

To all user of Artis systems containing a Multi Display
Manager of a specific lot

E-mail

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Date

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Customer Safety Information (CSI) for Field Safety Corrective Action: AX035/19/S

Subject: Customer Safety Information for all Artis systems containing a Multi Display Manager of a specific lot.

Dear Customer,

We would like to inform you about a potential problem of your Artis system containing a Multi Display Manager of a specific lot.

What is the issue and when does it occur?

During our product monitoring activities, a supplier informed us about a non-conformity in their manufacturing process. In rare cases this might lead to an increased electrical contact resistance up to the interruption of electrical contact in a specific lot of power distributors as part of Multi Display Managers.

What is the impact to the operation of the system and what are the possible risks?

In case the error occurs, there might be a malfunction within the Multi Display Manager which might lead to a situation, where the large display is not properly working anymore.

Therefore, consider the need to establish emergency procedures in such cases. In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

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How was the issue identified and what is the root cause?

The issue was identified during our manufacturing process of Artis systems and was not observed in the field so far. The issue was caused by the manufacturing process of a supplier of the power distributor during a specific period of time.

What actions are being taken by the manufacturer to mitigate possible risks?

Our Service organization will exchange the affected power distributor of the Multi Display Manager.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

We advise not to move the Multi Display Manager Container (see Figure 1) or to open the power distributor before the corrective action has taken place.

Multi Display Manager Container



Figure 1: Multi Display Manager Container

What is the efficiency of the correction?

This will eliminate the non-conformity and prevent it from reoccurring.

How will the correction be implemented?

Our service organization will get in contact with you for an appointment to perform the correction. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update AX036/19/S.

What about new Products?

The supplier implemented adequate measures to avoid reoccurrence of the non-conformity.

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

The manufacturer does not consider risks for patients who have previously been examined or treated.

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.

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 Healthcare GmbH
Business Area Advanced Therapies

