SIEMENS Healthineers

To all user of Siemens Cios Systems
Spin & Alpha

E-mail [redacted]

Date April, 2020

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

AX028/20/S

Subject: Customer Safety Information concerning the repair of the x-ray generator Polydoros M25 revision 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 the x-ray generator Polydoros M25 revision 04 is installed.

The systems with the following serial numbers are affected:

S-N°	Affected systems (Cios Alpha VA20)
10xxx	10019, 10033, 10034, 10080, 10093
11xxx	11101, 11200, 11605
12xxx	12300, 12339, 12358, 12362, 12377, 12413, 12415, 12448, 12551, 12560, 12618, 12722, 12849, 12853, 12892, 12904, 12924, 12946, 12957, 12964, 12972
13xxx	13019, 13034, 13035, 13045, 13213, 13214, 13217, 13218, 13219, 13220, 13221, 13222, 13223, 13224, 13225, 13226, 13227, 13228, 13229, 13230, 13231, 13232, 13233, 13234, 13235, 13236, 13237, 13238, 13239, 13240, 13241, 13242, 13243, 13244, 13245, 13246, 13247, 13248, 13249, 13250, 13251, 13252, 13253, 13254, 13255, 13256, 13257, 13258, 13259, 13260, 13261, 13262, 13263, 13264, 13265, 13266, 13267, 13268, 13269, 13270, 13271, 13272, 13273, 13274, 13275, 13276, 13277, 13278, 13279, 13280, 13281, 13282, 13283, 13284, 13285, 13286, 13287, 13288, 13289, 13290, 13291, 13292, 13293, 13294, 13295, 13296, 13297, 13298, 13299, 13300, 13302, 13303, 13304, 13305, 13306, 13308, 13309, 13311, 13312, 13313, 13314, 13315, 13316, 13317, 13318, 13319, 13320, 13321, 13322, 13323, 13324, 13325, 13326, 13327, 13328, 13329, 13330, 13331, 13332, 13333, 13334, 13335, 13336, 13337, 13338, 13339, 13340, 13341, 13342, 13343, 13344, 13345, 13346, 13347, 13348, 13349, 13350, 13351, 13352, 13353, 13354, 13355, 13356, 13357, 13358, 13359, 13360, 13361, 13362, 13363, 13364, 13365, 13366

S-N°	Affected systems (Cios Alpha VA30)
40xxx	40007, 40013, 40054, 40055, 40057, 40058, 40059, 40060, 40061, 40062, 40070, 40071, 40072, 40073, 40074, 40075, 40076, 40077, 40078, 40079, 40080, 40081, 40082, 40083, 40084, 40085, 40086, 40087, 40088, 40089, 40090, 40091, 40092, 40093, 40094, 40095, 40096, 40097, 40098, 40099, 40100, 40101, 40102, 40103, 40104, 40105, 40106, 40107, 40108, 40109, 40110, 40111, 40112, 40113, 40114, 40115, 40116, 40117, 40118, 40119, 40120, 40121, 40122, 40123, 40124, 40125, 40126, 40127, 40128, 40129, 40130, 40131, 40132, 40133, 40134, 40135

S-N°	Affected systems (Cios Spin VA30)
50xxx	50009, 50015, 50048, 50126, 50127, 50128, 50129, 50130, 50131, 50132, 50133, 50134, 50135, 50136, 50137, 50138, 50139, 50140, 50141, 50142, 50143, 50144, 50145, 50146, 50147, 50148, 50149, 50150, 50151, 50152, 50153, 50154, 50155, 50156, 50157, 50158, 50159, 50160, 50161, 50162, 50163, 50164, 50165, 50166, 50167, 50168, 50169, 50170, 50171, 50172, 50173, 50174, 50175, 50176, 50177, 50178, 50179, 50180, 50181, 50182, 50183, 50184, 50185, 50186, 50187, 50188, 50189, 50190, 50191, 50192, 50193, 50194, 50197

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). The unplugging of the main cable can cause an unsafe electrical voltage (up to 67,6 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).

