User's manual

Servo-air Ventilator System v4.6

GETINGE

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1 Introduction

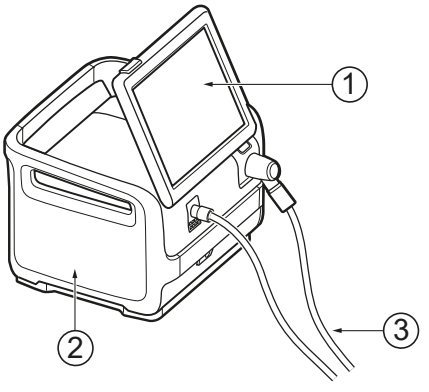
Table of contents

1.1 Device description

1.1.1 Device components

The ventilator system consists of:

1. User interface for setting ventilation modes and therapies, displaying data and indicating alarms
2. Patient unit for mixing gases and controlling gas delivery
3. Patient circuit for delivering and exchanging gases



1.1.2 Intended use

The Servo-air Ventilator System is intended for respiratory support, monitoring and treatment.

1.1.3 Intended patients

The Servo-air Ventilator System is intended for pediatric and adult patients.

1.1.4 Intended user

The Servo-air ventilator system is intended to be used only by healthcare professionals.

1.1.5 Intended use environment

The Servo-air Ventilator System is intended to be used only in professional healthcare facilities and for transport within these facilities.

1.1.6 Indications for use

The use of Servo-air Ventilator System is indicated when the patient's spontaneous ventilation is inadequate to maintain life. It is also indicated as prophylaxis for imminent collapse of other physiologic functions, or ineffective gas exchange in the lungs.

1.1.7 Clinical benefits

The main intended clinical benefit of the Servo-air Ventilator System for the patient is to provide adequate oxygenation and ventilation.

1.1.8 Possible side-effects

The following undesirable side-effects can appear during:

- Mechanical ventilation
  - Volutrauma
  - Barotrauma (e.g. pneumothorax)
  - Atelectotrauma
  - Ventilator induced diaphragmatic dysfunction (VIDD)
  - Ventilator associated pneumonia (VAP)
  - Oxygen toxicity
- Non-invasive ventilation (NIV)
  - Aspiration
  - Hypotension
- High Flow therapy
  - Abdominal distension
  - Aspiration

1.1.9 Contraindications

Non-invasive ventilation is contraindicated for patients with any of the following conditions:

- Respiratory arrest/unstable cardiorespiratory status
- Uncooperative patient
- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Facial/esophageal or gastric surgery
- Craniofacial trauma/burns
- Anatomic lesions of upper airway

1.1.10 Limitations

It is the responsibility of the user to select the appropriate respiratory mode for the underlying disease of the patient. For all ventilator settings, the user needs to consider the respiratory status and the general state of health of the patient in order to optimally adapt the ventilation settings to the patient's condition. Any changes to the patient's state need to be monitored continuously.

1.1.11 Cleaning and maintenance

Refer to the Servo-air cleaning and maintenance user's manual.

1.1.12 Servicing Guidelines

Regular Service: The ventilator system must be serviced at regular intervals by personnel who have received authorization and specialized training by the manufacturer.

Complete service records: All service performed on the ventilator system must be recorded in a service log in accordance with hospital procedures and local and national regulations.

Service Contract: It is strongly recommended that all service on the ventilator system should be performed as part of a service contract with the manufacturer.

1.1.13 Disclaimers

Non-professional servicing:

The manufacturer has no responsibility for the safe operation of the ventilator system if installation, service or repairs are performed by persons other than those authorized by the manufacturer.

1.1.14 Reconditioning, decommissioning, and incidents

The ventilator system may not be reused as a reconditioned system unless the reconditioning is performed by the manufacturer.

Contact a representative of the manufacturer regarding decommissioning of the equipment.

Any serious incident that has occurred in relation to the ventilator system must be reported to the manufacturer and the relevant competent authority.

1.2 Safety guidelines

Follow these safety guidelines. Additional warnings appear in context throughout this document.

Information is highlighted with Warning, Caution or Note, where:

WARNING!

Indicates critical information about a potential serious outcome to the patient or the user.

CAUTION!

Indicates instructions that must be followed in order to ensure the proper operation of the equipment.

NOTE:

Indicates information requiring special attention.

1.2.1 General

WARNING!

- The ventilator system may only be operated by authorized personnel who are properly trained in its use. It must be operated according to the instructions in this User´s Manual.
- After unpacking, perform a routine cleaning and a pre-use check.
- Always perform a pre-use check before connecting the ventilator system to a patient.
- Secure all tubing and cables to avoid the risk of unwanted movement of the equipment.
- If any of the following occurs, discontinue use of the ventilator system and contact a service technician:
  - unfamiliar pop-up windows on the screen
  - unfamiliar sounds
  - any unfamiliar or unexplained event
  - alarms that cannot be resolved
- Make sure that a manual resuscitator is readily available.
- The air inlet must not be occluded.
- Ventilation must be started manually from standby.
- Keep the ventilator system upright during use.

WARNING!

- Do not cover the ventilator system in any way, since the functioning of the equipment may be adversely affected.
- Do not modify or remove any original parts.
- The ventilator system must not be used during radiotherapy, since this may cause system malfunction.
- The ventilator system must not be used in a hyperbaric chamber.
- The ventilator system must be kept away from magnetic resonance imaging (MRI) equipment.
- Only accessories, supplies, and auxiliary equipment recommended by the manufacturer should be used with the ventilator system. Use of any other accessories, spare parts or auxiliary equipment may cause degraded system performance and safety.
- Do not use the equipment outside rated atmospheric pressure or outside temperature operating conditions. Using the equipment outside of this temperature range or above this atmospheric pressure can compromise the equipment performance which consequently can result in degradation of the health of the patient.
- During humidification, carefully monitor the airway pressure. Increased airway pressure could result from a clogged filter. Replace the filter if the expiratory resistance increases or according to the instructions for the filter, whichever comes first.
- Service, repair and installation must only be performed by personnel authorized by the manufacturer.
- The ambient sound needs to be taken into consideration when setting the alarm sound level.
- Always disconnect the patient from the ventilator system when performing operations that involve risk for the patient, such as replacing the O_2 cell, dismantling etc.
- The system uses a Luer connector for other functions than intravascular or hypodermic access. An accidental connection can occur between the system and another medical device or

WARNING!

accessory that uses a Luer connector. This can cause injury to the patient. Take special precautions to decrease the risk of injury.

- Do not use Portable Radio Frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Servo-air Ventilator System. Not keeping the distance can result in degradation of the performance of the equipment.
- Do not use RFID equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Servo-air Ventilator System including cables specified by the manufacturer. Not keeping the distance can result in degradation of the performance of the equipment.
- Do not use active high frequency (HF) surgical equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Servo-air Ventilator System. Not keeping the distance can result in degradation of the performance of the equipment.

CAUTION!

- When lifting or moving the ventilator system or parts of the system, follow established ergonomic guidelines, ask for assistance, and take appropriate safety precautions. The weight is specified on the ventilator system.
- The air inlet filter must be in place when the system is running.
- The expiratory channel and expired gas from the exhaust port may be contaminated.
- During operation any water traps must be checked regularly and if necessary emptied.
- When mounting an active humidifier adjacent to a patient, ensure that the humidifier is always positioned lower than the patient.
- All technical documentation is available for use by personnel authorized by the manufacturer.
- To avoid instability, do not load the ventilator equipment asymmetrically on the ventilator system. Refer to Accessories.

NOTE:

- When a patient is connected to the ventilator system, clinical personnel must be sufficiently near to notice and act on alarms from the ventilator system.
- If a scavenging system (i.e. gas evacuation) is connected to the ventilator system, it must conform to ISO 80601-2-13 guidelines for sub atmospheric pressure and induced flow.
- If the ventilator system is to be a part of another system it requires an evaluation of the requirements of the IEC 60601-1 standard.
- The ventilator system must be installed and put into service according to Electromagnetic Compatibility.
- Securely attach all cables, etc, to minimize the risk of unintentional disconnection.
- Do not use the ventilator system outside intended use conditions.
- While the ventilator system is in use, the wheels of the mobile cart must be locked and the mobile cart must be in a horizontal position.
- When the ventilator system is connected to a patient:
  - Do not lift or disconnect the expiratory cassette.
  - Continuously monitor the settings and measurements displayed on the screen.
- If a heated patient circuit is not used in the system, a water trap is recommended to be used on the expiratory tube to avoid condensation in the system when an active humidifier is used. During operation the water traps must be checked regularly and if necessary emptied.
- Thermoshell must be used when using the expiratory filter heater.
- Check that the cooling fan intakes are not covered. Do not place the ventilator system on soft surfaces.
- The air inlet filters must be checked regularly and replaced if necessary.
- Use inspiratory and expiratory filters when ventilating patients infected by highly pathogenic airborne microorganisms.
- All excess fluids must be disposed of according to hospital routines.
- The emergency air intake must not be blocked.
- Do not disconnect the expiratory cassette while the ventilator system is in operation; if necessary, disconnect the cassette while in *STANDBY*.
- Do not use antistatic or electrically conductive tubing with this system.

1.2.2 Power supply

WARNING!

- The power cord must be connected only to an AC mains power outlet with protective earth to avoid the risk of electric shock.
- The power supply cord must be plugged directly into the mains power outlet without the use of any multiple socket outlets. If a multiple socket outlet is used together with other products, total leakage current might be exceeded in the event of a fault in the protective earth.

NOTE:

In case of total loss of power during ventilation, an alarm will sound for 2 minutes. When power is restored, the ventilator system will start in the same state and with the same settings as before the power loss.

When the system is connected to an external power supply, all connected battery modules are being recharged. This does not affect ventilation.

Battery

WARNING!

- Do not use sharp tools when extracting the batteries.
- To guarantee reliable battery backup, make sure a battery is in place in slot 2 at all times during ventilation.
- Dispose of batteries according to local regulations and not with ordinary waste.

CAUTION!

- The battery modules must be charged before first use.
- Do not expose the batteries to water, fire or excessive heat.
- Do not crush, disassemble, puncture or short circuit the connector terminals.
- One battery can be added to an available slot during operation.
- Hold onto the battery strap when inserting a battery in the ventilator system.

NOTE:

- If a battery status message is displayed on the screen, always go to *SYSTEM STATUS/Batteries* for detailed information.
- Check battery in *SYSTEM STATUS/Batteries* window to ensure safe battery operation. Always charge the battery before use.
- Always replace batteries when the ventilator system provides notification of imminent expiration or of diminished operating capacity.
- When not in use, the ventilator system should always be connected to the mains power to ensure fully charged batteries.

Refer to *Battery status* on page 27.

1.2.3 Fire hazard

WARNING!

- Keep all sources of ignition away from the ventilator system and the oxygen hoses.
- Do not use a ventilator system with worn or frayed gas supply hoses or hoses that have been contaminated by combustible materials such as grease or oil.
- Oxygen-enriched gas is extremely flammable: if a burning odor is detected, disconnect the oxygen supply and mains power and remove the batteries.
- Make sure that both the mains power outlet and the power supply connector are accessible

1.2.4 Gases

WARNING!

Ensure that the oxygen source is compatible with the rated range of pressure, flow rate and oxygen concentration as marked on the ventilator system. The ventilator system must not be used with helium or any gas mixture containing helium.

Refer to *Ventilator system* on page 159. The ventilator system can be used with nitric oxide.

NOTE:

Nitric oxide must only be added in the ventilator system inspiratory tube.

1.2.5 Auxiliary equipment

CAUTION!

Measurements of numerical values provided by the ventilator system that have been processed by auxiliary equipment:

- may be inaccurate if equipment not authorized by the manufacturer is used
- should be disregarded if they conflict with information on the ventilator screen
- must not be used as a substitute for therapeutic or diagnostic decisions.

Accessories, supplies, and auxiliary equipment used with the ventilator system must be recommended by the manufacturer.

1.2.6 Electromagnetic Compatibility

NOTE:

The ventilator system must be installed and put into service according to section Electromagnetic Compatibility.

In order to ensure that the Servo-air Ventilator System, during electromagnetic disturbances, will deliver ventilation at the patient connection port within the alarm limits set by the user, or generate an alarm condition, the following essential performance (IEC 60601-1) has been monitored during electromagnetic immunity tests:

- Delivered volume
- Monitoring of:
  - Oxygen concentration
  - Airway pressure
  - Expired volume
  - Internal electrical power source
  - Mains power status
  - Gas supply
  - PEEP
  - Gas temperature
  - CO_2 concentration
- In High Flow therapy, monitoring of:
  - Flow rate
- Ability to generate alarms

The CO_2 measurement performance may be temporary degraded or disrupted by a transient electromagnetic disturbance. If this happens, the performance will be resumed to normal within a maximum of 30 seconds after the transient disturbance.

If RFID tags are placed on top of the ventilator enclosure, including the expiratory cassette, a RFID tag reading may lead to:

- Intermittent, incorrect, VTe/MVe values that are outside specification and displayed on the ventilator system.
- Short appearance of higher respiratory rate than the set value, depending on the trigger setting.

The disturbances will disappear as soon as the RFID tag reading is finished.

Small intermittent disturbances in the displayed VTe/MVe values, within specification, may appear when RFID tag reading is performed in the close vicinity of the ventilator system.

Small spikes in the curves on the display may occur when a power surge, high voltage disturbances, appears in the mains power distribution system.

No other effects on the ventilator system have been observed during the electromagnetic immunity tests.

The ventilator should not be used near active HF Surgical Equipment.

Other types of RF emitters that may cause electromagnetic disturbances are e.g. 5G cellular devices, Wireless power transfer devices, diathermy, electro cautery, RFID scanners and RFID security/inventory systems like electromagnetic anti-theft systems or metal detectors.

Some type of RF emitters, such as fixed installed types of RFID equipment, security/inventory systems, might be concealed and the electronic medical device may potentially be exposed to fields from these RF emitters without the awareness of the user.

In case an electronic medical device behaves unexpectedly only in a particular physical location, e.g. if an unexpected alarm occurs, it may be caused by an electromagnetic emitter at that location. If this occurs, look for RF emitters in close proximity. Do not forget to check if there are any fixed installed sources which may be concealed. Relocate the electronic medical device or the RF emitter to make the strange behavior disappears.

1.3 Version and configurations

This manual applies to version 4.6 of the Servo-air Ventilator System. Before use, make sure the system version displayed under *SYSTEM STATUS/General* corresponds to the system version described in the User's Manual.

1.3.1 Configurations

The ventilator system can be used in both invasive and non invasive ventilation.

There are two configurations, Servo-air and Servo-air NIV.

Refer to *System* on page 157.

1.3.2 Available modes and functions

Modes/Functions	Configuration	
	Servo-air	**Servo-air NIV**
PC	X	O
PRVC	O	O
VC	X	O
Bi-Vent/APRV	O	O
PS/CPAP	X	O
VS	O	O
Automode	O	O
SIMV (PC) + PS (PRVC) + PS (VC) + PS	 X O X	 O O O
NIV PC	O	X
NIV PS	O	X
High Flow therapy	O	X
CO_2 analyzer	O	O
Servo Compass	O	O
Nebulizer	X	X
Alarm output connection	O	O

X = standard — = not applicable O = option

2 System overview

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2.1 Ventilator

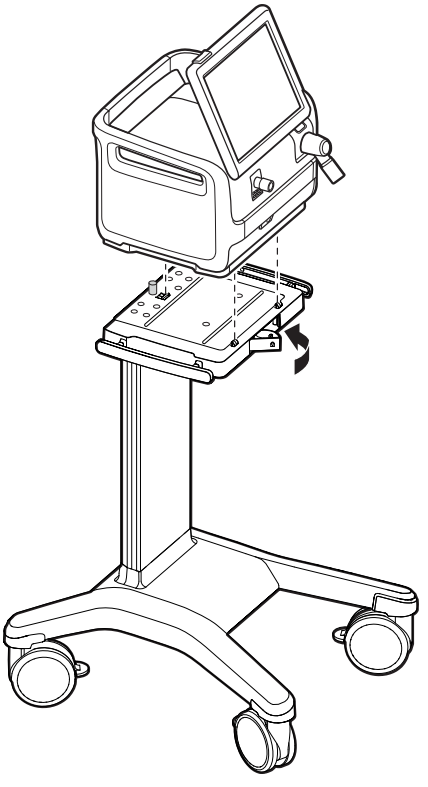
The ventilator consists of a user interface and a patient unit.

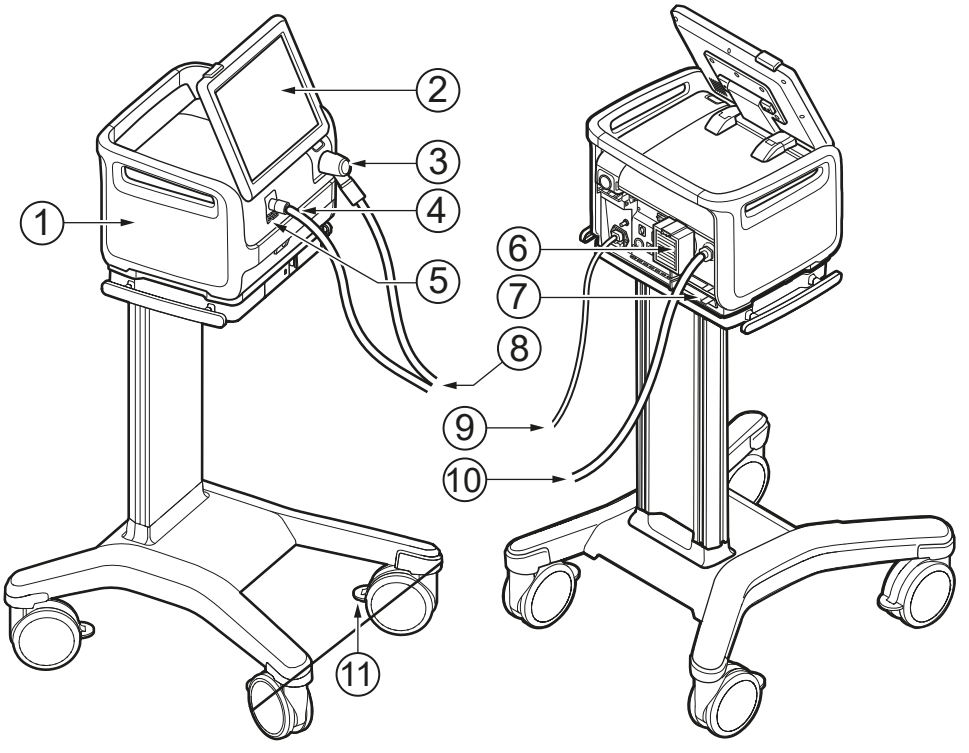
Air is supplied from ambient air by an internal turbine and O_2 may be supplied by a medical pipeline system or by gas cylinder.

2.1.1 Mounting on mobile cart

- Lock the wheels.
- Release the locking clamp on the mobile cart.
- Stand directly in front of the mobile cart when mounting the ventilator system.
- Tilt the ventilator system to fit the two front clamps in position on the mobile cart.
- Press down the rear end of the ventilator to fit the rear clamp in position.
- Lock the ventilator system to the mobile cart with the locking clamp.
- Ensure that the patient unit is firmly fixed to the mobile cart via the clamps and locking clamp.
- Lock the wheels whenever the ventilator system is standing still.

Make sure that cables and patient circuit is not obstructed or squeezed due to improper mounting.



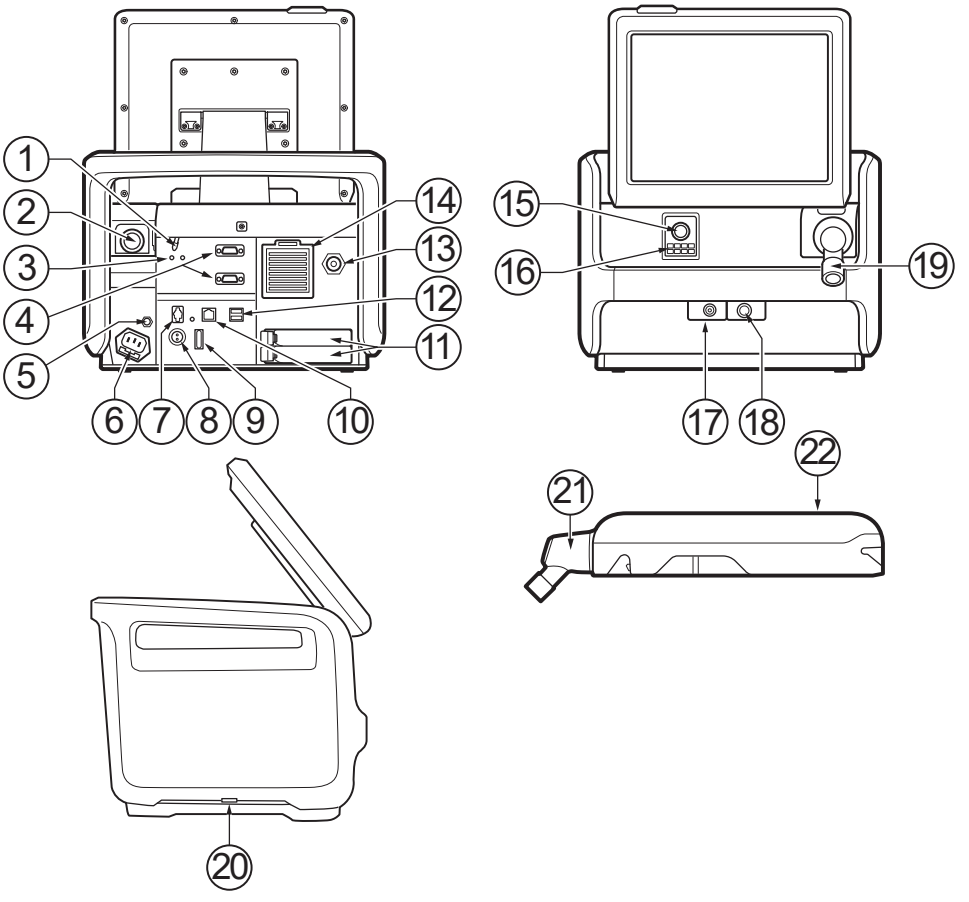


1. Patient unit
2. User interface
3. Expiratory inlet
4. Inspiratory outlet
5. Emergency air intake
6. Air inlet
7. Battery compartment
8. Patient circuit
9. AC mains power
10. O_2 supply
11. Wheel lock

WARNING!

The emergency air intake must not be blocked or covered.

2.2 Patient unit



1. On/Off switch

   The switch must be pulled downwards before it can be switched.
2. Expiratory outlet
3. Power indicators
4. RS-232 connectors
5. Potential equalization terminal
6. AC mains power source connector with fuse
7. Alarm output connection
8. External 12V battery inlet
9. Fuse for external DC power
10. Ethernet connection
11. Battery compartments
12. USB ports
13. Gas inlet for O_2
14. Gas inlet for air including air inlet filter
15. Inspiratory outlet
16. Emergency air intake
17. Nebulizer connector
18. CO_2 connector
19. Expiratory inlet
20. Cooling fan with filter (on both sides)
21. Expiratory inlet with moisture trap
22. Expiratory cassette

WARNING!

Only a USB memory stick may be connected to the USB ports.

External monitors or similar devices connected to the Mini DisplayPort of the system must be powered via a medical grade isolation transformer. No other use is allowed.

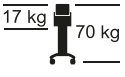
NOTE:

Only one USB memory stick may be connected to the USB ports at the same time.

2.2.1 Symbols on patient unit

Symbol	Description
CE 0123	CE mark - Indicates compliance with the requirements of the Medical Device Regulation 2017/745.
ETL CLASSIFIED C ETL US LISTED Intertek 5016764 Medical Electrical Equipment	ETL mark - indicates compliance with Canadian and US standards.
R-NNNNNNNN www.bis.gov.in	BIS mark - Indicates compliance with Indian standards.
	UDI Label - Unique Device Identification.
Rx ONLY	In the USA, federal law restricts this device to sale by or on the order of a physician.
	Type B—indicates classification according to IEC 60601-1
	Type BF applied part — indicates classification according to IEC 60601-1
	Do not push the ventilator system when the brakes are locked as it may tip over.
	Do not step on the mobile cart surface as the ventilator system may tip over.
	Potential equalization terminal

Symbol	Description
	Nebulizer connector
CO_2	CO_2 connector
RS232	RS-232/Serial port - connector for data communication
IP21	Ingress protection, IP21
	Fuse (specification)
	External 12V battery inlet
	Battery
	Expiratory gas flow from the patient
	Inspiratory gas flow to patient
	Mains power On/Off
	Mains connected, batteries charging
	Gas exhaust port—exhaust gas flow from ventilator system
	Network connection
	USB connection
	Alarm output connection
	Special waste
	Warning
	Caution

Symbol	Description
	Consult instructions for use
	Consult accompanying documentation
	Locked
	Unlocked
	Serial number
	Order number
	Weight of patient unit with user interface and ventilator including its safe working load.
	Use of ON/OFF switch The switch must be pulled downwards before it can be switched.
	Manufacturer The symbol is accompanied by manufacturer address and manufacturing date.
	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment.
	Contains substances that can be Carcinogenic, Mutagenic or toxic for Reproduction.
	Medical Device

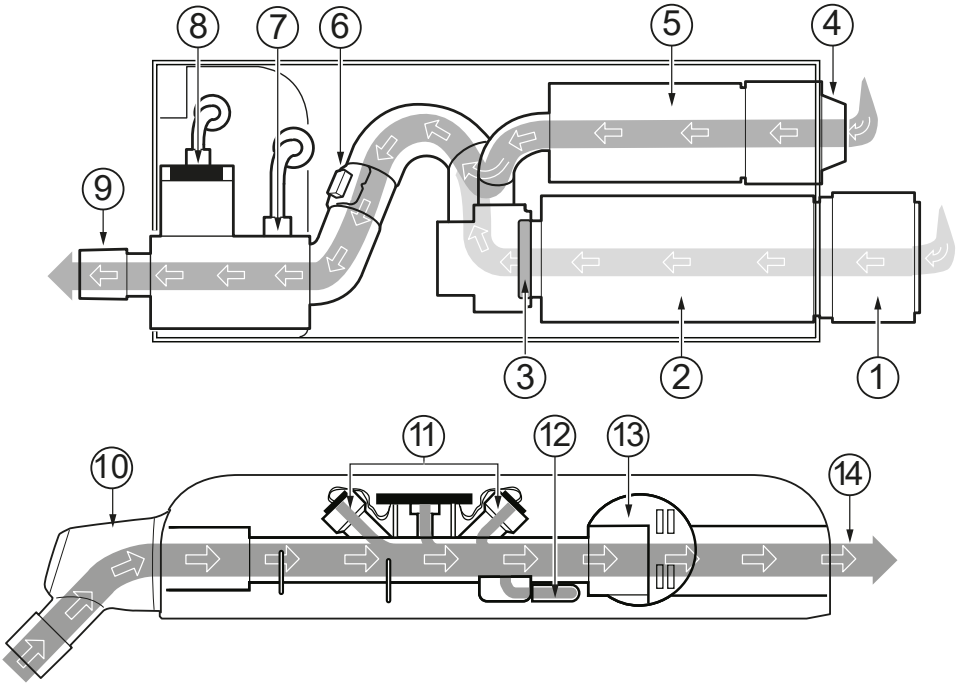
NOTE:

- **Special waste.** This product contains electronic and electrical components. Discard disposable, replaced and left-over parts in accordance with appropriate industrial and environmental standards.
- **Potential equalization terminal.** The potential equalization terminal is designed for the connection of a potential equalization conductor according to DIN 42 801 and IEC 60601-1. The function of the potential equalization terminal is to equalize potentials between the ventilator system and other medical devices that can be touched simultaneously. The potential equalization terminal must not be used for a protective earth connection.

2.2.2 Gas flow through the patient unit

NOTE:

The expiratory cassette can be exchanged between different Servo ventilator systems. Always perform a pre-use check after exchanging an expiratory cassette.



1. Air inlet with air inlet filter.
2. Turbine module for ambient air.
3. The check valve prevents the gas to flow backwards.
4. Gas inlet for O_2.
5. The gas module for O_2 regulates the O_2 gas flow.
6. The flow meter measures the gas flow.
7. The pressure of the mixed gas delivered to the patient is measured by the inspiratory pressure transducer. The transducer is protected by a bacterial filter.
8. The O_2 cell measures the oxygen concentration. The O_2 cell is protected by a bacterial/viral filter.
9. The inspiratory channel delivers the mixed gas to the patient circuit inspiratory tubing and contains a safety valve.
10. Expiratory inlet, which contains a moisture trap.
11. The gas flow through the expiratory channel is measured by ultrasonic transducers.
12. The pressure of the gas delivered to the patient is measured by the expiratory pressure transducer. The transducer is protected by a bacterial filter.
13. The expiratory valve regulates the pressure in the patient circuit.
14. The gas flow from the patient circuit leaves the ventilator system via the exhaust port.

2.3 Batteries

2.3.1 Charging battery modules

NOTE:

The battery modules are delivered partially charged and must be charged before use.

To charge the battery modules, insert the battery modules in the ventilator system. The ventilator must be connected to the mains. The battery modules are then charged automatically. The batteries can also be charged with the External battery charger, Servo-air.

2.3.2 Handling battery modules

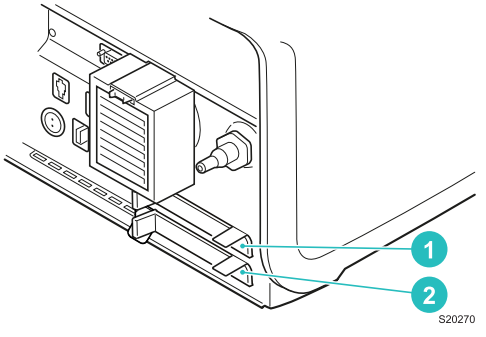
WARNING!

To guarantee reliable battery backup, make sure that there is always a battery in bottom slot 2 during ventilation.

The battery compartment is divided into two slots, 1 and 2.

Refer to batteries in *Power supply* on page 12

Depending on the type used, the battery module may have either a battery strap or a battery loop.

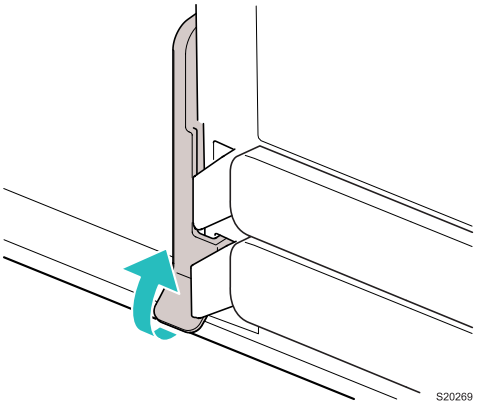


The battery module in slot 1 may be exchanged during ventilation.

NOTE:

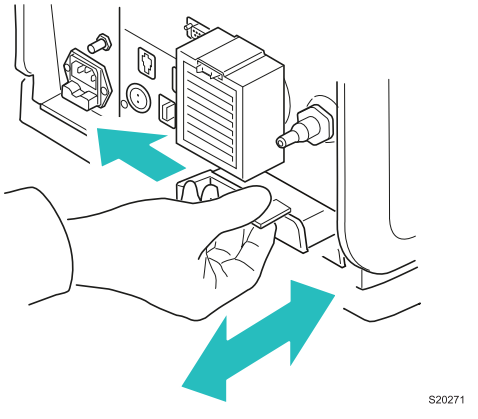
If the ventilator system has a safety latch on slot 2, it must be released before you can insert or remove a battery module in slot 2.

To release the safety latch, pull it straight out.



To remove a battery module:

- Press the release button to the left and pull the battery strap/loop.
- Remove the battery from the ventilator system.



To insert a battery module:

- When using batteries with a battery strap, hold onto the battery strap when inserting a battery in the ventilator system.
  If a battery with a battery strap is present in slot 2, check that the battery strap is not folded into the battery compartment when inserting a battery in slot 1.
- Ensure that the battery is fully inserted so that the release button returns to a completely closed position.

2.3.3 Battery status

NOTE:

- If *Replace battery* is displayed, the battery is unreliable, regardless of the operating time displayed under *Batteries*. In this situation, replace the battery even when the *STATUS* window indicates that significant operating time remains.
- At least one battery module must always be installed.

Detailed information about batteries is accessed via SYSTEM STATUS/ Batteries. There is also an indication in the status bar showing the power supply currently being used by the ventilator system.

If the ventilator system is running on battery power, the active battery in the battery symbol turns yellow and the mains power symbol disappears. The estimated remaining battery time in minutes is always displayed, regardless of the power supply in use.

The battery symbol also functions as a shortcut to the window otherwise accessed via SYSTEM STATUS/Batteries.

