ProFound AI®

Artificial Intelligence Solutions for 2D Mammography & Digital Breast Tomosynthesis

Precise, Powerful & Proven Technology to Improve Breast Cancer Detection

iCAD, the market leader in multi-vendor, artificial intelligence (AI) detection solutions for breast cancer with more than a thousand installations worldwide, introduces: ProFound AI® 3rd generation.

ProFound AI is a clinically proven solution designed to amplify radiologists' diagnostic accuracy and performance reading 2D mammography and digital breast tomosynthesis (DBT).

ProFound AI improves clinical confidence

This high-performing, concurrent-read, cancer-detection and workflow solution rapidly and accurately analyzes each image, or slice, detecting both malignant soft tissue densities and calcifications with unrivaled accuracy, including in dense breasts. Similarly, ProFound AI allows radiologists to quickly confirm and validate the absence of cancer.

ProFound AI is proven to offer superior clinical performance[1]

8% improvement in sensitivity

7% reduction in rate of recalls

52.7% reduction in reading time for radiologists

ProFound AI for 2D Mammography is clinically proven to:

- Offer superior sensitivity up to 91.5 %[2]
- Accurately detect up to 48% interval cancers, according to a retrospective study.[3]

ProFound AI 3rd generation performance[4]

The latest version of this software outperforms previous versions in sensitivity and specificity, with a significant reduction of false positive findings per image. Compatible with multiple mammography systems, ProFound AI offers offers

Patient Benefits:

Assists in early detection, which can lead to improved outcomes

Reduces false positives/recalls

Improves detection accuracy

Facility Benefits:

Enhances patient care with improved detection technology

Improves workflow efficiency

Increases diagnostic confidence

Supports mixed tomosynthesis environments

iCAD

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DMM258 Rev 2

critical insights for clinicians that can enhance clinical confidence and improve outcomes for women.

How does ProFound AI work?

Up to 10% specificity performance improvement

Up to 1% improvement in sensitivity

Up to 40% faster processing

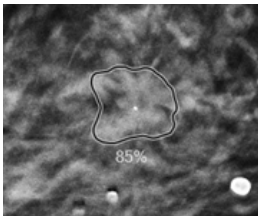
The ProFound AI algorithm rapidly and accurately analyzes each individual image, or slice, and identifies potentially malignant lesions. Trained with one of the largest available image datasets, ProFound AI provides radiologists with crucial information, such as lesion Certainty of Finding and Case Scores, which assists in clinical decision making and prioritizing caseloads.

Certainty of Finding and Case Scores

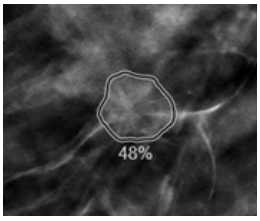
Certainty of Finding lesion and Case Scores are assigned to each lesion and each case respectively. These are are relative scores computed by the ProFound AI algorithm and represent the algorithm's confidence that a detection or case is malignant.

The scores are represented on a 0% to 100% scale. A higher score indicates a higher level of confidence in the malignancy of the detection or case. The Certainty of Finding and Case Scores serve as a guide to the interpreting radiologist to aid in determining if a suspicious finding or case needs further workup.

Examples with Certainty of Finding Scores for Soft Tissue Density Detections

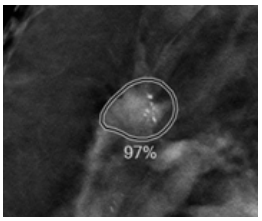


85% Certainty of Finding

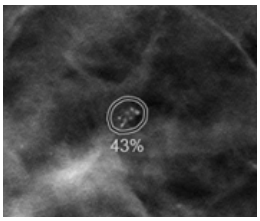


48% Certainty of Finding

Examples with Certainty of Finding Scores for Calcification Detections



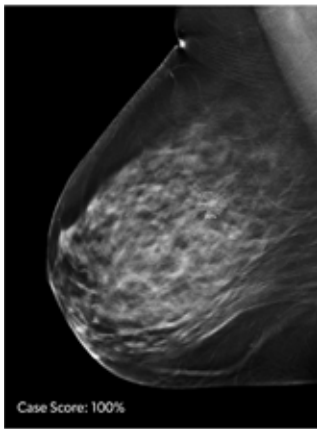
97% Certainty of Finding



43% Certainty of Finding

Platform

ProFound AI runs on the industry-leading PowerLook® server platform with NVIDIA® Graphical Processing Units (GPU), the latest in powerful GPU technology. PowerLook is a flexible and reliable DICOM platform that easily integrates with image modalities, mammography review workstations, PACS, and image storage systems. Leveraging the latest in GPU technology, the algorithm can rapidly process a 4-view tomosynthesis case, ensuring results are available to radiologists in the most efficient manner.



PowerLook (EC certificate #649468) and PowerLook Tomo Detection software (EC Certificate #672447), medical imaging post-processing software, are medical devices manufactured by iCAD, Inc. These medical devices are reserved for health professionals. These software programs have been designed and manufactured according to the EN ISO 13485 quality management system. Read the instructions in the User's Manual carefully before use. Manufacturer: iCAD, Inc. (USA). Medical devices Class IIa / Notified body: BSI. ©iCAD, Inc. / September 2021.

References:
1. Conant, E et al. (2019). Improving Accuracy and Efficiency with Concurrent Use of Artificial Intelligence for Digital Breast Tomosynthesis. Radiology: Artificial Intelligence. 1 (4). Accessed via https://pubs.rsna.org/doi/10.1148/ryai.2019180096
2. The value of 2D-AI-based CAD for second or third reading tested on 17,910 screening mammograms [RPS 702-4] by Sylvia H. HeyWang-Köbrunner MD, head of Referenzzentrum Mammographie München.(https://event.crowdcompass.com/ecr2020/activity/78pY0IUG4N)
3. Compared to previous versions of the software, the ProFound AI 3.0 algorithm off ers up to a 10% improvement in specifi city performance, up to 1% improvement insensitivity with ProFound AI for Tomosynthesis and 4% improvement with ProFound AI for 2D mammography, and up to 40% faster processing on the newPowerLook platform.
4. iCAD data on file. FDA filing: K203822. Standalone performance varies by vendor. FDA Cleared and CE Marked.

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