SIEMENS Healthcare

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To all users of
SIEMENS MAGNETOM mobile systems

Your letter of
Our reference 07-09147-MR-0719
Date 2.07.2008

Customer Advisory Notice

Re: Modification of the Helium venting for MAGNETOM Impact, Impact Expert, Harmony, Symphony and Sonata mobile systems

Dear customer,

This letter is intended to inform you about a modification of your MAGNETOM mobile system to improve the Helium venting. This modification prevents the Helium vessel from becoming blocked by the formation of ice.

Why is this modification required?

The modification has been defined as a preventive measure after the occurrence of an incident with a mobile MR system:

During a quench of a Symphony mobile system the secondary safety system was initiated releasing Helium into the imaging suite.

Due to the fact that mobile systems are often subject to frequent changes in altitude they are also subject to changes in atmospheric pressure. Therefore the Helium venting system needs special attention during maintenance which was not the case at this particular system. The insufficient maintenance eventually led to ice formation within the primary venting system. As a result, the Helium gas could not be vented, causing the pressure in the Helium vessel to steadily increase and eventually leading to a quench event. Since the primary quench vent was blocked the Helium gas was released via a secondary vent into the examination room. The incident occurred late in the evening when the system was not in use; no persons were injured.

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How will the issue be resolved?

Siemens has developed a modification that prevents the recurrence of such an incident. The update will be implemented on all mobile units with Impact, Impact Expert, Harmony, Symphony and Sonata systems.
The technical modification comprises an auxiliary vent assembly which will be inserted through an existing service port into the magnet turret. In the event of ice blockage in the neck tube, the auxiliary vent will provide a clear path from the top of the helium vessel, via a burst disc to the exterior. This solution prevents ice from forming a total block in the primary venting system.

In addition we decided to supply all mobile units with the "high altitude venting kit" sealing the magnet during rapid atmospheric pressure changes. This kit has been installed on those mobile units travelling above 6000ft MSL, but will now be retrofitted to all mobile units, as a system originally intended for use in lower altitudes may be travelling into higher areas at a later time without this prerequisite being noticed anymore.

We appreciate your understanding and cooperation with the implementation of this advisory letter.

Sincerely yours

[redacted]

[redacted]

Chief Executive Officer
Business Unit Magnetic Resonance

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Vice President
MR Quality Management

SCF 2007-05

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