LÖWENSTEIN
medical

Respiratory humidifier

User manual

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User manual LM 2000
Order no.: gba10450en2012

CE 0197

Supplementary instructions

About this instruction manual

This instruction manual was created for the respiratory humidifier LM 2000. Hereinafter the product is also referred to as “device”.

This instruction manual allows you to use the device safely and efficiently. The instruction manual is a component of the device and must be kept in close proximity to the device and be accessible to staff at all times.

Persons using the device must have carefully read and understood this instruction manual before commencing any work. The observance of all safety notes and instructions contained in this manual is a basic requirement for safe working.

Moreover, special provisions for using medical equipment at the location apply.

The illustrations in this manual are intended for the basic understanding and may differ from the actual design.

Customer service

Please contact our customer service with the following contact details:

Contact type	Contact details
Postal address	Löwenstein Medical SE & Co. KG Arzbacher Straße 80 56130 Bad Ems, Germany
	+49 2603 9600-0
	+49 2603 9600-50
	loewensteinmedical.com

Further information

If you have any questions or remarks regarding this instruction manual or the device, please contact your authorised regional specialist vendor or the manufacturer directly.

Copyright

Table of Contents

1. List of abbreviations

Table 1: Abbreviations and Terms

Abbreviation, Term	Description
Control temperature	The temperature at which the humidifier attempts to maintain the measured gas temperature.
Heated or unheated tube	Non-rigid ventilation tube with or without internal heating element, used to transport gases and/or vapours between the components of a ventilation system.
Heating cable	Cable that supplies power to the internal heating cables of the heated ventilation tube.
Heating plate	LM 2000 element for supplying the water chamber with thermal energy.
Mains cable	Cable connecting the humidifier with a power source.
Stand-by	The device’s operating mode at reduced performance
Temperature sensor	Sensor for measuring temperature.
Temperature sensor cable	Cable on which two temperature sensors are installed to monitor the temperature at the outlet of the water chamber and near the patient.
Ventilation system	All ventilation tubes, connectors and components which form the exhalation and inhalation tubes of the gas path between the ventilator and the patient.
Water chamber	Component of the humidifier in which evaporation or nebulisation takes place.

2. Safety

Symbol definition

Warnings

CAUTION

CAUTION indicates a latent hazard that does not represent a direct threat but can lead to physical injury if not avoided.

WARNING

WARNING indicates a hazard that represents a direct threat and can lead to severe injury or death if not avoided.

Other symbols in this instruction manual

To indicate instructions for action, result descriptions, lists, references and other items the following symbols and highlighting are used in this instruction manual:

1. Indicates step-by-step instructions for action.

(1) Indicates positions within illustrations.

▪ Indicates lists without a defined order.

– Indicates list entries without a defined order.

(see reference target on page) indicates references to chapters or specific contents in this manual.

This symbol highlights hints and recommendations as well as information for efficient and failure-free operation.

Medical purpose

Indication

The LM 2000 is a humidifier that adds water in the form of steam to the inspiratory gas of newborn, paediatric and adult patients.

The LM 2000 is a Category 1 humidifier, i.e. it is intended for use in patients with diverted (invasive ventilation) and non-diverted (non-invasive ventilation) airways. The LM 2000 is intended for use in hospital or healthcare facilities as well as at home.

Residual hazards

Patient transport

Do **not** use the humidifier when transporting patients, as water can escape from the chamber into the ventilation tube. Undulating and jerky movements, as well as the ventilator’s airflow, can cause this water to enter the patient's airways.

Temperature

Clinical operators or medical staff decide on the temperature to be set on the humidifier on their own responsibility.

Formation of condensation

Correctly set regulation temperatures of the humidifier/heated hose reduce the formation of condensate. Check several times daily that no condensation forms inside the ventilation system. The formation of condensate can cause an increased in flow resistance, influence the measurement of ventilation parameters and trigger an alarm from the ventilator. Excessive humidification can increase the viscosity of secretions and lead to the formation of condensation droplets that can enter the patient’s respiratory tract, causing infections. Excess condensation can enter the patient’s respiratory tract and cause injuries. Always remove excess water from the system and inspiration line.

Position

Using a special mounting accessory, position the humidifier horizontally on a solid surface or on a stand, ensuring that the humidifier is at a lower level than the patient and is not tilted.

Accessories

The LM 2000 may only be used with ventilation tubes and accessories from Löwenstein Medical, which have been specially developed for the correct operation of the device. The use of ventilation tubes and accessories not approved by Löwenstein Medical may impair performance or safety.

Ensure that the ventilator is compatible with the tubes used.

Medication

Do **not** use the LM 2000 to administer medication.

Ambient conditions

Löwenstein Medical does not guarantee correct operation if the humidifier is installed and/or used under ambient conditions other than those specified.

Ambient or inlet gas conditions at the limit of the recommended temperature range may limit performance.

- The LM 2000 must not be used in oxygen-saturated environments or with high concentrations of this gas (e.g. in hyperbaric chambers).
- Do not use the humidifier near flammable gases.
- Using the device at altitudes above 6,000 feet (2,000 meters) may affect its performance.

Electromagnetic compatibility

The LM 2000 meets the electromagnetic compatibility requirements according to EN 60601-1-2:2015. The device has not been tested or certified for use near X-ray, CT or MRI equipment. Keep the humidifier away from such equipment to prevent impaired performance.

The LM 2000 must not be placed and used in environments intended for magnetic resonance imaging, and never in environments with high electromagnetic fields.

The operation of high-frequency, short-wave or microwave surgical equipment in the vicinity of the humidifier may affect its operation. In this case, the humidifier near such devices must be removed.

Transport and storage temperature

Löwenstein Medical does not guarantee the correct operation of the LM 2000 if transported and stored outside the recommended temperature range of +10 °C to +50 °C.

Installation

- Initial installation must be performed by authorised/certified personnel.
- During installation, carry out a visual inspection to check that the humidifier, the temperature sensor cable and the heating cable are undamaged.

Do not cover or place in an unfavourable position

- For correct and safe operation of the humidifier, ensure that the ventilation slots on the underside and rear of the humidifier are free of blockages. Do not cover the LM 2000 with bed linen or other cloth during operation to prevent the humidifier from overheating.
- Install the humidifier in a location protected from draughts.
- Ensure that the humidifier is always at a lower level than the patient to prevent any condensation water from running off to the patient.
- Place the humidifier on a firm, stable, horizontal surface to avoid spilling liquid from the water chamber.

Temperature sensor

- The humidifier can only be operated with the temperature sensor cable correctly plugged in. This humidifier does not permit humidifying processes without using the sensors on the temperature sensor cable.
- Perform a visual inspection to check the mechanical integrity of the sensors. Damaged sensors can lead to humidifier malfunction.
- Check that the temperature sensors are fully inserted into the corresponding sockets on the ventilation tubes so that the tip of the sensors is in the middle of the tube. Incomplete insertion or accidental disconnection of at least one of the two temperature sensors during use could affect the correct operation of the humidifier and/or trigger repeated alarms.
- Position the temperature sensor near the patient on the outside of the incubator or outside the effective range of the radiation plate. Positioning this sensor inside the incubator or within the effective range of the radiation plate will affect the correct operation of the humidifier.

Connections and cables

- Make sure that the power source characteristics are compatible with the label of the humidifier.
- Pay attention to the positioning of the cables and ventilation tubes. If they are placed around the patient's head, they can cause strangulation.
- Always disconnect the plugs of the temperature sensor cable and the heating cable by pulling on the plug and not on the cable so as not to damage them.
- The plugs of the heating and temperature sensor cables are provided with guide arrows, such as the corresponding sockets on the side of the humidifier in order to insert them correctly. Unaligned, forced insertion can cause the sockets to break.
- The temperature sensor and heating cables must not be forcefully inserted in any way.

Start-up

- Do not switch on the humidifier before you start ventilation.
- When switched on, the humidifier automatically recognises the electrical configuration of the ventilation tubes with which it is equipped (heated inspiration and expiration tubes or heated inspiration tubes only).

Behaviour in the event of faults

- If liquid is spilt, do not touch the humidifier with your hands, but immediately disconnect the mains voltage via a main switch (if present) or by pulling out the mains plug (only after you have ensured that the liquid has not entered the humidifier).

Operation

- For inhalation, only use USP-grade sterile water or an equivalent product.
- Disconnecting the expiration tube's heating cable plug during a procedure started with both heated tubes can lead to condensation in this expiration tube.
- Do not touch the heating plate or the base of the chamber. Exposed surfaces of the metal may be hot and cause burns on contact.
- Always maintain a gas flow of at least one litre per minute in the respiratory system to prevent overheating. If ventilation is interrupted, the humidifier must be switched off.
- When air-oxygen mixtures are introduced into the heated tubes and humidification chamber installed in combination with the LM 2000, the concentration of the mixture must be measured near the patient interface.

Cleaning and maintenance

- Before cleaning and disinfecting, it is imperative that you shut down the device and disconnect it from the mains.

  (→ "Cleaning, disinfection and / or sterilisation" p. 50)
- The device may only be repaired and serviced by authorised personnel. Only components expressly approved by Löwenstein Medical for use with the device may be used.

Disposal

- After decommissioning, the device must be disposed of properly in accordance with EU Directive 2012/19/EU. Contact the responsible Löwenstein Medical sales partner.

Electromagnetic emissions and electromagnetic compatibility

Guidelines and manufacturer's declaration – Electromagnetic emissions

The LM 2000 system is suitable for operation in the electromagnetic environment specified below. Customers or users of the LM 2000 system must ensure its use in such a suitable environment.

Table 2: Guidelines and manufacturer's declaration – Electromagnetic emissions

Interference emissions test	**Conformity**	**Guidelines on the electromagnetic environment**
High-frequency interference emission test CISPR11	Group 1	The LM 2000 system uses high-frequency energy only for internal functions. It therefore emits very little high-frequency interference and is unlikely to interfere with nearby electronic equipment.
High-frequency interference emission test CISPR11	Class B	The LM 2000 system is suitable for use in all facilities, including private households and in facilities directly connected to the public low-voltage network for supplying private households.
Harmonic waves IEC 61000−3−2	Class A	
Voltage variations/flickers IEC 61000−3−3	full conformity	

Guidelines and manufacturer's declaration – Electromagnetic immunity

The LM 2000 system is suitable for operation in the electromagnetic environment specified below. Customers or users of the LM 2000 system must ensure its use in such a suitable environment.

Table 3: Guidelines and manufacturer's declaration – Electromagnetic immunity

Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Discharge of static electricity in accordance with EIEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should consist of wood or concrete or be covered in ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must amount to at least 30%.
Quick transient electrical interference / bursts in accordance with IEC 61000-4-4	± 2 kV for mains ± 1 kV for inlet and outlet lines	± 2 kV for mains (No signal lines available)	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges in accordance with IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV asymmetric disturbance	± 1 kV push-pull voltage ± 2 kV asymmetric disturbance	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations in the supply voltage in accordance with IEC 61000-4-11	< 5% U_T for ½ period (> 95% dip) 40% U_T for 5 periods (60% dip) 70% U_T for 25 periods (30% dip) < 5% U_T for 5 s (> 95% dip)	< 5% U_T for ½ period (> 95% dip) 40% U_T for 5 periods (60% dip) 70% U_T for 25 periods (30% dip) < 5% U_T for 5 s (> 95% dip)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the device is to be operated independently of the main power supply, we recommend that the LM 2000 system be powered by an uninterruptible power supply (UPS) or battery.
Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in the mains frequency must correspond to the typical values as found in a business or hospital environment.

Electromagnetic environment – Guidelines

The LM 2000 system is suitable for operation in the electromagnetic environment specified below. Customers or users of the LM 2000 system must ensure its use in such a suitable environment.

Table 4: Guidelines and manufacturer's declaration – Electromagnetic immunity

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - Guidance
Conducted HF-interference in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz – 80 MHz	3 V_{eff}	When using portable and mobile HF-communications equipment, all parts of the LM 2000 system (including cables) must be kept at least at the recommended distance calculated using the equation for the transmitter frequency. Recommended protective distances: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$, 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$, 800 MHz to 2.5 GHz
Radiated HF-interference in accordance with IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz	3 V/m	

P = rated power of the transmitter in watts [W] in accordance with the instructions of the transmitter manufacturer.
d = recommended protective distance in metres [m].

At all frequencies, the field strength of stationary radio transmitters should be lower than the compliance level in accordance with an on-site* examination**.

 Interference is possible in the environment of devices that bear the adjacent icon.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2: These guidelines may not be applicable in all cases. The distribution of electromagnetic variables is influenced by absorption and reflections from buildings, objects and human beings.

* The field strengths of stationary transmitters, such as the basic stations of radio telephones and mobile landline devices, amateur radio stations, AM and FM radio broadcasting and television transmitters can theoretically not be accurately predetermined. To determine the electromagnetic environment with regard to stationary transmitters, a study of the site should be considered. If the measured field strength at the location where LM 2000 system is used exceeds the above compliance level, the LM 2000 system should be observed in order to prove its proper function. If unusual performance characteristics are observed, additional measures may be necessary, e.g. modification or relocation of the LM 2000 system.

** Over a frequency range of 150 kHz to 80 MHz, the field strengths must be lower than 3V/m

Recommended safety distances between portable, mobile and fixed HF telecommunication equipment and the LM 2000

The LM 2000 system is is intended for operation in an electromagnetic environment in which radiated HF interference is controlled. The customer or user of the LM 2000 system can help to prevent electromagnetic interference by observing the minimum distances between portable and mobile HF communications equipment (transmitters) and the LM 2000 system, as recommended below in accordance with the maximum output performance of the communications equipment.

Table 5: Protective distance depending on the transmitter frequency

Rated power of the transmitter [W]	**Protective distance depending on the transmitter frequency [m]**		
	150 kHz − 80 MHz d = 1.2 √P	80 MHz − 800 MHz d = 1.2 √P	800 MHz − 2.5 GHz d = 2.3 √P
0.01	0.02	0.03	0.06
0.1	0.06	0.09	0.19
1	0.18	0.3	0.6
10	0.57	0.5	1.9
100	1.8	3.0	6.0

For transmitters whose power rating in the above table is not given, the distance can be determined in metres using the equivalence, which belongs to each column, whereby P is the power rating in watts [W] in accordance with the instructions of the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher value applies.

NOTE 2: These guidelines may not be applicable in every situation. The distribution of electromagnetic waves is influenced by absorption and reflections from buildings, objects and human beings.

Personnel qualifications

Users

This manual is intended for the following operators: senior clinical operators or healthcare professionals and non-professional operators. Before using the humidifier, the operating personnel must be trained accordingly and have read and understood the contents of the entire manual.

The device may only be operated by persons who, due to their training or their knowledge and practical experience, can guarantee proper handling and who are aware of the risks and advantages of the device used.

Medical personnel

This device should only be used by senior clinical operators or healthcare professionals and laypersons under the supervision of qualified medical personnel who have received appropriate training and have read and understood the contents of this manual.

Training

It must be ensured that all hazards, warnings and precautions listed in the manual have been adequately addressed during training. Laypersons should be instructed to contact the technical customer service in the event of any changes in humidifier performance.

Password

The responsible and authorised/certified personnel, who have an appropriate password, can use to select the ‘neonate configuration” or the “adult configuration”.

Liability and guarantee

Löwenstein Medical accepts no liability for defects or malfunctions resulting from:

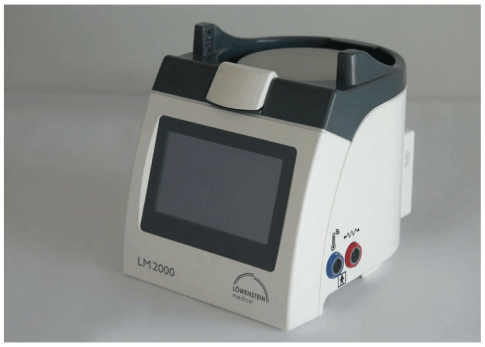
- Disregard of instructions in the operating manual
- Breakage of the device or part thereof caused by falls, impact or tampering
- Use of non-original accessories
- Unsuitable operating environment
- Damage caused by accidents or mishaps

If the device is serviced by persons who are not part of the Löwenstein Medical SE & Co KG maintenance and repair service, liability for the device function is always transferred to the owner or operator of the device. This also applies if the device is not used as intended.

Löwenstein Medical SE & Co KG accepts no liability for damage resulting from failure to observe these instructions. Guarantee and liability provisions of the sale and delivery conditions are supplemented by the above-mentioned instructions.

3. Device overview

Scope of delivery



The LM 2000 humidifier is supplied in ready-to-use sets with operating and quick reference guide.

A complete list of sales codes can be found in (→ "Accessories and replacement parts" p. 54).

Device description

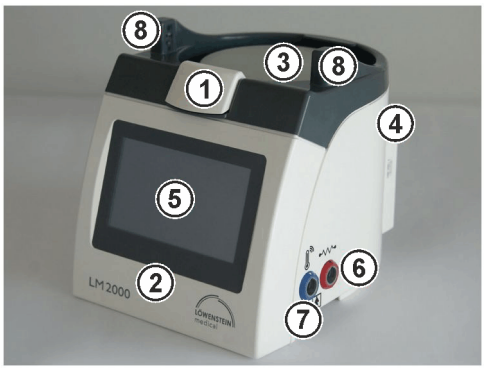
The LM 2000 humidifies and warms the breathing gas mixture administered to the patient by transferring heat to the sterile water in the water chamber. The water chamber is inserted onto the heating plate of the humidifier; the water in the water chamber is heated by the heating plate.

The LM 2000 can be used in both invasive and non-invasive ventilation thanks to the possibility of regulating the temperature of the inhaled gases.

The LM 2000 humidifier automatically controls the temperature and humidity of the gas by means of two temperature sensors located at the outlet of the water chamber and close to the patient. This ensures correct and safe gas administration to the patient.

The LM 2000 provides an automatic safety mechanism that intervenes in the event of absence, interruption or sudden change in gas flow by carefully controlling the power supplied to the hot plate and heated ventilation tube, therefore preventing potentially dangerous overheating situations.

The humidifier is also equipped with an automatic control system that prevents the formation of condensation in the airways in any operating situation.



Components of the LM 2000 humidifier

(1) Symbol for hooking/unhooking the water chamber
(2) LED light
(3) Heating plate
(4) Ventilation slots
(5) Touchscreen display
(6) Heating cable socket (red)
(7) Temperature sensor cable socket (blue)
(8) Water level sensor

Operating parameters

The control temperature range at the outlet of the water chamber can be set to between 29°C and 37°C. The control temperature interval at the sensor near the patient can be set to between 30°C and 40°C. The difference between the control temperature at the sensor near the patient and at the output of the water chamber is between +1°C and +4°C.

The graphic representations of the humidifier are indicative and only serve to facilitate its possible installation. The choice of ventilation system is the sole responsibility of the doctor who initiates the therapy.

WARNING

The usage of unauthorised accessories will result in damage to health and property!

The usage of unauthorised accessories may lead to damage to the health of the patient and the device.

- Use authorised accessories only.

Level sensor

The humidifier is equipped with an optical detection system for the maximum and minimum water level in the water chamber. This system triggers a first level alarm if the maximum level is exceeded or a second level alarm if the water level in the water chamber is insufficient.

You can activate the optical sensor to detect the minimum water level from the settings menu.

WARNING

Patient hazard - Insufficient oxygen supply due to water in the breathing circuit

If the water in the water chamber is above the maximum safety level, it can enter the patient's airways and prevent sufficient oxygen supply and ventilation.

- The LM 2000 may only be used with Löwenstein Medical's ventilation tubes, which have been specially developed for the correct operation of the device. The use of water chambers not approved by Löwenstein Medical may affect performance or safety; for example, the humidifier may not immediately signal that the maximum safety level of water in the water chamber is exceeded.
- Clinical operators or medical staff decide on their own responsibility whether to activate or deactivate the level sensor.

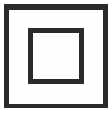
Icons

Table 6: Icons/labels

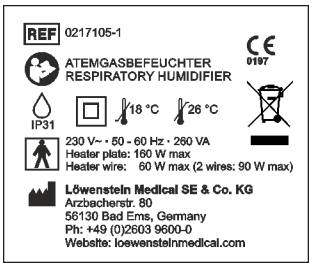
	Warning of a danger point
	Warning of electrical voltage Do not open the device when it is connected to a power source – risk of electric shock
	Warning of hot surfaces – Avoid direct contact
	Non-sterile
	Do not use blades
	Please observe the user manual
	Please observe the user manual
	Date of manufacture (Year – Month)

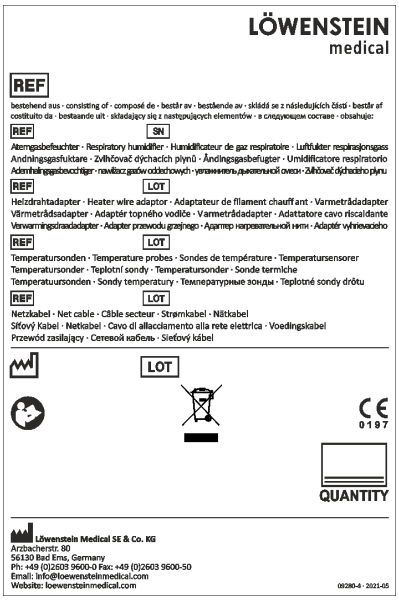
Table 6: Icons/labels	
	Manufacturer
	Do not use hooks
	This side up
	Batch code
	Product code
	Serial number
	Sensitive to moisture
	Sensitive toheat
	Temperature limits
	Fragile
	The device must be disposed of in accordance with EU Directive 2002/96/EC. Contact the responsible Löwenstein Medical sales partner.
	Applied parts type BF

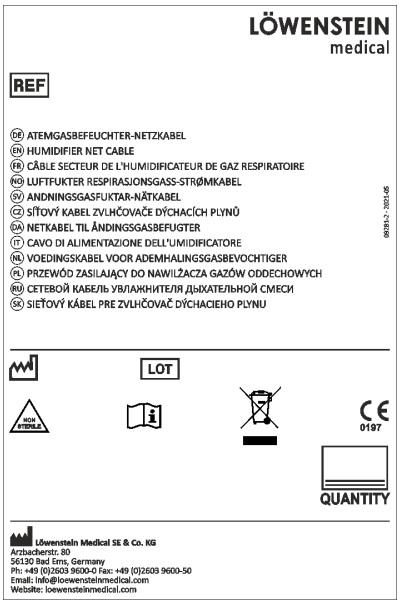
Table 6: Icons/labels

	Class II device
 IP31	Protection class of the device housing (against the ingress of foreign bodies from a size of 2.5 mm and against the vertical falling of water droplets)
CE 0197	The device complies with Directive 93/42/EC “Medical devices”. The device meets the requirements of EU Directive 93/42/EEC/Appendix II. Monitoring is carried out by TÜV Rheinland LGA Products GmbH, Nuremberg.
 F 1.6AL, 250V	Fuse
	Plug for heating cable
	Plug for temperature sensor cable
	Alternating current
	The type plate contains, among other things, the serial number, mains connection and fuse data.

Identification and labelling

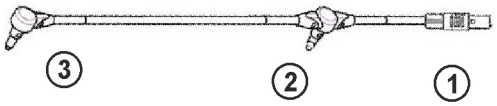






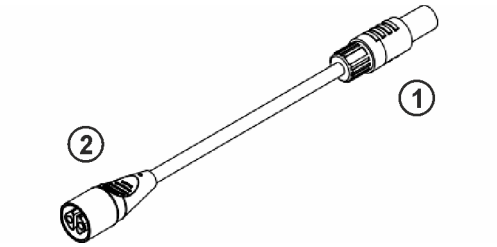
4. Configuration Service

Cable



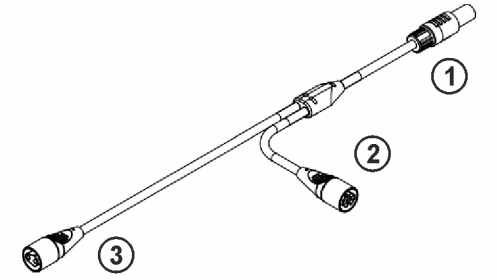
Temperature sensor cable

(1) Plug for connection to the humidifier (blue)
(2) Temperature sensor for measuring the temperature at the outlet of the water chamber
(3) Sensor to detect the temperature near the patient



Single heating cable

(1) Plug for connection to the humidifier (red)
(2) Plug for connection to the heated inspiration tube.



Dual heating cable

(1) Plug for connection to the humidifier (red)
(2) Plug for connection to the heated inspiration tube.
(3) Plug for connection to the heated expiration tube.

Neonate configuration

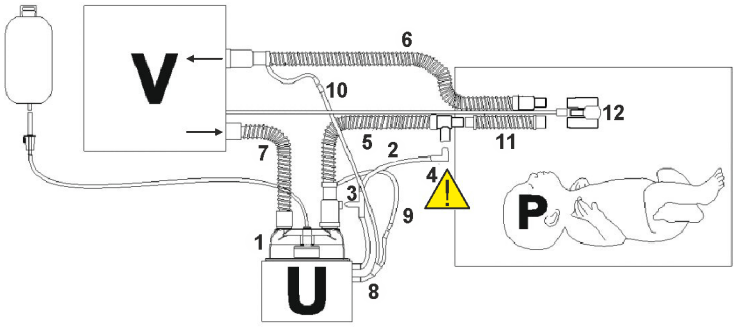
WARNING

Patient hazard - Incorrect positioning of temperature sensor

Positioning the temperature sensor inside the incubator or within the effective range of the radiation plate will affect the correct operation of the humidifier.

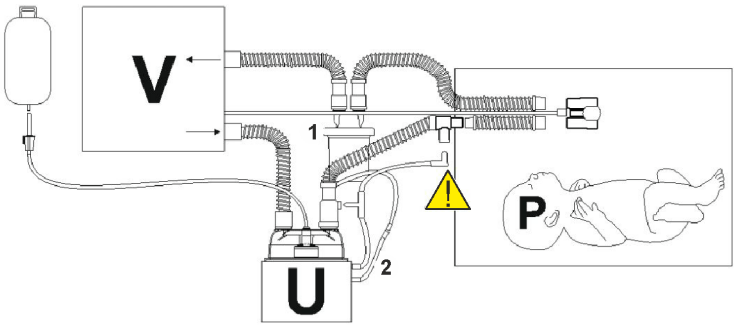
- Position the temperature sensor near the patient on the outside of the incubator or outside the effective range of the radiation plate.

Graphic display of the humidification system with heated inspiration and expiration tubes. The arrows indicate the direction of gas flow, with the ventilator represented by block “V”, the humidifier by block “U” and the patient by block “P”.



(1) Water chamber
(2) Temperature sensor cable
(3) Temperature sensor at the outlet of the water chamber
(4) Sensor to detect the temperature near the patient
(5) Inspiration tube
(6) Expiration tube
(7) Connecting tube to the ventilator
(8) Dual heating cable
(9) Connection to the internal heating cable of the inspiration circuit
(10) Connection to the internal heating cable of the expiration circuit
(11) Incubator tube
(12) Patient interface (nasal cannula or tracheal tube)

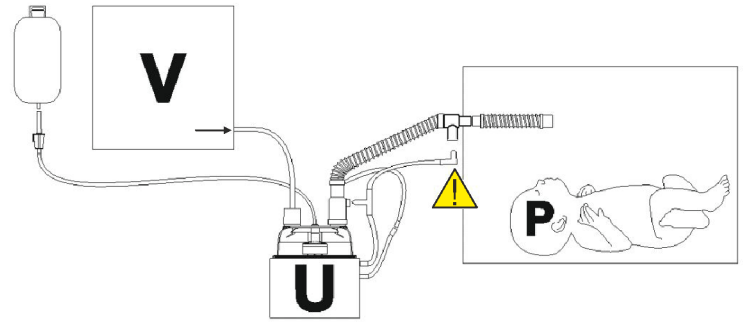
Graphic display of the humidification system with heated inspiration tube. The arrows indicate the direction of gas flow, with the ventilator represented by block “V”, the humidifier by block “U” and the patient by block “P”.



(1) Water trap
(2) Single heating cable

For further positions, refer to the illustration above.

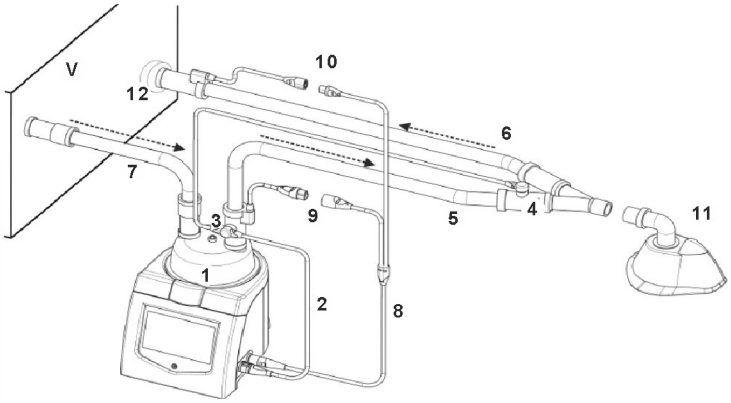
Graphic display of the humidification system with single tube circuit.



For all positions, refer to the illustration above.

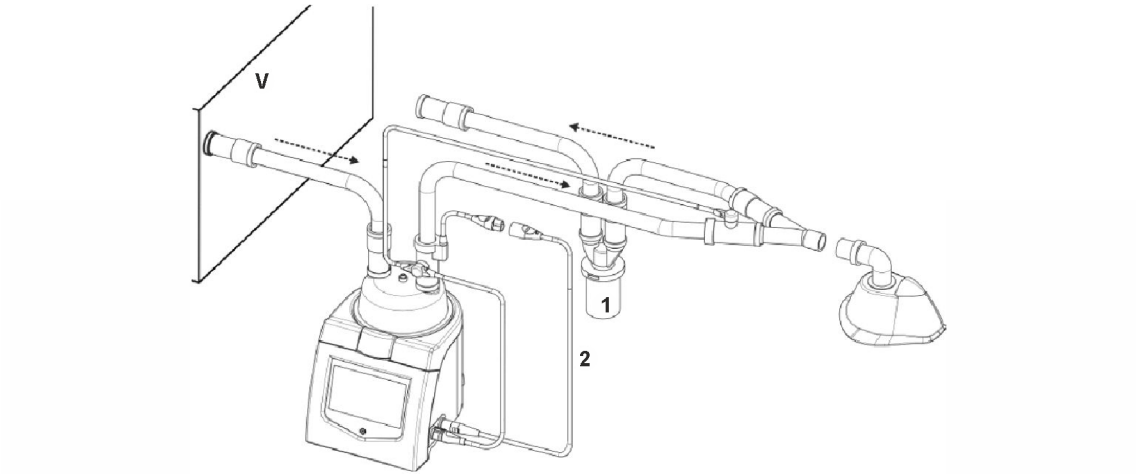
Adult configuration

Graphic display of the humidification system with heated inspiration and expiration tubes. The dotted arrows indicate the direction of gas flow, with the ventilator represented by block “V”.



(1) Water chamber
(2) Temperature sensor cable
(3) Temperature sensor at the outlet of the water chamber
(4) Sensor to detect the temperature near the patient
(5) Inspiration tube
(6) Expiration tube
(7) Connecting tube to the ventilator
(8) Dual heating cable
(9) Connection to the internal heating cable of the inspiration tube
(10) Connection to the internal heating cable of the expiration tube
(11) Patient interface
(12) Filter

Graphic display of the humidification system with heated inspiration tube only. The dotted arrows indicate the direction of gas flow, with the ventilator represented by block “V”.



(1) Water trap
(2) Single heating cable

For further positions, refer to the illustration above.

5. Start-up

1. Using a special mounting accessory, position the humidifier horizontally on a solid surface or on a stand, ensuring that the humidifier is at a lower level than the patient and is not tilted.
2. Position the water chamber on the heating plate and exert light pressure to ensure its correct seat. If seated correctly, it will engage with an audible “click”. For inhalation, only use USP-grade sterile water or an equivalent product. Please observe the user manual of the water chamber used.

Connecting the ventilation tubes with the patient

3. Connect the ventilation tubes (between water chamber and patient and between patient and ventilator) as shown in the illustrations in the following chapters.
   – *For Neonate configuration: (→ "Neonate configuration" p. 23)*
   – *For Adult configuration: (→ "Adult configuration" p. 24)*

   Always consider the choice made by the doctor. For further details please refer to the user manual for the water chamber and the ventilation tubes.

Connecting the plug

4. Connect the plug of the temperature sensor cable to the blue socket on the right-hand side of the humidifier as shown in the illustrations in the following chapters.

– *For Neonate configuration: (→ "Neonate configuration" p. 23)*
– *For Adult configuration: (→ "Adult configuration" p. 24)*

Connect the plug of the heating cable to the red socket, which is also located on the right-hand side of the humidifier. There is a guide arrow on the two plugs and the corresponding sockets for correct insertion. Observing the alignment of the guides, the plugs must be easy to insert, engaging with an audible “click”.

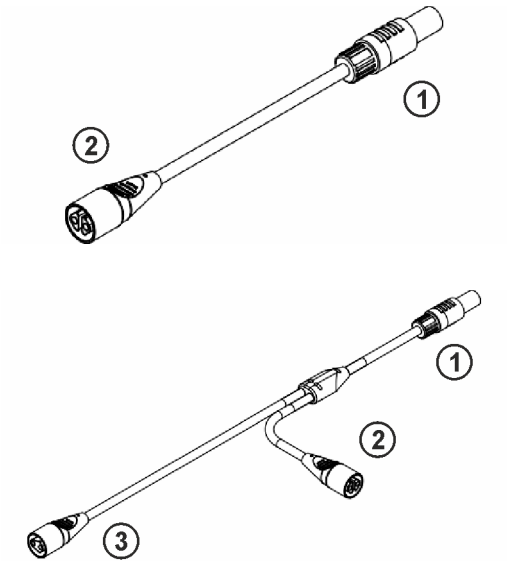
Unaligned, forced insertion can cause the plug to break.

Use the single heating cable if you are using a heated inspiration tube, and the dual heating cable if the expiration tube is also heated.

5. Connect the plug like the sensor cable to the socket of the humidifier until you hear a “click” and align the guide arrows on the cable plug and the corresponding socket on the side of the humidifier

Finally, connect plug 2 to the connector of the inspiration tube and, if the expiration tube is also heated, connect plug 3 to the connector of the expiration tube. Ensure that the shape of the heating cable plugs exactly matches the shape of the respective plugs of the heated inspiration and expiration tubes. Refer to illustrations in the following chapters:

– *For Neonate configuration: (→ "Neonate configuration" p. 23)*
– *For Adult configuration: (→ "Adult configuration" p. 24)*



Connecting the ventilation tubes in the device

6. Connect the ventilation tubes between the ventilator and the water chamber. Refer to illustrations in the following chapters:

– *For Neonate configuration: (→ "Neonate configuration" p. 23)*
– *For Adult configuration: (→ "Adult configuration" p. 24)*

Switching on the device

7. Connect the humidifier to the mains supply: The mains cable must be connected to a socket that is supplied with the mains voltage of the country in which the humidifier is used. The ON/OFF switch is located on the rear of the device. Check that the LED light on the front panel lights up when the humidifier is connected to the mains supply and the mains switch is pressed.

Switching off the device

8. You can switch off the device by pressing the switch on the rear of the device. This switch is used to simultaneously disconnect all poles of the device's circuits from the mains.

6. Operation

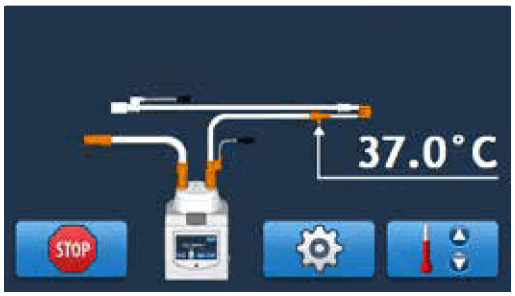
The “Neonate configuration” differs graphically from the “Adult configuration” by the breathing circuit displayed on the main screen.

Neonate configuration

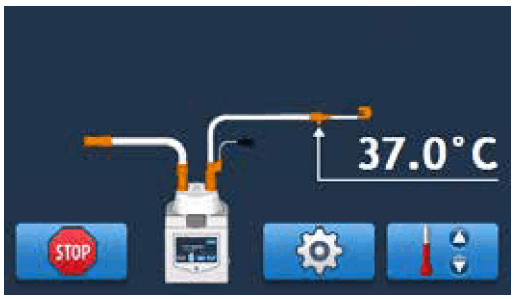
N – Operating screen

When the device is switched on, the operating screen is displayed: The humidifier is in operating mode and begins to heat the tubes and the water in the water chamber to the set control temperatures.

When the humidifier is switched on, it automatically recognises the electrical configuration of the connected ventilation tubes and displays a corresponding screen:



Screen display for humidifier in a configuration with heated inspiration and expiration tube



Screen display for humidifier in a configuration with heated inspiration tube only

If the humidifier is set to heat both tubes, an alarm screen will indicate a disconnected heating cable of the expiration tube.

Pressing (about half a second) the button to pause the audible alarm confirms the new configuration and the humidifier continues operation only with the heated inspiration tube.

If the humidifier is only equipped with the heated inspiration tube, no alarm is triggered when the heating cable of the expiration tube is connected and the humidifier continues operation with the new configuration (both tubes heated).

When switched on for the first time, the temperature value at the chamber outlet and near the patient is set to 34 or 37°C.

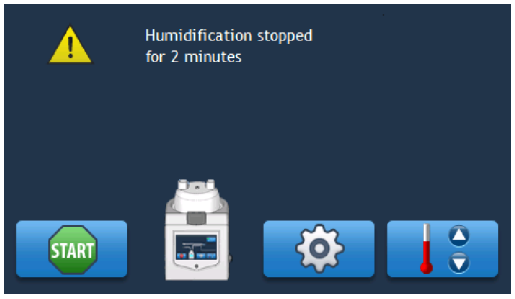
In operating mode, the green LED on the device will flash.

The temperature measured by the temperature sensor near the patient is displayed in white on the operating screen below the patient connection socket.

To access the temperature setting screen (→ "N – Temperature control screen" p. 29), press the adjacent button for about half a second.

Press the adjacent button to display the settings menu.

Humidification can be paused for two minutes by pressing the [STOP] button for about half a second.



If humidification is paused, the message “Humidification paused for two minutes” is displayed at the top of the screen. Simultaneously, the LED on the device lights up continuously in blue.

The use of this function is recommended when carrying out procedures that require interruption of humidification.

You can resume humidification before two minutes have passed by pressing the [START] button for about half a second.

The LED on the device lights up continuously in blue when humidification is paused.

N – Temperature control screen

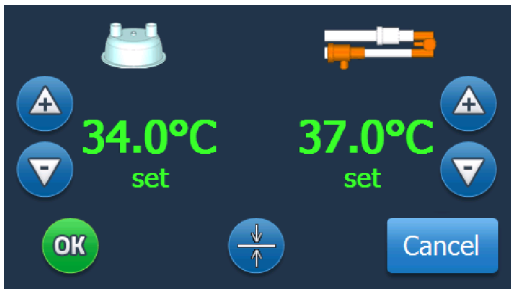
WARNING

Patient hazard - Inadequate oxygen supply due to condensation

Condensation forming in the inspiration tube and entering the patient's airways can prevent sufficient oxygen supply and ventilation.

- Regularly check that no condensation forms in the inspiration tube.
- In the event of condensation, disconnect the tube and drain it.
- Clinical operators or medical staff decide on the temperature to be set on the humidifier on their own responsibility.

After pressing the adjacent button for about half a second, the temperature control screen will be displayed:



The temperature control screen allows you to change the control temperature at the outlet of the water chamber (left) and on the sensor near the patient (right).

Adjust the temperatures by increasing the set value with the [+] button and decreasing it with the [-] button. The control temperature at the outlet of the water chamber can be set between 29 and 37°C, while the control temperature near the patient can be set between 30 and 40°C.

The two control temperatures can be set independently of each other without the control temperature near the patient being lower than that at the chamber outlet. To avoid the formation of condensation, the maximum adjustable gradient between the temperature near the patient and that at the outlet of the water chamber must be between +1 and +4°C.

Press the [Cancel] button to return to the operating screen without saving the settings.

Press the [OK] button for about half a second to confirm the set temperature parameters and return to the operating screen.

If the changes are not saved within 20 seconds, the screen closes WITHOUT saving the changes made, and the operating screen is displayed again.

If no changes are made after ten seconds, the humidifier automatically returns to the operating screen.

