

«Name»
«Kontaktperson»
«Straße»
«PLZ» «Ort»
«Land»

Date: 7/29/2024

Urgent safety information

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

Dear Sir or Madam,

Quality and safety are our highest priority, which is why it is important for us to publish the following urgent safety information in connection with the LUISA ventilator and a potential failure of the acoustic alarm system.

From:

Löwenstein Medical Technology GmbH + Co. KG

Addressee:

Specialist dealers, operators, and users of the LUISA ventilator.

Identification of the medical devices affected:

Ventilators in the LUISA, TIVAN LS, Life One (LM150TD) series, all serial number

Description of the problem including the cause identified:

In exceptional rare cases, an initialization problem with the ventilator's internal acoustic alarm system may result in only the visual alarm signal being emitted but not the acoustic alarm signal. This only occurs at alarm volume 1.

When using alarm volume 2 or higher, a visual as well as an acoustic alarm is guaranteed. The ventilator is delivered with an alarm volume of 2 set as standard.

From a technical point of view, this initialization problem can occur with firmware versions up to version 1.9.0016.

There are 2 known incidents from the market where this problem occurred at alarm volume 1. This corresponds to a percentage probability of occurrence of 0.00008% (with around 22 million potential uses). To date Löwenstein Medical Technology has not received any reports of harm to patients in relation to this issue.

What measures should be taken by the addressee?

- Please immediately inform your staff, affected patients, customers, and users about the potential risk.
- Until the firmware update is available, ensure that the device is always used with an alarm volume of 2 or higher. Detailed instructions on how to change the alarm volume are attached to this message. These instructions can also be found in this video:



https://youtu.be/xtIKjRA9_Sg

- You should update all LUISA, TIVAN LS, LifeOne (LM150TD) ventilators to firmware version 1.13.XXXX or higher by April 2025. The update is expected to be available in October 2024.

Measures planned by Löwenstein Medical Technology:

Löwenstein Medical Technology will release a firmware update to rectify the cause of the error described above. The update, which also includes other performance improvements, will be made available to users free of charge. The firmware update is expected to be available in October 2024.

Acknowledgment:

Please use the attached reply form to confirm receipt of this letter/that it has been forwarded.

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.

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

If you have additional questions, please contact us by e-mail via vigilance@loewensteinmedical.com.

Löwenstein Medical Technology GmbH + Co. KG apologizes for the inconvenience associated with this measure.

Dr. Christoph Lemke (with power of attorney)
CQO, Director Quality Management and Regulatory Affairs
Löwenstein Medical Technology

REPLY

to urgent safety information (FSN-2024-01)
for the LUISA ventilator (LM150TD)

Original letter sent to:

«Name»
«Kontaktperson»
«Straße»
«PLZ» «Ort»
«Land»

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

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

Email: **Hamburg.Customer-Care@loewensteinmedical.com**

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 read and understood its contents. This letter has been brought to the attention of all users of the product and other people in my organization who have to be informed.

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

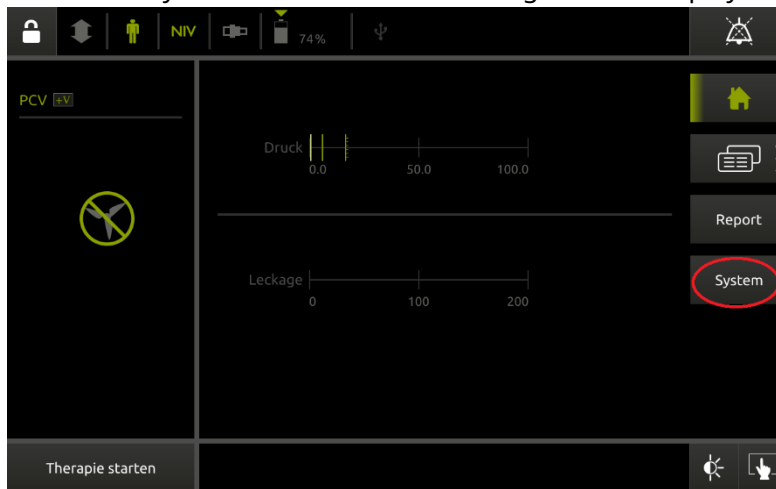
Instructions for setting the acoustic alarm volume on LUISA, Tivan LS and LifeOne (LM150TD) ventilators:

In extremely rare cases, an acoustic alarm may not sound if the alarm volume is set to level 1. However, all alarm messages are shown visually on the display.

This applies to both technical and physiological alarms. If your device is already set to an alarm volume of 2 or higher, an acoustic alarm is guaranteed and you do not need to do anything else.

You can set the alarm volume as follows:

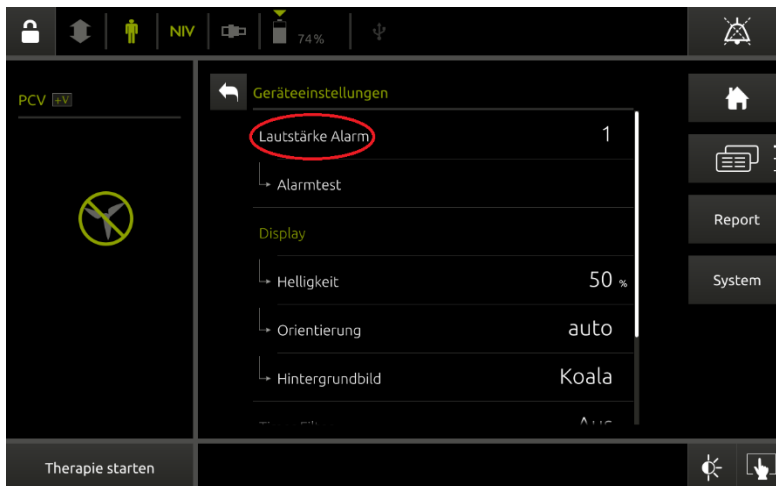
1. Select "system" in the menu on the right of the display:



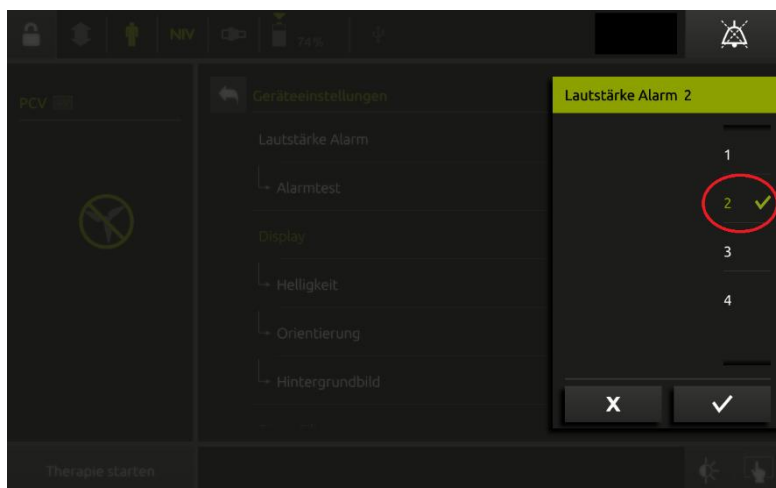
2. Then go to "device settings":



3. Then select “alarm volume”:



4. Select “Alarm volume 2” or higher and the corresponding alarm tone will be emitted once. Then press the confirm button. Now, you are guaranteed to have an acoustic alarm signal when the alarm goes off.



5. Press the home button to return to the main menu:

