PR1406020002

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:**
Unintentional touch screen activation due to liquids

Dear customer,

Agfa HealthCare wishes to bring to your attention the following information, which has also been communicated to the Competent Authority of your country.

Device:

This notice refers to the mobile Digital Radiography X-Ray System unit **DX-D 100**.

Problem:

When liquid comes in contact with the DX-D 100 touch screen, the device may incorrectly recognize this as user input altering device settings.

Background information:

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. For example, it could unexpectedly change the exposure settings.

Actions

Although medical staff are required to disinfect hands on a frequent basis, users must ensure their hands are dry before using the touch screen of the DX-D100 because liquid residue may activate the action buttons on the touch screen.

- **Do not operate touch screen monitor with wet hands!**
- **Do not let liquids come in contact with the touch screen while the DXD 100 is powered on!**
- **Always double check your parameter settings prior to exposing the patient.**

We would like to remind you of this specific warning statement in the DX-D100 User Manual:

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DX-D 100 Mobile X-Ray Unit User Manual (page 11)

IT IS THE RESPONSIBILITY OF THE OPERATOR TO ENSURE THAT ALL THE EXPOSURE PARAMETERS ARE CORRECT BEFORE PERFORMING AN EXAM TO THE PATIENT, BY VERIFYING THAT THE PARAMETER SELECTION HAS NOT BEEN MODIFIED UNINTENTIONALLY OR BY THE CONTACT OF EXTERNAL ELEMENTS ON THE CONTROL CONSOLE, IN ORDER TO AVOID THE OVEREXPOSURE OR THE NEED OF PERFORMING A NEW EXAM TO THE PATIENT.

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 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,

[redacted] Head of QARA Imaging Business Division

[redacted]

Agfa HealthCare NV
Septestraat 27
B-2640 Mortsel
Belgium

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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_Facility_Site»

Address: «IA_Street_Address»

«IA_City», «IA_State» «IA_Zip_Code»

Notice Reference: **PR1406020002**

Product Reference: **DX-D100**

☐ 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