Press the reset button to reset the temperatures to the default setting. The predefined temperatures at the outlet of the chamber and near the patient are 34 and 37°C respectively.

The activation of a button by the operator is confirmed by an audible signal (operation confirmed), if the button is not pressed long enough, another audible signal (operation failed) informs the operator of the failed operation.

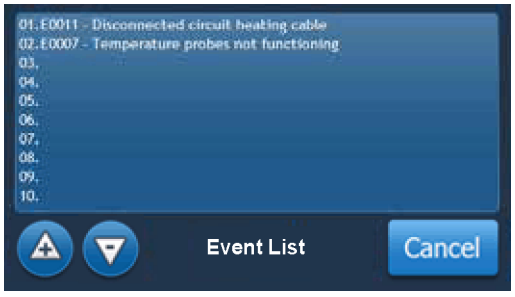
For all buttons where no minimum activation time is specified, activation is immediate when the button is pressed.

If condensation forms in the inspiration tube, proceed as follows:

- Disconnect the tube and drain the condensed water into a container. Ensure that it does not enter the patient's airways during this procedure.
- Ensure that the temperature sensor near the patient is located outside the incubator.
- Change the control temperatures (lowering the temperature at the chamber outlet and/or increasing the temperature near the patient will reduce the formation of condensation in the inspiration tube).

N – List of events

Press the adjacent button, which is located on the operating screen, to open the list of events.



Opening the screen page will display a list of the latest events that occurred after the LM 2000 was switched on.

The events are listed in chronological order. The most recent event is displayed at the top of the list. The oldest event is at the bottom of the list.

Pressing the [+] button opens a second page of the screen with events that occurred even earlier.

Pressing the [-] buttons returns you to the first page of recent events.

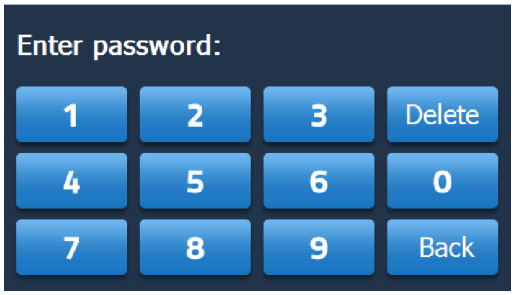
The list of events displays the significant events.

The list of events is reset by switching off the device.

Press the [Cancel] button to return to the operating screen.

N – Settings menu

By pressing the adjacent button, which is located on the operating screen, you can access the setting menu without interrupting humidification.



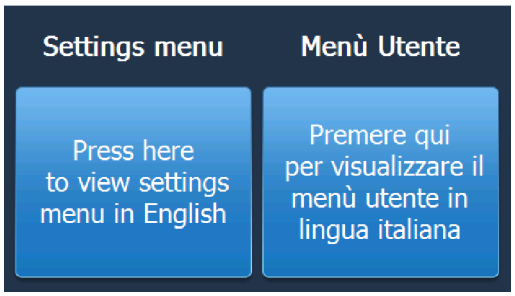
The first screen that appears is a numeric keypad that allows you to enter the authentication password. The operator can access the menu after entering the password.

Password: 1234

If you enter an incorrect password, an error message is displayed.

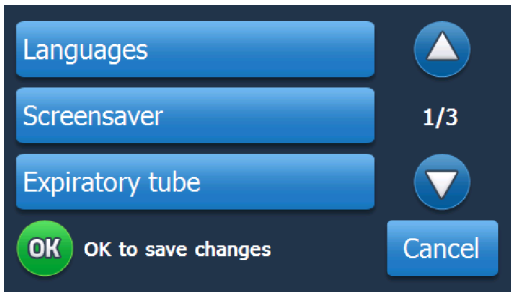
Pressing the [Delete] button allows you to delete the entered numbers and re-enter the password.

Press the [Back] button to return to the operating screen.

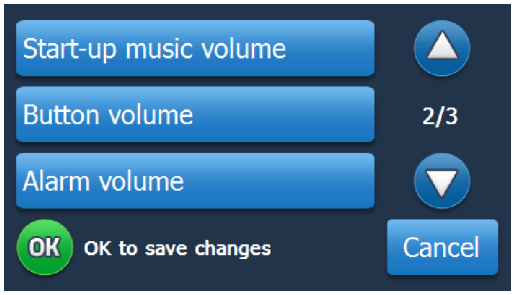


Once you have entered the password, you can select the language of the menu display.

LM 2000 suggests both the menu in English and the menu in the previously set language. Press the button corresponding to the menu language you want to use.



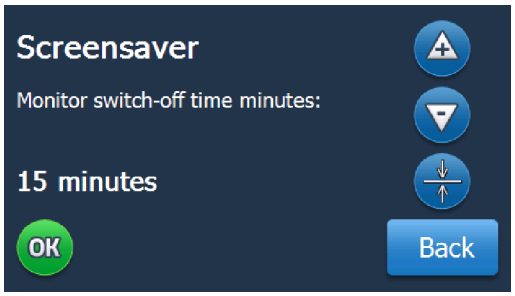
When you access the menu, the list of adjustable parameters is displayed.



To scroll between the pages of the parameter list, use the up and down arrows.

Press the [Cancel] button to exit the settings menu without saving the changes.

Press the button corresponding to the parameter you want to change.



This takes you to the screen where you can change the parameter (example: screen saver).

By pressing the [+] and [-] buttons, you can edit the following parameters:

- Selection from 13 languages
- Volume
  - Start-up music
  - Buttons
  - Alarms
- Activation time of the screen saver

In the Settings menu, you can also enable the display setting of the current temperature measured by the sensor at the outlet of the water chamber ([Chamber temperature] button) and enable or disable the display of the set temperatures in the water chamber and near the patient ([Set temperature] button). These temperatures are displayed in green on the operating screen below the respective temperatures measured at the outlet of the water chamber and near the patient.

Use the [Alarm MAX. Water Level in Chamber] button to disable the maximum level sensor of the water chamber.

Use the [Alarm MIN. Water Level in Chamber] button to enable the maximum level sensor of the water chamber.

The Reset button resets the parameter to the factory setting.

Pressing the [Back] button returns you to the list of adjustable parameters.

Press the [OK] button to save the changes made to the selected parameter.

The LM 2000 memorises the changes made. After all desired parameters have been changed, press [OK] in the parameter overview to save the changes.

N – Screen saver

The screen saver is activated when the LM 2000 is left in operation for a certain period of time (adjustable via the settings menu) without touching the screen.

The temperature displayed on the black background is the value measured by the temperature sensor near the patient.

Tap the screen to exit the screen saver and return to the operating screen.

The screen saver is automatically disabled when an alarm state is triggered.

N – Alarm screen

The LM 2000 has an alarm system that can indicate a potential or actual danger and emit visual and audible warning signals.

The visual alarm signal ensures that the adjacent button is displayed on the operating screen in the event of an alarm.

One or two buttons with the symbols for the type of detected alarm state are also displayed.

For a complete description of the causes of activation and possible solutions to the alarm states, see chapter (→ "Alarms" p. 43)

The indicator that appears on the screen of the humidification system makes it easier to locate the source of the danger that triggered the alarm.

When an alarm signal is triggered, a danger symbol is displayed on the screen:

For second-level alarms, the alarm icon is yellow.

For first-level alarms, the alarm icon is red.

In addition, a button can be displayed (yellow for a second-level alarm state or red for a first-level alarm state) to indicate the type of danger present.

The operator can read the description of the hazard that triggered the alarm signal and a list of possible solutions to remedy the alarm state by pressing the button with the hazard symbol (if the second hazard button is available, one of the two can be pressed).

The audible signal of the alarm can be stopped for 60 seconds in cases where this is possible. The audible signal is then reactivated if the condition that triggered the alarm has not been rectified.

To temporarily interrupt the audible alarm signal, press the adjacent button for about half a second. The icon is outlined in red and the visual signal of the alarm remains unchanged if the alarm state persists.

In some alarm states, the corresponding audible alarm signals cannot be interrupted.

(→ "Alarms" p. 43)

In the event of a second-level alarm, the LED on the device flashes yellow, while in the case of a first-level alarm, the LED is red

Alarms without latching function

The LM 2000 has an intelligent alarm system that enables it to constantly detect an alarm state and therefore manage the alarm signals in such a way that no latching function is necessary.

This means that in almost all alarm states the audible signals are automatically interrupted when the corresponding triggering event no longer exists.

The visual signals, i.e. the hazard buttons, will turn grey from the moment the alarm state is no longer present and will disappear automatically after five minutes.

Within the five minutes mentioned above, the operator can press the alarm buttons to display the description of the alarm state just resolved.

By pressing the adjacent button, the operator can manually remove the alarm buttons from the screen.

Some alarms have a latching function (→ "Alarms" p. 43).

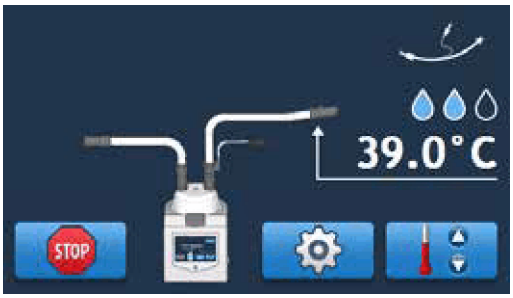
Adult configuration

A – Operating screen

When the device is switched on, the operating screen is displayed: The humidifier is in operating mode and begins to heat the tubes and the water in the water chamber to the set control temperatures.

When the humidifier is switched on, it automatically recognises the electrical configuration of the connected ventilation tubes and displays a corresponding screen:

Screen display for humidifier in a configuration with heated inspiration and expiration tube



Screen display for humidifier in a configuration with heated inspiration tube only

If the humidifier is set to heat both tubes, an alarm screen will indicate a disconnected heating cable of the expiration tube.

Pressing (about half a second) the button to pause the audible alarm confirms the new configuration and the humidifier continues operation only with the heated inspiration tube.

If the humidifier is only equipped with the heated inspiration tube, no alarm is triggered when the heating cable of the expiration tube is connected and the humidifier continues operation with the new configuration (both tubes heated).

When switched on for the first time, the temperature value at the chamber outlet and near the patient is set to 37 or 39°C.

In operating mode, the green LED on the device will flash.

The temperature measured by the temperature sensor near the patient is displayed in white on the operating screen below the patient connection socket.

To access the temperature setting screen (→ "A – Temperature control screen" p. 36), press the adjacent button for about half a second.

