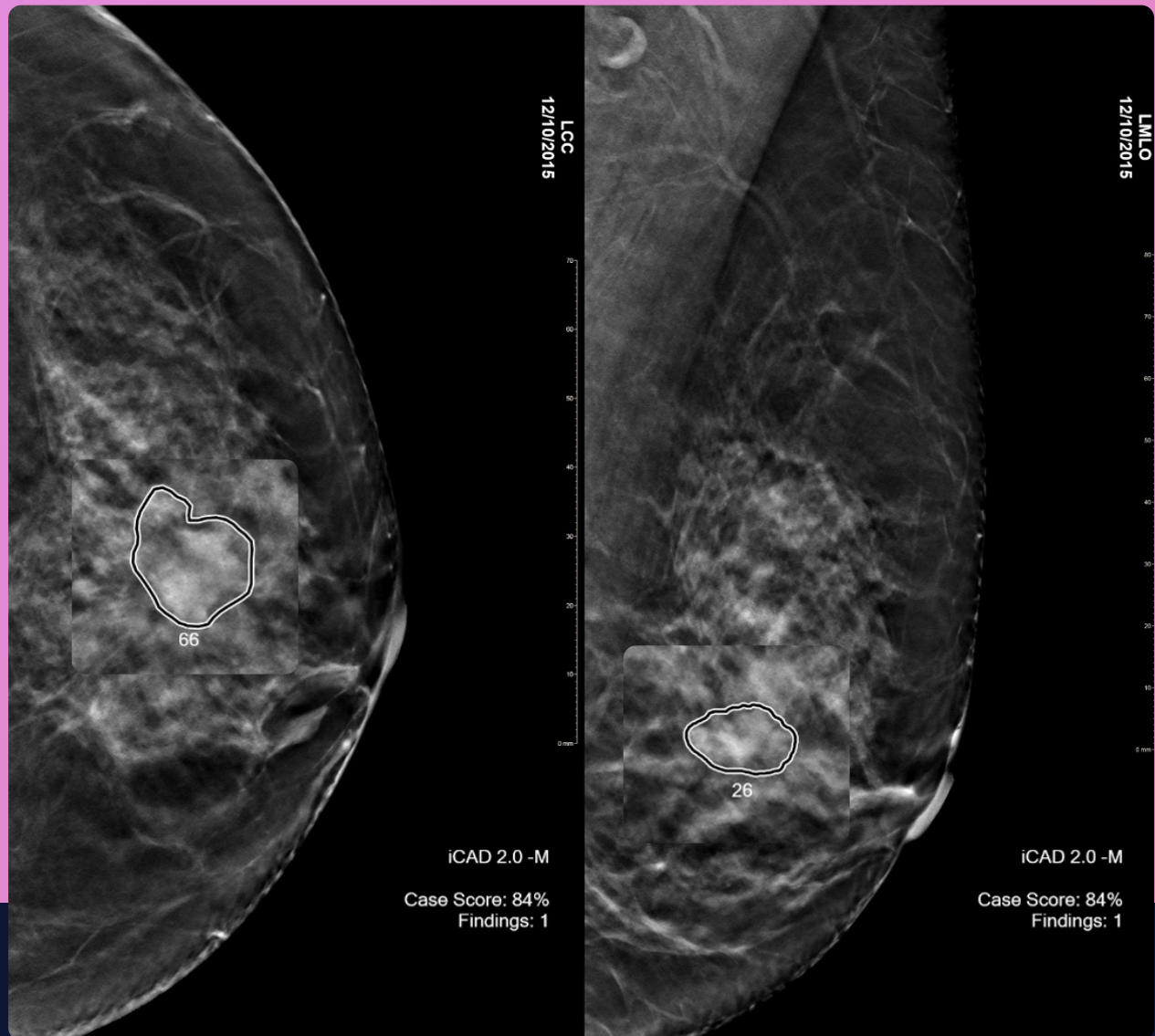


ARTERYS

BREAST AI

AI powered by iCAD[®]

Product Data Sheet



Breast AI provides innovative solutions for breast cancer detection, measure breast density and assess personalized risk that offer clinically proven benefits to clinicians and patients, and are designed to optimize efficiency, enhance the patient experience, and improve outcomes

Benefits

Increase Efficiency And Decrease Reporting Time

Breast AI analyzes each individual image or slice and identifies potentially malignant lesions in digital breast tomosynthesis exams – providing radiologists with superior clinical performance and crucial information, such as lesion Certainty of Finding and Case Scores, which assists in prioritizing caseload, clinical decision-making and reducing reading time by up to 52.7%¹⁻³.

Consistent Results

Breast AI automatically assesses breast density of 2D or 3D mammograms with the appropriate BI-RADS® density category and provides physicians with simplified and standardized breast density reporting and stratification, with accurate and reliable results.¹

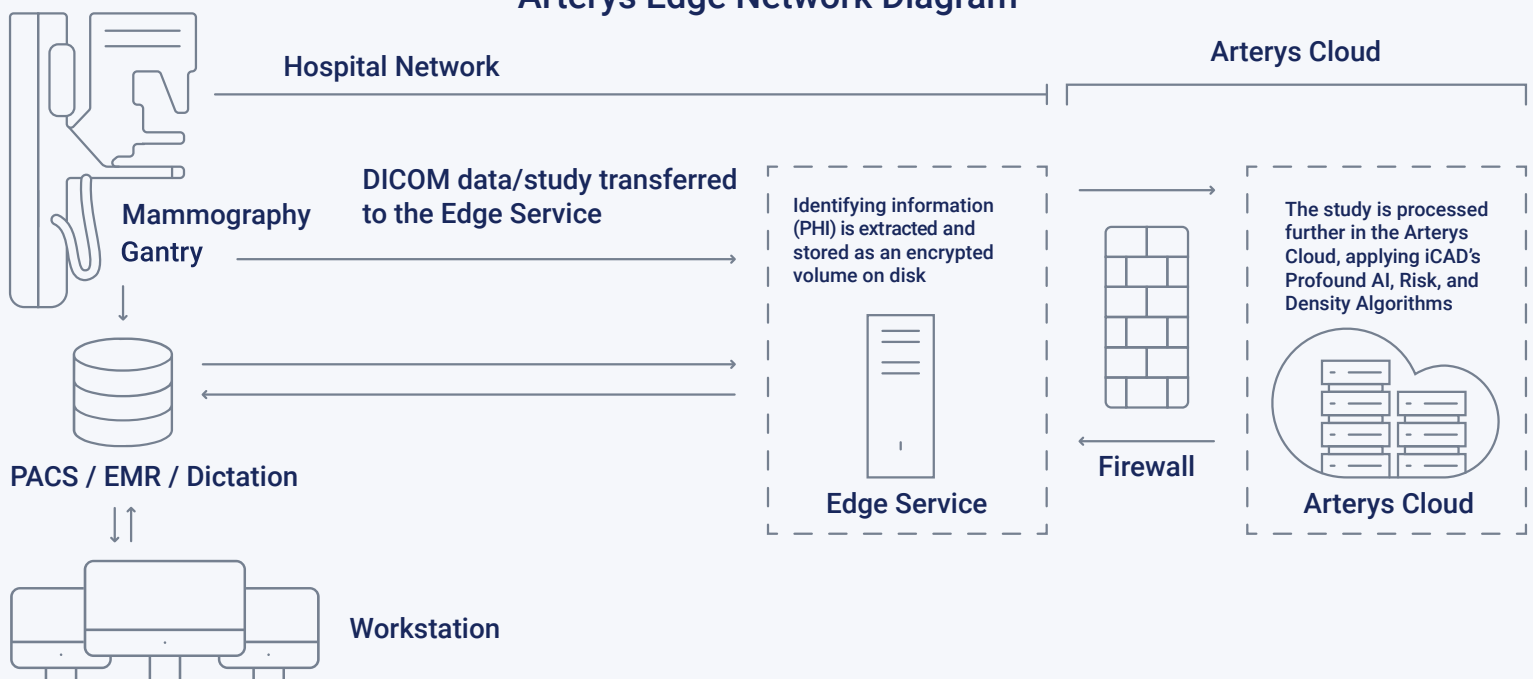
Superior Accuracy

Breast AI is a clinical decision support tool that provides a short-term, breast cancer risk estimation based on 2D or 3D mammograms with the highest AUC available, 0.80 (95% CI: 0.76, 0.83) offering greater accuracy compared to traditional risk assessment models^{1,4,5}.

