

February 5, 2013

URGENT FIELD SAFETY NOTICE

Vitreia Enterprise Suite, Vitrea, VitreaAdvanced, VitreaCore (VitalConnect) and Vitrea fX prior to version 6.3.3, except 6.1.6, 6.2.3 and 6.3

FSCA-identifier: EU13VI_A

Type of action: Device Modification; Caution Regarding Measurement Error

Dear Customer:

Vital Images has found an error regarding measurement that it wishes to bring to your attention. This error occurs when images are rotated at the time of reconstruction by the scanner in non-90 degree increments of the transverse/axial plane (rotation around the z-axis), while not being simultaneously rotated around the x-axis and y-axis. We have found this orientation adjustment to occur on rare occasions, such as to straighten tilts in head or neck scans, usually with minimal effect on measurements, but sometimes resulting in differences in length measurements of up to twenty-nine percent and in volume measurements of up to fifty percent, so please use caution when reviewing measurements of images reconstructed with orientations that are adjusted in such a manner. This issue was found through internal testing. No customer reports of the issue have been received.

This error affects all versions of Vitrea Enterprise Suite, Vitrea, VitreaAdvanced, VitreaCore (VitalConnect) and Vitrea fX prior to version 6.3.3, except 6.1.6, 6.2.3 and 6.3.

Immediate Action:

Please immediately inform all potential users of Vitrea of the information contained in this letter. We recommend that all measurements associated with the error described in this letter be verified against results from other technologies.

Vital Images is preparing patches for this error for versions 5.2, 6.0, 6.1, 6.2 and 6.3. You will be contacted by Vital Images Customer Support or by the customer support department of your distributor to arrange for installation of this patch on your system. We recommend that you implement the patch. If you have an earlier version, Vital Images Customer Support or your distributor will contact you to discuss your options for replacement.

Your Response Needed:

Please sign this Notice in the space below to verify that you have received and understood it, and return your signed Notice by email to fieldnotices@vitalimages.com.

The undersigned, on behalf of Vital Images, confirms that this Notice has been provided to the appropriate regulatory agencies.

If you have questions, direct customers of Vital Images should contact Vital Images Customer Support at 1-800-208-3005 or by e-mail to support@vitalimages.com; customers through a distributor of Vital Images products should contact that distributor.

Sincerely,



Jim Litterer
Vice President, Operations
Vital Images, Inc.

The undersigned confirms that this Notice regarding errors in measurements resulting from rotations around the axial plane has been received and understood. The undersigned further agrees to notify users of this error.

Institution

Name

Signature

Date