Press the adjacent button to display the settings menu.

Humidification can be paused for two minutes by pressing the [STOP] button for about half a second.

If humidification is paused, the message “Humidification paused for two minutes” is displayed at the top of the screen. Simultaneously, the LED on the device lights up continuously in blue.

The use of this function is recommended when carrying out procedures that require interruption of humidification.

You can resume humidification before two minutes have passed by pressing the [START] button for about half a second.

The LED on the device lights up continuously in blue when humidification is paused.

A – Temperature control screen

WARNING

Patient hazard - Inadequate oxygen supply due to condensation

Condensation forming in the inspiration tube and entering the patient's airways can prevent sufficient oxygen supply and ventilation.

- Regularly check that no condensation forms in the inspiration tube.
- In the event of condensation, disconnect the tube and drain it.
- Clinical operators or medical staff decide on the temperature to be set on the humidifier on their own responsibility.

After pressing the adjacent button for about half a second, the temperature control screen will be displayed:

When you call up the temperature control screen, the button with the green circle indicates the setting that is currently active for temperature control. If one of the other buttons were pressed, the green circle would move there.

On the temperature control screen, you can press the following buttons to select default temperature values:

The adjacent button allows the operator to change the humidity at the outlet of the water chamber.

The following parameters can be adjusted:

	Chamber: °C	Patient: °C
	35	39
	36	39
	37	39

Use the adjacent button to select the following default temperature values:

- at the outlet of the water chamber: 31°C
- near the patient: 34°C.

The weaning mode button allows the operator to set the weaning mode.

Select this mode only for weaning the patient off the tracheal tube.

In this mode, the target values are not displayed and the humidity output could be lower than specified in the technical data.

(→ "Technical data" p. 56)

Press the button you want to select for about half a second.

Then confirm by pressing the [OK] button for about half a second.

Press the [Cancel] button to return to the operating screen without saving the settings.

With the hand button, the operator can manually set the control temperature values at the outlet of the chamber and near the patient.

The temperature control screen allows you to change the control temperature at the outlet of the water chamber (left) and on the sensor near the patient (right).

Adjust the temperatures by increasing the set value with the [+] button and decreasing it with the [-] button. The control temperature at the outlet of the water chamber can be set between 29 and 37°C, while the control temperature near the patient can be set between 30 and 40°C.

The two control temperatures can be set independently of each other without the control temperature near the patient being lower than that at the chamber outlet. To avoid the formation of condensation, the maximum adjustable gradient between the temperature near the patient and that at the outlet of the water chamber must be between +1 and +4°C.

Press the [Cancel] button to return to the operating screen without saving the settings.

Press the [OK] button for about half a second to confirm the set temperature parameters and return to the operating screen.

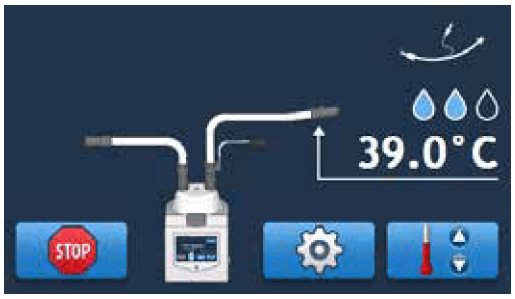
If the changes are not saved within 20 seconds, the screen closes WITHOUT saving the changes made, and the operating screen is displayed again.

If no changes are made after ten seconds, the humidifier automatically returns to the operating screen.

Press the reset button to reset the temperatures to the default setting. The predefined temperatures at the outlet of the chamber and near the patient are 37 and 39°C respectively.

The activation of a button by the operator is confirmed by an audible signal (operation confirmed), if the button is not pressed long enough, another audible signal (operation failed) informs the operator of the failed operation.

For all buttons where no minimum activation time is specified, activation is immediate when the button is pressed.



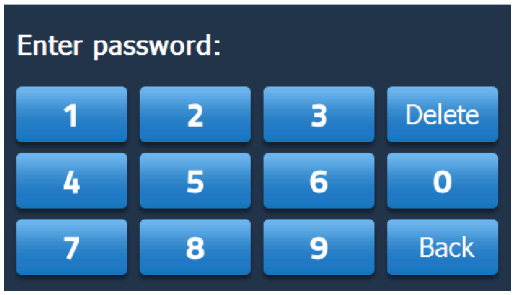
The icon of the selected temperature control button is located at the top right of the operating screen and serves display purposes only.

If condensation forms in the inspiration tube, proceed as follows:

- Disconnect the tube and drain the condensed water into a container. Ensure that it does not enter the patient's airways during this procedure.
- Change the control temperatures (lowering the temperature at the chamber outlet and/or increasing the temperature near the patient will reduce the formation of condensation in the inspiration tube).

A – Settings menu

By pressing the adjacent button, which is located on the operating screen, you can access the setting menu without interrupting humidification.



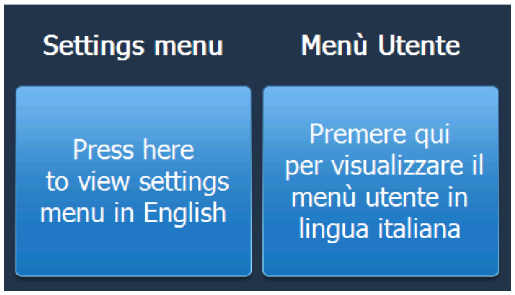
The first screen that appears is a numeric keypad that allows you to enter the authentication password. The operator can access the menu after entering the password.

Password: 1234

If you enter an incorrect password, an error message is displayed.

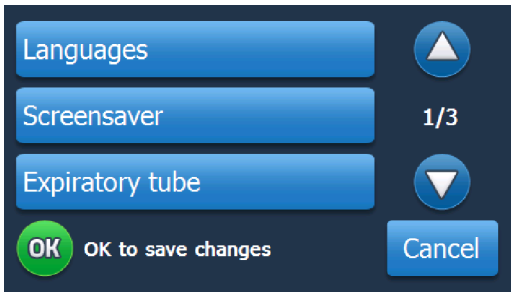
Pressing the [Delete] button allows you to delete the entered numbers and re-enter the password.

Press the [Back] button to return to the operating screen.

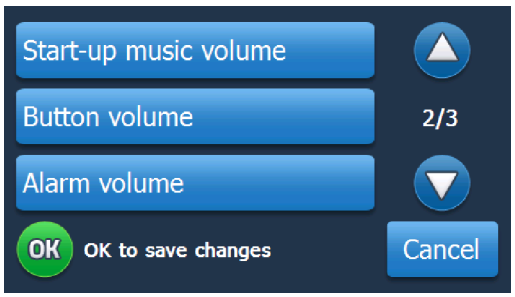


Once you have entered the password, you can select the language of the menu display.

LM 2000 suggests both the menu in English and the menu in the previously set language. Press the button corresponding to the menu language you want to use.



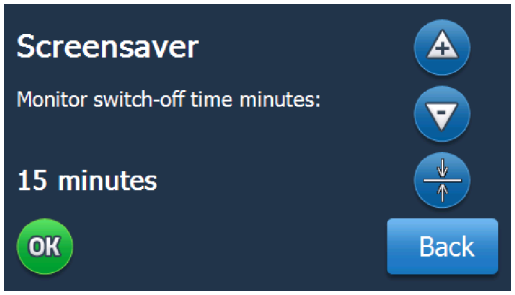
When you access the menu, the list of adjustable parameters is displayed.



To scroll between the pages of the parameter list, use the up and down arrows.

Press the [Cancel] button to exit the settings menu without saving the changes.

Press the button corresponding to the parameter you want to change.



This takes you to the screen where you can change the parameter (example: screen saver).

By pressing the [+] and [-] buttons, you can edit the following parameters:

- Selection from 13 languages
- Volume
  - Start-up music
  - Buttons
  - Alarms
- Activation time of the screen saver

In the Settings menu, you can also enable the display setting of the current temperature measured by the sensor at the outlet of the water chamber ([Chamber temperature] button) and enable or disable the display of the set temperatures in the water chamber and near the patient ([Set temperature] button). These temperatures are displayed in green on the operating screen below the respective temperatures measured at the outlet of the water chamber and near the patient.

Use the [Alarm MAX. Water Level in Chamber] button to disable the maximum level sensor of the water chamber.

Use the [Alarm MIN. Water Level in Chamber] button to enable the maximum level sensor of the water chamber.

The Reset button resets the parameter to the factory setting.

Pressing the [Back] button returns you to the list of adjustable parameters.

Press the [OK] button to save the changes made to the selected parameter.

The LM 2000 memorises the changes made. After all desired parameters have been changed, press [OK] in the parameter overview to save the changes.

A – Screen saver

The screen saver is activated when the LM 2000 is left in operation for a certain period of time (adjustable via the settings menu) without touching the screen.

The temperature displayed on the black background is the value measured by the temperature sensor near the patient.

Tap the screen to exit the screen saver and return to the operating screen.

The screen saver is automatically disabled when an alarm state is triggered.

A – Alarm screen

The LM 2000 has an alarm system that can indicate a potential or actual danger and emit visual and audible warning signals.

The visual alarm signal ensures that the adjacent button is displayed on the operating screen in the event of an alarm.

One or two buttons with the symbols for the type of detected alarm state are also displayed.

For a complete description of the causes of activation and possible solutions to the alarm states, see chapter (→ "Alarms" p. 43)

The indicator that appears on the screen of the humidification system makes it easier to locate the source of the danger that triggered the alarm

When an alarm signal is triggered, a danger symbol is displayed on the screen:

For second-level alarms, the alarm icon is yellow.

For first-level alarms, the alarm icon is red.

In addition, a button can be displayed (yellow for a second-level alarm state or red for a first-level alarm state) to indicate the type of danger present.

The operator can read the description of the hazard that triggered the alarm signal and a list of possible solutions to remedy the alarm state by pressing the button with the hazard symbol (if the second hazard button is available, one of the two can be pressed).

The audible signal of the alarm can be stopped for 60 seconds in cases where this is possible. The audible signal is then reactivated if the condition that triggered the alarm has not been rectified.

To temporarily interrupt the audible alarm signal, press the adjacent button for about half a second. The icon is outlined in red and the visual signal of the alarm remains unchanged if the alarm state persists.

In some alarm states, the corresponding audible alarm signals cannot be interrupted.

