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

**20.12.2023**

**Urgent safety information –**

**Error constellation alarm system in connection with the bronchoscopy maneuver**

**Software-Update for 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

**Addressees:**

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:
Software level 2.10.x – all software versions including 2.10.6
Software level 2.13.x – all software versions including 2.13.2



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**Handelsregister**
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St.-Nr. 30/201/00291
USt-IdNr. DE 270737704

**Bankverbindungen**
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**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: 1.11.03),
2.02.x / 2.04.x (current version 2.04.07),
2.06.x / 2.07.x / 2.08.x / 2.09.x (current version 2.09.15)

**Description of the problem and the identified root cause:**

To ensure stress-free therapy without constant alarms during bronchoscopy, the elisa 300/500/600/800/800VIT ventilators automatically extend the alarm limits when the *bronchoscopy maneuver* is started.

When the maneuver is completed, the originally set alarm limits are restored and displayed.

Due to an error constellation in the buffer memory, the audible and visual alarms are not triggered in accordance with the displayed alarm limits after the *bronchoscopy maneuver* is deactivated.

**Possible dangers:**

Due to this error constellation in buffer memory, most alarms are effectively disabled. If any parameter is changed (ventilation parameter, maneuver parameter, alarm limit), the correct values are copied back into the alarm system and everything functions again in accordance with the rules.

This error constellation is safety-relevant, as the ventilator does not give the correct acoustic and visual alarms for critical constellations in the time window between deactivation of the bronchoscopy maneuver and the change of a parameter (ventilation parameter, maneuver parameter, alarm limit).

**Required action by the operator/user:**

Clinics that have configured the *bronchoscopy maneuver* may no longer use this maneuver as a preventive measure.

We expressly recommend that the bronchoscopy maneuver option be permanently deactivated in the configuration by your person which is responsible for the devices!

Please confirm that you have received this safety notification to Löwenstein Medical with Appendix A.

**Disclosure of the information described herein:**

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this **Urgent Safety Information**. Please file a copy of the letter in the device book.

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

Please retain this information at least until the measure has been completed.



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**Corrective action by the manufacturer:**
Löwenstein Medical provide an update for each of the two software levels on the market (version 2.10.7 and 2.13.3), in which this error constellation is rectified and the correct alarm parameters are copied into the alarm system.

**Corrective action by providers and partners:**
The above-mentioned software update must be installed for all devices of software levels 2.10.x and 2.13.x at the latest as part of the next annual maintenance or when service is due.
The software update does not require instruction, provided that the update is carried out at the identical software level.

We apologize for the inconvenience this Field Safety Notice may have caused you, but we believe it is necessary as a preventive measure to increase patient safety.
If you have any questions about this, we will be happy to assist you at any time.
If necessary, please contact our technical support team: 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.



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Annex A

# Feedback to Löwenstein Medical

**To the safety information „ bronchoscopy maneuver“ Dezember 2023**

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 the 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 „ bronchoscopy maneuver“ Dezember 2023

List of serial numbers that we have identified as possibly affected.

| Pos | Description | Article No. | Serial number |
|---|---|---|---|
| | | | |