

Date: February 7th, 2022

Ref: MRBR-22H001

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu XTV system : SONIAOVISION G4, FLUOROsPEED

Description of issue (Reason):

It was found that the following problems may occur when certain operations are performed, in the course of product evaluation in the factory.

- (1) The X-ray irradiation rate (pulse rate) of pulsed fluoroscopy is different from the set value.
- (2) BH filter (Beam Hardening filter) for fluoroscopy is different from the set value.
- (3) The calculated dose displayed on the screen is higher than the actual dose. (The correct dose value is displayed if an area dosimeter is installed.)

How to identify the affected products:

Your authorized Shimadzu local representative or Shimadzu National Technical Support can investigate whether your product(s) is affected or not. Please contact your local Shimadzu representative or contact Shimadzu National Technical Support.

Corrective action plan by Shimadzu:

We will take field corrective action to avoid the problems described in the "Description of issue" section above.

Actions to be taken by customer:

To avoid problems, do not do any of the following until you are completed corrective action:

- Before study begins (before patient registration), fluoroscopy is done by pressing a foot switch.
- Change from continuous fluoroscopy to pulsed fluoroscopy by the touch panel. (Continuous fluoroscopy is not registered at the time of delivery)
- "Temporary Procedure Edit" is performed during study to change the fluoroscopy mode..
- After general radiographic examination, fluoroscopic examination is performed. (If fluoroscopy is performed after a general radiographic procedure, carry out the procedure selection again after the procedure is started. Reselect to get the correct setting.).
- While the fluoroscopic rate of 30 fps is selected, the visual field size is changed from a small field of view (12/9/6 inches) to a large field of view (17/15 inches), and the setting of the fluoroscopic tube voltage etc. is changed (IBS ON/OFF change, fluoroscopy density change, and manual change of fluoroscope voltage).

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You will be contacted by Shimadzu's local representative to determine whether your system requires the above corrective action. If you are not contacted by Shimadzu, please call Shimadzu National Technical Support.