



## Urgent Field Safety Notice

GE Healthcare

Healthcare Systems  
9900 Innovation Drive  
Wauwatosa, WI 53226  
USA

April 2011

GE Ref: FMI # 60804, 67814, 67906

To: Hospital Administrators / Risk Managers  
Radiology Managers  
Radiologists

RE: **SR Viewer Reporting Tool: Edits made on a report can be saved into incorrect reports**

GE Healthcare has become aware that edits made on a report in the SR Viewer application can be saved into incorrect reports. 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

When two or more reports are opened in the SR Viewer application, edits made on one report/exam can be saved into incorrect reports/exams. Scenario that can lead to this problem:

- 1) User opens SR Viewer with at least 2 editable DICOM structured reports
- 2) User opens the first report in edit mode
- 3) User switches to the second report in edit mode
- 4) User switches back to the first report
- 5) User edits data in the first report
- 6) User saves the result and this will create a new report based on the patient identification and measurements data of the second report with some of the edits entered for the first report

No injury has been reported related to this issue.

### Affected Product Details

Optima MR450w, Discovery MR450, Discovery MR750, Signa HDx, Signa HDxt, Signa HDi, Signa Vibrant, GE 1.5T Signa HDe, Optima MR360, Brivo MR355

All SR Viewer versions 2.4.1 and 2.6.13 on the MR console of the listed products identified above are affected. The software version is displayed in the upper left corner of the SR Viewer user interface window.

### Safety Instructions

Open only one patient report at a time when editing a report in SR Viewer.

### Product Correction

GE Healthcare will correct all affected systems by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

### 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 the appropriate Regulatory Agencies have been notified.

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  
9900 Innovation Drive  
Mail Stop: RP2130  
Wauwatosa, WI 53226, USA

 [@ge.com](mailto: [redacted]@ge.com)



Chief Medical Officer  
GE Healthcare  
3000 N Grandview Blvd  
Mail Stop: W440  
Waukesha, WI 53188, USA

 [@ge.com](mailto: [redacted]@ge.com)