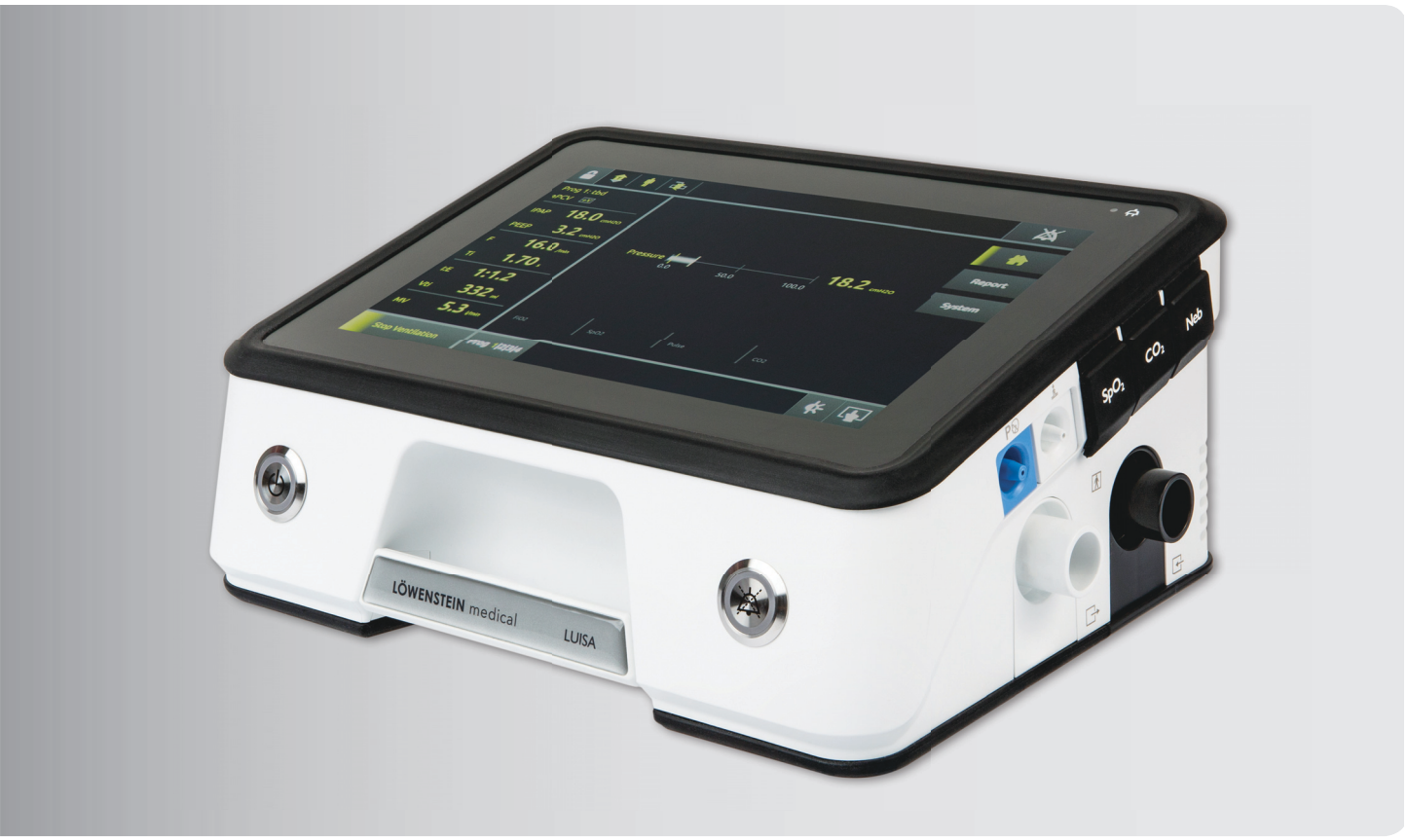
EN Instructions for use for patients for devices of type LMT150TD



LUISA

Ventilators

LÖWENSTEIN
medical

Contents

LMT 68651d 12/2022

1 Introduction

1.1 Intended use

The LM150TD LUISA 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 device can be used with both invasive and non-invasive patient/ventilator interfaces. The leakage circuit can also be used invasively.

A blower takes in ambient air through a filter and pumps it through the ventilation tube and the patient/ventilator interface to the patient. The blower is controlled to suit respiratory phases on the basis of the signals detected by the pressure and flow sensors.

The user interface is for displaying and setting the available parameters and alarms.

The device can be used with a leakage circuit, with a single circuit with valve or with a double circuit. With the leakage circuit, the exhaled air containing CO_2 is continuously flushed out via an exhalation system. With a single circuit with valve and with a double circuit, the patient's exhalation is controlled by a valve.

In High Flow mode (HFT mode), the device pumps the set flow to an external humidifier suitable for HFT. This conditions the respiratory gas in terms of temperature and humidity. The patient connection is made using accessories suitable for HFT. HFT mode (if available) and MPV mode are not respiration support modes within the meaning of standard ISO 80601-2-72. As no permanent and/or sealed connection is made between the corresponding interfaces and the patient's airway, some specifications such as disconnection detection do not apply.

Oxygen can be supplied via the oxygen inlet.

If required, the FiO_2 concentration delivered by the device can be measured using an integrated FiO_2 cell. External SpO_2 measurement can also be connected.

The power is supplied by an external power supply unit. The device has an integrated battery, so it can continue to be operated without interruption in the event of a power outage. In addition, a maximum of two external batteries can be connected to operate the device.

Therapy data are stored in the device and can additionally be loaded on a USB-C flash drive and analyzed by PC software.

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.

A distinction is drawn between specialist users (experts) and non-specialist users. The following groups of people make up both groups:

PERSON	DESCRIPTION	USER QUALIFICATION
Patient	Person receiving the therapy	Persons with no specialist medical or nursing knowledge. Following an introduction by the medical professional on how the device works and how to use it, these individuals are regarded as **non-specialist users**.
Non-specialist user	Patient, relative and other caregivers	
Owner/ operator	Health care 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).	Following training by the manufacturer or by a specialist expressly authorized by the manufacturer on how the device works and how to use it, these individuals are regarded as **specialist users**.

PERSON	DESCRIPTION	USER QUALIFICATION
Medical professional	Person with state-approved qualification in a medical profession (e.g., physician, respiratory therapist, medical technician)	Following training by the manufacturer or trained owner/operator on how the device works and how to use it, the persons with specialist knowledge of the therapy and device (e.g., medical specialists, nursing specialists, service specialist) are regarded as specialist users.
Nursing specialist	Person with state-approved qualification in a nursing profession	
Specialist dealer	Person or organization that markets, but does not itself manufacture a product. The specialist dealer can also provide a support function.	Following training by the manufacturer on how the device works and how to use it, these individuals are regarded as specialist users.

As an owner/operator or user, you must be familiar with the operation of this medical device.

The device is a medical device which may only be used as specified by the medical professional or the owner/operator.

Notice for blind or partially-sighted users
An electronic version of the instructions for use is available on the 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 the individual case, responsibility for deciding whether to use the device rests with the medical 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) or 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

When using the device, the following undesired side effects may occur in short-term or long-term use: 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.

2 Safety

2.1 Safety information

2.1.1 Handling the device, the components, and the accessories

If the device is damaged or its function is restricted, people may be injured.

⇒ Only operate the device and its components if they are externally undamaged.

⇒ Perform a function check at regular intervals (see “6.2 Function check”, page 20).

⇒ Only operate, store, and transport the device within the specified ambient conditions (see “9 Technical specifications”, page 31).

⇒ Do not use the device if the automatic function check issues error messages.

⇒ Always keep an alternative means of ventilation to hand in order to avoid a life-threatening situation if the device fails.

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

LMT 68651d 12/2022

⇒ Do not use the device in an MRT environment or in a hyperbaric chamber.
⇒ Do not reuse disposables. Disposables may be contaminated and/or their function may be impaired.
⇒ Do not use or supply anesthetic gases.
⇒ Set acoustic alarm volume high enough for the acoustic alarm to be heard.
⇒ Use breathing tubes with an internal diameter of 10 mm only on patients with a tidal volume <50 ml.
⇒ Eliminate leaks on the breathing mask or breathing tube. In the event of unintended leaks, the values displayed for volume and exhaled CO_2 will deviate from actual patient values.
⇒ Only use accessory parts from the manufacturer.
⇒ Do not use antistatic or electrically-conductive tubes.
⇒ The accuracy of the device may be impaired by the gas supplied by a pneumatic nebulizer.
⇒ Regularly check the breathing system filter for increased resistance and blockages. Moistening with nebulizers or humidifiers may increase the resistance of breathing system filters and thus change the therapeutic pressure delivered. In order to prevent increased resistance and blockages, replace the breathing system filter more frequently.
⇒ Set up external humidifiers below the device and the patient connection. Water in the device may damage the device or injure the patient.

2.1.2 Electromagnetic compatibility

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.
⇒ Portable high-frequency communication equipment (e.g. radios and cell phones), including their accessories such as antenna cables and external antennas, for example, must be used at a distance of at least 30 cm from the device and its cables.
⇒ Do not use the device in the vicinity of active high-frequency surgical equipment.
⇒ Operate the device within the EMC environment specified for this device (see “10.4 Electromagnetic interference immunity”, page 38) in order to prevent key performance characteristics being affected - for example, ventilation parameters being affected by electromagnetic interference.
⇒ Do not operate the device if the housing, cables or other equipment for electromagnetic shielding are damaged.
⇒ 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 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 Energy supply

Operating the device outside the specified energy supply may cause personal injury, damage the device or impair the performance of the device.
⇒ Operate the power supply unit only at voltages from 100 V to 240 V.
⇒ Use DC cable LMT 31597 for operation on voltages of 12 V or 24 V.
⇒ Keep access to the power supply connector and the power supply free at all times.
⇒ When using a battery-operated wheelchair: Connect the device to the wheelchair battery only if a connection of that kind is expressly provided in the instructions for use for the wheelchair.
⇒ When operating using the cigarette lighter socket in a car: Disable the car’s auto start/stop feature. Start the car first, then connect the device.

2.1.4 Handling oxygen

Supplying oxygen without a special safety device can lead to fire and injure people.
⇒ Follow the instructions for use for the oxygen supply system.
⇒ Set up oxygen sources at a distance of over 1 m from the device.
⇒ The oxygen rate supplied in l/min must not exceed the oxygen flow prescribed by the medical professional.
⇒ The oxygen rate supplied in l/min may not exceed the set HFT flow rate.
⇒ At the end of therapy, shut off the oxygen supply and allow the device to run on briefly to flush residual oxygen out of the device.

2.1.5 Transport

Operating the device in any kind of carrying bag may impair device performance and injure the patient. Water and dirt in the device may damage the device.
⇒ Only operate the device in the associated LUISA mobility bag.
⇒ Transport or store the device in the associated LUISA protective bag.

2.1.6 Wireless module

The device contains a wireless module. 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.

2.2 General information

- In order to react to an alarm and, if necessary, to use emergency ventilation, you must subject both patient and device to regular monitoring.
- The use of third-party articles may lead to incompatibility with the product. In such cases, please be aware that any claim under warranty and liability will be void if original spare parts are not used.
- Connection by cable to a patient monitor is not a substitute for a remote alarm system. Alarm data are transmitted only for documentation purposes.
- Have measures such as repairs, servicing, and maintenance work, as well as modifications to the product, carried out exclusively by the manufacturer or by specialists expressly so authorized by the manufacturer.
- Connect only the licensed products and modules in accordance with these instructions for use. The products must meet the product standard applicable to them. Non-medical equipment should be positioned out of the patient's vicinity.
- Follow the section on hygiene treatment (see “6 Hygiene treatment and servicing”, page 18) to avoid infection or bacterial contamination.
- In the event of a power outage, all settings including alarm settings are retained.
- 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.

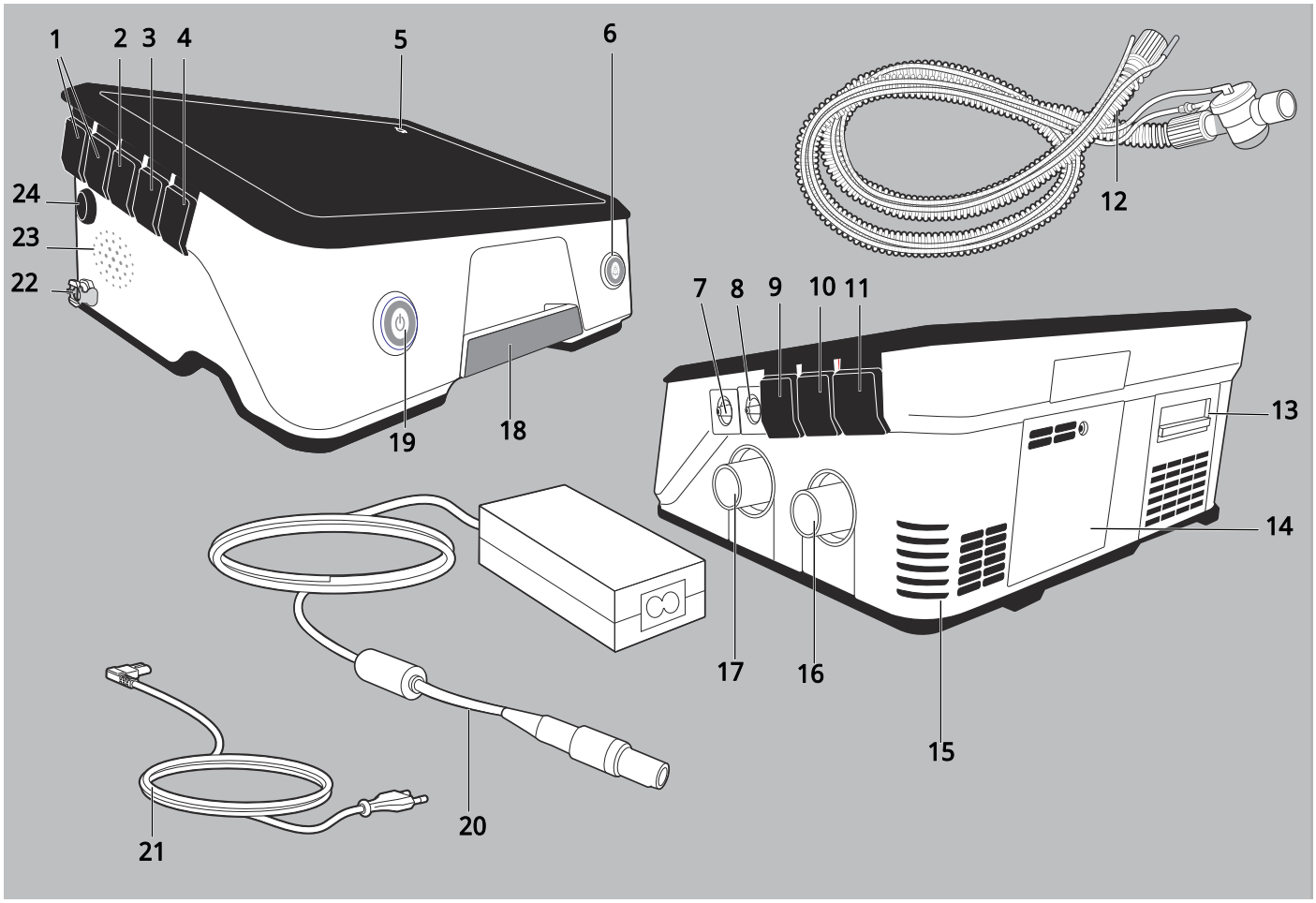
2.3 Safety information in these instructions for use

⚠ WARNING	Indicates an unusually significant hazardous situation. If you ignore this instruction, severe irreversible or fatal injuries may result.
⚠ CAUTION	Indicates a hazardous situation. If you ignore this instruction, mild or moderate injuries may result.
NOTICE	Indicates a harmful situation. If you ignore this instruction, material damage may result.
ⓘ	Indicates useful information within procedures.

LMT 68651d 12/2022

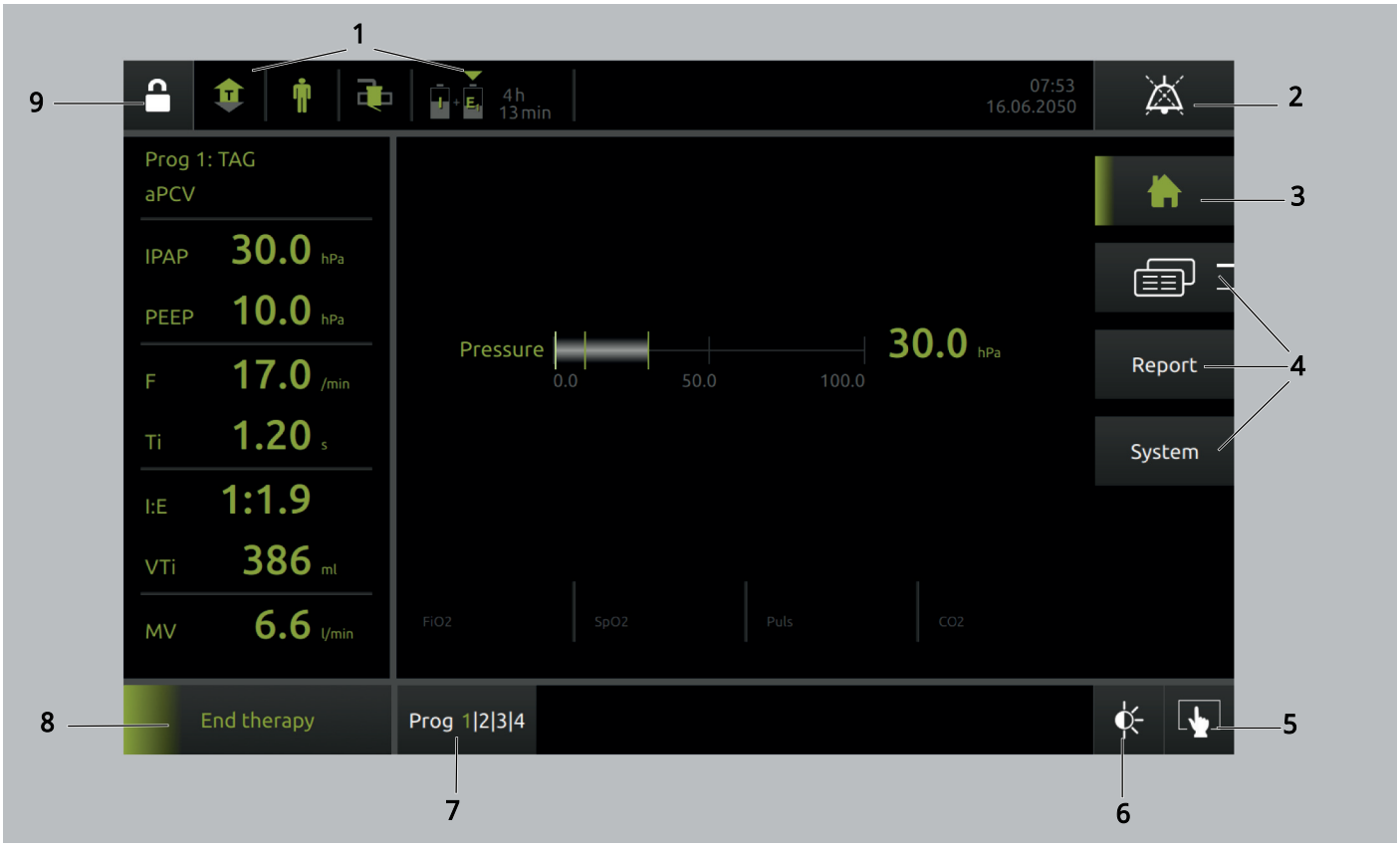
3 Product description

3.1 Overview



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

3.2 Control panel in display



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

2 Alarm acknowledgement key -
Press briefly: Acknowledges alarm. If the alarm persists, the alarm is muted for 120 seconds.
Press and hold: Mutes all acoustic alarms for 2 minutes.
Press briefly again: Suspends alarm muting.

3 Home key - switches the view back to the start screen.

4 Menu keys - provide access to the individual menus.

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

6 Dimmer key - switches to night mode and the display goes dark.
Touch the display to reactivate it.
Keep key depressed - opens the **Display** menu.

7 Program key - provides access to the ventilation programs. The medical professional or specialist dealer can preconfigure and enable up to four programs in the device for you. If you need different ventilation settings during the day compared to during the night, for example, you can change the program yourself here.

8 Ventilation key - starts or stops ventilation.

9 Access key - locks or unlocks the Expert menu.

LMT 68651d 12/2022

3.3 Symbols in display

SYMBOL	DESCRIPTION
	Device in Patient menu. Expert menu locked.
	Expert menu unlocked.
	Indicates respiratory status: • Arrow pointing upward: Inspiration • Arrow pointing downward: Exhalation • S: Spontaneous breath • T: Mandatory breath
	Device set for pediatric applications/ children.
	Device set for adults.
	Leakage circuit set.
	Single circuit with valve set.
	Double circuit set.
	Battery charging. If the gray area reaches the top, the battery is fully charged.
	Battery capacity high, battery discharging.
	Battery capacity medium, battery discharging.
	Battery capacity low, battery discharging.
	Battery capacity low.
	Battery fault
	Filter change function (only if function is activated).
	Service reminder function (only if function is activated).
	SpO_2 sensor: Gray: Not connected Green: Connected and high signal quality Yellow: Connected and moderate signal quality Red: Connected and poor signal quality
	FiO_2 cell Green: Activated and full Gray: Activated and empty Green and flashing: Calibration process in progress
	Patient monitor connected.
	Network connection present.

SYMBOL	DESCRIPTION
	Green: Bluetooth® (wireless technology) activated. Gray: Bluetooth® (wireless technology) not activated.
	Wireless connection present.
	Flight mode activated.
	Green: USB flash drive connected. Gray: USB flash drive faulty.
	Low-priority alarm triggered.
	Medium-priority alarm triggered.
	High-priority alarm triggered.
	All physiological alarms have been deactivated.
	Acoustic alarm paused.

3.4 Accessories (optional)

PART	DESCRIPTION
VENTI*remote* alarm	For remote transmission and display of the alarms output by the device
SpO_2 sensor	Determines SpO_2 and pulse frequency data
Breathing system filter	Prevents the transmission of particles and microorganisms to the breathing system
FiO_2 cell	Performs permanent FiO_2 measurement
Circuit	Supplies the patient with respiratory air
Exhalation system	Routes exhaled air into the environment
External battery	Serves as an additional external energy supply for the device
Protective bag for LUISA	Serves to transport and store the device with protection

Follow the instructions for use for the accessories. Here you will find further information about operation and combining accessories with the device.

3.5 Operating states

- **On**: Therapy is in progress. It is possible to make device and therapy settings.
- **Standby**: The blower is off and therapy is not in progress. However, the device is ready for operation immediately. It is possible to make device and therapy settings.
- **Off**: The device is switched off. No settings can be made and the display remains dark.

3.6 Batteries

3.6.1 Internal battery

- The device is fitted with an internal battery. If the device is no longer connected to the power supply or there is a power outage, the battery automatically starts supplying the device without interruption. This discharges the battery. This discharges the battery. The battery is charged automatically again as soon as the device is connected to the power supply.
  In operation via a 12 V or 24 V supply, the battery is charged only when the device is in **Standby** or **Off**.
- The internal battery is replaced by the manufacturer or by a specialist dealer.
- Battery life depends on ventilation settings and ambient temperature (see “9 Technical specifications”, page 31).
- When the **Battery capacity low** alarm appears, only a minimum of 15 minutes’ life remains. When the **Battery capacity critical** alarm appears, the device will switch off in a few minutes’ time (less than 5 minutes’ life remaining). Have an alternative ventilation option to hand and connect the device to the power supply.
- If device and battery have been stored outside the quoted operating temperatures, the device can only be started up once it has warmed up or cooled down to the permitted operating temperature.

3.6.2 External batteries

- External batteries can be connected to the device as an additional energy supply. If the device is connected to the power supply, the batteries are charged; first the internal battery, then the external batteries. In operation via a 12 V or 24 V supply, the batteries are charged only when the device is in the **Standby** or **Off** state.
- If the device is not connected to the power supply, a battery powers the device. The external batteries connected are discharged first, followed by the internal battery.

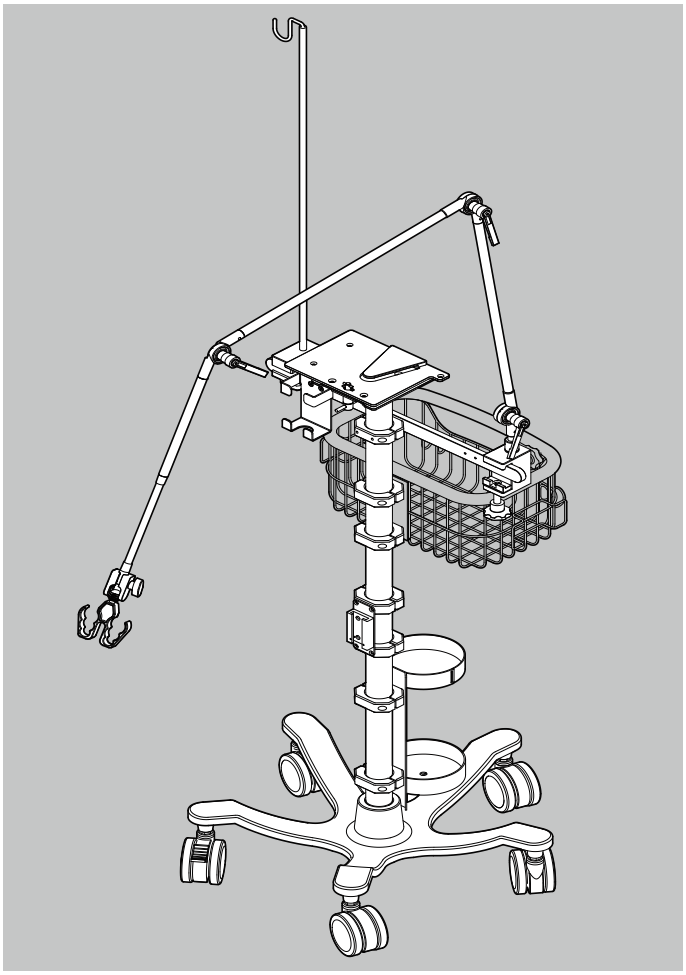
3.6.3 Display of remaining device life

Remaining device life in the case of battery and power supply operation is displayed in the status line and in the **Views** menu (see “5.2.1 Views menu in the Patient menu”, page 16).

	DEVICE ON STANDBY	DEVICE IN THE ON STATE
POWER SUPPLY	Value in %	Value in %
BATTERY SUPPLY	Value in %	Remaining battery life in h and min.

Remaining life is a prediction and always relates to the current mean consumption of the device.
Following the start of ventilation, no more than 3 minutes will elapse before remaining life is displayed.

3.7 Trolley 2.0



LMT 68651d 12/2022

You can use the oxygen cylinder clamp with oxygen cylinders up to 120 mm in diameter (this corresponds to a cylinder size of approx. 4 l to 6 l per cylinder). Note total cylinder height (cylinder including valve and accessories).

NOTICE

Material damage if incorrectly configured!
If trolley 2.0 is not used properly, it may tip over or be damaged.

⇒ Use the circuit holder only for the circuit.
⇒ Use the water bag holder only for the refill unit of the active humidification system.
⇒ 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 the trolley: Put the circuit holder in the folded-away position.

3.8 Data management/ compatibility

Anyone who integrates medical devices or medical software products in an IT network or installs them on a PC or integrates devices or software products in a medical IT network or installs them on a PC is responsible for complying with IEC 80001-1.

According to IEC 80001-1, the owner/operator is responsible for the risk management of any interactions in medical IT networks. Please note that the manufacturer does not accept any warranty or liability for interactions between system components in an IT network.

3.8.1 Saving and transmitting therapy data

Therapy data for the previous 30 therapy days (24 hours/day) are saved in the device. Pressure, flow and volume are saved at 20 Hz, all other recorded values at 1 Hz.
Statistical data for the previous 12 months are saved in the device.

A file in edf format is created for every day saved.

If you plug USB flash drive LMT 31414 into the device, the therapy data saved in the device will be transmitted to the flash drive in the form of edf files.

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

3.8.2 Updating the firmware

In order to perform a firmware update, plug a USB flash drive with an update file (one version higher than the current version) into the device and confirm that the update should go ahead.

The device configuration is retained following the update.

3.8.3 Setting up a connection to the LUISA app

The LUISA app is an app on a mobile terminal. The device can be connected to the LUISA app (see “4.7 Pairing device with LUISA app”, page 15).

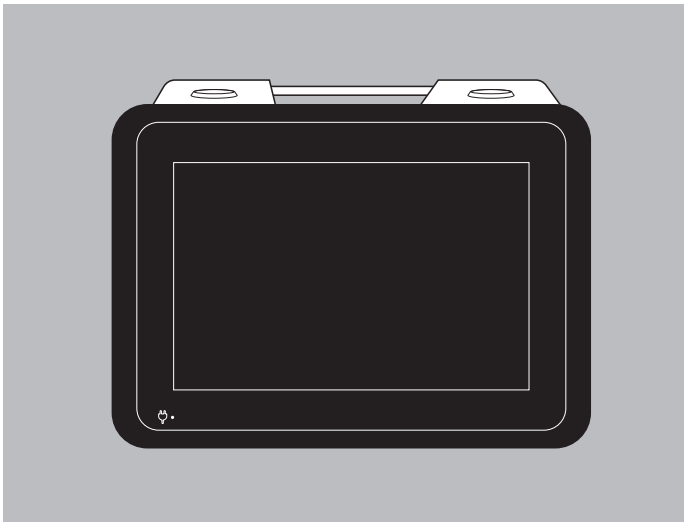
4 Preparation and operation

4.1 Setting up and connecting device

⚠ CAUTION

Risk of injury from inadequate therapy if air inlet and air outlet are blocked!
A blocked air inlet and/or air outlet can cause the device to overheat, impair therapy, and damage the device.

⇒ Keep the filter compartment clear (symbol).
⇒ Keep the device inlet port free (symbol).
⇒ Keep the intake area of the cooling fan free (symbol).

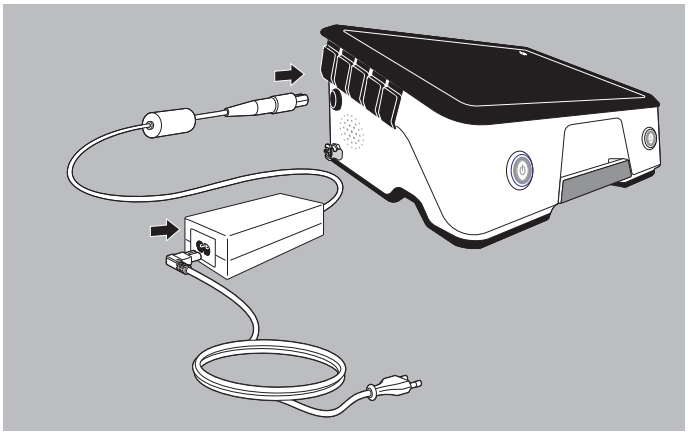


1. If required: Tilt the device to a horizontal or vertical position.
   The display adapts to the orientation automatically.

NOTICE

Material damage from overheating!
Excessive temperatures may lead to the device overheating and damage the device.

⇒ Do not cover device and power supply unit with textiles (e.g. bedclothes).
⇒ Do not operate device in the vicinity of a radiator.
⇒ Do not expose device to direct sunlight.
⇒ Only operate the device in the associated mobility bag for mobile use.



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

Alternatively, you can connect a direct voltage electricity supply (12 VDC or 24 VDC) as per ISO 80601-2-72.

4.2 Connecting circuit

⚠ WARNING

Risk of asphyxia if invasive or non-invasive patient/ventilator interfaces without an exhalation system are used!
If invasive or non-invasive patient/ventilator interfaces without an integrated exhalation system are used, CO_2 concentration may rise to critical values and put the patient at risk.

⇒ Use invasive or non-invasive patient/ventilator interfaces with an external exhalation system if there is no integrated exhalation system.
⇒ Follow the instructions for use for the exhalation system.

⚠ WARNING

Risk of injury from potential patient disconnection!
On circuits without proximal pressure measurement and with additional accessories such as HME or tube extension, for example, it is not possible to detect patient disconnection reliably.

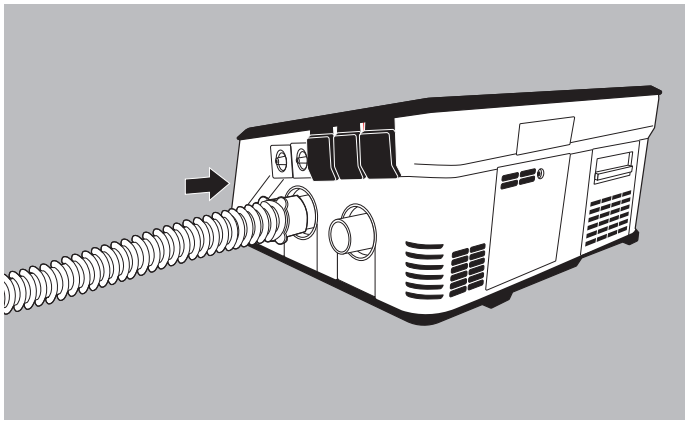
⇒ Use the VTe low alarm for the double circuit and the VTi high alarm for the single circuit with valve.

LMT 68651d 12/2022

⚠ CAUTION

Risk of injury from incorrectly routed circuits and cables!
Incorrectly routed circuits or cables may injure the patient.
⇒ Do not route circuits and cables along the neck.
⇒ Do not crush circuits and cables.

4.2.1 Connecting leakage circuit

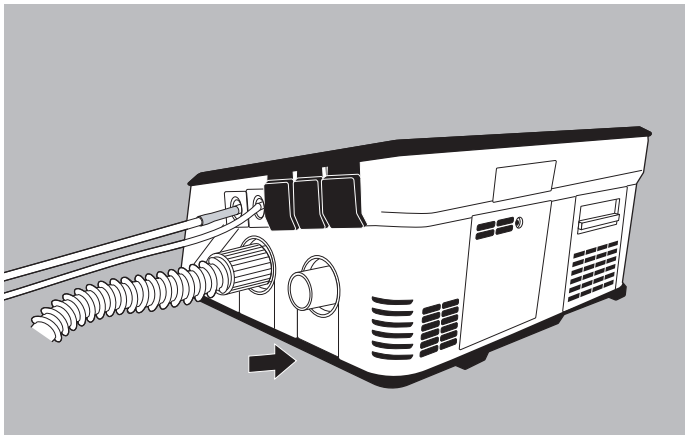


1. Push the inspiration tube onto the device outlet port.
2. Connect the patient interface (e.g., breathing mask) to the circuit (see instructions for use for the patient/ventilator interface).

4.2.2 Connecting single circuit with valve

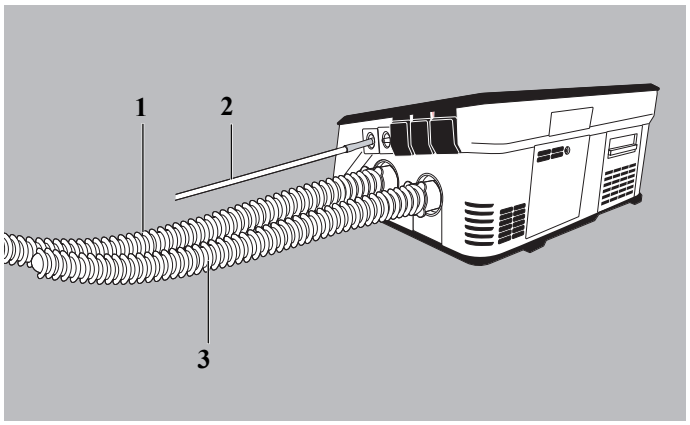
⚠ WARNING

Risk of injury if patient valve is covered!
If the patient valve is covered, exhaled air can no longer be routed away and the patient will be put at risk.
⇒ Always keep the patient valve free.



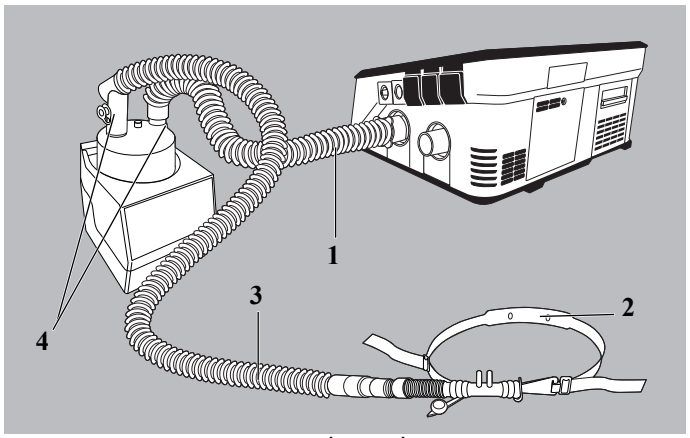
1. Push the inspiration tube onto the device outlet port.
2. Push the pressure measuring tube onto the inlet port for the pressure measuring tube $_{P}$.
3. Push the valve control tube onto the inlet port for the valve control tube ↓.
4. Connect the patient interface (e.g., breathing mask) to the circuit (see instructions for use for the patient interface).

4.2.3 Connecting double circuit



1. Push the inspiration tube **1** onto the device outlet port.
2. Push the expiration tube **3** onto the device inlet port.
3. Push the pressure measuring tube **2** onto the inlet port for the pressure measuring tube $_{P}$.
4. Connect patient interface (e.g., breathing mask) to Y-piece of the circuit (see instructions for use for the patient interface).

4.2.4 Connecting circuit for HFT mode



1. Push inspiration tube (short) **1** onto the device outlet port.
2. Push the other end of the inspiration tube (short) **1** onto the inlet port of the humidifier chamber **4** marked **In**.
3. Push the inspiration tube (long) **3** onto the outlet port of the humidifier chamber **4** marked **Out**.

4. Connect High Flow interface **2** to the inspiration tube (long)**3**.
5. If necessary, connect the tube heater and temperature probe to the inspiration tube (long) **3** (see instructions for use for the external humidifier).

As an alternative to the leakage circuit, it is also possible to use the single circuit with valve or the double circuit in HFT mode.

4.3 Before first use

The device must be configured before being used for the first time. If your specialist dealer has not yet done so, you must set language and time on the device.

The device is supplied with a charged internal battery. To charge the internal battery fully, leave the device connected to the power supply for at least 1 hour.

4.4 Switch device on and off / Start and end therapy

ACTION	REQUIREMENT	KEY	RESULT
Switch on device[1]		Briefly press the On/off key ⏻ on the device	Device on standby
Start therapy[1]	Device is switched on	Briefly press the On/off key ⏻ on the device *or* Press **Start therapy** in the display	Therapy starts
End therapy		Press and hold the On/off key ⏻ on the device *or* Press and hold **End therapy** in the display	Device on standby
Switch off device		Press and hold the On/off key ⏻ on the device	Display goes out
[1]The device automatically performs a few function tests. This may take a few seconds.			

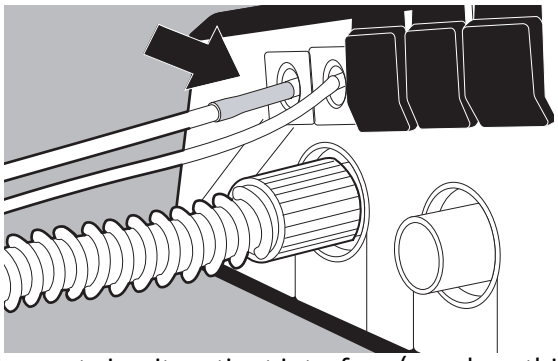
4.5 Performing circuit test

Perform a circuit test at every function check, on change of patient and as required. This checks for resistance, compliance, and leaks.

Requirement

Specialist dealer or medical professional selects the used circuit in the **Ventilation** menu.

1. Select the **System** > **Circuit test** menu.
2. In the **Overview of circuit test** section, select the desired ventilation program and press the **Start** key.
3. Select the appropriate option as a function of the circuit used:
   For a leakage circuit, select whether an exhalation system or a breathing mask (vented variant) is being used.
   or
   For a single circuit with valve or for a double circuit, select whether the circuit test is to be conducted with or without proximal pressure measurement. You can tell which is being used by checking whether or not the pressure measuring tube is connected to the pressure measuring tube inlet port P- .



4. Connect circuit, patient interface (e.g., breathing mask) and accessories to the device. If present: Disconnect the connection to the patient.
5. Follow instructions in the display.
6. Press the **Next** key to start the circuit test.
7. If the circuit test is successful, press the **Finish** key. If the circuit test is not successful, follow the instructions in the display and eliminate the faults.

4.6 Calibrating 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).

LMT 68651d 12/2022

1. Calibration is performed in the **System** > **FiO_2 cell** > **Start calibration** menu.
2. Interrupt O_2 supply. Wait approx. 30 seconds.
3. Press the **Ok** key to start calibration.
4. If calibration is successful, press the **Finish** key. If calibration is not successful, follow the instructions in the display and eliminate the faults.
5. Continue O_2 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 is fitted and replaced by a healthcare professional or nurse.

4.7 Pairing device with LUISA app

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

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

After pairing, the app will recognize the Bluetooth connection of the device. The pairing does not then need to be performed again. The saved pairing can be deleted in the LUISA app.

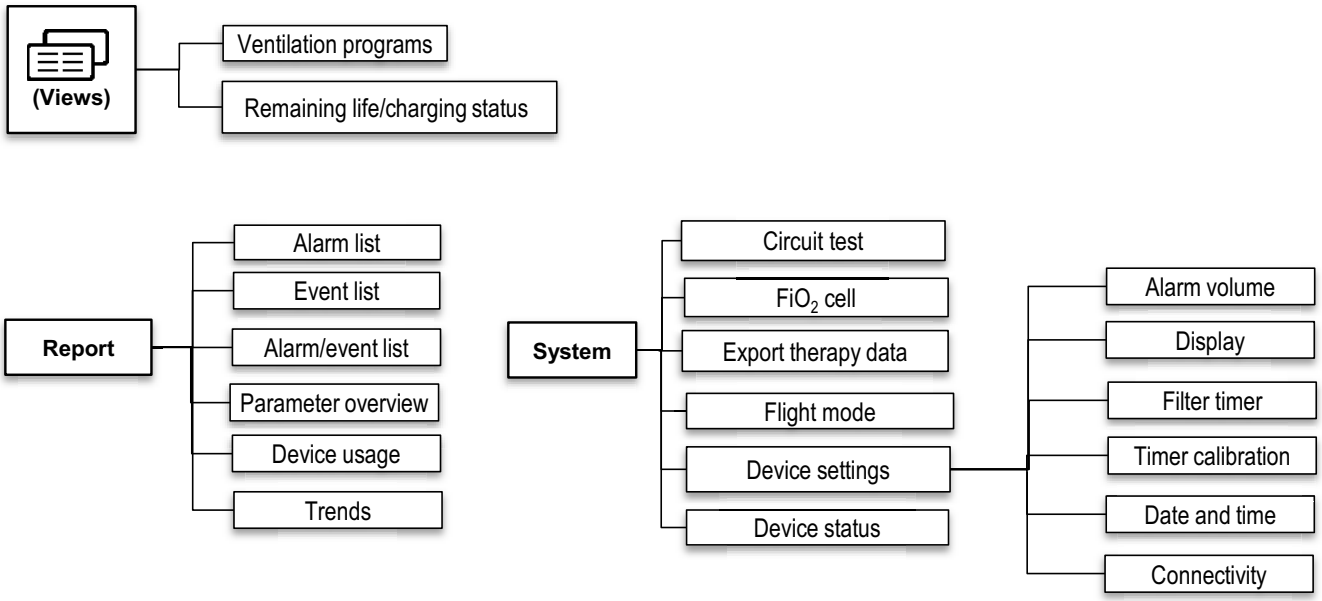
5 Settings in the menu

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. **System**, **Start therapy**, or  . Symbols on a black background are not function keys, but serve to provide information about device status (see “3.3 Symbols in display”, page 9).
Scroll in list	Navigate up or down

ACTION	FUNCTION
Press “Value”	Opens range of values for setting ventilation parameters
Move range of values up or down	Decrease or increase value
	Confirm value
	Discard selection
	Switches the view back to the start screen

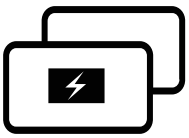
5.2 Patient menu structure



5.2.1 Views menu in the Patient menu

The **Views** menu shows 2 views.

Parameters and set values for the ventilation programs



In the **On** state: Remaining device life if being supplied by battery
In the **Standby** state: Charging state of the internal battery in percent assuming a power supply

To switch to the next view in each case, tap the Views key again. The horizontal lines on the Views key are the number of available views.

LMT 68651d 12/2022

5.2.2 Report menu in the Patient menu (usage data)

Information about the parameters in this menu can be found in the table below.

PARAMETER	DESCRIPTION
Alarm list	Lists the alarms which have occurred. The log is retained when the alarm system or the device is switched off. The start and end of ventilation is recorded. The log is retained even if the device is disconnected from the power supply and the batteries are removed. 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.
Event list	Lists the events that have occurred.
Alarm/event list	Lists the alarms and events which have occurred in chronological order.
Parameter overview	Lists all parameters and set values for the up to 4 ventilation programs which can be configured.
Device usage	Information about the patient's therapy (duration, days used, program proportions) and about device usage (operating time of the device and of the blower).
Trends	Access to the graphical displays of the therapy parameters

5.2.3 System menu in the Patient menu

Circuit test	Perform a circuit test here on change of patient and as required. This checks for resistance, compliance, and leaks (see "4.5 Performing circuit test", page 14).
FiO_2 cell	Activate or deactivate the FiO_2 cell and calibrate the FiO_2 cell here.
Export therapy data	You can export the set device settings here. A USB flash drive must be connected for exporting.
Flight mode	You can activate/deactivate flight mode here. With flight mode activated, all wireless communication (Bluetooth) is ended.
Device settings	You can configure the device here (see "5.2.4 Device settings submenu", page 17).
Device status	Obtain information here about the device (name, type, serial number of device and components, firmware version) and about the internal battery.

5.2.4 Device settings submenu

PARAMETER	DESCRIPTION
Alarm volume	The patient can set the alarm level here. 1= very quiet, 2= quiet, 3= loud, 4= very loud You can test the alarms here.
Display	You can set brightness and display background here.
Filter timer	You can activate and reset the filter change reminder function here.
Timer calibration	Here you can activate and reset the reminder function for calibrating the FiO_2 cell.
Date and time	You can set the current date and time here.
Connectivity	You can activate the Bluetooth function and pair the device with the LUISA app here.

6 Hygiene treatment and servicing

6.1 Hygiene treatment

⚠ WARNING

Risk of infection when the device and accessories are used again!
If the device is used by several patients, infections may be transmitted to the next patient and the device contaminated.
⇒ Do not reuse disposables.
⇒ Use the breathing system filter.

6.1.1 General information

- If you would like to use a disinfectant for cleaning purposes, refer to the instructions for use of the particular product. Solutions containing alcohol (25 g ethanol (94 %-strength), 35 g propan-1-ol per 100 g) are suitable. Recommended: Mikrozid AF liquid or perform advanced Alcohol EP.
- To prevent foreign bodies being taken in, ensure that filters are inserted following cleaning, hygiene treatment, maintenance or servicing.
- The following gas route components may be contaminated following use of the device:
  - LMT 31494 Device outlet port
  - LMT 31497 Seal for FiO_2 cell
  - 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 Central part of housing
  - WM 29389 Fine filter
  - LMT 31487 Coarse dust filter
  - LMT 31422 Filter holder

6.1.2 Cleaning intervals

INTERVAL	ACTION
Weekly	Clean device (see “6.1.3 Cleaning device”, page 18).
Monthly	Clean coarse dust filter (see “Cleaning coarse dust filter (gray filter)”, page 19).
	Replace fine filter (see “Replacing fine filter (white filter)”, page 19).
	Clean filter for cooling air fan (see “Cleaning filter for cooling air fan”, page 19).
Every 6 months	Replace coarse dust filter (see “Cleaning coarse dust filter (gray filter)”, page 19).
On change of patient	• Have the device subjected to a hygiene treatment by the manufacturer or by an authorized specialist dealer in line with the service and repair instructions. The Keredusy process can be used as an alternative to manual disinfection. • Clean or replace the exhalation module. The black expiration module (included in scope of delivery) is a disposable item and must be replaced if the device was used with the double circuit. The black translucent exhalation module (has to be ordered separately) is suitable for autoclaving. • Set device to factory settings.

6.1.3 Cleaning device

⚠ CAUTION

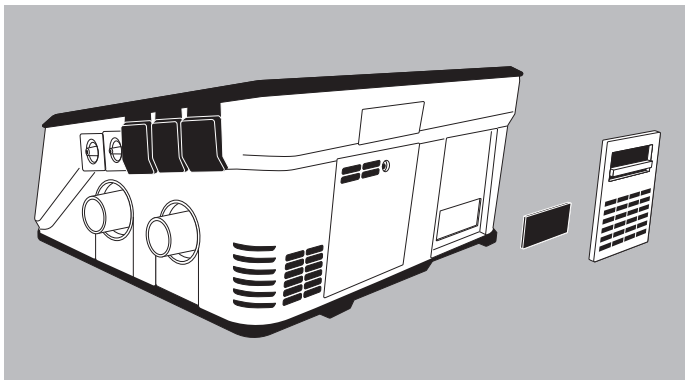
Risk of injury from electric shock!
Ingress of liquids may lead to a short-circuit, injure the user and damage the device.
⇒ Disconnect the device from the power supply.
⇒ Do not immerse the device and accessories in liquids.
⇒ Do not pour liquids over the device and accessories.

1. Wipe over the housing including the device outlet port, the power cord, and the display with a damp cloth. Use water or mild detergent.
2. Clean or replace the mask, circuit, coarse dust filter, fine filter, filter for the cooling air fan, and the breathing system filter (see “6.1.2 Cleaning intervals”, page 18). Consult associated instructions for use.

LMT 68651d 12/2022

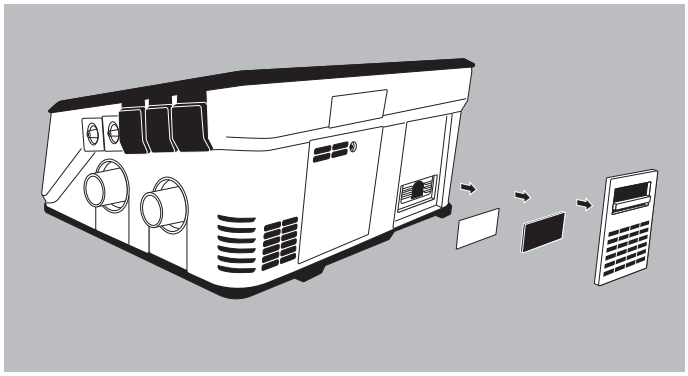
3. Perform function check (see “6.2 Function check”, page 20).

Cleaning coarse dust filter (gray filter)



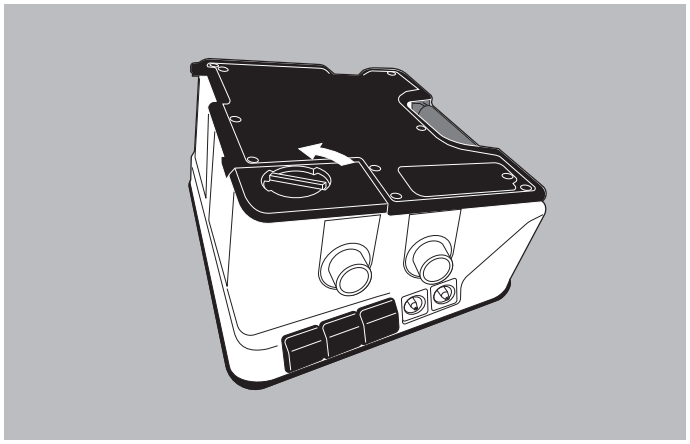
1. Open filter compartment.
2. Remove gray coarse dust filter.
3. Wash coarse dust filter under running water.
4. Allow coarse dust filter to dry.
5. Insert coarse dust filter.
6. Close filter compartment.

Replacing fine filter (white filter)

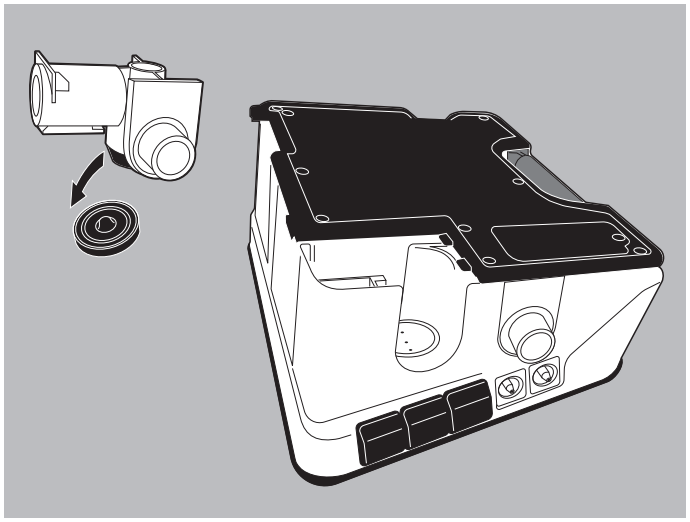


1. Open filter compartment.
2. Remove gray coarse dust filter.
3. Remove and replace white fine filter.
4. Insert coarse dust filter.
5. Close filter compartment.

Cleaning exhalation module



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

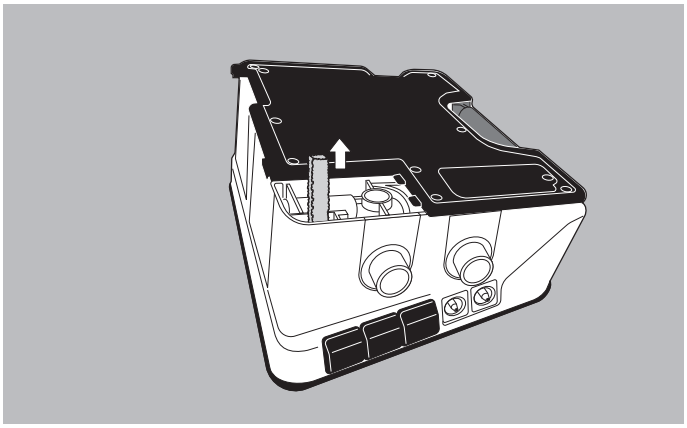


Only the black translucent module is suitable for cleaning. The black module is a disposable and must be replaced.

4. Remove membrane from the exhalation module.
5. Wipe over exhalation module and membrane with disinfectant.
   Both parts can be disinfected in an autoclave at 134 °C and 3.15 bar with a process time of 5 minutes (maximum 50 cycles).
6. Check exhalation module for cracks and damage. If necessary: Replace exhalation module.
7. Leave exhalation module and membrane to dry.
8. Put membrane back on exhalation module.
9. Replace exhalation module in the compartment.
10. Close exhalation module compartment.

Cleaning filter for cooling air fan

1. Open exhalation module compartment (see “Cleaning exhalation module”, page 19).



2. Remove filter for cooling air fan.
3. Wash filter under running water.
4. Allow filter to dry.
5. Insert filter.
6. Close exhalation 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.

1. Check device for external damage.
2. Check connectors, cables, and circuit for external damage.
3. Check accessories such as the breathing system filter, external batteries, and SpO_2 sensor for external damage.
   Follow the associated instructions for use.
4. Check that accessories are connected to the device correctly (see “4.2 Connecting circuit”, page 12).
5. Connect the device to the power supply (see “4.1 Setting up and connecting device”, page 12).
6. Switch on device (see “4.4 Switch device on and off / Start and end therapy”, page 14).
   The device automatically performs a few function tests on the sensor system. If the device is fully functional, the home screen is displayed and the device switches to standby.
7. Perform a circuit test (see menu: **System** > **Circuit test**).
   If the circuit test fails, follow the instructions on the display and troubleshoot the faults.
8. Seal the end of the tube and start ventilation. A brief acoustic alarm must be audible on starting.
   The device automatically performs a few function tests.
   The alarm key lights up yellow and red.
9. Compare the pressure shown in the display with the prescribed pressure.
10. Check the functionality of the batteries:
    - Disconnect the device from the power supply.
      The first external battery (if present) takes over energy supply (watch what is shown in display).
    - Disconnect the first external battery from the device.
      The second external battery (if present) takes over energy supply.
    - Disconnect the second external battery from the device.
      The internal battery takes over energy supply.
11. Check the charging state of the batteries (see “5.2.1 Views menu in the Patient menu”, page 16).
    If the batteries are not charged, connect the device to the power supply to charge the batteries.
12. If a FiO_2 cell is in use: Perform FiO_2 calibration (see “5.2.3 System menu in the Patient menu”, page 17).
13. If one of the items is not OK or pressure deviates by > 1 hPa: Do not use device or accessory and contact your specialist dealer.
14. If required: Check alarms (see “6.3 Checking alarms”, page 20).

6.3 Checking alarms

To check alarm functionality, simulate the kind of user error that triggers the particular alarm.

6.3.1 Non-specialist user

ALARM	ID NO.	REQUIREMENT	TEST
Leakage high *(High level of leakage)*	459	On a single circuit with valve: Alarm limit is set to a value <150 l/m With leakage circuit: Alarm limit is set to a value <60 l/m On a double circuit, 15 mm/22 mm: Alarm limit is set to a value <60 l/m On a double circuit, 10 mm: Alarm limit is set to a value ≤35 l/min	Leave inspiration tube open at patient connection. Start ventilation. Wait at least 30 seconds, more alarms may occur during this period.

LMT 68651d 12/2022

ALARM	ID NO.	REQUIREMENT	TEST
Pressure low *(Low airway pressure, low pressure on inspiration)*	457	Alarm limit is set to a value ≥6 hPa	Leave inspiration tube open at patient connection. Start ventilation.
Exhalation blocked *(Obstruction)*	757	Single circuit with valve is connected. *Alternatively* Double circuit is connected.	Connect test lung. Start ventilation. On a single circuit with valve: Seal exhalation opening of patient valve. On a double circuit: Take the expiration tube off the device inlet port and seal the connection on the tube.
Tidal volume low *(Low volume exhaled)*	450	Double circuit: Alarm limit is set.	Start ventilation. Take expiration tube off device inlet port. Wait 3 breaths.
FiO_2 low *(Oxygen concentration)*	494	FiO_2 cell is fitted and activated. Alarm limit is set. No external oxygen supply connected.	Start ventilation.
Battery capacity low	551	Device is not connected to the power supply.	Start ventilation until the internal battery has 15 minutes' life remaining before it discharges completely.
Battery capacity critical	550	Device is not connected to the power supply.	Start ventilation until the internal battery has 5 minutes' life remaining before it discharges completely.
Energy supply via internal battery	584	None	Disconnect power cord from device. Disconnect the cable for the external batteries from the device.

6.4 Servicing

The device is designed for a service life of 10 years.

If the device is used beyond this period, it needs checking by the manufacturer or by the specialist dealer.

For Germany: In accordance with §11 Medizinprodukte-Betreiberverordnung [German law governing the owners/operators of medical devices], the device must be subjected to a Technical Safety Check [Sicherheitstechnische Kontrolle (STK)] every 2 years. Country-specific requirements apply to all other countries.

The internal and the external battery must be replaced every 4 years or after 500 cycles.

The membrane of the nonreturn valve must be replaced every 4 years.

The blower must be replaced after an operating time of 35,000 h.

6.5 Disposal

Do not dispose of the product or any batteries present with domestic waste. To dispose of it 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

A distinction is made between two types of alarm: Physiological alarms relate to ventilation of the patient. Technical alarms relate to configuration of the device. The technical alarms are active and cannot be configured.

7.1 Sequence in which alarms are displayed

Alarms are divided into the three priority levels low △, medium △△, and high △△△.
If several alarms are triggered simultaneously, the highest-priority alarm is always shown first. The lower-priority alarm is retained and is displayed again once the higher-priority alarm has been rectified.

7.2 Muting alarms

FUNCTION	ACTION
Acknowledge alarm	Press alarm acknowledgement key briefly. If the alarm persists, the alarm is muted for 2 minutes. The fault continues to be displayed in the status line and the alarm acknowledgement key flashes until the fault has been rectified.
Mute all acoustic alarms for 2 minutes	Press and hold alarm acknowledgement key.
Suspend alarm muting	Press alarm acknowledgement key again briefly.

7.3 Configuring physiological alarms

All physiological alarms are deactivated on delivery or when the device is reset to factory settings. The medical professional can decide which physiological alarms are activated and make the alarm settings suitable for the patient. Various alarms can be configured depending on the ventilation mode selected.

Following a power supply outage of < 30 seconds, the set alarm settings are restored automatically.

⚠ WARNING

Risk of injury due to extreme alarm limit settings!
Alarm limits set to an extreme value may make the alarm system unusable and put the patient at risk.
⇒ Set sensible alarm limits.

⚠ WARNING

Risk of injury due to different alarm presets in different clinical spheres!
It can put the patient at risk if different alarm settings are used in different clinical spheres.
⇒ Make identical alarm settings in different spheres.
⇒ Before using the device, check whether the alarm presets are suitable for the patient.

DISPLAY	CODE	CAUSE	ACTION
Apnea △△△	458	No spontaneous breathing within set time.	Check therapy and alarm settings.
Pressure high △△△	456	Maximum pressure exceeded.	Check therapy and alarm settings.
Pressure low △△	457	Minimum therapy pressure undershot.	Clean/change dirty filters.
		Patient/ventilator interface leaking.	Re-adjust patient/ventilator interface.
		Patient/ventilator interface defective.	Replace patient/ventilator interface.
		Settings implausible.	Check therapy and alarm settings.

LMT 68651d 12/2022

DISPLAY	CODE	CAUSE	ACTION
Rate high	453	Maximum respiratory frequency exceeded.	Check therapy and alarm settings.
Rate low 	452	Minimum respiratory frequency undershot.	Check therapy and alarm settings.
Leakage high 	459	Leak	Check connection from device to patient interface at the patient via the circuit. Check that the patient/ventilator interface is in position correctly.
Minute volume high 	455	Maximum minute volume exceeded.	Check therapy and alarm settings.
Minute volume low 	454	Minimum minute volume undershot.	Check therapy and alarm settings.
Pulse high 	493	Ventilation parameter settings not suitable (upper alarm setting for patient pulse frequency exceeded).	Check therapy and alarm settings.
		Alarm settings implausible	
Pulse low 	492	Alarm settings implausible (lower alarm setting for patient’s pulse frequency undershot).	Check therapy and alarm settings.
SpO_2 high 	491	Upper alarm setting for patient's oxygen saturation exceeded.	Check therapy and alarm settings.
SpO_2 low 	490	Patient/ventilator interface faulty or defective.	Check patient/ventilator interface and replace if necessary.
		Oxygen supply faulty or inadequate.	Check therapy and alarm settings.
		Ventilation parameter settings not suitable.	
		Alarm settings implausible (lower alarm setting for patient’s oxygen saturation undershot).	

DISPLAY	CODE	CAUSE	ACTION
Tidal volume low △△△	450	Leakage in circuit.	Find and eliminate leak. If necessary: replace circuit.
		Leak in pneumatic unit (FiO_2 cell or expiration module).	Check FiO_2 cell or expiration module and fit correctly. Perform circuit test (see 4.5, p. 14).
		Patient breathing as well.	Check therapy settings.
		Filter dirty.	Clean/change filter.
		Patient/ventilator interface leaking.	Adjust headgear/headband so that the patient/ventilator interface seals.
		Patient/ventilator interface defective.	Replace patient/ventilator interface.
		Settings implausible (lower alarm setting for tidal volume undershot).	Check therapy and alarm settings.
		Minimum volume is not reached within the specified time in MPVv mode.	Check therapy and alarm settings.
Tidal volume high △△△	451	Patient breathing as well.	Check therapy settings.
Tidal volume on exp. low △△△	470	Minimum exhalation volume undershot.	Check therapy and alarm settings.
Tidal volume on exp. high △△△	471	Maximum exhalation volume exceeded.	Check therapy and alarm settings.
Minute volume on exp. low △△△	472	Minimum minute volume on exhalation undershot.	Check therapy and alarm settings.
Minute volume on exp. high △△	473	Maximum minute volume on exhalation exceeded.	Check therapy and alarm settings.
Tidal volume on insp. low △△△	474	Minimum tidal volume on inspiration undershot.	Check therapy and alarm settings.
Tidal volume on insp. high △△△	475	Maximum tidal volume on inspiration exceeded.	Check therapy and alarm settings.
Minute volume on insp. low △△△	476	Minimum minute volume on inspiration undershot.	Check therapy and alarm settings.
Minute volume on insp. high △△	477	Maximum minute volume on inspiration exceeded.	Check therapy and alarm settings.

LMT 68651d 12/2022

DISPLAY	CODE	CAUSE	ACTION
FiO_2 low 	494	Oxygen flow set too low.	Check whether the prescribed oxygen flow is set correctly at the oxygen source. Check settings.
		Leak	Find and eliminate leak.
		Oxygen supply interrupted.	Check oxygen supply and connections.
		FiO_2 cell calibrated incorrectly.	Calibrate FiO_2 cell (see 4.6, p. 14).
FiO_2 high 	495	Oxygen supply too high due to incorrectly-set oxygen flow.	Check whether the prescribed oxygen flow is set correctly at the oxygen source. Check settings.
		FiO_2 cell calibrated incorrectly.	Calibrate FiO_2 cell (see 4.6, p. 14).

