Important Customer Information

No.: 2023-27 via e-mail
December 2023

Dear customers,

We would like to inform you about an urgent field safety notice and the mandatory firmware update **V 1.9.0007** for LUISA (LM150TD).

This update addresses the issues described in the field safety notices from May and December 2023 and provides additional functionalities related to patient safety and improved handling.

Please note the following information attached:

- Urgent field safety notice for the ventilators LUISA, TIVAN LS, Life One (LM150TD) including the necessary measures.
- Feedback form to confirm receipt of the field safety notice.
- Detailed description of the content of firmware v 1.9.0007
- Technical Information as step-by-step installation instructions.

In addition, our Customer Service will provide you with an overview of the serial numbers of the delivered LUISA devices that need to be updated. Please send them back to the following email address:

Hamburg.Customer-Care@loewensteinmedical.com

For quick access to the mandatory update **V 1.9.0007**, please use this link:
Firmware (loewensteinmedical.de)

In addition to the firmware version, you will find all of the above information and additionally:
• the updated instructions for use,
• a video describing the installation steps and the main contents of the update.

All information is also available on our homepage at:
https://en.hul.de/safety-information-luisa/

With serial numbers:

- LUISA from   SN 50037667
- External battery / LMT 31540 from   SN 2307250045

the firmware update **1.9.0007** has been implemented.

We apologize for the inconvenience caused by this urgent safety notice in the run-up to Christmas. However, we are sure that with the **FW V 1.9.0007** available at the same time as a mandatory update, we will offer a measure to further increase patient safety and thus ensure the usual high quality of LUISA ventilators.

If you have any questions, please do not hesitate to contact your local sales representative.

Best regards,
Your Löwenstein Team

With people in mind