The following information is displayed under *Batteries* in SYSTEM STATUS/ Batteries for each connected battery module:

- *BATTERY CAPACITY* – usable backup time in minutes. An estimated backup time is shown in Standby. This estimate may differ from the actual usable backup time during running. Usable backup time depends on set mode and selected ventilation settings. The presented usable backup time is the sum of the estimated operation time displayed for each battery module minus 20 minutes.
- Slot number
- Serial number
- Remaining operation time in minutes for each battery
- Notification – may be displayed close to the remaining operation time in minutes.
- Remaining battery life.

2.4 Patient circuit configurations

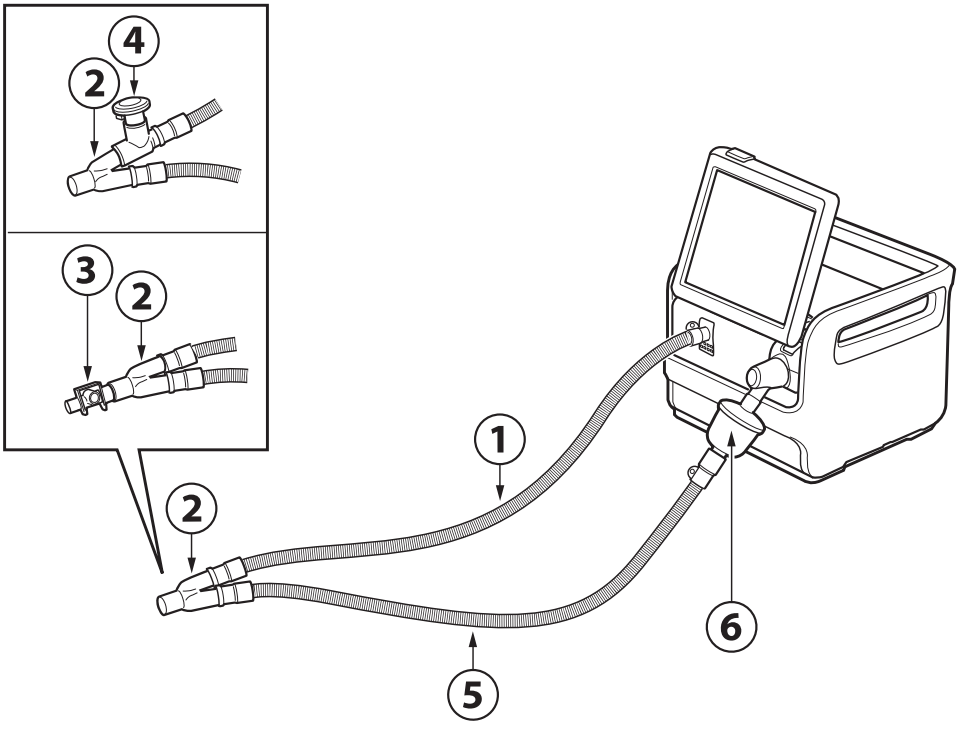
Refer to System Flowchart, Servo-air.

Extra care should be taken when handling tubes, connectors and other components of the patient circuit. The use of a support arm to relieve the patient from the weight of the tubing system is recommended.

2.4.1 Conventional ventilation

Patient circuit, non-heated

To ensure that the inspiratory gas temperature is below 43°C the patient circuit inspiratory tube must be at least 1.2 m to let the gas cool down.



1. Inspiratory patient tube
2. Y piece
3. CO_2 airway adapter
4. Aerogen Pro
5. Expiratory patient tube
6. Filter Servo Duo Guard

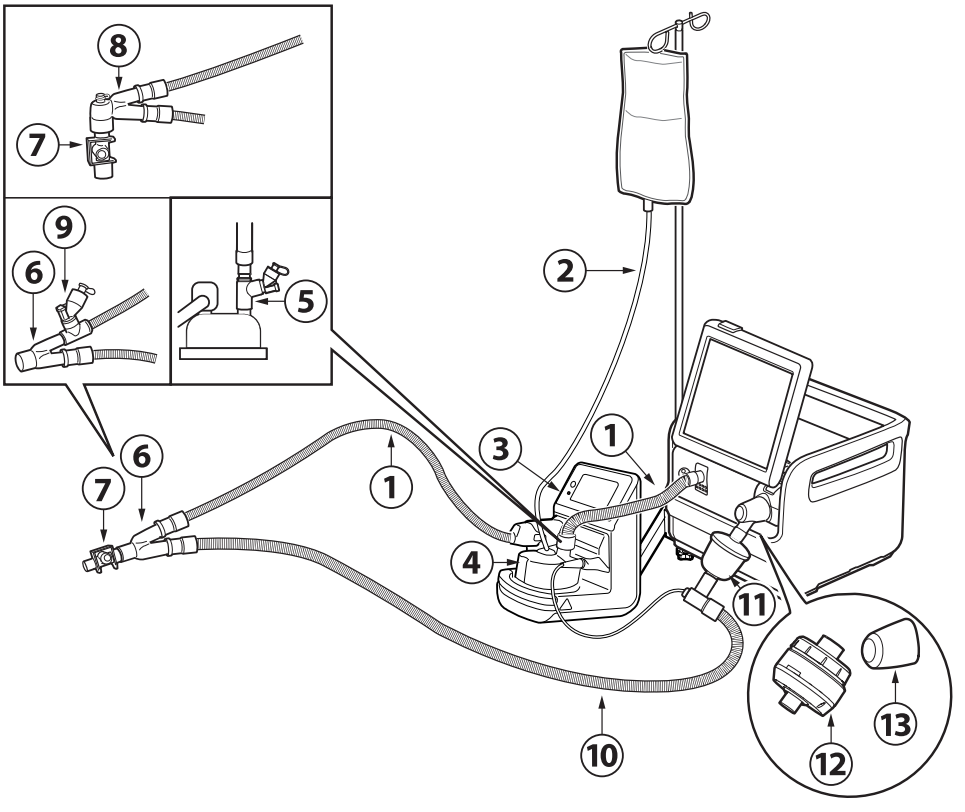
WARNING!

Do not use the nebulizer without a filter, e.g. Servo Duo Guard, connected to the expiratory inlet of the ventilator system.
Refer to the Servo Duo Guard User's Manual.

Patient circuit, dual heated

Thermoshell must be used when using the expiratory filter heater.

To ensure that the inspiratory gas temperature is below 43°C the patient circuit inspiratory tube must be at least 1.2 m to let the gas cool down.



1. Inspiratory patient tube
2. Water autofill
3. Active humidifier
4. Humidification chamber
5. Aerogen Solo, alternative placement
6. Y piece
7. CO_2 airway adapter
8. Angled Y piece
9. Aerogen Solo
10. Expiratory patient tube
11. Filter Servo Duo Guard
12. Expiratory heater Servo Duo Guard
13. Thermoshell, expiratory cassette

WARNING!

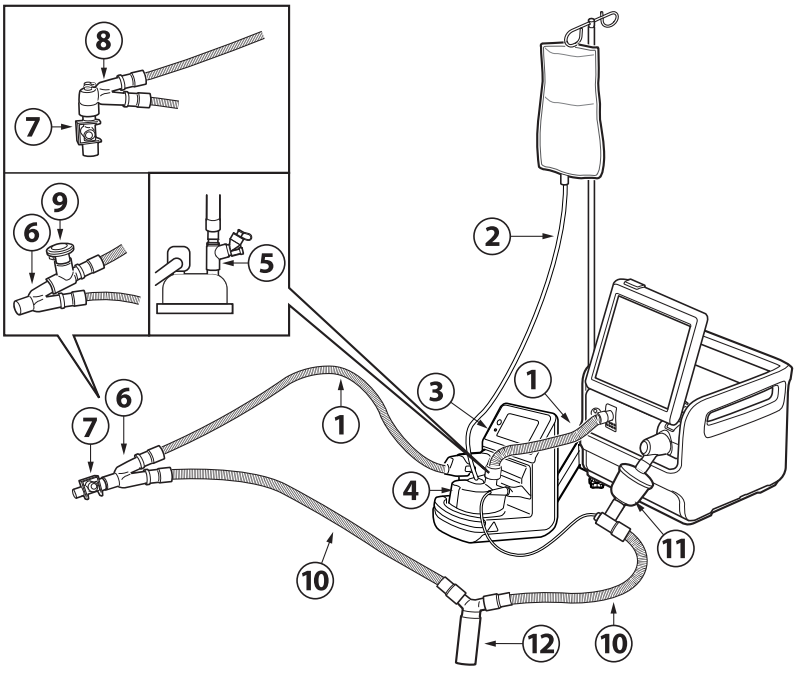
Do not use the nebulizer without a filter, e.g. Servo Duo Guard, connected to the expiratory inlet of the ventilator system.

Refer to the Servo Duo Guard User's Manual for use of the filter on the expiratory limb of the breathing circuit.

Patient circuit, single heated

A water trap is recommended if a single heated patient circuit is used.

To ensure that the inspiratory gas temperature is below 43°C the patient circuit inspiratory tube must be at least 1.2 m to let the gas cool down.



1. Inspiratory patient tube
2. Water autofill
3. Active humidifier
4. Humidification chamber
5. Aerogen Solo, alternative placement
6. Y piece
7. CO_2 airway adapter
8. Angled Y piece
9. Aerogen Pro
10. Expiratory patient tube
11. Filter Servo Duo Guard
12. Water trap

WARNING!

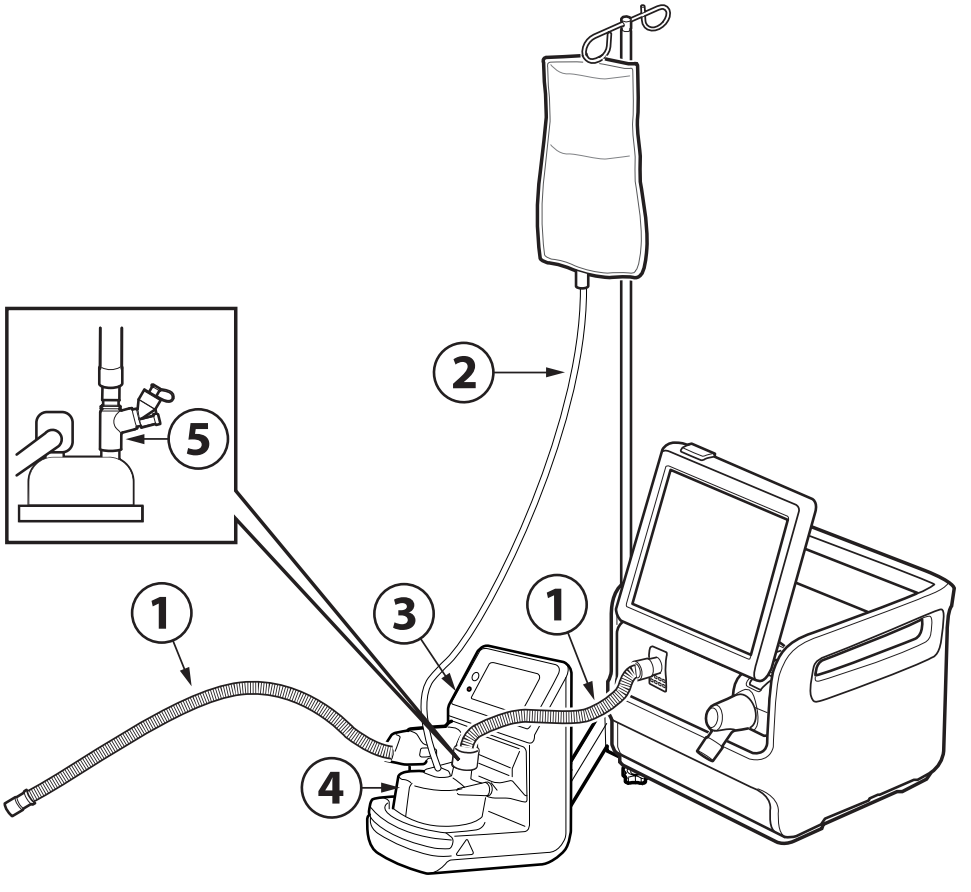
Do not use the nebulizer without a filter, e.g. Servo Duo Guard, connected to the expiratory inlet of the ventilator system.

Refer to the Servo Duo Guard User's Manual for use of the filter on the expiratory limb of the breathing circuit.

2.4.2 High Flow therapy

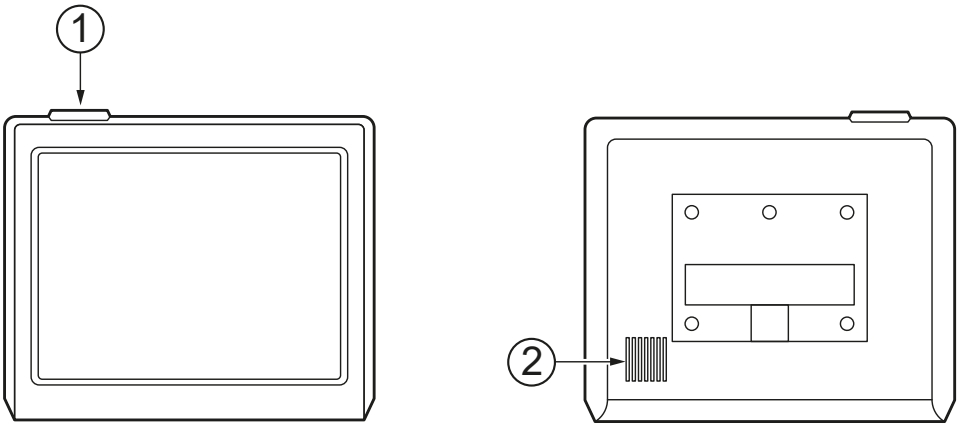
Connect high-flow nasal cannula or tracheostomy interface to the inspiratory tube.

To ensure that the inspiratory gas temperature is below 43°C the patient circuit inspiratory tube must be at least 1.2 m to let the gas cool down.



1. Inspiratory patient tube
2. Water autofill
3. Active humidifier
4. Humidification chamber
5. Aerogen Solo

2.5 User interface



1. Alarm indicator
2. Loudspeaker

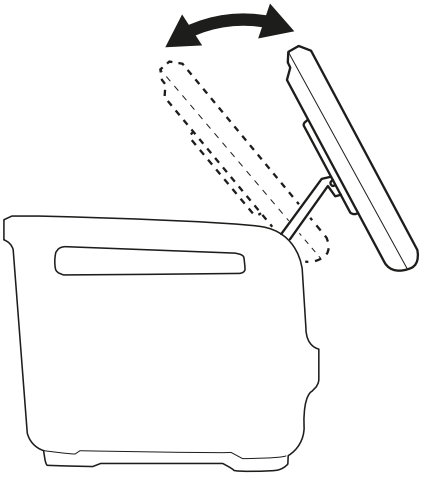
NOTE:

The user interface can on rare occasions restart. The restart is brief and ventilation continue according to settings.

No action is required of the user. The user interface touch screen is inactive during the restart.

No alarm is activated by the restart, but any alarms activated during the restart will be audible and after the restart, they will also be visual.

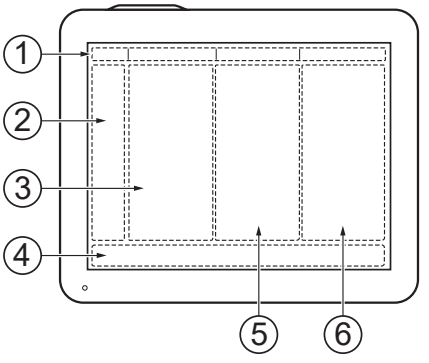
2.5.1 User interface adjustment



The user interface can be adjusted into different positions.

2.5.2 Interactive areas

The user interface is completely touch based and is divided into the following areas.



1. Status bar
2. Quick menu/extended menu
3. Display area
4. Direct access bar
5. Short trends area, available in *BASIC* and *ADVANCED* views
6. Numerical values

NOTE:

- Do not use sharp tools on the screen.
- Fluid on the screen can disturb touch functionality.

2.5.3 Navigating

To navigate the user interface, adjust settings and get support:

- Tap (the touchpad changes color when the navigating is registered).
- Tap and hold
- Scroll vertically or horizontally
- Drag and drop

2.5.4 User support

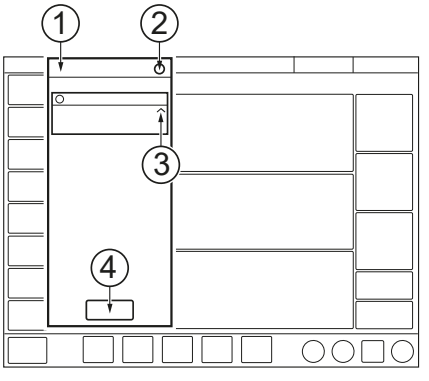
The user is supported by the following:

- Alarm management
- Safety scales
- Dynamic images
- Information texts
- Shortcuts
- Prompts

The following colors are used for settings:

- Red — not recommended
- Yellow — use with caution
- Green — normal

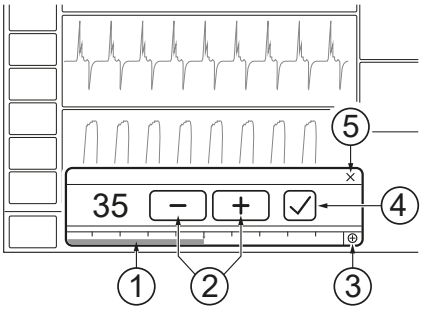
Alarm management



1. Alarm list
2. Number of active alarms
3. Alarm management checklist
4. Alarm history

Refer to *Alarm handling* on page 129.

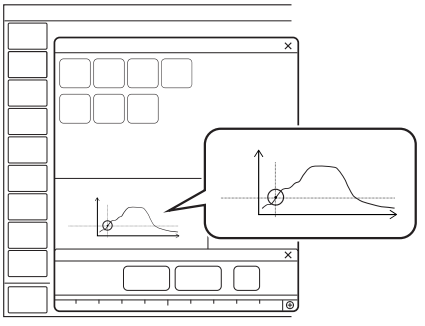
Safety scales



1. Slide bar
2. Increase/decrease setting
3. Access to full setting range
4. Accept
5. Cancel

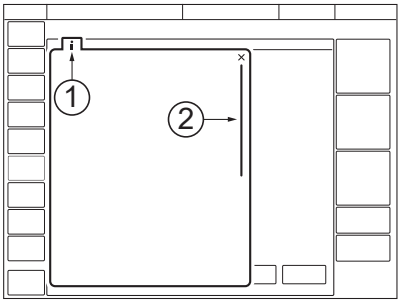
Refer to *Safety scales* on page 49.

Dynamic images



The dynamic image illustrates the effects of the changes made to selected ventilation settings.

Information texts

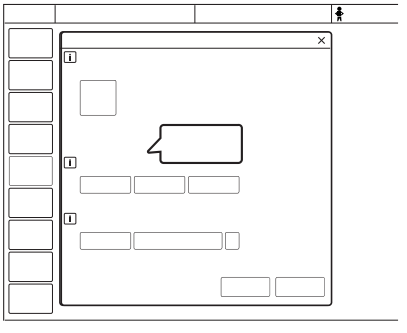


1. Information text is available.
2. Indication that more information is available by scrolling vertically in the middle of the information window.

Shortcuts

Some frequently used functions can be accessed via a shortcut. Refer to *Symbols on user interface* on page 36.

Prompts



Prompts indicate that input may be required.

2.5.5 Symbols on user interface

Symbol	Description
	Extended menu show/extended menu hide
	Start ventilation
	Stop ventilation/Standby
	Alarm limits/Alarm limits shortcut
	Audio pause
	Audio paused
	Audio off
	Audio paused - all alarms, active and inactive are pre-silenced.
	Alarm on
	Alarm off
	Check alarms
	Alarm sound level
	Alarm history
	Message
	Number of messages
	Adult/patient data shortcut

Symbol	Description
	Pediatric/patient data shortcut
	AC mains power
	Missing battery
	Unknown battery (not a battery from the manufacturer of the ventilator system)
	Charging battery
	Total battery capacity, active battery and battery status shortcut
	External 12V battery
	Backup on
	Backup off
	Reference marking, CO_2 calibration
	Zero marking, CO_2 calibration
	Circuit compensation on
	Circuit compensation off/Circuit compensation deactivation shortcut
	Invasive ventilation adult
	Invasive ventilation pediatric
	Non-invasive ventilation adult
	Non-invasive ventilation pediatric
	High Flow therapy

Symbol	Description
	Two overlay loops
	Reference loop
	Loop grid on
	Loop grid off
	Compensation
	Configuration
	Maneuvers
	Library
	Modes
	Patient data
	System status
	Trends & logs
	Views
	Screen layout
	Disconnect
	Service & Settings
	Biomed
	Service

Symbol	Description
	Licenses
	Exit
	CO_2 shortcut
	CO_2 off shortcut
	Nebulization period/Nebulization shortcut
	Continuous nebulization/Nebulization shortcut
	O_2 boost locked to 100 %
	Pneumatic trigger, pressure/flow
	Organize
	Panel locked
	Panel unlocked
	Progress
	Full settings range
	Normal settings range
	Recorder
	Recorder Recording waveforms 30 seconds
	Recording waveforms in progress
	Camera for taking screenshots

Symbol	Description
	User action needed before value is shown
	Value not within range
	Uncertain value
	Test failed (red)
	Test not performed (yellow)
	Test passed (green)
	Accept
	Decrease
	Increase
	Information text
	Cancel (red) Close (green)
	Switch between main/backup modes
	Additional values & settings hide/Additional values & settings show
	Additional information hide/Additional information show

2.6 Symbols on accessories and packaging

Symbol	Explanation
	Order number
	Number to identify the production batch

Symbol	Explanation
	Quantity
	Outer diameter in mm
	Inner diameter in mm
	Indicates the inner diameter of the endotracheal tube
	Use by date
	Do not re-use. Single use only.
	Do not use if packaging is damaged
	Consult accompanying documentation
	Keep away from sunlight
	Manufacturer
	Manufacturing date
	In the USA, federal law restricts this device to sale by or on the order of a physician.
	Recyclable material. Recycling must be performed in accordance with appropriate industrial and environmental standards.
	Special waste to be disposed of in accordance with appropriate industrial and environmental standards
	Gas cylinder
	Type BF applied part — indicates classification according to IEC 60601-1
	Type B—indicates classification according to IEC 60601-1

Symbol	Explanation
	Humidity limitation
	Temperature limitation
	Fragile — handle with care
	Keep away from water
	This way up — indicates correct upright position of the transport package
	Atmospheric pressure limitation
	Do not expose to heat or fire.
	Do not expose to mechanical force.
	Do not dismantle, open or shred.
	The support arm must be folded during transport.
	Lock
	Unlock
	Consult instructions for use
	Toxic or hazardous substances will not leak or mutate under normal operating conditions for 50 years.
	Contains substances that can be Carcinogenic, Mutagenic or toxic for Reproduction

2.7 Transport

2.7.1 Before intrahospital transport

Before transporting the ventilator system with or without a patient connected, follow facility guidelines:

Before transport of the ventilator system with or without a patient connected:

- Make sure that the patient unit, user interface, and plug-in modules are attached and locked.
- Make sure that there are no damages to the mobile cart and accessories.
- Make sure that the straps are firmly wrapped across the center of the gas cylinders to prevent the cylinders from moving during transport.
- Make sure that the humidifier holder is mounted on the patient circuit side of the ventilator, and that the humidifier is attached and locked.
- Make sure that the support arm is attached, locked, and folded.

Before transport of the ventilator system with a patient connected:

- Make sure that the gas cylinders are connected and have sufficient gas.
- Make sure that the battery in slot 2 is fully charged.
- Make sure the manual resuscitator functions.

2.7.2 During intrahospital transport

CAUTION!

To avoid instability, do not load the ventilator equipment asymmetrically on the ventilator system.

While transporting the ventilator system with or without a patient connected, follow facility guidelines and:

- Tilt the user interface into a horizontal position.
- Use the handles on the patient unit.
- Transport the bed and the ventilator system slowly, and watch the patient connection carefully to see that no pulling or other movement occurs.
- If triggering problems occur during intrahospital transport because of extreme vibrations, Pressure Control mode is recommended or to set the trigger so that it is less sensitive.
- Be careful not to tip the mobile cart when crossing an obstacle like a threshold.
- On arrival, connect the ventilator system to mains power and lock the brakes.

3 Operation overview

Table of contents

3.1 Workflow summary

1. Turn on the ventilator system and prepare the patient circuit.
2. Do a pre-use check.
3. Do a patient circuit test.
4. If applicable, do calibration and tests.
5. Select patient category.
6. Select ventilation type.
7. Set ventilation mode.
8. Set alarm limits.
9. Enter patient data, such as height, weight, and gender (optional).
10. Start ventilation and connect the ventilator system to a patient.
11. If necessary, pause or stop ventilation.

3.2 Pre-use check

WARNING!

- Always perform a pre-use check before connecting the ventilator system to a patient.
- Do not connect the ventilator system to a patient while a malfunction persists.

NOTE:

- When the pre-use check is completed, all sources of alarm signals and alarm conditions have been verified and the alarm system operates correctly.
- The volume of the patient circuit used during pre-use check should be the same as during ventilation. If the patient circuit is changed after the pre-use check is completed, perform a new patient circuit test.

To ensure correct system functionality, optimal performance and patient safety, a pre-use check must be performed.

The pre-use check contains a number of tests that the ventilator system automatically performs. Refer to *Pre-use check tests* on page 165.

The patient circuit test can be left out when running the pre-use test and be performed later without affecting the pre-use test result.

Each test starts automatically when the previous test is completed. The pre-use check will be passed if all individual tests are passed.

When the pre-use check is completed, all sources of alarm signals and alarm conditions have been verified and the alarm system operates correctly.

Malfunctions detected during the start-up procedure. Refer to *Alarms* on page 171 for more information.

High Flow therapy

If the ventilator system is to be used with High Flow therapy, a pre-use check must be performed with a patient circuit for conventional ventilation. When the pre-use check is *Passed*, the conventional patient circuit can be exchanged to a patient circuit for High Flow therapy. This does not affect the performance during High Flow therapy.

Refer to *Conventional ventilation* on page 28.

3.2.1 Start pre-use check

- Connect the ventilator system to a mains power outlet.
  Make sure that the battery in slot 2 is in place.
- Connect the ventilator system to gas supplies.
- Turn the ventilator system on. Refer to *Patient unit* on page 20.
- Tap *PRE-USE CHECK* in *STANDBY*.
- Tap *YES* in the *PRE-USE CHECK* window to start, and follow on-screen instructions.

3.2.2 Complete pre-use check

A symbol and a color marking appear on screen for each pre-use check test, as appropriate: *Passed*, *Failed* and *Not performed*.

- Tap *OK* to confirm or tap *Redo test* to restart a pre-use check test.

The ventilator system returns to *STANDBY* when the pre-use check is completed.

The status of the two latest pre-use checks and patient circuit tests is displayed under *SYSTEM STATUS* / *General*.

The status of the latest pre-use check and patient circuit test is also displayed in *STANDBY*.

3.3 Patient circuit test

CAUTION!

The patient circuit test must be performed with a complete patient circuit, including all accessories (e.g. active humidifier filled with water, filter, CO_2 analyzer and nebulizer), that is to be used with the patient.

NOTE:

- The patient circuit test does not replace the pre-use check.
- The active humidifier and the expiratory filter heater must be turned off during the patient circuit test.

In Standby, the patient circuit test may be performed separately from the pre-use check.

The patient circuit test measures resistance and compliance in the patient circuit. If the patient circuit is changed and no new patient circuit test is performed, the ventilator will compensate incorrectly based on the measurements of the previous patient circuit.

If the correct circuit is not tested, the following risks may arise:
- In volume-based modes, the volume delivered to the patient will be incorrect.
- In pressure-based modes, the volume measured will be incorrect.

Tap *PATIENT CIRCUIT TEST* and follow on-screen instructions.

The result from the patient circuit test is displayed in *PATIENT CIRCUIT TEST* in *STANDBY*. Detailed result is displayed in the *SYSTEM STATUS/General* window.

3.4 Calibration & tests

The following calibration and test procedures should be performed as appropriate:
- CO_2 analyzer calibration. Refer to *CO_2 analyzer calibration* on page 126.
- O_2 cell adjustment. Refer to *Adjust the O_2 cell* on page 128.

3.5 Select patient category

NOTE:

Always check the alarm settings after changing the patient category.

Changing the patient category affects the following settings:

- available modes
- default values for alarm limits
- Allowed ranges for alarm limits
- Default values for ventilatory settings
- Allowed ranges for ventilatory settings
- Pressure and flow regulation
- Scaling

The default values may have been changed by a previous user.

To select patient category in standby:

- Select the appropriate patient category.
  The patient data shortcut in the status bar changes accordingly.

3.5.1 Change patient category

To change the patient category during ventilation:

- Tap the patient data shortcut in the status bar or tap *PATIENT DATA* in the quick menu.
- Select the appropriate patient category.
- Follow on-screen instructions.

3.6 Select ventilation type

The appearance of the window may vary depending on configuration.

The default values may have been changed by a previous user.

- Select non-invasive ventilation or invasive in *STANDBY*.

3.7 Set ventilation mode

- Tap *MODES* in *STANDBY* to open the *MODES* window.
- Select mode.
  Tap and hold the tile to access more information about the selected mode.
- When a ventilation mode has been selected, all parameters can be set in the mode settings window.
- Tap a parameter to adjust its value.
- Tap *Accept* to confirm, or *Cancel* to cancel the settings.

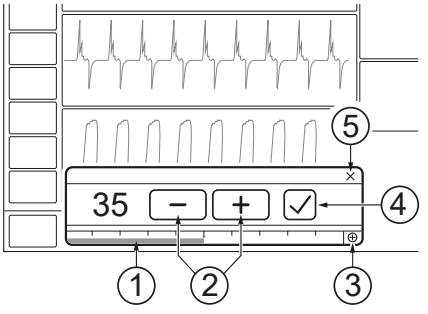
3.7.1 Settings

NOTE:

If one or several settings in the mode settings window are highlighted in yellow, this indicates that it/they should be considered for adjustment, as the values entered there may have been carried over from the previous mode.

Refer to *Ventilatory settings* on page 168.

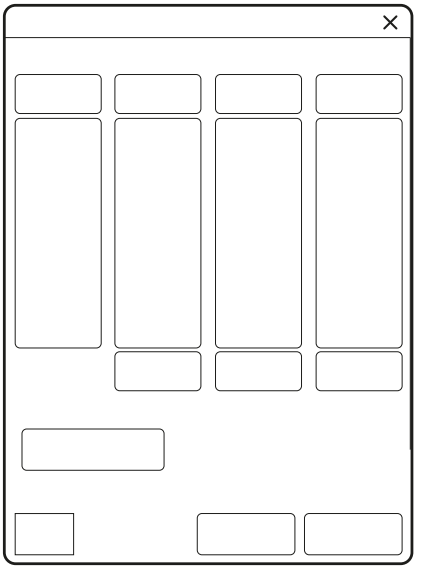
3.7.2 Safety scales



1. Slide the bar to the right or left to increase or decrease the settings. The scale displayed provides a safety mechanism to prevent unintentional setting of values outside the normal range for most patients.
2. Tap to incrementally increase or decrease the setting. Tap and hold to rapidly increase or decrease the setting.
3. Tap on full settings range to extend the safety scale setting range.
4. Confirm the setting by tapping *Accept*.
5. Exit settings without changing by tapping cancel.

3.8 Set alarm limits

- Tap *ALARM LIMITS* in the quick menu.
- The limits are set in the alarm limit bars in the *ALARM LIMITS* window.



- Tap the upper or lower value in the selected alarm limit bar.
- A scale appears, tap plus or minus or slide the bar to set the value.

Confirm each setting by tapping *Accept*.

Tap *Autoset all alarms*, if desired, to get alarm limit proposals for the following invasive modes:

- VC
- PC
- PRVC

NOTE:

Before accepting *Autoset all alarms* values, make sure they are appropriate for the patient. If not, enter settings manually.

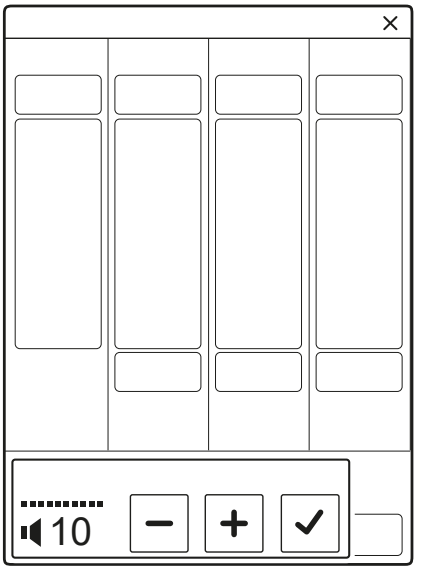
To activate the new alarm limits tap *Accept*.

Autoset all alarms is not available in supported or *NIV* modes or in *STANDBY* because the ventilator system requires patient values in order to propose alarm limits.

3.8.1 Set alarm sound level

The ambient sound needs to be taken into consideration when setting the alarm sound level.

- Tap *ALARM LIMITS* in the quick menu.
- Tap alarm sound level.



- Tap the sound level bar to set appropriate alarm sound level.
- Tap *Accept*.

3.9 Enter patient data

No patient data other than that specified in the *PATIENT DATA* window is stored in the ventilator.

If gender, height and weight have been entered, predicted body weight will be automatically displayed.

The gender and height entered will effect the displayed data in Servo Compass.

To enter patient data:

- Tap the patient data shortcut in the status bar or tap *PATIENT DATA* in the quick menu.
- Tap in the selected input field to open a keyboard or keypad.
- Tap Accept to confirm new data.
- Enter/edit the following data:
  - *Patient category*
  - *Gender*
  - *Height*
  - *Weight*

Refer to *Predicted body weight (PBW)* on page 106.

- Tap *Done* when entry is complete.

3.10 Start ventilation

Tap *START VENTILATION* in *STANDBY* or *START* in the quick menu to start ventilation.

WARNING!

Ventilation must be started manually from standby.

If the ventilator remains in *STANDBY* due to dialogs that need confirmation, a beep will be heard repeatedly every 4 s until ventilation is started.

3.11 Pause ventilation

To perform a brief pause of ventilation and alarms during invasive ventilation:

- Tap *DISCONNECTION* in the quick menu.

Refer to *Disconnection* on page 111.

3.12 Stop ventilation

To disconnect and stop ventilation:

- Physically disconnect the patient from the ventilator system.
- Tap *STANDBY* in the quick menu.
- Tap and hold *STOP VENTILATION* to stop ventilation.

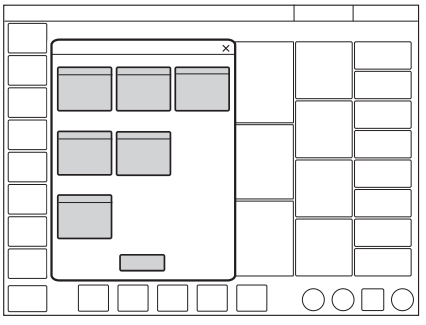
4 Displaying and saving data

Table of contents

4.1 Views

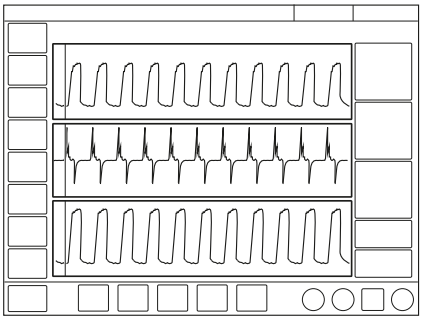
The ventilator system offers different views to suit different needs. They are accessed via the quick menu during ventilation.

The appearance of the window may vary depending on configuration.



4.1.1 Basic view

All non-invasive ventilation modes start in the *BASIC* view.



The view consists of:

- two or three waveforms -pressure and flow waveforms are always present, together with the volume waveform, if desired
- a single column of numerical values

It is possible to adjust the layout by tapping either *SCREEN LAYOUT* / *Layout* in the extended menu or *VIEWS* / *Layout* in the quick menu, or by tapping and holding a waveform. All three methods will open the *LAYOUT* window.

This makes it possible to show or hide the volume waveform.

Refer to *Adapting the waveform display* on page 63.

It is also possible to adjust the scaling, sweep speed and appearance of the waveforms in the *LAYOUT* window.

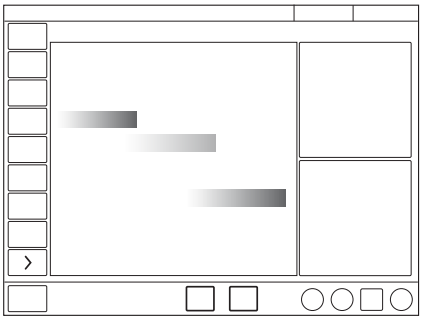
User interface brightness can be adjusted in *Menu* / *Views* / *Adjust brightness*.

The short trends area can be shown/hidden in both Basic and Advanced views.

Tap extended menu show to the right of the waveform area to show the short trends area.

Tap Additional values & settings to the right of the numerical values to show more numerical values.

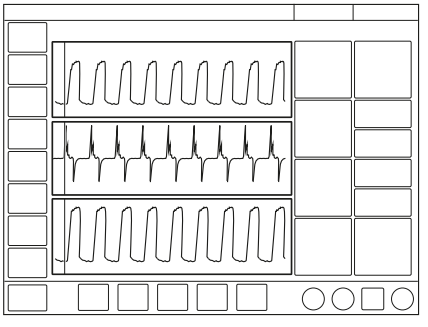
High Flow therapy



- The High Flow in Basic view contains two measured values: Inspiratory flow and FiO_2.
- To illustrate the flow, a flow animation is shown.

4.1.2 Advanced view

All invasive ventilation modes start in the *ADVANCED* view.



The view consists of:

- two to four waveforms – pressure and flow waveforms are always present, together with the volume waveform, if desired and the CO_2 waveform, if available.
- three columns of numerical values

The Servo Compass can be included in the *ADVANCED* view.

Refer to Servo Compass

It is possible to adjust the layout by tapping either *SCREEN LAYOUT* / *Layout* in the extended menu or *VIEWS* / *Layout* in the quick menu, or by tapping and holding a waveform. All three methods will open the *LAYOUT* window.

Refer to *Adapting the waveform display* on page 63.

It is also possible to adjust the scaling, sweep speed and appearance of the waveforms in the *LAYOUT* window.

User interface brightness can be adjusted by tapping *SCREEN LAYOUT* in the extended menu and toggling the Brightness button to the desired level in the window that opens. This can also be done in STANDBY.

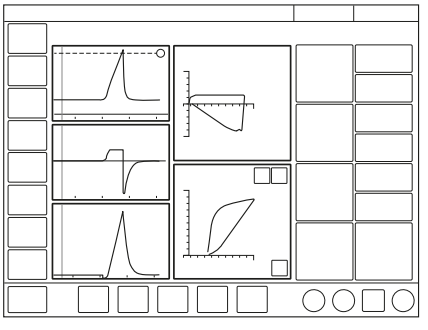
The short trends area can be shown/hidden in both Basic and Advanced views.

Tap extended menu show to the right of the waveform area to show the short trends area.

Tap Additional values & settings to the right of the numerical values to show more numerical values.

4.1.3 Loops view

Only available in invasive ventilation modes.



This view provides a graphical representation of the relationship between pressure-volume and volume-flow.

The view consists of:

- up to two loops – pressure-volume and volume-flow
- two to three waveforms – pressure and flow waveforms are always present, together with the volume waveform, if desired or CO_2 if available.
- two columns of numerical values

The Servo Compass can be included in the *Loops* view.

Refer to section Servo Compass in Loops view in Servo Compass.

It is possible to adjust the layout by tapping either *SCREEN LAYOUT* / *Layout* in the extended menu or *VIEWS* / *Layout* in the quick menu, or by tapping and holding a waveform. All three methods will open the *LAYOUT* window.

Refer to section Adapting the waveform display.

The loops may also be displayed with or without a loop grid by tapping *Loop grid*.

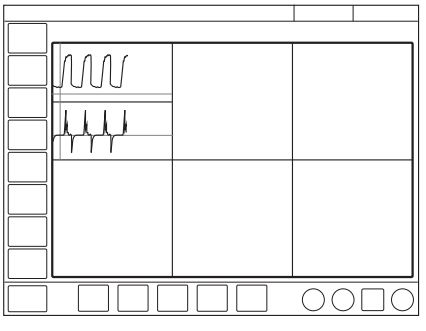
It is also possible to adjust the scaling, sweep speed and appearance of the waveforms in the *LAYOUT* window.

User interface brightness can be adjusted by tapping *SCREEN LAYOUT* in the extended menu and toggling the Brightness button to the desired level in the window that opens. This can also be done in STANDBY.

To store a reference loop or see two overlaid loops simultaneously:

1. Tap the reference loop symbol. A reference loop will then be displayed together with a time stamp.
2. Tap the two overlay loops symbol to display the two previous loops.

4.1.4 Distance view



The view is designed for optimal readability from a distance. Information displayed includes numerical values and waveforms.

There are six large tiles displaying:

- five enlarged numerical values
- the pressure, flow and volume waveforms or CO_2

The Servo Compass can be included in the *DISTANCE* view.

Refer to section Servo Compass in Distance view in Servo Compass.

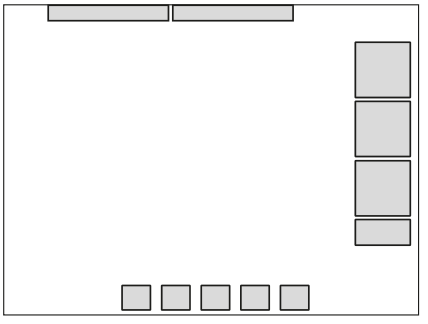
It is possible to adjust the layout by tapping either *SCREEN LAYOUT* / *Layout* in the extended menu or *VIEWS* / *Layout*in the quick menu, or by tapping and holding a waveform. All three methods will open the *LAYOUT* window.

Refer to section Adapting the waveform display.

It is also possible to adjust the scaling, sweep speed and appearance of the waveforms in the *LAYOUT* window.

User interface brightness can be adjusted by tapping *SCREEN LAYOUT* in the extended menu and toggling the Brightness button to the desired level in the window that opens. This can also be done in STANDBY.

4.1.5 Family view



The view has a neutral background image and may be used during family visits to hide the standard user interface.

Displayed information is minimized to:

- one column of numerical values
- the direct access bar
- alarms and messages in the status bar
- a dynamic representation (moving bubbles) showing that ventilator system is running.

Tap anywhere on the screen for rapid access to the most recently used view.

The screen layout cannot be adjusted.

User interface brightness can however be adjusted by exiting Family view and tapping *SCREEN LAYOUT* in the extended menu and toggling the Brightness button to the desired level in the window that opens.

4.1.6 Servo Compass

Servo Compass is only available in invasive ventilation modes.

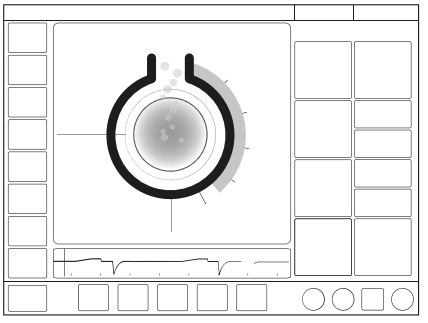
The Servo Compass can be included in *ADVANCED*, *LOOPS* and *DISTANCE* views.

It is not possible to adjust the layout but user interface brightness can be adjusted by tapping *SCREEN LAYOUT* in the extended menu and toggling the Brightness button to the desired level in the window that opens.

Displaying Servo Compass

Servo Compass visualizes volume and pressure in relation to set targets in invasive modes.

To set and monitor the volume target, PBW must first be calculated. Refer to section Predicted body weight (PBW).



The Servo Compass view consists of:

- two columns of numerical values
- one or two waveforms
- the Servo Compass - a graphical representation of actual numerical values for volume and pressure

Ventilation targets

Volume (VT/PBW)

The set tidal volume target is compared with the measured tidal volume. If the deviation is ±20%, or more the volume animation changes color from blue to orange to indicate that ventilation is suboptimal and adjustments should be considered.

Pressure (cmH_2O)

The aim is for the pressure to remain below the set target value. The target may be set as:

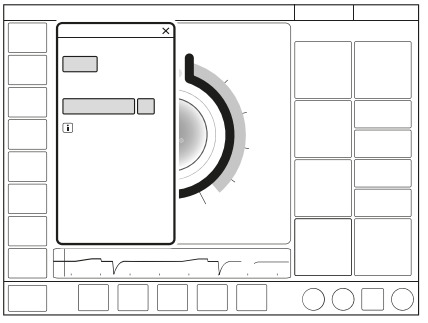
- total pressure i.e. measured end-inspiratory pressure
- driving pressure i.e. measured end-inspiratory pressure minus positive end-expiratory pressure (PEEP)

If the actual driving or total pressure exceeds the target value, the pressure animation will change color to indicate that ventilation is suboptimal and adjustments should be considered.

P_{drive} is displayed in the following ventilation modes:

- VC
- PC
- PRVC

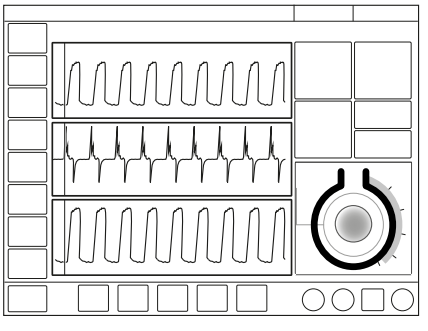
Refer to Driving pressure.



Tap in the Servo Compass view near the set targets to open the *VENTILATION TARGETS* window.

To store a reference measurement: Tap the Servo Compass reference measurement symbol. The reference measurements will be indicated by blue lines in Servo Compass together with a time stamp under the symbol.

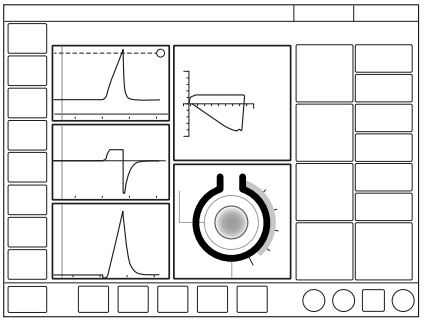
Servo Compass in Advanced view



The view consists of:

- two to four waveforms – pressure and flow waveforms are always present, together with the volume waveform, if desired and the CO_2 waveform, if available.
- three columns of numerical values
  When Servo Compass is activated in the *ADVANCED* view, the graphical representation is illustrated in the numerical values.

Servo Compass in Loops view

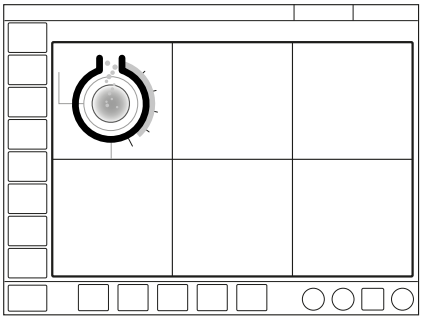


The view consists of:

- up to two loops – pressure-volume and volume-flow
- Servo Compass
- two to three waveforms – pressure and flow waveforms are always present, together with the volume waveform, if desired
- two columns of numerical values

Refer to Driving pressure.

Servo Compass in Distance view



There are six large tiles displaying:

- five enlarged numerical values
- Servo Compass

4.2 Displaying waveforms

The ventilator system can display a minimum of two waveforms and a maximum of four, depending on the view selected.

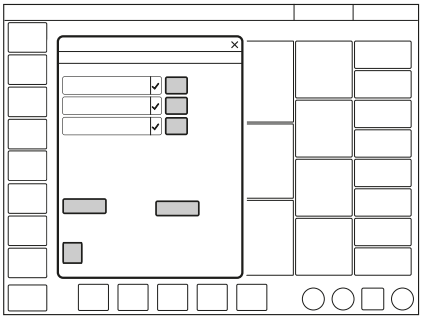
Pressure and flow waveforms are always mandatory except in the *FAMILY* view.

The waveforms displayed on the user interface are:

- P_{aw}
- Flow
- Volume – depending on view selected and layout adjustments
- CO_2 concentration - available if the CO_2 option is installed and a module is connected.

4.2.1 Adapting the waveform display

- It is possible to adjust the layout by tapping either *SCREEN LAYOUT* / *Layout* in the extended menu or *VIEWS* / *Layout* in the quick menu, or by tapping and holding a waveform. All three methods will open the *LAYOUT* window.
- Tap the tile shown in the figure directly to the right of each waveform name.



The scaling function can be adjusted manually here or use *Auto* to scale automatically.

It is also possible to show or hide non-mandatory waveforms in the *LAYOUT* window.

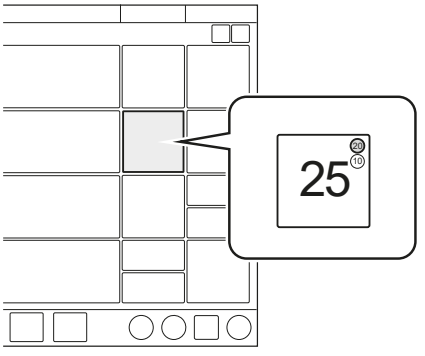
The sweep speed can also be adjusted by tapping *Sweep speed*.

Refer to *Sweep speed* on page 165.

In addition, there is a choice under *Appearance* between filled and unfilled waveforms.

4.3 Displaying numerical values

During ventilation, numerical values (measured or calculated) are displayed on the right side of the screen.



- Alarm limits (if applicable) are displayed in small digits for each numerical value.
- Values that are off the scale are replaced by three asterisks.
- Values that are uncertain are indicated by a single asterisk.

Depending on the view selected, one or more columns of numerical values are displayed.

To access additional values, tap the arrow at the right edge of the screen to display all numerical values

4.4 Displaying short trends

During ventilation in all ventilation modes, short trends of the numerical values in the first column can be displayed.

The short trends area can be shown/hidden in both Basic and Advanced views, by tapping the extend/collapse arrow to the right of the waveform area.

By default they show the last 15 minutes but can show a maximum of 72 hours.

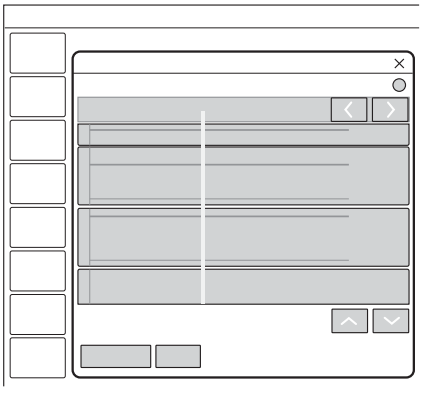
Trend values are stored every 60 seconds.

4.5 Trends, Logs & Library

TRENDS & LOGS in the quick menu includes *TRENDS*, *LOGS*, *LIBRARY* and *EXPORT FILES*.

4.5.1 Trends

Trend values are stored every 60 seconds and retained for a maximum of 72 hours. Stored events and system changes are also displayed here.

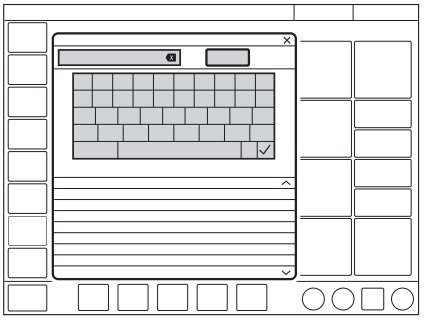


To view trends:

- In the extended menu, tap *TRENDS & LOGS* / *TRENDS*.
- To adjust the time resolution, tap the number of hours displayed.
- The time valid for the cursor position is displayed. If events have been stored, their number is displayed in the circle shown in the figure and an explanation appears to the left of this circle.
- If a recording is saved at a time corresponding to the cursor position, a recorder is displayed. To view the recording, tap this recorder.
- Tap *Organize trends* to place the trends in the desired order by dragging and dropping the different trended values presented.

Refer to Trends.

4.5.2 Logs



To view the event log:

- In the quick menu, tap *TRENDS & LOGS* / *LOGS*.
- Scroll among all the events listed.
- The *LOGS* window offers a search function. Tap the text field to open the keyboard and enter a search word. To display only log items that contain the search word entered, tap *Filter*. Tap again to deactivate the filter.
- Use the backspace arrow to delete the search word.

Each event includes the event time and date. The event log is cleared when a new patient is admitted.

Refer to *Event log* on page 178.

4.5.3 Library

Data can be saved in a number of ways:

- as screenshots
- as recordings
- as files for export including event log, trends and the above.

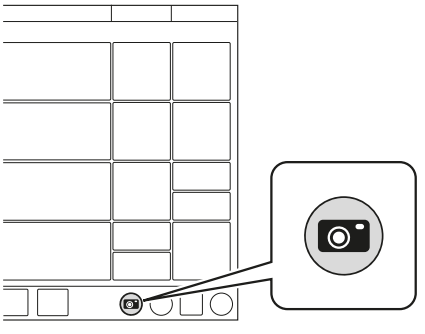
The screenshots, recordings and recruitment recordings are stored under *TRENDS & LOGS*/*LIBRARY*, which is accessed via the quick menu or tap Library in the status bar.

When the memory is full, a dialog with different options for saving is displayed.

Data can later be exported to a USB memory stick.

Saving screenshots

To save a screenshot, tap the camera in the status bar.



The screenshot will be stamped with the date and time it was taken and saved under the *Saved screens* tab in the *LIBRARY* window.

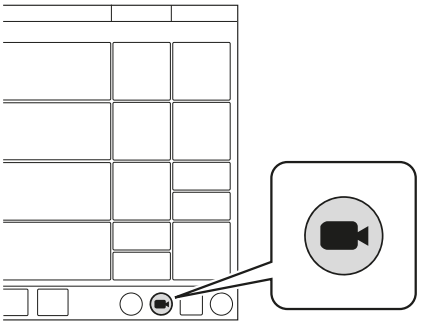
There is space for 40 screenshots under this tab. When the memory is full, it can be erased or oldest screenshot can be erased.

Viewing saved screens

To view screenshots, tap *TRENDS & LOGS*/*LIBRARY*/*Saved screens* in the quick menu. Choose the relevant screenshot displayed at the bottom of the window. If there are more than ten screens saved, scroll to the right to find more.

Recording waveforms

To make a recording, tap the recorder (not available in Standby) in the status bar.



A 30 second long recording will be made starting 15 seconds before, and lasting until 15 seconds after the time the recording was initiated. A blue progress bar will be displayed under the recorder while the recording is being made.

The recording will be stamped with the date and time that it was initiated and will be saved under the *Recordings* tab in the *LIBRARY* window. All settings applying at the time the recording is initiated will also be saved.

There is space for 40 recordings under this tab. When the space is full, the next recording made will erase the oldest one.

Viewing recordings

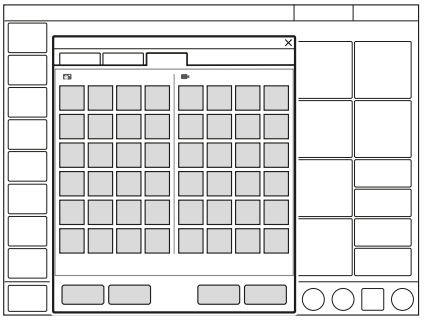
To view recordings, tap *TRENDS & LOGS*/*LIBRARY*/*Recordings* in the quick menu. Choose the relevant recording displayed at the bottom of the window. If more than ten recordings have been saved, scroll to the right to find more.

The cursor (pale green) is positioned on the dotted line indicating the middle point of the recording. It is activated by moving it or by pressing the arrows to the right of the recorder seen above the dotted line. The values at the cursor position are displayed in digits to the right of the waveform name in the recording window.

When viewing a recording, it is also possible to view the settings by tapping *Settings* at the bottom left of the window. This will open a list of the actual parameter settings in use at the time the recording was initiated.

Exporting and deleting data

To export or delete screenshots, recordings or recruitments, tap *TRENDS & LOGS*/*LIBRARY*/*Export & Delete* in the quick menu.



Both screenshots and recordings can be selected for export or deletion.

The following data will be exported to a USB memory stick:

- Event log
- Trends
- Saved screens & recordings

NOTE:

Only one USB memory stick may be connected to the USB ports at the same time.

4.5.4 Export files

To export all files to a USB memory stick, tap *TRENDS & LOGS* / *EXPORT FILES*, in the quick menu.

4.6 Ventilator configuration

The ventilator system will always start up with the stored configuration settings.

To view the stored configuration settings, tap *CONFIGURATION* in the extended menu.

The following configurations can be viewed:

- *Alarms*
  The appearance of the window may vary depending on configuration.
- *General*
- *Units*
- *Sensors*
- *Startup configuration*
  The appearance of the window may vary depending on configuration.

The alarms configuration can be viewed for each of the patient categories. The other configurations do not vary with patient category.

No editing can be done under *CONFIGURATION*.

Refer to *Service & Settings* on page 148.

4.7 System status

To view the current status of the ventilator system:

- Tap *SYSTEM STATUS* in the quick menu in Standby.
- Tap *SYSTEM STATUS* in the extended menu during ventilation.

The *SYSTEM STATUS* window that opens contains:

1. *General*
2. *Patient circuit*
3. *Pre-use check*
4. *Batteries*
5. *Expiratory cassette*
6. *Sensors*
7. *Turbine*
8. *O_2 cell*
9. *Installed options*

5 Ventilation modes and therapies

Table of contents

5.1 Introduction

5.1.1 General

The ventilator system is delivered preset with the following configuration options:

- Ventilatory settings are based on either minute volume or tidal volume.
- Ventilatory settings are based on either I:E ratio or inspiratory time.

5.1.2 Safety guidelines

Not all safety guidelines apply to all modes.

WARNING!

- The following warning applies to invasive ventilation modes only:
  - Autotriggering should be avoided. Do not set the trigger level too low.
- The following warnings apply to non invasive ventilation (NIV) modes only:
  - Avoid high inspiratory pressure as it may lead to gastric overdistension and risk of aspiration. It may also cause excessive leakage.
  - Ensure adequate external monitoring (for example, SpO_2) for High Flow therapy.

CAUTION!

Be sure to set alarm limits as appropriate for each mode, especially those for:

- expired minute volume
- apnea time
- airway pressure

NOTE:

- To protect the patient's lungs from excessive pressure it is important to set the upper pressure limit to a suitable value.
- It is important to avoid leakage so as to ensure the proper functioning of invasive modes such as:
  - PRVC
  - VS
  - Automode PRVC ⇄VS
  - SIMV (PRVC) + PS

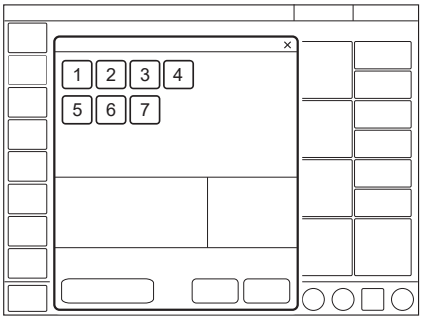
NOTE:

- The circuit compensation function should be used - it is important to make sure that the compressible volume of the patient circuit is not changed after the pre-use check/patient circuit test has been performed (e.g. filling an active humidifier with water or connecting a filter after the test has been performed).
- In the pediatric patient category, there is a leakage compensation function available in all invasive modes with some exceptions. For pediatrics the exceptions are Bi-vent/APRV, VC, VCVS, SIMV (VC). Refer to section *Compensation functions* on page 110

5.2 Pressure Control (PC)

Pressure Control (PC):

- Delivers a constant pressure over a preset inspiratory time and at a preset respiratory rate.
- Delivers the inspiration with a decelerating flow.
- Changes in resistance or compliance of the respiratory system will affect the volume delivered.



The following parameters are set:

1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. Respiratory rate (b/min)
4. PC above PEEP (cmH_2O)
5. I:E ratio or Inspiratory time (s)
6. Inspiratory rise time (% or s)
7. Trigger (l/min or cmH_2O)

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

The delivered tidal volume varies, and is dependent on the setting PC above PEEP and, resistance and compliance of the respiratory system and the patient circuit.

The flow during inspiration is decelerating. The patient can trigger extra assisted breaths. As the delivered tidal volume can vary, it is very important to set alarm limits for the minute volume to adequate levels.

PC ventilation is often preferred when there is leakage in the patient circuit, e.g. due to an uncuffed endotracheal tube, or in situations where the maximum airway pressure must be controlled.

If a patient tries to exhale during inspiration, pressure increases. When it increases 3 cmH_2O above the set inspiratory pressure level, the active expiratory valve opens and regulates the pressure down to the set inspiratory pressure level. If the pressure increases to the set upper pressure limit, e.g. if the patient is coughing, the expiratory valve opens and the ventilator system switches to expiration.

5.2.1 Pressure Control in detail

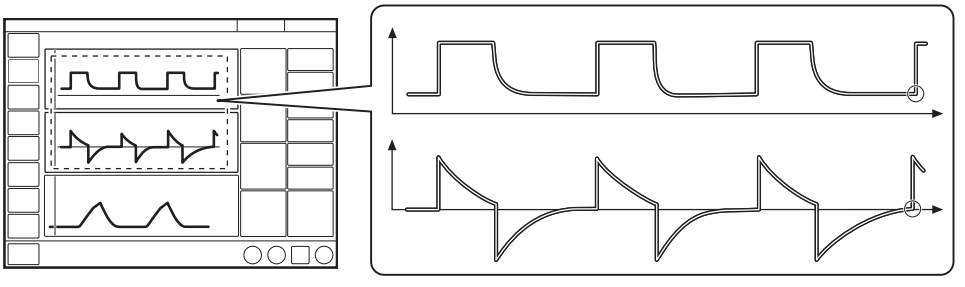


Fig. 1: The circles in the figure indicate patient triggering.

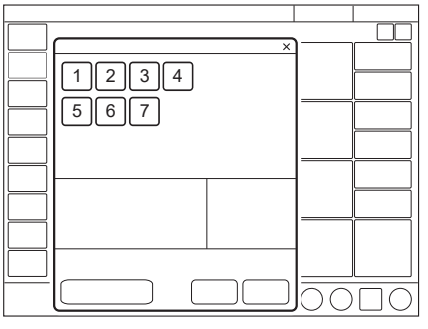
- PC ensures that the preset inspiratory pressure level is constant throughout inspiration. Breaths are delivered in accordance with the preset respiratory rate, inspiratory time and inspiratory pressure level, resulting in a decelerating flow.
- The preset pressure level is controlled by the ventilator system. The resulting volume depends on the set pressure level, the inspiratory time and the mechanical properties of the patient's respiratory system during each breath.
- Inspiration starts in accordance with the preset respiratory rate or when the patient triggers an assisted breath.
- Inspiration is terminated after the preset inspiratory time, or if the upper pressure limit is exceeded.

5.3 Pressure Regulated Volume Control (PRVC)

Pressure Regulated Volume Control (PRVC):

- combines the advantages of Volume Control and Pressure Control by delivering a preset tidal volume with a decelerating inspiratory flow at a preset respiratory rate
- maintains the lowest possible constant pressure throughout inspiration
- the inspiratory pressure of a breath will never exceed 5 cmH_2O below the upper pressure limit

The ventilator system can be configured so that either tidal volume or minute volume is set.



The following parameters are set:

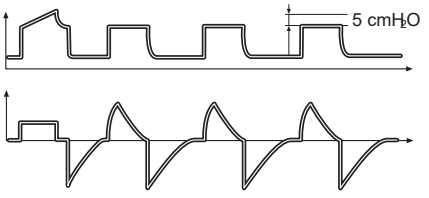
1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. Respiratory rate (b/min)
4. Tidal volume (ml) or minute volume (l/min)
5. I:E ratio or Inspiratory time (s)
6. Inspiratory rise time (% or s)
7. Trigger

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

The ventilator system delivers a preset tidal volume. The pressure is automatically regulated to deliver this volume but limited to 5 cm H_2O below the set upper pressure limit.

The flow during inspiration is decelerating. The patient can trigger extra assisted breaths.



When invasive leakage compensation is activated, the first breath is a pressure controlled breath given with 5 cmH_2O above PEEP.

If active leakage compensation is not used, the first breath is a volume controlled breath with the set tidal volume and 10% pause time, where the pause pressure is used as the pressure level for the following breath.

Following the initial breath, the ventilator system calculates and continuously regulates the pressure needed to deliver the preset tidal volume.

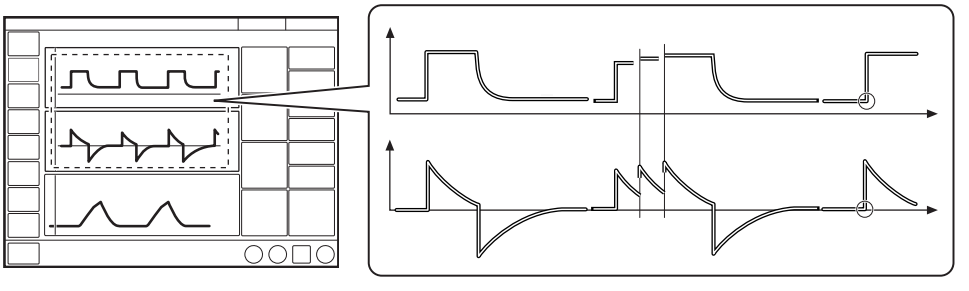
An alarm is activated if the targeted tidal volume cannot be delivered because the required pressure exceeds a level that is 5 cm H_2O below the set upper pressure limit.

NOTE:

Activated invasive leakage compensation ensures delivery of the preset tidal volume.

Refer to*Leakage compensation* on page 110.

5.3.1 PRVC in detail



The circles in the figure indicate patient triggering.

- PRVC ensures a preset tidal volume during a preset inspiratory time at a preset respiratory rate.
- The inspiratory pressure level is constant during each breath, but automatically adapts in small increments on a breath-by-breath basis to match the mechanical properties of the patient's respiratory system, thus ensuring delivery of the target volume.
- Inspiration starts in accordance with the preset respiratory rate or when the patient triggers.

Expiration starts:

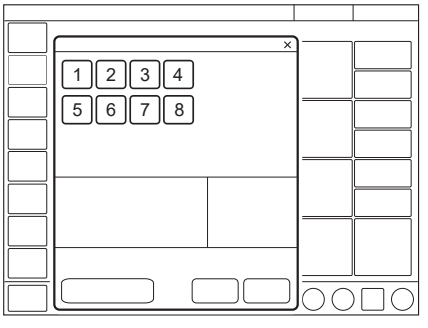
- After the termination of the preset inspiratory time.
- If the delivered tidal volume is 50% higher than set.
- If the upper pressure limit is exceeded.

5.4 Volume Control (VC)

Volume Control (VC):

- delivers a preset tidal or minute volume over a preset inspiratory time and at a preset respiratory rate, regardless of changes in resistance or compliance of the respiratory system.
- maintains a constant flow with varying peak pressure

The ventilator system can be configured so that either tidal volume or minute volume is set.



The following parameters are set:

1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. Respiratory rate (b/min)
4. Tidal volume (ml) or minute volume (l/min)
5. I:E ratio or Inspiratory time (s)
6. Pause time (% or s)
7. Inspiratory rise time (% or s)
8. Trigger

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

The flow adaptation setting and flow pattern setting may be enabled or disabled in *SERVICE & SETTINGS* / *BIOMED* / *CONFIGURATION* / *STARTUP CONFIGURATION*.

Refer to section Configuration.

When enabled, the flow adaptation and flow pattern can be activated/ deactivated in the *VOLUME CONTROL* window.

The airway pressure is dependent on the tidal volume, the inspiratory time and the resistance and compliance of the respiratory system. An increase in resistance and decrease in compliance will lead to an increased airway pressure. The delivered pressure can vary, so in order to protect the patient's lungs from excessive pressure, it is very important to set the upper pressure limit to a suitable value.

Patients may trigger extra assisted breaths if their spontaneous efforts reaches the set trigger level.

Flow adaptation

Patient inspiratory efforts can also result in a higher inspiratory flow and tidal volume than were preset. This is because the ventilator system enables the patient to modify both flow rate and timing.

Thus, if the patient demands a higher flow than the calculated constant flow, the system will sense any sudden pressure drop of > 3 cm H_2O and temporarily enables PS to deliver a higher flow adapted to patient demand.

Flow adaptation setting

The flow adaptation can be set to:

- Volume Control with flow adaptation
  The function is described in section Flow adaptation.
- Volume Control without flow adaptation
  Breathing frequency instead of flow may increase during inspiration for a patient who needs more ventilation.

Set trigger sensitivity at an adequate level. A patient who needs more ventilation may increase the breathing frequency instead of increasing the flow during inspiration.

5.4.1 Decelerating flow

VC delivers a constant flow or a decelerating flow with a set flow pattern.

The flow pattern describes the end-inspiratory flow in relation to the peak inspiratory flow.

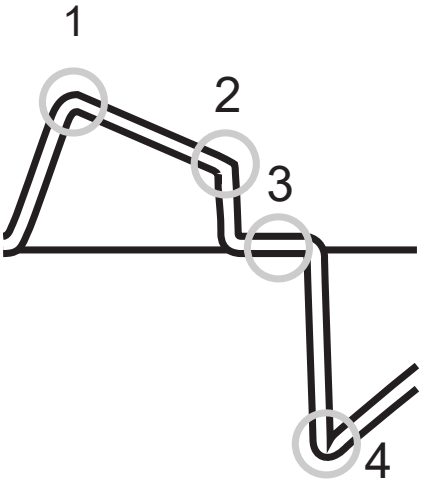
Flow pattern setting

The flow pattern can be set between 0-100%.

- A flow pattern setting of 100% equals constant flow.
- A flow pattern setting below 100% delivers a decelerating flow with greater deceleration the lower the setting.

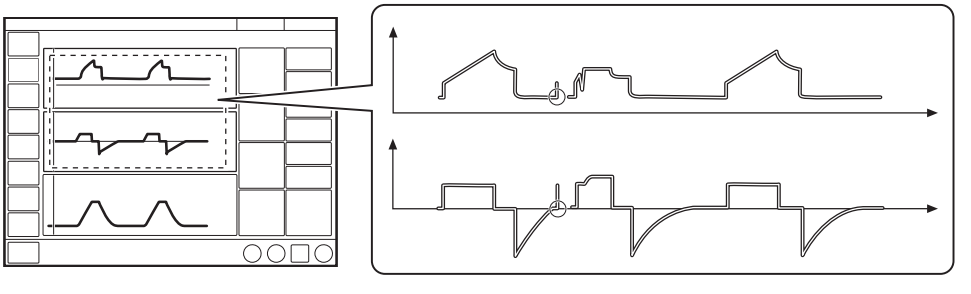
Flow adaptation is not available if the flow pattern is set to a decelerating flow.

Flow-time waveform



1. Peak inspiratory flow
2. End-inspiratory flow
3. Zero flow
4. Peak expiratory flow

5.4.2 Volume Control in detail



The circles in the figure indicate patient triggering.

- VC ensures a preset tidal volume during a preset inspiratory time at a preset respiratory rate.
- The inspiratory flow is constant or linearly decelerating and depends on the ventilatory settings.
- Inspiration starts in accordance with the preset respiratory rate or when the patient triggers an assisted breath.
- If the patient makes an inspiratory effort during the inspiratory period, when flow adaption is enabled and flow pattern is 100%, the ventilator system will switch to PS to satisfy the patient´s flow demand, as shown in the second breath in the figure.

5.5 Bi-Vent/APRV

Bi-Vent:

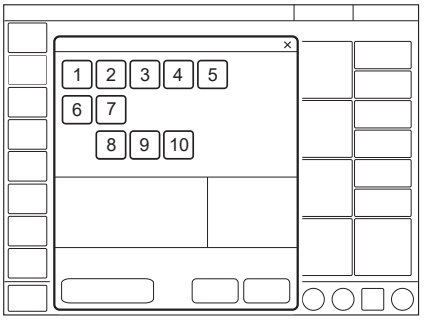
- is a time-cycled, pressure-limited mode that allows spontaneous breathing throughout the entire ventilatory cycle.
- has two time-cycled pressure levels and switches between these two levels. The patient can breathe spontaneously at both these levels and it is possible to give Pressure Support at both levels.

Airway Pressure Release Ventilation (APRV):

- is a time-cycled, pressure-limited mode that allows spontaneous breathing throughout the entire ventilatory cycle.
- alternates between two levels of positive airway pressure, with the main time on the high level and a brief expiratory release to facilitate ventilation.
- differs from Bi-Vent in that it uses an inverse I:E ratio.

Bi-Vent/APRV allows for spontaneous breathing/PS ventilation at two different pressure levels. These basic levels are individually set, as well as the time in seconds at each level. Bi-Vent and APRV functionality is differentiated by the I:E ratio, where APRV applies at I:E > 2:1.

The active mode is highlighted; Bi-Vent or APRV depending on the mode settings.



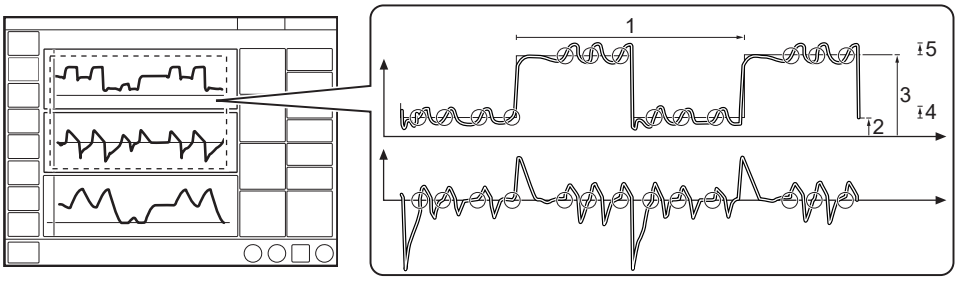
The following parameters are set:

1. Oxygen concentration (%)
2. Pressure at the lower pressure level (PEEP)
3. Pressure at the higher pressure level (P_{high}) (cmH_2O)
4. Time at the higher pressure level (T_{high}) (s)
5. Time at the lower pressure level (T_{PEEP}) (s)
6. Inspiratory rise time (s)
7. Trigger
8. PS above PEEP (cmH_2O)
9. PS above P_{high} (cmH_2O)
10. End inspiration (%)

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

5.5.1 Bi-Vent/APRV in detail



The circles in the figure indicate patient triggering.

1. Bi-Vent/APRV cycle = Thigh + TPEEP
2. PEEP
3. P_{high}
4. PS above PEEP
5. PS above P_{high}

Bi-Vent/APRV allows for spontaneous breathing/PS ventilation at two different pressure levels. These basic levels are individually set, as well as the time in seconds at each level. Bi-Vent and APRV functionality is differentiated by the I:E ratio, where APRV applies at I:E > 2:1.

Since Bi-Vent/APRV is partly a controlled mode of ventilation, apnea alarm and backup ventilation are not available. It is also important to set the lower and upper alarm limits for expired minute volume.

Each Bi-Vent/APRV cycle is regarded as autonomous and therefore most of the measured values are updated every cycle, i.e. minute volume, respiratory rate, mean pressure and end expiratory pressure. Associated alarms are also handled for every cycle.

As a result of switching between two different pressure levels, the tidal volumes may vary significantly between different breaths. This may also be the case for $etCO_2$ (end tidal CO_2) concentration.

NOTE:

To avoid lung overdistension, be careful when adding Pressure Support above the set P_{high}.

5.6 Pressure Support (PS)/CPAP

Pressure Support (PS):

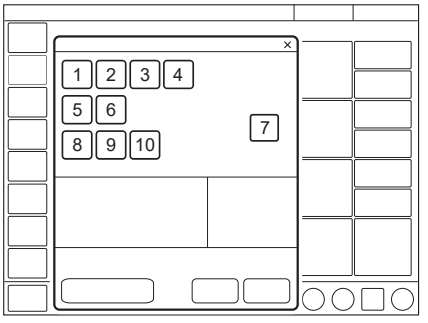
- Is initiated by the patient, who controls the respiratory rate and tidal volume
- Delivers ventilator support using the preset pressure level and with a decelerating flow
- Provides backup (PC) ventilation in case of apnea

Continuous Positive Airway Pressure (CPAP):

- Is initiated by the patient and works like PS except that the Pressure Support level is set to zero
- Is effectively a spontaneous breathing mode with continuous positive airway pressure to keep the airways open

The ventilator system provides this constant preset pressure when activated by patient effort. The patient determines the frequency and duration of the breaths, which have a decelerating flow pattern. Duration of inspiration can be adjusted with the help of the *End inspiration* setting.

CPAP may be seen as a special case of PS in which the inspiratory pressure level is set to zero.



The following parameters are set:

1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. PS above PEEP (cmH_2O) (PS level)
4. End inspiration (%)
5. Inspiratory rise time (s)
6. Trigger
7. Apnea time (s)
8. Backup respiratory rate (b/min)
9. Backup PC above PEEP (cmH_2O)
10. Backup I:E or Ti (s)

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

The higher the preset inspiratory pressure level from the ventilator system, the more gas flows into the patient. As the patient becomes more active, the PS level may be gradually reduced.

Always set the apnea time that is appropriate to the individual patient situation. If the apnea alarm limit is reached, the ventilator system will automatically switch to backup ventilation (PC).

The alarm should alert staff to take action by either returning to a supported mode or changing to a controlled mode of ventilation.

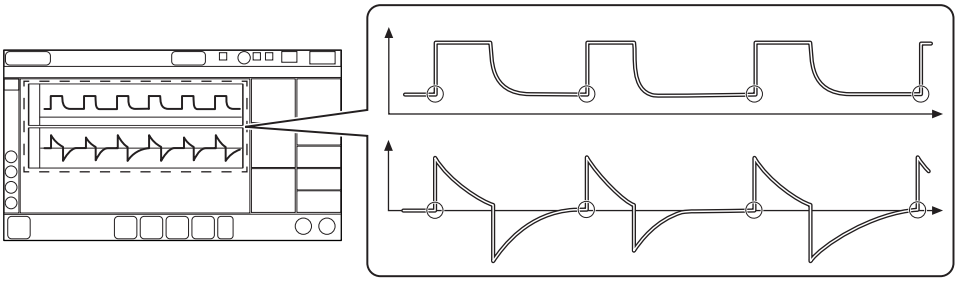
It is also very important to set the lower and upper alarm limits for expired minute volume.

The inspiratory rise time should be set to a comfortable value for the patient. In PS, the inspiratory rise time should normally be increased.

The *End inspiration* setting is important to patient comfort and ventilator synchronization with the patient. If the patient's expiratory resistance is high, the *End inspiration* setting should be raised to guarantee enough time for expiration.

It is important to monitor how this affects the tidal volume.

5.6.1 PS/CPAP in detail



The circles in the figure indicate patient triggering.

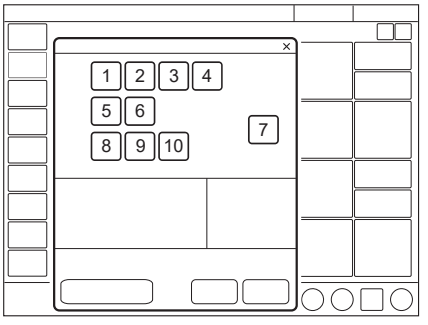
- PS ensures that a preset inspiratory pressure level is constantly maintained in response to patient effort.
- The preset pressure level is controlled by the ventilator system, while the patient determines the respiratory rate and inspiratory time.
- Inspiration starts when the patient triggers a breath and gas flows into the lungs at a constant pressure. Since the pressure provided by the ventilator system is constant, the flow will decrease until the level set for *End inspiration* is reached.
- Expiration starts when criteria for End inspiration is reached. Refer to section *End inspiration* on page 102.

5.7 Volume Support (VS)

Volume Support (VS):

- is initiated by the patient, who controls the respiratory rate
- delivers ventilator support with a variable peak pressure and decelerating flow to guarantee the preset tidal volume
- the inspiratory pressure of a breath will never exceed 5 cmH_2O below the upper pressure limit
- provides backup (PRVC) ventilation in case of apnea

A patient-adapted constant inspiratory support is supplied when activated by patient effort. The resulting volume is continuously monitored and the constant inspiratory pressure automatically adjusts to the required level. The patient determines the frequency and duration of the breaths which have a decelerating flow pattern.



The following parameters are set:

1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. Tidal volume (ml)
4. End inspiration (%)
5. Inspiratory rise time (s)
6. Trigger
7. Apnea time (s)
8. Backup respiratory rate (b/min)
9. Backup tidal volume (ml)
10. Backup I:E or Ti (s)

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

If patient activity increases, the inspiratory support will decrease provided that the set tidal volume is maintained. If the patient breathes below the set tidal volume, the inspiratory support will increase.

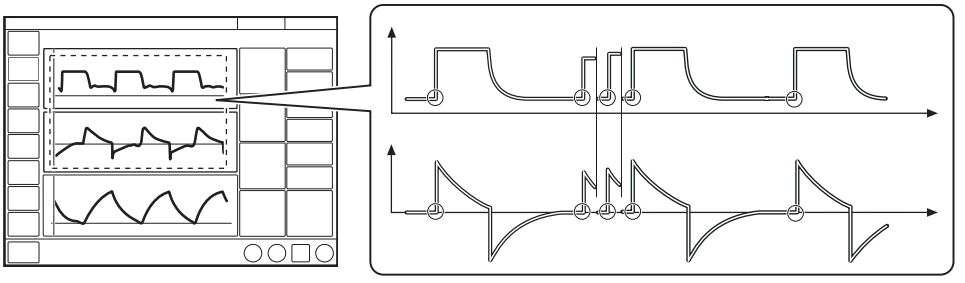
The initial breath provides support with 5 cmH_2O.

Following this breath, the ventilator system calculates and continuously regulates the pressure needed to deliver the preset tidal volume.

An alarm is activated if the set target volume cannot be delivered due to the fact that the pressure required to deliver it is higher than 5 cmH_2O below the set upper pressure limit.

In this mode it is also important to set the apnea time that is appropriate to the individual patient's situation. If this time is reached, the ventilator system will automatically switch to backup ventilation.

5.7.1 Volume Support in detail



The circles in the figure indicate patient triggering.

- VS ensures delivery of a set target tidal volume following patient effort by providing inspiratory pressure support that is adapted to the patient.
- The inspiratory pressure level is constant during each breath, but alters in small increments, on a breath-by-breath basis, to match the patient´s breathing ability and the mechanical properties of the lungs.
- Inspiration starts when the patient triggers.

5.8 Automode

In Automode, the ventilator system shifts automatically between controlled and supported ventilation, allowing better patient-ventilator interaction. When the patient is making a breathing effort, the ventilator system immediately switches to a supported mode of ventilation. If the patient is not making any breathing effort, the ventilator system will return to the controlled mode and deliver controlled breaths.

The parameters for each Automode combination are adjusted in the settings window and are basically the same as those for the relevant controlled or supported mode.

Refer to *Settings* on page 49.

Automode PC ⇄ PS:

- is an interactive mode automatically switching between the controlled mode PC and supported mode PS based on patient triggering
- delivers controlled breaths in the absence of patient breathing effort, switching to supported breaths when a breathing effort is detected
- serves as an aid to starting the weaning period
- adapts to the patient’s breathing capacity

Automode PRVC ⇄ VS:

- is an interactive mode automatically switching between the controlled mode PRVC and supported mode VS based on patient triggering
- delivers controlled breaths in the absence of patient breathing effort, switching to supported breaths when a breathing effort is detected
- serves as an aid to starting the weaning period
- adapts to the patient's breathing capacity

In this combination, the first supported breath delivered to the patient has the same pressure level as the preceding PRVC breath.

Automode VC ⇄ VS:

- is an interactive mode automatically switching between the controlled mode VC and supported mode VS based on patient triggering
- delivers controlled breaths in the absence of patient breathing effort, switching to supported breaths when a breathing effort is detected
- serves as an aid to starting the weaning period
- adapts to the patient's breathing capacity

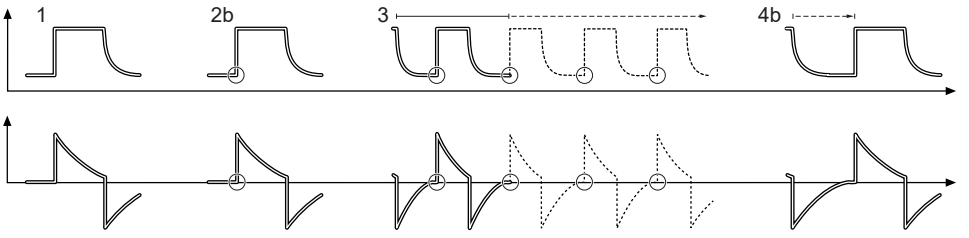
In this combination, the ventilator system uses the plateau pressure in the VC breath as a reference pressure for the first VS breath.

Refer to sections Volume Control (VC) and *Decelerating flow* on page 77.

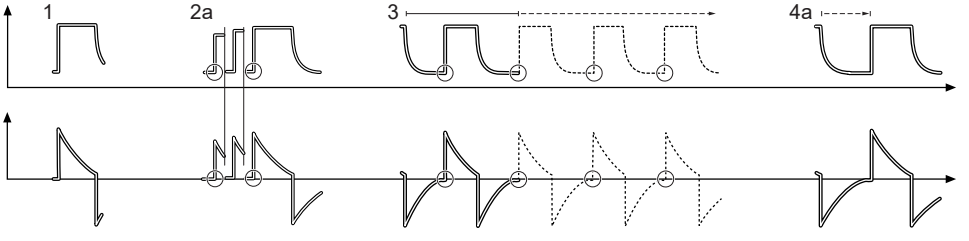
5.8.1 Automode in detail

1. The ventilator system starts in PC, PRVC or VC mode. If the patient triggers a breath, the ventilator system will turn to the relevant supported mode to encourage the patient's respiratory drive.
2. If the patient is breathing adequately:
   - In VS, the ventilator system adjusts the inspiratory pressure level on a breath-by-breath basis to ensure delivery of the preset target volume.
   - In PS, the ventilator system ensures that the preset inspiratory pressure level is maintained throughout inspiration.
3. The ventilator system initially adapts with an increasing apnea time.This means that for the spontaneously triggering patient, the apnea time increases successively until the level set in the settings window for the maximal apnea time parameter is reached after 10 consecutive spontaneously triggered breaths. Refer to *Settings* on page 49.
4. Exceeding the maximal apnea time setting without a sufficient patient effort will cause the following:
   - In VS, a PRVC or VC breath will be delivered according to the selected Automode functionality.
   - In PS, a PC breath will be delivered.
5. The rings in the figures indicate patient triggering.

PC ⇄ PS

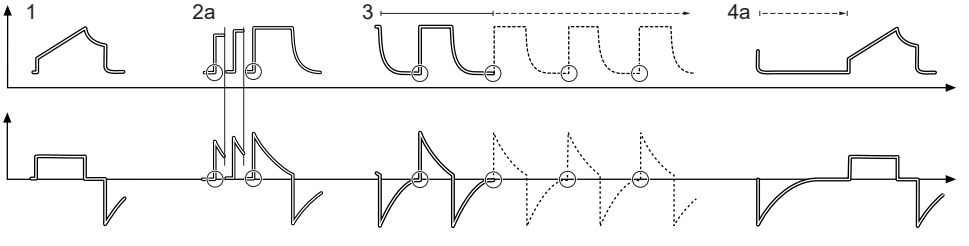


PRVC ⇄ VS



In the Automode PRVC ⇄VS combination, the first supported breath delivered to the patient has the same pressure level as the preceding PRVC breath.

VC ⇄ VS



In the Automode VC ⇄VS combination, the ventilator system uses the plateau pressure in the VC breath as a reference pressure for the first VS breath.

5.9 SIMV

SIMV stands for Synchronized Intermittent Mandatory Ventilation. In SIMV modes, mandatory controlled ventilation breaths are delivered with a preset SIMV rate. The patient can breathe spontaneously with PS between the mandatory breaths.

The parameters for each SIMV combination nare adjusted in the settings window and are basically the same as those for the relevant controlled or supported mode.

Refer to *Settings* on page 49.

SIMV (PC) + PS:

- delivers mandatory controlled breaths using a preset respiratory rate and a preset pressure
- delivers inspiratory support (PS) during spontaneous breaths taken between the mandatory breaths

SIMV (PRVC) + PS:

- delivers mandatory controlled breaths using a preset respiratory rate and a preset volume
- delivers inspiratory support (PS) during spontaneous breaths taken between the mandatory breaths

SIMV (VC) + PS:

- delivers mandatory controlled breaths using a preset respiratory rate and a preset volume
- delivers inspiratory support (PS) during spontaneous breaths taken between the mandatory breaths

In SIMV modes, the mandatory breath is defined by the basic settings.

Settings

	SIMV (PC) + PS	**SIMV (PRVC) + PS**	**SIMV (VC) + PS**
PC above PEEP	X	—	—
Tidal volume / Minute volume	—	X	X
SIMV rate	X	X	X
Breath cycle time	X[1]	X [1]	X [1]
I:E ratio / Inspiratory time	X	X	X
Insp. rise time	X	X	X
Pause time	—	—	X [1]

In the minute volume configuration, the tidal volume is determined by dividing the minute volume by the SIMV rate.

The breath cycle time is the length of the mandatory breath in seconds and is the same as the duration of an SIMV period.

In SIMV, the very first breath is always a mandatory one.

1 *Only when the ventilator system is configured for setting the I:E ratio.*

If the patient triggers a breath during the SIMV period, the breath delivered is a mandatory one. If the patient fails to trigger a breath within the first 90% of the SIMV period, a mandatory breath is delivered.

If the ventilator system is configured for setting the inspiratory time, an I:E ratio of 1:2 will be used to estimate the breath cycle time.

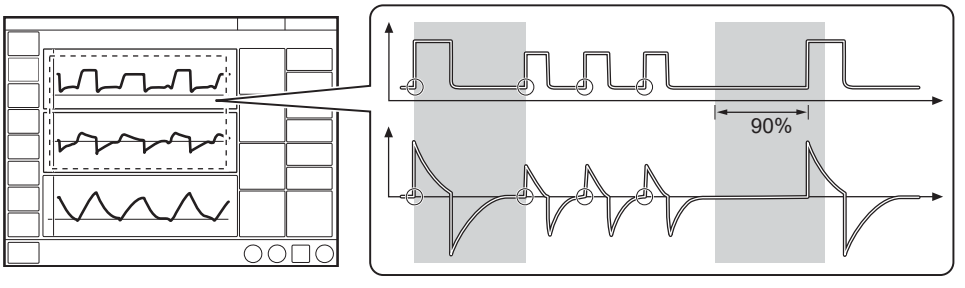
The spontaneous/Pressure Support breaths are defined by setting the level for Pressure Support above PEEP (PS above PEEP).

5.9.1 SIMV in detail

- This combination of controlled and supported ventilation allows for preset mandatory breaths that are synchronized with the patient's breathing.
- If there is no trigger attempt within a time window equal to 90 % of the set breath cycle time, a mandatory breath is delivered (the breath cycle time is the total time for one mandatory breath).
- The mandatory breath is defined by the basic settings (mode of ventilation, breath cycle time, respiratory pattern and volumes/pressures).
- The spontaneous/supported breaths are defined by the setting for PS.

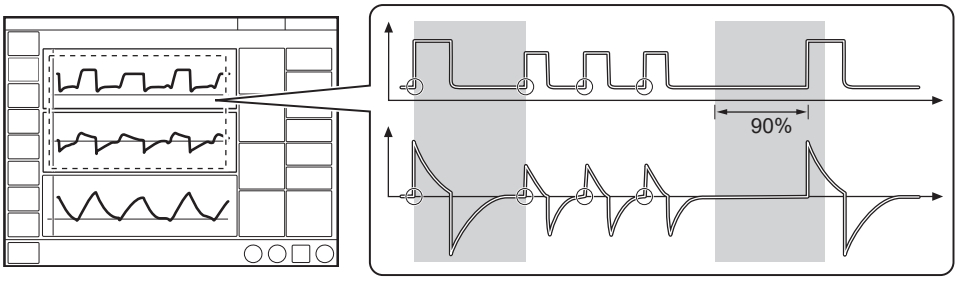
Refer to sections Volume Control (VC) and *Decelerating flow* on page 77.

5.9.2 SIMV (PC) + PS



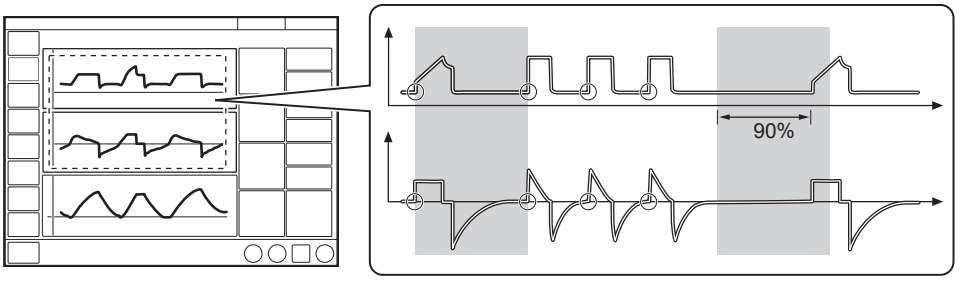
The circles in the figure indicate patient triggering.

5.9.3 SIMV (PRVC) + PS



The circles in the figure indicate patient triggering.

5.9.4 SIMV (VC) + PS



The circles in the figure indicate patient triggering.

5.10 Non-Invasive Ventilation (NIV)

5.10.1 Safety guidelines

WARNING!

- Avoid high inspiratory pressure as it may lead to gastric overdistension and risk of aspiration. It may also cause excessive leakage.
- The dead space will increase in NIV when using a mask or helmet.
- NIV is not intended to be used on intubated or tracheotomized patients.
- CO_2 measurement will be affected by mask/prongs leakage.
- In non-invasive ventilation, the measured expired volume may be different from the actual volume exhaled by the patient due to leakage around the mask.
- If nasal prongs are used, make sure that they are applied so that air can flow freely through both prongs.

CAUTION!

- Take care to minimize leakage towards the patient's eyes when using a nebulizer during NIV to avoid the nebulized drug coming into contact with the eyes.
- Mask/prongs leakage might affect nebulizer efficiency.
- The user shall follow the NIV interface manufacturer's instruction for use.

NOTE:

- The mask/prongs must be properly applied in order to minimize leakage.
- When selecting the mask/prongs, it is essential to consider such things as proper size and accurate adaptation to the patient.
- CO_2 rebreathing will increase in NIV when using an interface with a large volume.

5.10.2 Introduction

NIV refers to ventilation when the patient is not intubated or tracheotomized. It involves the use of a patient interface such as:

- nasal mask
- nasal prongs
- face mask
- total face mask
- NIV helmet

NOTE:

NIV patient interfaces must not have leakage valves.

In NIV, the ventilator system adapts to variations in leakage to maintain the required pressure and PEEP level. Excessive leakage will result in a high priority alarm. Ventilation will resume automatically if the leakage decreases. It can also be started manually by tapping *Resume ventilation* in the *LEAKAGE DETECTED* window that opens to inform about leakage.

In NIV, flow and volume curves and the following measured values are compensated for leakage: VTi, VTe, MVi, MVe.

Refer to *Alarm handling* on page 129.

In all NIV modes, there is an automatic detection of patient connection. This ensures that ventilation starts in a comfortable manner when the patient interface is applied to the patient's face. There is also an optional NIV disconnection functionality available that automatically pauses ventilation when the patient interface is removed, and delivers a continuous flow until re-connection is detected.

The NIV disconnection functionality can be set to Low flow, Disabled or High flow. Refer to *Service & Settings* on page 148

5.10.3 Using a NIV helmet

WARNING!

- The helmet application shall not be used with volume controlled modes.
- The helmet application must only be used with non invasive pressure supported ventilation modes.
- Do not rely on flow and volume parameters when using the helmet application. Ensure adequate external monitoring.

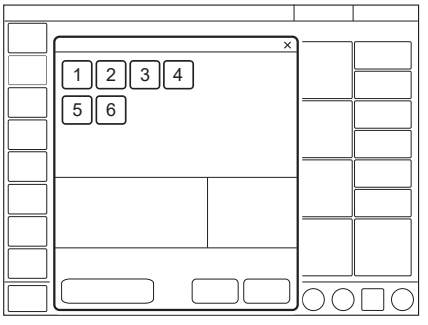
NOTE:

- When using NIV PS, the filling of the helmet **must** be initiated by tapping *START VENTILATION* or *Resume ventilation* on the screen. This must also be done after disconnection.
- To secure a proper patient triggering function, the PEEP level should never be set below 3 cmH_2O. When helmets with a safety valve are used, it is recommended to set a PEEP level of at least 5 cmH_2O.
- Alarms related to volume are not reliable. To avoid nuisance alarms the alarm limits must be properly set.
- It is essential to set pressure alarms adequately.
- It is possible to use a helmet for non invasive ventilation. Only use the adult patient category when using a helmet.
- For instructions for the helmet application, refer to the manufacturer's instructions for use. There are a few points to remember in order to use a helmet safely:
  - The volume in the helmet may cause delays in signals and patient triggering.
  - Make sure that the helmet used eliminates CO_2 re-breathing.
  - High pressure levels may affect the patient's ears and the flow may affect the patient's eyes.
  - The volume in the helmet may cause delays in signals and patient triggering.
  - Patients may perceive the helmet application as noisy. A Servo Duo Guard filter used on the inspiratory side will reduce the noise level. The noise level may vary between different helmets.
  - Do not use humidified ventilation gas as this will cause condensation on the helmet walls.
  - Do not use nebulizers.

5.11 NIV Pressure Control (NIV PC)

NIV Pressure Control (NIV PC):

- delivers a constant pressure over a preset inspiratory time and at a preset respiratory rate
- delivers the inspiration with a decelerating flow
- changes in lung or thorax resistance or compliance will affect the volume delivered
- is leakage compensated



The following parameters are set:

1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. Respiratory rate (b/min)
4. PC above PEEP (cmH_2O)
5. I:E ratio or Inspiratory time (s)
6. Inspiratory rise time (% or s)

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

Differences compared with invasive PC:

- When *START VENTILATION* is tapped, a waiting position dialog is displayed. All patient related alarms are turned off for 2 minutes. In this position, ventilation will start if the ventilator system detects patient activity.
- The trigger cannot be manually set in NIV.
- Detection of pressure below PEEP or expiratory volume decrease will start a new breath.

