



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 76164, 76168

To: Hospital Administrators / Risk Manager
Biomedical Engineering
Managers of Radiology / Managers of Cardiology

RE: **Potential for Exam Images to be Stored Under Incorrect Patient on Certain Vivid Ultrasound Products**

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

GE Healthcare has become aware of an issue where a patient other than the intended is incorrectly selected by the operator in situations where DICOM Worklist search response time is slow. This issue is limited to certain Vivid Ultrasound systems and can result in the incorrect patient information showing on the screen during the exam. If not detected by the operator, images from the actual (intended) patient will be stored under the incorrect patient after the exam. This issue could lead to misdiagnosis. There have been no injuries reported because of this issue.

Safety Instructions

1. After selecting a patient in the DICOM Modality Worklist, make sure to review and confirm that the patient demographics shown on the ultrasound scanner screen during the exam is from the intended patient.
2. In the scenarios where the incorrect and/or actual patient already exists in the patient archive, a 'Patient Match' dialog will be shown to inform you about patient information inconsistency. Make sure to review the patient demographics properly.
3. To reduce the probability of occurrence of the issue, reduce the size of the DICOM Worklist search by:
 - a) Setting 'Max. Results' to 75 in the Worklist dataflow Config dialog (available by selecting Config | Connectivity | Dataflow | Worklist* | Inputs | DicomWorklist | Properties) and/or
 - b) *Configuring the DICOM Worklist server to automatically delete 'Scheduled Procedure Steps' that have been performed on the ultrasound scanner. If this option is not available on your DICOM Worklist server, make sure to manually clear all 'Scheduled Procedure Steps' that have been performed from the DICOM Worklist on a regular basis (e.g. every day).

*The actual instructions on how to perform this step depends on which DICOM Worklist server is used in your department. Consult your IT department to find out how to perform the step.

Affected Product Details

Vivid E95/E90/E80 with software version 201, revision 54.0 and 61.0.
Vivid S70/S60 with software version 201, revision 55.0 and 63.0.
Vivid S70N/S60N with software version 201, revision 63.0.

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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 & Regulatory
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare