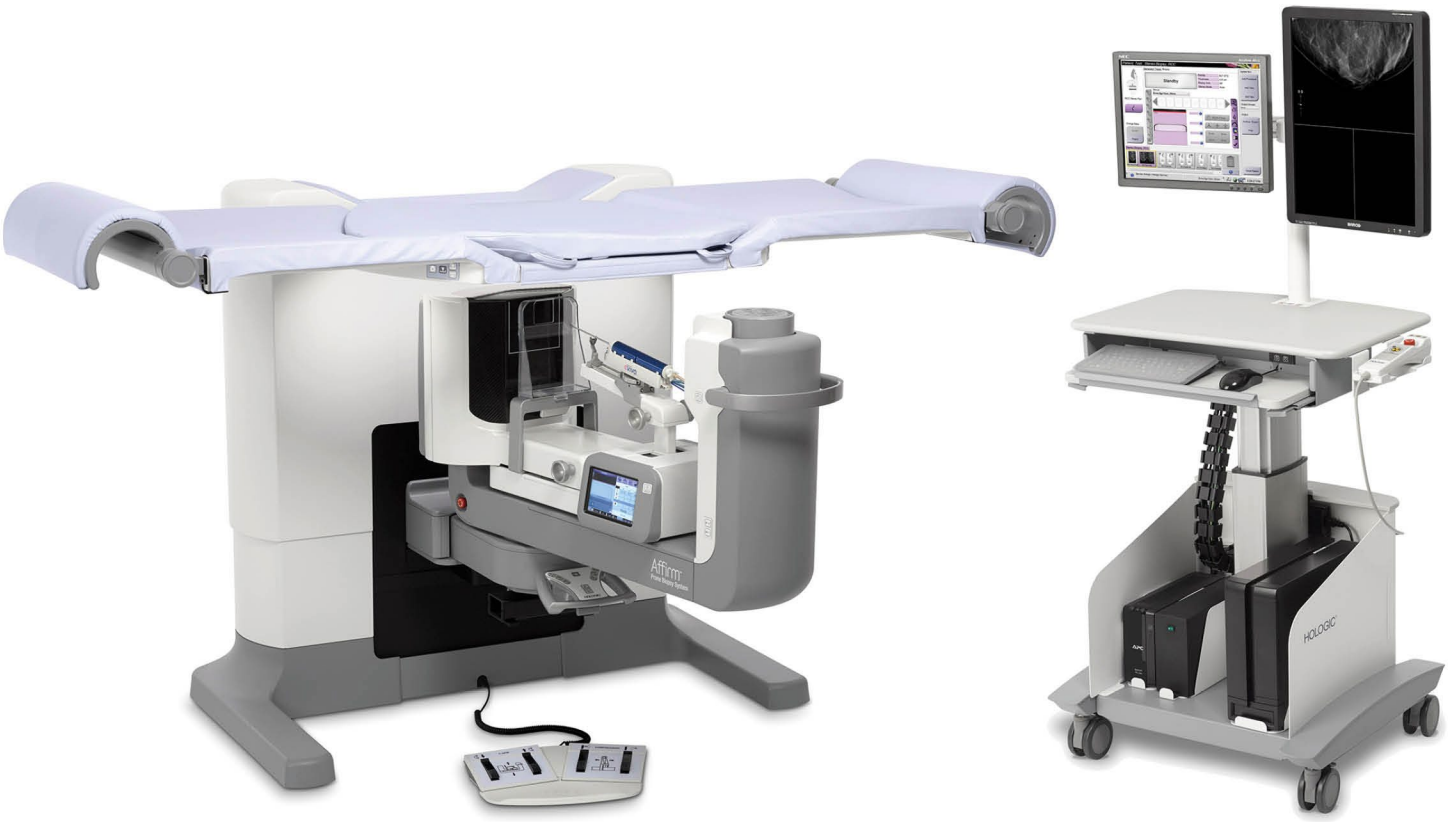
Affirm®
Prone Biopsy System



Service Manual

MAN-04482 Revision 006

HOLOGIC®

Affirm®

Prone Biopsy System

Service Manual

For Software Version 1.x

Part Number MAN-04482
Revision 006
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HOLOGIC®

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Table of Contents

List of Figures

List of Tables

Chapter 1 Introduction

1.1 Preface

Read all this information carefully before installation and operation. Follow all warnings and precautions as stated in this manual. Keep this manual available during procedures. Physicians should tell patients about all potential risks and adverse events described in this manual with respect to the operation of the system.

1.2 Intended Use

℞ Only Caution: Federal law restricts this device to sale by or on the order of a physician.

The Affirm® prone biopsy system is intended for lesion location for biopsy while the patient is in the prone position to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

1.2.1 Indications for Use

The Affirm prone biopsy system combines the function of a standard x-ray mammography unit with that of a lesion localization system to produce a device that has specific application in first accurately localizing lesions in the breast in two and/or three dimensions, and then providing guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices) for lesions determined to be suspicious through prior mammographic examination.

1.2.2 Contraindications

- Patient weighs more than 181 kg (400 pounds).
- Inability to visualize the lesion under mammographic imaging.
- Patient cannot remain in a prone position during the entire procedure.

1.3 Essential Performance

The essential performance requirements of the Affirm prone biopsy system is as defined in IEC-60601-2-45: 2005. These include: accuracy of loading factors, automatic control system, imaging performance, missed tissue at chest wall side, breast compression device, linearity of air kerma over limited intervals of loading factors, and reproducibility of the X-radiation output.

1.4 System Capabilities

The Affirm prone biopsy system is a tomosynthesis-capable mammography system for performing breast biopsies on patients lying in the prone position. The system localizes suspicious lesions, as determined through prior mammographic examinations, using either stereotactic or tomosynthesis techniques. The system then affords a physician the capacity of performing vacuum-assisted needle core biopsy or needle (wire) localization of the lesion.

Localization can be accomplished either via conventional stereotactic imaging, or by examination of a tomosynthesis data set. With tomosynthesis, the image plane or "slice" most fully containing the suspected lesion is chosen by the physician from the data set to identify the lesion depth within the breast.

1.5 User Profiles

1.5.1 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.
- Understands stereotactic breast biopsy procedures.
- Understands how to operate a computer and its peripherals.
- Understands sterile procedures.

1.5.2 Radiologists, Surgeons

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

1.5.3 Medical Physicist

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

1.6 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 incorrect system operation.

1.7 Quality Control Requirements

Perform all Quality Control tests within the correct time frame.

1.8 Warranty Statement

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

1.9 Technical Support

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

1.10 Product Complaints

Report any complaints or problems 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.

1.11 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 at *www.Hologic.com*.

1.12 Symbols

This section describes the Symbols on this system.

Symbol	Description
	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.

Symbol	Description
	Dangerous Voltage
	Manufacturer
	Date of Manufacture
	This system transmits radio frequency (RF) energy (non-ionizing radiation)
	Wi-Fi connection
	Caution—Radiation
	Alternating current
	Follow operating instructions
	Follow the *User Guide*
	Caution
	Fragile, handle with care
	Temperature limit
	Humidity limitation
	Do not immerse in any liquid
	No pushing

Symbol	Description
	No stepping on surface
	No sitting
	Combined weight of the equipment and its safe working load
EC REP	Authorized representative in the European community
REF	Catalog number
SN	Serial Number

1.13 Descriptions of 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 damage to equipment, loss of data, or damage to files in software applications.

Note
Notes show additional information.

Chapter 2 General Information

2.1 System Overview

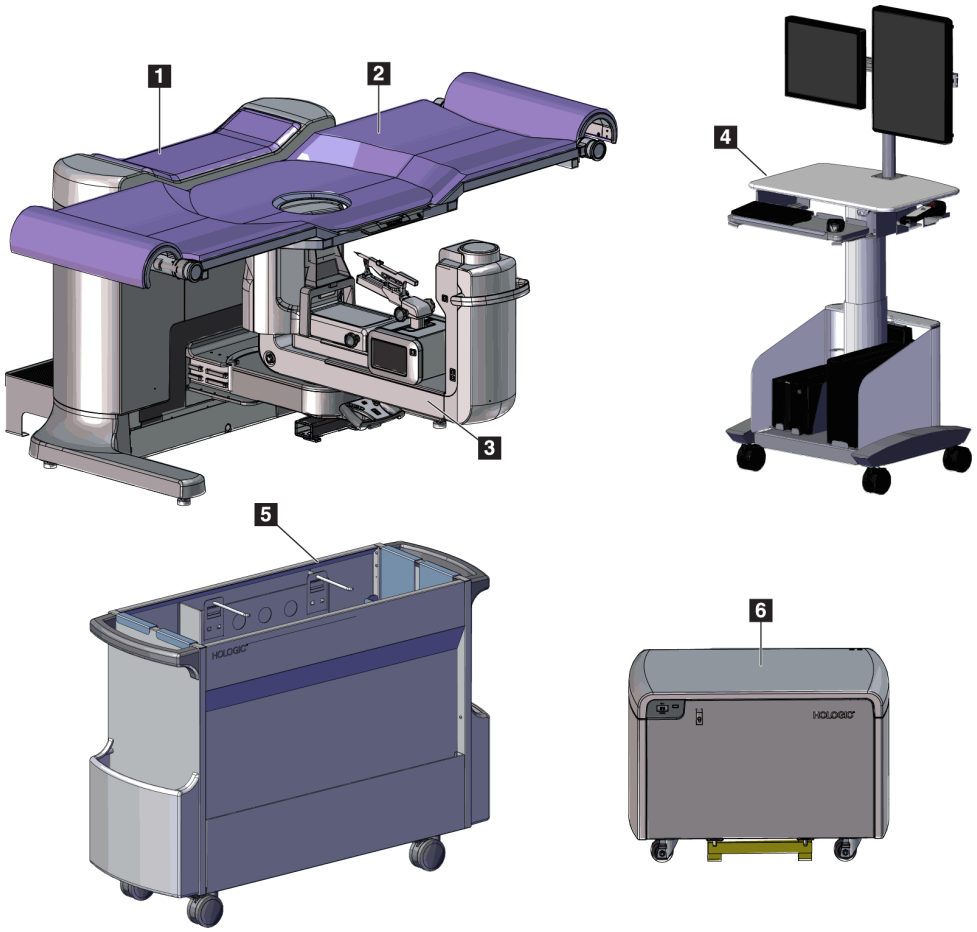

Figure 1: Affirm Prone Biopsy System

Figure Legend

1. Gantry
2. Patient Support Platform
3. C-Arm
4. Acquisition Workstation
5. Accessory Cart
6. High Voltage Generator

Note
A radiation shield is not provided with the Affirm prone biopsy system.

Note
The Acquisition Workstation has wheels for ease of positioning only. The system is NOT a mobile unit.

2.1.1 C-Arm Overview

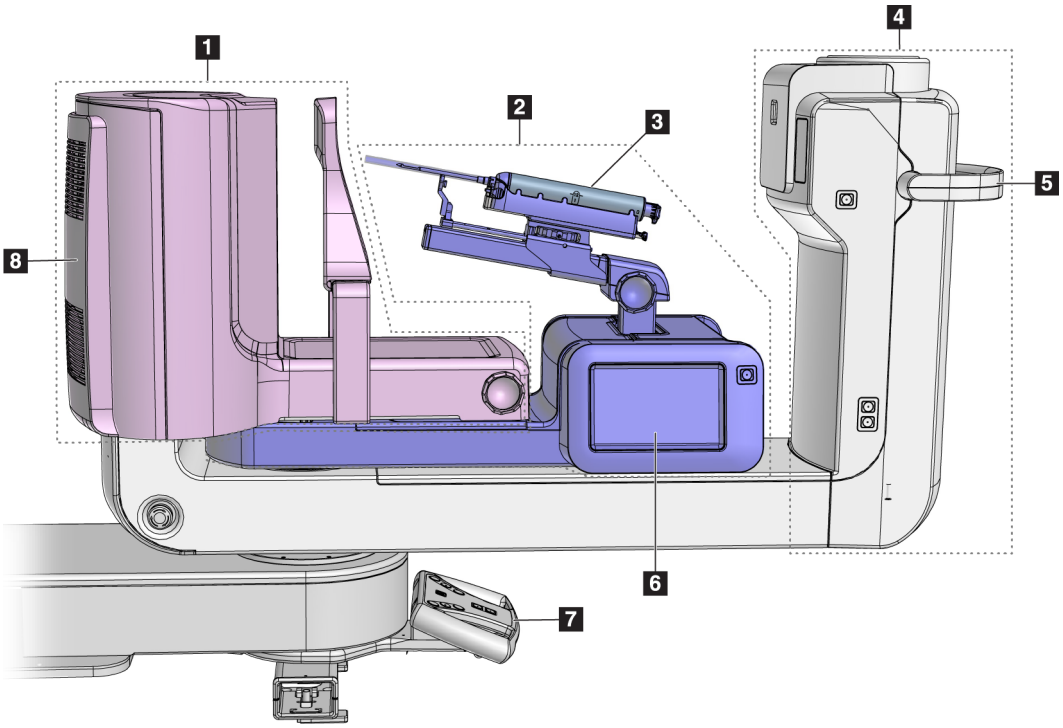

Figure 2: C-arm Overview

Figure Legend

1. Compression Arm
2. Biopsy Arm
3. Biopsy Device
4. Tubehead
5. C-arm Rotation Handle
6. Biopsy Control Module Display
7. Control Handle
8. Image Receptor

2.2 Safety Information

Read and understand this manual before you use the system. Keep the manual available during the patient procedures.

Always follow all the instructions in this manual. Hologic does not accept the responsibility for injury or damage from incorrect system operation. Hologic can schedule training at your facility.

The system has protective devices, but the Technologist must understand how to safely use the system. The Technologist must remember the health hazards of x rays.

2.3 Warnings and Precautions

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.

APPLIED PARTS include Compression Paddles, Breast Platform, and Patient Platform.

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

WARNING!
For North American electrical safety requirements, use a Hospital Grade receptacle to supply a correct Ground.

WARNING!
Electrical equipment used near flammable anesthetics can cause an explosion.

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, a diagnostic review workstation, or a hard copy printer) in the Patient Area.

WARNING!
Keep a 1.5 meter safe distance between the patient platform and the acquisition workstation.

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

WARNING!
The user must correct problems before the system is used. Contact an approved service representative for preventive maintenance.

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

Warning:
This device contains dangerous material. Send decommissioned material to Hologic or contact your service representative.

Warning:
C-arm movement is motorized.

Warning:
You increase the patient dose to high levels when you increase the AEC exposure adjustment. You increase the image noise or decrease image quality when you decrease the AEC exposure adjustment.

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

Warning:
The disk drives installed in this system are a Class I Laser Product. Prevent direct exposure to the beam. Hidden laser radiation exists if the case to a disk drive is open.

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

Warning:
Do not move the C-arm while the system retrieves the image.

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

Warning:
Do not leave the patient unattended during the procedure.

Warning:
Keep the hands of the patient away from all buttons and switches at all times.

Warning:
Place each footswitch in a position where, when used, they remain in reach of the Emergency Off Switches.

Warning:
Position the footswitches to prevent accidental operation by a patient or wheelchair.

Warning:
To prevent a higher radiation dose to the patient, only put approved materials in the x-ray beam path.

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

Warning:
Use protective radiation shielding with a lead equivalent of more than .08 mm.

Warning:
Do not sit on or step on the generator.

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

Caution:
Do not turn off the Acquisition Workstation circuit breaker except in emergency. The circuit breaker can turn off the Uninterruptible Power Supply (UPS) and risk data loss.

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

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

Caution:
Do not block or cover the fan ports located on the rear cover of the Digital Image Receptor.

Caution:
To prevent possible damage from thermal shock to the Digital Image Receptor, follow the recommended procedure to turn off the equipment.

Caution:
The display is calibrated for compliance to DICOM standards. Do not make any brightness or contrast adjustments to the display.

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

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

2.4 Emergency Off Switches

A red Emergency Off (E-Stop) switch is located on each side of the tube arm and on the x-ray remote control. The Emergency Off switch disables C-arm and Patient Platform movement and removes power from the Gantry.

Do NOT use the E-Stop switches for routine system shutdown.

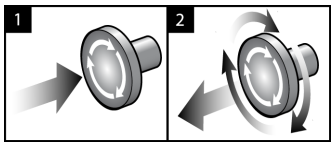

Figure 3: Emergency Off Switch Functionality

1. Press any of the Emergency Off switches to power OFF the Gantry.
2. To reset the Emergency Off switch, turn clockwise approximately one-quarter turn until the switch pops back out.

2.5 Interlocks

- The electronic System Lock only allows C-arm movement when the **System Lock** button on the Control Handle is in unlocked mode.
- The system does not allow x-ray exposure unless in a Ready state and the **System Lock** button on the Control Handle is in locked mode.
- If the x-ray button is released before the end of the exposure, the exposure stops and an alarm message shows.
- The system does not enter a Ready state following an exposure until the x-ray button is released.

2.6 Compliance

This section describes the system compliance requirements and the responsibilities of the manufacturer.

2.6.1 Compliance Requirements

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

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

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

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

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

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

Caution:
This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.

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

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

2.6.2 Compliance Statements

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

IEC:

- IEC 60601-1: 2005 - Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3: 2008 - General requirements for radiation protection in diagnostic x-ray equipment
- IEC 60601-1-6: 2010 - Collateral Standard: Usability
- IEC 60601-2-28: 2010 - Particular requirements for the basic safety and essential performance of x-ray tube assemblies for medical diagnosis
- IEC 60601-2-45: 2011 - Particular requirements for the basic safety and essential performance of mammographic x-ray equipment and mammographic stereotactic devices

FDA:

- 21 CFR §900 – Mammography Quality Standards Act (MQSA)
- 21 CFR §1020.30 – Diagnostic x-ray systems and their major components
- 21 CFR §1020.31 – Radiographic equipment

CE:

- 93/42/EEC – CE marking according to MDD
- 2006/42/EC – Machinery Directive of 17 May 2006
- 2002/95/EC – Restriction of Hazardous Substances Directive of 27 January 2003
- 2002/96/EC – Waste Electrical and Electronic Equipment Directive of 27 January 2003

CAN/CSA:

- CAN/CSA-C22.2 No. 60601-1 (2008): Medical electrical equipment - Part 1: General requirements for safety

ANSI/AAMI:

- ANSI/AAMI ES60601-1 (2005) - Medical electrical equipment— Part 1: General requirements for basic safety and essential performance

2.7 Label Locations

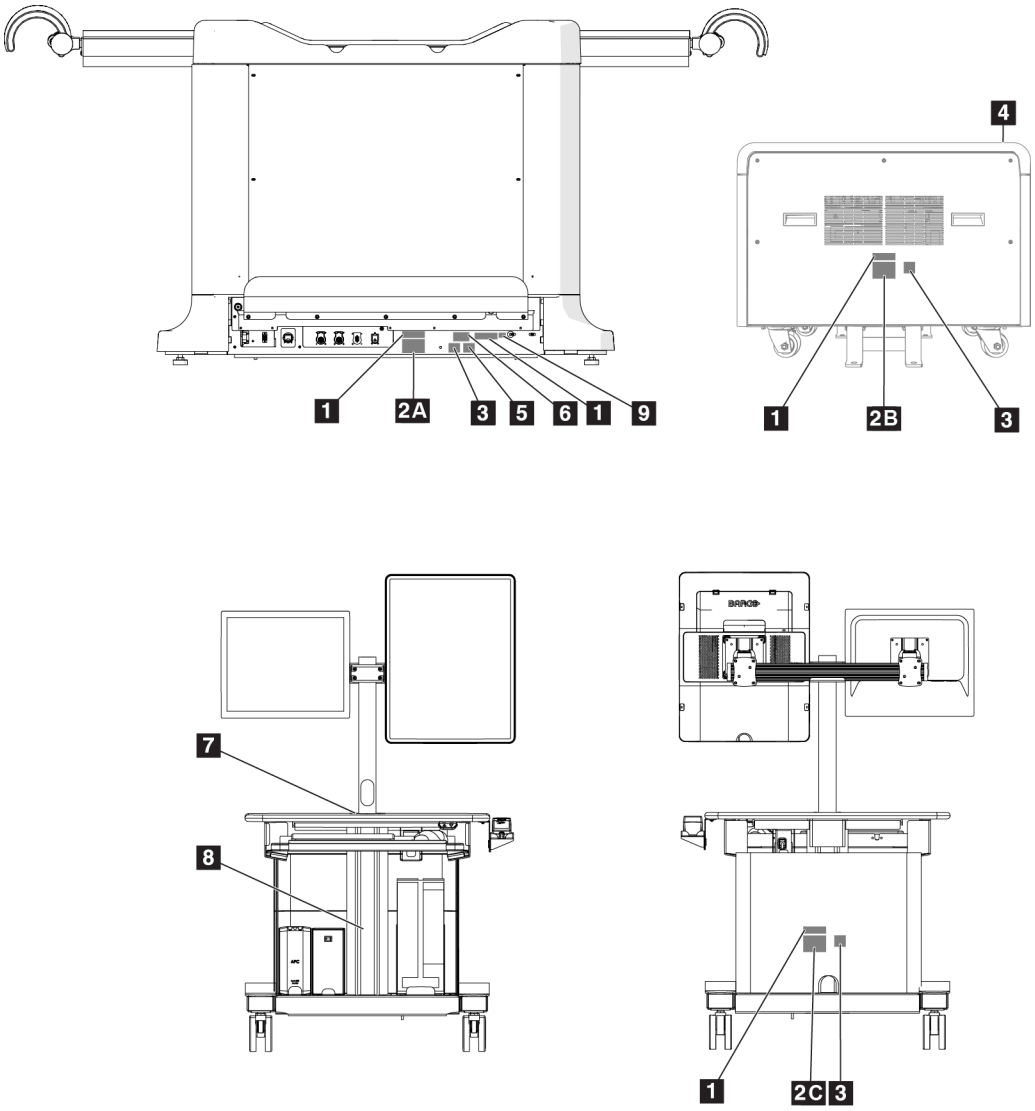

Figure 4: Label Locations

Table 1: System Labels

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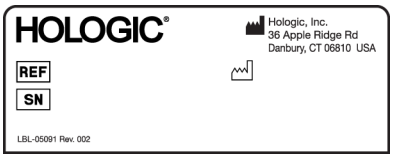

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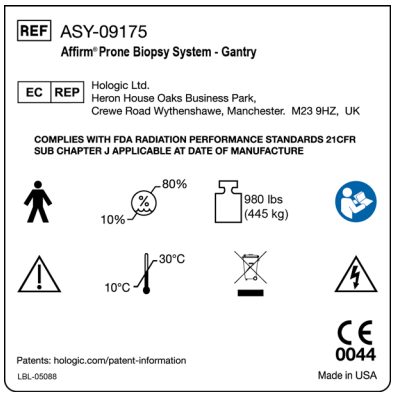

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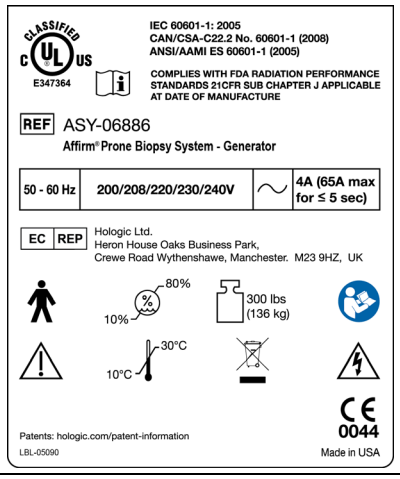
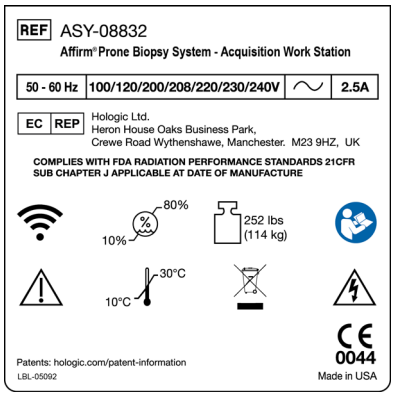


2C



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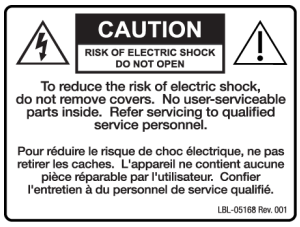

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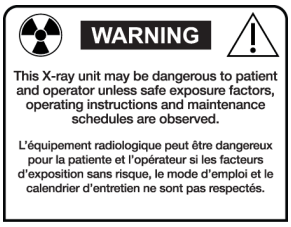

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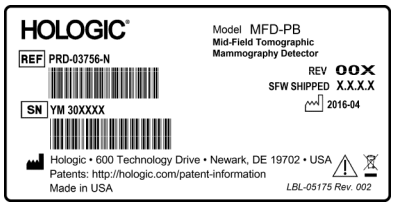

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Chapter 3 Installation

3.1 System Installation Overview

This chapter contains procedures for unpacking, installing, and setting up the Affirm™ Prone Biopsy System. Also included are directions for connecting the system to a power source, including measuring the voltage of the input power receptacle, and tapping the isolation transformer.

The unpacking procedure consists of inspecting the external package for evidence of shipping damage of received goods, and removing the system from the shipping crate.

Upon receipt of the Affirm system, examine all crates, packages, and boxes for external damage that may have occurred during shipment.

Note any evident damage on the shipping manifest and immediately notify the carrier of the incident. If you find shipping damage of a concealed nature, contact the carrier immediately and request an Inspection of Shipping Damage.

Warning:
Be sure to have the necessary machinery and personnel available to move heavy medical equipment safely.

3.2 Receiving Instructions

The Affirm Prone Biopsy System is shipped in sections on separate pallets. Each pallet is packed with several containers. There are containers for the:

- Gantry/C-arm Assembly
- Generator
- Patient Platform
- Acquisition Workstation
- Accessory Cart (optional)
- Image Detector (shipped separately; not part of any pallets)

Note
A Hologic representative must be present at the time of delivery and is responsible for unpacking the product.

Note
If there is a discrepancy between the contents received and the packing list or sales order, contact Hologic immediately. If there is any damage that has occurred during shipping, contact the carrier immediately. If it is necessary to repack any items for future installation, use the original packaging materials.

Note
If shipping damage is concealed, contact the carrier immediately after discovery.

Note
Refer to TB-01308 that documents the Affirm Prone system unpacking with more detail and illustrations than what is shown in this manual.

At the time of receipt, perform the following steps before opening the containers:

1. Inspect each container for damage.
2. Note any damage on the shipping manifest.
3. Notify Hologic of any external shipping damage that has occurred.

3.2.1 Unpack the Generator

Warning:
Be sure to have the necessary machinery and personnel available to move heavy medical equipment safely.

Warning:
To prevent injury to personnel and/or damage to equipment, care must be taken when uncrating the equipment.

Warning:
Do not sit on, step on, or push the generator.

Note
Refer to TB-01308 that documents the Affirm Prone system unpacking with more detail and illustrations than what is shown in this manual.

1. While still in the loading area, carefully remove all shipping materials (foam padding, tie-downs, straps, shipping wrap, and so on) from around the Generator.
2. Open all bags/packages stored with the Generator, and check their contents against the packing list and sales order. Report all discrepancies immediately.
3. Inspect each item for damage, then safely store them near the exam site.
4. Swing down the hinged, wood side panel of the container and carefully roll the Generator off the pallet. Roll the Generator from the loading area to the exam area.

3.2.2 Unpack the Gantry/C-Arm Assembly

Warning:
Be sure to have the necessary machinery and personnel available to move heavy medical equipment safely.

Warning:
To prevent injury to personnel and/or damage to equipment, care must be taken when uncrating the equipment.

Note
Refer to TB-01308 that documents the Affirm Prone system unpacking with more detail and illustrations than what is shown in this manual.

To unpack the Gantry/C-arm assembly from the shipping container:

1. While still in the loading area, carefully remove all shipping materials (foam padding, tie-downs, straps, shipping wrap, and so on) from around the Gantry assembly.
2. Open all boxes removed from around the Gantry assembly, and check their contents against the packing list and sales order. Report all discrepancies immediately.
3. Inspect each item for damage, then safely store them near the exam site.
4. Use rigging to carefully remove the Gantry assembly from the crate.
5. Transport the Gantry Assembly from the loading area to the exam area.
6. Remove the C-arm support braces.

3.2.3 Unpack the Patient Platform

Warning:
Be sure to have the necessary machinery and personnel available to move heavy medical equipment safely.

Warning:
To prevent injury to personnel and/or damage to equipment, care must be taken when uncrating the equipment.

Note
Refer to TB-01308 that documents the Affirm Prone system unpacking with more detail and illustrations than what is shown in this manual.

1. While still in the loading area, carefully remove all shipping materials (foam padding, tie-downs, straps, shipping wrap, and so on) from around the Patient Platform.
2. Open all boxes removed from around the Patient Platform, and check their contents against the packing list and sales order. Report all discrepancies immediately.
3. Inspect each item for damage, then safely store them near the exam site.
4. Carefully maneuver the Patient Platform off the pallet, and transport it from the loading area to the exam area.

3.2.4 Unpack the Acquisition Workstation

The Acquisition Workstation is crated and shipped upright. Most options and accessories are preinstalled on the workstation. Items such as the image display monitor, keyboard, and mouse are packed separately. These packages may be included in the workstation shipping container. The Acquisition Workstation cart comes with four casters mounted on the base that can be locked with integral foot brakes.

Warning:
Be sure to have the necessary machinery and personnel available to move heavy medical equipment safely.

Warning:
To prevent injury to personnel and/or damage to equipment, care must be taken when uncrating the equipment.

Note
Refer to TB-01308 that documents the Affirm Prone system unpacking with more detail and illustrations than what is shown in this manual.

To unpack the Acquisition Workstation from the shipping container:

1. While still in the loading area, carefully remove all shipping materials (foam padding, tie-downs, straps, shipping wrap, and so on) from around the workstation and wooden pallet. Remove any accessory boxes.
2. Open all boxes removed from the workstation shipping container, and check their contents against the packing list and sales order. Report all discrepancies immediately.
3. Inspect each item for damage, then safely store them near the exam site.
4. Swing down the hinged, wood side panel of the container. Remove the wooden block holding the workstation in place. Unlock the casters, and carefully roll the workstation off the pallet.
5. Place the keyboard and mouse at the desired location on the cart shelf.
6. Check the display for obvious damage and loose or missing hardware.
7. Check the control monitor screen surface for nicks, chips, scratches, cracks, or other damage.
8. Check the computer for obvious damage, loose or missing screws, loose or missing buttons or switches, and other damage. Check for cables and boards that may have become dislodged during shipping. Be sure to reseat boards and connectors if necessary.
9. Move the Acquisition Workstation to the exam area, and then lock the cart in place using the foot brakes.

3.2.5 Unpack the Accessory Cart

The accessory cart is crated and shipped upright on its own pallet. The accessory cart comes with four casters mounted on the base that can be locked with integral foot brakes.

Warning:
Be sure to have the necessary machinery and personnel available to move heavy medical equipment safely.

Warning:
To prevent injury to personnel and/or damage to equipment, care must be taken when uncrating the equipment.

Note
Refer to TB-01308 that documents the Affirm Prone system unpacking with more detail and illustrations than what is shown in this manual.

To unpack the accessory cart from the shipping container:

1. While still in the loading area, carefully remove all shipping materials (foam padding, tie-downs, straps, shipping wrap, and so on) from around the accessory cart and wooden pallet. Remove any accessory boxes.
2. Open all boxes removed from the shipping container, and check their contents against the packing list and sales order. Report all discrepancies immediately.
3. Inspect each item for damage, then safely store them near the exam site.
4. Lift the accessory cart with the handles (one person one each side) from the crate unto the floor.
5. Move the accessory cart to the exam area, and then lock the cart in place using the foot brakes.

3.2.6 Unpack the Image Detector

The image detector is shipped separately from the rest of the system in a temperature-controlled package.

Caution:
Move the Detector to a controlled area prior to unpacking.

Caution:
To prevent damage, use extreme care to unpack the image detector.

Caution
Leave the plastic shipping cover on the detector until actual installation. This plastic cover protects the mylar surface (the shiny silver section) from damage.

Note
If shipping damage is concealed, contact the carrier immediately after discovery.

To unpack the detector:

1. Upon receipt of the detector, move it to a controlled area which meets the environmental requirements (see Storage Environment).
2. Carefully open the multi-layer shipping container and check the contents for damage. Report all issues/discrepancies immediately.
3. Locate and check the temperature logger:
   - If it has a blinking/steady green LED (depends on logger model), that signifies the package stayed within the proper temperature range during shipment. Continue with step 2.
   - If it has a blinking/steady bold red LED (depends on logger model), that signifies the package strayed outside the proper temperature range during shipment. Call Hologic Tech Support for the proper follow-up action.
4. Remove the detector from its container and set aside. Leave the black plastic shipping covering on the detector until actual installation.
5. Locate and set aside the plastic bag containing the detector labels and the detector installation hardware.

3.3 Setting Up and Installing Components

The following sections detail setting up, positioning, and installing the system in the exam room.

Caution:
Make sure that there is an installed circuit breaker at the Mains that meets the following requirements:

40A Breaker, UL 489, or UL HACR listed

Caution

To avoid image artifacts from occurring:

- **If the system is installed in a mobile coach, care should be exercised not to locate or park the mobile coach near sources of high power (such as power transmission lines and outdoor transformers).**
- **Make sure that any mobile power generator, uninterruptable power system (UPS), or voltage stabilizer is at least 3 meters (10 feet) from the closest point of the image detector travel.**

Note
For those installations in regions with a seismic requirement, an Affirm Prone system Seismic Kit (ASY-09081) is available.

Note
For mobile installations, refer to MAN-05007, FMI, Affirm Prone, Mobile Installation.

Note
The network and communications equipment must be installed to meet IEC Standards. The complete system must be installed to meet IEC 60601-1 and IEC 60601-1-1.

Note
Thoroughly read all procedures before starting the installation.

3.3.1 Exam Room Layout

The following figure displays a typical exam room layout and the minimum clearance zones.

Note
The clearance dimensions referenced in the following figure are the minimum for general purposes. The customer needs to make sure that all installations meet local regulations.

Note
The system is not equipped with a radiation protection shield for the operator. The room must be designed to incorporate local, state, and federal guidelines for shielding.

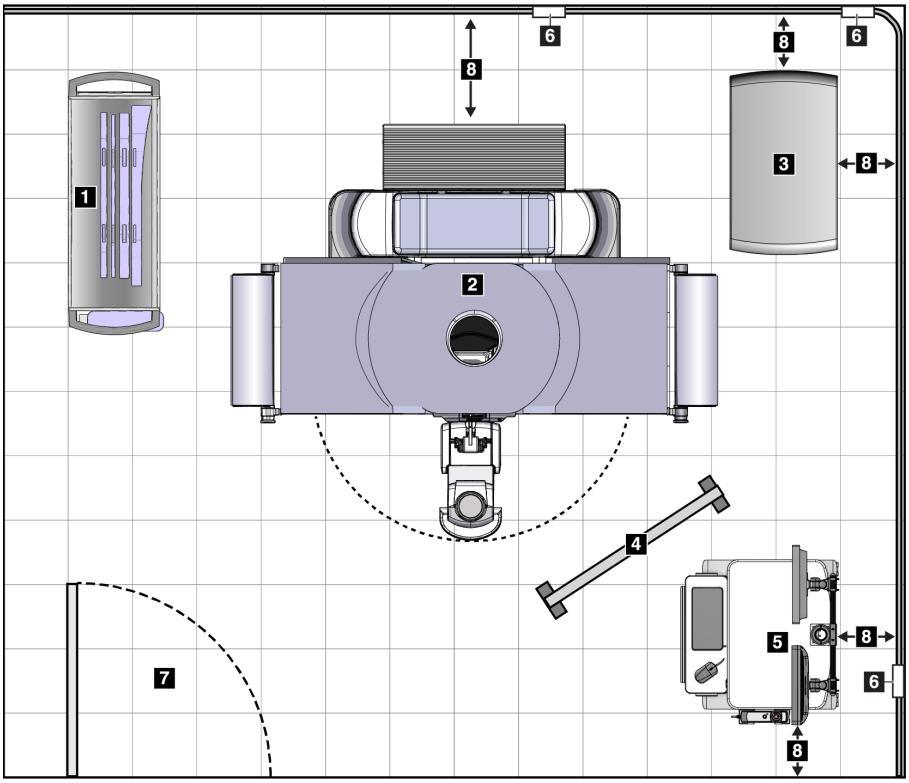


Figure 5: Typical Exam Room Layout

Item	Description	Minimum Clearance
1	Accessory Cart	Customer accessible
2	Gantry/Patient Platform Assembly	• 30.5 cm (12 inches) at the rear • 91.4 cm (3 feet) on each side of table for head/feet of patient • 91.4 cm (3 feet) at front for operator and patient access

Item	Description	Minimum Clearance
3	Generator	Service accessible
4	Radiation Shield (supplied by customer)	Customer accessible
5	Acquisition Workstation	• 30.5 cm (12 inches) at the rear • 91.4 cm (3 feet) at front for operator access
6	Wireway for Mains Circuit Breaker (40A Breaker, UL 489, or UL HACR listed) and interconnecting cables	Per local regulations
7	Doorway minimum clearance	91 cm (3 feet)
8	Equipment-to-wall clearances	Consult local regulations (if not specified in this table)

3.3.2 Install the Gantry/Patient Platform Assembly

Install the Patient Platform on the Gantry Assembly

Caution:
Before installing, make sure that the work area provides ample space to maneuver the patient platform into position on the Gantry. After installing, ensure that there is enough room around the Patient Platform for patient movement and C-arm rotation (refer to *Exam Room Layout* on page 27).

Warning:
Lifting and installing the Patient Platform onto the Gantry requires two people.

1. Move the Gantry into its final installation position.
2. Remove the shipping dollies and return to Hologic in the container shipped with the Gantry.
3. Remove the Gantry rear cover and inside metal plate (refer to *Covers Removal - Gantry Section* on page 182).

4. Locate the two table mounting brackets on top of the Gantry (see item 1 in the following figure). For *each* mounting bracket, loosen the:
   - six 1/8-16 allen hex bolts on top of the brackets
   - three 1/4-20 allen hex bolts on the side of the brackets
   - two 1/4-20 allen hex bolts on the bottom of the brackets

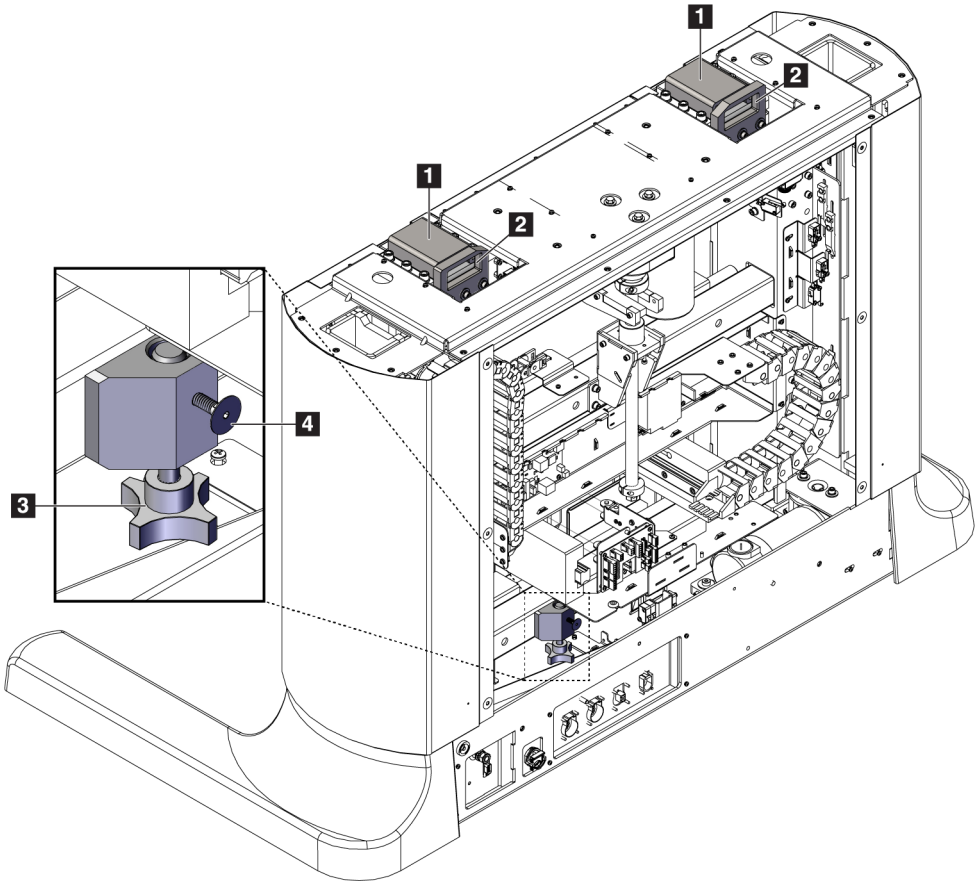


Figure 6: Patient Platform Mounting Brackets on Gantry

5. Remove the two securing pins for the Gantry yellow moving handle and slide the moving handle out of the two platform mounting collars/catches. (See the following figure).
6. Place the yellow handle in the return container shipped with the Gantry and return to Hologic.

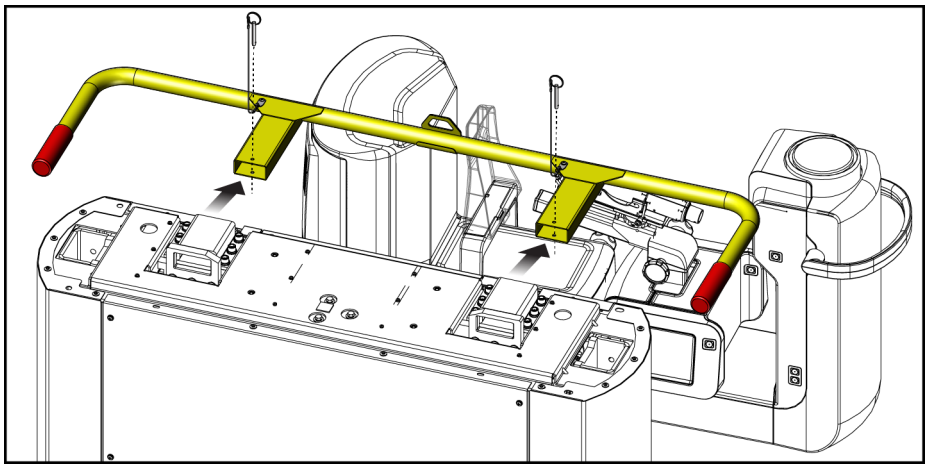


Figure 7: Remove Gantry yellow move handle

7. Verify/set the patient platform angle for each patient platform mounting bracket. Use TLS-05884 (Table Angle Support Setting Tool) for this procedure.
   a. Place TLS-05884 (item 1 in following figure) inside a mounting bracket flat against the mounting surface with the machined notch located above the adjustment block (item 2) as shown in the following figure.
   b. Make sure the table adjust plate meets the bottom undercut surface of TLS-05884 (item 2 in same figure) while remaining flat on the mounting surface.

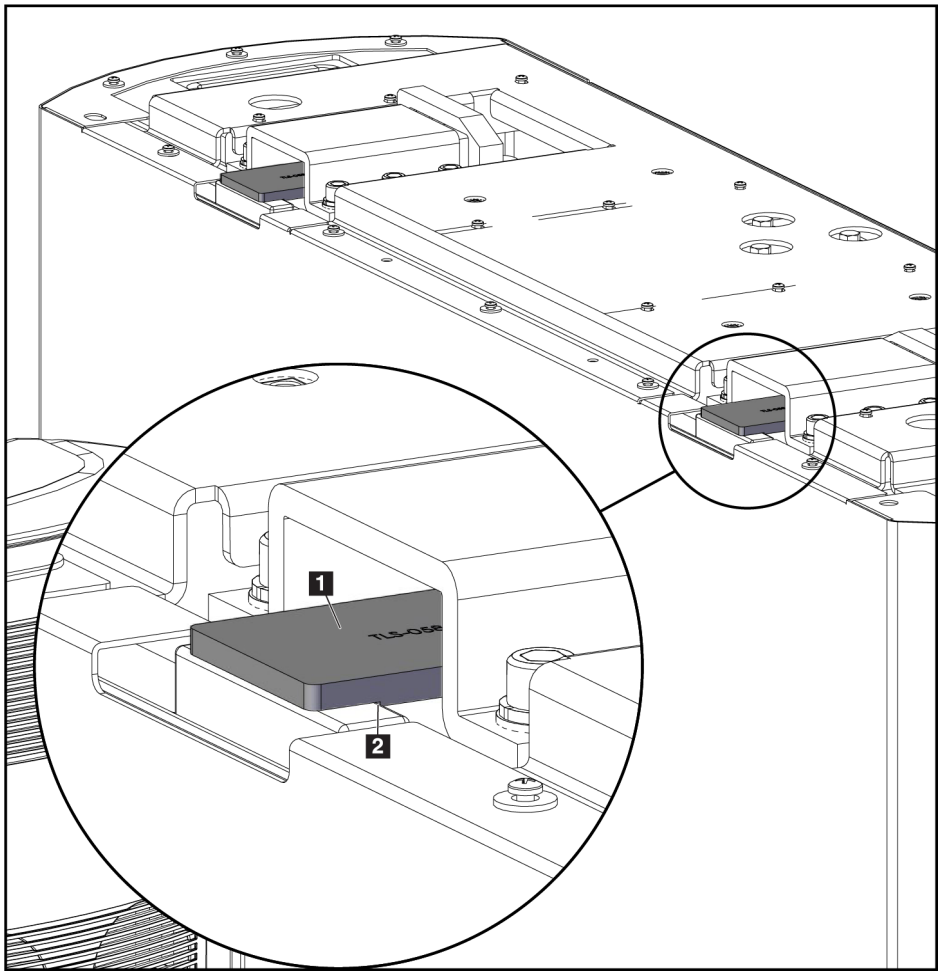


Figure 8: Tool in place for platform angle verification

If it does not, loosen and remove the jam nut (item 1 in following figure). (Early models may not have this jam nut.) Adjust the setscrew (1/4", item 2) under the jam nut until the table adjust plate meets the bottom undercut surface of TLS-05884. Lock the setscrew in place with the same jam nut (if available).

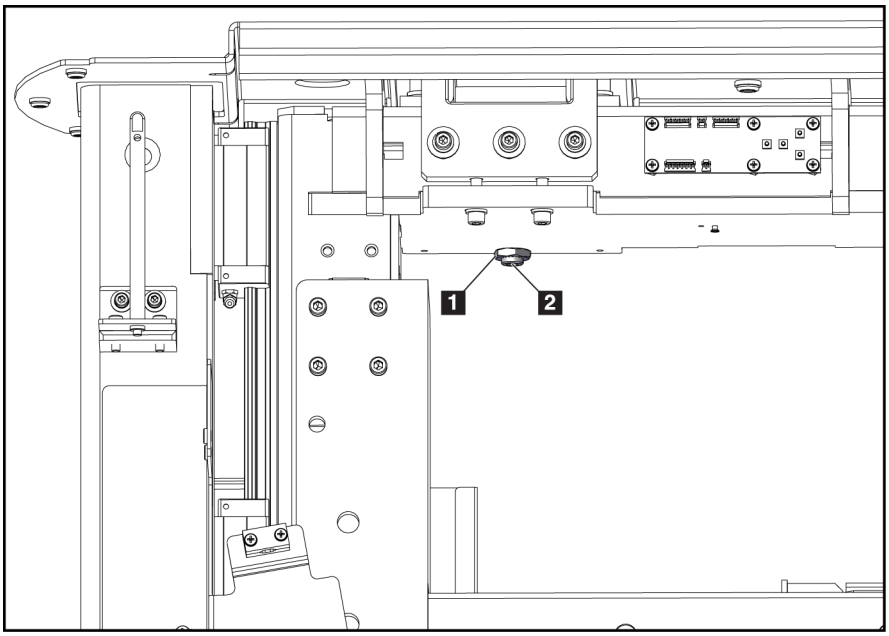


Figure 9: Adjusting platform angle (looking from rear of Gantry)

c. Repeat steps a - b for the other mounting bracket.

8. Using two people, lift and slide the mounting arms of the Patient Platform into the platform mounting brackets (see item 1 in the following figure) and platform mounting collars/catches (see item 2 in following figure) on top of the Gantry. Make sure that the mounting collars/catches are up (as shown in the following figure) when sliding the platform into place.

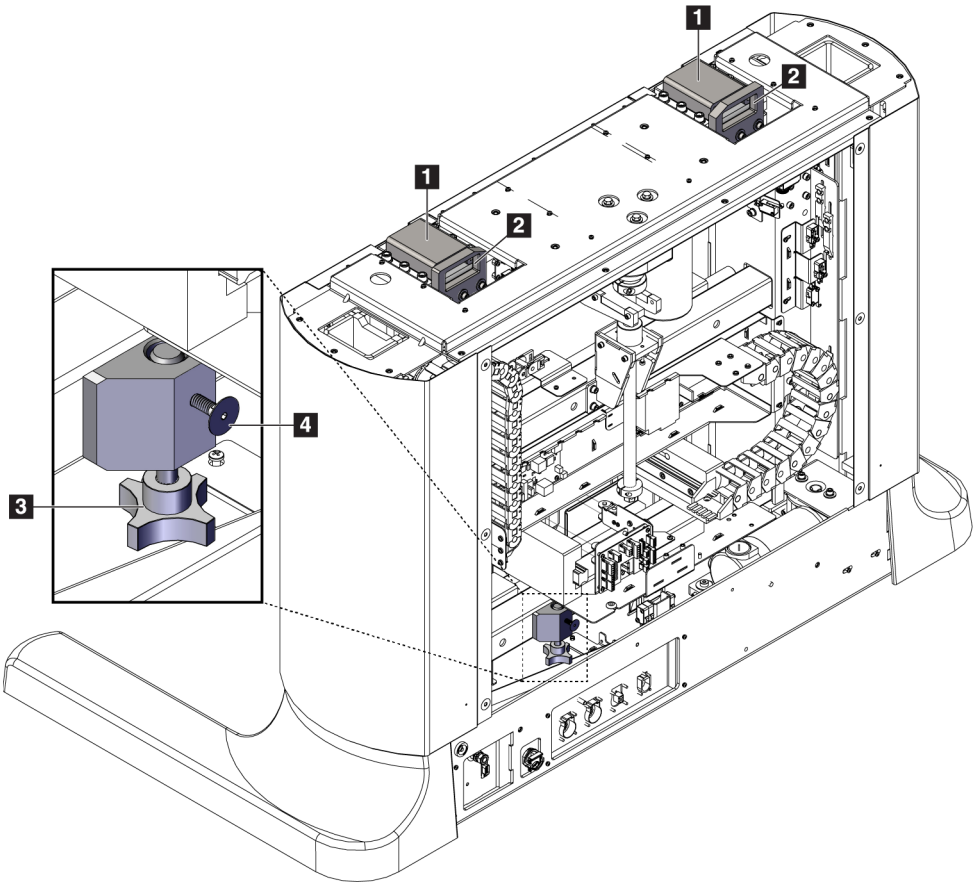


Figure Legend

1. Mounting Brackets for Patient Platform
2. Mounting Collars/Catches for Patient Platform
3. C-Arm Transport Lock Knob
4. Spring-Loaded Plunger for C-Arm Transport Lock

Figure 10: Patient Platform Mounting Brackets on Gantry

9. While the platform is being held level, tighten all Gantry mounting bolts.

10. Locate the C-arm transport locking mechanism in the back of the Gantry and do the following:
    a. Loosen the transport lock knob (see item 3 in previous figure).
    b. While loosening the knob, pull the spring-loaded plunger (see item 4 in previous figure).
    c. Continue loosening the knob so the locking shaft lowers to the point where it is flush with the block of the locking mechanism (as shown in the inset in the previous figure). This step allows the C-arm to move after you power up the system.
11. Locate the cable light/platform control harness tucked inside the platform and connect it to PLJ2 and PLJ4 on the Patient Platform Control Board (see following figure).

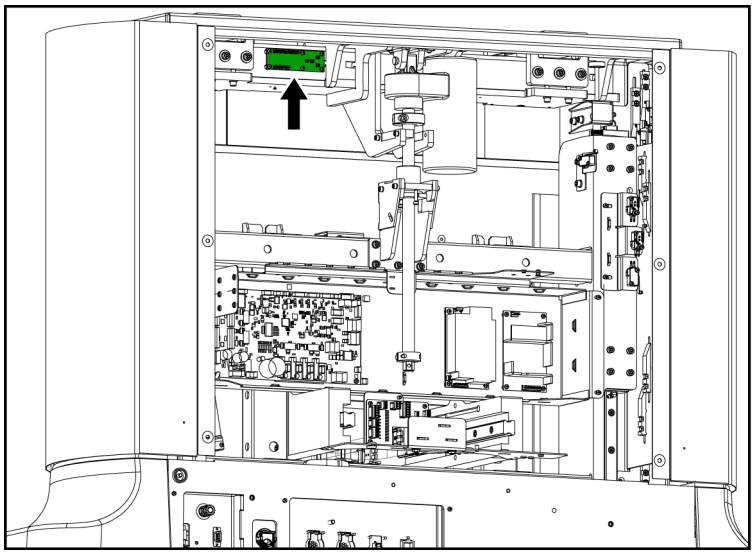


Figure 11: Patient Platform Control Board

Install the Armrest

The armrest assembly (part of the Maximum Comfort Package) is shipped preassembled.

1. Slide the armrest assembly into the armrest assembly holder on the bottom of the C-arm until you hear it click into place. (See the following figure, item 4).
2. Position the armrest assembly at the correct angle for the patient and for the C-arm (see following figure).

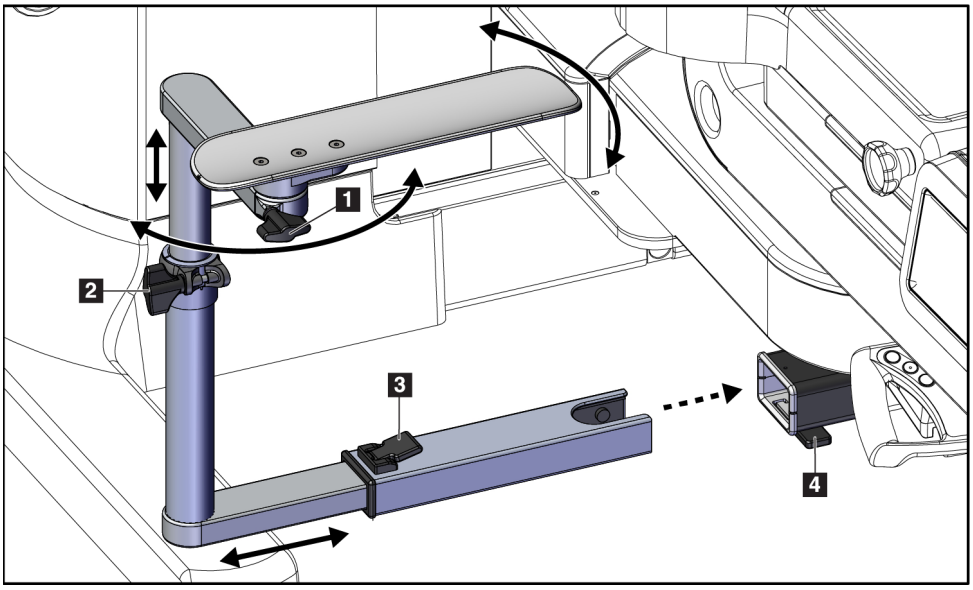


Figure 12: Installation and adjustment of Armrest Assembly on C-arm

Item	Description	Use
1	Armrest Rotation Knob	Allows you to rotate the armrest 360°.
2	Armrest Pole Position Knob	Allows you to raise/lower the armrest pole and rotate the support arm for the armrest 360°.
3	Armrest Bottom Adjust Lever	Allows you to move the armrest in and out from the C-arm.
4	Release Lever for Armrest Assembly	If needed, allows you to release and remove the armrest assembly and install it on the other side of the control handle.

Install the Footswitch

The footswitch assembly is shipped preassembled.

1. Place the footswitch assembly on the floor in operating proximity to the Gantry/Patient Platform assembly.
2. Connect the footswitch cable to its designated port on the front base of the Gantry/Patient Platform assembly (see following figure).

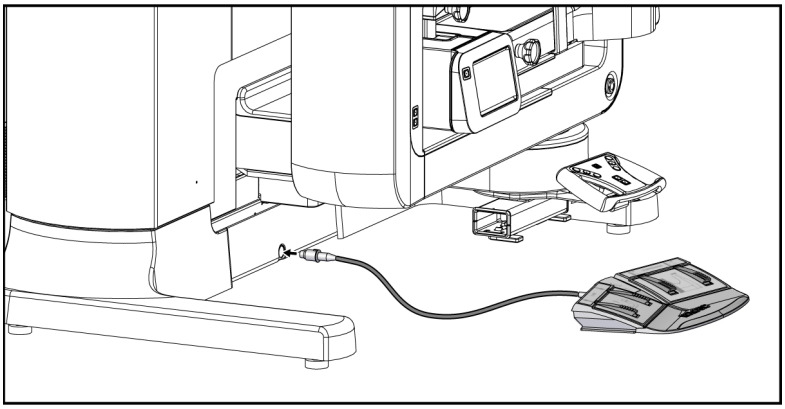


Figure 13: Installation of Footswitch in front of Gantry/Patient Platform

Connect the Gantry Cables

1. Connect the cables from/to the Generator to the appropriate connectors on the rear of the Gantry (see following figure).
2. Connect the cables from/to the Acquisition Workstation to the appropriate connectors on the rear panel of the Gantry (see following figure).

Note
If another device is near enough to the Gantry for a patient to touch both devices simultaneously, use the Potential Equalization Conductor nut to connect a potential ground cable to that other device. (See the following figure, item 2.)

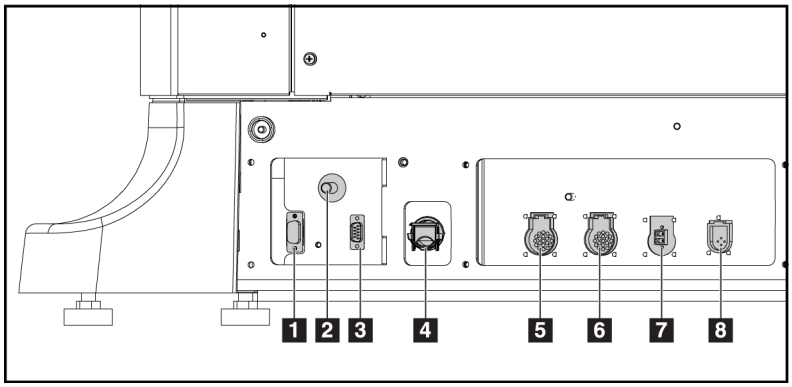


Figure 14: Cable Connections on Rear Panel of Gantry

Figure Legend

1. Service Port
2. Ground Conductor nut (for ground wire to Generator)
3. CAN Bus Connector (for cable to Generator)
4. High Voltage Connector (for cable to Generator)
5. Rotor Connector (for cable to Generator)
6. Filament Power Connector (for cable to Generator)
7. Fiber Optic Connector (for cable to AWS)
8. EPO Connector (for cable to Generator)

Install the Rear Step

1. Assemble the rear step (see the following figure).
   a. Turn over the rear step and attach the back plate to the step using the five pairs of screws supplied.
   b. Thread a nut on the backside of each screw.

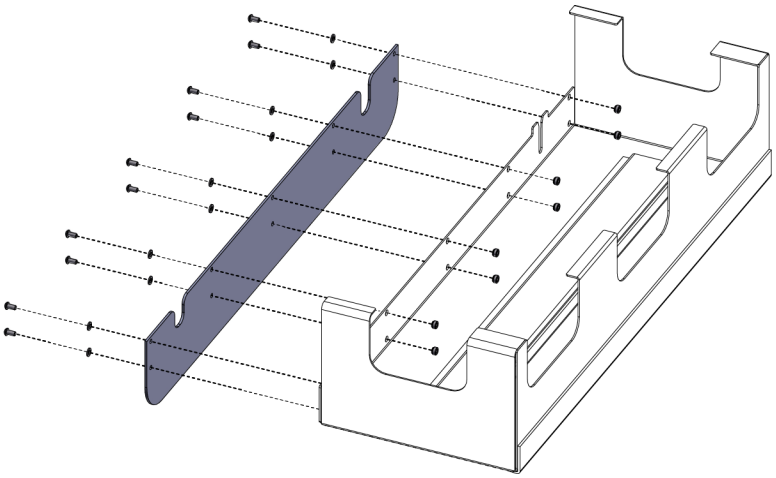


Figure 15: Assemble Rear Step (shown upside down)

2. Install the two step guide posts on the rear of the Gantry. (See the following figure).

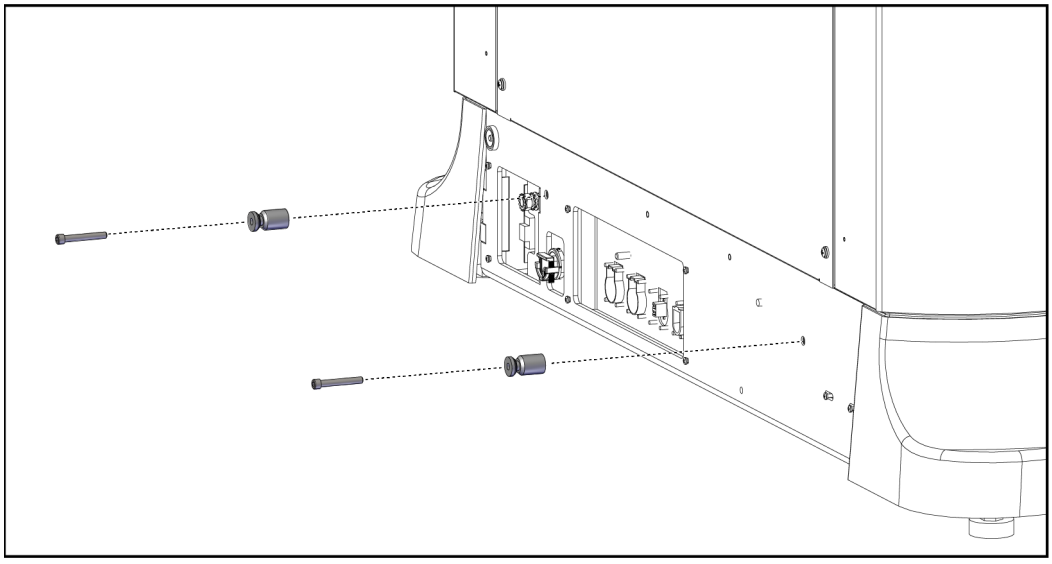


Figure 16: Install step guide posts on rear of Gantry

3. Carefully slide the rear step over the two step posts. (See the following figure.)

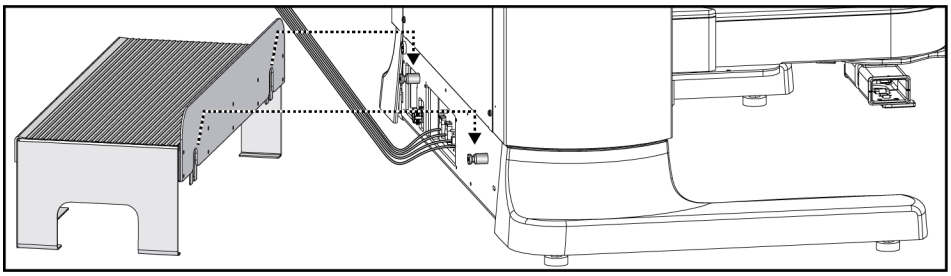


Figure 17: Installation of Rear Step on Gantry

4. Route the Gantry cabling underneath the rear step to avoid pinching of wires and to allow an unobstructed path for patient access to the rear step. (See following figure.)

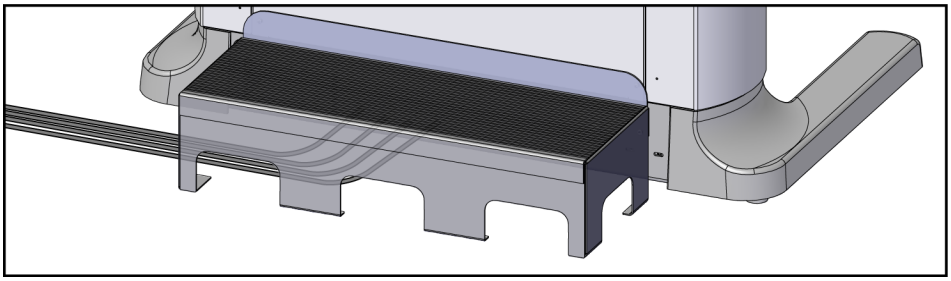


Figure 18: Routing of Cables under Rear Step on Gantry

3.3.3 Install the Generator

Configure the Isolation Transformer

The system ships configured for 240 VAC. Configure the isolation transformer in the Generator to match the power source at the site.

1. Remove the Generator top cover (refer to *Remove Generator Top Cover* on page 169), top plate (refer to *Remove Generator Top Plate Under Top Cover* on page 170), and rear cover (refer to *Remove Generator Rear Cover* on page 172) if not already removed.
2. Before connecting the Generator to the AC mains of the facility, verify the source voltage as follows:
   a. Measure voltage at the terminal.
   b. Ask about voltage fluctuations or voltage-related problems that have occurred in other equipment at the site.

3. After determining the input voltage range, verify that the isolation transformer is set correctly (see following figure).
   a. Set the circuit breaker on the front of the Generator to Off.
   b. Remove the top cover of the Generator to access the input power terminal block.
   c. Verify that the isolation transformer taps are wired to match the source voltage. If they do not match, configure the isolation transformer input wiring and taps.

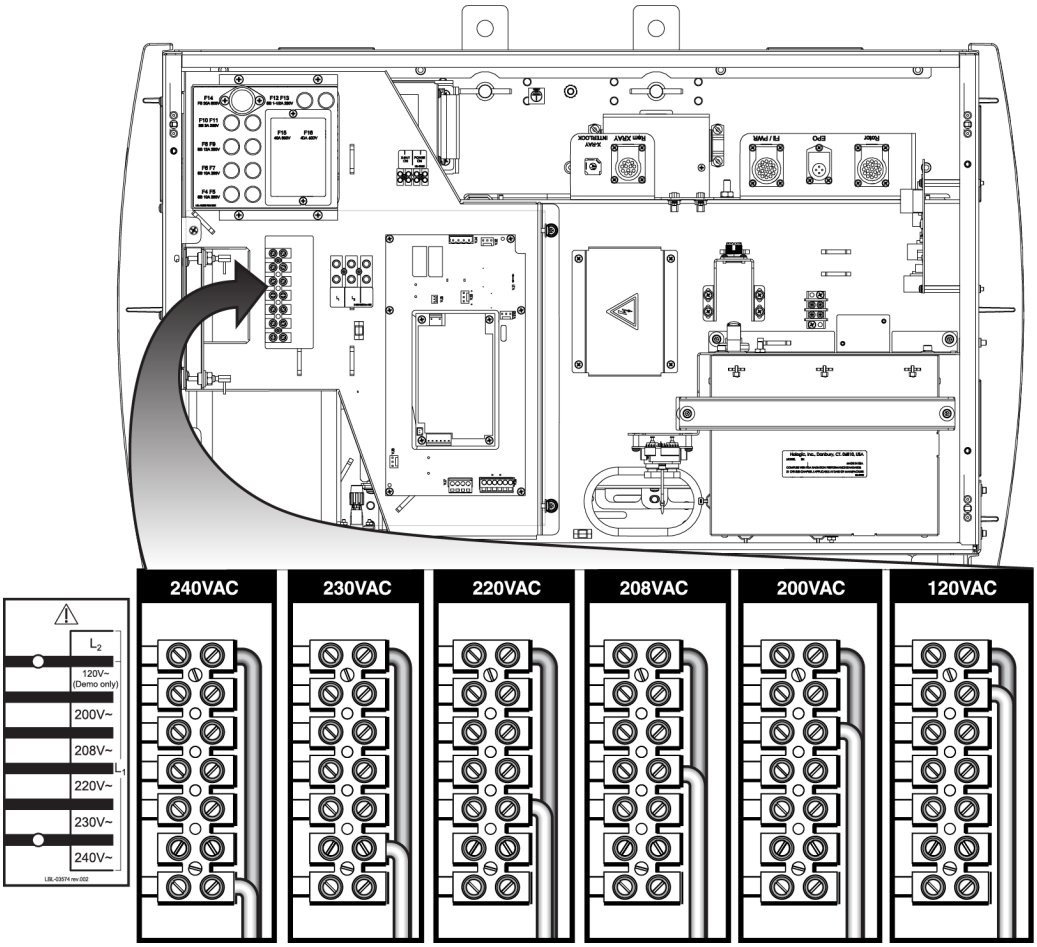


Figure 19: Isolation Transformer Taps on Generator

Caution:
120V Demo only is not for clinical use.

Connect the Generator Cables

1. Verify that the main circuit breaker of the Generator is OFF.
2. Remove the Generator top cover (refer to *Remove Generator Top Cover* on page 169), top plate (refer to *Remove Generator Top Plate Under Top Cover* on page 170), and rear cover (refer to *Remove Generator Rear Cover* on page 172) if not already removed.
3. Decide which side the cables are to enter the Generator and remove the appropriate (left or right) side entry plug.
4. Connect cables for the following (see the figure *Generator Connections* on page 42):
   - Filament/Power to Gantry/Patient Platform
   - EPO to Gantry/Patient Platform
   - Rotor for X-Ray Tube to Gantry/Patient Platform
   - High Voltage to Gantry/Patient Platform
   - CAN to Gantry/Patient Platform
   - Ground wire to Gantry/Patient Platform
   - CAN to AWS Computer
   - Ground wire to Workstation
5. Connect the control cable for the x-ray remote hand controller to item 6 in the figure *Generator Connections* on page 42.

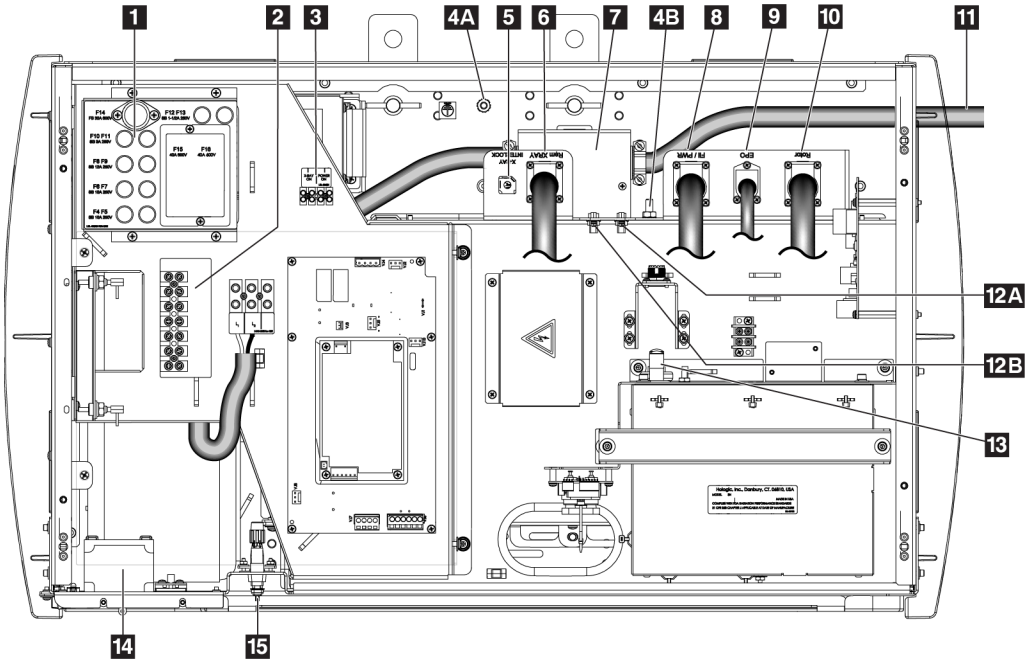


Figure 20: Generator connections (top view, covers removed)

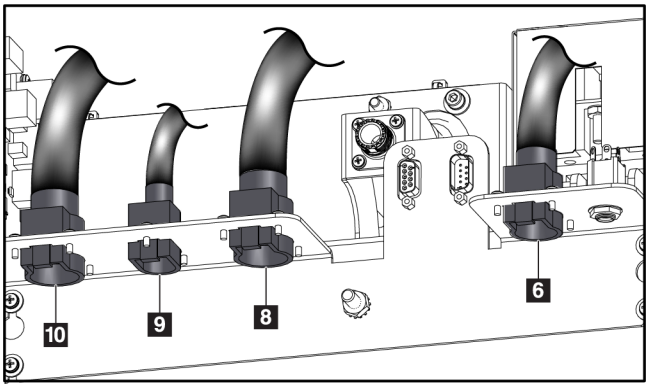


Figure 21: Generator connections shown from the rear (made underside when shown in top view)

Figure Legend	
1. Fuse Panel	8. Filament / Power Connector (cable to Gantry)*
2. Isolation Transformer Taps	9. EPO Connector (cable to Gantry)
3. X-Ray On/Power On (for remote indication lights)	10. Rotor Connector (cable to Gantry)*
4. A Ground Conductor Nut (for ground wire to Workstation) B Ground Conductor Nut (for ground wire to Gantry)	11. AC Mains Cable (from the facility power source)
5. X-Ray Interlock	12. A CAN Cable Connector (to Gantry) B CAN Cable Connector (to AWS Computer)
6. Remote X-Ray Remote Hand Controller connection	13. High Voltage Connector (cable to Gantry)
7. AC Mains Cable Junction Box	14. Gantry Circuit Breaker
	15. Gantry Service Port (service use only)
	*These two connectors look very similar but the cables associated with them are keyed so the proper cable can be connected.

1. Connect the AC mains power cable to the Generator:

Note
Some localities require a licensed electrician to make this connection. (Verify before proceeding.)

   a. Decide which side the AC mains cable (item 11 in the figure *Generator Connections* on page 42) is to enter the Generator.

   b. Remove the cover to the AC mains junction box (see the following figure, three screws) and route the AC mains cable into the box.

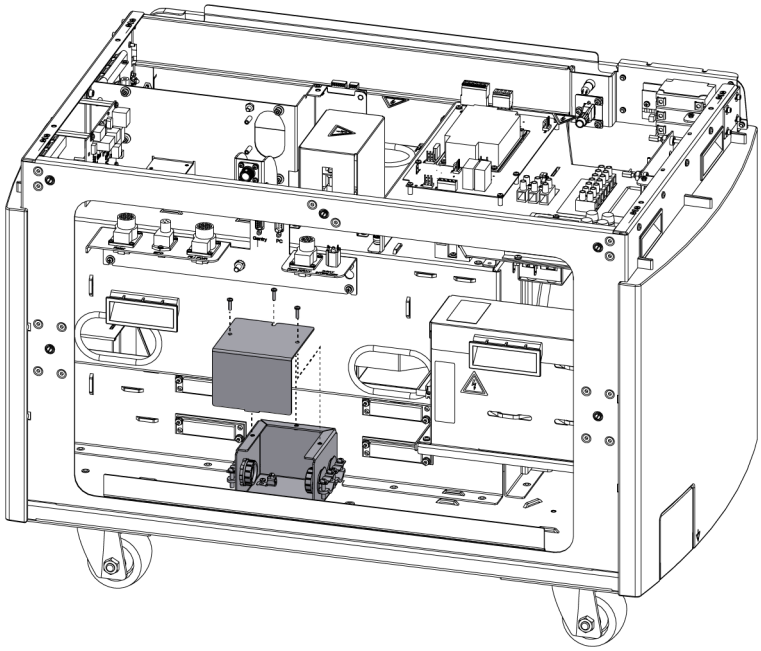


Figure 22: Removing cover to AC mains junction box (Generator rear view)

c. Verify a suitable cable terminal block exists inside the junction box to connect the AC mains cable with the Generator mains cable (see the following figure). We recommend Hologic part number MEL-00875 (Terminal Block, 3 POS 500V 57Amps Closed Back DBL Row 14.5MM Centers WO/Wire Protection) or equivalent if you need to obtain one.

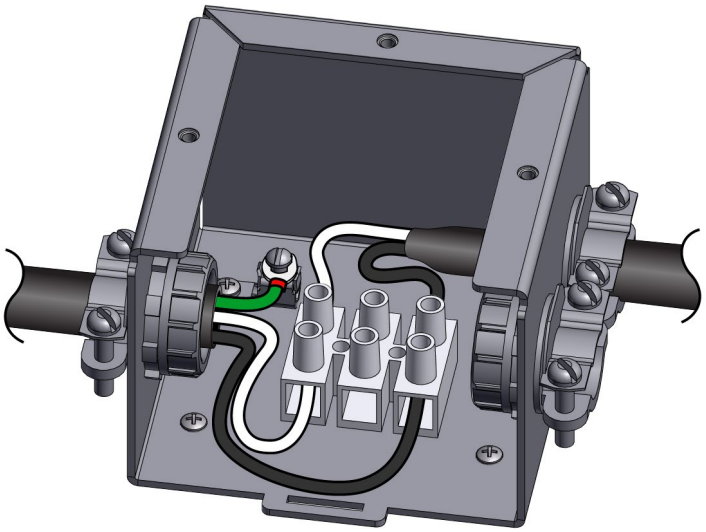


Figure 23: Connecting cables to terminal block inside AC mains junction box

Caution
When inserting the individual cables into the terminal block, make sure the cable strands have been twisted so that all strands are inserted completely into the block.

d. Match up the proper cable on both sides of the terminal block and attach the ground wire to the ground screw as shown in the previous figure.

e. Position and fasten the metal strain relief collars where cables enter and exit the junction box.

f. Reinstall the cover to the AC mains junction box.

2. Have a certified electrician hard wire the opposite end of the AC mains cable into the power source via a disconnect panel.

Connect Remote X-ray On/Power On Lamp

The system supports the ability to connect remote lights that indicate when the system is ON and when x rays are being taken. A certified electrician installs these lights—normally outside the exam room, above the door. The relay contacts are rated:

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

1. Install the remote Power On/X-ray On lights following local guidelines.
2. Route the remote cables from the lights to the Generator. Connect each cable to the appropriate location on the X-ray On/Power On terminal block inside the Generator (see item 3 in figure *Generator Connections* on page 42).

Calibrate the Generator

Note
A full generator calibration is needed after installation.

Because the length of the generator cables can vary per installation, perform a full generator calibration once the system is operational. Refer to *Inverter Drawer Calibration* on page 139 and use CalTool to perform *Generator kV, Gen mA Task (35 kV),* and *LG Filament (20kV- 49kV)* tasks.

3.3.4 Install the Image Detector

1. Remove the detector-end cover of the C-arm by removing two screws and pulling the cover out of snap fasteners.

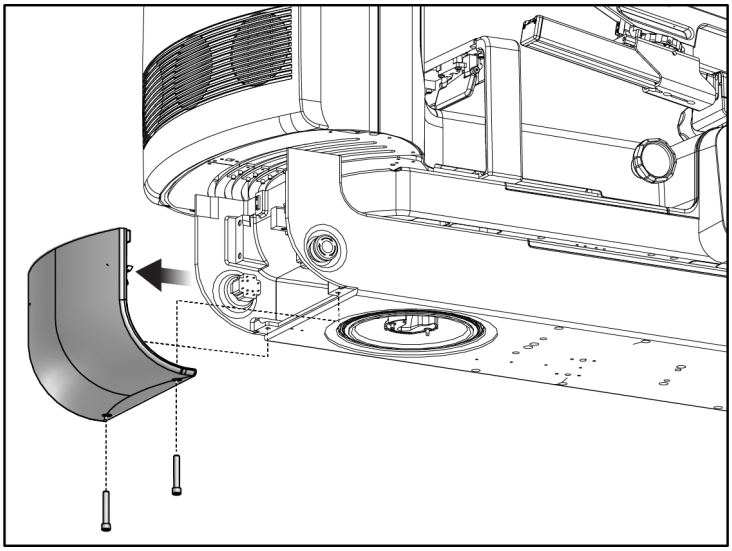


Figure 24: Removal of detector-end cover of C-arm

2. Remove the detector-end cover of the C-arm. (See the following figure.)
   a. Remove the two middle SEMS screws and the side screws (captive and spring-loaded) at the bottom two corners of the cover. The cover stays on after you remove the screws, but use caution.
   b. Partially pull off the cover.
   c. Before you fully remove the cover, move it out of position and disconnect the fan control harness connector. The connector is at the center edge of the joined pinch guards.
   d. Remove the fan control harness connector from the joined pinch guards.
   e. Remove the p-clip that is attached to one of the joined detector pinch-point guards. (Do not remove the other p-clip, which is fastened to the C-arm.)
   f. Finish removing the cover.

Note
The top and side edges of the detector-end cover fit (without screws) into the detector-end of the C-arm breast platform. After you remove the screws in the previous step, angle the bottom of the cover and pull it off. You may feel some resistance along the perimeter of the cover as you remove it.

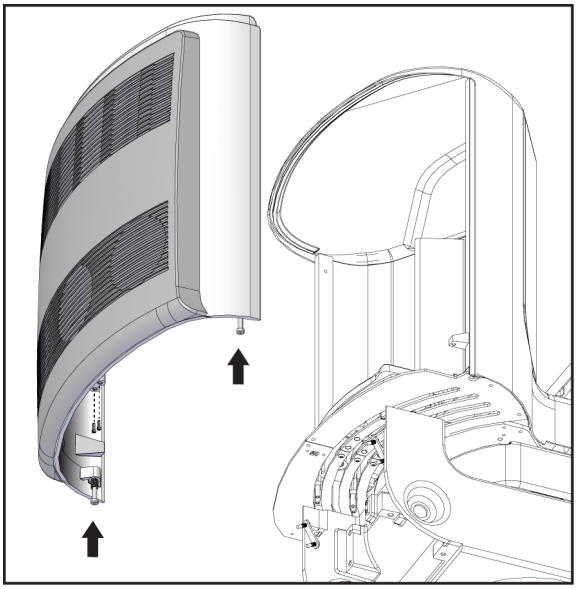


Figure 25: Removal of detector-end cover of C-arm

3. Remove the two joined detector pinch-point guards by removing the seven screws. (There are two screws at each end plus three in the middle.) Then slide out each of the two separated pinch guards. (See the following figure.)

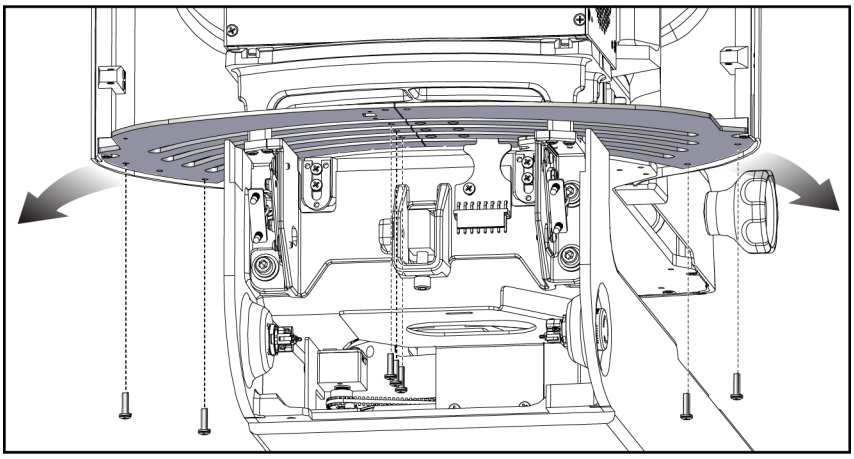


Figure 26: Removal of detector pinch-point guards

4. Locate and prepare the detector interface board and the detector fiber optic cable (see the following figure):
   a. Unfasten the detector interface board with ribbon cable (item 1) under the detector mounting platform and let it hang safely out of the way.
   b. Unclip the detector fiber optic cable (item 2) and let it hang safely out of the way under the mounting platform.

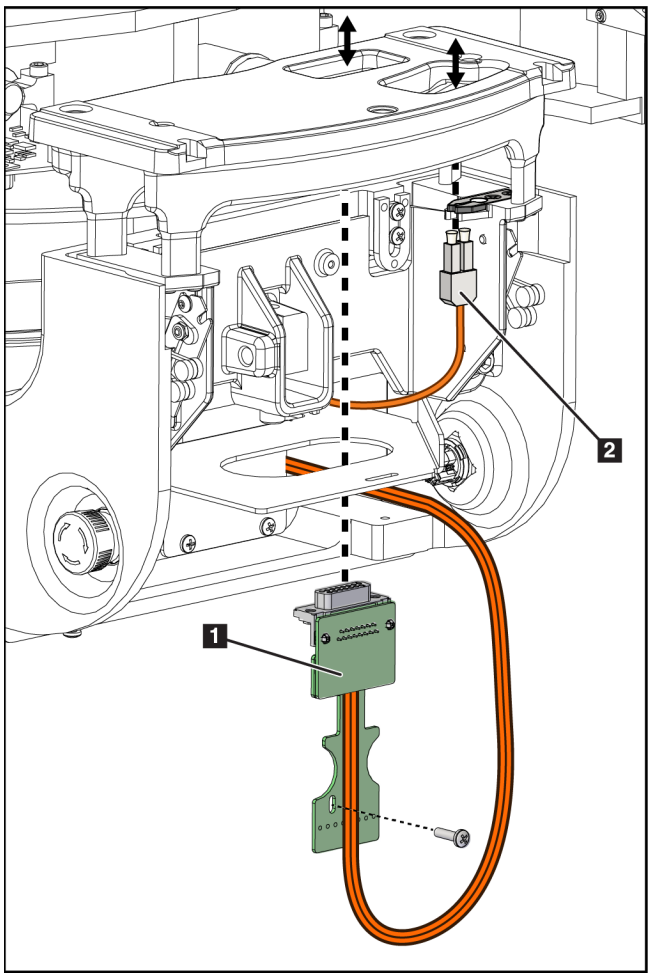


Figure 27: Preparing detector cables

5. Lower the detector mounting platform to obtain sufficient clearance to slide in the detector onto the mounting platform. (See the following figure.)
   a. Loosen the set screw (item 1) about one to two turns.
   b. Lower the two sets of u-brackets by loosening four screws (item 2) until the brackets are at end-of-travel. Then tighten the screws to secure the hard stops.
   c. Loosen the four screws under the mounting platform (item 3) about one to two turns.
   d. Back out the large height adjustment screw (item 4). Loosening this screw frees the mounting platform for vertical movement.
   e. Push down on the bracket (item 5) to lower the mounting platform.

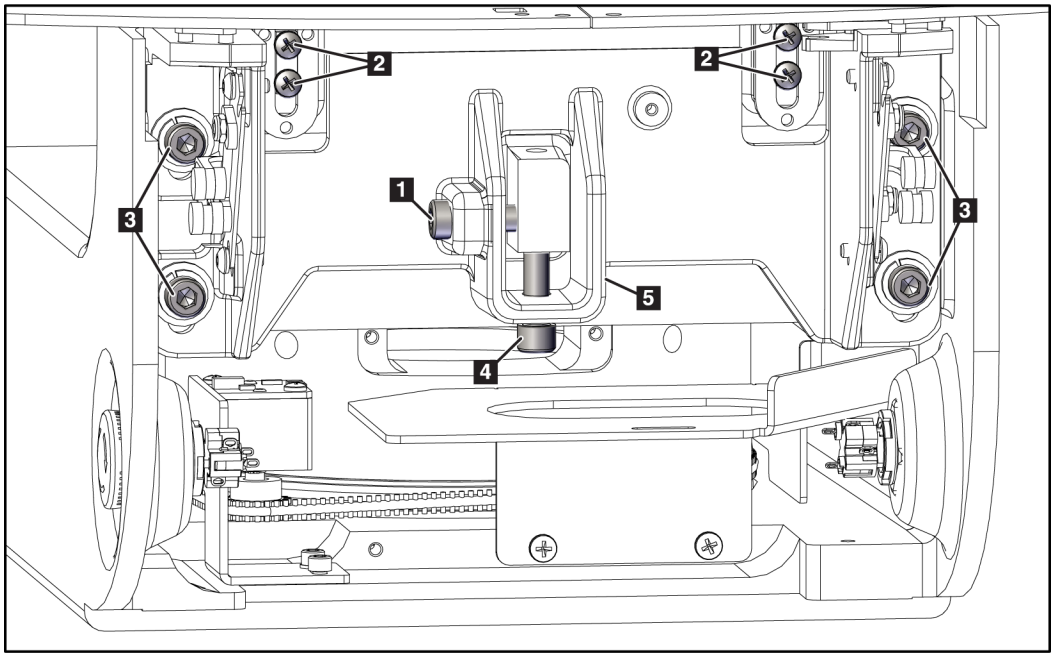


Figure 28: Loosen screws to lower detector mounting platform

6. Remove the plastic protective shipping cover from the detector (see the following figure) to expose the mylar surface (the shiny black section).

Caution
Avoid scratching the mylar surface (the shiny silver section) when unpacking/ installing the image detector.

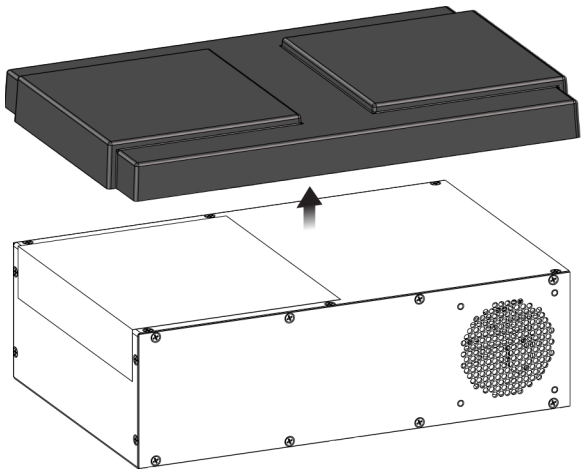


Figure 29: Removing protective cover from detector

7. Install the detector on the detector platform. Use the locator slots (see arrows in following figure) to align the detector on the detector platform when sliding it in.

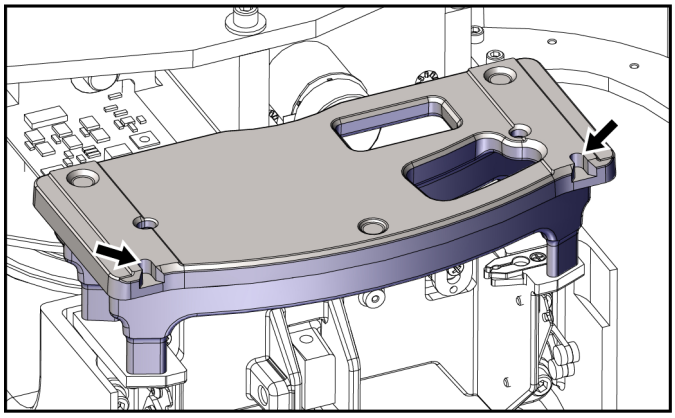


Figure 30: Locator slots on platform for detector

8. Install the two screws that secure the detector to its mounting platform.

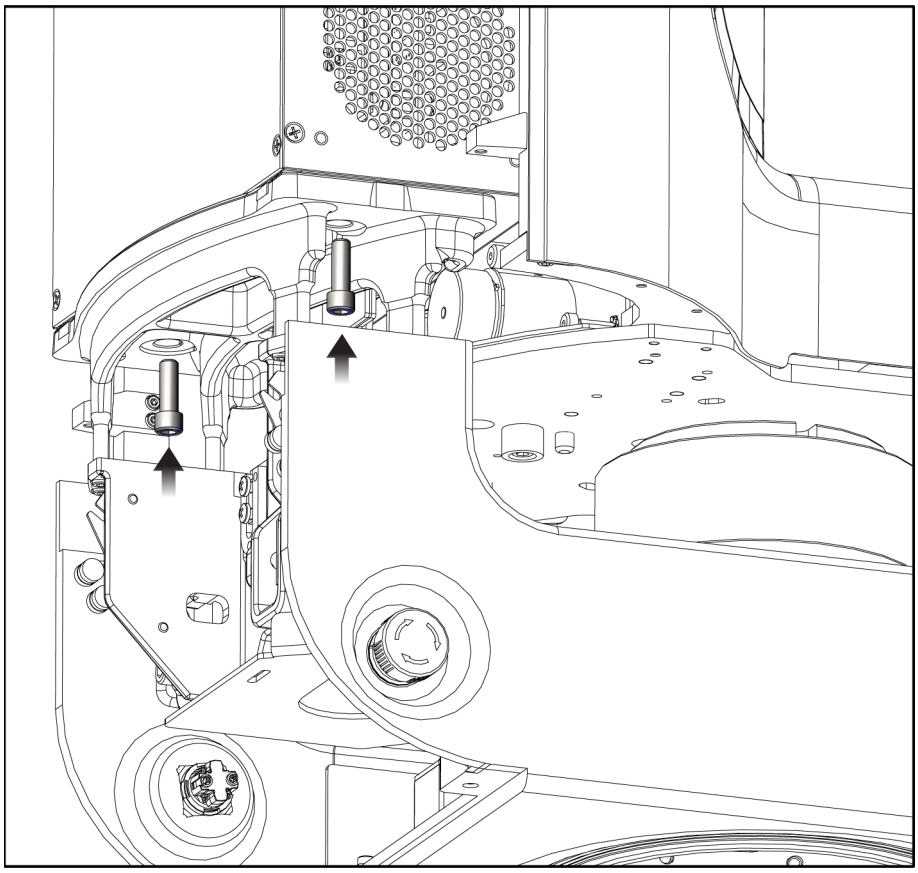


Figure 31: Fastening the detector

9. Connect and secure the detector interface board and detector fiber optic cable (see following figure):
   a. Insert the detector interface board (item 1) and detector fiber optic cable (item 2) through the bottom access opening of the detector mounting platform and connect to the detector.
   b. Under the detector platform, fasten the interface board with a screw and secure the fiber optic cable to its mounting clip.

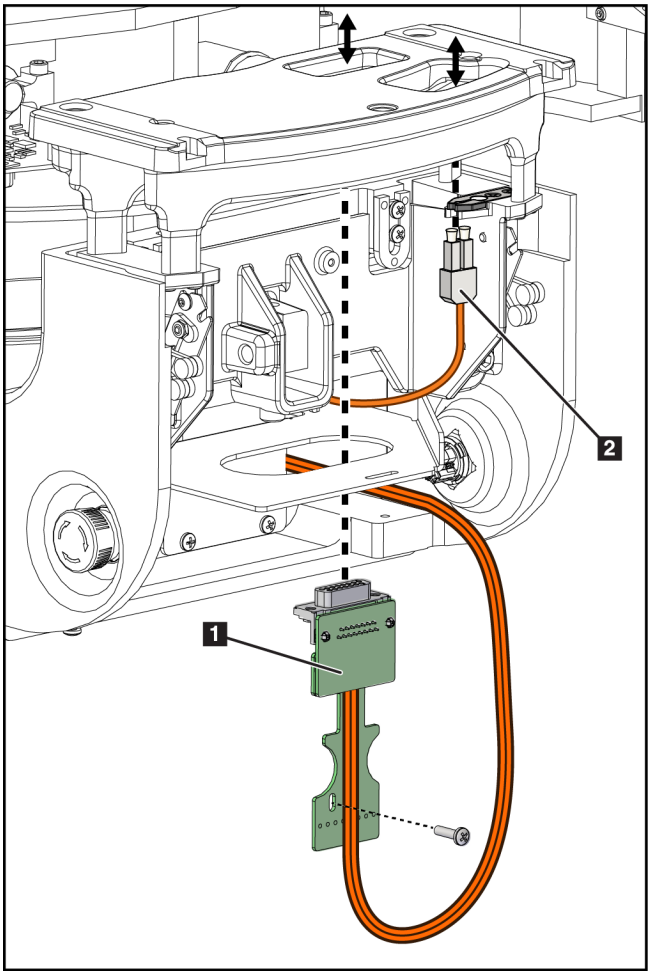


Figure 32: Route and connect detector cables to detector (detector not shown for better clarity)

10. Raise the detector mounting platform back up to its original position by tightening the large height adjustment screw (item 4 in the following figure).

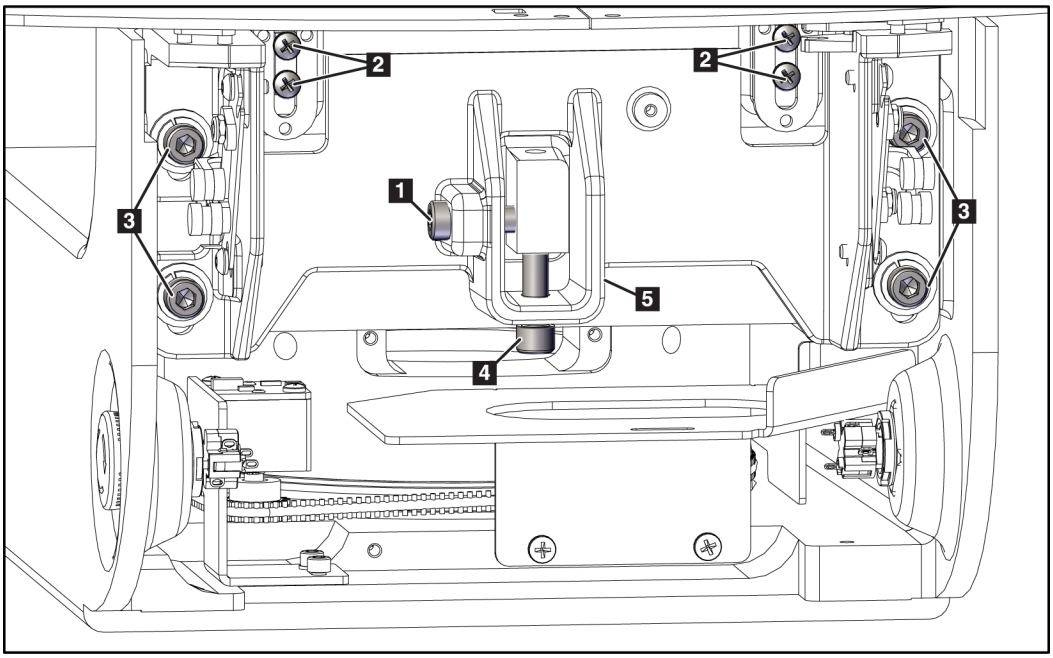


Figure 33: Screws to adjust the detector mounting platform

11. Tighten the four screws under the mounting platform (item 3 in previous figure) to secure the detector in place. Note that these four screws are also used to adjust the x-ray field detector alignment procedure in CalTool (refer to *X-Ray Field Detector Alignment* on page 145).
12. At this point, you can:
    - reinstall the detector covers and continue with step 13.

      OR
    - leave off the detector covers (for now). This method allows you to save time by not having to remove the covers later for any detector alignment that may be necessary after the system is powered up. This alignment is part of a series of procedures you perform after you install or replace a detector (refer to *Replace Image Detector* on page 207). If you do leave off the detector covers for now, refer back to this procedure to reinstall the detector covers after the alignment is complete.
13. Reinstall the detector pinch-point guards by rejoining both halves with the seven screws and securing to the underside of the detector.
14. Reinstall the p-clip and pinch screws previously removed from the joined pinch guard.
15. Reconnect the fan wire harness connector.
16. Reinstall the detector-end cover of the detector by sliding and fitting its top and side edges into the detector-end of the carbon fiber breast platform.

17. Reinstall the detector-end cover of the C-arm.
18. When the system is fully assembled and turned on, refer to the procedure *Replace Image Detector* on page 207 to finish the software installation/configuration for the image detector.

3.3.5 Affix the Image Detector Labels on the System

Affix the serial number label (LBL-05175) shipped with the detector on to the Gantry (refer to the diagram in *Label Locations* on page 16).

If you also find a safety label (LBL-05192) shipped with the detector, it is an extra copy and is not used (discard it).

3.3.6 Install the Acquisition Workstation

Configure the Isolation Transformer

The isolation transformer on the Acquisition Workstation ships configured for 240 VAC. Configure the isolation transformer to match the power source at the site.

1. Ensure that the isolation transformer power cord is unplugged from the AC mains of the facility.
2. Remove the isolation transformer:
   a. Unplug the UPS power cord from the isolation transformer.
   b. Remove the nut on the front mounting tab of the isolation transformer housing and remove the transformer from the workstation cart.
3. Remove the two screws holding the top cover and slide cover off towards the rear.
4. Reconfigure the taps to match site power requirements as required (see following figure).

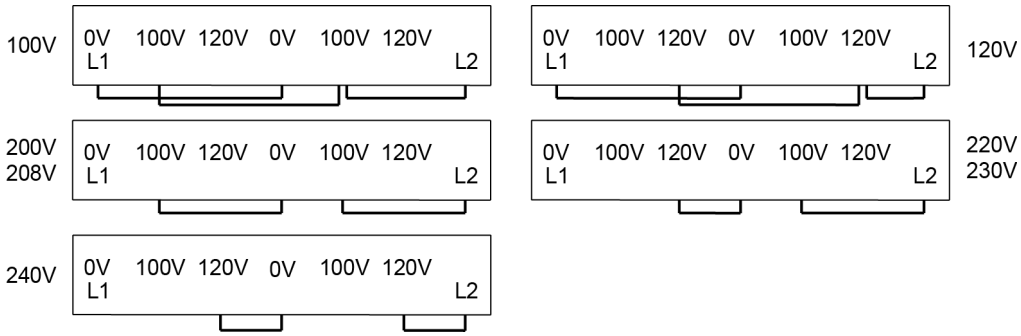


Figure 34: Isolation Transformer Taps on Acquisition Workstation

5. Replace the transformer cover.
6. Replace the isolation transformer into the workstation cart and fasten the nut on the front mounting tab of the isolation transformer housing.
7. Plug the UPS power cord into the transformer.

Activate UPS Battery

1. Carefully tilt up the UPS at its front while keeping its back end on the workstation.
2. Underneath the UPS, locate and slide off the UPS battery cover. (See the following figure.)
3. Insert the red positive cable into the positive terminal of the battery (item 1 in the following figure).

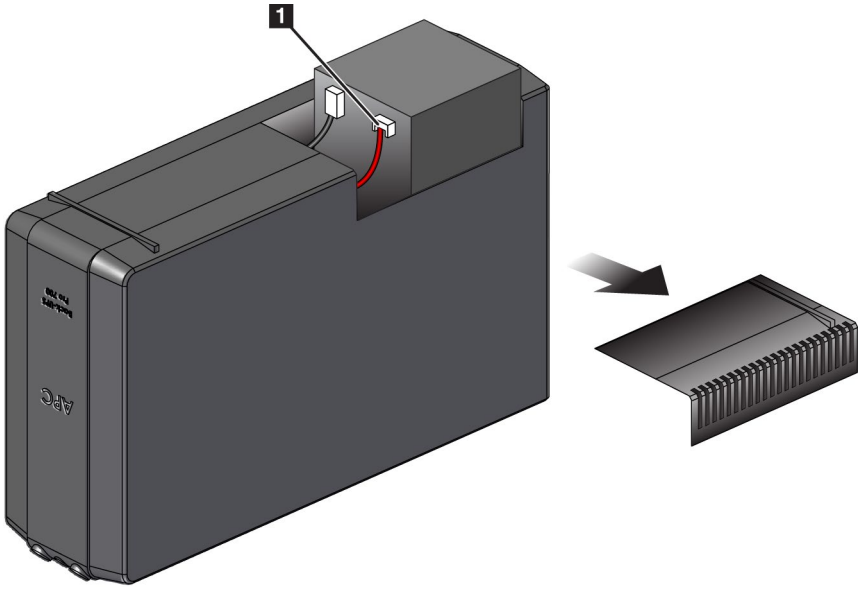


Figure 35: UPS battery connection (shown from underside of UPS)

4. Slide back on the UPS battery cover and carefully lower the UPS to the workstation.

5. If you need to disconnect the cables to the UPS and pull it out farther, use the following figure for reference.

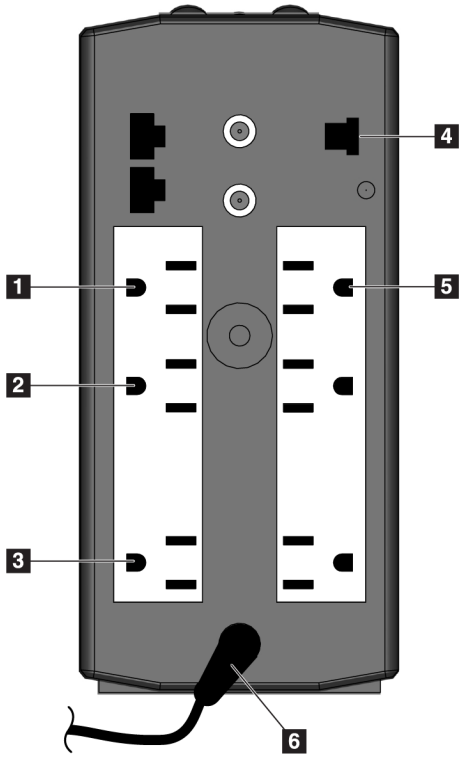


Figure Legend

1. Computer Power Outlet
2. Control Monitor Power Outlet
3. Work Surface Lift Power Outlet
4. Display Port Cable to Computer connector
5. Image Display Monitor Power Outlet
6. UPS Power Cord (plugs into Isolation Transformer)

Figure 36: Connections on rear of UPS

Connect the Acquisition Workstation Cables

The Acquisition Workstation cart comes pre-installed with the isolation transformer, UPS, and computer. You need to connect the image display monitor and control monitor to the computer, as well as several cable connections coming from the Gantry and Generator.

1. Connect the isolation transformer power cable to an appropriate AC mains outlet. Raise the work surface of the Acquisition Workstation cart to an operator level to allow you to make subsequent cable connections with the computer.

2. Install and connect these items at the back of the computer (see following figure):
   - mouse
   - keyboard
   - image display monitor
   - control monitor
   - power cable from UPS
   - USB data port cable from UPS
   - CAN cable going to/coming from the Generator
   - fiber optic cable going to/coming from the Gantry

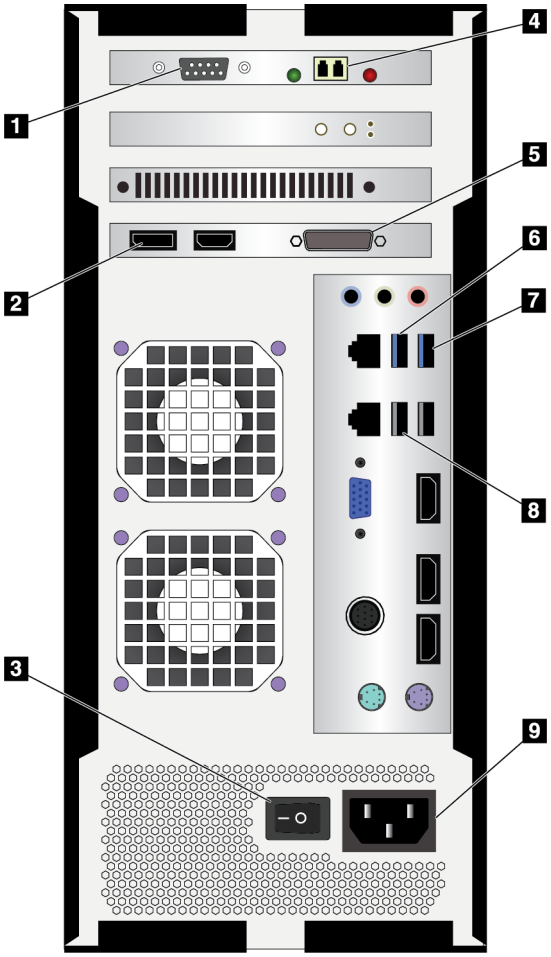


Figure 37: Rear panel of Acquisition Workstation computer

Figure Legend

1. CAN connector (for cable to Generator)
2. Image Display Monitor connector
3. Computer Power Switch, set to ON
4. Fiber Optic connector (for cable to Gantry)
5. Control Monitor connector
6. UPS USB data port cable connector
7. USB Mouse connector
8. USB Keyboard connector
9. Computer power cable connector

3. Connect the ground wire from the Generator to the left ground conductor on the rear of the workstation.

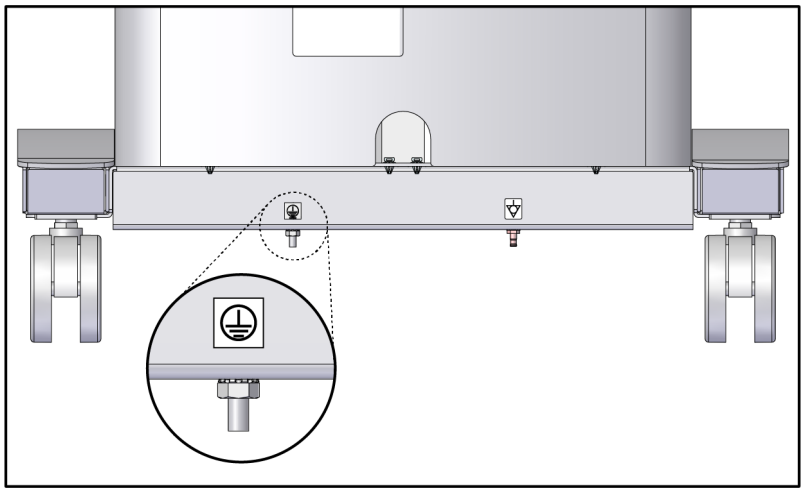


Figure 38: Connect ground wire to left ground nut on rear of workstation

Install Control Display Monitor

1. Power OFF the Acquisition Workstation system.
2. Install the control display onto the left monitor bracket (four screws).
3. Connect the DVI cable and power cable (120 VAC) dangling from the monitor post to the control display.
4. Power ON the Acquisition Workstation system.
5. Verify proper operation of the control display monitor.

Install Image Display Monitor

1. Raise the workstation surface to its highest level.
2. Power OFF the Acquisition Workstation system.
3. Install the image display (Barco) monitor onto the right monitor bracket (four screws).
4. Install the power supply for the image display monitor:

Note
The metal housing that holds the power supply of the image display monitor is located inside of the rear wall of the workstation cart. (See item 3 in the figure *Major Serviceable Components of Acquisition Workstation* on page 224.) The housing is sized to fit either the smaller 2-megapixel monitor power supply (plus a metal spacer) or the larger 3-megapixel monitor power supply (without a spacer).

a. [2-megapixel monitor power supply only] Install the metal spacer in the power supply housing.

b. Install the power supply on the power supply housing and secure with hook-and-loop fastener material.

c. Route the 120 VAC cable of the power supply to the UPS and plug it in (see figure *Connections on rear of UPS* on page 56).

5. Locate the monitor display port cable and connect one end to the computer (see figure *Rear panel of computer* on page 228).
6. Locate the 24 VDC power cable from the monitor power supply and monitor display port cable from the computer and run these cables through the e-chain cable housing (starting from the bottom). See the following figure (items 7 and 8) for the proper e-chain slots to thread these cables through.

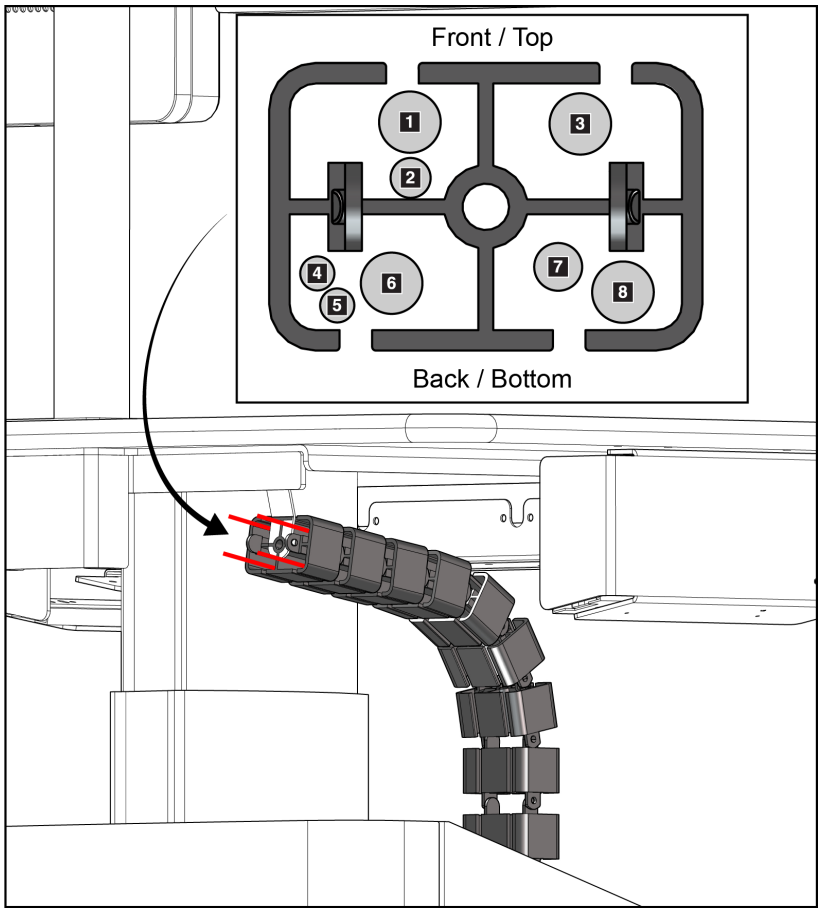


Figure 39: Routing of power and display port cables in e-chain cable housing (top of e-chain shown)

Figure Legend

1. Power cord for workstation surface lift
2. Ground cable
3. AC power cord for control display monitor
4. Mouse USB cable
5. Keyboard USB cable
6. Video cable for control display monitor
7. Display port cable for (Barco) image monitor
8. 24 VDC power cable for (Barco) image monitor

7. From the top of e-chain cable housing, run the monitor power and display port cables through the bottom of the monitor post and out the post side opening.

8. Apply spiral wrap or use wire ties to the two cables after they leave the monitor post to keep the cables together.
9. Remove the rear cover of the image display monitor and attach the 24 VDC power cable and display port cable. Replace the rear cover.
10. Power ON the Acquisition Workstation system.
11. Configure the new monitor using the on-screen menu of the monitor. (Refer to *Verify Settings of Barco Image Display Monitor* on page 60.)

Verify Settings of Barco Image Display Monitor

Note
This post-installation setup verification procedure pertains only to models of Barco image display monitors that have advanced settings.

1. Power ON the monitor. A single LED lights up in the lower right corner of the monitor frame. (See the following figure.)
2. Wait for the LED light to go out (approximately 50 seconds after power ON).

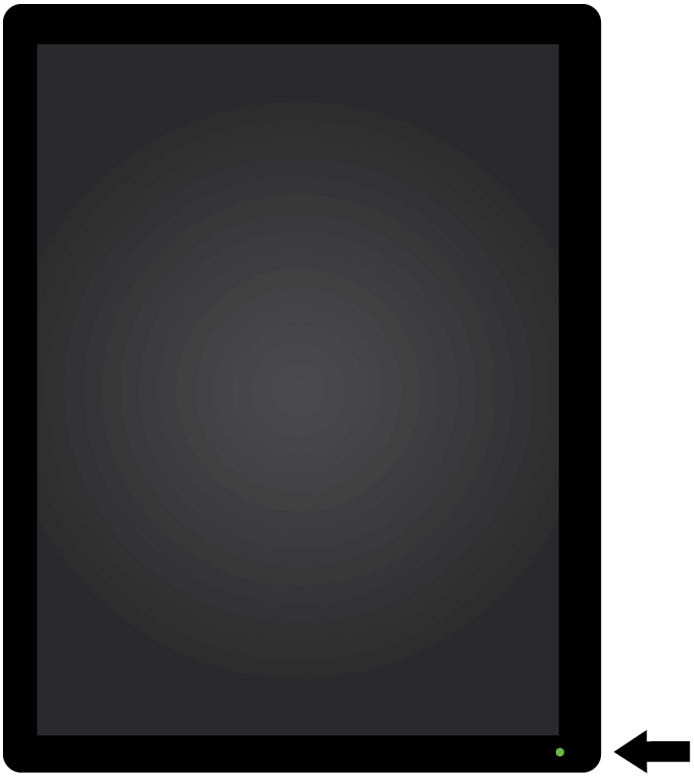


Figure 40: Waiting for single LED to turn OFF after power ON

3. Touch the monitor frame (not the screen), along the bottom near its lower right corner until four LED touch keys (embedded in the frame) light up. (See the following figure.)

Note
The operator of the workstation touches these LED keys to navigate and select the various screens, menus, and settings on the monitor.

4. Touch the LED under the menu symbol (second from right). (See the following figure.)

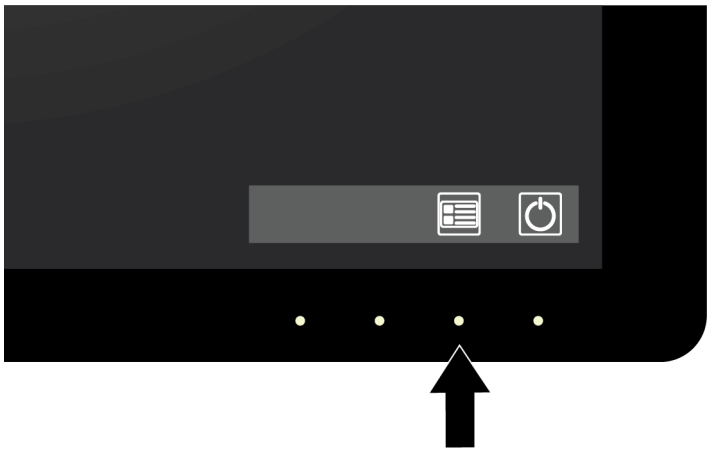


Figure 41: Touching LED under menu symbol (second from right LED) to display Main Menu

The Main Menu is displayed. (See the following figure.)

5. Using the touch-sensitive LEDs, navigate and select **Configuration** > **Image Source**.

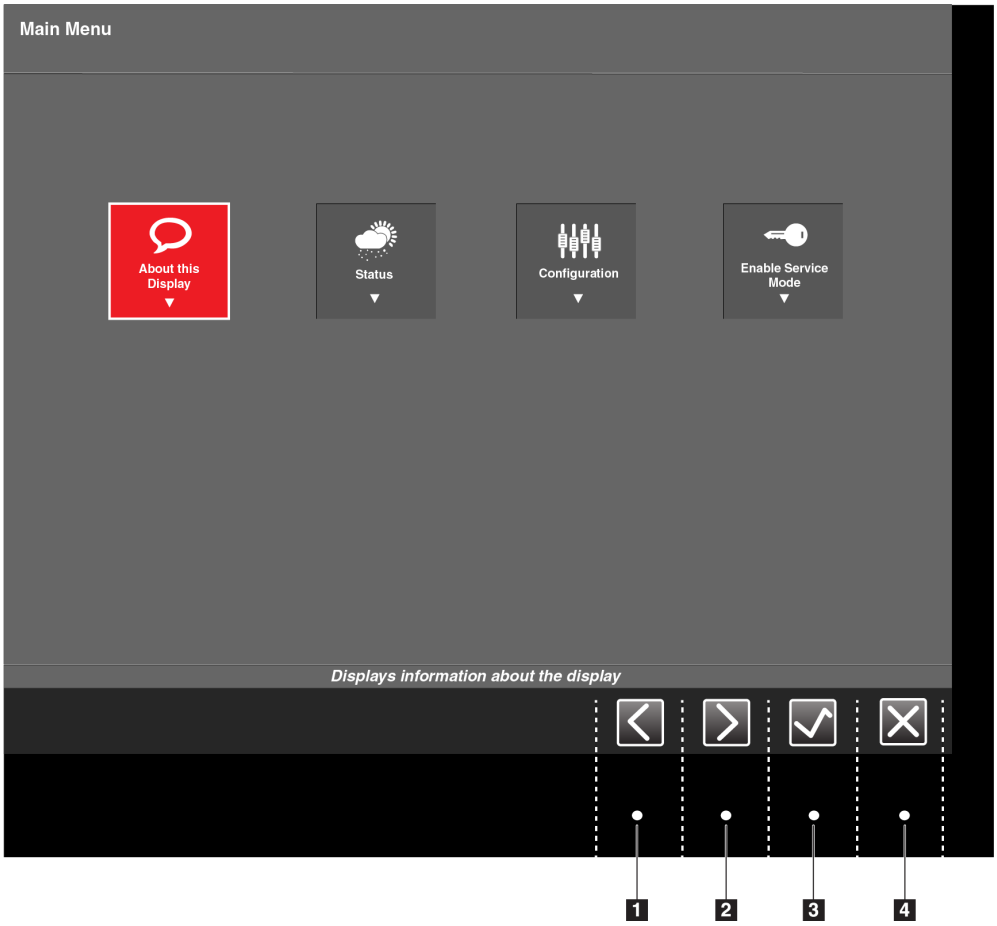


Figure 42: Configuration main menu

Figure Legend

1. Left key
2. Right key
3. Enter key (navigate into submenu)
4. Cancel key (exit out of submenu)

Note
The key icons (on-screen) are displayed above the LED keys (embedded in monitor frame). (See the previous figure.) Each icon is adapted to the function for which it is used (menu dependent).

6. Confirm all settings in the **Configuration** > **Image Source** screen, as shown in the following figure.

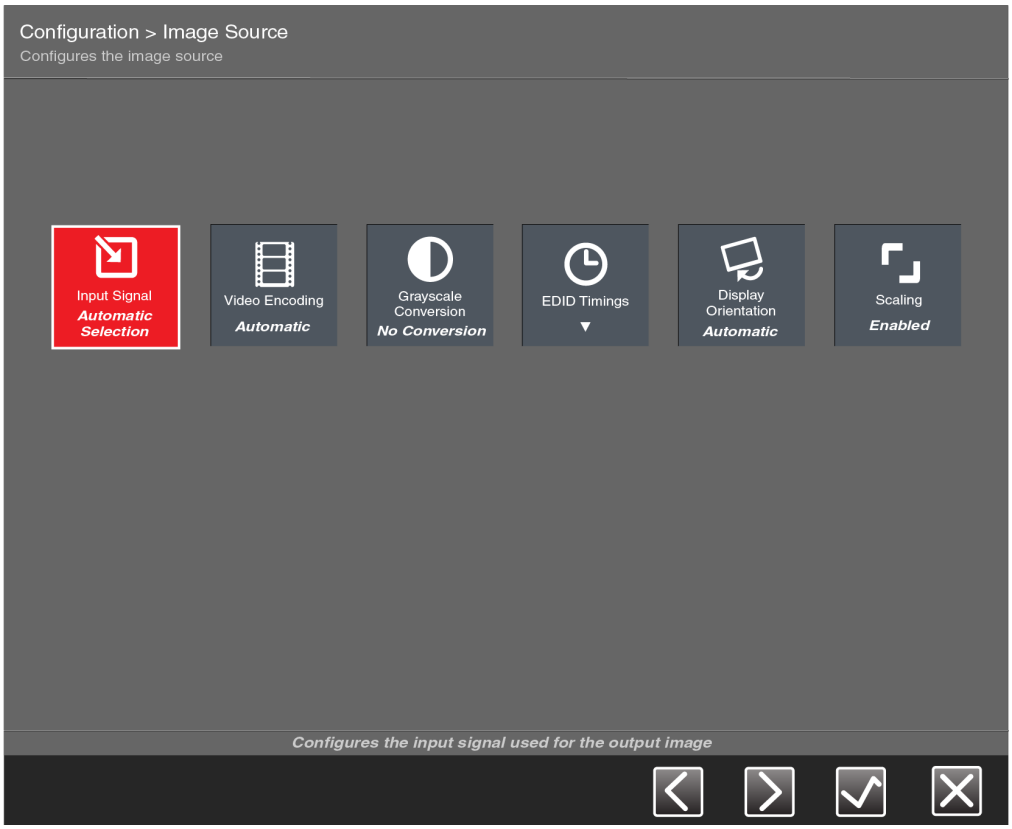


Figure 43: Confirmation of settings in Configuration > Image Source screen

7. Return to the main menu.
8. Navigate and select **Configuration** > **Calibration**.

9. Confirm all settings in the Configuration > Calibration screen, as shown in the following figure.

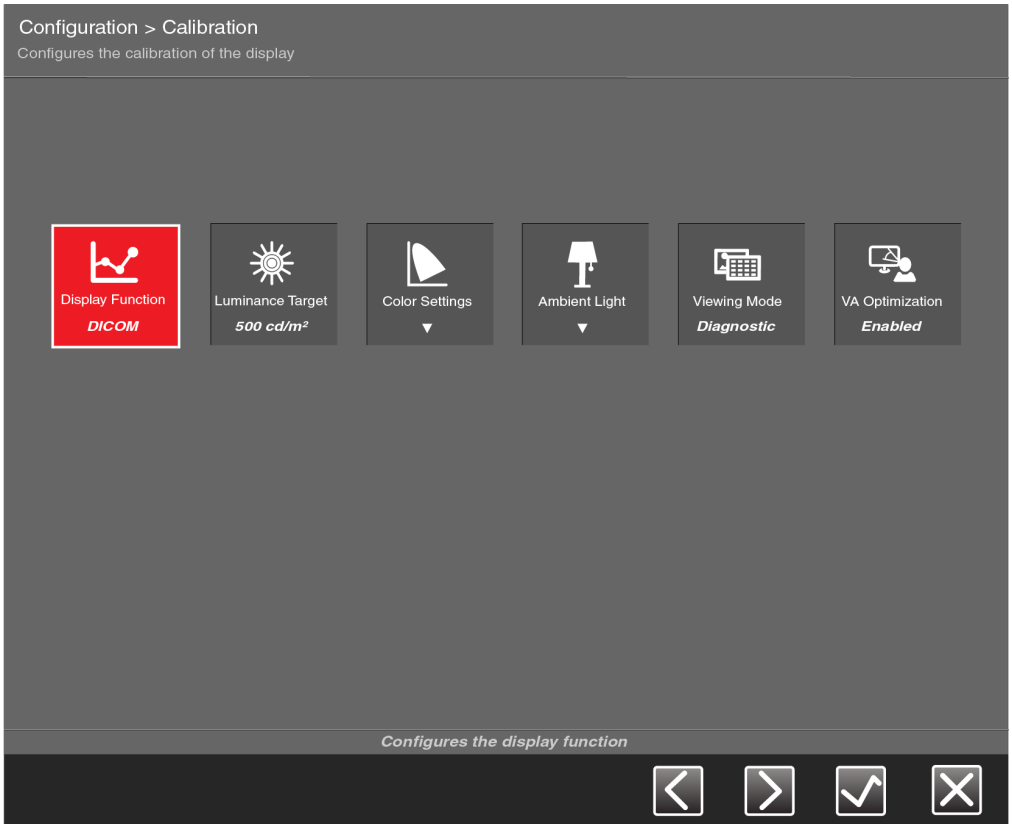


Figure 44: Confirmation of settings in Configuration > Calibration screen.

10. Return to the Main Menu.
11. Navigate and select **Status** > **Calibration**.

12. Confirm all settings in the Status > Calibration screen, as shown in the following figure.

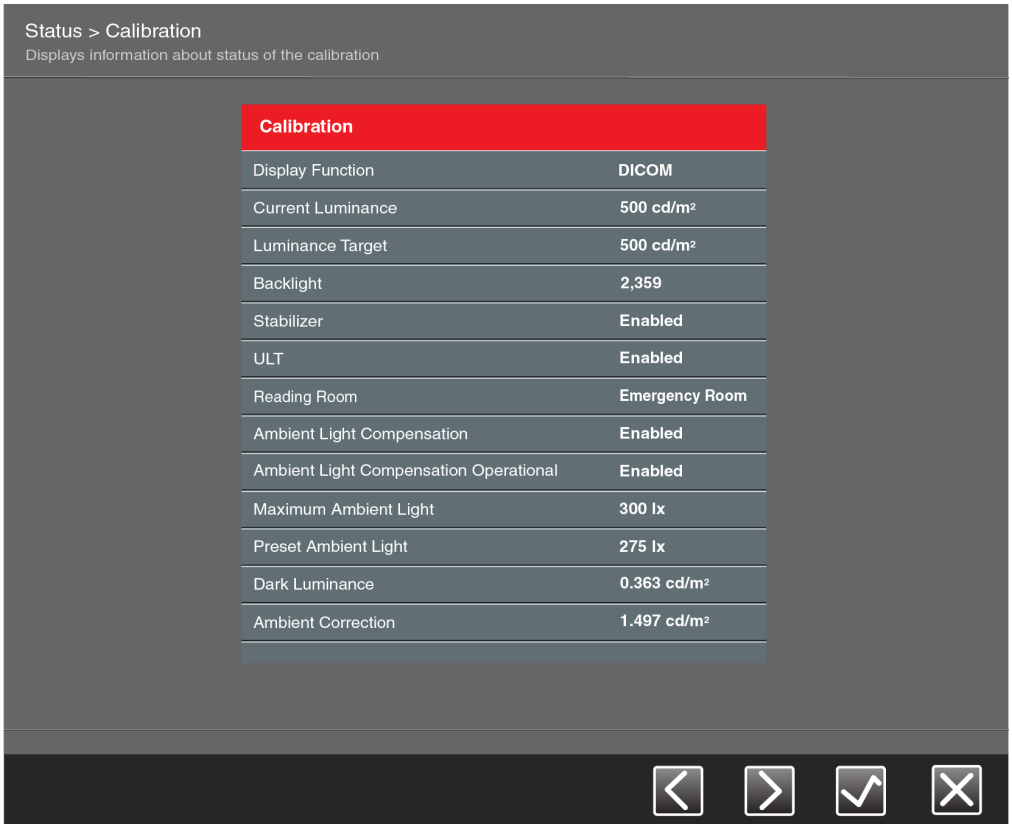


Figure 45: Verifying first three settings for new install, all settings for replacement install

13. In the Status > Calibration screen:
    - Confirm *all* settings for a *replacement* installation, as shown in the previous figure.
    - Confirm *only* the first three settings for a *new* installation, as shown in the previous figure.

      Make sure that:
      - Display Function = DICOM
      - Current Luminance = 500 cd/m²
      - Luminance Target = 500 cd/m²

3.3.7 Setting Proper Height Gap Between C-Arm and Patient Platform

1. Replace all covers on the Generator. If necessary, refer to *Remove Generator Top Cover* on page 169, *Remove Generator Front Cover* on page 171, *Remove Generator Top Plate Under Top Cover* on page 170.
2. Leave off the top patient padding, top cover, rear cover, and rear inside cover from the patient platform/Gantry for the time being.
3. Turn ON the facility power at the circuit breaker.
4. Turn ON the main circuit breaker of the Generator.
5. Position the C-arm at 90 degrees to the table and slide the C-arm all the way in towards the Gantry. The image receptor should be centered below the patient platform (see the following figure).

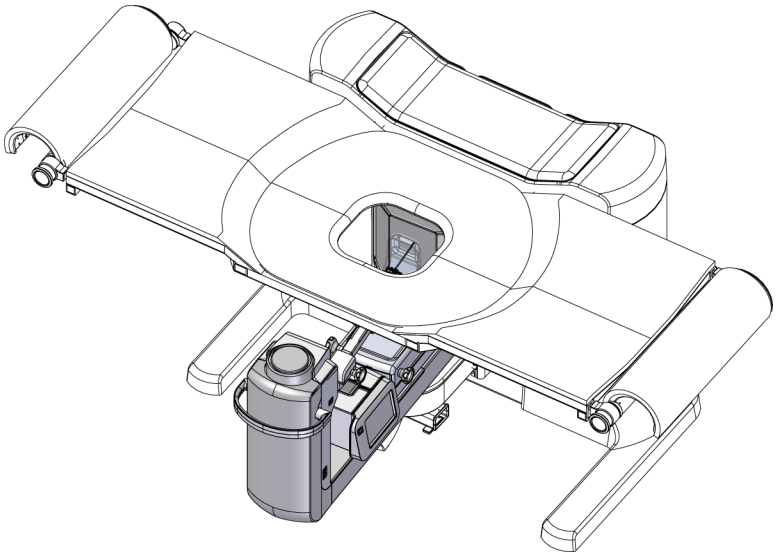


Figure 46: Positioning C-arm to verify proper upper height setting

6. Use the C-arm position buttons to move the C-arm in the fully up position.

7. Test that the C-arm upper travel stops at the desired 1/4-inch distance from the bottom of the patient platform. This gap can be tested by inserting TLS-05884 (which is 1/4 inch thick) between the top of the breast platform and the bottom of the patient platform (see the following figure). There should be a slight drag as you slide the gauge in and out.

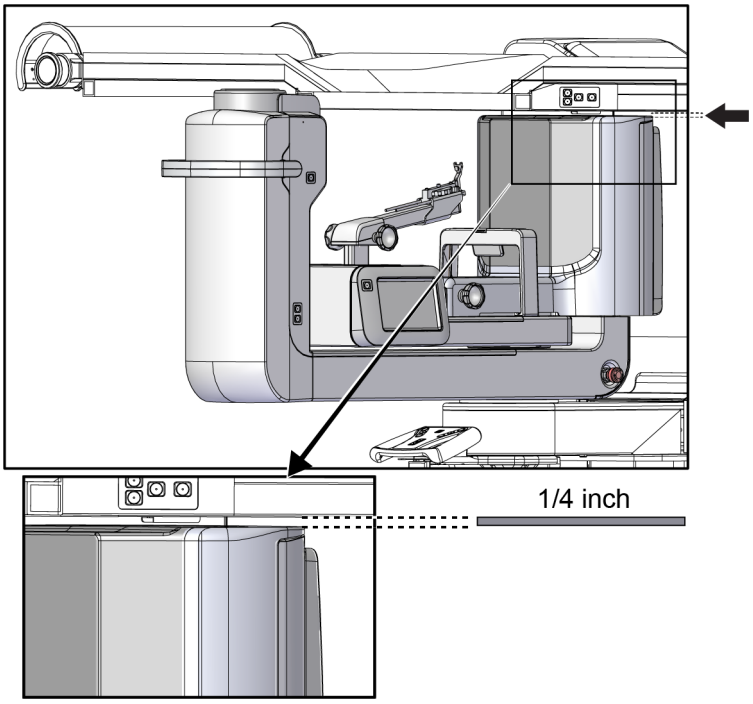


Figure 47: Checking for 1/4" gap using TLS-05884

8. At the rear of the Gantry (see the following figure), loosen the wing nut (item 2) and turn the knob (item 1) to adjust the plunger (item 3) to allow adjustment of the C-arm upper travel switch (item 4).

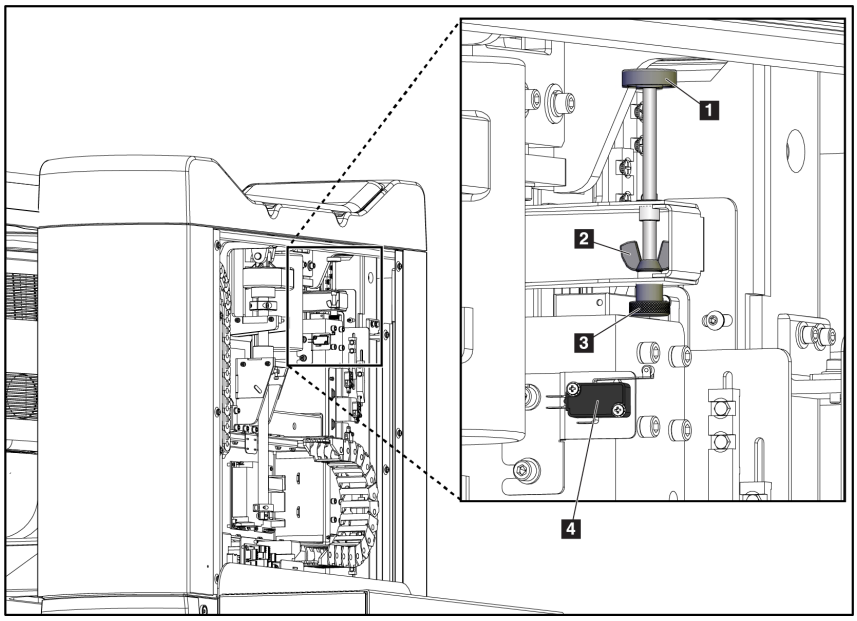


Figure 48: C-arm upper travel limit adjustment

9. Rotate the C-arm left and right (0 -180°) to make sure that here is no contact with the patient platform throughout the entire rotation.
10. When the proper gap has been established, tighten the wing nut in the rear of the Gantry (item 2 in figure *C-arm upper travel limit adjustment* on page 68) to hold the setting.
11. Do the following, based on the results:
    - If the C-arm has the proper clearance, no further adjustments are necessary. Continue at step 14.
    - If the proper C-arm clearance cannot be attained, continue with the next step.
12. Confirm that the maximum height travel switch is set correctly. The switch should stop the top of the breast platform 1/8 inch from its closest point to the bottom of the table top (see the following figure).

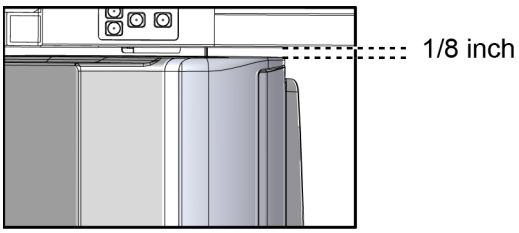


Figure 49: Proper setting of maximum height switch (1/8" gap between breast platform top and bottom of patient platform)

- If the maximum height travel switch height is not correct, do the following:

a. Loosen the two screws and move the switch ramp (see the following figure, item 1B) to its highest position for the maximum height switch item 1A.

b. Position the C-arm to the proper height of 1/8 inch clearance (see previous figure).

c. Adjust the switch ramp item 1B to this setting (this activates the maximum height switch 1A).

d. Lower the C-arm and then raise it back to the maximum height to confirm adjustment.

e. When finished, go back to step 8.

- If the adjustment cannot be obtained, go to the over-travel switch adjustment in step 13.

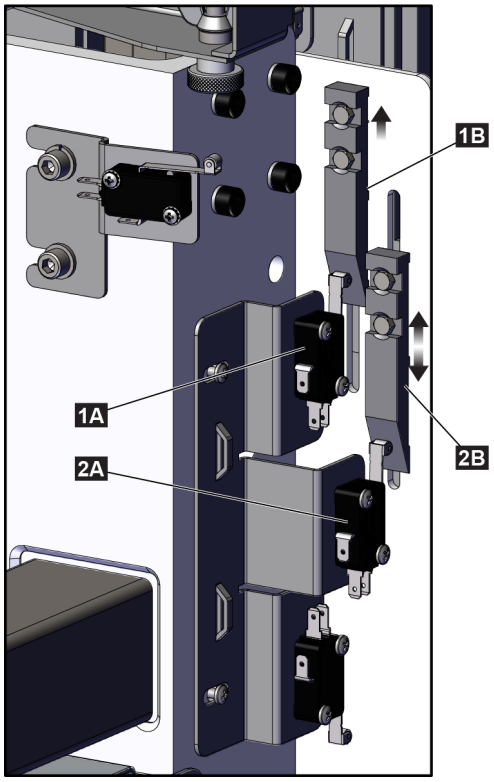


Figure 50: Adjusting maximum height switch (1A) by its switch ramp (1B)

Caution

If the C-arm maximum height adjustment is set too high:

- **The C-arm may activate the over-travel switch when the C-arm reaches its highest position and cause the system to shut down.**
- **Damage may occur to the C-arm during the auto-rotation for a scout image as the C-arm tries to traverse its path and it binds up under the patient platform.**

13. To confirm the over-travel switch adjustment, perform these steps (see following figure):

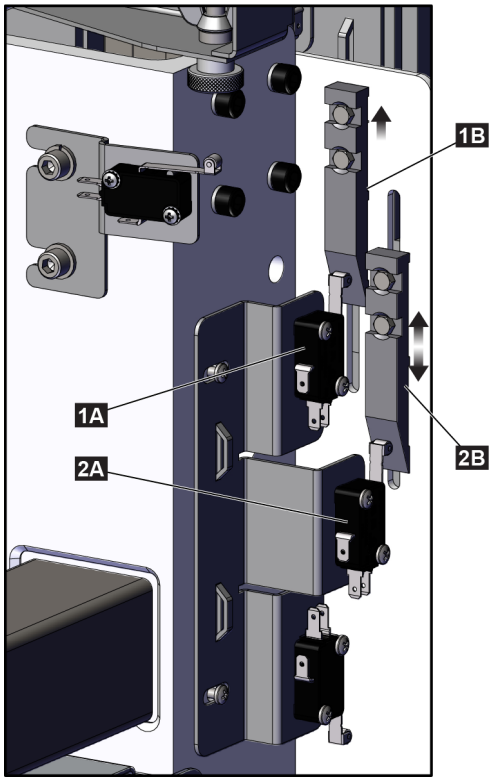


Figure 51: Adjusting over-travel switch (2A) by its switch ramp (2B)

a. Mark the location of switch ramp (item 1B) used for the maximum height switch (item 1A).

b. Loosen the two screws and move the switch ramp (item 1B) for the maximum height switch (item 1A) to it highest position. This step temporarily disables the maximum height switch to allow the checking of the adjustment of the over-travel switch.

c. Raise the C-arm to the point where the breast platform top just touches the bottom of patient platform without any pressure applied to the breast platform top (see the following figure). At this point, the over-travel switch (item 2A, see previous figure) should power off the Gantry.

If the adjustment is not correct, adjust switch ramp 2B (see previous figure) until switch item 2A disables power to the Generator.

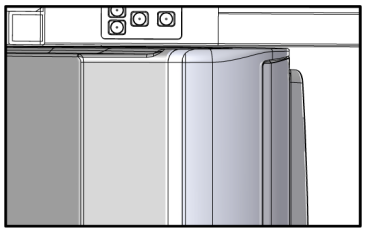


Figure 52: Proper setting of over-travel switch (breast platform top just touching bottom of patient platform)

d. Lower the C-arm and raise the C-arm to verify the setting is correct.

14. When done, go back to the maximum height switch adjustment in step 12.Replace the top patient padding, top cover, rear cover, and rear inside cover on the patient platform/Gantry. If necessary, refer to *Covers Removal - Gantry Section* on page 182.

3.3.8 Return the Shipping Container to Hologic

Return the image detector shipping container and the temperature monitoring device to Hologic as per the instructions in the container.

Chapter 4 System Controls and Indicators

4.1 System Power Controls

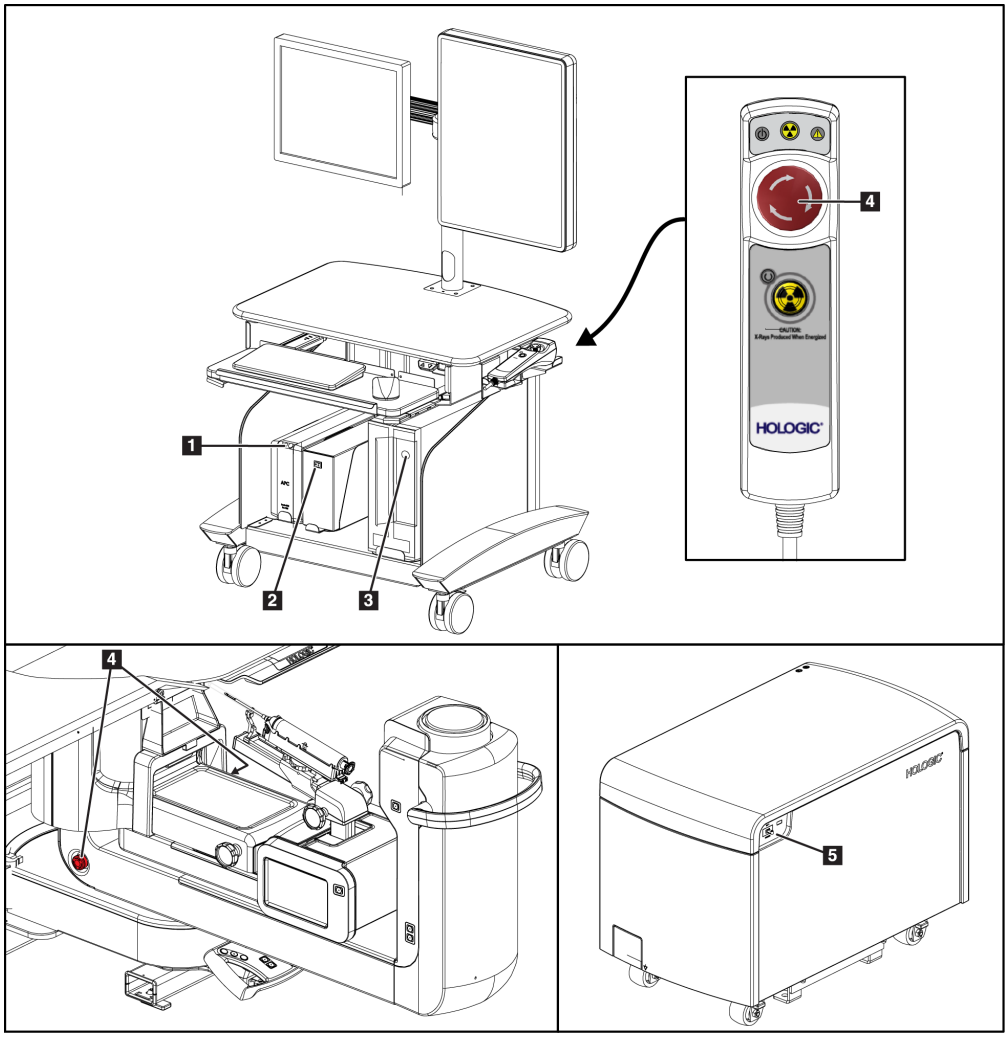


Figure 53: System Power Controls

Figure Legend

1. Uninterruptible Power Supply (UPS) Power/Reset Button
2. Isolation Transformer Power Switch
3. Computer Power On/Reset Button
4. Emergency Off (E-Stop) Switches
5. Generator Circuit Breaker

4.2 C-Arm Controls

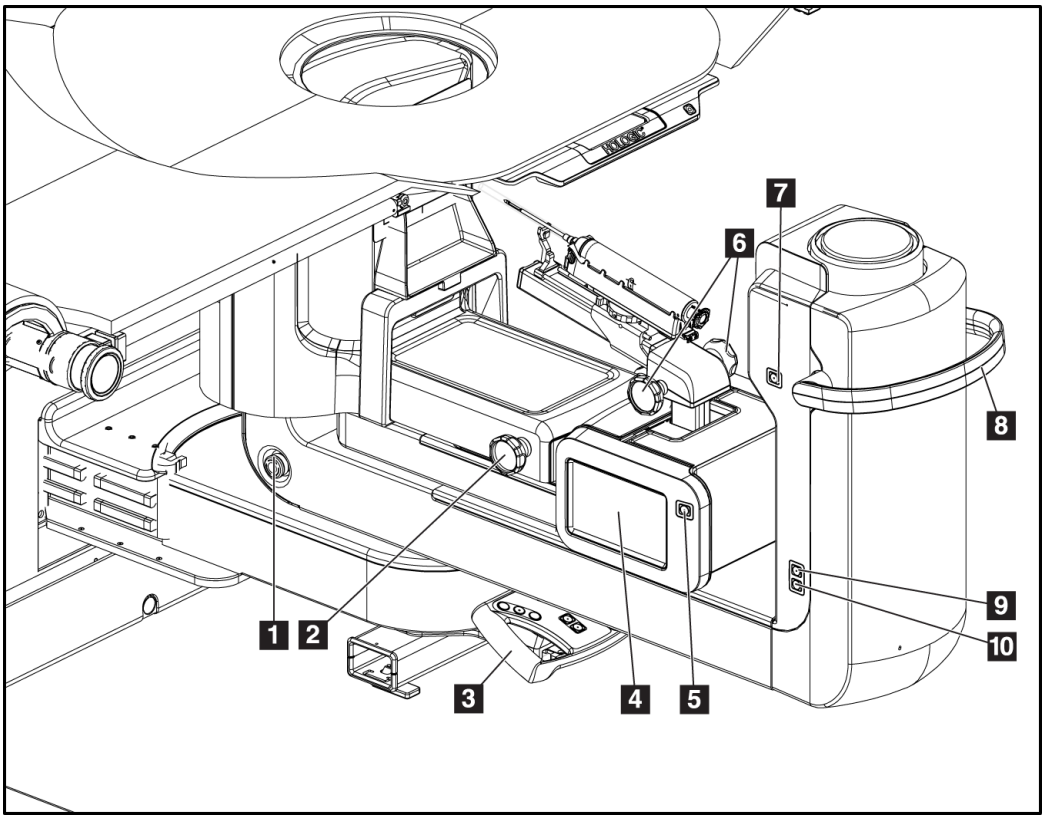


Figure 54: C-arm Controls and Displays

Figure Legend

1. Emergency Off (E-Stop) Switch
2. Manual Compression Adjust Knob
3. Control Handle
4. Biopsy Control Module Touch Screen Display
5. Biopsy Arm Motor Enable Button
6. Manual Biopsy Device Advance/Retract Knob
7. Task Lighting On/Off
8. C-arm Rotation Handle
9. C-arm Sweep – Away from User
10. C-arm Sweep – Toward User

4.2.1 Biopsy Arm Controls

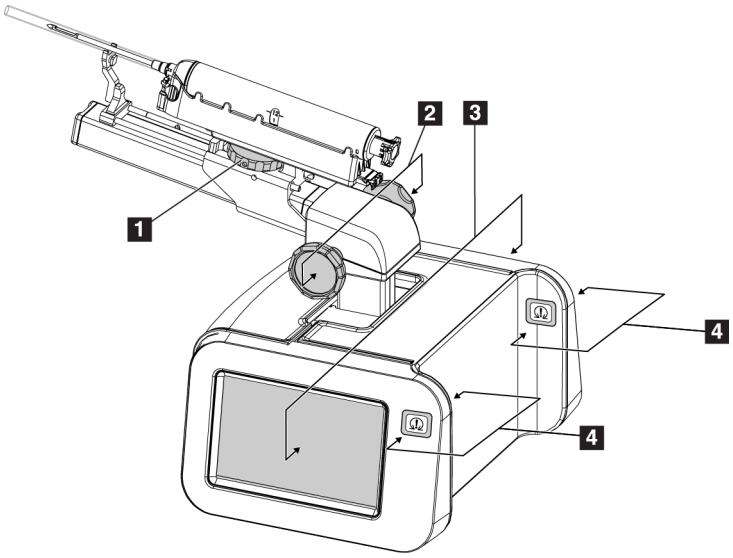


Figure 55: Biopsy Arm – Detailed View

Figure Legend

1. Biopsy Device Mount Knob
2. Manual Needle Advance/Retract Knobs
3. Biopsy Control Module Touch Screen Displays
4. Biopsy Control Module Motor Enable Buttons

Note
Refer to the Affirm Prone Biopsy System *User Guide* for information on using the Biopsy Control Module touchscreen display.

Note
The Biopsy Control Module motor enable buttons consist of two pairs of buttons located on either side of the Biopsy Control Module. Each pair is located back to back on one of the module cover extensions and is meant to be pinched with one hand. To enable the Biopsy Control Module motor, press and hold one of the Motor Enable button pairs.

4.2.2 Control Handle Controls

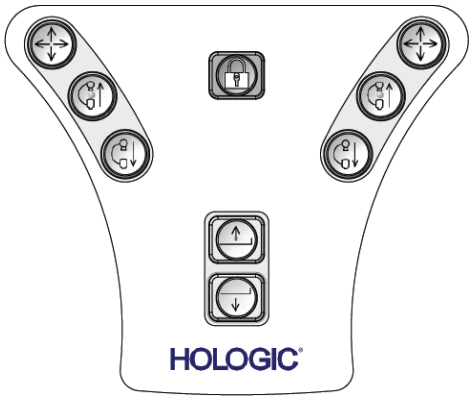


Figure 56: Control Handle -- Detailed View

Button	Function
	C-arm Translate (horizontal plane)
	C-arm Up
	C-arm Down
	System Lock
	Patient Platform Up
	Patient Platform Down

4.2.3 Footswitch Controls

Warning:
Place each footswitch in a position where, when used, they remain in reach of the Emergency Off Switches.

Warning:
Position the footswitches to prevent accidental operation by a patient or wheelchair.

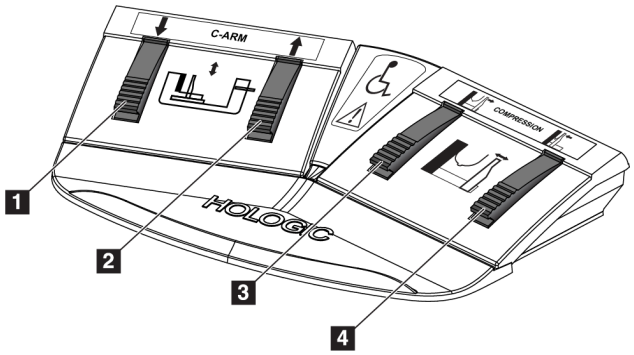


Figure 57: Footswitch – Detailed View

Figure Legend

1. C-arm Down
2. C-arm Up
3. Compression Release
4. Compression Apply

4.3 Patient Platform Controls

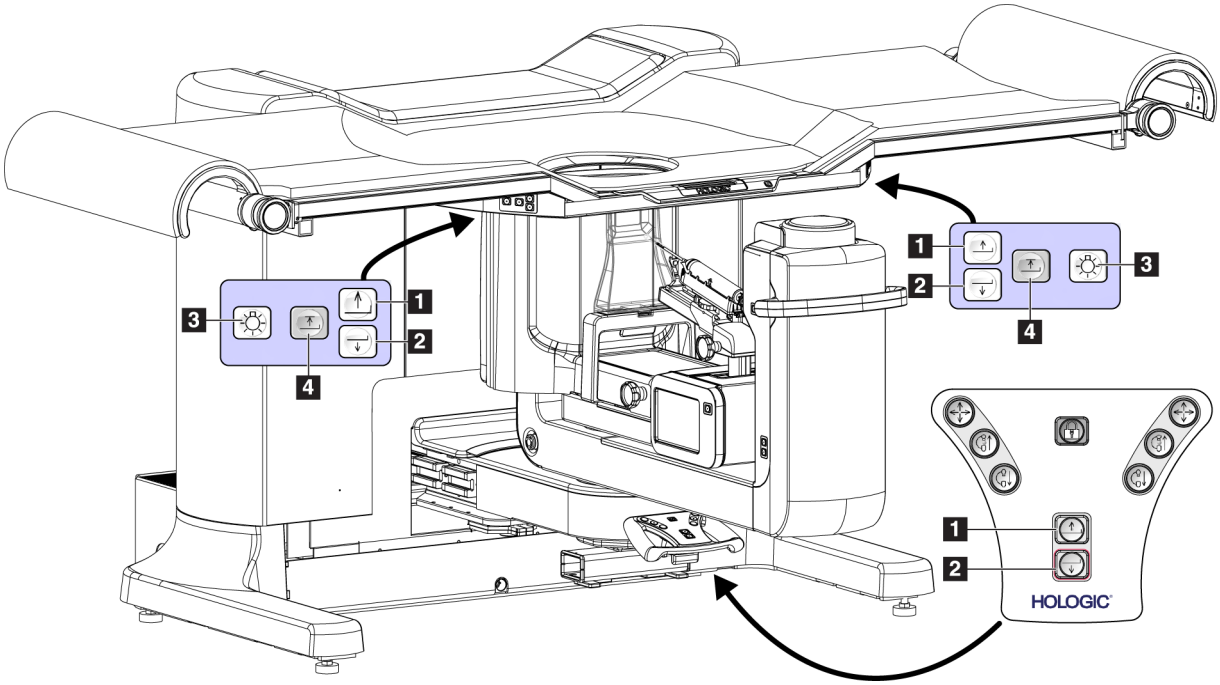


Figure 58: Patient Platform Controls

Figure Legend

1. Patient Platform Up
2. Patient Platform Down
3. Task Light On/Medium/Low/Off
4. Patient Platform Up Limit (Full Height)

4.4 Acquisition Workstation Controls

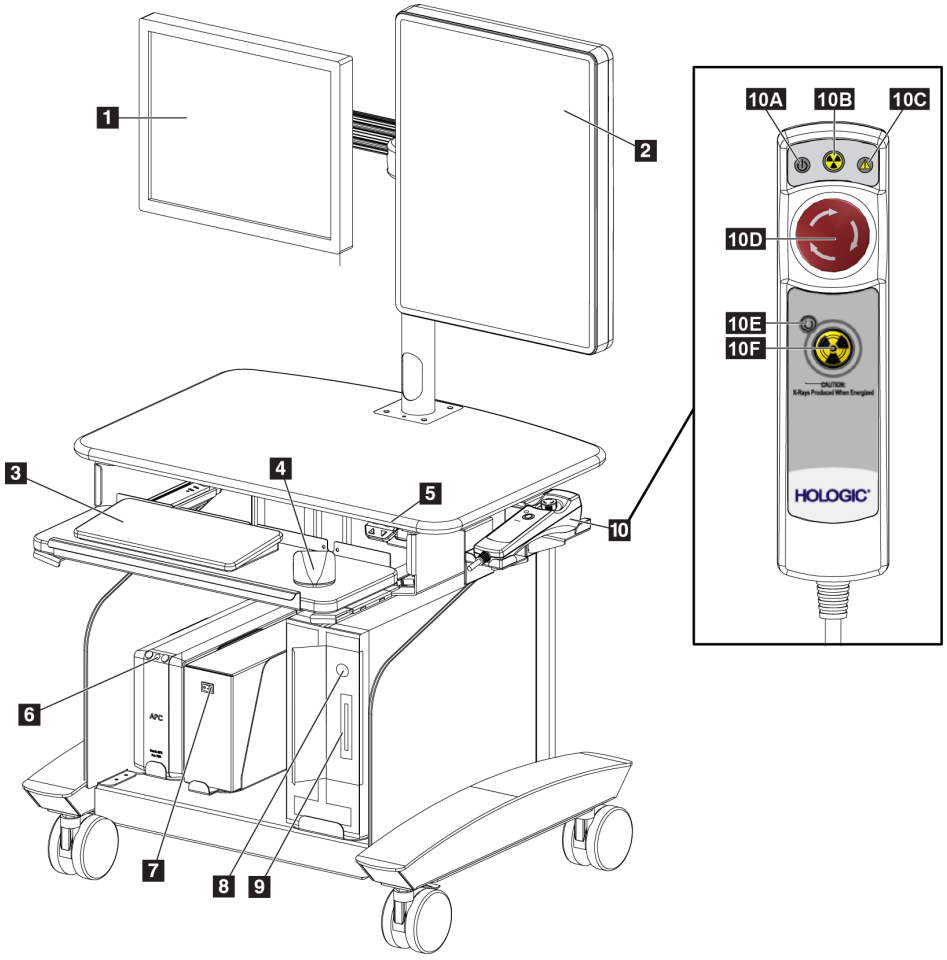


Figure 59: Acquisition Workstation Controls

Figure Legend

1. Control Monitor
2. Image Display Monitor
3. Keyboard
4. Mouse
5. Workstation Work Surface Up and Down Controls
6. Uninterruptible Power Supply (UPS) Power Button
7. Isolation Transformer Power Switch
8. Computer Power On/Reset Button
9. CD/DVD Drive
10. Emergency Off/X-ray Activation Remote
    - A. Power On Light
    - B. X-ray Active Light
    - C. System Alert Light
    - D. Emergency Off Switch
    - E. Ready for X-ray Light
    - F. X-ray Activation Button

4.5 How to Start the System

4.5.1 Preparation

1. Verify that there are no obstructions to C-arm, Patient Platform movement, or to the view of the Operator.
2. Make sure that all three Emergency Off switches are in the reset position (unpushed).

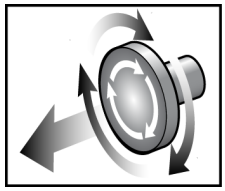


Figure 60: Turn to Reset the Emergency Off Switches

3. Make sure that the Generator circuit breaker is in the ON position.

4.5.2 Startup

1. Ensure that the Isolation Transformer power switch is in the ON position.
2. Ensure that the UPS is powered ON.

3. Press the **Power/Reset** button on the computer. The computer powers on and the *Startup* screen appears on the Acquisition Workstation Control monitor. The Gantry then automatically powers on.

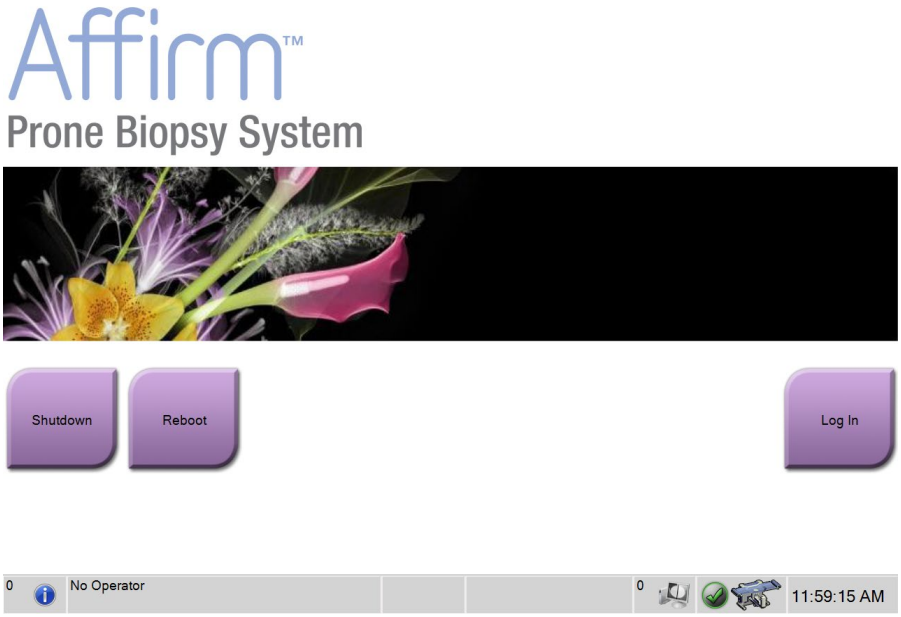


Figure 61: Startup Screen

Note
The *Startup* screen includes a **Shutdown** button that turns off the system, and a **Reboot** button that restarts the system.

Note
See the figure *System Power Controls* on page 73 for the locations of power buttons.

4.5.3 Log In

1. Select the **Log In** button on the *Startup* screen.
2. The *Select an Operator* (Log In) screen opens and shows a list of Manager and Technologist user names. Select the **Show All** button to list the Service, Applications, and Physicist user names.
3. Choose an operator by selecting the applicable button.

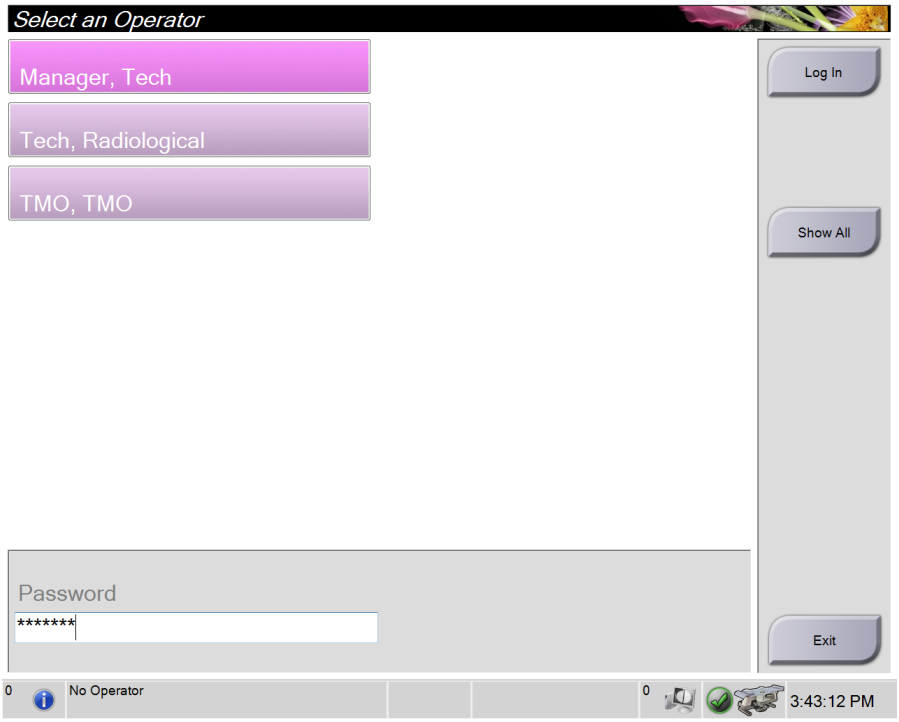


Figure 62: Select an Operator (Log In) Screen

4. Select the Password field and type in the password.
5. Select **Log In**.

Note
If Quality Control tasks are due, the *Select Function to Perform* screen opens. Perform the quality control tasks or select **Skip**.

4.6 Perform Functional Tests

Perform the functional tests as described in the *User Guide*.

4.7 Confirm Licensing

Confirm the licensed features for this system. In the system application, go to **Admin > About screen > Licensing** tab and verify the features and options installed.

If any additional features are required, locate the Sales Order number of the feature(s) and follow the directions in *Add Licensed Features* on page 109.

4.8 How to Turn Off the System

1. Close any open patient procedures.
2. From the *Select Patient* screen, select the **Log Out** button.
3. From the *Startup* screen, select the **Shutdown** button.
4. Select **Yes** in the confirmation dialog box.

4.8.1 How to Remove All Power from the System

1. Turn off the system.
2. Press the UPS power/reset button to power off the UPS.
3. Turn OFF the Isolation Transformer power switch.
4. Turn OFF the Generator circuit breaker.
5. Turn OFF the Facility Mains circuit breaker.

Chapter 5 Setup, Configuration, and Connectivity

5.1 About Screen

The About screen provides information about the machine, such as system level, IP address, licensed features, and serial number. This type of data can be useful when working with Hologic to configure the system or resolve a system issue.

The screen is accessed in two ways:

- From the *Select Patient* screen - select the **Gantry** icon (on Taskbar), then select **About…**
- From the *Admin* screen - select **About** (in System Grouping)

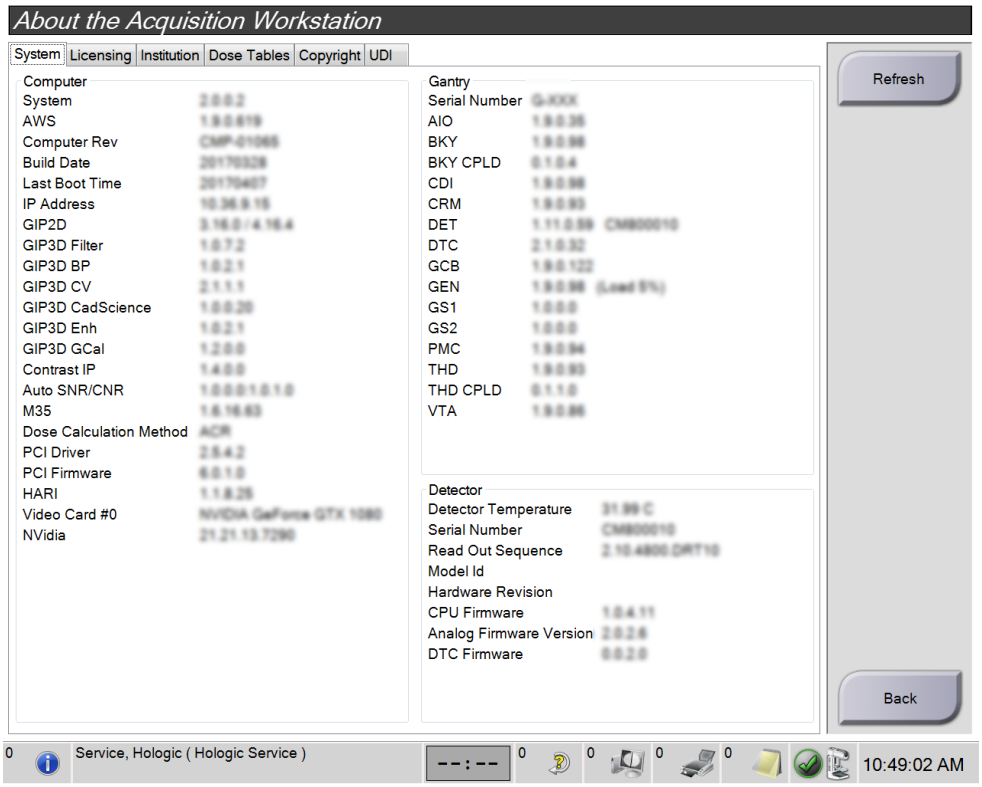


Figure 63: About Screen with the System Tab Showing (Service Login)

There are six tabs on the *About* screen:

- **System Tab** (default) - lists system configuration information
- **Licensing Tab** - lists the Hologic-licensed options installed on this machine
- **Institution Tab** - lists the name and address of the organization assigned to this machine
- **Dose Tables Tab** - lists the dose tables used on the system
- **Copyright Tab** - lists the copyrights of Hologic and third-party software installed on this machine
- **UDI Tab** - lists the unique device identifier(s) of this machine

5.2 The Admin Screen

The Admin screen provides access to system calibrations, tests, and reports. To access this screen, do the following.

1. At the Acquisition Workstation, log in to the system Capture application as Service.
2. At the *Select Patient* screen, select the **Admin** button.
3. The Admin screen opens.

Figure 64: Admin Screen (Service Login)

Refer to the following table for descriptions of the *Admin* screen functions.

Note
Depending on the license settings for your system, you may not see all the buttons listed here.

Table 2: Admin Screen Functions

Section	Button Name	Function
Operators	**Manage Operators**	Add, delete, or change Operator information
	My Settings	Change the information for the current Operator, including worklist settings
Procedures	**Procedure Editor**	Add or edit the procedures, or change the view order for each user
	Procedure Order	View and change the order for "Procedures" within a specific "Procedure Group" (such as Conventional, Tomo, etc.)
	View Editor	Add or edit the views
	QAS	Access the *QAS Test* screen

Table 2: Admin Screen Functions

Section	Button Name	Function
Quality Control	**Quality Control**	Select a Quality Control (QC) task to perform or mark completed
	QC Report	Create a Quality Control (QC) Report
	Test Patterns	Select and send the test patterns to output devices
	Reject and Repeat Report	Create a Reject and Repeat Report
System	**System Tools**	The interface provided for Service to configure the Affirm Prone biopsy system based on customer site required workflow. Configuration information within System Tools may also assist in troubleshooting with devices interfaced to the system.
	System Defaults	Set the Gantry default values
	System Diagnostics	Displays the status of all subsystems and provides the ability to turn on or off the Gantry and to restart the detector
	Preferences	Set the system preferences
	About	Describes the system (refer to *About Screen* on page 83)
	Exposure Report	Create a report of the number of exposures by modality.
	Biopsy Devices	Set and manage the biopsy devices.
	Log Viewer	Review the system log files.
	Turn NPT On	Puts the system in non-patient test mode (NPT), used specifically for system Node testing. When put into NPT mode, Gantry and Detector Nodes are put in a state unsuitable for clinical purposes.
	STX Calibration	Maps the needle coordinates to the detector space for the standard approach of a biopsy device
Connectivity	**Query Retrieve**	Configure the Query/Retrieve devices
	Import	Import the data from a DICOM source.
	Manage Output Groups	Add, delete, or edit output groups.
	Incoming Log	Shows log entries for images that do not import during manual import or DICOM store.
	Archive	Send local studies to networked storage or export to removable media devices.
You must have permission to access all features. The permission level controls the functions you can change.		

5.3 Operating System Settings

5.3.1 Adjust the Time Zone for Locale

The default time zone for the system is Eastern Standard Time for the USA. The time zone is changed through the Windows Control Panel. Follow these instructions to change the time zone as required.

1. Close the system application.
2. Open the Windows Control Panel (**Start > Control Panel**).
3. In the upper right-hand corner, make sure View by: is set to **Category**.
4. Select **Clock, Language and Reason**.
5. Under Date and Time, select **Change the time zone**.
6. On the Date and Time screen and tab, select **Change time zone...**

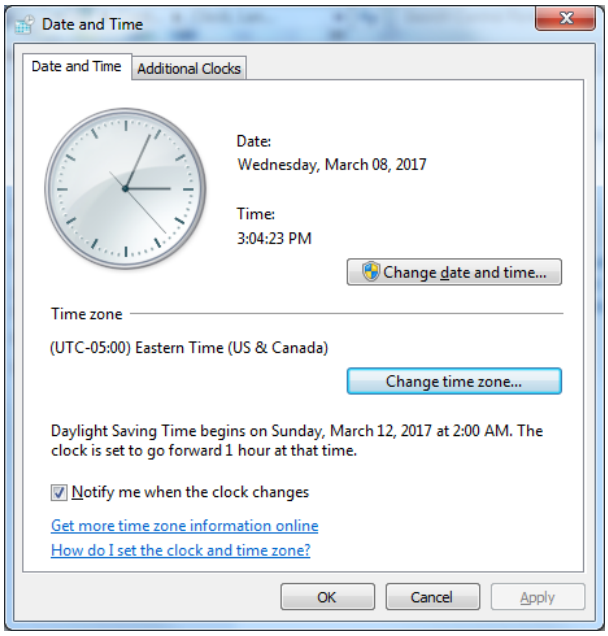


Figure 65: Windows Date and Time screen

7. Select the appropriate the time zone from the drop-down list and click **OK**.

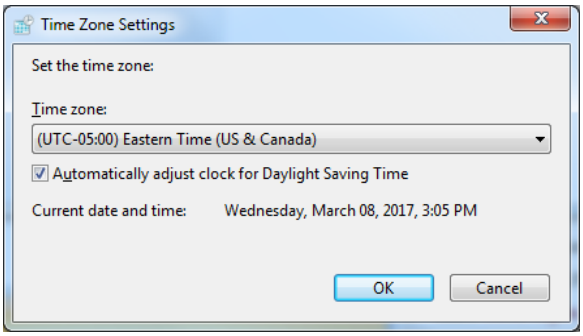


Figure 66: Time Zone selection

8. On the Date and Time screen, verify the correct time. Select **Apply**, then select **OK**.
9. Restart the system application for the changes to take effect.

5.3.2 Adjust the Time and Date Formats

The system defaults to a 12-hour clock format and M/d/yyyy date format. The time and date formats are changed through the Windows Control Panel. Follow these instructions to change the time and date presentation as required.

1. Close the system application.
2. Open the Windows Control Panel (**Start > Control Panel**).
3. In the upper right-hand corner, make sure View by: is set to **Category**.
4. Select **Clock, Language and Reason**.
5. Under Region and Language, select **Change the date, time, or number format**.

6. Under the Formats tab, make the appropriate choices (see the following figure):
   a. Select the desired language and country from the Format drop-down list (item 1).
   b. Select the desired date format from the Short date and Long date drop-down lists (item 2).
   c. Select the desired time format from the Short time and Long time drop-down lists (item 3).

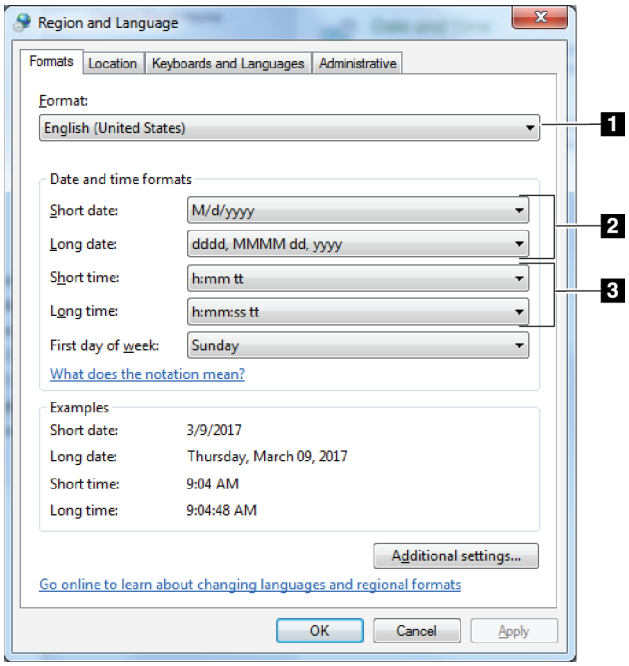


Figure 67: Windows Formats screen

7. Select **Apply**, then select **OK**.
8. Restart the system application for the changes to take effect.

5.3.3 Configure Network Parameters

The system application derives network identification parameters from entries you make using the Network and Sharing Center in Windows Control Panel. Use this procedure to enter the server host name, DNS server, IP address, subnet mask, and default gateway.

1. Close the system application.
2. Access the network properties in Windows by either of these two methods:
   - Right-click the desktop network icon and select **Properties.**

     OR
   - Navigate via Windows Control Panel.

   a. Select **Start > Control Panel**.
   b. In the upper right-hand corner, make sure View by: is set to **Category**.
   c. Under Network and Internet, select **View Network Status and Tasks**.

3. On the Network and Sharing Center screen, select **Local Area Connection**.

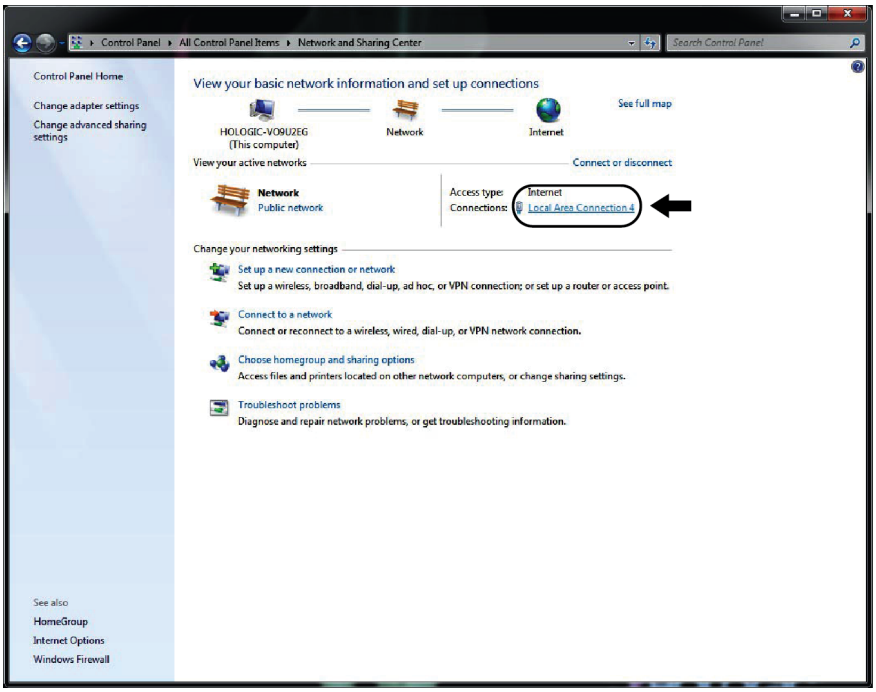


Figure 68: Network and Sharing Center screen

4. On the Local Area Connection screen, select **Properties**.

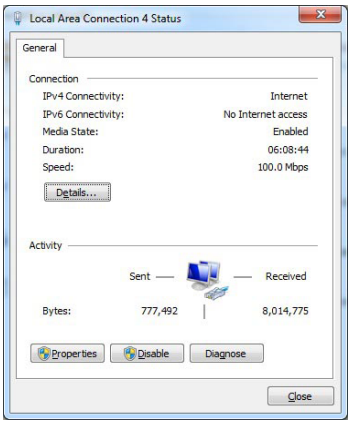


Figure 69: Local Area Connection screen

5. On the Networking screen, select **Internet Protocol Version 4(TCP/IPv4)** and click **Properties**.

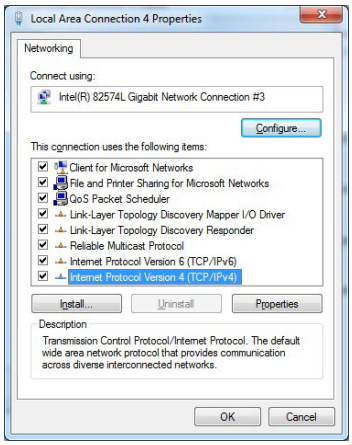


Figure 70: Networking screen

6. On the Internet Protocol Version 4 (TCP/IPv4) Properties screen, select the **Use the following IP address** option, and then enter the site **IP address, Subnet mask, Default gatewa**y, and **DNS server address**.
7. Click **OK**, then click **Close**.

8. Use the following substeps to change the system host name per conventions, guided by the customer IT staff of the customer, your Regional Connectivity Specialist, or your own convention consistent with Hologic training. Consult with the site IT administrator before changing the server host name.

   a. Access the Systems Properties screen by either of these methods.

      - On the desktop, right-click the **Computer** short-cut icon and select **Properties**.

      OR

      - Go to **Start,** right-click on **Computer,** and select **Properties**. Click **Advanced system settings**.

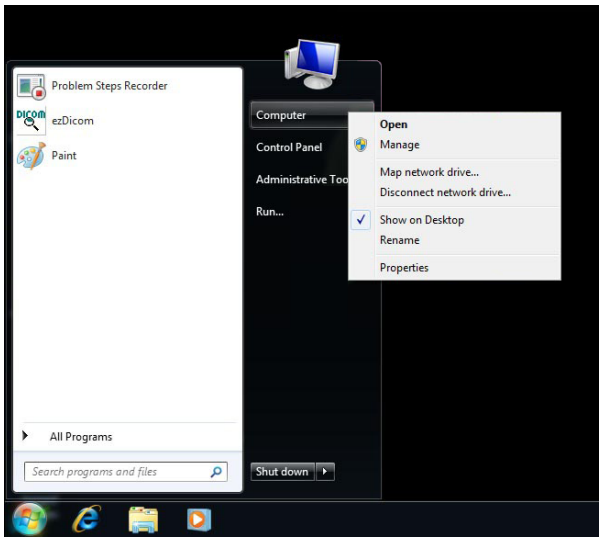


Figure 71: My Computer screen

   b. On the System Properties screen, click the **Computer Name** tab, then click **Change**.

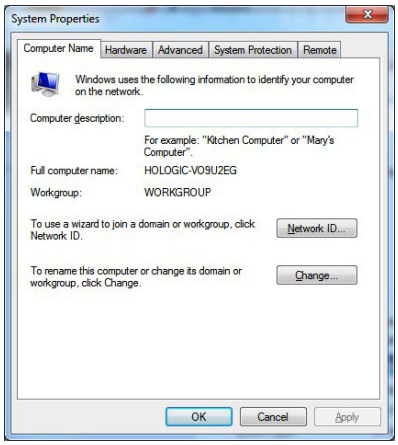


Figure 72: System Properties screen, Computer Name tab

c. On the computer Name/Domain Changes screen, enter the host name in the Computer name field.

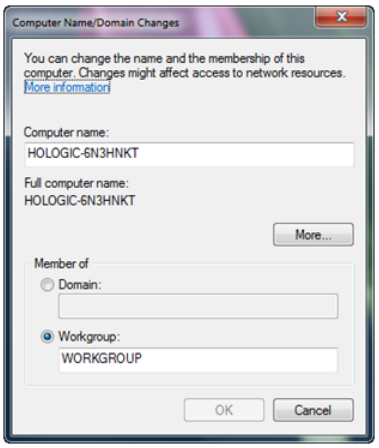


Figure 73: Computer Name Changes screen

d. Click **OK** (twice) to return the System Properties screen, then click **Close**.

e. On the System Settings Change screen, click **Restart** to restart the system.

5.4 Hologic Connect Configuration

Hologic Connect™ is a multi-functional, cloud-server based platform that provides system status via real-time monitoring as well as remote connection capabilities for any connected device. Hologic Connect allows Hologic Tech Support, Field Service, Applications, and Software Development to remotely access into a system for troubleshooting, maintenance, training, and data reporting purposes.

The following set of procedures explain how to configure Hologic Connect on the system using the Hologic Connect configuration tool.

5.4.1 Accessing Hologic Connect

1. From any system applications screen, press the Windows key.

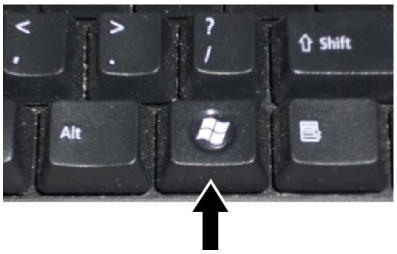


Figure 74: Windows Key on Keyboard

2. Right-click on the clock displayed in the tool bar in the lower right-hand side of the screen and select **Show the desktop**.

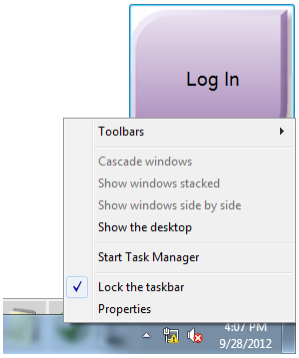


Figure 75: Show the Desktop

3. Find the Hologic Connect icon on the desktop and double-click it.

Figure 76: Hologic Connect Icon

5.4.2 Enter Site Information for Hologic Connect

1. Select the Site Details tab at the top of the Hologic Connect Control Panel screen.
2. Enter the specific site information consistent with corporate naming conventions. If in doubt, consult the sales order or corporate system such as Oracle and Salesforce.

   Be attentive to names used for other equipment and/or locations. For example, do not use "St." at one location and "Saint" at another. Always use the standard two letter abbreviation for the state (such as "TX" for Texas).

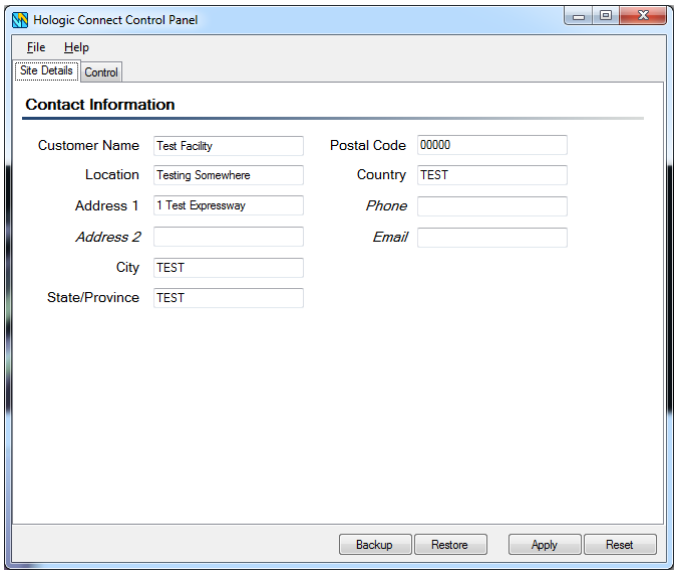


Figure 77: Hologic Connect Control Panel - Site Details

5.4.3 Enter Product Information for Hologic Connect

1. Select the **Control** tab at the top of the screen.

   If the Hologic Connect process is running, click the **Stop** button.

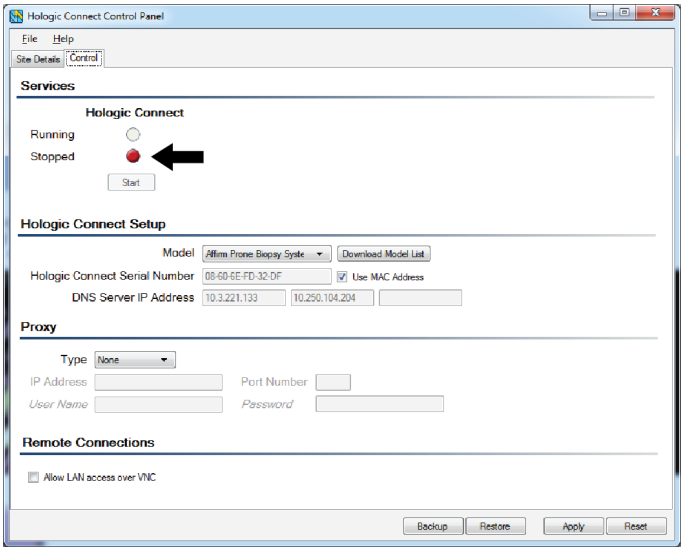


Figure 78: Hologic Connect Control Panel - Control Tab

2. In the Model field, choose **Affirm Prone Biopsy System** from the dropdown list.

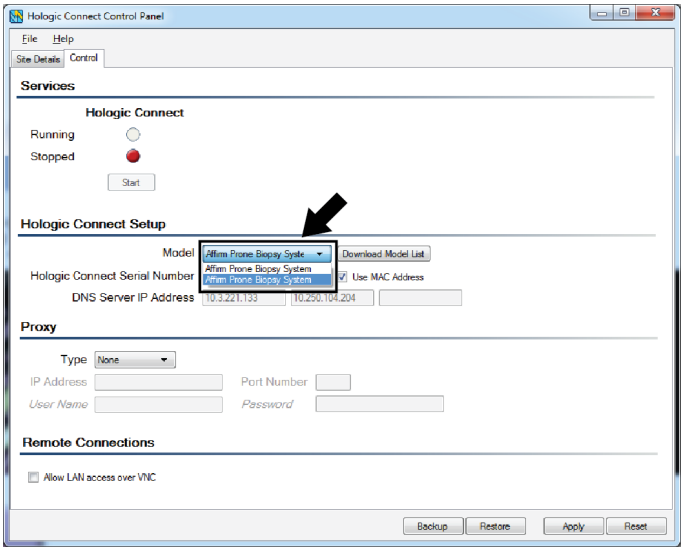


Figure 79: Hologic Connect Control Panel - Model Drop-Down Box

3. Deselect the **Use the MAC Address** checkbox (see the following figure).

4. Enter the System Serial Number in the Hologic Connect Serial Number field.

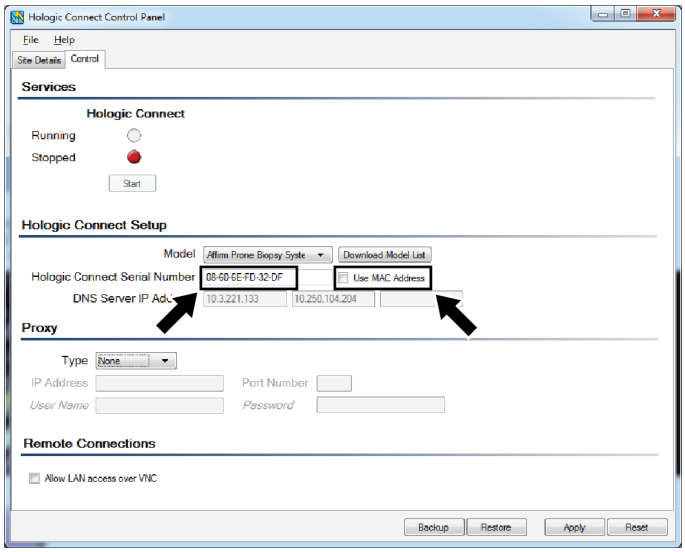


Figure 80: Hologic Connect Control Panel - Use MAC Address checkbox

5. Under the Remote Connections section at the bottom, the "Allow LAN access over VNC" field is normally left unchecked (for not to enable this feature).

   If the customer needs the system to communicate via a LAN going over a VNC (which is not as secure as a regular LAN, but may be needed in certain circumstances), select this option.

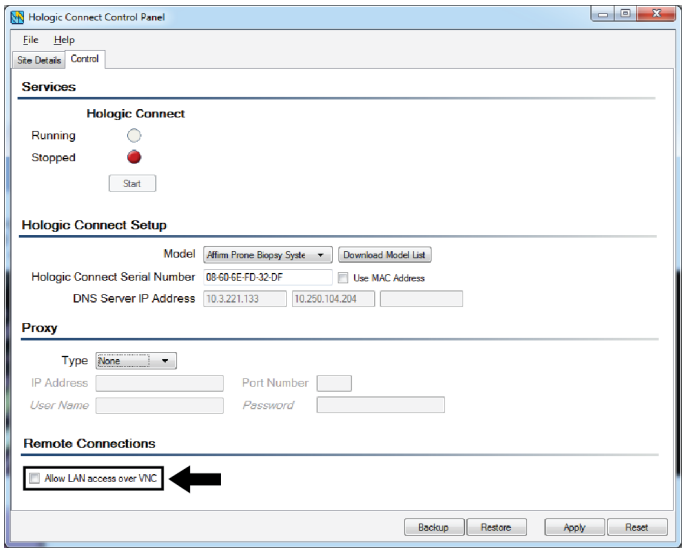


Figure 81: Hologic Connect Control Panel - Allow LAN access over VNC checkbox

6. Do the following, based on the situation:
   - If a proxy server is used by the site, continue with Configure a Proxy Server (If Needed).
   - If no proxy server is used by the site, proceed to *Test/Verify Hologic Connect Internet Access* on page 98.

5.4.4 Configure a Proxy Server (If Needed)

A proxy server may sit between a client and the Internet. It serves as an intermediary gateway to pass acceptable requests from clients, then forwards those requests to other servers. Refer to the Connectivity Site Survey for proxy server information.

Note
If no proxy server is used with this system, proceed to *Test/Verify Hologic Connect Internet Access* on page 98.

1. From the Hologic Connect Control Panel, select the **Control** tab. Select the appropriate proxy type from the Proxy field dropdown list.

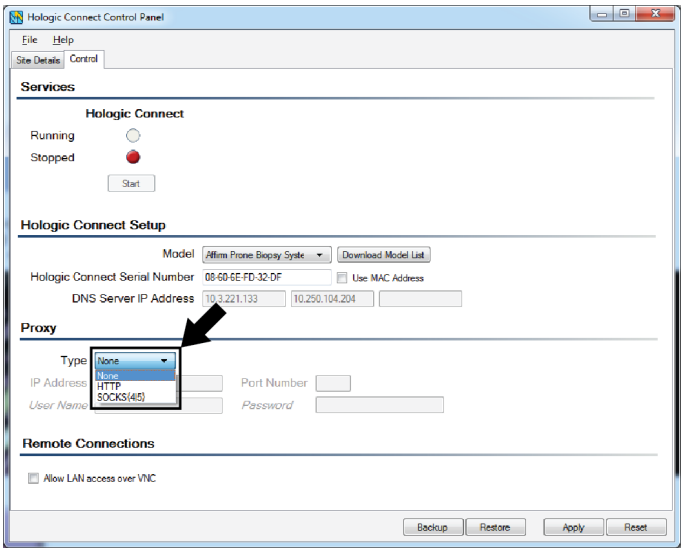


Figure 82: Hologic Connect Control Panel - Proxy Type

- *None*—No Proxy Server
- *HTTP*—The session connects through a Hypertext Transfer Protocol (HTTP) proxy server. HTTP is a communications protocol used to transfer information on intranet and the World Wide Web.
- *SOCKS{4|5}*—The session connects through SOCKS version 4 or 5 proxy server. SOCKS is an abbreviation for SOCKetS, and is an Internet protocol that allows client-server applications to transparently use network firewall services.

2. Enter the appropriate IP Address, Port, User Name, and Password for the proxy server of the customer.
3. Click **Apply** to save the settings. The server displays *Please restart the following service: Hologic Connect*.
4. Reboot the system.
5. Verify the Internet connection (refer to *Test/Verify Hologic Connect Internet Access* on page 98).

5.4.5 Test/Verify Hologic Connect Internet Access

1. After making changes in Hologic Connect, restart the system.
2. Launch Internet Explorer.

   If Internet Explorer is not easily accessible from the taskbar or as a desktop shortcut, do the following:

   a. Right-click on the Windows start icon [] and click **Search**.

   b. In the search box, type **iexplore**.

   c. Under Programs, click **iexplore.exe**.

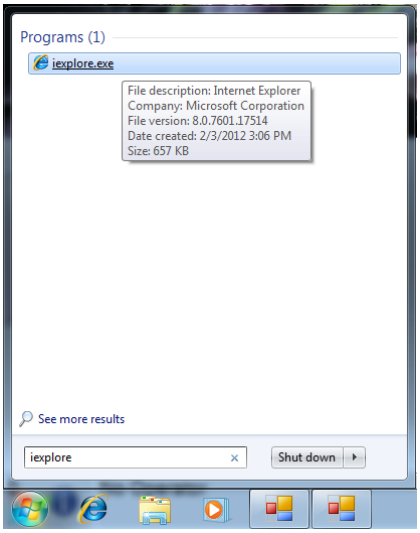


Figure 83: Searching for iexplore

3. The web browser opens. Go to *http://www.hologic.com* and verify that the website launches.

Note
If the website does not appear, there is no connection to the internet. Verify the Ethernet cable is attached to a working LAN port and refer to *Configure Network Parameters* on page 88 and *Configure a Proxy Server (If Needed)* on page 97 to review your network settings.

4. To update customer records, email Customer Support at *BreastHealth.Support@hologic.com*. Please include:
   - customer name
   - system serial number
   - MAC address for each system
5. To contact Hologic Technical Support, call **1.800.760.8342**, or email *imgsupport@hologic.com*.

5.5 System (Service) Tools

Note
If the Acquisition Workstation software is not in operation, you can start the System (Service) Tools from the shortcut on the desktop.

System (Service) Tools provides access to system configurations and settings. To access this application, do the following.

1. At the Acquisition Workstation, log in to the system application as Service.
2. At the *Select Patient* screen, select the **Admin** button.
3. At the Admin screen, select **System Tools**.

4. The System Tools screen displays.

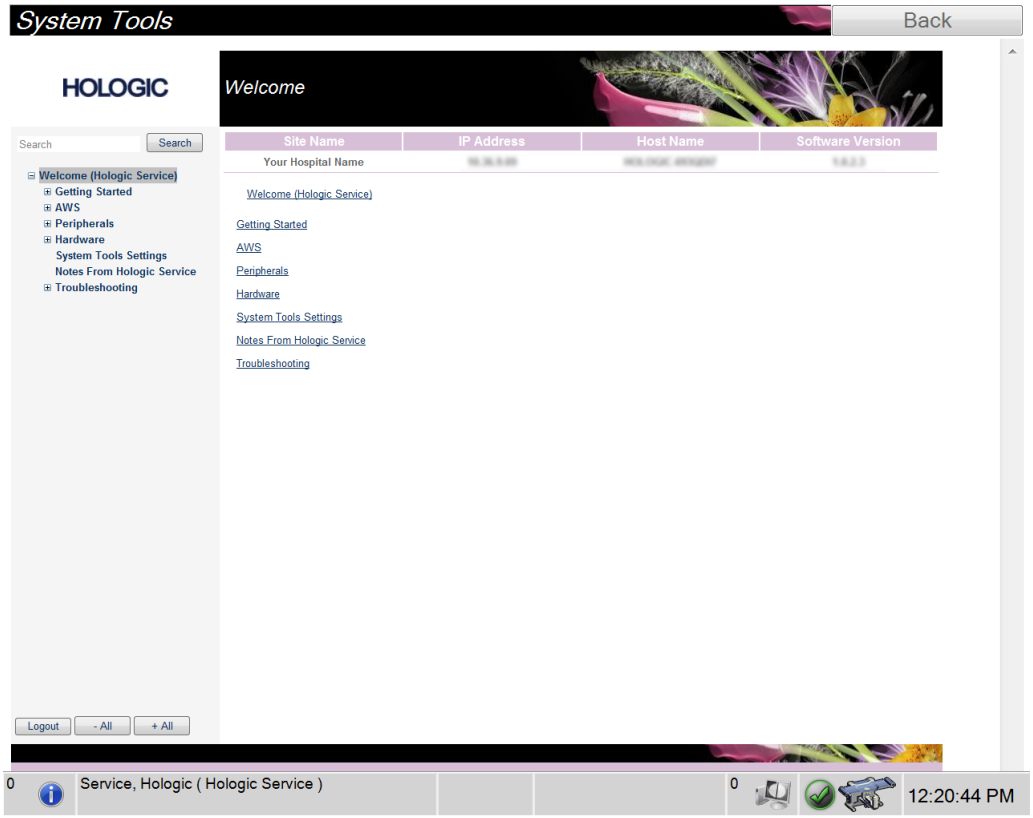


Figure 84: System Tools (Service Login)

Refer to the following table for descriptions of the System (Service) Tools functions.

Table 3: System (Service) Tools Functions (Service Login)

Item	Topic	Description
Getting Started	About	Introduction to using the service tool
	FAQ	List of frequently asked questions
	Glossary	List of terms and definitions
	Platform	List of directories, software version numbers, and system software statistics
	Index	Alphabetical list of topics
	Shortcuts	List of Windows® shortcuts

Table 3: System (Service) Tools Functions (Service Login)

Item	Topic	Description
(AWS) Acquisition Workstation	Connectivity	Provides the ability to install, list, and configure output devices as related DICOM functionality
	Film and Image Information	View, import, and edit image processing parameters
	Licensing	List, add, and remove licenses
	Notices	Configure export settings
	Import	Configure DB mappings and Filters
	JSS	View JSS Dispatcher Job Type information
	Hanging Protocol	Configure Hanging Protocol
	Reclaimer	Configure Reclamation defaults
	Procedures	Configure Procedure parameters
	DICOM	Configure DICOM settings
	User Interface	Configure UI defaults
	Simulation	
	Internationalization	Configure language and culture
	Global	Configure system, Repository (sets threshold of hard drive capacity remaining before system message displays), Institution settings
	QC	Procedure, periodicity, calibrations, phantom thickness
	AWM	Enable AWM Cluster
Peripherals	Removable Media	Configure image types exported to media

Table 3: System (Service) Tools Functions (Service Login)

Item	Topic	Description
Hardware	Paddles	Lists Paddle IDs
	Calibration	Lists calibration parameters
	Subsystem (Global)	Acquisition Workstation Settings, Mag settings, Gantry distances, temperature limits
	Biopsy Device List	Device list
	Biopsy Config	Biopsy, QAS configuration parameters
	Monitors	Heartbeat, exposure count, monitors
	Detector Configuration	Maximum pixel value for conventional and tomographic images
	Tube Filter Outputs	Lists Filter Tube Output and HVL tables
	Tube Loading	Configure tube load parameters
System Tools Settings		Idle Timeout
Notes from Hologic Service		Allows entry of Service PM/install notes in a database to track work done on visits
Troubleshooting	Acquisition Workstation	Self-tests, Database Viewer/Setup, Mappings, Role Permissions, Tagged Images, DICOM dump, Get Images/Quality files
	Computer	Windows Services/Processes, System Management, Network information
	Log	Log: downloader, Flags, Config, Management, Viewer, Audit Viewer, Screen image download
	Backups	Backup: Create, Restore, Management, Parameters

5.5.1 Configure System Institution and Locale Information

The system Capture application start-up and login screens have their own locale settings separate from any locale settings done through the Windows operating system. The locale settings for the system Capture application start-up and login screens are determined by settings in the Institution Information screen of System Tools.

Note
After logging in to the system Capture application, the locale of screens used by an operator are determined by the settings in Manage Operators feature. If you need to change this locale, go to **Admin > Manage Operators**. Select an operator, then go to **Edit operator > Next** screen and select a Locale.

There are also other settings in the Institution Information screen which are displayed within the Capture application and used to populate DICOM fields.

Perform the following instructions to configure the institution and locale information for the Capture application.

1. In System Tools, navigate to **AWS > Global > Institution** (see following figure).

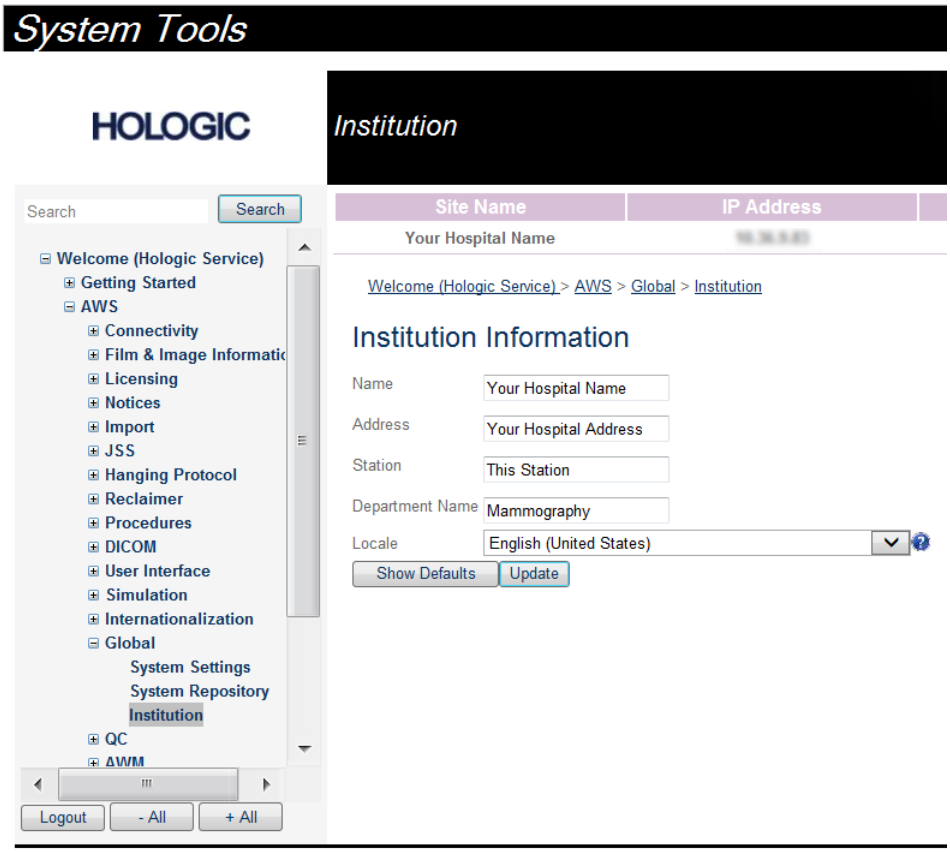


Figure 85: System Tools > AWS > Global > Institution

2. Enter **Name** and **Address** values consistent with corporate customer naming conventions, or as directed by the customer to populate DICOM fields and text printed on film.
3. Enter a **Station** name consistent with the desired DICOM Station Name field content. This field may be used by Modality Worklist and Print interfaces and should be noted among support records.

Note
Station name is a case sensitive field.

4. Use the **Department Name** field to indicate location information more specific than the Address field.
5. In the Locale field (item 1 in following figure), select the desired Locale from the dropdown list, then select **Update** (item 2).

Note
The Locale change does not take effect until the system application is restarted.

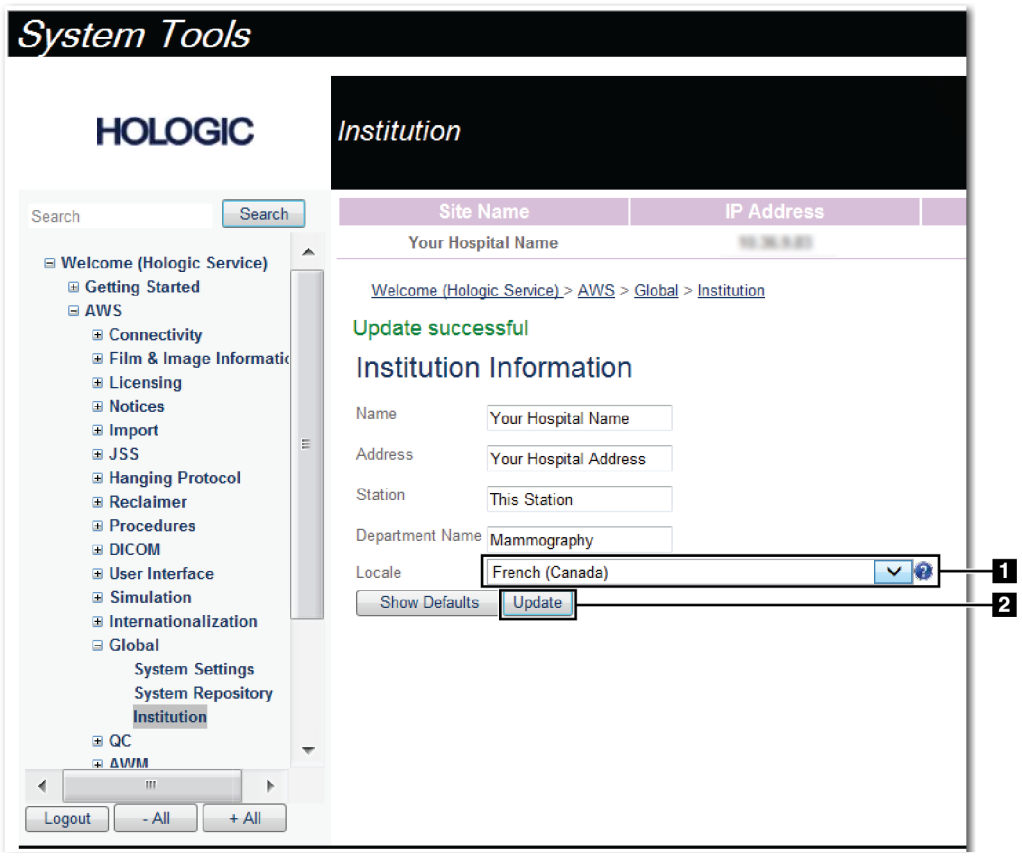


Figure 86: Updating Locale in Institution Information

6. Select **Back** to exit System Tools.

7. Select **Back** to exit the Admin screen.
8. Select **Logout** to log out of the system Capture application.
9. Close the system Capture application:
   a. On the Login screen, press **Ctrl** and select **Shutdown** simultaneously.
   b. On Startup screen, press **Ctrl** and select **Exit** simultaneously.
10. Restart the system Capture application. The start-up and login screens should now reflect the new locale (see the following figures).

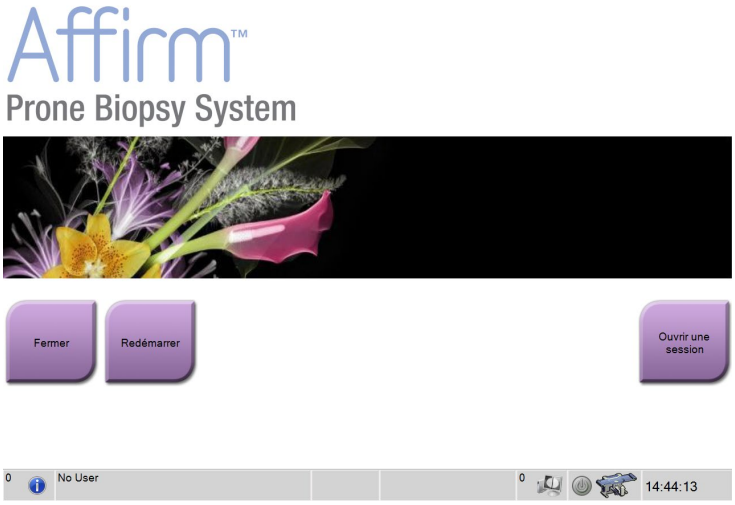


Figure 87: System Capture application startup screen with new locale

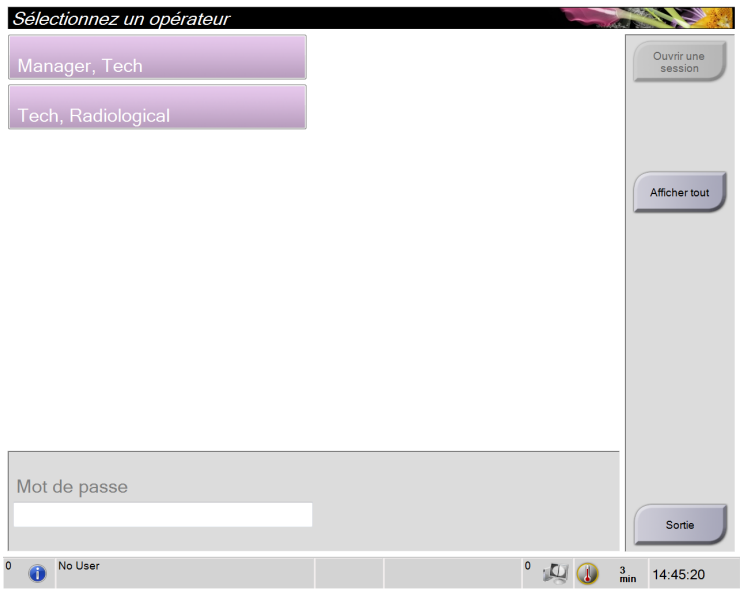


Figure 88: System Capture application login screen with new locale

5.5.2 Configure Serial Number in System Settings

Perform the following instructions to configure the system serial number. This setting populates the serial number in the DICOM header, which are used by other systems to identify its licensed systems.

1. In System Tools, navigate to **AWS > Global > System Settings**.
2. In the Serial Number field, enter the **System Serial Number** and click **Update**.

Figure 89: System Tools > AWS > Global > Global Configuration > Serial Number field

5.5.3 Configure Reclaimer Settings compatible with Storage Commitment Settings

The default Reclaimer settings are compatible with the choice NOT to configure DICOM Storage Commit services with a connected archive device. The default is compatible with most customer choices not to activate Storage Commitment.

Perform the following instructions ONLY if Storage Commitment is enabled and the customer wants images to be protected from deletion until storage confirmation has been received from the archive device.

1. In System Tools, navigate **to AWS > Reclaimer > System Level.**
2. The System Level Reclamation Settings screen opens. Scroll to the bottom of the configuration screen.

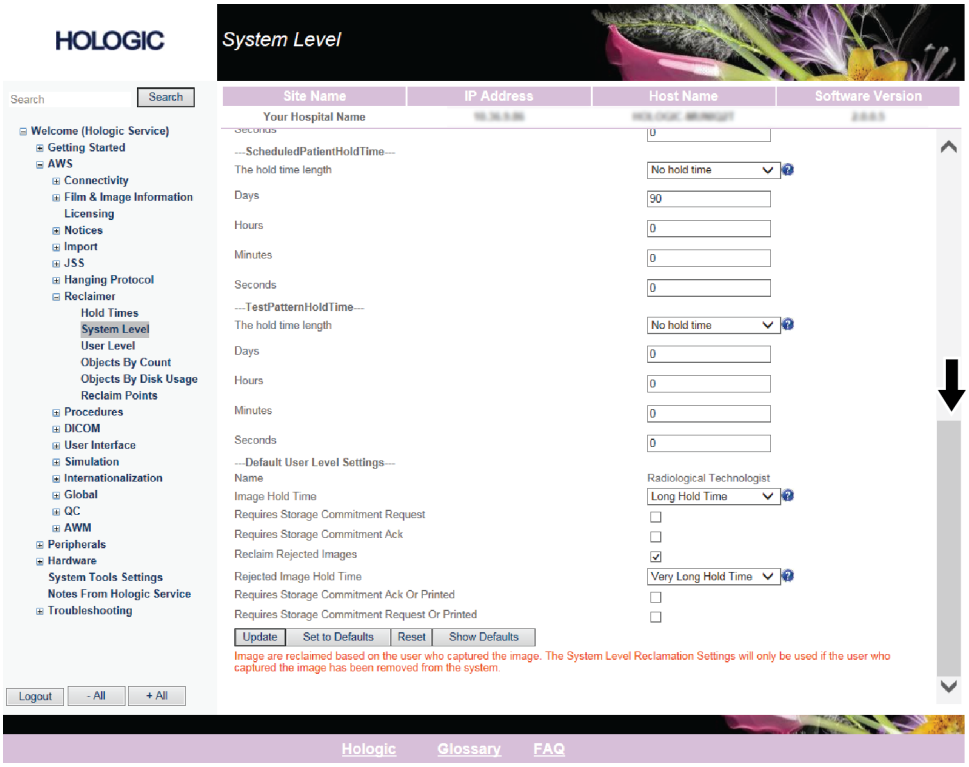


Figure 90: System Tools > AWS > Reclaimer > System Level

3. If Storage Commitment is being used with an archive device, and the customer wants images to be protected until a Storage Commitment acknowledgment is received, select one of the Storage Commitment choices as shown in the following figure. Click **Update**.

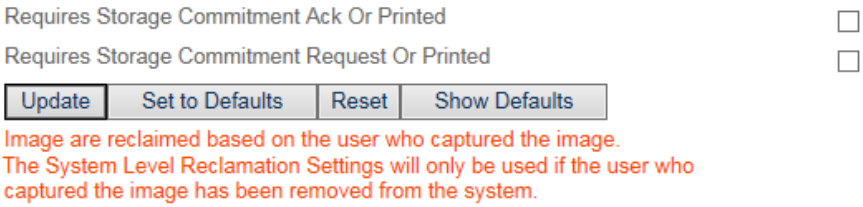


Figure 91: System Level screen, Storage Commitment fields

Note
By default, Storage Commitment is not enabled.

If a Storage Commitments Ack becomes the selected choice, the system may need to remain on at all times, depending upon the operation of the archive device. Some archives perform permanent storage operations overnight.

If Storage Commitment is NOT in use with any active output, ensure that the Storage Commitment settings are NOT checked. Otherwise, images are not reclaimed and the hard drive could eventually fill to capacity.

4. Navigate to **AWS > Reclaimer > User Level**.
5. The User Level Reclamation Settings screen opens. If Storage Commitment is being used with an archive device, select the desired "Requires Storage Commitment" setting for Radiologist, Technologist, and Manager users and other users of interest. Click **Update**.

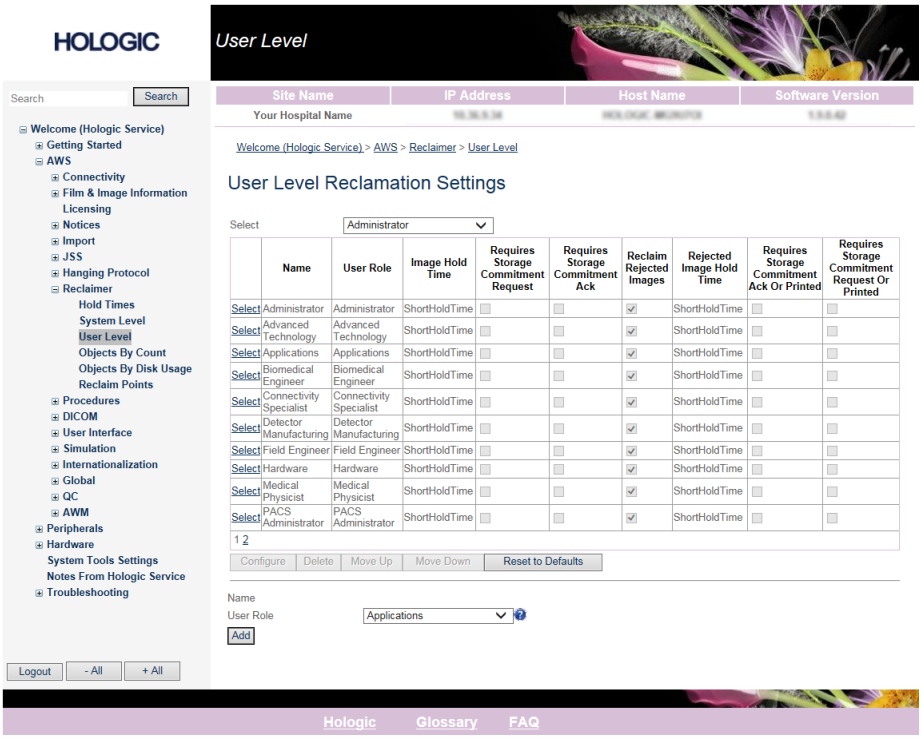


Figure 92: System Tools > AWS > Reclaimer > User Level Reclamation Settings

Note
By default, Storage Commitment is not enabled.

If Storage Commitment is NOT in use with any active output, ensure that the Storage Commitment settings are NOT checked for any users. Otherwise, images are not reclaimed and the hard drive could eventually fill to capacity

5.6 Add Licensed Features

When installing a new licensed feature on a system, or doing a new software install as part of a computer replacement in the workstation, follow these steps.

1. Obtain the following, based on the situation:
   - *Installing a new feature* - Obtain the Sales Order number for that feature.
   - *New software installation as part of a computer replacement* - Obtain the SN# of the system (on the back of the Gantry)
2. In the system Capture application, launch System (Service) Tools (**Admin** screen > **System Tools**).
3. Log in as **hologic service** and type the appropriate password.
4. Go to the **AWS > Licensing** page.
5. Generate a feature request file (xxxxxx.holx). This file includes all the features currently activated on the system and the MAC address of the computer.
   a. Click **Export**.
   b. Right-click on **Right-Click to Download**.
   c. Select **Save as target**.
   d. Navigate to the folder where you want to save the xxxxxx.holx file.
   e. Make sure **HOLX File** is selected as file type.
   f. Click **Save**.
6. Create an email and do the following, based on the situation:
   - *Installing a new feature* - Include the Sales Order # of the feature in addition to attaching the generated xxxxx.holx file. The Sales Order # is the only place where the new feature is identified in the license request procedure.
   - *New software installation as part of a computer replacement* - Include the SN # of the system in addition to attaching the generated xxxxx.holx file.
7. Send email to 3D@Hologic.com.
8. Receive a return email from 3D@Hologic.com with a new activation file (xxxxxx.holx). This file includes all the features currently activated on the system plus the new requested feature(s).
9. In the same screen as in step 4, import the new activation file.
   a. Select **Choose File**.
   b. Navigate to the folder containing the new activation file, select the file, and click **Open**.
   c. Click **Import**.
10. Exit from System Tools and reboot the computer.
11. In the system Capture application, go to **Admin > About screen >Licensing** tab and verify that the new software feature or the correct system software level is installed.

5.7 DICOM Interface Configurations

5.7.1 Configure System AE Title

1. In System Tools, navigate to **AWS > Connectivity > Connectivity (Global)**.
2. In the System AE Title field, enter the **System AE Title** (collected in the Connectivity Site Survey).
3. Scroll down to the bottom of the screen and click **Update**.

Note
It is necessary to restart the system Capture application for the change to take place. Complete the connectivity configurations, then restart the system Capture application.

5.7.2 Configure the Store Output Devices

Install/Test an Archive Interface

The system on its own is not designed to provide permanent storage for patient images. Install an interface to a PACS or other DICOM storage devices that will archive the images sent from the Affirm Prone system.

1. In System Tools, navigate to **AWS > Connectivity > Install a device**.
2. In the Category field, select **Archive** from the dropdown list.

Figure 93: System Tools > AWS > Connectivity > Install a Device > Archive Category field

3. In the dropdown list of the Model field, select the appropriate Archive choice for the environment of the customer.

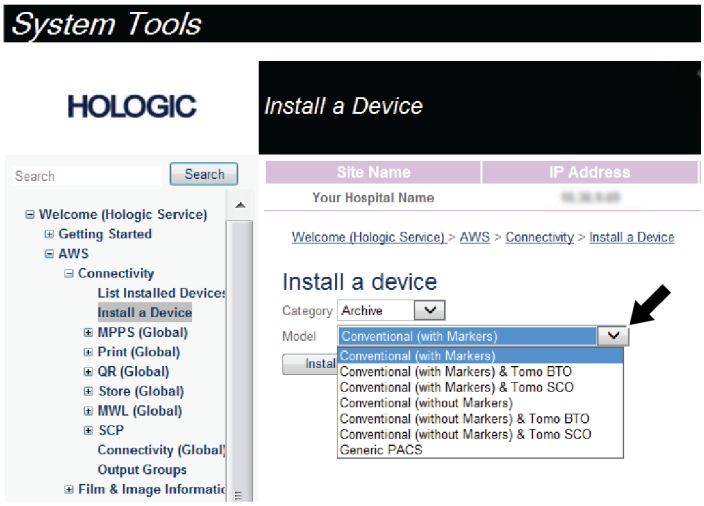


Figure 94: System Tools > AWS > Connectivity > Install a Device > Model field

- *Conventional (with Markers)* – Use this model file for all 2D-only installations where the customer has a preference for burned-in markers (not recommended). The burned in marker feature on the Affirm Prone system includes the image's laterality and view type. The control for marker settings can be found in *Advanced Store Settings* on page 121.
- *Conventional (with Markers) & Tomo BTO* – Use this model file for 3D systems where the customer has a preference for burned-in markers (not recommended) and where the Storage device supports DICOM Breast Tomosynthesis Objects (BTO).
- *Conventional (with Markers) & Tomo SCO* – Use this model file for 3D systems where the customer has a preference for burned-in markers (not recommended) and where the Sales Order indicates a customer request to use the DICOM Secondary Capture Object (SCO) to store proprietary 3D Mammography slice data. Use this model file when the customer environment does not support DICOM Breast Tomosynthesis Objects or when BTO data size is a concern.
- *Conventional (without Markers)* – Use this model file for all 2D-only installations.
- *Conventional (without Markers) & Tomo BTO* – Use this model file for 3D systems where the where the Storage device supports DICOM Breast Tomosynthesis Objects (BTO).
- *Conventional (without Markers) & Tomo SCO* – Use this model file for 3D systems where the Sales Order indicates a customer request to use the DICOM Secondary Capture Object (SCO) to store proprietary 3D Mammography slice data. Use this model file when the customer environment does not support DICOM Breast Tomosynthesis Objects or when BTO data size is a concern.
- *Generic PACS* – Use this model file where no indication is given on the Sales Order of a particular type of archive device.

Caution:
Be cautious using SCO to archive 3D Mammography images. The 3D SCO Mammography images are NOT stored in an interoperable format. Only Hologic products can display these images. Future charges may apply to convert 3D Mammography SCO tomosynthesis slice data to an interoperable format.

4. Click **Install this device**.
5. In the New Archive Installed screen, mouse over **Basic**, then click **Basic Store**.

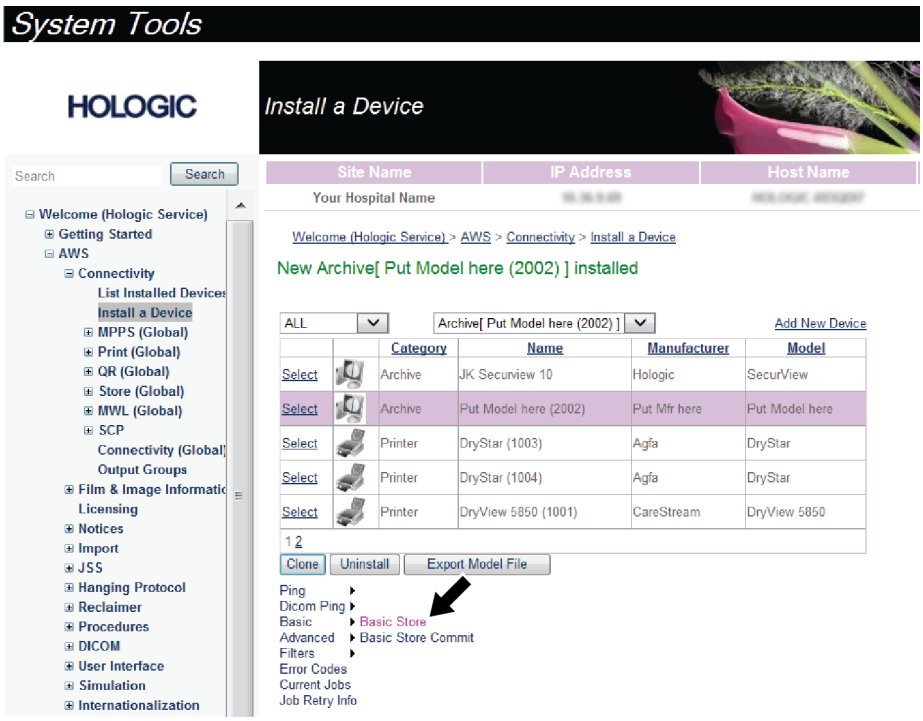


Figure 95: System Tools > AWS > Connectivity > Install a Device > New Archived Installed > Basic Store

6. In the Archive: Basic Store screen, enter the following information:

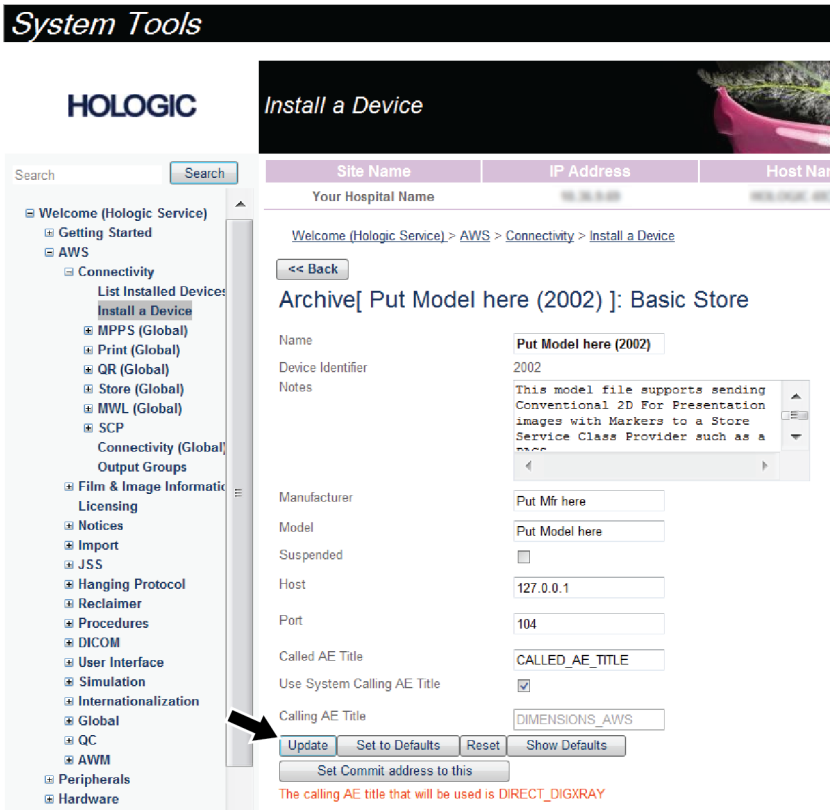


Figure 96: System Tools > AWS > Connectivity > Install a Device > Archive : Basic Store

- *Name* - the name used in the Output Group to identify the device
- *Manufacturer* - the manufacturer of the device (such as GE, Philips, Agfa)
- *Model* - the model (such as Centricity, IntelliSpace, Impax)
- *Host* - the IP address of the device
- *Port* - the TCP listening port on the archive device
- *Called AE Title* - the AE Title of the archive device

7. Do one of the following:
   - If System AE Title is being used, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen. Note that the System AE Title is configured at AWS > Connectivity > Connectivity (Global) screen.
   - If the System AE Title is not being used, enter the Store SCU application AE Title to use with this specific device in the **Calling AE Title** text box.
8. Click **Update**.
9. Click **<< Back**.

10. In the Install a Device screen, mouse over **Ping**, then click **Ping Store**. The system indicates if the ping was successful or failed. If the ping failed, check the Host IP address entered for that device.

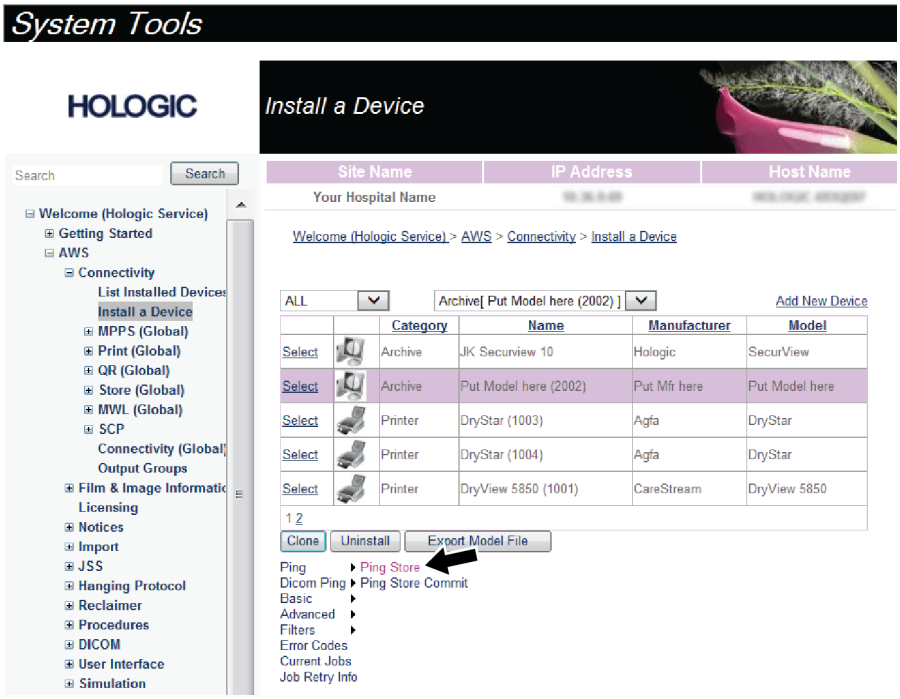


Figure 97: System Tools > AWS > Connectivity > Install a Device > Ping Store

11. Mouse over **Dicom Ping**,then click **Dicom Ping Store**. The system indicates if the DICOM ping was successful or failed. If the DICOM ping failed, check the Called AE Title, Calling AE Title and/or Port field; and Host IP address.

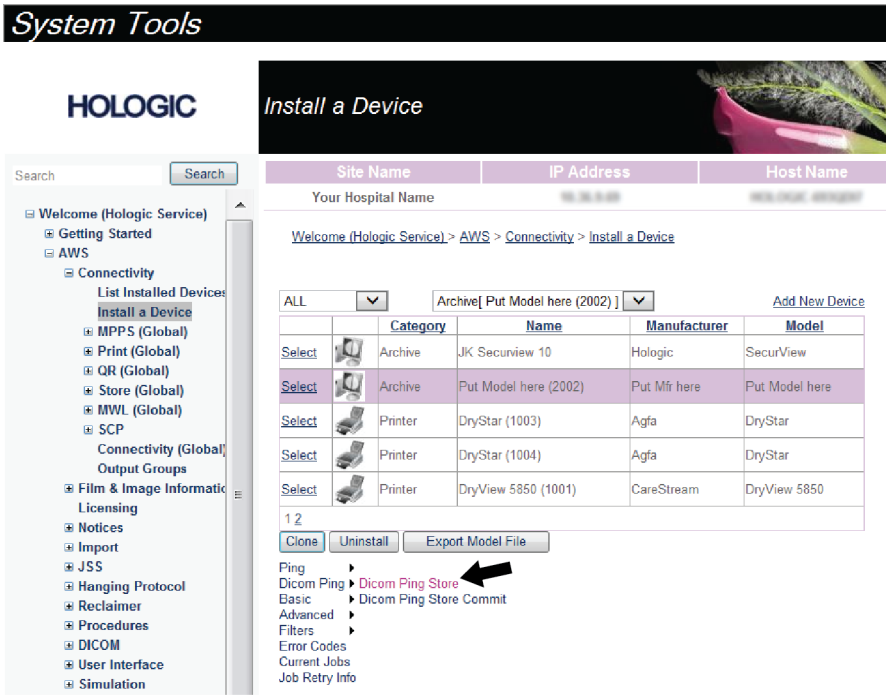


Figure 98: System Tools > AWS > Connectivity > Install a Device > Dicom Ping Store

12. Repeat these steps for other direct send interfaces to workstation devices.

Install/Test a Workstation Interface

Workstations may receive images in different ways; directly from the Affirm Prone system, through a PACS, or through an intermediary device (such as a SecurXchange router). Follow these instructions to install the proper type of workstation for your system.

1. In System Tools, navigate to **Welcome > AWS > Connectivity > Install a device**.
2. In the Category field, select **Workstation** from the dropdown list.

Figure 99: System Tools >AWS > Connectivity > Install a Device > Workstation Category field

3. In the dropdown list of the Model field, select the most appropriate default for the environment of the customer.

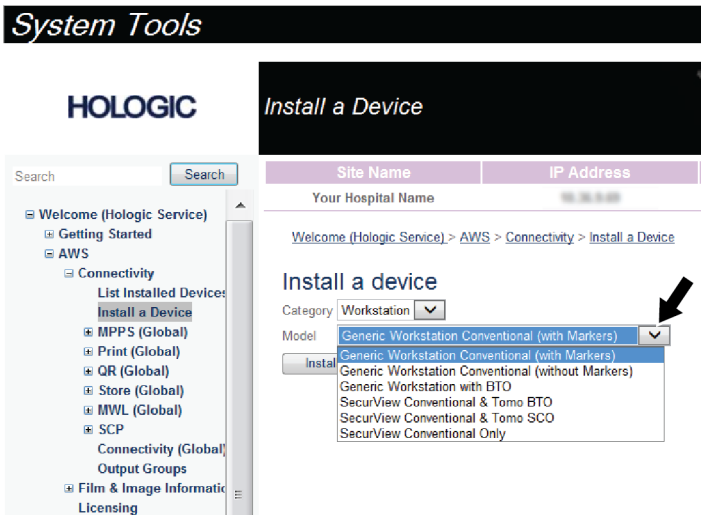


Figure 100: System Tools >AWS > Connectivity > Install a Device > Model Field

Generic (non-Hologic) Workstations

Typically, PACS workstations access mammography images through the PACS interface. If it is necessary to send image data directly to a Non-Hologic workstation, select one of the following models:

- *Generic Workstation Conventional (with Markers)* – Use this option where the customer has a preference for burned-in markers (not preferred by most customers for biopsy procedures). The burned in marker feature on the Affirm Prone system includes the image's laterality and view type. The control for marker settings can be found in *Advanced Store Settings* on page 121.
- *Generic Workstation Conventional (without Markers)* – This option is the preferred model file for Non-Hologic workstations for all 2D-only installations.
- *Generic Workstation Conventional with BTO* – This option is the preferred model file for Non-Hologic workstations for 3D installations. Note that if 3D Mammography Slices are sent to PACS and PACS workstations using the (BTO) object, any SecurView configurations must also be configured for BTO, else Annotations and Markings made on SecurView SCO images will not show up on the BTO images stored in PACS or displayed on Non-Hologic workstations.

SecurView (Hologic) Workstations

SecurView Workstation model files include sending both 3D Mammography Slice images (BTO or SCO format) and 3D Mammography projection images in SCO format. For more information on supported image types, refer to *Advanced Store Settings* on page 121.

- *SecurView Conventional & Tomo BTO* – This option is the preferred model file for 3D installations sending to SecurView workstations.
- *SecurView Conventional & Tomo SCO* – Use this option when the Sales Order indicates the customer's request to store 3D Mammography slice data as DICOM Secondary Capture Objects (SCO) to storage devices. This option should only be used when the environment of the customer cannot support the DICOM Breast Tomosynthesis Object or BTO data size is a concern. Keep in mind that when using this option, future charges to the customer may apply to convert this proprietary 3D format to the standardized BTO format.
- *SecurView Conventional Only* – This model file is for SecurView workstations for 2D-only installations.

4. Click **Install this device**.

5. In the New Workstation Installed screen, mouse over **Basic**, then click **Basic Store**.

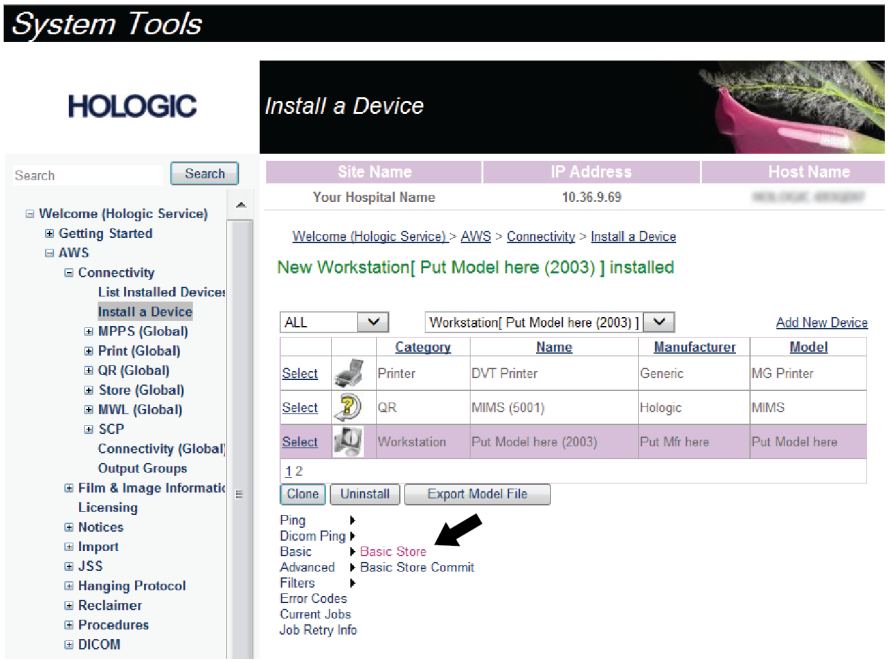


Figure 101: System Tools >AWS > Connectivity > Install a Device > Basic Store

6. In the Workstation: Basic Store screen, enter the following information:

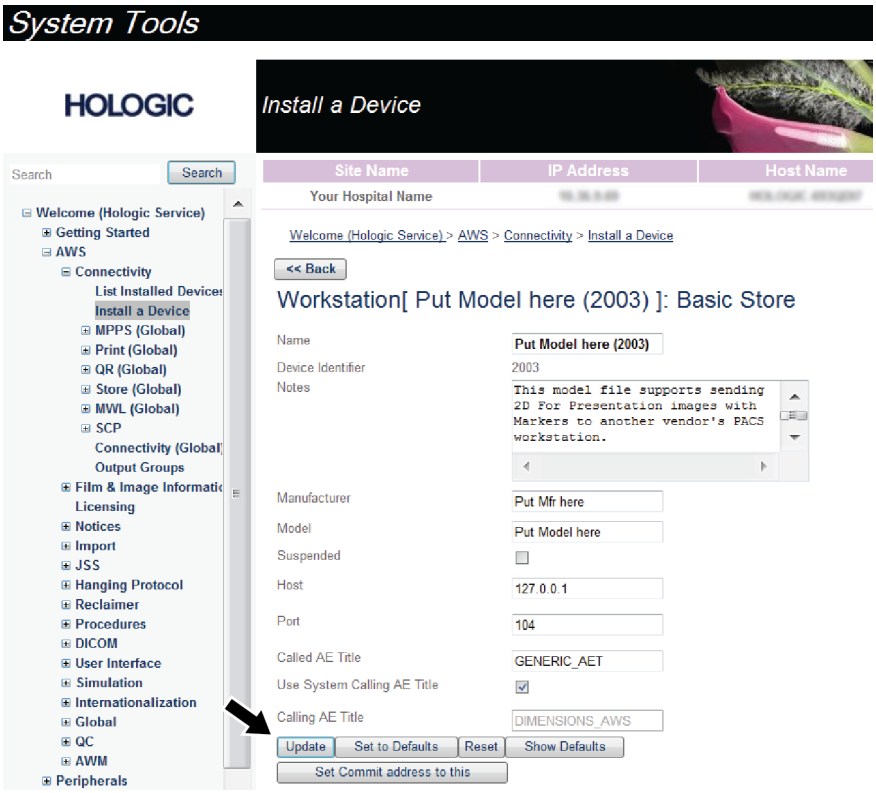


Figure 102: System Tools > AWS > Connectivity > Install a Device > Workstation: Basic Store

- *Name* - the name used in the Output Group to identify the device
- *Manufacturer* - the manufacturer of the device (such as GE, Philips, Agfa) *Model* - the model (such as Centricity, Intellispace, Impax)
- *Model* - the model (such as Centricity, IntelliSpace, Impax)
- *Host* - the IP address of the device
- *Port* - the TCP listening port on the device
- *Called AE Title* - the AE Title of the device

7. Do one of the following:
   - If System AE Title is being used, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen.
   - If the System AE Title is not being used, enter the Store SCU application AE Title to use with this specific device in the **Calling AE Title** text box.
8. Click **Update**.
9. Click **<< Back**.

10. Mouse over **Ping**, click **Ping Store**. The system indicates if the ping was successful or failed. If the ping failed, check the Host IP address entered for that device.

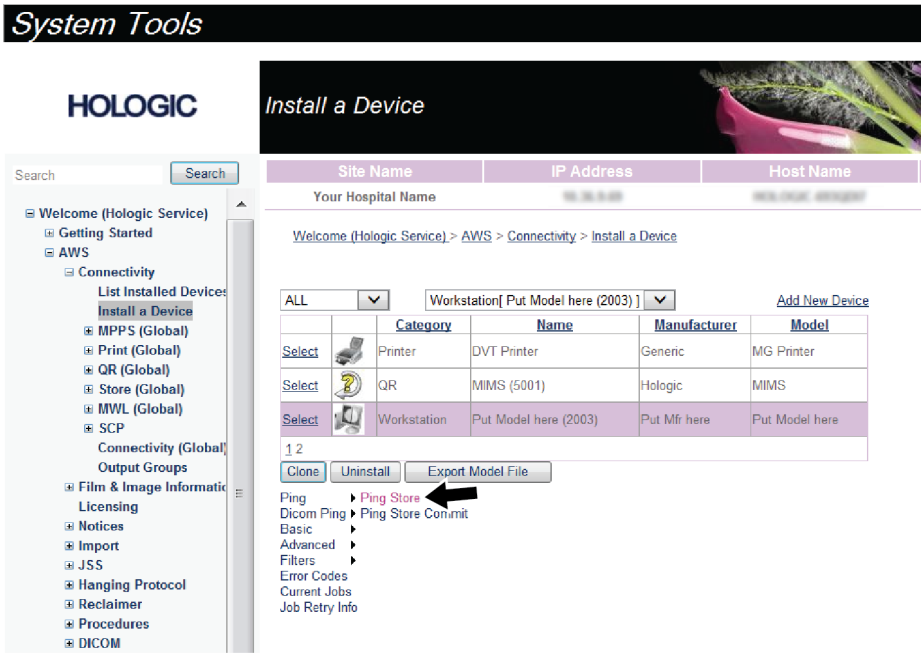


Figure 103: System Tools > AWS > Connectivity > Install a Device > Ping Store

11. Mouse over **Dicom Ping**, click **Dicom Ping Store**. The system indicates if the DICOM ping was successful or failed. If the DICOM ping failed, check the Called AE Title, Calling AE Title and/or Port fields; and Host IP address.

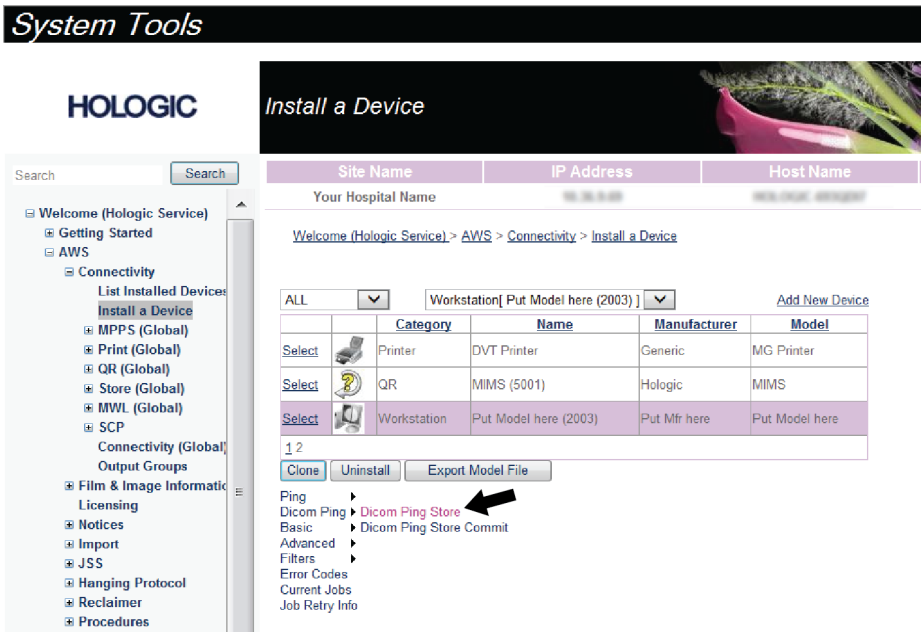


Figure 104: System Tools > AWS > Connectivity > Install a Device > Dicom Ping Store

12. Repeat these steps for other direct send interfaces to workstation devices.

Advanced Store Settings

Use these instructions to customize settings related to Transfer Syntaxes or Supported Image Types. Technical Support or Connectivity Specialists may require editing of Advanced Store settings.

1. In System Tools, navigate to **Welcome > AWS > Connectivity > List Installed Devices**.

2. In the Device field, select the device to be configured from the dropdown list.
   Make sure the device to be configured is highlighted in the List Installed Devices window.

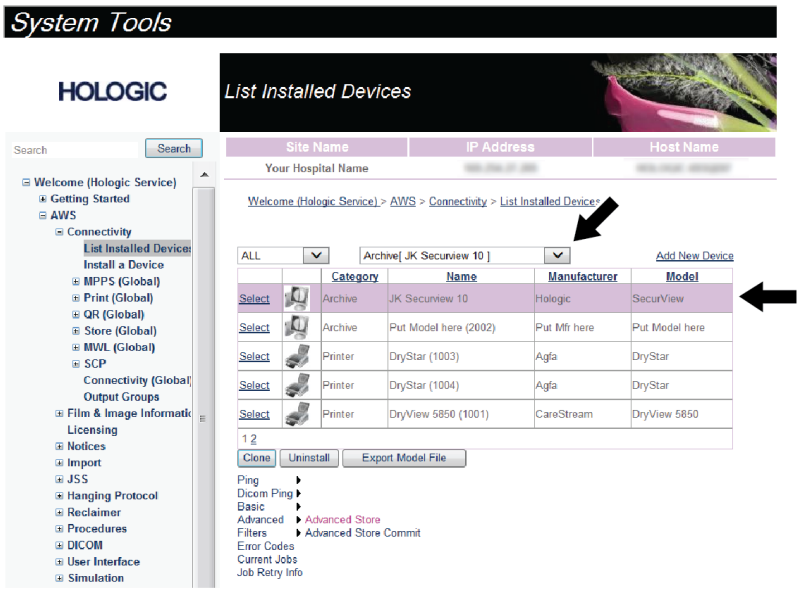


Figure 105: System Tools >AWS > Connectivity > List of Installed Devices > Select Device

3. Mouse over Advanced, then click **Advanced Store**.

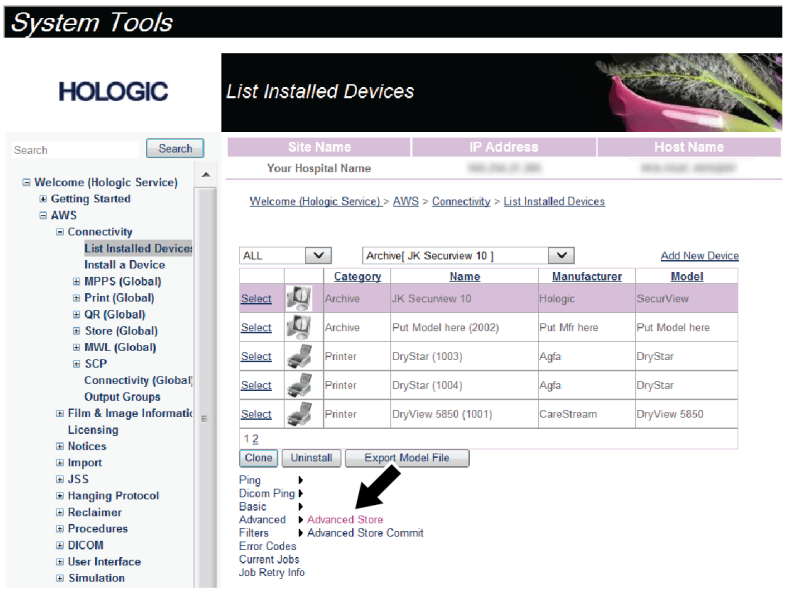


Figure 106: System Tools >AWS > Connectivity > List of Installed Devices > Advanced option

4. The Advanced screen opens. Scroll to the bottom of the screen.

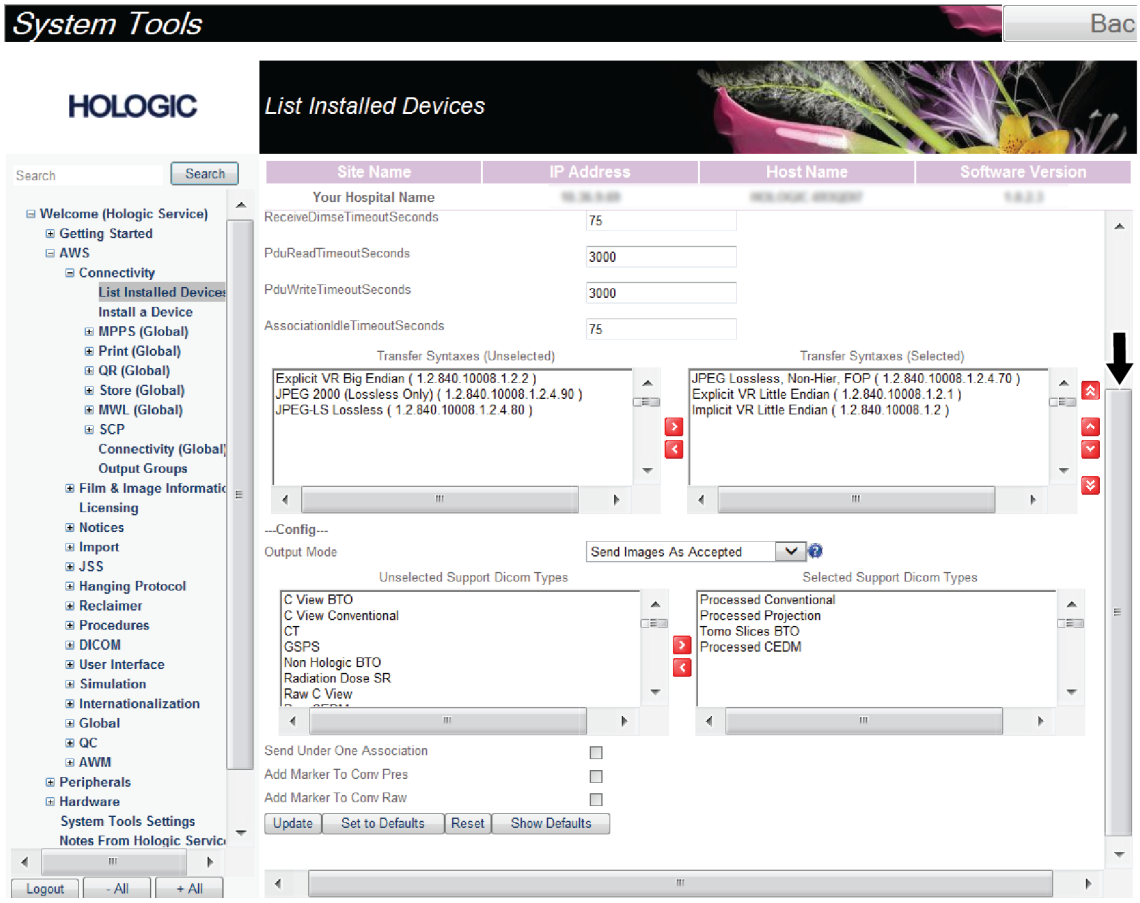


Figure 107: System Tools >AWS > Connectivity > List of Installed Devices > Advanced Store screen

To Change Transfer Syntax Settings

Transfer syntaxes determine how the data is encoded into bytes when transmitted over a network. Some transfer syntax selections also apply standardized compression algorithms before transmission. The transfer syntaxes negotiated with a device are listed in the Transfer Syntaxes (Selected) column. Choices are presented to the connected device from the bottom up. When sending data, the system chooses from the top to the bottom of the list among those syntaxes supported by the connected device (indicated though a DICOM association response).

a. Locate the Transfer Syntax configuration section under the Network section of the Advanced Store configuration screen.

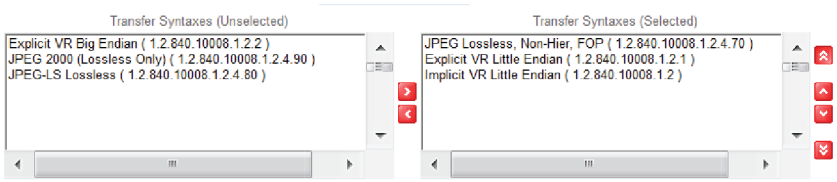


Figure 108: Transfer Syntax Configuration section in Advanced Store screen

- To add a selected transfer syntax, click the unselected choice to highlight. Click the **>** arrow to move the selection to the Transfer Syntax (Selected) box.
- To remove a selected transfer syntax, click the Transfer Syntax (Selected) choice to highlight. Click the **<** arrow to move the selection to the Transfer Syntax (Selected) box.

b. Click **Update** at the bottom of the configuration screen.

To Change DICOM Image Type Settings

Selected Dicom Image Type settings determine which types of image data are and are not sent to a specific device. If the *Selected Support Dicom Types* control box does not include an Image Type necessary to satisfy workflow requirements at the customer site, move the ImageType from the *Unselected Support Dicom Types* control box to the *Selected Support Dicom Type*s control box.

a. Locate the DICOM Type configuration section under the Config section of the Advanced Store configuration screen.

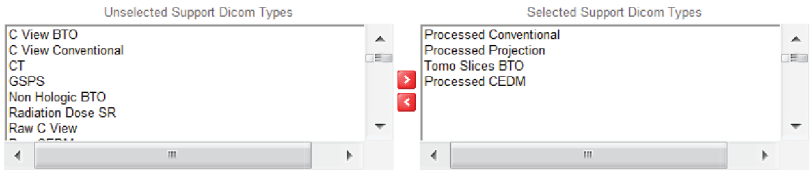


Figure 109: Dicom Types section in Advanced Store screen

b. Move the image types to their proper selection box:

- To send a DICOM image type to the device, click the unselected choice to highlight. Click the **>** arrow to move the selection to the Selected Dicom Types box.
- To NOT send a DICOM image type to the device, click the Selected Dicom Type choice to highlight. Click the **<** arrow to move the selection to the Unselected Dicom Types box.

c. Click **Update** at the bottom of the configuration screen.

5.7.3 Configure Query/Retrieve (Optional)

1. In System Tools, navigate to **Welcome > AWS > Connectivity > Install a device**.
2. In the Category field, select **QR** from the dropdown list.

Figure 110: System Tools >AWS > Connectivity > Install a Device > QR Category field

3. In the Model field, select the most appropriate model for the environment of the customer from the dropdown list.

Figure 111: System Tools >AWS > Connectivity > Install a Device > QR Model field

- *MIMS* – This model is based on the relational query model. Use this model only if the DICOM conformance statement of the device confirms support for and recommends using relational queries. SecurXchange and MIMS support relational queries.
- *Query and Retrieve – Hierarchical Query* – This model is based on the hierarchical query model, which DICOM query providers must support by default. Use this model unless the DICOM conformance statement of the device confirms support for and recommends using a relational query.

4. Click the **Install this device**.
5. In the New QR Installed screen, mouse over **Basic**, then click **Basic Query**.
6. Enter/change the following information:
   - *Name* - the name used to identify this query device
   - *Manufacturer* - the manufacturer of the query device (such as GE, Siemens, Phillips)
   - *Model* - the model and software version (such as Centricity, Syngo, IntelliSpace)
   - *Host* - the IP address of the query device
   - *Port* - the TCP listening port on the query/retrieve device
   - *Called AE Title* - the AE Title of the query/retrieve device
7. Do one of the following:
   - If the System Calling AE Title is being used for queries, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen.
   - If a customized Calling AE Title needs to be used for queries, uncheck **Use System Calling AE Title** and enter the appropriate **Calling AE Title**.
8. Click **Update**. Notice the global AE Title in red being used at the bottom.
9. Do one of the following:
   - If the query device is the same as the retrieve device:
     a. Select **Set Retrieve address to this**. The message "Retrieve address now matches the Query address field on this screen" appears at the top of the screen.
     b. Click **<< Back** (at the upper left side of the window).

- If the query device is different from the retrieve device:
  a. Click **<< Back** (at the upper left side of the window).
  b. Mouse over **Basic**, then click **Basic Retrieve**.
  c. Enter the following information:
     Name - the name used to identify the retrieve device
     Host - the IP address of the device from which to retrieve (this address may or may not be the same as the IP address of the query device)
     Port - the port of the retrieve device (this port may or may not be the same as the query device)
     Called AE Title - the AE Title of the retrieve device (this title may or may not be the same as the query device)
  d. Do one of the following:
     - If the System AE Title is being used, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen.
     - If the System AE Title is not being used, enter the **Retrieve SCU application AE Title** to use with this specific device in the Calling AE Title text box.
  e. Click **Update**.
  f. Click **<< Back**.

10. Mouse over **Advanced**, then click **Advanced Retrieve**.
11. To set the Move Destination for the retrieve request, do one of the following:
    - If the System AE Title is to be used as the Move Destination, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen.
    - If the Retrieve Service is using a customized Calling AE_Title (set under the Basic Retrieve configuration screen), select **Use Retrieve AE Title If Possible** to allow the customized Calling AE Title as the **Move Destination**.
    - If a Move Destination is different than the System AE Title and any customized retrieve service Calling AE Title, uncheck **Use System AE Title**, uncheck **Use Retrieve AE Title If Possible**, and enter the retrieve destination AE Title in the **Move Destination** field
12. Click **Update**.
13. Navigate to **AWS > Connectivity > SCP > Server**.
14. Enter the following information:
    - SCP Listening Port: should be **104**
15. Click **Update**.

5.7.4 Configure Modality Worklist (Optional)

1. In System Tools, navigate to **Welcome > AWS > Connectivity > Install a device**.
2. In the Category field, select **MWL**.

Figure 112: System Tools > AWS > Connectivity > Install a device > MWL Category field

3. In the Model field, click the down arrow and select the MWL Provider of the customer (such as Sectra). If the specific MWL provider is not listed, select **Default Query**.

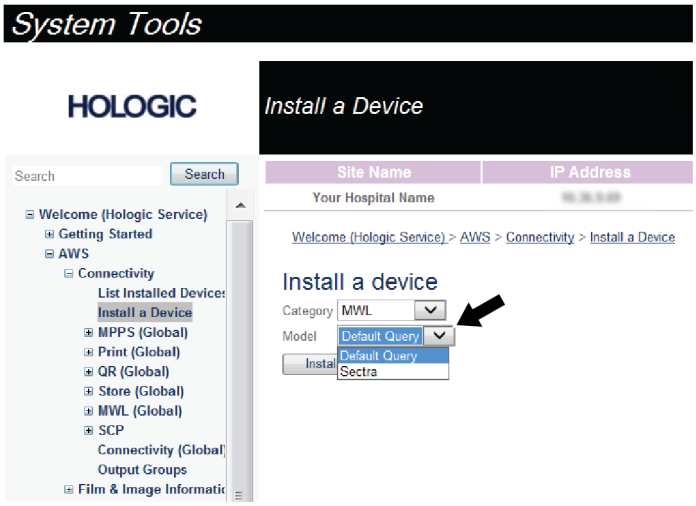


Figure 113: System Tools >AWS > Connectivity > Install a Device > MWL Model field

4. Click **Install this device**.
5. In the New MWL Installed screen, click **Basic.**

6. Enter the following information in these fields:
   - *Name* - the human readable name assigned to the worklist (such as Agfa).
   - *Manufacturer* - the name of MWL provider vendor
   - *Model* - the model name of the MWL provider application (such as Impax)
   - *Host* - the IP Address of the MWL (Modality Worklist) provider
   - *Port* - the TCP listening port on the MWL provider
   - *Called AE Title* - the AE (Application Entity) Title used by the MWL provider
7. Make the appropriate choice for the service of the worklist AE Title.
   - If System AE Title is being used for Modality Worklist, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen.
   - If the System AE Title is not being used for Modality Worklist, enter the Store SCU application AE Title to use with this specific device in the **Calling AE Title** text box.
8. Click **Update**. Verify any calling AE Title changes at the bottom of the screen.
9. Click **<< Back**.
10. Click **Advanced**.
11. Check that the Study Code field matches the field used by the MWL Provider for RIS codes.
    - If uncertain, set to the IHE framework choice. Click the down arrow and change the default value of *Req Proc Code Seq, Code Val* to **SPS Seq, Sched Prot Code Seq, Code Val**.
    - If interfacing to older McKesson worklist providers (which do not provide RIS codes), click the down arrow and change the default value of *Req Proc Code Seq, Code Val* to **SPS Seq, SPS Desc**.
12. Click **Update**.
13. Click **<< Back**.
14. Click **Ping** (An indication is presented if the test was successful or failed).
15. Click **DICOM Ping** to test. (An indication is presented if the test was successful or failed).
16. Click **Perform a Query** and use the right scrollbar to scroll until the query is visible.
17. Click **Query**.
18. In the Results window, the C-FIND-RQ sent to the MWL provider is displayed. If the MWL Provider returned any scheduled patients, the C-FIND-RSPs are also displayed in the Results window. Use this information to confirm the tag selected for the Study Code field.
19. Repeat these steps if another modality worklist source is required by the customer. A maximum of two MWL providers may be configured.

5.7.5 Configure Printers (Optional)

1. In System Tools, navigate to **Welcome > AWS > Connectivity > Install a device**.
2. In the Category field, select **Printer** from the dropdown list.

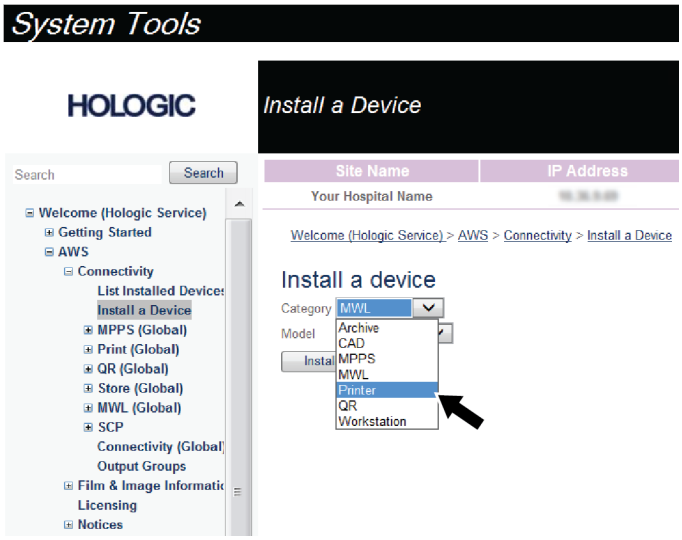


Figure 114: System Tools >AWS > Connectivity > Install a Device > Printer Category field

3. In the Model field, select the printer model from the dropdown list for the environment of the customer. Contact Technical Support if the model is not listed.

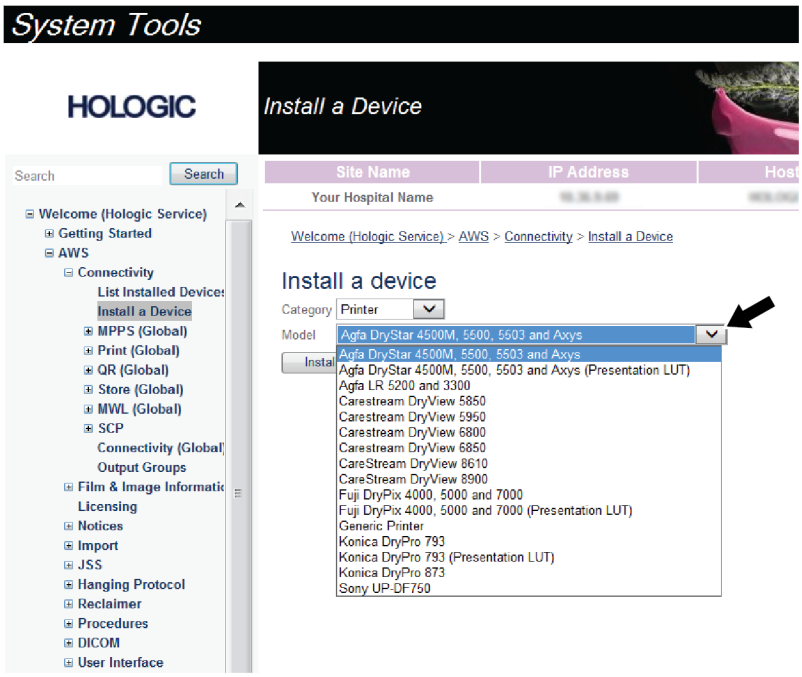


Figure 115: System Tools >AWS > Connectivity > Install a Device > Printer Model field

4. Click the **Install this device**.
5. In the New Printer Installed screen, mouse over **Basic** and click.

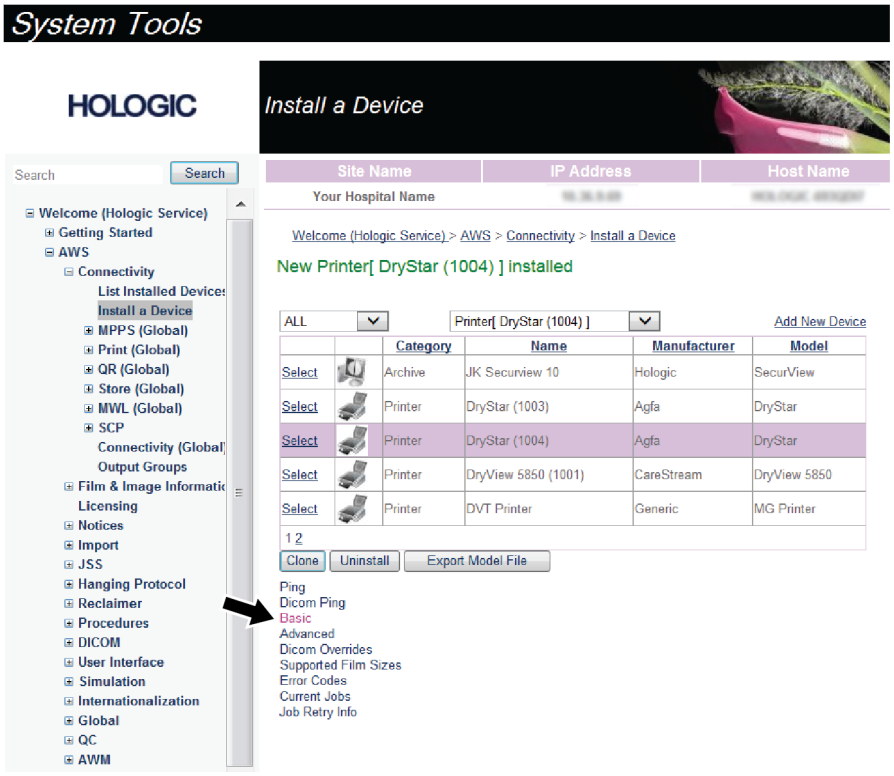


Figure 116: System Tools >AWS > Connectivity > Install a Device > New Printer Installed

6. Enter/change the following information:
   - *Name* - the name used in the Output Group to identify the printer
   - *Manufacturer* - the manufacturer of the device (such as Agfa, Carestream, etc.)
   - *Model* - the model (such as DryStar 4500M, DryView 6800, etc.)
   - *Version* - the version at the time of configuration of this device
   - *Host* - the IP address of the printer
   - *Port* - the TCP listening port on the printer
   - *Called AE Title* - the AE Title of the printer

7. Do one of the following:
    - If System AE Title is being used, select the **Use System Calling AE Title** checkbox. The system AE Title displays on the bottom of the screen.

Note
Using the correct AE Title. Printed images may looked washed out and not have the proper LUT applied if an incorrect AE Title is used.

    - If the System AE Title is not being used, enter the **Store SCU application AE Title** to use with this specific device in the Calling AE Title text box.
8. Click **Update**.
9. Click **<< Back**.
10. In the New Printer Installed screen, mouse over **Supported Film Sizes** and click.

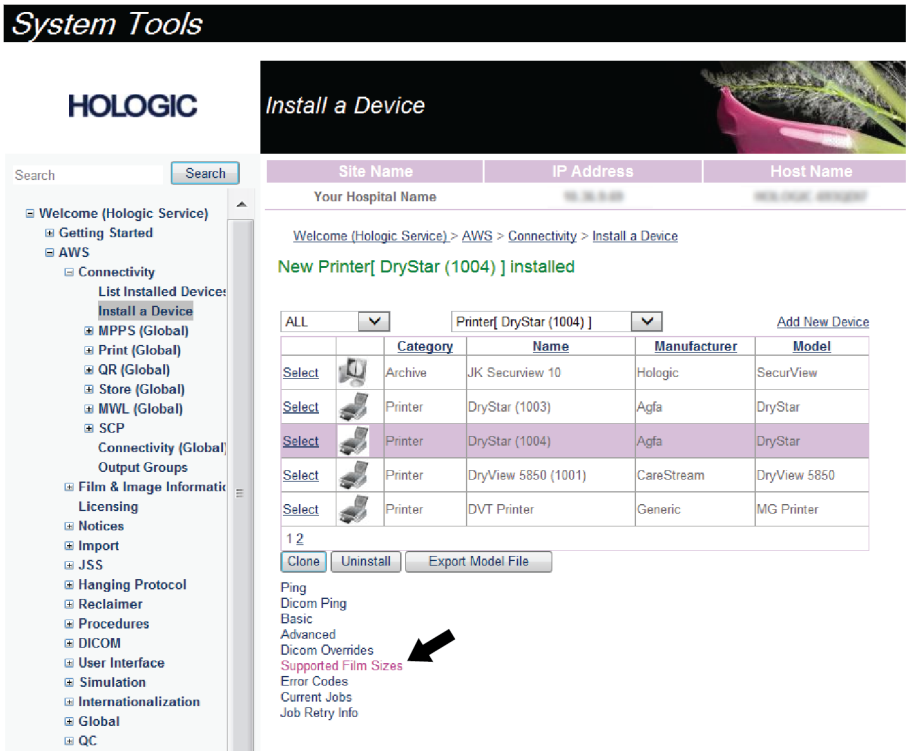


Figure 117: System Tools >AWS > Connectivity > Install a Device > New Printer Installed > Supported Film Sizes Field

11. On the Printer Supported Film Sizes screen, you can:
    - *Add film sizes not listed* - Contact Technical or Connectivity Support for assistance on correct settings and syntax.
    - *Remove film sizes not stocked by the site* - Follow these steps to delete film sizes:

    a. Use the dropdown labeled **Select** to choose the film size to delete.

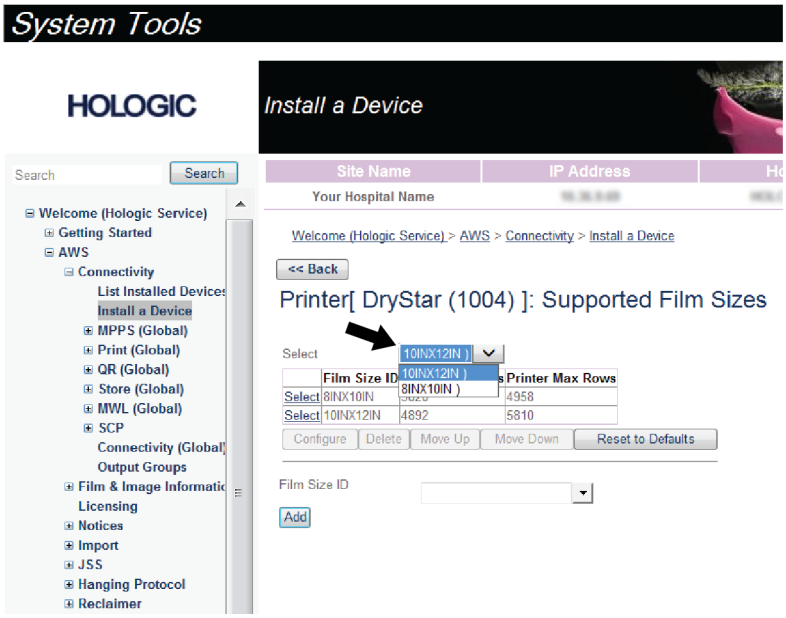


Figure 118: System Tools >AWS > Connectivity > Install a Device > Printer > Supported Film Sizes

b. Make sure that the film size you want to delete is highlighted in purple. Click **Delete.**

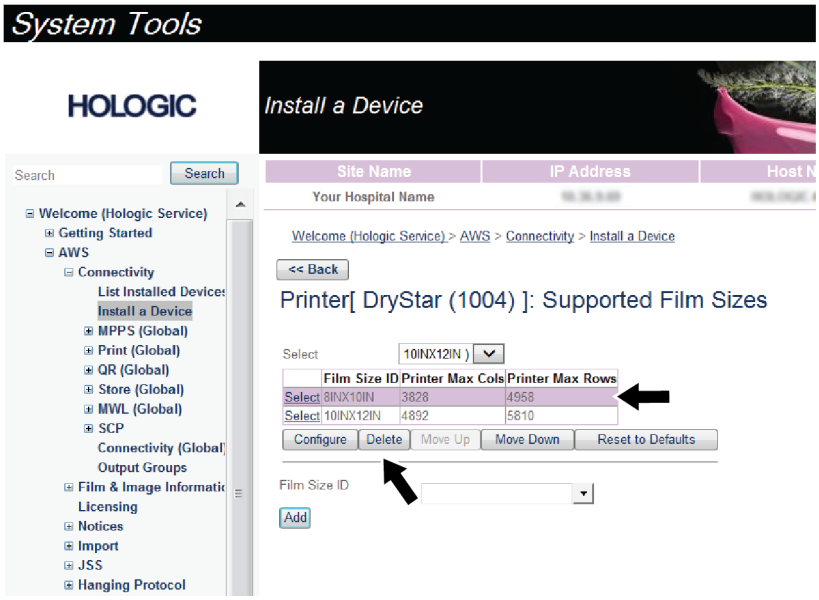


Figure 119: System Tools >AWS > Connectivity > Install a Device > Printer > Supported Film Sizes to Delete

12. Click **<< Back**.
13. Do the following tests:
    - To test the network communication, mouse over **Ping** and click. The system indicates if the ping was successful or failed. If the ping failed, check the IP address entered for that device.
    - To test the DICOM communication, mouse over **Dicom Ping** and click. The system indicates if the DICOM ping was successful or failed. If the DICOM ping failed, check the Called AE Title, Calling AE Title and/or Port fields.
14. Repeat these steps for other printers as needed.

Chapter 6 System Calibration and Performance Tests

6.1 System Calibration and Tests Overview

This chapter outlines the Preventive Maintenance schedule, calibration procedures, and performance tests.

Most system calibrations use the Calibration Tool (CalTool) (refer to *Calibration Tool (CalTool)* on page 138), while some adjustments use software tools from the Admin screen (refer to *The Admin Screen* on page 84).

Note
The procedures in this chapter are written for conventional (invasive) testing equipment. To use non-invasive testing equipment and techniques, follow the instructions provided by the manufacturer of the test equipment.

Before calibrating/testing the system, have on hand the Affirm Prone Service Tool Kit (TLS-05909).

Table 4: Service Tool Kit for Affirm Prone (TLS-05909)

Part Number	Description	Quantity
ASY-03949	ASSY, AFFIRM BGM QAS NEEDLE	1
ASY-08307	ASSY. TARGETING PHANTOM	1
ASY-08871	KIT, FUSES, HV GENERATOR	1
ASY-09944	ASSY, KIT, COLLIMATION ALIGNMENT, AFFIRM PRONE BIOPSY	1
ASY-09945	ASSY, CASE, AFFIRM PRONE BIOPSY, COLLIMATION ALIGNMENT	1
MME-01182	PIN, DOWEL .1251DIA+.0002/-.0000X1" LG+/-.010 STEEL RC 58-62	1
TLS-05434	C-FRAME SUPPORT STOP-SERVICE	1
TLS-05884	TABLE ANGLE SUPPORT SETTING TOOL	1
TLS-05908	TOOL, AFFIRM C-ARM / DETECTOR ALIGNMENT (6" X 5/16")	1
TLS-05910	TOOL, AFFIRM C-ARM / DETECTOR ALIGNMENT (2-1/2" X 5/16")	1
TLS-05913	TOOL, 5/64" T HANDLE	1
TLS-06106	TOOL, EXTENSION SET 3/8" DRIVE QUICK RELEASE LOCKING, 3 PC (3", 6" & 10"LG)	1

6.2 Preventive Maintenance Schedule

Note
The Preventive Maintenance Schedule for the User is in the *Affirm Prone Biopsy System User Guide.*

Table 5: Service Engineer Preventive Maintenance

Maintenance Task Description	Recommended Frequency	
	Semiannually	Annually
Clean and inspect the Gantry, Detector, and Acquisition Workstation	x	
Check all primary power connections	x	
Check interlocks, safety, and limit switches	x	
Inspect C-arm and lubricate drive lead screw	x	
C-arm / Verify all C-arm buttons	x	
Verify Compression Force Calibration	x	
Verify Detent Angle Calibration	x	
Verify C-arm Angle Calibration	x	
Perform C-arm Brake verification	x	
Verify Tomo Arm Positioning	x	
Verify kV Calibration and Tube Current Calibration	x	
Check HVL Evaluation	x	
Verify AEC Performance/Scaling	x	
Verify X-ray Tube Alignment	x	
Inspect/Lubricate Patient Platform Up/Down Drive Screws	x	
Perform System Resolution Test	x	
Perform Phantom Image Quality Evaluation	x	
Perform Image Artifact Evaluation	x	
Perform System Backup including Node Calibrations	x	
Empty Reject Bin	x	
Check UPS performance status	x	

Table 5: Service Engineer Preventive Maintenance

Maintenance Task Description	Recommended Frequency	
	Semiannually	**Annually**
Voltage Verification (via CalTool)	x	
Replace Detector Fan Filters	x	
Service Filter Wheel	x	
Service X-ray Tube	x	

6.3 System Calibration

Note
For dose calibration, refer to MAN-05621 Affirm Prone system Dose Calibrations, CalTool.

The primary software tool is the Calibration Tool (CalTool). This software application is resident on the Acquisition Workstation.

Note
Contact Hologic Technical Support for assistance using this tool if required.

6.3.1 Calibration Tool (CalTool)

A dongle needs to be connected to start the Calibration Tool (CalTool). If you do not have a dongle, contact 3D@hologic.com and request a code for a temporary license.

1. Launch CalTool (CalTool.bat) from the normal location/directory.
2. In the InitialForm, for CAN Mode, select **Real Gantry**.

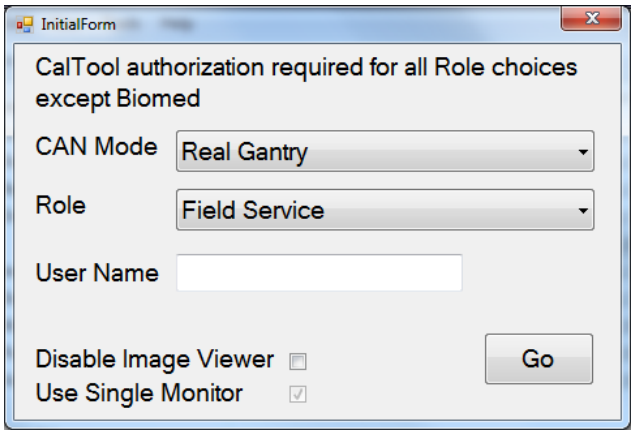


Figure 120: CalTool Initial Form screen

3. For Role, select **Field Service**.

   Role options include:

   - Biomed
   - Manufacturing
   - Field Service
   - Upgrade
   - Array Test
   - Developer

   The Field Service role is used for all Hologic service calibrations.
4. Select **Go** to open CalTool.
5. Click the **TASK BAR** to view tasks.
6. Select a task.
7. Perform the task.

   Click **Help** for more information.

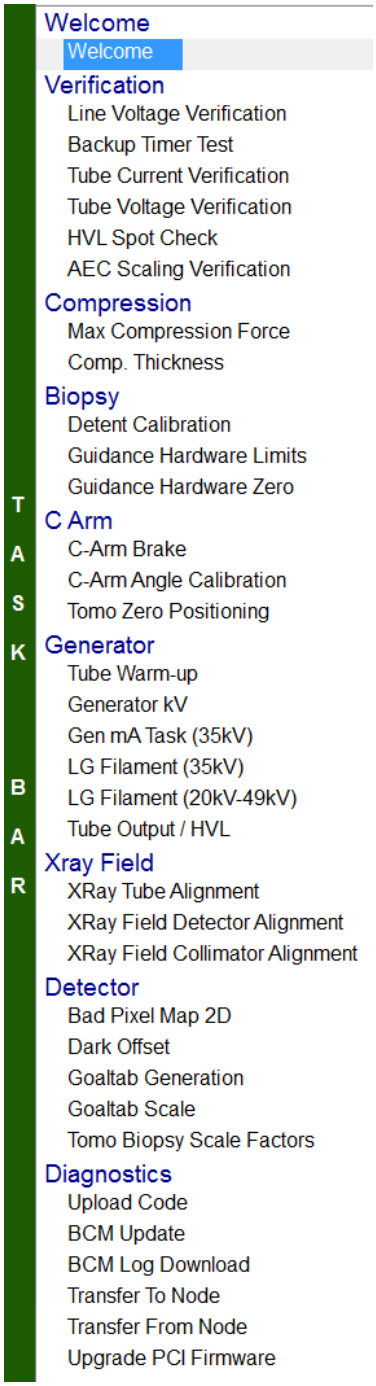


Figure 121: CalTool Task Bar

Note
Depending on Licensing (2D or 3D™), CalTool notifies availability of selected calibrations.

6.3.2 Inverter Drawer Calibration

Required Equipment/Tools

- Standard Tool Set
- High Voltage Divider Tanks or High Voltage probe
- Oscilloscope
- Digital Volt Meter (DVM)
- mAs meter

Note
The Inverter (ASY-07006) and Multiplier (ASY-06980) pair require adjustments to ensure proper waveform flatness.

Procedure

1. For access to adjustments, remove the plastic cover on the front panel of the Inverter.
2. kV leading waveform edge (Multiplier trim pot adjust).
   a. Use a Divider Tank to monitor kV waveforms with an Oscilloscope.
   b. Using CalTool, take 35kV, 100mA, 65mAs, Manual, LFS exposures and monitor the waveform.
   c. Adjust the feedback trim pot located on the Multiplier assembly above the mAs plug to obtain a square leading-edge waveform. (See the following figure.)

Note
The KV wave form must be adjusted before KV voltage adjustment.

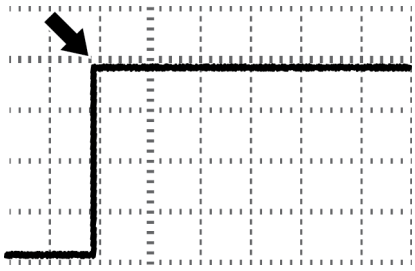


Figure 122: Correct Square Edge

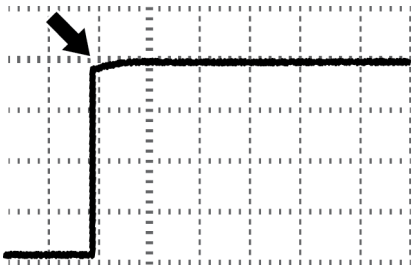


Figure 123: Undershoot, Adjustment Required

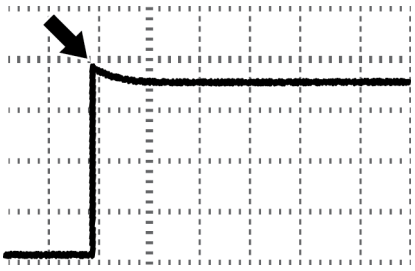


Figure 124: Overshoot, Adjustment Required

3. Standby voltage (Inverter): Filament idle current (standby voltage) is factory set to 2.5 amps. Verify the following:
   a. Monitor Filament idle current sense at TSTH1 pins 1-2 with voltmeter = 0.25 v (0.1 v = 1 amp)
   b. Acceptable range is 2.48 - 2.52 amps. Adjustment is done with FIL ADJ R14. If necessary, adjust before performing filament calibration.

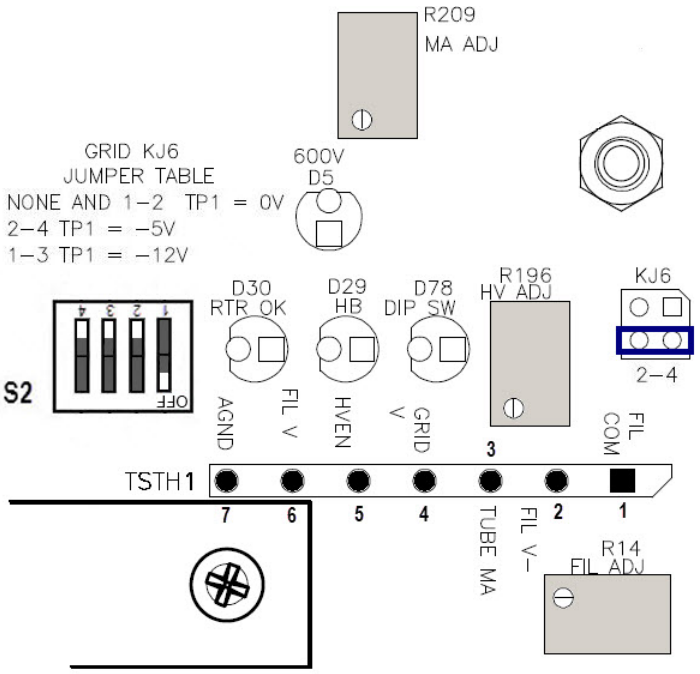


Figure 125: Front Panel Inverter Drawer (ASY-07006)

4. kV voltage (Inverter):
   a. "kV" output voltage adjustment is done with potentiometer R196 HV ADJ.
   b. Monitor the waveform levels using a tank and oscilloscope or measure voltage with a DVM.
   c. Use CalTool to verify Generator kV.
5. Tube current (Inverter):
   a. Tube current adjustment is done with MA ADJ R209. This potentiometer is factory set; adjust only if the measured mA is not correct.
   b. Use CalTool to verify Generator mA.
6. Grid voltage (Inverter):
   a. Grid voltage is a legacy parameter and is not used. The voltage is factory set to -5 (± 3) volts by jumper on KJ6 pins 2 and 4.
   b. Verify with voltmeter (+) to TSTH1 pin 4, voltmeter (-) to TSTH1 pin 7.

6.4 System Performance Tests

6.4.1 X-Ray Tube Current Calibration

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- mAs Meter (invasive mAs meter or equivalent)
- Tube Current Exposure Time Product Form—see *Tube Current/Exposure Time Product Forms* on page 283.

Setup

1. Turn the Generator Power OFF.

WARNING!
To reduce the risk of hazardous electrical shock, do not attempt service until the Red LED on the HV Inverter is extinguished (this takes approximately 5 minutes). Once the Red LED is extinguished, do not proceed until an additional 1 minute has elapsed.

2. Remove the mA shorting jumper and insert the mAs meter probe.
3. Cover the image receptor with lead.

Test

1. Turn the Generator power ON.
2. Configure the Exposure Techniques:

Mode	Filter
MAN	Ag

3. Refer to the Tube Current / Exposure Time Product Form. Configure the mAs and kV as shown in the first row and column—10 mAs, 25 kV.
4. Take an exposure and record the mAs output measured in the Form.
5. Reset the mAs meter for the next measurement.
6. Repeat the previous exposure sequence for each of the remaining mAs and kV combinations. Do not take an exposure for any of the cells which are grayed out.
7. Turn the Generator power OFF.

WARNING!
To reduce the risk of hazardous electrical shock, do not attempt service until the Red LED on the HV Inverter is extinguished (this takes approximately 5 minutes). Once the Red LED is extinguished, do not proceed until an additional 1 minute has elapsed.

8. Remove the mAs meter probes and replace the mAs shorting jumper.

6.4.2 X-Ray Tube Voltage

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- Invasive high voltage divider or a non-invasive system
- Digital voltmeter
- Coaxial cable and BNC to banana plug
- Adapter cable to connect the divider to the test receptacle on the HV Generator
- Peak Tube Potential Form—see *Peak Tube Potential Form* on page 283.

WARNING!
To reduce the risk of hazardous electrical shock, do not attempt service until the Red LED on the HV Inverter is extinguished (this takes approximately 5 minutes). Once the Red LED is extinguished, do not proceed until an additional 1 minute has elapsed.

Setup

1. Turn the entire system OFF.

WARNING!
To reduce the risk of hazardous electrical shock, do not attempt service until the Red LED on the HV Inverter is extinguished (this takes approximately 5 minutes). Once the Red LED is extinguished, do not proceed until an additional 1 minute has elapsed.

2. Connect a DC voltmeter to the low voltage terminals of a 1000:1 Voltage Divider using a coaxial cable and a BNC to banana plug splitter.
3. Position the meter where it can be read from behind the radiation shield.
4. Connect the ground lug of the high voltage divider to a chassis ground point located on the HV Multiplier Assembly.

Test

1. Power ON the entire system.
2. Boot up the computer, close out all applications, and open CalTool.
3. Click **Advanced Form**, then click the **Technique** tab.
4. Set up the manual mode KVs and mAs accordingly. Click the **Arm** button.
5. Using the Peak Tube Potential (kV) Form make an exposure at the first kV, mAs setting in the table, and record the meter reading.
6. Confirm that the meter reading falls into the range shown on the Form.
7. Repeat steps 4 and 5 for each of the remaining exposures.
8. Shut down the system.

WARNING!
To reduce the risk of hazardous electrical shock, do not attempt service until the Red LED on the HV Inverter is extinguished (this takes approximately 5 minutes). Once the Red LED is extinguished, do not proceed until an additional 1 minute has elapsed.

9. Remove the test equipment.

6.4.3 Half Value Layer (HVL)

Warning:
Always follow the safety precautions for x-ray exposures.

Follow the **HVL (Half Value Layer) Spot Check** test in CalTool. Record the results in CalTool also.

6.4.4 Linearity

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- Radiation Meter (for example, Rad Cal 2026C Series, Unfors, or equivalent)
- Linearity Form—see *Linearity Form* on page 284.

Setup

1. Connect the radiation probe per product the instructions of the manufacturer.
2. Place the readout/logic module where it can be easily read.
3. Select exposure in milliroentgen on the function switch.
4. Cover the image receptor with a lead shield.
5. Position the x-ray meter probe on the breast tray centered along the chest wall and 1 cm from the edge of the receptor. The plane of the probe surface must be aligned so that it is perpendicular to the x-ray beam axis.

Test

1. Configure the Exposure Techniques:

Mode	Filter	kV
MAN	Ag	35

2. Set the mAs to 10 and take an exposure.
3. Record the milliroentgen output on the Form.
4. Reset the meter.
5. Repeat the exposure sequence for each of the remaining mAs settings.
6. Remove the meter from the breast tray.

6.4.5 Reproducibility

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- Radiation Meter (for example, Rad Cal 2026C Series, Unfors, or equivalent)
- Rad Cal 20x6-6 mm Probe (or equivalent)
- Reproducibility Form—see *Reproducibility Form* on page 284.

Setup

1. Connect the radiation probe per product manufacturer's instructions.
2. Place the readout/logic module where it can be easily read.
3. Select exposure in milliroentgen on the function switch.
4. Cover the image receptor with a lead shield.
5. Position the x-ray meter probe on the breast tray centered along the chest wall and 1 cm from the edge of the receptor. The plane of the probe surface must be aligned so that it is perpendicular to the x-ray beam axis.

Test

1. Configure the Exposure Techniques:

Mode	Filter	kV
MAN	Ag	25

2. Take an exposure and record the milliroentgen output measured on the Form.
3. Reset the Meter.
4. Reset the kV and mAs settings to values different than those listed in the table, and then return them to their original values.
5. Repeat the exposure sequence as indicated previously until 10 complete exposures have been taken.
6. Calculate the Coefficient of Variation for all 10 readings:

   Coefficient of Variation = (Standard Deviation/Mean)
7. Remove the meter from the breast tray.

6.4.6 X-Ray Tube Alignment

The X-Ray Tube Alignment is performed to ensure that the x-ray tube is properly positioned over the collimator and detector.

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- Geometry Cal Phantom (ASY-08265)

Procedure

Follow the X-Ray Tube Alignment procedure listed in CalTool.

6.4.7 X-Ray Field Detector Alignment

The X-Ray Field Detector Alignment is performed to ensure that the X-ray field falls on the correct portion of the detector.

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- X-ray Field and Detector Alignment Paddle (TLS-05650)

Procedure

Follow the X-Ray Field Detector Alignment procedure listed in CalTool.

6.4.8 X-Ray Field Collimator Alignment

The X-Ray Field Collimator Alignment is performed to ensure that the collimator properly shapes the X-ray field.

Warning:
Always follow the safety precautions for x-ray exposures.

Required Equipment/Tools

- X-ray Field and Detector Alignment Paddle (TLS-05650)

Procedure

Follow the X-Ray Field Collimator Alignment procedure listed in CalTool.

6.4.9 Leakage from Diagnostic Source Test

Warning:
Always follow the safety precautions for x-ray exposures.

Note
Make sure that the system is operational and all covers are installed.

Required Tools/Equipment

- Any radiation survey probe capable of reading exposure in mR/hr. For example:
  - Unfors Xi Base Unit (Unfors #8201021-H)
  - Unfors Xi Survey Detector (Unfors #8202060-C)
- Floor Stand
- X-ray Shield
- X-ray Booth or Shields

Procedure

1. Verify that there is at least six feet between the Remote X-Ray Switch to the X-Ray Tube.
2. Lower the Patient/Platform Gantry to its lowest position.
3. Remove any paddles from the stage assembly if they are present.
4. Attach a lead blocker to the X-ray port.

5. Place the Radiation Probe onto a tripod and position the probe so that it is located two feet from the tubehead directly in front of the detector. The probe positions are shown in the following figure.

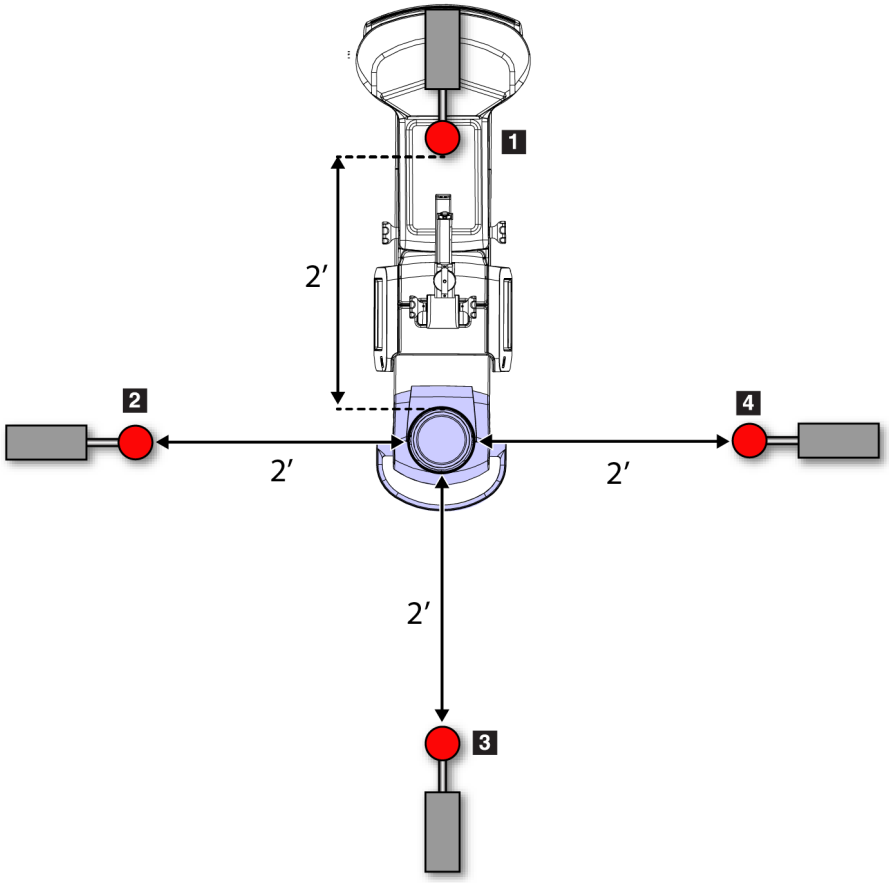


Figure 126: Probe positions from side of tubehead

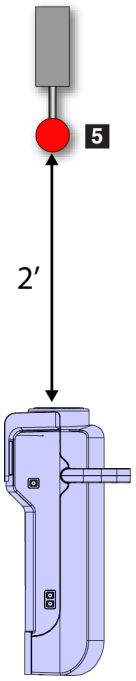


Figure 127: Probe position above tubehead

6. Adjust the probe height so that the center of the probe is in line with the Focal Spot of the Tube.
7. Place the readout / logic module onto the AWS.
8. Select exposure in milliRoentgen on the function switch.

9. Refer to the criteria in the following table.

Table 6: Leakage from Diagnostic Source (49kV, 140ma, 140mAs)

Probe Position (see previous figure)	Location	µR Measured in Dose Mode Meter Output (µR)	Exposure Scale Factor	Exposures In One Hour	Calculated Value (mR)	Safety Margin	Calculated Value (mR) ---------- 1.25*	Max Allowed (mR) in One Hour	Results
1	Front		2	48		1.25		100	
2	Left Side		2	48		1.25		100	
3	Back		2	48		1.25		100	
4	Right Side		2	48		1.25		100	
5	Top		2	48		1.25		100	

* Calculated (mR) x 1.25 = [(Measured Dose (microroentgen) x 2 x 48 x 1.25) / 1000]

10. Open the Calibration Tool.
11. Configure the Exposure Techniques as indicated in the table below.

Modality	Mode	Filter	kV	mA	mAs
Conv.	MAN	Ag	28	160	200

12. Take three warm-up exposures 45 seconds apart.
13. Configure **System to take Leakage Exposure**.
14. Configure the **Exposure Techniques** as indicated in the table and Image below.

Modality	Mode	Filter	kV	mA	mAs
Tomo	MAN	Al	49	140	140

15. In the Advanced Form, click the **Tomo** tab.
16. Set the Tomo Arc Mode to **Zero** in order to prevent the tube from moving during the exposure.
17. Configure the probe to take a measurement in dose mode.
18. Press the **Dose** button and then take an exposure.
19. Record the reading into the appropriate area of the Leakage from Diagnostic Source table.
20. Verify that the reading is within acceptable limits.
21. Repeat the exposure measurement sequence for each of the remaining probe locations indicated.

22. Record the pass/fail results in the Expected Results table.

Table 7: Expected Results

Probe Position (see previous figure)	Probe Location	Radiation measured in Dose Mode	Pass/Fail
1	Front	< 100 mR	
2	Left	< 100 mR	
3	Back	< 100 mR	
4	Right	< 100 mR	
5	Top	< 100 mR	

6.4.10 Image Artifact Evaluation

Follow the "Artifact Evaluation" test in the *1999 ACR QC Manual for Stereotactic Breast Biopsy*.

6.4.11 System Resolution Test

Follow the "Focal Spot Performance and System Limiting Spatial Resolution" test in the *1999 ACR QC Manual for Stereotactic Breast Biopsy.*

6.4.12 Phantom Image Quality Test

Follow the "Image Quality Evaluation" test in the *1999 ACR QC Manual for Stereotactic Breast Biopsy*.

6.4.13 AEC Function Performance/Scaling Test

Follow the "Automatic Exposure Control (AEC) or Manual Exposure Function Performance Assessment" test in the *1999 ACR QC Manual for Stereotactic Breast Biopsy*.

6.4.14 Target Dose Verification

Follow the "Breast Entrance Exposure, Average Glandular Dose, and Exposure Reproducibility" test in the *1999 ACR QC Manual for Stereotactic Breast Biopsy*.

For locations following ACR standards, verify that the dose is set for:

- Stereotactic Biopsy Dose - 1.60 mGy
- Tomosynthesis Dose, 30 projections - 1.80 mGy

For more dose calibration information, refer to MAN-05621 Affirm Prone system Dose Calibrations, CalTool.

6.4.15 Signal-to-Noise Ratio Test

Follow the "Digital Receptor Uniformity" test in the *1999 ACR QC Manual for Stereotactic Breast Biopsy*.

6.4.16 Standard System Test

Required Equipment/Tools

- Mammography Phantom

Procedure

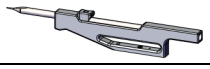
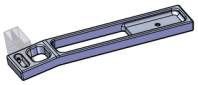
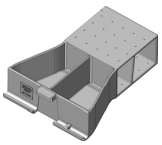
1. Turn system on.
2. Confirm system boots up and application loads correctly.
3. Acquire an image using a Mammography Phantom.
4. Verify that the image on the Acquisition Workstation meets the requirement of 5 Fibers, 4 Specs, and 4 Masses.

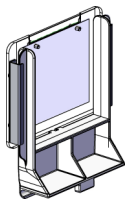
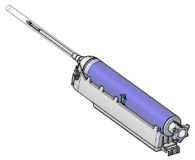
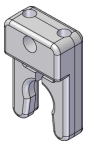
6.5 Biopsy Module Calibration

This section describes the tools and procedures required to perform the Biopsy module subsystem calibrations.

The Guidance Hardware calibrations do not involve imaging and can be implemented by using CalTool. The Geometry and STX calibrations require image capture.

6.5.1 Required Tools and Equipment

Description	Image	Part Number
QAS Phantom Needle		ASY-03949
Tomosynthesis QAS Phantom		ASY-06255
5 x 5 Standard Biopsy Paddle		ASY-08175
Geometry Calibration Phantom		ASY-08265
Stage Arm (Biopsy Arm) Calibration Tool		TLS-05629

Description	Image	Part Number
X-ray Field and Detector Alignment Paddle		TLS-05650
Biopsy Device with Holder		
Needle Guide		

6.5.2 Front Needle Guide Alignment

The purpose of this procedure ensures that the movable needle guide does not cause deflection of the needle in the XY plane as the guide is moved in Z direction. The Target Space-Guidance Space Transform Calibration makes sure that the Biopsy Guidance Module stage (and the biopsy device holder) is aligned to Target Space, but it cannot account for deviation of the device needle caused by movable needle guide alignment.

Required Equipment/Tools

- X-ray Field and Detector Alignment tool (TLS-05650)
- Biopsy Device with Holder
- Needle Guide

Procedure

1. Install the Needle Guide on the front Needle Guide mount.
2. Install the Biopsy Device with an appropriate gauge biopsy needle (inspect for bent or damaged needle) on the Biopsy Guidance Module so that the needle passes through the front Needle Guide. Tighten the Biopsy Guidance Module knob to secure the Biopsy Device in place.
3. Turn the Z-axis adjustment to position the Biopsy Guidance Module mount to the top of its travel.
4. Place the X-ray Field and Detector Alignment tool (TLS-05650) on the breast tray, ensuring the front locating pins are flush against the tray.
5. Slide the front Needle Guide fully toward the breast tray.

6. Using the Biopsy Control Module XY jog functions, move the X- and Y-axes until the needle tip is positioned over the QAS Needle Zero Reference point on the fixture. Use the Z-axis adjustment to position the needle tip just over the Reference point line intersection; it may be necessary to jog Y while adjusting Z.
7. Slowly slide the front Needle Guide upward until just short of full travel.
8. Observe the needle tip; if the position of the tip relative to the fixture Reference point line intersection has deviated in X, Y, or both axes:
   a. Loosen the screws securing the front Needle Guide.
   b. Move the Needle Guide to return the needle tip to the Reference point.
   c. Tighten the screws and recheck the needle movement.
9. Repeat as necessary until the needle tip does not deviate between the top and bottom front Needle Guide positions.

6.5.3 Biopsy Guidance Hardware Procedures

The Biopsy guidance hardware calibration consists of three procedures located in the Biopsy section of CalTool. The procedures are done in the order they are listed:

a. Detent Calibration
b. Guidance Hardware Limits*
c. Guidance Hardware Zero

Follow the directions in CalTool to perform these procedures.

*The Guidance Hardware Limits calibration can be done using the method described in CalTool, or it can be done by an alternate method as described later in this section.

Required Equipment/Tools

- Stage Arm (Biopsy Arm) Calibration Tool (TLS-05629)

WARNING!
These procedures require power to be connected to the system while certain covers are removed. Be careful to avoid contacting high-voltage components.

Caution:
Do not advance the X-axis or Y-axis assemblies past the point indicated in these procedures or damage to components may result.

Note
Perform these procedures after installing or servicing Biopsy Control Module hardware.

Cover Removal to Perform Tests

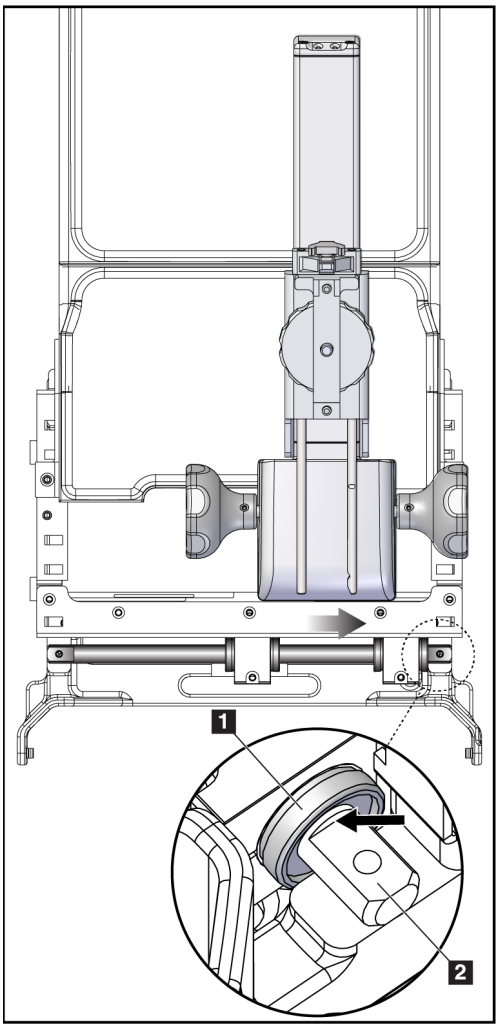
1. Rotate the Biopsy Control Module so it is perpendicular to the C-arm.
2. Remove the following covers:
   - Biopsy Arm front-end cover (refer to *Remove Front-end Cover of Biopsy Control Module* on page 192)
   - Biopsy Arm rear-end cover (refer to *Remove Rear-end Cover of Biopsy Control Module* on page 193)
   - Biopsy Control Module display covers (both sides, but only have one removed at any given time) (refer to *Remove Displays/Covers of Biopsy Control Module* on page 190)
   - Biopsy Control Module display bottom cover (refer to *Remove Bottom Cover of Biopsy Control Module Display* on page 194)
3. Keep power applied to system, as it is needed to perform the calibration.

Note
You can use the jog controls in CalTool or the controls on the Biopsy Control Module screen to jog the X-axis assembly and Y-axis assembly as prompted in these procedures. In either case, however, you must have at least *one* Biopsy Control Module display connected to be able to jog the X-axis and Y-axis assemblies. Consequently, you may need to alternate the removal and replacement of the Biopsy Control Module displays so there is as at least one display connected at all times during the setting of the min and max endpoints.

Alternate Method - Guidance Hardware Limits Calibration

The Guidance Hardware Limits calibration sets the minimum (min) and maximum (max) endpoints of the X-, Y-, and Z-axis. The following procedure uses a slightly different method to determine these endpoints than the steps shown in CalTool, but this alternate procedure stills use CalTool and the Stage Arm (Biopsy Arm) Calibration Tool (TLS-05629).

1. At the Acquisition Workstation, in CalTool, go to **Biopsy > Guidance Hardware Limits**.
2. Jog the X-axis assembly to the right until the X-axis support shaft bearing just meets the beginning of the flat on the support shaft (see arrow in the following figure).



Legend

1. Support Shaft Bearing
2. Flat of the Support Shaft

Figure 128: Moving X-axis assembly to reach max endpoint

3. When this point has been reached, click **Apply** under the Execute Procedure tab in CalTool. This step sets the X-axis "max" endpoint.

4. Click **Next** in CalTool. Jog the Y-axis assembly up until two screw threads on the Y-axis drive screw are just visible (see following figure).

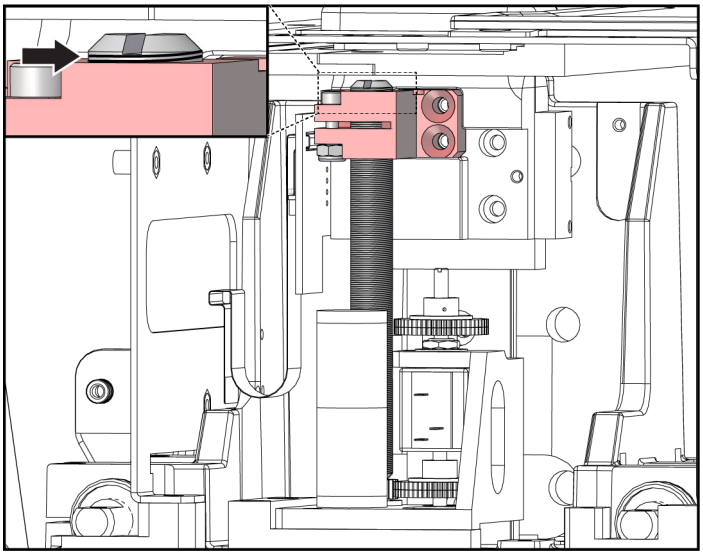


Figure 129: Moving Y-axis assembly to reach max endpoint

5. When this point has been reached, click **Apply** under the Execute Procedure tab in CalTool. This step sets the Y-axis "max" endpoint.
6. Click **Next** in CalTool. Rotate counterclockwise the needle advance/retract knob (representing the Z-axis) so the needle assembly is moving away from the breast platform (see following figure). Do this rotation until it reaches a hard stop.

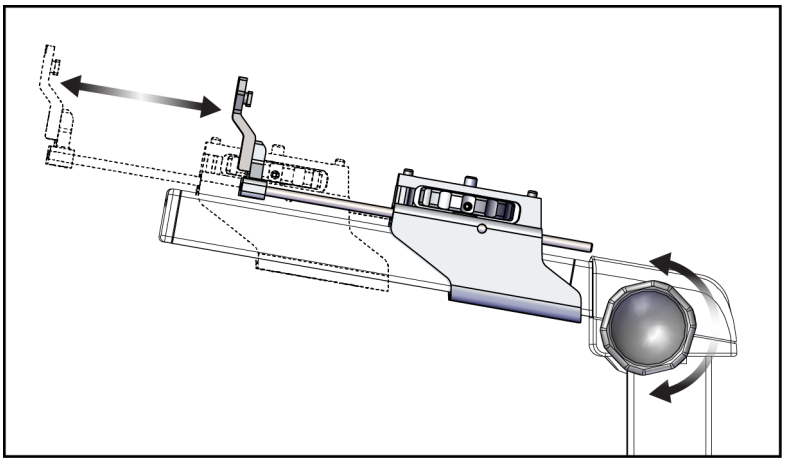
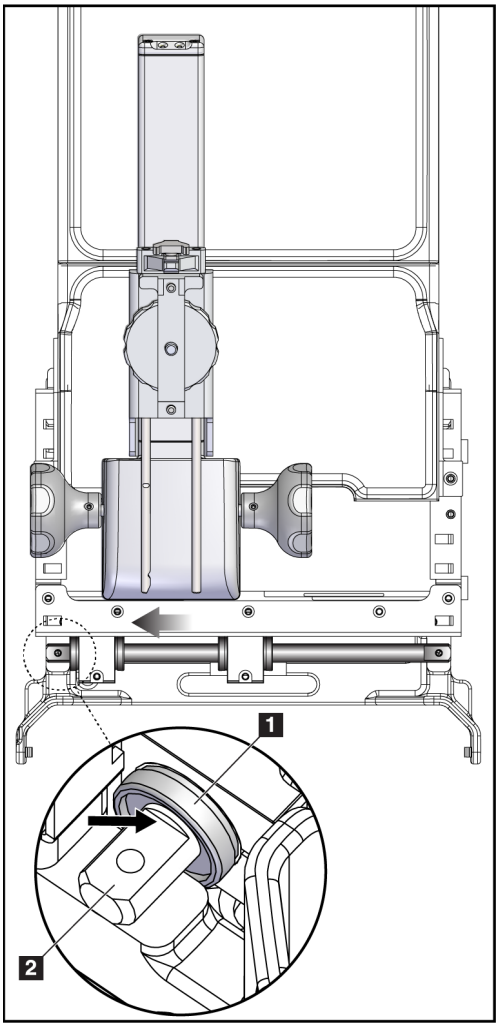


Figure 130: Moving Z-axis to determine min and max endpoints

7. When this point has been reached, click **Apply** under the Execute Procedure tab in CalTool. This step sets the Z-axis "max" endpoint.

8. Click **Next** in CalTool. Jog the X-axis assembly to the left until the X-axis support shaft bearing just meets the beginning of the flat on the support shaft (see the following figure).



Legend

1. Support Shaft Bearing
2. Flat of the Support Shaft

Figure 131: Moving X-axis assembly to reach min endpoint

9. When this point has been reached, click **Apply** under the Execute Procedure tab in CalTool. This step sets the X-axis "min" endpoint.

10. Click **Next** in CalTool.
    a. Before you start the next (Y-axis "min" endpoint) calibration, move the X-axis assembly back to the "max" endpoint position (as done in step 2) for better access.
    b. Slip the calibration tool (TLS-05629) between the bottom of the drive screw and bottom gear (see the following figure). Jog the Y-axis assembly down until it meets the calibration tool.

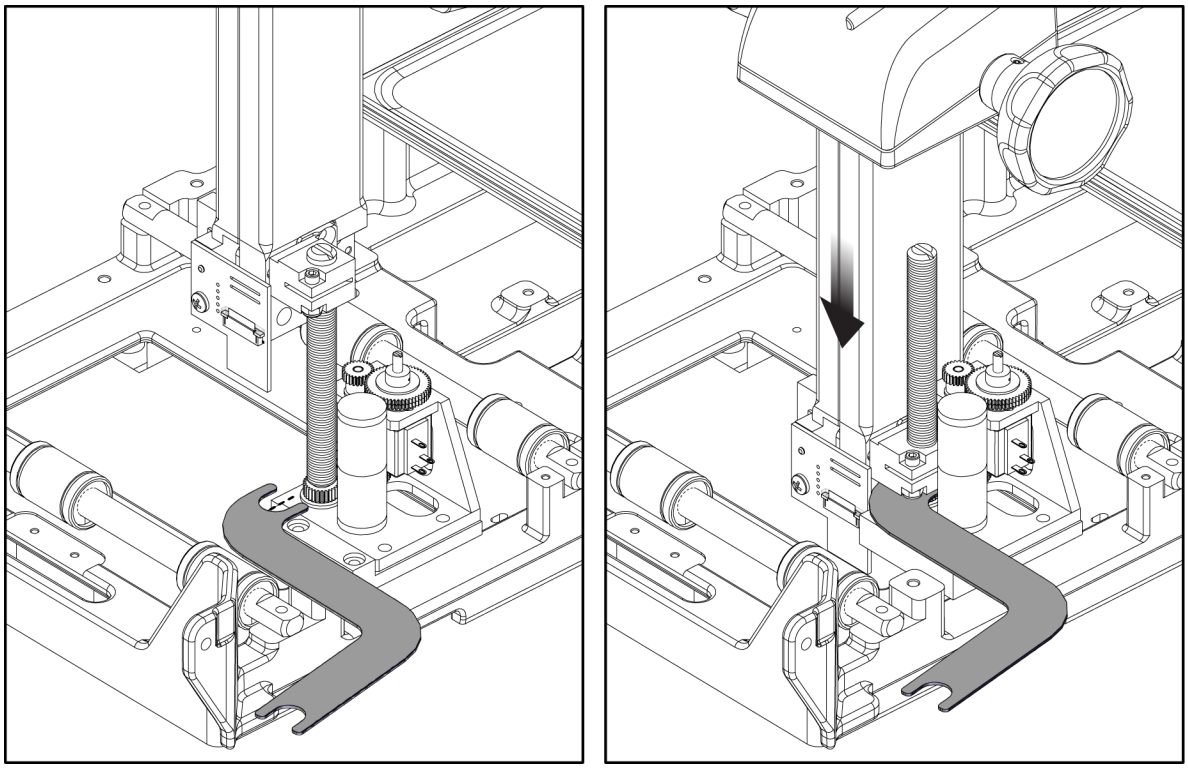


Figure 132: Moving Y-axis assembly to reach min endpoint with calibration tool

11. When this point has been reached, click **Apply** under the Execute Procedure tab in CalTool. This step sets the Y-axis "min" endpoint.
12. Remove the calibration tool (you may need to jog up the Y-axis assembly slightly).
13. Click **Next** in CalTool. Rotate clockwise the needle advance/retract knob so the needle assembly is moving towards the breast platform (see figure from step 6). Do this rotation until it reaches a hard stop.
14. When this point has been reached, click **Apply** under the Execute Procedure tab in CalTool. This step sets the Z-axis "min" endpoint.
15. When finished, replace the:
    - Biopsy Control Module display bottom cover
    - Biopsy Control Module displays (both sides)
    - Biopsy Arm front-end cover
    - Biopsy Arm rear cover

6.5.4 Geometry Calibration Procedure

Geometry calibration is required semiannually. Perform this calibration using the Geometry phantom supplied with the system.

Required Equipment/Tools

- Geometry Calibration Phantom (ASY-08265)

Procedure

1. Inspect the calibration phantom for damage.
2. Select the **Admin > Quality Control > Technologist tab > Geometry Calibration** procedure on the Acquisition Workstation.
3. Select **Start**.
4. Follow the instructions on the screen and take the predefined exposure. Do not change the preselected techniques.
5. **Accept** the image. When you see the message that the geometry calibration was completed successfully, click **OK**.
6. Select **End Calibration**.

6.5.5 STX Calibration

The STX calibration is used to map the needle coordinates to the detector space. The STX calibration requires moving the QAS needle to pre-defined coordinates and uses the QAS needle (not the QAS phantom). Keep in mind that you need to bring your own QAS needles, as they are not supplied to customers.

Note
You must be logged in as Service to be able to calibrate all 15 STX positions.

Note
Before you start the STX calibration, ensure that the Biopsy Hardware Calibrations have been performed first (refer to *Biopsy Guidance Hardware Procedures* on page 152). These calibrations ensure that the encoder hardware components in the biopsy arm are accurately calibrated.

Required Equipment/Tools

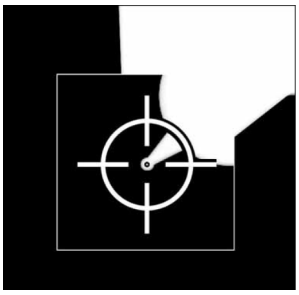
- QAS Phantom Needle (ASY-03949)

Procedure

1. Install the QAS needle on the Gantry and lock in place.
2. From the AWS, press the **Admin** button, then the **STX Calibration** button. The first target is automatically sent to the Biopsy Control Module.
3. Move to the first target by holding the motor enable buttons on the front and rear of the Biopsy Control Module.
4. Manually dial in the Z axis until you reach the target.
5. Take the first exposure.
6. Accept the image.

Tip:

For the following steps, use the zoom and/or magnification feature to enlarge the target area.



7. Accept the target.

8. Select the next stereo pair, and repeat steps 4 through 7 for the first five exposures.
9. After the first five exposures, move to the biopsy-arm angle shown on the Acquisition Workstation. Refer to the following table.

Table 8: Calibration Target List (for reference only)

	C-Arm Angle	Biopsy Arm Angle	X	Y	Z
1	+90.0°	0.0° Center	30.0	5.0	5.0
2	+90.0°	0.0° Center	30.0	45.0	95.0
3	+90.0°	0.0° Center	-30.0	40.0	5.0
4	+90.0°	0.0° Center	-30.0	15.0	95.0
5	+90.0°	0.0° Center	0	15.0	30.0
	C-Arm Angle	**Biopsy Arm Angle**	**X**	**Y**	**Z**
6	+90.0°	+90.0° Right	30.0	5.0	20.0
7	+90.0°	+90.0° Right	30.0	45.0	60.0
8	+90.0°	+90.0° Right	-30.0	40.0	20.0
9	+90.0°	+90.0° Right	-30.0	5.0	60.0
10	+90.0°	+90.0° Right	0	15.0	30.0
	C-Arm Angle	**Biopsy Arm Angle**	**X**	**Y**	**Z**
11	+90.0°	+90.0° Left	30.0	5.0	20.0
12	+90.0°	+90.0° Left	30.0	40.0	60.0
13	+90.0°	+90.0° Left	-30.0	45.0	20.0
14	+90.0°	+90.0° Left	-30.0	5.0	60.0
15	+90.0°	+90.0° Left	0	15.0	30.0

Note
If the points used during the STX calibration cannot be reached, perform the **Guidance Hardware Zero** procedure in CalTool. If that does not suffice, perform the Biopsy Arm hardware calibration (refer to the *Hardware Range Calibration* on page 285 in the appendix), then perform the **Guidance Hardware Zero** procedure in CalTool. When finished, restart at step 1 of this STX calibration.

10. When the 15 exposures are complete, rotate the biopsy arm to 0° (center position).
11. Press **End QC** to end calibration.

6.5.6 Biopsy Calibration Interaction

The interaction between the calibrations related to Guidance and Geometry is listed in the following table. Note that the only interdependency is that of the STX Calibration on the Guidance Hardware Calibration.

Table 9: Calibrations

A change to...	...affects this calibration		
	Guidance Hardware Cal	Geometry Cal	STX Cal
Guidance Hardware Cal	Yes	No	Yes
Geometry Cal	No	Yes	Yes
STX Cal	No	No	Yes

An STX Calibration is necessary if a Guidance Hardware Calibration Limits or Guidance Hardware Zero is performed from CalTool, or if the QAS Test fails. The Geometry Cal is the only Biopsy subsystem calibration the customer is expected to perform.

6.5.7 The QAS Test

Perform the Quality Assurance Standard (QAS) Test procedure to make sure of accurate alignment and performance of the needle guidance system when you use the system.

Note
You can use Auto C-Arm Stereo Mode or Manual C-arm Stereo Mode for the QAS Test. For more information about these modes, refer to the *User Guide*.

Caution:
When you use a QAS Needle Phantom, do not extend the needle unless it is attached to the Biopsy Guidance Module and the module is installed on the C-arm. Always retract the QAS Needle Phantom before moving the biopsy arm.

Required Equipment/Tools

- QAS Phantom Needle (ASY-03949)
- Tomosynthesis QAS Phantom (ASY-06255)

Procedure

1. From the console, select **Admin**, then **QAS**.
2. Do not change the preselected technique.

3. On the QAS screen, select the **Biopsy** tab. Verify that **Affirm QAS** appears in the Device field (see following figure).

Figure 133: Affirm QAS Device Selected in Biopsy Tab

4. Move the Biopsy Arm to the Standard 0 degree approach.
5. Remove the Compression Paddle.
6. Move the Z-axis slide rail to 55 mm and 65 mm.
7. Attach the QAS Phantom Needle (ASY-03949) at the top end of the Z-axis slide rail, fully extend the needle.
8. Select the QAS view.
9. Press and hold a right or left **Motor Enable** button on the Biopsy Control Module. The QAS Phantom Needle moves automatically to pre-programmed X and Y positions.
10. Turn the Z-axis Control Knob to show 0.0 (+/- 0.1) on the Differential line in all three columns of the Biopsy Control Module.
11. Acquire and **Accept** the first view in the procedure. The Auto-Accept feature is not enabled during the QAS procedure, and targeting on the QAS Phantom Needle occurs automatically.
12. Select **Create Target** to send the target to the Biopsy Control Module. Verify that the target coordinates are within ± 1 mm of X, Y, and Z numbers on the current line of the Biopsy Control Module.
13. Retract the QAS Phantom Needle.

Caution:
If the targeting coordinates are not within ± 1 mm, contact Technical Support. Do not try to adjust the system. Do not perform any biopsy procedure with the Affirm until Technical Support indicates that the system is ready for use.

Caution:
The user or a Service Engineer must correct problems before the system is used.

14. Move the Biopsy Arm to the -90 degree approach.
15. Extend the QAS Phantom Needle.
16. Select the **QAS Lateral -90** view.
17. Press and hold a right or left **Motor Enable** buttons on the Biopsy Control Module. The QAS Phantom Needle moves automatically to pre-programmed X and Y positions.
18. Turn the Z-axis Control Knob to show 0.0 (+/- 0.1) on the Differential line in all three columns of the Biopsy Control Module.
19. Acquire and **Accept** the view. The Auto-Accept feature is not enabled during the QAS procedure, and that targeting on the QAS Phantom Needle occurs automatically.
20. Select **Create Target** to send the target to the Biopsy Control Module. Verify that the target coordinates are within ± 1 mm of X, Y, and Z numbers on the current line of the Biopsy Control Module.
21. Retract the QAS Phantom Needle.
22. Move the Biopsy Arm to the +90 degree approach.
23. Extend the QAS Phantom Needle.
24. Select the **QAS Lateral +90** view.
25. Press and hold a right or left **Motor Enable** buttons on the Biopsy Control Module. The QAS Phantom Needle moves automatically to pre-programmed X and Y positions.
26. Turn the Z-axis Control Knob to show 0.0 (+/- 0.1) on the Differential line in all three columns of the Biopsy Control Module.
27. Acquire and **Accept** the view. The Auto-Accept feature is not enabled during the QAS procedure, and that targeting on the QAS Phantom Needle occurs automatically.
28. Select **Create Target** to send the target to the Biopsy Control Module. Verify that the target coordinates are within ± 1 mm of X, Y, and Z numbers on the current line of the Biopsy Control Module.
29. Retract and remove the QAS Phantom Needle.
30. Select the **Biopsy** tab.
31. Move the Biopsy Arm to the Standard 0 degree approach.
32. Select the **Tomo Biopsy** view.
33. Install the tomosynthesis QAS Phantom (ASY-06255).
34. Press and hold a right or left **Motor Enable** buttons on the Biopsy Control Module. The QAS Phantom Needle moves automatically to pre-programmed X and Y positions.
35. Turn the Z-axis Control Knob to show 0.0 (+/- 0.1) on the Differential line in all three columns of the Biopsy Control Module.

36. Acquire and **Accept** the view. The Auto-Accept feature is not enabled during the tomosynthesis QAS procedure, and that targeting on the tomosynthesis QAS Phantom occurs automatically.
37. Select **Create Target** to send the target to the Biopsy Control Module. Verify that the target coordinates are within ± 1 mm of X, Y, and Z numbers on the current line of the Biopsy Control Module.
38. Remove the tomosynthesis QAS Phantom.
39. Select **End QC** on the Acquisition Workstation screen.

6.5.8 Biopsy Calibration - Maximum Compression Force

Required Equipment/Tools

- 5 cm x 5 cm Standard Biopsy Paddle (ASY-08175)
- Force gauge

Procedure

1. Attach the Standard Biopsy Paddle to the Biopsy Arm.
2. In CalTool, run the Max Compression Force test to verify the compression force of the paddle.
3. Use the Z knob on the biopsy arm control to move Z to the position furthest away from the breast tray. This step allows motorized compression over the full range of the force calibration.
4. Hold the force gauge fixture on breast tray with the pressure plate towards the paddle. Compress using motorized compression until compression stops (use the foot switch to drive the compression down). Do NOT further compress by hand.
5. Examine the force gauge (the current reading is the maximum motorized compression force). The standard maximum is 16 lbs (71 Newtons). If the current reading is not 16, change the maximum current to the motor. Click **Change** and follow the instruction in the prompt.

Note
If your site requests a lower maximum motorized force, change the motor current until you achieve that force instead of 16 lbs.

6. When you are satisfied with the max compression force settings, the calibration is complete.

6.5.9 Compression Thickness Calibration

Required Equipment/Tools

- 5 cm x 5 cm Standard Biopsy Paddle (ASY-08175)
- 4 cm of BR12 (or equivalent)

Procedure

1. Attach the Standard Biopsy Paddle to the Biopsy Arm.
2. Place the BR12 on the breast platform.
3. In CalTool, run the Compression Thickness tool to calibrate the compression thickness of the paddle.

Chapter 7 System Maintenance - Generator

7.1 Introduction

This chapter describes maintenance information and instructions for the Generator, including:

- Component identification
- Cover removal
- Component replacement procedures

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Warning:
Always follow the safety precautions for x-ray exposures.

Caution:
Always obey Electrostatic Discharge (ESD) precautions when working with electronics and electronic components.

Note
If a procedure instructs you to remove any covers or panels, do not install the covers until all required procedures are completed.

Only Hologic-authorized, trained Service Engineers can service this system. The system is designed for module-level repair.

7.2 Major Serviceable Components of Generator (Illustrated)

The following figure illustrates the major serviceable components of the Generator.

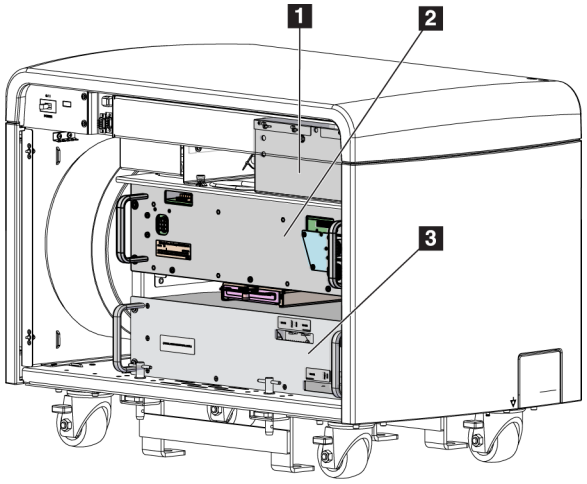


Figure 134: Major serviceable components of Generator

Figure Legend

1. High Voltage Multiplier Assembly
2. Inverter Drawer
3. Power Distribution Drawer

7.3 Covers Removal

To access components in the Generator, several covers must be removed. See the following topics, which illustrate the removal of the covers and panels.

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

7.3.1 Remove Generator Top Cover

1. Remove the two screws that are located above the Generator circuit breaker switch, at the upper left corner of the front cover. (See the following figure.)
2. Remove the top cover by lifting it up and separating it from the four ball stud fasteners that secure it to the top plate.

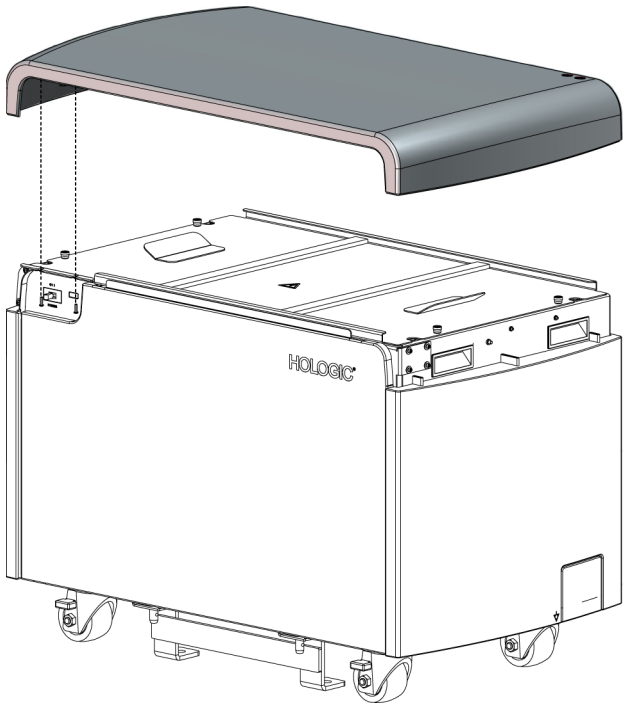


Figure 135: Removal/replacement of top cover of Generator

7.3.2 Remove Generator Top Plate Under Top Cover

1. Remove the top cover (refer to *Remove Generator Top Cover* on page 169).
2. Loosen (but do not remove) the four screws that secure the top plate to the Generator frame. (See the following figure.)
3. Remove the top plate by grabbing its handles and lifting it up from the frame.

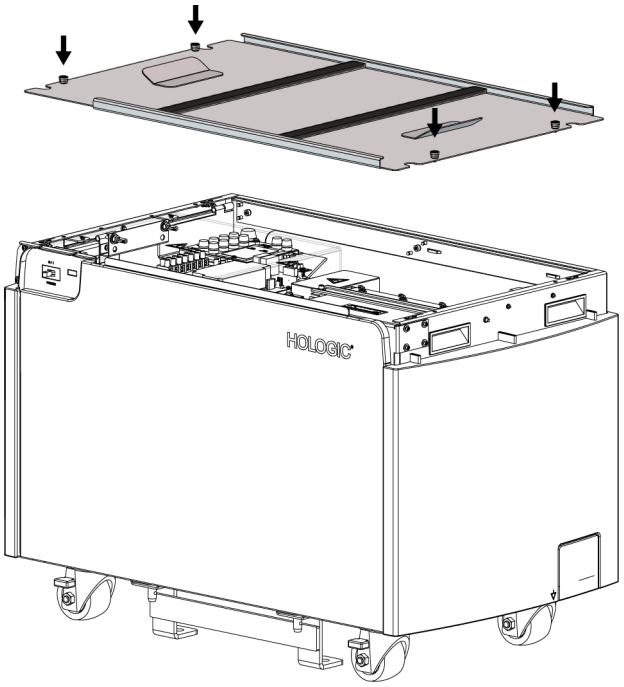


Figure 136: Removal of top plate under top cover of Generator

7.3.3 Remove Generator Front Cover

Note
The Generator top cover must be removed before removing the front cover.

1. Remove the Generator top cover (refer to *Remove Generator Top Cover* on page 169).
2. There are no fasteners to loosen on the front cover. Simply grasp the front cover from the bottom (see the arrows in the following figure) and pull out.
3. When reinstalling, slide the cover up and into place.

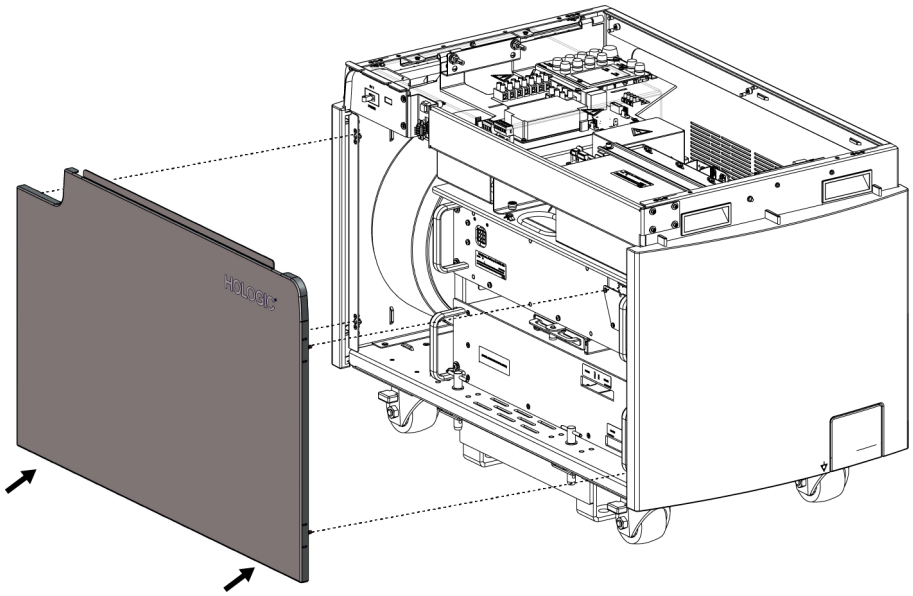


Figure 137: Removal of front cover of Generator

7.3.4 Remove Generator Rear Cover

1. Remove the five screws that secure the rear cover to the Generator frame. (See the following figure.)
2. Remove the rear cover from the Generator.

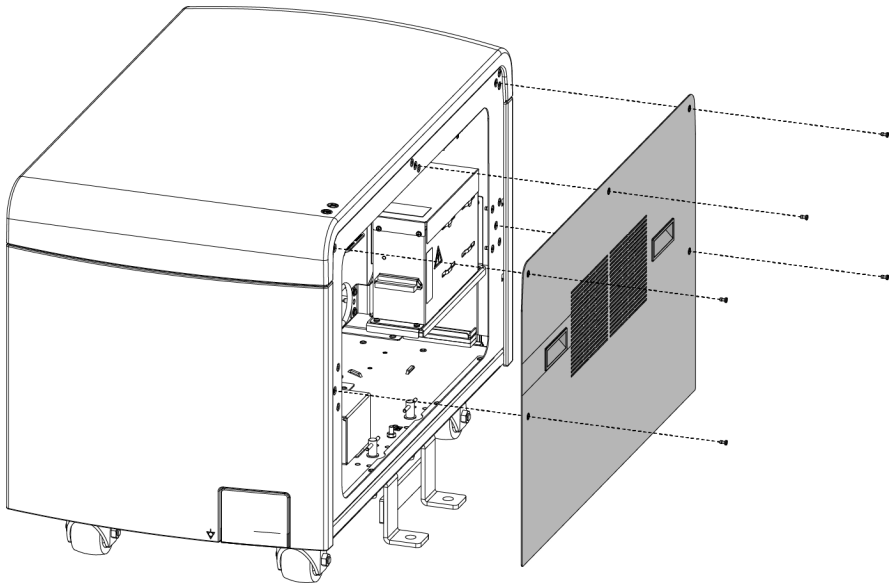


Figure 138: Removal of rear cover of Generator

7.4 Component Replacement Procedures

7.4.1 Replace Inverter Drawer

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system and power OFF at the facility disconnect box.
2. Ensure that the Generator circuit breaker is in the OFF position.
3. Remove the top cover (refer to *Remove Generator Top Cover* on page 169), front cover (refer to *Remove Generator Front Cover* on page 171), and top plate (refer to *Remove Generator Top Plate Under Top Cover* on page 170).
4. Disconnect all cable connections to the Inverter Drawer. Make note of each connection and its location.
5. Remove the four screws that secure the Inverter Drawer into place. (See the following figure.)
6. Slide the Inverter Drawer out from its location in the Generator.

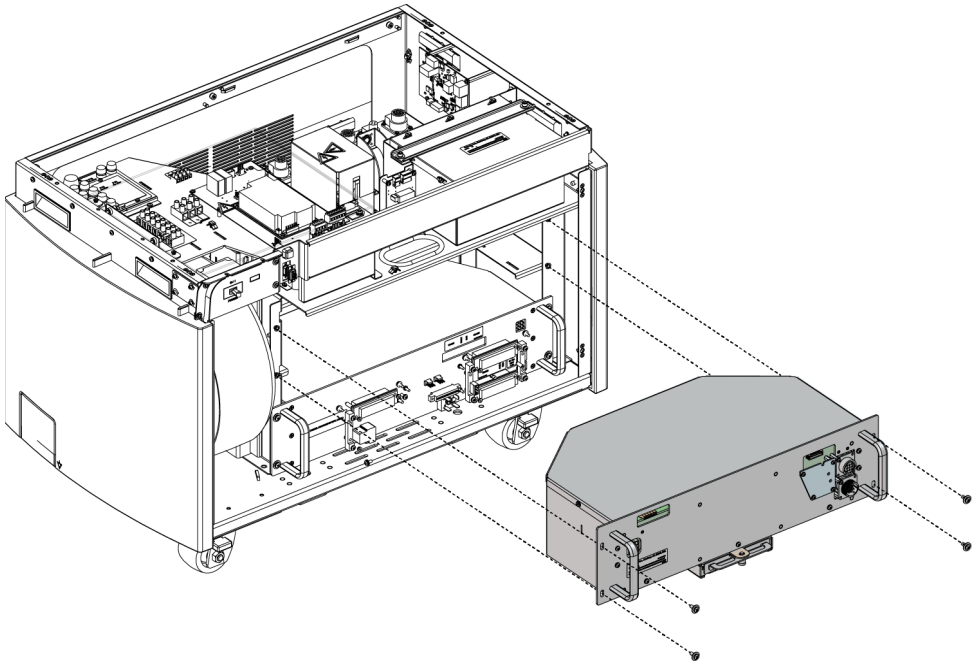


Figure 139: Removal/replacement of Inverter Drawer of Generator

Replacement

1. Install the new Inverter Drawer by sliding it into place. (See the previous figure.)
2. Secure the drawer with the four screws.
3. Restore all cable connections to the new Inverter Drawer.
4. Reinstall the previously removed covers to the Generator.
5. Power ON at the facility disconnect box and power ON the system.
6. Verify proper operation of the system.

7.4.2 Replace High Voltage Multiplier Assembly

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system and power OFF at the facility disconnect box.
2. Ensure that the Generator circuit breaker is in the OFF position.
3. Remove the top cover (refer to *Remove Generator Top Cover* on page 169), front cover (refer to *Remove Generator Front Cover* on page 171), and top plate (refer to *Remove Generator Top Plate Under Top Cover* on page 170).
4. Disconnect all cable connections to the High Voltage Multiplier Assembly. (Make note of each connection and its location.)

5. Remove the four screws that secure the rear panel of the Multiplier Assembly to its mounting bracket. (See the following figure.)
6. Remove the ground wire that is attached to one of the four screws removed in the previous step. (Not shown.)
7. Remove the two screws that secure the Multiplier Assembly to its mounting strip. (See the following figure.)
8. Remove the Multiplier Assembly by lifting it up and out from its location in the Generator.

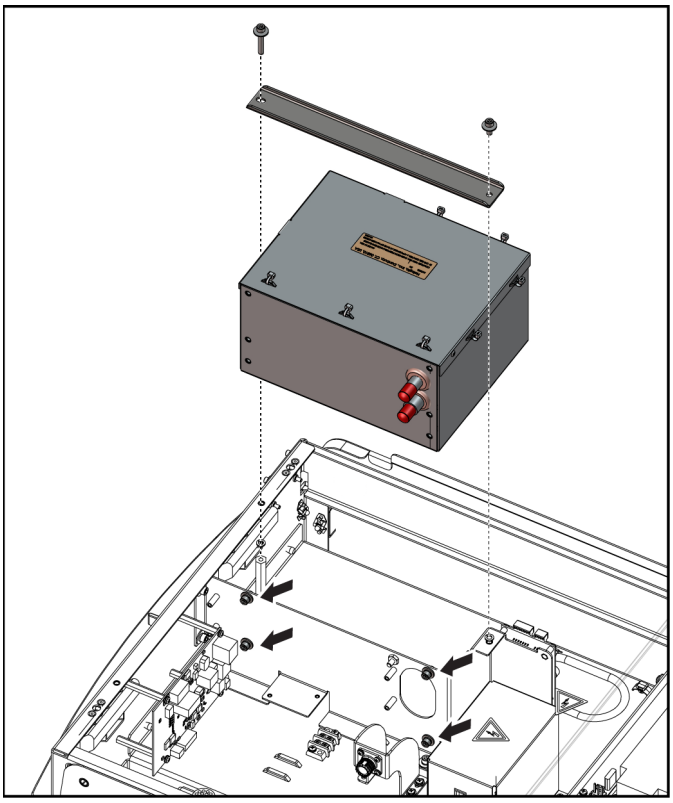


Figure 140: Removal/replacement of High Voltage Multiplier Assembly

Replacement

1. Install the new Multiplier Assembly by lowering it into place. (See the previous figure.)
2. Secure the rear panel of the multiplier to its mounting bracket (four screws). Reconnect the ground wire to one of the four screws.
3. Secure the top of the multiplier to its mounting strip (two screws).
4. Reinstall the previously removed covers to the Generator.
5. Power ON at the facility disconnect box and power ON the system.
6. Verify proper operation of the system.

7.4.3 Replace Power Distribution Drawer

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system and power OFF at the facility disconnect box.
2. Ensure that the Generator circuit breaker is in the OFF position.
3. Remove the top cover (refer to *Remove Generator Top Cover* on page 169), front cover (refer to *Remove Generator Front Cover* on page 171), and top plate (refer to *Remove Generator Top Plate Under Top Cover* on page 170).
4. Disconnect all cable connections to the Distribution Drawer. Make note of each connection and its location.

5. Remove the four screws that secure the Distribution Drawer into place. (See the following figure.)
6. Slide the Distribution Drawer out from its location in the Generator.

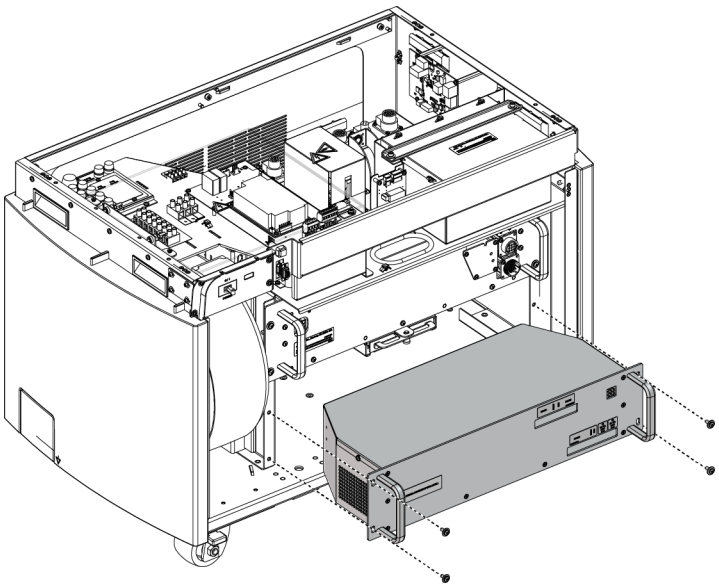


Figure 141: Removal/replacement of Power Distribution Drawer of Generator

Replacement

1. Install the new Distribution Drawer by sliding it into place. (See the previous figure.)
2. Secure the drawer with the four screws.
3. Restore all cable connections to the new Distribution Drawer.
4. Reinstall the previously removed covers to the Generator.
5. Power ON at the facility disconnect box and power ON the system.
6. Verify proper operation of the system.

Chapter 8 System Maintenance - Gantry/Patient Platform Assembly/C-arm

8.1 Introduction

This chapter describes maintenance information and instructions for the Gantry/Patient Platform/C-arm, including:

- Component identification
- Covers removal
- Component replacement procedures

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Warning:
Always follow the safety precautions for x-ray exposures.

Caution:
Always obey Electrostatic Discharge (ESD) precautions when working with electronics and electronic components.

Note
If a procedure instructs you to remove any covers or panels, do not install the covers until all required procedures are completed.

Only Hologic-authorized, trained Service Engineers can service this system. The system is designed for module-level repair.

8.2 Major Serviceable Components (Illustrated)

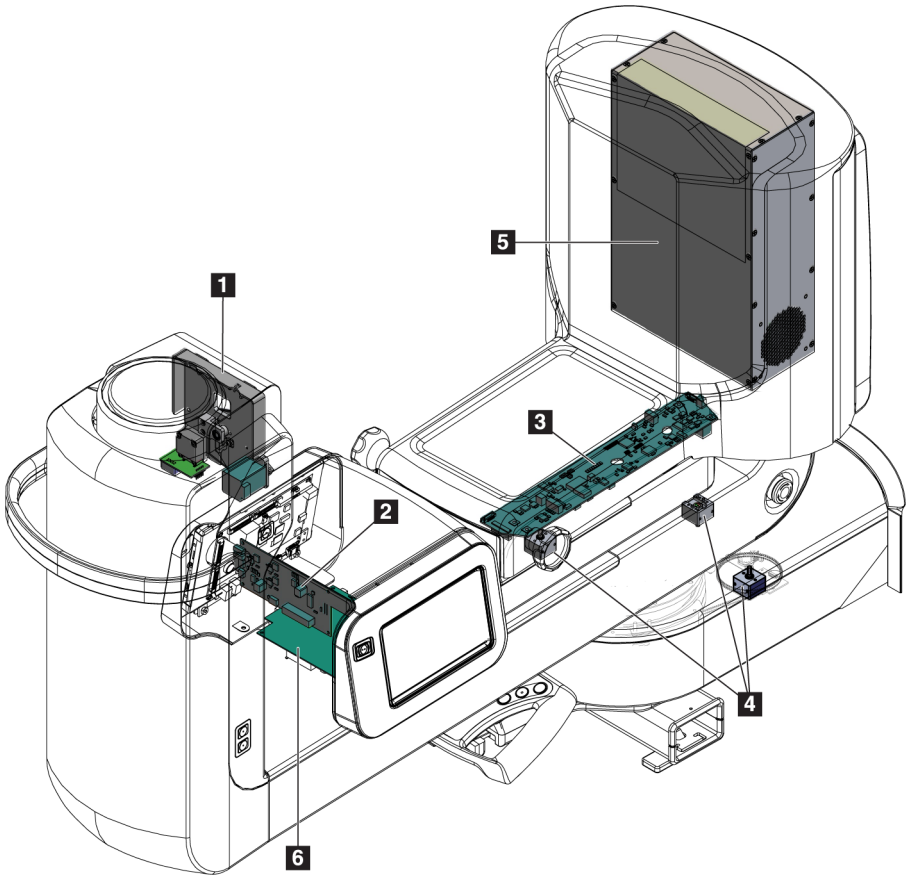


Figure 142: Major serviceable components of C-arm

Figure Legend

1. Filter Wheel Assembly
2. Biopsy Arm Motor Drive Board
3. Compression Arm Control Board
4. Magnetic Rotary Encoder Board Assemblies
5. Image Detector
6. Stage Arm Control Board

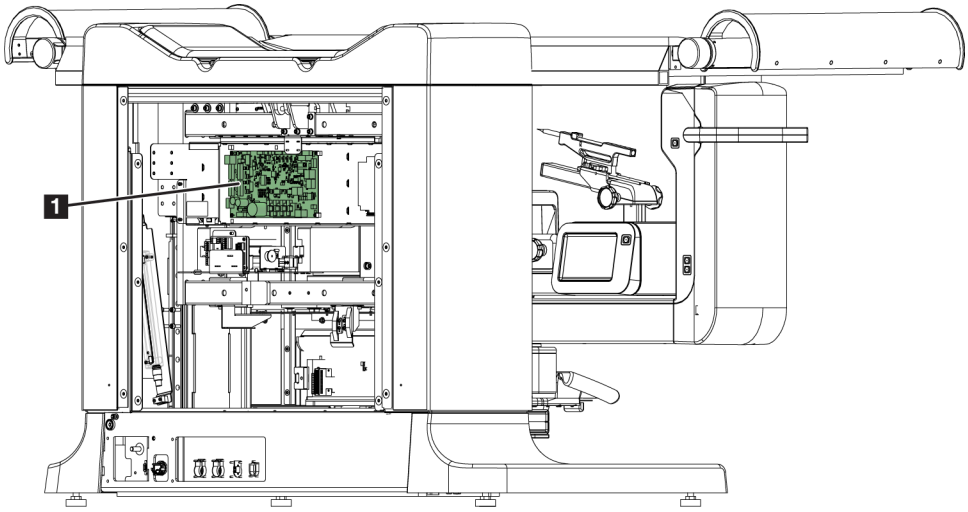


Figure 143: Major serviceable components of Gantry

Figure Legend

1. VTA Control Board

8.3 Covers Removal - Gantry Section

To access components in the Gantry/Patient Platform, one or more covers must be removed. See the following figures, which illustrate the removal of the covers and panels. The top cover must be removed before the rear cover, and the rear cover before the inside metal plate.

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal of Top Cover

1. Pull up on the patient padding (held on by hook and loop fasteners) and remove the top cover. (See the following figure, item 1.)
2. Unfasten the four screws and remove the top cover. (See the following figure, item 2.)

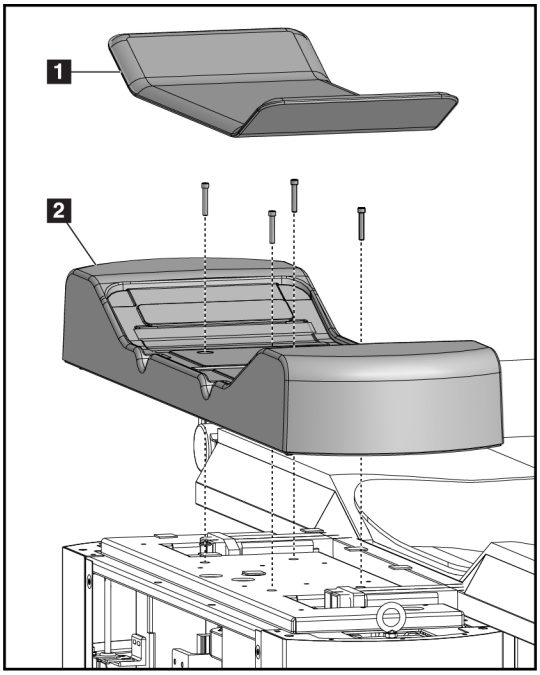


Figure 144: Removal of Gantry top covers

Removal of Rear Cover/Inside Metal Plate

1. Remove the top cover. (Refer to the previous procedure.)
2. Unfasten the four screws on top and three screws on each side to remove the rear cover. (See the following figure, item 1.)
3. Unfasten the three screws on each side to remove the metal plate behind the rear cover. (See the following figure, item 2.)

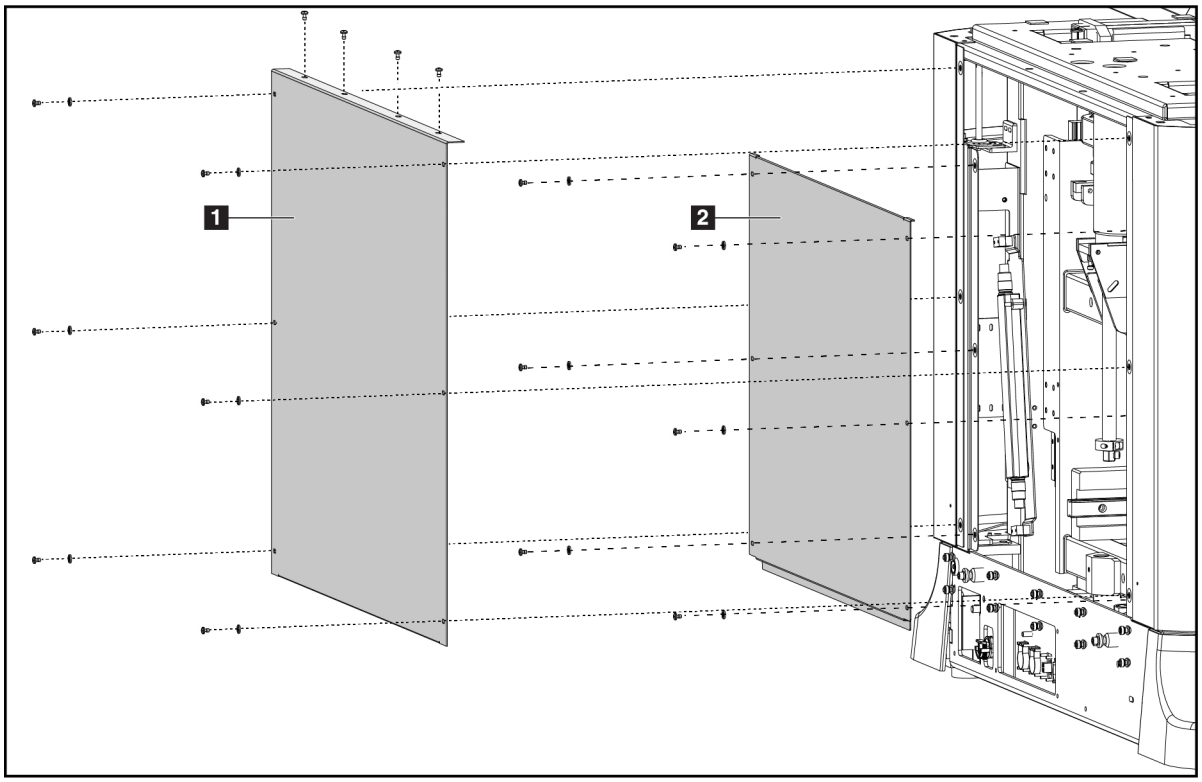


Figure 145: Removal of Gantry rear cover and inside metal plates

8.4 Covers Removal - C-Arm Section

To access components in the C-arm, one or more covers must be removed. See the following figures, which illustrate the removal of the covers and panels.

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

8.4.1 Remove Top Cover of Tube Arm Mechanism

1. Rotate the Biopsy Arm so that it is perpendicular to the Tube Arm Mechanism. (See the following figure, item 1.)
2. Remove the eight screws that secure the top cover from under the Tube Arm Mechanism.
3. Remove the top cover from the Tube Arm Mechanism. (See the following figure, item 2.)

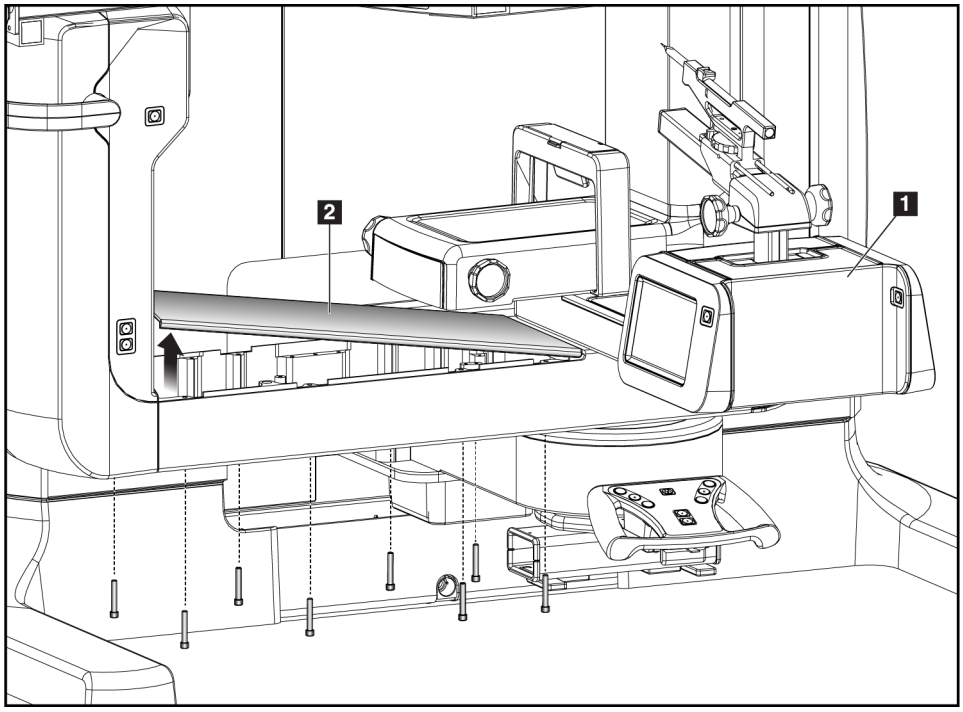


Figure 146: Removal of top cover of Tube Arm Mechanism

8.4.2 Remove Rear Cover of Tubehead

1. Remove the two screws from the bottom of the Tubehead.
2. Pull the rear cover down and away to remove it from the Tubehead. (See the following figure.)

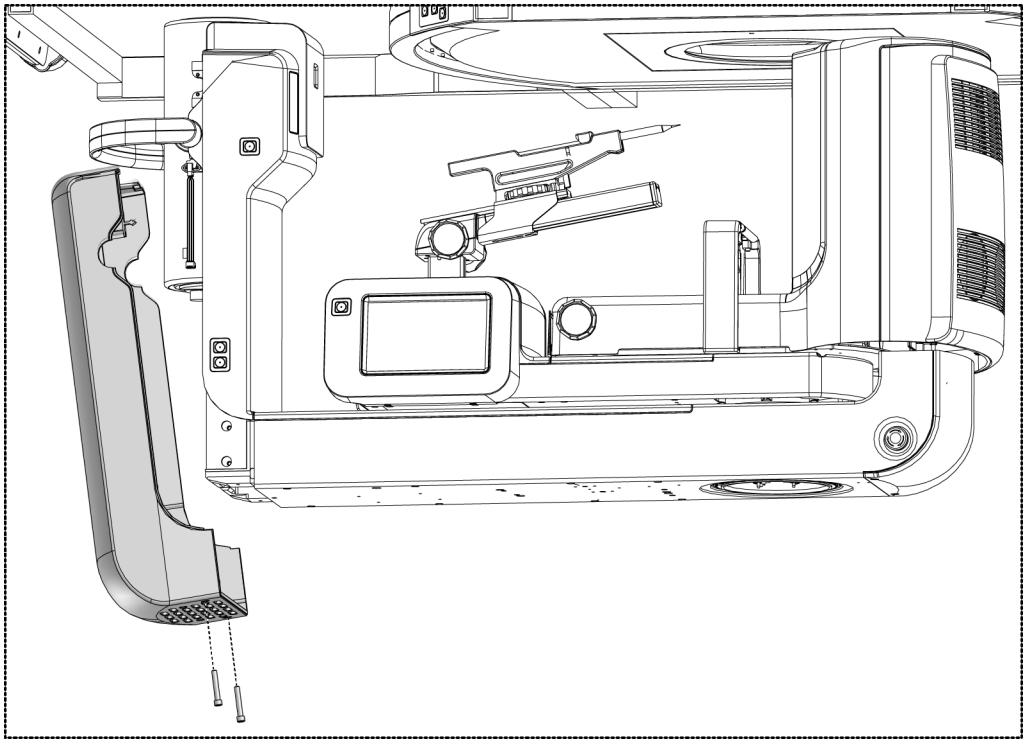


Figure 147: Removal of rear cover of Tubehead

8.4.3 Remove Front Cover of Tubehead

1. Remove the rear cover of the Tubehead. (Refer to *Remove Rear Cover of Tubehead* on page 185.)
2. Rotate the Biopsy Arm so it is perpendicular to the Tube Arm Mechanism. (See the following figure, item 1.)
3. Shutdown power to the system.

Caution:
System power must be OFF before disconnecting the harnesses to the LED boards (for the task lights on either side) inside the front tubehead cover. Otherwise, damage to the tubehead control board that the LED boards plug into may occur.

4. Disconnect the harnesses to the LED boards and side switches mounted to the front cover.
5. Remove the four screws that secure the front cover from the rear of the Tubehead.
6. Remove the front cover from the Tubehead. (See the following figure, item 2.)

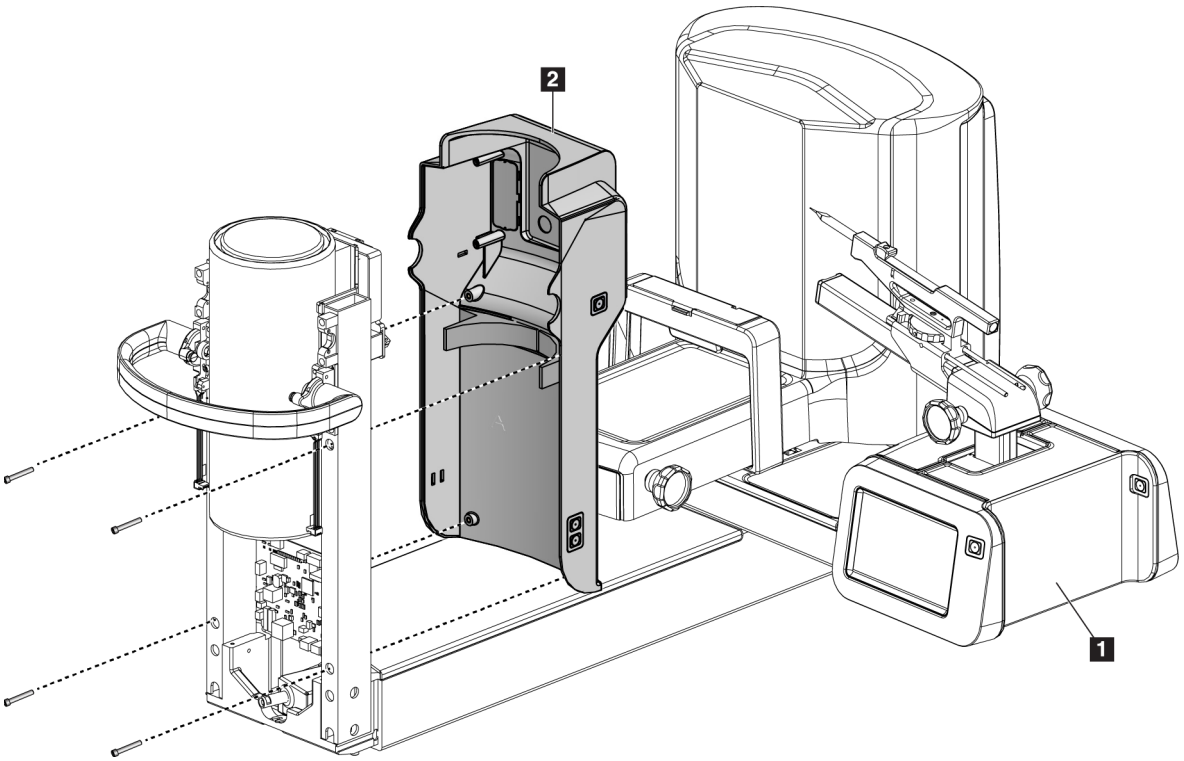


Figure 148: Removal of front cover of Tubehead

8.4.4 Remove Detector-end Cover of Tube Arm Mechanism

1. Remove the two screws under the Tube Arm Mechanism that secure the Detector-end cover. (See the following figure.)
2. Remove the Detector-end cover by pulling it *out to the side* (not down). (See the following figure.)

Note
As you begin to remove the Detector-end cover, if you feel some resistance from the snap fasteners, continue to remove the cover.

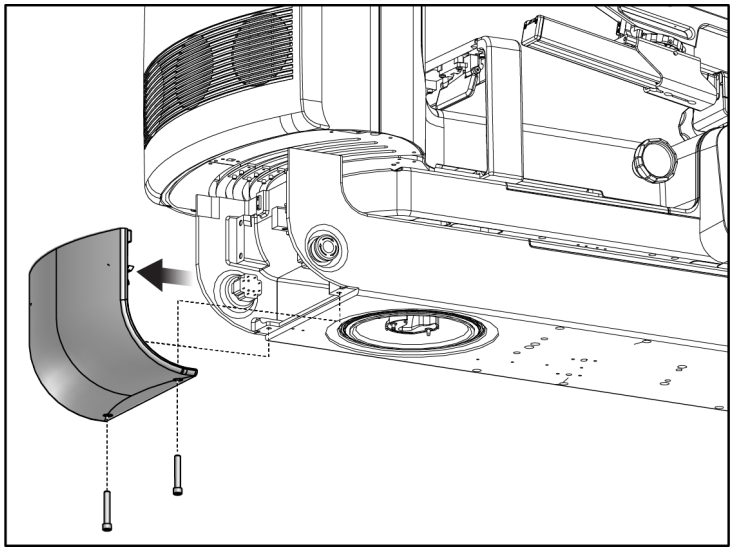


Figure 149: Removal of Detector-end cover of Tube Arm Mechanism

8.4.5 Remove Detector-end Cover of Compression Arm

1. Remove the four screws on the bottom of the Detector-end cover of the Compression Arm. (Two screws are held captive, as indicated with arrows in the following figure, at left, two are spring-loaded.)
2. Partially pull off the cover, disconnect the fan control harness connector, and then finish removing the cover.

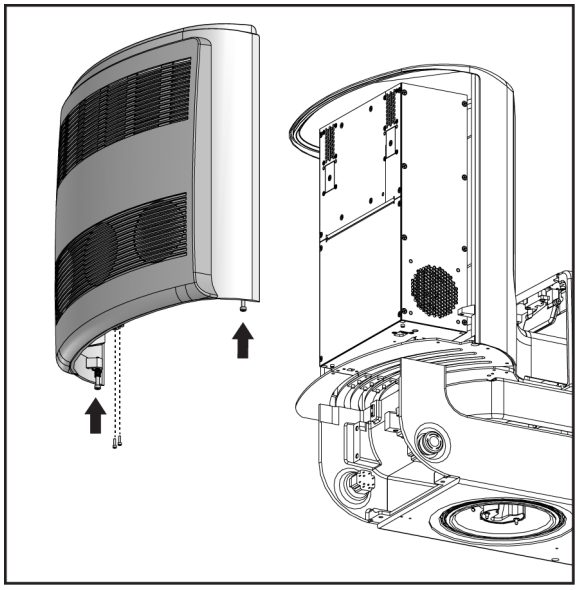


Figure 150: Removal of Detector-end cover of Compression Arm

8.4.6 Remove Front-end Cover of Compression Arm

1. Rotate the Biopsy Arm so it is perpendicular to the C-arm. (See the following figure, item 1.)
2. Remove the two screws under the rear-end (knobs-end) of the Compression Arm that secure the rear-end cover. (See the following figure, item 2.)
3. Remove the rear-end cover of the Compression Arm.

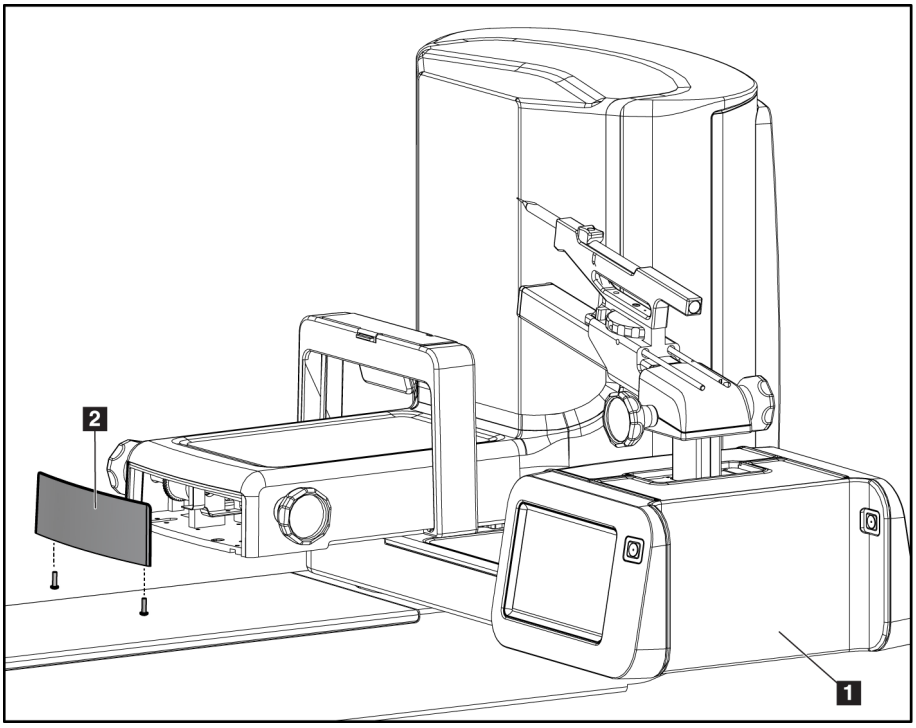


Figure 151: Removal of rear-end cover of Compression Arm

8.4.7 Remove Displays/Covers of Biopsy Control Module

1. Rotate the Biopsy Arm so it is perpendicular to the C-arm.
2. Remove the two screws from under the display cover of the Biopsy Control Module.
3. Disconnect the cables at the back of the display.
4. Remove the display cover.
5. Repeat the previous steps for the other side, if necessary. (See the following figure.)

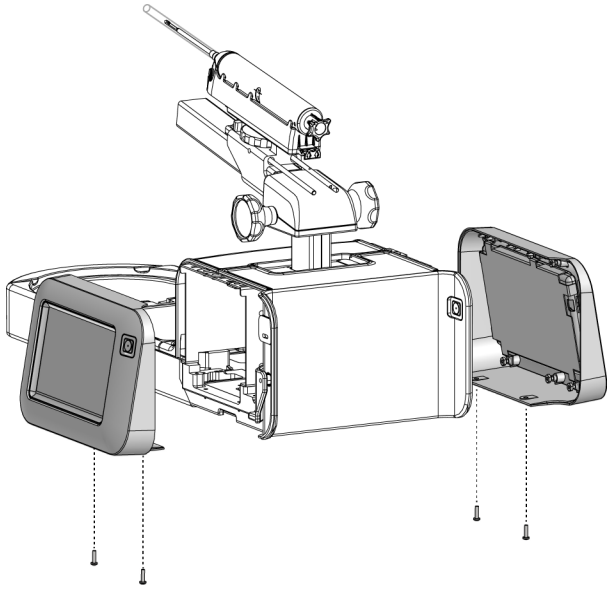


Figure 152: Removal of displays/covers of Biopsy Control Module

8.4.8 Remove Top Cover of Biopsy Arm

1. Remove the two displays and their covers from the Biopsy Control Module. (Refer to *Remove Displays/Covers of Biopsy Control Module* on page 190.)
2. Remove the front-end cover of the Biopsy Control Module. (Refer to *Remove Front-end Cover of Biopsy Control Module* on page 192.)
3. Loosen the four screws under the Biopsy Arm that secure the top cover. This action frees the top cover for removal. (See the following figure.)
4. Remove the top cover of the Biopsy Arm by lifting it up slightly, then sideways, away from the Biopsy Arm. (See the following figure.)

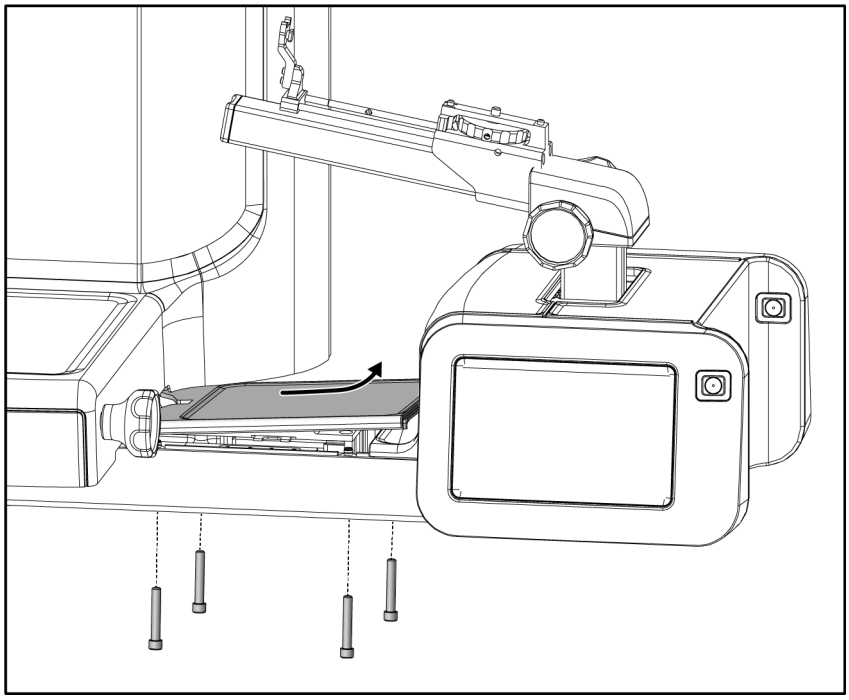


Figure 153: Removal of top cover of Biopsy Arm

8.4.9 Remove Front-end Cover of Biopsy Control Module

1. Rotate the Biopsy Arm so it is perpendicular to the C-arm.
2. Remove the two screws under the front end of the Biopsy Control Module that secure the front-end cover.
3. Remove the front-end cover. (See the following figure.)

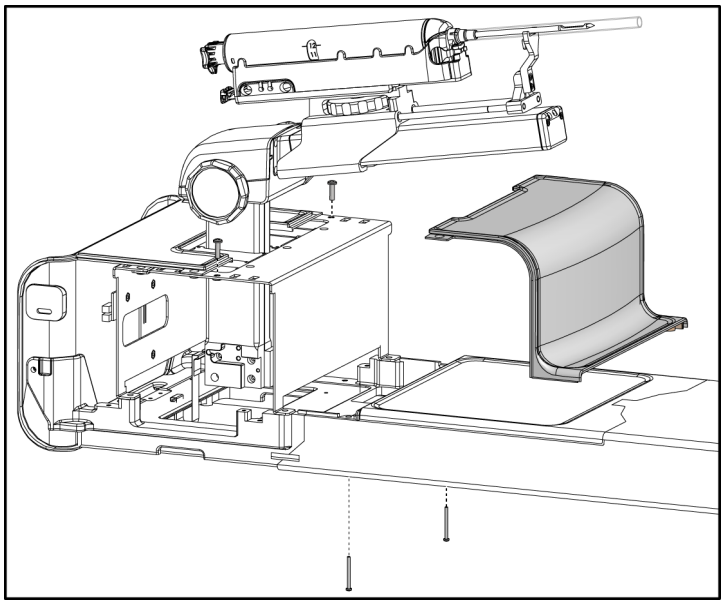


Figure 154: Removal of front-end cover of Biopsy Control Module

8.4.10 Remove Rear-end Cover of Biopsy Control Module

1. Rotate the Biopsy Arm so it is perpendicular to the C-arm.
2. Remove the four screws (two under the Biopsy Arm, one from the side, and one from the top). (See the following figure.)
3. Remove the rear-end cover of the Biopsy Control Module. (See the following figure.)

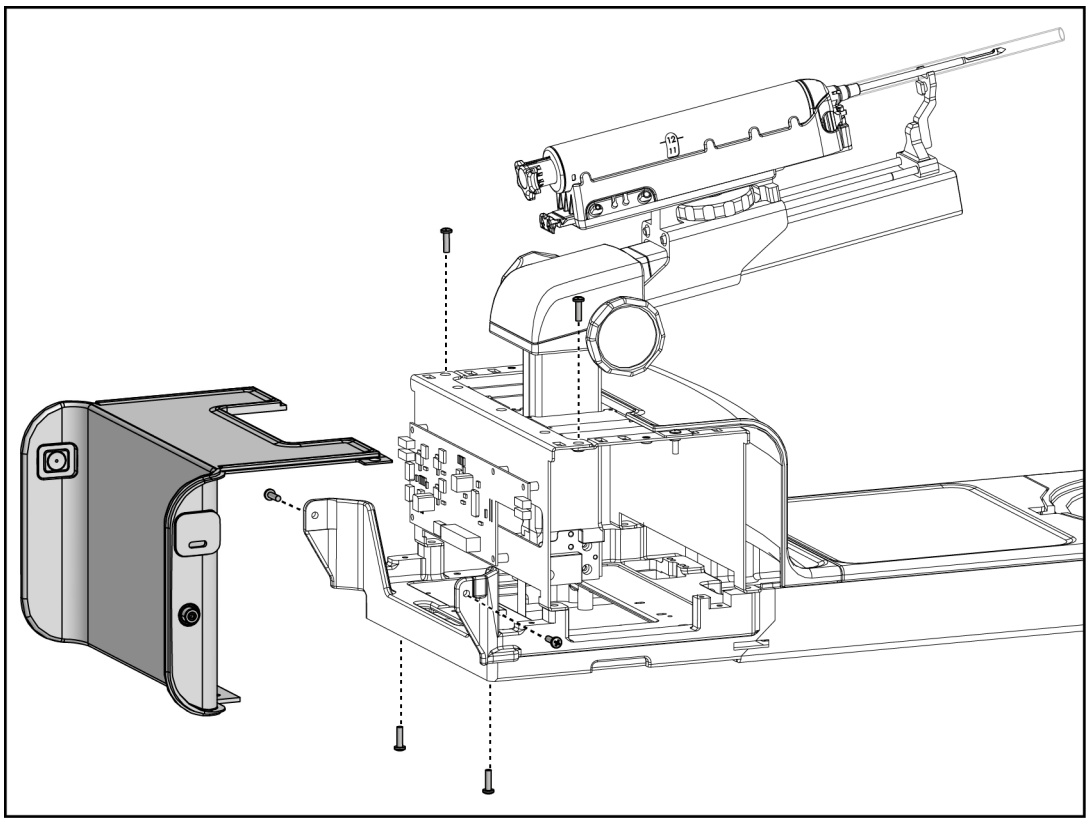


Figure 155: Removal of rear-end cover of Biopsy Control Module

8.4.11 Remove Bottom Cover of Biopsy Control Module Display

1. Rotate the Biopsy Arm so it is perpendicular to the C-arm.
2. Remove the four screws under the Biopsy Control Module that secure the bottom cover.
3. Remove the bottom cover of the Biopsy Control Module. (See the following figure.)

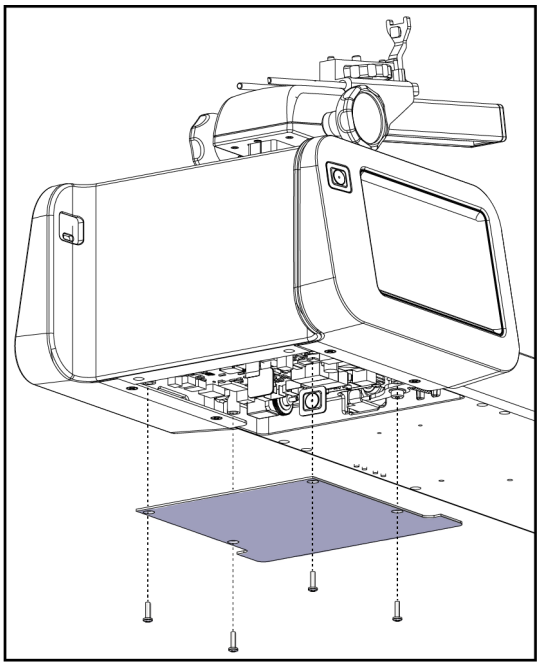


Figure 156: Removal of bottom cover of Biopsy Control Module

8.4.12 Remove Bottom Plate of Support Arm

1. Disconnect the Control Handle cable that is plugged into the external underside of the bottom plate of the Support Arm.
2. Remove the (sixteen) screws from the bottom plate. (See the following figure.)

Note
As you remove the 16 screws from the bottom plate, move the Control Handle as needed in order to obtain sufficient room to remove each screw.

3. Remove the bottom plate from the Support Arm.

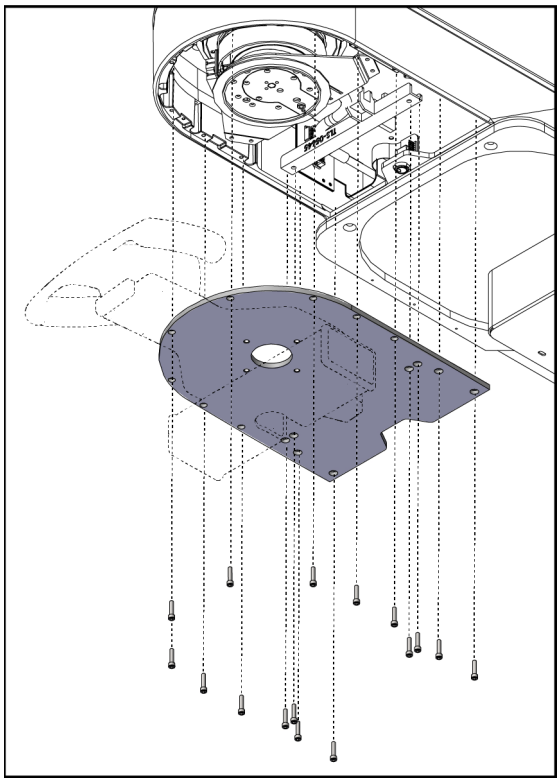


Figure 157: Removal of bottom plate of Support Arm

8.5 Component Replacement Procedures

8.5.1 Replace the Filter Wheel Assembly

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system.
2. Rotate the Biopsy Arm so that it is perpendicular to the C-arm.
3. Remove the rear cover of the Tubehead. (Refer to *Remove Rear Cover of Tubehead* on page 185.)
4. Remove the Tubehead front cover. (Refer to *Remove Front Cover of Tubehead* on page 186.)
5. Locate the Filter Wheel Assembly (see the following figure) and disconnect all assembly harnesses. Note the type and location of each connection.
6. Remove the four screws that secure the Filter Wheel Assembly (including mounting bracket) to the Tubehead. (See the following figure.)
7. Remove the Filter Wheel Assembly.

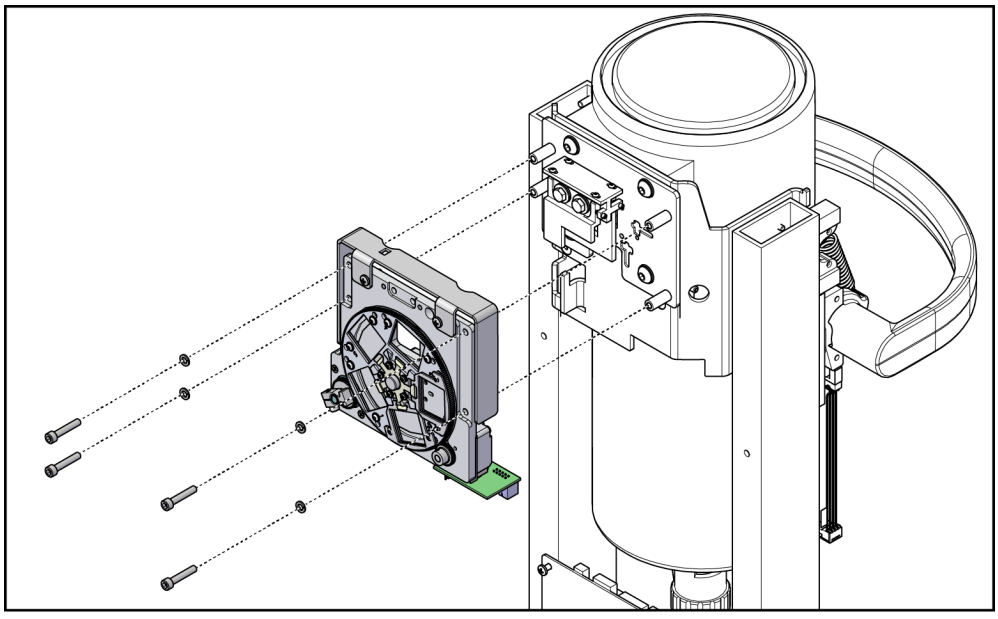


Figure 158: Removal/replacement of Filter Wheel Assembly

Replacement

1. Install the replacement Filter Wheel Assembly to the Tubehead, using the four screws. (See the previous figure.)
2. Reconnect the assembly harnesses.
3. Reinstall the front cover of the Tubehead.
4. Reinstall the rear cover of the Tubehead.
5. Rotate the Biopsy Arm so it is parallel with the C-arm.
6. Power ON the system and verify proper operation.

8.5.2 Replace Biopsy (Stage) Arm Motor Drive Board

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system.
2. Rotate the Biopsy Arm so it is perpendicular to the C-arm.
3. Remove the rear cover of the Biopsy Control Module. (Refer to *Remove Rear-end Cover of Biopsy Control Module* on page 193.)

4. Locate the Biopsy Arm Motor Drive Board and disconnect all harnesses/cables. (See the following figure.)
5. Unfasten the screws that secure the board to the Biopsy Arm assembly and remove the board. (See the following figure.)

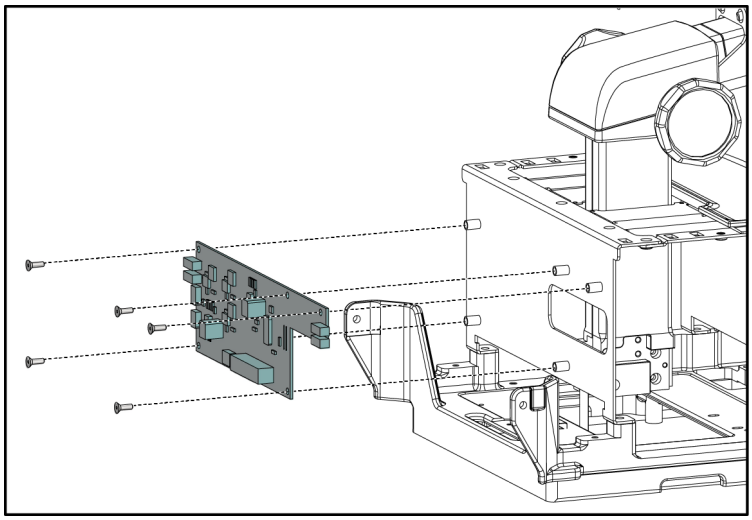


Figure 159: Removal/replacement of Biopsy Arm Motor Drive Board

Replacement

1. Secure the new motor drive board to the Biopsy Arm assembly.
2. Reconnect all harnesses/cables.
3. Reinstall the rear cover to the Biopsy Control Module.
4. (Optional) Rotate the Biopsy Control Module so it is parallel with the C-arm.
5. Power ON the system and verify proper operation.

8.5.3 Replace Compression Arm Control Board

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system.
2. Remove the covers and components necessary to gain access to the Compression Arm Control Board.
   a. Remove the Detector-end cover of the Tube Arm Mechanism. (Refer to *Remove Detector-end Cover of Tube Arm Mechanism* on page 187.)
   b. Remove the Detector-end cover of the Compression Arm. Refer to (*Remove Detector-end Cover of Compression Arm* on page 188.)
   c. Remove the Image Detector. (Refer to *Replace Image Detector* on page 207.)
   d. Remove the cover at the rear-end of the Breast Platform of the Compression Arm by removing the two screws underneath. (See the following figure.)

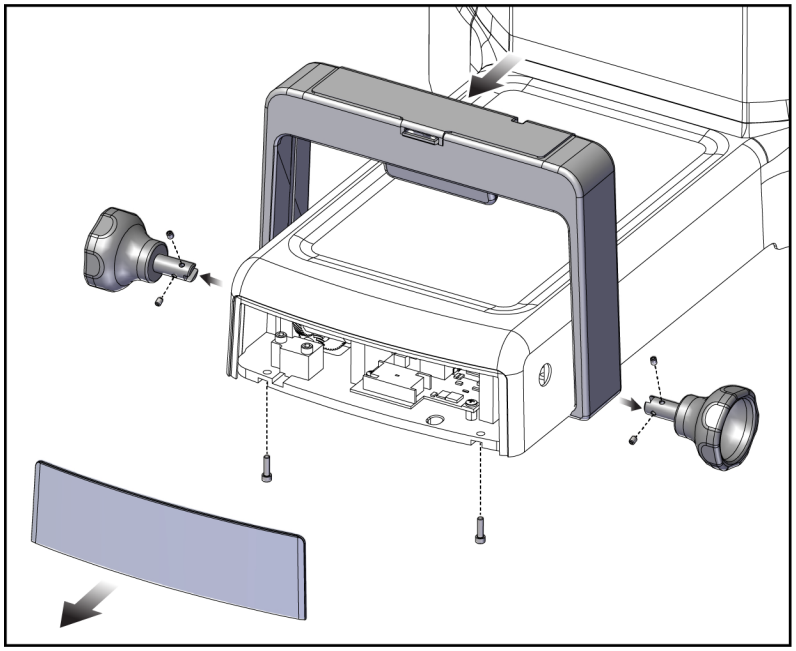


Figure 160: Removal of rear-end cover and knobs of Compression Arm

   e. Remove the two rotation release knobs from the Compression Arm platform by fully removing—not merely loosening—the two set screws for each knob. (See the previous figure.)
   f. Move the Paddle Mount as far as possible toward end-of-travel at the rear-end of the Breast Platform of the Compression Arm. (See the previous figure.)

g. Remove the six screws that secure the carbon fiber Breast Platform of the Compression Arm. (See the following figure, items 1, 2, and 3.)

- Two screws at the bottom corners of the Detector-end of the breast platform (item 1).
- Two screws in the central internal area (item 2).
- Two screws under the rear-end (item 3).

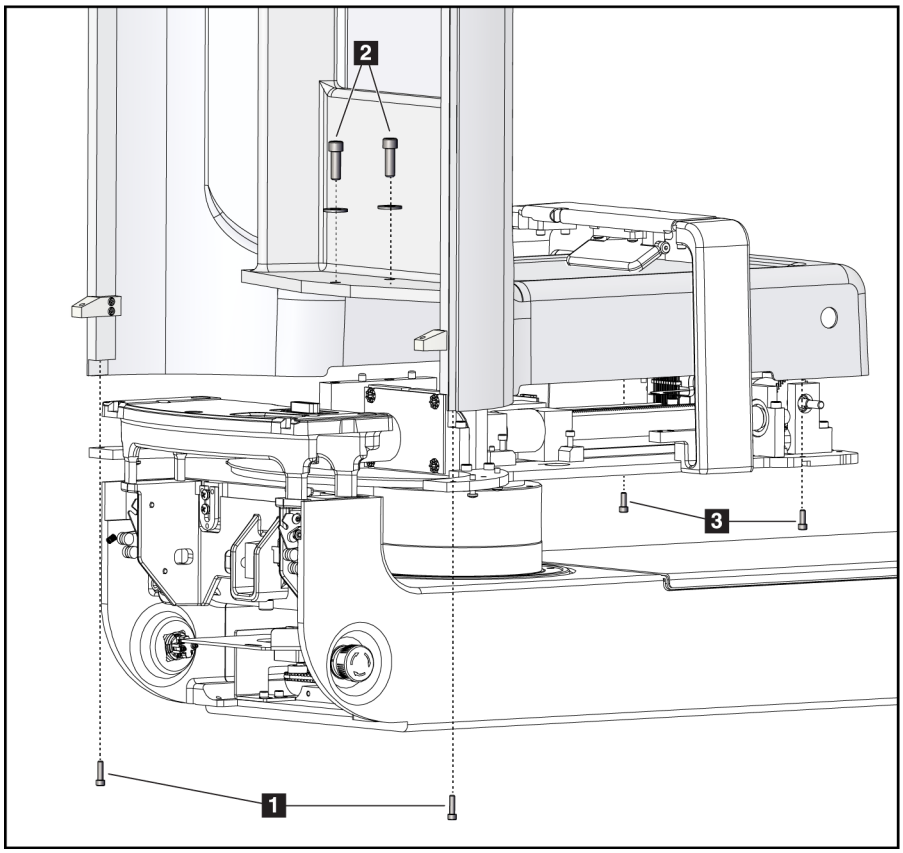


Figure 161: Removal of screws for Breast Platform of Compression Arm

h. Remove the entire carbon fiber Breast Platform of the Compression Arm—from Detector-end to rear-end—by pulling it out in the direction of the Detector-end.

3. Locate the Compression Arm Control Board (see the following figure) and disconnect all harnesses/cables.
4. Remove the Compression Arm Control Board (four screws). (See the following figure.)

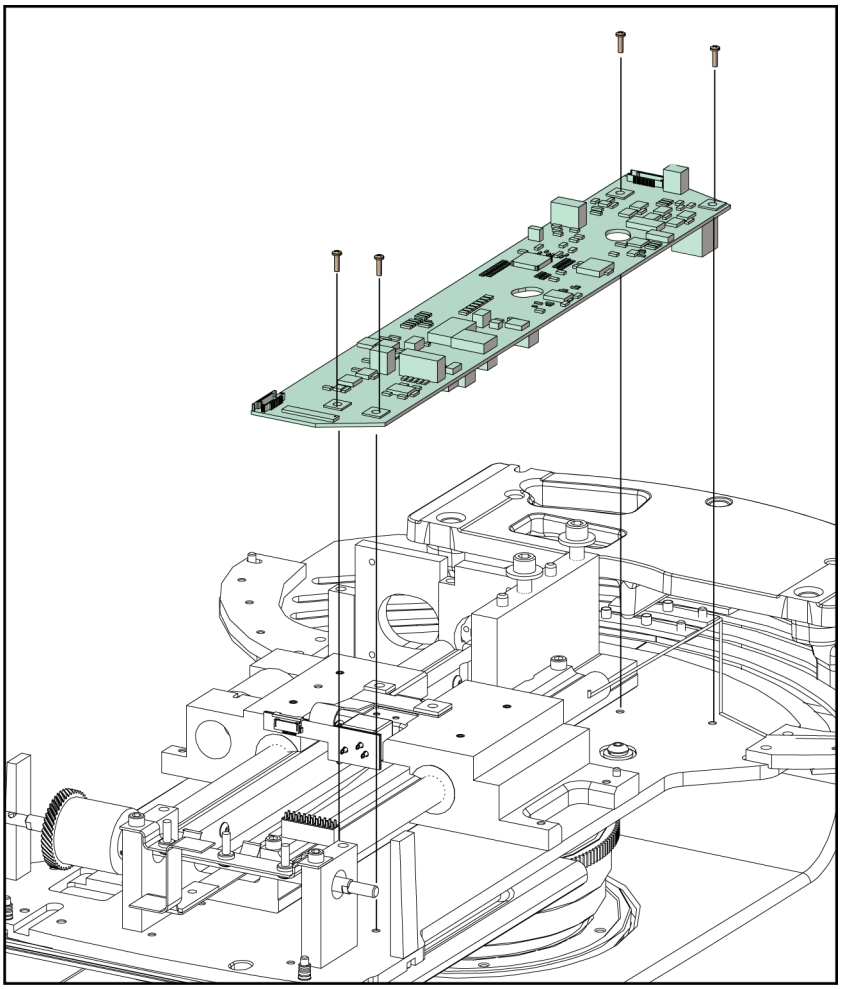


Figure 162: Removal/replacement of Compression Arm Control Board

Replacement

1. Install the new Compression Arm Control Board. (See the previous figure.)
2. Reconnect all harnesses/cables to/from the new board.
3. Reinstall the covers and components previously removed.
4. Power ON the system and verify proper operation.

8.5.4 Replace the Magnetic Rotary Encoder Assembly

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Refer to items 1, 2, and 3 in the following figure for a general view of where the three Magnetic Rotary Encoder Board assemblies are located. For each of the three encoder board assemblies, remove the appropriate covers or components in order to gain access to its location.

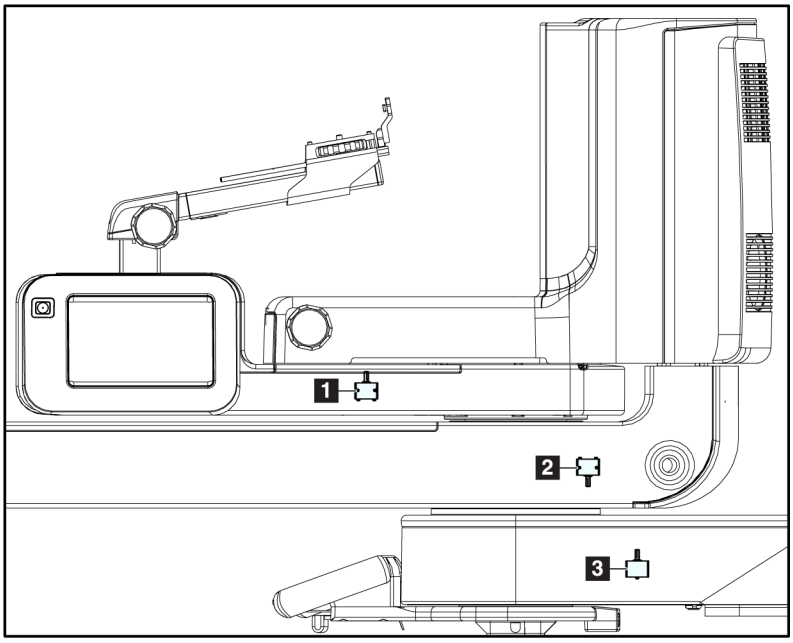


Figure Legend

1. Inside Biopsy Arm
2. Inside Tube Arm Mechanism
3. Inside Support Arm

Figure 163: Locations of Magnetic Rotary Encoder Board Assemblies

Removal

1. Power OFF the system.
2. Perform one of the following subset of steps that pertain to the encoder board assembly you are removing/replacing.

Tip
When removing the encoder board assembly, separate the assembly from any gear/belt by simply loosening the two screws of the encoder assembly bracket. This action provides you with sufficient slack to lift away the belt and remove/replace the encoder board assembly.

Removal of Encoder Board Inside Biopsy Arm

a. Remove the top cover of the Biopsy Arm. (Refer to *Remove Top Cover of Biopsy Arm* on page 191.)

b. Remove the entire encoder assembly (magnet, board, and bracket) by removing the two screws that secure the bracket to the frame. (See the adjacent figure.)

c. Remove the two screws that secure the encoder board assembly to the encoder.

d. Disconnect all connections to/from the encoder board assembly.

e. Remove the encoder board assembly. (See the adjacent figure.)

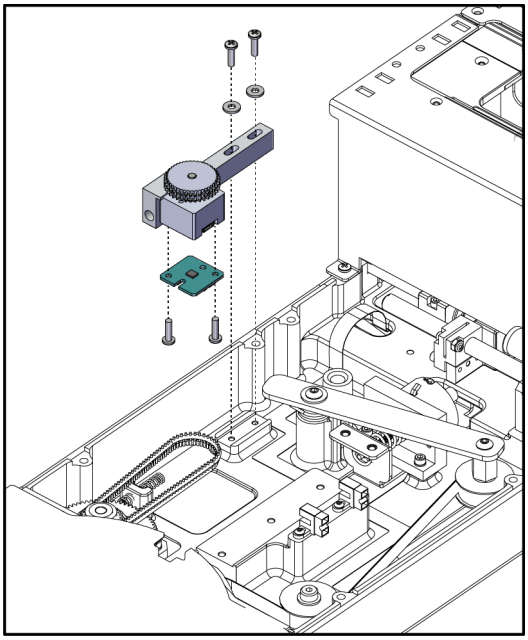


Figure 164: Magnetic Rotary Encoder Board Assembly inside Biopsy Arm

Removal of Encoder Board Inside Tube Arm Mechanism

a. Remove the Detector-end cover of the Tube Arm Mechanism (two screws). (Refer to *Remove Detector-end Cover of Tube Arm Mechanism* on page 187.)

b. Remove the entire encoder assembly (magnet, board, and bracket) by removing the two screws that secure the bracket to the frame. (See the adjacent figure.)

c. Remove the two screws that secure the encoder board assembly to the encoder. (See the adjacent figure.)

d. Disconnect all connections to/from the encoder board assembly.

e. Remove the encoder board assembly.

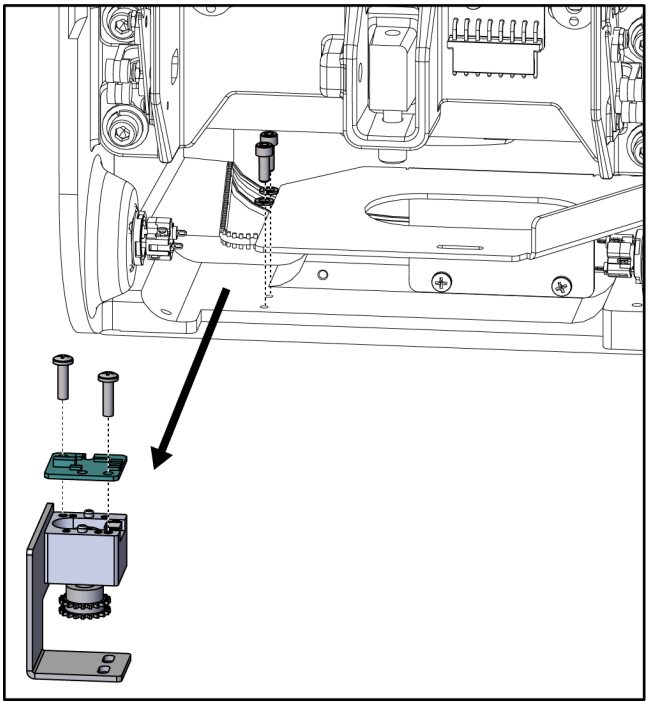


Figure 165: Magnetic Rotary Encoder Board Assembly inside Tube Arm Assembly

Removal of Encoder Board Inside Support Arm

a. Remove the bottom plate from the Support Arm. (Refer to *Remove Bottom Plate of Support Arm* on page 195.)

b. Remove the two screws that secure the encoder board assembly to the encoder. (See the adjacent figure.)

c. Disconnect all connections to/from the encoder board assembly.

d. Remove the encoder board assembly.

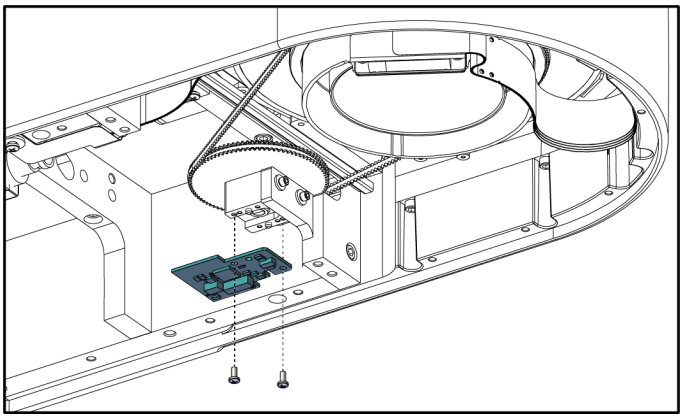


Figure 166: Magnetic Rotary Encoder Board Assembly inside Support Arm

Replacement

1. Install the new Magnetic Rotary Encoder Board assembly to the encoder. (See the previous figures in this section.)
2. Restore all connections to/from the encoder board and related components.
3. Reinstall the previously removed cover or plate.
4. Power ON the system and verify proper operation.

8.5.5 Replace Biopsy (Stage) Arm Control Board

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

1. Using the control handle, pull the C-arm away from the Gantry/patient platform as much as possible.
2. Rotate the Biopsy Arm so it is perpendicular to the C-arm.
3. Power OFF the system.
4. Unfasten the four screws for the bottom cover under the Biopsy Control Module and remove the cover.

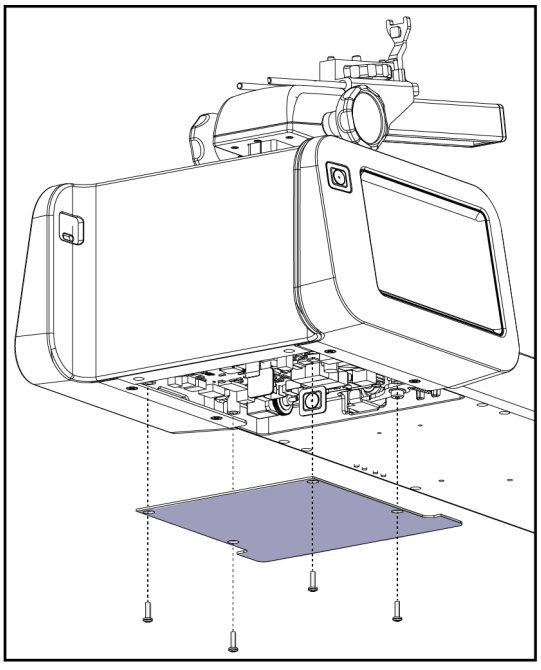


Figure 167: Removal of bottom cover of Biopsy Control Module

5. Locate the Stage Arm Control Board (see the following figure) and disconnect all harnesses/cables.
6. Unfasten the four screws that secure the Stage Arm Control Board and remove the board.

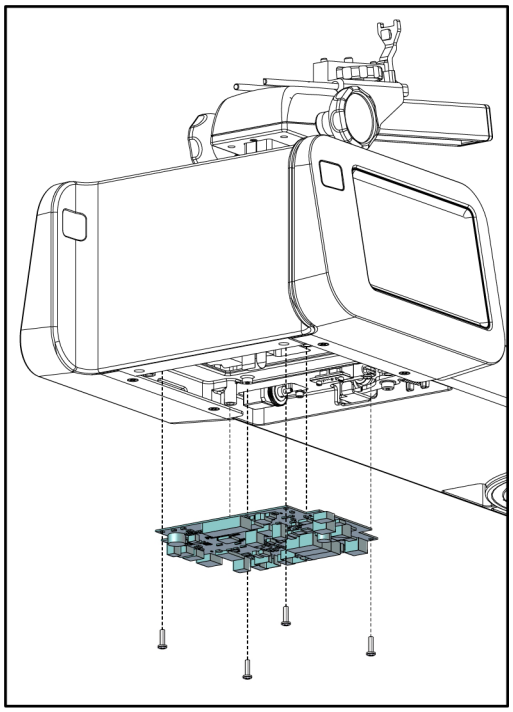


Figure 168: Removal/replacement of Stage Arm Board

7. Secure the new Stage Arm Board (four screws).
8. Reconnect all harnesses/cables.
9. Reinstall the bottom cover of the Biopsy Control Module.
10. Power ON the system.
11. Rotate the Biopsy Control Module and verify proper arm detent positions.
12. Perform the QAS test from the Admin menu (refer to *The QAS Test* on page 161).

8.5.6 Replace Image Detector

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Quick Checklist When Replacing the Image Detector

- ☐ A. Check for custom changes to image processing parameters (refer to *A. Check for Custom Changes in Image Processing Parameters* on page 208).
- ☐ B. Power down system (refer to *How to Remove All Power from the System* on page 82).
- ☐ C. Remove Image Receptor (refer to *C. Remove the Image Detector* on page 208).
- ☐ D. Install new Image Receptor (refer to *D. Install the New Image Detector* on page 213).
- ☐ E. Power up system (refer to *How to Start the System* on page 79).
- ☐ F. Copy detector files from CD to %M35_DET_DIR% (refer to *F. Copy Detector Files from CD to M35_DET_DIR* on page 214).
- ☐ G. Determine and Load the Proper Detector Software (refer to *G. Determine and Load the Proper Detector Software* on page 215).
- ☐ H. Verify correct detector versions and ROS have been loaded (refer to *H. Verify Correct Detector and ROS Versions Have Been Loaded* on page 216).
- ☐ I. In CalTool, perform the Detector tasks (Dark Offset, Goaltab Generation, Goaltab Scale, and Tomo Biopsy Scale Factor). Follow the steps listed in each task. (To access CalTool, refer to *Calibration Tool (CalTool)* on page 138).
- ☐ J. In CalTool, perform AEC Scaling Verification. Follow the steps listed in that task.
- ☐ K. Enter custom image processing parameters (if needed). Refer to *K. Enter Custom Image Processing Parameters (If Needed)* on page 218.
- ☐ L. Perform a system Gain Calibration (see the *User Guide*).
- ☐ M. In CalTool, perform the X-ray Field Detector Alignment (refer to *X-Ray Field Detector Alignment* on page 145).
- ☐ N. Perform Geometry calibration (refer to *Geometry Calibration Procedure* on page 158).
- ☐ O. Perform STX calibration (refer to *STX Calibration* on page 159).

A. Check for Custom Changes in Image Processing Parameters

1. From the Acquisition Workstation, select **Admin**.
2. Go to **System Tools > Film and Imaging > Image Processing > 2D > Edit Parameters**.
3. Check for any custom changes (bold values) to the image processing parameters and record those values and its parameter name. Take a screen shot if it is easier to capture (see following figure).

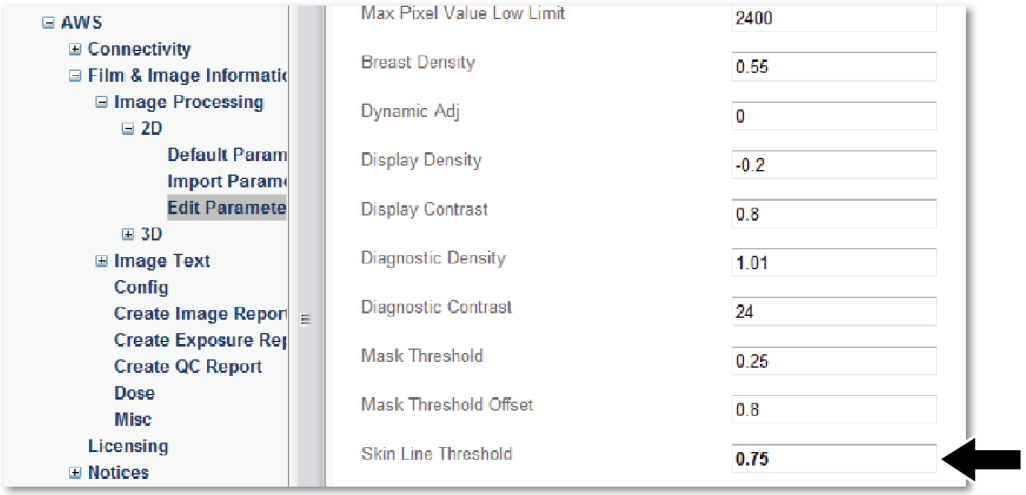


Figure 169: Custom Value (in bold) in Image Processing Parameters in System Tools

4. Exit System Tools and shutdown the application.

B. Power Down the System

Refer to *How to Remove All Power from the System* on page 82.

C. Remove the Image Detector

1. Remove the Detector-end cover of the Tube Arm Mechanism (by removing two screws and pulling the cover out of snap fasteners). (See the following figure.)

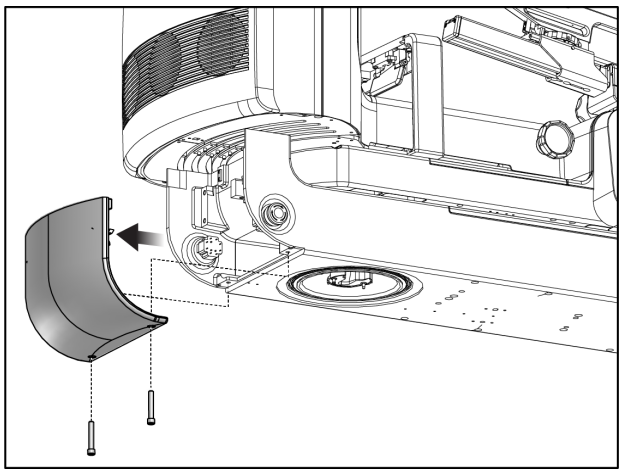


Figure 170: Removal of Detector-end cover of Tube Arm Mechanism

2. Remove the Detector-end cover of the Compression Arm. (See the following figure.)
   a. Remove the two middle SEMS screws and the side screws (captive and spring-loaded) at the bottom two corners of the cover. The cover stays on after you remove the screws, but use caution.
   b. Partially pull off the cover.
   c. Before you fully remove the cover, move it out of position and disconnect the fan control harness connector. The connector is at the center edge of the joined pinch guards.
   d. Remove the fan control harness connector from the joined pinch guards.
   e. Remove the p-clip that is attached to one of the joined pinch guards. (Do not remove the other p-clip, which is fastened to the Compression Arm.)
   f. Finish removing the cover. (Refer to the following note.)

Note
The top and side edges of the Detector-end cover fit (without screws) into the Detector-end of the Compression Arm Breast Platform. After you remove the screws in the previous step, angle the bottom of the cover and pull it off. You may feel some resistance along the perimeter of the cover as you remove it.

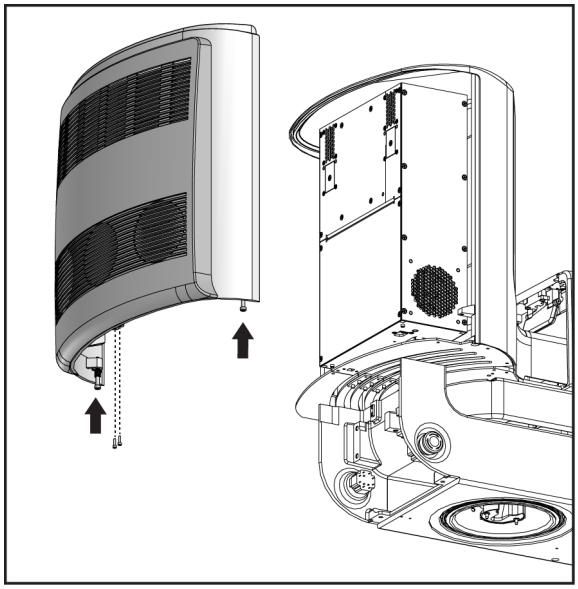


Figure 171: Detector-end cover of Compression Arm (left), Image Detector (upper right)

3. Remove the two joined pinch guards by removing the seven screws. (There are two screws at each end plus three in the middle.) Then slide out each of the two separated pinch guards. (See the following figure.)

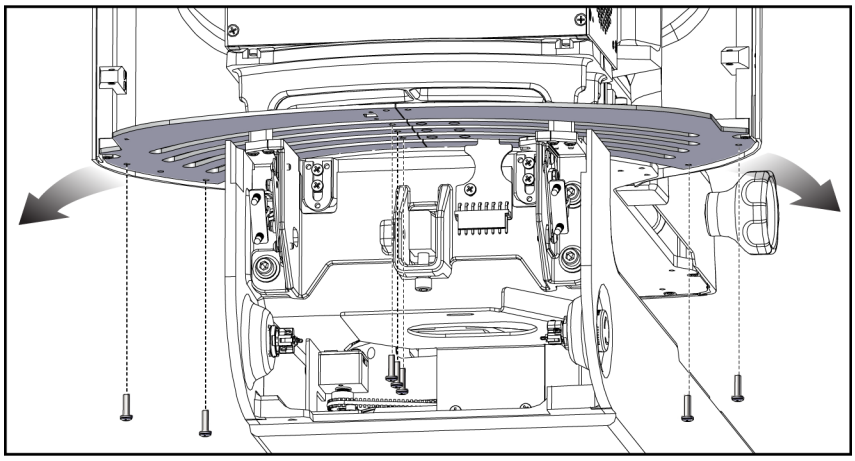


Figure 172: Removal of pinch guard from Image Detector

4. Disconnect the two cable connectors (electrical and fiber optic) from the Detector (see the following figure:
   a. Unfasten the detector interface board (one screw) with ribbon cable (item 1) under the detector mounting platform and let it hang safely out of the way.
   b. Unclip the detector fiber optic cable (item 2) and let it hang safely out of the way under the mounting platform.

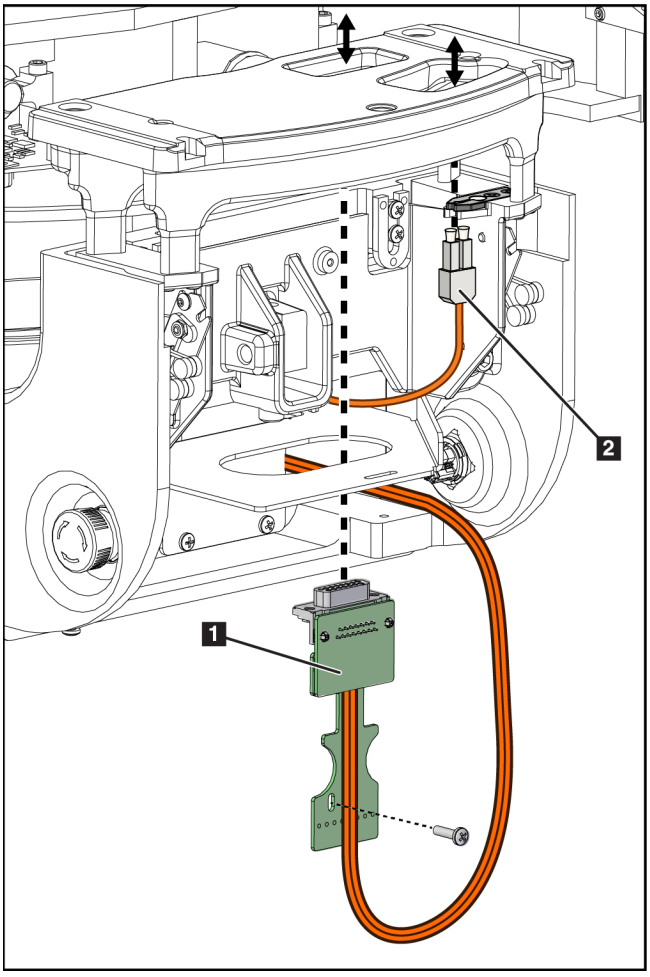


Figure 173: Disconnecting detector cables to detector (detector not shown for better clarity)

5. Lower the Detector mounting platform to obtain sufficient clearance at the top of the Detector to slide it out horizontally from under the Compression Arm platform:
   a. Loosen the set screw on the left side of the bracket that houses the height adjust screw for the Detector mounting platform. (Loosen the set screw about one to two turns.) (See the following figure. The height adjust screw is in the center of the illustration and is indicated with an arrow.)
   b. Lower the two U-brackets (under the Detector mounting platform) by loosening four screws (two in left bracket, two in right) until the brackets are at end-of-travel. Then tighten the screws to secure the hard stops. (See following figure.)
   c. Loosen the four screws under the Detector mounting platform, as indicated with four arrows in the following figure. (Loosen about one to two turns.)
   d. Loosen the fifth screw (indicated in the center of the following figure with an arrow) until the mounting platform height begins to lower. This screw is the height adjust screw for the Detector mounting platform. Loosening this screw frees the platform for vertical movement.
   e. Continue to lower the mounting platform until there is sufficient clearance at the top of the Detector.

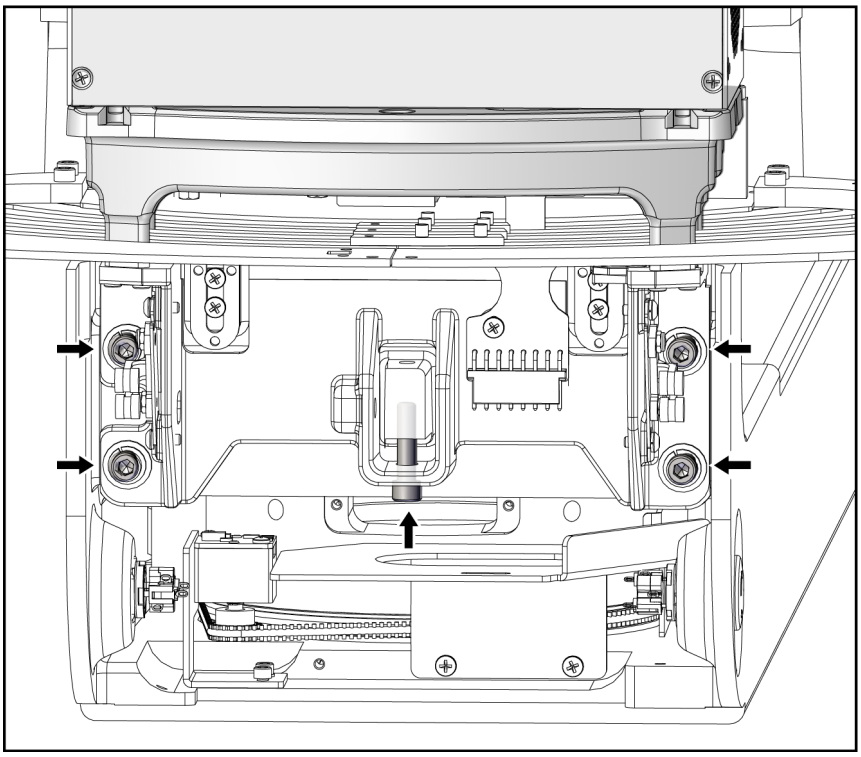


Figure 174: Loosen these screws to lower Detector mounting platform for removal

6. Remove the two screws that secure the Detector to its mounting platform. (See the following figure.)
7. Remove the Detector by pulling it horizontally out of its location. (See the following figure.)

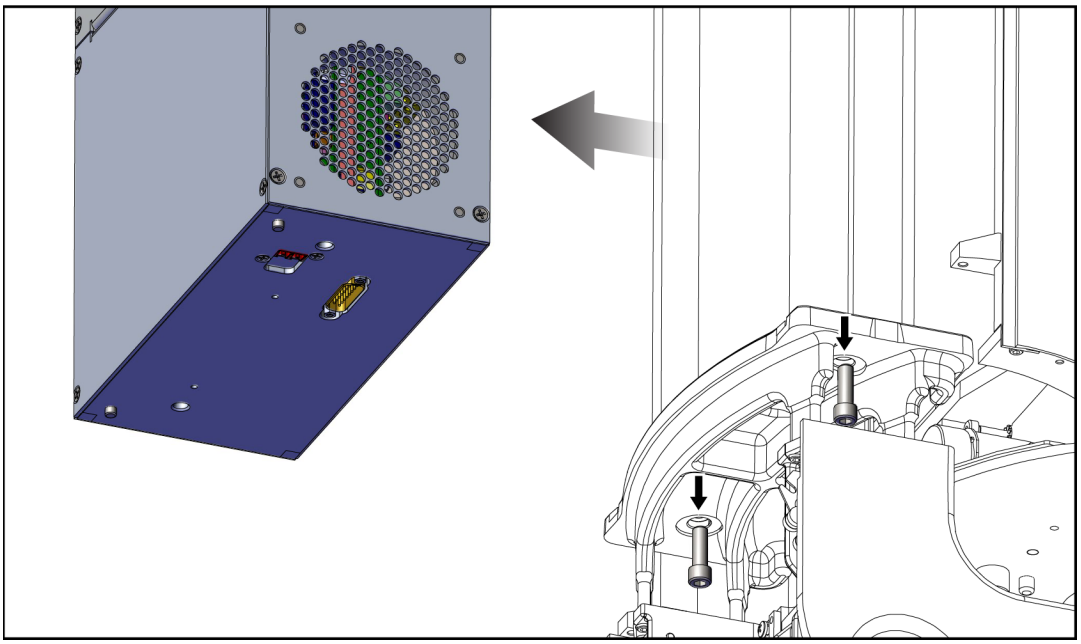


Figure 175: Removal of Detector from its platform

D. Install the New Image Detector

1. Install the new Detector on its platform and secure with its screws.
2. Reconnect the electrical and fiber optic connectors.
3. Raise the Detector mounting platform to its original height (see the figure *Adjusting Detector Mounting Platform* on page 212 for the mounting screw locations).
4. Reinstall the pinch guard by rejoining both halves with the seven screws and securing to the underside of the Detector.
5. Reinstall the p-clip and pinch screws previously removed from the joined pinch guard.
6. Reconnect the fan wire harness connector.
7. Reinstall the Detector-end cover of the Detector by sliding and fitting its top and side edges into the Detector-end of the carbon fiber Breast Platform.
8. Reinstall the Detector-end cover of the Tube Arm Mechanism.

E. Power Up the System

Refer to *How to Start the System* on page 79.

F. Copy Detector Files from CD to M35_DET_DIR

1. Verify that the serial number on the CD supplied with the detector matches the serial number of the detector.
2. Copy the Image Receptor files from the CD.
   a. From any Applications screen, press the Windows key.

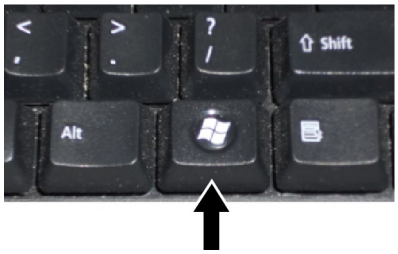


Figure 176: Windows Key on Keyboard

   b. Type **%M35_DET_DIR%** into the command box and press **Enter**.

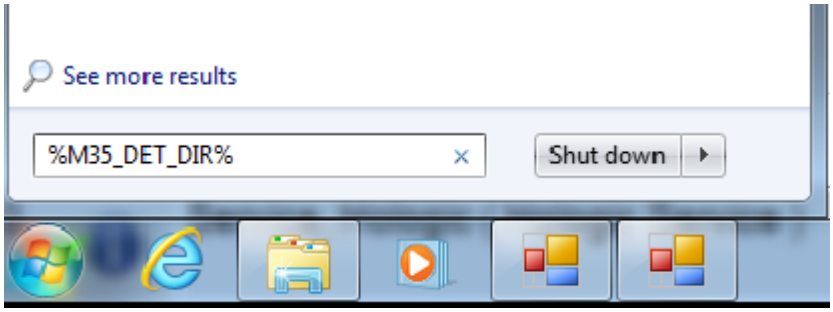


Figure 177: Accessing M35 Detector Directory

   c. If the command is typed correctly, the M35 Folder appears.

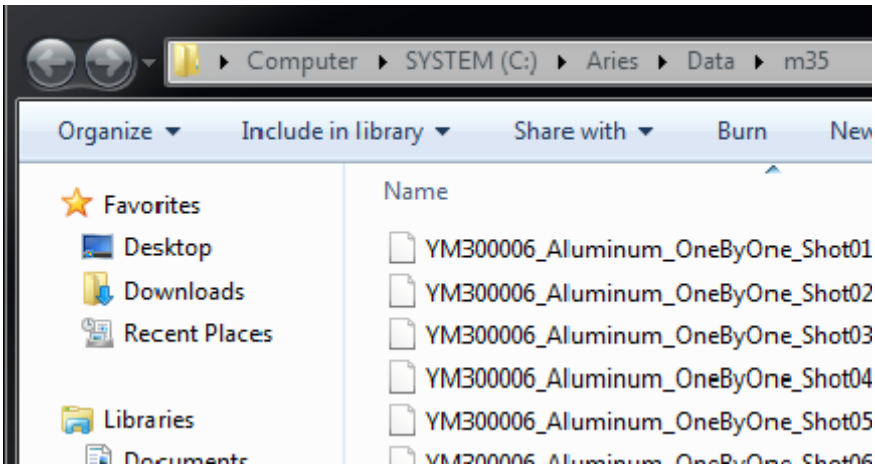


Figure 178: M35 Folder

   d. Copy the six detector files from the Image Receptor CD to the M35 folder.

G. Determine and Load the Proper Detector Software

1. Exit and close the application by selecting **LOGOUT** and holding down the CTRL key and clicking through the **SHUTDOWN**, then **EXIT** buttons.
2. Navigate to the **CalTools.bat** file and launch CalTool.
3. Select **Upload Code** under the *Diagnostics* section on the left side of the CalTool window.
4. Select the **Execute Procedure** tab.
5. Select **Auto Select** in the *Node to update* selection box.
6. Select **Next Step**.
7. If Auto Select succeeds, proceed to Step 8 to load the readout sequence.

