





# Azeer Neonatology Devices



# LIFETHERM 2000, 2002, 2003

User manual

**Rev. 4.8** 25.06.2020





# Copyright ® 2020 Löwenstein Medical GmbH & Co. KG

Subject to change 25.06.2020

Löwenstein Medical GmbH & Co. KG Arzbacher Straße 80 56130 Bad Ems/Germany P: +49 2603/9600-0

F: +49 2603/9600-50 Web: www.hul.de

User manual Lifetherm Order no.: ba-0070

# About this instruction manual

#### **Customer service**

#### **Further information**

# Copyright

# Supplementary instructions

This instruction manual was created for the product LIFETHERM 2000, 2002, 2003. 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.

In addition to this manual the instructions for the built-in components contained in the annex apply.

Please contact our customer service with the following contact details:

Contact type	Contact details
Postal address	Löwenstein Medical GmbH & Co. KG Arzbacher Straße 80 56130 Bad Ems/Germany
Telephone	+49 2603 9600-0
Fax	+49 2603 9600-50
E-mail	info@hul.de

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.

This instruction manual is protected by copyright law. Passing this manual on to third parties, duplication of any kind – even in form of excerpts – as well as the use and/or disclosure of the contents without the written consent of the manufacturer is not permitted, except for internal purposes.

Violation obligates compensation for damages. The right to further claims remains reserved.

# **Table of Contents**

1.	Safety	7
	Symbol definition	7
	Warnings	7
	Other symbols in this instruction manual	7
	Medical purpose	8
	Indication	8
	Contraindication	9
	Residual hazards	10
	Classification of the device	
	Guidelines and manufacturer's declaration – Electromagnetic emissions	12
	Guidelines and manufacturer's declaration – Electromagnetic immunity	13
	Recommended safety distances between portable, mobile and fixed HF telecommunicate equipment and LIFETHERM 2000, 2002, 2003	
	Personnel qualifications	16
	Liability and guarantee	16
2.	Device overview	17
	Device description	17
	LIFETHERM 2000 (heating bed)	17
	LIFETHERM 2002, LIFETHERM 2003	18
	Deck	19
	Control panel on front side	19
	Deck inclination	19
	Height adjustment	20
	Service interfaces	20
	Heat radiator (Lifetherm 2002, 2003)	21
	lcons	21
3.	Preparations	25
	Testing before initial operation	27
	Test before every use	28
	Deck	28
	Heat radiator (Lifetherm 2002, 2003)	29
4.	Operation	30
	Moving the device	31
	Deck	
	Heat radiator	33
	LIFETHERM 2002	33
	LIFETHERM 2003	36
5.	Alarms	38
	List of alarm messages	
	Factory settings of the alarms	
	Testing the alarms	
	LIFETHERM 2000 (heating bed)	
	LIFETHERM 2002	40
	LIFETHERM 2003	41

6.	Maintenance	42
	Preparations	42
	Cleaning and disinfection	
	Skin sensor (Lifetherm 2002)	43
	Silicone parts	
	Authorised cleaning agents and disinfectants	
	Maintenance instructions	45
7.	Technical data	46
	Heating bed	46
	Heat radiator (Lifetherm 2002, 2003)	
8.	Accessories and replacement parts	49

# 1. Safety

# **Symbol definition**

# Warnings



**ATTENTION** indicates important information, non-compliance with which could lead to damage to the device.



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



**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

Warming premature babies, neonates and infants up to a weight of 8 kg.

- The heat radiator and (or) the electronically controlled panel heating with the silicone gel mat intended as a lying surface offer infants and neonates protection against excessive heat loss, which can be potentially life-threatening.
- The hinged Plexiglass panels allow an unobstructed view and provide easy access to the infant.
- The inclination of the deck can be infinitely adjusted by means of easy-to-operate button switches, allowing the user to place the child in a head-up or head-down position.
- LIFETHERM 2002 and LIFETHERM 2003 can also be used to facilitate the transition period for children who are no longer dependent on an intensive-care incubator.

LIFETHERM 2002	LIFETHERM 2003
Heats using a manually or skin-temperature controlled heat radiator and a heated silicone gel mat.	Heats using a manually controlled heat radiator and a heated silicone gel mat.

### Mobile radio

Protective earth conductor

Do not use mobile radios within a radius of 5 m. Mobile phones can impair the electrical functions.

To avoid the risk of electric shock, this device may only be connected to a supply mains with a protective earth conductor.

# Contraindication

Do not use skin-temperature regulation in children in a state of shock or with a fever, as it is not possible to distinguish between a rise in core temperature when the skin is cold (fever) and too low a core temperature and skin temperature (hypothermia).

# Residual hazards

- The infant should never be left under the device unattended; it is imperative that the user monitor the infant's temperature independently.
   This temperature should be checked at regular intervals.
- When the device is switched on, the system carries out a self check. If an error is detected, it is indicated audibly and visually and a message appears: System error.
  - (refer to "Alarms" on page 38)
- The inclination of the deck from a horizontal position can change the characteristics of the heat radiator!
- Please note that rectal temperature measurements are not suitable for controlling the heat radiation of the device.
- Changing environmental conditions, such as drafts, can affect the temperature balance of the infant.
- Additional warming of transdermal medicinal applications (patches) can increase the supply of the medication and may potentially harm the infant
- It is possible that the heat radiator may cause the infant's water loss to increase unnoticed.
- LIFETHERM 2000, 2002, 2003 may not be modified without the manufacturer's permission.
- The devices LIFETHERM 2000, 2002, 2003 must be subjected to annual inspection and maintenance by a service technician authorised by LÖWENSTEIN MEDICAL. Inspections and maintenance must be recorded. For repairs and service, we recommend concluding an appropriate contract with LÖWENSTEIN MEDICAL GmbH & Co KG.
- Only use the accessories listed in the attachment. When using other accessories, make sure that they are certified as secure and safe to use.



