Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 210 **dated** 22/11/22 **Regarding NCMDR Field Safety Corrective Action of Vivid Ultrasound Systems from (mfr: GE Healthcare).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 210 / 2022

28 -04-1444 H

22-11-2022

Field Safety Corrective Action of Vivid Ultrasound Systems from GE Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17326
Product	Vivid Ultrasound Systems.
Description	Ultrasound imaging system.
Manufacturer	GE Healthcare.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Vivid S5, Vivid S5 N, Vivid S6, Vivid S6 N, Vivid i, Vivid i N, Vivid q, Vivid q N (if batteries are installed).
Reason	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.
Action	1. GE Healthcare is providing a user manual supplement with specific instructions regarding battery safety with the attached FSN. Instructions to access the service manual online are included in the Appendix. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

URGENT MEDICAL DEVICE CORRECTION

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.
8001243002 SaudiArabiaServiceCenter@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

Helena Haukilehto
Medical Director

GE Healthcare

GEHC Ref. # 76194

MEDICAL DEVICE NOTIFICATION 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

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) R2424458 (BT10) 5400908 (BT11) 5432774 (BT12)
Vivid S5 N / S6 N	FN092036 (BT07) FN092037 / FN092038 / FN092039 (BT10) FN092084 / FN092085 / FN092086 / FN092087 / FN092089 (BT12)
Vivid i	2378958 (BT04, BT05) R2422929 (BT09) R2424431 (BT10) 5400907 (BT11) 5432770 (BT12)
Vivid i N	FL092107 / FL092109 / FL092118 (BT09)
Vivid q	R2422929 (BT09) R2424431 (BT10) 5400907 (BT11) 5432770 (BT12)
Vivid q N	FQ092004 / FQ092005 / FQ092006 / FQ092018 (BT11) 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.