R2 Cenova™

R2 Cenova™ 1.3

User Manual

MAN-01222 Rev 002

HOLOGIC™

The Women's Health Company.

Digital Mammography

R2 Cenova™ 1.3

User Manual

MAN-01222 Rev 002

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MergeCOM-3 Advanced Integrator's
Tool Kit is a product of Merge
Healthcare.

Contents

Part 1: Introduction

1.1. Overview

This manual provides instructions for the operation and maintenance of the R2 Cenova™ 1.3 server in the clinical environment. The server processes mammography images using proprietary software algorithms.

The software applications available for the R2 Cenova 1.3 server are:

- R2 ImageChecker® CAD 9.3, computer-aided detection software used to identify and mark regions of interest on routine screening and diagnostic mammograms.

- R2 Quantra™ 1.3, volumetric assessment (VA) software used to calculate volumetric breast density from digital mammograms.

- R2 DigitalNow™ HD 1.0, software used to process digitized prior film images to produce lossy-compressed DICOM images that more closely resemble digital mammography images.

DICOM Conventions

DICOM (Digital Imaging and Communications in Medicine) is an international standard used for developing, transmitting, printing, and archiving medical imaging information. The DICOM standard specifies two classes of archivable digital mammography images with the following designations:

- DICOM Digital Mammography X-Ray Image – For Processing
- DICOM Digital Mammography X-Ray Image – For Presentation

To simplify, these designations are shortened to 'For Processing' and 'For Presentation' in this manual.

1.2. Resources Available

In addition to this manual, the following resources are available to assist you when working with the R2 Cenova server.

- **R2 Member Center:** This website provides quick access to manuals and training materials for Hologic R2 products and is available at no charge to our customers under warranty or Hologic service contract. You can find the R2 Member Center by visiting the Hologic website (www.hologic.com/training-center). See the R2U flyer that accompanies this product for more instructions.

- **Training:** The R2 Member Center (see above) provides training materials for R2 Cenova applications. 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.

- **Manuals:** The manuals for the R2 Cenova server and its applications are listed below:

    – *Understanding R2 ImageChecker CAD*
    – *Understanding R2 Quantra*
    – *Understanding R2 DigitalNow HD*
    – *R2 Cenova User Manual*
    – *R2 Cenova Service Manual*
    – *R2 Cenova Release Notes*
    – *R2 Cenova DICOM Conformance Statement*
    – *R2 Cenova Cybersecurity Best Practices*
    – *R2 Cenova Antivirus Software Installation Instructions*

    You can obtain additional copies of printed manuals through your Hologic Account Manager. The DICOM Conformance Statement, Cybersecurity Best Practices, and Antivirus Software documents are available at www.hologic.com.

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

Toll Free:	+1.866.243.2533 (+1.866.CHECKED)
Email:	r2support@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.

1.3. Warnings and Precautions

System Operation

- The system is intended to be used only by personnel who have read this manual and received training on how to use the system.

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

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

- 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 system.

- 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.

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

- 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 R2 Cenova mammography applications in clinical protocols.

- 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 manual, 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 her or his own expense.

Installation and Maintenance

This product contains no user-serviceable parts. To prevent damage to the system:

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

- Do not install or repair the R2 Cenova server. Only trained personnel, authorized by Hologic, are qualified to install or repair the system.

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

- Disconnect power cord before moving or servicing.

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

- To connect primary power to the system, 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.

Part 2: System Description

2.1. Indications for Use

R2 Cenova is a high-performance application server that provides proprietary software applications to assist radiologists in the analysis of digital mammography images. Hologic has developed three software applications for use with the server:

- R2 ImageChecker CAD, computer-aided detection software used to identify and mark regions of interest on routine screening and diagnostic mammograms.

- R2 Quantra, used to calculate volumetric breast density from digital mammograms.

- R2 DigitalNow HD, used to process digitized screen-film mammograms so that the resulting images more closely resemble digital mammography images.

R2 Cenova 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.

