

Medical Regulatory Policy Department Post Market Surveillance Section

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Date: Aug. 7th, 2024 Ref: MRBR-24H059

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu X-ray R/F System: SONIALVISION G4 / FLUOROspeed

<u>Description of issue (Reason):</u>

We have found that certain software versions of our X-ray TV system SONIALVISION G4 / FLUOROspeed may occasionally fail to display images when switching from Fluoroscopy mode to Radiography mode.

Even when this event occurs, it is possible to solve this problem by turning off the power of the system once and then pressing the reset switch on the digital radiography unit's control cabinet.

However, we cannot deny the possibility of delay or cancellation of the inspection because it is different from normal operation.

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 Upgrade to the corrected software.

Actions to be taken by customer:

When switching from the fluoroscopy mode to the radiography mode, if a phenomenon occurs in which the image is not displayed, Please turn off the power of the system once and press the reset switch on the image collection cabinet. Then restart the system.