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LAVI Patient ENG_2019-09-25_5.0

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LAVI user's manual for patients

LAVI
Ventilator

HOFFRICHTER
SERVONA RESPIRATORY CARE

User's manual
for patients

Applies to device types 9LV401 and 9VL402 from device software 1.400

LAVI

User's manual

for patients

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 following documents are available in addition to this user's manual:

- LAVI user's manual for physicians and medical professionals
- LAVI brief instruction
- Service manual
- Hygiene concept
- Maintenance schedule

Licensing information
The device software is in part based on freeware. You can save and read the list of software used as well as the corresponding licensing conditions by copying the data to an SD card.

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 provide the serial number in case of queries and complaints.

CE 0123

CE mark and number from the notified body. The medical device complies with the applicable regulations of EU 93/42/EEC for medical products.

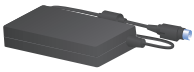
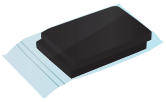
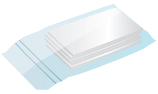
Table of contents

List of figures

Chapter 1
Introduction

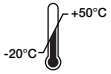
Please note: *This user's manual for patients is included in the scope of delivery. It does not replace the user's manual for physicians and medical professionals.*

Scope of delivery

Figure	Name		
	LAVI ventilator		Brief instructions
	Mains cable		User's manual for patients
	Internal battery RRC2054 (Only LAVI 40)		Final inspection log
	Carrying case		Spare filter cassette, complete (open) with filters
	Switched-mode power supply FSP090-RACM1		Spare course filter, 1 pack (2 units)
	Power supply unit holder with integrated strain relief		Spare fine filter, 1 pack (5 units)
	Leakage tube circuit (L = 180 cm, ∅ 22 mm)		
	Straight O_2 connection adapter		

Symbols

Symbols on the packaging

Symbol	Meaning
EAN	European Article Number
REF	Article number
SN	Serial number
CE 0123	CE mark and number from the notified body. The medical device complies with the applicable regulations of EU 93/42/EEC for medical products.
	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 during storage and transport
		CAUTION! Device contains lithium-ion batteries

Symbols on the rating plate

The rating plate is on the bottom of the device.

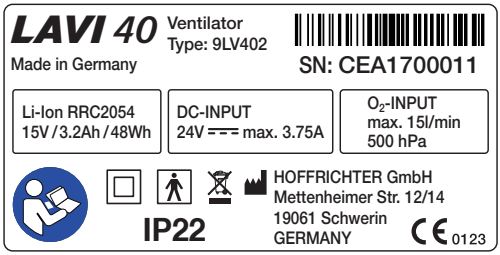


Figure 1: Rating plate

Symbol	Meaning
	Follow the instructions in the user's manual.
	Protection class II (protective insulation)
	BF application part
IP22	Protection 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 to 15°
SN	Serial number
CE 0123	CE mark and number from the notified body. The medical device complies with the applicable regulations of EU 93/42/EEC for medical products.
	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
Housing	
	Follow the instructions in the user's manual.
Connections	
	FiO_2 sensor connection
	DC connection
	COM interface
	Connection of remote alarm/nurse call (ESD-sensitive component – do not touch!)
	USB interface
	Oxygen connection
Control	
	Release button for the integrable humidifier
	On/off button

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 prevent 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.

⚠ **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 moderate injuries.
ATTENTION	This symbol denotes situations that may lead to material damage or damage to the device.
Please note:	*Notes provide tips and information for the efficient, correct use of the device.*

Intended purpose

The LAVI ventilator device may only be used for non-life-supporting respiration. It serves as intermittent respiration support as well as to provide respiration to patients with insufficient spontaneous breathing ability. The device is suitable for adults and children from a tidal volume of 100 ml and higher and is designed for home care and/or use in professional health care facilities. It must not be used for intensive ventilation.

LAVI is not intended for use in vehicles, planes or helicopters.

Description of function

The blower sucks in the ambient air via a filter and transports it to the patient at a set pressure via a leakage tube circuit (with passive exhalation valve). Ventilation can be invasive (e.g. using a tracheostoma) or non-invasive (using a mask).

Ventilation is carried out according to ventilation parameters set using the control elements. Ventilation can be monitored based on measurements and graphs on the display.

In case the custom and permanent alarm parameters are violated, visual and acoustic alarms are emitted. If the prescribed ventilation is no longer possible due to a technical error, an acoustic alarm is emitted for at least 2 minutes.

If LAVI is operated with an internal battery, ventilation can continue on without disruption in the event of a power failure.

LAVI can be connected to a low-pressure source of oxygen for ventilation with increased oxygen concentration. When oxygen is introduced but ventilation is not started, the oxygen supply is interrupted by a safety valve. Remaining oxygen can be released from the device via the oxygen outlet.

It is also possible to combine LAVI with the integrable humidifier “AquaTREND uni” or an external humidifier.

Therapy and statistical data, including alarms and events, can be copied onto an SD card and analysed using the PC software “easySET”.

For service purposes, LAVI features one USB and one COM interface.

Indication

LAVI can be used for the following indications:

- Obstructive ventilation disorders (e.g. COPD)
- Restrictive ventilation disorders (e.g. scoliosis, thorax deformities)
- Neurological, muscular and neuromuscular disorders (e.g. paralysis of the diaphragm)
- Central breathing regulation disorders

Regardless of the indications named here, use of the device always depends on the doctor's individual diagnosis.

Contraindications

⚠ WARNING **Risk of injury due to contraindications!**
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
- Gastric inflation

Mask ventilation:

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

General complications of mechanical ventilation:

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

User qualification

The respiration and alarm parameters may only be set by trained specialist personnel under the supervision of a doctor. Care staff and patients have been instructed on how to use and handle the device. These people must be familiarised with operation of the device and must have read all of and understood this user's manual before commissioning the device. In addition, the operator must inform the users of what accessories are compatible with the device.

Maintenance and repairs may only be performed by trained and authorised service companies.

Chapter 2
Safety Information

Please note: *Heed all important information in this user's manual. Otherwise, there is a risk of accidents, injury and material damage.*

⚠ WARNING **Risk of infection due to germs!**
Hygienically preparing and cleaning the device must be performed according to this user's manual and the applicable regulations of the hospital or nursing home.

⚠ CAUTION **Risk of injury due to incorrect device settings!**
- Only qualified, trained, specialist medical staff under the supervision of a physician may make adjustments to the ventilator.

Risk of injury due to incorrect accessories!
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.

- Please read first this user's manual carefully and in its entirety before first using the ventilator.
- Keep the instructions in close proximity to the device for immediate reference if necessary.
- In case of problems, unexpected events or unusual device behaviour (e.g. during commissioning, use or maintenance), inform the device operator immediately and document the incidents. You will generally find the operator contact data on the device as well as in the medical device book.
- The device must only be used by persons who have fully read and understood this user's manual before commissioning and have familiarised 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.
- 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 indicate it.
- LAVI is not intended for use in vehicles, planes or helicopters.
- Please take the care to ensure that the patient remains connected to the tubing circuit during ventilation.
- The device must not be used with flammable anaesthetics 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 treated hygienically.
- Equipment that is not part of the ventilation system must not be connected.

- 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.
- Safety-related testing and maintenance are required every two years for the ventilator.
- In case of excessive agitation on the part of the patient, there is a risk of hyper-ventilation in all ventilation modes with inspiration triggering.
- The device must not be steam-sterilised 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.
- 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 thus not permitted.
- Masks may only be used on the prescription of a physician and after training by qualified medical staff.
- Only use the mask after instruction by qualified medical staff. Clarify in particular the intake of medicines and possible contraindications and side effects associated with the use of the prescribed mask.
- 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.
- During operation, the power supply unit can reach a surface temperature of up to 57°C. For this reason, do not touch the power supply unit for more than 1 minute to prevent burns to the skin.
- Keep small parts of the respiratory therapy system out of the reach of children and animals.

Electrical safety

⚠ WARNING

Risk of injury due to electric shock!

- Do not try to open the device. Maintenance and repairs may only be performed by personnel authorised by HOFFRICHTER GmbH.
- Do not touch live parts of the mains cable or power supply unit if defective.
  ⇨ Replace a defective mains cable/power supply unit.
- The device must not be used in wet rooms, as humidity penetrating the device presents a risk of electric shock.

Risk of injury due to interrupted operation!

- The device must always be located at least 30 cm away from 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.
- 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.
- The use of accessories or power supplies we have not approved for the ventilator can increase the emission of electromagnetic radiation, reduce interference immunity or lead to an increased patient leakage current.

- Only the supplied power supply unit may be used for operating the ventilator.
- Only LAVI and a humidifier may be connected to a power strip. Additional power strips or extension cables must not be plugged in to this power strip.
- Portable power strips the LAVI/an external humidifier are connected to must not be placed on the floor.
- Do not exceed the permitted maximum load of the power strip. Refer to the user's manual for the maximum power consumption of the LAVI/humidifier.
- Respiratory therapy may be contraindicated for certain pre-existing conditions.
- The contacts for connecting the remote alarm/nurse call and the RS232 interface must not be touched at the same time as the patient to prevent current from being discharged via the patient.
- Only accessories approved by HOFFRICHTER that are not connected to the power supply may be connected to the remote alarm/nurse call and the RS232 interface.

- To disconnect the device from the mains supply, unplug it.
- Before cleaning the device, the plug must be disconnected from the electrical outlet.
- Do not reach for the device under any circumstances if it falls into water.

Installation requirements and transport

⚠CAUTION

Risk of injury due to the device falling down!

⇨ For operation, the device must be placed on a safe and level base.

Risk of injury due to unclean or insufficient air supply!

⇨ Please ensure the device is operated in an area where there is sufficient and clean ambient air.

Risk of injury due to overheated ventilation air!

The device must not be operated under any environmental conditions other than those stipulated. Excessive ambient temperatures can result in an increased ventilation air temperature.

⇨ Please note the operating, transport and storage conditions.

- The air inlet at the rear of the device, as well as all ventilation slots, must not be blocked.
- The display and the info LEDs must not be covered and must be visible to the user 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 + 50°C (with battery).
- The device must not be exposed to direct sunlight.
- Due to possible electromagnetic interference the ventilation device must not be placed directly next to other devices in which the electromagnetic radiation is not CE compliant and/or the limits values are exceeded (see page 93). If this is unavoidable, then ventilator operation must be monitored for trouble-free and correct operation.
- Do not place the device near water containers (baths).

Instructions before commissioning

- A malfunctioning device can endanger the patient or operator. Should the appliance not start properly, or if the device's automatic self-tests should fail, you must stop operating the device. In such cases, the service provider must be informed.
- Position the device so 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 oxygen

⚠CAUTION **Risk of injury due to increased oxygen supply!**
The oxygen supplied must not exceed a pressure of 500 hPa and a flow of 15 l/min. The oxygen must be dosed using an external flow meter.

- Before commissioning, the patient must be instructed on site in their home environment.
- Consult with your dealer regarding the use of oxygen.
- Make sure to follow your doctor's instructions.
- Observe the user's manual of the manufacturer or distributor from whom you obtain your oxygen.
- If the patient is supplied with oxygen via the device, the FiO_2 should be measured.
- On the LAVI, FiO_2 measurement is possible using the optional FiO_2 sensor. We recommend using this particular sensor exclusively.
- Keep the FiO_2 sensor out of the reach of children and animals.
- To prevent incorrect calibration of the FiO_2 sensor, make sure fresh air is supplied when operating the device.
- The FiO_2 sensor contains a caustic liquid. Avoid skin or eye contact if there is a sensor leak! Replace the sensor.
- When supplying oxygen via the O_2 connection on the device, ensure that only dry gas is used. 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 O_2 connection and the external O_2 source must be absolutely airtight. Otherwise, leakage losses may occur during ventilation.
- The oxygen supply should be stopped before ventilation is interrupted. We also recommend allowing the device to run for several respiratory cycles without oxygen supply after stopping ventilation.

- In the event of an oxygen leak, the oxygen supply should be shut off immediately. The room must be ventilated immediately. Any sparks, fire or potential fire 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

Front side of device

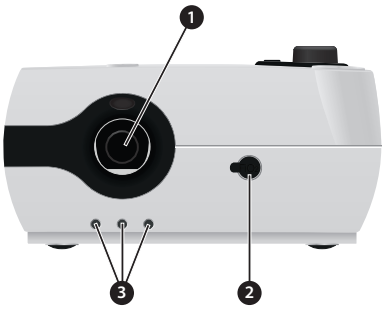


Figure 2: Front side of device

1 Connection leakage tube circuit/ humidifier

2 Connection FiO_2 sensor cable

3 Contact socket for integrable humidifier AquaTREND uni

Rear of device

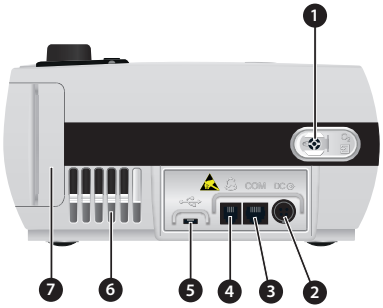


Figure 3: Rear of device

1 Oxygen connection

2 DC connection
The DC plug is connected here. See also page 35.

3 RS232 interface (service interface)

4 Connection of remote alarm/nurse call
Only relevant for clinical use.

5. Micro-USB connection (PC connection/service interface)

6 Ventilation slots

7 Filter cassette (coarse and fine filter)
(For information on exchange, see page 80.)

Left side of device

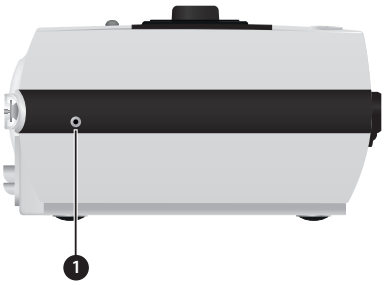


Figure 4: Left device side

1 Oxygen output
Outlet for excessive oxygen when ventilation is off

Bottom of device

Figure 5: Bottom of device

1 SD card slot
An SD card here can be inserted here.

2 Rating plate

3 Battery compartment cover
The internal battery is located under the cover. See also page 39.

Top of device

Figure 6: Top of device

1 Display

2 Info LED

3 It also provides information on the alarm/device status priority

Colour	State	Priority/status
Red	Flashing	HIGH
Yellow	Flashing	MEDIUM
Turquoise	Lit	LOW
Green	Lit	Ventilation is running
White	Flashing	Device is booting
	Lit	Device for operation

4 Softkeys
See also page 30.

5 Multi-function key MFK
(for navigating the menus)

6 On/off button

Function	Action
Start ventilation	Press briefly
Stop ventilation	Press briefly and confirm with MFK
Switching on the device	Press for > 4 s
Switching off the device	Press for > 4 s

7 Release button for integrable humidifier AquaTREND uni.

Explanation and functions of the softkeys

Symbol	Meaning

Alarm key

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

Escape key

Function	Action
Exit current screen	Press briefly
Exit selected parameter	Press briefly
Cancel action	Press briefly

Heater key

If an integrable humidifier is connected, the heating key is available:

- On the home screen and
- In the first level when the home screen icon is pressed on the home screen.

Function	Action
Switch on/off heating for the integrable humidifier	Press briefly

Home key

Function	Action
Return to the home screen	Press briefly

Error key

Function	Action
Error list display	Press briefly

Explanation of the toolbar icons

Symbol	Meaning
	Clinic mode active
	Home mode active
	Alarm active  Red: high priority  Yellow: middle priority  Turquoise: low priority
	Alarm inactive  Grey: inactive, regardless of the continuation of the alarm condition
	Audio alarm paused The audible alarm has been paused for 2 min. The audible alarm of 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.
	Audio alarm paused counter Indicates how much longer the audible alarm will be paused.
	Error detected On the home screen, press the error key to display the error message(s). You can find a list of all potential errors on on page86.
	Humidifier  Heating on  Heating in standby  Heating off  Heating deactivated due to battery operation or a fault in mains operation
	FiO_2 sensor connected
	FiO_2 sensor connected, but not calibrated
	SD card is inserted into the device

Symbol	Meaning
	Menu lock active The home and escape keys are deactivated and the MFK functions are restricted. It is not possible to access the menu.
	Internal battery charging
	Power level of the internal battery  green: about 60% ... 100%  red: about 20% ... 60%  yellow: about 0% ... 20% Please note: *If no percentage is shown, the battery requires maintenance (see page 83).*
	Replace internal battery • Defective battery or • Battery capacity too low or • Battery incompatible
	Mains operation active

Explanation of symbols on the pressure bar

Symbol	Meaning
	Trigger lock “On” setting
	Trigger lock triggered
	Spontaneous breathing detected The device has detected spontaneous breathing by the patient. This triggered the inspiration trigger. The symbol will remain visible during inspiration and will shut off with the beginning of the expiration.
	Safety cycle active The device is operating in PSV mode. The patient is not breathing spontaneously and is ventilated at the set frequency.

Chapter 4
Commissioning

General information

- Before commissioning the device, read the safety information from page 19.
- Before commissioning the ventilation system (ventilator, tube, humidifier etc.), check all connections for leaks, as well as the stability of the connected accessories.
- Never operate the device without the air filter.
- Only use original HOFFRICHTER filters.
- If the device was previously in an environment where the air temperature was not the same as in the new operating location, allow approximately 1 hour until the temperatures have evened out before commissioning.

Setting up the device

Place the device on a flat and stable surface. Make sure that the device is placed securely and that the air inlet at the rear of the device is not blocked. Make sure that the user is able to see the display and the info LED during ventilation. The device is designed for operation within arm's reach.

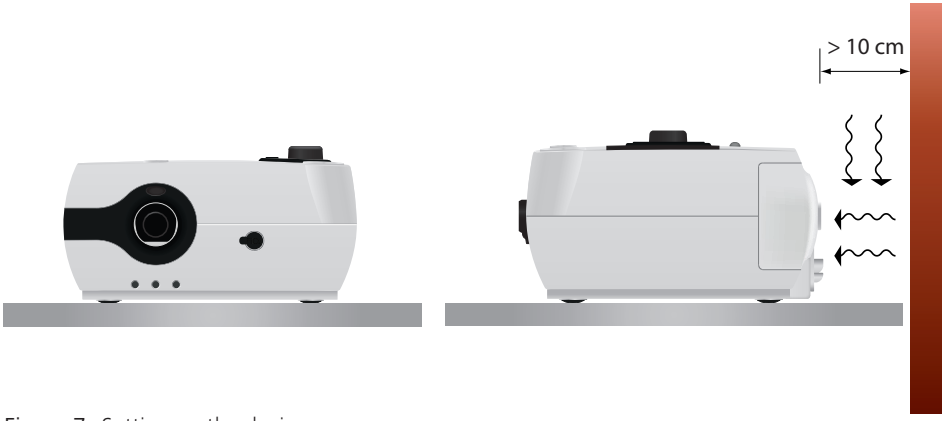


Figure 7: Setting up the device

Power supply

The ventilator can be supplied by two different power sources:

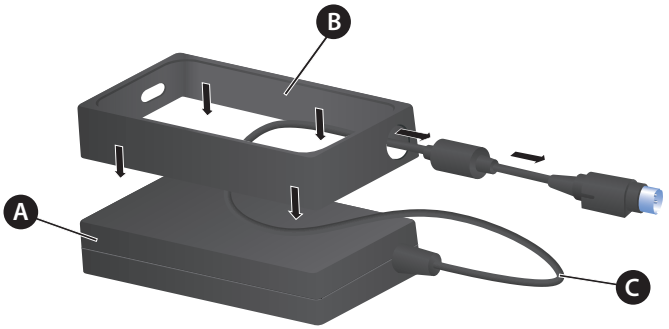
- Mains connection via power supply unit
- Internal battery

The ventilator automatically detects which power sources are available. If the device is connected to a power supply unit, the power supply unit is used as the primary source and the internal battery as the secondary source.

Mains operation

Mains operation means that the device is supplied with power by the power supply unit. The device can remain connected to the mains continuously without posing a risk. If inserted in the device, the internal battery is also charged.

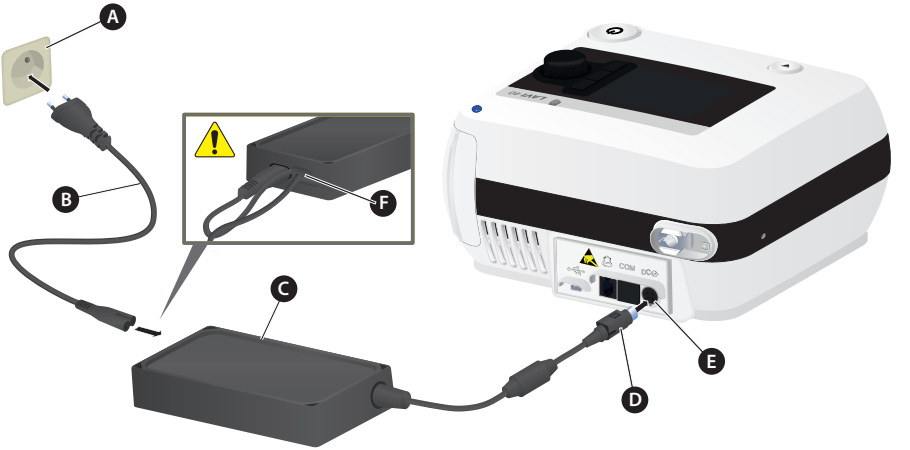
Connect the device to the mains supply as follows:



A Power supply unit B Power supply unit holder with integrated strain relief
C Power supply unit cable

Figure 8: Assembling the power supply unit and power supply unit holder

1. Pull the power supply unit cable through the round opening on the power supply unit holder.
2. Press the power supply unit into the power supply unit holder until you feel it click into place.



A Socket B Mains cable C Power supply unit D DC plug with snap lock
E DC connector socket F Strain relief

Figure 9: Mains connection via power supply unit

3. Connect the mains cable to the power supply and hook the mains cable behind the strain relief to secure it against accidental unplugging.

4. Insert the DC plug into the DC connector socket.

   Please note: *The DC plug is a POWER-DIN plug with snap lock. Do not pull on the cable to disconnect the cable from the device—instead, grasp the plug and disconnect it by pulling it in a straight line away from the device.*

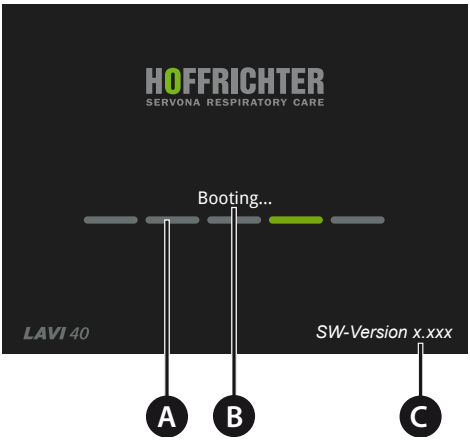
5. Insert the mains cable plug into the power socket (100 - 240 V, 50/60 Hz).

6. Press the on/off button for more than 4 s to switch on the LAVI.

7. The device boots while performing a self-test:
   - Testing the primary and secondary alarm sounds:
     Both alarm sounds give a short beep one-by-one.
   - Verifying alarm LED: the alarm LED lights up white.
   - Checking of other hardware components

The booting progress is displayed by a progress bar (A). The status (B) is also displayed:

- Booting... → Device is booting
- ⚠ Error message → Error detected, press MFK to continue. All error messages are listed on page86. The device cannot be started if certain errors are in effect. In this case, contact your service provider.



A Progress bar B Status C Software version

Figure 10: Start screen

If no errors were detected during the self-test or the errors have been confirmed, the display will switch to the home screen.

It takes up to 1 minute to boot the device, after which the device will be ready for operation.

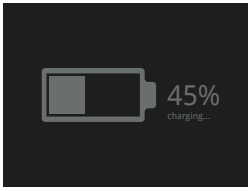
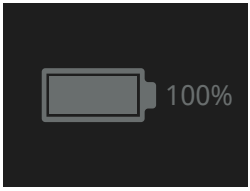
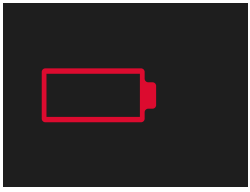
Standby operation

If device mains operation is switched on and respiration is switched off, the device can be placed into standby operation. This means that the device automatically moves into a sleep mode after the last operation. A standby screen will be displayed. If the device has an internal battery, this will be charged and the power level will be shown.

The time at which the device will switch to standby operation can be modified using the “Standby” parameter on the system screen. The default factory setting is 5 min. If you do not want the device to switch to standby operation, set the parameter to “off”.

To exit standby operation, press a key or the MFK.

In the event of an alarm, standby also stops and the home screen is displayed.

Standby screen	Meaning
	No battery in the device
	Battery charging
	Battery fully charged
	Replace internal battery • Defective battery or • Battery capacity too low or • Battery incompatible

Operation with internal battery

Battery operation means that the device is supplied with power by the internal battery. If the device is supplied with power by the internal battery, the device automatically switches off after two minutes if ventilation is not active.

Please note:

- *The internal battery is solely intended to provide temporary power in the event of outages in the mains supply and when changing the power source. It must not be used as the primary power source for ventilation.*
- *In battery operation, keep track of the battery power level and recharge it as needed.*
- *In order to ensure the full function of the battery, the battery must be maintained in accordance with the "Battery maintenance" on page 83.*
- *In battery operation, the device cannot be operated with a humidifier.*

Device operating times with a new, fully charged battery:

Battery power level	Time	Alarm
100 – 0%	approx. 200 min	-
> 20[1] – 0%	approx. 35 min	Low Internal Battery
approx. 5 – 0%	approx. 5 min	Internal Battery Empty
Measuring conditions: Output volume Vdel = 800 ml, ventilation frequency f = 20 rpm I:E ratio = 1:2, resistance R = 5 hPa (l/s)$^{-1}$ ± 10%, compliance C = 50 ml (hPa)$^{-1}$ ± 5%		

The internal battery enables operation of at least 1 hour at maximum power consumption.

⚠CAUTION **Ventilation failure!**
If the alarm "Internal battery empty" occurs, the device will switch off after 5 minutes.
⇨ Connect the device to an alternate power supply right away.

1 The display "Internal battery low" is shown at 20% of the battery's rated value.

The device will automatically switch off the ventilation 5 minutes after the "Internal battery empty" alarm occurs. A notice window will appear "Ventilation currently not possible. Internal battery empty". The device will switch off once another minute has passed. This prevents the battery from being fully drained and ensures the device shuts down properly.

Please note: *This 5-minute period cannot be maintained if the battery was deeply discharged and was not charged up to 10%. In such a case, ventilation will end immediately.*

Charge battery

To charge the battery, operate the device using the mains power. Recharging a fully discharged battery takes approximately 2.5 hours in mains operation. The device is fully functional during recharging.

Please note: *The battery begins charging when the power level falls below 95%.*

Power failure

Please note: *During a power failure, the battery capacity display must be monitored and an alternative power source kept ready.*

If the power supply is interrupted by a power failure and the device is on, 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".
When the power supply returns, the device is supplied with power from the mains supply and the internal battery is charged.

Operation without internal battery

Please note: *If the device is operated without a battery, it shuts off immediately in case of an interruption to the power supply. Connect the device to an alternate power supply right away.*

If the power supply is interrupted during ongoing ventilation, an acoustic signal is output for approx. 2 minutes. The acoustic signal can be deactivated by pressing the on/off button.

System setup, non-invasive ventilation

⚠ WARNING

Risk of injury due to tube circuit and cable!
If laid incorrectly, the tube circuit or other cables (e.g. pulse oximetry) could cause patient strangulation.
⇨ Tubes and cables must always be positioned so that they cannot wrap around the neck or limbs of the patient.

Risk of suffocation due to closed exhalation valve!
If the opening of the exhalation valve is closed, the patient could suffocate.
⇨ Make sure that the opening of the exhalation valve remains open so that expired air can escape.

During non-invasive ventilation, the user must always be able to exhale (expire). This can either be accomplished using a vented mask with integrated exhalation valve or a non-vented mask with separate exhalation valve.
The exhalation valve is optionally available as an accessory.

Setup with vented mask

Connect the components as follows:

A Vented mask B Leakage tube

Figure 11: System setup, non-invasive ventilation with vented mask

Setup with non-vented mask

Connect the components as follows:

A Non-vented mask B Passive exhalation valve C Leakage tube

Figure 12: System setup, non-invasive ventilation with non-vented mask

⚠ WARNING

Risk of injury due to tube circuit and cable!
If laid incorrectly, the tube circuit or other cables could cause patient strangulation.
⇨ Tubes and cables must always be positioned so that they cannot wrap around the neck or limbs of the patient.

Risk of suffocation due to missing exhalation valve!
If no option for exhaling through a separate valve is available in the invasive ventilation system, the patient could suffocate.
⇨ Use a separate exhalation valve.

Risk of suffocation due to closed exhalation valve!
If the opening of the exhalation valve is closed, the patient could suffocate.
⇨ Make sure that the opening of the exhalation valve remains open so that expired air can escape.

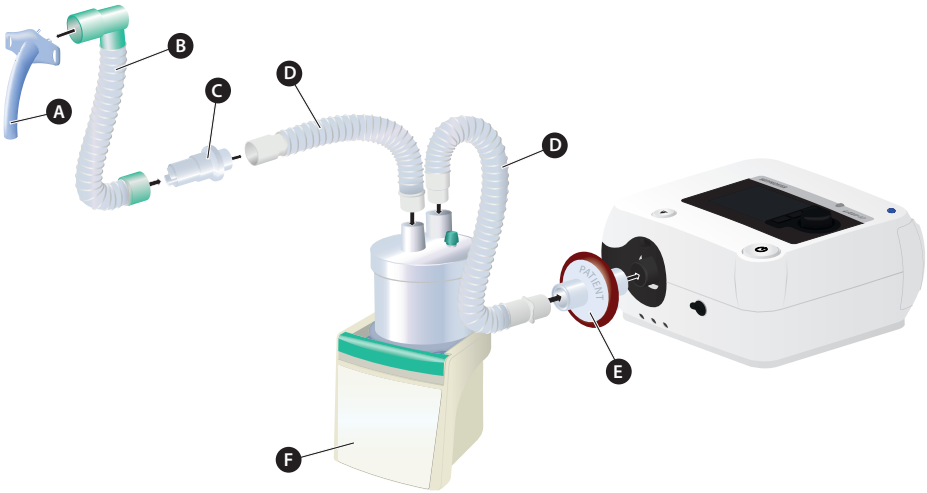
Risk of injury due to cold or dry breathing air!
Cold or dry breathing air presents an increased risk of collapsed lung and thus impaired gas exchange. This can also dry out the mucous membranes, resulting in an increased risk of infection. For this reason, the breathing air should be heated and humidified.
⇨ Use an external humidifier or HME filter.

Setup with external humidifier

Please note:

- *Use an approved humidifier according to DIN EN ISO 8185 with a humidity output of > 33 mg/l.*
- *Follow the manufacturer user's manual.*
- *The humidifier should be positioned below the patient and the device, so that no water can accumulate in the patient's lungs or in the ventilator. If water accumulates in the tube circuit, we recommend using water traps.*

Connect the components as follows:



A Tracheal cannula B Catheter mount tube C Passive exhalation valve D Leakage tube
E Bacterial filter F Humidifier

Figure 13: System setup, invasive ventilation with external humidifier

1. Connect all components as per Figure 13.

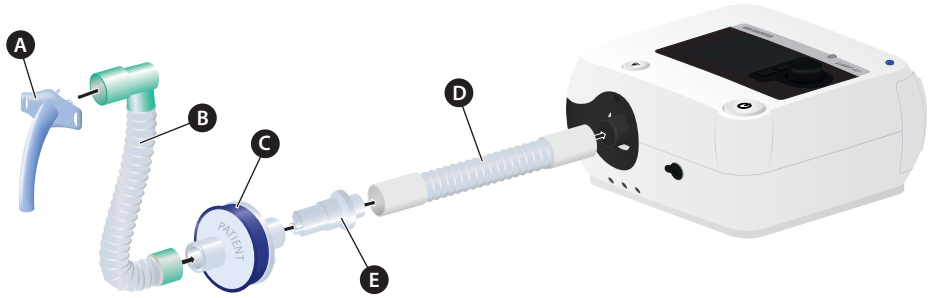
2. Calibrate the connected tube circuit (see page 45).

Setup with HME filter

If no humidifier is used, we recommend using an HME filter to maintain the moisture of the respiratory gas. A "combined filter" consisting of an HME filter and a bacterial filter is well-suited (e.g. Medisize Hygrovent HMEF).

Please note: *When using a HME filter, read the user's manual from the respective manufacturer. In particular, follow all information related to replacement intervals.*

Connect the components as follows:



A Tracheal cannula B Catheter mount tube C HME filter D Leakage tube
E Passive exhalation valve

Figure 14: System setup, invasive ventilation with HME filter

1. Connect all components as per Figure 14.
2. Calibrate the connected tube circuit (see page 45).

Calibrating the tube circuit

A tube calibration function is available in the device to enable use of different tube circuits and accessories. During tube calibration, the resistance of the circuit upstream of the air outlet is determined, which forms the basis for correct pressure measurement. Perform tube calibration when changes have been made to the system upstream of the air outlet. These may include connecting and disconnecting of the following components, for example:

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

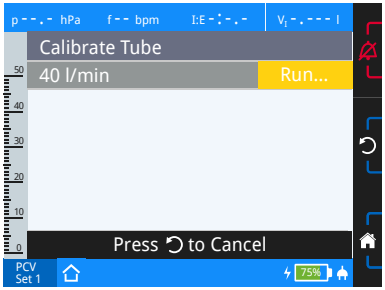
⚠CAUTION **Risk of injury due to incorrect pressure measurement!**
If the device is operating with incorrect calibration data, the pressure measurement may be distorted.
⇨ Before commissioning and changing the tube circuit, perform tube calibration.

To calibrate the tube circuit:

Please note: *During tube calibration, the patient tube circuit must be open and ventilation switched off. A mask can be connected.*

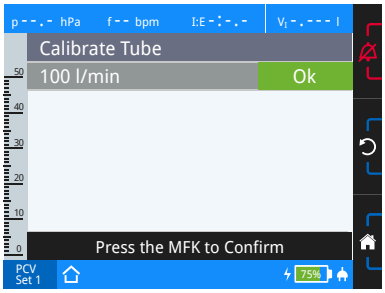
1. On the home screen, navigate to “System” and press the MFK.
2. Navigate to “Calibrate Tube” and press the MFK.

   During calibration, the system shows “Run...”.

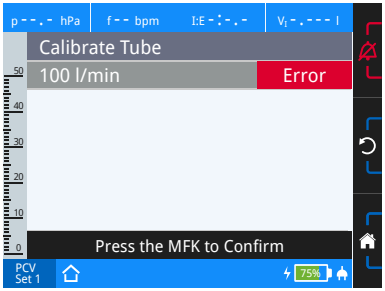


3. If the calibration was successful, “Ok” will appear after a few seconds.

   To finish, press the MFK. The calibration data are then applied. Until then, you can cancel calibration at any time by pressing the Escape key.



If the calibration was not successful, “Error” will appear.
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 or use another humidifier. Then rerun the calibration.



If you do not perform a tube calibration, the calibration data from the last tube calibration are used. When commissioning the device for the first time, the default calibration data[1] stored in the device are used.

1 Operation without humidifier:
Leakage tube circuit: ∅ 22 mm; 1.80 m
Height: ca. 44 m NHN, air pressure: approx. 1008 hPa
Connected ventilation components and accessories: no

Operation with humidifier:
Leakage tube circuit: ∅ 22 mm; 1.80 m
Height: ca. 44 m NHN, air pressure: approx. 1008 hPa
Connected ventilation components and accessories: Humidifier AquaTREND uni

Using an SD card

To be able to pass on therapy data to a doctor, you can copy the data to an SD card. You can use SD and SDHC cards up to 32 GB. You can format the SD card on LAVI and delete any existing data. This method is described under “Copy data”.

Please note: *We recommend using SD cards with a minimum of 8 GB memory.*

Copy the data as follows:

Please note: *We only recommended copying data when therapy is not in progress. If therapy is active, the data cannot be copied in full.*

1. Insert the SD card into the SD card slot until it clicks into place as shown in the illustration. then appears on the toolbar.

Figure 15: Inserting the SD card

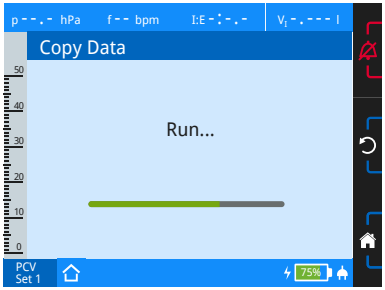
2. On the home screen, navigate to “System” and press the MFK.

3. Navigate to “Copy data” and press the MFK.

   Possible messages during the copying process:

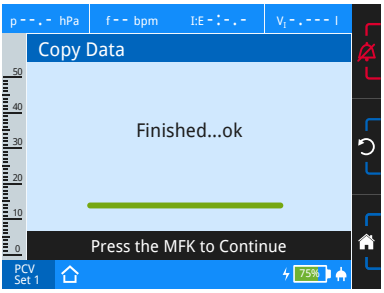
   “Run…”
   ⇨ The copying process is being performed

   “SD card full” or “Finished…error”
   ⇨ Format the SD card and copy again.
   Please note: *This will delete all data on the SD card.*
   ⇨ Use another SD card.



4. Once successfully copied, the message “Finished...ok” will appear.

   Press the MFK to close the notice window.



5. Press the MFK.

6. To remove the SD card, carefully press the SD card into the SD card slot. Then, remove the SD card.

Figure 16: Removing SD card

Using the functional bag

⚠ WARNING **Risk of injury due to insufficient monitoring of the device functions!**
If important device functions are not shown or available, proper operation cannot be guaranteed.
⇨ Only use the original HOFFRICHTER functional bag.

The functional bag protects the ventilator in mobile use (e.g. at the wheelchair or walker) from mechanical damage or effects of the weather. The functional bag is available as an accessory (see page 89).

Figure 17: Functional bag

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

- 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. Accidental disconnection of the accessory parts must be avoided.
- Follow all instructions in the user's manual when using the functional bag in combination with other accessory parts.

Switching on the device

The device requires up to one minute to boot before it is ready for use, after which the device will be ready for operation.

Please Note:

- *The tube circuit may be connected when the device is started up, but it must not be connected to the patient yet.*
- *If you are using oxygen therapy during ventilation, please note the safety information for using oxygen from page 24.*

Mains operation

Connect the device to the mains supply. To switch the LAVI on, press the on/off button for more than 4 seconds.

Battery operation

To switch the LAVI on in battery operation, press the on/off button for more than 4 seconds.

Switching off the device

Mains operation

Stop ventilation. To switch on the device, press the on/off button for more than four seconds.

Battery operation

Stop ventilation. The device shuts off after approximately two minutes. To switch the device off right away, press the on/off button for more than four seconds.

Please note: *The device boots down when you switch it off. This process takes a few seconds. Do not disconnect the device from the mains or remove the internal battery during this time. Otherwise, data may be lost.*

Start ventilation

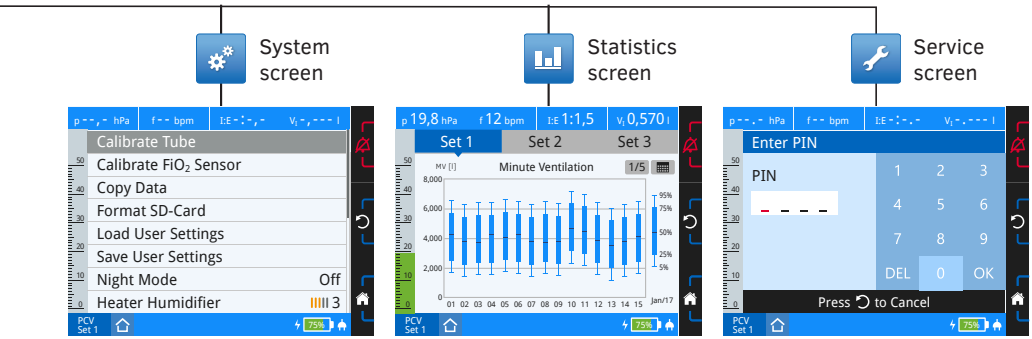
Press the on/off button. Ventilation begins.

Stop ventilation

Press the on/off button and confirm the prompt with “Yes”.

Chapter 5
Operating the Device

Menu structure


System screen
Statistics screen
Service screen
p --,- hPa
f -- bpm
I:E -:-,-
Vt -,--- l
Calibrate Tube
Calibrate FiO2 Sensor
Copy Data
Format SD-Card
Load User Settings
Save User Settings
Night Mode Off
Heater Humidifier 3
PCV Set 1
75%
p 19,8 hPa
f 12 bpm
I:E 1:1,5
Vt 0,570 l
Set 1
Set 2
Set 3
MV [l]
Minute Ventilation
1/5
8,000
6,000
4,000
2,000
0
95%
75%
50%
25%
5%
01 02 03 04 05 06 07 08 09 10 11 12 13 14 15
Jan/17
p --.- hPa
f -- bpm
I:E -:-.-
Vt -.--- l
Enter PIN
PIN
1 2 3
4 5 6
7 8 9
DEL 0 OK
Press to Cancel

Menu lock

The menu lock function can be used to protect against the accidental changing of device settings. It locks the following operating elements:

- Home key
- Escape key
- Turning and pressing the MFK exception: *if a notice window is displayed that requests operation is performed via the MFK, the MFK can be used as usual.*

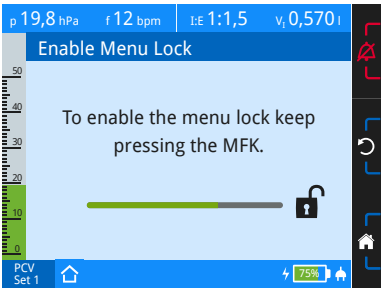
The following keys retain their full functionality:

- Alarm key
- Heating key
- On/off button

To activate the menu lock:

1. Hold the MFK in the home screen for longer than 1 second until the window appears at the side. Keep the MFK pressed until the progress bar has completed and is displayed. Then release the MFK.

   Please note: *If therapy is in progress, the measured values screen will automatically appear upon activating the menu lock. The home screen will be shown again once therapy is over.*



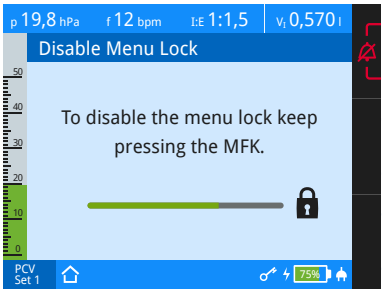
2. The symbol will appear on the toolbar.

To deactivate the menu lock:

1. Hold the MFK for more than 1 second until the window appears at the side.

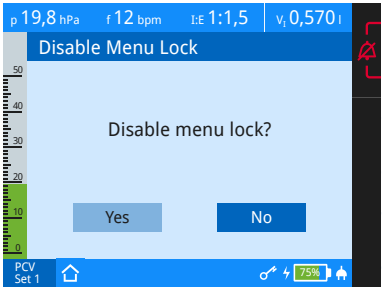
   Keep the MFK pressed until the progress bar has completed and is displayed.

   Then release the MFK.



2. Select “Yes” and then press the MFK.

   The symbol will be hidden from the toolbar.



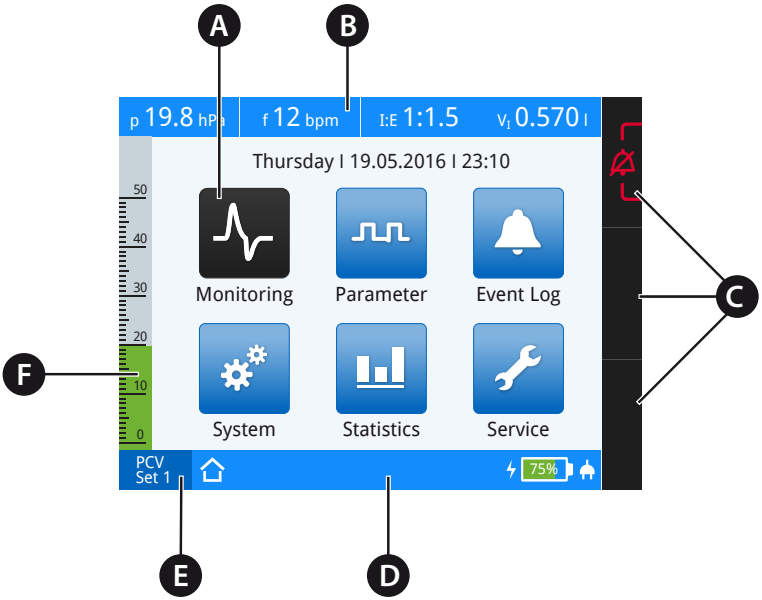
User profiles

For ventilation outside a clinic, the device must be operated in the “Home” user mode.
If the device is in the “clinic” mode” , contact your responsible physician or dealer.

Home screen

You can enable individual screens from the home screen:

- Monitoring screen
  - Measurements: Monitoring measurements (numerical)
  - Graphs: Monitoring measurements (graphs)
- Parameter screen
- Selecting the ventilation set, setting the ventilation and alarm parameters
- Event log screen
  - Alarms : Displays physiologically-dependent alarms
  - Alarms :Displays technically-dependent alarms
  - Events: Displays events
- 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 symbol B Measurement display C Softkeys D Toolbar
E Active ventilation mode and active set F Pressure bar

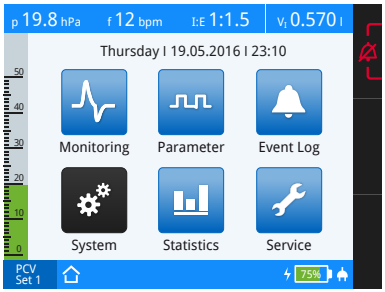
Figure 18: Home screen

To enable a screen:

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

Selected screen symbol
→ black

Symbol not selected
→ blue



2. Press the MFK to activate the selected screen.

Change the display mode

In the factory state, the screen switches automatically 2 minutes after the last operation:

- During ventilation to the measurements/graph screen (depending on which screen was most recently active) or
- When ventilation is off, to the home screen

The physician can set the time for the timer screen change on the system screen. He can also determine that the display should not change. In this case, the parameter should be set to “off”.

Monitoring screen

The ventilation parameters are shown in real time on the monitoring screen.

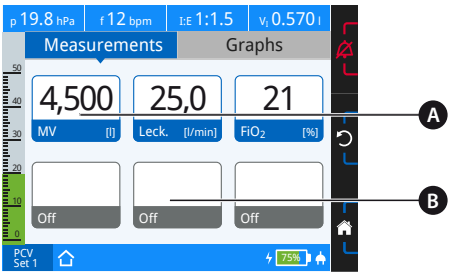
The monitoring screen is divided into 2 sections:

- Measurements
- Graphs

Measurements

Depending on the configuration, the following parameters are shown under “Monitoring” > “Measurements” when ventilation is active:

- Pressure (p),
- Frequency (f)
- Inspiration to expiration ratio (I:E)
- Minute ventilation (MV),
- Volume Inspiration (V_I),
- Leak rate
- FiO_2 concentration (FiO_2)



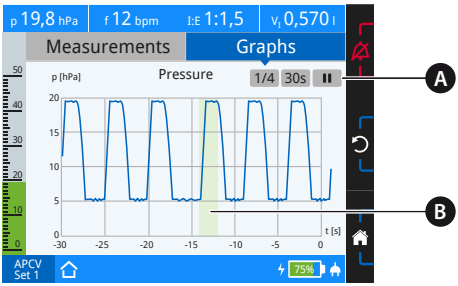
A Measurement configured
B No measurement configured

Figure 19: Measurement screen, factory setting

Graphs

The “Measurements” > “Graphs” section displays the following ventilation parameters when ventilation is running:

- Pressure
- Flow
- Volume
- FiO_2

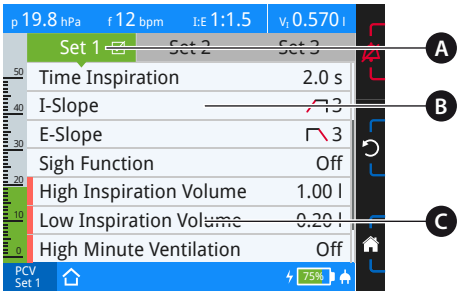


A Graph options B Inspiration triggered by patient

Figure 20: Graph screen

Parameter screen

The ventilation and alarm parameters are shown on the parameter screen. The physician can create up to 3 sets with different ventilation modes and parameters.



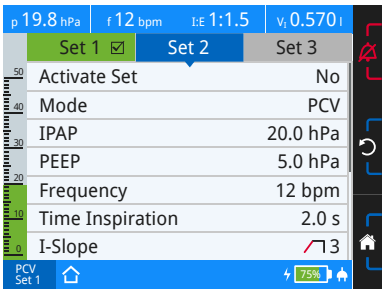
A Active set B Ventilation parameters
C Alarm parameters

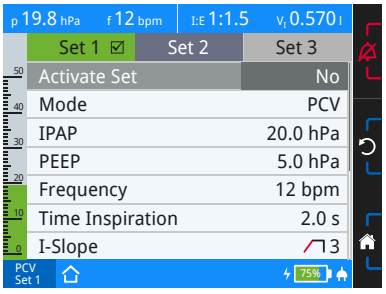
Figure 21: Parameter screen

Activating another ventilation set

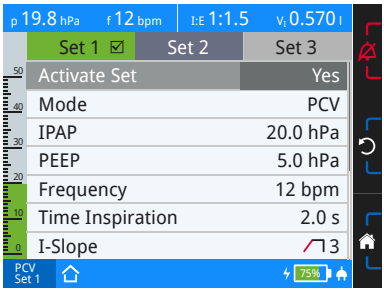
⚠CAUTION **Risk of injury due to activating the wrong ventilation set!**
The ventilation sets can contain different ventilation and alarm parameters. Sets are not suitable for all applications.
⇨ Only activate the sets that the doctor has discussed with you.

1. On the home screen, navigate to “Parameters” and press the MFK.
2. Navigate to the ventilation set you wish to activate.
3. Press the MFK twice. This brings you to the set to activate it.





4. Change the setting to “Yes” and press the MFK to confirm the setting.



Event log screen

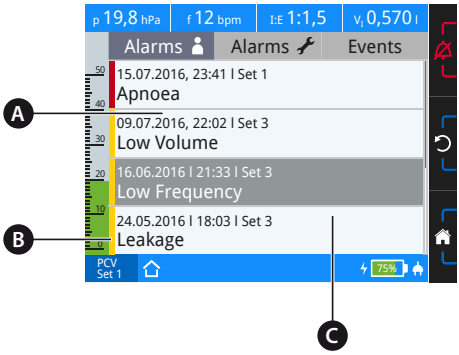
The event log screen is divided into three areas:

- Alarms
- Alarms
- Events

Alarms

Physiologically-dependant alarms whose alarm limits have been set in the parameter screen are stored under "Alarms". The only technically-dependent alarms saved under "Alarms", by contrast, are those whose alarm conditions are implemented and built into the device. You can view the last 50 alarm events.

For more information on the alarms, refer to chapter "Alarms and Messages" starting on page 65.

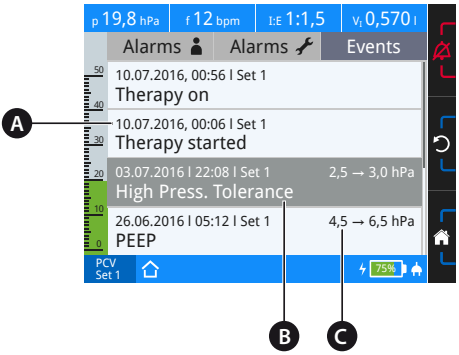


A Timestamp (date, time and set)
B Alarm priority C Selected alarm

Figure 22: Event log screen (alarms)

Events

Under "Events" you can see the last 50 parameter changes and events.



A Timestamp (date and time)
B Selected event C Parameter change

Figure 23: Event log screen (events)

System screen

On the system screen, you can set the basic device settings, perform calibrations and view device information.

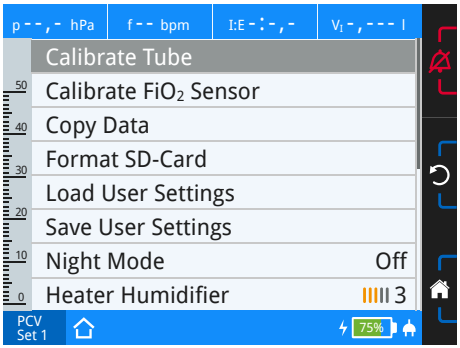


Figure 24: System screen

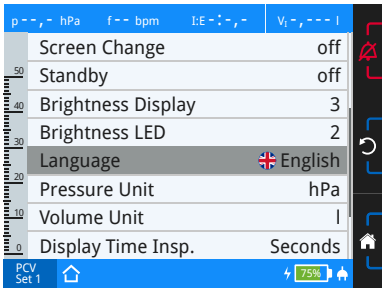
Parameter *Setting range*	Description
Calibrate Tube	Calibrate the connected tube circuit
Calibrate the FiO_2 sensor	Calibrate the FiO_2 sensor
Copy data	Copy data to the SD card
Format the SD card	Formats the SD card. This will delete all data from the SD card.
Night mode *on, off*	Switch night mode on/off In night mode, the display colours are reduced and the brightness delay is lowered to 5%.
Heater Humidifier *1 – 5*	Set the heating level for the AquaTREND uni humidifier Level 1 → lowest heating level Level 5 → highest heating level
Standby *off, 20 s – 20 min*	Set when the device switches to standby operation following the last operation action.
Brightness display *1 – 3*	Display brightness
Info LED brightness *1 – 3*	Info LED brightness
Language	Set the device language
Date	Set the date
Time	Set the time

Change the device language

To change the device language setting:

1. On the home screen, navigate to “System” and press the MFK.
2. Navigate to the 14th menu item with the MFK.

   Then, press the MFK.



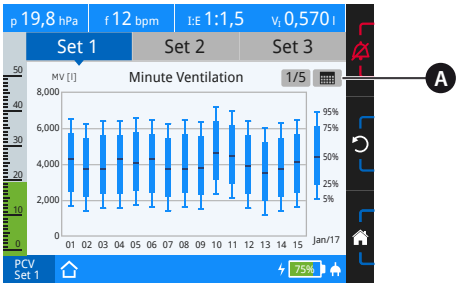
3. Change the language setting by turning the MFK, then confirm by pressing the MFK.

If your language is not set here, locate the desired language in the list below:

Sprache	Deutsch
Language	English
langue	Français
Lingua	Italiano
Dil	Türk

Statistics screen

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



A Statistics options

Figure 25: Statistics screen

Statistics are available for the following ventilation parameters:

- Minute Ventilation
- Frequency
- Tidal Volume
- I:E
- Leak Rates

The statistics options enable you to switch between statistics views and the date of the x-axis.

Service screen

On the service screen, authorised service companies can perform service work. Access is PIN-code protected.

Chapter 6
Alarms and Messages

General information

⚠CAUTION **Risk of injury due to failure to recognise alarm!**
Failure to recognise alarms can result in serious injuries for the patient.
⇨ Always operate the device so that the alarms are audible and visible by the user. Audible alarms can be forwarded using the alarm box.

Please note: *Alarms are switched off when the alarm event is no longer fulfilled and the priority has been lowered, but the alarm remains active until it has been confirmed with the alarm key.*

The LAVI ventilator is equipped with fixed and adjustable alarms, relating to the respective ventilation modes. There are three alarm priorities:

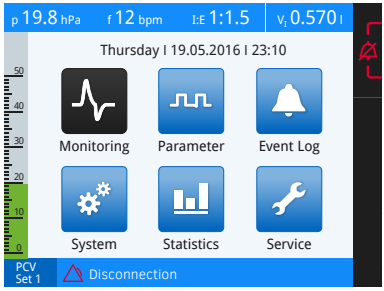
Alarm priority	What action is required?
HIGH	Immediate action is required. Monitor the patient and the cause of the alarm closely.
MEDIUM	Fast action is required for medium priority alarms. Correct the cause of the alarm.
LOW	User attention is requested for low-priority alarms. Low-priority alarms indicate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

Alarm test

The user does not have to perform any alarm tests. However, the following describes an option to call the “Disconnection” alarm in order to perform a manual check of the alarm system.

To check the “Disconnection” alarm:

1. Connect the device to the mains supply.
2. Switch the device on. Do not connect the leakage tube system!
3. Start ventilation.
4. After a few seconds, the “Disconnection” alarm occurs. If this is not the case, 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. You will find more information from page 69.

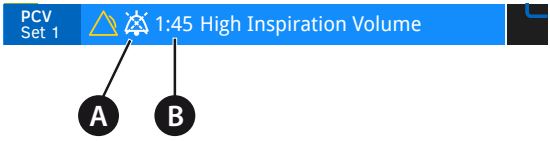
If the alarm sound equipment is defective and emits no sound, the audible alarms will be triggered by a second alarm sound transmitter which emits only a simple audible alarm.

Please note: *Audio alarms are switched off when the alarm event is no longer fulfilled.*

Pausing audio alarms (muting audio alarms)

Audio alarms can be paused for two minutes by pressing the alarm button (mute audio alarm). If this function is enabled, the audible alarm created by new alarm events will also be suppressed as well. The info 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.

Please note: *Some alarms cannot be muted. You will find these in the "Alarm overview" on page 69.*



A "Audio alarm paused" symbol B "Audio alarm paused" counter

Figure 26: Alarm displays on the toolbar

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" symbol indicates when the audio alarm is temporarily switched to mute. The counter tracks the time until the audio alarm will sound again.

Audio alarm volume

The doctor sets the volume of the audio alarm on the system screen.
If an alarm is not confirmed by pressing the alarm key and the alarm condition remains in place, the volume levels 1 and 2 are automatically raised to a level 3 within 2 minutes.

Visible alarm output

Visible alarms are displayed as follows:

- via the info LED
- on the toolbar
- as a textbox

Alarm output via the info LED

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

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

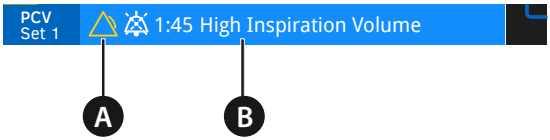
If multiple alarms are triggered simultaneously or in quick succession, the alarm with the highest priority will be displayed first. Still, all occurring alarms are listed in the event log.

Alarm output on the toolbar

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

- Red symbol → high-priority alarm
- Yellow symbol → medium-priority alarm
- Turquoise symbol → 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" symbol B Alarm message

Figure 27: Alarm output on the toolbar

Alarm overview
Adjustable alarms

The adjustable alarms are physiologically conditional alarms. Only the doctor can set the alarm limits on the parameter screen.

Please note: *Not all alarms can be paused.*

Alarm	Priority	Audible alarm	Info LED status	Cause	Time delay		
Apnoea	HIGH	c a f – a f	Red flashing	Set time ("Apnoea Alarm") has been exceeded	None	✓	-
FiO_2 too high	MEDIUM	C b a	Yellow flashing	Measured FiO_2 is greater than the set "Max. FiO_2"	None	✓	-
FiO_2too low	MEDIUM	C b a	Yellow flashing	Measured FiO_2 is less than the set "Min. FiO_2"	None	✓	-
Leak rate	MEDIUM	c a f	Yellow flashing	Leakage measured greater than "Leak Rate"	3 breaths in a row	✓	-
High pressure	MEDIUM	c a f	Yellow flashing	Pressure is higher than the set "High Pressure Tolerance"	3 breaths in a row	✓	-
Low pressure	MEDIUM	c a f	Yellow flashing	Presser below set "Low Pressure Tolerance"	3 breaths in a row	✓	-
High frequency	MEDIUM	c a f	Yellow flashing	Measured frequency greater than "Max. frequency"	3 breaths in a row	✓	-
Low frequency	MEDIUM	c a f	Yellow flashing	Measured frequency less than "Min. frequency"	3 breaths in a row	✓	-
High volume	MEDIUM	c a f	Yellow flashing	Tidal volume greater than "Max. tidal volume"	3 breaths in a row	✓	-

Alarm	Priority	Audible alarm	Info LED status	Cause	Time delay		
Low volume	MEDIUM	c a f	Yellow flashing	Tidal volume is lower than the "Min. tidal volume"	3 breaths in a row	✓	-
High minute ventilation	MEDIUM	c a f	Yellow flashing	Minute ventilation greater than "Max. minute ventilation"	3 breaths in a row	✓	-
Low minute ventilation	MEDIUM	c a f	Yellow flashing	Minute ventilation is lower than the "Min. minute ventilation"	3 breaths in a row	✓	-

= Muting = Can be deleted by pressing the MFK

Fixed alarms

Fixed alarms are alarms whose conditions are fixed in the device and thus cannot be changed by the user.

