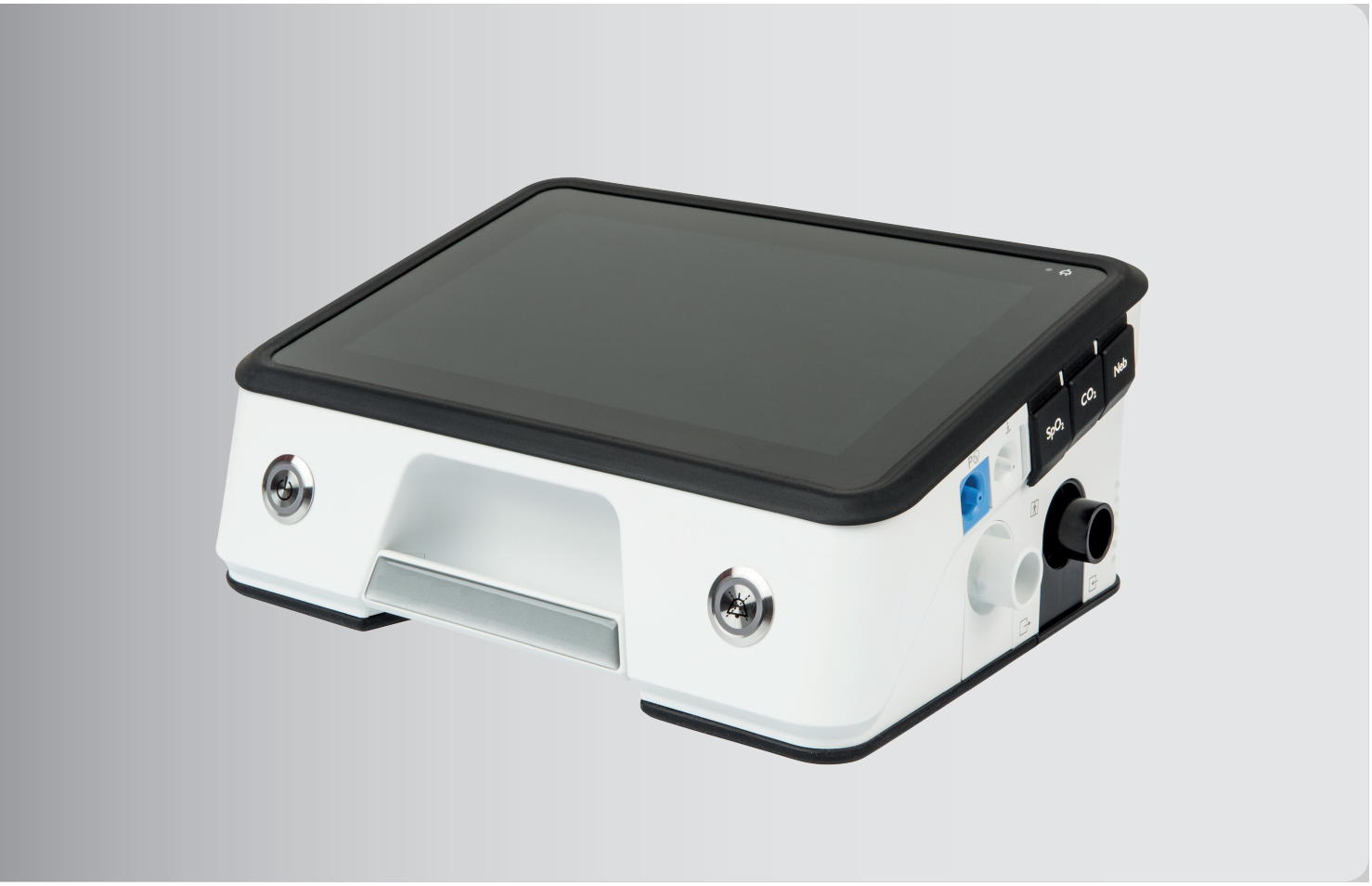
EN-US Instructions for use for patients
For devices of type: LM150TD



LUISA

Ventilator for home environment

LÖWENSTEIN
medical

Contents

68691 b 10/2024

1 Introduction

1.1 Intended purpose

The LM150TD ventilator is for the life-support and non-life-support ventilation of patients who require mechanical ventilation. It can be used for pediatric or adult patients with a minimum tidal volume of 30 ml.

The LM150TD is suitable for use in the domestic environment, in care facilities, and in hospitals, as well as for mobile applications, for example in a wheelchair or on a transport gurney. It can be used for invasive and non-invasive ventilation.

Non-specialist users with adequate training and specialist users can operate the device.

1.2 Description of function

The blower takes in ambient air through a filter and conveys it to the device outlet. From the device outlet, air flows through the circuit and the patient interface to the patient.

The blower output is controlled and the therapy pressure adjusted on the basis of the signals detected by the pressure and flow sensors.

An external SpO_2 sensor for measuring oxygen saturation and pulse rate can be connected.

With the leakage circuit, the exhaled air containing CO_2 escapes via an exhalation system. With the single circuit with valve and the double circuit, the exhaled air containing CO_2 escapes via the circuit's patient valve.

An FiO_2 cell for measuring the oxygen concentration of the inhaled air can be installed.

Oxygen equipment can be connected.

The device is operated via the display, the on/off key, and the alarm acknowledgement key.

1.3 User qualification

The person operating the device is referred to in these Instructions for Use as the user. All users must receive training or instruction on how to operate the device. The device must only be used as specified in the training or instruction. As an owner/operator or user, you must be familiar with the operation of this medical device.

A distinction is made between **specialist users** (experts) and **lay users**. The two types of users are made up of the following groups of people:

Person	Description	User qualification
Patient	Person receiving therapy who has no medical or nursing expertise.	After an induction by a healthcare professional into how the device works and is operated, patients are **lay users**.
Caregiver in a home environment	Person who supports the patient in everyday life and has no medical or nursing expertise (e.g. relatives).	After an induction by a healthcare professional into how the device works and is operated, other caregivers are **lay users**.
Health institution	Healthcare facility responsible for ensuring the compatibility of the device and of all the components or accessories associated with the patient before use (e.g. a hospital).	After training by the manufacturer or by service personnel expressly authorized by the manufacturer on how the device works and is operated, health institutions are **specialist users**.
Healthcare professional	Person with state-approved qualification in a medical profession (e.g. physicians, respiratory therapists, medical technology assistants).	After training by the manufacturer or a trained health institution on how the device works and is operated, healthcare professionals are **specialist users**.
Nurse	Person with state-approved qualification in a nursing profession.	After training by the manufacturer or a trained health institution on how the device works and is operated, nurses are **specialist users**.
Service personnel	Person with state-approved qualification in a technical profession.	After training by the manufacturer on how the device works and is operated, service personnel are **specialist users**.
Specialist dealer	Person or organization that markets, but does not itself manufacture a product. Specialist dealers can provide a support function.	After training by the manufacturer on how the device works and is operated, specialist dealers are **specialist users**.

The device is designed to be operated within arm's length. The viewing angle to the display should be at least 30°.

For blind and partially-sighted users

An electronic version of the instructions for use is also available on the manufacturer's website.

1.4 Indications

Obstructive ventilation disorders (e.g. COPD), restrictive ventilation disorders (e.g. scolioses, deformities of the thorax), neurological, muscular, and neuromuscular disorders (e.g. types of muscular dystrophy, pareses of the diaphragm), central respiratory regulation disorders, obesity hypoventilation syndrome, hypoxemic respiratory failure.

1.5 Contraindications

The following contraindications are known – in individual cases, responsibility for deciding whether to use the device rests with the healthcare professional. Threatening situations have not ever been observed.

Absolute contraindications: Severe epistaxis, high risk of barotrauma, pneumothorax or pneumomediastinum, pneumoencephalus, status following brain surgery and following surgical procedures on the hypophysis or middle or inner ear, acute inflammation of the nasal sinuses (sinusitis), middle ear infection (otitis media), and perforated eardrum. Mask ventilation must not be used in particular in the case of significant swallowing problems (bulbar syndrome) with the risk of aspiration.

Relative contraindications: Cardiac decompensation, severe cardiac arrhythmias, severe hypotension, especially in combination with intravascular volume depletion, head injury, dehydration.

1.6 Side effects

The following undesirable side effects may occur during both short-term and long-term use of the device: Pressure points from the mask and the forehead cushion on the face, reddening of the facial skin, dry throat, mouth, nose, feeling of pressure in the sinuses, irritated conjunctiva in the eyes, gastrointestinal insufflation of air ("bloating"), nosebleeds; muscular atrophy in the case of long-term ventilation. These are general side effects not attributable specifically to use of devices of type LM150TD.

1.7 General information

The device is a medical device that may only be used as directed and in accordance with the specifications of a healthcare professional.

In the EU: As a user and/or patient, you must report any serious incidents occurring in conjunction with the product to the manufacturer and to the responsible authority.

1.8 Clinical benefit

The clinical benefit for the patient is improved ventilation (improved blood gas values, less effort for the strained respiratory muscles).

NIV / IV / MPV in standard mode:

Restoration of proper ventilation/breathing regulation either via fixed settings or automatic reactions to the patient's needs, maintenance of adequate gas exchange in the event of acute respiratory failure, relief of the breathing pump/ support of the respiratory muscles, improvement of alveolar ventilation and blood gases, reduced daytime sleepiness, improvement of health-related quality of life and long-term prognosis of the disease, reduction of inpatient hospitalizations/exacerbations.

Additional clinical benefits of the HFT mode on the LM150TD:

Flushing out the dead space in the nasopharynx, thereby reducing the CO_2 level, improving mucociliary clearance by moistening and warming the upper respiratory tract, improving oxygenation/gas exchange, applying a small positive pressure to the upper respiratory tract, reducing the need for ventilation, breathing effort and shortness of breath, possibly reducing the respiratory rate during spontaneous breathing.

68691 b 10/2024 en-US

2 Safety

2.1 Safety information

2.1.1 Energy supply

Operating the device outside the specified energy supply may cause personal injury, damage the device or impair the performance of the device.

⇒ For operation, observe the prescribed energy supply (See Electronics and physical interfaces [▶ 30]).

⇒ All settings are retained in the event of a power outage.

⇒ Keep the plug and power supply accessible.

2.1.2 Electromagnetic compatibility (EMC)

The device is subject to special precautions with regard to EMC (electromagnetic compatibility). If these precautions are not followed, the device may malfunction and individuals may be injured.

⇒ Do not operate the device if the housing, cables or other equipment for electromagnetic shielding are damaged.

⇒ Operate the device only within the EMC environment specified for this device (See Electromagnetic interference immunity [▶ 37]) in order to prevent any influence on key performance characteristics – for example, influence on therapy parameters due to electromagnetic interference.

⇒ Portable high-frequency communication equipment (e.g. radios and cell phones), including their accessories such as antenna cables and external antennas, for example, should be used at a distance of at least 30 cm from the device and its cables.

⇒ The use of third-party accessories, third-party inverters, and third-party cables may lead to increased electromagnetic interference or reduced electromagnetic interference immunity of the device and to faulty operation. Only use the manufacturer's cables.

⇒ Do not use the device in the vicinity of active high-frequency surgical equipment.

⇒ Do not operate the device in the immediate vicinity of other devices or in a stacked arrangement, otherwise there may be malfunctions. If it is necessary to operate the device in the immediate vicinity of other devices or in a stacked arrangement, keep all the devices under observation to ensure that they are all operating properly

2.1.3 Ambient conditions

⇒ Only operate, store and transport the device under the specified ambient conditions (See Ambient conditions [▶ 30]).

⇒ Operate the device at the following altitude: 700 hPa to 1100 hPa (1100 hPa corresponds to an altitude of 3000 m above mean sea level). Do not operate the device outside the following temperature range: +5 °C to +40 °C. Operating the device outside of this temperature range or above this altitude can adversely affect device performance and result in a deterioration in the patient's health or in the death of the patient.

⇒ If the device and battery have been stored outside the specified operating temperature, the device cannot be started up until it has warmed up or cooled down to the permitted operating temperature (wait at least 4 hours).

⇒ Minimize risks associated with the home environment (pests, dust, heat from heating sources, etc.). Keep the device and accessories away from children and pets.

⇒ Keep small parts which may be inhaled or swallowed away from young children in particular.

⇒ Do not use the device in an MRT environment or in a hyperbaric chamber.

⇒ Place non-medical devices outside the vicinity of the patient.

2.1.4 Therapy

⇒ Ensure that the circuit and patient interface are correctly and securely in place.

⇒ The HFT mode of this device is only suitable for patients who are breathing spontaneously.

⇒ Always have an alternative ready-to-use ventilation aid available. The absence of an alternative ventilator (e.g., a self-inflating, manually operated respirator that conforms to ISO 10651-4:2023 with a mask) can result in a serious deterioration in the patient's health or in the death of the patient if the device fails.

⇒ The accuracy of the device and the therapy provided to the patient can be affected by the gas supplied to a nebulizer. Do not use or supply anesthetic gases.

⇒ Eliminate any leaks in the breathing mask or circuit. In the event of unintentional leakage, the values displayed for volume and CO_2 will deviate from actual patient values.

2.1.5 Alarms

⇒ To recognize the need for emergency ventilation in the event of an alarm or ventilator malfunction, monitor the patient and device regularly. This will help to prevent death or serious injury.

⇒ Set the alarm volume high enough for the alarm sound to be heard.

⇒ All alarm settings are retained in the event of a power outage.

⇒ Connection by cable to a patient monitor is not a substitute for a remote alarm system. Alarm data are transmitted only for documentation purposes.

2.1.6 Wireless communication

The device contains components for wireless communication. Operating the device in the immediate vicinity of people and/or other antennas may injure people, damage the device, or impair device performance.

⇒ Set up the device at least 20 cm away from any people.

⇒ Do not set up or operate the device with other antennas.

2.1.7 Cleaning and maintenance

Residues in the device and accessories or bacterial contamination of the device and accessories can cause infections and endanger the patient.

⇒ Observe the section on reprocessing (See Reprocessing [▸ 20]).

⇒ Do not reuse disposables. Disposables may be contaminated and/or their function may be impaired.

⇒ Do not use the device, components, accessories or spare parts if they are damaged.

⇒ Do not use the device, components, accessories or spare parts if the automatic function test issues error messages.

⇒ Perform a function check at regular intervals (at least every 6 months) (See Function check [▸ 21]).

⇒ Only use the device until the specified service life has been reached (See Maintenance [▸ 23]).

⇒ Have actions such as servicing, maintenance and repair work, and modifications to the product carried out exclusively by the manufacturer or by service professionals authorized by the manufacturer.

2.1.8 Accessories and spare parts

⇒ Observe the instructions for use of the accessories used. The products must meet the product standard applicable to them. If third-party accessories or spare parts are used, all claims under warranty and liability will be voided.

⇒ Use only accessories, spare parts, products and modules that are listed in these instructions for use and are intended for use with the therapy device (see instructions for use of the accessories). The use of third-party articles may result in disconnection, impaired performance, fires, burns, significant deterioration in health, or death of the patient.

⇒ Do not use antistatic or electrically conductive tubes.

⇒ Nebulization or humidification can increase the resistance of breathing system filters and HMEs (heat and moisture exchangers), thereby changing the delivery of therapy pressure. Regularly check breathing system filters and HMEs (heat and moisture exchangers) for increased resistance and blockages. To prevent increased resistance and blockages, replace breathing system filters and HMEs (heat and moisture exchangers) more frequently.