2.2. System Inputs and Outputs

This section provides a summary of image specifications and data formats passed between R2 Cenova and other devices that may be installed at your site. For more detailed information see the application manuals:

- *Understanding R2 ImageChecker CAD*
- *Understanding R2 Quantra*
- *Understanding R2 DigitalNow HD*

Inputs to R2 Cenova

R2 Cenova software processes mammography images that conform to the DICOM standard. Some DICOM images are not processed by the software, depending upon the application and mammography view shown in the image.

The server supports inputs from:

- **Digital Image Acquisition Systems:** R2 Cenova processes digital mammography images originating from up to four different Full-Field Digital Mammography (FFDM) image acquisition systems. Each FFDM device maps to an input port on the server. R2 Cenova supports inputs from FFDM devices distributed by Hologic, GE, and Siemens. Certain in-country restrictions may apply.

- **R2 Film Scanning Systems:** For film mammograms, R2 Cenova processes R2 DigitalNow images originating from any of the R2 film-scanning systems (R2 DMax, DM, DX, and LS). The server is not designed to process images produced by systems equipped with early R2 scanner models (Lumisys and Vidar DiagnosticPro), and it does not process DigitalNow ELC™ images. (ELC is a legacy format no longer provided with R2 film scanning systems.)

For each R2 Cenova server, you can purchase:

- Up to four ImageChecker CAD licenses and/or
- Up to four Quantra licenses and/or
- DigitalNow HD

Note that using more than four licenses with a single server can affect system response times. For assistance with license configurations, contact your Hologic representative.

The diagrams in section '2.3. Clinical Workflow' show that the server processes two types of DICOM images. Those sent by an FFDM following a mammography examination are known as *For Processing* images (also known as 'raw' images). Those sent by any of the R2 film-scanning systems are R2 DigitalNow *For Presentation* images. The DICOM header for each image includes an identifier that indicates the device from which the image originated.

In addition, images from an FFDM or R2 film-scanner can be sent to R2 Cenova from a PACS.

Results from R2 Cenova

R2 Cenova sends its results to diagnostic review workstations (such as Hologic SecurView_DX) and PACS devices. Depending upon the application, R2 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	✔	✔	✔	✔	
Quantra	✔	✔			
DigitalNow HD					✔

- **CAD SR** – The Mammography CAD SR format is the DICOM standard used for ImageChecker and/or Quantra results.

- **SC Image** – Mammography CAD SC (Secondary Capture) provides the case-processed views (normally the four screening views) with ImageChecker and/or Quantra results. This format is for workstations that do not support Mammography CAD SR.

- **RTSS** – The Radiotherapy Structure Set format was developed specifically to display ImageChecker results on certain GE review workstations.

- **Printer** – This format provides ImageChecker results for the case-processed views (normally the four standard 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 Mammography CAD SR objects but do support DICOM 6000 overlays, Hologic's DICOM 6000 Interface server can be used to convert the ImageChecker results. For more information, contact your Hologic Account Representative.

2.3. Clinical Workflow

Review of the mammogram by the radiologist is typically conducted using a protocol similar to the sequence shown in the following table:

For this step…	The radiologist…
Preliminary Review	Reviews the digital mammogram to get a preliminary sense of the patient's status.
R2 DigitalNow HD	Compares prior digitized film images to the new digital mammography study.
R2 Quantra	Reviews and notes the volumetric findings.
Preliminary Assessment	Examines the mammogram in detail and forms a primary diagnosis.
R2 ImageChecker	Views the CAD marks and evaluates other data produced by ImageChecker to determine if other areas on the mammogram warrant further review.
Final Assessment	Makes a final assessment and creates a report.

Workflow with ImageChecker and Quantra

The diagram below shows the flow of images to the server and results from the server. Depending upon the needs of the facility, other pathways can be configured.
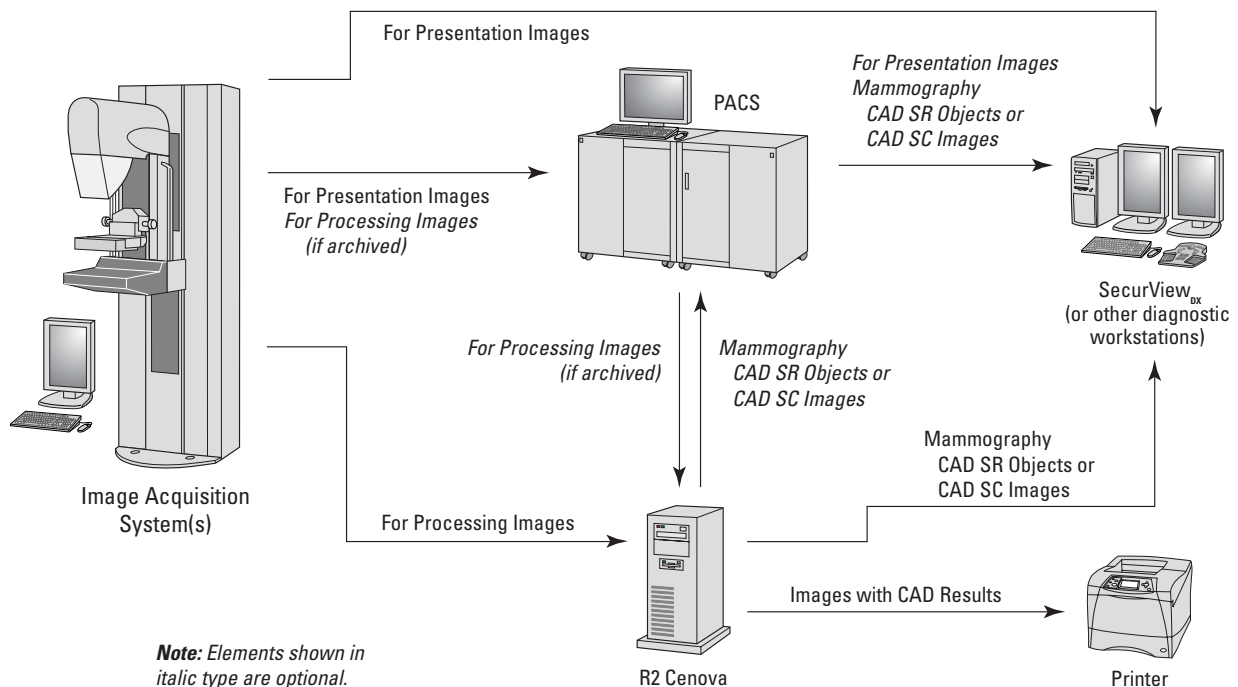
Data Flow with ImageChecker CAD and Quantra

Workflow with DigitalNow HD

The diagram below shows the flow of images to the server and results from the server. Depending upon the needs of the facility, other pathways can be configured.
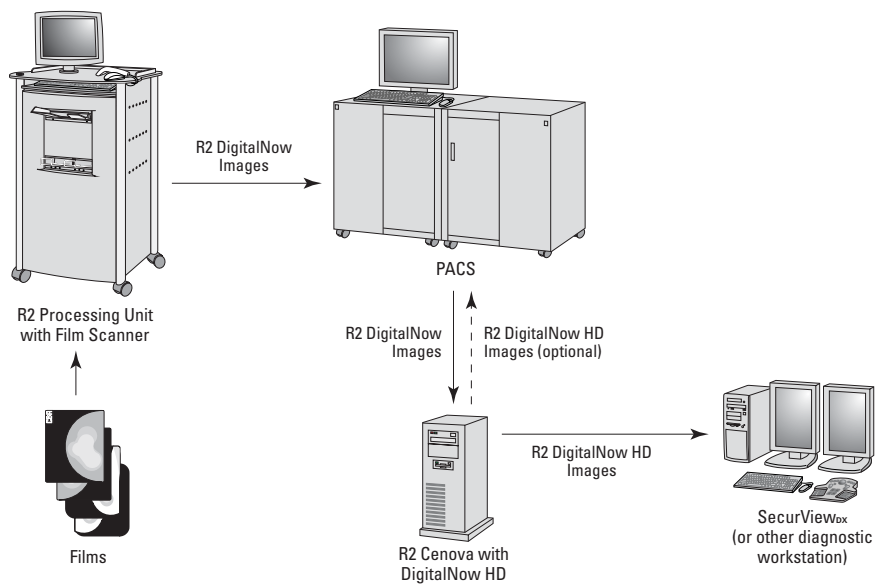
Data Flow with DigitalNow HD

Part 3: Software Applications

3.1. R2 ImageChecker CAD

R2 ImageChecker CAD is a software application that identifies and marks regions of interest on routine diagnostic and screening mammograms that may warrant a second review by the radiologist. Its purpose is to help minimize observational oversights.

R2 Cenova accepts images from a digital mammography device or archive, and then analyzes the images using the ImageChecker algorithm (i.e., a set of criteria) that identifies regions of interest. These regions include:

- Clusters of bright spots, which are regions suggestive of calcification clusters
- Dense regions with or without radiating lines, which are regions suggestive of masses or architectural distortions

The ImageChecker software generates marks and other data that identify and characterize regions of interest, and sends the results for display on a diagnostic review workstation or for storage on an archive system (PACS).

The original digital mammograms for a specific study are displayed on the workstation for review by the radiologist. After making an initial interpretation from the original mammograms, the radiologist displays the CAD marks and chooses whether or not to reinspect the marked regions on the original mammogram.

For more information on ImageChecker features, refer to the manual *Understanding R2 ImageChecker CAD.*

3.2. R2 Quantra

The Quantra algorithm analyzes each image within a study and produces two volume measurements for each breast:

- Volume of fibroglandular tissue (in cubic centimeters)

- Volume of the breast (in cubic centimeters)

It then divides the volumes to produce:

- Percentage of fibroglandular tissue (the ratio of the values above)

Studies have shown breast density to be a strong predictor of the risk of breast cancer. However, until now quantification of the amount of parenchymal tissue has traditionally relied on human perception, which is confounded by factors such as exposure parameters and image processing. Quantra provides numerical estimations of breast tissue volumes that will help researchers better understand the relationship between fibroglandular tissue and risk.

Quantra is an exclusive Hologic feature. Quantra measurements are based on analyses of technical factors of the X-ray imaging chain, which serve as the basis for creating a virtual model of the breast tissue. The software automatically aggregates measured values from each view in a study into a simple, concise assessment for each breast.

For more information on Quantra features, refer to the manual *Understanding R2 Quantra.*

3.3. R2 DigitalNow HD

The R2 DigitalNow HD application processes digitized mammography film images and produces new images for viewing on a diagnostic workstation. DigitalNow HD can adjust the contrast, brightness, and resolution of digitized film images, and produce images that more closely resemble the appearance of mammography images from FFDM systems.

DigitalNow HD is designed to:

- Provide several image-processing options to optimize image contrast
- Provide several value-of-interest look-up tables (VOI LUTs) for convenient selection of image brightness (for workstations compatible with DICOM VOI LUT selection)
- Adjust the original image contrast (window width) and brightness (window center) with a new window width / window center (WW/WC) value pair
- Resize images to a user-specified pixel spacing

DigitalNow HD is intended for use with most digitized film image objects produced by R2 DigitalNow film-scanning systems. As a general case, sites use R2 DigitalNow software to produce digitized images and send them to a Picture Archiving and Communications System (PACS) where they can be archived as a permanent record.

For more information on DigitalNow HD features, refer to the manual *Understanding R2 DigitalNow HD*.

Part 4: System Operation

4.1. General Usage

Once configured, little direct interaction with the R2 Cenova server is necessary. Any interaction with the server is through a web browser and a user-friendly interface.

Please note the following concerning the server's functional design:

- The server accepts the images automatically as they are sent from the FFDM, R2 film-scanner, or archiving device.

- For practical purposes, there is no limit to the number of images that can be processed together in one study.

For ImageChecker CAD and Quantra:

- If there is a processing error, the server typically includes a failure indication in the results sent.

- For studies that include just the four screening views (LCC, RCC, LMLO, and RMLO or their equivalents), you can send images in any order. The server reads the information stored with each image in the DICOM header and processes the image appropriately.

- When a study includes multiple images of any view and laterality (e.g., two RCC views), the server normally performs case processing on the *last* image produced by the FFDM device for each of the four screening views or their equivalents.

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

For more information, refer to *Understanding R2 ImageChecker CAD* and *Understanding R2 Quantra.*

For DigitalNow HD:

- The server attempts to process all R2 DigitalNow images it receives (except DigitalNow ELC™ images, a legacy format no longer supported).

For more information, refer to *Understanding R2 DigitalNow HD.*

4.2. Sending Images to the Server

The R2 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, see the *R2 Cenova Service Manual.*)
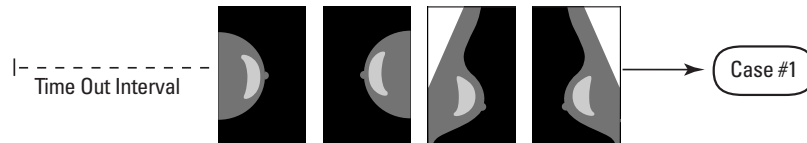
Server Assigns Images Received Before Timeout Elapses to One Case

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.
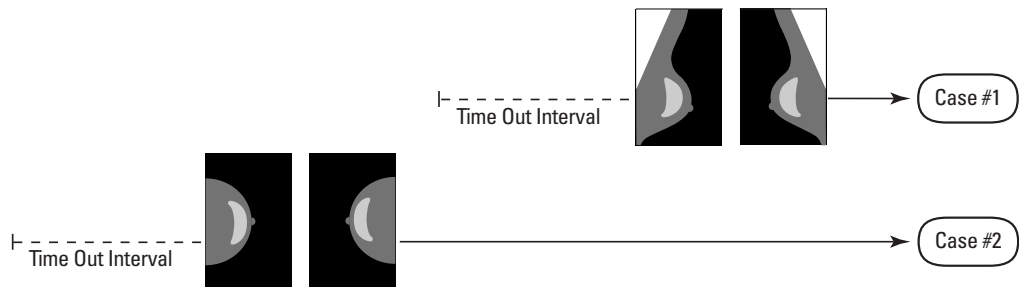
Server Assigns Images Received After Timeout Elapses to a New Case

To reduce the possibility of multiple results, Hologic recommends that images for each patient examination be sent from the acquisition device 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.*

The server can retain images for several thousand cases on its hard drive. (The exact number depends on the number of views collected for each case and the size of the hard drive.) When the hard drive fills up, the server deletes the oldest cases on a first-in, first-out basis.

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. For more about the data flow among the various devices, see '2.2. System Inputs and Outputs'.

4.3. Displaying Results

To view digital mammograms and results from the R2 Cenova server, follow the guidelines of your workstation vendor. A common reading scenario is as follows:

1 At the review workstation, read the original mammogram images using your normal protocol. Make an initial interpretation.

2 Compare the new digital mammography images to any prior digitized film images processed by DigitalNow HD.

3 Review and note the Quantra volumetric findings.

4 Examine the mammogram in detail and form a primary diagnosis.

5 Activate and view the CAD marks and evaluate other data produced by ImageChecker to determine if other areas on the mammogram warrant further review.

6 Make a final assessment and create a report.

4.4. Server Startup and Shutdown

The R2 Cenova server does not require regular maintenance. The only procedures you might need to perform are:

- Starting up the server
- Shutting down the server
- Restarting the server (turning off and on again)

For these procedures, you need to know the IP address for the computer. Ask your IT administrator for the R2 Cenova server IP address. Write that number here:

R2 Cenova Server IP Address: _____

Shutting Down the Server

You might need to shut down the R2 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 (e.g., Internet Explorer).

2 Type the IP address for the server in the address box and press $\boxed{\text{Enter↵}}$. 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   Click 'System Control' to display the following screen:
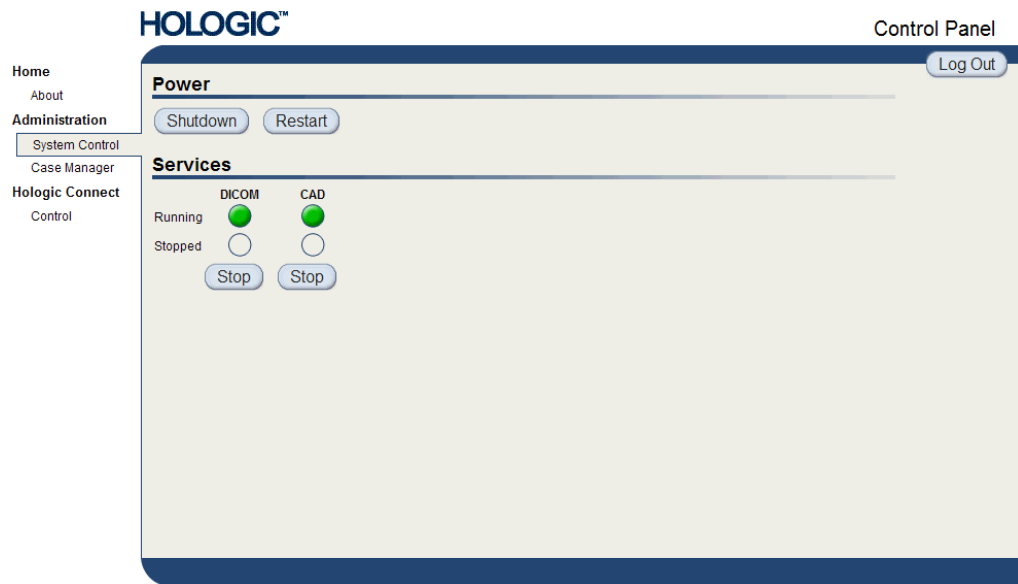
5   Click the Shutdown button. The server prompts 'Are you sure…'. Click the Shutdown button once more to switch the server off.

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 R2 Cenova software starts up automatically, and the server should be ready for use within 3–5 minutes.

Restarting the Server

You might need to restart the R2 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 R2 Cenova server, open a web browser.

2   Type the IP address for the R2 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, click 'System Control'.

5   From the System Control screen, click 'Restart'. The server prompts 'Are you sure…'. Click 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, you will need to refresh the browser by repeating steps 1-3.*

4.5. 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 data such as patient information, date processed, etc.
- Delete cases
- View DICOM information for any image

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. The column titles correspond to image DICOM header fields.

Click **Hide Navigation Panel** to expand the Case Manager viewing window.

▶ **To browse and sort cases:**

You can sort the values in any column by clicking 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. Click the column heading again to sort in descending order.

▶ **To search for data:**

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 values containing the characters you typed.

To remove the filter, click 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, click Clear Filters.

▶ **To delete cases:**

Display the case you want to delete and click the checkbox next to the case:

Then, click Delete.

▶ **To review DICOM information for an image:**

Click ⊞ to expand the case and review the Images and Output Jobs details:

		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	

Click ▭ to view additional details for each image.

Case ID: 26, View: LCC

Case

Case ID	26
Patient Name	10100191
Patient ID	10100191
Study Date	20060508
Algorithm	MAMMO
Case Result	SUCCESS

Image

Image ID	90
View	LCC
View Modifier	
State	PROCESSED
Start Time	1/31/2009 12:45:47 AM
End Time	1/31/2009 12:46:11 AM

AlgoName	Result
Masses	SUCCESS
Calcifications	SUCCESS
Volumetric Assessment	SUCCESS

ImageDetails.aspx?id=90

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