



Fritz Stephan GmbH
Medizintechnik
Kirchstr. 19
56412 Gackebach
Germany

Fon +49 6439-91 25-0
Fax +49 6439-91 25-111
info@stephan-gmbh.com
www.stephan-gmbh.com

 Clinical Experience
Technical Competence

Geschäftsführung
Rainer Hafermann
Bernd Höhne

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

Gackebach, May 31, 2021

Important safety information for all ventilators in the EVE family

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.

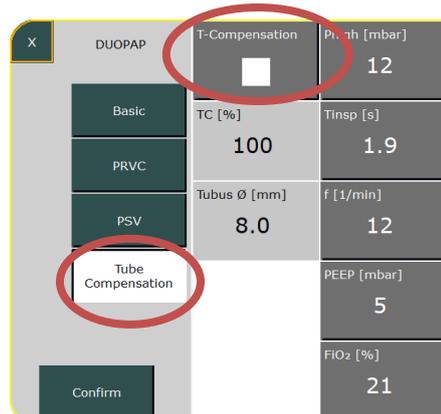
The following conditions must be met for the loss of PEEP to occur through this error:

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

Do not use the EVE family ventilators with the "T-Compensation" (tube compensation) ventilation option until the corrective measure has been implemented on your affected devices.



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

MEASURES BY THE MANUFACTURER

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

The Fritz Stephan GmbH service employees will contact you as soon as the software update is available.

CONTACT

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

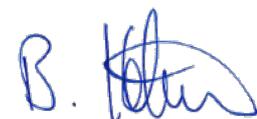
We are of course delighted to answer your questions:

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

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 fax, email or post to:

Fritz Stephan GmbH
 Kirchstraße 19
 56412 Gackebach
 Germany
 Fax ☎: +49 (0) 6439 9125-111
 Email ✉: vigilance@stephan-gmbh.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: _____