



## Philips Medical Systems

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### URGENT – DEVICE CORRECTION

September 4th, 2007

**Subject: User Notification, MRI Venting System Inspection  
Philips MR systems**

Dear Director of Radiology:

Philips Medical Systems recently became aware of an event where extensive damage occurred to the MRI equipment and MRI suite. The damage occurred due to water getting into the magnet helium venting system and settling in the vent pipe elbow connected to the MRI system. The accumulated water froze when a cryogen transfer took place, forming ice which blocked the ventilation exhaust system. Initial evidence indicates that within hours after the cryogen transfer a quench occurred due to some of the ice melting and entering the magnet. The gaseous helium was unable to vent properly and the magnet vessel ruptured, venting helium into the MR suite.

In response to this event, Philips is initiating the following field corrective action, FCO 78100209, which should occur before your next cryogen fill. The field action includes:

- 1) Drilling a small hole in the vent pipe to ensure that any water that may get into the vent system will drain out. This kit has been tested and verified that the hole in the vent pipe will not create a hazardous situation.
- 2) Inspecting the MRI helium venting system to verify that it was installed in compliance with the Philips specifications and instructions and perform any preventative measure required. Venting outside of the RF shielded room that is not in compliance with Philips' specification will be brought to your attention and you must correct any errors with the helium venting as soon as possible. Failure to rectify the situation can create a possible hazardous situation. If this portion of the venting system is constructed properly, the risk of any water in the vent system is greatly reduced.
- 3) Inspecting the RF room to ensure that the room meets Philips specifications.

To ensure a safe environment for your patients and users, the correction of any non-compliance is vital. Our Customer Services organization will contact you to arrange for this inspection. The visit and any corrective action will begin immediately and we expect to complete this activity by the end of December 2007. Should you need a cryogen refill prior to Philips conducting this corrective action please contact your local Field Engineer, who will implement this field correction 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 our Customer Services Organisation on **0870 532 9741**.

Sincerely,

Philips Medical Systems.