LÖWENSTEIN
medical

Löwenstein Medical · Arzbacher Straße 80 · 56130 Bad Ems

Medizinproduktesicherheit
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Kundennummer: <<KNR>>

Juni 2026

Urgent Safety Information –

Resolution of software-related system responses (Patient Safe, Failsafe, false alarm)

Software Update for the LEONI 4 Ventilator

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 information regarding a potential hazard.

Manufacturer:

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

Recipients:

Distributors, operators, and users of the LEONI 4 ventilator.

Affected products:

All LEONI 4 ventilators with all software versions up to and including version 1.25 are affected:

Description of the problem and the identified cause:

Based on customer feedback and internal analyses, several software effects were identified that could lead to safety-related system reactions under certain conditions:

- **UI Freeze (Patient Safe Trigger)**
  Under certain conditions, an excessive amount of data during autoscaling could overload the available processor capacity. For safety reasons, this resulted in an automatic switch to the “Patient Safe” state.
- **Failsafe Trigger Due to Ripple Voltage**
  When switching from AC to battery power (e.g., by unplugging the power cord), a brief voltage ripple could occur, which incorrectly triggered a failsafe.

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

- **False alarm “Speaker error”**

  A combination of driver behavior, monitoring sensitivity, and false-positive detections led, in rare cases, to a “speaker error” alarm that required a manual restart.

Corrective action

All of the issues described have been resolved in software version **1.26**.

In doing so, data processing was optimized, voltage monitoring was adjusted, and the alarm monitoring architecture was fundamentally revised.

System behavior was improved to prevent false triggers and enable automatic recovery in exceptional cases, while real errors continue to be reliably detected and reported.

Impact / Potential Hazards:

Under certain conditions, the described software effects can lead to safety-critical system reactions:

- In the event of a **UI freeze**, the device may switch to the “Patient Safe” state. In this state, ventilation continues, but operability is limited. This can lead to a temporary interruption of the intended function or therapy and may require user intervention.
- A **failsafe activation** may occur unexpectedly **when switching from mains to battery power**. In the failsafe state, ventilation is interrupted.
- A **false-positive “speaker error” alarm** can cause uncertainty for the user and, in its current form, may require a restart of the device, thereby temporarily limiting the system’s availability.

Assessment:

In all cases described, there is a potential risk of a **temporary interruption in device function**. Depending on the clinical application, this may require a delayed resumption of treatment or a short-term switch to alternative measures.

There is no evidence of permanent harm to patients; however, a delay in therapy cannot be completely ruled out in individual cases.

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Required actions by the operator/user:

- Ensure that the affected devices are updated to software version **1.26** as soon as possible. Contact the responsible service department if necessary.
- Until the software update is performed, the described effects (e.g., Patient Safe, failsafe activation, or false alarm) may occur in rare cases.

  In these cases, proceed in accordance with the applicable operating instructions, in particular by checking the device status and, if necessary, restarting the system.
- Users should ensure that, in the event of a temporary device interruption, appropriate **contingency measures** are available in accordance with clinical routine.
- Please inform all relevant staff of this notice and ensure that the content is understood and taken into account.
- Please acknowledge receipt of this Field Safety Notice in accordance with the provided instructions.

Action taken by the manufacturer:

A software update, version 1.26, has been made available for the affected software.

Action by distributors and service providers:

- Identify the customers to whom the affected devices were shipped.
- Inform these customers about this safety notice.
- Ensure that the new software versions are installed on the devices.

Please confirm receipt of this security notice by returning **the** completed **Appendix A**.

The required device updates must be completed by **November 30, 2026**, at the latest.

The software update does not require additional training.

The update to version 1.26 is mandatory.

We apologize for any inconvenience this security 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 or service representative or reach out to our support team in Bad Ems at SupportMD@loewensteinmedical.com.

Sincerely

Medical Device Safety Officer (PRRC)

Appendix A: Feedback Form for Löwenstein Medical
Appendix B: List of affected products that were delivered to your institution

Löwenstein Medical SE & Co. KG
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Amtsgericht Koblenz, HRB 28045

Appendix A

Feedback to Löwenstein Medical
Safety Information FSCA2026009 LEONI 4

Original letter sent to:

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

Please send this registration form, fully completed, to
RecallMD@loewensteinmedical.com
and do not forward this form to any other organization.
Alternatively, you can use the online form.
Scan the QR code or follow this Link.

E-Mail: RecallMD@loewensteinmedical.com

Löwenstein Medical
Medical Device Safety
Arzbacher Straße 80
56130 Bad Ems
Germany

Please fill out completely 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 relevant individuals within my organization will be made aware of this letter.

_____
Date, Signature

_____
Name (in block letters)

_____
Position (in block letters)

_____
Email (in block letters)

Anlage B

Delivery list of the affected products to your organization
regarding safety information FSCA2026009 LEONI 4

If the status of any listed devices has changed, please note this in the right-hand column and also forward this page to **Löwenstein Medical**.

Pos	Item number	Description	Serial number	Device status change?