

yyyy-mm-dd

URGENT FIELD SAFETY NOTICE

«IA_Customer_Name»
 «IA_Facility_Site»
 «IA_Street_Address»
 «IA_City», «IA_State» «IA_Zip_Code»

Dear customer,

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

- a problem we have with our product and under what circumstances the issue can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Agfa NV to correct the problem

1. Information on affected devices	
1.1	Device Type(s)* Digital Radiography X-Ray System DR 800 A product description can be found on our website DR 800 (https://medimg.agfa.com/main/direct-radiography/dr-800/)
1.2	Commercial name(s) DR 800
1.3	Unique Device Identifier(s) (B-UDI) 05414904272824
1.4	Primary clinical purpose of device(s)* The DR 800 is an X-ray modality. It is designed for general radiography and dynamic applications. The DR 800 will be used in a radiological environment by qualified staff to capture and route static and dynamic X-ray images. The DR 800 is not intended for mammography applications.
1.5	Device model/catalogue/part number(s)* Type number is 6010/200

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	Description of the product problem* Under specific conditions wrong calculation of the dose/minute for fluoroscopy exams Expected behavior is that a higher frame rate results in a lower dose per frame and vice versa to not exceed 88mGy/min. Due to a software bug incorrect calculation of the dose based on the frame rate is done and dose can be above 88mGy/min.
2.2	(Potential) hazard* Radiation hazard
2.3	Probability of problem arising Problem will only occur when several preconditions are fulfilled : 1) Fluoroscopy exam 2) ABS switched OFF

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 Country / regional legal address

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	3) Manually changing the frame rate Problem only occurs when frame rate is changed after switching off ABS. This workflow is uncommon but is theoretically possible.
2.4	Predicted risk to patient/users In worst case 3x higher than intended radiation in dynamic radiology

3. Type of action to mitigate the risk	
3.1	Action to be taken by the user* <input type="checkbox"/> Identify device <input type="checkbox"/> Quarantine device <input type="checkbox"/> Return device <input type="checkbox"/> Destroy device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified. <div style="border: 1px solid black; padding: 5px;"> To avoid issue always use device in automatic mode (ABS=ON). </div>
3.2	Is customer reply required? * <div style="float: right;">Yes "Customer Reply Form"</div>
3.3	Action being taken by the manufacturer <input type="checkbox"/> Product removal <input type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified. <div style="border: 1px solid black; padding: 5px;"> In near future Agfa will release a new software to solve issue </div>

4. General information		
4.1	FSN Type*	New
4.2	Further advice or information already expected in follow-up FSN? *	No

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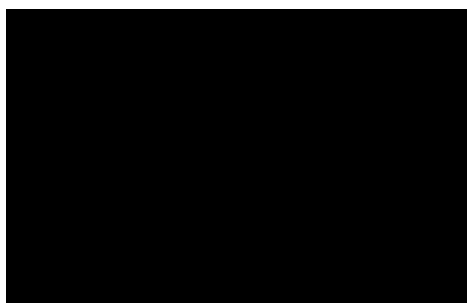
4.3	The competent (regulatory) authority of your country has been informed about this communication to customers.* "Yes"
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5. Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (as appropriate).</p> <p>Please transfer this notice to other organisations on which this action has an impact (as appropriate).</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the National Competent Authority if appropriate, as this provides important feedback..*</p>

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 NV organization:

Sincerely,



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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PRB2000435
FSN Date*	April 2020
Product/ Device name*	DR 800

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

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4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.