Löwenstein Medical Technology | P.O. Box 54 02 68 | 22502 Hamburg | Germany

«Name»
«Contact person»
«Street»
«Zip Code» «City»
«Country»

Date: 04/05/2305/02/23

Urgent – Field Safety Notice

for the LUISA ventilator (LM150TD) with use of accessories for invasive ventilation

Dear Sir or Madam,

Quality and safety are our highest priorities. Therefore, we are issuing this urgent safety information about a potential hazard related to the linking of external accessories to the LUISA ventilator.

Sender:
Löwenstein Medical Technology GmbH + Co. KG

Addressee:
Distributors, operators and users of the LUISA ventilator.

Identification of the affected devices:
Ventilators of the LUISA, TIVAN LS, Life One (LM150TD) series

Description of the problem and the identified cause:
When our ventilator is used, the circuit system must be calibrated with different accessories such as filters and tube extensions up to the patient connection port.
If changes are made to the linking of accessories by changing products or adding accessories, a new circuit test is required to determine the resistance of the system, among other things. When a disconnection occurs at the patient connection port, a disconnection alarm is reliably triggered if the circuit test has been performed to calibrate the system beforehand.
Disconnection at the patient connection port with accessories that have not been calibrated cannot be clearly detected for reasons involving the linking of accessories.

In the event of disconnections beyond the patient connection port, during decannulation of a patient for example, a disconnection may not be detected and the alarm may not be reliably issued. This is the case for cannulas with high resistance such as tracheal cannulas with small lumen used in pediatrics.

What action is to be taken by the addressee?
For the use of invasive accessories, such as tracheal cannulae that have not been calibrated with the circuit system, the following measures must be observed:

1. Correct calibration of the circuit: The circuit test must be performed with the accessories used up to the patient-connection port, as specified by the ventilator and in the instructions for use. The circuit calibration must be performed
   a. if the circuit and accessories have been assembled for the first time.
   b. if the circuit or the accessories have been changed.
2. Use of a supplemental monitoring system to monitor the patient, such as continuous pulse oximetry (SpO_2) monitoring or expiratory carbon dioxide (CO_2) monitoring.
3. Based on the circuit used, activation is required of the following additional alarms concerning tidal volume (VT) and minute volume (MV), inspiratory (i) or expiratory (e):
   - Single circuit with valve set: "VTi high", "MVi high".
   - Leakage circuit set: "VT low", "MV low", "Leakage high".
   - Double circuit set: "VTi low", "VTe low", "MVi low", "MVe low", "Leakage high".

   The corresponding alarms must be set adequately for the current ventilation situation. It should be taken into account that the resistance of the accessories can change during therapy, for example, when the tracheal cannula is moved or when a filter is saturated.

Planned actions by Löwenstein Medical Technology:
Löwenstein Medical Technology will release a software update to support ventilator users in the correct use of the ventilator, especially in combination with invasive ventilation accessories. The software is planned to be available from December 31, 2023, and will be provided free of charge to all users.

Acknowledgement
Please acknowledge receipt of this letter or its forwarding on the enclosed feedback form.

Distribution of the information described here
Please ensure that all users of the above-mentioned products and other persons who need this information are made aware of this safety information. If you provided the products to third parties, please forward a copy of this information or inform the contact person indicated below.

This corrective action will be reported to and coordinated with the responsible competent authorities.

If you have any questions, please contact us by sending an email to vigilance@loewensteinmedical.com.

Löwenstein Medical Technology GmbH + Co. KG regrets the inconvenience caused by this corrective action.

i. V. Dr. Christoph Lemke
CQO, Director Quality Management and Regulatory Affairs
Löwenstein Medical Technology

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Excise Tax ID, DE 118051598
WEEE-Reg. No. DE 63391140

Creditor-ID
DE25ZZZ00000353957

Banking Connection
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General Partner
Löwenstein Medical Technology Verwaltungs GmbH
Headquarters: Hamburg
Hamburg Municipal Court,
Dept. B, # 8678
Business Management:
Benjamin Löwenstein
Sascha Löwenstein

RESPONSE FORM

Regarding the safety information
"for the LUISA ventilator (LM150TD)"

Original letter issued to:

«name»

«Contact Person»

«Street»

«ZIP Code City»

«Country»

Please send us this feedback form completely filled out by fax, email or mail to:

Fax: +49 40 547 02-476

Email: customerservice@loewensteinmedical.de

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

Please fill in completely in block letters:

☐ **Company details are identical to the address field above**

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

Your customer ID: _____

Company + Adress: _____

_____

_____

☒ **I hereby acknowledge receipt of the safety notice and that I have read and understood its contents. All users of the product and other persons to be informed in my organization have received knowledge of this letter.**

In case we have provided the products to third parties, **a copy of this letter has been forwarded to them.**

_____ _____

Name (in block letters) **Date, signature**

_____

Position

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With people in mind