Change of the Authorized Representative

This document updates your product manuals to change the address of the European Commission Authorized Representative (EC Rep). This change is effective on the first day of November 2015. The new address is:

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Place this document with your product manuals for future reference.

MultiCare® PLATINUM

Stereotactic Breast Biopsy System

User Guide

MAN-02580 Revision 005

HOLOGIC®

MultiCare® PLATINUM

Stereotactic Breast Biopsy System

User Guide

for Software Version DSM 3.4

Part Number MAN-02580

Revision 005

April 2015

Technical Support

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HOLOGIC®

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Chapter 1: Introduction

1.1 Intended Use

℞ONLY United States federal law restricts this device to use by, or on the order of, a physician.

The MultiCare® Platinum device combines the function of a standard x-ray mammography unit with that of a stereotactic lesion localization system to produce a device that has specific application in first localizing, and then giving a physician the capacity of performing Fine Needle Aspiration or core biopsy of lesions determined to be suspicious through prior mammographic examination.

1.2 Intended Use for the User Guide

Always refer to the User Guide for instructions on using the system.

1.3 Product Complaints

Report any complaints or problem in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic. (See the title page for contact information.)

1.4 Technical Support

Refer to the title page of this manual for contact information for product support.

1.5 Hologic Cybersecurity Statement

Hologic continuously tests the current state of computer and network security to examine possible security problems. When necessary, Hologic provides the updates to the product.

For Cybersecurity Best Practices documents for Hologic products, refer to the Hologic Internet site.

1.6 Quality Control

Do all Quality Control tests at the necessary intervals.

1.7 Installation Instructions

Installation instructions are available in the Service Manual.

1.8 User Profiles

1.8.1 Mammography Technologist

- Meets all requirements that apply to the location in which the Mammography Technologist operates.
- Completed training on the mammography system.
- Has training in mammography positions.
- Knows about Stereotactic breast biopsy procedures.
- Knows how to operate a computer and its peripherals.
- Can lift 20 pounds to shoulder height with two hands (necessary for upright stereotactic systems).
- Understands sterile procedures.

1.8.2 Radiologists, Surgeons

- Meets all requirements that apply to the location in which the Physician operates.
- Knows about Stereotactic breast biopsy procedures.
- Knows how to operate a computer and its peripherals.
- Understands sterile procedures.
- Gives local anesthesia.
- Knows about basic surgical procedures for core biopsy.

1.8.3 Medical Physicist

- Meets all requirements that apply to the location in which the Medical Physicist operates.
- Knows about mammography.
- Has experience with digital imaging.
- Knows how to operate a computer and its peripherals.

1.9 Skills Needed for System Use

Users must have experience in the principles of mammography before following the instructions contained in this manual. Users must understand the operation of the MultiCare system. Users must understand how to use a personal computer system, use internal and external storage media (DVDs, CDs, USB devices), and use the external computer peripherals (keyboard, trackball, printers).

1.10 Training Requirements

In the United States, users must be Registered Radiologic Technologists meeting criteria to perform mammography. The mammography users must meet all applicable MQSA personnel requirements under FDA guidelines for conventional and digital mammography.

The user has options available for training, which include but are not limited to:

- Onsite applications training by a Hologic Clinical Services Specialist
- Onsite on the job training also known as peer training

Additionally, the user manual is a guide for directions on how to use the system.

All users must make sure that they receive training on correct operation of the system before use on patients.

Hologic does not accept the responsibility for injury or damage from wrong system operation.

1.11 Terms and Definitions

ACR	American College of Radiology
AEC	Automatic Exposure Control
CCD	Charge Coupled Device
DICOM	Digital Imaging and Communications in Medicine. An industry standard specification for communication between medical imaging equipment.
DSM™	Digital Spot Mammography
EMC	Electromagnetic Compatibility
Image Acquisition Modes	The pixel configurations to acquire and display the images 512x512—Provides the best imaging of low density lesions that require contrast resolution. 1024x1024—The application for microcalcifications in dense tissue that require excellent spatial resolution.
MQSA	Mammography Quality Standards Act
RF	Radio Frequency
ROI	Region of Interest.
Stereo Pair	The stereotactic image pair acquired from the ±15° projections.
Stroke	Excursion of needle when the biopsy instrument is fired. The Stroke is entered into the system and depends on the instrument used. Each instrument has a specified stroke.
Stroke Margin	The safety margin (in mm) which remains between the fired needle position and the breast platform. This margin is calculated by the system according to the "Z" coordinate, the Stroke, and the compression amount.
X-axis	Refers to the horizontal plane across the biopsy window. When the Needle Guidance Stage moves left of the reference point, the movement in the X direction is negative. When the stage moves right of the reference point (from the point of view of the patient), the movement is positive.
Y-axis	Refers to the vertical plane directly above the biopsy window. When the Needle Guidance Stage moves away the reference hole (from the point of view of the chest wall edge of the biopsy paddle), the Y direction movement increases in value. When the Stage moves toward the reference hole, Y decreases in value.
Z-axis	Refers to the depth through the biopsy window. The value of Z increases as the Stage moves toward the breast platform, and decreases as the stage moves away from the platform.

1.12 International Symbols

This section describes the International Symbols on this system.

	Type B Applied Part
	Potential Equalization terminal
	Protective Earth terminal
	"OFF" (power)
	"ON" (power)
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Manufacturer
	Date of Manufacture
	Caution—Radiation

1.13 Warnings, Cautions, and Notes

Descriptions of Warnings, Cautions, and Notes used in this manual:

WARNING!

The procedures that you must follow accurately to prevent possible dangerous or fatal injury.

Warning:

The procedures that you must follow accurately to prevent injury.

Caution:

The procedures that you must follow accurately to prevent the damage to equipment, loss of data, or damage to files in software applications.

Note

Notes show additional information.

Chapter 2: General Information

2.1 Warnings and Precautions

Read and understand this manual before you use the system. *Always* follow all the instructions in this manual.

This system is classified as CLASS I, TYPE B APPLIED PART, IPX0, permanently connected equipment, continuous operation with short term loading per IEC 60601-1. There are no special provisions to protect the system from flammable anesthetics or ingress of liquids.

WARNING!

Risk of electric shock. Only connect this equipment to supply mains with Protective Earth.

WARNING!

Only trained Service Engineers authorized through Hologic can open any of the panels. This system contains lethal voltages.

WARNING!

Electrical equipment used near flammable anesthetics can cause an explosion.

WARNING!

After power failure, remove the patient from the system before you apply power.

Warning:

Control the access to the equipment according to local regulations for radiation protection.

Warning:

This system can be dangerous to the patient and the user. Always follow the safety precautions for x-ray exposures.

Warning:

Keep your full body behind the radiation shield during the exposure.

Warning:	**This device contains dangerous material. Send decommissioned material to Hologic or contact your service representative.**
Warning:	**The user or a servicing engineer must correct problems before the system is used.**
Warning:	**The user must prepare for preventive maintenance by an approved servicing engineer.**
Warning:	**Only qualified users can use this system.**
Warning:	**The equipment has motors. You must be careful when you adjust the equipment for patient use. Observe equipment and patient at all times during setup. If a chair is necessary, use an adjustable chair set above its minimum height.**
Warning:	**Keep the hands of the patient away from all buttons and switches at all times.**
Warning:	**Do not leave the patient during the procedure.**
Warning:	**To prevent C-arm movement during procedures, turn the Keyswitch to the LOCKOUT position after compression is applied.**
Warning:	**Protect the control panel so that any fluids cannot enter the panel. Clear Plastic Banded Bag (P/N 2-700-0072) is available from Hologic.**

Caution:

The system is a medical device and not a normal computer. Only make approved changes to the hardware or software. Install this device behind a firewall for network security. The computer virus protection or network security for this medical device is not supplied (for example, a computer firewall). The network security and anti-virus provisions are the responsibility of the user.

Caution:

To prevent system damage, keep all air vents clear.

Caution:

Only persons authorized by Hologic to service the equipment are permitted to remove covers or perform service procedures.

Caution:

To prevent errors and possible data loss, only use approved accessories with this equipment.

Caution:

To prevent damage or mis-alignment of the Needle Guidance Stage, do not strike or mechanically shock the C-arm assembly.

2.2 Emergency Stop Switches

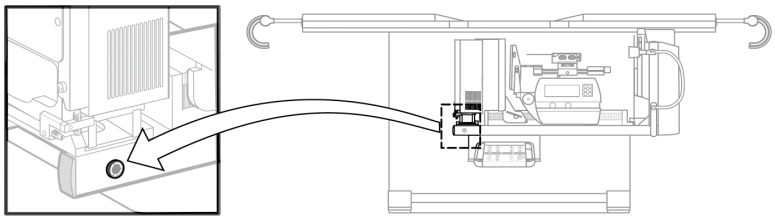


Figure 1: Emergency Stop Switches

A red Emergency Stop switch on each side of the tube arm disables vertical C-arm and Table movement. Compression continues to function. Turn the switch to reset. When the switch is reset, the C-arm and Table movement functions return.

2.3 Interlocks

Electric C-arm locks only allow C-arm movement when the C-arm Release button is depressed.

The system does not enter Ready state following an exposure until you release the x-ray button.

The system does not allow the x ray unless in a Ready state. Ready state is qualified by the DSM Ready signal from the DSM sub-system.

The system incorporates a relay circuit to automatically remove current from the rotor after 16 ±2 seconds following the start of an exposure.

2.4 Compliance

2.4.1 Compliance Requirements

The manufacturer has the responsibility for the safety, reliability, and performance of this equipment with the following provisions:

- The electrical installation of the room meets all requirements.
- The equipment is used according to Instructions for Use.
- The assembly operations, extensions, adjustments, changes, or repairs are performed only by authorized persons.
- The network and communication equipment must be installed to meet IEC Standards. The complete system (network and communications equipment and MultiCare Platinum System) must be in compliance with IEC 60601-1 and IEC 60601-1-1.

Caution: **Medical Electrical Equipment needs special precautions about EMC and must be installed, put into service and used according to the EMC information provided.**

Caution: **Portable and mobile RF communications can affect medical electrical equipment.**

Caution: **The use of unauthorized accessories and cables can result in increased emissions or decreased immunity. To keep the isolation quality for the system, attach only approved Hologic accessories or options to the system.**

Caution: **Changes or modifications not expressly approved by Hologic could void your authority to operate the equipment.**

Caution: **The Medical Electrical (ME) Equipment or ME System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, make sure that the ME Equipment or ME System operates correctly in this configuration.**

2.4.2 Compliance Statements

The manufacturer states that this device is manufactured/conforms to:

- CAN/CSA: ISO 13485:2003 / ISO 13485:2003
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1:1988 +A1+A2:1995 Medical Electrical Equipment - General requirements for safety
- IEC 60601-1-1:1998 Medical Electrical Equipment - Collateral standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2001 Medical Electrical Equipment - Collateral Standard: Electromagnetic Compatibility for Medical Electric Systems
- IEC 60601-1-3:1994 Medical Electrical Equipment - Collateral Standard: Requirements for Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-4:1996 +A1:1999 Medical Electrical Equipment - Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-2-28: 1993 Medical Electrical Equipment – Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis
- IEC 60601-2-32:1994 Medical Electrical Equipment - Particular Requirements for the Safety of Associated Equipment of X-ray Equipment
- IEC 60601-2-45:2001 Medical Electrical Equipment – Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices
- IEC 62 304: Medical Device Software—Software life cycle
- UL 60601: 2003 Medical Electrical Equipment, Part 1 – General Requirements for Safety
- CSA: Medical Electrical Equipment Part 1: CAN/CSA C22.2 No. 601.1-M90— General Requirements for Safety, 2003

The MultiCare Platinum system conforms to all applicable FDA regulations. Compliance Labels are affixed to the unit at several points (see the *figure Label Locations* on page 13).

2.4.3 Label Locations

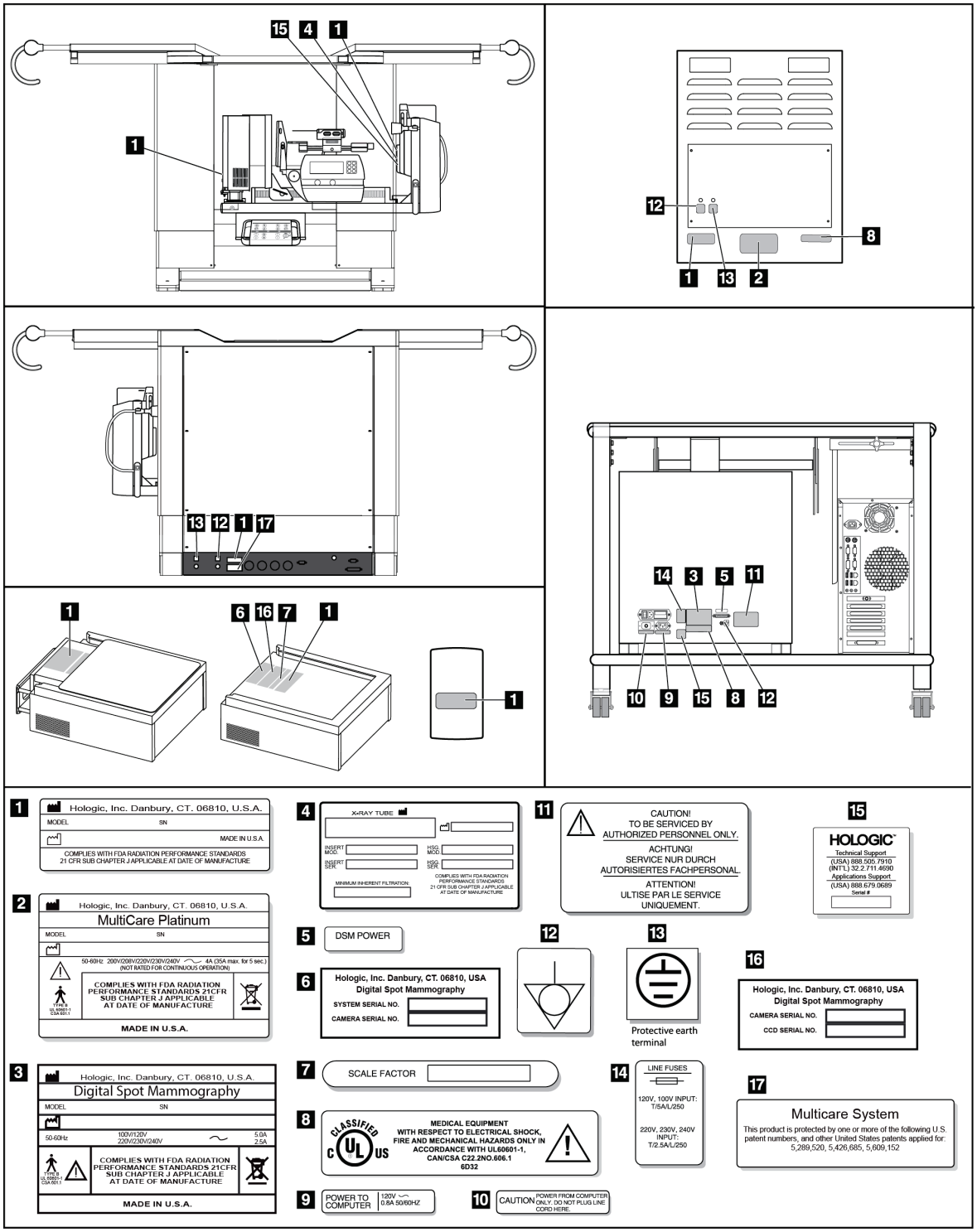


Figure 2: Label Locations

Chapter 3: Components and Controls

3.1 System Description

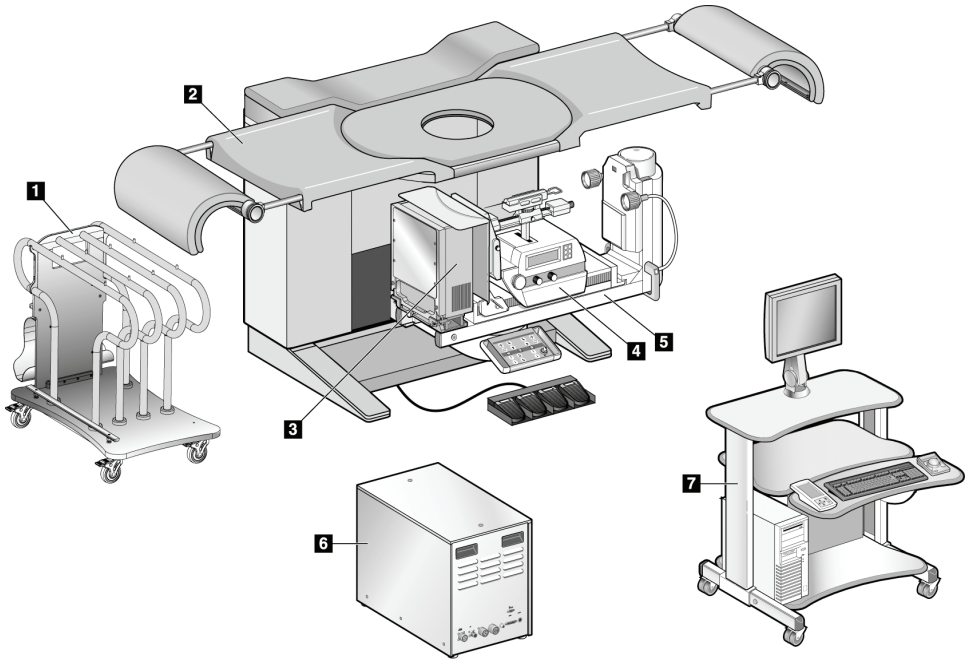


Figure 3: The MultiCare Platinum System

Figure Legend

1. Maximum Comfort Package Accessory Cart
2. Table
3. DSM Image Receptor
4. Needle Guidance Stage
5. C-arm
6. Generator
7. DSM Cart

3.2 System Controls

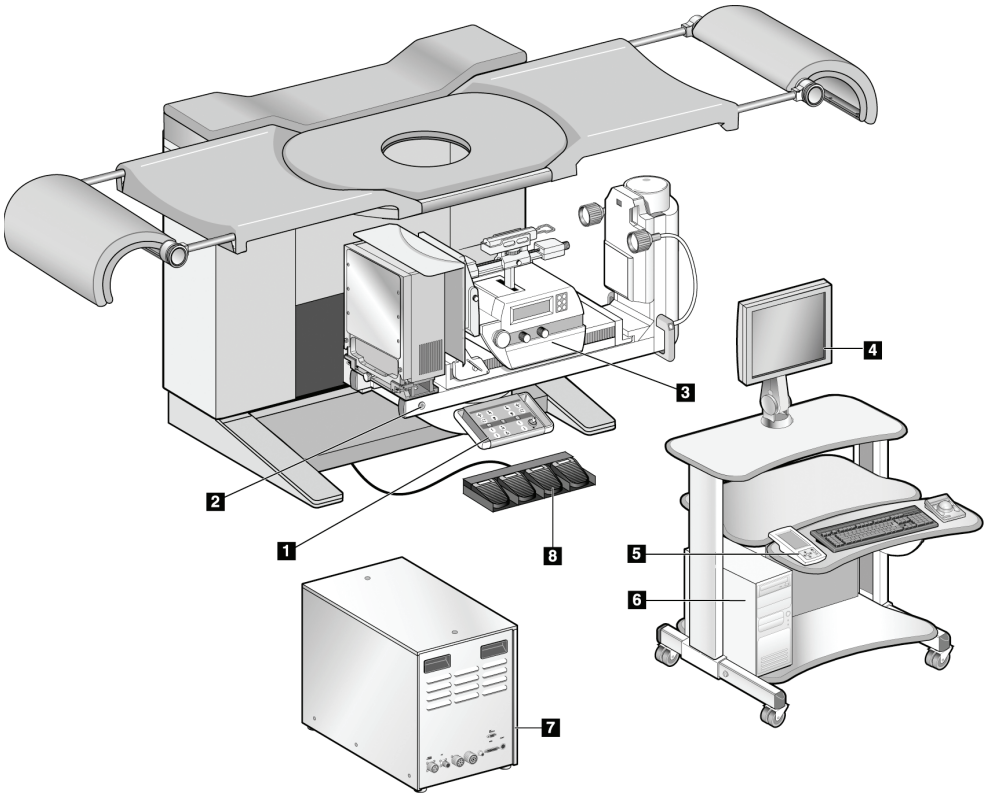


Figure 4: The System Controls

Figure Legend

1. Table Controls
2. Emergency Stop Switch
3. Stage Controls
4. DSM Display Controls
5. Handheld Console Controls
6. DSM Computer Controls
7. Generator
8. Footswitches

3.3 Table Controls

3.3.1 Table Control Panel

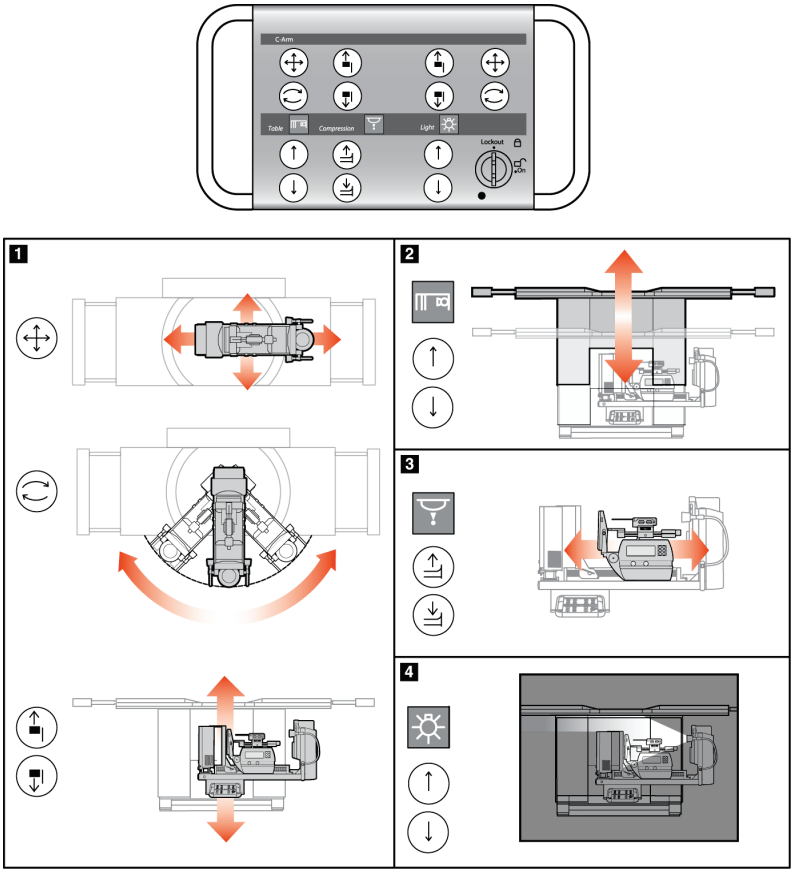


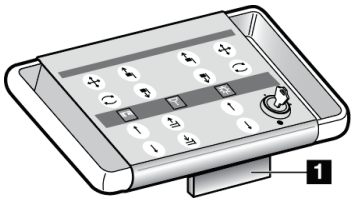
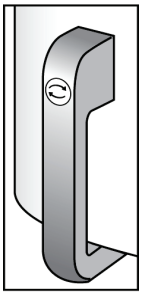
Figure 5: Table Control Functions

Figure Legend

1. C-arm Controls
2. Table Controls
3. Compression Control
4. Lamp Controls

A key-operated, two-position switch with an illuminated indicator prevents accidental control actuation during a clinical procedure. When the Keyswitch is On, all Control Panel operations function. When the Keyswitch is moved to the Lockout position, the red LED turns off and only the Light Up/Down control functions.	 *Figure 6: Safety Lockout Keyswitch*

Warning: **To prevent C-arm movement during procedures, turn the Keyswitch to the LOCKOUT position after compression is applied.**

A Panel release handle (item 1) permits the panel to rotate into one of five positions.	 *Figure 7: Release Handle*
The handle of the C-arm also has a rotation button. When a rotation button is pressed, the tube arm and compression arm move together. When the button is released, they move separately, but only to the +15° and -15° positions.	 *Figure 8: Rotation Button on C-arm*

3.3.2 Footswitches

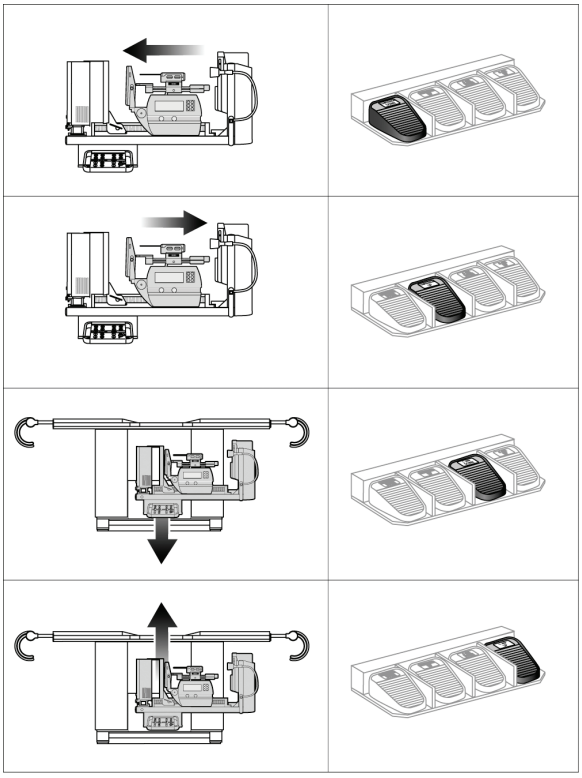


Figure 9: Footswitch Functions

3.3.3 Manual Compression Knob

After you use the footswitch or table panel for motorized pre-compression, use the manual compression knob (see the *figure Stage Controls and Indicators* on page 21, item 6) for final compression.

3.3.4 Breast Platform

The compression thickness determines the Breast Platform position. The release lever is on the side of the platform.
Move the platform to the position indicated by the compression thickness in the table below. You may have to release the patient and change the setting.
This information is recorded. The proper setting is indicated on the Patient Annotation screen, but it can be overridden. If you do not follow the recommended setting and change the setting on the annotation box, the field is labeled as an override.

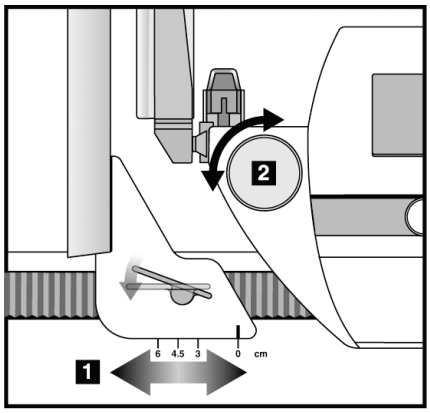


Figure 10: Breast Platform Position

Table 1: Breast Platform Positions

Compression Thickness	Platform Position
Service only	0
< 4.0 cm	3
4.0 to 5.5 cm	4.5
> 5.5 cm	6

3.3.5 Table Levelers

The table has four levelers to make the table level. If the C-arm "self-shifts" when the C-arm is moved, the table must be made level. Contact Technical Support.

Note If the system is moved, make sure to contact Technical Support to inspect and make the table level if necessary.

3.3.6 Emergency Stop Switches

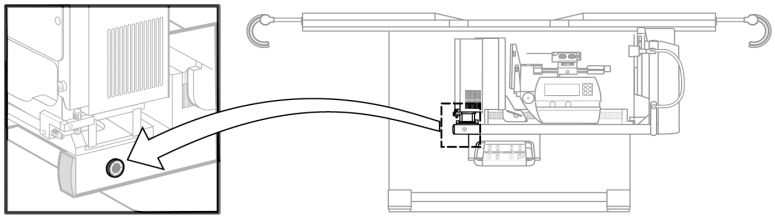


Figure 11: Emergency Stop Switches

A red Emergency Stop switch on each side of the tube arm disables vertical C-arm and Table movement. Compression continues to function. Turn the switch to reset. When the switch is reset, the C-arm and Table movement functions return.

3.4 Stage Assembly Controls and Indicators

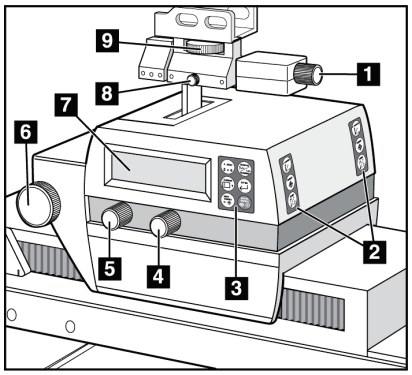


Figure 12: Stage Controls and Indicators

Figure Legend

1. Manual Z-axis Control
2. Motor Control Pad
3. Needle Guidance Control Pad
4. Manual X-axis Control
5. Manual Y-axis Control
6. Manual Compression Knob
7. SmartWindow Display
8. Z-axis Lock
9. Needle Mount/Thumbwheel

3.4.1 Manual Axis Controls

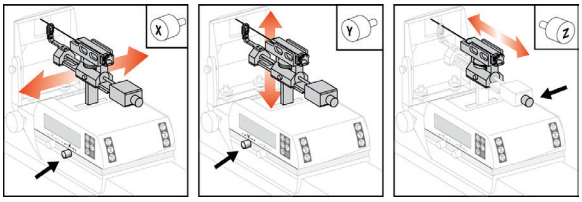


Figure 13: Function of Each Manual Axis Control

Drive motors move the Stage in the X and Y directions. To move the stage manually, you can rotate the X and the Y knobs on either side of the Stage assembly. To move the Stage in the Z direction, rotate the Z knob.

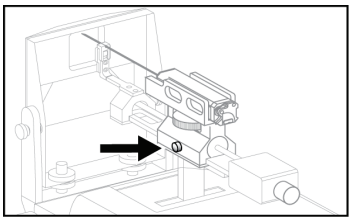


Figure 14: The Z-axis Lock

The Z-axis Lock locks the position of the Z-axis.

3.4.2 Needle Guidance Control Pad

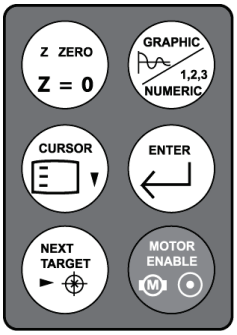


Figure 15: Needle Guidance Control Pad

These buttons are next to the SmartWindow. The buttons are used to work in the SmartWindow and to activate the buttons on the Motor Control Pad. For the functions of these buttons, see *SmartWindow Stage Display* on page 37 .

Note

All MCP Stage buttons except for Motor Enable are press and release to activate. The user must press and then release the button for its function to be activated.

3.4.3 Motor Control Pad

For location of these buttons, see the *figure Stage Controls and Indicators* on page 21.

Table 2: Buttons on Motor Control Pad

Control	Action
Z POSITION	Moves the stage to the top of the window to make it easy to Z Zero the needle The X-axis moves to 0.0 mm, and the Y-axis moves to +4.0 mm.
TARGET	Moves the stage to the selected X and Y coordinates.
HOME	Moves the stage from the X-ray beam path to the lowest position. Used for scout images.

Note

These buttons require that you press and hold the MOTOR ENABLE button on the Needle Guidance Control Pad. See the previous figure.

3.5 Handheld Console Controls and Indicators

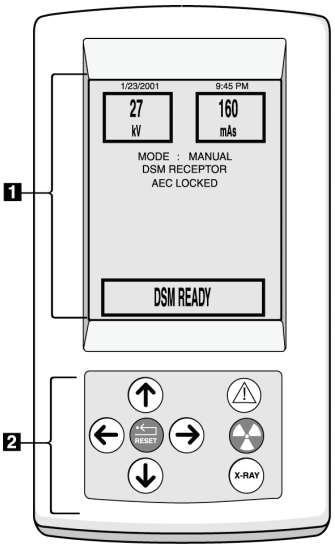


Figure 16: The Handheld Console Front Panel

Figure Legend

1. Display screen
2. Function Control Pad

When the generator has power, the Handheld Console display is On.

For the description of the function of the Handheld Console, see *How to Use the Handheld Console* on page 33.

3.6 DSM Cart Components

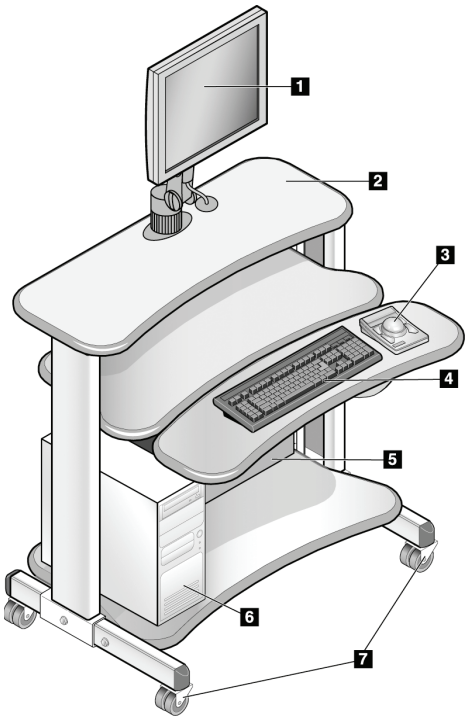


Figure 17: DSM Cart

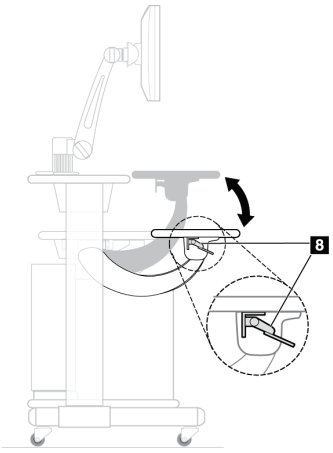


Figure 18: DSM Side View (Shelf release)

Figure Legend

1. Display
2. Cart
3. Trackball
4. Keyboard
5. Power Supply (the power On/Off switch is at the rear of power supply—not shown)
6. Computer
7. Front Casters that Lock
8. Shelf Release Mechanism

3.6.1 DSM Display (Totoku)

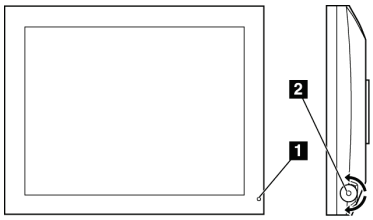


Figure 19: DSM Display Control and Indicator

Figure Legend

1. LED

- Green = Power On
- Amber = Power Save Mode

2. Control Dial

- Press for approximately one second for Power On or Power Off.

3.6.2 DSM Display (Barco)

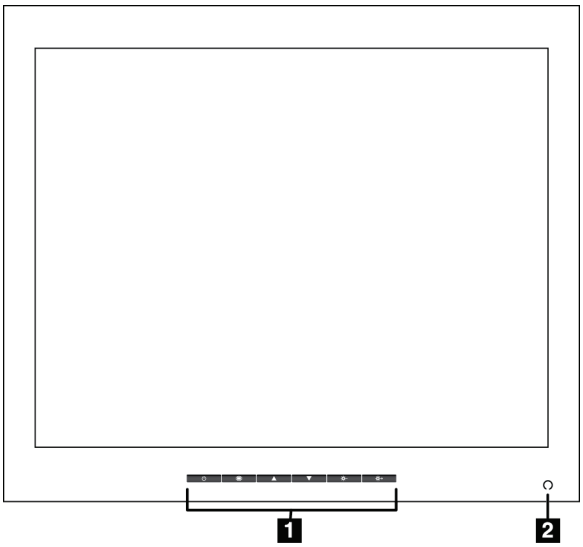


Figure 20: DSM Barco Display Control and Indicator

Figure Legend

1. Front panel push-buttons
Refer to the following note
2. LED

- Green = Power On
- Blinking Green = Power Save Mode

Note The front panel push-buttons are factory locked to avoid unintentional adjustment.

Note There is a main power "rocker" type switch located on the back of the display near the 120VAC power inlet.

3.6.3 DSM Computer

Note The computer operating system only reads the DVD or CD disks in the MS-DOS® or Windows format.

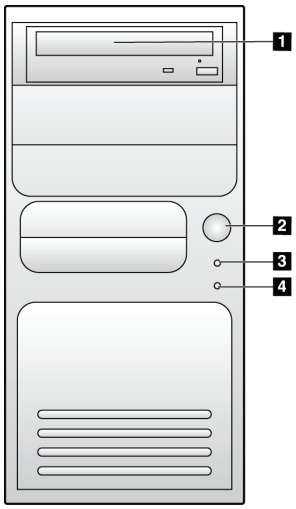


Figure 21: DSM Computer Controls and Indicators

Figure Legend

1. DVD/CD Drive	Opens the drive tray.
2. Power Switch	Turns on the DSM System.
3. Power Indicator	Illuminates a green color when the computer is On.
4. HDD Indicator	Illuminates when the disk is active.

3.6.4 DSM Trackball

The DSM Trackball is used to move the cursor, make selections, and adjust the brightness and contrast for Window/Level adjustments.

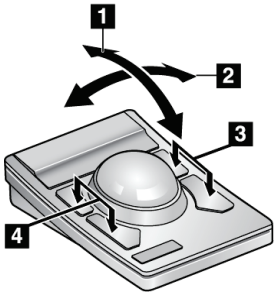


Figure 22: Trackball Use in Window/Level

Figure Legend

1. Contrast
2. Brightness
3. Original Image
4. Save and Close Dialog Box

3.6.5 Special Function Keys

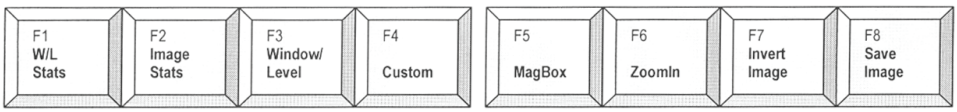


Figure 23: Function Keys on DSM Keyboard

The DSM program uses the function keys and key stroke combinations to perform some special functions. Move the cursor over the image and press the indicated function key on the keyboard. During Targeting only the F4, F5, and F6 function keys are active.

Table 3: DSM Keyboard

Key	Function
F1 key Window/Level Statistics	During Window/Level operations, shows detailed statistics. Toggles the statistics on/off.
F2 key Image Statistics	Displays the Image Statistics dialog box. Image Statistics operates on both images at the same time. • Move the cursor over important features like the Reference Hole. • Right-click to change the size of the cursor box. • Click to close the Image Statistics dialog box.
F3 key Window/Level	Displays the Window/Level. • Move the cursor into the image to modify. • Press **F3**. • Use the trackball and keyboard to make adjustments. Refer to *The DSM Window/Level Histogram* on page 56 for more information.
F4 key Custom	Displays the Custom dialog box to enhance the image. • Move the cursor into the image to be modified. • Press **F4**. • Click Save or the [x] box in the upper right corner of the dialog box to close without saving.
F5 key MagBox	Displays a Magnification Box. • Move the cursor into the image to be modified. • Press **F5**. • Use the trackball to move the MagBox. • Right click to change the MagBox size. • Click or Press **F5** again to paste the MagBox on the image. The largest MagBox size is selected by default. • Press again to close.

Table 3: DSM Keyboard

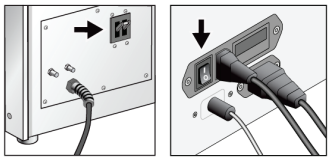
Key	Function
F6 key Zoom-In	Displays the image in ZoomIn mode. • Move the cursor into the image to be modified. • Press **F6**. • Press again to exit.
F7 key Invert	Inverts the image. • Move the cursor into the image to be modified. • Press **F7**.
F8 key Save Image	Saves Image with the Window/Level, Inversion and Filtering enhancements. • Move the cursor into the image to be modified. • Press **F8**.
Page Up/Page Down keys	Press to scroll through case studies.
Alternate (Alt) Key	• Press **Alt+M** to change the DSM main menu between display types (icons or buttons with labels). • Press **Alt+C** to change how the information appears in the annotation area (five shades of background colors).
Space Bar	• In the target window, press to change the target symbol. • In the Window/Level histogram, press to invert and revert the image.
+/- on the numeric keypad	Press to change the brightness in the Mag box.
Insert/Delete keys	Press to set the Locus Line on and off.
Esc key	Press to abort targeting.
Arrow keys	• Press to make fine Window/Level and target position adjustments. • Use with Ctrl keys to move a set distance when you are positioning a target.

3.7 Startup Procedure

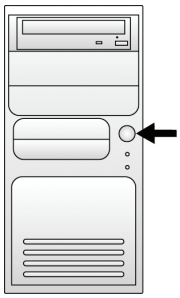
Note After startup, complete the Quality Assurance Tests in *Quality Assurance* on page 75.

Note The digital receptor requires 10 minutes to reach the operating temperature. During this period, x rays are not permitted.

Make sure the Generator circuit breaker and DSM Power Supply circuit breaker, on the back of each component, are On.



Turn on the DSM computer and the display. The main menu appears on the DSM monitor, the Handheld Console is illuminated, and the system is active.
If the Digital Stereo Aperture is not installed, insert it into the tubehead slot.



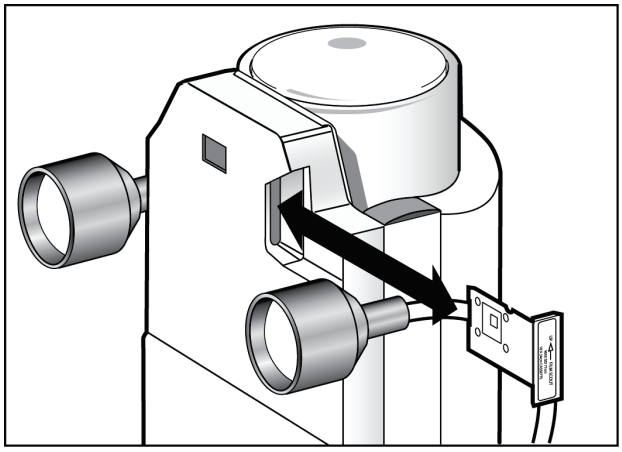


Figure 24: Insert the Digital Stereo Aperture

3.7.1 The Worklist

If a DICOM Modality Worklist is configured, a Modality Worklist request is sent automatically for patient information for the scheduled breast biopsy procedures for the day. The worklist is available on the DSM display from the Patient Annotation dialog box.

3.7.2 Multiple White Fields

When two or more Host systems share the DSM, the DSM uses the Multiple White Field data (provided at installation) to make sure the image quality is uniform for each Host system.
If the system detects Multiple White Field data, select a Host from the dialog box and click the OK button.

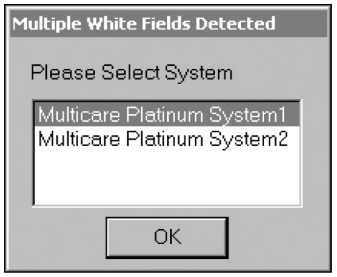


Figure 25: Multiple White Field Dialog Box

3.7.3 Host Verification Procedures

If the Receptor data line on the Handheld console does not read DSM, select the User Defaults screen and make the correction.

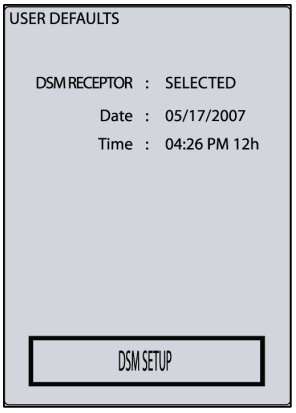


Figure 26: User Defaults screen

3.7.4 User Calibration and Verification

Always do the QAS Needle Test each day before clinical use.

Warning: **The user must prepare for preventive maintenance by an approved servicing engineer.**

Warning: **The user or a servicing engineer must correct problems before the system is used.**

3.8 Shutdown Procedure

Note To prevent software problems and possible loss of data, always use this procedure to shut down the system.

1. If your system is not configured to Auto Archive to PACS, make sure that a DVD/CD disk is in the DVD/CD disk drive. Perform the File Manager functions as necessary.
2. Click **Exit Program** on the DSM main menu. Click the **OK** button in the Exit Program dialog box.

   If the system detects new case studies on the hard disk drive, the DSM automatically performs Auto-Archive then shuts down.

Chapter 4: Introduction to System Interfaces

4.1 How to Use the Handheld Console

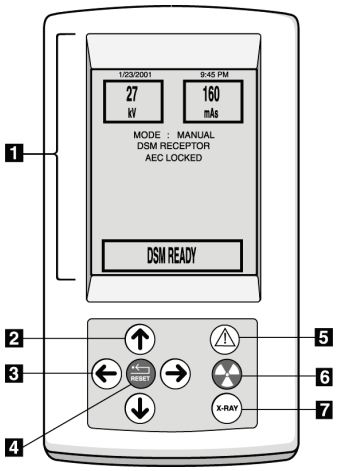


Figure Legend

1. Display screen
2. Scroll Buttons
3. Change Button
4. RESET Button
5. Function Button
6. Exposure Indicator
7. X-RAY Exposure Button

Figure 27: The Handheld Console Front Panel

Table 4: Handheld Console Icons

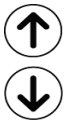
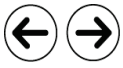
Item		Description
1. Display Screen		Shows the system status, alert messages, and system settings. Display is illuminated when generator has power.
2. Scroll		Up-and-down arrow buttons: • Move the highlight through the data fields. • Increase or decrease the values • Adjust the display contrast (with the Reset button).
3. Change		Left and right arrow buttons: • Increase or decrease the values, or set the options On or Off. • Cycle through the available selections.
4. RESET		• Adjust the display contrast (used with the Scroll buttons) • Access the User Default mode and Exposure Default mode (with the Change buttons) • Clears an alert message.

Table 4: Handheld Console Icons

Item		Description
5. Function		Service Mode Only.
6. Exposure Indicator		Illuminated when the system creates the x rays.
7. X-RAY Exposure		Begin the exposure.

4.2 Handheld Console Screens

The Status area displays the state of operation of the MultiCare, for example, DSM READY.

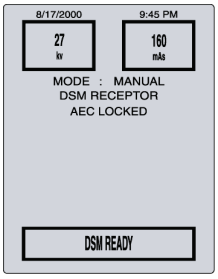
Note You must correct all alert conditions before the message clears with the RESET button.

4.2.1 Run Screen

The Run Mode screen displays after startup.

This interface indicates the system is ready for use and controls the exposure during clinical procedures.

Table 5: Run Mode Screen Options

Run Mode Screen	Field	Description
 *Figure 28: Run Mode Screen*	kV	Shows selected kV.
	mAs	Shows selected mAs in Manual mode or post mAs in Auto-Time.
	MODE	Manual = Select kV and mAs. Auto-Time = Select kV.
	DSM RECEPTOR	Only appears when Selected, which is the default value for normal operation.
	AEC LOCKED	Only appears when Locked. Uses the Scout AEC techniques for Stereo Acquisition in Auto-Time Mode.

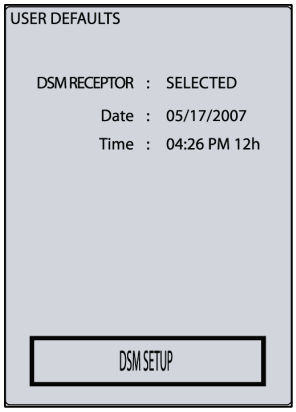
To select or change values, use the **Scroll** buttons (up-and-down arrows) to select the item, then use the **Change** buttons to change the value.

4.2.2 User Defaults Screen

Note You must select the DSM Receptor to enable the communication and control by the DSM. If you do not select the DSM Receptor, the Generator reaches Ready Status independently of the DSM. X rays can be generated, but for only calibration and test purposes.

To access the User Defaults screen or Exposure Defaults screen, hold the **RESET** button and press a **Change** button. Use this method to scroll forward and backward through the three screens.

Table 6: User Defaults Screen Options

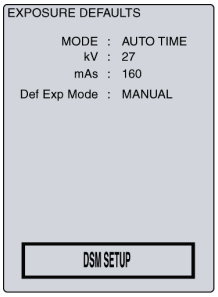
Set DSM and Date/Time	Field	Description
 *Figure 29: User Defaults Screen*	DSM RECEPTOR	SELECTED = Standard operation.
		NOT SELECTED = Make x rays for calibration and test purposes without the DSM. Note: When this is chosen, DSM no longer appears in the status window of the screen.
	Date	Sets the system date. Move through the Date and Time field numbers with the **Change** buttons and use the **Scroll** buttons to change the value. Select the placeholder between fields (forward slash or a dot) and press a **Scroll** button to change between US and International date formats.
	Time	Sets the system time. Select the 12H or 24H field and press a **Change** button to change between 12-hour and 24-hour formats.

4.2.3 Exposure Defaults Screen

This screen sets the exposure default values for each exposure mode. To return to the Run mode press the **RESET** and **Change** buttons.

Move through the fields with the Scroll buttons. Change the selection with the Change buttons.

Table 7: Exposure Defaults Screen Options

Set Default Value	Field	Description
 *Figure 30: Exposure Defaults Screen*	Mode	Manual or Auto Time. Select each mode and set defaults for kV and mAs.
	kV	Auto Time: 22 to 34
		Manual: 22 to 34
	mAs	Manual: 3 to 400. The mAs you can select depends on the kV selection.
	Def Exp Mode	Default exposure mode for startup.

4.3 SmartWindow Stage Display

4.3.1 Needle Guidance Buttons

You use the Needle Guidance buttons to:

- Select the mode of operation.
- Preset the biopsy Instrument or Needle stroke parameters.
- Perform the Z Zero sequence.
- Make the target selections.

The location of the button set is item 3 in *figure Stage Controls and Indicators* on page 21.

Table 8: Function of Needle Guidance Buttons

Control	Action
Z ZERO 	Records the 0.0 mm position on the Z stage line.
GRAPHIC/ NUMERIC 	Changes the display from graphic mode to numeric mode.
CURSOR 	Moves the highlight through the fields on the SmartWindow.
NEXT TARGET 	Selects the next set of coordinates.
MOTOR ENABLE 	Enables a Motor Control button on the Motor Control Pad.
ENTER 	Selects the field with the highlight on the SmartWindow.

4.3.2 Modes of Operation

The SmartWindow has four modes: Needle Core Biopsy (NCB), Z Zero Preset, Wire Localization (Wire Loc), and FNA (Fine Needle Aspiration).

To cycle through the modes, use the **Cursor** button to select **MODE**, then press the **ENTER** button until the mode you require appears.

The warning, "Warning Travel On Turn key to Lockout" appears if the key is in the On position when you select a procedure mode. Turn the key on the table panel to the Lockout position to disengage all C-arm and table movement when you perform a clinical procedure.

All modes of operation display:

- Current stage coordinates
- Target coordinates
- Difference between the stage and target
- Compression thickness in mm

Table 9: Available Options for the SmartWindow

Item	Selectable From	Available Options
Mode	Numeric display only	Needle Core Biopsy (NCB) Z Zero Preset Wire Localization (Wire Loc) Fine Needle Aspiration (FNA)
Stroke	Needle Core Biopsy Mode only	10.0 to 25.0 mm (in 1.0 mm increments)
Target Radius	Graphic Mode only	3.0, 5.0, 7.5, 10.0 or 15.0 mm

The coordinates for X, Y, and Z are transmitted from the Stereo Target box on the DSM display. You can not make any changes to their values from the SmartWindow.

If you use the Preset function, make sure the word PRESET appears in the upper right corner, or use Z ZERO to set a different needle length.

4.3.3 Needle Core Biopsy Screen

Press the **CURSOR** button to move the highlight to **MODE** then press the **ENTER** button.

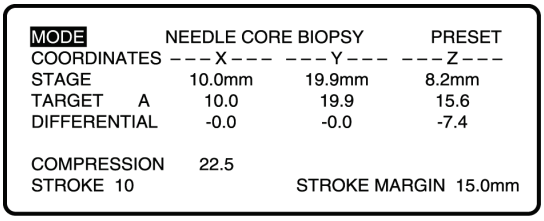


Figure 31: Numeric Needle Core Biopsy Screen

Table 10: Needle Core Biopsy Screen Use

Selectable Fields	How to Change the Field
MODE	Press the **ENTER** button to change screens.
TARGET	You can select the next target with the **NEXT TARGET** button if you selected multiple targets at the DSM.
STROKE	Press the **Cursor** button to select the field, then press the **ENTER** button to cycle through the values in 1 mm increments from 10 to 25. Confirm this value when you change a biopsy device.

The Needle Core Biopsy display includes the stroke and stroke margin.

The GRAPHIC/NUMERIC button on the Needle Guidance Control Pad selects a graphic or numeric display.

Note The Stroke Margin is the distance between the end of the Biopsy Instrument or Needle tip (after the device is fired) and the surface of the breast platform. Graphic Needle Core Biopsy Screen.

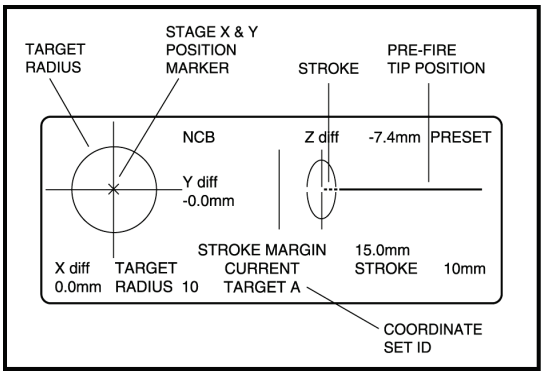


Figure 32: Graphic Needle Core Biopsy Screen

4.3.4 Wire Localization Screen

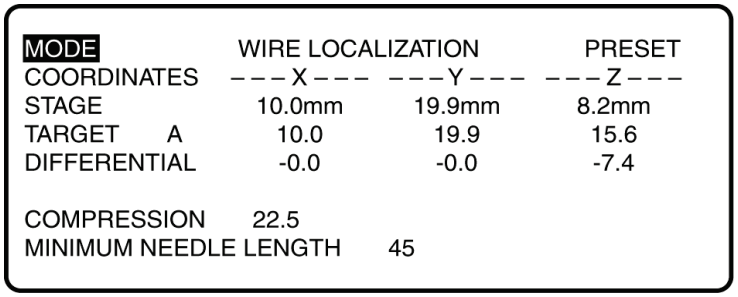


Figure 33: Wire Localization Screen

The Fine Needle Aspiration and Wire Localization screens include the minimum needle length.

You cannot change any fields on these two screens. The only selectable field is MODE.

4.3.5 Fine Needle Aspiration Screen

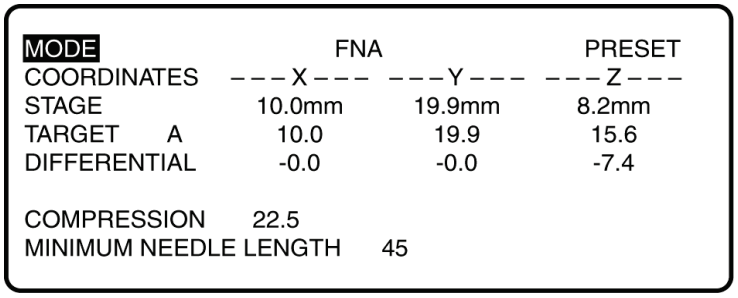


Figure 34: Fine Needle Aspiration Screen

4.3.6 System Setup for Z ZERO PRESET

1. Press the **Cursor** button to select **Mode**, and then press the **Enter** button to select the **Z Zero Preset** option.
2. Press the **Cursor** button to select the **Z Zero Mode** to calibrate (FNA, Wire Loc or Needle Core Biopsy).

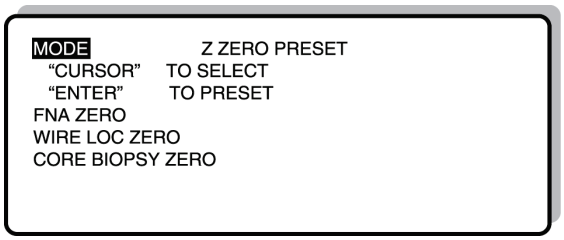


Figure 35: Z ZERO Presets Mode Display

3. Install the biopsy paddle.
4. Put the 5.0 Air Phantom to full pre-compression.
5. Compress and lock the paddle.
6. To do the Core Biopsy setup, follow the steps in the Needle Core Biopsy Z Zero Preset Procedure section. To do the Wire Localization setup, follow the steps in Wire Localization Z Zero Preset Procedure section. To do the FNA setup, follow the steps in the FNA Z Zero Preset Procedure section.

4.3.7 Z ZERO PRESET Setup Procedure for Needle Core Biopsy

1. Install the needle for the procedure on the biopsy device, then cock the device.

Warning: **Apply the biopsy device safety before you install the biopsy device. Do not cock the device while the device is on the stage.**

2. Install the biopsy device and its accessories (holder, needle arm, needle guides, etc.).
3. Press the **Motor Enable** and **Z Position** buttons to move the stage to X=0, Y= 4.
4. Align the needle tip just below the reference hole.
5. Press the **Enter** button. The mode line on the Z Zero Preset screen shows the message "PRESET".

Note When the length of the Biopsy Instrument or Needle is different from the Preset length, identify and zero the new value.

Note When the Z Zero button is pressed, the Preset Z Zero value is deactivated. To reactivate it, press the Z Zero and Enter buttons at the same time.

4.3.8 How to Calibrate a Needle with Z Zero During a Procedure

Use the same Biopsy Instrument or Needle length during clinical procedures as used for the Z Zero Preset. If you change the Biopsy Instrument or Needle length after the Z Zero Preset, calibrate the new needle length. Make sure that you use sterile procedures to put a new needle with a different length on the device.

1. Install the needle with a different length in the cocked position on the biopsy device.
2. Set a new stroke, if necessary.
3. Press the **Motor Enable** and **Z Position** buttons.
4. Use the Z Control to move the needle forward until the tip is below and in the same plane as the start of the reference bar.
5. Press the **Z Zero** button. The Stage Z Coordinate shows 0.0 and the PRESET message does not display. These two changes show that the preset Z Zero value is not in operation.

To return to the Z Zero Preset value, press the **Z Zero** and **Enter** buttons at the same time.

4.3.9 Z ZERO PRESET Set Up Procedure for Wire Localization

1. Attach the needle guide mount and correct needle guides.
2. Put the most common length needle used for wire locations into the guides.
   - Make sure that the needle hub remains against the stationary needle guide.
   - If you use sterile guides and needle, make sure that you follow sterile procedures.
3. Press the **Motor Enable** and **Z Position** buttons to move the stage to X=0, Y= 4.
4. Align the needle tip immediately below the reference hole.
5. Press the **Enter** button.
6. Make sure the Z Stage line shows 0.0 and that the word PRESET shows in the top right corner of the Wire Localization screen.

Note When the Z Zero button is pressed, the Preset Z Zero value is deactivated. To reactivate it, press the Z Zero and Enter buttons at the same time.

4.3.10 Z ZERO PRESET Setup Procedure for FNA

1. Attach the needle guide mount and correct needle guides.
2. Put the most common length needle used for FNA into the guides.
   - Make sure that the needle hub remains against the stationary needle guide.
   - If you use sterile guides and needle, make sure you follow sterile procedures.
3. Press the **Motor Enable** and **Z Position** buttons to move the stage to X=0, Y= 4.
4. Align the needle tip immediately below the reference hole.
5. Press the **Enter** button.
6. Make sure the Z Stage line shows 0.0 and that the word PRESET shows in the top right corner of the FNA screen.

Note When the Z Zero button is pressed, the Preset Z Zero value is deactivated. To reactivate it, press the Z Zero and Enter buttons at the same time.

4.4 DSM Screen

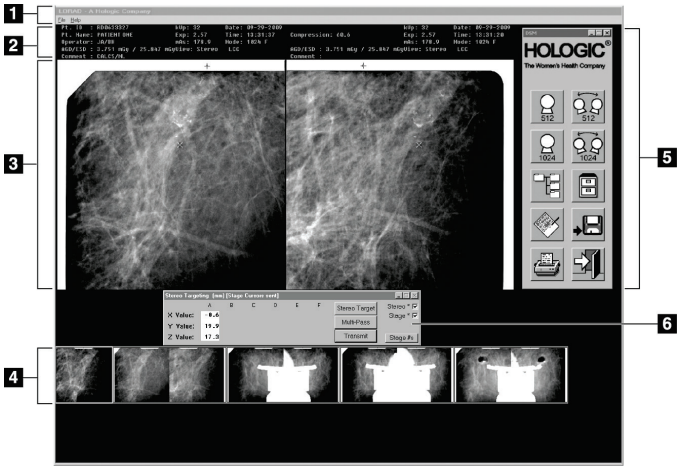


Figure Legend

1. *DSM File Menu* on page 44
2. *The Annotation Display Area* on page 47
3. *The Active Image Area* on page 49
4. *The Case Study Display Area* on page 49
5. *DSM Main Menu* on page 45
6. *The Stereo Targeting Dialog Box* on page 51

Figure 36: The DSM Screen

4.4.1 DSM File Menu

The DSM File Menu on the toolbar has these options:

Table 11: DSM File Menu Options

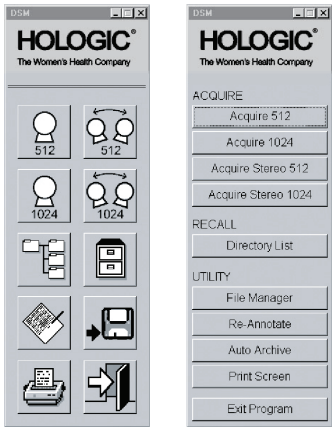
Menu Option	Description
Preferences	Change default values for the DSM display.
Image Statistics	Shows numerical statistics for the Active Image. See *Image Statistics* on page 50.
Format CD/DVD	See *DSM CD/DVD Archive Media* on page 74.
Transmit QAS Coordinates	Sends X, Y, Z values to the Stage.
Exit	Shuts down the computer system.

4.4.2 DSM Main Menu

The Main Menu is on the right side of the DSM Screen. You cannot change the position. The Main Menu buttons have icons or labels.

To change between the icons and the buttons with labels, press **Alt+M**.

Table 12: Main Menu Functions

Main Menu	Function	Description
 *Figure 37: DSM Main Menu Formats*	Acquire 512	Single image acquisition in 512 mode.
	Acquire 1024	Single image acquisition in 1024 mode.
	Acquire Stereo 512	Stereotactic image acquisition in 512 mode.
	Acquire Stereo 1024	Stereotactic image acquisition in 1024 mode.
	Directory List	List of all case studies on the Resident drive (computer's hard drive). Select the prior case studies to view.
	File Manager	Complete index of the images stored on a device. Copy, erase, move, recall, or print images.
	Re-Annotate	Edit the annotation information.
	Print Screen	Print the screen as displayed.
	Auto-Archive	Copy acquired images to archive storage device.
	Exit Program	Exit the DSM program, run the auto-archive, and shut down the system.

4.4.3 Patient Information

The Patient Annotation screen appears when you select an Acquisition Mode.

1. Click the **New Patient** button to clear all the fields.
2. Click the **View Worklist** button to display the Patient Worklist (automatically retrieved at startup). Select the patient from the Worklist to fill the Annotation dialog box with information from the server. Fill in the remaining fields.
3. Press the keyboard **Tab** key to move to the next field. When you finish entering information, and the compression and Breast Platform values, click the **OK** button.

