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Device type 9LV203

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CARAT II pro

Ventilator

User's manual

for patients

as of device software 1.000

User's manual ***CARAT II pro*** for patients

CARAT II pro Patient 1.000 ENG_2014-07-16_01

Article no.: 5000 0626

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User's manual

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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 physicians and medical professionals
- 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

The device complies with the requirements of Directive 93/42/EEC.

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LIST OF FIGURES

LIST OF TABLES

CHAPTER 1
INTRODUCTION

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

SCOPE OF DELIVERY

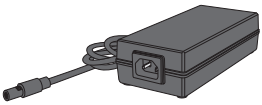
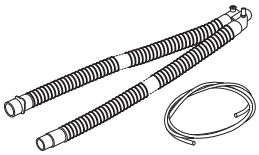
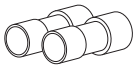
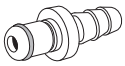
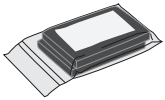
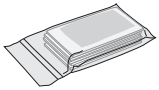
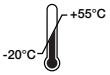
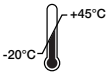
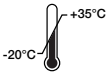
Illustration	Name
	CARAT II pro Ventilator
	Switched-mode power supply
	Mains cable
	Disposable double line patient circuit for adults with pressure measuring tube (L = 180 cm, ∅ 22 mm)
	Adapter for bacterial filter
	SD card
	Straight FiO_2 connection adapter
	Carrying case

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-Declaration of Conformity
	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

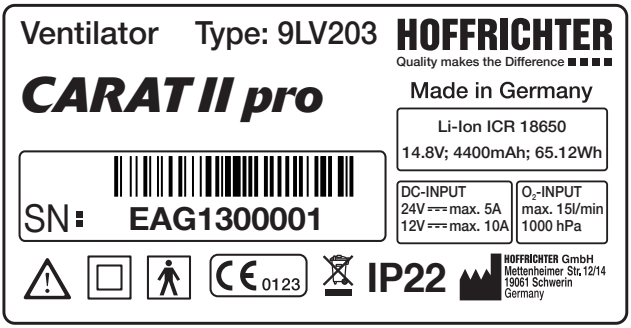


Figure 1: Rating plate

Symbol	Meaning
	Observe the warning and safety instructions in the user's manual.
	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-Declaration of Conformity
	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
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 ⊡	FiO_2 connection
O_2 ⊡	FiO_2 output
	SD card slot

Symbol	Meaning
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 USE

NOTICE
The use of the device contrary to its intended use can endanger the health of the patient.

CARAT II pro is used for continuous or intermittent respiratory support and for the ventilation of patients. The device is suitable for adults and children from a tidal volume of 50 ml and higher and is designed for home or clinical applications.

CARAT II pro has both pressure- and volume-controlled ventilation modes. The ventilation can be invasive (e.g using a tracheostoma) or non-invasive (using a mask). CARAT II pro has the technical prerequisites to allow it to run with a single line patient circuit with exhalation valve or with a double line patient circuit as required.

The device can be connected to a low-pressure source of oxygen for ventilation with increased oxygen concentration. There is also the option to combine CARAT II pro with an external humidifier.

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

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

- 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.

- When a nasal or full face mask is used for noninvasive ventilation, this 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.
- An annual 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.
- Respiratory therapy may be contraindicated for certain pre-existing conditions.
- The device must never be located near other devices or equipment such as defibrillators, diathermy units, mobile phones, microwaves, remote controlled toys, etc. Electromagnetic fields that exceed 10 V/m may adversely affect the operation of the ventilator.
- 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 LED's 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.
- Due to possible electromagnetic interference the ventilator may not be placed directly next to other devices in which the electromagnetic radiation is not CE compliant and/or the limits values exceed 10 V/m. If this is unavoidable, then the ventilator operation must be monitored for trouble-free and correct operation.
- Do not locate the device near water containers (baths).

INSTRUCTIONS BEFORE COMMISSIONING

- An malfunctioning device can endanger the patient or operator. Should the appliance not start properly, or if the device's automatically carried out self-tests should fail, you must stop operating the device. In such cases, the service provider must be informed.
- 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 FiO2 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.

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

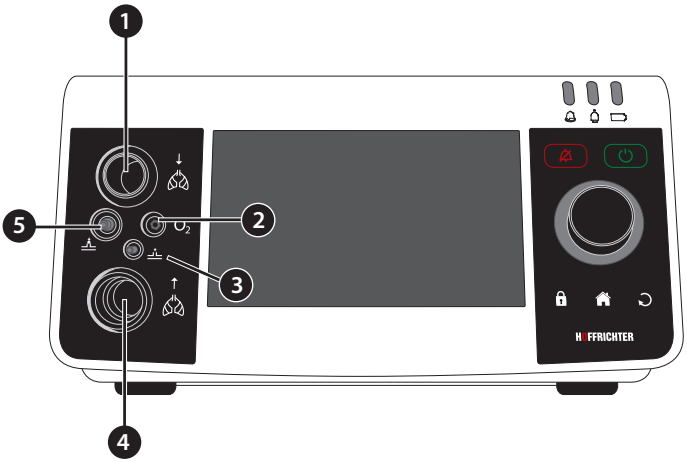


Figure 2: Connections at the front side of the device

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 48 and page 49.

2 O_2 Connection of FiO_2 sensor cable

Connect the FiO_2 sensor cable here for measuring the oxygen concentration. Refer to page 59.

3 Connection of pressure measuring tube

Refer to page 48 and page 49.

4 Connection of tube circuit - expiration

The expiration section of a double line patient circuit will be connected here. Refer to page 49.

5 Connection of control tube

Refer to page 48.

REAR SIDE CONNECTING POINTS

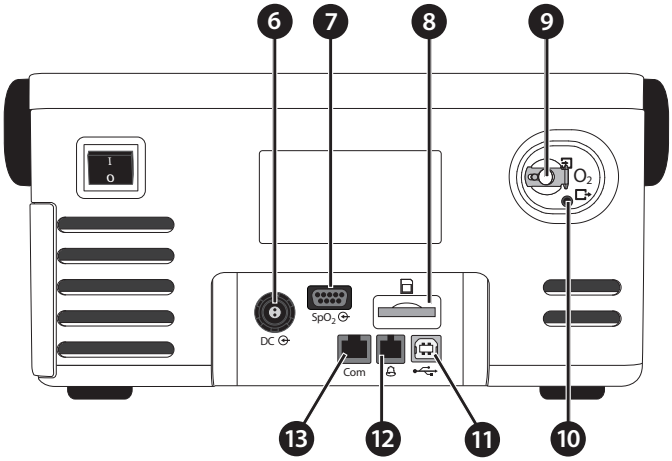


Figure 3: Connections at the rear side of the device

6 DC DC connection

The power supply plug is connected here. Refer to page 41.

7 SpO_2 Connection of SpO_2 sensor

A SpO_2 sensor can be connected here. page 55.

8 SD card slot

An SD card here can 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 57.

10 O_2 FiO_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). In order to be able to communicate with the device, the PC software "EASYset" must be installed on the PC.

12 Connection of remote alarm/nurse call

An alarm box (optional accessory) or a nurse call system may be connected here. Refer to page 54.

13 Com RS232 interface (service interface)

Accessories connection

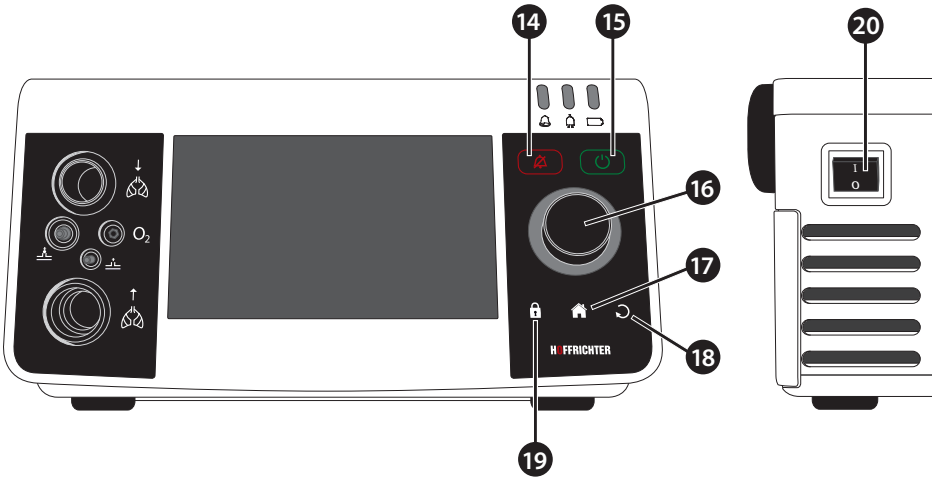


Figure 4: Control elements

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 90

16 Multifunctional key 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 62.

LED DISPLAYS

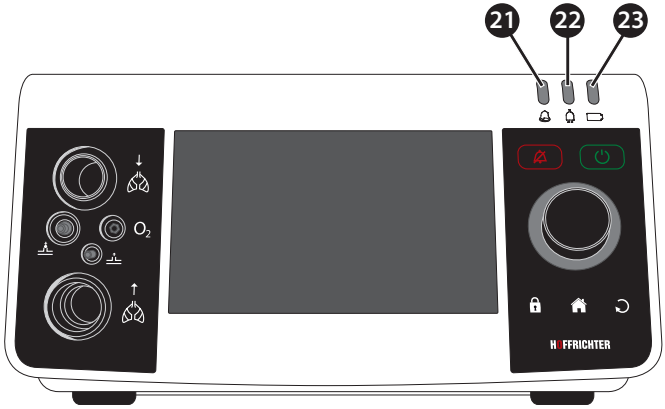


Figure 5: LED displays

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
Red	Flashes	HIGH
Yellow	Flashes	MEDIUM
Turquoise	Glows steadily	LOW

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	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	Flashes	Device shuts down

MOVABLE AND REMOVABLE HOUSING PARTS

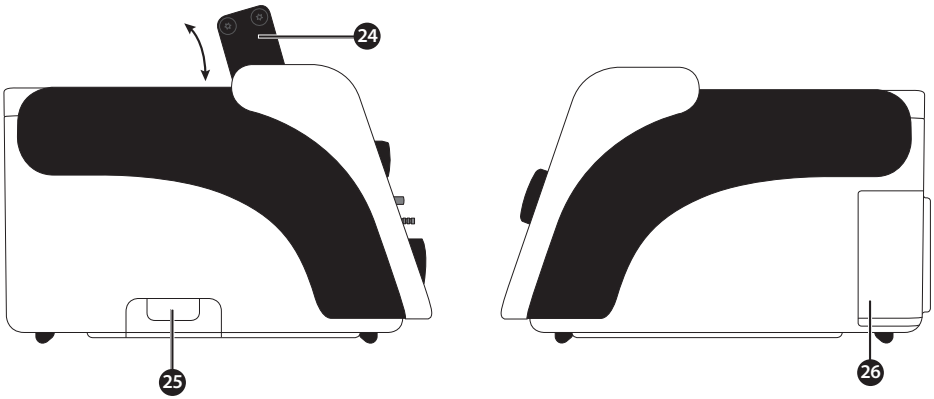


Figure 6: Left device side
Figure 7: Right device side

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.

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 107.

CHAPTER 4
COMMISSIONING

- Before commissioning the device, read the safety information as from page 21 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.

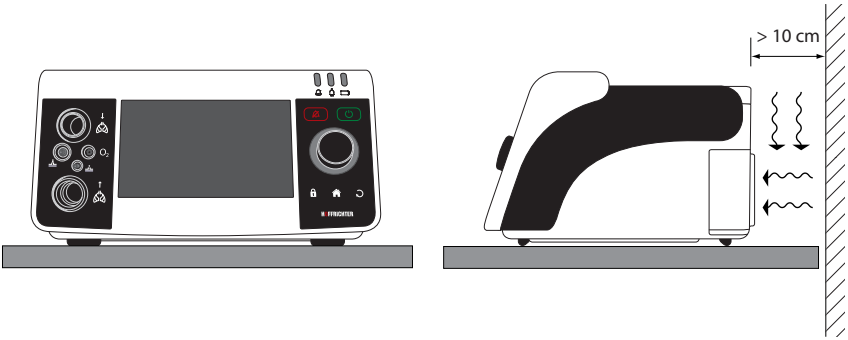


Figure 8: Setting up the device

POWER SUPPLY

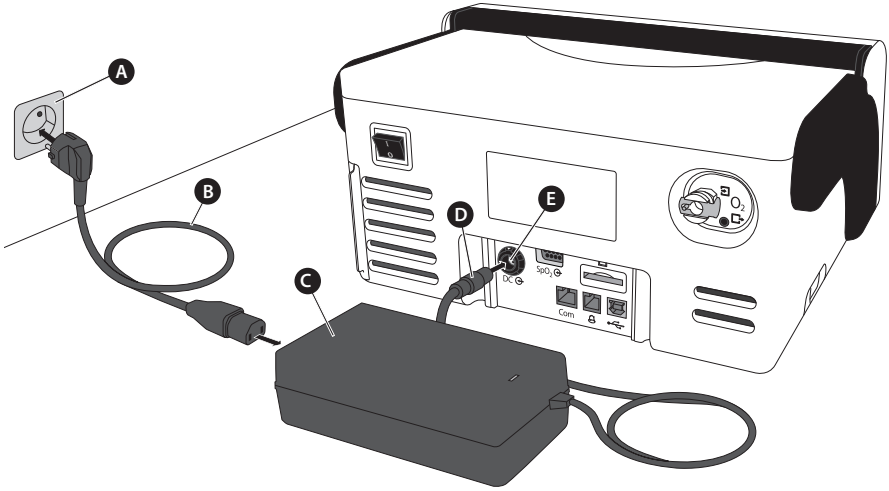
The ventilator may be supplied by three different power sources.

- 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.
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 71). 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 11 on page 115.

   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.

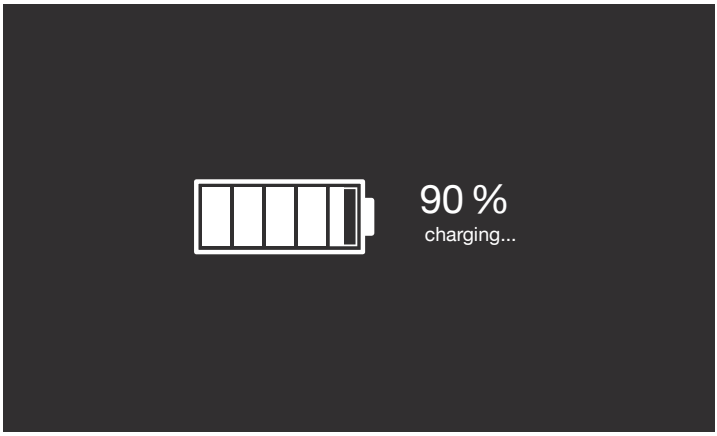


Figure 11: Standby screen

5. Switch on the ventilator by the main switch (see page 62).

NOTICE

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 page111 .

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 36.

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 126).

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 TRENDvent 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.

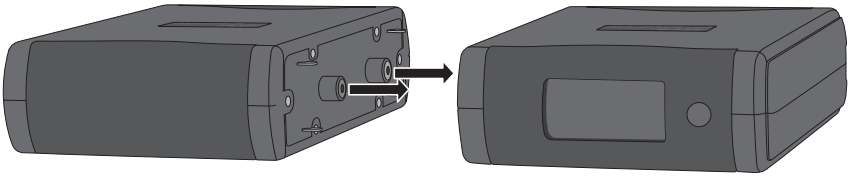
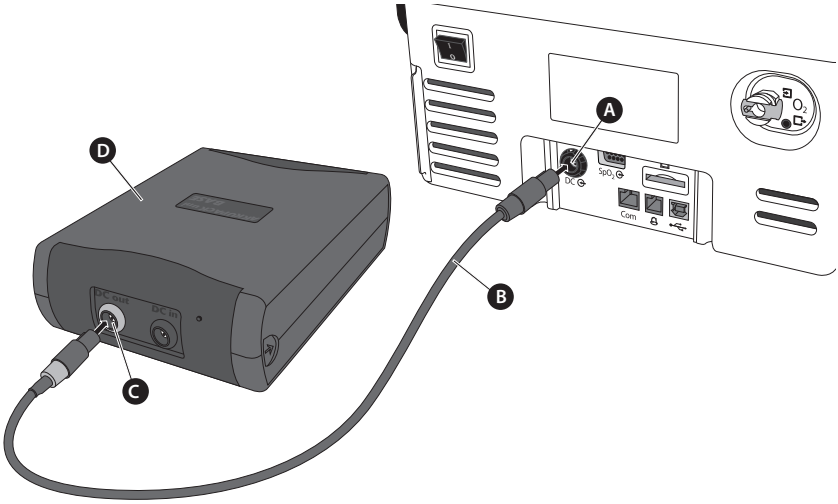


Figure 12: AKKUPACK uni BASE (right) / AKKUPACK uni PLUS (left)

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.

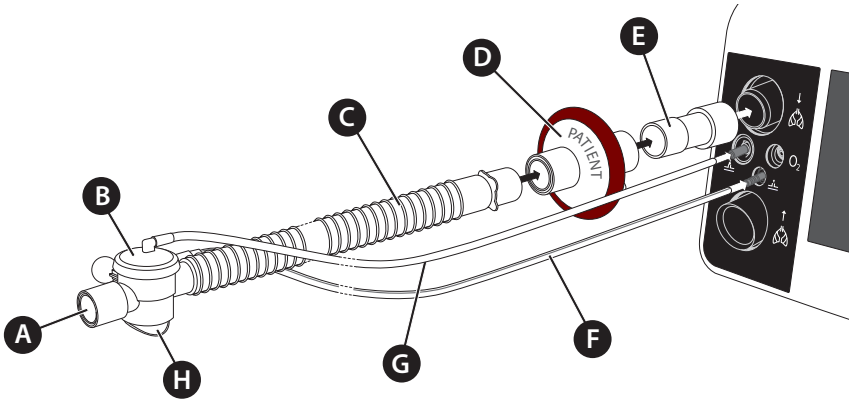
CONNECTING A SINGLE LINE PATIENT CIRCUIT

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

If water collects in the tubes, we recommend the use of water traps. Single line patient circuits with water traps are available as an accessory (see page 124).

Should you be using a tube circuit without pressure measuring tube, the circuit in use must be calibrated (see page 52).



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

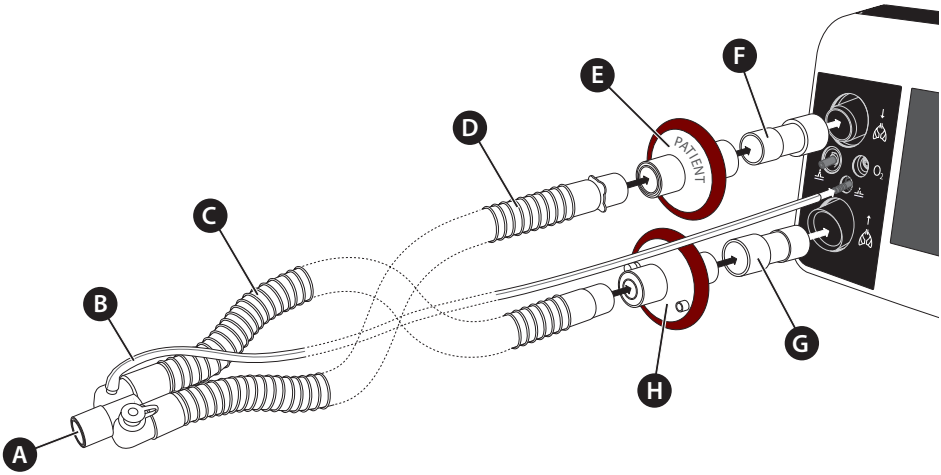
Figure 14: Connecting a single line patient circuit

CONNECTING A DOUBLE LINE PATIENT CIRCUIT

Connect the tube circuit to the device according to Figure 15.
Note: When using a bacterial filter, please read the instructions of use of this filter.

