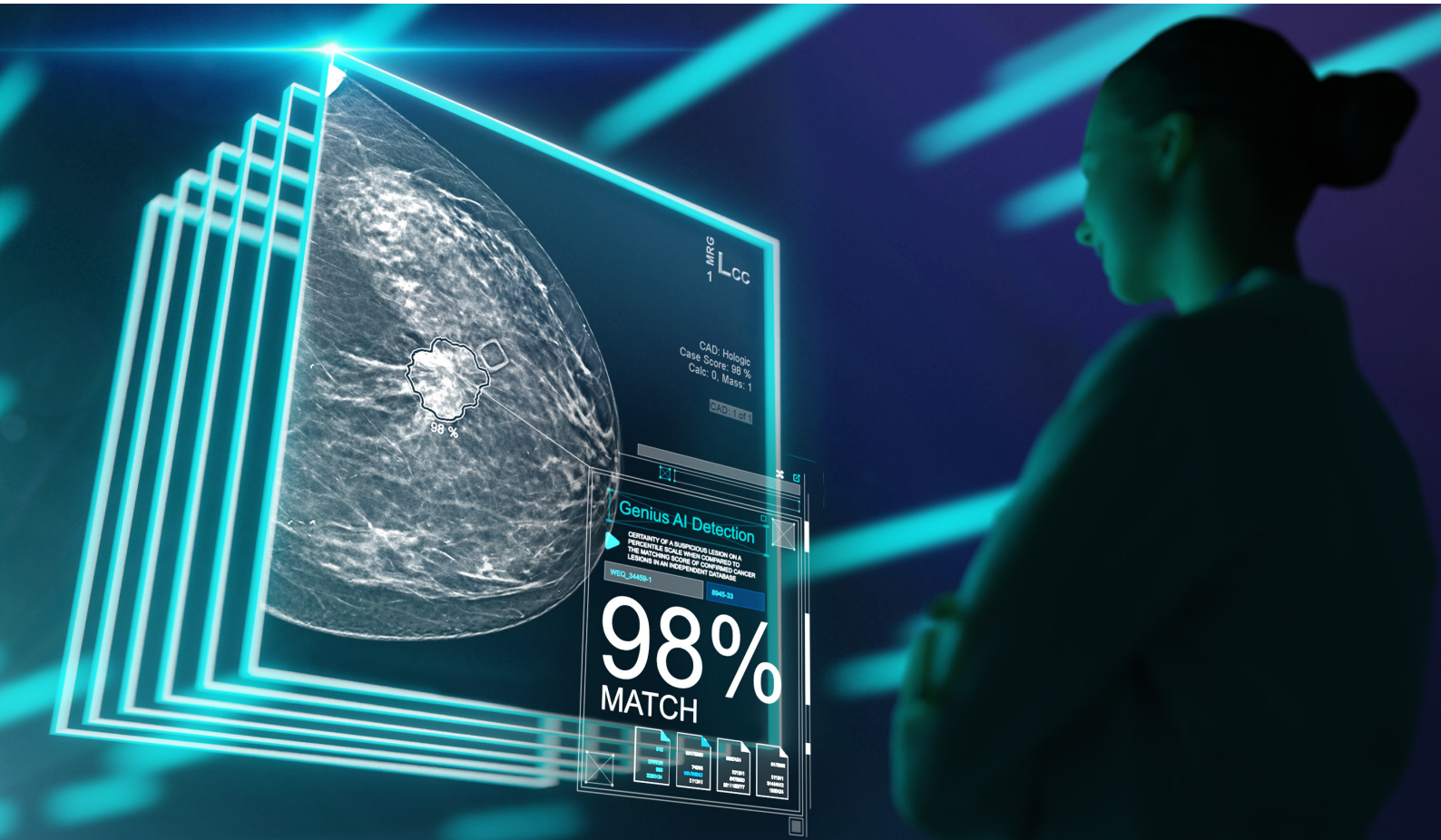HOLOGIC®
The Science of Sure

The next breakthrough in early breast cancer detection

Building on Hologic's history of technical innovation and commitment to saving lives of women, Genius AI™ Detection technology* represents the next breakthrough in helping radiologists identify breast cancers. Genius AI Detection technology is a deep-learning algorithm designed to aid radiologists' diagnostic performance and detect breast cancer from tomosynthesis images obtained using the Hologic Dimensions® Mammography Systems.