Optimized Workflow

Breast AI does not require on-premises hardware and results are accessible through a single user-interface and an internet connection. It seamlessly integrates with existing PACS, EHR, worklist, notification, and dictation systems ensuring exams are read accordingly and consistently.

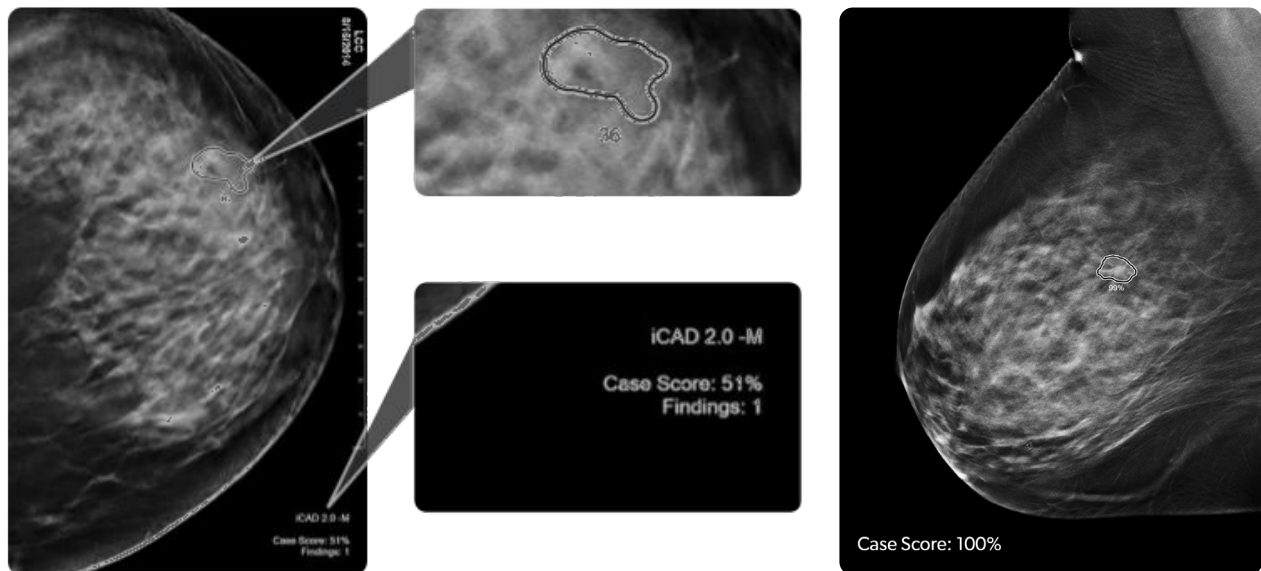
Arterys Edge Network Diagram



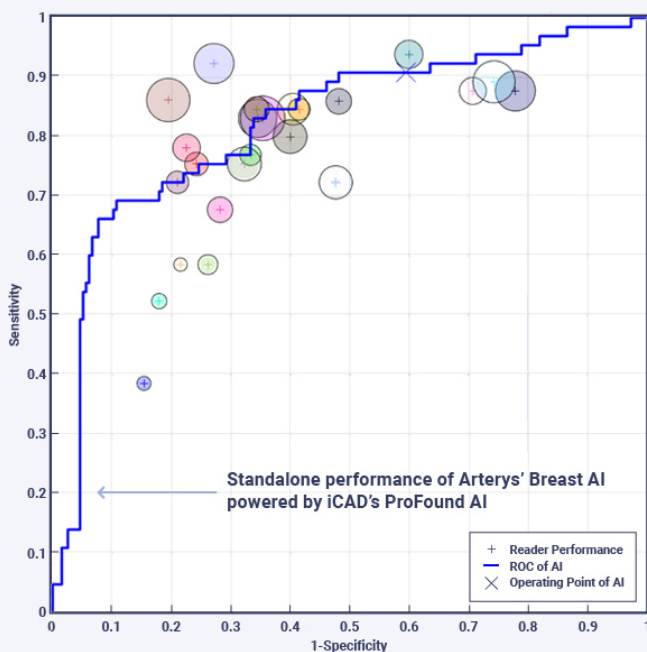
Features

Breast Cancer Detection

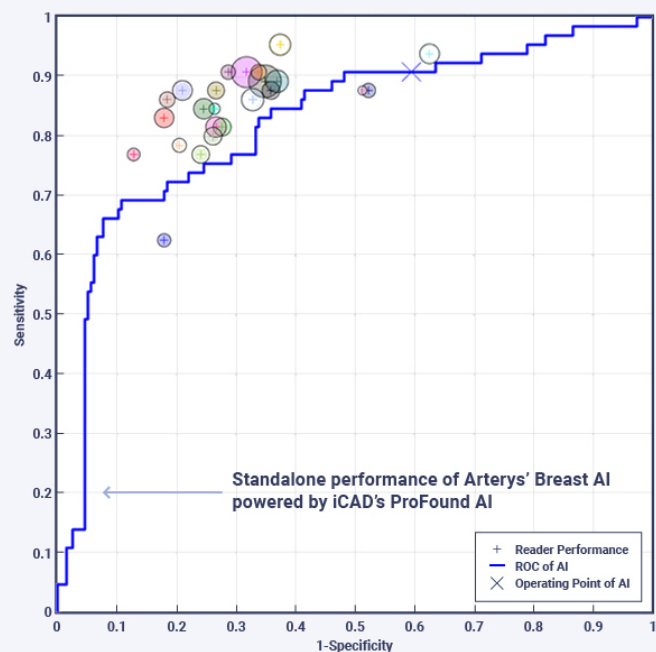
Breast AI uses deep learning technology that is intended to be used concurrently by radiologists while reading digital breast tomosynthesis (DBT) exams. The algorithm detects soft tissue densities (masses, architectural distortions, and asymmetries) and calcifications in 3D DBT slices. The suspicious areas that are detected and highlighted and the unique certainty of finding and case scores assist radiologists in identifying and assessing soft tissue densities and calcifications that may be confirmed or dismissed by the radiologist



Reader Sensitivity, Specificity and Reading Time **Without** AI

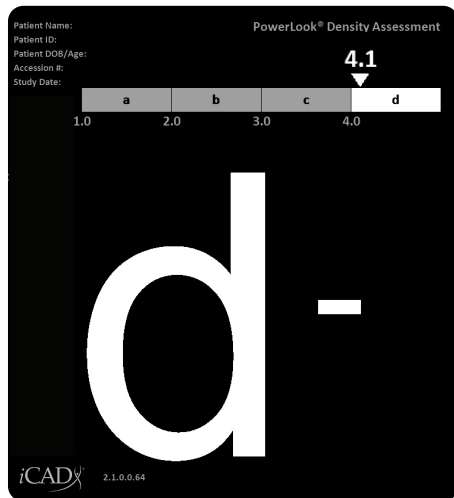


Reader Sensitivity, Specificity and Reading Time **With** AI

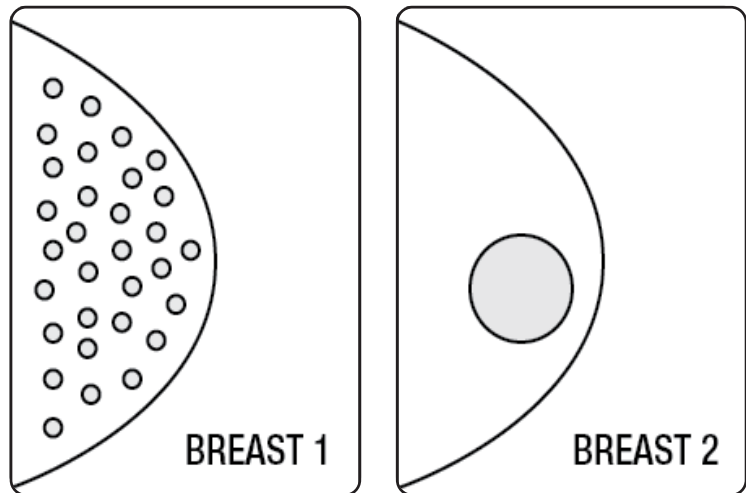


Breast Density Assessment

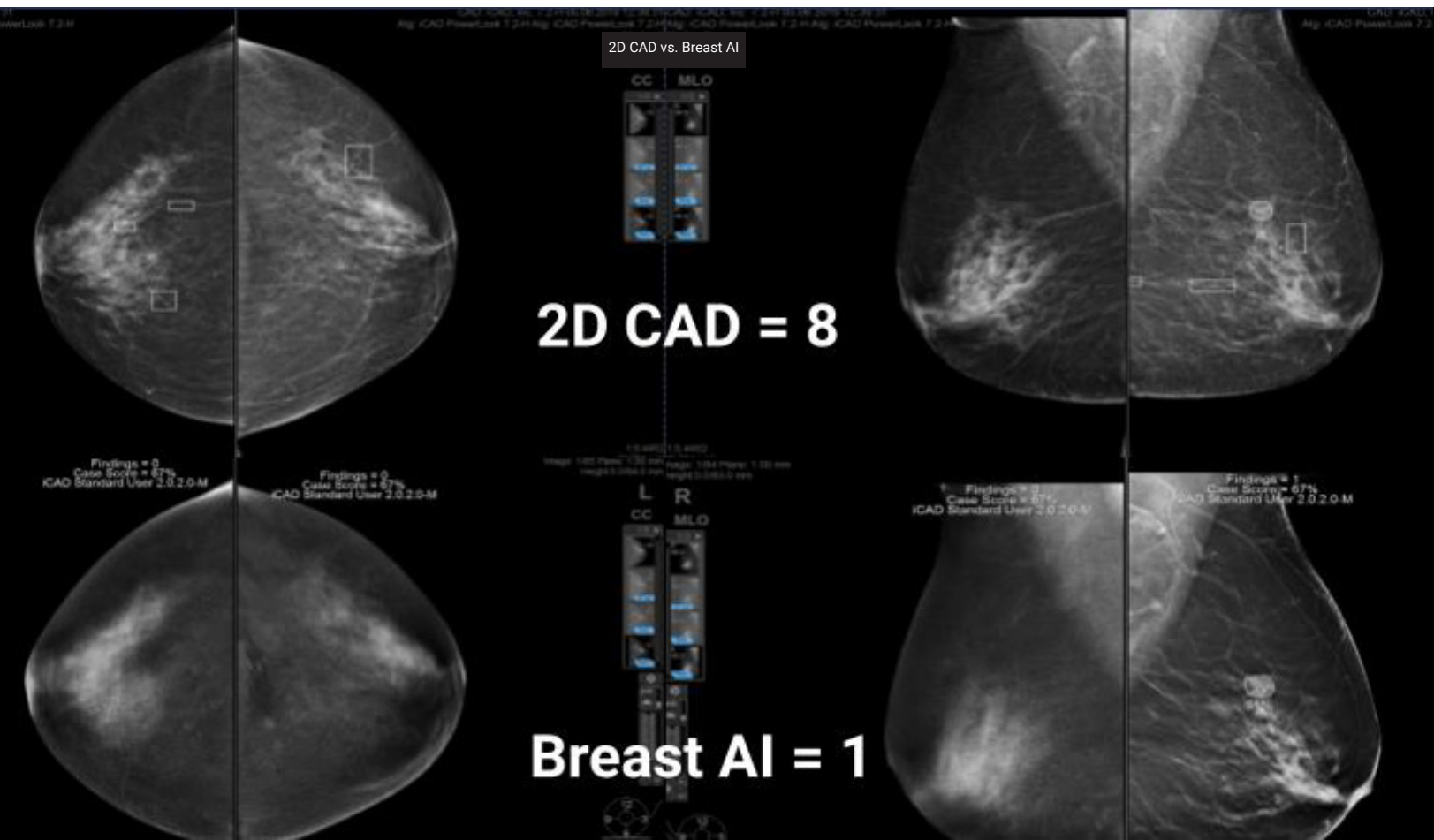
Breast AI removes the challenges of subjectivity in breast density reporting. Using full-field digital mammography (FFDM) or synthetic 2D images, it analyzes the dispersion and texture of breast tissue, delivering clinicians a consistent, accurate, and reliable patient-specific breast density assessment.



Clinical Support Decision Scorecard



Breast 1 may have a higher percentage of dense breast tissue by volume, but Breast 2 has the greater chance of obscuring a cancerous lesion



Personalized Breast Cancer Screening

Breast AI offers an equitable and inclusive approach to precision screening.⁴ It factors in clinically relevant global screening guidelines and more than 15 country incidence and mortality reference tables, for alignment with that country's general population. Breast AI incorporates multiple risk factors found in a screening mammogram:

- Age
- Breast Density
- Subtle Mammographic Features

This solution offers the highest AUC available 0.80 (95% CI: 0.76, 0.83) for providing a one-year future risk estimation based only on a screening mammogram.⁵ This advanced solution provides superior insights,^{1,2} that empower clinicians to tailor breast screening regimens and potentially identify cancers earlier, when they may be more easily treated.

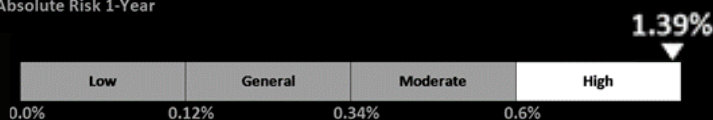
Customizable Reporting

Incorporate results directly into existing PACS, EHR, worklist, notification, and dictation systems ensuring exams are read more consistently and users have less clicks. Customizable output options of relevant clinical information. Image workflow and information workflow selectable outputs supported.

Breast Cancer Screening results include the short-term breast cancer risk category [low, general, moderate and high]

Patient Name: aecth0000002
Patient ID: aecth0000002
Patient DOB/Age: 071Y
Accession #:
Study Date: 10/14/2014 12:07:06 PM

ProFound AI® Risk: DBT
Absolute Risk 1-Year



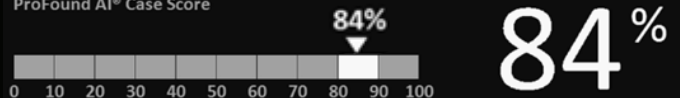
Average Risk at Age 71: 0.45%

H 1.39%

Patient Name:
Patient ID:
Patient DOB/Age:
Accession #:
Study Date:

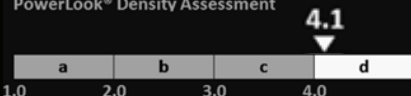
ProFound AI®
PowerLook® Density Assessment
ProFound AI® Risk

