

Löwenstein Medical · Arzbacher Straße 80 · 56130 Bad Ems

Medical Safety Office

<<Adr_1>>

<<Adr_2>>

<<Adr_3>>

<<Adr_4>>

<<Adr_5>>

email: export@loewensteinmedical.com

Customer No.: <<KNR>>

26-Feb-26

URGENT Safety Notice

FSCA2026005 Neonatal heat therapy devices
Lifetherm 2000 – Lifetherm 2002 – Lifetherm 2003

Dear Sir or Madam,
at Löwenstein Medical, quality and patient safety are our top priorities. For this reason, we are issuing the following urgent safety information regarding a potential hazard.

Manufacturer:

Löwenstein Medical SE & Co KG, Arzbacher Straße 80, 56130 Bad Ems Germany

Addressee

Operators and users of the products listed below

Affected products:

List of affected products manufactured from November 2025 onwards.

Trade name	Item number
Lifetherm 2000 heated bed, height-adjustable	0215000hul200
Lifetherm 2002 resuscitation unit	0216001hul300
Lifetherm 2003 resuscitation unit	0216002hul300

Serial numbers of affected devices outside of Germany:

0215000hul99945719; 0215000hul99945721; 0215000hul99945722; 0215000hul99945723; 0215000hul99945724;
0215000hul99945750; 0215000hul99945751; 0215000hul99945755; 0215000hul99945756; 0215000hul99945757;
0216001hul99950290; 0216001hul99950292; 0216001hul99950293; 0216001hul99950294; 0216001hul99950295;
0216001hul99950296; 0216001hul99950297; 0216001hul99950298; 0216002hul99955190; 0216002hul99955193

Description of the problem

The listed products contain display boards – Part-No. 0210026v01 with components that have been incorrectly assembled.

These components could become damaged after an indefinite period of operation. This could lead to device failure.

Risk assessment:

To date, no device failures resulting from the problem described have been reported to Löwenstein Medical.

No defects have been identified within the production process or during the associated product testing.

Should the components become damaged, this could lead to device malfunctions.

The heating function would fail and the device would emit an audible alarm.

FSCA2026005 2026-03-02

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Handelsregister
Amtsgericht Koblenz
HRA 20732
IK-Nr. 590711157
St.-Nr. 30/201/00291
USt-IdNr. DE 270737704

Bankverbindungen
Commerzbank Koblenz
BIC COBADEFFXXX
IBAN DE45 5704 0044 0200 1352 00
Volksbank Rhein-Lahn-Limburg
BIC GENODE51DIE
IBAN DE14 5709 2800 0200 4739 06

Komplementärin
Löwenstein Verwaltungs SE
Sitz: Bad Ems
Geschäftsführende Direktoren:
Reinhard Löwenstein
Benjamin Löwenstein
Amtsgericht Koblenz, HRB 28045

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In the event of damage, the component could also potentially lead to overheating and smoke development, although the probability of this occurring is considered extremely unlikely.

We consider the risk to patients to be extremely low, particularly due to the risk class of the products.

Action required by end customers and all users:

- Please observe the information in the operating instructions / Chapter 1 / Section Residual Risks, according to which the product should not be operated unattended.
- In the event of a fault, take the device out of service and contact your local distributor.

Action required by distributors:

- Please forward this safety information immediately to customers who received affected devices.
- Please confirm receipt of this letter by completing the FSN-form attached in Annex A and returning it by 31 March 2026 at latest.
- As corrective action the affected display board – Part-No. 0210026v01 must be replaced.
Dispose of the removed circuit board.
Replacement Instruction see Appendix C
- Löwenstein medical will send the required quantity.
- Please confirm implementation of the corrective action by completing the CA form attached in Annex B and returning it by 31 May 2026 at the latest.

Action required by the manufacturer:

- Forwarding of this safety information to affected distributors. (This document)
- Löwenstein Medical will send the required quantity of fault-free circuit boards to distribution partners.