5.12 NIV Pressure Support (NIV PS)

NIV Pressure Support (NIV PS):

- is initiated by the patient, who controls the respiratory rate and tidal volume
- delivers ventilator support using the preset pressure level and with a decelerating flow
- has a fixed trigger
- provides backup (PC) ventilation in case of apnea
- is leakage compensated

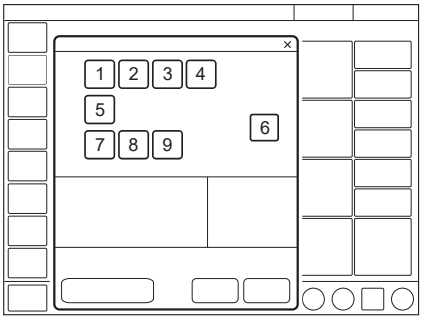
Continuous Positive Airway Pressure (CPAP):

- is initiated by the patient and works exactly like PS except that the Pressure Support level is set to zero
- maintains positive pressure in the airways at all times
- is effectively a spontaneous breathing mode with continuous positive pressure to keep the airways open
- is leakage compensated

PS is thus a patient-initiated breathing mode in which the ventilator system supports the patient with a set constant pressure.

The ventilator system provides this constant preset pressure when activated by patient effort. The patient determines the frequency and duration of the breaths, which have a decelerating flow pattern. Duration of inspiration can be adjusted with the help of the *End inspiration* setting.

CPAP may be seen as a special case of PS in which the inspiratory pressure level is set to zero.



The following parameters are set:

1. Oxygen concentration (%)
2. PEEP (cmH_2O)
3. PS above PEEP (cmH_2O) (PS level)
4. End inspiration (%)
5. Inspiratory rise time (% or s)
6. Apnea time (s)

7. Backup respiratory rate (b/min)
8. Backup PC above PEEP (cmH_2O)
9. Backup I:E or Ti (s)

Ventilation can be started from the settings window in Standby.

Refer to *Settings* on page 49.

Differences compared with invasive PS:

- When *START VENTILATION* is tapped, a waiting position dialog is displayed. All patient related alarms are turned off for 2 minutes. In this position, ventilation will start if the ventilator system detects patient activity.
- The ventilator system will not lock in backup ventilation. There is no limit on the number of times the ventilator system can switch between supported mode and backup.
- The trigger cannot be manually set in NIV.

5.13 High Flow therapy

WARNING!

- Ensure adequate external monitoring (for example, SpO_2) for High Flow therapy.
- For tracheostomy patients, always use a tracheostomy interface with openings to room air.
- The high-flow mode of this equipment is only suitable for a spontaneously breathing patient.
- Do not use sealed patient interfaces with this equipment, to avoid the risk of suffocation or barotrauma.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the equipment or accessories near sparks or open flames.
- Do not leave the nasal cannula or mask on bed coverings or chair cushions. If the equipment is turned on, but not in use, the oxygen will make the materials more flammable. Turn the equipment off when not in use to prevent oxygen enrichment.
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns.
- Do not lubricate fittings, connections, tubing, or other accessories of the equipment to avoid the risk of fire and burns.
- Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
- Ensure a sufficient intended leakage between the breathing system and the patient to allow the patient to exhale.

CAUTION!

Always use an active humidifier during High Flow therapy. Make sure it is activated and filled with water.

High Flow therapy delivers a set flow of heated and humidified gas with a set concentration of oxygen to the patient. It can be selected in both non-invasive and invasive ventilation as well as in Standby.

High Flow therapy can be started from the settings window in Standby. It is not possible to make any recordings during High flow therapy.

Perform a manual test to see if breathing tubes and accessories are suitable for High Flow therapy. After set-up of a patient circuit for High Flow therapy:

- Ensure gas flow is present at the end of the inspiratory tube.
- Verify that the Airway obstructed alarm is activated when the end of the inspiratory tube is occluded.
- Connect the patient end of the inspiratory tube to the patient interface to begin High Flow therapy.

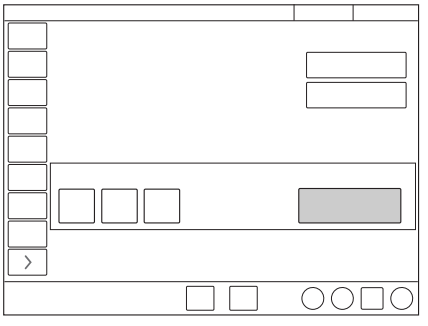
During High Flow therapy, the following applies:

- A high-flow nasal cannula of the appropriate size or a high-flow tracheotomy interface must be used.
- The patient must be breathing spontaneously.
- There is no disconnection alarm, apnea alarm, respiratory rate alarm, or minute volume alarm.
- Available clinical alarms are Airway obstructed and Flow through expiratory tube. Refer to section *Alarms* on page 138.

The Airway obstructed alarm activates if there is high pressure in the breathing circuit. This can occur because of occlusion of the patient interface or breathing circuit, or when the flow is set higher than the patient interface allows, meaning the set flow cannot be delivered to the patient. The alarm activates immediately when the circuit pressure reaches the pressure limit. When the alarm activates, gas delivery stops briefly and the safety valve opens to lower the pressure in the breathing circuit. When the pressure is lower, gas delivery starts again.

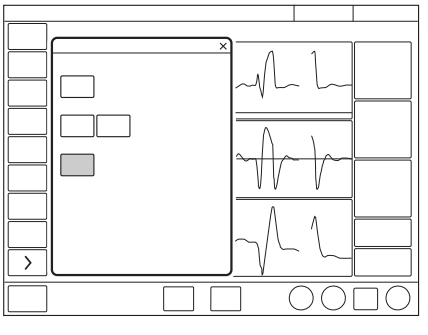
For information on the Airway obstructed alarm function, refer to section *Functions in ventilation modes and therapies* on page 176.

5.13.1 Start from Standby



- Tap *MODES* in the quick menu
- Tap *HIGH FLOW* / *Other Therapies*.
- O_2 concentration and flow can be adjusted.
- Tap *Accept*.
- Connect the patient to the high flow nasal cannula or tracheostomy interface and tap *START HIGH FLOW*.

5.13.2 Starting during Ventilation



- Tap *MODES* in the quick menu
- Tap *HIGH FLOW* / *Other Therapies*.
- Tap *Continue*. This will stop ventilation and begin high-flow preparation.
- Ventilation is stopped and alarms are silenced for 2 minutes. The remaining time is shown on screen.
- High Flow therapy can be started manually when the preparation is complete and the interface is connected to the patient.

6 Ventilatory settings and functions

Table of contents

6.1 SIMV breath cycle time

The SIMV breath cycle time:

- is the duration of the total respiratory cycle of the mandatory breath in SIMV (inspiration + pause + expiration)
- only applies if the inspiratory time is set using the I:E ratio
- together with a spontaneous period, makes up one full SIMV cycle

The breath cycle time is sometimes referred to as an SIMV period.

The breath cycle time parameter is not displayed when an SIMV mode is selected and inspiratory time is configured.

6.2 O_2 concentration

The O_2 concentration delivered to the patient is set in the mode settings window and is monitored by the ventilator system with upper and lower alarm limits. Refer to *Alarm limits* on page 171.

The O_2 concentration alarms are delayed after changing the O_2 concentration. Refer to *Alarms miscellaneous* on page 174.

6.3 Tidal volume/Minute volume

Depending on the ventilator configuration, the inspiratory volume can be set as either:

- tidal volume or
- minute volume

Whichever of these is set, the other will be displayed in the lower right information area of the mode settings window.

6.4 Pressure level

PC above PEEP is the set inspiratory pressure level for each mandatory breath in:

- PC
- SIMV (PC) + PS
- Automode PC ⇄ PS
- backup ventilation in PS

PS above PEEP is the set inspiratory pressure support level for triggered breaths in:

- PS
- all SIMV modes
- Automode PC ⇄ PS
- Bi-Vent

6.5 I:E ratio/Inspiratory time

The setting of ventilatory settings can be configured in two different ways, based on:

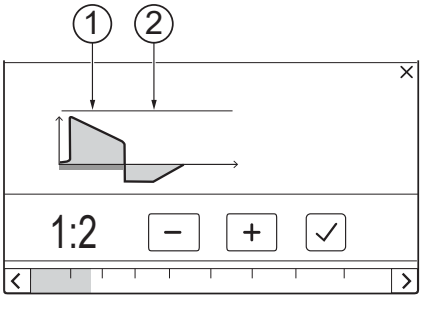
- I:E ratio or
- Inspiratory time, in seconds, to better meet the requirements for pediatric care.

6.5.1 I:E ratio

The I:E ratio expresses the relation between the inspiration phase and the expiration phase. Spontaneous breathing has an I:E ratio of around 1:1.5.

Note that increasing the inspiratory time may raise mean airway pressure and improve oxygenation but may also cause hyperinflation. Reversed I:E ratios (e.g. 1.5:1 or 2:1) will further lengthen inspiratory time and shorten expiration, which may be helpful if the lungs are very stiff, but requires low respiratory rates to avoid gas trapping.

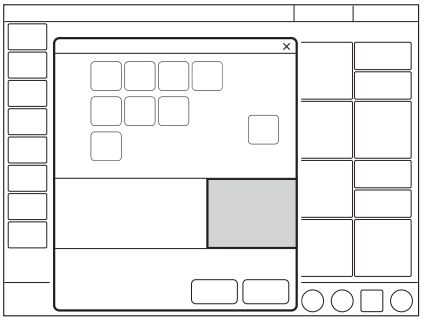
A prolonged expiration time (e.g. 1:3) may be used for weaning and in case of obstructive lung disease, but a short inspiratory time may also lower the tidal volume and lead to inadequate ventilation.



1. Inspiration
2. Expiration

An inverse I:E ratio is also used in Bi-Vent/APRV mode.

Refer to *Bi-Vent/APRV* on page 79.



When the ventilator system is configured for setting of I:E, the unit for pause time and inspiratory rise time (*Ti*) automatically switches to percent. The corresponding inspiratory time for each I:E is displayed in the lower left information area of the mode settings window.

6.5.2 Inspiratory time

The setting makes it possible to set the inspiratory time (*Ti*) to a fixed time in seconds.

With this configuration, the unit for inspiratory rise time and pause time automatically switches to seconds. The corresponding I:E ratio for each inspiratory time setting is displayed in the lower left information area of the mode settings window.

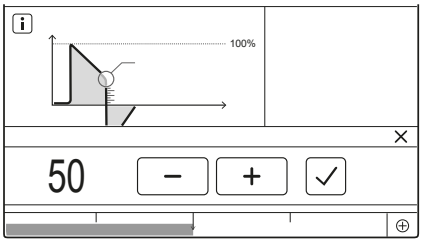
As the inspiratory time is explicitly set, a change in the respiratory rate, for example, will affect the I:E ratio. As a safety precaution, there will therefore be an indication when the resulting I:E ratio passes 1:1 in either direction.

When the inspiratory time is directly set, the breath cycle time parameter is not displayed when an SIMV mode is selected, since there is no need to set it.

6.6 End inspiration

End inspiration:

- is the point at which inspiration changes to expiration in supported ventilation



For PS and VS breaths, expiration starts:

- When the inspiratory flow decreases below a preset fraction of the peak inspiratory flow (*End inspiration* % setting).
- If the inspiratory pressure increases between 1 and 3 cmH2O above the target pressure, depending on the shape of the pressure waveform.
- If the upper pressure limit is exceeded.
- If the maximum time for inspiration is exceeded.
  Refer to section Functions in ventilation modes and therapies.

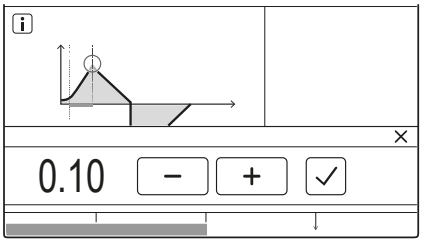
The End inspiration setting directly affects the inspiratory time:

- if set too low, inspiration will be longer, which may cause pulmonary hyperinflation and increased work of breathing.
- if set too high, inspiration will be shorter, which may mean that the patient receives insufficient tidal volume.

6.7 Inspiratory rise time

The inspiratory rise time (*Tinsp.rise*):

- is the time taken to reach peak inspiratory flow or pressure at the start of each breath
- is expressed in seconds or as a percentage of the respiratory cycle time depending on how the ventilator is configured



An increased inspiratory rise time will affect the rate of flow/pressure increase and can be evaluated by the shape of the flow and pressure waveforms.

The inspiratory rise time should be adjusted from default setting to enhance patient comfort.

Inspiratory rise time set as a percentage is applicable in:

- VC
- PC
- PRVC
- all SIMV modes
- all Automode modes
- NIV PC

Inspiratory rise time set in seconds is applicable in:

- PS
- VS
- Bi-Vent/APRV

When the ventilator system is configured for setting of inspiratory time rather than I:E ratio, the unit for inspiratory rise time automatically switches to seconds for all ventilation modes.

6.8 Trigger

6.8.1 Pneumatic trigger

Only available in invasive ventilation modes.

WARNING!

If the flow trigger level is very low (too far to the left on the scale), an auto triggering condition may be reached. This condition can also be reached if there is leakage in the patient circuit, e.g. if an uncuffed endotracheal tube is used. Triggering will then be initiated by the ventilator system and not by the patient. This should always be avoided by increasing the patient effort required to trigger the ventilator system, moving further to the right on the scale.

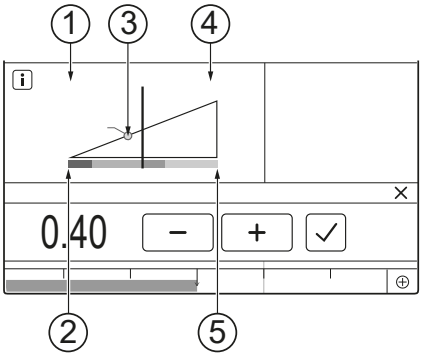
The ventilator system has a pneumatic trigger (flow or pressure based) functionality. It is only available in invasive ventilation modes. In NIV, the trigger sensitivity is automatically adjusted.

The pneumatic trigger setting:

- determines the level of patient effort needed to trigger the ventilator to inspiration
- may be set as either flow or pressure triggering, where flow triggering allows the patient to breathe with less effort
- should generally be set so that it requires minimal patient effort without causing auto triggering

During expiration, the ventilator system continuously delivers a gas flow (bias flow), which is measured in the expiratory channel.

Refer to *Ventilatory settings* on page 168.

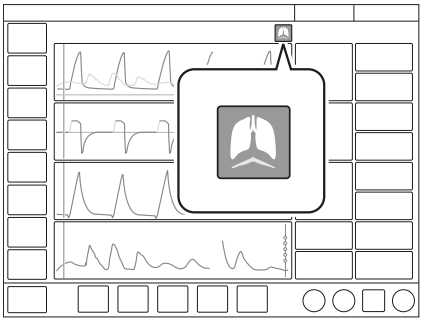


1. Flow
2. Less effort
3. Trigger setting
4. Pressure
5. More effort

When triggering is based on flow, to the left on the scale, the ventilator system senses deviations in the bias flow delivered during expiration. These deviations are caused by the inspiratory efforts of the patient. The further to the left on the scale, the less effort the patient has to make. At the far left of the scale, there is a risk of auto triggering, and the scale and value are therefore marked in red. The trigger setting is marked with a circle in the dynamic image.

When triggering is based on pressure, to the right on the scale, the ventilator system senses deviations in the pressure below PEEP created by the patient. The pressure below PEEP required to initiate a breath is displayed when the setting is made.

The further to the right on the scale, the greater the patient effort required to trigger. The trigger scale has different colors based on the setting. Green indicates a normal setting for pneumatic triggering. Red indicates that the setting is not recommended, e.g. when the risk of auto triggering may increase. Yellow is used as a warning color.



Patient triggering (flow or pressure) is indicated by a symbol in the status bar.

The pressure or flow curve will also be highlighted in white depending on which type of trigger is used.

6.9 Apnea time

Apnea time is the time without a patient breathing effort that the ventilator system will allow to elapse in supported ventilation before the *No patient effort* alarm is activated and the ventilator system switches to the backup mode.

Refer to *Apnea management* on page 114.

6.9.1 Maximal apnea time

In Automode, the apnea time becomes longer as spontaneous breathing becomes more regular. It is therefore set, in Automode only, as *Max. apnea time*.

The maximal apnea time:

- is the maximum time without a patient breathing effort that the ventilator will allow to elapse in supported ventilation before switching to controlled ventilation.

6.10 Driving pressure

Driving pressure (P_{drive}) is the difference between the end-inspiratory pressure and the positive end-expiratory pressure at zero flow condition.

P_{drive} is displayed in the following ventilation modes:

- VC
- PC
- PRVC
- Automode
- SIMV mandatory breath
- Backup ventilation in support modes

P_{drive} is displayed in numerical values. The placement can be either in additional values or replacing P_{mean} depending on the configuration. The configuration can be set with a default setting in *SERVICE & SETTINGS* / *BIOMED* / *CONFIGURATION*, but can also be changed in the *Ventilation target* window by tapping the Servo Compass.

6.11 Predicted body weight (PBW)

Definition of PBW/BW:

- For adult patients outside the height range 130-200 cm, PBW is the same as the patient weight (BW).
- For pediatric patients, PBW is the same as the patient weight (BW).

In mechanical ventilation, predicted body weight can be used to help reduce the risk that differences in body weight will affect the estimated ventilation needs of different patients.

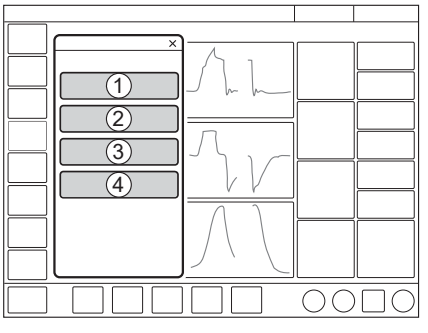
The ventilator monitors the ratio of tidal volume to PBW (VT/PBW) in ml/kg.

In the adult patient category PBW is calculated according to the Devine Formula and requires that height and gender are entered.

The tidal volume setting will, when tapped, present a calculated value for VT/PBW if the necessary patient data has been entered under *PATIENT DATA*. The value will also be presented in the numerical values and trended under *TRENDS & LOGS*/*TRENDS*.

6.12 Maneuvers

The following functions can be accessed under *MANEUVERS* (only available during ventilation) in the quick menu.



1 Nebulization
2 Static measurements
3 Manual breath
4 O_2 boost level

6.12.1 Static measurements

The inspiratory and expiratory hold can be used to perform certain measurements:

- $PEEP_{tot}$: set PEEP + intrinsic PEEP
- C_{static}: static compliance, a measure of the elastic properties of the respiratory system. A decrease in compliance implies stiffer lungs.
- E: elastance, is the inverse of compliance (1/C). An increase in elastance implies stiffer lungs.
- R_i: inspiratory resistance

- R_e: expiratory resistance
- T_c: time constant, calculated as C_{static} x R_e. Some lung units have decreased compliance, and some have increased resistance, or both. Differences in R_e and C_{static} affect the speed at which the lung units are filled and emptied. An expiration time of three time constants is recommended to avoid auto PEEP.
- P_{plat}: pressure during end inspiratory pause

Static measurements are available in invasive ventilation modes.

Inspiratory hold

This function is activated by pressing *INSPIRATORY HOLD* for a maximum of 30 seconds. The inspiratory and expiratory valves close after inspiration. This function can provide an exact measurement of the end inspiratory lung pressure. It can be used to pause ventilation during X-ray or to determine the plateau pressure (P_{plat}), or, together with the expiratory hold, to calculate static compliance.

Expiratory hold

Expiratory and inspiratory valves are closed after the expiration phase is completed for as long as *EXPIRATORY HOLD* is pressed, but only up to a maximum of 30 seconds. Expiratory hold provides an exact measurement of the end expiratory pause pressure. It can be used to determine total PEEP and, together with inspiratory hold, static compliance (C_{static}).

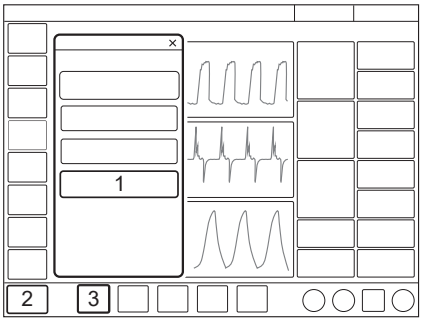
6.12.2 Manual breath

When *MANUAL BREATH* is tapped, the ventilator system will initiate a new breath cycle according to the current ventilator settings.

6.12.3 Nebulization

Refer to *Nebulization* on page 108.

6.12.4 O_2 boost level



1 O_2 boost level
2 O_2 boost function
3 O_2 concentration setting (*O_2 conc.*)

By tapping *O_2 BOOST LEVEL*, it is possible to change the desired level for the O_2 boost function. It is possible to lock the O_2 boost level to 100 %. It is also possible to set it to 0 %, in which case the O_2 boost function will no longer be active and will be replaced by three asterisks.

The value entered under *O_2 boost (%) level* specifies the number of percentage units that will be added to the value set for the O_2 concentration.

For example: if the current O_2 concentration is 40 % and the O_2 boost level is 30 %, the O_2 boost function will, when tapped, deliver 70 % O_2.

The O_2 boost function figure displayed will change accordingly. Since the minimum O_2 concentration is 21 %, the *O_2 boost (%) level* scale goes from 0 to 79 %.

Refer to *Ventilatory settings* on page 168 and to *Configuration* on page 151.

6.12.5 O_2 boost function

To use the O_2 boost function, tap and hold *O_2 boost* at the bottom left corner of the screen. When tapped, *O_2 boost* is activated and the displayed oxygen setting is delivered for 1 minute. Use of O_2 boost also pre-silences alarms.

All clinical alarms are silenced during the time *O_2 boost* is active.

The O_2 boost function can be interrupted by tapping the cancel symbol in the O_2 boost timer window anytime during the 1 minute interval.

6.13 Compensation functions

6.13.1 Leakage compensation

Leakage compensation is always active for all patient categories in non invasive modes.

The function is designed to help maintain PEEP throughout the breath and is activated by default.

The delivered measured volume and flow values are automatically leakage compensated, as indicated by the symbols on the affected values.

Leakage is measured and presented in percent.

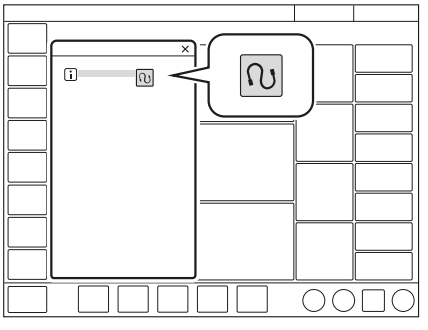
Leakage compensation may also affect important ventilatory parameters, such as patient triggering and the termination of inspiration.

6.13.2 Circuit compensation

Part of the volume of each inspiration will not reach the patient because of gas compression in the ventilator and expansion of the tubing. All components in the patient circuit affect such losses.

When circuit compensation is activated, the delivered measured flow, volume waveforms, and values are automatically compensated for these losses, as indicated by the symbols on the affected values.

The patient circuit test must be passed in order to activate circuit compensation.



To deactivate or reactivate, tap *COMPENSATION* in the extended menu/ *CIRCUIT COMPENSATION*. Follow on-screen instructions.

NOTE:

When monitoring VT/PBW, circuit compensation must be activated.

6.14 Disconnection

NOTE:

- Alarms are turned off during the *Patient disconnected* phase for a maximum of 60 seconds. If the patient has not been reconnected within 60 seconds, alarms are activated.
- The minimum PEEP level during disconnection is 3 cmH_2O. The ventilator system will adjust to the minimum level if the PEEP level is below 3 cmH_2O in order to detect disconnection of the patient.

DISCONNECTION is not available in NIV modes or when *Manual breath* is activated. During the *Patient disconnected* phase, the nebulizer is temporarily paused.

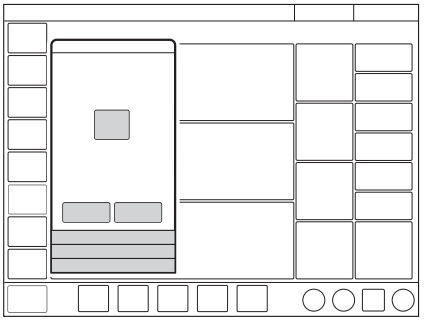
If O_2 is not connected, an elevated oxygen level cannot be set during the preparation phase as elevated oxygen concentration can only be achieved with O_2 connected. In this case, the post-oxygenation phase will be skipped.

DISCONNECTION enables automatic inhibition of the ventilator system during a tracheal suction procedure or when briefly pausing ventilation in invasive modes. It is also possible to manually initiate inhibition of cycling by pressing the pause ventilation button during the pre-oxygenation phase. The ventilator system is prevented from cycling without activating alarms.

Refer to *Ventilatory settings* on page 168 and to section Configuration.

Tap *DISCONNECTION* in the quick menu during ventilation to open the *DISCONNECTION* window.

The window always opens in *Preparation*.



Adjust the O_2 concentration, if desired, then tap *Accept*.

Tapping *Cancel* will close the *DISCONNECTION* window.

6.14.1 Preparation

There are three phases following *Preparation*:

- *Pre-oxygenation*
- *Patient disconnected*
- *Post-oxygenation*

Pre-oxygenation

Pre-oxygenation of the patient begins automatically after *Accept* is tapped during preparation.

The *Patient circuit disconnected* alarm is turned off. The maximum duration of the pre-oxygenation phase is 120 seconds. After this, the system automatically returns to ventilation using the previous oxygen setting. The same thing happens if *Cancel* is tapped.

Patient disconnected

The system automatically enters the *Patient disconnected* phase when the patient is disconnected during the pre-oxygenation phase.

During the *Patient disconnected* phase, the following alarms are turned off for up to 60 seconds:

- apnea
- minute volume
- tidal volume
- respiratory rate
- $etCO_2$
- PEEP

When the patient is reconnected, the system automatically enters the post-oxygenation phase and then resumes ventilation. It is also possible to restart ventilation manually by tapping *START VENTILATION*.

WARNING!

If leakage is excessive when the patient is reconnected, the system may fail to resume ventilation when entering the post-oxygenation phase. Tap *START VENTILATION* to resume ventilation.

Post-oxygenation

After reconnection, the ventilator system will deliver the same oxygen concentration as in the pre-oxygenation phase for 60 seconds.

After 60 seconds the system automatically returns to ventilation using the previous oxygen concentration setting.

6.15 Suction

6.15.1 Open suctioning

For open suctioning procedures, use Disconnection function. Refer to *Disconnection* on page 111.

6.15.2 Closed suctioning

The O_2 boost function can be used for oxygenation purposes.

If no pre-oxygenation is necessary, consider pre-silencing alarms before suctioning.

Use one of the pressure-based modes listed here. Adjust settings to levels suitable for the patient and follow hospital guidelines for closed suctioning.

- PC
- PS/CPAP
- Bi-Vent/APRV
- Automode PC ⇄ PS
- SIMV (PC) + PS

6.16 Previous mode

When *MODES* is tapped in the quick menu during operation, the current mode tile is always highlighted and the previous mode tile is marked *PREVIOUS*, together with the date and time it was used.

If the previous mode was non invasive and the current mode is invasive, or vice versa, it is necessary to go to Standby and choose the relevant ventilation type to find the previous mode.

The previous mode function is not available:

- after a pre-use check
- after changing the patient category
- after admitting a new patient
- after using the same ventilation mode for more than 24 hours
- after restarting the system.

When the previous mode function is activated during backup ventilation, the ventilator system returns to the mode that was active before the supported mode was initiated.

A recall of previous settings is only possible after a change of ventilation mode.

To recall the previous ventilation mode used:

- Tap the tile marked with an arrow in the *MODES* window.
- A dialog will open asking *Do you want to keep the previous settings for the mode?*
- Tap one of the two choices *Yes* or *No* as appropriate.
  - If *Yes* is tapped, the mode settings window will open with the previous settings intact.

NOTE:

If one or several settings in the mode settings window are highlighted in yellow, this indicates that it/they should be considered for adjustment, as the values entered there may have been carried over from the previous mode.

- If *No* is tapped, the mode settings window will open with default settings, which may then be adjusted.

6.17 Apnea management

6.17.1 Apnea time

Apnea time is the time without a patient breathing effort that the ventilator system will allow to elapse in supported ventilation before the *No patient effort* alarm is activated and the ventilator system switches to the backup mode.

The relevant backup mode is highlighted in white in the heading on the screen and the alarm *No patient effort* is displayed.

If the patient triggers a breath, the ventilator system automatically switches back to supported ventilation and the *No patient effort* alarm disappears.

Apnea time is available in all supported modes and in all SIMV modes. Set the apnea time that is appropriate for each patient in the mode settings window.

NOTE:

In SIMV modes, there is no backup ventilation and the apnea time only controls the *No patient effort* alarm. The apnea time is therefore set in the *ALARM LIMITS* window.

Refer to *Alarm handling* on page 129 and to *Alarm limits* on page 171.

6.17.2 Backup ventilation

For invasive modes, backup ventilation entails a switch in case of apnea:

- from VS to PRVC
- from PS/CPAP to PC
- from VC to VS

For non-invasive modes, the switch is from NIV PS to NIV PC.

When the relevant backup mode is activated while ventilating in a supported mode, the name of the mode is highlighted in white in the mode heading and the backup parameters in the direct access bar are shown as active.

The following parameters are set under the backup mode heading in the mode settings window:

- PC above PEEP (cmH_2O) for PS backup. The minimum backup pressure level is 5 cmH_2O.
- Tidal volume (ml) for VS backup.
- Respiratory rate (b/min)
- I:E or Ti (s) (depending on configuration)

Refer to *Settings* on page 49.

Backup ventilation trends

The number of switches to backup ventilation per minute is trended under *TRENDS & LOGS*/*TRENDS*.

The percentage time spent in backup ventilation per minute is also trended.

No consistent patient effort

This alarm occurs in invasive ventilation only.

If the patient fulfils the criteria for the *No consistent patient effort* alarm, the ventilator system will lock in backup ventilation.

A dialog *Backup ventilation active – review ventilation settings or continue in supported mode.* is displayed on the screen. A choice must be made or this dialog will remain open and the ventilator system will remain in backup ventilation.

Tap *Review ventilation settings* in the dialog window to return to the mode settings window.

- Tap *Cancel* to close the mode settings window without changes being applied. Ventilation will continue as before, i.e. in backup ventilation.
- Tap *Accept* to accept the settings and continue in the supported mode with a reset apnea time.

Alternatively, tap *Continue in supported mode* in the dialog window to return to the supported mode. The apnea time will be reset.

Refer to *Alarm handling* on page 129 and to *Alarm limits* on page 171.

6.17.3 Deactivating backup ventilation

It is possible to deactivate backup ventilation for invasive PS/CPAP and VS. If backup ventilation is deactivated, the *No patient effort* alarm will be activated at the end of the apnea time but no backup ventilation will start.

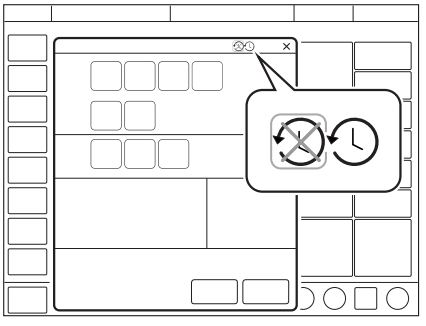
To allow deactivation of backup ventilation:

- Tap *SERVICE & SETTINGS* in the extended menu in *STANDBY*.
- Tap *BIOMED* and enter the code, then tap *CONFIGURATION*/ *STARTUP CONFIGURATION*/ *Deactivation of backup function*.
- Change from *Not allowed* to *Allowed*.

If this choice is made, *Deactivate backup ventilation* is displayed at the top right of the mode settings window during ventilation.

NOTE:

It is only possible to deactivate backup ventilation during ventilation.



To deactivate backup ventilation:

- Tap *Deactivate backup ventilation* in the mode settings window.
- A confirmation dialog *Do you really want to deactivate backup ventilation?* is displayed. Confirm by pressing *Yes*.
- Tap *Accept* in the mode settings window.
- *Backup ventilation off* is displayed after the mode name in the heading when ventilation then begins.

The backup function is automatically re-activated if:

- a change is made to a controlled mode of ventilation
- the ventilator system is switched to Standby
- the system is turned off.

Backup ventilation remains inactive if a change of mode is made between PS/ CPAP and VS.

6.18 Nebulization

6.18.1 Aerogen nebulizers

The nebulizer is intended for administering drugs to patients requiring mechanical ventilation.

The nebulizer operates for a specific period of time or continuously regardless of ventilation mode setting. No extra gas volume is added, i.e. ventilator system settings and values are not affected.