7.4 Technical alarms

DISPLAY	CODE	CAUSE	ACTION
Service necessary. Please get in touch with your specialist dealer.	Various	Technical fault which can only be eliminated by a specialist dealer.	Contact your specialist dealer. Have device repaired.
Fault on touch display 	173	Touch controller has failed.	Press on/off key to restart the device.
Intake air temperature high 	262	Ambient temperature too high.	Operate device at an ambient temperature of 5 °C to 40 °C.
Main board temperature high 	263	Ambient temperature too high.	Operate device at an ambient temperature of 5 °C to 40 °C.
Computer module temperature high 	264	Ambient temperature too high.	Operate device at an ambient temperature of 5 °C to 40 °C.
Unable to reach flow 	364	Set flow not reached.	Check flow setting and accessories.
Disconnection device outlet port 	460	Circuit is not connected to the device correctly or is not connected at all.	Check circuit and the correct fit of circuit.
Disconnection airway pressure 	461	Pressure measuring tube is not connected to the device correctly or is not connected at all.	Check pressure measuring tube.
Disconnection exhalation module 	463	Exhalation module is not connected to the device correctly or is not connected at all.	Check exhalation module.

DISPLAY	CODE	CAUSE	ACTION
Disconnection patient 	464	Device operated with open patient/ventilator interface (mask not applied).	Check circuit and patient/ventilator interface.
		Double circuit selected in menu but expiration tube not connected.	
		Double circuit selected in menu but single circuit with valve or leakage circuit connected.	Have the medical professional or the specialist dealer set the connected circuit in the device.
Temperature of battery E1 critically high 	547	External battery 1 too warm.	Battery will switch off due to temperature. Operate device at an ambient temperature of 5 °C to 40 °C.
Temperature of battery E2 critically high 	548	External battery 2 too warm.	Battery will switch off due to temperature. Operate device at an ambient temperature of 5 °C to 40 °C.
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 critically high 	555	Internal battery too warm.	Battery will switch off due to temperature. Operate device at an ambient temperature of 5 °C to 40 °C.
Internal battery overheated 	556	Internal battery overheated.	Battery has switched off due to temperature. Operate device at an ambient temperature of 5 °C to 40 °C.
Unable to charge internal battery 	558	Internal battery defective.	Contact your specialist dealer. Have battery replaced.
Temperature of internal battery high 	559	Internal battery too warm.	Operate device at an ambient temperature of 5 °C to 40 °C.
Temperature of internal battery low 	560	Internal battery too cold.	Operate device at an ambient temperature of 5 °C to 40 °C.
Life of internal battery at an end 	561	Internal battery life at an end.	Contact your specialist dealer. Have battery replaced.

LMT 68651d 12/2022

DISPLAY	CODE	CAUSE	ACTION
Life of battery E1 at an end 	562	External battery 1 life at an end.	Replace battery.
Life of battery E2 at an end 	563	External battery 2 life at an end.	Replace battery.
Battery E1 overheated 	564	External battery 1 overheated.	Battery has switched off due to temperature. Operate device at an ambient temperature of 5 °C to 40 °C.
Battery E2 overheated 	565	External battery 2 overheated.	Battery has switched off due to temperature. Operate device at an ambient temperature of 5 °C to 40 °C.
Unable to charge battery E1 	566	External battery 1 defective.	Contact your specialist dealer.
Unable to charge battery E2 	567	External battery 2 defective.	Contact your specialist dealer.
Temperature of battery E1 high 	568	External battery 1 too warm.	Operate device at an ambient temperature of 5 °C to 40 °C.
Temperature of battery E2 high 	569	External battery 2 too warm.	Operate device at an ambient temperature of 5 °C to 40 °C.
Temperature of battery E1 low 	570	External battery 1 too cold.	Operate device at an ambient temperature of 5 °C to 40 °C.
Temperature of battery E2 low 	571	External battery 2 too cold.	Operate device at an ambient temperature of 5 °C to 40 °C.
Error internal battery communication 	572	Internal battery defective. Device defective.	Contact your specialist dealer.
Error battery E1 communication 	573	External battery 1 defective. Device defective.	Contact your specialist dealer.
Error battery E2 communication 	574	External battery 2 defective. Device defective.	Contact your specialist dealer.
Error battery E1 	575	External battery 1 defective.	Contact your specialist dealer.

DISPLAY	CODE	CAUSE	ACTION
Error battery E2 ⚠⚠⚠	576	External battery 2 defective.	Contact your specialist dealer.
Error internal battery temperature ⚠⚠⚠	577	Ambient temperature too high.	Operate device at an ambient temperature of 5 °C to 40 °C.
Error battery E1 temperature ⚠⚠⚠	578	Ambient temperature too high.	Operate device at an ambient temperature of 5 °C to 40 °C.
Error battery E2 temperature ⚠⚠⚠	579	Ambient temperature too high.	Operate device at an ambient temperature of 5 °C to 40 °C.
Power outage ⚠⚠⚠	580	Power supply failed.	Use alternative ventilation option.
Energy supply via internal battery ⚠	581	Power supply failed.	Check that the power cord is securely connected. Check function of socket.
		External battery and power supply not connected.	Note remaining battery life (see 3.6.3, p. 10). If necessary, connect power supply.
No exhalation valve ⚠⚠⚠	753	No exhalation system present.	Check circuit and patient interface. Connect exhalation system.
Pressure permanently low ⚠⚠⚠	755	Mask leakage too high.	Check and correct position of mask.
Tidal volume permanently low ⚠⚠⚠	756	Settings implausible.	Check therapy and alarm settings.
Exhalation blocked ⚠⚠⚠	757	Exhaled air outlet is blocked.	Check exhalation system and expiration module.
Constant pressure level ⚠⚠⚠	758	Respiratory frequency or set pressure difference too low.	Check therapy settings.
Intake area blocked ⚠⚠	759	Intake area blocked.	Keep intake area free.
Pressure measuring and valve control tubes switched ⚠⚠⚠	760	Valve control and pressure measuring tubes switched.	Check circuit for correct fit (see 4.2.3, p. 13).
		Valve control tube kinked.	Check valve control tube for blockages and damage. If necessary: Replace circuit.
Error FiO_2 cell ⚠⚠	770	FiO_2 cell faulty.	Contact healthcare professional or nurse. Have FiO_2 cell replaced.
No FiO_2 cell ⚠⚠	771	No FiO_2 cell fitted.	Contact healthcare professional or nurse. Have FiO_2 cell fitted.

LMT 68651d 12/2022

DISPLAY	CODE	CAUSE	ACTION
FiO_2 cell empty ⚠⚠	773	FiO_2 cell empty.	Contact healthcare professional or nurse. Have FiO_2 cell replaced.
Blower temperature high ⚠⚠⚠	789	Blower temperature too high. Cooling air filter blocked.	Cool device immediately or therapy will end. Check cooling air filter. If necessary: Have cooling air filter replaced by specialist dealer.
SpO_2 signal weak ⚠⚠	792	SpO_2 sensor not connected to the finger correctly.	Check connection with the finger. If alarm persists: Contact your specialist dealer.
SpO_2 signal weak ⚠⚠	790	Signal interfered with by nail varnish or contaminants.	Remove nail varnish. Clean finger.
SpO_2 sensor removed ⚠⚠	791	SpO_2 sensor removed.	Reconnect SpO_2 sensor. If the alarm persists: Replace SpO_2 sensor.
SpO_2 cable removed ⚠⚠	793	SpO_2 cable removed.	Reconnect SpO_2 cable.
Therapy ended ⚠⚠⚠	794	Device is switched off.	Switch device back on.
Faulty circuit ⚠⚠⚠	795	Single circuit with valve selected in menu but double circuit connected.	Change circuit or have the medical professional or the specialist dealer set the connected circuit in the menu.
			Have the medical professional check the settings.
		Leakage circuit selected in menu but single circuit with valve connected.	Change circuit or have the medical professional or the specialist dealer set the connected circuit in the menu.
			Have the medical professional check the settings.
			Change circuit or have the medical professional or the specialist dealer set the connected circuit in the menu.
		Circuit defective.	Check circuit and the correct fit of circuit. If necessary, replace circuit.
Re-inhalation ⚠⚠⚠	796	Valve does not open in exhalation (medication has caused it to stick, for example).	Check circuit and the correct fit of circuit. If necessary, replace circuit.
		Patient's re-inhalation volume excessive at high frequency.	
Disconnection valve control pressure ⚠⚠⚠	798	Single circuit with valve selected in menu: Valve control tube not connected correctly or not connected at all.	Check valve control tube and connect correctly.
		Single circuit with valve selected in menu but leakage circuit connected.	Change circuit or have the medical professional or the specialist dealer set the connected circuit in the menu.
Blower overheated ⚠⚠⚠	799	Blower has overheated.	Therapy will end. Allow device to cool down.

DISPLAY	CODE	CAUSE	ACTION
Maximum device pressure exceeded ⚠⚠⚠	811	Resistance on inspiration too high.	Reduce resistance and restart device. If alarm recurs: Contact your specialist dealer.
Maximum device pressure reached ⚠⚠⚠	825	Resistance on inspiration too high.	Reduce resistance and restart device. If alarm recurs: Contact your specialist dealer.
Disconnection patient ⚠⚠	465	Device operated with open patient/ventilator interface (mask not applied).	Check circuit, fit of circuit, and patient interface at the patient.
		Circuit is not connected to the device correctly or is not connected at all.	

7.5 Nurse call and remote alarm

For support in monitoring patient and device, especially in the case of life-support ventilation, the device has a remote alarm connection. All alarms are passed on to this connection.

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

In a domestic environment, you can connect the device to the VENTI*remote* alarm case via the remote alarm connection. The remote alarm case is for the remote transmission and amplification of the acoustic and visual alarms output by the device.
Please also follow the instructions for use for the remote alarm connection and the associated cables.

8 Faults

FAULT	CAUSE	ACTION
No running noise, no display on screen.	No power supply present.	Check that the power cord is securely connected. Check function of socket.
Device does not reach set target pressure.	Coarse dust filter soiled.	Clean coarse dust filter. If necessary: Replace filter (see 6, p. 18).
	Breathing mask leaking.	Adjust headband so that the mask does not leak (see instructions for use for the mask). If necessary: Replace defective mask or patient/ventilator interface.
	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 is switched off.	Switch on device (see 4.4, p. 14).
Device does not respond to display inputs.	Electronics in device have failed.	To restart the device, hold down the on/off key ⏻ for 30 s.

LMT 68651d 12/2022

9 Technical specifications

9.1 Physical specifications and classifications

Dimensions (W x H x D)	30 cm x 13 cm x 21 cm
Weight	3.8 kg
Diameter of inspiration tube connection to ISO 5356-1	Standard 22 mm tapered connector
Application part	Patient interface (e.g. breathing mask, endotracheal tube, tracheal cannula), circuit, breathing system filter, SpO_2 sensor
Materials - Housing - Fine filter - Coarse dust filter - Circuit	 Fire-retardant technical thermoplastics and silicones, stainless steel Polypropylene Polyurethane Polyethylene All parts of the devices are free from latex.
Maximum air flow at 20 hPa	> 220 l/min
Product class to 93/42/EEC	IIb
Classification to IEC 60601-1-11	Class of protection against electric shock: Class II Degree of protection against electric shock: Type BF
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
Expected service life	10 years
Servicing interval - Internal and external battery - Membrane of the nonreturn valve - Blower	 4 years or 500 cycles 4 years 35,000 h running time

9.2 Ambient conditions

Temperature range - Operation - Transport and storage - Transport and storage at +70 °C - Transport and storage at -25 °C	 +5 °C to +40 °C -25 °C to +70 °C Allow to cool to room temperature for 4 hours before starting up. Allow to heat to room temperature for 4 hours before starting up.
Humidity - Operation, transport and storage	 Relative humidity 10% to 90%, no condensation > 35 °C to 70 °C at a water vapor pressure up to 50 hPa
Air pressure range	700 hPa to 1100 hPa, corresponds to an altitude of 3000 m above mean sea level

9.3 Noise

Mean sound pressure level/operation to ISO 80601-2-72 at ≥ 500 ml at ≥ 150 ml at ≥ 30 ml Accuracy	 38.5 dB(A) 37 dB(A) 41 dB(A) ± 3 dB(A)
Sound power level/operation to ISO 80601-2-72 at ≥ 500 ml at ≥ 150 ml at ≥ 30 ml Accuracy	 46.5 dB(A) 45 dB(A) 49 dB(A) ± 3 dB(A)
Sound pressure level of acoustic alarm to IEC 60601-1-8 for all alarm conditions	Level 1 low priority: 68 dB(A) medium priority: 68 dB(A) high priority: 68 dB(A) Accuracy: ± 3 dB(A) Level 4 low priority: 90 dB(A) medium priority: 90 dB(A) high priority: 90 dB(A) Accuracy: ± 5 dB(A)

