

Field Safety Corrective Action Response Form FSCA-20-001

Details of affected parts and products:

Affected Products

Model	REF No.	Software Version(s)
fabian HFO	112001	5.0.x (with VG function) 5.1.x (with VG function)
fabian HFO Light	111001	
fabian HFOi	113001	
fabian HFOi Light	111001.01	
fabian +nCPAP evolution	122001	

Refer to the *User Work Instruction (TS-AA-027e)* and the *fabian Information (FI) Card* for further information about how to identify affected devices and instructions to follow for this FSCA.

User Declaration

Number of affected devices (total)	
FOR EACH AFFECTED DEVICE PLEASE PROVIDE (if necessary, attach extra page)	
Device Serial Number	Software Version

Please verify the following by checking the box below.

- I have received the FSCA package, including the *Field Safety Notice (FSCA-20-001-FSN)*, the *FSCA Response Form*, *User Work Instruction TS-AA-027e*, and the *fabian Instruction (FI) Card*, and understood the content and will follow and implement the instructions accordingly.
- I confirm that all users of the affected devices were and will be informed about the FSCA immediately and the FSCA package provided.
- I have identified all affected devices and have entered them on or attached them to this response form.
- I have printed out the *fabian Instruction (FI) Card* for affected devices and ensured it is or will be made available to all potential users, is kept together with the Instructions for Use, and will be retained until further notice.

- I confirm that affected devices were transferred to another location/organization and the complete FSCA package was forwarded to the respective users accordingly.
 - ❖ List contact details of recipients _____

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

PLEASE SEND THIS RESPONSE FORM TO THE FOLLOWING ADDRESS:

Contact Information

For 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

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