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***Millennium MyoSIGHT* Nuclear Medicine Imaging System Site Preparation Manual**

GE Healthcare

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Appendix A – EMC COMPLIANCE

Chapter 1 - Overview

1.1 Manual Objective

The objective of this manual is to provide a reference for site requirements and presenting site planning information for the Millennium MyoSIGHT system. It is important to read this manual carefully and thoroughly in order to ensure a successful installation.

The manual covers the *Millennium* MyoSIGHT system which includes the following parts:

- Ring Gantry
- Patient Table
- Collimator Cart
- GENIE Acquisition Computer
- Monitor and Keyboard Mobile Cart
- Networking

The information provided is to be used by an installation or architectural planner. It is assumed that this person is familiar with:

- GE medical product line (knows product names, functions, and general characteristics).
- National and local electrical wiring codes.
- Customer procedures and associated requirements for equipment location.
- Special architectural requirements, such as seismic codes.

The secondary user of this manual will be the service personnel who install the system.

1.2 Purchasers Responsibility

The purchaser is responsible for all site preparation, which may include the following:

- Procuring the material to carry out the work.
- Cost of modifications when not specifically provided for in the sales contract.
- Carrying out the necessary pre-installation work, before delivery and installation of the system equipment.
- Storage of the equipment, if necessary.

1.3 Pre-installation Work

Pre-installation work will cover the following items:

- Verification of room size and relative positioning of system components within the room.
- Accessibility for the equipment - doors, corridors, elevators (spacing and loading limitations) and service access around equipment.
- Floor loading, floor leveling and any building works necessary.
- Evaluation of HVAC requirements.
- Installation of the electrical conduit, junction boxes, ducts and earth reference terminal (ERT).
- Power availability at time of delivery, in room and along route to room location.
- Network configuration and hardware installed.

Please direct any problems or questions to your local GE Sales/Service representative who will be glad to help.

1.4 System Configuration

The *Millennium MyoSIGHT* systems are configured with two rectangular detectors. Each detector has a 520 mm x 370 mm field of view and provides optimized capability for cardiac tomographic studies. The Detectors of the *Millennium MyoSIGHT* are positioned in 101.25° for cardiac scan and in 180° for Collimator Exchange (refer to Figure 1-1).

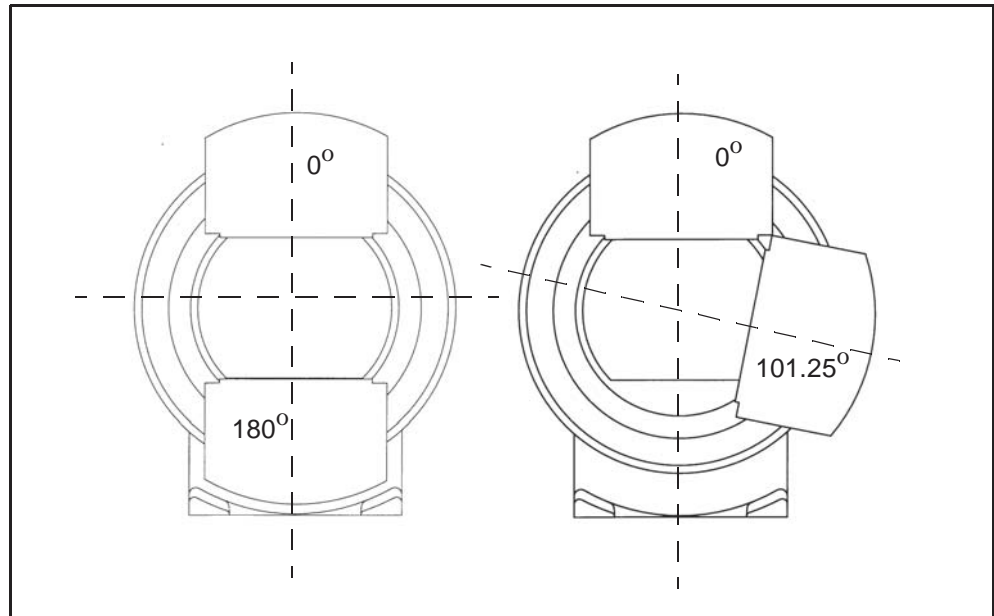


Figure 1-1: Millennium MyoSIGHT Configuration Modes

Chapter 2 - Physical Specifications

2.1 GENIE Acquisition Mobile Cart

The GENIE Acquisition mobile cart consists of a standard keyboard/mouse and a monitor. The keyboard is located on an adjustable keyboard/mouse platform whereas the monitor is located on a monitor tray. Refer to [Figure 2-1](#).

Note

To assure proper airflow and cooling a clearance of at least 310 mm (12") above monitor, as least 80 mm (3") to the back of the monitor, and at least 80 mm (3") to each side of the monitor of must be maintained.

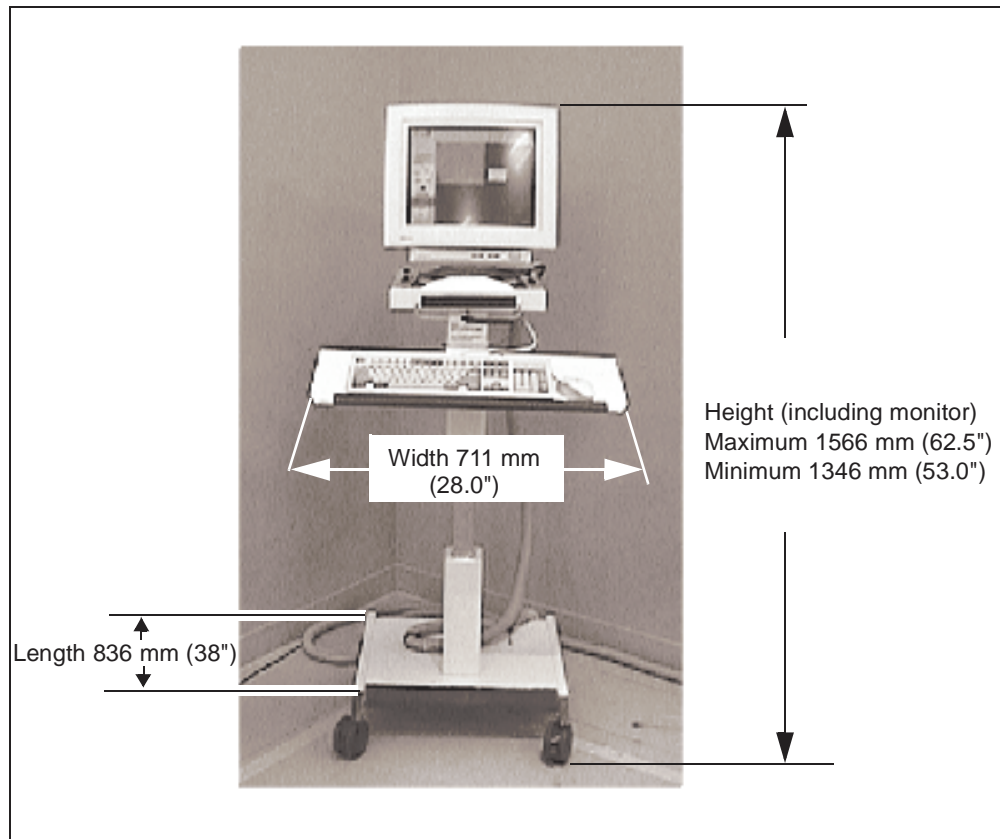


Figure 2-1. Acquisition Mobile Cart Dimensions

2.1.1 GENIE Acquisition Computer Tower

The GENIE Acquisition Computer Tower must be positioned vertically. It should be positioned at a fixed point, not mounted on the mobile cart or in a location where the tower can be bumped, kicked or jarred during operation. Refer to [Figure 2-2](#) and [Table 2-1](#) for PC Acquisition Computer Tower dimensions.

Note

For airflow and cooling purposes, allow clear space of 150 mm (6") in back, 100 mm (4") in front, and 100 mm (4") along sides of the PC Acquisition Computer Tower.

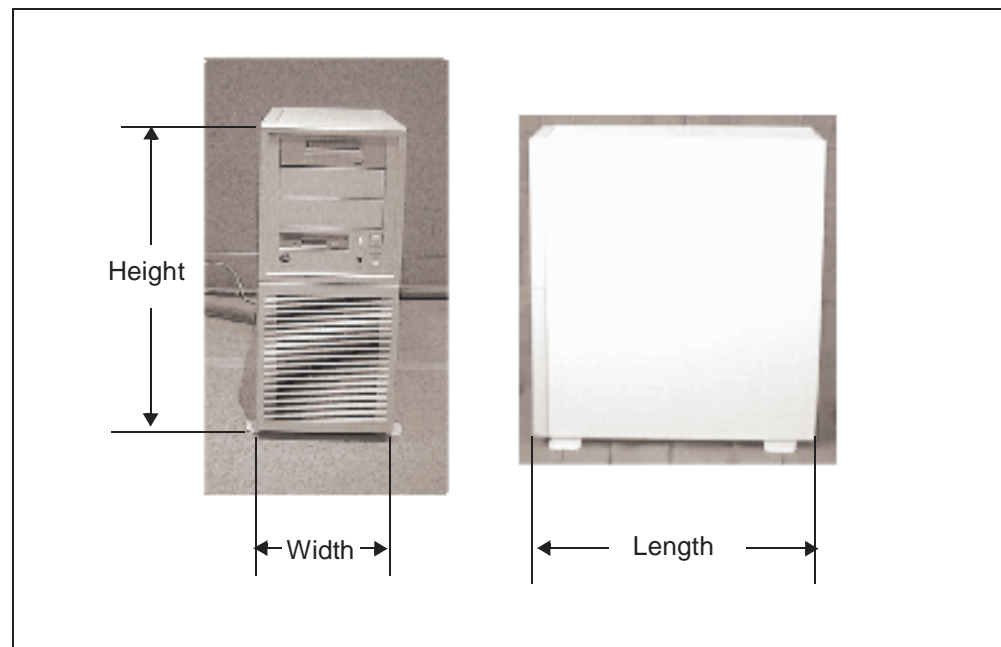


Figure 2-2: PC Acquisition Computer Tower

Table 2-1: PC Acquisition Computer Tower Dimensions

Height	Width	Length
483 mm (19")	254 mm (10")	457 mm (18")

2.1.2 Physical Specifications

Table 2-2: Physical Specifications Acquisition Unit

System Component	Shipping Dimensions in mm	LxWxH in inches	Installed Dimensions in mm	LxWxH (min-max) in "
Mobile Cart				
without Monitor	571 x 597 x 724	22.5 x 23.5 x 28.5	838 x 711 x 914-1130	33 x 28 x 36-44.5
with Monitor	N/A	N/A	838 x 711 x 1346-1562	33 x 28 x 53-61.5
Monitor	546 x 520 x 584	21.5 x 20.5 x 23	470 x 432 x 432	18.5 x 17 x 17
Computer Tower	610 x 63.5 x 381	24 x 25 x 15	457 x 215 x 483	14 x 10 x 5.25
Keyboard	500 x 230 x 51	19.5 x 9 x 2	356 x 254 x 133	14 x 10 x 5.25
* Modem	457 X 254 X 102	18 X 10 X 4	254 X 159 X 38	10 X 6.25 X 1.5

* Depending on modem manufacture.

Table 2-3: Weight and Power Specifications Acquisition Unit

System Component	Shipping Weight Kg (lb)	Installed Weight Kg (lb)	Radiated Heat (BTU per hour)	Power Requirement
Mobile Cart	27.7 (61)	23.6 (52)	N/A	N/A
Monitor	25.4 (56)	22.7 (50)	35 (in use)	* 115 V AC± 10%
Computer Tower	16.3 (36)	14.5 (32)	600	* 115 V AC± 10%
Keyboard	1.0 (2.2)	1.0 (2.2)	N/A	N/A
Modem	1.0 (2.2)	1.0 (2.2)	N/A	** 120 V AC± 10%

* Powered from IPS.

** Powered by local power.

2.2 Gantry

There are two forms of shipping dollies available. For local/truck shipments the gantry is shipped on an open shipping dolly. In this configuration the gantry is wrapped to be protected against mechanical impact.

For long distance (airborne or ship transit) shipments, the gantry is shipped on the same dolly in a wooden container designed to support the gantry. The wooden container provides protection against mechanical impact during the long distance shipments. The over all Gantry specifications are listed in [Table 2-4](#) and [Table 2-5](#).

Part of the gantry shipping dolly is a Local Transit Dolly (LTD) designed to maneuver the gantry to its final location where hallways and door openings are narrow. The part of the gantry shipping dolly that forms the Local Transit Dolly is shown in [Figure 2-3](#).

2.2.3 Dolly for Short Distance Shipments

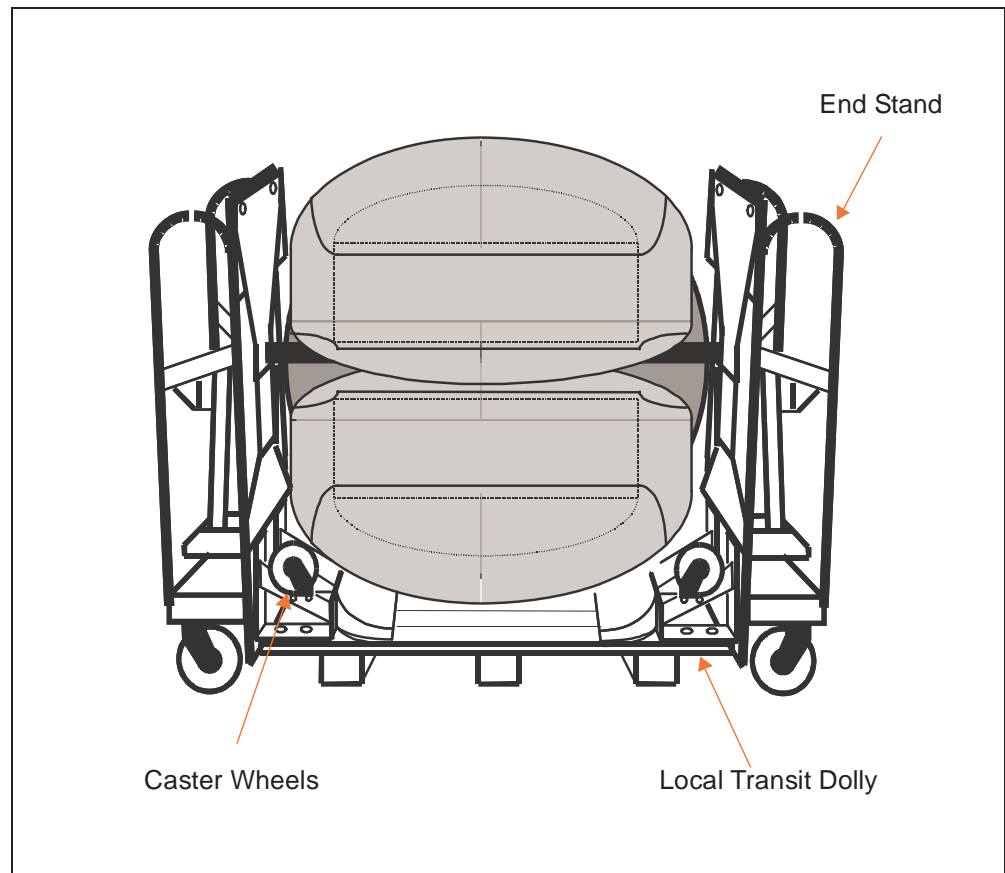


Figure 2-3: Gantry on Shipping Dolly

2.2.4 Shipping Dolly

The shipping dolly consists of two shipping dolly end stands, shipping bracket, and a cross bracket. The Local Transit Dolly (LTD) utilizes just the shipping brackets located between the gantry base and two shipping end stands.

Four caster wheels (mounted on the shipping brackets) are used to move the gantry without the use of the end stands. Moving the gantry without the end stands reduces the overall length of gantry with dollies when moving the gantry into elevators or small room locations.

The end stands are easily removed by removing the screws holding the shipping brackets to the end stands. A distance of at least 25.4 mm (1") must be maintained between floor and gantry base when using shipping dolly for clearance of gantry leveling pads during transit.

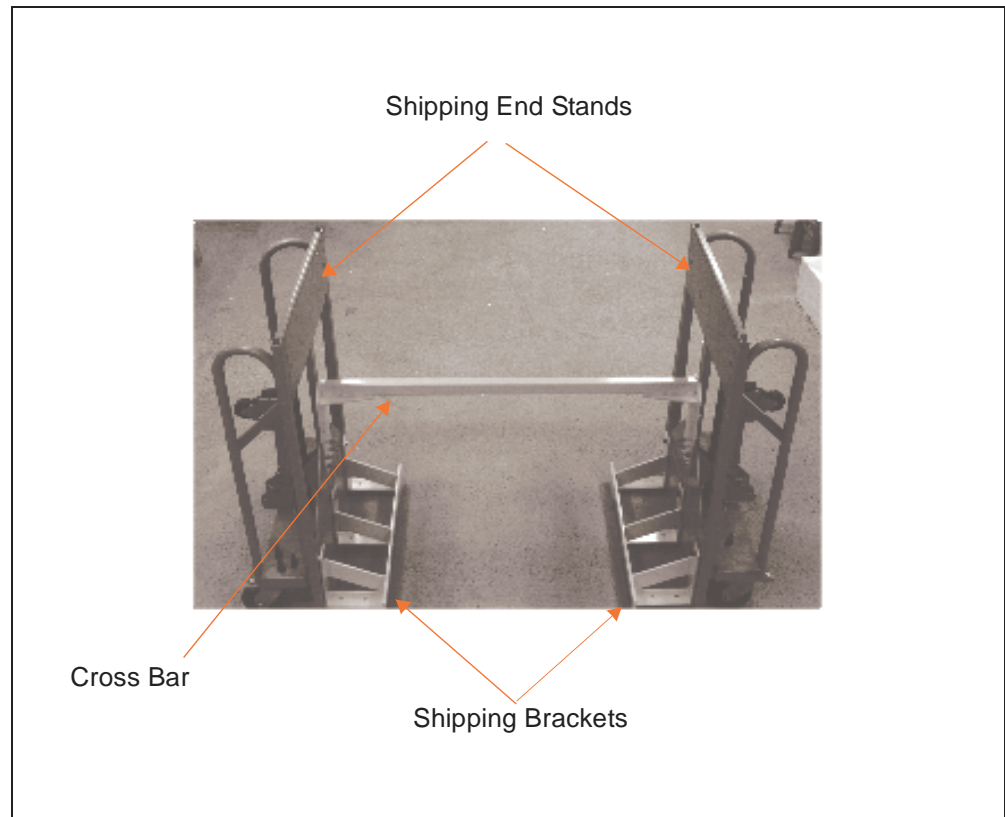


Figure 2-4: Gantry Transit Shipping Dolly

2.2.5 Gantry for Long Distance Shipments

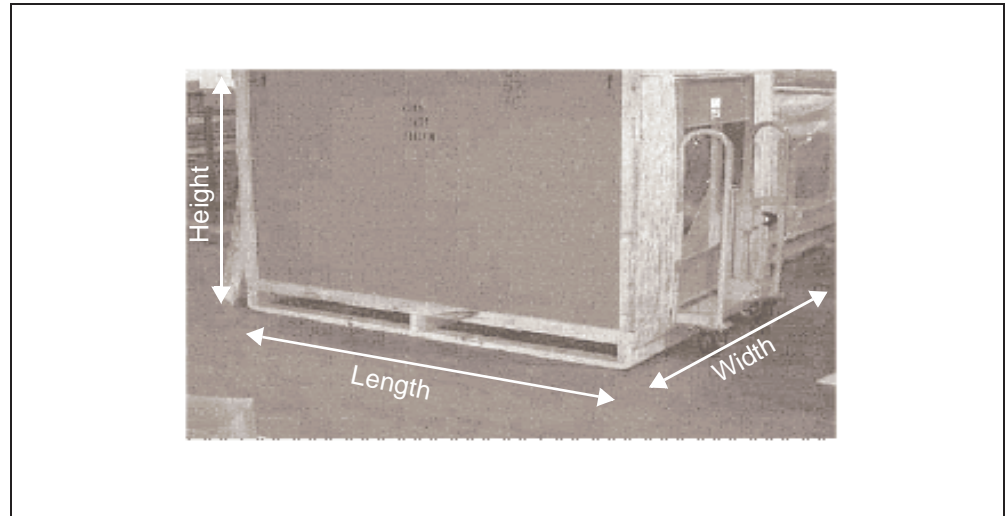


Figure 2-5: Gantry in Wooden Shipping Container

2.2.6 Physical Specifications

Table 2-4: Physical Specifications of Gantry

System Component	Shipping Dimensions LxWxH		Installed Dimensions LxWxH (Min - Max)		Dimensions of Shipping Dolly LxWxH	
	in mm	in inches	in mm	in inches	in mm	in inches
Gantry including Detectors (Excluding IPS)	1870x1260x1680	73.6 x 49.6 x 66.1	(1250-1530) x 1330* x (1430-1570)	(49.2-60.2) x 52.4* x (56.3-61.2)	1875x96.6x1455	73.8 x 38 x 57.3

* Includes IPS

Table 2-5: Weight and Power Specifications of Gantry

System Component	Shipping Weight Kg (lb)	Weight on Dolly Kg (lb)	Installed Weight Kg (lb)	Radiated Heat BTU per hour)	Power Requirement
Gantry including Detectors (Excluding IPS)	1580 (3483)	1490 (3285)	1510 (3329) Including IPS & LEGP collimators	See power specifications for IPS	See power specifications for IPS

2.3 Table

The table is shipped in a wooden container designed to support the table. The wooden container provides protection against mechanical impact. Refer to [Figure 2-6](#).

The over all table dimensions are listed in [Table 2-6](#) and [Table 2-7](#).

2.3.7 Table Shipping Container

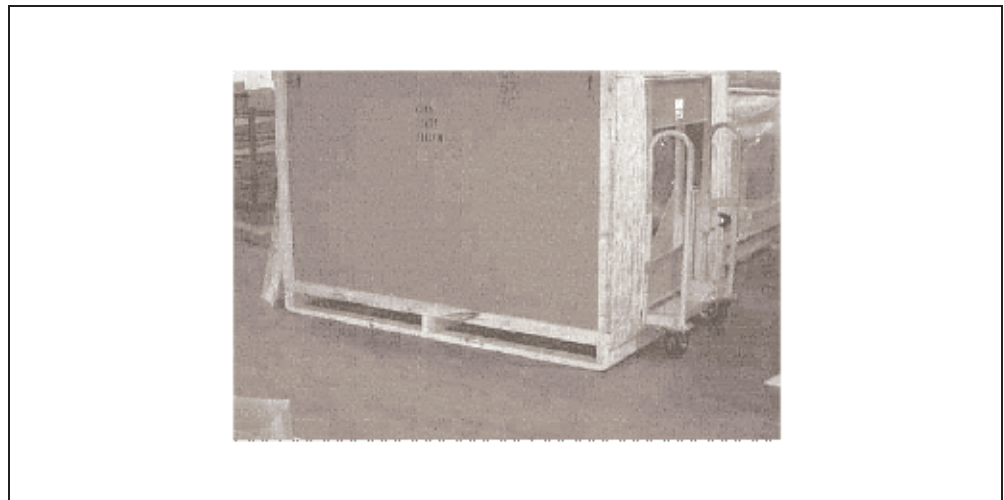


Figure 2-6: Table in Wooden Container

2.3.8 Physical Specifications

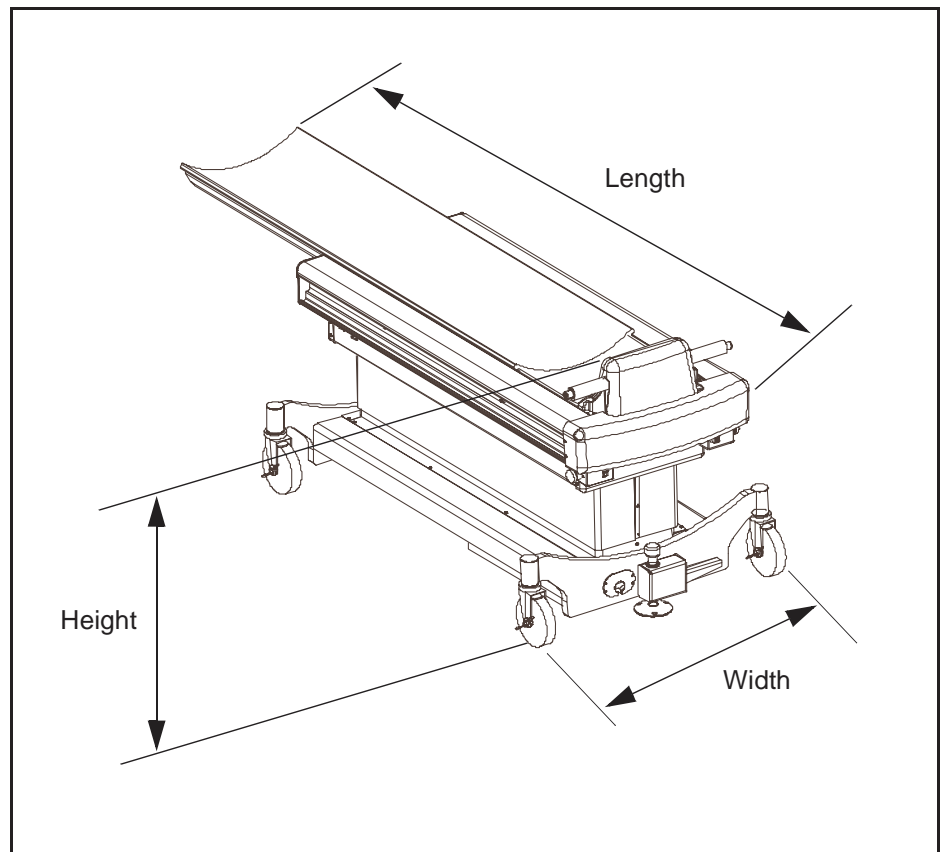


Figure 2-7: Table Dimensions

Table 2-6: Physical Specifications of Table

ROW Shipping Dimensions LxWxH		Installed Dimensions LxWxH (min-max)	
in mm	in inches	in mm	in inches
L: 2460 W: 1060 H: 1200	L: 96.9 W: 41.7 H: 47.2	L: 2225-3170 W: 864 H: 816-1075	L: 87.6-124.8 W: 34.0 H: 32.1-42.3

Table 2-7: Weight and Power Specifications of Table

Shipping Weight Kg (lb)	Installed Weight Kg (lb)	Radiated Heat (BTU per hour)	Power Requirement
610 (1345)	327 (721)	N/A	Powered from IPS

2.4 IPS

The IPS Integrated Power Supply (IPS) is shipped as a separate unit to be attached to the rear of the gantry at installation (refer to [Figure 2-8](#)).

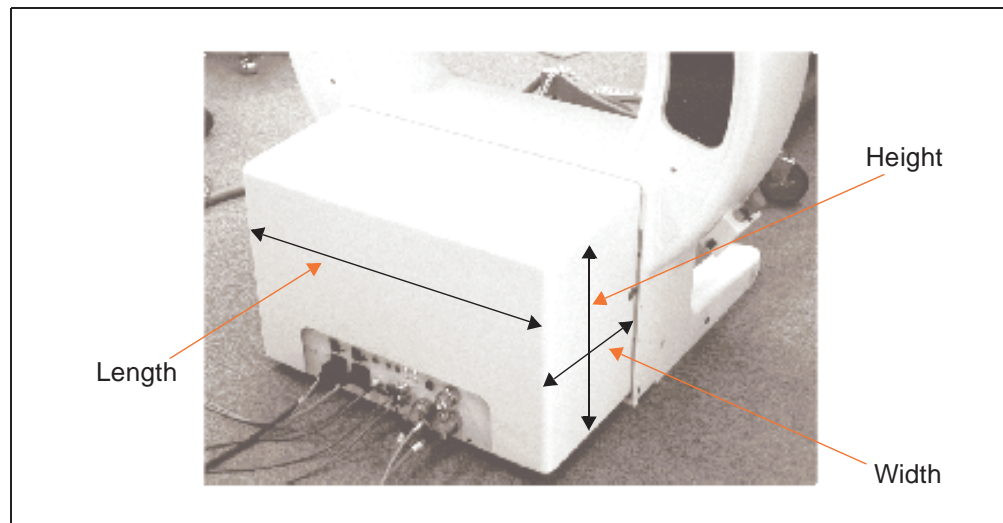


Figure 2-8: IPS on the Gantry

The IPS is designed with four wheels for easy maneuvering of the unit to its final position at the rear of the gantry. Two handles are provided to lift the unit onto the IPS mounting bracket and locks provided to secure IPS to the gantry. Refer to [Figure 2-9](#).

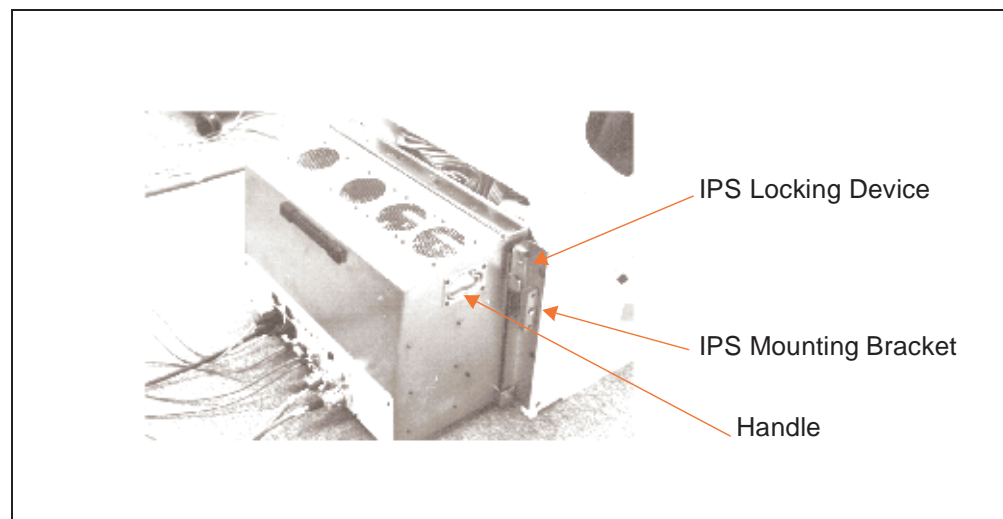


Figure 2-9: IPS - Mounting

2.4.9 Physical Specifications

Table 2-8: Physical Specifications IPS

Shipping Dimensions LxWxH		Installed Dimensions LxWxH	
in mm	in inches	in mm	in inches
940 x 490 x 800	37.0 x 19.3 x 31.5	810 x 350 x 540	31.9 x 13.8 x 21.6

Table 2-9: Weight and Power Specifications IPS

Shipping Dimensions LxWxH		Installed Dimensions LxWxH	
in mm	in inches	in mm	in inches
82 *181)	60 (132)	Idle: 1200 W 4095 BTU	100, 120, 200, 220, 240 VAC \pm 10% at 50/6- Hz \pm 3 Hz

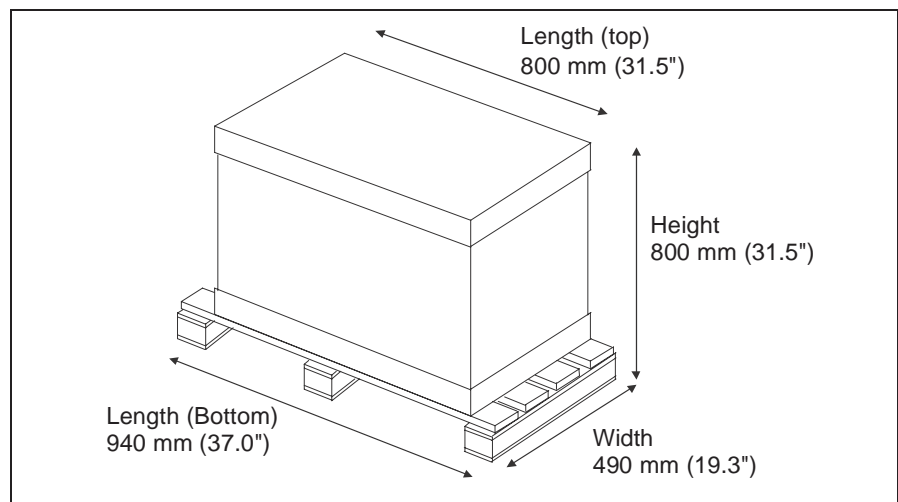


Figure 2-10: IPS Shipping Container

2.5 Collimator Cart

The collimator cart is designed to handle and store a set of two collimators. The over all dimensions for the cart are shown in [Figure 2-11](#).

A set of two collimators is attached to the collimator cart during shipment.

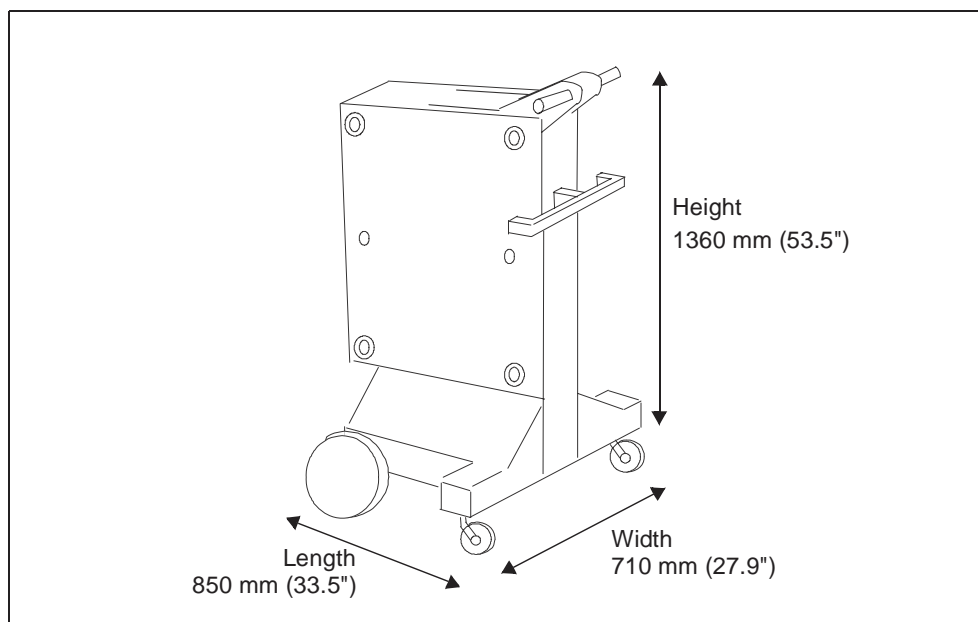


Figure 2-11: Collimator Cart

2.5.10 Physical Specifications

Table 2-10: Physical Specifications of Collimator Cart

Shipping Dimensions LxWxH		Installed Dimensions LxWxH	
in mm	in inches	in mm	in inches
910 x 920 x 1500	35.8 x 36.2 x 59.1	850 x 710 x 1360	33.5 x 27.9 x 53.5

Table 2-11: Weight Specifications of Collimator Cart

Shipping Weight Kg (lb) with collimator	Shipping Weight Kg (lb) without collimator	Installed Weight Kg (lb) without collimator
Min: 208 (459)* Max: 298 (657)*	106 (235)	76 (168)

* For specific collimator weights, refer to [Table 2-12](#).

[Figure 2-12](#) shows the overall dimensions of the collimator cart shipping container.

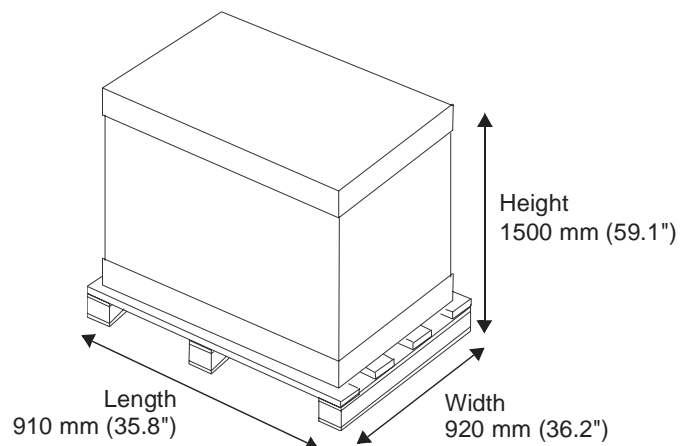


Figure 2-12: Collimator Cart Shipping Container

2.6 Collimators

The following collimators are available for the system.

Table 2-12: Collimators for the MyoSIGHT Detectors

Abbreviation	Collimator Type	Type	Shipping Weight Kg (lb)	Installed Weight Kg (lb)
LEGP	Low Energy General Purpose	Cast	112 (246.6)	52 (114.6)
LEHR	Low Energy High Resolution	Cast	112 (246.6)	52. (114.6)
MEGP	Medium Energy General Purpose	Cast	143 (315.0)	83 (183.))
HEGP	High Energy General Purpose	Cast	157 (345.8)	97 (213.8)
LEUHS	Low Energy Ultra High Sensitive	Cast	109 (240.0)	49 (108.0)
LEPINH	Low Energy Pinhole	Cast	140 (308.4)	80 (176.4)

2.7 Options

2.7.11 ECG Trigger

Device which detects patient ECG signals and generates a trigger output.

- Size
 - Length - 400 mm (15.7")
 - Width - 312 mm (12.3")
 - Height - 160 mm (6.3")

2.7.11.1 Power

Table 2-13: Power Requirements

Voltage	Frequency	Amps
120 V AC	60 Hz	0.5 A
100 V AC	50 Hz	0.5 A
240 V AC	50 Hz	0.2 A

- Heat dissipation is 50W (171 BTU/h)
- Weight is 5 Kg (11 lbs)
- Cable Length
 - Mains Cable = 2.1M (6'9")
 - Signal Cable to CPU = 15M (50')
 - Patient Cable = 3.74M (12'3")

2.7.11.2 Pre-Installation Work

Planning only. You may wish to mount the unit on a wall or table close to the imaging table, or on a movable trolley. A mains power wall socket should be made available within cable limitations.

Note

A table, trolley or cart is not supplied with the ECG Trigger unit.

Chapter 3 - Room Requirements

3.1 General

This chapter provides information required for room layout, site considerations and provides the requirements for the Nuclear Medicine Suite.

When laying out the installation room, thought should be given to provide the best possible functional and personnel working conditions.

Evaluate with respect to the room size the best possible relative positioning of the Gantry / Patient Table and PC Acquisition console within the room.

Allow access around the entire Gantry / Patient Table for personnel to move and help with patient positioning, and patient assistance during emergencies. Access to the system by patients confined to hospital beds should also be considered (enough room to maneuver and position the bed).

Bear in mind that the patient table must be removed during changing of the collimators. Consider where to position the collimator carts (one for each set of collimators) when these are not in use and where to position the patient table during collimator changing.

Pay attention to cable routing. Cables running between the Gantry and the PC Acquisition console should not be routed across path of patient tables and personnel walkways.

Consider cable lengths between system components and the power connections to mains sockets and the position of those sockets.

Note

After these provisional site plans are completed, they should be submitted to your GEHC representative for validation.

GEHC accepts no responsibility for installation problems resulting from site plans which have not been approved by GEHC.

3.2 Required Systems Clearances

Consult your local GE Sales and Project Manager of Installation (PMI) about your specific needs. Some possible room size dimensions are shown in the table below.

3.2.1 Room Size Dimensions

Room Options	Size in cm (feet)
Minimum/Typical room size	455 (14'11") x 245 (8'0")

Component dimensions are in [Figure 3-1](#) through [Figure 3-3](#) of this document. Consult your local General Electric Project Manager of Installation (PMI) for your appropriate room specifications. For equipment clearance requirements, refer to [Chapter 2](#).

Remember, sufficient Regulatory, Service and Egress clearances must be maintained around equipment for full operation, service and safety.

Cable length is an important consideration in room layout. The system is shipped with standard length cables.

Note, also, that the cable should enter the gantry from the rear side. Alternate cable entry is possible to the left or right of the gantry.

Excess cable length can be stored behind the IPS. Long cable must not be cut or shortened. All NEC 70-E Electrical Regulations must be observed.

3.2.2 Regulatory and Service Clearances

3.2.3 Regulatory Clearances

MINIMUM CLEARANCES UNDER U.S. FEDERAL REGULATIONS AND NATIONAL STANDARDS: 29 CFR 1910 (OSHA), NFPA 70E (STANDARD FOR ELECTRICAL SAFETY IN THE WORKPLACE), AND NFPA 101 (LIFE SAFETY CODE):

A diagram of clearance requirements for U.S. regulatory compliance is shown in [Figure 3-1](#). See the clearance tables on the following pages for detailed dimensional clearances.

Please note all systems installed in the United States must comply with all Federal and local regulations.

For installations outside the United States, country-specific or other local regulatory clearance requirements must be met.

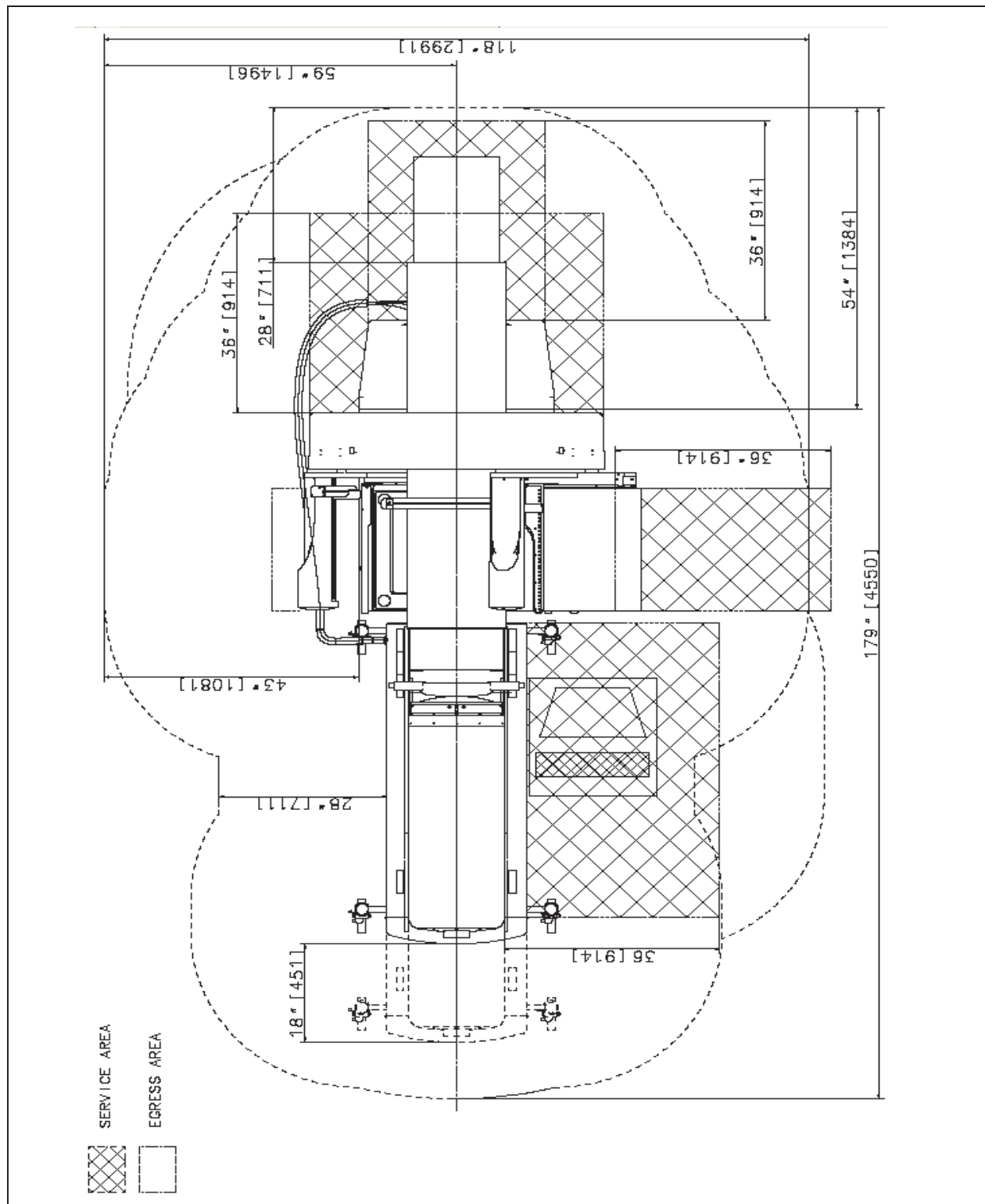


Figure 3-1: Clearance Requirements for U.S. Regulatory Compliance

Note

The Egress Area can be defined on either side of the system, depending on equipment positioning and space availability.

3.2.4 Regulated Minimum Working Clearance by Major Subsystem

- Requirements apply to equipment operating at 600 V or less, where examination, adjustment, servicing, or maintenance is likely to be performed while live parts are exposed.
- Direction of Service Access is defined as perpendicular to the surface of the equipment being serviced.
- Required regulatory clearance distances must be maintained and may not be used for storage. This includes normal system operation as well as service inspection or maintenance.
- For the Gantry and Table, distances are measured from the enclosure, not the finish covers.

Work Space Requirement	Min Clear Space in mm (inches)	Additional Conditions
Direction of Service Access	914.4 (36)	*48 inches (1219.2 mm), if exposed live parts of 151 - 600 volts are present on both sides of the work space with the operator between *42 inches (1066.8 mm), if opposite wall is grounded and exposed live parts of 151 - 600 volts are present.
Service Access Width	762 (30)	This is the width of the working space in front of the equipment. 30 inches (762 mm) min or the width of the equipment, whichever is greater

3.2.5 Terms and Definitions

EGRESS

The path of exit from within any room. U.S. regulatory requires a minimum of 28 inches (711.2 mm) of continuous and unobstructed space including trip hazards along the path of exit.

WORK SPACE

This is the dimensional box required for safe inspection or service of energized equipment. It consists of depth, width, and height. The depth dimension is measured perpendicular to the direction of access. U.S regulation is minimum of 36 inches (914.4 mm). Additional conditions can increase the minimum requirement. GE Healthcare defines this as the envelope of the component superstructure. For the gantry and table, it is with the patient or external covers removed.

SERVICE ACCESS WIDTH

This is the width of the working space in front of the equipment, a minimum of 30 inches (762 mm), or the width of the equipment whichever is greater.

HEAD CLEARANCE

This is the height dimension of “Work Space”. The height of the work space measured from floor at the front edge of equipment to ceiling or overhead obstruction(s), 78 inches (1981.2 mm) or height of equipment, which ever is greater.

GROUNDING WALL

Any wall that can be electrically conductive to earth ground. Masonry, concrete, or tile, are considered conductive. Additional commonly found aspects of a wall should also be considered as grounded. This is not an all-inclusive list:

- Medical Gas ports
- Metal door and window frames
- Water sources and metallic sink structures
- Metallic wall mounted cabinets
- A1 disconnect panel
- Equipment Emergency Off panels
- Industrial equipment such as air conditioners and vents
- Expansion joints

The following are not considered as grounded elements of a common wall:

- Standard wall outlet
- Light switches
- Telephones
- Communication wall jacks

MINIMUM

The lowest limit permitted by law or other authority.

DIMENSIONS AND CLEARANCES

Consisting of, or representing the lowest possible amount of degree for freedom permissible for equipment siting. This relationship must meet all safety, service, and regulatory requirements to be acceptable.

PRE-INSTALLATION ESCALATION

Process to consult with Engineering, the Design Center or EHS regarding pre-installation issues related to your siting concerns.

3.3 Minimum/Typical Room Layout

Figure 3-2 shows a typical (standard) room layout drawing showing location of all basic units for a Millennium MyoSIGHT system. Observe that requirements for clinical access, and for peripheral clinical equipment placement, such as storage cabinets, sinks, etc., must be taken into considerations during the room layout.

- For General Requirements, see Table 3-2.
- For Service Conditions, see Table 3-3.

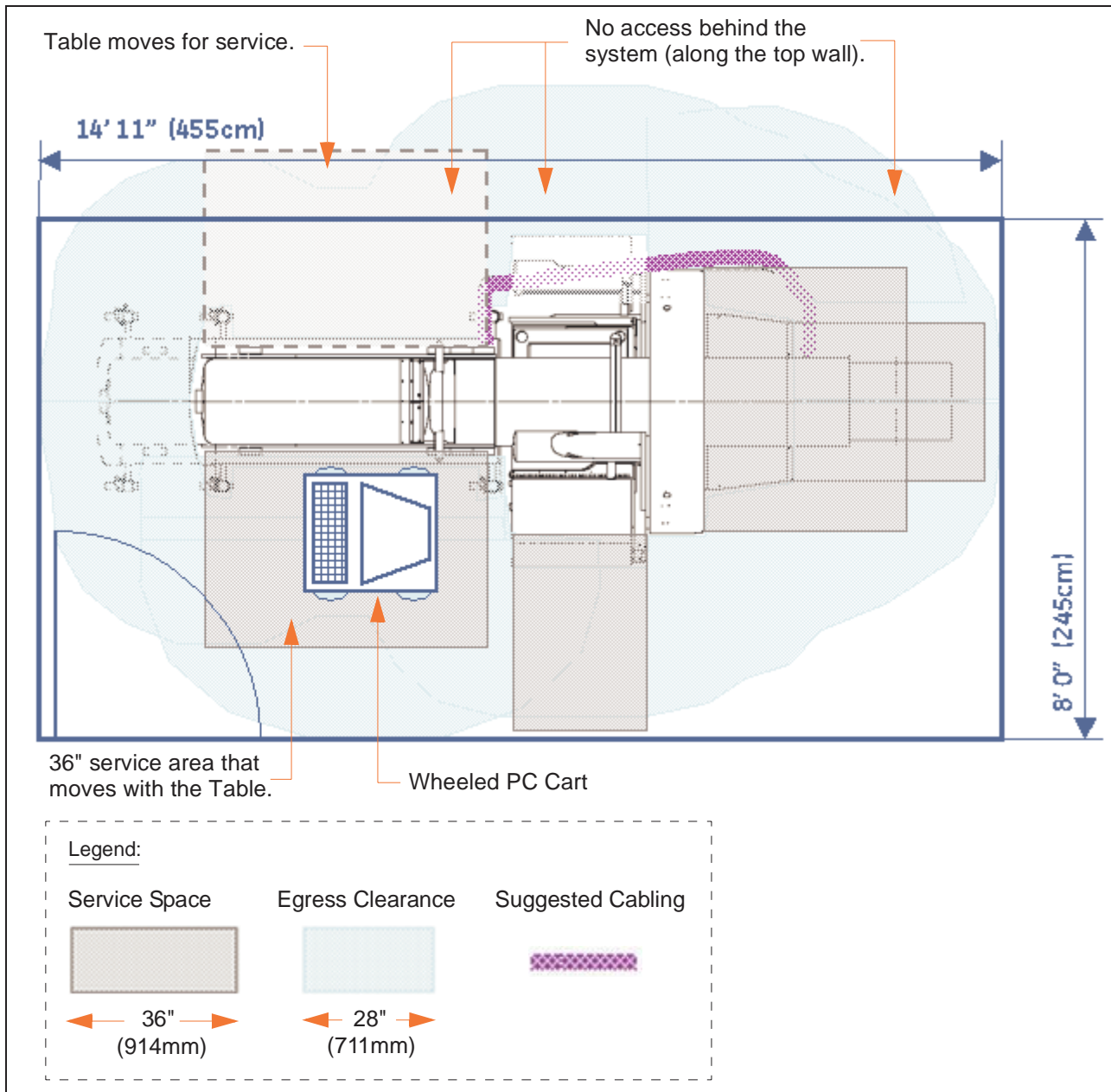


Figure 3-2: Minimum/Typical Room Layout

Table 3-1: Minimum/Typical Room: Dimensions

Room Dimensions	Length & Wide	Ceiling Height
Optimal Floor Space	4550 mm x 2450 mm 14'11" x 8' 0"	2300 mm 7'6"

Table 3-2: Minimum/Typical Room: General Requirements

- Stationary items (storage, UPS) must fit in blank spaces.
- Wheeled items must not interfere with normal operation.
- Room can be mirrored.

Table 3-3: Minimum/Typical Room: Service Conditions

- All gantry service done on the right side as shown in [Figure 3-2](#).
- Table moves for rear and side service access, as shown in [Figure 3-2](#).
- Walls should be grounded.

3.4 Floor Loading Area

Note

Illustration of the gantry and patient table positions identified below, should only be used to determine floor area inside the room in which the system will be installed.

Note

Area under gantry base must support floor loading requirements of gantry. Area in patient table locations must support floor loading requirements of patient table.

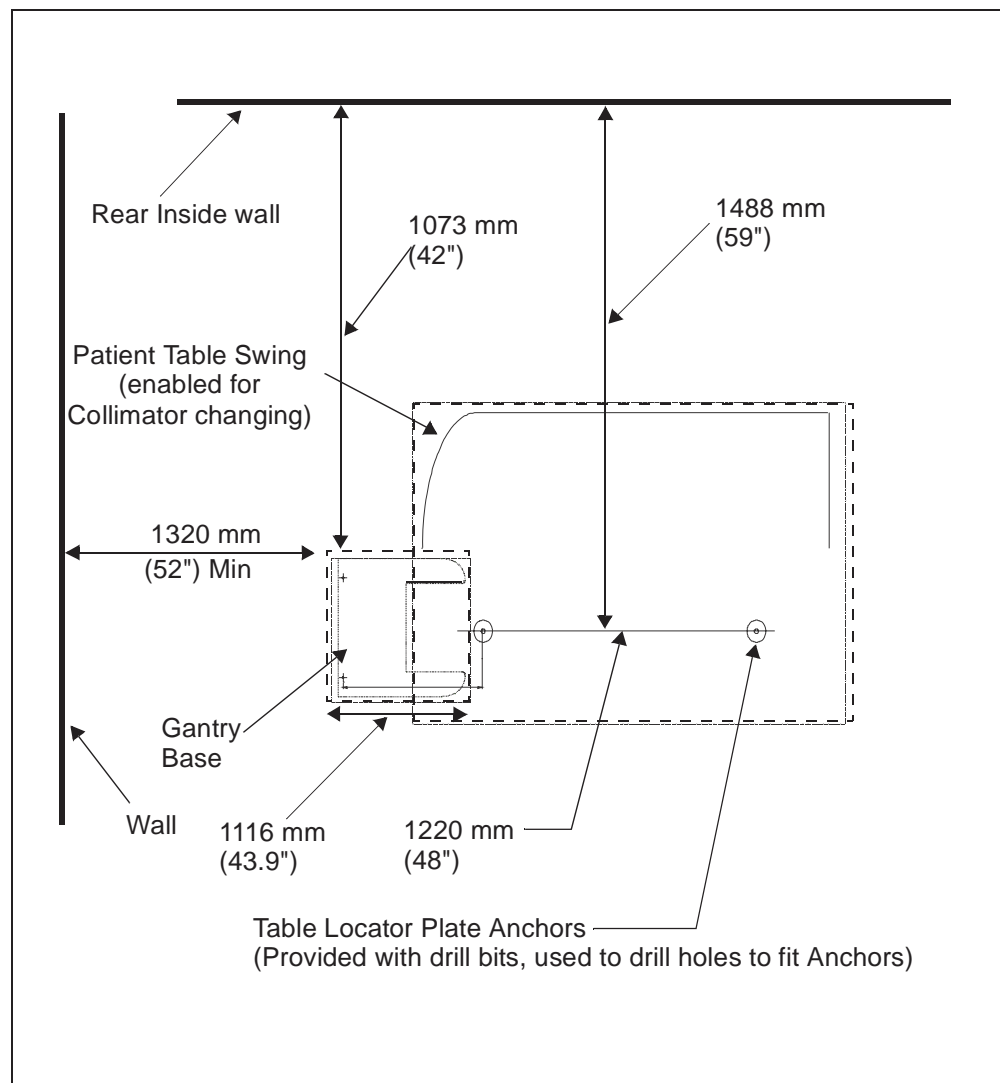


Figure 3-3: Millennium MyoSIGHT System Patient Table Illustration

3.5 Gantry Base Anchoring and Center of Gravity

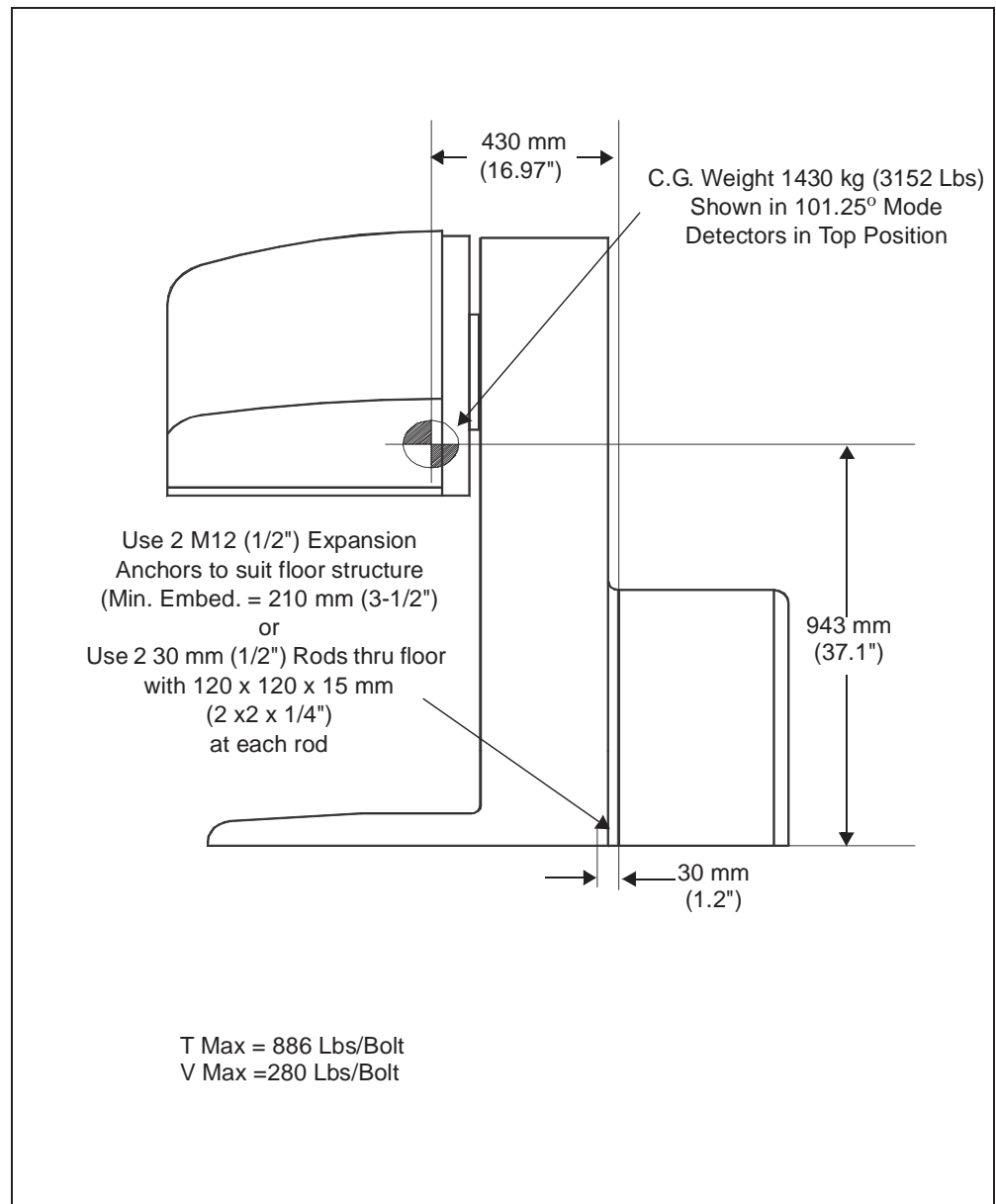


Figure 3-4: Gantry - Side Elevation

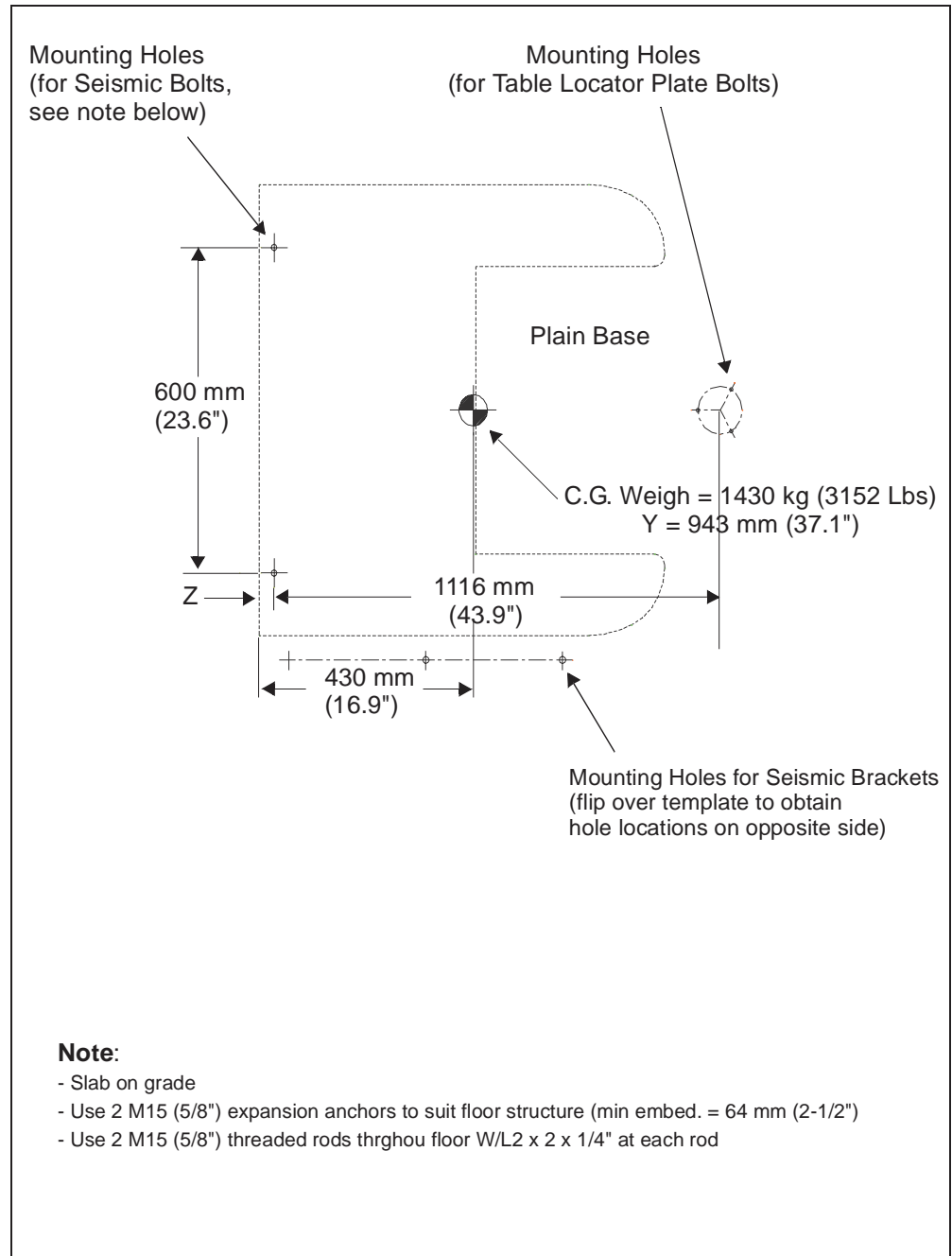


Figure 3-5: Gantry Base

3.6 Seismic Considerations

Depending on the legislation and regulations of the country/region concerned, provision may be necessary for seismic anchoring of the gantry.

The method and approval of the seismic anchoring is available from the GE service representative.

3.7 Floor Loading

Model	Millennium MyoSIGHT System
Model Number	2184116
Leveling Pad Point Loading Includes: HEGP collimators installed on detectors	175 lb/in ² (12.3 kg/cm ²)

Model	Millennium MyoSIGHT Patient Table
Model Number	2186646
Wheel Point Loading	197.3 lb/in ² (13.8 kg/cm ²)

3.8 Floor Levelness & Flatness

The specification for the floor levelness is 4 mm per meter in the area of the room in which the equipment is positioned. To verify floor meets these specifications, the measurements must be taken in three directions as follow: diagonally, width and length of the usable floor space where the equipment is placed. Using one point as a reference and comparing each measurement to the reference point verifying that 4 mm or less can be obtained in each direction per meter.

3.9 Temperature Requirements

A temperature within 15° C (59° F) and 27° C (81° F) is recommended for operating temperature. The ambient storage temperature should be within 7° C (45° F) and 40° C (104° F).

Do not expose the detectors for a temperature-time gradient greater than 3° C (5° F) / hour. Due to this requirement, do not locate the detectors near heating equipment, air conditioning outlets or open windows.

3.10 Humidity Requirements

Relative humidity should be maintained at 20 - 80% non-condensing.

Very low relative humidity increases the risk of damage to sensitive devices due to Electrostatic Discharges (ESD).

Excessive humidity can cause problems such as corrosion and leakage paths for high voltage due to moisture contamination within the equipment.

3.11 Shielding Requirements

Note

Customer is responsible for determining radiation shielding requirements.

Nuclear camera detectors must be located in ambient static magnetic fields of less than 1 Gauss AC or DC fields to guarantee specified imaging performance.

Nuclear computer equipment must be located in ambient static magnetic fields of less than 3 Gauss for specified imaging performance.

The system complies with the IEC 801-3 - radiated radio frequency immunity standard.

For ADditional information, see [Appendix A - EMC COMPLIANCE](#).

3.12 Equipment Access

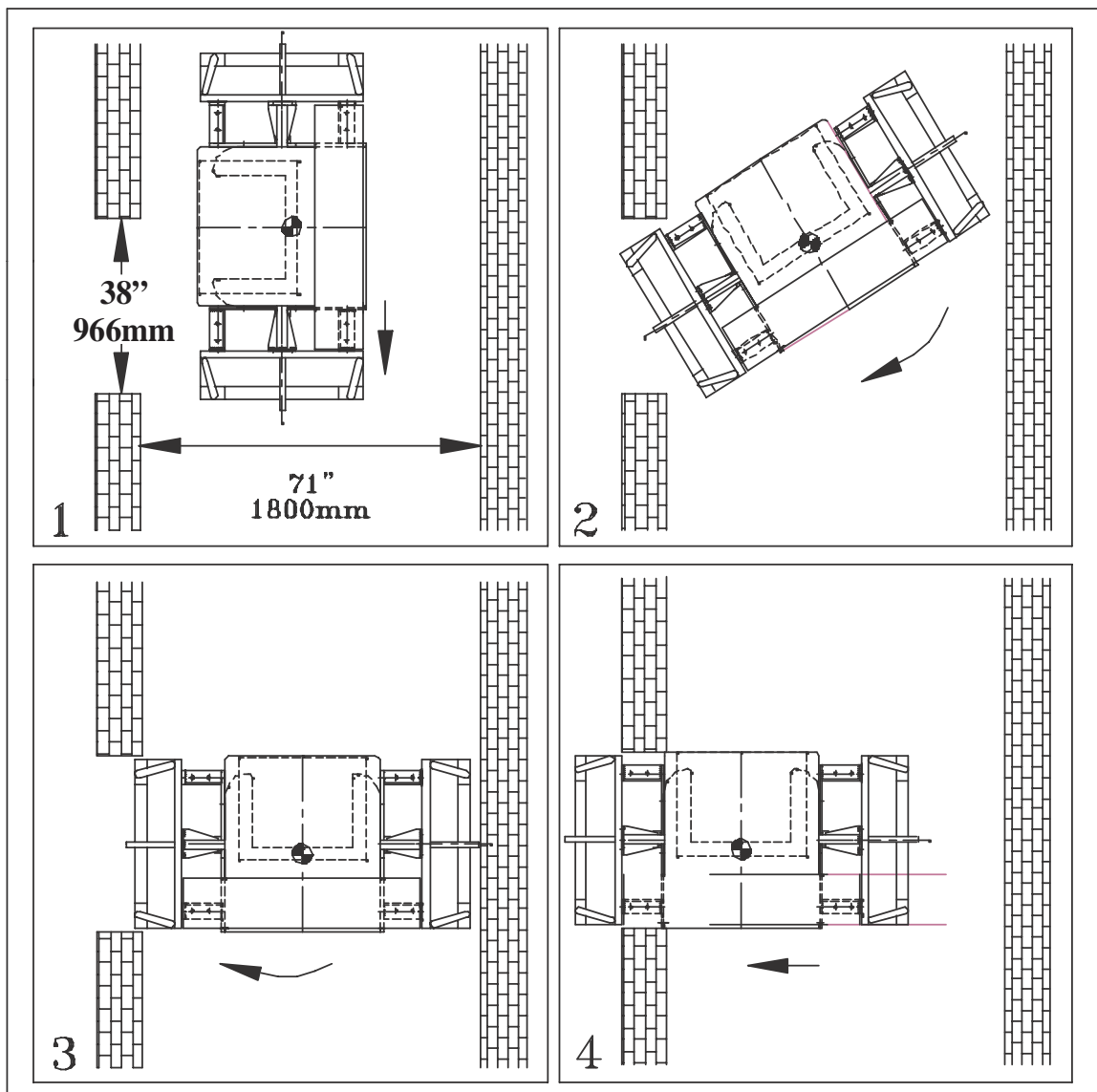


Figure 3-6: Maneuvering Gantry through Minimum Doorway Hallway Passage on Shipping Dolly without Container.

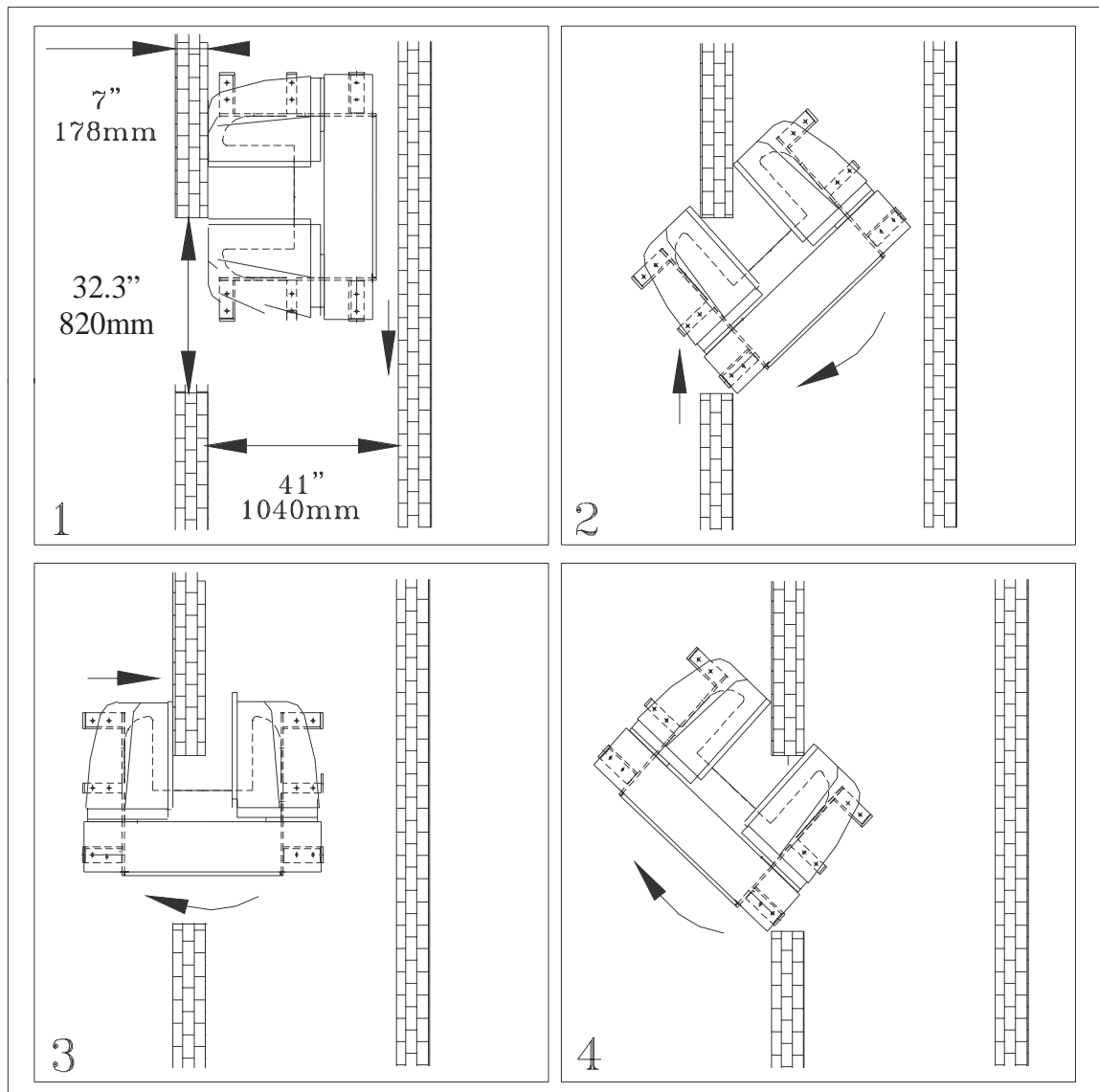
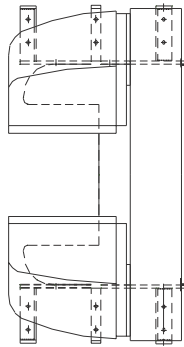


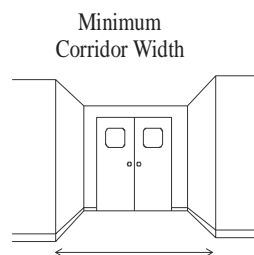
Figure 3-7: Maneuvering Gantry Through Minimum Doorway and Hallway Passage on Local Transit Dolly Only



To move Gantry through narrow doorways, the following minimum door opening can be passed. However, it is required to remove the shipping brackets from the detectors and to power up the gantry to move the detectors to maximum radial position:

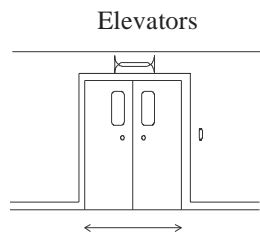
For Gantry on LTD:

- Minimum opening size is 820 mm (32.3")
- Minimum distance from opening to wall is 1040 mm (41")



To maneuver the Gantry/Table into the installation room executing a 90° turn, the following minimum corridor width is required:

- For Gantry on Local Transit system:
1040 x 1040 mm
(41 x 41").
- For Table: 1170 x 1170 mm (46 x 46")



Elevators (lifts) should be checked for size and load capability to ensure safe transport of individual system components.

All elevators used should be capable of carrying loads of 1800 Kg. (3968 Lbs.) minimum.

3.13 Telephone Lines

Communication Network lines (including VPN connection and jack) must be available before equipment is delivered to the site for both voice and modem communications. See [Chapter 4](#) for additional details related to voice and modem communications.

- Voice to be located within reach of the GENIE Acquisition operation InSite communications.
- Modem location will be determined by InSite access (either direct to GENIE Acquisition operator or via the P&R station.

Chapter 4 - Networking Requirements

4.1 Purpose

During the installation of the GENIE Acquisition system you will need to configure a number of site specific parameters. This section describes the information you will need to get prior to the installation in order to configure the site specific parameters.

Refer to the descriptions and/or procedures given in [Section 4.3 Site Assignment Matrix Components on page 4-2](#) and log the information in [Table 4.1 Site Assignment Matrix](#), located below.