WARNING

# No operation in potentially explosive areas

Using flammable gases, anaesthetics or cleaning agents poses a fire risk.

- The device must not be operated in potentially explosively areas.
- Do not use the device together with flammable gases or anaesthetics or cleaning agents.



WARNING

# Coupling with electrical devices

The installation of a medical electrical system can lead to a reduced safety level.

 Electrical coupling with devices that are not mentioned in this instruction manual may only be carried out after consulting the manufacturer or an expert.



### The us of HF surgical devices and endocardiac catheters

There is a risk of electric shock, fire or electromagnetic interference to the operating heating device when using HF surgical instruments or endocardiac catheters.

 Additional equipotential bonding is required when using HF surgical devices and endocardiac catheters.

# Classification of the device

Table 1: Classification	
Device group in accordance with 93/42/EEC Appendix IX	IIb
Protection class acc. to EN 60601-1	BF
IP acc. to EN 60601-1	Device X2 Silicon gel mat X7
Operation type	suitable for intermittent use

Documentation for LIFETHERM 2000, 2002, 2003 encompasses:

- LIFETHERM 2000, 2002, 2003 instruction manuals
- LIFETHERM 2000, 2002, 2003 Service manual

# Guidelines and manufacturer's declaration – Electromagnetic emissions

Table 2: Guidelines and manufacturer's declaration – Electromagnetic emissions		
Interference emissions test Conformity		Conformity
High frequency interference emission test CISPR11		Group 1
		Class A
Harmonic waves IEC 61000-3-2 Class A		Class A
Voltage variations/flickers IEC 61000-3-3 full conformity		full conformity
NOTE 1: Interference or impairment from other electronic devices located in the vicinity of LIFETHERM 2000, 2002, 2003 is low, as the interference emissions of LIFETHERM 2000, 2002, 2003 are very low in the high-frequency range.		

households.

# Guidelines and manufacturer's declaration – Electromagnetic immunity

LIFETHERM 2000, 2002, 2003 are intended for operation in the electromagnetic environment specified below. The customer or user of LIFETHERM 2000, 2002, 2003 should ensure that they are operated in such an appropriate environment.

Portable, mobile and fixed radio equipment should not be used at a distance from LIFETHERM 2000, 2002, 2003, including cables, that is less than the recommended distance calculated in accordance with the equation applicable to the transmission frequency:

Table 3: Equivalence for protective distance depending on the transmitter frequency

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - Guidelines Recommended safety distance	
Conducted HF-interference in accordance with	3 V <sub>eff</sub> 150 kHz – 80 MHz outside of the ISM-bands*	3 V <sub>eff</sub>	$d^{**} = \frac{3.5}{3} \times \sqrt{P} = 1.17 \times \sqrt{P}$	/P
IEC 61000-4-6	10 V <sub>eff</sub> 150 kHz - 80 MHz within the ISM-bands	10 V <sub>eff</sub>	$d = \frac{12}{10} \times \sqrt{P} = 1, 2 \times \sqrt{P}$	
Radiated HF-interference in accordance with IEC 61000-4-3	10 V/m 80 MHz – 2.5 GHz	10 V/m	$d = \frac{12}{10} \times \sqrt{P} = 1, 2 \times \sqrt{P}$	80 MHz - 800 MHz
			$d = \frac{23}{10} \times \sqrt{P} = 2,3 \times \sqrt{P}$	800 MHz – 2.5 GHz

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 ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.
- \*\* CONFORMITY LEVELS in the ISM bands between 150 kHz and 80 MHz and in the 80 MHz and 2.5 GHz frequency ranges are intended to reduce the likelihood that mobile/portable/fixed communication equipment can cause harmful interference when inadvertently brought into the PATIENT area. For this reason, the additional factor of 10/3 is applied when calculating the recommended safety distances in these frequency ranges.
- \*\*\* 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 LIFETHERM 2000, 2002, 2003 are used exceeds the above compliance level, LIFETHERM 2000, 2002, 2003 should be observed in order to prove their proper function. If unusual performance characteristics are observed, additional measures may be necessary, e.g. modification or relocation of LIFETHERM 2000, 2002, 2003.
- \*\*\*\* 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 LIFETHERM 2000, 2002, 2003

LIFETHERM 2000, 2002, 2003 are intended for use in the electromagnetic environment specified below in which the HF disturbance variables are controlled. The customer or user of LIFETHERM 2000, 2002, 2003 can therefore help to avoid electromagnetic interference by keeping the minimum distance between portable, mobile and fixed HF telecommunication equipment (transmitters) and LIFETHERM 2000, 2002, 2003, depending on the output power of the communication equipment, as specified below.

Table 4: 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 outside of the ISM bands	150 kHz - 80 MHz within the ISM bands	80 MHz – 800 MHz	800 MHz - 2.5 GHz
	$d = 1,17 \times \sqrt{P}$	$d = 1,2 \times \sqrt{P}$	$d = 1,2 \times \sqrt{P}$	$d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.2	1.2	2.3
10	3.70	3.79	3.79	7.27
100	11.70	12.0	12.0	23.0

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 frequency range applies.
- NOTE 2: The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.
- NOTE 3: CONFORMITY LEVELS in the ISM frequency ranges 150 kHz and 80 MHz and in the 80 MHz and 2.5 GHz frequency ranges are intended to reduce the likelihood that mobile/portable communication equipment can cause harmful interference when inadvertently brought into the PATIENT area. For this reason, the additional factor of 10/3 is applied when calculating the recommended safety distances in these frequency ranges.
- **NOTE 4:** 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**

User

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** 

Heat radiators may only be used by adequately trained personnel and under the supervision of qualified medical personnel who are aware of the risks and benefits of using heat radiators.

Interpretations and conclusions from the measured temperatures are the responsibility of the doctor.

