

## **URGENT - Field Safety Notice** ***DuraDiagnost X-ray System***

### ***Improper installation of Tube arm/Tube may cause it to fall***

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips ***DuraDiagnost*** X-Ray system, 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
- 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:

<Philips representative contact details to be completed by the KM / country>

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

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>

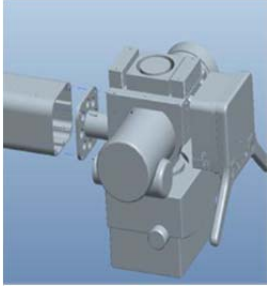
<Name>

<Function>

## URGENT - Field Safety Notice

### *DuraDiagnost X-ray System*

#### *Improper installation of Tube arm/Tube may cause it to fall*

<b>AFFECTED PRODUCTS</b>	DuraDiagnost	
<b>PROBLEM DESCRIPTION</b>	<p>If the screw threads for the mounting of the x-ray tube were not properly aligned during installation or service, the tube could be unstable.</p> <p>The illustration shows the location of the screw threads in question.</p>	
<b>HAZARD INVOLVED</b>	<p>Risk of injury due to falling X-Ray tube.</p> <p>The risk occurs if screw threads for the mounting of the X-Ray tube are not properly aligned during installation or service. Patients and users in the vicinity of the X-Ray tube are at risk if the fault occurs.</p>	
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>The following DuraDiagnost serial numbers (SN) are affected, you can find your serial number on the product label:</p> <p>SN130001/SN130002/SN130003/SN130004/SN130005/ SN130006/SN130007/SN130009/SN130010/SN130011/ SN130012/SN130013/SN130014/SN130015/SN130016/ SN130017/SN130018/SN130019/SN130020/SN130021/ SN130022/SN130023/SN120001/SN120002/SN120003</p>	
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>Please follow DuraDiagnost Instructions for Use during use scenario.</p> <p>If you notice that the X-Ray tube housing does not appear to be mounted sufficiently, or have questions or concerns please contact your local Philips representative immediately.</p>	
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips Healthcare will provide a new X-Ray tube arm structure to support the X-Ray tube assembly, which is less susceptible to screw thread damage during servicing or replacement.</p> <p>A Philips Healthcare Service Engineer will contact you to install the solution.</p>	
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative. &lt;Philips representative contact details to be completed by the KM / country&gt; Please reference FCO 71200115 when contacting your local Philips representative.</p>	