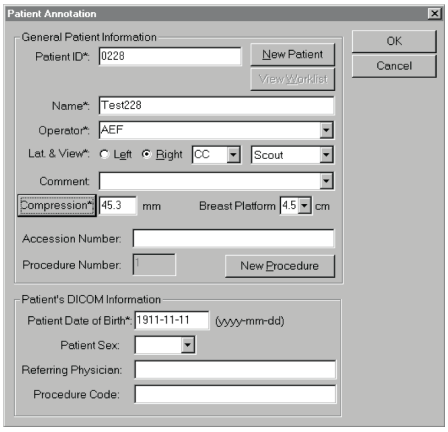


Figure 38: The Patient Annotation Dialog Box

Table 13: The Patient Annotation Dialog Box

Field	Details
Patient ID*	ID number (to 64 characters).
Name*	Name (to 64 characters). A space separates Last First Middle names. The total number of characters for the entire name (including spaces) must not exceed 64 characters.
Operator*	New (31 characters) or select from the drop-down menu.
Lat. & View*	Select the laterality and view information. View advances automatically after a stereo pair from Stereo to pre-fire to post-fire to post-exam.
Comment	Optional. Enter new (32 characters), or select from the menu.
Compression*	When you finish applying compression, click the compression button to update the field with information from the Stage. The field clears for all scout images. The Breast Platform information is the correct setting for the compression. Override that entry if a different setting is used.

Table 13: The Patient Annotation Dialog Box

Field	Details
Accession Number	Optional. Enter the accession number (16 characters).
Patient Date of Birth*	Enter the date of birth in the format yyyy-mm-dd.
Patient Sex	Select a gender (F, M, O).
Referring Physician	Enter the Referring Physician (64 characters).
Procedure Code	Enter the CPT code (16 characters).
**All fields with an asterisk must contain an entry before you can make an exposure.*	

4.4.4 The Annotation Display Area

The Annotation Display area above the image shows the patient case and exposure information. When a stereo pair or two single images display, the Annotation Area shows the information for each image. The Patient and Operator information appears only above the left image.

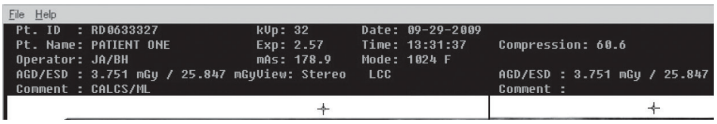


Figure 39: Annotation Display Area

Table 14: Fields in the Annotation Display Area

Field	Description
Pt. ID:	Patient identification number (21 characters)
Pt. Name:	Patient name (21 characters)
Operator:	Operator name (21 characters)
AGD/ESD:	Calculated dose for each image. The field uses either ACR or EUREF guideline to calculate dose (see *Configuring the Calculated Dose* on page 48).
Comment:	The notes about the patient or the exam. (Maximum of 32 characters.)
kVp:	kV in the Active Image Area
Exp:	Exposure time (in seconds)
mAs:	Exposure mAs
Date:	Date of the exposure
Time:	Time of Day of the exposure
Mode:	Shows the image acquisition mode. F also shows here for images saved with the Filter enhancements, if a Filter is applied.
View:	The image shown in the Active Image Area
Compression:	The compression thickness in mm

Information about Character Display

A maximum of 64 characters for the Patient ID, 64 characters for the Patient Name, and 31 characters for the Operator fields are saved and retrieved with each image.

- The Patient Annotation dialog box shows all the characters when you scroll in the field.
- The Annotation fields above the image show the first 21 characters of the Patient ID, Patient Name, Referring Physician, and Operator fields.
- The Directory List, File Manager, Worklist, and Query Results dialog boxes display from 16 to 31 characters.

Configuring the Calculated Dose

The AGD and ESD Dose Information is calculated, stored and displayed for each image. You can select the ACR or the EUREF guideline for dose calculation.

To select the guideline:

1. Select **File>Preferences**.
2. Click the radio button of the preferred guideline.
3. Click **OK** in the Set Preferences dialog box.

When an image is displayed that was not taken with dose information the dose line displays n/a.

Figure 40: Annotation Without a Valid Dose Calculation

4.4.5 The Image Display Area

The Active Image Area

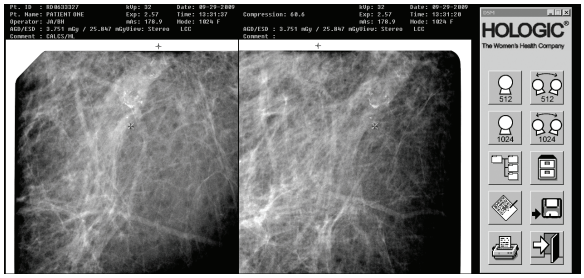


Figure 41: Active Images

The Active Image Area has two windows for side-by-side examination of single image views, or a Stereo Pair of images. Image processing and coordinate targeting are performed here.

When a Stereo Pair is in the Active Image Area, the Stereo Targeting window has the Stereo Target and Multi-Pass features. You can target a maximum of six targets, or a maximum of five additional passes of the same target.

The Case Study Display Area

Figure 42: Thumbnail Images in the Case Study Display Area

The Case Study Display Area shows all images (single and stereo pairs) taken of the same patient on the same day. The images display as thumbnails and in the order in which they were taken. The first image taken shows on the left end of the case study. The most current image is the last image on the right end.

To select from the menu to display the image in the right or left Active Image Area, right-click a thumbnail image.

To display the image in the Active Image Area, double-click a thumbnail image. The Stereo images are displayed as a pair and use both windows.

When you retrieve or acquire an image, the DSM examines the disk for additional images related to that case. Additional images appear in this area.

Image Statistics

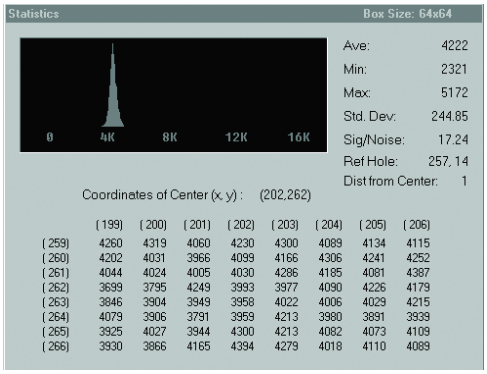


Figure 43: The Image Statistics Dialog Box

Image Statistics are available from the DSM File Menu. Select **File>Image Statistics**. The F2 key also displays Image Statistics. A right-click cycles through the sizes of the ROI box. A left-click closes the Statistics box.

4.4.6 Targeting and the Stereo Target Dialog Box

Two Methods of Targeting

The DSM has two procedures to calculate the X, Y, and Z coordinates of the lesion:

- ScoutMarc Targeting uses the single scout image to replace either stereo image.
- The Stereo Targeting marks the lesion location in the two views of the stereo pair.

ScoutMarc Target Preparation

Note If the lesion was targeted on a ScoutMarc Stereo, Stage Cursors are not available.

Note There is an increased error in the true Z-axis when you use ScoutMarc Targeting. The error margin can be more than one mm.

If you cannot use the Stereo Targeting procedure, use this procedure.

1. Right-click the single thumbnail image immediately before the Stereo Pair.
2. Click **ScoutMarc Left** or **ScoutMarc Right** to put the image in the left or right Active Image Area.

A new Stereo Pair appears in the case study area and the Stereo Target dialog box appears so that you can begin the target procedure.

The Stereo Targeting Dialog Box

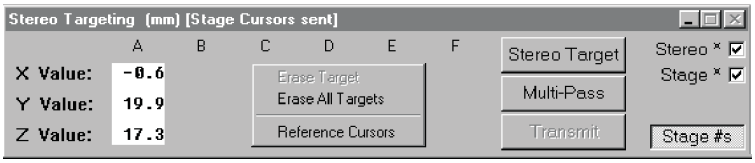


Figure 44: Stereo Targeting Dialog Box

The Stereo Targeting dialog box appears when the image window shows the following stereo image pair types:

- ±15° projections (standard stereo pair)
- Right-side, single image and left-side 15° projection (ScoutMarc right)
- Left-side, single image and right-side 15° projection (ScoutMarc left)

The Stereo Targeting dialog box permits the following:

- The **Stereo Target** button acquires one or more stereotactic target sequences.
- The **Multi-Pass** button starts the Multi-Pass sequence after a lesion is targeted.
- The **Transmit** button sends the coordinates to the Control Module.

The dialog box shows each of the coordinate sets (X, Y, and Z) calculated for the case shown. The DSM calculates and shows a maximum of six coordinate sets in columns A through F.

4.4.7 Target the Lesion

1. Click the **Stereo Target** button and answer the Reference Cursors dialog box question. Retarget the Reference Cursors if necessary. See *Options in the Stereo Target Dialog Box* on page 52. Start with step 2.
2. If you acquired a 1024-mode image, move the MagBox until the lesion is visible then click to set the MagBox in each image. Move the target symbol to either image and click to display the Locus Line in the other image.
3. Click again to mark the lesion.
4. Move the target symbol to the other image over the lesion in that image and click to mark.
5. To add another target, repeat steps 1 to 5.
6. Click the **Transmit** button to send the information to the Control Module..

The F4 (Custom), F5 (Mag Box), and F6 (Zoom-In) function keys are available during the targeting sequence. Press Esc to cancel the targeting process at any time. You can right click an image to display a menu that allows you to change cursors, stop targeting or process the image.

Hide or Show the Stereo and Stage Cursors

Clear the Stereo check box to hide all the stereo cursors in the image pair after the target sequence. Check the Stereo check box to show the stereo cursors.

Clear the Stage check box to hide all the stage cursors. Check the Stage check box to show the stage cursors. The Stage check box is checked by default.

Note If the lesion was targeted on a ScoutMarc Stereo, Stage Cursors are not available.

Display Last Transmitted Coordinates

To show the last set of coordinates that were transmitted to the Stage, check the **Stage #s** button in the Stereo Targeting dialog box. To return the display to the current set of coordinates, clear the **Stage #s** button.

4.4.8 Multi-Pass Mode

Select the **Multi-Pass** button after you mark the first coordinate set (column A) to select Multi-Pass Mode. This mode lets you mark a maximum of five more targets around the first target.

4.4.9 Options in the Stereo Target Dialog Box

A menu with more options is available when you right-click the Stereo Targeting dialog box.

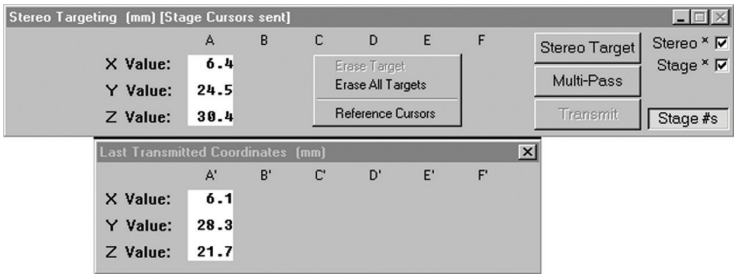


Figure 45: Options on the Stereo Targeting Dialog Box

Erase Target Coordinates

- To remove one set of coordinates from the Stereo Targeting dialog box, right-click the column heading (A-F) and then select the **Erase Target** option.
- To remove all the targets shown, right-click in the dialog box and then select the **Erase All Targets** option.

Note When you select a new patient, targets are removed from the Control Module.

Reference Cursors

If you must re-target the reference holes:

1. Right-click the Stereo Targeting dialog box then click the **Reference Cursors** button.
2. When The MagBox appears use the + or - keys to identify the reference hole, then click to place.
3. The mag box moves to the right image. Use the + or - keys to identify the reference hole, then click to place.
4. Put the target symbol exactly on the reference hole, then click to place.
   - Window level within the MagBox to find the reference hole if needed.
   - Accuracy is extremely important. The Arrow keys can be helpful when making fine adjustments to the placement of a targeting cursor before clicking.
5. Place the target symbol over the reference hole in the right image.
6. Put the target symbol exactly on the reference hole, then click to place.
   - Window level within the MagBox to find the reference hole if needed.
   - Accuracy is extremely important. The Arrow keys can be helpful when making fine adjustments to the placement of a targeting cursor before clicking.

4.5 DSM Image Processing Menu

Right-click on the image to show the Image Processing menu (see following figure), and select the option from the menu. Or, move the cursor over the image and press the related function key on the keyboard while the menu is not shown.

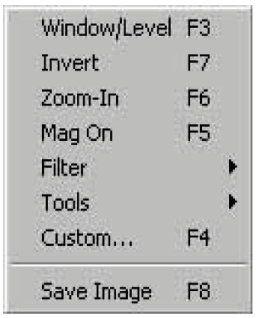


Figure 46: Image Processing Menu

Table 15: The Image Processing Menu Options

Menu Option	F key	How to Use the Feature	Saves?	How to Close
Window/ Level	F3	Roll the trackball. For instructions on the function keys, see *Special Function Keys* on page 26.	Yes	Click, right-click, or press F3.
Invert	F7	Click the image to invert it.	Yes	Right-click or press F7.
Zoom-In	F6	Click **Zoom** to Zoom image to a Full screen.	No	Right-click and then click **Zoom-out** or press F6.
Mag On	F5	Click **Mag On**. Use the trackball to move the Magnification window over the image. Right-click to scroll through five window dimensions. Click to Paste the magnification window on the image.	No	Right-click to show the menu, and then select **Mag Off** or press F5 two times.
Filter	None	Click **Filter**. The available options are: Click a **Sharpen Level.** Click **Equalize Low** or **Equalize High.** When a sharpen level is selected, **Smoothing** is set as the default.	Yes	Right-click to show the menu and then select **Filter** to remove or change.

Table 15: The Image Processing Menu Options

Menu Option	F key	How to Use the Feature	Saves?	How to Close
Tools	None	Select **Ruler, Target**, or **Calipers**. Use the trackball to move the tool within the image. A right-click rotates the ruler, or changes the color ring from black to white. Click to identify the first endpoint of the caliper and click again to set the point. You can make many caliper measurements.	No	Click to clear the Ruler and Target. Right-click to clear Calipers.
Custom	F4	Shows a dialog box that shows all the available functions except tools.	Click **Save**.	Click Save or [x] in the right corner.
Save Image	F8	Click the menu item to save changes. If the image is stored, select **Yes** to replace the image or **No** to close the menu without saving.	N/A	N/A

4.5.1 The DSM Window/Level Histogram

The Window/Level histogram appears automatically after an image is acquired. It shows the contrast and brightness of the selected image. Press the F1 key to show the digital number value of the image data.

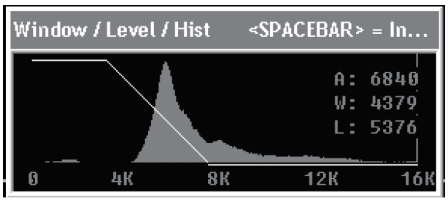


Figure 47: Window/Level Histogram Example

A = Average Contrast Value of Full Image
W = Window (Contrast)
L = Level (Luminance)
The Average value can be used to compare the pixel value of images to the digital numbers (DN) set by service.

Use the trackball and the keyboard to make Window/Level adjustments.

Window/Level Trackball Functions

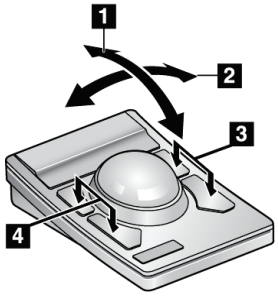


Figure 48: Trackball Functions

1. Roll the trackball up-and-down to change the contrast.
2. Roll the trackball left and right to change the brightness.
3. Right-click to close the window and return to the Original Image.
4. Click to close the dialog box and save changes temporarily.

Window/Level Keyboard Functions

Arrow keys	Make fine adjustments.
Spacebar	Invert and revert the image.
Right-click	Return the Window/Level to the last saved values.
"X" key	Resample the image and apply new Window/Level values.
F3 key	Close and save changes temporarily.

4.5.2 The Custom Image Processing Dialog Box

The Custom option in the Image Processing menu gives access to all Image Processing Options from a dialog box.

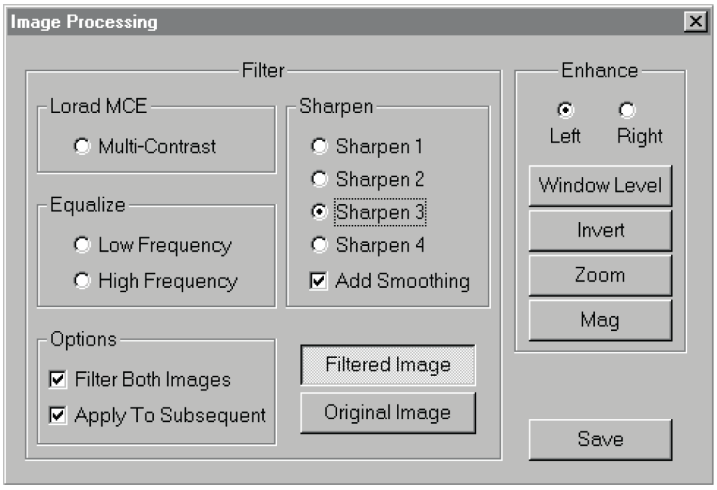


Figure 49: The Custom Dialog Box

The [x] at the upper right of the dialog box closes the dialog box and does not save the changes.

Image Processing and Filters

Table 16: Image Processing

Field	Description
Multi-Contrast	The preferred procedure. Multi-Contrast increases image contrast and adds a slight sharpening to the image.
Equalize	Evens-out the gray scale in the image, so that image details remain visible at high contrast levels.

Table 17: Filters

Field	Description
Sharpen 1-4	Sharpen increases the contrast differences and increases the definition of the object edge. Each level makes the image sharper.
Add Smoothing	The Add Smoothing function softens the edges that were enhanced to create uniform changes from black to white, or white to black. When a Sharpen level is selected, Smoothing is set as the default. The Add Smoothing option becomes available after selection a Sharpen option.

Image Enhancements

Table 18: Enhancements

Field	Description
Left or Right Image	Select the image to enhance.
Image Enhancements	Select the Option to apply. The buttons on the screen do the same procedure as their related function keys.

Options

Table 19: Filtered Image Options

Field	Description
Filter Both Images	The selected filter is applied to both the Left and Right image. If the Filter Both Images option is not selected, the filter is applied to the image that is selected.
Apply to Subsequent	Applies the current filter to following images or new images.
Select Filter Image or Original Image	Changes between the original image and the filtered image.
Save	Saves the enhanced images. The only changes that save are: Window/Level, Invert, and Filter.

Chapter 5: Attachments

5.1 Biopsy Paddles

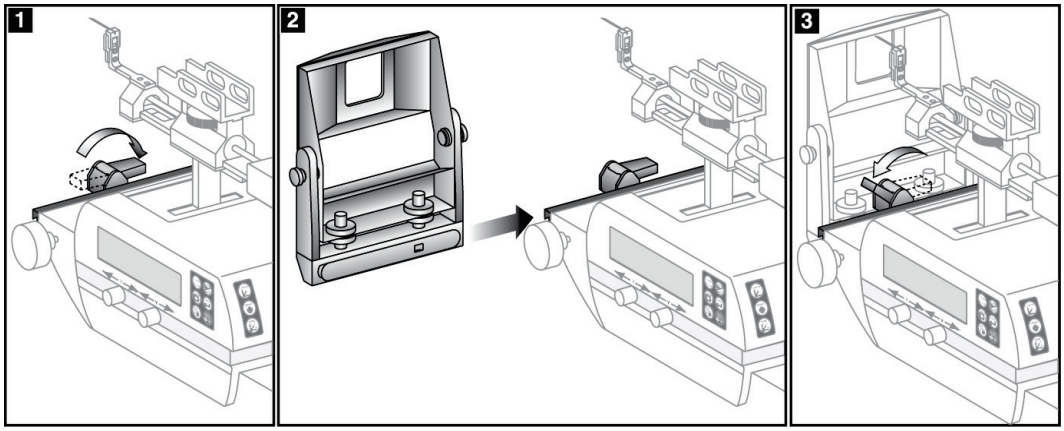


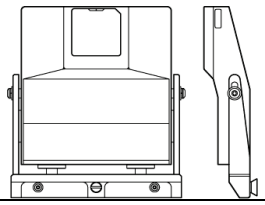
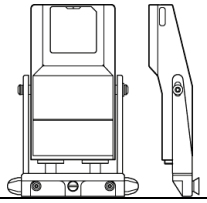
Figure 50: How to Install the Biopsy Paddles

Figure Legend

1. Release the locking lever.
2. Slide the paddle into the mount until the paddle clicks into position.
3. Lock the Paddle mount.

There are two paddles used with the system.

