

Urgent Field Safety Notice

FSN Ref: FSN_PR20210830-01_EN_NL

FSCA Ref: FSCA_PR20210830-01

Risk of unstable fixation of accessories

For the attention of: Healthcare professional and system distributor

Contact details of local representative:

Canon Medical Systems Europe Zilverstraat 1 2718 RP Zoetermeer THE NETHERLANDS pstaakman@delftdi.com

Information on Affected Devices

Device type											
<p>Affected devices are:</p> <p>This FSN concerns the standard accessory Footrest and optional accessory Shoulder Support, designed for use with Celex and Intelli-C diagnostic medical X-ray systems.</p>											
Commercial name(s)											
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 2px;">Name</th> <th style="text-align: left; padding: 2px;">REF</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Celex, Right</td> <td style="padding: 2px;">03200000</td> </tr> <tr> <td style="padding: 2px;">Celex, Left</td> <td style="padding: 2px;">03200010</td> </tr> <tr> <td style="padding: 2px;">Intelli-C EU, Right</td> <td style="padding: 2px;">03500000</td> </tr> <tr> <td style="padding: 2px;">Intelli-C EU, Left</td> <td style="padding: 2px;">03500010</td> </tr> </tbody> </table>	Name	REF	Celex, Right	03200000	Celex, Left	03200010	Intelli-C EU, Right	03500000	Intelli-C EU, Left	03500010	
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Involved accessories:											
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Footrest	03282000 (delivered as standard with all devices)										
Shoulder Support	03283000 (optional accessory)										
Primary clinical purpose of device(s)											
<p>Accessories designed for use with diagnostic medical X-ray system, Celex and Intelli-C</p>											
Reason for Field Safety Corrective Action (FSCA)											
Description of the product problem											
<p>This FSN is distributed to inform users about a risk that a friction rubber block, used in the clamping mechanism of the mentioned accessories, may become loose from the clamping profile.</p>											
Hazard giving rise to the FSCA											

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<p>If the friction rubber become loose, the accessory may not sufficiently grab on to the patient tabletop, resulting in an unsecure fixation.</p>
<p>Probability of problem arising</p>
<p>The probability of the problem arising again (recurrence) is low if the instructions in the Operators Manual are followed.</p>
<p>Background on Issue</p>
<p>The described scenario has been reported to us on one occasion from a customer using the Footrest.</p>
<p>Other information relevant to FSCA</p>
<p>The condition of the friction rubber (one on each side of the accessory) may be easily checked by the user (see appendix B), and if they are found to be loose, the accessory should not be used.</p>
<p style="text-align: center;">Type of Action to mitigate the risk</p>
<p>Action To Be Taken by the User</p>
<p style="text-align: center;"><input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> On-site device inspection</p> <p>Please inspect your Footrest and optional Shoulder Support as specified in appendix B. If you find that the friction rubber is loose or damaged, arrange with your local dealer to have the affected accessories repaired.</p>
<p>By when should the action be completed?</p>
<p>As soon as possible.</p>
<p>Is customer Reply Required?</p>
<p>Yes, please fill in the Customer Reply Form on the last page.</p>
<p>Action Being Taken by the Manufacturer</p>
<p>A new clamping profile with a bolted-on friction rubber is being designed and NRT will arrange for replacement of the old clamping profiles, starting April 2022.</p>
<p>By when should the action be completed?</p>
<p>We plan for completion of all actions by end of 2022.</p>
<p style="text-align: center;">General Information</p>
<p>FSN Type</p>
<p>New</p>
<p>Manufacturer information</p>

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(For contact details of local representative refer to page 1 of this FSN)	
Company Name	NRT X-Ray A/S
Address	Birkegaardsvej 16, Hasselager, Denmark
Website address	www.nrtxray.com
List of attachments/appendices	
Appendix A: List of affected devices Appendix B: Friction rubber inspection instructions	
Name/Signature	
Transmission of this Field Safety Notice	
<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>	

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Customer Reply Form	
Please fill in the below section	
<input type="checkbox"/>	The undersigned hereby confirm to have read and understood the information in this FSN
<input type="checkbox"/>	We confirm that we intend to perform the required actions, as specified
Date	
Site name and address	
Name (type)	
Signature	

Important!

Please return the signed Customer Reply Form as soon as possible, either scanned via e-mail or take a photo with your smartphone and e-mail – to support@nrtxray.com