



FSN Reference QM234 24.03.2025

Gackebach, March 24, 2025

## **Important safety information for the neonatal ventilator family SOPHIE 2020**

### **FSN QM234**

### **Possible inoperability of the SOPHIE 2020 ventilator**

#### **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>
10386142x	Device models of Sophie 2020
103861430	

#### **MANUFACTURER:**

Fritz Stephan GmbH  
Kirchstraße 19  
D-56412 Gackebach

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

Fritz Stephan GmbH has been informed that the "Touch" operating component has failed on Sophie 2020 appliances. These failures occur in two different forms. In one case, no touch input is registered on the screen and the appliance can still be operated via the rotary/push button (IGR).

In another case, faulty signals are emitted by the touch, which are registered by the software as touch input of the user. In this case, the device can no longer be operated. Due to the lack of operability, any necessary adjustments to the ventilation parameters can no longer be made, which could lead to the patient being over- or undersupplied.

#### **MEASURES BY THE RECIPIENTS**

If the device can still be operated using the rotary/push button due to the touch failure in the first version, the device can continue to be used without restriction. If the device can no longer be operated due to the touch failure in the second version, ventilation should be taken over by an alternative ventilator as soon as the



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ventilation situation permits. The device can then be switched to standby mode and then switched off completely using the off switch and the rotary/push button which can then be used again.

**MEASURES BY THE MANUFACTURER**

- Fritz Stephan GmbH has provided new control software for the touch controller.
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- The customer service of Fritz Stephan GmbH will contact you to arrange an appointment to update the control software for the touch controller.

**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)**



**Fritz Stephan GmbH  
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**RESPONSE TO SAFETY INFORMATION**

**FSN QM234**  
**Possible inoperability of the SOPHIE 2020**

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: \_\_\_\_\_