoracic impedance: Obesity Contact of electrodes Malposition of electrodes Pneumothorax	- Check patient status - Check for underlying causes - Check skin contact - Check electrodes - Change position of electrodes - Check cables - Check connection to device - Adjust current levels
Noisy ECG signal	- Contact of electrodes - Malposition of electrodes - Electromagnetic interference	- Check skin contact - Check electrodes - Change position of electrodes - Check for EMI sources
Over-sensing	Detection of artifact signals (muscle tremor, T waves)	- Change position of ECG electrodes - Change monitoring lead - If measures fail: Select Fix Mode
Under-sensing	The intrinsic cardiac activity is not detected	- Change position of ECG electrodes - Change monitoring lead

CAUTION:

Regularly check the effectiveness of the pacing by assessing the central and/or peripheral pulses.

CAUTION:

The patient must remain under continuous monitoring and surveillance. If the patient is not continuously attended during treatment, non-invasive pacing therapy shall be delivered in FIXED mode only.

NOTE:

After defibrillation therapy:

Remove electrodes by gently peeling them from the surface of the skin.

If therapy is going to be repeated over a prolonged period of time, check the skin, and replace the electrodes in a different location, according to the instructions of use.

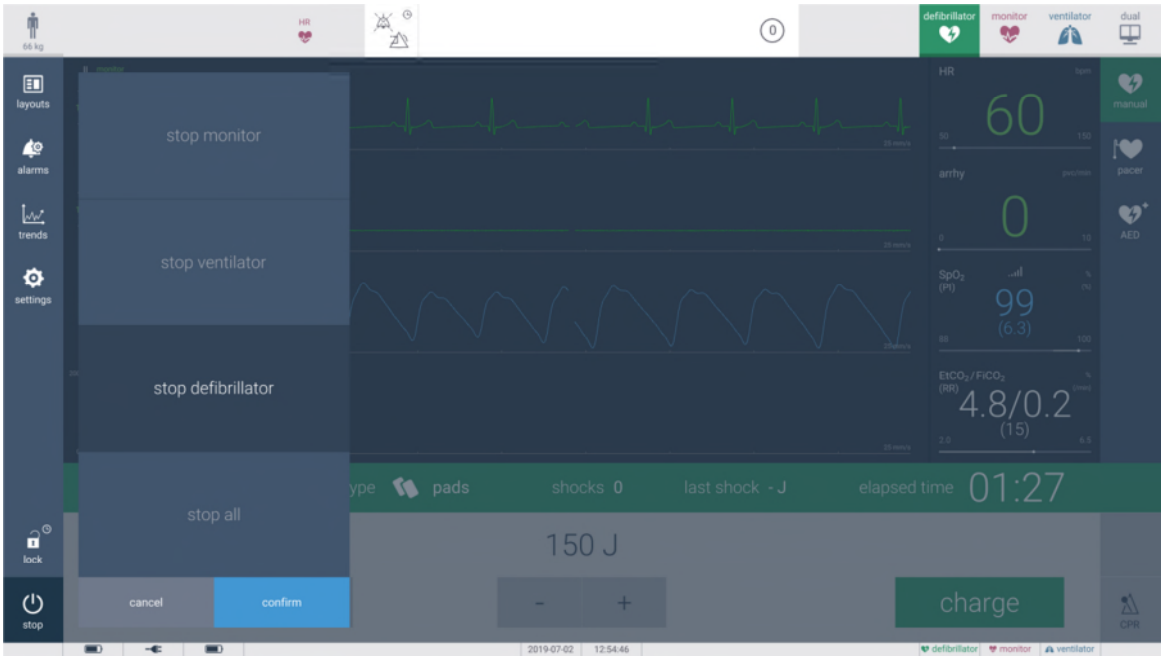
Check periodically the skin surface area for any changes; document and monitor accordingly to institutional protocols.

6.6.2 Stopping defibrillator

The Defibrillator Module can be stopped quickly, accessing **the ON/OFF button**, located at the bottom of the left tool bar.

By pressing this button, the options for **Stop** for every module are available. The operator must press **Stop Monitor** to cease the functions of the module. The Defibrillator operation will be stopped after confirmation.

The stopping of a module can be done without interference with the Ventilator and Monitor Modules.



6.7 Capnography (Optional)

6.7.1 Starting patient monitoring

The following parameters are adjustable by the user:

Field	Description	Value Range	Default
Apnea Timeout	Time elapsed since last breath. For the purpose of apnea detection.	20 to 60 seconds	20 seconds
Atmospheric Pressure	Atmospheric pressure in which the device is used.	700 to 1060 hPa	1013 hPa

NOTE:

- The default measurement value for Capnography is vol%.
- The user should check the atmospheric pressure setting before every use.
- When selecting other measurement units (mmHg or kPa), the user must introduce the value corresponding to the atmospheric pressure of the environment in which the device is active, to ensure the accuracy of the gas measurement.

Zero calibration

WARNING:

Incorrect capnography probe zeroing may result in false gas readings.

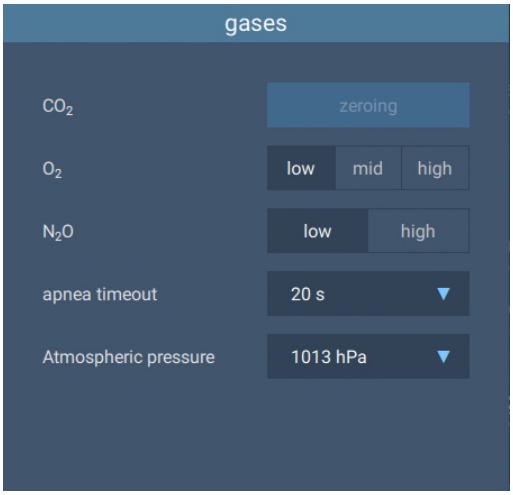
NOTE:

The ISA CO_2 analyser performs zeroing when a steady operating temperature is achieved (typically 30 minutes after start) and thereafter every 24 h.

Performing a zeroing is recommended if gas reading does not show 0% or if an unspecified accuracy message is displayed.

To zero the IRMA sensor

1. Allow at least 10 seconds for the probe to warm up after power on and after changing the adapter before starting the zeroing procedure
2. Open the probe vent to atmosphere. This is done by snapping the adapter to the sensor before connecting the adapter to the breathing circuit. The presence of room air (21% O_2 and 0% CO_2) is important for correct zeroing.
3. Open the gas sensor calibration menu from the ‘Gases’ button in the Function Bar, which is located at the right side of the screen for the Ventilator and Monitoring modules. If there is a probe connected to the corresponding module, the button ‘zeroing’ is available. If not, the button is greyed out.



4. Tap on the ‘zeroing’ button. During the zeroing process the green LED on the probe will be blinking for approx. 5 seconds.

The ISA CO_2 analyser performs zeroing when a steady operating temperature is achieved (typically 30 minutes after start) and thereafter every 24 h.

7 Maintenance and training

7.1 Repair and service

Service manual

The following parts of Jenny® are detachable and wear parts and may have to be replaced:

- The air inlet filter in the ventilation module
- The inspiratory filter in the ventilation module
- The galvanic oxygen cell
- The reserve battery in the Docking Station
-

7.2 Periodical safety relevant controls

NOTE:

It is necessary to test the equipment and its accessories on a daily basis (By clinical operator), especially the procedures to test visual and acoustical alarm signal.

These tests are described in section 8. Tests.

It is also necessary to test the equipment on a scheduled basis for preventive maintenance, as a service activity. The maintenance schedules can be found in the service manual.

NOTE:

Only for Germany: The device must periodically undergo a safety check (STK). The legal deadline for the implementation of Safety checks according to §11 Medical Device Operator Ordinance (Medizinprodukte-Betreiberverordnung) is 2 years.

7.2.1 Daily inspections

- Visual inspection of completeness, recognizable damage, absences, cracks as well as any safety decreasing contamination, foreign substances or wear of the product.
- Check safety relevant labeling and inscriptions - control regarding legibility.
- Visual inspection of monitoring module, connectors and cables and electrodes against damages (broken pins, bent connectors, etc.). Replace as required.
- Check completeness of accessories for use (ventilator, monitor, defibrillator)
- Visual inspection of defibrillator module, electrode therapy cable, paddles plate, paddles handle against damages. Replace as required.
- Check ventilation patient circuits and tubes to check their readiness for function against damages. Replace as required.
- Check power supply: Disconnect AC cable and check battery operation.
- Visually inspect batteries against worn or broke contacts, damage or leakages. Make sure that you have spare battery packs.

- Switch on and check sounds (alarms and buzzer test) and correct start up procedure.
- Check the operation of the alarm system (Acoustic and optical alarm signals)
- Check Module data/power supply connectors for dust/dirt.

7.2.2 Yearly inspections

- Verify the gas readings of the capnometry IRMA sensor at regular intervals with a calibrated reference instrument or with calibration gases. The suggested interval is once a year.

7.3 Calibrations

7.3.1. Capnography

The IRMA mainstream analyzers and the ISA sidestream analyzers are permanently factory calibrated and require no routine user calibration.

For additional Calibrations, please refer to the Service Manual.

7.4 Maintenance of accessories

For the maintenance of other accessories, please refer to the Service Manual.

7.4.1. Capnography

7.4.1.1. Gas span check

Gas readings should be verified at regular intervals with a reference instrument or with calibration gas. The suggested interval for gas span check is once every year.

The gas span check procedure requires the use of a suitable calibration gas mixture. A cylinder containing such mixture may be acquired from the vendor of choice, provided the following gas concentrations and accuracy. Depending on application, a CO_2 calibration mixture shall be used:

ISA CO2 / IRMA CO2	
Gas	**Concentration**
CO_2	4.0 to 11. %
O_2	21%

Accuracy for all gases: ±-0.03 vol% or ± (0.02vol% +0.1% of reading), whichever is greatest.

7.4.1.2. Maintenance Tasks (ISA Analyzers only)

Once every year or whenever gas readings are questionable, perform a leakage check according to section 7.5.4 and verify gas readings with a reference instrument or with

calibration gas. Calibration gases shall be handled and disposed of in accordance with local regulations.

The Masimo Gas Master can be used to complete the maintenance tasks.

Leakage check

1. Connect a new NomoLine sampling line with male Luer lock to the ISA gas inlet connector and check that the gas inlet connector shows a steady green light.
2. Connect a short silicon tubing with an inner diameter of 3/32" (2.4 mm) to the NomoLine male Luer.
3. Exhale a long breath into the silicon tubing until the CO_2 concentration is greater than 4.5 vol% or 34 mmHg.
4. Quickly connect the silicon tubing tightly to the exhaust port.
5. Wait 1 minute until the CO_2 concentration has stabilized. Note the value.
6. Wait 1 minute and check that the CO_2 concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the NomoLine. Do not operate the ISA if there is a major leakage in the unit.

Leak test

This test can be performed as an alternative to the leakage test described above.

1. Connect a Nomoline Adapter and a Nomoline Extension sampling line or equivalent to the ISA gas analyzer, with the analyzer connected to Masimo Gas Master.
2. Tightly block the gas inlet of the Nomoline sampling line.
   Check the field *"Atm press – cuvette press [kPa]"* in Masimo Gas Master – the pressure value will start to rapidly increase, until the internal pump stops.
   When the internal pump stops and while keeping the inlet blocked, quicly block the exhaust port tightly. When blocked, the *"Atm press – cuvette press [kPa]"* in Masimo Gas Master shall be > 6 kPa.
3. Stop the pump by sending parameter *"Stop Pump"* under "*Installation & maintenance"* in Masimo Gas Master.
4. Wait about 10 seconds until the *"Atm press – cuvette press [kPa]"* value as shown by the Masimo Gas Master is stable. Note the value.
5. Wait additional 10 seconds.
6. Check that the *"Atm press – cuvette press [kPa]"* value has not changed more than 3 kPa in 10 seconds.
7. If the *"Atm press – cuvette press [kPa]"* value changes more than 3 kPa in 10 seconds, check tubing and fittings for leakage. If the problem persists, return the analyzer to manufacturer.

NOTE:

In step 5, if the "Atm press – cuvette press [kPa]" is less than 6 kPa, repeat steps 1 to 3 blocking the exhaust port quicker.

Gas span calibration

CAUTION:

Only perform the gas span calibration if the gas span check fails repeatedly.

Before performing the gas span calibration, ensure that the SETO2 and SETN2O values are set (if applicable for the gas analyzer model) correctly to match the corresponding calibration gas.

Span calibration can be performed using gas within the range:

$4.0\% \leq CO_2 \leq 11.0\%$.

The accuracy of the individual components of the calibration gas mixture shall each have an accuracy of at least ±-0.03 vol% or ± (0.02vol% +0.1% of reading), whichever is greater.

NOTE:

Gas span calibration should be performed only for the gas components that failed in the Gas Span Check.

1. Warm up the ISA gas analyzer for at least 1 min.
2. Send "Pre span calibration zeroing" and make sure that the surrounding gas is normal air (21% O_2 and 0% CO_2).
3. For each gas that failed the Gas span check, perform step 4 to 7. Always perform the span calibration with the gases in order O_2, CO_2.
   Example: *Span calibration of O_2 and CO_2 only, start with O_2 then CO_2.*
4. Supply the calibration gas and wait for at least 30 seconds.
5. Send the corresponding span calibration command.
6. Wait until the gas span calibration is no longer in progress. The calibration gas can be turned off when "span calibration is in progress" no longer is set, but the O_2 span calibration continues for about 40 s with a special zeroing during which the Servomex paramagnetic O2 sensor is sensitive to mechanical movements.
7. Verify the gas readings.

NOTE:

If the calibration process fails, the flag SPAN_ERR is set, and will stay active until the next successful calibration is passed.

7.5 Cleaning, disinfection and sterilization

WARNING:

Do not clean, disinfect or reuse single patient use accessories or components. Doing so may increase the risk of cross-contamination, compromise device functionality and reduced performance.

WARNING:

The Docking Station, the modules and its accessories must NOT be sterilised with autoclave steam, chemical methods or radiation unless otherwise indicated in the corresponding Operating Instructions provided by the manufacturer of the accessories or supplies.

WARNING:

To avoid damages to the system, including all accessories the following instructions have to be followed:

•Do NOT use any sharp-edged objects to remove remains from the surfaces

•Do NOT use povidone iodine (i.e., Povidine®) or benzalkonium chloride (i.e., Sagrotan®).

•Do NOT use strong solvents like acetone, ethers, gas, chlorinated hydrocarbons.

•Do NOT use abrasives like steel-wool or metal-polish.

•Do NOT apply large amounts of liquids.

•Many detergents must be diluted before application. Please, follow the instructions of manufacturer of the corresponding detergent.

•The Docking Station, the modules or any of the electrical cables or sensors must never be inmersed in liquid!

•During the cleaning procedure do not pour liquid on the system.

•Do not leave detergents for evaporation on the system. Wipe them off immediately.

7.5.1 Routine cleaning of exterior surfaces

To routinely clean Jenny®:

- Follow internal hospital rules for cleaning.
- Surfaces of all components of the entire system must be kept free from dust and dirt.
- Docking Station and installed modules housing must be cleaned regularly by smooth wiping. Use a soft lint-free cloth. The cloth can be dampened with mild soap and

warm water solution (40 °C maximum) or with a mild cleaning solution (i.e. 70% of isopropyl alcohol). Do not allow any liquid or spray to penetrate the housing or the connection sockets. Wipe around, not over, all connection sockets. Special attention must be paid to the interfaces between the modules and the Docking Station (module bays).

To routinely clean the display:

- Take extra care when cleaning the display. Use the screen lock function to clean the display while the system is into operation. To keep the screen free of scratches, carefully brush dust and dirt particles with a soft sponge moistened with a mild conventional detergent solution. For a deeper cleaning, to remove visible fingerprints and stains, use a soft cloth with a specific commercial glass cleaning solution. Do not wipe a dry screen or use alcohol or solvents containing chlorinated hydrocarbon. If disinfection of the display is required, use a low alcohol disinfection tissue (i.e. Bacillol 30 ® Tissues). Clean any blood stain as soon as possible. It may be hard to remove dried blood from the screen. You can also use hydrogen peroxide (3% solution) to remove dried blood.

7.5.2 Cleaning and disinfection after each patient application

To clean Jenny®:

1. Turn Jenny® power off and remove mains cable from the Docking Station before cleaning.
2. Extract the operational battery to clean it separately.
3. Completely remove all modules attached to the Docking Station to clean them separately.

To disinfect Jenny®

The following components and accessories must be disinfected before connecting a new patient to the device:

The following disinfection agents can be used:

Type	**Example**
Hydrogen peroxide	Terralin protect® (Schülke&Mayr)
Formaldehyde dilution	Aldasan 2000 ® (Lysoform)
Chlorine	Lysoformin spezial (Lysoform)
Chlorine	Clorina® (Lysoform)
Potassium peroxymonosulphate/Sodium benzoate	Perform® (Schülke&Mayr)
Phenol	Amocid® (Lysoform)

NOTE:

MS Westfalia recommends only the cleaning and disinfection products listed by the Robert Koch-Institute.

7.5.3 Component cleaning and disinfection

7.5.3.1 Batteries

To disinfect the batteries

Apply a damp cloth with one of the disinfection solutions listed above before installing a battery in the devices. Special care must be taken when transferring the battery from one Docking Station to another.

To clean the batteries

During normal use clean the surface of the battery as demanded. Avoid any liquid or spray from entering in contact with the battery connectors.

7.5.3.2 Ventilator module

WARNING:

To prevent infection and cross-contamination, make sure that the inspiratory bacteria filter is installed before ventilating a patient.

NOTE:

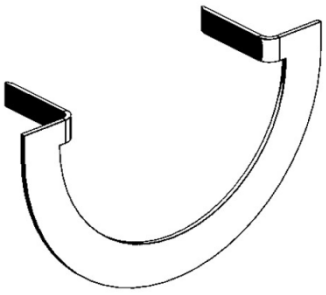
It is recommendable for this procedure to be performed by a trained hospital technician.

Note that the inspiratory filter is always integrated in the ventilator and that ventilation is not possible when the filter is not installed. There will be no portions of the gas pathways that can become contaminated with body fluids or expired gases.

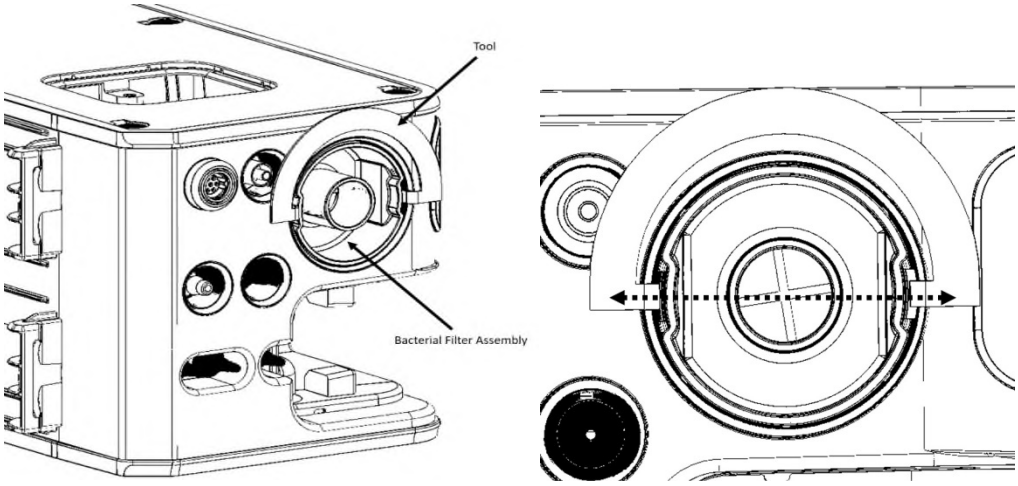
To clean the ventilator module, use the same method as described above for the Docking Station. While cleaning be careful not to spill any liquid into plug connectors or the pneumatic ports.

To replace the Bacterial Filter

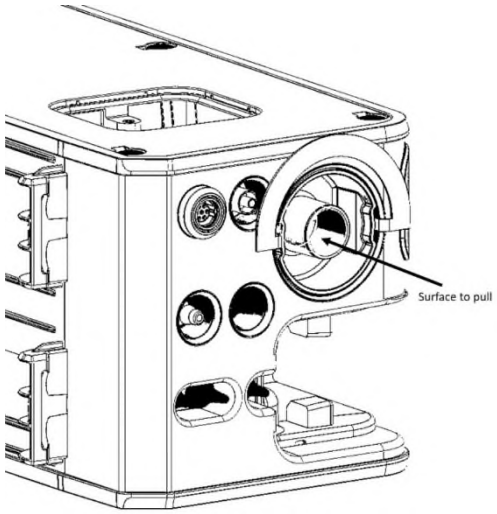
In order to replace the bacterial filter, the VM Tool is required**.**



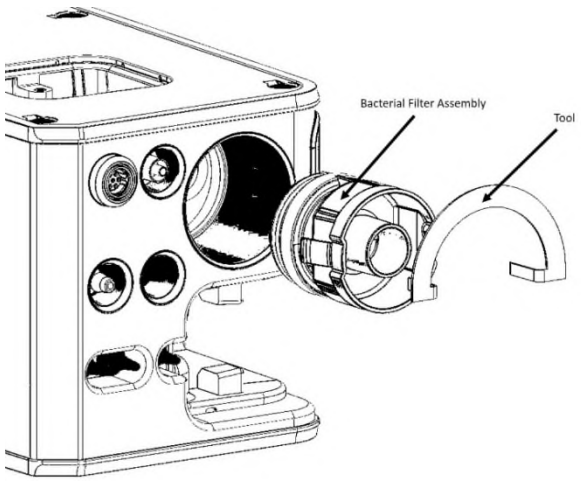
1. Set the VM Tool as shown in the picture at the Ventilator Module Filter Male Housing. Ensure that the VM Tool touches the arms of the housing.



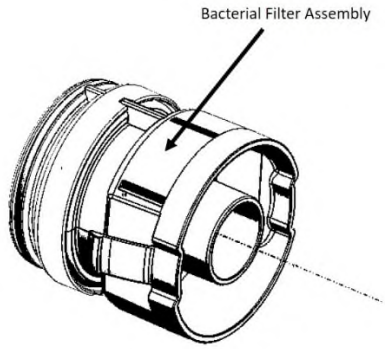
2. Grab with the thumb in the middle of the VM Filter Male Housing. The surface to pull is indicated with a black arrow.



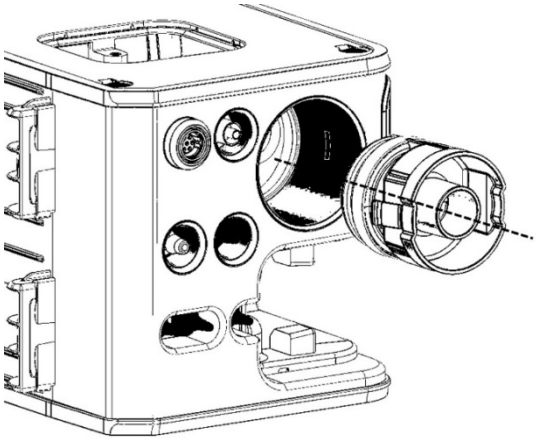
3. Pull out the VM Bacterial Filter Assembly. Light rotational movements can be helpful for the removal of the assembly.



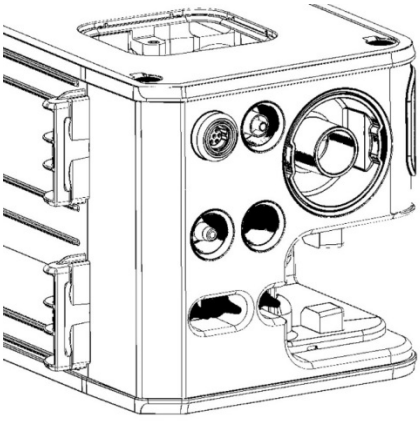
4. Replace with a new VM Bacterial Filter Assembly.



5. Put the new Bacterial Filter Assembly in the VM Housing. Ensure that the arms of the Bacterial Filter Assembly are properly positioned.



6. Press the Bacterial Filter Assembly in the main Housing of the Ventilator Module.



To clean and disinfect the Medijet ® nCPAP generator

All instruments must be cleaned, disinfected and sterilized before each use; this also applies in particular to initial use after delivery, since all instruments are delivered non-sterile (cleaning and disinfection after removal from protective transport packaging; sterilization after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization.

Before treatment

1. Directly after use (within a maximum of two hours), heavy contamination must be removed from the instruments. Do not disassemble the instruments to do so.
2. Use running water or a disinfectant solution for this purpose; the disinfectant solution should be aldehyde free (otherwise contamination from blood will be set), have certified efficacy, be suitable for the disinfection of the instruments, and be compatible with the instruments.
3. To remove contamination manually, use only a soft brush or a clean, soft cloth which you only use for this purpose; never use metal brushes or steel wool.
4. Rinse the thin instrument tube five times using a disposable syringe (minimum volume 50 mL) and rinse the thick tube for at least 1 min. under running water.
5. Subsequently disassemble the instruments only then (remove the two tubes from the connectors on sides, the push ring and the extender as well as unscrew the bolt in the connector for the thicker tube (however the bolt should still be kept loose on the connector).
6. Please be aware that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step to be performed later – after cleaning has taken place.

Manual cleaning and disinfection

1. Place the disassembled instruments for the specified contact time in the cleaning bath so that the instruments are sufficiently covered; facilitate the cleaning using ultrasound and careful brushing with a soft brush). Ensure that the instruments do not touch one another.
2. Rinse the thin instrument tube at least five times at the start and at the end of the contact time using a disposable syringe (minimum volume 50 mL).
3. Then remove the instruments from the cleaning bath and flush them thoroughly at least three times with water. Rinse the thin instrument tube at least five times using a disposable syringe (minimum volume 50 mL) and rinse the thick tube for at least 1 min. under running water.
4. Inspect the instruments.

 **CAUTION:**

Check all instruments after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipping and contamination and discard damaged instruments. Instruments which are still contaminated must be cleaned and disinfected once again.

5. Place the disassembled, cleaned and inspected instruments in the disinfection bath for the specified contact time such that the instruments are sufficiently covered. Ensure that the instruments do not touch one another.
6. If applicable: Rinse the thin instrument tube at least five times at the start and at the end of the contact time using a disposable syringe (minimum volume 50 mL).

7. Then remove the instruments from the disinfection bath and flush them thoroughly at least five times with water. Rinse the thin instrument tube at least five times using a disposable syringe (minimum volume 50 mL) and rinse the thick tube for at least 1 min. under running water.
8. Dry the instruments by blowing them off/blowing them out with filtered compressed air.
9. Pack the instruments as promptly as possible after removal (if necessary at a clean location after additional subsequent drying).

CAUTION:

Please package the disassembled instruments in disposable sterilization packaging (single or double packaging) which meets the following requirements:

• DIN EN ISO/ANSI AAMI ISO 11607

• Suitable for steam sterilization (resistant to temperatures up to at least 138°C (280°F), sufficient steam permeability)

• Sufficiently protect the instruments and sterilization packaging from mechanical damage.

To sterilize the device

For sterilization, only use the methods listed below; other methods are not permissible.

The instruments may only be sterilized when disassembled.

Steam sterilization

- Fractionated vacuum method or gravity displacement method (with sufficient product drying)

NOTE:

The use of the less effective gravity displacement method is only permissible if the fractionated vacuum method is not available.

- Steam sterilizer according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79
- Corresponding to DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134) validated (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- Maximum sterilization temperature 134°C (273°F; plus tolerance according to DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilization time (exposure time at the sterilization temperature) at least 33 min (or 18 min for prion inactivation)
- (fract. Vacuum method) or 53 min (gravity displacement method) at 132°C (270°F)/134°C (273°F)

In addition, do not use any hot air sterilization, no radiation sterilization, no formaldehyde or ethylene oxide sterilization and no plasma sterilization.

To store the device

After sterilization, the instruments must be stored in the sterilization packaging and kept dry and free of dust.

To reuse the device

The instruments may – given appropriate care and provided that they are undamaged and uncontaminated – be reused up to 100 times; any re-use beyond this or use of damaged and/or contaminated instruments falls under the responsibility of the user.

7.5.3.3 Monitor module

To clean the Monitor module, use the same method as described above for the Docking Station. While cleaning, be careful not to spill any liquid into the female plug connectors.

CAUTION:

Do not submerge the Monitoring Module in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.

Lead ECG cables

To clean ECG cables

1. Clean the cables with a soft cloth moistened with mild soap and water solution. Prevent moisture entering the plug connector.

NOTE:

Clean the cable carefully to avoid breaking internal wires

To disinfect ECG cables

1. Clean the cables as described above with one of the disinfectant agents.
2. Remove any remains of the disinfectant on the cable with a soft cloth moistened with water.
3. Dry the cable with a dry cloth and let it air dry before using them again.

SpO_2 sensors

CAUTION:

Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from power source.

To clean SpO_2 sensors

1. Clean the sensor with an soft cloth , dampened with isopropyl alcohol 70%
2. Allow the sensor to dry and store for its next use.

CAUTION:

When cleaning/disinfecting SpO_2 sensors, do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth, dampened with cleaning solution. Do not attempt to sterilize.

To disinfect SpO_2 sensors

The recommended disinfections agents are: isopropyl alcohol 70%. A 10% decoloring solution can be used for sterilization at lower standard. Don't use undiluted decoloring (5%-5.25% sodium hypochlorite) or other non-recommended disinfector to avoid damage to sensor.

IBP transducers

To clean the IBP transducers

1. Clean all blood and other foreign matter from the external surfaces of the transducers, cables and domes using a damp cloth and a mild detergent solution. Never immerse the transducers in liquid Do not use alcohol or solvents on the clamps
2. Rinse thoroughly and dry the cable with a dry cloth and let air dry before using them again.

CAUTION:

Do not autoclave or use ETO to sterilise reusable transducers, cables, clamps or brackets.

Temperature sensors

1. Clean the cable before sterilization.
2. Clean the cable surface with a soft cloth dampened with water or neutral soapy water.
3. Scrub the cable with a soft cloth dampened with disinfection solution.
4. Wipe off the disinfection solution that might be remaining on the cable with a soft cloth dampened with water.
5. Put the cable in a shady and cool environment for airing.

CAUTION:

• Do not repeatedly sterilize and use disposal temperature sensor.

• To avoid long-time harm to sensor, it is suggested that sterilization to the product be conducted only when necessary according to hospital regulations.

• The sensor can only withstand a temperature of 80-100 °C for a short time and the heating temperature must not exceed surpass 100 °C.

NIBP cuffs

1. Regularly clean the NIBP cuffs.
2. Remove the cuff from its connector and pull out the airbag from its sheath.
3. Submerge a clean and soft medical gauze pad or other soft cleaning tool into water or neutral soapy water, and when dampened, wipe the airbag and pipe.
4. Wash the cuff sheath in clean, neutral soapy water.
5. Put the sheath and the airbag in a shady, cool environment for drying.
6. Once the sheath and airbag are completely dry, enclose the airbag with the cuff sheath.

CAUTION:

• Excessive cleaning may damage the airbag. Clean the cuff only when necessary.

• Do not dry airbag and sheath in high temperature.

• If higher sterilization level is required, please choose disposal cuff.

• One disposal cuff can only be used for one patient.

• Carefully keep water and cleaning solution out of the connecting parts of cuff and monitor.

7.5.3.4 Defibrillation module

Shock paddles

To clean the shock paddles

1. Disconnect the paddles from the Defibrillator Module.
2. Clean the paddles after each application with a soft cloth moistened with a mild soap and water solution.
3. Remove the residues of contact gel in the space between the paddles plates and the handles since they can result in a hazard for you and for the patient.
4. Avoid any liquid or moisture entering the plug connector.
5. Dry the paddles, cable and plug thoroughly.

To disinfect the shock paddles

Wipe the paddles plate with one of the disinfection agents listed above.

Spoon electrodes

To clean shock spoons and handles (cable)

 **WARNING:**

- Disconnect the device from the mains and remove the mains plug before cleaning.
- Do not inmerse the spoons in liquid.
- Do not apply tension to the sensor cable.
- Do not use aggressive cleaners.
- Do not use any phenol-based agents or peroxide compounds for cleaning the spoons.
- Reusable sensors (spoons) must be treated as bologically dangerous material after usage and sterilized accordingly.

1. Do not place the connector in the cleaning solution.
2. Wipe the spoons and the cables down with a gaze pad moistened with soap water.
3. Use disinfectant to disinfect the spoons and leads.
4. Before using the spoons again, make sure that they are completely dry.
5. If the handles are immersed in cleaning or disinfection liquid, blow the screw holes with compressed air to make sure that no liquid remains in the holes.

To sterilize shock spoons

1. The spoons can be sterilized with ethylene oxide, vapor (134 °C) or by use of the “STERRAD” process (hydrogen peroxide).
2. Ensure that internal defibrillation electrodes are sterilized before each use!

To sterilize the handles (cable)

1. After intensive use of the spoon electrodes, the handles and cable should also be sterilized.
2. The handles and cable can be autoclaved (max. 144 °C, for 20 minutes and at 2.05 bar).
3. Check the electrical connection (cable connector/electrodes) after each sterilization (multimeter).
4. Numbering the handles facilitates keeping track of the sterilization cycles.

NOTE:

After approximately 50 sterilization cycles, the cable and handles need to be replaced.

7.5.3.5 Capnography (Optional)

To clean the capnography probe

If needed the sensor/probe can be cleaned by wiping it with mild soap and warm water solution (40 °C maximum) or with a mild cleaning solution (i.e. ethanol or 70% of isopropyl alcohol).

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its sampling gas inlet connector, keep the Nomoline Family sampling line fitted while cleaning the analyzer.

CAUTION:

The IRMA and ISA CO_2 airway adapters are non-sterile devices. Do not attempt to sterilize the adapters.

CAUTION:

Never sterilize or immerse the IRMA probe or ISA CO_2 analyzer in liquid.

7.6 Storage

Please be aware of the environmental conditions for storage defined in chapter 9 before storing the equipment for a prolonged period.

To store Jenny®

1. Detach all modules from the Docking Station.
2. Clean the equipment thoroughly and remove all batteries and accessories.

To put Jenny® into operation after storage

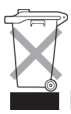
1. Check the manufacturing date of the batteries. If the batteries are more than 2 years old, replace with new batteries
2. Make sure that the batteries are fully loaded before installing them
3. Clean the equipment thoroughly and insert the corresponding modules and accessories.

CAUTION:

Before using the equipment after a long storage period, allow its temperature to stabilze at ambient conditions.

7.7 Disposal

7.7.1 Product end of life



Do not dispose the device in the household waste. Comply with local laws in the disposal of the device and/or its accessories. For proper disposal of the device, contact a

licensed, certified Electronic waste recycler. This address is available in the EU at your Environment Officer or your local authority.

7.7.2 Disposal of calibration gases

If sampling gas bottles are used for the calibration of gas sensors, please regard the disposal of the bottles. In most cases the company or organization that provided the bottles will be collecting the bottles to recycle or reuse them. If the gas supplier is unknown or not available, it is recommended to contact an authorized waste company for the collection or disposal of the bottles.

7.8 Training

MS Westfalia GmbH offers two types of training for Jenny®:

Service Training

This course is designed to introduce the biomedical professional to the modular critical care station Jenny®. This course will focus on the assemblies/sub-assemblies and gain a depth of knowledge and understanding of the device functions through various lecture and hands-on exercises. The participant will be able to complete a preventive maintenance inspection, perform basic troubleshooting and repairs and operation verification. Only persons that have obtained the official training certificate can conduct repairs in the equipment.

Application Training

During this course, the medical professional will receive information about the new and advanced technologies associated with the Jenny® critical care station.

The qualified medical professionals will be able to use the system in an advance level, starting from basic use, safety instructions and calibration procedures and cleaning and maintenance recommendations.

For in-house organization of trainings, you can send your request to mv.service@mswestfalia.de.

8 Tests

8.1 System functional tests

To test the Docking Station (DS):

1. Switch on DS. The buzzer must beep two times.
2. Alarm LEDs will be displayed in blue and the loud speaker beeps for three times.
3. The Home screen must be shown within 15 seconds, with corresponding alarm and main symbols.

To test the shutdown:

1. The DS must be turned on.
2. Press the power on/off button on the left side of the Docking Station for at least 1 second.
3. Shutdown menu appears.
4. To cancel shutdown request:
    a. Press Cancel button in the shutdown menu. Shutdown menu disappears.
    b. Press the power ON/OFF button on the left side of the Docking Station until shutdown menu is visible. Wait 10 seconds. Shutdown menu disappears (no shut down of the system).
5. Press the power on/off button on the left side of the Docking Station until shutdown menu is visible. Confirm shutdown. The system is switched off.

To test the Alarm Silence:

1. Press Alarm silence/reset button.
2. The Counter must start timer from 120 to 0 seconds.
3. To cancel the Alarm Silence: Press alarm silence/reset button again. The countdown is stopped and disappears from the screen.

To test New Patient function:

1. Press New Patient button
2. Patient data input screen opens, and the new patient input data can be changed.

To test Last Patient function:

1. Press Last Patient button
2. Patient data input screen opens, and the New Patient input data cannot be changed.

To test Home Screen:

1. Press the Home button
2. The Home Screen must be displayed.

To test the Trends Screen:

1. Press the Trends button
2. The Alarm log must be displayed.

To test the Settings Screen:

1. Press the Settings button
2. The Settings Screen must be displayed.

8.2 Ventilator tests

8.2.1 Self-test

The self-test is performed either by switching on the Docking Station with the Ventilator Module already inserted or after inserting the Module into a running Docking Station.

The self-test consists of the following sub-tests:

- System self-test
- Determine zero state for system sensors
- Perform basic electrical tests for main sensors and actuators

When an error is detected during self-test, the Ventilator module reports an error to the Docking Station, and an alarm will be generated.

8.2.2 Testing ventilation alarms

To test the occlusion alarm

1. Start ventilation.
2. Wait for four or five breaths until the ventilation stabilizes
3. Disconnect the inspiratory limb from the inspiration port in the ventilation module
4. Block the gas flow from the inspiratory port in the ventilation module
5. Keep the blockage and check that the ‘Occlusion’ red alarm is announced during the expiration phase.
6. Check that an Emergency Release message appears and that the pressure is released.

7. Reconnect the circuit.

Occlusion alarm condition determination

Obstruction can only be detected during expiration, because the expiratory limb should release the pressure through the expiration valve and this does not happen.

The detection of the obstruction event is made by checking that there is not enough pressure released at the end of an expiration.

During an occlusion event, the ventilator system opens the safety valve until the end of the expiration to relief the pressure.

To test the circuit disconnection alarm

1. Start ventilation.
2. Wait for four or five breaths will the ventilation is stable
3. Disconnect the test lung from the ventilation circuit.
4. Wait for the 'Circuit disconnection' alarm to appear
5. Reconnect the circuit
6. Check that the alarm signals stop.

To test the airway pressure alarm

1. Start ventilation.
2. Compress the test lung firmly or block the circuit at the Y-piece.
3. The alarm High Airway Pressure shall occur (red alarm).
4. Back to normal condition again
5. Reset the alarm.

To test the low expiratory volume alarm

1. Start ventilation.
2. Wait a few breaths for stabilization.
3. Set the alarm limit lower than the actual given volume.
4. The Low Minute Volume alarm shall be activated (red alarm).
5. Back to normal condition again
6. Reset the alarm.

To test the high expiratory volume alarm

1. Start ventilation.
2. Wait a few breaths for stabilization.
3. Set the alarm limit higher than the actual given volume.
4. The High Minute Volume alarm shall be activated (red alarm).
5. Back to normal condition again.

6. Reset the alarm.

To test the electrical supply disconnection

1. Start the ventilation.
2. Disconnect the mains cable. The charger icon in the Status bar disappears.
3. Then take out the operation battery. An alarm will show that the device is running with the reserve battery.

To test the gas supply disconnection

1. Connect both the air and oxygen supply.
2. Disconnect air supply.
3. An alarm No Air supply shall occur (red alarm).
4. The ventilator should switch to the internal blower automatically.
5. Connect the air supply again and switch back the air supply from blower to high pressure.
6. Disconnect the oxygen supply.
7. An alarm No oxygen supply shall occur (red alarm).
8. Connect the oxygen supply.

To test the FiO_2 alarm

1. Connect an oxygen source to the ventilator module
2. Start a ventilation
3. Set the delivered FiO_2 setting to 40 %
4. Set the alarm limit higher than the actual measured FiO_2
5. The oxygen low alarm shall be activated (yellow alarm).
6. Set the alarm limits back to default values
7. Stop ventilation

To test the $EtCO_2$ alarm

1. Connect the IRMA probe to the ventilator module
2. Connect a HME filter to the adapter in the IRMA probe
3. Breath in and out through the HME filter
4. Set the alarm limit higher than the actual measured $EtCO_2$.
5. The $EtCO_2$ high alarm shall be activated (yellow alarm).
6. Remove the HME filter
7. Set the alarm limits back to default values

To test the ultrasound nebulizer

Perform a functional test of the nebulizer system prior to first use or at any time to verify proper operation. This test is to be carried out prior to inserting the nebulizer into a circuit or accessory.

1. Visually inspect each part of the system for cracks or damage and replace if any defects are visible.
2. Pour 1-6 mL of normal saline (0.9%) into the nebulizer.
3. Connect the nebulizer to the controller using the controller cable. Connect the AC/DC adapter to the controller and plug the AC/DC adapter into an AC power source.
4. Press and release the blue On/Off power button and verify that the green 30 Min. indicator light illuminates and that aerosol is visible.
5. Disconnect the nebulizer from the controller. Verify that the amber Error Indicator lights. Reconnect the nebulizer to the controller.
6. Disconnect the AC/DC adapter from the controller and verify that nebulization continues and that the battery status indicator turns off.
7. Power off the controller. Reconnect the AC/DC adapter to the controller. Press and hold the button for at least 3 seconds. Verify that the green Continuous indicator light illuminates and that aerosol is visible.
8. Turn the system off and verify that the 30 Min. and Continuous indicators are off.

To test the reserve power source

1. Remove mains (as described in section 5.2.2.3)
2. Remove the operation battery (as described in section 5.2.2.4)
3. Check the alarms

8.3 Monitoring tests

ECG testing

To test the ECG view:

1. Switch the ECG view to 12-lead
2. All ECG curves must be correctly displayed.

To test the ECG connection:

1. The Patient simulator must be connected.
2. With no cables connected, set the Heart Rate to 60 bpm and switch on.
3. Connect the 12-lead ECG cable, and set the type to 12-lead.
4. The ECG curves must be displayed correctly, and the HR must display 60 as value.

IBP testing

To test the IBP1/IBP 2 view:

1. Plug in the sensor on IBP1/2.

2. Enable the IBP overlapping on all channels.
3. Connect transducers to IBP1 and IBP2.
4. Press 100 mmHg button on both transducers.
5. A flat line must be shown in IBP1/2 curves when pressing the button on the transducers.

To test the IBP3/IBP 4 view:

1. Plug in the sensor on IBP3/4.
2. Enable the IBP overlapping on all channels.
3. Connect transducers to IBP3 and IBP4.
4. Press 100 mmHg button on both transducers.
5. A flat line must be shown in IBP3/4 curves when pressing the button on the transducers.

NIBP testing

To test with the BP simulator:

1. Insert the cuff extension tube plug into the NIBP socket of monitor and make the plug and socket in good contact.
2. Connect the other side of the cuff extension tube with the simulator.
3. The configuration of the simulator must be 120/80 (93).
4. Start a NIBP measurement; the value should be around 120/80 mmHg.
5. Observe whether there is a big deviation between the measured value and the set value of the simulator. (Generally within 5 mmHg).

Pulse CO-Oximetry testing

CAUTION:

Electrical Shock Hazard: Carry out periodical tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safe standards. The summation of leakage currents must be checked and in compliance with IEC-60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater, or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

NOTE:

A functional tester cannot be used to assess the accuracy of the Pulse-CO oximeter.

The Tester is intended for use by biomedical engineers to test devices equipped with Masimo Rainbow SET technology.

The Tester allows the user to verify the proper operation of a device by allowing the device to report fixed values for the installed parameters.

The Tester may be used in the field to spot check Masimo-equipped instruments in order to confirm proper operation of the system. The Tester may also be used to confirm proper assembly and operation of Masimo equipped instruments during production.

The tester is connected to the 25 pin round connector on the instrument. The tester powers itself on and begins generating the test signal to the device being tested. The device will then display parameter readings for the available installed parameters.

Temperature testing

To test the Temperature 1 view:

1. Plug in the temperature sensor in Temp1 socket.
2. The ambient Temperature must be shown in Temp1 field.

To test the Temperature 2 view:

1. Plug in the temperature sensor in Temp2 socket.
2. The ambient Temperature must be shown in Temp2 field.

To test with the resistance box:

1. Connect the two sockets of any of TEMP socket of monitor with the two sides of the resistance box using two wires.
2. The setup of resistance box is 1354.9Ω (the corresponding TEMP value is 37℃).
3. Observe the monitor's display value shall not exceed 37±0.2℃

$EtCO_2$ testing

To test $EtCO_2$ view:

1. Connect the Gas sensor and breathe through it with filter
2. The $EtCO_2$ value must change from – to 0 and the curve must display a breathing pattern.
3. The value field then shows the measurement

To test the $EtCO_2$ apnea alarm:

1. Stop breathing.
2. The $EtCO_2$ apnea alarm must be active.

8.3.1 Disconnection alarms

To test the Monitoring Module disconnection alarms:

1. Connect IPBs, Temp probe, SpO_2 sensor and ECG leads to the monitor and remove the items again.
2. Press Alarm reset.
3. All sensor disconnection alarms must be displayed.

8.4 Defibrillator tests

8.4.1 Defibrillator self-test

The self-test is performed either by switching on the Docking station with the defibrillation module already inserted or after inserting the defibrillator module into a running docking station.

The self-test consists of the following sub-tests:

- Self-test 1: Start-up
- Self-test 2: HV-part. The module checks the integrity of the defibrillation units
- Self-test 3: Memory integrity. Checks the correct operation of memories by calculation of checksum
- Self-test 4: Power supply. The module checks the correct operation of power supplies

When an error is detected during self-test, the defibrillation module reports an error to the Docking Station, and an alarm will be generated.

8.4.2 Defibrillator runtime-test

To guarantee full functionality, the defibrillator module performs an automatic test while the device is running.

This test checks the communications between the defibrillator module and the docking station.

When an error is detected during runtime test, the defibrillator module enters the safe-state which, among others, discharges the capacitor, set all signals to default levels, sends an alarm to the docking station and it inhibits the function to charge the capacitor. The safe-state can only be left after a complete restart of the defibrillator module.

8.4.3 Defibrillator functional check

The functional checks are intended as a preventive maintenance of the defibrillator module and to keep the operator familiar with the use of the defibrillator functions.

Perform the following functional checks daily and before using the defibrillator. Do not perform this test when a patient is receiving defibrillator module therapy.

1. Check integrity of electrode (pads and paddles) cables before connecting them to the defibrillator module.
2. Check paddles handle and housing integrity
3. Check integrity of pads pouches and expiry date validity
4. Check Docking Station batteries for integrity and charge.
5. Replace defect parts if necessary
6. Insert the defibrillator module in the Docking Station
7. Check that the device is switched on
8. Check that the defibrillator module is detected (Defibrillator buttons available in the home screen, Defibrillator icon and message in the connected modules information)
9. Check that the defibrillator has successfully performed the self-test (no alarms are generated)
10. Place the paddles into a defibrillator checker plate or a defibrillator simulator
11. Select Adult patient
12. Press Manual Defibrillation button
13. Select 200 Joules
14. Press charge
15. Press shock buttons in the paddles
16. Confirm that the defibrillator delivers a shock

8.4.4. Testing defibrillator alarms

To test the charge of the capacitor

1. Start the Defibrillator Module and select Manual Defibrillation
2. Charge to 200 J
3. When the charge is complete, disconnect the cable of paddles of electrodes
4. The alarm message “no electrodes connected” is displayed and the capacitor is discharged

To test the buttons of paddles

1. Start the Defibrillator Module and select Manual Defibrillation
2. Charge to 200 J
3. While charging, press and hold the buttons of the paddles.
4. The message “Shock Button Paddles Permanent On” must be displayed

To test the capacitive buttons of Docking Station

1. Start the Defibrillator Module and select Manual Defibrillation
2. Charge to 200 J
3. While charging, press and hold the buttons of the Docking Station.
4. The message “Shock Button DS Permanent On” must be displayed

To test the connection of electrodes

1. Start the Defibrillator Module and select Manual Defibrillation
2. Disconnect the electrodes
3. The message “No Electrodes Connected” must be displayed

To test adequacy of electrodes

1. Start the Defibrillator Module
2. Select a patient category (as example, Neonates).
3. Connect the paddles to the Defibrillator
4. The message “Invalid Electrodes” must be displayed

To test the connection of electrodes during Pacing Therapy

1. Start the Defibrillator Module and select Pacer
2. Start Pacing mode
3. Disconnect the electrodes
4. The message “Electrodes Disconnect During Pace” must be displayed

8.5 Capnography tests

To test the $EtCO_2$ alarm

1. Connect the IRMA probe to the monitor module
2. Connect a HME filter to the adapter in the IRMA probe
3. Breath in an out on the filter
4. Set the alarm limit higher than the actual measured $EtCO_2$.
5. The $EtCO_2$ high alarm shall be activated (yellow alarm).
6. Remove the HME filter
7. Set the alarm limits back to defaults

To test the $FiCO_2$ alarm

1. Connect the IRMA probe to the monitor module
2. Connect a HME filter to the adapter in the IRMA probe
3. Breath in an out on the filter
4. Set the alarm limit higher than the actual measured $FiCO_2$.
5. The $FiCO_2$ high alarm shall be activated (yellow alarm).
6. Remove the HME filter
7. Set the alarm limits back to defaults

9 Specifications

9.1 Docking Station. General specifications

9.1.1 Product life cycle

The Docking Station has a life time of minimum of 8 years.

NOTE:

The lifetime of the device is guaranteed only in the case that all the maintenance and service tasks, as well as the replacement of components have been performed accordingly to the indications given in the Service Manual.

9.1.2 Physical specifications

Physical specifications	
Dimensions	
Height	400 mm
Width	400 mm
Depth	221 mm
Weight	
Weight	6.40 Kg

9.1.3 Environmental specifications

Environmental specifications	
Temperature	
Operating temperature range	-20 to + 50 °C (at ≤ - 10 °C for at least 20 minutes)
Storage temperature range	-10 to + 50 °C
Humidity	
Operating humidity range	30 to 75% non-condensing
Air pressure	
Operating air pressure range	700 hPa to 1060 hPa
Maximum operating altitude	Approx. 3000 meters
IP protection level	
Protection against water and dust	IP54

9.1.4 Electrical specifications

9.1.4.1 Power supply / Energy management

External AC/DC adaptor	
Medical AC adapter	Class II
Input Voltage (AC)	100-240 VAC
Frequency	50-60 Hz
Input current range	3.3-1.3 A
Output voltage (DC)	19 V
Output current	13.2 A
Output power	250 W MAX
Power cord cable length	2.5 m
RoPD connector cable length	1.5 m

9.1.4.2 Batteries

Physical specifications	
Dimensions	
Height	80 mm
Width	155 mm
Depth	25 mm
Weight	
Weight	0.4 kg

Environmental specifications	
Temperature	
Operating temperature range	-10 to +40 °C
Storage temperature range	-10 to + 50 °C
Humidity	
Operating humidity range	30 to 75% non-condensing
Air pressure	
Operating air pressure range	700 hPa to 1060 hPa
Maximum operating altitude	Approx. 4000 meters
IP protection level	
Protection against water	Non applicable

Electrical specifications	
Type	Li-Ion
Nominal voltage	14.4 V
Nominal capacity	6.0 Ah
Nominal energy	86.4 Wh
Battery operational time	Approx. 8 hours (4 hours per battery)
Charging time (from <10% to >90%)	2 hours and 30 minutes
Charging intervals	0-80%: 1 hour 15 minutes 0-90%: 1 hour 53 minutes 0-100%: 2 hours 30 minutes
Life span	Approx. 300 cycles

9.1.5 Performance specifications

9.1.5.1 Units / languages

This section describes the units available in the system for the different magnitudes for the GUI.

Units	Description	Range	Resolution
Pressures - Ventilation			
hPa	**Hectopascal** – 1 hPa = 100 Pascal (Pa) Pascal - pressure exerted by a force of magnitude one Newton perpendicularly upon an area of one square meter. 1 Pa = 1 N/m² = 1 kg/m*s² = 1 J/m³ Unit of derived pressure approved by the SI.	0 to 102 hPa	1 hPa
mbar	**Millibar** - 1 one-thousandth bar, or 1×10−3 bar 1 bar - Exactly equal to 100,000 Pa Not approved by the SI.	0 to 102 mbar	1 mbar
cmH_2O	**Centimeter of water** - Unit of pressure derived from pressure head calculations using metrology. 1 cmH2O (4°C) = 999.9720 kg/m3 × 9.80665 m/s2 × 1 cm = 98.063754138 Pa ≈ 98.0638 Pa	0 to 102 cmH_2O	1 cmH_2O
Gas measurements – CO2			

Units	Description	Range	Resolution
Vol %	**Percentage by volume** - volume fraction expressed with a denominator of 100. Used to assess composition of mixtures with a dimensionless quantity. Vol % = Volume of solute / Volume of solution * 100	0.0 to 13.3 %	0.1 %
mmHg	**Millimeter of Mercury** – 133.322387415 pascals Manometric unit of pressure - External pressure generated by a column of mercury one millimeter high. Not approved by the SI.	0 to 101 mmHg	1 mmHg
kPa	**Kilopascal** - 1 kPa = 1000 Pa = 1 centibar	0.0 to 13.5	0.1 kPa
Pressures - Monitoring			
mmHg	**Millimeter of Mercury** – 133.322387415 pascals	-50 to 400	1 mmHg
kPa	**Kilopascal** - 1 kPa = 1000 Pa = 1 centibar	-7 to 53 kPa	1 kPa

The available language for the current version of the Jenny ® is English.

9.1.5.2 Patient data

This section contains the specification of parameters displayed in the new patient configuration panel.

Patient Height

Symbol Units	Description	Range	Res.	Default
Height Cm	Patient height input. For adult and pediatric patients only.	**Adult** 140 cm to 250 cm	1 cm	**Male** 171 cm **Female** 166 cm
		Pediatric 65 cm to 150 cm	1 cm	125 cm

Patient Weight

Symbol Units	Description	Range	Res.	Default
Weight Grams	Patient weight. For neonatal patients only.	300 g to 7000 g	1 g	3000 g

PBW calculation

The Predicted Body Weight is calculated as a function of the patient category, the gender and the height input. This is applicable for Adult and Pediatric patients only.

Patient	Description	Range	Res.	Default
Adult	**Male** PBW (kg) = 50 + 0,91 (**Height (cm)** – 152,4)	39 kg to 139 kg	1 kg	70 kg
	Female PBW (kg) = 45,5 + 0,91 (**Height (cm)** – 152,4)	34 kg to 134 kg	1 kg	62 kg
Pediatric	**Male or Female** PBW (kg) = (**Height (cm)**)^2 x 1,65/1000	7 kg to 37 kg	1 kg	26 kg

9.1.5.3 Display

Display specifications	
Diagonal Size	15.6 inches (39.6 cm)
Format	16:9
Resolution	Full HD, 1920 x 1080 pixels
Luminance	400 cd/m²
Viewing angles	88° from 4 sides
Color depth	24 bits
Power consumption	14 Watts
Connection	eDP
Life time	Minimum 50,000 hours

9.1.5.4 Data interfaces

Touchscreen specifications	
Screen technology	Capacitive touch MSC technology
Multi-touch setting	Ten finger
Connection	USB and I²C interface
Touch	Stadium IGT - 35mm Illuminated Capacitive switch (P/N:-3323-13-01)
Connector to LB9 mainboard	Connected via cable
Audio specifications	
Audibility	Mean sound pressure level at 1W/1m is 77 dB Frequency range between 300-20000Hz
Waterproof resistant	Yes
Quality	Stereo, two speakers per DS
Microphone quality	38+/-3 (0dB=1V/Pa. 1kHz)
PC peripherals	
USB	3 USB 2.0 connectors
Ethernet	2 Ethernet connectors
Cell phone connectivity	Connector for telephony & GPS module
Cell phone USB	1 USB port for the cell-phone module
Cell phone SIM card	2 mini SIM-card
WiFi, Bluetooth and NFC module	Combo module Built-in antenna
WLAN support	WEP-64 WEP-128, WPA-PSK, WPA2-PSK
Bluetooth support	BR/EDR: SPP and LE
NFC	ISO 14443A/B, ISO 15693, ISO 18092, NFCIP-2, NFC Forum.

9.1.5.5 Operating time

When powered with mains, the Docking station can work uninterruptedly in any of the product configurations described in chapter 4.3.

While battery powered, the Docking Station can work for **at least 6 hours** with the complete product configuration under the following normal conditions of use:

Docking Station

- Two fully loaded batteries inserted
- The display brightness is set to 50%
- The sound is set to 60 %

Ventilator

- Air source: Turbine
- Mode: PCV
- Inspiratory pressure: 24 mbar
- PEEP: 5 mbar
- Rate: 12 bpm
- I:E ratio: 1:2
- Max volume: 750 ml
- Capnography sensor is connected and operative

Monitor

- IBP: At least 6 hours with fully charged batteries
- NIBP: 1 measurement every 10 minutes (20 seconds pumping)
- 12-channel ECG running
- SpO2: At least 6 hours with fully charged batteries

Defibrillator

- 20 x 200 J shocks in 1 hour and if ventilator is paused during defibrillation.
- Noninvasive pacing is off

Peripherals shall comply to 60601-1 or isolation unit shall be used.

Operating time specification with batteries

Operating time	Ventilator only (Conditions above)	Monitor only (Conditions above)	Defibrillation only (Discharge 200 J@20°C)	Pacer only (minutes, fixed mode)
From fully loaded batteries to shutdown				
Average	6 hours	6:25 hours	490	6 hours
Min.	5:30 hours	6 hours	400	4 hours
From 'Batteries lower than 20%' alarm message to shutdown				
Average	30 min	35 min	20	25 min
Min.	30 min	35 min	20	25 min

9.1.5.6 Docking Station alarm messages

A comprehensive description of the technical alarms is available in the Appendix A of this manual.

9.2 Ventilator module (Optional)

9.2.1 Product life cycle

The Ventilation module has a life time of minimum of 8 years or 30.000 hours of operation.

WARNING:

Do not use Jenny® in a hyperbaric chamber.

NOTE:

The lifetime of the device is guaranteed only in the case that all the maintenance and service tasks, as well as the replacement of components have been performed accordingly to the indications given in the Service Manual.

