

3D MAMMOGRAPHY: FREQUENTLY ASKED QUESTIONS

What Is a 3D Mammogram?

A mammogram is an x-ray examination of the breasts that is used to detect and diagnose breast disease. Each year there are approximately 40 million mammograms performed in the United States. 3D mammography, also known as breast tomosynthesis, is a procedure that uses multiple low-dose images to create a 3-dimensionsal view of the breast. Think of reading a traditional 2-dimensional mammogram as similar to looking at an unopened book. If you look at just the cover, you cannot see the individual pages. However, a 3D mammogram allows you to open the book and go through it page by page to see everything between the covers.

During a 3D mammogram, the X-ray arm sweeps in a slight arc over the breast, taking multiple images in just seconds. Those images are reconstructed to form a stack of very thin layers. Instead of viewing all the complexities of the breast tissue in a flat image as with a traditional mammogram, 3D mammography allows the doctor to examine the 3D breast layer by layer. Fine details are more clearly visible, no longer hidden by the tissue above and below.

What Are the Benefits of 3D Mammography?

Clinical studies have shown that the addition of 3D mammography to a traditional mammogram significantly increases invasive cancer detection by as much as 40 percent and finds cancers missed with 2D mammography alone. 3D mammography also gives doctors the confidence to significantly reduce unnecessary callbacks, minimizing the chance that a patient will be asked to return for follow-up tests.

What Should a Woman Expect During the 3D Mammogram?

Women will see little difference between a conventional mammogram and a 3D mammogram. The exam takes just seconds and positioning is the same. The difference is in the information available to the doctor.

Who Can Have a 3D Mammogram?

Hologic's 3D mammography technology is approved by the Food and Drug Administration (FDA) for all women who would be undergoing a standard mammogram, in both the screening and diagnostic settings. iv

What Is the Difference Between Screening and Diagnostic Mammography?

A screening mammogram is an X-ray examination of the breast in women who have no signs of breast cancer. Sometimes doctors may ask a woman to come back for follow-up images, called a diagnostic mammogram, if the screening mammogram shows an unclear area in the breast or if there is a breast complaint, such as a mass, nipple discharge, pain, or skin irritation that needs to be evaluated. The 3D mammogram can reduce this call back rate by as much as 40 percent. iii



Which Women Will Benefit from 3D Mammography?

Clinical studies have shown that all women may benefit from the use of tomosynthesis imaging and that the technology is particularly effective for women with dense breasts. V

How Can a Woman Find a Facility that Offers 3D Mammograms?

Currently, Hologic is the only manufacturer with a 3D mammography system approved by the FDA. Women and referring physicians can go to www.Hologic3D.com to find the facility closest to them that offers 3D mammography.

Is There More Radiation Dose with a 3D Mammogram?

Very low x-ray energy is used during the exam, and while it does add more dose compared to a conventional digital mammogram, the radiation exposure is below the FDA safety limits.

When Should a Woman Get Screened?

The American Cancer Society recommends the following guidelines for detecting breast cancer:

- Women in their 20s and 30s should have a clinical breast exam by a healthcare professional every 3 years.
- Women aged 40 and older should have a screening mammogram and a clinical breast exam by a healthcare professional every year.

Products/Mammography Quality Standards Act and Program/Facility Score card/ucm 113858. htm

¹ U.S. Food and Drug Administration. "MQSA National Statistics." Last modified February 1, 2013. http://www.fda.gov/Radiation-Emitting

ⁱⁱ Skaane P, Bandos A, Gullien R, et. al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Radiology. 2013 Jan 7 [Epub ahead of print].

Philpotts, Liane, et. al. "Initial Experience With Digital Breast Tomosynthesis in Screening Mammography." Paper presented at the annual meeting of the American Roentgen Ray Society Annual Meeting, Vancouver, British Columbia, May 3, 2012.

^{iv} Hologic, Inc. FDA PMA submission P080003

^v Rafferty E, Niklason L. FFDM vs FFDM with Tomosynthesis for Women with Radiographically Dense Breasts: An Enriched Retrospective Reader Study. Presented at RSNA 2011, MSVB31-10 Breast Series: Emerging Technologies in Breast Imaging.