SIEMENS Healthcare

Siemens Shenzhen Magnetic Resonance Ltd, SSMR-AX QM

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To all users of SIEMENS *Artis one* Systems

Important safety information for customers regarding a field corrective action

AX049/14/S

Information regarding the field corrective action for Artis one Systems

Dear Customer,

We would like to inform you about a potential malfunction of the *Artis one* system in conjunction with the monitor system.

What problem is behind this corrective action and when does the problem occur

During our regular product monitoring in the field, a *potential malfunction of the ER (Examination Room) monitor display was* identified. The problem is not systematic but sporadic on single units.

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

In case the problem occurs, the impact to an ongoing procedure may be limited functionality up to failing of a system. The monitor may fail intermittently or even permanently and does require a power circle (shutdown and then power on) to get back to operation again.

How was the subject identified and what is the root cause

The subject was identified during our regular field observation on single systems of Artis One. The root cause of the problem was determined as a signal attenuation of the Display Port Transceiver connected between the graphic card and ER monitor.

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What measures are being taken to mitigate possible risks

The problem will be eliminated by realization of the field corrective action update AX048/14/S. This measure persists of updating Display Port Transceiver to improve the signal quality.

What is the efficiency of the corrective actions

This corrective action eliminates the root cause for the nonconformity and prevents from recurrence.

How will the corrective action be implemented

Our service organization will get in contact with you for an appointment 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 *049/14/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 safety information. We also want you to promptly notify and instruct all the staff at your organization who need to be aware of this problem accordingly. Please forward this safety information to any other organizations (if any) 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 information 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 Shenzhen Magnetic Resonance Ltd.
Business Unit SSMR-AX

[redacted]

Dr. Pu ZhengRong
GM SSMR-AX

[redacted]

Guo Yong Li
Quality Management