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Urgent Field Safety Notice (Revision to Urgent Field Safety Notice dated August 3, 2017)

August 17, 2017

To: All customers with McKesson Radiology Manager (MRM)

This notice is being provided to communicate newly available information to customers.

Upon further investigation of the issue originally described in the Urgent Field Safety Notice dated August 3, 2017, additional information about this issue and the potential impact has been identified.

Re: Missing content from the report when the report is viewed, printed or sent as a pass-through HL7 message

McKesson Medical Imaging Company (McKesson) has identified a software issue with MRM that affects patient reports imported via an HL7 message into MRM from external systems, and patient reports created or modified in MRM. Under specific circumstances, this issue results in missing content from the report when the report is viewed, printed or sent as a pass-through HL7 message.

Products affected

- All versions of MRM

Circumstances under which the issue occurs

This issue is triggered by a presence of "<" symbol in the report. When this symbol is present in the report, either by itself or in combination with other characters, one of the following symptoms may be observed during display, print or transmission of the report:

- "<" symbol may be omitted, or
- Text containing the "<" symbol may be truncated or missing, or
- "<" symbol followed immediately by a non-alphanumeric character may get substituted with additional characters

Risk to patient

If the specific circumstances above occur, there is a potential for incorrect clinical decisions to be made if clinically relevant information included in the patient report is truncated or omitted.

Immediate actions to take to reduce the risk to patient

McKesson recommends that customers:

1. Contact McKesson Support to review possible configuration changes to help prevent further occurrences of this issue;
2. View patient reports in the original external system used to create the report, when making clinical decisions.

Product updates that will address the issue

McKesson will contact customers known to have a system that is configured in the manner described above, and review possible configuration changes to prevent this issue from occurring.

In addition, McKesson is developing a software update that will prevent future occurrence of this issue.

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

Alert other parties affiliated with your organization, which 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.

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

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

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

We strongly encourage you to contact McKesson Support as soon as possible for the software update.

Thank you.

Sincerely,

Rick Gary
VP Global Customer Success