

SQBR-16018

December 2016

URGENT - Security Message

Software Update

Sonialvision Series (G4/Safire17/UD150B-40)

Problem with anode plate of the X-ray tube

Dear Customer,

A potential problem with the anode plate of the X-ray tube installed in the Sonialvision series has been detected. If the problem occurs, patient and user/operator may be at risk.

When might the problem occur and what are the risks?

When operating the radiography/fluoroscopy system Sonialvision G4/Safire17/ UD150B-40, the thermal load of the anode in the X-ray tube may become higher than expected under certain application conditions. When this happens, the anode plate may be damaged to such an extent that the tube housing leaks (oil leakage). The problem may only occur with newly installed X-ray tubes which have not yet been aged. No incidents with personal injury have been reported.

What you can do to avoid this risk

- 1. For Sonialvision Safire 17 with generator S/W up to and excl. rev. 2.497 and Sonialvision G4 with system S/W up to and excl. rev. 01.08.02 incl. generator S/W 7.07**

Please, avoid the following operation: serial X-ray images with 3 or more images/sec and maximum tube parameters (800mA/>100kV). Even if such radiographs do not pose a problem for the 80kW generator and the X-ray tube as single exposures, serial X-ray images with identical parameters close to the 80kW limit will exceed the load limit of the anode plate.

- 2. For Sonialvision Safire 17 with generator S/W rev. 2.497 and Sonialvision G4 with system S/W rev. 01.08.02 incl. generator S/W 7.07**

Starting from the above S/W revisions, these settings can no longer be selected manually. If X-ray parameters outside the permissible values are input manually despite of this or are still set in the stored anatomical programs, an error message is displayed (TUBE LOAD OVER) and an exposure can no longer be initiated.

Countermeasures by Shimadzu

A Shimadzu service engineer will contact you to make an appointment for performing the S/W update. The corrective action has the reference number **SQBR-16018**

Questions?

Should you have any further questions or require information about the planned S/W update, please contact your local service engineer. Phone: 0203/7687337 or 0172-2568259

Further contacts:

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Best regards