

«Name»
«Point of contact»
«Street»
«Zip code» «City»
«Country»

Hamburg, Thursday, January 28, 2021

Important safety information:

Field safety corrective action due to a potential malfunction when the LUISA ventilator switches from power supply to battery pack operation during ventilation

Dear Sir or Madam,

Quality and safety are our highest priority, which is why it is important to us to publish the following safety information in connection with the potential risk associated with failure of the LUISA ventilator from Löwenstein Medical Technology.

From

Löwenstein Medical Technology GmbH + Co. KG

Addressee

Users and operators of LUISA-type ventilators.

Identification of the medical devices affected

LUISA ventilator LM150TD

Article numbers: 31410, 31430

Serial numbers affected: All serial numbers

Description of the problem including the cause identified

As already explained in our earlier correspondence, in exceptional cases, the switch from power supply to battery pack operation may not work perfectly during ventilation with the LUISA device.

In a small number of power supply units, voltage drops so slowly that internal detection of the voltage drop and thus the switch to battery pack operation may not work reliably in certain circumstances; LUISA then switches off.

What measures should be taken by the addressee?

Under certain circumstances, LUISA-type ventilators may switch off during the automatic switch to battery pack operation when disconnected from the power supply. Please inform your staff and affected customers and users accordingly about the potential risk when the external power supply is lost on devices with a firmware version below 1.1.0004. If you have specific questions about the firmware version installed, please contact Löwenstein Medical Technology Technical Service on +49 40-54702-400.

Measure for customers/operators

The malfunction can be eliminated by updating the firmware to version 1.1.0004. This firmware update is obligatory for all LUISA ventilators produced and supplied to date and must be recorded on the enclosed reply form.

Acknowledgment

Please confirm on the enclosed reply form that you have updated the firmware to version 1.1.0004.

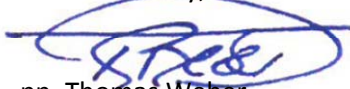
Passing on the information given here

Please ensure that this safety information is brought to the attention of all users of the above-mentioned products and of other people to be informed in your organization. If you have passed these products on to third parties, please forward a copy of this information to them or inform the point of contact given below.

In his capacity as Safety Officer, the undersigned is available to answer any questions you may have - call +49 40 54702 116 or e-mail vigilance@loewensteinmedical.de.

Löwenstein Medical Technology GmbH + Co. KG apologizes for the inconvenience and disruption to your operational processes.

Yours sincerely,



pp. Thomas Weber

Director Quality Management and Regulatory Affairs

REPLY

confirming implementation of the field safety corrective action due to a potential malfunction when the LUISA ventilator switches from power supply to battery pack operation during ventilation

Original letter sent to:

«Name»
«Point of contact»
«Street»
«Zip code» «City»
«Country»

Please complete this reply form in full and return it to us by fax, e-mail or post:

Fax: **+49 40 547 02-476**

e-mail: customerservice@loewensteinmedical.de

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

Please complete in full in block capitals:

- Company details are **identical** to the above address field
- Company details are **different** from the above address field. The company details are as follows:

Your customer number: _____

Company + address: _____

- I hereby confirm receipt of this safety information and that I have performed the corrective action. All LUISA ventilators according to the list of serial numbers have been updated to current firmware version **1.1.0004**.

Where we have passed on these products to third parties, a **copy of this letter has been forwarded to them.**

Name (in capitals)

Date, signature

Position