If water should collect in the tubes, we recommend the use of water traps. Double line patient circuits with water traps are available as an accessory (see page 124).

Should you be using a tube circuit without pressure measuring tube, the used circuit must be calibrated (see page 52).



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 15: Connecting a double line patient circuit

CONNECTING A HUMIDIFIER

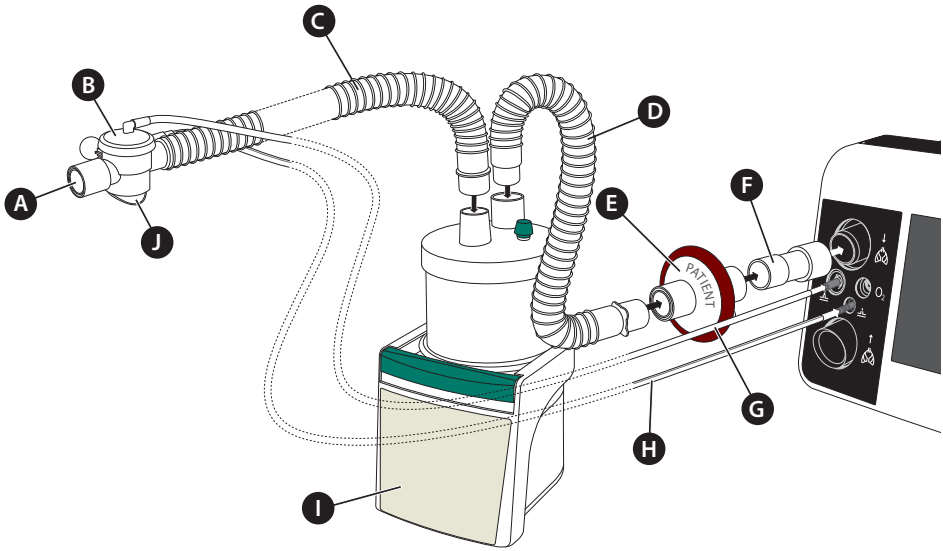
A humidifier is used to humidify the breathing air. If you use a humidifier, be sure to follow the manufacturer's user's manual.

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 lungs or in the device. If water accumulates in the tube circuit, we recommend using water traps. The respective tube circuits with water traps are available at HOFFRICHTER (see page 124).

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 16. When using a tube circuit without pressure measuring tube, the used tube circuit must be calibrated page 52).

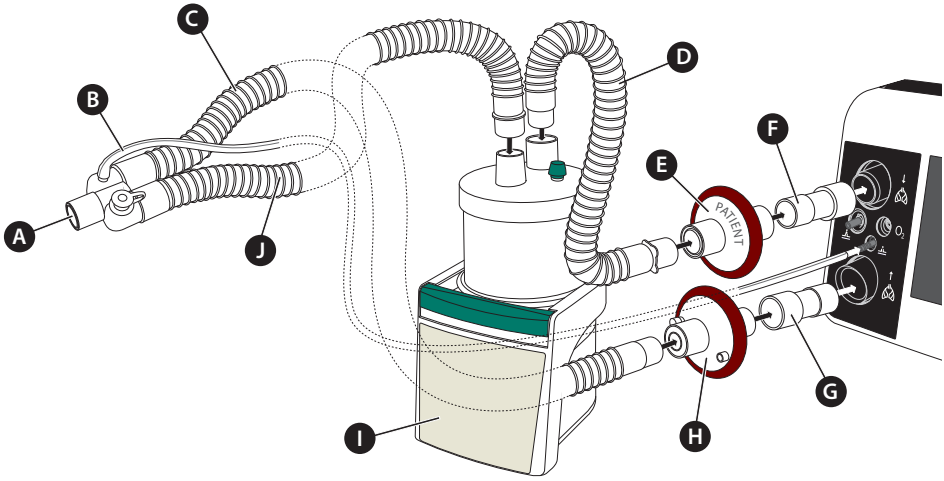


A Patient side connection **B** Expiration valve **C** Ventilation tube
D Connecting tube for inspiration **E** Bacterial filter **F** Adapter for bacterial filter
G Control tube **H** Pressure measuring tube **I** Humidifier **J** Air outlet

Figure 16: Connecting the humidifier - single line patient circuit

Double line patient circuit

Connect the tube circuit to the humidifier and the device according to Figure 17. When using a tube circuit without pressure measuring tube, the used tube circuit must be calibrated (see page 52).



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

Figure 17: Connecting the humidifier - double line patient circuit

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, water trap, etc.

If you do not perform a tube calibration, the stored standard calibration data is used for the tube calibration. After starting the ventilation a message box (see Figure 18) is displayed. Although the ventilation is continued, however, the pressure measurement may be incorrect. A tube calibration is therefore recommended.

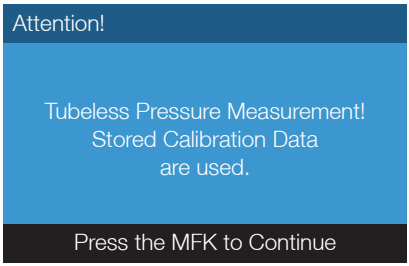


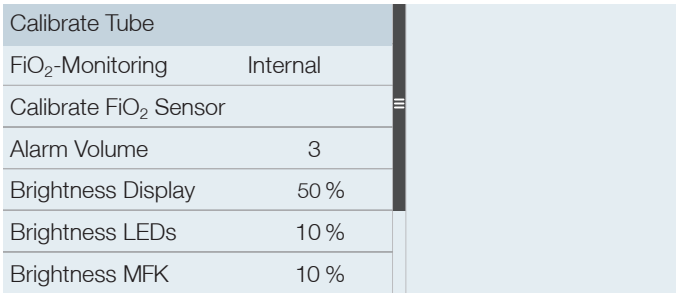
Figure 18: "Measurement without pressure tube" message box

To calibrate the tube circuit:

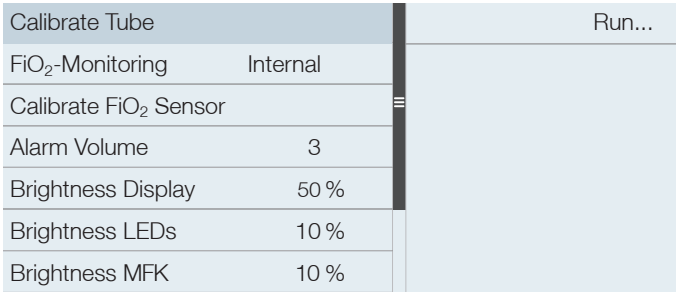
1. Disconnect the tube circuit from the patient. The patient side connection of the tube circuit must be unobstructed and left open to the air during tube calibration (a mask may be connected).
2. Navigate to "System" in the home screen by turning the MFK.

3. Press the MFK.

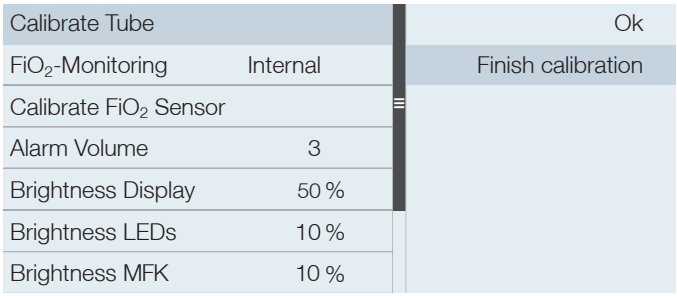
4. Navigate to "Calibrate Tube" by turning the MFK.



5. Press the MFK. Tube calibration begins.



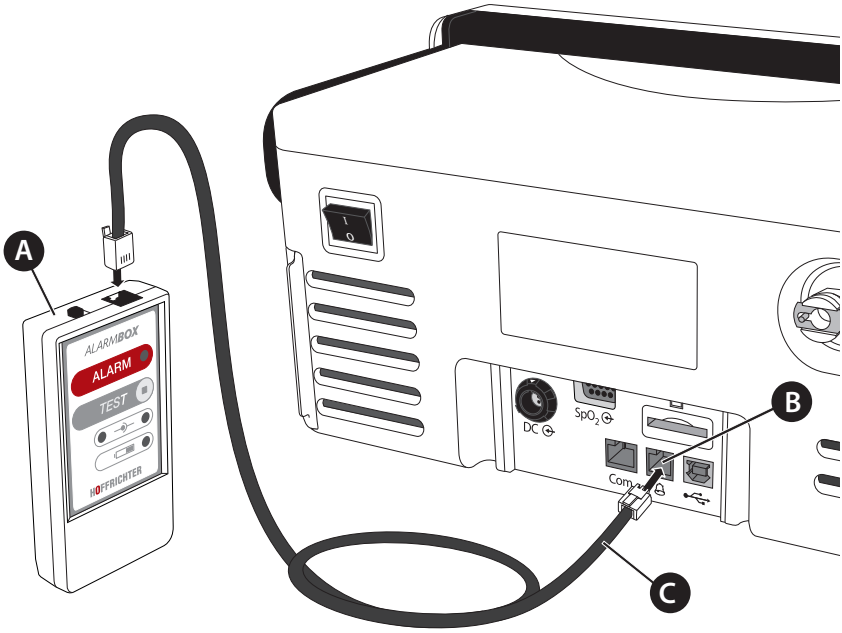
6. If the calibration was successful, "OK" will appear after a few seconds. If the calibration was not successful, "Error" will display. In the event of an error, check the entire system. Resistance in the overall system may be too high. You may, for example, have to exchange the bacterial filter(s)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



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

CONNECTING THE ALARM BOX OR THE NURSE CALL

Connect the alarm box to the device as shown in Figure 19.



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

Figure 19: Connecting alarm box

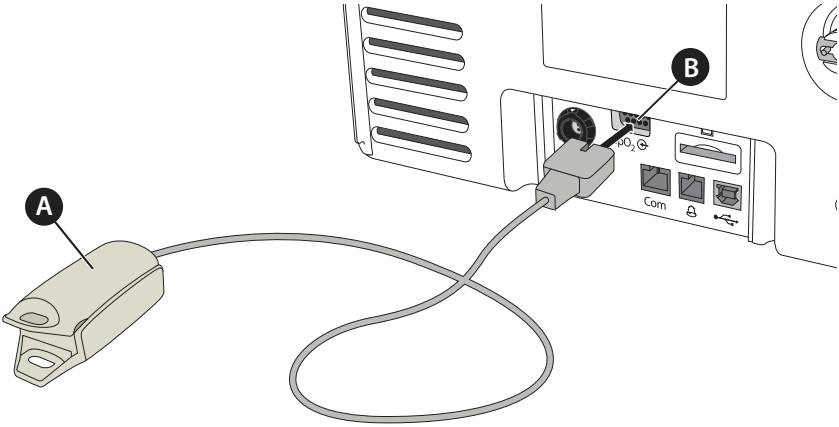
Alarm boxes are available as an accessory (see page 127).

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 127).

Additional information on alarm boxes and forwarding alarms is available in the section "Forwarding alarms" on page96.

SpO_2 SENSOR CONNECTION

Connect the SpO_2 sensor to the device as shown in Figure 20. 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.



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

Figure 20: 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 21. The toolbar will then show the icon.

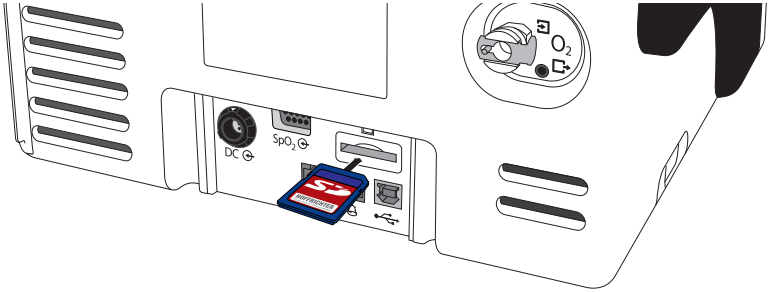


Figure 21: Inserting SD card

SD and SDHC cards up to 32 GB may be used. More information on SD cards is available on page 114.

REMOVING THE SD CARD

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 completely shut down when the power and battery LEDs no longer flash after the device has been turned off.

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

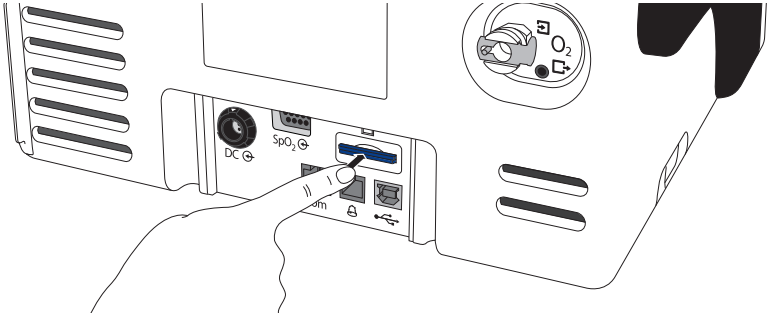


Figure 22: Removing SD card

USING OXYGEN

⚠WARNING
Before using oxygen, the safety instructions must be read as of page 26.

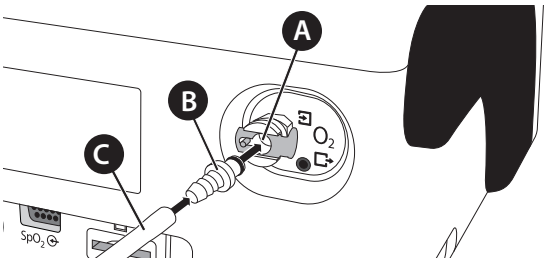
ATTENTION
Oxygen may only be supplied during active ventilation.

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 23.



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

Figure 23: 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 125). The FiO_2 sensor must be calibrated for exact results (see page 59).

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 by a physician. The factory default is set to a measuring with a FiO_2 sensor (FiO_2 monitoring "Internal")

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

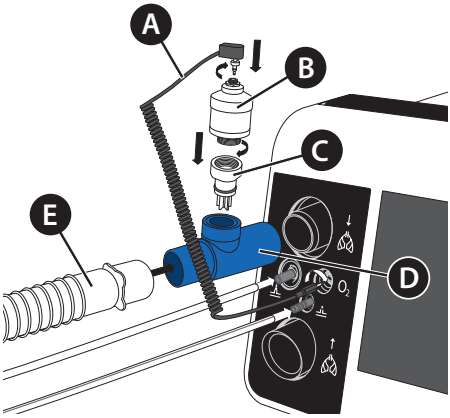
If the FiO_2 sensor is disconnected and reconnected during ventilation, then the oxygen supply is interrupted for at least 30 seconds, so that the oxygen content in the FiO_2 therapy air is reduced. After successful calibration, the oxygen supply is restored and the FiO_2 values will be displayed in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

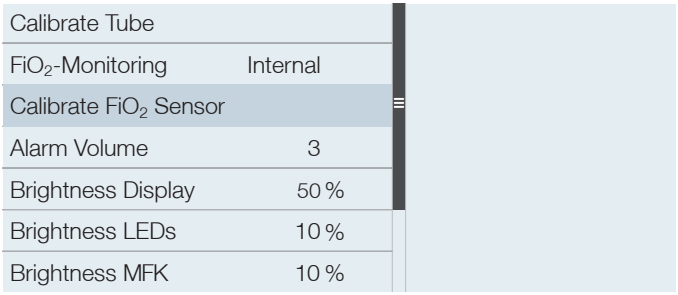
1. Make sure that the ventilator has been switched off.
2. Install the FiO_2 sensor according to Figure 24.
   Tip: Plug and screw the straight plug of the connecting line (A) to the device and then connect the right-angled to with the FiO_2 sensor.



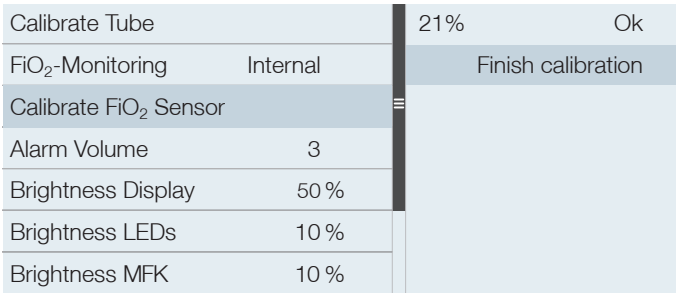
A Connecting line **B** FiO_2 sensor **C** Housing gas duct
D T adapter **E** Tube circuit

Figure 24: 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.

USING THE FUNCTIONAL BAG

⚠CAUTION
Use only the original HOFFRICHTER functional bag.

We recommend using our functional bag for transporting the CARAT II pro on wheelchairs, walkers or in transport vehicles. The functional bag is available as an accessory (see page 127).

Figure 25: 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.

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 57.

To switch on the device:

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

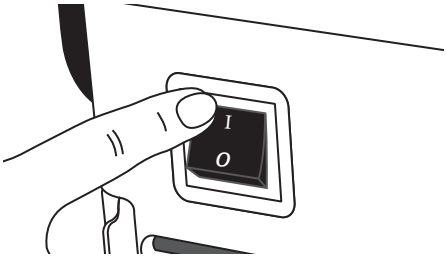


Figure 26: Switching on the device

2. The home screen (see page 71) 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").

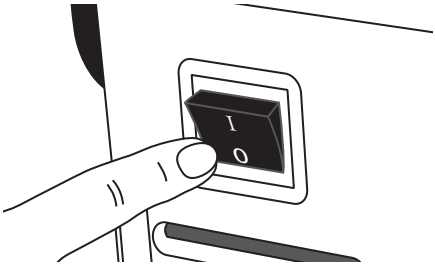


Figure 27: Switching off the device

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.

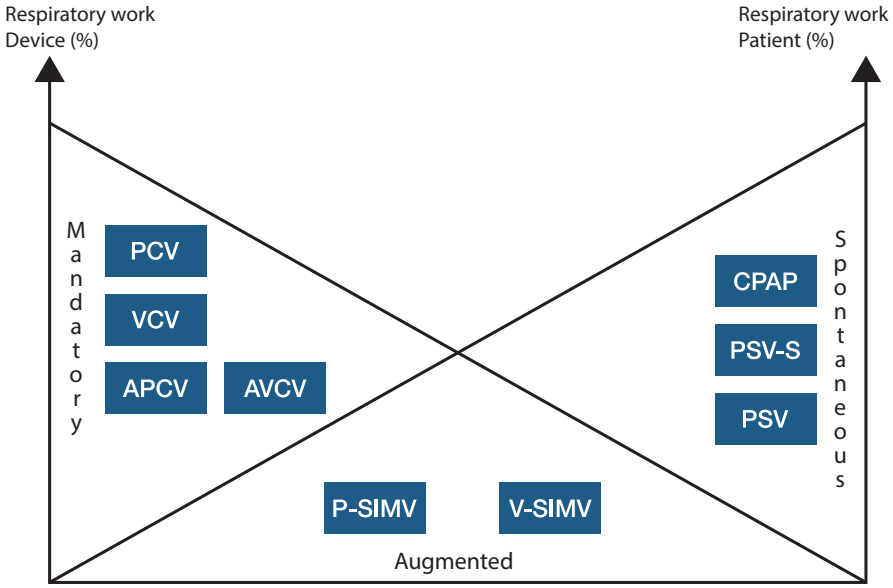


Figure 28: Ventilation modes overview

Table 2: Overview ventilation modes

Mode	Description
Mandatory ventilation modes	
PCV	Pressure Controlled Ventilation
APCV	Assisted Pressure Controlled Ventilation
VCV	Volume Controlled Ventilation
AVCV	Assisted Volume Controlled Ventilation
Augmented ventilation modes	
P-SIMV	Pressure Controlled Synchronized Intermittent Mandatory Ventilation
V-SIMV	Volume Controlled Synchronized Intermittent Mandatory Ventilation
Spontaneous ventilation modes	
CPAP	Continious Positive Airway Pressure
PSV	Pressure Supported Ventilation
PSV-S	Pressure Supported Ventilation-Spontaneous

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.

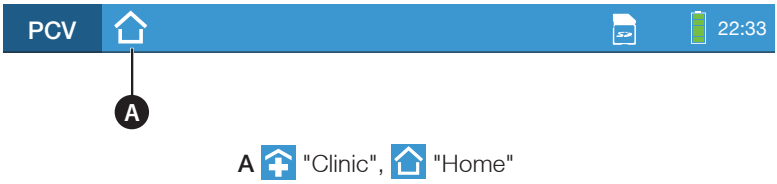


Figure 29: User profile in the toolbar

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

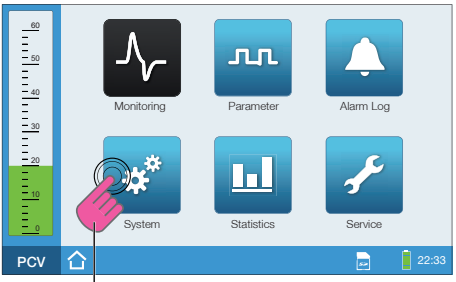
Use the control elemtents on the right or the touch screen to operate the device.

OPERATING WITH CONTROL ELEMENTS

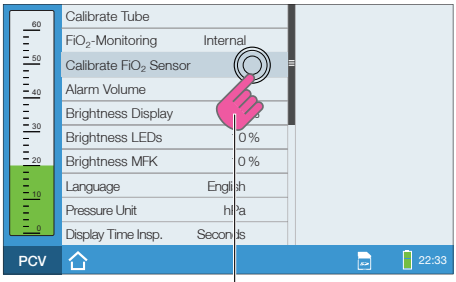
The control elements functions are described starting with page 33.

TOUCH SCREEN OPERATION

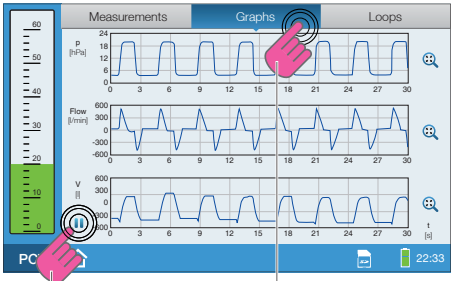
The following operations can be initiated with the touch screen:



Screen selection

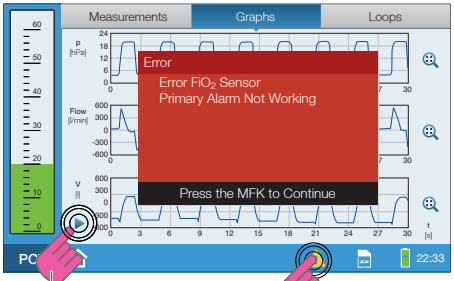


Parameter selection



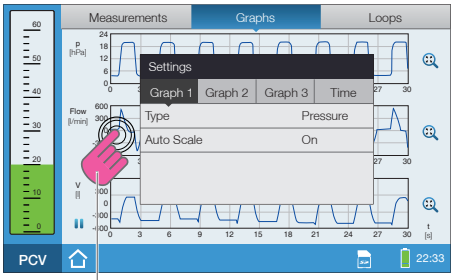
Freeze real-time curve on the monitoring screen

Select tab

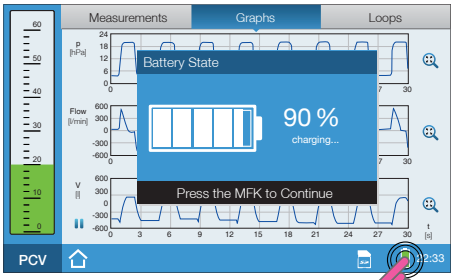


Continue real-time curve on the monitoring screen

Show errors (if present)



Open settings window



Show battery state

BASIC SCREEN LAYOUT

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

Figure 30: 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.
	FiO_2 sensor connected
	"FiO_2-Monitoring" setting has been set to "External" in the system screen. Measurement of oxygen concentration is performed with an external FiO_2-Monitoring unit.
	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
	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 page115).
	Internal battery fully charged
	Internal battery being charged (1 bar ≙ 20 % of charge)

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 31: 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.

NOTICE

During active ventilation the device will switch to the monitoring screen 2 minutes after the last completed operation. If ventilation is not active the device will switch over to the home screen after 2 minutes.

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)

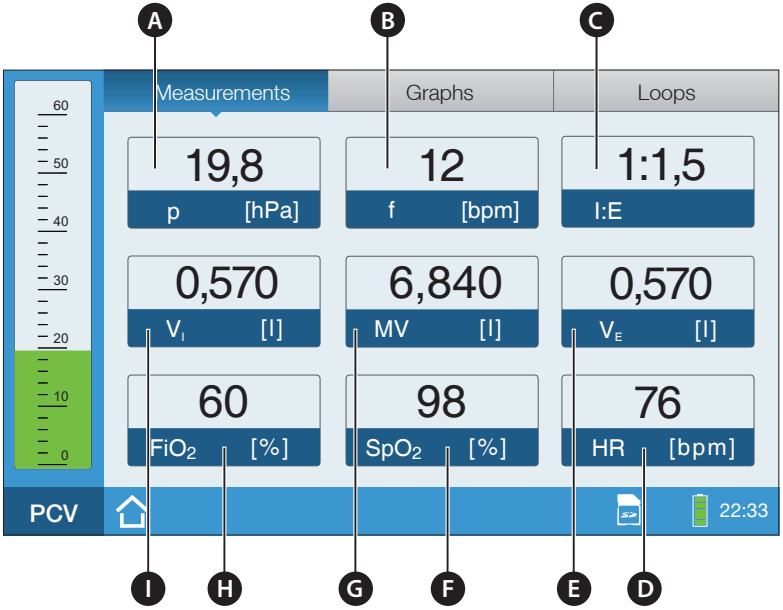
NOTICE

The measured values are displayed on the parameter screen during active ventilation.

How to call up to the data:

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

2. Press the MFK.



A Pressure **B** Frequency **C** I:E ratio **D** Heart rate **E** Expiration volume **F** SpO_2 saturation **G** Minute ventilation **H** FiO_2 concentration **I** Inspiration volume

Figure 32: Monitoring screen (data)

GRAPHS DISPLAY

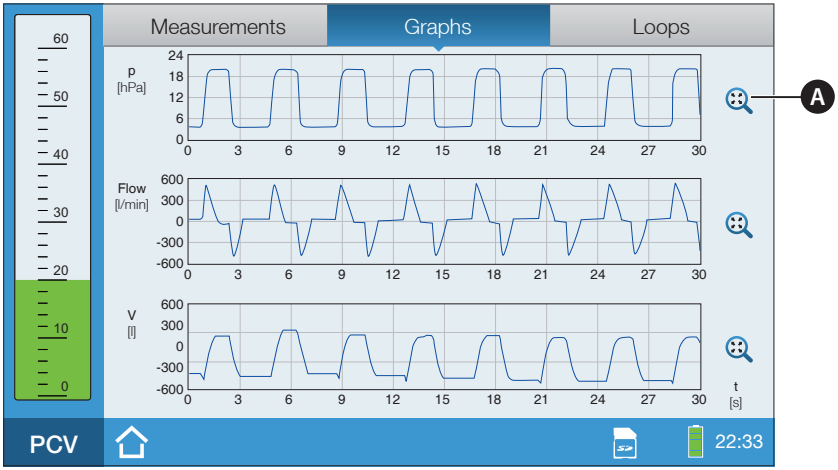
Depending on your settings, "Curves" will graphically display the following ventilation parameters during running ventilation:

- 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 33: Monitoring screen (graphs)

Freezing the real-time curve:

1. Press the pause symbol ❚❚.

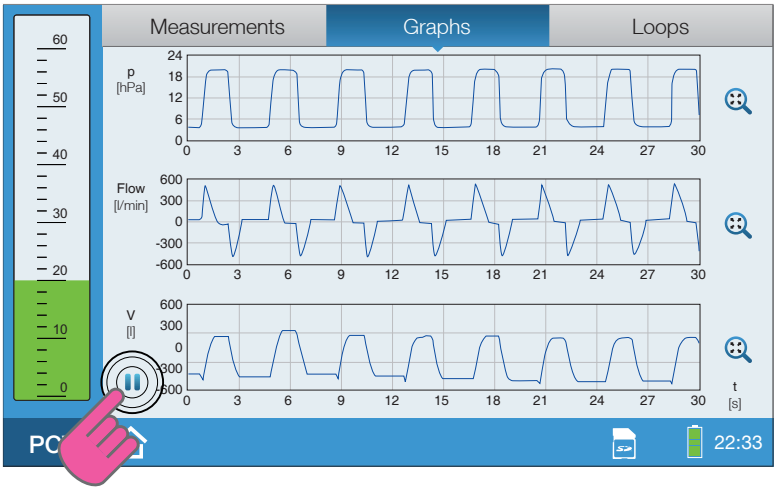


Figure 34: Monitoring screen (freeze graphs)

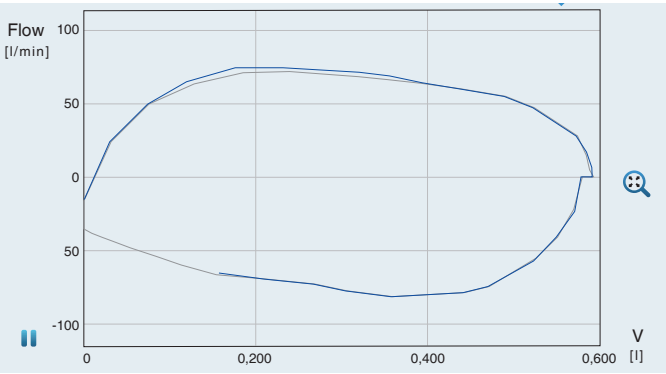
2. Press the start symbol to restart the real-time curve ▶.