	Priority	Audible alarm	Info LED status	Cause	Correction			
Error flow sensor	HIGH	Ccc–Cc	Red flashing	Flow sensor defective	Device must be serviced	✓	-	-
Pressure sensor error	HIGH	Ccc–Cc	Red flashing	Pressure sensor defective	Device must be serviced	✓	-	-
Motor brake error	HIGH	Ccc–Cc	Red flashing	Motor brake defective	Device must be serviced	-	-	-
Motor controller error	HIGH	Ccc–Cc	Red flashing	e.g. overcurrent	Switch device on and off. If the error occurs again, return the device for servicing	✓	-	-

	Priority	Audible alarm	Info LED status	Cause	Correction			
No system flow	HIGH	C c c – C c	Red flashing	No leak in the ventilation system	Use an exhalation valve for the ventilation mask. Check the air outlet with a CPAP mask.	✓	-	-
Low leak rate	HIGH	c a f – a f	Red flashing	Leak rate < 50% than necessary leak rate	Check the exhalation valve for the ventilation mask. Check the air outlet with a CPAP mask.	✓	-	-
Motor speed low	HIGH	C c c – C c	Red flashing	Minimum motor speed exceeded	Switch device on and off. If the error occurs again, return the device for servicing	✓	-	-
Stenosis	HIGH	c a f – a f	Red flashing	No volume detected for 3 breaths	Check tube circuit and tubes for wear	✓	-	-
Ventilation off	HIGH	C c c – C c	Red flashing	Ventilation has been switched off due to one of the following alarms: – None System flow – Low leak rate – Motor speed low – Overcurrent – Overpressure	-	-	-	✓
Overpressure	HIGH	c a f – a f	Red flashing	Pressure switch triggered five times within 2 s	Restart device. If the error occurs again, return the device for servicing	✓	-	-
Overcurrent fuse	HIGH	c a f – a f	Red flashing	Excessive motor current	Restart device. If the error occurs again, return the device for servicing	✓	-	-

	Priority	Audible alarm	Info LED status	Cause	Correction			
Minimum volume not reached	HIGH	c a f – a f	Red flashing	Measured minimum volume less than set "Minimum Volume"	-	✓	-	-
Internal communication error	HIGH	c c c – c c	Red flashing	Communication to controller interrupted for more than 10 s	Switch device on and off. If the error occurs again, return the device for servicing	✓	-	-
Disconnection	HIGH	c a f – a f	Red flashing	Tube circuit not connected to device	Connect the tube circuit to the device	✓	-	-
Internal battery error	MEDIUM	c c c	Yellow flashing	Defective battery	Replace battery	-	✓	-
Internal Battery Empty	MEDIUM	C c c	Yellow flashing	Device operating on battery power supply, battery charge ≤ 5%	Battery must be charged; only 5 minutes until power supply fails completely; ventilation only possible with external power supply	-	-	-
Power failure	MEDIUM	C c c	Yellow flashing	Power supply from the mains (AC) connection has failed	Restore the power supply	-	-	✓
FiO_2 sensor[1] error	MEDIUM	C b a	Yellow flashing	FiO_2 sensor has been separated or used up by device	Connect the FiO_2 sensor to the device	-	✓	-
Low Internal Battery	LOW	e C	Glows steadily in turquoise	Device in battery operation, battery charge approx. 20%[2]	Charge battery	✓	-	-
Humidifier defective	LOW	e C	Glows steadily in turquoise	Humidifier defective	Humidifier must be serviced	-	-	✓

	Priority	Audible alarm	Info LED status	Cause	Correction	

1 This alarm is only possible if at least one of the alarms "Max. FiO_2" or "Min. FiO_2" is activated.
2 Nominal battery value

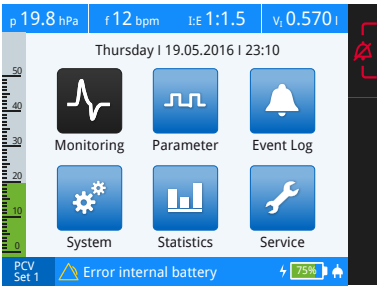
= Muting = Inactive (can be disabled) = Can be deleted by pressing the MFK

Fixed inactive alarms

The "Internal battery error" and "FiO_2 sensor error" alarms can be disabled by pressing the alarm button as long as the alarm condition still exists.

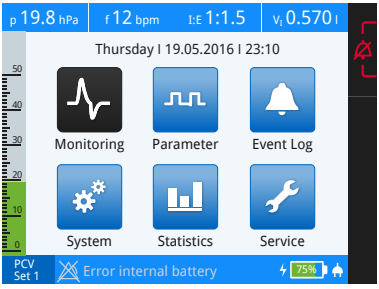
If one of these alarms appears on your device's toolbar, proceed as follows:

1. First, the respective alarm is shown with the symbol and the corresponding error text.



2. Press the alarm button to disable the alarm.

   Please note: *After the alarm has been disabled by pressing the alarm button, it is still shown on the toolbar with the symbol and the corresponding error message.*



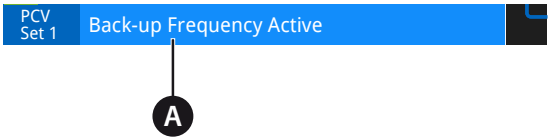
3. The alarm is only deleted after the error has been eliminated. For more information on eliminating the error, go to page 70.

   Please note: *If the problem persists, please contact your service partner.*

Messages

Message output on the toolbar

Messages are shown on the toolbar. If an error occurs, the alarm is shown in place of the message, as the alarm has a higher priority.



A Message

Figure 28: Messages on the toolbar

Message overview

Message	Cause	Time delay
Safety cycle active	The device is in PSV mode, the patient is not breathing spontaneously and is ventilated at the set frequency	None

Chapter 7
Cleaning and Exchange of Components

Important information

- Before cleaning the device, remove the power plug from the power supply.
- Cleaning the device must be performed according to this user's manual and the applicable regulations of the hospital or nursing home.
- 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.

Component	Name	Cleaning	Replace
	LAVI ventilator	as needed	-
	Power supply unit	as needed	-
	Mains cable	as needed	-
	Leakage tube circuit	weekly	in accordance with manufacturer instructions
	Mask	daily	in accordance with manufacturer instructions
	Passive Exhalation valve	weekly	-

Component	Name	Cleaning	Replace
	Oxygen connection adapter	as needed	-
	Carrying case	as needed	-
	Filter cassette (without filter)	as needed	-
	Coarse filter	weekly	Cleaning
	Fine filter	no	monthly, if severely contaminated
	FiO_2 sensor	as needed	in accordance with manufacturer instructions
	Bacterial filter	no	daily
	Functional bag	as needed[1]	-

1 For cleaning information, please read the section"Cleaning the functional bag" on page 80.

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.

Cleaning the mask

⚠CAUTION **Risk of injury due to damaged mask!**
A heavily worn or damaged mask can result in insufficient ventilation and thus health issues.
⇨ Dispose of heavily worn or damaged masks and replace them with a new one.

Clean the mask according to the manufacturer's instructions.

Cleaning the tube circuit

⚠CAUTION **Risk of injury due to damaged tube circuit!**
A heavily worn or damaged tube circuit can result in insufficient ventilation and thus health issues.
⇨ Dispose of heavily worn or damaged tube circuits and replace them with a new one.

The supplied leakage tube circuit is intended for use on one patient only. It must not be used for other patients.

For reasons of hygiene, clean it weekly. To do so, proceed as follows:

1. Clean the tube with mild soapy water. Do not use any other agents!
2. Rinse the tube thoroughly with clear water.
3. Let the tube air-dry completely.

When using other tube circuits, the manufacturer's instructions must be observed. Tube circuits not designed for reuse must be disposed of properly.

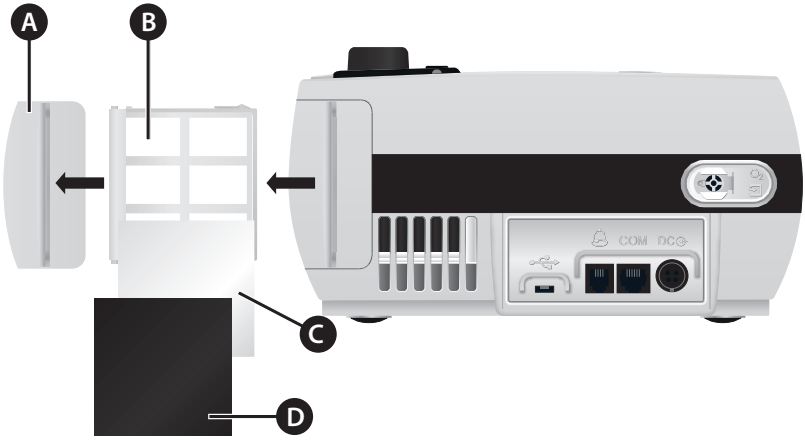
Cleaning the exhalation valve

For reasons of hygiene, clean the exhalation valve once a week. To do so, proceed as follows:

1. Clean the exhalation valve with mild soapy water. Do not use any other agents!
2. Rinse the exhalation valve thoroughly with clear water.
3. Let the exhalation valve air-dry completely.

When using other exhalation valves, the manufacturer's instructions must be observed. Exhalation valves not designed for reuse must be disposed of properly.

Cleaning/exchanging the air filter



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

Figure 29: Filter cassette structure

Cleaning the coarse filter

Clean the black course filter weekly.

1. Remove the filter cassette from the device (see Figure 29).
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 air-dry completely.
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.

Cleaning the functional bag

Please note: *The functional bag is not suited for cleaning in a washing machine or dry-cleaning.*

To clean the functional bag, use a cloth moistened with water. A mild cleaning agent may also be used if necessary.

Replacing the fine filter

Replace the white fine filter monthly, or in case of heavy soiling.

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.

Replacing 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 8
Routine Tests and Maintenance Work

Please note: *You must not perform any testing or maintenance work. Maintenance work may only be performed by an authorised service company.*

The device has an expected service life of min. 5 years provided the maintenance work listed in the following overview is performed by an authorised service company and the device is used according to the user's manual.

Overview

When?	What action is required?	By whom?
Before commissioning	Safety-related test	Operator
Weekly	Clean/replace the coarse filter (see page 80)	User
	Visually check the fine filter	User
Monthly, or before, if heavily contaminated	Replace fine filter (see page 80)	User
Every 12 months during storage	Charge battery[1]	User
Every 2 years	Maintenance 2 (refer to the service manual)	Provider/Service
	Safety-related test	Provider/Service
After 15,000 h blower run time or Every 5 years	Maintenance 5 (refer to the service manual)	Provider/Service

1 Batteries must be charged after no more than 1 month.

Battery maintenance

The LAVI internal battery is a powerful lithium-ion battery. To reach the full capacity of the battery, it is important to charge it on a regular basis.
If the "Battery maintenance" message appears, you should charge the battery to 100%, discharge it and then charge it to 100% again to recalibrate the battery indicator.