   If Auto Select fails, the node software must be loaded manually by following the substeps. The following software needs to be loaded:

   - loader-mfd_DESIRED VERSION.package
   - mfd_DESIRED VERSION.package
   - mfd-mac-fpga-fDESIRED VERSION-hpDESIRED VERSION.package

   a. Select **DET** in the *Node to update* selection box. Refer to the software list in previous three bullets.

   b. Browse to the first software file on the list corresponding to the detector family and select **Open** to upload the file.

   c. Select **Next** to continue the procedure. The download begins automatically. Be patient, as the download and detector configuration may take some time, depending on the package. It is normal for the detector to reboot after completion of the operation.

   d. When the download has completed successfully, the bottom right message window displays something similar to the following:

      Status:Success(0x00)

      If the output contains the word "fail", repeat the download process. To repeat the download, click the **Next** button until you are at the DET node selection, then repeat the steps b - d.

      Sometimes the detector may not come back on. Wait some time and then cycle the Gantry power off and back on.

   e. Select **Next** again.

   f. At the prompt *Do you wish to perform another software upgrade?*, click **Yes.**

   g. Repeat Steps a – f for the remaining software package files.

8. Load the readout sequence. The readout sequence is not loaded as a part of Auto Select and must be loaded separately.
   a. Select **DET** in the *Node to update* selection box. The following readout sequence needs to be loaded:
      - MFD_DESIRED VERSION.ros.package
   b. Browse to the desired readout sequence package and select **Open** to download the file.
   c. Select **Next** to continue the procedure. The download begins automatically.
   d. When the download has completed successfully, the bottom right message window displays something similar to the following:

      END NODE DOWNLOAD

      Status:Success(0x00)

      If the output contains the word "fail", repeat the download process. To repeat the download, click the **Next** button until you are at the DET node selection, then repeat the steps b - d.

H. Verify Correct Detector and ROS Versions Have Been Loaded

1. While still in CalTool in the Upload Code, Execute Procedure tab, click **Advanced Form**.
2. Check the Nodes window and verify versions.

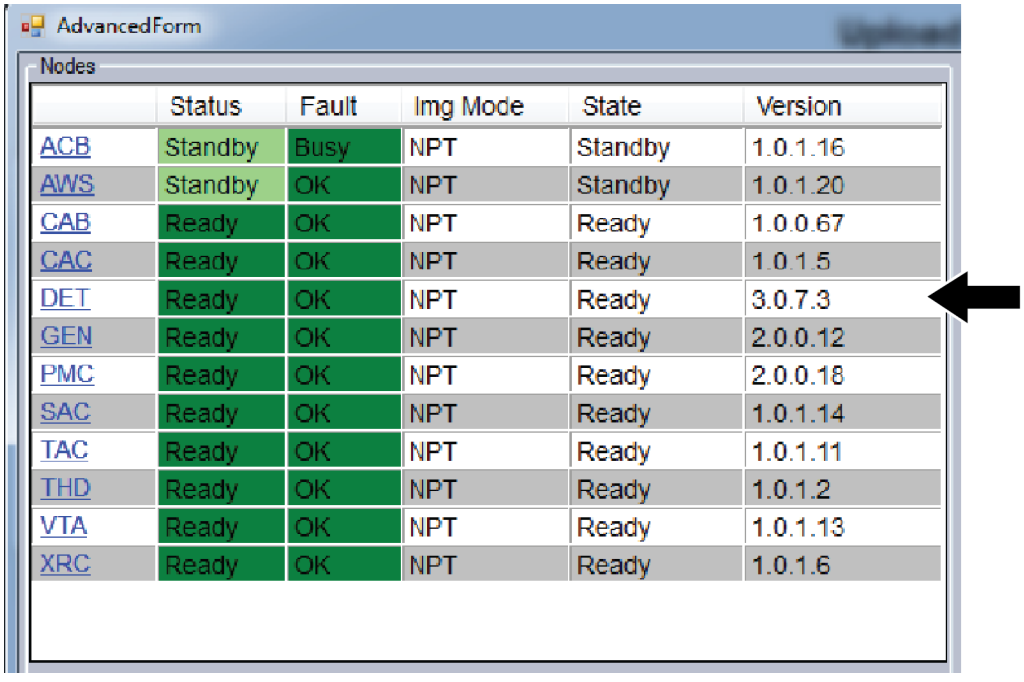


Figure 179: Verifying Versions in Nodes Window

3. Click the **DET** tab (item 1 in following figure); then click the **Settings** tab (item 2).
4. Verify the proper versions in the fields called out in items 3 and 4 in the following figure.

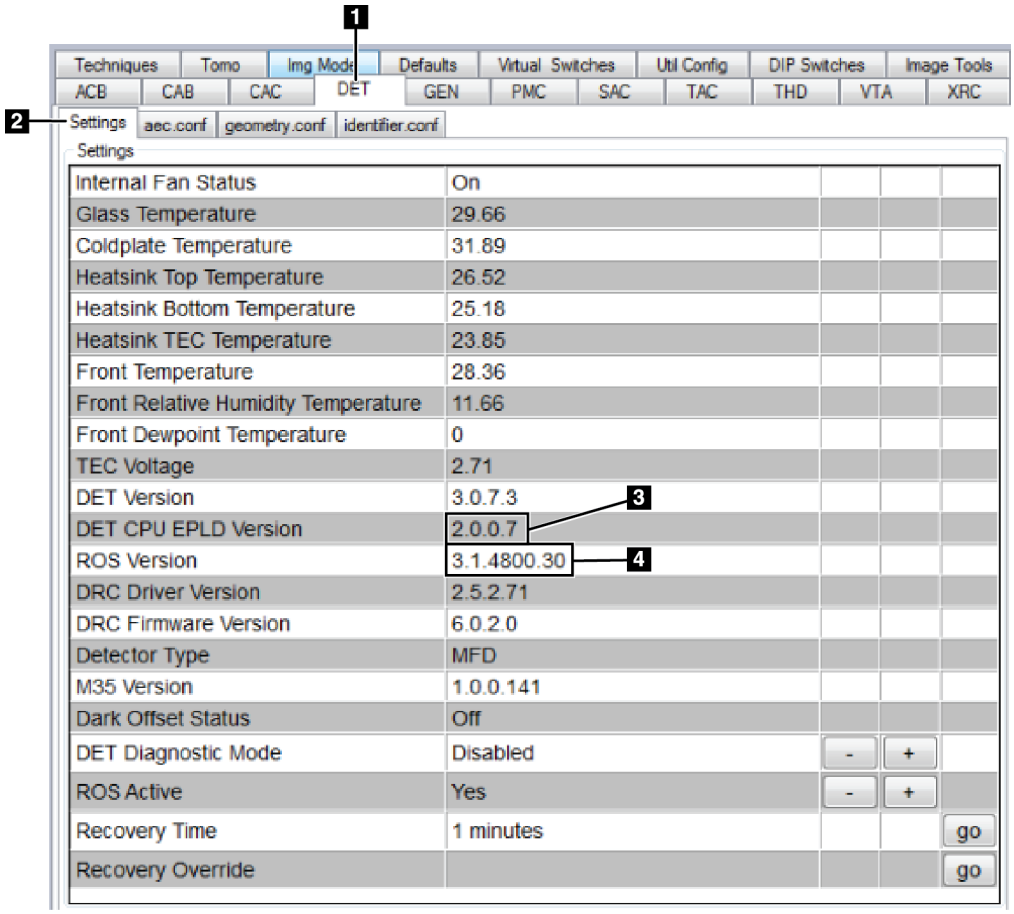


Figure 180: Verifying Versions in Settings Tab

5. Allow the detector time to stabilize.

I. Perform Detector Tasks using CalTool

In CalTool, under the Detector group in the Task Bar, perform the tasks of Dark Offset, Goaltab Generation, Goaltab Scale, and Tomo Biopsy Scale Factor in that order. Follow the steps listed for each task. To access CalTool, refer to *Calibration Tool (CalTool)* on page 138.

J. Perform AEC Scaling Verification using CalTool

In CalTool, under the Verification group in the Task Bar, perform AEC Scaling Verification. Follow the steps listed in the task. To access CalTool, refer to *Calibration Tool (CalTool)* on page 138.

K. Enter Custom Image Processing Parameters (If Needed)

1. Exit CalTool.
2. Start the application and log in as Service.
3. If custom image processing parameters were found in step *A. Check for Custom Changes in Image Processing Parameters,* go to **System Tools > Film and Imaging > Image Processing > 2D > Edit Parameters**.
4. Modify as needed to replace the default values with the custom values previously recorded.

L. Perform System Gain Calibration

Refer to the *User Guide*.

M. Perform X-Ray Field Detector Alignment using CalTool

Refer to *X-Ray Field Detector Alignment* on page 145.

N. Perform Geometry Calibration

Refer to *Geometry Calibration Procedure* on page 158.

O. Perform STX Calibration

Refer to *STX Calibration* on page 159.

8.5.7 Replace the VTA Control Board

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system.
2. Remove the rear cover and rear inside cover from the Gantry assembly. Refer to *Covers Removal - Gantry Section* on page 182.
3. Locate the VTA Control Board (See the following figure.)
4. Disconnect all cable connections to/from the board. Note the type and location of each connection.
5. Remove the VTA Control Board (four screws).

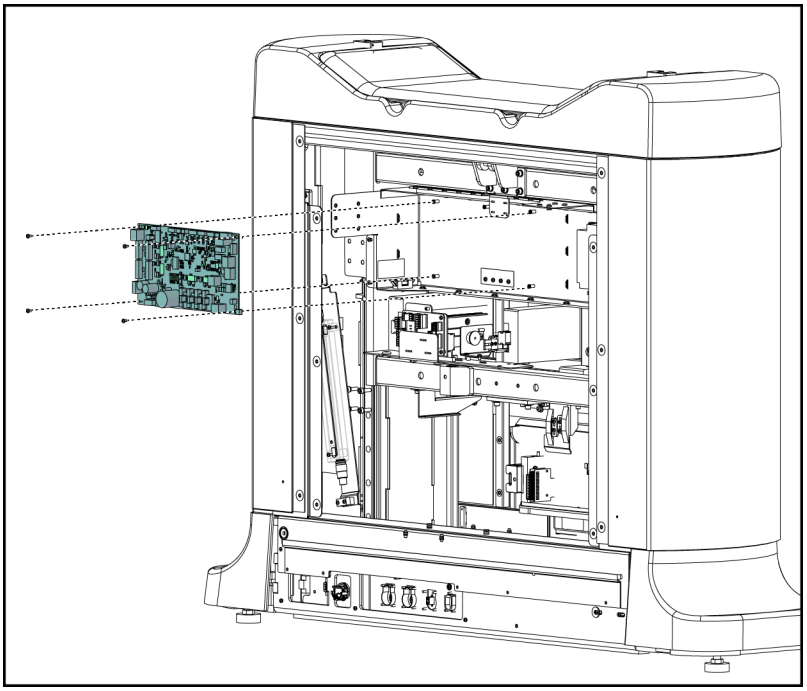


Figure 181: Removal/replacement of VTA Control Board of Gantry

Replacement

1. Install the new VTA Control Board (four screws). (See the previous figure.)
2. Restore all cable connections to the new board.
3. Reinstall the rear cover and inside metal plate to the Gantry.
4. Power ON the system and verify proper operation.

8.6 Maintenance Procedures

8.6.1 Replace Detector Fan Filter

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Removal

1. Power OFF the system.
2. Remove the Detector-end cover of the Tube Arm Mechanism (by removing two screws and pulling the cover out of snap fasteners). (See the following figure.)

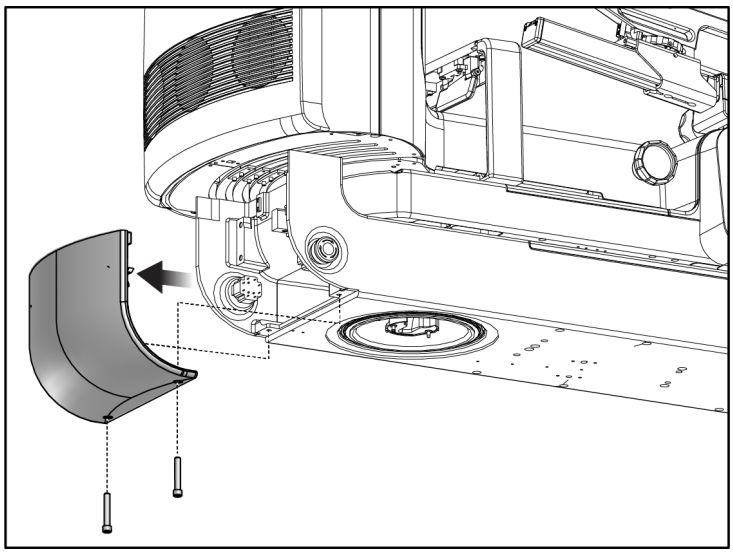


Figure 182: Removal of Detector-end cover of Tube Arm Mechanism

3. Remove the Detector-end cover of the Compression Arm. (See the following figure.)
   a. Remove the two middle SEMS screws and the side screws (captive and spring-loaded) at the bottom two corners of the cover. The cover stays on after you remove the screws, but use caution.
   b. Partially pull off the cover.
   c. Before you fully remove the cover, move it out of position and disconnect the fan control harness connector. The connector is at the center edge of the joined pinch guards.
   d. Remove the fan control harness connector from the joined pinch guards.
   e. Remove the p-clip that is attached to one of the joined pinch guards. (Do not remove the other p-clip, which is fastened to the Compression Arm.)
   f. Finish removing the cover. (Refer to the following note.)

Note
The top and side edges of the Detector-end cover fit (without screws) into the Detector-end of the Compression Arm Breast Platform. After you remove the screws in the previous step, angle the bottom of the cover and pull it off. You may feel some resistance along the perimeter of the cover as you remove it.

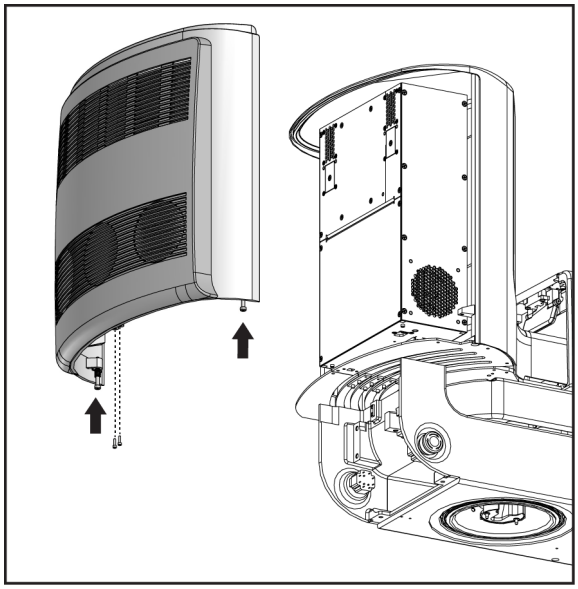


Figure 183: Detector-end cover of Compression Arm

4. Locate the two wedge-shaped filter stoppers (see item 1 in the following figure). Unfasten and remove the stoppers (one screw each).
5. Pull down and out the old filters (item 2, ASY-09689).

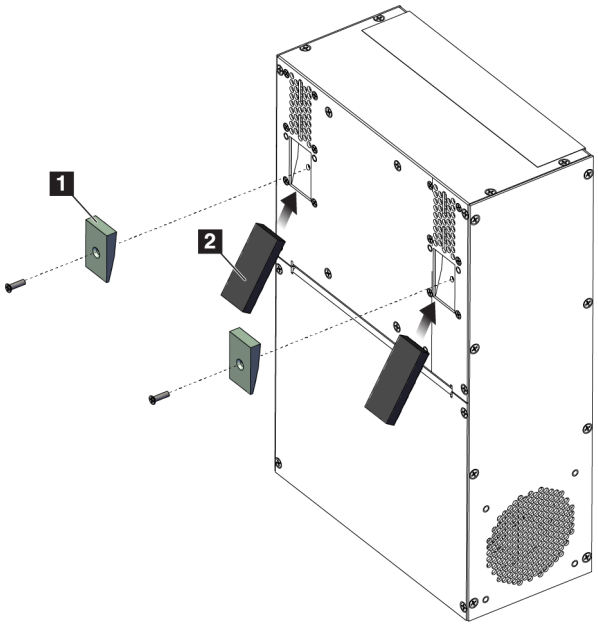


Figure 184: Replacing Detector fan filters

Replacement

1. Install the new fan filters by sliding each up at an angle into the filter receptacle (see the previous figure.)
2. Refasten the two wedge-shaped filter stoppers (one screw each side).
3. Reinstall the Detector-end cover.
4. Reinstall the Detector-end cover of Tube Arm Mechanism.
5. Power ON the system and verify proper operation.

Chapter 9 System Maintenance - Acquisition Workstation

9.1 Introduction

This chapter describes maintenance information and instructions for the Acquisition Workstation, including:

- Component identification
- Component replacement procedures

WARNING!
Verify that the system is disconnected from the AC line before performing any removal or replacement procedures.

Warning:
Always follow the safety precautions for x-ray exposures.

Caution:
Always obey Electrostatic Discharge (ESD) precautions when working with electronics and electronic components.

Note

If a procedure instructs you to remove any covers or panels, do not install the covers until all required procedures are completed.

Only Hologic-authorized, trained Service Engineers can service this system. The system is designed for module-level repair.

9.2 Major Serviceable Components (Illustrated)

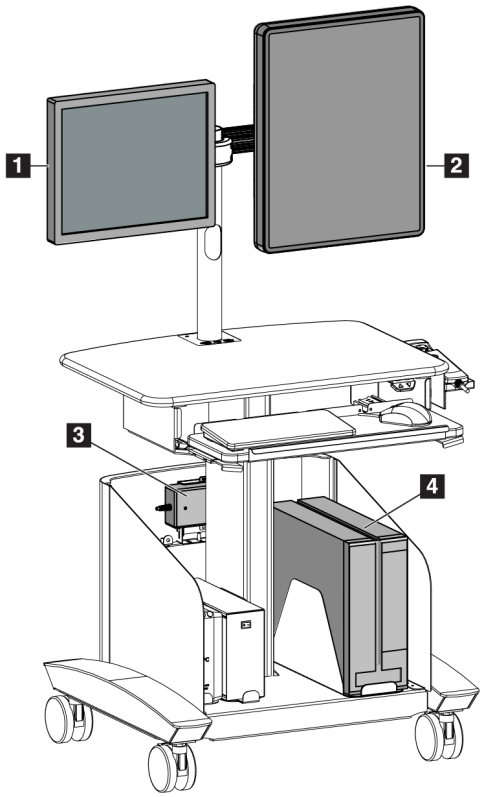


Figure Legend

1. Control display monitor
2. Image display monitor
3. Power supply for image display monitor
4. Computer

Figure 185: Major serviceable components of Acquisition Workstation

9.3 Component Replacement Procedures

9.3.1 Replace Control Monitor

Removal

1. Power OFF the Acquisition Workstation system.
2. Disconnect the power cable and video cable from the rear of the control display monitor.
3. Remove the control display monitor from its mounting bracket (four screws).

Replacement

1. Install the new monitor onto the monitor bracket (four screws).
2. Connect the video cable and power cable to the new monitor.
3. Power ON the Acquisition Workstation system.
4. Verify proper operation of the monitor.

9.3.2 Replace Image Display Monitor

Removal

1. Power OFF the Acquisition Workstation system.
2. Remove the rear cover of the image display (Barco) monitor and disconnect the power cable and video cable.
3. Remove the image display monitor from its mounting bracket (four screws).
4. Do the following, based on the situation:
   - If you are swapping out a monitor with an exact replacement (say, a 2-megapixel display with a 2-megapixel display) and there is no need to change monitor cables, go to the following *Replacement (No Cabling Involved)* procedure.
   - If you are changing the monitor with a different model (say, an upgrade from 2-megapixels to 3-megapixels display) and/or you need to replace the power supply/power cable/video cables as well as the monitor, go to the following *Replacement (Cabling Involved)*.

Replacement (No Cabling Involved)

1. Install the replacement image display monitor onto the right monitor bracket (four screws).
2. Remove the rear cover of the monitor and attach the 24 VDC power cable and display port cable. Replace the rear cover.
3. Power ON the Acquisition Workstation system.
4. Configure the new monitor using the on-screen menu of the monitor. (Refer to *Verify Settings of Barco Image Display Monitor* on page 60.)

Replacement (Cabling Involved)

1. Remove any spiral wrap/wire ties to the 24 VDC power cable and display port cable above the monitor post. Pull both cables through the monitor post and out the bottom of the post.
2. Remove the 24 VDC power cable and display port cable from e-chain cable housing. See the following figure (items 7 and 8) for the e-chain slots to remove these cables.

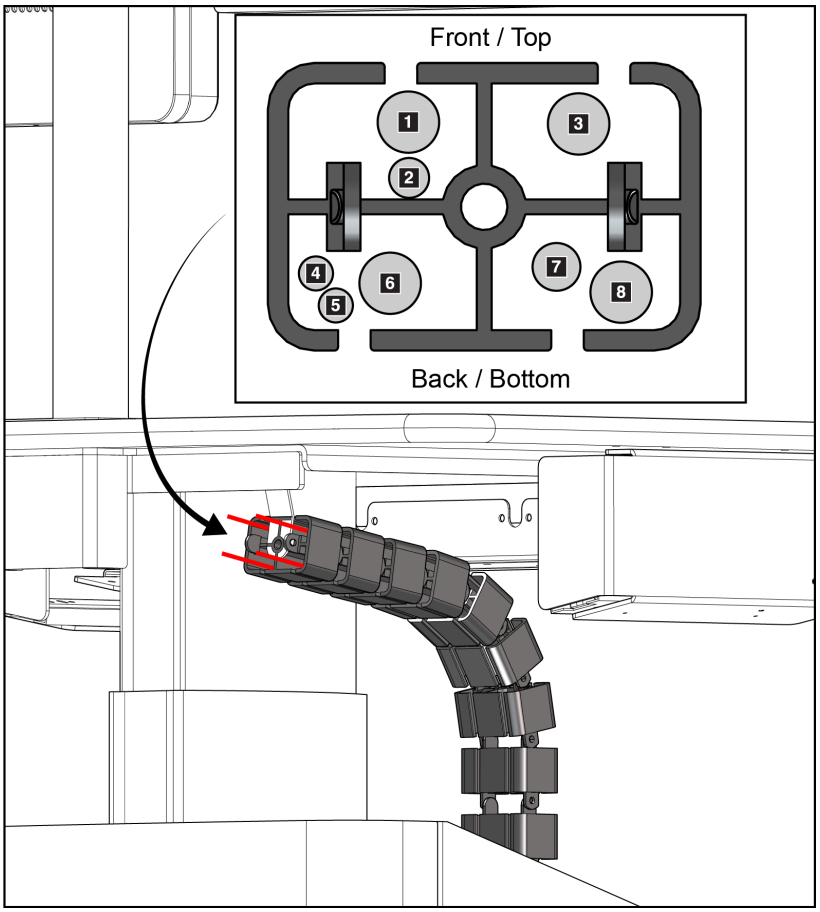


Figure Legend

1. Power cord for workstation surface lift
2. Ground cable
3. AC power cord for control display monitor
4. Mouse USB cable
5. Keyboard USB cable
6. Video cable for control display monitor
7. Display port cable for (Barco) image monitor
8. 24 VDC power cable for (Barco) image monitor

Figure 186: Routing of power and display port cables in e-chain cable housing (top of e-chain shown)

3. Disconnect the display port cable at the computer.
4. If you are changing the monitor power supply, do the following:

Note
The metal housing that holds the power supply of the image display monitor is located inside of the rear wall of the workstation cart. (See item 3 in the figure *Major Serviceable Components of Acquisition Workstation* on page 224.) The housing is sized to fit either the smaller 2-megapixel monitor power supply (plus a metal spacer) or the larger 3-megapixel monitor power supply (without a spacer).

a. Disconnect the 120 VAC cable of the monitor power supply from the UPS.

b. [If upgrading from a 2-megapixels to 3-megapixels display] Remove the metal spacer that was installed with the 2-megapixel power supply.

c. Remove the hook-and-loop fastener strip that secures the power supply within the housing and remove the power supply.

d. Install the replacement power supply into the housing.

e. Secure the power supply with hook-and-loop fastener material.

f. Route the 120 VAC cable of the replacement power supply to the UPS and plug it in (see figure *Connections on rear of UPS* on page 56).

5. Locate the replacement display port cable and connect one end to the computer (see figure *Rear panel of computer* on page 228).
6. Locate the 24 VDC power cable from the monitor power supply and monitor display port cable from the computer and run these cables through the e-chain cable housing (starting from the bottom). See items 7 and 8 in figure *Routing of power and display port cables in e-chain cable housing (top of e-chain shown)* on page 226 for the proper e-chain slots to thread these cables through.
7. From the top of e-chain cable housing, run the monitor power and display port cables through the bottom of the monitor post and out the top side opening.
8. Apply spiral wrap or use wire ties to the two cables after they leave the monitor post to keep the cables together.
9. Install the replacement image display monitor onto the right monitor bracket (four screws).
10. Remove the rear cover of the monitor and attach the 24 VDC power cable and display port cable. Replace the rear cover.
11. Power ON the Acquisition Workstation system.
12. Configure the replacement monitor using the on-screen menu of the monitor. (Refer to *Verify Settings of Barco Image Display Monitor* on page 60.)

9.3.3 Replace Computer

Removal

1. Power OFF the Acquisition Workstation system.
2. Tilt or slide the computer forward to gain easier access to its rear panel.
3. Disconnect all cable connections to/from the rear panel. Take note of the location of each cable connection. (See the following figure.)
4. Remove the computer from the workstation cart.

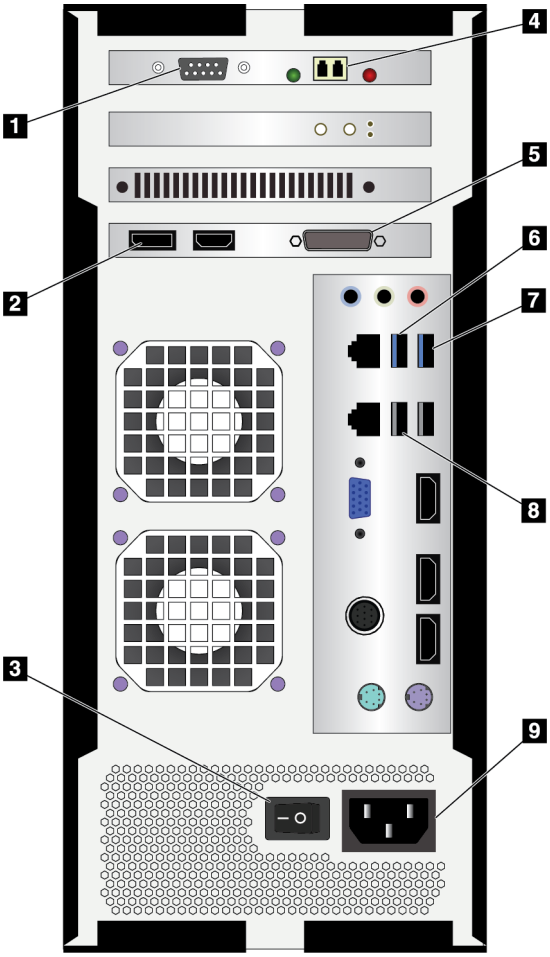


Figure Legend

1. CAN connector (for cable to Gantry)
2. Image display monitor
3. Computer power switch, set to ON
4. Fiber optic connector (for cable to Gantry)
5. Control display monitor
6. USB connector for cable to/from Uninterruptible Power Supply (UPS)
7. USB connector for mouse
8. USB connector for keyboard
9. Computer power cable that connects to Uninterruptible Power Supply (UPS)

Figure 187: Rear panel of Acquisition Workstation computer

Replacement

1. Temporarily place the new computer near its ultimate location on the workstation cart. Allow yourself enough room to access the rear panel.
2. Make all cable connections to the rear panel of the computer. (See the previous figure.)

3. Fit the computer into its intended location on the workstation cart.
4. Power ON the Acquisition Workstation system.
5. Verify proper operation of computer.

Appendix A Specifications

A.1 Product Measurements

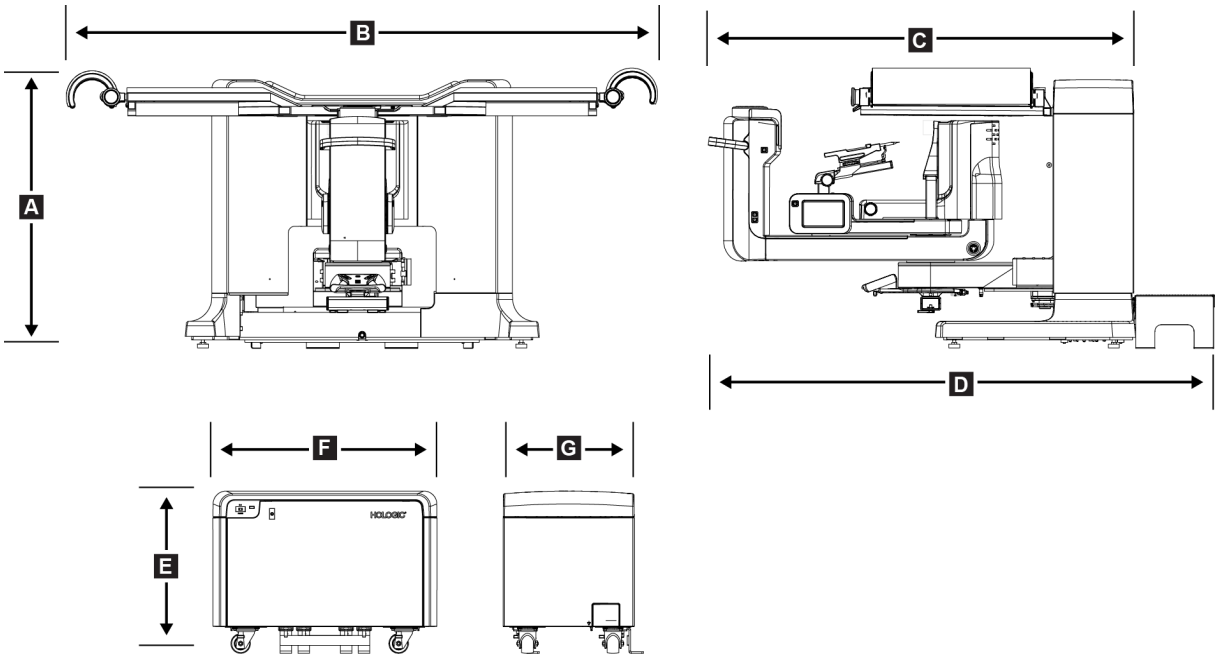


Figure 188: Gantry and Generator Dimensions

Gantry/Patient Platform Dimensions

A.	*Height*	*107 cm (42 inches)*
B.	*Width*	*229 cm (90 inches)*
C.	*Depth with C-arm*	*178 cm (70 inches)*
D.	*Overall Depth*	*198 cm (78 inches)*
	Total Weight	*445 kg (980 pounds)*

Generator Dimensions

E.	*Height*	*63 cm (25 inches)*
F.	*Width*	*87 cm (34 inches)*
G.	*Depth*	*55 cm (22 inches)*
	Weight	*136 kg (300 pounds)*

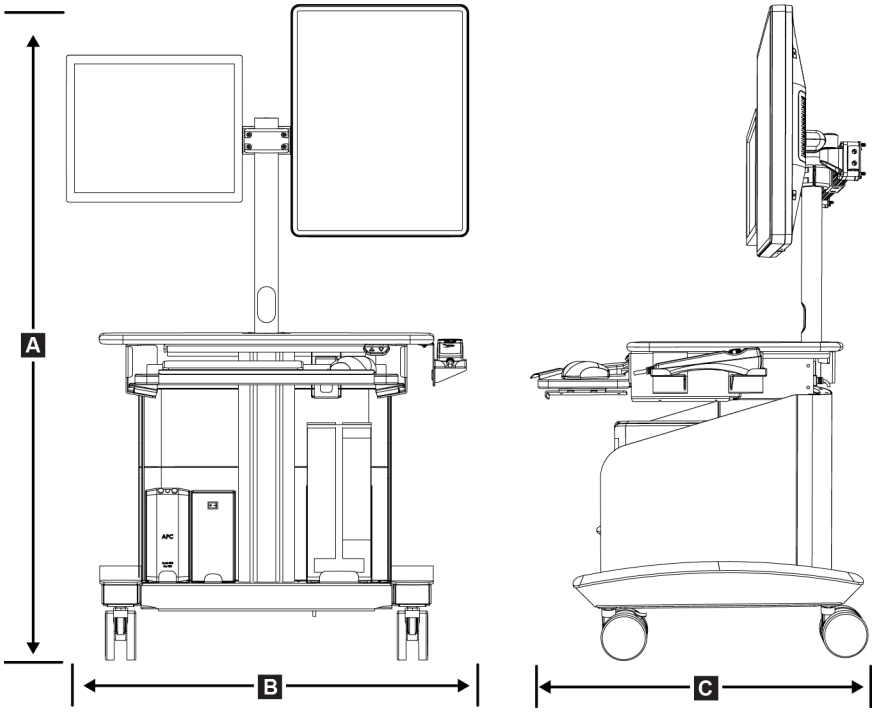


Figure 189: Acquisition Workstation Dimensions

Acquisition Workstation Dimensions

A.	*Height*	*138.4 cm (54.5 inches)*
	Overall Height Range	*138.4 cm (54.5 inches) to 179.1 cm (70.5 inches)*
	Height Range (floor to work surface)	*71.1 cm (28 inches) to 111.8 cm (44 inches)*
B.	*Width*	*85.4 cm (34 inches)*
C.	*Depth*	*75.1 cm (30 inches)*
	Total Weight	*114 kg (252 pounds)*

A.2 Operation and Storage Environment

A.2.1 General Conditions for Operation

Temperature Range	*10 °C (50 °F) to 30 °C (86 °F)*
Relative Humidity Range	*10% to 80% without condensing moisture*
BTU Output	*less than 5700 BTU per hour*

A.2.2 General Conditions for Transport and Storage

Temperature Range	*10 °C (50 °F) to 35 °C (95 °F)*
Relative Humidity Range	*10 to 80%, not packaged for outdoor storage*

A.3 Electrical Input

A.3.1 Generator/Gantry

Mains Voltage	*200/208/220/230/ 240 VAC ±10%*
Mains Impedance	*Maximum line impedance not to exceed 0.20 ohms for 208/220/230/240 VAC, 0.16 ohms for 200 VAC*
Mains Frequency	*50/60 Hz ±5%*
Average Current over 24 Hours	*< 5 A*
Line Current	*4 A (65 A maximum for < 5 seconds)*

A.3.2 Acquisition Workstation

Mains Voltage	*100/120/200/208/220/230/240 VAC ±10%*
Mains Frequency	*50/60 Hz ±5%*
Power Consumption	*< 1000 watts*
Duty Cycle	*13.3% ~ 8 minutes per hour or 2 minutes on, 13 minutes off*
Line Current	*2.5 A*

A.4 Gantry Technical Information

A.4.1 C-arm

Rotation Range	*180°*
Source-to-Image Distance (SID)	*80 cm*
Stereo Range	*±15°*
Tomosynthesis Range	*±7.5°*

A.4.2 Compression System

Manual Compression Force	*300 N (67.4 lb) maximum*
Motorized Compression Force	*62.3 N (14.0 lb) minimum*
	200 N (45.0 lb) maximum

A.4.3 Biopsy Guidance Module

Accuracy of Biopsy Arm Controller	*maximum deviation: 1 mm in either direction of target coordinate*
Combined Accuracy of Biopsy Guidance Module and Biopsy Device	*maximum deviation: 2 mm in either direction of target coordinate*

A.4.4 X-ray Tube

Focal Spot	*Large (0.3 mm) Nominal*
Tube Voltage	*20-49 kVp in 1 kVp increments*
Anode Material	*Tungsten*
X-ray Window	*0.63 mm Beryllium*
Reference Angle (angle of the reference axis to the plane of the image reception area)	*90°*

A.4.5 X-ray Beam Filtration and Output

Filtration	*Aluminum, 0.70 mm (nominal)*
	Silver, 0.050 mm ±10%

kV/mA Range

Table 10: Maximum mA as a Function of kV

kV	LFS mA	kV	LFS mA
20	100	35	200
21	110	36	190
22	110	37	180
23	120	38	180
24	130	39	180
25	130	40	170
26	140	41	170
27	150	42	160
28	160	43	160
29	160	44	150
30	170	45	150

Table 10: Maximum mA as a Function of kV

kV	LFS mA	kV	LFS mA
31	180	46	150
32	190	47	140
33	200	48	140
34	200	49	140

A.4.6 X-ray Generator

Type	*Constant potential, three-phase, high frequency inverter*
Rating	*7.0 kW (large focus) maximum, mid focus 4.08 KW(120 mA at 34kV)*
Electrical Power Capacity	*9.0 kW maximum*
kV Range	*20-49 kVp in 1 kVp increments*
kV Accuracy	*±5%*
mA Range	*10-200 mA*
mAs Accuracy	*±(10% + 0.2 mAs)*
mAs Range	*3-500 mAs, 45 steps: 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1, 8, 9, 10, 11, 12.5, 14, 16, 18, 20, 22, 25, 28, 32, 36, 40, 45, 50, 56, 63, 71, 80, 90, 100, 110, 125, 140, 160, 180, 200, 220, 250, 280, 320, 360, 400, 450, 500 mAs*

A.4.7 Image Receptor Technical Information

Dimensions	
Height	*33 cm (13 inches)*
Width	*21.5 cm (8.46 inches)*
Depth	*10 cm (3.94 inches)*
Weight	*7.3 kg (16 pounds)*
Imaging Area	*14 cm x 12 cm*
Effective Field of View	*12.4 cm x 10.2 cm at the Breast Platform*
Image Device	*Direct conversion amorphous Selenium coated TFT array*
Pixel Count	*2048 (H) x 1792 (V)*
Pixel Size	*70 µm (H) x 70 µm (V)*
Digitizing Resolution	*14 bit data*

Detective Quantum Efficiency (DQE)	*Not less than 50% at 0.2 lp/mm (stereotactic mode)* *Not less than 30% at 0.2 lp/mm (tomosynthesis mode)* *Not less than 15% at 7.1 lp/mm (stereotactic and tomosynthesis modes)*
Modulation Transfer Function (MTF)	*Not less than 40% at 7.1 lp/mm*
Synchronization	*Interlocked with x-ray control signal*

A.4.8 Shielding

Operator	*Radiation shield (customer supplied) between patient platform and handheld remote for x-ray activation*
Patient	*The patient platform provides the necessary radiation protection.*

A.5 Acquisition Workstation Technical Information

A.5.1 Network Environment

Network Interface	*100/1000 BASE-T Ethernet*

A.5.2 Acquisition Workstation Cart

Monitor Arm Weight Rating	*11.3 kg (25 pounds)*

Appendix B System Messages and Alerts

B.1 Error Recovery and Troubleshooting

Most faults and alert messages are cleared without result to your workflow. Follow the instructions on the screen or fix the condition then clear the status from the Taskbar. Some conditions require a system restart or indicate that more action is necessary (for example, to call Hologic Technical Support). This appendix describes the message categories and your actions to return the system to normal operation. If errors repeat, contact Hologic Technical Support.

B.2 Types of Messages

B.2.1 Fault Levels

Each Message has a particular set of the following characteristics:

- Aborts an exposure in progress (yes/no)
- Prevents an exposure from starting (yes/no)
- Displays a message to the user on the Acquisition Workstation (yes/no)
- May be reset by the user (yes/no)
- May be reset automatically by the system (yes/no)

Displayed Messages

All displayed messages will be shown in the user's selected language.

Any message which aborts an exposure or prevents an exposure from starting will always display a message directing the user's actions required to proceed.

Additional Message Information

Technical information about the message is available in the log file.

Some messages always show as a critical fault (a system restart is necessary). These messages result from a condition which prevents an exposure, and which cannot be reset by the user or the system.

B.2.2 System Messages

When the following system messages show, do the step shown in the User Action column to clear the message and allow the next exposure.

Table 11: System Messages

Icon	Message	User Action

Table 11: System Messages

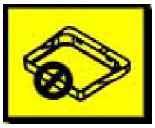
Icon	Message	User Action
	Waiting for Detector	No action needed.
	(C-arm) Lockout Switch activated	Release the C-arm handle.
	(System) Lockout Switch not activated	Press the System Lock button on the control handle to lock the system. If necessary, unlock and relock.
	Biopsy STX cal required	Install the gain paddle and perform Gain Calibration.
	Biopsy geometry calibration required	Install the geometry paddle and perform Geometry Calibration.
	Invalid detector calibration: Repeat flat field calibration	Repeat Gain Calibration.
	Invalid geometry calibration: Repeat geometry calibration	Repeat Geometry Calibration.
	Invalid use of compression paddle	Install the correct paddle.
	Configuration file is missing	Call Service.
	An E-Stop has been pressed	When safe, turn the Emergency Off switch one-quarter turn to reset the switch.

Table 11: System Messages

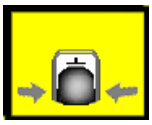
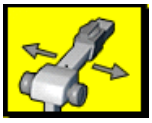
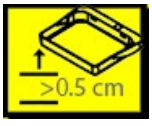
Icon	Message	User Action
	Tube needs to be manually positioned (move to 0 degrees)	Manually rotate the C-arm to 0 degrees.
	Tube needs to be manually positioned (moved to +15 degrees)	Manually rotate the C-arm to the right.
	Tube needs to be manually positioned (moved to -15 degrees)	Manually rotate the C-arm to the left.
	The needle needs to be moved to the correct location	Move the needle to the correct location.
	The stage arm needs to be moved to either the lateral left or right position	Move the biopsy arm to either lateral left or right.
	The stage arm needs to be moved to the -90 position	Move the biopsy arm to -90 degrees approach.
	The stage arm needs to be moved to the +90 position	Move the biopsy arm to +90 degrees approach.
	The stage arm needs to be moved to the standard approach	Move the biopsy arm to 0 degree approach.
	The stage arm control is not locked	Lock the biopsy arm.
	Compression too low for tomo reconstructions	Move the Compression Paddle to greater than 0.5 cm.

Table 11: System Messages

Icon	Message	User Action
	Compression is less than 4.5 cm during calibration	Move the Compression Paddle to greater than 4.5 cm.
	*not licensed	A license is necessary to use this feature or function. (Call Service to install the license.)

B.3 UPS Messages

Note
The User Guide for the UPS is supplied with the system. Refer to the UPS *User's Guide* for complete instructions.

The LCD Display Interface in the Uninterruptible Power Supply (UPS) shows the status of various utility and battery backup conditions.

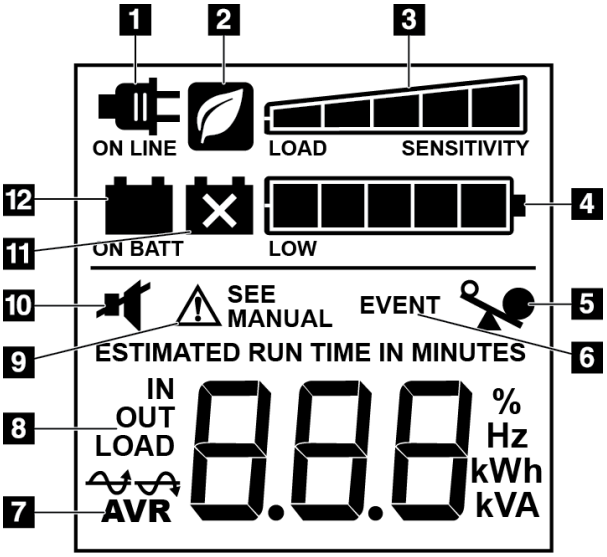


Figure 190: UPS LCD Display

Figure Legend

1. On Line Power
2. Power-Saving Mode On
3. Load Capacity
4. Battery Charge Level
5. UPS Overload
6. Event
7. Automatic Voltage Regulation
8. Input/Output Voltage
9. System Fault
10. Mute
11. Replace Battery
12. On Battery Power

If the UPS battery expires, the Replace Battery icon shows. Contact your service representative to replace the battery.

Appendix C Field Replaceable Units

C.1 Replacement Parts List

The Parts Lists are located in the following tables, with each part listing a:

- **Part Number:** The order number for the Field Replaceable Unit/part. Hologic Service Support requires this number when placing an order.
- **Description:** The name of the Field Replaceable Unit/part
- **Refer To:** The section and page number in this manual for the removal and replacement procedures for that Field Replaceable Unit/part.

Table 12: Generator Parts List

Part Number	Description	Refer To
ASY-06980	High Voltage (HV) Multiplier Drawer Assembly	*Replace High Voltage Multiplier Assembly* on page 174
ASY-06981	Capacitor and Bridge Assembly	
ASY-07006	Inverter Drawer Assembly	*Replace Inverter Drawer* on page 173
ASY-08871	Fuse Kit for High Voltage Generator	
ASY-08936	Power Distribution Drawer Assembly	
PCB-00443	External User Indicator Board	
PCB-00709	Front Panel Feedback Board	
PCB-00964	Remote X-Ray Control Board	
PWR-00200	DC Power Supply (+24 VDC @ 6.3 Amps, 150 watts, Voltage Input 90-264 VAC, Single Output)	

Table 13: C-Arm Parts List

Part Number	Description	Refer To
2-230-4001	Belt, Timing 32p 3/32dia Linear Pitch .0982, Pitch Length Bulk 50ft, Material Dacron Core	
ASY-04186	Y-Axis Ground Assembly Flex Cable	

Table 13: C-Arm Parts List

Part Number	Description	Refer To
ASY-06533	Magnetic Rotary Encoder Assembly (3 in system)	*Replace the Magnetic Rotary Encoder Assembly* on page 202
ASY-07458	Carriage Brake Assembly	
ASY-07569	Filter Wheel Assembly	*Replace the Filter Wheel Assembly* on page 196
ASY-08174	Paddle, Biopsy, Axilla, 5 Cm X 5 Cm	
ASY-08175	Paddle, Biopsy, Standard, 5 Cm X 5 Cm	
ASY-08176	Paddle, Biopsy, Standard, 6 Cm X 7 Cm	
ASY-08642	Stage Arm Smart Window, RH Assembly	
ASY-08643	Stage Arm Smart Window, LH Assembly	
ASY-08956	C-Arm Handle Optical Sensor Assembly	
ASY-08986	Detent In Optical Sensor Assembly	
ASY-08987	Detent Out Optical Sensor Assembly	
ASY-09070	Support Arm Interconnect Assembly	
ASY-09072	High Voltage Resistor, Gen II Assembly	
ASY-09170	Footswitch with Coiled Cable Assembly	
ASY-09689	Replacement Filters for Mid-Field Detector	
ASY-09702	Phantom, Brake Actuator Motor Assembly	
CBL-02006	Tube Arm CAN Cable 1	
CBL-02007	Tube Arm CAN Cable 2	

Table 13: C-Arm Parts List

Part Number	Description	Refer To
CBL-02397	High Voltage Cable-Resistor to Tube Assembly	
FAB-10785	Breast Platform, Main Cover, Compression Arm	
FAB-13473	X-Y Axis Flex Cable	
FAN-00084	Fan, 12vdc 60.4/102.6cfm 17.7dba 1200rpm 0.20amps W/Wire Leads, 17.1lg 12.7mm(4.72)X120mm(4.72)X25mm(1")Thk Axial	
MME-02432	Elt, Posidrive, 32 Pitch, 24.740 Length, Belt Core St Stl, Body Polyurethane	
MME-02629	Belt, Timing 32p 95pins, Core Dia 3/23, Circular Pitch 0.0982, Pitch Length 9.327, St Stl Reinforced Polyurethane, Blue	
MTR-00088	Compression Motor	
OSC-00065	X-Ray Tube, Varian M-119t (Affirm Prone Biopsy System)	
PCB-00186	Paddle Position Sensor	
PCB-00918	Compression Arm Control Board	*Replace Compression Arm Control Board* on page 199
PCB-00944	C-Arm Angle Encoder Board	
PCB-00989	Tube Arm Control Board	
PCB-01005	Tubehead Control Board	
PCB-01016	Filament Protect Board	
PCB-01032	Support Arm Flex Board	
PCB-01038	Biopsy (Stage) Arm Control Board	*Replace Biopsy (Stage) Arm Control Board* on page 205
PCB-01056	Biopsy (Stage) Arm Motor Drive Board	*Replace Biopsy (Stage) Arm Motor Drive Board* on page 197
PCB-01060	Stage Y-Axis Interface Board	

Table 13: C-Arm Parts List

Part Number	Description	Refer To
PCB-01078	Table Interconnect Board	
PCB-01081	Compression Arm Flex Board	
PCB-01099	Tube Arm Flex Board	
PCB-01101	Compression Device Flex Board	
PCB-01118	Support Arm Extension Flex Assembly	
PCB-01197	Compression Arm Power Board	
PCB-01281	Stage Arm Flex Board	
PCB-01313	Tube Arm Magnetic Encoder Board	
PRD-03756-N	Mid-Field Image Detector	*Replace Image Detector* on page 207
SWC-00149	Motor Enable Membrane Switch	

Table 14: Gantry Parts List

Part Number	Description	Refer To
PCB-00174	Gantry Service Port Board	
PCB-00923	VTA Control Board	*Replace the VTA Control Board* on page 219

Table 15: Acquisition Workstation Parts List

Part Number	Description	Refer To
ASY-09162	X-Ray Handheld Remote	
ASY-09400	AWS Power Distribution	
ASY-11635	Computer (CMP-01560) With Software Loaded	
CBL-02238	Video Cable [6.6 ft Lg (2.0 meters) DVI-A (16+1) Male To VGA HD 15 pins Male, PVC Black]	

Table 15: Acquisition Workstation Parts List

Part Number	Description	Refer To
CMP-00811	Control Monitor (17" Flat Panel Color 1280 x 1024 Viewing Area, 56-76 Hz)	*Replace Control Monitor* on page 225
CMP-00819	Mouse (USB & PS/2 3 Button Optical w/Scroll Wheel, 6 ft cord)	
CMP-01560 (formerly CMP-01154)	Computer	*Replace Computer* on page 228
CMP-01270	Image Display Monitor	*Replace Image Display Monitor* on page 225
MME-02464	Keyboard Transparent Cover with Keyboard	
MME-02465	Keyboard Transparent Cover (alone)	
PCB-01011	Video Board for Detector (HDT PCIE VLC PCB)	Located in the computer
PWR-00246	UPS (120 VAC 50/60 Hz, 420 Watts, 6 Outlets)	

C.2 Interconnect Cables

Table 16: Affirm Prone Biopsy System Interconnect Cables

Part Number	Description
ASY-09040	20 Foot Interconnect Cables, Generator to Gantry
ASY-09041	40 Foot Interconnect Cables, Generator to Gantry
ASY-09042	60 Foot Interconnect Cables, Generator to Gantry
ASY-09054	20 Foot Interconnect Cables, AWS to Generator
ASY-09055	40 Foot Interconnect Cables, AWS to Generator
ASY-09056	60 Foot Interconnect Cables, AWS to Generator
ASY-09057	80 Foot Interconnect Cables, AWS to Generator
ASY-09058	100 Foot Interconnect Cables, AWS to Generator

Appendix D Use in a Mobile Environment

D.1 General Information

This appendix describes the Affirm prone biopsy system installed in a mobile environment.

D.2 Conditions for Safety and Other Precautions

An acceptable, stable, clean VAC power source is required to make sure that the system meets all its performance specifications. Where available, shore power correctly supplied to the system provides the best performance. If a mobile power generator is used, you must keep the specifications for input power during all load conditions.

Caution:
When shore power is unavailable, mobile power sources that provide equivalent performance may be employed. (Refer to *Specifications for Mobile Use* on page 248.) Proper system function and performance can only be ensured if continuous true sinusoidal VAC power is supplied per the system power input specifications and loading characteristics. Intermittently, the power source must provide 65 Amps at 208 VAC for a minimum of 5 seconds, and 4 Amps maximum continuous otherwise. This load must be supported once every 30 seconds. In the event of shore or mobile power service interruption, the UPS must be capable of providing the operational power described above for a minimum of 4 minutes. Acquisition Workstation and Gantry power must be fed on separate dedicated circuits. The use of an uninterruptible power supply with active line conditioner is recommended on each power circuit. Accordingly, all ancillary mobile coach power should be distributed by other circuits. The electrical installation must be verified to meet system power input specifications and IEC 60601-1 safety requirements after initial installation and upon each relocation of the mobile coach.

Caution:
The temperature and humidity inside the vehicle must be maintained at all times. Do not allow environmental conditions to exceed stated specifications when the unit is not in use.

Caution:
Voltages cannot change by more than ±10% when the x-ray unit or other equipment (for example, heating or air conditioning) is operated.

Caution

To avoid image artifacts from occurring:

- **Do not locate or park the mobile coach near sources of high power (such as power transmission lines and outdoor transformers).**
- **Make sure that any mobile power generator, uninterruptible power supply (UPS), or voltage stabilizer is at least 3 meters (10 feet) from the closest point of the image detector travel.**

D.3 Specifications for Mobile Use

The following system specifications are for mobile use only. For all other specifications, refer to the section *Specifications* on page 231.

D.3.1 Shock and Vibration Limits

Vibration Limit	*Maximum of 0.30 G (2 Hz to 200 Hz), measured at the point where the system mounts to the coach.*
Shock Limit	*Maximum of 1.0 G (1/2 sine pulse), measured at the point where the system mounts to the coach. An "air ride" coach suspension is recommended.*

D.4 Prepare the System for Travel

Note

Start preparing the system for travel with the system power on. (Do not power off the system until the C-arm is correctly positioned and supported.)

1. Push the footrests fully in.
2. Raise the patient platform to its full height.
3. Rotate the biopsy arm to 0 degrees.
4. From the acquisition workstation, select the table icon in task bar and rotate the tube arm to 0 degrees.
5. Rotate the C-arm to +180 degrees. Raise the C-arm above the height needed to place the C-arm cradle in position.

6. Put the C-arm cradle into position under the C-arm. Confirm that the cradle is correctly seated on the circular mounting block.

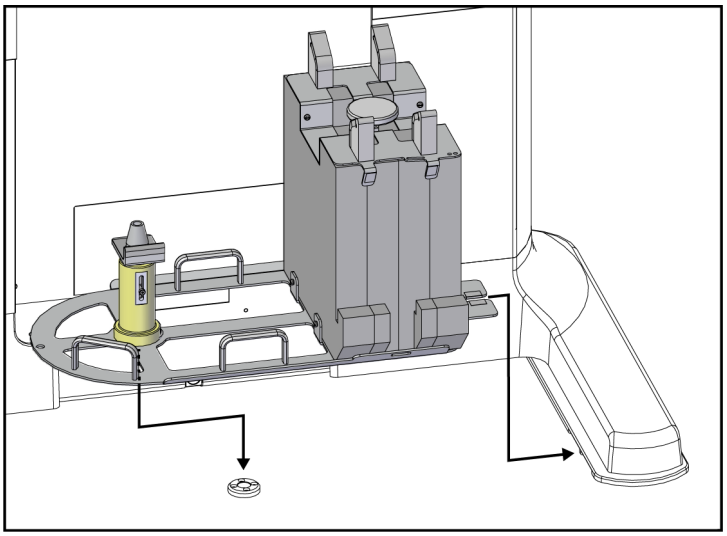


Figure 191: Set the C-arm Cradle

7. A height tool is tethered to the C-arm cradle. Use the height tool to set the C-arm height in relation to the patient platform. Put the height tool flat on the tubehead. Raise the C-arm until there is no space between the tool and the bottom of the platform. Remove the height tool.

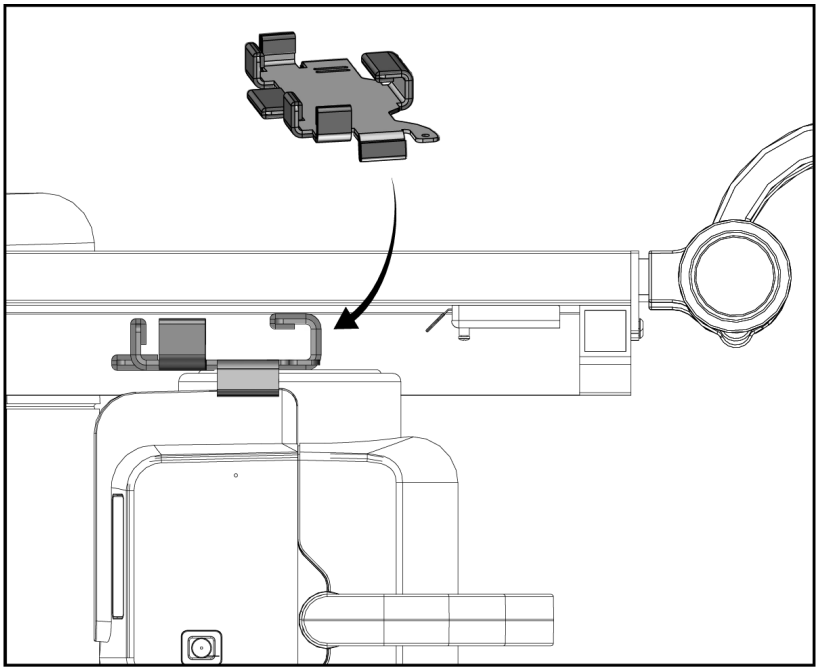


Figure 192: Set the C-arm Height with the Height Tool

8. Use the height tool to lock the biopsy arm in position. Place the tool on the tube arm between the biopsy arm and the tubehead. Make sure to use the hook and loop strap for extra support.

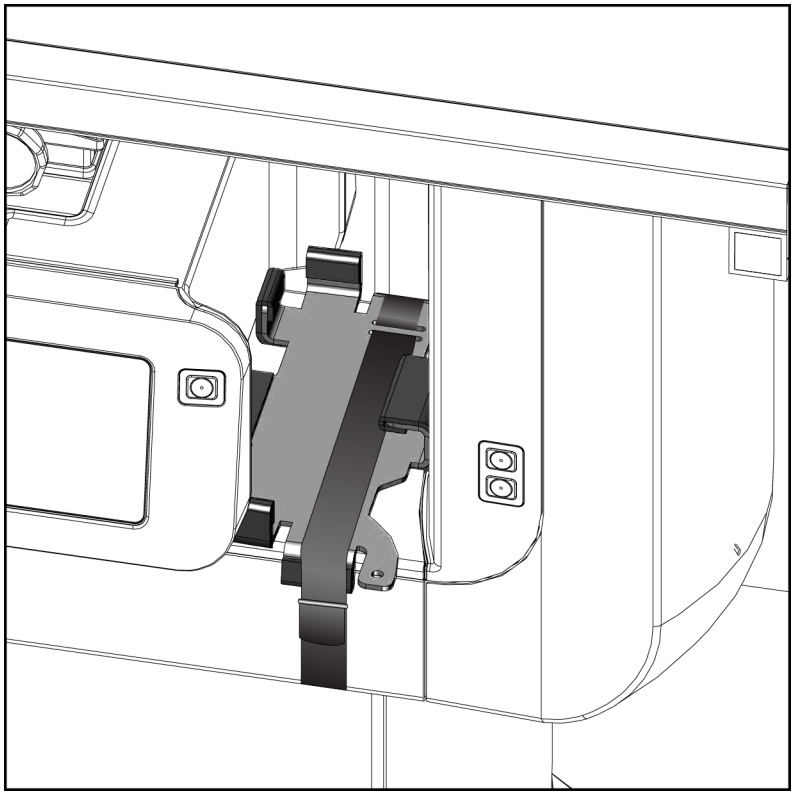


Figure 193: Lock the Biopsy Arm with the Height Tool

9. Put the footswitch into the footswitch channels in the C-arm cradle and secure with the hook and loop strap.

Caution:
Make sure that the footswitch cord is positioned safely to prevent damage from being compressed between the C-arm and the C-arm cradle.

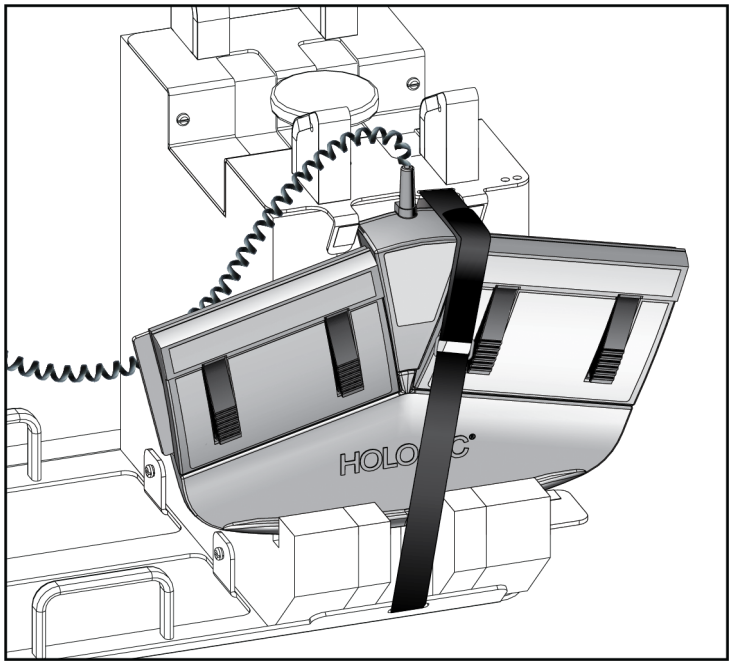


Figure 194: Correct Footswitch Storage

10. While pressing the **C-arm Translate** button, push the C-arm in completely toward the Gantry.

11. Continue pressing the **C-arm Translate** button and adjust the C-arm as needed while lowering the patient platform into the C-arm cradle. The marking on the C-arm aligns with the support bracket on the C-arm cradle.

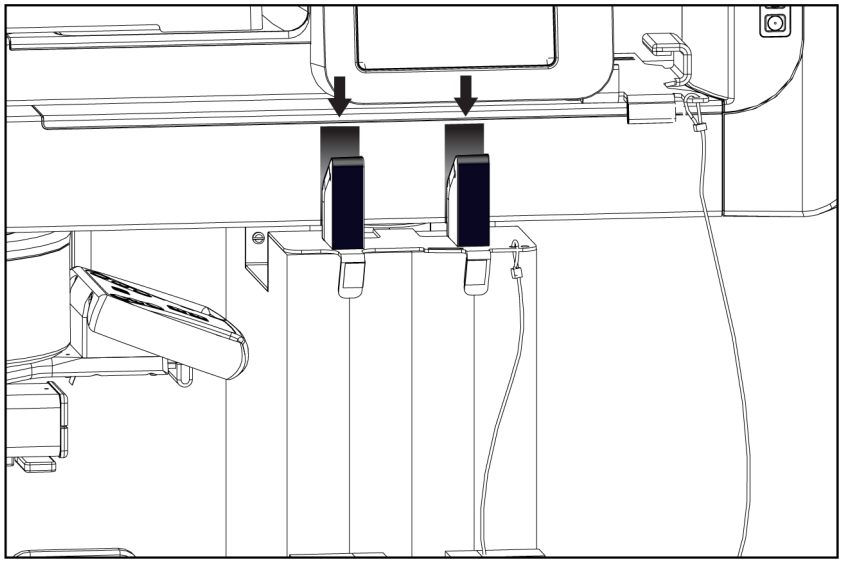


Figure 195: Alignment of Markings on the C-arm with the C-arm Cradle

12. Lower the work surface on the acquisition workstation to the minimum height.
13. Shut down the system.
14. Make sure the x-ray switch is secure in its holder.
15. Put the mouse in the mouse holder on the right of the keyboard tray (see item 2 in the following figure).

16. Close and lock the keyboard tray.

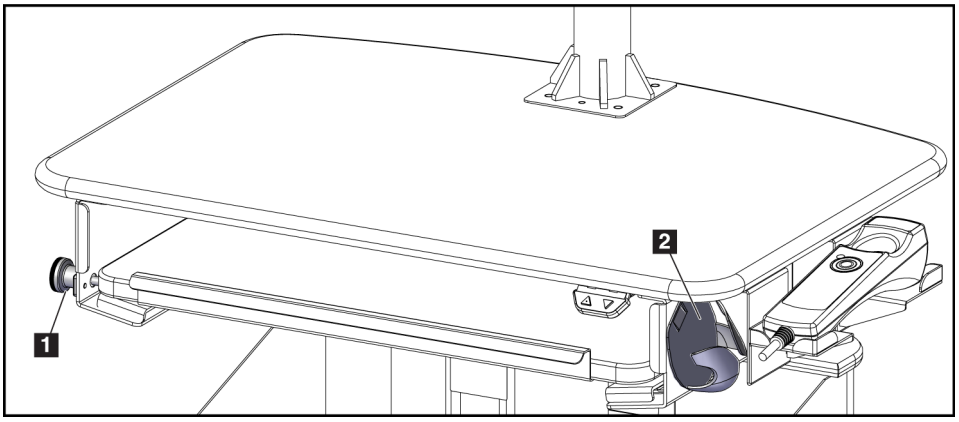


Figure 196: Mouse Holder (2) and Keyboard Tray Lock Knob (1)

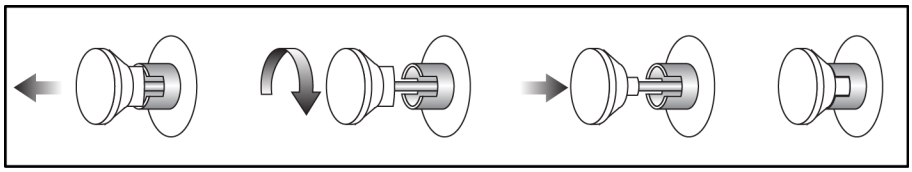


Figure 197: Set the Lock Knob to Locked Position

17. Release the monitor lock knobs to adjust the monitors for transport. Swivel the monitors to center position until the lock knobs lock. Tilt the monitors fully forward until the lock knobs lock.

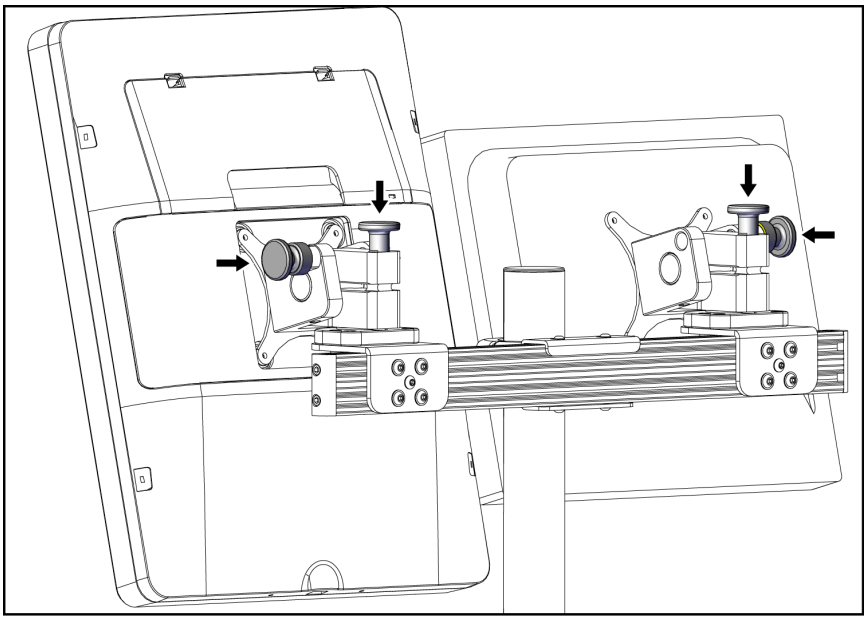


Figure 198: Release the Lock Knobs on the Monitors

D.5 Prepare the System for Use

1. Unlock and adjust the monitors.
2. Adjust the work surface height of the acquisition workstation.
3. Unlock and open the keyboard tray.
4. Remove the mouse from the mouse holder.
5. Power on the system.
6. Raise the patient platform to its full height.
7. Remove the footswitch from the C-arm cradle. Follow all safety requirements when positioning the footswitch.
8. Remove the height tool from the C-arm. Store the height tool in the C-arm cradle.
9. Remove the C-arm cradle and put in a safe storage area.

D.6 Test the System after Travel

D.6.1 Functional Tests After Travel

Perform the Functional Tests. Refer to the section Functional Tests.

- Compression Apply and Release
- C-arm Up and Down
- Patient Platform Up and Down
- Patient Platform Up Limit

D.6.2 Quality Control Tests After Travel

Perform the Quality Control tests as recommended for the non-mobile Affirm prone biopsy system.

Appendix E Technical References

E.1 Center of Gravity Specifications for Gantry

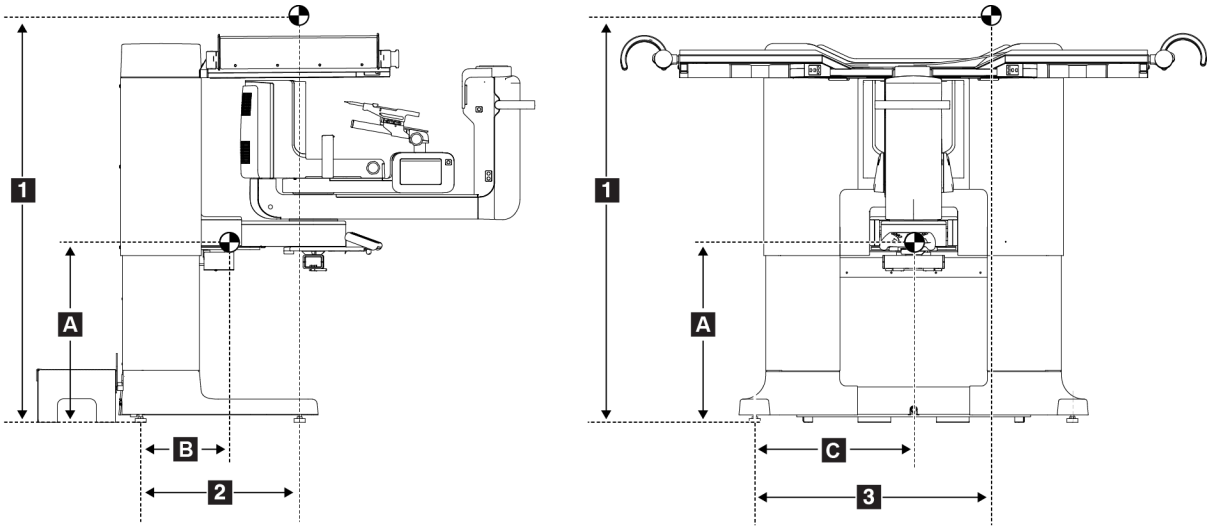


Figure 199: Center of Gravity for Gantry

Without Patient on Table

Item	Measurement	
A	70.1 cm	27.6 inches
B	34.8 cm	13.7 inches
C	62.5 cm	24.6 inches

With Patient on Table (Up to 400 lb.)

Item	Measurement	
1	155 cm	61 inches
2	62 cm	24.4 inches
3	90.4 cm	35.6 inches

E.2 Center of Gravity Specifications for Generator

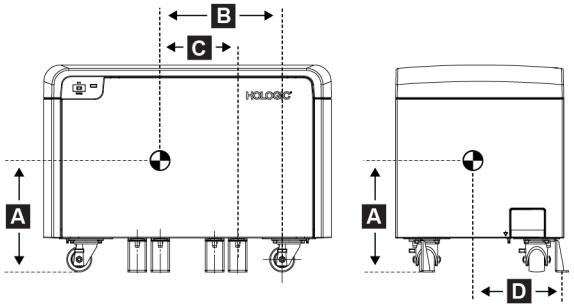


Figure 200: Center of Gravity for Generator

Item	Measurement	
A	33.8 cm	13.3 inches
B	37.1 cm	14.6 inches
C	23.6 cm	9.29 inches
D	27.1 cm	10.7 inches

E.3 Center of Gravity Specifications for Acquisition Workstation

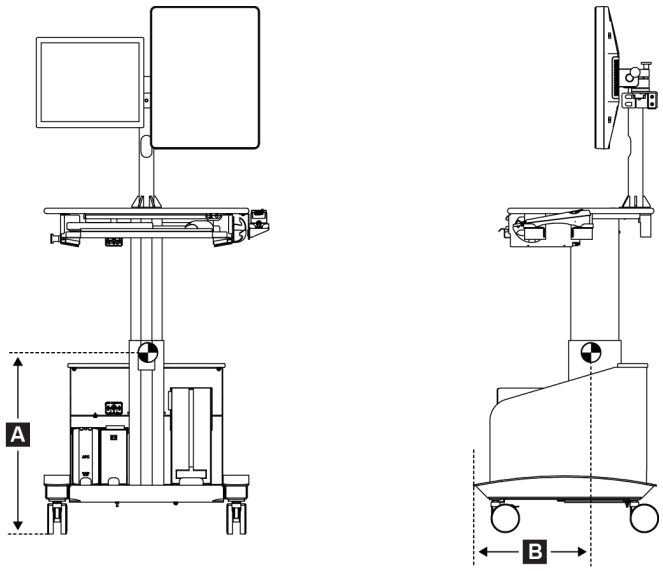


Figure 201: Center of Gravity for Acquisition Workstation

Item	Measurement	
A	59.3 cm	23.4 inches
B	38.1 cm	15 inches

E.4 Electromagnetic Compatibility

This section provides information about the electromagnetic compatibility of system per IEC 60601-1-2.

