LÖWENSTEIN
medical

Löwenstein Medical · Arzbacher Straße 80 · 56130 Bad Ems

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

E-Mail: export@loewensteinmedical.com

07.01.2025

Field Safety Notice –

Software error with automatic patient detection (APD)

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

Dear Sir or Madam,

Quality, safety and customer satisfaction are our highest priorities. For this reason, it is important for us to pass on to you the following urgent safety information in connection with a potential hazard due to an influence on the elisa 300/500/600/800/800VIT 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

Addresses:

Distributors, operators and users of the intensive care ventilators elisa 300/500/600/800/800VIT.

Affected products:

Affected are all intensive care ventilators elisa 300, elisa 500, elisa 600, elisa 800 and elisa 800VIT with the following software versions:
SW Version 2.13.6

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56130 Bad Ems, Deutschland
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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

Devices with the following installed software versions of the software levels are not affected:
1.10.x / 1.11.x (current version: 1.11.3),
2.02.x / 2.04.x (current version 2.04.7),
2.06.x / 2.07.x / 2.08.x / 2.09.x (current version 2.09.16)
2.10.x (current version 2.10.9)
2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.13.5 und 2.13.7 (current version 2.13.7)
2.16.x (current version 2.16.1)

Description of the problem and the identified root cause:

As part of our market monitoring, we identified three cases in the Middle East where ventilation failed due to a software error, depending on the configuration used in the clinic.

When Automatic Patient Detection (APD) is configured and activated, the ventilator automatically switches to patient detection mode after a disconnection (e.g., during suctioning). In this mode, a constant flow of 6 l/min is delivered without further ventilation until the patient is detected again. However, the software error prevents both patient detection and the reset of the disconnection.

Despite this issue, the high-priority E7 alarm for “disconnection” is triggered in all cases, ensuring reliable alarming.

Possible dangers:

A ventilation failure can lead to hypoxia despite a high-priority alarm, potentially causing a significant deterioration in the patient’s health and, in the worst case, resulting in a fatal outcome.

Required action by the operator/user:

Operators and users can continue to use the ventilators but must ensure that alarms are responded to appropriately. Automatic Patient Detection (APD) must be deactivated until a software update is available. This will result in the disconnection alarm being triggered, but ventilation will continue.

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

Passing on the information described here:

Please ensure that all users of the named products and other relevant individuals in your organization are informed of this Urgent Safety Information. Additionally, file a copy of this letter in the device logbook.

If you have passed the products on to third parties, please forward a copy of this notification to them or inform Löwenstein Medical accordingly.

Retain this information until all necessary measures have been completed.

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Corrective action by the manufacturer:
A software update (version 2.13.7) will be provided to address the errors described. With this version, both patient recognition and disconnection reset will function correctly.
The software update (version 2.13.7 or higher) must be installed on all affected devices by July 31, 2025, at the latest.
No additional training is required for this update, provided it is applied to the same software level. However, an update of all elisa intensive care ventilators with the affected software version is generally required.

Corrective action by providers and partners:
A software update (version 2.13.7) will be provided to address the errors described in the affected software version 2.13.6. With this update, both patient recognition and disconnection reset will function correctly.
All partners are required to ensure that the software update (version 2.13.7 or higher) is installed on all devices currently running version 2.13.6 by July 31, 2025, at the latest.

No additional training for users is required as long as the update remains within the same fundamental software version (2.13.x) and does not introduce functional changes. However, all elisa intensive care ventilators with the affected software version must be updated without exception.

We apologize for any inconvenience this Field Safety Notice may have caused. However, we believe it is a necessary preventive measure to enhance patient safety.
If you have any questions, we are happy to assist you at any time.
For further assistance, please contact our technical support team at: SupportMD@loewensteinmedical.com.

With best regards

Jens Schmidt

Person Responsible for Regulatory Compliance (PRRC)

Annex A
Feedback form to Löwenstein Medical.
Annex B
List of products and serial numbers that we have supplied to you.

Löwenstein Medical SE & Co. KG
Arzbacher Straße 80
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Komplementärin
Löwenstein Verwaltungs SE
Sitz: Bad Ems
Geschäftsführende Direktoren:
Reinhard Löwenstein
Benjamin Löwenstein
Amtsgericht Koblenz, HRB 28045

Feedback to Löwenstein Medical

To the safety information „ patient detection (APD) “ Januar 2025

Original letter was sent to:

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

Please send us this completed filled form to RecallMD@loewensteinmedical.com, please do not forward this form to any other organization.
As option, you can use the online form. Scan the QR code or follow this link.

E-Mail: RecallMD@loewensteinmedical.com

Löwenstein Medical
Medizinproduktesicherheit
Arzbacher Strasse 80
56130 Bad Ems
Germany

Please fill the form:

✓ I hereby acknowledge 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 are to be informed will be notified.

_____
Date, Signature

_____
Name (in block letters)

_____
Position (in block letters)

_____
E-Mail (in block letters)

Annex B

To the safety information „ patient detection (APD) “ Januar 2025

Below you will find a list of serial numbers identified by Löwenstein Medical as affected.
We kindly ask you to check the respective devices and provide us with the current status. Please send the updated list to the following email address: RecallMD@loewensteinmedical.com.
Thank you for your support and prompt response!

Affected Products:

All elisa 300, elisa 500, elisa 600, elisa 800, and elisa 800VIT intensive care ventilators with the following software versions are affected:

- **Software level 2.13.6**

Devices with the following software versions are NOT affected:

- Software levels:
  - 1.10.x / 1.11.x (current version: 1.11.3)
  - 2.02.x / 2.04.x (current version: 2.04.7)
  - 2.06.x / 2.07.x / 2.08.x / 2.09.x (current version: 2.09.16)
  - 2.10.x (current version: 2.10.9)
  - 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.13.5, and 2.13.7 (current version: 2.13.7)
  - 2.16.x (current version: 2.16.1)

Pos	Bez.	Art. Nr.	SN	Status der Geräte	Installierte SW