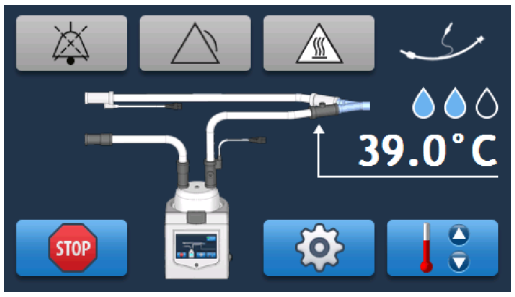
(→ "Alarms" p. 43)

In the event of a second-level alarm, the LED on the device flashes yellow, while in the case of a first-level alarm, the LED is red

Alarms without latching function

The LM 2000 has an intelligent alarm system that enables it to constantly detect an alarm state and therefore manage the alarm signals in such a way that no latching function is necessary.

This means that in almost all alarm states the audible signals are automatically interrupted when the corresponding triggering event no longer exists.



The visual signals, i.e. the hazard buttons, will turn grey from the moment the alarm state is no longer present and will disappear automatically after five minutes.

Within the five minutes mentioned above, the operator can press the alarm buttons to display the description of the alarm state just resolved.

By pressing the adjacent button, the operator can manually remove the alarm buttons from the screen.

Some alarms have a latching function (→ "Alarms" p. 43).

7. Alarms

WARNING

Patient hazard - disregarding alarm signals

Alarms ignored by the operator can cause serious injury to the patient.

- Ensure that the volume of the alarms is high enough to be heard.
- If the audible signal of the alarms is interrupted, the patient must be monitored continuously.
- The air flow to the water chamber must not be interrupted. An interruption can prevent alarm signals from being triggered.

Alarm hierarchy

Table 7: Alarm hierarchy

Text colour	Alarm level	Audible signal
Red	First level	Continuous
Yellow	Second level	Interrupted

The alarms are structured hierarchically so that priority is given to those that ensure the safety of the patient, the operator, the therapeutic procedure, etc. The alarm icons are displayed at the top of the screen.

Opposite you will find a table with the characteristics that distinguish first- and second-level alarms.

When an alarm state is triggered, the alarm buttons are displayed at the top of the operating screen. The alarm buttons include the button for interrupting the audible alarm signal and the button(s) for explaining the alarm state with all related possible solutions for remedying it.

The icons used to represent the alarms are as follows:


General warning icon - the red colour is associated with first-level alarms.


General warning icon - the yellow colour is associated with second-level alarms.


Icon for high temperature - the red colour is associated with first-level alarms.


Icon for high temperature - the yellow colour is associated with second-level alarms.


Icon for low temperature - the yellow colour is associated with second-level alarms.


Icon for high condensation - the red colour is associated with first-level alarms.


Icon for fast plate heating - the yellow colour is associated with second-level alarms.

First-level alarms

First-level alarms prevent the device from starting or stopping, and therefore ensure patient safety. These alarms are indicated by a continuous audible signal.

Table 8: First-level alarms

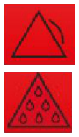
Icons on the display	Alarm description	Triggering state	Causes and/or remedies	Error codes	Alarms without latching function	Alarm system delays
	Hardware errors	Serious hardware failure in LM 2000	Contact the technical customer service.	E0100 or E0002 or E0006	No	< 5 seconds
	Water level in the chamber	Water level in water chamber above max. level	Check for correct insertion of the water chamber. Check the level in the water chamber. Interrupt ventilation and replace the chamber. Possible hardware error. Contact the technical customer service.	E0003	Yes	< 10 seconds
	Patient's inspiratory temperature too high	The temperature at the inlet to the patient has exceeded 43°C	Check that the gas flow is within permissible operating limits. Check for correct installation of the temperature sensor cable. Check that the permissible operating conditions are observed under ambient conditions. Possibly defective temperature sensor cable.	E0003	Yes	< 5 seconds
	Cannot check for condensation	The compensation mechanism to prevent condensation was not effective	Check that the gas flow is within permissible operating limits. Check for correct installation of the temperature sensor cable. Check that the permissible operating conditions are observed under ambient conditions. Possibly defective temperature sensor cable.	E0005	Yes	< 30 minutes

Table 8: First-level alarms

Icons on the display	Alarm description	Triggering state	Causes and/or remedies	Error codes	Alarms without latching function	Alarm system delays
	Heating plate temperature too high	The heating plate temperature has exceed 95°C.	Check for correct insertion of the water chamber.	E0012	Yes	< 5 seconds
	Humidifier overheated	The internal temperature of the LM 2000 has exceeded 70°C	Wait a few minutes before resuming operation. Check that the permissible operating conditions are observed under ambient conditions. Check that the humidifier is correctly positioned and that the ventilation openings (under and behind the device) are not blocked.	E0014	Yes	< 5 seconds

Second-level alarms

Second-level alarms usually signal pre-alarm states (which generally become first-level alarms if they are not resolved) and are characterised by an intermittent audible signal.

Table 9: First-level alarms

Icons on the display	Alarm description	Triggering state	Causes and/or remedies	Error codes	Alarms without latching function	Alarm system delays
	Water level in the chamber	The level in the water chamber is below the minimum.	Check for correct insertion of the water chamber. Check the level in the water chamber. Interrupt ventilation and replace the chamber. Possible hardware error. Contact the technical customer service.	E0003	Yes	< 10 seconds
	Temperature sensors not in operation	LM 2000 does not detect the connection of the temperature sensors	Check for correct installation of the temperature sensor cable. Possibly defective temperature sensor cable	E0007	Yes	< 10 seconds
	Temperature sensors not in operation	LM 2000 does not detect the correct position of the temperature sensors in the circuit	Check for correct installation of the temperature sensor cable. Possibly defective temperature sensor cable.	E0010	Yes	< 30 minutes
	Disconnecting the heating circuit cable	LM 2000 does not detect the connection of the heating circuit cable	Check the connection. Replace the tube.	E0011	Yes	< 10 seconds
	Plate heats up too quickly	The temperature of the heating plate rises too quickly	Check for correct insertion of the water chamber. Check the level in the water chamber.	E0013	Yes	< 5 minutes
	Plate does not heat up	Possible problem with the thermal fuse or pilot triac	Switch off and on again after at least 5 minutes Contact the technical customer service.	E0018	No	< 5 seconds

Table 9: First-level alarms

Icons on the display	Alarm description	Triggering state	Causes and/or remedies	Error codes	Alarms without latching function	Alarm system delays
	Disconnection or malfunction of the expiration tube	LM 2000 does not detect the connection to the expiration circuit (only valid when using an expiration heating circuit)	Check the connection. Replace the tube.	E0020	Yes	< 5 seconds
	The set temperature cannot be reached	The desired temperature for the patient was not reached within an appropriate time	Check that the gas flow is within permissible operating limits. Check for correct installation of the temperature sensor cable. Check that the permissible operating conditions are observed under ambient conditions. Possibly defective temperature sensor cable.	E0021	No	< 30 minutes
	Low inspiratory temperature at the patient	Alarm – The temperature at the patient is low compared to the desired value	Check that the gas flow is within permissible operating limits Check for correct installation of the temperature sensor cable Check that the permissible operating conditions are observed under ambient conditions Possibly defective temperature sensor cable	E0022	Yes	< 30 minutes
	Temperature set on the chamber not maintained	The average temperature at the chamber outlet deviates by more than +/- 2°C over a period of 5 minutes	Ensure that the gas flow is within the recommended operating range Check that the temperature sensor cable is correctly connected Check that the ambient conditions have been observed.	E0024	Yes	< 30 minutes
	Patient set temperature not maintained	The average temperature at the chamber outlet deviates by more than +/- 2°C over a period of 5 minutes	Ensure that the gas flow is within the recommended operating range Check that the temperature sensor cable is correctly connected Check that the ambient conditions have been observed.	E0025	Yes	< 30 minutes

Testing the functionality of the alarm system

WARNING

The use of ventilation tubes and accessories not approved by Löwenstein Medical may impair performance or endanger safety.

- For correct operation, the LM 2000 may only be used with specific ventilation tubes and accessories from Löwenstein Medical.

The functions of the alarm system can be tested at any time if the LM 2000 is in operation and humidification has not been stopped. Löwenstein Medical recommends that this test is carried out before the LM 2000 is used on the patient.

Install the humidifier and all accessories correctly to test that the alarm system is working properly. Perform the test points in the order described below to obtain correct results. Before any action, wait until the previous alarm is cleared.

Do not use the device on a patient if the following alarms are not shown on the display. In this case contact the technical customer service of Löwenstein Medical.

Table 10: Testing the functionality of the alarm system

Test sequence	Alarm codes shown on the display	State triggering the alarm	Alarm system delay	Steps to clear the alarm
Start humidifier without inserted water chamber	E0013	The temperature of the heating plate rises too quickly	< 5 minutes	Insert water chamber correctly and switch off humidifier
Fill the water chamber with water above the black line for the maximum fill level	E0003	The level of the water is above the maximum fill level	< 10 minutes	Remove as much water as needed to reach the correct fill level
Remove the blue plug from the humidifier's temperature sensor cable	E0007	LM 2000 does not detect the connection of the temperature sensors	< 10 seconds	Connect the temperature sensor cable
Remove the red plug from the humidifier's heating cable	E0011	LM2000 does not detect the connection of the heating cable	< 10 seconds	Connect the heating cable
Connect the expiration tube and then electrically disconnect the expiration tube from the heating cable (only applies when using an expiration heating circuit).	E0020	LM 2000 does not detect the connection to the expiration circuit (only applies when using an expiration heating circuit).	< 5 seconds	Connect the expiration circuit

8. Maintenance

Technical safety controls

Daily testing

The operator must visually inspect the humidifier to check for the following:

- Integrity of the housing
- Integrity of the display
- Integrity of the sockets
- Integrity of the heating plate and connection button of the water chamber
- Legibility of the type plate
- Integrity of the mains cable

If the integrity is compromised, the device must not be used. Contact the technical customer service of Löwenstein Medical.

Annual testing

Before you carry out the necessary annual tests, install the ventilation system.

(→ "Start-up" p. 25)

The annual tests may only be carried out by competent and authorised/certified personnel in accordance with the maintenance manual of Löwenstein Medical. Löwenstein Medical accepts no responsibility for the proper functioning and safety of the LM 2000 humidifier if the annual tests required by the maintenance manual have not been carried out by competent and authorised/certified personnel.

