

FIELD SAFETY CORRECTIVE ACTION

May 19, 2016

Dear Director of Radiology,

FUJIFILM Medical Systems USA, Inc. (FMSU) is hereby notifying you of a potential issue concerning the following Fujifilm Synapse PACS software:

- Fujifilm Synapse PACS software version 4.4.000,
- Fujifilm Synapse PACS software version 4.4.001,
- Fujifilm Synapse PACS software version 4.4.004,
- Fujifilm Synapse PACS software version 4.4.010 and
- Fujifilm Synapse PACS software version 4.4.020.

This issue exists in the above listed versions. It does not exist in versions prior to 4.4.000 and is fixed in 4.4.100 and later versions.

Description of the Issue:

Fujifilm has received a small number of reports where Synapse cannot display image files.

The "Image Not Loaded" message displays whenever an image cannot be loaded from the storage server. This message may display for a number of reasons. In this specific case, the message displays because the image was physically deleted from the storage server because of a software error in the Ad hoc deletion functionality. This situation extends to DICOM SR files and/or Annotation files, although no reported issues have been received.

Sites not using the Manage Content (Ad hoc Deletion) feature in Synapse are not affected by this Software error.

The reported issue occurs where the Manage Content (Ad hoc Deletion) feature in Synapse is used by the PACS Administrator for the following tasks:

1. Deleting a study and resending the same study on the same day
2. Under certain specific circumstances, if an authorized user deletes an image or a DICOM Object such as a DICOM SR file that is shared with other images then the image or DICOM SR file will be removed from all the series/studies that have the shared image/DICOM SR file.

Under normal operation, when a DICOM Object (series, study, single image, SR file, etc.) is intentionally deleted by an authorized user, the DICOM Object is placed in the recycle bin. When the Ad hoc Deletion retention period has been exceeded, the DICOM Object that was deleted by the user will be purged from the recycle bin and is unrecoverable.

Because of the error, when task 1 above is performed, Synapse will purge the original study and the resent study. When Task 2 is performed, Synapse will purge both the DICOM Object that was originally intended to be deleted and will also delete the DICOM Object that was shared with another study. As a result, for both Task 1 and 2, Synapse cannot access the image file or DICOM Object and displays the "Image Not Loaded" message.

Discussions for the Tasks listed above:

1. Deleting a study and resending the same study on the same day.

There is no need to delete a study prior to resending to Synapse. This extra step is unnecessary. Avoiding this unnecessary step will avoid the issue.

2. Under certain specific circumstances, if an authorized user deletes an image or a DICOM object such as a DICOM SR file that is shared with other images then the image or DICOM SR file will be removed from all the series or studies that have the shared image or DICOM SR file.

Images that have the same UID are typically not shared between series and studies. DICOM SR files may be shared.

Interim Actions:

- Immediately extend the data retention period as follows: On the System > Deletion Management > Adhoc Deletion Mgt page in SWAT, set a higher retention value than the default in the *Retention (in months) for Adhoc Deletion box*. FMSU recommends that all users change the retention time to a minimum of 24 months as an interim solution until you upgrade. If the retention period is set high enough, this will prevent a permanent loss of image files. OR
- Stop using Ad-hoc Deletion functionality until the System has been upgraded to Synapse 4.4.100 or above. Ad-hoc Deletion functionality is a privileged functionality where rights can be disabled using the Synapse Web Administration Tool and privileges can be easily removed for all user groups.

Potential Risk:

Images are lost and would not be available if one wishes to compare historical images with recent ones. This may present a risk in situations wherein the progress or effectiveness of patients' treatment may require historical images for comparison.

Root Cause:

FUJIFILM has determined the root cause to be an issue with the software program.

Please perform the following actions:

- Extend the Ad hoc deletion retention period or discontinue use of Ad Hoc Deletion.
- Submit the attached response form to Fujifilm.

FUJIFILM will be contacting you to schedule the following:

1. A time to run a script that will compare the image storage locations within the database and ensure that a file exists in that location. In the event that a file is missing we will explore all avenues for file restoration. For Synapse systems where FMSU has remote access, the script can be started remotely and runs in the background, having minimal or no effect on the operation of your Synapse system.
2. A time to update your system to Synapse v4.4.100 or higher, which will address this issue.

Yours sincerely,

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