

Automated Breast Density Assessment for Accurate and Objective Breast Density Scoring

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

Challenge:

Establishing meaningful, accurate, consistent breast density assessment.

Solution:

PowerLook[®] Density Assessment

Automatically and rapidly evaluates mammograms in much the same manner as experienced radiologists do: by analyzing the **structure, texture, and dispersion** of the tissue, rather than simply estimating total fibroglandular volume. PowerLook Density Assessment equips physicians with an innovative tool to employ into their existing mammography screening program.

Clinical Relevance of Automated Breast Density – Going Deeper Than Volume

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

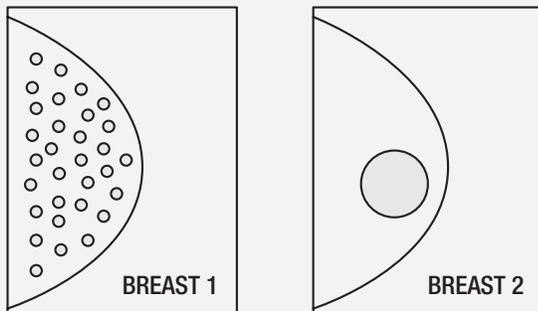
- Approximately 50% of American Women have heterogeneously or extremely dense breasts¹
- Mammography is only 48% sensitive in dense breasts²
- As breast density increases, the risk of developing breast cancer increases³

PowerLook Density Assessment adds a critical dimension to the analysis of dense breast tissue. It aligns with the BI-RADS 5th edition standard of identifying dense tissue in the breast that could be masking cancer. The masking risk is correlated to not only the amount, but also the **distribution** – the actual **dispersion** – of fibroglandular tissue. PowerLook Density Assessment is the only commercially available, FDA-cleared system that employs this scientific methodology.

Advanced Breast Density Algorithm

The PowerLook Density Assessment 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.

In the below 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.



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.

Clinical Support Decision Scorecard

BI-RADS® breast density category

PowerLook
DENSITY ASSESSMENT Version: 2.1.0.0.64

Patient Demographics

Patient Name: Jane Doe
 Patient ID: CAD000060
 Patient DOB: 10/20/1934
 Accession #: 87
 Study Date: 03/06/2000 09:28:15 AM

Density Assessment Results

	Right	Left
Breast Area (cm ²)	214	197
Fibroglandular Tissue Area (cm ²)	64	59
Breast Density (%)	31	30
iReveal Density Category	b	

iCAD®

b⁺

D

C

B

A

← 2.8

Optional viewable results

Scale showing the breast density threshold assessment and BI-RADS® density class

In a clinical study, PowerLook Density Assessment 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 PowerLook Density Assessment's percentage of breast density to the BI-RADS 5th Edition breast density assessment categories.

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