

Patient Safety Advisory

March 2, 2009

To: Diagnostic Imaging organizations performing digital Radiology and Mammography

Re: Digital acquisition devices and PACS

This communication is provided to bring a patient safety issue to your attention and, as a preventative measure, to recommend your organization take measures to ensure that patient safety is not negatively impacted.

Patient Safety Issue: A facility performing digital mammography has recently identified an issue with incorrect spatial measurement values being reported on PACS. This issue was confirmed in response to a customer-released PACS Advisory Notice from one PACS provider alerting customers to the possibility of incorrect measurements being reported on PACS with certain acquisition devices.

This PACS Advisory Notice identified the different approaches in interpretation of the DICOM standard that may possibly be encoded by the acquisition devices and the fact that the PACS system **may not** have the software and configuration to support a change in interpretation of Estimated Radiographic Factor (ERMF) by some projection radiography acquisition devices. The testing of certain acquisition devices at the above-mentioned facility revealed that the digital mammography acquisition device encoded a different interpretation approach to magnified images and the PACS did not support the interpretation. The result was incorrect measurements being reported on magnified mammography images using PACS.

The possibility of mismatch in measurements resulted from a change in the interpretation of the DICOM standard (CP-586: Pixel spacing and calibration in projection radiography – finalized in January 2006) and the fact that some acquisition device manufacturers have begun introducing new models and software versions to conform to a clarification of the DICOM standard in interpretation of Estimated Radiographic Magnification Factor (ERMF) that affects how pixel scale information should be encoded in certain kinds of images, and, thus, how downstream systems, such as PACS should report scale and associated spatial measurements made on these images.

Note: Any acquisition vendor may change their software to conform to the expectations of CP-586 with respect to ERMF in any updated version. This will include any mammography acquisition device claiming IHE mammography profile conformance. The PACS software and configuration **must** support pre-and post-implementation of CP-586.

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The above-mentioned Advisory Notice identified images from the following types of acquisition devices that **may** be affected:

- Digital X-Ray (DX IOD)
- Mammography (DX IOD)
- X-Ray Angiography (XA IOD)
- Radio-Fluoroscopy devices (RF IOD)

Note: Computed Radiography (CR) images are not affected

Clinical Implications: A mismatch in the scaling interpretation approach between the source device which created the magnified image and the PACS system may potentially result in incorrect diagnosis due to an inaccurate spatial measurement value being reported. This includes both linear and area measurements made using PACS display workstation tools as well as “eye-ball” measurements made with visual comparison with a displayed scale overlay.

Recommended Actions: *To ensure patient safety at your organization, it is recommended that you investigate and rule-out potential occurrence of a mismatch in spatial measurements.*

You are encouraged to discuss this Patient Safety Advisory with your PACS provider to determine if your system may be at risk and if so take the necessary actions to address any mismatch in spatial measurements.

You are asked to notify the DAP of any systems where mismatch of measurements is identified.

If you require any further information please do not hesitate to direct your inquiries to Brenda Watson, Accreditation & Research Development Officer, Diagnostic Accreditation Program.

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