

Medical Regulatory Policy Department Post Market Surveillance Section

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Date: Aug.7th, 2024

Ref: MRBR-24H060 1/2

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu Digital Angiography System: Trinias (System with KS-100)

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

In a particular Trinis angiographic system combined with the Catheterization Table KS-100 (hereinafter referred to as the table), it has been found that when certain operations such as FPD forward or backward movement and C-arm movement are performed simultaneously while the direct memory is being operated, only the table continues to move up or down to the preset position even when the direct memory switch is released.

Even when this event occurs, the movement of the table is slow and the operation can be stopped with the stop switch.

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 software.

Actions to be taken by customer:

Press EMERGENCY STOP SWITCH when a phenomenon occurs in which lifting operation is continued.



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

Do not perform the following operations while holding down Direct Memory.

- · C-Arm / FPD forward or backward movement lever check switch
- · Cancel switch
- Automatic operation switch other than direct memory (Return to center, park, position change, etc.)
- · Table top Lift Switch (except for the tilt console switch)
- Hand switch for ceiling traveling of L-arm
- · FPD side switch