SIEMENS Healthcare

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To all users of Artis Q systems

BU contact:
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Important customer safety notice regarding field measure:

AX017/15/S

Information about a corrective action for Artis Q/Q.zen systems

Dear Customer,

We are writing to inform you about a potential problem in connection with your Artis Q/Q.zen system (floor/ceiling/biplane).

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

It is possible that an electrical connection in the equipment cabinet has not been installed correctly. In potential fault scenarios (e.g. if several live wires become defective) and under certain conditions, this may prevent a safety mechanism on the system side from taking effect, thus compromising the electrical safety of the system.

What action will be taken?

The potentially defective connection in the equipment cabinet will be inspected and, if necessary, corrected.

How was the issue detected and what is the cause?

The potential problem described above was detected during routine quality assurance in production. The resulting potential hazard situation has not yet occurred.

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How effective are the corrective actions?

Once the action has been carried out, the cause of the potential inefficiency of the safety mechanism on the system side will be eliminated, enabling the safety mechanism to take effect without restriction.

How will the corrective action be implemented?

Our service organization will contact you shortly to arrange a date to perform this corrective action. You can, of course, arrange a date yourself with our service organization to carry out the corrective action. This letter will be distributed to affected customers as Update AX018/15/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 would also request you to inform us of the identity of the device's new owner where possible.

Yours sincerely

SIEMENS AG Healthcare
AX Business Unit

[redacted]

Dr. Heinrich Kalen
Chief Executive Officer

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Wolfgang Hofmann
Medical Device Safety Officer