

# MEDICAL IMAGING

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## FDA Approved!

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*Thanks to FDA clearances, many industry firsts are hitting the market. The following is a sneak peak at what's changing medical imaging.*

BarcoView LLC (Duluth, Ga) has obtained FDA 510(k) approval for its Coronis 5MP Mammo display system. The system builds on Coronis technology, and introduces several innovations, including per-pixel uniformity (PPU) and defect-pixel compensation (DPC), to further optimize accuracy and provide diagnostic confidence. The PPU technology measures and adjusts the luminance output of every individual pixel, thereby eliminating distracting screen noise. To ensure that no information is missing, the DPC feature detects and identifies defect pixels in each individual display. The Coronis 5MP Mammo also features the I-Guard sensor technology, which continually guards and adjusts the luminance output of the actual diagnostic viewing area at the front of the display, ensuring continuous DICOM accuracy over time and across displays.



The Coronis 5MP Mammo display has the 5 megapixels necessary for effective mammography evaluation-and the FDA gave BarcoView the clearance to forge ahead.

DR Systems Inc (San Diego) has received FDA clearance to add digital mammography to its PACS, the Dominator Diagnostic Workstation. As part of the DR Systems image diagnostic capability, mammography reading can now be integrated into the same RIS/PACS workflow efficiencies for patient image and information management, automated reporting, storage, archiving, and Web-based distribution. Based on the company's version 6 software, the Dominator enables physicians to perform primary readings of digital mammography images, connect to any FDA-cleared DICOM digital mammography device or mammography digitizer, and perform image interpretation on commercially available FDA-cleared monitors. The system also enables physicians to distribute images and reports via CD as well as over the Internet for remote viewing with other physicians.



By adding recently FDA-cleared digital mammography to its Dominator PACS solution, DR Systems plans to "dominate" the PACS market.

The FDA has given GE Healthcare (Waukesha, Wis) the nod to market its advanced MR technology, which improves the capability to perform targeted imaging studies throughout the body. The new technology-integrated in the Signa 1.5 Tesla (1.5T) and Signa 3T systems-further expands the Excite system product line, which provides clinicians with better diagnostic information in shorter and less invasive exams. The system's platform increases speed and power by enabling simultaneous imaging in multiple channels in increments of 16. As channels are added, image processing power increases in proportion. The coil elements that detect the signal, the receivers that digitize it, and the array processors that perform calculations are scaled together so that simultaneous imaging can be performed without imaging processing delays. This feature enables clinicians to gather vast amounts of data in a short time and perform MR studies that otherwise would be impractical.

The FDA has approved a premarket approval application from Siemens Medical Solutions USA Inc (Malvern, Pa) for the company's Mammomat NovationDR, a full-field digital mammography system. The system, which provides digital screening, diagnosis, and stereotactic biopsy capabilities in one system, features a flat-panel detector based on amorphous Selenium detector technology. This technology enables a direct conversion of X-ray to digital information and provides higher spatial resolution as well as greater clinical detail. At 25 x 29 cm, the size of the Mammomat NovationDR's image detector also enables imaging of a larger range of patient sizes. Also, the system features a new paddle designed



for easier and more comfortable patient positioning.

The full-field digital mammography system from Siemens, Mammomat Novation<sup>DR</sup>, has received premarket approval from the FDA.

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