SIEMENS Healthineers

To all user of Siemens Cios Systems Spin & Alpha

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# Customer Safety Information (CSI) for Field Safety Corrective Action:

# AX014/20/S

**Subject: Field Safety Notice for: Exchange of a printed circuit board ("main control D80" with revision less than 04) which is included in certain Cios Spin & Cios Alpha systems.**

**Dear Customer,**

We would like to inform you about a potential problem concerning certain Cios Spin and Cios Alpha systems on which a main control D80 with revision less than 04 is installed.

The affected systems can be identified by their serial number. Please refer to the following list to check if your system is affected.

| # | Affected systems |
|---|---|
| **10xxx** | 10001; 10003; 10010 – 10027; 10029 – 10031; 10033 – 10040; 10042 – 10045; 10048 – 10052; 10054 – 10110; 10112 – 10119 |
| **11xxx** | 11000 – 11004; 11006 – 11028; 11030 – 11101; 11103 – 11183; 11185 – 11205; 11207 – 11372; 11374 – 11387; 11600 – 11608 |
| **12xxx** | 12000 – 12014; 12016 – 12024; 12026 – 12045; 12047 – 12052; 12054; 12200 – 12207; 12301 – 12493; 12495 – 12505; 12507 – 12522; 12524 – 12550; 12552 – 12571; 12573; 12575 – 12610; 12612 – 12746; 12800 – 12803; 12805 – 12811; 12813 – 12889; 12891 – 12959; 12961 – 12973; 12975 – 12999 |
| **13xxx** | 13000 – 13085; 13087; 13088; 13092; 13103 – 13105; 13114; 13121 |
| **4xxxx** | 416; 40000; 40001; 40003 – 40021; 40030; 40038; 40070 |
| **5xxxx** | 50001 – 50053; 50055; 50075 |

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

Our Cios systems offer a "hot plugging" feature between trolley and main unit (c-arm). The "hot plugging" feature enables the clinical user to plug/unplug the X10 connector of the main cable (please refer to figure 1 below) at any time during clinical session, provided that the system is electrically connected and powered on. In very few cases the "hot plugging" feature could cause an electrical malfunction on the main control D80 of the generator which is part of the main unit (c-arm).

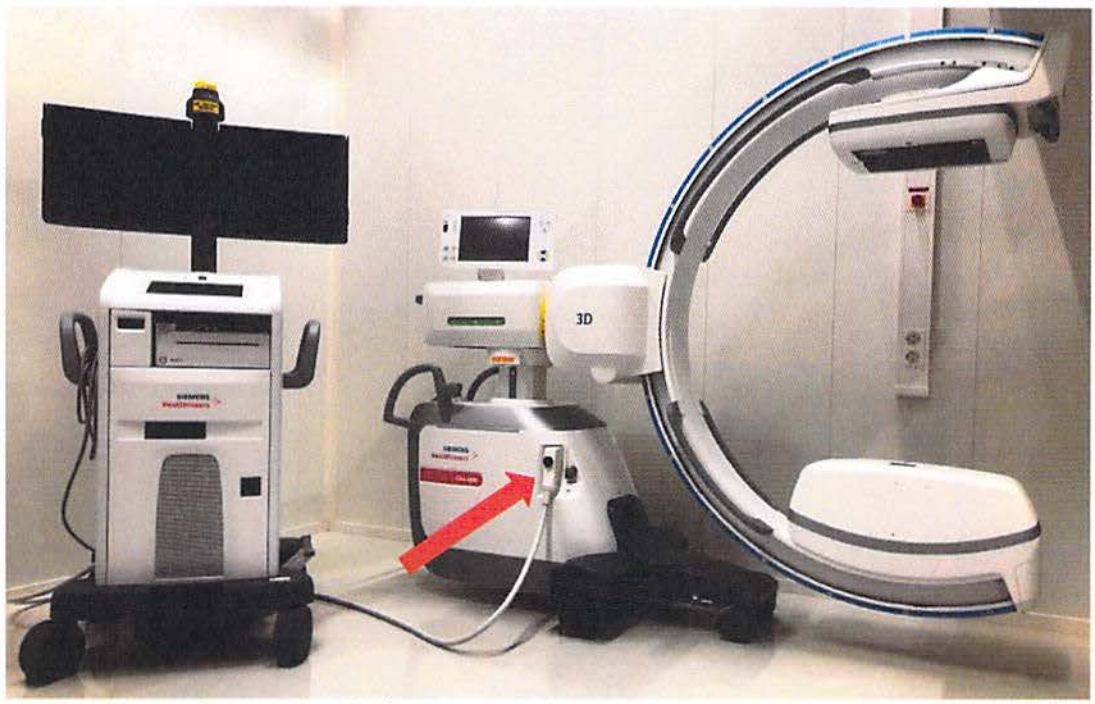


*figure 1: example of X10 connector with main cable, connected to Cios Spin c-arm*

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

If the malfunction described above occurs during "hot plugging", this will cause a permanent loss of imaging functionality and interruption of the clinical procedure. In this case, a service intervention with corresponding hardware replacement is necessary to put the affected device back into operation.

**How was the problem identified and what is the root cause?**

The subject was identified during a demo session when application engineer wanted to perform the "hot plugging" feature of a Cios Alpha VA30 system. The root cause is a design flaw in the component main control D80 with revision less than 04.

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

We advise urgently to cease the use of the above-described "hot plugging" feature until the pending hardware update AX014/20/S has been completed.

**What measures are being taken to mitigate possible risks?**

A service engineer will replace the main control D80 of your affected system by a revised main control.

**What is the efficiency of the corrective actions?**

After replacement of the main control D80 the probability that the above-described malfunction of the main control and the resulting interruption of the procedure occurs when using the "hot plugging" feature will be reduced.

**How will the corrective action be implemented?**

The corrective action will be implemented by upcoming hardware update AX014/20/S on your site by a service engineer.

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 all affected customers as update AX013/20/S.

**What about new Products?**

New products are already equipped by production with a revised main control D80.

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

There is no risk for patients who have previously been examined or treated using affected systems.

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,

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