

## URGENT - Field Safety Notice Eclipse 1.5T MRI System

### MR Eclipse 1.5T RF Connector Block

Attn: Director of Radiology

Dear Customer,

A problem has been detected concerning the Philips Eclipse 1.5T MRI System which could potentially pose a risk for patients and users. This Field Safety Notice is intended to inform you about:

- The problem and the circumstances under which it can occur
- The actions that should be taken by the customer / user in order to prevent risks for patients and users
- The actions planned by Philips Healthcare 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.

Philips has received one report of an incident involving an Eclipse 1.5T MRI system. In this one reported incident during a routine scan sequence, the system in question displayed a "Coil Mode Set Failed" error message on the monitor. The site reported smoke and ignition of the RF connector block which was promptly extinguished. No injury occurred.

Philips does not believe this incident is likely to reoccur, as it has only occurred once in the 9 years that this product has been in use. However; Philips has identified a corrective action that can eliminate the potential for reoccurrence. Philips is in process of re-designing the connector block. The newly designed connector blocks will be available early 2010. Once these parts are available, a Philips Service Representative will be contacting you to schedule the replacement. Until this can occur, Philips suggests that technicians be observant of this connector block and notify a Philips Service Technician if anything unusual such as excess heat or smoke odor is identified in the area of the connector. You should also ensure that the patient comfort pad kit is installed and used for all patient studies. Follow normal good practice of maintaining frequent contact with each patient during scanning.

Philips apologizes for any inconveniences caused by this issue.

Sincerely,

[Redacted Signature]

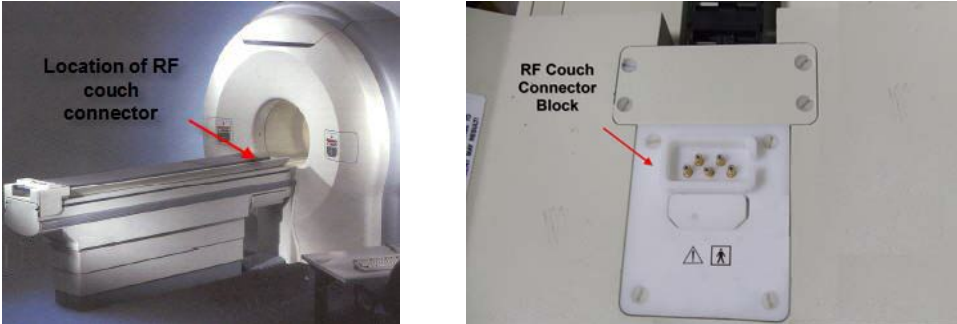
[Redacted Name]

Sr. Mgr., Quality and Regulatory  
MR Quality and Regulatory  
Philips Healthcare



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**Eclipse 1.5T MRI System**

**MR Eclipse 1.5T RF Connector Block**

<b>AFFECTED PRODUCTS</b>	Item number: <b>453566228381</b> Catalog item: <b>781230</b> Shipped between <b>June 23, 1997 thru June 30, 2002</b>
<b>PROBLEM DESCRIPTION</b>	The RF connector block on the tabletop has the potential to smoke and ignite during scanning due to a combination of arcing of electrical components below the connector and the flame rating of the connector block material.
<b>HAZARD INVOLVED</b>	Possible injury to patient.  The potential harm would be injury to patient if flames or smoke were present. The general practice of technologists frequently checking on patient status would provide some mitigation.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	Ensure to maintain frequent contact with patients during scanning and that the patient comfort kit is installed for all patient studies.
<b>ACTIONS PLANNED BY PHILIPS</b>	Beginning mid February, a Philips Field Service Technician will visit your facility to inspect your system and replace the existing part with the new RF Connector Block.
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact your local Philips representative or 1-800-722-9377:

