SIEMENS Healthcare

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To all users of Artis zee and Artis zeego systems in conjunction with a triple-focus X-ray tube assembly from a specific production lot

Important customer safety notice regarding the field corrective action:

AX054/14/S

Information regarding a field corrective action for Artis zee and Artis zeego systems used in conjunction with a triple-focus X-ray tube assembly from a specific production lot

Dear Customer,

This letter is to inform you of a corrective action for your Artis zee or Artis zeego system.

What is the underlying issue requiring corrective action and when does the issue occur?
Due to a production fault in a specific production lot of the triple-focus X-ray tube assembly, there is a possibility that the "small focus" may fail. If this occurs, no further radiation release will be possible from this focus source. The "large focus" and "microfocus" will still be operational.
This malfunction occurs only sporadically and is not a systematic fault.

What action has been taken to date?
A software change was introduced as a first corrective action in the field. In the above fault scenario, the system automatically switches to the "large focus". Thus, any ongoing procedures can be continued with compromised image quality.

The corrective action was implemented for VC14 systems as update AX025/14/S and for VC21 systems as Update AX027/14/S.

What other actions will now be taken?
All potentially affected X-ray tube assemblies will be replaced by a version in which the cause of the potential malfunction has been eliminated.

How effective are the corrective actions?
Once implemented, the corrective action will prevent recurrence of the malfunction.

What is the impact on system operation and what is the potential risk?
Once the tube assemblies have been replaced, there will be no further impact on system operation and no related risks.

How was the issue detected and what is the cause?
The issue was identified during regular field observation. The issue occurred because a ground connection of a focus in the X-ray tube had sporadically become disconnected.

How will the corrective action be implemented?
Our service organization will contact you to arrange a date to perform the corrective action. Please feel free to contact our service organization for an earlier appointment. This letter will be distributed to affected customers as Update AX 054/14/S.

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 fault that had no influence on the treatment of patients.

We thank you for your cooperation in dealing with this customer safety notice and request that you promptly notify and instruct accordingly all the staff at your organization who need to be aware of this problem. 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 also kindly request that you inform us of the identity of the device's new owner where possible.

Sincerely,

SIEMENS AG Healthcare
AX Business Unit

Dr. Heinrich Kolem
Chief Executive Officer

Wolfgang Hofmann
Medical Device Safety Officer