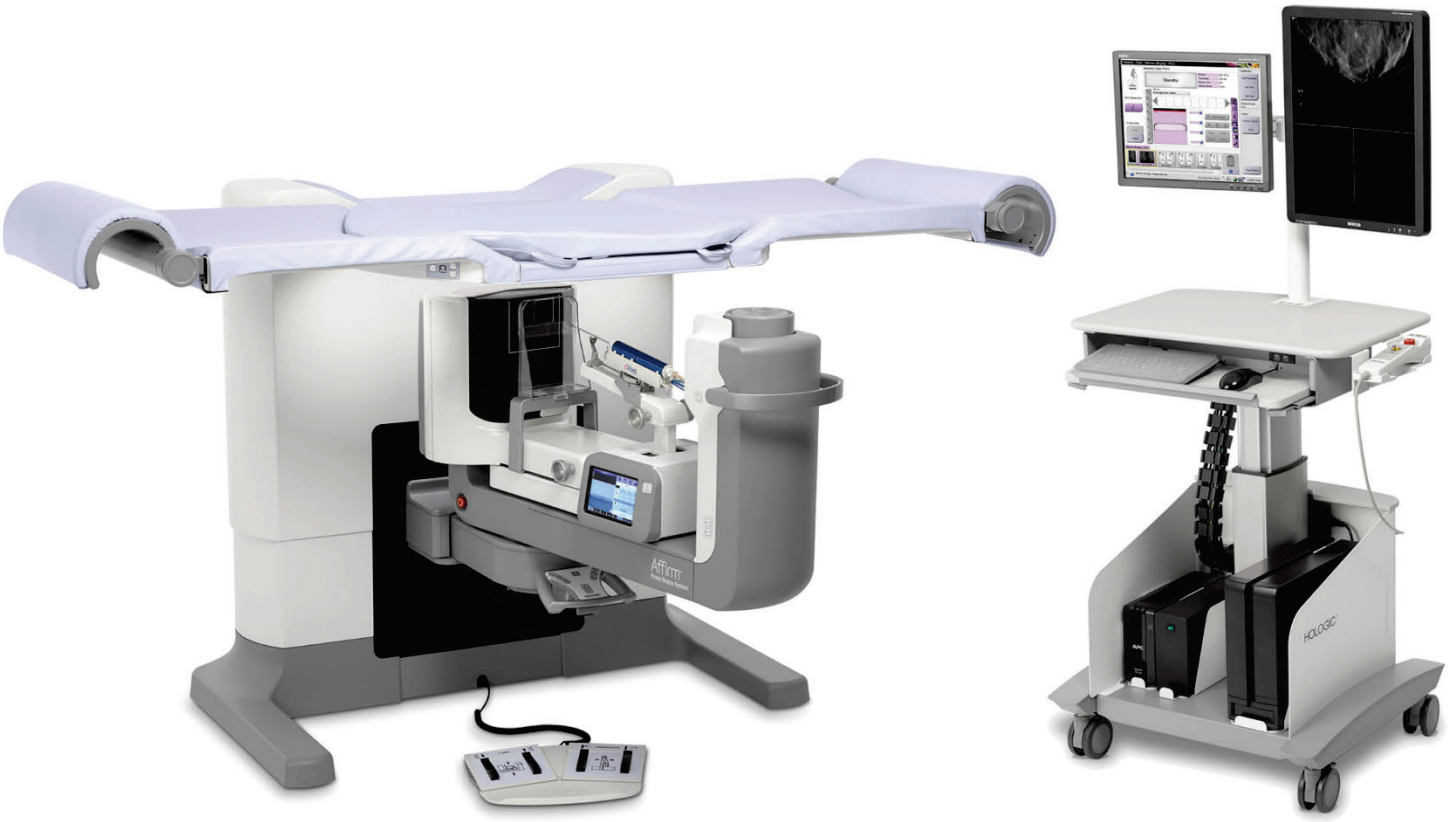
Affirm®
Prone Biopsy System



Site Planning and Pre-Installation Guide
for Mobile Use
MAN-04886 Revision 002

HOLOGIC®

Affirm®

Prone Biopsy System

Site Planning and Pre-Installation Guide for Mobile Use

Part Number MAN-04886
Revision 002
July 2018

HOLOGIC®

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Chapter 1 General Information

1.1 Introduction

This guide is an aid for the Installation Coordinator responsible for site planning and preparation. It contains all product information, specifications, and directions necessary for determining the installation requirements. All information in this guide is important and relevant to the planning process.

Caution:
Ensure that all installations meet local regulations. A licensed electrician must perform the necessary electrical services.

Caution:
Hologic strongly recommends using experienced contractors who specialize in constructing mobile medical vans. Hologic will not warrant systems going into recreational vehicles that may have the required space, but not the required protection from shock and vibration.

Note
Hologic is not responsible for the mounting scheme in the coach.

Note
The mounting diagrams provided in this manual are recommendations only; the final responsibility for proper installation belongs to the Installation Coordinator.

1.2 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 *Mobile Specifications* on page 14.) 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.

Note
If a mobile power generator is used, make sure that it is at least 3 meters (10 feet) from the system. If this distance requirement cannot be met, additional EMI or RF shielding can be required.

1.3 System Overview

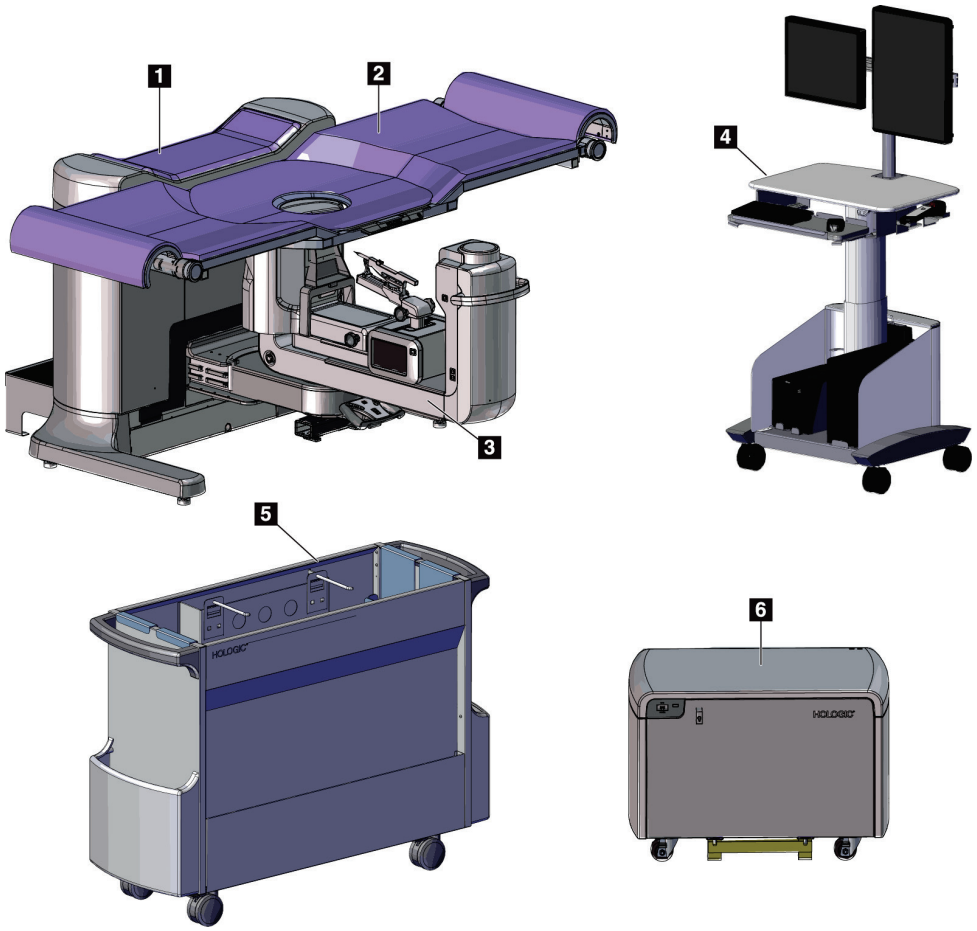


Figure 1: Affirm Prone Biopsy System

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.

1.4 System Location Considerations

The *Site Planning Checklist* on page 19 is set up to assist you with the following topics when selecting a location for the system:

1. System component sizes and weight
   - Flooring type for mounting and weight considerations
   - Doorway clearance
   - Installation space
   - Relocation of equipment
2. Room size
   - Movement clearance—Allocate space for patient and technologist movement. Avoid obstructions in the room that hinder access to the unit controls or the patient.
   - Storage—Provide convenient storage for system accessories. If it is not possible to store accessories within the exam room, arrange for safe storage close by.
3. Location for patient throughput
4. Power source requirements
   - Interlocks (room, door, lights, and so on)
   - Service access
5. Networking requirements (DICOM, PACS, and so on)
6. Physical and environmental requirements
7. Shielding requirements
8. Cabling and wireways

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.**

1.5 Safety

1.5.1 Isolation Integrity

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.

1.5.2 Shielding

Structural Shielding

A Medical Physicist should review the room walls in which this system is used to ensure that the room meets local guidelines for radiation shielding. Refer to the table *X-ray Shielding Requirements* in Chapter 3 of this document.

Note
An operator shield is not supplied with the system. The customer must provide sufficient shielding.

Operator Radiation Shield

The coach manufacturer must supply sufficient x-ray shielding.

- The attenuation equivalence of the shield must comply with all regulatory requirements for its intended use. Minimally, the shield must comply with IEC 60601-2-45, clause 29.208.101. However, local, regional, or other regulations may impose additional shield requirements.
- The shield should be secured and appropriately attached to the coach frame in compliance with all applicable safety regulations.

1.5.3 Remote X-ray On/Power On Indicators

The system has provisions for remote lights which indicate when the system is On and when x rays are being taken. These lights are usually installed outside the exam room, above the door. Have a certified electrician install these lights.

The relay contacts are rated:

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

1.5.4 X-ray Interlock

The X-ray Interlock connector in the Generator provides a normally closed (NC) contact (5V 10mA). When an external interlock is used (for example a door or shield switch), a contact opens and an exposure cannot take place. A switch closure on the contact must occur for an exposure to occur.

Note
If the X-ray Interlock is utilized, the state of the interlock contacts should be displayed by visual means to the operator per IEC 60601-2-45:2011 (3rd Edition), Clause 203.6.2.1.101.

1.6 Compliance

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

1.6.1 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.

1.6.2 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

1.6.3 Electromagnetic Compatibility

This section provides information about the electromagnetic compatibility of the system per IEC 60601-1-2.

Table 1: 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 2: 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 3: 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 4: 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.			

Chapter 2 System Specifications

2.1 Product Measurements

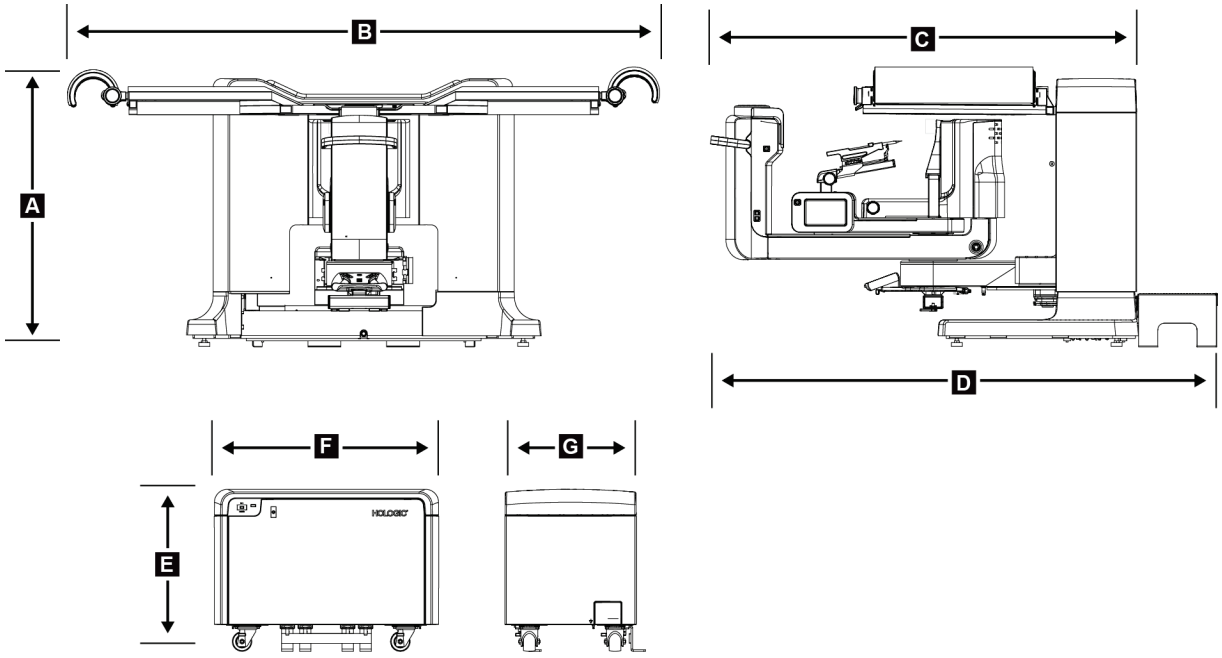


Figure 2: Gantry and Generator Dimensions

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)*

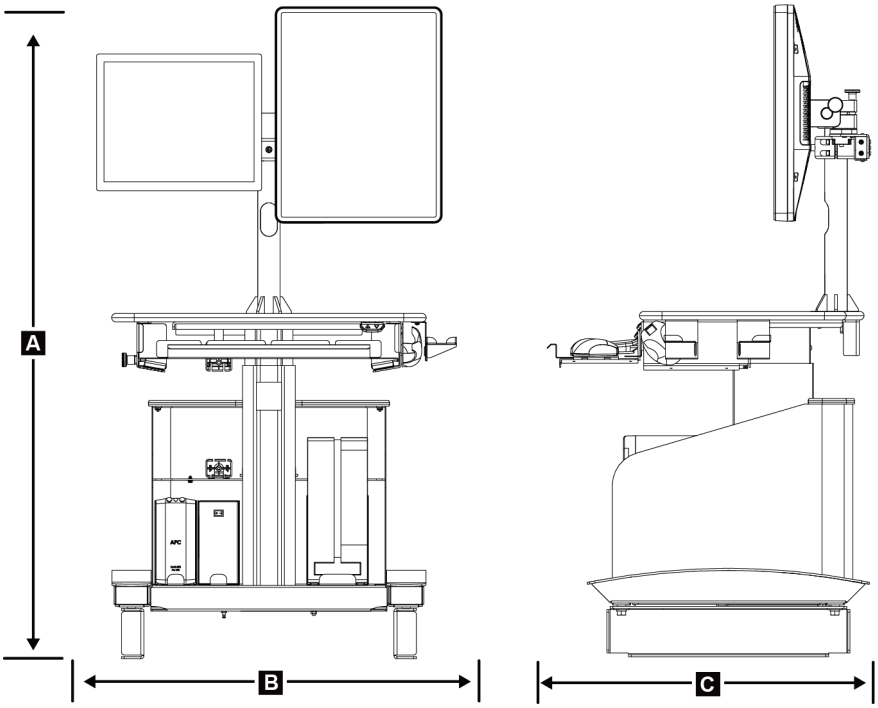


Figure 3: Acquisition Workstation Dimensions

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)*

2.2 Mobile Specifications

2.2.1 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.*

2.2.2 Coach Environment

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*

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*

2.3 Electrical Input

2.3.1 Electrical Input

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)*

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*

2.3.2 Coach UPS Recommendations

- Dedicated UPS for only the Generator and Acquisition Workstation
- Dual Conversion UPS (Uninterruptible Power Supply and Power Conditioner)
- Single Phase
- Hardwired (Multi) Input 208/220/230/240
- Hardwired (Multi) Output 120/208/240
- IGBT Technology (refer to note below)
- Output Current >55Amps @ 240 VAC
- Internal Isolation Transformer (separate module not preferred)
- Power Factor Correction Technology Input Power Factor >.95 / Output Power Factor ≥.85
- Output Voltage Regulation not to exceed ±3% (1% typical)
- Minimum Battery Back-up time at Full charge ≥ 7 minutes

Note
If the UPS does not use IGBT Technology the UPS specification must be for a minimum 2X the systems kW rating.

Placement of the UPS relative to the detector must be a minimum of 3.05 meters (10 feet) line-of-sight.

2.4 Center of Gravity Reference

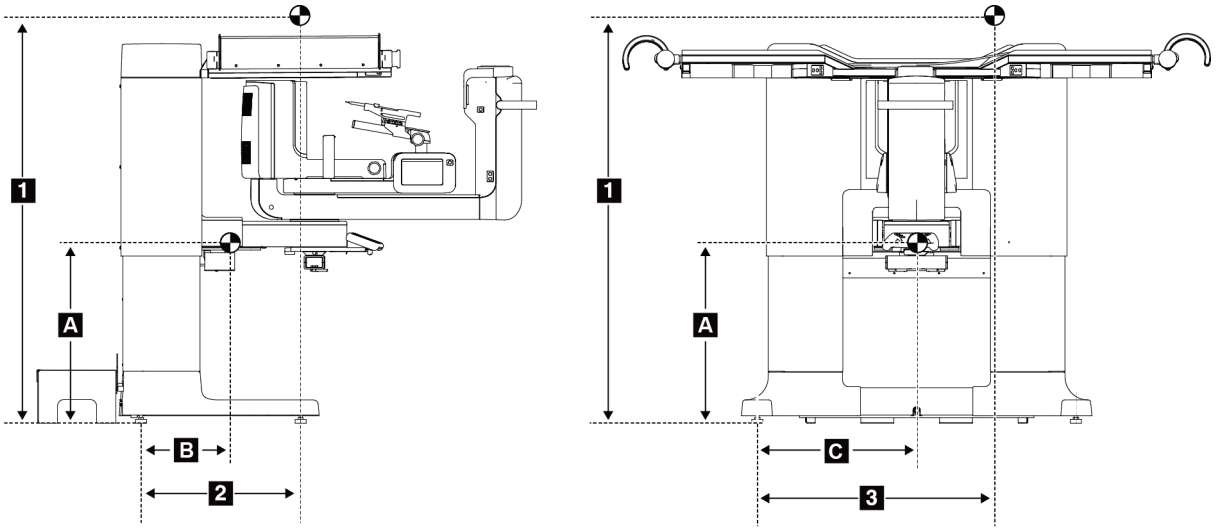


Figure 4: Patient Platform/Gantry/C-Arm Center-of-Gravity Reference

Highest Position		*Lowest Position*	
1	*155 cm (61.0 inches)*	*A.*	*70.1 cm (27.6 inches)*
2	*62.2 cm (24.5 inches)*	*B.*	*34.8 cm (13.7 inches)*
3	*90.4 cm (35.6 inches)*	*C.*	*62.5 cm (24.6 inches)*

