



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 14017

To: Director of Radiology/Cardiologists
Risk Manager/Hospital Administrator
Director of Biomedical Engineering

RE: DPX-NT, DPX Bravo, DPX Duo, DPX-MD, Prodigy, Prodigy Advance Systems running enCORE software from version 9.0 to version 10.0 - Reports may be sent to the PACS under the wrong patient per the DICOM/PACS header.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

Under certain conditions, when using DICOM Worklist along with DICOM MPPS, a report for a bone density exam may be sent to PACS with the incorrect patient information in the DICOM header. The correct patient information will be listed on the DICOM report image; however, the report may appear under a different patient’s name in the PACS. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue using your system by disabling the DICOM MPPS feature as follows:

1. In enCORE, select Tools | Connectivity Options.
2. Select DICOM tab.
3. Press Configure Connections in DICOM Worklist section.
4. In the MPPS SCP Settings, clear the AE Title and the TCP/IP Address fields
5. Press OK to all.

A GE Healthcare representative will contact you to arrange for the correction.

Affected Product Details

All DPX-NT, DPX Bravo, DPX Duo, DPX-MD, Prodigy, Prodigy Advance Systems running enCORE software from version 9.0 to version 10.0.

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact your local Service Representative at:

Toll Free number (Inside Saudi Arabia Only): DI 8001243002 LCS: 8004292222

or by email SaudiArabiaServiceCenter@ge.com .

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare