PowerLook® Density Assessment

Automated Breast Density Assessment for Accurate and Objective Breast Density Scoring

Challenge

Establishing meaningful, accurate, consistent breast density assessment.

Solution

PowerLook Density Assessment is an automated breast density solution that is designed to standardize the assessment of breast density in 2D and 3D[1] mammography. PowerLook Density Assessment assists radiologists in evaluating and scoring breast density to identify patients who may need supplemental screening or be at higher risk of developing breast cancer. This solution uses an appearance-based approach to assess dense tissue, to deliver automated, rapid and reproducible assessments of breast structure, texture, and fibroglandular dispersion. This innovative technique calibrates the patient's breast density to the appropriate density category corresponding to BI-RADS® reporting system.

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 – 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.

Breast Health Solutions

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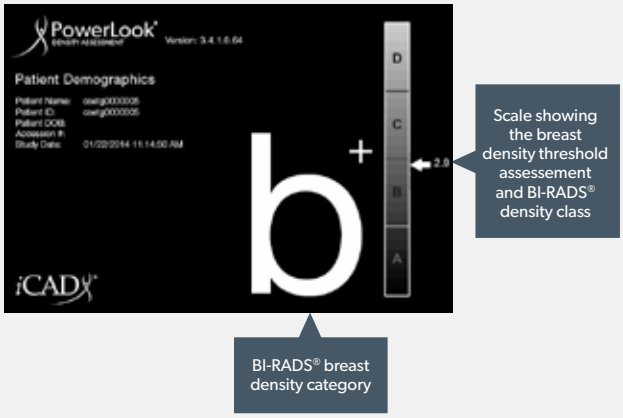
There is also growing evidence that a higher percentage of dense breast tissue increases the risk of developing breast cancer.

Breast Density Statistics

- Approximately 50% of American Women have heterogeneously or extremely dense breasts[2]
- Mammography is only 48% sensitive in dense breasts[3]
- As breast density increases, the risk of developing breast cancer increases[4]

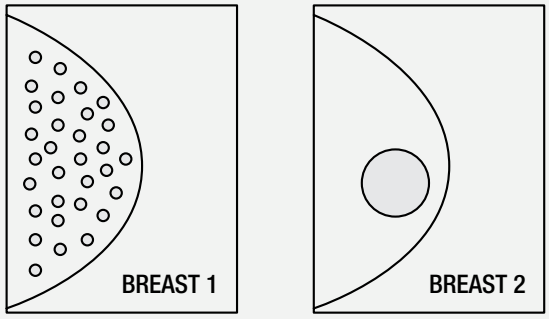
Clinical Support Decision Scorecard



PowerLook Density Assessment adds a critical dimension to the analysis of dense breast tissue. It aligns with the BI-RADS 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 first 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.



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 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.

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 breast density assessment categories.

1. PowerLook Density Assessment is now validated and available for the following Tomosynthesis systems: GE Pristina and Senoclaire: V-Preview images, Hologic Dimensions: C-View images
2. Diagnostic Performance of Digital versus Film mammography for Breast-Cancer Screening, Pisano ED., et al, NEJM, 353;17, October 27, 2005 (2)
3. 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
4. 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 Epidemial Biomarkers Prev, Vol. 15, pp. 1157-1169