

# Improving the early detection and diagnosis of **breast cancer**.

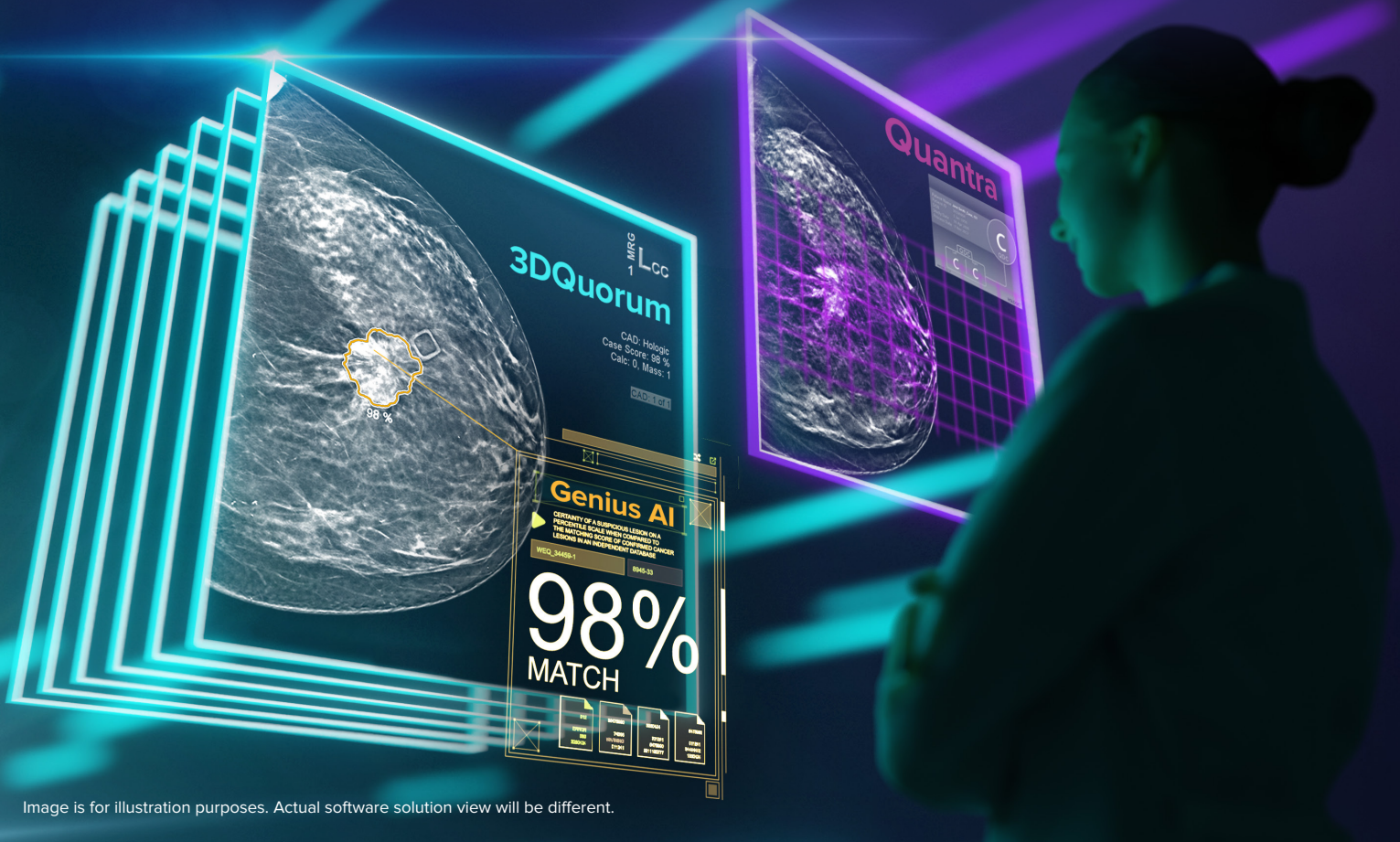


Image is for illustration purposes. Actual software solution view will be different.

