

To all Customers, Users and Distribution Partners of the
Intensive Care Ventilators
elisa 300, elisa 500, elisa 600, elisa 800 und elisa 800^{VIT}

Important Field Safety Notice! FSN 19068_001

Limitation of the setting range of parameter PEEP due to unintentional acceptance of the value of Pmax when changing the ventilation mode

2019-05-17

Dear Sir or Madam,

in one case, the following malfunction of the intensive care ventilators elisa 300, elisa 500, elisa 600 elisa 800 and elisa 800^{VIT} has become known to us.

Affected Devices:

Affected from this malfunction are solely the software versions 2.02.0 and 2.02.1 for the intensive care ventilators elisa 300, elisa 500, elisa 600, elisa 800 and elisa 800^{VIT}.

Problem description:

In volume-controlled and dynamic modes, the parameter Pmax limits the maximum ventilation pressure applied upwards. Depending on the value set for Pmax, the possible setting ranges for Pressure Support and PEEP are also influenced. For example, the highest adjustable PEEP is calculated according to the formula:
<< Highest PEEP >> = Pmax - Pressure Support - 2mbar upwards limited. If a higher PEEP is to be set, a corresponding message appears on the selector indicating which parameter limits the current setting.

For BiLevel or comparable ventilation modes, the parameter Pmax is not necessary because the ventilation pressure is fixed. Consequently, the limitation of the PEEP by this parameter should also be omitted.

The problem described here is a software bug which is responsible for the fact that in ventilation modes without Pmax the limitation described is still effective and the value set in a previous mode or the default value of 35mbar is used as Pmax. This means that PEEP can no longer be freely set.

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Possible risks:

In the ventilation modes BiLevel, BiLevel ST, CPR, PC-APRV, PC-SIMV, PCV and PSV, PEEP can no longer be set in the entire specified range, but is limited by the height of the previously defined Pmax (or by its default value of 35 mbar) with the above formula.

This problem occurs particularly when the Pmax parameter has previously been used in a volume-controlled ventilation mode as a limit value for generating a decelerating inspiratory flow and has been greatly reduced for this purpose.

Necessary activities of the customer / user:

A software update (version 2.03.0) will be provided at short notice to solve this problem.

Until then, the behavior can be corrected by tapping the "Ventilation" button during ventilation or in standby to open the ventilation menu for setting the ventilation parameters.

In this menu, you must now tap a ventilation mode that contains Pmax as an adjustable parameter. This ventilation mode does not need to be confirmed or activated. In this selected ventilation mode, the value of Pmax can be increased accordingly after activating the key for Pmax. The value of Pmax increased in this way is then used for limitation. After confirming the entry of Pmax, the menu can be closed again.

Note:

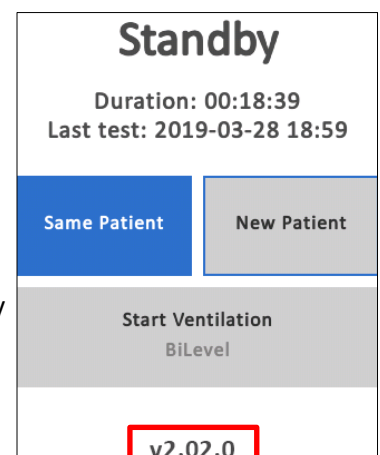
Please attach a copy of this letter to your device documentation and the user manual.

Identification of the regarding devices:

1. Turn on the ventilator.
2. The software version is displayed in the „Standby-Mode“ and the systemtest-screen in the lower left corner, as shown on the figure.
3. If the displayed software-version is 2.02.0 and 2.02.1, your ventilator is affected of the corrective action.

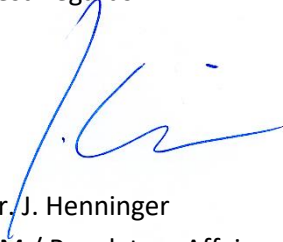
We apologize for any inconvenience, which may be associated with this Field Safety Notice, but this Field Safety Notice is necessary to ensure patient safety.

A Löwenstein Medical Innovation service technician or one of our service partners will contact you to schedule the software update.



We thank you for your cooperation. In case you have further questions please do not hesitate to contact us.

Best Regards



Dr. J. Henninger
QM / Regulatory Affairs

Attachment



Reply to Löwenstein Medical Innovation GmbH & Co. KG

Regarding: SW Update elisa 300 – 500 - 600 - 800 – 800^{VIT} –
Field Safety Notice – PEEPmax – FSN 19068_001

This notice has been sent to:

Customer:

Address:

City:

Country:

Please reply to:

Fax: +49 6173 93 33 29

E-Mail: qm@loewensteinmedical.com

Löwenstein Medical Innovation GmbH & Co. KG
Quality Management
Niederhochstaedter Str. 62
61476 Kronberg
Germany

Please complete in block capitals:

- Company details are the same as the above address field
- Company details are different from the above address field. The company details are as follows:

Your customer number: _____

Company and address: _____

- I hereby confirm receipt of this safety information and further confirm that I have read and understood its content. This letter has been brought to the attention of all responsible people in my organization.

In cases, in which we have passed on these products to third parties, a copy of this letter has been forwarded to these third parties.

Date, signature

Full Name + Email address



Reply to Löwenstein Medical Innovation GmbH & Co. KG

Regarding: SW Update elisa 300 – 500 - 600 - 800 – 800^{VIT} –
Corrective Action – PEEPmax – FSN 19068_001

This notice has been sent to: Please reply to:

Customer: Fax: +49 6173 93 33 29
 Email: qm@loewensteinmedical.com
 Address: Löwenstein Medical Innovation GmbH & Co. KG
 City: Quality Management
 Country: Niederhochstaedter Str. 62
 61476 Kronberg
 Germany

In my responsibility, as _____, I herewith confirm the completion of the Software Update as indicated in the instructions for the following device.:

No.	Device	Serial number	SW Update 2.03.0 (insert date)	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				