

McKesson Medical Imaging Company
#130-10711 Cambie Road
Richmond, BC
Canada V6X 3G5
604.279.5422 Tel
604.279.5468 Fax



Urgent Field Safety Notice

May 20, 2014

To: Customers with McKesson Horizon Medical Imaging (HMI) products versions 4.6.1 to 11.9 and McKesson Radiology 12.0

Re: Possible data loss within image folders due to multiple software processes modifying the same data simultaneously.

Terminology

- Write lock – used when multiple users or processes need to access the image folder for writing/modification; this prevents data from being lost.
- Image folder – used for storage of:
 - DICOM images
 - Non-Image DICOM files (e.g. KIN, GSPS, CAD-SR)
 - Presentation changes (e.g. annotations, window leveling)
 - HMI Meta data (e.g. sequencing, file indexes)

On rare occasions, when two or more processes attempt to modify the same image folder within fractions of a second, the write lock mechanism may fail to prevent concurrent modification of the same data. This may result in loss of data within the image folder. As both simultaneous write access and lock mechanism failures are rare, the likelihood of experiencing this problem is very low.

Products affected

HMI 4.6.1

HMI 5.0 (Service Pack 1; Service Pack 5; Service Pack 7; Service Pack 8)

HMI 11.0 (11.0.3; 11.0.4; 11.0.5; 11.0.6; 11.0.6 FR EXP2; 11.0.7; 11.0.8)

HMI 11.5 (11.5.1; 11.5.2)

HMI 11.6

HMI 11.7

HMI 11.8

HMI 11.9

McKesson Radiology 12.0

Circumstances under which the issue occurs

The issue may occur when conducting any workflow using the system, and is not related to specific actions taken by a user.

Risk to patient

If the specific circumstances identified above occur, it is possible that clinical decisions will be made using a potentially incomplete study. This may result in inappropriate care leading to patient harm and/or a need to retake images.

Immediate actions to take to reduce the risk to patient

Technologist should ensure that all expected images are present in the study prior to completing the Technologist workflow.

Product updates that will address the issue

McKesson will provide a resolution to this issue through a software update which may require changing your software version.

This notice needs to be distributed to all those within your organization who need to be aware.

Alert other parties affiliated with your organizations that are affected by this field safety notice.

Please maintain awareness of this notice and resulting action until the defect has been corrected to ensure effectiveness of the corrective action.

All customers receiving this safety notice must acknowledge that they have read and understood this Field Safety Notice and contact McKesson Support as soon as possible at 1-800-663-2533 to arrange installation of the software update.

If you have any questions regarding this notice, please call our Customer Support department and ask to speak to your Support Manager.

Once again, until the product update is installed at your site, McKesson recommends the immediate actions (described above) be taken.

A copy of this field safety notice has been submitted to the appropriate regulatory agency.

Thank you.

Sincerely,

Jose Vergara
Vice President, Enterprise Support