Table 20: Biopsy Paddles

Paddle	Description
Standard Biopsy: 	Stereotactic imaging during the Needle Core Biopsy, Fine Needle Aspiration, or Wire Localization procedures
Axillary 4-inch Biopsy: 	Stereotactic imaging during the Needle Core Biopsy, Fine Needle Aspiration, or Wire Localization procedures

5.2 Compatible Biopsy Devices

5.2.1 Needle Guide Components

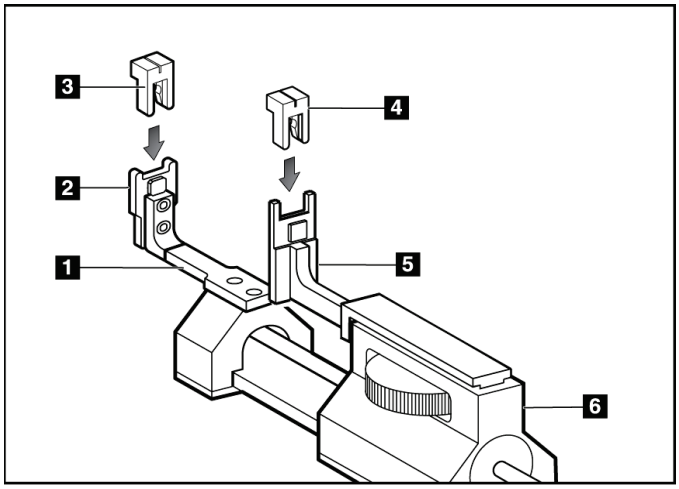


Figure Legend

1. Front Needle Guide Mount
2. Needle Guide Post
3. Needle Guide
4. Needle Guide
5. Rear Needle Guide Mount
6. Stage

Figure 51: Needle Guide Components

5.2.2 The Rear Needle Guide Mount

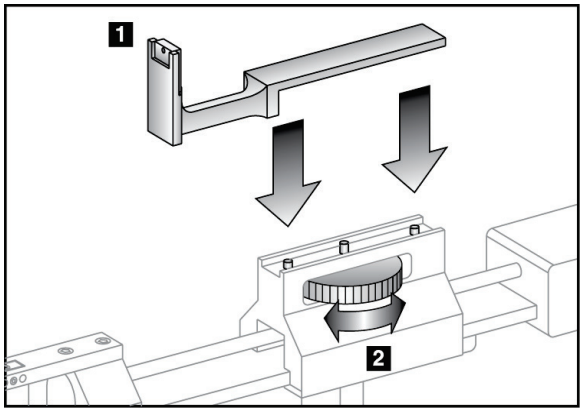


Figure 52: How to Install the Rear Needle Guide Mount

To attach the Needle Guide Mount:

1. Align the mount with the pins on the Stage platform and put the mount on the platform.
2. Turn the thumbwheel to tighten.

5.2.3 The Front and Rear Needle Guides

Warning: **Always use sterile techniques when you use Needle Guides during the patient procedures.**

Put the needle guide over the post and press until the guide locks into position.

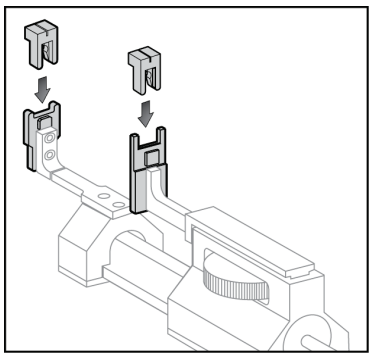


Figure 53: Installation of the Needle Guides

Note Provide support for the guide post while you install each guide.

5.2.4 Install a Biopsy Device Holder on the Stage

Contact Technical Support to confirm compatibility of your biopsy device. Install the biopsy device holder as shown below, then install the biopsy device. (Refer to the user manual provided by the biopsy device manufacturer for installation and operating instructions.)

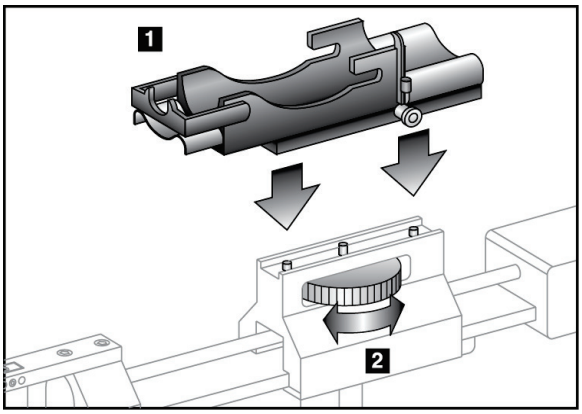


Figure 54: How to Install a Biopsy Device Holder on the Stage

1. Align the Biopsy Device holder with the pins on the Stage platform, and put the holder on the platform.
2. Turn the thumbwheel to tighten the Biopsy Device holder.

5.2.5 Install a Biopsy Device on a Device Holder

Warning: **Always apply the device safety and cock the biopsy device before you install the device in the holder.**

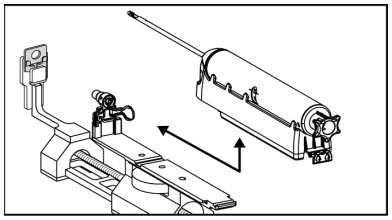


Figure 55: Install the Biopsy Device in the Device Holder

1. Turn the Z-control knob to move the holder completely back (toward the x-ray tube).
2. Install a needle guide on the front Needle Guide Mount (see *The Front and Rear Needle Guides* on page 60).
3. Move the Needle Guide Mount completely toward the biopsy paddle.
4. Slide the device completely into the holder from the rear (open end).
5. Make sure that the needle goes through the hole in the sterile needle guide.
6. Confirm the correct value for the device stroke is set.

5.3 The Control Panel Cover

WARNING! **Discard the cover and drapes like any material with possible contamination.**

Warning: **Protect the control panel so that any fluids cannot enter the panel. Clear Plastic Banded Bag (P/N 2-700-0072) is available from Hologic.**

1. Cover the control panel with a new clear Plastic Banded Bag (P/N 2-700-0072).
2. Drape the stage area, as required.
3. Turn the Safety Lockout keyswitch to the On position.

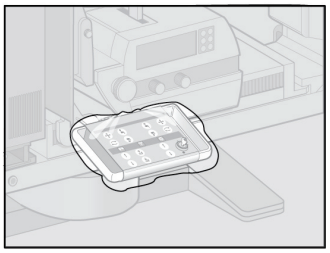


Figure 56: Control Panel with the Plastic Banded Bag

A drape system is available to prevent fluid contamination of the Stage or C-arm assembly.

5.4 Maximum Comfort Package

General Instructions for installation and use are given in the table below. For specific instructions for using the Arm Through accessories, see the *table Installation of the Arm Through Maximum Comfort Package* on page 64.

Table 21: Installation and Use of the Maximum Comfort Package

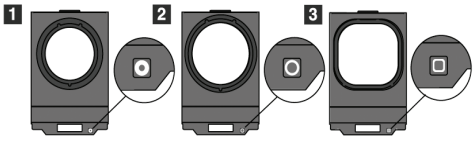
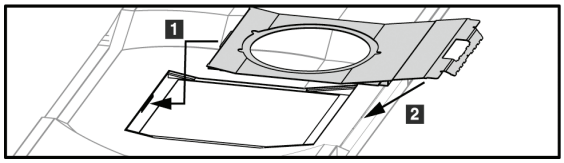
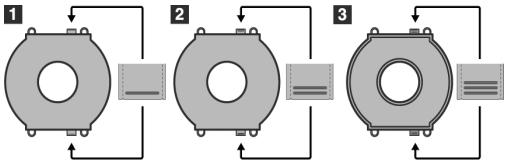
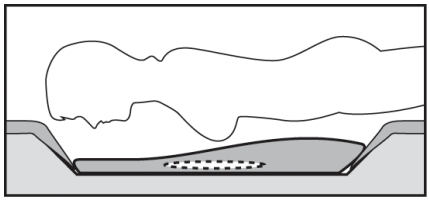
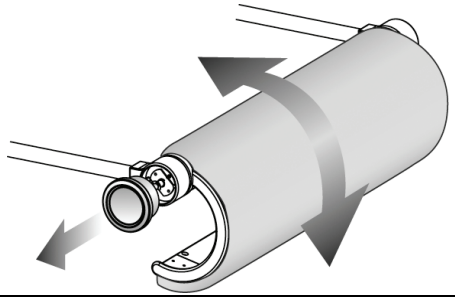
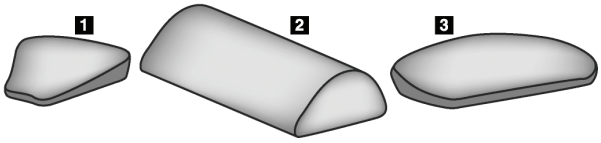
Step	What the step looks like
1. Select the table aperture. • item 1 Standard • item 2 Large • item 3 Arm Through (see the *table Installation of the Arm Through Maximum Comfort Package* on page 64).	
2. Install the table aperture into the slot in the table (item 1) then lower the aperture into position until the latch fastens (item 2).	
3. Select the aperture cushion. • item 1 Maximum Access • item 2 Standard • item 3 Maximum Comfort 4. Put the tabs by the hip of the patient.	
5. Put the cushion on the table in the correct direction. Position the patient on the table.	
6. Adjust the footrest. a. Pull and hold the knob on the footrest. b. Rotate the footrest. c. Release the knob to lock the footrest.	
7. Use additional cushions for support as needed. • item 1 Head cushion • item 2 Wedge cushion • item 3 Hip cushion	

Table 22: Installation of the Arm Through Maximum Comfort Package

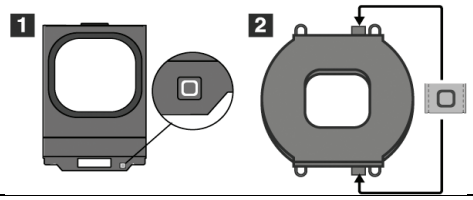
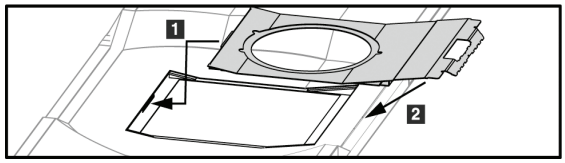
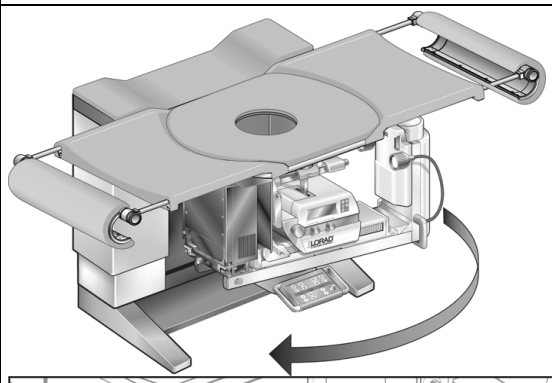
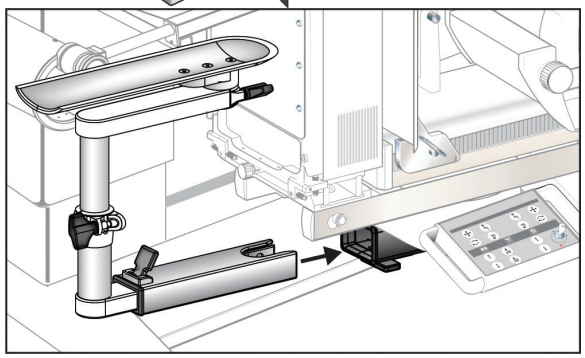
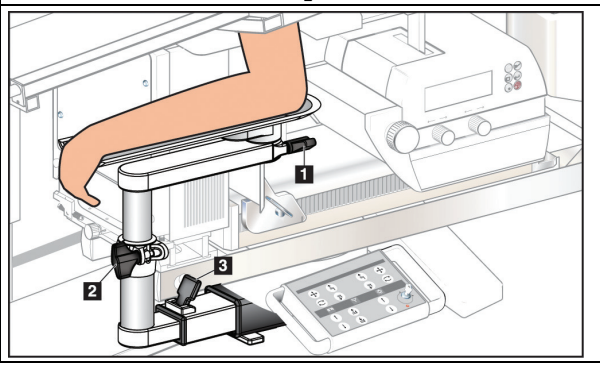
Step	What the step looks like
1. Select the Arm Through accessories. • item 1 Table aperture • item 2 Aperture cushion	
2. Install the table aperture into the slot in the table (item 1) then lower the aperture into position until the latch fastens (item 2). 3. Install the Aperture cushion.	
4. Rotate the C-arm to the approach angle. Install the arm rest on the bottom of the C-arm	 

Table 23: Use of the Arm Through Maximum Comfort Package

Step	What the step looks like
1. Position the patient on the table. 2. Position the arm of the patient on the arm support and lock the support into position. There are three locks: • item 1 Position lock • item 2 Height lock • item 3 Bottom attachment lock	

Chapter 6: The Directory List and File Manager

Caution:

When the computer starts, the software finds all removable drives. If devices are added or removed (like an optical drive or USB storage device), you must restart the DSM software.

6.1 Directory List

To open the Directory List window, select the **Directory List** button (or icon) on the DSM main menu.

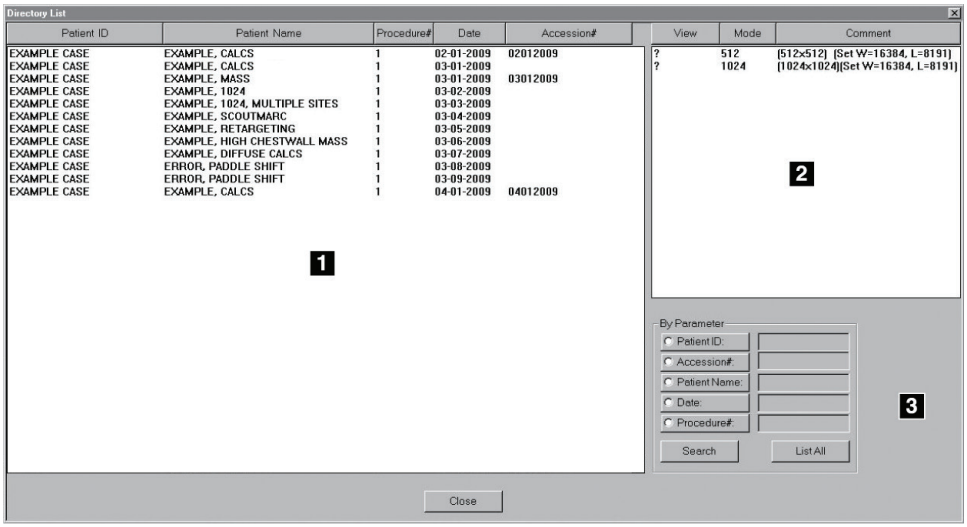


Figure 57: The Directory List Window

Figure Legend

1. Case Study List	Shows all case studies stored on the DSM computer. The column headings show the annotations in the Case Study. Click a heading to sort the list. Click again to reverse.
2. Image List	Shows all images saved with each Case Study.
3. Parameter (Search)	Sets limits for search.

6.1.1 Parameter (Search) Menu

1. Select the parameter (see the *figure The Directory List Window* on page 65).
2. Type the search terms (not case sensitive) in the field for the parameter. Type the first characters to show a wider search.
3. Click the **Search** button. The Results appear in the Case Study List.
4. Click the **List All** button to redisplay all Case Studies stored on the DSM computer.

6.1.2 Recall a Case Study

Double-click a Case Study to recall that Case Study in the Directory List window. The oldest image in the case study appears in the left Active Image Window.

Double-click an image in the Image List area of the Directory List window to recall that image. The selected image appears in the left Active Image Window.

All associated images in the case appear as thumbnails in the Case Study Display Area.

6.1.3 File Manager

To open the File Manager window, select the **File Manager** button (or icon) on the DSM main menu.

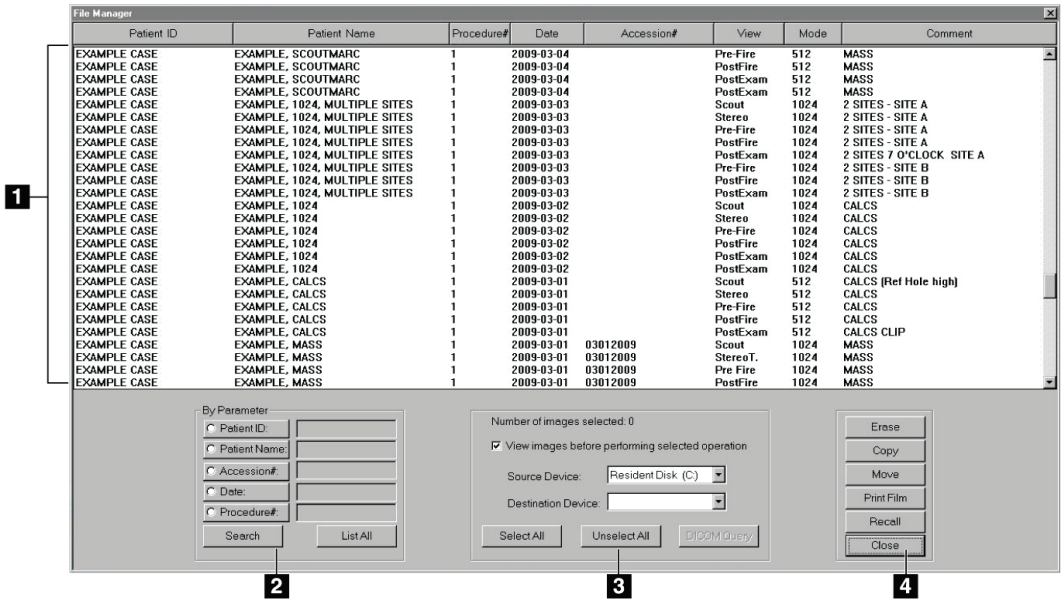


Figure 58: File Manager Window

Figure Legend

1. Image List
2. Parameter (Search) Options
3. Options Area
4. Functions

Table 24: File Management Functions

Function	Result
Erase	Deletes the selected image files from a local source device.
Copy	Copies the image files from a source device to a destination device.
Move	Moves the files to a destination device.
Print Film	Prints selected images to a DICOM printer.
Recall	Recalls an image to the screen.
Close	Closes the File Management window.

Image List

The image list shows all images on the selected device. Click a heading on the first four columns to sort the list.

Parameter (Search) Menu

The search functions in the Parameter (Search) menu work like the Parameter (Search) Menu for the Directory List. See *Parameter (Search) Menu* on page 66 for full instructions.

Options Area

The Options area lets you to set the default values for File Manager functions (Erase, Copy, Move, Print Film, Recall, and Close). Set these Options before you start a File Manager function.

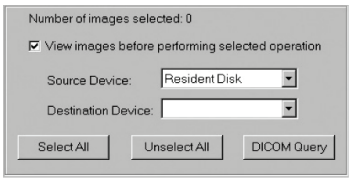


Figure 59: The Options Area

Note The Source Device and the Destination Device must be different.

Table 25: The Options Area Selections

Option	Description
Number of Images Selected	Shows the total number of images selected in the image list.
View Images before performing selected operation	Select this option to have a prompt appear to make sure that the File Manager operation for each image (the recommended option). Deselect to have a one-time prompt appear for confirmation to remove all the selected images.
* Source Device	Select the storage device for the retrieval of images.
* Destination Device	Select the storage device that receives the images from the Copy or Move operations. This selection is not necessary when you erase, print, or recall an image file.
Select All Button	Selects all the image files on the source device.
Unselect All Button	Deselects all the image files on the source device.
DICOM Query	Finds and retrieves the Case Studies from a DICOM Storage Server. See *DICOM Query* on page 70 for instructions.
** When the software starts, the DSM finds all removable drives. If devices are added* or *removed (like optical drives or USB storage devices), restart the DSM software.*	

Erase, Copy, or Move Images

1. In the Options area, select:
   - **Source Device**
   - **Destination Device**
   - **View Images** option
   - **DICOM Query (**and select your search parameters)
2. Select the images. You can arrange the displayed list of images with Quick Sort.
3. Make sure the **View Images** option is set and the correct images are selected.
4. Click the **Erase**, **Copy**, or **Move** button.
5. When all File Manager operations are complete, click the **Close** button.

Select Images

Click an image to select or deselect only that image. Double-click one image to select or deselect all images in that case study.

To select a range of images:

1. Press the **Shift** key, then click the first and last images in the range.
2. Click **Select All** to select all the images in the list.
3. Click **Unselect All** to deselect all the images.

The Recall Button

The Recall button only searches the Archive Disk.

To recall an image to the screen:

1. Select the **Source Device**:
   a. Put the storage media (DVD/CD) into the drive if necessary.
   b. Click the **Source Device** field to open the drop-down menu.
   c. Select the **Archive Disk**.
2. Select the image to **Recall**:
   a. Use a Search function to improve the search for an image.
   b. Sort the list results.
3. Click the required image.
4. Click **Recall** in the Operation menu. The File Manager closes, and the selected image appears.
5. When all File Manager operations are complete, click **Close** to return to the DSM main menu.

Note You can enhance a recalled image, but you cannot save the image with these enhancements. You are not permitted to change an image file on an archive disk.

6.2 DICOM Query

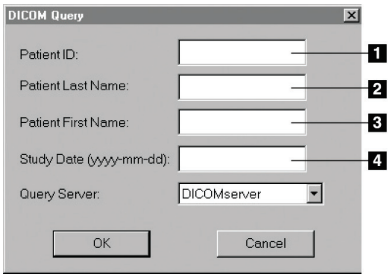


Figure 60: DICOM Query Dialog Box

1. Select the **DICOM Query** button in the Options area.
2. In the DICOM Query dialog box, type the information.
   - Necessary: Item 1 or Item 2
   - Optional: Item 3 and Item 4
3. Select a Query Server from the drop-down list.
4. Select the **OK** button. The Results window appears.

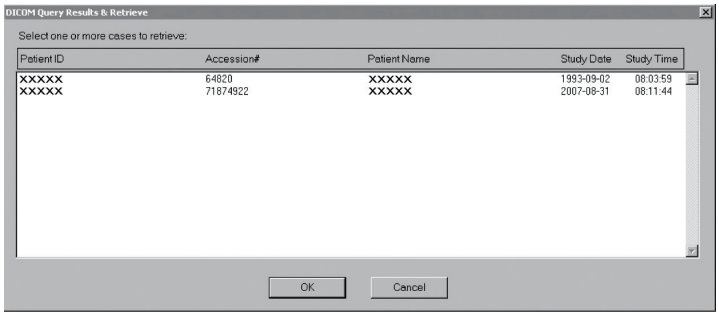


Figure 61: DICOM Query Results and Retrieve Dialog Box

5. Select the case studies to retrieve.
6. Select the **OK** button. The Directory list and File Manager list are updated.

