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Digital mammography system developed at Mass General Hospital receives FDA approval

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A digital mammography system developed based on concepts originally tested at Massachusetts General Hospital (MGH) has been approved by the U.S. Food and Drug Administration. GE Healthcare received approval to market the SenoClaire Digital Breast Tomosynthesis system, which is based on patented technology licensed from the MGH and developed under the leadership of Daniel B. Kopans, MD, founder and senior radiologist in the Breast Imaging Division of the MGH Department of Radiology.

Soon after wide-spread screening mammography was introduced in the mid-1980s, Kopans notes, U.S. death rates from breast cancer – which had remained unchanged for more than 40 years – began to decline. But the limitations of conventional mammography reduce its ability to find all tumors while avoiding false positive readings. "A conventional mammogram presents the radiologist with an image that is like a book with transparent pages," he explains. "You can hold that book up to the light and look through it, but the words are superimposed on each other, providing an image that can be confusing. Sometimes cancers can be hidden by normal tissues, and at other times normal tissues superimposed on top of each other give the false appearance of a tumor, requiring patients to be recalled for further screening."

Kopans originally proposed applying a theoretical technique called tomosynthesis – construction of a 3D image from digital readings taken

at many different tissue depths – to the problem of superimposition in 1978, but the digital image detectors and powerful computers required to construct such images were not available until the 1990s. The device developed by Kopans and his team – including Richard Moore, director of Breast Imaging Research – allows radiologists to page through the mammographic "book" one page at a time. Clinical trials have shown this elimination of tissue superimposition can reveal tumors hidden on conventional mammograms and reduces false positive readings.

"This is an exciting time in breast imaging," says Kopans, who is a professor of Radiology at Harvard Medical School. "Conventional mammography, even with its limitations, has helped to dramatically reduce deaths from breast cancer. The availability of digital breast tomosynthesis should help to drive breast cancer deaths down even further, and this FDA approval should make the technology available to more and more woman. We all hope for ways to totally prevent or cure breast cancer, but until such methods are available, we will continue working to find more ways to detect breast cancer earlier to save the lives of patients with breast cancer."

Provided by Massachusetts General Hospital

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