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To all user of Siemens Cios Systems
 Spin & Alpha

Customer Safety Advisory Notice (CSAN): AX030/20/S

Subject: Customer Safety Advisory Notice concerning the repair of the X-ray Generator with an integrated Energy Storage Unit (ESU) 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 equipped with X-ray Generator with an integrated Energy Storage Unit (ESU).

The systems with the following serial numbers are affected:

| S-N° | Affected systems (Cios Alpha VA20) |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10xxxx | 109, 10001, 10011, 10012, 10014, 10022, 10024, 10038, 10039, 10053, 10059, 10060, 10063, 10064, 10067, 10070, 10071, 10080, 10085, 10087, 10094, 10099, 10106, 10108, 10111, 10112, 10114, 10117 |
| 11xxxx | 11001, 11026, 11028, 11046, 11069, 11070, 11071, 11072, 11096, 11109, 11110, 11112, 11115, 11125, 11129, 11131, 11135, 11137, 11138, 11142, 11145, 11151, 11154, 11155, 11160, 11166, 11180, 11183, 11184, 11188, 11191, 11193, 11207, 11210, 11217, 11218, 11228, 11230, 11236, 11242, 11247, 11268, 11277, 11278, 11279, 11296, 11297, 11299, 11304, 11305, 11309, 11310, 11324, 11331, 11334, 11337, 11339, 11342, 11345, 11354, 11361, 11362, 11368, 11377, 11383, 11384, 11603, 11608 |
| 12xxxx | 12000, 12001, 12002, 12008, 12012, 12017, 12020, 12024, 12029, 12032, 12033, 12036, 12039, 12041, 12042, 12044, 12048, 12049, 12206, 12302, 12342, 12344, 12382, 12386, 12408, 12409, 12410, 12418, 12425, 12445, 12451, 12455, 12470, 12488, 12506, 12511, 12516, 12518, 12522, 12527, 12573, 12587, 12591, 12613, 12614, 12615, 12616, 12628, 12633, 12643, 12648, 12656, 12659, 12660, 12664, 12675, 12676, 12731, 12734, 12741, 12746, 12801, 12814, 12822, 12827, 12839, 12841, 12844, 12856, 12863, 12877, 12883, 12890, 12892, 12896, 12907, 12911, 12923, 12927, 12929, 12941, 12946, 12951, 12968, 12996 |
| 13xxxx | 13013, 13027, 13034, 13044, 13051, 13067, 13075, 13103, 13108, 13116, 13117, 13118, 13125, 13155, 13215, 13220, 13222, 13228, 13234, 13245, 13248, 13252, 13254, 13260, 13297, 13300, 13301, 13307, 13310, 13322, 13344, 13352 |

| S-N° | Affected systems (Cios Alpha VA30) |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 40xxxx | 40001, 40003, 40004, 40006, 40011, 40021, 40022, 40024, 40026, 40031, 40032, 40037, 40043, 40044, 40045, 40047, 40048, 40057, 40060, 40070, 40075, 40085, 40087, 40091, 40099, 40102, 40104, 40106, 40107, 40108, 40111, 40114, 40120, 40124, 40126, 40127, 40129, 40132, 40134, 40135, 40136 |

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 WEEE-Reg.-No. DE 64872105

| S-N° | Affected systems (Cios Spin VA30) |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 50xxx | 50002, 50004, 50014, 50023, 50026, 50028, 50029, 50030, 50032, 50033, 50037, 50044, 50045, 50048, 50049, 50050, 50051, 50054, 50068, 50073, 50074, 50075, 50076, 50077, 50078, 50079, 50081, 50088, 50091, 50092, 50094, 50096, 50098, 50101, 50102, 50107, 50109, 50111, 50120, 50121, 50122, 50124, 50125, 50127, 50128, 50129, 50130, 50131, 50132, 50134, 50135, 50136, 50138, 50154, 50155, 50158, 50160, 50161, 50164, 50166, 50167, 50171, 50172, 50175, 50176, 50178, 50179, 50180, 50185, 50192, 50196 |

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

During the operation of the Cios system the monitor trolley of the Cios system is electrically connected with the main unit (c-arm) of the Cios System by a main cable. The main cable can be plugged or unplugged from the X10 connector which is part of the main unit (c-arm) at any time during clinical session (see figure 1 and 2). If the system displays the error message “Err 16305 / 80: Confirm this error and repeat your last action” the unplugging of the main cable can cause a dangerous electrical voltage (up to 125 V DC) at the X10 connector which can result in an electrical shock if the user or other persons touch the contact pins of the X10 connector. These contact pins of the X10 connector are accessible when the main cable is unplugged from the X10 connector (see figure 2 and 3).

