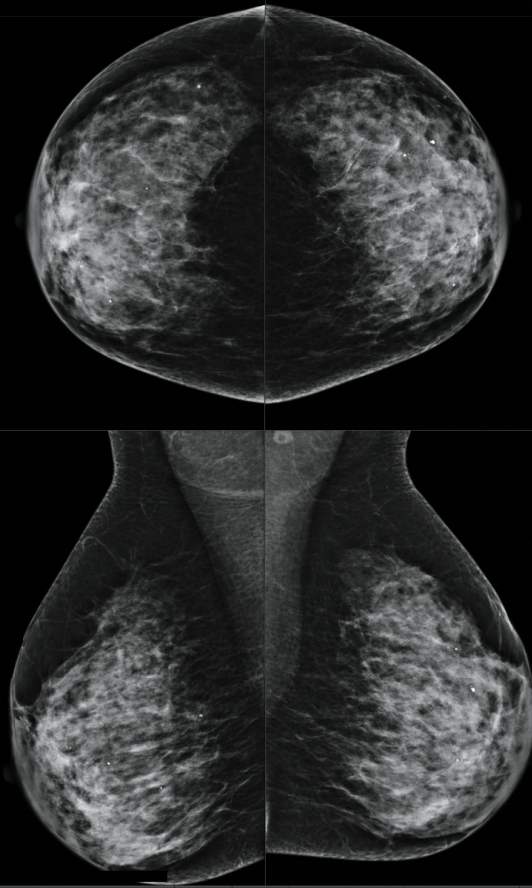


Per Subject	Per Breast	Per Image
2011-06-26		
Total		
<b>Quantra</b>		
Vfg (cm3)	393	
Vb (cm3)	1357	
Vbd (%)	28	
Abd (%)	48	
Vbd-score	1.52568	
Vfg-score	1.244335	
Q_abd	4	
q_abd	3.74234	

Per Subject	Per Breast	Per Image
2011-06-26		
R L		
<b>Quantra</b>		
Vfg (cm3)	202	191
Vb (cm3)	671	686
Vbd (%)	30	27
Abd (%)	50	46
Vbd-score	1.52568	1.43653
Vfg-score	1.244335	1.203805
Q_abd	4	4
q_abd	3.74234	3.68197

Per Subject	Per Breast	Per Image		
2011-06-26				
RCC RMLC LCC LMLO				
<b>Quantra</b>				
Vfg (cm3)	202	188	183	191
Vb (cm3)	671	666	676	686
Vbd (%)	30	28	27	28
Abd (%)	54	47	48	44
Vbd-score	1.557741	1.493615	1.401375	1.471685
Vfg-score	1.273452	1.215219	1.168878	1.238734
Q_abd	4	4	4	4
q_abd	3.76147	3.72321	3.64073	3.72321



# Understanding Quantra™ 2.0 User Manual

MAN-02004 Rev 004



Breast Density Assessment Software



Image Analytics Servers



The Women's Health Company





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# Understanding Quantra™ 2.0

## User Manual

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MAN-02004 Rev 004

## Technical Support

For support in North America contact:

Toll Free: +1.866.243.2533 (+1.866.CHECKED)

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Hours: Monday – Friday, 6:00 AM – 5:00 PM, PT (GMT –8:00)

Website: [www.hologic.com](http://www.hologic.com)

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

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## Chapter 1: Introduction

- ▶ 1.1. Intended Use
- ▶ 1.2. Using This Manual
- ▶ 1.3. Resources Available
- ▶ 1.4. Warnings and Precautions
- ▶ 1.5. Overview of Quantra
- ▶ 1.6. Benefits of Quantra
- ▶ 1.7. System Requirements

Quantra™ is a software application used by radiologists to calculate volumetric and area breast densities from two-dimensional digital mammography 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 manual is intended to serve as a reference for radiologists and clinic personnel who need to understand how Quantra operates and how volumetric 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; and area breast density as a ratio of fibroglandular tissue area and total breast area estimates. It segregates breast density into BI-RADS-like breast composition categories, which may be useful in the reporting of consistent breast composition values as mandated by certain state regulations. Quantra provides these numerical values for each image, breast, and subject, to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information; it is not an interpretive or diagnostic aid. Quantra runs on a Windows platform.

## 1.2. Using This Manual


This manual 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 mammography views, and how to manage workflow.
- **Chapter 3: Algorithm Description** describes how the Quantra algorithm analyzes mammography images.

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

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

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

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

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

## 1.3. Resources Available

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

- **Hologic Member Center:** This website provides quick access to electronic (pdf) versions of manuals and training materials for Hologic products. The Member Center is available at no charge to our customers under warranty or Hologic service contract. You can find the Member Center by visiting the Hologic website (<http://www.hologic.com>).
- **Training:** The Hologic Member Center provides training materials for this application. 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.



## 1.4. Warnings and Precautions



**⚠ Note:** For warnings and precautions related to the installation, operation, and maintenance of the Cenova server, refer to the Cenova User Manual.

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

- *Quantra is intended to provide adjunctive information; it is not an interpretative or diagnostic aid.*
- *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).*
- *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.*

**⚠ 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 contains a mixture of fibrous connective tissue (stroma) and glandular tissue (epithelial cells), and usually appears brighter than surrounding tissue on a mammogram.

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 fibroglandular tissue. Through arithmetic division the algorithm determines and reports the ratio of fibroglandular tissue as a percentage of total breast volume. The Quantra algorithm estimates two volumes:

- Volume of fibroglandular tissue in cubic centimeters (cm<sup>3</sup>)
- Volume of the breast in cm<sup>3</sup>

It then divides the volumes to produce:

- Volumetric fraction of breast fibroglandular tissue as a percentage

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

Based on partial products from the volumetric assessments, Quantra also calculates the ratio of the area of fibroglandular 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 fibroglandular tissue in the breast.

For more information on the individual measures produced by Quantra, see [3.2. Volumetric Assessment](#) and [3.3. Area Assessment](#).

## 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 prominent human classification system is the BI-RADS® composition scale from the Breast Imaging Reporting and Data System Atlas, Fourth 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
1	The breast is almost entirely fat (<25% glandular)
2	There are scattered fibroglandular densities (approximately 25–50% glandular)
3	The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51–75% glandular)
4	The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular)

Characterization of breast composition, as described in BI-RADS, depends on the radiologist's assessment of both tissue pattern (the text portion of each description in the table) and density (the numerical range provided with each description).

Assessment of breast composition by BI-RADS classification is difficult because tissue pattern in a mammogram may not correlate with density in the same mammogram, 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 unrepeatable.

Quantra has been developed in order to provide estimations of breast tissue volumes. Through a proprietary software algorithm, Quantra produces an estimate of fibroglandular 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	1 GHz	1 GHz
Memory (RAM)	1 GB	2 GB
HDD Free Disk Space	5 GB	20 GB
Optical Drive	CD-ROM	CD-ROM

---

## Chapter 2: Image Processing and Supported Views


- ▶ 2.1. Image Processing
- ▶ 2.2. Image Acquisition Systems
- ▶ 2.3. Inputs and Supported Views

This chapter explains how information flows through systems with Quantra and the supported mammography 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 A Full-Field Digital Mammography (FFDM) system produces two-dimensional digital x-ray images in two forms:
  - DICOM Digital Mammography X-Ray Image – For Processing
  - DICOM Digital Mammography X-Ray Image – For Presentation
- 2 The FFDM system sends the For Processing images to the server software and sends the For Presentation images to a review workstation or PACS.
- 3 The server software receives the For Processing images, groups them by the identified study, and passes the studies to the 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 For Presentation images produced by the FFDM 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 the following FFDM systems:

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

Whether images are transmitted directly from the FFDM system or obtained from a PACS, the Quantra software expects to receive For Processing (raw) images rather than For Presentation (processed) images. As many sites do not store raw images, it is important that images in the correct format be available for Quantra if a retrospective research study is planned in the absence of stored Quantra results.

## 2.3. Inputs and Supported Views

Quantra analyzes digital mammography images that conform to the DICOM standard. The Quantra software processes the four mammography screening views:

LCC – Left Cranio-Caudal

RCC – Right Cranio-Caudal

LMLO – Left Medio-Lateral Oblique

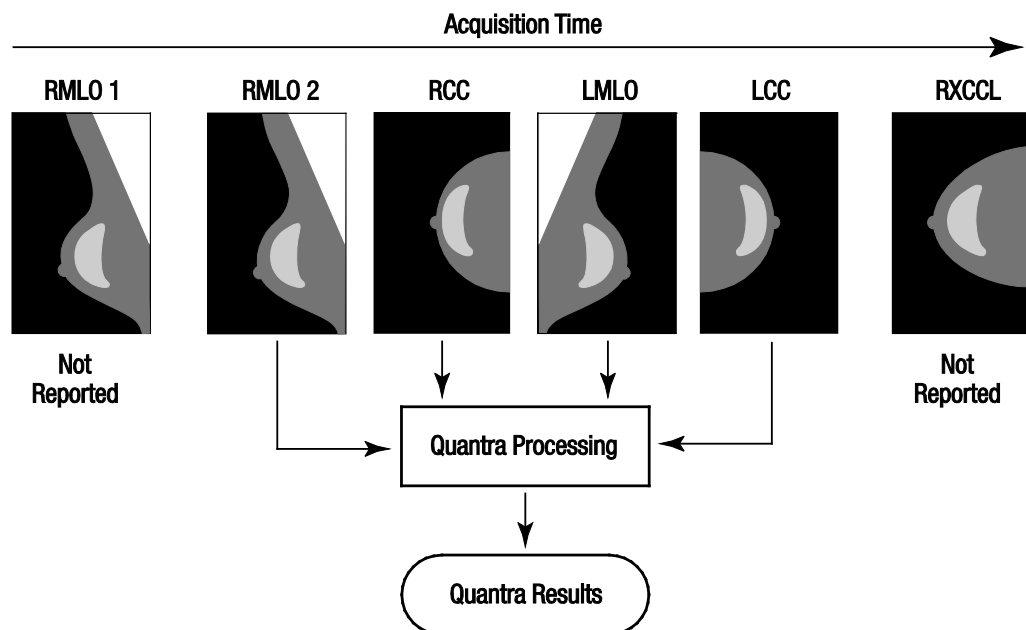
RMLO – Right Medio-Lateral Oblique

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 FFDM device 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, the diagram below 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 FFDM 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.

---

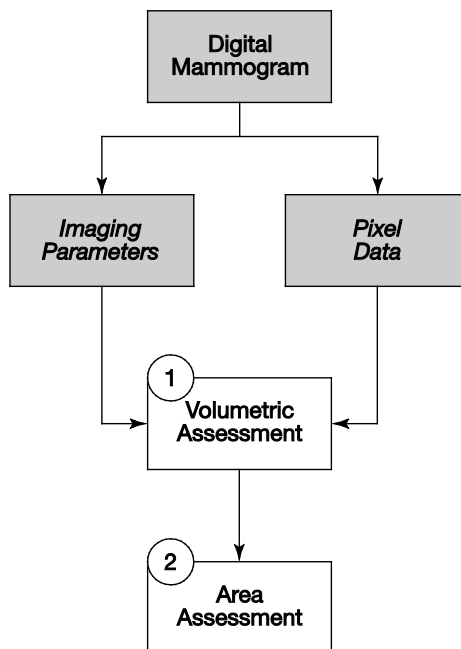
## Chapter 3: Algorithm Description

- ▶ 3.1. Quantra Algorithm Structure
- ▶ 3.2. Volumetric Assessment
- ▶ 3.3. Area Assessment
- ▶ 3.4. BI-RADS-Like Scores
- ▶ 3.5. Combination of Quantra Results
- ▶ 3.6. Quantra Result Ranges
- ▶ 3.7. Examples of Quantra Results
- ▶ 3.8. Temporal Display of Quantra Results
- ▶ 3.9. Comparison with BI-RADS Categories
- ▶ 3.10. Atypical Images
- ▶ 3.11. Performance Testing

This chapter describes the Quantra algorithms and results produced when Quantra analyzes mammography images.

### 3.1. Quantra Algorithm Structure

Quantra contains a hierarchy of algorithms that derive estimates of breast density and related information from digital mammography images. Quantra uses the digital mammography image components to perform volumetric assessment estimates and calculation of statistical measures based on the volume estimates (1). 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 volumetric assessment algorithm is based on a physical model of the x-ray imaging chain that relates breast tissue x-ray attenuation to the digital mammography images provided to the radiologist. Quantra bases its volumetric assessments 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<sup>1</sup>
- x-ray spectra for the target material<sup>2</sup>
- kVp, mAs, and thickness of the imaged tissue

Quantra estimates the amount of fibroglandular tissue that an x-ray must have penetrated in order to deposit a measured amount of energy at the detector. It also compensates for the penetration through skin in order to eliminate the impact that skin has on the estimate of fibroglandular tissue volume. Quantra then calculates a height in centimeters of fibroglandular tissue penetrated (Hfg) at each pixel in the image.

The algorithm then derives statistical measures that estimate the measures for an individual subject relative to a reference population. In the case of Quantra 2.0, the baseline values for the reference population were derived from a large number of mammograms 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.<sup>3</sup>

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

---

<sup>1</sup> 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.

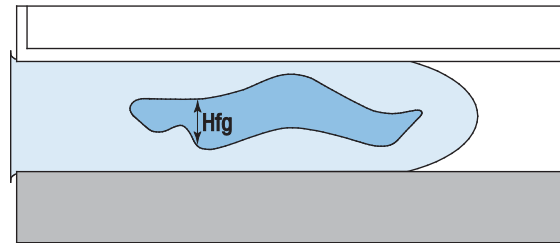
<sup>2</sup> J. M. Boone, T. R. Fewell, and R. J. Jennings, 'Molybdenum, rhodium, and tungsten anode spectral models using interpolating polynomials with application to mammography,' *Med. Phys.* 24, 1863–1874 1997.

<sup>3</sup> 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.



### Fibroglandular Tissue Volume (Vfg)

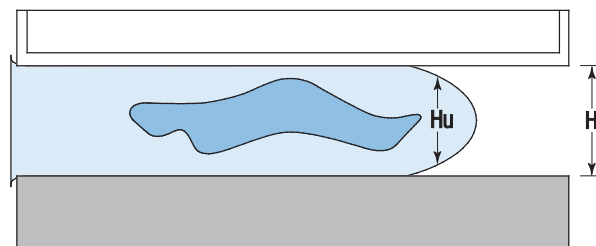
After Quantra completes its analysis on a pixel-by-pixel basis inside the breast (excluding the pectoral muscle), it aggregates the Hfg heights for each pixel value into the volume of fibroglandular tissue, given in cubic centimeters (cm<sup>3</sup>).



Assessment of Fibroglandular Tissue Volume

### Total Breast Volume (Vb)

Through a similar process, Quantra considers the entire imaged breast outline, including those portions of the breast that were not compressed. In the following 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 Total Breast Volume

### Volumetric Breast Density (Vbd)

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

**⚠ Note:** *Quantra volumetric breast density (Vbd) is different from traditional human viewing of mammograms 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 Fibroglandular Tissue Score (Vfg-score)

The Vfg-score indicates how far the subject Vfg value is from the mean Vfg value of the reference population, measured in standard deviations. The score is *positive* if the Vfg 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 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 partial products from the Quantra volumetric assessment algorithm described above. It selects pixels (based on the Hfg values calculated in the volumetric assessment algorithm) that can be associated as representing significant fibroglandular 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. BI-RADS-Like Scores

#### **Fractional Quantized Density (q\_abd)**

Quantra maps the estimated volumetric breast density into q\_abd, an estimate of overall breast composition relative to the reference population. The q\_abd 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.

#### **Quantized Density (Q\_abd)**

Q\_abd is derived by rounding off the q\_abd value. It provides an estimate of overall breast composition that is analogous to the four-point breast composition scale of the BI-RADS Atlas 4.0 used by radiologists in many countries to report breast composition. The Q\_abd value is an integer in the range 1–4.

## 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:

Measures	Method
Vfg, Vb	Take maximum Per-Image values from CC and MLO views
Vbd	Divide Per-Breast result of Vfg by Per-Breast result of Vb
Abd, Vbd-score, Vfg-score, q_abd	Average Per-Image values from CC and MLO views
Q_abd	Round-off Per-Breast q_abd value

### Per-Subject Results

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

Measures	Method
Vfg, Vb	Sum Per-Breast values from L and R breasts
Vbd	Divide Per-Subject result of Vfg by Per-subject result of Vb
Abd	Average Per-Breast values from L and R breasts
Vbd-score, Vfg-score, q_abd, Q_abd	Take maximum Per-Breast values from L and R breasts

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

### 3.6. Quantra Result Ranges

The following table provides the ranges for the results produced by Quantra.

Measure	Description	Nominal Range	Units	Notes
Vfg	Fibroglandular Tissue Volume	0 to size of breast	cm <sup>3</sup>	Normally much less than size of breast
Vb	Total Breast Volume	0 to size of breast	cm <sup>3</sup>	
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 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
Vfg-score	Volume of Fibroglandular Tissue Score – how far the patient’s Vfg value is from the mean Vfg 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
Q_abd	Quantized Density – rounding of q_abd such that the integral Q_abd values have the same BI-RADS distribution as a reference population	1 to 4	Unit-less	
q_abd	Fractional Quantized Density – mapping of volumetric breast density relative to the reference population	≥ 0.5 and ≤ 4.5	Unit-less	Continuous mapping

### 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.

01-01-2011				
	RCC	RMLO	LCC	LMLO
<b>Quantra</b>				
Vfg (cm3)	177	150	121	194
Vb (cm3)	1704	1831	1564	1934
Vbd (%)	10	8	8	10
Abd (%)	23	9	11	16
Vbd-score	-0.07	-0.47	-0.56	-0.13
Vfg-score	1	0.8	0.55	1.11
Q_abd	2	2	2	2
q_abd	2.3	2.03	1.96	2.27

**Quantra Per-Image Results**

01-01-2011		
	R	L
<b>Quantra</b>		
Vfg (cm3)	177	194
Vb (cm3)	1831	1934
Vbd (%)	10	10
Abd (%)	16	13
Vbd-score	-0.27	-0.34
Vfg-score	0.9	0.83
Q_abd	2	2
q_abd	2.16	2.12

**Quantra Per-Breast Results**

Per Subject	Per Breast	Per Image
	01-01-2011	
	Total	
<b>Quantra</b>		
Vfg (cm3)	371	
Vb (cm3)	3765	
Vbd (%)	10	
Abd (%)	15	
Vbd-score	-0.27	
Vfg-score	0.9	
Q_abd	2	
q_abd	2.16	

**Quantra Per-Subject Results**

SecurView workstations can also display results in DICOM Secondary Capture Image format, as is shown in the following example:

	1/6/2005						
	Total	R	L	RCC	RMLO	LCC	LMLO
<b>Quantra</b>	V2.0						
<b>Vfg (cm3)</b>	284	113	171	79	113	135	171
<b>Vb (cm3)</b>	2304	1061	1243	992	1061	1226	1243
<b>Vbd (%)</b>	12	11	14	8	11	11	14
<b>Abd (%)</b>	11	8	14	8	9	12	17
<b>Vbd-score</b>	0.02	-0.48	0.02	-0.69	-0.27	-0.14	0.19
<b>Vfg-score</b>	1.17	0.69	1.17	0.55	0.82	1.08	1.26
<b>Q_abd</b>	3	2	3	2	2	3	3
<b>q_abd</b>	2.61	2.32	2.61	2.22	2.42	2.5	2.72

**Quantra Results in DICOM SC Image Format**

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:

	2011-06-27	2010-06-24	2009-12-29
	Total	Total	Total
<b>Quantra</b>			
Vfg (cm3)	198	164	234
Vb (cm3)	1487	1504	1475
Vbd (%)	13	10	15
Abd (%)	20	16	19
Vbd-score	0.42	-0.10	0.48
Vfg-score	0.66	0.42	0.72
Q_abd	3	3	3
q_abd	2.89	2.55	2.93

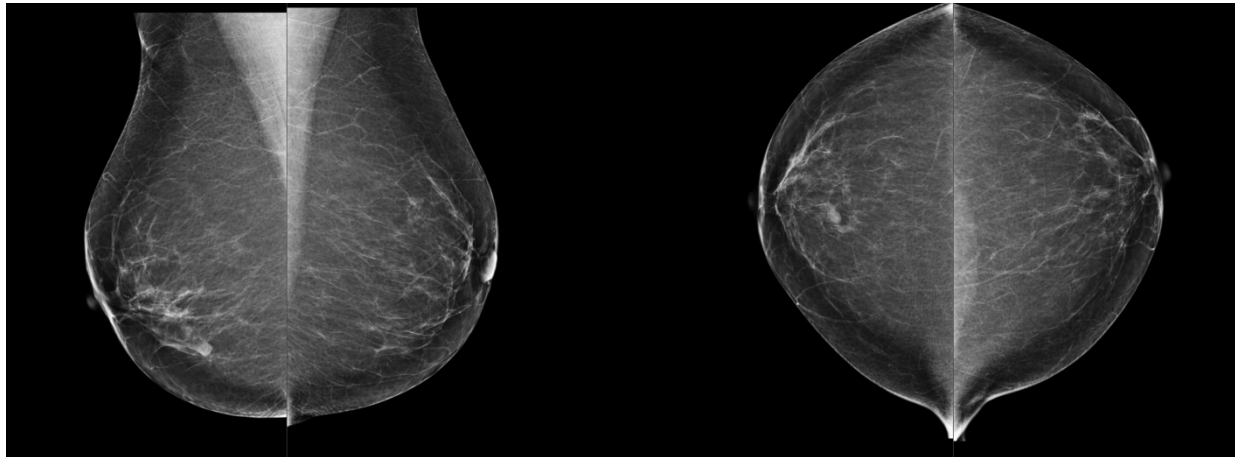
**Quantra Temporal Display on SecurView**

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 category followed by the Quantra results for each case as they appear on Hologic's SecurView workstation.

#### BI-RADS 1: <25% Glandular (mostly fat)



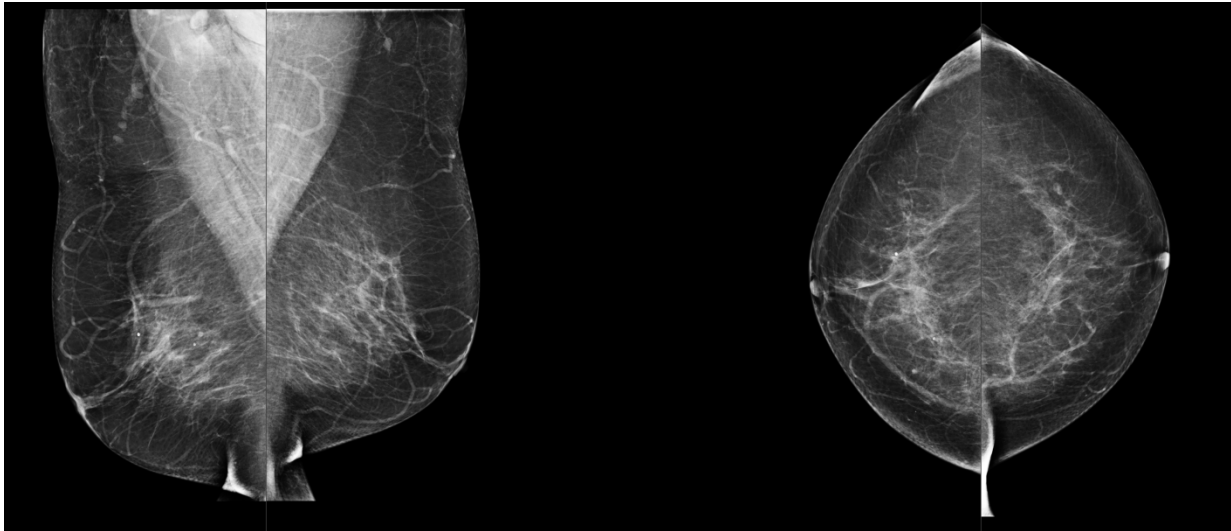
Hologic Imaging Biomarkers	
Per Subject	Per Breast
2006-11-29	
Total	
<b>Quantra</b>	
Vfg (cm3)	40
Vb (cm3)	1589
Vbd (%)	3
Abd (%)	0
Vbd-score	-2.28
Vfg-score	-1.37
Q_abd	1
q_abd	0.98

Hologic Imaging Biomarkers		
Per Subject	Per Breast	Per Image
2006-11-29		
R L		
<b>Quantra</b>		
Vfg (cm3)	25	15
Vb (cm3)	785	804
Vbd (%)	3	2
Abd (%)	0	0
Vbd-score	-2.28	-2.86
Vfg-score	-1.37	-1.66
Q_abd	1	1
q_abd	0.98	0.78

Hologic Imaging Biomarkers				
Per Subject	Per Breast	Per Image		
2006-11-29				
RCC RMLO LCC LMLO				
<b>Quantra</b>				
Vfg (cm3)	16	25	15	15
Vb (cm3)	692	785	804	756
Vbd (%)	2	3	2	2
Abd (%)	0	1	0	0
Vbd-score	-2.55	-2.02	-2.89	-2.83
Vfg-score	-1.59	-1.15	-1.65	-1.67
Q_abd	1	1	1	1
q_abd	0.88	1.07	0.77	0.79



**BI-RADS 2: 25–50% Glandular (scattered fibroglandular densities)**

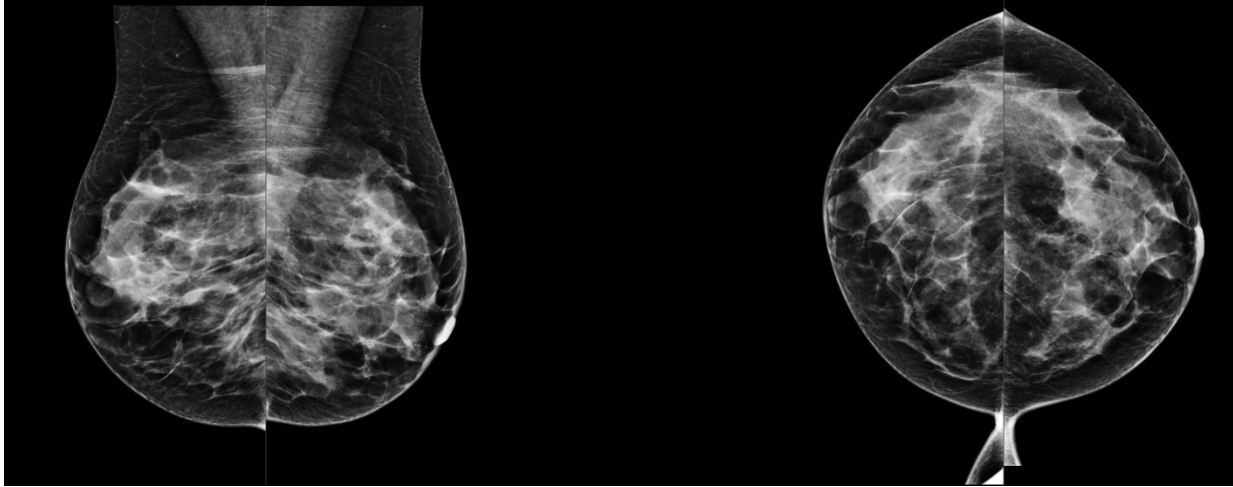


Hologic Imaging Biomarkers	
Per Subject	Per Breast
2006-09-20	
Total	
<b>Quantra</b>	
Vfg (cm3)	102
Vb (cm3)	1627
Vbd (%)	6
Abd (%)	4
Vbd-score	-1.19
Vfg-score	-0.74
Q_abd	2
q_abd	1.52

Hologic Imaging Biomarkers		
Per Subject	Per Breast	Per Image
2006-09-20		
R L		
<b>Quantra</b>		
Vfg (cm3)	57	45
Vb (cm3)	839	788
Vbd (%)	7	6
Abd (%)	3	4
Vbd-score	-1.25	-1.19
Vfg-score	-0.75	-0.74
Q_abd	2	2
q_abd	1.51	1.52

Hologic Imaging Biomarkers				
Per Subject	Per Breast	Per Image		
2006-09-20				
RCC RMLO LCC LMLO				
<b>Quantra</b>				
Vfg (cm3)	23	57	31	45
Vb (cm3)	606	839	628	788
Vbd (%)	4	7	5	6
Abd (%)	3	4	3	5
Vbd-score	-1.74	-0.77	-1.31	-1.07
Vfg-score	-1.23	-0.28	-0.93	-0.55
Q_abd	1	2	1	2
q_abd	1.2	1.82	1.44	1.6

**BI-RADS 3: 51–75% Glandular (heterogeneously dense)**

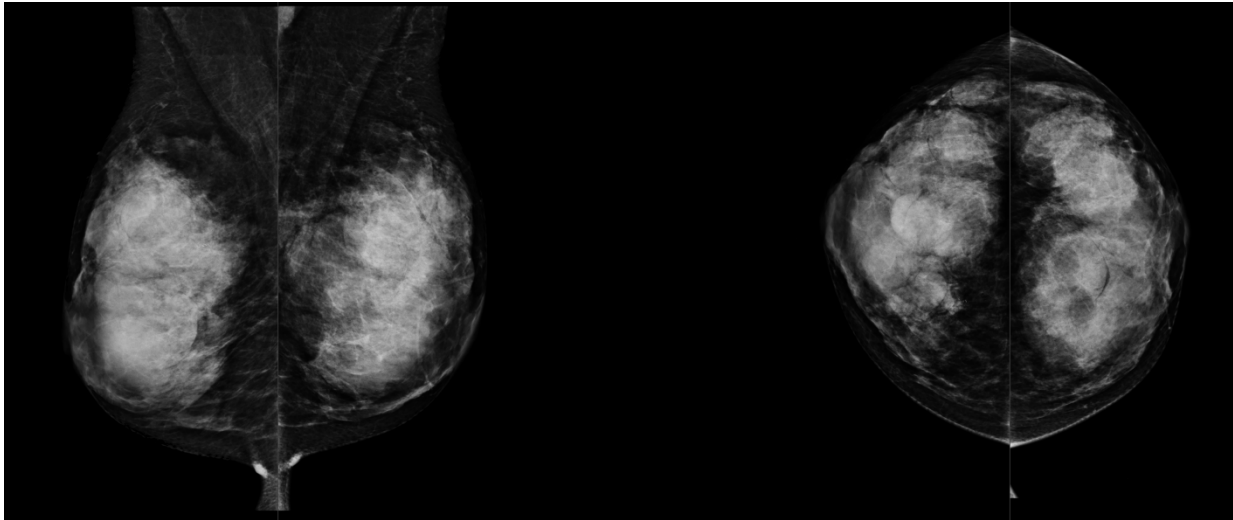


Hologic Imaging Biomarkers	
Per Subject	Per Breast
2006-12-11	
Total	
<b>Quantra</b>	
Vfg (cm3)	167
Vb (cm3)	993
Vbd (%)	17
Abd (%)	29
Vbd-score	0.69
Vfg-score	-0.01
Q_abd	3
q_abd	2.88

Hologic Imaging Biomarkers		
Per Subject	Per Breast	Per Image
2006-12-11		
R    L		
<b>Quantra</b>		
Vfg (cm3)	76	91
Vb (cm3)	507	486
Vbd (%)	15	19
Abd (%)	27	31
Vbd-score	0.56	0.69
Vfg-score	-0.02	-0.01
Q_abd	3	3
q_abd	2.77	2.88

Hologic Imaging Biomarkers				
Per Subject	Per Breast	Per Image		
2006-12-11				
RCC   RML0   LCC   LMLO				
<b>Quantra</b>				
Vfg (cm3)	76	71	91	59
Vb (cm3)	467	507	486	421
Vbd (%)	16	14	19	14
Abd (%)	33	21	40	23
Vbd-score	0.68	0.44	0.93	0.44
Vfg-score	0.02	-0.05	0.23	-0.25
Q_abd	3	3	3	3
q_abd	2.88	2.66	3.09	2.66

**BI-RADS 4: >75% Glandular (extremely dense)**



Hologic Imaging Biomarkers	
Per Subject	Per Breast
2006-12-20	
Total	
<b>Quantra</b>	
Vfg (cm3)	728
Vb (cm3)	1346
Vbd (%)	54
Abd (%)	60
Vbd-score	2.92
Vfg-score	2.03
Q_abd	4
q_abd	4.28

Hologic Imaging Biomarkers		
Per Subject	Per Breast	
2006-12-20		
	R	L
<b>Quantra</b>		
Vfg (cm3)	411	317
Vb (cm3)	776	570
Vbd (%)	53	56
Abd (%)	57	62
Vbd-score	2.92	2.81
Vfg-score	2.03	1.73
Q_abd	4	4
q_abd	4.28	4.25

Hologic Imaging Biomarkers				
Per Subject	Per Breast			
2006-12-20				
	RCC	RMLO	LCC	LMLO
<b>Quantra</b>				
Vfg (cm3)	392	411	317	301
Vb (cm3)	596	776	570	849
Vbd (%)	66	53	56	35
Abd (%)	65	50	62	41
Vbd-score	3.11	2.73	2.81	2.03
Vfg-score	2	2.06	1.73	1.66
Q_abd	4	4	4	4
q_abd	4.35	4.22	4.25	3.86

### 3.10. Atypical Images

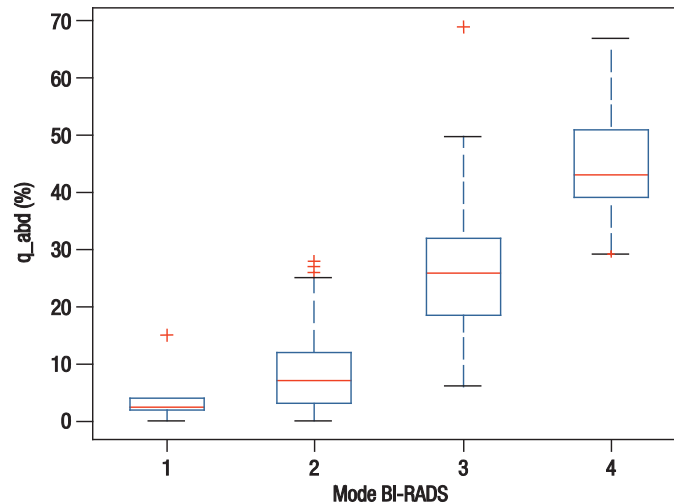
Some atypical images can affect Quantra results. The following table provides explanations and recommendations for these situations:

Observation	Explanations, Recommendations, and Notes
<p><b>Small object:</b> An image of the breast contains a small man-made object, such as a 'BB'.</p>	<p><b>Explanation:</b> 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 fibroglandular tissue.</p> <p><b>Recommendation:</b> Since women's breasts tend to be grossly symmetrical, consider using the values from the contralateral breast as substitute values.</p> <p><b>Note:</b> <i>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.</i></p>
<p><b>Large object:</b> An image of the breast contains a large man-made object, such as a paddle.</p>	<p><b>Explanation:</b> 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.</p> <p><b>Recommendation:</b> Since women's breasts tend to be grossly symmetrical, consider using the values from the contralateral breast as substitute values.</p> <p><b>Note:</b> <i>Diagnostic views that are not described accurately in the DICOM header may not produce reliable Quantra results.</i></p>
<p><b>Skin fold:</b> An image of the breast contains a skin fold within the compressed region of the breast.</p>	<p><b>Explanation:</b> 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 fibroglandular tissue.</p> <p><b>Recommendation:</b> Since women's breasts tend to be grossly symmetrical, consider using the values from the contralateral breast as substitute values.</p>
<p><b>Dense breasts:</b> An image is of an extraordinarily dense breast with little visible fat.</p>	<p><b>Explanation:</b> Quantra relies on the detection of fat for a portion of its internal adjustments. Quantra may underestimate the volume of fibroglandular tissue in such instances.</p> <p><b>Recommendation:</b> Validate with visual assessment.</p>

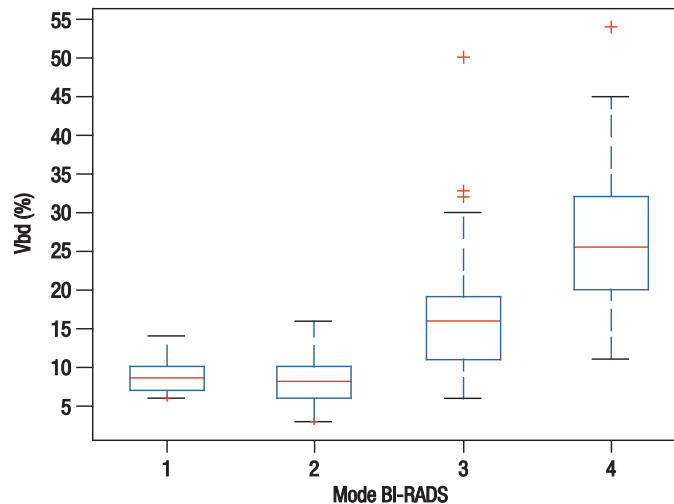
### 3.11. Performance Testing

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 q\_abd (fractional quantized volumetric density) values.

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



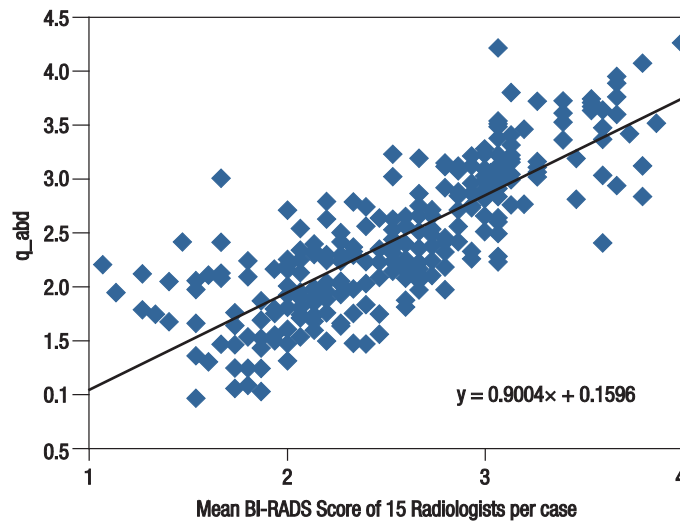
**Abd Values versus the Mode of 15 Radiologists' Scores**



**Vbd Values versus the Mode of 15 Radiologists' Scores**

As shown in the Vbd plot, the BI-RADS 1 readings included some fibroglandular tissue even in predominately fatty breasts (as there will always be some volumetric measurable fibroglandular tissue present). This phenomenon is not seen in the Abd plot because this small amount of fibroglandular tissue typically falls below the threshold for Abd inclusion.

The following figure presents a scatter plot of  $q_{abd}$  versus the mean BI-RADS values of the 15 radiologists. The Pearson's Correlation Coefficient (PCC) of the two continuous variables is 0.81.



**q-abd Values versus the Mean of 15 Radiologists' Scores**

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

The following table shows the PCC values for each score across the Hologic, GE and Siemens FFDMs.

Measure	Type of Correlation	Hologic PCC n=5358	GE PCC n=2417	Siemens PCC n=161
Vfg-score	CC / MLO	0.89	0.90	0.78
	L / R	0.91	0.91	0.90
Vbd-score	CC / MLO	0.82	0.89	0.78
	L / R	0.85	0.91	0.87

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