

March 25, 2013

## URGENT FIELD SAFETY NOTICE

**Update: Vitrea Z-Axis Measurement Error for Vitrea software versions 6.3.2 and prior**

**FSCA-identifier: EU13VI\_A**

**Type of action: Device Modification; Caution Regarding Measurement Error**

This is a follow-up communication to the original voluntary recall initiated by Vital Images, Inc. on February 5, 2013. This is a voluntary action, supporting our dedication to provide quality products to our physicians and patients.

Products affected by this amended notification are Vitrea Enterprise Suite, VitreaAdvanced, VitreaCore (VitalConnect) and Vitea fX including all versions 6.3.2 and prior.

**Note: Versions 6.3.0, 6.2.3 and 6.1.6 are now impacted by this amended notification.**

Vital Images has made a decision to perform a voluntary field correction to the above software versions. Vital Images has identified an error regarding measurements for images that are viewed using Vitrea.

This error occurs when images are rotated only around the Z-axis. Images rotated around the X-axis or Y-axis will not be affected, whether or not they are also rotated around the Z-axis.

Further, this error exists in rotations 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. Vital found this orientation adjustment to occur on rare occasions, such as to straighten tilted head or neck scans, usually with minimal effect on measurements. However, under certain conditions, this error may result in large length, area, and volume measurement differences.

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.

### Next Steps

1. Immediately inform all potential users of Vitrea of the information contained in this field safety notice letter.
2. It is recommended that all measurements associated with this error be verified against results from other technologies.
3. Follow your institutions policy and procedures on FDA Class II recalls.
4. Please send the signed enclosed Effectiveness Check form to [fieldnotices@vitalimages.com](mailto:fieldnotices@vitalimages.com) or fax to +1 952-540-3717. *Your facility must complete and return this form even if you are not currently impacted by this action.* This information is essential in order to maintain recall effectiveness information required by FDA.

Vital Images is preparing upgrades for this error for versions 4.1, 6.0 and 6.2. Upgrades are currently available for version 6.3. Those customers using versions 6.4 or higher are unaffected by this error.

Direct customers of Vital Images and customers of Toshiba America Medical Systems (TAMS) will be contacted by Vital Images Customer Support to arrange for an upgrade. Customers who received the products through a distributor will be contacted by their distributor to arrange for installation of the upgrade. We recommend that you implement the upgrade.

### **Vital Contact**

If you have questions, direct customers of Vital Images and customers of TAMS should contact Vital Images Customer Support at +1-800-208-3005 or by e-mail to [support@vitalimages.com](mailto:support@vitalimages.com); customers who are serviced through a distributor should contact their distributor directly.

We apologize for any disruption that this issue may cause. Vital is committed to providing your facility with high quality and safe products. We appreciate your understanding as we take corrective action to ensure patient safety.

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

Sincerely,

A handwritten signature in black ink, appearing to be 'Jim Litterer', with a stylized, sweeping flourish at the end.

Jim Litterer  
Vice President, Operations  
Vital Images, Inc.

Enclosure

**PRODUCT RECALL**

**Effectiveness Check**

**PLEASE FILL OUT AND RETURN**

The undersigned confirms that this Notice regarding Vitrea Z-Axis Measurement Error has been received and understood. The undersigned further agrees to notify users of this error.

AMENDED RECALL- Vitrea Z-Axis Measurement Error

Vitrea Software Version Number: \_\_\_\_\_

FACILITY NAME		
Location(s)/ Address		
Printed Name		
Title		
Contact Information	Phone	
	Email	
Signature		

Submit form to [fieldnotices@vitalimages.com](mailto:fieldnotices@vitalimages.com) **or** fax to +1 952-540-3717.