Field Safety Notice

Philips Healthcare

FSN S/N: 20080404
Date: April 04, 2008

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

Malfunction of "Timed Scan" may result in unnecessary X-ray

Dear customer,

A problem has been detected in the Philips **MX 4000** *(Product no. MCU 1731)*, **MX 4000 Dual** *(Product no. 989605651351)*, **MX 6000 Dual** *(Product no. 989605651341)* CT scanners, if it were to re-occur, could pose a risk for patients or doctors. 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.

Please retain a copy with the equipment Instruction for Use.

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,

[redacted]
Director Quality & Regulatory

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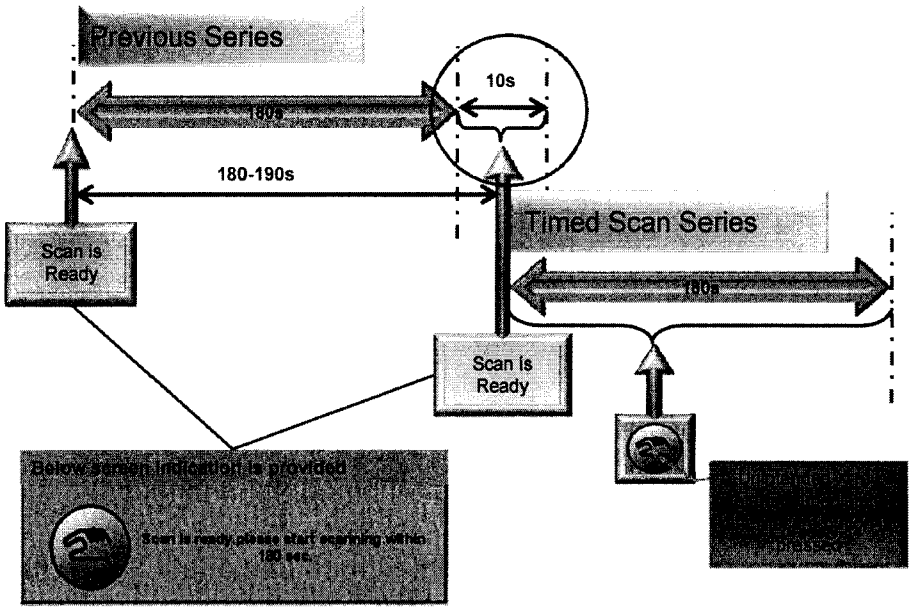
AFFECTED PRODUCTS	See **Affected System List** attached as Annex A The affected product model are identified by Product no. as follows: **MX 4000** *(Product no. MCU 1731)*, **MX 4000 Dual** *(Product no. 989605651351)*, **MX 6000 Dual** *(Product no. 989605651341)*
PROBLEM DESCRIPTION	An issue associated with "Timed Scan" application was found. After investigation it was concluded that the problem will affect MX series CT products (MX 4000, MX 4000 Dual, MX 6000 Dual scanners). The "Timed Scan" function is supposed to allow the operator to program a time delay for initiation of scanning. The system does not wait for the programmed time interval and starts X-ray after selection of the scan button when all below 3 criteria's are met. 1. A "Timed Scan" series occurs after one or multiple scan series; 2. Time span between two "Scan is ready" indications is within 180-190 seconds; 3. Scan button is pressed within 180seconds after the "Scan is ready" display of "Timed Scan".  The system provides audible and visual indications when a scan starts with X-ray, therefore the unintended X-ray can be detected and stopped by the doctor/operator to prevent excessive radiation.
HAZARD INVOLVED	1. The possible effect is that the patient *may* need to be re-scanned with contrast medium to get the required scan. 2. The user/operator *may* suffer unnecessary X-ray radiation.
HOW TO IDENTIFY AFFECTED PRODUCTS	Detailed information is attached as Annex B

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ACTION TO BE TAKEN BY CUSTOMER / USER	Users must follow the instruction below in order to avoid this issue: **Ensure a minimal 3 minutes (180 seconds) interval between the two time points below:** **1. The images reconstructed of preceding series is completed.** **2. Click "Go" on the screen to start a "Timed Scan"**
ACTIONS PLANNED BY Philips Medical Systems	Philips will correct all affected systems free of charge by means of a software upgrade. Implementation is planned to start in June 2008. You will be contacted by your Philips representative for the planning of the software update
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your Philips Medical Systems Service Support Department.

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Annex A: Affected System List

No.	Product	S/N	Country/Area

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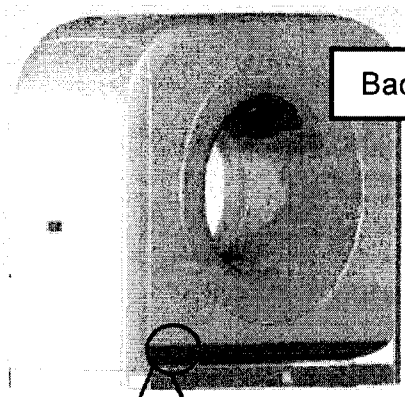
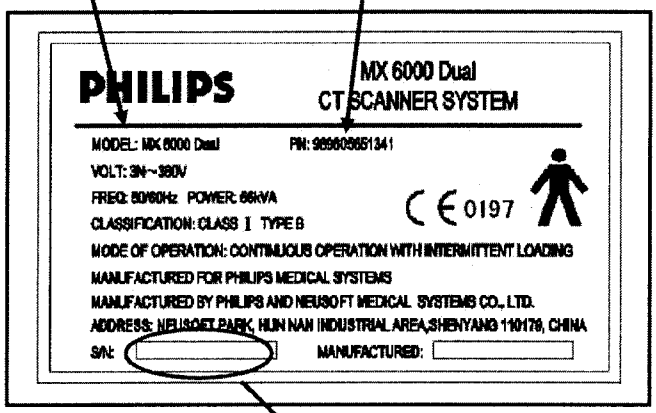
Annex B: Method to Identify Affected Products:

1. Locate the system label at the left bottom corner of the backside cover.
2. Read and record carefully the product S/N. Systems with an S/N that is listed in the ASL are affected.

Product Model	*Product No.*
MX 4000 CT Scanner System	MCU 1731
MX 4000 Dual CT Scanner System	989605651351
MX 6000 Dual CT Scanner System	989605651341



Back of Gantry



System Label of CT scanner

Product S/N