<Date> **HQ_1111020003**

URGENT FIELD SAFETY NOTICE

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

Product:	**DX-D 10G, DX-D 10C, DX-D 20G & DX-D 20C - Digital detectors (connected via cable) for Direct Digital imaging size 35*43cm.**
Concerns:	**There is a potential risk that the detector cable gets damaged due to: being run over, excessive bending/twisting or other misuse.** **This damage could result in a cable short circuit and there is a risk of excessive heat in the damaged area, possibly radiating down the cable from that point.**

Dear customer,

Agfa HealthCare wishes to bring to your attention the following information, which has been communicated as well to the Competent Authorities of your country.

Device

This Safety Notice refers to our products: DX-D 10G, DX-D 10C, DX-D 20G & DX-D 20C, Digital detectors (connected via cable) for Direct Digital imaging, size 35*43cm.

Agfa's records indicate your facility has the described product configuration

Follow this link for a product description:

DX-D 10:

http://www.agfahealthcare.com/global/en/main/products_services/direct_radiography/detectors/dx-d10.jsp

DX-D 20:

http://www.agfahealthcare.com/global/en/main/products_services/direct_radiography/detectors/dx-d20.jsp

Issue

Our supplier informed us that there is a potential risk that the detector cable may develop an internal short circuit when the cable is damaged due to: being run over, excessive bending/twisting or other misuse.
In the event of cable damage and resulting cable short circuit, there is a risk of excessive heat in the damaged area, possibly radiating down the cable from that point and possibly causing patient harm if accidentally in contact with the patient.

Actions

As an attachment please find enclosed a label, which you should stick in a highly visible, suitable position on the cable of the portable detector (for instruction see attachment).

<Date> **HQ_1111020003**

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.

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 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,

[redacted], Head of QARA Imaging Business Division

Agfa HealthCare NV
Septestraat 27
B-2640 Mortsel
Belgium

<Date> **HQ_1111020003**

URGENT FIELD SAFETY NOTICE FEEDBACK FORM

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

Customer/Facility Name:	«IA_Customer_Name» «IA_Facility_Site»
Address:	«IA_Street_Address»
	«IA_City», «IA_State» «IA_Zip_Code»
Notice Reference:	**HQ_1111020003**
Product Reference:	**DX-D 20 G, DX-D20 C** **DX-D 10 G, DX-D10 C**

☐ 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.

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