



## URGENT FIELD SAFETY NOTICE

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 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,

A handwritten signature in black ink, appearing to read "James W. Dennison". The signature is fluid and cursive, with a large initial "J" and "D".

James W. Dennison  
Vice President - Quality Assurance  
GE Healthcare

A handwritten signature in black ink, appearing to read "Jeff Hersh". The signature is more compact and stylized than the one on the left, with a prominent "J" and "H".

Jeff Hersh, PhD MD  
Chief Medical Officer  
GE Healthcare