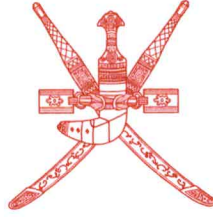


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصحة
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. 207... dated 25/11/21 Regarding NCMDR Field Safety Corrective Action of Vscan Extend devices 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

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT

Circular No. 207/2021


20 -04-1443 H

25 -11-2021



سلطنة عمان
وزارة الصحة
الديريته العامة للأدوية
والرقابة الدوائية
مسقط

Field Safety Corrective Action of Vscan Extend devices from GE Healthcare.

Source	NCMDR- National Centre for Medical Devices Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15929
Product	Vscan Extend devices.
Description	Ultrasound system, imaging, general-purpose.
Manufacturer	GE Healthcare.
The affected products	All Vscan Extend devices GTIN 00840682121651
Local agent	Waleed Pharmacy & Stores LLC.
Reason	An issue where the Vscan Extend will not power on because of a depleted internal battery.
Action	<ol style="list-style-type: none">1. GE Healthcare is advising customers that they can continue to use the device by following the instructions in the attached FSN.2. GE Healthcare will contact affected customers to arrange for software update. After the device software has been updated, discontinue usage of software version R1.2.3 or earlier.3. Contact the local agent for remedial action.
Product image	
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





URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref. 73091

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

RE: **Vscan Extend - Battery Depletion**

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 of an issue where the Vscan Extend will not power on because of a depleted internal battery. This issue can occur if the device is not turned off prior to the external battery being removed or when connected to a Personal Computer (PC) without connecting to AC power. In these situations, the device is not available for use until it is connected to AC power and charged for approximately 10 minutes. This could cause a delay in treatment.

Actions to be taken by Customer/User You can continue to use your device by following the instructions below.

1. Make sure to power off the Vscan Extend device before removing the external battery.
2. Always connect the device to AC power when it is connected to a PC.
3. If your Vscan Extend is being used outside of the normal hospital or clinic setting where it is the only imaging device available, please ensure device functionality is checked daily or before each shift.

Please ensure the correct email address and phone number are included in the attached acknowledgement response form.

Affected Product Details All Vscan Extend devices
GTIN: 00840682121651

Intended Use: Vscan Extend is a general-purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid.

Product Correction GE Healthcare will provide a software update, which will turn off the device automatically in the situations described above, at no cost to you. GE Healthcare will contact you to arrange for the correction.

After the device software has been updated, discontinue usage of software version R1.2.3 or earlier and destroy any software media containing previous versions of the device software, version R1.2.3 or earlier.

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

8004292222

SaudiArabiaServiceCenter@ge.com