⇒ As the health institution, you must ensure that the device and the accessories used are compatible.

⇒ Set up external respiratory air humidifiers lower than the device and lower than the patient connection port. Water in the device may damage the device or injure the patient.

2.1.9 Transportation and mobile use

Water and dirt in the device may damage the device.

⇒ Operating the device in any bag can impair the performance of the device and cause the patient's death. When used on the move, only operate the device in the associated mobility bag.

⇒ Only transport and store the device in the associated protective bag.

2.1.10 SpO_2 measurement

⇒ Only use the SpO_2 sensors and cables mentioned in these instructions for use. Third-party SpO_2 sensors and cables can impair the performance of the device.

⇒ For photodynamic treatments, note the peak values of wavelengths, optical output power, and the use (see instructions for use of the 8000SX sensor).

⇒ Check and, if possible, eliminate environmental influences that can impair the function or accuracy of the SpO_2 sensors: excessive periphery lighting, excessive movement, interference due to electrosurgical instruments, moisture in the sensor, incorrectly attached sensor, carboxyhemoglobin, restriction of the blood flow (due to arterial catheters, blood pressure cuffs, infusion lines, etc.), incorrect sensor type, poor pulse quality, venous pulse, anemia or low hemoglobin concentrations, cardiovascular dyes, dysfunctional hemoglobin, artificial fingernails or nail polish, residues (e.g., dried blood, dirt, oil, grease) in the light path.

2.2 Safety information in these instructions for use

DANGER

Indicates an unusually significant hazardous situation. If you ignore this instruction, severe, irreversible or fatal injuries will result.

WARNING

Indicates an unusually significant hazardous situation. If you ignore this instruction, severe, irreversible or fatal injuries may result.

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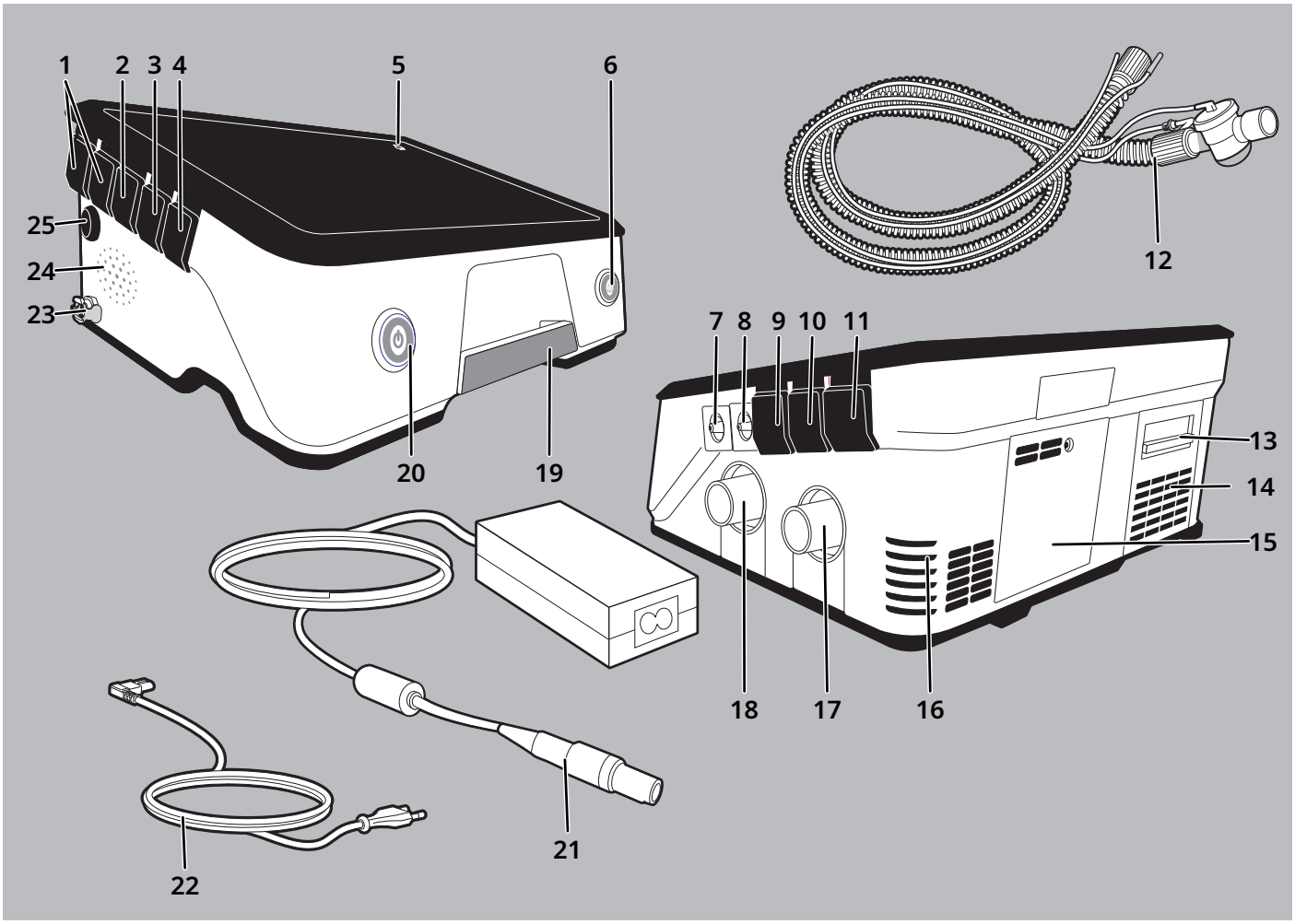
CAUTION
Indicates a hazardous situation. If you ignore this instruction, mild or moderate injuries may result.

NOTE
Indicates a harmful situation. If you ignore this instruction, material damage may result.

Indicates useful information and hints.

3 Product description

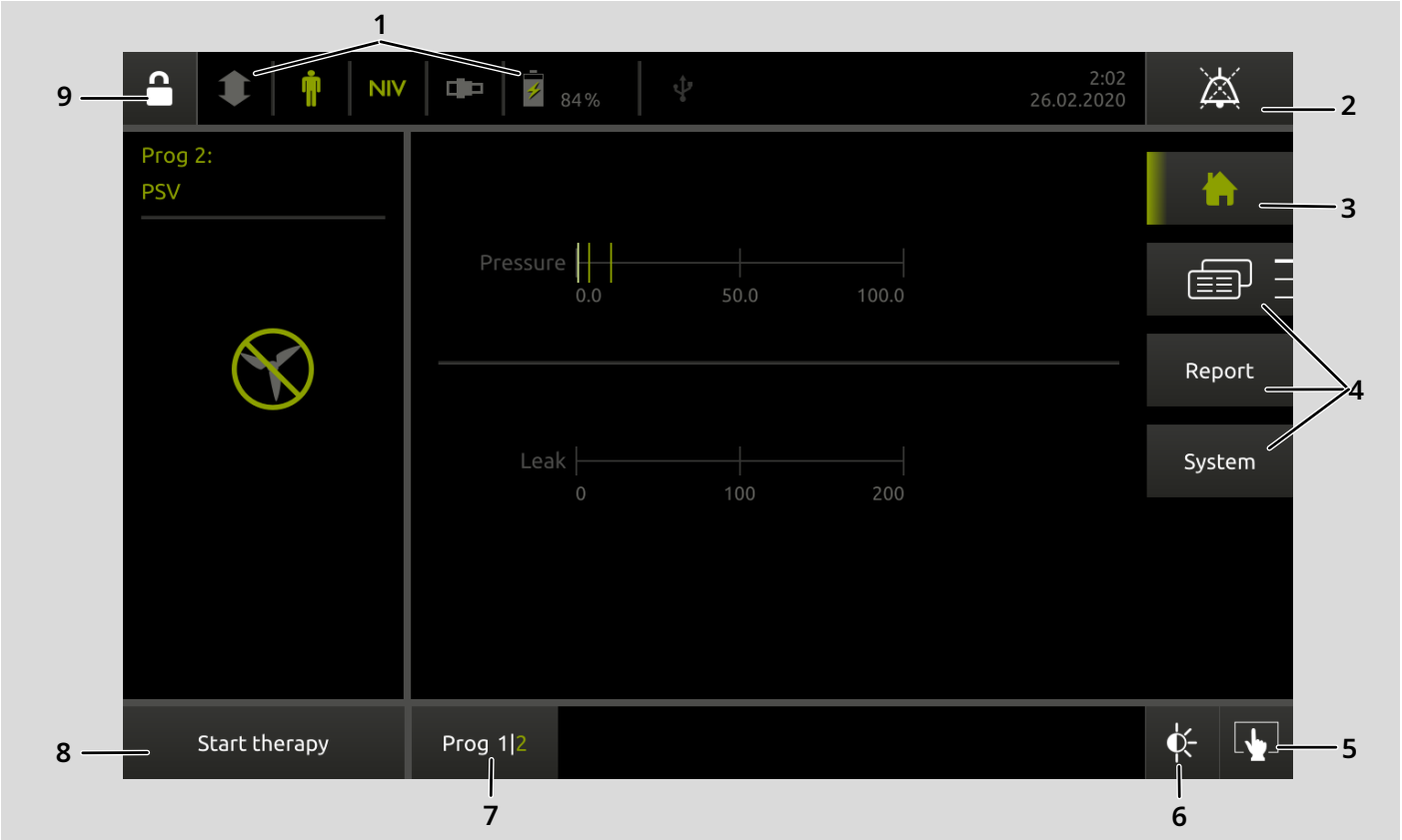
3.1 Overview



1	Connection for external batteries
2	Connection for monitor
3	Connection for USB-C
4	Remote alarm connection
5	Power supply indicator
6	Alarm acknowledgement key
7	Inlet port for pressure measuring tube
8	Inlet port for valve control tube
9	Inlet port for SpO_2 sensor
10	Inlet port for CO_2 measurement (not in use)
11	Inlet port for nebulizer (not in use)
12	Circuit (single circuit with valve)
13	Filter compartment with coarse dust filter and fine filter
14	Air intake area, patient air
15	Compartment for internal battery
16	Intake area for cooling fan
17	Device inlet
18	Device outlet
19	Handle
20	On/off key
21	Power supply unit with cable for power supply unit
22	Power cord
23	O_2 inlet
24	Loudspeaker
25	Connection for power supply unit

68691 b 10/2024 en-US

3.2 Display



1 Status line - symbols indicate current device status (e.g. accessories connected, battery capacity).

2 Alarm acknowledgment key - acknowledges and mutes alarms.

3 Home key - switches the view back to the home display.

4 Menu keys - provide access to the individual menus.

5 Display lock key - locks or unlocks the display, so that no settings can be made as a result of accidental contact.

6 Dimmer key - the display dims. Touching the display re-activates it. Keep key depressed to open the Display menu.

7 Program key - provides access to the therapy programs.

8 Ventilation button - starts or stops ventilation.

9 Access key - locks or unlocks the expert menu.

3.3 Symbols in the display

Symbol	Description
	Device in Patient menu. Expert menu locked.
	Device in Expert menu. Expert menu unlocked.
S T	Indicates respiratory status: - Arrow pointing upward: Inspiration - Arrow pointing downward: Exhalation - S: Spontaneous breath - T: Mandatory breath
	Device set for pediatric applications/children (selection and configuration of ventilation modes limited).
	Device set for adults.
IV	Invasive patient interface set.

Symbol	Description
NIV	Non-invasive patient interface set.
	Leakage circuit set.
	Single circuit with valve set.
	Double circuit set.
I	Battery is discharging. - Green: Battery capacity high - Yellow: Battery capacity medium - Red: Battery capacity low - Letter “I”: Internal battery - Letter “E”: External battery
	Battery charging. If the gray area reaches the top, the battery is fully charged.
	Battery faulty

Symbol	Description
	Change filter (only if function is activated)
	Service reminder function (only if function is activated)
	Alarm triggered - One symbol: Low priority - Two symbols: Medium priority - Three symbols: High priority
	Alarm sound paused.
	USB-C flash drive: • Green: Data transfer • Gray: connected, no data transmission • Red: faulty
	SpO_2 sensor - Gray: Sensor not connected to SpO_2/Xpod® cable or SpO_2 flowmeter delivers unusable values - Green: connected, high signal quality - Yellow: connected, moderate signal quality - Red: connected, poor signal quality
	FiO_2 cell - Green: Activated - Gray: Deactivated - Green and flashing: Calibration in progress - Orange: Maintenance reminder (only if activated)
	Flight mode activated
	Bluetooth® (wireless technology) - Green: Activated, device connected - Gray: Not activated - Red: Faulty
	Gray: USB modem connected Flashing gray: USB modem establishing a connection.
	USB modem has established a connection. The green bars denote signal quality.
	Data transmission
	USB modem faulty

3.4 Operating states

Operating state "On" and therapy running

- It is possible to make device and therapy settings.
- The on/off key is not illuminated.

If the device is not operated for 10 minutes, the display changes to a screen saver showing the pressure curve of the current therapy. Touching the display or pressing the on/off key interrupts the screen saver.

The screen saver is terminated immediately if an alarm message appears.

Operating state "On" and therapy not running

- It is possible to make device and therapy settings.
- The on/off key is illuminated.

After 10 minutes without operation, the display goes dark.

If the device is in battery mode and is not operated for 40 minutes, it will switch off to save energy. The on/off key is not illuminated.

Operating state "Off"

The device is switched off. Therapy is not running. It is not possible to adjust device or therapy settings. The on/off key is not illuminated.

3.5 Batteries

3.5.1 Internal battery

The device is fitted with an internal battery.

If the device is disconnected from the power supply or the power supply fails, the internal battery takes over the energy supply of the device. This will discharge the internal battery.

The internal battery will also discharge if the device is not connected to the power supply for a prolonged period.

If the device should always be ready for use (charged internal battery), do not disconnect the device from the power supply.

The internal battery should be replaced by the manufacturer or a specialist dealer.

3.5.2 External battery

External batteries can be connected as an additional energy supply.

In battery supply, any external batteries that are connected will be discharged first, followed by the internal battery.

3.5.3 Battery charging

Internal and external batteries are charged as soon as the device is connected to the power supply.

3.5.4 Battery life and battery capacity

The battery life depends on the therapy settings and the operating temperature (See Ambient conditions [▶ 30]). Battery life is reduced at low or high operating temperatures.

When the device is on battery or power supply, the remaining battery life is displayed in the status bar and in the **Views** menu (See Views menu [▶ 18]). Remaining life is a prediction and always relates to the current mean consumption of the device.

After therapy has started, a maximum of 3 minutes will elapse before the remaining time is displayed.

68691 b 10/2024 en-US

If battery capacity alarms are triggered, the device will switch itself off within a few minutes (See Alarms [▸ 24]). Connect the device to the power supply as soon as any battery capacity alarms go off.

Always have an alternative ventilation option ready when the device is on battery supply.

3.6 Data management/compatibility

The health institution is responsible for the application of risk management for medical IT networks in accordance with IEC 80001-1. Medical IT networks are IT networks in which at least one medical device is integrated.
The manufacturer does not accept any warranty or liability for interactions between system components in a medical IT network.
The manufacturer is not a system configurator.

