

Field Safety Notice

PHILIPS HEALTHCARE

FSN BUCT S/N: 72800383

Date: Jul. 22, 2008

URGENT - Field Safety Notice MX4000, MX4000 Dual, MX6000 Dual

Incorrect Reference Line in Surview

Dear customer,

A problem has been detected in the Philips MX 4000, MX 4000 Dual, MX 6000 Dual CT scanners, if it were to re-occur, could pose a risk to patients and to 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.

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.

If you need any further information or support concerning this issue, please contact our Service Support Department.

This notice is reported to the appropriate Regulatory Agency.

We apologize for any inconveniences caused by this problem.

Sincerely,

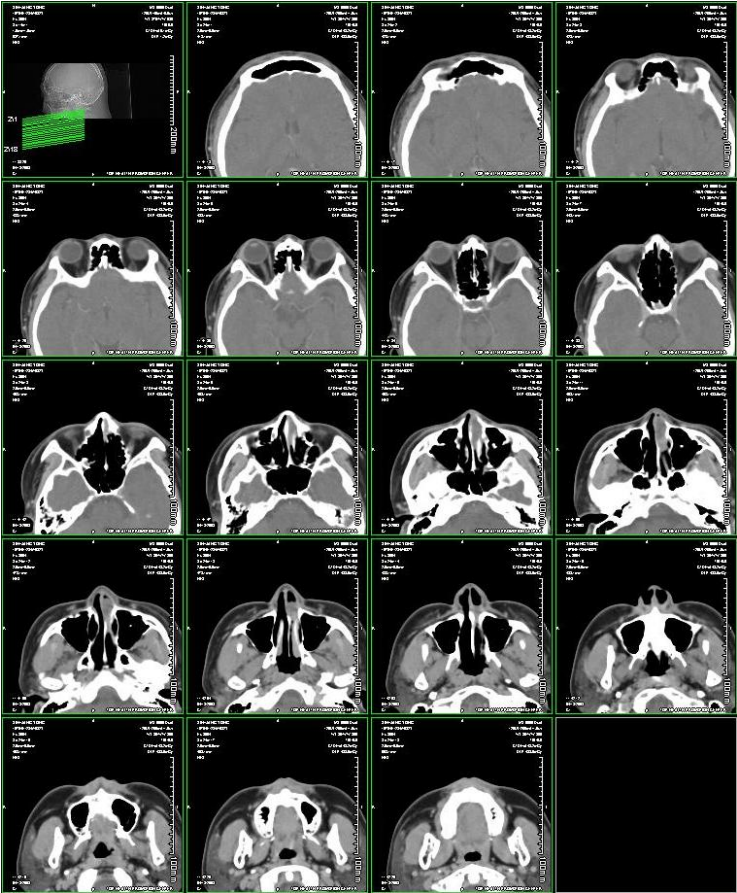


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AFFECTED PRODUCTS	MX4000, MX4000 Dual, MX6000 Dual
PROBLEM DESCRIPTION	<p>An Field Problem Report with respect to incorrect reference line in the film was received on May 2008.</p> <p>When a "head first, couch out" or a "feet first, couch in" Surview scan is started then paused midstream, the image generated is what the doctor expects, but the reference lines appear in the incorrect position in the "FILM" display mode. The acquired images accurately represent the exact positions planned on the original Surview.</p> <p>Investigation concluded that the problem may affect MX series CT products (MX 4000, MX 4000 Dual, MX 6000 Dual scanners). The images below are example of green reference line does not match the scanned position in the film.</p> 



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HAZARD INVOLVED	Unmatched reference line in film that may result in incorrect diagnosis or incorrect operative site location.
HOW TO IDENTIFY AFFECTED PRODUCTS	See <u>Annex A</u> to understand where to locate the system label. You will be contacted directly by a Philips representative to determine if the scanner you use is affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	Users must follow the instruction below in order to avoid this issue: Do not stop or pause scan during Surview acquisition. For planning purposes use only uninterrupted Surview.
ACTIONS PLANNED BY Philips Healthcare	Philips will provide updated software to all affected systems free of charge to correct this problem. You will be contacted by your Philips representative for the planning of this software update.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your Philips Healthcare Service Support Department.



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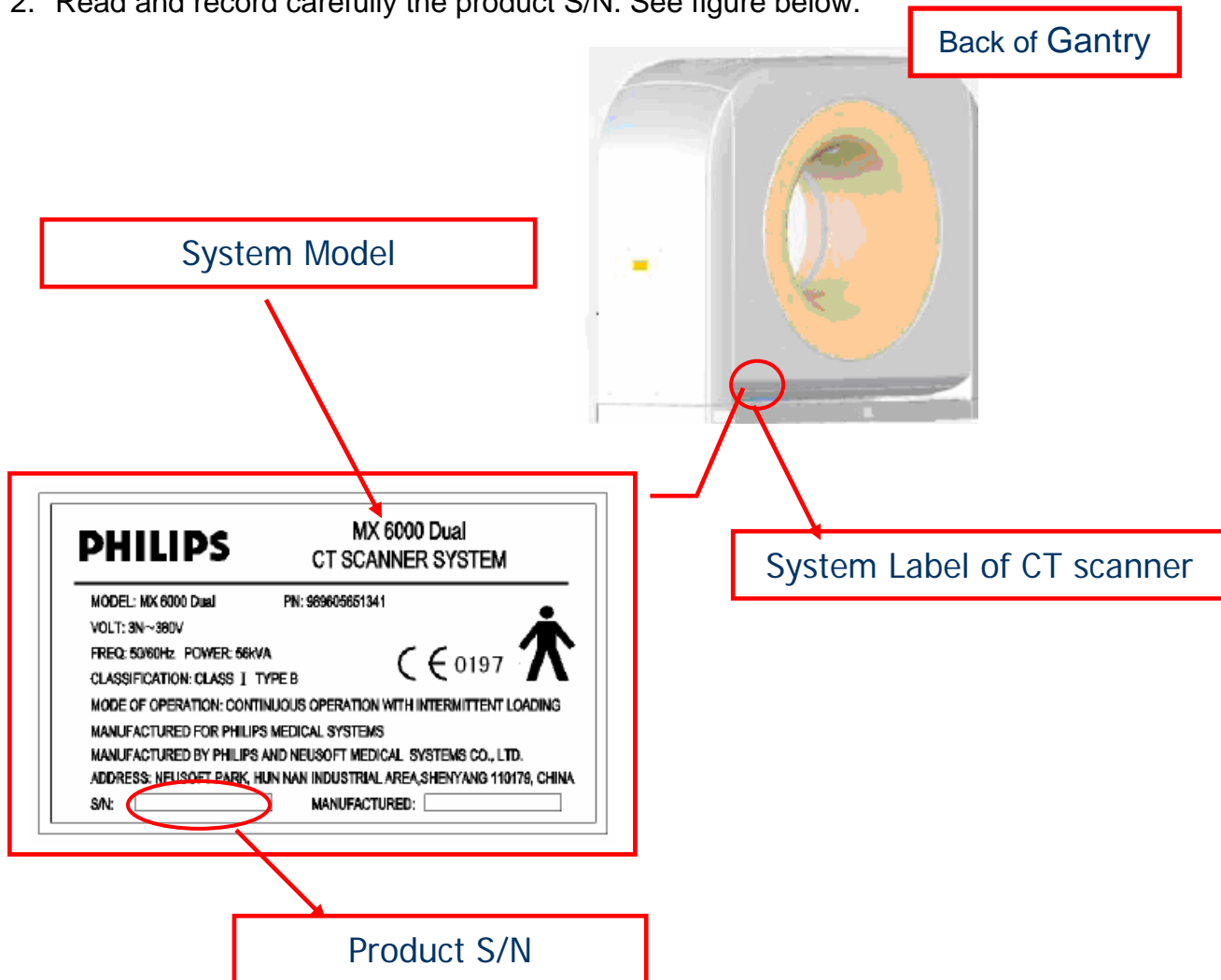
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Annex A: Method to Identify Affected Products:

1. Locate the system label at the left bottom corner of the backside cover.
2. Read and record carefully the product S/N. See figure below.



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