

URGENT FIELD SAFETY NOTICE

Attention: DX-D600: Potentially unsecured mechanical detent marker

Dear customer,

This Urgent Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by you in order to prevent risks for patients or users
- the actions planned by Agfa HealthCare to correct the problem.

Reference: PRB0052065

Device:

This Safety Notice refers to your DR unit "DX-D 600" (DX-D 600 Automatic System, DX-D 600 Semi-Automatic System, DX-D 600 Analog Manual, DX-D 600 Automatic Wall stand Only and DX-D 600 Semi-Automatic Wall stand Only). A product description can be found on our website → [DX-D 600](http://www.agfahealthcare.com/global/en/diagnostic_imaging/digital_radiography/dr_dx_d_600/index.jsp)
(http://www.agfahealthcare.com/global/en/diagnostic_imaging/digital_radiography/dr_dx_d_600/index.jsp)

Problem:

Agfa was notified of one instance in which the mechanical detent marker on a DX-D 600 became detached.



Actions:

Actions undertaken by Agfa HealthCare

Soon Agfa HealthCare will release a solution for the above mentioned problem and will upgrade your installation accordingly. Additionally a general inspection will be done.

Recommended actions to be taken by you:

If you notice that either of the mechanical detent markers on your unit have become loose, please notify your Agfa HealthCare Service contact at once.

Please distribute this information within your facility to all those who need to be aware of it.

It is important to take the actions detailed in this Urgent Field Safety Notification and to acknowledge receipt of this notification.

Should the above information not apply to your facility or should the device have been transferred to another organization, please be so kind as to indicate this on the attached feedback form and pass this Urgent Field Safety Notice to the organization where the device has been transferred.

We apologize for the inconvenience we have caused and we thank you for your careful attention to this issue and your continued support.

If you have any questions about this matter, please contact your local Agfa HealthCare organization:

Agfa HealthCare Singapore Pte Ltd
Tel: 62140622

Sincerely,
Paul Merckx, QARA Director BD Imaging



Agfa HealthCare NV
Septestraat 27, 2640 Mortsel
Belgium

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Feedback form

We kindly ask you to fax back or email the attached information as soon as possible. Your reply provides Agfa HealthCare, and subsequently the Regulatory Authority, with the means to monitor the progress of the Urgent Field Safety Corrective Actions. Thanks for your co-operation.

Customer /Facility:

Address:

Notice reference

PRB0052065

Product reference:

DX-D 600

- ☐ I confirm that I have received and understand the attached notice.
- ☐ This notice does not apply to my facility.
- ☐ The device has been transferred to another organization. Name and address of other organization: _____

Customer

Name:

Position:

Signature:

Date:

Phone number:

- ☐ Please correct our contact information as follows:

Customer / Facility name:

Address: