FDA National Breast Density Notification Requirement

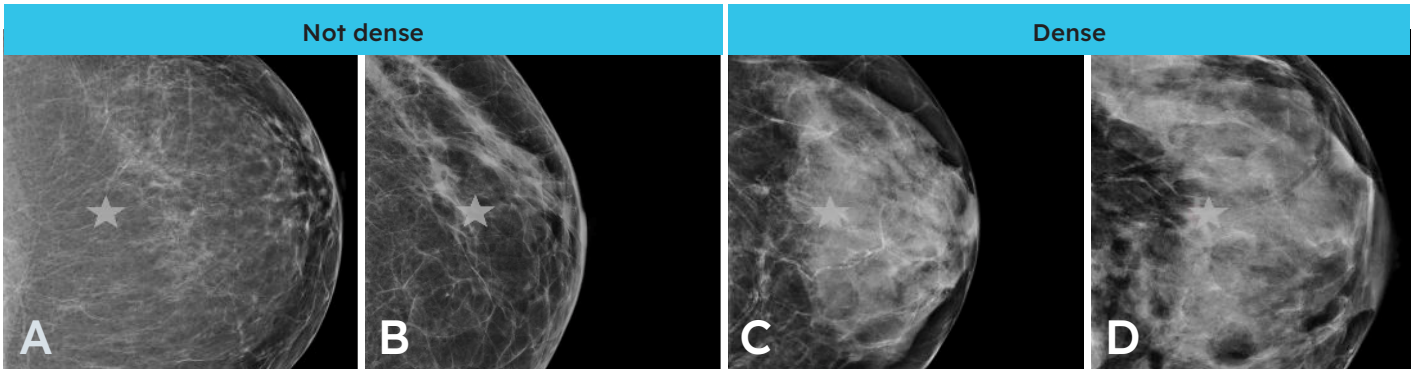
Dense breast tissue is common but has been linked to an increased risk for breast cancer and can also dramatically impact early detection. In the United States, nearly half of all women over 40 years old have dense breasts.[1] As breast density increases, the accuracy of mammography decreases.

The FDA announced changes to the **Mammography Quality Standards Act (MQSA)**, making breast density notification a federal requirement, **effective September 10, 2024.**

What you need to know	Patient standard language
The mammography report summary that is provided to patients must identify whether the patient has dense or non-dense breast tissue and includes a prescribed paragraph on the significance of breast density.	**The lay letter must include one of the following statements:** **NOT DENSE:** "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." **DENSE:** "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."
	Referrer standard language
Reports for healthcare providers must include an assessment of breast density using the BI-RADS® 5th Edition categories	Four classifications include: A The breasts are almost entirely fatty. B There are scattered areas of fibrograndular density. C The breasts are heterogeneously dense, which may obscure small masses. D The breasts are extremely dense, which lowers the sensitivity of mammography.

Your checklist

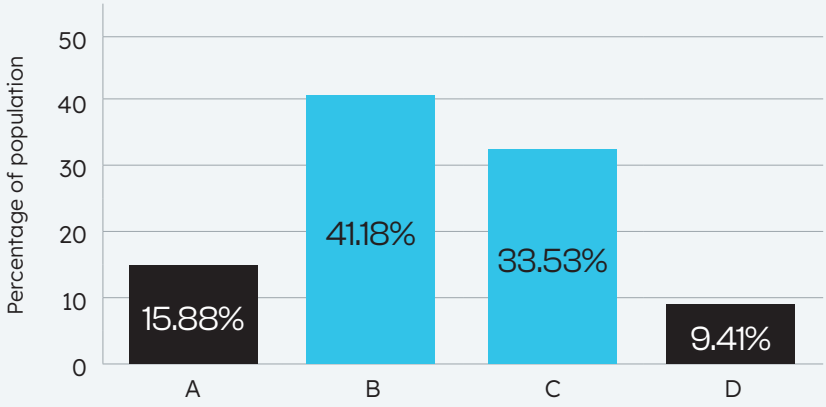
- ☐ Review **MQSA Rules**
- ☐ Consider your state-level language for insurance coverage
- ☐ **Contact** the MQSA program for assistance if needed
- ☐ Request letter content review from your legal team
- ☐ Update results letter template(s) and referrer reports in mammography reporting and tracking software
- ☐ Prepare/distribute referrer communication regarding report language changes
- ☐ Prepare/train patient-facing staff on new language
- ☐ Evaluate available educational content
- ☐ Work with vendor to optimize education and dense breast screening program



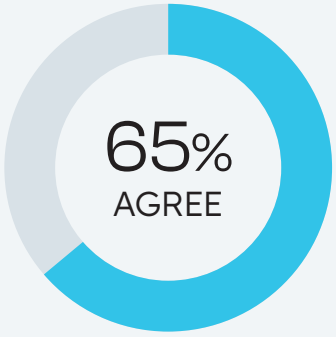
*The star in the images represents how cancer may be hidden on a mammogram.

Getting non-dense vs. dense right

Nearly 75% of patients will be assessed in either the B or C density categories.
Accurate classification between a BI-RADS B and C is essential.



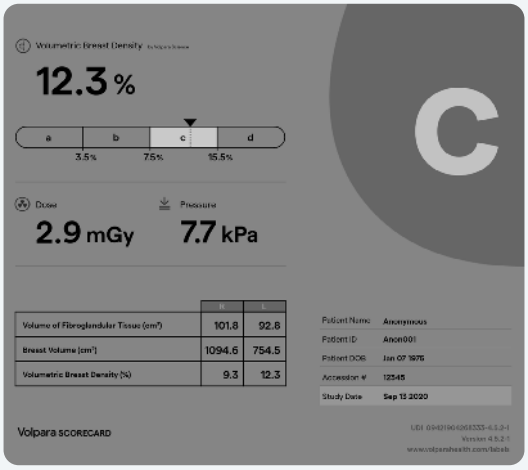
BI-RADS classification of breast density by categories A to D[2]

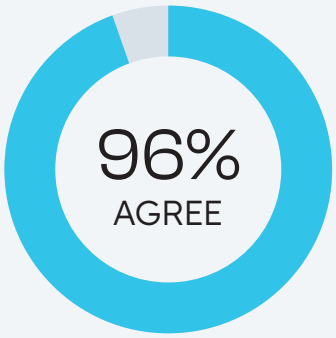


Two experts agreed about 65% of the time on a BI-RADS density category in a blind study.[3]

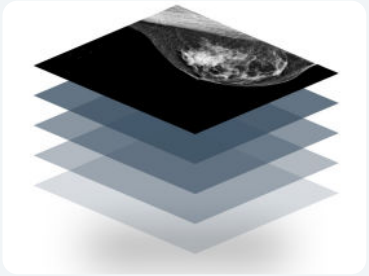
Volpara Scorecard: #1 tool for automated breast density assessment

Research has shown that radiologists who assess breast density visually assign density categories inconsistently.[4] The objective **TruDensity®** algorithm in **Volpara® Scorecard™** is proven to reduce reader variability. TruDensity automatically assesses the volumetric breast density percentage (VBD%) of each mammogram on a continuous scale. This differentiates each woman on a continuum of density—whether her density is a "high B" or a "low C." This gives the radiologist important insight to evaluate patients on the dense, non-dense threshold more precisely.





Radiologists typically agree with Volpara Scorecard's assessment of non-dense (A or B) or dense (C or D) 96% of the time.[5]



Over 23 million women worldwide have had their breast density assessed by our products.*

*Supported by internal data, February 2026.

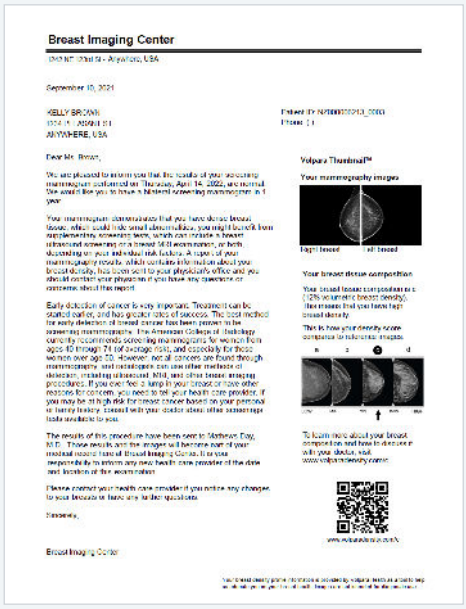
"We have found the product to decrease inter- and intra-observer variation in breast density determination, thereby optimizing the care of our patients."

Dr. Kathy Schilling, Lynn Women's Health Institute at Boca Raton Regional Hospital, Baptist Health

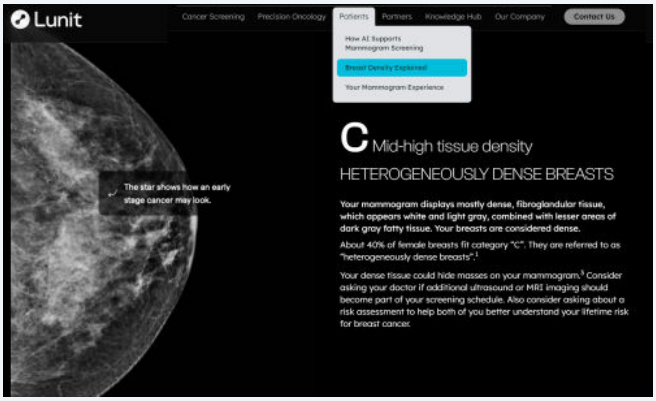
The TruDensity physics-based AI algorithm is cleared by the FDA, Health Canada, and TGA (Australia); is CE marked; and has been validated in more than **400 articles and research abstracts**.

Going beyond density inform to understanding + action

Thumbnail™ empowers patients to understand their breast density with image-enhanced mammography results letters. Patients are shown two non-diagnostic images of their breasts and an explanation of what their density category means in simple-to-understand terms and visuals.



Scan this QR code with the camera app on your cell phone for more about breast density.



Professional Services to lower your burden and unlock success

Our team of experts is available to help breast imaging centers educate referrers and patients, and to maximize the value of dense breast screening programs.

New dense breast screening program development

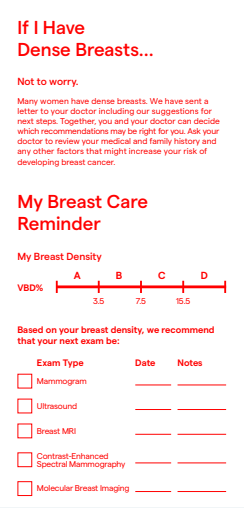
Project services include:

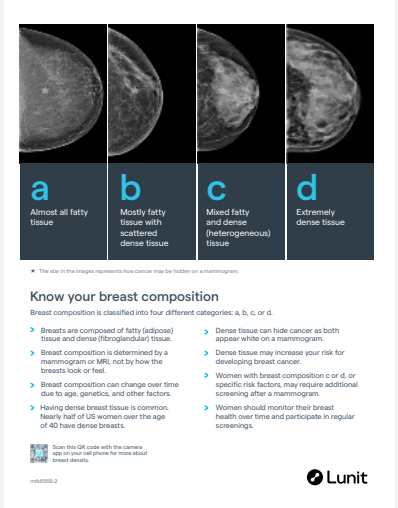
- Audit workflow, resources, and potential volume
- Goals and KPI identification
- Referrer and patient education
- Quarterly program audits/optimization

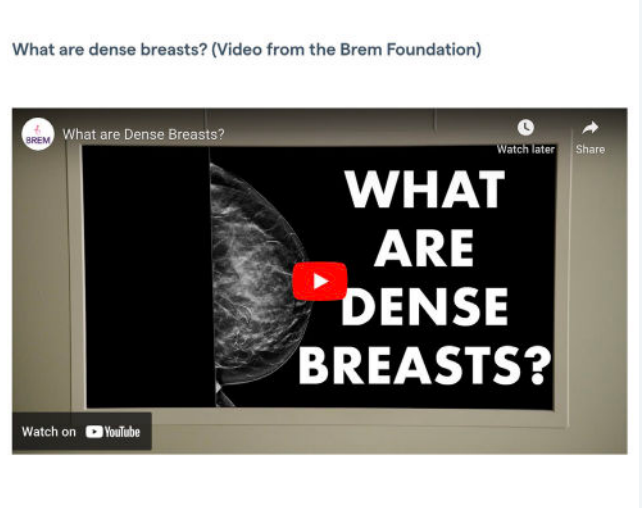
Breast density awareness and education services

Project services include:

- Referrer Lunch & Learns
- Ready to use patient education presentations
- Branded, customized digital and printed collateral
- Technologist and front desk scripts/training







The Find It Early Act: Closing the Gap in Breast Imaging Coverage

The nationwide law for density inform, introduced in 2024, is a key step towards helping those with dense breasts better understand their risk and the importance of other screening methods. However, it does not address coverage for these additional lifesaving screenings.

The Find It Early Act is a bipartisan federal bill introduced in the House and Senate that would require all health insurance plans to cover screening and diagnostic breast imaging at no out-of-pocket cost for women with dense breasts or those at higher risk for breast cancer.

By removing insurance barriers to additional imaging, the Find It Early Act supports earlier breast cancer detection and improves access to appropriate screening for women who need it most.

50 states + DC

required to inform patients of their breast density, as part of the federal density inform ruling

---

Risk Pathways provides a smooth workflow for healthcare providers to assess hereditary and lifetime breast cancer risk. Our volumetric breast density assessment is the only automated, continuous measure **validated for use** with the Tyrer-Cuzick v8 (TC8) Risk Evaluation Tool.

The product interfaces with major genetics labs – including Ambry, Myriad, Natera, and Invitae – to offer the freedom to select a preferred lab or work with multiple labs as needs and/or patient insurance coverage requirements change.

"The key improvement that Volpara brings to density reporting is an objective, reproducible density value that can be used in risk assessment models. These models are increasingly used to determine if a woman qualifies for MRI-based screening, and also to decide if the risk is high enough to warrant preventive therapy to reduce risk."

Professor Jack Cuzick, developer of TC8

References: 1. www.cancer.gov/types/breast/screening/dense-breasts / 2. Panta, Ritu & Shrestha, Shanta & Jha, Anamika. (2020). Glandular density distribution in digital mammography. Grande Medical Journal. 2. 5-9. 10.3126/gmj.v2i1.45080. / 3. Ciatto et al, The Breast 2005. / 4. Redondo A, Comas M, Macià F, Ferrer F, Murta-Nascimento C, Maristany MT, Molins E, Sala M, Castells X. Inter- and intraradiologist variability in the BI-RADS assessment and breast density categories for screening mammograms. Br J Radiol. 2012 Nov;85(1019):1465–70. doi: 10.1259/bjr/21256379. Epub 2012 Sep 19. PMID: 22993385; PMCID: PMC3500788. / 5. Data on company file. Analysis from 36,642 cases across four clinics.

Copyright © Lunit International Limited 2026. All rights reserved.

For full disclaimer, scan the QR code and refer to section 1.

Lunit International Limited, Level 4, 1 Victoria Street Wellington Central, Wellington, 6011 New Zealand

Document number: MM00328