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.

BREAST IMAGING SOLUTIONS

M-IV™ Screen-Film Mammography System
User Guide

MAN-01879 Revision 003

M-IV™

Screen-Film Mammography System

HOLOGIC®

M-IV™

Screen-Film Mammography System

Instructions for Use

Part Number MAN-01879

Revision 003

September 2014

Refer to Introduction for Manual Applicability

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Chapter 1 Introduction

1.1 System Introduction

The M-IV™ screen-film mammography system is a multiprocessor controlled, x-ray mammography system. The M-IV is a complete diagnostic system that uses standard image receptors or the HTC™ Grid system for film imaging.

The M-IV is available with DSM™ and StereoLoc® II for vertical stereotactic procedures. The StereoLoc II and the DSM are not available for use with the M-IV Mobile system.

1.2 Intended Use

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

The M-IV Mammography System is intended to produce radiographic images of the breast. Its specific intended use is for screening and diagnostic mammography.

1.2.1 Potential Adverse Effects

The following is a list of possible adverse effects that applies to mammography and applies to mammography that uses the M-IV.

- Excessive breast compression
- Excessive x-ray exposure
- Electric shock
- Infection
- Skin irritation, abrasions, or puncture wounds

1.3 Intended Use for the User Guide

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

1.4 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.)

1.5 Technical Support

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

1.6 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.

1.7 Quality Control

Do all Quality Control tests at the necessary intervals.

1.8 Installation Instructions

Installation instructions are available in the Service Manual.

1.9 User Profiles

1.9.1 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 how to operate a computer and its peripherals.

1.9.2 Radiologist

- Meets all requirements that apply to the location in which the Radiologist operates.
- Knows how to operate a computer and its peripherals.

1.9.3 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.

1.10 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

AEC	Automatic Exposure Control.
AGD	Average Glandular Dose
Collimator	Device at the x-ray tube that controls the area of the receptor that is exposed
CPT	Common Procedural Terminology
ESD	Entrance Skin Dose
FAST Paddle™	Fully Automatic Self-Adjusting Tilt Paddle
Grid	Element within the Bucky which reduces scatter radiation during exposure
IR	Image Receptor
IRSD	Image Receptor Support Device
Mag	Magnification
mA	Milliamperes
MIS	Mammography Information System
Mo	Molybdenum
MQSA	Mammography Quality Standards Act
OD	Optical Density
Rh	Rhodium
RIS	Radiology Information System
SID	Source to Image Distance

1.12 International Symbols

This section explains the International Symbols used on this system.

	Type B Applied Part
	Potential Equalization terminal
	Protective Earth terminal
	"OFF" (power)
	"ON" (power)
	"OFF" for part of the equipment
	"ON" for part of the equipment
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.
	Dangerous Voltage
	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.

1.14 M-IV Manual Set

The M-IV Manual Set contains the following documentation:

Title	P/N	Use
User Guide	MAN-01879	M-IV system user instructions
User Companion	MAN-01880	User companion manual
M-IV Site Planning and Pre-Installation Guide	MAN-00243	Directions for determining the installation requirements
Service Manual	MAN-01929	M-IV system service
Schematics	9-500-0277	Troubleshooting supplement to the Service Manual

1.15 Manual Applicability

This manual applies to M-IV Mammography Systems using Host software Version 6.2.5 or higher, manufactured after June 2010.

For systems using Host software Version 6.2.5 or higher and manufactured before June 2010, use part number MAN-00340.

For Systems using Host Version 5.4.1 only, use part number MAN-00222.

For Systems using Host Version 5.3.0 and earlier, use part number 9-500-0275.

Chapter 2
General Information

2.1 Warnings and Precautions

You must read and understand this manual completely before you use the system. Always follow all the instructions in this manual.

The Technologist must know about radiation safety. When you operate the system, you must consider the health hazards of x rays.

The users must have experience and certification in the principles and application of mammography before following the instructions contained in this manual.

Only an authorized Service Engineer must remove covers from the M-IV system. A qualified Service Engineer authorized by Hologic must perform the service.

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!

To correctly isolate the system, attach only approved accessories or options to the system. Only approved personnel can change the connections.

WARNING!

Keep a 1.5 meter safe distance between the patient and any non-patient devices.
Do not install non-patient system components (like the Workflow Manager, the diagnostic review workstation, or the hard copy printer) in the Patient Area.

WARNING!

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:	**Put the footswitches away from the patient and C-arm area to prevent any accidental footswitch operation. When the patient has a wheelchair, put the footswitches away from the area.**
Warning:	**Control the access to the equipment according to local regulations for radiation protection.**
Warning:	**This device contains dangerous material. Send decommissioned material to Hologic or contact your service representative.**
Warning:	**Keep your full body behind the radiation shield during the exposure.**
Warning:	**This system can be dangerous to the patient and the user. Always follow the safety precautions for x-ray exposures.**
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:	**Do not leave the patient during the procedure.**
Warning:	**Keep the hands of the patient away from all buttons and switches at all times.**

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

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

Caution: **Risk of data loss. Do not put any magnetic media near or on devices that create any magnetic fields.**

2.2 Radiation Safety

The radiation safety of the system meets all requirements of 21 CFR, Part 1020, and IEC 60601.

The Operator control panel contains two **X-ray** buttons. You must press both buttons at the same time for the complete period of the exposure. An audible tone sounds during the entire exposure time.

The following safety features limit the exposure time:

- Premature release of the **X-ray** buttons.
- The microprocessor pre-set backup time.
- A separate "safety" hardware backup timer.
- Generator fault detection.

2.2.1 Operator Radiation Shield

The rear of the Operator Console contains a permanently installed Radiation Shield, that protects the system operator from exposure during the procedure. The radiation shield meets requirements of 21CFR 1020 and IEC 60601-2-45.2001. The radiation shield provides a minimum of 0.5 mm of lead equivalent attenuation at 35 kV.

Note Verify that the Shield is not damaged every day before use.

The M-IV Mobile system does not have a radiation shield. The installer provides and installs the radiation shield during system installation.

2.2.2 Other Shielding

Internal shielding prevents exposure to random, direct, and scatter radiation:

- The Image Receptor Support Device shielding prevents any x rays below the breast tray.
- The tubehead shielding absorbs all x rays except for the beam that leaves through the collimation assembly.

2.2.3 Patient Face Shield

The Patient Face Shield keeps the face of the patient from the radiation field. The face shield does not provide any protection from radiation.

2.2.4 Exam Room Door Indicators

- Power On Indicator—There is a provision in the system to meet local regulations that require an X-ray System Power-On Indicator at the door.
- X-ray On Indicator—There is a provision in the system to meet local regulations that require an X-ray Exposure In Progress indicator at the door.

2.3 Mechanical Safety

The equipment meets the requirements of IEC 60601-1, UL 60601-1, and CST 22.2 No. 601.1 by these safety features:

- The C-arm rotation mechanism prevents rotation of the C-arm if electrical power is removed.
- Compression release is disabled when a localization paddle is installed.
- Motorized compression force has a limit of 200 N (45 pounds).
- All C-arm functions can operate at the same time.
  - Vertical drive
  - C-arm rotation
  - Compression up or down
  - Compression Release
  - Light field
- When 13 pounds (58 N) or more of compression force displays, vertical drive and rotation are disabled.

2.4 Emergency Off Switch

The Emergency Off Switches are found on both sides of the Gantry and on the left side of the Operator Console.

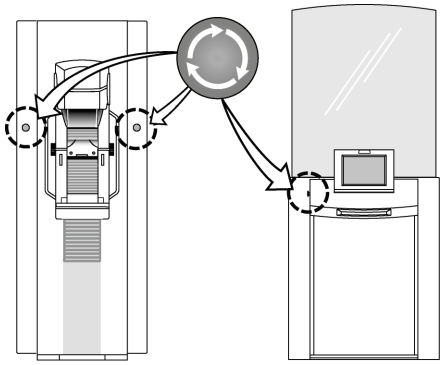


Figure 1: Location of Emergency Off Switches

Press an Emergency Off switch to remove power from the Gantry and Console. Refer to *Emergency Off Switches* on page 16 for complete information about these switches.

2.5 Remote X-ray On/Power On Indicators

- Power On Indicator—There is a provision in the system to accommodate local regulations that require an X-ray System Power-On indicator at the door.
- X-ray On Indicator—There is a provision in the system to accommodate local regulations that require an X-ray Exposure in Progress indicator at the door.

These indicators are normally installed above the door to the exam room by a certified electrician.

The relay contacts provided have a rating of:

- 10 A, 250 VAC (normally open)
- 10 A, 30 VDC (normally open)

2.6 Interlock System

The M-IV has interlocks so that an x-ray exposure is prevented unless:

- The film cassette is installed with Bucky use.
- Both x-ray buttons are pressed at the same time.

These interlocks and conditions are described next.

2.6.1 The Film Cassette Interlock

The film cassette interlock prevents the exposure for either of these conditions:

- There is no film cassette in a Bucky Device.
- The failure to remove an exposed film cassette from the Bucky Device.

2.6.2 The Early Release Interlock

Press and hold both **X-ray** buttons for the complete period of the exposure. If you release an **X-ray** button before the end of the exposure, the exposure stops and an alarm message appears.

2.6.3 C-Arm Movement Interlocks

When 58 Newtons (13 pounds) or greater of compression force is displayed, C-arm vertical drive and rotation is disabled.

2.6.4 The Automatic Compression Release Interlock

The installation of the Localization Paddle automatically disables the motorized compression release function.

2.6.5 The Image Receptor Support Device Interlock

When the Image Receptor Support Device is removed (stereotactic configurations only), the Image Receptor Support Device interlock prevents all C-arm movement and x ray release.

2.6.6 Mirror and Filter Interlocks

When the Light Field Mirror or the Filter is not put into position correctly, x-ray exposure is prevented.

2.7 Compliance

2.7.1 Compliance Requirements

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

- The electrical installation of the room meets the correct requirements.
- The equipment is used according to the instructions for use.
- Only the authorized persons perform the assembly operations, extensions, adjustments, changes, or repairs.
- The installed network and communications equipment must meet an IEC Standard.
- The complete system (network/communications equipment and M-IV) must be installed 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.**

2.7.2 Compliance Statement

The manufacturer states this device is made to meet the following requirements:

- CAN/CSA: ISO 13485:2003/ISO 13485:2003
- FDA, 21 CFR [Parts 820, 900 and 1020]
- IEC 60601-1:1988 +A1+A2:1995 +A13:1996 Medical Electrical Equipment—General Requirements for Safety
- IEC 60601-1-1:2000-12 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 60601-2-28:1993-03 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
- UL 60601-1:2003 Medical Electrical Equipment, Part 1—General Requirements for Safety
- CSA: Medical Electrical Equipment Part 1: C22.2 No. 601.1–M90—General Requirements for Safety

2.8 Label Locations

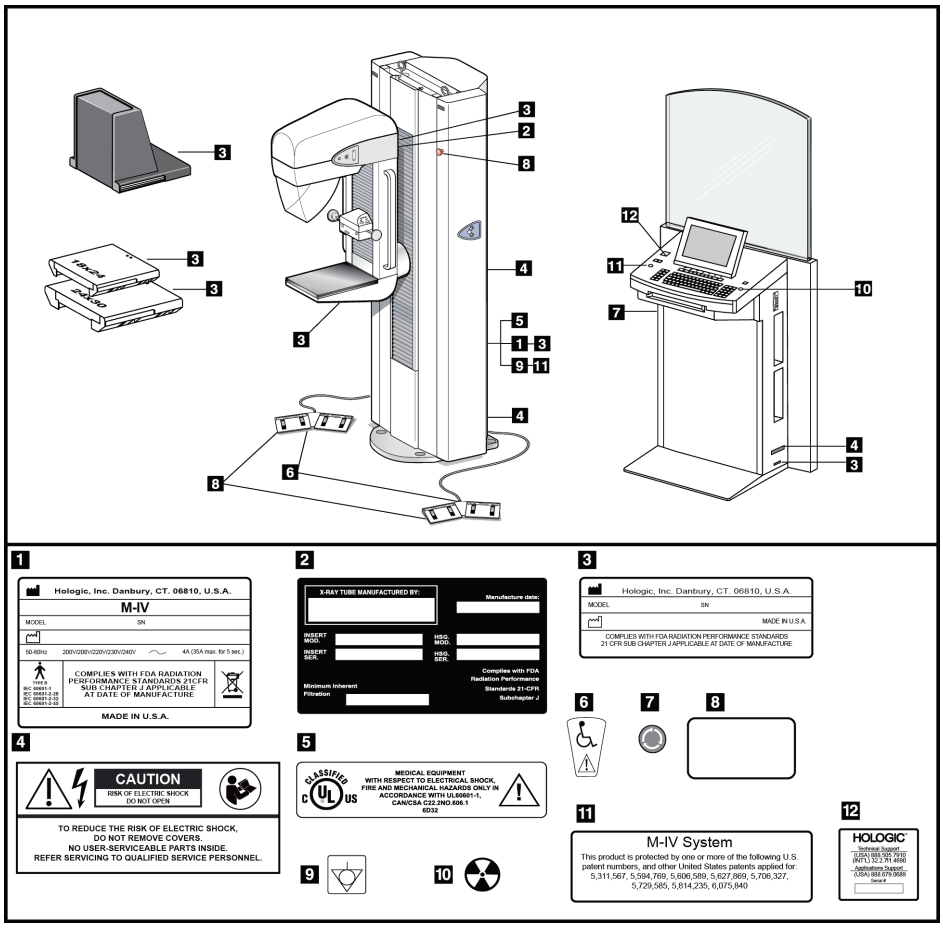


Figure 2: Label Locations

*Label 8, supplied by a vendor, refers to a Hologic® part number.

Chapter 3
System Controls, Displays, and Tests

3.1 Introduction

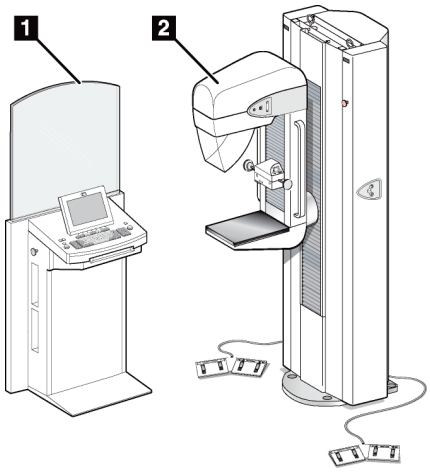


Figure 3: M-IV System Controls

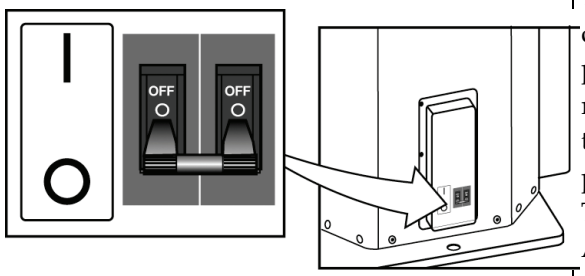
The system controls and indicators are in two main groups.

Figure Legend

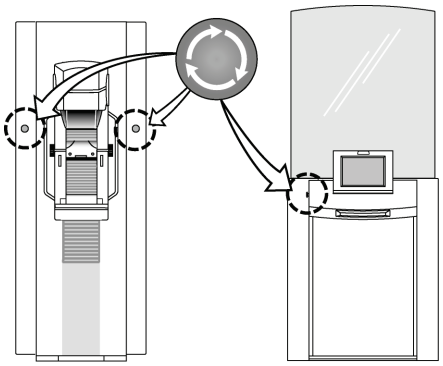
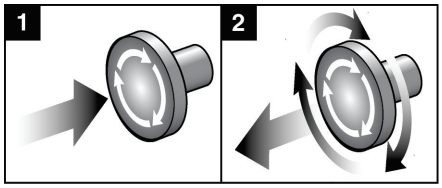
1. Operator Console controls.
2. Tubestand controls, includes control points on the Gantry and the C-arm.

3.2 System Power Controls

3.2.1 Circuit Breaker

Location of Circuit Breaker	Description
 *Figure 4: Circuit Breaker*	The circuit breaker, on the lower right corner of the back panel of the Gantry, provides protection from overload and removes power from the system. Use the circuit breaker only to remove power to the system in an emergency. The circuit breaker is normally On. Always confirm the circuit breaker status before you turn on the system each day. When the switch is in the Up position, the power is turned on. When the switch is in the down position, the power is turned off.

3.2.2 Emergency Off Switches

Location of Emergency Off Switches	Description
 *Figure 5: Location of Emergency Off Switches*	There are three Emergency Off switches on the M-IV, one on each side of the Gantry and one on the Operator Console. To remove the power to the system immediately, press any Emergency Off switch. After you have used the Emergency Off switch, to reset the switch, turn the switch by one-quarter turn in the directions of the arrows. Remove the patient from the system, then press the On button ⊙ on the console to restart the system.  *Figure 6: Operation of an Emergency Off Switch*

3.3 The Operator Console

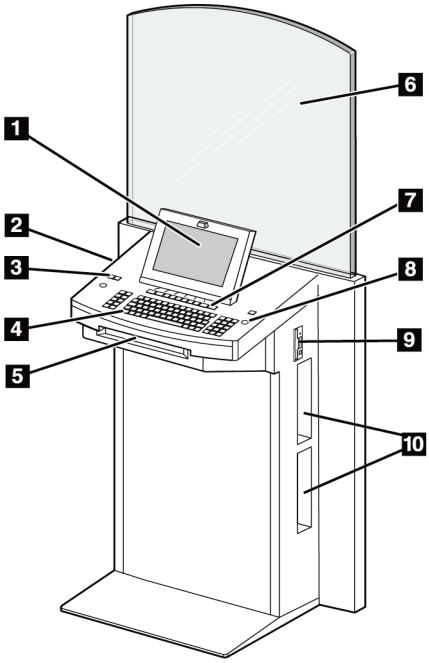


Figure 7: The Operator Console

Figure Legend

1. Flat Panel Display
2. Emergency Off Switch
3. Power Buttons (On/Off)
4. Keyboard
5. Auto Film ID
6. Radiation Shield
7. Exposure Controls
8. X-ray Buttons
9. Film Cassette Storage

3.4 The Tubestand

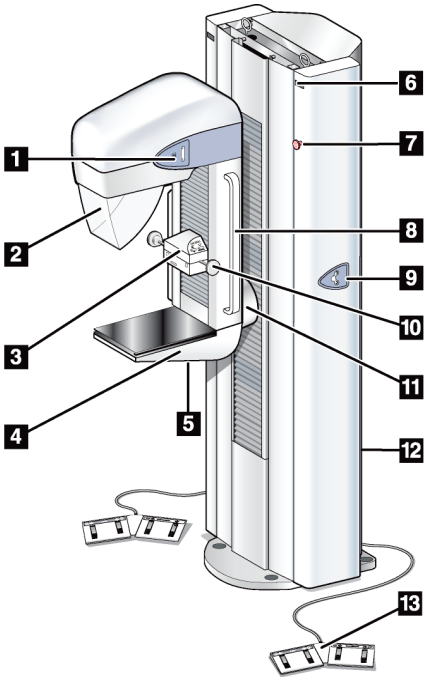


Figure 8: The Tubestand

Figure Legend

1. Tubehead
2. Face Shield
3. Compression Device
4. Image Receptor Support Device
5. AEC Position Selector
6. C-Arm Angle LED (both sides)
7. Emergency Off Switch (both sides)
8. Patient Handles
9. C-Arm Rotation Switches (on both sides of the Gantry)
10. Compression Handwheels
11. C-Arm Controls
12. Circuit Breaker
13. Footswitches

3.5 Tubestand Controls and Displays

3.5.1 The Gantry Controls and Displays

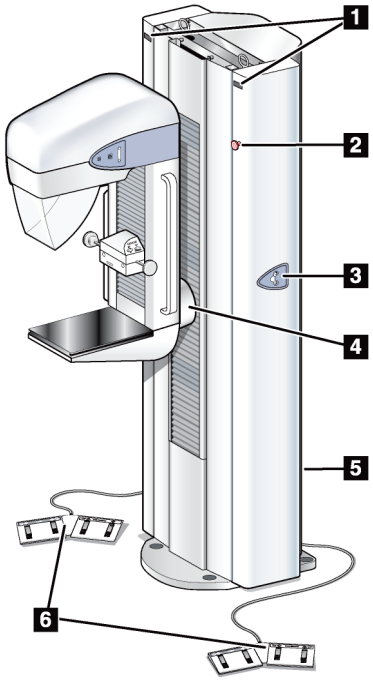


Figure 9: M-IV Gantry

Figure Legend

1. The C-Arm Angle LED display on each side displays the C-arm angle.
2. The Emergency Off switches on each side immediately remove power from the system.
3. The Rotation Switches on the Gantry (both sides) rotate the C-arm.
4. The C-Arm Pivot Tube rotates the C-arm.
5. The Circuit Breaker is found on the back of the Gantry.
6. The footswitches activate C-arm and Compression Device Movement.

3.5.2 C-Arm Controls and Displays

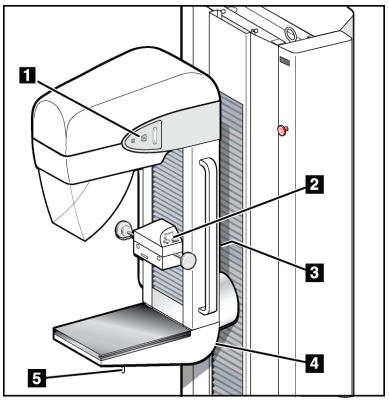


Figure 10: Tubehead Controls

The **C-arm Controls** are on the Tubehead, the Compression Device, the C-arm Side Rails, and the rear of the Image Receptor Support Device.

The **Tubehead Controls** on each side of the x-ray tube side covers provide the Collimator Override, the C-Arm Rotation, and Light-field functions.

Figure Legend

1. Tubehead Controls
2. Compression Device
3. Rear of the C-Arm Side Rails
4. Rear of the Image Receptor
5. AEC Position Lever

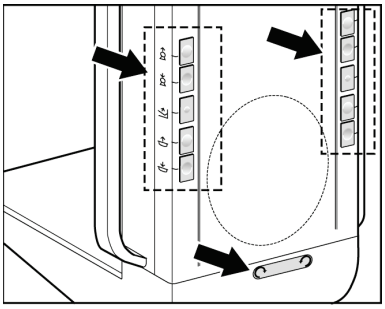


Figure 11: C-Arm Push-button Controls

The rear edges of the *C-Arm Side Rail* contain recessed push-button controls for motorized compression and C-arm movement. The rear of the *Image Receptor* has an additional C-Arm Rotation switch.

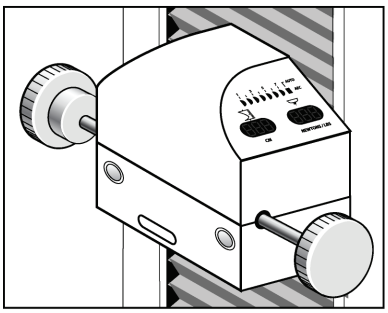


Figure 12: Compression Device

The Compression Device contains AEC Sensor Position LEDs, and displays the compressed breast thickness and the force. The Handwheels allow manual compression control to position the patient and apply final compression force.

Note The system senses the type of image receptor and compression paddle installed, and correctly adjusts the thickness display.

3.5.3 Compression Device Controls and Displays

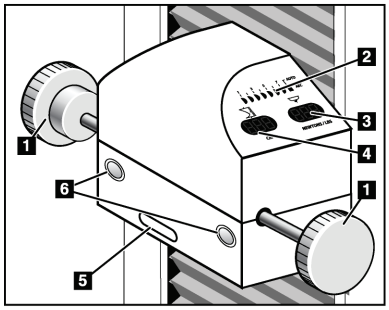


Figure 13: Compression Device Controls and Displays

Figure Legend

1. Compression Handwheels
2. AEC Sensor Position Display.
3. Compression Force Display indicates the compression force through the range of 10 pounds to 67.4 pounds (44.5 N to 300 N) in 1 pound (4.4 N) steps.
4. The Compression Thickness Display indicates the thickness from 0 and 15 cm above the image receptor in 0.1 cm steps.
5. Compression Paddle Sensor Receptacle.
6. Compression Paddle Docking Sleeves.

3.5.4 Dual Function Footswitches

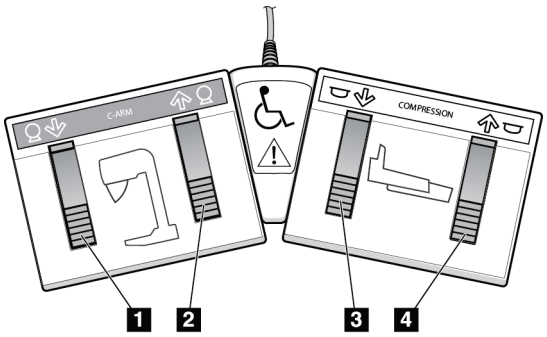


Figure 14: The Dual Function Footswitch

The system has two footswitches for C-arm and Compression Up/Down movement. Place the footswitches so that you have access from either side of the C-arm.

Figure Legend

1. C-Arm Down
2. C-Arm Up
3. Compression Down
4. Compression Up

Warning:

Put the footswitches away from the patient and C-arm area to prevent any accidental footswitch operation. When the patient has a wheelchair, put the footswitches away from the area.

3.6 How to Turn the System On and Off

3.6.1 Procedure for Startup

3.6.1.1 Pre-Startup Procedures

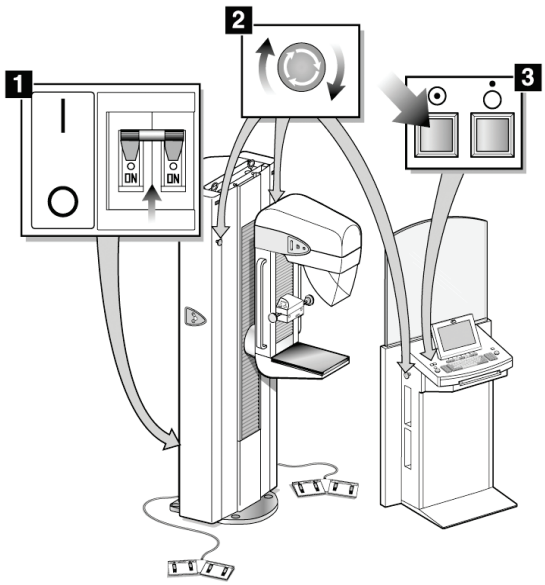


Figure 15: Startup Sequence

1. Make sure that the circuit breaker is turned On (item 1).
2. Reset all Emergency Off switches (item 2).
3. Inspect for system damage.
4. Remove any obstructions to the Operator view or C-arm movement.

3.6.1.2 Startup Procedure

Press the Power On button on the Operator Console (item 3) in the Startup Sequence figure.

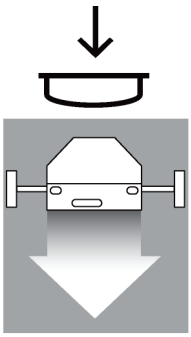
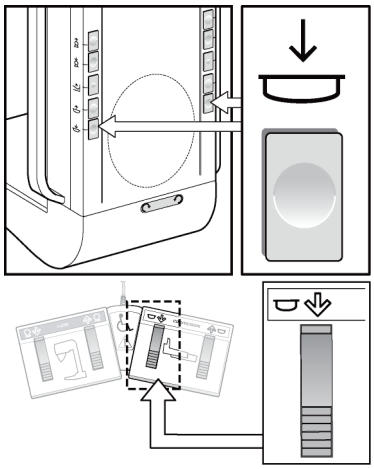
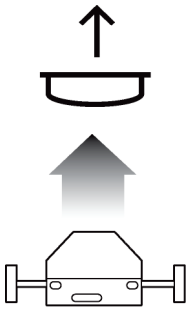
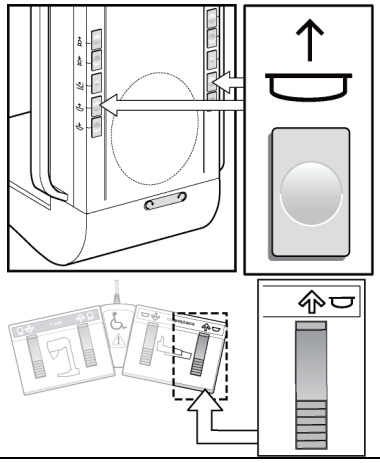
3.6.1.3 Post-Startup Procedures

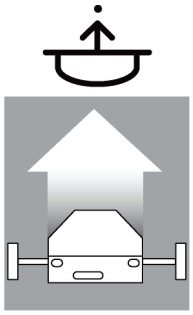
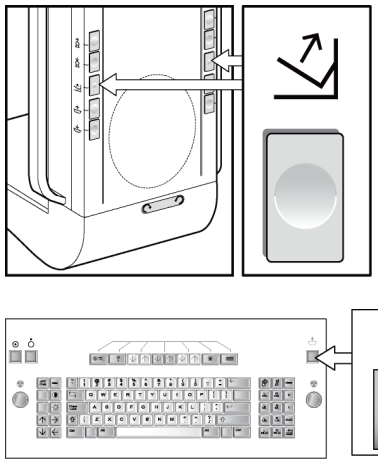
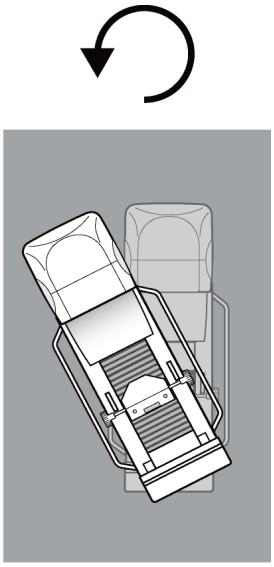
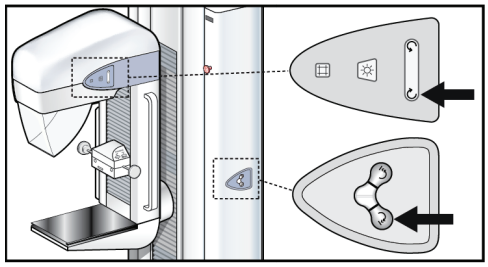
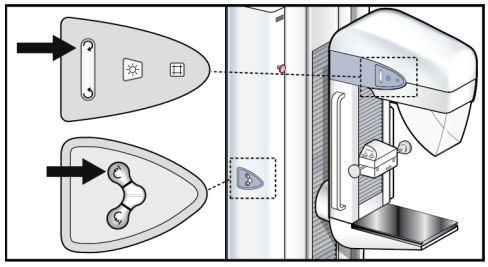
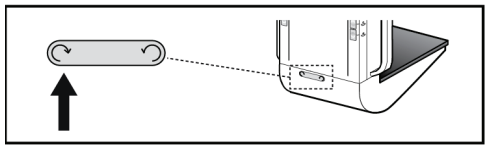
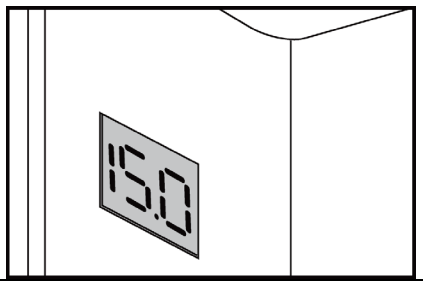
After the system is started, perform the Functional tests. Refer to *Perform the Functional Tests* on page 22.

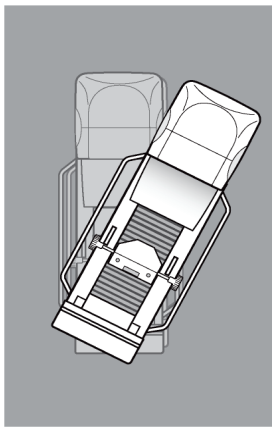
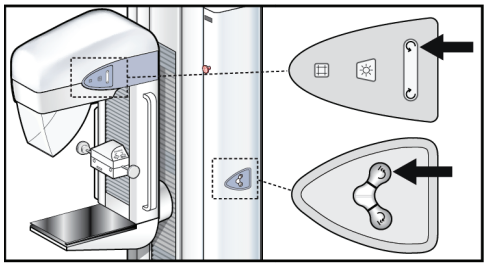
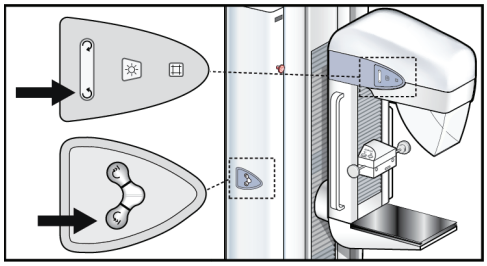
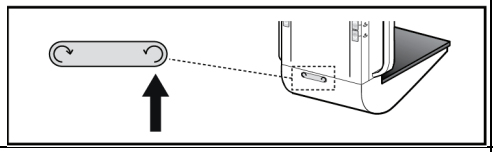
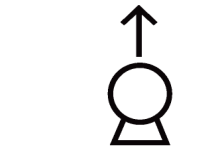
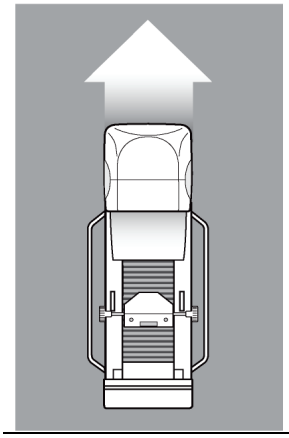
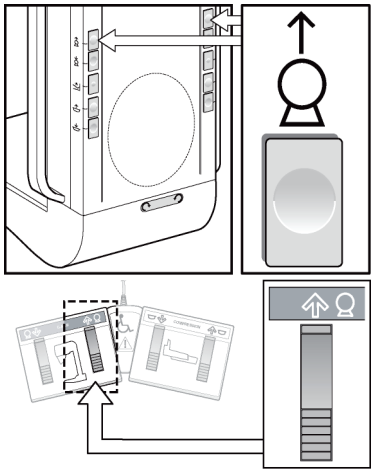
3.6.2 How to Turn the System Off

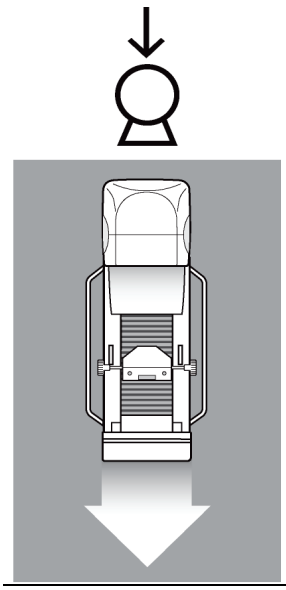
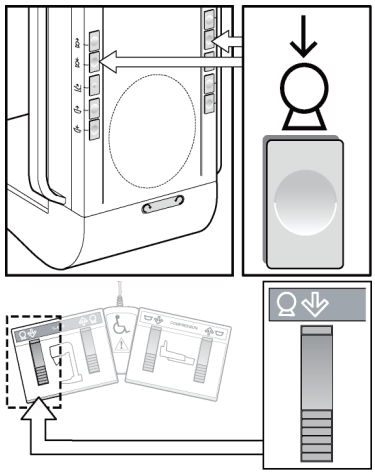
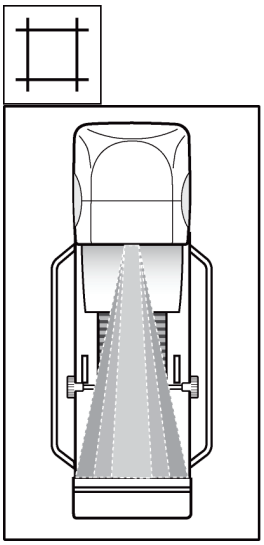
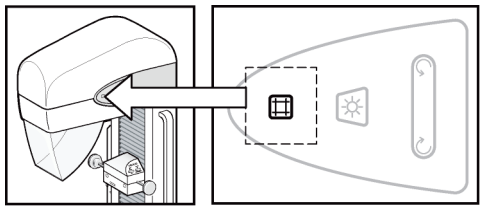
Press the Off button on the Operator Console. Do not normally use the Circuit Breaker or Emergency Off switches to turn off the system.

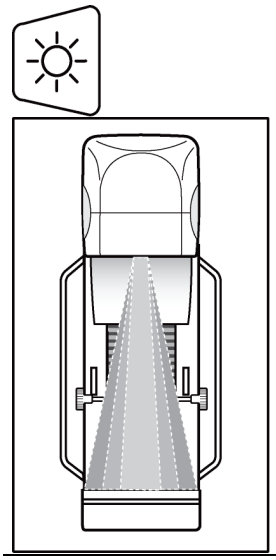
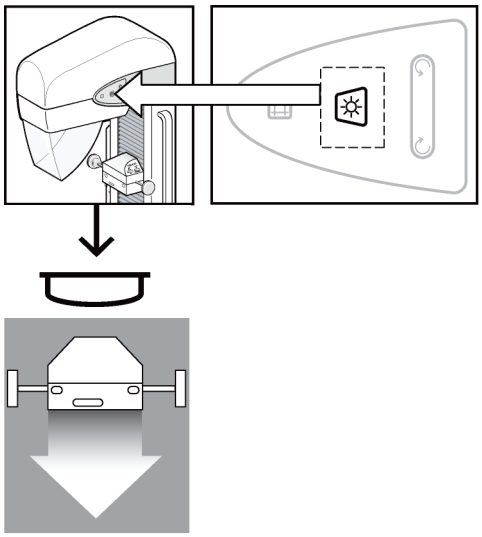
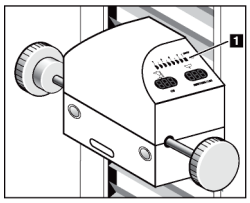
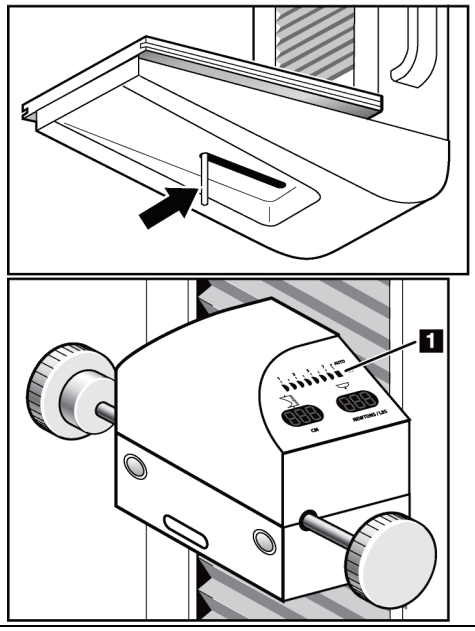
3.7 Perform the Functional Tests

Compression Down 		Press a button and confirm the system: • Engages the compression brake • Illuminates the light field lamp • Lowers the Compression Device *Note… The compression brake remains engaged until compression release is pressed.* Confirm that Motorized compression down movement automatically stops: • When the button is released • When the compression reaches the compression down force limit • At the lower compression travel limit
Compression Up 		Press a button, and confirm the system: • Lifts the Compression Device • *Does not* release or activate the compression brake Confirm that Motorized compression up movement automatically stops: • On release of the button • When the Compression Device reaches the upper compression travel limit

Compression Release 	 	When the system has at least 53 N (12 lb.) of compression, press a release button, and confirm the system: • Releases the compression brake. • Lifts the Compression Device a preset distance. *Note… When a localization paddle is installed, the system disables all compression release buttons and automatic compression release, if enabled. Use the compression up buttons to release the patient.*
Counterclockwise C-arm Rotation 	  	Press a button and confirm: • The C-arm rotates left. • The rotation stops on the release of the button. • When compression force of 58 N (13 pounds) or greater is applied, C-arm movement is disabled. • The displays of C-arm Angle Rotation reflect the changes in rotation. • When the C-arm rotates to the left, the display changes to a more negative reading. 

Clockwise C-Arm Rotation  	  	Press a button, and confirm: • The C-arm rotates to the right. • When compression force of 58 N (13 pounds) or greater is applied, C-arm movement is disabled. • Confirm that the C-arm Angle Rotation Displays on the Gantry reflect the changes in rotation. • When the C-arm rotates to the right, the display changes to a more-positive reading.
C-Arm Up  		Press this button and confirm: • The Motorized C-Arm Up movement automatically stops on the release of the button or when the upper C-arm travel limit is reached. • When compression force of 58 N (13 pounds) or greater is applied, C-arm movement is disabled.

C-Arm Down 		Press the button and confirm: • The Motorized C-Arm Down movement automatically stops on the release of the button or when the lower C-arm travel limit is reached. • When compression force of 58 N (13 pounds) or greater is applied, C-arm movement is disabled.
Collimator Override 		The button moves the collimator through the calibrated x-ray fields that are available. 1. Press the button: 2. Press the Light-Field Lamp button to show the x-ray field. 3. Press the Collimator Override button and confirm the collimator device changes the size of the x-ray and light-field. 4. Change the paddle to a different size and confirm that the collimator changes the light-field to the correct size in Automatic mode. 5. Change the size of the Bucky and confirm that the light-field changes to the correct size in either mode. Automatic or Manual collimator mode is selected in Setup. *Note… the collimation override does not allow the size of the field to be larger than the size of the attached Image Receptor.*

Light Field Lamp 		Press the **Light Field Lamp** button and confirm: • The button illuminates the light field lamp for approximately 30 seconds. • The Light Field Lamp automatically illuminates when a **Compression Down** button is pressed.
AEC Position 		1. Change the AEC position with the AEC Sensor handle under the Image Receptor Support Device. 2. Confirm the position indicator display (item 1) matches the current position.

3.8 Operator Console Keypads

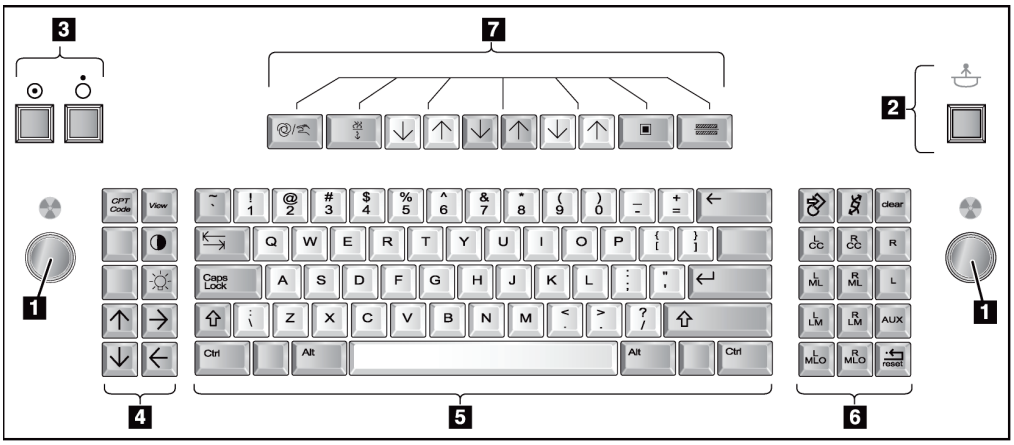


Figure 16: Operator Console Keys

Figure Legend

1. X-ray Exposure Buttons (2)
2. Compression Release Button
3. On And Off Buttons
4. Function Keypad
5. Keyboard
6. View Keypad
7. Exposure Technique Keypad

3.8.1 The Keyboard

The keyboard is used to enter patient and Technologist data and other general information. Some key caps are different if required by the language.

Note

Two command keys: Ctrl and Alt are not used. Press the Shift and Clear keys at the same time to cancel the Auto Film ID function. When the CAPS LOCK is on, the label "CAPS" appears in the upper right corner of the Run Mode screen.

3.8.2 Functional Keys

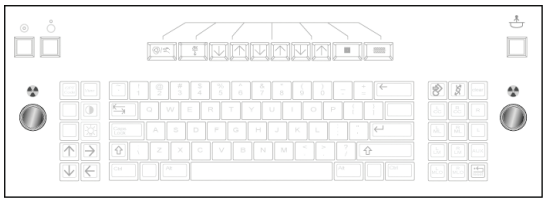
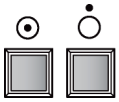
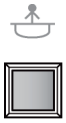


Figure 17: Functional Keys



Power Buttons. Turns the system On ⊙ or Off ○.



Compression Release button. Releases the compression motor brake and raises the compression device approximately 10 cm.

X-ray buttons. One on either side of the Control Panel. Press and hold both for the exposure time.

Contrast key (display only). Makes the screen brighter. Press and hold with the Shift key makes the screen darker.

Light Field Lamp key. Illuminates the light field lamp for approximately 30 seconds.

Reset key. Clears the alert message and resets the system.

3.8.3 Navigation and Data Entry Keys

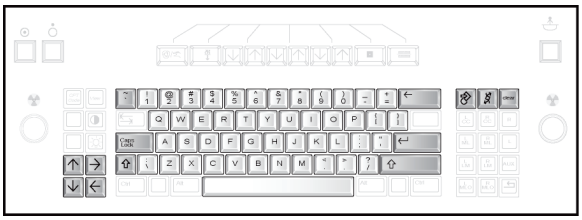
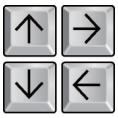


Figure 18: Navigation and Data Entry Keys



Arrow keys. Moves the highlight on the screen as shown by the arrow.

Change key. Scrolls through data field options.

Clear key. Clears the patient and Tech ID information, moves the cursor to the Patient ID field, and resets the exposure techniques to default values.

Run/Setup key. Selects Run and Setup mode screens.

3.8.4 The Exposure Technique Keypad

Use the Exposure Technique keypad above the keyboard to set the exposure parameters.

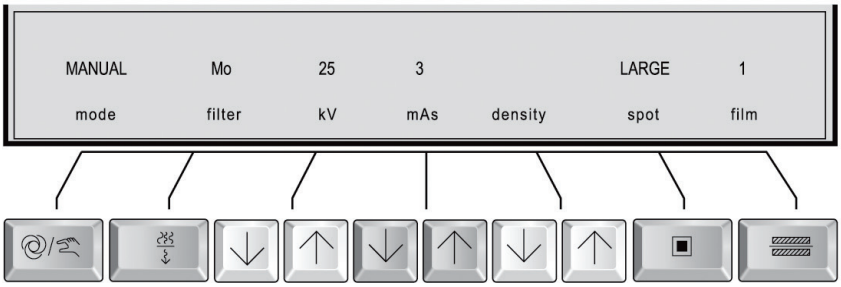
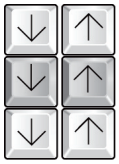


Figure 19: The Exposure Technique Keypad

Mode key. Changes Exposure Mode (Manual, Auto-Time, Auto-kV, Auto-Filter)

Filter Change key. (Mo or Rh)



kV set keys. Increases or decreases kV (Manual, Auto-Time Modes only)

mAs set keys. Increases or decreases mAs (Manual Mode only)

Density Adjustment keys. Increases or decreases film density for AEC modes (Auto-Time, Auto-kV, Auto-Filter only)

Change Focal Spot key. (Large or Small)

Screen-film Combinations key. Selects one of three film types calibrated by a Service Engineer for AEC modes.

3.8.5 The CPT and View Keys

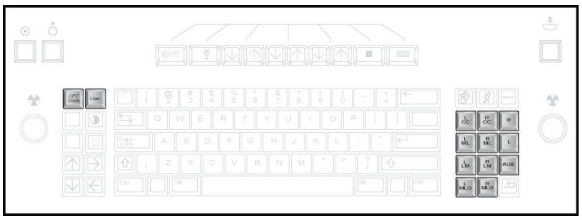


Figure 20: CPT and View Keys

CPT Code key. Scrolls through scheduled exam CPT codes when the cursor is in the CPT field. Use in the CPT Code screen.

View key. Scrolls through available exam views on the Run screen after a CPT code is entered.

Mammography View keys. Selects a clinical view label in the Run Screen View Field.
The eight most common mammography views have specific keys.

3.8.6 How to Use the Mammography View Keys with AUX, R, and L Keys

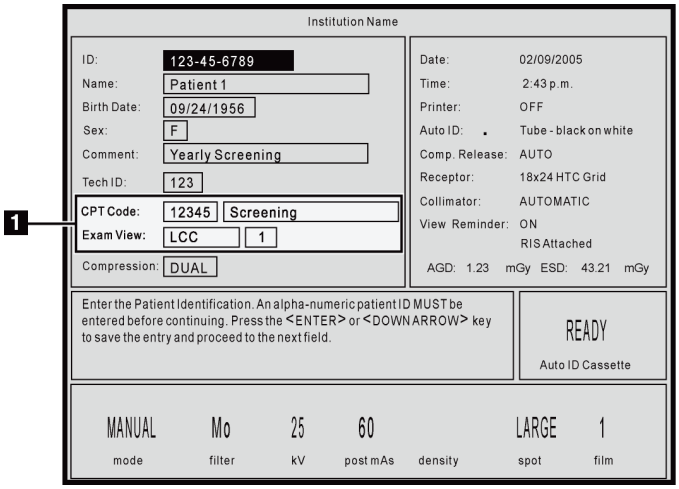


Figure 21: Run Screen that shows a Selected View (#1)

3.8.6.1 How to Use the AUX Key for QC Tests

Press **AUX** without a view in the view field to select the Phantom label. PHANTOM appears in the view field.

3.8.6.2 How to Use the AUX Key with a Displayed View

To add "roll" view position as a suffix to the views displayed in the view field, press **AUX** to scroll through the following:

RL	Rolled Lateral
RM	Rolled Medial
ID	Implant Displaced

3.8.6.3 How to Use the AUX Key with R and L Keys

To select a view that is different from the eight common views:

1. Select the lateral prefix:

Figure 22: Right

Figure 23: Left

2. Press **AUX** to scroll through the clinical views:

ID	Implant Displaced
SIO	Superlateral to Infermedial Oblique
LMO	Lateromedial Oblique
FB	From Below
TAN	Tangential
XCCL	Exaggerated Caudal
CV	Cleavage
AT	Axial Tail

3. Press the **Enter** key to complete the clinical view selection.

3.8.6.4 Results of Different Key Combinations in the View Field

Sample View Field Displays after using View key combination

View	AUX	View + AUX	R/L + AUX	Magnification Table
R CC R ML R MLO	PHANTOM	L CC **RM** L CC **RL** L CC **ID**	L **ID** L **SIO** L **LMO** L **FB** L **TAM** L **XCCL** L **CV** L **AT**	View = R**M** **M**L L**M** CC View + AUX= L**M** **C**C RL R/L + AUX = L**M** XCCL L**M** CV

Note

When the magnification table is on the image receptor support device, the letter "M" appears after the lateral identification. For example, R**M** MLO is a Right Magnification Mediolateral Oblique view.

Chapter 4
The User Interface

4.1 The Startup Screen

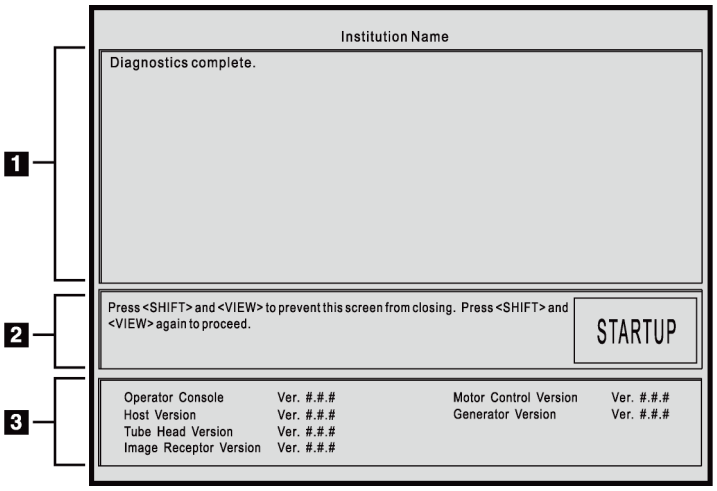


Figure 24: Startup Screen

The Startup screen appears when the system is turned On.

Figure Legend

1. The **Information Pane** displays all startup information, prompts, and error messages.
2. The **Message Pane** displays messages and reports system status.
3. The **Subsystem Report Pane** displays version information about the system subprocessors.