9.2.2 Physical specifications

Physical specifications	
Dimensions	
Height	143 mm
Width	400 mm
Depth	164 mm
Weight	
Weight	3.11 kg

9.2.3 Environmental specifications

Environmental specifications	
Temperature	
Operating temperature range	-20 to + 50 °C (at ≤ - 10 °C for at least 20 minutes)
Storage temperature range	-10 to +50 °C
Humidity	
Operating humidity range	30 to 75% non-condensing
Air pressure	
Operating air pressure range	700 hPa to 1060 hPa
Maximum operating altitude	Approx. 4000 meters
IP protection level	
Protection against water	IP54
Sound pressure	
A-Weighted sound pressure level at a distance <1m (average)	40.8 dB

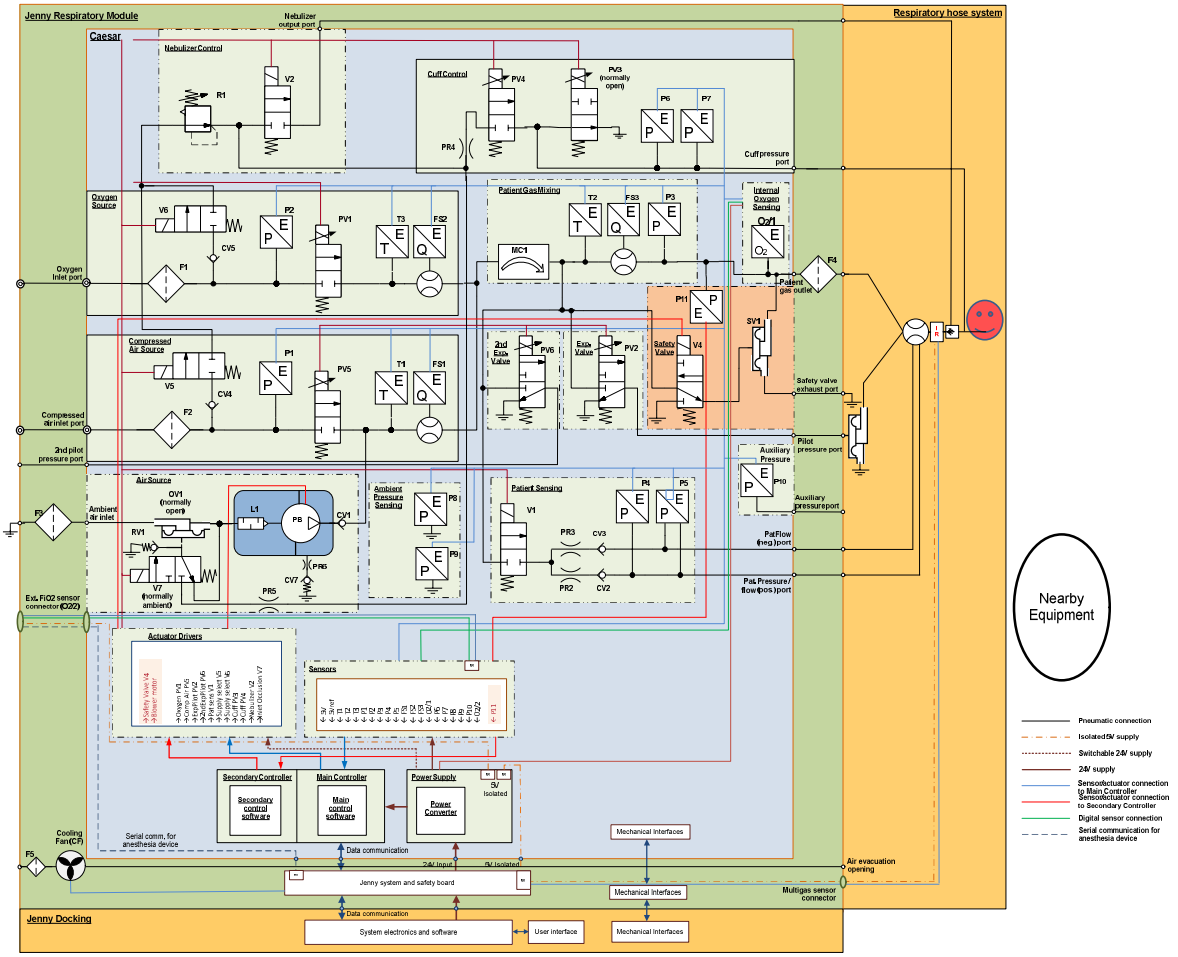
9.2.4 Pneumatical specifications

Oxygen and air inlets specification	
Connector type	NIST
Supply pressure	3 to 6 bar
Flow	40 to 120 L/min
Minimum pressure	1.8 Bar @ 5 L/min
Low pressure oxygen inlet	
LPO connector type	Spiral fitting
Supply pressure	

Oxygen and air inlets specification	
Maximum flow rate	<= 15 L/min
Gas mixing system	
Pressure delivery range	0 to 100 mbar
Plim max	125 mbar
Peak flow rate (with blower)	200 L/min [STPD]
Continuous flow (with blower)	
Auxiliary pressure port	
Gas type	Non-condensing air-oxygen gas mixtures
Temperature range	-20 to 70 °C
Pressure range	-120 to 120 mbar
Exhalation valve control port	
Gas type	Non-condensing air-oxygen gas mixtures
Temperature range	-20 to 70 °C
Pressure range	0 to 100 mbar
Connectors	
Inspiratory hose connector	ISO 22 mm male
Expiration hose connector	ISO 22 mm male

9.2.5 Performance specifications

9.2.5.1 Electro-pneumatic diagram



Subsystem	Components	Symbol in diagram
Oxygen Source	Oxygen gas supply inlet port	-
	Oxygen inlet filter	F1

Subsystem	Components	Symbol in diagram
	Oxygen Selection Valve	V6
	One way check valve	CV5
	Oxygen Supply Pressure measurement	P2
	Oxygen Control Valve	PV1
	Temperature sensor	T3
	Oxygen flow sensor (based on pressure drop)	FS2
Compressed Air Source	Compressed air inlet port	-
	Compressed air inlet filter	F2
	Compressed air selection valve	V5
	One way check valve	CV4
	Compressed air supply pressure measurement	P1
	Compressed air control valve	PV5
	Temperature sensor	T1
	Air flow sensor (based on pressure drop)	FS1
Air Source	Ambient air inlet	-
	Blower inlet sound reduction	L1
	Primary blower	PB
	Inlet occlusion valve	V7
	Inlet occlusion pneumatic valve	OV1
	Pneumatic resistor	PR5
	Pneumatic resistor	PR6
	One way check valve	CV1
	One way check valve	CV7
	Overpressure release valve	RV1
Patient Gas Mixing	Mixing chamber	MC1
	Temperature sensor	T2
	Output flow sensor (based on pressure drop)	FS3
	Output gas pressure measurement for safety	P11
	Output gas pressure measurement	P3
	Patient gas outlet	-
Safety Valve	Pilot pressure on/off valve	V4
	Pneumatic safety exhaust valve	SV1
	Safety valve exhaust port	-
Patient Sensors	Patient pressure sensor	P4
	Patient flow sensor	P5
	Pneumatic resistor	PR2
	Pneumatic resistor	PR3
	One way check valve	CV2
	One way check valve	CV3
	Purge Valve	V1
	Patient Flow (neg.) port	-
	Patient Pressure / Flow (pos.) port	-
Pilot Valve	Pilot pressure control valve for expiration	PV2
	Pilot pressure port	-
2nd Pilot Valve	Second pilot pressure control valve	PV6
	Second pilot pressure port	-
Internal Oxygen Sensing	Oxygen sensor internal	O2/1
Ambient Pressure Sensing	Ambient pressure sensor 1	P8
	Ambient pressure sensor 2	P9

Subsystem	Components	Symbol in diagram
Auxiliary Pressure	Auxiliary pressure sensor	P10
	Auxiliary pressure port	-
Nebulizer Control	Manual adjustable gas pressure reduction valve	R1
	Nebulizer valve	V2
	Nebulizer output port	-
Cuff Control	Cuff pressure control valve	PV4
	Cuff pressure exhaust valve	PV3
	Cuff pressure sensor	P6
	Redundant cuff pressure sensor	P7
	Pneumatic resistor	PR4
	Cuff pressure output port	-
Actuator Drivers	-	-
Sensors	-	-
Main Controller	Main control software	-
Secondary Controller	Motor control software	-
Power supply	Power converter	-
	24V Input	-
	Isolated 5V (For Jenny® System Board)	-
	Isolated 5V (for Ext. FiO2 sensor connector)	-
	EPP interface	-

9.2.5.2 Ventilation modes and options

The ventilation modes available in Jenny® can be divided in two different groups:

- Pressure Controlled Ventilation Modes: PCV, PCVR, PVC a/C, PC-SIMV, CPAP, APRV.

- Volume Controlled Ventilation Modes: VCV, VCV a/c, VC-SIMV, MMV, High Flow. In each group of modes, in turn, can be allocated 2 more groups: Mandatory modes (PCV, CPAP, APRV, VCV) and Synchronized modes (PCV a/c, PC-SIMV, VCV a/c, VC-SIMV, MMV, High Flow). This separation is necessary to understand the trigger mechanism operation. Trigger is a special mechanism, that initiates inspiration or expiration cycle of breathing, so, there are 2 types of triggering (by intention)-inspiratory and expiratory triggers.

Inspiratory triggering can be caused by breathing attempts of the patient or by the ventilator itself.

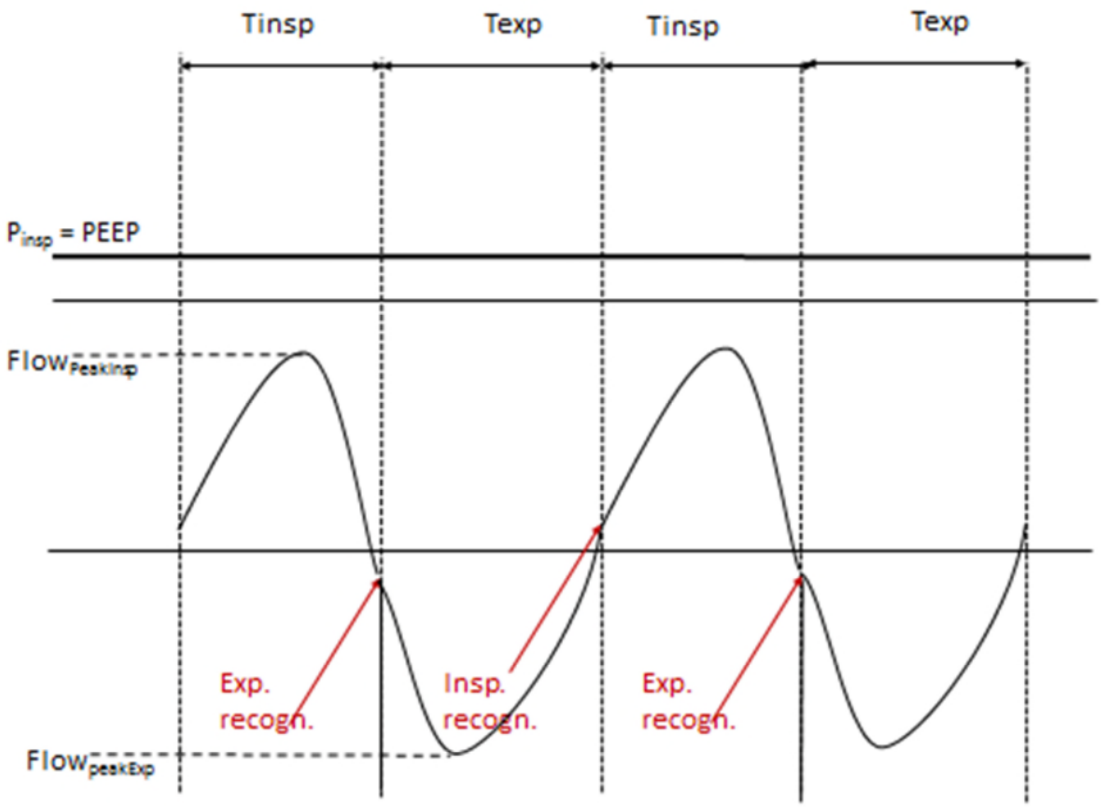
Inspiratory patient trigger is applicable only for Synchronized modes, listed above. Jenny® has 2 types of inspiratory patient trigger: pressure trigger and flow trigger. Patient's breathing attempts cause change of pressure and flow in breathing system. Jenny® has special sensors (flow and pressure sensors), that detect this changes and send the signal to START inspiration. Sensors sensitivity can be changed by the user. Inspiratory trigger caused by ventilator is applicable for both Synchronized and Mandatory modes, listed above. Inspiratory trigger is also called time trigger, as the ventilator starts inspiration basing on the duration of the respiratory cycle and the number of breaths per minute. These parameters are set by the user.

Expiratory trigger is the mechanism that initiates the exhalation phase of breathing cycle. It activates when the inspiratory flow is reduced to the value set by the user. Expiratory Flow trigger is available in PC-SIMV and High Flow modes of Jenny®. In all

other modes expiration trigger is based on time-triggering and depends on Inspiration time, I:E ratio, number of breaths per minute, that are set by the user.

CPAP

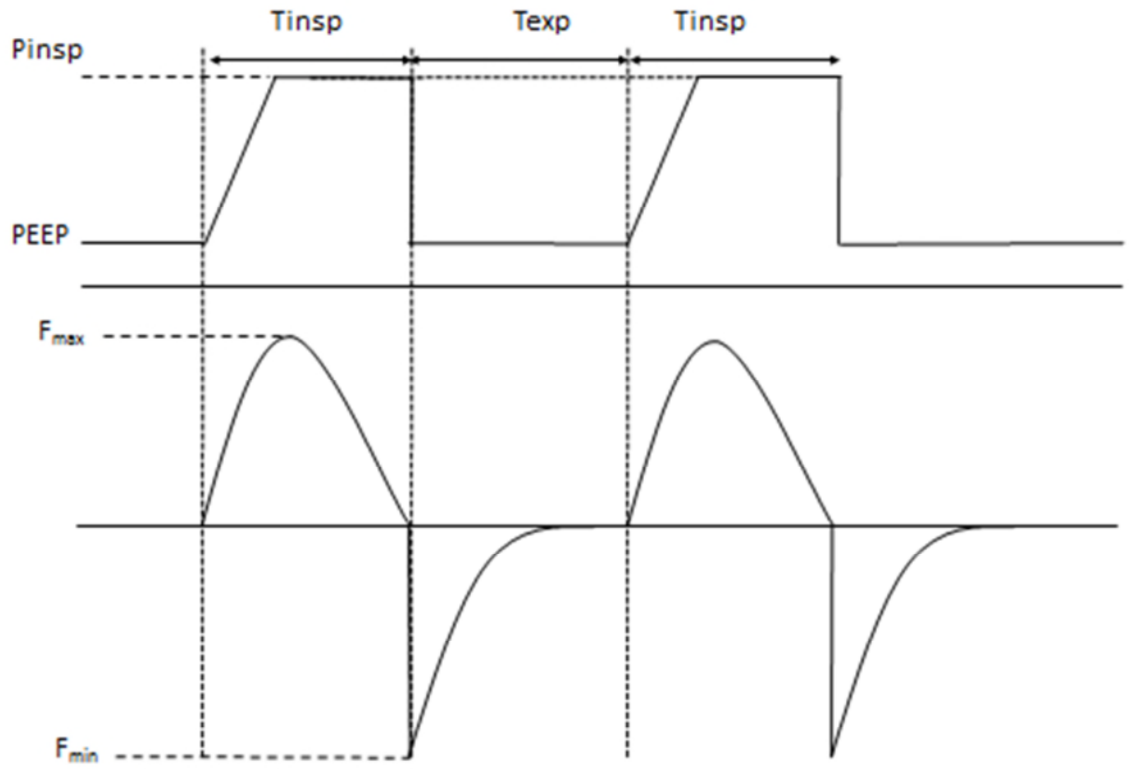
CPAP (Continuous Positive Airway Pressure) is a ventilation mode in which the patient breathes spontaneously. This is possible because it is a pressure controlled mode. In CPAP, with no options activated, the ventilator does not deliver any mandatory or triggered breaths. The spontaneous breathing phases (inspiration and expiration) are detected with by using inspiratory and expiratory phase recognition, using a flow level detector.



PCV

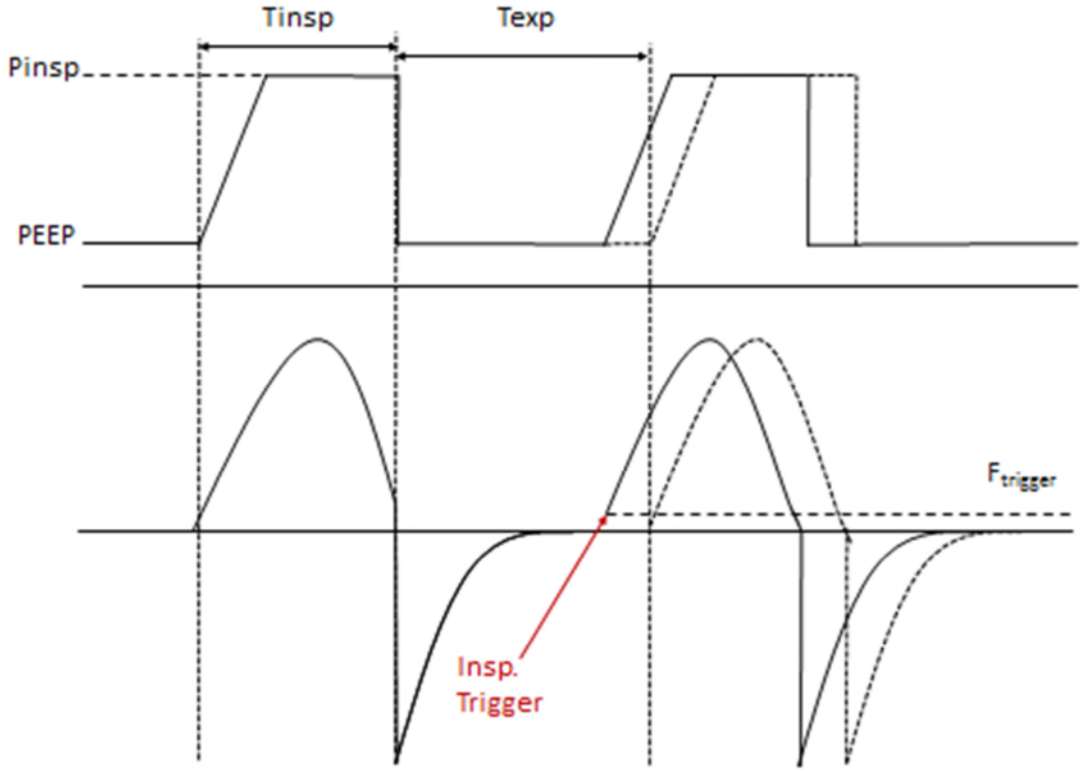
PCV (Pressure Controlled Ventilation) is a controlled, mandatory ventilation mode in which the ventilator fully controls the ventilation. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time. They are not triggered by the patient. The patient can breathe spontaneously, but this does not influence the cycling of the breathing phases.



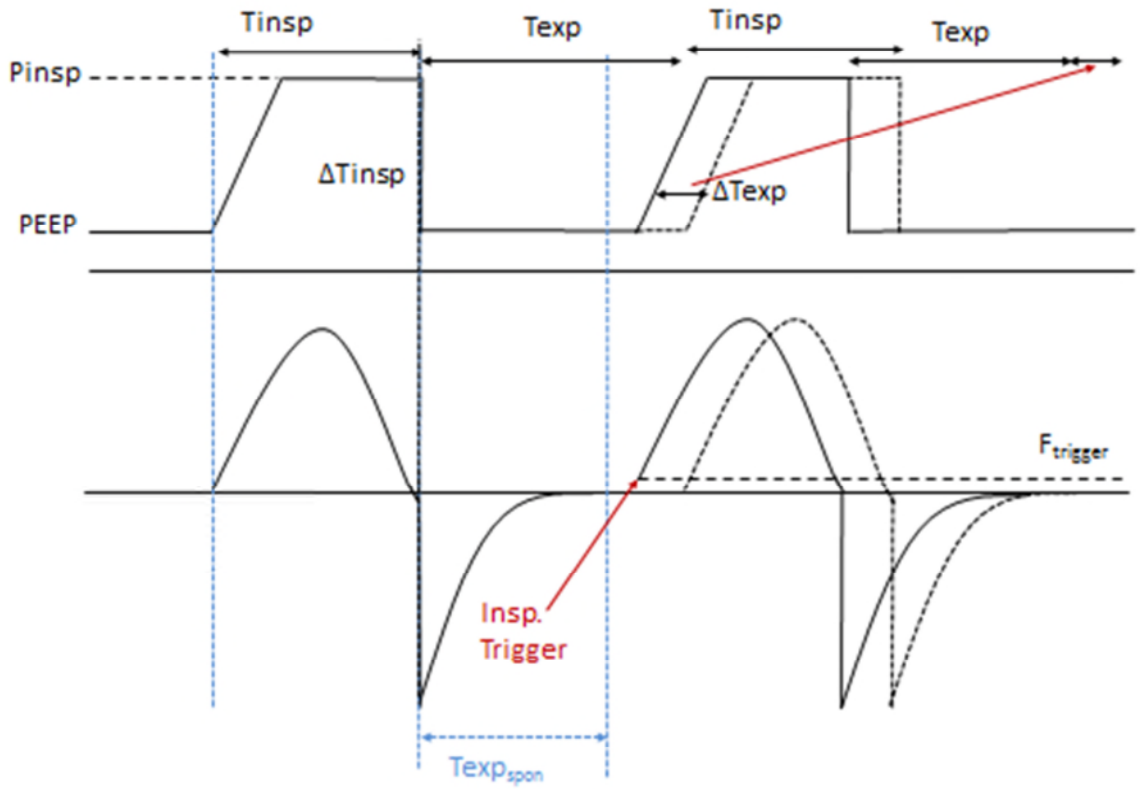
PCV a/c

PCV a/c (Pressure Controlled Ventilation – Assist/Control) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the breathing frequency or respiratory rate (RR).



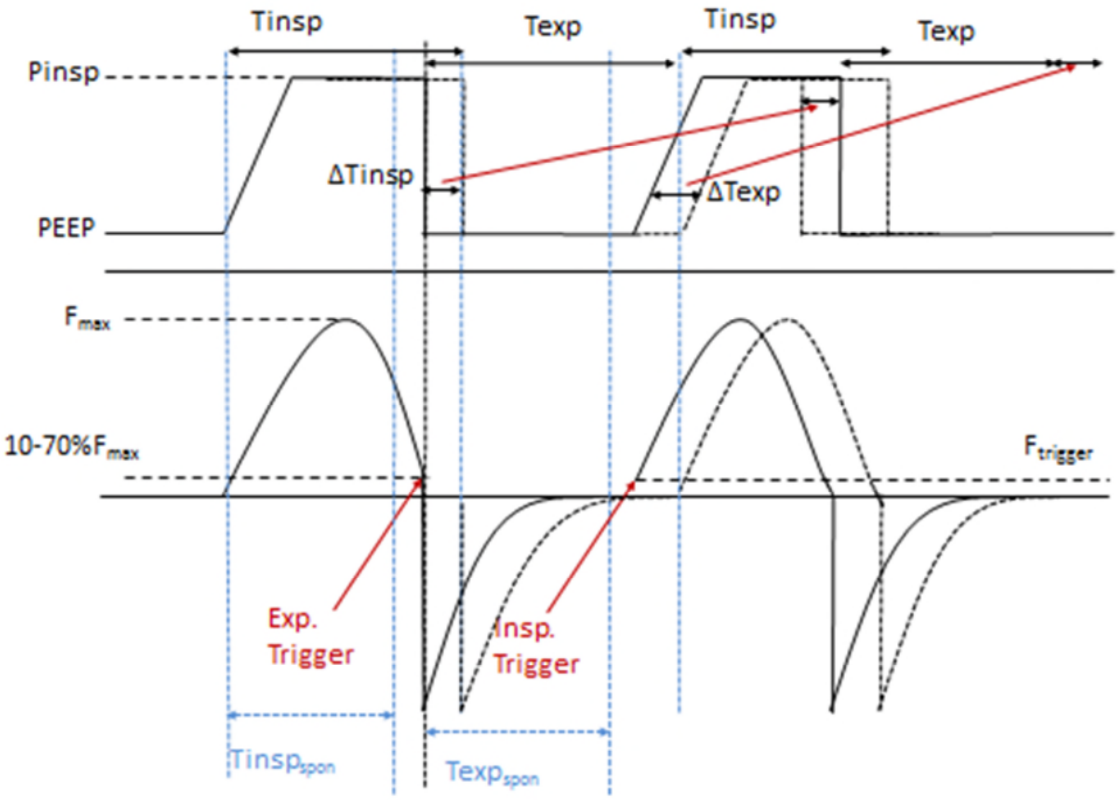
PC-SIMV

PC-SIMV (Pressure Controlled – Synchronized Intermittent Mandatory Ventilation) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time set by $Texp_{spon}$ has elapsed. The period the inspiration is started earlier is compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering.



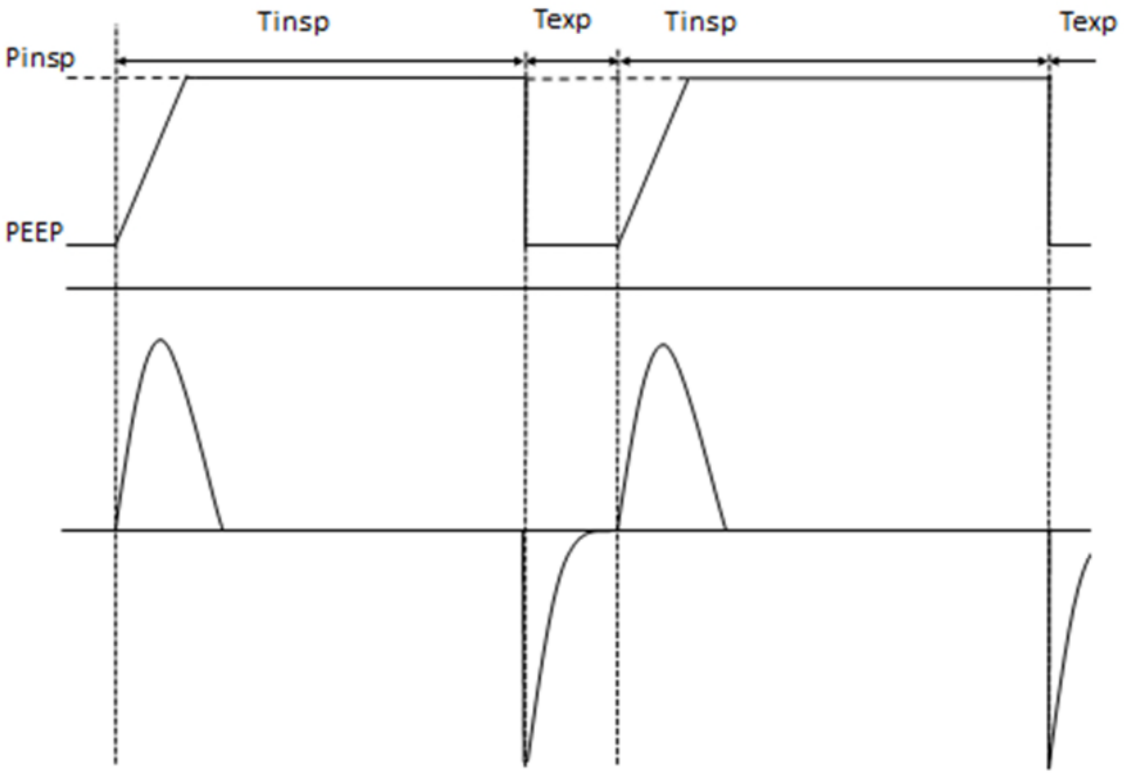
BILEVEL

BILEVEL is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. It is also known as PC-BIPAP, DuoPAP or BiLevel ventilation. The inspiration and expiration are pressure controlled. The patient can breathe spontaneously during inspiration and expiration. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time set by $Texp_{spon}$ has elapsed. The period the inspiration is started earlier is compensated in the next expiration. During inspiration, an expiration can be triggered by the patient, during a trigger window. This window starts after the time set by $Tinsp_{spon}$ has elapsed. The period the expiration is started earlier is compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering.



APRV

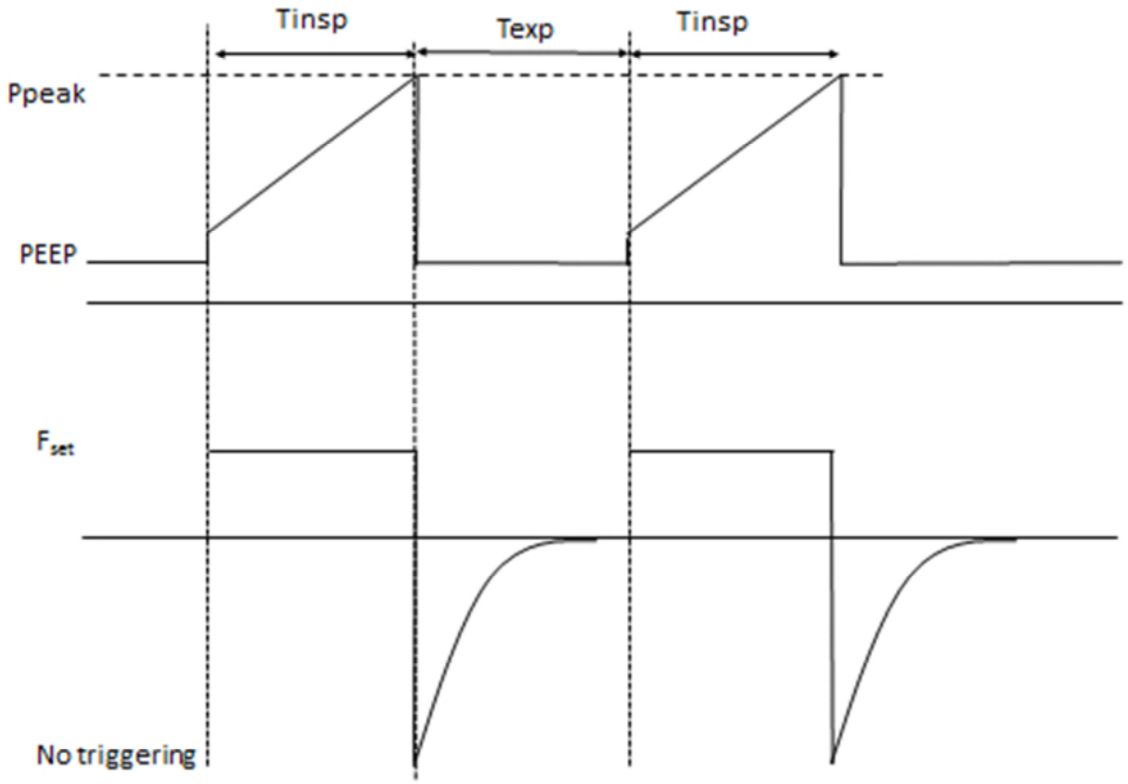
APRV (Airway Pressure Release Ventilation) is a ventilation mode in which the ventilator fully controls the ventilation. The inspiration and expiration are pressure controlled. The inspiration time is much longer than the expiration time. The patient can breathe spontaneously during inspiration. In general, the expiration time is too short to breathe spontaneously. PC-APRV can be seen as breathing on a high CPAP level, with mandatory short expirations induced by the ventilator to support CO_2 elimination. The alternation between the two pressure levels is machine-triggered and time cycled. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time. They are not triggered by the patient. The patient can breathe spontaneously, but this does not influence the cycling of the breathing phases.



