

# ImageChecker<sup>®</sup>

Computer-Aided Detection



## Understanding ImageChecker<sup>®</sup> CAD 9.4 User Manual

MAN-11041 Revision 004

**HOLOGIC<sup>®</sup>**



# Understanding ImageChecker<sup>®</sup> CAD 9.4

Computer-Aided Detection

## User Manual

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**HOLOGIC<sup>®</sup>**

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## Chapter 1: Introduction

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ImageChecker® CAD is a software application used by radiologists for analyzing two-dimensional digital mammography images. The software is a licensed option with Hologic's Cenova™ image analytics server or any server with comparable functionality (that meets the ImageChecker CAD data input and output requirements).

The information in this manual is intended to serve as a reference for radiologists and clinic personnel who need to understand how computer-aided detection (CAD) can be integrated into their practices.

**RxOnly** United States federal law restricts this device to use by, or on the order of, a physician.

### 1.1. Intended Use

ImageChecker CAD is a software application intended to identify and mark regions of interest on routine screening and diagnostic mammograms to bring them to the attention of the radiologist after the initial reading has been completed.

ImageChecker CAD assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.

ImageChecker CAD runs on a Windows platform.

## 1.2. Using This Manual


This manual is organized as follows:


- **Chapter 1: Introduction** provides an overview of the ImageChecker CAD application including features, benefits, and precautions for use.
- **Chapter 2: Image Processing and Workflow** explains how information flows through systems with ImageChecker CAD, the supported mammography views, and how to manage workflow.
- **Chapter 3: Algorithm Description** describes how the ImageChecker CAD algorithm analyzes mammography images.

This manual uses the following conventions to provide technical and safety information of special interest.

 **WARNING!** An instruction that, if not followed, can result in a hazardous condition.

 **CAUTION:** An instruction that, if not followed, can result in damage to the system.

 **Important:** An instruction provided to ensure correct results and optimal performance, or to clarify limitations of the device.

 **Note:** Information provided to clarify a particular step or procedure.

## 1.3. Resources Available

In addition to this manual, the following resources are available to assist you.

- **Training:** The Hologic Applications team is available to train your staff, should you feel they need additional training. To purchase additional personalized instruction, contact your Hologic Account Manager.
- **Website:** The Hologic website ([www.hologic.com](http://www.hologic.com)) provides quick access to electronic versions of User Guides. You can also obtain additional copies of printed User Guides through your Hologic Account Manager or through the Hologic Technical Assistance Center (1-877-371-4372).



## 1.4. Warnings and Precautions



**Note:** For Warnings and Precautions related to the installation, operation, and maintenance of the Cenova server, refer to the Cenova User Manual.

**Important:** Before reviewing images processed with ImageChecker CAD, observe the following instructions that are provided to ensure correct results and optimal performance, or to clarify limitations of the algorithm.

- The radiologist should base interpretation only on diagnostic-quality images and not depend on ImageChecker CAD marks for interpretation.
- ImageChecker CAD is a detection aid, not an interpretative aid. The radiologist should activate ImageChecker marks only after the first reading.
- ImageChecker CAD does not enhance what the user sees; rather it helps to identify regions on mammograms that should be re-examined.
- Workstations using Hologic's CAD marking schema identify calcification findings with triangles (Calc marks) and mass findings with asterisks (Mass marks). If mass and calcification findings occur at the same location on the image, then the workstation identifies the findings with marks shaped like the four points of a compass (Malc marks). These findings may not represent cancer, and the skill of the user is still required for proper interpretation of the marked areas.
- EmphaSize (variable-size) marks – Sites may choose to display EmphaSize marks, in which case the size of a Calc, Mass, or Malc mark is proportional to the prominence of the features calculated for each finding. The marked findings may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device.
- During routine interpretation of mammograms and results produced by ImageChecker CAD, Hologic recommends use of a mammography workstation that has been FDA-approved, recently calibrated, and employs Hologic's CAD marking schema.
- The ImageChecker CAD software does not identify all areas that are suspicious for cancer.
  - The software does not mark all lesions and a user should not be dissuaded from working up a finding if the software fails to mark that site.
  - The software is not designed to detect changes from prior mammograms.
  - The software is not designed to detect skin thickening or nipple retractions.
  - Conditions of the breast that diminish mammographic sensitivity, such as density of normal tissue, also diminish the sensitivity of the software.
  - The software is more sensitive for detection of calcifications than masses, and the sensitivity depends on the site-specific operating points chosen. For sensitivity values, see **3.9. CAD Operating Points**. In addition to not marking all masses, the algorithm has a lower sensitivity for masses greater than 2.5 cm in diameter.
  - Individual practice patterns may influence results obtained when using ImageChecker CAD. Therefore, each facility and radiologist should carefully monitor the results that the software has on their practice of mammography in order to optimize its effectiveness.
- For a lesion on or near the pectoral muscle, ImageChecker CAD may, on rare occasions, report a negative value for the chest wall distance.
- The performance of ImageChecker CAD has not been characterized for mammographic images showing less than 2.5 cm<sup>2</sup> of breast tissue.

- *ImageChecker CAD does not process images that include the following DICOM view modifiers (with SNOMED\* codes):*
  - *Cleavage (R-102D2)*
  - *Magnification (R-102D6)*
  - *Spot Compression (R-102D7)**\*SNOMED = Systematized Nomenclature of Medicine.*
- *The performance of ImageChecker CAD has not been characterized for mammograms from patients with:*
  - *Breast implants. However, ImageChecker CAD effectively processes implant-displaced views with less than 2.5 cm (1 in) of the breast implant appearing on the image. Also see [Images with Breast Implants](#) on page 14.*
  - *Partial views (e.g., 'mosaic' views) without a complete breast border. Process only views with complete breast borders. Also see [Images with Partial Views](#) on page 14.*

## 1.5. Overview of ImageChecker CAD

ImageChecker CAD identifies regions of interest, which can include clusters of bright spots (suggestive of calcification clusters), and dense regions with or without radiating lines (suggestive of masses or architectural distortions). The algorithm identifies visually perceptible structures that have some of the generally accepted geometric characteristics of calcifications or masses. The marked areas may be something other than an actual abnormality, which the radiologist generally recognizes upon a second review of the original images.

ImageChecker CAD is delivered with a number of licensed features in place. Upon installation, the Hologic field service engineer will tailor the software to enable or disable selected features based on the preferences of site personnel. Thereafter, your Hologic representative can help you add new licenses and enable or disable features.

### Citra

The standard set of ImageChecker CAD features is included in the Citra™ license group, which includes the following features:

- RightOn™ CAD Marks
- EmphaSize™
- PeerView®
- LesionMetrics™

EmphaSize, PeerView, and LesionMetrics are exclusive Hologic features supported by some diagnostic review workstations. When viewed at the workstation, the results help radiologists understand better why a region of interest received a CAD mark.

The Citra features are briefly discussed in the following pages. For more information, see [Chapter 3: Algorithm Description](#).

**⚠ Important:** *In order to display results from each ImageChecker CAD feature, the workstation must be equipped with software that can interpret the output produced by the server software. Individual Citra features can usually be disabled at either the server or the diagnostic workstation. Some workstations can interpret only a subset of Citra features. Consult with your workstation vendor concerning availability and integration of ImageChecker CAD features with your workstation.*

### RightOn CAD Marks

Workstations using Hologic's CAD marking schema provide three types of RightOn CAD marks (Mass, Calc, and Malc) that can appear in the results. You can choose to display any or all of the three types of marks. Each mark identifies a region of interest for the radiologist to review.



**Calc** – Marks regions suggestive of calcifications



**Mass** – Marks regions suggestive of densities/masses/architectural distortions



**Malc** – Composite mark indicates Calc and Mass marks occurring in the same location on the image

### EmphaSize

This feature allows the review workstation to display marks of variable size that correlate to the significance of the finding. When the algorithm determines that a region is more significant, the CAD mark appears larger, indicating that the region should receive more attention from the radiologist. EmphaSize marks can be disabled if clinic staff choose not to use them. For more information see [3.3. EmphaSize Marks](#).

### PeerView

PeerView enables the radiologist to understand better why a region of interest was marked. On advanced review workstations such as Hologic's SecurView DX, PeerView highlights physical findings detected by the algorithm. For more information see [3.4. PeerView](#).

### LesionMetrics

LesionMetrics provides data computed by ImageChecker CAD for each region of interest marked by the algorithm. Depending upon the type of lesion, the software can compute metrics such as lesion size, distance to nipple, distance to chest wall, degree of spiculation, calcification contrast, number of calcifications, and mass density. For more information see [3.5. LesionMetrics](#).

### Operating Points

The ImageChecker CAD algorithm offers three operating points (i.e., CAD algorithm thresholds) to accommodate differing radiologist preferences: operating point 0, which emphasizes specificity (a low false-mark rate), operating point 1, which is a balanced intermediate point, and operating point 2, which emphasizes sensitivity. The algorithm performance for each of the operating points is summarized below:

Operating Point	0	1	2
Calcification Sensitivity	95%	98%	99%
Mass Sensitivity	87%	89%	91%
False Marks per Case	1.1	1.5	2.0

When your system is installed, the server software is configured to use operating point 1 for masses and operating point 2 for calcifications. You can choose other settings, or your service representative can change the operating points at a later time. For new customers, Hologic recommends using the default settings for the first four to six weeks to allow you to become familiar with the ImageChecker marks and algorithm behavior.

For more information, see [3.9. CAD Operating Points](#).

## 1.6. Benefits of ImageChecker CAD

The interpretation of mammograms is challenging. Normal breast tissue varies widely among women, even for the same woman over time. The radiologist also has to balance the need for accurate detection of cancer with the need to limit the number of unnecessary procedures. The combination of viewing a large number of cases, radiologist fatigue, the complex image of the breast structure, and the subtle nature of certain observable characteristics of the disease can result in false-negative readings. In fact, studies show that many undetected cancers are missed due to observational oversights.<sup>1,2,3</sup> The prevalence of observational oversights is not strongly related to experience and may be inevitable with human observers.

ImageChecker CAD functions like a spellchecker for medical images. It is designed to help radiologists in reducing the number of false-negative readings due to observational oversight by drawing their attention to areas that may warrant a second review.

ImageChecker CAD was the first computer-aided detection software approved by the FDA for full-view diagnostic and screening mammograms. Since that first approval, the ImageChecker CAD software has been refined many times, resulting in an algorithm that is highly sensitive with few false marks.

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**1** Martin JE, Moskowitz M, Milbrath JR. Breast Cancer Missed by Mammography. *AJR*. 1979; 132:737-739.

**2** Harvey JA, Fajardo LL, Innis CA. Previous Mammograms in Patients with Impalpable Breast Carcinoma: Retrospective vs Blinded Interpretation. *AJR*. 1993; 161:1167-1172.

**3** Burhenne LJW, Wood SA, D'Orsi CJ, et al. Potential Contribution of Computer-aided Detection to the Sensitivity of Screening Mammography. *Radiology*. 2000; 215:554-562.

## 1.7. System Requirements

The table provides the minimum recommended specifications for the server that runs the ImageChecker application. Specifications are subject to change without notice.

Operating System	Windows XP	Windows 7
Processor Speed	1 GHz	1 GHz
Memory (RAM)	1 GB	2 GB
HDD Free Disk Space	5 GB	20 GB
Optical Drive	CD-ROM	CD-ROM

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## Chapter 2: Image Processing and Workflow

- ▶ 2.1. Image Processing
- ▶ 2.2. Image Acquisition Systems
- ▶ 2.3. Inputs and Supported Views
- ▶ 2.4. Image and Case Processing
- ▶ 2.5. Managing Workflow

This chapter explains how information flows through systems with ImageChecker CAD, the supported mammography views, and how to manage workflow.

### 2.1. Image Processing

The ImageChecker CAD software is provided on a server that manages DICOM images and processes the algorithm results. Image and data flows are generally as follows:

- 1 A Full-Field Digital Mammography (FFDM) system produces two-dimensional digital x-ray images in two forms:
  - DICOM Digital Mammography X-Ray Image – For Processing
  - DICOM Digital Mammography X-Ray Image – For Presentation
- 2 The FFDM system sends the For Processing images to the server software and sends the For Presentation images to a review workstation or PACS.
- 3 The server software receives the For Processing images, groups them by the identified study, and passes the studies to the ImageChecker CAD software.
- 4 ImageChecker CAD analyzes the images and studies, produces results for each study in the form of an .xml file, and outputs the file to the server software.
- 5 The server software generates results, usually in the form of DICOM Mammography CAD SR (Structured Report) objects that include the type and location of CAD marks and other data identifying and characterizing the regions of interest.
- 6 For each study, the review workstation displays the ImageChecker CAD results with the For Presentation images produced by the FFDM system.

**Note:** *The appearance of the images on the workstation is dependent upon the acquisition modality and the workstation's display capabilities, and is not affected by the ImageChecker CAD software.*

At the review workstation, the radiologist begins by examining the For Presentation images. After making an initial interpretation, the radiologist displays the ImageChecker CAD results. The radiologist can then switch off the CAD results, reinspect the marked areas, and form a diagnosis.

### 2.2. Image Acquisition Systems

ImageChecker CAD processes images originating from the following FFDM systems:

- Hologic Selenia, Hologic Selenia Dimensions (2D)
- GE Senographe 2000D, GE Senographe DS, and GE Senographe Essential
- Siemens Mammomat Novation<sup>DR</sup>

## 2.3. Inputs and Supported Views

The ImageChecker CAD software analyzes digital mammography images that conform to the DICOM standard. If your system has the ImageChecker CAD license, all images are CAD-processed if the views (and any DICOM view modifiers) are supported by the software, as is shown in the following table:

Supported DICOM Views and View Modifiers	ACR MQCM 1999* View Label	
<b>Screening Views</b>	Cranio-Caudal	CC
	Medio-Lateral Oblique	MLO
<b>Equivalent Views</b>	Medio-Lateral	ML
	Cranio-Caudal Exaggerated	XCC
	Cranio-Caudal Exaggerated Laterally	XCCL
	Cranio-Caudal Exaggerated Medially	XCCM
<b>Reversed Equivalent Views</b>	Latero-Medial	LM
	Latero-Medial Oblique	LMO
	Cranial-Caudal From Below	FB
	Inferomedial to Superolateral Oblique	ISO
	Superolateral to Inferomedial Oblique	SIO
<b>View Modifiers</b>	Axillary Tail (modifies MLO views only)	AT
	Tangential	TAN
	Rolled Inferior	...RI
	Rolled Lateral	...RL
	Rolled Medial	...RM
	Rolled Superior	...RS
	Implant Displaced	...ID
	Nipple in Profile	...NP
	Anterior Compression	...AC
	Infra-Mammary Fold	...IMF
	Axillary Tissue	...AX

\*American College of Radiology Mammography Quality Control Manual 1999

 **Important:** Be aware of the following:

- **Unsupported view modifiers.** ImageChecker CAD does not process images with the following view modifiers (with SNOMED codes):
  - Cleavage (R-102D2)
  - Magnification (R-102D6)
  - Spot Compression (R-102D7)
- **Breast implants.** ImageChecker CAD will process images with breast implants, although under some situations the software may not produce results. For more information, see [Images with Breast Implants](#) on page 14.
- **Partial views.** ImageChecker CAD will process partial views. However, users should be aware that CAD results can be affected by the order in which the images were taken. For more information, see [Images with Partial Views](#) on page 14.



## 2.4. Image and Case Processing

ImageChecker CAD can process individual images and images that have been grouped by study for a single patient in the server software. There is no specified limit to the number of images that can be included in a study. However, for many patients, a study consists of the four screening views:

- LCC – Left Cranio-Caudal
- RCC – Right Cranio-Caudal
- LMLO – Left Medio-Lateral Oblique
- RMLO – Right Medio-Lateral Oblique

### Image Processing

During processing, the ImageChecker CAD software analyzes each received image, as long as the view is supported by the software. The algorithm searches for patterns suggestive of calcification clusters and masses or architectural distortions, characterizes each suspected lesion, and finally determines the location and numbers of CAD marks for the image. This initial analysis is known as *image processing*.

### Case Processing

As an additional step when a study includes two or more views, the ImageChecker CAD algorithm selects up to four views and compares the images to each other in a process known as *case processing*. By checking for similarities and differences between the images, the algorithm can further refine its findings for the four selected views. When case processing is complete, the ImageChecker CAD algorithm produces an .xml file containing the results for both the images selected for case processing and the remaining images.

As a result of the case processing analyses, ImageChecker CAD may produce a different set of CAD marks for an individual image than when the image is part of a case. ImageChecker CAD may add or discard marks when it applies the more sophisticated case processing rules. For example:

- Some large masses are marked only when the image is part of the bilateral asymmetry analysis used for case processing.
- Some marks may be discarded when the image is subjected to the mark capping limit applied during case processing. For more information, see [Limiting the Number of Marks](#) on page 17.

For more information about image and case processing, see [3.7. Detecting Calcifications](#) and [3.8. Detecting Masses](#).

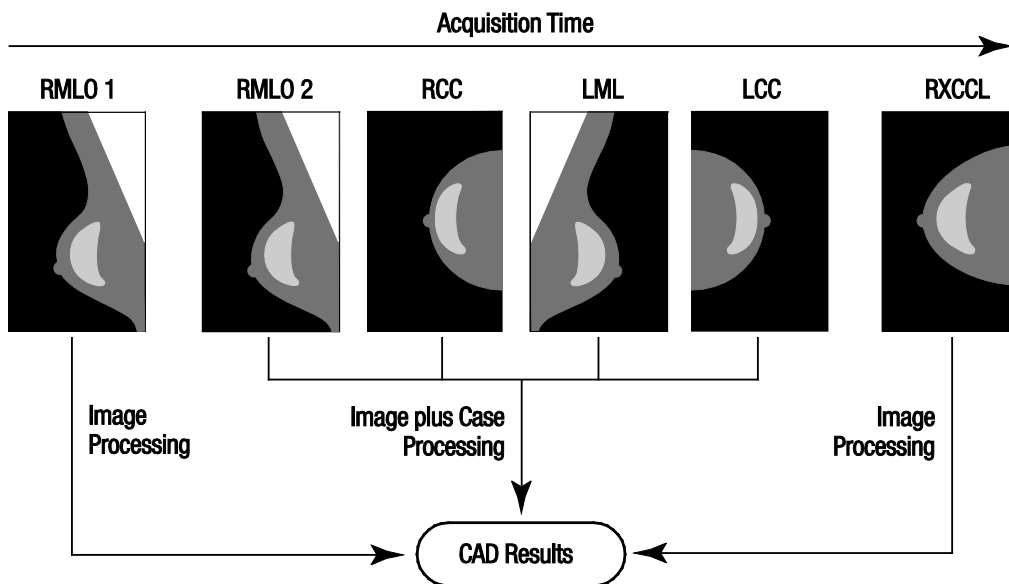
### Selecting Images for Case Processing

The ImageChecker CAD algorithm uses the following criteria to determine which images will be case-processed:

- If a study includes one image for each of the four screening views or their equivalents, ImageChecker CAD case-processes all images.
- If a study includes multiple images of the same view and laterality (e.g., two RCC views), ImageChecker CAD case-processes the *last* image produced by the FFDM device for each of the four screening views or their equivalents. (There is an exception for Implant Displaced views – see next bullet.) The image-acquisition time is included in the DICOM header for each image. (Refer to the diagram on the following page.)
- ImageChecker CAD always case-processes Implant Displaced images in favor of any equivalent-view images that are not displaced. Any other supported view modifiers, if present, do not affect which images are selected for case processing.
- If a study does not include one or more of the four screening views, ImageChecker CAD case-processes the equivalent views (or the reversed equivalent views), if they are present. Screening views are given preference over equivalent views, which in turn are given preference over reversed equivalent views.
- If a study includes multiple equivalent (or reversed equivalent) views, ImageChecker CAD case-processes views based on the following preference order:

Preference Order	CC Equivalent	MLO Equivalent
1	CC	MLO
2	FB	ML
3	XCC	LM
4	XCCL	LMO
5	XCCM	SIO
6	—	ISO

For example, the diagram below shows how ImageChecker CAD selects images for a study that includes three of the four screening views plus an LML image, an extra RMLO image, and an RXCCL image.



#### ImageChecker CAD Image and Case Processing

The diagram shows that when ImageChecker CAD selects images for processing, the algorithm first processes all images separately. However, for case processing, the algorithm:

- Includes only the *last* RMLO image acquired by the FFDM device (along with the other three screening views).
- Includes the LML image because there is no LMLO view, and the LML view is an equivalent view for LMLO.
- Selects the RCC image over the RXCCL image even though the RXCCL image is newer, because ImageChecker CAD always selects screening views over equivalent views when both are present.

## 2.5. Managing Workflow

There are no special considerations when a study consists solely of the four screening views (LCC, RCC, LMLO, and RMLO or their equivalents). For studies that include just the four screening views, you can send images in any order. The server reads the information stored with each image in the DICOM header and processes the image appropriately.

### Multiple Images of the Same View

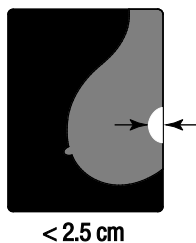
Whenever a study includes multiple images of the same view and laterality (e.g., two RCC views), CAD results can be affected by the order in which the technologist takes the images. As explained in [2.4. Image and Case Processing](#), CAD processing is optimized for the case-processed views, that is, the *last* image produced by the FFDM device for each of the four screening views (except when one or more Implant Displaced views are present).

As a general rule, the best CAD results are obtained when the technologist images the view with the greatest amount of dense tissue *later* in the exam. For example, when imaging partial views, first take the image with the most fatty tissue, and then take the image with the most glandular tissue.

### Images with Breast Implants

ImageChecker CAD processes images with implants, but the algorithm may not produce results if a significant portion of the implant is visible on the image. The software produces optimal CAD results from breast implant images when the implant is displaced. Note the following:

- ImageChecker CAD does process images that include the Implant Displaced view modifier.
- The Breast Implant Present attribute, if it is present in the DICOM header, has no effect on ImageChecker CAD processing.
- If more than 2.5 cm (1 in) of the implant (measured from the chest wall) is visible, ImageChecker CAD may not produce CAD results for the image.
- When both the Breast Implant Present and Implant Displaced views are included in a study, ImageChecker CAD always selects the Implant Displaced views for case processing.
- Implant Displaced views may be taken as a group or interleaved with the Breast Implant Present views.



### Images with Partial Views

Some studies require segmented breast views, that is, multiple images of the same view and laterality. In such cases, order the views so that the view with the most clinical significance is taken last in the sequence. For example, if the study requires three RCC views, consider imaging the most glandular region of the breast last. That way, ImageChecker CAD will use the view with the most glandular tissue for optimized case processing (because it has a later DICOM acquisition time).

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## Chapter 3: Algorithm Description

- ▶ [3.1. RightOn CAD Marks](#)
- ▶ [3.2. Limiting the Number of Marks](#)
- ▶ [3.3. EmphaSize Marks](#)
- ▶ [3.4. PeerView](#)
- ▶ [3.5. LesionMetrics](#)
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- ▶ [3.9. CAD Operating Points](#)
- ▶ [3.10. Performance Specifications](#)

This chapter describes how the ImageChecker CAD algorithm analyzes mammography images. The algorithm looks for characteristics commonly associated with cancer – specifically, calcifications and masses (including architectural distortions). The algorithm ranks its findings by likelihood, places marks on those regions above a fixed threshold of likelihood (operating point), and then sends the results to the review workstation.

The algorithm offers three operating points to accommodate differing radiologist preferences. For more information, see [3.9. CAD Operating Points](#).

### 3.1. RightOn CAD Marks

Workstations using Hologic's CAD marking schema provide three types of ImageChecker CAD marks. Each mark indicates a region of interest for the radiologist to review. There are two basic types of marks plus a composite mark:




**Calc** – Marks regions suggestive of calcifications



**Mass** – Marks regions suggestive of densities/masses/architectural distortions



**Malc** – Composite mark indicates Calc and Mass marks occurring in the same location on the image

 **Note:** *Not all mammography workstations can display Malc marks. Consult with your workstation vendor concerning availability and integration of ImageChecker CAD features with your workstation.*

## 3.2. Limiting the Number of Marks

The software limits or 'caps' the number of CAD marks for each image and case. The actual number of CAD marks produced depends upon the individual case and the operating point selected for the CAD algorithm.

Views	Per Image Limit	Per Case Limit
Screening views (RCC, LCC, RMLO, LMLO)	4 Calc marks 2 Mass marks <sup>1</sup> 2 Malc marks	8 Calc marks 4 Mass marks <sup>1</sup> 4 Malc marks
Extra views	3 Calc marks 2 Mass marks 2 Malc marks	Dependent upon the number of images <sup>2</sup>

**1** For standard screening views, the number of mass marks may exceed the quoted per-image limit for exceptionally suspicious lesions.

**2** For cases with more than four views, the maximum number of marks per case depends upon the number of images in the case.

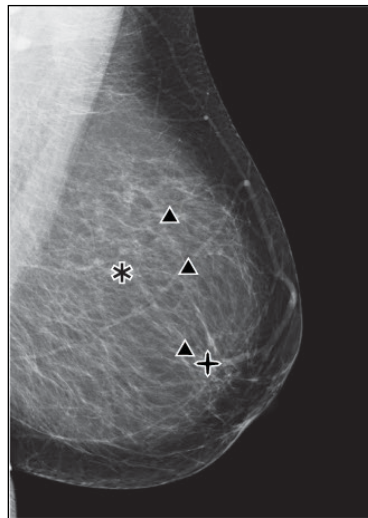
When ImageChecker CAD processes an individual image, it may show a set of CAD marks different from the marks reported when the image is part of a case. The differences are due to the fact that ImageChecker first processes the images individually before analyzing the case. When ImageChecker applies the more sophisticated case processing rules (such as bilateral asymmetry analysis), it may discard marks for regions that are less suspicious. For more information, see [2.4. Image and Case Processing](#).

### 3.3. EmphaSize Marks

EmphaSize is an optional feature that provides variable-size CAD marks that scale according to the significance of the finding. When the ImageChecker CAD algorithm considers a region to be more significant, certain review workstations can be configured to increase the size of the EmphaSize CAD mark.\* The size of the mark does not correlate to the size of the lesion.

As the algorithm evaluates regions of interest, each region is given a ranking. This ranking along with the selected algorithm operating point determines whether or not the region of interest is marked with a CAD mark.

Normally the review workstation displays all CAD marks at the same size regardless of ranking. If your site has enabled the EmphaSize feature and configured the review workstation to use it, the workstation can adjust the size of each mark according to its ranking. The EmphaSize feature can be disabled if you do not want to use it.




**CAD without EmphaSize**



**CAD with EmphaSize**

- **Calcifications** – The size of a suspected lesion is of variable significance, since small lesions may be highly significant and large lesions may be nonactionable. However, there are other key characteristics. For calcifications, the algorithm looks at characteristics such as signal intensity, number of calcifications in a cluster, shape of the calcifications (i.e., pleomorphism), and other important features to determine lesion significance.
- **Masses** – For masses, the algorithm looks at characteristics such as degree of spiculation, lesion shape, contrast to surrounding tissue, and other important features which help determine lesion significance.
- **Masses with Calcifications (Malc marks)** – Regions containing both a mass and calcifications are suspicious and should be carefully evaluated.

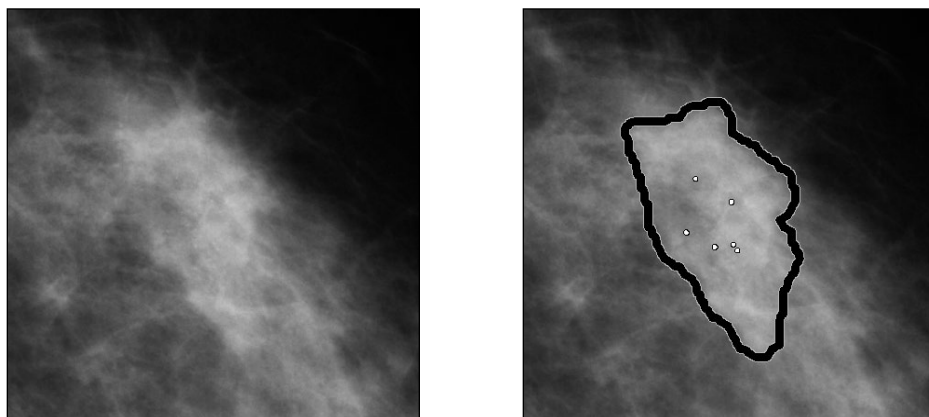
 **\*Note:** Not all mammography workstations can display EmphaSize marks. Consult with your workstation vendor concerning availability and integration of ImageChecker CAD features with your workstation.



## 3.4. PeerView

PeerView is an optional, licensed feature designed to help radiologists better understand why a region of interest was marked. At the review workstation, the radiologist can use PeerView to highlight regions of interest detected by the ImageChecker CAD algorithm.

- **Calcifications** – PeerView outlines individual calcifications in the cluster marked by the algorithm. PeerView may not outline all calcifications in a cluster, and it may show findings suggestive of calcifications that are not calcifications.
- **Masses** – PeerView defines and outlines the central density of the mass so the radiologist can evaluate the margin, shape, and interior characteristics of the CAD-detected mass or distortion. The outline does not generally include spiculations associated with the mass, although the shape of the central density may lead the eye to larger spicules.
- **Masses with Calcifications** – For composite Malc marks, which indicate that one or more Mass and Calc marks occur at the same location on the image, PeerView highlights the calcifications and outlines the central density of the mass and/or distortion found in the CAD analysis. The same region is shown below with and without a PeerView Malc mark (mass with calcifications).




**Note:** *Not all mammography workstations can display PeerView highlights. Consult with your workstation vendor concerning availability and integration of ImageChecker CAD features with your workstation.*

### 3.5. LesionMetrics

LesionMetrics is an optional, licensed feature that provides data computed by the ImageChecker CAD algorithm for each marked region of interest. The LesionMetrics are summarized in the following table.

LesionMetric	Description	Calc	Mass	Malc
Number of Calcifications	Number of individual calcifications detected by the algorithm at the current operating point.	✓		✓
Size (long axis)	Long axis in cm for the calcification cluster or mass.	✓	✓	✓
Distance to Nipple*	The radial distance in cm from the center of the lesion to the estimated nipple location.	✓	✓	✓
Distance to Chest Wall*	The estimated perpendicular distance in cm from the center of the lesion to the chest wall. For lesions in an upper quadrant, this metric may resolve to the perpendicular distance to the pectoral muscle, which can be reported as a negative value.	✓	✓	✓
Calcification Contrast (%)	The average difference in brightness between the individual calcifications and their immediate background normalized on a scale of 0 to 100.	✓		✓
Mass Density (%)	The average brightness of a lesion relative to its immediate background normalized on a scale of 0 to 100.		✓	✓
Degree of Spiculation (%)	A measurement proportional to the number of pixels that lie on lines pointing to a common origin inside the potential lesion, reported on a normalized scale of 0–100 containing the entire spectrum of biopsy-proven malignant masses.		✓	✓
Operating Point	The operating point (algorithm threshold) with the lowest sensitivity that the algorithm determines would detect the lesion.	✓	✓	✓

 **\*Note:** The accuracy of the measurement is subject to the positioning of the patient and other factors such as confluence of tissue and radiographic exposure. In any given image the distance can be determined manually using the workstation measurement tool.

The LesionMetrics feature is implemented on a limited number of review workstations. On SecurView DX (version 6-0 or later) you can enable or disable any or all of the LesionMetrics. Refer to your workstation's documentation to determine whether these features are implemented and, if they are, how to use them.

## 3.6. What the Algorithm Detects

The ImageChecker CAD algorithm searches an image for clusters of bright spots that are suggestive of calcification clusters, for patterns of dense regions, and for dense regions with radiating lines suggestive of masses or architectural distortions.


### Calcifications

The algorithm marks:

- Clusters with three or more elements
- Elements that are at or within 3 mm of each other
- Where each element is at least 150 microns in size

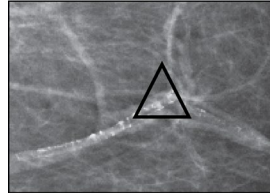
The algorithm does not mark:

- Clusters with fewer than three elements\*
- Clusters where each element is separated by more than 3 mm
- Elements it considers to be of benign morphology
- Low-contrast elements
- Lead skin markers or clips

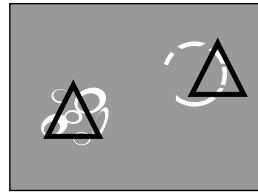
 **\*Note:** The algorithm marks two elements if the elements have significant contrast or shape, as defined by the cluster filter. See [3.7. Detecting Calcifications](#).

The algorithm occasionally marks:

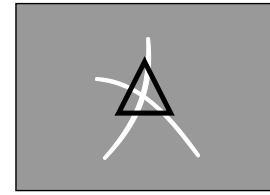
- Calcified arteries
- Cluster or rim benign calcifications
- Crossing linear tissues



Calcified Artery

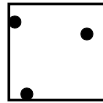


Cluster or Rim  
Benign Calcifications

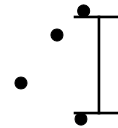


Crossing Linear  
Tissues

To be considered a cluster, elements need only be at or within 3 mm of another element within the cluster, as shown next:

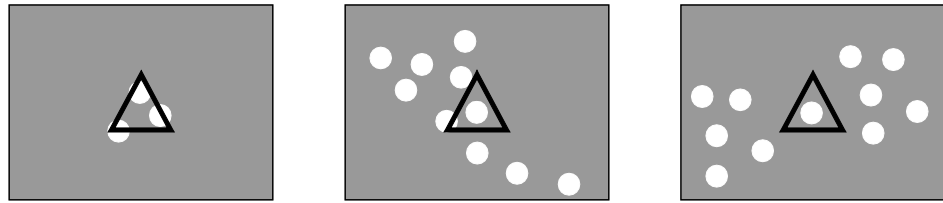


$\leq 3$  mm square



Each element is  
at or within 3 mm

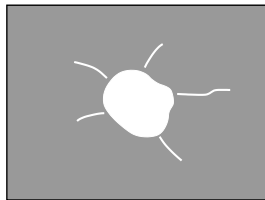
When a finding in the mammogram meets the ImageChecker CAD criteria, the algorithm places a triangular CAD mark over the center of that region (not over a particular element), as is shown next:



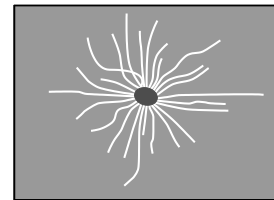
### Masses/Architectural Distortions

To detect masses, the ImageChecker CAD algorithm searches the image in a progressive manner looking for circular, dense regions and lines radiating from a common center. The algorithm marks:

- Regions suggestive of masses/architectural distortions
- Dense regions
- Regions with radiating lines



Less pronounced radiating lines  
but with a central mass



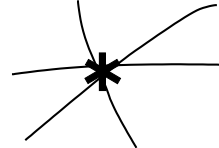
No central mass but  
pronounced radiating lines

The algorithm occasionally marks:

- Ducts and tissue radiating from the nipple
- Inadvertent crossing of parenchymal tissue
- Well circumscribed masses
- Lymph nodes
- Vague opacities, skin thickening, or nipple retraction



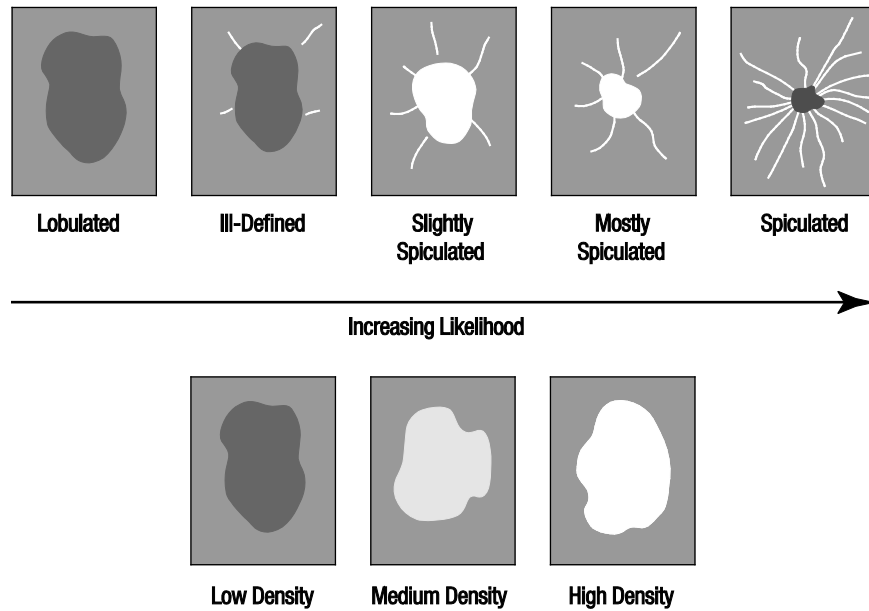
Ducts and tissue radiating from nipple



Inadvertent crossing of parenchymal tissue

The likelihood of a mass/architectural distortion being marked is affected by the:

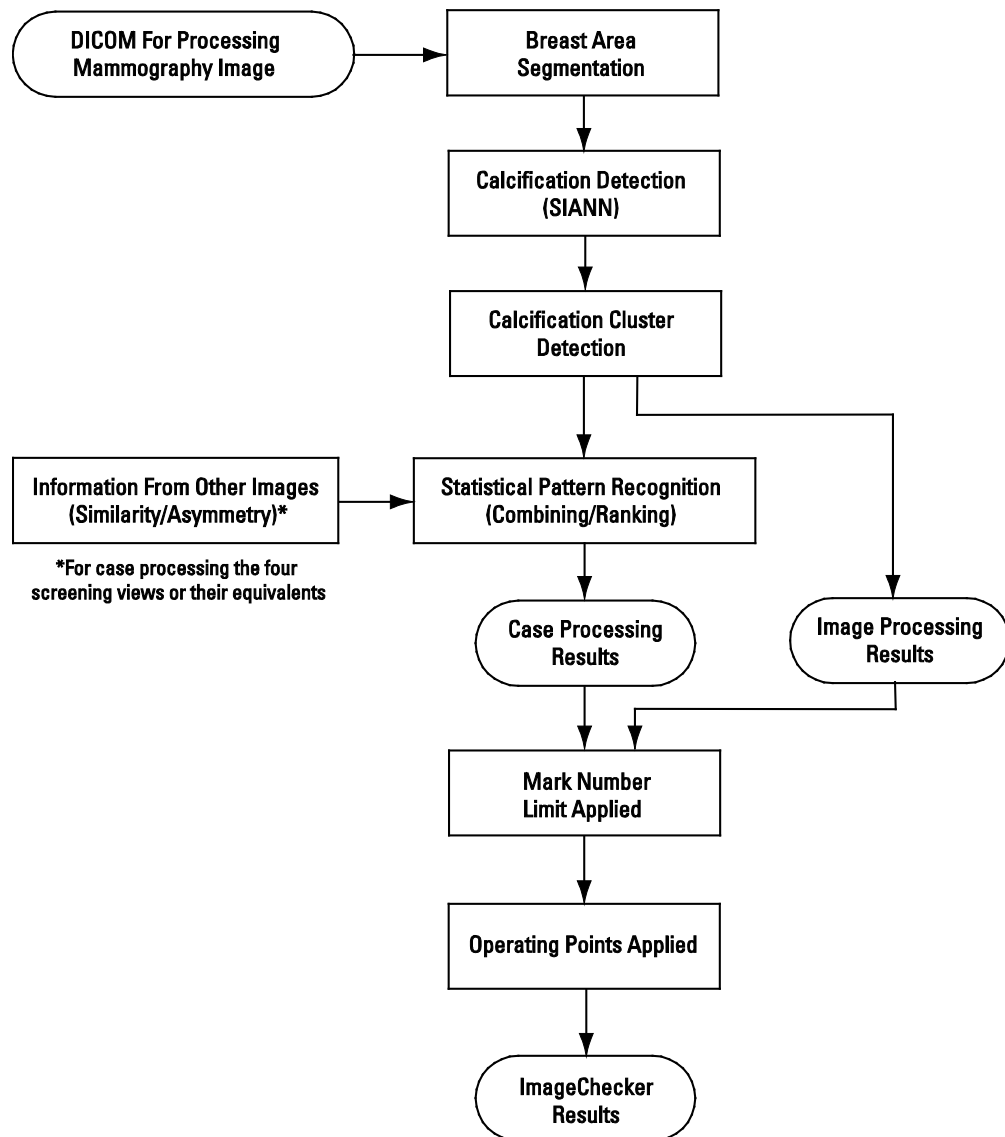
- Margin of the mass (the greater the spiculation, the more likely)
- Degree of density (the higher the density, the more likely)
- Presence of left/right breast asymmetry



When the algorithm finds patterns associated with masses, it places an asterisk at the point of maximum convergence on the image.

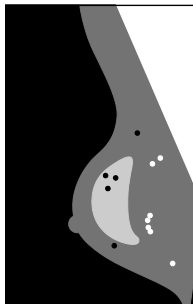
### 3.7. Detecting Calcifications

To detect calcifications, ImageChecker CAD performs a series of analyses:



**ImageChecker CAD Calcification Detection**

#### Image Processing for Calcifications



For each image, the algorithm uses two filters (artificial neural networks) to identify calcifications and their characteristics:

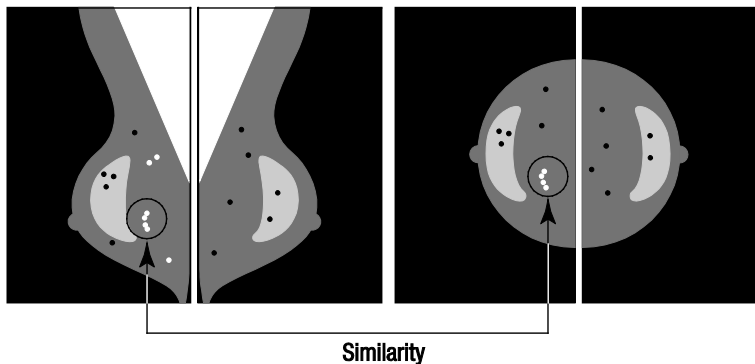
- First, it runs each image through a Shift-Invariant Artificial Neural Network (SIANN), a calcification detection filter that has been optimized using Hologic's large training database. SIANN is a patented technology developed through more than 10 years of research at the University of Chicago.
- Then, it analyzes the resulting calcifications using a cluster filter that weights over a dozen different characteristics, including contrast, shape, and size.



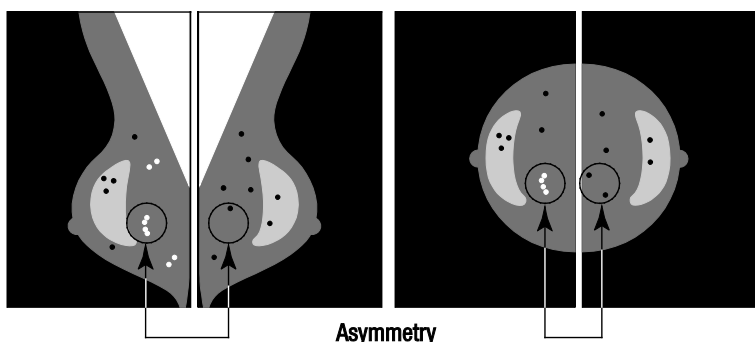
In addition, the algorithm segments the breast and identifies the location of the cluster within the breast.

### Case Processing for Calcifications

In addition to processing images individually, ImageChecker CAD selects up to four images that represent the screening views – RCC, LCC, RMLO, and LMLO (or their equivalents). The algorithm reviews the findings from each image and looks for similarities in the findings by comparing complementary orthogonal views (for example, LMLO and LCC):



It also looks for asymmetries between views from each side, for example, LMLO and RMLO:



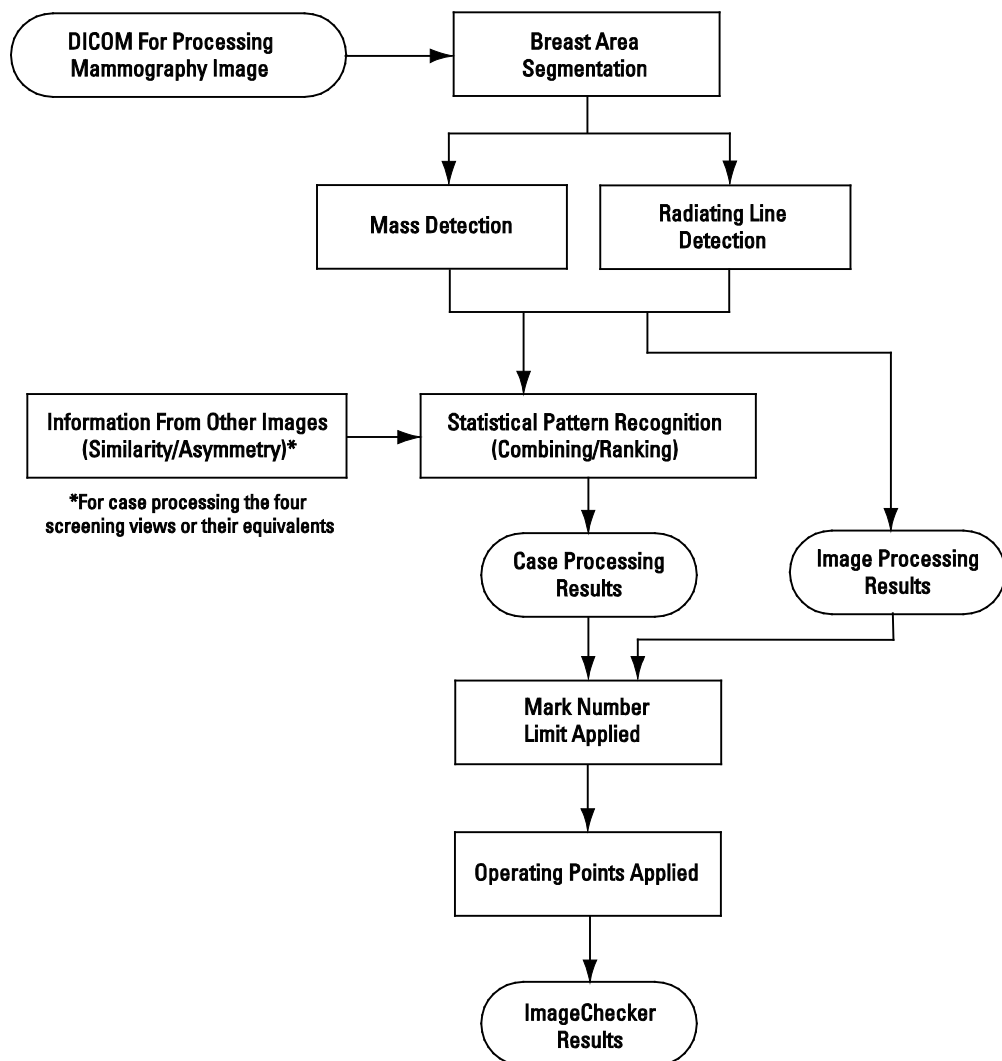
The algorithm combines the results of these various analyses, analyzes the resulting cluster and context data, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible clusters. It then selects the Calc marks that best meet the algorithm criteria (mark capping), and applies the selected operating point, thereby limiting the number of marked findings.

Finally, if the algorithm determines that a selected Calc mark is coincident with a Mass mark, then ImageChecker CAD converts the marks into a Malc mark.

For more information see [2.4. Image and Case Processing](#).

### 3.8. Detecting Masses

To detect masses, ImageChecker CAD performs a series of analyses:



**ImageChecker CAD Mass Detection**

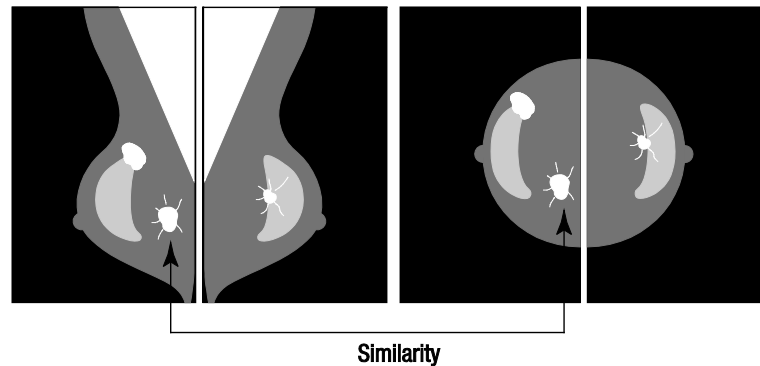
#### Image Processing for Masses



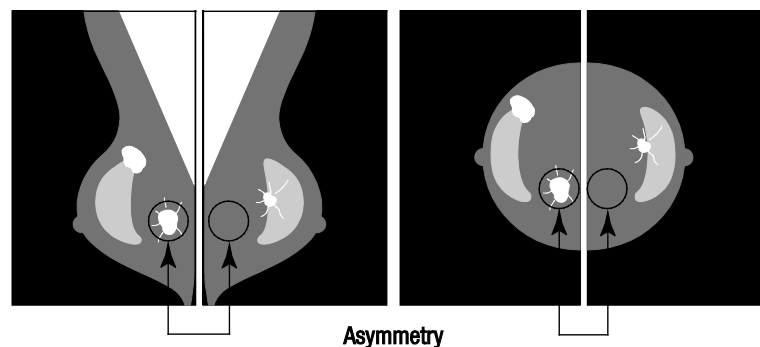
For each image, the algorithm uses patented technology to segment the breast. It then identifies masses by evaluating structures based on their density, shape, and margin characteristics. It also searches for structures appearing as radiating lines, and, if they are present, the degree of spiculation.

### Case Processing for Masses

In addition to processing images individually, ImageChecker CAD selects up to four images that represent the screening views – RCC, LCC, RMLO, and LMLO (or their equivalents). The algorithm reviews the findings from each image and looks for similarities in the findings by comparing complementary orthogonal views (for example, LMLO and LCC):



It also looks for asymmetries between views from each side, for example, LMLO and RMLO:



The algorithm then runs the resulting data against the training database to determine the ranking for each of the possible masses. Finally, the algorithm either marks or does not mark the masses, based on the ranking and operating point.

The algorithm combines the results of these various analyses, analyzes the resulting findings, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible findings. It then selects the Mass findings that best meet the algorithm criteria (mark capping), and applies the selected operating point, thereby limiting the number of marked findings.

Finally, if the algorithm determines that a selected Mass mark is coincident with a Calc mark, then ImageChecker converts the marks into a Malc mark.

For more information see [2.4. Image and Case Processing](#).

### 3.9. CAD Operating Points

Sites with ImageChecker CAD can choose between three different operating points (i.e., CAD algorithm thresholds). Each site can choose a different operating point for calcifications than for masses, which provides a total of nine options for operating point combinations. The operating points are summarized below:

- Operating point 0 trades off a lower false-mark rate for a lower overall sensitivity. This operating point is suited for sites that want to display the fewest false marks.
- Operating point 1 represents a balanced intermediate point. Improvements in the algorithm have allowed points 0 and 2 to be set quite far apart, and some sites may want balanced behavior from the CAD algorithm.
- Operating point 2 focuses on sensitivity. It gives the best performance for marking regions of interest (i.e., CAD sensitivity), with a higher false-mark rate. It is suited for sites that want to display the highest number of marks possible, regardless of the higher false-positive mark rate.

For example, if you want high sensitivity for calcifications but a moderate balance between sensitivity and false positives for masses, choose operating point 2 for calcifications and operating point 1 for masses.

You can discuss the choices that are right for your site with your Applications Specialist or, if you would like to change configurations, contact your technical support representative.

## 3.10. Performance Specifications

The table below gives the sensitivity and false-mark rate values for the three operating points for ImageChecker CAD software version 9.4, as measured on Hologic's digital test database of biopsy-proven malignancies and confirmed normal cases for the four screening views (RCC, LCC, RMLO, and LMLO).

Operating Point:	0	1	2
<b>Calcification Cases</b> (n = 222)			
Sensitivity <sup>1</sup>	95%	98%	99%
95% Confidence Interval	92.77–98.22%	96.45–99.95%	97.86–99.99%
<b>Mass Cases</b> (n = 578)			
Sensitivity <sup>1</sup>	87%	89%	91%
95% Confidence Interval	84.10–89.61%	86.94–91.95%	88.48–93.18%
<b>Overall</b> (n = 800)			
Sensitivity <sup>1</sup>	89%	92%	93%
95% Confidence Interval	87.10–91.40%	89.98–93.77%	91.37–94.88%
<b>Screening Normals</b> (n = 828) <sup>2</sup>			
Calcification FP/Image	0.08	0.12	0.15
Mass FP/Image	0.19	0.27	0.36
Total FP/Case	1.1	1.5	2.0
Specificity	56%	42%	29%
95% Confidence Interval	53.02–59.78%	38.19–44.90%	25.90–32.08%
<b>Screening and BI-RADS 0 Normals</b> (n = 911) <sup>3</sup>			
Calcification FP/Image	0.08	0.13	0.16
Mass FP/Image	0.20	0.28	0.38
Total FP/Case	1.1	1.6	2.1
Specificity	54%	39%	27%
95% Confidence Interval	50.66–57.13%	36.13–42.47%	24.44–30.23%

**1** '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.

**2** 'False-Positive' (FP) and 'Specificity' data were developed from a review of confirmed normal cases (defined as those rated as BI-RADS 1 and 2 in radiology reports). 'FP/Image' refers to the average number of false-positive marks per image measured on normal cases. 'Specificity' refers to the percentage of normal cases that, when processed, show no CAD marks.

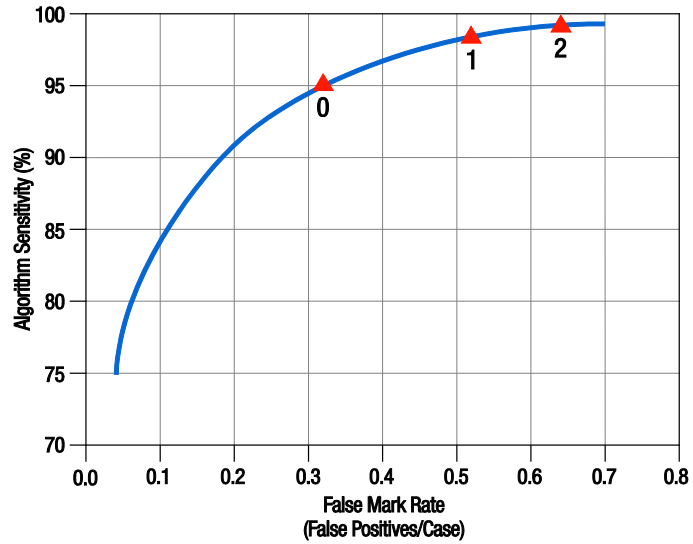
**3** 'False-Positive' (FP) and 'Specificity' data were developed from a review of confirmed normal cases (defined as those rated as BI-RADS 0, 1, and 2 in radiology reports). The normal cases were enriched with 10% BI-RADS 0 cases wherein the BI-RADS 0 assessment for these subjects resulted in one or 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.

To determine false-mark rates, Hologic processes normal screening cases through the ImageChecker CAD software and measures the number of false marks per image. Screening cases with additional views or diagnostic studies may have a different mix of images and, as such, may produce results that fall outside the measured normal case mark rate. Since the mark rate is measured per image, a larger number of images in a case should correspond on average with a higher total mark count for that case. While clinical experience demonstrates some variation in mark rates, Hologic has not found the false-mark rate to vary dramatically when averaged over a large number of cases.

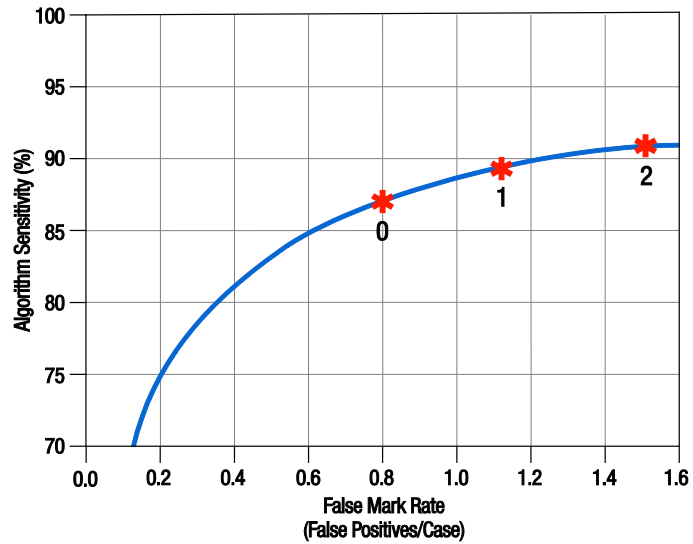
To determine a true positive calcification cluster for estimating sensitivity, the CAD algorithm identifies a list of spots contained in one cluster. Likewise, the reference standard (truth) consists of a list of spots per cluster. To be counted as a true positive, the center of a spot must be within 250 $\mu$ m of the center of a reference standard spot center.

To determine a true positive mass lesion for estimating sensitivity, the CAD algorithm identifies an outline for a mass consisting of a closed contour polygon outlining the extent of the detected mass. The algorithm identifies the geometric center (centroid or center of mass) of the outline. If the center lies within the closed contour reference standard, the mark is considered to be a true positive.

The following graphs show plots of algorithm sensitivity vs. false-mark rate based on cases with the four screening views, with data points for each of the three operating points using Hologic's digital test database of 800 biopsy-proven malignant cancers and 911 screening and BI-RADS 0 normals.



**Calcification Performance**



**Mass Performance**

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