

URGENT - Field Safety Notice DigitalDiagnost

Automatic stitching and ruler handling

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 DigitalDiagnost, we have identified two issues that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issues are, and under what circumstances they 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>

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AFFECTED PRODUCTS	DigitalDiagnost with software version 2.x and the image stitching option.
PROBLEM DESCRIPTION	<p>Potential misdiagnosis due to improper Philips image ruler handling: If an image is used for clinical measurements, then it has to be calibrated. The current Instructions for Use recommend that a lead ruler be used to calibrate the image. Philips provides a specialized image ruler as an option to enable automatic image stitching. Some clinicians have used this Philips image ruler for clinical measurements or to calibrate an image. Unlike other lead rulers, the Philips image ruler is not suitable for these purposes: if it is not positioned in the same plane as the anatomical image detail to be measured, measurements made with this ruler may be inaccurate. Moreover, unless a properly calibrated lead ruler is also used, this measurement inaccuracy may not be detected.</p> <p>Potential misdiagnosis due to improperly automatically stitched images: When automatic stitching is not successful, the original images may not be properly aligned and the composite image can be misinterpreted, e.g. to indicate a broken bone, wrong number of vertebrae, shunt in wrong place.</p>
HAZARD INVOLVED	There is the potential for misdiagnosis or suboptimal surgical treatment when using images with uncalibrated rulers or automatically stitched images in which the accuracy of the stitching is not verified by a clinician.
HOW TO IDENTIFY AFFECTED PRODUCTS	All systems with software version 2.x and image stitching option. The software version is displayed at the user interface monitor: select tab "System", then select tab "General". Check the section "Workspot data" for the software version and the section "License status" for the option "Auto_Stitching_Acquisition".
ACTION TO BE TAKEN BY CUSTOMER / USER	<p><u>Ruler handling for measurements:</u> When a lead ruler is used for clinical measurements, then please carefully follow the Instruction for Use chapter "Measurements" of the Eleva Workspot manual. Do not use the Philips image ruler for measurements.</p> <p><u>Automatic stitching:</u> Automatic stitching is not always successful. Always check the composite stitched image results against the single images carefully prior to using it for any clinical purpose. Incorrectly stitched images must be manually corrected. For stitching procedures, only use the Philips image ruler. Do not use the Philips image ruler for other examinations than stitching examinations. Do not use the Philips image ruler for measurements.</p> <p>Should you feel uncertain regarding these instructions, you can contact Philips.</p>

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ACTIONS PLANNED BY PHILIPS	Philips plans to supply an Addendum to the Instructions for Use containing the information above. A Philips Service Engineer will contact you as soon as the Field Action Kit is ready to be implemented. Should you need to communicate with Philips with regard to this program, please reference FCO-71200060.
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>