VCV

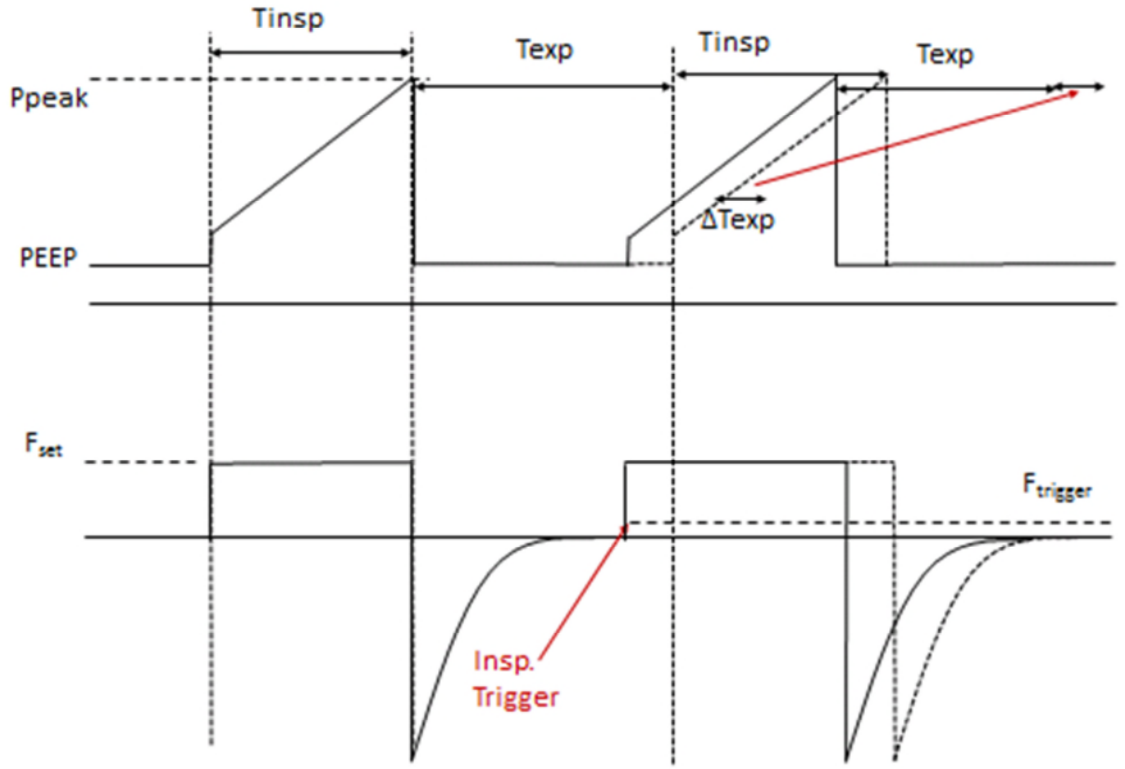
VCV (Volume Controlled Ventilation) is a controlled, mandatory ventilation mode in which the ventilator fully controls the ventilation. The patient cannot breathe spontaneously during inspiration, because it is flow controlled. During expiration, spontaneous breathing is possible, but this does not influence the cycling of the breathing phases.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time. They are not triggered by the patient. The inspiration is flow controlled and the expiration is pressure controlled (maintains PEEP level).



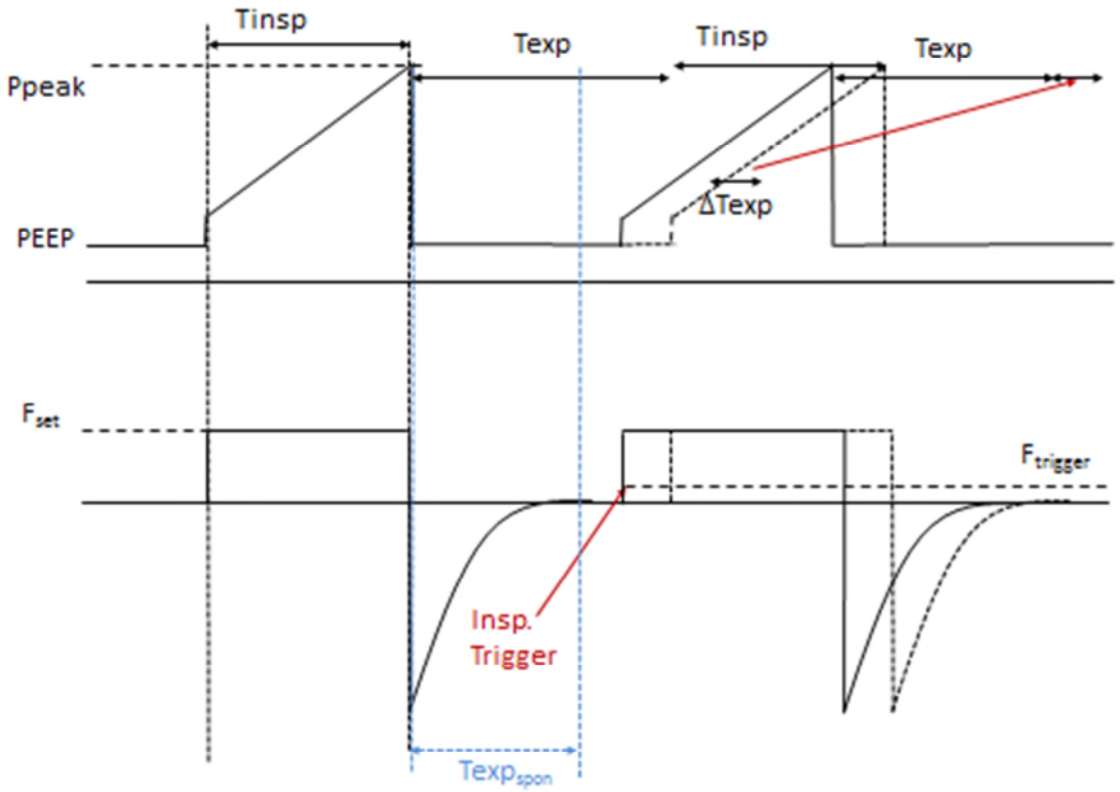
VCV a/c

VCV a/c (Volume Controlled Ventilation – Assist/Control) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration is flow controlled and the expiration is pressure controlled (maintaining PEEP level). The patient cannot breathe spontaneously during inspiration, because it is flow controlled. During expiration, spontaneous breathing is possible. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the breathing frequency or respiratory rate (RR).



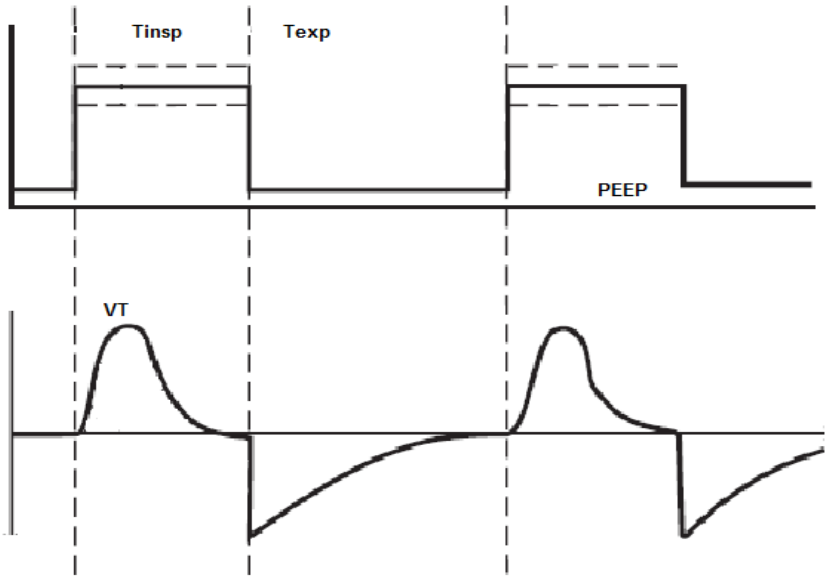
VC-SIMV

VC-SIMV (Volume Controlled – Synchronized Intermittent Mandatory Ventilation) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration is flow controlled and the expiration is pressure controlled (maintains PEEP level). The patient cannot breathe spontaneously during inspiration, because it is flow controlled. During expiration, spontaneous breathing is possible. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time set by $T_{expspon}$ has elapsed. The period the inspiration is started earlier is compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering.



MMV

MMV (Mandatory Minute Volume) is a ventilation mode in which the ventilator controls the ventilation, but it can be influenced by the patient. The inspiration is flow controlled and the expiration is pressure controlled. The patient can breathe spontaneously only during expiration. This ventilation mode guarantees that the patient always gets at least the set minute volume (MV), where MV=VT*RR. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, when the patient does not breathe spontaneously. When the Inspiratory Minute Volume (MVi) drops below the set minute volume, a mandatory time cycled inspiration is initiated. This mandatory stroke will be synchronized with the patient's breathing attempt.



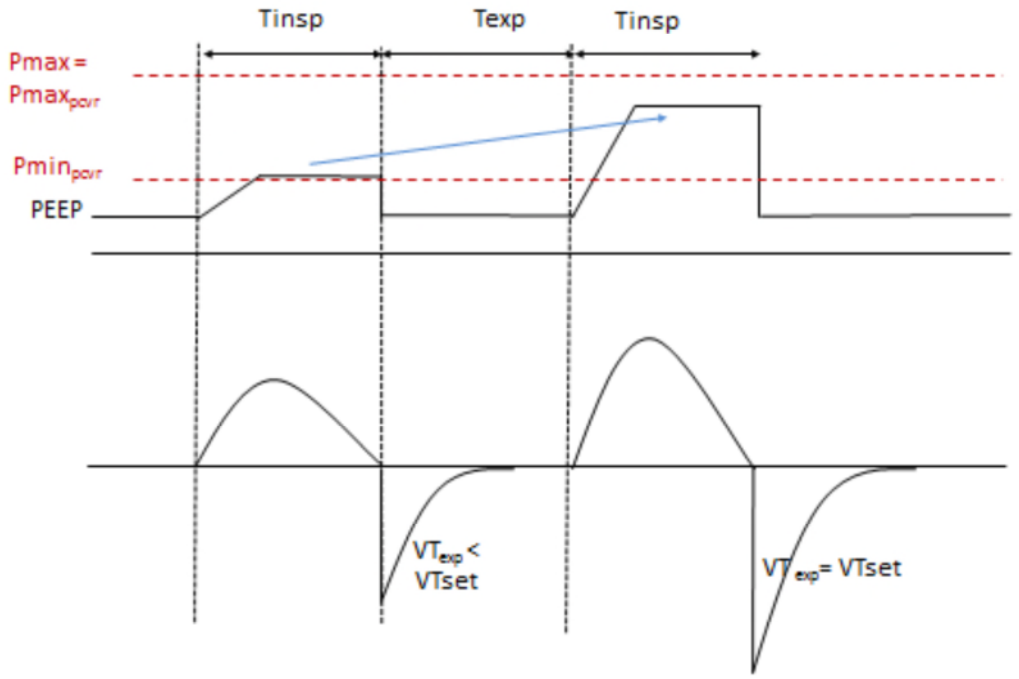
PCVR

PCVR (Pressure-Controlled Volume-Regulated) is a ventilation mode that assures a set tidal volume (VT) by adjusting the inspiratory pressure level (Pinsp) of the ventilation. It can be activated during pressure controlled ventilation modes.

When the measured expiratory tidal volume is too low the inspiratory pressure setting of the next inspiration is increased a little bit until the target volume is reached. Likewise, when the volume is too high the pressure is decreased. The algorithm starts with 3 or 4 test strokes, depending on the measured tidal volume. After the test strokes, the regular algorithm starts, that computes the target airway pressure during each breath. This target airway pressure is matched to the calculated compliance of the patients lung during the test strokes.

The user must set an upper and lower boundary for the inspiratory pressure range that is suitable for the patient's therapy. If this PCVR-controller is limited by such a pressure boundary it activates a corresponding event signal to indicate that the target volume cannot be reached due to one of these limitations. The maximum pressure difference between two consecutive inspirations is 3 mbar in both directions.

When the regular breathing pattern is interrupted, e.g. due to a recruitment maneuver or a disconnected breathing hose, the volume measurements cannot be used for the PCVR algorithm. If such interrupts occur the algorithm is temporarily suspended.



High Flow Oxygen

High Flow Oxygen Mode is a ventilation mode in which the ventilator delivers a constant flow with a set oxygen concentration. A gas mixture of air and oxygen, with a FiO_2 ranging between 0.21–1.0, that undergoes 100% humidification and is heated to approximately normal body temperature is delivered.

The adjustable settings are flow rate, oxygen concentration and trigger levels. When the pressure reaches 25 mbar, the flow is stopped for 3 seconds. After that time the flow restarts. If the trigger setting is active, the inspiration and expiration efforts of the patient will be recognized and the flow delivery is active in inspiration phase only using the pressure trigger. When the proximal flow sensor is selected, the standard flow and pressure trigger shall be used. When the proximal flow sensor is not selected, the internal sensors shall be used for triggering.

Kinking or obstruction of the hose may lead to inappropriate triggering or increase of pressure, which is detected by the flow and pressure sensors, stopping the flow if needed.

9.2.5.3 Ventilation settings per mode

Adult and Pediatric Patient Categories

Setting	Ventilation modes										
	PCV	PCV a/c	APRV	PRVC[1]	VCV[1]	VCV a/c[1]	BI LEVEL	CPAP	PC-SIMV	MMV[1]	VC-SIMV[1]
Pressure											
P_{in}	•	•	•[4]				•[4]	•[4]	•		
$P_{in\text{-}min}$				•							
$P_{in\text{-}max}$				•							
P_{limit}					•	•				•	•
P_{safety}[2]	•	•	•	•	•	•	•	•	•	•	•
P_{high}			•				•				
PS_{low}							•				
PS_{high}			•				•				
PS								•	•	•	•
PEEP	•	•	•	•	•	•	•		•	•	•
$P_{trigger}$[3]			•			•	•	•	•	•	•
Plateau					•					•	•
Volume											
VT				•	•	•				•	•
VT_{limit}	•	•	•[4]				•[4]	•[4]	•		
MV										•	
Time											
f (RR)	•	•	•	•	•	•	•	•[4]	•	•	•
T_{apnea}[2]	•	•	•	•	•	•	•	•	•	•	•
T_i	•	•	•[4]	•	•	•	•[3]	•[4]	•	•	•
T_{insp_max}											
T_{high}			•				•				
T_{low}											
T_{ramp}	•	•	•	•			•		•		
T_{limit} PS[2]	•	•	•	•	•	•	•	•	•	•	•
Oxygen											
FiO_2	•	•	•	•	•	•	•	•	•	•	•

[1] Only in invasive mode
[2] Safety setting
[3] Trigger setting only invasive mode
[4] Apnea backup setting

Neonatal Patient Category

Setting	Ventilation modes						
	PCV	PCV a/c	APRV	PRVC[1]	BILEVEL	CPAP	PC-SIMV
Pressure							
P_{in}	•	•	•[4]		•[4]	•[4]	•
$P_{in\text{-}min}$				•			
$P_{in\text{-}max}$				•			
P_{safety}[2]	•	•	•	•	•	•	•
P_{high}			•		•		
PS_{low}					•[3]		
PS_{high}			•[3]		•[3]		
PS						•[3]	•[3]
PEEP	•	•	•	•	•		•
Plateau							
Volume							
VT				•			
VT_{limit}	•	•	•[4]		•[4]	•[4]	•

Setting	Ventilation modes						
MV							
Time							
f (RR)	•	•	•	•	•	•[4]	•
T_{apnea}							
T_i	•	•	•[4]	•	•[4]	•[4]	•
T_{insp_max}							
T_{high}			•		•		
T_{low}							
T_{ramp}	•	•	•	•	•		•
T_{limit} PS[2]	•	•	•	•	•	•	•
Oxygen							
FiO_2	•	•	•	•	•	•	•

[1] Only in invasive mode
[2] Safety setting
[3] Trigger setting only invasive mode
[4] Apnea backup setting

9.2.5.4 Ventilation settings description

Symbol Units	**Description**	**Range** Resolution			**Default Settings**		
		Adult	**Pediatric**	**Neonate**	**A**	**P**	**N**
Pressure							
P_{in} mbar	Setting for the delivered inspiratory pressure in pressure controlled strokes	1 to 100 1	1 to 90 1	1 to 80 1	24	18	18
P_{limit} mbar	Maximum pressure allowed in volume controlled strokes	1 to 100 1	1 to 90 1	1 to 80 1	35	25	25
P_{safety} mbar	Maximum airway pressure setting allowed in the ventilator	2 to 100 1	2 to 100 1	2 to 100 1	50	50	50
P_{high} mbar	Upper pressure level in APRV and BILEVEL modes	5 to 100 1	5 to 90 1	5 to 90 1	20	15	15
P_{low} mbar	Lower pressure level in APRV and BILEVEL modes	0 to 50 1	0 to 50 1	0 to 50 1	5	5	5
P_{in_max} mbar	Maximum inspiratory pressure during PRVC ventilation	5 to 50 1	5 to 50 1	5 to 50 1	35	25	25
P_{in_min} mbar	Minimum inspiratory pressure during PRVC ventilation	2 to 30 1	2 to 30 1	2 to 30 1	24	18	18
PS_{high} mbar	Pressure support level relative to the higher pressure level in BILEVEL mode for patient triggered spontaneous breaths	0 to 99 1	0 to 89 1	0 to 79 1	5	5	5
PS_{low} mbar	Pressure support level relative to the lower pressure level in BILEVEL mode for patient triggered spontaneous breaths	0 to 50 1	0 to 40 1	0 to 30 1	5	5	5
PS mbar	Pressure support level relative to the PEEP level in SIMV, MMV and CPAP modes for patient triggered spontaneous breaths	0 to 50 1	0 to 40 1	0 to 40 1	5	5	5
PEEP mbar	Positive End-Expiratory Pressure	0 to 50 1	0 to 50 1	0 to 50 1	8	5	5
$P_{trigger}$ mbar	Sets the Inspiration pressure trigger threshold relative to PEEP	-20 to -0.5 1	-20 to -0.5 1	-20 to -0.5 1	-2	-2	-1
Flow							

Symbol Units	Description	Range Resolution			Default Settings		
F_i L/min	Sets the Inspiratory flow delivered during volume controlled strokes	1 to 200 1	1 to 90 1	0.5 to 30.0 0.1	18	9	1.9
$F_{trigger}$ L/min	Inspiration flow trigger threshold	0.1 to 20.0 0.1	0.1 to 20.0 0.1	0.1 to 20.0 0.1	5	3	3
Volume							
VT mL	Setting for the delivered tidal volume in volume controlled strokes	100 to 3000 10	20 to 300 10	2 to 50 1	500	200	21
VT_{max} mL	Maximum volume allowed in pressure controlled strokes	100 to 3000 10	20 to 300 10	2 to 50 1	500	200	21
MV L/min	Minute volume delivered to the patient during volume controlled strokes	0.5 to 25 0.1	0.5 to 25 0.1	0.1 to 7.5 0.1	6	3	0.6
Time							
I:E -	Sets the inspiratory to expiratory time ratio in controlled, assisted/controlled and PRVC modes	1:10 to 4:1	1:10 to 4:1	1:10 to 4:1	1:2	1:2	1:2
f(RR) /min	Sets the number of mandatory breaths per minute in controlled, assisted/controlled and PRVC modes	4 to 100 1	4 to 120 1	4 to 200 1	12	15	30
	Sets the number of mandatory breaths per minute in BILEVEL, MMV and SIMV modes	1 to 60 1	1 to 60 1	1 to 60 1	12	15	30
T_{apnea} s	Sets the time after which, if no patient breath is detected, the ventilator switches to apnea backup ventilation in CPAP mode	5 to 60	5 to 60	5 to 60	20	15	10
T_i s	Sets the inspiration time for mandatory breaths in SIMV and MMV modes	0.15 to 15.0 0.05	0.15 to 15.0 0.05	0.15 to 10.0 0.05	1.7	1.3	0.7
$T_{limit\ PS}$ s	Maximum inspiration time for pressure supported breaths	0.5 to 5.0 0.1	0.5 to 5.0 0.1	0.5 to 5.0 0.1	5.0	5.0	5.0
T_{high} s	Sets the duration of the upper pressure level in BILEVEL mode	0.15 to 15.0 0.05	0.15 to 15.0 0.05	0.15 to 15.0 0.05	1.7	1.3	0.7
	Sets the duration of the upper pressure level in APRV mode	0.15 to 15.0 0.05	0.15 to 15.0 0.05	0.15 to 15.0 0.05	5.4	3.5	1.4
T_{low} s	Sets the duration of the lower pressure level in APRV mode	0.15 to 59.8 0.05	0.15 to 59.8 0.05	0.15 to 59.8 0.05	0.6	0.5	0.2
T_{ramp} s	Sets the time it takes to reach the target pressure level in pressure controlled strokes	0.0 to 2.0 0.1	0.0 to 2.0 0.1	0.0 to 0.5 0.1	0.1	0.1	0.1
Oxygen							
FiO_2 %	Sets the inspired oxygen concentration	21 to 100 1	21 to 100 1	21 to 100 1	40	40	21

9.2.5.5 Ventilation curves and loops

Symbol units	Description	Range	Res.	Accuracy
Curves				
Pressure mbar	Measured airway pressure	-5 to 105	0.1	± (2 mbar + 4 % of reading)
P_{trach} mbar	Calculated endotracheal pressure when TC is active (see TC). Displayed with the pressure curve	-10 to 110	0.1	± (5 mbar + 10 % of reading)

Symbol units	**Description**	**Range**	**Res.**	**Accuracy**
P_{cuff} mbar	Measured cuff pressure when cuff control is active (see Cuff Control). Displayed with the pressure curve	-5 to 120	0.1	± (2 mbar + 4 % of reading)
P_{aux} mbar	Measured pressure at the pressure auxiliary port	-105 to 105	0.1	± (4 mbar + 8 % of reading)
Flow L/min	Measured inspiratory and expiratory flow at the proximal flow sensor	**Adult/Pediatric** -200 to 200 **Neonate** -30 to 30	0.1	**Adult/Pediatric** ± 15% of reading or +/-1% FSS* mL/min, whichever is greater **Neonate** ± 15% of reading or +/-1% FSS mL/min, whichever is greater * Flow sensor spec. Depends on the flow sensor used. See compatible flow sensor specifications.
Volume mL	Real-time volume calculated from the patient flow sensor measurement	-6500 to 6500	1	**Adult/Pediatric** ± 15% of reading or +/-15 ml, whichever is greater **Neonate** ± 15% of reading or +/-2 mL, whichever is greater
CO_2 %	CO_2 calculated in vol% (optional)	0 to 25	0.1	± (2 kPa + 4 % of reading)
Loops				
P-V	Pressure vs Volume			
V-F	Volume vs Flow			
P-F	Pressure vs Flow			
V-CO_2	Volumetric capnography			

9.2.5.6 Ventilation alarm messages

Non-technical alarms

Prio.	**Alarm message**	**Possible cause**	**Proposed remedy**
M	Air inlet blocked	- Measured air flow is low which is an indication for a clogged input filter or air intake obstruction Blower mode only. Blower cannot generate enough flow	- Check filter - If possible, switch to high pressure air input - If not, replace the ventilator module or provide an alternative ventilation.
H	Apnea	- No spontaneous inspiration detected since the set apnea time	- Check patient status - Check apnea settings - Check trigger settings - If necessary, switch to a mandatory ventilation mode.
-	Backup gas active	- Backup Gas Source Active. Set, when the required gas is not available and another source is used.	- Check gas supply status

Prio.	Alarm message	Possible cause	Proposed remedy
H	Circuit disconnection	- Breathing circuit was disconnected on patient side and/or on ventilation side - Significant leakage	- Check patient status - Reconnect circuit
H	Circuit occlusion	- There is an occlusion in the expiratory limb of the breathing circuit. On an occlusion event, the pressure will be released to ambient.	- Check patient airway for obstructions - Check breathing circuit and expiratory valve - If necessary, replace ventilation circuit - If error persists, replace ventilation module or provide an alternative ventilation.
L	Expiratory hold active	- Expiratory hold maneuver is active	- If needed, stop maneuver
H	FiO2 high	- The measured FiO2 is > than the set alarm limit - O2 sensor calibration necessary	- Check patient status - Check oxygen settings and alarm limits - If error persists, recalibrate the oxygen sensor
H	FiO2 low	- The measured FiO2 is < than the set alarm limit - O2 sensor calibration necessary	- Check patient status - Check oxygen settings and alarm limits - Check for leakages - If error persists, recalibrate the oxygen sensor
M	Input air temperature high	- The input air gas temperature was higher than 40°C for more than 2 seconds - Ambient temperature too high	- Move the device to a cooler area
M	Inspiratory flow high	- The measured inspiratory flow is higher than the set alarm limit	- Check ventilation settings and alarms - Monitor changes in patient's resistance and compliance.
M	Inspiratory flow low	- The measured inspiratory flow is lower than the set alarm limit	- Check ventilation settings and alarms - Monitor changes in patient's resistance and compliance.
L	Inspiratory hold active	- Inspiratory hold maneuver is active	- If needed, stop maneuver
M	Replace Ventilator	- The supply voltage for the ventilation module is lower than 9 V	- Check the connection of the ventilation module to the Docking Station
H	Leak high	- Leakage Volume is high -	- Check hoses, circuits and interfaces for leakages

Prio.	Alarm message	Possible cause	Proposed remedy
L	LPO error	- Oxygen supply pressure > 800 mbar when LPO is active	- Check oxygen supply status - Adjust Oxygen source settings
M	Mean airway pressure high	- The measured mean airways pressure is higher than the set alarm limit	- Check pressure settings - Check PEEP settings
M	Mean airway pressure low	- The measured mean airways pressure is lower than the set alarm limit	- Check pressure settings - Check PEEP settings
H	Minute volume high	- The measured expiratory minute volume is > than the set alarm limit - Possibility of hyperventilation due to inappropriate frequency and volume settings	- Check ventilation settings and alarms - Monitor changes in patient's resistance and compliance.
H	Minute volume low	- The measured expiratory minute volume is > than the set alarm limit - Possibility of hypoventilation due to inappropriate frequency and volume settings - Possible partial occlusion of the expiratory limb	- Check ventilation settings and alarms - Monitor changes in patient's resistance and compliance. - Check breathing circuit
M	Motor temperature high	- Motor Temperature > 70 °C => -	- Reduce the ventilation settings to prevent overheat
H	Motor temperature high	- Motor Temperature > 110°C. Blower is disabled (until the temperature is below 70°C).	- Reduce the ventilation settings to reduce overheat If not possible, replace the ventilator module or provide an alternative ventilation.
H	No Air supply	- The compressed air supply pressure is too low (< 1.5 bar). The ventilator will switch to Blower mode	- Check patient - Check air source
H	No O2 supply	- The oxygen supply pressure is too low (< 2.5 bar)	- Check oxygen source - Provide an alternative oxygen source
H	Output gas temperature high	- Output gas temperature is > 68°C for more than 2 seconds - Ambient temperature too high - Extremely high pressure setting during ventilation with blower - Extremely high inspiration time while ventilation with blower - Blower temperature high	- Move to a cooler area - Decrease inspiratory pressure - Increase Tramp - Increase expiration time

Prio.	Alarm message	Possible cause	Proposed remedy
H	Output gas temperature low	- Temperature of the output gas is < 5°C	- Move to a warmer area - If needed, use a heated humidifier system - Increase inspiratory pressure - Decrease Tramp - Reduce expiration time
H	Patient flow measurement invalid	Proximal flow sensor defective	- Replace flow sensor
L	PCVR Pin-max reached	- The set tidal volume cannot be reached with the set Plim_max	- Reduce set tidal volume - Increase Plim_max
L	PCVR Pin-min reached	- The pressure delivered in PCVR is under the minimum pressure set	- Increase set tidal volume - Reduce Plim_min
H	Peak pressure high	- Patient airways obstruction - Wrong intubation - Kinked hoses, ET tube - Wrong ventilation settings	- Check patient airways - Check hoses and ET tube - Check ventilation settings and alarms
H	Peak pressure low	- Circuit leakage - Significant leakage in mask (NIV) - Wrong intubation - Wrong ventilation settings	- Check patient circuit for leakages - Check ET tube - Check mask adjustment to the patient (NIV) - Check ventilation settings and alarms
M	PEEP deviation	- Set PEEP – Measured PEEP > 10% of setting or 3 mbar (whichever is greater) for 3 consecutive breaths -	- Check patient airways - Check hoses and ET tube - Check ventilation settings and alarms
M	PEEP high	- The measured PEEP is > than the set alarm limit - Patient airways obstruction - Wrong intubation - Kinked hoses, ET tube - Defective exhalation valve - Wrong ventilation settings	- Check patient airways - Check hoses and ET tube - Check ventilation settings and alarms
M	PEEP low	- The measured PEEP is < than the set alarm limit - Significant leakage in the expiratory limb or exhalation valve control hose - Expiratory valve defective	- Check patient circuit for leakages - Check exhalation valve - Check ventilation settings and alarms

Prio.	Alarm message	Possible cause	Proposed remedy
H	Possible filter contamination	- Emergency valve has opened	- Check bacterial filter status - Check expiratory valve - If needed, replace bacterial filter
L	Pressure limit reached	- The measured patient pressure is higher than the safety pressure for more than 20 milliseconds - The maximum pressure set in a volume controlled mode is reached before the set volume is delivered	- Increase Psafety - Increase Pmax
L	Relief to ambient pressure	- The measured patient pressure is higher than the Pmax setting for more than 300 milliseconds	- The ventilator changes to ambient pressure as a safety measure
L	Relief to PEEP	- The measured patient pressure is higher than the Pmax setting for more than 170 milliseconds	- The ventilator changes to PEEP level as a safety measure
M	RR high	- The total measured respiration rate is higher than the set alarm limit - Hyperventilation - Auto-trigger - Uncalibrated flow sensor	- Check ventilation settings and alarms - Check trigger sensitivity setting - Check flow sensor
M	RR low	- The total measured respiration rate is lower than the set alarm limit - Hyperventilation - Triggered breaths may not be recognized - Uncalibrated flow sensor	- Check ventilation settings and alarms - Check trigger sensitivity setting - Check flow sensor
M	Safety pressure reached	- The safety pressure limit set by the user has been reached - Patient airways obstruction - Wrong intubation - Kinked hoses, ET tube - Wrong ventilation settings	- Check patient airways - Check hoses and ET tube - Check ventilation settings - Check Psafety setting
M	Tidal volume high	- The measured expiratory volume is higher than the set alarm limit	- Check ventilation settings and alarms - Monitor changes in patient's resistance and compliance.

