URGENT FIELD SAFETY NOTICE

Vitrea CT Brain Perfusion 2D

FSCA-identifier: EU13VI B

Type of action: Device Limitation; Description of product limitations for supported and

unsupported wide coverage brain perfusion exams

The following information and required actions are due to a voluntary recall initiated by Vital Images, Inc. This is a voluntary action, supporting our dedication to provide quality products to our physicians and patients.

Products affected by this notification are the Vitrea CT Brain Perfusion 2D application on versions 6.0 and above for Vitrea Enterprise Suite, Vitrea, VitreaAdvanced and Vitrea fX.

A decision was made to complete a field correction based on a product labeling deficiency. Vital received one report about potential user confusion when viewing a brain perfusion scan on Vitrea CT Brain Perfusion 2D when the scan was performed using a wide coverage shuttle acquisition technique. User confusion may result in patient treatment delays, misdiagnosis or mistreatment.

The Vitrea CT Brain Perfusion 2D application has technical limitations that currently do not support all types of wide coverage brain perfusion exams. Please note that versions of **Vitrea 5.2**, **Vitrea Enterprise Suite 1.3**, **and Vitrea fX 3.1 or lower** do not support **any** wide coverage brain perfusion exams.

Please read the below product limitations for Vitrea CT Brain Perfusion 2D:

Vitrea CT Brain Perfusion 2D supports standard axial scans with no table motion for all scanner manufacturers.

Vitrea CT Brain Perfusion 2D supports helical shuttle scans from both GE and Siemens scanners, except for scans that have slice levels greater than 50 or scans that are sent as more than one series. Helical shuttle has not been validated for any other scanner manufacturer.

Vitrea CT Brain Perfusion 2D supports jog shuttle scans for GE scanners, except for scans that have slice levels greater than 30 or scans that are sent as more than one series. Jog shuttle has not been validated for any other scanner manufacturer.

When loading unsupported wide-coverage data in Vitrea CT Brain Perfusion 2D, the perfusion maps may not be accurate. Known behaviors include a potential for perfusion differences between the top half of the scan and the bottom half of the scan.

PLEASE NOTE: NO OTHER VITAL PRODUCTS ARE INVOLVED IN THIS RECALL.

Next Steps:

- 1. Verify your current software version of Vitrea.
- 2. Verify if your facility is using wide coverage brain perfusion exams from only GE or Siemens and your Vitrea software version is 6.0 or higher.
 - a. If so, you are not impacted.
 - b. Complete the "Effectiveness Check" form and return to Vital.
- 3. If your facility IS using wide coverage shuttle acquisition methods from a manufacturer other than GE or Siemens, such as Philips Jog Mode, or if your Vitrea software version is 5.2 or earlier, immediately inform all users of this product limitation and discontinue sending wide coverage brain perfusion exam volumes through the Vitrea CT Brain Perfusion 2D application.
 - a. Prior exams completed in Vitrea CT Brain Perfusion 2D should be reviewed for patient outcomes.
 - b. Vitrea CT Brain Perfusion 2D will still support standard axial scans.
 - c. **Note**: All versions of Vitrea CT Brain Perfusion 2D are potentially impacted.
- 4. Please send the signed enclosed Effectiveness Check form to field-notices@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 not providing a software upgrade or software change related to this issue. Please communicate with your facility the product limitations discussed in this notice.

Vital Contact

If you have questions, direct customers of Vital Images and customers of Toshiba America Medical Systems (TAMS) should contact Vital Images Customer Support at +1-800-208-3005 or by e-mail to support@vitalimages.com; customers through a distributor other than TAMS should contact that distributor.

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.

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 product limitations of Vitrea CT Brain Perfusion 2D for wide coverage brain perfusion exams has been received and understood. The undersigned further agrees to notify users of this error.

RECALL- <u>Vitrea CT Brain Perfusion 2D</u>	
Vitrea Software Version Number:	
☐ We do not utilize Vitrea CT Brain Perfusion 2D at this/these Facility(s).	
☐ We do utilize Vitrea CT Brain Perfusion 2D at this/these Facility(s).	
FACILITY NAME	
Location(S)/ Address	
Printed Name	
Title	
Contact Information	Phone
	Email
Signature	
Date	

Submit form to <u>fieldnotices@vitalimages.com</u> <u>or</u> fax to +1 952-540-3717.