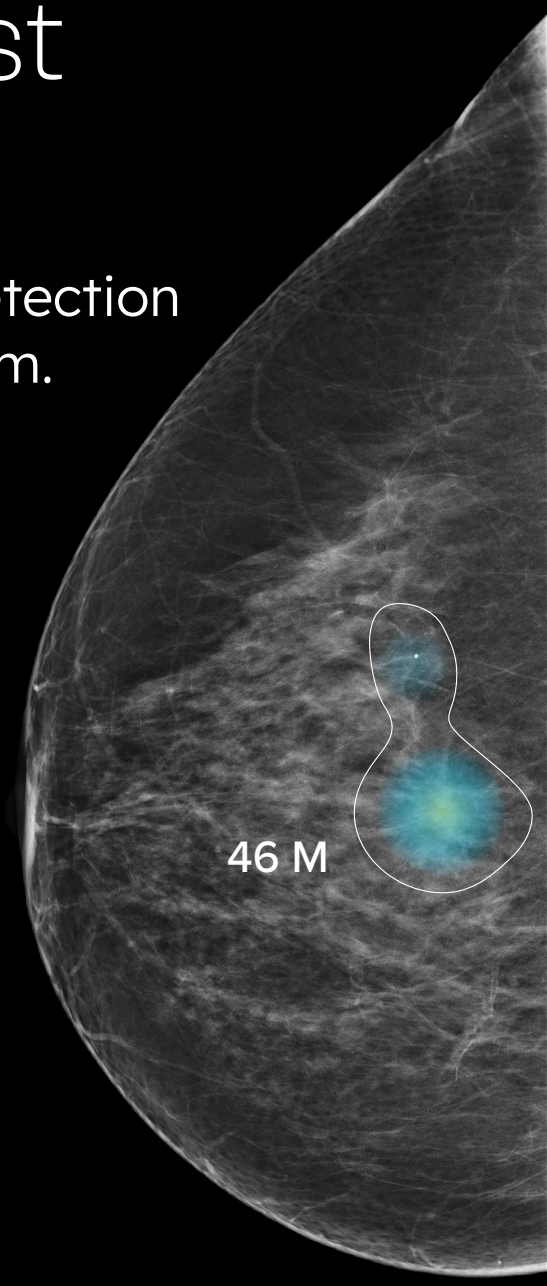
Lunit

The Lunit Ecosystem: Transforming Breast Cancer Care

Unifying risk, quality, density, and detection within a single, AI-powered ecosystem.



The Era of the Ecosystem

Why Ecosystems Matter Now

Healthcare is entering the era of the ecosystem. Just as no part of a living system thrives in isolation, no single tool in breast cancer screening can achieve the best outcomes alone. When the right parts work together, radiologists gain time, patients gain confidence, and health systems unlock measurable impact.

Today, radiology faces mounting pressures. The industry is rapidly shifting toward a need for full-suite, integrated platforms that streamline workflows and scale across sites. In breast cancer screening, this evolution is especially critical – the tools to save lives are at our fingertips. The question is: why not use them?

Artificial intelligence (AI) in breast imaging has evolved significantly since the early days of computer-aided detection (CAD) and is having a positive impact on radiologists, patients, and healthcare centers worldwide.

Lunit is leading this transformation. By uniting intelligent, AI-powered products across the screening pathway, the Lunit Breast Cancer Ecosystem is intended to accelerate detection, strengthen clinical confidence, and support more personalized care.

> "We're entering a new phase of AI adoption – where AI no longer just supports radiologists but becomes an essential part of healthcare itself. The true value of AI is in connecting data across the entire diagnostic journey.
>
> Ultimately, this isn't just about detecting cancer earlier.
>
> It's about rethinking how we predict, detect, and manage breast health as a connected, data-driven continuum."
>
> **Brandon Suh,** CEO, Lunit



The Power of One Ecosystem, One Partner

Lunit delivers a comprehensive breast cancer screening ecosystem that spans **quality, density, risk, detection, and patient management**. The days of relying on hardware OEMs or fragmented point solutions are gone. By partnering with a single, proven AI vendor, your team gains consistency, interoperability, and scalability across your care settings and workflows.

We have been at the **forefront of breast cancer innovation** for over 15 years. Our ecosystem is built on diverse datasets, grounded in science, and backed by robust clinical validation — ensuring it's applicable across disparate populations and reliable in the real world. It fits naturally into your current workflows and integrates with a number of systems.

What sets us apart isn't just the technology, it's the people behind it. Our team includes seasoned radiologists, technologists, radiology managers, and PhDs. So when you have questions, you're not just talking to a vendor — you're talking to people who understand your world and how our products fit into it. You also have the ongoing support of a dedicated customer success manager and access to our exclusive online community, empowering your team to demonstrate measurable outcomes and refine your use of AI.

At Lunit, we're not just improving breast cancer screening — we're redefining what's possible when technology, clinical expertise, and partnership come together.
Are you ready to join us?

Streamline. Scale. Succeed.

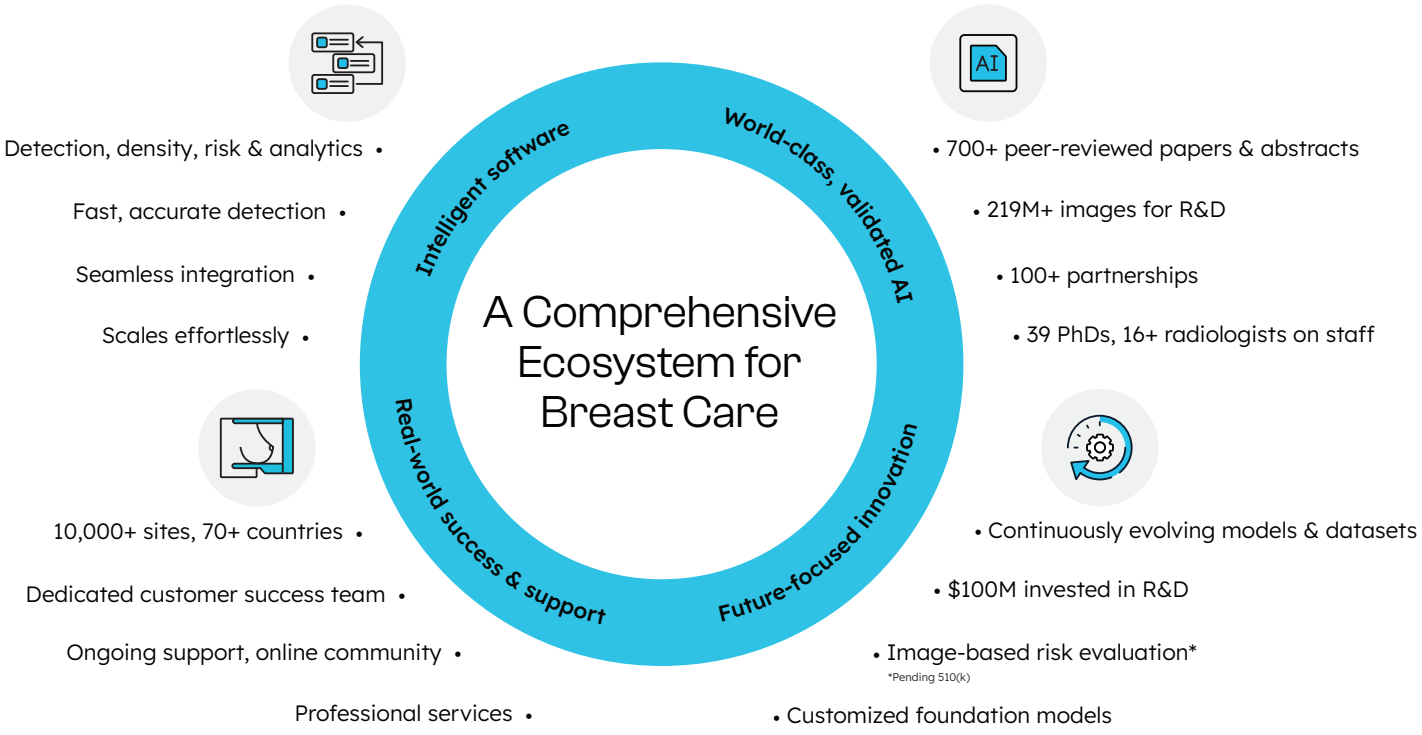
One ecosystem, infinite insight
Detection, density, risk, quality, and compliance — all from one vendor. Designed to give you greater confidence and help you find more cancers, earlier.

Flexibility & scale
Ideal for mixed environments, our ecosystem works across mammography manufacturers and PACS systems for a standard approach to optimizing your screening program.

Simplified procurement, unified data
A single contract, integration, cloud-based implementation options, and analytics framework for easier IT management and data consistency.

Future-proof investment
A SaaS subscription model ensures you have the latest and greatest as AI evolves — no need for additional purchases as new technologies emerge.

Proven approach
Deployed across 10,000+ sites in over 70 countries, with measurable improvements in image quality, efficiency, and early detection.



An AI-powered breast ecosystem that connects every step of the screening pathway.



Risk Pathways™
Identifies patients at elevated breast cancer risk, quickly and easily.



Analytics™
Objective insights to improve image quality, staff performance, and compliance.

Volpara® Live™
Provides on-the-job feedback to optimize technologists' positioning and compression.



Lunit INSIGHT® Breast Suite
Helps detect cancers earlier and more accurately in 2D and 3D mammography reading, even in dense breasts.

Lunit INSIGHT® Image-Based Risk
Estimates a woman's 5-year risk of developing breast cancer using only mammographic images and age.*



Volpara® Scorecard™
Consistent, objective breast density assessments to support screening decisions.



Patient Hub™
Automates and improves patient tracking, reporting, and communications.

Lunit INSIGHT® Image-Based Risk*: Transforming how we understand and predict breast cancer risk

Our image-based risk model aims to predict a woman's future 5-year risk of breast cancer using only screening mammography and age—no questionnaires or manual inputs required.

It is designed for women with negative screening exams, focusing on future risk rather than current disease, and supporting radiologists to help inform personalized screening and prevention.

- Uses only age and routine FFDM or synthetic 2D images—removing dependency on incomplete clinical data and enabling scalable, equitable risk.
- Designed to output calibrated and absolute risk scores aligned to SEER incidence, supporting clear and confident clinical interpretation.
- Trained and validated exclusively in cancer-free screening populations, ensuring prediction of future likelihood—not detection of existing lesions.
- Part of Lunit's broader ecosystem spanning risk and detection, integrating seamlessly into existing screening workflows without added burden.



*The related product is currently under 510(k) review and is not yet commercially available. Its function or intended use may be subject to change.

Lunit

The Lunit Breast Cancer Ecosystem in Action

Lunit INSIGHT® Breast Suite

Strengthen Your Foundation for Earlier Cancer Detection

AI-powered software that improves accuracy and efficiency in 2D and 3D mammography reading.

Rising workloads and complex imaging put pressure on teams

On a daily basis, radiologists are facing rising case volumes, complex imaging, and staff shortages — leading to additional strain on already overburdened teams and affecting patient outcomes.

It's more important than ever that clinics have the support they need to speed up and streamline detection across 2D and 3D mammography.

Proven performance for earlier, more accurate breast cancer detection

The Lunit INSIGHT® Breast Suite combines AI for 2D (Lunit INSIGHT MMG) and 3D (Lunit INSIGHT DBT) mammography into a single, connected platform. It supports radiologists in detecting cancers earlier and more consistently, even in dense tissue, and reduces false positives and unnecessary callbacks.

Designed to integrate seamlessly into PACS and viewer workflows, the Lunit INSIGHT Breast Suite helps radiologists focus on high-priority cases and manage growing workloads with confidence.

Key benefits & real-world impact

- **Detect cancers earlier and more consistently**, especially in dense breasts, with AI-driven malignancy scores and lesion highlights. Lunit INSIGHT DBT **correctly localized nearly one-third of interval cancers** on screening mammograms in a recent study[1].
- **Reduce false positives**, improving patient experience and workflow efficiency.
- **Classify lesions with clarity** — masses (includes asymmetry and distortion) or calcification or both, and current-prior comparison to support confident decision-making.
- **Speed up reading** with auto slice navigation and streamlined AI-guided workflows.
- **Built on a diverse, biopsy-rich dataset** — offering real-world generalizability.

> "They tell me: you're finding the smallest cancers we didn't see before. It's making a real difference… with AI, we're not just reading images faster – we're changing lives."
>
> **Dr. Megha Gupta, MD**
> Breast and Body Radiologist, Sol Radiology, Victorville, California on Lunit INSIGHT MMG

Fewer false marks

94% reduction in false positive marks[2] (MMG)

More confidence with dense breasts

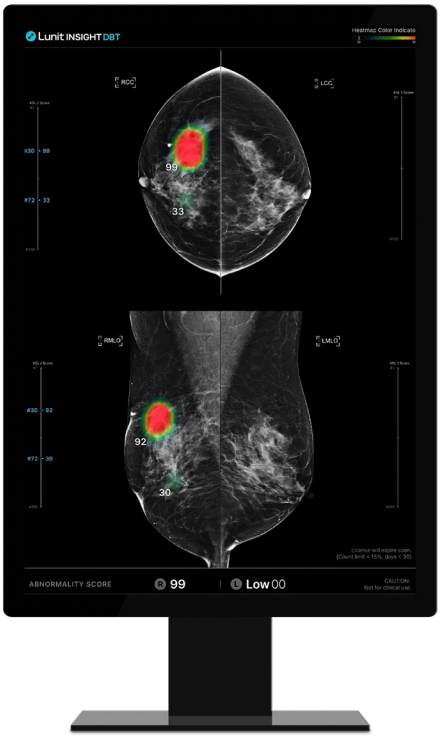
89% sensitivity in dense breasts[3] (MMG)

