

Cenova™

Image Analytics Servers



Cenova Image Analytics Server User Guide

Software Version 4.0

MAN-09779-001 Revision 001

HOLOGIC®

Cenova™

Image Analytics Server

User Guide

For Software Version 4.0

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Table of Contents

1: Introduction	1
1.1 Overview	1
1.2 Using This Guide	2
1.3 Resources Available	2
1.4 Warnings and Precautions	3
1.4.1 System Operation	4
1.4.2 Installation and Maintenance	5
1.5 Symbol Glossary	6
1.6 Warranty Statement	7
2: System Description	9
2.1 Inputs to Cenova	9
2.1.1 Input Devices	9
2.1.2 Image Formats	9
2.1.3 Input Ports and Application Licenses	10
2.2 Results from Cenova	10
2.3 Data Flows	11
2.3.1 ImageChecker CAD Data Flow	11
2.3.2 Hologic Imaging Biomarkers Data Flow	13
3: System Operation	15
3.1 Clinical Workflow	15
3.2 Sending Images to the Server	15
3.3 Server Startup and Shutdown	16
3.3.1 Shutting Down the Server	17
3.3.2 Starting Up the Server	18
3.3.3 Restarting the Server	18
3.4 Accessing Unique Device Identifier (UDI) Information	18
3.5 Using Case Manager	19
Index	23

Chapter 1 Introduction

1.1 Overview

This guide provides instructions for operating and maintaining the Cenova™ Image Analytics Server in the clinical environment. The server processes mammography images using proprietary software algorithms.

The Cenova server is a high-performance application server that provides proprietary software applications to assist radiologists in the analysis of digital mammography images. Cenova server is designed to be used by radiologists working in a hospital, outpatient clinic, or a breast imaging center. The server also may be used for research-related activities.

The server can be located in any non-patient environment, provided it is connected to the mammography network. Once configured, little direct interaction with the server is necessary. Any interaction is through a user-friendly web browser interface.

DICOM Conventions

DICOM (Digital Imaging and Communications in Medicine) is an international standard used for developing, transmitting, printing, and archiving medical imaging information. Hologic uses the following DICOM standard designations for digital mammography images:

- DICOM Digital Mammography X-Ray Image – For Processing
- DICOM Digital Mammography X-Ray Image – For Presentation
- DICOM Secondary Capture Image – Raw Projection
- DICOM Secondary Capture Image – Raw Synthesized 2D

To simplify, this guide shortens these designations to 'For Processing images', 'For Presentation images', 'Raw Projection images', and 'Raw Synthesized 2D images.'

1.2 Using This Guide

This guide is organized as follows:

- [Introduction](#) on page 1 provides background information on the Cenova server and related documentation.
- [System Description](#) on page 9 provides a summary of image specifications and data formats passed between the Cenova server and other devices that may be installed at your site.
- [System Operation](#) on page 15 provides information about managing clinical workflow, shutting down and powering up the server, accessing UDI information, and using the Cenova Case Manager.

1.3 Resources Available

In addition to this user guide, the following resources are available to assist you when working with the Cenova server.

- **Training:** This user guide serves as the training for the Cenova server.
The Hologic Applications team is available via remote training, should you feel your staff needs additional training for either the ImageChecker® CAD or Quantra™ applications on the Cenova server. Additional training for the Quantra application is also available via an E-learning found under the training section of the Hologic Website (www.hologic.com).
- **Documents:** Hologic provides the following documents for the Cenova server and its applications:
 - *Cenova Image Analytics Server User Guide*
 - *Understanding ImageChecker CAD User Guide*
 - *Understanding Quantra User Guide*
 - *Understanding DigitalNow HD User Guide*
 - *Cenova Image Analytics Server Installation and Service Manual*
 - *Cenova Image Analytics Server Release Notes*
 - *Cenova Image Analytics Server System Requirements*
 - *Cenova Image Analytics Server DICOM Conformance Statement*
 - *Cenova Image Analytics Server Cybersecurity Product Report*

You can obtain additional copies of printed documents through your Hologic Account Manager. You can find the DICOM Conformance Statement and Cybersecurity Product Report on the Hologic website.

- **Technical Support and Service:** For support in North America, contact:

Toll Free: +1.877.371.4372

Email: BreastHealth.Support@hologic.com

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

Website: www.hologic.com

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

1.4 Warnings and Precautions

This 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.

Before using the system, read the following warnings and precautions.

1.4.1 System Operation



Warning:

The server is intended for use only by personnel who have read this guide and received training on how to use the server. Hologic does not accept responsibility for injury or damage associated with improper or unsafe system operation.



Warning:

Use the server only outside the patient environment. The server is rated for use only in an office environment.



Warning:

Do not place liquid containers on the device. In the event of a spill, shut down power to all components prior to cleaning to minimize the possibility of electrical shock. If internal components are exposed to liquid, do not operate the device – contact your service representative.



Caution

Always shut down the computer according to the procedures provided in this guide. Improper system shutdown can cause loss of data or damage to the computer operating system.



Important

For proper system operation, the technical quality of the images (e.g., contrast) should be acceptable to the interpreting radiologist and meet the requirements of the Mammography Quality Standards Act (MQSA) or the appropriate national standards.



Important

The device design and mode of operation are consistent with current standard mammography clinical practices, as governed by the MQSA. Users are advised to comply with the MQSA for the United States, or the appropriate national standards, when implementing Cenova mammography applications in clinical protocols.



Important

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction guide, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at the user's expense.

1.4.2 Installation and Maintenance



Warning:

The symbol next to the power connector indicates a potential shock hazard. To reduce the likelihood of electrical shock or fire hazard, connect the computer only to a power receptacle that is properly grounded and provides voltage and current within the specifications of the server.



Warning:

To connect primary power to the server, always use a three-conductor grounded power cable that meets local regulatory standards. Use of a two-prong adapter disconnects the utility ground and creates a severe shock hazard.



Warning:

Cenova servers are heavy! If you have any concerns about lifting or positioning the server, request assistance.



Warning:

Before cleaning the server, always shut down the server according to the procedures in this guide and disconnect the power cord to prevent electrical shock. Never use alcohol, benzene, thinner, or other flammable cleaning agents.



Caution

Maintain equipment in a well-ventilated, air-conditioned environment that meets the temperature and humidity specifications provided in the product service guide.



Caution

Do not install or repair the Cenova server. Only trained personnel, authorized by Hologic, are qualified to install or repair the server.



Caution
















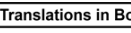

Disconnect power cord before moving or servicing.



Caution

Install the server behind the institution firewall for network security and antivirus protection. Hologic provides no computer virus protection or network security for the server. If antivirus software is required, visit the Hologic website for information about the Hologic cybersecurity program and antivirus software installation guidance.

1.5 Symbols

Symbol	Description	Standard
	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
	Prescription use only	FDA 21 CFR 801.109
	Catalog number	ISO 15223-1, Reference 5.1.6
	Serial number	ISO 15223-1, Reference 5.1.7
	Revision	Hologic
	Warning	ISO 7010, Reference W001
	Caution	ISO 15223-1, Reference 5.4.4
	Note	Hologic
 <small>www.hologic.com/package-inserts</small>	Consult Instructions for Use	ISO 15223-1, Reference 5.4.3
	Date of manufacture	ISO 15223-1, Reference 5.1.3
	Country of Manufacture	ISO 15223-1, Reference 5.1.11
	Manufacturer	ISO 15223-1, Reference 5.1.1
	Medical device	ISO 15223-1, Reference 5.7.7
	Quantity	Hologic
	CE Mark European Conformity	MDR regulation (EU) 2017/745
	Translations in Box	Hologic
	Patents	Hologic

1.6 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 System Description

This chapter describes the flow of data passed between Cenova and other devices that may be installed at your site.

2.1 Inputs to Cenova

2.1.1 Input Devices

The server supports inputs from the types of devices listed below. Certain in-country restrictions may apply.

- **Full Field Digital Mammography Systems:** Cenova processes two-dimensional digital mammography images originating from Full-Field Digital Mammography (FFDM) image acquisition systems. Cenova supports inputs from FFDM devices manufactured by Hologic Inc. (Danbury, CT), GE Healthcare (Waukesha, WI), and Siemens AG (Munich, Germany).
- **Digital Breast Tomosynthesis Systems:** Cenova processes 3D Mammography™ datasets and synthesized 2D images originating from Hologic Selenia® Dimensions® systems.
- **Film Digitizing Systems:** For film mammograms, Cenova processes DigitalNow™ images originating from any Hologic film-scanning systems.



Note

DigitalNow HD is no longer available for sale, but it is still supported for existing customers.

In addition, images produced by any of these systems may be sent to Cenova from a Picture Archiving and Communication System (PACS).

For more information about supported input devices, see the document for the specific software application.

2.1.2 Image Formats

The Cenova server processes digital mammography image objects that conform to the DICOM standard. The server processes the following types of DICOM image objects:

- Image objects sent to Cenova by an FFDM system following a conventional mammography examination known as *For Processing* images (also referred to as 'raw' 2D images).
- Image objects sent to Cenova by Hologic 3D Mammography™ systems known as *Raw Projection* images.
- Image objects sent to Cenova by Hologic 3D Mammography™ systems known as *Raw Synthesized 2D* images.
- Image objects sent to Cenova by any of the Hologic film-digitizing systems known as *For Presentation* images.

Some DICOM image objects are not processed by the software, depending upon the application and mammography view shown in the image.

For more information on image formats, see the diagrams in [Data Flows](#) on page 11.

2.1.3 Input Ports and Application Licenses

Each device that produces digital mammography image files maps to an input port on the Cenova server. The DICOM header for each image object includes an identifier (e.g., a serial number) that indicates the device from which the image originated.

For each Cenova server, sites can support:

- Up to four licenses for any or all of the 2D software applications plus a single license for DigitalNow HD, or
- A single license for DigitalNow HD

Note that exceeding these guidelines with a single server can affect system response times.

Each Cenova software application requires one software license for each input device. For example, if there are four FFDM devices, then the Cenova server must be configured with four software licenses for each desired Cenova software application.

The Cenova server can also process images sent from any number of PACS devices, as long as the images originated from one of the licensed input devices.

For assistance with license configurations, contact your Hologic Account Manager.

2.2 Results from Cenova

Cenova sends its results to diagnostic review workstations (such as Hologic SecurView DX) and PACS devices. Depending upon the application, Cenova can transmit results in one or more forms. The table below shows output formats for each application.

Application	CAD SR	SC Image	RTSS	Printer	MG Image
ImageChecker CAD	X	X	X	X	
Hologic Imaging Biomarkers	X	X			
DigitalNow HD					X

- **CAD SR** – The Mammography CAD SR format is the DICOM standard used for ImageChecker CAD and/or Hologic Imaging Biomarker results.
- **SC Image** – Mammography CAD SC (Secondary Capture) provides the case-processed views (normally the four screening views) with ImageChecker CAD, or Hologic Imaging Biomarkers. For ImageChecker CAD and Hologic Imaging Biomarkers, this format is for workstations that do not support Mammography CAD SR.
- **RTSS** – The Radiotherapy Structure Set format was developed specifically to display ImageChecker CAD results on certain GE review workstations.

- **Printer** – This format provides ImageChecker CAD results for the case-processed views (normally the four screening views).
- **MG Image** – This format (DICOM Digital Mammography X-Ray Image – For Presentation) provides DigitalNow HD images.

For workstations and PACS devices that do not support ImageChecker CAD Mammography CAD SR objects but do support DICOM 6000 overlays, the Hologic DICOM 6000 Interface solution has been used to convert the ImageChecker CAD results. This solution is no longer available for sale but may continue to be used on a Windows 7 computer separate from the Cenova server.

**Note**

DICOM 6000 Interface version 1.1.7 is required to support CAD on synthesized 2D image results as DICOM 6000 overlay.

**Note**

DICOM 6000 Interface cannot reside on a Cenova 4.0 server. DICOM 6000 Interface is not validated to run on Windows 10.

2.3 Data Flows

This section describes how information flows among the various devices for the Cenova applications.

**Note**

Mammography systems may have different configurations, depending upon the devices installed at your site.

2.3.1 ImageChecker CAD Data Flow

The diagram below shows how information typically flows through systems with ImageChecker CAD.

**Note**

ImageChecker CAD also applies to synthesized 2D images. Raw synthesized 2D images are sent to the Cenova server. Corresponding Breast Tomosynthesis Image or For Presentation images are sent to the diagnostic review workstation(s) and PACS.

**Note**

When both conventional 2D mammography and synthesized 2D images are sent to Cenova for a ComboHD study, the Cenova server will produce separate ImageChecker CAD results for the conventional 2D mammography and synthesized 2D images, respectively.

Image Acquisition System(s)

1, 2, 3: FFDM systems can be configured to send digital mammography x-ray images to any device that conforms to the DICOM standard. The FFDM device sends two types of images, For Processing images to the Cenova server, and For Presentation images to the diagnostic review workstation(s) and PACS.

