



Fritz Stephan GmbH  
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Clinical Experience  
Technical Competence

Geschäftsführung  
Rainer Hafermann  
Bernd Höhne

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

Gackebach, 29. November 2021

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

### **Faulty component can lead to loss of ventilation**

#### **RECIPIENTS:**

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

#### **AFFECTED PRODUCTS:**

THIS SAFETY NOTICE APPLIES EXCLUSIVELY TO THE SOPHIE (2020) MODELS WITH TOUCHSCREEN FUNCTION

103861420 Sophie (2020)

103861425 Sophie (2020) with automatic Refill system

#### **MANUFACTURER:**

Fritz Stephan GmbH  
Kirchstraße 19  
D-56412 Gackebach

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

Fritz Stephan GmbH was informed about a case in which the failure of an electronic component led to the loss of the internal 12V voltage supply and was indicated by a high-priority alarm.

The failure of the voltage supply leads to the loss of ventilation!

Insufficient dimensioning of an electronic component was identified as the cause of the failure.



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## MEASURES BY THE USER

### Danger



Allways have a separate manual breathing bag handy  
Lack of an alternative ventilation method may result in patient death if the ventilator fails.

- If possible, use an alternative ventilator if a brief interruption of mechanical ventilation could pose an excessive risk to the patient!
- Ensure that a ventilation alternative is immediately available in case of ventilator failure, as described in the instructions for use!
- Ensure that every patient ventilated with an affected ventilator is adequately monitored!

## MEASURES BY THE MANUFACTURER

Fritz Stephan GmbH will replace the boards with the affected component free of charge.

The customer service of Fritz Stephan GmbH will contact you shortly to arrange an appointment to carry out the corrective action.

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

Yours truly,

**Fritz Stephan GmbH**





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**RESPONSE TO SAFETY INFORMATION**

**Faulty component can lead to loss of ventilation**

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  
 D-56412 Gackebach  
 Deutschland  
 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: \_\_\_\_\_