COMPANY LETTERHEAD

FIELD SAFETY NOTICE

Corrective Actions for Canon X-ray interventional system

Date

Attention: Radiology Manager/Director

DETAILS ON AFFECTED DEVICES:
MODEL & S/N of the affected system that this customer owns

The purpose of this letter is to bring to your attention a certain problem with your Canon XR medical device. The problem is described below together with the corrective measure. We strongly request that you share the contents of this letter with all users of the above-mentioned device in your facility.

We will soon make contact with you to apply the necessary corrective action.
We regret that this action is necessary, and very much appreciate your understanding and cooperation. We apologize for any inconvenience that this may cause you.

DESCRIPTION OF THE PROBLEM:

The table surface/top may tilt by dropping several millimetres because the bolts that hold the longitudinal movement parts are loose. In such situation, the manual operation of the tabletop longitudinal movement will become heavy or will not move. Note however that the tightening parts including the tabletop will not fall because they are structured in consideration of safety.

The cause for the loose bolts is an insufficient work procedure in the factory.

CORRECTIVE MEASURES:

We will correct this issue by checking and tightening the bolts of your device. Your service representative will contact you for an appointment.

ADVICE ON ACTION TO BE TAKEN BY THE USER:

Should this problem occur before our correction on your device, please stop using the device and call your service representative.

TRANSMISSION OF THIS FIELD SAFETY NOTICE:

Please share this notice with all users and reviewing radiologist as well as clinical engineering or biomedical group at your facility, or to any organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

This notice has been notified to the appropriate National Competent Authority via a Field Safety Corrective Action notification.

Please complete and return the attached form via faxing it to FAX NR or via email to EMAIL.

We thank you for your urgent attention to this matter. If you have any questions regarding this letter please feel free to contact your Canon Representative at [contact details].

Sincerely,

Name
Title
Tel. nr / E-mail

Attachment
USER REPLY FORM

Subject: Medical Device Correction of a Canon XR device

Device:
Serial Number:

Facility:

Contact Information:

Name:_____

Title:_____

Telephone Number:_____ Fax Number:_____

Were the instruction contained in the "**ADVICE ON ACTION TO BE TAKEN BY THE USER:"** section of the attached letter understood?

☐ Yes ☐ No

If "No", please explain:

_____
_____

Was the information shared with your staff? ☐ Yes ☐ No

If "No", please explain:

_____
_____

Signature:_____

Date:_____