6.3 Print Utilities

You can print a film image to a DICOM compatible printer with either the Print Screen or Print Film utility.

6.3.1 Print Screen

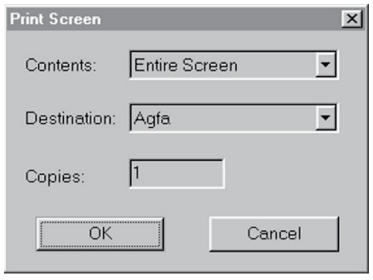
Note The Print Screen function prints only what is displayed on the screen. It does not print what was saved in the image file. This function cannot be used in the ZoomIn screen mode.

Note For DICOM printing, use the Print Film function in the File Manager.

This utility allows you to save an image file in the Windows Bitmap format or print to a DICOM device.

1. Acquire or recall any scout image or image pair.
2. Select **Print Screen** on the DSM main menu.

Table 26: Print Screen Dialog Box Options

	Fields	Option
 *Figure 62: Sample Print Screen Dialog Box*	Contents	Left Image Right Image Image Pair Entire Screen
	Destination	DICOM Printer #1 DICOM Printer #2 File to Resident Disk (C:) File to Archive Disk (D:) Any removable disk A USB drive is shown with the next available drive letter. The user must restart the system if the drive is added or removed while the software is in use.
	Copies	Enter the number of films to print

3. Select the part of the screen to capture from the Contents drop-down menu.
4. Select the destination device from the Destination drop-down menu.
5. Enter the number of copies.
6. Click the **OK** button.

6.3.2 Print Film

Use the Print Film utility on the File Manager window to print images to a DICOM compatible film laser printer. You must select the images to print with File Manager, begin the print sequence, and then select the film format.

Note The system does not separate the stereo pairs for print.

Note You can continue to use the system while the film prints in the background.

Prepare the System for Print

1. Open **File Manager** on the DSM main menu.
2. Select the source device.
3. Select the image or images to print.
4. Click **Print Film** in the Operation menu.

Select the Printer Options

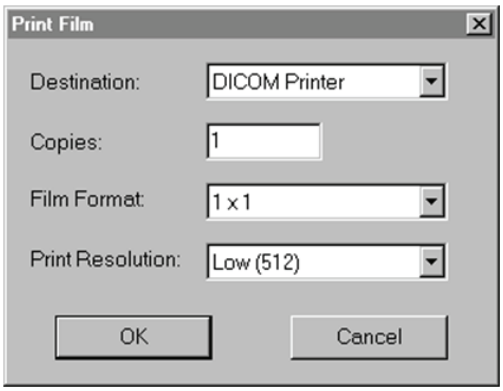


Figure 63: Print Film Dialog Box

1. Select the printer from the **Destination** field.
2. Enter the number of copies to print.
3. Select the film format.
4. Select the **Print Resolution**.
5. Click the **OK** button.

6.4 Re-Annotate

Use the Re-Annotate utility on the main menu to change the annotation information. The changes save with the image.

1. Select the **Directory List** option from the DSM main menu.
2. Double-click the case study, then double-click the thumbnail image to display the image for annotation in the left window.
3. Select **Re-Annotate** in the DSM main menu. The Patient Annotation screen displays.

Table 27: Fields in the Patient Annotation Dialog Box

Field	Details
Patient ID*	ID number (to 64 characters).
Name*	Name (to 64 characters). A space separates Last First Middle names. The total number of characters for the entire name (including spaces) must not exceed 64 characters.
Operator*	New (31 characters) or select from the drop-down menu.
Lat. & View*	Select the laterality and view information. View advances automatically after a stereo pair from stereo to pre-fire to post-fire to post-exam.
Comment	Optional. Enter new (32 characters), or select from the menu.
Compression*	The compression thickness is transmitted from the Stage. The field clears for all scout images.
Accession Number	Optional. Enter the accession number (16 characters).
Patient Date of Birth*	Enter the date of birth in the format yyyy-mm-dd.
Patient Sex	Select a gender (F, M, O).
Referring Physician	Enter the Referring Physician (64 characters).
Procedure Code	Enter the CPT code (16 characters).

**All fields with an asterisk must contain an entry before you can make an exposure.*

4. Edit the fields that require a change.
5. Select the **OK** button to save the new data. If the image was in an archive, a warning box appears. Select the **Yes** button.

Note If you select the **Cancel** button before you select the **OK** button, the image remains in its original state.

You can cancel the Re-Annotation procedure any time before you select the **OK** button. Any changes made to the annotation fields are discarded, and the image remains in its original state.

6.5 Auto Archive Utility

Note The DSM images from older versions cannot be archived to a DICOM server.

The Auto Archive function is a DSM utility which automatically saves new Case Studies to the archive storage device. The Auto Archive utility also controls the minimum capacity on the hard disk drive. The utility removes the oldest files on the disk drive that are in an archive.

When the DSM program closes, the Auto Archive function starts. If there are no new cases on the DSM computer, the Auto Archive Progress dialog box shows momentarily and then the Auto Archive utility stops.

To use the Auto Archive utility, close any open utility window (for example, File Manager or Directory List), and make sure that the archive media is in the disk drive unless the archive is configured to send to PACS. Click **Auto Archive**, and click the **Yes** button.

When the Auto Archive is complete, the Auto Archive utility shows a dialog box then stops.

6.6 DSM CD/DVD Archive Media

Note You can use RW disks with data if the disk is reformatted. It can take up to 20 minutes to format RW disks. CD-R disks take approximately 5-10 seconds to reformat.

- DVD disks are not recommended because database management times increase as the disk becomes full.
- Roxio® automatically formats a new **R media** (CD or DVD+/-R) through DirectCD. Roxio® also automatically assigns a volume label to the disk. To enter a CD volume label of your choice, you must format the CD manually.
- You must format a blank **RW media** (CD or DVD +/-RW) manually.

Chapter 7: Quality Assurance

7.1 User Calibration and Verification

Always do the QAS Needle Test each day before clinical use.

Warning: **The user must prepare for preventive maintenance by an approved servicing engineer.**

Warning: **The user or a servicing engineer must correct problems before the system is used.**

7.2 Recommended Tests

The following tests are recommended to make sure of the performance and that the system is correctly aligned. These tests are in the sections that follow.

Table 28: Recommended Tests

Test	Frequency
Compression Thickness Accuracy Test	Daily
QAS Needle Test	Daily - before clinical use
Mammography Phantom Test	Weekly
QC with the SMPTE Pattern	Monthly
Visual Checklist	Refer to the ACR Manual
QC Test for DSM	Annually by Medical Physicist

7.3 Compression Accuracy Test

The Compression Accuracy Test confirms the accuracy of the compression value display.

1. Set Breast Platform at 4.5 cm.
2. Install and lock the biopsy paddle.
3. Use the compression handwheel to move the biopsy paddle to the breast platform.

Caution: **Do not force the paddle on the platform.**

4. Make sure that the SmartWindow Compression display reads 0.0 mm ±1.0 mm.
5. Make sure that the compression readout changes as the compression device moves related to the image receptor.

7.4 QAS Needle Test

7.4.1 Required Equipment

- QAS Needle (P/N 9-060-0069)
- Needle Guide Mount (P/N 3-000-2847)
- 5.0 cm Air Phantom (P/N FAB-00289)
- Two 14–gauge non-sterile needle guides (P/N 3-255-0004)
- Tape

7.4.2 System Preparation

1. On the DSM workstation, click **File>Transmit QAS Coordinates**.
2. Compress the Air Phantom and lock the Compression Device in position.
3. Put the Needle Guide Mount on the stage and the Needle Guides onto their holders.
4. Inspect QAS needle for defects.
   - Put the hub over the edge of flat surface.
   - Roll the needle to make sure that the needle is straight.
5. Insert the needle into the Needle Guides.
   - Make sure that the needle hub is against the fixed Needle Guide.
   - Apply clear tape to the hub in the Needle Guide.

7.4.3 Z Zero the Z-axis

1. Press and hold the **Motor Enable** and **Z Position** buttons at the same time. Release the buttons after the beep when the Stage is at X=0.0, Y=+4.0.

Note The hub of the needle must stay against the rear needle guide during the complete procedure, or incorrect results occur.

2. Rotate the manual Y-axis control knob until **Y=0.0** on the Stage line.
3. Make sure that the Stage line reads 0.0 for X and Y.
4. Slowly turn the Z control until the mock lesion of the QAS Needle touches the reference hole.
5. Make sure that the hub of the needle stays in position against the upper needle guide and that the movable needle guide is fully extended.
6. Press and release the **Z Zero** button until you hear a beep. Make sure that the Z Stage line indicates Z=0.
7. Turn the Z control to move the needle away from the biopsy paddle.
8. Rotate the manual Y-axis control knob to move the needle tip in the biopsy window (about +5.0 mm).
9. Turn the Z control slowly until the Z Stage line reads +0.5 mm.
10. Press the **Z Zero** button until you hear a beep.

7.4.4 Position the Mock Lesion

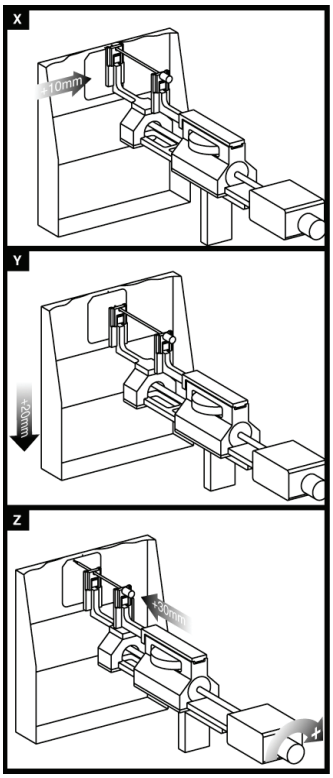


Figure 64: Position the Stage

1. Press the **MOTOR ENABLE** and **TARGET** buttons to move the stage to the correct X and Y positions, X=10 and Y=20.
2. Rotate the manual Z control knob until the Stage line reads Z= +30.
3. Make sure that the front needle guide is moved completely toward the biopsy paddle.

Note

The hub of the needle must remain against the upper needle guide during the procedure for the results to be accurate.

7.4.5 Acquire a Stereo Pair

1. Click the **Acquire Stereo 512** button on the DSM display.
2. Complete the Patient Annotation of the image for a QAS test. Click the **OK** button.
3. Set the exposure techniques to Manual, 22 kV, 4 mAs on the DSM Monitor.

Note Take the +15º image first for correct calculation of the coordinates.

4. Move the C-arm to the +15º position.
5. Step behind the radiation shielding. Acquire the first image.
6. Adjust the Window/Level as needed.
7. Click to close the dialog box and save the image.
8. Move the C-arm to the -15º position.
9. Acquire the second image.
10. Adjust the Window/Level as needed.
11. Click to close the dialog box and save the image.
12. Click **Done**. The Stereo Targeting dialog box appears.

7.4.6 Identify the Lesion Coordinates

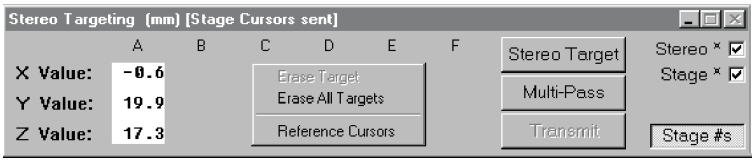


Figure 65: Target Coordinates in the Stereo Targeting Dialog Box

1. Click **Stereo Target** in the Stereo Targeting dialog box.
2. Make sure that the Reference Cursors are over the reference hole in the two views.
   - If the position of the Reference Cursors is correct, select **Yes**.
   - If the position of the Reference Cursors is not correct, select **No** and correct their positions. See *Reference Cursors* on page 53.

Warning: **When you accept an incorrect cursor position, you compromise the targeting precision.**

3. Move the Magnification box over the point of the QAS needle, then click to set the Magnification Box in each image.
4. Move the target symbol over the middle of the needle tip in either image.
5. Click to put the Locus line in the other image.

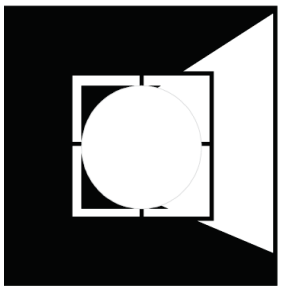


Figure 66: Image Magnified and Ball Aligned in the Box Cursor (Target Symbol)

6. Click to put the target in the first image. Use the Arrow keys for fine adjustment of the target location.
7. Accurately move the target symbol to the middle of the mock lesion in the other image, and then click to mark the target in that image.
8. Make sure that the mock lesion coordinates that appear in the Stereo Targeting dialog box in Column A are ±1.0 mm of X= +10, Y= +20 and Z= +30.

7.4.7 Check the Coordinates

Figure 67: Sample Stereo Targeting Result

1. Select the **Transmit** button, then make sure that the coordinates display in the Smart Window.
2. If the coordinates are not within ±1.0 mm, do the following:
   a. If there is an X error, make sure that the biopsy paddle is locked into the detent correctly.
   b. If there is a Y error, make sure that the movable needle guide is fully extended.
   c. If there is a Z error, check that hub of the QC needle rests against the rear needle guide and the biopsy paddle is locked.
   d. Repeat the QAS needle test:
      - Erase the target.
      - Select **Stereo Target** and target the center of the 1 mm ball at the tip of the QAS needle. Use the arrow keys on the keyboard to move the cursor to the target location, and then click to mark.
      - Move the target symbol to the opposite image, move the cursor to the target location, then click to mark.
      - Select **Transmit**. Make sure that the coordinates on the Target coordinate line and the Stage coordinates line match within ±1.0 mm.

   If the system continues to fail, contact Technical Support. Do not use the DSM System for patient procedures until corrective action is complete and the system performance and accuracy is correct.
3. To activate the Preset values, press, at the same time, the **Z Zero** button and the **Enter** button.

Warning:

If you use Z Zero Preset: When QAS is finished, press the Z Zero **and** Enter **buttons to start the Preset values. PRESET appears in the upper right corner of the SmartWindow, and makes sure that you started the Z Zero Preset.**

7.5 System Performance Tests

- Each day, before you use the system, do the Quality Assurance Test.
- Operate all controls one time each month for the correct responses.
- If there is a problem with system performance, contact Technical Support.
- Prepare for annual inspection by an approved Service Engineer of the x-ray tube, the ground connections and the high-voltage connections.
- Schedule preventive maintenance two times a year.

Warning: **The user or a servicing engineer must correct problems before the system is used.**

Warning: **The user must prepare for preventive maintenance by an approved servicing engineer.**

7.6 Mammography Phantom Test (Weekly)

7.6.1 Image Quality Test Preparation

1. Move the breast platform to the 4.5-cm position.
2. Put the mammography phantom so that the Evaluation objects are within the biopsy window.
3. Compress the Phantom.

Note If the test fails for either mode, make sure that the exposure factors and the Phantom position in the biopsy window are correct.

7.6.2 Procedure

1. Click the **Acquire 512** button on the DSM main menu.
2. Enter **512 Phantom Test** as the image name and complete the Annotation. The Lat. & View should be marked as CC QA. Click OK.
3. Set an exposure at 28 kV, Auto-Time mode.
4. Acquire the image.
5. Process the image as necessary.
6. Click to close the dialog box and save the image.
7. Repeat this test for the 1024 mode.
8. Enter **1024 Phantom Test** as the image name.

7.6.3 Criteria

The DSM image must clearly show:

- The fifth fiber (Mammography Phantom) or the third fiber (mini-phantom).
- The fourth Speck Group (Mammography Phantom), or the third Speck Group (mini-phantom).
- 3.5 masses (Mammography Phantom) or 2.5 masses (mini-phantom).

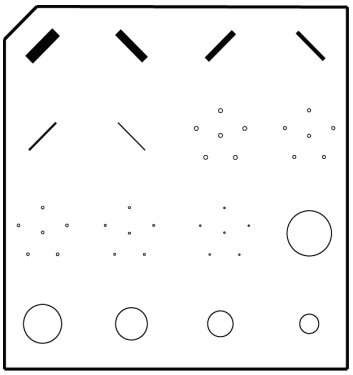


Figure 68: The Mammography Phantom

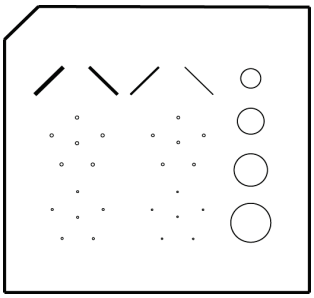


Figure 69: The Stereotactic-Phantom

Minimum Score:

- 5 Fibers
- 4 Speck Groups
- 3.5 Masses

Minimum Score:

- 3 Fibers
- 3 Speck Groups
- 2.5 Masses

7.6.4 Additional Image Inspections

Inspect the Phantom Image for artifacts, non-uniform areas, and other problems.

7.7 AEC Function Test

This test validates your system to confirm the AEC calibration remains within specifications. An Applications Representative or a Service Engineer can do this test to make sure the AEC functions correctly. This test is not part of the necessary Quality Control tests for this equipment.

1. Obtain the target DN for 512 mode and 1024 mode used to calibrate AEC on your stereotactic system. This number should be on the technique chart. If there is no number, then contact your Application Specialist or Service Engineer.
2. Open the weekly 512 mode Phantom image.
3. Right-click the image and select Window/Level.
4. Press the F1 function key to display the DN in the histogram window.
5. Compare the DN of the weekly Phantom to the target 512 mode DN. This number should be within ±500 counts of the Target DN. If the value is outside this range, contact Technical Support.
6. Repeat the above steps for the 1024 mode Phantom and target DN.

7.8 Stroke Margin Accuracy Test

This test is not a requirement of an accreditation sequence, but Hologic recommends that you do this test when these conditions occur:

- Negative Stroke Margin precision is questioned.
- There is no negative Stroke Margin shown, but the needle strikes the breast platform when fired.

Steps in the Stroke Margin Accuracy Test

1. On the DSM Workstation, click **File** > **Transmit QAS** coordinates.
2. Lock the Compression Device in position.
3. Put the QAS Air phantom in the middle of the biopsy window, and apply full compression.
4. Install the biopsy device on the stage.
   - Make sure that the device is cocked and in the ready-to-fire position.
   - Make sure that the stroke of the biopsy device is correctly programmed (lower left corner of the control module window).
5. Zero the needle.
   - Press the **Motor Enable** and **Z Position** buttons.
   - Turn the Z control to move the needle toward the image receptor. Stop when the needle tip is at the same plane as the reference hole.
   - Press the **Z Zero** button. Listen for the audible tone and make sure that the Z stage line shows Z = 0.0.
6. Press the **Motor Enable** and **Target** buttons to move the stage to X = 10.0 and Y = 20.0. Make sure that the needle is in the biopsy window.
7. Fire the biopsy device.
8. Turn the Z control to move the needle toward the breast platform. Stop when the Stroke Margin in the control module window reads 0.0.
9. Look at the distance between the fired needle tip and the breast platform.
   a. To measure, carefully turn Z control to move the needle until the fired needle tip touches the breast platform.
   b. Read the Stroke Margin display.

   The measurement must be no less than 4 mm, ideally within 4-8 mm. The measurement is shown as -4.0 to -8.0.
10. If the stroke margin measurement is out of the range, contact Technical Support.

7.9 Quality Control with the SMPTE Test Pattern

Use this test pattern to examine these results:

- Film density and contrast
- Brightness or density linearity
- High contrast resolution
- Low contrast resolution
- Spatial linearity
- Uniformity and artifacts
- Display of all information in the test pattern
- Sharpness of image elements
- White and black window distortion

These systems ship from the factory in the DICOM Display mode. In this mode, contrast and brightness adjustments are not available to the user.

7.9.1 SMPTE Test Pattern Use

The DSM has SMPTE test patterns for 512 and 1024 in the SMPTE file. The recommended test pattern for the printer is the 1024.

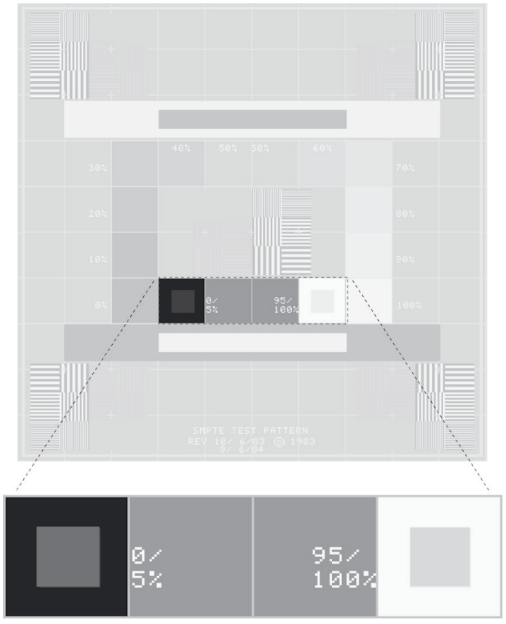


Figure 70: 5% and 95% Inset Test Patches

Note The print procedure decreases the visual differences in the test patches in this figure.

7.9.2 How to Optimize the Printed Images

Note Before you do this test, make sure that the film printer is calibrated.

