SIEMENS Healthineers

All users of Cios Alpha systems with Material #10308191 delivered December 2013 – December 2017.

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Customer Safety Information (CSI): AX068/19/S

Inspection of C-arm holder for all Cios Alpha systems with Material #10308191 delivered December 2013 – December 2017.

Dear Customer,

This letter is to inform you of a corrective action that will be performed on Cios Alpha systems with Material #10308191 delivered December 2013 - December 2017. Systems delivered after December 2017 are not affected by this corrective action.

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

During a routine inspection of a Cios Alpha system, a crack on the C-arm holder was discovered. The problem has not been reported at other customer sites and is currently classified as a single event.

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

In the event the C-arm holder has a crack, the stability of the C-arm may be compromised and could lead to deformations of the C-arm. In very unlikely cases, an extreme impact to the C-arm such as heavy collision with a wall or table, may lead to a detachment of the C-arm and could potentially result in injury to patients and staff. Siemens advises that any system with a crack should be taken out of clinical routine. This potential hardware issue had no influence on the previous treatment or diagnosis of patients.

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

During a routine inspection, after removing the covers on the C-arm holder, a crack formation was discovered. Upon closer inspection and analysis, this crack formation was found in the C-arm holder structure. An analysis of the C-arm holder structure showed that the material used was error-free, however, the casting process was not performed under ideal process conditions and material binding was not present at the crack line.

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What measures are taken to mitigate possible risks?

All systems with Material #10308191 delivered December 2013 – December 2017 will be inspected by trained service staff. After evaluation and assessment of the system, you will be informed if further steps are necessary. To reduce possible risks please avoid collisions with other objects. Please inform us if collisions with the C-arm have occurred, for example with the patient table or walls.

How will the corrective action be implemented and what is the efficiency of the corrective actions?

To verify that your system is not affected by this problem, a visual inspection will be carried out by trained service staff. If no crack is found during the visual inspection, the C-arm can be used again in its original functionality in patient operation.

Should a non-conformity be found and require repair, your device will be sent to the manufacturer and an equivalent loan device will be provided to you at no cost for the duration of the necessary repairs. Following the repair, the C-arm can be used again in its original functionality.

Our service organization will contact you shortly to arrange a date to perform this corrective action. Following the correction, the cause is eliminated, and any recurrence of this potential fault is prevented. This letter will be distributed as update **AX067/19/S** to affected customers.

We thank you for your cooperation, and request that you promptly notify and instruct accordingly all the staff at your organization who need to be aware of this notice and will comply with the recommendations therein. Please ensure that this safety advisory is retained in your product related records appropriately. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. If the device has been sold and is therefore no longer in your possession, please forward this notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible. Please forward this safety information to any other organizations that could be affected by this measure.

With best regards,

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