URGENT FIELD SAFETY NOTICE

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

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.

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

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

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 check this box if your Vscan Extend is used outside of the normal hospital or clinic setting where it is the only imaging device available, such as ambulances.

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 Recall73091@ge.com

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