1. Open the Directory List and double-click the 1024 "SMPTE" image in the image list.
2. Right-click the image, then select **Window/Level**.
3. Press the **F1** function key to set the Window and Level numeric display to the **On** position. If the Window width is not at 16384 and the Level is not at 8191, adjust to these values.
4. Right-click the image, then select the **Filter** option. Make sure that the image is not filtered and the only option with a checkmark is "Original Image".

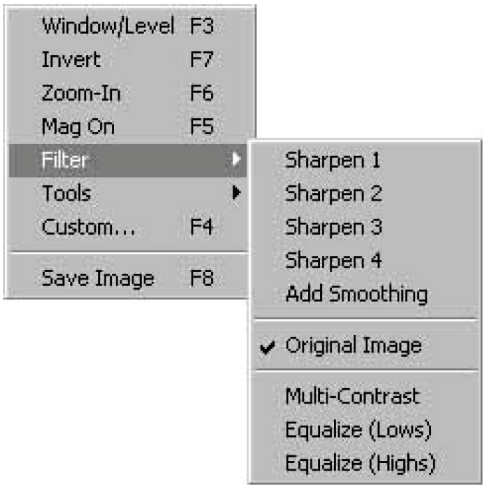


Figure 71: Filter Settings

5. Right-click the image and select **Save Image**.
6. Open the File Manager and select **SMPTE** from the list.
7. Select **Print File** and select **High (1024)** resolution.
8. Select the **OK** button to print the SMPTE test pattern on film or on a paper printer.
9. If the printed 5% and 95% patches are not sharp, adjust the printer controls so that the alphanumerics are seen clearly.
10. Print the test pattern again and repeat step 9.

7.9.3 Hard Copy Output Quality Test (Digital Only)

If your system connects to a laser printer, do this test.

Objective

To make sure that the quality of hard copy output is consistent and matches the gray scales on the display.

Frequency

Do this test or an equal test from the printer manufacturer a minimum of one time each month.

Required Test Equipment

- Densitometer
- SMPTE (Society of Motion Picture and Television Engineers) Test pattern, or test pattern that is equal, or a Phantom image with a wide range of gray scales. (Use the same image for each test.)

Procedure

1. Show the SMPTE pattern image on the display with the Window/Level value.
2. From the File Manager, print the image on a film. Make sure that the resolution is high.
3. Use the densitometer to measure the optical density at four consistent locations on the film. To record the values, use the Hardcopy Output Quality Control Form.

Data Analysis and Interpretation

1. Compare all optical density measurements to the measurements from the image of the month before.
2. When the procedure results are consistent between the display and film, use these values for your control level.
3. Record the Window/Level values and measured optical density film values.

Recommended Performance Criteria and Corrective Action

When viewed with the same window width and level adjustments used to print, the image on the film must not be lighter or darker than the image on the display. If there are important differences, have the Medical Physicist or Service Engineer inspect the contrast and brightness of the display. If the display is set correctly according to manufacturer instructions, contact the hard copy output device manufacturer for service.

When the optical densities measured at the four locations are different by more than 0.20 from the control values, make sure that the same window width and level adjustments used to create control levels are used. If differences remain, repeat the test. When the optical density differences in the repeated test are different from control levels by more than 0.20, contact the hard copy output device manufacturer for service.

7.9.4 Other Image Quality Tests

Follow these procedures to do other image quality tests for hard copy images.

High Contrast Resolution

1. Look at the high contrast (black and white) test patterns in the middle and in four corners of the SMPTE test pattern.
2. Make sure that the contrast level of the vertical and horizontal lines in the test pattern appears the same.
3. Compare the patterns from the middle to the patterns in the corners.

When there is a significant difference in the contrast levels, such as:

- Between the vertical and horizontal lines, or
- Between the middle and the corners,

Check the printer adjustments and then contact the printer manufacturer for repair.

Low Contrast Resolution

1. Look at the low contrast (gray) test patterns in the middle and the four corners of the SMPTE test pattern. These test patterns are at 1%, 3%, and 5% contrast.
2. Make sure that all test patterns are visible when using a window width of 16384 and a level of 8191.

If you cannot see any of the low contrast test patterns, check the printer adjustments and then contact the printer manufacturer for repair.

Spatial Linearity

Look at the fine line grid pattern over the complete image. Make sure that the lines in the two directions appear straight and well-defined.

Uniformity and Artifacts

Look at the film density to make sure that the test pattern background is uniform.

Display of All Information

Look at the dual border around the outer edges of the SMPTE test pattern. Make sure that all of the information in the image shows on the hard copy image.

Chapter 8: Maintenance and Cleaning

8.1 General Information About Cleaning

Before each examination, clean and use a disinfectant on any part of the system which touches a patient. Give the attention to the paddles and the image receptor.

Caution: **Do not use any hot source (like a heating pad) on the image receptor.**

Be careful with the compression paddles. Inspect the paddles. Replace the paddle when you see damage.

8.1.1 For General Cleaning

Use a lint-free cloth or pad and apply a diluted dishwashing liquid.

Caution: **Use the least possible amount of cleaning fluids. The fluids must not flow or run.**

If more than soap and water is required, Hologic recommends any one of the following:

- 10% chlorine bleach and water with one part commercially available chlorine bleach (normally 5.25% chlorine and 94.75% water) and nine parts water
- Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
- 3% maximum concentration of hydrogen peroxide solution

After you apply any of the above solutions, use a pad and apply a diluted dishwashing liquid to clean any parts which touch the patient.

Warning: **If a paddle touches possible infectious materials, contact your Infection Control Representative to remove contamination from the paddle.**

Caution: **To prevent damage to the electronic components, do not use disinfectant sprays on the system.**

8.1.2 How to Clean the Keyboard

Wipe the surfaces with a CRT wipe. If necessary, clean the keyboard with a vacuum. If liquids enter the keyboard, contact Technical Support for a replacement.

8.1.3 To Prevent Possible Injury or Equipment Damage

Do not use a corrosive solvent, abrasive detergent, or polish. Select a cleaning/disinfecting agent that does not damage the plastics, aluminum, or carbon fiber.

Do not use strong detergents, abrasive cleaners, high alcohol concentration, or methanol at any concentration.

Do not expose equipment parts to steam or high temperature sterilization.

Do not let liquids enter the internal parts of the equipment. Do not apply cleaning sprays or liquids to the equipment. Always use a clean cloth and apply the spray or liquid to the cloth. If liquid enters the system, disconnect the electrical supply and examine the system before returning it to use.

Caution: **Wrong cleaning methods can damage the equipment, decrease imaging performance, or increase the risk of electric shock.**

Always follow instructions from the manufacturer of the product you use for cleaning. The instructions include the directions and precautions for the application and contact time, storage, wash requirements, protective clothing, shelf life, and disposal. Follow the instructions and use the product in the most safe and effective method.

8.2 Routine Maintenance and Cleaning

8.2.1 Plastic Components

Inspect the Breast Shield and other plastic components frequently. If a plastic component begins to crack, replace the component before the component can not be used or becomes a danger.

Clean acrylic surfaces with one of the recommended solutions. To disinfect acrylic surfaces, use the normal hospital procedures.

8.2.2 Patient Table and DSM Console

Always use a disinfectant on the top surface of the cover after each procedure. To clean and disinfect the bottom side of the cover and the steel surface of the table, remove the cover.

Clean the table and DSM Console one time each day with a slightly damp cloth. When cleaning the system, do not spill water or drip wet cloths, tissues, or sponges as the electronic components can be damaged. If stains remain, use a cloth lightly moistened with a solution of warm water and a mild detergent solution. Clean the surfaces of the following items as described in *For General Cleaning* on page 89:

- Table Control Panel buttons
- DSM Console

8.2.3 Breast Platform Shield

To clean the Breast Platform Shield, remove the Shield from the Breast Platform.

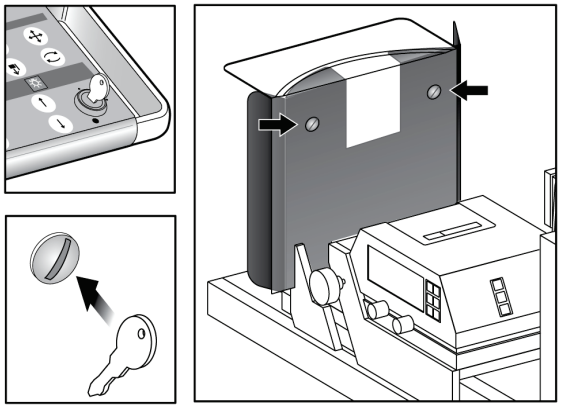


Figure 72: Breast Platform Shield Removal

Note Make sure to return the safety key to the console.

1. Remove the two breast platform shield screws that hold the shield in position. Use the safety key for the console, or a coin.
2. Slide the shield toward the top to remove.
3. Clean the shield, following the procedures in *For General Cleaning* on page 89.

To install the breast platform shield after cleaning, slide the shield into position, and fasten the shield with the breast platform shield screws.

8.3 Sterilization of Biopsy Paddles

The biopsy paddles can be steam autoclaved. Follow the instructions provided by the manufacturer of the autoclave for sterilization cycle parameters. Validate any differences from the recommended method. The biopsy paddles were tested for sterilization according to:

AAMI TIR No. 12-1994 - "Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Manufacturers."

The tests indicated that the following autoclave cycles provide a minimum sterility assurance level of 1x10-6 with the test organism Bacillus stearothermophilus:

- Gravity Displacement
- Wrapped Item
- 250 °F (121 °C)
- 15 minute exposure time
- Gravity Displacement
- Unwrapped Item
- 270 °F (132 °C)
- 10 minute exposure time

Warning: **Do not loosen any part of the paddle as this action will cancel the calibration.**

8.4 Preventive Maintenance Schedules

The *MultiCare Service Manual* has the Preventive Maintenance for Service.

Table 29: Preventive Maintenance - User

Maintenance Task Description	Each Use	Weekly	Monthly
Clean and disinfect paddle	x		
Clean and disinfect Breast Shield	x		
Check QAS Accuracy	x		
Compression Thickness Accuracy Test	x		
Check Image Quality (ACR Mammography Phantom)		x	
Ensure user displays are functioning and properly illuminated	x		
SMPTE test (Laser Printer only)			x
Perform Visual Checks			x

Appendix A: Specifications

A.1 MultiCare Table and Generator Dimensions

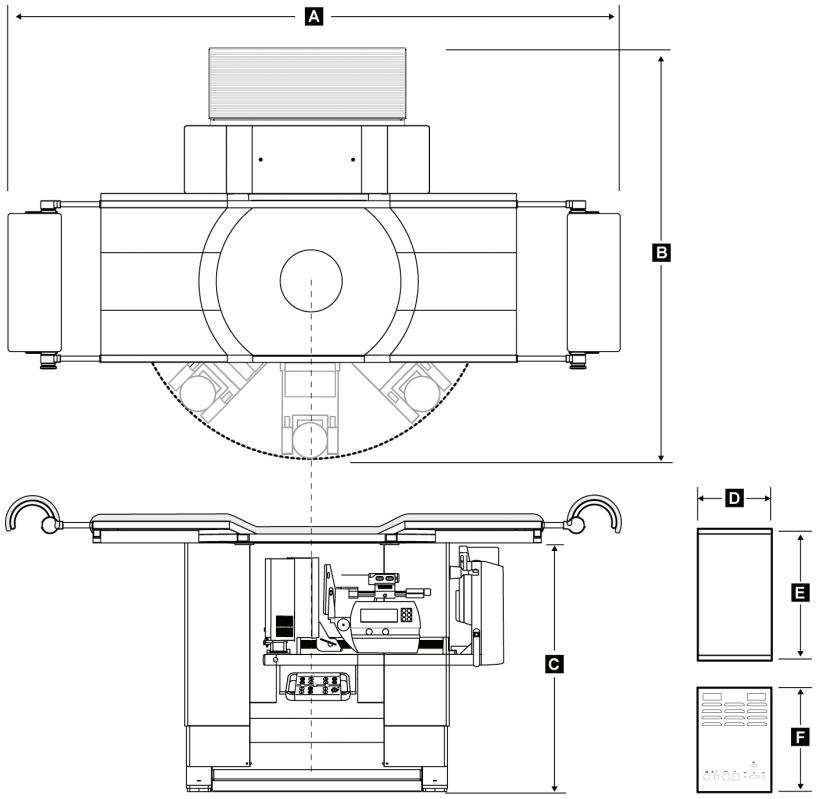


Figure 73: Table and Generator Dimensions

Table Dimensions

A.	*Width*	*290 cm (114 inches)*
B.	*Depth*	*193 cm (76 inches)*
C.	*Height*	*132 cm (52 inches) (without leveling feet)*
	Total Weight	*426 kg (940 lb)*

Generator Dimensions

D.	*Width*	*38 cm (15 inches)*
E.	*Depth*	*64 cm (25 inches)*
F.	*Height*	*51 cm (20 inches)*
	Weight	*85.3 kg (188 lb)*

A.2 System Electrical

Electrical Interface Mains Voltage	*200/208/220/230/240 VAC ±10%, 50/60 Hz Hard-wired*
Impedance	*Not greater than 0.2 Ohms at 200 VAC input. Not to exceed 0.25 Ohms at all other input voltages.*
Power Consumption	*7.0 kVA for 5 seconds (maximum)*
Standby Current	*4 A maximum*
Maximum Line Current	*35 A, 5 seconds*
Dedicated Circuit Breaker Rating	*25 A—time delay curve to allow for inrush currents, 200% overload for 7 seconds. (Requires 35 A in-house fuse for ROW [Rest of World] installation.)*
Duty Cycle	*Maximum of 15 minutes on in 1 hour, for both the Table motion and the X-ray Generator*
Leakage Currents	*Less than 5000 μA*
Protective Earth Impedance	*Less than 0.1 ohm maximum*

A.3 Table and Generator

A.3.1 System Performance

Tube Potential	*22 kVp to 34 kVp in 1 kV increments, constant potential*
Tube Current	*80 mA at 22 kVp to 28 kVp* *70 mA at 29 kVp to 34 kVp*
Focal Spot	*0.25 mm square, nominal*
Regulation Statement	*Constant potential output maintains specified kV and mAs accuracy through the nominal input range.*
SID	*88 cm—DSM Receptor*
Exposure Mode	*User selects Manual or Auto-Time Mode*
Exposure Technique Control	*User selects kV and mAs (Manual Mode only) values*
C-arm Rotation Angle	*0° to 180° continuously variable17*
Stereo Angle	*±15°*
Coordinate Measurement Device	*Digital Spot Mammography System (DSM)*
Beam Indication	*Permanent marking*
Stage X, Y, and Z display accuracy	*0.1 mm*

A.3.2 Mechanical

Table Type	*Bi-directional*
Table Surface Measurements:	
Height	*88.9 cm (35 inches) to 132.1 cm (52 inches) (See the Note below.)*
Size	*183 cm (72 inches) L, 71 cm (28 inches) W 43 cm (17 inches) leg support extensions on either side*
Work Area Light	*2 adjustable lamps mounted on C-arm, aperture lighting*
C-arm Motion	*Longitudinal: ±10.2 cm (±4 inches) Transverse: ±10.2 cm (±4 inches)*
Independent Vertical C-arm Movement	*19.7 cm (7.25 inches)*
Table Aperture Diameter	*Variable, aperture dependent*
Localization Accuracy	*±1 mm*
Maximum Lifting Patient Weight	*136.1 kg (300 lb)*
Maximum Stationary Patient Weight (non-moving):	*158.7 kg (350 lb)*

Note Table Surface Measurements are for reference only and may vary as a result of the leveling pads, and/or the table top mounting angle. The table top mounting angle is determined by the shims that are used when mounting the table top to establish the pre-loaded table angle. In all cases the table height surface travel is factory set to approximately 43.5cm /17 inches.

A.3.3 Compression

Biopsy Window Opening	*5.6 cm x 5.6 cm*
Pre-Compression	*Motorized*
Full Compression	*Manual, Handwheel driven*
Compression Release	*Motorized*
Compression Controls	*Controlled by buttons on Control Panel, or by dual pedal footswitch*
Motorized Compression Force	*133 N ±13 N (30 lb ±3 lb) Service-adjustable from 53 to 156 N ±13 N (12 to 35 lb ±3 lb)*
Motorized Compression Speed	*1 inch per second*
Compression Thickness Display Accuracy	*0.1 mm*

A.3.4 Generator

Output Rating	*2.38 kW (70 mA at 34 kV) maximum*
Ripple	*Not greater than 4% peak-to-peak*
mAs Range	*3 to 400 mAs*
Circuit Breaker Rating	*15 A*

A.3.5 X-ray Tube

Manufacturer/Model	*Varian Eimac (M-149 Insert, B-110 Housing)*
Target Material	*Molybdenum*
Diameter	*3.1 inches*
Window Material	*Beryllium*

X-ray Tube - Maximum Ratings

Tube Potential	*39 kV*
Tube Current	*80 mA*
Leakage Technique Factor	*4.0 mA @ 39 kV*

X-ray Tube - Anode Ratings

Rotation	*60 Hz, 3600 rpm*
Angle	*10°*
Heat Capacity	*300,000 heat units*
Over-Temperature Protection	*Internal sensor opens at 80 °C (175° F)* *Internal sensor closes at 60 °C (140° F)*
Heat Dissipation	*60,000 HU/minute (maximum)*
Permanent Filtration	*30 microns Mo (minimum)*
Tube Cooling	*The system automatically computes and adjusts anode current according to the manually selected kV. A 30 second standby interval is imposed between successive exposures. These control provisions limit heat accumulation in the x-ray tube and housing. Heat storage and temperatures remain below the maximum values derived from tube rating and cooling curves.*

A.3.6 Shielding

Operator	*Radiation Shield (customer supplied) between Patient Table and Handheld Console*
Patient	*The Patient Table provides the necessary radiation protection*

A.3.7 Environmental

Maximum Altitude	*2.4 kilometers (8,000 ft.) above sea level*

Operating Environment

Temperature Range	*10 to 35 °C*
Relative Humidity Range	*20 to 80%, non-condensing*

Storage Environment

Temperature Range	*-9.4 °C to +70 °C*
Relative Humidity Range	*0 to 95%, non-condensing (not for outdoor storage)*
Cushions	*The cushions must be stored at room temperature. If they are too cold, there is a possibility of damage to the foam.*

A.3.8 Technique Accuracy

kV	*The actual value does not differ by more than ±1 kV from the indicated value.*
mAs	*±5% or ±2 mAs, whichever is greater, from indicated, measured on the ground side of the tube circuit.*
mA	*Actual value does not differ by more than ±5% from the indicated value.*

A.4 Handheld Console

Communications Interface	*RS-422, differential input/output*

A.5 DSM

A.5.1 DSM Cart Dimensions

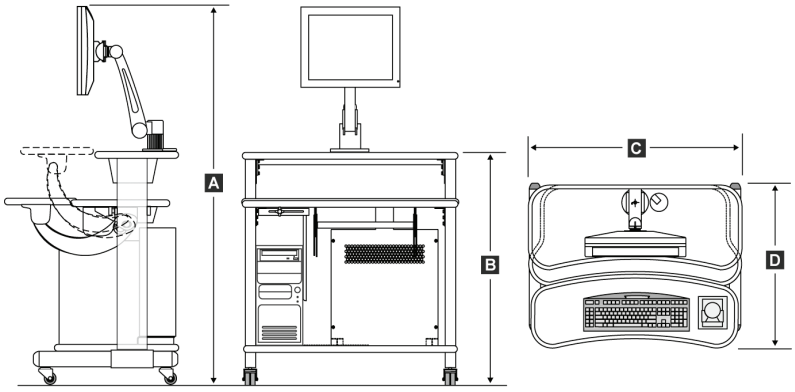


Figure 74: DSM Cart Dimensions

A.	*Maximum Height including display*	*157.5 cm (62 inches)*
B.	*Height*	*96.5 cm (38 inches)*
C.	*Width*	*91.4 cm (36 inches)*
D.	*Depth*	*71.1 cm (28 inches)*
	Weight	*117.0 kg (258 lb)—complete system*

A.5.2 DSM Cart Electrical Requirements

Mains Voltage/Current

Domestic	*120 VAC, 5A fuse*
International	*220, 230, 240 VAC, 2.5 A fuse in each leg*
Japan	*100 VAC, 5A fuse in each leg*

A.5.3 System Features

Tissue Imaging Area	*5.5 cm x 5.5 cm at the Breast Platform (4.5 cm Platform Offset)*
Near real-time image display	*512 mode - approximately 5 seconds* *1024 mode - approximately 8 seconds*
Acquisition Modes	*512 x 512 pixels (High Sensitivity)* *1024 x 1024 pixels (High Resolution)*
Image Manipulation Functions	*Window/Level (Contrast, Luminance), Invert Gray Scale, Zoom, Mag Box, Various Image Filtering functions, Measuring Tools*
System Spatial Resolution	*$\geq$ 6.5-7 lp/mm (1024 mode)*

A.5.4 Digital Image Receptor

Dimensions	
Height	*27.9 cm (11 inches)*
Width	*32.1 cm (12.66 inches)*
Depth	*12.7 cm (5 inches)*
Weight	*11.3 kg (25 lb)*
Actual Image Area	*6.8 cm x 6.8 cm at Phosphor screen*
Image Device	*CCD Sensor coupled to high-efficiency lens*
Pixel Count	*1024 (H) x 1024 (V)*
Pixel Size	*24 µm (H) x 24 µm (V)*
Digitizing Resolution	*14 bit data*
Dark Field Read Noise	*25 electrons (rms)*
CCD Operating Temperature	*-23 °C (CCD cooled to reduce noise)*
Synchronization	*Interlocked with x-ray control signal*