If you have any questions, please do not hesitate to contact us using the above contact details, or get in touch with your usual colleagues in our service support.

We apologize for any inconvenience caused by this measure.

Sincerely

Medical Device Safety Officer (PRRC)

Annex A: FSN-Feedback to Löwenstein Medical

Annex B: FSCA-Feedback to Löwenstein Medical

Annex C: Replacement Instruction

Annex A - FSN-Feedback

Feedback of Field Safety Notice FSN to Löwenstein Medical Regarding FSCA2026005 Lifetherm

Original letter sent to:

<<Adr_1>>
<<Adr_2>>
<<Adr_3>>
<<Adr_4>>
<<Adr_5>>

Please send this completed feedback form to
RecallMD@loewensteinmedical.com
and do not forward this return receipt to any other organization.

Löwenstein Medical
Medical device safety
Arzbacher Strasse 80
56130 Bad Ems
Germany

Please complete in block letters:

- ✓ I hereby confirm receipt of this letter and that I have read and understood its contents.
All users of the product and other persons in my organization who need to be informed will be made aware of this letter.

Name (in block letters)

Position (in block letters)

Email (in block letters)

Date

Signature

Annex B - FSCA-Feedback

Feedback of corrective action to Löwenstein Medical

Regarding FSCA2026005 Lifetherm

Delivery list of affected products to your organization
for safety information FSCA2026005 Lifetherm.

Description	serial number

Original letter sent to:

<<Adr_1>>
<<Adr_2>>
<<Adr_3>>
<<Adr_4>>
<<Adr_5>>

Please return this feedback form to RecallMD@loewensteinmedical.com once you have completed the corrective action as described.

Löwenstein Medical
Medical device safety
Arzbacher Strasse 80
56130 Bad Ems
Germany

Please complete in block letters:

- ✓ We hereby confirm that the **corrective action** on the devices listed above have been successfully completed as described.

Name (in block letters)

Position (in block letters)

Email (in block letters)

Date

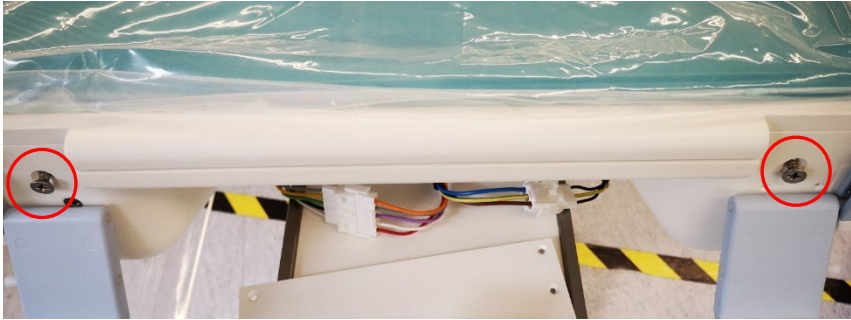

Signature

Annex C - Replacement Instruction

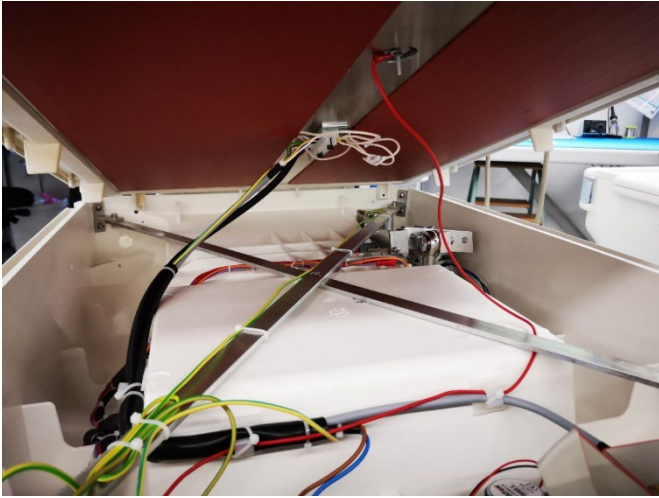


This instruction describes how to replace the display board (part number 0210026v01) of Liftherm 2000 / 2002 and 2003.

