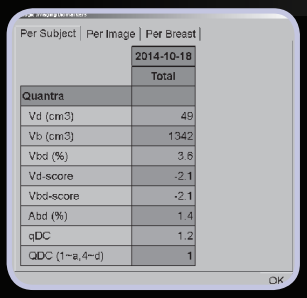
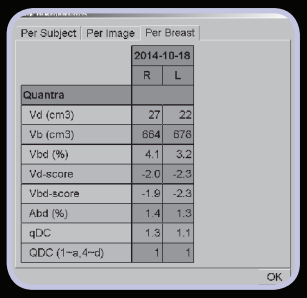

Per Subject | Per Image | Per Breast

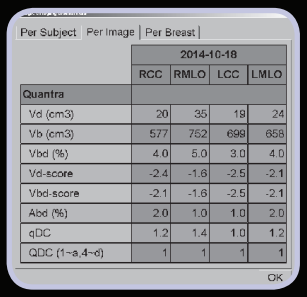
	2014-10-18
	Total
Quantra	
Vd (cm3)	49
Vb (cm3)	1342
Vbd (%)	3.6
Vd-score	-2.1
Vbd-score	-2.1
Abd (%)	1.4
qDC	1.2
QDC (1~a,4~d)	1

OK


Per Subject | Per Image | Per Breast

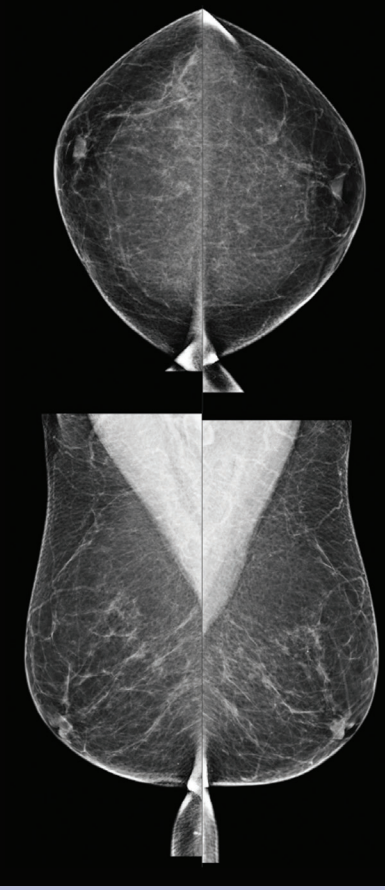
	2014-10-18	
	R	L
Quantra		
Vd (cm3)	27	22
Vb (cm3)	664	678
Vbd (%)	4.1	3.2
Vd-score	-2.0	-2.3
Vbd-score	-1.9	-2.3
Abd (%)	1.4	1.3
qDC	1.3	1.1
QDC (1~a,4~d)	1	1

OK


Per Subject | Per Image | Per Breast

	2014-10-18			
	RCC	RMLO	LCC	LMLO
Quantra				
Vd (cm3)	20	35	19	24
Vb (cm3)	577	752	699	658
Vbd (%)	4.0	5.0	3.0	4.0
Vd-score	-2.4	-1.6	-2.5	-2.1
Vbd-score	-2.1	-1.6	-2.5	-2.1
Abd (%)	2.0	1.0	1.0	2.0
qDC	1.2	1.4	1.0	1.2
QDC (1~a,4~d)	1	1	1	1

OK



Understanding Quantra™ 2.1
User Manual

MAN-04259 Rev 001

Quantra™

Breast Density Assessment Software

Cenova™

Image Analytics Servers

HOLOGIC®

Quantra™
Breast Density Assessment Software

Understanding Quantra™ 2.1
User Guide

MAN-04259 Rev 001

HOLOGIC®

Technical Support

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Website: **www.hologic.com**

For support in Europe, South America, or Asia, contact your local dealer or distributor.

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Contents

Chapter 1: Introduction

Quantra is a software application used by radiologists to calculate volumetric and area breast densities from digital breast x-ray images. The software is a licensed option with Hologic's Cenova™ server or any server with comparable functionality (that meets the Quantra data input and output requirements).

The information in this User Guide is intended to serve as a reference for radiologists and clinic personnel who need to understand how Quantra operates and how breast density assessment can be integrated into their practices.

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

1.1. Intended Use

Quantra is a software application intended for use with images acquired using digital breast x-ray systems. Quantra calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Quantra also provides area breast density as a ratio of fibroglandular tissue area and total breast area estimates. Quantra segregates breast density into categories, which may be useful in the reporting of consistent BI-RADS® breast composition categories as mandated by certain state regulations. The Quantra results for each image, breast, and subject, are intended to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information; it is not an interpretive or diagnostic aid.

1.2. Using This User Guide

This User Guide is organized as follows:

- **Chapter 1: Introduction** provides an overview of the Quantra application including features, benefits, and precautions for use.
- **Chapter 2: Image Processing and Supported Views** explains how information flows through systems with Quantra, the supported digital breast x-ray views, and how to manage workflow.
- **Chapter 3: Algorithm Description** describes how the Quantra algorithm analyzes digital breast x-ray images.

This User Guide 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 User Guide, 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) 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 (1-866-243-2533).

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 Guide.*

⚠ ***Important:*** *Please note the following:*

- *Quantra is intended to provide adjunctive information; it is not an interpretative or diagnostic aid. The radiologist should base assessment of breast density on diagnostic quality images.*
- *The performance of the Quantra software has been evaluated only for images labeled as the four standard screening views: LCC, RCC, LMLO, and RMLO.*
- *Results are not reported for:*
  - *Images that are 'equivalent' or 'reversed equivalent' views (e.g., ML, XCCL, or LM, LMO).*
  - *Images labeled with the view modifiers M, CV, or S (magnified, cleavage, or spot-compressed views).*
  - *Digitized images (scanned film images).*
  - *C-View 2D images.*
- *Images showing breast implants may be processed by the software, although the software has not been designed for that purpose. The software is likely to produce inaccurate Quantra results for patient images with breast implants.*
- *Images of partial views of the breast that are not correctly identified as such may be processed by the software, although the software has not been designed for that purpose. The software is unlikely to produce accurate Quantra results for partial view images.*
- *Quantra estimates BI-RADS breast composition category based on percentage of dense tissue in the breast. At this time, it does not consider parenchymal patterns.*

⚠ ***Note:*** *Quantra does **not** use data compression.*

1.5. Overview of Quantra

Quantra is a software application used to produce assessments of breast composition, both of the breast as a whole and the fibroglandular tissue. Fibroglandular tissue, also referred to as dense tissue, contains a mixture of fibrous connective tissue (stroma) and glandular tissue (epithelial cells), and usually appears brighter than surrounding tissue on a digital breast x-ray image.

The Quantra algorithm first estimates the volume of the imaged portion of the breast, and then separates the breast into portions of fat and portions of dense tissue. Through arithmetic division, the algorithm determines and reports the ratio of dense tissue as a percentage of total breast volume. The Quantra algorithm estimates two volumes:

- Volume of dense tissue in cubic centimeters (cm^3)
- Volume of the breast in cm^3

It then divides the volumes to produce:

- Volumetric fraction of breast dense tissue as a percentage

From these measurements, Quantra reports categories that compare the results to those of a reference population.

Based on the results from volumetric assessment, Quantra also calculates the ratio of the area of dense tissue relative to the total area of the breast in a result known as:

- Area breast density

The Quantra results serve as a convenience to assist the radiologist in assessing the proportion of dense tissue in the breast.

For more information on the individual measures produced by Quantra, see **3.2. Volumetric Assessment** and **3.3. Area Assessment**.

⚠ ***Note**: When both conventional 2D mammography and Hologic 3D Mammography images are provided to Quantra for a Combo or ComboHD study, only one set of Quantra results (2D or 3D) is generated.*

1.6. Benefits of Quantra

In recent years, the medical community has shown increasing interest in understanding the relationship between the gross morphology of breast tissue and the risk of developing cancer. Most literature discussing the analysis of breast tissue composition has focused on visual (human) assessments of breast tissue.

Currently the most commonly used human classification system is the BI-RADS composition category from the Breast Imaging Reporting and Data System Atlas, Fifth Edition, developed by the American College of Radiology (ACR). BI-RADS provides a standardized breast composition classification system for mammographic studies. The ACR recommends that radiologists practicing in the United States make a visual assessment of breast composition as a part of the reading of a study.

The BI-RADS Atlas divides breast composition into the following categories:

BI-RADS Composition	Description
a.	The breasts are almost entirely fatty
b.	There are scattered areas of fibroglandular density
c.	The breasts are heterogeneously dense, which may obscure small masses
d.	The breasts are extremely dense, which lowers the sensitivity of mammography

Characterization of breast composition, as described in BI-RADS, depends on the radiologist's assessment of tissue pattern and density.

Assessment of breast composition by BI-RADS classification is difficult because tissue pattern in a digital breast x-ray image may not correlate with density in the same digital breast x-ray image, and dense tissues may be concentrated in one region of the breast. The radiologist must decide whether density or pattern is the more important factor in assigning a classification in any specific case. This, along with variations in image processing and inter-observer differences, makes composition classification imprecise and difficult to reproduce.

Quantra has been developed in order to provide estimations of breast tissue volumes. Through a proprietary software algorithm, Quantra produces an estimate of dense tissue volume relative to total breast volume that is not subject to human imprecision.

Quantra is not intended as a substitute for BI-RADS composition assessment; rather, it serves as an adjunct technology that can help the radiologist make more consistent breast composition assessments.

1.7. System Requirements

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

Operating System	Windows XP/Windows 7
Processor Speed	2 GHz
Memory (RAM)	4 GB
HDD Free Disk Space	130 GB
Optical Drive	DVD-ROM
Network Interface Controller	100 Mbps capable NIC

Chapter 2: Image Processing and Supported Views

This chapter explains how information flows through systems with Quantra and the supported digital breast x-ray views.

2.1. Image Processing

The Quantra software runs on a server that manages DICOM images and processes the algorithm results. Image and data flows are generally as follows:

1. Images are acquired using a digital breast x-ray system.
2. The digital breast x-ray 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 Quantra software.
4. Quantra analyzes the images, 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 in the form of DICOM Structured Report (SR) or DICOM Secondary Capture Image.
6. For each study, the review workstation displays the Quantra results with the processed images produced by the digital breast x-ray system. Radiologists can review the Quantra results at any time as a normal part of the diagnostic reading process.

⚠ ***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 Quantra software.*

2.2. Image Acquisition Systems

Quantra processes images originating from digital breast x-ray systems manufactured by Hologic, GE, and Siemens. Quantra processes conventional 2D mammography images from all supported manufacturers, and Hologic 3D Mammography.[1]

Quantra supports the following acquisition systems:

- Hologic Selenia, Hologic Selenia Dimensions
- GE Senographe™ 2000D, GE Senographe DS, and GE Senographe Essential
- Siemens Mammomat® Novation^{DR}

Whether images are transmitted directly from the digital breast x-ray system or obtained from a PACS, the Quantra software expects to receive raw images rather than processed images. As many sites do not store raw images, it is important that images in the correct format be available for Quantra for any future processing needs.

[1] Quantra analyzes 2D center projection images from Hologic 3D Mammography.

2.3. Inputs and Supported Views

Quantra analyzes digital breast x-ray images that conform to the DICOM standard. The Quantra software processes the four digital breast x-ray screening views:

RCC – Right Cranio-Caudal LCC – Left Cranio-Caudal

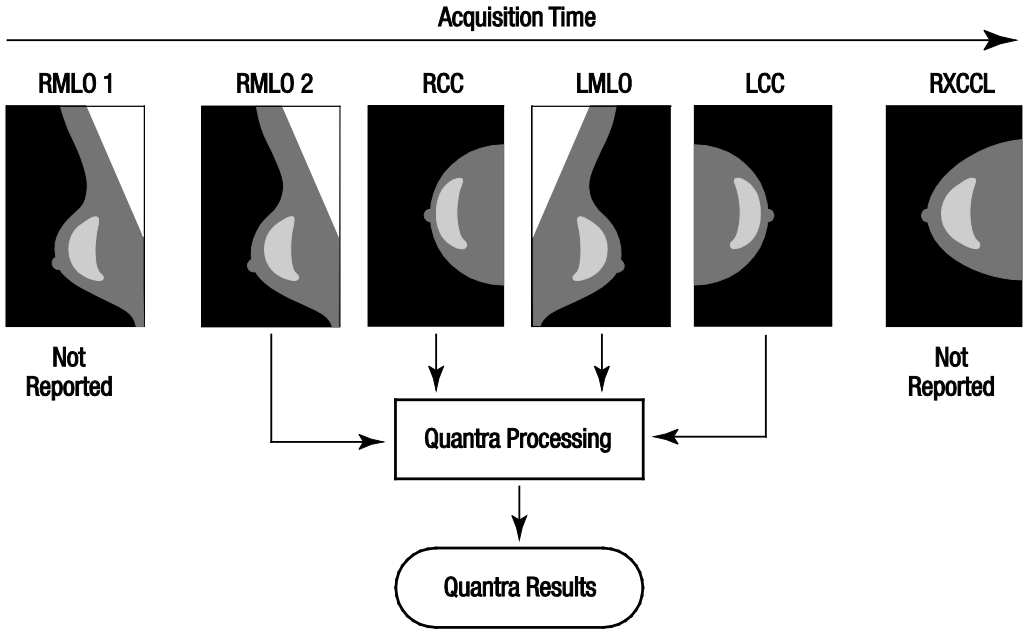
RMLO – Right Medio-Lateral Oblique LMLO – Left Medio-Lateral Oblique

The server software reads the DICOM header of each received image and groups successive images from a single subject into a study, which then passes to the Quantra algorithm. The following criteria determine which images will be used when reporting results:

- If a study includes exactly one image for each of the four screening views, then Quantra processes all images.
- If a study includes multiple images of the same view and laterality (e.g., two RCC views), then the results are derived only from the *last* image produced by the digital breast x-ray system for each of the four screening views. The image-acquisition time is included in the DICOM header for each image.

  ⚠ ***Note:*** *As an exception to this rule, Quantra processes images with the Implant Displaced DICOM view modifier, even if they are acquired before the implant views.*

For example, this diagram shows how images are selected for a study that includes the four screening views, an extra RMLO image, and an RXCCL image.



Quantra Image Processing

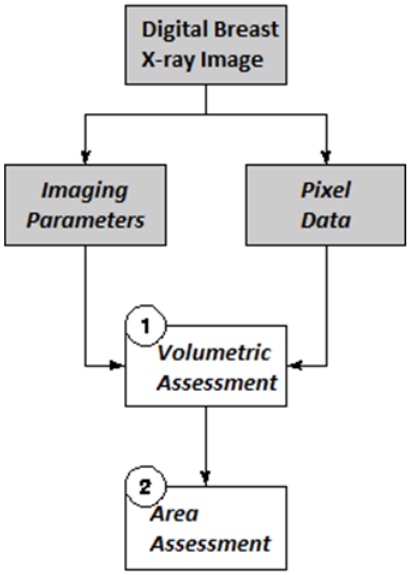
The diagram shows that when Quantra selects images, the algorithm reports results only for the *last* RMLO image acquired by the digital breast x-ray device (along with the other three screening views). In addition, even though the RXCCL image is newer than the RCC image, results for the RXCCL image are not reported because Quantra does not process equivalent views.

Chapter 3: Algorithm Description

This chapter describes the Quantra algorithms and results produced when Quantra analyzes digital breast x-ray images.

3.1. Quantra Algorithm Structure

Quantra contains a hierarchy of algorithms that derive estimates of breast density and related information from digital breast x-ray images. Quantra uses the digital breast x-ray image components to perform volumetric assessment estimates and calculation of statistical measures based on the volume estimates (1) as shown in the Quantra Algorithm Flow diagram. Quantra then derives area assessment estimates and calculation of statistical measures based on the area estimates (2).



Quantra Algorithm Flow

3.2. Volumetric Assessment

The Quantra algorithm is based on a two-compartment (fat and dense tissue) model of the x-ray imaging chain that relates breast tissue x-ray attenuation to the pixel values in digital breast x-ray images. Quantra calculations are based on published physical parameters for the breast and the imaging system, as well as information about individual x-ray exposures, including:

- attenuation coefficients for breast tissue[1]
- x-ray spectra for the target material[2]
- kVp, mAs, and thickness of the imaged tissue

The software estimates the thickness of dense tissue by using the difference in effective attenuation coefficient of the fat and dense tissue. This difference along with the pixel values in the raw digital breast x-ray image is used in an x-ray attenuation model equation to estimate thickness of fibroglandular tissue at each image pixel inside the breast.

Quantra calculates an intermediate result in centimeters of dense tissue penetrated at each pixel in the image, which is used as a basis to calculate various Quantra parameters described in this section.

The algorithm then derives statistical measures that estimate the measures for an individual subject relative to a reference population. The baseline values for the reference population were derived from a large number of digital breast x-ray images from multiple institutions across the United States.

A comparison of age and BI-RADS density distributions of the reference population with the DMIST study demonstrated that the reference population is representative of the population of approximately 43,000 women as described in the large multicenter American College of Radiology sponsored trial and peer-reviewed publication.[3]

Quantra calculates the statistical measures for both the volume of dense tissue and the volumetric breast density as the number of standard deviations from the mean of the reference population.

---

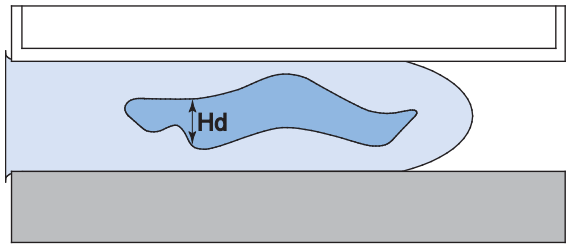
1 P. C. Johns and M. J. Yaffe. X-ray characterization of normal and neoplastic breast tissue. *Physics in Medicine and Biology*, 32:675-695, 1987.

2 J. M. Boone, T. R. Fewell, and R. J. Jennings, 'Molybdenum, rhodium, and tungsten anode spectral models using interpolating polynomials with application to mammography,' Med. Phys. 24, 1863–1874 1997.

3 E. D. Pisano, C. Gatsonis, E. Hendrick et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. N Engl J Med. 353(17):1773–83, 2005 Oct 27.

Volume of Dense Tissue (Vd)

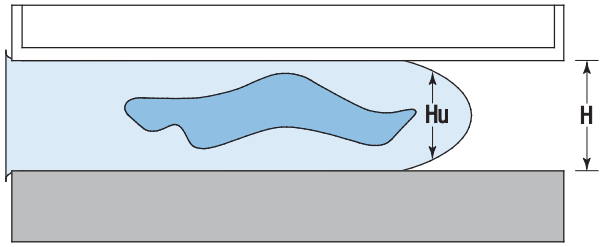
After Quantra completes its analysis on a pixel-by-pixel basis inside the breast (excluding the pectoral muscle), it aggregates the Hd heights for each pixel value into the volume of dense tissue, given in cubic centimeters (cm^3).



Assessment of Volume of Dense Tissue

Volume of Breast (Vb)

Through a similar process, Quantra considers the entire imaged breast outline, including those portions of the breast that were not compressed. In this diagram, note the difference between the compressed thickness H and the thickness of the breast in the uncompressed region Hu. Quantra compensates for such uncompressed regions in its estimations of breast volume.



Assessment of Volume of Breast

Volumetric Breast Density (Vbd)

Quantra divides the estimated dense tissue volume by the estimated breast volume to determine the volumetric percentage of dense tissue in the breast.

⚠ ***Note:*** *Quantra volumetric breast density (Vbd) is different from traditional human viewing of digital breast x-ray images in that its measurements are based on estimates of breast tissue* ***volumes****, rather than on human estimates of* ***areas****. As a result, the volumes produced tend to be lower than one might determine from visual inspection.*

Volume of Dense Tissue Reference Score (Vd-score)

The Vd-score indicates how far the subject Vd value is from the mean Vd value of the reference population, measured in standard deviations. The score is *positive* if the Vd value is greater than the mean, and *negative* if it is less than the mean. Quantra reports the score for each image, breast, and subject.

Volumetric Breast Density Reference Score (Vbd-score)

The Vbd-score indicates how far the subject Vbd value is from the mean Vbd value of the reference population, measured in standard deviations. The score is *positive* if the Vbd value is greater than the mean, and *negative* if it is less than the mean. Quantra reports the score for each image, breast, and subject.

3.3. Area Assessment

The Quantra area assessment algorithm operates on results from the Quantra volumetric assessment algorithm described above. It selects pixels (based on the Hd values calculated in the volumetric assessment algorithm) that can be associated as representing significant dense tissue. The area of the selected dense pixels is the basis for the area assessments.

Area Breast Density (Abd)

Quantra calculates the area breast density as the ratio of the area of the pixels selected as dense divided by the total area of the breast, derived from a standard mammographic breast segmentation method. When in view, Quantra excludes the pectoralis muscle from the estimate of the total breast area used in the Abd calculation.

3.4. Breast Composition Categories

Quantra Breast Density Category - fractional (qDC)

Quantra maps the estimated volumetric breast density into qDC, an estimate of overall breast composition relative to the reference population. The qDC value is a continuous measure of breast composition, ranging from 0.5 for fatty breasts with very low breast density to 4.5 for extremely dense breasts with very high volumetric breast density.

Quantra Breast Density Category (QDC)

QDC is derived by rounding off the qDCvalue to the value of the nearest integer and then converting the values of 1, 2, 3, and 4 to a, b, c, and d, respectively. It provides an estimate of overall breast composition that is analogous to the four breast composition categories of the BI-RADS Atlas Fifth Edition used by radiologists in many countries to report breast composition.

3.5. Combination of Quantra Results

Quantra produces three different levels of results. It first calculates the individual Per-Image parameters for each supported image view. Once it completes the Per-Image calculations, it aggregates the results first into Per-Breast results, and further into Per-Subject results.

Per-Image Results

The server software assesses each received image to see if the image is suitable for Quantra. This excludes images such as spot compressions, magnification views, partial views and those with implants in view. Quantra processes each of the accepted images and calculates Per-Image results for each of the parameters described previously.

Per-Breast Results

After calculating the Per-Image results, Quantra combines the results into Per-Breast results. Quantra combines results from the orthogonal views (e.g., LCC and LMLO) as follows, in this order:

Per-Breast	Method
Vbd	Average of per-image values from CC and MLO views.
Vb	Average of per-image values from CC and MLO views.
Vd	Multiplication of per-breast Vbd by per-breast Vb.
Abd, Vbd-score, Vd-score	Average of per-image values from CC and MLO views.
qDC	Converted from per-breast Vbd using the Vbd-to-breast composition category mapping.
QDC	Round-off of the per-breast qDC value.*

* Results are derived by rounding off the qDC value to the value of the nearest integer and then converting the values of 1, 2, 3, and 4 to a, b, c, and d, respectively. This format accommodates the BI-RADS Atlas Fifth Edition.

Per-Subject Results

Quantra combines the left and right Per-Breast results to produce Per-Subject results as follows, in this order:

Per-Subject	Method
Vbd	Average of the per-breast values of left and right breasts.
Vb	Sum of the per-breast values of left and right breasts.
Vd	Multiplication of per-patient Vbd by per-patient Vb.
Abd	Average of per-breast values of left and right breasts.
Vb-score, Vd-score	Average of per-breast values of left and right breasts.
qDC	Converted from per-patient Vbd using the Vbd-to-breast composition category mapping.
QDC	Round-off of the per-patient qDC value.*

* Results are derived by rounding off the qDC value to the value of the nearest integer and then converting the values of 1, 2, 3, and 4 to a, b, c, and d, respectively. This format accommodates the BI-RADS Atlas Fifth Edition.

For unilateral studies, Quantra reports the Per-Breast values.

3.6. Quantra Result Ranges

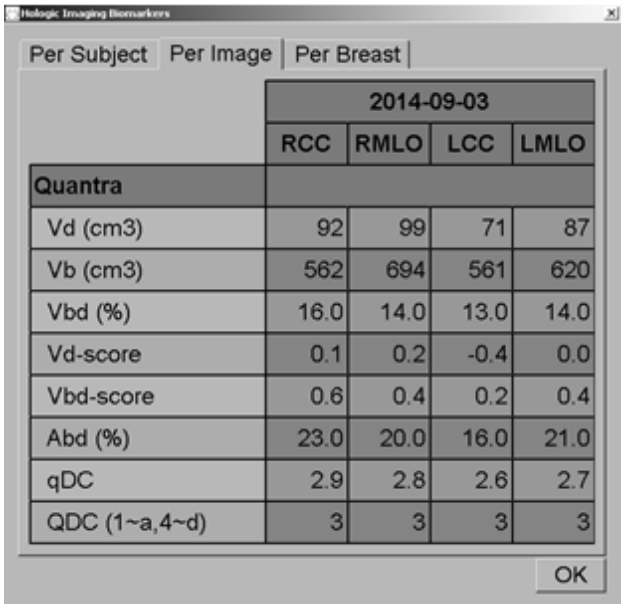
This table provides the ranges for the results produced by Quantra.

Measure	Description	Nominal Range	Units	Notes
Vd	Volume of Dense Tissue	0 to size of breast	cm^3	Normally much less than size of breast
Vb	Volume of Breast	0 to size of breast	cm^3	
Vbd	Volumetric Breast Density	0–100	Percent (%)	Normally less than 50% even for very dense breast since this is a 'volumetric' measurement
Abd	Area Breast Density	0–100	%	Normally higher than Vbd due to Area vs. Volume characteristics
Vbd-score	Volumetric Breast Density Reference Score – how far the patient's Vbd value is from the mean Vbd of the reference population	–3 to +3	Number of Standard Deviations from the mean	99.73% of the data will lie within 3 standard deviations from the mean
Vd-score	Volume of Dense Tissue Reference Score – how far the patient's Vd value is from the mean Vd of the reference population	–3 to +3	Number of Standard Deviations from the mean	99.73% of the data will lie within 3 standard deviations from the mean
qDC	Fractional number representing Quantra volumetric breast density values mapped into quartile index based on breast composition distribution of reference population	≥ 0.5 and ≤ 4.5	Unit-less	Continuous variable
QDC	Quantra generated breast composition categories obtained by rounding of qDC	a, b, c, d	Unit-less	Quantra estimates BI-RADS breast composition category based on percentage of dense tissue in the breast. At this time, it does not consider parenchymal patterns.

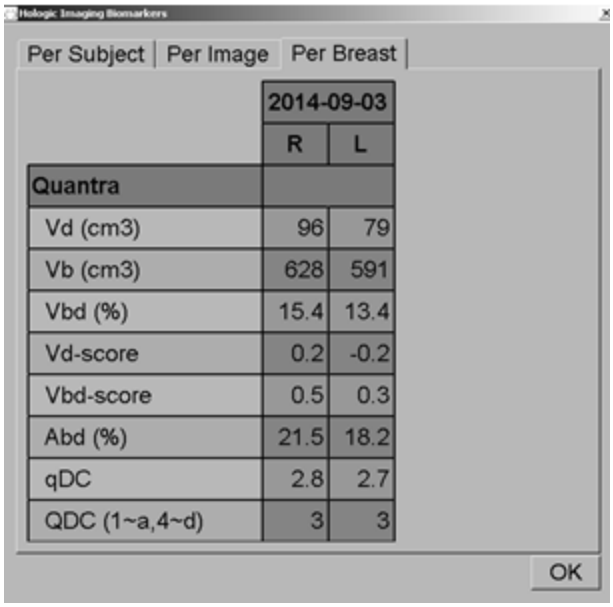
3.7. Examples of Quantra Results

This section provides examples of Quantra results. These examples show how the Hologic SecurView diagnostic review workstation displays Quantra results when it receives results in DICOM SR format.

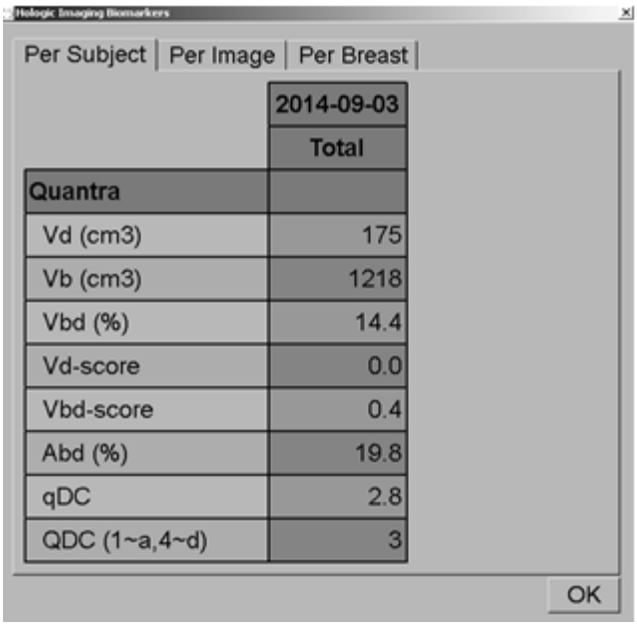
⚠ ***Note:*** *The display of Quantra results varies depending upon how they are implemented on the diagnostic review workstation.*



Quantra Per-Image Results

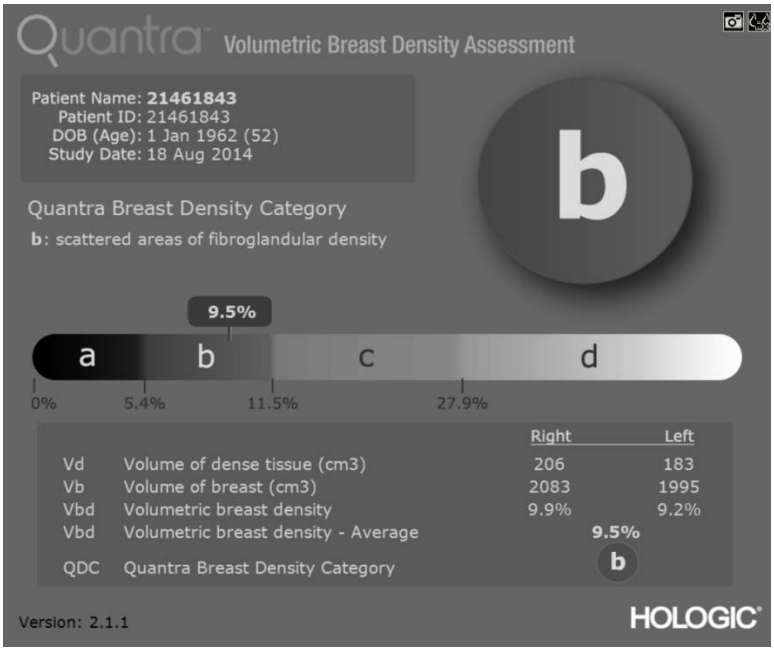


Quantra Per-Breast Results

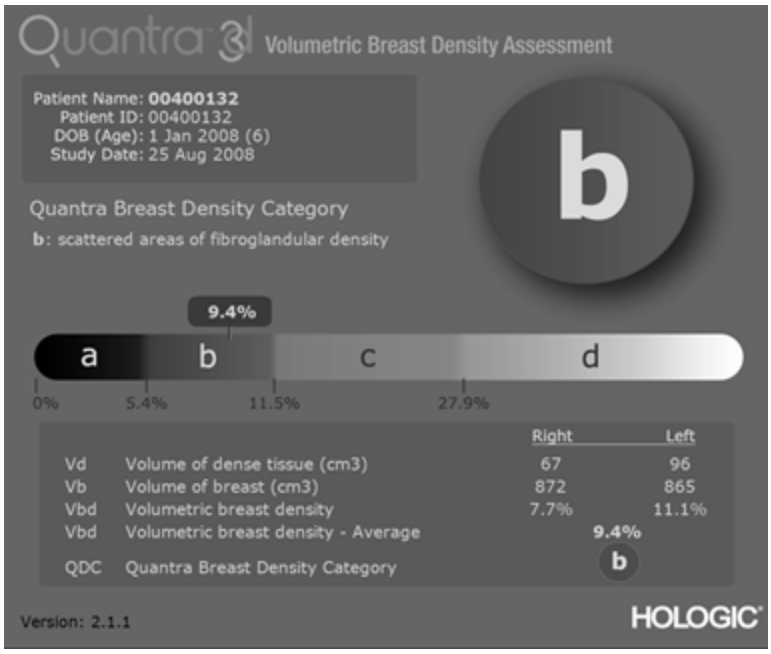


Quantra Per-Subject Results

Most workstations can display results in the new DICOM Secondary Capture Image format (default):



Quantra 2D Results in the new DICOM SC Image Format (Default)



Quantra 3D Results in the new DICOM SC Image Format (Default)

Most workstations can also display results in the original DICOM Secondary Capture Image format, tabular (optional):

⚠ ***Note:*** *If Quantra SC output is preferred in the original tabular format, contact Hologic Technical Support.*

		11/3/2014						
		Total	R	L	RCC	RMLO	LCC	LMLO
Quantra		V2.1.1						
Vd	Volume of dense tissue (cm3)	389	206	183	241	168	153	213
Vb	Volume of breast (cm3)	4077	2083	1995	2005	2160	1998	1991
Vbd	Volumetric breast density (%)	9.5	9.9	9.2	12.0	8.0	8.0	11.0
Abd	Area breast density (%)	6.0	7.5	4.6	12.0	3.0	3.0	6.0
Vbd-score	Volumetric breast density reference score	-0.4	-0.3	-0.4	0.1	-0.7	-0.7	-0.1
Vd-score	Volume of dense tissue reference score	1.4	1.5	1.3	1.9	1.2	1.0	1.7
QDC	Quantra Breast Density Category	b	b	b	c	b	b	b
qDC	Quantra Breast Density Category - fractional	2.2	2.2	2.1	2.6	1.9	1.9	2.4

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Quantra 2D Results in the original DICOM SC Image Format (Tabular)

		8/25/2008						
		Total	R	L	RCC	RMLO	LCC	LMLO
Quantra 3D		V 2.1.1						
Vbd	Volumetric breast density (cm3)	164	67	96	64	70	86	106
Vb	Volume of breast (cm3)	1737	872	865	854	889	879	851
Vbd	Volumetric breast density (%)	9.4	7.7	11.1	8.0	8.0	10.0	12.0
Abd	Area breast density (%)	2.5	0.7	4.3	1.0	1.0	2.0	6.0
Vbd-score	Volumetric breast density reference score	-0.4	-0.7	0.0	-0.8	-0.7	-0.2	0.3
Vd-score	Volume of dense tissue reference score	-0.2	-0.5	0.2	-0.6	-0.4	0.0	0.4
QDC	Quantra Breast Density Category	b	b	c	b	b	b	c
qDC	Quantra Breast Density Category - fractional	2.2	1.9	2.5	1.9	1.9	2.3	2.6

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Quantra 3D Results in the original DICOM SC Image Format (Tabular)

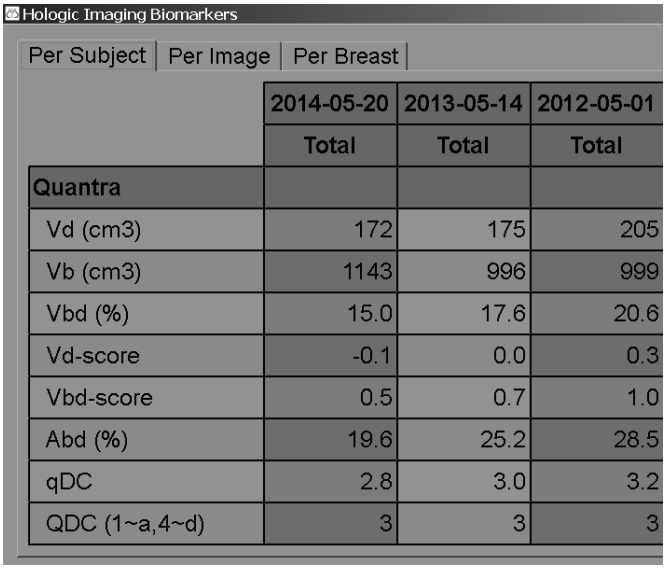
For some studies, Quantra may not be able to report results:

- For incomplete studies, Quantra displays an empty cell in the appropriate column(s).
- For images that cannot be processed, Quantra displays a dash (—).

⚠ ***Important:*** *Presentation of results depends upon how the Quantra output is configured to appear on the review workstation. Results may appear differently depending upon the software versions of the Quantra algorithm and the review workstation.*

3.8. Temporal Display of Quantra Results

Hologic SecurView has the ability to display Quantra results from multiple DICOM SR objects for the same subject. This allows the radiologist to view temporal differences in Quantra assessments. The studies are presented from latest (left) to earliest (right) as shown in this example from the SecurView diagnostic review workstation:


Hologic Imaging Biomarkers

Per Subject | Per Image | Per Breast

	2014-05-20	2013-05-14	2012-05-01
	Total	Total	Total
Quantra			
Vd (cm3)	172	175	205
Vb (cm3)	1143	996	999
Vbd (%)	15.0	17.6	20.6
Vd-score	-0.1	0.0	0.3
Vbd-score	0.5	0.7	1.0
Abd (%)	19.6	25.2	28.5
qDC	2.8	3.0	3.2
QDC (1~a,4~d)	3	3	3

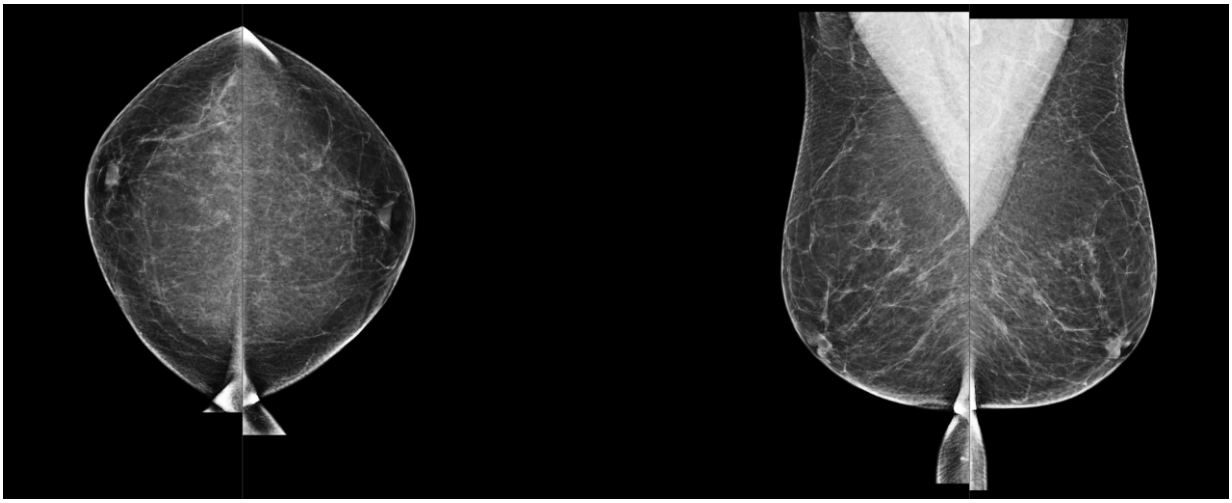
Quantra Temporal Display on SecurView

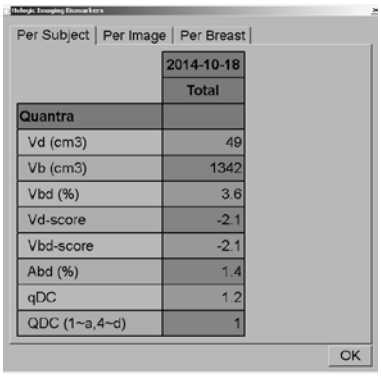
In order to use the temporal display feature, the Quantra DICOM SR object from the previous exam must be retrievable from the PACS.

3.9. Comparison with BI-RADS Categories

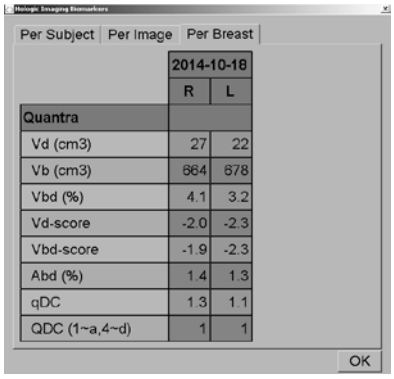
This section shows images of a typical case for each BI-RADS Atlas Fifth edition category followed by the Quantra results for each case as they appear on Hologic's SecurView workstation.

BI-RADS a: Almost entirely fatty

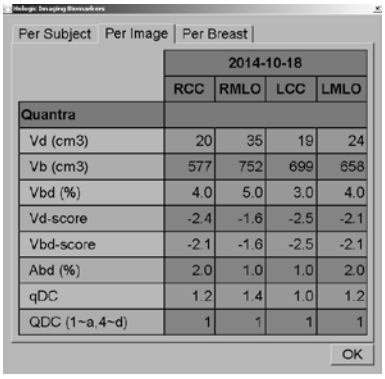




Quantra	2014-10-18 Total
Vd (cm3)	49
Vb (cm3)	1342
Vbd (%)	3.6
Vd-score	-2.1
Vbd-score	-2.1
Abd (%)	1.4
qDC	1.2
QDC (1~a,4~d)	1

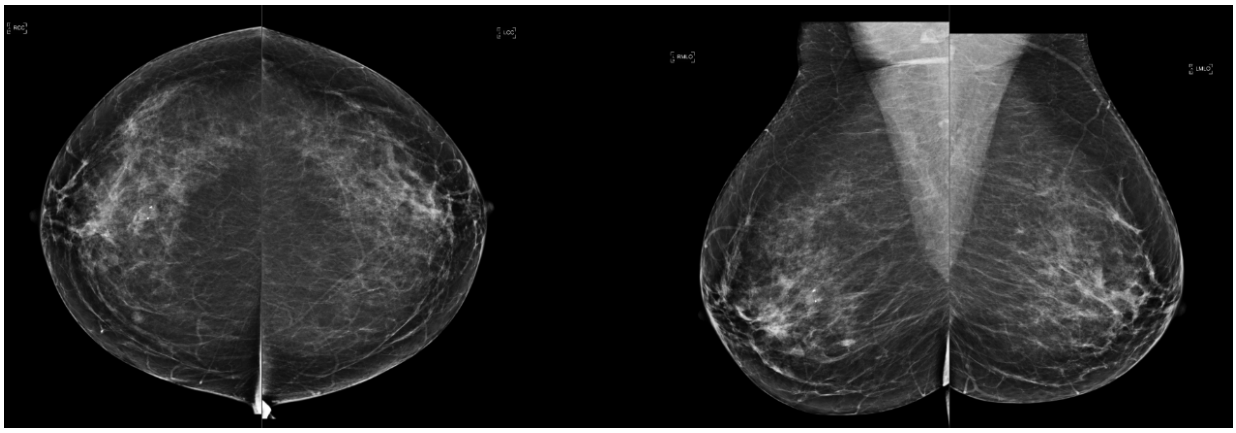


Quantra	2014-10-18 R	L
Vd (cm3)	27	22
Vb (cm3)	664	678
Vbd (%)	4.1	3.2
Vd-score	-2.0	-2.3
Vbd-score	-1.9	-2.3
Abd (%)	1.4	1.3
qDC	1.3	1.1
QDC (1~a,4~d)	1	1



Quantra	2014-10-18 RCC	RMLO	LCC	LMLO
Vd (cm3)	20	35	19	24
Vb (cm3)	577	752	699	658
Vbd (%)	4.0	5.0	3.0	4.0
Vd-score	-2.4	-1.6	-2.5	-2.1
Vbd-score	-2.1	-1.6	-2.5	-2.1
Abd (%)	2.0	1.0	1.0	2.0
qDC	1.2	1.4	1.0	1.2
QDC (1~a,4~d)	1	1	1	1

BI-RADS b: Scattered areas of fibroglandular density



Per Subject | Per Image | Per Breast

Quantra	2014-08-18 Total
Vd (cm3)	389
Vb (cm3)	4077
Vbd (%)	9.5
Vd-score	1.4
Vbd-score	-0.4
Abd (%)	6.0
qDC	2.2
QDC (1~a,4~d)	2

OK

Per Subject | Per Image | Per Breast

Quantra	2014-08-18 R	L
Vd (cm3)	206	183
Vb (cm3)	2083	1995
Vbd (%)	9.9	9.2
Vd-score	1.5	1.3
Vbd-score	-0.3	-0.4
Abd (%)	7.5	4.6
qDC	2.2	2.1
QDC (1~a,4~d)	2	2

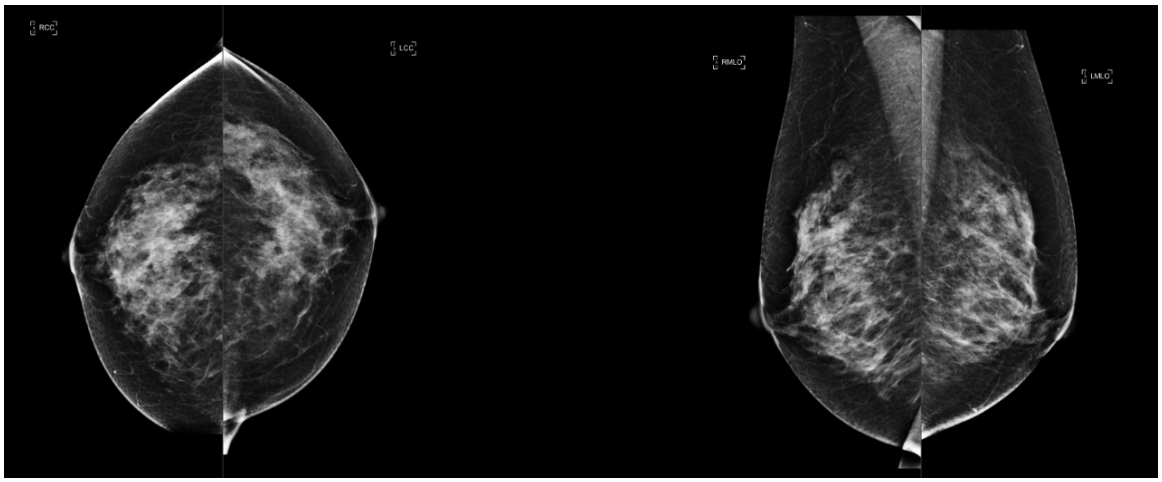
OK

Per Subject | Per Image | Per Breast

Quantra	2014-08-18 RCC	RMLO	LCC	LMLO
Vd (cm3)	241	168	153	213
Vb (cm3)	2005	2160	1998	1991
Vbd (%)	12.0	8.0	8.0	11.0
Vd-score	1.9	1.2	1.0	1.7
Vbd-score	0.1	-0.7	-0.7	-0.1
Abd (%)	12.0	3.0	3.0	6.0
qDC	2.6	1.9	1.9	2.4
QDC (1~a,4~d)	3	2	2	2

OK

BI-RADS c: Heterogeneously dense



Per Subject | Per Image | Per Breast

	2014-09-03
	Total
Quantra	
Vd (cm3)	175
Vb (cm3)	1218
Vbd (%)	14.4
Vd-score	0.0
Vbd-score	0.4
Abd (%)	19.8
qDC	2.8
QDC (1~a,4~d)	3

OK

Per Subject | Per Image | Per Breast

	2014-09-03	
	R	L
Quantra		
Vd (cm3)	96	79
Vb (cm3)	628	591
Vbd (%)	15.4	13.4
Vd-score	0.2	-0.2
Vbd-score	0.5	0.3
Abd (%)	21.5	18.2
qDC	2.8	2.7
QDC (1~a,4~d)	3	3

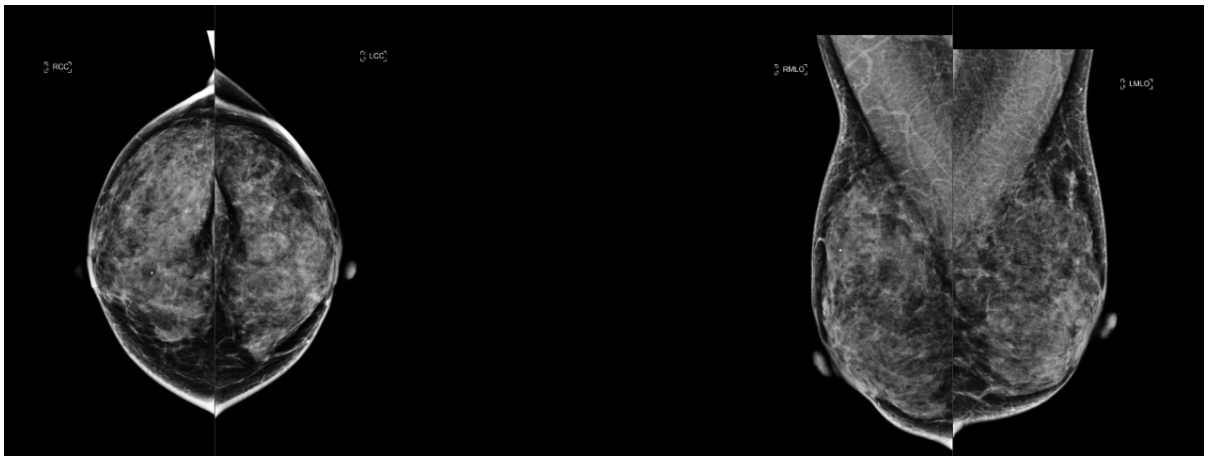
OK

Per Subject | Per Image | Per Breast

	2014-09-03			
	RCC	RMLO	LCC	LMLO
Quantra				
Vd (cm3)	92	99	71	87
Vb (cm3)	562	694	561	620
Vbd (%)	16.0	14.0	13.0	14.0
Vd-score	0.1	0.2	-0.4	0.0
Vbd-score	0.6	0.4	0.2	0.4
Abd (%)	23.0	20.0	16.0	21.0
qDC	2.9	2.8	2.6	2.7
QDC (1~a,4~d)	3	3	3	3

OK

BI-RADS d: Extremely dense



Per Subject | Per Image | Per Breast

	2014-10-17
	Total
Quantra	
Vd (cm3)	158
Vb (cm3)	533
Vbd (%)	29.7
Vd-score	-0.2
Vbd-score	1.7
Abd (%)	59.6
qDC	3.6
QDC (1~a,4~d)	4

OK

Per Subject | Per Image | Per Breast

	2014-10-17	
	R	L
Quantra		
Vd (cm3)	73	85
Vb (cm3)	259	274
Vbd (%)	28.3	31.2
Vd-score	-0.3	0.0
Vbd-score	1.6	1.8
Abd (%)	58.5	60.8
qDC	3.5	3.6
QDC (1~a,4~d)	4	4

OK

Per Subject | Per Image | Per Breast

	2014-10-17			
	RCC	RMLO	LCC	LMLO
Quantra				
Vd (cm3)	94	55	87	84
Vb (cm3)	278	240	284	265
Vbd (%)	34.0	23.0	31.0	32.0
Vd-score	0.1	-0.8	0.0	-0.1
Vbd-score	1.9	1.2	1.8	1.8
Abd (%)	65.0	52.0	57.0	65.0
qDC	3.7	3.3	3.6	3.7
QDC (1~a,4~d)	4	3	4	4

OK

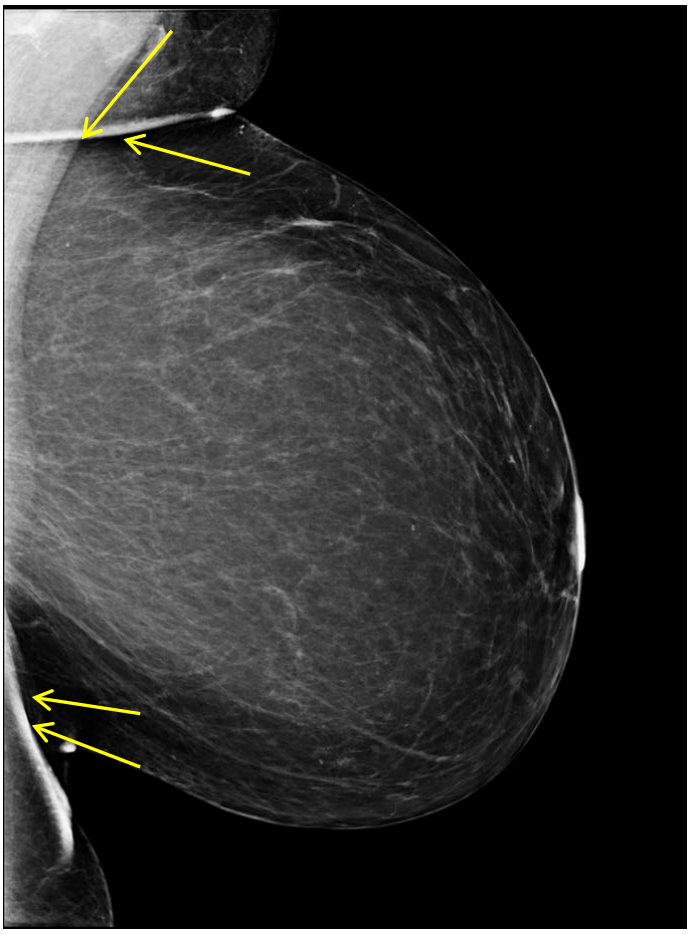
3.10. Atypical Images

Some atypical images can affect Quantra results. This table provides explanations and recommendations for these situations:

Observation	Explanations, Recommendations, and Notes
Small object: An image of the breast contains a small man-made object, such as a 'BB'.	**Explanation:** The object creates an air gap that may cause the algorithm to misjudge the breast thickness. In such instances, Quantra may overestimate the volume of dense tissue. **Recommendation:** Since women's breasts tend to be grossly symmetrical, consider using the values from the contralateral breast as substitute values. ⚠ ***Note:*** *Objects with very small dimensions (such as J-wires) or those completely contained within the breast (such as biopsy markers and surgical staples) will not cause air gaps and therefore not cause thickness calibration problems.*
Large object: An image of the breast contains a large man-made object, such as a paddle.	**Explanation:** Quantra is designed to run on standard screening views. However, some small paddles imaged on large detectors may cause Quantra adjustment errors, especially if the paddle edge lies over breast tissue. Because the content of such images is so varied, it is impossible to predict whether Quantra results will be less reliable. **Recommendation:** Since women's breasts tend to be grossly symmetrical, consider using the values from the contralateral breast as substitute values. ⚠ ***Note:*** *Diagnostic views that are not described accurately in the DICOM header may not produce reliable Quantra results.*
Skin fold: An image of the breast contains a skin fold within the compressed region of the breast.	**Explanation:** A skin fold can contain air and may cause the algorithm to misjudge the breast thickness. In such instances, Quantra may overestimate the volume of dense tissue. **Recommendation:** Since women's breasts tend to be grossly symmetrical, consider using the values from the contralateral breast as substitute values.
Dense breasts: An image is of an extraordinarily dense breast with little visible fat.	**Explanation:** Quantra relies on the detection of fat for a portion of its internal adjustments. Quantra may underestimate the volume of dense tissue in such instances. **Recommendation:** Validate with visual assessment.
Compression effects: An image of the breast demonstrates inadequate and uneven compression due to excessive or inverted tilt of the paddle.	**Explanation:** Images taken with an inverted slant of the compression paddle (meaning the compression is thinner at the chest wall and thicker toward the front of the breast) may cause incorrect Quantra measures. If the compression paddle is overly tilted toward the front of the breast, it may also cause incorrect Quantra results. These issues are caused due to the air gaps that usually occur from the lack of contact between the breast and the compression paddle. **Recommendation:** Validate with visual assessment.