4.2 The Run Screen

4.2.1 The Components of the Run Screen

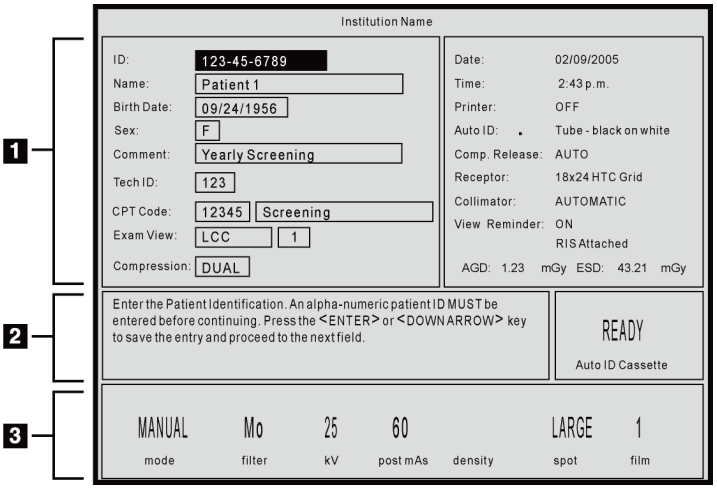


Figure 25: The Run Screen

The Run screen appears after the startup is done, accepts the patient and exposure information, and displays the device configuration information and status messages.

Figure Legend

1. Setup Pane
2. Message Pane
3. Exposure Technique Pane

4.2.2 The ID Column on the Run Mode Screen

Press the **Clear** key 

to clear the information in the ID fields.

1. The keyboard enters information in the ID Fields. The **Change** key  selects an option.
2. The **Enter** key saves the information and moves to the next field.

4.2.3 The CPT Code Field

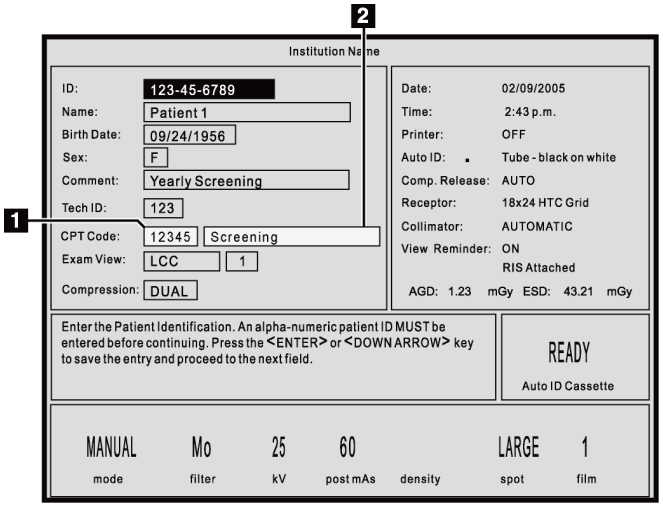


Figure 26: CPT Code Field

Figure Legend

1. The **CPT Code** field displays the Billing Codes for the scheduled exam.
2. The **Exam Description** field displays the name of the exam defined by the billing code in the CPT Code field.

The CPT Code key 

scrolls through the scheduled CPT Codes. The Change key  scrolls through the preset CPT codes. The Enter key stores the CPT Code, up to a maximum of 10 codes for a patient. The Exam Description field and CPT Codes are preset in the **Additional Setup>CPT Setup** Screen. When you enter a CPT Code with the keyboard, you must also select an Exam View.

4.2.4 Automatic Entries in the Exam View Field

When a CPT Code is entered, the first selected view appears (item 1 in the figure).

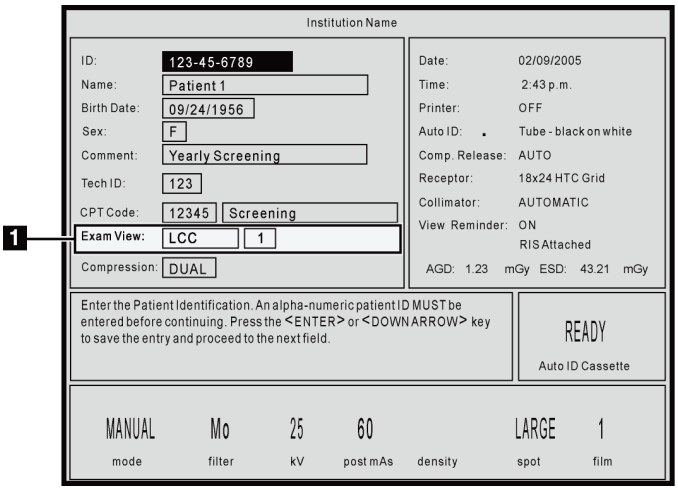


Figure 27: Exam View Field

Press the View key 

to scroll through remaining views for that CPT Code. The views in the field appear bright when "Selected" and dim when "Optional".

4.2.5 Add entries in the Exam View Field

To add an exam view that is not preset:

1. Select the **Exam View** field.
2. Press a **Mammography View** key or use the **Change** key  to scroll through the views.
3. Press the **Enter** key to select the exam view for the patient.

4.2.6 The Exam View Count Box

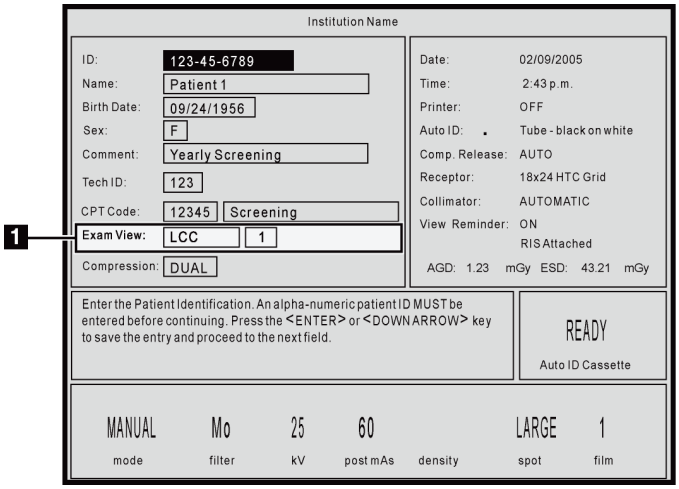


Figure 28: Exam View Count Box (Second Box in Field)

The Exam View Count box (item 1 in the figure), shows the total exposures for the view. You cannot enter any information in this field.

4.2.7 The View Reminder

The view reminder prevents an exposure until an exam view is selected. Use the Setup screen and set the View Reminder "On" (enabled) for clinical examinations. Set the reminder to "Off" to perform QC, or calibrate the unit.

4.2.8 The Compression Field

Motorized compression has three force modes:

- **Pre Compression**. This setting applies the initial motorized compression force to position the breast.
- **Full Compression**. This setting applies full motorized compression force.
- **Dual Compression**. This setting applies pre-compression the first time you press a Compression Down control. Each additional press applies additional compression force until the full user-selected compression force value is reached.

To change the compression force mode:

1. Select the **Compression** field.
2. Press the **Change** key to scroll through the three options.

4.2.9 The Exposure Technique Fields

The Exposure Technique Fields display each exposure technique with its preset default value.

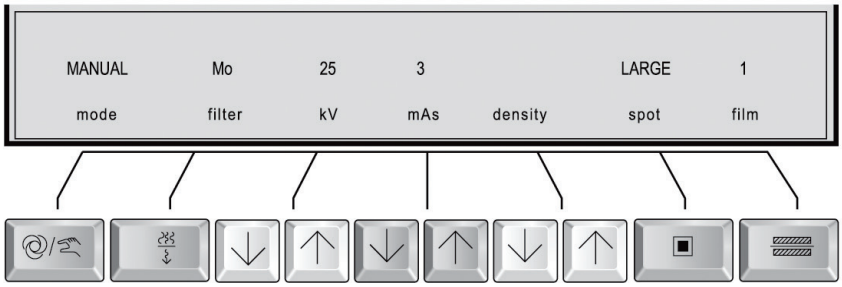


Figure 29: Exposure Technique Fields and Related Keyboard Keys

4.2.9.1 The Mode Field

Press the Mode button to scroll through the available modes. When you install a Magnification Table, the Mode field says "MAG".

4.2.9.2 Exposure Techniques Options

Press the exposure technique key to change the selection. (Refer to *The Exposure Technique Keypad* on page 29.)

4.2.10 The Status Column

These fields display the installed devices, the peripheral device status, and the current date and time. You cannot change the Status Column fields (item 1 in the figure) from the Run screen. Change these fields in the Setup Mode, or change the type of devices installed on the system. The printer field displays the status of an optional label printer.

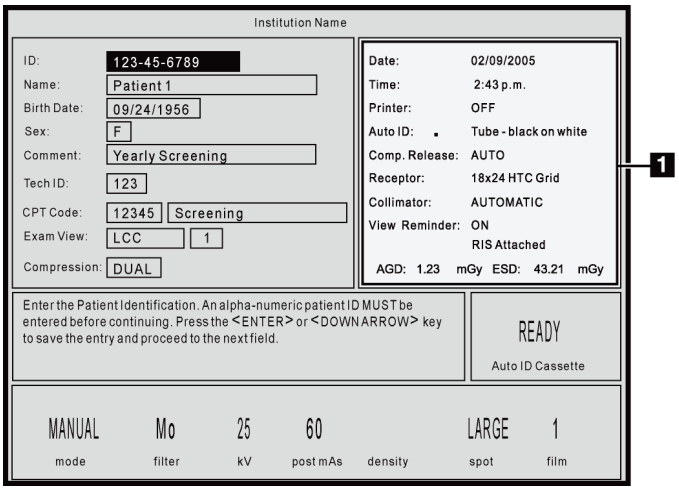


Figure 30: Status Column

Note

When a localization paddle is installed, the automatic compression release function is disabled and the system enters Locked-Out mode. The Comp. Release field displays LOCKED-OUT. Use a Compression Up button or footswitch for release.

4.3 The Setup Screen

Press the **Run/Setup** key to change from the Run screen to the Setup screen. Use the Setup Mode to set the exam and exposure default values. Those values appear on the Run screen when you turn on the system. The Setup screen is divided into three sections:

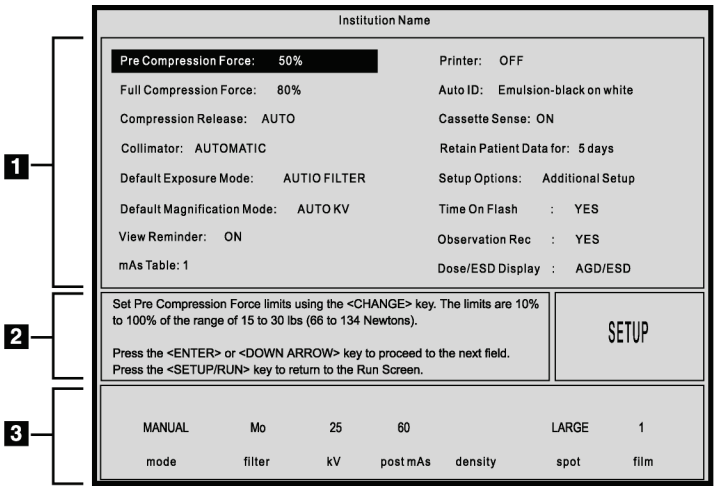


Figure Legend

1. Setup Pane
2. Message Pane/Status Pane
3. Exposure Technique Pane

Figure 31: The Setup Screen

When you access the Setup screen, the cursor (highlight bar) always appears in the first field of the **Setup** Pane. The **Message** Pane displays information about and instructions to change the system default values for the selected field. The **Status** Pane always reads SETUP. The **Exposure Technique** Pane sets the default values for the exposure techniques for each of the modes.

4.3.1 How to Change the Field Selections

Note

Use this procedure to make field selections for all the fields in the Setup Pane.

1. Push the arrow keys or the Enter key to move the highlight through or across the columns and select a field.
2. Push the **Change** key to scroll through the selections for that function. Use the keyboard for text entries.
3. Push the Enter key to change the selection and move to another field.

4.3.2 Display of Estimated Dose

The Dose display is selected with the enable/disable function in Setup. If the Dose Display is enabled and the Host has accepted the required data, the system calculates and displays Average Glandular Dose (AGD) and Entrance Skin Dose (ESD). The calculation of Dose uses a breast composition of 50% adipose, 50% glandular. The displayed dose values are cleared when:

- A new patient name or ID is entered.
- The patient fields are cleared.
- The Setup screen is accessed.
- The system is turned on.

4.3.3 How to Select the Exposure Technique Default Values

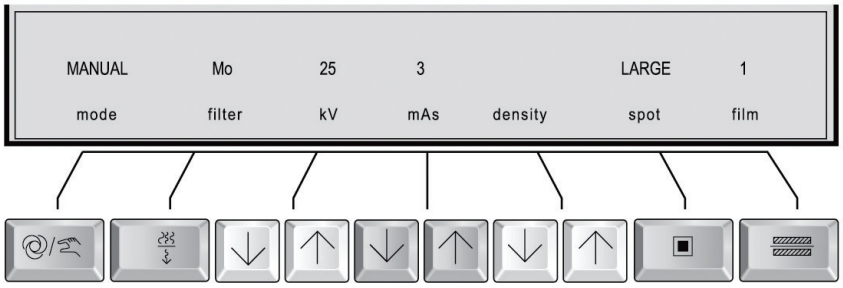


Figure 32: Exposure Default Screen

The bottom pane sets the default values for the Exposure Technique Pane in the Run mode screen. Press an Exposure Technique key to change the Default Value. Select a set of Exposure Techniques for *each* exposure mode, including magnification modes.

4.3.3.1 Select the Film Type Default Value

The **Film Type**  button sets the default value for the film you normally use.

Note The Film types displayed on the screen are only labels until the film types are calibrated by a Service Engineer for both filters.

4.3.3.2 Exposure Modes—How to Set Default Values

Note Auto-Filter exposure mode is not available for magnification case studies.

To set the default values for each of the exposure modes:

1. Press the **Run/Setup** key  to display the Setup screen.
2. Press the **Mode** key  .
3. Use the arrow keys to select the mAs table or the Auto-kV window field, if displayed. Press the **Change** key to select the mAs table in Manual or the Auto-kV window in Auto-kV then press the Enter key.
4. Press an **Exposure technique** key to scroll through the options.
5. Repeat step 4 until all of the default values are set.
6. Press the **Mode** key to display the next mode screen and continue to select the default values.

4.3.4 Setup Options

The Setup Options screens are: the Additional Setup, Technologist ID, and CPT Code/View. Refer to additional information in *The Additional Setup Screen* on page 43.

The **Additional Setup** screen:

- Sets the compression force units
- Sets the system for use with the Mammography Information System (MIS) when a Radiological Information System (RIS) is attached
- Sets the film and flash time preferences
- Changes the date and time

The **Technologist ID** screen enters Technologist data and sets the selected compression mode and the exam view orders.

The **CPT Code/View** screen selects or edits CPT codes and exam descriptions used in the Run Mode.

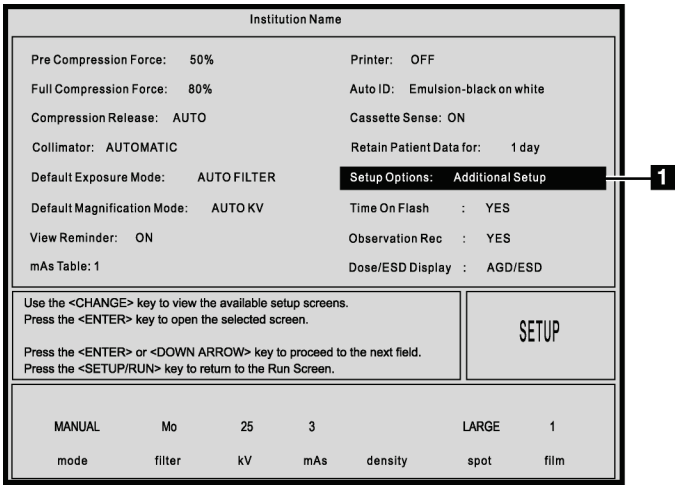


Figure 33: How to Display the Additional Setup Screen

To display one of these three screens:

1. Highlight **Setup Options: Additional Setup**. (item 1 in the figure).
2. Press the **Change** key  to scroll through the screen names.
3. Press the **Enter** key to select the required Additional Setup option.

Press the **Run/Setup** key  to return to the Main **Setup** Screen. Press the **Run/Setup** key two times to display the **Run** screen.

4.4 The Additional Setup Screen

4.4.1 Introduction to the Additional Setup Screen

The Additional Setup screen:

- Sets the compression force units display
- Enables a Mammography Information System (MIS) connection
- Assigns names for up to three screen-film combinations. A Service Engineer must calibrate each screen-film to be used.

The selections appear on the Run screen.

The Additional Setup screen is divided into two sections:

The Message Pane displays instructions to help you enter data into the selected field.

When the M-IV is connected to a Mammography Information System (MIS), a direct link to the Radiological Information System (RIS) patient database accesses stored patient data, and prevents changes to the data. If the system cannot communicate with the RIS system, the RIS timeout displays the time in seconds before an error message appears.

4.4.2 How to Change the Additional Setup Default Values

Use the Arrow keys or the Enter key to move from field to field. Use the keyboard or the **Change** key to make changes. You must press the **Enter** key to record the change.

4.5 The Technologist ID Setup Screen

Use the **Technologist ID Setup** screen to:

- Assign Tech ID codes.
- Select your preferences for the Compression mode.
- Select the view order for the Screening Exam.

To access the Technologist ID Setup screen:

1. From the **Run** screen, press the Run/Setup key to access the Setup Screen.
2. Press the Down Arrow to select the **Setup Options: Additional Setup** field.
3. Press the **Change** key until the **Technologist ID Setup** appears as the indicated option.
4. Press the Enter key to access the **Tech ID Setup** screen.

4.6 The CPT Setup Screen

The CPT Setup screen sets the view options for the eight CPT-codes default values. The screen also has an additional 12 CPT codes with descriptions and selected views.

To access the *CPT Setup* screen:

1. From the **Run** screen press the Run/Setup key to access the Setup Screen.
2. Press the Down Arrow key to highlight **Setup Options: Additional Setup**.
3. Press the **Change** key until **CPT CODE / VIEW** is selected.
4. Press the Enter key to access the **CPT Setup** screen.

To return to the Run screen, press the Run/Setup key two times.

Select views for each of the CPT Codes you must change.

Chapter 5
Schedule Features and Data Storage

5.1 Manual Schedule

The Schedule feature enters the patient information before the examination.

5.1.1 How to Enter Schedule Data

1. Enter the patient identification information (ID and Name) in the **Run** Screen.
2. Enter any known demographics (Sex, Birth Date, CPT Code, and Exam View).
3. Enter the Tech ID (if known).
4. Enter any necessary comments.
5. Review each field for accuracy and make changes or corrections as necessary.

When a new Patient ID number is entered, the information is recorded in system memory. You must repeat the data entry process for each patient on that day or session.

5.1.2 How to Retrieve Scheduled Data

1. Select the **Patient ID** field.
2. Enter the exact Patient ID number, or scroll through the list of numbers.
3. Press the **Enter** key.

The system retrieves the scheduled data and fills in the fields. You can change any field (except the Patient ID field) as necessary.

Note The scheduled data is only saved in the database for the amount of time selected in the "Retain Patient data" field.

5.2 Automated MIS Interface Scheduling (Optional)

The MIS Interface provides the access to the stored RIS patient data through a Mammography Information System (MIS) Gateway. This link transfers scheduled patient data to the M-IV. When the identification number for the patient is entered, all the patient data displays in the fields on the Run Mode screen. An Observation Record is also transferred to the RIS system. Refer to *The Run Screen* on page 35 for additional information.

5.3 Post-Exposure Storage

Use the MIS Interface to save the Post-exposure and patient demographic data to another computer. If enabled, an Observation Record with exposure information is sent from the M-IV to the site's RIS system or other computer at the end of each exposure.

Table 1: Observation Record Data Fields

Field	Maximum Number of Characters	Data Description
Patient ID	15	Alpha-numeric
Patient Name	25	Alpha-numeric, comma delimiters, Last name, First name, MI
Current View	10	Alpha-numeric, spaces R MLO RL
Date of Birth	10	Form: mm\dd\yyyy or dd:mm:yyyy 12\14\1984
Age	3	numeric
Sex	1	'M', 'F', 'O'
Exam Date	10	Same as DOB
Exam Time	8	HH:MM:SS (am or pm if 12 hour) 06:15:45 am
Tech ID	3	Alpha-numeric
Exposure Mode	4	Alpha AFL, AKV, ATM & MAN, (Mag) MAFL, MAKV, MATM and MMAN
KV	6	Range: 22 - 39
Filter	3	'Mo' or 'Rh'
mAs	10	Decimal point if less than 100
Density	5	D:-5 to D:+5
AEC Position	2	1 to 7
Spot Size	2	'L' or 'S'
C-Arm angle	6	-155 to 199
Compression Force	5	Force in Lb. or Newtons 30.5# 125N
Compression Thickness	4	Thickness in CM. 25.6
AGD/ESD Field included only if AGD/ESD Display is enabled	18	Dose in mGy or mrad ADG: 1.23 mGy ESD: 43.21 mGy (if mGy units) AGD: 123 mrad ESD: 4321 mrad (if mrad units)

Uses for this information may include:

- Repeat Analysis evaluation; the number of exposures per patient is available.
- Time management; the time of each exposure is available.

Chapter 6
Accessories

6.1 The Patient Face Shield

The Face Shield keeps the head and face from the x-ray field during the examination. Remember to inspect its condition before use each day. The Face Shield attaches to the tubehead around the port of the x-ray tube.

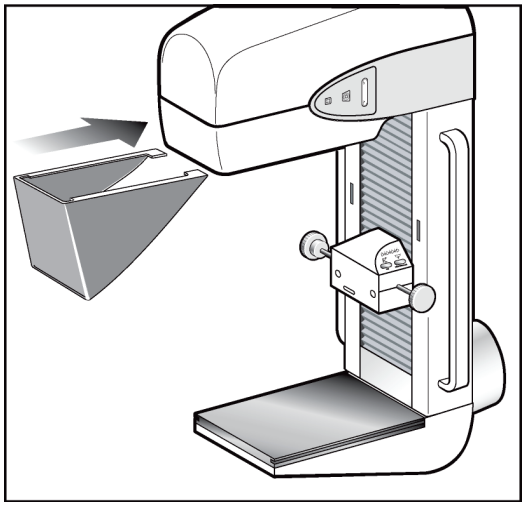


Figure 34: How to Install the Face Shield

6.1.1 How to Install the Face Shield

To install the face shield:

1. Hold the opening toward the C-arm. Separate the rear tabs slightly.
2. Slide the open end of the face shield into the slots on the tubehead mount until locked.

6.1.2 How to Remove the Face Shield

To remove the face shield:

1. Separate the rear tabs until you can move the shield.
2. Pull the shield from the mount.

Warning: **The Face Shield must be attached for all exposures except magnification case studies.**

Warning: **The Face Shield does not protect the patient from radiation.**

6.2 The Image Receptor Support Device

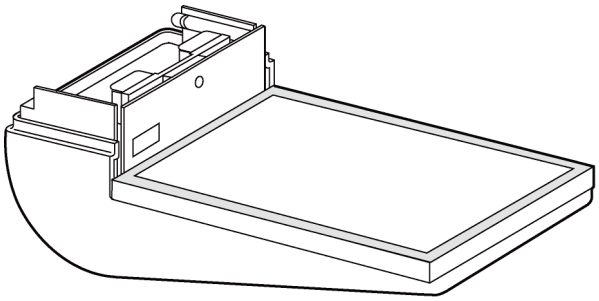


Figure 35: The Image Receptor Support Device

The Image Receptor Support Device (IRSD), on the M-IV C-arm, accepts the Magnification Table, the SRL2000 Bucky, and the HTC Bucky. The IRSD identifies Hologic accessories and automatically:

- Changes the collimator field to the correct dimension for the installed image receptor.
- Changes the Receptor status line on the Run screen to the type and dimension of the installed device.

6.3 Bucky Devices

6.3.1 How to Install and Remove the Bucky Device

The M-IV Bucky devices accept only DIN-style film cassettes with a sliding window for the Auto Film ID to photographically record exposure information.

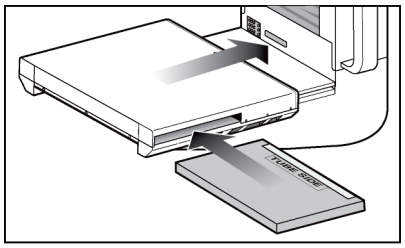


Figure 36: Install the Bucky and Film Cassette

Inspect the Bucky connector pins before installation. Do not install the Bucky if the connector pins are not correctly aligned or are damaged.

To install a Bucky device:

1. Align the side rails on the bottom of the Bucky device with the edges of the IRSD.
2. Slide the Bucky device on the IRSD until the Bucky locks into position. The amber LED illuminates.

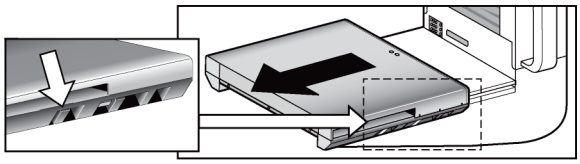


Figure 37: How to Remove the Bucky Device

To remove a Bucky device:

1. Pull the Bucky Release lever, on right side of the device, back to unlock.
2. Slide the device from the IRSD.

6.3.2 How to Load and Remove the Film Cassette

To load a film cassette into the Bucky device.

1. Align a film cassette with the film cassette slot on either side of the Bucky device.
2. Slide the film cassette into the opening until the film cassette locks into position. The green LED illuminates.

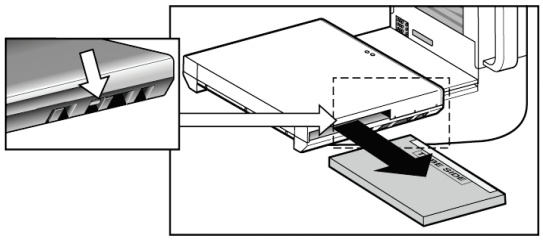


Figure 38: How to Remove the Film Cassette From the Bucky

To remove a film cassette from the Bucky:

1. Push the Film Cassette Eject lever on either side of the Bucky forward until the film cassette slides from the film cassette slot.
2. Pull the film cassette straight away from the Bucky. The amber LED illuminates.

6.3.3 Cassette Sense Indicators

Two indicator lights (amber and green) are on the top surface of each Bucky device. The lights tell you if there is a film cassette in the Bucky. The lights also indicate the exposure status of the cassette if Cassette Sense is enabled in the Setup screen.

Green. Ready status. Film cassette installed, ready for exposure.

Amber. Standby status. Change the film cassette (post-exposure), or the film cassette is missing.

Warning: **The system senses an installed cassette but does not sense the status of the film in the cassette.**

6.3.4 Integrated Bucky Markers

The Integrated Bucky Markers are installed on the Bucky and are used to mark the eight common views.

6.3.4.1 How to Use the Markers

To select one marker:

1. Slide the smaller metal button on the left or right marker set. This movement exposes the set of markers.
2. Select one of the four options.
3. Rotate the wheel to the left until the correct marker is in the image field.

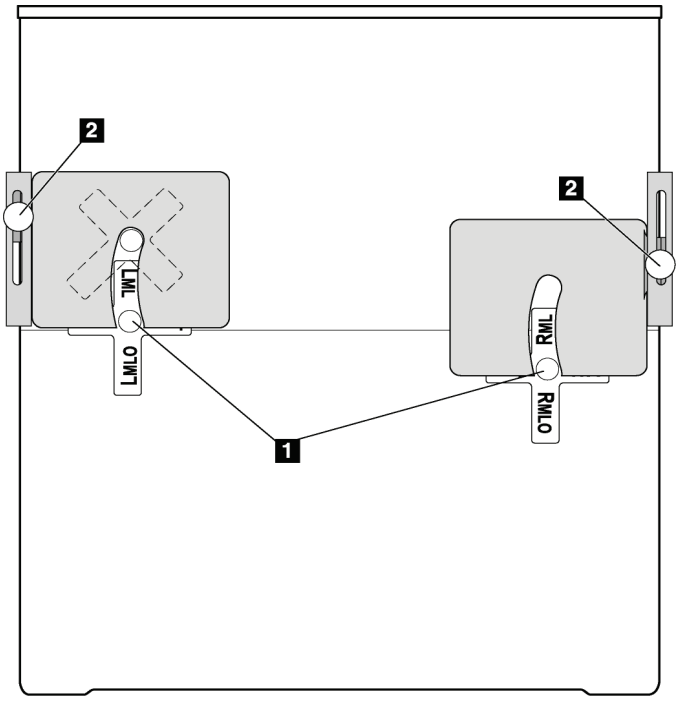


Figure Legend

1. Marker buttons
2. Adjustment knobs

Figure 39: Position of the Bucky Markers

6.3.4.2 How to Move the Markers

Loosen the adjustment knob to move the marker housing. Slide the markers along the upper part of the Bucky with the markers on each side, away from the patient. Tighten the adjustment knob to lock the markers in position.

6.3.4.3 How to Align the Markers

Align the left set of markers parallel to the white film cassette indicator line on the Bucky. You must align the housing so that none of the housing is in the image. If any of the housing is in the primary beam, loosen the adjustment knob and move the housing back away from the chest wall. When the best position is found, tighten the adjustment knob to lock the marker in position.

Align the right set of markers away from the lead blocker for patient information. When the position is set, tighten the adjustment knob to lock the marker in position.

6.3.4.4 To Remove and Replace the Markers

Remove the adjustment knob and slide the markers and the housing from the rail.

To replace, align the housing with the rail and slide back on the rail. Replace the adjustment knob and tighten.

6.4 The Magnification Table

For magnification case studies, use the Magnification Table and a magnification paddle. The Magnification Table has an internal image-receptor holder and slides on the IRSD like the Bucky device.

6.4.1 To Install and Remove the Magnification Table

To install the Magnification Table:

1. Remove the Face Shield (refer to *How to Remove the Face Shield*), Bucky (refer to *How to Install and Remove the Bucky Device*), and Compression Paddle (refer to *How to Install and Remove the Compression Paddles*).
2. Move the Compression Device fully up.
3. Align the side rails on the bottom of the Magnification Table with the edges of the IRSD. Slide the Magnification Table on until locked into position.
4. Make sure that the Receptor field reads: MAG TABLE, the Mode field reads: MAG MODE and the Spot field reads: SMALL.
5. Only use magnification paddles with the Magnification table.

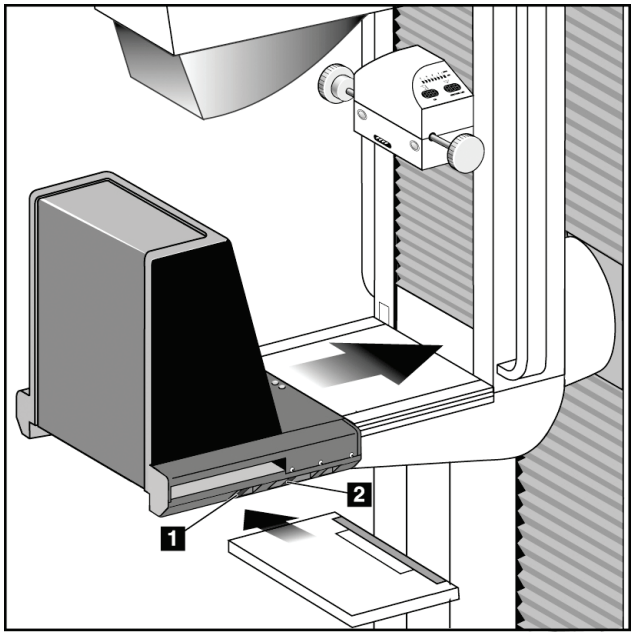


Figure 40: How to Install the Magnification Table

To remove the Magnification Table:

1. Pull the release lever, on the right side of the device, back to unlock (item 1 in the adjacent figure).
2. Hold the sides of the device, and pull the table straight away from the IRSD.
3. Replace the Face Shield.

6.4.2 How to Load and Unload the Magnification Table

To load the Magnification Table, push the film cassette into either side of the Magnification Table until locked into position.

To remove a film cassette from the Magnification Table:

1. Push the Film Cassette Eject lever (item 1 in the *Figure How to Install the Magnification Table* on page **Error! Bookmark not defined.**) on either side of the Magnification Table until the film cassette slides from the film cassette slot.
2. Pull the film cassette from the device.

6.4.3 The Magnification Table Cassette Sense Indicators

The film cassette holder in the Magnification Table has two indicator lights (green and amber).

- Green light = a film cassette is loaded
- Amber light = there is no film cassette loaded, exposures are not prevented.

6.5 Compression Paddles

The M-IV uses different types of Compression Paddles. Use the information that follows as a guide to select the correct Compression Paddle for the mammography examination.

6.5.1 How to Use the FAST Paddle™

The Fully Automatic Self-adjusting Tilt (FAST) Paddle is for use when the composition of the breast tissue prevents uniform compression across the complete breast with a flat compression paddle. For these patients, not enough compression can cause the image to appear out of focus at the anterior region from involuntary movement and not enough compression.

The FAST paddle use with this type of breast provides these features:

- Decreased motion artifacts, because the compression is more effective.
- The compression is more uniform from the chest wall to the nipple.
- Maximum patient comfort, because over compression at the chest wall is prevented.

The FAST paddle automatically tilts when the compression is applied. The paddle is in a flat position until a compression force of approximately 20 pounds (89 Newtons) is applied. The paddle then tilts until it reaches the maximum angle at a force of approximately 30 pounds (133 Newtons).

The FAST paddle does not require excessive compression, but you must use enough compression to prevent the movement of the breast. You should use a consistent amount of compression, especially for related left and right views.

The FAST paddle may not be best for breasts that are equal or symmetrical in thickness from the chest wall to the anterior area of the breast.

6.5.2 How to Install and Remove the Compression Paddles

Note If you remove the compression paddle by the plastic, you can cause damage to the plastic.

All Compression Paddles use the same installation and removal method.

To install the Compression Paddle:

1. Align the mounting pins with the mounting holes in the Compression Device.
2. Push the paddle into the Compression Device until the paddle stops.
3. Pull carefully until the paddle clicks into position. (This action sets the detents of the mounting pins.)

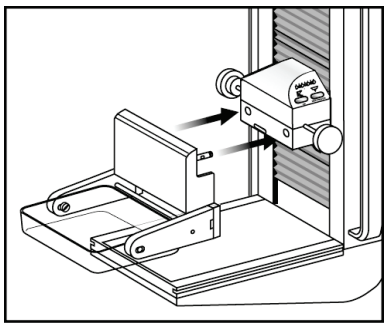
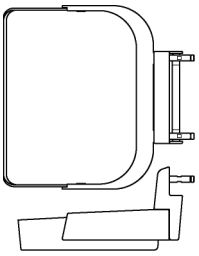


Figure 41: Install the Compression Paddles

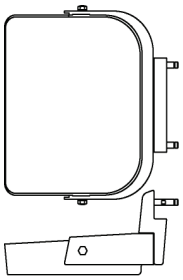
To remove the Compression Paddle:

1. Hold either side of the metal frame of the Compression Paddle.
2. Pull the Compression paddle straight away from the mounting holes.

