URGENT – FIELD SAFETY NOTICE

Fixing Strap of the Laser Aiming Device Image Intensifier

Fixing strap may inadvertently detach

Dear Customer,

A problem has been detected with an option, which is supplied for Philips Mobile X-Ray systems with Image Intensifier that, if it were to re-occur, could pose a risk for patients. 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.

The fixing strap of the Laser aiming device II 9" / 12" may inadvertently be detached and land on a patient. This can happen, because the mounting strap for the II-Laser can be accidentally released during a procedure in such a way that a device that is suspended above the patient falls down.

Please see the attached Field Safety Notice which provides information on how to identify affected devices and instructions on actions to be taken. Please pay special attention to the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

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,

J. Derikx
QR&S Manager iXR

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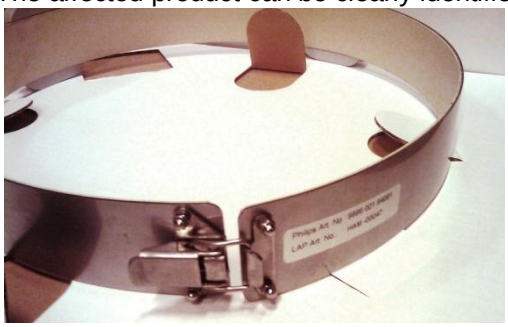
AFFECTED PRODUCTS	The fixing strap of the Laser aiming device II 9" / 12" (sales number: NMCA240, NMCA241, NMCA242, NMCA243). The device is an option delivered for Philips mobile X-ray units: 718022 BV Libra, Mobile X-ray unit 718040 FIELD EXTENSIONS for BV LIBRA 718074 BV Endura, rel. 2 718095 BV Pulsera, rel. 2.3 718120 FIELD EXTENSIONS for BV ENDURA and 718121 FIELD EXTENSIONS for BV PULSERA.
PROBLEM DESCRIPTION	The fixing strap of these laser aiming devices may inadvertently be detached and land on a patient.
HAZARD INVOLVED	The mounting strap for the II-Laser can be accidentally released during a procedure such that a device that is suspended above the patient falls down.
HOW TO IDENTIFY AFFECTED PRODUCTS	The affected product can be clearly identified by the local Philips Organization  For identification of the affected product please see the product label as shown. Only products identified by the numbers as mentioned below are affected: • 989600194081 • 989600194091
ACTION TO BE TAKEN BY CUSTOMER / USER	 Philips urgently asks users of the affected device to fix the closed latch body of the draw latch to the metal band using a tie wrap. This will eliminate any immediate risk to the patient. Without such temporary measure, the device should not be used.
ACTIONS PLANNED BY PHILIPS	A definitive solution will be delivered by introducing a new straight loop fixing strap design via a mandatory Field Correction Order. The expected issue date of FCO71800035 will be Q1 2011. You will be contacted by Philips for implementation of the corrective action

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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>