

Hologic Receives FDA Approval for First 3-D Digital Mammography System



Hologic, a developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, has announced that the Company has received approval from the U.S. Food and Drug Administration (FDA) for its Selenia Dimensions digital breast tomosynthesis system (Dimensions 3-D).

Mammography systems using conventional 2-D imaging have limitations caused by tissue overlapping tissue in the breast that may hide lesions or cause benign areas to appear suspicious. Clinical trials using Hologic's Dimensions 3-D system showed measurable improvement in clinical performance over conventional mammography. These trials also showed significant gains in specificity - the confidence to rule out cancer without recalling the patient for further study and other benefits including improved lesion and margin visibility and the ability to accurately localize structures in the breast. The combination of measurable improvements in accuracy and detection, and improved sensitivity, makes the Dimensions 3-D system a superior system vs. conventional digital mammography systems.

"We are extremely proud to be the first company to receive FDA approval of a 3-D digital mammography system and to offer women this ground-breaking, superior imaging technology," said Rob Cascella, President and Chief Executive Officer. "Our Dimensions 3-D takes advantage of all of the benefits of digital mammography and quite simply makes it better with the combination of fast, high quality 3-D breast imaging. We believe tomosynthesis has the potential to change how screening and diagnostic mammography is performed, and over time will prove invaluable to the earliest possible detection of breast cancer and in the reduction of unnecessary diagnostic interventions."

According to Jay Stein, PhD, Hologic co-founder and Chief Technology Officer, "Tomosynthesis scans can be performed quickly with Dimensions. This means enhanced performance not just for diagnostic problem solving, but in everyday routine screening. Over the next several years we view Dimensions as a platform technology for other imaging modalities to aid in the fight against breast cancer."

Hologic's Dimensions 3-D system is available commercially in more than 40 countries including countries in Europe, Latin America and Asia. In North America, commercial systems are already installed in Canada and Mexico.

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