SIEMENS Healthcare

Siemens Healthcare GmbH, HC AT IR OPM, Siemensstr. 1, 91301 Forchheim

To all users of Artis systems with large display

BU contact:
Name:
Departmet:
E-mail:
Date:

Important customer safety notice regarding the field corrective action:

A025/15/S

Information regarding a field corrective action for Artis systems with large display

Dear Customer,

We would like to inform you of the appropriate measures that will be carried out, in order to prevent possible loss of image displayed on the large display in the examination room.

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

Due to improper soldering in limited components of a specific production lot of large display bypass module (lot delivered from 18.12.2014 to 09.03.2015), a loss of video signal could potentially occur. This is not observed in the field and only sporadic cases are observed in factory screening.

What action will be taken?

The affected hardware, namely the bypass module, will be proactively exchanged with unaffected production lots to eliminate the problem.

How effective are the corrective actions?

Once implemented, the corrective action will prevent occurrence of the malfunction.

What is the impact on system operation and what is the potential risk?

There is no impact on system operation. If such defect occurs, it will result in loss of video signal to the large display (large display will not show any image). Radiation can still be applied without image, which could result in dose to the patient without clinical benefit.

How was the issue detected and what is the cause?

The issue was identified during regular screening in factory. It has not been observed before and it has not been observed in the field.

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 026/15/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 Healthcare GmbH
Business Area AT

Dr. Heinrich Kolem
Head of Business Area AT

Wolfgang Hofmann
Medical Device Safety Officer