Refer also to the manufacturer's operating manual for instructions for use.

6.18.2 Safety guidelines

WARNING!

- Do not use the nebulizer without a filter, e.g. Servo Duo Guard, connected to the expiratory inlet of the ventilator system. Refer to the Servo Duo Guard User's Manual.
- During nebulization, carefully monitor the airway pressure. Increased airway pressure could result from a clogged expiratory filter. Replace the filter if the expiratory resistance increases.
- Do not use an HME during nebulization. The humidifier can become blocked or the drug can become caught in the filter.
- The nebulizer must not be left unattended when connected to a patient.
- Before administering any medication via the nebulizer, consult the manufacturer regarding the appropriateness of nebulization for that medication. Only use physician prescribed solutions.
- The ventilator system accuracy can be affected by the gas added by use of other nebulizers than Aerogen nebulizer.
- During nebulization, check frequently that aerosol is being generated.
- To avoid explosion hazards, do not use flammable agents such as ether and cyclopropane or aerosolize alcohol-based medications which can ignite in oxygen enriched air under high pressure with this device.
- To avoid mechanical or electrical damage, do not drop the nebulizer unit.

CAUTION!

- Before starting the nebulizer, check that the medication cup is undamaged and firmly in place.
- If the nebulizer is used with active humidification, then the particle size of the medication may be affected.
- Perform a function test prior to use to verify proper operation.

NOTE:

- Condensate can collect and occlude ventilator system circuits. Always position ventilator system circuits so that fluid condensate drains away from the patient.
- Do not touch the domed aperture plate in the center of the nebulizer.
- Do not use the AerogenPro nebulizer unit in the continuous nebulization.
- Always maintain the nebulizer in a vertical position (with the filler cap uppermost) while in the patient circuit. This position prevents condensate from blocking the nebulizer and ensures proper nebulization.
- When removing the nebulizer unit from the patient circuit, always replace the T piece plug to maintain circuit pressure.
- The nebulizer unit and T piece, as packaged, are not sterile.
- Never use reusable connectors with disposable nebulizer units and vice versa.

Refer to section Use guidelines.

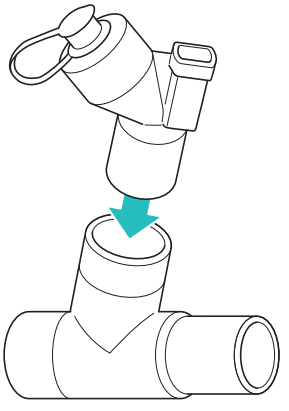
6.18.3 Use guidelines

Assemble nebulizer unit

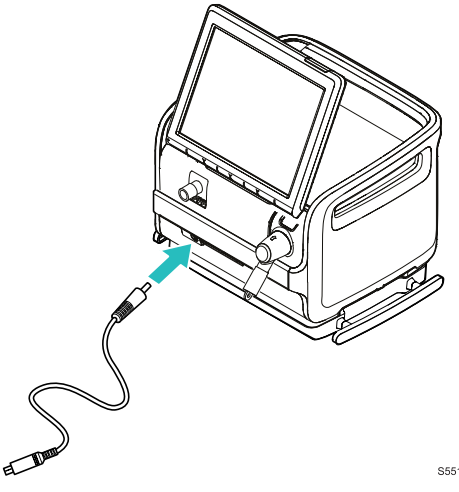
NOTE:

Use only with components specified by Aerogen or the manufacturer of the ventilator system.

- Perform a function test prior to use to verify proper operation.
  Refer to section Nebulizer function test below.
- Connect the nebulizer unit to the T piece by pushing the nebulizer unit firmly onto the T piece.



- Insert the nebulizer and the T piece into the inspiratory tube of patient circuit close to the Y piece.
- Connect the control cable to the ventilator system.



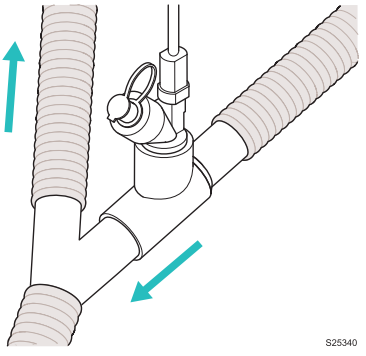
Connection to patient circuits

WARNING!

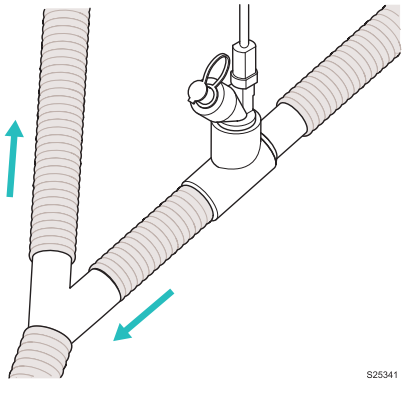
Do not use an HME during nebulization. The humidifier can become blocked or the drug can become caught in the humidifier.

Connect the nebulizer between the inspiratory tube and the Y piece **or** between the inspiratory tube and the dry side of the humidifier. Connect the control cable to the ventilator system.

Connecting to 15 mm patient circuits

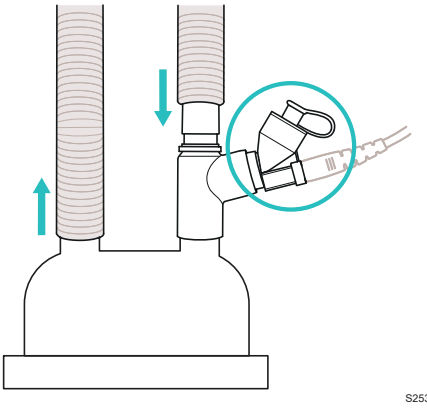


Connecting to 10/12 mm patient circuits



Connecting to the dry side of the humidifier

This configuration can be used with a nasal interface (Aerogen Solo only).



Nebulizer function test

Perform a function test prior to first use or at any time to verify proper operation.

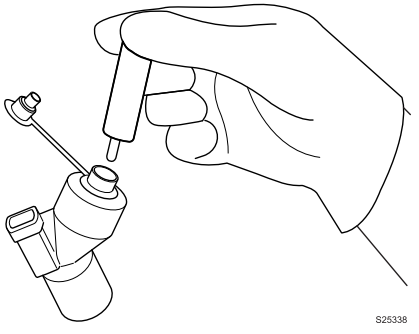
- Visually inspect each part of the system for cracks or damage and replace if any defects are visible.
- Pour 1-6 ml of sterile water or normal saline (0.9%) into the nebulizer unit.
- Connect the control cable to the ventilator system.
- Start nebulization.
- Check that the aerosol is visible.
- Discard any remaining liquid before patient use.

Adding medication

NOTE:

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

- Open the filler cap plug on the nebulizer unit.
- Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer unit.
- Close the filler cap plug.



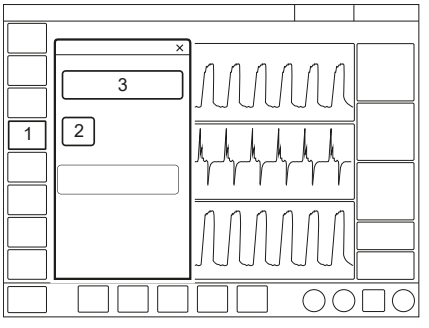
Medication can also be added in this manner during nebulization. This does not interrupt nebulization or ventilation.

Nebulization

Nebulization can be either:

- switched on/off for a certain period of time
- continuous, only Aerogen Solo

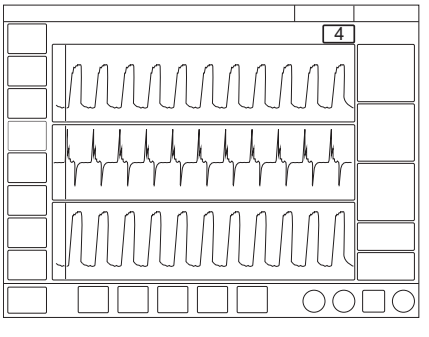
Nebulization On/Off



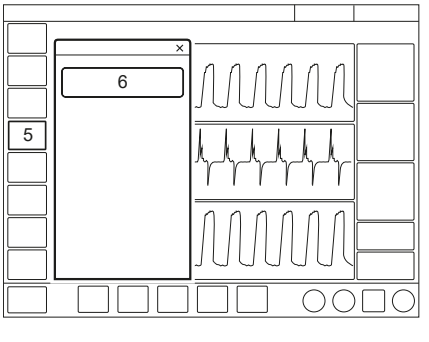
To operate the nebulizer for a specific period of time (on/off):

1. Tap *MANEUVERS/NEBULIZATION*.
2. Tap *Time* if more or less than 10 minutes is required and adjust the figure up or down.

If the nebulizer cable is not connected, a dialog *Check nebulizer cable connection* is displayed on the screen. Tap *OK* to accept.



- Tap *START NEBULIZATION PERIOD*. The default is 10 minutes.
- Check that nebulization is in progress and how much time remains by looking at the progress symbol.



- To stop nebulization tap *MANEUVERS/NEBULIZATION* or the nebulization shortcut in the status bar.
- Tap *STOP NEBULIZATION PERIOD*.

6.18.4 Solo nebulizer unit

WARNING!

Do not use the Solo nebulizer in conjunction with the administration of volatile anesthetics as this may have an adverse effect on the Solo nebulizer or T piece plastics.

NOTE:

This is a single patient use device not to be used on more than one patient to prevent cross-infection.

When the nebulizer unit is connected into the inspiratory tube, the filler cap plug can be opened and closed in between doses without causing loss of circuit pressure.

Refer to *Aerogen Solo nebulizer* on page 179.

Continuous nebulization

See Aerogen Continuous Nebulization Tube assembly instructions.

CAUTION!

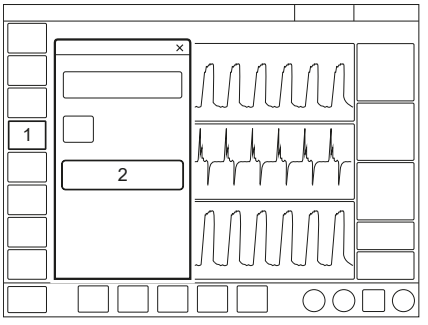
- Check regularly the level of medication in the nebulizer unit during continuous nebulization.
- There is no alarm to indicate that the nebulizer is empty.

NOTE:

To ensure correct and safe connection between the nebulizer and the medication reservoir, follow the medication tube from the nebulizer to the medication reservoir to make sure that the medication tube is connected to the correct source.

The input rate of medication into the nebulizer unit during continuous nebulization must not exceed 0.2 ml per minute or 12 ml per hour. Dose volumes and concentrations must be determined accordingly.

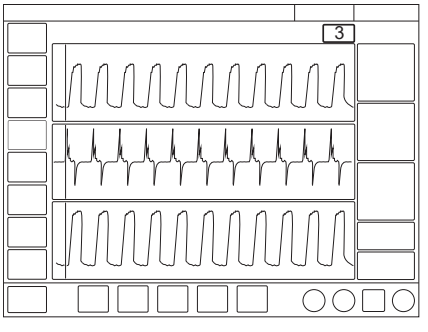
To operate the nebulizer in continuous mode:



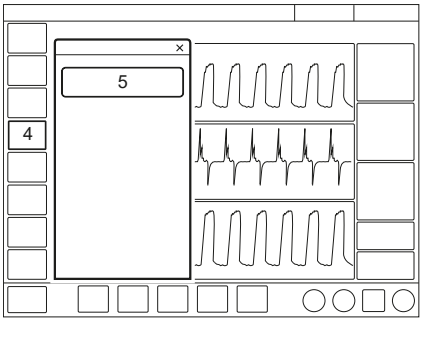
1. Tap *MANEUVERS/NEBULIZATION*.
2. Tap *START CONTINUOUS NEBULIZATION*.

   A dialog *Ensure that an Aerogen Solo nebulizer unit is connected* is displayed on the screen.

   Tap *Accept*.



3. Check that nebulization is in progress by looking at the progress symbol.



4. To stop nebulization tap *MANEUVERS* / *NEBULIZATION* or the nebulization shortcut in the status bar.
5. Tap *STOP CONTINUOUS NEBULIZATION*.

6.19 CO_2 monitoring

6.19.1 CO_2 analyzer

When the CO_2 analyzer is in use, the following data is displayed on the screen:

- CO_2 concentration (waveform)
- $etCO_2$ concentration
- CO_2 minute elimination
- CO_2 tidal elimination

CAUTION!

If a nebulizer and CO_2 analyzer are in use simultaneously, the CO_2 reading may be affected.

Alarm limits for high and low $etCO_2$ can be individually set.

NOTE:

If the upper alarm limit is set above the maximum measuring range, no alarm will be activated even if the upper limit is exceeded.

6.19.2 Use guidelines

WARNING!

The CAPNOSTAT 5 CO_2 sensor is not intended for direct patient contact. The sensor temperature can be approximately 10 degrees above the ambient temperature. Use caution to prohibit patient contact at high ambient temperatures.

The sensor and airway adapter windows should be placed vertically to reduce the possibility of optical interference due to window contamination. Connect the airway adapter between the Y piece and the endotracheal tube/face mask.

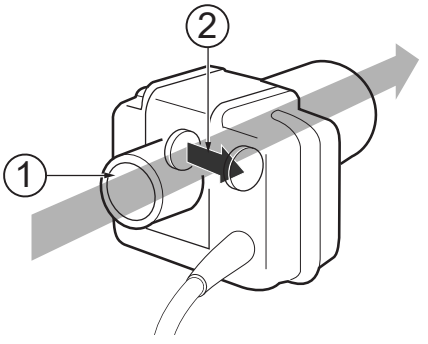
Check the CO_2 analyzer when replaced.

Use only an airway adapter from the manufacturer of the ventilator system together with the sensor

If the message *Check CO_2 airway adapter* appears, then make sure that the adapter is completely inserted.

Wipe the airway adapter if necessary. Refer to the Cleaning and maintenance user's manual.

6.19.3 CO_2 analyzer components



1. Gas flow through the airway adapter in the sensor.
2. The sensor uses a solid state and IR based optical system with no moveable parts. It measures the difference between a reference light beam and one filtered for CO_2 wavelengths.

CAUTION!

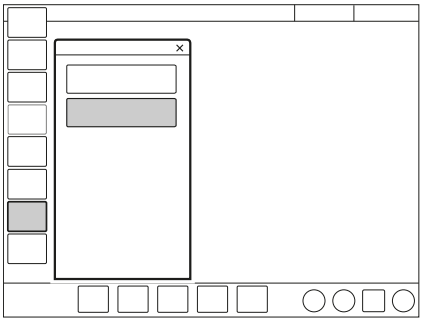
The disposable airway adapter is intended for single patient use only, do not re-use, clean or sterilize.

6.19.4 CO_2 analyzer calibration

The CO_2 sensor must be calibrated with an airway adapter that corresponds to the patient category.

Before beginning the calibration procedure the sensor needs to be warm, this is done automatically when plugged in. The CO_2 waveform is shown. If calibration is needed, a message will appear.

During the calibration, the waveform has reduced accuracy and no CO_2 values are shown.

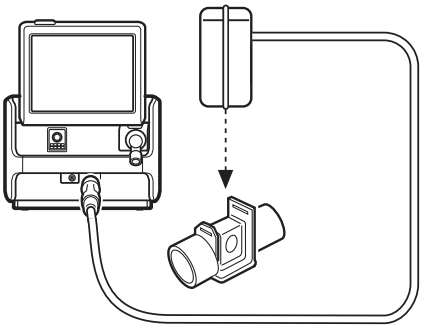


To calibrate the CO_2 analyzer:

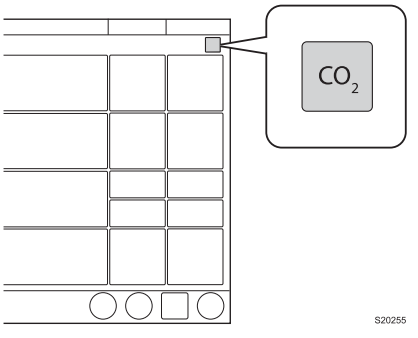
1. Tap *CALIBRATION & TEST* / *CO_2 SENSOR CALIBRATION* in the quick menu if in Standby or CO_2 in the status bar if in running to open the *CO_2 SENSOR CALIBRATION* window.
2. Activate the CO_2 sensor and tap *Calibrate*.

   Follow on-screen instructions.

If the CO_2 analyzer is connected during running *Calibrate* is shown on top of the CO_2 waveform. Tap *Calibrate* to open the *CO_2 calibration* window.



Place the sensor on an unconnected airway adapter, containing room air. Tap *OK*.



CO_2 monitoring and alarms can be enabled and disabled by tapping CO_2. The CO_2 sensor keeps the calibration while deactivated. If the CO_2 sensor is disconnected, the calibration must be performed again.

6.20 Adjust the O_2 cell

If the ventilator system has been in continuous use for an extended period, the measured O_2 concentration may drop due to normal degradation of the oxygen cell. In order to avoid nuisance alarms in this situation, it is possible to temporarily adjust the O_2 cell during ventilation.

When performing a O_2 cell adjustment, the O_2 cell is adjusted so that the current measured O_2 concentration is equal to the set O_2 concentration. This temporary adjustment will be valid until the ventilator system is switched off.

NOTE:

Before using the ventilator system, always perform a pre-use check to make sure the O_2 cell is properly calibrated.

To adjust the O_2 cell:

- Tap *CALIBRATION & TESTS* in the extended menu.
- Tap *O₂ CELL ADJUSTMENT* once, then again.
- Tap *Yes* to perform the O_2 cell adjustment.
- Tap *OK*.

7 Alarm handling

Table of contents

7.1 Introduction

7.1.1 General

The ventilator system is equipped with an alarm system to help ensure patient safety. It is active as long as the ventilator system is switched on

Visual and audible alarms warn about:

- patient breathing problems e.g. apnea
- power problems e.g. loss of mains power
- problems with gases e.g. low supply pressure
- technical problems e.g. hardware failure

7.1.2 Safety guidelines

WARNING!

A potential hazard can arise if different default alarm settings are used on ventilator systems or similar equipment which are located within the same intensive care unit.

CAUSTION!

Always make sure relevant values are set. Extreme settings may render the alarm system unusable.

NOTE:

Those responding to alarms must be healthcare professionals who have experience in ventilation treatment and who have been trained in the use of this ventilator system.

Refer to *Set alarm limits* on page 50.

7.1.3 Conditions leading to default alarm settings

Alarm limits are set to their default values when:

- powering on the ventilator system
- changing ventilation type (non-invasive/invasive)
- changing patient category in *STANDBY*

7.2 Handling alarms

7.2.1 Alarm indication

The alarms are divided into three priorities:

- high priority — all alarm indications are red
- medium priority — all alarm indications are yellow
- low priority — all alarm indications are blue

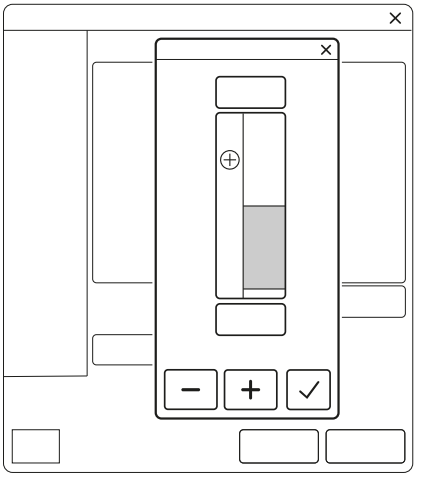
Technical error messages indicating a technical problem are presented together with a numeric code, TE: x.

When the alarm log is full, the oldest data is discarded when new alarms are added.

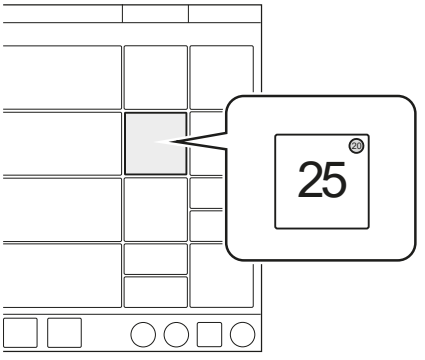
The alarm log is not affected by system shutdown or a temporary loss of power (supply mains and/or battery power).

An alarm message explaining the cause of the alarm is displayed in the alarm list in the status bar.

The numerical value for the parameter causing the alarm highlighted with the color of the alarm priority and its exceeded alarm limit is marked.



A flashing numerical value is also a shortcut to an alarm limit window for adjusting the alarm limits for that parameter.



Alarm sound level

When one or more alarms are activated, the system will present the audio signal corresponding to the alarm with the highest priority that is not silenced or turned off.

The alarm sound level can be set in the *ALARM LIMITS* window.

Refer to *Set alarm sound level* on page 51.

The set alarm sound level is not maintained, when changing between non-invasive and invasive ventilation and vice versa.

The default alarm sound level can be set in *SERVICE & SETTINGS* / *BIOMED* / *CONFIGURATION* / *ALARMS* window.

Refer to *Alarms* on page 138.

7.2.2 Viewing active alarms

If more than one alarm is active, open the alarm list in the status bar.

All alarms are displayed by priority in the alarm list. The list will be continuously updated when additional alarms occur.

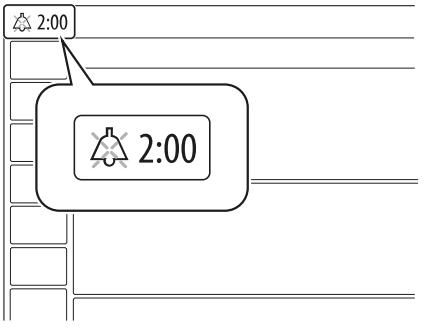
Each alarm is displayed together with a list of recommended actions.

Tap *Alarm history* in the alarm list to open the *ALARM HISTORY* window.

7.2.3 Responding to alarms

Active alarms can be silenced for two minutes by tapping *Audio pause* in the status bar.

Audio pause along with the time remaining in the silent period are displayed.



Audio pause must be tapped for each new alarm that is activated.

If *Audio pause* is tapped before the silent period has expired, then the alarm signal will be turned on again if the alarm is still active.

The *No battery capacity* alarm and high priority technical alarms cannot be silenced.

To respond to alarms:

- Tap *Audio pause* to silence the alarm for two minutes.
- Take action to resolve the alarm condition.

Low and medium priority alarms are automatically reset once the alarm condition ceases.

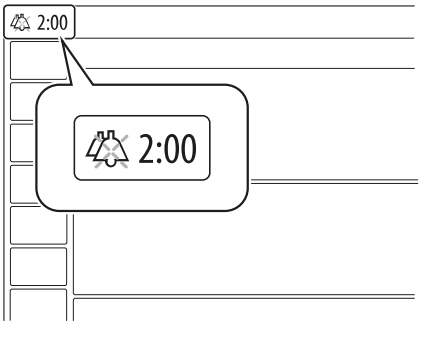
High priority alarms are reset automatically or by confirmation of the alarm.

7.2.4 Pre-silencing alarms

To silence most alarms for two minutes, tap *Audio pause* when no alarms are active.

A crossed double bell, *Audio paused – all alarms*, along with the time remaining in the silent period are displayed.

Tap and hold to pre-mute incoming alarms and prolong the pause time when an alarm already is active.



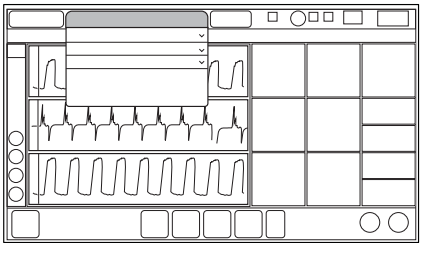
7.2.5 Responding to technical alarms

In some cases, restarting the system may resolve a technical alarm. However, technical alarms often necessitate taking the ventilator system out of operation and having it serviced.

Refer to *Technical error alarms* on page 145.

7.2.6 Previous alarms

Previous alarms is an indication of high priority alarms that have ceased. The alarm indication remains visible in the status bar and in the alarm list until the *Previous alarms* window is opened.



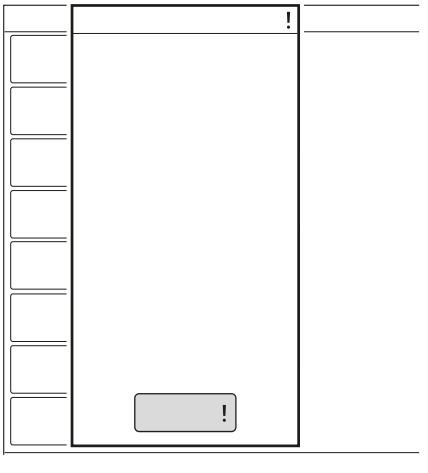
To reset Previous alarms:

Tap *Previous alarms* in the alarm list.

The window opens and the alarms are reset when closing it. The indication is cleared from the screen.

7.2.7 Check alarms

Check alarms is an indication of high priority alarms that have ceased. The alarm indication remains visible in the status bar and in the alarm list until the *Check alarms* window is opened.



To reset *Check alarms*:

Tap *Check alarms !* in the alarm list.

The window opens and the alarms are reset when closing it. The indication is cleared from the screen.

7.3 Permanently silencing alarms

Certain alarms can be permanently silenced.

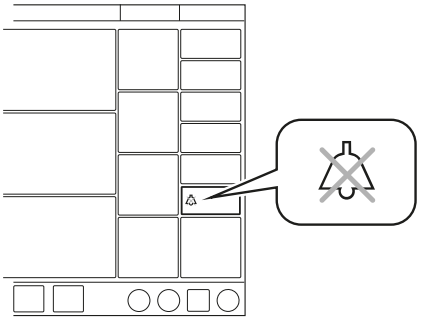
In non-invasive ventilation:

- respiratory rate
- end expiratory pressure
- expiratory minute volume
- end tidal CO_2
- PEEP
- expiratory minute volume (lower alarm limit)

This is only available in the pediatric patient categories.

To permanently silence alarms:

- Tap *ALARM LIMITS* in the quick menu.
- Tap *Audio pause* below the alarm limit setting to open the alarm window.
- Tap *Audio pause*. *Audio off* is shown as selected setting.
- Tap *Accept*.



Audio off is displayed in the corresponding parameter in the numerical values area and a message is displayed in the status bar. A message indicating the number of permanently silenced alarms is also displayed in the status bar. Tap to display the list.

NOTE:

The default alarm settings are automatically set when switching between invasive and non-invasive modes.

The alarms can be set to permanently silenced as default in *SERVICE & SETTINGS* / *BIOMED* / *CONFIGURATION* / *ALARMS* window.

Refer to *Alarms* on page 138.

7.4 Turning off alarms

Some alarms can be permanently turned off and the default values can be set in the *SERVICE & SETTINGS* / *BIOMED* / *CONFIGURATION* / *ALARMS* window.

7.4.1 Turning off leakage and volume alarms

The following alarms can be turned off in non-invasive ventilation:

- Leakage too high
- Expiratory minute volume low
- Expiratory minute volume high

This is available in the following ventilation modes:

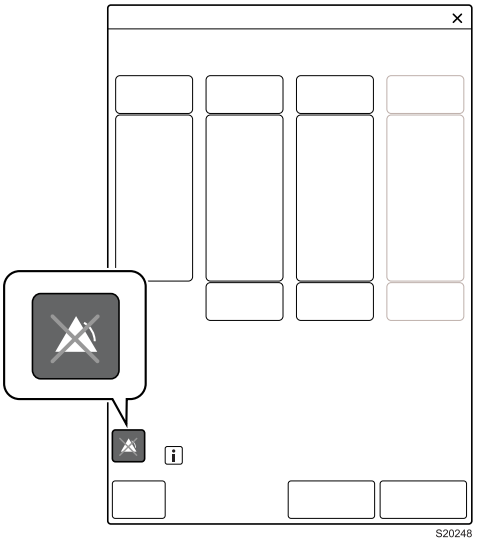
- NIV-PC
- NIV-PS

WARNING!

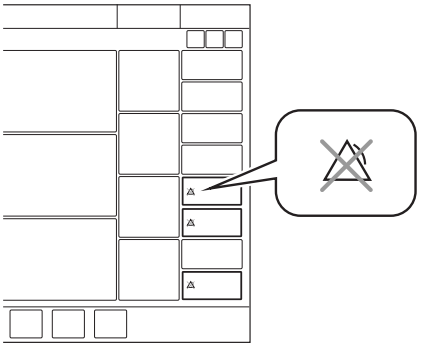
Always ensure adequate external patient monitoring (e.g. SpO_2, CO_2) when the Expiratory minute volume low alarm is turned off.

To turn off the leakage and volume alarms:

- Tap *ALARM LIMITS* to open the *ALARM LIMITS* window.
- Tap *Alarm on*. *Alarm off* is shown as selected setting.
  Tap *Accept*.
  When the *Leakage alarms* is set to off, all alarms listed above will be turned off.



Alarm off is displayed in the corresponding parameter in the numerical values area and a message is displayed in the status bar.



The “ALARM OFF for leakage alarms” shall be disabled whenever any of the below occurs:

- Cold start
- Patient Category or ventilation type is changed in Standby.
- Ventilator is set to Standby.
- Leakage compensation is deactivated (only in invasive modes where applicable).
- Patient category or ventilation mode selected where "ALARM OFF for leakage alarms" function is not available.

7.4.2 Turning off expiratory tidal volume alarms

The following alarms can be turned off in invasive ventilation:

- Expiratory tidal volume low
- Expiratory tidal volume high

The alarms are not available in Bi-Vent/APRV.

To turn off the expiratory tidal volume alarms:

- Tap *ALARM LIMITS* to open the *ALARM LIMITS* window.
- Tap *Alarm on. Alarm off* is shown as selected setting.
  Tap *Accept*.

Alarm off is displayed in the corresponding parameter in the numerical values area and a message is displayed in the status bar.

7.5 Alarms

7.5.1 High priority alarms

Alarm message	Possible causes	Alarm management checklist
Airway pressure high	Airway pressure exceeds preset upper pressure limit. Kinked or blocked tubing. Mucus or secretion plug in endotracheal tube or in airways. Patient coughing or fighting ventilator. Inspiratory flow rate too high. Improper alarm setting. Blocked expiratory filter.	Check patient circuit. Check expiratory filter. Check ventilator settings. Check alarm limits.
Apnea	Time between two consecutive inspiratory efforts exceeds the set alarm limit.	Check patient. Check ventilator settings.
Check tubing	Patient circuit disconnected Problems with patient circuit or expiratory pressure transducer. Disconnected pressure transducer (expiratory or inspiratory). Blocked pressure transducer (expiratory or inspiratory). Water in expiratory limb of ventilator. Wet or clogged expiratory filter. Excessive leakage.	Check patient circuit. Perform a pre-use check Contact service technician.
Patient circuit disconnected	Problems with patient circuit. Excessive leakage. **NOTE:** This alarm does not detect decannulation or extubating.	Check patient circuit.
Time in waiting position > 2 min	Time in waiting position is exceeded. Patient is not connected to the ventilator or leakage is excessive.	Connect patient. Check patient circuit.

Alarm message	Possible causes	Alarm management checklist
Leakage too high	Leakage too high. The mask/ prongs may not be adjusted properly for the patient or may be the wrong size.	Check patient interface. Check patient circuit.
Gas supply pressures low	O_2 supply is below 2.0 kPa x 100 (29 psi). O_2 gas supply disconnected.	Check gas supply.
Expiratory minute volume low	Preset or default alarm limit exceeded. Low spontaneous patient breathing activity. Leakage around the cuff. Leakage in the patient circuit. Improper alarm setting.	Check patient. Check patient circuit. Check ventilator settings. Check support level.
Low battery voltage	Battery voltage too low. Cannot guarantee continued ventilator system operation.	Connect to mains power. Replace all batteries.
Airway pressure continuously high	Obstruction leading to airway pressure higher than the limit for 5 s or two breaths whichever is longer.15 ± 1.5 s if less than two breaths are triggered before then. Default limits: ▪ set PEEP +15 cmH_2O, except in Bi-Vent ▪ set Phigh +10 cmH_2O, in Bi-Vent	Check patient circuit. Check ventilator settings. Check alarm limits. Contact service technician.
O_2 concentration low	Measured O_2 concentration is below the set value by more than 5 vol.% or concentration is below 18 vol.% which is independent of settings. Gas delivered in O_2 supply line is not O_2. O_2 cell uncalibrated. Gas module for O_2 faulty.	Check O_2 supply. If using an O_2 cell, perform O_2 cell adjustment. Perform a pre-use check. Contact service technician.
Patient disconnected > 1 min	Patient circuit disconnected.	Reconnect patient. Check patient circuit.
Alarm limits invalid	Alarm limits lost.	Replace the ventilator immediately.

