

Company
Contact
Name
Street
Zip Code City

Date: 8/15/2022

Urgent – Field Safety Notice

**Software update for the LUISA ventilator (LM150TD)
Affected are devices with firmware 1.5.0030**

Dear Sir or Madam,

Quality and safety are our highest priorities. For this reason, it is important to us to issue the following urgent field safety notice in connection with a potential hazard due to influence on the ventilation function of the LUISA (LM150TD) ventilator.

Sender:

Löwenstein Medical Technology GmbH + Co. KG

Addressee:

Distributors, operators and users of the LUISA (LM150TD) ventilator.

Identification of the affected devices:

Ventilators of the LUISA series (LM150TD) with firmware version 1.5.0030:

- Serial number range of the devices produced with this firmware version: 50013752 - 50017318
- All LUISA (LM150TD) devices that have been updated to this firmware version

Description of problem and identified cause:

A malfunction of the inspiratory trigger of the LUISA ventilators with firmware version 1.5.0030 may occur in rare cases if the ventilator is used with a single circuit valve system. Under certain circumstances the device can independently trigger additional inspiration cycles. As a result, the respiratory rate may increase significantly, causing the risk of insufficient ventilation.

Devices that are operated together with a double limb circuit or a leakage circuit system are not affected.

Furthermore, devices with a different firmware version are not affected.

As of today, no serious incidents related to this issue have been reported.

What measures does the addressee have to take?

- Please inform your employees, affected customers, and users immediately of the potential hazard
- Update all devices with affected firmware version to firmware version 1.5.0031 or higher
Update devices before delivery to operators / patients
- If therapy shall be continued with affected devices that are currently used with single circuit valve system until the device is updated, it is necessary to change to a double limb circuit or a leakage circuit system
- Devices with older firmware version must not be updated to version 1.5.0030

Acknowledgement

Please acknowledge receipt of this letter or its forwarding on the enclosed feedback form.

Distribution of the information described here

Please ensure that all users of the above-mentioned products and other persons who need this information are made aware of this safety information. If you provided the products to third parties, please forward a copy of this information or inform the contact person indicated below.

This corrective action will be reported to and coordinated with the responsible competent authorities.

If you have any questions, please do not hesitate to contact the safety officer at +49 40 54702 258 or via email at vigilance@loewensteinmedical.com.

Löwenstein Medical Technology GmbH + Co. KG regrets the inconvenience caused by this corrective action.



i. V. Dr. Christoph Lemke
CQO, Director Quality Management and Regulatory Affairs
Löwenstein Medical Technology

RECALL FORM

Regarding the safety information
"Software update for the LUISA ventilator (LM150TD)"

Original letter issued to:

«name»

«Contact Person»

«Street»

«ZIP Code City»

«Country»

Please send us this feedback form completely filled out by fax, email or mail to:

Fax: +49 40 547 02-476

Email: customerservice@loewensteinmedical.de

Löwenstein Medical Technology GmbH + Co. KG
Safety Officer for Medical Devices
Kronsaalsweg 40
22525 Hamburg
Germany

Please fill in completely in block letters:

Company details are identical to the address field above

Company details are different from the address field above. The company details are as follows:

Your customer ID: _____

Company + Address: _____

I hereby acknowledge receipt of the safety notice and that I have read and understood its contents. All users of the product and other persons to be informed in my organization have received knowledge of this letter.

In case we have provided the products to third parties, a copy of this letter has been forwarded to them.

Name (in block letters)

Date, signature

Position