

**URGENT - Field Safety Notice
BV Pulsera and Endura**

Reliability Stand-Trolley cable

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 failing Pulsera and Endura release 2.2 Systems.

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,


QR&S Manager BU GXR



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AFFECTED PRODUCTS	BV Pulsera and Endura release 2.2.
PROBLEM DESCRIPTION	Due to reliability problems with the stand-trolley cable the communication between stand and trolley may be not be optimal. This, intermittently, may result in a not properly functioning System.
HAZARD INVOLVED	If during a critical procedure on a critical moment the doctor does not have a live fluoro image, this might impose a risk for the patient. Some critical invasive procedures may lead to serious patient injuries.
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	As unreliable stand-trolley communication can lead to intermittent problems, there is no workaround possible to minimize the occurrence. Patient risks can be minimized by not performing critical procedures until the implementation of this mandatory FCO is finished.
ACTIONS PLANNED BY PHILIPS	A mandatory Field Safety Corrective Action will be issued. This will be identified as FCO71800024 and will be free of charge. The corrective action will be the exchange of the stand-trolley cable with a more reliable one. 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>

