ImageChecker®
Computer-Aided Detection

Understanding ImageChecker® CAD User Guide
Version 10.0
MAN-11077-002 Revision 002

HOLOGIC®

ImageChecker®

Computer-Aided Detection (CAD)

User Guide

For Software Version 10.0

Part Number MAN-11077-002
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HOLOGIC®

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Chapter 1 Introduction

ImageChecker® CAD is a software application used by radiologists for analyzing two-dimensional digital mammography images. The software is a licensed option that can be used on the Cenova™ Image Analytics Server, certain versions of Selenia® Dimensions®/3Dimensions™ digital mammography systems, 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.

1.1   Intended Use

R℟ONLY   Caution: United States federal law restricts this device to sale by or on the order of a physician.

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.

1.2   Intended User

ImageChecker CAD is intended to be used by physicians or radiation technologists working in a hospital, outpatient clinic, or a breast imaging center.

1.3   Patient Target Group

The device is intended to be used in the population of patients undergoing screening mammography.

1.4 Contraindications

There are no known contraindications.

1.5 Using This Manual

This manual is organized as follows:

- *Introduction* on page 1 provides an overview of the ImageChecker CAD application including features, benefits, and precautions for use.
- *Image Processing and Workflow* on page 11 explains how information flows through systems with ImageChecker CAD, the supported mammography views, and how to manage workflow.
- *Algorithm Description* on page 19 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.

1.6 Resources Available

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

- **Training:** Training is available. Contact your Hologic representative for more information.
- **Website:** The Hologic website (*www.hologic.com*) provides access to electronic versions of User Guides. For printed copies, contact your Hologic representative.
- **Technical Support and Service:** For information, see the copyright page of this guide.

1.7   Product Complaints

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic Authorized Representative and Competent authority of the respective member state or country.

The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

1.8   Symbols

Symbol	Description	Standard
RX ONLY	Prescription use only	FDA 21 CFR 801.109
EC REP	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
REF	Catalog number	ISO 15223-1, Reference 5.1.6
SN	Serial number	ISO 15223-1, Reference 5.1.7
REV	Revision	Hologic
⚠	Warning	ISO 7010, Reference W001
⚠	Caution	ISO 15223-1, Reference 5.4.4
✓	Note	Hologic
📖 www.hologic.com/package-inserts	Consult Instructions for Use	ISO 15223-1, Reference 5.4.3 Hologic
〜	Date of manufacture	ISO 15223-1, Reference 5.1.3
〜CC	Country of Manufacture	ISO 15223-1, Reference 5.1.11
▲	Manufacturer	ISO 15223-1, Reference 5.1.1
MD	Medical device	ISO 15223-1, Reference 5.7.7
CE	CE Mark European Conformity	MDR Regulation (EU) 2017/745
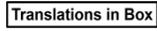
Symbol	Description	Standard
Translations in Box	Translations in Box	Hologic
Patents	Patents	Hologic

1.9   Warnings and Precautions

Note

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

For Warnings and Precautions related to the installation, operation, and maintenance of the Selenia Dimensions/3Dimensions digital mammography system, refer to the respective Selenia Dimensions/3Dimensions *User Guide*.

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 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.

> **Important**
>
> 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 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 *CAD Operating Points* on page 32. 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 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.
> - ImageChecker CAD marks on a conventional 2D mammography image and the corresponding generated 2D image of a ComboHD procedure may differ due to differences in image characteristics.

> **Note**
>
> A generated 2D image is a two-dimensional image synthesized from tomosynthesis reconstructed slices.
>
> - The performance of ImageChecker CAD has not been characterized for mammographic images showing less than 2.5 cm² of breast tissue.
> - ImageChecker CAD does not process images that include the following DICOM view modifiers (with Systematized Nomenclature of Medicine (SNOMED) codes):
>   - Cleavage (R-102D2)
>   - Magnification (R-102D6)
>   - Spot Compression (R-102D7)
> - 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 17.
>   - 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 18.

1.10   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.

1.10.1 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™ (not available when the ImageChecker CAD application is run on a Dimensions/3Dimensions system)

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 *Algorithm Description* on page 19.

Important
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 your workstation vendor concerning availability and integration of ImageChecker CAD features with your workstation.

1.10.2 RightOn CAD Marks

Workstations using Hologic 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

1.10.3 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 *EmphaSize Marks* on page 20.

1.10.4 PeerView

PeerView enables the radiologist to understand better why a region of interest was marked. On advanced review workstations such as Hologic SecurView® DX, PeerView highlights physical findings detected by the algorithm. For more information, see *PeerView* on page 22.

1.10.5 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 *LesionMetrics* on page 23.

Note
LesionMetrics is not available when the ImageChecker CAD application is run on a Dimensions/3Dimensions system.

1.10.6 Operating Points

Conventional 2D Mammography Images

The ImageChecker CAD algorithm for conventional 2D mammography images offers three operating points (that is, 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.

When your system is installed, the server software is configured to use the default operating point 1 for masses and 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.

Generated 2D Images

The ImageChecker CAD algorithm for generated 2D images offers only one operating point (that is, CAD algorithm threshold) at this time. The operating point corresponds to the calcification and mass default settings for conventional 2D mammography images.

For more information, see *CAD Operating Points* on page 32.

1.11   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.[1, 2, 3] 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.

1.12   System Requirements

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

Table 1: Server Specifications

Characteristic	Minimum Requirements
Processor Type	Intel-Based, Multicore
Operating System	Windows 7 Pro SP1 64-bit or Windows 7 Pro Embedded SP1 64-bit or Windows 10
Memory (RAM)	4 GB
HDD Free Disk Space	120 GB
Network Card	100 Mbps
Optical Drive	CD-ROM

1.13   Warranty Statement

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

Chapter 2 Image Processing and 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

2.1.1 Cenova Image Analytics Server

The ImageChecker CAD software runs 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:
   - Images suitable for processing by various software applications (raw images)
   - Images suitable to be viewed on a review workstation (processed images)

2. The FFDM system sends the raw images to the server software and sends the processed images to a review workstation or PACS.

3. The server software receives the raw 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 processed images produced by the FFDM system.

   At the review workstation, the radiologist begins by examining the processed 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.

Note
The display of ImageChecker CAD features is dependent on the workstation's capabilities to interpret ImageChecker CAD results. Some workstations can display only a subset of ImageChecker CAD features.

2.1.2 Dimensions/3Dimensions Systems

The ImageChecker CAD software runs on the appropriate Dimensions/3Dimensions Acquisition Workstation. Image and data flows are as follows:

1. The system produces two-dimensional digital x ray images in two forms:

   - Images suitable for processing by various software applications (raw images)
   - Images suitable to be viewed on a review workstation (processed images)

2. When the user closes a procedure as complete on the Acquisition Workstation, ImageChecker CAD analyzes the eligible acquired and accepted raw images, produces results for the study, and provides the results to the Acquisition Workstation software.

3. The Acquisition Workstation 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.

4. For each study, the Acquisition Workstation displays a thumbnail image representation of the ImageChecker CAD results for the study.

5. For each study, the review workstation displays the ImageChecker CAD results with the processed images produced by the Dimensions/3Dimensions system.

   At the review workstation, the radiologist begins by examining the processed 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.

Note

The display of ImageChecker CAD features is dependent on the workstation capabilities to interpret ImageChecker CAD results. Some workstations can display only a subset of ImageChecker CAD features.

2.2 Image Acquisition Systems

ImageChecker CAD, when running on a Cenova Image Analytics server, processes 2D images originating from the following FFDM systems:

- Hologic Selenia®
- Hologic Selenia Dimensions® 2D
- Hologic Selenia Dimensions 3D™ systems (2D and generated 2D images only)
- GE Senographe® 2000D
- GE Senographe DS
- GE Senographe Essential
- Siemens Mammomat® Novation[DR]

ImageChecker CAD, when running on a Dimensions/3Dimensions system, processes 2D and generated 2D images under these conditions:

- Dimensions/3Dimensions system images acquired on version 1.10/2.1 or later.

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:

Table 2: Supported DICOM Views and View Modifiers

Supported DICOM Views and View Modifiers		ACR MQCM 1999* View Label
Screening Views	Cranio-Caudal	CC
	Medio-Lateral Oblique	MLO
Equivalent Views	Medio-Lateral	ML
	Cranio-Caudal Exaggerated	XCC
	Cranio-Caudal Exaggerated Laterally	XCCL
	Cranio-Caudal Exaggerated Medially	XCCM
Reversed Equivalent Views	Latero-Medial	LM
	Latero-Medial Oblique	LMO
	Cranial-Caudal From Below	FB
	Inferomedial to Superolateral Oblique	ISO
	Superolateral to Inferomedial Oblique	SIO
View Modifiers	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 17.
> - **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 18.

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

2.4.1 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*.

2.4.2 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 20.

For more information about image and case processing, see *Detecting Calcifications* on page 27 and *Detecting Masses* on page 30.

2.4.3 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 (for example, 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:

Table 3: Preference Order for Case Processing

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 following diagram 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.
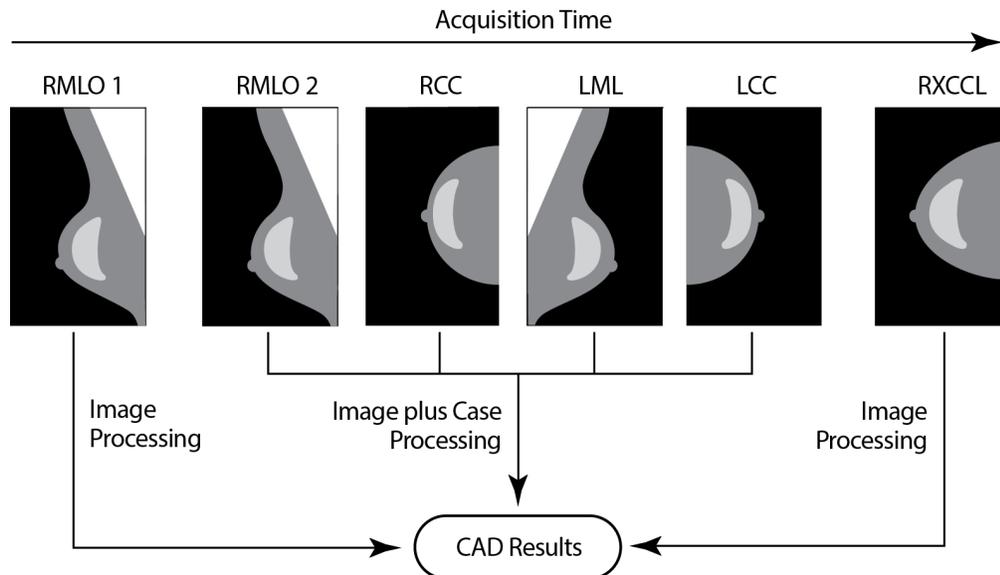

Figure 1: ImageChecker CAD Image and Case Processing

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.

2.5.1   Multiple Images of the Same View

Whenever a study includes multiple images of the same view and laterality (for example, two RCC views), CAD results can be affected by the order in which the technologist takes the images. As explained in *Image and Case Processing* on page 14, 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.

2.5.2   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:
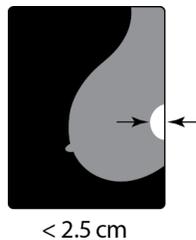
< 2.5 cm

- 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.

2.5.3   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).

Chapter 3 Algorithm Description

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 for conventional 2D mammography images to accommodate differing radiologist preferences. At this time, only one operating point is offered for generated 2D images. For more information, see *CAD Operating Points* on page 32.

3.1   RightOn CAD Marks

Workstations using Hologic 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.

Table 4: Software Limits on the Number of CAD Marks

Views	Per Image Limit	Per Case Limit
Screening views (RCC, LCC, RMLO, LMLO)	4 Calc marks 2 Mass marks[a] 2 Malc marks	8 Calc marks 4 Mass marks[a] 4 Malc marks
Extra views	3 Calc marks 2 Mass marks 2 Malc marks	Dependent upon the number of images[b]

(a) For mammographic screening views, the number of mass marks may exceed the quoted per-image limit for exceptionally suspicious lesions.

(b) 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 *Image and Case Processing* on page 14.

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.
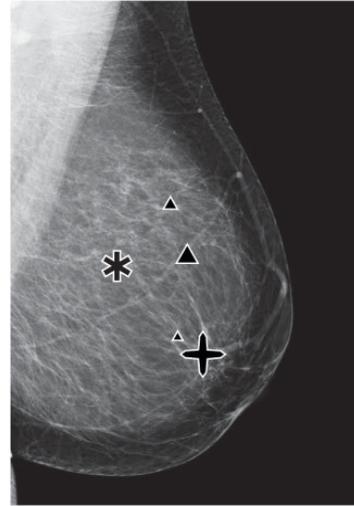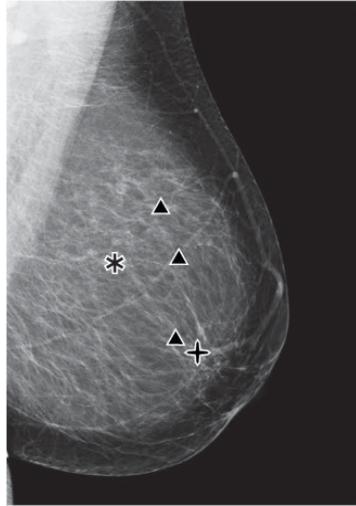

Figure 2: CAD without EmphaSize   *Figure 3: CAD with EmphaSize*

- **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 (that is, 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 your workstation vendor concerning availability and integration of ImageChecker CAD features with your workstation.

3.4   PeerView

PeerView is a 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 in the following figures with and without a PeerView Malc mark (mass with calcifications).
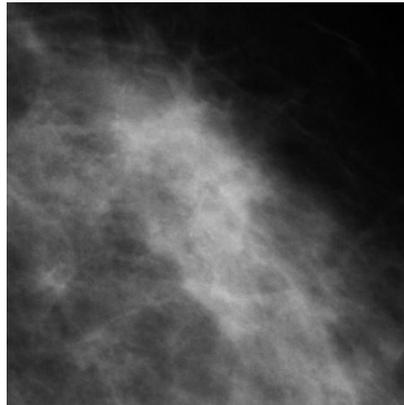

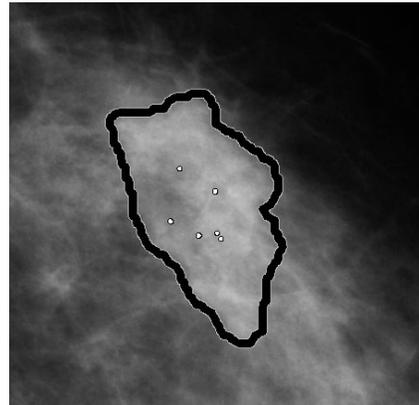*Figure 4: Region without a PeerView Malc*   *Figure 5: Region with a PeerView Malc*

Note

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

3.5   LesionMetrics

> **Note**
> LesionMetrics is not available when the ImageChecker CAD application is run on a
> Dimensions/3Dimensions system.

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

Table 5: Summary of LesionMetrics

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.

On SecurView DX (version 6-0 or later), you can enable or disable any or all of the LesionMetrics. Refer to your workstation 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.

3.6.1   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

Note
The algorithm marks two elements if the elements have significant contrast or shape, as defined by the cluster filter. See *Detecting Calcifications* on page 27.

- 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

The algorithm occasionally marks:

- Calcified arteries
- Cluster or rim benign calcifications
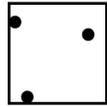- Crossing linear tissues
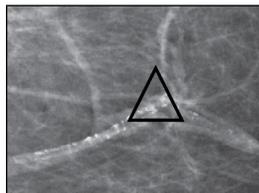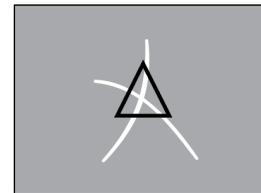
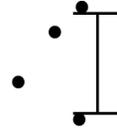Calcified Artery   Cluster or Rim Benign   Crossing Linear Tissues
                                  Calcifications

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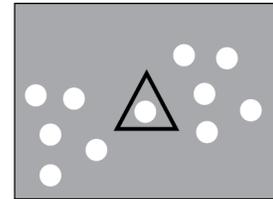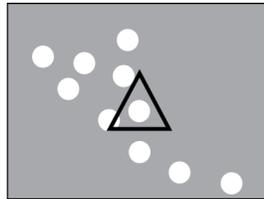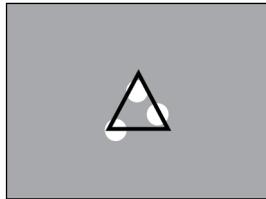
≤ 3 mm square

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:

3.6.2   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
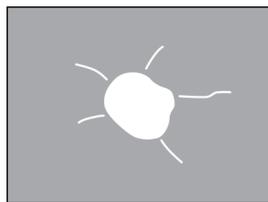
Less pronounced radiating lines
but with a central mass
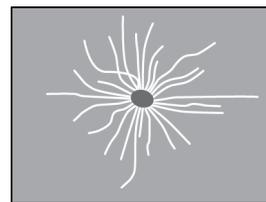
No central mass but
pronounced radiating lines

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
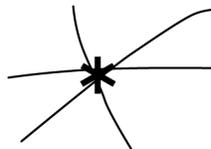
Inadvertent crossing of
parenchymal tissue

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)
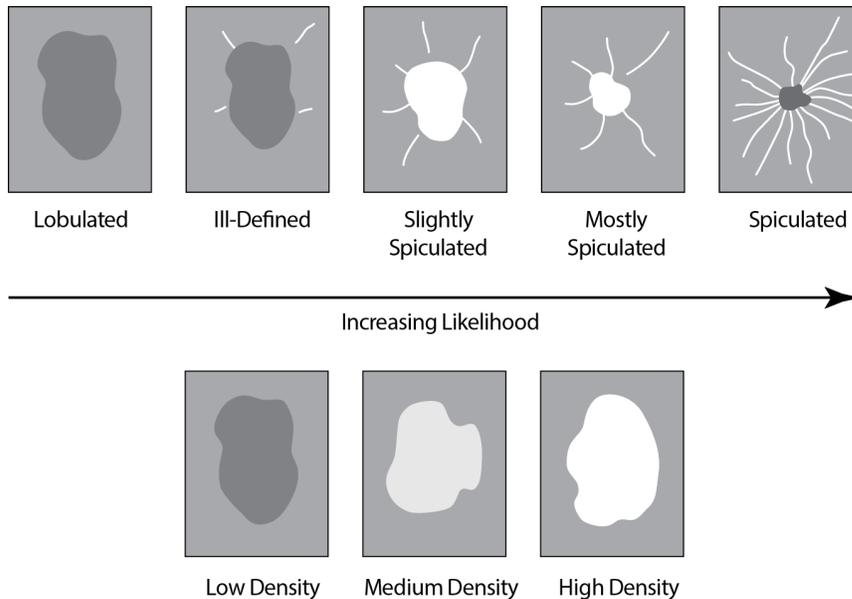- Presence of left/right breast asymmetry

| Lobulated | Ill-Defined | Slightly Spiculated | Mostly Spiculated | Spiculated |

Increasing Likelihood

| Low Density | Medium Density | High Density |

Figure 6: Likelihood of a mass/architectural distortion being marked

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

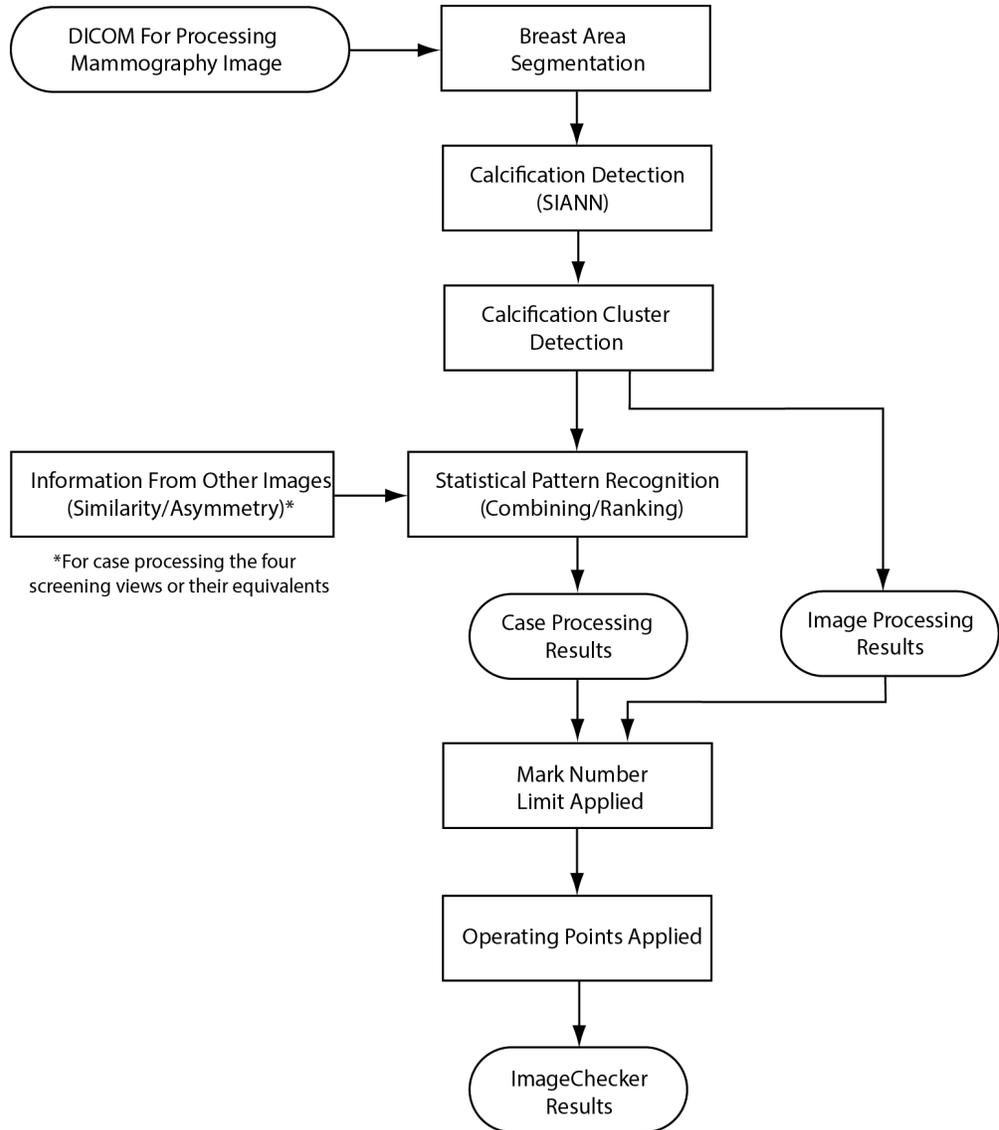To detect calcifications, ImageChecker CAD performs a series of analyses:

Figure 7: ImageChecker CAD Calcification Detection

### 3.7.1   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.

3.7.2   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):

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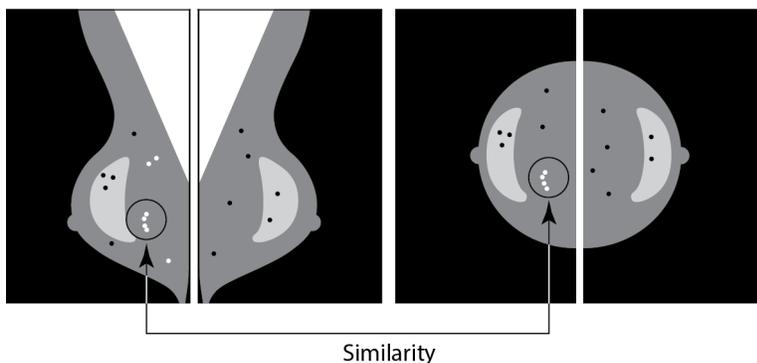
It also looks for asymmetries between views from each side; for example, LMLO and RMLO:

Asymmetry
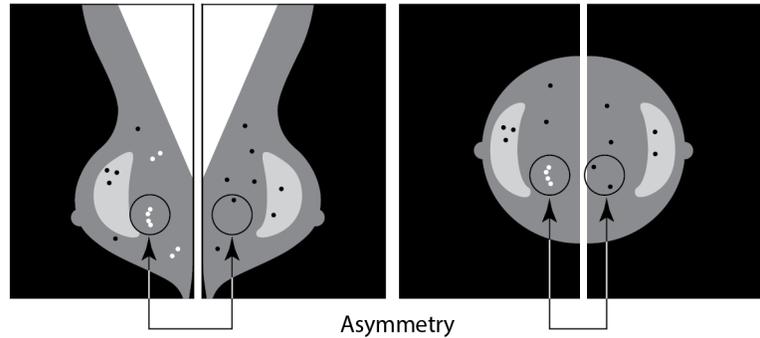
The algorithm combines the results of these various analyses, analyzes the resulting cluster and context data, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible clusters. It then selects the Calc marks that best meet the algorithm 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 *Image and Case Processing* on page 14.

3.8   Detecting Masses

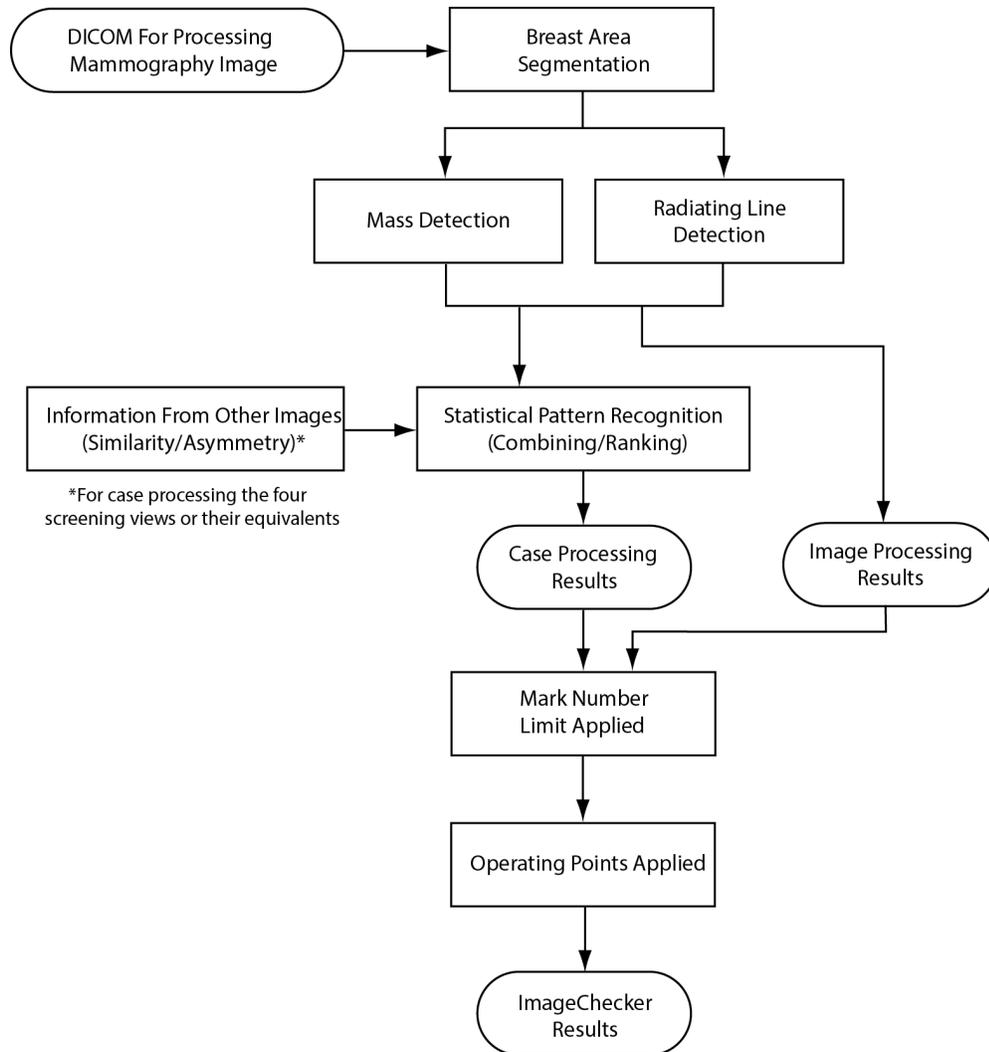To detect masses, ImageChecker CAD performs a series of analyses:

*Figure 8: ImageChecker CAD Mass Detection*

3.8.1 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.

3.8.2 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):

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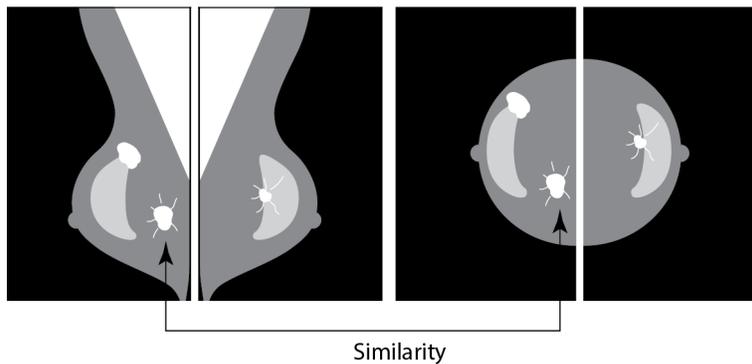
It also looks for asymmetries between views from each side (for example, LMLO and RMLO):

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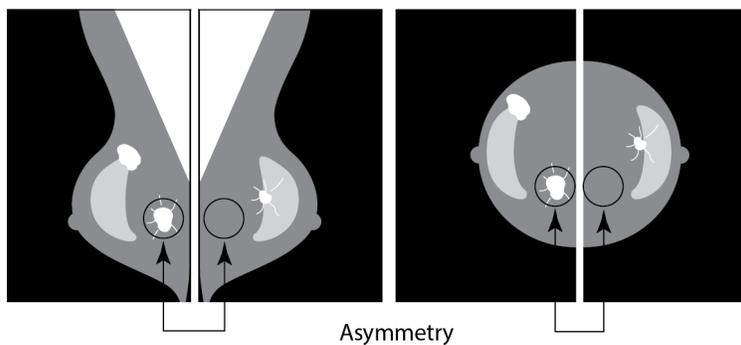
The algorithm then runs the resulting data against the training database to determine the ranking for each of the possible masses. Finally, the algorithm either marks or does not mark the masses, based on the ranking and operating point.

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 *Image and Case Processing* on page 14.

3.9   CAD Operating Points

Conventional 2D Mammography Images

Sites with ImageChecker CAD can choose between three different operating points (that is, 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 (that is, 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.

2D Images Generated from Binned or Unbinned Tomosynthesis

Sites using CAD with generated 2D images only have one operating point available at this time, which is the default operating point for 2D:

- The operating point for calcifications corresponds to operating point 2 for conventional 2D mammography images.

- The operating point for masses corresponds to operating point 1 for conventional 2D mammography images.

3.10   CAD Performance

Performance of CAD algorithms is measured using image test databases of known radiological and pathological outcomes. Sensitivity, false marker rate and specificity are well-accepted metrics to evaluate performance. ImageChecker CAD performance is presented on two separate test databases: 1) conventional 2D mammography images where CAD performance on 2D images is evaluated and 2) generated 2D images with matched conventional 2D mammography images where CAD performance on generated 2D images and matched conventional 2D images is evaluated.

> **Note**
> The composition of an image test database affects measured CAD performance. Therefore, direct comparison of CAD performance using different test databases is not meaningful.

Test Database 1: Conventional 2D Mammography Images

Test Database 1 is used to measure performance of ImageChecker CAD on conventional 2D mammography images. The database consists of 1,711 cases including biopsy proven cancer, screening normal (BI-RADS® 1 or 2) and recall (BI-RADS 0) cases. The database contains images collected over several years from multiple sites in the United States and Europe and includes images from Hologic (Selenia and Selenia Dimensions) and GE (Senographe 2000D, Senographe DS, and Senographe Essential) systems. ImageChecker CAD also supports Siemens Mammomat Novation[DR] which uses the same detector as the Hologic Selenia system.

The following table provides performance metrics at three operating points for ImageChecker CAD on Test Database 1 consisting of conventional 2D mammography images where each case contains the four mammographic screening views (RCC, LCC, RMLO, and LMLO).

Table 6: Performance Metrics of ImageChecker CAD 10.0 on Test Database 1

Operating Point:	0	1	2
Calcification Cases (n = 222)Sensitivity[c]	96%	98%	99%
95% Confidence Interval	93.35–98.54%	96.45–99.95%	97.86–99.99%
Mass Cases (n = 578)Sensitivity[c]	86%	89%	91%
95% Confidence Interval	83.53–89.13%	86.18–91.33%	88.28–93.03%
Overall (n = 800)Sensitivity[c]	89%	91%	93%
95% Confidence Interval	86.83–91.17%	89.43–93.32%	91.23–94.77%
Screening and BI-RADS 0 Normals (n = 911)[d]			
Calcification FP/Image	0.09	0.13	0.16
Mass FP/Image	0.20	0.29	0.38
Total FP/Case	1.14	1.67	2.16
Specificity	53.46%	39.85%	29.31%
95% Confidence Interval	50.22–56.70%	36.67–43.03%	26.35–32.26%

Test Database 2: Generated 2D Images with Matched Conventional 2D Mammography Images

Test Database 2 is used to measure performance of ImageChecker CAD on both generated 2D images and conventional 2D mammography images. The database consists of 911 cases including biopsy-proven cancer, screening normal (BI-RADS 1 or 2) and recall (BI-RADS 0) cases. The database contains generated 2D images and conventional 2D mammography images acquired on Hologic Selenia Dimensions tomosynthesis systems.[4] Both generated 2D images and conventional 2D mammography images are acquired under a single compression with no repositioning. The database reflects cases from multiple sites throughout the United States.

The following table provides the performance metrics for ImageChecker CAD on Test Database 2 consisting of generated 2D images and matched conventional 2D mammography images where each case contains the four mammographic screening views (RCC, LCC, RMLO, and LMLO).

Table 7: Performance Metrics of ImageChecker CAD 10.0 on Test Database 2

Image Type:	Generated 2D Images	Conventional 2D Images
Calcification Cases (n = 91)Sensitivity[c]	96%	93%
95% Confidence Interval	91.39–99.82%	88.31%–98.51%
Mass Cases (n = 220)Sensitivity[c]	85%	85%
95% Confidence Interval	80.80–90.11%	80.80–90.11%
Overall (n = 311)Sensitivity[c]	88%	88%
95% Confidence Interval	84.87–91.98%	84.14%–91.42%
Screening and BI-RADS 0 Normals (n = 660)[d]		
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%

(c) '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.

---

[4] The generated 2D images in Test Database 2 were originated from 140 micron resolution Hologic tomosynthesis projection image data. Hologic generated 2D images that are created for ImageChecker CAD from 70 micron resolution Hologic tomosynthesis projection image data match the characteristics of the generated 2D images represented in Test Database 2, resulting in equivalent ImageChecker CAD performance.

(d) '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.

Standalone Study of Generated 2D Images and Matched Conventional 2D Mammography Images

A standalone study was conducted to compare the performance of ImageChecker CAD on generated 2D images with their matched conventional 2D mammography images. Generated 2D images and the matched conventional 2D mammography images from Test Database 2 were analyzed independently using ImageChecker CAD 10.0. The performance metrics of these two image types were compared. The standalone study results indicated that the performance of ImageChecker CAD 10.0 on generated 2D images was comparable to that on conventional 2D mammography images.

Scoring Methodology

To determine false-mark rates, Hologic processes screening and BI-RADS 0 normal cases (as defined above for Table 1 and Table 2[(d)]) 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 μm 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 on conventional 2D mammography images using the Hologic Test Database 1 of 800 biopsy-proven malignant cancers and 911 screening and BI-RADS 0 normals (as defined above for Table 1 and Table 2[d]).
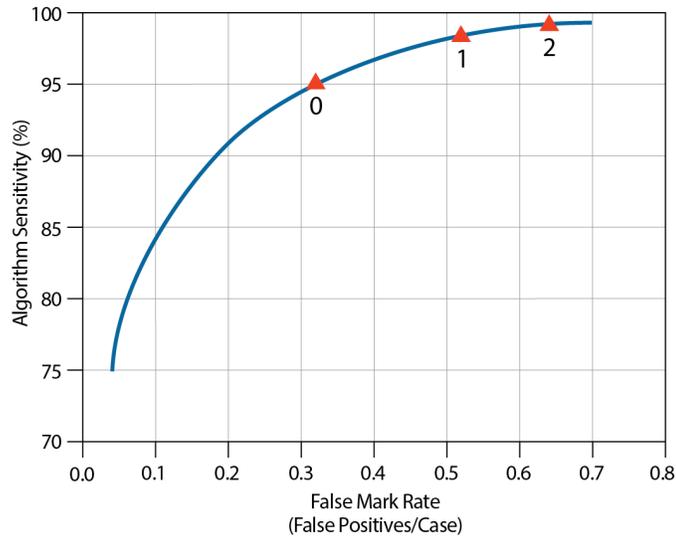
Calcification Performance
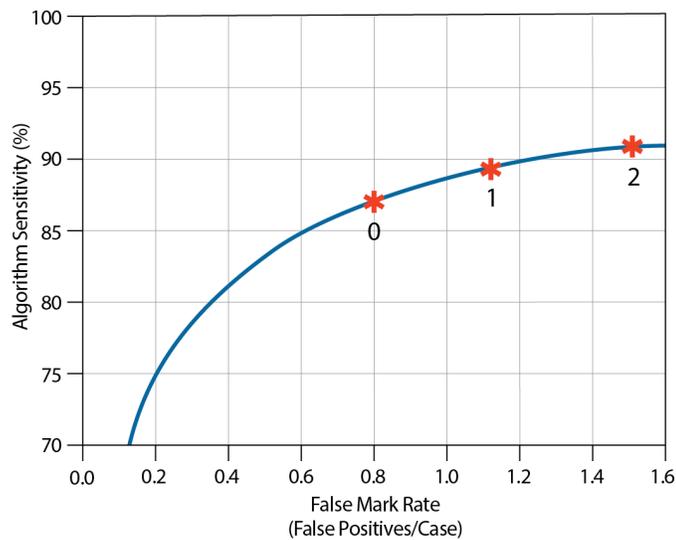
Mass Performance

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