Cenova Server

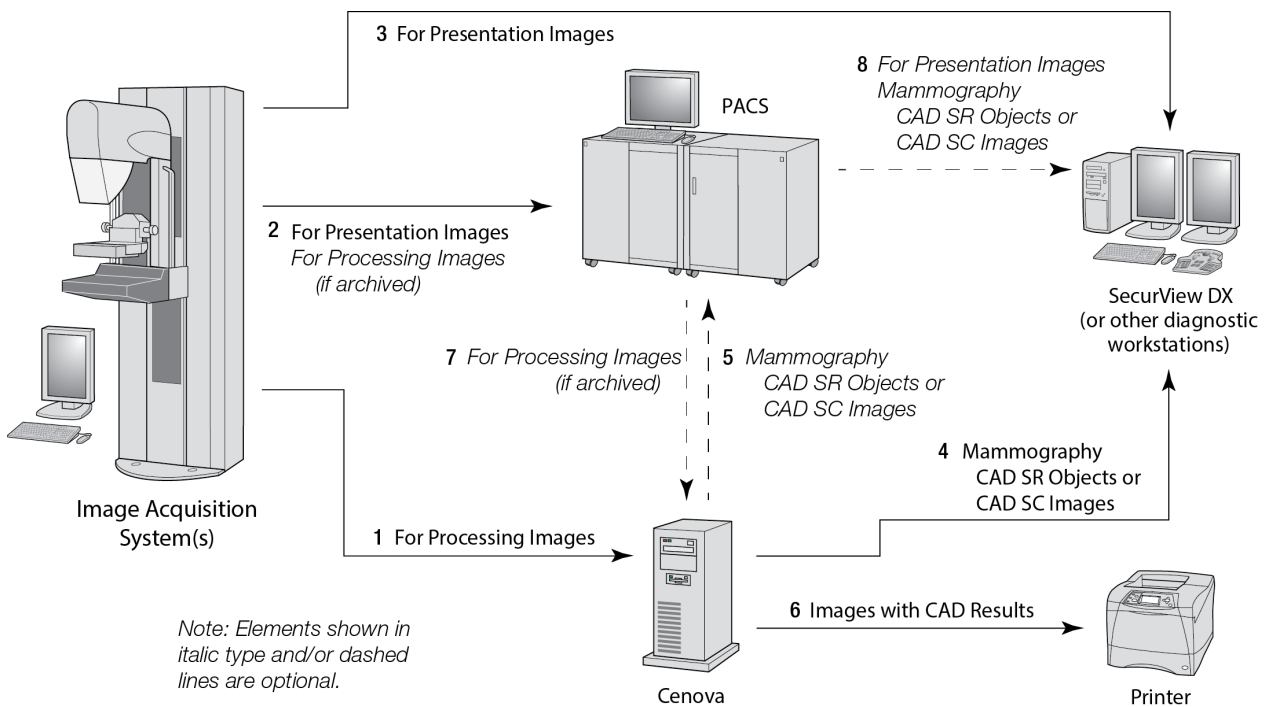
4, 5, 6: The Cenova server sends results (for example, Mammography CAD SR objects or CAD SC images) to one or more diagnostic review workstation(s) and/or PACS devices. The Cenova server can also provide printed results showing the four case-processed views with CAD marks.

Diagnostic Review Workstation(s) and PACS

3, 4, 8: The review workstation(s) are configured to receive the For Presentation images (3, 8) and ImageChecker CAD results (4, 8), which are then reviewed by the radiologist.

7, 8: The PACS can be configured to send:

- For Processing images to Cenova (7), which processes the images and distributes the CAD results according to its configuration, and/or
- ImageChecker CAD results and/or For Presentation images to the review workstations (8).



ImageChecker CAD Data Flow

2.3.2 Hologic Imaging Biomarkers Data Flow

The figure below shows the data flows among the various devices for the Quantra application.



Note

When both conventional 2D mammography and Raw Projection images are sent to Cenova for a Combo or ComboHD study, the Cenova server will produce one set of Quantra results for either the 2D or 3D images, per Cenova configuration.

Image Acquisition Device(s)

1, 2, 3: The Hologic FFDM device sends For Processing images to the Cenova server, and For Presentation images to the diagnostic review workstation(s) and PACS. The Hologic 3D Mammography™ device sends Raw Projection images to the Cenova server, and Reconstructed Slices to the diagnostic review workstation(s) and PACS.

Cenova Server

4, 5: The Cenova server sends Hologic Imaging Biomarker results (DICOM SR objects or DICOM SC images) to one or more diagnostic review workstation(s) and/or PACS devices simultaneously.