# Liability and guarantee

If the device is serviced by persons who are not part of the Löwenstein Medical GmbH & 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.

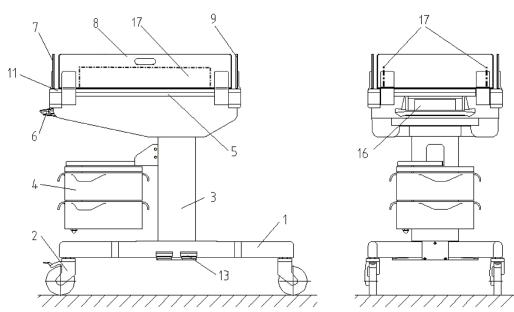
Löwenstein Medical GmbH & Co KG accepts no liability for damage resulting from failure to observe these instructions. Guarantee and liability provisions of the sale and delivery conditions are supplemented by the above-mentioned instructions.

# 2. Device overview

# **Device description**

# LIFETHERM 2000 (heating bed)

LIFETHERM 2000 (heating bed) does not feature a heat radiator. Therefore, only descriptions that do not concern the heat radiator are to be considered in this user manual.



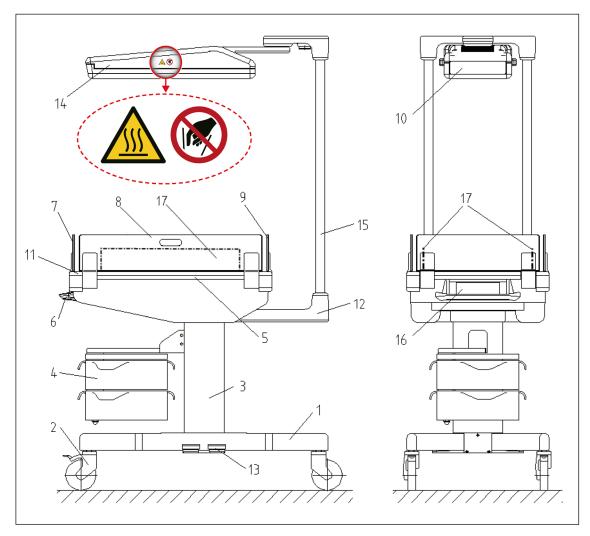
- (1) Chassis
- (2) Castors (4x lockable)
- (3) Lifting pillar
- (4) Drawer block
- (5) Deck
- (6) Handle

- (7) Front panel (with 2 tube feed-throughs)
- (8) Side panel
- (9) Rear panel (with 3 tube feed-throughs)
- (11) Silicon gel mat
- (13) Foot operation, height adjustment
- (16) Control panel for deck
- (17) Safety panels

In addition to the hinged side panels (8), 2 safety panels (17) can be inserted from above into the holders provided on the inside, parallel to the hinged side panels, which prevent the infant from falling out when the side panels are open. In this case a narrower silicone gel mat is used.

(refer to "Accessories and replacement parts" on page 49)

# LIFETHERM 2002, LIFETHERM 2003

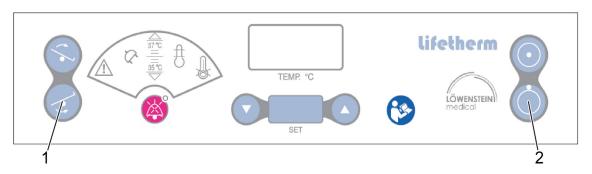


- (1) Chassis
- (2) Castors (4x lockable)
- (3) Lifting pillar
- (4) Drawer block
- (5) Deck
- (6) Handle
- (7) Front panel
- (8) Side panel

- (9) Rear panel
- (10) Control panel for heat radiator
- (11) Silicon gel mat
- (12) Pillar bracket
- (13) Foot operation, height adjustment
- (14) Heat radiator
- (15) Rail
- (16) Control panel for deck
- (17) Safety panels

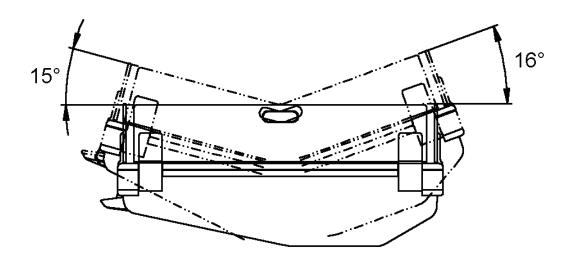
# Deck

# Control panel on front side



- (1) Buttons for inclination adjustment
- (2) ON/OFF buttons

# **Deck inclination**



# Height adjustment

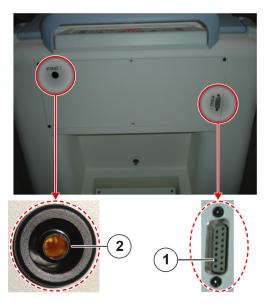
# without height adjustment

The heating bed version without lifting pillar has no height adjustment and the height of the lying surface is 94 cm.

# with height adjustment

If the heating bed has a lifting pillar, the deck can be raised from a height of 93 cm to a height of 118 cm. The lifting pillar is controlled via 2 pedals († Table 7 Pos. 13). The right pedal is used to extend the lifting pillar (deck is raised) and the left pedal is used to retract it (deck is lowered).

# Service interfaces



On the underside of the deck there are two connections (interface 1/interface 2), which are only used for service purposes.

- (1) Interface 1
- (2) Interface 2

# Heat radiator (Lifetherm 2002, 2003)

The built-in ceramic heater has very good radiation properties and produces non-visible infra-red radiation in the range of 3  $\mu$ m. This radiation spectrum is very well absorbed by the skin and is not dangerous for the eyes.



The height of the heat radiator is not adjustable.

