

Date: Jun 27, 2025

Ref: MRBR-25H060

Dear Customer,

Field Safety Notice

Shimadzu has identified a potential safety issue with the X-ray high voltage generator incorporated into the X-ray diagnostic equipment listed in Table 1. This URGENT Field Safety Notice is intended to inform you about:

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

It was found that the contacts of the electromagnetic contactors used inside the cabinet of the X-ray high-voltage generator were welded, and the current might continue to be supplied to the power supply circuit even if the power of the device is cut off. As a result, it cannot be denied that the circuit in question overheats and damages the surrounding parts. It may also cause smoke.

2. Hazard/harm associated with the issue

Overheating can damage the circuit and render the device unusable.

Even if the circuit is damaged due to overheating, the damage to the surrounding area will not spread because the circuit and its nearby parts are made of flame-retardant materials and the circuit is covered with a metal cabinet (housing). However, we cannot deny the possibility that smoke is generated in the machine room and the fire alarm is activated.

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

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

- For safety reasons, please turn off the breaker of the distribution board to which the power cord of the unit is connected after turning off the power of the unit according to the operation manual.
- Do not forget to turn off the breaker of the distribution board until the replacement of the contactor is completed.

5. Actions planned by Shimadzu to correct the problem

We are informing customers of this issue through this Urgent Field Safety Notice. Additionally,

Therefore, we will take measures to prevent the current from continuing to flow even if the electromagnetic contactor is welded.

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

Table1

No.	Product Name
1	X-RAY HIGH VOLTAGE GENERATOR UD150B-40
2	X-RAY HIGH VOLTAGE GENERATOR UD150V-40
3	X-RAY HIGH VOLTAGE GENERATOR UD150L-40
4	X-RAY HIGH VOLTAGE GENERATOR UD150G-40
5	X-RAY HIGH VOLTAGE GENERATOR UD150L-40E
6	X-RAY HIGH VOLTAGE GENERATOR UD150L-40F
7	Digital Angiography System Trinias
8	Digital Angiography System BRANSIST safire
9	Digital Angiography System BRANSIST safire Plus
10	Digital Angiography System BRANSIST alexa
11	Digital Angiography System HeartSpeed 10 Plus
12	RADspeed Pro
13	Digital Radiography System RADspeed Plus
14	Digital Radiography System RADspeed safire
15	Radiography System RADspeed fit
16	X-RAY TV SYSTEM SONIALVISION G4
17	X-RAY TV SYSTEM SONIALVISION safire17
18	X-RAY TV SYSTEM SONIALVISION safire Plus
19	X-RAY TV SYSTEM SONIALVISION safire
20	X-RAY TV SYSTEM SONIALVISION VERSA 100
21	X-RAY TV SYSTEM SONIALVISION VERSA 80
22	X-RAY TV SYSTEM SONIALVISION VERSA Plus
23	REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION