3DQuorum™

User Guide Supplement

MAN-10627-002 Revision 001

HOLOGIC®

3DQuorum™

Software

User Guide Supplement

For Selenia® Dimensions® Systems and 3Dimensions™ Systems

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1 Introduction

Read all this information carefully before operating the system. Follow all warnings and precautions as stated in this manual. Keep this manual available during procedures. Physicians should tell patients about all potential risks and adverse events described in this manual with respect to the operation of the system.

Note
Hologic configures some systems to meet specific requirements. Your system configuration may not have all the options and accessories included in this manual.

1.1 Intended Use

1.1.1 Intended Use for Selenia Dimensions System

Rx Only

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

The Hologic® Selenia® Dimensions® system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Selenia Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the Selenia Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set; or
- a 2D and 3D image set, where the 2D image can be either an FFDM or a 2D image generated from the 3D image set and the 3D image set can be viewed as either 1-mm 3D slices or 6-mm 3D SmartSlices.

The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.

Note
In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either an FFDM image or 2D image generated from the 3D image set).

Contrast Enhanced Digital Mammography

Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.

1.1.2 Intended Use for 3Dimensions System

Rx Only

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

The Hologic® 3Dimensions™ system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The 3Dimensions (2D or 3D) system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. Specifically, the 3Dimensions system can be used to generate 2D digital mammograms and 3D mammograms. Each screening examination may consist of:

- a 2D FFDM image set; or
- a 2D and 3D image set, where the 2D image can be either an FFDM or a 2D image generated from the 3D image set and the 3D image set can be viewed as either 1-mm 3D slices or 6-mm 3D SmartSlices.

The 3Dimensions system may also be used for additional diagnostic workup of the breast.

Note
In Canada and Singapore, Tomosynthesis is not approved for screening, and must be used in conjunction with a 2D image (either an FFDM image or 2D image generated from the 3D image set).

Contrast Enhanced Digital Mammography

Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the 3Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.

1.2 About 3DQuorum Software

Note
3DQuorum™ imaging technology may not be available in all regions. Contact your sales representative for information

3DQuorum™ software uses image data available from a high-resolution breast tomosynthesis acquisition to generate SmartSlices, which are "slabbed" 3D images. The SmartSlices are created without the need for an additional digital tomosynthesis exposure. A SmartSlice can be perceived as a "thick" version of a tomosynthesis slice and is equivalent to six slices (6 mm) from the original tomosynthesis reconstruction. The SmartSlice volume consists of sequentially synthesized slices. Each SmartSlice shares half of its contents with the SmartSlice before and the other half with the SmartSlice after. Therefore, when reviewing SmartSlices, the images are advanced three 1-mm tomosynthesis slices at a time. The resulting number of images to be reviewed by a radiologist in a study is one-third the number of a tomosynthesis 1-mm reconstruction image set.

SmartSlices are designed to reduce the total tomosynthesis screening study interpretation time by decreasing the total number of images a radiologist is required to review. SmartSlices images are not intended to be used without the synthesized 2D images to make a clinical decision or diagnosis.

1.3 3DQuorum Software Warnings

Warning:
Do not make a clinical decision or diagnosis from the SmartSlice images without reviewing the accompanying synthesized 2D image set.

Warning:
Refer to the imaging system *User Guide* **for a complete list of warnings and cautions.**

Use SmartSlices in the same way you would use the 3D 1-mm slices (or tomosynthesis reconstructed slices) when reviewing a tomosynthesis screening study. Users should ensure they are adequately trained and are familiar with the appearance of SmartSlices before using them in place of tomosynthesis reconstructed slices.

1.4 3DQuorum Software Theory of Operation

Overview

3DQuorum software is an image processing application for post-processing a limited number of slices of tomosynthesis data, captured on a Hologic tomosynthesis imaging system, into a combined 3D image. The SmartSlices image set reduces the number of images to one-third compared to tomosynthesis reconstructed slices data set while maintaining clinical information. As a result, read times for the radiologist can be reduced by about 13%. And for archival and transmission purposes, file sizes can be reduced by over 50%. SmartSlices can be used in place of the tomosynthesis reconstructed slices when reviewing a screening study employing tomosynthesis. SmartSlices achieve the same sensitivity as reading 1-mm 3D™ slices.

Configuration

3DQuorum software has no user-configurable settings that influence the appearance of the resulting SmartSlices. SmartSlices are stored and transmitted as a series of frames using the DICOM Breast Tomosynthesis Image object format. The DICOM header for SmartSlices contains the information needed to differentiate it from any accompanying tomosynthesis reconstructed slices in the same view. An annotation ("3DQuorum") is also burned into the SmartSlices pixel data.

During the initial installation of 3DQuorum software, the system is configured to allow sending of tomosynthesis reconstructed slices and SmartSlices to PACS and diagnostic workstations. The default output groups can be configured to send only SmartSlices, only tomosynthesis reconstructed slices, or both to the preferred devices automatically. The site PACS administrator, in consultation with Hologic connectivity engineers, can select the output formats most appropriate for the site's IT infrastructure and workstations.

As with the introduction of any new imaging technology, Hologic advises testing SmartSlices with your PACS, workstations, and other Imaging Enterprise devices to ensure compatibility.

Workflow

As with any imaging study, the technologist selects the patient and identifies the type of imaging procedure that will be done. For tomosynthesis screening exams with 3DQuorum software, the process of imaging the subject and completing the study is all that is necessary. The 3DQuorum software itself operates with no direct human intervention.

2 User Interface

2.1 Summary of Changes

3DQuorum software affects the user interface on the control monitor in two major ways:

- Adds the SmartSlices button to the Display Modes.
- Changes preconfigured output groups and storage devices using standardized names.

2.2 Close a Patient

Follow the standard procedure to close a patient. If there are SmartSlices that have not completed processing, a dialog box opens with the following message:

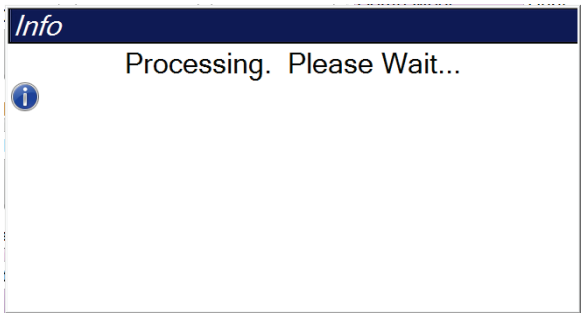

Figure 1: Processing Message

Wait for processing to complete before you open the next patient.

2.3 Output Groups

The accepted images are sent automatically to the output devices in the selected Output Group. The system configuration controls if the images are sent after a patient is closed or immediately after each image is accepted.

Note
Tomosynthesis images are not sent to a print device in the selected Output Group. You can print selected tomosynthesis slices and SmartSlices from the *Print* screen.

2.3.1 Select an Output Group

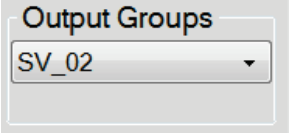

Figure 2: Output Groups Field

Select an output device group like PACS, diagnostic workstations, CAD devices and printers from the Output Groups drop-down list in the *Procedure* screen.

Note
Images are not sent if an Output Group is not selected.

2.3.2 SmartSlices Output Groups

Note
The configuration of Output Groups occurs during installation, but you can edit existing groups or add new groups.

During the installation of 3DQuorum software, new default Output Groups are created in the system to incorporate output options for SmartSlice images. The new output groups allow you to control whether SmartSlices, tomosynthesis reconstructed slices, or both are sent to the preferred devices automatically. See the following table for a description of the output groups.

Table 1: Output Groups for 3DQuorum Software

Output Group Name	Explanation of the Configuration
SmrtSlces,DBT,2D	Sends all configured data types.
SmartSlices,2D	Sends SmartSlices and 2D data types (synthesized 2D or FFDM). No 1-mm reconstructed slices are sent.
DBT,2D	Sends 1-mm reconstructed slices and 2D data types (synthesized 2D or FFDM). No SmartSlices are sent.
Custom	Provides on-demand selection of outputs and data types.

In order to create the three new output group types, each ImageStorage output device is configured to have three Installed Device entries. This allows maximum flexibility for experimenting with whether SmartSlices are always used in diagnostic reading, are always archived, or are only sent on-demand. See the following table for a description of the installed output device settings.

Table 2: Output Device Settings for 3DQuorum Software

Output Name	**Explanation of the Configuration**
Device name	Sends all desired data types except SmartSlices and 1-mm reconstructed slices.
Device name - 3D 1mm Slices	Sends only 1-mm reconstructed slices.
Device name - SmartSlices	Sends only SmartSlices.

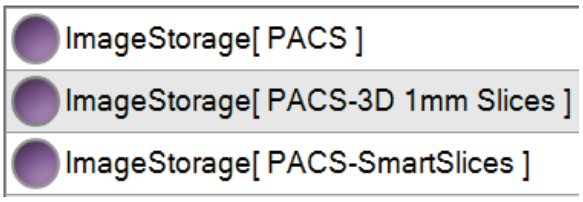

Figure 3: Example of the Output Device Settings

As decisions are made regarding which data to send to workstations for diagnosis, which data to archive, and which data to only send on-demand, the default configurations can be further customized. Changes can be made during Clinical Applications Training or by contacting Hologic Technical Support.

3 Images

3.1 Image Display Screen

After you make an exposure, the acquired image opens on the Image Display monitor. Patient and procedure information can be displayed on the screen. To turn the information on or off, go to the **Tools** tab in the *Procedure* screen and select the **Patient Information** button.

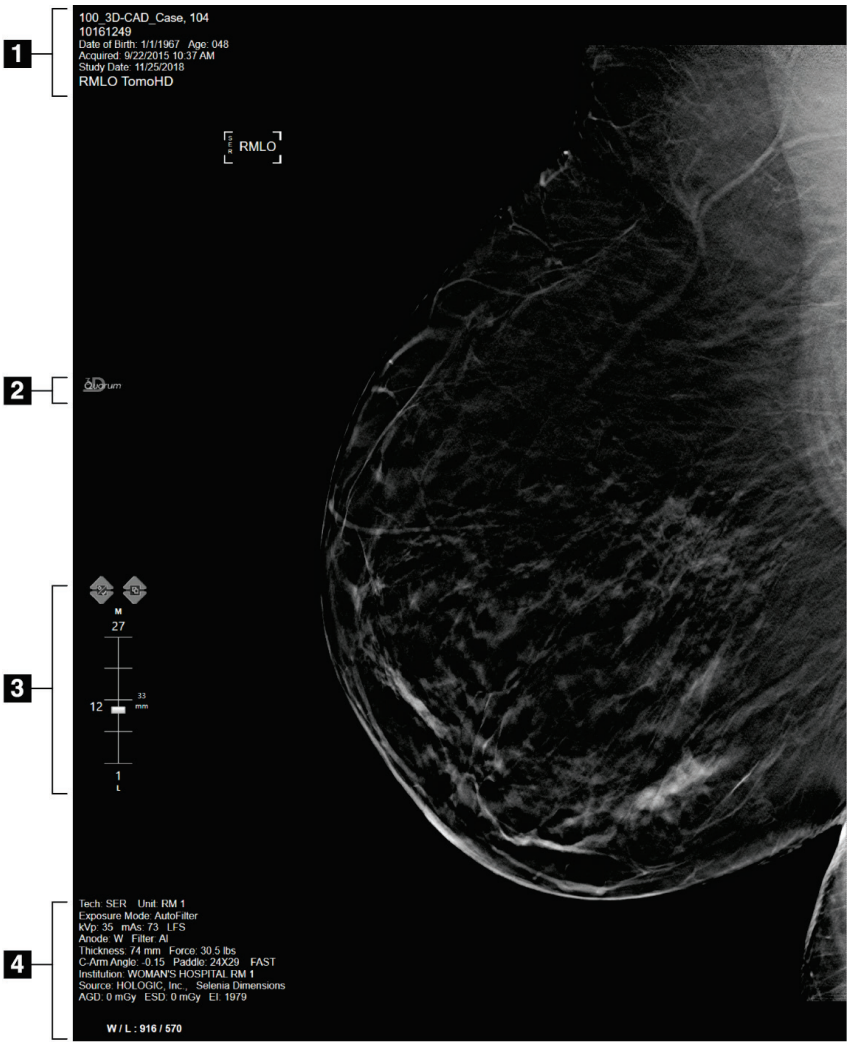

Figure 4: Image Display Screen (SmartSlices option shown)

Figure Legend

1. Patient information and exam date
2. 3DQuorum software logo
3. Slice Indicator
4. Exposure information

3.2 How to Acquire an Image

Follow the standard procedure to acquire a high-resolution tomosynthesis image set. The 3DQuorum software automatically generates the SmartSlices.

3.3 How to Review the Images

Review of the images involves use of the thumbnails, image review tools, and display modes.

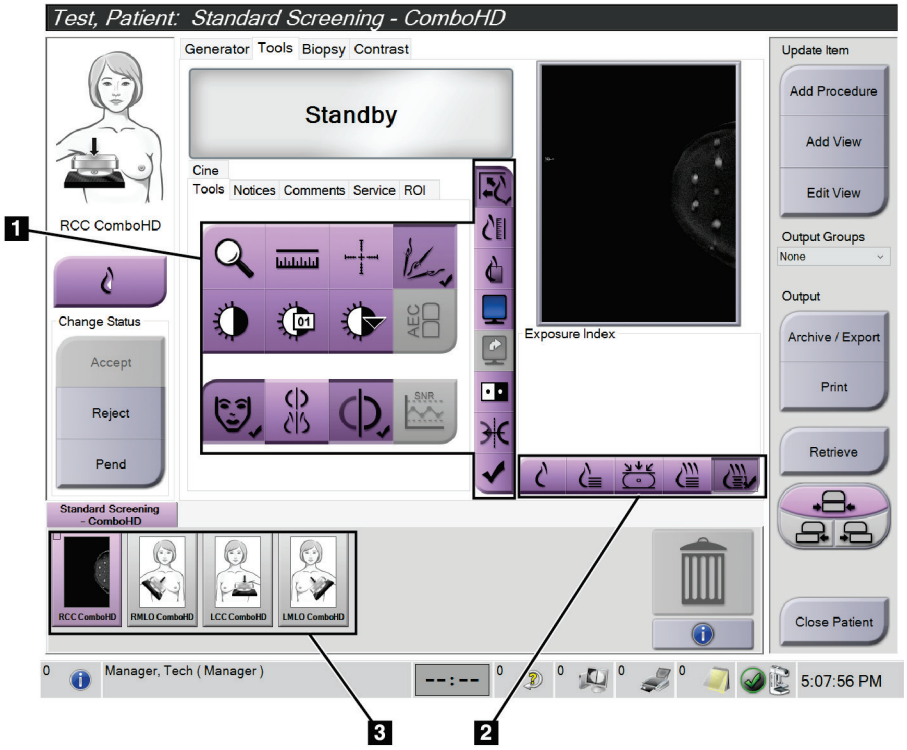

Figure 5: Tools Tab (SmartSlices option shown)

Figure Legend

1. Image Review Tools - refer to your system *User Guide* for complete information about the image review tools.
2. Image Display Modes - refer to *Display Modes* on page 12.

3. Thumbnail Views and Thumbnail Images. Select any thumbnail image to display that image on the Image Display monitor.

3.3.1 Display Modes

Use the buttons in the Display Modes area of the screen to select the type of view to show on the Image Display monitor. You can change between conventional, generated 2D, projections, reconstructions, and SmartSlices to show the combination images.

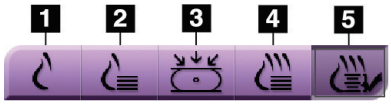

Figure 6: Display Modes

Figure Legend

1. **Conventional** button shows conventional 2D images.
2. **Generated 2D** button shows a 2D image generated from the acquired tomographic image.
3. **Projections** button shows the projection images from the 15° sweep.
4. **Reconstructions** button shows 1-mm reconstructed slices.
5. **SmartSlices** button shows 6-mm slices from the 3DQuorum software.

3.3.2 Slice Indicator

The Slice Indicator on the Image Display monitor shows only on tomographic reconstructions, including SmartSlices.

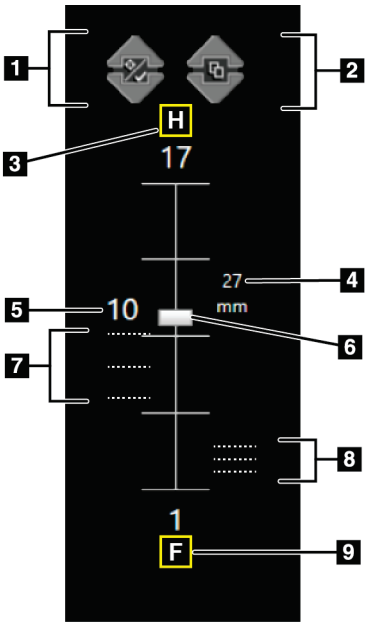

Figure 7: Slice Indicator (SmartSlice option shown)

Figure Legend

1. **Up** and **Down** arrows let you change between slices that contain a lesion target and slices that are tagged for printing.
2. **Up** and **Down** arrows let you change between slices that contain notices.
3. "H" (anatomical reference to head direction)
4. Height within the breast volume (for SmartSlices)
5. Number of the tomosynthesis reconstructed slice or SmartSlice image
6. Scroll bar moves through the slices of the reconstruction.
7. Slices that contain targets or are tagged for printing.
8. Slices that contain notices.
9. "F" (anatomical reference to foot direction)

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