ProFound AI® Case Score



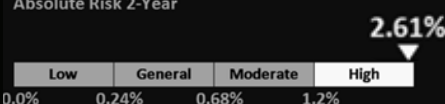
84%

PowerLook® Density Assessment



d⁻

ProFound AI® Risk: FFDM
Absolute Risk 2-Year



H 2.61%

Average Risk at Age 50: 0.44%

The Arterys Platform Benefits

Cloud-based Supercomputing	Zero Footprint Diagnostic Web Viewer	AI Augmentation, Interaction	Clinical Workflow Integration	Secure and Resilient
<ul style="list-style-type: none"> ✓ Blazing fast processing of imaging data with Multi GPU based rendering ✓ No heavy IT infrastructure required on-prem! ✓ Elastic scalability means you never have to worry about performance ✓ Low maintenance, always up-to-date, no-cost automatic continual updates 	<ul style="list-style-type: none"> ✓ Access images and tools anywhere ✓ All you need is internet ✓ Easily share cases and workspaces ✓ FDA and CE Cleared ✓ Fully interactive real-time visualization of DICOM images ✓ Web-based zero footprint viewer with full-screen mode ✓ Mac, PC, tablet and phone 	<ul style="list-style-type: none"> ✓ More consistent, accurate diagnostics ✓ Eliminates tedious and error-prone manual tasks ✓ CE marked & FDA cleared algorithms ✓ Data-driven decisions ✓ Vendor neutral AI, easily integrate any algorithm into clinical workflow 	<ul style="list-style-type: none"> ✓ Speed diagnosis with automated reporting ✓ Improve physician collaboration across geography ✓ Inject results and image/video into your reports. ✓ Study in-context URL launching with single sign-on means Arterys automatically moves with your workflow 	<ul style="list-style-type: none"> ✓ GDPR, HIPAA, SOC2 ISO 27001, Information Security Certified ✓ World class security comes standard, with ISO-27001, SOC-2 and HIPAA requirements for data security. ✓ Constant monitoring of adverse events maximize uptime, impact. ✓ Real-time interactive support is also available through in-app chat feature

System Requirements

Arterys is completely hosted in the cloud using Amazon Web Services (AWS) servers in several regions accessible globally through a Microsoft Edge or Google Chrome web browser by navigating to <https://app.arterys.com>

Internet Speed 3 Mbps up/down Internet connection with a maximum of 100 ms latency.

Website Access WebGL is enabled on the device used to access the Arterys website. WebSocket is not blocked.
Consistent experience across Mac, PC and mobile devices.
 Zero foot-print viewer no software installation required.

Browser Google Chrome Web Browser version 82 or above.
 Microsoft Edge Web Browser version 80 or above.

Edge Service Custom software installed on a server within the hospital network or in the cloud to automate the sending of DICOM objects from the scanner to the cloud and to PACS while ensuring that the patient's protected health information (PHI) remains within the hospital network (refer to Edge Data Sheet)

1. iCAD data on file.

2. iCAD ProFoundAI FDA filing: K203822.

3. Conant E, Toledano A, Periaswamy S, et al. Improving Accuracy and Efficiency with Concurrent Use of Artificial Intelligence for Digital Breast Tomosynthesis. *Radiol Artif Intell.* 2019 Jul 31;1(4):e180096. doi: 10.1148/ryai.2019180096

4. Eriksson M, Czene K, Strand F et al. Identification of Women at High Risk of Breast Cancer Who Need Supplemental Screening. *Radiology.* 2020; 297(2): 327-333. doi.org/10.1148/radiol.2020201620. Epub Sep 8.

5. iCAD ProFound AI Risk for DBT 1-year AUC performance: 0.80 (95% CI: 0.76, 0.83); ProFound AI Risk for FFDM 2-year AUC performance 0.73 (95% CI: 0.68, 0.77). Performance varies by mammography system..

The Arterys Platform with Premium Applications

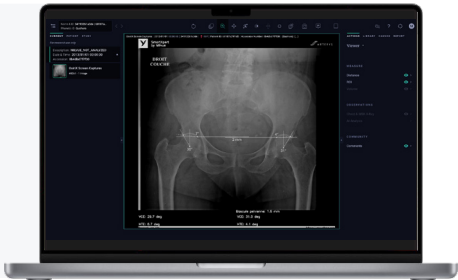
CARDIO AI MR



LUNG AI



CHEST | MSK AI XR

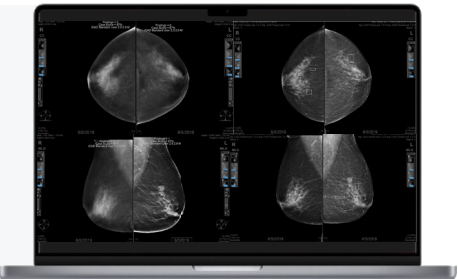


NEURO AI



BREAST AI

AI powered by *iCADx*



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Software version 28.8