

Medical Regulatory Policy Department Post Market Surveillance Section

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Ref: MRBR-24H021

Date: March 18, 2024

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu CVS system: Trinias

Description of issue (Reason):

We have identified a potential problem with the Shimadzu CVS system described above.

It has been reported that the optional wireless footswitch from Trinias makes it difficult to return the fluoroscopic/radiographic pedal.

As a result of the investigation, it was confirmed that the screws inside the footswitch were loose, and the head of the screws interfered with the pedal of the footswitch, making it difficult for the pedal to return.

How to identify the affected products:

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.

Corrective action plan by Shimadzu:

Since similar events can occur with footswitches of the same structure, we will implement measures to reduce the looseness of screws as a corrective action.

Actions to be taken by customer:

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

If the foot switch pedal does not return, X-rays may continue to be output.

Please use the wired FOOT Switch until the corrective action is completed.



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If the problem occurs while using the wireless FOOT Switch, take the following actions.

If SMART Touch is installed as shown in Figure 1, press the "X-Ray OFF" button shown in Figure 2 to stop X-ray output.

If SMART Touch is not installed, turn off the system and stop X-ray output.

In addition, stop using the wireless foot switch and contact your service representative.

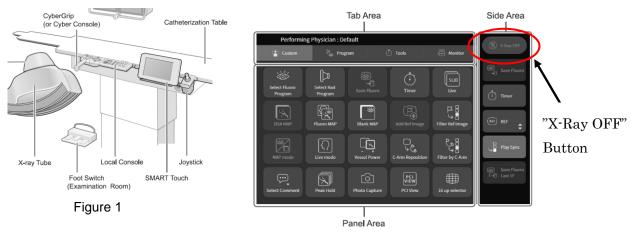


Figure 2