# **Icons**

# Table 5: Icons/labels No touching (radiator) Warning of a danger point Warning of electrical voltage Warning of hot surface (radiator) Follow the instructions Applied part type BF. Type BF: = "Body Floating" Insulated application part for use on the body but not on the open heart Applied part type B Type B: = "Body" Application part for use on the body, but not on the open heart Do not dispose of the electrical or electronic device as normal household waste. The product must be taken to a collection point for the recycling of electrical and electronic devices for proper disposal, reuse and recycling. This symbol is only valid within the European Union

Table 5: Icons/labels	
$\bigvee$	Equipotential (connection for potential equalisation)  Additional equipotential bonding is a preventive measure to protect the patient, user and third parties from touch voltages that can arise from voltage potentials between touchable conductive parts and mobile devices.
<b>C €</b> 0197	Conformité Européen Directive 93/42/EEC on medical devices with indication of the certifying body
	Fuse
M	Date of manufacture
	Manufacturer
0	Electric input (skin sensor)
%	Manual operation, set value heat output in % of total output
°C	LIFETHERM 2002 Automatic operation (control via skin sensor), setting variable temperature °C
mW	LIFETHERM 2003  Manual operation, set value heat output in mW/cm²

Table 6: Icons/buttons		
	Switching off the audible signal temporarily (LED flashes in the event of a muted alarm for 15 min)	
	ON for a part of a device; switch on	
	OFF for a part of a device; switch off	
%°C	Lighting ON/OFF LIFETHERM 2002 Change between automatic operation of the heat radiator, heat output in (°C) and control via skin sensor and manual operation, heat output in (%) with LED display of operating mode	
% mW	Lighting ON/OFF LIFETHERM 2003 Manual operation, heat output in % or mW/cm²	
	Tilting the patient table (head-down position)	
	Tilting the patient table (feet-down position)	
	Increasing the temperature	
	Decreasing the temperature	
<b>1</b>	Foot control, direction of height adjustment (higher)	
1	Foot control, direction of height adjustment (lower)	

Table 7: Icons/LEDs		
$\triangle$	Warning of a danger point	
-	Mains plug	
	Temperature/output safe range upper limit (exceeded temperature alarm)	
	Temperature safe range lower limit (under-temperature alarm)	
f	Target temperature alarm (exceeding or undercutting the target temperature by more than 1°C)	
8	Sensor alarm	

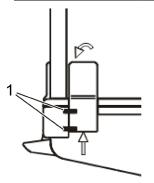
# 3. Preparations



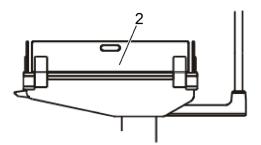
# Risk of injury by falling out

If the barriers are not installed correctly, the infant may fall out of the deck.

- Check the locks and hinges of the barrier regularly.
- Ensure that the retaining bolts are correctly seated.

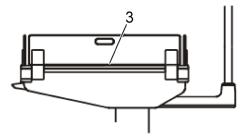


- 1. Insert the panels.
  - The two lateral retaining bolts (1) must be fully inserted into the guide groove of the corners.
  - The lower bolt must rest on the bottom of the guide groove.
- To open, lift the pane up to the stop and fold it down.
- To close, turn the panes upwards until the upper bolt is back in the guide groove.

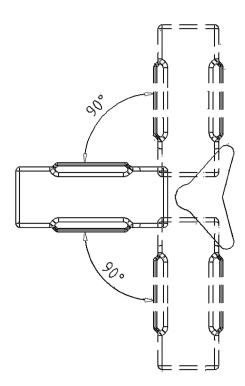


In addition to the side panels (2), two safety panels can be inserted inside to prevent the infant from falling out when the side panels are open.

(refer to "LIFETHERM 2000 (heating bed)" on page 17)

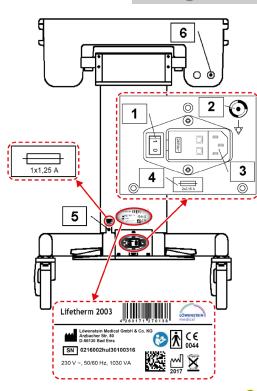


- **2.** Place the silicone gel mat provided flat on the deck (3).
  - Only use the original Löwenstein Medical GmbH & Co KG silicone gel mat! (refer to "Accessories and replacement parts" on page 49)
    - Pos. 21 (with safety panel, broad silicon gel mat)
    - Pos. 30 (with safety panel, narrow silicon gel mat)



- Home position: continuous line
- Positions swivelled by 90°: dotted line

# **Testing before initial operation**



- 1. Set up the device so that the mains input can be easily reached at all times.
- **2.** Check the specified operating voltage and frequency on the type plate to ensure that they match the mains voltage or frequency.
- 3. Insert the mains plug.
- 4. Activate on the main switch.
- (1) Main switch
- (2) Connection for potential equalisation
- (3) Low-heat device socket (mains input)
- (4) Fuse for mains input
  - LIFETHERM 2000 (heating bed):
     2 x 2.0 AT
  - LIFETHERM 2002, LIFETHERM 2003: 2 x 3.15 AT
- (5) Fuse for lifting pillar: 1 x 1.25 AT
- (6) Main sensor connection (only LIFETHERM 2002)
- When replacing the fuses, do not touch the touchable contacts of the bracket and the patient simultaneously.

To replace the fuses at the mains input, remove the cover of the fuse insert with a screwdriver. The fuse brackets can now be removed individually.

# Test before every use

The following items must be tested before every use. The device may only be used if all points have passed the test.

# **Deck**

- The device is cleaned and disinfected.
- Function and condition of the side panels are perfect
  - Free of cracks and splinters
  - Retaining bolts engage safely
- The surface of the deck is free from mechanical damage.
- A silicone gel mat is present and free from mechanical damage.
- The number on the silicone gel mat describes the width (60760 narrow, 60770 wide) and the second part of the number describes the batch of the silicone gel mat.

Only use the original Löwenstein Medical GmbH & Co KG silicone gel mat.

# Heat radiator (Lifetherm 2002, 2003)

- The device is cleaned and disinfected.
- The heat radiator is in home position
- The heat radiator is undamaged.
- The heating element is working properly.
- The lighting is working properly.



# Risk of injury due to faulty temperature control

When the panel heating is switched off, the infant's body temperature can cool down.

Temperature control can be influenced by other heat sources. Accessories such as phototherapy, heat radiators or sunlight can cause the infant's body temperature to rise to a dangerous level.

- The panel heater for the silicone gel mat may only be operated with other heat sources intended for this purpose.
- Skin sensors may not be positioned between the infant and the silicone gel mat.
- The infant may not be placed higher than the contact surface of the silicone gel mat.



#### Fire hazard due to covered heat radiator

If the heat radiator is covered, there is a risk of fire due to heat development.

The heat radiator may not be covered.

# 4. Operation



# Risk of injury by falling out

If the panel is open, the infant may fall out of the deck.

 Do not leave the infant unattended when the panel is open and do not leave the heating bed.



# Health hazard due to incorrect operation of the panel heater

- Do not operate the panel heater without the silicon gel mat.
   Only use the original Löwenstein Medical GmbH & Co KG silicone gel mat.
- Position the silicone gel mat flat on the deck
   Do not cover the silicone gel mat with pillows or other objects (insulation between silicone gel mat and infant)
- Duration of heating the silicone gel mat from 23°C to 37°C => approx.
   90 min. Until the target temperature is reached, cover and/or dress the infant.

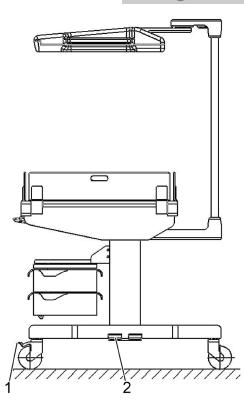


# Damage to the silicon gel mat

Sharp objects may damage the silicon gel mat.

Do not place sharp-edged objects on the silicone gel mat.

# Moving the device



- **1.** Bring the heat radiator into home position.
- 2. Unlock the lockable castor (1).
- **3.** Bring the deck to minimum height with the corresponding pedal plate (2), ensuring a free stroke range.
- **4.** Take the device to the required place.
- **5.** Lock the lockable castor (1).
- Only move the device with retracted pillar and the heat radiator in the home position.

# Deck TEMP. °C LÖWENSTEIN medical

(1) Alarm field

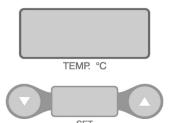
# (2) Temperature display field



**1.** Activate the panel heater using the ON/OFF switch.

When the device is switched on, an alarm signal sounds for approx. one second and the visual indicators in the alarm field light up (power failure LED does not light up). This procedure checks all alarm functions.

The temperature display field will show the value 88.8 for approximately one second. This serves to check the function of all light segments.



- **2.** Use the arrow keys in the "**SET**" field to set the desired temperature of the deck to between 28°C and 38.5°C.
  - The currently measured temperature of the deck is shown in the temperature display field "TEMP °C".
  - Reaching the set temperature will take no more than 90 minutes.



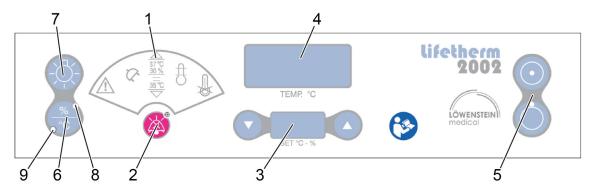
If the temperature should exceed 37°C or fall below 35°C (leaving the safe range), this must be confirmed with the MUTE ALARM key.



- **3.** Use the buttons located on the left-hand control panel to set the desired tilt angle of the deck.
  - Head-down position
  - Head-up position

# **Heat radiator**

# **LIFETHERM 2002**



- (1) Alarm field
- (2) Temperature display field
- (3) Temperature adjustment field
- (4) Temperature display field for measured temperature
- (5) ON/OFF buttons

- (6) Toggling the temperature display from °C to %
- (7) Lighting ON/OFF
- (8) LED operation of the heat radiator via skin sensor
- (9) LED manual operation of the heat radiator
- **1.** Connect the temperature sensor to the socket provided in the deck.

The temperature sensors to be used must be attached to the infant as follows:

 Skin sensor: fixed on the skin of the chest with tape.



 Activate the ceramic heater using the ON/OFF switch. When the device is switched on, an alarm signal sounds for approx. one second and the visual indicators in the alarm field light up (power failure LED does not light up). This procedure checks all alarm functions.

The temperature display field will show the value 88.8 for approximately one second. This serves to check the function of all light segments.

- When switched on, the device always shows the last set values. If a value greater than 30 % heat output was last set, this value must first be confirmed by pressing the "Mute Alarm" button as otherwise there will be a heat output of 30%.
  - 2. Use the arrow keys in the "SET" field to set the desired temperature to between 32°C and 37.5°C.
    - The temperature currently measured by the skin sensor is shown in the temperature display field "TEMP °C".
    - The temperature of the heat radiator is controlled so that the temperature measured by the skin sensor corresponds to the temperature set in the "SET" field.
  - In the preheating phase of the heat radiator, the temperature is not regulated to the infant's temperature. The infant should only be placed in the device in "manual" or "skin temperature control" mode.



TEMP. °C

If the temperature should exceed 37°C or fall below 35°C (leaving the safe range), this must be confirmed with the "MUTE ALARM" key.



- The upper button on the left-hand control panel is used to switch a halogen lamp in the radiator for lighting the deck ON and OFF.
- Use the lower button to switch between automatic operation of the heat radiator via skin sensor (°C) and manual operation (%). Operation is indicated by illumination of the corresponding LED.