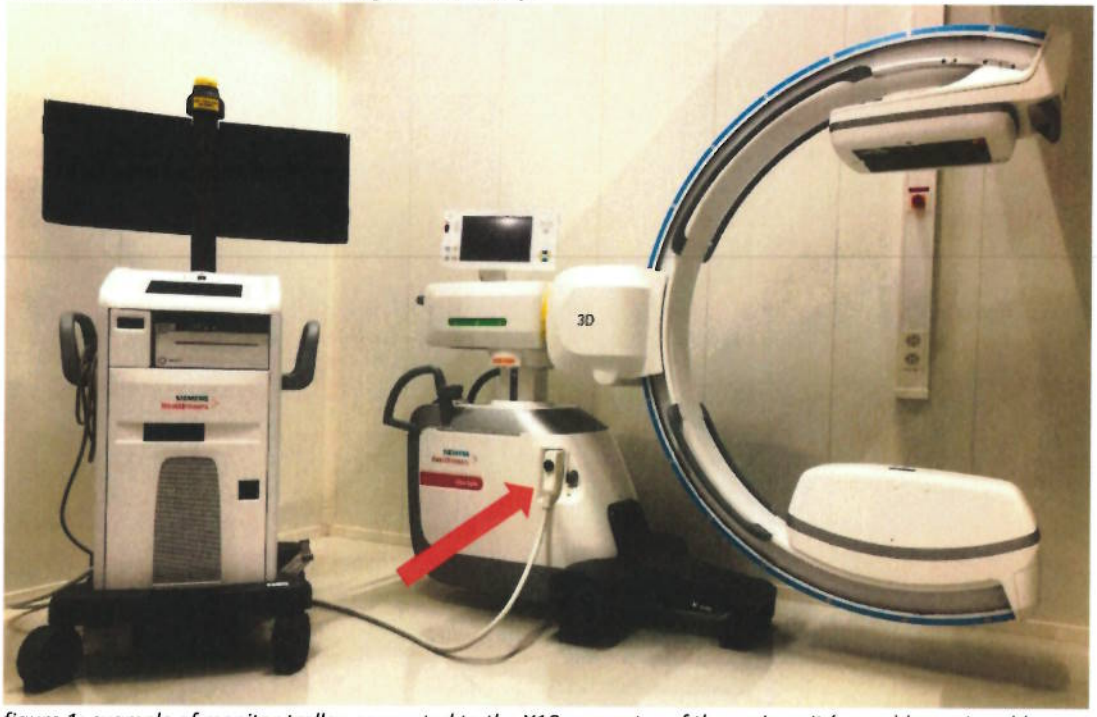

figure 1: example of monitor trolley connected to the X10 connector of the main unit (c-arm) by main cable

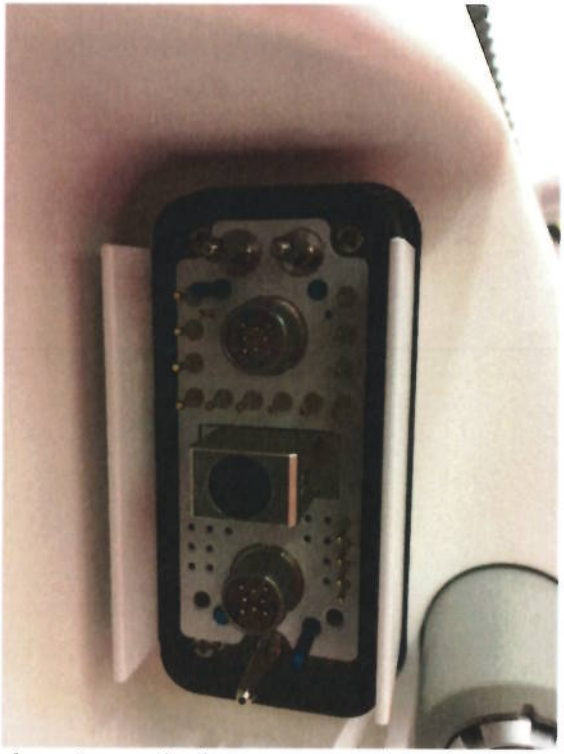

figure 3: example of X10 connector without the plug of the main cable being plugged in

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

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

There is no impact to the operation of the system but there is a danger to health of the user or other persons due to the above described risk of an electrical shock when the main cable is unplugged and the user or other persons touch the contact pins of the X10 connector.

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

The problem was identified by the manufacturer during system assembly when the plug of the main cable was unplugged. The root cause is a design flaw in a generator component of the generator Polydoros M25 revision 04.

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

We strongly recommend to not unplug the main cable until the generator is repaired by a service engineer.

What measures are being taken to mitigate possible risks?

A service engineer will repair the generator of your affected system at your site.

What is the efficiency of the corrective actions?

After repair of the generator the root cause which led to the unsafe electrical voltage at the X10 connector will be eliminated.

How will the corrective action be implemented?

In general, the service engineer directly carries out the repair of the generator upon handing over this customer safety information to you. If this is not possible 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 AX027/20/S

What about new Products?

New products are already equipped by production with a revised generator.

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

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