

Date: NOV. 21st, 2025

Ref: MRBR-25H151 1/2

Dear Customer,

Field Safety Notice

Affected Products:

Digital Angiography System Trinias

Shimadzu has identified a potential safety issue with the Angiographic C-arm Support for the above system. This URGENT Field Safety Notice is intended to inform you about:

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

The Angiographic C-arm Support MH-300, MH-500, MH-600, and MH-700, which are components of the affected products, were found to have mounting bolts that were not tightened with the required torque and could become loose during use.

We will take corrective measures.

2. Hazard/harm associated with the issue

<MH-300>

If the mounting bolt of the sub-ASSY of the horizontal shaft drive section becomes loose and the driving gear of the C-arm propeller rotation becomes disengaged, it cannot be denied that the C-arm rotated by its own weight may collide with a patient or nearby staff, causing injury such as bruising, or damage by colliding with peripheral equipment.

<MH-500>

If the mounting bolts loosen and go unnoticed until they have all come out, the drive gear that rotates the C-arm propeller may disengage, causing the C-arm to rotate under its own weight and collide with patients or nearby staff, resulting in bruises or other injuries, or it may collide with peripheral equipment and cause damage.

<MH-600, MH-700>

Regarding this problem, looseness of multiple mounting bolts was confirmed in the product in the manufacturing process. In addition, 1 case of abnormal noise during product operation due to looseness of mounting bolts at the hospital side was confirmed in MH-700, but no health hazard to patients or operators occurred.

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

Perform daily inspections as described in the Digital Angiography System Trinias operation manual to check for wobbling, shaking, or abnormal noise. If any abnormality is observed, discontinue use and contact our company service provider.

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 be taken additional measures to ensure that the Support Section is maintained in all circumstances.

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