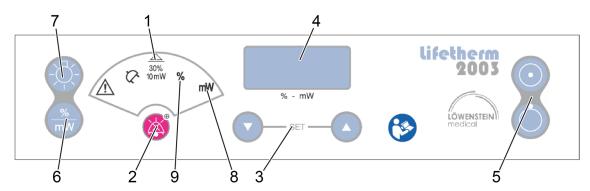


- With manual operation (%), a heating output of 30%, corresponding to a power of 10 mW/cm² at deck level, is provided as standard. If a heat output of 30% is to be exceeded (leaving the safe range), this must be confirmed with the "Mute Alarm" button. After 15 minutes, the device returns to the heating power of 30% with an audible alarm.

  During manual operation, "---" is displayed in the temperature display field "TEMP °C".
- If the skin sensor is removed from the infant's skin, the system switches to manual mode and emits an "Low-temperature alarm", which can only be cancelled by pressing the MUTE ALARM button. The heat radiator deactivates.
  - When the heat radiator is switched off, the infant's body temperature can cool down
- The operating mode via skin sensor (°C) should be used as often as possible, as a controlled heat output of greater or smaller than 30 mW/cm² can be emitted here over a longer period of time.

#### **LIFETHERM 2003**

The LIFETHERM 2003 heat radiator has **no** automatic operation with regulation via a skin sensor. Only manual operation is possible.

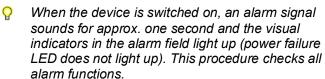


- (1) Alarm field
- (2) Mute Alarm button
- (3) Heat output control panel
- (4) Heat output display field for set heat output
- (5) ON/OFF buttons

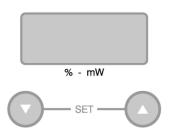
- (6) Toggling the temperature display from % to mW (selected operation is shown in the alarm field)
- (7) Lighting ON/OFF
- (8) Set value heat output in mW/cm2
- (9) Set value heat output in%



 Activate the ceramic heater using the ON/OFF switch.



The temperature display field will show the value 88.8 for approximately one second. This serves to check the function of all light segments.



- **2.** Use the arrow keys to set the desired heat output in % or in mW/cm².
  - The desired heat output in % or in mW/cm² is shown in the heat output display field "% mW".



If a heat output of 30 % or 10mW/cm² is to be exceeded (leaving the safe range), this must be confirmed with the "**Mute Alarm**" button.



- The upper button on the left-hand control panel is used to switch a halogen lamp in the radiator for lighting the deck ON and OFF.
- In manual operation of the heat radiator, the lower button can be used to switch between the set value for heating output in % and heating output in mW/cm². Operation is indicated by illumination of the corresponding LED (9) or (8).

Table 8: Relationship between heat output in mW/cm² and heat output in %

Heat output		Heat o	output
mW/cm²	%	mW/cm²	%
2	10	18	60
6	20	22	70
10	30	24	80
12	40	26	90
14	50	30	100

# 5. Alarms

# List of alarm messages

Alarm	Description	Removal	Limit value	Filtering	Priority	LED
Mains alarm	Occurs in the event of a power failure with the panel heating switched on (audibly and visually for at least 10 minutes)	Remedy mains outage		-	1	-
	Occurs in the event of the mains plug being pulled out with the panel heating switched on (audibly and visually for at least 10 minutes)	Insert mains plug				
Target temp. alarm *	If the temperature exceeds or falls below the set temperature by more than 1°C	Press the "Mute Alarm" button. This mutes the audible alarm again until the set temperature is reached. (Duration of audible suppression with "Mute Alarm" button, max. 15 minutes). When the device is switched on, the alarm is automatically suppressed for 30 minutes during warm-up.	Set temperature ± 1°C	2 s	1	#
Sensor alarm	Occurs when a temperature sensor breaks (audible and visual). The panel heating is switched off	If the error is not fixed by a restart or it is repeated, notify a service technician authorised by Löwenstein Medical	Interruption / Short- circuit	2 s	1	*
	Occurs during a possible faulty measurement of a temperature sensor (audible and visual). The panel heating is switched off	(Duration of audible suppression with " <b>Mute Alarm</b> " button, max. 15).	-	2 s	1	
	Occurs when the deck temperature of 40°C is exceeded (audible and visual). The panel heater is switched off		40°C	2 s	1	
	Does not occur with inserted sensor	Insert sensor or change to manual operation	-	2 s	1	
System alarm	occurs with a system error in the software	If the error is not fixed by a restart or it is repeated, notify a service technician authorised by Löwenstein Medical (Duration of audible suppression with "Mute Alarm" button, max. 15)	-	2 s	1	<u> </u>

Alarm	Description	Removal	Limit value	Filtering	Priority	LED
High- temperature alarm	Occurs with temperature setting > 37°C (audible and visual)	Lower temperature setting (Duration of audible suppression with "Mute Alarm" button, max. 15)	> 37°C	2 s	1	
Low- temperature alarm	Occurs with temperature setting < 35°C (audible and visual)	Increase temperature setting (Duration of audible suppression with "Mute Alarm" button, max. 15)	< 35°C	2 s	1	$\overline{\nabla}$
	Occurs when the skin sensor is removed	Attach skin sensor (Duration of audible suppression with " <b>Mute Alarm</b> " button, max. 15)	-	2 s	1	
Audible alarm	Occurs when the device should exceed the heating capacity of 30% in manual operation	Reset with "Mute Alarm" button	-	2 s	1	
	Occurs when the device returns to 30% heat output in manual mode	Reset with "Mute Alarm" button	-	2 s	1	

<sup>\*</sup> Two independent temperature sensors (PT 100) are embedded in the panel heater. One temperature sensor is responsible for heat control, the other for the display of the deck temperature.

# Factory settings of the alarms

Table 10: Factory settings of the alarms		
Mains alarm	OFF	
Target temp alarm	OFF*	
Sensor alarm	OFF	
System alarm	OFF	
High-temperature alarm	OFF	
Low-temperature alarm	OFF	

<sup>\*</sup> When the device is switched on, the alarm is automatically suppressed for 30 minutes during warm-up.