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

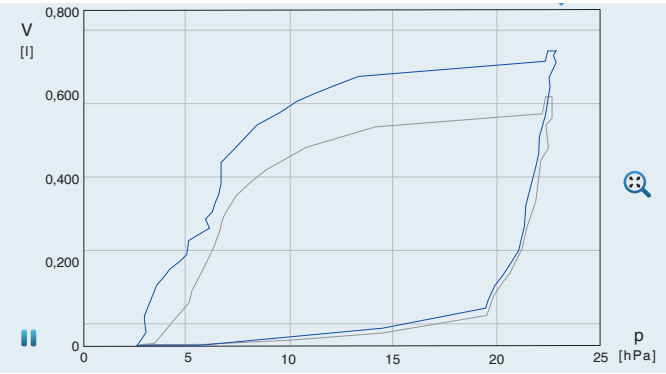
Flow-Volume-Loop



— Current breath — Last breath

Figure 35: Flow-Volume-Loop

Volume-Pressure-Loop



— Current breath — Last breath

Figure 36: 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.

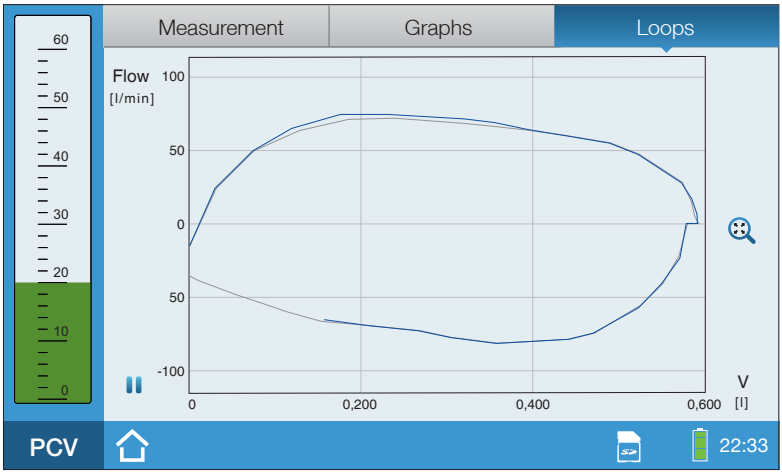


Figure 37: Flow-Volume-Loop

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.

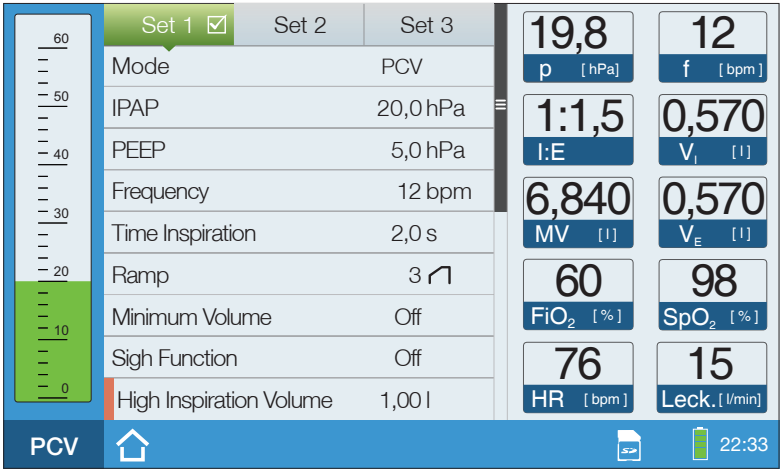


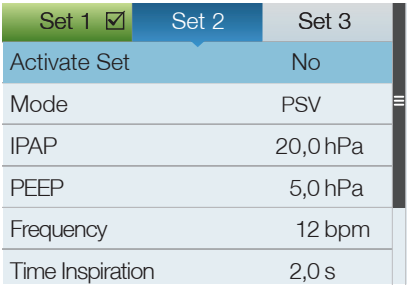
Figure 38: Parameter screen

NOTICE

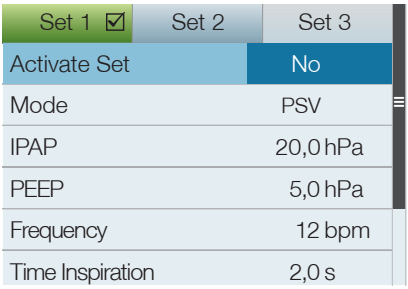
The active setting is highlighted in green and has a check mark ☑.

To activate a ventilation set:

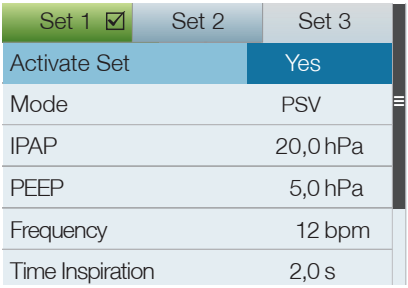
1. Navigate to the ventilation set you wish to activate by turning the MFK.



2. Press the MFK twice.



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



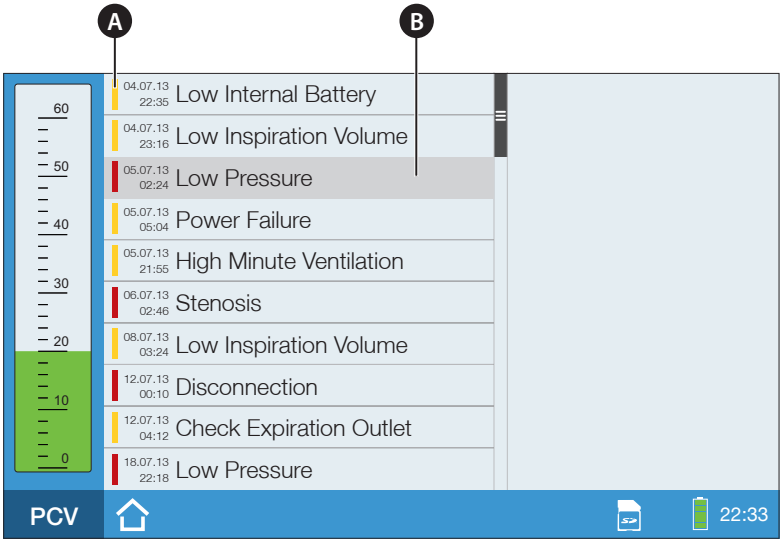
4. Press the MFK to confirm the new setting.

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 move between the alarm entries by turning the MFK.



A Alarm priority **B** Selected alarm

Figure 39: Alarm log screen

For more information on the alarms, refer to chapter "Alarms and messages" starting on page 91

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.

Menu item	Explanation	Adjustable (Home profile)
Calibrate Tube	Calibrating the connected tube circuit (see page 52)	✓
FiO_2-Monitoring	Setting, if oxygen concentration measurements are to be taken with internal FiO_2 monitoring or with external FiO_2 monitoring	-
Calibrate O_2 Sensor	Calibrating the FiO_2 sensor (see page 59)	✓
Alarm Volume	Volume of the primary alarm sound	-
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 key	✓
Language	Setting the device language	-
Pressure Unit	Setting the device pressure 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.	-
Recent Ventilation Hours	Ventilation hours since the last reset	-
Ventilation Hours Total	Total ventilation hours (can be reset with PC software)	-

Menu item	Explanation	Adjustable (Home profile)
Standby Hours	Hours, during which the device was turned on (without ventilation 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.

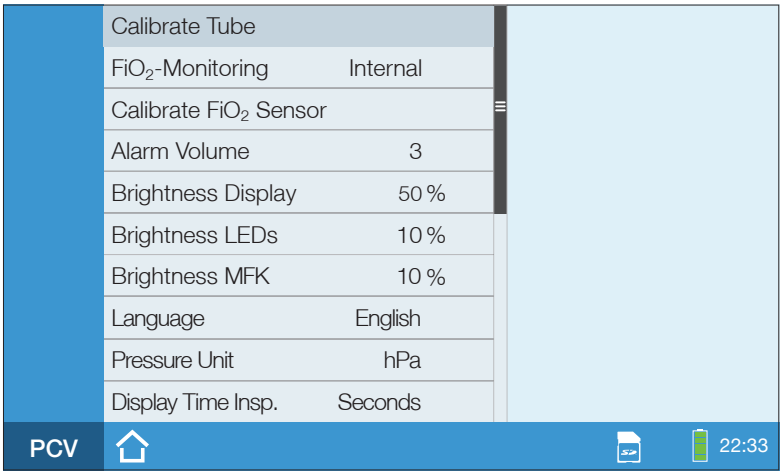


Figure 40: System screen

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

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

Calibrate O_2 Sensor	
Alarm Volume	3
Brightness Display	50 %
Brightness LEDs	10 %

2. Press the MFK.

Calibrate O_2 Sensor	
Alarm Volume	3
Brightness Display	50 %
Brightness LEDs	10 %

3. Change the setting by turning the MFK.

Calibrate O_2 Sensor	
Alarm Volume	3
Brightness Display	70 %
Brightness LEDs	10 %

4. Press the MFK to confirm the new setting.

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	13.02.14 10:36
Number Ventilation Sets	3
User Profile	Home ⌂
Tightness Check	
Recent Ventilation Hours	65 h
Ventilation Hours Total	342 h
Standby Hours	622 h

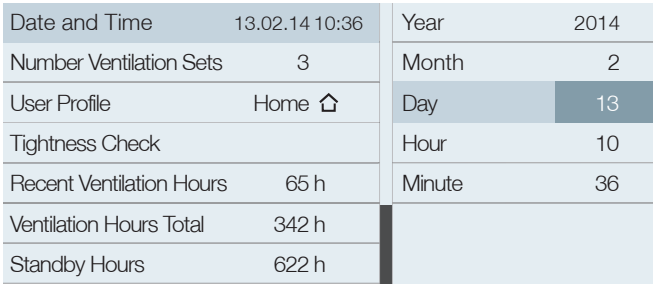
4. Press the MFK.