Before you start:

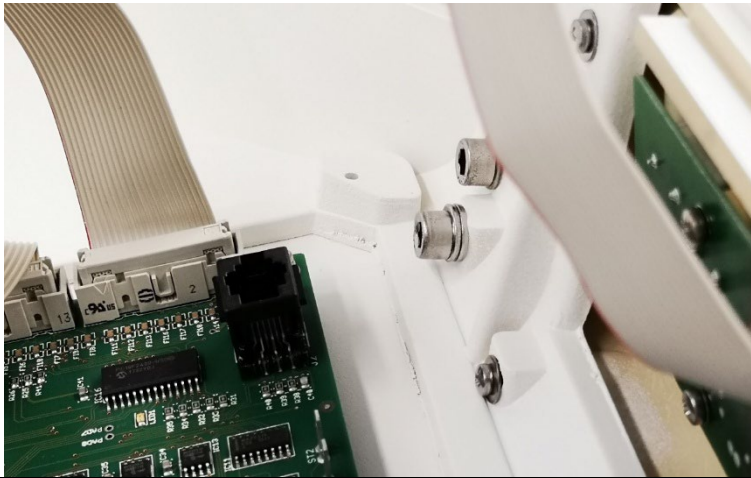
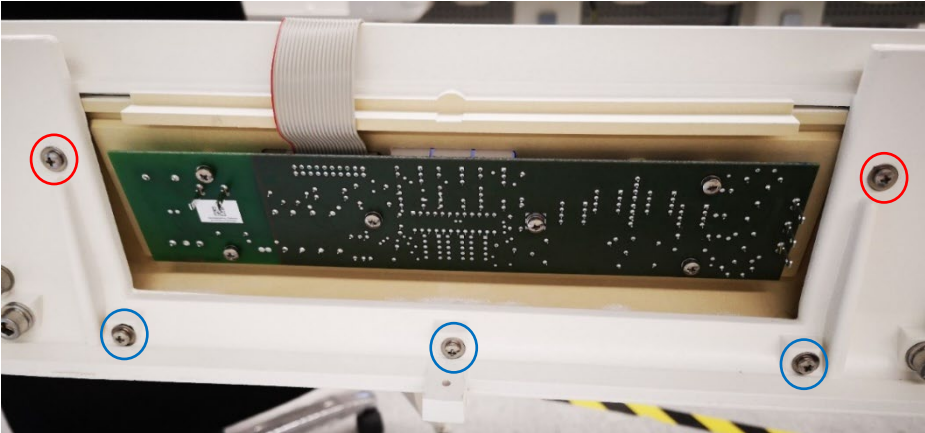

Disconnect the Liftherm from the **mains AC voltage!**

Step 1	
	<ul style="list-style-type: none"> Remove screws on the front and back sides
	<ul style="list-style-type: none"> Remove screws on left and right sides

