

FIELD SAFETY NOTICE

for Canon XR System INFX-8000C/G5 s/n serial number
Infinix-i Sky, Ceiling mounted vascular system including standard table. FPD size 30x40cm

Dear Customer,

The purpose of this letter is to bring to your attention the following problem occurring with your Canon X-Ray system: The table top may tilt unexpectedly by dropping several millimeters.

A description of the problem is set out below along with the corrective measure.

Affected products

Affected systems are some Infinix and Alphenix Angiographic systems with a CAT-850 table.

Description of the Problem:

The table top may tilt unexpectedly by dropping several millimeters 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 may not move at all. Note however that the tightening parts including the tabletop itself cannot fall because they have built in safety features that prevent such from occurring.

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

ACTION: We recommend to take the following actions

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

Actions Being Taken by Canon

We corrected this issue by checking and tightening the bolts of your device.

Device Vigilance

The problem has already been reported to the authorities.

Transmission of the Field Safety Notice

Please pass on these instructions to all relevant staff and potential users of this system, including Clinical Engineering and Bio-Medical teams.

Confirmation of receipt

Please return the reply form on the last page to Canon, either by fax, email or the enclosed reply paid envelope.

Further information

Should you have further questions, please do not hesitate to contact our service and/or QARA department. Details you will find below.

Canon Medical Systems Europe B.V.

Zilverstraat 1

2718 RP Zoetermeer

The Netherlands

EU.vigilance@eu.medical.canon

Thank you for your understanding and attention to this matter.

Yours sincerely,

For Canon Medical Systems Europe


Director of Regulatory Affairs and Quality Assurance

USER REPLY FORM

Subject: Field Safety Notice for Canon XR System INFX-8000C/G5 s/n serial number Infinix-i Sky, Ceiling mounted vascular system including standard table. FPD size 30x40cm

Ref: COM-0000000162

Affected Systems: some Infinix and Alphenix Angiographic systems with a CAT-850 table.

Facility: _____

Contact Information: _____

Name: _____

Title: _____

Telephone Number: _____ **Fax Number:** _____

Were the instruction contained in the "**ACTION: We recommend to take the following actions:**" 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: _____