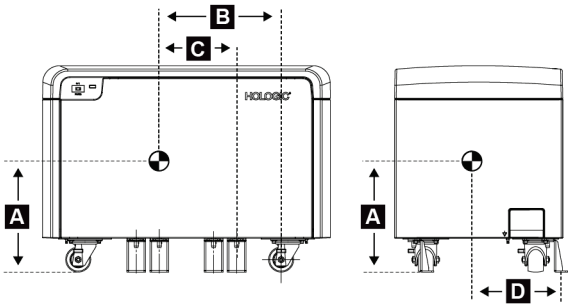


Figure 5: Generator Center-of-Gravity Reference

A. 33.8 cm (13.3 inches)

B. 37.1 cm (14.6 inches)

C. 23.6 cm (9.3 inches)

D. 27.2 cm (10.7 inches)

Chapter 3 Site Planning Checklist

Table 5: Clearance Requirements

Item	Minimum Requirements	Actual	Corrective Action	Done (Initials/Date)
Service Access Clearance				
Acquisition Workstation/ Gantry/Generator	Consult local regulations for equipment clearance requirements			
Patient Provider Clearance				
Acquisition Workstation	91.4 cm (3 feet) at front for operator access			
Gantry	91.4 cm (3 feet) on each side of table for patient's head/feet, 91.4 cm (3 feet) at front for operator and patient access and for complete C-Arm rotation			
Generator	91.4 cm (3 feet) between Generator and Acquisition Workstation or Gantry			
Note: Refer to specifications.				

Additional Notes		
Note #	Topic	Notes

Table 6: Power Requirements

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Power Requirements				
Electric Input	Dedicated circuit breaker with lockout capability. Before installation, 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 All incoming power must conform to local codes. Refer to Specifications			
Acquisition Workstation	Refer to Specifications			
X-Ray Generator	Refer to Specifications			
Light Indicator Relay Contact Ratings[1]	10 A, 250 VAC (N.O.) 10 A, 30 VDC (N.O.)			
Notes:				

1. There are provisions in the system to accommodate local regulations that require an **X-ray System Power-On**, and **X-ray On Indicators** at the door. These lights are normally installed above the door to the exam room.

Additional Notes		
Note #	Topic	Notes

Table 7: Environmental Requirements

Item	Requirements	Actual	Corrective Action	Done (Init/Date)
Non-Operating/Transit				
Temperature Range	10 °C (50 °F) to 30 °C (86 °F) indefinitely 10 °C (50 °F) to 35 °C (95 °F) for up to 12 hours			
Relative Humidity Range	10% to 80% non-condensing			
Maximum Rate of Temp .Change	<10 °C/hr.			
Operating				
Temp. Range	20 °C to 30 °C (68 °F to 86 °F)			
Relative Humidity Range	20% to 80% non-condensing			
Shock and Vibration Limits				
Vibration Limit	Maximum of 0.30 G (2 Hz to 200 Hz), as measured at the point where the system mounts to the coach.			
Shock Limit	Not greater than 1.0 G (½ sine pulse), as measured at mounting point of system to coach. An "air ride" coach suspension is recommended.			
Notes: 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.				

Additional Notes		
Note #	Topic	Notes

Table 8: Cable Requirements (Mobile)

Item	Recommendations	Actual	Corrective Action	Done (Initials/Date)
Generator to Gantry				
AC Mains Cable to Generator	Supplied by coach manufacturer per local regulations. If Mains box is over 15 m (50 feet) away, custom lengths should drop 2 gauges when length is doubled.			
High Voltage Interconnect Cable	6.1 m (20 feet)			
Generator External Rotor Cable	6.1 m (20 feet)			
EPO Interconnect Cable	6.1 m (20 feet)			
Interconnect Cable	6.1 m (20 feet)			
Filament External Power Cable	6.1 m (20 feet)			
Ground Cable to Generator	6.1 m (20 feet)			
Generator to Acquisition Workstation				
CAN Interconnect Cable	6.1 m (20 feet)			
Ground Cable	6.1 m (20 feet)			
Remote X-ray Extension	6.1 m (20 feet)			
Acquisition Workstation to Gantry				
Fiber Optic Interconnect Cable	6.1 m (20 feet)			
Notes: Strain relief for Mains cable: Cable should not flex, move, etc. Considered "permanently connected" per its safety classification. Hologic does not provide the Gantry power cable for some countries. If the power cable is not provided, the installed cable must meet the following requirements and all local codes that apply: 3 conductor, 8 AWG (10 mm2) copper not more than 25 feet (7.62 meters) in length.				

Additional Notes		
Note #	Topic	Notes

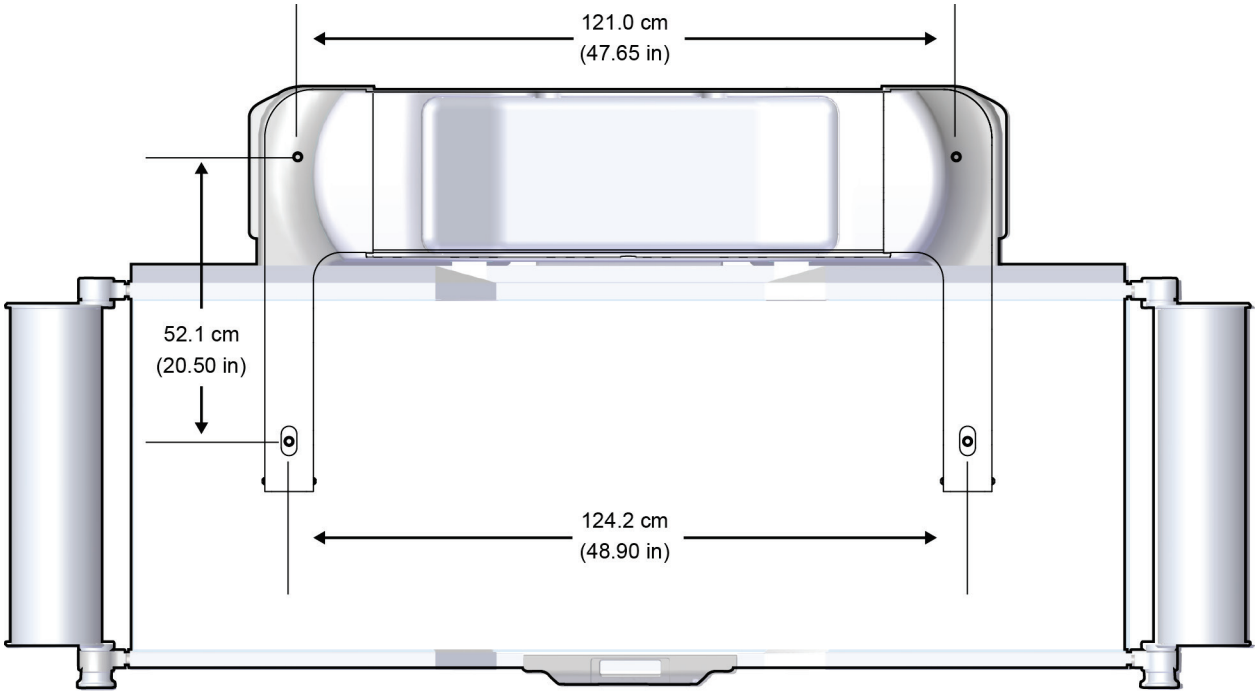
Table 9: X-Ray Shielding Requirements

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
X-ray Shielding				
Operator Shielding	Customer supplied. Must meet or exceed all local requirements for operator shielding. Must be positioned between patient platform and handheld remote.			
Patient Shielding	The patient platform provides the necessary radiation protection.			
Room Shielding	Must meet state and local codes based on Medical Physicist's test results.			
Notes:				

Additional Notes		
Note #	Topic	Notes

Table 10: Mounting Requirements - Gantry

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Gantry	Dependent on recommendations of the coach manufacturer. At a minimum, must be 1/2-inch hardware.			



Notes: *The final responsibility for proper installation belongs to the coach manufacturer. Make sure that all installations meet local regulations.*

Table 11: Mounting Requirements - Acquisition Workstation

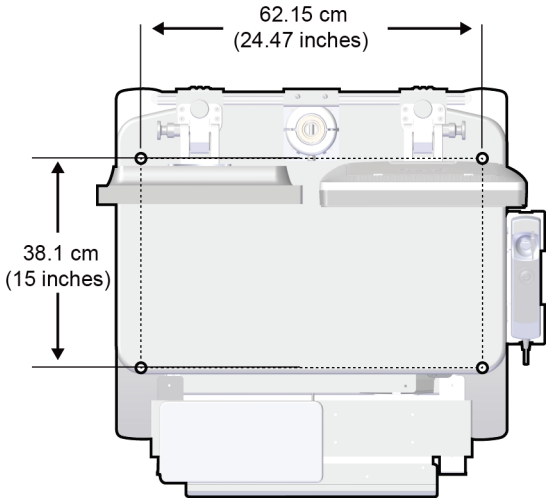
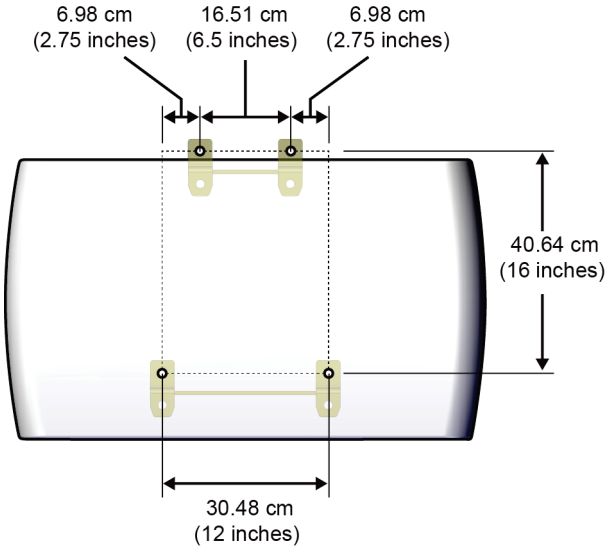
Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Acquisition Workstation	Dependent on recommendations of the coach manufacturer. At a minimum, must be 1/2-inch hardware.			
				
