



**URGENT MEDICAL DEVICE
CORRECTION**



GE Healthcare

ViewPoint
Bildverarbeitung
GmbH
Argelsrieder Feld 12
82234 Weßling
Germany

March 18, 2009

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **GE Healthcare ViewPoint Image Archiving and Reporting System with software version 5.6.6 and 5.6.7. Images and/or reports can be assigned to the wrong patient.**

GE Healthcare has become aware of a potential issue associated with the GE Healthcare ViewPoint with software versions 5.6.6 and 5.6.7. 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 After a software update to GE Healthcare ViewPoint to versions 5.6.6 and 5.6.7, images and reports may be assigned to the wrong patient. This issue can occur during the software update to version 5.6.6 or 5.6.7 if there are any clients left open during the update process. This issue will not recur once the clients are shut down after the update is completed.

According to our records, your installation may be affected with this issue.

Affected Product Details GE Healthcare ViewPoint Image Archiving and Reporting System
Versions 5.6.6 and 5.6.7

Safety Instructions **GE Healthcare Short Term recommendations**

You may continue to use the product, however to ensure no recurrence of this issue, please check all clients on the server to ensure that they are all on the same software version, either 5.6.6 or 5.6.7. To do this, open the help menu to check the version. The version will be shown in the About submenu.

If any of the clients are not at the same software version, please shut down the client immediately to allow it to synchronize the version with the server. After restarting the client, recheck the software version to ensure that it has been updated.

Product Correction A GE Healthcare representative will be contacting you to evaluate if a correction is required to your database to appropriately assign images and/or reports. If required, your database will receive the correction at no charge.

**Contact
Information**

If you have any questions, please contact the GE ViewPoint Helpdesk tel.: 08153/93 11 11 or via email at vpsupport@med.ge.com.

This information has been communicated to the appropriate National Competent Authorities.

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.

Thank you,



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Geschäftsführer
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