



URGENT FIELD SAFETY NOTICE

GE Healthcare

GE Healthcare IT
540 W. Northwest Hwy
Barrington IL 60010
USA

2nd June 2015

GEHC Ref# 85386B

To: Director/Manager of Radiology
Hospital Administrator
Head of Radiology Department
PACS Administrator
Director of IT Department

RE: **Centricity PACS-IW with Universal Viewer version 5.0 Sp6 or higher customers.**

GE Healthcare has recently become aware of a potential safety issue with prior versions of the Centricity PACS-IW product.

Safety Issue A database deadlock could occur during the image acquisition process affecting the completeness of acquired images. There was the potential that one or more images would be missing from exams. While infrequent, database deadlocks do occur during normal database operations.

No actual patient injuries have been reported.

Safety Instructions None. No User activity required. The software version you currently have installed does not have this issue.

Affected Product Details Centricity PACS IW with Universal Viewer version 5.0.x up to 5.0 Sp5.1

Product Correction This issue is no longer occurring in the software you have installed as it has been resolved via a software correction in version 5.0 Sp6 and higher.

GE Healthcare has completed a remote inspection of your system and determined that there are cases in your database that were impacted by this issue while running a prior software version. A GE service representative will contact you to arrange for a correction.

Contact Information Please contact your local GEHC-IT Region Services Manager, Alasdair Thompson, at phone number +44 07920230005 or email address: alasdair.J.thompson@ge.com with any questions regarding this issue.

Our Customer Service Center can also be reached at the following telephone number:
UK - 08457 333999
Northern Ireland - 08000720248
ROI - 1-800 992 557

GE Healthcare confirms that this notice has been notified to the appropriate regulatory agencies.

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,

Handwritten signature of Russell Roberson in blue ink.

Russell Roberson
Vice President QARA
GE Healthcare IT

Handwritten signature of Jeff Hersh, MD in blue ink.

Jeff Hersh, MD
Chief Medical Officer – Medical Solutions
GE Healthcare

Customer Reply Form

PLEASE COMPLETE and FAX to GE Healthcare

CUSTOMER CONTACT INFORMATION

Note: please list all site locations and names if you are responsible for more than one site or if your site is known by other names. Thank you.

Site Name		Site Contact	
Other site			
Street Address		City	
State		Postal Code	Country
Phone		Email	

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

<u>Name and Title</u>	<u>Date</u>
<u>Signature</u>	

Please FAX back to:

+44 (0) 1 75 341 7098

Or Email to:

SafetyNotice@ge.com

Attention:

GE Healthcare
 EMEA Customer Safety letters Specialist
 283, rue de la Minière
 78530 Buc - France