

REPORTED SERVICE INFORMATION

0180 INTUITION

Nr	Name	Description	Date
02	SI_2017_101_0180_Intuition	Anti-scatter grid position	2017-04-07
01	SI_2016_100_0180_Intuition	New software release	2016-03-02



System type:	Serial numbers:	Date issued:
Intuition 4C	n.a	2017-04-07
ServiceInfo number:	Issued by:	Approved by:
SI_2017_101_0180_Intuition	Jonas Petersson	Mikael Högberg
Time for action:	Report back to Arcoma:	Ref nr: (ÄBO, Complaint)
WHEN CONVENIENT	N.a	N.a
Subject:		
Anti-scatter grid position		

1 INFORMATION

Arcoma 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.

A mechanical device preventing incorrect insertion will be implemented in production for the assembly of Intuition system s/n 2036. See image below.

2 IMMEDIATE ACTION

Inform all users of the contains of this SI. The grid has a centre line that always must face the x-ray tube. Distribute updated page(s) for the manual where applicable.

3 CORRECTIVE FIELD ACTION

A field upgrade kit will be available from Arcoma AB. Please identify the quantity of kits needed by your organization and order them FOC from service@arcoma.se All systems of the specific configuration mentioned above must be upgraded on the next scheduled service intervention.

- Install the upgrade kit and replace page(s) in the User manual in accordance to the supplied instruction.
- Sign and return the confirmation form to Arcoma AB as soon as the required action has been performed.

No parts must be returned to Arcoma AB

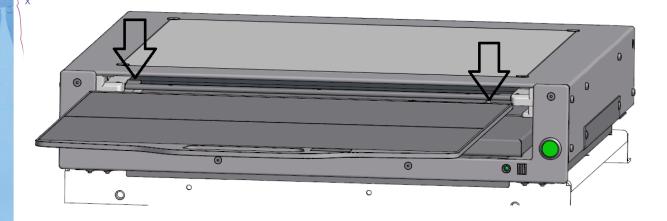
4 LIMITATION

This SI is valid for all systems using Acoma AB detector holders for removeable antiscatter grids. Note that these detector holders could have been used as upgrades for other system types.

5 QUESTIONS

If you have any questions regarding this SI, please contact Arcoma service department on <u>service@arcoma.se</u> or +46 470 706970.





6 ACKNOWLEDGE OF RECEIPT / UPGRADE

I hereby confirm as the responsible installer of the ARCOMA Intuition system with Serial number ______ that I received Service Information SI_2017_101_0180_Intuition and performed the upgrade in accordance with the upgrade instruction.

Date

Authorized dealer

Confirmed by

Function

Clarification of signature

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

Best regards

Jonas Petersson Service Manager Arcoma AB

©Arcoma AB Annavägen 1 S-352 46 Växjö, Sweden

Phone: +46 (0) 470 70 69 00 Fax: +46 (0) 470 70 69 59



ATTENTION

Service information

The service information is an important way for ARCOMA to reach out to our dealers and there technicians. The information is a part of our CAPA-process (Corrective And Preventive Action) and this part is to correct problems or inform you about essential parts of this process, and prevent an incident or miss use to occur.

The CE-mark to MDD Class II products is fulfilled through MDD ANNEX 2 93/42/EEC including our Quality system, the CAPA-process is a part of our Quality system.

Please take this information serious and if there is any information that is not clear do not hesitate to contact us.

Arcoma service department sends out the service information and we communicate with our E-mail. Please confirm that you have received the e-mail and understand the content.

We use an e-mail group for all our dealers; so if you change e-mail or want to have it sent to another address, please inform us.

Best regards ARCOMA AB

Service information guide

The information starts with a list of content of all sent Service information from Arcoma since the rutin was official. If any one is missed in your folder please let us know. The present **SI** is marked **bold**.

Stand type	:	Product that the service information concerns, name and/ or product id ex. 0070 ArcoCeil
Serial numbers	:	The product serial number, -s that is concerned. This can be an interval ex. 501 – 620. If no serial number mentioned it means all.
Date issued	:	The date the service information was sent out.
Service info number	:	The number of the service information. SI_YYYY-##
Issued by	:	The person creating and sending the information
Approved by	:	The person that has approved the information
Time for action		This information states the action that has to be carried out.
Urgent action	:	Immediate action or closing the lab
• As soon as possible	:	Book the room at the hospital as soon as it is possible. If it is
• When convenient	:	information to the hospital please send it at once. At next service booked
Only if problems	:	If a problem as described appear take action.
Report back	:	Report back with serial number when action has been performed
Subject	:	A header of the Service information
Ref nr:	:	Reference to internal or external reference number. Ex 13467, ÄBO_50430_01

E-mail Content

The E-mail field "subject" has the following standard text: Service info number + Time for action ex SI_2001_5 URGENT ACTION.

©Arcoma AB Annavägen 1 S-352 46 Växjö, Sweden

Phone: +46 (0) 470 70 69 00 Fax: +46 (0) 470 70 69 59

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