



Urgent Field Safety Notice – 28 September 2017

INTELEPACS Versions 3.5.1 and up

Our reference: 569622

To: Chief Executive Officer
Head of Radiology

Following a complaint from a client, Intelrad is hereby notifying you of a problem that could occur on your IntelePACS software.

Intelrad has validated that your IntelePACS software is in fact affected by this problem. Intelrad is hereby providing you with additional information and recommendations below regarding this problem.

Affected products

INTELEPACS Versions 3.5.1 and later versions

Description of the problem:

The Magnification Tool functionality may display incorrect images if user is using reverse ordering. In this instance, the image shown in the tool will not be the one in the current viewport. The tool is displaying the magnified image for a different slice of the series.

This software defect could lead radiologists to delay their diagnosis/report.

No patient incident has been reported at this moment. This problem is reported as a precaution.

Corrective Action:

For all clients with IntelePACS InteleViewer version 3-5-1 and up, the software update will be deployed within a timeframe to be agreed upon with clients.

Intelrad Medical Systems
Central Station
895 de la Gauchetière W., Suite 400
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Your workflow will not be impacted. The update will result in approximately five minutes of downtime per server while we perform a full service restart. Impact on users is minimal, if any.

Customer Action:

- 1- Advise all users of the system of this problem.
- 2- Complete the attached Client Response Form and return the response form by fax to 1-514-931-4653 or scan the response form and send it by email to regulatory@intelerad.com.

Transmission of this Recall for Product Correction Notice:

This notice needs to be passed on to all those who need to be aware within your organization. Please maintain awareness of this notice until your IntelePACS software has been updated.

Additional information

In accordance with national regulations, we must keep track of client's responses. We are therefore asking you to please complete and return the attached Client Response Form.

Intelerad Medical Systems Inc., sincerely regrets any inconvenience caused to your organization.

Best regards.

Rick Rubin
Chief Engineering Officer
Intelerad Medical Systems
Incorporated
Dated: 28 September 2017



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CLIENT RESPONSE FORM

Our reference: 569622

Please complete and return this form by fax or e-mail as soon as possible.

SITE CODE (if known)

SITE NAME

POSTAL ADDRESS

TELEPHONE #

FAX #

I hereby acknowledge that all required personnel have been notified of the problem and all personnel using the medical device have been advised to follow the recommended safety instructions.

OR

I hereby acknowledge that we have been notified of the problem however we do not use the system under the described conditions.

NAME

TITLE

SIGNATURE

DATE

PLEASE RETURN COMPLETED FORM TO

Fax +1-514-931-4653

OR

e-mail regulatory@intelerad.com

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