



Fritz Stephan GmbH
Medizintechnik
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Clinical Experience
 Technical Competence

Geschäftsführung
Tanja Stephan
Rainer Hafermann

USt-IdNr.: DE199109395
Handelsregister Amtsgericht
Montabaur HRB 4241

Gackebach, 1st June 2018

Important Safety Notice

Field Safety Corrective Action for the automatic refill system of the ventilator SOPHIE

RECIPIENT:

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

PRODUCTS AFFECTED:

- 103861401 Pediatric ventilator Sophie with automatic water refilling system
- 103861404 Pediatric ventilator Sophie with automatic water refilling system and external trigger
- 103861411 Pediatric ventilator Sophie SpO2C with automatic water refilling system and external trigger

MANUFACTURER:

Fritz Stephan GmbH
Kirchstraße 19
D-56412 Gackebach

REASON FOR THIS SAFETY NOTICE:

The Fritz Stephan GmbH had been informed about an incident where the automatic refill system of the integrated humidifier of the ventilator Sophie did not detect the water level of the humidifier chamber due to a mechanical defect of the German version of the coupling mechanism. The resulting overfilling of the humidifier chamber generated a significant amount of water in the hose system.

Devices distributed outside of Germany were not affected by that possible risk!

Further investigations regarding the above-mentioned corrective action revealed that although the sensor failure has been properly detected, the humidifier chamber may be overfilled if the refill hose has not been properly inserted into the pinch valve or accidentally removed.

An incident due to such a situation has not been observed, however.

We take this reference to a possible risk very seriously and have decided to initiate further corrective actions.



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ACTIONS TO BE TAKEN BY USERS

When using the automatic refill system, always ensure that the refill hose is properly inserted into the pinch valve.

ACTIONS BY THE MANUFACTURER

The Fritz Stephan GmbH has developed a solution consisting of

- a) a change in the inserting mechanism for the refill hose and
- b) a software update

to minimize the risk of overfilling the humidifier chamber.

The pinch valve is equipped with a micro switch. This switch electronically activates the refill system as soon as the valve arm is in the correct position above the refill-connector of the patient component. Due to the mechanical change, this position can no longer be achieved if the water hose is not properly inserted into the receptacle. Forcing the valve arm into position squeezes the refill hose which also prevents inadvertent water flow.

The software update includes an adjustment of the water level detection and limitation and the need for manual intervention by the user to restart the automatic refill after a sensor failure was detected.

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

Wolfgang Braun (Deputy Safety Officer)



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Customer Response to Field Safety Notice

Corrective Action for the automatic refill system of the ventilator SOPHIE

Customer Information	
Customer Name	
Address:	
ZIP, Town:	
Country:	

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

Fritz Stephan GmbH
 Kirchstraße 19
 D-56412 Gackebach
 Germany
 Fax ☎: +49 (0) 6439 9125 – 111
 Email ✉: 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 _____