

yyyy-mm-dd

URGENT FIELD SAFETY NOTICE

«|A_Customer_Name»
«|A_Facility_Site»
«|A_Street_Address»
«|A_City», «|A_State» «|A_Zip_Code»

Attention: Digital Radiography X-Ray System DR 800 with Tomosynthesis:
Tomosynthesis image acquisition sequence did not stop automatically after expected number of exposures.

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 the customer / user in order to prevent risks for patients or users

Reference → PRB2000387

Product name and version(s)

This Important Information refers to your x-ray device "DR 800". A product description can be found on our website → [DR 800 \(https://medimg.agfa.com/main/direct-radiography/dr-800/\)](https://medimg.agfa.com/main/direct-radiography/dr-800/)

Information:

Symptom

Agfa became aware about one incident at customer site where Tomosynthesis sequence did not stop automatically.
Typically it can be reproduced at low non clinical relevant exposure values (0,1 and 0,2mAs).

Cause

Unknown, investigation is ongoing

Actions to be taken by you:

With this letter, Agfa is informing you that the DR 800 system still can be used including for Tomosynthesis for mAs values which are larger than 0,2 mAs.

In case Tomosynthesis image acquisition sequence does not stop automatically after the expected number of exposures, release the exposure button as this will stop the sequence and notify your Agfa 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.

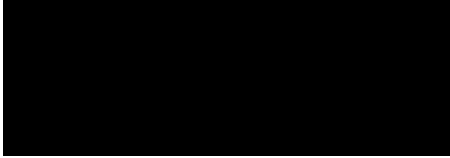
We apologize for the inconvenience we have caused and we thank you for your careful attention to this issue and your continued support.

yyyy-mm-dd

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

[Name of contact person - Title](#)
[Phone number - Email address@agfa.com](#)

Sincerely



Agfa NV
Septestraat 27, 2640 Mortsel
Belgium

yyyy-mm-dd

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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, 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: <IA_Facility_Site>

Address: <IA_Street>

<IA_City>, <IA_Zip_Code>, <IA_State>, <IA_Country>

Notice reference PRB2000387

Product reference: DR 800

- 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: