



Breast Density Assessment Software



Understanding Quantra™ 2.2 User Guide

MAN-11079-002 Revision 001

HOLOGIC®

Quantra™

Breast Density Assessment Software

User Guide

For Software Version 2.2

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Chapter 1 Introduction

Quantra™ is a software application used by radiologists that automatically estimates breast composition categories from mammographic images acquired using Hologic digital mammography systems. 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 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 the Quantra application operates and how Quantra breast density assessment can be integrated into their practices.

1.1 Intended Use/Indications for Use

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

The Quantra™ software application is intended for use with mammographic images acquired using digital breast x-ray systems. The Quantra software 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 software reports a result for each subject, which is intended to aid radiologists in the assessment of breast tissue composition. The Quantra software produces adjunctive information; it is not a diagnostic aid.

1.2 Intended User

Quantra software 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 Quantra application including features, benefits, and precautions for use.
- [Image Processing and Supported Views](#) on page 9 explains how information flows through systems with the Quantra application, the supported digital mammographic views, and how to manage workflow.
- [Algorithm Description](#) on page 13 describes how the Quantra algorithm analyzes digital mammographic 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 via E-Learning found under the training section of the Hologic website (www.hologic.com).
- **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 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:

Please note the following:














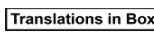


- The Quantra application is intended to provide adjunctive information; it is not a diagnostic aid. The radiologist should base assessment of breast density on diagnostic quality images.
 - The performance of the Quantra application has been evaluated only for images labeled as the four standard screening views: LCC, RCC, LMLO, and RMLO.
 - Results are not reported for:
 - Images that are 'equivalent' or 'reversed equivalent' views (for example, 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).
 - Synthesized 2D images.
 - Images showing breast implants may be processed by the application, although the application has not been designed for that purpose. The application 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 application, although the application has not been designed for that purpose. The application is unlikely to produce accurate Quantra results for partial view images.
 - The Quantra application estimates breast composition category based on distribution and texture of parenchymal tissue.
-



Note

The Quantra application does **not** use data compression.

1.9 Symbols

| Symbol | Description | Standard |
|---|---|---------------------------------|
| R_X ONLY | Prescription use only | FDA 21 CFR 801.109 |
|  | Warning | ISO 7010, Reference W001 |
|  | Caution | ISO 15223-1, Reference 5.4.4 |
|  | Note | Hologic |
|  | Manufacturer | ISO 15223-1, Reference 5.1.1 |
|  | Authorized representative in the European Community | ISO 15223-1, Reference 5.1.2 |
|  | Consult Instructions for Use | ISO 15223-1, Reference 5.4.3 |
|  | Catalog number | ISO 15223-1, Reference 5.1.6 |
|  | Revision | Hologic |
|  | Country of Manufacture | ISO 15223-1, Reference 5.1.11 |
|  | Medical Device | ISO 15223-1, Reference 5.7.7 |
|  | CE Mark European Conformity | MDR Regulation (EU) 2017/745 |
|  | Serial Number | ISO 15223-1, Reference 5.1.7 |
|  | Patents | Hologic |
|  | Translations in Box | Hologic |
|  | Date of manufacture | ISO 15223-1, Reference 5.1.3 |
|  | CE Mark with Notified Body reference number | MDR Regulation (EU) 2017/745 |

1.10 Overview of the Quantra Application

Quantra is a software application used to produce assessments of breast composition and to categorize them. Breasts consist of fat and 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 mammographic image. Abnormal lesions also appear bright on a mammogram and can be obscured or masked by fibroglandular tissue.

The Quantra algorithm is designed to estimate breast composition categories by analyzing distribution and texture of parenchymal tissue patterns, which can be responsible for the masking effect during mammographic reading.



Note

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

1.11 Clinical Benefits and Adverse Effects of the Quantra Application

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.

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 mammographic image may not correlate with density in the same digital mammographic 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.

The Quantra application has been developed in order to provide estimations of breast tissue composition categories. Through a proprietary software algorithm, the Quantra application analyzes images for distribution and texture of parenchymal tissue and categorizes breasts in four breast composition categories.

The Quantra application 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.

Adverse effects can be found in the Selenia Dimensions and 3Dimensions User Guides.

1.12 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 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 |

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 Supported Views

This chapter explains how information flows through systems with the Quantra application and the supported digital mammographic views.

2.1 Image Processing

2.1.1 Cenova Image Analytics Server

The Quantra application runs on a Cenova Image Analytics Server that manages DICOM images and processes the algorithm results. Image and data flows are generally as follows:

1. Images are acquired using a Hologic digital mammography system.
2. The Hologic digital mammography 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 application.
4. The Quantra application 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 Hologic digital mammography 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 display capabilities; it is not affected by the Quantra application.

2.1.2 Dimensions/3Dimensions System

The Quantra application runs on the appropriate Dimensions/3Dimensions Acquisition Workstation. Image and data flows are as follows:

1. The system produces digital x ray images in two forms:
 - Images suitable for processing by various software applications (raw images; Quantra runs on 2D or 3D 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, the Quantra application 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 in the form of DICOM Structured Report (SR) or DICOM Secondary Capture Image.
4. For each study, the Acquisition Workstation displays a thumbnail image representation of the Quantra results for the study.
5. For each study, the review workstation displays the Quantra results with the processed images produced by the Dimensions/3Dimensions 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 display capabilities; it is not affected by the Quantra application.

2.2 Image Acquisition Systems

The Quantra application processes images originating from Hologic digital mammography systems. The Quantra application processes Hologic conventional 2D mammography images and images from Hologic 3D Mammography™ systems.¹

Whether images are created on/transmitted from a Hologic digital mammography system or obtained from a PACS, the Quantra application 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 the Quantra application for any future processing needs.

¹ The Quantra application analyzes 2D center projection images from Hologic 3D Mammography™ systems.

2.3 Inputs and Supported Views

The Quantra application analyzes digital mammography images that conform to the DICOM standard. The Quantra application processes the four digital mammographic 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 the Quantra application 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 Hologic digital mammography 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, the Quantra application 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.

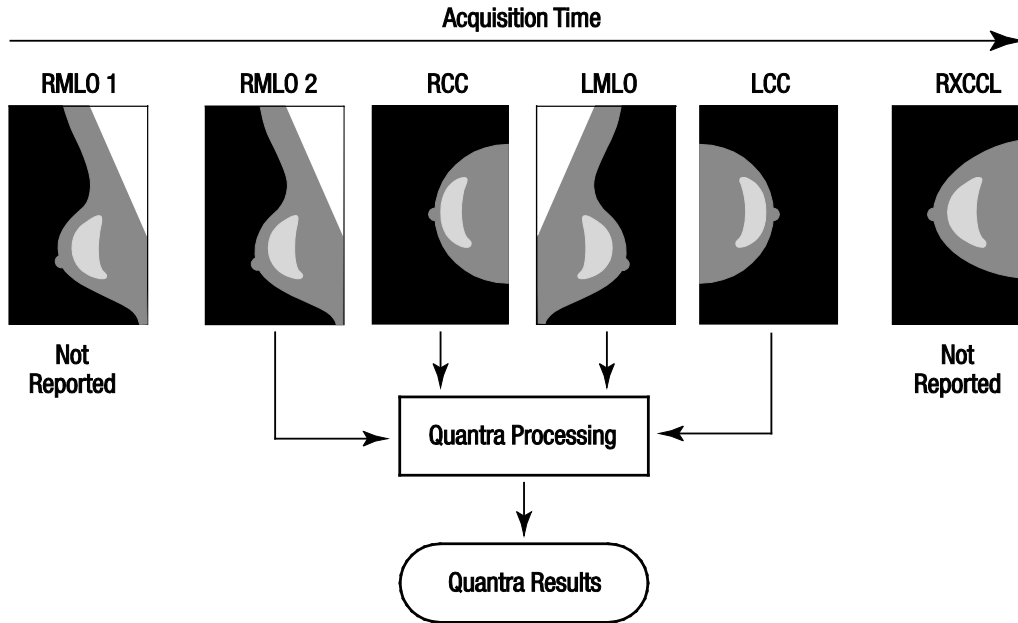


Figure 1: Quantra Image Processing

The diagram shows that when the Quantra application selects images, the algorithm reports results only for the last RMLO image acquired by the Hologic digital mammography system (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 the Quantra application does not process equivalent views.

Chapter 3 Algorithm Description

This chapter describes the Quantra algorithms and results produced when the Quantra application analyzes digital mammographic images.

3.1 Quantra Algorithm Overview

The Quantra application contains a hierarchy of algorithms that derive estimates of breast composition categories from digital mammographic images. The Quantra application also uses the digital mammographic image pixel data to extract information related to texture and distribution of breast tissue. The Quantra algorithm analyzes the pixel data from digital x-ray images for quantification of features related to texture and pattern of fibro-glandular tissue. These features are then further used by a classification scheme to assign a breast composition category to each breast.

3.2 Quantra Density Category (QDC)

The Quantra algorithm processes image pixel data to calculate various features that quantify distribution and texture of the parenchymal tissue. These features are based on variations in pixel values inside breast boundary. The statistical methods to quantify distribution and texture in the form of numeric features range from estimation of simple variance of pixel values to more complicated methods to capture properties such as homogeneity of pixel value distribution. A series of such features are then analyzed by a discriminatory classifier model that has been trained on a large number of images categorized by expert radiologists. Based on the outcome of the model, the Quantra algorithm assigns a breast composition category QDC value of a, b, c, or d to each breast, as described in the figure below. QDC is intended to provide an estimate of overall breast composition based on distribution of dense tissue pattern. The final assignment of QDC for each patient is done using the densest category of the left and right breasts.

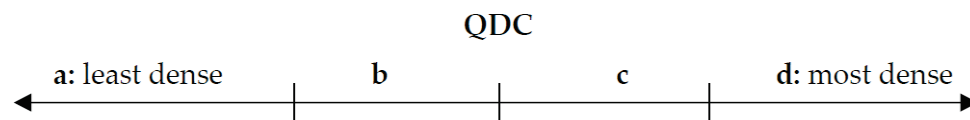


Figure 2: Quantra Density Categories

3.3 Examples of Quantra Results

This section provides an example of Quantra results. The following example shows how most diagnostic review workstations will display Quantra results generated in DICOM Secondary Capture Image format.

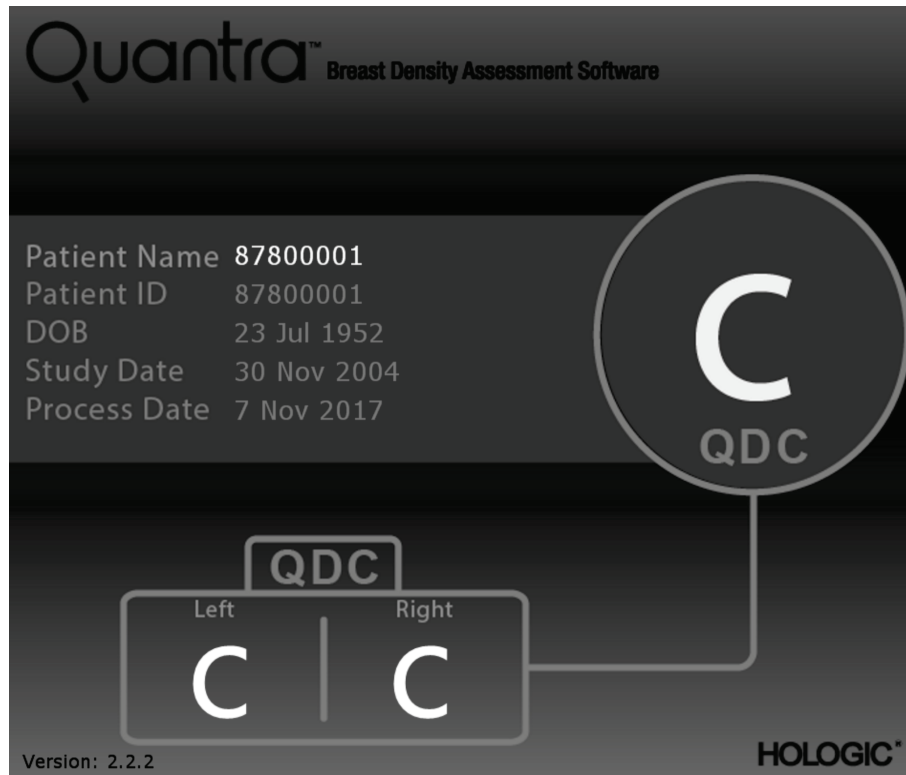


Figure 3: Quantra results displayed on a typical diagnostic review station

3.4 Illustrations of Quantra Breast Density Categories

This section shows images of a typical case for each Quantra Breast Density Category followed by the Quantra results for each case as they appear on diagnostic review workstations.

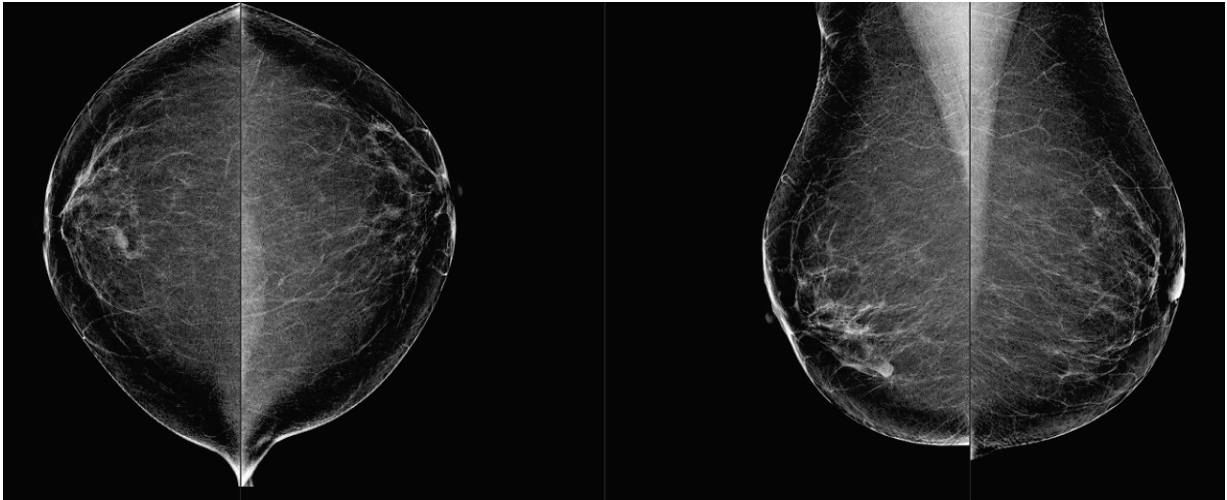


Figure 4: Example of breast category 'a'

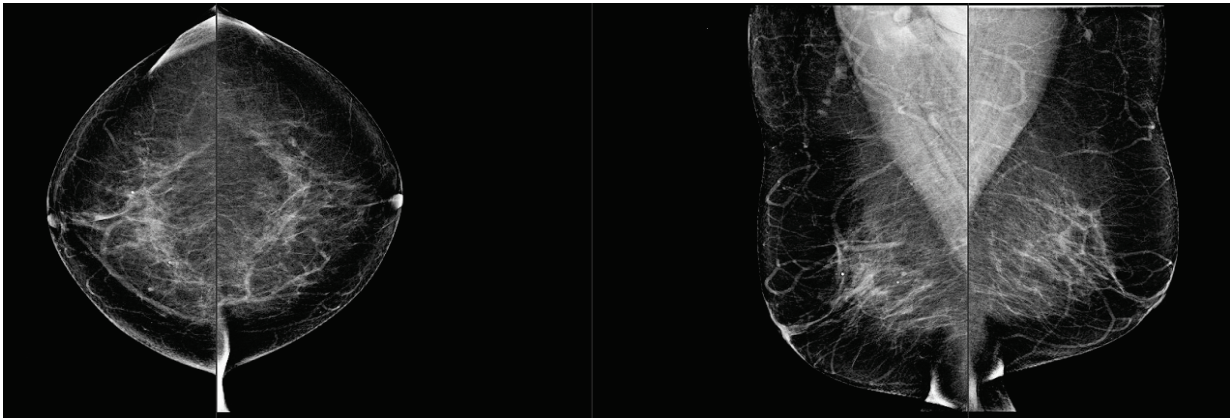


Figure 5: Example of breast category 'b'

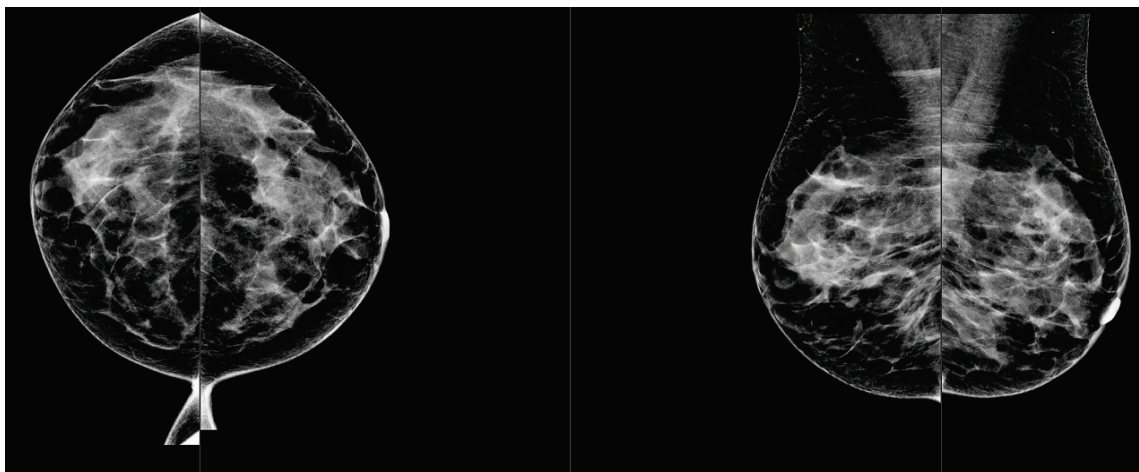


Figure 6: Example of breast category 'c'

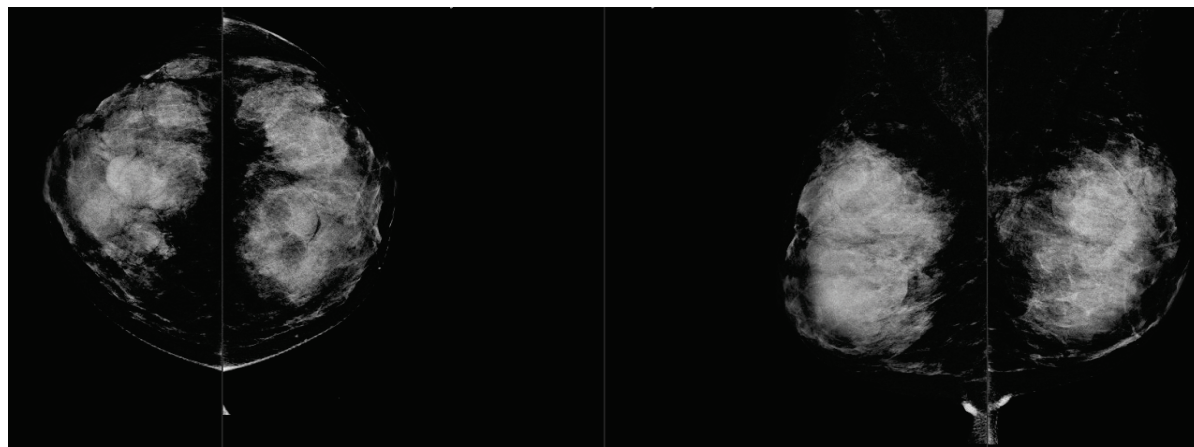


Figure 7: Example of breast category 'd'

3.5 Performance Testing

The accuracy of the Quantra algorithm was evaluated by using a set of 230 negative cases that were read by 5 radiologists independently in order to assign a BI-RADS density category using the ACR BI-RADS Fifth Edition published in 2013. All the cases were acquired using Hologic’s Selenia® Dimensions® system using "Combo" mode, where the tomosynthesis and conventional 2D images are acquired under same breast compression. The radiologists reviewed the tomosynthesis images as well as the conventional 2D images to assign a single breast density category for each case. The ground truth for each case then was obtained by calculating the median value of the categories assigned by 5 independent radiologists. Since the Quantra algorithm supports conventional 2D images as well as tomosynthesis images, QDC values from both these options were obtained.

Table 1 provides a comparison of Quantra (conventional 2D images) results with radiologists’ ground truth and corresponding accuracy in each category. Table 2 provides the comparison of Quantra (tomosynthesis images) results with radiologists’ ground truth and corresponding accuracy in each category.

Table 1: Contingency table between the QDC values for conventional 2D images

| Quantra 2.2 QDC - 2D | | | | | | |
|----------------------|----|----|----|----|--------------------|----------|
| | a | b | c | d | Per category total | Accuracy |
| a | 21 | 11 | 0 | 0 | 32 | 65.6% |
| b | 9 | 64 | 8 | 0 | 81 | 79.0% |
| c | 0 | 1 | 61 | 23 | 85 | 71.8% |
| d | 0 | 0 | 1 | 31 | 32 | 96.9% |
| Total | | | | | 230 | |

Table 2: Contingency table between the QDC values for tomosynthesis images

| Quantra 2.2 QDC - Tomo | | | | | | |
|------------------------|----|----|----|----|--------------------|----------|
| | a | b | c | d | Per category total | Accuracy |
| a | 20 | 12 | 0 | 0 | 32 | 62.5% |
| b | 11 | 61 | 9 | 0 | 81 | 75.3% |
| c | 0 | 7 | 53 | 25 | 85 | 62.4% |
| d | 0 | 0 | 1 | 31 | 32 | 96.9% |
| Total | | | | | 230 | |

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