
Urgent Field Safety Notice
0180-Intuition / 0072-Precision
17-0007_2018-03-16
Device modification

Date: 2018-03-16

Attention: Potential risk of incorrect grid insertion.

Details on affected devices:

This UFSN is valid for all 0180-Intuition and 0072-Precision systems using detector holders manufactured by Arcoma AB. Note that these detector holders could have been used as upgrades for other system types.

Description of the problem:

Arcoma AB received complaints related to the fact that anti-scatter grids can be inserted the wrong way in some models of detector holders for both table and wall stands.

Inserting the grid incorrectly may affect image quality and cause additional x-ray exposures to patients.

Grids have specification labels and a center line indicating correct tube side, but the received complaint has resulted in a clarified instruction in the user manual.

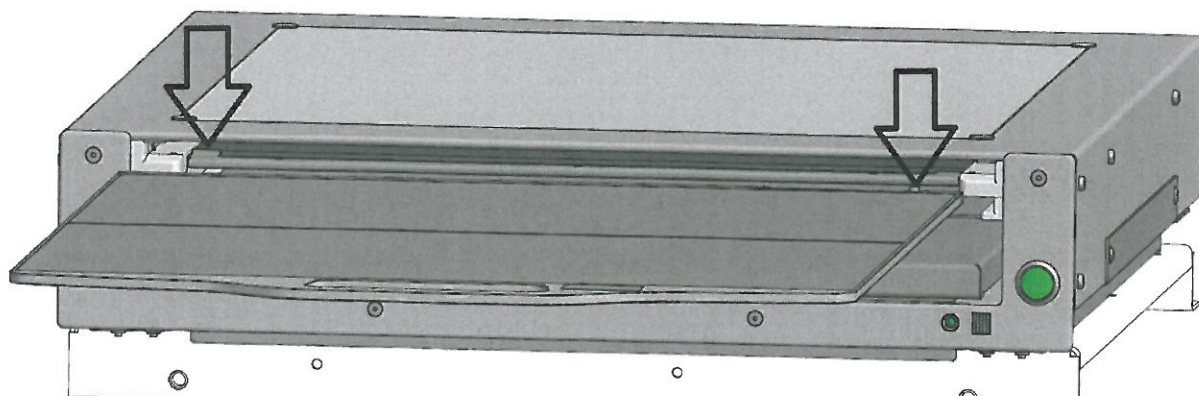
A mechanical device preventing incorrect insertion has also been implemented in production for the assembly of Precision system s/n 2105 and Intuition system s/n 2036. See image below.

Advise on action to be taken by the user:

A field upgrade kit will be available from Arcoma AB. Please identify the quantity of kits needed by your organization and order them from service@arcoma.se

All systems of the specific configuration mentioned above can and must be upgraded during the next scheduled service intervention.

- Install the upgrade kit and replace page(s) in the User manual in accordance to the supplied instruction.



Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.



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Service Manager



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ACKNOWLEDGE OF RECEIPT / UPGRADE

I hereby confirm, as the responsible installer of the Arcoma Intuition / Precision system with serial number _____, that I received *uFSN 17-0007_2018-03-16* and performed the upgrade in accordance with the upgrade instruction.

Date

Authorized dealer

Confirmed by

Clarification of signature

Please return this page signed to service@arcoma.se as soon as the upgrade has been carried out.