



Fritz Stephan
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Clinical Experience
Technical Competence

URGENT - Field Safety Notice

To all users of the SOPHIE Ventilators family

Re: Possible overfilling of the humidifier due to incorrectly installed refill hose by the operator

Dear customer,

This letter is to inform you the risk of overfilling the humidifier due to an incorrectly installed refill hose.

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

The pressure difference between the water reservoir and the patient component after the end of the system test can lead to a flow of water into the humidifier bottle of the patient component if the refill hose has not been inserted into the pinch valve. If the amount of water flowing down is too large, this is detected by the Sophie's level sensors and indicated by the high-priority alarm "Water level high".

In extreme cases, this can cause the water to overflow into the ventilation tubes. In this situation, starting mechanical ventilation may pose an unacceptable risk to the patient.

With this safety notice, Fritz Stephan GmbH would like to inform you about a software change that will prevent the start of mechanical ventilation if the maximum fill level has been exceeded and the high priority alarm "Water level high" has been activated.

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

Users are advised to:

- Always follow the instructions of use for the correct installation and use of the Sophie's refill system.
- Make sure that the refill hose has been correctly inserted into the pinch valve before hanging the water reservoir on the provided holder.
- Only use the original holder to hang the water reservoir and do not use infusion stands.
- If too high a water level is detected, turn the water reservoir with the spike upwards to



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prevent further overflow.

- Empty the humidifier bottle at least down to the "Max" mark and check whether any water has already

run into the ventilation tubes. Remove any overflowing water if necessary.

- Always check the water level and the breathing circuits before starting ventilation.

How will the issue finally be resolved?

Fritz Stephan GmbH developed a software solution that will prevent the start of machine ventilation if the maximum fill level has been exceeded and the high priority alarm "Water level high" has been activated.

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




19th September 2023

Contact person of this notification
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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

Possible overfilling of the humidifier due to incorrectly installed refill hose by the operator

Place : _____

Date : _____

Name : _____

Signature : _____

Company stamp :