Alarm message	Possible causes	Alarm management checklist
No battery capacity (with two batteries)	Less than 5 minutes left of battery operation.	Connect to mains power to charge battery. Replace the battery in slot 1.
No battery capacity (with one battery)	Less than 5 minutes left of battery operation.	Connect to mains power to charge battery. Insert an additional battery in the empty slot.
Airway obstructed	Kinked or blocked tubing. Blockage in patient interface. High-flow nasal cannula is displaced. Size of high-flow nasal cannula is too small for the set flow.	Check patient. Check patient interface. Check patient circuit. Check size of high-flow nasal cannula.

7.5.2 Medium priority alarms

Alarm message	Possible causes	Alarm management checklist
Expiratory cassette disconnected	The expiratory cassette is disconnected or not connected properly.	Check that the expiratory cassette is properly inserted.
Limited battery capacity (with two batteries)	Less than 10 minutes left of battery operating time.	Connect to mains power to charge battery. Replace battery in slot 1.
Limited battery capacity (with one battery)	Less than 10 minutes left of battery operating time.	Connect to mains power to charge battery. Insert an additional battery in the empty slot.
O_2 supply pressure low	O_2 supply pressure below 2.0 kPa x 100 (29 psi). O_2 supply pressure at gas inlet is too low. Gas supply line disconnected. **NOTE:** This alarm can be permanently silenced (*Audio off*) when activated.	Check O_2 supply.

Alarm message	Possible causes	Alarm management checklist
PEEP high	The measured end expiratory pressure is above the preset or default alarm limit for three consecutive breaths.	Check patient circuit. Check expiratory filter. Check alarm settings. Check ventilator settings.
PEEP low	The measured end expiratory pressure is below the preset or default alarm limit for three consecutive breaths. Setting the alarm to zero turns the alarm off. Leakage in patient circuit. Leakage at patient connection (cuff, tracheal tube).	Check patient circuit. Check alarm settings. Check ventilator settings.
O_2 concentration high	▪ Flow meters poorly calibrated. ▪ Technical problems	Perform a pre-use check. Contact service technician.
O_2 supply pressure high	O_2 supply pressure above 6.0 kPa x 100 87 psi). O_2 supply pressure at gas inlet is too high.	Check O_2supply.
O_2 cell/sensor failure	O_2 cell missing or disconnected.	Replace the ventilator as soon as it is safe for the patient.
Pressure delivery restricted	The inspiratory flow has reached its upper limit, which restricts pressure delivery.	The inspiratory flow has reached its upper limit, which restricts pressure delivery. Check for leakage Check ventilator settings.
Pressure limited by P_{peak} alarm	Pressure is set higher than set P_{peak} alarm limit. Pressure limited to 3 cmH_2O below the alarm limit.	Check ventilator settings. Check P_{peak} alarm limit.
$etCO_2$ low	Hyperventilation. Leakage with high bias flow.	Check patient. Check ventilator settings. Check patient circuit. Check CO_2 sensor.

Alarm message	Possible causes	Alarm management checklist
$etCO_2$ high	Hypoventilation. Leakage with high bias flow.	Check patient. Check ventilator settings. Check patient circuit. Check CO_2 sensor.
Respiratory rate high	Respiratory rate too high. Auto triggering.	Check patient. Check ventilator settings. Check patient circuit.
Respiratory rate low	Respiratory rate too low. Trigger setting incorrect. Large tidal volume.	Check patient. Check ventilator settings. Check patient circuit.
Expiratory minute volume high	Increased patient ventilation activity. Ventilator auto triggering. Improper alarm limit setting.	Check patient. Check ventilator settings. Check patient circuit.
Expiratory tidal volume high	Preset or default alarm limit exceeded. Increased patient activity. Improper alarm limit setting.	Check patient. Check patient circuit. Check ventilator settings. Check alarm settings.
Expiratory tidal volume low	Preset or default alarm limit exceeded. Decreased patient activity. Leakage in patient circuit. Improper alarm limit setting.	Check patient. Check patient circuit. Check ventilator settings. Check alarm settings.
Leakage too high	Leakage too high. The mask/ prongs may not be adjusted properly for the patient or may be the wrong size.	**In non-invasive ventilation:** Check patient circuit. Check patient interface.
Expiratory cassette error	Technical problem with the expiratory cassette.	Replace the expiratory cassette. Perform a pre-use check. Contact service technician.
Nebulizer hardware error	Technical problem with nebulizer hardware. Technical problem with connection cable.	Contact service technician.

Alarm message	Possible causes	Alarm management checklist
Nebulizer disconnected	The nebulizer is disconnected during nebulization. Technical problem with connection cable.	Check nebulizer connection.
No patient effort	An apnea has caused the ventilator to switch to backup ventilation.	Check patient. Check ventilator settings.
CO_2 sensor error	Hardware error in CO_2 sensor	Replace CO_2 sensor.
CO_2 sensor temperature too high	Possible hardware error.	Replace CO_2 sensor.
CO_2 sensor temperature too low	▪ Too low ambient temperature. ▪ Electromagnetic disturbances from RF transmitters.	The CO2 sensor accuracy may not be within limits. ▪ In case of too low ambient temperature, wait until alarm is cleared. ▪ In case of suspected electromagnetic disturbances: – Look for RF transmitter in close vicinity to CO2 sensor. – Relocate the sensor cable (and/or sensor or the RF transmitter) to see if the alarm disappears.
CO_2 sensor disconnected	CO_2 sensor is not attached.	—
CO_2 module error	CO_2 hardware error.	Contact service technician.
External communication failure	Serial port connection lost	Check connection at RS-232 Port (x).
Internal temperature too high	Temperature inside the ventilator is too high.	Check the room temperature. Clean the fan filters. Replace the ventilator.

Alarm message	Possible causes	Alarm management checklist
Blocked air inlet	Possible occlusion of air inlet filter Replacement of dust filter necessary Replacement of air inlet filter is necessary due to occlusion	Check that the air inlet filter is not occluded. Check the dust filter and replace it if necessary. Replace the air inlet filter if the problem remains.
Delivered gas temperature high	Temperature exceeds 43 ºC.	Check air inlet for obstructions.. Decrease ambient temperature
No battery backup	No battery is installed.	No battery is installed. At least one battery in slot 2 is required.
Flow through expiratory tube	Improper connection of patient circuit. The high-flow nasal cannula may be connected to Y piece with expiratory tubing still connected to the ventilator.	Check patient circuit. Connect high-flow nasal cannula or tracheostomy interface to the inspiratory tube.

7.5.3 Low priority alarms

Alarm message	Possible causes	Alarm management checklist
Battery operation	The mains power is interrupted.	Check mains power connection.
Volume delivery is restricted	The pressure is limited to 5 cmH_2O below the set upper pressure limit, which restricts the volume delivery.	Check ventilator settings. Check alarm limits.
Expiratory cassette replaced	The expiratory cassette has been replaced during operation. A pre-use check is not performed after the replacement.	Perform a pre-use check.
Turbine temperature high	Air inlet filter is obstructed. Ambient temperature is too high. Ventilator settings are outside normal ranges. Technical failure in turbine.	Check air inlet filter and patient circuit. Check ambient temperature close to air inlet. Check ventilator settings.

Alarm message	Possible causes	Alarm management checklist
No slot 2 battery capacity	Less than 3 minutes left of battery operation in battery in slot 2	Connect to mains power to charge battery. Replace the battery in slot 2.

7.5.4 Technical error alarms

Most technical problems require the attention of service personnel.

High priority alarms

Error code number	Possible causes	Alarm management checklist
1 - 6, 75 - 82	Internal power failure.	Replace the ventilator immediately.
10, 11	Control system error.	Replace the ventilator immediately.
37, 40001-40011	Expiratory flowmeter error.	Replace the ventilator immediately.
7, 60	Internal error.	Replace the ventilator immediately.
42, 44, 56, 10003	Internal memory error.	Replace the ventilator immediately.
16, 25, 35, 43, 55, 20005	Internal communication error.	Replace the ventilator immediately.
8, 9	Timeout error.	Replace the ventilator immediately.
38, 39	Barometric error	Replace the ventilator immediately.
40	Monitored value not within range.	Replace the ventilator immediately.
62	Very high turbine temperature	Replace the ventilator immediately.
7	Inspiratory valve error	Replace the ventilator immediately.
74	Inspiratory flow meter error	Replace the ventilator immediately.
63, 83	Turbine communication error	Replace the ventilator immediately.
64 - 69	Turbine failure	Replace the ventilator immediately.

Medium priority alarms

Error code number	Possible causes	Alarm management checklist
51	On/Off switch error.	Replace the ventilator as soon as it is safe for the patient.
28, 20004	Panel audible alarm error.	Replace the ventilator as soon as it is safe for the patient.
22, 24, 27	Backup audible alarm error.	Replace the ventilator as soon as it is safe for the patient.
40	Monitored value not within range.	Replace the ventilator as soon as it is safe for the patient.
20002	Backlight error.	Replace the ventilator as soon as it is safe for the patient.
71	Ambient air temperature RH % sensor error	Replace the ventilator as soon as it is safe for the patient.
72	Inspiratory gas temperature sensor error	Replace the ventilator as soon as it is safe for the patient.
84	O_2 evac fan failure	Replace the ventilator as soon as it is safe for the patient.
92, 93	Internal communication error.	Replace the ventilator as soon as it is safe for the patient.

Low priority alarms

Error code number	Possible causes	Alarm management checklist
48	Control system error.	Replace the ventilator when convenient.
29	Memory backup battery depleted.	Replace the ventilator when convenient.
57, 58	Internal memory error.	Replace the ventilator when convenient.
61, 94, 10005	Internal error.	Replace the ventilator when convenient.
10004, 20006	Internal communication error.	Replace the ventilator when convenient.
46	Remote alarm internal error	Remote alarm inactive.

Error code number	Possible causes	Alarm management checklist
		Replace the ventilator when convenient.

After replacing the ventilator system, contact a service technician

7.6 Alarm output connection (option)

The ventilator system is equipped with the alarm output connection, alarms can be transferred to an external signaling system. The alarm output signal is active as long as the alarm audio is active on the ventilator system.

WARNING!

Never leave the patient unattended. The external alarm is designed to alert those already in attendance.

CAUTION!

The manufacturer cannot guarantee a distributed alarm system, according to IEC 60601-1-8, where the alarm output is a component. It is recommended that users establish a procedure to check this application before use.

8 Service & Settings

Table of contents

8.1 Introduction

The device stores data about system use and treatment in event logs and trends. Make sure data is copied/saved before sending the device for service outside of the healthcare facility as data may be deleted.

To access *SERVICE & SETTINGS*:

Tap *SERVICE & SETTINGS* in the extended menu.

The ventilator system must be in Standby.

The following choices are available:
- *BIOMED*
- *SERVICE*
- *LICENSE*
- *EXIT*

8.2 Biomed

BIOMED is used for viewing and editing the ventilator settings. The logs can also be managed.

Available options depend on the installed configuration.

To access *BIOMED*:
- Tap *BIOMED*.
- Enter the access code (the factory setting is 1973) and tap Accept.

The following choices are available:
- *STATUS*
- *LOGS*
- *SERVICE REPORT*
- *CONFIGURATION*
- *COPY CONFIGURATION*
- *INSTALLATION*
- *EXIT*

8.2.1 Status

STATUS is used for viewing system information and installed software options.

To access *System Info* and *Options*:
- Tap *BIOMED / STATUS*

The following information is available for *System Info*:
- *O_2 CELL*
- *EXPIRATORY CASSETTE*
- *BATTERY STATUS*

The following information is available for *Options*:

- *INSTALLED OPTIONS*

8.2.2 Logs

LOGS is used for viewing event logs for a certain period of time. A date interval can also be set and a search function is available.

The event log has a capacity of 2000 events such as:

- *Alarms*
- *Functions*
- *Settings*
- *Configuration*

If the log reaches its maximum capacity, the oldest information will be overwritten.

The event log is maintained during power down of the ventilator system and even if the ventilator system experiences a total loss of power for an infinite duration, with the exception of that the last data (up to one minute before the power down) may be lost.

The time of power down is not captured; however, it is estimated and stored at the next power up of the ventilator system.

To access LOGS:

- Tap BIOMED/LOGS and select appropriate filter.

8.2.3 Service report

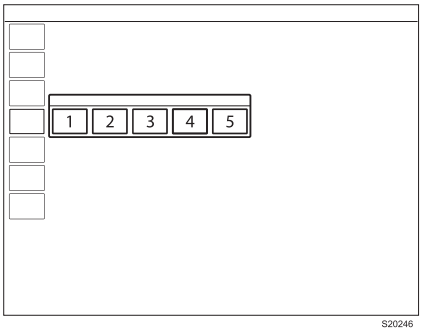
SERVICE REPORT is used for reporting service tasks.

8.2.4 Configuration

CONFIGURATION is used for viewing and editing the startup configuration settings and alarms as well as for setting date and time and the biomed code.

To access *CONFIGURATION*:

- Tap *BIOMED* / *CONFIGURATION*.



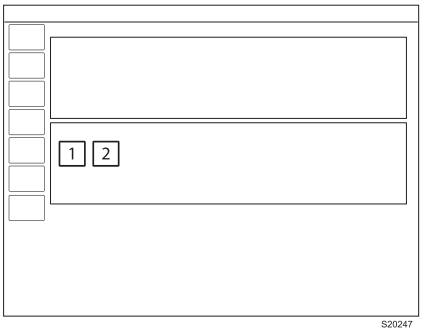
The following configurations can be viewed and edited:

1. *SETTINGS*
2. *STARTUP CONFIGURATION*
3. *ALARMS*
4. *SET DATE & TIME*
5. *BIOMED CODE*

Settings

To access *SETTINGS*:

- Tap *BIOMED* / *CONFIGURATION* / *SETTINGS*.



The following items can be viewed and edited:

UNITS

1. *Height*
2. *Weight*

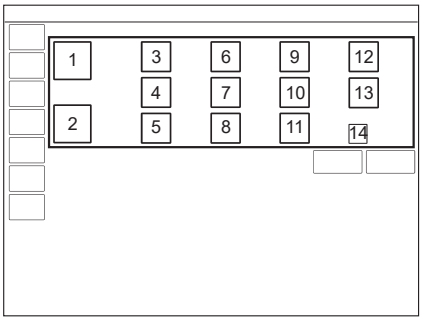
Startup Configuration

The appearance of the window may vary depending on configuration.

To access *STARTUP CONFIGURATION*:

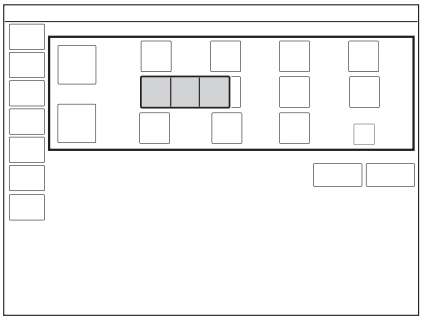
- Tap *BIOMED* / *CONFIGURATION* / *STARTUP CONFIGURATION*.

The following items can be viewed and edited:



1. Patient category
2. Ventilation type (non-invasive (NIV) or invasive)
3. *Volume setting* (Tidal volume, Minute volume)
4. *NIV disconnection functionality* (Low flow, Disabled or High flow)
5. *VC flow pattern setting available* (On, Off)
6. *Breath cycle setting* (I:E, T_i)
7. *Extended leakage test* (Off, On)
8. *Default VC flow pattern* (%)
9. *Temporary O_2 increase* (%)
10. *Use 0 (s) as default pause time* (Off, On)
11. *VC flow adaptation setting available* (On, Off)
12. *Deactivation of backup function* (Not allowed, Allowed)
13. *Type of measured pressure*
14. *Default VC flow adaptation* (with or without flow adaptation)

Edit NIV disconnection function

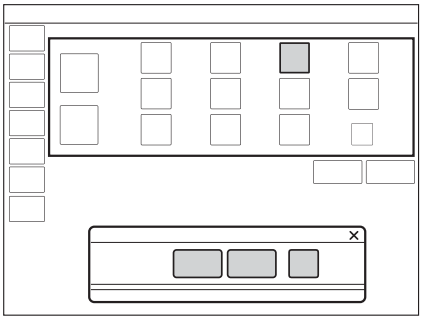


To edit the *NIV disconnection functionality*:

- Tap *CONFIGURATION* / *STARTUP CONFIGURATION* / *NIV disconnection functionality*.
- Choose *Low flow*, *Disabled* or *High flow*.

Refer to section *Functions in ventilation modes and therapies* on page 176.

Edit Temporary O_2 increase (%)



To edit the oxygenation concentration:

- Tap *CONFIGURATION* / *STARTUP CONFIGURATION* / *O_2%* and adjust.

The setting entered in the window that opens determines the default setting for the *O_2 BOOST LEVEL* and the oxygen level increase during pre- and post-oxygenation when *DISCONNECTION* is used.

It does not affect the *O_2 BOOST LEVEL* function in the adult patient category where the default is 100%.

NOTE:

The ventilator system must be restarted to activate the new settings.

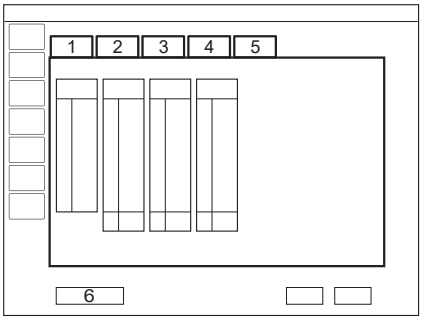
Alarms

The appearance of the window may vary depending on configuration.

The alarm settings are the default settings that the ventilator system is delivered with. These defaults can be changed.

To access *ALARMS*:

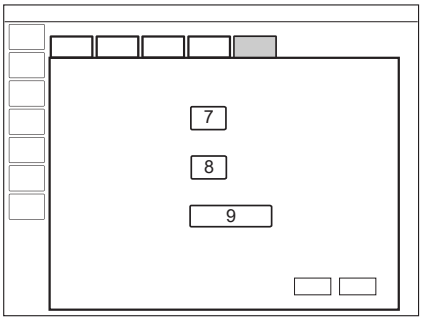
- Tap *BIOMED* / *CONFIGURATION* / *ALARMS*.



The following alarm categories can be viewed and managed depending on the installed configuration:

1. Pediatric
2. Pediatric NIV
3. Adult
4. Adult NIV
5. Alarm sound level
6. Restore default alarm limits

To change the alarm sound level, tap the *Alarm sound level* tab.



The following can be adjusted:

7. Default alarm sound level at start-up
8. Set minimum alarm sound level
9. Restore default audio level

Options to restore defaults, cancel or save changes are available for all alarms.

Set date & time

Options to change the date and time are available.

To access *SET DATE & TIME*:
- Tap *BIOMED* / *CONFIGURATION* / *DATE & TIME*.

Biomed code

The current access code is displayed with an option to enter and save a new access code.

To access *BIOMED CODE*:
- Tap *BIOMED* / *CONFIGURATION* / *BIOMED CODE*.

8.2.5 Copy configuration

The configuration settings can be copied from or to a USB memory stick.

To access *COPY CONFIGURATION*:
- Tap BIOMED/ COPY CONFIGURATION.

When the copy is complete, a message will be displayed on the screen.

8.2.6 Installation

INSTALLATION is used for viewing permanent options and installing new options.

To access *INSTALLATION:*
- Tap BIOMED/ INSTALLATION.

8.3 Service

The Service menu should only be accessed by a trained service technician that has been certified by the manufacturer.

8.4 License

LICENSE is used for viewing the list of software components, versions and licensing conditions.

9 Technical data

Table of contents

9.1 System

General	
Standards	▪ IEC 60601-1: 2005 + A1:2012 + A2:2020, Class I, continuous operation Applied parts – Equipment making physical contact with the patient and the gas path ways. Type B – Nebulizer patient unit and cable. Type BF – CO_2 sensor. Type BF Applied parts, that is, equipment making physical contact with the patient, are described in System Flowchart Servo-air. ▪ ISO 80601-2-12:2020 [2] ▪ ISO 80601-2-55:2018 ▪ ISO 80601-2-90:2021 ▪ EN 13544-1:2007 + A1:2009
Electromagnetic disturbance	According to IEC 60601-1-2:2014 + A1:2020. Refer to *Electromagnetic compatibility* on page 189
Patient category	**Tidal volume** ▪ Pediatric: 20 - 400 ml ▪ Adult: 100 - 2000 ml **Patient weight** ▪ Pediatric: 5 - 50 kg ▪ Adult: 15 kg and above
Ingress protection	IP 21 The IP 21 classification implies that the enclosure is protected against solid foreign objects represented by a test finger with a diameter of 12 mm pressed with a force of 10 N, and a sphere with a diameter of 12.5 mm pressed with a force of 30 N against all openings in the enclosure, as well as dripping water with a flow rate of 1 mm/min for ten minutes.
Noise	▪ A-weighted sound pressure level (LpA): <53 dB, measured at a distance of 1 m ▪ A-weighted sound power level (LWA): <61 dB
Information signal	Single beep
Safe working load	70 kg

2 *When using humidifiers Fisher & Paykel Healthcare, MR810 or Fisher & Paykel Healthcare, MR850, the ventilator system is in compliance with ISO 80601-2-12:2011.*

Operating Conditions	
Operating temperature range	10 to 40°C
Relative humidity	15 to 95 % non-condensing
Atmospheric pressure	660 to 1060 hPa
Lowest pressure in patient circuit	-400 cmH_2O

Non operating conditions	
Storage temperature	5 to 40°C
Storage relative humidity	5 to 85% non-condensing
Storage atmospheric pressure	660 to 1060 hPa

Power supply	
Power supply, automatic range selection	Rated input power ▪ 100 - 240 V AC ±10%, 50-60 Hz
Typical mean power consumption, range	30 - 100 W
External 12 V battery	12.0 V lead acid battery, minimum 7 Ah Applicable standard: UL 1989 **NOTE:** The external battery needs to be disconnected from the ventilator during charging. Fuse: 15 A/32 V Miniblade Information regarding connector wiring is available from the manufacturer.
Battery module lifetime	At least 4 years from manufacturing date or 300 charge cycles, whichever comes first.
Battery operating time for aged batteries	90 min
Battery module disposal	Do not dispose of battery modules with ordinary waste.

Power supply	
Battery module	▪ 1 - 2 battery modules rechargeable 14.4 V ▪ Battery backup time factory new battery 2 h fully charged. ▪ Typical recharge time approximately 2 h/battery (90%), up to 4 h (100%) if battery is completely discharged. Usable backup time depends on set mode and selected ventilation settings. When the ventilator system is in storage, keep the ventilator system connected to mains power to maintain full charge in the battery modules.
Battery module lifetime	At least 4 years from manufacturing date or 300 charge cycles, whichever comes first.
Battery operating time for aged batteries	90 min
Battery module disposal	Do not dispose of battery modules with ordinary waste.

9.2 Ventilator system

General	
Dimensions	▪ User interface: W 300 x D 34 x H 248 mm ▪ Patient unit: W 375 x D 350 x H 275 mm
Weight	Approx. weight: 17 kg

Gas supply	
Ambient air	Dust and HEPA filtered ambient air.
Gas quality, O_2	Supplied gas must meet the requirements for medical grade gases according to applicable standards.
Maximum level, O_2	▪ H_2O < 20 mg/m^3 ▪ Oil < 0.3 mg/m^3
Inlet gas, O_2	▪ Pressure: 2.0 – 6.0 kPa x 100 (29 – 87 psi) ▪ Maximum continuous flow 60 l/min ▪ O_2: 99 - 100%
Connection standards available	AGA, DISS, NIST, or French

Patient system connectors	
Conical fittings	Nominal 22 mm and 15 mm, in accordance with ISO 5356-1
Gas exhaust port	Male 30 mm cone

9.3 Standard condition specification

Inaccuracy ranges in this document assume the following standard conditions, normal use and the worst case, i.e. all errors are summarized positive.

Standard condition specification	
Ambient pressure	101.3 kPa
Room temperature	21°C
Inlet pressure	4.3 kPa x 100
Pre-use check	▪ Pre-use check performed on a warmed up ventilator system ▪ Pre-use check performed with ≥99% oxygen content in O_2 supply
Circuit compensation	Circuit compensation is activated.
Settings	Default settings unless otherwise specified
I:E	Set I:E is less than 1:1.
Ventilatory frequency	Set ventilatory frequency is less than or equal to 100 breaths/minute.
Leakage	Constant leakage below 30% in NIV modes.
BTPS	All measured, preset and indicated flows and volumes are referenced to BTPS. Body Temperature and Pressure Saturated. All measured, preset and indicated flows and volumes at 37°C, local atmospheric pressure and relative humidity 100% (saturated).
STPD	All measured inlet gas pressures and flows are referenced to STPD. Standard Temperature and Pressure Dry. All measured, inlet gas pressures and flows at 20°C (standard temperature), standard pressure 101.3 kPa and relative humidity 0% (dry).

9.4 Essential performance

The essential performance for the ventilator system and its options are the delivery of ventilation at the patient connection port within the alarm limits set by the user or generation of an alarm condition.

Essential performance according to IEC 60601-1	
Essential performance	▪ Oxygen level ▪ Airway pressure ▪ CO_2 level ▪ Disconnection ▪ Expired volume ▪ Electrical supply failure ▪ Internal electrical power source near depletion ▪ Gas supply failure ▪ Gas temperature ▪ Obstruction ▪ PEEP
Essential performance during High Flow therapy	▪ Flowrate ▪ Gas supply failure ▪ Internal electrical power source near depletion ▪ Obstruction ▪ Oxygen level ▪ Internal electrical power failure

9.5 Patient circuit

Patient circuit configurations	
Range of inspired tidal volumes	▪ Pediatric: 10 - 12 mm tubing, tidal volumes 20 - 100 ml ▪ Pediatric: 15 mm tubing, tidal volumes 20 - 400 ml ▪ Adult: 22 mm tubing, tidal volumes 100 - 2000 ml

Refer to System Flowchart, Servo-air and to System Flowchart, Servo-air Lite.

9.5.1 Patient circuit test

In the pre-use check, the patient circuit is tested to determine if it is within these recommended ranges. If the tested parameters are within the specified ranges, the inaccuracies stated are maintained.

Values slightly outside the ranges are accepted to account for measurement variations between patient circuits.

Patient circuit test	
Inspiratory resistance	Pediatric/Adult ▪ VT up to 100ml: 0 - 35.0 cmH_2O/l/s at flow rate 10 l/min ▪ VT more than 100ml: 0 - 10.0 cmH2O/l/s at flow rate 60 l/min
Expiratory resistance	Pediatric/Adult ▪ VT up to 100ml: 0 - 30.0 cmH_2O/l/s at flow rate 10 l/min ▪ VT more than 100ml: 0 - 7.0 cmH_2O/l/s at flow rate 60 l/min
Compliance	Pediatric/Adult ▪ VT up to 100ml: 0 - 2.0 ml/cmH_2O at airway pressure 50 cmH_2O ▪ VT more than 100ml: 0.4 - 3.0 ml/cmH_2O at airway pressure 50 cmH_2O

9.6 Inspiratory channel

Inspiratory channel	
Pressure drop	Maximum: 6 cmH_2O at a flow of 60 l/min
Gas delivery system	Air turbine and O_2 valve
Gas delivery device	▪ Flow range: – Pediatric: 0 - 240 l/min – Adult: 0 - 240 l/min ▪ Maximum pressure setting: – Pediatric: 80 cmH_2O Inaccuracy: ±(1 cmH_2O +10% of set value)[3] – Adult: 100 cmH_2O Inaccuracy: ±(1 cmH_2O +7% of set value) [3]
Maximum airway pressure	125 cmH_2O
NIV max. leakage compensation level	▪ Pediatric: Inspiratory leakage up to max inspiratory flow. Expiratory leakage up to 25 l/min. ▪ Adult: Inspiratory leakage up to max inspiratory flow. Expiratory leakage up to 65 l/min.
O_2 concentration	▪ Setting range: 21 - 100% Inaccuracy: ±(5% + 5% of set value) [4], [5]

3 *Characteristics valid at conditions specified in ISO 80601-2-12, table 201.104.*

4 *Characteristics valid at conditions specified in ISO 80601-2-12, table 201.103.*

5 *±(5% + 10 % of set value) during transport*

Inspiratory channel	
Inspiratory tidal volume	Air/O_2 Setting range: ▪ Pediatric: 20 - 400 ml ▪ Adult: 100 - 2000 ml Inaccuracy[4]: ±(6 ml + 10% of set volume) [6]
Inspiratory minute volume	Air/O_2 Setting range: ▪ Pediatric: 0.3 - 20 l/min ▪ Adult: 0.5 - 60 l/min
High Flow therapy	Flow setting range: ▪ Pediatric: 2 - 50 l/min. ▪ Adult: 5 - 60 l/min. Inaccuracy: ±(0.5 l/min + 8% of set value)
O_2 concentration response time from 21% to 90% [7]	▪ Maximum 30 s at VT = 500 ml, for patient categories and circuit configurations intended to provide VT ≥300 ml ▪ Maximum 35 s at VT = 150 ml, for patient categories and circuit configurations intended to provide 50 ml ≤ VT ≤ 300 ml ▪ Maximum 55 s at VT = 30 ml, for patient categories and circuit configurations intended to provide VT ≤ 50 ml
Maximum delivered gas temperature	43ºC

9.7 Expiratory channel

Expiratory channel	
Pressure drop	Maximum: 3 cmH_2O at a flow of 60 l/min
Internal compressible factor	Maximum: 0.1 ml/cmH_2O
PEEP regulation	Microprocessor controlled valve
PEEP setting range	0 - 50 cmH_2O ▪ PEEP = 0 Inaccuracy: ±1.5 cmH_2O ▪ PEEP > 0 Inaccuracy: ±(1 cmH_2O + 5 % of set value)

6 *At high altitudes, when using VC with low volumes, tidal volumes may be lower than the set value.*

7 *Characteristics valid at conditions specified in ISO 80601-2-12, table 201.105.*

Expiratory channel	
Expiratory flow measurements	▪ 0 - 192 l/min
Bias flow during expiration	2 l/min

9.8 Monitoring

Monitoring	
Inspiratory tidal volume	Air/O_2 Range/Inaccuracy: ▪ Pediatric: ±(2.5 ml + 10% of actual volume) for VT 20 ml - 400 ml ▪ Adult: ±(4 ml + 7% of actual volume) for VT 100 ml - 2000 ml
Expiratory tidal volume	Air/O_2 Range/Inaccuracy: ▪ Pediatric: ±(4 ml + 15% of actual volume) for VT 20 ml - 400 ml ▪ Adult: ±(4 ml + 15% of actual volume) for VT 100 ml - 2000 ml
Expiratory minute volume	Air/O_2 Range: ▪ Pediatric: 0.3 - 20 l/min ▪ Adult: 0.5 - 60 l/min
Respiratory rate	▪ Range: 1 - 160 b/min Respiratory rate must be measured with a maximum inaccuracy of ±1 b/min.
O_2 concentration	▪ Range: 0 – 100% Inaccuracy: ±(2.5 vol% + 2.5% of actual gas concentration) ▪ Stability (within 8-hour period): ±(2.5% volume + 2.5% of actual gas concentration) The inaccuracy of the measurement is dependent on the oxygen content of the supplied gases during the pre-use check.
System response time O_2	The total system response time of the O_2 monitor when exposed first to air and then to a gas mix with 60% O_2 is <30 s.
Barometric pressure compensation	Automatic

Monitoring	
Airway pressure	▪ Range: -40 - 160 cmH_2O Inaccuracy: ±(1 cmH_2O + 4.5% of actual value) [8]
Gas pressure	▪ Range: 0 - 7 bar Inaccuracy: ± 5% of read value
Signal filtering	The measured and calculated values displayed or used for control have in some cases been subjected to filtering and smoothing techniques. This is done to capture the important patterns in the data while excluding noise and make the data shown clinically relevant. These techniques are part of the inaccuracy specified in the technical data. ▪ Pressure waveform: Low pass filtered (time constant 15 ms) ▪ CO_2 waveform: Low pass filtered (time constant 15 ms)
High Flow therapy	▪ Range: 0 - 60 l/min Inaccuracy: ±(0.5 l/min + 8% of actual value)

9.8.1 Sweep speed

Sweep speed	
Sweep speed	5, 10 or 20 mm/s.

9.9 Pre-use check tests

Test	Description	Remedy if test fails
Internal	Audio test and other internal tests (memory and safety-related hardware). Checks occlusion of the air inlet filter and calibrates the pressure transducer.	▪ Check that the air inlet filter is inserted correctly. ▪ Check the air inlet filter for occlusion. ▪ Check the date of first use for the filter. ▪ Contact a service technician.
Barometer	Checks the barometric pressure measured by the internal barometer.	Check the barometric pressure value in the extended menu *Status/ System Info* window.

