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CARAT II pro Klinik ENG_2019-11-22_12.0

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User's manual ***CARAT II pro*** for physicians and medical professionals

Device type 9LV203

HOFFRICHTER
SERVONA RESPIRATORY CARE

CARAT II pro

Ventilator

User's manual

for physicians and medical professionals

as of device software 3.300

CARAT II pro

User's manual

for physicians and medical professionals

The HOFFRICHTER GmbH reserves the right to amend or replace this user's manual without prior notice.
Please ensure that you are always working with the most current version of this user's manual. Should you have any questions, please contact the ventilation device provider, or check our information at www.hoffrichter.de.

The respiratory device may only be operated and maintained by trained personnel.

The following documents are available for CARAT II pro in addition to this user's manual:

- User's manual for CARAT II pro for patients
- Brief instructions for CARAT II pro
- Service manual
- Hygiene concept
- Maintenance plan

Please read first this user's manual carefully and in its entirety before first using the ventilator.

In particular, follow all safety and cleaning instructions.

Keep the instructions in close proximity to the device for immediate reference if necessary.

Every HOFFRICHTER GmbH device is supplied with a serial number for traceability purposes.

Please enter your device's serial number here. You will find the serial number on the rating plate on the bottom of the device.

SN .....

Please always quote the serial number for all queries and complaints.

CE 0123

CE mark and number of the notified body. The medical device complies with the relevant requirements of the EU Directive 93/42/EEC for medical devices.

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CHAPTER 1
INTRODUCTION

This chapter contains general information on the use and operation of the ventilator.

SCOPE OF DELIVERY

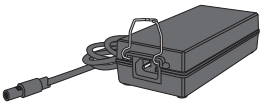
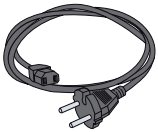
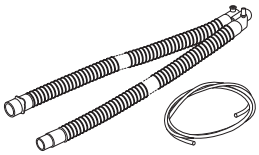
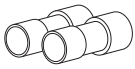
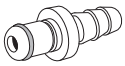
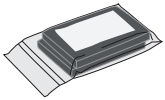
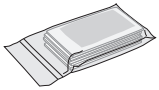
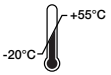
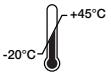
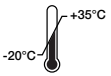
Illustration	Name
	CARAT II pro Ventilator
	Switched-mode power supply
	Mains cable
	Disposable double line patient circuit for adults with pressure measuring tube (L = 180 cm, ∅ 22 mm)
	Adapter for bacterial filter
	SD card
	Straight FiO_2 connection adapter
	Carrying case

Illustration	Name
	Spare filter cassette, complete (open) with filters
	Spare coarse filter, 1 pack (2 ea)
	Spare fine filter, 1 pack (5 ea)
	User's manual for the patient
	Brief instructions
	Final inspection certificate

SYMBOLS

PACKAGING SYMBOLS

Symbol	Meaning
EAN	European Article Number
REF	Article number
SN	Serial number
CE 0123	CE mark and number of the notified body. The medical device complies with the relevant requirements of the EU Directive 93/42/EEC for medical devices.
	Transport and store package with arrows pointing up at all times
	Fragile contents
	Protect from moisture!
	Humidity range during storage and transport
	Air pressure range during storage and transport
	Temperature range for storage and transport up to 1 month
	Temperature range for storage and transport up to 6 months
	Temperature range for storage and transport longer than 6 months
 	CAUTION! Device contains lithium-ion batteries

SYMBOLS ON THE RATING PLATE

The rating plate is on the back of the device

Figure 1: Rating plate

Symbol	Meaning
	Protection class II (protective insulation)
	BF application part
IP22	Protect against: • solid foreign objects with diameters from 12.5 mm • access to hazardous parts with a finger • falling / dripping water, as long as the housing is tilted up to15°
SN	Serial number
	CE mark and number of the notified body. The medical device complies with the relevant requirements of the EU Directive 93/42/EEC for medical devices.
	Manufacturer
	Do not dispose of the device with the household waste. Please contact the relevant customer services department to find out how to properly dispose of the device.

SYMBOLS ON THE DEVICE

Symbol	Meaning
General	
	Follow the user's manual.
Connecting points	
	Inspiration tube connection
	Expiration tube connection
	Control tube connection
	Pressure measuring tube connection
O_2	FiO_2 sensor connection
DC 	DC connection
SpO_2 	SpO_2 sensor connection
Com	Com-interface
	Remote alarm/nurse call connection
	USB interface
O_2	O_2 connection

Symbol	Meaning
	O_2 output
	SD card slot
Operation	
	Alarm key
	ON/OFF key
	Safe key
	Home key
	Escape key
LEDs	
	Alarm LED
	Mains LED
	Battery LED

SYMBOLS USED IN THIS USER'S MANUAL

Important information is denoted by symbols in this user's manual. Please ensure that you follow these instructions in order to avoid accidents, personal injury and material damage.
In addition, the local accident prevention regulations and general safety regulations in force in the area of use must be observed.

This symbol denotes general safety instructions. Follow these instructions to avoid accidents, personal injury or material damage.

⚠ DANGER
This symbol denotes hazardous situations that lead to serious injuries or death.

⚠WARNING
This symbol denotes hazardous situations that may lead to serious injuries or death.

⚠CAUTION
This symbol denotes hazardous situations that may lead to light or severe injuries.

ATTENTION
This symbol denotes situations that may lead to material damage or damage to the device.

NOTICE
This symbol denotes information, tips and instructions for the efficient, correct use of the device.

INTENDED PURPOSE

The CARAT II pro ventilator may be used for life-sustaining ventilation and, when using a two-tube system, provides continuous respiratory support and ventilation of patients without spontaneous respiration.

When using a single-tube system, the CARAT II pro may only be used for non-life-sustaining ventilation and provides intermittent respiratory support and ventilation of patients who demonstrate sufficient spontaneous breathing.

The device is suitable for adults and children from a tidal volume of 50 ml and higher and can be used in home health care and/or in professional healthcare facilities. It must not be used for intensive care ventilation.

The CARAT II pro is not suitable for use in vehicles, airplanes and helicopters.

FUNCTION DESCRIPTION

The blower sucks in the ambient air via a filter and conveys it at the set pressure via a single line patient circuit with exhalation valve or with a double line patient circuit to the patient. The ventilation can be invasive (e.g. via a tracheostomy) or non-invasive (via a mask).

Ventilation is based on ventilation parameters which are set using the controls. Ventilation can be monitored on the display using the measurements and graphs.

If the alarm parameters which have been set and stored in the device are breached, visual and acoustic alarms are emitted. If the prescribed ventilation is no longer possible due to a technical error, an alarm will sound for at least 2 minutes.

If the CARAT II pro is operated with an internal battery, it can continue to be operated without any interruption in the event of a power failure.

For ventilation with an increased oxygen concentration, the CARAT II pro can be connected to a low-pressure oxygen source. If oxygen is introduced and the ventilation is not running, the oxygen supply is interrupted by a safety valve. Residual oxygen can escape from the device via the oxygen outlet.

Furthermore, it is also possible to combine the CARAT II pro with an external humidifier.

The therapy and statistic data can be evaluated with the PC software "easySET".

The CARAT II pro has a USB port and a COM port for service purposes.

INDICATION

The CARAT II pro can be used for the following indications:

- Obstructive ventilation disorders (e.g., COPD)
- Restrictive ventilation disorders (e.g., scoliosis, thorax deformities)
- Neurological, muscular and neuromuscular disorders (e.g., diaphragmatic paralysis)
- Central respiratory regulation disorders

Irrespective of the indications listed here, the device must always be used in accordance with the physician's individual diagnosis.

CONTRAINDICATIONS

⚠WARNING
Ventilation may be contraindicated for certain pre-existing conditions.

The following conditions may be a contraindication for non-invasive ventilation:

- Severe cardiac arrhythmia
- Severe hypotension
- Severe epistaxis
- Pneumothorax or pneumomediastinum
- Pneumoencephalus
- Cranial trauma
- Status after cranial or brain surgery
- Acute inflammation of the paranasal sinuses, middle ear infection or a perforated ear drum
- Aspiration hazard

In individual cases, the attending physician must decide on the therapy.

SIDE EFFECTS

The following undesired side effects may occur in connection with artificial respiration:

Invasive ventilation:

- Complications due to tube / tracheal cannula

Mask ventilation:

- Pressure points and skin defects in the face
- Eye irritation due to leaks
- Gastric inflation
- Aspiration
- Sinusitis
- Nose bleeds

General complications of mechanical ventilation:

- Pulmonary barotrauma / volutrauma caused by ventilation
- Ventilator-associated pneumonia
- Effects on the cardio-vascular system

USER QUALIFICATIONS

The ventilation and alarm parameters must only be set by qualified, specialist staff, under the supervision of a physician. Nursing staff and patients should be instructed in the operation and handling of the device. It is essential that these persons are familiar with operation of the device and that they have read and understood the entire user's manual before commissioning. Furthermore, it must be ensured that users have been notified by the provider as to which accessories are compatible with the device.

Repairs and maintenance work on the device may only be carried out by a qualified and authorized service company.

CHAPTER 2

SAFETY INFORMATION

This chapter contains safety instructions on the following topics:

- General safety instructions
- Electrical safety
- Installation and transport
- Commissioning
- Use of oxygen
- Safety-related test

GENERAL SAFETY INSTRUCTIONS

⚠WARNING

In the event that the acoustic alarm fails during ventilation, the patient should be continuously monitored by qualified and trained healthcare professionals. The monitoring person must be able to take appropriate measures in the event of an alarm or in the event of device malfunction.

- Only qualified, trained, specialist medical staff under the supervision of a physician may make adjustments to the ventilator. The device must only be used by persons who have fully read and understood this user's manual before undertaking and have familiarized themselves with the device. Disregarding these instructions can lead to life-threatening situations for the patient.
- In cases of emergency, an alternative ventilation option, such as a second ventilator or an emergency ventilation bag, must be available at all times and for use by the attending person.
- For patients who are unable to breathe independently or are completely dependent on the ventilation system, additional monitoring depending on and adapted to the disability is recommended.
- The device must only be used on the responsibility and prescription of the physician.
- The device must only be used on patients whose clinical record requires its application.
- Please take the utmost care to ensure that the patient remains connected to the tubing circuit during ventilation.
- The device must not be used with flammable anesthetics or ambient air that contains explosive gases. This may cause fires or explosions.
- Before being used again on another patient, all parts that come into contact with respiratory gas must be hygienically prepared.
- The directions given in this user's manual and the applicable regulations of the hospital or nursing home must be adhered to when hygienically preparing and cleaning the device.

- We recommend the use of the tube systems tested and approved for use by the manufacturer. Using other tube systems may lead to aberrant results.
- Manufacturer tested and approved accessories are recommended for the device. If other accessories are used, this may lead to insufficient ventilation or the use of hazardous materials may lead to further, secondary complications.
- Equipment which are not part of the ventilation system must be not be connected.
- When a nasal or full face mask is used for non-invasive ventilation, this non-vented mask must not contain any expiration opening.
- If used with a single line patient circuit, the controlled expiration valve must not meet any resistance during exhalation and must allow quick ventilation of the ventilation tube system.
- In order to ensure patient safety, the device must be operated in such a way that all adjustable alarms are activated and adjusted to the patient.
- Alarms must not be ignored. They indicate conditions that require an immediate action.
- After changing any ventilation or alarm parameters, the tubing system, or the system configuration (e.g., humidifier, filter, oxygen addition, etc.), the effectiveness of ventilation and alarms should be checked.
- Every two years a safety-related test and maintenance is required for the ventilator.
- In case of exessive agitation on the part of the patient, there is a risk of hyperventilation in all ventilation modes with inspiration triggering.
- The device must not be steam-sterilized in an autoclave.
- Filters and other parts that are connected to the device must be regularly replaced. Please dispose of the used parts according to the regulations for used medical material and/or the local environmental protection rules.
- The connection of accessories or other components to the respiratory system of the ventilator can lead to increased expiratory pressure at the patient connection opening.

- Please ensure that the total resistance of the ventilation system does not exceed 6 hPa with a flow of 60 l/min for adults and 30 l/min for children.
- Any modification to the device poses a threat to its reliability and is accordingly not permitted.
- Masks may only be used on the prescription of a physician and after training by qualified medical staff.
- Masks may only be used after training by qualified medical staff. The intake of medicines and possible contraindications and side effects associated with the use of the prescribed mask should be clarified.
- Please note the operating, transport and storage conditions.
- Temperatures lower than + 5 °C and higher than + 40 °C can impair the function of the device.
- Please be sure to check the ventilation and alarm parameter settings after all servicing work.
- Please ensure that no water has accumulated in the pressure measuring tube during ventilation.

ELECTRICAL SAFETY

- Only the supplied power supply unit may be used for operating the ventilator.
- Only the CARAT pro and a humidifier should be connected to a multiple socket. Additional multiple sockets or extension cables must not be connected to the multiple socket used for CARAT pro and humidifier.
- Portable multiple sockets to which the CARAT pro or a humidifier is connected must not be laid on the floor.
- The permissible maximum load of the multiple socket must not be exceeded. The maximum power consumption of the CARAT pro or the humidifier is contained in the respective user's manual.
- Respiratory therapy may be contraindicated for certain pre-existing conditions.

- Portable RF communications equipment (radios) (including their accessories such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the CARAT pro, including cables specified by Hoffrichter GmbH. A non-observance may result in a reduction in the performance of the device.
- In order to disconnect the device from the mains supply, the plug must be pulled.
- Before cleaning the device, the plug must be disconnected from the electrical outlet.
- The use of accessories or power supplies, not approved by us for the ventilator, can increase the emission of electromagnetic radiation, reduce interference immunity or can lead to an increased patient leakage current.
- During certain examinations or treatments, mutual interference between the ventilator and other medical devices may occur. Please observe the information regarding electromagnetic compatibility and monitor the devices with regard to error-free and proper operation.
- Do not reach for the device under any circumstances if it falls into water.
- Do not try to open the device. Maintenance and repairs may only be performed by personnel authorized by HOFFRICHTER GmbH.

INSTALLATION REQUIREMENTS AND TRANSPORT

- For operation, the device must be placed on a safe and level base.
- The air inlet at the rear of the device, as well as all ventilation slots, must not be blocked.
- Please ensure the device is operated in an area where there is sufficient and clean ambient air.
- The display and the alarm LEDs must not be covered and must be visible at all times.
- No objects must be placed on the device.

- The system must never be stored or transported at ambient temperatures under - 20 °C and over + 60 °C.
- The device must not be exposed to direct sunlight.
- Use of this device next to other equipment or with other equipment in a stacked form should be avoided, as this could result in an abnormal operation. If use is still necessary in the manner described above, this device and the other devices should be observed to make sure they are working properly.
- Do not locate the device near water containers (baths).

INSTRUCTIONS BEFORE COMMISSIONING

⚠WARNING

Only a properly functioning device may be used on the patient. After connection to the mains, the device performs a hardware test (see on page 42). Make sure that you hear two different alarms and the LEDs are flashing. If you do not hear the alarm sounds or if not all LEDs are flashing, then the device must not be used.

- Locate the device in such a way that the mains plug is easily accessible and can be unplugged quickly in the event of a potential hazard.
- Do not use the device if the housing or the cable of the device or the power supply are damaged.

USING OF OXYGEN

- Please be sure to observe the user's manual of the manufacturer or distributor from whom you obtain the oxygen.
- If the patient is supplied with oxygen via the device, the FiO_2 should be measured.
- CARAT II pro offers a FiO_2 measurement via the optional FiO_2 sensor. We recommend using this particular sensor exclusively.
- The FiO_2 sensor contains a caustic liquid. Avoid skin or eye contact if there is a sensor leak! Replace the sensor.
- The oxygen supplied must not exceed a pressure of 1000 hPa and a flow of 15 l/min. The oxygen must be dosed using an external flow meter.
- When supplying oxygen, please ensure that only dry gas (FiO_2) is used. Increased residual moisture may lead to device defects. If necessary, a humidifier can be connected between the air outlet of the device and the patient.
- The connection between the FiO_2 connection and external FiO_2 source must be absolutely airtight. Otherwise, leakage losses may occur during ventilation.

- The oxygen supply should be stopped before the ventilation is interrupted. We further recommend that, after stopping the ventilation, the device is allowed to run for several respiratory cycles without an oxygen supply.
- In the event of an oxygen leak, the oxygen supply should be closed off immediately. The room must be ventilated immediately. At the same time, any sparks, fire or potential flammable sources in the vicinity of the device must be avoided.
- Oxygen supports combustion. Therefore, observe the fire protection regulations applicable for using oxygen. Please ensure that the oxygen fittings, as well as all ports and surfaces near the oxygen lines are free of grease. Do not smoke and do not handle naked flames. When using oxygen, an increased oxygen concentration in the ambient air can occur.

INTEGRATION INTO IT NETWORKS

- Integrating the device into an IT network that also includes other devices can lead to previously unknown risks. The user is therefore responsible for assessing and evaluating the risks and for risk minimization.
- Changes to the IT network can lead to new, unknown risks. This includes changes to the network configuration, the integration and removal of elements as well as performing updates and upgrades of devices in the IT network.

SAFETY-RELATED TEST

- In order to ensure the operating safety of the device, a safety-related test or maintenance must be carried out at the prescribed intervals.

CHAPTER 3
DESCRIPTION OF DEVICE

This chapter describes the connections, operation and display elements of the device.

FRONT SIDE CONNECTING POINTS

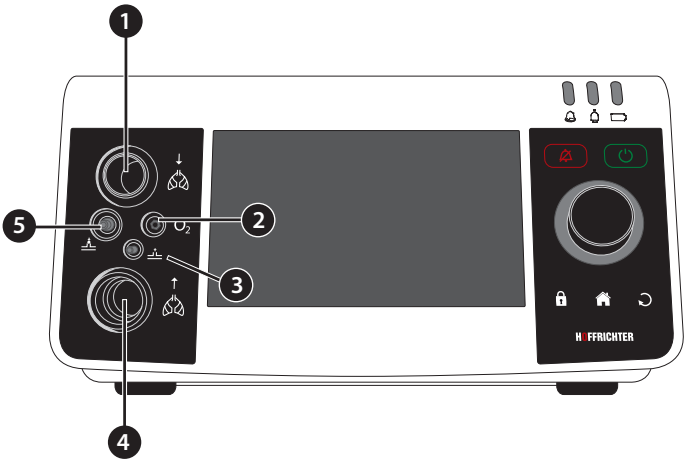


Figure 2: Connections at the front side of the device

1 Connection of tube circuit - inspiration

The single line patient circuit or the inspiration section of a double line patient circuit is connected here. Refer to page 50 and page 51.

2 O_2 Connection of FiO_2 sensor cable

Connect the FiO_2 sensor cable here for measuring the oxygen concentration. Refer to page 69.

3 Connection of pressure measuring tube

Refer to page 50 and page 51.

4 Connection of tube circuit - expiration

The expiration section of a double line patient circuit will be connected here. Refer to page 51.

5 Connection of control tube

Refer to page 50.

REAR SIDE CONNECTING POINTS

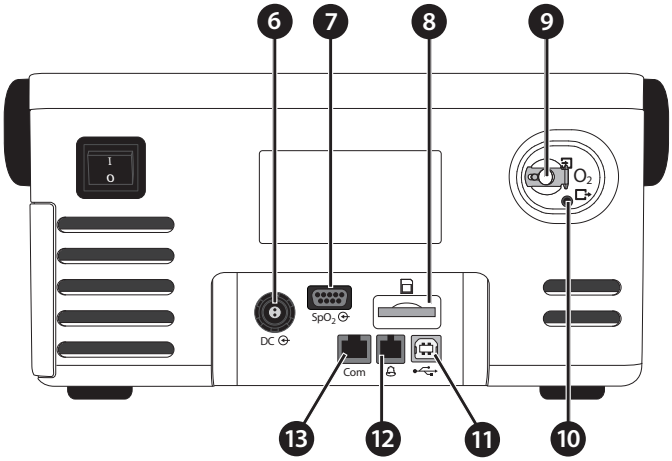


Figure 3: Connections at the rear side of the device

6 DC DC connection

The power supply plug is connected here. Refer to page 42.

7 SpO_2 Connection of SpO_2 sensor

A SpO_2 sensor can be connected here. page 60.

8 SD card slot

An SD card an be inserted here.

9 O_2 FiO_2 connection

During oxygen input the oxygen source is connected here. Use the supplied oxygen connection adaptor for this purpose. Refer to page 65.

10 O_2 O_2 output

Oxygen monitoring:
This is the exit for excess oxygen from the oxygen valve of the unit when ventilation has been turned off.

Pressure monitoring:
Excess oxygen pressure is exhausted to the outside from this exit during oxygen therapy. This is the case, when the pressure is higher than 1 hPa above the set ventilation pressure setting. In volume controlled modes, the value also opens when the measured breathing volume is more than 10 % higher than the set value.

11 USB interface (Connection of PC)

A PC may be connected here with a USB cable (optional accessory). Refer to page 64. In order to be able to communicate with the device, the PC software "easySET" must be installed on the PC.

NOTICE
Only devices conforming to IEC 60601-1 and IEC 60950-1 may be connected.

12 Connection of remote alarm/nurse call

An alarm box (optional accessory) or a nurse call system may be connected here. Refer to page 59.

13 Com RS232 interface (service interface)

Accessories connection

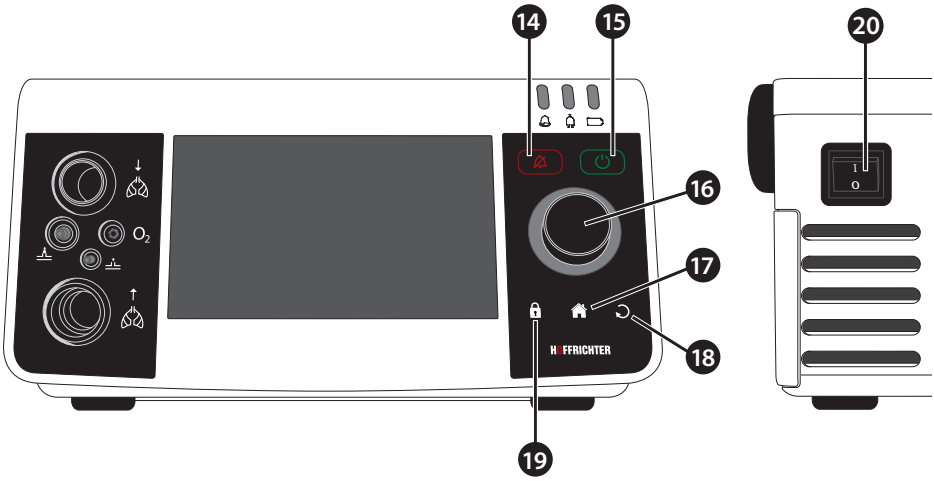


Figure 4: Control elements

14 Alarm key

The alarm key has several functions:

Function	Condition	Action
Confirm all current alarms	Active alarms	Press briefly
Confirm no longer active alarms	Stored alarms	Press briefly
Mute the audible alarm for 2 min (audio alarm pause)	Active alarms	Press briefly
Cancel the audible alarm suppression	Audio alarm paused	Press briefly

When multiple events occur at the same time, only one event is confirmed each time the key is pressed, and in the order they are listed above.

15 ON/OFF key

Function	Action
Start ventilation	Press briefly
Stop ventilation	Refer to page 147

16 Multifunctional knob MFK

Function	Action
Select another parameter	Turn
Set parameters	Turn
Confirm parameter selection	Press briefly
Confirm modified parameter value	Press briefly
Open adjustment window for graphs and loops in the monitoring screen	Press briefly

The MFK is backlit (only when "MFK brightness" > 0 %). The color of the light depends on the operating status or the alarm priority of the currently displayed alarm. The backlight intensity of the MFK can be adjusted in the system screen.

17 Home key

Function	Action
Return to the home screen	Press briefly

18 Escape key

Function	Action
Exit the current screen	Press briefly
Leave selected parameter	Press briefly
Cancel	Press briefly

19 Safe key

Function	Action
Activate key lock	Press briefly and confirm with MFK
Deactivate key lock	Press briefly and confirm with MFK

20 Main switch

Switch the device on and off with the main switch.
For more information, refer to page 74.

LED DISPLAYS

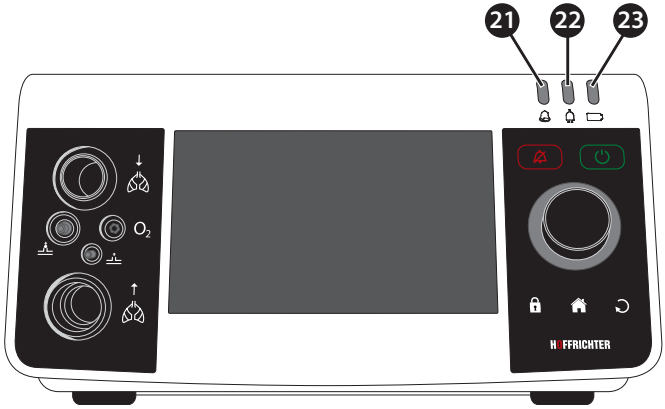


Figure 5: LED displays

21 Alarm LED

The alarm LED lights/flashes in the event of an alarm. It also provides information on the alarm priority.

Color	Status (light)	Priority/Status
Red	Flashes	HIGH
Yellow	Flashes	MEDIUM
Turquoise	Glows steadily	LOW
White	Glows steadily	Device boots

22 Power LED

The power LED gives information on the status of the power supply.

Color	Status (light)	Status
Green	Glows steadily	Mains operation
Yellow	Glows steadily	Unacknowledged power failure
White	Glows steadily	Device boots
White	Flashes	Device shuts down
None	Off	Confirmed AC power failure or no mains voltage / battery power

23 Battery LED

The battery LED provides information on the state of the internal battery charge.

Color	Status (light)	Battery charge state
Green	Glows steadily	≥ 60 %
Yellow	Glows steadily	≥ 20 % ... < 60 %
Red	Glows steadily	≥ 0 % ... < 20 %
White	Glows steadily	Device boots
White	Flashes	Device shuts down

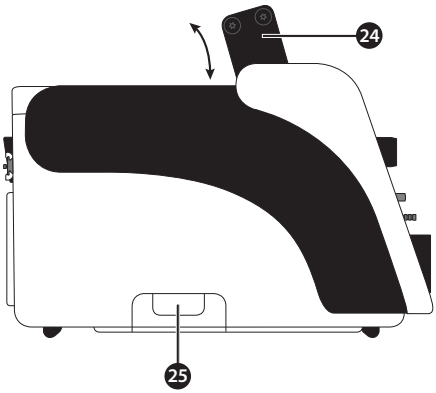


Figure 6: Left device side

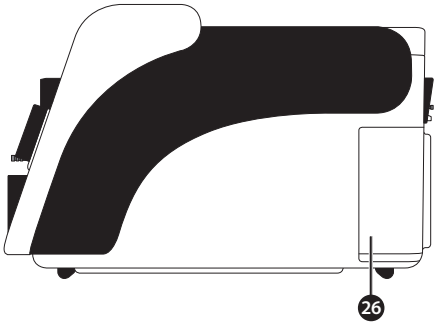


Figure 7: Right device side

24 Handle (pull-out)

The handle may be pulled out for device transport.

25 Bottom flap

Valve membrane (expiration) is located under the bottom flap, which must be replaced before every change of patient or maintenance work. Refer to page 172.

26 Filter cassette

The filter cassette contains the two air filters (coarse and fine filter). For information on how to replace and clean the filter, refer to page 165.

CHAPTER 4
COMMISSIONING

- Before commissioning the device, read the safety information as from page 23 onwards.
- Before commissioning the ventilation system (ventilator, tube, humidifier, etc.), check all connections for leaks, as well as the stability of the connected accessories.
- Never operate the device without the air filter.
- Only use Original HOFFRICHTER filters.

If the device was previously in an environment where the air temperature was not the same as in the new operating location, allow approximately 1 hour until the temperatures have evened out before commissioning.

SETTING UP THE DEVICE

Place the device on a flat and stable surface. Make sure that the device is placed securely and that the air inlet at the rear of the device is not blocked. Make sure that the display and the LEDs are positioned in the user's field of vision during ventilation. The device is designed for operation within arm's reach.

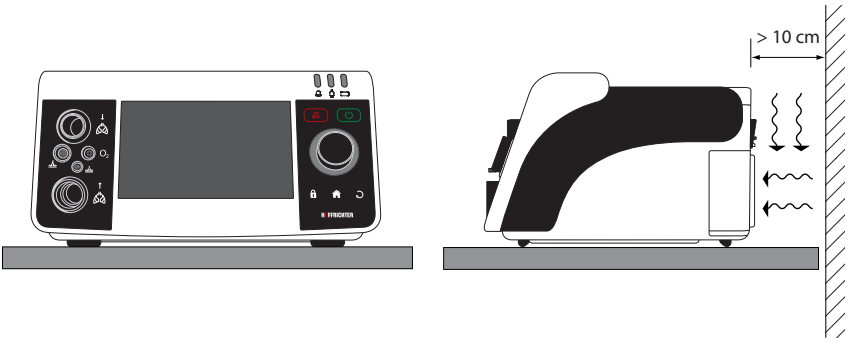


Figure 8: Setting up the device

POWER SUPPLY

The ventilator may be supplied by three different power sources.

- Mains connection via switched-mode power supply unit
- Internal battery
- External battery pack (optional accessory)

The ventilator automatically detects which power sources are available. If the device is connected to an external power source (power supply or external battery pack), it will always use this source first and then switch to the internal battery as needed. In each case, the used power source being drawn on will be indicated by the power LED or battery LED.

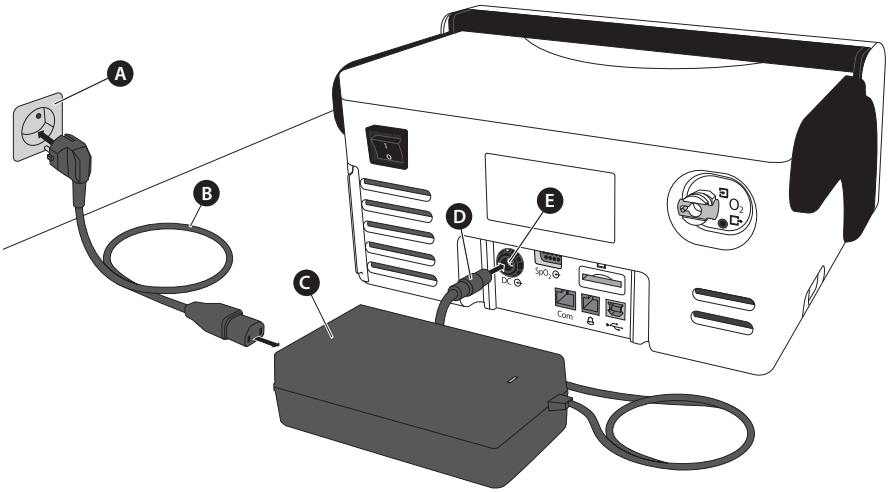
MAINS OPERATION

1. Insert the power supply plug into the DC connector socket.

NOTICE

Do not pull on the cable to disconnect the power supply plug from the DC socket. The snap-lock ODU plug can easily be disconnected by pulling back on the outer sleeve of the connector housing.

2. Connect the mains cable to the power supply.
3. Insert the mains cable plug into the power socket (100 - 240 V, 50/60 Hz).



A Power socket **B** Mains cable **C** Power supply **D** Power supply plug
E DC connector socket

Figure 9: Mains connection via power supply unit

4. The device boots and performs the following hardware tests:
   - Testing the primary and secondary alarm sounds: Both alarm sounds give a short beep one-by-one.
   - Checking of other hardware components.

   If errors are detected during the hardware test, they will be displayed at the bottom left of the screen.

   Each error must be confirmed by pressing the MFK. Then the system switches to the home screen (see page 115). If the error message "System locked" appears, a serious error has occurred. The device should not be put into operation. In this case, contact your service provider. All error messages listed in the Table 13 on page 180.

   All three LEDs will glow white during the booting process. This allows the user to determine if the LEDs are working correctly.

A Software version **B** Error message

Figure 10: Start screen

If no errors were detected during the hardware test or the errors have been confirmed, the display will switch to the standby screen. The current level of battery charge will be displayed on the standby screen.

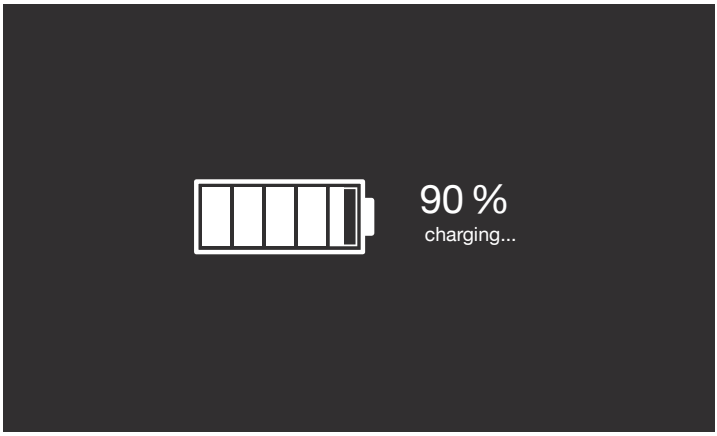


Figure 11: Standby screen

5. Switch on the ventilator by the main switch (see page 74).

OPERATION WITH INTERNAL BATTERY

NOTICE

The internal battery is exclusively used for power failures bridging and power supply when changing the power source. It must not be used as primary power source for ventilation.

To prevent the internal battery from discharging, the device should stay connected to the mains power during standby times.

In order to ensure the full function of the battery, the battery must be maintained in accordance with the section "Battery maintenance" on page173 .

With a fully charged battery the device can be operated up to 4 hours on the factory default settings.

Table 1: Operating time with battery power and factory default settings

Battery power level	Time	Alarm
100 – 10 %	199 min	-
10 – 0 %	39 min	Low Internal Battery
0 % – complete power loss	1 min	Internal Battery Empty

The internal battery enables operation of at least 1 hour at maximum power consumption. Information about the battery charge level is indicated by the battery LED and by touching the battery icon.

⚠CAUTION

If the alarm "Low Internal Battery" appears, the ventilator must immediately be connected to an alternative power source.
The alarm will continue until the battery charge has exceeded 10%.

Recharging a fully discharged battery takes approximately 3.5 hours. The device is fully functional during recharging.
If the device switched on without having a connection to the mains supply, an audible alarm will sound, the alarm message "Battery Operation" will appear, and the alarm LED will flash yellow. The battery LED glows depending on state of charge.

POWER FAILURE

NOTICE

During a power failure, the battery capacity display must be monitored and an alternative power source kept ready. For further details on the battery state display, please refer to page 38.

If the power supply is interrupted by a power failure, the device is supplied with power via the internal battery.

Power failure and thus the switch to the internal battery is indicated by an alarm sound, as well as by the message "Power Failure". In addition, the alarm LED flashes yellow and the power LED glows yellow. The battery LED glows according to the state of charge.

When the power supply returns, the device is supplied with power from the mains supply and the internal battery is charged and the power LED glows green again.

OPERATION WITH EXTERNAL BATTERY

IMPORTANT

Only the HOFFRICHTER AKKUPACK uni BASE may be used for the external power supply. Before initial commissioning, please read the user's manual for AKKUPACK uni BASE.

The AKKUPACK uni BASE enables the device to be operated independently of the mains power supply. The battery pack is optionally available as an accessory (see page 197).

To supply the battery pack with power, use the power cable and the power supply unit of the ventilator. If the battery pack is connected to the ventilator, the power LED glows green.

At full capacity and factory settings, the AKKUPACK uni BASE enables CARAT II pro to operate for up to 8 hours. Using AKKUPACK uni BASE together with AKKUPACK uni PLUS doubles operation time to up to 16 hours.

For further information on connecting and handling the device, please refer to the AKKUPACK uni BASE user's manual.

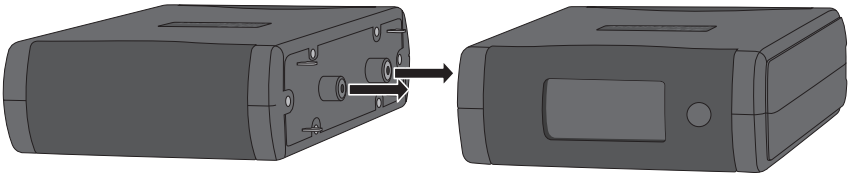
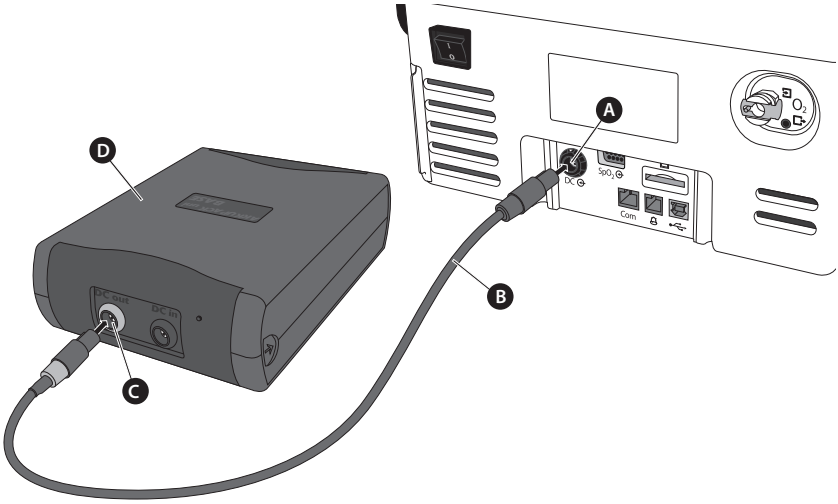


Figure 12: AKKUPACK uni BASE (right) / AKKUPACK uni PLUS (left)

CONNECTING EXTERNAL BATTERY "AKKUPACK uni BASE"

Connect the AKKUPACK uni BASE to the device according to Figure 13.



A DC port **B** DC cable for ventilation **C** DC out (device connection)
D AKKUPACK uni BASE

Figure 13: Connecting AKKUPACK uni BASE

CONNECTING THE TUBE CIRCUIT

The following decsribes it is described how to connect the tube circuit to the device. We recommend the use of bacterial filters, in particular for clinic operations, when using the device for more than one patient.

⚠WARNING

Tubes and cables must always be positioned so that they cannot wrap around the neck or limbs of the patient, thus avoiding the risk of strangulation.

⚠CAUTION

Make sure that the bacterial filter is installed as shown in the illustrations.

When using bacterial filters and a tube circuit without pressure measuring tube, a tube calibration must be performed. Otherwise the pressure measurement values may be incorrect.

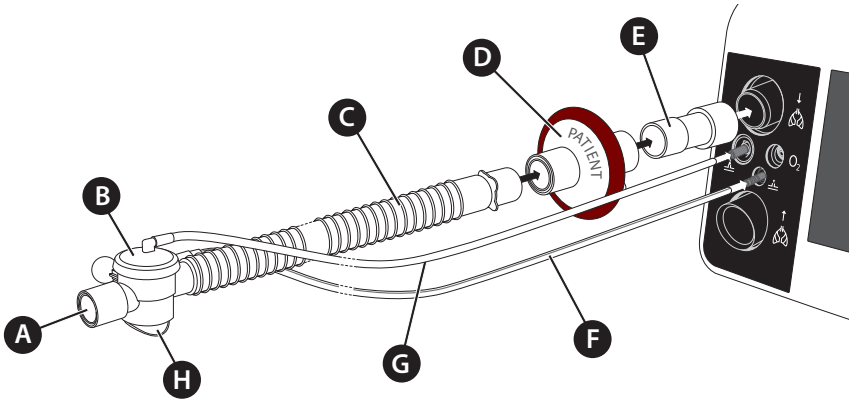
NOTICE

Please be sure to replace the bacterial filter daily and follow the manufacturer's user's manual.
When a nasal or full face mask is used for noninvasive ventilation, the mask must not contain any expiration opening.

CONNECTING A SINGLE LINE PATIENT CIRCUIT

⚠CAUTION
If the CARAT II pro ventilator is operated with a single line patient circuit, it must not be used as a life-supporting device.

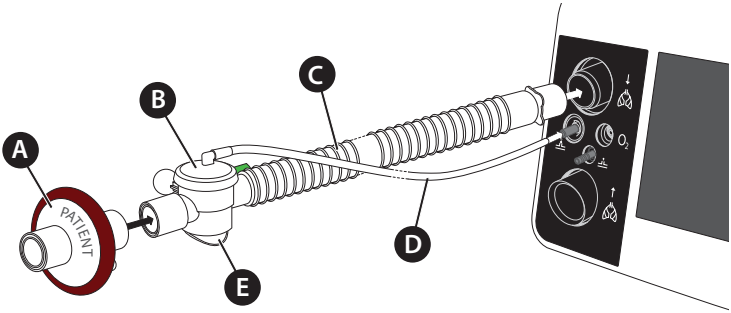
Connect the tube circuit to the device according to Figure 14 or Figure 15.



A Patient side connection **B** Expiration valve **C** Ventilation tube
D Bacterial filter **E** Adapter for bacterial filter **F** Pressure measuring tube
G Control tube **H** Air outlet

Figure 14: Connecting a single line patient circuit with pressure measuring tube

Should you be using a tube circuit without pressure measuring tube (Figure 15), the circuit in use must be calibrated (see page 55).

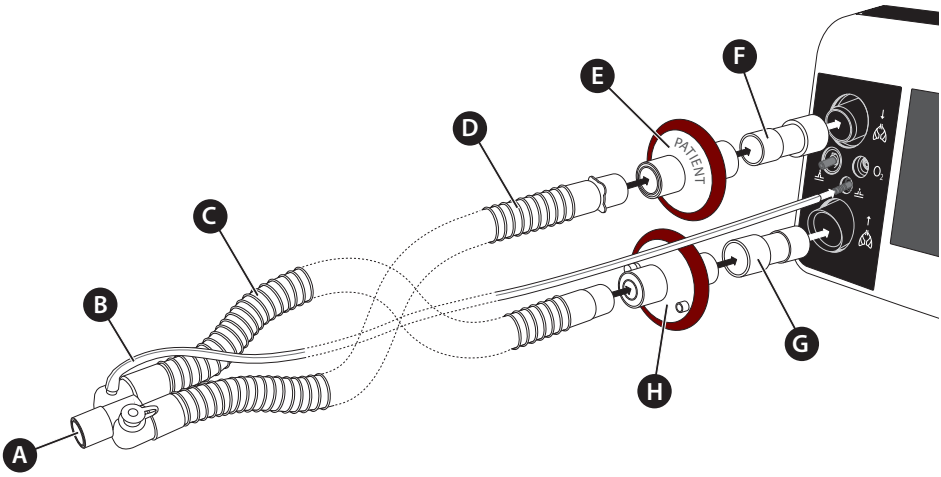


A Bacterial filter **B** Expiration valve **C** Ventilation tube **E** Control tube
E Air outlet

Figure 15: Connecting a single line patient circuit without pressure measuring tube

CONNECTING A DOUBLE LINE PATIENT CIRCUIT

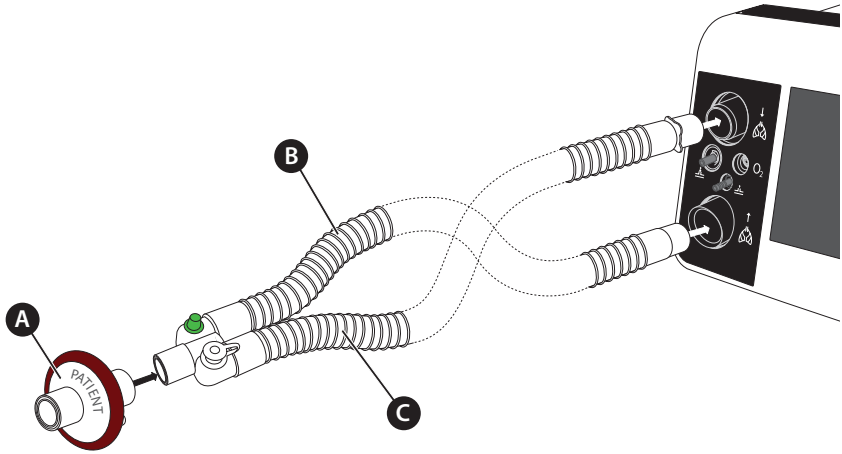
Connect the tube circuit to the device according to Figure 16 or Figure 17.



A Patient side connection **B** Pressure measuring tube **C** Expiration tube
D Inspiration tube **E**+**H** Bacterial filters **F**+**G** Adapters for bacterial filters

Figure 16: Connecting a double line patient circuit with pressure measuring tube

Should you be using a tube circuit without pressure measuring tube (Figure 17), the circuit in use must be calibrated (see page 55).



A Bacterial filter **B** Expiration tube **C** Inspiration tube

Figure 17: Connecting a double line patient circuit with pressure measuring tube

CONNECTING A HUMIDIFIER

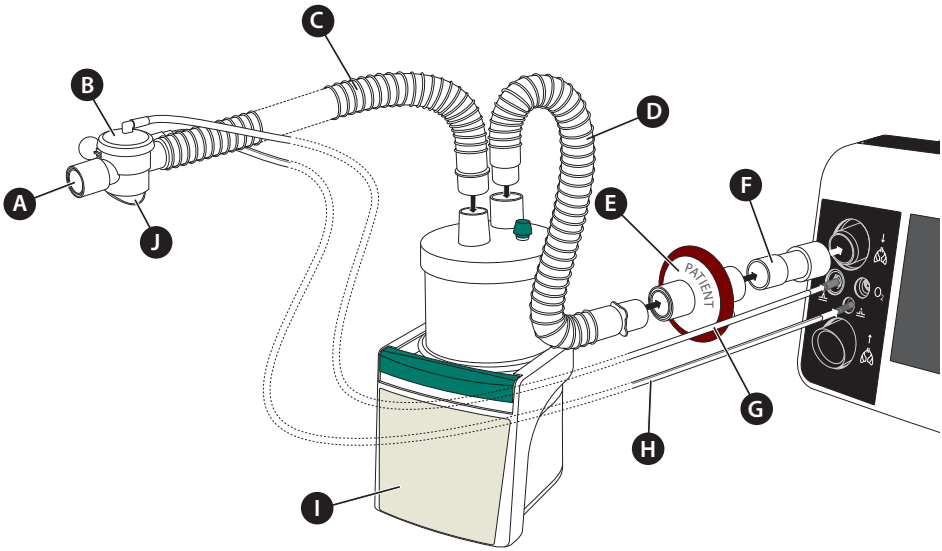
A humidifier is used to humidify and warm the breathing air. If you use a humidifier, be sure to follow the manufacturer's user's manual.

The humidifier is integrated into the inspiration section. It should be positioned below the patient and the device, so that no water can accumulate in the patient's lung or in the device.

Note: When using a bacterial filter, please read the instructions of use of this filter.

Single line patient circuit

Connect the tube circuit to the humidifier and the device as shown in Figure 18. When using a tube circuit without pressure measuring tube, the used tube circuit must be calibrated page 55).



A Patient side connection **B** Expiration valve **C** Ventilation tube
D Connecting tube for inspiration **E** Bacterial filter **F** Adapter for bacterial filter
G Control tube **H** Pressure measuring tube **I** Humidifier **J** Air outlet

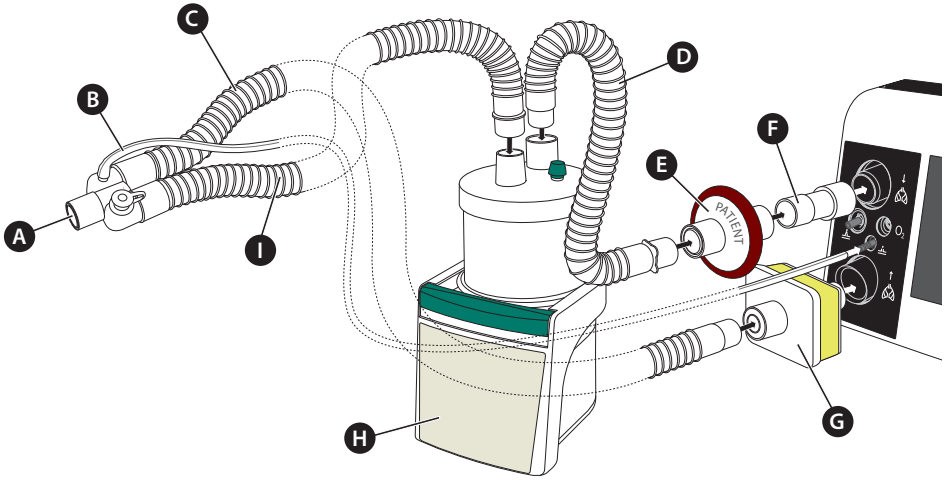
Figure 18: Connecting the humidifier - single line patient circuit

Double line patient circuit

ATTENTION

During active humidification and if medication is administered via a nebulizer, a hydrophobic filter (e.g. Air-Guard Clear) must be used in the expiration branch to keep the expiration connector dry and avoid damage to the flow sensor.

Connect the tube circuit to the humidifier and the device according to Figure 19. When using a tube circuit without pressure measuring tube, the used tube circuit must be calibrated (see page 55).



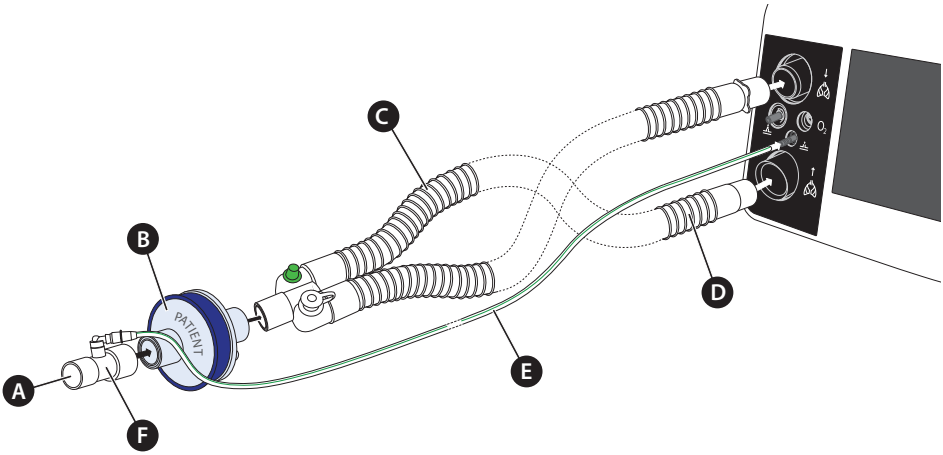
A Patient side connection **B** Pressure measuring tube **C** Expiration tube
D Connecting tube for inspiration **E** Bacterial filter **F** Adapter for bacterial filter
G Hydrophobic filter **H** Humidifier **I** Inspiration tube

Figure 19: Connecting the humidifier - double line patient circuit

USING HME FILTERS

If no humidifier is in operation during non invasive ventilation, we recommend to apply HME filter to moisten the respiratory gas. A "combination filter" of HME filter and bacterial filter is recommended (e.g. Medisize Hygrovent HMEF). When using HME filter, please observe the manufacturer instruction and follow the respective and recommended replacement intervals.

Connect all components according to Figure 20. Should you be using a tube circuit without pressure measuring tube, the circuit in use must be calibrated (see page 55).



A Patient side connection **B** HME filter **C** Expiration tube
D Inspiration tube **E** Pressure measuring tube **F** Pressure measurement adapter

Figure 20: Using HME filter - double line patient circuit with pressure measuring tube

SETTING AN ALARM TO DETECT DISCONNECTION OF THE TUBE SYSTEM

When filters or other components are used in the tube system, an increased resistance is created which often prevents a disconnection from being detected. Consequently, the device does not give an alarm. This represents a life-threatening risk for patients who are dependent on ventilation. The alarms should therefore be set so that an alarm is triggered in the event that a disconnection occurs. The alarm settings shown in Table 2 are suitable for detecting a disconnection.

⚠WARNING
If changes are made to the tube system, the alarms must be retested and their effectiveness checked.

⚠CAUTION
For a disconnection to be reliably detected, the alarms must be adapted to the tube system and the patient. Then perform a disconnection test (see page 53). We recommend a disconnection test both at the patient end and at the ventilation device. Adjust the alarm settings accordingly. If the alarm is not reliably activated, alternative monitoring must be carried out.

Table 2: Alarms for detecting a disconnection

Tube system	Pressure-controlled modes	Volume-controlled modes
Single line patient circuit	**Min. Pressure**, Apnoea Alarm, High Inspiration Volume, High Minute Ventilation, Low SpO_2	**Low Pressure**, Apnoea Alarm
Double line patient circuit	**Min. Pressure**, Apnoea Alarm, High Inspiration Volume, High Minute Ventilation, Leak Rate, Low SpO_2	

The disconnection test is performed as follows:

After setting the alarms, you should check whether the alarm(s) is/are triggered.

1. Start ventilating the patient and let the ventilation run for a few breaths.
2. Disconnect the tube system directly at the patient.
3. Check whether at least one of the set alarms is activated.
4. Then reconnect the tube system. The alarms should switch off again automatically.
5. Repeat the alarm test by disconnecting other connections within the tube system.

CALIBRATING THE TUBE CIRCUIT

NOTICE

The tube calibration must be performed only by using a tube system without measuring tube.

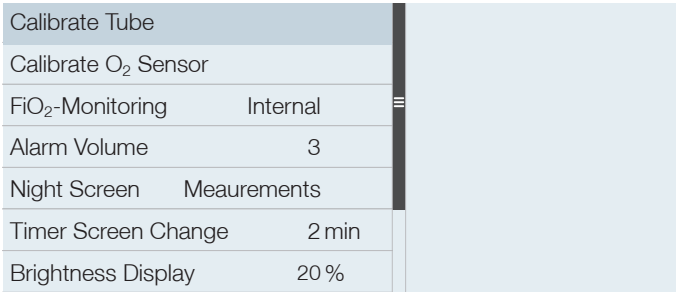
A tube calibration should be performed after an interruption in the power supply (on/off switching when running on battery power) and if changes have been made to the circuit system. These may include connecting and disconnecting of the following components, for example:

- Bacterial filter, humidifier, tube circuit, mask, FiO_2 sensor etc.

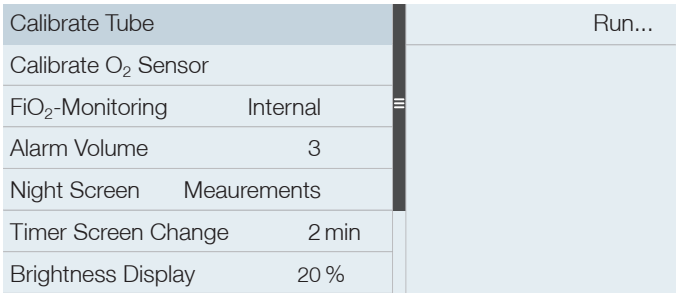
To calibrate the tube circuit:

1. Disconnect the tube circuit from the patient. The patient side connection of the tube circuit must be unobstructed and left open to the air during tube calibration (a mask may be connected).
2. Navigate to "System" in the home screen by turning the MFK.

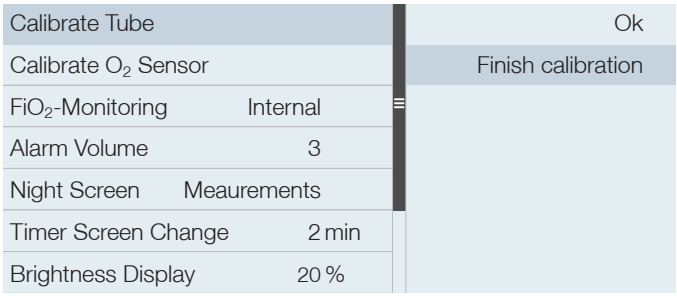
3. Press the MFK.
4. Navigate to "Calibrate Tube" by turning the MFK.



5. Press the MFK. Tube calibration begins.



6. If the calibration was successful, "OK" will appear after a few seconds. If the calibration was not successful, "Error" will display. In the event of an error, check the entire system. Resistance in the overall system may be too high. You may, for example, have to exchange the bacterial filter(s) or use another humidifier. Then rerun the calibration.



7. Press the MFK to exit the tube calibration process.

USING THE DEVICE WITHOUT TUBE CALIBRATION

If no calibration is performed, the last stored calibration data are used. During the initial commissioning, the standard calibration data[1] are used.

If you start the ventilation, following message box will be displayed.

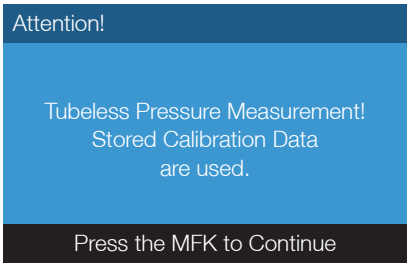


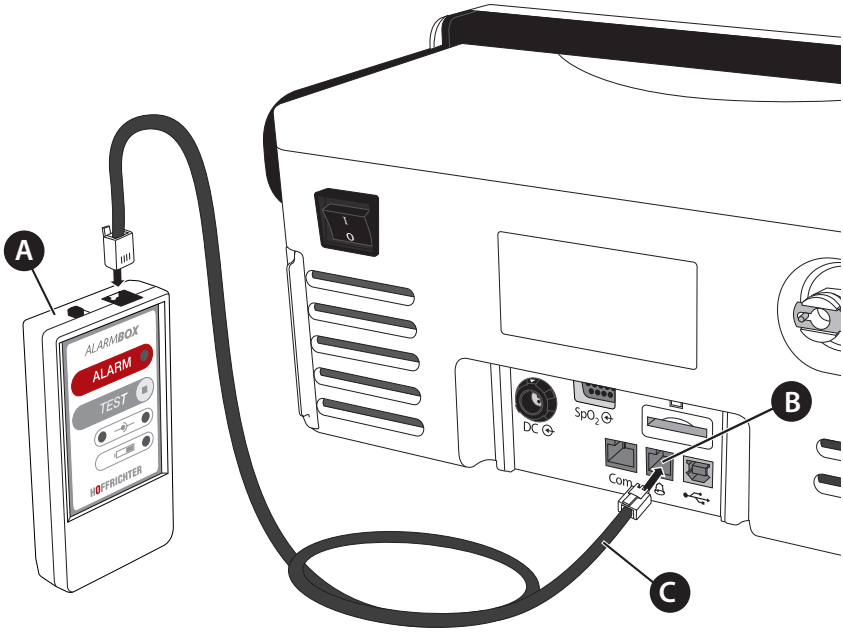
Figure 21: "Measurement without pressure tube" message box

The message box is disappeared by pressing der MFK. Although the ventilation is continued, however, the pressure measurement could be distorted. It is therefore recommended performing a tube calibration.

1 Valve and leakage tube system: ∅ 22 mm; l = 1.80 m
Altitude: approx. 44 m above mean sea level
Air pressure: approx. 1008 hPa
Bacterial filter, humidifier, mask, oxygen sensor etc.: no

CONNECTING THE ALARM BOX OR THE NURSE CALL

Connect the alarm box to the device as shown in Figure 22.



A Alarm box **B** Remote alarm/nurse call connection **C** Alarm box cable

Figure 22: Connecting alarm box

Alarm boxes are available as an accessory (see page 197).

An on-site nurse call can also be connected to the remote alarm/nurse call connection point as well. You will need a cable with a RJ10 plug to do this. The cables are available as an accessory (see page 197).

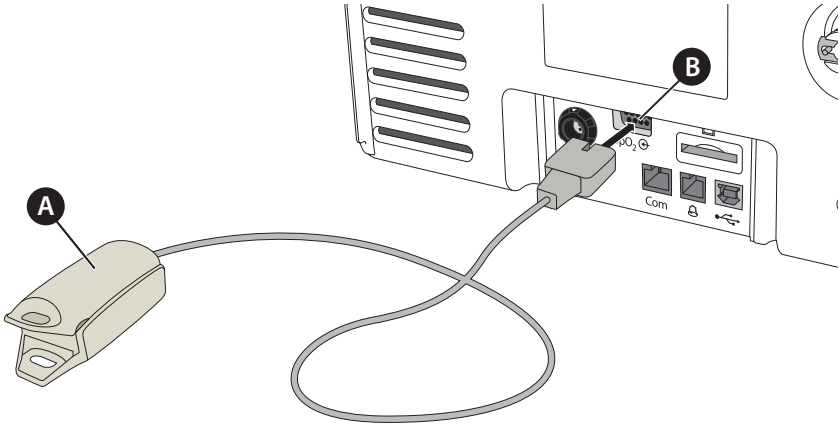
Additional information on alarm boxes and forwarding alarms is available in the section "Forwarding alarms" on page154.

SpO_2 SENSOR CONNECTION

Connect the SpO_2 sensor to the device as shown in Figure 23. The toolbar will then show the SpO2 icon. If the sensor is connected to the patient, the oxygen saturation and heart rate are displayed in the monitoring screen; if ventilation is in progress, it will also show in the parameter screen.

NOTICE

In the case of a malfunction (abnormal operation) dashes are displayed instead of the measured value.



A SpO_2 finger clip sensor **B** SpO_2 sensor connection

Figure 23: Connecting the SpO_2 sensor

INSERTING THE SD CARD

Insert the SD card into the SD card slot until it clicks into place as shown in Figure 24. The toolbar will then show the icon.

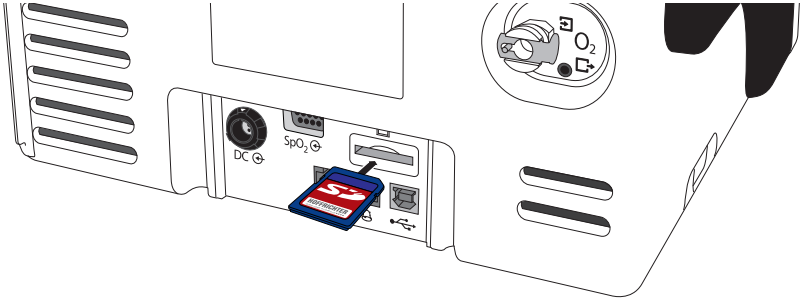


Figure 24: Inserting SD card

SD and SDHC cards up to 32 GB may be used. More information on SD cards is available on page 179.

REMOVING THE SD CARD SAFELY

To remove the SD card:

1. Touch the SD card symbol in the toolbar.

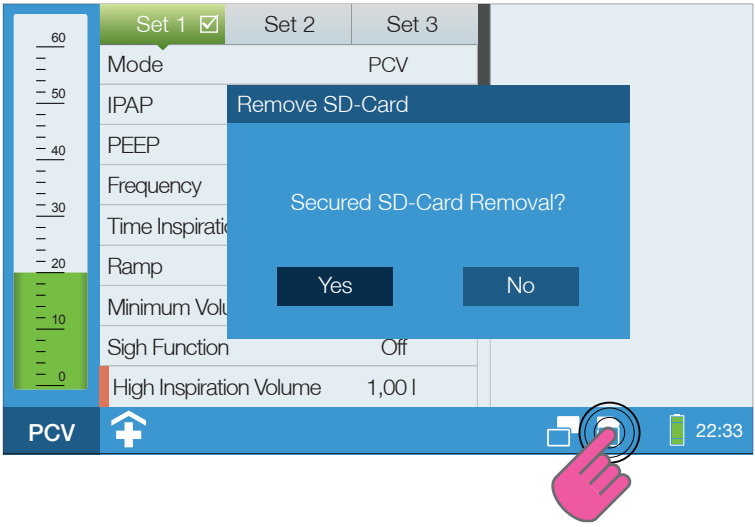
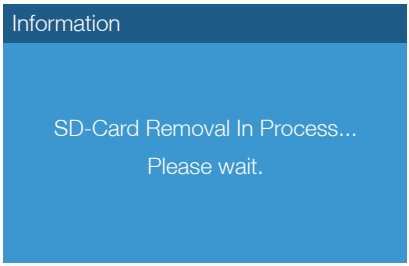
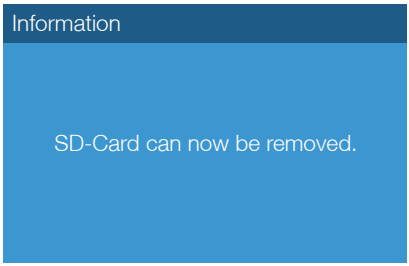


Figure 25: Removing the SD card safely

2. Navigate to "Yes" by turning the MFK.
3. Press the MFK.
4. While this message box is displayed, data is still being written on the SD card, and the SD card cannot be removed.



5. When this message box appears, you must remove the SD card.



Gently press the card into the SD card slot and remove the card.

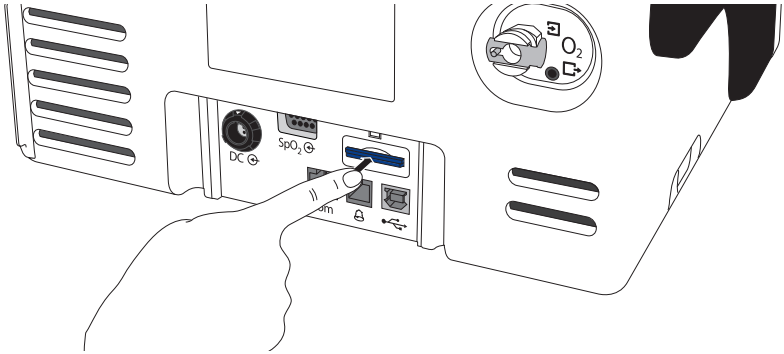


Figure 26: Removing SD card

If you would like to remove the SD card after powering off the device, please note the following:

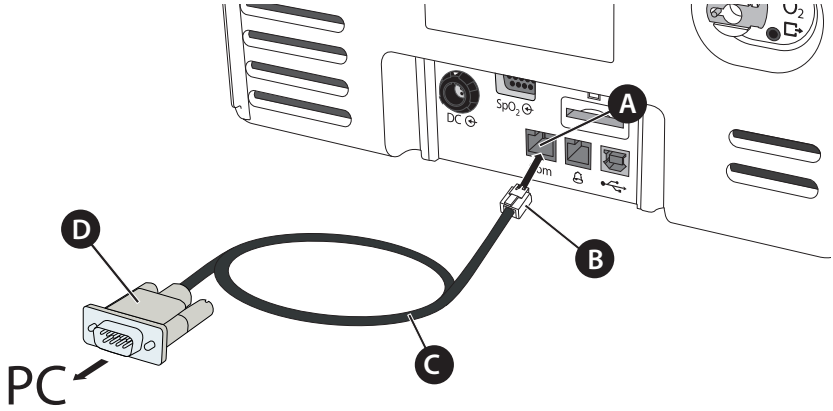
ATTENTION

Remove the SD card only when the device is turned off and is disconnected from the main power supply to ensure that the data storage of the SD-card is not damaged. The device is powered off if the power and battery LED do not flash.

CONNECTING A PC

By using the “easySET” PC software, service technicians can easily access the device and perform routine maintenance. The detailed procedure is described in the CARAT pro service manual.

Connect the PC according to Figure 27 to the device. You will need a USB cable with a type B plug (see page 197). If a communication to “easySET” exists, will displayed in the toolbar.



A USB interface **B** USB type B plug **C** USB cable (PC cable) **D** USB type A plug

Figure 27: Connecting a PC

USING OXYGEN

⚠WARNING
Before using oxygen, the safety instructions must be read as of page 29.

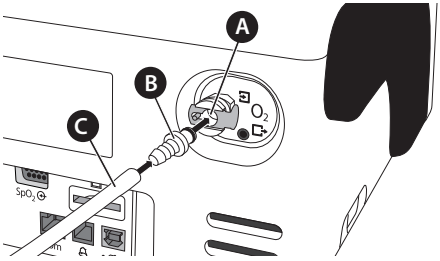
ATTENTION
Oxygen may only be supplied during active ventilation.

The supply of oxygen is possible in all ventilation modes. Please note that any changes to the ventilation parameters, as e.g. pressure, I:E, frequency, will lead to a change of the FiO_2 concentration.

CONNECTING THE OXYGEN SOURCE

ATTENTION
Only the oxygen connection adapter supplied may be used to connect oxygen. Otherwise, there is a risk that the back-stop in the connection is damaged.

Connect the oxygen source to the device as shown in Figure 28.



A Oxygen connection **B** Oxygen connection adapter, straight
C Tube from the oxygen source

Figure 28: Connecting the oxygen source (rear of unit)

MEASURING OXYGEN CONCENTRATION

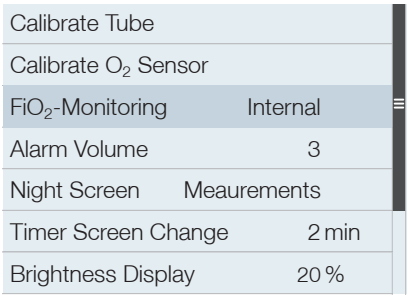
The oxygen concentration may be inconsistent when feeding in a fixed value oxygen flow (FlowO_2). The inspirational oxygen concentration (FiO_2) can vary depending on pressure, ventilation pattern of the patient, mask or leakage. The oxygen concentration should therefore always be measured with a FiO_2 sensor when oxygen is being supplied (see accessories on page 196). The FiO_2 sensor must be calibrated for exact results (see page 69).

In addition, the device will allow you to measure the inspiratory oxygen concentration FiO_2 with an external monitoring device during oxygen therapy, under the supervision of a physician. The FiO_2 monitoring device should be connected according to the manufacturer's instructions before commissioning the ventilator. It must also be equipped with an alarm system which is able to detect an alarm event for unacceptably high oxygen content. The measuring of the oxygen concentration with an external FiO_2 monitoring device must be set up in the system screen. The factory default is set to a measuring with a FiO_2 sensor (FiO_2 monitoring "Internal")

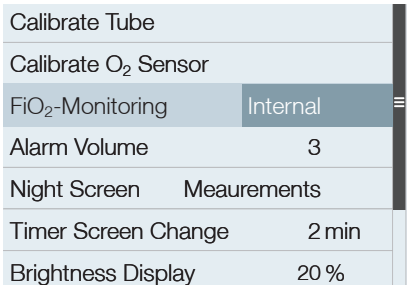
The following are the instructions for measuring the oxygen concentration with an external FiO_2 monitoring device:

1. Navigate to "System" in the home screen by turning the MFK:

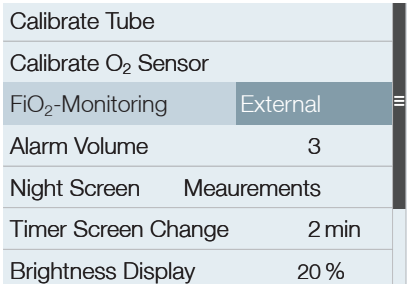
2. Press the MFK.
3. Navigate to "FiO_2-Monitoring" by turning the MFK.



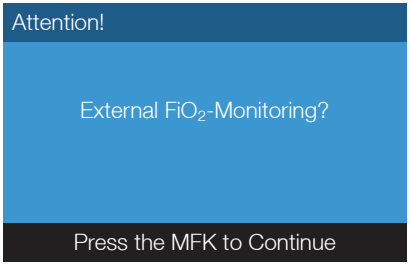
4. Press the MFK.



5. Change the setting by turning the MFK setting to "External".



6. Press the MFK. The O_2 icon is displayed in the toolbar.
7. After turn on the device the following message box appears:



8. Press the MFK to confirm the setting.

STARTING THE SUPPLY OF OXYGEN

⚠ DANGER
Use only certified and clean oxygen sources.

1. Switch the device on.
2. Start ventilation and wait for several respiratory cycles.
3. Start supplying the oxygen.

STOPPING THE SUPPLY OF OXYGEN

1 Stop the supply of oxygen at the oxygen source.
2 Continue ventilation for a number of respiratory cycles.
3. Stop ventilation.

CALIBRATING THE FiO_2 SENSOR

Calibration is done in relation to the ambient air with an assumption of an oxygen content of 21 %.

Automatic calibration when the device is switched on (recommended)

When the device is switched on and you connect the FiO_2 sensor to the device, the FiO_2 sensor will be calibrated automatically. The FiO_2 value readout will be displayed in the monitoring screen.

Automatic calibration during running ventilation

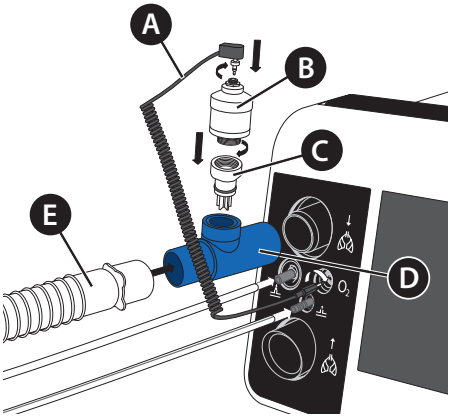
If the FiO_2 sensor is disconnected and reconnected during ventilation, then the oxygen supply is interrupted for at least 30 seconds, so that the oxygen content in the FiO_2 therapy air is reduced. After successful calibration, the oxygen supply is restored and the FiO_2 values will be displayed in the monitoring screen again.

Manual calibration

A manual calibration may be performed in the system screen at any time. During continuous oxygen therapy we recommend manual calibration of the FiO_2 sensor once a week.

To calibrate the FiO_2 sensor:

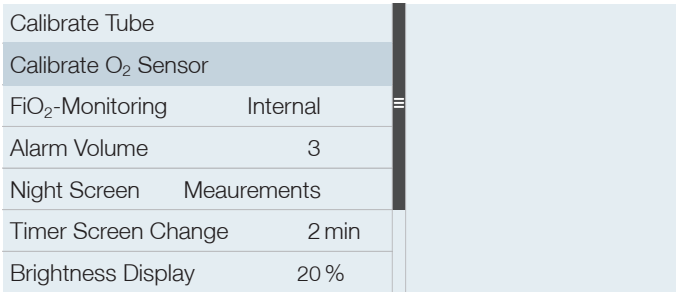
1. Make sure that the ventilator has been switched off.
2. Install the FiO_2 sensor according to Figure 29.
   Tip: Plug and screw the straight plug of the connecting line (A) to the device and then connect the right-angled to with the FiO_2 sensor.



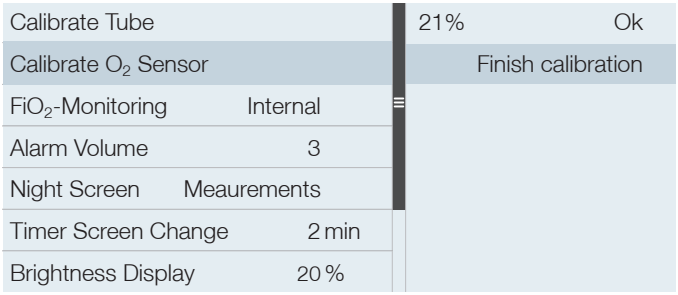
A Connecting line **B** FiO_2 sensor **C** Housing gas duct
D T adapter **E** Tube circuit

Figure 29: Connecting the FiO_2 sensor (single line patient circuit example)

3. Navigate to the system screen using the MFK  . Press the MFK.
4. Navigate to "Calibrate FiO_2 Sensor" by turning the MFK.



5. Press the MFK. Calibration begins.
6. If the calibration was successful, "OK" will appear after a few seconds. If the calibration was not successful, "Error" will display. In the event of an error, repeat the calibration. If the calbration is still unsuccessful, replace the FiO_2 sensor.



7. Press the MFK to end the FiO_2 sensor calibration.

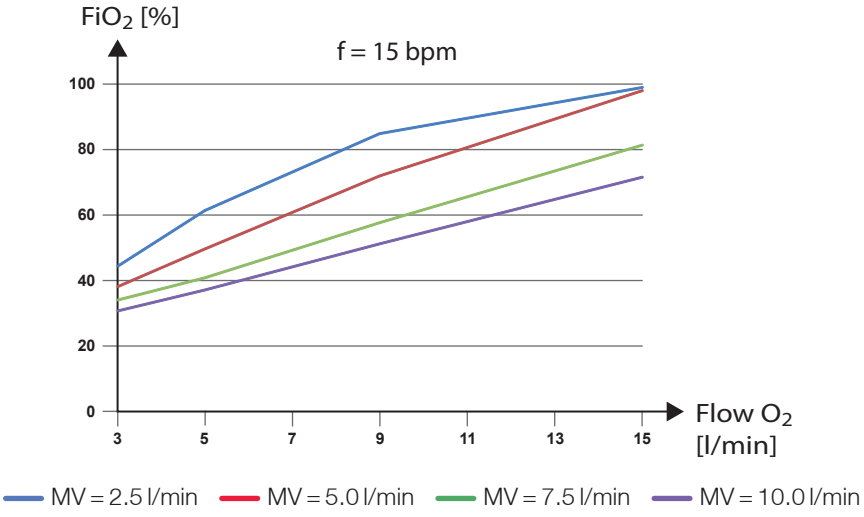
Depending on environmental conditions and the storage time, the sensor may take up to 15 minutes after connecting to reach signal stability again.

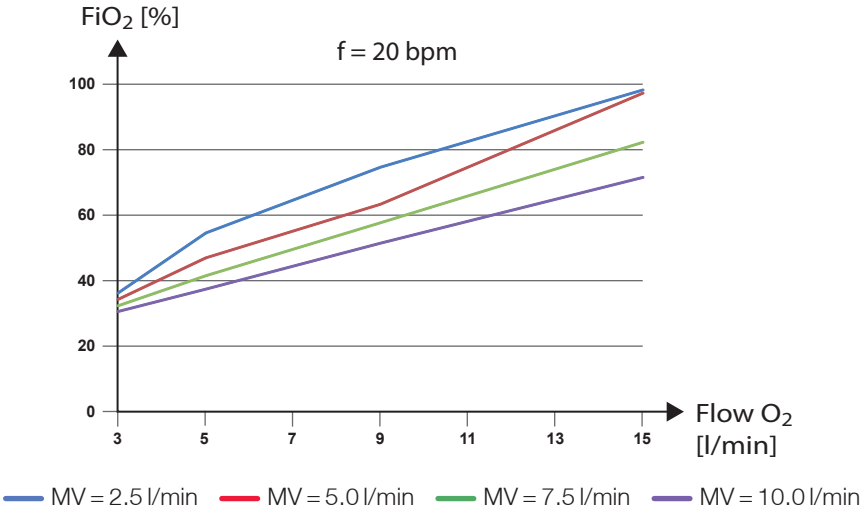
NOTICE

FiO_2 sensors have a limited service life. The service life of the sensors is approx. 1 year at a oxygen concentration for about 40 %. After that, the FiO_2 sensor must be replaced by a new one. The sensor should not be storaged more than 6 month. For the longest possible sensor service life, we recommend storage at +5 °C to + 30 °C.

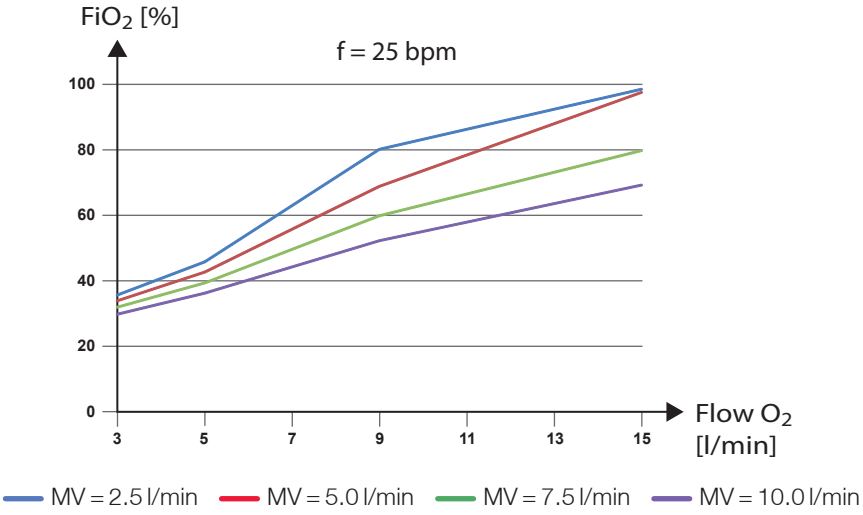
DETERMINING OXYGEN CONCENTRATION

The oxygen concentration (FiO_2) in the patient's respiratory system depends on the flow rate (Flow O_2) of the oxygen supply and the breathing minute ventilation (MV) of the patient. The following diagrams provide values for determining oxygen concentration at the frequencies of 15 bpm, 20 bpm and 25 bpm.[1]

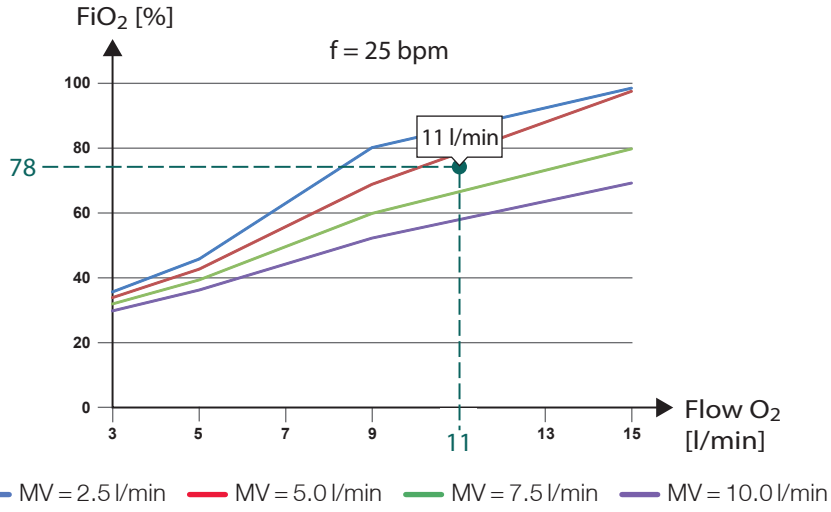




1 The measurement has been performed using a test lung (PEEP = 3 mbar, resistance 20 mbar/l/s, tidal volume max. 1000 ml). Depending on the condition of the patient's lung, the oxygen concentration values may differ from the ones measured here. Measurement deviation can be up to max. 10 %. The actual oxygen concentration also depends on the age and condition of the FiO_2 sensors.



Example



At an oxygen flow rate of 11 l/min and a minute ventilation of approximately 6 l/min, an oxygen concentration of approximately 78 % can be reached.

USING THE FUNCTIONAL BAG

⚠WARNING

Risk of injury from insufficient monitoring of the device functions!

If important device functions are not visible or are inaccessible, proper operation cannot be ensured.

⇨ Only use the original HOFFRICHTER functional bag.

The functional bag protects the ventilator from mechanical damage or weathering during mobile use (eg on a wheelchair or walker). The functional bag is available as an accessory (see page 195).

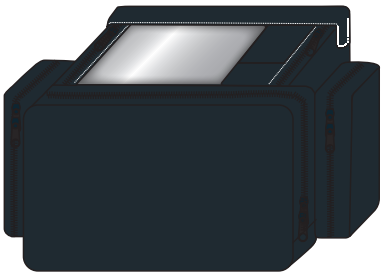


Figure 30: Functional Bag

When using the device in the functional bag the following instructions must be observed to ensure safe and trouble-free operation:

- Set the alarm sound to level 3.
- Make sure that all alarm messages are visible through the viewing window and that the air vents of the bag are not blocked. The air supply for the device must be guaranteed at all times.
- Use the bag in such a way that the device is protected from overheating, dust and water.
- All accessories connected, such as tube, filter, supply lines, etc, must be arranged so that they cannot cause any malfunctions of the device.
- If necessary, also observe the instructions in the user´s manuel for using the function bag in combination with other accessories.

SWITCHING THE DEVICE ON

NOTICE

The tube circuit may be connected when the device is started up, but it may not yet be connected to the patient yet.

If you are using oxygen therapy during ventilation, please note the section "Using oxygen" from page 65.

To switch on the device:

1. Press the main power switch on the back of the device (position "I").

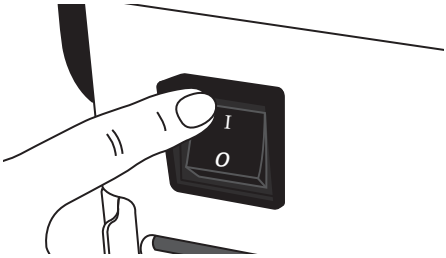


Figure 31: Switching on the device

2. The home screen (see page 115) will be displayed.

SWITCHING THE DEVICE OFF

1. Stop the ventilation.
2. Switch off the power with the main power switch on the rear panel (position "0").

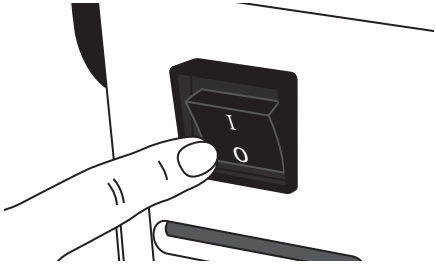


Figure 32: Switching off the device

CHAPTER 5
VENTILATION MODES

The device has three types of ventilation modes:

- Mandatory ventilation modes,
  where the device performs the respiratory work for the patient completely.
- Augmented ventilation modes,
  where the device performs part of the respiratory work, alternating or overlapping with the patient's breathing rate.
- Spontaneous ventilation modes,

  where the patient does the respiratory work with the support of the device. The patient determines the frequency.

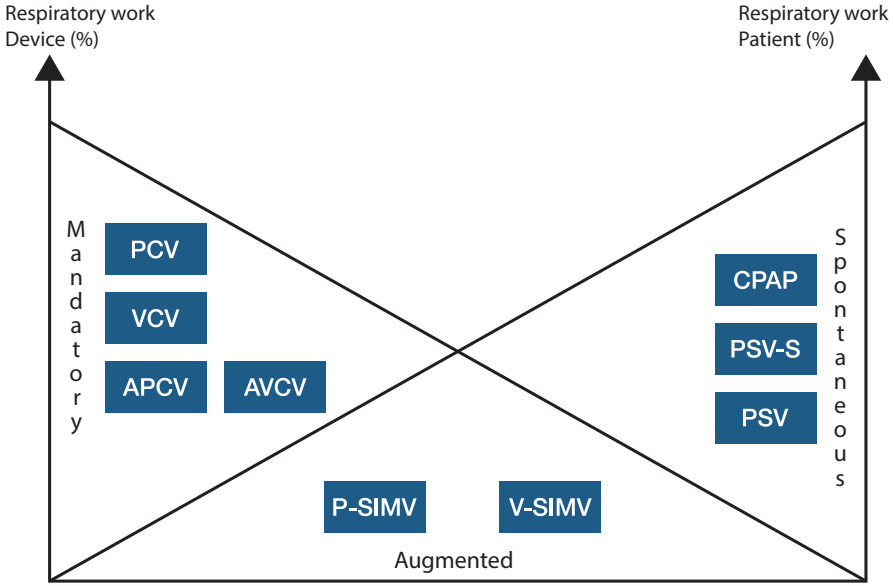


Figure 33: Ventilation modes overview

PCV MODE

Pressure Controlled Ventilation

Main features

- Pressure controlled
- Device triggered
- Time controlled
- Fixed frequency
- No spontaneous breathing possible

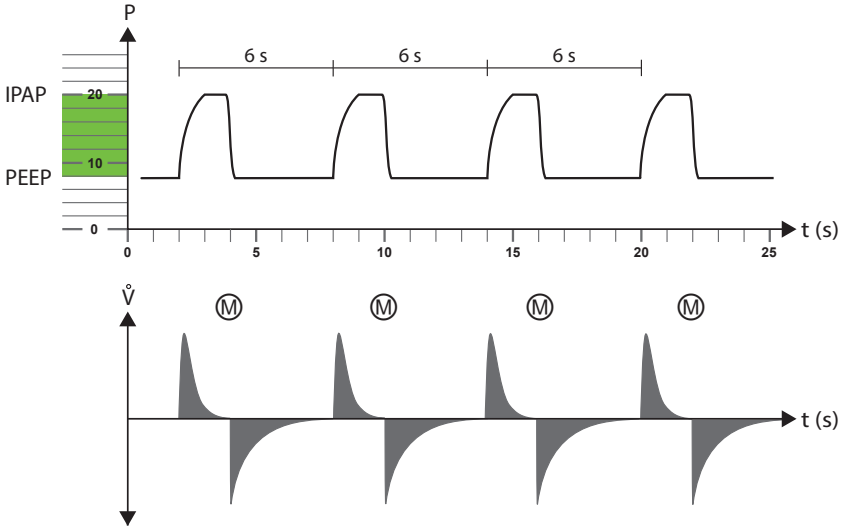
In this ventilation mode, the ventilation is exclusively controlled by the device. Spontaneous breathing on the patient's part is not possible. The ventilation period is based on the set frequency and a defined I:E ratio.

The inspiration pressure (IPAP) as well as the end-expiratory pressure (PEEP) defines the range of pressure for ventilating the patient. The rise in pressure can be selected by setting a ramp defining the form of the flow curve.

The inspiration volume is automatically adjusted to the condition of the lung (compliance and resistance).

To ensure a minimum volume, it is possible to specify a value and to optionally increase the pressure (IPAP + Additional Pressure) to reach this minimum volume.

Important settings	Tips
• Alarm limit "High Inspiration Volume" • Alarm limit "Low Inspiration Volume" • Alarm limit "High Expiration Volume" • Alarm limit "Low Expiration Volume"	• Adjustable "Minimum Volume " • Adjustable "Additional Pressure" to reach the minimum volume



IPAP = 20 hPa **PEEP** = 8 hPa **I:E** = 1:2 (2 s : 4 s) **f** = 10 bpm
Ⓜ Mandatory ventilation

Figure 34: PCV mode diagram

APCV MODE

Assisted Pressure Controlled Ventilation

Main features

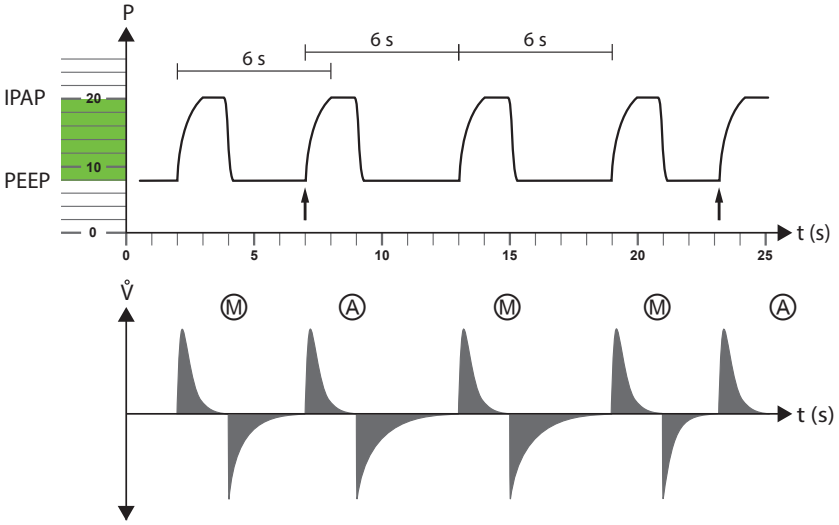
- Pressure controlled
- Device or patient triggered
- Time controlled
- Backup frequency
- Spontaneous breathing possible

In its ventilation parameters, the pressure controlled assisted ventilation is equal to the exclusively controlled ventilation.

By setting an inspiration trigger, however, the patient can stop expiration by inspiration efforts once he reaches the trigger threshold and initiate the next inspiration phase. As in the case with exclusively controlled ventilation, these additional respiratory strokes are only controlled by the device.

The inspiration time is defined. The patient can only shorten the expiration time by his own breathing efforts, thus increasing the set frequency rate.

Important settings	Tips
• Alarm limit "High Inspiration Volume" • Alarm limit "Low Inspiration Volume" • Alarm limit "High Expiration Volume" • Alarm limit "Low Expiration Volume" • Alarm limit "High Frequency"	• Adjustable "Minimum Volume" • Adjustable "Additional Pressure" to reach the minimum volume • Adjustable "Trigger Lock" for the inspiration trigger



IPAP = 20 hPa **PEEP** = 8 hPa **I:E** = 1:2 (2 s : 4 s) **f** = 10 bpm
↑ Spontaneous breathing Ⓜ Mandatory ventilation
Ⓐ Pressure controlled, assisted ventilation

Figure 35: APCV mode diagram

PSV MODE

Pressure Supported Ventilation

Main features

- Pressure supported
- Device or patient triggered
- Flow controlled
- Backup frequency
- Spontaneous breathing possible

Pressure supported ventilation is intended to support spontaneous breathing and to initiate mechanical ventilation whenever spontaneous breathing is absent.

The inspiration pressure (IPAP) and the positive end-expiratory pressure (PEEP) define the range of pressure for ventilating the patient.

The trigger thresholds of the inspiration trigger and the expiration trigger can be adjusted according to the patient's requirements.

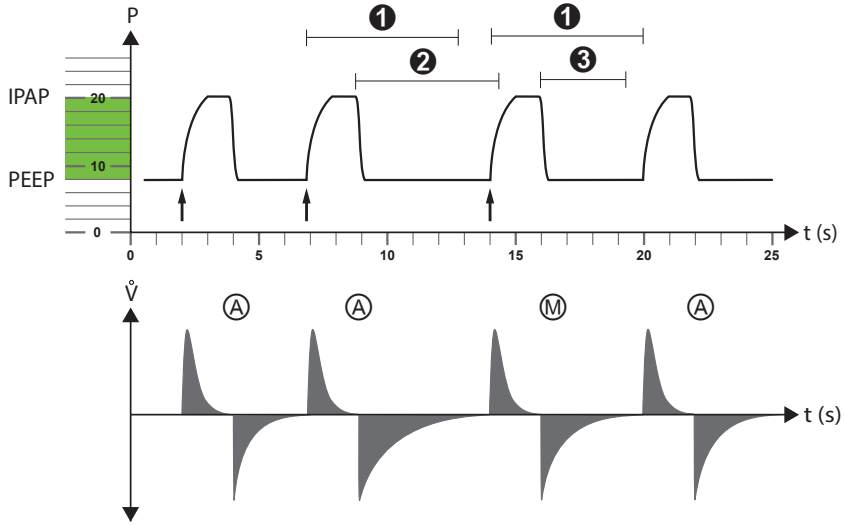
The adjustable frequency is set as a backup frequency. As long as the patient reaches or exceeds this frequency, the ventilator reacts with the pressure support to each spontaneous inspiration, following the patient's breathing. If the backup frequency fails to be reached, the device assumes mechanical ventilation until it registers the next spontaneous breath.

To permit respiratory pauses between the patient's breathing efforts, an apnoea time can be set to delay the start of the mechanlical ventilation.

The rise in pressure between PEEP and IPAP can be selected by setting a ramp which defines the course of the flow curve. The tidal volume is automatically adjusted to the condition of the lung (compliance and resistance).

To ensure a minimum volume, it is possible to specify a value and to optionally increase the pressure (IPAP + Additional Pressure) to reach this minimum volume.

Important settings	Tips
• Alarm limit "High Inspiration Volume" • Alarm limit "Low Inspiration Volume" • Alarm limit "High Expiration Volume" • Alarm limit "Low Expiration Volume" • Alarm limit "High Frequency" • Alarm limit "Low Frequency"	• Adjustable "Minimum Volume" • Adjustable "Additional Pressure" to reach the minimum volume • Adjustable "Trigger Lock" of the inspiration trigger • Adjustable "Apnoea Time" • Adjustable minimum (Ti Min) and maximum (Ti Max) inspiration time



IPAP = 20 hPa **PEEP** = 8 hPa ↑ Spontaneous breathing
❶ Backup frequency ❷ Apnoea time > Expiration time
❸ Apnoea time < Expiration time
Ⓜ Mandatory ventilation
Ⓐ Pressure controlled supported ventilation

Figure 36: PSV mode diagram

PSV-S MODE

Pressure Supported Ventilation-Spontaneous

NOTICE
Using PSV-S the device responds only to spontaneous breathing of the patient.

Main features

- Pressure supported
- Patient triggered
- Flow controlled
- Device will responds only to spontaneous breathing
- Apnoea alarm

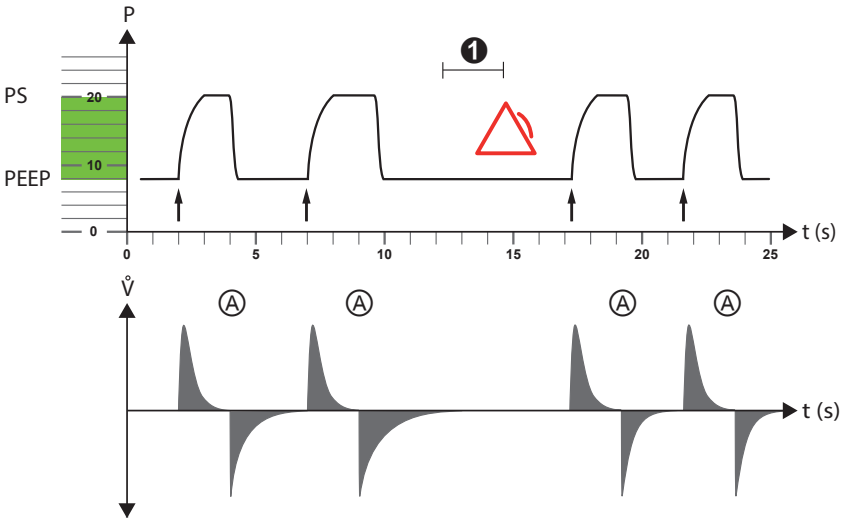
In its ventilation parameters, the PVS-S mode is equal to the PSV mode.

The PSV-S mode ventilation parameters adjustment options are the same as those of the PSV mode.

Inspiration triggers are only actuated by the patient's spontaneous breathing, since there is no frequency setting.

The apnoea time is an alarm parameter ("Apnoea Alarm").

Important settings	Tips
• Alarm limit "High Inspiration Volume" • Alarm limit "Low Inspiration Volume" • Alarm limit "High Expiration Volume" • Alarm limit "Low Expiration Volume" • Alarm limit "High Frequency" • Alarm limit "Low Frequency" • Alarm limit "Apnoea Alarm"	• Adjustable "Minimum Volume" • Adjustable "Additional Pressure" to reach the minimum volume • Adjustable "Trigger Lock" of the inspiration trigger • Minimum (Ti Min) and maximum (Ti Max) inspiration times are adjustable



PS = 20 hPa **PEEP** = 8 hPa ↑ Spontaneous breathing
❶ t > Apnoea time △ Apnoea alarm
Ⓐ Pressure controlled assisted ventilation

Figure 37: PSV-S mode diagram

P-SIMV MODE

Pressure Controlled Synchronized Intermittent Mandatory Ventilation

Main features

- Pressure controlled
- Device or patient triggered
- Time controlled
- Fixed frequency
- Spontaneous breathing possible

The SIMV mode provides a combination of pressure controlled ventilation and pressure assisted spontaneous breathing.

Pressure controlled ventilation is based on a defined respiratory rate and a defined inspiration time.

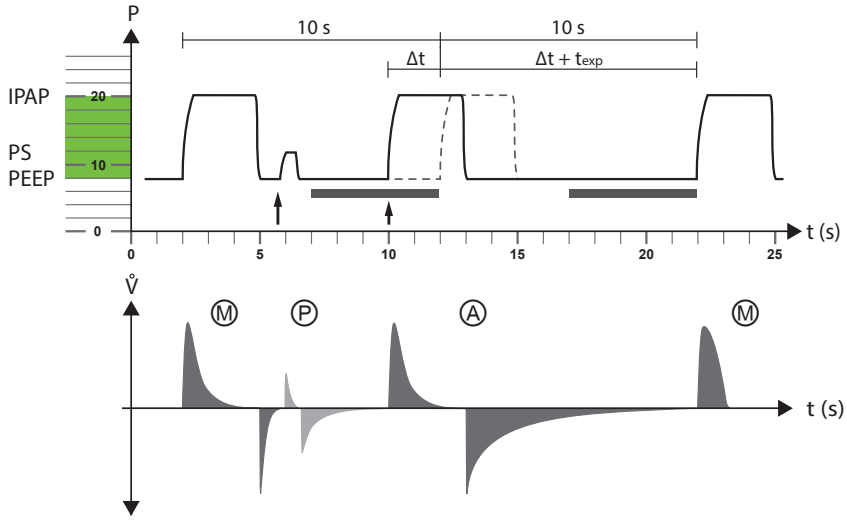
The inspiratory pressure (IPAP) as well as the end-expiratory pressure (PEEP) define the range of pressure for ventilating the patient. The pressure increase time from PEEP to IPAP can be set via the "Ramp" parameter in 5 levels.

The inspiration volume is automatically adjusted to the condition of the lung (compliance and resistance). The mechanical ventilation cannot influence by the patient spontaneous breathe.

Spontaneous breathing on the patient's part is possible between the ventilator strokes if the trigger thresholds for inspiration and expiration triggers are reached. During inspiration, spontaneous breathing is supported by a pressure (PS) that can be selected beforehand and is independent of the IPAP. The length of the spontaneous breaths and the inspiration time are exclusively defined by the patient.

The mechanical breaths are adjusted to spontaneous breathing in terms of time. If, for example, a spontaneous inspiration occurs shortly before a SIMV period is started (within a specific expected time window = 5 seconds), the mechanical ventilation is synchronized to the breathing of the patient. Since the synchronization of the mandatory ventilation shortens controlled ventilation by Δt and the frequency would be increasing, the following breath will be extened by Δt.

Important settings	Tips
• Alarm limit "High Inspiration Volume" • Alarm limit "Low Inspiration Volume" • Alarm limit "High Expiration Volume" • Alarm limit "Low Expiration Volume" • Alarm limit "High Frequency"	• Adjustable "Trigger Lock" of the inspiration trigger • Minimum (Ti Min) and maximum (Ti Max) inspiration times are adjustable



IPAP = 20 hPa **PS** = 12 hPa **PEEP** = 8 hPa
Frequency = 6 bpm ↑ Spontaneous breathing
▬ Expected time window = 5 s
Ⓜ Mandatory ventilation
Ⓟ Pressure supported ventilation
Ⓐ Pressure controlled assisted ventilation

Figure 38: P-SIMV mode diagram

VCV MODE

Volume Controlled Ventilation

Main features

- Volume controlled
- Device triggered
- Time controlled
- Fixed frequency
- No spontaneous breathing possible

In this ventilation mode, ventilation is controlled exclusively by the device.

Spontaneous breathing on the patient's part is not possible.

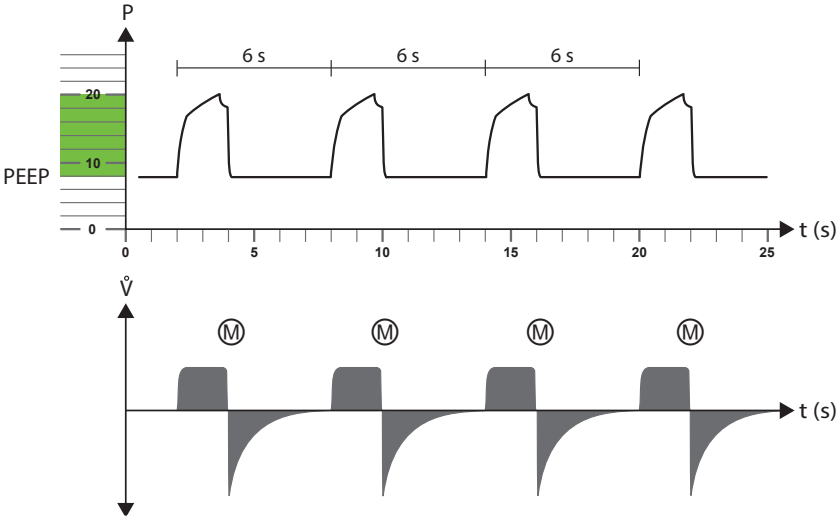
The ventilatory period is based on the set frequency and requires a defined I:E ratio.

The inspiration volume is defined such that the corresponding pressure is based on the condition of the lung (compliance and resistance).

It is also possible to set the positive end expiratory pressure (PEEP).

The inspiration flow ("Flow Ramp") can be selected as constant flow, as decelerating flow or as accelerating/decelerating flow.

Important settings	Tips
• "Max. Pressure" • "Min Pressure" • Alarm limit "High Frequency" • Alarm limit "High Pressure Tolerance" • Alarm limit "Low Pressure Tolerance"	• "Max. Pressure" limits the pressure to reach the set volume • Adjustable "Flow Ramp"



PEEP = 8 hPa **V** = 1 l **I:E** = 1:2 (2 s : 4 s) **f** = 10 bpm
Ⓜ Mandatory ventilation

Figure 39: VCV mode diagram

AVCV MODE

Assisted Volume Controlled Ventilation

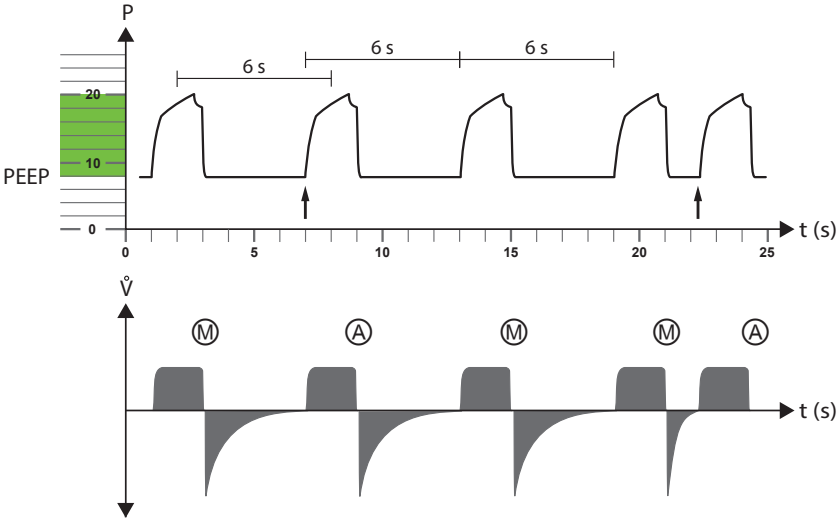
Main features
• Volume controlled • Device or patient triggered • Time controlled • Backup frequency • Spontaneous breathing possible

In its ventilation parameters, the volume controlled assisted ventilation is equal to the volume controlled ventilation (VCV).

By setting an inspiration trigger, however, the patient can stop expiration by inspiration efforts once he reaches the trigger threshold and initiate the additional breathes. This additional breathes are only controlled by the device.

The inspiration time is defined by the device. The patient can only shorten the expiration time by his own breathing efforts, thus increasing the set frequency.

Important settings	Tips
• "Max. Pressure" • "Min Pressure" • Alarm limit "High Frequency" • Alarm limit "High Pressure Tolerance" • Alarm limit "Low Pressure Tolerance"	• Adjustable "Trigger Lock" of the inspiration trigger • Adjustable "Flow Ramp"



PEEP = 8 hPa **V** = 1 l **I:E** = 1:2 (2 s : 4 s) **f** = 10 bpm
Ⓜ Mandatory ventilation
Ⓐ Volume controlled assisted ventilation

Figure 40: AVCV mode diagram

V-SIMV MODE

Volume Controlled Synchronized Intermittent Mandatory Ventilation

Main features

- Volume controlled
- Device or patient triggered
- Time controlled
- Backup frequency
- Spontaneous breathing possible

V-SIMV is a combination of volume controlled ventilation (VCV) with possible pressure supported ventilations (PSV) during the expiration phases.

The mechanical ventilation is based on a fixed frequency and an inspiration time.

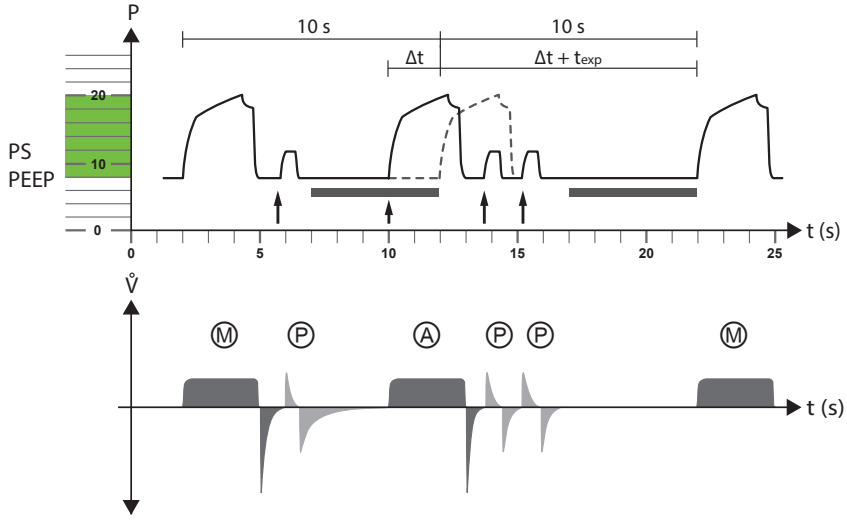
The inspiration volume is defined such that the corresponding pressure is based on the condition of the lung (compliance and resistance).

The patient can breathe spontaneously between mechanical ventilations when the inspiration and expiration trigger thresholds are reached. Spontaneous breathing is supported during inspiration by a predetermined and selectable pressure (PS), which is independent from the IPAP. Only the patient can predefine the length of the ventilations as well as the duration of the inspiration.

The mechanical breaths are adjusted to spontaneous breathing in terms of time. If, for example, a spontaneous inspiration occurs shortly before a SIMV period is started (within a specific expected time window = 5 seconds), the mechanical ventilation is synchronized to the breathing of the patient. Since the synchronization of the mandatory ventilation shortens controlled ventilation by Δt and the frequency would be increasing, the following breath will be extened by Δt.

The ventilation pressure is held at PEEP level during expiration.

Important settings	Tips
• "Max. Pressure" • "Min Pressure" • Alarm limit "High Frequency" • Alarm limit "High Pressure Tolerance" • Alarm limit "Low Pressure Tolerance"	• Adjustable "Trigger Lock" of the inspiration trigger • Minimum (Ti Min) and maximum (Ti Max) inspiration times are adjustable • Adjustable "Flow Ramp"



PS = 12 hPa **PEEP** = 8 hPa
Frequency = 6 bpm ↑ Spontaneous breathing
▬ Expected time window = 5 s
Ⓜ Mandatory ventilation
Ⓟ Pressure supported ventilation
Ⓐ Volume controlled assisted ventilation

Figure 41: V-SIMV mode diagram

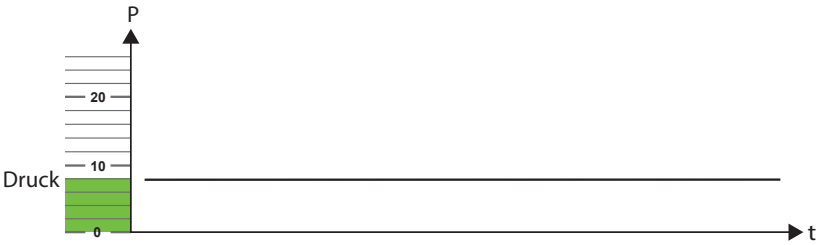
CPAP MODE

Continous Positive Airway Pressure

Main features

- Pressure controlled
- Independent respiration

In the CPAP mode, the device provides continuous positive pressure. The patient must be able to breathe spontaneously.



Pressure = 8 hPa

Figure 42: CPAP mode diagram

OVERVIEW OF VENTILATION MODES

The following table shows which ventilation and alarm parameters can be set in the ventilation modes.

Table 3: Overview of the ventilation and alarm parameter (adjustable)

Parameter	PCV	APCV	PSV	PSV-S	P-SIMV	VCV	AVCV	V-SIMV	CPAP
Tidal Volume						•	•	•	
Pressure									•
IPAP	•	•	•	•	•				
PS					•			•	
PEEP	•	•	•	•	•	•	•	•	
Frequency	•	•	•		•	•	•	•	
Apnoea Alarm			•						
Time Inspiration	•	•	•		•	•	•	•	
Ti Max			•	•	•			•	
Ti Min			•	•	•			•	
I:E	•	•	•		•	•	•	•	
Ramp	•	•	•	•	•			•	
Flow Ramp						•	•	•	
Inspiration Trigger		•	•	•	•		•	•	
Expiration Trigger			•	•	•			•	
Trigger Lock		•	•	•	•		•	•	
SMART Function		•	•	•	•		•	•	
Minimum Volume	•	•	•	•					
Additional Pressure	•	•	•	•					
Sigh Function	•	•	•	•	•	•	•	•	
Max. Pressure						•	•	•	
Min. Pressure						•	•	•	
Apnoea Alarm				•					•

Table 3: Overview of the ventilation and alarm parameter (adjustable)

Parameter	PCV	APCV	PSV	PSV-S	P-SIMV	VCV	AVCV	V-SIMV	CPAP
High Frequency		•	•	•	•		•	•	•
Low Frequency			•	•					•
High Inspiration Volume	•	•	•	•	•				•
Low Inspiration Volume	•	•	•	•	•				•
High Expiration Volume	•	•	•	•	•				•
Low Expiration Volume	•	•	•	•	•				•
High Minute Ventilation	•	•	•	•	•	•	•	•	•
Low Minute Ventilation	•	•	•	•	•	•	•	•	•
Leak Rate	•	•	•	•	•	•	•	•	•
High FiO_2	•	•	•	•	•	•	•	•	•
Low FiO_2	•	•	•	•	•	•	•	•	•
High. SpO_2	•	•	•	•	•	•	•	•	•
Low SpO_2	•	•	•	•	•	•	•	•	•
High Heart Rate	•	•	•	•	•	•	•	•	•
Low Heart Rate	•	•	•	•	•	•	•	•	•
High Pressure Tolerance	•	•	•	•	•	•	•	•	•
Low Pressure Tolerance	•	•	•	•	•	•	•	•	•

VENTILATION PARAMETERS PESCRIPTION

TIDAL VOLUME

VCV AVCV V-SIMV

The tidal volume is the adjustable inspiration volume, which is applied to the patient on each inspiration.

NOTICE

The "Tidal Volume" setting is directly related to the "Max. Pressure" ventilation parameters. When "Max. Pressure" has been set up too low, the set tidal volume may not be reached. In that case, the "Volume too low" alarm will be triggered.

PRESSURE

CPAP

The pressure is the CPAP mode ventilation pressure, which is applied to the patient for each mechanical ventilation during inspiration and exxpiration.

IPAP

PCV PSV PSV-S APCV P-SIMV

IPAP (= Inspiratory Positive Airway Pressure) is the ventilation pressure in the PCV-/APCV, PSV-/PSV-S and P-SIMV mode, which is applied to the patient with each breath during inspiration. The set IPAP value is not summed up to the set PEEP, but it represents the maximum inspiratory pressure.

PS

P-SIMV V-SIMV

PS (= Pressure Support) is the pressure applied to the patient in the SIMV mode, which supports the patient in his/her own spontaneous inspiration. In the SIMV mode, PS is exclusively intended as pressure support of the patient's spontaneous inspiration. The set PS value is not summed up to the set PEEP, but it represents the maximum inspiratory pressure.

PEEP

PCV APCV PSV PSV-S VCV AVCV P-SIMV V-SIMV

The PEEP (= Positive End Expiratory Pressure) is the positive pressure which is available to the patient during expiration before starting the new inspiration. It can be spontaneous as well as mechanically controlled.

FREQUENCY

PCV APCV PSV VCV AVCV P-SIMV V-SIMV

The frequency is set in the controlled ventilation modes (PCV / VCV) as a defined specification by the machine. In the PSV mode and in the assisted APCV or AVCV mode, the set frequency is defined as the minimum frequency, which can be increased by spontaneous breaths of the patient.

In the SIMV modes, the frequency is defined as the frequency used to supply the mandatory breaths to the patient at the specified IPAP and during the specified inspiration time. Thus, the set frequency ensures the patient's minimum frequency. In between the mandatory breaths, the patient can increase the frequency by means of spontaneous inspiration.

APNOEA TIME

PSV

The apnoea time is intended to provide an additional time interval for patient, who can spontaneously breaths after the mandatory period has expired. The apnea time begins at the end of the inspiration period. The device begins ventilation if there are no patient breaths for the duration of the apnoea time. If the set apnoea time ends before the frequency-depend expiration period expires, the set apnoea time will not be considered (see Figure 36 on page 81).

TIME INSPIRATION / I:E

PCV APCV PSV VCV AVCV P-SIMV V-SIMV

You can choose in the system screen if you setting up the inspiration time or the I:E ratio.
The inspiration time defines the duration of inspiration (in seconds). The frequency must be taken into account when setting the inspiration time. Setting up a fixed inspiration time, the I:E ratio is calculated depending on the respiratory frequency. The I:E ratio is the ratio of inspiration to expiration of a breath. Setting up a fixed I:E ratio, the inspiration time depends on the set frequency.

Ti Max

PSV | PSV-S | P-SIMV | V-SIMV

The "Ti Max" setting limits inspiration time so that a late switchover to the expiration phase is prevented and a better syncronization of patient and device can be achieved.

Ti Min

PSV | PSV-S | P-SIMV | V-SIMV

Setting up the "Ti Min" defines the minimum inspiration time so that a premature switchover to the expiration phase is prevented.

RAMP

PCV | APCV | PSV | PSV-S | P-SIMV | V-SIMV

In the pressure controlled ventilation modes the ramp define the pressure increase time in the inspiration phase. The pressure increase time ia determined by setting the ramp level, which stored as a flow curve. The pressure increase time also depends on the resistance and the compliance of the patient's lung.

When setting a ramp, the currently set inspiration time must be taken into consideration.

The following examples shows the change in the pressure increase time depending on various ramp settings of a healthy lung:

Table 4: Pressure increase times of the ramp

Ramp setting	Pressure increase time[1]
1	1.7 s [2]
2	1.0 s [2]
3	0.6 s [2]
4	0.4 s [2]
5	0.3 s [2]

1 Pressure increase time in seconds at an IPAP = 20 hPa / PEEP = 5 hPa

2 The values specified are reference times and depends on the pressure range set and the lung condition.

FLOW RAMP

VCV | AVCV | V-SIMV

The flow ramp can be set in the volume controlled modes as a constant inspiration flow (level 1 ), as decelerating inspiration flow (level 2  , level 3  , level 4 ) or as an accelerating/decelerating inspiration flow (level 5 ). The flow curve can be changed depending condition of lung (compliance and restistance).

INSPIRATION TRIGGER

APCV | PSV | PSV-S | AVCV | P-SIMV | V-SIMV

The inspiration trigger is a volume trigger. It specifies the inspiration efforts of patient equired to obtain pressure or volume support from the ventilator in the case of spontaneous breathing.

NOTICE

Please always consider the patient's clinical record when setting the trigger levels in order to avoid the risk of auto triggering.

Once the set inspiratory trigger threshold (see Table 5) is reached, the device starts the inspiratory phase.

Table 5: Thresholds inspiratory trigger

Level	Volume threshold value	Flow change in 30 ms
1	5 ml (± 20 %)	1,2 l/min
2	10 ml (± 20 %)	1,5 l/min
3	15 ml (± 20 %)	1,8 l/min
4	20 ml (± 20 %)	2,1 l/min
5	25 ml (± 20 %)	2,4 l/min
6	30 ml (± 20 %)	2,7 l/min
7	35 ml (± 20 %)	3,0 l/min
8	40 ml (± 20 %)	3,3 l/min
9	45 ml (± 20 %)	3,6 l/min
10	50 ml (± 20 %)	3,9 l/min

To avoid auto triggering, which are cause by artifacts of the single line patient circuit expiration valve, the "SMART Function" can be set (see page 100).

EXPIRATION TRIGGER

PSV | PSV-S | P-SIMV | V-SIMV

The expiration trigger is a flow trigger both in the case of using of a single line patient circuit and a double line patient circuit. The peak flow of the inspiration is measured with each breath. The setting of the expiration trigger defines the percentage of the peak flow at which the ventilator switches over to expiration.

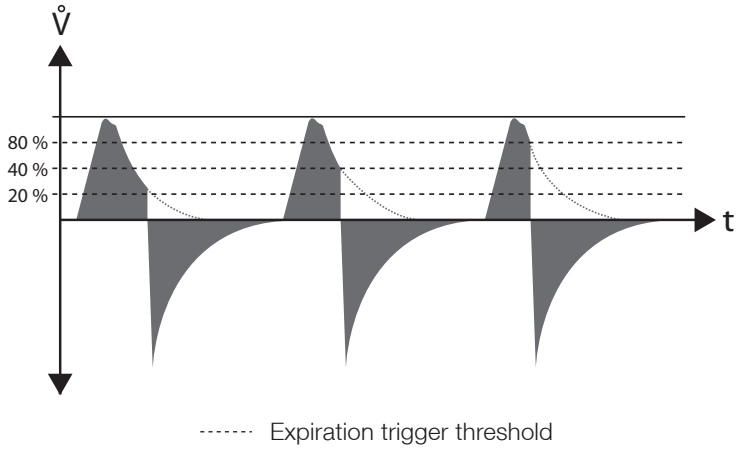


Figure 43: Flow trigger (setting a percentage value)

TRIGGER LOCK

APCV | PSV | PSV-S | AVCV | P-SIMV | V-SIMV

The trigger lock is especially applicable in the ventilation of patients with obstructive pulmonary diseases (e.g., COPD). In these patients, fluctuations often occur during the expiration phase. This leads to the device registering spontaneous respiration and the inspiration trigger is released too soon. To prevent false triggering, it is possible to define a period of time (trigger lock) for the expiration phase, in which the inspiration trigger is suppressed.

SMART FUNCTION

APCV | PSV | PSV-S | AVCV | P-SIMV | V-SIMV

The "SMART Function" can be set to avoid auto triggering, which are cause by artefacts of the single line patient circuit expiration valve. These artifacts lead to a breath triggering in the absence of effort by the patient during expiration.

Without SMART Function

The inspiration trigger is initiated by artefacts.

