URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 73088

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

RE: Vscan Extend overestimation bias in calculated values using LVivo EF app.

This document contains important information for your product. Please ensure that 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 overestimation bias in automatically calculated ejection fraction (EF) values while using LVivo EF app on the Vscan Extend product. When using the LVivo EF application on Vscan Extend to measure EF, the displayed end-diastolic and end-systolic volumes can be incorrect and EF values can be overestimated. For example, this error can lead to false negatives with mild and moderate dysfunction appearing as normal. There have been no injuries reported as a result of this issue.

Safety Instructions

Users should discontinue use of the LVivo EF app until a correction is available and installed on the Vscan Extend. Vscan Extend can continue to be used for all other existing cleared indications including all other Vscan Extend apps and measurements.

Affected Product Details

LVivo EF app on Vscan Extend

The LVivo EF app is a separate app which our records show you have installed on your device(s) via the GE Marketplace. If the LVivo EF icon is available when in the cardiac preset during freeze (see attached picture) your device has the affected LVivo EF app installed.

Please note, if you have more apps installed, you may have to expand the action bar to see the LVivo EF app icon.

Product Correction

GE Healthcare will correct all affected products at no cost to you.
When the LVivo EF app update is available through GE Marketplace, customers will receive an email notification sent to the email address they set up during the Vscan Extend device registration process.

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,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

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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 Ref# 73088.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

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

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

Signature: _____

Printed Name: _____

Title: _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:
Recall73088@ge.com

You may obtain this e-mail address through the QR code below: