

**URGENT - Field Safety Notice
DigitalDiagnost Release 3**

Missing protective cover on Control Handle for Ceiling Suspension

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 Digital Diagnost, 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

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>


Director Q&R DXR Hamburg



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AFFECTED PRODUCTS	DigitalDiagnost Release 3
PROBLEM DESCRIPTION	<p>During an in-house inspection, some systems of DigitalDiagnost Rel.3 were found to be missing a small, metal protective cover on the bottom side of the control handle for the ceiling suspension. This exposes electrically live parts on the printed circuit board of the control handle to the potential for direct contact. The live voltage that is exposed to potential contact is only 25 volt, but it is a deviation from the IEC standard.</p>  <p style="text-align: center;">Bottom view of Control Handle with mounted protective cover.</p>
HAZARD INVOLVED	There is a potential low risk for harm if the user or patient places his or her hand in the open slot where electrically live parts may be touched.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>This correction applies to the following affected units of DigitalDiagnost Rel. 3 systems, produced between June 2011 and October 2011: Type number - 9890 010 83903 Serial numbers - 11000001 to 11000028.</p> <p>The system type number and serial number can be found on the label attached to the lower end of the ceiling suspension telescope. (Refer to the Instructions for Use for further description of the labeling location.)</p> <p>Please note: This cover may not be missing from all systems.</p>

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ACTION TO BE TAKEN BY CUSTOMER / USER	Do not place your hand in the open slot below the Control Handle and ensure that no patient places his/her hands there.
ACTIONS PLANNED BY PHILIPS	Philips has issued a Field Change order instructing Service Engineers to check affected systems and install the cover where it is missing free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

