



iReveal

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iReveal®, an automated breast density solution, is designed for radiologists that read mammography and want to standardize the assessment and reporting of breast density. iReveal helps radiologists identify patients whose dense breast tissue may impact the ability of a mammogram to clearly identify concerning lesions, and those who may benefit from supplemental screening or surveillance protocols. iReveal uses an appearance-based approach to automatically assess breast structure, texture, and fibroglandular dispersion, to determine the appropriate density category corresponding to BI-RADS standards. The results are automated, rapid, and reproducible.

Benefits include:

- Addresses clinical need to standardize breast density assessment between radiologists
- Delivers automatic and consistent breast density results across all patient populations
- Simulates the radiologist's diagnostic process to quickly and accurately assess breast density
- Assists in communication of breast density with referring physicians
- Provides a consistent protocol to manage the screening process

Clinical Relevance of Automated Breast Density

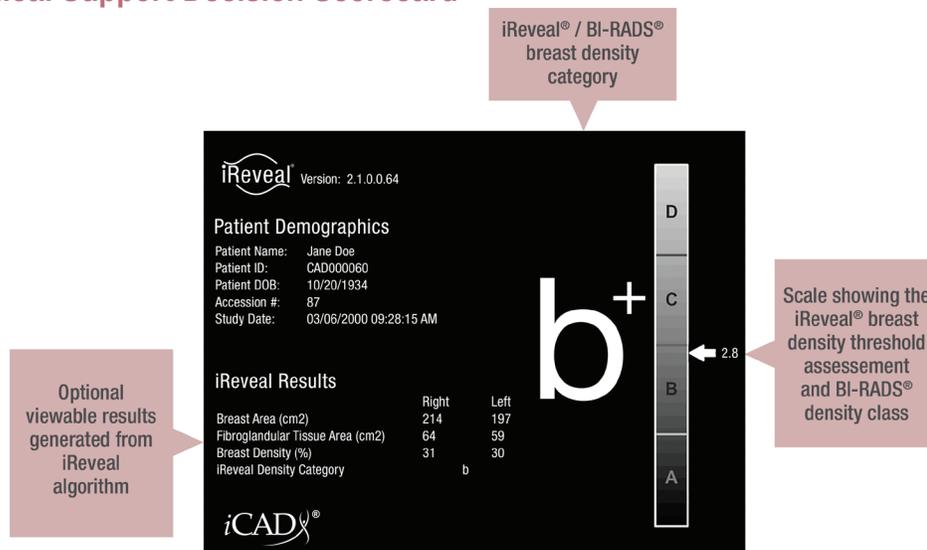
Mammography is considered to be the gold standard in breast cancer screening. However, mammography has been proven to be less effective in women with dense breast tissue. Patients may experience reduced sensitivity of digital mammography based on their dense breast tissue. There is also growing evidence that a higher percentage of dense breast tissue increases the risk of developing breast cancer.

Breast Density Statistics

- Approximately 50% of American Women have heterogeneously or extremely dense breasts¹
- Mammography is only 48% sensitive in dense breasts²
- As breast density increases, the risk of developing breast cancer increases³

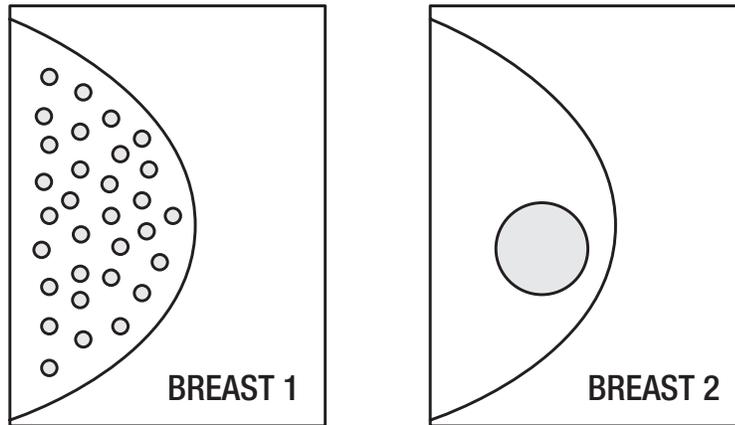
iReveal is designed to analyze dense tissue present in a mammogram. It identifies the risk of potentially masking a cancer, then maps the iReveal results to a density category corresponding to BI-RADS standards.

Clinical Support Decision Scorecard



Advanced Breast Density Algorithm

The iReveal algorithm uses an innovative technique that analyzes the structure, texture, and dispersion of the fibroglandular tissue. The breast density measurement is aligned with the new BI-RADS standard of identifying dense breast tissue in the breast that could be masking cancer. The masking risk is correlated to both the amount and distribution of fibroglandular tissue.



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.

In the above diagram, the focally dense structure in Breast 2 is more likely to hide a cancerous lesion by reducing the ability to visualize details and fine structures that could be a sign of a malignant abnormality. In this example, dispersion, in combination with percent breast density, best depicts results consistent with an expert radiologist's interpretation of breast density.

In a clinical study, iReveal was shown to have statistical agreement with a panel of 10 expert radiologists specializing in breast imaging when assessing the percentage of breast density of over 500 mammography cases. The radiologists' results were used to align iReveal's percentage of breast density to the BI-RADS breast density assessment categories. iReveal is a breast density assessment solution that radiologists can trust.⁴

1. Diagnostic Performance of Digital versus Film mammography for Breast-Cancer Screening, Pisano ED., et al, NEJM, 353:17, October 27, 2005 (2)
2. Individual and Combined Effects of Age, Breast Density, and Hormone Replacement Therapy Use on the Accuracy of Screening Mammography Ann Intern Med. 2003;138(3):168-175
3. Breast density and parenchymal patterns as markers of breast cancer risk: a meta-analysis. McCormack, Valerie A. and dos Santos Silva, Isabel, 6, Jun 2006, Cancer Epidemiol Biomarkers Prev, Vol. 15, pp. 1157-1169
4. Data on file at iCAD



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