
iCAD Signs Global Distribution Agreement with Sectra

Agreement will expand access to ProFound AI and ProFound AI Risk to more facilities and imaging centers worldwide

NASHUA, N.H. – June 8th, 2021 - iCAD, Inc. (NASDAQ: ICAD), a global medical technology leader providing innovative cancer detection and therapy solutions, today announced it has signed a worldwide distribution agreement with Sectra, an international medical imaging IT and cybersecurity company. Through this agreement, ProFound AI® and ProFound AI Risk will be offered through the Sectra Amplifier Marketplace, which will expand their access to more facilities and imaging centers worldwide.

“iCAD’s technology offers unparalleled benefits to clinicians and patients alike. ProFound AI is clinically proven to enhance breast cancer screening by improving radiologists’ accuracy and efficiency. ProFound AI Risk is the first and only commercially available clinical decision support tool that provides an accurate two-year breast cancer risk estimation that is personalized for each woman, based solely on a screening mammogram,” according to Michael Klein, Chairman and CEO of iCAD. “These technologies empower clinicians to provide more accurate and personalized breast cancer screening.”

Sectra develops and sells imaging IT solutions. It provides healthcare providers worldwide with enterprise imaging solutions comprising picture archiving and communications systems (PACS) for imaging-intense departments (radiology, pathology, cardiology, orthopedics), vendor neutral archives (VNA) to store all types of medical images and information, as well as solutions for sharing and collaborating around medical imaging.

“To help healthcare providers get on the AI adoption journey, we have created the Sectra Amplifier Marketplace. We aim to facilitate easier access and usage of AI applications in medical imaging. This distribution agreement is an example of that. With iCAD’s tools deeply embedded in the Sectra diagnostic workspace, we provide our radiologists with enhanced diagnostic confidence for breast imaging reading,” said Nynke Breimer, Global Product Manager AI Radiology, Sectra.

In December 2019, ProFound AI for Digital Breast Tomosynthesis (DBT) became the first 3D tomosynthesis software using artificial intelligence (AI) to be FDA cleared; it is also CE marked and Health Canada licensed. It is a high-performance, deep-learning, workflow solution trained to detect malignant soft tissue densities and calcifications. It is also available for 2D mammography. In a reader study published in *Radiology: Artificial Intelligence*, ProFound AI for DBT was shown to offer clinically proven time-savings benefits to radiologists, reducing reading time by 52.7 percent, improving radiologists’ sensitivity by 8 percent, and reducing false positives and unnecessary patient recall rates by 7.2 percent.^[i]

ProFound AI Version 3.0 for Digital Breast Tomosynthesis (DBT) was recently cleared by the U.S. Food and Drug Administration (FDA) in March 2021. Compared to previous versions of the software, the ProFound AI 3.0 algorithm offers up to a 10% improvement in specificity performance and up to 1% improvement in sensitivity.^[ii] ProFound AI Version 3.0 also offers up to 40% faster processing on the new PowerLook platform.ⁱⁱ ProFound AI Version 3.0 was developed using over five million images from 30,000 cases, including almost 8,000 biopsy-proven cancers, and validated on approximately one million images from 3,500 cases that included 1,200 biopsy-proven cancers.ⁱⁱ

ProFound AI Risk uniquely combines aspects within mammographic images, as well as age and breast density, to provide a highly accurate short-term risk estimation that is specific to each woman. The technology provides clinicians with a two-year breast cancer risk category [low, general, moderate and high] and absolute breast cancer risk score for each patient, based on information garnered from a standard bilateral two-view full field digital mammogram. ProFound AI Risk is supported by a recent study, which showed ProFound AI Risk significantly outperforms existing breast cancer risk models, with an area under the curve (AUC) of 0.73 (95% CI 0.71, 0.74).^[iii] AUC is a standard performance measurement for AI technology that incorporates sensitivity and specificity into a single metric of overall performance. ProFound AI Risk’s AUC of 0.73 indicates high accuracy for risk assessment.

“Although ProFound AI and ProFound AI Risk are already available throughout a growing number of leading institutions in the U.S. and the rest of the world, we are energized by this agreement with Sectra, as it will enable more clinicians and women around the world to benefit from iCAD’s transformative, first-in-kind innovations,” Klein added. “Sectra offers unique access to recurring revenue segments of the global market. Particularly noteworthy is Sectra’s strong presence in the European market, which we see as integral to enhanced growth of our ProFound AI product offering.”

[i] 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>

[ii] iCAD data on file. Standalone performance varies by vendor. FDA Cleared.

[iii] Eriksson M., Czene K., Strand F., et al. Identification of Women at High Risk of Breast Cancer Who Need Supplemental Screening. [published online ahead of print September 8, 2020]. Radiology. Accessed via <https://doi.org/10.1148/radiol.2020201620>

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