



FSN Reference QM229 Update 07.01.2025

Gackebach, 07. January 2025

## **Urgent Field Safety for the neonatal ventilator family SOPHIE**

### **FSN QM229**

### **Possible mean airway pressure loss within HFO+IMV**

#### **RECIPIENTS:**

Specialists and care staff as well as service technicians in medical facilities where ventilators of type SOPHIE are used.

#### **AFFECTED PRODUCTS:**

<b>Ref.</b>	<b>Product</b>
1038614xx	All device models of Sophie und Sophie 2020

#### **MANUFACTURER:**

Fritz Stephan GmbH  
Kirchstraße 19  
D-56412 Gackebach

#### **REASON FOR THE SAFETY NOTICE:**

Two cases were reported to Fritz Stephan GmbH in which a drop of mean airway pressure occurred under the combined ventilation mode HFO+IMV.

During that very specific mode of ventilation, an excessive loss of ventilation pressure, e.g. due to a disconnection, will lead to the effect that the pressure will not return to the set PEEP level after the remedy of the ventilation pressure loss. This leads to a decrease of the mean airway pressure.

The decreased mean airway pressure can lead to a serious deterioration in the health of the patient in 2 ways:

1. Oxygenation deteriorates due to the lower oxygen partial pressure. This can lead within minutes to a drop in the oxygen saturation.
2. Development of atelectasis with impact on the lung mechanics and possibly deterioration of the perfusion. This can lead to a delayed reduction in gas exchange, resulting in hypercapnia and hypoxia.

This Field Safety Corrective Action has been reported to the related competent authorities.



**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

FSN Reference QM229 Update 07.01.2025

**MEASURES BY THE RECIPIENTS**

- Provide this Field Safety Notice to all users and other people in your facility who must be informed.
- Avoid HFO-IMV mode if possible.  
If, however, the use of HFO-IMV mode is indicated, you the measured value display for PEEP and Mean Airway Pressure must be observed and checked immediately after each technical alarm.
- Avoid VBS disconnection or disconnection of the device from gas supply during active ventilation operation. Switch to "Pause" or "Standby" for intended intermediate disconnections.
- If the PEEP and/or Mean Airway Pressure decreased unintentional, the pressure controller must be reset by temporarily switching from HFO-IMV to HFO-CPAP and back.

**MEASURES BY THE MANUFACTURER**

- Fritz Stephan GmbH will develop a software solution to prevent a drop in PEEP and MAP under HFO-IMV and introduce additional pressure monitoring.
- The customer service of Fritz Stephan GmbH will contact you as soon as the software solution is available to arrange an appointment.

**CONTACT**

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

We will be pleased to answer your questions:

Tel: +49 (0) 64399125-0

Email: [info@stephan-gmbh.com](mailto:info@stephan-gmbh.com)

Sincerely,

**Fritz Stephan GmbH**

**Bernd Höhne (CEO)**



FSN Reference QM229 Update 07.01.2025

**RESPONSE TO SAFETY INFORMATION**

**FSN QM229**

**Possible mean airway pressure loss within HFO+IMV**

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](mailto: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: \_\_\_\_\_