

MR Suzhou

FSN MA-FCO78100504

01-Nov-2019

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

Poor Protective Earth of the Patient Support Table

<Hospital/Clinic Name>

cc: Chairman Medical Board and relevant Head of Departments

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.

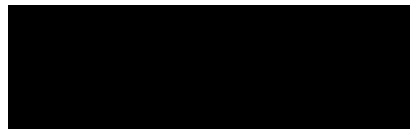
If you need any further information or support concerning this issue, please contact your local Philips representative.

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




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AFFECTED PRODUCTS	Prodiva 1.5T CX, Prodiva1.5T CS
IDENTIFICATION OF MANUFACTURER	Manufacturer Name: Philips Healthcare Suzhou Co.,Ltd Manufacturing Site Registration Number (FDA): 3009529630 Manufacturing Single Registration Number (SRN in EUDAMED): N/A
PROBLEM DESCRIPTION	Philips received a report from the field that grounding bolts on the bottom plate of the Prodiva 1.5T table were missing during installation. These grounding bolts are used for connecting the earth wire to the bottom cover for protective earth. No injuries were reported.
HAZARD INVOLVED	Electric shock (> 24v to mains voltage) to patient, operator and service engineer may occur only when all of the following conditions take place: <ul style="list-style-type: none"> • The grounding bolts on bottom plate of patient table are lost or missing ; • The resistance from any part of bottom cover to bottom plate exceeds 40 mΩ; • Basic insulation of hazardous voltages inside the patient table is broken; • Hazardous voltages exist on bottom cover of the patient table and someone touches the bottom cover of the patient at the same time.
HOW TO IDENTIFY AFFECTED PRODUCTS	Prodiva 1.5T systems (model REF 781070 & 781069) with below UDIs are affected: (01)00884838064799(21)82084; (01)00884838064805(21)83088 (01)00884838064799(21)82101; (01)00884838064805(21)83120 (01)00884838064799(21)82145; (01)00884838064799(21)82096 (01)00884838064805(21)83119; (01)00884838064799(21)82163 (01)00884838064805(21)83142; (01)00884838064799(21)82117 (01)00884838064805(21)83153; (01)00884838064799(21)82151 (01)00884838064805(21)83121; (01)00884838064805(21)83150 (01)00884838064799(21)82171; (01)00884838064799(21)82115 (01)00884838064799(21)82164 Example for system label : <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>Magnetic Resonance Equipment</p> <p>Model: Prodiva 1.5T CS</p> <p>REF 781069</p> <p>SN NNNNN</p> <p>Date: YYYY-MM-DD</p> <div style="display: flex; justify-content: space-around; align-items: center;">  <div style="text-align: left;"> <p>(01) 00884838064799</p> <p>(21) NNNNN</p> </div> </div> <p>12NC: 4598 014 33361</p> </div>

Copies are uncontrolled unless otherwise identified
Before using this document, consult Agile for the latest revision and effective date.

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ACTION TO BE TAKEN BY CUSTOMER / USER	In general the system can continue to be used according to the Instruction for Use. Contact your local Philips representative if you have any concern or if support is required on this issue.
ACTIONS PLANNED BY PHILIPS	<p>Philips will schedule a correction for these affected Prodiva 1.5T CS&CS MRI systems to install the missing grounding bolt and complete the protective earth to eliminate the potential risk to health.</p> <p>The correction is part of a free of charge Field Change Order with reference FCO78100504 which is planned in the Q4 of 2019.</p> <p>Should you need to communicate with Philips with regard to this program, please reference FCO78100504.</p>
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).