

Urgent Field Safety Notice

- Image Suite 3.0 with Mini-PACS Options and Hot Fix 3004 software patch
- Image Suite 4.0 with Mini-PACS and DICOM Store

Carestream Health FSCA MA-2016-004 Device modification

Date: 22 April 2016

Attention: Potential for the L (Left)/R (Right) and A (Anterior)/P (Posterior) overlay text to be displayed reversed on Computed Tomography (CT) and Magnetic Resonance (MR) images received in Image Suite software.

Details on affected devices:

- Image Suite 3.0 with Mini-PACS Options and Hot Fix 3004 software patch
- Image Suite 4.0 with Mini-PACS and DICOM Store

Description of the problem:

Carestream has identified a software issue that if the Image Suite software receives Computed Tomography (CT) and Magnetic Resonance (MR) images with the Image Orientation (Patient) Tag specified, and the overlay is configured to display this tag, the L (Left) and R (Right) and A (Anterior) and P (Posterior) overlay text could be displayed reversed. If the radiologist does not recognize that the annotation tags are incorrect with respect to the actual anatomy of the image being reviewed, misdiagnosis or incorrect care is possible.

Advice to users:

Customers who have this Image Suite configuration but do not use it for CT or MR Imaging do not need to take any action. Customers who do use the product for CT or MR Images are asked to make users aware of the problem and take additional steps to check correct orientation of any markers, until the software is updated.

Please complete and send back the attached confirmation form within 5 working days.

Action taken by the manufacturer:

Carestream has created a software update to Image Suite to resolve this issue. Carestream's representative will contact you and schedule a convenient time within the next 6 months to update the software (irrespective if you currently use the device for CT and/or MRI).

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions or in the event of any concern, please call your local Service support number.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We regret any inconvenience this may cause to your operation.



Kevin Wright
Director, International Regulatory Affairs



FSCA Appendix – Notification Acknowledgement

Please read and complete all information below and send this form within 5 working days to: emeaehs@carestream.com. Thank you.

I hereby acknowledge receipt of the Field Safety Notice related to the following Field Safety Corrective Action:

Carestream Health FSCA MA-2016-004 / Device modification (software update)

- Image Suite 3.0 with Mini-PACS Options and Hot Fix 3004 software patch
 - Image Suite 4.0 with Mini-PACS and DICOM Store
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I certify that the users/departments are aware of the advices given in the Field Safety Notice.

Comments (optional): _____

Name of the site: _____

Address of the site: _____

Name of the person: _____

Title of the person: _____

Signature: _____

Date: _____