



Fritz Stephan
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Clinical Experience
Technical Competence

URGENT - Field Safety Notice

To all users of the SOPHIE Ventilators

Re: Potential hazard of device failure due to defective heater cable.

Dear customer,

This letter is to inform you of a potential hazard of device failure due to defective heater cable.

When does this malfunction occur and what are the potential risks?

The "measure menu" in the display of a Sophie ventilator was opened without the user input. This behaviour can be caused by an inadvertent contact of the heater cable live wire with the wire mesh shielding, in this case of a defect or an inappropriate repair of the breathing circuit heater wires or its adapter cable.

In the event of a direct short circuit in the adapter cable of the disposable hose systems or heating wire itself, the device will be inoperable which leads to a loss of ventilation.

What steps can the user take to avoid the potential risk of this issue?

Users are advised to perform a software update that make the device more resilient against defects of the heater cable. Also, if a fault of the heating system is detected and alarmed, the heating must now be switched on again manually in the heating menu after the fault has been remedied.

Users are also advised that the update cannot be performed with the patient connected to the device but consider a forced implementation by removing the patient for the update. Removing the patient just for the update would be associated with considerable disruptions in clinic operations.



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How will the issue finally be resolved?

Fritz Stephan GmbH has developed a software update for Sophie that will resolve this potential hazard. The field software update is already available from 07/11/2023.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours



Kelvin Kho

07 November 2023



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| Contact person of this notification ...Kelvin Kho..... Department ...Chief Representative..... Telephone+603-74914467..... Fax+603-74991167..... E-mail ...kkho@sephan-gmbh.com..... |
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Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the SOPHIE ventilator with the Serial number _____ (optional) that I received the following document:

Field Safety Notice

Potential Hazard of Device Failure due to defective heater cable.

Place : _____

Date : _____

Name : _____

Signature : _____

Company stamp :