A.5.5 DSM Computer

Dimensions	
Height	*42.2 cm (16.00 inches)*
Width	*20.1 cm (7.9 inches)*
Depth	*48.0 cm (18.9 inches)*
Weight	*11.3 kg (25 lb) approximate (CPU, keyboard, trackball)*
Microprocessor	*Intel-based CPU workstation*
Archive Media	*DVD+R/RW, CD-R/RW*

A.5.6 DSM Display (Totoku)

Type	*Flat Panel: 46 cm (18.1 inches) monochrome LCD*
Viewing Angle	*170° (typical)*
Dimensions	
Height	*48.3 cm (19 inches)*
Width	*43.2 cm (17 inches)*
Net Weight	*9.4 kg (21 lb)*
Power Supply	
Power Consumption	*100 Watts (nominal)*
Input Voltage	*90 to 130 VAC, 220 to 250 VAC*
Resolution	*1280x1024 (minimum)*
Contrast Ratio	*600:1 (minimum)*

A.5.7 DSM Display (Barco)

Mechanical	*19 inch diagonal LCD color display. VESA standard mounting interface*
Resolution	*1280x1024 (native)*
Image Sizes	*376 mm x 301 mm or 14.8 inches x 11.8 inches*
Aspect Ratio	*5:4*
Input/Output	*HDMI/DP input for digital and VGA input for analog video*
User Interface	*6 keys (located at the bottom/front part) of display for brightness adjustment and OSD menu access. Keys are locked to avoid unintentional adjustment/menu access.*
Input Power	
Input Voltage	*100-240 Vac*
Mains Voltage Range	*90-264 Vac*
Input Frequency	*50/60 Hz*
Power Switch	*Selectable at rear of monitor*
LCD Panel Characteristics	
Active Screen Diagonal	*482.6 mm (19 inches)*
Active Screen Width	*376.3 mm (14.8 inches)*
Active Screen Height	*301.1 mm (11.8 inches)*
Contrast Ratio	*800:1 typical — 640:1 min*

A.6 Maximum Comfort Package Accessory Cart

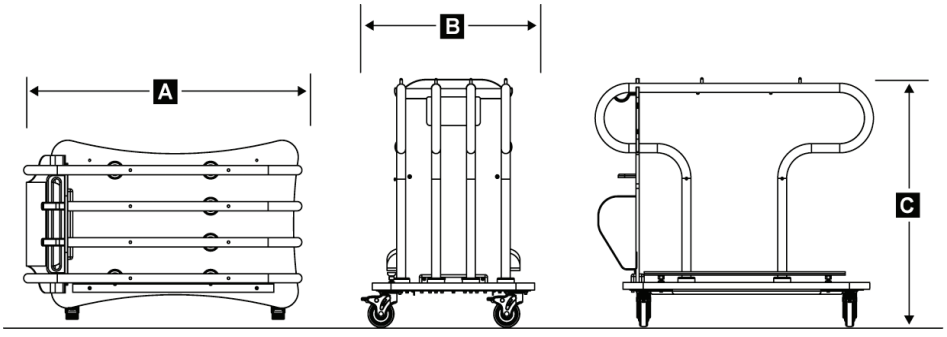
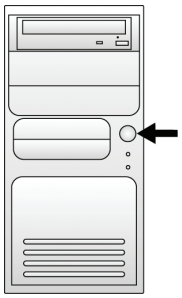
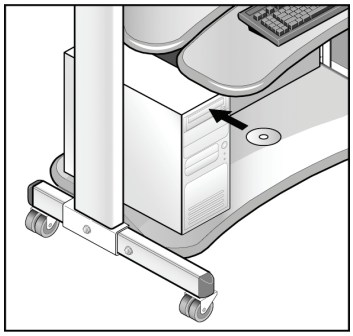
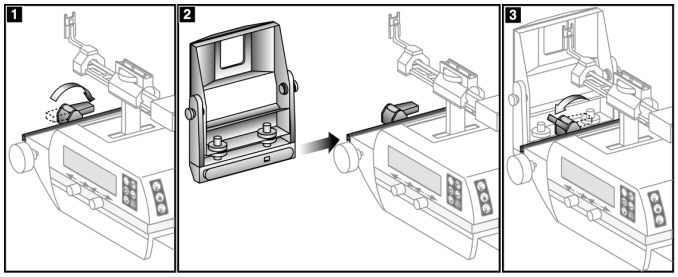


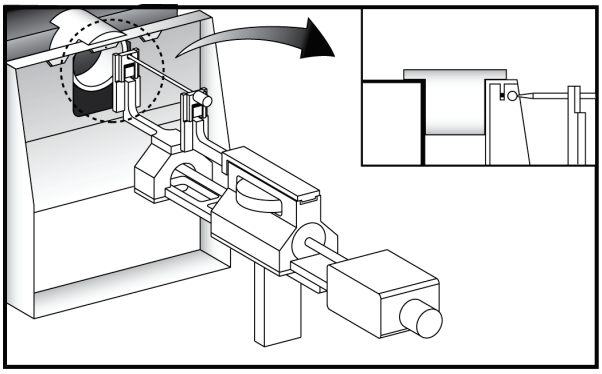
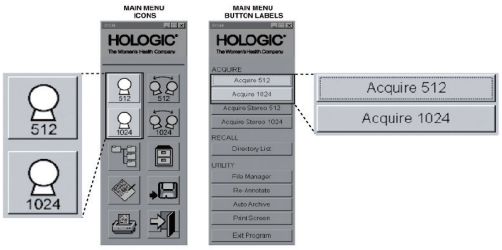
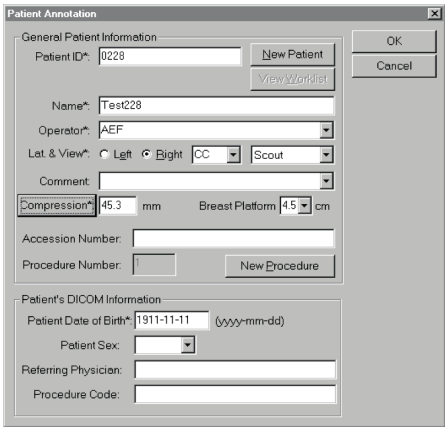
Figure 75: Maximum Comfort Package Accessory Cart Dimensions

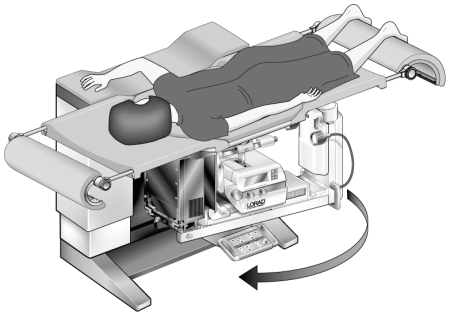
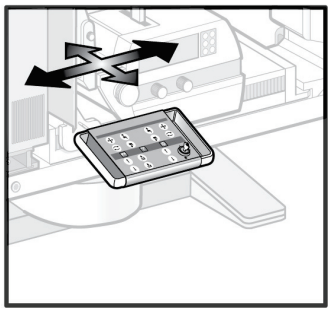
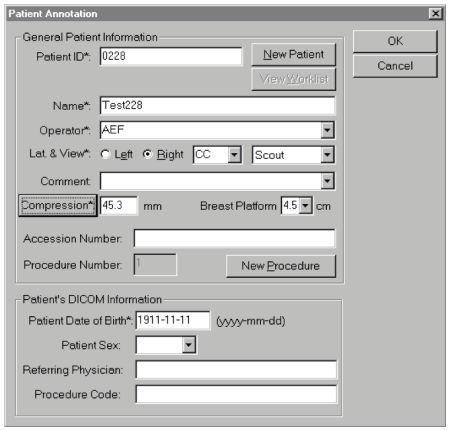
A. Width	*102.9 cm (40.5 inches)*
B. Depth	*65.0 cm (25.5 inches)*
C. Height	*94.0 cm (37 inches)*
Weight (loaded)	*70.7 kg (156 lb)*

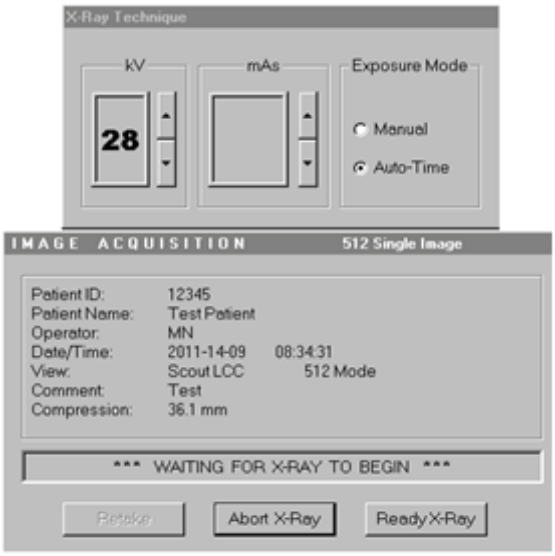
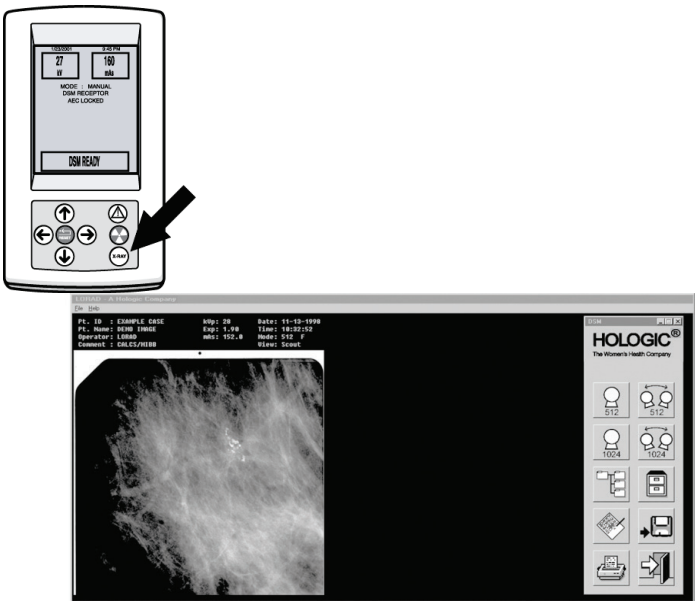
Appendix B: Recommendations

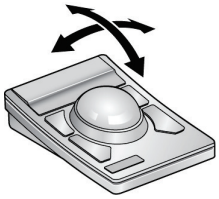
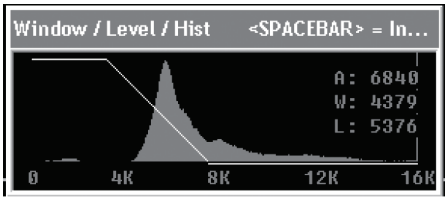
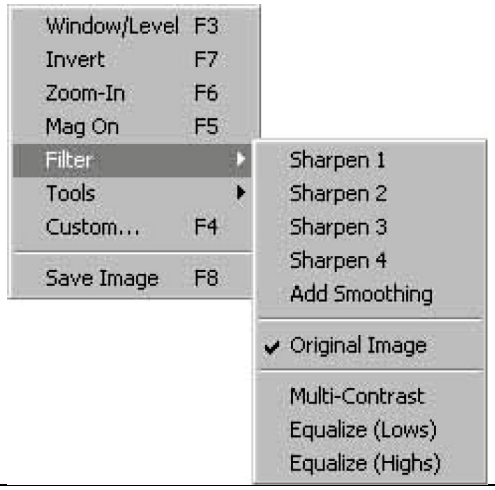
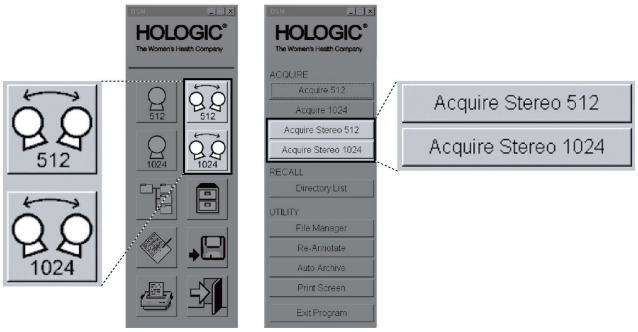
B.1 Example Sequence of Operation

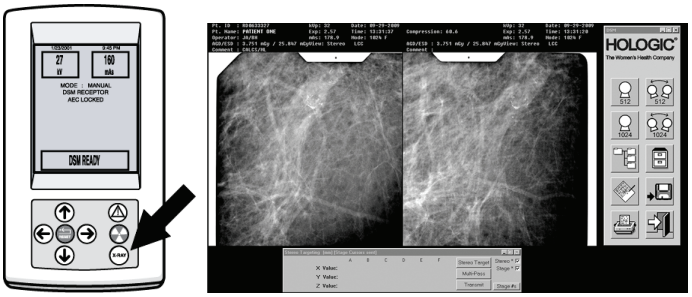
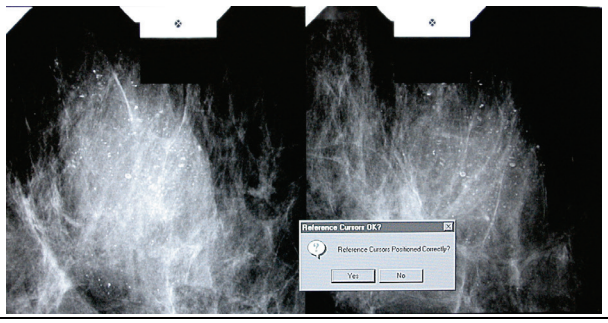
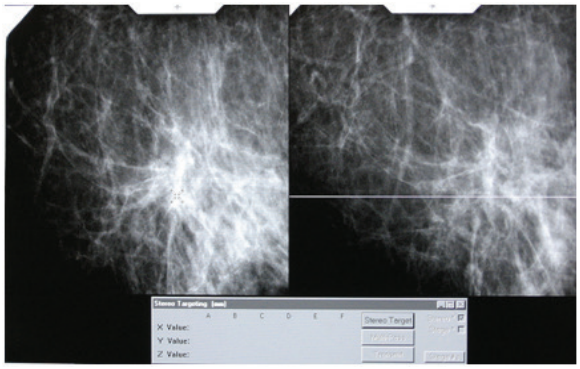
Step	Where this action is done
Turn on the DSM computer.	
Put the Archive Media in the disk drive if necessary.	
Install the biopsy paddle.	

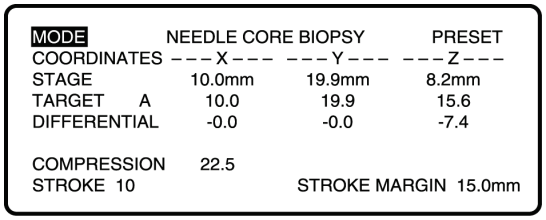
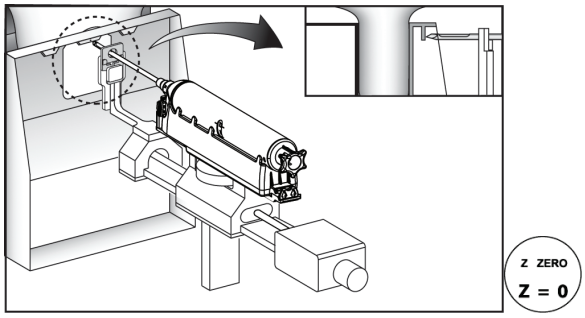
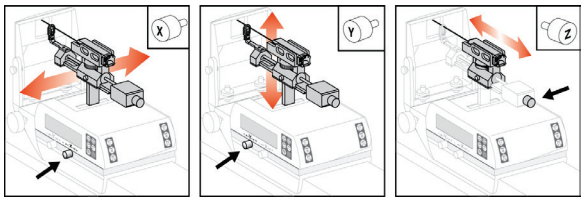
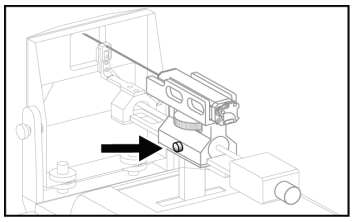
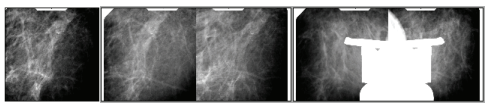
Step	Where this action is done
Perform the QA Tests.	 
Prepare for the patient. Select the Single Image Acquisition Mode.	
Complete the Patient Annotation information except the compression and breast platform fields. Do not click OK.	

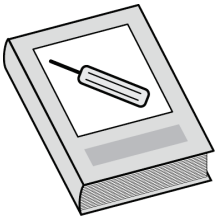
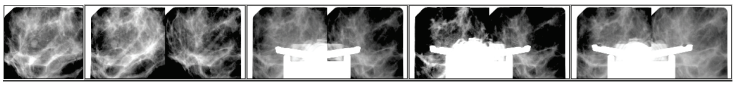
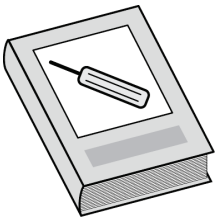
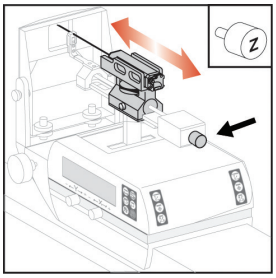
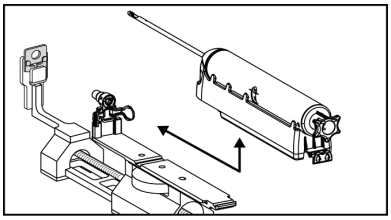
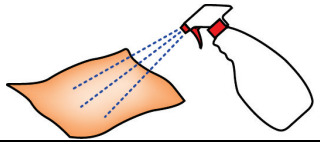
Step	Where this action is done
Position the Table, Patient, and C-arm.	 
Set the Breast Platform. Compress the Patient with the foot pedal or button on the Table Control panel. Finish the compression with the handwheel. Click the compression button on the Patient Annotation box to update the compression. Observe the breast platform information to see if a change is necessary. Click OK.	

Step	Where this action is done
Select the Exposure Technique on the DSM display.	
Acquire the Scout Image.	

Step	Where this action is done
Set the Window/Level and apply post processing.	  
Select the Stereo Image Acquisition Mode.	

Step	Where this action is done
Acquire the Stereo Pair. Select Stereo Target.	
Confirm the Reference cursors are correct.	
Target the Lesion and Transmit the target to the Stage.	

Step	Where this action is done
Check targets in the SmartWindow and Stroke, if a Needle Core Biopsy.	
Use sterile techniques and Z Zero the needle if you are not using Presets.	
Move the Stage to the first X,Y Position. Use the Z control to position the needle.	
Tighten the Z-axis lock.	
Acquire pre-fire stereo pair and confirm position.	

Step	Where this action is done
Fire the Biopsy device following the biopsy device instructions from the manufacturer.	
Acquire post-fire stereo pair to make sure that the needle is in the correct position.	
Complete the procedure following the biopsy device instructions from the manufacturer.	
Use the Z Control and remove the needle from the breast.	
Remove the biopsy device from the holder.	
Clean the System per cleaning instructions	

B.2 Technique Tables

Table 30: 512 Imaging Mode: DN Target = _____ ±500

Thickness	**kV**
2	22
3	25
4	28
4.5 (ACR Phantom)*	**28**
5	30
6	32
7	34
7.5**	34

*The 4.5 cm thick ACR Phantom is equivalent to 4.2 cm thick 50% glandular tissue and 50% fat breast.

**If the system returns an AEC error, use Manual Exposure Mode at 34 kV 240 mAs.

Table 31: 1024 Imaging Mode: DN = _____ ±500

Thickness (cm)	**kV**
2	23
3	26
4	28
4.5 (ACR Phantom)*	**28**
5	31
6	33
7	34
7.5**	34

*The 4.5 cm thick ACR Phantom is equivalent to 4.2 cm thick 50% glandular tissue and 50% fat breast.

**If the system returns an AEC error, use Manual Exposure Mode at 34 kV, 350 mAs.

Appendix C: Forms

C.1 Stereotactic QC Log Form

Stereotactic QC Log

Date	Tech Initials	Compression Accuracy Test 0.0 mm ± 1.0 mm	QAS Needle Test				Phantom Image						
			X = 10	Y = 20	Z = 30	P/F	Phantom Mfg: Serial Number: Specks	Fibers	Masses	P/F	kV	mAs	

Comments / Corrective Action

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C.2 Hardcopy Output Quality Control Form

Hardcopy Output Quality Control

Site: _____ Room: _____ Year: _____

Hardcopy Display Unit: _____ Image(s) Used for Hardcopy Output Check: _____

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Note: Circle Values Established as Control Values												
Filming Window Level												
Filming Window Width												
Hardcopy & Monitor Demonstrate Comparable Gray Scales (Yes/No)												
FILM Location #1 _____												
FILM Location #2 _____												
OD Location #3 _____												
OD Location #4 _____												
All measured Film ODs are within ±0.2 of Control Levels (Yes/No)												
Performed By												

Date: _____ **Action:** _____

_____ _____

_____ _____

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