URGENT - Field Safety Notice
TraumaDiagnost

C-arm fell could fall down

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips TraumaDiagnost, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

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 or the UK Philips Customer Care Service Centre on 0870 532 9741.

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

Karmen Gruenert
Director Q&R DXR Hamburg

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AFFECTED PRODUCTS	TraumaDiagnost
PROBLEM DESCRIPTION	The Trauma supporting block (connecting the Trauma arm with the Ceiling suspension telescope) is fixed with 3 screws, which are also used to adjust the correct alignment of it. In case this is not done in the correct way, the Trauma arm is not fastened securely anymore and could fall down.
HAZARD INVOLVED	There is a potential that the C-arm could fall down onto the table and hit the patient or bystander. Following factors are needed that this situation could occur: - Unusual wear and tear, e.g. multiple collisions - More than one broken fixation screw (out of 3) without being noticed by the user - Operator touches/moves/operates Trauma arm - Person below Trauma arm
HOW TO IDENTIFY AFFECTED PRODUCTS	All TraumaDiagnost systems delievered until 8th of Juli 2007 are affected. Customers will be informed by Philips.
ACTION TO BE TAKEN BY CUSTOMER / USER	The Instruction for Use (IfU) require the operator not to use the system and call for service, if a mechanical defect or malfunction is suspected. In this special case, it is recommended not to position the Ceiling supension with the Trauma arm directly above a patient as long as this Field Change Order is not yet installed. Should you feel uncertain regarding these instructions, please contact Philips.
ACTIONS PLANNED BY PHILIPS	Philips plans to repair the affected systems. A Philips Service Engineer will contact you as soon as the Field Action Kit is ready to be implemented. Should you need to communicate with Philips with regard to this program, please reference Field Change Order 72000014.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.