

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

Important Field Safety Notice!

Unintended pressure increase when using the function PEEPFinder

2017-03-06

Dear Sir or Madam,

during a demonstration of the intensive care ventilators elisa 600, elisa 800 und elisa 800^{VIT} the following malfunction occurred.

Affected Devices:

Affected from this malfunction is the Function PEEPFinder, of the software-version 1.07.x for the intensive care ventilators elisa 600, elisa 800 and elisa 800^{VIT}.

Problem description:

In rare cases, an alarm condition may occur during the use of the PEEPFinder function, so that the intended termination of the function is not performed correctly.

Possible risks:

This malfunction can lead to a pressure rise up to PLimit.

Necessary activities of the customer / user:

The only measure to abort is a disconnection of patients with possibly following recruitment.

A software update to solve the above described problem will be available at short notice.

Until then the function PEEPFinder should not be used.

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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 SALVIA medical 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

Two solid black rectangular redaction boxes covering the signature and name of the sender.