

Study Published in European Radiology Further Supports the Use of Hologic's Breast Tomosynthesis in Cancer Screening in Practices Using Double Reads

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Breast cancer screening with tomosynthesis finds cancers missed by 2D screening alone utilizing the double read with arbitration approach used in many countries of the world

BEDFORD, Mass., April 16, 2013 /PRNewswire/ -- Hologic, Inc. (Hologic or the Company) (NASDAQ: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced that a new study published online in advance of print by European Radiology supports the use of breast tomosynthesis in combination with 2-dimensional (2D) imaging in breast cancer screening programs using independent double reading with arbitration.

The study, "Prospective Trial Comparing Full-field Digital Mammography (FFDM) versus Combined FFDM and Tomosynthesis in a Population-based Screening Programme Using Independent Double Reading with Arbitration," was led by Per Skaane, M.D., Ph.D. of Oslo University Hospital Ullevaal. [1] The analysis included a total of 12,621 screening examinations of women participating in the Oslo Tomosynthesis Screening Trial. In double reading, two radiologists independently read the same case and if the radiologists disagree on the diagnosis, there is an arbitration or consensus meeting where the final diagnosis of the case is decided. Double reading has been shown to increase cancer detection and is the standard method used for interpretation of mammograms for most countries outside of the U.S. with organized population-based screening programs. This study compares double reading of 2D mammography with double reading of 2D mammography plus tomosynthesis.

The researchers used Hologic's breast tomosynthesis cancer screening technology and found:

- Tomosynthesis-based screening was successfully implemented in a large prospective screening trial.
- Double reading of tomosynthesis-based examinations significantly reduced false-positive interpretations.

False-positive interpretations were decreased by 18% using 2D plus tomosynthesis.

- Double reading of tomosynthesis-based examinations significantly increased the detection of breast cancers by approximately 30%. The detection of invasive cancers was increased by approximately 40%.

"It is very encouraging, though not surprising, to see confirmation of the strong benefits our tomosynthesis technology can bring to users across different clinical environments," said Peter Soltani, Hologic's Senior Vice President and General Manager of Breast Health. "The Oslo data clearly indicates that double reading of 2D plus tomosynthesis imaging results in a large increase in the detection of invasive cancers and a reduction in false positives when compared with 2D double readings alone. This study reinforces a previous study measuring the benefits of tomosynthesis for a single reader and demonstrates that tomosynthesis provides major improvements in breast cancer screening for both single and double-reading screening methods. We believe that Hologic's breast tomosynthesis technology can make significant inroads in overcoming the limitations of conventional mammography, namely missed cancers and unnecessary recalls, and we expect the results of this study to further support the adoption of our tomosynthesis technology."

The European Radiology paper is the first peer-reviewed publication comparing the performance of double reading of 2D exams with double reading of 2D plus tomosynthesis imaging in a large prospective clinical trial.

Hologic's breast tomosynthesis technology has been approved for use for breast cancer screening and diagnosis in countries recognizing the CE mark since 2008. It was approved for use in the U.S. in February, 2011. Hologic systems are now in use in 48 states in the U.S. and over 50 countries.

For more information about Hologic's breast tomosynthesis technology, please visit www.BreastTomo.com (for healthcare providers) and www.Hologic3D.com (for patients).

About Hologic, Inc.

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems, and surgical products. The Company operates four core business units focused on diagnostics, breast health, GYN surgical and skeletal health. With a comprehensive suite of technologies and a robust research and development program, Hologic is committed to improving lives. The Company is headquartered in Massachusetts.

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Forward Looking Statement Disclaimer.

This News Release may contain forward-looking information that involves risks and uncertainties, including

statements about the use of Hologic digital mammography systems. There can be no assurance the systems will achieve the benefits described herein and 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 systems can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to the data or statements presented herein to reflect any change in the Company's expectations or any change in events, conditions or circumstances on which any such data or statements are based.

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[1] Skaane P, Bandos A I, Gullien R, Eben E B, Ekseth U, Haakenaasen U, Izadi M, Jebsen I N, Jahr G, Krager M, Hofvind S. Prospective trial comparing full-field digital mammography (FFDM) versus combined FFDM and tomosynthesis in a population-based screening programme using independent double reading with arbitration. *European Radiology*. Published on line in advance of print, April, 2013.

SOURCE Hologic, Inc.