

McKesson Medical Imaging Company
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Urgent Field Safety Notice

February 18th, 2016

To: Customers with McKesson Horizon Medical Imaging (HMI) products versions 4.6.1 to and including 11.9 and McKesson Radiology (MR) products 12.0, and 12.1.1.

Re: When images for a study are received in PACS, under certain circumstances, the system may store them in a non-unique directory location on the disk, resulting in two different patients sharing the same set of images.

McKesson has identified an issue where, under rare circumstances, imported images/studies may re-use a non-unique image directory.

This issue may cause an incorrect study to be displayed for a patient.

McKesson may be able to manually correct the image location for some image directories associated to an incorrect location; however, a subset of images may be permanently unavailable.

Products affected

The following versions are affected:

McKesson Radiology

12.1.1

12.0

Horizon Medical Imaging

11.9

11.8

11.7

11.6

11.5.2

11.5.1

11.0.8

5.0

4.6.1

Circumstances under which the issue occurs

The issue can **only** occur under the following circumstances:

- i. The PACS contains patient records indicating that images/studies reside in the cache storage, and
- ii. The indicated images/ studies were erroneously moved or deleted by a user, or have been lost due to an unrelated failure condition (e.g. due to a defective or corrupt hard drive), and
- iii. The patients records affected by the data loss have not been reconciled by McKesson Support

When images for a new study are subsequently received by PACS, the system may incorrectly re-use the disk location previously used by a study that has been affected by a prior data loss condition described above. If this situation occurs, the end result would be two patient records incorrectly sharing the same set of images.

Potential Impact to Patients

If the specific circumstances above occur, it is possible that clinical decisions will be made using an incorrect set of images. If undetected, this may result in inappropriate care leading to potential patient harm.

Immediate actions to take to reduce the risk to patient

All customers receiving this safety notice must contact McKesson Support as soon as possible at 1-800-663-2533 US/Canada and International Toll Free Radiology - 00 800 626 20009:

- 1) To acknowledge that they have read and understood this Field Safety Notice**

And

- 2) Arrange installation of software update/upgrade.**

This notice should be distributed to all personnel within your organization who need to be aware of this issue and the required actions, and alert other affiliated parties that are affected by this Field Safety Notice.

A copy of this Field Safety Notice has been submitted to appropriate regulatory agencies.

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

Thank you.

Sincerely,

Jose Vergara
Chief Customer Officer