# URGENT FIELD SAFETY NOTICE

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188 USA

<Date of Letter Deployment>

GEHC Ref# 76194

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

RE: **Smoke or fire in certain legacy Vivid Ultrasound Systems with batteries**

***This document contains important information for your product. Please ensure all potential Users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.***

**Safety Issue**

GE Healthcare has become aware that if batteries in certain legacy Vivid systems are not replaced at 2 years, as recommended in the Service Manual, they can fail and in rare occasions, they can emit smoke, or catch fire.

There have been no injuries reported as a result of this issue.

**Actions to be taken by Customer/ User**

You can continue to use your device.

Please follow the safety instructions provided in the appendix to this letter and place the appendix with your product labeling.

Please replace the battery:

1. every 2 years, or
2. if the battery is not capable of powering the system for more than 30 minutes (instead of the expected 60 minutes).

**Affected Product Details**

Affected products (if batteries are installed):
Vivid S5, Vivid S5 N, Vivid S6, Vivid S6 N, Vivid i, Vivid i N, Vivid q, Vivid q N

**Intended Use:**
Vivid systems are high performance diagnostic ultrasound imaging systems intended for echocardiography, with additional capability in vascular and general imaging.

**Product Correction**

GE Healthcare is providing a user manual supplement with specific instructions regarding battery safety with this letter. Instructions to access the service manual online are included in the Appendix.

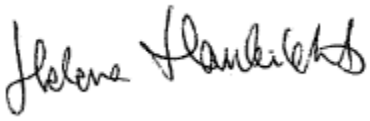
**Contact Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Helena Haukilehto
Medical Director
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GE Healthcare

GEHC Ref. # 76194

**FIELD SAFETY NOTICE ACKNOWLEDGEMENT**
**RESPONSE REQUIRED**

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

There are two options for your convenience:

1) Electronic response form (this page)

   OR

2) Manual filled and scanned response form (next page)

**Please scan the QR code or follow the link below to complete the workflow**

https://supportcentral.ge.com/esurvey/GE_survey/takeSurvey.html?form_id=18446744073710382240

**In case of issues with the link, please contact GE Healthcare at 1-800-437-1171**

**Alternatively, if the workflow on the previous page is not possible, 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): _____

Please return completed form by scanning or taking a photo of the completed form and email to:
Recall.76194@ge.com

**Appendix**

# Technical Publication

## Vivid™ S5 / Vivid S5 N / Vivid S6 / Vivid S6 N / Vivid i / Vivid i N / Vivid q / Vivid q N

All versions

FN092102-199

**Rev. 01**



This technical publication is a reference for all models of the Vivid S5, Vivid S5 N, Vivid S6, Vivid S6 N, Vivid i, Vivid i N, Vivid q, and Vivid q N ultrasound systems. It applies to all revisions of the software for the Vivid S5, Vivid S5 N, Vivid S6, Vivid S6 N, Vivid i, Vivid i N, Vivid q, and Vivid q N ultrasound systems, which will hereafter be listed as Vivid S5 / S6, Vivid S5 N / S6 N, Vivid i / q and Vivid i N / q N. All information in this publication is relevant for the eight systems unless otherwise specified.

# Revision History

Reason for change

| REVISION | DATE (YYYY-MM) | REASON FOR CHANGE |
|---|---|---|
| 01 | 2022-10 | Initial version |

List of effective pages

| PAGE NUMBER | REVISION |
|---|---|
| All pages | 01 |

Please verify that you are using the latest revision of this document. Information pertaining to this document is maintained on ePDM (GE electronic Product Data Management). If you need to know the latest revision, contact your distributor, local GE Sales Representative or in the USA call the GE Ultrasound Clinical Answer Center at 18006825327 or 12625245698.

Vivid S5 / Vivid S5 N / Vivid S6 / Vivid S6 N / Vivid i / Vivid i N / Vivid q / Vivid q N

This Technical Publication is a supplement to the following user manuals:

| System | User manual |
|---|---|
| Vivid S5 / S6 | R2419715 (BT07, BT08)<br>R2424458 (BT10)<br>5400908 (BT11)<br>5432774 (BT12) |
| Vivid S5 N / S6 N | FN092036 (BT07)<br>FN092037 / FN092038 / FN092039 (BT10)<br>FN092084 / FN092085 / FN092086 / FN092087 / FN092089 (BT12) |
| Vivid i | 2378958 (BT04, BT05)<br>R2422929 (BT09)<br>R2424431 (BT10)<br>5400907 (BT11)<br>5432770 (BT12) |
| Vivid i N | FL092107 / FL092109 / FL092118 (BT09) |
| Vivid q | R2422929 (BT09)<br>R2424431 (BT10)<br>5400907 (BT11)<br>5432770 (BT12) |
| Vivid q N | FQ092004 / FQ092005 / FQ092006 / FQ092018 (BT11)<br>FQ092023 / FQ092024 / FQ092025 / FQ092026 / FQ092027 (BT12) |

**Battery replacement**

**DANGER**: To avoid the risk of personal injury and/or property damages due to potential battery fire, the system battery in the Vivid S5 / Vivid S5 N / Vivid S6 / Vivid S6 N / Vivid i / Vivid i N / Vivid q / Vivid q N systems needs to be replaced or removed if either of the following two conditions should occur:

1. The batteries are two years old, or
2. The fully charged battery is maintaining system power for less than 30 minutes (the expected capacity of a new, fully charged battery, is 60 minutes).

Instructions for replacement and removal of the batteries are found in the corresponding Service Manual:

- Vivid S5 / S6: 2421482-100 (all versions)
- Vivid S5 N / S6 N: FN091019 (v2.0.8, v3.0.10), FN091065 (BT12)
- Vivid i / q: R2423164-100 (all versions)
- Vivid i N: FQ091013 (BT06, BT09), FL091021 (BT09)
- Vivid q N: FQ091013 (BT11), FQ091019 (BT12)

The service manual was provided to you with the system as hard copy or on software CD/UFD. It can also be found in the following link: https://customer-doc.cloud.gehealthcare.com

If the service manual is not available to you, or you have any other questions, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.