



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 12169

December 2011

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Senographe 2000D Mammography systems: Potential inaccurate measurement on GE magnified images, acquired with a Magstand, when reviewed on workstations or PACS that are not adapted to GE Imager Pixel Spacing coding.**

GE Healthcare has become aware of inaccurate measurement on GE magnified images, acquired with a Magstand, provided by Senographe 2000D Mammography systems when reviewed on workstations or PACS that are IHE compliant only. This issue may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Imager Pixel Spacing is one of the DICOM attributes saved with Mammo Images created by Senographe systems. This attribute is used by the image review station for measurement tools.

There are two ways to code Imager Pixel Spacing tag in the industry:

1. "Film Like" coding, implemented by GE since 2000
2. IHE coding recommended since 2006

If a GE magnified image is acquired with Magstand 1.5 or 1.8 on a Senographe system and reviewed on a workstation or PACS that only supports IHE coding, then measurement value will be incorrect: it will be divided by mag factor of 1.5 or 1.8. There is a risk for the medical staff to underestimate a lesion or a tumor in the breast.

Some Workstations and PACS vendors implemented a distance measurement calculation that follows IHE recommendation only. Measurements on hard copy of such images could be incorrect. There is no measurement issue in contact mode, when the breast is directly in contact with the detector and no Magstand used.

It is possible that some workstations or PACS are not able to interpret the GE coding, nor the IHE coding. In this case, if measures are performed on magnified images, they will also be incorrect.

GE review workstations IDI and Seno Advantage are able to interpret GE "film-like" coding and "IHE" coding, or have a labeling warning the user about a potential measurement issue on magnified images.

Safety Instructions

The measures performed on magnified images depend on the workstation or PACS receiving those images from the Senographe system. If your review workstation or PACS is not a GE system, and is not capable to interpret the GE coding for the Imager Pixel Spacing tag, then measures performed on magnified images pushed from a Senographe system will be incorrect. For this reason, it is mandatory to always confirm all measures performed on magnified images by measures performed on contact images.

This recommendation applies to both newly acquired images and to archived images. Magnified images, acquired with a Magstand, can be easily recognized as there is a "M" on the top left corner of the image, in front of the scanview.

If you do not know if your system is capable to interpret the "GE film like" coding, please contact your system's vendor to get further information.

Affected Product Details All Senographe 2000D Mammography systems.

Product Correction None.

Contact Information If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/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.

Sincerely,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare