Cenova™

R2 Cenova™ 2.0

User Manual

MAN-01975 Rev 002

HOLOGIC™

The Women's Health Company.

R2 Cenova™ 2.0

User Manual

MAN-01975 Rev 002

HOLOGIC™

The Women's Health Company.

Technical Support

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.

Hologic Inc.
35 Crosby Drive
Bedford, MA 01730-1401 USA
Tel: +1.781.999.7300
Sales: +1.781.999.7453
Fax: +1.781.280.0668

Hologic N.V.
Authorized Representative
Leuvensesteenweg 250A
1800 Vilvoorde, Belgium
Tel: +32.2.711.4680
Fax: +32.2.725.2087

For more information about Hologic products, services, and facilities, visit **www.Hologic.com**.

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

CE

Contents

Part 1: Introduction

1.1. Overview

This manual provides instructions for the operation and maintenance of the R2 Cenova™ 2.0 server in the clinical environment. The server processes Digital Breast Tomosynthesis (DBT) datasets using proprietary software algorithms.

R2 Cenova 2.0 software runs exclusively on the R2 Cenova T-Series server, which is a high-performance computer capable of processing DBT datasets. The server supports the following software application:

- R2 ImageChecker 3D Calc CAD 1.0, computer-aided detection software used to identify and mark clusters of microcalcifications on breast tomosynthesis images.

1.2. Resources Available

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

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

- **Training:** The Hologic Training 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 3D Calc CAD*

  - *R2 Cenova User Manual*

  - *R2 Cenova Release Notes*

  You can obtain additional copies of printed manuals through your Hologic Account Manager.

- **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

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 the limitations of the device.*

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

Before using the R2 Cenova server, read the following warnings and precautions.

System Operation

⚠ **WARNING!** *Observe the following instructions, that if not followed, can result in a hazardous condition:*

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

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

- *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 grounded properly 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.*

⚠ **CAUTION:** *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.*

⚠ **Important:** *Observe the following instructions that are provided to ensure correct results and optimal performance, or to clarify the limitations of the device.*

- *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 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 the user's expense.*

Installation and Maintenance

⚠ **WARNING!** *Observe the following instructions, that if not followed, can result in a hazardous condition:*

- *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.*

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

- *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.*

⚠ **CAUTION:** *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.*

- *Disconnect power cord before moving or servicing.*

- *Install the system behind the institution firewall for network security and antivirus protection. Network security and antivirus provisions are the responsibility of the user. No computer virus protection or network security for the system is provided. If antivirus software is required, visit the Hologic website for information on Hologic's cybersecurity program and validated antivirus products.*

1.4. Product Complaints

Any healthcare professional who has complaints or is dissatisfied with the quality, durability, reliability, safety, effectiveness, and/or performance of this product should notify Hologic.

If there is reason to believe the device caused or contributed to a serious injury of a patient, notify Hologic immediately by telephone, fax, or written correspondence.

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. The following software application is available for use with R2 Cenova 2.0:

- R2 ImageChecker 3D Calc CAD, computer-aided detection software used to identify and mark clusters of microcalcifications on breast tomosynthesis 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 manual, *Understanding R2 ImageChecker 3D Calc CAD.*

Inputs to R2 Cenova

R2 Cenova 2.0 processes breast tomosynthesis datasets originating from the Hologic Selenia Dimensions image acquisition system or sent from a PACS. The software does not process some datasets, depending upon the application and mammography view shown in the image. For each R2 Cenova server, you can purchase one ImageChecker 3D Calc CAD license.

The diagram in section **2.4. Data Flow with ImageChecker 3D Calc CAD** shows that the server processes DICOM *For Processing Projection* images (also known as 'raw' images). The DICOM header for each image includes an identifier that indicates the device from which the image originated.

Results from R2 Cenova

R2 Cenova sends its results to Hologic SecurView workstations in the form of a Hologic Secondary Capture Image with proprietary content.
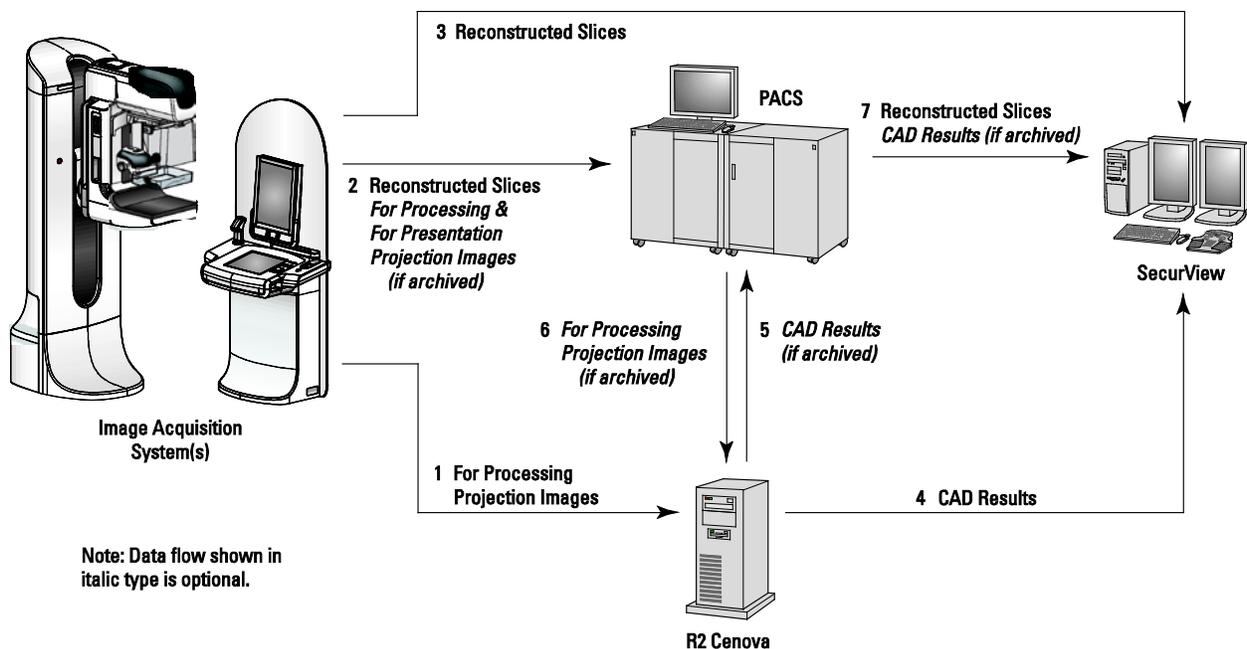
2.3. R2 ImageChecker 3D Calc CAD

The R2 Cenova server configured with ImageChecker 3D Calc CAD software analyzes digital breast tomosynthesis datasets produced by the Selenia Dimensions system. The proprietary ImageChecker 3D Calc CAD algorithm identifies regions of interest that include clusters of bright spots (suggestive of calcification clusters). The server generates results in the form of proprietary Hologic Secondary Capture Image objects that include CAD marks and other data identifying and characterizing the regions of interest. At the review workstation, the results are matched with the tomosynthesis images produced by Selenia Dimensions.

After making an initial interpretation from the original diagnostic-quality images, the radiologist displays the ImageChecker 3D Calc CAD results and chooses whether or not to reinspect the marked regions on the original images. The ImageChecker 3D Calc CAD algorithm marks visually perceptible structures that have some of the generally accepted geometric characteristics of calcifications. The marked areas may be something other than an actual abnormality, which is generally recognized by the radiologist upon a second review of the original images.

For more information on ImageChecker features, refer to the manual *Understanding R2 ImageChecker 3D Calc CAD*.

2.4. Data Flow with ImageChecker 3D Calc CAD

The diagram below shows the flow of images to the server and results from the server.

Data Flow with ImageChecker 3D Calc CAD

Part 3: System Operation

3.1. 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 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 3D Calc CAD:

- 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.

For more information, refer to *Understanding R2 ImageChecker 3D Calc CAD*.

3.2. 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*.)
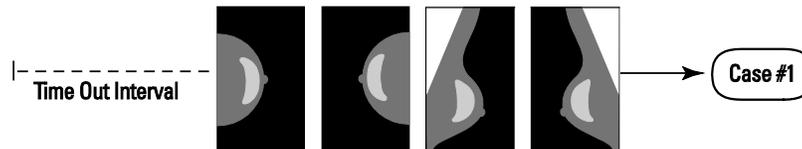
Server Assigns Images Received Before Timeout Elapses to One Case

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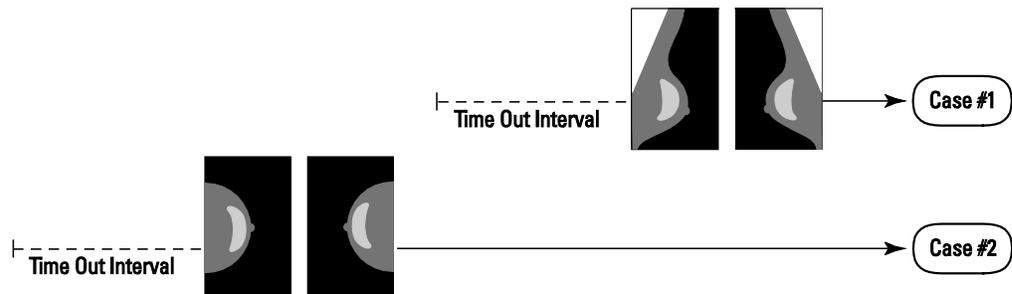
Server Assigns Images Received After Timeout Elapses to a New Case

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**.

3.3. 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 Read the case at the review workstation using your normal protocol. Make an initial interpretation.

2 Examine the images in detail and form a primary diagnosis.

3 Activate and view the CAD marks. Evaluate the ImageChecker data to determine whether other regions warrant further review.

4 Make a final assessment and create a report.

3.4. 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 [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:
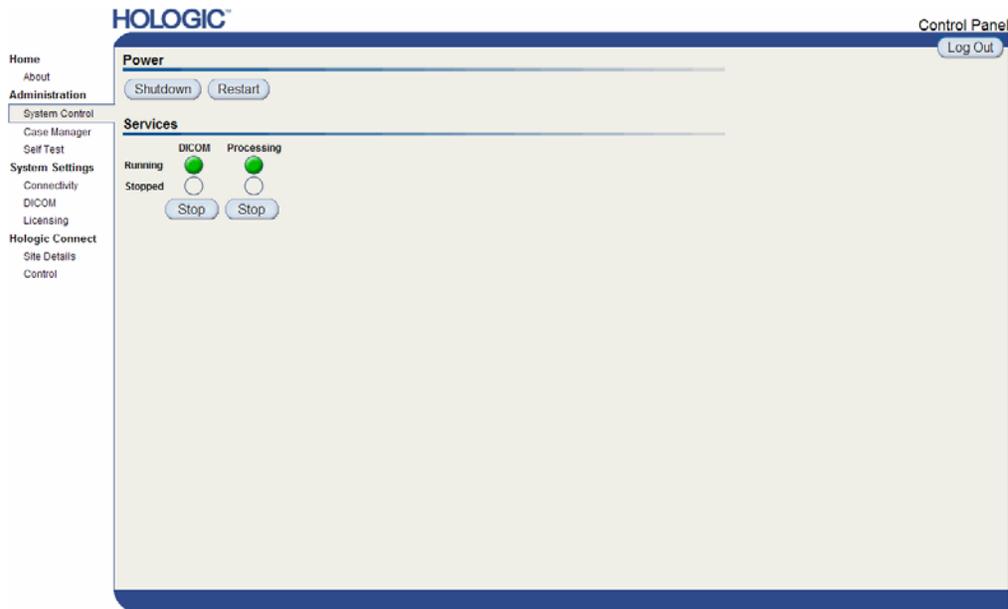
5 Click the Shutdown button. The server prompts 'Are you sure…'. Click the Shutdown button once more to switch the server off.

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.*

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 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:**

Click on the case you want to delete and then click Delete.

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

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

| | 87800002 | | 87800002 | | 64001 | | PROCESSED |

Images:4

	Image ID	View	View Modifier	Case Processing	State	
	150	LCC		✓	PROCESSED	
	151	RCC		✓	PROCESSED	
	152	LMLO		✓	PROCESSED	
	153	RMLO		✓	PROCESSED	

Output Jobs:3

Job ID	Format	Destination	Status	
4	SC - VA	sqa122	Complete	
5	SC - CAD	sqa122	Complete	
6	9.4 SR - CAD+VA	sqa122	Complete	

Click 🗂 to view additional details for each image.

Case ID: 3, View: RCC

Case

Case ID	3
Patient Name	R2SelfTest
Patient ID	R2SelfTest
Study Date	20040818
Algorithm	MAMMO
Case Result	SUCCESS

Image

Image ID	3
View	RCC
View Modifier	
State	PROCESSED
Start Time	8/31/2010 10:43:19 AM
End Time	8/31/2010 10:43:29 AM

AlgoName	Result
Masses	NOT_RUN
Calcifications	NOT_RUN
Volumetric Assessment	NOT_RUN
Breast Arterial Calcium	SUCCESS

Index

C
Case Manager, 12–14
customer support resources, 2

D
DICOM, 5
   header, 7
digital ports. *See* ports, input

F
FFDM systems, 5
   sending images from, 7

I
images
   maximum in study, 7
   specifications, 5

P
PACS devices, 5
ports, input, 5
precautions, 3–4
product complaints, 4

R
R2 Cenova server
   configuration, 8
   restarting, 11
   shutdown, 10–11
   startup, 11
   system operation, 7–14
   usage guidelines, 7
   warnings and precautions, 3–4
R2 ImageChecker 3D Calc CAD,
   1, 5, 6
resources, 2
restarting the server, 11
results
   displaying, 9
   formats, 5
review workstation, 8

S
screening views, 7
SecurView diagnostic review
   workstation, 5
Selenia Dimensions system, 5, 6
shutting down the server, 10–11
starting up the server, 11
support, technical, ii

T
training, 2

V
views, order of, 7

W
warnings, 3–4

HOLOGIC™

The Women's Health Company.