The LM 2000 must undergo the following planned annual tests every twelve months to maintain its performance and safety.

Visual inspections

- Integrity of the housing
- Integrity of the display
- Integrity of the sockets
- Integrity of the heating plate
- Integrity of the attachment symbol of the water chamber
- Legibility of the type plate
- Integrity of the mains cable
- Integrity of the heating cable

Operating inspections

- Functionality of LED and display
- Measuring accuracy of the temperature sensor cable and testing for integrity
- Accuracy of temperature measurement
- Calibration of the temperature test sensor

Electrical safety tests

- Operating current
- Insulation resistance

Repairs

Repairs may only be carried out by Löwenstein Medical. For any necessary repairs, please contact customer service.

(→ "Customer service" p. 3)

Cleaning, disinfection and / or sterilisation

WARNING

Working with live components!

Risk of injury through electrocution.

- Unplug the device from the mains before opening the housing.
- Ensure it is not plugged in again without authorisation!

Löwenstein Medical has approved the following methods for cleaning, disinfection or sterilisation. These methods do not impair the integrity and function of the humidifier and accessories. The validation of other methods is the responsibility of the user.

Cleaning and disinfecting the humidifier

WARNING

The heating plate on the humidifier can be very hot

Risk of burning

- Before cleaning, leave the heating plate to cool.

The humidifier and the supplied cables must be regularly disinfected immediately after use by one patient and before use by another patient in accordance with medical instructions.

Follow the disinfectant manufacturer's instructions to ensure effective disinfection.

Notes on avoiding damage to or malfunction of the device

- Do not subject the humidifier to any sterilisation process.
- Do not use alcohol, solvents or scouring agents. These substances could damage the device and cause it to malfunction.

- Do not immerse the humidifier in liquids as these could penetrate the device and cause malfunctions.

Procedure for cleaning and disinfection

1. Disconnect the cables from the water chamber.
2. Wait for the heating plate to cool.
3. Clean the surfaces of the humidifier with a disposable cloth moistened with microfiltered sterile water. Ensure that all organic residues have been removed.
4. Disinfect the outer surfaces of the humidifier at an ambient temperature of at least 20°C with a disposable cloth moistened with a suitable product (e.g. the disinfectant solution Sporicidin® or similar products containing approx. 1.5% “buffered phenol”).

Cleaning and disinfecting the heating cable and power cable

The humidifier and the supplied cables must be regularly disinfected immediately after use by one patient and before use by another patient in accordance with medical instructions.

Follow the disinfectant manufacturer's instructions to ensure effective disinfection.

Notes on avoiding damage to or malfunction of the device

- Do not use alcohol, solvents or scouring agents. These substances could damage the device and cause it to malfunction.
- Do not immerse the connector plugs in liquids as these could penetrate the plugs and cause malfunctions.
- Do not perform steam sterilisation (STEAM, in the pressure vessel) to avoid damaging the cable.

With regard to the heating cable, follow the cleaning and disinfection instructions contained in the warnings.

Procedure for cleaning and disinfection

1. Disconnect the power cable from the mains.
2. Clean the outer surfaces of the cables with a disposable cloth moistened with microfiltered sterile water. Ensure that all organic residues have been removed.
3. Disinfect the outer surfaces of the cables at an ambient temperature of at least 20°C with a disposable cloth moistened with a suitable product (e.g. the disinfectant solution Sporicidin® or similar products with approx. 1.5% “buffered phenol”). Make sure that the surfaces are wetted with the product for at least 10 minutes to ensure bactericidal, fungicidal and virucidal effectiveness.

Cleaning and sterilising the heating cable and power cable

Notes on avoiding damage to or malfunction of the device

- Do not perform steam sterilisation (STEAM, in the pressure vessel) to avoid damaging the cable.

Procedure for cleaning and disinfection

1. Disconnect the power cable from the mains.
2. Clean the outer surfaces of the cables with a disposable cloth moistened with microfiltered sterile water. Ensure that all organic residues have been removed.
3. Dry the cables carefully with a disposable cloth.
4. Place the cable in a bag suitable for the selected sterilisation method.
5. Sterilise using one of the following procedures:
   - with ethylene oxide (EO) at a maximum temperature of 55°C;
   - with hydrogen peroxide (H_2O_2) (Sterrad®).

Cleaning and disinfecting the temperature sensor cable

The humidifier and the supplied cables must be regularly disinfected immediately after use by one patient and before use by another patient in accordance with medical instructions.

Follow the disinfectant manufacturer's instructions to ensure effective disinfection.

Notes on avoiding damage to or malfunction of the device

- Do not use alcohol, solvents or scouring agents. These substances could damage the device and cause it to malfunction.
- Do not immerse the connector plugs in liquids as these could penetrate the plugs and cause malfunctions.
- Do not perform steam sterilisation (STEAM, in the pressure vessel) to avoid damaging the cable.

With regard to the temperature sensor cable, follow the cleaning and disinfection instructions contained in the warnings.

Procedure for cleaning and disinfection

1. Disconnect the temperature sensor cable from the humidifier.
2. Immerse the temperature sensors in water and remove visible contaminated residues with a small brush. Ensure that the electrical connector plug is not immersed in the water.
3. Dry the sensors carefully with a disposable cloth.

4. Disinfect the sensors by immersing them in one of the following antiseptic solutions:
   – 2.0 - 4.0% glutaraldehyde
   – 0.55% ortho-phthalaldehyde
   – 7.5% hydrogen peroxide

   Ensure that the electrical connector plug is not immersed in the water.
5. Rinse with microfiltered sterile water.
6. Dry the sensors again with a disposable cloth.
7. Store the cable as aseptically as possible until it is used again.

Cleaning and sterilising the temperature sensor cable

As an alternative to the process of cleaning and disinfection, the process of cleaning and sterilisation can also be performed.

Notes on avoiding damage to or malfunction of the device

- Do not perform steam sterilisation (STEAM, in the pressure vessel) to avoid damaging the cable.

Procedure for cleaning and disinfection

1. Immerse the temperature sensors in microfiltered sterile water and remove visible contaminated residues with a small brush. Ensure that the electrical connector plug is not immersed in the water.
2. Dry the sensors carefully with a disposable cloth.
3. Place the cable in a bag suitable for the selected sterilisation method.
4. Sterilise using one of the following procedures:
   – with ethylene oxide (EO) at a maximum temperature of 55°C;
   – with hydrogen peroxide (H_2O_2) (Sterrad®).

9. Disposal

The operator must contact local authorities to identify the appropriate disposal method for potentially biologically hazardous components and accessories (e.g. temperature sensor cables).

Disposal at the end of the humidifier's service life must be carried out through separate waste collection (electrical and electronic equipment) in accordance with local regulations.

RoHS III

All components used in the manufacture of the humidifier are strictly certified according to RoHS III (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2019).

10. Accessories and replacement parts

Table 11: List of order numbers

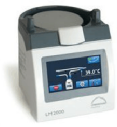
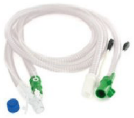
Article illustration	Art. no.	Description
0217105-1 	0217105-1	Humidifier LM 2000 230 V
0217106-1 	0217106-1	Humidifier LM 2000 120 V
0217117 	0217117	Disposable water chamber with automatic filling
0217117-1 	0217117-1	Water chamber with automatic filling including non-return valve (Leonie+)
p180v2c 	p180v2c	Heated dual circuit for Children with water chamber with automatic filling (1.80 m)
a180v2c 	a180v2c	Heated dual circuit for Adults with water chamber with automatic filling (1.80 m)
n160v2c 	n160v2c	Tube system for Neonates with dual heating (i + e) with water chamber with automatic filling (1.60 m)
0217107 	0217107	Temperature control cable 1.80 m

Table 11: List of order numbers

Article illustration	Art. no.	Description
0277121 	0277121	Temperature control cable 1.40 m
0217108-1 	0217108-1	Single-heating cable for LM 2000
0217108 	0217108	Dual-heating cable for LM 2000
0217140 	0217140	AC power cable with angled IEC socket and safety plug
0217141 	0217141	AC power cable with angled IEC socket and BS-1363 plug
0217142 	0217142	AC power cable with angled IEC socket and US type B plug

Löwenstein Medical manufactures a complete range of approved and specific ventilation tubes and accessories for the correct operation of the LM 2000 humidifier. A full list of approved models is available upon request.

11. Technical data

Table 12: Standards and guidelines	
IP protection class	IP31
Electrical protection class	II
Applied parts	Type BF

Table 13: Performance data	
Supply frequency	50-60 Hz
Supply voltage	(→ "Accessories and replacement parts" p. 54)
Power consumption	260 VA
Heating plate output	160 W
Output of the internal heating cable	max. 60 W (2 cables: max. 90 W)
Alarms	Audio volume > 50 dB at a distance of 1m
Humidity output	≥ 33 mg/l at a chamber outlet temperature of ≥ 32°C
Maximum operating pressure	Follow the user manual for the water chamber and the ventilation tubes.
Heating time	< 20 minutes

Ensure that the power source characteristics are compatible with the label of the humidifier.

Table 14: Environmental conditions	
Height	0 – 2.000 m (0–6.000 ft)
Transport and storage temperature	-10 – +50°C
Recommended ambient temperature range	18-26°C
Recommended inlet gas temperature range	18-25 °C
Recommended range of relative ambient humidity during operation	10–95%
Recommended range of ambient pressure during operation	700–1.100 hPa

Table 15: Dimensions and weights	
Dimensions	152 x 171 x 200 mm (W x H x D) (without water chamber)
Weight	approx. 1.6 kg (without water chamber) approx. 1.8 kg (with prefilled water chamber)

Table 16: Fuses	
Thermal fuse	115°C

Table 17: Operating data	
Display	Touch screen
Accuracy of temperature sensor measurement	± 2°C
Uncertainty regarding the tolerance limit of the instrument	± 0.3°C
Life	10 years The applied parts (heating cable, temperature sensor cable and power cable) must be checked regularly in accordance with the service manual. Should the applied parts prove no longer suitable during these inspections, they must be replaced.

The manufacturer may at any time, without prior notice, make changes to the device which will affect these specifications.

If you require further technical information, please contact Löwenstein Medical Service.

Subject to change

As at 06.05.2021

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User manual LM 2000

Order no.: gba10450en2012

CE 0197