

Hologic - MediaRoom

Hologic's 3Dimensions™ Mammography System Now Available in Europe

--Fastest, Highest Resolution Breast Tomosynthesis System is Designed to Increase Clinical Confidence, Accuracy and Patient Comfort--



MARLBOROUGH, Mass., September 11, 2017 — Hologic, Inc.

(Nasdaq: [HOLX](#)) announced today that the 3Dimensions™ mammography system, the fastest, highest resolution breast tomosynthesis system ever, is available for purchase in Europe.^[1] The new product is the latest addition to Hologic's portfolio of market-leading breast cancer screening, diagnostic and interventional solutions. It offers a variety of groundbreaking features designed to provide higher quality 3D™ images for radiologists, enhanced workflow for technologists, and a more comfortable mammography experience, with low-dose options, for patients.

Hologic is the world leader in breast cancer screening technology and pioneered the 3D Mammography™ exam, which detects up to 65 percent more invasive breast cancers and is the only mammogram approved by the U.S. Food and Drug Administration as superior for women with dense breasts compared to 2D alone.^{[2],[3]}

"We are excited to introduce our new 3Dimensions mammography system, a major advance in Hologic's mission to expand our leadership in breast health through transformational technology that is rooted in meaningful customer insights and supported by superior clinical evidence," said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "The 3Dimensions system offers a number of innovative features that improve image clarity and help manage dose, setting it apart from every other screening technology on the European market."

The new 3Dimensions system features Clarity HD high-resolution 3D™ imaging, which provides the industry's fastest, highest resolution 3D™ images to accelerate screening and analysis. The system is designed to clearly reveal subtle lesions and fine calcifications to help pinpoint cancers early. Clarity HD technology's advanced detector and innovative 3D™ imaging algorithm work together to deliver exceptional 3D™ images, regardless of breast size or density. Designed to increase clinical confidence and achieve more accuracy the first time, Clarity HD reduces recalls by up to 40 percent compared to 2D alone.^{[4],[5],[6],[7]}

"Clinicians across Europe have made clear their desire for breast cancer screening technology that offers improved accuracy, clarity and workflow, and the 3Dimensions system addresses each of those specific areas," said Jan Verstreken, Hologic's Regional President for EMEA and Canada. "We are thrilled to introduce this comprehensive solution, which will undoubtedly make a positive impact on European radiologists, technologists and patients alike."

In addition, the 3Dimensions system offers Intelligent 2D™ imaging technology, which works with Clarity HD technology to deliver unprecedented clarity, contrast and detail at a lower dose.^{1,[8]} Intelligent 2D imaging technology features smart mapping, which enables radiologists to instantly move from suspicious areas detected on the 2D image to the point of interest on the 3D slice, saving time and optimizing workflow.^[9]

The 3Dimensions system also includes the new SmartCurve™ breast stabilization system, which is clinically proven to deliver a more comfortable mammogram without compromising image quality, workflow or dose.^[10] The SmartCurve system has been shown to improve comfort in 93 percent of women surveyed who reported moderate to severe discomfort with standard compression.¹⁰ The system features a curved compression surface that mirrors the shape of a woman's breast to reduce pinching and allow uniform compression over the entire breast. Advanced processing software, specifically developed for the SmartCurve system, ensures optimal image quality.

Another feature available with the 3Dimensions system is the Quantra™ 2.2 breast density assessment software, which enables standardization in patient protocols, providing reproducible and consistent breast density assessment.

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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References

[1] Data on file.

[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% increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1,000 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] FDA submissions P080003, P080003/S001, P080003/S004, P080003/S005.

[4] Zuckerman SP, Conant EF, Keller BM, et al. Implementation of Synthesized Two-dimensional Mammography in a Population-based Digital Breast Tomosynthesis Screening Program. *Radiology*. 2016 Dec;281(3):730- 736.

[5] Skaane P, Bandos A, Eben EB, et al. Two-view digital breast tomosynthesis screening with synthetically reconstructed projection images: comparison with digital breast tomosynthesis with full-field digital mammographic images. *Radiology*. 2014 Jun;271(3):655-63.

[6] 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.

[7] McDonald ES, Oustimov A, Weinstein SP, et al. Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening. *JAMA Oncol*. 2016 Jun 1;2(6):737-43.

[8] Compared to 2D alone

[9] Feature is used in combination with SecurView®DX diagnostic review workstation mapping tool in v9.0.1 and above.

[10] Smith, A. Improving Patient Comfort in Mammography. Hologic WP-00019 Rev 001 (2017).