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 Clinical Experience
Technical Competence

Geschäftsführung
Rainer Hafermann
Bernd Höhne

USt-IdNr.: DE 199109395
Handelsregister Amtsgericht
Montabaur HRB 4241

Gackebach, August 4th, 2021

Important safety information for all ventilators in the EVE family

UPDATE - Potential PEEP loss combined with tube compensation

RECIPIENTS:

Specialist and care staff as well as service technicians in medical facilities where EVE type ventilators are used.

AFFECTED PRODUCTS:

- 107061400 Emergency ventilator EVE TR
- 107061401 Emergency ventilator EVE TR with Masimo rainbow® SET technology
- 107061410 Intensive care ventilator EVE IN
- 107061411 Intensive care ventilator EVE IN with Masimo rainbow® SET technology
- 107061420 Neonatal intensive care respirator EVE NEO
- 107061421 Neonatal intensive care respirator EVE NEO with Masimo rainbow® SET technology

MANUFACTURER:

Fritz Stephan GmbH
Kirchstraße 19
D-56412 Gackebach

REASON FOR THE SAFETY NOTICE:

Fritz Stephan GmbH was informed about a case in which there was a loss of PEEP when using the tube compensation that could only be restored by changing the ventilation mode. A software error was identified as the reason for the loss of PEEP.

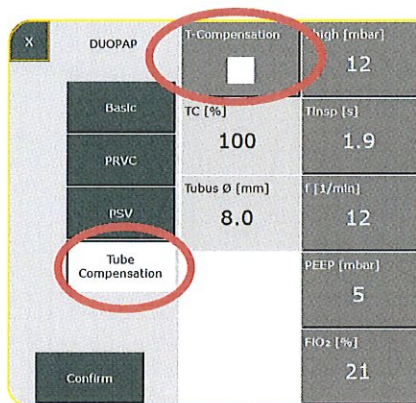
The following conditions must be met for the loss of PEEP to occur through this error:

1. Tube compensation (T-Compensation) must be active.
2. The patient must exhale by force for at least 3 successive expiration cycles.
3. The forced expiration must take place alongside the expiration started through the ventilator.

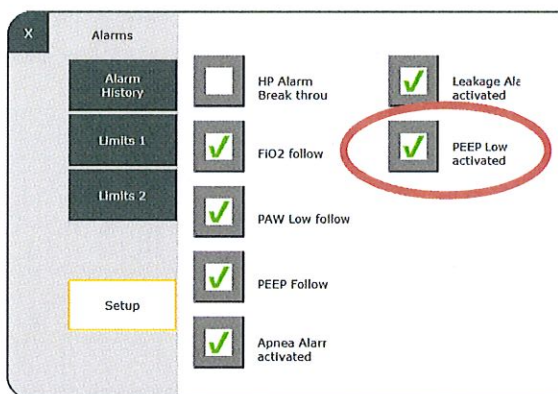
The pressure regulator can only be reset in this situation by briefly switching to standby mode.

MEASURES BY THE USER

1. Deactivate the ventilation option "T-Compensation" (tube compensation) for ventilators of the EVE family.
2. If loss of PEEP has already occurred, switch to standby mode, deactivate Tube Compensation and then continue ventilation without "T-Compensation".



3. Switch on the function "PEEP low activated" to monitor the PEEP permanently



Until the stated corrective measure has been implemented, you can continue to use your EVE ventilator with the tube compensation switched off.



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MEASURES BY THE MANUFACTURER

Fritz Stephan GmbH has developed a software solution that corrects the error in connection with the tube compensation.

The customer service of Fritz Stephan GmbH will contact you shortly to arrange an appointment to carry out the corrective measure.

CONTACT

If you have any questions, please contact your local medical product advisor or us directly.

We are of course delighted to answer your questions:

Tel: +49 (0) 64399125-0

Email: info@stephan-gmbh.com.

Yours truly,

Fritz Stephan GmbH

Bernd Höhne (director)



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RESPONSE TO SAFETY INFORMATION

UPDATE - Potential PEEP loss combined with tube compensation

Customer information	
Name of health facility:	
Street, no.:	
Postal code/city:	
Country:	

Please complete this response form using capital letters and return it by email to:

fmi@anandic.com

I have read and understood the safety information and confirm this with my signature. All users and other people who must be informed in my facility are aware of this letter.

Name (in capital letters): _____

Job title (in capital letters): _____

Date: _____

Signature: _____