

Field Safety Corrective Action (FSCA) End User Response Form FSCA-2021-002

Details of affected parts and products:

Affected products according to the Field Safety Notice FSCA-2021-002-FSN-1

Affected Parts	Part Number	Software Version(s)
Diagnostics Package Pulse Oximetry Adult/Pediatric	301.113.000	Not applicable for this FSCA
Diagnostics Package Capnography Mainstream	301.114.000	

Refer to the *Field Safety Notice FSCA-2021-002-FSN-1* for instructions to determine whether you have any affected products.

User Declaration

Number of affected devices (total)		
FOR EACH AFFECTED DEVICE PLEASE PROVIDE (if necessary, attach extra page)		
Part Number	Serial Number	Software Version
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Please verify the following by checking the appropriate boxes below.

- I have received the FSCA package, comprising *the Field Safety Notice (FSCA-2021-002-FSN-1)* and *FSCA End User Response Form*, and understood the content and will follow and implement the instructions accordingly.
- I confirm that all users of the affected devices were or will be informed about the FSCA immediately and the FSCA package was/will be provided.
- I have identified all affected products and have entered them on or attached them to this response form.
- I have removed the affected product(s) from use as indicated in the *Field Safety Notice (FSCA-2021-002-FSN-1)*.
- 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 _____.

FORM Field Safety Corrective Action (FSCA) End User Response			

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

PLEASE SEND THIS RESPONSE FORM TO THE FOLLOWING EMAIL ADDRESS:
GMB-AMS-FSCAresponsecentre@vyaire.com

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.

Sincerely,

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