

Date: July 16th, 2025

Ref: MRBR-25H107 1/2

Dear Customer,

Field Safety Notice

Affected Products:

REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION

Shimadzu has identified a potential safety issue with The REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

As a result of the manufacturer's investigation, it was found that due to a software malfunction, when switching to the dual-tube option's console (GSC option) to take radiography for the FLEXAVISION (F3/F4 version) with dual-tube option immediately after selecting serial radiography, X-rays are exposed with values different from the radiography conditions displayed.

In addition, there is a possibility that the product may not meet the requirements of the harmonized (recognized) standard.

we will be taken countermeasures to this issue.

2. Hazard/harm associated with the issue

The X-ray may be taken under suboptimal conditions, resulting in an image with an insufficient or excessive X-ray dose. If an image that is not suitable for diagnosis is obtained, a re-radiography may be necessary.

We have not received any reports of health hazards.

3. Affected products and how to identify them

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.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

This problem will not occur if you selection off the serial radiography after using serial radiography, so after using serial radiography, turn the selection off once before taking the next radiography.

5. Actions planned by Shimadzu to correct the problem

Shimadzu is informing customers of this issue through this Urgent Field Safety Notice. Additionally,

We will update the affected equipment to the corrective software.

This Urgent Field Safety Notice letter has been reported to the appropriate Competent Authorities.