6.5.3 Routine Screening Paddles

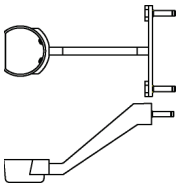


24 x 30 cm Compression Paddle

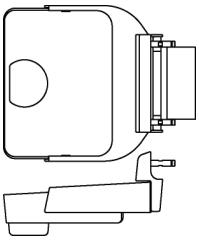


24 x 30 cm FAST Paddle

6.5.4 Contact and Spot Compression Paddles

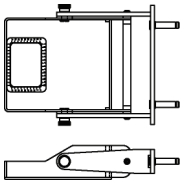


7.5 cm Spot Contact Paddle

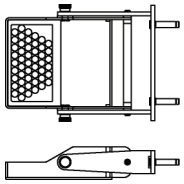


Frameless Spot Paddle

6.5.5 Magnification Paddles

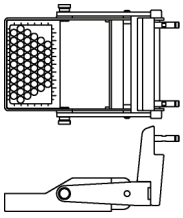


15 cm Magnification Open Rectangular Paddle

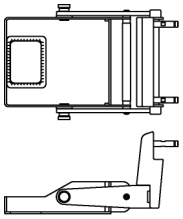


15 cm Magnification Perforated Localization Paddle

6.5.6 Localization Paddles



15 cm Perforated Localization Paddle



15 cm Rectangular Open Localization Paddle

6.5.6.1 Compression Paddle Detector

The system senses the type of paddle installed and performs one of the following:

- *Automatic Collimation mode*. Moves the automatic collimator to the correct size of field for the paddle.
- *Manual Collimation mode.* Moves the automatic collimator to the correct size of field for the Image Receptor.

When the installed, the Compression Paddle is a Localization Paddle. The Compression Release mode changes to LOCKED-OUT.

6.5.7 AEC Sensor Marks

The transparent surfaces of the Compression Paddles are marked with AEC Sensor positions to help you accurately adjust the AEC Detector during automatic-mode exposures.

6.5.8 Maintenance and Cleaning

You must clean the Paddles, Bucky tray, and Patient Handles after each use. Refer to *For General Cleaning* on page 67 for cleaning instructions.

6.5.9 How to Align the Front Edge of the Paddle

Always make sure the paddle front edge is parallel with and aligned to the Image Receptor.

To confirm the edge alignment:

1. Install the paddle and apply 133 N (30 pounds) of compression force.
2. Make sure that the front edge is parallel with and aligned to the Image Receptor. See the adjacent figure.

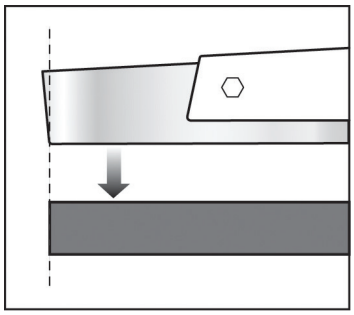


Figure 42: Paddle Alignment

To align the edge when it is not aligned as shown:

1. Release the compression and remove the paddle.
2. If the paddle is a screening, or a frameless spot paddle, turn the paddle upside down. Loosen, a complete turn, the hardware that holds the paddle to the frame.
3. Turn the paddle right-side up (if necessary) and loosen the two inside screws. See the adjacent figure.
4. Install the paddle and apply 133 N (30 pounds) of compression force.
5. Move the paddle until aligned. (Do not release the compression.)
6. Tighten both inside screws. See the adjacent figure.
7. Release the compression and remove the paddle.
8. If the paddle is a screening or frameless spot paddle, turn the paddle over and tighten the hardware that holds the paddle to the frame.
9. To confirm the alignment, install the paddle and apply 30 pounds (133 N) of compression force.

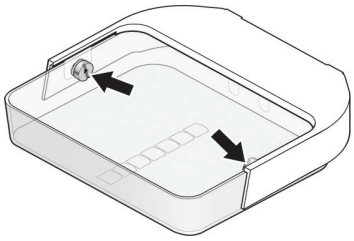


Figure 43: Adjustment Screws for Paddle Alignment

6.6 Crosshair Devices

6.6.1 How to Install and Remove the Loc Crosshair Device

To install the Loc Crosshair device:

1. Remove the face shield.
2. Move the compression device below the C-arm mounting slots.
3. Hold the Loc Crosshair device by the support brackets and put the hooks into the C-arm slots.
4. Slide the device toward the bottom to lock the bracket.

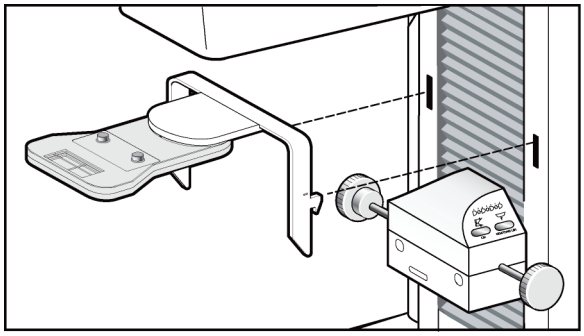


Figure 44: How to install the Loc Crosshair

To remove the Loc Crosshair device:

1. Flip the crosshair device to either side.
2. Press on the locking levers inside each mounting arm. (See item 1 in the *Figure: Locking Lever and Adjustment Lock Screw* on page 57.)
3. Lift the frame and remove from the C-arm slots.

6.6.2 How to Align the Loc Crosshair Device to the Localization Paddle

Note

Before you perform the following adjustment, make sure the localization paddle is adjusted correctly with the edge of the image receptor. Refer to *How to Align the Front Edge of the Paddle* on page 55.

1. Install the Rectangular Localization paddle.
2. Loosen the adjustment lock screw found on the bottom of the Loc Crosshair device (item 2 in the figure).
3. Put a piece of white paper on the breast tray to make the shadows of the crosshairs easier to see.
4. Move the localization paddle to approximately six centimeters above the image receptor.
5. Turn on the light field.
6. Move the Loc Crosshair device until the rectangle of light aligns with the opening in the localization paddle.
7. Tighten the adjustment screw; item 1.

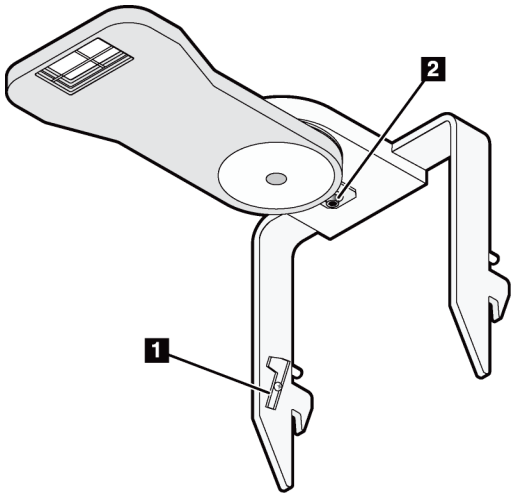


Figure 45: Locking Lever and Adjustment Lock Screw

6.6.3 How to Install and Remove the Mag Crosshair Device

To install the Mag Crosshair device:

1. Remove the face shield.
2. Align the Mag Crosshair device with the slots in the face shield rails.
3. Push the device forward until locked into position.

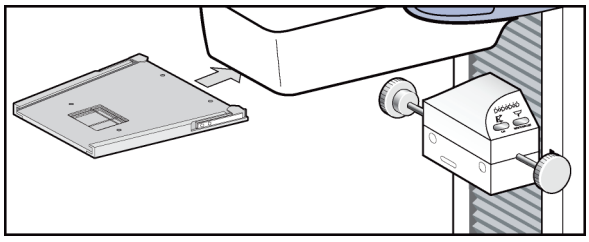


Figure 46: Install the Mag Crosshair

To remove the Mag Crosshair device, slide the device toward you.

6.7 Film Labels

The system provides labels on mammograms with identification and exposure technique factors with the Auto Film ID unit.

The Auto Film ID label includes a graphic model of the breast position and the approach angle of the x-ray beam. This graphic changes to show the orientation of the exposure.

The Auto Film ID removes the requirement to attach a label to the mammogram. The unit requires you to use DIN-style film cassettes. The Auto Film ID "flashes" a photographic image of patient demographics and the exposure factors on the film before it is processed.

6.7.1 How to Use the Auto Film ID

You must enable the Auto Film ID option in the Setup Mode screen before the exposure. After the exposure, the Auto Film ID makes a tone until you put the film cassette into the Auto Film ID.

6.7.2 How to Resend Exposure Data

When a dot [•] shows in the Auto Film ID field, you can send the last exposure data to the Auto Film ID. Use this option when the Auto Film ID was canceled but the information is required.

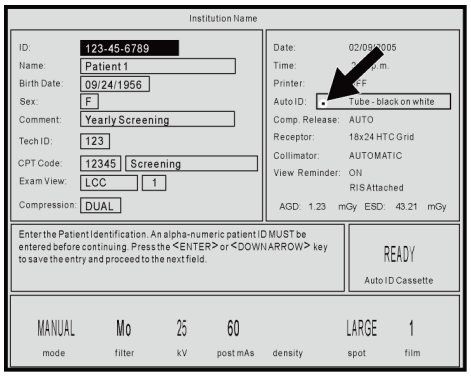


Figure 47: An Auto Film ID Field which displays the dot

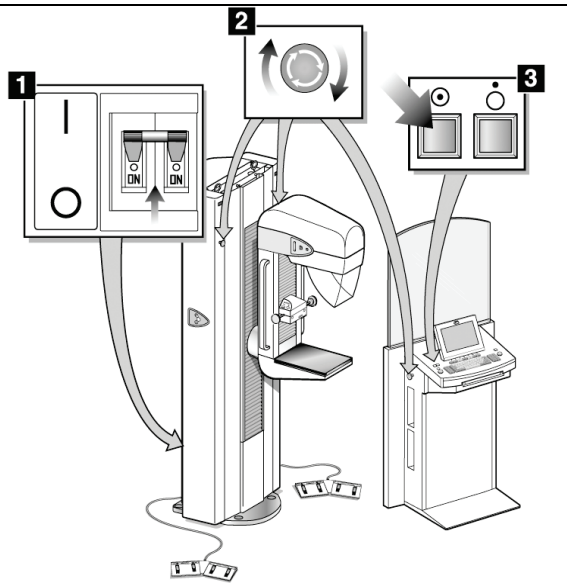
Caution: **Only the last exposure information is available.**

Caution: **If you press the Clear key, this dot [•] does not show and the last exposure information is not available.**

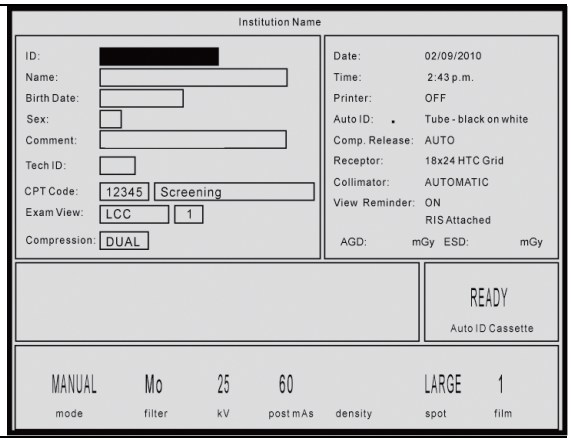
Chapter 7
How to Make Exposures

7.1 Recommended Clinical Sequence

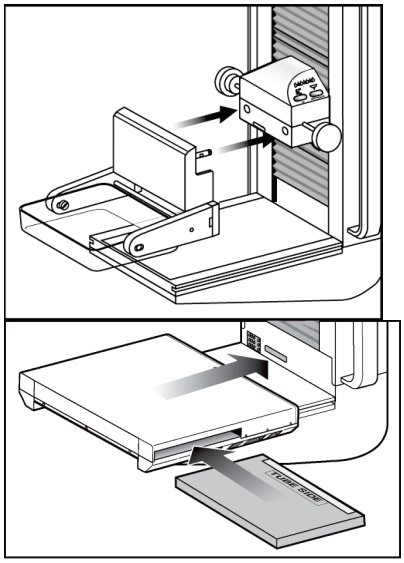
Note…Always correct all errors before you make exposures. Follow the recommended startup sequence.



Look at the Operator Console display for startup errors and diagnostic messages. Confirm that the M-IV continues to the Run Mode screen.

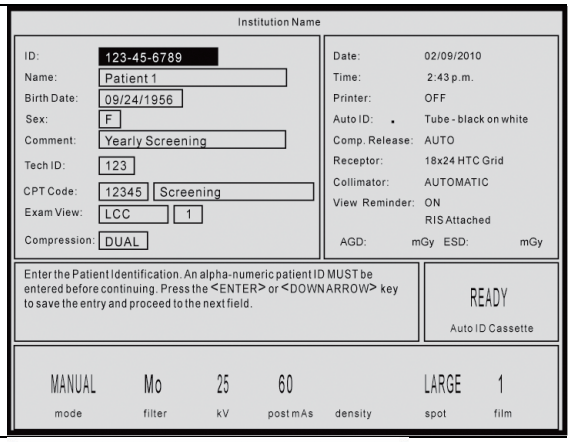


Install the correct accessories.



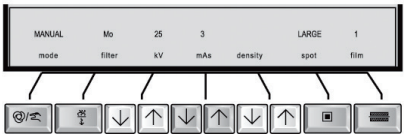
Enter the Patient ID number and Exam Information or verify RIS information. Make sure the "Receptor" field indicates a Bucky is loaded.

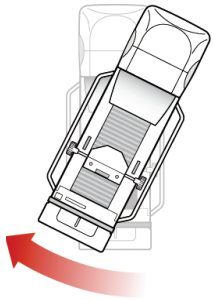
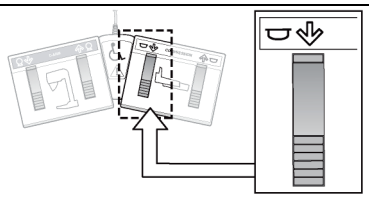
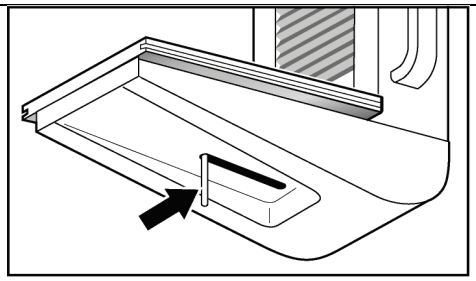
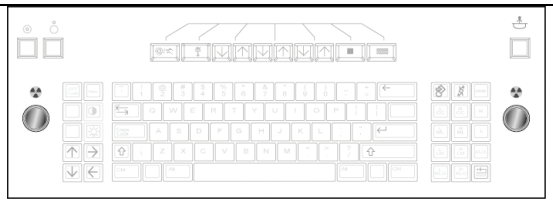
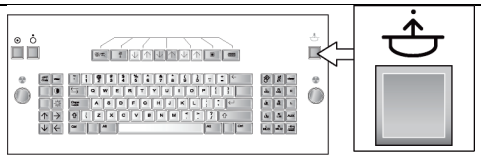
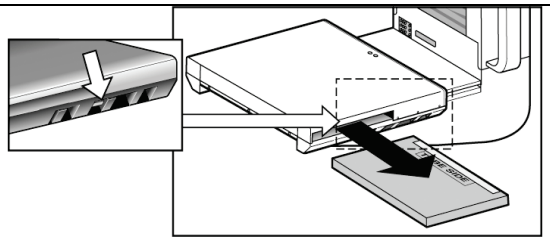
Note…*When patient demographics are entered with the schedule feature, patient information fields fill automatically after you enter the identification number.*

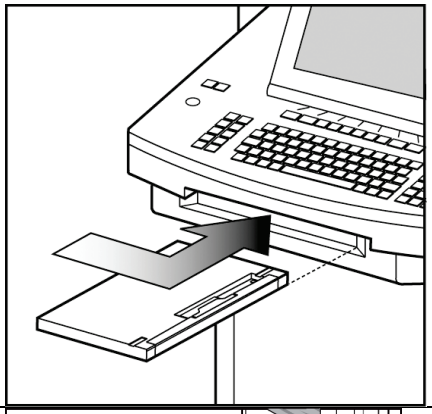
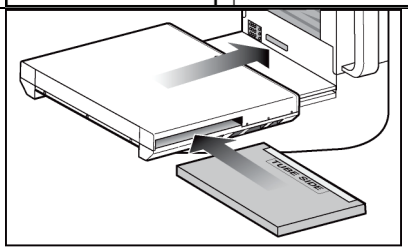
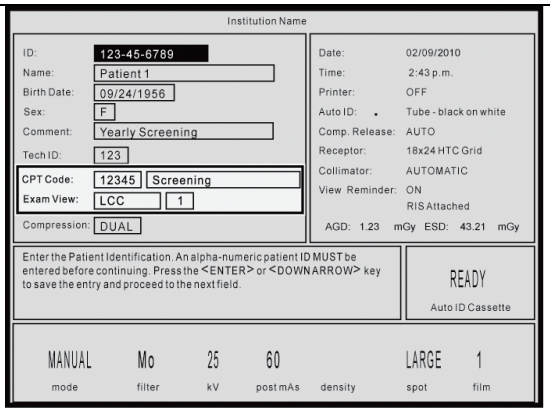
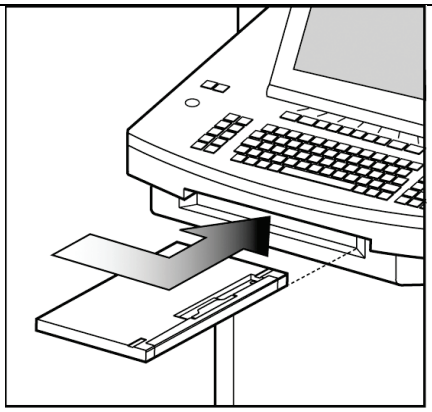


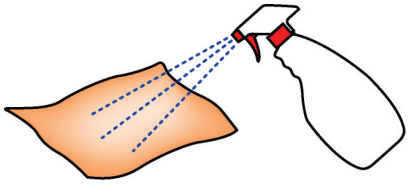
Use the default exposure mode or:

- Select Manual or Automatic Exposure Mode.
- Select the Exposure Techniques.
- Adjust the film density setting—all modes except Manual.
- Select the screen-film combination.