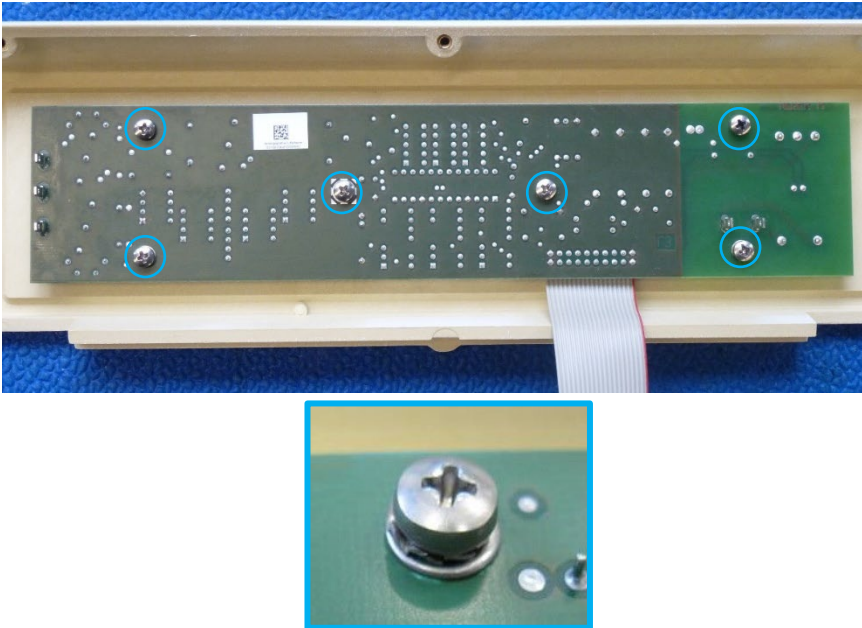
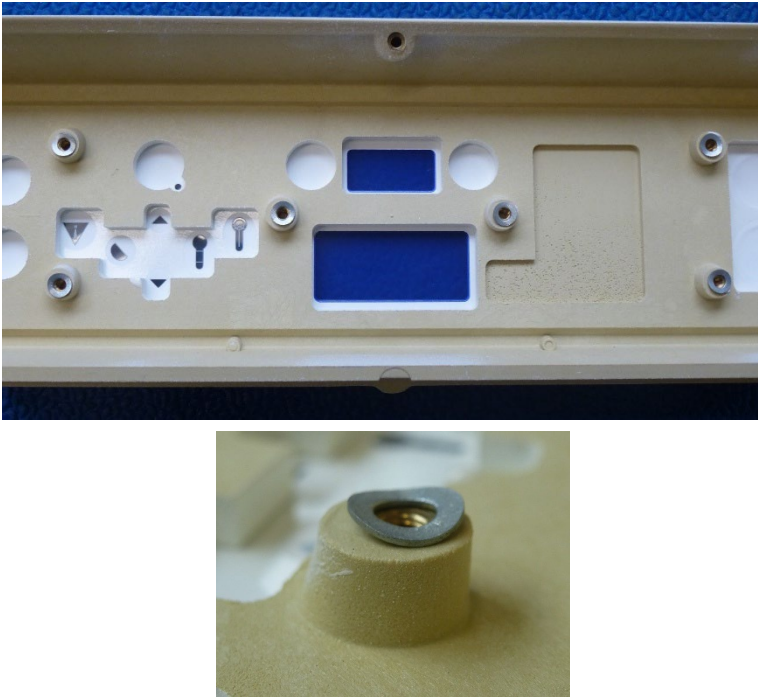
Annex C - Replacement Instruction

Step 2	Description
	<ul style="list-style-type: none"> • Rotate lying surface by 90° and put it on base body
Step 3	Description
	<ul style="list-style-type: none"> • Remove red, white and violet cable
	<ul style="list-style-type: none"> • Remove both brown cables

Annex C - Replacement Instruction

Step 4	Description
	<ul style="list-style-type: none"> Remove flat cable
Step 5	Description
 	<ul style="list-style-type: none"> Remove screws (2x) M3x12 and washer 3,2 Remove screws (3x) M3x16 and washer 3,2 Remove complete user interface

Annex C - Replacement Instruction

Step 6	Description
	<ul style="list-style-type: none"> Remove screws (6x) and washer Remove display board
Step 7	Description
	<ul style="list-style-type: none"> Replace the new display board Be careful with the washer placed over the threads bushings
<p>Assemble in reverse order</p>	
<p>Dispose of the removed circuit board. It should never be used as a spare part!</p>	
<p>Test the device in accordance with the Service manual LIFETHERM 2000, 2002, 2003 - Rev. 3.0.0</p> <p>If you have any technical issues, you can contact our service support team: supportmd@loewensteinmedical.com</p>	