Note

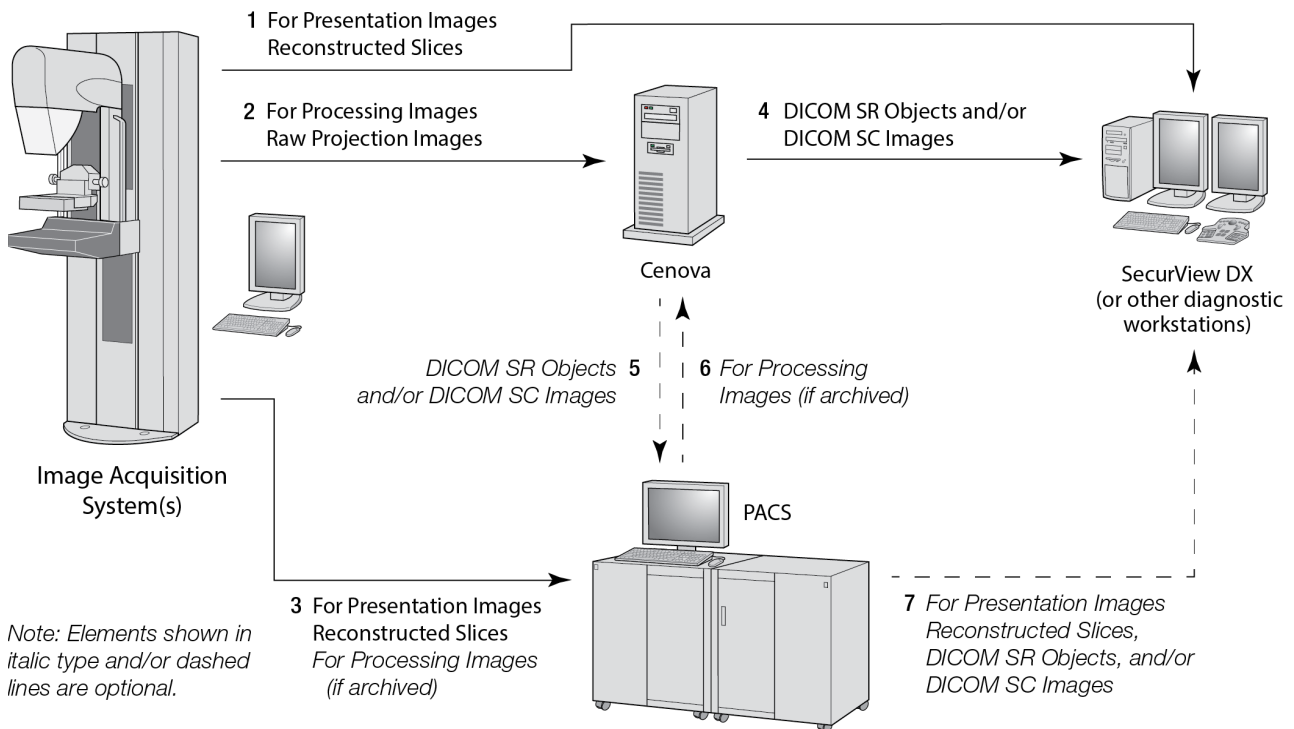
The Hologic SecurView DX workstation, some non-Hologic workstations, and several reporting applications will display Biomarker results content from DICOM Mammography CAD SR. For applications that are not capable of interpreting and displaying the SR content, or for customers who prefer a more user-friendly Biomarker results output, the Cenova server can be configured instead to send Biomarker results as a DICOM Secondary Capture Image.

Diagnostic Review Workstation(s) and PACS

1, 4, 7: The review workstation(s) are configured to receive the For Presentation images, Reconstructed Slices, and Biomarker results, which are then reviewed by the radiologist.

6, 7: As an option, the PACS can be configured to send:

- For Processing images to Cenova (6), which processes the images and distributes the Biomarker results according to its configuration, and/or
- Biomarker results and/or For Presentation images to the review workstations (7).



Hologic Imaging Biomarkers Data Flow

Chapter 3 System Operation

Once configured, little direct interaction with the Cenova server is necessary. Any interaction with the server is through a web browser and a user-friendly interface.

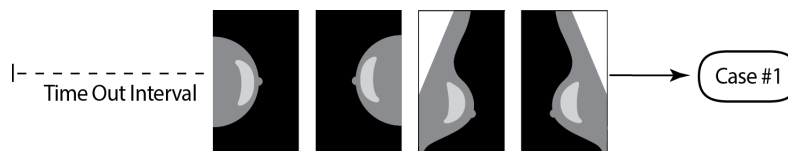
3.1 Clinical Workflow

To view results produced by the Cenova server with the patient mammography images, follow the guidelines of your workstation vendor. Radiologists typically review mammography images using a protocol similar to the sequence shown in the following table:

For this step	The radiologist
Preliminary Review	Reviews the mammography images to get a preliminary sense of the patient status.
DigitalNow HD	Compares prior digitized film images to the new mammography images.
Hologic Imaging Biomarkers	Reviews and notes the Biomarker findings.
Preliminary Assessment	Examines the mammography images in detail and forms a primary diagnosis.
Computer Aided Detection	Views CAD marks and evaluates related ImageChecker data to determine if other areas on the images warrant further review.
Final Assessment	Makes a final assessment and creates a report.

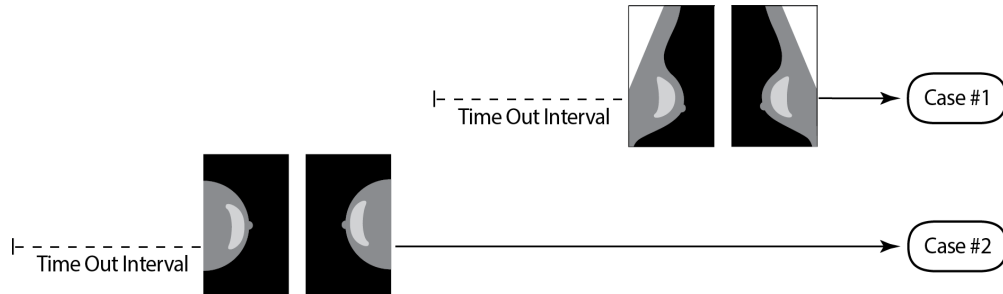
3.2 Sending Images to the Server

The server accepts the images automatically as they are sent from the image acquisition system, film-scanner, or archiving device. The Cenova server groups successive images with the same DICOM study instance UID (unique identifier) into a case if the images are received within a time-out period configured by the service representative upon system installation. The time-out period is not fixed; the server automatically adjusts the time-out period to maximize throughput. (For more information, contact Hologic Technical Support.)



Server Assigns Images Received Before Timeout Elapses to One Case

The server assigns any image received after the time-out period to a new case using the same study instance UID. At the review workstation, two sets of results will be seen, distinguishable by the date and time they were produced by the server.



Server Assigns Images Received After Timeout Elapses to a New Case

To reduce the possibility of multiple results, Hologic recommends that images for each patient examination be sent from the image acquisition system together at the close of the study and in rapid succession.



Note

As an alternative, the server can be configured to group all images with the same study instance UID automatically into a single case, no matter when they were received (i.e., include images from a previous case). For more information, consult with a technical support representative.

It is the service representative's responsibility to set up your system such that the images are sent correctly to the server in addition to the review workstation and to the desired final destinations. For more about the data flow among the various devices, see [Data Flows](#) on page 11.

3.3 Server Startup and Shutdown

The Cenova server does not require regular maintenance. The only procedures you might need to perform are:

- [Shutting Down the Server](#) on page 17
- [Starting Up the Server](#) on page 18
- [Restarting the Server](#) on page 18 (turning off and on again)

For these procedures, you need to know the IP address for the computer. You can get the IP address from the Cenova *System Settings – Connectivity* screen. Write that number here:

Cenova Server IP Address: _____

3.3.1 Shutting Down the Server

You might need to shut down the Cenova server if you are going to move the computer, or if you know the power is going out for a period of time.

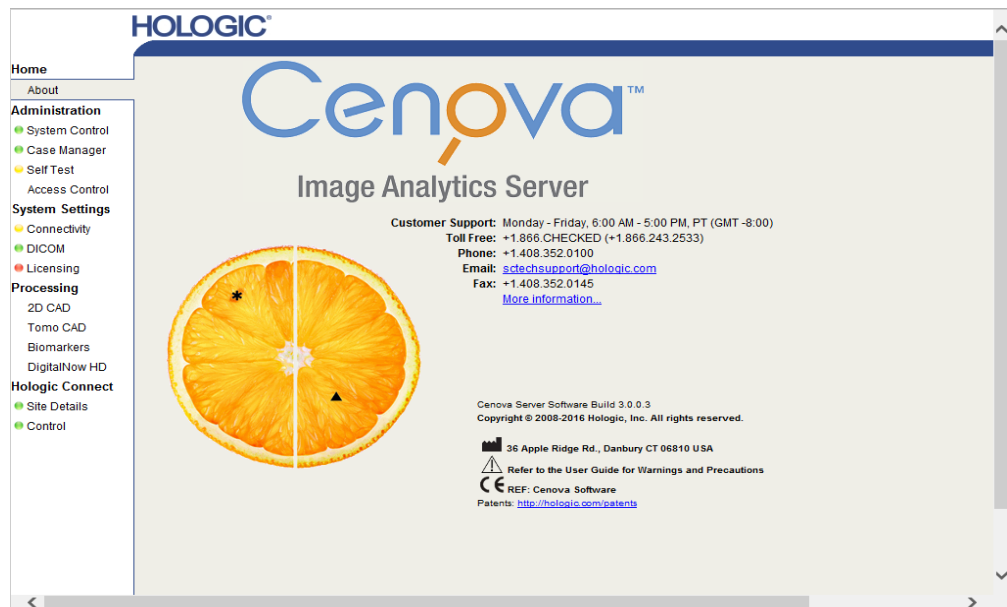


Important

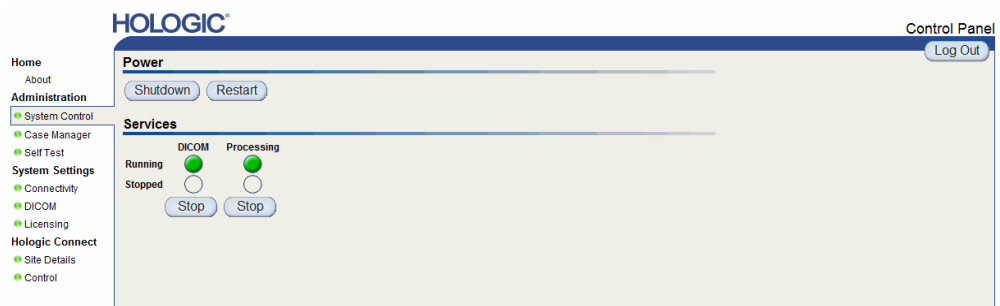
If you shut down the server from a remote location, be aware that in order to switch the server back on, you will need to have physical access to the server.

To shut down the server:

1. Using a computer that is on the same network as the server, open a web browser (for example, Internet Explorer).
2. Type the IP address for the server in the address box and press **Enter**. You do not need to type 'http' or anything other than the IP address.
3. At the log-in screen, enter the user name (siteadmin) and password. The *About* screen should appear as shown below.



4. Select **System Control** to display the following screen:



5. Select **Shutdown**. The server prompts 'Are you sure...?' Select **OK** to switch the server off.



Note

Physical access to the server is required to restore power from a shutdown. If the server is in a remote location, use **Restart**.

3.3.2 Starting Up the Server

If the server has been powered off, you can switch it back on by pressing the power switch on the front of the computer. (An indicator light indicates whether the server is on or off.) The Cenova software starts up automatically, and the server should be ready for use within 3–5 minutes.

3.3.3 Restarting the Server

You might need to restart the Cenova server if results are not transferring. Often, restarting the server clears any errors. In some cases, your service representative will ask you to restart the server.

To restart the server:

1. Using a computer that is on the same network as the Cenova server, open a web browser.
2. Type the IP address for the Cenova server in the address box and press **Enter**. You do not need to type 'http' or anything other than the IP address.
3. At the log-in screen, enter the user name ('Administrator') and password. The *About* screen should appear as shown in the previous procedure.
4. On the *About* screen, select **System Control**.
5. From the *System Control* screen, select **Restart**. The server prompts 'Are you sure...?' Select the **Restart** button once more. The server should shut down and then restart automatically. The server should be ready for use within about 5 minutes.



Note

To continue using the server, refresh the browser by repeating steps 1–3.

3.4 Accessing Unique Device Identifier (UDI) Information

Unique Device Identifier (UDI) is a unique numeric or alphanumeric code that identifies a medical device through distribution and use. UDI information is displayed in the *About* screen of the Cenova application.

To access UDI information in Cenova:

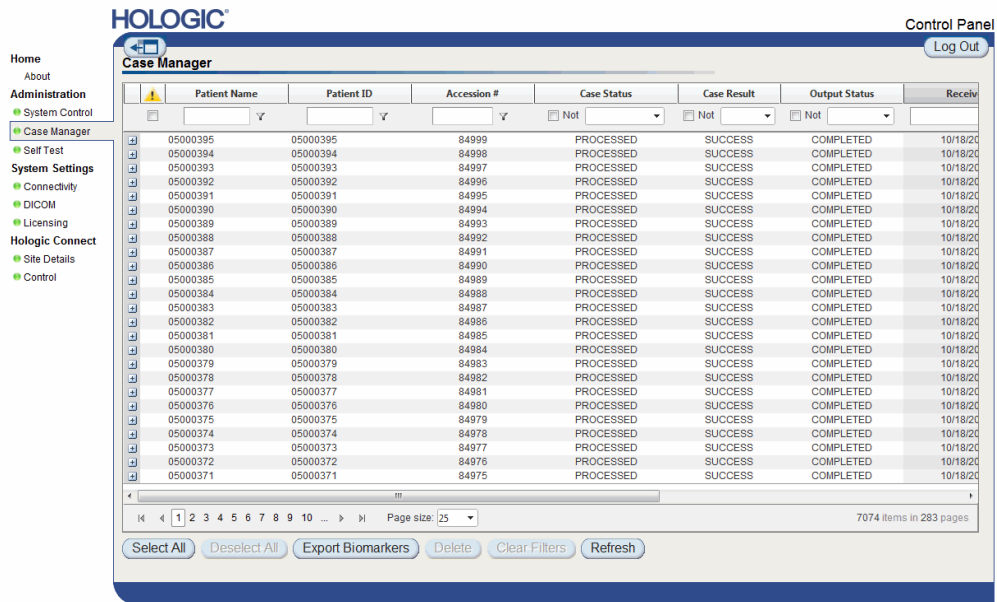
1. Launch the Cenova application and log in (see [Server Startup and Shutdown](#) on page 16). The *About* screen appears.
2. On the *About* screen, select **More Information**.
UDI information is displayed on the subsequent screen.

3.5 Using Case Manager


Case Manager allows you to display, analyze, and troubleshoot cases from within the Cenova Control Panel. You can use Case Manager to:

- Browse and sort cases
- Search for a study using data such as patient information, date processed, etc.
- Export Biomarker results
- Delete cases
- Review details for a study

When you select the Case Manager option from the Cenova Control Panel, a screen similar to the following appears:



By default, the cases appear in reverse chronological order (newest first). The records are arranged in rows and columns. Each row shows one case.

Select **Hide Navigation Panel** () to expand the Case Manager viewing window.


To browse and sort cases

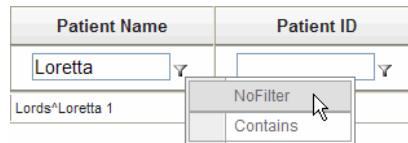
You can sort the values in any column by selecting any of the column headings (Patient Name, Patient ID, etc.). The server sorts the values in ascending order either alpha-numerically or by date and time, depending upon the type of data to be sorted. Select the column heading again to sort in descending order.



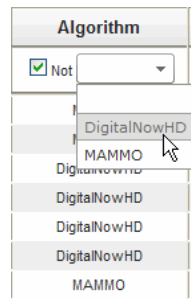
To search for a study

In any of the column heading boxes, enter text or numbers you want to find and press **Enter**. The server searches its database and returns only studies with values containing the characters you typed.

To remove the filter, select **Filter** () and select **NoFilter** in the drop-down list:



For some columns, you can exclude a search criterion by using the **Not** box



To clear selected search criteria, select **Clear Filters**.

To export Biomarker results



Warning:

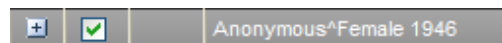
The Export Biomarkers feature provides values that are for research purposes only. This feature is not intended for clinical use.

You can collect Biomarker results and export the results to a .csv file, which can be opened using a spreadsheet application. To use this feature, the server must be configured with a valid Hologic Imaging Biomarkers license.

1. Select one or more cases using the Case Manager search function. If you do not select any cases, then the server will export all Biomarker results.
2. Select **Export Biomarkers** to display the *File Download* dialog box.
3. Select **Save**. In the *Save As* dialog box, navigate to the location where you wish to save the file and select **Save**.


To delete cases











Display the case you want to delete and select the check box next to the case:



Then select **Delete**.

To review details for a study

Select  to expand the case and review the 'Images' and 'Output Jobs' details:

	<input type="checkbox"/>	87800006	87800006	PROCESSED	SUCCESS	
Images:4						
		Image ID	View	View Modifier	Case Processing	State
		92	RCC		✓	PROCESSED 
		93	LCC		✓	PROCESSED 
		94	LMLO		✓	PROCESSED 
		95	RMLO		✓	PROCESSED 
Output Jobs:1						
		Job ID	Format	Destination	Status	
		40	5.X SR - CAD	DVT_STORE2	Complete 	

Select  to view additional details for each image.

Case ID: 26, View: LCC	
Case	Image
Case ID: 26	Image ID: 90
Patient Name: 10100191	View: LCC
Patient ID: 10100191	View Modifier:
Study Date: 20080508	State: PROCESSED
Algorithm: MAMMO	Start Time: 1/31/2009 12:45:47 AM
Case Result: SUCCESS	End Time: 1/31/2009 12:46:11 AM
AlgoName	Result
Masses	SUCCESS
Calcifications	SUCCESS
Volumetric Assessment	SUCCESS
ImageDetails.aspx?id=90	

Index

A

antivirus products • 5

C

Cenova server

 restarting • 18

 shutdown • 17

 startup • 18

 system operation • 15

 usage guidelines • 15

cybersecurity • 5

D

DICOM • 1

 image classes • 11

DigitalNow HD

 clinical workflow • 15

H

Hologic Imaging Biomarkers • 15

I

ImageChecker CAD

 clinical workflow • 15

M

Mammography CAD SC • 11

Mammography CAD SR • 11

P

ports, input • 10

 Quantra • 13

printout • 11

Q

Quantra • 13

R

restarting the server • 18

results

displaying • 15

S

SecurView diagnostic review workstation • 11

shutting down the server • 17

starting up the server • 18

U

Unique Device Identifier • 15, 18

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