

URGENT - Field Safety Notice

PHILIPS MX 16-slice Computed tomography x-ray system

Software upgrade from v2.0.0.21479 to v2.0.0.21480

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 MX 16-slice Computed tomography 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.

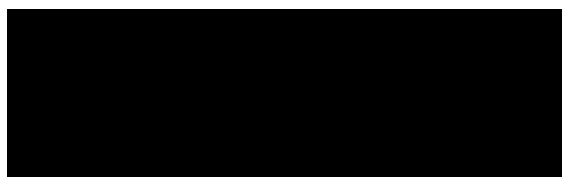
If you need any further information or support concerning this, please contact your local Philips representative:

<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,

Alina Zhou
Site Q&R Leader, IS China

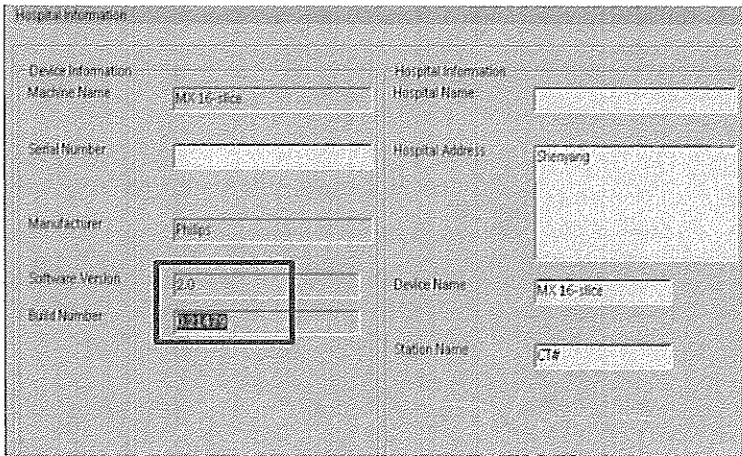


19 - Oct - 2015

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AFFECTED PRODUCTS	Philips MX 16-slice CT Systems with software version v2.0.0.21479
PROBLEM DESCRIPTION	<p>In 2D and Filming function, when image is zoomed and saved as derived DICOM format, the measurement on new created image is incorrect.</p> <p>This issue only occurs on MX16 systems with software version v2.0.0.21479, including MX16 EVO2 systems and MX 16 systems upgraded to MX16 EVO2 using the MX16 iDose4 Upgrade Kit.</p>
HAZARD INVOLVED	Image with incorrect measurement value may be used to guide clinical procedures where measurement is critical. This may lead to misdiagnosis.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Identify affected units by the software revision v2.0.0.21479</p> <p>User can identify the existing software version following the steps below:</p> <ol style="list-style-type: none"> 1. Log On the application software with User Name "Config". 2. Click Processing > Service > System Setting> Hospital Information (see Figure 1). 3. Check whether the Software Version is 2.0 and the Build Number is 0.21479 (see Figure 1).  <p>Figure 1: Check the existing software version</p>
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Do not save images to derived DICOM in 2D. If derived DICOM images are needed, users can save the images in MPR*. Correct measurement result can be obtained on derived DICOM images in MPR.</p> <p>(* MPR is one of the post-processing applications.)</p>

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ACTIONS PLANNED BY PHILIPS	<p>Philips will release Field Change Order (FCO) 72800646 to upgrade the software free of charge.</p> <p>A Philips Field Engineer will contact you to schedule this correction.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p><Philips representative contact details to be completed by the KM / country></p>