URGENT FIELD SAFETY NOTICE

14-Jun-23 GE HealthCare Ref. # 76195

To: Hospital Administrators / Risk Manager
Biomedical Engineering
Head of Cardiac Ultrasound Department

RE: **Certain Vivid S60 / Vivid S70 / Vivid S60N / Vivid S70N Ultrasound Systems**

Safety Issue

GE HealthCare has become aware that certain Vivid ultrasound systems cannot boot up in a timely fashion. If this occurs, it can delay availability of the device in time-critical emergency situations.

Actions to be taken by Customer/ User

You can continue to use your device. Please follow clinical practice guidelines, which include having a backup imaging plan when performing time-critical examinations or image-guided interventions.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please complete and return the attached acknowledgement form to Recall.FMI76195@ge.com.

Please retain this document for your records.

Affected Product Details

Affected products:
Vivid S60 v203, v204
Vivid S70 v203, v204
Vivid S60N v203, v204, v205, v206
Vivid S70N v203, v204, v205, v206

Intended use:
Vivid systems are ultrasound imaging systems intended for echocardiography, with additional capabilities in vascular and general imaging

Product Correction

GE HealthCare will correct all affected products at no cost to you.
A GE HealthCare representative will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.
Service center: T: +44 8457 333 999 – Email : uk.customerserviceoffice@ge.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare Ref. # 76195

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.FMI76195@ge.com