8 *PEEP accuracy may decrease for RR≥60 b/min together with VT ≤20 ml.*

Test	Description	Remedy if test fails
Internal leakage	Checks for internal leakage, with test tube connected, using the inspiratory and expiratory pressure transducers. Allowed leakage: 20 ml/min at 50 cmH_2O.	If message *Leakage* or *Excessive leakage* appears: ▪ check that the test tube is correctly connected, ▪ check all connections for the expiratory cassette and inspiratory channel, ▪ make sure the expiratory cassette and the inspiratory channel are clean and dry, OR ▪ contact a service technician.
Turbine and gas supply	Checks that the O_2 supply pressure measured by the internal gas supply pressure transducer is within the specified range. Checks the turbine performance and time of operation.	Check that the O_2 supply pressure is within the specified range, and that the gas used is approved for the ventilator system. Refer to *Ventilator system* on page 159
Pressure transducer	Calibrates and checks the expiratory pressure transducer.	If the Internal leakage test passed (see above): ▪ check that there is no excess water in the expiratory cassette ▪ check/replace the expiratory pressure transducer. Contact a service technician.
Safety valve	Checks and if necessary adjusts the opening pressure for the safety valve to 117 ± 3 cmH_2O.	Check the inspiratory section: ▪ check that the safety valve closes properly when the pre-use check is started (distinct clicking sound from the valve) ▪ check that the safety valve membrane is correctly seated in the inspiratory pipe ▪ check that the inspiratory pipe is correctly mounted in inspiratory section
O_2 cell	Calibrates and checks the O_2 cell at 21% O_2 and 100% O_2. Checks if the O_2 cell is worn out. Because different gas mixtures are required for this test, it will not be performed if one gas is missing.	▪ Check that the connected gas supply pressure and air pressure are within the specified range. ▪ Replace the O_2 cell.

Test	Description	Remedy if test fails
Flow transducer	Calibrates inspiratory and expiratory flow meters. If O_2 is missing, no calibration of the expiratory flow transducer will be performed.	Check that the O_2 gas supply pressure is within the specified range. Check that the expiratory cassette is correctly seated in the expiratory cassette compartment.
Battery switch	If battery modules are installed, checks battery status and switching between AC and battery power.	Check that the total remaining time for the connected battery modules are at least 10 minutes. If not, replace the discharged battery with a fully charged battery and repeat the test.
Patient circuit	Checks the patient circuit leakage, compliance and resistance, with patient tubing connected, using the inspiratory and expiratory pressure transducers. Allowed leakage: 80 ml/min at 50 cmH_2O. Will allow the system to calculate a compensation for circuit compliance (if the leakage requirements are met). For ranges and accuracies, see *Patient circuit test* on page 161.	If the internal leakage test has passed, the leakage is located in the patient circuit. Check for leakage or replace the patient circuit.
Alarm state	Checks that no Technical error alarms are active during the pre-use check. Checks that the alarm activation functions correctly.	Check that the cable is connected to the external system. Contact a service technician.

9.10 Ventilatory settings

The ability of resumption of settings after power interruption is at least 24 hours.

Settings	**Factory set default values (Standard configuration)**		**Setting range**	
				
Maximum apnea time in Automode (s)	3	7	3 – 15	7 - 12
Breath cycle time, SIMV (s)	1	4	0.5 - 15	1 - 15
Respiratory rate (b/min)	30	15	4 - 150	4 - 100
Respiratory rate (b/min) in NIV	30	15	4 - 150	4 - 100
Circuit compensation	ON	ON	ON/OFF	ON/OFF
Flow trigger level in invasive modes, (l/min) **NOTE:** Flow trigger is not available in NIV.	1.6	1.6	0 - 2	0 - 2
I:E ratio	1:2	1:2	1:20 - 4:1	1:20 - 4:1
I:E ratio in backup	1:2	1:2	1:20 - 4:1	1:20 - 4:1
End inspiration (% of peak flow)	30	30	1 - 70	1 - 70
End inspiration (% of peak flow) in NIV	30	30	10 - 70	10 - 70
Inspiratory rise time (%)	8	5	0 - 20	0 - 20
Inspiratory rise time (s)	0.15	0.15	0 - 0.5	0 - 0.5

Settings	**Factory set default values (Standard configuration)**		**Setting range**	
				
Inspiratory rise time (s) in NIV	0.2	0.4	0 - 0.5	0 - 0.5
Maximum permitted absolute pressure (cmH_2O)	80	100	—	—
Maximum permitted absolute pressure in NIV (cmH_2O)	62	62	—	—
Minute volume (l/min)	2.4	6	0.3 - 20	0.5-60
Nebulizer	OFF	OFF	ON/OFF	ON/OFF
Nebulizer time (min)	10	10	5 - 30, continuous nebulization	5 - 30, continuous nebulization
O_2 boost level (%)	30	30	0 - 79	0 - 79
O_2 concentration (%)	40	40	21 - 100	21 - 100
PEEP (cmH_2O)	5	8	0 - 50	0 - 50
PEEP in NIV (cmH_2O)	5	5	2 - 20	2 - 20
P_{high} (cmH_2O)	15	18	2 - 50	2 - 50
Pressure trigger level (cmH_2O)	—	—	-1 - -20	-1 - -20
Pressure level above PEEP (cmH_2O)	10	15	0 - 80	0 - 100

Settings	**Factory set default values (Standard configuration)**		**Setting range**	
				
Pressure level above PEEP in NIV (cmH_2O)	5	5	0 - 60	0 - 60
Pressure level above PEEP in backup (cmH_2O)	10	15	5 - 80	5 - 100
Pressure level above PEEP in NIV backup (cmH_2O)	5	5	5 - 60	5 - 60
PS above PEEP in Bi-Vent/APRV (cmH_2O)	0	0	0 - 80	0 - 100
PS above P_{high} in Bi-Vent/APRV (cmH_2O)	0	0	0 - 78	0 - 98
Respiratory rate in backup (b/min)	30	15	4 - 150	4 - 100
SIMV frequency (b/min)	20	5	1 - 60	1 - 60
T_{high} (s)	1	2	0.2 - 30	0.2 - 30
Ti (s)	0.5	0.9	0.1 - 5	0.1 - 5
Ti in backup (s)	0.5	0.9	0.1 - 5	0.1 - 5
Tidal volume (ml)	80	400	2 - 400	100 - 2000
Tidal volume in backup (ml)	80	400	2 - 400	100 - 2000
T_{pause} (%)	10	10	0 – 30	0 – 30
T_{pause} (s)	0	0	0 - 1.5	0 - 1.5
T_{PEEP} (s)	1	2	0.1 - 10	0.1 - 10

Settings	**Factory set default values (Standard configuration)**		**Setting range**	
				
VC Flow pattern (%)	100	100	0-100	0-100
Flow in High Flow therapy (l/min)	8	35	2 - 50	5 - 60

9.11 Alarms

9.11.1 Alarm limits

Parameter	**Factory set default**		**Setting range**	
				
Airway pressure, upper limit (cmH_2O) [9]	30	40	16 - 90	16 - 100
Airway pressure, upper limit (cmH_2O) in NIV [9]	25	25	16 - 70	16 - 70
Airway obstructed pressure limit (cmH_2O)[10]	50	60	—	—
Apnea time to alarm (s)	10	20	2 - 45	15 - 45
Expiratory tidal volume low (ml) [11]	5	50	50 - 440	50 - 1900

9 *If Paw rises 6 cm H2O above the set limit or if system pressure exceeds 117 ± 5 cm H2O, the safety valves opens.*

10 *Only applicable in High Flow therapy. Refer to section Functions in ventilation modes and therapies* on page 176 *for details.*

11 *Not applicable in Bi-Vent/APRV.*

Parameter	**Factory set default**		**Setting range**	
				
Expiratory tidal volume, high (ml) [11]	450	2000	60 - 450	60 - 2000
End expiratory pressure, upper limit (cmH_2O)	15	15	1 - 55	1 - 55
End expiratory pressure, lower limit (cmH_2O) [12]	2	2	0 - 47	0 - 47
Expired minute volume, lower limit (l/min)	2	4	0.1-15	0.5 - 40
Expired minute volume, upper limit (l/min)	8	20	0.15 - 20	1 - 60
Respiratory rate, lower limit (b/min)	20	5	1 - 159	1 - 159
Respiratory rate, upper limit (b/min)	50	30	2 - 160	2 - 160
$etCO_2$ Lower alarm limit				
%	4	4	0.5 - 19.9	0.5 - 19.9
mmHg*	30	30	4 - 149	4 - 149
kPa*	4	4	0.5 - 19.9	0.5 - 19.9
$etCO_2$ Lower alarm limit in NIV [13]				
%	4	4	0 - 19.9	0 - 19.9
mmHg*	30	30	0 - 149	0 - 149
kPa*	4	4	0 - 19.9	0 - 19.9

12 *Setting the alarm limit to 0 (zero) is equivalent to turning off the alarm.*

13 *In NIV, low limit can be set to 0 (zero).*

Parameter	**Factory set default**		**Setting range**	
				
$etCO_2$ Upper alarm limit [14]				
%	6.5	6.5	0.6 - 20	0.6 - 20
mmHg*	49	49	5 - 150	5 - 150
kPa*	6.5	6.5	0.6 - 20	0.6 - 20
$etCO_2$ Upper alarm limit in NIV				
%	6.5	6.5	0.5 - 20	0.5 - 20
mmHg*	49	49	4 - 150	4 - 150
kPa*	6.5	6.5	0.5 - 20	0.5 - 20
O_2 concentration, lower alarm limit (vol%)	Set value -5 vol% or ≤18 vol% [15]		—	—
O_2 concentration, upper alarm limit (vol%)	Set value +5 vol% [16]		—	—
O_2 gas supply	<2.0 kPa x 100 or >6.0 kPa x 100		—	—
High continuous pressure	▪ set PEEP +15 cmH_2O, except in Bi-Vent ▪ set Phigh +10 cmH_2O, in Bi-Vent		—	—

* Nominal values depending on current barometric pressure.

Always make sure relevant values are set.

Refer to section *Conditions leading to default alarm settings* on page 130

14 *If the alarm limit is set outside the measuring range, no alarm will be activated even if the limit is exceeded.*

15 *When the set O2 concentration is higher than 90 %, the O2 concentration low alarm is set to 85 %.*

16 *When the set O2 concentration is higher than 90 %, the O2 concentration high alarm is deactivated.*

9.11.2 Auto set alarm limits - controlled modes only

Auto set alarm limits - controlled modes only	
High airway pressure	Mean peak pressure +10 cmH_2O or at least 35 cmH_2O
Expiratory tidal volume (upper alarm limit)	Mean expiratory tidal volume +50%
Expiratory tidal volume (lower alarm limit)	Mean expiratory tidal volume -50%
Expiratory minute volume (upper alarm limit)	Mean expiratory minute volume +50%
Expiratory minute volume (lower alarm limit)	Mean expiratory minute volume -50%
Respiratory rate (upper alarm limit)	Mean respiratory rate +40%
Respiratory rate (lower alarm limit)	Mean respiratory rate -40%
End expiratory pressure (upper alarm limit)	Mean end expiratory pressure +5 cmH_2O
End expiratory pressure (lower alarm limit)	Mean end expiratory pressure -3 cmH_2O
End-tidal CO_2 concentration (upper alarm limit)	Mean end-tidal CO_2 concentration +25%
End-tidal CO_2 concentration (lower alarm limit)	Mean end-tidal CO_2 concentration -25%

9.11.3 Alarms miscellaneous

Alarms miscellaneous	
Audio paused (Alarm silenced)	Two-minute silence
Alarm sound level	The alarm sound level can be set in 10 steps (to between 56-78 dB(A) ±6 dB(A)) ▪ High priority alarm: A sequence of 3 + 2 beeps, short pause, 3 + 2 beeps, long pause ▪ Medium priority alarm: A sequence of 3 beeps, long pause ▪ Low priority alarm: A sequence of 2 beeps, long pause
Alarm delay after changing the O_2 concentration	▪ 60 s for RR ≤ 4 ▪ 40 s for RR > 4
Maximum alarm condition delay of the disconnection alarms	10 s

Alarms miscellaneous	
Maximum delay for alarms (distributed alarm system)	<1 s

9.12 Ventilation modes

Ventilation mode	**Ventilation-mode systematic code as defined in ISO 19223:2019, Annex E**
PC	A/C-PC ▪ Selectable decreasing flow pattern
PRVC	A/C-vtPC
VC	A/C-VC
Bi-Vent/APRV	IMV-PC\PS\PS
PS/CPAP	CSV-PS/CPAP ▪ CPAP when ΔPs or VT is set to zero.
VS	CSV-vtPS ▪ CPAP when ΔPs or VT is set to zero.
Automode PC ⇄ PS	CSV-PS ▪ Includes CMV-PC and automatically adapted apnea time. ▪ CPAP when ΔPs or VT is set to zero.
Automode PRVC ⇄VS	CSV-vtPS ▪ Includes CMV-vtPC and automatically adapted apnea time. ▪ CPAP when ΔPs or VT is set to zero.
Automode VC ⇄VS:	CSV-vtPS ▪ Inclusive CMV-VC and automatically adapted apnea time. ▪ CPAP when ΔPs or VT is set to zero.
SIMV (PC) + PS	SIMV-PC ▪ CPAP when ΔPs or VT is set to zero.
SIMV (PRVC) + PS	SIMV-vtPC ▪ CPAP when ΔPs or VT is set to zero.
SIMV (VC) + PS	SIMV-VC ▪ Selectable decreasing flow pattern ▪ CPAP when ΔPs or VT is set to zero.
(NIV) PC	A/C-PC
(NIV) PS	CSV-PS
HIGH FLOW	HIFLOW

9.13 Functions in ventilation modes and therapies

Functions in ventilation modes	
Maximum inspiration time	▪ Pediatric: 1.5 s ▪ Adult: 2.5 s
NIV disconnection flow	Pediatric: ▪ Low flow: 7.5 l/min ▪ High flow: 15 l/min ▪ Disabled: the ventilator system will continue to deliver assist even when leakage is excessive. Adult: ▪ Low flow: 7.5 l/min ▪ High flow: 40 l/min ▪ Disabled: the ventilator system will continue to deliver assist even when leakage is excessive.
High Flow therapy - Airway obstructed alarm	Alarm limit: ▪ Pediatric: 50 cmH_2O ▪ Adult: 60 cmH_2O Timing: ▪ Pressure is decreased in the inspiratory tube in 200 ms or less when the alarm limit is reached. ▪ Flow delivery starts again when pressure in the inspiratory tube has decreased to a minimum of 15 cmH_2O less than the alarm limit.

9.14 Trends

Peak airway pressure	P_{peak}
Pause airway pressure	P_{plat}
Mean airway pressure	P_{mean}
Driving pressure	P_{drive}
Positive end expiratory pressure	PEEP
Spontaneous breaths per minute	RR_{sp}
Respiratory rate	RR
Spontaneous expiratory minute volume	$MV_{e\ sp}$
Inspired minute volume	MV_i
Expired minute volume	MV_e
Leakage (%)	Leakage
Inspired tidal volume	VT_i

Expired tidal volume	VTe
End expiratory flow	Flow$_{ee}$
Measured oxygen concentration	O_2 conc.
CO_2 end tidal concentration	etCO_2
CO_2 minute elimination	VCO_2
CO_2 tidal elimination	VTCO_2
Dynamic compliance	C$_{dyn}$
Static compliance	C$_{static}$
Inspiratory resistance	R$_i$
Expiratory resistance	R$_e$
Work of breathing, ventilator	WOB$_{vent}$
Work of breathing, patient	WOB$_{pat}$
Elastance	E
P 0.1	P 0.1
Shallow Breathing Index	SBI
Ratio of expired tidal volume to predicted body weight	VT/PBW
Switch to backup (/minute)	Backup Σ
Backup (%/min)	Backup %
Ratio of tidal volume to predicted body weight *Based on VTe*	VT/PBW
Switch to backup (/minute)	Backup Σ
Backup (%/min)	Backup %
Stress Index	SI

9.15 Logs

9.15.1 Event log

The following events are logged:

- Activation/deactivation of clinical alarms
- Calibration results
- Alarm limit changes
- Ventilator settings
- Apnea periods
- Pre-use checks
- Manual breath
- O_2 boost
- Inspiratory hold
- Expiratory hold
- Activation/deactivation of circuit compensation
- Connection/disconnection of CO_2 sensor
- Full calibration/zero offset adjustment of CO_2 sensor
- Turning backup on/off
- Operator initiated return from backup to supported ventilation
- Automatic return from backup to supported ventilation
- Disconnection and reconnecting of patient
- Activation/deactivation of nebulization
- Deactivation of backup ventilation

9.15.2 Diagnostic log

The following items are logged:

- Technical information
- Test results
- Service records
- Software installation
- Configuration information

9.16 Service

WARNING!

- Preventive maintenance must be performed by authorized personnel at least once every 5000 hours of operation or once every 12 months, whichever comes first. The time to next preventive maintenance is displayed from the extended menu, *SYSTEM STATUS* / *General window*.
- Service, repair and installation must only be performed by personnel authorized by the manufacturer.
- Service and settings should only be used without a patient connected to the ventilator system.

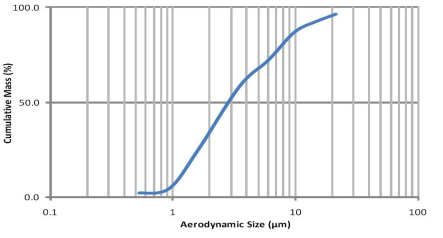
CAUTION!

- All technical documentation is available for use by personnel authorized by the manufacturer.
- Information regarding assembling the system or options to obtain a proper mechanical assembly is available from the manufacturer.
- Original parts from the manufacturer must be used.
- Disconnect the mains power cable from the outlet to isolate the ventilator system from mains power.

9.17 Aerogen nebulizer

9.17.1 Aerogen Solo nebulizer

Aerogen Solo nebulizer	
Weight	Approximate 13.5 g
Dimensions	W 48 x L 25 x H 67 mm
Operating temperature	10°C to 38°C

Aerogen Solo nebulizer	
Particle size, graph	Representative particle size distribution for Salbutamol (Albuterol) as per EN 13544-1. 
As measured with the Anderson Cascade Impactor:	
Specification range Average tested	1 - 5 µm. 3.1 µm
As measured with the Marple 298 Cascade Impactor:	
Specification range Average tested	1.5 - 6.2 µm. 3.9 µm
Flow rate	>0.2 (average: ~0.38) ml/min
Max volume, medication cup	6 ml
Residual volume	<0.1 ml for 3 ml dose
Control cable	1.8 m
Aerosol output rate	0.30 ml/min with starting dose 2 ml
Aerosol output	1.02 ml with starting dose 2 ml
Medication temperature	The temperature of the medication will not rise more than 10°C (18°F) above ambient temperature during normal use.
Lifetime	▪ Intermittent use a maximum of 28 days based on a typical usage profile of four treatments per day. ▪ Continuous use a maximum of 7 days. Do not exceed the recommended usage time.

9.18 CO_2 analyzer

General - CO_2 analyzer	
Measured parameters	▪ CO_2 End Tidal Concentration ▪ CO_2 Minute Elimination ▪ CO_2 Tidal Elimination The End Tidal CO_2 Concentration is measured as the maximum CO_2 concentration during the expiration.
Measuring method	Mainstream, dual-wavelength, non-dispersive infrared.
Oxygen concentration compensation	Automatic. Values supplied from the ventilator system
Barometric pressure compensation	Automatic. Values supplied from the ventilator system
Measurement conditions	CO_2 minute elimination and CO_2 tidal elimination measurements are referenced to STPD (Standard Temperature Pressure Dry) at 0°C (standard temperature), standard pressure 1013 hPa and relative humidity 0% (dry). Standard gas mixture of CO_2, balance saturated air at 33ºC, gas flow rate 2 l/min, halogenated hydrocarbons <5%.

CAPNOSTAT 5 - CO_2 analyzer	
Size	Sensor: 32.0 x 47.0 x 21.6 mm
Weight	▪ Sensor: 20 g ▪ Airway adapter: 10 g
Sensor cable	2.8 m
Measuring range	▪ 0 to 100 mmHg CO_2 partial pressure ▪ 0 to 13.3 kPa CO_2 partial pressure ▪ 0 to 13.2 % CO_2 volume (at a barometric pressure of 1013 hPa)

CAPNOSTAT 5 - CO_2 analyzer	
Inaccuracy	The end-tidal CO_2 is calculated as the highest CO_2 reading measured during expiration. [17] ▪ ±(3.3 mmHg + 8% of reading) ▪ ±(0.44 kPa + 8% of reading) ▪ ±(0.43% of total volume fraction + 8% of reading) The inaccuracy of the end tidal CO_2 has been verified by a CO_2 reference gas that has been altered with air. Refer to *Standard condition specification* on page 160.
Stability (within 6-hour period)	Meets the specified accuracy requirements for not less than 6 h.
System response time CO_2	The total system response time of the CO_2 monitor when exposed first to air and then to a gas mix with 5.0% CO_2 is <250 ms.
Warm-up time	15 s to initial CO_2 indication maximum 2 minutes to full specification
Digitizing rate	100 Hz
Airway adapter dead space	▪ Pediatric: <1 cm^3 ▪ Adult: <6 cm^3

9.19 Communication/interface

Communication/interface	
Serial ports	Isolated RS-232C. For data communication via the Servo Communication Interface (SCI) Information regarding connector wiring is available from the manufacturer.
Servo Communication Interface (SCI)	A protocol for data communication with external devices
Alarm output connection (option)	Isolated 4-pin modular connector for communication of all active alarms Switching capability: Max 40 V DC, Max 500 mA, Max 20 W Information regarding connector wiring is available from the manufacturer.

[17] *CO_2 accuracy may decrease for RR >40 b/min.*

Communication/interface	
Data Transfer via USB port	Non-isolated For transfer of trends, logs, screen shots and recordings to a USB memory stick
Ethernet port	Isolated For connection to the ventilator system.

Connection of the ventilator system to other equipment through the communication interfaces, forming a medical electrical system, could result in previously unidentified risks to patient, users or third parties.

The responsible organization should identify, analyze, evaluate and control these risks.

Subsequent changes to the medical electrical system could introduce new risks and require additional analysis.

Changes to the medical electrical system include configuration changes, connection of additional items, disconnection of items, update or upgrade of connected equipment.

For non-isolated connection ports a *separation device* (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a *separation device* is required when a network connection is made. The requirement for the *separation device* is defined in IEC 60601-1, edition 3, clause 16.5.

If a multiple socket outlet is used to conveniently supply the system, the total protective earth impedance, from each equipment in the system, shall be maximum 0.2 ohm measured to the earth pin in the mains plug of the multiple socket outlet.

9.20 Accessories

To avoid instability, load the ventilator equipment symmetrically on the ventilator system.

Mobile cart (option)	
Weight	15.0 kg
Dimensions	W 647 x L 547 x H 860 mm

Storage bin (option)	
Weight	0.9 kg
Dimensions	W 331 x L 223 x H 104 mm
Load weight	2.5 kg

Humidifier holder (option)	
To avoid instability, mount the humidifier holder in the front part of the carrier.	
Weight	0.5 kg
Dimensions	W 76 x L 125 x H 140
Maximum load	5 kg (excluding water bag/IV pole)

Water bag/IV pole (option)	
Weight	0.4 kg
Dimensions	W 148 x L 26 x H 1007
Maximum load	1.5 kg

Support arm 179 (option)	
Weight	1.9 kg
Dimensions	Length 900 mm
Maximum load	0.5 kg Refer to Support arm 179 Installation Instructions. When the knob on the support arm is loosened it also releases the lock to the column.

Gas cylinder restrainer kit (option)	
Make sure that the gas cylinder restrainer straps are placed on the middle of the gas cylinders.	
Weight	1.0 kg
Dimensions	Upper: W 104 x L 65 x H 48 Lower: W 106 x L 162 x H 76
Maximum load	Two 8 kg bottles

Shelf base (option)	
Make sure that the shelf base is securely fixed on the table or shelf.	
Weight	3.0 kg
Dimensions	W 340 x L 270 x H 43

Y piece holder (option)	
Dimensions	W 42 x L 52 x H 46

Cable holder for handle (option)	
Weight	0.1 kg
Dimensions	W 138 x L 92 x H 155
Maximum load	2.5 kg

Other accessories (option)	
Expiratory heater, Servo Duo Guard	Refer to the Expiratory heater, Servo Duo Guard User's Manual.
Servo Duo Guard	Refer to the Servo Duo Guard User's Manual.
Servo Guard	Refer to the Servo Guard User's Manual.
Fisher & Paykel Healthcare, MR850 Respiratory humidifier	Refer to the Fisher & Paykel Healthcare, MR850 Respiratory humidifier User's Manual.
Fisher & Paykel Healthcare, MR810 Respiratory humidifier	Refer to the Fisher & Paykel Healthcare, MR810 Respiratory humidifier User's Manual.
Fisher & Paykel Healthcare, F&P 950 Respiratory humidifier	Refer to the Fisher & Paykel Healthcare, F&P 950 Respiratory humidifier, User instructions.

Refer to Servo-air system flowchart for information regarding use of accessories to be used with the ventilator system.

9.21 Health and Environment

9.21.1 EU regulations

Carcinogenic, Mutagenic or toxic for Reproduction (CMR) substances

Some parts in the inspiratory gas pathway of the patient unit are made of alloys containing CMR-substance Lead (CAS 7439-92-1) in concentrations above 0.1 weight %.

The residual risk for patient or user is found acceptable and no precautionary measures are needed.

9.22 UDI label

UDI Label	
Unique Device Identification number	Global standard for identifying Medical Equipment, example: (01)07325710000007(11)140625(21)01311141
Application Identifier (AI)	Each UDI number can be divided into several parts, each referred to by their AI number '(#)'.
(01)	GTIN - Global Trade Item Number
(241)	Part number
(10)	Batch no.
(11)	Manufacturing date (YYMMDD)
(17)	Exp. date (YYMMDD)
(20)	Revision
(21)	Serial number
(30)	Count of items
The GTIN consists of four parts: a. Package level b. GS-1 company prefix c. Item reference d. Check digit	0 732571 000021 a b c d

9.23 Technical description

The technical description is intended for the responsible organization and service personnel.

Topic	Information
Signal filtering	Refer to section *Monitoring* on page 164.
Detachable parts	Refer to section Gas flow through the patient unit.
Start and end the inspiratory phase	Refer to chapter Ventilation modes.
Automatic check of alarm system.	Refer to section Pre-use check.
Measurement uncertainty for disclosed tolerances	Refer to sections *Inspiratory channel* on page 162, *Expiratory channel* on page 163 and *Monitoring* on page 164.
Safe operation	Refer to section *Safety guidelines* on page 7.
Transport and storage	Refer to section *Transport* on page 43.
Measures or conditions for installing the ventilator system.	Information regarding installation is available from the manufacturer.
Operation overview	Refer to chapter Operation overview.
Safety signs and symbols ▪ Marking on equipment ▪ Consult accompanying documents ▪ Mechanical stability ▪ Protective packaging	Refer to sections Symbols on patient unit, Symbols on user interface and *Symbols on accessories and packaging* on page 40.
Identification of the ventilator system and software version	Refer to the title page of Servo-air Ventilator System v4.6 and section Version and configurations.
Power sources	Refer to section System.
IP classification	Refer to section System.
Applied part — type of classification	Refer to sections *Symbols on accessories and packaging* on page 40 and System.
Mode of operation	Refer to section System.
Fuses	Refer to chapter Operation overview and System.
External pressure source	Refer to section *Ventilator system* on page 159.

Topic	Information
Modification of the ventilator system	Do not modify or remove any original parts.
Service and installation ▪ Qualifications for service personnel ▪ Replacement of parts ▪ Installation requirements ▪ Documentation	Refer to section *Service* on page 179.
Isolate from mains power	Isolate the ventilator system from mains power by disconnecting the mains power cable from the outlet.
Alarms preset	Refer to section Configuration.
Technical data	Refer to chapter Technical data.
System overview	Refer to chapter System Overview.

10 Electromagnetic compatibility

Table of contents

10.1 Information to the responsible organization

The electromagnetic compatibility (EMC) information in this manual is according to IEC 60601-1-2:2014 + A1:2020, “Electromagnetic disturbances” for medical electrical equipment.

10.2 Electromagnetic environment

WARNING!

- Avoid using this equipment adjacent to or stacked with other equipment, it can result in incorrect operation. If such use is necessary, observe all equipment to verify that it is operating correctly.
- Do not use Portable Radio Frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Servo-air ventilator system. Not keeping the distance can result in degradation of the performance of the equipment.
- Do not use RFID equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Servo-air ventilator system including cables specified by the manufacturer. Not keeping the distance can result in degradation of the performance of the equipment.
- Do not use active high frequency (HF) surgical equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Servo-air ventilator system. Not keeping the distance can result in degradation of the performance of the equipment.

The intended electromagnetic environment for Servo-air ventilator system is within professional health care facility environments.

10.2.1 Cables

System specific cables

To not affect the electromagnetic performance of Servo-air ventilator system, only use system specific cables that fulfil the following characteristics:

- Mains power cable (length 3.5 m)

- Alarm output: Unshielded - not supplied by Getinge.
- 12V battery supply (unshielded, length 1.5 m) - not supplied by Getinge.

Generic cables

WARNING!

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment can result in incorrect operation and increased electromagnetic emissions or decreased electromagnetic immunity of the equipment.

To not affect the electromagnetic performance of Servo-air ventilator system, only use generic cables that fulfil the following characteristics:

- Ethernet: Shielded
- RS232: Shielded, max length 2.9 m
- USB: Shielded, max length 2.5 m

Only use transducers and cables compatible with Servo-air ventilator system from the manufacturer.

Refer to system flowchart, Servo-air.

10.3 Electromagnetic compliance

Servo-air ventilator system fulfills IEC 60601-1-2:2014 + A1:2020.

10.3.1 Emission

Electromagnetic emission compliance	
Emissions test	**Compliance**
CISPR 11	Group 1
CISPR 11	Class A

NOTE:

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If the equipment is used in a residential environment, which usually requires CISPR 11 class B, it might not offer sufficient protection to radio frequency communication services. The user might need to take mitigating measures, such as relocating or reorienting the equipment.

10.3.2 Immunity

Electromagnetic immunity compliance	
Immunity test	**System compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge
Electrical fast transient/burst IEC 61000-4-4	+ 2 kV Mains power supply + 1 kV Ethernet cable, Alarm output cable and potential equalization conductor
Surge IEC 61000-4-5 Line to line Line to ground	 ± 0.5 kV, ± 1 kV ± 0.5 kV, ± 1 kV, ± 2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% UT: 0.5 cycle, 10 ms at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT: 1 cycle, 20 ms at 0° 70% UT: 25 cycles, 0.5 s at 0° 0% UT: 250 cycles, 5 s
Power frequency (50/60 Hz) magnetic fields. IEC 61000-4-8	30 A/m
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V, 80% AM at 2 Hz, 0.15 - 80 MHz 10 V* 80% AM at 2 Hz, in ISM bands 0.15 - 80 MHz
Radiated RF IEC 61000-4-3	10 V/m*, 80% AM at 2 Hz, 0.08 - 2.7 GHz
Conducted disturbances induced by RF fields CO_2, Nebulizer IEC 61000-4-6	3 V, 80% AM at 2 Hz, 0.15 - 80 MHz 6 V, 80% AM at 2 Hz, in ISM bands 0.15 - 80 MHz
Radiated RF CO_2, Nebulizer IEC 61000-4-3	3 V/m, 80% AM at 2 Hz, 0.08 - 2.7 GHz

NOTE:

U_T is the a.c. mains voltage before application of the test level.

* Higher immunity levels than IEC 60601-1-2:2014 + A1:2020.

The following frequency bands have been tested in accordance with table 9 in IEC 60601-1-2:2014 + A1:2020 to ensure that a distance of 0.3 m to radio communication equipment is safe.

Electromagnetic immunity to portable and mobile RF communications equipment		
Frequency band (MHz)	**Immunity level (V/m)**	**Modulation**
380 - 390	27	Pulse modulation, 18 Hz
430 - 470	28	FM ± 5 kHz deviation 1 kHz sine
704 - 787	9	Pulse modulation, 217 Hz
800 - 960	28	Pulse modulation, 18 Hz
1 700 - 1 990	28	Pulse modulation, 217 Hz
2 400 - 2 570	28	Pulse modulation, 217 Hz
5 100 - 5 800	9	Pulse modulation, 217 Hz

In addition to above tested frequencies, related to high frequency RFID, two low RFID frequencies has been tested to ensure that a distance of 0.3 m to RFID equipment is safe.

Electromagnetic immunity to low frequency RFID equipment		
Frequency	**Immunity level**	**Pulse modulation frequency**
134.2 kHz	65 A/m	2.1 kHz
13.56 MHz	7.5 A/m	50 kHz

10.3.3 Maintenance

No special maintenance regarding electromagnetic immunity is necessary for the Servo-air ventilator system.

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CE 0123

Manufacturer:
Maquet Critical Care AB · Röntgenvägen 2 · 171 54 Solna · Sweden

www.getinge.com

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Servo-air Ventilator System v4.6

User's manual