3.6.1 Saving and transmitting therapy data

The therapy data from at least the last 30 days of therapy is saved in the device in high resolution at up to 20 Hz. The statistical data from the last 12 months is also saved in the device.

Saving therapy data to a USB-C flash drive

A file in .edf format is created for each therapy session. If you connect a USB-C flash drive, the therapy and statistical data saved in the device is transferred to the USB-C flash drive as .edf files.

It is also possible to save a more detailed data set in the System menu (See System menu [▸ 19]).

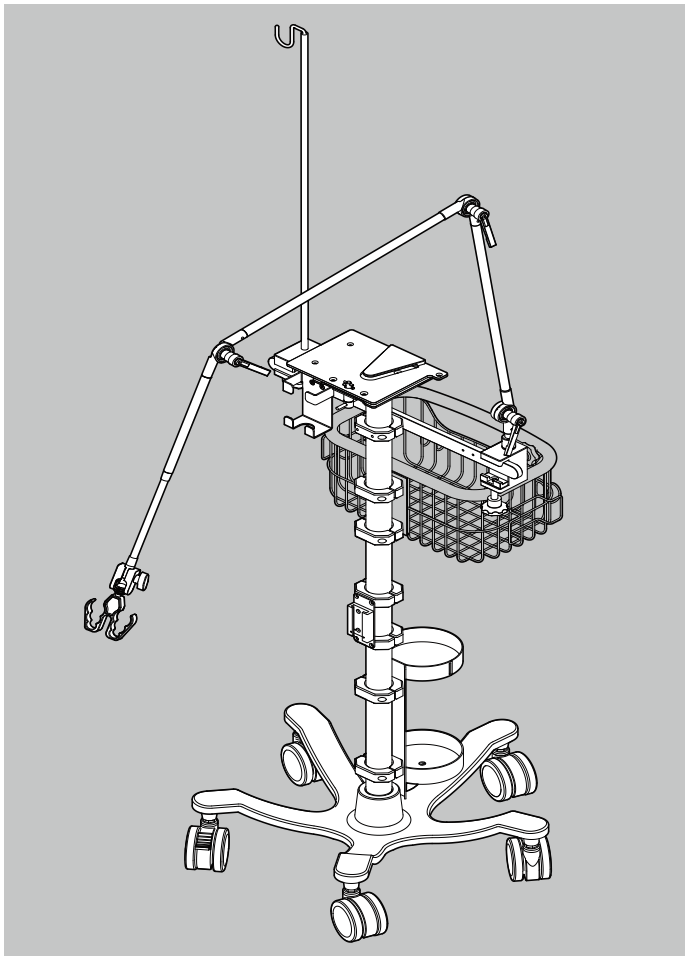
The therapy data saved on the USB-C flash drive can be read into and displayed in the prismaTS software and the prisma CLOUD.

3.6.2 Performing the firmware update

1. Connect a USB-C flash drive with an update file (at least one version higher than the current firmware version).
2. Confirm execution of the firmware update.

The firmware update may trigger a battery update. The device configuration is retained after the firmware update.

3.7 Trolley 2.0



WARNING
Risk of injury with incorrect configuration of trolley 2.0!
If trolley 2.0 is not used properly, it may tip over and injure persons.

⇒ Observe assembly instructions. Set trolley according to manufacturer's information.
⇒ Use trolley 2.0 only on a maximum incline of 10°.
⇒ Ensure that the total weight of trolley 2.0 when fully equipped is < 25 kg.
⇒ Before moving trolley 2.0: Put the circuit holder in the folded-away position.

4 Preparation and operation

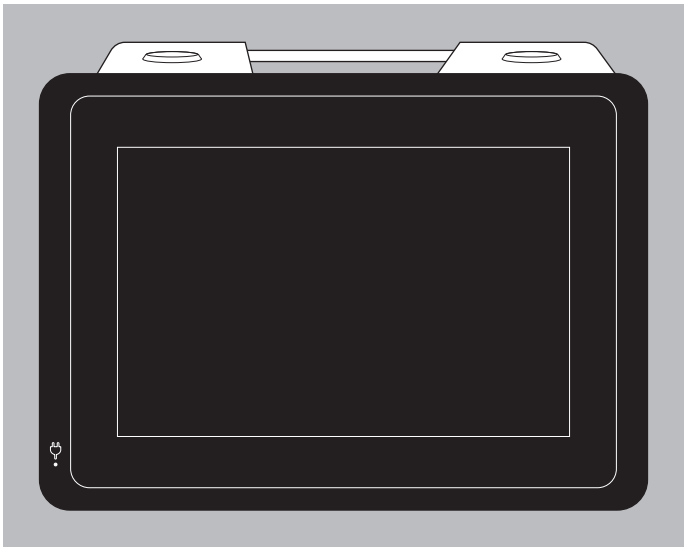
4.1 Setting up and connecting the device

1. Please note the information on electromagnetic compatibility (EMC) (See Electromagnetic compatibility (EMC) [▶ 5]).
2. Place the device on a level surface in a freestanding position.

WARNING
Risk of injury due to incorrect positioning!
If the device is incorrectly positioned, the device and power supply unit may overheat, impairing therapy and possibly injuring the patient.
Therapy may be impaired and the patient injured if the airways are blocked.
- ⇒ Do not expose the device and power supply unit to direct sunlight.
- ⇒ Do not cover the device and power supply unit with textiles (e.g. bed covers or curtains) that could block the applied flow of cooling air.
- ⇒ Do not set up the device and power supply unit in the direct vicinity of a heat source.
- ⇒ Keep openings and ventilation slits (symbol) clear so as not to impair therapy.

3. Connect the power cord to the power supply unit and the socket.
4. Connect the power cord to the device.

Alternatively, you can connect the device to a direct current power supply (12 V DC or 24 V DC) that complies with ISO 80601-2-72.



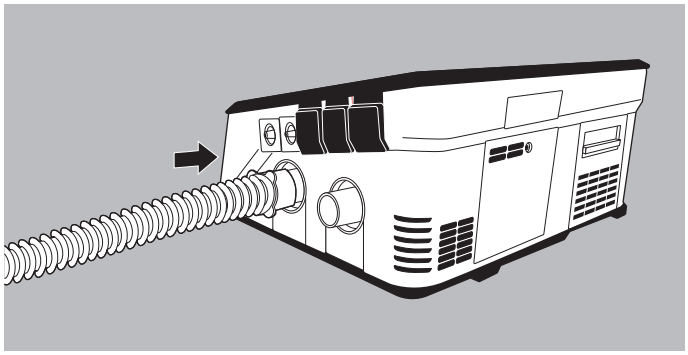
5. If required: Tilt the device to a horizontal or vertical position.
The display adapts to the orientation automatically.

4.2 Connect circuit

WARNING
Risk of injury from incorrectly routed circuits and cables!
- ⇒ Do not run circuits or cables along the patient's neck.
- ⇒ Do not crush circuits and cables.

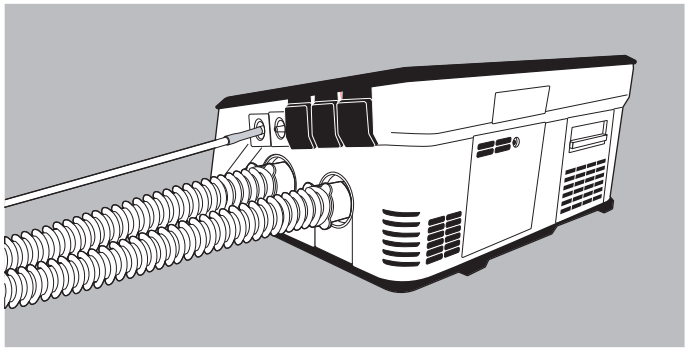
4.2.1 Connecting leakage circuit

1. If a patient interface or circuit without an integrated exhalation system is used, connect an external exhalation system (see instructions for use of the exhalation system).



2. Push the inspiration tube onto the device outlet.
3. Connect the patient interface (e.g. breathing mask) to the circuit.
4. Keep exhalation systems clear.

4.2.2 Connecting double circuit



1. Push the inspiration tube onto the device outlet.
2. Push the expiration tube onto the device inlet.
3. Attach the pressure measuring tube (marked blue) to the inlet port for the pressure measuring tube P.

It is possible to use the device without the pressure measuring tube. If the device is used without the pressure measuring tube, this must be selected during the circuit test.

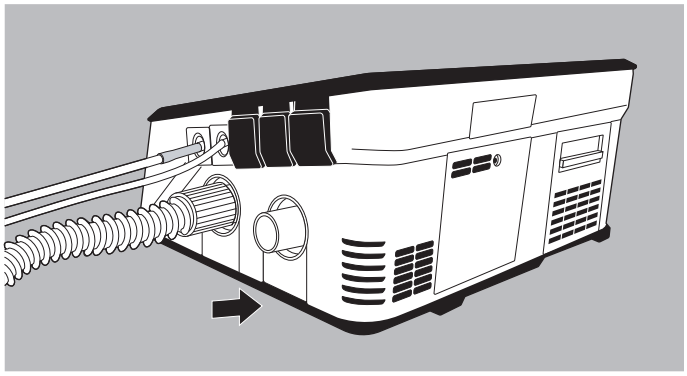
4. Connect the patient interface (e.g. breathing mask) to the circuit.
5. Keep exhalation systems clear.

68691 b 10/2024 en-US

4.2.3 Connecting single circuit with valve

WARNING
Risk of injury from limited disconnection detection!
If no proximal pressure measurement is used, a disconnection when accessories (endotracheal tube extension, HME/F etc.) are connected is only recognized to a limited extent.
⇒ Check alarm settings and adjust to the therapy if required.

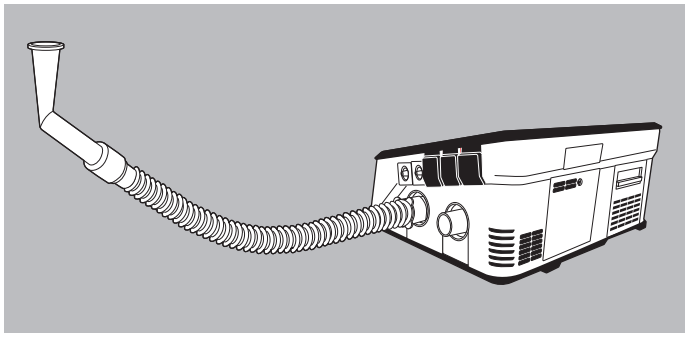
WARNING
Risk of injury if patient valve is covered!
If the patient valve is covered, exhaled air can no longer be routed away.
⇒ Keep patient valve clear.



1. Push the inspiration tube onto the device outlet.
2. Attach the pressure measuring tube (marked blue) to the inlet port for the pressure measuring tube P-.
3. Push the valve control tube onto the inlet for the valve control tube.
4. Connect the patient interface (e.g. breathing mask) to the circuit.

It is possible to use the device without the pressure measuring tube. If the device is used without the pressure measuring tube, this must be selected during the circuit test.

4.2.4 Connecting circuit for mouthpiece ventilation

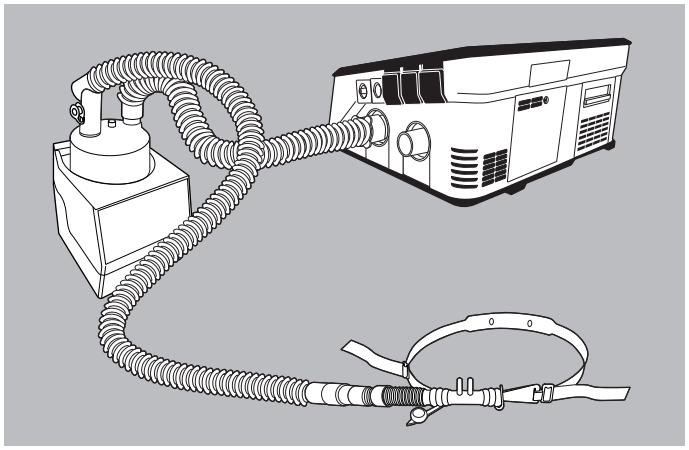


1. Attach the free end of the leakage circuit to the device outlet. It is also possible to use a single circuit with valve or a double circuit.
2. Connect mouthpiece to the tube (see instructions for use for the patient interface).

4.2.5 Connecting the circuit for HFT mode

WARNING
Risk of injury due to suffocation or barotrauma!
⇒ To prevent the tubes or the circuit from disconnecting during use, especially during outpatient use, use tubes with a holding force that complies with ISO 5367 or ISO 80601-2-74.
⇒ Do not use a sealed patient interface to avoid the risk of suffocation or barotrauma.
⇒ Ensure there is sufficient intentional leakage between the ventilator breathing system and the patient so that the patient can exhale.

As an alternative to the leakage circuit, the single circuit with valve or the double circuit can be used.



1. Attach the inspiration tube (short tube) to the device outlet.
2. Attach the other end of the inspiration tube (short tube) to the inlet of the humidifier chamber marked **In**.
3. Attach the second inspiration tube (long tube) to the outlet of the humidifier chamber marked **Out**.
4. Connect the HFT nasal cannula to the inspiration tube (long tube).
5. If required: Use a heated circuit (see instructions for use of the external humidifier).

4.3 Before first use

The language can only be set by a specialist user (expert).

Before the initial use, you must set the date and time on the device if your specialist dealer has not already done so.

The device is delivered with an internal battery. Connect the device to the power supply until the internal battery is fully charged.

4.4 Switch device on and off / Start and end therapy

Action	Requirement	Key	Operating state achieved
Switch on device[1]	Device is connected (See Setting up and connecting the device [▶ 12]).	Briefly press the on/off key ⏻ on the device.	On, therapy not in progress
Switch off device	-	Press and hold the on/off key ⏻ on the device.	Off
Start therapy	Device is switched on.	Briefly press the on/off key ⏻ on the device *or* Press **Start therapy** on the display.	On, therapy in progress
End therapy	-	Press and hold the on/off key ⏻ on the device. *or* Press and hold **End therapy** on the display. Confirm end of therapy in the display (**OK** key).	On, therapy not in progress

[1)] The device performs function tests when it is switched on (approx. 20 seconds). It cannot be operated until the function tests have been completed.

4.5 Circuit test

During the circuit test, the resistance, compliance and leakproofness of the circuit are tested.

A circuit test should be performed in the following scenarios:

- During the function check (See Function check [▶ 21])
- After a change of patient
- After changing or replacing accessories and spare parts
- As required

Performing circuit test

Requirement

✓ Patient type and patient interface have been set by a specialist user (expert).

1. Select **System** > **Circuit test** menu.
   The therapy programs are listed in the **Overview of circuit test** section. The green check mark indicates the selected therapy program.
2. If necessary, use the (See Display [▶ 9]) program key to select the therapy program for which a circuit test is to be performed.
3. Press the **Start** key.
4. When using a leakage circuit: Select the circuit configuration (with exhalation system/without exhalation system).
5. When using a single circuit with valve or a double circuit: Select the circuit configuration (with prox. pressure measuring/without prox. pressure measuring).
6. Follow instructions in the display.
7. If the circuit test is successful, press the **Finish** key.
8. If the circuit test is not successful, follow the instructions on the display to rectify the fault.

4.6 Taking an SpO_2 measurement

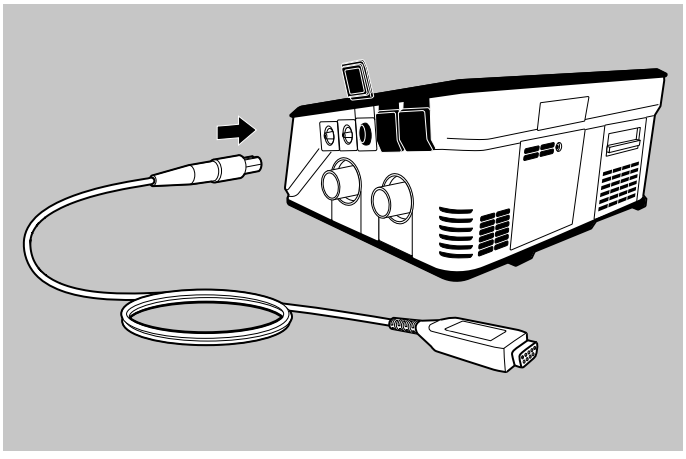
You can measure oxygen saturation (SpO_2) and the pulse rate with the SpO_2 sensor. The measured values (SpO_2 and pulse rate) are shown on the home display.

The measured values can be exported and read into the prismaTS software system (See System [▶ 19]). Alarms can be set to monitor the measured values (SpO_2 and pulse rate) (See Setting alarms [▶ 24]).

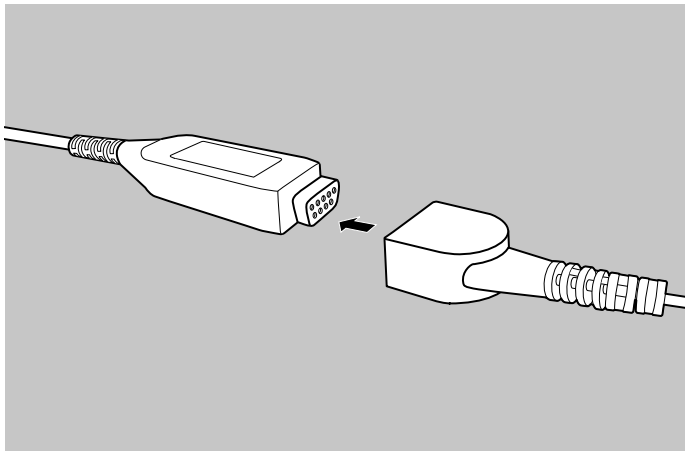
Following a power outage lasting more than 30 seconds, all settings and data are retained. The latest settings of the SpO_2 sensor are restored.

Requirement

✓ The SpO_2 sensor has been calibrated to display functional oxygen saturation.



1. Connect the SpO_2/Xpod® cable to the device.



2. Connect the SpO_2/Xpod® cable to the SpO_2 sensor.

CAUTION
Risk of injury due to pressure points!
- ⇒ Avoid excessive pressure caused by the SpO_2 sensor.
- ⇒ Check that the SpO_2 sensor is attached properly every 6 to 8 hours to ensure that the sensor is positioned correctly and the skin is undamaged. The sensitivity of the patient may vary depending on their state of health or skin condition. Take any allergies into account.

3. Place the SpO_2 sensor on the patient (e.g., on the finger).

4.7 Supplying oxygen

WARNING
Risk of injury due to burns!
Smoking or open flames during the supply of oxygen or the supply of oxygen without special protective devices can cause burns, fires or death.
- ⇒ Smoking or open flames are not allowed in the oxygen supply area. If patients wish to smoke, turn off the therapy device and oxygen equipment, remove the HFT nasal cannula or mask and leave the room with the equipment. If the room cannot be left, turn off the therapy device and oxygen equipment and wait 10 minutes.
- ⇒ Avoid open flames within 2 m of the therapy device and oxygen equipment.
- ⇒ Before and during oxygen therapy, only use water-based lotions or ointments that are oxygen-compatible. Do not use petroleum- or oil-based lotions or ointments.
- ⇒ Do not grease any fittings, connections, circuits or other accessories of the therapy device.

WARNING
Risk of injury due to burns!
There is a risk of fire associated with the enrichment of oxygen during oxygen therapy. Oxygen has an oxidizing effect and can accumulate in clothing, bedding and hair.
- ⇒ Do not leave the HFT nasal cannula or mask on bed covers or chair cushions when the therapy device and oxygen equipment are switched on.
- ⇒ To avoid oxygen accumulation, switch off the therapy device and oxygen equipment as soon as they are not in use.
- ⇒ Do not use the therapy device and oxygen equipment near sparks or open flames.

WARNING
Risk of injury due to impaired therapy!
It is the responsibility of the responsible health institution to ensure that the oxygen source is compatible with the rated range of pressure, flow rate and oxygen concentration as indicated on the device and in the instructions for use, as this may affect the performance of the device or pipeline system and consequently lead to a significant deterioration in health or the death of the patient.
Excessive oxygen concentrations can have a long-term toxic effect.
- ⇒ Follow the instructions for use of the oxygen supply system.
- ⇒ Use medical oxygen.
- ⇒ Observe maximum oxygen flow (See Technical specifications [▶ 30]).
- ⇒ The dosage of oxygen is determined by a healthcare professional. The set oxygen flow must not exceed the specified oxygen flow.
- ⇒ The oxygen flow (in l/min) must not exceed the set HFT flow.

Requirement

✓ A low-pressure O_2 connection nozzle is available.

1. Connect the O_2 tube to the O_2 connection nozzle.
2. Connect the O_2 connection nozzle to the O_2 inlet (latch engages).
3. Connect the other end of the O_2 tube to the oxygen equipment.
4. Start therapy.
5. Start the oxygen supply and set the desired oxygen flow.
6. At the end of therapy, stop the oxygen supply and allow the device to continue running briefly to remove any residual oxygen from the device.
7. To remove the O_2 connection nozzle from the device, push the latch to the left.

4.8 Calibrating the FiO_2 cell

You can use the optional FiO_2 cell to perform continuous FiO_2 measurement. You must activate the FiO_2 cell before use and calibrate it every 6 weeks.

Calibration can take place during ventilation. You cannot perform FiO_2 measurement during the calibration process (duration approx. 5 minutes).

1. Open **System** > **FiO2 cell** > **Calibrate** menu.
2. Interrupt the oxygen supply.
3. Wait approx. 30 seconds.
4. Press the **OK** key to start calibration.
5. If calibration is successful, press the **Finish** key. If calibration is not successful, follow the instructions in the display and eliminate the faults.
6. Resume the oxygen supply.

The FiO_2 cell is continuously emptied as a result of contact with oxygen. If the FiO_2 cell is almost empty, a message will appear that the FiO_2 cell must be replaced. The FiO_2 cell should be replaced by an authorized specialist dealer or by a specialist user (expert).

4.9 Pairing device with LUISA app

The LUISA app (optional) is an app on a mobile terminal that you can use to read off the patient's therapy data.

1. Activate the Bluetooth function in the **System** > **Device settings** > **Connectivity** menu.
2. In the **Device list** menu, select **Add new device**.
3. Download the LUISA app onto a mobile terminal and follow the instructions in the LUISA app.

The pairing with the ventilator is saved in the LUISA app and does not need to be repeated. The saved pairing with the ventilator can be deleted in the LUISA app.

4.10 Contaminated components

After the device has been used, the following components, which are located in the air path, may be contaminated:

- LMT 31494 Device outlet
- LMT 31503 FiO_2 cell
- LMT 31497 FiO_2 cell sealing
- LMT 31496 Flow sensor
- LMT 31505 Nonreturn valve, complete
- LMT 31530 Sound insulation case, pressure side
- LMT 31490 Blower
- LMT 31525 Sound insulation case, intake side
- LMT 31446 Housing central part LM150TD
- WM 29389 Fine filter
- LMT 31487 Filter for cooling fan
- LMT 31422 Filter holder

4.11 Transferring data with the USB modem

The USB modem establishes a wireless connection between the device and the prisma CLOUD software. It is used only for transmitting data from the device to prisma CLOUD. The modem cannot be used to make changes to the device or the settings.

The USB modem is not available in all countries. For more information, contact your specialist dealer.

4.11.1 Connecting the USB modem

To connect the USB modem to the device, follow the modem's installation instructions.

If the serial number of the device is known in prisma CLOUD, the USB modem will automatically connect to prisma CLOUD. The display shows the connection status and signal strength of the modem connection. If the USB modem is connected to prisma CLOUD, there are only limited options for setting the date and time on the device.

If the USB modem does not connect automatically, your specialist dealer will have to set it first. Contact your specialist dealer.

4.11.2 Transmitting data

Automatic data transmission by USB modem

Once the USB modem is configured and connected, data is transmitted in the activated device regardless of whether therapy is in progress.

The therapy data is transmitted to prisma CLOUD twice a day. The time of transmission is specified in prisma CLOUD.

Transmission progress and transmission errors are shown in the display. The signal strength of the wireless network is shown as a symbol in the display (See Symbol in display [▶ 10]). If the signal strength is low, carry the device to an area with stronger signal strength.

If the following restrictions apply, data is transmitted at a later point in time:

- Airplane mode activated
- Low battery capacity
- Inadequate signal strength

To check the time of the last data transmission, call up menu **System** > **Device status** > **Connectivity** > **Modem**.

Manual data transmission by USB modem

As an alternative to automatic transmission, you can also transmit therapy data manually using the connected USB modem.

68691 b 10/2024 en-US

1. Call up menu **System** > **Device settings** > **Connectivity** > **Modem**.
2. Select menu **Transmit current data**.

The number of manual data transmissions per day is limited in the patient menu.

4.12 Transmitting data with the COM cable for monitor

The COM cable for monitor is used to transmit data from LUISA ventilators to Philips IntelliVue monitors that use the Philips IntelliBridge EC10 Interface Module or the IntelliBridge EC10 Integrated Interface Board.

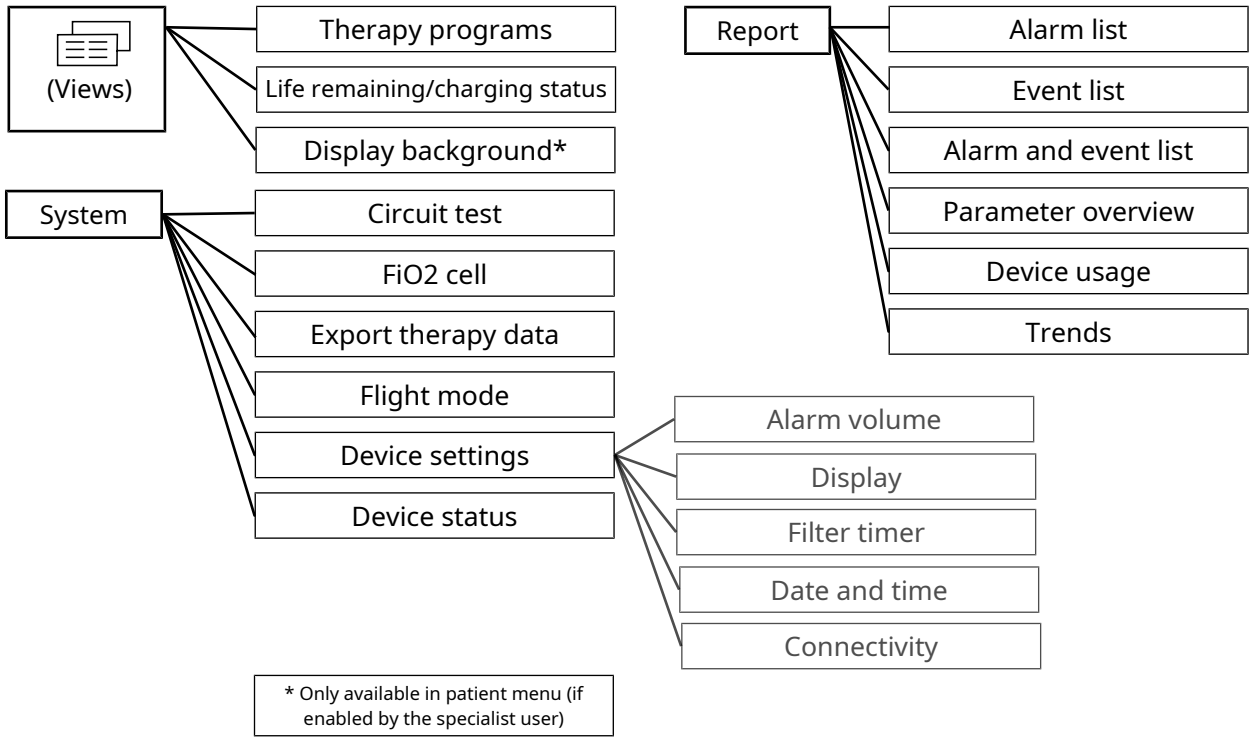
Follow the relevant instructions for use for the COM cable for monitor and the Philips IntelliVue monitor used.

5 Settings in the menu

5.1 Navigating in the menu

Action	Function
Press function key	Function keys have a gray background and the function is displayed on the key in text or as a symbol, e.g. **Start therapy**. Symbols on a black background are not function keys, but serve to provide information about device status (See Symbols in display [▶ 9]).
Scroll in list	Navigate up or down.
Press “Value”	Open range of values to set therapy parameters.
Move range of values up or down	Decrease or increase value.
✓	OK the value.
✗	Discard selection.
	Back to home display.

5.2 Menu structure



5.2.1 Views menu

The Views menu displays various views. To switch to the next view, press the Views key again.

The horizontal lines on the Views key are the number of available views.

	Parameters and set values for the therapy programs

	Operating state **On, therapy in progress**: Remaining device life if being supplied by battery
	Operating state **On, therapy not in progress**: State of charge of the internal battery in percent assuming a power supply
	View is only available in the patient menu if a screen background has been selected in the device settings of the expert menu.

68691 b 10/2024 en-US

5.2.2 Report menu

Alarm list	Lists the alarms which have occurred.
Event list	Lists the events that have occurred.
Alarm and event list	Lists the alarms and events which have occurred in chronological order.
Device usage	Lists the usage time for the device and the therapy duration for the patient.
Parameter overview	Lists the parameters set for the therapy programs.
Trends	Displays therapy data from the last 30 days in the form of a graph.

5.2.3 System menu

Circuit test	Perform circuit test (See Performing a circuit test [▶ 14]).
FiO2 cell	Activate, deactivate and calibrate FiO_2 cell (See Calibrating the FiO2 cell [▶ 16]).
Export therapy data	Export a detailed data set (therapy data, statistical data, log data, etc.) to a USB-C flash drive. A USB-C flash drive must be connected.
Flight mode	When flight mode is activated, no wireless communication (e.g. Bluetooth, USB modem) is possible.
Device settings	Set the device (see table below).
Device status	Information about the device (name, type, serial number of the device and components, firmware version) and about the internal battery. General information about the modem (if a modem is connected, more detailed information)

5.2.3.1 Device settings

Alarm volume	Set alarm volume and perform manual alarm test (See Checking alarms [▶ 22]).
Display	Set brightness, orientation and screen background of the display.
Filter timer	Activate and reset reminder function for filter changes.
Timer calibration	Activate and set reminder function for calibrating the FiO_2 cell. Only available if FiO_2 cell has been activated.
Date and time	Set current date and time.
Connectivity	Activate and deactivate Bluetooth. Trigger manual data transmission by USB modem. (if modem connected).

6 Reprocessing and maintenance

6.1 Reprocessing

WARNING
Risk of infection when reusing device and accessories!
During a change of patient, infections can be transmitted and the device contaminated.
⇒ Use breathing system filters and replace them during a change of patient.
⇒ Do not reprocess single-use items.

6.1.1 General information

- Make sure that new filters are inserted after reprocessing, maintenance or servicing to prevent foreign bodies from being sucked in.
- After reprocessing by a specialist dealer, the device is suitable for a change of patient.
- To avoid skin irritation from the disinfectant, wear suitable protective equipment (e.g. protective gloves, goggles, face mask) during disinfection.
- Observe the instructions for use of the disinfectant used.
- The times for the disinfectant to take effect depend on the disinfectant used. Refer to the manufacturer's instructions for the times to take effect and adhere to these.
- Alcoholic solutions with the following composition are suitable: 100 g of solution contain the following active ingredients: 25 g ethanol (94%), 35 g propan-1-ol.
  Recommended: *Mikrozid AF wipes* and *Mikrozid liquid.* If the recommended disinfectant is not available, use other disinfectants with an identical active ingredient composition.

Make sure that cleaning is carried out carefully and that no cleaning agent residue remains. Rinse all parts with clean water.

6.1.2 Intervals

Interval	Action
Weekly	Clean device (See Cleaning the device [▶ 20]).
Monthly	Clean coarse dust filter (See Clean coarse dust filter [▶ 20]).
	Replace fine filter (See Replacing the fine filter [▶ 21]).
	Clean filter for cooling fan (See Cleaning the filter for cooling fan [▶ 21]).
Every 6 months	Replace coarse dust filter

6.1.3 Reprocessing the device

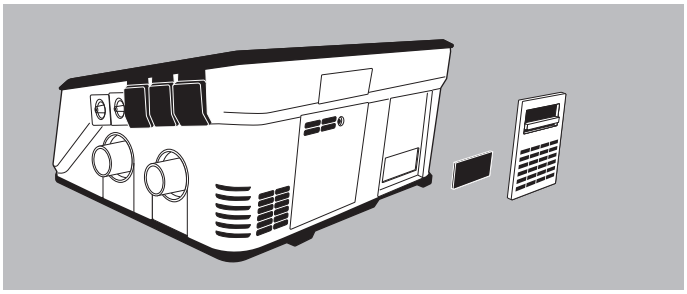
WARNING
Risk of injury from electric shock!
Ingress of liquids may lead to a short-circuit, injure the user, and damage the device.
⇒ Disconnect the device from the power supply before reprocessing.
⇒ Do not immerse the device or accessories in liquids.
⇒ Do not pour liquids over the device or accessories.

WARNING
Risk of injury from use of ozone!
Ozone can damage the materials and endanger the patient as a result.
⇒ Clean device, accessories, and patient interface only in accordance with the associated instructions for use.
⇒ Do not use ozone cleaning devices.

Cleaning the device

1. Unpair accessories and cables from the device.
2. Wipe over the housing including the device outlet, the power cord, and the display with a damp cloth. Use a lint-free cloth lightly soaked in water and/or a mild detergent.
3. Clean or replace the mask, circuit, coarse dust filter, fine filter, filter for cooling fan, and breathing system filter. Follow the instructions for use from the accessory manufacturer.
4. Perform a function check (See Function check [▶ 21]).

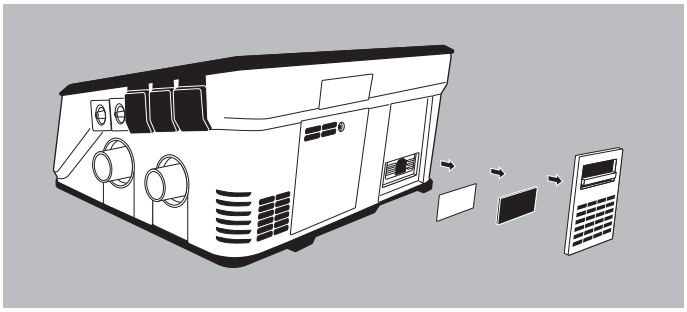
Clean coarse dust filter (gray filter)



1. Open filter compartment.
2. Remove coarse dust filter.
3. Wash coarse dust filter under running water.
4. Allow coarse dust filter to air dry.
5. Insert coarse dust filter.
6. Close filter compartment.

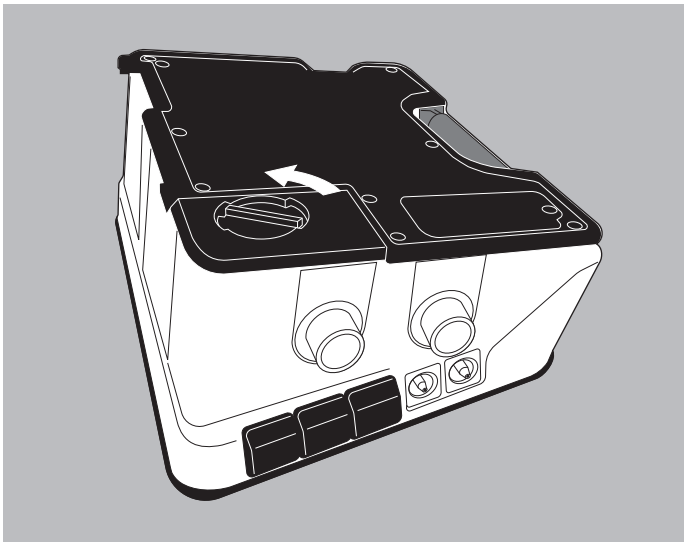
68691 b 10/2024 en-US

Replacing the fine filter (white filter)

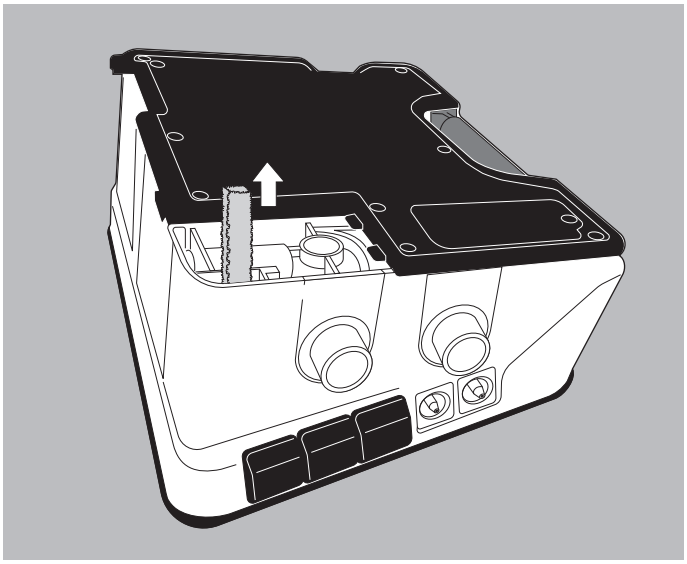


1. Open filter compartment.
2. Remove gray coarse dust filter.
3. Remove and replace white fine filter.
4. Insert coarse dust filter.
5. Close filter compartment.

Cleaning the filter for cooling fan



1. To open the expiration module compartment on the rear of the device, turn the latch counterclockwise to the symbol.
2. Remove cover.



3. Take out filter.
4. Wash filter under running water.
5. Allow filter to air dry.
6. Insert filter.
7. Close expiration module compartment.

6.2 Function check

Carry out a function check before using the device for the first time, after every hygiene treatment, and after every repair, but at least every 6 months.

If one of the items is not OK: Do not use device or accessory and contact your specialist dealer.

Perform a visual inspection

1. Check device for external damage.
2. Check connectors, cables, and accessories for external damage. Consult associated instructions for use.
3. Check that accessories are connected to the device correctly.

Performing automatic function tests

1. Connect the device to the power supply (See Set up device and connect [▶ 12]).
2. Switch on device.
   The device automatically performs a few function tests on the sensor system. The home display appears with full functionality.

Check the functionality of the batteries

1. Disconnect the device from the power supply. The first external battery (if present) takes over energy supply (watch what is shown in display).
2. Disconnect the first external battery from the device. The second external battery (if present) takes over energy supply.
3. Disconnect the second external battery from the device. The internal battery takes over energy supply.

Check battery capacity

If the battery capacity is low, connect the device to the power supply.

Check circuit

1. Perform circuit test (See Performing a circuit test [▶ 14]). If the circuit fails the test, follow the instructions on the display and troubleshoot the faults.
2. Seal the end of the circuit and start the therapy. A brief signal must be audible on starting. The device automatically performs a few function tests. The alarm acknowledgement key lights up yellow and red.
3. Compare the therapy pressure displayed with the prescribed pressure. If the pressure deviation is > 1 hPa: Do not use device or accessory and contact your specialist dealer.

Calibrate FiO_2 cell

1. If a FiO_2 cell is in use: Calibrate FiO_2 cell (See Calibrating the FiO2 cell [▶ 16]).

Test SpO_2 sensor

When using an SpO_2 sensor:

1. Check whether the SpO_2 sensor calculates measured values and these are shown on the display (SpO_2, pulse rate).
2. Check whether the $_{SpO2}$ symbol in the status line lights up green.

Do not use a functional tester to assess the accuracy of an SpO_2 sensor or a pulse oximeter.

Checking alarms

If required: Check alarms (See Checking alarms [▶ 22]).

6.2.1 Checking alarms

Physiological alarms

Alarm	ID no.	Requirement	Test
Leakage high	459	On a single circuit with valve: Alarm limit is set to a value <150 l/min. With leakage circuit: Alarm limit is set to a value <60 l/min. On a double circuit, 15 mm/22 mm: Alarm limit is set to a value <60 l/min.	Leave inspiration tube open at patient connection port. Start therapy. Wait at least 30 seconds, more alarms may occur during this period.
Pressure low	457	Alarm limit is set to a value ≥ 6 hPa.	Leave inspiration tube open at patient connection port. Start therapy.
Tidal volume low	450	Leakage circuit is connected	Connect test lung. Start therapy. Read off delivered volume (VT). Set alarm limit to a value above the volume delivered.
FiO2 low	494	FiO_2 cell is fitted and activated. Alarm limit is set. No external oxygen supply connected.	Start therapy.
Tidal volume on exp. low	470	Double circuit	Connect test lung. Start therapy. Read off delivered volume (VTe). Set alarm limit to a value above the volume delivered.
Tidal volume on insp. low	474	Single circuit with valve or double circuit	Connect test lung. Start therapy. Read off delivered volume (VTi). Set alarm limit to a value above the volume delivered.

Technical alarms

Alarm	ID no.	Requirement	Test
Exhalation blocked	757	Single circuit with valve is connected. or Double circuit is connected.	Connect test lung. Start therapy. On a single circuit with valve: Seal patient valve. On a double circuit: Take expiration tube off the device inlet and seal expiration tube.
Battery capacity low	551	Device is not connected to the power supply.	Start therapy until the internal battery has 15 minutes remaining before it is fully discharged.
Battery capacity critical	550	Device is not connected to the power supply.	Start therapy until the internal battery has 5 minutes remaining before it is fully discharged.
Supply via internal battery	581	None	Disconnect power cord from the device. Disconnect external batteries from the device.

68691 b 10/2024 en-US

Performing a manual alarm test

You can perform a manual alarm test to check the acoustic alarm system.

1. Select **System** > **Device settings** > **Alarm volume** > **Alarm test**.
2. Select volume and press **Start** key.
   A signal is played once at the selected volume.
3. Confirm or deny whether the signal was heard.
4. If the signal was not heard, switch off the device and briefly disconnect it from the power supply.
5. Reconnect the power supply and switch on the device.
6. Repeat alarm test.
   If the signal still cannot be heard, contact your specialist dealer.

If the primary alarm system fails, a second alarm system is activated. During the manual alarm test, the signal is also transmitted via the remote alarm connection (See Nurse call and remote alarm [▶ 28]).

6.3 Maintenance

The device is designed for following service life: 10 years. If the device is used beyond this period, it needs checking by the manufacturer or by an authorized specialist dealer.

For Germany: In accordance with Section 11 of the German Medical Devices Operator Ordinance, the device must be subjected to a technical safety inspection every two years. Country-specific requirements apply to all other countries.

Expected useful life	10 years
Servicing interval for batteries	4 years or 500 charging cycles
Servicing interval for membrane of expiration valve	4 years
Servicing interval for blower	35.000 h running time

6.4 Disposal

Do not dispose of the product or any batteries present with domestic waste. To dispose of properly, contact a licensed, certified electronic waste disposal merchant. This address is available from your Environment Officer or from your local authority. The device packaging (cardboard and inserts) can be disposed of in paper recycling facilities.

7 Alarms

7.1 General information

The device uses acoustic and visual alarms to alert you to an acute or impending hazard that requires your attention and intervention.

Priority levels

Alarms are divided into three priority levels: low ⚠, medium ⚠⚠, and high ⚠⚠⚠.

If several alarms are triggered simultaneously, the highest-priority alarm is shown first. The lower-priority alarm is retained and is displayed once the higher-priority alarm has been rectified.

Alarm data and alarm settings

Alarm data is saved in the alarm list. The log is retained when the alarm system or the device is switched off. The start and end of ventilation is recorded. The log can store 1,000 alarms. Once this capacity limit has been reached, the oldest alarm is deleted and the new alarm is saved.

7.2 Responding to an alarm

1. Check the patient's ventilation and oxygen supply.
2. To temporarily mute an alarm, briefly press the alarm acknowledgement key.
   or
   To mute all alarms for 2 minutes, press and hold the alarm acknowledgement key.
   The fault continues to be displayed in the status line and the alarm acknowledgement key flashes until the fault has been rectified.
   To stop muting the alarms, press the alarm acknowledgement key again briefly.
3. Take action to rectify the alarm situation (See Physiological alarms [▶ 24]) and (See Technical alarms [▶ 26]).
4. To acknowledge an alarm after the fault has been rectified, briefly press the alarm acknowledgement key.

7.3 Setting alarms

All physiological alarms except **SpO2 low** are deactivated upon delivery and when factory settings are restored. The healthcare professional activates the physiological alarms and makes the appropriate alarm settings for the patient. Different alarms can be configured depending on the therapy mode selected.

Procedure

1. In the expert menu, open the **Alarms** menu.
2. Select the desired alarm.
3. Set and confirm the desired value.
   When doing so, observe the following conditions:
   - Set sensible alarm limits.
   - Set the same alarms in different clinical areas.
   - Before use, check whether all alarm settings are suitable for the patient.
4. Set the alarm volume in the **System** > **Device settings** > **Alarm volume** menu.
   Make sure that the alarm sound can be heard clearly.

7.4 Physiological alarms

Physiological alarms relate to ventilation of the patient.

If the set parameter ranges are exceeded or not reached, the device issues an alarm.

Display	Code	Cause	Action
Apnea ⚠⚠⚠	458	No spontaneous breathing within set time.	Check therapy and alarm settings for plausibility and suitability for the patient.
Pressure high ⚠⚠⚠	456	Set therapy pressure exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
Pressure low ⚠⚠	457	Filter dirty.	Clean or replace filter.
		Patient interface leaking or defective.	Check patient interface and ensure that it is correctly fitted. If necessary, Replace patient interface.
		Set therapy pressure not achieved.	Check therapy and alarm settings.
Rate high ⚠⚠	453	Set respiratory rate exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
Rate low ⚠⚠	452	Set respiratory rate not achieved.	Check therapy and alarm settings for plausibility and suitability for the patient.
Leakage high ⚠⚠	459	Leakage	Check circuit and patient interface and ensure that the circuit and patient interface are correctly fitted.
Minute volume high ⚠⚠	455	Set minute volume exceeded.	Check therapy and alarm settings.
Minute volume low ⚠⚠⚠	454	Set minute volume not achieved.	Check therapy and alarm settings for plausibility and suitability for the patient.

68691 b 10/2024 en-US

Display	Code	Cause	Action
Pulse high ⚠⚠	493	Set pulse rate exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
Pulse low ⚠⚠⚠	492	Set pulse rate not achieved.	Check therapy and alarm settings for plausibility and suitability for the patient.
SpO2 high ⚠⚠	491	Set oxygen saturation exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
SpO2 low ⚠⚠⚠	490	Patient interface leaking or defective.	Check patient interface and ensure that it is correctly fitted. If necessary, Replace patient interface.
		Quantity of oxygen supplied too low.	Adjust therapy.
		Set oxygen saturation not achieved.	Check therapy and alarm settings.
Tidal volume low ⚠⚠⚠	450	Leak in the circuit or in the pneumatic unit (FiO2 cell or expiration module).	Check circuit and pneumatic unit (FiO_2 cell and expiration module) for leaks and ensure that they are fitted correctly. Perform circuit test. If necessary, Replace defective part.
		Filter dirty.	Clean or replace filter.
		Patient interface leaking or defective.	Check patient interface and ensure that it is correctly fitted. If necessary, Replace patient interface.
		Set tidal volume not achieved. Patient breathing as well.	Check therapy and alarm settings for plausibility and suitability for the patient.
		Minimum volume is not reached within the specified time in MPVv mode.	Check therapy and alarm settings for plausibility and suitability for the patient.
Tidal volume high ⚠⚠⚠	451	Set tidal volume exceeded. Patient breathing as well.	Check therapy and alarm settings for plausibility and suitability for the patient.
Tidal volume on exp. low ⚠⚠⚠	470	Minimum exhalation volume undershot.	Check therapy and alarm settings for plausibility and suitability for the patient.
Tidal volume on exp. high ⚠⚠⚠	471	Maximum exhalation volume exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.

Display	Code	Cause	Action
Minute volume on exp. low ⚠⚠⚠	472	Minimum minute volume on exhalation undershot.	Check therapy and alarm settings for plausibility and suitability for the patient.
Minute volume on exp. high ⚠⚠	473	Maximum minute volume on exhalation exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
Tidal volume on insp. low ⚠⚠⚠	474	Minimum tidal volume on inspiration undershot.	Check therapy and alarm settings for plausibility and suitability for the patient.
Tidal volume on insp. high ⚠⚠⚠	475	Maximum tidal volume on inspiration exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
Minute volume on insp. low ⚠⚠⚠	476	Minimum minute volume on inspiration undershot.	Check therapy and alarm settings for plausibility and suitability for the patient.
Minute volume on insp. high ⚠⚠	477	Maximum minute volume on inspiration exceeded.	Check therapy and alarm settings for plausibility and suitability for the patient.
PEEP high ⚠⚠⚠	469	Pressure at end of expiration high.	Check therapy and alarm settings for plausibility and suitability for the patient.
FiO2 low ⚠⚠⚠	494	Quantity of oxygen supplied too low.	Check whether the prescribed oxygen flow is set correctly at the oxygen source.
		Leak	Check circuit, patient interface and oxygen supply for leaks and ensure they are fitted correctly.
		FiO_2 cell calibrated incorrectly.	Calibrate FiO_2 cell.
FiO2 high ⚠⚠⚠	495	Quantity of oxygen supplied too high.	Check whether the prescribed oxygen flow is set correctly at the oxygen source.
		FiO_2 cell calibrated incorrectly.	Calibrate FiO_2 cell.
Disconnection patient ⚠⚠⚠	464	Patient interface leaking or defective.	Check patient interface and ensure that it is correctly fitted. If necessary, Replace patient interface.
Disconnection patient ⚠	465	Patient interface leaking or defective.	Check patient interface and ensure that it is correctly fitted. If necessary, Replace patient interface.

7.5 Technical alarms

Technical alarms relate to configuration of the device. The technical alarms are active and cannot be configured.

Display	Code	Cause	Action
Service life of internal battery soon at an end ⚠	542	Service life of internal battery soon at an end.	Contact your specialist dealer. Have internal battery replaced.
Life of battery E1/2 soon at an end ⚠	543 544	Service life of external battery soon at an end.	Contact your specialist dealer. Have external battery replaced.
Temperature of battery E1/2 high ⚠⚠⚠	547 548	External battery too warm.	Battery will switch off due to temperature. Operate the device at the following temperature: +5 °C to +40 °C. Connect the device to the power supply.
Error internal battery ⚠⚠⚠	549	Internal battery defective.	Contact your specialist dealer. Have internal battery replaced.
Battery capacity critical ⚠⚠⚠	550	Battery discharged (remaining battery life: 5 minutes)	Connect the device to the power supply.
Battery capacity low ⚠⚠	551	Battery discharged (remaining battery life: 15 minutes)	Connect the device to the power supply.
No internal battery ⚠⚠⚠	553	No internal battery.	Contact your specialist dealer. Have internal battery inserted.
Temperature of internal battery too high ⚠⚠⚠	555	Internal battery too warm.	Battery will switch off due to temperature. Operate the device at the following temperature: +5 °C to +40 °C. Connect the device to the power supply.
Internal battery overheated ⚠⚠⚠	556	Internal battery overheated.	Battery has switched off due to temperature. Operate the device at the following temperature: +5 °C to +40 °C.
Unable to charge internal battery ⚠⚠	558	Internal battery defective.	Contact your specialist dealer. Have internal battery replaced.
Temperature of internal battery high ⚠⚠	559	Internal battery too warm.	Operate the device at the following temperature: +5 °C to +40 °C.
Temperature of internal battery low ⚠⚠	560	Internal battery too cold.	Operate the device at the following temperature: +5 °C to +40 °C.
Life of internal battery at an end ⚠⚠	561	Life of internal battery at an end.	Contact your specialist dealer. Have internal battery replaced.
Life of battery E1/2 at an end ⚠⚠	562 563	Life of external battery at an end.	Replace battery.
Battery E1/2 overheated ⚠⚠⚠	564 565	External battery 1 overheated.	Battery has switched off due to temperature. Operate the device at the following temperature: +5 °C to +40 °C.
Unable to charge battery E1/2 ⚠⚠	566 567	External battery 1 defective.	Contact your specialist dealer.
Temperature of battery E1/2 high ⚠⚠	568 569	External battery 1 too warm.	Operate the device at the following temperature: +5 °C to +40 °C.
Temperature of battery E1/2 low ⚠⚠	570 571	External battery 1 too cold.	Operate the device at the following temperature: +5 °C to +40 °C.
Error internal battery communication ⚠⚠	572	Internal battery defective. Device defective.	Contact your specialist dealer.
Error battery E1/2 communication ⚠⚠	573 574	External battery defective. Device defective.	Contact your specialist dealer.
Error battery E1/2 ⚠⚠⚠	575 576	External battery defective.	Contact your specialist dealer.

68691 b 10/2024 en-US

Display	Code	Cause	Action
Error internal battery temperature ⚠⚠⚠	577	Ambient temperature too high.	Operate the device at the following temperature: +5 °C to +40 °C.
Error battery E1/2 temperature ⚠⚠⚠	578 579	Ambient temperature too high.	Operate the device at the following temperature: +5 °C to +40 °C.
Energy supply outage ⚠⚠⚠	580	Power supply failed.	Use alternative ventilation option. Check connection from device to power supply.
Supply via internal battery ⚠	581	Power supply failed.	Check connection from device to power supply.
		External battery and power supply not connected.	Note remaining battery life. Connect device to the power supply.
Error FiO2 cell ⚠⚠	770	FiO_2 cell defective.	Contact your specialist dealer. Have FiO_2 cell replaced.
No FiO2 cell ⚠⚠	771	No FiO_2 cell.	Contact your specialist dealer. Have FiO_2 cell Inserted.
FiO2 cell empty ⚠⚠	773	FiO_2 cell empty.	Contact your specialist dealer. Have FiO_2 cell replaced.
SpO2 signal weak ⚠⚠ SpO2 signal weak ⚠	790 792	SpO_2 sensor not connected to the finger.	Check position of SpO_2 sensor. If alarm persists: Contact your specialist dealer.
		Nail varnish or soiling is interfering with the SpO_2 sensor signal.	Remove nail varnish. Clean finger.
SpO2 sensor removed ⚠⚠	791	No SpO_2 sensor.	Connect SpO_2 sensor. If alarm persists: Replace SpO_2 sensor.
Cable for SpO2 sensor removed ⚠⚠	793	Cable for SpO_2 sensor removed.	Connect cable for SpO_2 sensor.
Service necessary	Various	Technical fault which can only be eliminated by a specialist dealer.	Contact your specialist dealer. Have device repaired.
Display error ⚠⚠⚠	173	Display not working.	Press on/off key to restart the device.

Display	Code	Cause	Action
Temperature of ambient air high ⚠⚠⚠	262	Ambient temperature too high.	Operate the device at the following temperature:+5 °C to +40 °C.
Temperature of main board high ⚠⚠⚠	263	Ambient temperature too high.	Operate the device at the following temperature:+5 °C to +40 °C.
Computer module temperature high ⚠⚠⚠	264	Ambient temperature too high.	Operate the device at the following temperature:+5 °C to +40 °C.
Check flow setting and/or accessories ⚠⚠	364	Set flow not reached.	Check therapy settings. Check accessories and fit of accessories.
No exhalation system ⚠⚠⚠	753	No exhalation system.	Connect exhalation system. Check circuit and patient interface and fit of circuit and patient interface.
Pressure permanently low ⚠⚠⚠	755	Mask leakage too high.	Check mask position.
Tidal volume permanently low ⚠⚠⚠	756	Settings implausible (alarm limit for tidal volume not reached).	Check therapy and alarm settings.
Exhalation blocked ⚠⚠⚠	757	Outlet for exhaled air blocked.	Check exhalation system and expiration module.
Therapy pressure constant ⚠⚠⚠	758	Respiratory rate or set pressure difference too low.	Check therapy and alarm settings.
Intake area blocked ⚠⚠	759	Intake area blocked.	Keep intake area free.
Pressure measuring and valve control tubes switched ⚠⚠⚠	760	Valve control tube and pressure measuring tube switched.	Check circuit for correct fit.
		Valve control tube kinked.	Check valve control tube. If required: Replace valve control tube.

Display	Code	Cause	Action
Connection to patient monitor disconnected ⚠⚠	788	Connection to patient monitor disconnected.	Check connection to patient monitor.
Blower temperature high ⚠⚠⚠	789	Blower temperature too high. Cooling air filter blocked.	Operate the device at the following temperature:+5 °C to +40 °C.
Therapy ended ⚠⚠⚠	794	Therapy ended.	Start therapy.
Circuit defective ⚠⚠⚠	795	Single circuit with valve set in menu, but double circuit connected.	Change circuit or select connected circuit in the menu.
		Leakage circuit set in menu but single circuit with valve connected.	
		Circuit defective.	Check circuit and fit of circuit.
Rebreathing ⚠⚠⚠	796	Valve soiled. Valve does not open in expiration.	Check circuit and fit of circuit. If required: replace circuit.
		Patient's re-inhalation volume excessive at high back-up rate.	
Blower overheated ⚠⚠⚠	799	Blower overheated.	Therapy will end. Allow device to cool down.
Maximum device pressure exceeded ⚠⚠⚠	811	Resistance on inspiration too high.	Reduce resistance and restart device. If the alarm persists, contact your specialist dealer.
Maximum device pressure reached ⚠⚠⚠	825	Resistance on inspiration too high.	Reduce resistance and restart device. If the alarm persists, contact your specialist dealer.

7.6 Nurse call and remote alarm

The device has a remote alarm connection to support patient and device monitoring (especially during life-support ventilation). All alarms are forwarded to this connection.

In a clinical setting, the device can be connected to the hospital's internal alarm system via the remote alarm connection.

68691 b 10/2024 en-US

8 Troubleshooting

Fault	Cause	Action
No running noise, nothing in the display.	No power supply.	Check connection of device to power supply. Check socket.
Device is unable to reach the set therapy pressure.	Coarse dust filter soiled.	Clean coarse dust filter. If necessary, replace filter.
	Mask leaking.	Adjust mask so that it does not leak (see instructions for use of the mask). If necessary, replace defective mask.
	Breathing circuit leaking.	Check circuit and eliminate leaks. If necessary, replace circuit.
	Device defective.	Contact your specialist dealer.
Dark display does not react to display being touched. Display remains dark.	Device switched off.	Switch on device.
Device does not respond to display input.	Electronics in device have failed.	Restart device (hold down on/off key ⏻ for 30 s).

In the event of an error that results a system recovery of the ventilator, therapy is interrupted for a maximum of 8 seconds. The alarms are not available for a maximum of 20 seconds.

9 Technical specifications

9.1 Ambient conditions

Temperature range, operation	+5 °C to +40 °C
Temperature range, transport and storage	-25 °C to +70 °C
Humidity for operation, transport and storage	Relative humidity 15% to 90%, non-condensing > 35° C to 70° C at a water vapor pressure of up to 50 hPa
Air pressure range	700 hPa to 1100 hPa (1100 hPa corresponds to an altitude of 3000 m above mean sea level)

9.2 Physical specifications and classifications

Dimensions (W x H x D)	30 cm x 13 cm x 21 cm
Weight	3.8 kg
Classification to IEC 60601-1: Application part	Patient interface (e.g. breathing mask, endotracheal tube, tracheal cannula), circuit, breathing system filter, SpO_2 sensor
Classification to ISO 5356-1: Diameter of device outlet connection	Standard 22 mm tapered connector
Classification to MDR (EU) 2017/745: Product class	IIb
Classification to IEC 60601-1-11: Degree of protection against electric shock	Type BF
Classification to IEC 60601-1-11: Class of protection against electric shock	Class II
Protection against ingress of solids and water	IP22: Protection against finger-sized objects and against drips with an inclination of up to 15 degrees
Classification to IEC 60601-1: Operating mode	Continuous duty
Standards applied	EN ISO 80601-2-72: Particular requirements for the basic safety and essential performance of home ventilation devices for patients dependent on the device

9.3 Materials

Housing	Fire-retardant technical thermoplastics and silicones, stainless steel
Fine filter	Synthetic fiber blend, combined with fleece made of PP (polypropylene)
Coarse dust filter	Polyester foam
Circuit	Polyethylene

9.4 Electronics and physical interfaces

Maximum electrical power consumption	48 V DC: 2.7 A / 24 V DC: 5.4 A / 12 V DC: 7.0 A
System interface	3 V DC: 0.2 A
USB-C interface Maximum power output (no power input)	5 V DC: 1.1 A
Power consumption, operating state **On** (therapy not in progress)	230 V AC: 0.07 A / 48 V DC: 0.30 A / 24 V DC: 0.61 A / 12 V DC: 1.21 A[1)]
Power consumption, operating state **On** (therapy in progress)	230 V AC: 0.18 A / 48 V DC: 0.81 A / 24 V DC: 1.61 A / 12 V DC: 2.86 A[1) 2)]
Power consumption, nurse call	60 V DC: 1 A (maximum)

[1)] without battery charge, screen brightness 90%,
[2)] with the following settings: Mode: T, Patient: Adult, leakage circuit 15 mm, IPAP: 40 hPa, EPAP: 4 hPa, F: 26.5 / min, Ti: 1.1s, pressure increase: Level 1, pressure reduction: Level 1, test lung, additional accessories: Breathing system filter, WilaSilent exhalation system

68691 b 10/2024 en-US

9.5 Power supply unit

Output voltage/maximum current	48 V DC: 2.7 A
Input frequency	50-60 Hz
Input voltage/maximum current	100-240 V AC: 2.0 A - 1.0 A (tolerance: -20% + 10%)

9.6 Therapy

All physiological flow and volume values are displayed in BTPS conditions (target volume, tidal volume, minute volume).

