



CC Chairman Medical Board and
Relevant Head of Departments

Siemens Shenzhen Magnetic Resonance Ltd, SSMR-AT HC
R&D SZN
Siemens MRI center, Gao Xin C. Ave., 2nd, Hi-Tech Industrial
Park, 518057 Shenzhen, P.R.China

**To all user of Artis one systems with
DP Transceiver below revision 03**

BL-Contact:

Name: Wang Jian

Department:

HC AT R&D SZN

Phone:

+86(755) 23185886

E-Mail:

[wang_jian@siemens-
healthineers.com](mailto:wang_jian@siemens-healthineers.com)

Important customer safety notice regarding corrective field action:

AX036/17/S

**Important safety information for customers regarding a field corrective action:
for Artis one systems shipped with DP Transceiver below revision 03.**

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent a possible hazard to patients, operators, other persons and equipment.

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

During regular field observation, ER (Examination Room) monitor display was identified with blinking, blue/black screen issues.

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

In case the problem occurs, the impact to an ongoing procedure may be limited functionality up to failing of a system. In most of cases, a power circle (shutdown and then power on) can bring system back to normal. In very rare case while power circle does not work, it might be necessary to cancel or restart a clinical procedure or transferring it to a functioning system.

What action will be taken?

The DP Transceivers with revision 03 will be updated to the field affected systems through update AX036/17/S.

How was the issue detected and what is the cause?

The issue was identified during regular field observation. The issues were caused by malfunction of DP Transceiver.

How effective are the corrective actions?

The cause will be eliminated after update of DP Transceiver, thus preventing a recurrence of the fault.

How will the corrective action be implemented?

Our service organization will contact you shortly to arrange a date to perform this corrective action. Please feel free to contact our service organization for an earlier appointment. This letter will be distributed to affected customers as Update AX040/17/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 defect 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 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 Shenzhen Magnetic Resonance Ltd.
Business Line SSMR-AT

Ye Wei
GM SSMR-AT

Guo Yong Li
Quality Management Representative