4.2 Site Assignment Matrix

The following information is required to configure the GENIE Acquisition system. See the following section for details.

Table 4.1: Site Assignment Matrix

Hospital Name:		
Hospital Network Contact		
IP Address:		
Subnet Mask:		
Network Type: (Thin, Thick, Twisted Pair, Fiber)		
Station Name:		
Ethernet Address:		
StarLink		
System Name	System Type (e.g., StarCam, GENIE P&R)	Ethernet (LAN) Address
Modem Phone #:		
CARES/MUST ID:		
Acq_SLIP_IP		
InSite_PM_IP		
Use Processing & Review InSite Gateway? Y/ N		
InSite Gateway System Name:		
InSite Gateway IP Address:		

4.3 Site Assignment Matrix Components

The following describes each field in [Table 4.3 NP & S Phone Numbers](#).

4.3.1 Hospital Name

This is also referred to as the Institution ID and is used as a label for the GENIE Acquisition main screen. Acquisition provides one 40 character line for this information.

This is not a critical parameter.

4.3.2 Internet Protocol (IP) Address

Note

This is a critical piece of information. It creates the system's absolute uniqueness in the global networking environment and is required for site licensing of software **before system is shipped**.

The **Internet Protocol (IP) Address** is the unique allocation given to any stand alone information system capable of communicating with any other similarly structured system. Every address must be *Globally Unique*. For that reason all such numbers conform to a set structure and are issued from a single global source. The IP address is used for InSite connections now and will be used for DICOM network connections in the future.

Obtain this IP address number using one of the following methods:

Table 4.2: IP Addresses Obtaining Methods

Situation	Method for Obtaining IP Address
Site has a Network/System Manager, Information Systems Manager, Computer Center Manager, or person of a similar title/function, who has structured the site's current network.	Obtain IP Address from this person. Depending on the network structure a subnet mask may also be assigned.
Site does not currently have a person who can assign an IP Address and the Starlink LAN will be connected to another LAN or Wide Area Network (WAN) within or outside the site.	Note The Customer owns the IP Address.
Site does not currently have a person who can assign an IP Address and the LAN will not be connected to any external LAN or WAN.	Contact your nearest Network Products & Services (NP&S) group (see Section 4.3.2.1 , Table 4.3). The NP&S group will assign a <i>Private Network</i> IP Address. Note: GEMS owns the Private Network IP Address. If the LAN is ever connected to another TCP/IP based LAN/WAN, a real IP Address will be needed. A new license will be required if IP Address is changed.

4.3.2.1 NP & S Support Centers

Following are the global numbers for NP & S support.

Table 4.3: NP & S Phone Numbers

Pole	Group	Phone Number
Americas	USA, On-Line Center	800-321-7937, 1
Europe	ESC Nuclear (Paris), France	05 49 33 71
	Austria	0660 8459
	Belgium	0 800 11733
	Germany	0130 81 370
	Italy	1678 744 73
	Luxembourg	0800 2603
	Netherlands	06 022 3797
	Portugal	05 05 33 7313
	Spain	900 95 3349
	Sweden	020 795 433
	Switzerland	155 5306
	UK	0800 89 7905
	Other Countries (No toll free)	International code + 33 1 39 20 0007
Asia	Japan, Tokyo (YMS Support Center)	426 560 033
	Australia, Sydney	2 316 3771

Note

Country codes are not listed as part of the telephone number and need to be included when dialing.

4.3.3 Subnet Mask

Some sites with sophisticated TCP/IP networking utilize a **netmask** to distinguish between the network component of the IP address and the host component of the IP address. If a netmask is used on the network where the system will be connected, this netmask must be set on all nodes, including any Acquisition and/or Processing and Review nodes; otherwise, networking will not work correctly at the site. This procedure describes how to set the netmask on Acquisition nodes.

Note

It is important to find out if netmasking is needed at the site, and if so, this information must be available prior to configuring the Acquisition computer. If required by the site, it will be necessary for correct operation of the InSite connection, which utilizes the TCP/IP network protocol.

If the GENIE Acquisition system exists on a private network with no other TCP/IP nodes with the exception of a Processing and Review station, or if the local Information System or Network Administrator indicates no netmask is used at this site, this item can be left blank on the Site Assignment Matrix. Otherwise report site's specified netmask value.

4.3.4 Network Type

The GENIE Acquisition system will utilize a network to transfer data to a processing, filming, and archiving station elsewhere at the site. Some sort of network cable will be required to run from the system to the site's network for this connection.

Common **Network Types** are:

- Coaxial cable with BNC connectors (sometimes called "ThinNet".)
- Shielded Twisted Pair (looks like telephone wire) with RJ45 connectors.
- Fiberoptic cable.
- Thick yellow Ethernet cable (sometimes called "ThickNet".)
- Thick Twisted Pair (AUI cable using DB25 connector)

Identify which of the above cable types will be used for the physical connection from the site's network to the GENIE Acquisition system and enter it on the Site Assignment Matrix. All Acquisition computers

have an AUI connector. A network transceiver will then be required to convert this AUI connection to the site's network media.

Note

It will be necessary to specify the correct network type and physical connection during the network needs assessment process, so that the correct network transceiver is procured prior to system shipment. Failure to have the correct transceiver type for the site's network type will prevent establishment of network connections.

4.3.5 Station Name

The **Station Name** (sometimes also referred to as the “**hostname**”) can be an up to 15-character alphanumeric value beginning with a letter. Since this name will be typed in several places during installation, a shorter name such as up to eight characters is recommended. Station Names are case insensitive. Valid characters are **a-z**, **A-Z**, **0-9**, and **_** (the underscore character.) The hostname should be unique among the other stations on the network.

4.3.6 Ethernet Address

The **Ethernet Address** of the Acquisition system will not be available until the system is shipped and installed.

4.3.7 Starlink/GenieLink Configuration

In order for the Acquisition system to communicate to systems on the Starlink network, the Ethernet address of each these systems must be entered in the **Network Configuration** file. This includes all Starcam, PC Review, P-Link, M-link and Processing & Review systems.

The Ethernet addresses for all systems currently using the Starlink network can be obtained by displaying the contents of the *Stations Study*, in the *Starlink Patient* of any StarCam system currently on the Starlink LAN.

The Ethernet address of a Processing & Review system can be obtained by referring to the *System Information Card* in the Processing & Review Software CD jewel case or via the **lanscan** command in any Processing & Review UNIX window.

Record the **Ethernet Address** along with a **System Name** in the *Site Assignment Matrix*, located above. The system name will be used in the Link configuration table and to label a User Interface button in the Starlink tool.

Note

The system name you assign should be no more than 12 characters long and only contain the following characters; A-Z, a-z, 0-9 and “_”.

Note

The Ethernet Address is a critical parameter for the Starlink network to function properly.

4.3.8 InSite Modem Telephone Number

If the direct InSite connection is used via a modem on the acquisition system, the system should have been shipped with InSite software and a suitable modem. The license is enabled as part of the entitlement process during installation. The phone number to be used is required in this case.

4.3.9 GE Cares/MUST ID

Follow the normal GE process for the allocation of such a number. This number will be tied to InSite functionality.

4.3.10 GENIEAcq_SLIP_IP

The **GENIEAcq_Slip_IP** address is usually the IP address of the Acquisition computer. If the computer was set up with two Ethernet and IP addresses (to act as an IP gateway) then it would be the main IP address provided to the On-line Center. Since all Acquisition computers currently sold have only one Ethernet and IP port this value should be the same as the IP Address identified in [Section 4.3.2](#) above. It should have the format *x.x.x.x*.

4.3.11 InSite_PM_IP

The **Insite_PM_IP** value is the IP address of the portmaster at the On-Line Center. Contact an OLC Engineer to obtain this address. It should have the format *x.x.x.x*.

4.3.12 Processing & Review InSite Gateway Configuration

There are two ways to provide an InSite connection to an Acquisition-based system:

- The Insite modem can be connected directly to the serial port on the back of the Acquisition system. In this case, skip this section and all questions about InSite Gateways.
- Alternatively, the InSite modem connected to the serial port of a Processing & Review station may be shared by the Acquisition system and accessed via the network (assuming the Acquisition and Processing & Review stations are networked together). In this case the Processing & Review system acts as an **InSite Gateway**.

If a Processing & Review system acts as the InSite Gateway, the Processing & Review and Acquisition systems will communicate via the TCP/IP network protocol in addition to the Starlink protocol used to send image data. The Internet Protocol (IP) Address of these systems will need to be known to each other and entered into each other's TCP/IP configuration files.

Obtain the IP Address for the Processing & Review station that will serve as the InSite Gateway. It should be recorded with the system's documentation. It can also be found by displaying the contents of the **/etc./hosts** file on the system.

Record the IP Address of the Processing & Review InSite Gateway along with its system name in [Table 4.1- Site Assignment Matrix](#). The system name will be used in the TCP/IP network look-up table.

Note

The system name you assign should be no more than 12 characters long and only contain the following characters; A-Z, a-z, 0-9 and “_”.

Note

The IP Address of the remote systems is a critical parameter for network communication to function properly.

4.4 Network

4.4.13 Overview

The acquisition system requires a connection to the Starlink Local Area Network (LAN) in order to communicate with the various StarCam and Processing & Review systems.

The Acquisition system includes an IEEE 802.3 AUI connector which provides the connection point for the LAN.

It is expected that any cable installation and hardware required to provide the connection between the Acquisition AUI port or any network node's AUI port and the LAN be completed prior to the installation of the Acquisition system. This includes:

- Extending or tapping the current network bus.
- Providing all required transceivers.
- When applicable, running drop cables (AUI or UTP) to the installation site of the Acquisition system and any network peripheral.

Note

A transceiver is NOT included with every Acquisition system. That is why it is critical that an NP & S Needs Assessment be done prior to system shipment.

Note

To ensure that all aspects of the network interface are addressed, the GENIE Acquisition order requires a NP & S Needs Assessment. From this, a quote and work order should be generated to ensure all of the above items are completed before the installation

4.4.14 Network Installation Verification

Ensure that the installation of the Ethernet cable, transceivers, and drop cable is complete and functional prior to the installation of Acquisition system.

If the customer is taking responsibility for the network installation, you will still need to ensure the work is complete prior to the installation.

Note

The network installation must comply with IEEE standards, as specified in document "IEEE 802.3 Local Area Network Standards, CSMA/CD Access Method and Physical Layer Specification"

Note

System installation will be delayed if the network is not ready.

4.4.15 Network LAN Layout

Note

NP & S recommends the Twisted Pair (UTP) Hub topology for all new LANs.

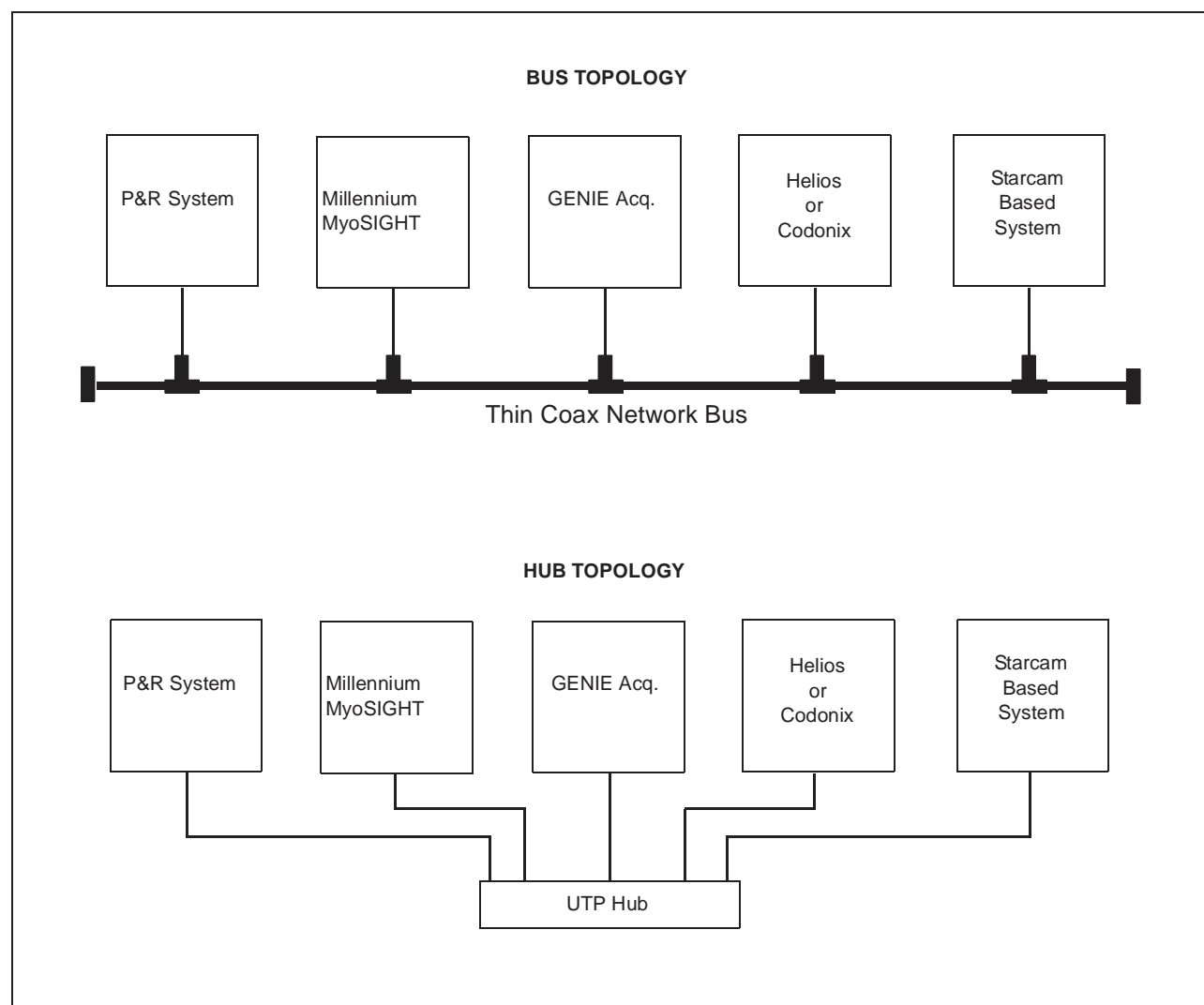


Figure 4-1: Nuclear LAN Samples

4.5 InSite Requirements

4.5.16 InSite Description

InSite provides remote diagnostic services using standard telephone lines. All systems have InSite and require a direct telephone line to provide remote access to the system during the warranty period.

