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Field Safety Corrective Action FSCA-21-004 FSCA-21-004 End User Response Form fabian[™] HFOi Ventilator Bias Flow Selection Buttons unavailable in the User Interface after incorrect selection of device configuration during software update

Affected products according to Field Safety Notice FSCA-21-004-FSN

Potentially affected devices: all fabian[™] HFOi ventilators with **software version older than 5.2.1**.

Device	REF No.	Description	Serial Number Prefix	Potentially Affected Software Versions
fabian™ HFOi	113001	Neonatal and pediatric ventilator	AI	Software versions older than 5.2.1

Refer to Field Safety Notice FSCA-21-004-FSN for instructions to determine whether you have any affected devices.

User Declaration (Required for devices that have not been updated to software 5.2.1)

Total mumber of fab			•				
	Total number of fabian [™] HFOi devices						
(state 0 (zero) if nor							
			oftware version older than				
5.2.1 and missing E	5.2.1 and missing Bias Flow selection buttons						
(state 0 (zero) if not	(state 0 (zero) if none)						
FOR EACH fabian [™] HFOi DEVICE, RECORD THE SERIAL NUMBER AND SOFTWARE VERSION.							
IF SOFTWARE VE	IF SOFTWARE VERSION IS OLDER THAN 5.2.1, PLEASE PROVIDE CONFIRMATION WHETHER:						
BIAS FLOV	V SELECTION BUTTO	NS ARE OR	ARE NOT AVAILABLE				
> IF NOT AV	AILABLE, SERVICE H	AS BEEN CO	ONTACTED TO UPDATE THE	SOFTWARE TO			
VERSION							
VERGION							
		Bias Flow Buttons Available?					
Device Serial	Installed Software	(Mark (✓) as appropriate)					
Number	Version			,			
Number	Version	VEO	NO				
Number	Version	YES	NO (Contact authorized service	for software upgrade)			
Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			
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Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			
Number	Version	YES		for software upgrade)			

Please provide extra sheets with tables if the tables in this document have insufficient space.

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Please provide a response to each of the following questions by checking the appropriate boxes.

1.	Have you received the full FSCA package, comprising the Field Safety Notice (FSCA-21-004-FSN) and this FSCA-21-004 End User Response Form?	YES 🗆	NO 🗆	
2.	Have you read the Field Safety Notice (FSCA-21-004-FSN) and understood the content and will you follow and implement the instructions accordingly?	YES 🗆	NO 🗆	
3.	Were all users of the fabian™ HFOi devices informed immediately about the FSCA and the FSCA package provided?	YES 🗆	NO 🗆	
4.	Have you identified all fabian TM HFOi devices with software version older than $5.2.1$ by serial number and entered them on or attached them to this response form, indicating whether the Bias Flow buttons are available or not?	YES 🗆	NO 🗆	
5.	For those fabian [™] HFOi devices where the Bias Flow selection buttons are missing from the user interface, have you contacted or will you contact your dealer/service provider to arrange a software update?	YES 🗆	NO 🗆	
6.	Were fabian [™] HFOi devices transferred to another location/organization?	YES 🗆	NO 🗆	
7.	If devices were transferred, was the complete FSCA package forwarded to the respective users accordingly?	YES 🗆	NO 🗆	
List contact details of recipients:				

If you answered NO to questions 1, 2, 3, 4, 5 or 7 above, please contact your service partner urgently for clarification.

User Details					
Contact person (name)					
Hospital (address)					
Country					
Email address					
Date	Signature				

AS THIS IS A MANDATORY FIELD SAFETY CORRECTIVE ACTION, ONLY FULLY COMPLETED FORMS WILL BE ACCEPTED. PLEASE FULLY COMPLETE AND SEND THIS RESPONSE FORM TO THE FOLLOWING EMAIL ADDRESS: GMB-AMS-FSCAresponsecentre@vyaire.com

Contact Information

For responses, feedback, questions, concerns, or any events that reasonably suggest being related to the subject of this FSCA or to related forms, please email: **GMB-AMS-FSCAresponsecentre@vyaire.com**

Sincerely,

Abir Roy QA Manager, Post Market Surveillance / FSCA Coordinator

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