

Löwenstein Medical • Arzbacher Straße 80 • 56130 Bad Ems

Medical Safety Office

<<Adr_1>>

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<<Adr_5>>

E-Mail: <<E-Mail>>

Customer No: <<KNR>>

May 2026

Field Safety Notice –

Software bug related to detecting a disconnection when PEEP=0

Software update for the intensive care ventilator elisa 300/500/600/600 R-VIT/800/800 R-VIT/800^{VIT}

Dear Sir or Madam,

Quality, safety, and customer satisfaction are our top priorities. For this reason, we feel it is particularly important to share the following urgent safety information with you. It concerns a potential hazard related to a malfunction in the ventilation function of elisa intensive care ventilators.

Manufacturer:

Löwenstein Medical Innovation GmbH + Co. KG, Weißkirchener Str. 1, 61449 Steinbach, Germany

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

Recipient:

Distributors, operators, and users of intensive care ventilators elisa.

Betroffene Produkte:

All intensive care ventilators elisa 300, elisa 500, elisa 600, elisa 600 R-VIT, elisa 800, elisa 800 R-VIT, elisa 800^{VIT} und elisa 800 VIT RO All software versions are affected.

Description of the problem and the identified cause:

Internal audits have revealed that, in some cases, a disconnection goes undetected during ventilation with PEEP OFF (PEEP = 0). This is due to the current design of the disconnection detection system. A disconnection refers to an interruption in the connection between the patient and the ventilator.

If this interruption goes unnoticed, it can have serious consequences.

FSCA2023024 2026-05-19

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BIC COBADEFFXXX
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Volksbank Rhein-Lahn-Limburg
BIC GENODE51DIE
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Komplementärin
Löwenstein Verwaltungs SE
Sitz: Bad Ems
Geschäftsführende Direktoren:
Reinhard Löwenstein
Benjamin Löwenstein
Amtsgericht Koblenz, HRB 28045

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Impact / Potential Hazards:

If a disconnection goes unnoticed, ventilation may be interrupted or inadequate. This can quickly lead to oxygen deprivation and a dangerous rise in carbon dioxide levels in the blood. As a result, the patient's condition can deteriorate rapidly and, in the worst case, become life-threatening or fatal.

Rating:

There are currently no known reports of such incidents in clinical practice, as ventilation with PEEP = 0 is typically used only in exceptional cases. However, since this setting is available, measures are needed to prevent the risk of an undetected disconnection.

Required actions by the operator/user:

Operators and users may continue to use the ventilators. However, it is essential to ensure that a PEEP value greater than 0 is always set during ventilation. A PEEP value of at least 0.5 mbar ensures reliable detection of a disconnection. Please ensure that all users of the products mentioned, as well as other relevant personnel within your organization, are informed of this Urgent Safety Notice. Please also file a copy of this letter in the equipment log. If you have transferred the products to third parties, please forward a copy of this notice or inform Löwenstein Medical accordingly.

Please confirm receipt of this safety notice by returning **Annex A**.

Action taken by the manufacturer:

Updates for the affected software will be provided until October 1, 2026. The issue has been resolved starting with the versions listed.

Affected versions	Starting with these versions, the bug has been fixed.
1.x.x to 1.11.3	1.11.4
2.02.x / 2.04.x to 2.04.8	2.04.9
2.05.x / 2.06.x / 2.07.x / 2.08.x / 2.09.x bis 2.09.16	2.13.10 or 2.16.5
2.10.x to 2.10.9	2.13.10 or 2.16.5
2.13.x to 2.13.9	2.13.10 or 2.16.5
2.16.x to 2.16.4	2.16.5
2.18.0	2.16.5

Action taken by retailers and service providers:

- Identify the customers to whom the affected devices were shipped.
- Please inform these customers about this safety notice.
- Make sure that the new software versions are installed on the devices.

Please confirm receipt of this safety notice by returning the completed **Annex A**.

The necessary updates to the devices must be completed by **March 31, 2027** at the latest.

The software update does not require any additional training, provided it is performed within the same software version.

Updating all **elisa intensive care ventilators** with the affected software version 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.

If you have any questions, please do not hesitate to contact us. If necessary, please reach out to your account manager or customer service representative, or contact our support team in Bad Ems at SupportMD@loewensteinmedical.com.

Sincerely,

Medical Device Safety Officer (PRRC)

Annex A: Feedback Form for Löwenstein Medical

Annex E-Mail: List of affected products that were delivered to your institution

Feedback to Löwenstein Medical

Safety Information FSCA2026013 elisa-PEEP

The original letter was 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 pass this return slip on to another organization. Alternatively, you can use the online form. Scan the QR code or follow this link [Link](#).

E-Mail: RecallMD@loewensteinmedical.com

Löwenstein Medical
Medizinproduktesicherheit
Arzbacher Strasse 80
56130 Bad Ems
Germany

Please fill out completely in block letters:

- ✓ I hereby confirm that I have received 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)