Table 17: Electronic Emissions

Electromagnetic Emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Meets Class A Compliance. The system is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 18: Electromagnetic Immunity Part 1

Electromagnetic Immunity – Part 1			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95 % dip in Ut) for 0,5 cycle 40% Ut (60 % dip in Ut) for 5 cycles 70% Ut (30 % dip in Ut) for 25 cycles <5% Ut (>95 % dip in Ut) for 5 s	<5% Ut (>95 % dip in Ut) for 0,5 cycle 40% Ut (60 % dip in Ut) for 5 cycles 70% Ut (30 % dip in Ut) for 25 cycles <5% Ut (>95 % dip in Ut) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or battery.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at l4evels characteristic of a typical location in a typical commercial or hospital environment.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Table 19: Electromagnetic Immunity Part 2

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	[V1] = 3 V	**Recommended separation distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[*E*1] = 3 V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 20: Separation Distances for RF Equipment

Recommended Separation Distances for Portable and Mobile RF Communications Equipment and the system			
The system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.38
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

E.5 Leakage Radiation

All important x-ray safety features meet 21 CFR, Chapter I, 1020.31, IEC 60601-1-3, and IEC 60601-2-45.

Typical values of x-ray leakage shown are in one hour at a distance of 1 meter from the tube focal spot, at maximum kVp, and adjusted for a maximum in use duty cycle of 0.027.

Duty cycle comes from a maximum throughput of 12 patients per hour x 4 exposures, or 48 exposures per hour with a maximum exposure time of 2 seconds.

The meter measures x-ray leakage in units of mR. The meter reading for a single 2 second exposure is multiplied by the total number of exposures per hour to get the correct leakage value (Reading for single exposure x 48) and is compared with the maximum allowed criteria of 100 mR in one hour.

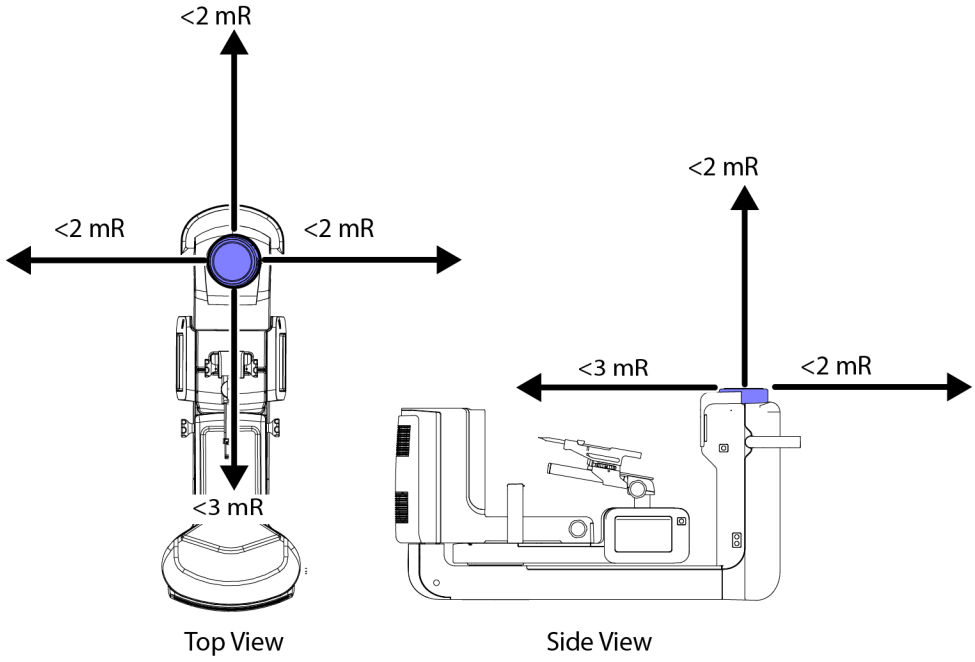


Figure 202: Leakage Radiation

E.6 List of Fuses

These fuses are located on the Generator fuse panel, on the individual boards in the Gantry, and in the Acquisition Workstation.

Table 21: Fuses

Description	Fuse	Rating	Circuit	Part No.
Generator Fuse Panel				
	F14	FB 30A 600V	600 VDC Rail	1-070-1119
	F10, F11	SB 3A 250V	Sec 120 VAC	1-070-1076
	F8, F9	SB 12A 250V	Sec 65 VAC	1-070-1327
	F6, F7	SB 10A 250V	Sec 24 VAC	1-070-1275
	F4, F5	SB 10A 250V	Sec 24 VAC	1-070-1275
	F12, F13	SB 1.5A 250V 3AG	Line (PRI)	1-070-1263
	F15	40A 600V	Sec 380 VAC	CKB-00027
	F16	40A 600V	Sec 380 VAC	CKB-00027
Gantry Board Fuses				
PCB-01005	F1	1.5A SB 2AG	Tubehead Microprocessor Board	1-070-1245
PCB-00183	F2	10A SB 250V 3AG	Power Distribution Board	1-070-1275
	F3	10A SB 250V 3AG		1-070-1275
	F4	0.125A 250V 2AG		1-070-1220
PCB-00964	F1	1/2A SB 2AG	Remote X-ray control	1-070-1242
PCB-00989	F2	4A SB 2AG	Tube Arm Control	1-070-1246
PCB-01038	F1	3A SB 2AG	Stage Arm (Biopsy Arm) Control	1-070-1248
PCB-00923	F1	4A SB 2AG	VTA Control Board	1-070-1250
PCB-01197	F1	4A SB 2AG	Compression Arm Power	1-070-1250
PCB-00110	F1	FB 25A 600V	HV Inverter Drawer	1-070-1118
	F2	FB 8A 600V	HV Inverter Drawer - Rotor	1-070-1112
PCB-00158	F1	0.1A 600V Fast Acting Cartridge	Fast Bleed - Capacitor and Bridge Assembly	CKB-00025

Table 21: Fuses				
Description	**Fuse**	**Rating**	**Circuit**	**Part No.**
Acquisition Workstation Fuses				
ASY-09400	F1	2.5A 250V SB 3AG 1/4X1-1/4	AWS Isolation Transformer	1-070-1266
	F2	2.5A 250V SB 3AG 1/4X1-1/4		

E.7 PCB Jumpers and LED Configurations

Table 22: Jumper Configuration		
PCB Assembly	**Jumpers installed**	**Jumpers not installed**
PCB-00918	JP1	JP2
PCB-00923	JP1	JP2, JP3, JP4, JP5
PCB-00944	JP1, JP2	JP3
PCB-00964	JP1	JP2, JP3
PCB-00989	JP1	JP2, JP3
PCB-01005	JP1	JP2, JP3, JP4
PCB-01038	JP1	JP2, JP3
PCB-01197	JP1	

Table 23: LED Information							
PCB Assembly	**Run LED**	**Fault LED**	**+3.3V**	**+5V**	**+15V**	**+24V**	**+90V**
PCB-00918	D17	D16	D19	D58	D59		
PCB-00923	D15	D16	D4	D58	D59	D41	D2
PCB-00944	D1	D2					
PCB-00964	D5	D6	D15	D13			
PCB-00989	D10	D11	D28	D27	D36	D24	D30
PCB-01005	D2	D1	D2	D5		D1	
PCB-01038	D21	D20	D20	D19	D25		
PCB-01197						D1	

Appendix F Checklists and Forms

Make copies of these checklists and forms for your use during installation and maintenance.

F.1 Installation and Preventive Maintenance Checklist

The following checklist forms represent the individual pages taken from the Affirm Prone System Maintenance Report PDF form (CSD-0042-F20).

To access the latest electronic version of this PDF form:

1. From the Hologic intranet (myhologic.com), go to **More Links > BigTinCan - Hub**.
2. Navigate to **Content > Affirm Prone Biopsy System > Reference Material**.
3. Locate and open the **Affirm Prone System Maintenance Report**.

F.1.1 Checklist Forms

Affirm® Prone Biopsy System Maintenance Report

HOLOGIC®
The Science of Sure

☐ Installation Report ☐ Preventative Maintenance Report

Customer Name

Room Identification

Date of Service | System SN | System Software Version | Detector SN

Contact Name

Street Address

Email

City | State | Zip Code

Engineer/Title

Case #

System Check

- ☐ System Cleaning
- ☐ System Lubrication
- ☐ System Integrity

Functional Check

- ☐ CalTool Verification
- ☐ Line Voltage
- ☐ X-ray Tube Voltage
- ☐ Generator mA
- ☐ Filaments

- ☐ X-ray Tube Current
- ☐ Half Value Layer
- ☐ AEC Performance
- ☐ Target Dose
- ☐ Image Quality
- ☐ QAS

Installation

- ☐ Complete

Preventative Maintenance

- ☐ Complete

Preventative Maintenance Period

- ☐ Semiannual
- ☐ Annual

Page 1 CSD-0042-F20 Rev 002

Test Equipment

Digital Multimeter

Model # _____ Serial # _____ Cal. Date _____

Oscilloscope

Model # _____ Serial # _____ Cal. Date _____

Compression Gauge

Model # _____ Serial # _____ Cal. Date _____

Radiation Measurement

Model # _____ Serial # _____ Cal. Date _____

High Voltage Tank / Probe

Model # _____ Serial # _____ Cal. Date _____

Licensed Features

☐ Tomo

Other Features

☐ Mobile Unit

Hardware Installation

Generator

- ☐ Configure Transformer Tap
- ☐ Connect Generator Cables
- ☐ Install Remote X-ray On/Power On Lamp Connection (Optional)

Patient Platform/Gantry

- ☐ Install Table
- ☐ Set bottom of Table to Breast Platform Gap to 1/4"
- ☐ Install Detector
- ☐ Verify Detector Read Out Sequence
- ☐ Install Patient Arm Rest
- ☐ Install Comfort Package Pads
- ☐ Install Footswitch
- ☐ Connect Cables
- ☐ Install Rear Step
- ☐ Install Compliance Label

Acquisition Workstation

- ☐ Configure Transformer Tap
- ☐ Connect Ground Wire from Generator
- ☐ Install Image Monitor
- ☐ Install Control Monitor
- ☐ Review Radiation Shield Requirements with Customer

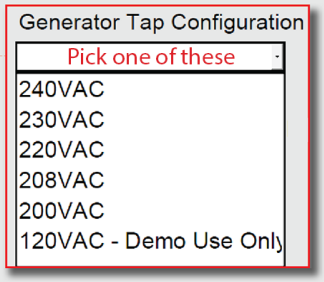
Accessory Cart

- ☐ Inventory Pads and Apertures
- ☐ Review Placement of Accessory Cart with Customer

Hardware Installation (cont'd)

Mobile Kit Installation

- ☐ Fasten Gantry to the Floor
- ☐ Fasten Generator to the Floor
- ☐ Secure AWS Computer, UPS and Isolation Transformer with Straps
- ☐ Remove Wheels and Fasten AWS to the Floor
- ☐ Remove Monitor Crossbar and Replace with Mobile Crossbar and Post
- ☐ Attach Mouse Holder to AWS
- ☐ Attach Remote X-ray Controller to AWS
- ☐ Attach Locking Keyboard Tray Bracket
- ☐ Install Mobile Brake on VTA
- ☐ Install Mobile C-arm Retainer Mounting Block
- ☐ Install Mobile Footrest Retainers



- ☐ Hardware Installation Complete

Voltage Verification

Use CalTool Line Voltage Verification Task

Generator Tap Configuration ☐

Record Generator Idle Line Voltage ☐

Record Generator Line Voltage with 28kV ~3 Second Exposure ☐

- ☐ Voltage Verification Passed
- ☐ Verify AWS Tapped Correctly

The Measured Voltages are within +/-10% of Tap Configuration

System Check

System Cleaning

- ☐ Inspect Table and AWS for Cleanliness
- ☐ Clean Image and Control Monitors
- ☐ Check Computer Fans for Cleanliness
- ☐ Replace Detector Filters (ASY-09689, Package of Two)

System Lubrication

- ☐ Apply Grease to the Tubehead Filter Wheel Assembly Gear (2-580-0207 Using TLS-05368)
- ☐ Inspect and Lubricate VTA Assembly (PN 2-580-0207)
- ☐ Clean and Reapply X-ray Tube Grease (Dow Corning Silicone 540-0108)

Customer Concerns

☐ Customer Concerns Were Resolved

System Integrity

- ☐ Inspect Wiring for Safety and Integrity
- ☐ Check Function of Safety Interlocks, Switches and Limit Switches
- ☐ Inspect X-ray Tube High Voltage Cable and Connector
- ☐ Verify C-arm Angle Calibration
- ☐ Verify C-arm Brake Function
- ☐ Verify C-arm Lock Function
- ☐ Verify Tomo Arm Function
- ☐ Verify Compression Thickness Calibration
- ☐ Verify Compression Force
- ☐ Verify Table Up/Down Switch Operation
- ☐ Verify Table Home Switch Operation
- ☐ Verify Table light Switch Operation
- ☐ Verify Detector to Bottom of Table Clearance is at Least 1/4"
- ☐ Check Table to X-ray Tube Clearance
- ☐ Verify BCM Screen Brightness/Quality
- ☐ Verify Operation of BCM Movement Switches
- ☐ Check UPS Performance Status
- ☐ Verify Software Node Software Version
- ☐ Clean AWS Database

CalTool Verification

- ☐ X-Ray Field Detector Alignment
- ☐ X-Ray Field Collimator Alignment

X-ray Tube Voltage

Use CalTool Tube Voltage Verification Task

Measured Voltage		Min - Max
20kV		19.20 - 20.80
25kV		24.00 - 26.00
30kV		28.80 - 31.20
35kV		33.60 - 36.40
39kV		37.44 - 40.56

All Values Must Be Within 4% of the Requested Configuration Value.

☐ X-ray Tube Voltage Verification Passed

Generator mA and Exposure Count

☐ Generator mA

Value Must Be 100mA +/-0.5mA

☐ Generator mA Pass

☐ Generator Exposure Count

Filament Calibration

☐ Filament Calibration Complete

X-ray Tube Current

Use CalTool Tube Current Verification Task

10mAs	Enter mAs - Range 8-12
25kV	
30kV	
35kV	

100mAs	Enter mAs - Range 96-104
25kV	
30kV	
35kV	

200mAs	Enter mAs - Range 192-208
30kV	
35kV	

400mAs	Enter mAs - Range 384-416
35kV	

500mAs	Enter mAs - Range 480-520
35kV	

☐ X-ray Tube Current Verification Passed

HVL Verification

Use CalTool HVL Spot Check Task

Ag(28kV)		Al(29kV)	
Measured mR		Measured mR	
Measured HVL		Measured HVL	
Tube Output		Tube Output	
HVL in File		HVL in File	
TO in File		TO in File	

Measured Value Must Be Within 5% of File Value to Pass.

☐ HVL Verification Pass

Image Quality Verification

☐ Gain Calibration Completed

Traditional ACR Phantom

	Fibers	Specks	Masses	Pass	
2D Requirements	5 Fibers	4 Groups	4 Masses	☐	3.5 Masses are Acceptable per 1999 ACR QC
Measured	☐	☐	☐		
3D Requirements	4 Fibers	3 Groups	3 Masses	☐	
Measured	☐	☐	☐		

ACR 2016 Phantom

	Fibers	Specks	Masses	Pass
2D Requirements	≥2.0	≥3.0	≥2.0	☐
Measured	☐	☐	☐	

☐ Ag Filter No Artifacts

☐ Al Filter (3D) No Artifacts

☐ Image Quality Verification Pass

Target Dose Verification mGy

Modality	Target	Measured	kV	mAs	EI
2D					
3D					

☐ Dose Verification Pass +/- 0.1 mGy

Phantom Used

☐ ACR

☐ PMMA

AEC Performance Use CalTool AEC Scaling Verification Task

Thick	Filter	kV	mAs	Dose	mAs Mult	Adj. EI	Low	High	Result
2cm	Ag	☐	☐	☐	☐	☐	☐	☐	☐
4cm	Ag	☐	☐	☐	☐	☐	☐	☐	☐
6cm	Ag	☐	☐	☐	☐	☐	☐	☐	☐
8cm	Ag	☐	☐	☐	☐	☐	☐	☐	☐
2cm	Al	☐	☐	☐	☐	☐	☐	☐	☐
4cm	Al	☐	☐	☐	☐	☐	☐	☐	☐
6cm	Al	☐	☐	☐	☐	☐	☐	☐	☐
8cm	Al	☐	☐	☐	☐	☐	☐	☐	☐

☐ AEC Performance Pass

QAS Verification

Lateral -90 Degrees

	Target	Actual
X	-30.0	
Y	40.0	
Z	50.0	

Lateral +90 Degrees

	Target	Actual
X	30.0	
Y	40.0	
Z	50.0	

Standard 0 Degrees

	Target	Actual
X	30.0	
Y	40.0	
Z	50.0	

Tomo 0 Degrees

	Target	Actual
X	30.0	
Y	40.0	
Z	50.0	

☐ QAS Verification Pass

All Measured Values are +/-1.0 mm of Target.

Computer Settings (Installation Only)

- ☐ Configure Windows Time Zone and Date
- ☐ Configure Network Settings
- ☐ Configure Computer Host Name
- ☐ Configure/Verify/Email Hologic Connect Settings (Optional)

- ☐ Computer Setting Complete

Application Settings (Installation Only)

- ☐ Configure Institution, Address, Station Name and Locale
- ☐ Configure Serial Number in System Settings
- ☐ Verify Reclaimer System Settings (Factory Default No Storage Commit)
- ☐ Verify Reclaimer User Settings (Factory Default No Storage Commit)
- ☐ Verify / Install Licenses
- ☐ Set System AE Title in Connectivity (Global)
- ☐ Configure Procedure RIS Codes (when available)

- ☐ Application Settings Complete

Interface Configuration (Installation Only)

- ☐ Install Modality Worklist Interface(s)
- ☐ Install Archive/Router Devices
- ☐ Install Workstation Devices (as Needed)
- ☐ Install printer Devices (as Needed)
- ☐ Install Query/Retrieve Interfaces
- ☐ Set/Verify Retrieve Address for Query/Retrieve Devices
- ☐ Configure Installed Device's Info, IP Address, AE Title and Port Data
- ☐ Verify/Install Optional Image Types for Store Devices
- ☐ Verify/Install Optional Transfer Syntaxes for Store Devices
- ☐ Verify/Configure Film Sizes for Printer Devices
- ☐ Configure Output Groups
- ☐ Install/Configure Optional Features as Needed (i.e. Dose Reporting, MPPS)
- ☐ Restart System

- ☐ Interface Configuration Complete

Interface Tests (Installation Only)

- ☐ Verify MWL Query Results
- ☐ Verify MWL RIS Code Mapping is Set Correctly
- ☐ Verify Images are Stored On PACS (Verify Selected DICOM Support Types are being Stored/Selected as Applicable)
- ☐ Verify Images can be Viewed and Oriented Correctly on PACS
- ☐ Verify Images can be Retrieved from PACS (Verify All Selected Support Types can be Retrieved/Viewed)
- ☐ Verify Images can be Sent to Workstations (Optional)
- ☐ Verify Images are Sent to DICOM Printer (Optional)
- ☐ Verify that Correct TOMO Format is Sent to PACS and Workstation (3D System)
- ☐ Verify Export Settings for Removable Media

- ☐ Interface Tests Complete

Final Tasks

- ☐ Verify 2D Image Processing, SHARP is Default
- ☐ Equipment Placement/Fastening
- ☐ Connection of Modules/Cable Management
- ☐ Ship Back Detector Packaging and Dolly (Installation)
- ☐ Clean System Exterior
- ☐ Check and Store All Accessories
- ☐ Discuss Location of Accessory Cart with Customer (Installation)
- ☐ Perform System Backup Including Node Calibrations
- ☐ Complete Installation Report (Installation)
- ☐ Complete FDA 2579 Form (Installation)
- ☐ Final Tasks Complete

Attach this PDF file to the Hologic Installation Form via the Attachment Box at the Bottom of the Web Page.

Comments

F.2 Compliance Forms

F.2.1 Tube Current/Exposure Time Product Forms

Table 24: Tube Current Exposure Time Product Expected Results

mA Setting	mAs Setting	mAs Reading at 25kV	mAs Reading at 30 kV	mAs Reading at 35 kV	mAs Reading at 40 kV*	mAs Reading at 45 kV*	mAs Reading at 49 kV*	Minimum Permitted mAs	Maximum Permitted mAs
50	10							9.0	11.0
100	100							90	110
150	200							180	220
200	400							360	440
170	160							144	176
150	140							126	154
140	140							126	154
200	500							450	550

*Using Tomo setting

F.2.2 Peak Tube Potential Form

Table 25: Peak Tube Potential Form

kVp	mA Setting	mAs Setting	Tube Voltage (kV)	Minimum Permitted kV	Maximum Permitted kV
20	100	100		19.00	21.00
25	100	100		23.75	26.25
30	150	200		28.50	31.50
35	200	400		33.25	36.75
39	200	400		37.05	40.95
40*	170	160		38.00	42.00
45*	150	140		42.75	47.25
49*	140	140		46.55	51.45

*Using Tomo setting

F.2.3 Linearity Form

Table 26: Linearity Expected Test Results

mAs Setting	mAs	Meter Reading mR	Quotient mR / mAs	Difference [ABS] (Previous Quotient - This Quotient)	Sum (Previous Quotient + This Quotient)	Difference / Sum
10						
12.5						
16						
20						
32						
50						
100						
200						
320						
400						
500						

F.2.4 Reproducibility Form

Table 27: Reproducibility Form

	Meter Reading mR	$\frac{(mR - Mean\ mR)^2}{9}$	Test Results:
1			**Standard Deviation** (/(Sum of Quotients))
2			
3			
4			
5			
6			**Coefficient of Variation** (Std.Dev./Mean mR)
7			
8			
9			
10			
	Sum (mR Readings)	Mean mR (Sum/10)	Sum of Quotients

Appendix G Biopsy Arm Hardware Range Calibration

G.1 Hardware Range Calibration

Perform the hardware range calibration when you replace components in the Biopsy Guidance Module, or you cannot reach points specified in the STX calibration. The hardware range calibration ensures that the X-axis and Y-axis encoder pots are mechanically aligned with the mid-point of the drive screws for the respective X-axis and Y-axis assemblies.

G.2 Required Tools

- Stage Arm (Biopsy Arm) Alignment Dowel Pin (MME-01182) - used for mechanically aligning the X-axis and Y-axis encoder pots
- Digital Multimeter (DMM) - used to find the electrical midpoint of the X-axis and Y-axis encoder pots
- CalTool

G.3 Cover Removal to Gain Access

1. Rotate the Biopsy Control Module so it is perpendicular to the C-arm.
2. Shut down the system.
3. Remove the following covers:
   - Biopsy Arm front-end cover (refer to *Remove Front-end Cover of Biopsy Control Module* on page 192)
   - Biopsy Arm rear-end cover (refer to *Remove Rear-end Cover of Biopsy Control Module* on page 193)
   - Biopsy Control Module display covers (both sides, refer to *Remove Displays/Covers of Biopsy Control Module* on page 190)
   - Biopsy Control Module display bottom cover (refer to *Remove Bottom Cover of Biopsy Control Module Display* on page 194)

G.4 Mechanically Aligning the X-Axis and Y-Axis Encoder Pots

1. Insert the dowel pin (MME-01182) into the center alignment hole for the X-axis assembly (see following figure).

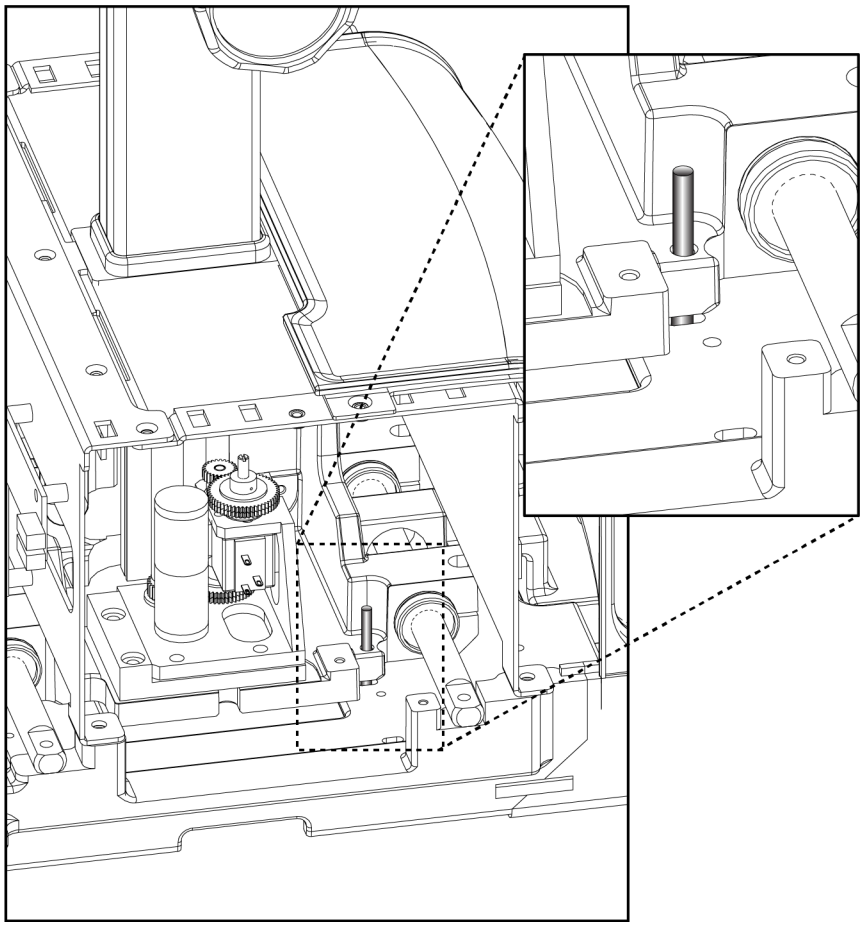


Figure 203: Dowel pin in center alignment hole for X-axis assembly

2. With a screwdriver, turn the slotted end of the drive screw for the X-axis assembly (see following figure, item 2) so the X-axis dowel pin drops into the center alignment slot. (The previous figure shows the X-axis assembly in the center position with the dowel pin dropped in the center alignment slot.)

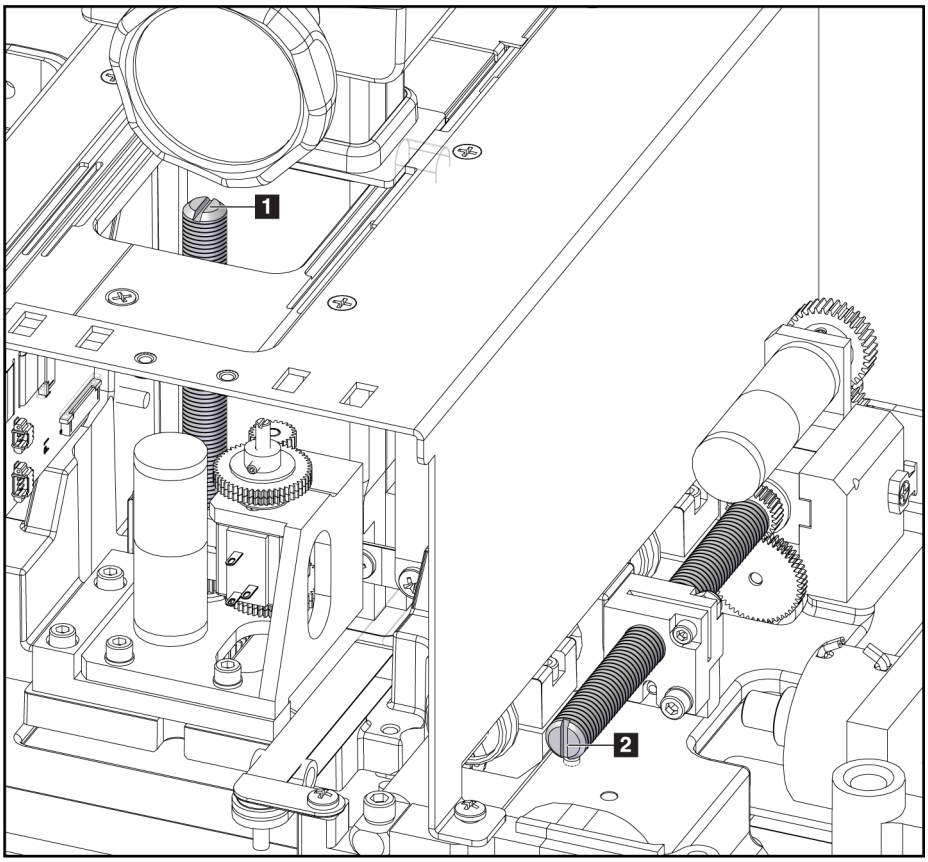


Figure 204: Y-axis assembly drive screw (1), X-axis assembly drive screw (2)

Caution:
Do not force the shaft to turn while the dowel pins is in the alignment slot. Doing so may cause the X-axis drive gear to become loose and slide off the end of the shaft.

3. Locate the X-axis encoder pot (see following figure, item 1). Loosen the setscrew and remove the anti-backlash gear (see following figure, item 2) from the pot shaft.

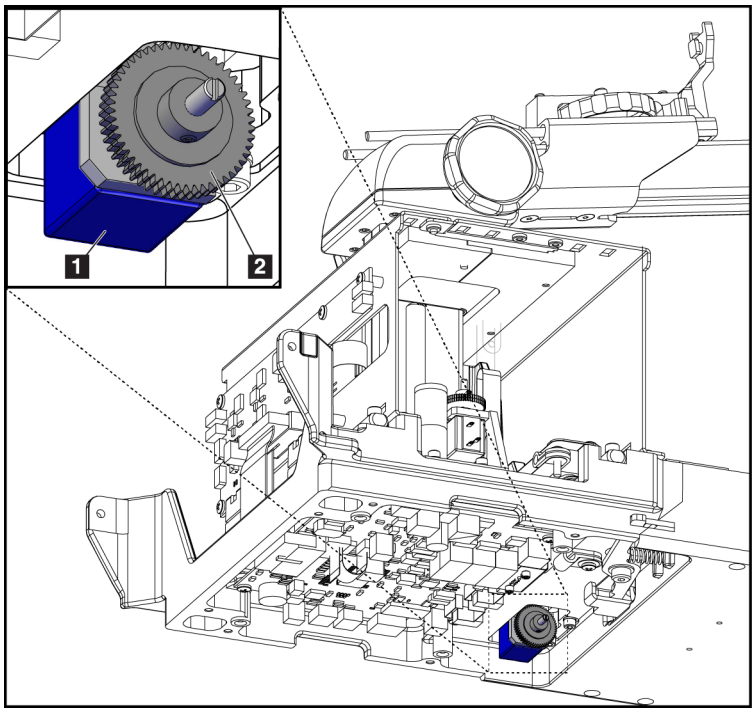


Figure 205: X-axis encoder pot (1) with anti-backlash gear (2)

4. Disconnect the harness for the X-axis encoder pot from the Biopsy Module Motor Drive Board and do the following (see following figure):
   a. Place the DMM leads on Pin 1 and Pin 3 of the encoder pot and measure the full resistor value on the ohms scale.
   b. Keep one lead on Pin 1 and place the other lead on Pin 2. Turn the encoder pot shaft so the DMM reads ½ of the measured full resistor value.
   c. Keep one lead on Pin 2 and place the other lead on Pin 3. The DMM measured value should be within +/- 0.02 of the value found in substep b. If it does, this location represents the center position for the pot.
   d. Repeat substeps a to c if necessary to get the proper readings.

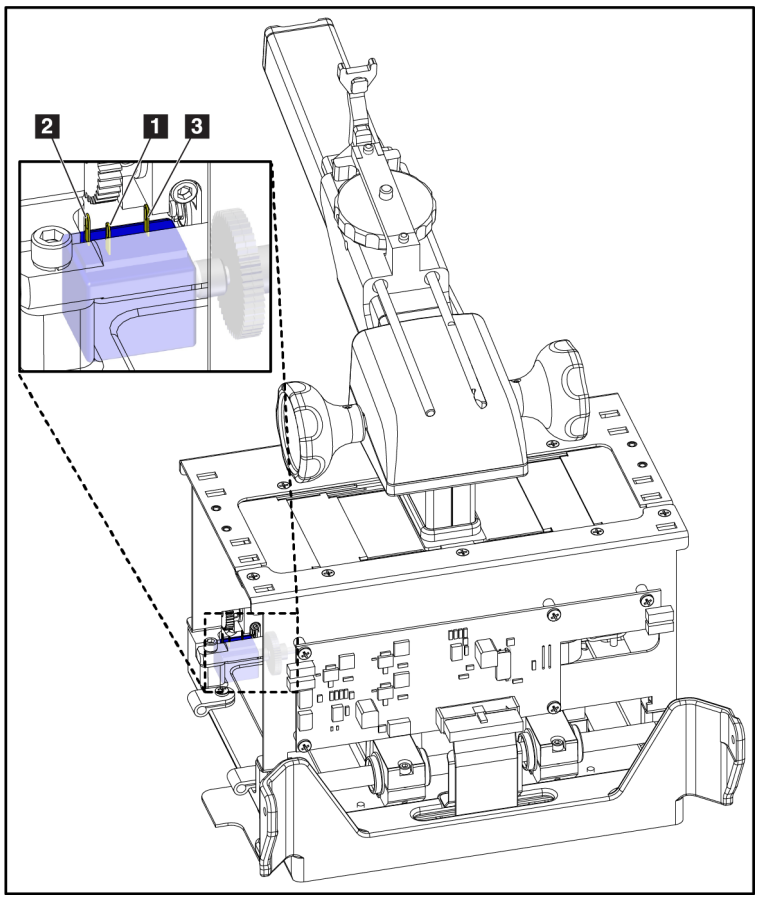


Figure 206: Location of pins 2, 1, and 3 on X-axis encoder

5. Reconnect the harness for the X-axis encoder pot.
6. Reinstall the anti-backlash gear on the pot shaft. Make sure that you rotate and engage the gear three-teeth in the process and tighten the setscrew. The X-axis encoder pot should now be aligned.
7. Remove the dowel pin from the X-axis center alignment hole.

8. Insert the dowel pin into the center alignment hole for the Y-axis assembly (see following figure).

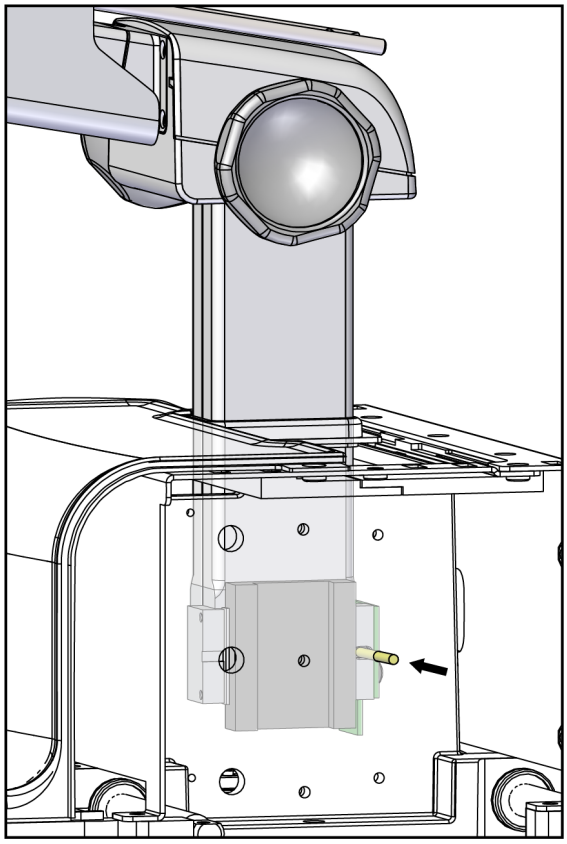


Figure 207: Dowel pin in center alignment hole for Y-axis assembly

9. With a screwdriver, turn the slotted end of the drive screw for the Y-axis assembly (see following figure, item 1) until you can push the dowel pin with your finger into the center alignment slot. (The previous figure shows the Y-axis assembly in the center position with the dowel pin pushed in the center alignment slot).

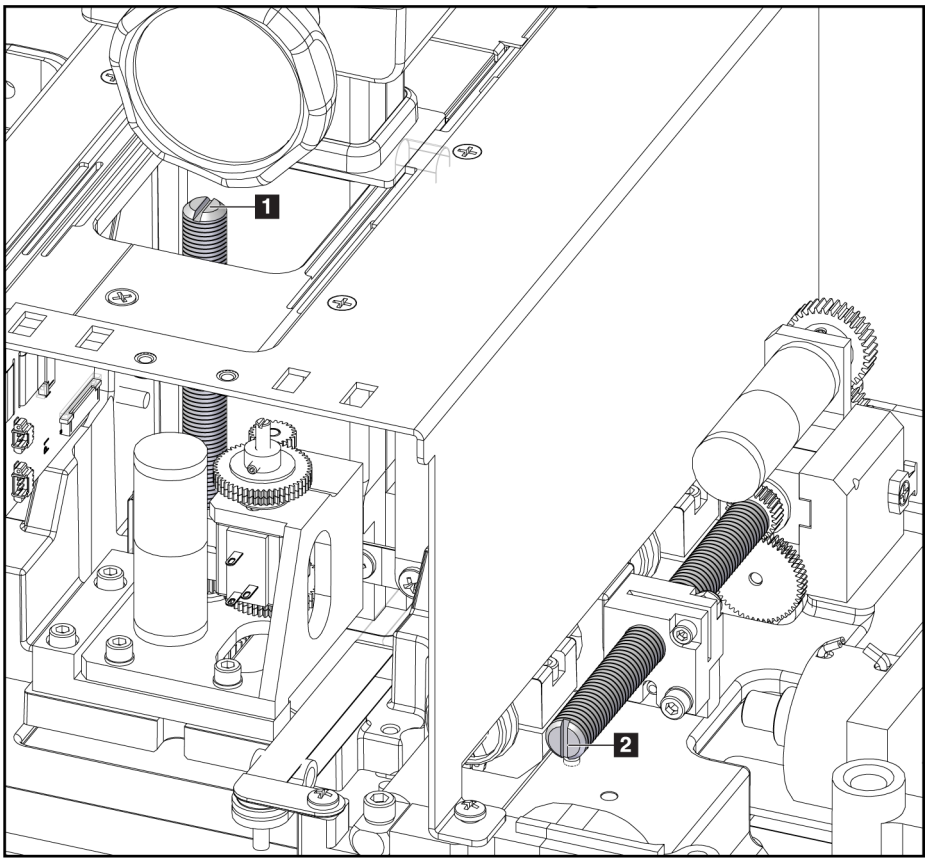


Figure 208: Y-axis assembly drive screw (1), X-axis assembly drive screw (2)

10. Locate the Y-axis encoder pot (see following figure, item 1). Loosen the setscrew and remove the anti-backlash gear (see following figure, item 2) from the pot shaft.

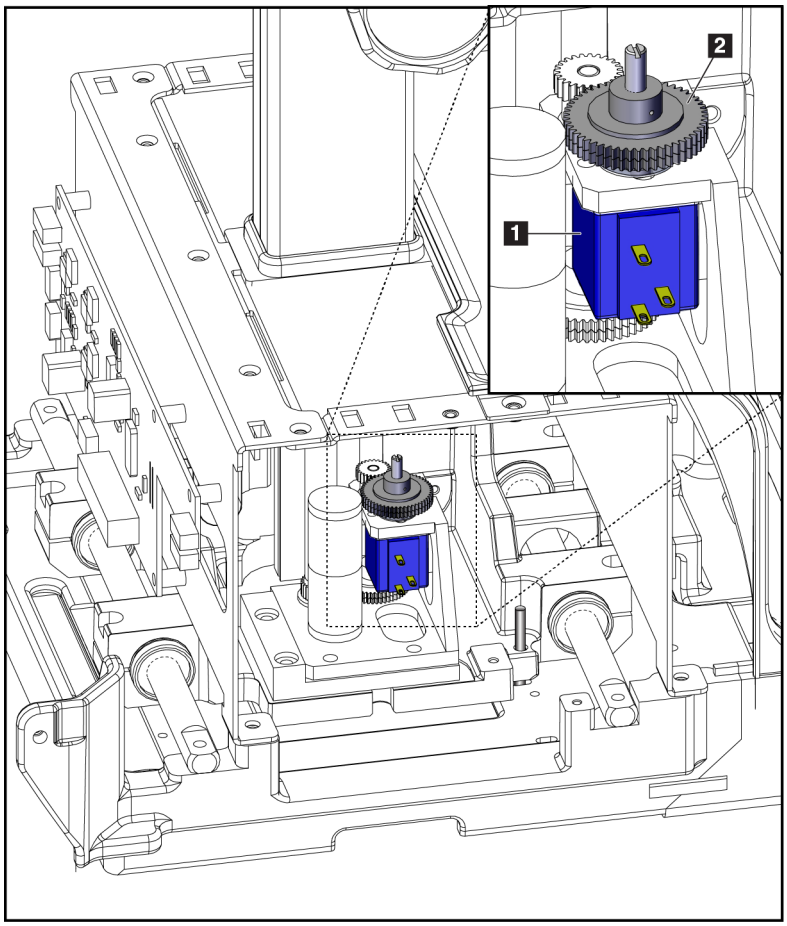


Figure 209: Y-axis encoder pot (1) with anti-backlash gear (2)

11. Disconnect the harness for the X-axis encoder pot from the Biopsy Module Motor Drive Board and do the following (see following figure):
    a. Place the DMM leads on Pin 1 and Pin 3 of the encoder pot and measure the full resistor value on the ohms scale.
    b. Keep one lead on Pin 1 and place the other lead on Pin 2. Turn the encoder pot shaft so the DMM reads ½ of the measured full resistor value.
    c. Keep one lead on Pin 2 and place the other lead on Pin 3. The DMM measured value should be within +/- 0.02 of the value found in substep b. If it does, this location represents the center position for the pot.
    d. Repeat substeps a to c if necessary to get the proper readings.

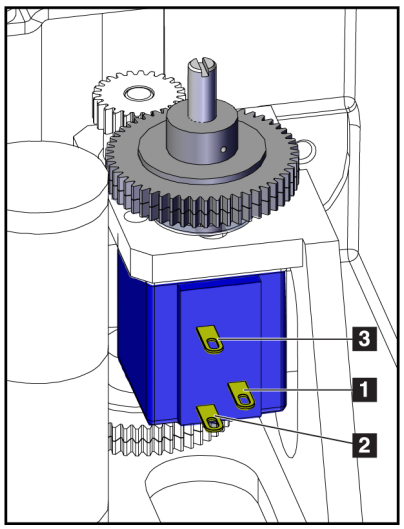


Figure 210: Location of pins 3, 1, and 2 on Y-axis encoder

12. Reconnect the harness for the Y-axis encoder pot.
13. Reinstall the anti-backlash gear on the pot shaft. Make sure that you rotate and engage the gear three-teeth in the process and tighten the setscrew. The Y-axis encoder pot should now be aligned.
14. Remove the dowel pin from the Y-axis center alignment hole.
15. Replace the:
    - Biopsy Control Module display bottom cover
    - Biopsy Control Module displays (both sides)
    - Biopsy Arm front-end cover
    - Biopsy Arm rear cover

Appendix H Biopsy Device Validation Using Targeting Phantom

H.1 Introduction

This appendix provides information for validating biopsy devices from manufacturers other than Hologic factory-verified devices listed in the *table* on page 296. The procedures in this appendix are written for use with the Hologic ASY-08307 Targeting Phantom.

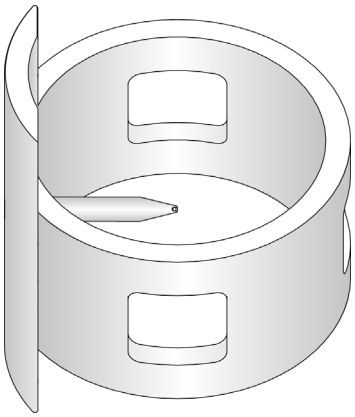


Figure 211: Hologic ASY-08307 Targeting Phantom

H.1.1 Please Read Prior to Performing Calibration

These procedures are designed to be used *in conjunction with* (not to replace) the procedures in the Affirm Prone Biopsy System Service Manual and User Guide, as well as the procedures in the User Guide of any biopsy device that is used with the Affirm system. These procedures provide step-by-step instructions for validating biopsy devices for use with the Affirm Prone Biopsy System.

The validation procedures shall only be performed by those who have received training on the Affirm Prone Biopsy System before use on patients. Hologic training programs address the MQSA training requirements for any Technologist or Physician. Hologic will bear no risk for the use of the Affirm Prone Biopsy System with biopsy devices that have not been validated using the procedures outlined herein, and does not accept responsibility for injury or damage from incorrect system operation.

H.2 Hologic Factory-Verified Biopsy Devices

Table 28: Hologic Factory-Verified Biopsy Devices

Manufacturer	Description	Model
Hologic	Affirm QAS Needle	ASY-03949
Hologic	ATEC® 9 g x 12 cm, 12 mm (Petite)	ATEC 0912-12
Hologic	ATEC 9 g x 12 cm, 20 mm	ATEC 0912-20
Hologic	ATEC 12 g x 12 cm, 20 mm	ATEC 1212-20
Hologic	ATEC 9 g x 9 cm, 12 mm (Petite)	ATEC 0909-12
Hologic	ATEC 9 g x 9 cm, 20 mm	ATEC 0909-20
Hologic	ATEC 12 g x 9 cm, 20 mm	ATEC 1209-20
Hologic	ATEC 9 g x 14 cm, 20 mm	ATEC 0914-20
Hologic	Brevera® 9 g x 13 cm, 20 mm (Standard) or 12 mm (Petite)	BREV09
Hologic	Eviva® 9 g x 13 cm, 12 mm (Blunt Petite)	Eviva 0913-12
Hologic	Eviva 9 g x 13 cm, 12 mm (Trocar Petite)	Eviva 0913-12T
Hologic	Eviva 9 g x 13 cm, 20 mm	Eviva 0913-20
Hologic	Eviva 12 g x 13 cm, 20 mm	Eviva 1213-20
Hologic	Eviva 9 g x 10 cm, 12 mm (Blunt Petite)	Eviva 0910-12
Hologic	Eviva 9 g x 10 cm, 12 mm (Trocar Petite)	Eviva 0910-12T
Hologic	Eviva 9 g x 10 cm, 20 mm	Eviva 0910-20
Hologic	Eviva 12 g x 10 cm, 20 mm	Eviva 1210-20

H.3 Configuring Device and Needle

H.3.1 Add or Edit Biopsy Device Information

Whether you add a new (or edit an existing) biopsy device, keep each parameter within the valid range as stated in the following table. If you believe that a parameter for your device is outside the valid range, contact Hologic Technical Support desk for guidance on how to proceed.

Table 29: Biopsy Device Parameters (see also following parameters diagrams)

Name	Description	Valid Range (in mm)
Aperture	Opening of the biopsy device	0 to 50.0
Dead Space	Distance from needle tip to opening-edge	0 to 20.0
Needle Diameter	Outside-to-outside distance of biopsy device, assuming biopsy device is cylindrical	0 to 25.00
Needle Front	The length from the alignment pin to the front-most point of the needle guide (when the needle guide is in its most retracted position)	0 to 120.0
Needle Length	Length of needle, measured from Biopsy Guidance Module Locality pin to needle tip in post-fire position	160 to 300.0
Needle Offset	Needle Offset, measured from Biopsy Guidance Module surface to center of needle cylinder	0.01 to 100.0
Needle Width	The width of the needle body with adapter installed. (With some models, the adapter is wider than the needle and you need to include this added width as part of the needle width dimension.)	0 to 60.0
Pre-Fire Pullback	Distance between target and pre-fire position of aperture center	-30.0 to 30.0
Stroke	Distance between needle tip position before and after firing biopsy device, measured along firing-axis	0 to 30.0

Items to remember

- Data entry accepts any information. Make sure entries stay within the valid range for each parameter.
- A validity check (range limit met) is not performed immediately upon entry, but only after the biopsy device is selected in the Procedure screen. If a parameter is outside the range when the needle is selected in a procedure, a **Targeting Failed because the system has been configured with invalid biopsy device parameters** error displays.
- The stereo pair using the QAS needle acquired in the first steps of this procedure is used throughout the procedure. You are closing the patient and returning to the patient throughout. Always close "In Progress".
- It is critically important that the phantom not move during this procedure. Do not release compression on the phantom, as that may cause the phantom to move. If the phantom moves, the procedure must be restarted.
- It is important to know how your device operates. When the procedure states that the device should be in the extended (post-fire) position, it is assumed the devices are in their maximum extended position. However, some devices in the post-fire position retract slightly when the aperture is opened. In this case, the aperture should be closed for the device to be in their maximum extended position.

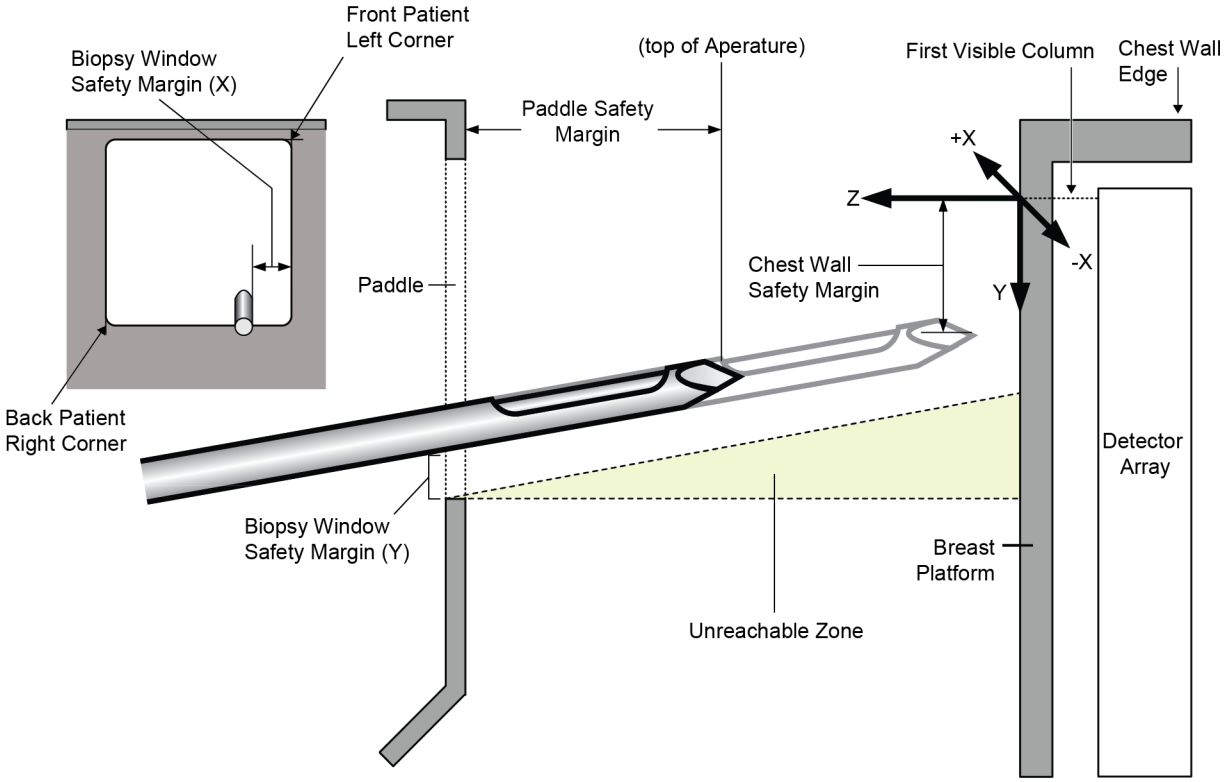


Figure 212: Biopsy Device Parameters (Diagram 1)

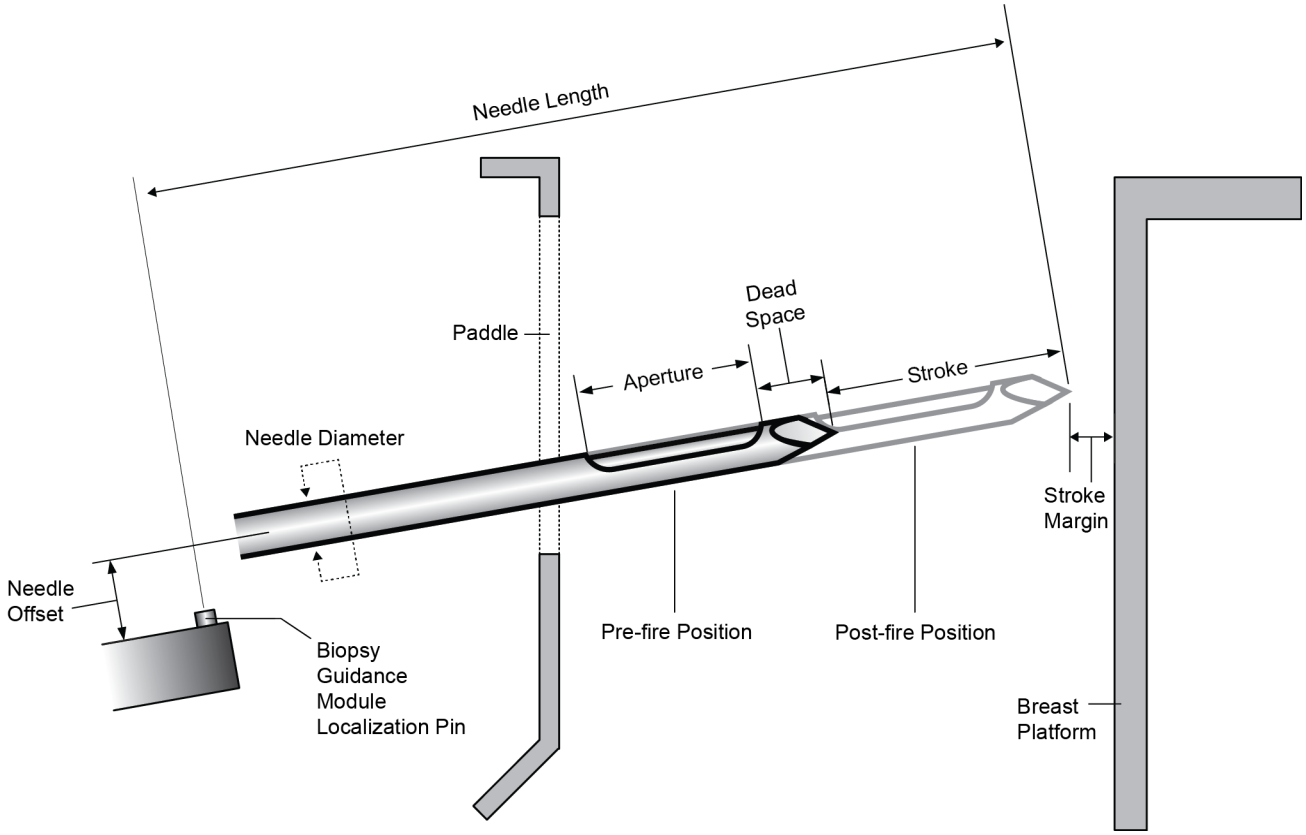


Figure 213: Biopsy Device Parameters (Diagram 2)

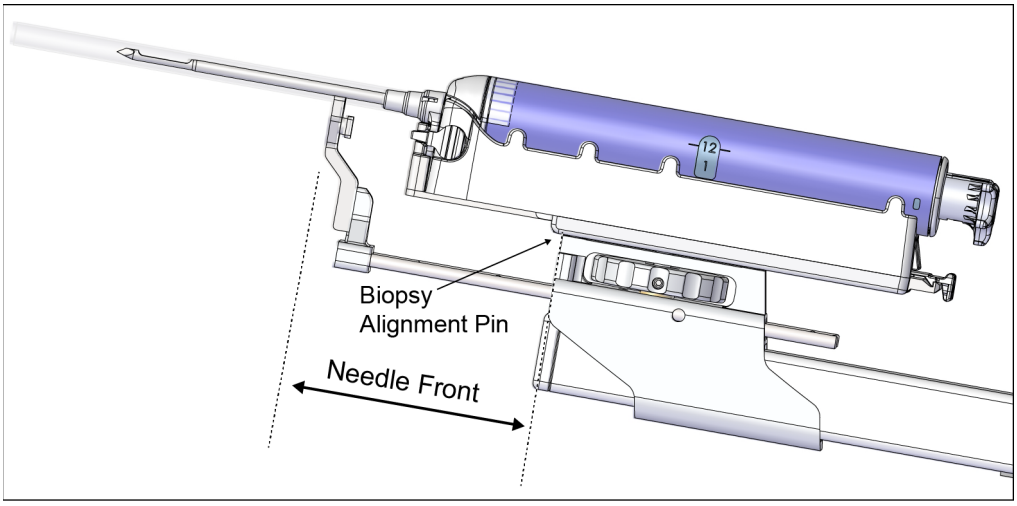


Figure 214: Biopsy Device Parameters (Diagram 3)

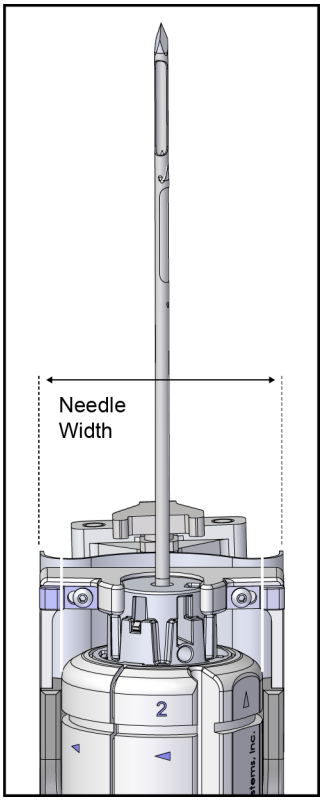


Figure 215: Biopsy Device Parameters (Diagram 4)

H.3.2 Needle Validation Process

Note
All manual jogs in the following procedure are performed from the Biopsy Control Module Target Screen, not from the Service Screen. (This screen affects the target numbers.) The Jog is used to move the needle (and target) away from the phantom tip, which prevents a collision of the needle tip and phantom tip. This method also conveniently provides intuitive results without having to correct for the Jog movement.

Verify the System is Correct for a Known Needle

1. Sign on to the Acquisition Workstation as a Service User.
2. Install a biopsy Compression Paddle.
3. Position the Targeting Phantom on the breast tray and center it in the Biopsy Paddle window (does not have to be exact).
4. Compress the Targeting Phantom with ~10 pounds/~45 newtons of force.
   IMPORTANT: Do not move the phantom for the remainder of this procedure.

5. Install the QAS needle in the extended position.
6. At the Biopsy Control Module, select a **Home** position and press and hold the front and back **Motor Enable** buttons.
7. At the Acquisition Workstation, create a **Biopsy** test patient. Select a name that is easy to remember as you are exiting and entering this patient throughout this procedure.
8. Select **Stereo Pair**.
9. Acquire and accept a stereo image pair of the validation phantom using 25 kVp at 12 mAs.
10. Select the **QAS needle** at the Acquisition Workstation.

QAS Needle Verification Procedure

1. Target on the tip of the needle (not the center of the ball) in each of the two stereo images, and then select **Accept (Create) Target**.
2. At the Biopsy Control Module, press and hold the **Motor Enable** buttons to move to the target.
3. Select the **Jog** button, then the **Jog away from the chest wall** once. Press and hold the **Motor Enable** buttons. This essentially moves the "target" 0.5 mm away from the phantom tip to allow easier positioning of the QAS needle tip. It also avoids a collision between the QAS tip with the phantom tip.
4. Move the Z down to so that the tip of the QAS needle is at the same level as the tip of the phantom.
5. Visually verify the alignment of X and Y. If X or Y appears to be off, press **Motor Enable** to be sure that the motorized movement was completed. Do not make any other adjustments. Do not move the phantom.
6. Inspect the **Diff** line for ± 1 mm (maximum) X, Y, and Z values on the Biopsy Control Module.
7. Raise the Z and carefully remove the QAS Needle. Do not move the compression or the phantom.
8. Close the procedure "In Progress".
   - To configure a "New" needle, proceed to *Obtain Needle Specifications* on page 302.
   - To edit an existing needle, proceed to *Edit Information for an Existing Biopsy Device* on page 303
   - To validate an existing needle, proceed to *Validate Needle* on page 304.
   - To configure a new Wire Localization needle, proceed to *Validate Needle* on page 307, "*Validate the Wire Localization Needle*" on page 305.

Configure a New Biopsy Needle

Obtain Needle Specifications

1. Record the following technical details from the biopsy device manufacturer:

Needle Name	_____
Aperture	_____mm
Dead Space	_____mm
Diameter	_____mm
Length x 2	_____mm
Per-Fire Pullback (calculate by adding dead space + 1/2 aperture, then subtract the stroke)	_____mm
Stroke	_____mm

2. Measure the Offset parameter with the device in the extended (or post-fire) position.
   a. Install the fired device in the holder, and place the holder on a flat surface.
   b. Measure from the flat surface to the estimated center of needle barrel (see the following figure). Offset =_____mm.

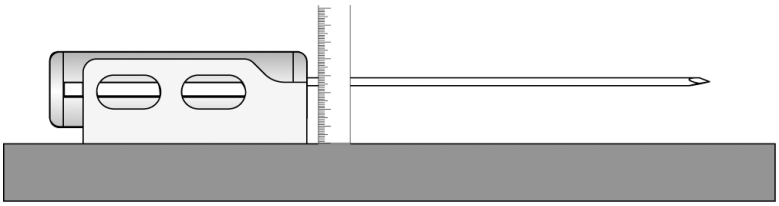


Figure 216: Offset Measurement, Device in Extended (post fired) Position

3. Add a (new) biopsy device to the Acquisition Workstation.
   a. Select **Admin**; then in the **System** section, select **Biopsy Devices**.
   b. Select **New**.
   c. **Enter "0" for Aperture and Dead Space.**

      This setting allows the reference to be the needle tip (instead of the center of the aperture) for determining accurate needle length (NL).
   d. Enter the remaining biopsy device parameter information. See the *table* on page 297 for valid parameter ranges.
   e. Select **Add**. The measurements are now available on the Acquisition Workstation.

Edit Information for an Existing Biopsy Device

1. Select **Admin**; then in the **System** section, select **Biopsy Devices**.
2. Select the biopsy device from the list.
3. Select **Edit**.
4. Enter "0" for **Aperture and Dead Space.**
5. Edit any other parameters for the selected biopsy device as needed. See the *table* on page 297 for valid parameter ranges.
6. Select **Save**. The measurements are now available on the Acquisition Workstation.
7. Continue with Calculate New Needle Parameters.

Calculate New Needle Parameters

1. Open the same procedure used earlier with the QAS needle.
2. Select the same stereo pair acquired earlier.
3. Select the new **Device** from the list.
4. Select **OK** at the warning message *Target outside biopsy aperture.*
5. Select **Resend Target**.
6. At the Biopsy Control Module, press and hold the **Motor Enable** buttons to move to the target.
7. Install the new Needle Guide and device in the extended (post-fire) position.
8. Jog 0.5 mm away from the chest wall.
9. Move the Z down to align the needle tip at the same height as the tip of the Phantom pin.
10. Note the **Z Diff** from the Biopsy Control Module. This number is adjusted to the previously entered length in the Acquisition Workstation Biopsy Devices menu in the next procedure.
11. At the Acquisition Workstation, close the patient "In Progress".

Adjust the Needle Length at the Acquisition Workstation

1. Select **Admin**; then in the **System** section, select **Biopsy Devices**.
   a. Select the **Biopsy Device** in the list.
   b. Select **Edit**.
   c. Calculate the "Length".

      Length = Manufacturer Length x 2 +/- Z Diff

      Length was recorded earlier in Obtain Needle Specifications.

      Z Diff was noted earlier in Calculate New Needle Parameters.
2. Enter the new calculate **Length** as the "Length".
3. Replace the previously entered "0" for the **Aperture** and **Dead Space** with the values from the manufacturer for **Aperture** and **Dead Space** as recorded in Obtain Needle Specifications.
4. Select **Save**.

Validate Needle

1. Open the same procedure used earlier with the QAS needle and select the previously acquired stereo pair.
2. Select the **Device** from the list.
3. Select **Resend Target**.
4. If necessary, remove the device and reinstall with the aperture opened.
5. On the Biopsy Control Module, press and hold **Motor Enable** until the X and Y motion stops.
6. Jog in 0.5 steps 2 mm away from the chest wall (four steps).
7. Move the Z knob until the tip of phantom pin is aligned with the center of the biopsy needle aperture.
8. Jog back towards the chest wall the same amount you moved away from the chest wall in the earlier step.
9. Confirm that the X Diff, Y Diff, and Z Diff value reads ±2.0 mm maximum (The system and the new needle each contribute 1.0 mm.)
   - If the 'X' target value is not correct, recheck the Needle Guide alignment.
   - If the 'Y' target value is not correct, recheck the Offset measurement.
   - If the 'Z' target value is not correct, recheck needle length, Aperture, and Dead Space values. *Note: Some Needle Core Biopsy devices retract the biopsy needle tip in the pre-fire (open aperture) position. For these devices, the Z diff value may exceed ±2 mm. This value is acceptable provided the phantom pin tip lies within the middle one-third of the aperture.*
10. Jog the needle away from the chest wall before removing the needle.

Note
Loaner biopsy devices require revalidation. Use professional judgment to determine needle validation. Be aware of any changes in devices by vendors.

Note
If you are validating a Wire Localization Needle, also perform the steps in Validate the Wire Localization Needle.

H.4 Configuring the Wire Localization Needle

H.4.1 Validate the Wire Localization Needle

Note
Do not validate needles 7.5 cm or shorter.

1. Record the following technical details from the biopsy device manufacturer (all in mm):
   - Needle Name _____
   - Diameter _____mm
   - Length x 2_____mm
2. Measure the following parameters with the needle installed in the holder.

   Offset

   a. Install the needle in the holder, and place the holder on a flat surface.

   b. Measure from the flat surface to the estimated center of the needle barrel. _____mm

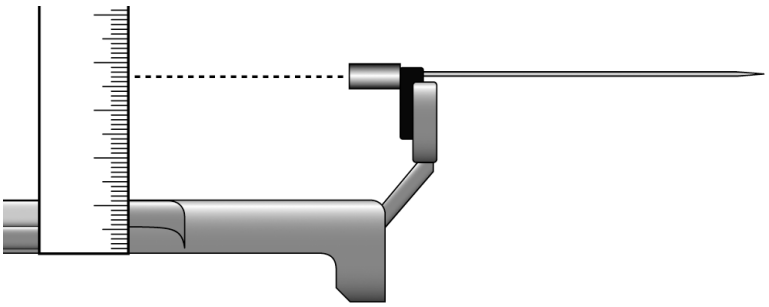


Figure 217: Adapter Surface to the Center of Needle Barrel

Length

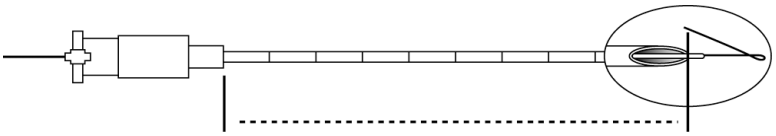


Figure 218: Length Measurement

3. Select **Admin**; then in the **System** section, select **Biopsy Devices**.
4. Select **New**.

5. Enter the following values; leave all other fields at 0.0:
   - Name
   - Enabled (confirm box is checked)
   - Diameter
   - Length x 2
   - Offset (calculated earlier)
6. Check the **Needle Localization** check box.
7. Select **Add**. The measurements are now available on the Acquisition Workstation.

H.4.2 Calculate and Confirm the New Wire Localization Needle Parameters

1. Open the procedure used with the QAS needle, and select the stereo pair.
2. Select the new **Device** from the list.
3. Select **Resend Target**.
4. At the Biopsy Control Module, press and hold the **Motor Enable** buttons to move to the target.
5. Install the new Needle Guides and needle.
6. Move the Z down to align the tip of the needle with the tip of the Phantom Pin.
7. Read the **Z Diff** from the Biopsy Control Module. This number is adjusted to the previously entered **Length** in the Acquisition Workstation Biopsy menu in the next procedure.

   Length = Manufacturer Length x 2 +/- Z Diff

   Length was recorded earlier in Obtain Needle Specifications.

   Z Diff was noted earlier in Calculate New Needle Parameters.
8. At the Acquisition Workstation, close the patient "In Progress".

H.4.3 Adjust the Needle Length on the Acquisition Workstation

1. Select **Admin**; then in the **System** section, select **Biopsy Devices**.
   a. Select the **Wire Loc needle** in the list.
   b. Select **Edit**.
   c. Enter the new calculate **Length** in the length field.
2. Select **Save.**

H.4.4 Validate Needle

1. Open the procedure used earlier with the QAS needle, and select the previously acquired stereo pair.
2. Select the needle from the list.
3. Select **Resend Target**.
4. At the Biopsy Control Module, press and hold the **Motor Enable** buttons to move to the target.
5. Move the Z down to align the tip of the needle with the tip of the Phantom Pin.
6. On the Biopsy Control Module, confirm that the X Diff, Y Diff, and Z Diff value reads ±2.0 mm. (The system and the new needle each contribute 1.0 mm.)
   - If the 'X' target value is not correct, recheck the Needle Guide alignment.
   - If the 'Y' target value is not correct, recheck the Offset measurement.
   - If the 'Z' target value is not correct, recheck needle length (refer to *Calculate and Confirm the New Wire Localization Needle Parameters* on page 306).

Note
Loaner biopsy devices require revalidation. Use professional judgment to determine needle validation. Be aware of any changes in devices by vendors.

Glossary of Terms

ACR

American College of Radiology

AEC

Automatic Exposure Control

BCM

Biopsy Control Module

Collimator

A device at the x-ray tube to control the x-ray beam exposure area.

DICOM

Digital Imaging and Communications in Medicine

EMC

Electromagnetic Compatibility

Image Receptor

Assembly of the x-ray detector and carbon fiber cover.

Lateral Needle Approach

Biopsy device approach that is parallel to the imaging plane and perpendicular to the plane of compression.

MQSA

Mammography Quality Standards Act

PACS

Picture Archiving and Communications System. A computer and network system that transmits and archives digital medical images.

ROI

Region of Interest

SID

Source to Image Distance

Standard Needle Approach

Biopsy device approach that is parallel to the plane of compression and perpendicular to the imaging plane.

Stereo Pair

The stereotactic image pair acquired from the ±15° projections.

Stroke

Excursion of needle when the biopsy instrument is fired. The Stroke is entered into the system and depends on the instrument used. Each instrument has a specified stroke.

Stroke Margin

The safety margin (in mm) which remains between the fired needle position and the breast platform. This margin is calculated by the system according to the "Z" coordinate, the Stroke, and the compression amount.

Tomosynthesis

An imaging procedure that combines a number of breast images taken at different angles. The tomosynthesis images can be reconstructed to show focal planes (slices) within the breast.

UPS

Uninterruptible Power Supply

X-axis

Refers to the horizontal plane across the biopsy window. When the Needle Guidance Stage moves left of the reference point, the movement in the X direction is negative. When the stage moves right of the reference point (from the point of view of the patient), the movement is positive.

Y-axis

Refers to the vertical plane directly above the biopsy window. When the Needle Guidance Stage moves away from the reference hole (from the point of view of the chest wall edge of the biopsy paddle), the Y direction movement increases in value. When the Stage moves toward the reference hole, Y decreases in value.

Z-axis

Refers to the depth through the biopsy window. The value of Z increases as the Stage moves toward the breast platform, and decreases as the stage moves away from the platform.

Index

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

R

S

T

U

V

W

X

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