Notes: *The final responsibility for proper installation belongs to the coach manufacturer. Make sure that all installations meet local regulations.*				

Table 12: Mounting Requirements - Generator

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Generator	Dependent on recommendations of the coach manufacturer. At a minimum, must be 1/2-inch hardware.			
				
Notes: *The final responsibility for proper installation belongs to the coach manufacturer. Make sure that all installations meet local regulations.*				

Additional Notes		
Note #	Topic	Notes

Coach Planning Templates

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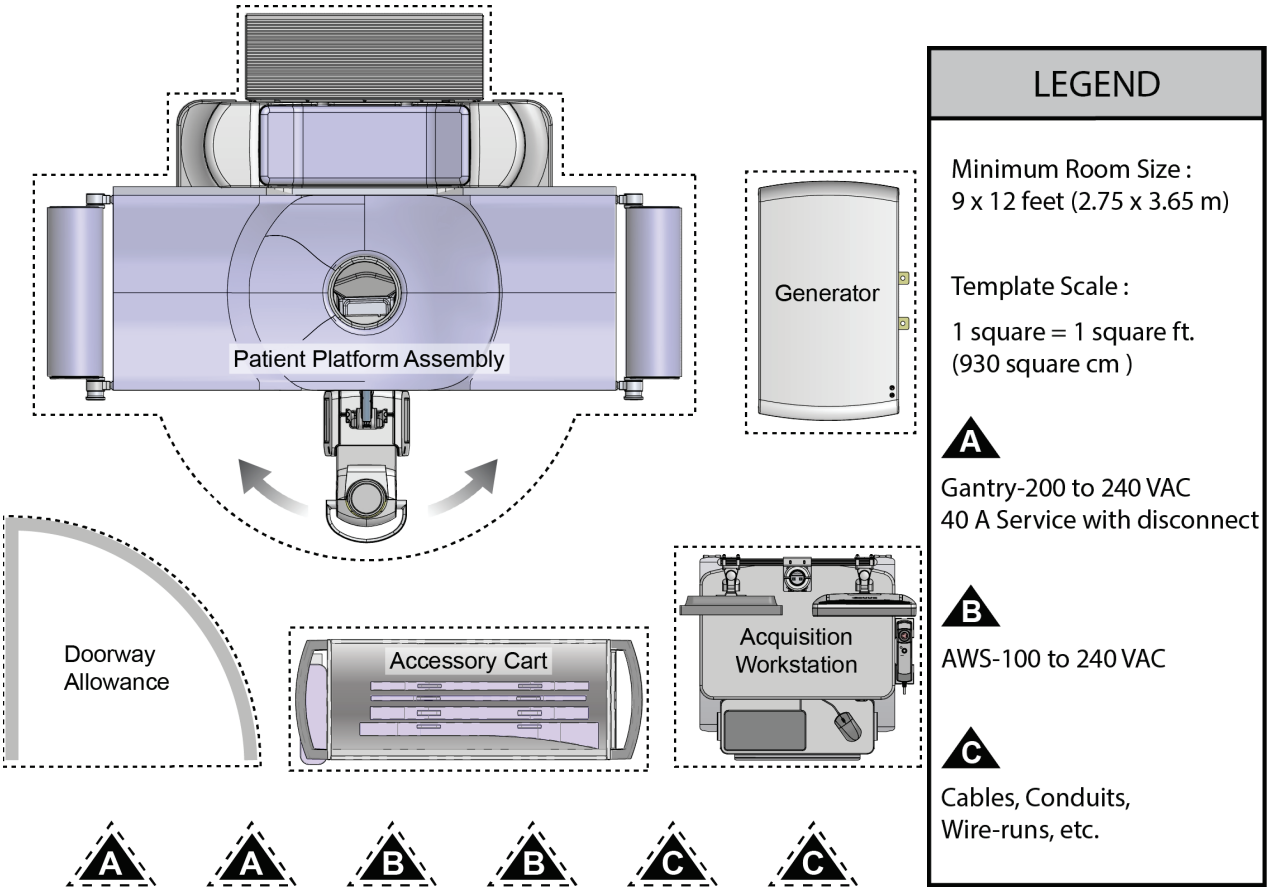
Room Layout Worksheet

