FSN *MA FCO-72000015* *April 2020*

URGENT - Field Safety Notice
TraumaDiagnost

Check of integrity for Trauma Arm

Dear Customer,

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: **0800 80 3000**

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Michael Mizrachi
Head of Q&R DXR Hamburg

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AFFECTED PRODUCTS	All TraumaDiagnost
PROBLEM DESCRIPTION	A trauma arm is a U-shaped carrier of tube assembly and cassette holder, which are therefore always centered for easy positioning with trauma patients. It allows the operator to make all relevant diagnostic projections without moving the patient. The Trauma arm is connected to the telescopic column of the ceiling suspension by a shaft, which is fixed to a supporting block. If the shaft breaks, the trauma arm can fall down.
HAZARD INVOLVED	There is the potential for a serious injury if one of the following occurs: • Fatigue fracture (crack) of the shaft • Crack increases during lifetime without being noticed by the operator or service engineer (unusual angle of Trauma arm) • Shaft breaks • Person located nearby falling trauma arm

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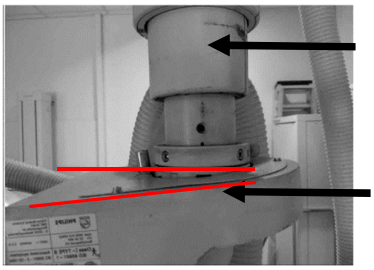
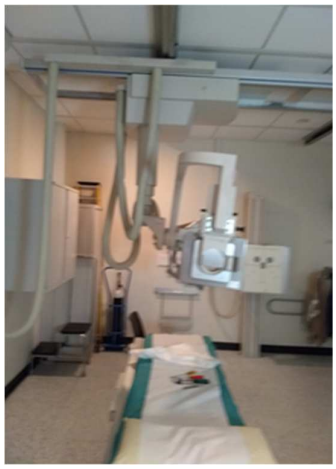
HOW TO IDENTIFY AFFECTED PRODUCTS	An operator noticed an unusual angle of the trauma arm with respect to the telescopic column of the ceiling suspension.  
ACTION TO BE TAKEN BY CUSTOMER / USER	The IfU (Instruction for Use) require the operator to not use the system and call for service, if a mechanical defect or malfunction is suspected. As soon as a deformation is determined, the system may no longer be used and call the service engineer. Should you feel uncertain regarding these instructions, please contact Philips.
ACTIONS PLANNED BY PHILIPS	The affected systems will be get an onsite check of the status of the Trauma arm for deformations as shown on the pictures.
FURTHER INFORMATION AND SUPPORT	If you would like any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**