1.38 extra cancers for every 10 detected

13.8% increase in cancers detected in screening mammography[4] (MMG)

Less time on reading cases

13% reading time reduction on all cases[5] (DBT)



This product is not available for sale or distribution in all countries.

Risk Pathways™

Automated Risk Evaluations for Proactive, Personalized Care

A multi-cancer risk assessment solution that simplifies evaluations, connects workflows, and supports enterprise-wide precision care.

Manual workflows make meaningful risk insights harder to achieve

Cancer risk assessment often relies on paper questionnaires and manual data entry across multiple systems. This can slow down workflows, make it harder for clinics to collect crucial patient data, and cause delays in identifying and managing high-risk patients — when early action matters most.

Accurate risk assessments with less effort

Risk Pathways™ streamlines cancer risk assessment by automatically integrating patient data into a single workflow, helping clinicians gain clearer insights with less manual effort.

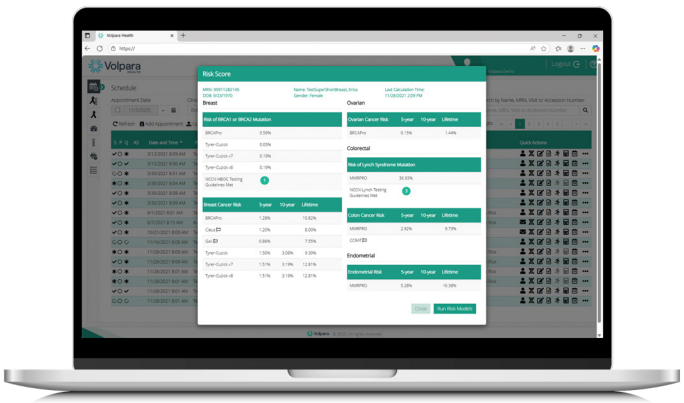
It supports multi-cancer risk evaluation, recommending personalized care paths including genetic testing, medications, lifestyle changes, and screening adjustments.

As part of an enterprise strategy, Risk Pathways supports consistent, precision care across all points of entry — ensuring every woman receives the same level of attention, wherever she enters the system.

Key benefits & real-world impact

- **Identify high-risk patients sooner** with automated, integrated risk scoring across multiple validated models — including Tyrer-Cuzick, Gail, Claus, BRCAPRO, and more.
- **Support multi-cancer risk assessment** for breast, colorectal, endometrial, ovarian, prostate, and pancreatic cancers — enabling personalized care paths.
- **Simplify genetic testing workflows** by ordering and tracking tests through integrated lab partnerships.
- **Deep Epic® integration** reduces duplicate data entry, enables risk assessment at every patient encounter, and keeps care team decisions aligned in the EHR.
- **Standardize risk assessment across the enterprise —** from imaging centers to OB/GYN and primary care — so every woman receives consistent, precision care.
- **Remain compliant** with NCCN, USPSTF, and ACS clinical guidelines.
- **Quick, confident decision-making** helps patients understand their risk and take proactive steps toward prevention.

> “We have a 56-year-old patient whose life was changed by understanding her risk and getting access to additional imaging beyond her annual mammogram.”
>
> **Lisa Stempel, MD,** Division Chief of Breast Imaging, Rush University Medical Center



15+
years' experience supporting risk assessment programs.

3M+
assessments conducted per year*.

*Data on company file
This product is not available for sale or distribution in all countries.

Lunit

Analytics™

Smarter Insights for Objective, Compliant Mammography

Actionable insights to improve image quality, support staff development, and maintain compliance.

Consistent, high-quality mammograms aren't always easy to achieve

Without objective feedback and ongoing insights, technologists may struggle to understand what affects image quality or compression — leading to repeat exams, workflow delays, and added pressure. These challenges also make it harder for facilities to meet performance standards and stay compliant with regulations like MQSA.

Take control of quality, performance, and compliance

Analytics™ delivers objective, actionable feedback to help technologists improve positioning and compression. Our proprietary TruPGMI® and TruPressure® metrics give precise insight into image quality and consistency across staff and equipment.

