SIEMENS **Healthcare**

Siemens AG, H IM AX QM SCM, Siemensstr. 1, 91301 Forchheim

Department head

Name Claus Kolbert
Department H IM AX MK IPM
E-mail Claus.Kolbert@siemens.com
Date July 2nd 2014

To all users of Artis Q and Artis Q zen systems

Important customer safety notice regarding field measure: **AX012/14/S**

Information on a safety-related corrective measure for Artis Q and Artis Q zen systems
This letter will be distributed to affected customers as Update AX 013/14/S

Dear Customer,

We would like to draw your attention to possible problems with the VD10D software version of your Artis Q or Artis Q zen system.

When do these problems arise and what are the possible risks?

In the course of our product monitoring activities a problem was found regarding unintended blockage of radiation release. The problem consists of the following aspects:

a) In certain circumstances the release of radiation is blocked in connection with a Large Display; for example, if the image cannot be displayed on the Large Display. In rare cases the system misinterprets the status of the Large Display and blocks the release of radiation even though the Large Display would be able to display images.
b) In the case of installations configured with a hospital emergency power supply for the entire system, radiation release may be blocked due to a software error, because a non-existent emergency power situation is detected by mistake.
c) The coupling of failures caused by an electronic control element might lead to a radiation abort.

What measures are being taken to mitigate possible risks?

Corrective measure AX012/14/S provides a software modification to remedy the issues described under a) and b). The software limits the blockage of radiation release to three seconds if the problem described under a) occurs, and the screen in the examination and control room displays the message: „NO XRAY, try again". After the next attempt, radiation can then be released without any restrictions.

SIEMENS

The following message „Display problem - Try system restart" recommends a prompt system reboot in order to eliminate the error for good.
The software modification prevents misinterpretation of the problem described under b) and thus incorrect blockage of radiation release.
An additional hardware element will be fitted for signal suppression to deal with the problem described under c). This prevents the coupling of failures and a possible radiation abort.

Further non-safety-relevant corrections will be implemented in the course of remedying this fault.

What risks are there for patients who have previously been examined or treated using this system?

We do not consider it necessary to re-examine any patients in this case. This is a possible hardware and software fault which has no influence on any previous treatment of patients.

We thank you for your cooperation in dealing with this customer safety notice, and request that you promptly notify all the staff at your organization who need to be aware of this problem, and instruct them accordingly. Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

With best regards,
SIEMENS AG Healthcare Sector
Business Unit AX

ppa

Dr. Heinrich Kolem
CEO H IM AX

i.V.

Wolfgang Hofmann
Safety Officer Medical Devices