HealthManagement
Promoting Management and Leadership

FDA Warns About Full-Field Digital Mammography Units

This is in violation of regulation 21 CFR 900.12(c)(5), and means that the view and laterality may not always appear near the axillary portion of the breast in either the soft or hard copy images as required by regulation 21 CFR 900.12(c)(5)(iii).

This may result in pathology being overlooked or incorrectly localized. This situation is especially important if the images are sent to another facility that is unfamiliar with the configuration of equipment being used at the facility performing the mammogram. Therefore, FDA recommends that all facilities check to ensure that all image-identifying information is correctly displayed on all their soft and hard copy mammography images.

Published on : Fri, 1 Aug 2008

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