

### **Philips Medical Systems**

**GXR** -1/2- CIL APP-FCO 73200026 2007 Dec 17

# Customer Information EasyVision RAD

## Inaccurate Measurements using EasyVision Release 4.2 V2

**Applicable to:** 9896 050 03232 ... 8

In systems: 732 020 / 023/ 025/ 026/ 028/ 031/ 040/ 042/ 044/ 048/ 050/ 052/ 075/ 076/ 077/ 078

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 Customer Information letter 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

PCR images on an EasyVision RAD can be displayed with different manually selected zoom factors. If any zoomed image is exported to a PACS then an electronic measurement on the PACS can give a wrong result because during the export process this image is sent with the new pixel matrix but the pixel size information in the image has not been changed.

#### 2 ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

Philips will contact you soon in order to install a software patch which disables the export of zoomed images. After the installation of this patch the images will be exported always with the original full matrix and then an electronic measurement on the PACS gives precise values. On the EasyVision RAD itself all the zoom functionality will still be possible. Otherwise the system can be used as usual.

In the meantime, it must be ensured by your organization that measurements on PACS / viewing stations are only made once the image has been calibrated on the PACS.



#### 3 ACTIONS PLANNED BY PHILIPS

Philips has implemented a service pack (FCO73200026) which brings the system to latest production level and solves the zooming / exporting problem.

#### 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>