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Clinical Experience  
Technical Competence

Geschäftsführung  
Rainer Hafermann  
Bernd Höhne

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

Gackebach, 1<sup>st</sup> July 2019

## Important Safety Notice

### Field Safety Corrective Action for the SpO<sub>2</sub>-Controller „SPO2C“ of the ventilator SOPHIE

#### RECIPIENT:

Application specialists, nursing staff and service technicians in medical facilities where the pediatric ventilator SOPHIE is operated.

#### PRODUCTS AFFECTED:

- 103861410 Pediatric ventilator Sophie SpO<sub>2</sub>C with external trigger
- 103861411 Pediatric ventilator Sophie SpO<sub>2</sub>C with automatic water refilling system and external trigger

#### MANUFACTURER:

Fritz Stephan GmbH  
Kirchstraße 19  
D-56412 Gackebach

#### REASON FOR THIS SAFETY NOTICE:

The ventilator's SpO<sub>2</sub> controller adjusts the applied oxygen concentration according to the patient's oxygen saturation (SpO<sub>2</sub>). Oxygen saturation is measured by an external patient monitor. The measured SpO<sub>2</sub> value is transmitted to the ventilator's SpO<sub>2</sub> controller via the serial port. In the event of an error (SpO<sub>2</sub> sensor error, communication error), the oxygen concentration should be set to a safe FiO<sub>2</sub> value (Backup-FiO<sub>2</sub>).

The Fritz Stephan GmbH has been informed about a case in which the values for oxygen saturation and pulse frequency received from the connected monitor (Radical 7C, Masimo) remained unchanged over a clinically not plausible period. The SpO<sub>2</sub> controller gradually increased the oxygen concentration up to the set FiO<sub>2</sub> limit based on the (persistently low) SpO<sub>2</sub> value.



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### **ACTIONS TO BE TAKEN BY USERS**

For Masimo SpO2 Monitor Radical 7, only use the averaging speed of 8s when using the monitor with the SpO2 controller on the SOPHIE ventilator.

Use the "FiO2 Limit" function of the SpO2 controller to limit the automatic increase of the FiO2 if necessary.

### **ACTIONS BY THE MANUFACTURER**

The Fritz Stephan GmbH has developed a software solution that detects clinically implausible periods of unchanged pulse and saturation values and indicates a communication error.

In this situation, the applied oxygen concentration FiO2 is set the value "Backup FiO2".

The authorized service representative of Fritz Stephan GmbH will contact you shortly to organize the implementation of this corrective action.

### **CONTACT**

If you have any questions, please contact our local authorized representative or contact us directly.

Of course, we are happy to answer your questions:

Tel: +49 (0) 64399125-145

Email: info@stephan-gmbh.com.

Sincerely,

**Fritz Stephan GmbH**

**Bernd Höhne (Geschäftsführer)**



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### Customer Response to Field Safety Notice

#### Field Safety Corrective Action for the SpO2-Controller „SPO2C“ of the ventilator SOPHIE

Customer Information	
Name of the health facility	
Address:	
ZIP, Town:	
Country:	

Please return this confirmation form completely in block letters by fax, email or post:

Fritz Stephan GmbH  
 Kirchstr. 19  
 D-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. The information has been brought to the attention of all users and other concerned persons in our facility.

Name (in block letters): \_\_\_\_\_

Position (in block letters): \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_