
1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan Phone: +81-75-823-1928 Fax: +81-75-823-2530

Date: June 6th, 2024

Ref: MRBR-24H033A

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu Digital Angiography System : Trinias (Biplane system only)

Description of issue (Reason):

The following problems were found to occur in Trinias biplane systems with firmware of specific versions.

This problem only occurs on biplane systems with firmware of specific versions.

Trinias has a single plane system with one C-arm equipped with a X-ray tube and a detector, and a biplane system with two C-arms equipped with a single X-ray tube and a detector, allowing viewing from two directions.

It was found that only when the biplane fluoroscopy was performed at 10 frame / second, there was a possibility that the X-ray irradiation which was originally performed alternately in the frontal plane and the lateral plane was simultaneously irradiated.

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 install the improved firmware.

Actions to be taken by customer:

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

Do not use 10 frame / second for biplane fluoroscopy.