

# CureMetrix Receives FDA Clearance for cmAngio®, First-Of-Its-Kind Solution For Detecting Breast Arterial Calcification

*The Artificial Intelligence (AI)-based deep learning algorithm helps radiologists identify breast arterial calcifications (BAC) in screening mammograms.*

SAN DIEGO, CA, UNITED STATES, October 16, 2023 /EINPresswire.com/ -- [CureMetrix, Inc.](https://www.curemetrix.com) today announced U.S.

Food and Drug Administration (FDA) 510(k) clearance of the company's cmAngio® breast arterial calcification (BAC) detection and localization software. cmAngio analyzes both full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) screening mammograms in order to identify and mark these anomalies which are currently only identified as incidental findings. Importantly, cmAngio allows radiologists to use existing screening mammograms to identify women who have BAC and as appropriate refer them for additional evaluation.

"With this historic clearance, the first for a product to detect breast arterial calcification in mammograms, CureMetrix is poised to help advance screening mammography for patients and radiologists. cmAngio shifts a screening mammogram into a two-for-one exam with no additional radiation for the patient and no new procedures for the radiologist. We are excited to move forward into the market and help improve outcomes and healthcare," said Navid Alipour, CEO of CureMetrix.

cmAngio works across all levels of breast density, is compatible with both FFDM and DBT mammograms, and has an adjustable operating point allowing the software sensitivity and specificity to be aligned with imaging center clinical protocols.

"The recent FDA clearance of cmAngio represents a tremendous stride in women's health. It is a groundbreaking innovation to aid radiologists in identifying Breast Arterial Calcifications, an underreported incidental finding in standard screening mammograms. It is exciting to see an



advance like this that has the potential to improve women's health globally," said Nitesh Nerlekar, MD, MPH, PhD, Cardiologist and Cardiac Imaging Specialist at Monash Health and Director of Clinical Research, Cardiology at CureMetrix.

"There is a growing consensus among the medical community that the presence of breast arterial calcifications should be included on mammogram reports," said Lisa Watanabe, MD, FACR, Chief Medical Officer at CureMetrix. "The cmAngio software will be a tremendous aid for radiologists like myself in providing timely and accurate results for BAC detection. I am hopeful that cmAngio will someday be widely incorporated in breast imaging practices as a useful application of artificial intelligence that can enhance physician decision-making, reporting, and patient care."

Among women who have had screening mammograms, the prevalence of BAC varies from around 12 to 42.5% (source 1). However, less than 5% of all instances of incidental findings of BAC in mammograms are reported (source 2). With this prevalence rate, CureMetrix focused on high specificity to reduce false positives and an adjustable operating point that meets the clinical goals of a healthcare facility.

"We are extremely proud to have cmAngio enter the market. As a company we have always focused on developing AI-based products that lead the way in Women's Health," said Kevin Harris, President of CureMetrix. "Through accurate and reliable detection of BAC, cmAngio has the potential to reduce costs in our healthcare system while saving lives. Helping to identify this underreported incidental finding creates more clinical value from a single screening mammogram. As part of Breast Cancer Awareness Month, we encourage women to get screened and 'Ask For cmAngio!'"

To learn more about cmAngio®, please visit [curemetrix.com/cmangio](https://curemetrix.com/cmangio).

For FDA clearance details, please visit:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232367>

Sources

1 <https://csbi.ca/canadian-society-of-breast-imaging-position-statement-on-breast-arterial-calcification-reporting-on-mammography/>

2 Internal CureMetrix analysis of 346,000 mammograms collected from 2008-2018

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