Please note: *Regularly check the battery power level. Operate the device on the mains to ensure the battery is always charged.*

As the number of charging cycles of lithium-ion batteries is limited, the internal battery must be replaced and disposed of after a certain period of time. This is the case when the "Replace battery" message appears.

Please note: *If the "Replace battery" message appears, please contact the device operator right away.*

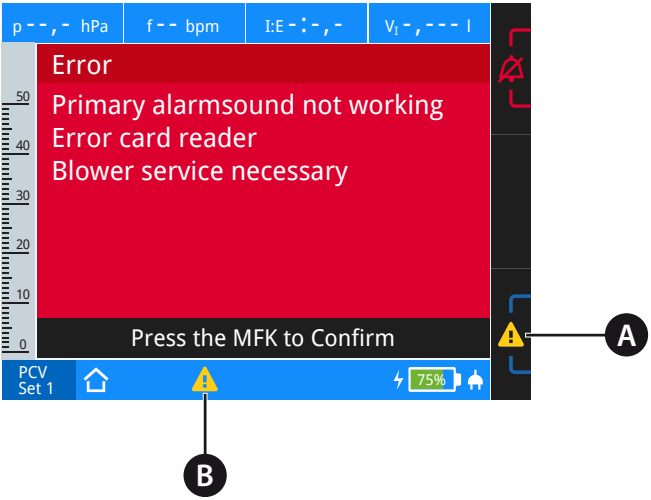
Chapter 9
Annex

Error messages

The following error messages may arise while booting the device:

Error message	Cause	Solution
Flash not working	No access to the flash	Device cannot be booted and must be serviced
Default parameters are on the device	No valid parameter set available or faulty	The device uses the default parameters (factory settings) and can continue to be utilised
Calibration data corrupt	Sensor calibration data corrupt	Device can continue to be used, perform flow sensor calibration
Event log file faulty	Reading of event data failed	Device can continue to be used but must be serviced
Primary Alarm Not Working	Primary alarm sound transmitter is defective	Device can continue to be used but must be serviced
Secondary alarm sound transmitter is defective	Secondary alarm sound transmitter is defective	Device can continue to be used but must be serviced
No alarm sound transmitter available	Primary and secondary alarm sound transmitter are defective	Device can continue to be used but must be serviced
RYB LED error	Info LED defective	Device can continue to be used but must be serviced
Real-time clock error	Real-time clock defective or clock battery low/depleted	Device can continue to be used but must be serviced Please note: *Date recording contains incorrect date and time information.*
Card reader error	Card reader defective	Device can continue to be used but must be serviced
Boot error + error number	Device booting failed due to a critical error	Device cannot be booted and must be serviced
Blower servicing required	Maximum blower run time reached	Device can continue to be used but must be serviced

After booting, any errors in effect will be displayed on the toolbar via the error symbol. To show the error list detailing existing errors, press the error key on the home screen.



A Error button B Error symbol

Figure 30: Error list

Technical data

Mains operation	100 to 240 V AC (-20%, +10%), 50 to 60 Hz
DC operation	24 V DC / 3.75 A
Internal battery operation	Lithium-ion battery, 15 V (nominal voltage) / 3.2 Ah
Max. power consumption	75 W
Electrical protection class	Protection class II

Specifications and performance characteristics	
Dimensions (W x D x H)	215 x 203 x 115 mm
Weight	2.2 kg
Max. inspiratory working pressure[1]	LAVI 30: 30 hPa LAVI 40: 40 hPa
Min. inspiratory working pressure[1]	4 hPa

Supply voltage

Operating conditions	
Temperature range	+ 5°C to + 40°C
Relative humidity	10% to 95%, non-condensing
Air pressure range[3]	600 hPa to 1100 hPa (approx. 4000 to -400 m)

[1] Ensured by pressure control.
[2] AquaTREND uni
[3] The air flow rate decreases with increasing altitude.

Transport conditions	
Temperature range	
With battery	- 20°C to + 50°C
Without battery	- 25°C to + 70°C
Relative humidity	5% to 90%, non-condensing
Air pressure range[1]	250 hPa to 1100 hPa (approx. 10000 to -400 m)
Storage conditions	Store in a dry, vibration-free place, in an upright position; store device and accessories in their original packaging

Accessories

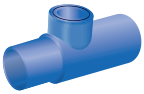
Please note: *Make sure to follow all general safety guidelines when using accessories from page 20.*

To order accessories, please contact a HOFFRICHTER service partner.

Name Article number					Figure
Mask	Size XS	Size S	Size M	Size L	Size XL
With exhalation valve (vented)					
Standard nose mask		00003440	00003434	00003435	
Standard mouth/nose mask		00003441	00003436	00003437	
Cirri Mini Comfort nose mask		00003551	00003452	00003498	
Cirri Comfort nose mask	00003497	00003486	00003487	00003488	
Cirri Comfort mouth/nose mask		00003483	00003484	00003485	
Nasal Pillow 4in1			00003499		
Without exhalation valve (non-vented)					
Standard NIPPV mouth/ nose mask		00003461	00003442	00003438	0003462
Standard NIPPV mouth/ nose mask, autoclavable				00003439	
Cirri Comfort mouth/nose mask NIPPV		00003489	00003490	00003491	

ComfortTube system consisting of:
Heated leakage tube, power supply unit, power switch
00003479

Humidifier AquaTREND uni
00002073

Name Article number	Figure
Passive exhalation valve 00014157	
Bacterial filter 00004932	
O_2 connection adapter angled 41000087	
FiO_2 measurement set consisting of: FiO_2 sensor, T adapter, FiO_2 sensor adapter, FiO_2 sensor connecting line with screw connector 00004944	
FiO_2 sensor 23000018	
T adapter 23000019	
FiO_2 sensor adapter 23000020	
FiO_2 sensor connecting line with screw connector 00014116	

Name Article number	Figure
Remote alarm box, complete including accessories 00014122	
Remote alarm box without accessories 00004834	
Cable for remote alarm box 00014115	
LAVI functional bag 00013082	

Manufacturer's declaration on electromagnetic compatibility

LAVI complies with standard DIN EN 60601-1-2:2016-05 and is intended for use in the electromagnetic environment described in the following. Any deviating ambient conditions can affect its main performance characteristics (e.g. pressure accuracy or alarms) or cause the device to fail.

Guidance and manufacturer's declaration - electromagnetic emissions		
The LAVI ventilator is intended for operation in environments as described below. The user of the LAVI ventilator must ensure it is operated in such an environment.		
Emitted interference	Compliance	Electromagnetic environment - guidance
HF emissions according to CISPR 11	Group 1	The LAVI ventilator only uses HF energy for its internal functions. Its HF emissions are thus very low and interference with nearby electronic devices is unlikely.
HF emissions according to CISPR 11	Class B	The LAVI ventilator is suited for use in all facilities including those connected directly to a public supply network that also supplies buildings used for residential purposes.
Emission of harmonic oscillations as per IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flickers as per IEC 61000-3-3	In compliance	

Guidance and manufacturer's declaration - electromagnetic immunity

The LAVI ventilator is intended for operation in environments as described below. The user of the LAVI ventilator must ensure it is operated in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Discharge of static electricity (ESD) as per IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge ± 2, 4, 8, 15 kV air discharge display	Floors should be made of wood or concrete, or be lined with ceramic tiles. If the floor is lined with a synthetic material, the relative humidity must be at least 30%.
Emitted HF disturbance as per IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m	Portable and mobile HF communication devices (including wires and antenna) should be used at least 0.3 m (suggested safety distance) to the LAVI ventilator.
	27 V/m 385 MHz PM: 18 Hz	27 V/m	
	28 V/m 450 MHz FM ± 5 Hz: 1kHz sine	28 V/m	
	9 V/m 710, 745, 780 MHz PM:217Hz	9 V/m	
	28 V/m 810, 870, 930 MHz PM: 18 Hz	28 V/m	
	28 V/m 1720, 1845, 1970 MHz PM: 217 Hz	28 V/m	
	28 V/m 2450 MHz PM:217Hz	28 V/m	
	9 V/m 5240, 5500, 5785 PM:217Hz	9 V/m	

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Rapid transient disturbances/bursts as per IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	± 2 kV for power cables ± 1 kV for input and output cables	The quality of the supply voltage should correspond to one of the typical business or hospital environments.
Surges/ as per IEC 61000-4-5	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-earth	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-earth	The quality of the supply voltage should correspond to one of the typical business or hospital environments.
Conducted HF disturbances as per IEC 61000-4-6	3 $V_{Effective\ value}$ 150 kHz – 80 MHz 6 $V_{Effective\ value}$ in ISM and amateur radio bands between 150 kHz and 80 Mhz	3 V 6 V	Portable and mobile radio devices should be used spaced at least at the suggested safety distance to the LAVI ventilator, including wires, which is calculated using the equation for transmission frequency. Suggested safety distance: 0.3 m
Magnetic fields at supply frequency (50/60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at supply frequency should correspond to typical values for business and hospital environments.

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, temporary interruptions and voltage fluctuations in the voltage supply lines as per IEC 61000-4-11	> 95 % dip of U_T for 1/2 period	> 95 % dip of U_T for 1/2 period	The quality of the supply voltage should correspond to one of the typical business or hospital environments. If the user of the LAVI ventilator requires continued functioning even in the event of an interruption to the power supply, we recommended supplying the LAVI ventilator using an uninterruptable power supply (UPS) or a battery.
	> 95 % dip of U_T for 1 period	> 60 % dip of U_T for 5 periods	
	> 30 % dip of U_T for 25 (50 Hz) periods/ 30 (60 Hz) periods	> 30 % dip of U_T for 25 periods	
	> 95 % dip of U_T for 250 (50 Hz) periods / 300 (60 Hz) periods	> 95 % dip of U_T for 5s or 6s	

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.
Batteries must not be disposed of when discharged. If a battery is not fully charged, there is a risk of a short circuit. Short circuits can be prevented by insulating the contacts with adhesive strips.

Packaging

The packaging is taken back by the distributor but it can alternatively be disposed of separately with 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 authorised 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 purposes 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.

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