Prio.	Alarm message	Possible cause	Proposed remedy
M	Tidal volume low	- The measured expiratory volume is lower than the set alarm limit - Possible partial occlusion on the expiratory limb	- Check ventilation settings and alarms - Monitor changes in patient's resistance and compliance. - Check breathing circuit
L	Vti reached	- The maximum tidal volume set in a pressure controlled mode is reached before the set pressure is delivered	- Increase Vtmax - Decrease set inspiratory pressure
M	Cuff Pressure High	- Measured Cuff Pressure > Cuff Pressure Target – (Cuff Pressure Offset + 10% Cuff Pressure Target for at least 1 sec	- Check patient status - Deflate cuff
M	Cuff pressure low	- Measured Cuff Pressure < Cuff Pressure Target – (Cuff Pressure Offset + 10% Cuff Pressure Target) for at least 2 sec	- Check patient status - Check cuff status - Inflate cuff
M	Cuff disconnection	- Measured cuff pressure is within the band 0-8 mbar for more than 2 sec	- Check connecting line - Check patient status

Technical alarms

Refer to the Appendix A for a description of the technical alarms.

9.2.5.7 Alarm delays

Alarm	**Delay**
P_{peak} mbar	At the beginning of the following inspiration
P_{mean} mbar	At the beginning of the following inspiration
PEEP mbar	At the beginning of the following inspiration
MV_e L/min	Calculated over the last 20 (adults) or 10 (neonates) seconds, every second
V_e mL	Average over the last 3 breaths, at the beginning of the following inspiration
F_i L/min	At the beginning of the following inspiration
f /min	Average over the last 8 breaths or 25 s (whatever is reached first), at the beginning of the following inspiration
FiO_2 %	After 9 s (analog sensor) or 11 s (digital sensor), at the beginning of the following inspiration

9.2.5.8 Ventilation monitored values

Type	Description
Stroke-Wise Measurements	Updated with every 'respiratory cycle and resettable (when they are activated): • Spontaneous measurements • Mandatory measurements • ``MandOrCPAP`` measurements • Total Measurements
Real-time measurements	Calculated continuously, directly based upon sensors (e.g. Air Flow, Oxygen Flow). The signals which are send over the interface are not the raw measured values, they are filtered at 10Hz.
Tracheal pressure	Estimation of the pressure in the trachea based on the patient airway pressure and patient flow. The accuracy depends entirely on the settings (tube diameter and length) as given by the user.
Patient Volume	Running integral of the leakage-compensated patient flow. Reset to zero at the start of every mandatory or CPAP inspiration.

Symbol	Description	Range	Res.	Accuracy
Pressure				
P_{peak}	Maximum patient pressure measured during inspiration cycle	-5 to 105	1	± (2 mbar + 4 % of reading)
PEEP	Patient pressure measured at the end of expiration	-5 to 105	1	± (2 mbar + 4 % of reading)
P_{mean}	Average pressure in a respiratory cycle	-5 to 105	1	± (2 mbar + 4 % of reading)
P_{min}	Minimum patient pressure measured during expiration cycle	-5 to 105	1	± (2 mbar + 4 % of reading)
P_{plat}	Patient Pressure measured at the end of inspiration	-5 to 105	1	± (2 mbar + 4 % of reading)
$P_{ambient}$	Ambient pressure	500 to 1100	1	± 35 mbar
$P_{0.1}$ mbar	P0.1 pressure after maneuver	-105 to 5	1	± (2 mbar + 25 % of reading)
P_{ipeep} mbar	Intrinsic peep pressure after maneuver	-5 to 105	1	± (2 mbar + 10 % of reading)
P_{nif} mbar	NIFpressure after maneuver	-105 to 5	1	+/- (6% of measured value or 2mbar whichever is greater)
Flow				
F_i	Peak flow during inspiration cycle	**Adult/ Pediatric** 0 to 200 **Neonate** 0 to 30	1	**Adult/Pediatric** ± 15% of reading or +/-1% FSS* mL/min, whichever is greater **Neonate** ± 15% of reading or +/-1% FSS mL/min, whichever is greater * Flow sensor spec. Depends on the flow sensor used. See compatible flow sensor specifications.
F_e	Peak flow during expiration cycle	**Adult/ Pediatric** -200 to 0 **Neonate** -30 to 0	1	**Adult/Pediatric** ± 15% of reading or +/-1% FSS mL/min, whichever is greater **Neonate** ± 15% of reading or +/-1% FSS mL/min, whichever is greater
F_{leak}	Average leakage flow	0 to 50	1	-
Volume				
V_{comp}	Compressible volume of the hose system	0 to 5000	1	-

Symbol	Description	Range	Res.	Accuracy
V_i mL	Total inspired tidal volume	0 to 6500	1	± (2 ml + 15 % of reading)
$V_{i\text{-}spont}$ mL	Spontaneous inspired tidal volume	0 to 6500	1	**Adult/Pediatric** ± (4 ml + 15 % of reading) **Neonate** ± (2 ml + 15 % of reading)
V_e mL	Total expired tidal volume	0 to 6500	1	**Adult/Pediatric** ± (4 ml + 15 % of reading) **Neonate** ± (2 ml + 15 % of reading)
$V_{e\text{-}spont}$ mL	Spontaneous expired tidal volume	0 to 6500	1	± (2 ml + 15 % of reading)
V_{leak} mL	Measured volume of leakage flow during a respiration cycle	0 to 5000	1	Indicative
MV_i L/min	Measured total inspiratory minute volume	0 to 100	0.1	**Adult/Pediatric** +/-400 mL/min ± 15% of reading **Neonate** ± 15% of reading or +/-50 mL/min, whichever is greater
MV_e L/min	Measured total expiratory minute volume	0 to 100	0.1	**Adult/Pediatric** +/-400 mL/min ± 15% of reading **Neonate** ± 15% of reading or +/-50 mL/min, whichever is greater
$MV_{e\text{-}spont}$ L/min	Measured spontaneous expiratory minute volume	0 to 100	0.1	**Adult/Pediatric** +/-15% of reading or +/-400 mL/min, whichever is greater **Neonate** ± 15% of reading or +/-50 mL/min, whichever is greater
$MV_{e\text{-}mand}$ L/min	Measured mandatory expiratory minute volume	0 to 100	0.1	**Adult/Pediatric** +/-15% of reading or +/-400 mL/min, whichever is greater **Neonate** ± 15% of reading or +/-50 mL/min, whichever is greater
$V_{real\text{-}time}$ mL	Real-time volume based on the patient flow sensor	0 to 6500	1	**Adult/Pediatric** +/-15% of reading or +/-15 mL, whichever is greater **Neonate** ± 15% of reading or +/-2 mL, whichever is greater
Time				
I:E -	Ratio inspiratory time to expiratory time			-
f(RR) /min	Total respiratory rate	0 to 250	1	± 10% of reading or 2bpm, whichever is greater
f_{spont} /min	Respiratory rate of spontaneous breaths	0 to 250	1	± 10% of reading or 2bpm, whichever is greater
$\%f_{spont}$ %	Percentage of the spontaneous breaths	0 to 100	1	± 10% of reading or 2bpm, whichever is greater
T_i s	Inspiration time	0 to 100	0.1	± (50 ms + 5% of reading)
T_e s	Expiration time	0 to 100	0.1	± (50 ms + 5% of reading)
Oxygen				
FiO_2 %	Fraction of inspired Oxygen	15 to 100	1	± (2.5 vol% + 2.5% of reading)

Symbol	Description	Range	Res.	Accuracy
P_{O2} bar	Pressure of the oxygen supply source	0 to 9.5	1	± (200 mbar + 5% of reading)
Respiratory mechanics				
C_{stat} mL/mbar	Patient lung compliance calculated from airways pressure and patient flow with a least squares approximation during a mandatory respiration cycle	0 to 1000	1	± (5mL/mbar + 20% of reading)
C_{dyn} mL/mbar	Measured compliance C_{dyn} = VT/(PIP-PEEP)	0 to 1000	1	± (5mL/mbar + 20% of reading)
C_{20}/C_{dyn} -	Ratio of dynamic compliance during the last 20% of inspiration to the total dynamic compliance	0 to 10	1	-
C_{20}/C_{stat} -	Ratio of static compliance during the last 20% of inspiration to the total static compliance	0 to 10	1	-
R mbar/L/s	Patient airways resistance calculated from airways pressure and patient flow with a least squares approximation during a mandatory respiration cycle	0 to 1000	1	± (5mbar/L/s + 20% of reading)
Other calculated values				
RSBI -	Ratio of spontaneous respiratory rate to spontaneous expiratory volume	0 to 10000	1	10 breaths/min/L or 25% of reading, whichever is greater
WOB J	Work of Breath	0 to 100	1	± (0.5 J + 10% of reading)

9.2.5.9 Delivery accuracy

Setting	Accuracy
Inspiratory pressure	± (2 mbar + 5 % of setting)
End expiratory pressure	± (2 mbar + 5 % of setting)
Tidal volume *Flow-controlled Ventilation* *(Inspiratory Flow > 3 L/min + VT > 50 mL)*	**Adult/Pediatric** ± (20 mL + 15% of setting) **Neonate (PCVR only)** ± (2 mL + 15% of setting)
O_2 concentration	± (3 vol% + 3% of setting)
Inspiratory rise time	± (25% of T_{ramp} setting + 10 milliseconds)
Cuff pressure offset	± (5 mbar + 10% of setting)
Continuos flow (High Flow Oxygen)	± (0,5 L + 10% of setting)

Note: Accuracy is maintained only: if the device is used in specified environmental conditions, used only as intended and all maintenance procedures are done as described in this document.

9.2.5.10 Measured uncertainty

Measured parameter	Measurement Uncertainty
Flow	**Adult/Pediatric** 0.1 SLPM or 1.75 % of reading **Neonate** Low Flow: ±1.75 % of reading or ±0.05 sl/min
Pressure	**Adult/Pediatric** 0.1 mbar or 0.3 % of reading **Neonate** ±0.75% of reading or ±0.1 mbar
Oxygen concentration	1 % of reading
Ambient pressure	5 mbar or 1 % of reading
Temperature	0.5 °C or 1.75 % of reading

NOTE:

For all derived parameters (volume, compliance, etc.) the uncertainty will be a combination of the primary parameters involved in the measurement calculation.

9.2.5.11 Oxygen Delay

Setting	Accuracy
Adult/Pediatric Compliance: 20, Resistance: 5, PEEP: 5, VT: 500 mL Compliance: 20, Resistance: 20, PEEP: 5, VT: 150 mL	Response time till 90%: 25 s Base flow set to lowest level per default: 3 L/min Response time till 90%: 25 s Base flow set to lowest level per default: 3 L/min
Neonate (PCVR mode) Compliance: 3, Resistance: 50, PEEP: 5, VT: 30 mL	Response time till 90%: 70s

9.2.5.12 Ventilation alarm limits

Symbol units	**Range** Resolution			**Default Settings**						**Auto set**
	Adult	**Pediatric**	**Neonate**	**Adult**		**Pediatric**		**Neonate**		
				L	**H**	**L**	**H**	**L**	**H**	
P_{peak} mbar	0 to 102 1	0 to 102 1	0 to 102 1	5	35	5	25	5	25	P_{peak} ± 5
P_{mean} mbar	0 to 82 1	0 to 82 1	0 to 82 1	5	30	5	20	5	20	P_{mean} ± 5
PEEP mbar	0 to 52 1	0 to 52 1	0 to 52 1	0	10	0	10	0	10	PEEP± 2
MV_e L/min	0 to 200 0.5	0 to 100 0.5	0 to 15 0.05	3	20	1.5	10	0.2	6	MV_e ± 30 %
V_e mL	0 to 2000 10	0 to 500 10	0 to 75 1	250	750	100	300	10	30	V_e ± 50 %
f /min	0 to 200 1	0 to 200 1	0 to 200 1	5	40	5	60	10	80	Rate ± 40 %
FiO_2 %	15 to 103 1	15 to 103 1	15 to 103 1	20	100	20	100	20	100	Oxygen ± 5 %
$FiCO_2$ %	1 to 4 1	1 to 4 1	1 to 4 1	-	1.0	-	1.0	-	1.0	-
$EtCO_2$ vol%	0 to 13 1	0 to 13 1	0 to 13 1	2.0	6.5	2.0	6.5	4.0	6.0	$EtCO_2$ ± 0.8

9.2.5.13 Power Source Specifications

Power Source Specifications	
Switchover to the Internal electrical power source or External reserve electrical power source	The ventilator continues working without interruption or change in behavior.
When Internal electrical power source or External reserve electrical power source are recharging	The ventilator continues working without interruption or change in behavior.

9.2.6 Breathing system characteristics

VBS technical characteristics	
Inspiratory gas pathway resistance	
Adult	From 0.2 to 12.5 $cmH_2O/L/s$
Pediatric	From 0.2 to 7.5 $cmH_2O/L/s$
Neonate	From 0.2 to 3.5 $cmH_2O/L/s$
Expiratory pathway resistance	

VBS technical characteristics	
Adult	From 0.2 to 12.5 $cmH_2O/L/s$
Pediatric	From 0.2 to 7.5 $cmH_2O/L/s$
Neonate	From 0.2 to 3.5 $cmH_2O/L/s$
VBS compliance	
Adult	From 1.0 to 12 mL/cmH_2O
Pediatric	From 1.0 to 9 mL/cmH_2O
Neonate	From < 0.25 to > 3.5 mL/cmH_2O

9.2.7 Breathing filters characteristics

Breathing filters technical characteristics	
Inspiratory filter Resistance	
Inspiratory filter Resistance	1.19 mbar @ 30 L/min
Air inlet filter resistance	
Air inlet filter resistance	0.2 mbar @ 30 L/min
HME filter Resistance recommended ranges	
Adult	From 0.9 to 1.6 mbar@30 L/min (dead spaces from 55 to 90 mL)
Pediatric	From 0.4 to 1.6 mbar@30 L/min (dead spaces from 25 ml)
Neonate	Until 1.9 mbar @ 15 L/min (for a 2mL dead space filter) From 0.4 to 0.6 @ 5 L (min (for 8 or 10 mL dead space)

9.2.8 Oxygen Sensors Specifications

Galvanic Oxygen Sensor (OOM102-HS) Specifications	
Physical Specifications	
Weight	Approx. 28 grams
Environmental Specifications	
Operating Temperature	0 to 50°C
Operating Humidity	0-99 % RH non-condensing
Storage Temperature	-20 to +50 °C
Recommended Storage	+5 to +15 °C
Electrical Specifications	
Electrical Interface	3pin-Molex (22-11-1031)
Output in ambient air	13 to 16mV
Zero Offset Voltage	< 200 µV in 100 % nitrogen applied after 5 min
Recommended Load	10 kOhms
Performance Specifications	
Technology	Galvanic
Measurement Range	0-100 % oxygen
Accuracy and Repeatability	< 1 % vol. O2 when calibrated at 100 %
Oxygen Linearity error	< 3 % relative
Response time	< 12sec. to 90 % of final value
Influence of Humidity	0.03 % rel. per % RH at 25°C
Influence of Pressure	Proportional to change in oxygen partial pressure
Influence of Mechanical Shock	< 1% relative after a fall from 1m
Temperature Compensation	Built-in NTC compensation
Effect of Temperature Compensation (steady state):	Between +25°C and +40°C: 3 % relative error Between 0 °C and +50 °C: 8 % relative error
Long Term Output Drift	< 1 % vol. oxygen per month Typically < - 15 % relative over lifetime
Warm-Up Time	< 30 minutes, after replacement of sensor
Cross Interference	Meets EN ISO 21647 requirements
Nominal Sensor Lifetime	1.000.000 % vol. oxygen hours

Note: All specifications are applicable at standard conditions: 1013 hPa, 25°C dry ambient air

Paramagnetic Oxygen Sensor Specifications	
Physical Specifications	
Weight	70 g(2.47 oz)
Environmental Specifications	
Operating Temperature	5 to 50 °C
Operating Humidity	0 to 95%, non-condensing
Storage Temperature	-30 to +70 °C
Operating Pressure Range	±33 kPag (±5 psig)
Electrical Specifications	
Power Consumption	350 mW
External Power Supply	5V DC, 70 mA nominal
Performance Specifications	
Technology	Paramagnetic
Measurement Range	0-100 % oxygen (with overrange -15 % to + 200% oxygen)
Accuracy (Intrinsic Error)	±0.2% O2
Linearity	±0.2% O2
Repeatibility	±0.2% O2
Zero Drift	±0.4% O2 in the first 24 h, then ±0.2% O2/week, then ±0.2% O2/month
Response Time ($T_{10} – T_{90}$)	11 to 20 seconds (dependent on application and filter selection)
Signal Output	Digital UART or linear mV output (0.5 mV or 10 mV per %O2)
RoHS	Complies with RoHS Directive 2002/95/EC

9.3 Monitoring module (Optional)

9.3.1 Product life cycle

The Monitor module has a life time of minimum of 5 years.

NOTE:

The lifetime of the device is guaranteed only in the case that all the maintenance and service tasks, as well as the replacement of components have been performed accordingly to the indications given in the Service Manual.

9.3.2 Physical specifications

Physical specifications	
Dimensions	
Height	71 mm
Width	400 mm
Depth	164 mm
Weight	
Weight	1.72 kg

9.3.3 Environmental specifications

Environmental specifications	
Temperature	
Operating temperature range	-20 to + 50 °C (at ≤ - 10 °C for at least 20 minutes)
Storage temperature range	-10 to +50 °C
Humidity	
Operating humidity range	30 to 75% non-condensing
Air pressure	
Operating air pressure range	700 hPa to 1060 hPa
Maximum operating altitude	Approx. 4000 meters
IP protection level	
Protection against water	IP54

9.3.4 Electrical specifications

Safety specifications	
Protection against electric shock	
Type of protection against electric shock	**Class II**
Degree of protection against electric shock	**ECG-** Type CF defibrillation protected **IBP -** Type CF defibrillation protected **Temperature-** Type CF defibrillation protected **SpO2 –** Type CF defibrillation protected **NIBP** – Type CF defibrillation protected **Capnography –** Type CF measured with the capnometry probe connected
Mode of operation	**Continuous**

9.3.5 Performance specifications

9.3.5.1 ECG

Monitoring ECG Specifications	
General	
Standards	EN 60601-2-27 / IEC 60601-2-27, IEC 60601-2-25
Lead type	3 lead: I, II, III 5 lead: I, II, III, aVR, aVL, aVF, V 12 lead: I, II, III, aVR, aVL, aVF, V1-V6
Lead standard	AHA, IEC
Gain	2.5 mm/mV, 5 mm/mV (0.25x), 10 mm/mV (1x), 20 mm/mV (2x), Auto
CMRR	**Diagnostic mode:** ≥ 89 dB **Monitor mode:** ≥ 105 dB **Surgery mode:** ≥ 105 dB
Bandwidth (-3 dB)	**Diagnosis mode:** 0.05 - 120 Hz **Monitor mode:** 0.5 - 40 Hz **Surgery mode:** 1 - 25 Hz
Input impedance	≥ 5.0 MΩ
ECG signal range	± 10.0 mV
Electrode offset potential	± 500 mV
Isolation	Break Down Voltage: 4000 VAC
Electrode offset potential	± 500 mV
Patient leakage current	< 10 uA
System noise	≤ 30 μVpp (RTI)
Power line filter (50/60 Hz)	**Monitor and Surgery mode:** On **Diagnosis mode:** Off
Baseline recovery	**Monitor mode:** ≤ 3 s (< 5 s after defibrillation) **Surgery mode:** ≤ 1 s (< 5 s after defibrillation)
Recovery time of electrodes after defibrillation	Recovery to baseline in 10 s.
ESU protection (cauterization unit)	Cut mode: 300 W Coagulation mode: 100W HR variation ≤10% Resuming time: ≤10s
Input circuit current	< 0.1uA
Pacemaker pulse display capability	**Pacing pulse amplitudes:** ±2 mV to ±700mV **Pacing pulse widths:** 0.1 milliseconds to 2.0 milliseconds **Rise time:** 10 us to 100 us
Pacer pulse mark	Pacemaker pulse indicator displayed in the screen with amplitude ≥ 0.2 mV (2mm for a 10mm/mV gain)
Pacemaker pulse rejection	Rejection of pacemaker pulses with amplitudes from ±2 mV to±700 mV and widths from 0.1 milliseconds to 2.0 milliseconds (Method A)
Heart Rate Meter	
Measurement range	**Adult:** 10 bpm to 300 bpm **Pediatric and Neonate**: 10 bpm to 350 bpm
Resolution	1 bpm
Accuracy	±1% or ±1 bpm, whichever is greater
Detecting sensitivity (II lead)	≥0.20mVpp
Response time to changes in HR	HR change from 80 bpm to 120 bpm: less than 10 s HR change from 80 bpm to 40 bpm: less than 10 s
Tall T-Wave rejection capability	The HR meter rejects all T-waves with amplitudes less than 1.2 mV.
Response to QRS complex with amplitude 1mVpp and width 10 milliseconds.	**Adult:** No response

Monitoring ECG Specifications	
Heart rate averaging	≤ 50 bpm: Once every two beats; 50 bpm to 120 bpm: Once every four beats > 120 bpm: Once every six beats.
HR meter accuracy and response to irregular rhythm	**A1:** Ventricular bigeminy: 80 bpm **A2**: Slow alternating ventricular bigeminy: 60 bpm **A3:** Rapid alternating ventricular bigeminy: 120 bpm **A4:** Bidirectional systoles: 90 bpm
Arrhythmias	
Time to alarm ventricular tachycardia (V-Tach)	**B1:** Amplitude 1 mVpp and HR 206 bpm Gain 0.5x: Range 6.5 s to 8.4 s, Average 7.2 s Gain 1x: Range 6.1s to 6.9 s, Average 6.5 s Gain 2x: Range 5.9s to 6.7s, Average 6.3 s
	B2: Amplitude 2 mVpp and HR 195 bpm Gain 0.5x: Range 5.4s to 6.2s, Average 5.8s Gain 1x: Range 5.7s to 6.5s, Average 6.1s Gain 2x: Range 5.3s to 6.1s, Average 5.7s
ST segment analysis	
Measurement range	-2.0 mV to +2.0 mV
Resolution	0.01 mV
Accuracy	**-0.8 mV to +0.8 mV**: ±0.02 mV or ±10%, whichever is greater; **Over ±0.8mV:** Not specified
User Selectable ST Measurement Points:	0 to 400 milliseconds after the R-peak in steps of 4 milliseconds
Default ST Measurement Point	108 milliseconds
User selectable ISO point	0 to 400 milliseconds before the R-peak in steps of 4 milliseconds
Default ISO Point	80 milliseconds
ECG Printer	
Type	Thermal dot array
Paper width	10 cm
Paper length	480 cm
Printing speed	25 mm/s, 50 mm/s
Printing field	Up to 12 ECG waveforms (in 6x2 or 4x3)
Printing display	Real time (3 or 4 leads), report (Standard, Cabrera), HES
Horizontal resolution	8 dots/mm (at 25 mm/s paper speed)
Vertical resolution	8 dots/mm

9.3.5.2 Pulse-CO Oximeter

Masimo Rainbow SET ® Pulse-CO Oximetry specifications	
Display Ranges	
Oxygen Saturation (SpO_2)	0-100%
Pulse Rate (beat per minute or bpm)	25-240 bpm
Carboxyhemoglobin Saturation (SpCO)	0-99%
Methemoglobin Saturation (SpMet)	0-99.9%
Total Hemoglobin (SpHb)	0-25 g/dL
Total Oxygen Concentration (SpOC)	0-35 ml/dL
Perfusion Index (PI)	0.02-20%
Pleth Variability Index (PVI)	0-100%
Oxygen Reserve Index	0.00 – 1.00
Accuracy	

Masimo Rainbow SET ® Pulse-CO Oximetry specifications	
SpO2, No Motion	60 - 80 ± 3%, adults/pediatrics/infants 70-100 ± 2%, adults/pediatrics/infants, ± 3 neonates
SpO2, Motion	70 – 100 ± 3%, adults/pediatrics/infants/neonates
SpO2, Low Perfusion	70 – 100 ± 2%, adults/pediatrics/infants/neonates
Pulse Rate, No Motion	25-240 ± 3 bpm, adults/pediatrics/infants/neonates
Pulse Rate, Motion	25-240 ± 5 bpm, adults/pediatrics/infants/neonates
Pulse Rate, Low Perfusion	25-240 ± 3 bpm, adults/pediatrics/infants/neonates
SpCO	1-40 ± 3%, adults/pediatrics/infants
SpMet	1 – 15 ± 1%, adults/pediatrics/infants/neonates
SpHb	8 -17 ± 1 g/dL (arterial or venous), adults/pediatrics
General	
Resolution	SpO_2: 1% Pulse Rate: 1 bpm SpCO: 1% SpMet: 0.1% SpHb: 0.1 g/dL
Measurements	Perfusion Index (PI) Total Oxygen Concentration (SpOC) Pleth Variability Index (PVI) Oxygen Reserve Index (ORI)
Electrical specifications	
Power (AC)	Voltage Input Range: 100-240 VAC, 47-63 Hz
Circuitry	Microprocessor controlled Automatic self-test of Pulse-CO Oximeter when powered on Automatic setting of default parameters Automatic alarm messages Trend data output
Firmware	Rainbow SET Technology, MX Board/Circuitry
Mechanical specifications	
Material	Polycarbonate/ABS Blend
Environmental specifications	
Operating Temperature	0 to 50 °C
Storage Temperature	-40 to 70 °C
Relative Storage Humidity	10 to 95% non-condensing
Operating Altitude	Pressure: 500 – 1060 mbar Altitude: - 304 to 5486 m
Mode and Sensitivity	
SpO_2 Averaging Mode	2,4,6,8,10,12 and 16 secs; FastSat™
SpO_2 Sensitivity	APOD, Normal, Maximum
Alarms	
Volume Level Adjustment: Pulse/Tone	OFF, 25% to 100% in 4 increments
Alarm Silence	120 seconds delay; All mute: Continuous silence
Out of Limit Alarms: SpO_2, Pulse Rate, SpCO, SpMet, SpHb, PI, PVI	High/Low Alarms
Sensor Condition Alarm	No Sensor; Sensor Off; Sensor Defect
System	System Failure
Battery Alarm	Low Battery
Display and Indicators	

Masimo Rainbow SET ® Pulse-CO Oximetry specifications	
Data Display	SpO_2 (%) Pulse rate (bpm) SpCO (%) SpMet (%) SpHb (g/dL) SpHbv (g/dL) SpOC (ml/dL) Perfusion Index – PI (%) Pleth Variabilty Index PVI (%) Pleth waveform Signal IQ Sensitivity indicator Sensor status Sensor time Status messages Alarm status Battery Status ORI
Output Interface	
Satshare	Connection to Multiparameter monitors (SpO_2 only)
Serial Port (RS-232 connector)	PC/printer connection Philips Vuelink Spacelabs Universal Flexport RadNet Patient Safety Net Trends
Compliance	
EMC Compliance	EN 60601-1-2, Class B
Electrical Safety	IEC 60601-1, 2d edition, UL 60601-1
Type Of Protection (AC Power)	Class I
Degree of Protection (Patient cable)	Type BF – applied part
Degree of Protection (Satshare cable)	Type CF – applied part
Liquid ingress – Degree of Protection	IPX1
Mode of Operation	Continuous

Footnotes:

1. SpO_2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO_2, 0-40% SpCO and 0-15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO_2 abd 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet.
2. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
3. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
4. The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
5. The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
6. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range 8-17 g/dL SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
7. The following substances may interfere with pulse CO-Oximetry measurements:
    a. Elevated levels of methemoglobin (MetHb) may lead to inaccurate SpO_2 and SpCO measurements.
    b. Elevated levels of carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
    c. Very low arterial Oxygen Saturation (SpO_2) levels my cause inaccurate SpCO and SpMet measurements.
    d. Severe anemia may cause erroneous SpO_2 readings.
    e. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.

f. Elevated levels of total bilirubin may lead to inaccurate SpO_2, SpMet, SpCO and SpHb readings.