Date and Time	13.02.14 10:36	Year	2014
Number Ventilation Sets	3	Month	2
User Profile	Home ⌂	Day	13
Tightness Check		Hour	10
Recent Ventilation Hours	65 h	Minute	36
Ventilation Hours Total	342 h		
Standby Hours	622 h		

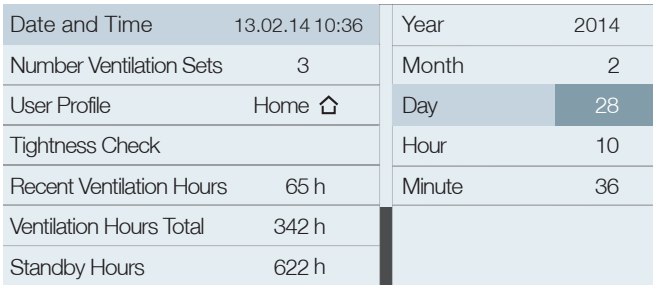
5. Navigate to the desired parameter by turning the MFK.

Date and Time	13.02.14 10:36	Year	2014
Number Ventilation Sets	3	Month	2
User Profile	Home ⌂	Day	13
Tightness Check		Hour	10
Recent Ventilation Hours	65 h	Minute	36
Ventilation Hours Total	342 h		
Standby Hours	622 h		

6. Press the MFK.



7. Change the setting by turning the MFK.



8. Press the MFK to confirm the new setting.

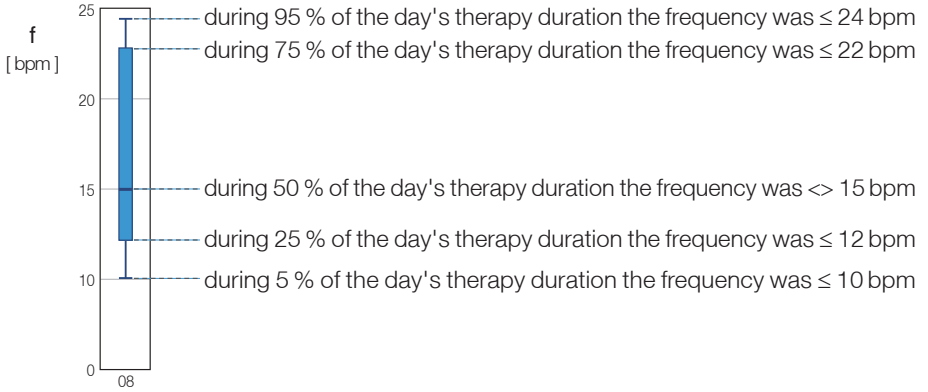
STATISTICS

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.

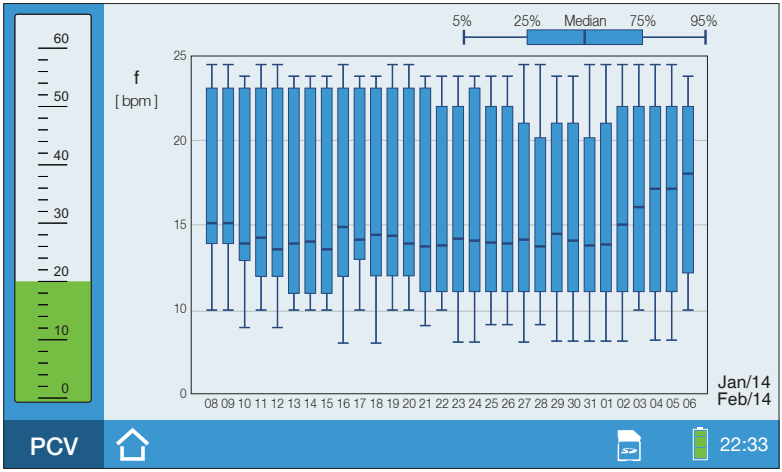


Figure 41: Statistics screen (1 ventilation parameter)

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 .

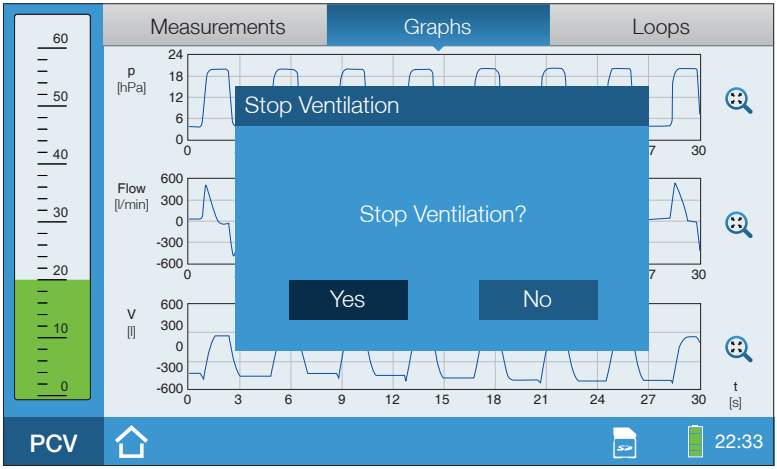


Figure 42: Stop ventilation

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.

ALARM SOUND TEST

A hardware test is performed with each device start-up. The primary and secondary alarm sound transmitters are tested (see page 41). 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 97.

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

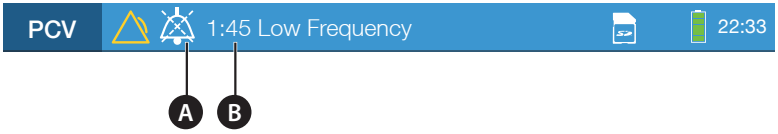
An audio alarm will switch off when the alarm event is no longer fulfilled and the priority has been lowered but the alarm will stay in active until it has been confirmed with the alarm key.

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 43: Alarm displays in the toolbar

NOTICE

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

VISIBLE ALARM OUTPUT

Visible alarms are displayed as follows:

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

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.

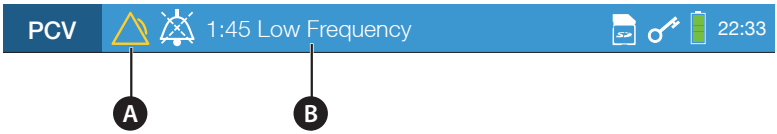
More information on alarm LEDs is available on page 35.

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 44: Alarm output in the toolbar

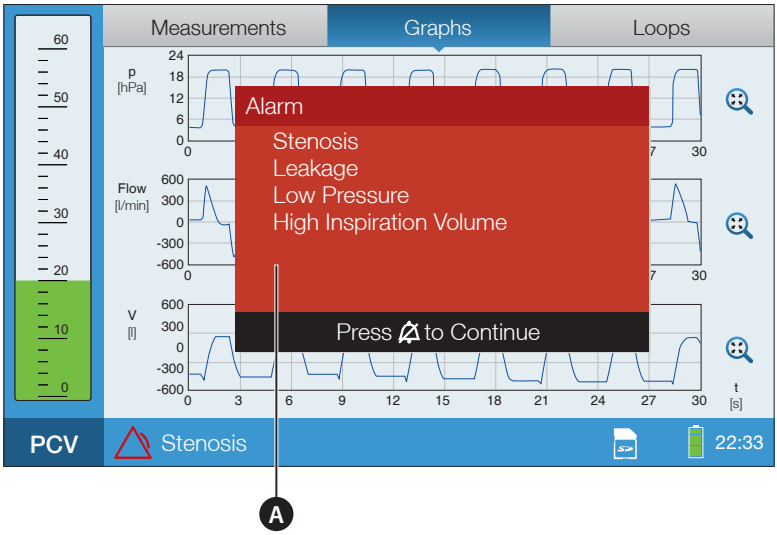
ALARM OUTPUT AS A TEXTBOX

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 45: Alarm output in the textbox

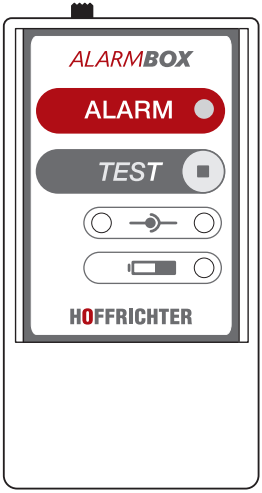
ALARM OUTPUT VIA THE MULTIFUNCTIONAL KEY

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 54.
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 54.

Figure 46: 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. The alarm limits can only be set by the physician in the parameter screen.

Table 3: 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 "High Pressure Tolerance"	for 10 breaths in a row

Table 4: 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 "High Frequency"	for 3 breaths in a row
High Inspiration Volume	MEDIUM	c 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 Inspiration Volume"	for 3 breaths in a row
Low Expiration Volume	MEDIUM	c a f	Yellow - flashes	Expiration volume is lower than the "Low Inspiration Volume"	for 3 breaths in a row
Low SpO_2	MEDIUM	C b a	Yellow - flashes	Measured SpO_2 is lower than the set "Low SpO_2"	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 5: 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
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 6: 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 Expiration Outlet	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
Check Measuring Tube	LOW	e c	Turquoise glows steadily	Measurement tube kinked or not connected to the device	Check for kinks in the measuring tube
					Check measuring tube at the device

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 47: Messages in the toolbar

MESSAGES OVERVIEW

Table 7: 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 8: Cleaning intervals - overview

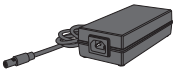
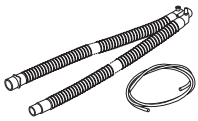
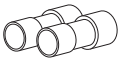
Component	Name	Clean	Disinfect	Replace
	CARAT II pro Ventilator	As needed	With every new patient	-
	Power supply unit	As needed	With every new patient	-
	Mains cable	As needed	With every new patient	-
	Disposable double line circuit	No	No	Every change of patient In accordance with manufacturer instructions
	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 8: 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 schülke® 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

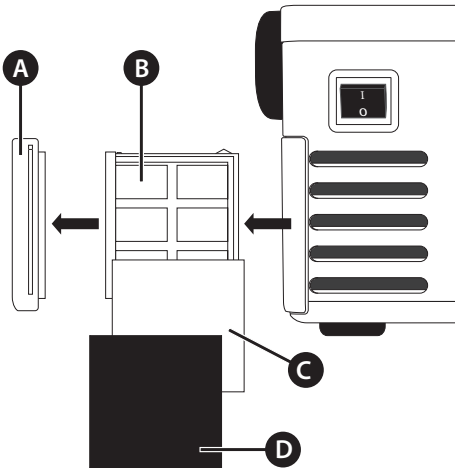
⚠CAUTION
A heavily worn or damaged mask must not be reused and should be disposed of correctly.

