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 Clinical Experience  
Technical Competence

Geschäftsführung  
Rainer Hafermann  
Bernd Höhne

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

Gackebach, October 2023

## Important safety information for the neonatal ventilator family SOPHIE

**FSN QS.19-14357**

**Potential hazard of device failure due to defective heater cable**

### RECIPIENTS:

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

### AFFECTED PRODUCTS:

Ref.	Product
1038614xx	All device models of Sophie and Sophie 2020

### MANUFACTURER:

Fritz Stephan GmbH  
Kirchstraße 19  
D-56412 Gackebach  
Germany

### REASON FOR THE SAFETY NOTICE:

Fritz Stephan GmbH has been informed about a case where the measuring menu of a Sophie 2020 was opened without a user input.

A defective heating cable was identified as the cause of this behaviour. If, due to a defect, an inadvertent contact of the live wire with the shielding occurs, the signal inputs of the operating buttons that are no longer used in the Sophie 2020 can be triggered by the resulting disturbances. This interference can cause the measuring menu to open and close by itself, thereby impairing further operation of the unit.

During our internal investigation, it was also found that in the event of a direct short-circuit in the adapter cable of the disposable hose systems or the heating wire itself, the power supply for the heating could toggle. This can subsequently lead to a drop in the internal 24V voltage supply and thus to failure of the ventilator.

A direct short circuit in the adapter cable of the disposable tubing systems or the heating wire is very unlikely, but cannot be completely ruled out.

We are not aware of any incidents in connection with such a direct short circuit.



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

If the following instructions are observed, the Sophie unit can still be used without restrictions:

- Observe the Instructions for Use for the test before start-up.
- Perform a visual and functional check of the heater before each start-up.  
Damaged or defective adapter cables of the hose heating must not be used and must be replaced.  
Repair of the adapter cables is not permitted!
- Make sure that a ventilation alternative is immediately available in case of failure of the ventilator as described in the Instructions for Use!

#### **MEASURES BY THE MANUFACTURER:**

- Fritz Stephan GmbH will provide a software update that intercepts the triggering of the unused signal inputs and makes them ineffective. At the same time, the internal error detection of the heating system will be adapted so that the heating no longer switches on independently in the event of a detected error.
- If a fault of the heating system is detected and alarmed, the heating must be switched on again manually by the user in the heating menu after the fault has been remedied.
- The customer service of Fritz Stephan GmbH will contact you 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 will be pleased to answer your questions:

Tel: +49 (0) 64399125-0

Email: info@stephan-gmbh.com.

Sincerely,

**Fritz Stephan GmbH**

**Bernd Höhne (CEO)**



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**RESPONSE TO SAFETY INFORMATION**

**FSN QS.19-14357**

**Potential hazard of device failure due to defective heater cable**

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

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: \_\_\_\_\_