

DXR Suzhou

FSN MA-FCO71200173

2017-May-23

URGENT - Field Safety Notice

Medical Device Correction

STOP USE

Philips DuraDiagnost X-ray system

Tube stand vertical carriage brackets welding issue

Dear Customer,

A problem has been detected in the Philips *DuraDiagnost X-ray systems* that, if it were to re-occur, could pose a risk for patients or users. This *FSN MA-FCO71200173* 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,

Alina Zhou
Q&R Director, IS China

DXR Suzhou

FSN MA-FCO71200173

2017-May-23

URGENT - Field Safety Notice

Medical Device Correction

STOP USE

Philips DuraDiagnost X-ray system

Tube stand vertical carriage brackets welding issue

AFFECTED PRODUCTS	DuraDiagnost X-ray systems
PROBLEM DESCRIPTION	As a result of a report from the field, Philips discovered that some welding joints on the vertical carriage brackets of the tube stand may crack. As a result, the tube arm assembly may exhibit uncharacteristic sideways movement, with the tube becoming off center. If all of the welding joints cracked, the tube arm assembly could fall down.
HAZARD INVOLVED	If all welding joints cracked, a patient on the examination table or anyone in the vicinity could be struck by the falling tube arm assembly resulting in serious injury or death.
HOW TO IDENTIFY AFFECTED PRODUCTS	The DuraDiagnost systems with Product Number 712210 and 712211 are affected: DuraDiagnost (R1.0, Product Number 712210) DuraDiagnost (R2.0, Product Number 712211) DuraDiagnost (R3.0, Product Number 712211)
ACTION TO BE TAKEN BY CUSTOMER / USER	Philips is advising that facilities stop using the device until a Philips Engineer go on-site to perform the FCO71200173; contact your local Philips representative if you have any concern or support required on this issue.
ACTIONS PLANNED BY PHILIPS	Philips will inspect the welding joints of tube stand vertical carriage brackets and install the safety hooks structure through FCO71200173 free of charge, which will prevent tube arm assembly from falling down even if all the bracket welding joints were cracked. A Philips Service Engineer will contact you to schedule this field action.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. Please reference FCO71200173 when contacting your local Philips representative.