Field Safety Notice

PHILIPS

Philips Healthcare

BU General X-Ray -1/2- XDB087-080476/BW
FSN 71800026 2008-08-06

URGENT - Field Safety Notice
BV Pulsera and Endura

Unreliable C-arm brake function

Dear Customer,

At Philips Healthcare, safety has the highest priority. Medical equipment is sophisticated, complex technology. Even with all the safety measures and tests performed during the design phase, the risk for occasional and exceptional unwanted situations can not be eliminated completely.
In spite of all measures taken during System development, we were informed by some of our Customers about an unreliable extended C-arm rotation brake function of the Pulsera and Endura release 2 Systems. Due to the extended C-arm rotation option the brake does not always functions properly.

We are working on a solution for the installed base. In the mean while we want to inform you via this Field Safety Notice 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:
<Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]
QR&S Manager BU GXR

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AFFECTED PRODUCTS	BV Pulsera and Endura release 2.
PROBLEM DESCRIPTION	Unreliable extended C-arm rotation brake function of the Pulsera and Endura release 2 Systems. Due to the extended C-arm rotation option the rotation brake does not always functions properly. The brakes are functioning well, if the C-arm is rotated to its maximum positions.
HAZARD INVOLVED	Unintentional caused manual C-arm movements may be a risk for the patient, especially during neuro cases in the brains or vascular (roadmap) procedures.
HOW TO IDENTIFY AFFECTED PRODUCTS	The affected Systems will be clearly identified by the local Philips Organization. (If you receive this letter, your System is involved)
ACTION TO BE TAKEN BY CUSTOMER / USER	If critical procedures need to be done the user must take care that the C-arm is placed in its maximum extended position were the brakes are working properly. Furthermore care must be taken that the C-arm is not touched during critical procedures especially when the C-arm is not in one of its maximum positions. With this workaround the Systems can be used safely until the FCO is implemented.
ACTIONS PLANNED BY PHILIPS	A mandatory Field Safety Corrective Action will be issued. This will be identified as FCO71800026 and will be free of charge. The corrective action will be a mechanical improvement of the C-arm brake. The planned issue date of this FCO will be the last week of August 2008. You will be contacted by Philips for implementation of this corrective action
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>