

August 2026

Update V2: Urgent Safety Information –
Overheating of an Electronic Component (Patient Safe, Failsafe)
LEONI plus HFO, LEONI plus transport

Dear Sir or Madam,

Quality and safety are our top priorities. For this reason, it is important to us to publish the following urgent safety notice regarding a potential hazard.

Manufacturer:

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

Recipients:

Distributors, operators, and users of the products listed below.

Affected products:

Description	Part Number	Serial number
LEONI plus	0217001	0217001hul41000479 through 0217001hul99960589
LEONI plus HFO	0217004	0217004hul45501299 to 0217004hul99971231
LEONI plus transport	0217400	0217400hul10100020 to 0217400hul99990051

as well as all devices in which the internal gas mixer (part numbers beginning with 0217550 or 0217551) has been replaced since July 1, 2016.

Description of the problem and the identified cause:

- In the listed products, an electronic component may overheat internally.

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Impact / Potential Hazards:

- Overheating over an extended period of time can lead to impaired functionality or even device failure. Furthermore, prolonged overheating may result in smoke generation and, in the worst case, could lead to a fire.

Required actions by the operator/user:

- It is recommended that you do not leave devices in standby mode. Instead, devices should be turned off completely when not in use. The device may be connected to the power supply to charge the internal battery, provided that the device is turned off.
- Users should generally ensure that, in the event of a malfunction, appropriate **contingency measures** are available in accordance with clinical routine.
- Please inform all users of this notice and ensure that its contents are understood and followed.
- Please confirm receipt of this safety notice by returning **the** completed **Appendix A** to your local distributor.

Action by the service provider:

- Distribution of this safety information to all affected customers
- Implementation of the additional measures outlined in 'FSCA2026011 Service Instruction.
- Check all gas mixers in your stock for this issue.

The required inspection of the devices must be completed by **January 31, 2027**, at the latest.

We apologize for any inconvenience this safety notice may cause you. However, this measure is essential as a preventive step to enhance patient safety.

We are available to answer any questions you may have at any time. If necessary, please contact your assigned customer service representative.

Sincerely,

Medical Device Safety Officer

Appendix A: Feedback form for end customers

Revision	Change
V1 2026-06-25	-
V2 2026-08-28	Implementation deadline: January 31, 2027 Impact / Potential Hazards:

Feedback form for end customers

**Urgent Safety Information FSCA2026011–
LEONI plus / LEONI plus HFO / LEONI plus transport Ventilators**

Please send this registration form, fully completed, to your local distributor

Name of your healthcare facility	
Address of your healthcare facility	
Name of the contact person	
Title or Position	
Phone number	
Email	

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

Date, Signature