3.10.1. Examples of Atypical Images

Skin Folds and Air Gaps

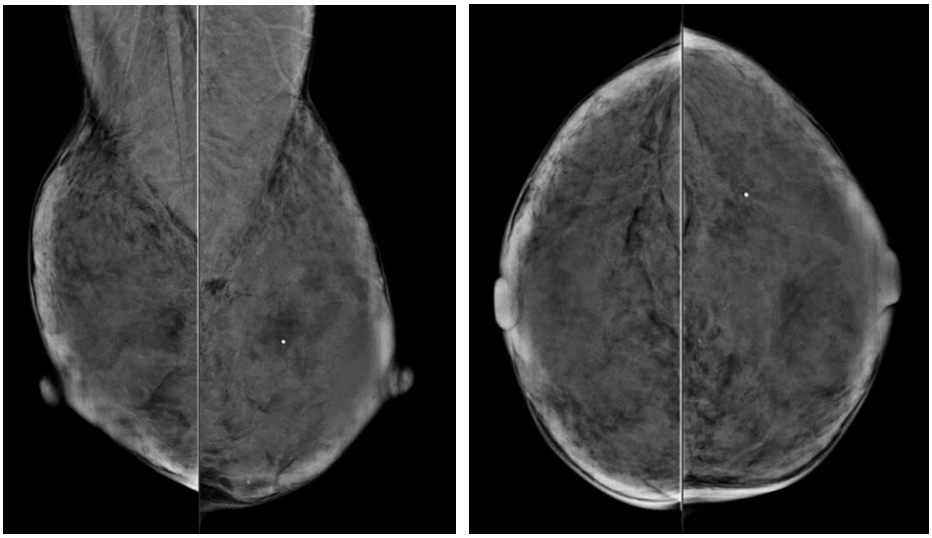


A skin fold can contain air and may cause the algorithm to misjudge the breast thickness. In such instances, Quantra may overestimate the volume of dense tissue.

In this example, the folds in the axillary region and the IMF region (denoted by the yellow arrows) cause the air gaps. The axillary fold causes a positive density as well as a negative density by preventing the breast tissue from touching the detector. The abdominal fold in the image causes a thickness and prevents the breast tissue from contacting the detector.

In such instances, Quantra typically overestimates the breast density.

Dense Breasts



Quantra relies on the detection of fat for a portion of its internal adjustments. Quantra may underestimate the volume of dense tissue in such instances.

In these examples, little or no fat appears in the breast tissue. Since the Quantra algorithm relies on the detection of some fatty tissue to estimate the amount of dense tissue, absence of fat in the image may cause Quantra to underestimate the amount of dense tissue in the breast.

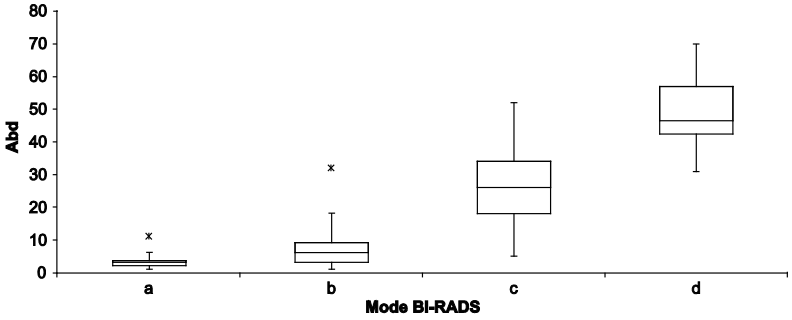
Compression Effects

This example illustrates inadequate compression in the anterior portion of the breast, which may cause incorrect Quantra results.

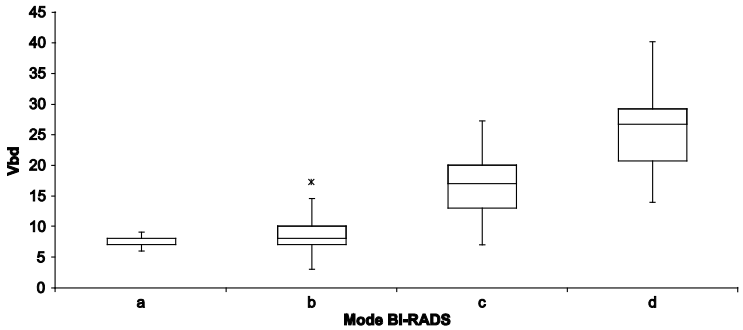
3.11. Performance Testing

Quantra performance was tested against a database of 263 cases, each with a BI-RADS density assessment from 15 different radiologists. The mode (the most frequent value) of the 15 radiologists' readings for each case was used as the 'truth', which was then compared to the measured Quantra values for Abd (area breast density), Vbd (volumetric breast density) and qDC (Quantra Breast Density Category - fractional) values.

These box plots show the results of these comparisons for the Abd and Vbd values.



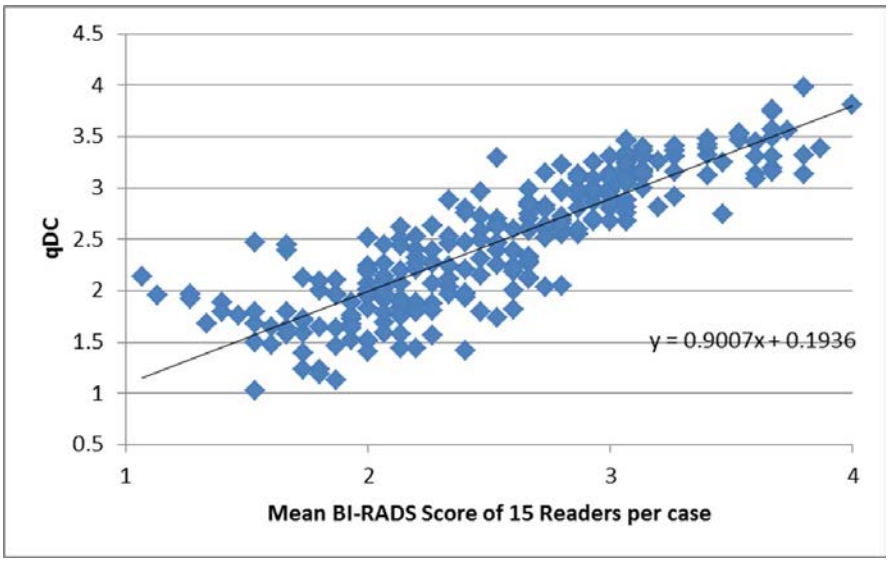
Abd Values versus the Mode of 15 Radiologists' Scores



Vbd Values versus the Mode of 15 Radiologists' Scores

As shown in the Vbd plot, the BI-RADS a readings included some dense tissue even in predominately fatty breasts (as there will always be some volumetric measurable dense tissue present). This phenomenon is not seen in the Abd plot because this small amount of dense tissue typically falls below the threshold for Abd inclusion.

This figure presents a scatter plot of qDC versus the mean BI-RADS values of the 15 radiologists. The Pearson's Correlation Coefficient (PCC) of the two continuous variables is 0.86.



qDC Values versus the Mean of 15 Radiologists' Scores

The Vbd-score and Vd-score measures were validated by correlating the CC / MLO values of the same breast and right and left breasts of the same patient.

This table shows the PCC values for each score across the Hologic, GE and Siemens digital breast x-ray systems.

Measure	Type of Correlation	Hologic PCC n=5619	GE PCC n=2417	Siemens PCC n=161
Vd-score	CC / MLO	0.96	0.87	0.78
	L / R	0.97	0.89	0.86
Vbd-score	CC / MLO	0.81	0.88	0.73
	L / R	0.85	0.85	0.81

Index

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