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 48: 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.

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.

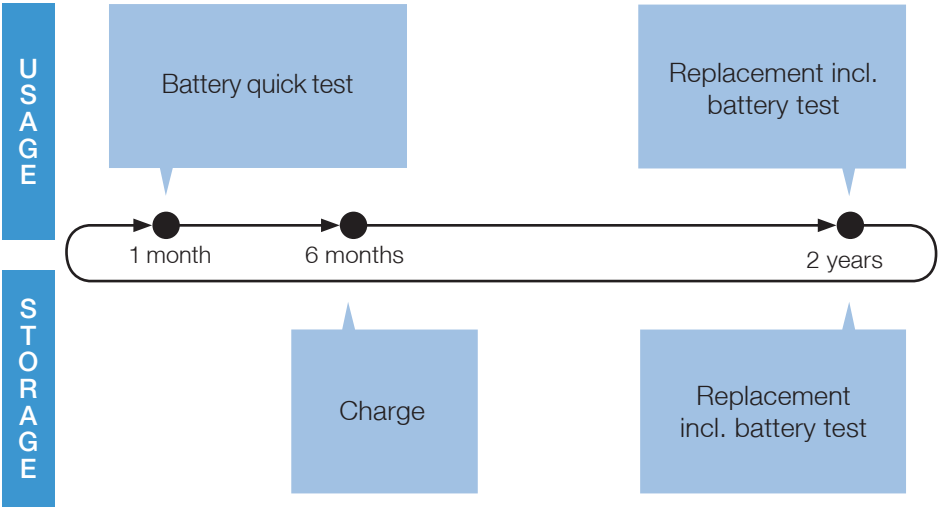
Table 9: Service intervals - overview

When?	What?	By whom?
Before commissioning	Safety-related test	Provider/Service
Weekly	Clean/replace the coarse filter (see page 107)	User/Patient
	Visually check of the fine filter	User/Patient
Monthly, or before, if heavily contaminated	Replace fine filter (see page 108)	User/Patient
Monthly	Battery quick test (see page 112)	User/Provider
Every 6 months during in storage	Charge battery to 100 % (see page 111)	User/Provider
Every 6 months without bacterial filter	Replace the valve membrane (expiration)	Provider/Service
Every 12 months	Maintenance 1 (refer to the service manual)	Provider/Service
	Safety-related test	Provider/Service
Every 2 years	Maintenance 2 (refer to the service manual)	Provider/Service
After 15,000 h blower run time or every 5 years	Maintenance 5 (refer to the service manual)	Provider/Service

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 after a certain time the batteries must be replaced and disposed. Tips for disposal can be found on page 129.

MAINTENANCE/REPLACEMENT INTERVALS



CHARGING THE BATTERIES

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

PERFORM THE BATTERY QUICK TEST

The battery quick test must be carried out monthly as follows.

1. Make sure that the battery is 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.

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

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 56.

The following data will be saved:

Table 10: 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 11: 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
An older parameter set is on the device	Current parameter set is incorrect	The device uses the old parameter set and can continue to be utilized.
Default parameters are on the device	No valid parameter set available or they are faulty	The device uses the default parameter set and can continue to be utilized.
The flow sensor shows an error	Flow sensor is defective	Device must be serviced
The FiO_2 sensor shows an error	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

Table 12: Error messages during operation and at device start-up

Error message	Cause	Correction
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

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. working pressure	50 hPa
Min. working pressure	0 hPa
Max. flow	175 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

Pressure at 60 l/min		
Inspiratory resistance of the device at the patient connection port	Single line patient circuit	Double line patient circuit
	2.8 hPa	2.9 hPa
Expiratory resistance of the device at the patient connection port	Single line patient circuit	Double line patient circuit
	3.9 hPa	4.2 hPa
Total resistance of the system	< 6 hPa	

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
Pressure bar	0 – 60 hPa	15 Pa	0.0 – 100 hPa	1.0 hPa or 5 % of the measured value
Volume	0 – 2.5 l	0.01 l	Calculated from flow measurements	0.03 l or 20 % of the measured value
Flow	0 – 200 l/min	1 l	-200 – 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
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 %
Leak Rate	0 – 230 l/min	1 l/min	0 – 230 l/min	10 l/min

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

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)

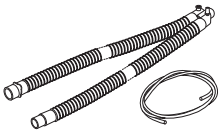
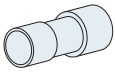
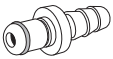
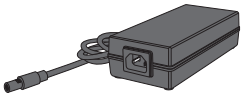
REPLACEMENT PARTS AND ACCESSORIES

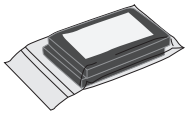
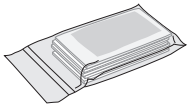
NOTICE

Make sure to follow all general safety guidelines when using replacement parts and accessories page 22.

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

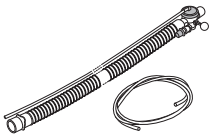
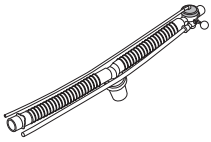
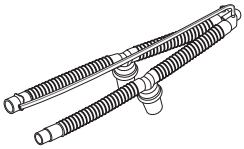
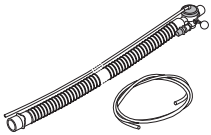
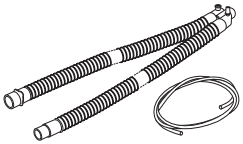
REPLACEMENT PARTS

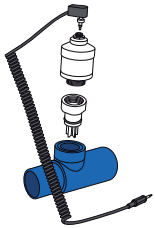
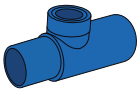
Name Article number	Figure
Disposable double line circuit for adults with pressure measuring tube (L = 180 cm, ∅ 22 mm) 00007969	
Bacterial filter adapter 00004933	
Straight FiO_2 connection adapter 41000104	
SD card, 2 GB 11200010	
Mains cable 31100023	
Switched-mode power supply 00014206	
Filter cassette, complete (open) 00002145	

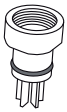
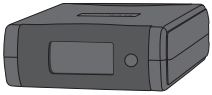
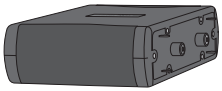
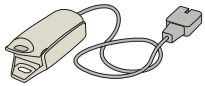
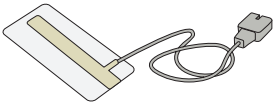
Name Article number	Figure
Filter cassette, complete (closed) 00002146	
Filter cassette, complete (open) with filters 00002038	
Filter cassette, complete (closed) with filters 00002058	
Filter cassette cover 42101301	
Coarse filter, 1 pack (2 ea) 00014950	
Course filter 00002993	
Fine filter, 1 pack (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	

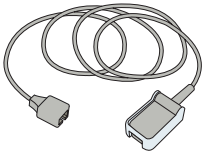
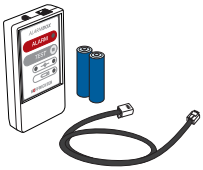
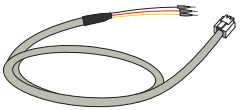
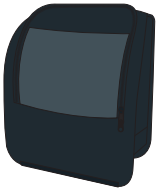
Name Article number	Figure
Brief instructions for CARAT II pro 50000645	
Carrying case 00004875	

ACCESSORIES

Name Article number	Figure
Disposable single line circuit for adults with an expiratory valve and the pressure measuring and control tube (L = 180 cm, ∅ 22 mm) 00014967	
Disposable single line circuit for adults with an expiratory valve and the pressure measuring and control tube plus water trap (L = 180 cm, ∅ 22 mm) 00014995	
Disposable double line circuit for adults with pressure measuring tube and water traps (L = 180 cm, ∅ 22 mm) 00007996	
Disposable single line circuit for children with an expiratory valve, pressure measuring and control tube (L = 180 cm, ∅ 15 mm) 00014923	
Disposable double line circuit for children with pressure measuring tube (L = 180 cm, ∅ 15 mm) 00004928	
CPAP Silicon nasal mask, size S 00004960 CPAP Silicon nasal mask, size M 00003440 CPAP Silicon nasal mask, size L 00003434	

Name Article number	Figure
CPAP Silicon full face mask, size S 00003441 CPAP Silicon full face mask, size M 00003436 CPAP Silicon full face mask, size L 00003437	
NIPPV Silicon full face mask, size S 00003461 NIPPV Silicon full face mask, size M 00003442 NIPPV Silicon full face mask, size L 00003438 NIPPV Silicon full face mask, size XL 00003462 NIPPV PSU Silicon full face mask, size L (autoclavable) 00003439	
Bacterial filter 00004932	
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	

Name Article number	Figure
FiO_2 sensor adapter 23000020	
FiO_2 sensor connecting cable with screw connector 00014116	
FiO_2 connection adapter, angled 41000087	
Cover for expiration tube connection 42100449	
USB cable (PC cable) 00005291	
AKKUPACK uni BASE "Ventilation" 00011100	
AKKUPACK uni PLUS 00011099	
SpO_2 finger clip sensor, cable length 2 m 00005292	
SpO_2 adhesive sensor for adults and children (finger and toe), cable length 2 m 00005294	

Name Article number	Figure
Extension cable for SpO_2 sensor, cable length 1 m 00005293	
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	
"EASYset" PC software	

MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

The CARAT II pro must be commissioned in accordance with the provisions in these user's manual. Wireless home network devices, mobile phones, cordless phones and their base stations, walkie-talkies etc. can affect the CARAT II pro. Close proximity to these devices should therefore be avoided.

Example: A distance of 3.25 m has to be maintained for a typical mobile phone with a maximum output power of 2 W to preserve an electromagnetic immunity of 10V/m.

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.