

Important customer information

No.: 2024-15 via e-mail
7, 2024

Dear Customers,

We hereby inform you of a safety message for the LUISA, TIVAN LS and LifeOne (LM150TD) ventilators. In extremely rare cases at alarm volume 1 the acoustic alarm may not sound. The extensive firmware update v1.13.XXXX detailed in the message is expected to be available for download in October 2024.

We regularly optimize our devices based on customer feedback with the aim of making patient care with LUISA even more flexible and effective.

Update contents:

- Optimization of alarm conditions for volume alarms, e.g. for asynchronies
- Reduction of false positive disconnection alarms in HFT mode
- User-friendly and timely maintenance information on the service life of the internal and external batteries, enabling smooth maintenance planning
- Compliance with changed standards requirements

This mandatory update also addresses the ensuring of an acoustic alarm at alarm volume 1, as described in the safety message. Until then, please follow the actions detailed in the message.

Another new feature is the USB modem, which will be available from September 2024 (exact date depends on country) and provides you with the following options:

- Telemonitoring for adherence, leakage and therapy data, and display of alarm and event list in prisma CLOUD
- Automatic transfer of therapy and device data every 12 hours and available on demand in prisma CLOUD

Please observe the following information in the appendix:

- Urgent safety information for the LUISA, TIVAN LS, LifeOne (LM150TD) ventilators and the actions to be taken.
- Reply form to confirm receipt of these safety measures.

We apologize for any inconvenience caused by the urgent safety notice. We are confident that with the mandatory FW v1.13.XXXX update, we are providing a measure to further increase patient safety and thus ensure the usual high quality of LUISA ventilators.

If you have any questions, please contact your sales representative.

Yours faithfully,
The Löwenstein Team