



Fritz Stephan  
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 Clinical Experience  
Technical Competence

## **URGENT - Field Safety Notice**

To all users of the SOPHIE Ventilators

### **Re: SOPHIE Ventilators with Incorrect Frequency with SIMV in connection with the External Trigger**

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the SIMV in connection with the external trigger of the SOPHIE.

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

When using the external trigger in invasive SIMV ventilation with flow sensor switched OFF, it is possible that, due to software anomaly, every spontaneous breath detected triggers a mechanical breath.

The machine frequency then corresponds to the spontaneous breathing frequency, which means that the unit behaves as under assisted-controlled ventilation (Ass./Co.).

The increased minute volume can lead to a decrease in  $paCO_2$  and thus a decrease in respiratory drive.

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

Users are advised to ensure that any patient ventilated with an affected ventilator is adequately monitored and only use external trigger in conjunction with the non-invasive ventilation modes.


#### **How will the issue finally be resolved?**

Fritz Stephan Southeast Asia Sdn.Bhd. is preparing a software update SOPHIE that will resolve this potential malfunction. The field software update will be available from 28/04/2022.



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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

  
 Jack Chan



5<sup>th</sup> May 2022

Contact person of this notification ...Jack Chan..... Department ...Technical..... Telephone .....+603-74914467..... Fax .....+603-74991167..... E-mail ...jchan@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

SOPHIE Ventilators with Incorrect Frequency with SIMV in connection with the External Trigger

Place : \_\_\_\_\_

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

Name : \_\_\_\_\_

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

Company stamp :