Compliance for ACR accreditation selection is streamlined, and EQUIP image review forms are automatically generated. Plus, seamless integration with EHR, PACS, and other existing systems simplifies clinic workflows and reduces manual data entry.

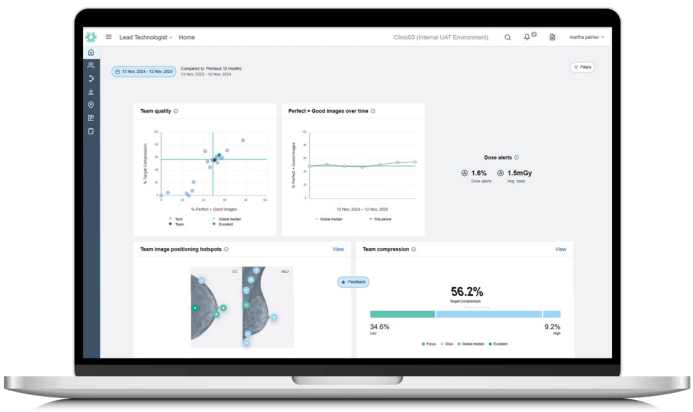
ACR accreditation

We have qualified for the American College of Radiology® (ACR®) Learning Network Vendor Partner designation. As part of the ACR ImPower Program's Mammography Positioning Improvement Collaborative, we partner with participating sites to use Analytics in identifying opportunities to improve breast cancer detection through optimized mammography positioning.

Key benefits & real-world impact

- **Ensure consistent, high-quality imaging** with TruPGMI positioning and TruPressure compression feedback on every mammogram.
- **Empower technologists with personalized coaching**, dashboards, and on-demand learning resources.
- **Strengthen MQSA compliance** and stay inspection-ready with built-in document storage via Quiver.
- **Improve efficiency with integrated workflows** that reduce manual effort and retakes.

> "We can't go back; we won't go back. The use of Analytics for our reporting requirements has saved us."
>
> **Shelley Conkey**
> Mammography Manager, University of Utah



1500+
sites in the US use Analytics to maintain their quality*.

78%
reduction in repeats and recalls reported by Virginia Mason in a study using Analytics[6].

15
minutes per site vs. 2-3 days by automating MQSA reporting at Spartanburg Medical Center[7].

*Data on company file
This product is not available for sale or distribution in all countries.

Volpara® Live™

Improve Image Quality and Performance at the Point of Care

On-the-job, AI-powered feedback on mammogram positioning and compression that builds confidence.

Technical repeats or recalls disrupt workflow and increase patient stress

Variations in staff technique and patient anatomy can sometimes make it tricky to capture consistently high-quality images—technologists often don't know whether the positioning and compression are sufficient until after the scan has been completed.

When exams need to be repeated, the impact goes beyond workflow delays. Each repeat adds strain to busy teams, increases costs, and can heighten anxiety for patients waiting on results.

On-the-job feedback for confident, consistent imaging

Volpara® Live™ provides on-the-job feedback on image quality and compression during the mammogram. Powered by our proprietary TruPGMI® and TruPressure® metrics, technologists can immediately identify positioning or compression issues and adjust technique on the spot. This feedback loop enhances learning, builds confidence, and helps staff continually refine their skills with every patient.

Embedded directly into the technologist workflow, Volpara Live ensures that imaging quality remains consistent, best practices are met, and every patient receives the same standard of care.

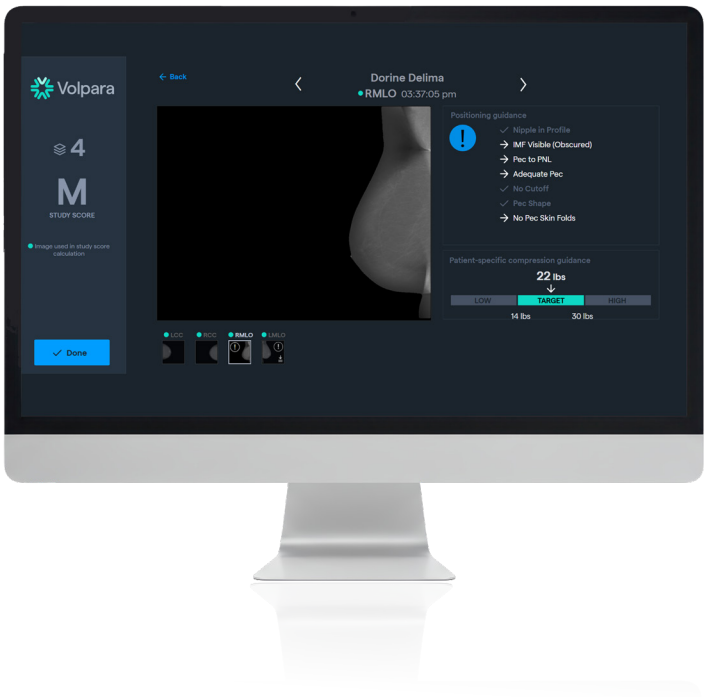
Key benefits & real-world impact

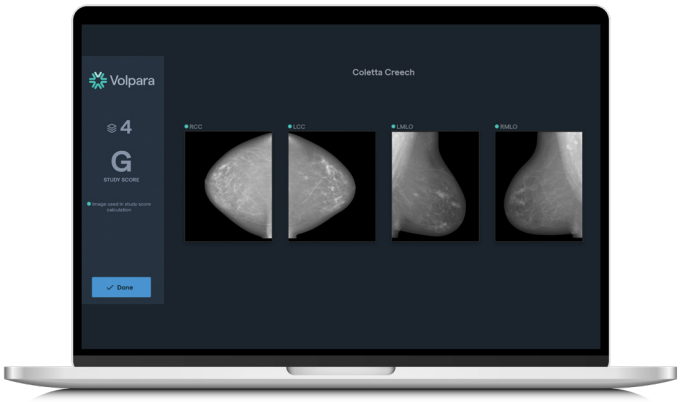
- **Ensure high-quality imaging** from technologists with on-the-job feedback.
- **Reduce image variation** across technologists and locations.
- **Boost patient confidence** with visible, real-time quality tools.
- **Supports a system-wide culture of consistency** in breast imaging.

It's as easy as 1, 2... that's it!

1. Start imaging
2. Volpara Live will engage as soon as an image or study is accepted/sent to PACS

Easy! No login PIN needed for image assessment or review.





This product is not available for sale or distribution in all countries.

Lunit

Volpara® Scorecard™

AI-Powered Breast Density Assessments to Support Screening Decisions

Objective density assessment software for clearer screening decisions and more confident follow-up care.

Accurately assessing breast density is critical, but not always simple

Assessing breast density accurately is vital for identifying women at higher risk of breast cancer.

Without objective, quantifiable measures, it's harder to provide clear evidence for supplemental screening, and patients with dense breast tissue may miss out on essential imaging while still in the clinic. These gaps add cost, strain, and the risk of missing early detection—when it matters most.

Consistent volumetric insights you can rely on

Powered by our FDA-cleared TruDensity™, Volpara® Scorecard™ provides objective, volumetric density measurements for consistent and reproducible breast density assessments. As the only breast density assessment software validated for use with Tyrer-Cuzick v8 (TC8), it provides precise data to support lifetime breast cancer risk assessment—helping identify patients who may need additional imaging or preventive measures.

When combined with Risk Pathways and Lunit INSIGHT MMG/DBT, Volpara Scorecard can give a consolidated view of a patient's risk factors.

> "The key improvement that Volpara brings to density reporting is an objective, reproducible density value that can be used in risk assessment models."
>
> **Professor Jack Cuzick, developer of TC8**

Key benefits & real-world impact

- **Deliver consistent, objective breast density measurements** using TruDensity™ volumetric analysis.
- **Reduce variability in assessments** between clinicians, improving confidence in screening and follow-up decisions.
- **Support risk-based patient management** with validated integration into Tyrer-Cuzick v8.
- **Provide clear, patient-friendly letters** with Thumbnail™ that enhance communication and compliance.

23M+

Scorecards processed, as of February 2026.*

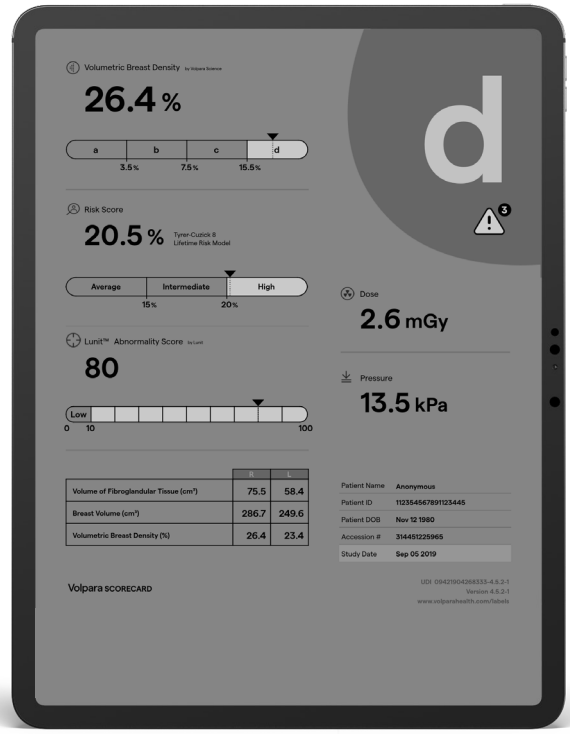
96%**

of radiologists agree with our density assessment.

4.5%

of patients may have changes to their medical management when Volumetric Breast Density is used in TC8.[8]

> "We have found Volpara to decrease inter and intraobserver variation in breast density determination, thereby optimizing the care of our patients."
>
> **Kathy Schilling, MD,**
> Boca Raton Regional Hospital



The Abnormality Score feature is currently available at the standard threshold of 10.

*Data on company file.
**Data on company file. Analysis from 36,642 cases across four clinics.
This product is not available for sale or distribution in all countries.

Patient Hub™

Simplifying Mammography Reporting and Patient Tracking

Fast, efficient, and compliant mammography patient tracking software.

Manual reporting workflows can slow communication and care

At high-volume screening sites, managing reports, coordinating patient follow-ups, and handling administrative tasks can be complex and time-consuming.

Manual processes increase workloads and can cause inconsistent communication between radiologists, referring providers, and patients.

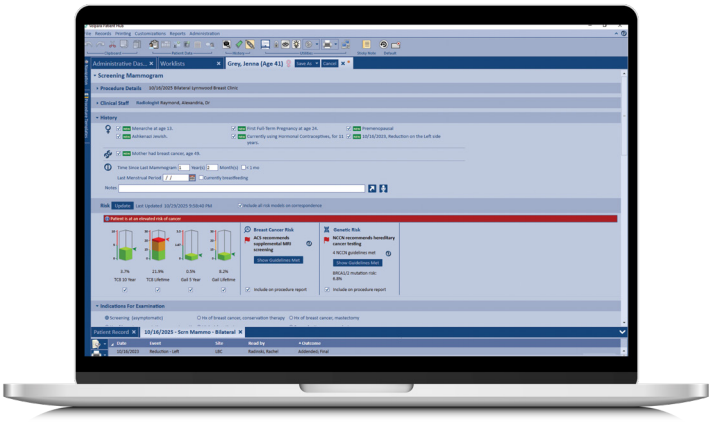
Streamlined patient tracking and communication workflows

Patient Hub is a vendor-neutral software used by leading breast imaging centers to deliver high-quality, timely care in their communities. Whether used as a stand-alone patient-tracking software or as part of a broader risk-informed workflow, Patient Hub keeps patients engaged, informed, and on track.

Patient Hub integrates into existing RIS, PACS, and EMR systems, helping your team manage every step of the reporting and follow-up process in one place. The software also has worklists that can be set up for separate roles in the clinic, so it can fit easily into your current workflow.

Key benefits & real-world impact

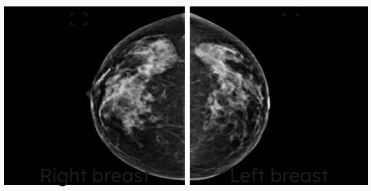
- **Reduce manual steps, improve reporting accuracy,** and accelerate turnaround times with the Enhanced Results Interface.
- **Ensure MQSA compliance** with standardized, easy-to-understand patient letters.
- **Improve operational workflow efficiency –** empower your team to work quickly and intelligently with customizable worklists.
- **Ensure consistent and compliant communication** through automated patient and provider outreach.
- **Simple risk assessment integration –** pair Patient Hub with Risk Pathways to identify high-risk patients and deliver screening recommendations that align with national guidelines.



Empowering patients with Thumbnail™

Thumbnail helps patients understand their breast density through image-enhanced mammography results letters that include two non-diagnostic breast images and a clear explanation of their density category. Thumbnail transforms patient education into an engaging experience—delivering interactive content instantly through a simple QR code for seamless care involvement.

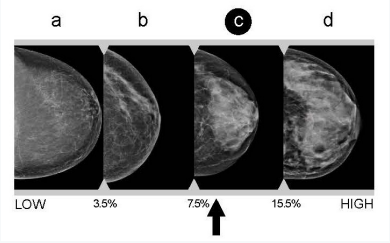
1 **Your mammography images**



2 **Your breast tissue composition**

Your breast composition is **c** (8% volumetric breast density). This means that you have high breast density.

3



4 For more information about breast density and what to ask your doctor, visit **www.lunit.io/en/patients/breast-density-explained/**

5 **https://www.lunit.io/en/patients/breast-density-explained/**

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Lunit

Powered by Science, Driven by Customers, Focused on the Future

Lunit is transforming how the world detects and treats breast cancer—boldly, intelligently, and with humanity at the core. Our solutions are grounded in clinical evidence, our services are innately focused on your success, and our vision for the future is revolutionary.

Built on validated, world-class AI

Objective, physics-based algorithms	Robust algorithms built on a deep understanding of mammography physics, biology, and clinical practice.
Access to images and clinical data	Secure access to mammographic images linked to clinical data means continued improvement for our products.
219M+ images for R&D	Our large dataset ensures all populations are represented and allows us to benchmark performance.
700+ peer-reviewed papers & abstracts	Don't just take our word for it — our technology has been thoroughly researched and validated.

Real-world support and success, way beyond implementation

Dedicated customer success team	From day one, you'll have a dedicated customer success manager committed to your specific needs and goals.
Professional services to guide your team	Personalized, expert implementation guidance to ensure sound clinical workflows and the flexibility to take on new clinical pathways as needed.
Exclusive online customer community	Learn from other product users, share your knowledge, provide feedback to our product teams, and more.
One vendor means efficient workflows	One vendor, one ecosystem: reduce friction, streamline workflows, and scale efficiently across sites and skill levels.

Innovation driving the future of breast cancer care

Continuously evolving models & datasets	Our secure, cloud-connected AI solutions process millions of images, screening procedures, and risk assessments every month — advancing datasets and informing the ongoing evolution of our AI models and products.
Image-based risk evaluation	Developed at Washington University, and with FDA Breakthrough Device Designation, Lunit INSIGHT Image-Based Risk is designed to use only a patient's mammogram and age to predict five-year breast cancer risk. Pending 510(k).
Foundation Model Services (FMS)	Create custom AI models tailored to your unique environment, and adapted to local data and workflows — supported by scalable infrastructure and expert services.
Dedicated investment in R&D	Backed by 16+ physicians and 39 PhDs, and an investment of over $100M, our R&D team delivers deep learning algorithms that power diagnostic and therapeutic applications.

Lunit

Conquering Cancer Through AI

Join us in the future of breast cancer care.

Get in touch to learn more about the Lunit ecosystem — scan the QR code below.

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For full disclaimer, scan the QR code and refer to section 5.

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Individual results may vary. Testimonials are not intended to represent typical clinical outcomes.

*Product availability and regulatory status may vary by country. Some of the products featured in this booklet are not classified as medical devices. Please contact your local representative for details on the regulatory status and availability of specific products in your region.

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1. Bahl M, Langarica S, Lamb LR, et al. AI to Reduce the Interval Cancer Rate of Screening Digital Breast Tomosynthesis. Radiology. 2025. / 2. Lee, Si Eun, et al., Comparison of conventional CAD and AI-CAD applied to digital mammography in respect of false-positive marks, Journal of the Korean Society for Breast Screening, 2020 / 3. Destounis S et al. Using Volumetric Breast Density to Quantify the Potential Masking Risk of Mammographic Density. AJR Am J Roentgenol. 2017 Jan;208(1):222-227. doi: 10.2214/AJR.16.16489. Epub 2016 Nov 8. PMID: 27824483. / 4. Chang, YW, et al., Artificial intelligence for breast cancer screening in mammography (AI-STREAM): preliminary analysis of a prospective multicenter cohort study. Nat Commun 16, 2248 (2025). / 5. Eun Kyung Park, et al., Impact of AI for Digital Breast Tomosynthesis on Breast Cancer Detection and Interpretation Time, Radiology Artificial Intelligence, 2024. / 6. Eby PR, Martis L, Paluch J, Jang J, Chan A. Reduction in technical repeat and recall rate after implementation of artificial intelligence driven quality improvement software. 2022 RSNA Annual Meeting, Chicago, USA. / 7. Customer story: From nail-biting to confidence - https://www.volparahealth.com/news/customer-stories/from-nail-biting-to-confidence / 8. Destounis, S. V., et al. (2021, November–December). Impact on risk categorization with inclusion of mammographic density in the Tyrer-Cuzick model. Abstract presented at the Radiological Society of North America (RSNA) 107th Scientific Assembly and Annual Meeting, Chicago, IL.

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