## **Testing the alarms**



Always check the alarms before using the device.

### LIFETHERM 2000 (heating bed)

#### Mains alarm

 Pull the mains plug while the device is switched on.

The LED for mains failure alarm lights up and the audible signal sounds.

2. Connect the mains cable.

The audible and visual alarm stops.

#### Target temp. alarm

- **3.** Set a target value < 1° of the measured value. This triggers an audible and visual alarm.
- **4.** Set the value within 1° deviation for the alarm to stop.

#### **LIFETHERM 2002**

#### Sensor alarm

1. Disconnect the skin sensor.

The red LED for sensor breakage lights up and the audible signal sounds

**2.** Connect the sensor. The alarm signal and LED stop.

Heating output alarm

**3.** Switch the heat radiator to "Percent control" and set a heat output value of < 40%.

This triggers an audible and visual alarm after 15 minutes.

Mains alarm

**4.** Pull the mains plug while the device is switched on

The LED for mains failure alarm lights up and the audible signal sounds (applies to deck and heat radiator of the front panel).

Connect the mains cable. The audible and visual alarm stops.

Target temp. alarm

- **6.** Set a target value < 1° of the measured value. This triggers an audible and visual alarm (applies to deck and heat radiator).
- **7.** Set the value within 1° deviation. The alarm stops.

If 30% is exceeded, an audible and visual alarm is triggered.

10mW/cm² were exceeded from 30% to 40%

#### **LIFETHERM 2003**

Heating	output	alarm
HUGHING	output	aiaiiii

 Switch the heat radiator to "Percent control" and set a heat output value of < 30 %.</li>
 This triggers an audible and visual alarm after 15 minutes.

Mains alarm

2. Pull the mains plug while the device is switched

The LED for mains failure alarm lights up and the audible signal sounds (applies to deck and heat radiator of the front panel).

- **3.** Connect the mains cable. The audible and visual alarm stops.
- **4.** Set a target value < 1° of the measured value. This triggers an audible and visual alarm (applies to deck).
- **5.** Set the value within 1° deviation. The alarm stops.

Target temp. alarm

#### 6. Maintenance

## **Preparations**

- 1. Switch off the device.
- 2. Disconnect the mains plug
- **3.** Remove additional parts (tubes, tube feed-through, etc.).
- **4.** Remove the sensor and sensor cable.
- 5. Remove the silicon gel mat
- **6.** Remove water-absorbing parts (nappies, cellulose, etc.)
- 7. Remove peripheral devices.
- 8. Bring the heat radiator into transport position.

## Cleaning and disinfection



Incorrect cleaning and sterilisation!

#### Risk of device damage

- Do not autoclave the silicone gel mat.
- Do not cold-sterilise the plug connection of the skin sensor or bring it into contact with cleaning solution.
- Do not autoclave or sterilise the skin sensor with gas.
- Do not immerse the sensor in liquid cleaning agents.
- Do not use cleaning and disinfection procedures other than those recommended by the manufacturer without first checking with the manufacturer whether these proposed procedures will damage the device.



Cleaning and disinfection should be carried out at least once per week and after every patient change. In the case of auxiliary devices, the corresponding instruction manual must be observed.

- **1.** Wipe off any dirt on the device with a damp cloth and cleaning agent.
- 2. Wipe-disinfect all surfaces.
- **3.** Dry the device to prevent germs.
- Clean the silicone gel mat and wipe-disinfect it with a suitable disinfectant.

#### Skin sensor (Lifetherm 2002)

- 1. Pull the skin sensor from the device.
- **2.** Clean the skin sensor carefully with a soft cloth moistened with a suitable disinfectant.
- **3.** After cleaning, dry the sensor thoroughly.
- The skin sensor is guaranteed for 1 year or a maximum of 52 cleaning cycles. Damage caused by neglect is excluded from this guarantee. No guarantee is given for damage to electrical components of the skin sensor caused by improper handling, especially during cleaning.

#### Silicone parts

- **1.** Wash silicone parts with detergent and then rinse them with clean water.
- 2. Sterilise the components.
  - Use a disinfectant bath. Remove the components after the prescribed time. Rinse the components with clean water and dry them.

or

Sterilize the components at 120°C (glove programme).

## Authorised cleaning agents and disinfectants

#### **Plexiglass**

Plexiglass is sensitive to certain solvents. When using these agents, hairline cracks (stress corrosion) occur in the material.

Be sure to observe the compatibility list below.

Table 11: Approved cleaning agents for Plexiglass			
	Brand product	Manufacturer	
++	Dismozon Pur	Bode Chemie	
++	Perform	Schuelke & Mayr	
++	Incidin Extra N	Ecolab	
++	Mikrozid® universal	Schülke	
++	Mikrozid® sensitiv	Schülke	

#### Skin sensor (Lifetherm 2002)

The following cleaning solutions can be used to disinfect the skin sensor:

Table 12: Approved cleaning agents for the skin sensor

	Mixture	Maximum concentration
++	Sodium hypochlorite (bleach)	0.5 % solution in water
++	Glutaric aldehyde	2 %
++	Hydrogen peroxide	6 %
++	lodophor solution	0.27 %
++	Cavicide ®	100 % Spray

The sensor may be damaged if the cleaning/disinfection solutions contain chemicals (such as alcohol, acetone, etc.) that are not listed above, or if their concentration is higher than the concentration listed above.

#### **Maintenance instructions**

- 1. Pull the mains plug.
- 2. Cleaning and disinfect the device.
- When replacing the light source, do not touch the touchable contacts of the light and the patient at the same time.
- Q LIFETHERM 2002:

The skin sensor does not require calibration.

#### Inspection and maintenance

The devices LIFETHERM 2000, 2002, 2003 must be subjected to annual inspection and maintenance by a service technician authorised by Löwenstein Medical. The inspection is performed as described in the Service Manual.

