URGENT – Field Safety Note

IntelliSpace Portal Software Versions 5 and 6

Software Issues on IntelliSpace Portal May Lead to Misdiagnosis

Dear Customer,

We have identified several software issues with the IntelliSpace Portal Software Versions 5 & 6, which could lead to misdiagnosis. Philips has identified interim solutions that can be implemented until your software can be updated to Version 5.0.2.3 or 6.0.2.3, which do not exhibit these issues. Your local Field Service Engineer (FSE) will be contacting you shortly to schedule the software update to your system.

This Field Safety Notice 88100023_88100024 is intended to inform you of the following:

- The problems and under what circumstances they can occur
- The actions that should be taken in order to prevent risks to patients
- The actions planned by Philips to correct the problems

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's Instruction for Use.

If you need any further information or support concerning these issues, please contact your local Philips representative or local Philips Healthcare office.

For North America and Canada contact the Customer Care Solutions Center (1-800-722-9377, option 1: Enter Site ID or follow the prompts).

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

Director Quality and Regulatory

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AFFECTED PRODUCTS	• IntelliSpace Portal DX/HX/EX, Software Versions 5 and 6 • IntelliSpace Portal IX, Software Versions 5 and 6 • IntelliSpace Portal LX SPECT, Software Versions 5 and 6
PROBLEM DESCRIPTION	The following software issues have been identified in the affected products. Problem 1: When reopening a bookmark generated from processing a MUGA (Multi-Gated Acquisition) scan within the NM Cardiac Application, the ejection fraction (EF) displayed should be the same as the ejection fraction (EF) originally displayed when the bookmark was first created. In some instances, the ejection fraction (EF) may be different. Problem 2: When processing using one of the following NM clinical applications: AutoQUANT, Emory Cardiac Toolbox, Corridor4DM, or NeuroQ, the patient study presented to the reviewing physician within the application may be for a different patient than the one selected from the patient directory. Note: The data presented to the reviewing physician is the data for the patient presented by the application labeling. Problem 3: While using the NM Viewer application, an arrow annotation added to a display moves away from its original position if the viewer is subsequently maximized or if the image within the viewer is subsequently zoomed in or out. Problem 4: While displaying PET images within CT Viewer, the SUV results displayed may be calculated with an SUV method different from the one specified in system preferences. This issue affects the CT Viewer and Multi-Modality Tumor Tracking applications. The expected behavior in such a case is that the application displays a warning that SUV cannot be calculated due to missing information, and the images are displayed with the original acquisition units (BQ/ML). Instead, in affected systems, if the patient height has not been entered and the selected SUV calculation method requires height data (i.e., SUV-BSA), the system may display an SUV calculated using a different method (SUV-BW) without providing any warning that required data had not been entered or informing the user of the change.

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HAZARD INVOLVED	Following are the potential risks associated with the above mentioned problems: • Problem 1: There is a risk of the patient receiving an incorrect treatment plan. • Problem 2: There is risk of the patient receiving an incorrect treatment plan due to misdiagnosis • Problem 3: Incorrect area indicator annotation results in an erroneous final Nuclear Medicine report, which may cause subsequent mistreatment. • Problem 4: There is a risk of misdiagnosis if SUV calculation method applied is not the method selected by the user.
HOW TO IDENTIFY AFFECTED PRODUCTS	To identify the software version of the product: • Click the "Help" button, • Select "About", and the software version is displayed. The affected versions are 5.0.0, 5.0.1, 5.0.2, 6.0.0, 6.0.1, 6.0.2 Refer to the "AFFECTED PRODUCTS" section of this Field Safety Notice for the list of systems and software versions affected by this correction.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Until your site's software is updated, Philips Healthcare advises users to perform the following workarounds based upon the above problem descriptions: Problem 1: The reviewing physician should make sure there is no disparity between the reported EF ((Ejection Fraction) and the visible cardiac wall motion. A secondary capture of the NM Cardiac application MUGA (Multi-Gated Acquisition) results screen should be created for comparison to the bookmark results during review. Problem 2: • The physician reviewing a study should confirm the patient information displayed within the NM 3rd party clinical application is the same patient that was selected from the patient directory. • After deleting patient studies, force a log off from the IntelliSpace Portal for all users Problem 3: Do not zoom or maximize an image viewer within NM Viewer after the addition of arrow + text annotation. If arrow + Text annotation is needed: • Manipulate the image or viewer size then add the arrow + text annotation. • Create a secondary capture of any images with the arrow + text annotation • Delete the annotation prior to manipulating the image or viewer size again. Problem 4: When the SUV calculation method selected is other than SUV Body Weight (BW), the technologist operating the scanner needs to confirm all the required patient information for the SUV calculation is entered during the acquisition setup.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare is initiating a correction consisting of : • Distribution of this Field Safety Notice • Installation of updated software versions 5.0.2.3 and 6.0.2.3, in which the above issues have been corrected. Corrective version will be available on 01 August 2014. A Philips Service Engineer will contact the customer for implementation of the software update on the affected systems.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. For North America and Canada contact the Customer Care Solutions Center (1-800-722-9377, option 1: Enter Site ID or follow the prompts).