Philips Medical Systems

GXR



FSN MA-FCO 70600029

2007 Dec 17

URGENT - Field Safety Notice Easy Diagnost Eleva family Easy Diagnost Classic family Diagnost 76 plus family

-1/2-

Check of counterweight-steelband & safety switch

Applicable to:

Diagnost 76 (plus) Easy Diagnost classic/digital Easy Diagnost Eleva 706 38-41 706 030/31 706 032

Dear Customer,

A problem has been detected in the Philips products listed above, that, if it were to re-occur, could pose a risk for patients or users. 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.

1 PROBLEM DESCRIPTION

In addition to the supporting main steel band for the longitudinal movement of the Serial Changer a safety steel band is installed which is connected to the main counterweight. It runs in the same castors as the supporting steel band but it is not stressed. The supporting main steel band is installed pre-stressed ex factory.

In case the supporting main steel band is no longer stressed or even rips in, for instance, the 90° tilting position, the falling down of serial changer and main counterweight is prevented by the safety steel band. A respective mechanism in the safety switches detects that stress is applied to the safety steel band and that the supporting main steel band is damaged or even torn.

Further operation of the tilting drive is possible only towards 0°, a respective error number is logged and an error message appears on the user interface.

2 ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

In case further operation of the tilting drive is only possible towards 0° and an error message appears on the user interface, you have to stop operation of the system immediately and Philips has to be informed. Otherwise the system can be used as usual.



3 ACTIONS PLANNED BY PHILIPS

Philips has analyzed for all systems installed where the respective safety switch has been exchanged or adjusted. This indicates a possible stress of the safety steel band. In a Mandatory Action Philips will inspect all systems indicated by these investigations. As part of the Mandatory Action both steel bands will be inspected in detail as well as the proper function of the safety switch. In case of any kind of abnormity the steel bands will be replaced.

4 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>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature>

<Name> <Function>