Use original Löwenstein Medical GmbH & Co KG spare parts for maintenance.

Repairs may only be carried out by a service technician authorised by Löwenstein Medical.

Instructions and descriptions of the repairs including circuit diagrams and component lists can be found in the Service Manual.

#### Repairs

## 7. Technical data

Table 13: Life	
Heating bed	8 years
Heat radiator	8 years

# **Heating bed**

Table 14: Environmental conditions		
<b>During operation</b>	Temperature	10 to 35 °C
	Atmospheric pressure	760 to 1060 hPa
	rel. humidity	30 to 90 %
During transport and storage	Temperature	-20 to 60 °C
	Atmospheric pressure	500 to 1060 hPa
	rel. humidity	10 to 90 %

Table 15: Performance data for the deck		
Heating output	240 W	
Set temperature	28 – 38.5 °C	
Control accuracy	0.1 °C	
Alarms (15 min interval)	Mains outage Target temperature Temp. < 35°C Temp. > 37°C	
Temperature difference	>1°C deviation	
Electrical mains connection	230 V 50/60 Hz	
Mains supply line	3 m	

Table 16: Dimensions and weights			
LIFETHERM 2000 (heating bed)	Dimensions (L x W x H)	900 x 600 x 1080 mm	
	Weight (without heat radiator)	120 kg	
LIFETHERM 2002, LIFETHERM 2003	Dimensions (L x W x H)	1150 x 600 x 1900 mm	
	Weight (with heat radiator)	130 kg	
Surface		0.41 m²	
Surface height (with	hout lifting pillar)	940 mm	
Surface height (with	h lifting pillar)	930 mm to 1180 mm	
Inclination angle		Head up 16°, head down 15°	
max. patient weight	İ.	8 kg	
max. load on drawe	er block	2 kg	
max. load on device	e rail	5 kg	
max. load on monit	or shelf tray	10 kg	
Table 17: Measurem	ents		
2 x Temperature sensors (internal)		NTC	
Thermo switch		Safety shut-off 50°C	
Table 18: Deck power	er		
Deck power panel h	neater	240 W (2x120 W)	
Lifting pillar		90 – 100 W	
Inclination motor		36 W	
Electronics		33.5 W	
		1	
Table 19: Fuses			
LIFETHERM 2000 (heating bed)	Mains input	2 x 2.0 AT 6.3 x 32 mm (US)	
	Lifting pillar (if available)	1 x 1.25 A T 20 x 5 mm	
LIFETHERM 2002, LIFETHERM 2003	Mains input	2 x 3.15 A T 6.3 x 32 mm (US)	
LII LIIILIXIVI 2003	Motherboard	2 x 0.08 A T	
Table 20: Interfaces			
Interface 1		only use for purposes of service	
Interface 2		only use for purposes of service	
Interface 2		only use for purposes of service	

# Heat radiator (Lifetherm 2002, 2003)

Table 21: Performance data		
Heat output	600 W / 250 V	
Set temperature	32 – 37.5 °C	
Control accuracy	0.1 °C	
Alarms (15 min interval)	Mains outage Target temperature Temp. < 35°C Temp. > 37°C Sensor break (defective)	
Electrical mains connection	230 V 50/60 Hz	
Halogen spotlight	20 W	

Table 22: Dimensions and weights		
Dimensions	approx. 700 x 280 x 135	
Weight	9.7 kg	

Table 23: Measurements (only LIFETHERM 2002)		
Temperature measurement	1 x skin temperature	
Skin measurement control	+/- 0.2°C	

Table 24: Deck power		
Deck power panel heater	240 W (2x120 W)	
Lifting pillar	90 – 100 W	
Inclination motor	36 W	
Electronics	33.5 W	

Table 25: Fuses	
Motherboard	2 x 0.16A T

# 8. Accessories and replacement parts

Pos.	Name	Standard	Optional	Art. no.
1	Side panel low	Lifetherm 2002 + 2003		0126062-5
2	Rear panel low	Lifetherm 2002 + 2003		0216063-5
3	Front panel low	Lifetherm 2002 + 2003		0216063-5
7	Skin temperature sensor	Lifetherm 2002		0216021
8	Side panel high	Lifetherm 2000		0216058
9	Rear panel high	Lifetherm 2000		0216061
10	Front panel high	Lifetherm 2000		0216059
11	Mains cable	all		0170078
12	Drawer block incl. attachment set		all	0215510
13	Monitor shelf tray		Lifetherm 2002 + 2003	0215545
14	Device rail set, both sides		all	0215570
15	Device rail between the tiebars		Lifetherm 2002 + 2003	0215520
16	Device rail for injector and/or O <sub>2</sub> flow meter		Lifetherm 2002 + 2003	0215535
17	Device rail on lifting pillar		all	0216075
18	Adapter for tube holder		all	0216069
19	Tube feed-through		all	0216070
20	Tube support arm set		all	0216068
21	Silicon gel mat (770 x 520 x 13)		all	0210043
22	Blind mandril Ø4.6 mm with art. no. 210043		all	0150090
23	Universal bracket		all	0215700
24	Infusion bottle holder		all	0140060 + 0140061
25	Bottle holder		all	0210013- 2bg
26	Folding Plexiglass hood (only for high panels)		all	0215550
27	Closed Plexiglass hood (only for high panels)		all	0215560
28	Safety panel incl. brackets		all	0216067
29	Silicon gel mat (760 x 470 x 13) with art. no. 216067		all	0210048



Subject to change

As at 25.06.2020



#### Löwenstein Medical GmbH & Co. KG

Arzbacher Straße 80 56130 Bad Ems/Germany

P: +49 2603/9600-0 Fax: +49 2603/9600-50

Internet: www.hul.de

User manual Lifetherm

Order no.: ba-0070

**C** € 0197