9.3.5.3 Temperature

Temperature measurement performance	
Measurement method	Thermal resistance NTC
Number of channels	2
Measurement Range	0.0 °C - 50.0 °C
Accuracy	0.0 °C -50.0°C ±0.1°C (not including the probe)
Resolution	0.1 °C
Update rate	Every 1 to 2 s
Self-test	About every 5-10 mins
Recommended temperature probe type	YSI400 series
Temperature probe nominal resistance	2522Ω@25 °C
Recovery time after defibrillation	< 5 s

9.3.5.4 IBP

IBP measurement performance	
Number of channels	4
Transducer sensitivity	5uV/V/ mmHg, ±2%
Transducer impedance	300Ω to 3000Ω
Static pressure measurement range	-50 mmHg to +400 mmHg
Static pressure measurement accuracy	(±4 mmHg or ±4% of the reading), whichever is the greater. (probe included)
Dynamic pressure measurement range	-50 mmHg to +400mmHg
Dynamic pressure measurement accuracy	(±4mmHg or ±4% of the reading), whichever is t greater
Resolution	1 mmHg
Units	mmHg
Bandwidth	DC 15Hz
Waveforms Measurement ranges	**IBP/ART/RVP/LBP:** - 50 mmHg to 400 mmHg **PA:** 0 to 40 mmHg **CVP/RAP/LAP/ICP:** - 50 mmHg to +400 mmHg
Recovery time after defibrillation	< 5 s
LogiCal® Pressure Transducer Performance Specifications	
Sensitivity	5.0 µV/V/mmHg nominal
Balance, Unbalance	0 ± 50 mHg
Zero Drift	< 2 mmHg in 4-hrs after 5-min. warmup
Excitation Voltage Range	4–8 V (DC to 5 kHz)
Phase Shift	< 5°
Excitation Impedance	630 Ohms nominal
Single Impedance	300 Ohms ± 10%
Calibration Requirement	100 mmHg ± 3
Accuracy	Meets or exceeds AAMI specs (mmHg)
Compensated Temperature Range	15 to 40 °C
Storage Temperature Range	- 25 to 70 °C
Temperature Coefficient of Sensitivity	0 ± 0.1%/°C
Temperature Coefficient of Offset	0 ± 0.3 nominal mmHg/°C
Operating Pressure	- 30 to + 300 mmHg
Overpressure, Pressure Range, Over range Capability	400 to 4000 mmHg
15% Transducer Bandwidth	> 200 Hz
Symmetry	1 ± 5%
Defibrillator Withstand	5 in 5-min. at 360J
Risk Current of 115 VAC at 60 Hz	< 5 µA
Light Sensitivity	1 mmHg shift
Mechanical Shock Withstand	3 falls from 1 m
Life cycle	Reusable (only cartridge is disposable)

9.3.5.5 NIBP

NIBP measurement performance			
Measurement Method	Oscillometry		
Measurement Mode	Manual/Auto cycle/ STAT		
Auto Cycle Mode interval	1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes, 2, 4, 8, 16 hours		
STAT	5 minutes continuance, 5 seconds measurement interval		
Parameters	SYS, DIA, MEAN, Pulse rate		
Measurement ranges	**Adult**	**Pediatric**	**Neonatal**
Systolic pressure	30 to 270 mmHg	30 to 235 mmHg	30 to 135 mmHg
Diastolic pressure	10 to 220 mmHg	10 to 220 mmHg	10 to 110 mmHg
Mean arterial pressure	20 to 235 mmHg	20 to 225 mmHg	20 to 125 mmHg
Recovery time after defibrillation	< 5 s		
Measurement Range of cuff pressure	0 to 280 mmHg		
Pressure Resolution	1 mmHg		
Accuracy Static Pressure Clinical	±3 mmHg Average deviation: ±5 mmHg Standard deviation: ≤8 mmHg		
Pulse Rate Range	40 to 240 bpm		
Automatic Cuff Deflation	The cuff will automatically deflate when the measurement time exceed 120s (90s for neonate), power down, or cuff pressure exceed software/hardware safety limit.		
Complete Measurement Time	20 to 45s typical (depend on HR and motion interference)		
Software Over Pressure Protection	Adult: 297±3 mmHg Pediatric: 252±3 mmHg Neonate: 147±3 mmHg		
Hardware Over Pressure Protection	Adult: 315±10 mmHg Pediatric: 265±10 mmHg Neonate: 155±10mmHg		
Automatic Zero Pressure Calibration	Execute automatic zero pressure calibration in the following conditions: After power on, 60s after measurement finished or receives reset/self-test command.		

9.3.5.6 Monitor Alarm Messages

Non-technical alarms

Prio.	Alarm message	Possible cause	Proposed remedy
ECG			
M	HR low	- HR measuring value is below the lower alarm limit - Bradycardia	- Check monitoring settings and alarms - Check patient status
M	HR high	- HR measuring value is above the higher alarm limit - Tachycardia	- Check monitoring settings and alarms - Check patient status
M	I lead off	- Electrode disconnection from patient or poor electrode-skin contact - ECG cable pin disconnection form electrode - ECG cable disconnection from the monitoring module	- Check that the adhesive electrodes are attached to the patient skin in the correct location - Check that the ECG cable pin is attached to the electrode - Check that the ECG cable
M	II lead off		
M	LL lead off		
M	V1 lead off		
M	V2 lead off		
M	V3 lead off		
M	V4 lead off		

Prio.	Alarm message	Possible cause	Proposed remedy
M	V5 lead off	- ECG cable is broken	is connected to the monitoring module - If necessary, replace ECG cable
M	V6 lead off		
L	RA lead off?	- Electrode polarization	- Check that the electrode patch is attached to the patient skin in the correct location. If the error persists, change electrodes - Check for movement artifacts
L	LA led off?		
L	V1 lead off?		
L	V2 lead off?		
L	V3 lead off?		
L	V4 lead off?		
L	V5 lead off?		
L	V6 lead off?		
L	Leads off?		
ST analysis			
M	ST-I low	- ST segment elevation measurement in the corresponding lead is below the lower alarm limit	- Check ST analysis setting and alarm - Check patient for STEMI
M	ST-II low		
M	ST-III low		
M	ST-aVR low		
M	ST-aVL low		
M	ST-aVF low		
M	ST-V1 low		
M	ST-V2 low		
M	ST-V3 low		
M	ST-V4 low		
M	ST-V5 low		
M	ST-V6 low		
M	ST-I high	- ST segment elevation measurement in the corresponding lead is above the lower alarm limit	- Check ST analysis setting and alarm - Check patient for STEMI
M	ST-II high		
M	ST-III high		
M	ST-aVR high		
M	ST-aVL high		
M	ST-aVF high		
M	ST-V1 high		
M	ST-V2 high		
M	ST-V3 high		
M	ST-V4 high		
M	ST-V5 high		
M	ST-V6 high		
Arrhythmias			
H	ASYSTOLE	- An arrhythmia of this type has been detected	- Check patient status
H	V-FIB		
M	Run PVCs		
M	Couplet		
M	Bigeminy		
M	Trigeminy		
M	R on T		
M	VPB		
M	Tachycardia		
M	Bradycardia		
M	Missed Beats		
M	Pacemaker not pacing		
M	Pacemaker not captured		
M	Arrhythmia noise		
-	Arrhythmia relearning		

Prio.	Alarm message	Possible cause	Proposed remedy
M	V-TACH		
M	PVC counter exceeded		
M	Arrhythmia alarming off	Alarm for arrhythmias is off	Check alarm parameters
Masimo ® Rainbow SET optical parameters			
M	SpO2 Low	Measurement is below the upper alarm limit	Check patient status
M	SpO2 High	Measurement is above the lower alarm limit	Check patient status
M	Pulse Low	Measurement is below the upper alarm limit	Check patient status
M	Pulse High	Measurement is above the lower alarm limit	Check patient status
M	PI Low	Measurement is below the upper alarm limit	Check patient status
M	PI High	Measurement is above the lower alarm limit	Check patient status
M	SpCO Low	Measurement is below the upper alarm limit	Check patient status
M	SpCO High	Measurement is above the lower alarm limit	Check patient status
M	SpMet Low	Measurement is below the upper alarm limit	Check patient status
M	SpMet High	Measurement is above the lower alarm limit	Check patient status
M	SpHb Low	Measurement is below the upper alarm limit	Check patient status
M	SpHb High	Measurement is above the lower alarm limit	Check patient status
M	PVI low	Measurement is below the upper alarm limit	Check patient status
M	PVI high	Measurement above the lower alarm limit	Check patient status
M	SpOC Low	Measurement is below the upper alarm limit	Check patient status
M	SpOC High	Measurement is above the lower alarm limit	Check patient status
M	ORI Low	Measurement is below the lower alarm limit	Check patient status
Temp			
M	Temp1 low	Patient Temp 1 low	Check patient status
M	Temp1 high	Patient Temp 2 high	Check patient status
M	Temp2 low	Patient Temp 2 low	Check patient status
M	Temp2 high	Patient Temp 2 high	Check patient status
M	Dtemp high	Difference Temp high	Check patient status
IBP			
M	Pressure systolic low (IBPi/Art/RVP/LVP)	- Patient pressure low	Check patient status
M	Pressure systolic high (IBPi/Art/RVP/LVP)	- Patient pressure high	Check patient status
M	Pressure diastolic low (PA)	- Patient pressure low	Check patient status
M	Pressure diastolic high (PA)	- Patient pressure high	Check patient status
M	Pressure mean low (CVP/RAP/LAP/ICP)	- Patient pressure low - Transducer disconnection	Check patient status
M	Pressure mean high (CVP/RAP/LAP/ICP)	- Patient pressure high	Check patient status
M	Pressure pulse low	- Patient pulse low - Transducer disconnection	Check patient status
M	Pressure pulse high	- Patient pulse high	Check patient status
H	IBPi catheter disconnection	- Disconnection of catheter from patient side	Check catheter patient side for disconnection!!!

Prio.	Alarm message	Possible cause	Proposed remedy
NIBP			
L	NIBP sys over range	The patient systolic pressure exceeds the software high limitation in the device	Use an alternative NIBP
L	NIBP sys under range	The patient systolic pressure exceeds the software low limitation in the device	Use an alternative NIBP
L	NIBP dia over range	The patient diastolic pressure exceeds the software high limitation in the device	Use an alternative NIBP
L	NIBP dia under range	The patient diastolic pressure exceeds the software low limitation in the device	Use an alternative NIBP
L	NIBP MAP over range	The patient mean pressure exceeds the software high limitation in the device	Use an alternative NIBP
L	NIBP MAP under range	The patient mean pressure exceeds the software low limitation in the device	Use an alternative NIBP
M	NIBP sys low	The patient systolic pressure is too low	Check patient status
M	NIBP sys high	The patient systolic pressure is too high	Check patient status
M	NIBP dia low	The patient diastolic pressure is too low	Check patient status
M	NIBP dia high	The patient diastolic pressure is too high	Check patient status
M	NIBP map low	The patient mean pressure is too low	Check patient status
M	NIBP map high	The patient mean pressure is too high	Check patient status
M	NIBP pulse low	The patient pulse rate is too low	Check patient status
M	NIBP pulse high	The pulse rate pressure is too high	Check patient status
L	Invalid NIBP	NIBP System Failure	Restart module. If fails, replace module.
L	NIBP loose cuff	The Cuff is loose cannot build pressure	Check cuff tightness. Use an alternative NIBP method.
L	NIBP pressure error	Pressure error	Use an alternative NIBP method.
L	NIBP signal too weak	The oscillatory signal is too weak	Use an alternative NIBP method. Check patient category
L	NIBP range exceeded	Measurement range exceeded	Repeat the measure. If error persist, change NIBP.
L	NIBP artifact	Movement during measure	Repeat the measure taking care that the patient does not move.
M	NIBP overpressure	An overpressure is measured in the cuff	Repeat the measure. If error persist, change NIBP.
L	NIBP saturation	Signal saturation by measurement	Repeat measurement
L	NIBP leakage	Leakage in the pneumatic system	Check hoses and cuff for leakages
H	Invalid NIBP	Error in NIBP Self-test	Use an alternative NIBP method. Check patient category
L	NIBP timeout	Timeout to deliver results	Check patient status
L	NIBP wrong cuff	Cuff installed does not correspond with the patient category selected	Check patient category Check cuff diameter for correctness

Prio.	Alarm message	Possible cause	Proposed remedy
L	NIBP off	NIBP powered off	Restart module. If fails, replace module.

Technical alarms

Prio.	Alarm message	Possible cause	Proposed remedy
General alarms			
-	Printer paper error	Printer paper error or missing	Check availability and/o position of paper
-	Printer error	Printer hardware error	Restart device. If error persists, replace module
ECG			
M	Invalid ECG	ECG12 module error: Self-test error	Restart module. If fails, replace module.
M	ECG Leads disconnected	More than one lead of the ECG cable is disconnected from the patient	Check cable connection to the patient
M	Primary lead disconnected	The primary lead has been disconnected	Check primary lead connection to the patient
Masimo ® Rainbow SET			
H	Replace Monitor	Board Failure	Replace Module
-	Board not Started	The Masimo Board is not operating	Replace Module
L	No SpO2 Cable Connected	The cable is not connected to the monitor	Check cable connection to the monitor
L	Incompatible SpO2 Cable	The cable is not compatible with the monitor	Replace cable
L	Replace SpO2 cable	- Expired Cable - Unrecognized Cable - Defective Cable	Replace cable
L			
L			
L	Check SpO2 Cable and Sensor	SpO2 Cable and Sensor Fault	- Check cable and sensor - Replace cable and/or sensor
L	Check SpO2 Sensor Connection	The sensor is not appropriately connected to the monitor	- Check sensor connection to the monitor - Replace sensor
L	No SpO2 Sensor Connected	- Sensor is disconnected from the monitor - Adhesive sensor is disconnected from the monitor	- Check sensor connection to the monitor
L	Replace SpO2 Sensor	The sensor or the adhesive sensor is: - Expired - Defective - Unrecognized	Replace sensor
L	Incompatible SpO2 Sensor	- The sensor is not compatible with the monitor - The adhesive sensor is not compatible with the monitor.	Replace sensor
L	Sensor Off Patient	The sensor is disconnected from the patient	Check sensor connection to the patient

Prio.	Alarm message	Possible cause	Proposed remedy
-	Replace Cable Next Patient	Cable expired in Use	Replace cable
-	Cable near expiration	The cable in operation is near its expiration time	Replace cable next patient
-	Sensor expired in Use	The sensor or adhesive sensor in operation is expired	Replace sensor
-	Replace Sensor Next Patient	Sensor or adhesive sensor near expiration	Replace sensor
-	Sensor Near Expiration	The sensor or adhesive sensor in operation is near its expiration time	Replace sensor next patient
-	Sensor Initializing	The sensor initiates the connection to the device	Check cable and sensor connections
-	Pulse Search	The sensor attempts to detect an appropriate pulse waveform.	Check sensor connection to the patient
-	Interference Detected	The connection is being altered due to interference	- Check cable and sensor connection - Check for possible interference sources
-	PI low	PI value has reached a very low level	- Check patient for shock, blood flow obstruction - Check sensor placement
-	Demo Mode	The SpO2 in Demo Mode	
-	SpO2 Only Mode	If the Rainbow parameters (SpHb, SpOC, SpCO and SpMet) are unable to be obtained upon startup, the system still attempts to determine and display the non-Rainbow parameters (SpO_2, PR, PI and PVI) in a 2-LED mode.	- Remove and re-apply the sensor or - Cycle power to the host monitor
-	SpO2 SIQ Low	Low signal IQ	- Check patient for shock, blood flow obstruction - Check sensor placement - Check for excessive artifact or interference
-	SpO2 Startup	SpO2 Startup mode	
-	Masimo PR Low SIQ	Low PR Confidence	
-	Masimo PR Startup	PR Startup mode	
-	PI SIQ Low	Low PI Confidence	
-	PI Startup	PI Startup mode	
-	SpCO SIQ Low	Low SpCO Confidence	
-	SpCO PI Low	Low SpCO Perfusion Index	
-	SpCO Startup	SpCO Startup mode	
-	SpMet SIQ Low	Low SpMet Confidence	
-	SpMet PI Low	Low SpMet Perfusion Index	
-	SpMet Startup	SpMet Startup mode	
-	SpHb SIQ Low	Low SpHb Confidence	
-	SpHb PI Low	Low SpHb Perfusion Index	
-	SpHb Startup	SpHb Startup mode	
-	SpOC SIQ Low	Low SpOC Confidence	
-	SpOC PI Low	Low SpOC Perfusion Index	
-	SpOC Startup	SpOC Startup mode	
-	PVI SIQ Low	Low PVI Confidence	
-	PVI Startup	PVI Startup mode	
-	ORI SIQ Low	Low ORI Confidence	
-	ORI PI Low	Low ORI Perfusion Index	

Prio.	Alarm message	Possible cause	Proposed remedy
-	ORI Startup	ORI Startup state	
Temperature			
L	Temp1 probe off	Temp1 probe disconnection	Check connection of the probe to the monitor module.
L	Temp2 probe off	Temp2 probe disconnection	
L	Temp1 over range	Temp1 exceeds the upper limit of measurement range	Check patient status
L	Temp1 under range	Temp1 exceeds the lower limit of measurement range	
L	Temp2 over range	Temp2 exceeds the upper limit of measurement range	
L	Temp2 under range	Temp2 exceeds the lower limit of measurement range	
L	Invalid TEMP	Temp module error: Self-test error	Restart module. If fails, replace module.
NIBP			
M	Invalid NIBP	NIBP Communication error	Restart module. If fails, replace module.
L	NIBP off	NIBP powered off	Use an alternative method.
IBP			
L	IBP1 sensor off IBP2 sensor off IBP3 sensor off IBP4 sensor off	- The IBP cable has been disconnected from the monitor side. (in that case, you will get all four alarms simultaneously) - The IBP cable has been disconnected from the corresponding transducer.	- Check connection of the IBP cable to the monitor module. - Check connection of the cable to the transducer
H	IBP1 catheter off IBP2 catheter off IBP3 catheter off IBP4 catheter off	- There is a significant pressure drop on the patient side of the transducer - Catheter disconnected from sensor - Catheter disconnected from patient	- CHECK patient for catheter disconnection!!! - Check transducer
M	IBP1zero cal. failed IBP2 zero cal. failed IBP3 zero cal. failed IBP4 zero cal. failed	- Defective transducer - Defective dome - Stopcock not vented to atmosphere	- Check transducer - Check dome - Check stopcock - Repeat calibration

9.3.5.7 Monitor alarm settings and limits

Symbol units	**Range** Resolution			**Default Settings**						**Auto set**
	Adult	**Pediatric**	**Neonate**	**Adult**		**Pediatric**		**Neonate**		
				L	**H**	**L**	**H**	**L**	**H**	
HR bpm	30 to 300 1	30 to 300 1	30 to 350 1	50	150	60	180	90	200	**HR** ± 30 %
ST mV	-2 to 2 0.01	-2 to 2 0.01	n/a	-0.20	0.20	-0.20	0.20	n/a	n/a	n/a
RR /min	1 to 149 1	1 to 149 1	1 to 149 1	5	20	12	60	20	80	**RR** ± 40%
SpO2 %	1 to 99 1	1 to 99 1	1 to 99 1	n/a	88	n/a	88	n/a	99	SpO2 ± 20%
SpO2 Alarm Delay secs	0 to 15	0 to 15	0 to 15	15 secs		10 secs		10 secs		n/a

Symbol units	**Range** Resolution			**Default Settings**						**Auto set**
Pulse Rate bpm	30-235 1	30-235 1	30-235 1	50	140	50	140	100	180	PR ± 20%
PI * %	0.03 to 19	0.03 to 19	0.03 to 19	Off	0.3	Off	0.3	Off	0.3	PI ± 20%
PVI **%**	1 to 99 1	1 to 99 1	1 to 99 1	5	40	5	40	5	40	PVI ± 20%
SpMet * %	0,1 to 99.5 0.1	0.1 to 99.5 0.1	0.1 to 99.5 0.1	Off	3	Off	3	Off	3	SpMet ± 20%
SpCO %	1 to 98 1	1 to 98 1	1 to 98 1	Off	10	Off	10	Off	10	SpCO ± 20%
SpHb g/dL	1.0 to 23.5 0.10	1.0 to 23.5 0.10	1.0 to 23.5 0.10	7	17	7	17	7	17	SpHb ± 20%
SpOC mLO_2/dL blood	1 to 34 1	1 to 34 1	1 to 34 1	10	25	10	25	10	25	SpOC ± 20%
ORI Low Limit	0.01 to 1.00 0.01	0.01 to 1.00 0.01	0.01 to 1.00 0.01	Off		Off		Off		n/a
T1 °C	34 to 44 0.1	34 to 44 0.1	34 to 44 0.1	36	39	36	39	36	39	**T1**± 2%
T2 °C	34 to 44 0.1	34 to 44 0.1	34 to 44 0.1	36	39	36	39	36	39	**T2**± 2%
dTemp °C	-10 to 10 0.1	-10 to 10 0.1	-10 to 10 0.1	-2	2	-2	2	-2	2	**dTemp** ± 25%
IBP*i* Sys mmHg	-50 to 400 1	-50 to 400 1	-50 to 400 1	90	160	70	120	55	90	**IBPi ±** 20%
IBP*i* Dia mmHg	- 50 to 400 1	- 50 to 400 1	- 50 to 400 1	0	16	-4	4	-4	4	**IBPi ±** 20%
IBP*i* Map mmHg	-50 to 400 1	-50 to 400 1	-50 to 400 1	0	10	0	4	0	4	**IBPi ±** 20%
NIBP Sys mmHg	30 to 270 1	30 to 235 1	30 to 135 1	90	160	70	120	40	90	**NIBP ±** 20%
NIBP Dia mmHg	10 to 220 1	10 to 220 1	10 to 110 1	50	90	40	70	20	60	**NIBP ±** 20%
NIBP Map mmHg	20 to 235 1	20 to 225 1	20 to 125 1	60	110	50	90	24	70	**NIBP ±** 20%

NOTE:

IBP*i* Sys: IBP1/2/3/4 and Art/RVP/LVP only

IBP*i* Dia: PA only

IBP*i* Map: CVP/RAP/LAP/ICP only

9.3.5.8 Monitor alarm delays

The delay in the generation of alarm signals in the monitor module is < 10 s for the alarm conditions listed above.

9.4 Defibrillator module (Optional)

9.4.1 Product life cycle

The Defibrillation module has a service life time of minimum of 8 years.

NOTE:

The lifetime of the device is guaranteed only in the case that all the maintenance and service tasks, as well as the replacement of components have been performed accordingly to the indications given in the Service Manual.

9.4.2 Physical specifications

Physical specifications	
Dimensions	
Height	71 mm (Slim version) 110 mm with paddles holder (without paddles) 180 mm with paddles holder (with paddles)
Width	400 mm
Depth	164 mm
Weight	
Weight	Slim Version: 1.72 kg Paddles Version: 2.55 kg (with paddles)

9.4.3 Environmental specifications

Environmental specifications	
Temperature	
Operating temperature range	-20 to + 50 °C (at ≤ - 10 °C for at least 20 minutes)
Storage temperature range	-10 to +50 °C
Humidity	
Operating humidity range	30 to 75% non-condensing
Air pressure	
Operating air pressure range	700 hPa to 1060 hPa
Maximum operating altitude	Approx. 4000 meters
IP protection level	
Protection against water	IP54

9.4.4 Electrical specifications

9.4.4.1 Safety specifications

Safety specifications	
Protection against electric shock	
Type of protection against electric shock	**Class II**
Degree of protection against electric shock	**Defibrillator** – Type CF **Capnography –** Type CF measured with the capnometry probe connected
Mode of operation	**Continuous**

9.4.5 Performance specifications

9.4.5.1 Therapy electrodes ECG

Therapy ECG specification	
Lead type	1 channel ECG derived from defibrillation electrodes

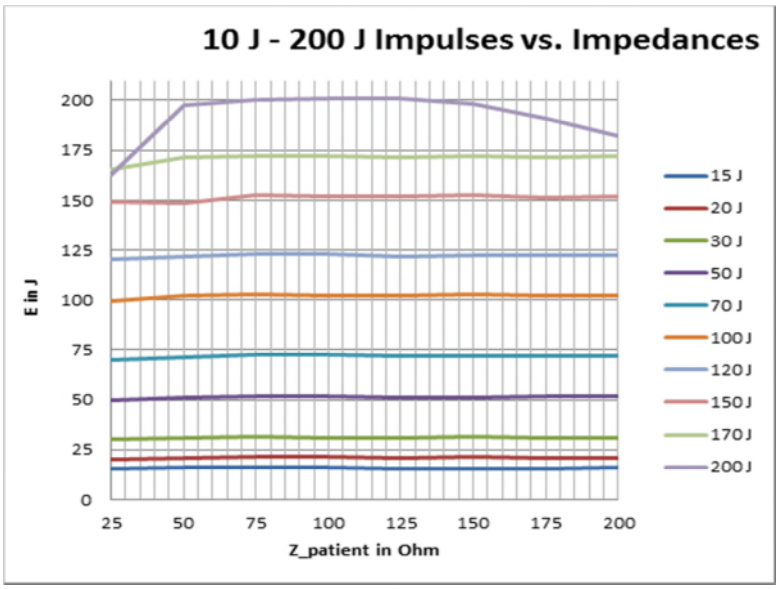
Therapy ECG specification	
Gain	10 mm/mV
Bandwidth	TBD
Sampling frequency	300 Hz
Impedance range	0 to 500 Ω
HR display	No
Detecting sensitivity	Asystole: < 200 µVpp for 5 s
Power line filter (50/60 Hz)	On
Life cycle (spoons)	100 sterilization cycles

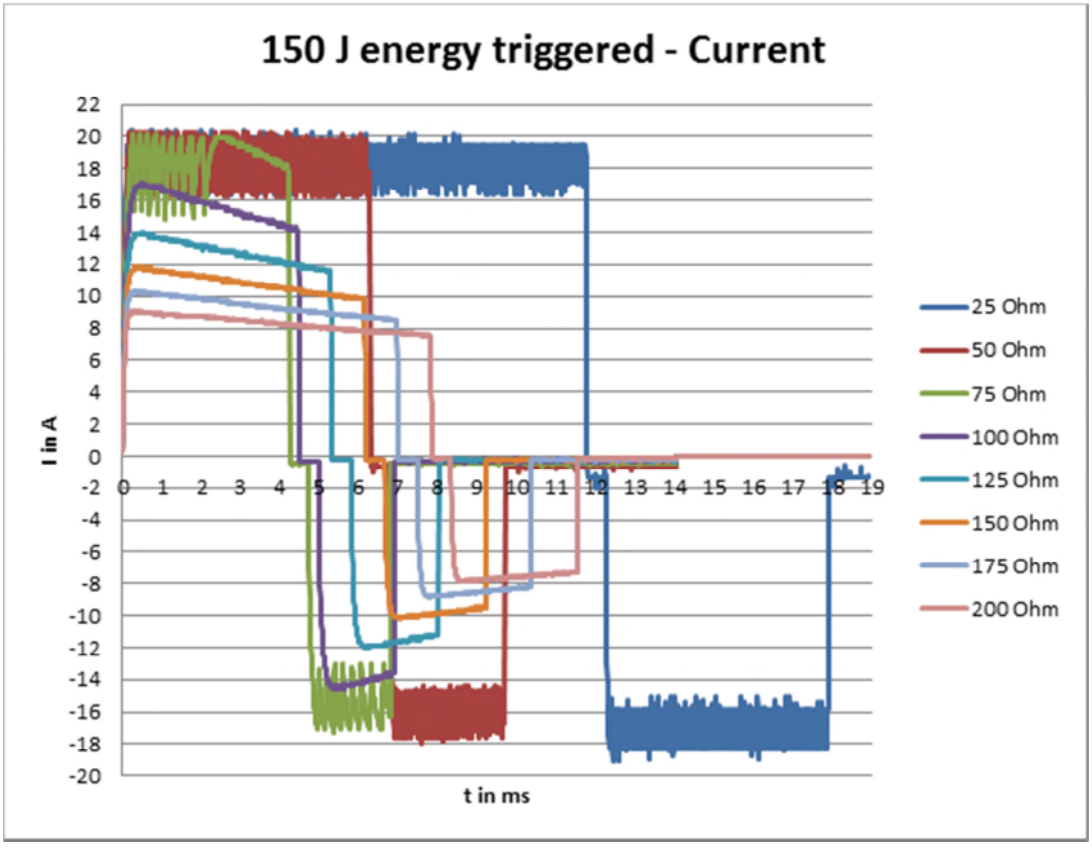
9.4.5.2 Defibrillator

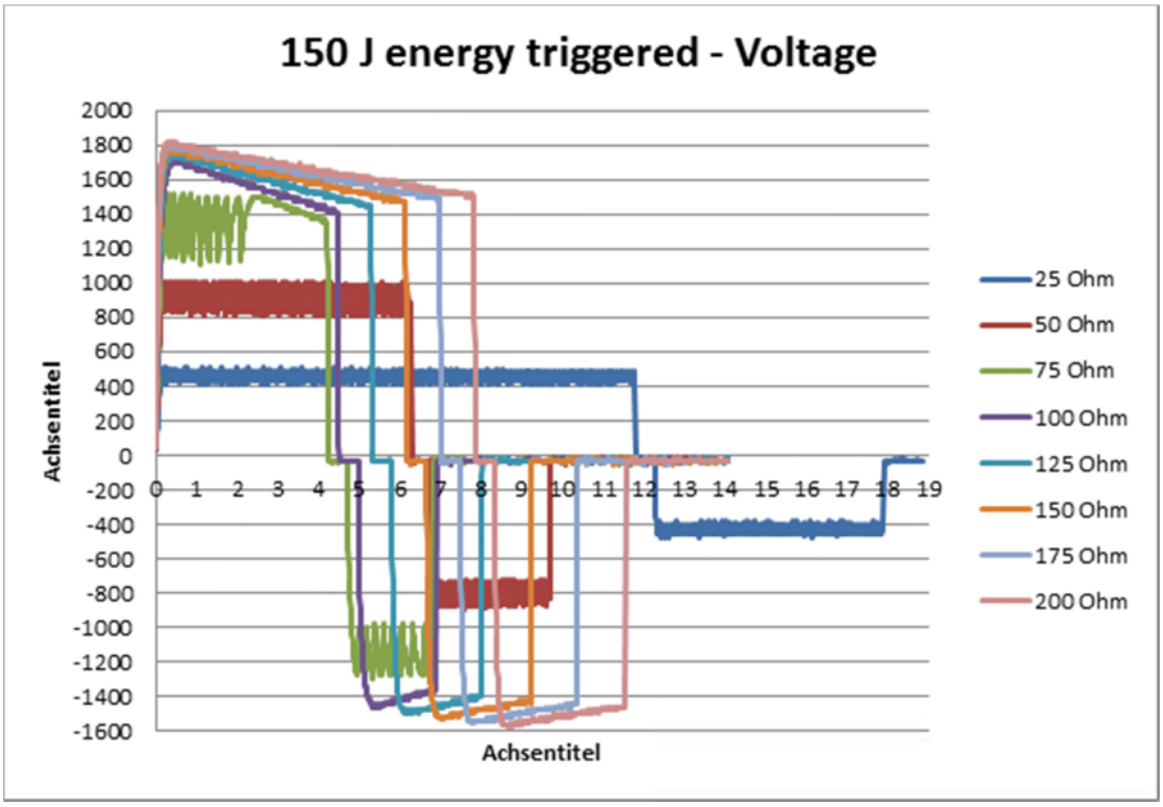
Defibrillator specification	
Pulse	
Type	Biphasic rectangular, current controlled
Duration	--
Patient impedance	
Patient detection minimum	> 0 Ω When patient impedance is below this limit, the defibrillator inhibits its output.
Patient detection maximum	< 500 Ω. When patient impedance is above this limit, the defibrillator inhibits its output.
Operating modes	
Defibrillation modes	AED, Manual defibrillator
Manual mode	
Operating energy range	0.5 to 200 J
Adult selection range	1 J, 2 J, 3 J, 4 J, 5 J ,6 J, 7 J, 8 J, 9 J, 10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J, 120 J, 150 J, 170 J, 200 J
Adult default shock energy With paddles and SavePads With spoons	 150 J 50 J
Pediatric selection range	0,5 J, 1 J, 2 J, 3 J, 4 J, 5 J ,6 J, 7 J, 8 J, 9 J, 10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J
Pediatric default shock energy With paddles and SavePads With spoons	 100 J 50 J
Neonate selection range	0.5 J, 1 J, 2 J, 3 J, 4 J, 5 J ,6 J, 7 J, 8 J, 9 J, 10 J, 15 J, 20 J
Neonate default shock energy	20 J with paddles, SavePads and spoons
Capacitor charging time	< 8 s, with (10V, 10 A)
Internal discharge timeout	30 s
Time from switch on to ready to shock @ 200 J	< 8 s
Number of shocks J @ 20 °C	Approx. 518 shocks at 200 J
AED mode	
AED type	Semi-automatic
AED protocol	After ERC 2015
AED Adult shock energy	200 J. Non-escalating
AED Pediatric shock energy	100 J. Non-escalating
Time from start of analysis to ready to shock	with fully charged batteries < 16 s after 15 maximum energy discharges < 16 s
Time from switch on to ready to shock @ 200 J	with fully charged batteries < 30 s after 15 maximum energy discharges < 30 s
Number of pre-programmed shocks with full battery	400 at 150 J
ECG rhythm analysis	
Analysis time	< 8 s
Shockable rhythms	VF/VT
Sensitivity	VT > 75 % VF > 90 %
Specificity	Normal sinus > 95 % Asystole> 95% Other non-shockable rhythms > 95 %

