LÖWENSTEIN
medical

Löwenstein Medical · Arzbacher Straße 80 · 56130 Bad Ems

Medical Device Safety
<<Adr_1>>
<<Adr_2>>
<<Adr_3>>
<<Adr_4>>
<<Adr_5>>

Phone: <<Phone>>
Email: <<Email>>

Customer Number: <<KNR>>

November 2026

Urgent Safety Information

Software-Related System Responses on the LEONI 4: Touch Controls, User Interface, and Failsafe Mode

Software Update and Additional Safety Measures for the LEONI 4 Ventilator

Dear Sir or Madam,

As part of our ongoing product monitoring, we have identified several situations that, under certain conditions, may impair the operation or functionality of the device. Devices with software versions up to and including 1.27 are affected.

Manufacturer

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

SRN: DE-MF-000006028

Basic UDI-DI: 426055656Leoni4ZB

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 1.27 are affected:

Part Number: 0730000

Löwenstein Medical SE & Co. KG
Arzbacher Straße 80
56130 Bad Ems, Deutschland
T. +49 2603 9600-0
F. +49 2603 9600-50
info@loewensteinmedical.com
loewensteinmedical.com

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
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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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Description of the Problem and the Identified Cause

1. Limited touchscreen operation

In some cases, unintended touch signals may occur at the edge of the display. This can temporarily limit or completely block operation via the touchscreen.

Ventilation is not affected by this and continues to operate. The display content, the secondary display, and the alarm functions remain active. Operation via the rotary encoder is also still possible. However, an activated screen lock cannot be disabled via the rotary encoder in this situation.

Immediate Action by the User

Do not use a screen lock. If the screen lock is active and a touchscreen malfunction occurs at the same time, the device can no longer be operated using the regular controls. In this case, the device's **"Emergency Off"** function is required.

What to Do in Case of a Malfunction

If the described condition occurs and operation via the touchscreen is no longer possible, the device can be restarted using the rotary encoder, provided that the screen lock is not activated. Before restarting, ensure that the patient is being ventilated using a suitable alternative ventilation method.

Corrective Action

A new software version 1.30 is available that corrects this behavior.

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2. Behavior in the Event of High Negative Pressure During Suctioning

Under certain conditions, a strong negative pressure can develop in the ventilation system during suction. If this reaches a value of −50 mbar, the device may incorrectly interpret this as a pressure sensor error and subsequently switch to failsafe mode. In this mode, ventilation is interrupted.

Immediate Action by the User

When performing closed suctioning, take care to avoid unnecessarily high negative pressures. Excessive negative pressure can not only trigger the device behavior described above but also pose a potential hazard to the patient.

Action to Take in Case of a Malfunction:

If this condition occurs, the patient's ventilation must be immediately ensured manually. The device must then be restarted to restore proper operation.

Corrective Action

A new software version 1.30 is available that corrects this behavior.

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3. Malfunction or Failure of the User Interface

In rare cases, a delay or failure of the user interface may occur. As a result, the user interface may temporarily stop responding or the screen may remain completely black.

Ventilation is not affected by this and continues to operate. The auxiliary display and alarm functions also remain active.

Immediate Action by the User

Ensure that the devices have been properly configured in collaboration with an application consultant. This applies in particular to the correct connection and configuration of any PDMS (Patient Data Management System) that may be in use.

What to Do in Case of a Malfunction

First, ensure that the patient receives alternative ventilation, and then take the affected device out of service. The device can be reset using the **"Emergency Off"** function.

Emergency Off Function

Press the On/Off button repeatedly, spacing the presses about one second apart, until the device turns off. This process may take up to 30 seconds.

Once the device has completely powered down, it can be turned back on.

The device may be used again after restarting if the system test has been successfully completed and no further error messages occur during recovery.

Corrective Action

Software version 1.30 corrects the error scenarios described in points 1 and 2.

The software update scheduled for release by the end of the first quarter of 2027 will improve the stability of the user interface. Known causes of failure will be corrected. In addition, the update is designed to trigger an automatic recovery or restart of the user interface upon detection of a failure. Ongoing ventilation will not be interrupted during this process.

Required Actions by the Operator/User

- Inform all relevant staff members about this notice and ensure that the content is understood and followed.
- Ensure that a suitable alternative ventilation option is immediately available at all times while the device is in use. In the event of a malfunction or failure of the user interface, this will allow ventilation to continue safely while the device is being restored or restarted.

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Actions by the manufacturer

A software update to version 1.30 is available for the error scenarios described in points 1 and 2.

For the error scenario described in point 3, a further software fix is planned by the end of the first quarter of 2027. The corresponding software version has not yet been determined.

Actions by Dealers and Service Providers

- Identify the customers to whom affected devices were shipped.
- Inform these customers about this security advisory.
- Ensure that the software update to version 1.30 is installed on the affected devices by January 31, 2027, at the latest.

We apologize for any inconvenience this security notice may cause you. However, the measures described are necessary to further enhance patient safety.

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

We are happy to answer any questions you may have at any time. If necessary, please contact your assigned account manager or service representative, or reach out to our support team in Bad Ems at SupportMD@loewensteinmedical.com .

Sincerely,

Person Responsible for Regulatory Compliance (PRRC)

Appendix A: Feedback Form for Löwenstein Medical
Appendix B: List of affected products that were delivered to your institution
Link: end user information in several languages https://link.loewensteinmedical.com/fsca2026029

Löwenstein Medical SE & Co. KG
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Appendix A

Response to Löwenstein Medical
regarding safety information FSCA2026029 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.

Email: 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)

Appendix B

List of affected products shipped to your organization
regarding safety information FSCA2026029 LEONI 4

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

Item No.	Item Number	Description	Serial number	Device Status: Change?