To all user of the following systems Art is one with Display Port transceiver

Product/ Trade Name: *Artis one*

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Date Sep, 2020

Corrective Acti on ID AX052/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject : Artis one Display Port transceiver replacement

Dear Customer,

We would like to info rm you about a potential issue with your **Art is one** system and a corrective act ion that will be performed.

What is the issue and when does it occur?

A potential malfunction was detected in the field that the examination room monitor may be intermittently dysfunctional (e.g., no display/ flicking/ wrong resolution).
The problem occurs sporadically and might occur during an ongoing procedure.

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

In case the problem occurs, the system cannot be operated as intended . In most cases, the system can be recovered after restarting, which may result in a procedure minor/ mid-term delay; while in rare cases, the system cannot be further operated due to complete failure of Display Port transceiver, which may result in a situation where the clinical treatment has to be cancelled or continued on an alternative system. Please make sure that an alternative system can be used to continue treatment in such cases.

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

The issue was detected by regular field observation. The root cause is determined as signal un-stability or interrupt ion between the exam monitor and graphic card which is caused by the quality issue of a hardware component called Display Port transceiver.

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

In most cases when the problem occurs, customers can recover the system by restarting the system.

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

The problem will be eliminated by realization of the field corrective action AX052/20/S. The measure is to replace current Display Port transceiver by a succeeding solution as a design improvement to enhance stability and quality.

What is the efficiency of the corrective action(s)?

The replacement of Display Port transceiver will mitigate the occurrence of the problem.

How will the corrective action be implemented?

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

This letter will be distributed to affected customers as update AX053/20/S.

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 in format ion 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 finalize d. 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 langer 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 Shenzhen Magnetic Resonance Ltd.
Business Area Advanced Therapies (AT)

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