NEWS RELEASE

Hologic's AI-Powered Mammography Technology Flagged a Third of Breast Cancer Cases Initially Interpreted as Negative in Study of 7,500 Screening Exams

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Retrospective analysis at top-tier medical facility highlights AI solution's ability to help spot previously missed cancers and correctly localize suspicious areas on mammograms

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX), a leading medical technology company dedicated to improving women's health, today announced new data that highlights how the company's advanced AI-powered mammography solution can aid in detecting more breast cancers.

Hologic's AI-Powered Mammography Technology

"At Hologic, we are constantly pushing ourselves to innovate and enhance the quality and reliability of our technologies," said Mark Horvath, President of Breast and Skeletal Health Solutions. "This study underscores AI's potential to uncover cancers that might otherwise remain hidden, while also giving us critical insights to guide the development of future innovations. As we continue to advance this technology based on customer and provider feedback, we're excited to see its impact in real-world settings."

In a new study1 published in the American Journal of Roentgenology, researchers at Massachusetts General Hospital in Boston performed a retrospective analysis of 7,500 digital breast tomosynthesis (3D mammography) screening exams using Hologic's Genius AI® Detection solution. Among the 7,500 exams performed between 2016 and 2019, there were 100 false-negative cases, which are mammograms read as negative but followed by a breast cancer diagnosis within the next year. The Genius AI Detection solution marked approximately one-third (32%) of these cases as including areas of suspicion, accurately identifying the location where breast cancer was

subsequently diagnosed.

Of the 500 breast cancer cases previously identified by radiologists, the Genius AI Detection technology flagged almost 90% and correctly localized their locations. The AI technology was more likely to flag invasive ductal carcinomas and lymph node-positive cancers in the study. It was less likely to flag invasive lobular carcinomas and grade I invasive carcinomas.

One instance of a false-negative case flagged by AI cited in the study involved a 54-year-old woman whose results were initially interpreted as negative. Eleven months later, she returned to her doctor after noticing a lump in her left breast and was diagnosed with grade 1 invasive ductal carcinoma. On retrospective evaluation of the initial screening mammogram, the AI algorithm marked and correctly localized the area where the cancer was located as suspicious.

“In this study, not only did the AI identify the case as suspicious and warranting additional review, but it also correctly localized the region of interest,” said Dr. Manisha Bahl, MD, MPH, Associate Director of Quality for Breast Imaging at Mass General Brigham and Associate Professor of Radiology at Harvard Medical School. “While additional research is needed, these findings are promising and highlight AI’s tremendous potential to redefine breast cancer detection in the years ahead.”

Study Limitations

This study was performed at a single academic medical center with a predominantly Caucasian patient population and was conducted with Hologic’s Genius AI Detection 2.0 software, and the results may not be generalizable to other practice settings or to other AI-based algorithms. Additionally, the small sample sizes within certain subgroup limit the statistical power and generalizability of the subgroup analyses. The study also did not evaluate the impact of AI on patient outcomes or its integration into real-world clinical workflows.

About Genius AI Detection Solution

Hologic’s Genius AI Detection solution is an innovative mammography screening technology designed to locate lesions likely to represent breast cancer. Suspicious areas are highlighted at radiologists’ workstations for concurrent reading to support smart, decisive interpretation. Hologic's deep learning algorithm is fed by the accumulation of a large, diverse patient base, providing rich insight and intelligence. For more information, please visit **Genius AI Detection Technology**.

About Hologic, Inc.

Hologic, Inc. is a global leader in women's health dedicated to developing innovative medical technologies that effectively detect, diagnose and treat health conditions and raise the standard of care around the world. To learn more, visit **www.hologic.com** and connect with us on **LinkedIn**, **Facebook**, **X, Instagram** and **YouTube**.

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.

References

1 Bahl M, Kim K, Kim H, Alkhadrawi A, Do S. Commercial Artificial Intelligence (AI) Tool for Screening Digital Breast Tomosynthesis: Factors Associated With AI-Based Breast Cancer Detection. AJR Am J Roentgenol. 2025 Dec 3. doi: 10.2214/AJR.25.33792. Epub ahead of print. PMID: 41334895.

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