Field Safety Notice

PHILIPS MEDICAL SYSTEMS

FSN S/N: 72800346
Date: May. 18, 2008

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

R-host detached from the gantry

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,

[redacted]
Director Quality & Regulatory

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AFFECTED PRODUCTS	MX 4000 MX 4000 Dual MX 6000 Dual
PROBLEM DESCRIPTION	Incident was reported from a MX 4000 Dual system in Columbia, South America that the R-host box and components inside were detached of its mounting during the gantry rotor rotation. Several components were damaged inside the system gantry. No injury to patients or users occurred. Investigation concluded that the problem may affect MX series CT products (MX 4000, MX 4000 Dual, MX 6000 Dual scanners).
HAZARD INVOLVED	1. The device may be damaged and de-functionalized; 2. Though extremely unlikely, the internal components could be expelled from the system gantry and injure the patient, operator, bystander, or service people.
HOW TO IDENTIFY AFFECTED PRODUCTS	See appendix A 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 shall: For those systems to which an 0.8 sec rotation speed option was provided, users should disable this function until the field upgrade is implemented.
ACTIONS PLANNED BY Philips Medical Systems	Philips will provide to all affected systems free of charge additional bracket for the R-host. This field correction will be implemented in all affected MX 4000, MX 4000 Dual, MX 6000 Dual CT scanners worldwide. You will be contacted by your Philips representative for the planning of this repair.
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: **A**ffected **S**ystem **L**ist

No.	Product	S/N	Country/Area

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Annex B: Affected **S**ystems **L**ist within **EEA** and **Switzerland** (it is part in the above list)

No.	Product	S/N	Country/Area

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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. Systems with an S/N that is listed in the ASL are affected.