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URGENT - FIELD SAFETY NOTICE
Telemis-Medical Software
Reference FSN 25512

Date : 16th December 2020

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 an issue with the mammo / tomo functionality that can potentially cause the tomo track bar to display incorrectly.

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.

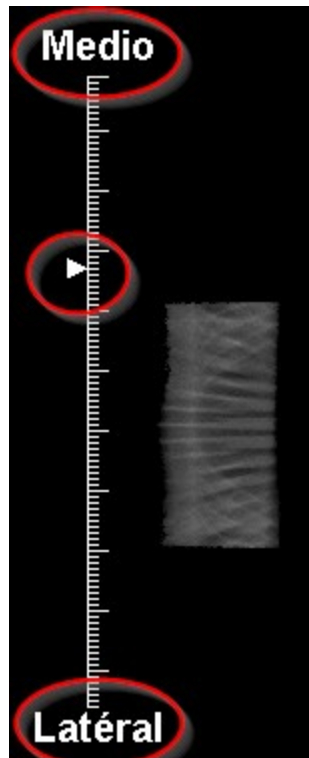
Impacted systems

All sites with TM-Mammo using tomography images with affected views, from version 4.80 up to and including version 4.95-u00.3, are potentially impacted.

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

Problem 1: laterality issue

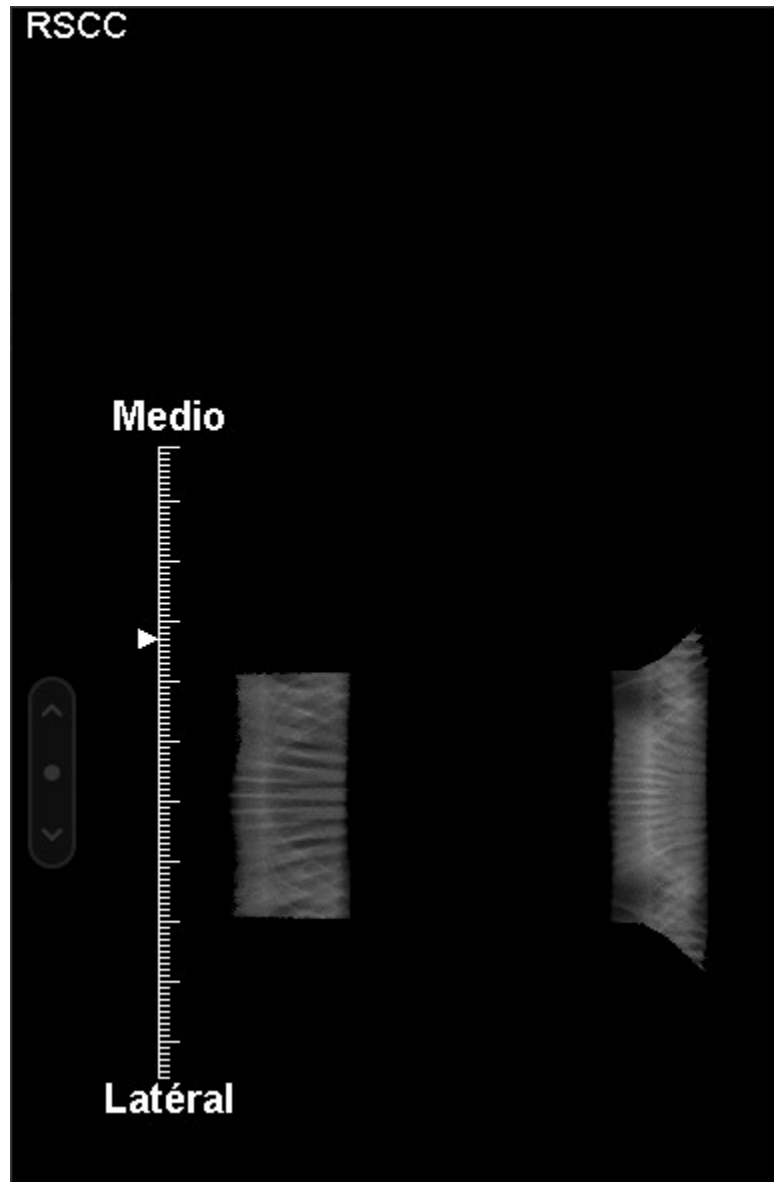
The position of the image in relation to the laterality indicators in the navigation track bar can be reversed. For example, the cursor may be located on the “medio” side while the image is actually on the “lateral” side.



This issue was detected on ML, MLO views.

Problem 2: ML navigation bar for CC

If a CC tomo series contains the attribute "View Modifier Code Sequence" (0054,0222), it can be detected as having an ML view. See the example below (the navigation bar displays Medio-Lateral instead of Cranio-Caudal):



Note: in this case, the indexName in the database is "RSCC" ("S" is the Viewer Modifier Code). It needs to be RCC for the track bar to be correct.

Problem 3: Misleading view indicator

The view indicator does not differentiate view direction, for example MLO and LMO both use the same 'MLO' label (same for ML/LM and CC/FB).



Medical risk

These three problems could lead to user confusion and therefore could impact the patient health as the diagnostic could be wrong due to laterality indicators.

Security recommendations

Correction will be available as part of a software patch expected in December 2020.

In the meantime, users should be vigilant and take extra care when viewing such tomo images. The display order is usually Left CC / Right CC / Left MLO / Left Tomosynthesis / Right MLO / Right TMS, but there are different working protocols. In all cases, it is imperative to have the 2 base incidences with unambiguous marking

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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Telemis confirms that the National Authorities have been informed of this safety notice.

Sincerely,

Jean-Claude Spelte
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