

Field Safety Notice

Philips Healthcare

Computed Tomography

-1/3-

FSN 72800509

2010 September 29

URGENT – Field Safety Notice Comprehensive Cardiac Analysis (CCA) - Functional Analysis Feature

CCA Functional Analysis – Wall Thickening Polar Maps

Dear Customer,

A problem has been detected in the Philips Comprehensive Cardiac Analysis application that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

NOTE: You may have previously reviewed this information in the Customer Information Letter, CIL 72800450, October 3, 2009, and CIL 88200360, December 8, 2009.

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 issue, please contact your local Philips representative:

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



Senior Director
Quality & Regulatory, CT/NM

NOTE: This FSN is also applicable to 72800510, 72800512, 72800513 and 88200360.



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AFFECTED PRODUCTS	CCA application running on the Extended Brilliance Workspace (EBW) v2.0.5, v2.0.11, v3.0, v3.0.1, v3.0.2, v3.5, v3.5.2, v3.5.3, v3.5.4, v3.5.35, v4.0.1, v4.0.2, v4.0.3, v4.5.1 and Brilliance Workspace Portal v2.5.1.17, v2.5.1.19.
PROBLEM DESCRIPTION	<p>The CCA application contains a “functional analysis” tool which displays polar maps depicting the relative changes in the heart wall. The displayed values are labeled as being the percentage of increase in the wall thickness between the end diastolic and the end systolic states. However, what is actually being displayed is the decrease in wall thickness from the end systolic to the end diastolic state.</p> <hr/> <p>In EBW 2.x, 3.x and Portal 2.x: The formula displayed is: The actual calculation used is:</p> <p>Wall Thickening (%) $\frac{ES - ED}{ED}$ $\frac{ES - ED}{ES}$</p> <hr/> <p>In EBW 4.x: The calculation that is used and displayed is: Wall Thickening (%) $\frac{ES - ED}{ES}$</p> <hr/> <p>The equation for Wall Thickening (%) should be:</p> <p style="text-align: center;">Wall Thickening (%) $\frac{ES - ED}{ED}$</p> <p>The magnitude of the percentage change identified as an increase in wall thickness actually represents a decrease in wall thickness. However, relative changes in wall thickness depicted in the Wall Thickening Polar Maps are correct.</p>
HAZARD INVOLVED	There is potential hazard, caused by the Wall Thickening Polar Maps reflecting the differences between the heart regions and the actual numeric percent increase of wall thickening.



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HOW TO IDENTIFY AFFECTED PRODUCTS	To identify the version of software installed on your system, click on the Help button.
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Be aware that the numbers displayed for “Wall Thickening” actually represent a reduction in wall thickness from ES to ED.</p> <p>However, when using Wall Thickening Polar Maps (regional or detailed views), the <i>relative</i> changes between the heart regions as represented by the colors of the polar maps are correct.</p> <p>This letter should be placed in your Instructions for Use until otherwise notified, and replaces CIL 72800450 and CIL 88200360.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips Healthcare is notifying all affected customers and will be providing a software update to resolve this issue.</p> <p>Patient and product safety continues to be our primary focus. As a valued customer of Philips Healthcare, we want to ensure that your Philips equipment is being used in a safe manner.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative: Customer Care Service Center in the U.S. at 1-800-722-9377, option 5: Diagnostic Imaging, option 1: CT or your local Philips representative.</p>



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