PHILIPS

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to the Philips Prodiva 1.5T CS/CX MR Systems due to FCO 78100491. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Serial number>

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

| Acknowledged By: |
| --- |
| Customer Name/Signature: |
| Company Name/Stamp: |
| Date: |

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Reg. No 199705989C

**MR Suzhou** FSN78100491 28-AUG-2018

# URGENT - Field Safety Notice
# Medical Device Correction
## Philips Prodiva MRI System

### Skin Burns Due to Contact with Hot Coil Cable

Dear Customer,

A problem has been detected in the Philips Prodiva MRI System; that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice 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.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Xin Li
Q&R Director, IS China

**MR Suzhou** FSN78100491 28-AUG-2018

# URGENT - Field Safety Notice
# Medical Device Correction
## Philips Prodiva MRI System

### Skin Burns Due to Contact with Hot Coil Cable

| | |
|---|---|
| **AFFECTED PRODUCTS** | *Prodiva 1.5T CX, Prodiva1.5T CS* |
| **PROBLEM DESCRIPTION** | The MRI system dissipates energy from various sources. This can lead to a temperature rise of components surrounding the patient such as cables and RF coils. Usually, the end temperature of these components does not exceed body temperature. The coil cables may become hot enough to cause skin burns if they are in contact with the patient and the cables are not positioned as directed in the system's instructions for use. Circumstances in which this heating can occur include:<br>• Coil cables are placed in loops or twisted inside the Quadrature Body Coil (RF area); or<br>• Coil cable is in direct contact with bore wall; or<br>• Coil cable is close to end ring. |
| **HAZARD INVOLVED** | Skin burns may result if a hot coil cables comes in contact with the patient's skin. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | The Prodiva 1.5T systems with Product Number 781070 and 781069 are affected:<br>Prodiva1.5T CX (Product Number 781070)<br>Prodiva1.5T CS (Product Number 781069) |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | In preparing for examinations, follow the Instructions for Use for properly aligning cables and isolating the patient's skin from the coil cable using the spacers or cushions supplied with the system if necessary.<br><br>Related warnings as can be found in the "section 2" of Instructions for Use: Safety -> Safety during scanning -> Coil and cable positioning. |
| **ACTIONS PLANNED BY PHILIPS** | Philips will schedule a correction for all Prodiva MRI systems to add a Balun on each coil cable, which can reduce cable heating to avoid skin burns even when the coil cable is improperly positioned close to the patient's skin without sufficient isolation.<br><br>The correction is part of a free of charge Field Change Order with reference FCO78100491 which is planned in the Q4 of 2018.<br><br>Should you need to communicate with Philips with regard to this program, please reference FCO78100491. |
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative. |