

**URGENT - Field Safety Notice**  
***Mobile Detecor Holder***

***Mobile Detector holder Trolley -clamp issue***

Dear Customer,

As part of Philips' focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Mobile Detector Holder we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur,
- the actions you can take to avoid or minimize the occurrence of the issue and
- the actions planned by Philips to correct the issue.

**This document contains important information for the continued safe and proper use of your equipment**

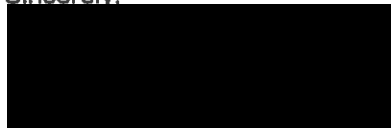
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning this, please contact your local Philips representative:

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,



Karmen Gruenert  
Director Q&R DXR Hamburg

DXR

Quality Management System DXR

DXR Field Safety Notice

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FSN MA-FCO 71200174

2017-Jul-14

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### *Mobile Detecor Holder*

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<b>AFFECTED PRODUCTS</b>	Mobile Detector Holder (9890-010-88152)
<b>PROBLEM DESCRIPTION</b>	If the lock mechanism of the movable clamp of the mobile detector holder is not adjusted properly or not secured, the portable detector can drop down when the moveable clamp is at the bottom (below of the detector) and additional force is applied. This may happen when the detector is rotated clockwise from landscape to portrait position.
<b>HAZARD INVOLVED</b>	The Wireless Portable Detector (WPD) is fixed in the Mobile Detector Holder via a lock mechanism. The 4 countersunk screws, that are used to attach the lock mechanism, can become loose. If this happens and the mechanism fails, the detector may fall down when the holder is rotated 90° clockwise from landscape.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	All Mobile Detector Holders
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	The customer should check the lock mechanism of the Mobile Detector Holder. The lock mechanism can be moved without pressing the actuator, the holder should not be rotated clockwise.
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips will:</p> <ol style="list-style-type: none"> <li>1. secure the four affected screws,</li> <li>2. correctly position the release trigger screw correctly and</li> <li>3. test the clamp force.</li> </ol> <p>A Philips Service Engineer will contact you to schedule this action.</p> <p>Should you need to communicate with Philips with regard to this program, please reference Field Change Order 71200174.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	If you would like any further information or support concerning this issue, please contact your local Philips representative.

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the <product name> due to FCO XXXXXXXX . Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: XXXXXX, XXXXXX, XXXXXXXX, XXXXXX

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date: