

URGENT - Field Safety Notice
PHILIPS MX 16-slice Computed tomography x-ray system

V1.1.4.21426 from V1.1.3_ V1.1.4.21425

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 or the UK Philips Customer Care Centre on 0870 532 9741.

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.


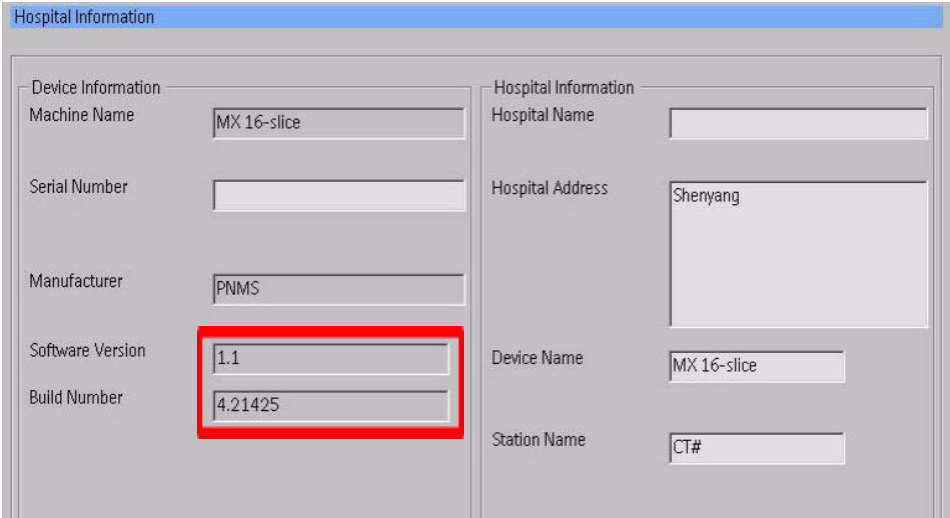
Sincerely,

CT Business Unit
Philips Healthcare

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AFFECTED PRODUCTS	PHILIPS MX 16-slice CT System
PROBLEM DESCRIPTION	The orientation of images is displayed incorrectly. When operator chooses "gantry on the right side" from operation console, and the patient position is HF DL, HF DR, FF DL or FF DR, the patient position picture and text is not consistent. "L" and "R" of scan images are reversed and this is not consistent with the patient actual position.
HAZARD INVOLVED	Potential misdiagnosis or incorrect anatomy classification leading to unnecessary treatment/procedure.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Identify affected units by the software revision: v1.1.3.1167; v1.1.4.21425; v1.1.4.21424; v1.1.4.21422</p> <p>How the user can identify: For V1.1.3 system, user can always go to "Help" page from the screen top, and see the software revision there. It should be 1.1.3.1167</p>  <p>For V1.1.4.21425 and later, user can navigate to "Processing" → "Service" → "System Setting" → "Hospital Information" to find the software revision information.</p> 

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ACTION TO BE TAKEN BY CUSTOMER / USER	<ol style="list-style-type: none">1. When error is encountered, restart the Console and Application software.2. Avoid using "Gantry on the Right side" Orientation to scan patients.3. After the Console is started, wait for a few minutes, and then start up the application software.
ACTIONS PLANNED BY PHILIPS	<p>Philips plans to install updated software in a Service Pack, the product correction will be issued and will be implemented free of charge. The Service Pack will also correct the following other issues:</p> <ul style="list-style-type: none">• When a surview which is longer than 557mm is stopped by using "Abort" function during the scan process, the position of scan box in surview image is not correct.• For dental applications, when a patient scan is taken with Gantry tilted, and the tilt angle falls in the range from 1 to -1 degree (not including 0 degree position), the data post-processing may not operate normally and the images may not be displayed.• If the user stops a surview using the "Abort" function during the second part of the scan, the positions of the scan box are not consistent. <p>A Philips Field Engineer will contact you shortly to schedule this correction.</p>
FURTHER INFORMATION AND SUPPORT	<p>For any further questions, please contact your local Philips representative or the UK Philips Customer Care Centre on 0870 532 9741.</p>