

Hologic - Investor Relations

Hologic Introduces a More Comfortable Mammogram with the Launch of the SmartCurve™ Breast Stabilization System

93% of Women Surveyed Reported Improved Comfort with the New System*

MARLBOROUGH, Mass., Sept. 26, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) today announced the commercial availability of its new SmartCurve™ breast stabilization system, which has been clinically proven to deliver a more comfortable mammogram without compromising image quality, workflow or dose.¹ The SmartCurve system is available exclusively with Hologic's Genius™ 3D Mammography™ exam, the only mammogram that detects more invasive cancers, reduces false positives, and is FDA approved as superior to conventional 2D mammography for all women, including those with dense breasts.^{2,3,4}

For years, women have reported avoiding regular mammograms due in large part to the fear of discomfort associated with breast compression. In fact, a recent survey of 10,000 women found that fear of physical discomfort was the top reason cited for avoiding a mammogram by women who never had one.⁵ With this in mind, Hologic's research and development team, led by Tracy Accardi, Global Vice President of Research and Development, set out to reduce breast pain without compromising image quality or exam accuracy.

"As a woman, I know firsthand that all too often, annual mammograms are considered a necessary evil. We understand the critical role the exam plays in the early detection of breast cancer, but we know how uncomfortable, and sometimes even painful, the exam can be," said Accardi. "The associated anxiety causes many women to avoid or delay this potentially life-saving exam, something we set out to change when developing the first-of-its-kind SmartCurve system."

Breast pain experienced during a mammogram is directly related to the time spent under compression and the pressure distribution on the breast, two factors that must be addressed to improve the mammography experience. The SmartCurve system features a proprietary curved surface that mirrors the shape of a woman's breast to reduce pinching and allow better distribution of force over the entire breast. The system also features proprietary image processing algorithms that ensure the preservation of image quality and accuracy. The SmartCurve system, combined with the fastest 3D™ mammogram available, makes the Genius exam the obvious choice for women wanting a more accurate exam that is also more comfortable.

In a recent clinical study comparing the SmartCurve breast stabilization system to traditional flat paddle compression, the SmartCurve system improved comfort in 93 percent of women who reported moderate to severe discomfort with standard compression. In addition, 95 percent of those surveyed would recommend facilities that use the system.¹ The system includes options to accommodate a majority of women and breast sizes, and can be used with Hologic's MammoPad® breast cushion for even greater comfort.⁶

In addition to providing women with increased comfort and the accuracy they have come to expect from the Genius exam, the SmartCurve system's image processing algorithm ensures there is no change in positioning or workflow for radiologists and technologists administering the exam. Clinicians can feel confident they are offering patients an improved experience while maintaining efficiency within their facilities.

"Hologic is the world leader in breast cancer screening technology, and with that leadership comes a responsibility to develop products that provide optimal patient satisfaction without sacrificing clinical performance," said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "We are thrilled to introduce the new SmartCurve system which, when used with the Genius exam, is the first and only 3D mammography system that is clinically proven to deliver a more comfortable and more accurate mammogram, compared to 2D mammography alone. This game-changing product is yet another example of our dedication to innovation designed to meet the needs of our customers and their patients."

Hologic's Genius exam is the only mammogram clinically proven to detect 20 to 65 percent more invasive breast cancers compared to 2D mammography alone.² It also reduces unnecessary callbacks and is the only mammogram FDA approved as superior to conventional 2D mammography for women with dense breasts.³⁻⁴

Sheryl Crow, Genius exam spokeswoman, said, "I've already been telling women that the Genius exam is the best option for their annual screening. Now that it's also a more comfortable exam thanks to the SmartCurve system, I'm urging women everywhere to stop making excuses and ask their doctors about the Genius exam today."

The SmartCurve system is available standard on Hologic's new 3Dimensions™ mammography system and as an enhancement option to existing Hologic Selenia® Dimensions® systems.

The Genius™ 3D Mammography™ exam is only available on a Hologic® 3D Mammography™ system. The exam consists of a 2D and 3D™ image set, where the 2D image can be either an acquired 2D image or a 2D image generated from the 3D™ image set. There are more than 4,000 Hologic 3D Mammography™ systems in use in the U.S., so women have convenient access to the Genius exam. To learn more about the Genius exam, visit <http://www.Genius3DNearMe.com>.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

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*Compared to standard compression

¹ Smith, A. Improving Patient Comfort in Mammography. Hologic WP-00119 Rev 001 (2017).

² Results from Friedewald, SM, et al. "Breast cancer screening using tomosynthesis in combination with digital mammography." JAMA 311.24 (2014): 2499-2507; a multi-site (13), non-randomized, historical control study of 454,000 screening mammograms investigating the initial impact the introduction of the Hologic Selenia® Dimensions® on screening outcomes. Individual results may vary. The study found an average 41% (95% CI: 20-65%) increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1000 screening exams were found in women receiving combined 2D FFDM and 3D™ mammograms acquired with the Hologic 3D Mammography™ system versus women receiving 2D FFDM mammograms only.



³ Bernardi D, Macaskill P, Pellegrini M, et. al. Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study. Lancet Oncol. 2016 Aug;17(8):1105-13.

⁴ U.S. Food & Drug Administration Premarket Approval (PMA). FDA.gov
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003S005> accessed June 5, 2017.

⁵ Kadence International, Ten Thousand Quantitative Findings Research Study (5107), April 2017.

⁶ Coryell T. Increasing Mammography Tissue Acquisition through Positioning Training and Use of a Foam Breast Cushion. National Consortium of Breast Centers, 16th Annual National Interdisciplinary Breast Conference, Las Vegas, NV (2006)

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<http://investors.hologic.com/2017-09-26-Hologic-Introduces-a-More-Comfortable-Mammogram-with-the-Launch-of-the-SmartCurve-TM-Breast-Stabilization-System>