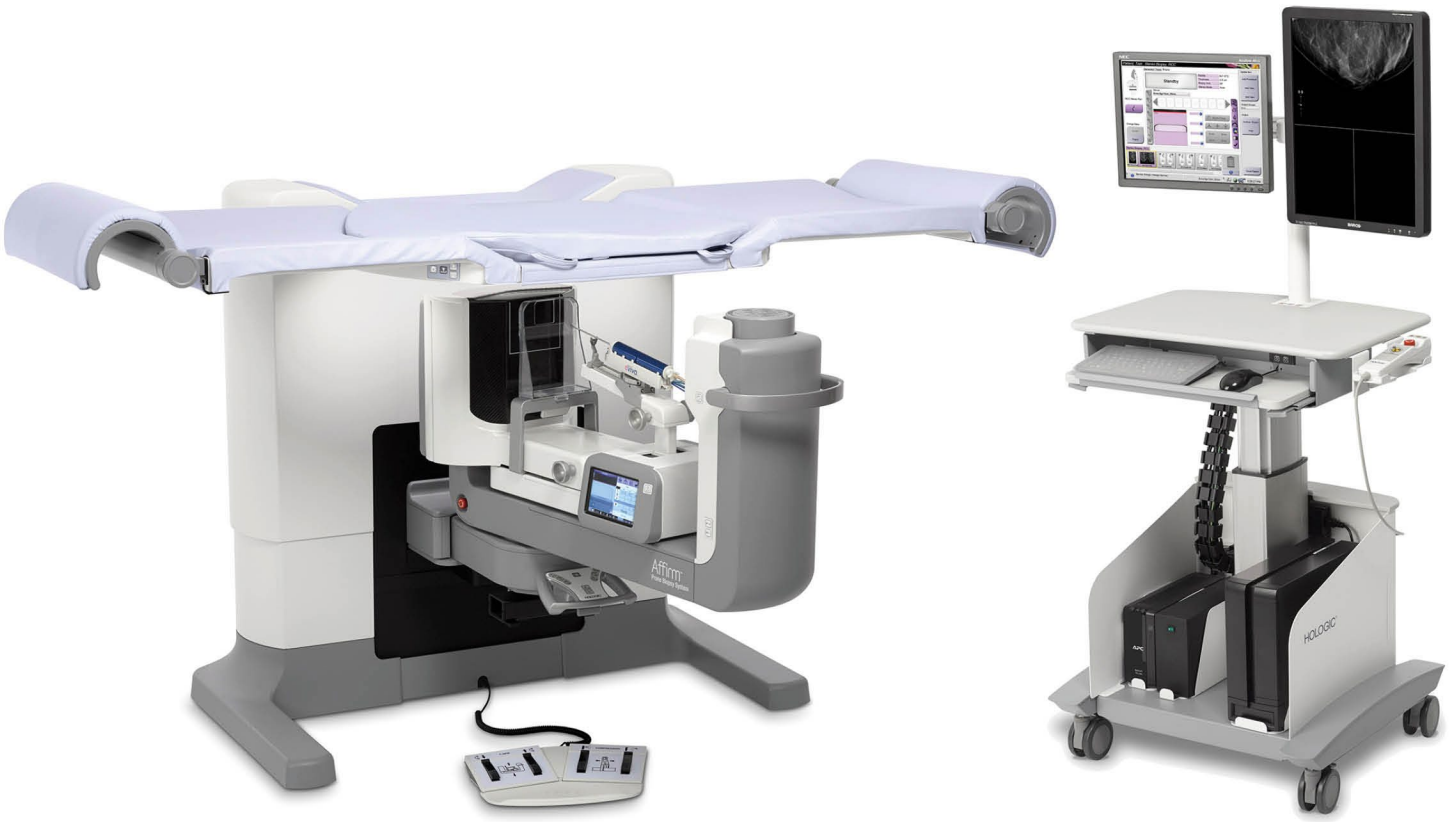
Affirm®
Prone Biopsy System



Site Planning and Pre-Installation Guide

MAN-04484 Revision 005

HOLOGIC®

Affirm®

Prone Biopsy System

Site Planning and Pre-Installation Guide

Part Number MAN-04484
Revision 005
September 2019

HOLOGIC®

Technical Support

USA: +1.877.371.4372

Europe: +32 2 711 4690

Asia: +852 37487700

Australia: +1 800 264 073

All Other: +1 781 999 7750

Email: BreastHealth.Support@hologic.com

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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.

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

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

1.2 System Overview

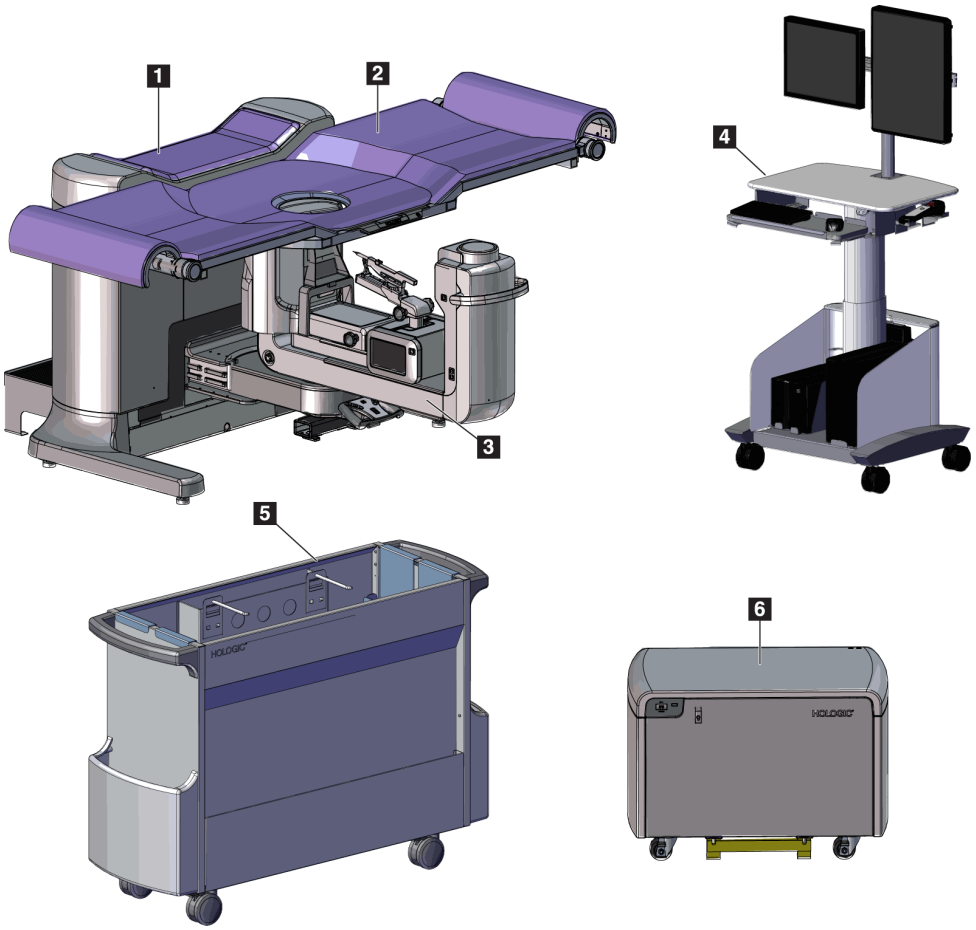


Figure 1: Affirm Prone Biopsy System

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.

1.3 System Location Considerations

The *Site Planning Checklist* on page 15 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.**

1.4 Safety

1.4.1 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.

1.4.2 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.

1.4.3 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.

1.5 Compliance

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

1.5.1 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.

1.5.2 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

1.5.3 Electromagnetic Compatibility

This section provides information about the electromagnetic compatibility of 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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80MHz 3 V/m 80 MHz to 2.5 GHz	[V1] = 3 V [*E*1] = 3 V/m	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. **Recommended separation distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 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

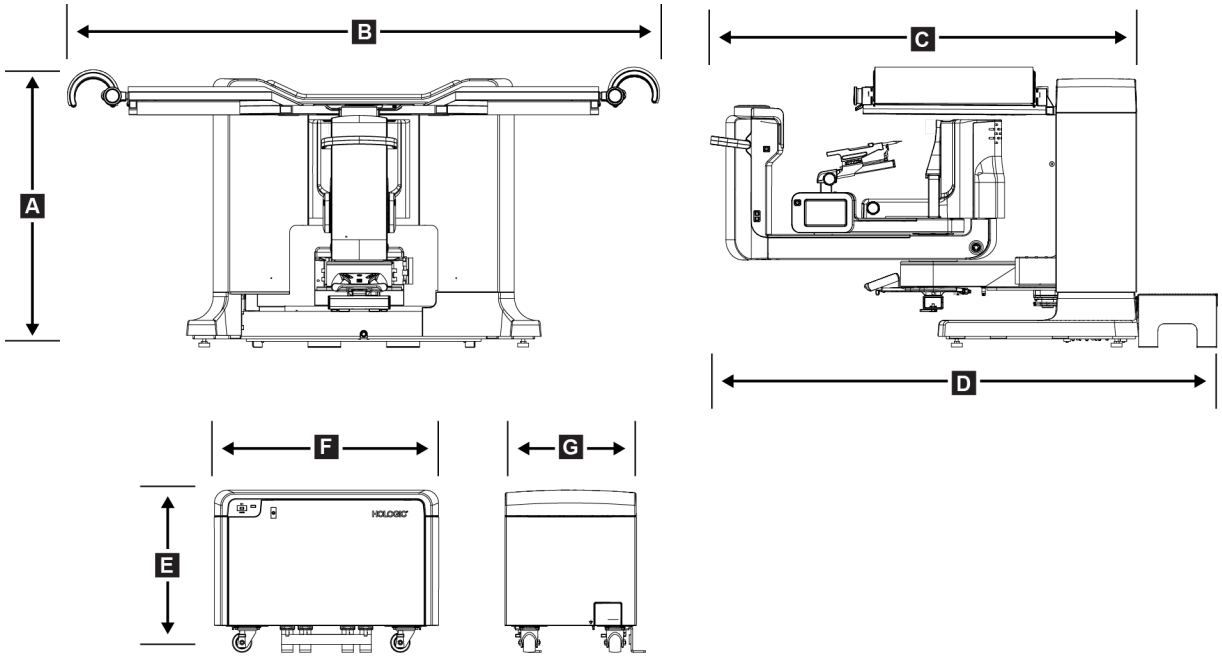


Figure 2: Gantry and Generator Dimensions

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)*

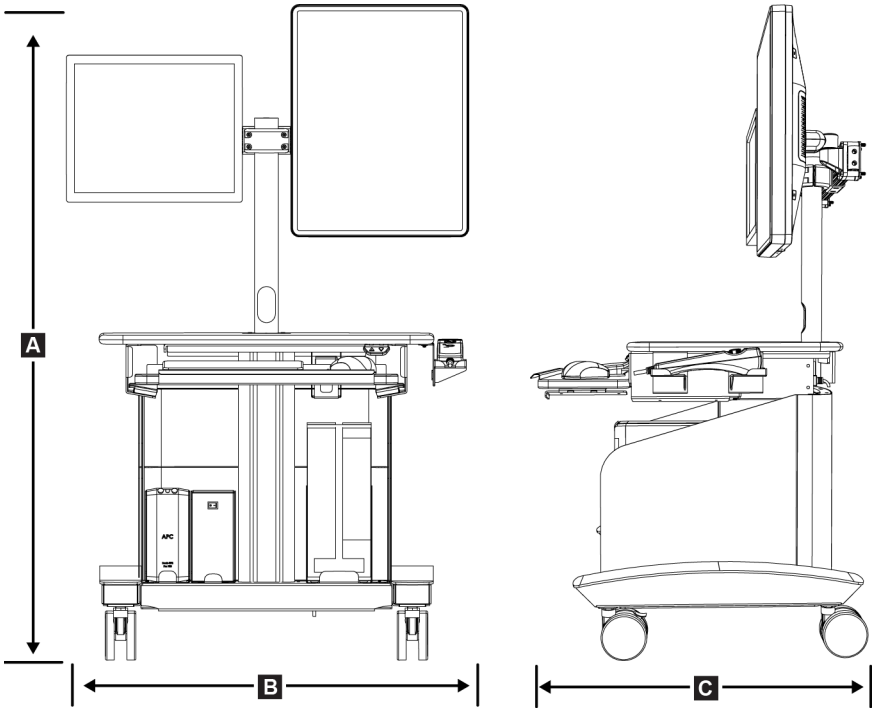


Figure 3: Acquisition Workstation Dimensions

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 Operation and Storage Environment

2.2.1 General Conditions for Operation

Temperature Range	*10°C to 30°C*
Relative Humidity Range	*10% to 80%, non-condensing*
Atmospheric Pressure	*697hPa - 1060hPa*
BTU Output	*less than 5700 BTU per hour*

2.2.2 General Conditions for Transport and Storage

Temperature Range	*10°C to 35°C*
Relative Humidity Range	*10 to 80%, not packaged for outdoor storage*

2.3 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*

Chapter 3 Site Planning Checklist

Table 5: Room Requirements

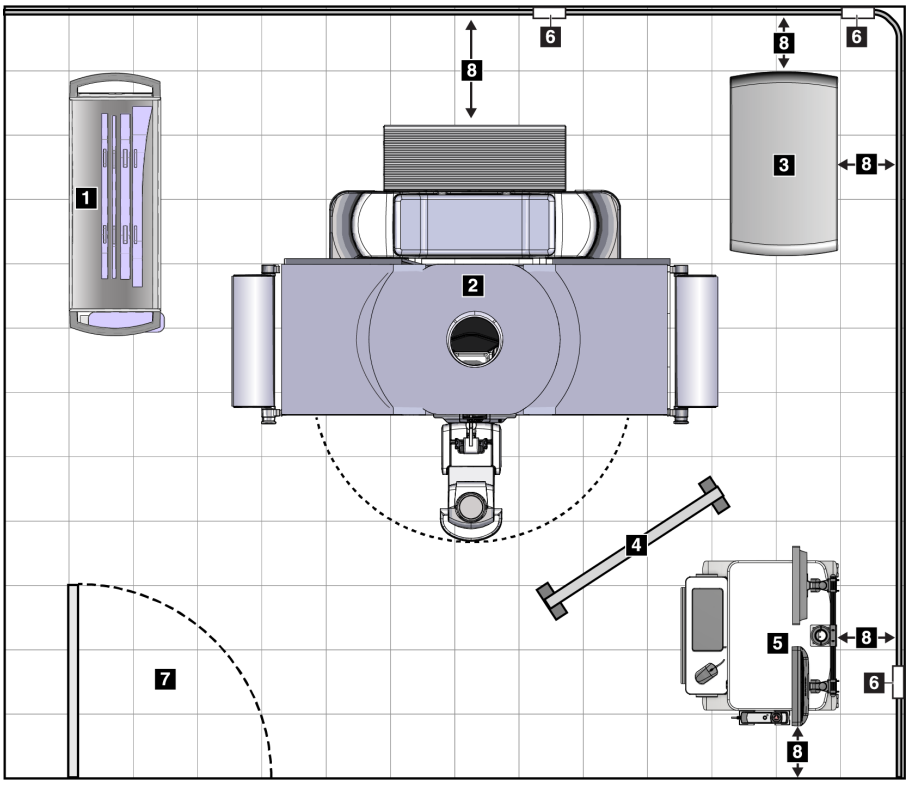
Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Room Size				
Length	365 cm (12 feet)			
Width	365 cm (12 feet)			
Ceiling	244 cm (8 feet)			
Door	203 cm x 91 cm (6.6 x 3 feet)			

Notes:

The exam room layout should be pre-planned before the arrival of the system. Refer to Room Layout Worksheet. A typical room layout is shown here. Check specific local or hospital requirements for additional data. Check the route from the loading dock to the room.

Figure Legend

1. Accessory Cart
2. Gantry/Patient Platform Assembly
3. Generator
4. Radiation Shield (supplied by customer)
5. Acquisition Workstation
6. Mains Circuit Breaker (40A Breaker, UL 489, or UL HACR listed)
7. Doorway minimum clearance of 91 cm (3 feet)
8. Consult local regulations for minimum clearances



Additional Notes		
Note #	Topic	Notes

Table 6: 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 7: 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 8: Environmental Requirements

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Environmental Requirements: Operating				
Temperature Range	10° C to 30° C (50° F to 86°F)			
Relative Humidity Range	10% to 80% non-condensing			
Notes:				

Additional Notes		
Note #	Topic	Notes

Table 9: Cable Requirements

Item	Recommendations	Actual	Corrective Action	Done (Initials/Date)
Generator to Gantry				
AC Mains Cable to Generator*	If Mains box is over 15 m (50 feet) away, custom lengths should drop 2 gauges when length is doubled.			
High Voltage Interconnect	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet)			
Generator External Power	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet)			
Generator External Rotor	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet)			
EPO Interconnect	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet)			
CAN Interconnect	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet)			
Ground Cable (between Generator and Gantry)	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet)			

Table 9: Cable Requirements

Item	Recommendations	Actual	Corrective Action	Done (Initials/Date)
Acquisition Workstation to Generator				
Ground Cable (between AWS and Generator)	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet) 24.4 m (80 feet) 30.5 m (100 feet)			
CAN Interconnect	6.1 m (20 feet) 12.2 m (40 feet) 18.3 m (60 feet) 24.4 m (80 feet) 30.5 m (100 feet)			
Remote X-ray Extension	6.1 m (20 feet, standard with AWS) 12.2 m (40 feet total with extension) 18.3 m (60 feet total with extension) 24.4 m (80 feet total with extension) 30.5 m (100 feet total with extension)			
Acquisition Workstation to Gantry				
Fiber Optic Cable	6 m (19 feet) 13 m (42 feet) 19 m (62 feet) 25 m (82 feet) 31 m (102 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 10: Wireway and Threshold Requirements

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Interconnects				
Wireways	Horizontal surface wireways can be installed where local codes permit.			
Thresholds (if required)	Length depends on cable run.			
Notes: Make sure that all mains wiring (in-wall, external wall, and external floor) meets the criteria described in Electrical Input.				

Additional Notes		
Note #	Topic	Notes

Table 11: 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 12: Mounting Requirements

Item	Requirements	Actual	Corrective Action	Done (Initials/Date)
Mounting Requirements				
Gantry	Dependent on recommendations of the site representative			
Acquisition Workstation	Dependent on recommendations of the site representative			
Seismic (Seismic installations are dependent on local regulations.)	Consult a professional structural engineer familiar with seismic requirements.			
Notes: *The mounting diagrams provided in this document are recommendations only; the final responsibility for proper installation belongs to the site field engineer. Make sure that all installations meet local regulations.*				

Additional Notes		
Note #	Topic	Notes

Room Planning Templates

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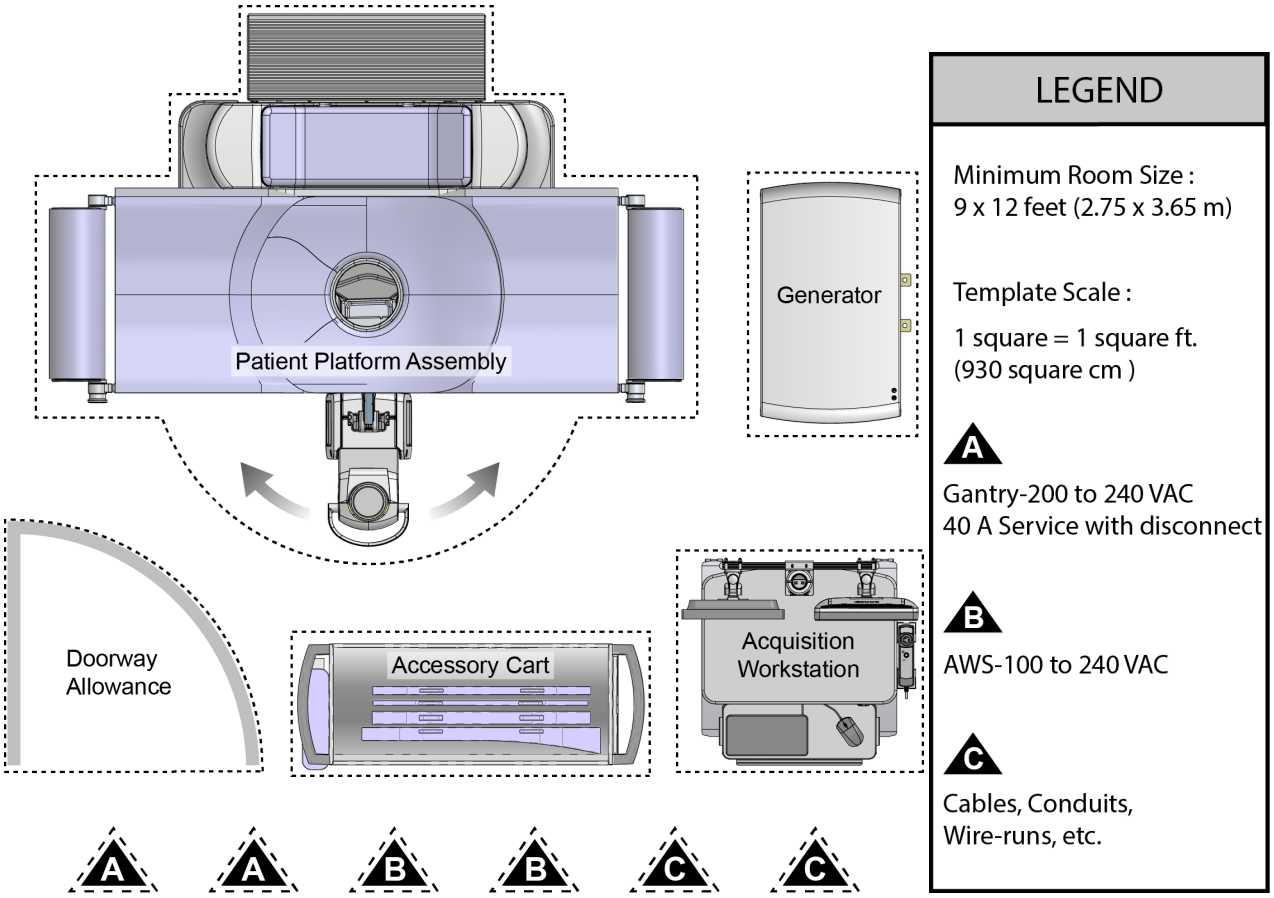
Room Layout Worksheet

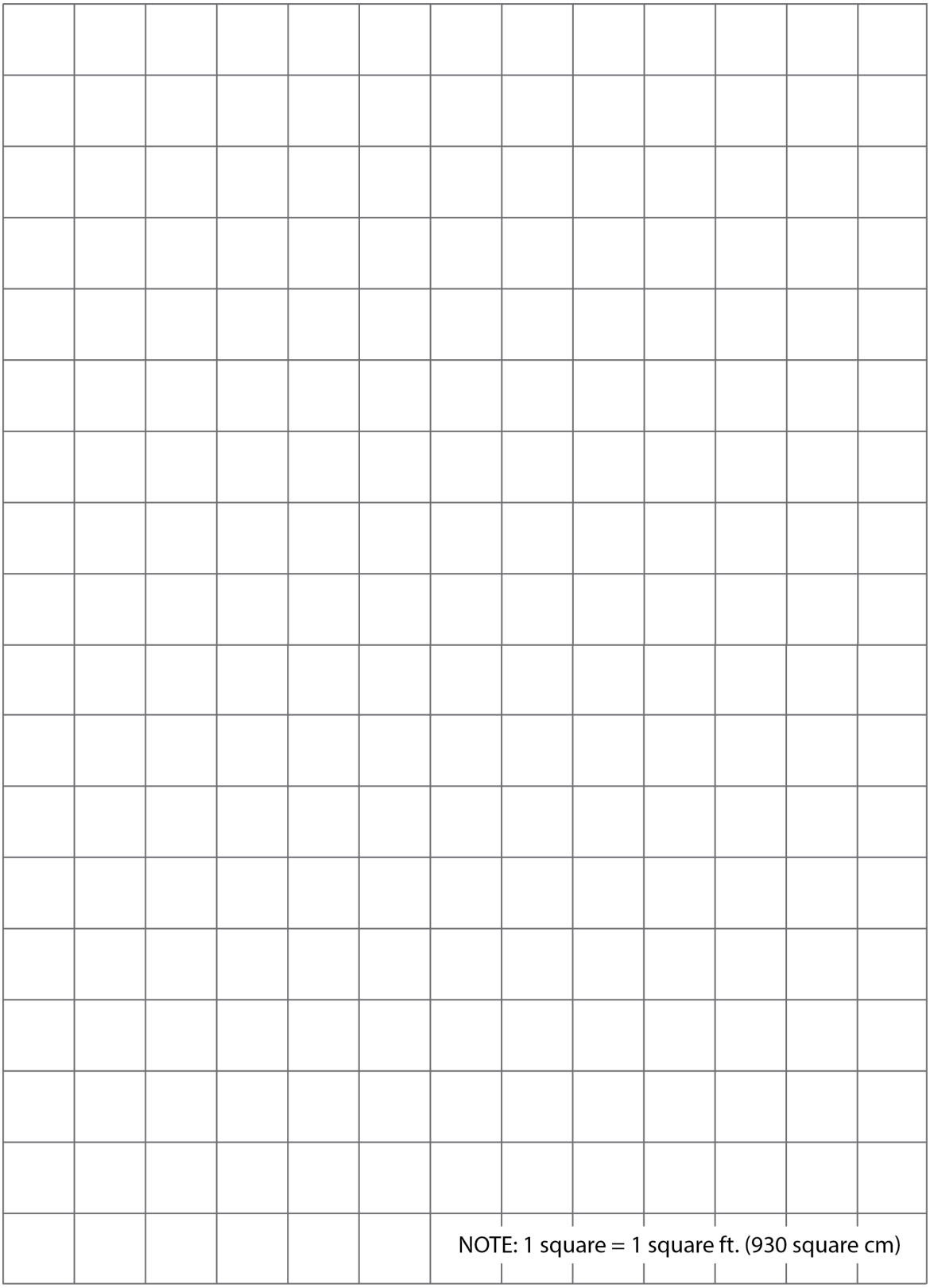
These templates can be used to establish a functional room layout.



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)

HOLOGIC®

Hologic Inc.
36 Apple Ridge Road
Danbury, CT 06810 USA
1 800 447 1856

Brazilian Contact: Imex Medical Group do Brasil
Rua das Embaúbas, 601- Fazenda Santo Antônio
São José /SC - Brasil - 88104-561
+55 48 3251-8800
www.imexmedicalgroup.com.br