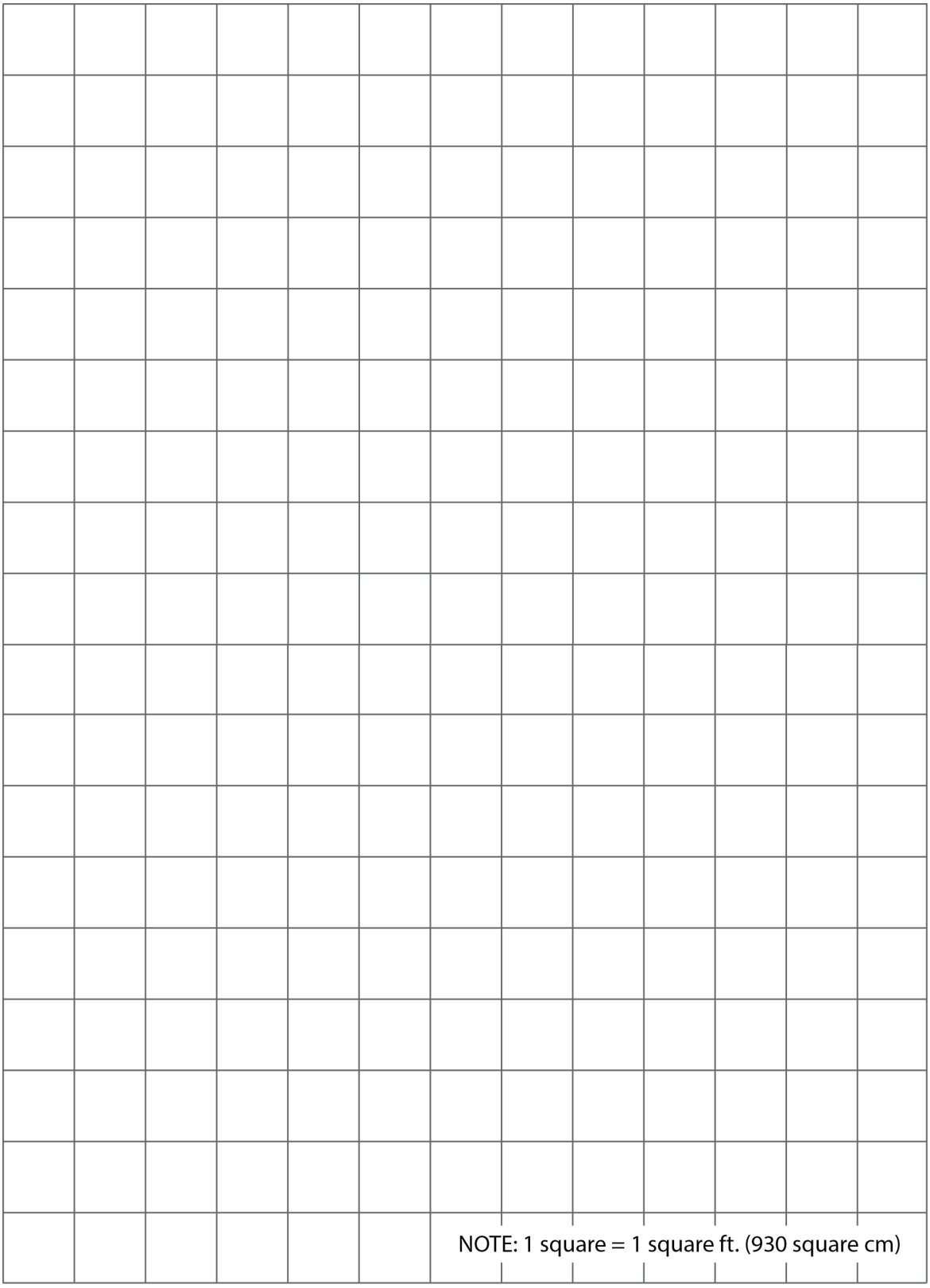
These templates can be used to establish a functional room layout.



Instructions: Make copies of the grid and the system component cutouts. Outline the designated room size (to scale) on the grid, and then cut out the system components from the copy. Position the component cutouts on the grid to layout the desired work space.

Allow sufficient and convenient storage for accessories. Be sure to include access clearances for service personnel. Avoid areas that may hinder access to the equipment and patient. Also avoid equipment positioning near heat ducts or air-conditioning vents.

To protect from radiation exposure, locate the Acquisition Workstation so the radiation shield provides complete protection for the operator. If possible, include extra space and power outlets for future expansion of clinical services.


NOTE: 1 square = 1 square ft. (930 square cm)

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