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Clinical Experience  
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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.

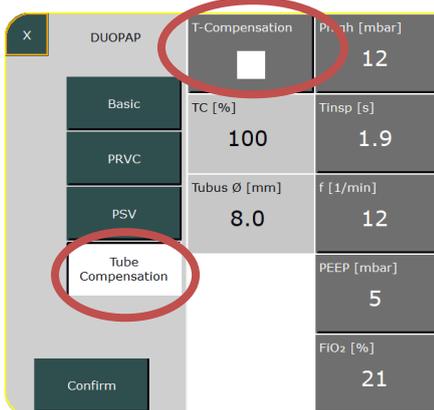
The following conditions must be met for the loss of PEEP to occur through this error:

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.

Anandic Medical Systems AG 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.

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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 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: \_\_\_\_\_