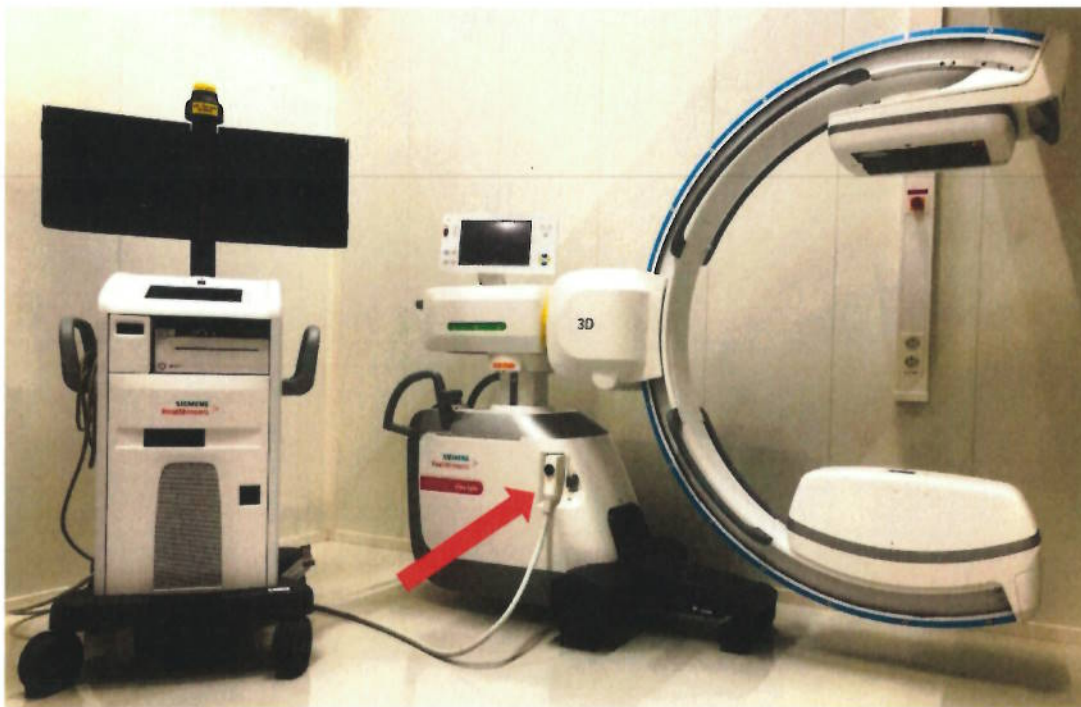


figure 1: example of monitor trolley connected to the X10 connector of the main unit (c-arm) by main cable



figure 3: example of X10 connector without the plug of the main cable being plugged in



figure 2: example of X10 connector contact pin area which must not be touched

What is the impact to the operation of the system

There is no impact to the operation of the system user or other persons due to the above described is unplugged and the user or other persons touch

How was the subject identified and what is the

The problem was identified during follow-up investigated generator fault (AX027/20/S). The root component.

and what are the possible risks?

but there is a danger to health and life of the risk of an electrical shock when the main cable the contact pins of the X10 connector.

root cause?

examinations in connection with a previously cause is a design flaw in a generator

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

Until the problem has been solved by our service team, we strongly recommend to not disconnect the main unit from the monitor trolley when the system displays the following system error message: "Err 16305 / 80: Confirm this error and repeat your last action".

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

We are currently working on a solution to eliminate the root cause of this problem. As soon as a solution is available, our service organization will get in contact with you to for an appointment to perform the corrective action.

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,

Siemens Healthcare GmbH
Business Area Advanced Therapies



Dr. Reinmar Killmann
Vice President Project & Portfolio Management



Johann Böck
Safety Officer Medical Devices AT