Magnetic Resonance FSN 781 00496 April 2019

URGENT - Field Safety Notice
Ingenia Ambition S, Ingenia Ambition X

Magnet Energization Device (MED) can have a residual voltage on output terminal

Dear Customer,

A problem has been detected in the Philips Ingenia Ambition S and Ingenia Ambition X MR systems, that, if it were to re-occur, could pose a risk for servicing personnel. This FSN781 00496 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,

Paul Sherlock
Head of Quality and Regulatory BIU,
Magnetic Resonance Imaging

AFFECTED PRODUCTS	Ingenia Ambition S (781359), Ingenia Ambition X (781356) MR systems
PROBLEM DESCRIPTION	The Ingenia Ambition S (System Code (SC) 781359) and Ingenia Ambition X (SC 781356) are equipped with a Magnet Energization Device (MED). The MED is used to energize the magnet. The MED is located in the Technical Room of the imaging suite. Within the Technical Room, the MED is housed in the Data Acquisition and Control Cabinet (DACC), which is a cabinet in the Technical Room and all power contacts are behind locked protective covers. The MED is only actively used during the energizing period of the MR system. At all other times, the MED is switched on standby and electronically disconnected from the magnet. When the MED is in standby, the output terminals can be charged to a high voltage. Philips was informed by the supplier of the MED that a relatively high residual voltage (up to 180 Volt) can be present on the output terminals of the MED. When servicing of the MED, MDD (Magnet Discharge Device) or connected cabling is required, the DACC is switched off and the protective covers removed. The residual charge on the output terminal that can stay for many hours, may cause electrical shocks to personnel servicing the MED, MDD or connected cabling.
HAZARD INVOLVED	Residual voltage (up to 180 Volt) on the output terminals of the MED can result in painful shocks to personnel servicing the MED, MDD (Magnet Discharge Device) or connected cabling.
HOW TO IDENTIFY AFFECTED PRODUCTS	Ingenia Ambition S (SC 781359) and Ingenia Ambition X (SC 781356) MR systems with Magnet Energization Device (MED), 12nc:459801472041.
ACTION TO BE TAKEN BY CUSTOMER / USER	There is no risk for users or patients. The MR system can be used normally, according the Instructions for Use. No action from the customer or user of the device is required, as the Magnet Energization Device (MED) is located in a cabinet in the Technical Room, with the output terminals of the MED located behind locked protective covers. Only qualified servicing personnel have access to this.
ACTIONS PLANNED BY PHILIPS	FCO78100496 will be rolled out to the affected systems. With this FCO the Magnet Energization Device (MED) will be replaced by a new version, which does not have this problem.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**