Position the C-arm and Patient.	
Apply motorized compression (Pre, Full, or Dual). Finish with manual compression.	
Adjust the AEC Sensor if using AEC (Locations 1-7).	
Give the Patient final instructions not to breathe. Make the Exposure.	
Release the patient if not in Automatic Compression Release mode.	
Remove the cassette from the Bucky.	

Label the film	
Reload the Bucky	
Take the next view	
Remove the cassette from the Bucky. Label the film. Assist the patient from the system.	

Clean the system.	

7.2 Details for Making Exposures

7.2.1 The Collimator Override

Note The automatic collimator restricts the maximum size of the x-ray field to the size of the image receptor.

In either mode, manual or automatic, use the **Collimator Override** button to adjust the collimator blades for a different size from the pre-set size.

1. Install the correct image receptor and compression paddle.
2. Press the **Collimator Override** button to illuminate the light field lamp and change the collimator blades to a different size. The available sizes depend on the selected collimation mode and installed devices.

7.2.2 Select the Manual or Automatic Exposure Mode

The system starts in the default mode.

- If you use Manual Mode, set the Exposure Techniques.
- If you choose to use a different Automatic Mode, select the exposure mode. The system reads the compression thickness and sets the correct exposure factors.

Auto-Time	Set the **kV, Focal Spot, Density, Filter**, and **Film Type**.
Auto-kV	Set the **Focal Spot, Filter, Density** and **Film Type**.
Auto-Filter	Select the **Density** and **Film Type**.

7.2.3 Position the C-Arm and Patient

Warning: **Use care when adjusting motorized equipment for patient use. Observe equipment and patient at all times during set up. If a chair is necessary for a procedure, where possible, use a variable height chair set above its minimum height to assist with the set up process.**

Warning: **Put the footswitches away from the patient and C-arm area to prevent any accidental footswitch operation. When the patient has a wheelchair, put the footswitches away from the area.**

Warning: **Be aware of the position of the patient's hands and arms relative to any of the C-arm controls.**

7.2.4 Make the Exposure

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

To make the exposure:

1. Move completely behind the radiation shield.
2. Press and hold both x-ray buttons for the complete exposure period, until the tone stops.

Note If you release either or both x-ray buttons before the exposure ends, the system automatically cancels the exposure and an error appears

7.2.5 Special Types of Exposures

7.2.5.1 Spot Exposure

When you use a spot paddle, make sure the collimation changes to the small spot and the light field only illuminates the spot area (Auto Collimation). If you use AEC, move the AEC Sensor against the chest wall edge.

7.2.5.2 Magnification Exposure

Only use Magnification paddles with the Magnification table. When you use a magnification paddle:

- The Mode reads MAG MODE.
- The Receptor field reads MAG TABLE.
- The Focal spot reads SMALL.
- The collimation moves and the light field illuminates only the magnification area (Auto Collimation).

7.2.5.3 Localization Exposures

1. Make sure the Compression Release setting is set for Manual. Change the Compression Release setting to Manual if set for Automatic. For information about how to make the change refer to *The Setup Screen* on page 40.
2. Install the Localization paddle and the Crosshair Device. Install the Localization Paddles like the standard paddles. The system identifies the Localization Paddles and disables Compression Release.
3. Rotate the C rosshair Device from the field before you take the scout image.
4. Take the scout image with AEC or acceptable exposure mode.

Note Locked-Out mode, active with a localization paddle, disables all compression release buttons and automatic compression release, if enabled. Use the compression Up buttons or footswitch to release the patient.

5. Process the film. Identify the position of the lesion on the film.
6. Move the crosshair device into the field and turn on the light field lamp.
7. Adjust the crosshair knobs. Put the crosshair shadows on the reference points of the localization paddle to indicate the position of the lesion on the Scout film.
8. Mark the lesion position on the skin.
9. Move the crosshairs from the field before you continue.
10. Continue with the Localization Procedure, changing paddles if required.
11. Use standard screening steps for the remainder of the Procedure.
12. When the Procedure is complete:
    a. Remove the localization paddle if installed.
    b. Return the Compression Release to Automatic, if Automatic is the site default value. Refer to *The Setup Screen* on page 40.

7.2.5.4 Magnification Localization Exposures

1. Install the Magnification Table, the Magnification Crosshair device, and a Magnification Localization paddle.
2. Turn the crosshair dials to move the crosshairs from the field.
3. Take the scout image.
4. Process the film. Identify the position of the lesion on the film.
5. Adjust the crosshair knobs. Put the crosshair shadows on the reference points of the localization paddle to indicate the position of the lesion on the Scout film.
6. Mark the lesion position on the skin.
7. Turn the dials to move the crosshairs from the field before you continue with the procedure.

8. When the Procedure is complete:
   a. Remove the localization paddle if installed.
   b. Return the Compression Release to Automatic, if Automatic is the site default value. Refer to *The Setup Screen* on page 40.

7.2.6 Release the Patient

When done, press any Compression Release button to lift the Compression Device if not in Automatic Compression Release mode. If in Locked-Out mode, use a Compression Up button or footswitch.

7.2.7 Label the Film

1. Remove the film cassette from the Bucky device.
2. Put the film cassette (DIN-style only) into the Auto Film ID.
3. After the audible tone sounds, remove the film cassette and process the film.

7.2.8 Take the Next View

1. Change the film in the film cassette and load it into the Bucky.
2. Move the C-arm (rotation and height) as necessary for the next clinical view.
3. Review the Run Mode screen and make any necessary changes.

Note If the Tech ID sequence is interrupted, the Operator must select the views for the remaining exposures. When a new Patient ID is entered, the view sequence returns.

4. Continue the procedure.

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.

8.2 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.**

8.3 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.

8.4 How to Clean the Operator Console

8.4.1 Display

Avoid touching the display screen.

Use care when cleaning the outer surface of the LCD screen. Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths are recommended.

- Never use a spray or flow a liquid on the display.
- Never apply any pressure to the display area.
- Never use a detergent with fluorides, ammonia, alcohol, or abrasives.
- Never use any bleach.
- Never use any steel wool.
- Never use a sponge with abrasives.

There are many commercially available products to clean LCD displays. Any of the products free of the ingredients described above and used according to the directions of the manufacturer can be used.

8.4.2 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.

8.5 How to Clean the Integrated Bucky Markers

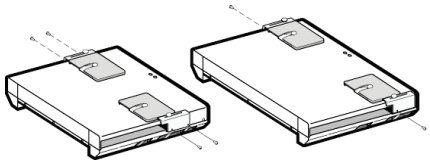
8.5.1 Routine Cleaning

To clean the Bucky Markers:

1. Use the general cleaning procedures. Refer to *For General Cleaning* on page 67.
2. Remove the Bucky Markers from the Bucky for cleaning if needed. Refer to *To Remove and Replace the Markers* on page 51 for removal instructions.

8.5.2 How to Clean the Surfaces of the Marker Rail

Note This procedure is not part of a normal cleaning routine.



1. Remove the Bucky from the IRSD and put on a flat surface. Remove the marker assembly from the Bucky (1 or 2 screws on each side of the Bucky). Use a 0.050 hex key (supplied with the Bucky Marker).
2. Remove the large adjusting knob to separate the marker.
3. Use a disinfectant solution and a swab to clean the rails.
4. Assemble, then attach the marker to the Bucky.

8.6 Preventive Maintenance

Table 2: Radiologic Technologist

M-IV Platinum Recommended Preventive Maintenance	**Recommended Frequency**			
Maintenance Task Description	**Each Use**	**Daily**	**Weekly**	**Monthly**
Clean and disinfect the paddle	x			
Clean and disinfect Bucky	x			
Visually inspect all paddles for crazing, cracks, etc.	x			
Verify operation of all modes		x		
Perform Phantom exposure			x	
Verify operation of all functions				
Vertical travel				x
Rotation				x
Compression and thickness				x
Wire Localization Compression lockout and release (manual and automatic)	x			
Paddle sensing				x
Bucky sensing				x
Film cassette sensing				x
Displays all reading				x
All compression modes				x
Collimation, collimator lamp, and collimation override				x
Emergency Stops		x		

Appendix A
System Specifications

A.1 Unit Measurements

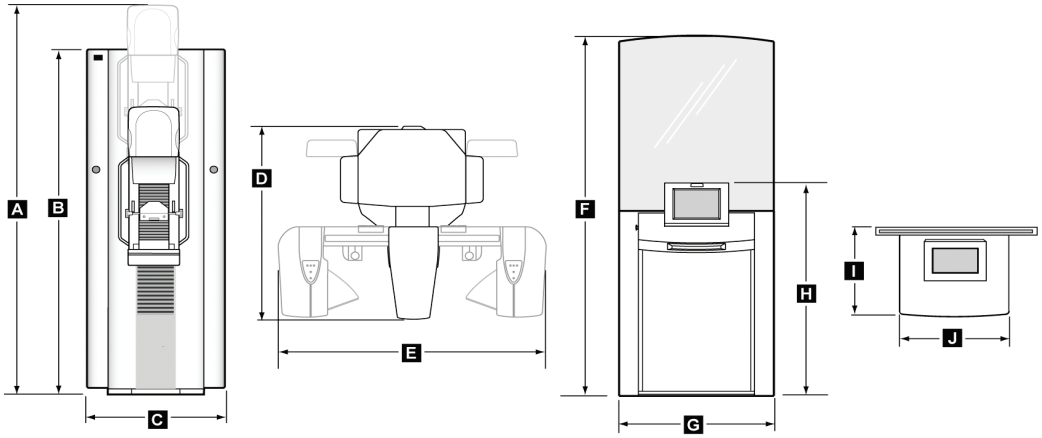


Figure 48: M-IV Dimensions

Gantry with C-Arm

A. Height (C-arm at top of travel)	*213.4 cm (84 inches)*
B. Height (top of Gantry)	*190.5 cm (75 inches)*
C. Width	*64.2 cm (25.5 inches)—C-arm at 0° position*
D. Depth	*110 cm (43.5 inches)*
E. Horizontal Rotation	*134.7 cm (53 inches)*
Weight	*750 pounds (340 kg)*

Radiation Shield

F. Height	*189.2 cm (74.5 inches) installed (maximum)*
G. Width	*81.3 cm (32 inches)*
Pb equivalent	*0.5 mm Pb equivalent (minimum at 35 kV)*

Operator Console

G. Width (includes radiation shield support)	*81.3 cm (32 inches) (minimum)*
H. Height (to Operator display)	*90.2 cm (35.5 inches) at front (minimum)* *42 inches (106.7 cm) at rear (maximum)* *118.0 cm (46.5 inches) top of display at maximum height*
I. Depth	*43.2 cm (17 inches) including the radiation shield*
J. Width at the shield (with the Emergency Off switch)	*53.3 cm (21.0 inches)*
K. Weight	*96.3 kg (214 pounds)*

A.2 Electrical Input

Main Power Supply Voltage	*200, 208, 220, 230, or 240 VAC Nominal (tap selected at installation) ±10%, 50/60 Hz, permanently connected*
Main Power Supply Impedance	*Maximum line impedance does not exceed: 0.20 ohms for 220, 230, or 240 VAC, 0.16 ohms for 200 VAC (IEC 60601-2-45, Clause 10.2.2)*
Maximum Power Use	*6.5 kVA for 5 seconds*
Rated Line Current	*4 A (35A for 5 seconds)*
Circuit Breaker Rating	*25 A—time delay curve to allow for inrush currents, 200% overload for 7 seconds. (Requires a 35 A in-house fuse for ROW [Rest of World] installation.)*
Duty Cycle	*Full load 5 seconds on, 30 seconds off*

A.3 Operating Environment

Temperature Range	*10° C to 40° C (50° F to 104° F)*
Relative Humidity Range	*30% to 75% non-condensing*
BTU output	*Normal Range 1700–2500 BTU/hour*
ESD Susceptibility	*3 kV for contact discharge to non-grounded conductive accessible parts. 8 kV air discharge to all other accessible parts. Meets the requirements of IEC 60601-1-2.*
EMI Susceptibility	*The system is immune to levels of EMI radiation per IEC 60601-1-2*
EMI Generation Limits	*The system meets the requirements of IEC 60601-1-2*
Input Line	*Surge, fast transient/burst per IEC 60601-1-2*

A.4 Storage Environment

Temperature Range	*-25° C to +60° C (-13° F to 140° F)*
Humidity	*Zero to 95% humidity— non-condensing (not in a package for external storage)*

A.5 Tubestand

A.5.1 C-Arm

Motorized Rotation	*Variable speed (18° for each second maximum). The Service Engineer sets the rotation speed: 50% to 100%. Shown on the Host Microprocessor Board as 40% through 90% in 5% steps. The Motor Control supplies soft start and dynamic braking.*
C-arm Rotation	*+195° +2° /-0° to 0° ±0.5° to -150° +0° /-2°, with electrical detents at 0°, +90° and -90°. The rotation angle displays on two sides of Gantry.*

Vertical Travel (minimum)	*26.5 inches to 55 inches (67 cm to 140 cm) from the center of the Bucky surface to the floor for both 0° and 90° position. There are controls on the C-arm and footswitch.*
Alignment of Focal Spot, Compression Device, and Image Receptor	*The focal spot of the x-ray tube is set so that the x ray that falls on the edge of the image receptor closest to the chest wall is perpendicular to the image receptor. The system allows the plane of the focal spot and the chest wall of the device to be perpendicular to that ray. The movement of the compression device supplies parallel compression of the breast regarding the plane of the image receptor. You can adjust the compression paddle, chest wall to the nipple, to provide for this alignment requirement.*
Source to Image Distance (SID)	*65 cm from the nominal position of the Large Focal Spot to the image receptor (film) within the Bucky.*
Magnification	*1.8 x for objects 22.5 mm above the magnification stand breast-support surface. (Breast support surface supplies approximately 1.7 x magnification and is 16.7 cm wide x 12 cm depth). The surface material of the breast support is carbon fiber. The magnification table is designed as a tower to provide rigidity.*
Image Receptor Support Device (IRSD)	*You can remove the IRSD from the C-arm. The IRSD is mechanically locked with an electrical interlock to prevent any x-ray exposure from the M-IV if not installed. You must install the IRSD to restore power to the system.* *The IRSD contains a three-cell AEC detector, which you can move to seven positions at 1.7 cm steps.* *The IRSD minimizes the x ray transmission to a maximum of 0.1 mR for the maximum technique exposure. This limit meets 21 CFR, section 1020.31 and meets the 1 µGy for each exposure as required by IEC 60601-1-3, section 29.207.2.*

A.5.2 Compression

Manual Compression Force	*The force has a limit of a maximum of 300 N (67.4 pounds),+0/-89 N + (0 pounds /-20 pounds) from 0° to ±90° C-arm rotation. There are not less than 169 N (38 pounds) for a C-arm angle range greater than +150° and an angle less than -150°.*
Motorized Compression	*Functions in three modes of operation, user selected through the software.*
Pre Compression Force	*70 N +0/-22.3 N to 133.5 N ±22.3 N (15.7 pounds +0/-5 pounds to 30 pounds ±5 pounds) User selected.*
Full Compression Force	*89 N ±22.3 N to 178 N ±22.3 N (20 pounds ±5 pounds to 40 pounds ±5 pounds).*

Dual Mode Compression	*Provides Pre Compression force on the first press of compression switch. If the switch is activated within two seconds, then the force is increased. This increase is by a set amount of force for each additional switch press to a maximum of the user selected Full Compression force.*
Compression Controls	*Up/Down controls are on both sides of the C-arm and on the two-position footswitch (Motorized). There is a handwheel on both sides of the Compression Device (Manual).*
Compression Release	*The Motorized Release mode is controlled by buttons on both sides of the C-arm and on the Operator Console. The user selected automatic release mode lifts the Compression Device on the exposure termination. This mode is available through the Setup Mode field. All release functions are disabled if a Localization Paddle is installed, including automatic compression release.*
Automatic Compression Release	*Lifts the compression device a set distance (5, 7.5, 10, or 12.5 cm, service selected at installation). This distance can be less for Magnification Mode*
Back Drive After Compression	*Back drive is not more than 1.5 mm in either motorized or manual drive between -90°, 0°, and +90° positions. Back drive is not greater than 3 mm in all other positions.*
Compression Down Motion Variable Speed	*Selected from approximately 10% through 100% of full speed. The selection is displayed on the host microprocessor board as 0% through 90% in 10% steps. Selected at installation by Service Engineer.*
Compression Force Display	*Two LED Displays on the Compression Device show the compression force. The range is 44.5 N to 300 N (10 pounds to 67.4 pounds) in 4.4 N (1 pound) steps.*
Compression Force Display Accuracy	*±20 N (±4.5 pounds)*
Compression Thickness Display	*Two LED Displays on the Compression Device measure between 0 and 15 cm above the image receptor. The display adjusts for the type of image receptor installed (for example, there is no receptor, film cassette holder, Bucky, and magnification device). The display is in 0.1 cm steps. The display is visible from both sides of the patient.*
Compression Thickness Accuracy	*Within 0.5 cm for measured thicknesses between 0.5 cm and 15 cm.*

Compression Paddles	*The compression paddles are transparent and the full field paddles are marked with the location of the AEC sensor positions.* *The paddles are made of polycarbonate.* *When an image is taken with 1 cm of acrylic attenuator at 20 kV to an optical density of 1.2 OD, you cannot detect the sensor position marks on the film.* *Paddle attenuation is less than 15% (reduction of mR/mAs) at 25 kV. The paddles provide a parallel plane to the image receptor. The paddles do not have a deflection of more than 1 cm from any surface which provides a compression of less than 25 pounds of force (except for F.A.S.T. and Frameless Spot paddles).* *The paddles are adjustable to provide the requirement for focal spot, compression device and image receptor alignment.*
Available Compression Paddles	*24 x 30 Standard Screening Paddle* *7.5 cm Contact Spot Paddle* *10 cm Contact Paddle* *15 cm Contact Paddle* *7.5 cm Magnification Spot Paddle* *10 cm Magnification Paddle* *15 cm Magnification Paddle* *10 cm Open Localization Paddle* *10 cm Perforated Localization Paddle* *15 cm Open Localization Paddle* *15 cm Perforated Localization Paddle* *15 cm Magnification Open Rectangular Paddle* *15 cm Magnification Perforated Paddle* *15 cm Ultrasound Paddle* *18 x 24 FAST Paddle* *24 x 30 FAST Paddle* *Small Breast Paddle* *Frameless Spot Paddle*

A.6 X-ray Tube

Focal Spot (NEMA / IEC) Focal spot	*Large (0.3 mm)* *Small (0.1 mm)*
Tube Voltage	*20 kV - to 39 kV (maximum)*
Tube Current	*Large Focal Spot = 100 mA 25 - 32 kV* *Small Focal Spot = 30 mA 25 - 32 kV*
Anode Rotation	*180 Hz (9600 RPM minimum)*
Anode Angle	*Bi-angular: Large focal spot at 16°, Small focal spot at 10°. The x-ray tube angle is at 6° to provide 22° (Large Focal Spot) and 16° (Small Focal Spot) anode to film plane angle. Provides the size of film of 24 x 30 cm for Large Focal Spot and 18 x 24 cm for Small Focal Spot (magnification).*
Anode Material	*Molybdenum*
X-ray Window	*Beryllium - 0.8 mm thickness (maximum)*

A.7 X-ray Tube Housing

Over Temperature Protection Sensor	*Internal connection in series with the stator common lead.*
Maximum Temperature, Surface of Tube Housing	*55°C (131°F)*
Maximum Temperature, Surface of Tube-Head Cover	*41°C (106°F)*
Safety Class	*IEC 60601-1, Class I, IEC 60601-2-28*

A.8 X-ray Beam Filtration and Output

Inherent Tube Filtration	*0.0 mm Al equivalent*
Added Filtration	*The filter-changer mechanism has two positions with a 30-micron (0.03 mm) Molybdenum foil filter and a 30-micron (0.03 mm) Rhodium foil Filter. The type of filter is user selected.*
Beam Quality, HVL for Mo/Mo Operation	*At a given kilovolts, the measured HVL with the compression paddle in the x ray beam is equal to or greater than the value of kV /100 +0.03 (in units of mm of aluminum), but less than the value of kV /100 +0.12 (in units of mm of aluminum).*
Beam Quality, HVL for Mo/Rh Operation	*At a given kilovolts, the measured HVL with the compression paddle in the x ray beam is equal to or greater than the value of kV /100+0.03 mm Al (in units of mm of aluminum), but less than the value of kV /100+0.19 mm Al (in units of mm of aluminum).*
Radiation Output	*Equal to or greater than 800 mR/second for a minimum of 3 seconds. The Output is measured through the Compression Paddle, 4.5 cm above the breast support, 4.0 cm from the chest wall edge, using exposure techniques of Mo/Mo target/filter, large focal spot, and 28 kV.*

A.9 X-ray Collimation

X-ray Collimation	*The system detects the attached image receptor and automatically adjusts the size of the field to confine the beam as required by 21 CFR. When an accessory is not installed, the beam is confined to the size of the image receptor support device (18 x 24 cm).*

A.10 Light Field Indication

Light Field Lamp	*A Light Field switch is found on either side of the x-ray tubehead or the Operators Console (Lamp Key). A Compression Down switch also activates the light. When one of the switches is pressed, the light illuminates for 30 seconds, ±5 seconds. The light turns off automatically at the start of the exposure.*
Light Field Illuminance	*160 lux (minimum)—meets 21 CFR, Sub-chapter J, section 1020.31 requirements. A shatter shield is provided. The lamp is adjustable to align the light field to the x-ray field.*
Light Field-to-X-ray Field Alignment	*The acceptable difference in the alignment of the x-ray field to light field for both length and width is ≤□2% of SID (1.30 cm). Meets standards of IEC 60601-1-3 and 21 CFR 900.12.*

A.11 High Voltage Generator

Electrical Power Capacity	*4.1 kW maximum*
Output Rating	*3.2 kW, maximum (isowatt), 100 mA @ 32 kV*
Ripple	*2% or less (normal), maximum 4%*
Topology	*Pulse-width modulated High Frequency, active servo controlled*
Duty Cycle	*5 seconds on, 30 seconds off*
kV/mA Range:	

Table 3: kV/mA Range

Large Focal Spot		Small Focal Spot	
Tube Voltage kV	**Tube Current mA**	**Tube Voltage kV**	**Tube Current mA**
20	75 mA	20	20 mA
21	80 mA	21	22 mA
22	85 mA	22	24 mA
23	90 mA	23	26 mA

Table 3: kV/mA Range

Large Focal Spot		Small Focal Spot	
Tube Voltage kV	**Tube Current mA**	**Tube Voltage kV**	**Tube Current mA**
24	95 mA	24	28 mA
25-32	100 mA	25-32	30 mA
33	85 mA	33-34	28 mA
34-35	80 mA	35-37	26 mA
36-37	75 mA	38-39	24 mA
38-39	70 mA		

mAs Range — *The M-IV uses an integrated mAs timer for manual timing and the backup timer. An additional hardware-safety timer is used.*

Large Focal Spot Manual mAs Range:

Table 1 (Default Value): — *3 mAs through 500 mAs, 23 steps - 3, 4, 5, 6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, and 500. Each additional change results in an optical density change of approximately 0.15 OD.*

Table 2 (User Selected): — *3 mAs through 500 mAs, 59 steps - 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 220, 240, 260, 280, 300, 325, 350, 375, 400, 425, 450, 475, 500.*

Small Focal Spot Mag Manual mAs Range:

Table 1: — *3 mAs through 125 mAs, 17 steps - 3, 4, 5, 6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, and 125*

Table 2: — *3 mAs through 150 mAs, 41 steps - 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 110, 120, 130, 140, and 150.*

A.12 Accuracy, Reproducibility, and Linearity

Reproducibility	*0.05 coefficient of variation for 10 consecutive exposures (21 CFR).*
Linearity	*0.10 for adjacent mAs selections per the following: (X1-X2) is less than or equal to 0.10 (X1+X2) where X1 and X2 are average mR/mAs values for consecutive exposures (21 CFR).*
kV Accuracy	*The accuracy is within 1 kV of the indicated kV level.*
mAs Accuracy	*The accuracy of the display is the greater of ±5% or ±2mAs, from the mAs, measured in the ground side of the tube circuit.*
Post mAs Display	*The displayed post-exposure mAs accuracy is the greater of ±5% or ±2mAs, from the mAs. The display remains until the start of the next exposure.*

A.13 Image Receptors

Types	*18 x 24 cm Full-pass Linear Bucky* *24 x 30 cm Full-Pass Linear Bucky* *18 x 24 cm HTC Bucky* *24 x 30 cm HTC Bucky* *StereoLoc II (Film)* *StereoLoc II DSM* *DSM* *Magnification Table*

A.14 Exposure Control

AEC Detector	*Solid-state, three square centimeters active sensing area created from three 1cm square sensors.*
AEC Detector Position	*The detector is centered laterally in the Image Receptor Support Device and can move forward or backward to 1 of 7 detent locations. The detent position of the AEC sensor is displayed on the LED of the AEC Position Indicator, and its position is indicated on the Auto Film ID label. Detents are provided in 1.7 cm steps. Position #1 is 1 cm from the chest wall.*
AEC kV and Thickness Tracking	*AEC compensates for kV between 20 kV and 39 kV, and for breast thickness tracking, that includes different breast compositions. The tracking includes the film reciprocity-law failure compensation.* *The AEC operates so that the nominal dose to the ACR MAP Phantom is not greater than 300. When the system is operated with Auto-kV and Auto-Filter modes, the system has a service-selected setting for 200 mrad (2 mGy). The modes are selected.* *Optical density is within 0.15 OD from the mean optical density value at any point within the clinically defined range of kV for breast thicknesses between 2 and 8 cm of breast tissue equivalent material.*

Exposure Termination	*The AEC system calculates if the exposure reaches the Back-up Time, and stops the exposure within one of the following limits:* *1) 50 ms (100 ms in Auto-kV and Auto-Filter)* *2) 5 mAs (10 mAs in Auto-kV and Auto-Filter)* *3) With an entrance exposure to the ACR Accreditation Phantom of less than 50 mR (100 mR in Auto-kV and Auto-Filter modes).* *Indication is made to the Operator. A manual reset is required to continue.*
Density Range	*There are 11 density-adjustment steps, -5 through +5. These steps are adjustable between 4%, 6%, 8%, 10%, 12.5%, or 15% of adjacent mAs values. Default value is 10% and is set on installation by the Service Engineer.* *You can adjust the exposure mAs to a maximum of ±247% by an increase of the DENSITY function. If the system calculates that the exposure will be more than the "Back-up Time", the exposure is stopped.*
Manual Exposure Mode	*Type of Film, Filter, Focal Spot, kV, and mAs are selected. If you use the Large Focal Spot, mA is reduced if the selected mAs gives an exposure time of less than 400 ms. (The result is a longer exposure at the original mAs selection.) The reduced mA is a percentage of the full mA available at the selected kV (60%, 30%, 20%, or 10 mA).*

Note The reduced mA function applies only to Large Focal Spot.

Auto-Time Exposure Mode	*Type of Film, Density, Filter, Focal Spot, and kV are selected. The system calculates pre-mA (100%, 60%, 30%, or 10 mA) from the compression thickness and the kV. The system performs a sample exposure and reads the signal from the AEC detector, then calculates mA and mAs before full exposure. The system can use the full mA available or select from four reduced-mA settings (60%, 30%, 20%, or 10 mA). The Small Focal Spot has one mA value (30% of the full mA value in Large). The Post-mAs display indicates the mAs value at the end of the exposure and remains displayed until the start of the next exposure.*
Auto-kV Exposure Mode	*Type of Film, Density, Filter, and Focal Spot are selected. The system calculates the pre-kV and pre-mA from the compression thickness. When the pre-kV and pre-mA are calculated, the exposure continues as an Auto-Time exposure. The Operator can override the pre- kV and pre- filter. The final kV and post-mAs are displayed on termination of the exposure.*

Auto-Filter Exposure Mode	*Auto-Filter is not enabled in Small Focal Spot.* *Type of Film and Density are selected. The system calculates the pre-kV from the compression thickness and the pre-filter from the value of the Rhodium Switch kV. When the pre-kV and pre-filter are calculated, the exposure continues as an Auto-Time exposure.* *The Operator can override the pre-kV, the pre-filter will change accordingly. When the Rh filter requirement is calculated by the Auto-Filter algorithm, the exposure is stopped while the Rhodium filter is moved into the beam instead of the Molybdenum filter. After the algorithm has selected the kV or kV/filter, the Auto-Time function completes the exposure.* *When the exposure ends, the final kV, Post-mAs and Filter are displayed.*

Note

Auto-Filter exposure mode is not available for magnification case studies.

Dose Calculation and Display	*You can enable or disable the Dose Display mode with the Setup screen. The calculation of the dose assumes a breast composition of 50% adipose, 50% glandular.* *The displayed dose values are within ±10% of the dose.* *The system requires the entry of the exposure data before it can display the dose. Dose values are displayed on the Operator Console, film data flashed by the Auto Film ID, and Mammography Information System (MIS) exposure record.*
Dose Display Selection Options	*Dose Display options are AGD or AGD/ESD.* *If AGD/ESD is selected, then both AGD and ESD appear on the Operator Console, Auto Film ID, and MIS exposure record.* *If AGD is selected, then only AGD appears on the Auto Film ID. Both AGD and ESD appear on the remote console, and MIS exposure record.*

Dose Display Function	*When Dose Display is disabled, there is no display of either dose or the field labels for dose.* *When Dose display is enabled but the Host has not received required data, the dose fields display "N/A".* *When Dose Display is enabled and the Host has accepted the required data, the system calculates and displays dose as shown below.* *If Dose Display is enabled, and a DSM, StereoLoc/DSM, or StereoLoc/Film are installed on the M-IV, the fields display "N/A."* *Half-Value Layer (HVL) values displayed by the system are within 0.01mmAl of the HVL values. Half-Value Layer values meet regulations.* *The Tube Output values displayed by the system are within 1% (total range of 2%) of the tube output values.* *The displayed AGD and ESD values are within 5% (total range of 10%) of the dose values.*
Dose Display Resolution	*The units for Mean Glandular Dose calculation selection are: System International (SI) and Common units.* *Standard International (SI):* *AGD.=X.XX mGy* *ESD=XX.XX mGyCommon:* *AGD.=X.XX mrad* *ESD=XX.XX mrad.*

Appendix B
Alert Codes

Table 4: Alert Codes

Message	Description	User Action
Premature release of Exposure Switch	The exposure switch was released before the end of the exposure.	Press the x-ray buttons for the complete exposure.
Exposure Terminated by back up timer	The exposure time required was more than the software backup time. (500-mAs backup timer)	Call Technical Support.
Calculated exposure time exceed back up time	Auto-Time, Auto-kV and Auto-Filter modes. The calculated exposure is more than five seconds.	Call Technical Support.
X-ray switches not released after exposure	X-ray buttons not released during post exposure routine.	Release the button and make sure the buttons operate. If a problem remains, call Technical Support.
X-ray switches on at power up	X-ray buttons are closed during unit power up.	Release the button and make sure the buttons operate. If a problem remains, call Technical Support.
Calculated exposure time is less than available exposure time	Host Software version 5.4.1 and earlier. HTC only: Minimum time for grid operation is 400 ms.	Insufficient or no compression used. Re-compress and re-expose.
System Error 20	Rotor Error:	Call Technical Support.
System Error 21	Start from Host without x-ray switch fault	Call Technical Support.
System Error 22	Tube Arc Fault	Call Technical Support.
System Error 23	Tube Overcurrent	Call Technical Support.
System Error 24	Tube Overvoltage	Call Technical Support.
System Error 25	High Voltage Inverter overcurrent fault	Call Technical Support.
System Error 26	High Voltage Interlock fault	Call Technical Support.
System Error 27	Filament overcurrent fault	Call Technical Support.
System Error 28	Filament overvoltage fault	Call Technical Support.
System Error 29	Filament grid error	Call Technical Support.
System Error 30	Error in data from Host: The error can indicate a software lockup with the Host.	Call Technical Support.
System Error 31	Hardware backup timer	Call Technical Support.
System Error 32	Software Timeout. Timer greater than five seconds.	Call Technical Support.
System Error 33	Image Receptor exposure error	Call Technical Support.
System Error 34	Focal spot relay fault	Call Technical Support.

Table 4: Alert Codes

Message	Description	User Action
System Error 35	The Tube current error	Call Technical Support.
System Error 43	mAs error	Call Technical Support.
System Error 50	Bucky fault, (not HTC grid)	Call Technical Support.
System Error 51	Bucky fault	Call Technical Support.
System Error 60	CCW rotation switch closed	Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 61	Clockwise rotation switch closed.	Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 62	The Lamp switch closed: Inspect the tubehead switches.	Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 63	Compression "Up" switch closed: Inspect C-arm and footswitches.	Inspect C-arm and footswitches. Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 64	Compression "Down" switch closed: Inspect C-arm and footswitches.	Inspect C-arm and footswitches. Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 65	Compression "Release" switch closed: Inspect C-arm and footswitches.	Inspect C-arm and footswitches. Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 66	C-arm Vertical "Up" switch closed: Inspect C-arm and footswitches.	Inspect C-arm and footswitches. Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
System Error 67	C-arm Vertical "Down" switch closed:	Inspect C-arm and footswitches. Release the switch and make sure the switches operate. If a problem remains, call Technical Support.
SL II Motion Error 68	StereoLoc II not in alignment	Call Technical Support.
Motion Error 69	C-arm drive motor communication fault.	Call Technical Support.
Tubehead Error 70	Motorized collimator error.	Call Technical Support.
Tubehead Error 71	Motorized mirror error.	Call Technical Support.
Tubehead Error 72	Motorized filter error.	Call Technical Support.

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