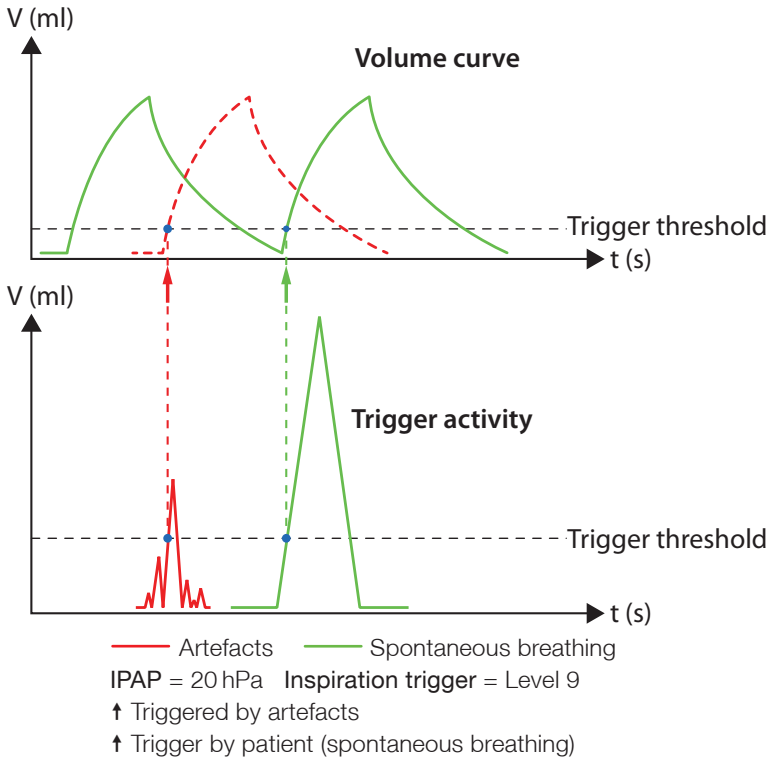


Figure 44: Inspiration trigger without SMART Function

Using SMART Function

The inspiration trigger is **not** initiated by artefacts.

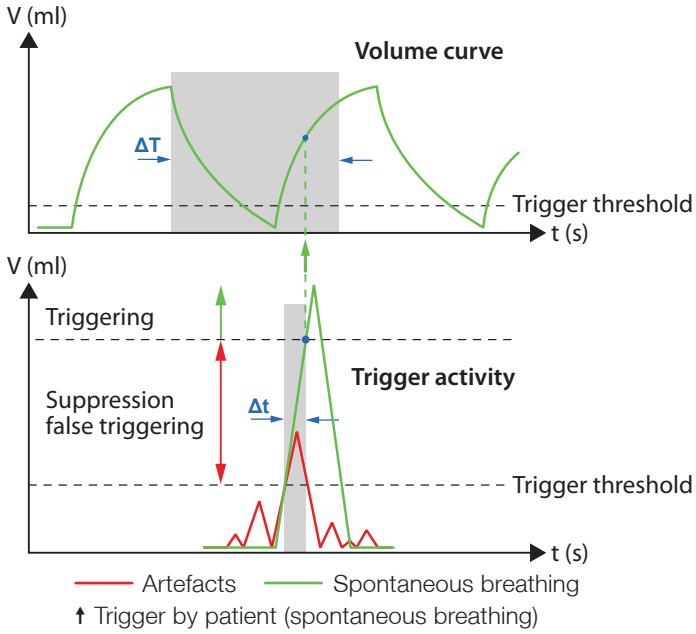


Figure 45: Inspiration trigger using SMART Function

If the "SMART Function" is active, the device distinguishes between patient efforts and artefacts.

An inspiration trigger is initiated according to the following conditions:

A time period ΔT is calculated depending on the IPAP and starting with the expiration period. If the inspiration trigger threshold is reached, an additional IPAP-dependent time period Δt is calculated. If a patient effort meets the trigger condition within this time period Δt, an inspiration trigger will initiate. If this is not the case, the device supposes an artefact and an inspiration trigger will not initiate.

After the time period ΔT has expired, an inspiration trigger is immediately initiated after exceeding the trigger thresholds.

NOTICE

If an auto trigger is occurred although the SMART Function is active, we recommend to increase the trigger level or to set a trigger lock.

MINIMUM VOLUME

PCV APCV PSV PSV-S

The minimum volume is the minimum tidal volume, which is considered as a volume guarantee during a pressure controlled ventilation.

ADDITIONAL PRESSURE

PCV APCV PSV PSV-S

The additional pressure is graduately added by 2 hPa to the IPAP or PS pressure until the set additional pressure is reached, if the minimum volume has not been reached in order to guarantee the set minimum volume.

SIGH FUNCTION

PCV APCV PSV PSV-S VCV AVCV P-SIMV V-SIMV

If using a volume controlled mode and the sigh function is activated, 150% of the set volume is administered in the inspiration phase at each 100th breath. If using a pressure controlled mode, the IPAP is increased so that approx. 150 % of the messured tidal volume of the previously breath is reached. This may help to reopen or keep open any collapsing pulmonary alveolar.
If in the P-SIMV and V-SIMV modes the 100th breath is a spontaneous pressure supported breath, only the next ventilation will be performed as a "sigh".

MAX. PRESSURE

VCV AVCV V-SIMV

The "Max. Pressure" setting limits the pressure towards the top and does affect the "Tidal Volume" setting.

MIN. PRESSURE

VCV AVCV V-SIMV

The "Min. Pressure" setting limits the bottom pressure.

DESCRIPTION OF ALARM PARAMETERS

APNOEA ALARM

PSV-S CPAP

The "Apnoea Alarm" setting establishes the time when the "Apnoea" alarm will be triggered in case of an apnoea event.

HIGH FREQUENCY

APCV PSV PSV-S AVCV P-SIMV V-SIMV CPAP

If the measured frequency is higher than the "High Frequency" setting, the "High Frequency" alarm will be triggered.

LOW FREQUENCY

PSV PSV-S CPAP

If the measured frequency is lower than the "Low Frequency" setting, the "Low Frequency" alarm will be triggered.

HIGH INSPIRATION VOLUME

PCV APCV PSV PSV-S P-SIMV CPAP

If the measured tidal volume is higher than the "High Inspiration Volume" setting, the "High Inspiration Volume" alarm will be triggered.

LOW INSPIRATION VOLUME

PCV APCV PSV PSV-S P-SIMV CPAP

If the measured tidal volume is lower than the "Low Inspiration Volume" setting, the "Low Inspiration Volume" alarm will be triggered.

HIGH EXSPIRATION VOLUMEN

PCV APCV PSV PSV-S P-SIMV CPAP

If the measured expiration volume is higher than the "High Expiration Volume" setting, the "High Expiration Volume" alarm will be triggered.

LOW EXSPIRATION VOLUMEN

PCV | APCV | PSV | PSV-S | P-SIMV | CPAP

If the measured expiration volume is lower than the "Low Expiration Volume" setting, the "Low Expiration Volume" alarm will be triggered.

HIGH MINUTE VENTILATION

PCV | APCV | PSV | PSV-S | P-SIMV | V-SIMV | CPAP | VCV | AVCV

If the measured minute volume be higher than the "High Minute Ventilation" setting, the "High Minute Ventilation" alarm will be triggered.

LOW MINUTE VENTILATION

PCV | APCV | PSV | PSV-S | P-SIMV | V-SIMV | CPAP | VCV | AVCV

If the measured minute volume is lower than the "Low Minute Ventilation" setting, the "Low Minute Ventilation" alarm will be triggered.

LEAK RATE

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V_SIMV | CPAP

Double line patient circuit

If the difference between the expiration and inspiration volume is higher then the "Leak Rate" setting, the "Leak Rate" alarm will be triggered.

Single line patient circuit

If the inspiration volume is higher than 2.54 l, the "Leak Rate" alarm will be triggered.

HIGH FiO_2

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured oxygen concentration is higher than the "High FiO_2" setting, the "High FiO_2" alarm will be triggered.

LOW FiO_2

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured oxygen concentration is lower than the "Low FiO_2" setting, the "Low FiO_2" alarm will be triggered.

HIGH SpO_2

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured oxygen saturation is greater than the "High SpO_2" setting, then the "High SpO_2" alarm will be triggered.

LOW SpO_2

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured oxygen saturation is lower than the "Low SpO_2" setting, the "SpO_2 too low" alarm will be triggered.

HIGH HEART RATE

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured pulse frequency is higher than the "High Heart Rate" setting, the "High Heart Rate" alarm will be triggered.

LOW HEART RATE

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured pulse frequency is lower than the "Low Heart Rate" setting, the "Low Heart Rate" alarm will be triggered.

HIGH PRESSURE TOLERANCE

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured pressure is higher than the set pressure plus the setting "High Pressure Tolerance", then the alarm "High Pressure" will be triggered.

LOW PRESSURE TOLERANCE

PCV | APCV | PSV | PSV-S | VCV | AVCV | P-SIMV | V-SIMV | CPAP

If the measured pressure is lower than the set pressure minus the setting "Low Pressure Tolerance" then the "Low Pressure" alarm will be triggered.

CHAPTER 6
DEVICE OPERATION

This chapter decribes the device operation in more detail.

KEY LOCK

The key lock function is designed to protect against the accidental changing of device settings. It deactivates all control functions, except:

- ON/OFF key to start ventilation
- ON/OFF key + MFK to stop the ventilation
- Alarm key

LOCK/UNLOCK KEYS

1. Press the Safe key. Flashes on the toolbar for about 5 s.
2. Press the MFK during that time.

USER PROFILES

The device can operated in 2 different profiles - Clinic and Home. The user has access to all device settings in the clinic mode. In contrast, the ventilation and alarm parameters cannot be set up in the home mode.

The currently active user profile displays in the toolbar.

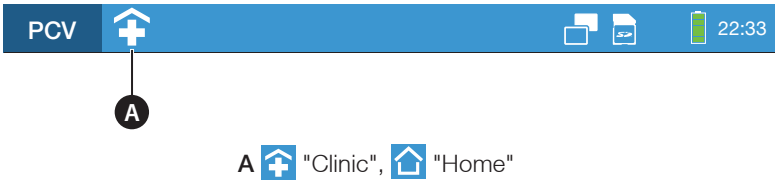


Figure 46: User profile in the toolbar

SETTING THE USER PROFILE

To set the user profile:

1. Navigate to "System" in the home screen by turning the MFK :

2. Press the MFK.
3. Navigate to "User Profile" by turning the MFK.

Date and Time	13.02.16 10:36
Number Ventilation Sets	3
User Profile	Clinic
Tightness Check	
Recent Ventilation Hours	65 h
Ventilation Hours Total	342 h
Operating Counter	622 h

4. Press the MFK.

Date and Time	13.02.14 10:36
Number Ventilation Sets	3
User Profile	Clinic
Tightness Check	
Recent Ventilation Hours	65 h
Ventilation Hours Total	342 h
Operating Counter	622 h

5. Change the setting by turning the MFK.

Date and Time	13.02.14 10:36
Number Ventilation Sets	3
User Profile	Home
Tightness Check	
Recent Ventilation Hours	65 h
Ventilation Hours Total	342 h
Operating Counter	622 h

MENU STRUCTURE

- Home screen
  - Monitoring screen
    - Measurements (p, V_I, V_E, MV, f, I:E, FiO_2, SpO_2, HF)
    - Graphs (p, $\dot{V}$, V, FiO_2)
    - Loops (V-Flow-Loop, p-V-Loop)
  - Parameter screen
    - Set 1
    - Set 2
    - Set 3
  - Alarm log screen
  - System screen
  - Statistics screen
  - Service screen

BASIC OPERATION

Use the control elemtents on the right or the touch screen to operate the device.

OPERATING WITH CONTROL ELEMENTS

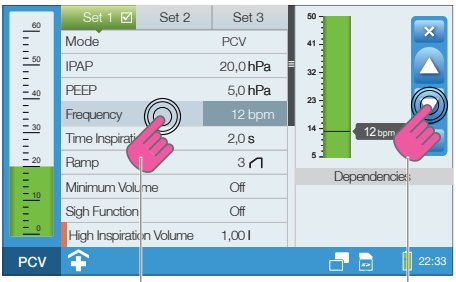
The control elements functions are described starting with page 35.

NOTICE

The touch operation is a comfort feature for quick and intuitive menu control. If the touch operation is not possible, the device can still be operated using the multifunction knob and the keys.

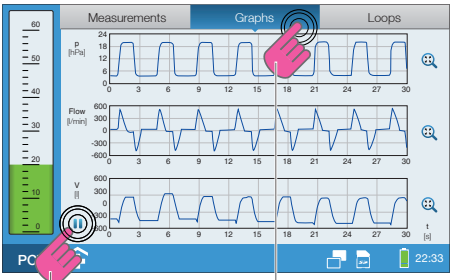
The following operations can be initiated with the touch screen:

Screen selection



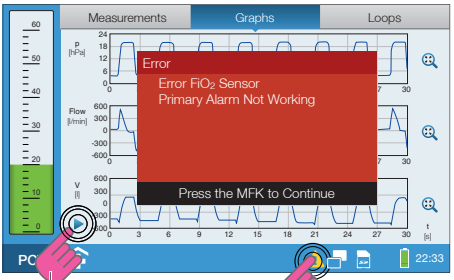
Parameter selection

Setting parameters



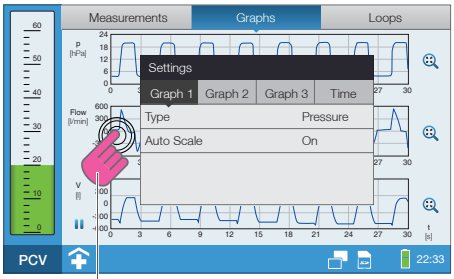
Freeze real-time curve on the monitoring screen

Select tab

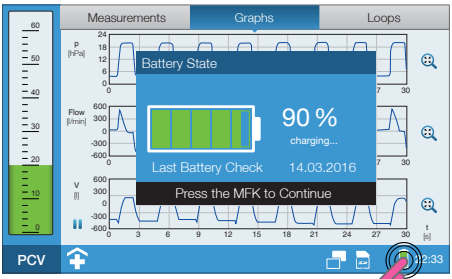


Continue real-time curve on the monitoring screen

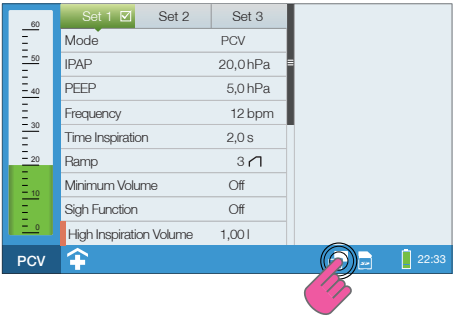
Show errors (if present)



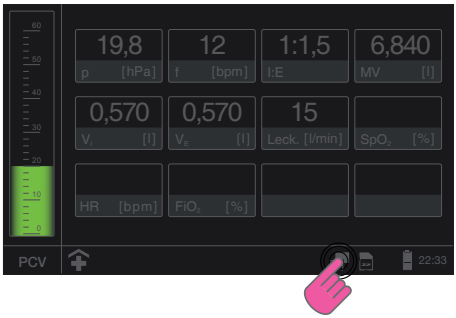
Opening/closing the settings window



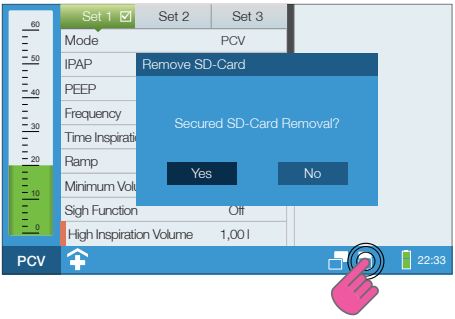
Show battery state and date of the last battery check



Switching on night screen



Switching off night screen



Removing the SD card safely

BASIC SCREEN LAYOUT

A Pressure bar (during running ventilation) **B** Screen content
C Toolbar **D** Active ventilation mode

Figure 47: Basic screen layout

EXPLANATION OF TOOLBAR ICONS

Icon	Meaning
	Clinic mode active
	Home mode active
	Alarm active  Red icon → High priority alarm  Yellow icon → Medium priority alarm  Turquoise icon → Low priority alarm
	Audio alarm paused The audible alarm has been paused for 2 min. The audible alarm of even a new alarm event will also be paused for 2 min. The audible alarm may be deactivated by pressing the alarm key before an alarm event occurs. Pressing the key again reactivates the audible alarm in case an alarm event has occurred.
	Counter "Audio alarm paused counter" Indicates how much longer the audible alarm will be paused.
	Key lock activated The functions of all controls are disabled, except for the ON/OFF and alarm key.
	A FiO_2 sensor is connected and "FiO_2-Monitoring" setting has been set to "Internal" in the system screen.
	The "FiO_2-Monitoring" setting has been set to "External" in the system screen. Measurement of oxygen concentration is performed using an external FiO_2-Monitoring unit.
	A FiO_2 sensor is connected, the "FiO_2-Monitoring" setting has been set to "Internal" in the system screen and oxygen is supplied.
	The "FiO_2-Monitoring" setting has been set to "External" in the system screen. Measurement of oxygen concentration is performed using an external FiO_2-Monitoring unit and oxygen is supplied.
	Spontaneous breathing detected The device has detected spontaneous breathing by the patient. This triggered the inspiration trigger. The icon will remain visible during inspiration and will shut off with the beginning of the expiration.

Icon	Meaning
	Trigger lock "On"
	Trigger lock momentarily active
	Switching on night screen (touch symbol)
	Switching off night screen (touch symbol)
	SD card is inserted into the device
	No SD card inserted into the device
	SpO_2 sensor connected
	PC is connected via the USB port
	**Error detected** Selecting this icon results in a list of all current errors (see "Error messages" on page180).
	Internal battery fully charged (1 bar ≙ 20 % of charge)  green bar → charge level ≥ 60 %  yellow bar → charge level ≥ 20 % ... < 60 %  red bar → charge level 0 % ... < 20 %
	Internal battery being charged

ENABLING A SCREEN

The following screens are accessible from the home screen:

- **Monitoring screen**
  Monitoring measurements (numerical and graphs)
- **Parameter screen**
  Ventilation and alarm parameters of the active ventilation mode
- **Alarm log screen**
  Display of alarms with time stamp and measurements
- **System screen**
  System settings, calibrations, counters and device information
- **Statistics screen**
  Statistical evaluation reports
- **Service screen**
  System calibration and tests for service work (PIN code protected)

A Selected screen icon

Figure 48: Home screen

To enable a screen:

1. Navigate to the desired screen by turning the MFK.

The selected screen icon → Black

Icon not selected → Blue

2. Press the MFK to activate the selected screen.

CHANGING THE TIMER SCREEN

The factory default setting of "Time Screen Change" is 120 seconds. The device switches 120 seconds after the last operation to the following screens:

- to the monitoring screen (measured values) during ventilation, or
- to the home screen in standby mode

This time can be set in the system screen. A screen switch can be disabled by setting the "Timer Screen Change" parameter to "Off".

MONITORING

In the monitoring screen the ventilation parameters are shown in real-time.

The monitoring screen is divided into three sections:

- Measurements
- Graphs
- Loops

MEASUREMENTS DISPLAY

The "Measurements" section displays the following ventilation parameters when ventilation is running:

- Pressure (p),
- Inspiration volume (V_I),
- Expiration volume (V_E),
- Minute ventilation (MV),
- Frequency (f)
- Inspiration to expiration ratio (I:E)
- FiO_2 concentration (FiO_2) (only using a FiO_2 sensor)
- Oxygen saturation (SpO_2) (only using an SpO_2 sensor)
- Heart rate (HR) (only using an SpO_2 sensor)

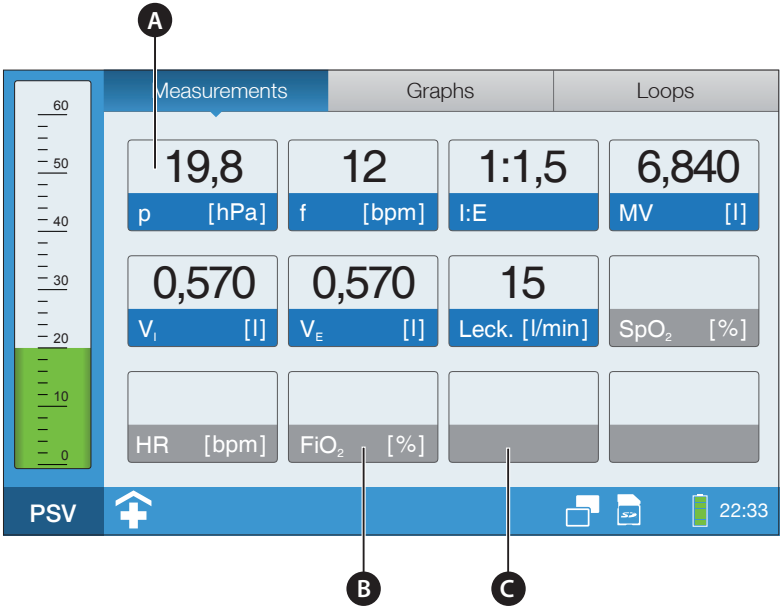
NOTICE

The measured values are displayed on the parameter screen during active ventilation (see page 126).

How to call up to the data:

1. Navigate to "Monitoring" in the home screen by turning the MFK:

2. Press the MFK.



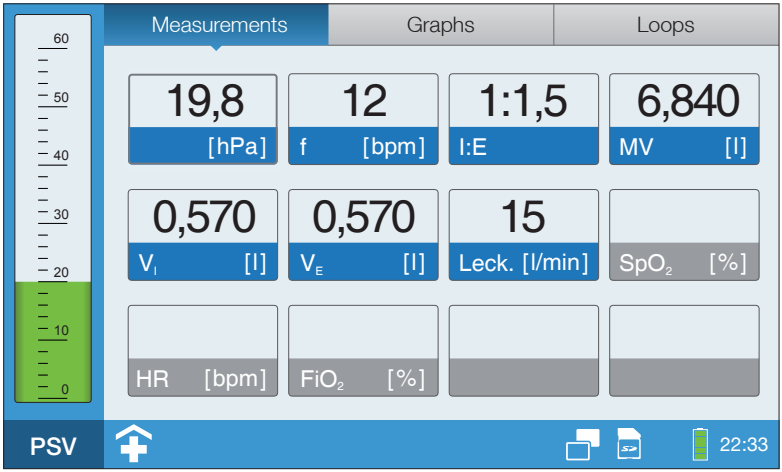
A configured neasuring value
B configured measuring value configured, sensor not connected
C no configured measuring value

Figure 49: Monitoring screen (data), factory setting

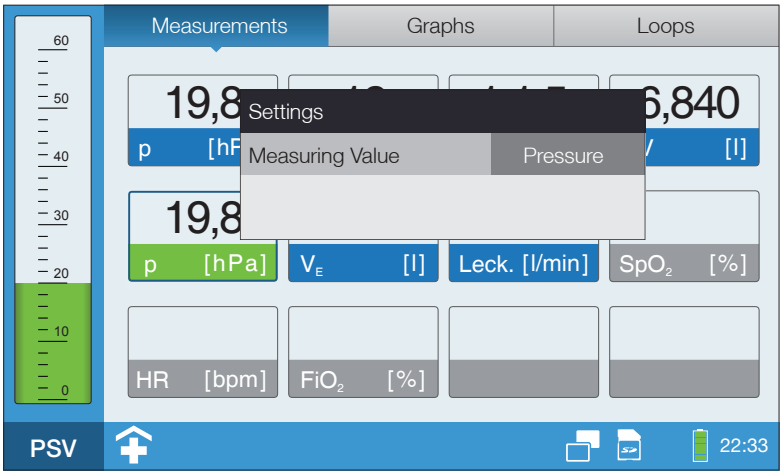
Figure 49 shows the factory default configuration. The measured value can also be configured as follows.

To configure the measured values:

1. Press the MFK. The first measured value box is marked.



2. Navigate to the measured value box that you would like to configure by turning the MFK. Press the MFK to activate the measured value box.
3. Change the measured value by turning the MFK.



4. Press the MFK to confirm the settings.

GRAPHS DISPLAY

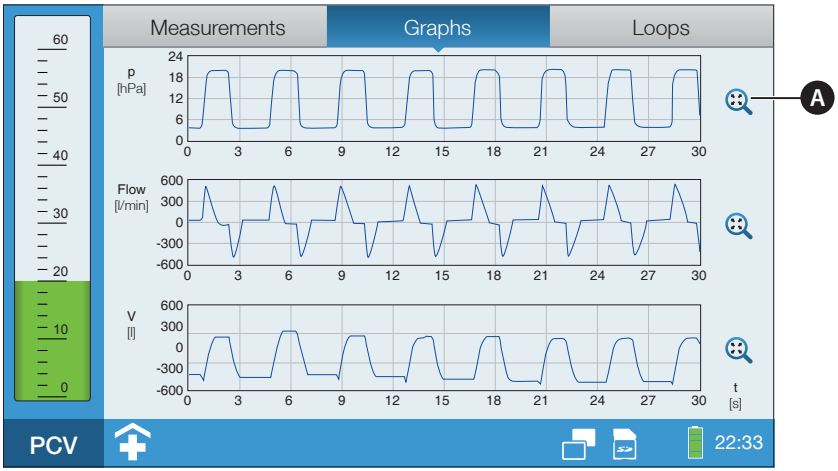
Depending on your settings, "Graphs" will graphically display the following ventilation parameters during running ventilation:

- Pressure (p),
- Flow ($\dot{V}$),
- Volume (V)
- Oxygen (FiO_2)

How to call up to the graphs:

1. Navigate to "Monitoring" in the home screen by turning the MFK:

2. Press the MFK.
3. Navigate to "Graphs" by turning the MFK.



A Automatic scaling is on

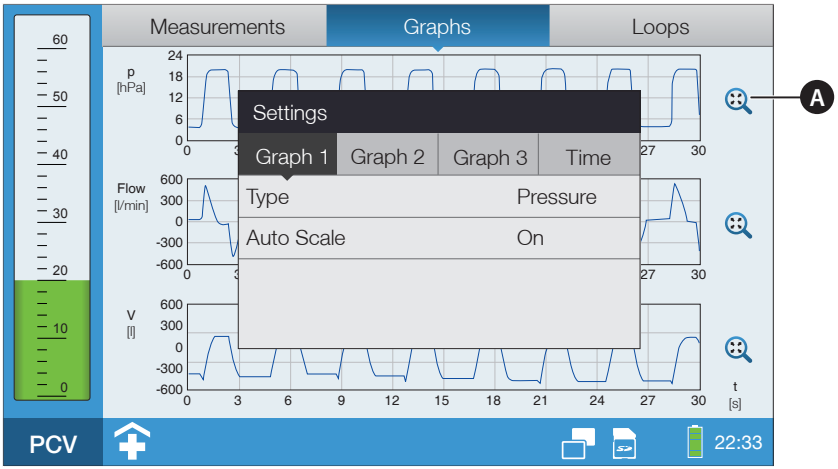
Figure 50: Monitoring screen (graphs)

The graphs can be set as follows:

- Number of graphs (1,2 or 3)
- Type of graph parameter
- Scaling
- Timescale

To change the graphs representation:

1. Press the MFK or touch the display.



A Automatic scaling is on

Figure 51: Monitoring screen (change the parameters)

2. You can switch between "Graph 1", "Graph 2", „Graph 3" and "Time" by turning the MFK.
3. Press the MFK.
4. Navigate to the desired line by turning the MFK.
5. Press the MFK to activate the line.
6. Change the parameter by turning the MFK.
7. Press the MFK to confirm the settings.

Freezing the real-time curve:

1. Press the pause symbol ❚❚.

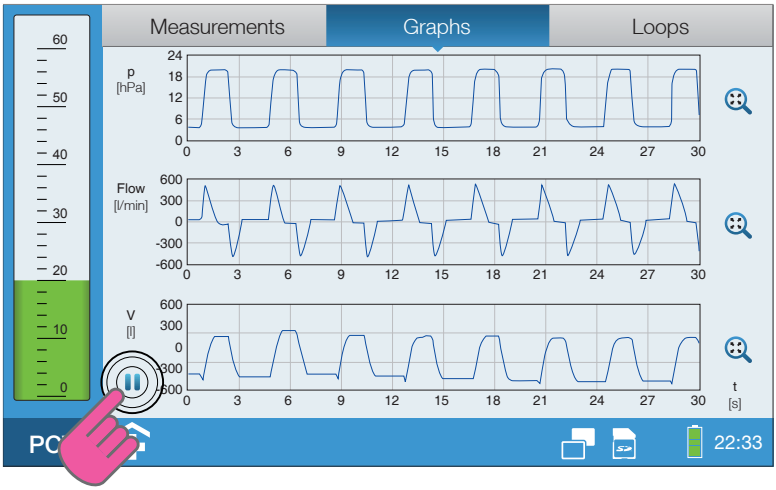


Figure 52: Monitoring screen (freeze graphs)

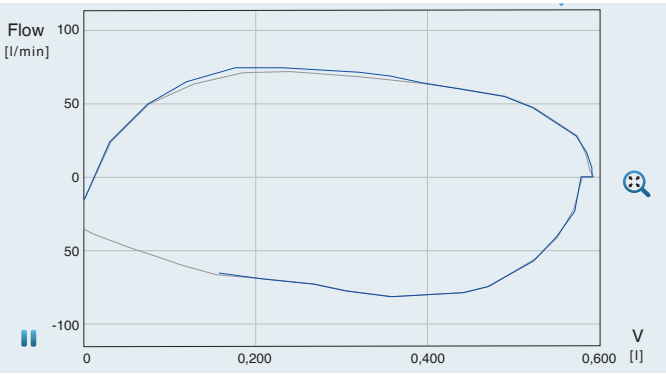
2. Press the start symbol to restart the real-time curve ▶.

