Field Safety Notice

June, 2008

Subject: User Notification, MRI Magnet Venting System Inspection
Philips MR systems, FCO 78100232

Dear Customer:

Philips Medical Systems has become aware of potential magnet venting installation issues where water may collect in the vent pipe elbow. During a cryogen transfer, the accumulated water can freeze, blocking the ventilation system. If a quench occurs before the ice melts, overpressure can develop within the magnet vessel, rupturing it and venting helium into the MRI suite.

To adequately ensure the safe operating environment for our users, Philips is scheduling inspections of magnets and installations that may have a similar configuration at no cost to you. If our inspection identifies that a part of the venting system manufactured or installed by Philips/Picker/Marconi (within the RF-shielded room) does not meet our specifications, Philips will correct it at no charge. If we find any other non-compliance of the venting system with Philips specifications, we will inform you so that you can promptly arrange to have it returned to specification at your cost. Failure to rectify such a non-compliance may create a hazardous situation for patients and users.

You were sent this notice because our records indicate that you have a magnet that may be affected by this program. Potentially affected systems are: Edge, Vista, Eclipse, Polaris, Infinion, and Panorama 0.6T MRI systems containing magnets originally manufactured by Oxford Magnet Technologies (now Siemens Magnet Technologies).

In addition to verifying that the MRI magnet helium venting system was installed in compliance with Philips/Picker/Marconi specifications and instructions, the inspection will also install drain plugs in the magnet vent line per instructions provided by the magnet manufacturer and verify whether the examination room contains an emergency venting system or the door to the examination room opens outward.

To ensure a safe environment for patients and users, this inspection and any necessary corrective actions shall be performed prior to your next cryogen refill.

Philips is beginning the inspections in June 2008 and we expect to complete this activity by the end of 2008. Should you need a cryogen refill prior to this scheduled inspection, please contact your local Field Engineer, who will conduct the inspection before the cryogen refill.

We apologize for any inconvenience this may represent and appreciate your forwarding this information to the appropriate individuals within your organization. You are a valued Philips customer and our primary concern is providing products that are safe and effective for patients and users. If you have any questions, please feel free to contact me at <Philips representative contact details to be completed by the KM / country>.

Sincerely,
<Signature>
<Name>
<Function>