<Date>



URGENT FIELD SAFETY NOTICE

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

Caution: Digital Radiography X-Ray System DX-D 100 Type 5410 or DX-D 100 Wireless Type 5411: Sporadic unintended movement and unintentional touch screen activation.

Dear customer,

Agfa HealthCare wishes to bring to your attention the following information, We will implement an update to already improved firmware of the unit/s and want to inform you that Agfa Service will contact you soon to perform the update.

Device

This Safety Notice refers to your DR unit/s "DX-D 100" and/or "DX-D 100 Wireless" version. A product description can be found on our website $\rightarrow \underline{\text{DX-D100}}$ (http://www.agfahealthcare.com/global/en/diagnostic_imaging/digital_radiography/dr_dx_d_100/index.jsp)

Problem

When using the DX-D 100 unit, sporadic unintended movements caused by an electrostatic discharge of the unit to the ground may occur.

Capacitive touch screens rely on the electrical properties of the human body to enable you to operate the device with very light touches of a finger. However, when liquid comes in contact with the touch screen it may incorrectly recognize this as user input.

Actions

By the customer:

The unit is equipped with a safety switch in the drive handle. In case of an unintended movement, you should release the drive handle and the unit will stop.

The operator must make sure that both his or her hands and the touch screen are dry before utilizing the touch screen. In addition, the operator always should double check and verify the selected parameters and settings immediately before making an exposure (ref. former letter and/or User Manual addendum communication).

By Agfa Healthcare:

Against electrostatic discharges a new designed arrestor with a resistance of 1M ohm between frame and floor (ground) will be installed. Together with an update of Digital Motion Control (DMC) firmware this will prevent sporadic unintended movements.

A software update to change the behaviour of the touch screen so that holding the up or down button will change the value setting just a single step will limit the influence of an unintentional touch screen activation.

Please distribute this information within your facility to all those who need to be aware of it. Please complete the feedback form as soon as possible and return it to us.

Page 1/3



PR1406020002 PR1411200006 PR1501190003



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 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: **<Name of contact person>** at **<Tel>**.

Sincerely, Paul Merckx, Head of QARA Imaging Business Division

Agfa HealthCare NV Septestraat 27 B-2640 Mortsel Belgium

<Date>

PR1406020002 PR1411200006 PR1501190003



URGENT SAFETY NOTICE FEEDBACK FORM

We kindly ask you to send back the attached information as soon as possible. Thank you for your co-operation.

Customer/Facility Name:	«IA_Customer_Name» «IA_Faclity_Site»
Address:	«IA_Street_Address»
	«IA_City», «IA_State» «IA_Zip_Code»
Notice Reference:	PR1406020002, PR1411200006 and PR1501190003
Product Reference:	DX-D 100 Type 5410 or DX-D100 Wireless Type 5411
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. Insert name and address of other organization:	
Customer	
Name:	
Position:	
Signature:	
Date:	
Phone number:	
Please correct our contact information as follows: Customer/Facility Name:	
Address:	

Fax this completed form to <*fax no.*> or email us on <*email address>* indicating the reference code above in the subject line

Agfa HealthCare [Insert country/regional legal entity address here] (remove this guidance from final document)