DISPLAY LOOPS

Depending on your settings, you may display the following loops graphically in "Loops", while ventilation is running:

- Flow-Volume-Loop
- Volume-Pressure-Loop

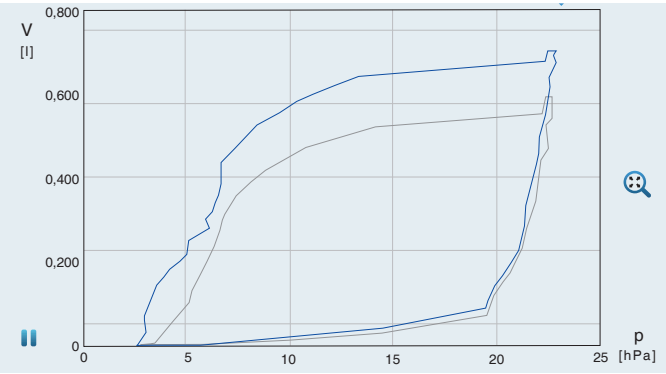
Flow-Volume-Loop



— Current breath — Last breath

Figure 53: Flow-Volume-Loop

Volume-Pressure-Loop



— Current breath — Last breath

Figure 54: Volume-Pressure-Loop

How to call up to "Loops":

1. Navigate to "Monitoring" in the home screen by turning the MFK.

2. Press the MFK.
3. Navigate to "Loops" by turning the MFK.

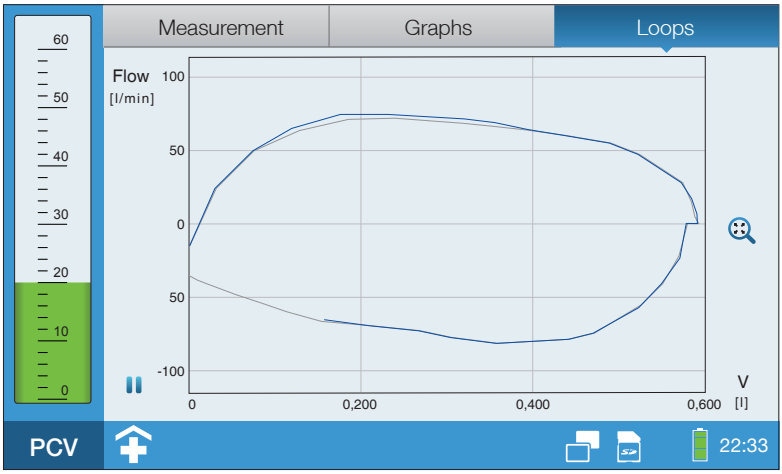


Figure 55: Flow-Volume-Loop

You can adjust the loop as follows:

- Type of loop
- Scaling

To change the loop representation:

1. Press the MFK or touch the display.

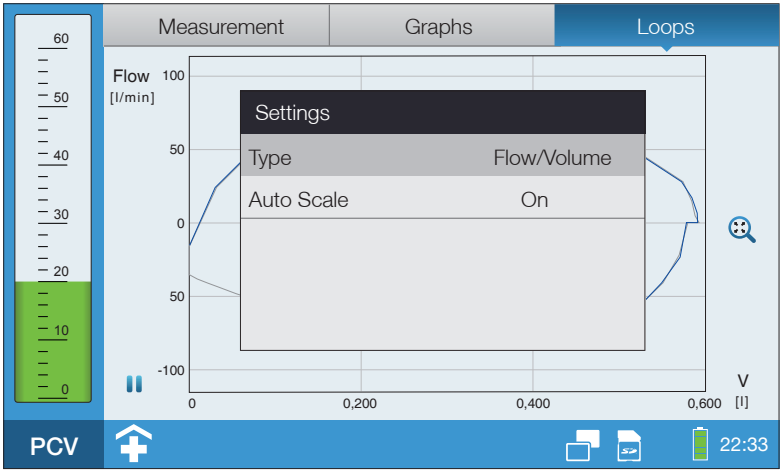


Figure 56: Monitoring screen (change the loop)

2. Navigate to the desired line by turning the MFK.
3. Press the MFK to activate the line.
4. Change the parameter by turning the MFK.
5. Press the MFK to confirm the setting.

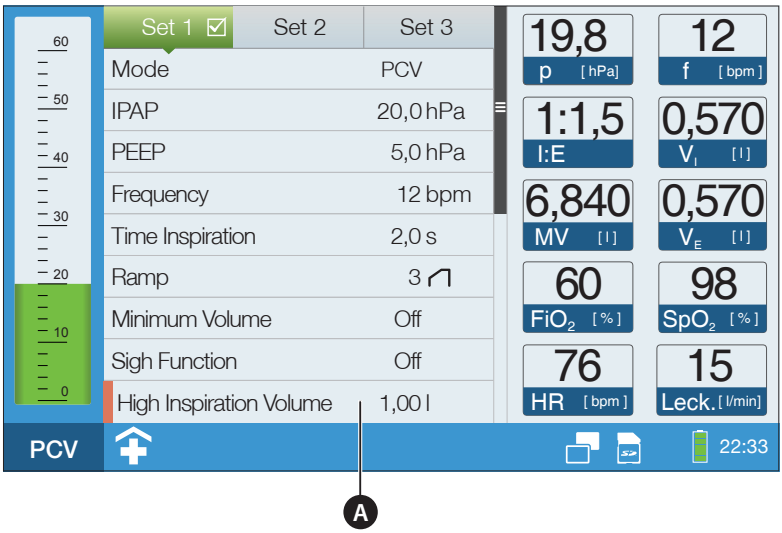
TO CHANGE VENTILATOR AND ALARM PARAMETERS

The adjustable alarm parameters are marked with an orange bar in contrast to the ventilation parameters. You can find a list of all adjustable alarms on page 155.

How to call up to the ventilator and alarm parameters:

1. Navigate to "Parameter" in the home screen by turning the MFK:

2. Press the MFK.

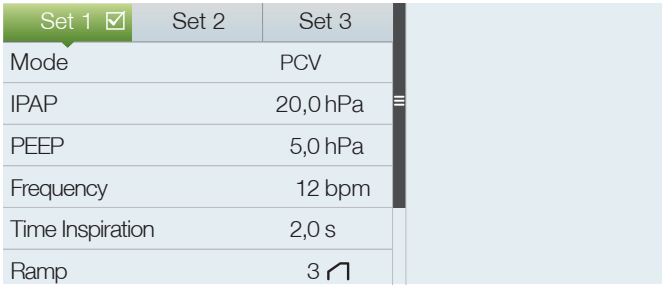


A Alarm parameter

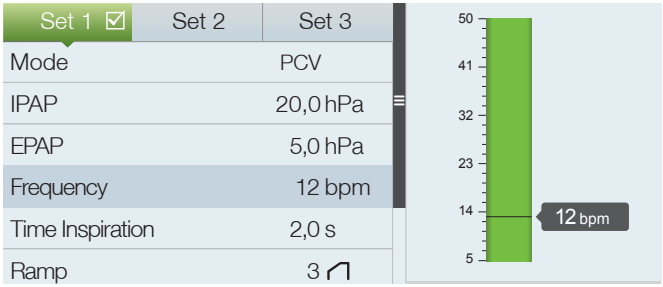
Figure 57: Parameter screen

How to change a ventilation or alarm parameter:

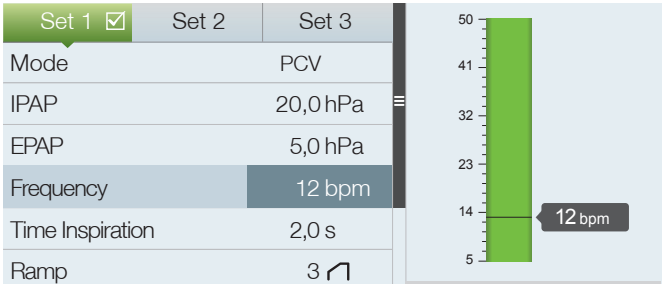
1. Select the set to be changed by turning the MFK.



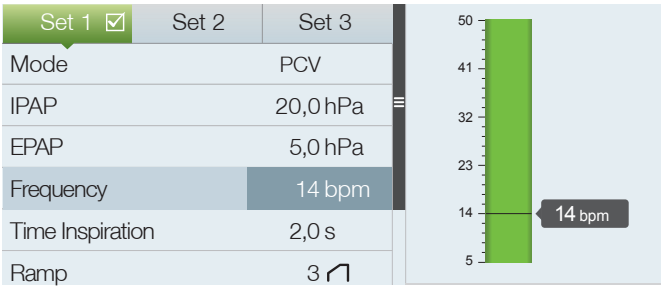
2. Press the MFK.
3. Navigate to the desired ventilation or alarm parameter by turning the MFK.



4. Press the MFK. The value is highlighted.



5. Change the setting by turning the MFK.



6. Press the MFK to confirm the new setting.

ACTIVATING A VENTILATION SET

How to call up to the set settings:

1. Navigate to "Parameter" in the home screen by turning the MFK

2. Press the MFK.

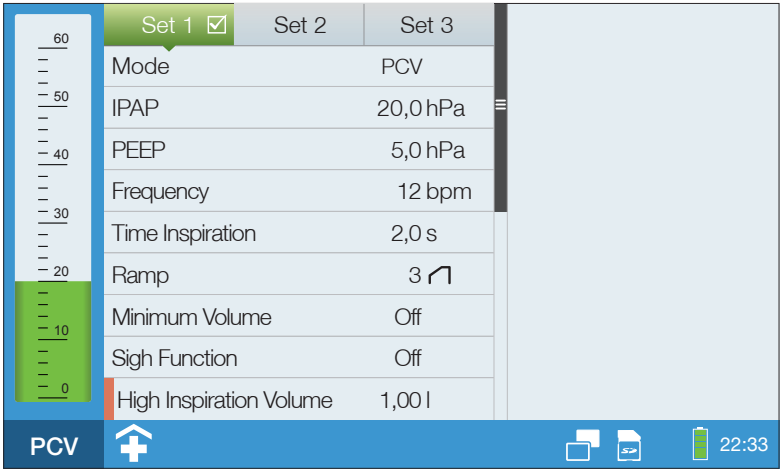
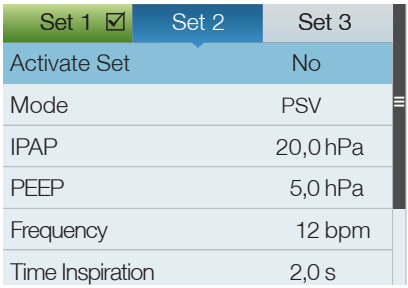


Figure 58: Parameter screen

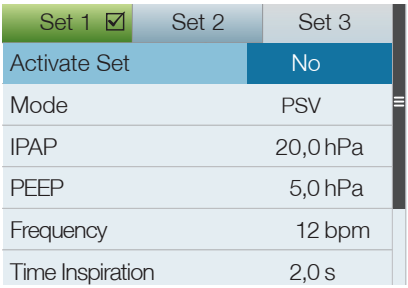
NOTICE
The active setting is highlighted in green and has a check mark ☑.

To activate a ventilation set:

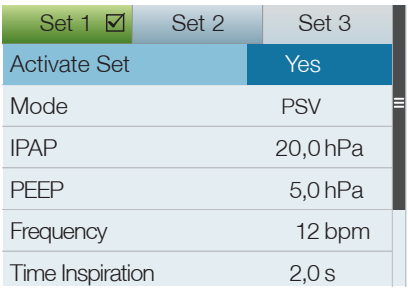
1. Navigate to the ventilation set you wish to activate by turning the MFK.



2. Press the MFK twice.



3. Change the setting to "Yes" by turning the MFK.



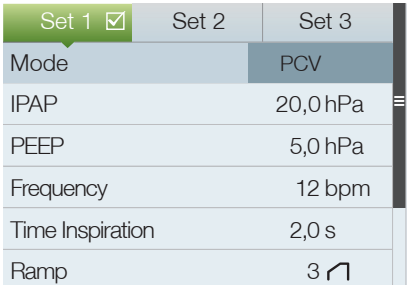
4. Press the MFK to confirm the new setting.

CHANGING A VENTILATION MODE DURING VENTILATION

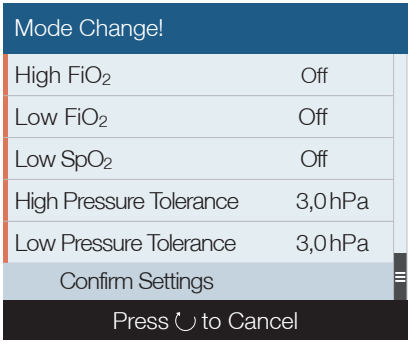
To change to ventilation mode:

1. Navigate to "Parameter" in the home screen by turning the MFK.

2. Navigate to the active ventilation set by turning the MFK.
3. Press the MFK twice.



4. Set the desired ventilation mode by turning the MFK.
5. Press the MFK.



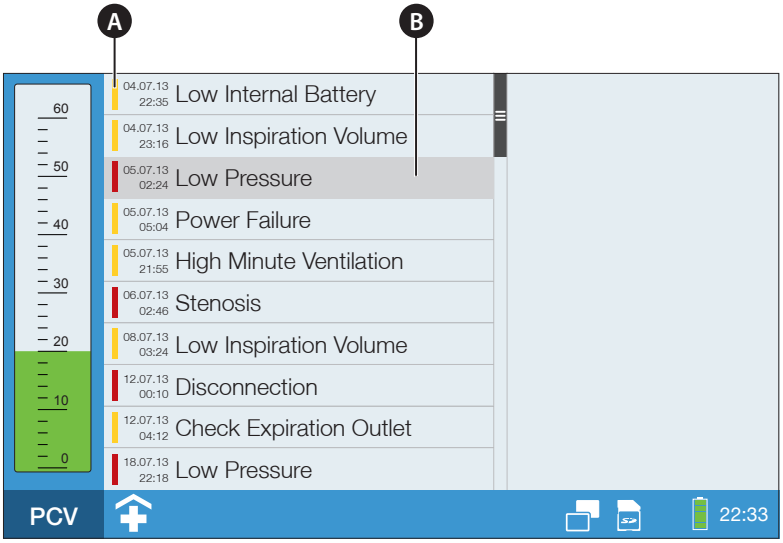
6. Make sure the ventilation and alarm parameters are adapted to the patient. Scroll to the "Confirm Settings" line and press the MFK.

DISPLAY OF STORED ALARMS

How to call up the alarm log screen:

1. Navigate to "Alarm log" in the home screen by turning the MFK.

2. Press the MFK.
3. You can scoll up and down the entries by turning the MFK.



A Alarm priority **B** Selected alarm

Figure 59: Alarm log screen

For more information on the alarms, refer to chapter "Alarms and messages" starting on page 149

SYSTEM SETTINGS

In the system screen basic device settings, calibrations and tightness check can be made. Selecting the system screen device information can be obtained.

Table 6: System Settings- Overview

Menu item	Explanation
Calibrate Tube	Calibrating the connected tube circuit (see page 55)
Calibrate O_2 Sensor	Calibrating the FiO_2 sensor (see page 69)
FiO_2-Monitoring	Setting, if oxygen concentration measurements are to be taken with internal FiO_2 monitoring or with external FiO_2 monitoring
Alarm Volume	Volume of the primary alarm sound
Night Screen	Setting the night screen layout
Timer Screen Change	The device switches to the home screen (during standby) and to the monitoring screen (during ventilation) after the last operation and set "Time Screen Change".
Brightness Display	Brightness of the display
Brightness LEDs	Brightness of the alarm LED, power LED and battery LED
Brightness MFK	Background lighting brightness of the multifunctional knob
Language	Setting the device language
Pressure Unit	Setting the device pressure unit
Volume Unit	Setting the volume unit
Display Time Insp.	Setting to etablish whether the inspiration time can be set in seconds or as I:E ratio in the parameter screen
Date and Time	Date and time settings
Number of Ventilation Sets	Setting to etablish how many ventilation sets is displayed in the parameter screen
User Profile	Setting the user profile Clinic: full access to all settings Home: restricted access to the settings
Tightness Check	Here you can perform a tightness check. The tightness check serves to detect leaks in the tube circuit (see page 139)
Recent Ventilation Hours	Ventilation hours since the last reset(see page 141)

Table 6: System Settings- Overview

Menu item	Explanation
Ventilation Hours Total	Total ventilation hours (can be reset with PC software)
Operating Counter	Ventilation hours + Standby hours
Blower Service in	Number of hours after which the blower must be replaced
SW-Version	Software version of the device
Serial Number	Serial number of the device

SYSTEM SETTING CHANGES

How to call up to the system settings:

1. Navigate to the home screen by turning the MFK to "System":

2. Press the MFK.

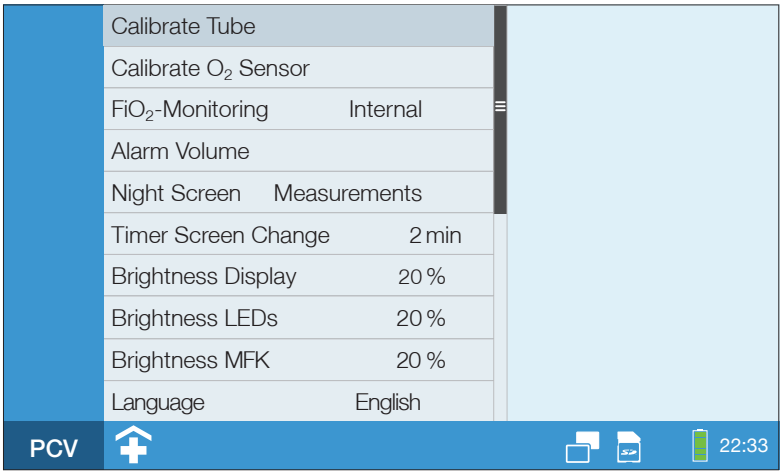


Figure 60: System screen

To change the system settings (e.g. alarm volume):

1. Navigate to the desired parameter by turning the MFK.

Calibrate Tube	
Calibrate O_2 Sensor	
FiO_2-Monitoring	Internal
Alarm Volume	3

2. Press the MFK.

Calibrate Tube	
Calibrate O_2 Sensor	
FiO_2-Monitoring	Internal
Alarm Volume	3

3. Change the setting by turning the MFK.

Calibrate Tube	
Calibrate O_2 Sensor	
FiO_2-Monitoring	Internal
Alarm Volume	1

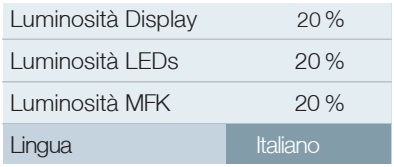
4. Press the MFK to confirm the new setting.

CHANGING THE DEVICE LANGUAGE

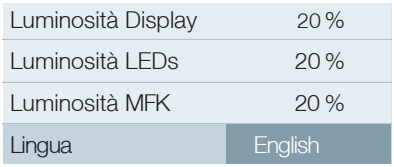
To change the device language setting:

1. Navigate to the 10th menu item by turning the MFK.

2. Press the MFK.



3. Change the language setting by turning the MFK.



4. Press the MFK to confirm the new setting.

The following list supports you to find the menu item "Language", in case of your language is not set:

Sprache	Deutsch
Γλωσσα	Ελληνικά
Language	English
Langue	français
Idioma	Español
Lingua	Italiano
Język	Polski
Dil	Türk
语言	中文

DATE AND TIME CHANGES

To change the date and time:

1. Navigate to "System" in the home screen by turning the MFK:

2. Press the MFK.
3. Navigate to "Date and Time" by turning the MFK.

Date and Time	13.02.16 10:36
Number Ventilation Sets	3
User Profile	Clinic
Tightness Check	
Recent Ventilation Hours	65 h
Ventilation Hours Total	342 h
Operating Counter	622 h

4. Press the MFK.

Date and Time	13.02.14 10:36	Year	2016
Number Ventilation Sets	3	Month	2
User Profile	Clinic	Day	13
Tightness Check		Hour	10
Recent Ventilation Hours	65 h	Minute	36
Ventilation Hours Total	342 h		
Operating Counter	622 h		

5. Navigate to the desired parameter by turning the MFK.

Date and Time	13.02.16 10:36	Year	2016
Number Ventilation Sets	3	Month	2
User Profile	Clinic	Day	13
Tightness Check		Hour	10
Recent Ventilation Hours	65 h	Minute	36
Ventilation Hours Total	342 h		
Operating Counter	622 h		

6. Press the MFK.

Date and Time	13.02.16 10:36	Year	2016
Number Ventilation Sets	3	Month	2
User Profile	Clinic	Day	13
Tightness Check		Hour	10
Recent Ventilation Hours	65 h	Minute	36
Ventilation Hours Total	342 h		
Operating Counter	622 h		

7. Change the setting by turning the MFK.

Date and Time	13.02.16 10:36	Year	2016
Number Ventilation Sets	3	Month	2
User Profile	Clinic	Day	28
Tightness Check		Hour	10
Recent Ventilation Hours	65 h	Minute	36
Ventilation Hours Total	342 h		
Operating Counter	622 h		

8. Press the MFK to confirm the new setting.

PERFORMING A TIGHTNESS CHECK

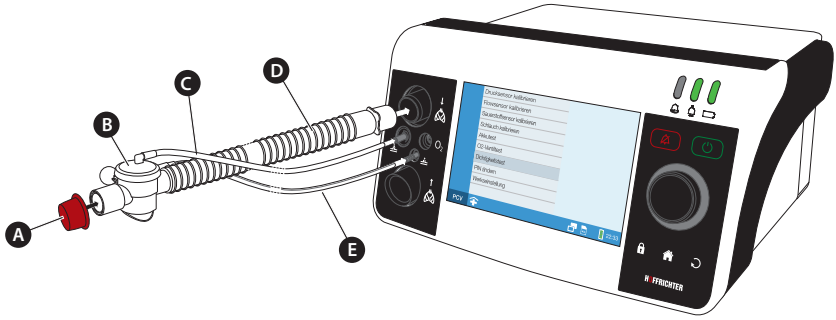
The tightness check serves to detect leaks in the the tube cicuit.

NOTICE

Hold on to the end cap during the tightness check and do not direct the tube at anyone.

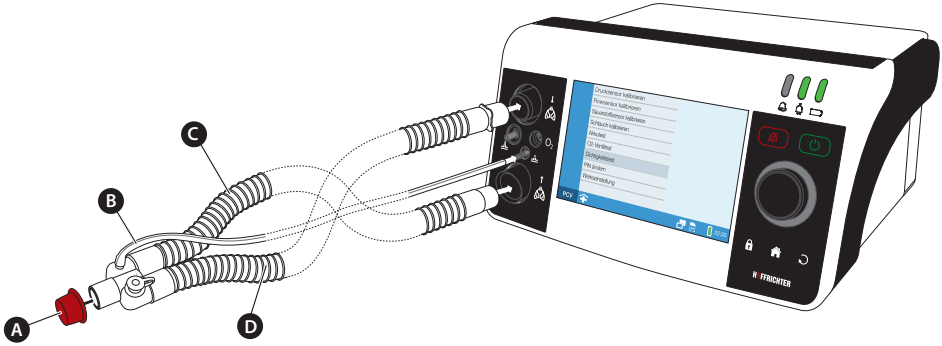
To perform the tightness check:

1. Connect the tube circuit to the device.



A End cap (supplied with the tube circuit) **B** Expiration valve
C Control tube **D** Ventilation tube **E** Pressure measuring tube

Figure 61: Circuit configuration tightness check single line patient circuit

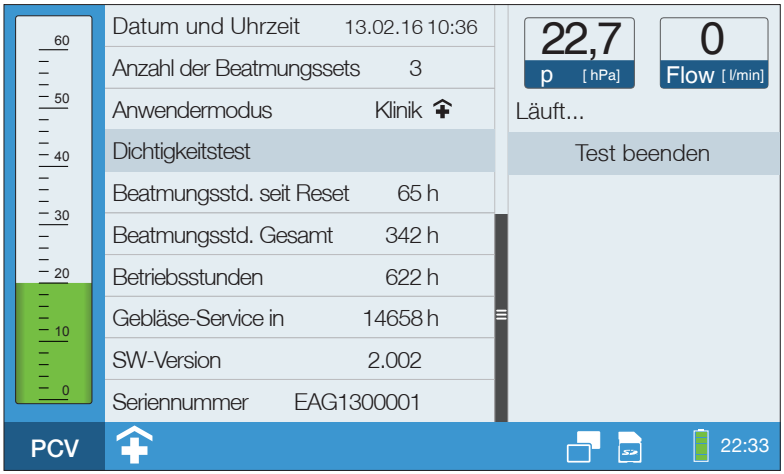


A End cap (supplied with the tube circuit) **B** Pressure measuring tube
C Expiration section **D** Inspiration section

Figure 62: Circuit configuration tightness check double line patient circuit

2. Navigate to the home screen by turning the MFK to "System":

3. Press the MFK.
4. Navigate to "Tightness Check" by turning the MFK.
5. Press the MFK



The pressure is gradually inceased to the maximum pressure by the device. Observe the flow value. If the flow value exceeds 5 l/min during the tightness check, there is a leak in the tube circuit. In that case, check the entire circuit for leaks in tubes and at tube connections. As long as the flow remains under 5 l/min the tightness check is positive. Press the MFK to complete the test.

NOTICE

If the pressure (p) exceed 60 hPa during the tightness check, the device must be returned for servicing.

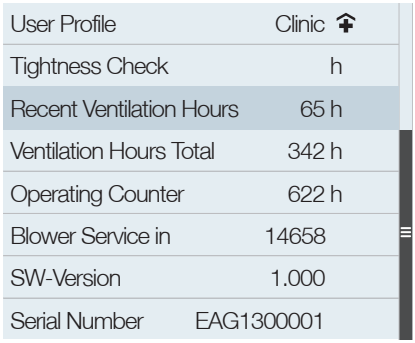
RESETTING VENTILATION HOURS

The ventilation operational period is displayed in the system screen as "Total Ventilation Hours". In addition, there is a ventilation hours counter, which can be reset by the user. The counter is located in the system screen as "Recent Ventilation Hours“.

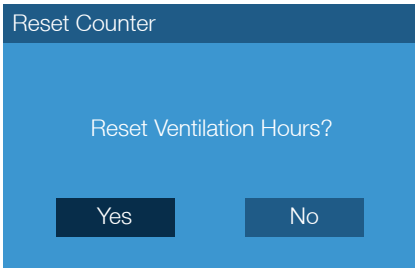
To reset the ventilation hours:

1. Navigate to "System" in the home screen by turning the MFK:

2. Press the MFK.
3. Navigate to "Recent Ventilation Hours" by turning the MFK.



4. Press the MFK.
5. Navigate to "Yes" by turning the MFK.



6. Press the MFK.

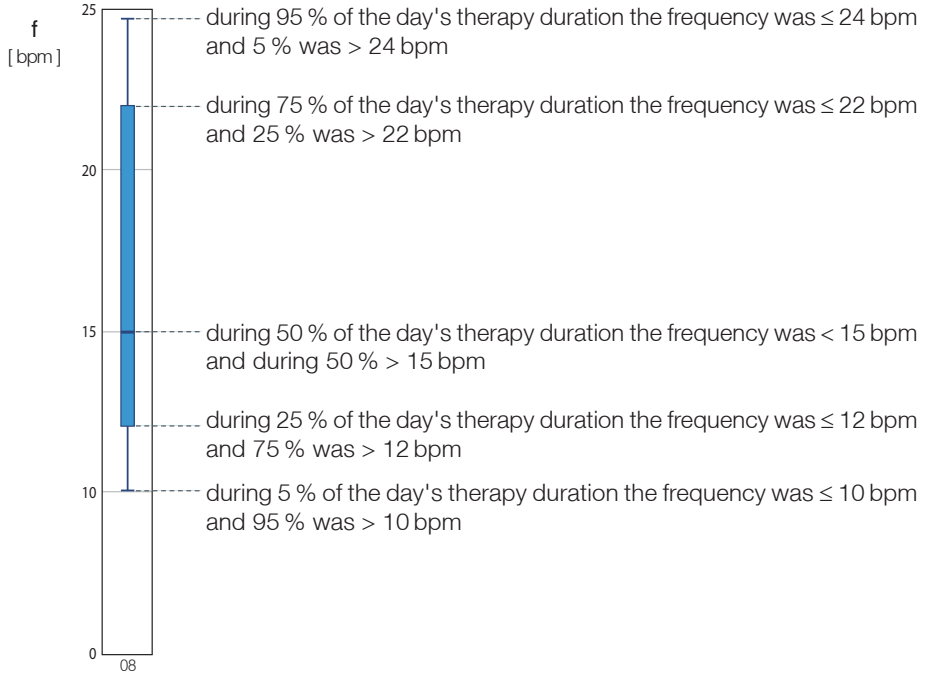
STATISTICS

The statistics screen contains statistical evaluations of the following ventilation parameters.

- Minute volume
- Frequency
- SpO_2
- Leak Rate
- Tidal Volume
- I:E Ratio

The evaluation of the ventilation parameters is based on percentiles. Percentiles are the dispersion measurement of the statistical data distribution during ventilation sessions.

An example based on frequency



How to call up to the statistical values:

1. Navigate to the home screen by turning the MFK to "System":

2. Press the MFK.

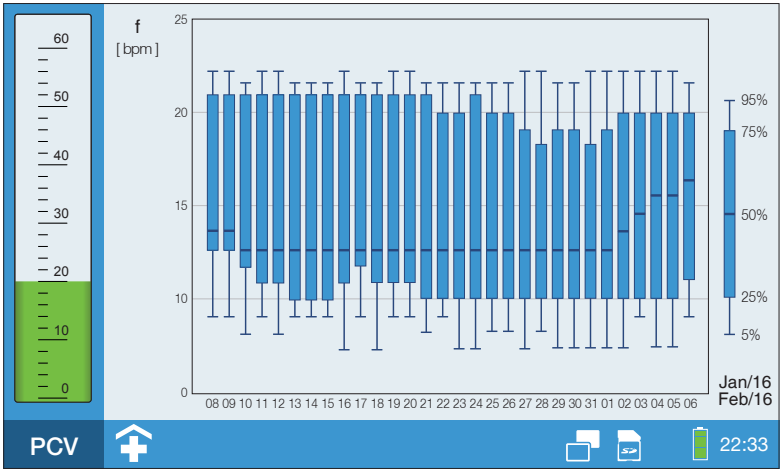


Figure 63: Statistics screen (1 ventilation parameter)

In the statistics screen you can set if the statistics of 1 or 2 ventilation parameters are to be displayed.

Setting for statistics to be displayed:

1. Press the MFK or touch the display.

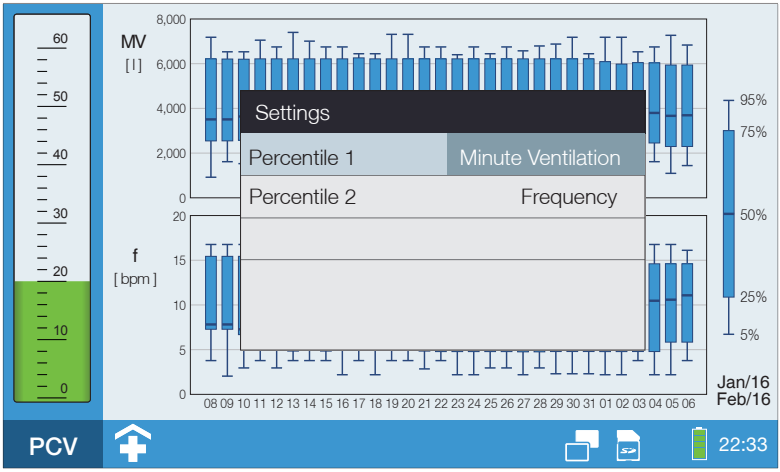


Figure 64: Statistics screen (2 ventilation parameter)

2. You can switch between "Percentile 1" and "Percentile 2" by turning the MFK.
3. Press the MFK to activate the line.
4. Change the parameter by turning the MFK.
5. Press the MFK to confirm the settings.

NIGHT SCREEN

In a dark environment, the brightness of the display is often perceived as disturbing. The night screen provides a remedy. Due to the reduced backlighting, the display no longer shines as brightly. Furthermore, the MFK lighting is deactivated and the mains LED and the battery LED are darkened. Nevertheless, all important functions such as the pressure bar and toolbar are very easy to read.

The night screen is displayed both in standby mode and during ventilation.

NIGHT SCREEN LAYOUT SETTING

The following night screen layouts can be set in the system screen:

- "Measurements"
- "Light" (with moon)
- "Dark" (without moon)

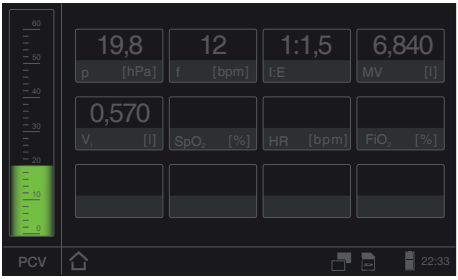


Figure 65: "Measurements" night screen

Figure 66: "Light" night screen (with moon)

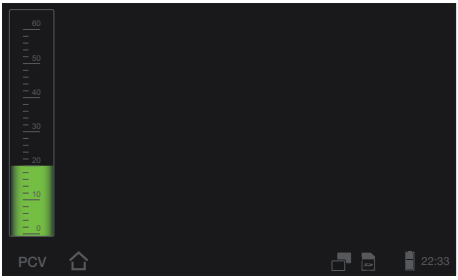


Figure 67: "Dark" night screen (without moon)

To change the layout of the night screen:

1. Navigate to the home screen by turning the MFK to "System".

2. Press the MFK.
3. Navigate to "Night Screen" by turning the MFK and then press the MFK.
4. Change the parameter by turning the MFK to "Measurements", "Light" or "Dark".
5. Press the MFK to confirm the setting.

SWITCHING THE NIGHT SCREEN ON AND OFF

To switch on the night screen:

Touch  in the toolbar (see page 111).

To switch off the night screen:

Touch  in the toolbar (see page 111) or press any control element (except Safe key).

STARTING VENTILATION

⚠WARNING
The expiration valve air outlet has to be open during running ventilation. Make sure that the opening is not blocked as the expired air will be unable to escape and will affect the ventilation process.

1. Switch on the device using the main power switch on the rear of the device
2. Press the ON/OFF key . Ventilation begins.

STOPPING VENTILATION

1. Press the ON/OFF key .

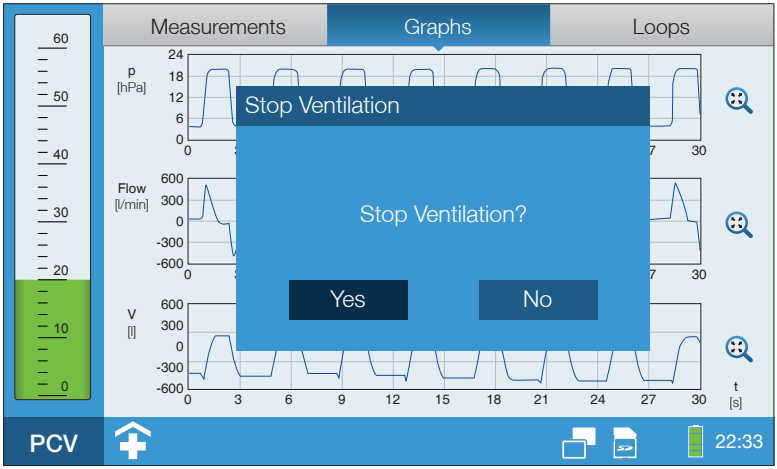


Figure 68: Stop ventilation

2. Navigate to "Yes" by turning the MFK.
3. Press the MFK.

CHAPTER 7
ALARMS AND MESSAGES

This chapter describes alarms and messages, their cause, and what measures need to be taken in case of an alarm event.

GENERAL INFORMATION

⚠CAUTION
The device must be operated so that the alarm is audible and visible by the user. Audible alarms can be forwarded using the nurse call or the alarm box.

The CARAT II pro ventilator is equipped with fixed and adjustable alarms, relating to the respective ventilation modes.

There are 3 alarm priorities:

Alarm priority	What action is required?
HIGH	Immediate action is required. Monitor the patient and the cause of the alarm closely.
MEDIUM	Fast action is required for medium priority alarms. Correct the cause of the alarm.
LOW	User attention is requested for low-priority alarms. Low-priority alarms indicate a change at "normal" device operation. Check the cause of the alarm.

NOTICE
Alarms will lowered in the priority when the alarm event is no longer fulfilled. The alarm will stay in active until it has been confirmed with the alarm key.

ALARM SOUND TEST

A hardware test is performed with each device start-up. The primary and secondary alarm sound transmitters are tested (see page 42). Both alarm sound transmitters must emit a short beep in sequence. Otherwise, an error message is issued and the device must be returned for servicing.

AUDIBLE ALARM OUTPUT (AUDIO ALARMS)

Audio alarms are issued in a sequence of beeps. Alarm tones differ depending on alarm cause and priority. For more information, please see page 155.

If the alarm sound equipment is defective and emits no sound, the audible alarms will be triggered by a second alarm sound transmitter which emits only a simple audible alarm.

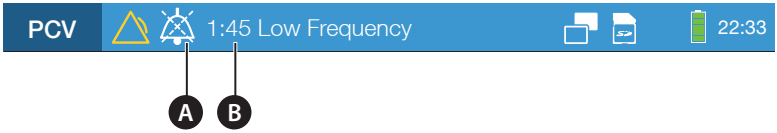
NOTICE
Audio alarms will switch off when the alarm event is no longer fulfilled.

TO TEMPORARILY MUTE AUDIO ALARMS (AUDIO ALARM PAUSED)

Audio alarms can be muted for 2 minutes by pressing the alarm key (audio alarm paused). If this function is enabled, the audible alarm created by new alarm events will also be suppressed as well. The alarm LED will visibly indicate an alarm event, even when the audible alarm has been temporarily suppressed. If the cause of the alarm is not corrected, the audible alarm will sound again after two minutes.

The audio alarm may also be suppressed by pressing the alarm key even before an alarm event occurs, e.g. before the tube circuit is temporarily disconnected for suctioning the patient. The audio alarm can be reactivated after correcting the alarm cause, even within the two minute period, by pushing the alarm key again.

The "Audio alarm paused" icon will indicate when the audio alarm is temporarily switched to mute. The counter tracks the time until the audio alarm will sounds again.



A "Audio alarm paused" icon **B** "Audio alarm paused" counter

Figure 69: Alarm displays in the toolbar

NOTICE
The "Internal Battery Empty" audible alarm cannot be set to pause while the device is in battery operation.

AUDIO ALARMS VOLUME

The audio alarm volume can be set to 3 levels in the system screen:

- Level 1 → low volume (55 dB)
- Level 2 → medium volume (60 dB)
- Level 3 → high volume (65 dB)

The volume of levels 1 and 2 are automatically raised to a level 3 in case the alarm event still exists after 1 minute of audible alarm.

VISIBLE ALARM OUTPUT

Visible alarms are displayed as follows:

- via the alarm LED
- in the toolbar
- as a textbox
- lighting up the multifunctional knob

ALARM OUTPUT VIA THE ALARM LED

The alarm LED may take on 3 different statuses, to signify the current alarm priority.

- Red, flashes rapidly (2 Hz) → high-priority alarm
- Yellow, flashes (0.5 Hz) → medium-priority alarm
- Turquoise, glows steadily → low-priority alarm

If multiple alarms are triggered simultaneously or in quick succession, the alarm with the highest priority will be displayed first.

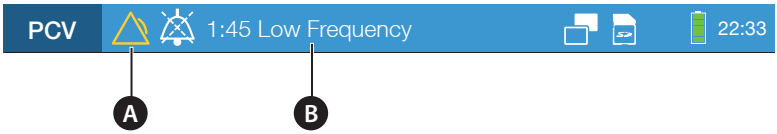
More information on alarm LEDs is available on page 37.

ALARM OUTPUT IN THE TOOLBAR

Alarms are shown in the toolbar by the "Alarm active" icon and displayed with an alarm message. The icon's color indicates the alarm priority:

- Red icon → high-priority alarm
- Yellow icon → medium-priority alarm
- Turquoise icon → low-priority alarm

If multiple alarms are triggered simultaneously or in quick succession, the alarm with the highest priority will be displayed first.



A "Alarm active" icon **B** Alarm

Figure 70: Alarm output in the toolbar

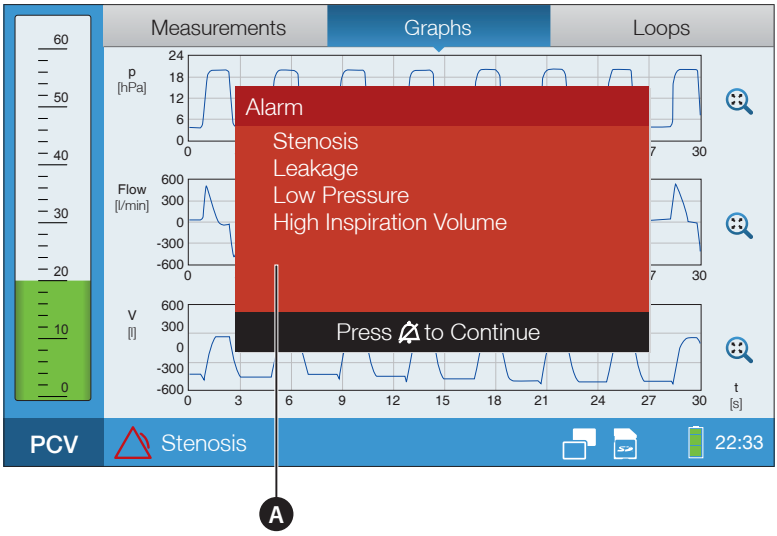
ALARM OUTPUT AS A TEXTBOX

120 seconds after the last performed operation the alarms will also display in a textbox as well. The textbox will disappear as soon as you press the alarm key.

The textbox color corresponds to the highest priority alarm:

- Red textbox → high-priority alarm
- Yellow textbox → medium priority alarm
- Turquoise textbox → low-priority alarm

If multiple alarms occur at the same time the alarms are sorted and displayed in order of priority.



A Textbox

Figure 71: Alarm output in the textbox

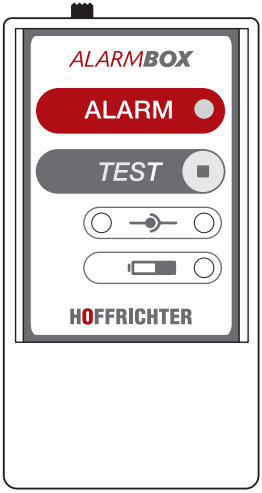
ALARM OUTPUT VIA THE MULTIFUNCTIONAL KNOB

The backlighting of the MFK either glows steadily or flashes in the event of an alarm, depending on the alarm priority (only when " MFK brightness" > 0 %).

ALARM LOG

The device stores the last 50 alarm events. When additional alarms occur, the oldest entry will be overwritten. You can view the alarms in the alarm log screen. For more information, please refer to page 59.
Alarms are permanently stored even during a complete power failure.

FORWARDING ALARMS



Alarms can be forwarded by using a nurse call or the optionally available alarm box. This allows even better monitoring of the device at the home or clinic. The use of the remote alarm box or a nurse call is especially recommended when several ventilators are used in one room, as this allows the device generating the alarm to be easily identified. The alarms will be forwarded without delay to the nurse call or the alarm box.

Instructions on how to connect the HOFFRICHTER alarm box or nurse call can be found on page 59.

Figure 72: Alarm box

NOTICE
The alarm box is an optional accessory to facilitate remote output of the alarm. It does not replace monitoring of the ventilator's primary alarm sound!

ALARM OVERVIEW

ADJUSTABLE ALARMS

The adjustable alarms are physiologically conditional alarms. You can set the alarm limits in the parameter screen (see page 126).

Table 7: Adjustable alarms

Alarm	Priority	Audible alarm	LED alarm Status	Cause	Time delay
Apnoea	HIGH	c a f – a f	Red - flashes	Set time ("Apnoea Alarm") has been exceeded	None
High FiO_2	MEDIUM	C b a	Yellow - flashes	The FiO_2 measured is higher than the set "High FiO_2"	None
Low FiO_2	MEDIUM	C b a	Yellow - flashes	The FiO_2 measured is lower than the set "Low FiO_2"	None
High Leak Rate	MEDIUM	c a f	Yellow - flashes	Double line circuit: Difference between expiration and inspiration volume is higher then the set "Leak Rate" value	for 3 breaths in a row
				Single and double line circuit: when $V_I > 2{,}54$ l	for 3 breaths in a row
High Pressure	MEDIUM	c a f	Yellow - flashes	Pressure is higher than the set "High Pressure Tolerance"	for 3 breaths in a row
	HIGH	c a f – a f	Red - flashes	Pressure is higher than the set "High Pressure Tolerance"	for 10 breaths in a row
Low Pressure	MEDIUM	c a f	Yellow - flashes	Pressure is lower than the set "Low Pressure Tolerance"	for 3 breaths in a row
	HIGH	c a f – a f	Red - flashes	Pressure is higher than the set "Low Pressure Tolerance"	for 10 breaths in a row

Table 7: Adjustable alarms

Alarm	Priority	Audible alarm	LED alarm Status	Cause	Time delay
High Frequency	MEDIUM	c a f	Yellow - flashes	Measured frequency is higher than the "High Frequency"	for 3 breaths in a row
Low Frequency	MEDIUM	c a f	Yellow - flashes	Measured frequency is lower than the "Low Frequency"	for 3 breaths in a row
High Inspiration Volume	HIGH	c a f – a f	Yellow - flashes	Tidal volume is higher than the "High Inspiration Volume"	for 3 breaths in a row
Low Inspiration Volume	MEDIUM	c a f	Yellow - flashes	Tidal volume is lower than the "Low Inspiration Volume"	for 3 breaths in a row
High Minute Ventilation	MEDIUM	c a f	Yellow - flashes	Ventilation minute volume is higher than the "High Minute Ventilation"	for 3 breaths in a row
Low Minute Ventilation	MEDIUM	c a f	Yellow - flashes	Ventilation minute volume is lower than the "Low Minute Ventilation"	for 3 breaths in a row
High Expiration Volume	MEDIUM	c a f	Yellow - flashes	Expiration volume is higher than the "High Expiration Volume"	for 3 breaths in a row
Low Expiration Volume	HIGH	c a f – a f	Yellow - flashes	Expiration volume is lower than the "Low Expiration Volume"	for 3 breaths in a row
High SpO_2	MEDIUM	C b a	Yellow - flashes	Measured SpO_2 is higher than the "High SpO_2"	None
Low SpO_2	MEDIUM	C b a	Yellow - flashes	Measured SpO_2 is lower than the "Low SpO_2"	None
High Heart Rate	MEDIUM	C b a	Yellow - flashes	Measured Pulse is higher than the "High Heart Rate"	None
Low Heart Rate	MEDIUM	C b a	Yellow - flashes	Measured Pulse is lower than the "Low Heart Rate"	None

FIXED ALARMS

The fixed alarms are technically conditional alarms. Alarm conditions are built into the device and are non-adjustable by the user.

Table 8: Fixed Alarms

Alarm	Priority	Audible alarm	State of the alarm LED	Cause	Correction
Error Internal Battery	HIGH	c c c – c c	Red - flashes	Defective battery	Device must be serviced
Overcurrent fuse	HIGH	C c c – C c	Red - flashes	Motor current too high	Restart the device, in the event of a recurrence the device must be serviced
Stenosis	HIGH	c a f – a f	Red - flashes	No flow for more than 3 breaths	Check tube circuit and tubing for obstructions
Error Internal Communication	HIGH	c c c – c c	Red - flashes	Communication with the control unit has been interrupted for more than 10s	Restart the device, in the event of a recurrence the device must be serviced.
Disconnect	HIGH	c a f – a f	Red - flashes	Inspiration- and/ or expiration lines of the tube circuit are not connected to the device	Connect the inspiratory and/ or expiration line to the device
				Flow sensor is defective	Device must be serviced
Internal Battery Empty	HIGH	C c c – C c	Red - flashes	Battery empty (Current state of charge of the battery = 0 %)	Battery must be recharged; maximum 1 minute left until complete mains failure; ventilation process will only be possible with external power supply

Table 8: Fixed Alarms

Alarm	Priority	Audible alarm	State of the alarm LED	Cause	Correction
Over Pressure	MEDIUM	c a f	Yellow - flashes	Over pressure detected throughout 3 breaths or 15s	Device must be serviced, or check if the alarm may have been triggered by the patient coughing
Battery Operation	MEDIUM	C c c	Yellow - flashes	Mains power supply has failed, the device is running on battery power	Restore mains power supply
Low Internal Battery	MEDIUM	C c c	Yellow - flashes	Device operating on battery power supply, battery charge ≤ 10 %	Battery must be recharged; Alarm remains, until the battery charge is > 10 %
Mains Failure	MEDIUM	C c c	Yellow - flashes	Power supply from the mains (AC) connection has failed	Restore mains power supply
Check Tube System	MEDIUM	c a f	Yellow - flashes	Expiratory flow during inspiration detected or expiration flow too low during expiration	Check control tube connection on the device and the tube circuit
					Check expiration outlet
				Measurement tube kinked or not connected to the device	Check for kinks in the measuring tube
					Check measuring tube at the device
				Flow sensor is defective	Device must be serviced

Table 8: Fixed Alarms

Alarm	Priority	Audible alarm	State of the alarm LED	Cause	Correction
Error FiO_2 sensor [1]	MEDIUM	C b a	Yellow - flashes	FiO_2 sensor disconnected from the decice	Connect the FiO_2 sensor to the device
Check SpO_2 sensor [2]	MEDIUM	C b a	Yellow - flashes	SpO_2 sensor disconnected from the decice	Connect the SpO_2 sensor to the device
				SpO_2 sensor disconnected from the patient	Connect the SpO_2 sensor to the patient

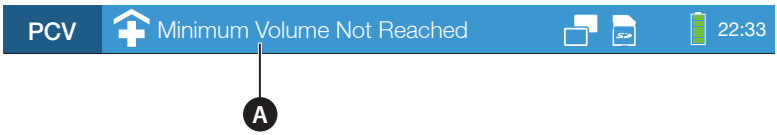
1 The alarm message is only possible, if at least one of alarms “High FiO_2“ or “Low FiO_2” is enabled.

2 The alarm message is only possible, if at least one of alarms “High SpO_2”, “Low SpO_2”, “High Heart Rate“ oder “Low Heart Rate” is enabled.

MESSAGES

MESSAGE DISPLAY IN THE TOOLBAR

Messages are displayed in the toolbar. When an alarm occurs, the alarm is displayed instead of the message, since the alarm has a higher priority.



A Message

Figure 73: Messages in the toolbar

MESSAGES OVERVIEW

Table 9: Messages

Messages	Cause	Time delay
Back-up Frequency Active	Device operates in PSV mode, patient has no spontaneous breath and is ventilated at the set frequency	None
Minimum Volume Not Reached	Measured minimum volume lower than set "Minimum Volume"	3 breaths in a row

CHAPTER 8

CLEANING AND DISINFECTION

- Before cleaning the device, remove the power plug from the power supply.
- If ventilation is running, insert a spare coarse filter for the duration of the cleaning or insert a complete replacement filter cassette into the device.
- Hygienically preparing and cleaning the device must be performed according to the user's manual and the applicable regulations of the hospital or nursing home.
- The device cannot be sterilized by using standard sterilization methods.
- Do not use any aggressive or abrasive cleaning agents (e. g., acetone).
- Do not immerse the device in water or solvents.
- Follow the accessory manufacturer's instructions for cleaning and disinfection.

OVERVIEW

The following overview table describes the cleaning intervals of articles delivered by HOFFRICHTER. For articles by other manufacturers, please follow their cleaning instructions.

Table 10: Cleaning intervals - overview

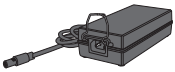
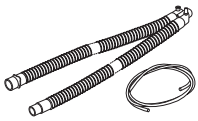
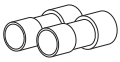
Component	Name	Clean	Disinfect	Replace
	CARAT II pro Ventilator	As needed	With every new patient	-
	Power supply unit	As needed	With every new patient	-
	Mains cable	As needed	With every new patient	-
	Disposable double line circuit	No	No	Every change of patient In accordance with manufacturer instructions
	Mask	Daily	No	Every change of patient In accordance with manufacturer instructions
	Adapter for bacterial filters	As needed	With every new patient	Every change of patient
	Oxygen connection adapter	As needed	No	Every change of patient
	Carrying case	As needed	No	Every change of patient

Table 10: Cleaning intervals - overview

Component	Name	Clean	Disinfect	Replace
	Filter cassette (without filter)	As needed	With every new patient	-
	Course filter	Weekly	No	Instead of cleaning, when patient changes
	Fine filter	No	No	Monthly, if severely contaminated, or for a patient change
	FiO_2 sensor	As needed	No	In accordance with manufacturer instructions
	Bacterial filters	No	No	Daily, and whenever patient changes

CLEANING THE DEVICE

Domestic use

For cleaning the surface of the device, use a cloth moistened with soapy water. Then wipe with a cloth moistened with clear water in order to remove any remaining of the soapy water. The device must be completely dry before commissioning.

Clinical use

⚠WARNING
Disinfect the device surface on a regular basis, or when there is any possibility of contamination.

We recommend a nonalcohol desinfect, e.g. schülke mikrozid sensitive wipes. Similar disinfectant wipes are also acceptable as well. The device must be completely dry before commissioning.

CLEANING THE TUBE CIRCUIT

⚠CAUTION
A heavily worn or damaged tube system should be disposed of correctly and replaced by a new one.

The tube circuit supplied is intended for use on one patient only. It must not be cleaned and used for other patients. When using other tube circuits, the manufacturer's instructions must be observed.
Tube circuits not designed for reuse must be disposed of properly.

CLEANING THE MASK

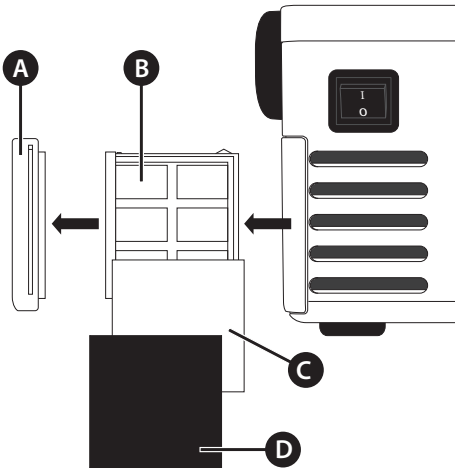
⚠CAUTION
A heavily worn or damaged mask must not be reused and should be disposed of correctly.

1. Disconnect the mask from the tube circuit.
2. Clean the mask with mild soapy water. Do not use any other agents!
3. Rinse the mask thoroughly with clear water.
4. Let the mask dry completely in the air.

CLEANING THE HEADGEAR

1. Disconnect the headgear from the mask.
2. Clean the headgear as described in the headgear manufacturer's users'manual.

CLEANING / REPLACING THE FILTER



A Filter frame cover **B** Filter cassette **C** Fine filter (white)
D Coarse filter (black)

Figure 74: Filter cassette structure

CLEANING THE COARSE FILTER

1. Pull the filter cassette from the device.
2. Remove the coarse filter (black) from the filter cassette.
3. Clean the filter with mild soapy water. Do not use any other agents!
4. Rinse the filter thoroughly with clear water.
5. Let the filter dry completely in the air.
6. Insert the cleaned filter back into the filter cassette.
7. Slide the filter cassette into the device.

Instead of cleaning the filter, you can insert a new one or replace the entire filter cassette with a new one.

REPLACING THE FINE FILTER

The white fine filter cannot be cleaned. It must be replaced with a new one.

1. Pull the filter cassette from the device.
2. Remove the coarse filter (black).
3. Remove the fine filter (white) and replace it with a new one.
4. Insert the coarse filter back into the cassette.
5. Slide the filter cassette into the device.

CHANGING THE FILTER CASSETTE

1. Pull the filter cassette from the device.
2. Pull apart the filter cassette and the filter frame cover.
3. Reassemble the replacement cassette and the filter frame cover.
4. Slide the filter cassette into the device.

USING THE DEVICE FOR MORE THAN ONE PATIENT

If the device is intended for use by more than one patient (e.g., in operation in clinics), a suitable bacterial filter (e.g., MEDISIZE BARR-VENT S) should be used continuously to protect the device from contamination by human pathogens. The bacterial filter must be changed daily.

⚠WARNING

If the device has not been continuously protected by a bacterial filter, it must be thoroughly cleaned and disinfected between use by different patients to ensure free of pathogenic germs. If in doubt, always assume that the device is contaminated, and has hygienically reconditioned according to the hygienic concept.
If a contamination with multi drug restistant bacteria or contamination due to a reportable infectious disease is suspected, the device must be packaged with the appropriate labeling and disinfected accordingly.

Before using the device for another patient you must complete the following procedures:

Component	What action is required?
Bacterial filters	Replace
Mask	Replace or recondition according to the manufacturer's guidelines if possible
Tube circuit	Replace or recondition according to the manufacturer's guidelines if possible
Humidifier	Clean
Filter	Replace
Device	Disinfect the device surfaces with a disposable germicidal wipe. We recommend a nonalcohol desinfect, e.g. schülke mikrozid sensitive wipes. Make sure that no liquid is drawn into the device through the openings. Let the disinfectant soak in according to the disinfectant manufacturer's instructions. Wipe any disinfectant agent residues from the device using a disposable wipe.

CHAPTER 9

ROUTINE CHECKS AND MAINTENANCE WORK

Routine checks and scheduled maintenance are necessary in order to maintain safe functioning of the device. This chapter describes which and when tests and maintenance works must be performed.

NOTICE

You must not perform any testing or maintenance work while the patient is still connected to the device. Provide an alternative ventilation system for the patient during that time.

OVERVIEW

Table 11: Service intervals - overview

When?	What?	By whom?
Before commissioning	Safety-related test (see page 171)	Provider/Service
Weekly	Clean/replace the coarse filter (see page 165)	User
	Visually check of the fine filter	User
Monthly, or before, if heavily contaminated	Replace fine filter (see page 166)	User
Every 6 months	Battery quick test (see page 174)	User/Provider
Every 6 months during in storage	Charge battery to 100 % (see page 173)	User/Provider
Every 6 months without bacterial filter	Replace the valve membrane (expiration) (see page 172)	Provider/Service
Every 2 years	Maintenance 2 (refer to the service manual)	Provider/Service
	Safety-related test (see page 171)	Provider/Service
After 15,000 h blower run time or every 5 years	Maintenance 5 (refer to the service manual)	Provider/Service

SAFETY-RELATED TEST (SRT)

NOTICE
All procedures performed are to be recorded.

To maintain and check the device functions, the device must be subjected to an safety-related test every two years, carried out by an authorized service technician.

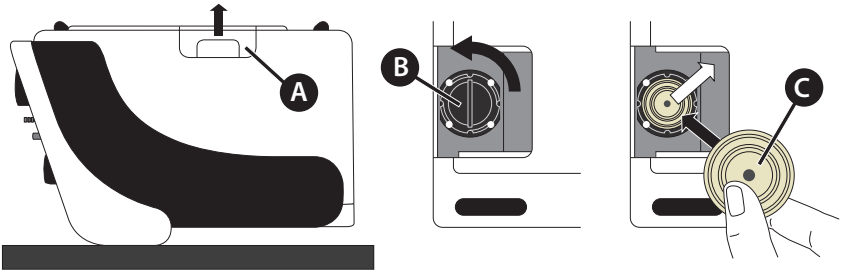
The safety-related check comprises:

- a visual check for outside damage of the ventilator,
- a functional check and
- a visual inspection of the accessories according to manufacturer's instructions (tube circuit, FiO_2 sensor, etc.)

All measures to be performed for the safety-related check are described in the CARAT pro service manual.

REPLACING THE VALVE MEMBRANE (EXPIRATION)

When?	By whom?
• Every 6 months, if the device is operated without bacterial filter	Provider/Service



A Bottom flap **B** Valve cover **C** Valve membrane

Figure 75: Replacing valve membrane (expiration)

Replace the valve membrane as follows:

1. Turn the device over and place it on a soft surface.
2. Remove the bottom flap.
3. Turn the valve cover to the left and lift it off.
4. Replace the valve membrane with a new one. Make sure it is placed into the correct position!
5. Reinstall the valve cover and the bottom flap.

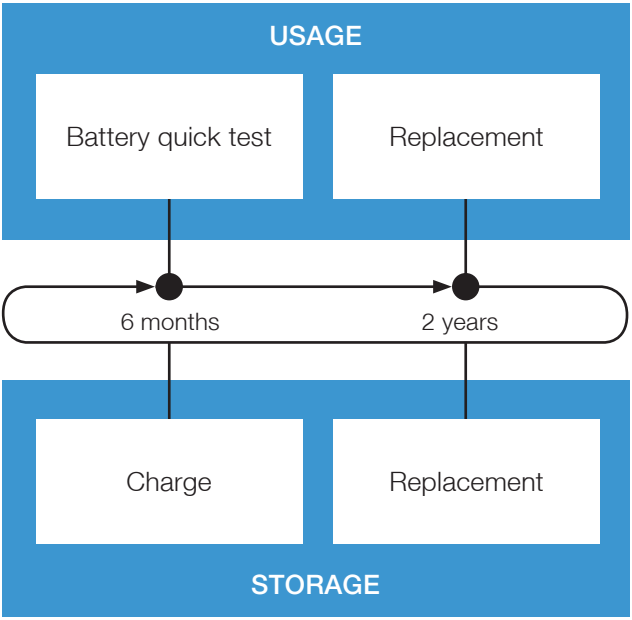
BATTERY MAINTENANCE

The batteries in CARAT II pro are powerful lithium-ion batteries. To obtain the full capacity of the batteries it is important to charge and maintain them on a regular basis. The number of charging cycles of lithium-ion batteries is limited. Therefore the batteries must be replaced and disposed, when the battery quick test fails or at the latest after 2 years. Tips for disposal can be found on page 201.

NOTICE

Regularly check the charge state of the batteries. Operate the device via main power, so that the batteries are always fully charged.

MAINTENANCE/REPLACEMENT INTERVALS



CHARGING THE BATTERIES

During storage, charge the batteries every 6 months up to 100 % by operating the devices via mains supply.

PERFORM THE BATTERY QUICK TEST

The battery quick test verifies whether the device in case of a power failure can be operated on battery for at least one hour. When the device is used the battery quick test must be performed out by the provider or user every 6 months. However, a monthly check is recommended.

1. Make sure that the batteries are fully charged (100%).
2. Disconnect the device from the mains and operate the device for 1 hour on battery power.
3. The test is positive if after 1 hour the battery capacity is > 10 % and the alarm "Low Internal Battery" has not sounded. If the battery capacity has fallen below 10 % and the alarm "Low Internal Battery" has sounded, the batteries must be replaced by an authorized service technician.
4. Charge the batteries up to 100 % by operating the devices via mains.

REPLACE THE BATTERIES

The batteries must be replaced every 2 years by an authorized service technician. The procedure is described in the CARAT pro service manual.

CHAPTER 10
APPENDIX

INSTRUCTIONS FOR VENTILATION OUTSIDE OF A CLINICAL SETTING

You should take the following into consideration before discharging a patient requiring at home ventilation.

1. Limit the number of sets needed by the patient should use.
2. Adjust all parameters and settings for home ventilation.
3. Finally, switch the user profile to “Home”.
4. Train the patient in the use of this device. In addition, explain which accessory equipment may be used and how to maintain and care for the device (e.g. battery care, cleaning the device).
5. Discuss how the patient should act, particularly if he or she is in danger or if an alarm sounds. Provide a phone number to the patient to call in case of emergency.

TECHNICAL SPECIFICATIONS FOR THE DEVICE

ESSENTIAL PERFORMANCE FEATURES

The essential performance features of the CARAT II pro are:

- pressure-controlled mechanical support with a pressure accuracy of ± (2 % of the scale value + 8 % of the actual measured value),
- sounding of an alarm when inspiration pressure is exceeded, and alert by remote alarm,
- the volume-controlled, mechanical support with a volume accuracy of ± 20 % for a tidal volume above 100 ml or at a minute volume above 3 l/min,
- sounding of an alarm when the alarm parameter “Low Inspiration Volume” is not met or when the alarm parameter “High Inspiration Volume” is exceeded, and alert by remote alarm,
- sounding of an alarm when the alarm parameter “Low Expiration Volume” is not met or when the alarm parameter “High Expiration Volume” is exceeded, and alert by remote alarm,
- sounding of an alarm when the alarm parameter “Low Frequency” is not met or when the alarm parameter “High Frequency” is exceeded, and alert by remote alarm,
- sounding of an alarm when the alarm parameter “Low FiO_2” is not met and alert by remote alarm (only with an external FiO_2 monitoring),
- the alarm “Internal Battery Empty” in case of imminent failure of the mains supply (< 1 min) and the distribution by remote alarm and

- Acceptance criteria for electromagnetic immunity: no permanent damage to the device, restart of ventilation within 15 seconds or alarm after respiratory failure (EN 60601-1-2: 2015 Chapter 8.1, section 18)

The essential performance features can be affected by EMC interferences (see section "Manufacturer's declaration on electromagnetic compatibility" on page198).

IMPORTANT COMPONENTS

The CARAT II pro ventilator comprises the following components:

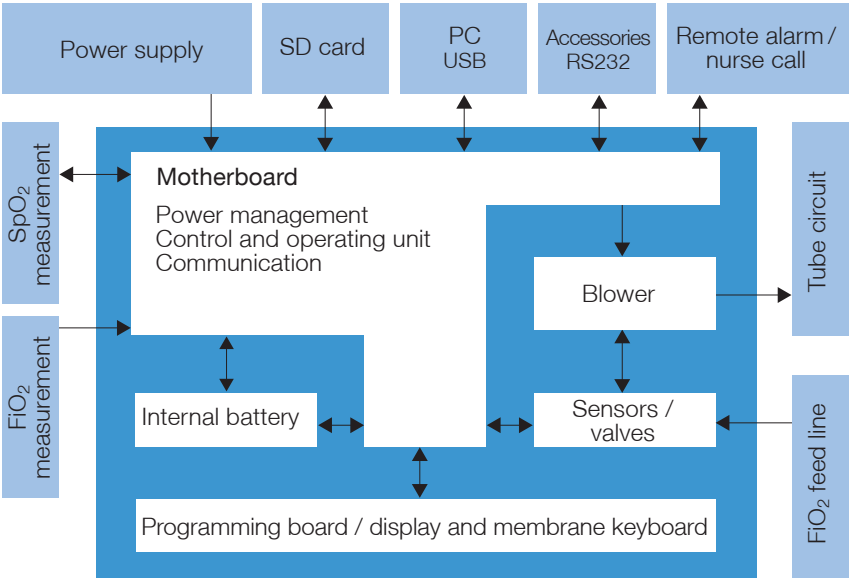


Figure 76: Block diagram for the device

PNEUMATIC BLOCK

The pneumatic block is the connector unit for the double- or single line circuit and consists of the following components:

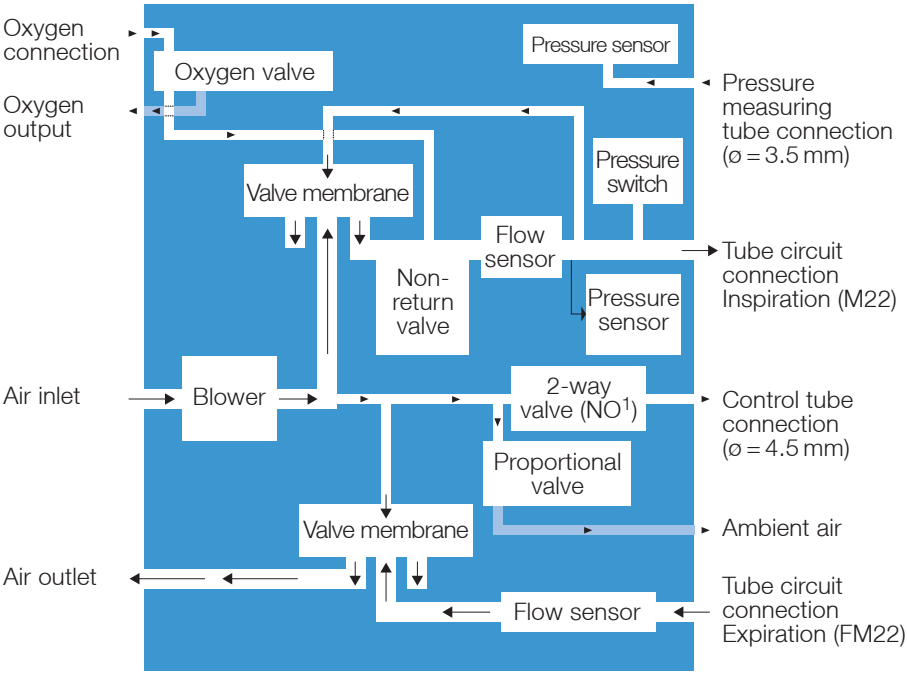


Figure 77: Pneumatic block diagram

1 normally open

DATA MANAGEMENT

The device has an internal memory to recording data. We recommend operating the device with an SD card to save larger amounts of data. More information about SD cards are available on page 61.

The following data will be saved:

Table 12: Data management

Data and parameters	Inside the device	SD card
Alarms and events with date and time stamp	Yes (approx. 15,000 entries)	Yes (approx. 15,000 entries)
Statistics	Yes	No
Device settings and counter	Yes	No
Update files	No	Yes
Initialization files	No	Yes
Measurement parameters (Pressure, volume, flow, FiO_2)	No	Yes (approx. 50 days at a recording rate of 20 values per second)

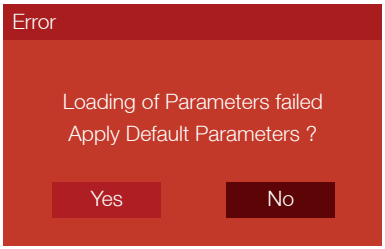
ERROR MESSAGES

Table 13: Error messages during operation and at device start-up

Error message	Cause	Correction
Error SpO_2 sensor	Communication to SpO_2 measuring module not possible	Device must be serviced
	SpO_2 sensor defective	Replace SpO_2 sensor
SD card is full	No storage space available on the SD card	Insert blank SD card
Flash Not Working	No access to the flash	Device must be serviced
Default Parameters Loaded	No valid parameter set available or they are faulty	see page 181
Error Flow Sensor	Flow sensor is defective	Device must be serviced
Error FiO_2 Sensor	FiO_2 sensor is defective	Check FiO_2 sensor connection
		Recalibrate FiO_2sensor
		Replace FiO_2 sensor
Error Pressure Sensor	Defective pressure sensor	Device must be serviced
Calibration File Damaged	Calibration data for sensors is damaged	Device must be serviced
Eventlog File Damaged	Event read data failed	Device must be serviced
Primary Alarm Not Working	Primary alarm sound unit is defective	Device must be serviced
Secondary Alarm Not Working	Secondary alarm sound transmitter is defective	Device must be serviced
No Alarm Available	Primary and secondary alarm sound units are defective	Device must be serviced
Booting Error	Boot failed	Device must be serviced
Fatal Error	Fatal error occurred	Device must be serviced
Maintenance 5 necessary	Maximum blower run times reached	Device must be serviced

Error message “Default Parameters Loaded”

If the error “Default Parameters Loaded” occurs, an error window appears:



If the boot process is initialized during ventilation, ventilation continues. However, the device can no longer be operated. The user now has the following options:

- Press No:

If there are other errors, an error list is displayed:

To hide the error list, press the MFK. The default parameters are not loaded. If ventilation is active, it continues to run with the user-defined settings. However, the device can no longer be operated.

- Press Yes:

If there are other errors, an error list is displayed:

When the MFK is pressed, the default parameters are subsequently loaded, i.e., the device is reset to the factory settings. If ventilation is active, it continues to run with the factory settings. The device is again fully operational.

TECHNICAL DATA

The manufacturer reserves the right to make technical changes without notice.

Power supply	
Mains operation	100...240 V AC (-20 %, +10 %), 50...60 Hz
DC operation	12 V DC / 10 A or 24 V DC / 5 A
Internal battery operation	Lithium ion battery, 14.8 V (nominal voltage) / 4.4 Ah / 65.12 Wh
External battery operation AKKUPACK uni BASE/PLUS	 20...26 V (nominal voltage) / 5 A
Maximum power consumption	75 W
Electrical protection class	Class II

Specifications and performance	
Dimensions (W x D x H)	304 x 253 x 160 mm
Weight	4.72 kg
Max. stable limit pressure	60 hPa
Min. stable limit pressure	0 hPa
Max. inspiratory working pressure	50 hPa
Min. inspiratory working pressure	4 hPa
Max. flow at 50 hPa	180 l/min
Max. flow at 4 hPa	250 l/min

Operating conditions	
Temperature range	+ 5 °C to + 40 °C (+ 41 °F to + 104 °F)
Relative humidity	10 % ... 95 %, non-condensing
Air pressure range	600 hPa ... 1100 hPa

Storage and transport conditions	
Temperature range	
< 1 day	+ 20 °C to + 60 °C (+ 68 °F to + 140 °F)
< 1 month	+ 20 °C to + 55 °C (+ 68 °F to + 131 °F)
< 6 months	+ 20 °C to + 45 °C (+ 68 °F to + 113 °F)
> 6 months	+ 20 °C to + 35 °C (+ 68 °F to + 95 °F)

Storage and transport conditions	
Relative humidity	5 % ... 95 %, non-condensing
Air pressure range	250 hPa ... 1100 hPa
Storage conditions	Store in a dry, vibration-free place, in an upright position; store device and accessories in their original packaging.

Sound pressure range of audible alarm signal (at 1 m distance)	
Lowest value	55 dBA, Level 1
Medium value	60 dBA, Level 2
Highest value	65 dBA, Level 3

Resistance in the first event of a fault		
Inspiratory pressure of the device at the patient connection port at 60 l/min	Single line patient circuit	Double line patient circuit
	2.9 hPa	3.7 hPa
Expiratory pressure of the device at the patient connection port at 60 l/min	Single line patient circuit	Double line patient circuit
	2.1 hPa	5.0 hPa
Measurement conditions	Device with single line patient circuit (art. no. 00014967) without any accessories	Device with double line patient circuit (art. no. 00007969) without any accessories

Application parts
Mask, Tracheal cannula, Endotracheal tube, SpO_2 finger clip sensor

Technical requirements for accessories	
Oxygen inlet	
Connection type	Quick-connect coupling
Pressure	≤ 1000 hPa
Flow	≤ 15 l/min
Bacterial filter	
Connections	22 / 15 mm cone (according to EN1281-1)
Resistance	< 2.3 hPa at 60 l/min
Compressible volume	< 66 ml
Internal volume	< 200 ml

Measured values				
Parameter	Display area	Display increments	Measurement	Accuracy
Pressure	0 – 100 hPa	0.1 hPa	0.0 – 100 hPa	1.0 hPa or 5 % of the measured value[1]
Pressure bar	0 – 60 hPa	15 Pa	0.0 – 100 hPa	1.0 hPa or 5 % of the measured value[1]
Volume	0 – 2.5 l	0.01 l	Calculated from flow measurements	0.03 l or 20 % of the measured value[1]
Flow	0 – 200 l/min	1 l/min	0 – 200 l/min	± 4 l/min
Oxygen	0 – 100 %	1 %	0 – 100 %	5 %
Frequency	0 – 99 bpm	1 bpm	Calculated from period duration of inspiration + expiration in 0.002 s	1 bpm
I:E	1:0.1 – 1:25	0.1	Calculated from period duration of inspiration + expiration in 0.002 s	0.2
MV (minute volume)	0 – 25 l	0.1 l	Calculated from flow measurements	0.03 l or 20 % of the measured value[1]
SpO_2	35 – 100 %	1 %	35 – 100 %	± 2 % at 70 – 100 % ± 3 % at 50 – 70 % Not defined < 50 %
Pulse	30 – 240 bpm	1 bpm	30 – 240 bpm	± 2 bpm or ± 2 %[1]
Leak Rate	0 – 230 l/min	1 l/min	0 – 230 l/min	10 l/min or 20 % of the measured value[1]

All flow and volume values are measured at 25°C (77°F) and 1030 hPa.

1 The higher value is always applied.

SETTINGS RANGES AND CONTROL ACCURACY

VENTILATION PARAMETERS

Table 14: Setting ranges and control accuracy of ventilation parameters

Parameter	Setting range	Setting increments	Accuracy
Tidal Volume	0.05 – 2 l [V < 1,5 l/s x inspiration time]	0.01 l	0.03 l or 20 % of the measured value
Pressure	4 – 20 hPa	0.5 hPa	1.0 hPa or 5 % of the measured valuey
IPAP	4 – 50 hPa	0.5 hPa	1.0 hPa or 5 % of the measured value
PS	4 – 50 hPa	0.5 hPa	1.0 hPa or 5 % of the measured value
PEEP	0 – 20 hPa [PEEP ≤ IPAP-3 hPa]	0.5 hPa	1.0 hPa or 5 % of the measured value
Frequency	4 – 50 bpm	1 bpm	1 bpm
Apnoea Time	0 – 60 s	1 s	1 s
Time Inspiration	0.3 – 8 s	0.1 s	0.1 s
Ti Max	1 – 10 s	0.1 s	0.1 s
Ti Min	0.4 – 5 s	0.1 s	0.1 s
I:E	4.00 : 1 – 1 : 4.00	0.1	0.1
Ramp	Level 1 – 5	1 level	-
Flow Ramp	Level 1 – 5	1 level	-
Inspiration Trigger	Level 1 – 10, auto	1 level	-
Expiration Trigger	10 – 90 %	10 %	1 %
Trigger Lock	Off; 0.5 - 4 s [≤ 80 % of the max. expiration time]	0.1 s	0.1 s
SMART Function	On, Off	-	-
Minimum Volume	Off; 0.05 – 2 l [when IPAP > 47 hPa, then always from]	0.01 l	0.03 l or 20 % of the measured value

Table 14: Setting ranges and control accuracy of ventilation parameters

Parameter	Setting range	Setting increments	Accuracy
Additional Pressure	3 – 10 hPa [Additional Pressure ≤ 50 hPa – IPAP]	0.5 hPa	1,0 hPa or 5 % of the measured value
Max. Pressure	11 – 50 hPa [≥ PEEP+3 hPa]	0.5 hPa	1,0 hPa or 5 % of the measured value
Min. Pressure	2 – 40 hPa [≤ IPAP-1 hPa, ≥ PEEP+2 hPa]	0.5 hPa	1,0 hPa or 5 % of the measured value

ALARM PARAMETERS

Table 15: Setting ranges and control accuracy of alarm parameters

Parameter	Setting range	Setting increments	Accuracy
Apnoe Alarm	Off, 1 – 60 s	1 s	1 s
High Frequency	Off; 10 – 120 bpm	1 bpm	1 bpm
Low Frequency	Off; 1 – 50 bpm	1 bpm	1 bpm
High Inspiration Volume	Off; 0.2 – 2.5 l	0.01 l	0.03 l or 20 % of the measured value
Low Inspiration Volume	Off; 0.1 – 2 l	0.01 l	0.03 l or 20 % of the measured value
High Expiration Volume	Off; 0.2 – 2.5 l	0.01 l	0.03 l or 20 % of the measured value
Low Expiration Volume	Off; 0.1 – 2 l	0.01 l	0.03 l or 20 % of the measured value
High Minute Ventilation	Off; 0.8 – 25 l	0.01 l	0.03 l or 20 % of the measured value
Low Minute Ventilation	Off; 0.1 – 20 l	0.01 l	0.03 l or 20 % of the measured value
Leak Rate	On, Off	-	-

Table 15: Setting ranges and control accuracy of alarm parameters

Parameter	Setting range	Setting increments	Accuracy
High FiO_2	Off; 30 – 100%	1 %	1 %
Low FiO_2	Off; 18 – 90 %	1 %	1 %
High SpO_2	Off, 70 – 100 % [min. 1 % greater then "Low SpO_2"]	1 %	1 %
Low SpO_2	Off; 70 – 100% [min. 1 % lower than "High SpO_2"]	1 %	1 %
High Heart Rate	Off, 60 – 200 bpm [min. 10 bpm greater then "Low Heart Rate"]	1 bpm	1 bpm
Low Heart Rate	Off, 30 – 90 bpm [min. 10 bpm lower then "High Heart Rate"]	1 bpm	1 bpm
High Pressure Tolerance	1 – 10 hPa	0.5 hPa	1.0 hPa or 5 % of the measured value
Low Pressure Tolerance	1 – 10 hPa	0.5 hPa	1.0 hPa or 5 % of the measured value

FACTORY SETTINGS

VENTILATION PARAMETERS

Table 16: Factory settings of ventilation parameter

	Mode		
Parameter	PCV (Set 1)	PSV (Set 2)	P-SIMV (Set 3)
IPAP	20 hPa	20 hPa	20 hPa
PEEP	5 hPa	5 hPa	5 hPa
Frequency	12 bpm	12 bpm	12 bpm
Time Inspiration	2 s	3 s	2 s
Ti Max	-	4 s	4 s
Ti Min	-	0.4 s	0.4 s
Apnoea Time	-	10 s	-
Ramp	3	3	3
Inspiration Trigger	-	3	3
Expiration Trigger	-	30 %	30 %
Trigger Lock	-	Off	Off
SMART Function	-	On	On
Minimum Volume	Off	Off	-
Sigh Function	Off	Off	Off

ALARM PARAMETERS

Table 17: Factory settings of alarm parameter

	Mode		
Parameter	PCV (Set 1)	PSV (Set 2)	P-SIMV (Set 3)
High Frequency	30 bpm	30 bpm	30 bpm
Low Frequency	-	4 bpm	-
High Inspiration Volume	1 l	1 l	1 l
Low Inspiration Volume	0.2 l	0.2 l	0.2 l
High Expiration Volume	1 l	1 l	1 l
Low Expiration Volume	0.2 l	0.2 l	0.2 l
High Minute Ventilation	Off	Off	Off
Low Minute Ventilation	Off	Off	Off
Leak Rate	Off	Off	Off
High FiO_2	Off	Off	Off
Low FiO_2	Off	Off	Off
High SpO_2	Off	Off	Off
Low SpO_2	Off	Off	Off
High Heart Rate	Off	Off	Off
Low Heart Rate	Off	Off	Off
High Pressure Tolerance	3 hPa	3 hPa	3 hPa
Low Pressure Tolerance	3 hPa	3 hPa	3 hPa

Table 18: Factory settings of device parameters

Parameter	Factory setting	Setting range	Setting increments
FiO_2-Monitoring	Internal	Internal, External	-
Alarm Volume	3	1 – 3	1
Night Screen	Measurements	Measurements, Light, Dark	-
Timer Screen Change	2 min	Off, 20 s – 20 min	20 s – 100 s: 20 s 2 min – 20 min: 1 min
Brightness Display	100 %	5 – 100 %	5 %
Brightness LEDs	100 %	5 – 100 %	5 %
Brightness MFK	100 %	5 – 100 %	5 %
Language	English	Deutsch, English and others	-
Pressure Unit	hPa	hPa, mbar, cmH_2O	-
Volume Unit	l	l, ml	-
Display Time Insp.	Seconds	Seconds, I:E	-
Number of ventilation sets	3	1 – 3	1

STANDARDS

The device complies with the following standards:

- DIN EN 60601-1-2

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified)

- DIN EN 60601-1-4

  Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996 + A1:1999)

- Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006 + A1:2012)

- DIN EN ISO 10651-6

  (only for use with the single line circuit)

  Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)

- DIN EN ISO 10651-2

  (only for use with the double line patient circuit)

  Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004)

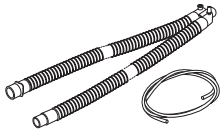
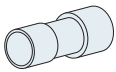
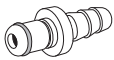
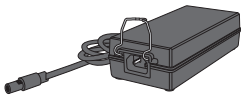
REPLACEMENT PARTS AND ACCESSORIES

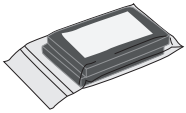
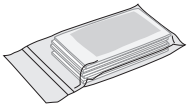
NOTICE

Make sure to follow all general safety guidelines when using replacement parts and accessories page 24.

For ordering of replacement parts and accessories, please contact a HOFFRICHTER service partner.

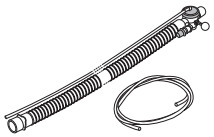
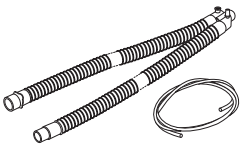
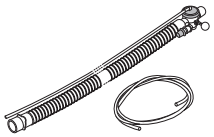
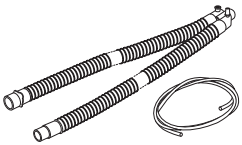
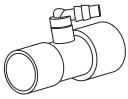
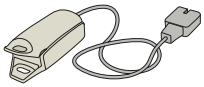
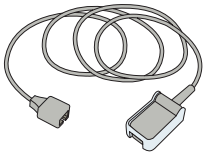
REPLACEMENT PARTS

Name Article number	Figure
Disposable two-hose system with optionally usable pressure measuring hose and Velcro fastener (L = 180 cm, ∅ 22 mm) 00014972	
Bacterial filter adapter 00004933	
Straight FiO_2 connection adapter 41000104	
SD card, 2 GB 11200010	
Mains cable 31100023	
Switched-mode power supply 00014207	
Filter cassette, complete (open) 00002145	

Name Article number	Figure
Filter cassette, complete (closed) 00002146	
Filter cassette, complete (open) with filters 00002038	
Filter cassette, complete (closed) with filters 00002058	
Filter cassette cover 42101301	
Coarse filter, 1 pack (2 ea) 00014950	
Course filter 00002993	
Fine filter, 1 pack (5 ea) 00014951	
Fine filter 00002994	
User's manual for CARAT II pro for physicians and medical professionals 50000625	
User's manual for CARAT II pro for patients 50000626	

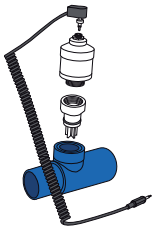
Name Article number	Figure
Brief instructions for CARAT II pro 50000645	
Carrying case 00004875	

ACCESSORIES

Name Article number	Figure
Disposable single-tube system with exhalation valve, control line and optionally usable pressure measuring tube (L = 180 cm, ∅ 22 mm) 00014970	
Disposable two-hose system with optionally usable pressure measuring hose and Velcro fastener (L = 180 cm, ∅ 22 mm) 00014972	
Disposable single-tube system with exhalation valve, control line and optionally usable pressure measuring tube (L = 150 cm, ∅ 15 mm) 00014971	
Disposable two-hose system with optionally usable pressure measuring hose and Velcro fastener (L = 150 cm, ∅ 15 mm) 00014973	
Pressure measurement adapter 00004943	
Bacterial filter 00004932	
SpO_2 finger clip sensor, cable length 2 m 00005292	
Extension cable for SpO_2 sensor, cable length 1 m 00005293	

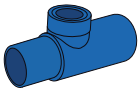
Name Article number					Figure
Masks	Size XS	Size S	Size M	Size L	Size XL
Standard NIPPV Full Face Mask		00003461	00003442	00003438	0003462
Standard NIPPV Full Face Mask autoclavable				00003439	
Cirri Comfort Full Face Mask NIPPV		00003489	00003490	00003491	

FiO_2 measurement set consisting of:
FiO_2 sensor, T-adapter, FiO_2 sensor adapter, FiO_2 sensor connecting cable with screw connector
00004944

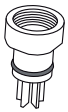


FiO_2 sensor OOM103-1
23000018

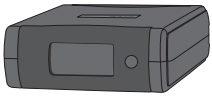
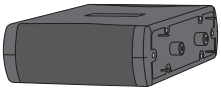
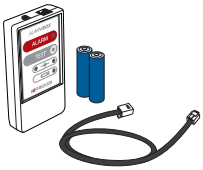
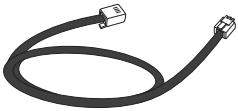
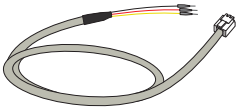
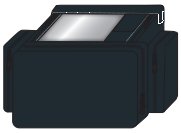
T adapter
23000019



FiO_2 sensor adapter
23000020



Name Article number	Figure
FiO_2 sensor connecting cable with screw connector 00014116	
FiO_2 connection adapter, angled 41000087	

Name Article number	Figure
Cover for expiration tube connection 42100449	
USB cable (PC cable) 00005291	
AKKUPACK uni BASE "Ventilation" 00011100	
AKKUPACK uni PLUS 00011099	
Remote alarm box, complete including accessories 00014122	
Remote alarm box without accessories 00004834	
Cable for remote alarm box 00014115	
Cable for nurse call 00014117	
Functional bag 00004879	

MANUFACTURER'S DECLARATION ON ELECTRO-MAGNETIC COMPATIBILITY

CARAT II pro satisfies the IEC 60601-1-2:2014 standard and is intended for use in the electromagnetic environment described below. Deviating ambient conditions can impair the essential performance features such as pressure accuracy and alarm, or lead to the breakdown of the device.

Guidance and manufacturer's declaration – electromagnetic emissions		
The CARAT II pro ventilator is intended for use in the electromagnetic environment specified below. The user of the **CARAT II pro ventilator** should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions acc. to CISPR 11	Group 1	The **CARAT II pro** ventilator uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 11	Class B	The **CARAT II pro** ventilator is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The CARAT II pro ventilator is intended for use in the electromagnetic environment specified below. The user of the **CARAT II pro ventilator** should ensure that it is used in such an environment.

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge acc. to (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air ± 2, 4, 8, 15 kV air display	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF disturbances acc. to IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1kHz	10 V/m	Portable and mobile communications equipment (including cables and antennas) should be used no closer to any part of the CARAT II pro home ventilator than the recommended separation distance of 0.3 m.
	27 V/m 385 MHz PM: 18Hz	27 V/m	
	28 V/m 450 MHz FM ± 5Hz: 1kHz sinus	28 V/m	
	9 V/m 710, 745, 780 MHz PM:217Hz	9 V/m	
	28 V/m 810, 870, 930 MHz PM: 18Hz	28 V/m	
	28 V/m 1720, 1845, 1970 MHz PM: 217Hz	28 V/m	
	28 V/m 2450 MHz PM:217Hz	28 V/m	
	9 V/m 5240, 5500, 5785 PM:217Hz	9 V//m	
Electrical fast transient/burst acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Surges acc. to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV voltage line(s) - earth	± 1 kV line(s) to line(s) ± 2 kV voltage line(s) - earth	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF disturbances acc. to IEC 61000-4-6	3 V_{rms} 150 kHz – 80 MHz 6 V_{rms} in ISM and amateur radio bands between 150 kHz – 80 MHz	3 V 6 V	Portable and mobile communications equipment should be used no closer to any part of the CARAT II pro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety distance: 0.3 m
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines acc. to IEC 61000-4-11	> 95 % dip in U_T for 0.5 cycle > 95 % dip in U_T for 1 cycle 30 % dip in U_T for 25(50 Hz) cycles/ 30(60 Hz) cycles 95 % dip in U_T for 250 (50 Hz) cycles/ 300 (60 Hz) cycles	> 95 % dip in U_T for 0.5 cycle > 95 % dip in U_T for 1 cycle 30 % dip in U_T for 25 cycles > 95 % dip in U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CARAT II pro ventilator requires continued operation during power mains interruption, it is recommended that the CARAT II pro ventilator is powered from an uninterrupted power supply (UPS) or a battery.

DISPOSAL

Proper disposal saves natural resources and prevents harmful substances being released into the environment.

DEVICE

The device must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

BATTERIES

Replaced batteries must be disposed in accordance with the respective local laws. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

PACKAGING

The packaging is taken back by the distributor but it can alternatively be disposed of separately with the normal household waste.

FiO_2 SENSOR

The FiO_2 sensor must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

DISCLAIMER

HOFFRICHTER GmbH accepts no liability for consequences in terms of safety, reliability and performance of the product if:

- interventions, modifications, extensions, calibration, repairs and maintenance are carried out by persons not authorized by us,
- other manufacturers' accessories and spare parts are used that have not been approved by us for use on the product,
- the product is used for pusposes other than stipulated in the user's manual or
- the hygiene and cleaning instructions stipulated in the user's manual have not been complied with.

Statutory guarantee rights remain unaffected by this disclaimer.