MORE CONFIDENT CANCER DETECTION

Study shows +9% improvement in observed reader sensitivity for cancer cases.**[1,2~]

Works on standard and high-resolution tomosynthesis images; overlay on 3DQuorum™ SmartSlices and synthesised 2D images.

TOOLS FOR EASY LESION IDENTIFICATION

The algorithm looks for 3 main groups of suspicious lesions: calcifications; masses, densities and distortions; and the combination of the above.

Outputs may vary on different reading workstations.

EFFICIENT OPERATIONAL WORKFLOW

Integration on the acquisition workstation allows flagging of high-risk cases for immediate reading.

Provides case level metrics helping categorise cases for priority reading.

Evolves with Hologic's imaging innovations

Genius AI™ Detection technology supports all Hologic image types, including 3DQuorum™ SmartSlices. Radiologists can read 15% more cases per hour when utilising 3DQuorum SmartSlices instead of Hologic's high-resolution tomosynthesis images.[3,4] As Hologic continues to innovate, Genius AI Detection technology will evolve to ensure compatibility into the future. Using insights from radiologists and clinical experts, Genius AI Detection technology has been developed to integrate seamlessly within the clinical workflow.

Identifying cancers during case review

Suspicious areas are highlighted at the radiologist's workstation for concurrent reading to aid in interpretation. Marks can be displayed on individual tomosynthesis slices and overlaid on 3DQuorum™ SmartSlices and synthesised 2D images with advanced tools to provide quick navigation to relevant slices.

The software identifies three characteristics commonly associated with cancer.

- **Calc marks:** Marks regions suggestive of calcifications
- **Mass marks:** Marks regions suggestive of densities/masses/architectural distortions
- **Malc marks:** Indicates Calc and Mass marks occurring in the same location on the image

Workstation software typically allows support for display of marks in different formats:

- **PeerView™ marks:** Outline individual calcifications in the cluster and/or the central density of the mass
- **RightOn™ marks:** Show the centre of the region of interest
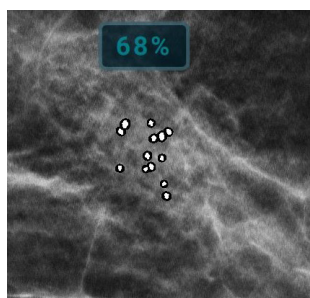
Clinical Decision Support

Results can be used to prioritise case review based on suspicious lesions and certainty that a case contains a cancer.

- **Lesion Score:** Indicates the confidence that a suspicious area represents cancer. The lesion score is displayed alongside the lesion mark.
- **Case Score:** Indicates the confidence that a case contains a cancerous lesion. The case score is typically displayed during image review and in the patient list to allow for sorting of cases.

Note: Check your PACS system and version for specific Genius AI Detection technology features availability.
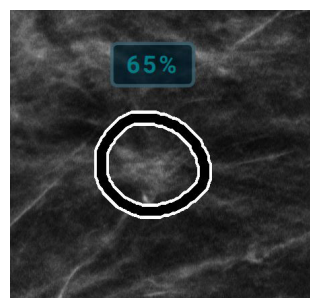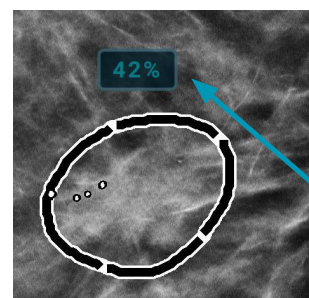

Calc marks
Indicate calcification clusters

Mass marks
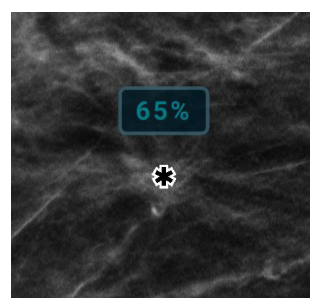Indicate soft tissue lesions

Malc marks
Indicate soft tissue lesions associated with a calcification cluster

PeerView™ marks: Outlines the region of interest

RightOn™ marks: Indicates the centre of the region of interest

68%

65%

42%

68%

65%

42%

Lesion Score: Confidence that a suspicious area represents cancer
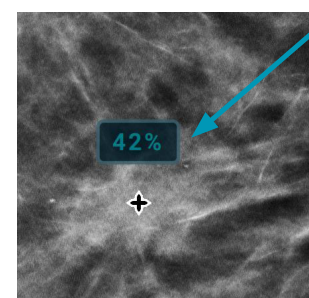
Genius AI™ Detection technology streamlining operational workflow

In addition to identifying potential cancers, Genius AI Detection software provides case level metrics that can be used to categorise cases for reading and to enhance workflow. On the SecurView® workstation and on some PACS workstations, radiologists can use this capability to sort cases to generate customised worklists for different readers.

