

Siemens Healthcare GmbH, HC AT RO PT QT, Hofmannstr. 26, 91052 Erlangen

To all users of SIEMENS Robot Imager and Gantry Imager (10143434, 10351198)

Name
Department
Telephone
E-mail
Date March 15, 2017
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Customer safety information

Robot Imager and Gantry Imager with a possible leak in the detector cooling system and a possible impairment of the tube cooling system by contamination with biomass

Dear customer,

This letter is to inform you of the following corrective actions that will be performed for the AXIOM Artis dFA a component of the Robot Imager and Gantry Imager (material number 10143434, 10351198) to prevent:

1. a possible leak in the detector cooling system and its possible consequences.
2. contamination of the tube cooling system which could result in damage to the pump system.

When does this issue occur?

We were informed by our supplier that:

1. Due to a leak in the detector cooling system of the AXIOM Artis dFA, fluids could seep into the equipment cabinet and could cause a short circuit and in worst case a burn in the cabinet. This leak can occur sporadically in the affected systems.
2. And contaminants in the form of biomass can develop in the tube cooling system and can impair the performance of the pump. As a consequence this can result in damage to the pump system. This fault can lead to a functional failure of the system. The tube assembly can become overheated so that no x-ray image can be performed any more.

What are the possible risks to health?

1. Loss of coolant can result in detector cooling system failure. In the worst case scenario this leak can cause system failure. In case of the Robot Imager or the Gantry Imager this could

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Thomas Rathmann, Michael Reitermann

Hofmannstr. 26
91052 Erlangen
Germany

Tel.: +49 (9131) 84-0
siemens.com/healthcare

Chairman of the Supervisory Board: Siegfried Russwurm
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

cause a repetition of a position verification and therefore additional X-ray dose to the patient.

2. Contaminants in the form of biomass can develop in the cooling system of Artis systems, which can result in damage to the pump system. In this case an error message will be indicating that the system will stop the operation soon because of tube overheating.

There is no risk that fluids can drip down onto the patient.

We do not consider it necessary to re-examine any patients in this case. Both issues are possible hardware faults that had no influence on the treatment of patients.

What steps can the user take to avoid the possible risks associated with this issue?

- There is no preventive action possible on the side of the user.

How will the issue finally be resolved?

Actions will be taken to:

1. Protect against consequential damage resulting from leaking fluids out of the detector cooling system. The affected plastic couplings are being replaced with metal couplings.
2. Fit an additional, external filter in the cooling-water circuit of the tube cooling system will implement a protective mechanism to prevent the functional failure of the pump system as a result of contamination.

The update PT018/16/P eliminates the causes of damages to both cooling systems (detector and tube cooling system) ensuring they do not reoccur for the Robot Imager and the Gantry Imager.

Dissemination of the content of this notice

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

The <relevant National Competent Authority> will be informed of this notice, if required.

Sincerely yours

Siemens Healthcare GmbH

Date: March 15, 2017