## Integrated Artificial Intelligence Solutions

### Genius AI<sup>®</sup> Detection Solution

Using deep learning technology, Genius AI Detection solution\*\* aids radiologists' performance<sup>1</sup> by identifying potential cancers in tomosynthesis images with high accuracy.<sup>1</sup>

### 3DQorum<sup>®</sup> Imaging Technology

3DQorum software uses AI to uniquely reconstruct high-resolution 3D Mammography™ data, creating 6 mm SmartSlices designed to expedite reading time.

### Quantra<sup>®</sup> 2.2 Breast Density Assessment Software

Driven by machine learning, Quantra software analyses breast texture and pattern to provide an automated, objective breast density score.

# Genius AI® Detection Solution

## What if you could detect almost one additional cancer?¹\*\*

Genius AI Detection solution enables you to offer superior mammography screening through accurate markings, fast triaging tools, and optimized point-of-care results.¹

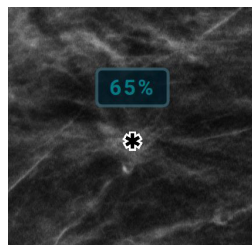
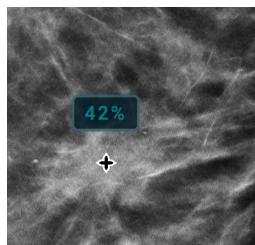
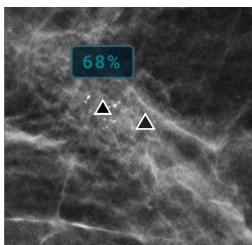
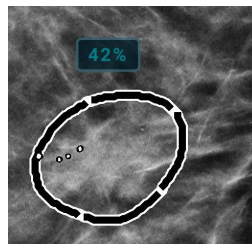
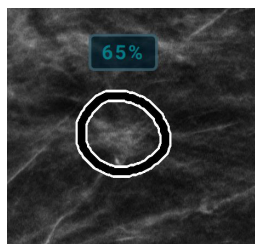
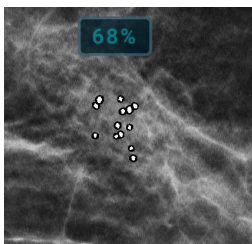
Genius AI Detection solution is a deep-learning algorithm designed to aid radiologists' diagnostic performance and to detect potential breast cancer from tomosynthesis images obtained using the Hologic Dimensions® mammography systems.¹

The algorithm is designed to locate lesions likely to represent breast cancer by searching each slice of the tomosynthesis image set. Suspicious areas are highlighted at the radiologist's workstation for concurrent reading to aid interpretation.

### Fully integrated on the Dimensions platform

Genius AI Detection solution is the one deep-learning software to run on the acquisition workstation of the mammography system, without the need for a separate server. It provides a simple, convenient, and secure point-of-care solution.

Genius AI Detection solution is designed to find cancers with greater accuracy than Hologic's previous generation computer-aided detection algorithms.¹,²



**Calc marks**  
Indicate calcification clusters

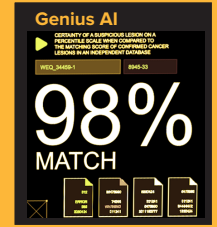
**Mass marks**  
Indicate soft tissue lesions (masses, densities, architectural distortions)

**Malc marks**  
Indicate a soft tissue lesion associated with calcification cluster

### Workflow tools to enhance your practice

Integration of Genius AI Detection solution on the Dimensions platform provides unique workflow opportunities facilitating review and case prioritization.

