



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 12274

To: Director of Biomedical Engineering
Director of Radiology
Chief of Cardiology

RE: Senographe Crystal Nova – Potential patient mismatch in certain clinical scenarios

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

Safety Issue

Patient exams could be mixed between Patient Demographics (Patient Name, ID, Sex, Birthdate & Age) and Patient Information (X-ray image) in situations where system background activities cause system performance to slow. This situation can occur when the following features are used on your Senographe Crystal Nova:

- *Edit or Copy*, in Browser mode, or
- *Print or eContrast* reprocessing, in Viewer mode.

This issue could result in an incorrect diagnosis. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use your Crystal Nova System in accordance with user manuals and the instructions below:

1. In Browser Mode

Patient List View:

- You can continue to use all features.

Study List View:

- **DO NOT use *Edit* and *Copy* features until your system has been corrected.**
- You can continue to use *Export*, *Delete*, *Send* and *Append* features.

Image List View:

- **DO NOT use *Copy* feature until your system has been corrected.**
- You can continue to use *Export*, *Delete* and *Send* features.

2. In Viewer Mode

- **DO NOT use *Print* and *eContrast* features until your system has been corrected.**
- You can continue to use *Export*, *Delete*, *Send* and *Auto Print* features safely.

Affected Product Details

All Senographe Crystal Nova systems.

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

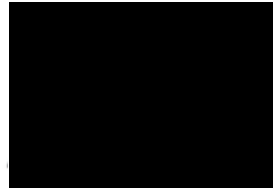
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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 Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare