

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 <input type="checkbox"/>	NO <input type="checkbox"/>
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 <input type="checkbox"/>	NO <input type="checkbox"/>
3. Were all users of the fabian™ HFOi devices informed immediately about the FSCA and the FSCA package provided?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
4. Have you identified all fabian™ 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 <input type="checkbox"/>	NO <input type="checkbox"/>
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 <input type="checkbox"/>	NO <input type="checkbox"/>
6. Were fabian™ HFOi devices transferred to another location/organization?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
7. If devices were transferred, was the complete FSCA package forwarded to the respective users accordingly?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
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