

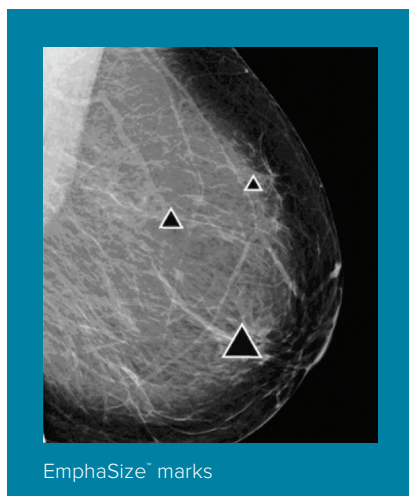
Optimal Clinical Flexibility

Hologic understands the constantly changing clinical mammography environment and the need for a flexible, compatible CAD solution. ImageChecker CAD provides detection for conventional 2D images as well as C-View™ and Intelligent 2D™ synthesized images derived from a tomosynthesis dataset. ImageChecker CAD is now available on the 3Dimensions™ and Dimensions® systems' AWS* allowing image review at the point of care and eliminating the need for a separate server. ImageChecker CAD provides proven performance and continues to be a leading CAD technology.

Using sophisticated software algorithms, ImageChecker CAD searches digital mammograms for potential microcalcifications and masses—characteristics commonly associated with breast cancer. Marks are placed on the regions-of-interest to focus the radiologist's attention. The highly evolved algorithms, refined to deliver extremely sensitive results without excessive false-positive marks, provide streamlined case review. When used on synthesized 2D images in combination with Smart Mapping, clicking on a finding in the synthesized 2D image allows for easy navigation to the slice of interest in the tomosynthesis stack.

Advanced Technology

In addition to detecting regions of interest, the ImageChecker CAD algorithms also incorporate anatomic correlation technology. This advanced technology analyzes corresponding findings in the contralateral breast and different views of the same breast.

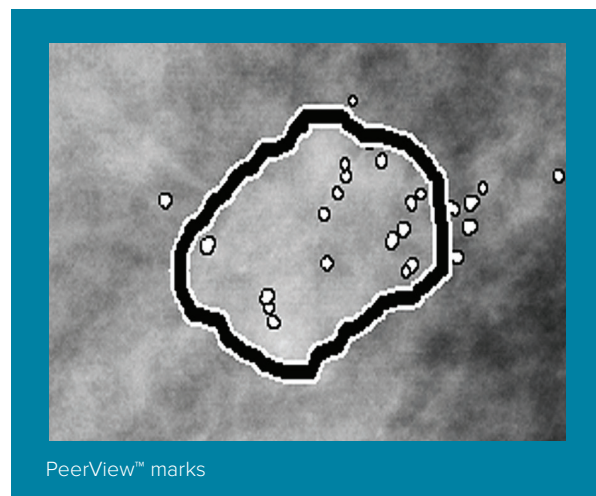


Flexible Solutions

ImageChecker CAD provides optimal flexibility by allowing a site to select sensitivity settings, or operating points, that are most suitable for the practice's needs. ImageChecker CAD ranks findings in order of the prominence of features in a given region. A region will be marked only if the ranking falls above a chosen operating point. Clinical practices can select from three different operating points for conventional 2D images, providing nine combinations from which to choose. One operating point is available for synthesized 2D images.

Cost Effective Architecture

ImageChecker software can be licensed directly on the Dimensions Acquisition Workstation, without the need for a dedicated Cenova™ server. DICOM compatible results can be sent directly to the radiologist workstation or PACS upon completion of the exam. The elimination of the requirement for a separate server simplifies the configuration and reduces security concerns.



* ImageChecker CAD operates on the 3Dimensions or Dimensions AWS systems with software version 2.1/110.

ImageChecker CAD 10.0 Algorithm Performance¹

Image Type	Synthesized 2D Images	Conventional 2D Images
Calcification Cases (n=91) Sensitivity* 95% Confidence interval	96% 91.39 — 99.82%	93% 88.31% — 98.51%
Mass Cases (n=220) Sensitivity* 95% Confidence interval	85% 80.80% — 90.11%	85% 80.80% — 90.11%
Overall (n=311) Sensitivity* 95% Confidence interval	88% 84.87 — 91.98%	88% 84.14% — 91.42%
Screening and Bi-RADS 0 Normals (n=660)**		
Calcification FP/Image	0.23	0.23
Mass FP/Image	0.46	0.46
Total FP/Case	2.74	2.75
Specificity	22%	25%
95% Confidence Interval	19.10 — 25.45%	21.16 — 27.83%

* "Sensitivity" refers only to the sensitivity of the CAD algorithm to detect biopsy-proven malignancies, not to the sensitivity of the radiologist using the device.

** "False Positive" (FP) and "Specificity" data were developed from a review of confirmed normal cases (those rated as BI-RADS 1 and 2) in addition to recall cases (those rated as BI-RADS 0). The normal cases were enriched with 10% BI-RADS 0 cases wherein the BI-RADS 0 assessment for these subjects resulted in one or more of the following: additional mammography views; additional ultrasound imaging; short-term follow up; request for additional images. All cases were subsequently determined to be normal with no further intervention. 'FP/Image' refers to the average number of false-positive marks per image measured on normal cases (including BI-RADS 0). 'Specificity' refers to the percentage of normal cases (including BI-RADS 0) that, when processed, show no CAD marks.

Operating Environment

Operating platform	AWS with minimum 3Dimensions 2.1 or Dimensions 1.10 software OR Cenova™ server
Output supported	PACS or DICOM workstations

Performance on Cenova™ Server

Maximum number of digital ports	4 (optional)
Case throughput (four-image)	30-60 cases/hr ²

These features can be viewed on a Hologic workstation³ and are included in the ImageChecker CAD (Citra® Core³) license group.

RightOn™ CAD Marks	Assorted "shaped" markers indicate the types of features that were detected.
EmphaSize™	Markers that are scaled according to the prominence of features.
PeerView™	Markers that provide anatomic outlines of tissue.

1. Please refer to "Understanding ImageChecker CAD 10.0 User Guide" for more detailed information.
2. Performance dependent on recommended hardware, network bandwidth and input rate of images.
3. Available on Unifi Workstations and SecurView workstations 8.2 and higher.

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