“Name”
“Contact”
“Street”
“Zip code” “City”
“Country”

Date: 2026-10-06

Urgent safety information

for LUISA, TIVAN LS, Life One (LM150TD) ventilators
FSN-2026-01

Dear Sir or Madam,

Quality and safety are our highest priority. This is why it is important for us to publish the following urgent safety information in connection with the ventilator model LM150TD and a potential communication failure of the battery.

It is **not** currently necessary to return the product. If the measures described below are followed, it is possible to continue using the product safely.

From:
Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40, 22525 Hamburg
Germany
Single Registration Number (SRN): DE-MF-000006010

Addressee:
Specialist dealers, health institutions and users of LUISA, TIVAN LS, and Life One ventilators

Identification of the medical devices concerned:
This concerns all LUISA, TIVAN LS, and Life One (LM150TD model) ventilators which were supplied with firmware versions 1.15.0010 and 1.15.0018, or have been updated to these firmware versions.

Description of the problem including the cause identified:
A communication failure between the device electronics and the internal or external battery may occasionally occur in the case of LM150TD model ventilators with firmware versions 1.15.0010 and 1.15.0018. In consequence of this fault, the battery charging status is no longer updated correctly. The display remains at the value last registered before occurrence of the communication failure and no longer reflects the actual charging state. At the same time, the battery charging function is impaired, as neither the internal nor the external battery is charged by the device during mains-powered operation.

If the communication failure remains unnoticed, the battery may become fully discharged during battery mode without this being identifiable by means of the battery capacity displayed. If the device is used in battery mode or if the external power supply fails, the actual battery capacity available may be lower than the capacity displayed. This means that the device can unexpectedly switch off without any prior alarm. An alarm occurs only after switch-off, indicating the energy outage and shutdown of the device.

Following switch-off caused by an energy outage, operation can be resumed via mains power supply or the connection of an adequately charged external battery. This restart automatically restores communication with the discharged battery.

The phenomenon has been identified during internal laboratory testing. To date Löwenstein Medical Technology is not aware of any incidents from the market or any harm to health in connection with this phenomenon.

Description of the risk to health:
In the case of devices that are permanently operated via mains power supply, no risk exists unless there is a switchover to battery power supply. A full and unnoticed discharge of the battery in battery mode may lead the device to switch off unexpectedly and thus to an interruption in ventilation. In the case of patients with a high or complete dependence on ventilation, this could have serious health consequences, possibly leading to death, unless appropriate countermeasures are taken.

As far as is currently known, occasional occurrence of the phenomenon can be assumed. This means that although the phenomenon may fundamentally occur, it is not to be frequently expected. The firmware version 1.15.0010 was only made available in Germany to a limited extent. Moreover, as the firmware version 1.15.0018 did not become available until 3 August 2026 and no relevant reports are known to date from the market, this classification is based on the currently low number of potentially concerned devices in the field.

What action should be taken by the addressee?

- Please immediately inform your staff, affected patients, customers, and users about this safety information.
- Please first check whether one of the firmware versions 1.15.0010 or 1.15.0018 is installed on the device. Information on displaying the firmware version can be found in section 5.2.3 of the instructions for use (“System menu → Device status”).
- Please immediately update all ventilators concerned to the firmware version 1.15.0020 or higher. The firmware update is already available with publication of this safety information free of charge:

  https://leoworld.loewensteinmedical.com/

  Information on performing the firmware update can be found in the instructions for use under section 3.6.2 “Performing the firmware update”. If you require any assistance with performing the firmware update, please do not hesitate to contact us. We would be pleased to coordinate the next steps with you.

If you are unable to install the firmware update immediately:

- At all cases first perform a device reset. To do so, press the Power and Alarm key simultaneously for around 10 seconds (see Figure 1). After about 10 seconds, the screen will turn black, and the device restarts. This restores communication with the battery. This reset should be repeated **once a day and before each mobile use** by way of precaution.

  WARNING: With a reset during ongoing therapy, ventilation will be temporarily interrupted for around 5 seconds. Therapy thereupon resumes automatically.



Fig. 1: Press the Power and Alarm keys (outlined in red in this figure) simultaneously for around 10 seconds to force a device reset. After about 10 seconds, the screen will turn black, and the device restarts.

- Where an external battery is available, it is recommended leaving it continuously connected to the device by way of precaution until completion of the firmware update. This may significantly reduce the likelihood of occurrence of the communication failure described.
- Where possible, devices with firmware versions 1.15.0010 and 1.15.0018 should be permanently operated via mains power supply.
- Please perform the reset described above with the display of an implausible battery charging status that remains unchanged even when used in battery mode for a lengthy period, or where the above communication failure is suspected.

Action performed by Löwenstein Medical Technology:
Löwenstein Medical Technology has published the firmware version 1.15.0020, which eliminates the cause of the communication failure described above. The firmware update is immediately available to users free of charge.

Acknowledgment:
Please use the attached reply form to immediately confirm receipt/forwarding of this letter.

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 health institution. 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.

This measure will be reported to the relevant authority and the course of action agreed on.

In the case of queries, please contact us by e-mail at Hamburg.Customer-CARE@loewensteinmedical.com or call +49 40 54702-100

We apologize for the inconvenience associated with this measure.

Löwenstein Medical Technology

REPLY

relating to the urgent safety information (FSN-2026-01)

for LUISA, TIVAN LS, and Life One (LM150TD) ventilators

Original letter sent to:

"Name"
"Contact"
"Street"
"Zip code" "City"
"Country"

Please complete this reply form in full and send it by e-mail or post to:

E-mail: **Hamburg.Customer-CARE@loewensteinmedical.com**
Post: **Löwenstein Medical Technology GmbH + Co. KG**
PRRC (person responsible for compliance with the regulatory requirements)
Kronsaalsweg 40
22525 Hamburg
Germany

Please complete in full in block capitals:

☐ Company details are identical to the above address field.
Your customer number: _____

☐ 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 read and understood its contents. This letter has been brought to the attention of all users of the product and other persons to be informed in my health institution.
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