

Date: November 15, 2018

Ref: SQBR-18033

Dear Customer,

## **Field Safety Notice**

### **Affected Products: Shimadzu CVS system Trinias and BRANSIST alexa**

#### **Description of issue (Reason):**

SHIMADZU CORPORATION has identified a potential issue in “Digital Angiography System Trinias” and Digital Angiography System BRANSIST alexa” .

We became aware that there was a possibility that the following events occurred in this device.

#### Event 1

In rare cases, when a synchronization error may occur in the data transmission circuit in the device due to external noise or the like, the visibility of the displayed image may be corrupted (images become bit-shifted abnormal images). If this event occurs, it may become difficult to see the object, which may hinder the examination and treatment, but it is possible to restore the normal state by restarting the device.

#### Event 2

Although it is not a usual operation, If new study is created just at the same time of starting fluoroscopy after device startup, the application of the device may restart. After rebooting, it become impossible to use fluoroscopy or radiography normally, until the service engineer solve this event. Note that this event occurs only during the first fluoroscopic operation after device startup and will not occur even if the same operation is performed for the second time onwards. If this event occurs, clinical procedure may be required postponing or proceeding with another system.

#### **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:**

As our planned field correction at the affected sites, we will install the improved software.

**Actions to be taken by customer:**

Please keep in mind the following matters during the period until modification and use it.

**Event 1:**

If generating Bit-shifted abnormal image, please reboot the angiography system. For Bi-plane system, it is possible to continue using the system without rebooting the digital radiography system for fluoroscopy or radiography.

**Event 2:**

1. Please do not perform fluoroscopy at the start of study registration.
2. If perform fluoroscopy at the start of study registration and application terminates abnormally in the X-ray exposure operation, fluoroscopy other than study is available by closing the study. Restore to the normal use mode, you will be needed a service representative. Please contact our service representatives.

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.