All other flow and volume values are displayed in STPD conditions.

Most disadvantageous circuit

Single circuit with valve (measured volume ≤ 50 ml)	LMT 31383 / 271734 Breathing system filter: WM 27591
Single circuit with valve (measured volume > 50 ml)	LMT 31382 / 271733, Breathing system filter: WM 27591
Leakage circuit	WM 29988, Breathing system filter: WM 27591
Double circuit	LMT 31577 / 271732, Breathing system filter: WM 27591

Therapy pressure

IPAP (leakage circuit)	4 hPa - 50 hPa
IPAP (single circuit with valve, double circuit)	4 hPa - 60 hPa
IPAP accuracy	±(2 hPa + 4% of the set value)
EPAP (leakage circuit)	4 hPa - 25 hPa
EPAP accuracy	±(2 hPa + 4% of the set value)
PEEP (single circuit with valve, double circuit)	0 hPa - 25 hPa
PEEP accuracy	±(2 hPa + 4% of the set value)
CPAP	4 hPa - 20 hPa
CPAP accuracy	±(2 hPa + 4% of the set value)
Increment for therapy pressure	0.2 hPa
Speed of pressure increase, adult	Level 1=100 hPa/s; level 2=80 hPa/s; level 3=50 hPa/s; level 4=20 hPa/s
Speed of pressure increase, pediatric	Level 1=135 hPa/s; level 2=100 hPa/s; level 3=80 hPa/s; level 4=50 hPa/s
Speed of pressure increase, MPV mode	Level 1=60 hPa/s; Level 2=45 hPa/s; Level 3=30 hPa/s; Level 4=15 hPa/s
Speed of pressure decrease, adult	Level 1=-100 hPa/s; Level 2=-80 hPa/s; Level 3=-50 hPa/s; Level 4=-20 hPa/s
Speed of pressure decrease, pediatric	Level 1=135 hPa/s; level 2=100 hPa/s; level 3=80 hPa/s; level 4=50 hPa/s
Maximum pressure in the event of a fault	< 90 hPa
Maximum applied flow at 20 hPa	> 220 l/min

Rate

Adjustable rate, adult	2 - 60 bpm
Adjustable rate, pediatric	5 - 80 bpm
Increment of adjustable rate	0.5 bpm
Accuracy of adjustable rate	±0.5 bpm

Volume

Adjustable target volume, pediatric	30 ml to 400 ml

Adjustable target volume, adult	100 ml to 3000 ml
Increment for the adjustable target volume from 30 ml to 100 ml	5 ml
Increment for the adjustable target volume from 100 ml to 3000 ml	10 ml
Accuracy of the volume measured by the ventilator ≤ 50 ml	± (4ml + 15% of the current value); leakage circuit without humidification chamber: ± (4ml + 15% of the current value); leakage circuit with humidification chamber: ± (20 ml + 15% of current value)
Accuracy of the volume measured by the ventilator > 50 ml	± (4 ml + 15% of current value)
Measurable minute volume (average value of the last 5 breaths)	0.1 l/min to 40 l/min

Times

Duration of inspiration, pediatric	0.2 s - 0.8 s in steps of 0.05 s / 0.8 s - 4 s in steps of 0.1 s
Duration of inspiration, (adult)	0.5 s - 0.8 s in steps of 0.05 s / 0.8 s - 4 s in steps of 0.1 s
Duration of inspiration, auto	Ti timed only
Duration of inspiration, accuracy	±0.05 s
I:E ratio	1:59 to 2:1

Trigger

Trigger levels, inspiration	1 (very sensitive) to 10 (not very sensitive)
Increment for trigger levels, inspiration	1
Trigger levels, expiration	95% to 5% of the peak respiratory flow'
Increment for trigger levels, expiration	5 %

The inspiratory trigger is activated when the respiratory flow during inspiration exceeds the trigger threshold. The expiratory trigger is activated when the respiratory flow during inspiration falls to the percentage value of the maximum respiratory flow during inspiration.

Oxygen supply

Permitted pressure at oxygen inlet	≤ 1000 hPa
Maximum additional oxygen flow	≤ 30 l/min

9.7 Noise

Device (operation to ISO 80601-2-72)

	Sound pressure level	Sound power level
Tidal volume ≥ 500 ml	38.5 dB(A)	46.5 dB(A)
Tidal volume ≥ 150 ml	37 dB(A)	45 dB(A)
Tidal volume ≥ 30 ml	41 dB(A)	49 dB(A)
Accuracy	±3 dB(A)	±3 dB(A)

Sound pressure level of alarm messages to IEC 60601-1-8 for all alarm conditions

	Volume level 1	Volume level 4
Low priority	69 dB(A)	88 dB(A)
Medium priority	69 dB(A)	88 dB(A)
High priority	68 dB(A)	86 dB(A)
Accuracy	±4 dB(A)	±5 dB(A)

68691 b 10/2024 en-US

9.8 Batteries

Type	Li-ion
Nominal capacity	3200 mAh
Nominal voltage	29.3 V
Energy	93.7 Wh
Typical discharge cycles	500
Duration of complete battery charge	< 6 hours
Duration of 80% battery charge	< 5 hours
Operating time of internal battery	≥ 6 hours[1)]

[1)] with the following settings: Double circuit, mode: PCV, f: 20 min, Ti: 1s, PEEP: Off, Vt: 800 ml, passive lung: Resistance R= 5 hPa /(l/s); compliance C = 50 ml/hPa

9.9 Software

Devices of type LM150TD use the following open-source software: Kernel 4.19 .132, Buildroot 2020.02.3. The software of this device contains code which is subject to the GPL. You can obtain the source code and the GPL on request.

9.10 Accessories

Classification, fine filter	Filter class E10, separation efficiency of particles up to 1 µm > 99.5%, separation efficiency of particles up to 0.3 µm > 85%, service life approx. 250 h
Dead space, breathing system filter	25 ml
Components for wireless communication: Frequency band	2.412 GHz to 2.4835 GHz

9.11 Accuracy of used measuring devices

Pressure	± 0.75% of measured value or ± 0.1 hPa
Flow	± 2% of actual value
Temperature	±0.3 °C
Sound pressure level	±1.4 dB
Volume	< 100 ml: greater than ± 2.5% of the measured value or 2.5 ml; 100 ml - 1000 ml: greater than ± 2% of the measured value or 20 ml
Time	±0.05 Hz / ± 0.001 bpm

9.12 SpO_2 sensor

Display range, SpO_2 measurement	0 to 100%
Increment, SpO_2 measurement	1 %
Display range, pulse rate measurement	0 to 255 bpm
Increment, pulse rate measurement	1 bpm
Accuracy	See instructions for use for 8000SX sensor
Data collection	Average over 4 beats
Data update	every 1.5 s
Alarm preset: SpO_2 measurement	85 %
Alarm preset: Pulse rate measurement	Off
Delay of alarm condition	1.5 s
Delay of alarm generation	15 s after alarm limit reached

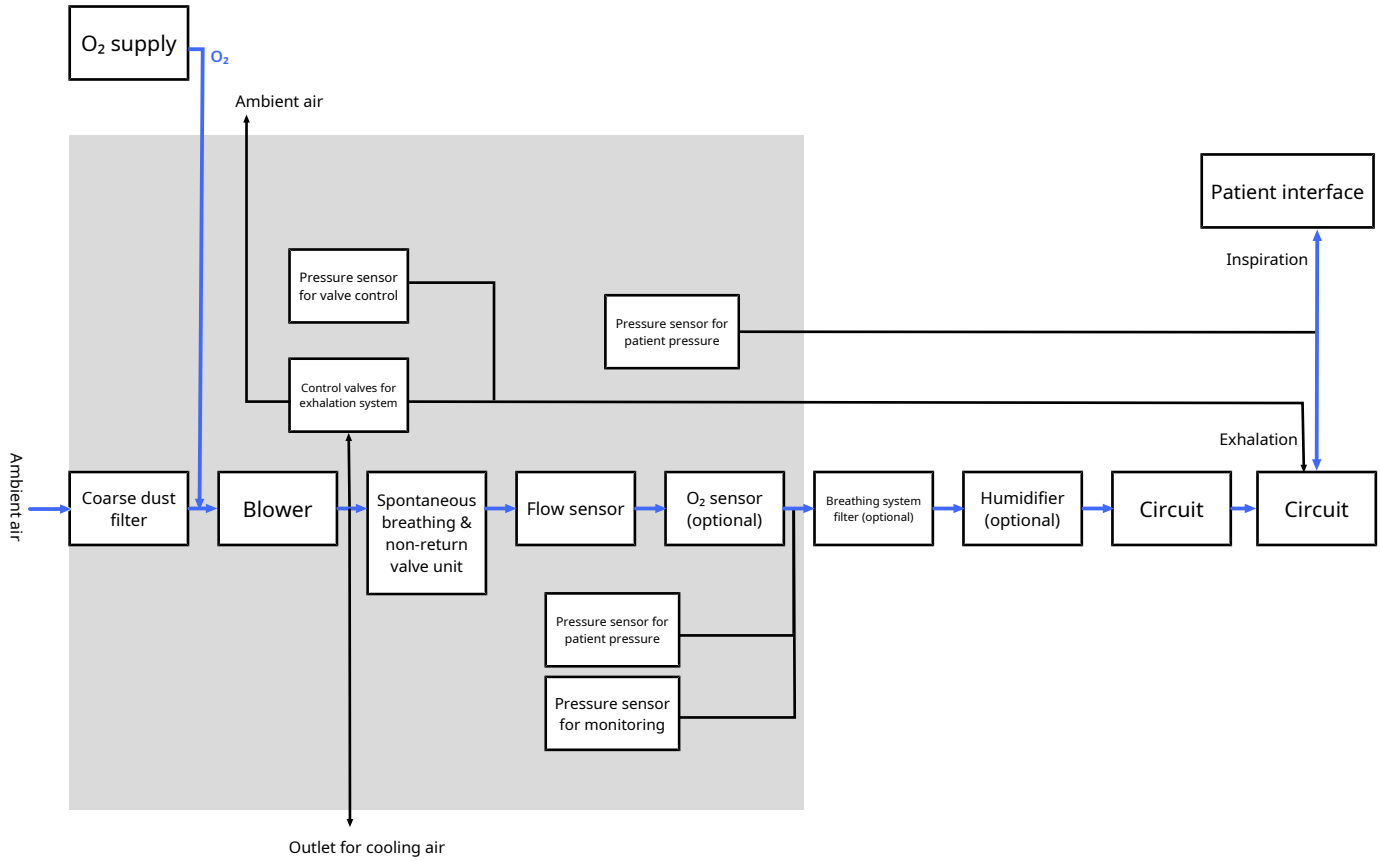
The SpO_2 sensors listed in these instructions for use have been validated and tested in accordance with ISO 80601-2-61.

68691 b 10/2024 en-US

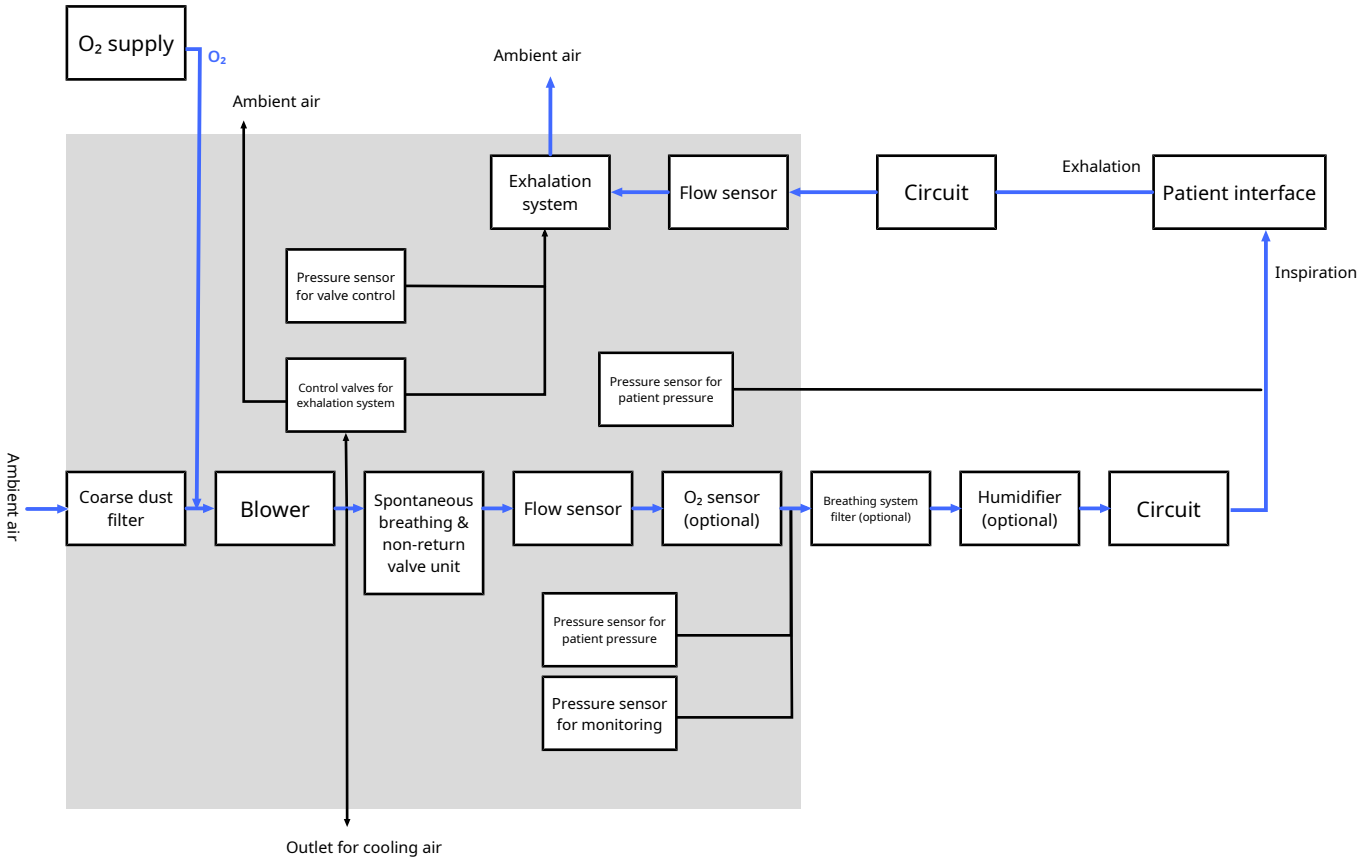
10 Annex

10.1 Pneumatic diagram

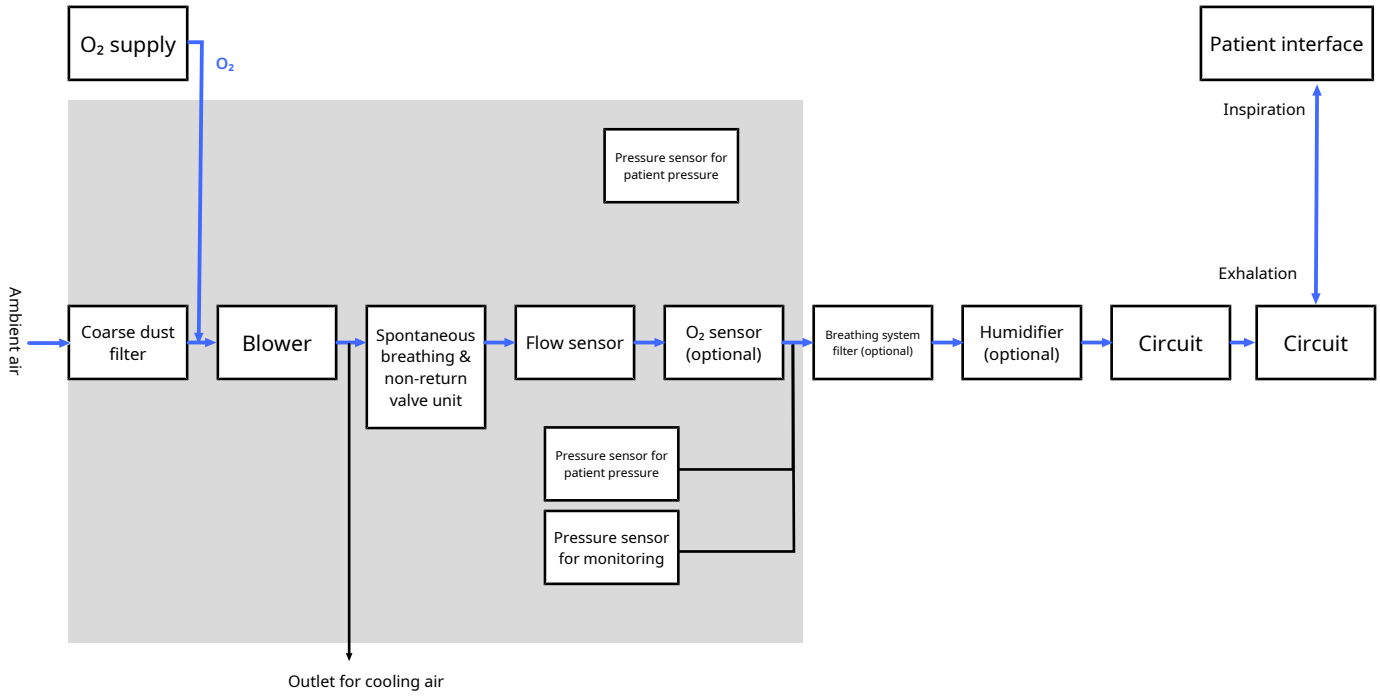
10.1.1 Single circuit with valve



10.1.2 Double circuit



10.1.3 Leakage circuit



10.2 System resistances

Essential performance as per ISO 80601-2-72

- Accuracy of airway pressure
- Accuracy of the volume delivered in a single breath
- No faulty setting of therapy parameters

68691 b 10/2024 en-US

- Functionality of alarms

The total pneumatic resistance of the connected circuit and of the connected accessories (e.g. humidifier, breathing system filter) between the device and the patient must not exceed the following value:

- Circuits with a diameter of 15 mm and 22 mm: Pressure reduction < 3.2 hPa at a flow = 30 l/min (BTPS).

The pressure reduction values of the individual components can be added to form a total resistance value that must not exceed the value mentioned above.

Maximum error in pressure measurement: 0.0125 hPa

Article no.	Article name	Flow (BTPS) in l/min	Pressure reduction in hPa
LMT 31382 / 271733	Single circuit with valve, 180 cm, 22 mm Ø	30	0.11
LMT 31383 / 271734	Single circuit with valve, 150 cm, 15 mm Ø	30	0.46
LMT 31577 / 271732	Double circuit, 150 cm, 15 mm Ø	30	Inspiration tube: 0.76 Inspiration tube from patient to device: 0.92 Expiration tube: 0.69
LMT 31581 / 271737	Double circuit, 180 cm, 22 mm Ø	30	Inspiration tube: 0.17 Inspiration tube from patient to device: 0.24 Expiration tube: 0.17
WM 27591	Teleflex Iso-Gard breathing system filter	2.5	0.06

Only use 10 mm Ø circuits for tidal volumes ≤ 50 ml.

Only use 22 mm Ø circuits for tidal volumes > 50 ml.

10.3 Emission of electromagnetic interference

Measurements of interference emission	Compliance
Conducted and radiated emissions (CISPR 11)	Group 1/Class B
Distortion due to harmonics (IEC 6100-3-2)	Class A
Voltage fluctuations and flicker (IEC 6100-3-3)	Complies
Conducted and radiated interference for devices in aircraft (RTCA DO-160G - Section 21, Category M)	Complies

10.4 Electromagnetic interference immunity

Interference immunity tests	Compliance level
Discharge of static electricity (ESD) (IEC 61000-4-2)	± 8 kV contact discharge ± 15 kV air discharge
Radiated HF interference (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz
Electrical fast transients (IEC 61000-4-4)	± 2 kV for cables for power supply units ± 1 kV for input and output cables
Surge immunity (IEC 61000-4-5)	± 1 kV line to line
Conducted HF interference (IEC 61000-4-6)	3 Vrms 150 KHz to 80 MHz 6 Vrms in ISM and amateur radio frequency range between 150 kHz and 80 MHz
Magnetic field at power supply frequency 50/60 Hz (IEC to IEC 61000-4-8)	30A/m
Voltage dips/short interruptions and variations in power supply (IEC 61000-4-11)	0 % UT; 1/2 period 0 % UT; 1 period 70 % UT; 25/30 periods 0 % UT; 250/300 periods
Magnetic fields in close proximity (IEC 61000-4-39)	8 A/m at 30 kHz 65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz

High-frequency electromagnetic fields in immediate proximity to wireless communication equipment (IEC 61000-4-3)	9 to 28 V/m* 385 MHz to 5.785 GHz* * tested to IEC 60601-1-2:2020 Table 9
	27 to 84 V/m* 385 MHz to 5.785 GHz* * tested to IEC 60601-1-2:2020 Table 9 with test levels three times higher. Corresponds to a distance of 0.1 m from wireless communication equipment.

10.5 Markings and symbols

The following markings and symbols may be applied to the device, accessories or packaging.

Symbol	Description
	Manufacturer and, if necessary, date of manufacture
	Unique device identifier (unique product code for medical devices)
	Order number
	Indicates the product is a medical device
	Follow the instructions for use
	CE symbol (confirms that the product conforms to the applicable European directives/ regulations)
	Permitted temperature range for transport and storage
	Permitted humidity range for transport and storage
	Pressure measuring tube connection
	Valve control tube connection
	Opening for patient's breathing air. Do not block opening.
	Inlet; do not block openings
	Outlet
	Follow Instructions for Use
	Direct current
	Suitable for use in aircraft. Meets RTCA/ DO-160G Section 21, Category M.
	Degree of protection against electric shock: Protection class II product
	Do not dispose of the product in domestic waste
IP22	Degree of protection against contact with a finger. Protection against vertically falling water drops when enclosure tilted up to 15°.

Symbol	Description
	Type BF application part
	Protect from moisture
	Fragile. Do not throw or drop
	Use multiple times on a single patient
	MR-unsafe: Do not use the product in an MR (magnetic resonance) environment
	Lot number

10.6 Scope of supply

10.6.1 Device without HFT mode

The parts below are included in the standard scope of supply:

Part	Article no.	LMT 31400-1110	LMT 31420-1110
Basic device without HFT mode	LMT 31430	X	X
Single circuit with valve, 180 cm, 22 mm Ø	LMT 31382 / 271733	X	X
External power supply unit	LMT 31569	X	X
Cable for power supply unit	WM 24177	X	X
Oxygen connection nozzle	WM 30669	X	X
Set, 12 pollen filters/fine filters	WM 29652	X	X
Set, 2 air filters/coarse dust filters	WM 29928	X	X
Protective bag LM150TD	LMT 31417	X	X
USB-C flash drive	LMT 31414	X	X
ID card for patient	1P-10088	X	X
LM patient information	WM 28209	X	-
Set, documents as per Medizinprodukte-Betreiberverordnung [German law governing the owners/ operators of medical devices]: Medical devices manual, handover log	WM 15100	X	X
Final inspection log LM150TD	LMT 31588	X	X
Accessories bag	LMT 31440	X	X
Instructions for use	Varies depending on language	X	X

68691 b 10/2024 en-US

10.6.2 Device with HFT mode

The parts below are included in the standard scope of supply:

Part	Article no.	LMT 31380-1110	LMT 31390-1110
Basic device with HFT mode	LMT 31410	X	X
Single circuit with valve, 180 cm, 22 mm Ø	LMT 31382 / 271733	X	X
External power supply unit	LMT 31569	X	X
Cable for power supply unit	WM 24177	X	X
Oxygen connection nozzle	WM 30669	X	X
Set, 12 pollen filters/fine filters	WM 29652	X	X
Set, 2 air filters/coarse dust filters	WM 29928	X	X
Protective bag LM150TD	LMT 31417	X	X
USB-C flash drive	LMT 31414	X	X
ID card for patient	1P-10088	X	-
LM patient information	WM 28209	X	-
Set, documents as per Medizinprodukte-Betreiberverordnung [German law governing the owners/operators of medical devices]: Medical devices manual, handover log	WM 15100	X	-
Final inspection log LM150TD	LMT 31588	X	X
Accessories bag	LMT 31440	X	X
Instructions for use	Varies depending on language	X	X

10.7 Accessories and spare parts

Part	Article no.
Mobility bag LM150TD	LMT 31554
LUISA app	-
Teleflex Iso-Gard breathing system filter	WM 27591
WILAsilent exhalation system	WM 27589
Single circuit with valve, 150 cm, 15 mm Ø	LMT 31383 / 271734
Single circuit with valve, 180 cm, 22 mm Ø	LMT 31382 / 271733
Double circuit, 150 cm, 15 mm Ø	LMT 31577 / 271732
Double circuit, 180 cm, 22 mm Ø	LMT 31581 / 271737
Leakage circuit/breathing tube, 15 mm Ø	WM 29988
Leakage circuit/breathing tube (black), 19 mm Ø	WM 23962
Leakage circuit/breathing tube, autoclavable, 19 mm Ø	WM 24667
Leakage circuit/breathing tube mouth piece ventilation, 15 mm Ø	WM 27651
Leakage circuit/ breathing tube, heated (i), autofill chamber, passive valve, 150 cm + 60 cm, 15 mm Ø for LM150TD	WM 271704
Leakage circuit/ breathing tube, heated (i), autofill chamber, passive valve, 150 cm + 60 cm, 22 mm Ø for LM150TD	WM 271705
Set, 90° tube adapter	LMT 15984
Internal battery	LMT 31550
External battery LM150TD	LMT 31540
Battery charger	LMT 31594
External power supply unit	LMT 31569
Set, clinic trolley, consisting of:, consisting of: Trolley 2.0 (LMT 31355) Set, plate for trolley 2.0 Set, mounting plate for devices LM150TD/ LM300CD Set, trolley 2.0 extension Power supply holder for trolley 2.0 Water bag holder for trolley 2.0 Oxygen bottle holder for trolley 2.0 Circuit holder for trolley 2.0	LMT 31370
Set, homecare trolley, consisting of:, consisting of: Trolley 2.0 (LMT 31355) Set, plate for trolley 2.0 Set, mounting plate for devices LM150TD/ LM300CD Set, trolley 2.0 extension Power supply holder for trolley 2.0	LMT 31360
Set, plate for trolley 2.0	LMT 31371
Set, mounting plate for devices LM150TD/ LM300CD	LMT 31359
VENTIremote alarm LM150TD, 10 m	LMT 31560
VENTIremote alarm LM150TD, 30 m	LMT 31570
Cable 10 m, nurse call LM150TD	LMT 31510
Cable 30 m, nurse call LM150TD	LMT 31520
prismaTS / prismaTSlab software	WM 93335
USB-C flash drive	LMT 31414
COM cable for monitor	LMT 31578
USB modem (not available in all countries. Contact your specialist dealer.)	LMT 31763
FiO_2 cell, complete	LMT 31502
Expiration module (disposable)	LMT 31404
Expiration module (autoclavable)	LMT 31413
Set, expiration module panel	LMT 15986
Oxygen connection nozzle	WM 30669
Protective bag LM150TD with doming	LMT 31010
Accessories bag	LMT 31440
Set, 2 air filters/coarse dust filters	WM 29928
Set, 12 pollen filters/fine filters	WM 29652
SpO_2/Xpod® cable	LMT 31593
SpO_2 sensor size S	LMT 31580

Part	Article no.
SpO_2 sensor size M	LMT 31396
SpO_2 sensor size L	LMT 31388
Single circuit with valve, heated (i), autofill chamber, 150 cm + 60 cm, 15 mm Ø	LMT 31384
Double circuit, heated (i+e), autofill chamber, 150 cm + 60 cm, 22 mm Ø	LMT 31583
Double circuit, heated (i+e), A-shaped adapter, autofill chamber, 150 cm + 60 cm, 15 mm Ø	LMT 31582
Double circuit, heated (i+e), autofill chamber, 120 cm + 60 cm, 10 mm Ø	LMT 31386

10.8 Warranty

Löwenstein Medical Technology gives the purchaser of a new original Löwenstein Medical Technology product and of a spare part fitted by Löwenstein Medical Technology a limited manufacturer warranty in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase listed below. The warranty conditions are available on the manufacturer's website. We will also send you the warranty conditions on request.

Please bear in mind that any claim under warranty and liability shall be void if neither the accessories recommended in the instructions for use nor original spare parts are used.

In the event of a claim under warranty, contact your specialist dealer.

Product	Warranty periods
Masks including accessories	6 months
Devices including accessories	2 years
Batteries (unless otherwise specified in the technical documentation), sensors, circuits	6 months
Disposable products	None

10.9 Declaration of conformity

The manufacturer Löwenstein Medical Technology GmbH + Co. KG (Kronsaalsweg 40, 22525 Hamburg, Germany) hereby declares that the product complies with the relevant provisions of the Medical Device Regulations (EU) 2017/745. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

68691 b 10/2024 en-US

68691b 10/2024 EN-US

CE 0197

Manufacturer
Löwenstein Medical
Technology GmbH + Co.KG
Kronsaalsweg 40
22525 Hamburg, Germany
T: +49 40 54702-0
F: +49 40 54702-461
www.loewensteinmedical.com

LÖWENSTEIN
medical

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