



NEWS RELEASE

Hologic Applauds FDA's Proposed Rule to Update Mammography Regulations Issued Under the Mammography Quality Standards Act (MQSA) of 1992

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Proposed rule highlights the risks of breast density and emphasizes important advances in mammography technology, including 3D mammography

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX), the world leader in breast cancer screening technology and the company behind the Genius™ 3D Mammography™ exam, applauds the U.S. Food and Drug Administration's proposed rule updating its regulations issued under the **Mammography Quality Standards Act (MQSA)** of 1992. The proposed amendments, the first changes made to the act in 20 years, emphasize the significant role breast density can play in cancer detection and require uniform reporting of a patient's breast density to patients and medical providers nationwide.

"We commend the FDA for recognizing the significance of breast density and wholeheartedly believe that arming women with this critical knowledge is a major step forward for breast health," said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "Better informed patients make smarter decisions, like screening with the Genius™ exam, the only mammography exam FDA approved to find more cancers in dense breasts."

Nearly half of women between the ages of 40 to 74 have dense breasts, which can make it difficult to detect breast cancer during annual screenings as the dense tissue can obscure cancers.^{1,2} Additionally, women with very dense breasts are four to five times more likely to develop breast cancer than women with less dense breasts.^{3,4} Hologic's Genius™ exam provides radiologists with a series of images, allowing them to evaluate the breast layer by layer and identify cancers that may be hidden by breast tissue. The Genius™ exam is the only mammography exam FDA approved to find more cancers and reduce recalls in dense breasts.⁵

Today, more than 50 percent of mammography systems across the country utilize breast tomosynthesis, according to MQSA data. Since 2011, Hologic has installed more than 6,000 3D Mammography™ systems throughout the United States. The Genius™ Mammography System is the only mammography exam clinically proven to detect 20 to 65 percent more invasive breast cancers compared to 2D alone, and is only available on a Hologic® 3D Mammography™ system.⁶ To learn more about the Genius™ exam, visit www.mygenius3d.com.

The Genius™ 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.

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.

Forward-Looking Statements

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient, as the actual effect of the use of the products can only be determined on a case-by-case basis. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such data or statements are based.

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References

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- 2 Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. *J Natl Cancer Inst*. 106(10), 2014.
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postmenopausal women according to tumor characteristics. J Natl Cancer Inst. 103(15):1179-89, 2011.

5U.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.

6 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 of the introduction of the Hologic Selenia® Dimensions® system on screening outcomes. Individual results may vary. The study found 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.

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