9.4 Electric and electronic interfaces

Maximum electrical power consumption of the device	48 V DC / 2.7 A 24 V DC / 5.4 A 12 V DC / 7.0 A
Power supply unit Input voltage/maximum current Input frequency Output voltage/maximum current	 100-240 V AC / 2.1 A; tolerance: -20% + 10% 50-60 Hz 48 V DC / 2.7 A
System interface Direct current	3 V DC / 0.2 A When the prisma HUB device is connected: 24 V DC / 0.2 A
USB-C interface Maximum power output No power input	 5 V / 1.1 A
Power consumption on standby without battery charging, screen brightness 90% Nurse call	 230 V AC / 0.07 A 48 V DC / 0.30 A 24 V DC / 0.61 A 12 V DC / 1.21 A maximum 60 V DC / 1 A
Power consumption during ventilation without battery charging, screen brightness 90% with the following ventilation settings: - Mode: T - Configuration: Adult - Leakage circuit 15 mm - Additional accessories: Breathing system filter, WilaSilent exhalation system - IPAP=40 hPa, EPAP=4 hPa, F=26.5 /min, Ti=1.1 s - Pressure rise: Level 1, pressure drop: Level 1 - Test lung	 230 V AC / 0.18 A 48 V DC / 0.81 A 24 V DC / 1.61 A 12 V DC / 2.86 A

LMT 68651d 12/2022

Internal / external battery - Type - Nominal capacity - Nominal voltage - Energy - Typical discharge cycles	 Li-ion 3200 mAh 29.3 V 93.7 Wh 500 charging cycles Battery capacity is reduced when the device is operated at low temperatures.
Operating hours of internal battery assuming following settings: - Double circuit - Mode: PCV, f=20 min, Ti =1 s, PEEP=off, Vt=800 ml - Passive lung: Resistance R= 5 hPa /(l/s); compliance C = 50 ml/hPa	≥ 6 hours
Duration of complete battery charge Duration of 80% battery charge	< 6 hours < 5 hours

9.5 Ventilation

Respiratory rate - Adult - Pediatric - Accuracy	 2 - 60 bpm in 0.5 bpm increments 5 - 80 bpm in 0.5 bpm increments ± 0.5 bpm
Tidal volume (VT) Step width target volume Accuracy	30 ml to 400 ml (pediatric) 100 ml to 3000 ml (adult) 5 ml (from 30 ml - 100 ml) (pediatric) 10 ml (from 100 ml - 3000 ml) (adult) Most disadvantageous circuit LMT 31383 < 50 ml: ± (4 ml + 20% of current value) Most disadvantageous circuit LMT 31382 ≥ 50 ml: ± (4 ml +15% of current value)
Respiratory volume per minute (averaged over previous 5 breaths)	0.1 l/min to 40 l/min
Insp.-exp. ratio (I:E)	1:59 to 2:1
IPAP Accuracy	4 hPa - 50 hPa (most disadvantageous circuit for leakage circuit: circuit WM 29988, breathing system filter WM 27591) 4 hPa - 60 hPa (most disadvantageous circuit for valve ventilation: circuit LMT 31383, breathing system filter WM 27591) ± (2 hPa + 4% of the set value) / ± (2 cm H_2O + 4% of the set value)
EPAP Accuracy	4 hPa - 25 hPa (most disadvantageous circuit for leakage circuit: breathing tube WM 29988, breathing system filter WM 27591) ± (2 hPa + 4% of the set value) / ± (2 cm H_2O + 4% of the set value)
PEEP Accuracy	0 hPa - 25 hPA (most disadvantageous circuit for valve ventilation: circuit LMT 31383, breathing system filter WM 27591) ± (2 hPa + 4% of the set value) / ± (2 cm H_2O + 4% of the set value)
CPAP Accuracy	4 hPa - 20 hPa (most disadvantageous circuit for leakage circuit: circuit WM 29988, breathing system filter WM 27591) ± (2 hPa + 4% of the set value) / ± (2 cm H_2O + 4% of the set value)
Pressure increment	0.2 hPa

Maximum pressure in the event of a fault	≤ 90 hPa
Inspiration time (Ti min, Ti max, Ti timed) Accuracy	0.2 s - 0.8 s (pediatric) in 0.05 s increments 0.5 s - 4 s (adult) in 0.1 s increments auto (Ti timed only) 0.05 s
Speed of pressure rise - Adult - Pediatric - MPV mode	 Level 1=100 hPa/s; level 2=80 hPa/s; level 3=50 hPa/s; level 4=20 hPa/s Level 1=135 hPa/s; level 2=100 hPa/s; level 3=80 hPa/s; level 4=50 hPa/s Level 1=60 hPa/s; level 2=45 hPa/s; level 3=30 hPa/s; level 4=15 hPa/s
Speed of pressure drop (in leakage circuit only) - Adult - Pediatric	 Level 1=-100 hPa/s; level 2=-80 hPa/s; level 3=-50 hPa/s; level 4=-20 hPa/s Level 1=-135 hPa/s; level 2=-100 hPa/s; level 3=-80 hPa/s; level 4=-50 hPa/s
Trigger - Inspiration - Exhalation	 1 (high sensitivity) to 10 (low sensitivity) (step 1) 95% to 5% of maximum flow in 5% increments
Trigger device	The trigger on inspiration is triggered when patient flow exceeds the trigger threshold. The trigger on exhalation is triggered when patient flow on inspiration drops to the percentage value of maximum patient flow on inspiration.
Oxygen supply - Permitted flow - Permitted pressure	 ≤ 30 l/min ≤ 1000 hPa

9.6 Accessories

Fine filter - Classification - Particle up to 1 µm - Particle up to 0.3 µm - Service life	 Filter class E10 Degree of separation ≥ 99.5% Degree of separation ≥ 85% approx. 250 h
Breathing system filter	Dead space: 26 ml
USB flash drive	USB-C 3.0
Heating of respiratory air	Maximum +3 °C
Modem - Frequency band - Wireless standard	 2.412 GHz to 2.4835 GHz ETSI EN 300 328

9.7 Accuracy of used measuring devices

Pressure:	± 0.75 % of measured value or ± 0.1 hPa
Flow:	± 2 % of actual value
Volume	± 3 % of actual value
Temperature:	± 0.3 °C
Time	± 0.05 Hz/± 0.001 bpm

All physiological flow and volume values are displayed in BTPS (patient flow, target volume, breath volume, minute volume). All other flow and volume values are displayed in STPD.

The right to make design modifications is reserved.

All parts of the device are free from latex.

LMT 68651d 12/2022

Standard 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.

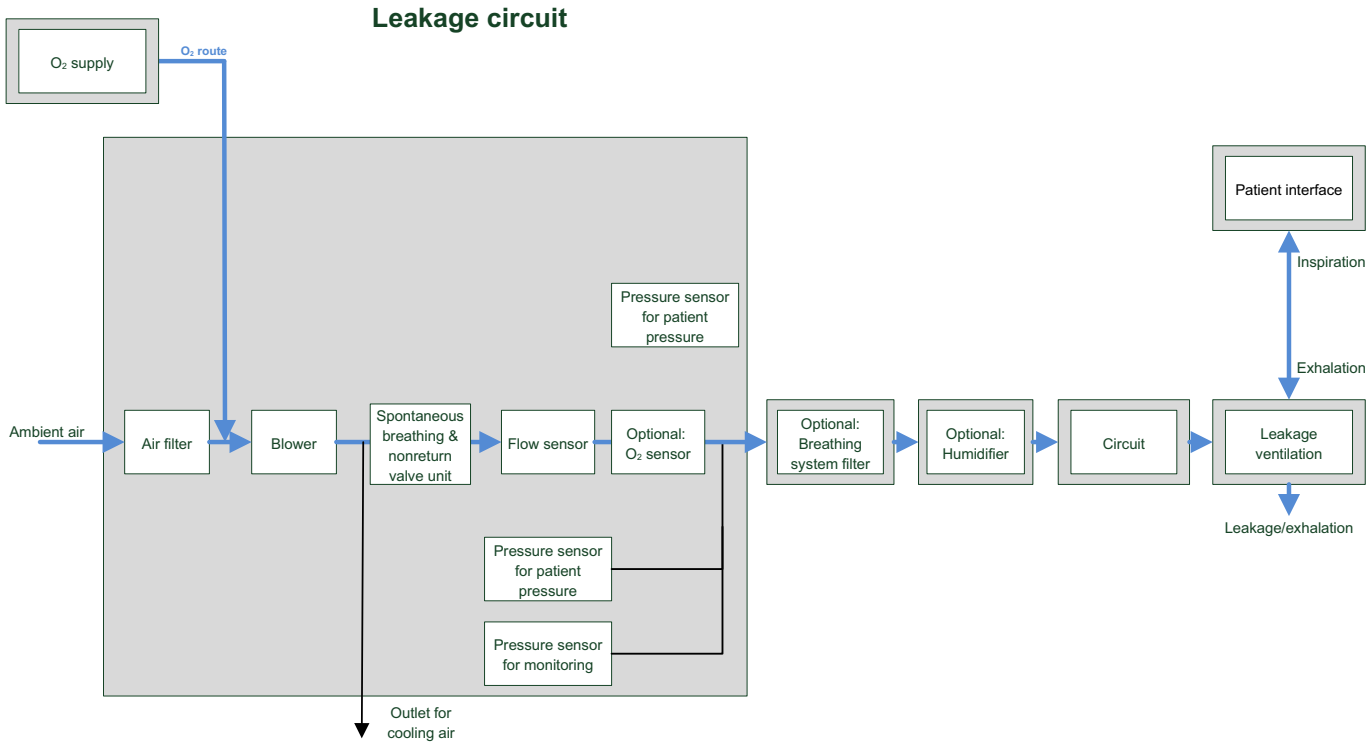
Devices of type LM150TD use the following open-source software: Linux Kernel 4.19.132, Buildroot 2020.02.3

The software of this device contains code which is subject to the GPL. You can obtain the source code and the GPL on request.