Defibrillator specification	
Synchronizer specification	
QRS markers during synchronization	White triangles on
Max Time to synchronized shock delivery	30 ms, measured with the oscilloscope from QRS peak to starting edge of defibrillation discharge into a 50 Ω resistive load.
Time of shock delivery when no R-wave is detected (Auto mode)	1 second

9.4.5.3 Shock Waveforms







9.4.5.4 Delivered energy accuracy

Energy [J]	Nominal Energy delivered to patient impedance								Accuracy
	Patient impedance [Ω]								
	25	**50**	**75**	**100**	**125**	**150**	**175**	**200**	
0.5	0,6	0,6	0,6	0,6	0,7	0,6	0,7	0,8	± 3J
1	1	1,1	1,2	1,2	1,2	1,2	1	1,2	± 3J
2	2,2	2,1	2,2	2,2	2,2	2,1	2,4	2,4	± 3J
3	3	3,2	3,3	3,4	3,2	3,3	3,1	3,2	± 3J
4	4	4,3	4,3	4,4	4,5	4,5	4,2	4,4	± 3J
5	5,2	5,2	5,4	5,4	5,5	5,4	5,2	5,2	± 3J
6	6,2	6,3	6,4	6,4	6,5	6,6	6,6	6,4	± 3J
7	7	7,4	7,6	7,6	7,5	7,5	7,3	7,6	± 3J
8	8,2	8,4	8,7	8,8	8,5	8,4	8,7	8,4	± 3J
9	9	9,7	9,7	9,6	9,5	9,6	9,8	9,6	± 3J
10	10,2	10,6	10,9	10,6	10,5	10,5	10,5	10,8	± 3J
15	15,2	15,8	15,9	15,8	15,7	15,6	15,7	16	± 3J
20	20,4	20,8	21,4	21,4	21	21,3	21	20,8	± 15%
30	30,2	31,2	31,5	31,2	31,2	31,5	31,1	31,2	± 15%
50	49,6	51,2	51,7	51,8	51,2	51,3	51,7	51,5	± 15%
70	69,8	71,4	72,4	72,7	71,9	72,2	72	71,9	± 15%
100	99,5	102,4	103	102,1	102,2	102,5	102,1	102,3	± 15%
120	120,1	121,9	122,8	122,7	121,9	122,6	122,4	122,3	± 15%
150	149,5	148,8	152,3	152,1	151,6	152,3	151,4	151,8	± 15%
170	165,3	171,6	171,8	172,3	171,6	172,3	171,7	172,2	± 15%
200	162,9	197,9	200,2	201,1	201,3	198,4	190,9	182,2	± 15%

9.4.5.5 Noninvasive Pacer

Noninvasive pacer specifications	
Pacing pulse	
Type	Monophasic rectangular
Duration	20 ms (± 4 ms)
Patient impedance	
Patient detection minimum	> 0 Ω
Patient detection maximum	< 1000 Ω
Operating modes	
Fixed, Demand and Overdrive modes	Default mode: Demand
Intensity [mA]	
Operating range	0 to 150 mA
Default	0 mA
Pacing frequency	
Operating range	30 to 150 bpm
Default value (Fixed and Demand modes)	70 bpm
Operating range (Overdrive mode)	30 to 300 bpm

9.4.5.6 Defibrillator alarm messages

Technical alarms

Prio.	Alarm message	Possible cause	Proposed remedy
SafetyDM alarms			
H	Replace Defibrillator	Selftest Error SafetyDM MCU (power on self-test)	Restart defibrillation module Restart Docking station If error persists, replace module
		Selftest Error CoM (boot, test)	
		Communication error (timeout) between SafetyDM and CoM	
		Alarm message send from SafetyDM not acknowledged SafetyDS	
		SPI flash read	
		Write Error	
Board of Defibrillation Module alarms			
L	State Change Not Allowed	Target-state in State Change-command invalid	Check change parameters
L	DEFIB. Not Ready to Charge	Not ready to charge	Try to charge again. If error persists, replace module
L	Shock Energy Out of Range	Configured Shock energy out of range	Check parameter
L	Pacing Current Out of Range	Configured Pacing current out of range	Check parameter
L	Pacing Freq. Out of Range	Configured Pacing frequency out of range	Check parameter
L	Shock Energy Invalid	Configured Shock energy invalid	Check parameter
L	Pacing Current Invalid	Configured Pacing current invalid	Check parameter
L	Pacing Freq. Invalid	Configured Pacing frequency invalid	Check parameter
L	Patient type change not allowed	Patient type change during Non-Idle mode not allowed	Check patient type
H	Patient type not supported	Patient type not supported (e.g. neonates in AED mode)	Check patient type
H	Patient Type Invalid	Patient type is invalid	Check patient type

Prio.	Alarm message	Possible cause	Proposed remedy
L	Cap is Charged	Shock/AED options not accepted while HV cap is charged	Discharge the capacitor or wait for internal discharge (< 30 sec). If error persists, replace Module.
L	Shock Mode Invalid	Invalid shock mode options parameter	Improper mode selection
L	Autosync Timeout Invalid	Configured autosync timeout is invalid.	Check parameter. If error persists, replace module.
H	Alarm Line On	ALARM_DSP line from BDM module active	Replace module
H	Replace Defibrillator	12V supply out of range	Replace module
		5V supply out of range	
		Watchdog reset detected	
		No self-test result send from BDM to SafetyDM (timeout)	
		Write of log data to SPI Flash failed	
H	Replace Paddles	Shock button paddles permanently on	Replace module
H	Replace Docking Station	Shock button DS permanently on	Replace module
M	External Trigger Failure	The trigger signal is defective	Replace module
M	Shock Energy Auto-Limit	Shock energy limited (due to connected spoons)	Spoons are connected and more than 50 J are selected
M	No Electrodes	No electrodes connected	Connect compatible electrodes to the defibrillator module.
H	Invalid Electrodes	Invalid electrodes connected (e.g. spoons in AED)	Connect compatible electrodes to the defibrillator module.
H	READY FOR SHOCK !!!	Defibrillator HV capacitor loaded; Ready for delivering Shock	Information that the defibrillator is charged and ready to shock
M	Internal error	Trying to change to shock/pace/AED without valid options	Check parameters
H	Electrodes disconnected	Electrodes disconnect from patient while pacing is running	Check the pads on the patient side for disconnection.
H	DEFIB. Shock Sync Timeout	No SYNC (intern/extern) arrived after push SHOCK Enable Button (TIMEOUT 6 sec)	Replace module
H	DEFIB. Shock Sync Abort	SYNC (intern/extern) aborted after SHOCK Enable Button release	Replace module

9.5 Capnography (Optional)

9.5.1 General

Specifications for IRMA Capnography (Optional)		
General		
Operating temperature range	0 to +40 °C (-20–50°C for 20 minutes)	
Storage/transport temperature	-40 to + 70 °C	
Operating atmospheric pressure	525 to 1200 hPa (corresponding to a max altitude of 5211 m)	
Storage atmospheric pressure	200 to 1200 hPa (corresponding to a max altitude of 11760 m)	
Mechanical strength	Withstands repeated 1.8 m drops on a hard surface. Complies with requirements for shock and vibration for professional transportation according to EN ISO 80601-2-55:2011 and EN 60601-1-12:2015.	
Warm up time	< 10 seconds full accuracy	
Cool down time after storage at +70° C	In operation and full accuracy within 10 s	
Drift of measurement accuracy	No drift	
Measurement range	0-15 vol%	
Calibration	Not needed	
Analyzer response time	< 1 second	
Humidity		
Operating humidity range	<40 hPa H2O (non-condensing) 95% RH at 30°C	
Storage/transport humidity range	10–95%RH (95%RH at 40°C)	
Probe/sensor		
Dimensions (WxDxH)	38 x 37 x 34 mm	
Cable length	2.5 meter	
Technic	Infra-red optical	
Airway Adapter		
Type	Disposable, single use	
Size	Adult/Pediatric or Infant	
Weight	< 25 grams	
Dead space volume Adult/Ped adapter	< 6 ml	
Dead space volume Infant adapter	< 1 ml	
Pressure drop Adult/Ped adapter	< 0.3 cm H_2O @ 30 LPM	
Pressure drop Infant adapter	< 1.3 cm H_2O @ 10 LPM	
Infant adapter	Endotracheal tube size ≤4.0 mm	
Accuracy		
CO_2 Accuracy – standard conditions	**Range**	**Accuracy**
	0 to 15 vol%	± (0.2 vol% + 2% of reading)
CO_2 Accuracy – all conditions	±(0.3 kPa + 4% of reading)	

Specifications for ISA CO_2 Capnography (Optional)	
General	
Dimensions (Width x Depth x Height)	33 x 78 x 49 mm
Cable length	0.5 m ± 0.025 m
Operating temperature range	0 to +50 °C
Storage temperature range	-40 to + 70 °C
Operating atmospheric pressure	525 to 1200 hPa (corresponding to a max altitude of 5211 m)
Storage atmospheric pressure	200 to 1200 hPa (corresponding to a max altitude of 11760 m)
Ambient CO_2	≤ 800 ppm (0.08 vol%)
Mechanical robustness	Meets the shock and vibration requirements for transport of IEC 60601-1-12:2014 clause 10.1.3 and EN 1789:2007 clause 6.3.4.2.

Specifications for ISA CO_2 Capnography (Optional)		
Power supply	< 1.4 W (normal op.), < 1.8 W (peak @ 5 VDC)	
Recovery time after defibrillation	Unaffected	
Drift of measurement accuracy	No drift	
Interface	RS-232 serial interface	
Sampling flow rate	50 ± 10 sml/min	
Airway Adapters	NomoLine Adult/Pediatric Airway Adapter Sets: ≤ 6 ml dead space NomoLine Infant/Neonate Airway Adapter Sets: : ≤ 0.7 ml dead space	
Compliance	MDD 93/42/EEC EN ISO 80601-2-55:2011 EN 60601-1:2006 + A1:2013, A12:2014, AC1: 2014 EN 60601-1-2:2015 EN 1789:2007 +A1:2010 +A2:2014 (ISA CO2)	
IP protection level		
Protection against water	IPX4	
Humidity		
Operating humidity range	<4 kPa H2O (non-condensing) 95% RH at 30°C	
Storage humidity range	5 to 100% RH[1] (100%RH at 40 °C)	
Water handling	Nomoline ® Family sampling lines with proprietary water removal tubing	
Data output		
Breath detection	Adaptive threshold, minimum 1 vol% change in CO_2 concentration	
Respiration rate	0 to 150 ± 1 breaths/min	
Fi and ET	Fi and ET are displayed after one breath and have a continuously updated breath average. CO_2 $ET=ET_{nom}\times(125/RR)$ for $RR_{th} > 125$	
Gas Analyzer		
Sensor head	2 channel NDIR type gas analyzer measuring at 4 to 0µm Data acquisition rate 10 kHz (sample rate 20Hz/channel)	
Compensations	Automatic compensation for pressure and temperature	
Calibration	No span calibration is required for the IR bench. An automatic zeroing is performed typically 1-3 times per day.	
Warm-up time	<10 seconds (concentrations reported and full accuracy)	
Rise time at 50 sml/min sample flow	≤ 200 ms	
Total system response time	< 3 seconds	
Accuracy		
CO_2 Accuracy – standard conditions	**Range**	**Accuracy**
	0 to 15 vol% 15 to 25 vol%	± (0.2 vol% + 2% of reading) Unspecified
CO_2 Accuracy – all conditions	± (0.3 kPa + 4 % of reading)	

9.5.2 Performance specifications

9.5.2.1 Capnography probe status LED indicator

Indication	Status message
Steady green light	System is OK
Blinking green light	Zeroing is in progress
Steady red light	Sensor error
Blinking red light	Check adapter

9.5.2.2 Capnography alarm messages in the GUI

Non-technical alarms

Prio.	Alarm message	Possible cause	Proposed remedy

Prio.	Alarm message	Possible cause	Proposed remedy
M	CO2 RESP rate high	- The measured respiration rate is higher than the set alarm limit	- Check patient
M	CO2 RESP rate low	- The measured respiration rate is lower than the set alarm limit	- Check patient
H	MG: Apnea	- No breath detected since the set apnea time	- Check patient
M	MG: CO2 outside specified range	- CO2 concentration outside specified accuracy range	- Check patient
M	Expired CO2 high	- The measured EtCO2 is higher than the set alarm limit - Hypercapnia	- Check patient status - Check alarm limits - If necessary increase minute volume
M	Expired CO2 low	- The measured EtCO2 is lower than the set alarm limit - Hyperventilation	- Check patient status - Check alarm limits - Check the ventilation system for leakages - If necessary decrease minute volume
M	Inspired CO2 high	- Patient is rebreathing	- Check mask (NIV) - Check ventilation settings and alarms

Technical alarms

Prio.	Alarm message	Possible cause	Proposed remedy
M	MG sensor error	Capnometry software error	- If available, connect another capnography sensor - If possible, continue ventilation without capnography - If necessary, replace ventilator module
H	MG sensor error	Capnometry hardware error	
H	MG: sensor error (ISA analyzer)	Motor speed out of bounds	
L	MG sensor error	Factory calibration missing	
M	MG: Zeroing required	Zero reference failed	

Prio.	Alarm message	Possible cause	Proposed remedy
M	Phasein communication error	MG communication error	
L	MG: Check sampling line (ISA analyzer)	No sampling line is detected in the ISA analyzer	Check sampling line
L	MG: Check sampling line (ISA analyzer)	Defective sampling line	Check sampling line
L	MG: Check adapter (IRMA analyzer)	No airway adapter in the sensor	Check adapter
M	MG: Replace adapter (IRMA analyzer)	Defective airway adapter	Check adapter
M	MG: Replace sensor	Incompatible sensor is connected	Replace sensor for a compatible sensor (ISA CO2 or IRMA CO2)
L	MG: Unspecified accuracy	Inappropriate operating temperature	Operate device within its temperature range
L	MG: Unspecified accuracy	Inappropriate operating pressure	Operate device within its pressure range

9.5.2.3 Capnography alarm delays

Alarm	**Delay**
FiCO2 %	After 2 s, every breath
EtCO2 %	After 2 s, every breath

9.6 Guidance and Manufacturer's Declaration

WARNING:

Portable and mobile RF communications equipment can affect the performance of the system. Install and use this device according to the information described in this manual.

WARNING:

Jenny® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is excepcionally neccesary, the equipment should be observed to verify normal operation in any of the system configurations.

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions		
The Jenny® Critical Care Hybrid is intended for use in the electromagnetic environment specified below. The customer or the user of the Jenny® Critical Care Hybrid should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment- Guidance**
RF emissions CISPR 11:2016	Group 1	The Jenny® Critical Care Hybrid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11:2016	Class B	The Jenny® Critical Care Hybrid is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2:2018	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3:2017	Complies	
RTCA DO 160G:2010 RTCA DO 160G Section 21.4 RTCA DO 160G Section 21.5	Cat. M	

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity			
The Jenny® Critical Care Hybrid is intended for use in the electromagnetic environment specified below. The customer or the user of the Jenny® Critical Care Hybrid should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment -Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient/burst IEC 61000-4- 4:2012	± 1 kV for input/output lines ± 2 kV for power supply lines	± 1 kV for input/output lines ± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2014	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11:2017	< 5 % UT (> 95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Jenny® Critical Care Hybrid requires continued operation during power mains interruptions, it is recommended that the Jenny® Critical Care Hybrid be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

Table 3 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment -Guidance**
Conducted RF IEC 61000-4-6:2013	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Jenny® Critical Care Hybrid including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance D = 1,2 √P D = 1,2 √P 80 MHz to 800 MHz D = 1,2 √P 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) per the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur near equipment marked with the following symbol:
Radiated RF IEC 61000-4-3:2010	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Jenny® Critical Care Hybrid is used exceeds the applicable RF compliance level above, the Jenny® Critical Care Hybrid should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Jenny® Critical Care Hybrid

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the Jenny® Critical Care Hybrid			
The Jenny® Critical Care Hybrid is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Jenny® Critical Care Hybrid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Jenny® Critical Care Hybrid as recommended below, per the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance per frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) per the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

9.6.1 Essential performance

The Jenny® Critical Care Hybrid satisfies the essential performance requirements specified in the applicable standards.

9.6.1.1 Ventilation module

- Respiratory gas supply to the PATIENT connector opening within the alarm limits set by the operator or the generation of an alarm condition.
- Alarm condition for the Oxygen concentration
- Airway pressure
- Alarm condition for blocking
- Alarm condition for partly closing
- Exhaled volume
- Interruption of power supply
- Internal device power supply is nearly exhausted
- Interruption of the gas supply
- Gas leakage - crossflow
- Respiratory gas supply to the PATIENT connector opening within the alarm limits set by the operator or the generation of an alarm condition.

9.6.1.2 Monitor module

- Defibrillation protection
- Interruption of power supply/ Supply mains to ME equipment
- Protection against depletion of battery
- Essential performance of ECG includes:
    - Accuracy of signal reproduction
    - Input dynamic range and diff. Offset voltage
    - Input impedance
    - Input Noise
    - Multichannel crosstalk
    - Gain control and stability
    - Sweep speed
    - Frequency and impulse response
    - Gain indicator
    - Baseline reset
    - Pacemaker pulse display capability
    - Rejection of pacemaker pulses
    - Sync. pulse for cardioversion
    - Heart rate, Accuracy and QRS detection range
    - Channel height and aspect ratio
    - Tall T rejection capability
    - Time to alarm for HR alarm conditions
- Technical alarm condition indicating inoperable ME EQUIPMENT
- Interruption of power supply/ Supply mains to ME equipment
- Protection against depletion of battery
- Essential performance of ME Equipment

- Recovery time after disturbances through electro surgery units
- Error limits of the manometer pressure
- or generation of a technical alarm
- Measuring and display tolerances
- Reproducibility of the BLOOD PRESSURE DETERMINATION
- Accuracy of pressure measurements
- Electrosurgery disturbances
- Delay to or from a distributed alarm system
- Electrosurgery interference
- Delays to or from a Distributed alarm system
- Accuracy and gas measurement alarm handling includes:
    - Accuracy, Accuracy drift, Accuracy in gas mixtures, Response and rise times, display of units of measurement, Display of the operation mode (Demo, Self-test, Standby ….)
- Alarm-condition priority
- Generation of a Technical alarms for power supply interruption
- For pulse oximeters, which are equipped with an alarm system which can recognize physiological alarm conditions:
- SpO2-accuracy, pulse-frequency accuracy and limits for alarm conditions
- Additional requirements for alarm condition priorities
- OR- the production of a technical alarm
- Signal inadequacy
- Additional Specific First Errors
- Accuracy of pulse rate
- OR indications of abnormal operation
- Fault detection on the pulse oximetry sensor and on the sensor extension cable

9.6.1.3 Defibrillator module

- Delivery of defibrillation therapy. This includes accuracy of controls and displays.
- Delivery of a synchronized defibrillation therapy.
- Distinction between defibrillable and non-defibrillable heart rhythms.

9.6.1.4 Standards and Approvals

The Jenny Critical Care System has been developed in accordance with pertinent international standards.

The device is manufactured within an EN ISO 13485, Council Directive 93/42/EEC, Annex II, Article 1 certified quality management system.

The device meets the Essential Requirements of Council Directive 93/42/EEC, and its modules are classified accordingly:

- Ventilator Module: Class IIb device.
- Monitoring Module: Class IIb device.
- Defibrillator Module: Class IIb device.

The device meets relevant parts of the following standards:

- EN 6061-1/ IEC 60601-1: Medical electrical equipment, Part 1: General requirements for safety. The device classification is: Class II, Type B applied part (ventilator breathing system, monitoring electrodes, defibrillation electrodes).
- EN 60601-1-2/ IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- DIN EN ISO 80601-2-12: Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- EN 60601-1-12: Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment, section 10.1.4 Requirements for airborne use
- EN 1789:2014: Medical vehicles and their equipment – Road ambulances (without accessories, except for Ventilation Breathing System (Breathing circuit, Flow sensor, HME filter), ECG cable, NIBP hose, IBP cables, Pulse-CO Oximeter cable, Temperature sensor, defibrillation paddles and batteries)
- EN 794-3:2009 Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators
- EN 13718-1: Medical vehicles and their equipment – Air ambulances - Part 1: Requirements for medical devices used in air ambulances
- RTCA/DO-160G, section 21: Environmental Conditions and Test Procedures for Airborne Equipment
- EN 60601-2-4:2011: Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

- EN 80601-2-49:2011: Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- EN 80601-2-30:2009: Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- EN 60601-2-34:2011: Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- EN 80601-2-61: 2011: Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- EN ISO 80601-2-55:2011: Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors. For use with IEC 60601-1: 2005 (Third Edition) + CORR.1 (2005) + CORR. 2 (2007)

Appendix A

List of technical alarms

Prio.	Alarm message	Possible cause	Proposed action
Docking Station processor			
H	Replace Docking Station	SafetyDS power-on selftest error	Replace Docking Station
H	Replace Docking Station	Communication timeout between SafetyDS and CoM	
H	Replace Docking Station	Alarm message sent from SafetyDS not acknowledged by CoM	
H	Replace Docking Station	SPI flash read error	
H	Replace Docking Station	SPI flash write error	
DS environmental conditions			
M	Docking station outside OP temp	Mainboard temperature above limit	Move to a cooler environment
M	Docking station outside OP temp	Mainboard temperature below limit	Move to a warmer environment
M	DS CPU Temp high	Internal CoM temperature above limit	Move to a cooler environment Replace Docking Station
M	DS CPU Temp low	Internal CoM temperature below limit	Move to a warmer environment
M	Replace Docking Station	Fan speed too low	Restart device Replace Docking Station
DS Power management			
H	Replace left battery	Operation Battery – permanent failure or recovery charge failed	- Check batteries - If necessary, replace batteries - If necessary, replace Docking Station
H	Replace right battery	Reserve Battery – permanent failure or recovery charge failed	
L	Left battery missing	Operation Battery – no communication possible via SMB or battery not present	
L	Left battery door open	Operation Battery – door open	
H	Right battery missing	Reserve Battery – no communication possible via SMB or battery not present	
H	Right battery door open	Reserve Battery – door open	
M	Right battery < 40 %	Lack of energy on reserve battery (remaining capacity < 40%)	
H	Right battery < 30 %	Lack of energy on reserve battery (remaining capacity < 30%)	
H	Right battery < 20 %	Lack of energy on reserve battery (remaining capacity < 20%)	
M	DC Power exception	Exceptional operation with external DC-power supply	
-	Replace Docking Station	Degradation (+/- 10%) of voltage VCC3V3 for SafetyDS MCU	
L	Powered by reserve battery	Power supply switched to Reserve Battery	
H	Battery extremely low	Device working with low battery capacities and no external supply	
DS Alarm signaling			
H	AUDIO loudspeaker error	Replace docking station	Restart device. If error persists, replace Docking Station
H	Buzzer sound (via speaker) not detected during selftest	Replace docking station	
H	ALARM LED error (current out of range)	Replace docking station	
H	Unknown Alarm	Replace system	
H	Speaker sound not detected during selftest	Replace docking station	
DS Display and touch			
M	Replace docking station	Left touch-button LED Error	Restart device. If error persists, replace Docking Station
M	Replace docking station	Right touch-button LED Error	
H	Replace docking station	Left touch button error	
H	Replace docking station	Right touch button error	
H	Replace docking station	Display Touch Error	
M	Replace docking station	Display Backlight Error (current out of range)	

Prio.	Alarm message	Possible cause	Proposed action
DS Module related			
H	Slot 4 forced power off	Current overload situation, module slot 4 (upper) power switched off	Restart the device. If error persists, replace the corresponding module. If error persists, replace Docking Station
H	Slot 3 forced power off	Current overload situation, module slot 3 power switched off	
H	Slot 2 forced power off	Current overload situation, module slot 2 power switched off	
H	Slot 1 forced power off	Current overload situation, module slot 1 (lower) power switched off	
H	Slot 4 improper disconnection	Unexpected disconnection of module in slot 4 (upper)	Informs you that a module has been disconnected
H	Slot 3 improper disconnection	Unexpected disconnection of module in slot 3	
H	Slot 2 improper disconnection	Unexpected disconnection of module in slot 2	
H	Slot 1 improper disconnection	Unexpected disconnection of module in slot 1 (lower)	
H	Replace module in slot 4	Module on slot 4 (upper) signals alarm via alarm GPIO	A module has been disconnected while delivering therapy!! Check Patient status
H	Replace module in slot 3	Module on slot 3 signals alarm via alarm GPIO	
H	Replace module in slot 2	Module on slot 2 signals alarm via alarm GPIO	
H	Replace module in slot 1	Module on slot 1 (lower) signals alarm via alarm GPIO	
L	Remove duplicate module	Module of connected type already registered	Insert the module in the other orientation. If error persists, placed the module in another slot If error persist, replace module
L	Module not compatible	The hard- or software of the module is not compatible to the system	
L	Module patient type error	At least one module did not accept the patient type	
L	Slot 4 communication error	Module 4 Communication Error	Make sure that only 1 module of each type is installed in a Docking Station Send the module top service If possible, insert the module in another slot. If error persists, replace module
H	Slot 3 communication error	Module 3 Communication Error	
H	Slot 2 communication error	Module 2 Communication Error	
H	Slot 1 communication error	Module 1 Communication Error	
H	Lock module in slot 4	Module lock mechanism, module slot 4 (upper) unlocked	Check locking mechanism in the Docking station If error persists, replace docking station
H	Lock module in slot 3	Module lock mechanism, module slot 3 unlocked	
H	Lock module in slot 2	Module lock mechanism, module slot 2 unlocked	
H	Lock module in slot 1	Module lock mechanism, module slot 1 (lower) unlocked	
H	Replace system	At least one module did not accept the system setting (no content at all or invalid data in SPIFLASH)	Replace module
L	Replace module in slot 4	Module connected to slot 4 (upper) failed handshake test on connection	If possible, insert the module in another slot. If error persists, replace module
L	Replace module in slot 3	Module connected to slot 3 failed handshake test on connection	
L	Replace module in slot 2	Module connected to slot 2 failed handshake test on connection	
I	Replace module in slot 1	Module connected to slot 1 (lower) failed handshake test on connection	
Monitoring Module			
-	Forced Stop of Monitor	Monitor stopped, used for deactivating alarms, when Monitoring is stopped	Disconnect and reconnect monitoring module. If error persists, replace module
L	Gas sensor disconnected	Disconnection of gas sensor. No new message received since 500 ms	Check gas sensor connection to the monitoring module
H	Replace monitor	Selftest Error SafetyMM MCU (power on selftest)	Disconnect and reconnect monitoring module. If error persists, replace module
H	Replace monitor	Selftest Error CoM (boot, test)	
H	Replace monitor	Communication error (timeout) between SafetyDS and CoM	
H	Replace monitor	Alarm message send from SafetyDM not acknowledged SafetyDS	
H	Replace monitor	SPI flash read error (SN, manufacturer information, options…)	

