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URGENT - FIELD SAFETY NOTICE
Telemis-Medical Software
Reference FSN 24892

Date : 14th November 2019

Recipients of this document

This document is intended for all users of the Telemis-Medical software, and in priority to the chief of radiology, the PACS Manager and the IT Manager.

Subject

Telemis recently discovered a security problem when using the "filmer" where, under very specific conditions, a new series identifier could be the same as an existing one. This causes the existing (older) series from potentially another patient to be associated to the new study.

This problem could affect patient security. Please ensure that all potential users in your institution have read this security notice and the security recommendations.

No incident impacting a patient has been observed to date.

Impacted systems

All sites running any versions up to and including 4.90-u00.5 release of the software are potentially affected.

Problem description, situations in which the problem may occur and possible consequence

When the filmer generates new films, it has to create a new identifier for the created series (Series UID). This identifier is generated from the identifier of the study (StudyUID).

Due to limitations specified in the DICOM specifications, the identifier must not exceed a specific size. To avoid exceeding the limit the study identifier is truncated before appending a series identifier. This can cause the new series identifier to be the same as an existing one.

The problem will occur when this series is sent back to the PACS. If an existing series has the same identifier and the same number of images, it is considered as already existing and only the meta data of the image will be updated. **This causes the existing (older) series from potentially another patient to be associated to the new study**.

For this to happen, the following specific conditions must be met : the modality has generated a long study identifier and the generated filmer series have all the same number of images. There is a high probability that the conflicting series had also been generated by the filmer.

Important: *in this case the new filmed image is lost*

Note: the filmed image displays the original patient name even if associated with the wrong patient. This can be used to detect the problem. See below:

Medical risk

Linking images to a wrong patient can have various impact on patient's health:
- Wrong or impossible diagnosis (image not found)
- Wrong diagnosis (pathology could be reported to another patient)
- Additional radiation (if the examination is to be redone)

Security recommendations

Correction will be available as part of a software patch expected in November 2019.

In the meantime, users must be careful and check that the displayed patient name in the image (bottom left) matches the identity of the selected patient.

Corrective action

As soon as the new release of the software is available, your Telemis-Medical installation will be updated, free of charge, and you will be informed of the correction.

Rest assured that the development engineers of Telemis are making every possible effort to resolve this problem as soon as possible. This is our top priority.

If you have any question, please contact our product support :
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- France: +33 534 273 840
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Telemis confirms that the National Authorities have been informed of this safety notice.

Sincerely,

Jean-Claude Spelte   Damien Martinquet
Quality Manager   *Head of Support Services*
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