

Medical Regulatory Policy Department Post Market Surveillance Section

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Ref: MRBR-21H012

Date: November 15, 2021

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu CVS system: Trinias, BRANSIST alexa, BRANSIST safire X-ray High Voltage Generator: UD150G-40

Description of issue (Reason):

It was found that the irradiated x-ray may exceed the x-ray radiation dose rate specified in regulations and/or standards in some specific case of fluoroscopic mode due to inadequate adjusting criteria in installation.

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:

As our planned field correction at the affected sites, we will readjust the equipment in an appropriate criteria.

Actions to be taken by customer:

Please pay attention to the following point until the work is completed.

In HLC fluoroscopy or 30 pps fluoroscopy mode, the dose rate may exceed the legal or standard dose rate depending on the combination with the selected program.



The current shooting program and fluoroscopy program are displayed at the bottom of the monitor. However, if "① the shooting program category is "Cardio" and "② the shooting program" is other than DA, such as DSA, RSM-DSA, ROT-DA, please do not use HLC fluoroscopy (③ the fluoroscopy program is indicated with "/ H").



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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.