



Telemis s.a.
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URGENT - FIELD SAFETY NOTICE
Telemis-Medical Software
Reference FSN 28146

Date : 24th January 2023

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 enhancement curves which may be incorrect in some cases when multiple ROIs have been done on different slices.

The 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 using enhancement curves in *Telemis-Medical* PACS up to version 4.96 (latest patch is 08) are potentially impacted.

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

Sequence of actions to reproduce the problem:

1. Create at least 2 ROIs on different slices (on multi-phase series)
2. Generate enhancement curves for all ROIs in the same graphic.

For each ROI:

- a. right click on the ROI
- b. "display enhancement curve"

Consequence:

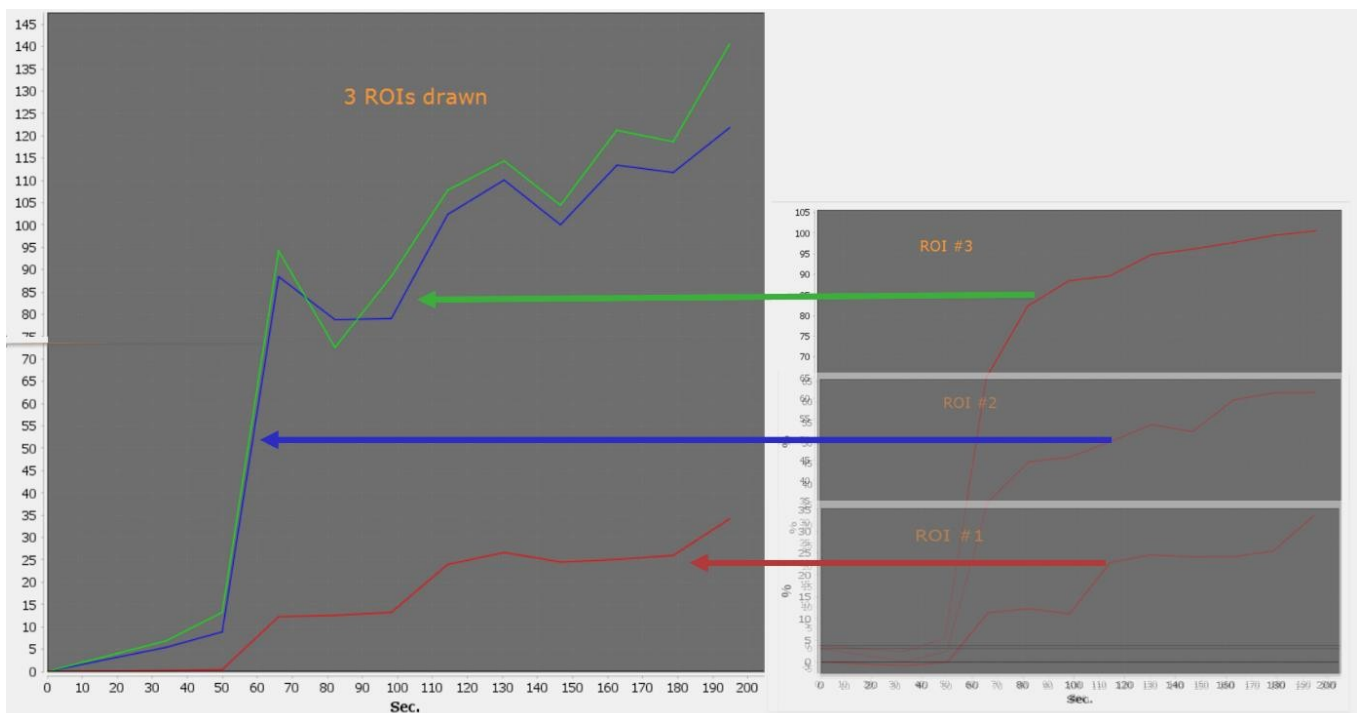
When adding the second ROI, the generated graph may be incorrect.

Medical risk

When the problem occurs the displayed enhancement curves are confusing and not what the user would expect.

This can lead to a misinterpretation and could therefore impact the patient health.

The following picture shows, on the left, the result of adding the 3 curves on the right (calculated individually). It clearly shows that the shape of the curves are changed as well as their absolute values.



Security recommendations

Correction will be available as a 4.96 patch expected in February 2023 as well as in the official 4.97 release.

In the meantime, enhancement curves must only be generated with one ROI at a time.

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.

Be 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,

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