- Marks can be displayed on individual tomosynthesis slices and overlaid on 3DQuorum® imaging SmartSlices and Intelligent 2D™ synthesized 2D images with advanced tools to provide quick navigation to relevant slices.
- Results can be used to prioritize case review based on suspicious lesions and case scores at the point-of-care or on the reading workstation.
- Genius AI Detection 2.0 solution includes automated CC and MLO lesion correlation feature to provide radiologists with correlate lesions in different views.¹



### FAST

Ability for quick triage on the patient worklist for high priority or no CAD marking cases based on Genius AI Detection solution results to drive reading efficiency.



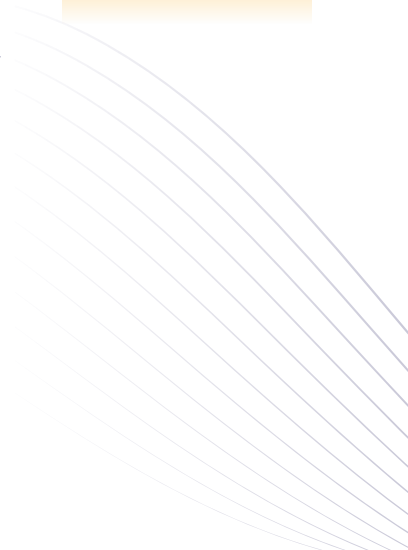
### ACCURATE

Find more cancers with a solution that has 94% sensitivity.¹

**Over 70% reduction in false positive marks per case** comparing Genius AI Detection 2.0 solution with ImageChecker® CAD.⁸

**PeerView™ marks:**  
Outlines the calcifications

**RightOn™ marks:**  
Indicates the center of the region of interest



# 3DQuorum® Imaging Technology

## Our highest resolution 3D™ imaging, faster.

### Advanced Reconstruction

3DQuorum imaging uses AI-powered analytics to reconstruct high-resolution 3D Mammography™ data to produce 6 mm SmartSlices.

### Confident Clinical Decisions

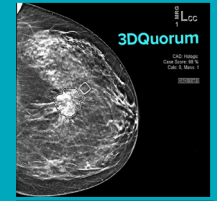
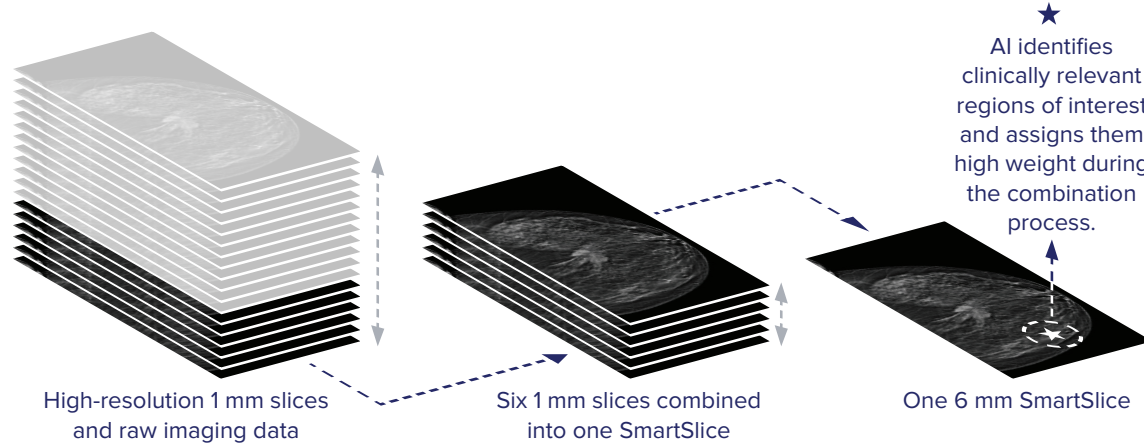
During the reconstruction process, AI identifies clinically relevant regions of interest and assigns them a high weight enhancing their visibility.

### Expedited read times

When reading SmartSlices instead of 1 mm slices, the number of images to review is reduced by two-thirds. Each SmartSlice overlaps the previous one by 3 mm, ensuring no loss of 3D™ image data and continuity of scrolling.<sup>3,7</sup>

### Optimal Connectivity Workflow

3DQuorum imaging also reduces the typical Hologic Clarity HD® and Intelligent 2D™ study size by over 50%, bringing the storage space and network impact back down to that of standard resolution 3D™ imaging.<sup>3,5</sup>



### FAST

SmartSlices expedite read time by reducing the number of images to review with no compromise in image quality, sensitivity or accuracy.<sup>3,5</sup>

Reduced average number of images to review by two-thirds.<sup>3,5</sup>

Reduces the typical high resolution with synthesized 2D study size by 50%.<sup>3,5</sup>

“ The 3DQuorum algorithm lessens what would otherwise be a voluminous and untenable dataset into one more palatable for our PACS and network systems and **more easily interpreted by radiologists with reduced turnaround time, fatigue, and digital eye strain.**”

### Jason McKellop, MD

Director of Women's Imaging,  
Beverly Radiology Medical Group and  
Medical Director, Breastlink Tarzana

*The Next Paradigm Shift: Embracing Hologic's  
3DQuorum® Imaging Technology as a Breakthrough  
in Early Breast Cancer Detection, 2022*

# Quantra® 2.2 Breast Density Assessment Software

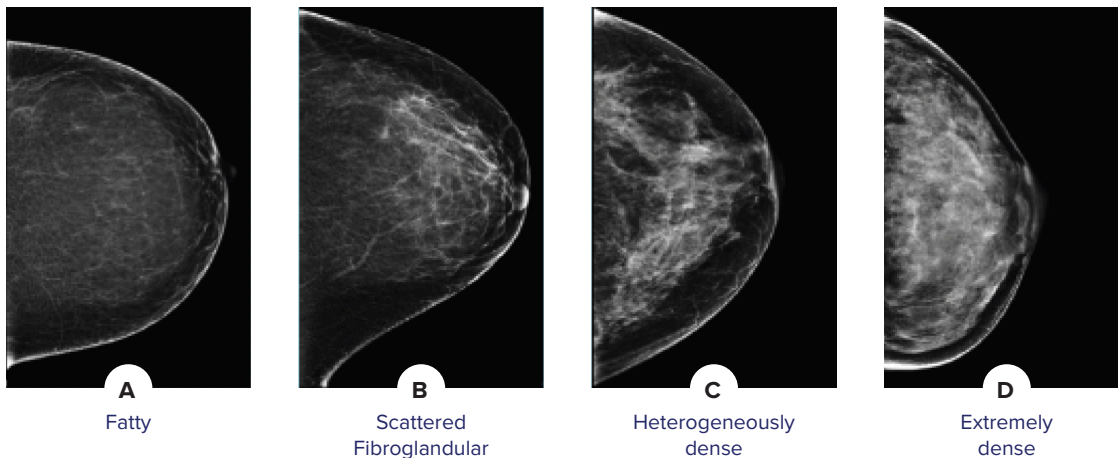
## Standardizing breast density analysis with machine learning, at the point of care.

As awareness of breast density as a risk factor for cancer grows, so does the need for accurate analysis. Powered by machine learning, Quantra software analyzes both 2D and tomosynthesis images for pattern and texture of parenchymal tissue. Further, it categorizes breasts into four breast composition categories consistent with guidance from the American College of Radiation (ACR) BI-RADS Atlas 5th Edition.<sup>6</sup>

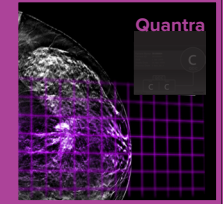
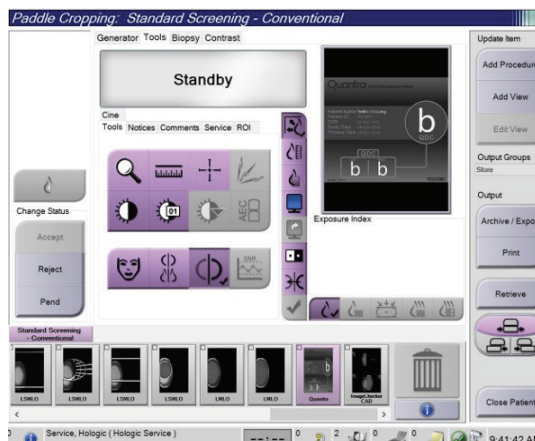
Quantra software is designed to deliver consistent and reliable information enabling radiologist confidence to implement patient-specific screening pathways and provide the highest quality care. It does this by:

- **Automated assessment:** Objective machine learning algorithm assigns breast density category based on analysis of breast tissue texture and patterns
- **Standardization:** Overcoming individual radiologist subjectivity in visual assessment and elevating the standard of care and standardization of reporting across the whole radiology practice
- **Smoother patient pathway:** Displaying density on the acquisition workstation in the exam room to facilitate patient management protocols for potential supplemental imaging at the point of care.

### Breast composition categories described in ACR BI-RADS Atlas



Example of a density score of "b" on the 3Dimensions™ Hologic acquisition workstation.



### FAST

Potential increase in workflow efficiency to improve patient triaging to additional imaging modalities at the point of care compared to waiting for radiologist assessment at time of study review.\*



### ACCURATE

Provide more consistent and reproducible breast density assessment and offer more confidence in selecting which patient for additional screening.\*

Analyze each patient's pattern and texture (parenchymal tissue) based on BI-RADS 5th edition so that you can provide patient-specific density.

*\*Compared to individual radiologist assessment at reading workstation*

# DISCOVER

## the Hologic suite of integrated, future-proofed AI Solutions.

Designed to improve early detection and diagnosis of breast cancer, assist acceleration of reading workflow, and enable personalized patient care.





[www.hologic.com/hologic-products/breast-health-solutions/image-analytics](http://www.hologic.com/hologic-products/breast-health-solutions/image-analytics)



\*\*Based on analysis that do not control type I error and therefore cannot be generalised to specific comparisons outside this particular study. In this study: The average observed AUC was 0.825 (95% CI: 0.783, 0.867) with CAD and 0.794 (95% CI: 0.748, 0.840) without CAD. The difference in observed AUC was +0.031 (95% CI: 0.012, 0.051). The average observed reader sensitivity for cancer cases was 75.9% with CAD and 66.8% without CAD. The difference in observed sensitivity was +9.0% (99% CI: 6.0%, 12.1%). The average observed recall rate for non-cancer cases was 25.8% with CAD and 23.4% without CAD. The observed difference in negative recall rate was +2.4% (99% CI: 0.7%, 4.2%). The average observed case read-time was 52.0s with CAD and 46.3s without CAD. The observed difference in read time was 5.7s (95% CI: 4.9s to 6.4s)<sup>1</sup>

<sup>1</sup>Acquisition workstation (AWS) with minimum 3Dimensions 2.1 or Dimensions 1.10 software

#### References

1. FDA 510(k) Clearance K201019, K220449, K230096.
2. Keller, B. (2020). Clinical Report: Genius AI Detection Clinical Safety and Effectiveness Data. Refer to Hologic document (CSR-00130).
3. Selenia Dimensions Technical File (TFL-00059), 2022.
4. Data on File: Clinical Study Report CSR-00116.
5. Physician Labelling. (2019). Refer to Hologic document (MAN-06153).
6. ACR BI-RADS Atlas 5th Edition. 2013. Available at: <https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Bi-Rads> (Accessed on 30/12/2019).
7. FDA Submission P080003/S008, 2019.
8. Kshirsagar, A. (2023). Comparison between ImageChecker CAD and GAID algorithm on sequestered FDA database. Refer to Hologic document (DHM-14593).

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