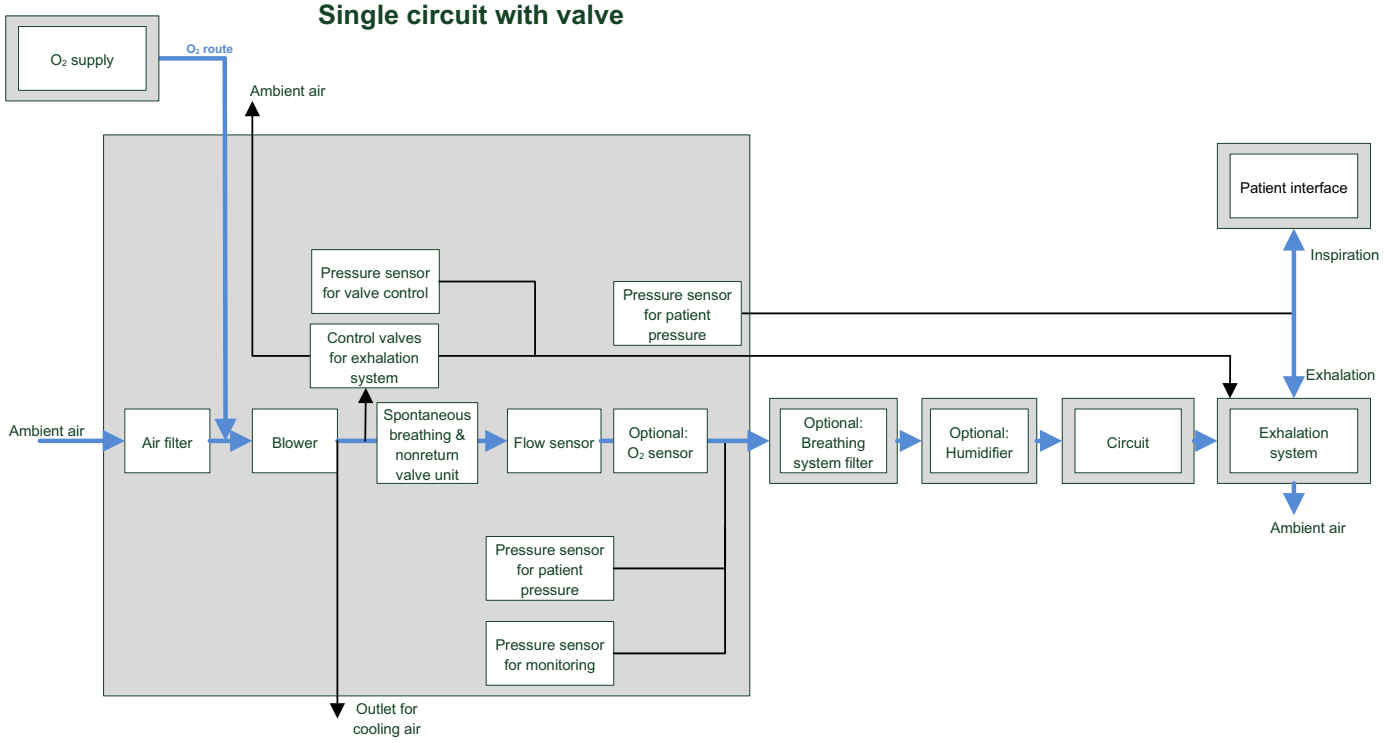
10 Annex

10.1 Pneumatic diagram

10.1.1 Leakage circuit

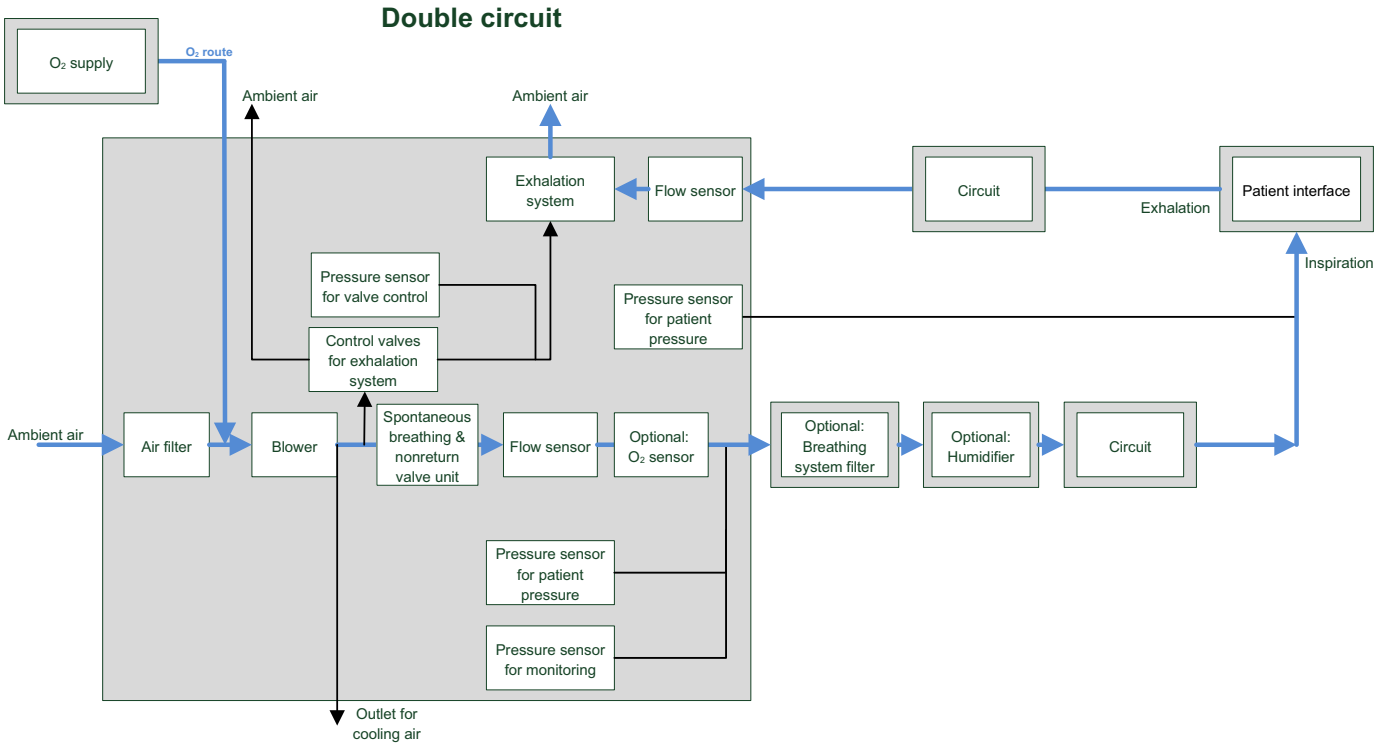


10.1.2 Single circuit with valve



LMT 68651d 12/2022

10.1.3 Double circuit



10.2 System resistances

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 connection may not exceed the following value:

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

Circuits with a **diameter of 10 mm** (intended for volumes delivered of ≤ 50 ml): **Pressure drop ≤ 3.2 hPa at a flow = 2.5 l/min (BTPS)**.

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

Maximum error in pressure measurement: 0.0125 hPa

ARTICLE NUMBER	ARTICLE NAME	FLOW (BTPS) IN L/MIN	PRESSURE DROP IN HPA
LMT 31382	LUISA, single circuit with valve, 180 cm, 22 mm Ø	30	0.11
LMT 31383	LUISA, single circuit with valve, 150 cm, 15 mm Ø	30	0.46
LMT 31384	LUISA, single circuit with valve, heated (i), autofill chamber, 150 cm + 60 cm, 15 mm Ø	30	2.04
WM 271704	LUISA, leakage circuit, heated (i), autofill chamber, passive valve, 150 cm + 60 cm, 15 mm Ø	30	2.03
WM 271705	LUISA, leakage circuit, heated (i), autofill chamber, passive valve, 150 cm + 60 cm, 22 mm Ø	30	0.31
LMT 31577	LUISA, double circuit, 150 cm, 15 mm Ø	30	Inspiration tube: 0.76 Inspiration tube from patient to device: 0.92 Exhalation tube: 0.69
LMT 31581	LUISA, double circuit, 180 cm, 22 mm Ø	30	Inspiration tube: 0.17 Inspiration tube from patient to device: 0.24 Exhalation tube: 0.17

ARTICLE NUMBER	ARTICLE NAME	FLOW (BTPS) IN L/MIN	PRESSURE DROP IN HPA
LMT 31582	LUISA, double circuit, heated (i+e), A-shaped adapter, autofill chamber, 150 cm + 60 cm, 15 mm Ø	30	Inspiration tube: 2.03 Inspiration tube from patient to device: 2.05 Exhalation tube: 2.06
LMT 31383	LUISA, double circuit, heated (i+e), A-shaped adapter, autofill chamber, 150 cm + 60 cm, 22 mm Ø	30	Inspiration tube: 0.22 Inspiration tube from patient to device: 0.32 Exhalation tube: 0.37
LMT 31386	LUISA, double circuit, heated (i+e), A-shaped adapter, autofill chamber, 120 cm + 60 cm, 10 mm Ø		Inspiration tube: 0.17 Inspiration tube from patient to device: 0.16 Exhalation tube: 0.09
WM 27591	Teleflex Iso-Gard bacteria filter	2.5	0.06

10.3 Emission of electromagnetic interference

MEASUREMENTS OF INTERFERENCE EMISSION	COMPLIANCE
HF emissions to CISPR 11	Group 1/Class B
Harmonic distortion	Class A
Voltage fluctuations and flicker	Complies

10.4 Electromagnetic interference immunity

INTERFERENCE IMMUNITY TESTS	COMPLIANCE LEVEL
Discharge of static electricity (ESD) to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge
Radiated HF interference to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz
Test specifications for the interference immunity of sheathing to high-frequency wireless communication equipment IEC 61000-4-3	Table 9 of EN 60601-1-2:2014
Electrical fast transients/bursts to IEC 61000-4-4	± 2 kV for power supply cables ± 1 kV for input and output lines
Surge immunity to IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground
Conducted HF interference to IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz 6 Vrms in ISM frequency bands between 150 kHz and 80 MHz
Magnetic field at the power supply frequency (50/60 Hz) to IEC 61000-4-8	30 A/m
Voltage dips/short interruptions and variations in power supply to IEC 61000-4-11	0 % UT; 250/300 periods

Key performance characteristics of the device as per ISO 80601-2-72

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

10.5 Markings and symbols

The following symbols may be applied to the device, the device ID plate, accessories or packaging.

LMT 68651d 12/2022

SYMBOL	DESCRIPTION
	Pressure measuring tube connection
	Valve control tube connection
	Patient's exhaled air outlet on double circuit; do not block outlet
	Inlet; do not block openings
	Outlet
	Follow instructions for use
	Direct current: 12 V, 24 V or 48 V
TYPE:	Type designation of the device
	Order number
	Suitable for use in aircraft. Meets RTCA/ DO-160G Section 21, Category M.
	Unique device identifier (uniform product code for medical devices)
	Serial number
	Degree of protection against electric shock: Protection class II product
	Do not dispose of the product in domestic waste
	Follow the instructions for use
IP22	Degree of protection against contact with a finger. Protection against vertically falling water drops when enclosure tilted up to 15°.
	Type BF applied part

SYMBOL	DESCRIPTION
	Manufacturer and, if necessary, date of manufacture
	Indicates the product is a medical device
	Permitted temperature range for transport and storage
	Permitted humidity range for transport and storage
	Protect from moisture
	Fragile. Do not throw or drop
	CE symbol (confirms that the product conforms to the applicable European directives and regulations)
	Use multiple times on a single patient

10.6 Scope of delivery

10.6.1 Scope of delivery for LMT 31380-1110 LUISA with HFT mode

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

PART	ARTICLE NUMBER
Basic device with HFT mode	LMT 31410
Exhalation module (disposable)	LMT 31425
Single circuit with valve, 22 mm Ø	LMT 31382
Power supply unit	LMT 31569
Power cord	WM 24177
Oxygen connecting bushing	WM 30669
Set, 12 fine filters	WM 29652
Set, 2 coarse dust filters	WM 29928
Protective bag	LMT 31010
Bag pendant	LMT 31408
USB flash drive	LMT 31414
Instructions for use	LMT 68651
Patient record	1P-10088de2002
LM patient information	WM 28209

PART	ARTICLE NUMBER
Set, documents in accordance with Medizinprodukte-Betreiberverordnung [German law governing the owners/ operators of medical devices]: Medical devices manual, handover log	WM 15100
Final inspection log	LMT 31588
Accessories bag	LMT 31440

10.6.2 Scope of delivery for LMT 31390-1110 LUISA with HFT mode

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

PART	ARTICLE NUMBER
Basic device with HFT mode	LMT 31410
Exhalation module (disposable)	LMT 31425
Single circuit with valve, 22 mm Ø	LMT 31382
Power supply unit	LMT 31569
Power cord	WM 24177
Oxygen connecting bushing	WM 30669
Set, 12 fine filters	WM 29652
Set, 2 coarse dust filters	WM 29928
Protective bag	LMT 31010
Bag pendant	LMT 31408
USB flash drive	LMT 31414
Instructions for use	LMT 68651
Final inspection log	LMT 31588
Accessories bag	LMT 31440

10.7 Accessories

PART	ARTICLE NUMBER
Teleflex Iso-Gard breathing system filter	WM 27591
Oxygen sensor, complete	LMT 31502
Wilasilent Exhalation system	WM 27589
Silentflow 3 Exhalation system	WM 25500
Single circuit with valve, 15 mm Ø	LMT 31383
Single circuit with valve, 22 mm Ø	LMT 31382
Double circuit, 15 mm Ø	LMT 31577
Double circuit, 22 mm Ø	LMT 31581
Leakage circuit, 15 mm Ø	WM 29988
Leakage circuit, 22 mm Ø	WM 23962
Leakage circuit, autoclavable, 22 mm Ø	WM 24667
Leakage circuit, mouthpiece ventilation 15 mm Ø	WM 27651
Mobility bag	LMT 31554

PART	ARTICLE NUMBER
LUISA hospital trolley, consisting of: - Trolley 2.0 (LMT 31355) -Set, LUISA plate for trolley 2.0 (LMT 31371) -Power supply unit clamp (LMT 31351) -Water bag holder (LMT 31353) -Oxygen cylinder clamp (LMT 31352) -Hinged arm (LMT 31354)	LMT 31370
LUISA Homecare trolley, consisting of: -Trolley 2.0 (LMT 31355) -Set, LUISA plate for trolley 2.0 (LMT 31371) -Power supply unit clamp (LMT 31351)	LMT 31360
Power supply unit clamp for trolley 2.0	LMT 31351
Water bag holder for trolley 2.0	LMT 31353
Oxygen cylinder clamp for trolley 2.0	LMT 31352
Hinged arm for trolley	LMT 31354
Set, LUISA mounting plate	LMT 31359
Set, LUISA plate for trolley 2.0	LMT 31371
Wall bracket for standard rail	LMT 31368
Exhalation module (disposable)	LMT 31404
Exhalation module (autoclavable)	LMT 31413
Spare internal battery for LUISA	LMT 31550
External battery	LMT 31540
Battery charger	LMT 31594
VENTI*remote* alarm, 10 m	LMT 31560
VENTI*remote* alarm, 30 m	LMT 31570
Cable, 10 m, nurse call for LUISA	LMT 31510
Cable, 30 m, nurse call for LUISA	LMT 31520
CD-ROM with prismaTS software	WM 93331
USB flash drive	LMT 31414
COM cable for monitor	LMT 31578
Set, 90° tube adapter	LMT 15984
Cable, 12 V/24 V, vehicle/FCC	LMT 31597
SpO_2 sensor, size S	LMT 31580
SpO_2 sensor, size M	LMT 31396
SpO_2 sensor, size L	LMT 31388
Cable, SpO_2/Xpod sensor	LMT 31593

10.8 Removable parts

PART	ARTICLE NUMBER
Filter holder	LMT 31422
Exhalation module cover	LMT 31481
Exhalation module (disposable)	LMT 31425
Set, exhalation module (can be subjected to hygiene treatment)	LMT 15961
Exhalation module orifice	LMT 31574

LMT 68651d 12/2022

10.9 Warranty

Löwenstein Medical Technology gives the purchaser of a new original 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.

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

PRODUCT	WARRANTY PERIODS
Devices including accessories (Exception: Masks)	2 years
Masks including accessories, batteries (unless quoted differently in the technical documentation), sensors, circuits	6 months
Disposable products	None

10.10 Declaration of Conformity

Löwenstein Medical Technology GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany, the manufacturer, hereby declares that the product complies with the relevant regulations of the Medical Device Directive 93/42/EEC. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

LMT 68651d 12/2022 EN

CE 0197

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

LMT 68651d

LÖWENSTEIN
medical