Magnetic Resonance FSN78100485 April 2018

URGENT - Field Safety Notice
Certain MRI systems with a metal burst disk

Potential risk for helium gas inside the MR Examination room during a magnet quench

Dear Customer,

A problem has been detected in certain Philips MRI systems with a metal burst disk, that if it were to re-occur, could pose a risk for patients or users. This FSN 78100485 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.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning this issue, please contact your local Philips representative:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Austin O'Connell

Head of Quality & Regulatory BG DI,
Magnetic Resonance Imaging

AFFECTED PRODUCTS	Certain MRI systems equipped with a 3” metal burst disk. Certain T5, T10-NT, ACSNT, Intera 0.5T/1.0T/ 1.5T, Achieva 1.5T, Multiva 1.5T, Ingenia CX 1.5T and Panorama 1.0T systems.
PROBLEM DESCRIPTION	In rare cases, helium gas may escape into the examination room when superconductivity is lost (also known as quenching of the magnet) and at the same time the designed helium ventilation path is impeded. Philips has become aware of one instance where this happened in a Philips system. Investigation found the metal burst disk assembly in the vent path did not perform according to specifications.
HAZARD INVOLVED	A failure of the helium vent path during a magnet quench may result in helium gas escaping into the MR examination room. If persons inside the MR examination room are not evacuated in a timely manner, there is a potential for death or serious injury (suffocation).
HOW TO IDENTIFY AFFECTED PRODUCTS	The customer cannot identify if a metal burst disk is part of the helium venting path. Therefore Philips has determined that inspection of these Philips magnets in the field is necessary to examine and replace this 3” metal burst disk assembly.
ACTION TO BE TAKEN BY CUSTOMER / USER	During a quench, a large amount of helium evaporates and is vented outside the building through a venting system. A quench causes immediate removal of the static magnetic field. A quench can occur spontaneously or can be induced if there is an emergency. In case helium gas escapes into the examination room during a magnet quench ensure strict adherence to the Instructions for Use: ***“Release of helium gas in the examination room*** *If helium gas is not vented properly after the Magnet Emergency Off button is used or during a quench (for example if the helium vent pipe is blocked) a high concentration of helium gas may build up in the examination room. This gas forms clouds of cold mist.* *Helium gas dilutes the oxygen in the air. High concentrations of helium gas can lead to suffocation.* *If helium enters the examination room:* *• Immediately remove all persons from the examination room.* *• Do not switch off air circulation and ventilation in the examination room.* *• Do not reenter the examination room until it is confirmed that the air oxygen content is at a safe level.*

	Emergency procedures *The User is required to establish emergency procedures for the following situations:* • *A medical emergency* • *A fire* • *An emergency that requires immediate removal of the magnetic field* • *The release of helium gas into the examination room* *Philips MRI systems have an Emergency Table Stop button in case there is an emergency during tabletop movement.*" (Instructions for Use R5.3)
ACTIONS PLANNED BY PHILIPS	Philips will schedule an inspection of all MRI systems that may be affected by this notice. If applicable the spare 3" metal burst disk on site will also be replaced during this inspection. Metal Burst disks on all affected systems will be replaced by a dedicated Philips team. Planning will be carefully done by the Philips organization as much as possible during off hours to reduce the disturbance to the customer. The inspection and corrective action are part of a free of charge Field Change Order with reference FCO78100485 for the inspection and FCO78100486 for the replacement and are planned for the second quarter of 2018. Should you need to communicate with Philips with regard to this program, please reference FCO78100485.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**