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To all users of Artis systems with 19" Live Display.

Important customer safety notice regarding corrective field action:

AX012/16/S

Information about corrective action for Artis systems with 19" Live Display.

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent the possible loss of the image display for live images in the examination room after system startup.

What is the underlying issue requiring this corrective action and when does the issue occur?

Owing to an error in the 19" Live Display, image reproduction may fail in the examination room. The loss of image can only occur immediately after system startup. This failure does not occur during normal operation or when the live image is displayed. Only systems which use a Live Display (reference DSHC1914-DC with part number 10656055) in the examination room are affected. Live Displays with other part numbers are not affected by this issue.

What action will be taken?

The error will be eliminated for the displays by means of an update to the firmware.

How was the issue detected and what is the cause?

The error occurs sporadically directly after system startup. It was identified during regular field observation.

How effective are the corrective actions?

The action eliminates the problem, ensuring it does not recur.

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 13/16/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 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 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.

Best regards,

Siemens Healthcare GmbH
AT Business Area

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Dr. Heinrich Kolem
President Advanced Therapies

i.V.

Wolfgang Hofmann
Safety Officer Medical Devices