URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 21001

To: Chief Physician
Clinical Director
Chief Radiologist
Director of IT
Hospital Administrators/Risk Managers

RE: **SUV Tool Issue on MIM 7.2.0 - 7.2.6**

Safety Issue

MIM Software, a GE HealthCare Company, has become aware of an issue with the Standardized Uptake Value (SUV) tool within MIM Software versions 7.2.0 through 7.2.6. You may have had access to these versions through local installation or through MIM Anyware 1.1.

In situations where two images with differing Fields of View (FOV) complete an image fusion, an incorrect, elevated Maximum SUV could result. This could lead to mistaken assessment of disease status, progression or response to treatment and potential inappropriate therapy.

MIM Software has received no reports of patient injury as a result of this issue.

Actions to be taken by Customer/ User

You can continue to use your device if you are not using the SUV tool or if you access a non-impacted version of MIM when using the SUV tool.

If using a non-default workflow and fusing a PET or SPECT image with another image with a different FOV, **do not incorporate the Maximum SUV value into assessment of disease status, progression or response to treatment**.

NOTE: MIM's default workflows do not fuse images with differing FOV, and the Maximum SUV values reported are correct.

If you are using the SUV tool and are unsure if you are affected by this issue, please contact your MIM Site Development Manager, your Distributor for MIM Software, or MIM Customer Support.

Please complete and return the attached acknowledgement form to recall.21001@MIMsoftware.com.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Affected Product Details

Version	UDI
MIM Anyware 1.1	Not Applicable
MIM 7.2.0	(01)00850009343192(10)L917-02(8012)7.2.0
MIM 7.2.1	(01)00850009343192(10)LB19-02(8012)7.2.1
MIM 7.2.2	(01)00850009343192(10)M127-01(8012)7.2.2
MIM 7.2.3	(01)00850009343192(10)M314-02(8012)7.2.3

MIM 7.2.4	(01)00850009343192(10)M609-00(8012)7.2.4
MIM 7.2.5	(01)00850009343192(10)M621-05(8012)7.2.5
MIM 7.2.6	(01)00850009343192(10)M825-02(8012)7.2.6

Intended Use:
MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images including but not limited to CT, MR, CR, DX, MG, US, SPECT, PET and XA. MIM provides a variety of tools and features (as detailed in the Indications for Use) to support the display, processing, fusion, modification, contouring, and analysis of medical images.

Product Correction

MIM Software will correct all affected products at no cost to you.
Your MIM Site Development Manager or your Distributor for MIM Software will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact your MIM Site Development Manager, your Distributor for MIM Software, or MIM Customer Support.

GE HealthCare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Safety Officer
GE HealthCare

GE HealthCare

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FIELD SAFETY NOTICE ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to MIM Software, a GE HealthCare Company, promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Field Safety Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

Please select one of the options below. Once this letter is returned and based on your selection below, you will be contacted by your MIM Site Development Manager or Distributor for MIM Software.

☐ Please have my MIM Site Development Manager or Distributor for MIM Software contact me to initiate a review and upgrade of any affected software version.

Upgrade Customer Contact Name: _____

Upgrade Customer Contact Email Address: _____

☐ I acknowledge that my institution does not have any affected versions of MIM (7.2.0 - 7.2.6) installed or accessible and do not wish to be contacted by my MIM Site Development Manager or Distributor for MIM Software for an upgrade.

Signatory Customer Contact Name: _____

Signatory Customer Contact Email Address: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Field Safety Notice, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: recall.21001@MIMsoftware.com