Case Complexity Index: Cases are categorised according to complexity, based on the number of suspicious areas identified in the case. (Multiple findings, Single finding, No findings).

Read Time Indicator: Based on a deep learning algorithm, cases are categorised to indicate High, Medium, or Low predicted reading time. It can be used to evenly distribute cases among a group of radiologists to ensure a balanced workload across the team.

Reading Priority Indicator: Flags the most concerning cases at the time of the exam so that a site can choose to read those cases immediately. The results are available to the technologist in the exam room, facilitating communication with the patient and with the radiologist. A case that is tagged as having a higher level of concern can be triaged according to site protocol.

The integration of Genius AI Detection software on the Dimensions platform provides unique workflow opportunities that have the potential to benefit both patients and health care providers.

Genius AI Detection technology on SecurView Workstation

Radiologists can use the **CAD Complexity** Index to sort cases by complexity to generate customised worklists for different readers.

| Patient Manager | User Preferences | About |

Patient List | Sessions | Log

| Reset Columns | Resend | Notices | | Cancel Editing | Create Session | Review | Clea |
| Update Patient List | Merge Patients | | | Cancel Import | Import... | Suspend And Review | Relo |

Patient List

Study Date	Name	Patient ID	Date of Birth	Modality	State	Type	CAD	CAD Complexity	Reading Priority	N
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1955	MG+	Not Read	Screening	Medium	Single finding	Normal	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1952	MG+	Not Read	Screening	Medium	Multiple findings	Normal	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1973	MG+	Not Read	Screening	Low	Single finding	Normal	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1965	MG+	Not Read	Screening	Medium	No findings	Normal	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1963	MG+	Not Read	Screening	Medium	Multiple findings	High	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1959	MG+	Not Read	Screening	Low	No findings	Normal	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1967	MG+	Not Read	Screening	High	Multiple findings	Normal	
12-29-2020	100-GENIUS_Detection_...	100-GENI...	01-01-1953	MG+	Not Read	Screening	Medium	Multiple findings	Normal	
04-29-2015	02_Patient, 018_ScrExt_...	02_Patient...	08-16-1964	MG	Old		+			
11-22-2014	02_ImageAnalytics_103_14	14ImageA...	01-01-1957	MG+	Old		+			

Radiologists can use the **Reading Priority** (to categorise cases for batch reading or to prioritise cases for more efficient workflow).

Product summary

- The Genius AI™ Detection software applies deep learning AI to Hologic high-resolution Clarity HD® and standard resolution tomosynthesis images. Results can be displayed on tomosynthesis slices, 3DQuorum™ SmartSlices, and C-View™ or Intelligent 2D™ synthesised 2D images.

- Overlaying the marks on the synthesized 2D images helps the radiologist by providing an overview image with suspicious areas clearly indicated and quick navigation with SmartMapping to the tomosynthesis slice or 3DQuorum SmartSlice where the mark was originally identified.

- The software resides on the Dimensions acquisition workstation computer, eliminating the complexity and additional cost associated with a separate server. It allows the technologist to view the results in the exam room.

- The output is encapsulated in a DICOM CAD Structured Report (SR) object that can be displayed on review workstations.

- Sensitivity was shown to be 93%-94% and specificity was shown to be 37%-41% in standard resolution and high-resolution modes.[1]

Requirements:

- 3Dimensions™ or Selenia® Dimensions® software minimum 1.11.1/2.2.1 (with a high-performance computer with Windows 10 software). AWM software minimum 1.1

- Hologic workstation software minimums: SecurView® DX and RT workstation and SecurView DX and RT manager 11.0

- For customers reading on PACS workstations, minimum requirements will vary depending on the vendor. Our connectivity team works with major imaging product vendors to provide sample data and guidelines to facilitate integration of Genius AI Detection technology.

*Not CE marked. Not available for sale in Europe.

**Based on analyses 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).[1]

References
1. MAN-07021: Genius AI Detection Physician User Guide **2.** Hologic data on file: CSR-00130 **3.** Hologic data on file: TFL-00059 **4.** Hologic data on file: CSR-00116

No Compromise. No Comparison.