Prio.	Alarm message	Possible cause	Proposed action
H	Replace monitor	SPI flash read error (SN, manufacturer information, options…)	
M	Invalid IBP1/2	Board ibp1/ibp2 output timed out	Measurement may be not correct. If necessary, replace module
M	Invalid NIBP	Board nibp output timed out	Measurement may be not correct. If necessary, replace module
M	Invalid TEMP	Board temperature output timed out	Measurement may be not correct. If necessary, replace module
M	Invalid IBP3/4	Board ibp1/ibp2 (ibp3/ibp4) output timed out	Measurement may be not correct. If necessary, replace module
M	Invalid ECG	ECG12 output timed out	Measurement may be not correct. If necessary, replace module
M	Invalid Masimo SpO2	Board output timed out	Measurement may be not correct. If necessary, replace module
M	Invalid monitoring	Board output is invalid	Measurement may be not correct. If necessary, replace module
M	Invalid IBP1/2	Board ibp1/ibp2 output is invalid	Measurement may be not correct. If necessary, replace module
M	Invalid NIBP	Board nibp output is invalid	Measurement may be not correct. If necessary, replace module
M	Invalid TEMP	Board temperature output is invalid	Measurement may be not correct. If necessary, replace module
M	Invalid IBP3/4	Board ibp1/ibp2 (ibp3/ibp4) output is invalid	Measurement may be not correct. If necessary, replace module
M	Invalid ECG	ECG12 output is invalid	Measurement may be not correct. If necessary, replace module
L	Replace gas sensor	Message received from sensor is invalid or cannot be processed	Measurement may be not correct. If necessary, replace module
M	Invalid Masimo SpO2	Board output is invalid	Measurement may be not correct. If necessary, replace module
M	Invalid monitoring setting	Board input (command from gui) is invalid/forbidden/not understood	Measurement may be not correct. If necessary replace module
M	Invalid IBP3/4 setting	Board ipb1/ibp2 (ibp3/ibp4) input (command from gui) is invalid/forbidden/not understood	Measurement may be not correct. If necessary replace module
M	Invalid ECG setting	ECG12 input (command from gui) is invalid/forbidden/not understood	Measurement may be not correct. If necessary replace module
L	Invalid gas sensor setting	Message from GUI to gas sensor is invalid/forbidden	Measurement may be not correct. If necessary, replace module
M	Invalid Masimo SpO2	Board input (command from gui) is invalid/forbidden/not understood	Measurement may be not correct. If necessary, replace module
L	Replace monitor	internal vref is lo (aka external vref is hi)	Module power supply may be not working correctly. Monitor
L	Replace monitor	internal vref is hi (aka external vref is lo)	
L	Replace monitor	power rail '5V' is lo	
L	Replace monitor	power rail '5V' is hi	
L	Replace monitor	power rail '12V' is lo	
L	Replace monitor	power rail '12V' is hi	
L	Replace monitor	power rail '8V' is lo	
L	Replace monitor	power rail '8V' is hi	
L	Replace monitor	power rail '3V3' is lo	

Prio.	Alarm message	Possible cause	Proposed action
L	Replace monitor	power rail '3V3' is hi	module can continue to operate, but check for other possible alarms
L	Replace monitor	power rail '5V mod' is lo	
L	Replace monitor	power rail '5V mod' is hi	
L	Replace monitor	power rail '27V' is lo	
L	Replace monitor	power rail '27V' is hi	
L	Monitor outside OP temp	internal temperature is lo	
L	Monitor outside OP temp	internal temperature is hi	
Ventilator Module general technical alarms			
L	Gas sensor disconnected	Disconnection of gas sensor. No new message received since 500 ms	Check gas sensor connection to ventilator module
H	Replace ventilator	Selftest error MCU on power-on when watchdog fails.	Disconnect and reconnect ventilator module. If error persists, replace module
H	Replace ventilator	Selftest error MCU on power-on when 5V is out of range (< 4 or > 5.5V)	
H	-	Communication error (timeout) between SafetyDS and CoM	
H	Replace ventilator	Alarm message send from SafetyVM not acknowledged by SafetyDS	
H	Replace ventilator	No new message received from Caesar in time (500 ms)	
H	Replace ventilator	SPI flash read error (SN, manufacturer information, options…)	
H	Replace ventilator	SPI flash write error (SN, manufacturer information, options…)	
M	Fan error - FiO2 21%	Fan error (speed < 219 pulses/s)	
L	Ventilator outside OP temp	Temperature of board mounted sensor < -20 °C (resolution 0.1)	Move to a warmer environment
L	Ventilator outside OP temp	Temperature of board mounted sensor > 60 °C (resolution 0.1)	Move to a cooler environment. If necessary, replace ventilator module
H	Replace ventilator	Unknown message (or length) from Caesar received or handler missing.	Disconnect and reconnect Ventilator module. If error persists, replace module
H	Internal error	Caesar input (command from gui) is invalid/forbidden/not understood/out of range	
L	Replace gas sensor	Message received from sensor is invalid or cannot be processed	Check gas sensor
L	Internal error	Message from GUI to gas sensor is invalid/forbidden	
L	Replace ventilator	MCU internal Vref < 1.18 V	Module power supply may be not working correctly. Ventilator module can continue to operate, but check for other possible alarms
L	Replace ventilator	MCU internal Vref > 1.24 V	
L	Ventilator outside OP temp	MCU internal temperature < -20 °C	
L	Ventilator outside OP temp	MCU internal temperature > 70 °C	
L	Replace ventilator	5V supply < 4.5V	
L	Replace ventilator	5V supply > 5.25V	
L	Replace ventilator	3V3 supply < 3.135V	
L	Replace ventilator	3V3 supply > 3.465V	
Ventilator Module Additional Alarms			
H	Replace ventilator	No gas sources available	Replace ventilator module
H	Replace ventilator	One ambient pressure sensor is defect. The remaining one overtakes.	
H	Replace ventilator	Module output pressure sensor broken.	
H	Replace ventilator	Blower not available	
H	Replace ventilator	Air Input Gas Temperature Sensor T1 measures open/short circuit.	
H	Replace ventilator	Output Gas Temperature Sensor T2 measures open/short circuit.	
H	Replace ventilator	Oxygen Gas Temperature Sensor T3 measures open/short circuit.	
H	Replace ventilator	Compressed Air Supply Pressure Sensor P1 Malfunction.	
H	Replace ventilator	Oxygen Supply Pressure Sensor P2 Malfunction.	
H	Replace ventilator	Output Pressure Sensor P3 Malfunction.	
H	Replace ventilator	Airway Pressure Sensor P4 Malfunction.	
H	Replace ventilator	Patient flow Sensor P5 Malfunction.	
H	Replace ventilator	Cuff Pressure Sensor P6 Malfunction.	
H	Replace ventilator	Redundant Cuff Pressure Sensor P7 Malfunction	
H	Replace ventilator	Ambient Pressure Sensor 1 P8 Malfunction	

Prio.	Alarm message	Possible cause	Proposed action
H	Replace ventilator	Ambient Pressure Sensor 2 P9 Malfunction	Replace ventilator module
H	Replace ventilator	Auxiliary Pressure Sensor P10 Malfunction	
H	Replace ventilator	Redundant Output Pressure Sensor P11 Malfunction	
H	Replace ventilator	Air Flow Sensor FS1 Malfunction	
H	Replace ventilator	Oxygen Flow Sensor FS2 Malfunction	
H	Replace ventilator	Output Flow Sensor FS3 Malfunction	
H	Replace ventilator	Caesar module selftest failed	
H	Replace ventilator	Oxygen Valve PV1 Malfunction.	
H	Replace ventilator	Air Valve PV5 Malfunction.	
H	Replace ventilator	Safety Valve V4 Malfunction.	
H	Replace ventilator	Blower Malfunction.	
H	Replace ventilator	Ambient Pressure Measurement Error.	
H	Replace ventilator	Internal Flow Sensor Measurement Error.	
H	Replace ventilator	Communication between main and secondary processor fails.	
H	Replace ventilator	ADC Malfunction.	
H	Replace ventilator	Motor Temperature Sensor Malfunction.	
H	Replace ventilator	Output Pressure Measurement Error	
M	Calibrate O2 sensor	FiO2 Deviation.	Calibrate O2 sensor. If error persists, replace oxygen sensor.
H	Replace ventilator	Output Flow Sensor Malfunction	Replace ventilator module
H	Replace ventilator	Aux Pressure Sensor Malfunction Basic Result	
H	Replace ventilator	Red Output Pressure Sensor Malfunction Basic Result	
H	Replace ventilator	Output Pressure Sensor Malfunction Basic Result	
H	Replace ventilator	Airway Pressure Sensor Malfunction Basic Result	
H	Replace ventilator	Temperature OxygenIn Sensor Malfunction Basic Result	
H	Replace ventilator	Temperature Air In Sensor Malfunction Basic Result	
H	Replace ventilator	Oxygen Supply Sensor Malfunction Basic Result	
H	Replace ventilator	Air Supply Sensor Malfunction Basic Result	
H	Replace ventilator	P ambient Sensor2 Malfunction Basic Result	
H	Replace ventilator	P ambient Sensor1 Malfunction Basic Result	
H	Replace ventilator	Air Flow Sensor Malfunction Basic Result	
H	Replace ventilator	Oxygen Flow Sensor Malfunction Basic Result	
H	Replace ventilator	Oxygen Valve Error Basic Result	
H	Replace ventilator	Output Pressure Measurement Error Extended Result	
H	Replace ventilator	Internal Flow Measurement Error Extended Result	
H	Replace ventilator	Motor Temperature Sensor Malfunction Basic Result	
H	Replace ventilator	Ambient Pressure Measurement Error Basic Result	
H	Replace ventilator	Temperature Out Sensor Malfunction Basic Result	
H	Replace ventilator	Blower Air Source Error Extended Result	
H	Replace ventilator	Compressed Air Source Error Extended Result	
H	Replace ventilator	Oxygen Source Error Extended Result	
H	Replace ventilator	Safety Valve Malfunction Basic Result	
H	Replace ventilator	Internal cuff leakage Basic Result	
H	Replace ventilator	Pilot Valve Error Basic Result	
H	Replace ventilator	Blower Error Basic Result	
H	Replace ventilator	AirValve Error Basic Result	
H	Replace ventilator	Air Source Check Valve Error Extended Result	
H	Replace ventilator	Oxygen Selection Valve Error Extended Result	
H	Replace ventilator	Air Selection Valve Error Extended Result	
H	Replace ventilator	Safety Valve Error Extended Result	
H	Replace ventilator	Error_Ram	
H	Replace ventilator	Error_Rom	
H	Replace ventilator	Error_InternalWatchdog	
H	Replace ventilator	Error_ExternalWatchdog	
H	Replace ventilator	MCU_BL_IBB Error	
H	Replace ventilator	MCU_BL_Checksum Error	
H	Replace ventilator	MCU_APP_IIB Error	

Prio.	Alarm message	Possible cause	Proposed action
H	Replace ventilator	MCU_APP_Checksum Error	Replace ventilator module
H	Replace ventilator	SCU_BL_IBB Error	
H	Replace ventilator	SCU_BL_Checksum Error	
H	Replace ventilator	SCU_APP_IIB Error	
H	Replace ventilator	SCU_APP_Checksum Error	
H	Replace Ventilator	Caesar response timeout in startup self-test	
H	Replace ventilator	O2 value could not be restored after O2 flush maneuver	
H	Check flow sensor	Patient Flow Sensor Malfunction	Replace sensor
H	Disconnect cuff. Inflate manually	Red Cuff Pressure Sensor Malfunction Basic Result	Inflate cuff manually
H	Disconnect cuff. Inflate manually	Cuff Pressure Sensor Malfunction Basic Result	
H	Disconnect cuff. Inflate manually	Cuff Pressure Measurement Error Extended Result	
H	Disconnect cuff. Inflate manually	Cuff Source Valve Error Extended Result	
H	Replace O2 sensor	Oxygen Concentration Sensor Malfunction.	Replace O2 sensor
H	Check O2 sensor	Oxygen Conc Sensor Malfunction Basic Result	Calibrate O2 sensor. If error persists, replace oxygen sensor.
H	Check expiration valve	Expiration Valve Error Extended Result	Check and replace valve. If error persists, replace ventilator module.
H	O2 Flush Error	Ventilation setting O2 value differs from O2 flush value set	If necessary, replace module
H	O2 Flush Error	O2 flush value was set but not accepted by Ventilator	If necessary, replace module
H	Nebulizer defect	Setting nebulizer option failed	If necessary, replace module
H	Leakage too high	VBS Leakage Too High	Check VBS components for leakage. If error persists, replace ventilator module.

Appendix B

Text Printouts and Diagnostic Statements from Hannover ECG System (HES)

Code	Description
GROUP 1: Type of QRS Position	
1000	Extreme right axis deviation
1001	Normal axis
1002	Normal axis
1003	Normal axis
1004	Normal axis
1005	Left axis deviation
1006	QRS angle < -90 degrees
1007	Sagittal type
1008	SI/QIII-type
1009	QI/SIII-type
1010	QIII-left-type
GROUP 2: "Technical Directions"	
2000	Probably limb leads reversed
2001	Probably limb leads reversed
2002	Noise ;; µv small
2003 n	Noise ;; µv medium
2004	Noise ;;;; µv high
2005	Check ECG - repeat recording
2006	Low voltage in chest leads, total QRS < 1.0 mv
2007	Low voltage in limb leads, total QRS< 0.5 mv
2008	Less than ; of ;; cycles averaged -
2009	Baseline shift ;;;;; µv
2010	Questionable ECG measurement in ; lead(s)
2011	No further evaluation
2012	Consider artificial ECG
2013	Rms: ;;; ;;; ;;; ;;; ;;; ;;; ;;; ;;;
2015	High offset in:
20160	
20161	P-QRS fusion
20170	
20171	Possible TP fusion
20172	P and T wave recognition questionable
2018	Questionable ECG measurement and interpretation
2019	High amplitude in:
2020	Spikes in ECG
2021	PQ+QT > RR: Check Pon and Toff Fiducials
GROUP 3: Evaluation Directions about the QRST Complex	
3000	Broad QRS
3002	No QRS-T evaluation because of reversed limb electrodes
30030	Slow QRS onset or delta wave
30031	1 in :
3005	M form in
3006	Q in :
3007	QS in :
3008	R loss or reduction in:
3009	Reduced R in :
3010	Broad R in :
3011	Tall R in :
3012	Broad R' in :
3013	Tall R' in :
3014	Late R in :

Code	Description
3015	Abnormal R/S in :
3016	Small S in :
3017	Broad S in :
3018	Deep S in :
3019	ST elevation in :
3020	ST depression in :
3021	LI leads :
3022	CH leads :
3023	
3024	Short PR segment
3025	Diag tests:
30260	
30261	Distinct ST elevation/depression in limb and chest leads
30262	Myocardial injury or acute infarction
3027	High voltage QRS
3030	QT-Dispersion : Std ;;; ms Max ;;; ms from ;/8 leads
3031	QTc-Dispersion : Std ;;; ms Max ;;; ms from ;/8 leads
3032	QT dispersion : Std ;;; ms Max ;;; ms from ;/6 CH-leads
3033	QTc dispersion : Std ;;; ms Max ;;; ms from ;/6 CH-leads
3034	QT dispersion : only ;/8 valid leads - no calculation
3035	QTc dispersion : only ;/8 valid leads - no calculation
3036	QT dispersion : only ;/6 valid leads - no calculation
3037	QTc dispersion : only ;/6 valid leads - no calculation
GROUP 4: Atrial Diagnostics	
4000	Possible left atrial enlargement
4001	Left atrial enlargement
4002	Possible right atrial enlargement
4003	Right atrial enlargement
4004	Possible biatrial enlargement
4005	Atrial conduction defect
4006	Abnormal P axis
GROUP 5: Indications of Repolarisation Disturbances	
5000	T amplitude > 0.9 mv in
5001	Flat T waves in
5011	Nonspecific T wave abnormalities in
5012	Nonspecific ST segment abnormalities in
5013	Abnormal repolarization in
5014	Abnormal repolarization with downsloping ST in
5021	ST segment elevation in
5022	Consider injury
5023	ST segment elevation in
5024	Consider injury
5025	T wave abnormalities in
5026	Consider ischemia
5027	T wave abnormalities in
5028	Consider ischemia
5030	Nonspecific ST-T abnormalities in
GROUP 6: Diagnostic Directions (Category B) - Conduction Defects -	
6001	Complete left bundle branch block
6002	Probable complete left bundle branch block
6003	Possible complete left bundle branch block
6011	Incomplete left bundle branch block
6012	Probable incomplete left bundle branch block
6013	Possible incomplete left bundle branch block
6021	Complete right bundle branch block
6022	Probable complete right bundle branch block
6023	Possible complete right bundle branch block
6031	Incomplete right bundle branch block
6032	Probable incomplete right bundle branch block

Code	Description
6033	Possible incomplete right bundle branch block
6041	Intraventricular conduction delay
6042	Probable intraventricular conduction delay
6043	Possible intraventricular conduction delay
6044	Intraventricular conduction delay/check for LBBB
6051	Left anterior fascicular block
6052	Probable left anterior fascicular block
6053	Possible left anterior fascicular block
6061	Left posterior fascicular block
6062	Probable left posterior fascicular block
6063	Possible left posterior fascicular block
60700	Prolongation of intraventricular conduction for age
6071	Prolongation of intraventricular conduction
6081	Ventricular preexcitation
6082	Probable ventricular preexcitation
6083	Possible ventricular preexcitation
6091	Ventricular preexcitation
6092	Probable ventricular preexcitation
6093	Possible ventricular preexcitation
6101	6entricular preexcitation
6102	Probable ventricular preexcitation
6103	Possible ventricular preexcitation
6110	Probable trifascicular block
6111	Right delay
6112	Left delay
GROUP 7: Diagnostic Directions (Category A) - Normal, Hypertrophy, Infarctions -	
7000	QRS significantly prolonged
7001	QRS extremely prolonged
7005	All QRS complexes paced by PM
7009	1 intrinsic QRS complex measured
7010	;; intrinsic QRS complexes measured
7011	
7012	No measurement - less than 3 sequential intrinsic beats
7013	No measurement - all intrinsic beats rejected
7101	Possibly normal
7102	Probably normal
7103	Normal
7201	Possible right ventricular hypertrophy
7202	Probable right ventricular hypertrophy
7203	Right ventricular hypertrophy
7207	Consider right ventricular hypertrophy
7301	Possible left ventricular hypertrophy
7302	Probable left ventricular hypertrophy
7303	Left ventricular hypertrophy
7307	Consider left ventricular hypertrophy
7401	Possible biventricular hypertrophy
7402	Probable biventricular hypertrophy
7403	Biventricular hypertrophy
7407	Consider biventricular hypertrophy
7410	Consider ventricular enlargement
7501	Possible anterior myocardial infarction, probably old
7502	Probable anterior myocardial infarction, probably old
7503	Anterior myocardial infarction, probably old
7504	Possible acute anterior myocardial infarction
7505	Probable acute anterior myocardial infarction
7506	Acute anterior myocardial infarction
7507	Consider anterior myocardial infarction
750a	Possible recent anterior myocardial infarction
750b	Probable recent anterior myocardial infarction

Code	Description
750c	Recent anterior myocardial infarction
750d	Possible anterior myocardial infarction, age indeterminate
750e	Probable anterior myocardial infarction, age indeterminate
750f	Anterior myocardial infarction, age indeterminate
7601	Possible inferior myocardial infarction, probably old
7602	Probable inferior myocardial infarction, probably old
7603	Inferior myocardial infarction, probably old
7604	Possible acute inferior myocardial infarction
7605	Probable acute inferior myocardial infarction
7606	Acute inferior myocardial infarction
7607	Consider inferior myocardial infarction
760a	Possible recent inferior myocardial infarction
760b	Probable recent inferior myocardial infarction
760c	Recent inferior myocardial infarction
760d	Possible inferior myocardial infarction, age indeterminate
760e	Probable inferior myocardial infarction, age indeterminate
760f	Inferior myocardial infarction, age indeterminate
7701	Possible myocardial infarction, probably old
7702	Probable myocardial infarction, probably old
7703	Myocardial infarction, probably old
7704	Possible acute myocardial infarction
7705	Probable acute myocardial infarction
7706	Acute myocardial infarction
7707	Consider myocardial infarction
7708	Consider acute myocardial infarction
770a	Possible recent myocardial infarction
770b	Probable recent myocardial infarction
770c	Recent myocardial infarction
770d	Possible myocardial infarction, age indeterminate
770e	Probable myocardial infarction, age indeterminate
770f	Myocardial infarction, age indeterminate
7811	Possible posteroinferior myocardial infarction, probably old
7812	Probable posteroinferior myocardial infarction, probably old
7813	Posteroinferior myocardial infarction, probably old
7814	Possible acute posteroinferior myocardial infarction
7815	Probable acute posteroinferior myocardial infarction
7816	Acute posteroinferior myocardial infarction
7817	Consider posteroinferior myocardial infarction
781a	Possible recent posteroinferior myocardial infarction
781b	Probable recent posteroinferior myocardial infarction
781c	Recent posteroinferior myocardial infarction
781d0	Possible posteroinferior myocardial infarction,
781d1	Age indeterminate
781e0	Probable posteroinferior myocardial infarction,
781e1	Age indeterminate
781f	Posteroinferior myocardial infarction, age indeterminate
7821	Possible lateral myocardial infarction, probably old
7822	Probable lateral myocardial infarction, probably old
7823	Lateral myocardial infarction, probably old
7824	Possible acute lateral myocardial infarction
7825	Probable acute lateral myocardial infarction
7826	Acute lateral myocardial infarction
7827	Consider lateral myocardial infarction
782a	Possible recent lateral myocardial infarction
782b	Probable recent lateral myocardial infarction
782c	Recent lateral myocardial infarction
782d	Possible lateral myocardial infarction, age indeterminate
782e	Probable lateral myocardial infarction, age indeterminate
782f	Lateral myocardial infarction, age indeterminate

Code	Description
7831	Possible anteroseptal myocardial infarction, probably old
7832	Probable anteroseptal myocardial infarction, probably old
7833	Anteroseptal myocardial infarction, probably old
7834	Possible acute anteroseptal myocardial infarction
7835	Probable acute anteroseptal myocardial infarction
7836	Acute anteroseptal myocardial infarction
7837	Consider anteroseptal myocardial infarction
783a	Possible recent anteroseptal myocardial infarction
783b	Probable recent anteroseptal myocardial infarction
783c	Recent anteroseptal myocardial infarction
783d	Possible anteroseptal myocardial infarction, age indeterminate
783e	Probable anteroseptal myocardial infarction, age indeterminate
783f	Anteroseptal myocardial infarction, age indeterminate
7841	Possible anterolateral myocardial infarction, probably old
7842	Probable anterolateral myocardial infarction, probably old
7843	Anterolateral myocardial infarction, probably old
7844	Possible acute anterolateral myocardial infarction
7845	Probable acute anterolateral myocardial infarction
7846	Acute anterolateral myocardial infarction
7847	Consider anterolateral myocardial infarction
784a	Possible recent anterolateral myocardial infarction
784b	Probable recent anterolateral myocardial infarction
784c	Recent anterolateral myocardial infarction
784d	Possible anterolateral myocardial infarction, age indeterminate
784e	Probable anterolateral myocardial infarction, age indeterminate
784f	Anterolateral myocardial infarction, age indeterminate
7851	Possible myocardial infarction (ant. + infer.), probably old
7852	Probable myocardial infarction (ant. + infer.), probably old
7853	Myocardial infarction (ant. + infer.), probably old
7854	Possible acute myocardial infarction (ant. + infer.)
7855	Probable acute myocardial infarction (ant. + infer.)
7856	Acute myocardial infarction (ant. + infer.)
7857	Consider myocardial infarction (ant. + infer.)
785a	Possible recent myocardial infarction (ant. + infer.)
785b	Probable recent myocardial infarction (ant. + infer.)
785c	Recent myocardial infarction (ant. + infer.)
785d	Possible myocardial infarction (ant. + infer.), age indeterminate
785e	Probable myocardial infarction (ant. + infer.), age indeterminate
785f	Myocardial infarction (ant. + infer.), age indeterminate
7861	Possible myocardial infarction (septal + infer.), probably old
7862	Probable myocardial infarction (septal + infer.), probably old
7863	Myocardial infarction (septal + infer.), probably old
7864	Possible acute myocardial infarction (septal + infer.)
7865	Probable acute myocardial infarction (septal + infer.)
7866	Acute myocardial infarction (septal + infer.)
7867	Consider myocardial infarction (septal + infer.)
786a	Possible recent myocardial infarction (septal + infer.)
786b	Probable recent myocardial infarction (septal + infer.)
786c	Recent myocardial infarction (septal + infer.)
786d	Possible myocardial infarction (septal + infer.), age indeterminate
786e	Probable myocardial infarction (septal + infer.), age indeterminate
786f	Myocardial infarction (septal + infer.), age indeterminate
7871	Possible inferolateral myocardial infarction, probably old
7872	Probable inferolateral myocardial infarction, probably old
7873	Inferolateral myocardial infarction, probably old
7874	Possible acute inferolateral myocardial infarction
7875	Probable acute inferolateral myocardial infarction
7876	Acute inferolateral myocardial infarction
7877	Consider inferolateral myocardial infarction

Code	Description
787a	Possible recent inferolateral myocardial infarction
787b	Probable recent inferolateral myocardial infarction
787c	Recent inferolateral myocardial infarction
787d0	Possible inferolateral myocardial infarction,
787d1	Age indeterminate
787e0	Probable inferolateral myocardial infarction,
787e1	Age indeterminate
787f	Inferolateral myocardial infarction, age indeterminate
7901	Possible myocardial infarction with left ventricular enlargement
7902	Probable myocardial infarction with left ventricular enlargement
7903	Myocardial infarction with left ventricular enlargement
7907	Consider myocardial infarction with left ventricular enlargement
7911	Indeterminate ECG
7912	Indeterminate ECG
7913	Indeterminate ECG
7914	Possible ischemia
7915	Rhythm abnormalities
7920	Possible right or biventricular hypertrophy
79210	Probable right ventricular hypertrophy,
79211	Possibly biventricular
79220	Right ventricular hypertrophy,
79221	Possibly biventricular
7923	Consider biventricular hypertrophy
7930	Possible left or biventricular hypertrophy
79310	Probable left ventricular hypertrophy,
79311	Possibly biventricular
79320	Left ventricular hypertrophy,
79321	Possibly biventricular
7933	Consider biventricular hypertrophy
7934	With ST segment abnormalities
7935	With T wave abnormalities
7936	With ST segment abnormalities
7937	With ST segment abnormalities
7940	Check averaged intrinsic beat for extrasystole
GROUP 8: Diagnostic Directions (Category B) Rhythm -	
80000	
80001	
8101	Sinus-rhythm
8102	Sinus arrhythmia
8103	Respiratory
8104	Atrial escape rhythm
8105	Changing pacemaker
8106	Respiratory changes of p-vector
8107	Absolute arrhythmia; atrial fibrillation/flutter
8108	Absolute arrhythmia; possible atrial fibrillation/flutter
8110	Atrial escape rhythm (PR < 100 ms)
8120	A-V block 1st degree PR duration ;;; ms
8121	Check A-V block of higher degree
8140	Atrial bigeminus
8141	Intermittent atrial bigeminus
8161	With ;; sinus PB with compensatory pause probable
8162	With ;; atrial extrasystoles
8164	With atrial extrasystoles
8165	With ;; A-V extrasystoles
8170	All ventricular pacemaker spikes captured
8180	;; of ;; ventricular pacemaker spikes captured
8190	;; atrial pacemaker spikes
8196	No pacemaker activity detected in the recording
8200	Regular rhythm

Code	Description
8201	Regular ventricular rhythm
8202	Escape-rhythm
8203	Arrhythmia
8206	Possible retrograde disconnection of sinus node
8207	Arrhythmia (PR < 100 ms)
8208	Regular rhythm, tachycardia
8209	Regular ventricular rhythm, tachycardia
8210	Asystole, please check ECG data
8240	Bigeminus
8241	Intermittent bigeminus
8242	Trigeminus
8243	Intermittent trigeminus
8260	With ;; ventricular extrasystoles
8261	With ;; polyform VES
8262	With ;; VES with compensatory pause
8264	With ;; interposed VES
8265	With ;; escape systoles
8266	With ;; aberrant complex(es)
8270	With ;; aberrant QRS with P-wave
8271	Possible intermittent bundle branch block
8280	Cycle :
8281	Prematurity index:
8300	Pacemaker ECG
8301	Probable pacemaker ECG
8302	Possible pacemaker ECG
8310	ECG with ventricular pacemaker
8311	Probable ECG with ventricular pacemaker
8312	Possible ECG with ventricular pacemaker
8320	ECG with atrial pacemaker
8321	Probable ECG with atrial pacemaker
8322	Possible ECG with atrial pacemaker
8330	ECG with atrial + ventricular pacemaker
8331	Probable ECG with atrial + ventricular pacemaker
8332	Possible ECG with atrial + ventricular pacemaker

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