The GENIE Acquisition system supports two means to access InSite:

- A direct modem connection via the serial port on the back of the Acquisition computer or
- An indirect modem connection via the network from an Acquisition system to a Processing & Review system. In this way, multiple cameras can share the same InSite modem and phone line. The Processing & Review system acts as an InSite Gateway.

If a direct modem connection is used, continue through this section. If the Processing & Review InSite Gateway approach is used, ensure the site requirements, as identified in the relevant P&R System Site Preparation Manual (e.g., *Genie Processing & Review System Pre-Installation Direction 2142604-100*), are followed.

4.5.17 Telephone Line

The **customer** should provide a telephone line meeting the following requirements:

- The InSite facility uses a standard exchange telephone line. This is a telephone line that is direct to the standard telephone exchange.
 - The line need not be leased, but must be dedicated, i.e., not shared with other extensions.
 - A caller outside the building, or private exchange, must be able to dial the modem directly without going through a switchboard or into an internal system which automatically switches to another number if the connection is busy.
 - The modems are capable of dialling a 9 to connect to an “outside” line, and can handle most other dialling situations as long as the connection can be made automatically without operator intervention.
- A telephone jack, located near the workstation, must be provided for the modem. In North America a RJ11 type jack should be provided. In other countries, consult the modem supplier, if there is any question about the type of telephone connection required.

- A telephone set is not required for InSite operation, but could be useful for voice communication in coordinating data transfer.

4.5.18 Modem

When a modem connection is not available via a “gateway” (e.g., GENIE P&R), a modem must be ordered with the system as described below:

- In the Americas, the modem supplied is the US Robotics Courier V.34 or equivalent.
- In Europe and Japan, the modem supplied depends on the particular country.

4.5.18.2 “Smart” Command Minimum Requirements

Any modem used with the InSite must be “smart” in that it must be capable of directly receiving and acting upon commands entered from the system console. All of these commands are prefixed by the letters “AT” and therefore specify that the modem is required to perform some action or store an operating parameter. The repertoire of usable commands varies from modem to modem.

Any modem used in InSite must, at minimum, support the following “AT” commands:

- AT - Reset Command Mode.
- ATSO - 0,1 - Disable, enable auto-answer.
- AT&B - 1 Set - Terminal data rate independent of data line rate.

4.5.18.3 Other Requirements

Apart from the “smart” capability, any modem selected must conform to the following minimum specifications:

- Full duplex communication on 2-wire dial-up telephone lines.
- Auto-dial, auto-answer.
- Asynchronous, 8-bit binary, serial terminal interface (without parity).
- Verbal results response.
- CTS/RTS flow control, set by software (enable, disable).
- Self-test with analog loop-back (enable loop-back, report results, disable).
- Transmit and receive data buffering (4 kBytes minimum).

4.5.18.4 Terminal Line Interface Requirements

The modem must use a RS232C terminal line interface with a female DB-25 connector.

It must be possible to configure the modem so that the terminal line runs at 9600 bits/sec independently of the communication line data rate. If the modem connects at 2400, 1200 or any other line rate, the terminal rate must be maintained at 9600 bits/sec.

4.5.18.5 Permission

In many countries it is necessary to obtain permission from the telephone authorities before installing a modem. The modem supplier should be able to help with the information needed. While modems and public telephone exchange equipment are designed to be compatible with each other, there is some chance that a particular modem will not work with a private exchange system or internal telephone system. If there is any doubt, check with the person in your facility who provides technical support.

Chapter 5 - Electrical Requirements

5.1 Power Specifications

5.1.1 General

When installed the Millennium MyoSIGHT Acquisition system requires operating power as described in this section. However, if during installation the gantry has to be rotated from its shipping position to pass through a doorway of less than 914 mm (36") while on the installation dolly, power must be available along the delivery route.

5.1.2 Power Consumption

All system components receive their power from the IPS (Integrated Power Supply) mounted on the rear of the gantry. The Acquisition CPU, the monitor and the keyboard are powered from an isolated 120 VAC power output. This provides adequate isolation and limit leakage current. System components must only be powered from the IPS.

The power consumption for the Millennium MyoSIGHT system excluding options is shown in [Table 5.1](#).

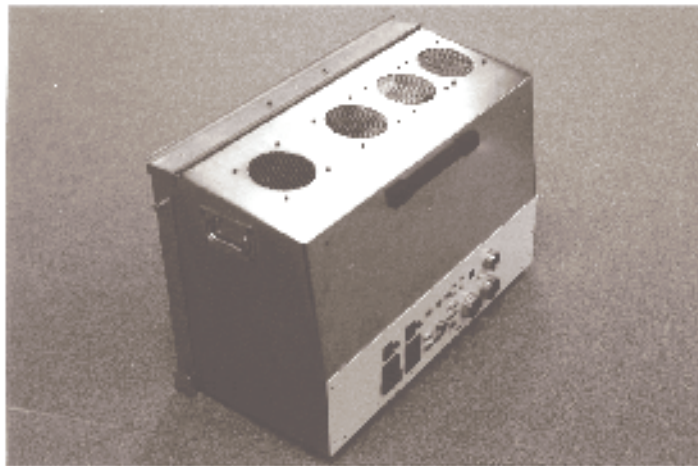


Figure 5-1: IPS Power Supply

Table 5.1: System Power Consumption

Nominal Line Voltage / Frequency	Nominal SS Current (No Motion) Amps RMS	Nominal Current (Maximum Unbalanced - Roll motion - other axis enabled) Amps RMS	Peak Current (1st cycle) AMPS Peak	Peak Current (2nd cycle) AMPS Peak	Time Constant to SS Current mSec
100V / 60Hz	5.9 #	12.5 *	98 *	57 *	30 #
120V / 60Hz	5.2 #	10.0 #	90 #	50 #	30 #
200V / 50Hz	3.0 *	6.8 *	80 *	46 *	30 #
220V / 50Hz	2.6 *	5.2 *	76 *	39 *	30 *
240V / 50Hz	2.4 *	4.6 *	62 *	34 *	30 #

* = Measured Value, # = Estimated Value

5.1.3 Installation According To UL Regulations

The Millennium MyoSIGHT system installed to UL regulations requires a hospital grade power outlet for the complete system. Field engineers must utilize lockout/tagout practices when servicing the equipment.

System options require a hospital grade power outlets type; 15A 125V NEMA S style 5-15.

5.1.4 Installation According To IEC Regulations

The Millennium MyoSIGHT system installed to IEC regulations require to be hard wired to a wall mounted switched outlet breaker with lockout-tagout capability.

Options require outlets suitably rated to meet the power requirements of the option and to be in accordance with the wiring standards relevant to the country of installation.

5.1.5 Power Ratings

The two power ratings are required, as follows:

- 100-120 V, 15 A @ 50/60 Hz, 1.5kVA Volt Amps Max.
- 200-400 V, 10 A @ 50/60 Hz, 1.5 kVA Volt Amps Max.

5.2 Line Voltage Specifications

- The Millennium MyoSIGHT system requires a Single Phase Grounded power line.
- The power supply must be completely free of noise or transients (especially RF) from other electrical equipment.
- Surges, sags or instantaneous variations in line voltage from external sources must not exceed 5% or have more than 0.1 second (5 cycles) duration, or occur more than 10 times per hour.
- The maximum allowable transient amplitude is 2.5 times the RMS line voltage. Any supply with a transient level in excess of this value may require mains filters.
- The systems and all option power outlets shall be supplied from a distribution panel fitted with a suitable circuit breakers.
- Circuit breaker should have a time delay of greater than one second to withstand switch-on surge.
- All options shall be connected to the same phase of the dedicated power line as the main system.
- Line drop out maximum: 20 msec.
- The line voltage specifications for the Millennium MyoSIGHT system components are listed in [Table 5.2 - Line Specifications](#).

Table 5.2: Line Specifications

Nominal Line Voltage / Frequency	Line Voltage Deviation	Line Frequency Deviation
100VAC / 60Hz	90 - 110 VAC	47 - 63 Hz
120VAC / 60Hz	108 - 133 VAC	47 - 63 Hz
200VAC / 50Hz	180 - 220 VAC	47 - 63 Hz
220VAC / 50Hz	198 - 242 VAC	47 - 63 Hz
240VAC / 50Hz	216 - 264 VAC	47 - 63 Hz

Note

The Millennium MyoSIGHT system is equipped with metal oxide varistors (MOVs). This supplies some protection against surges. If local power supply is not according to the above specification, additional power considerations should be seriously considered. UPS or line conditions will need to handle 1.5 kVA load (Millennium MyoSIGHT power ratio).

5.2.1 Power Source Test

Customer Responsibility: If the site has experienced previous line power problems, the line power should be monitored over a continuous fourteen day period to verify that power requirements listed are met. Use an analyzer such as the DRANETZ MODEL 606-3 (three channel with 101 frequency option), or DRANETZ MODEL 626 (with three-phase AC monitor option). Review the results of this analysis with the local service representative to determine whether a voltage/frequency stabilizer, power line protector or filter are required. If required, these items should be installed as part of the pre-installation work.

5.3 Electrical Noise/Grounding

The noise on the mains power supply must not exceed 50 mV p-p. This is measured between line return and ground, from DC to 30 MHz. To ensure this is a dedicated power line with AC, a ground may be necessary.

The power outlet must have a **Protective Earth Terminal** in order to meet safety requirements.

5.3.1 Grounding Requirements

The basic system and all options must be connected to a mains outlet with protecting earth terminal to comply to UL 2601-1 and EN60601-1 safety regulations.

Grounding must meet specific Country grounding requirements where applicable.

Millennium MyoSIGHT safety classification:

- UL 2601-1 Medical and Dental Equipment.
- EN60601-1 Safety for Medical Electrical Equipment. Class I, type B.
- DIRECTIVE 93/42/EEC concerning medical devices Class Iia.

Chapter 6 - System Cable Interconnection

6.1 General

This section describes all cabling between major components in the Millennium MyoSIGHT system including options. Interconnecting maps indicate the location of the connection points and all cables are identified by number, name, function and length. This information is useful when laying out the installation room evaluating cable length and routing. The basic interconnecting map contains information for connecting only the essential components for the system, whereas cabling for any option that can be added to the system is shown in the optional interconnecting map. [Figure 6-1](#) provides an interconnecting map for a typical room layouts. Use this as a guideline to a suitable room layout with respect to cable length and routing.

6.2 Cable Listing

Table 6.1: Cable Listing for the System

Item	Description	From System Component	To System Component	Length
1	Power Cord	IPS connector panel	Mains outlet	4m (13.0')
2	Cable Acquisition Cart	Acquisition CPU connector panel	Acquisition Cart	5m (16.4')
3	Cable Acquisition CPU	IPS connector panel	Acquisition CPU connector panel	6m (19.8')
4	Network Drop Cable	Acquisition CPU connector panel	Transceiver box on Ethernet work	5m (16.4')
5	Cable Table	Table connector panel	IPS connector panel	5m (16.4')
6 *	Cable Handset	Gantry or Table	Hand Held Controller (HHC)	Flexi cable

* 5 Connection Points; 2 on Gantry, 2 on Table, and 1 on IPS.

6.3 System Interconnections

6.3.1 System Interconnection Map

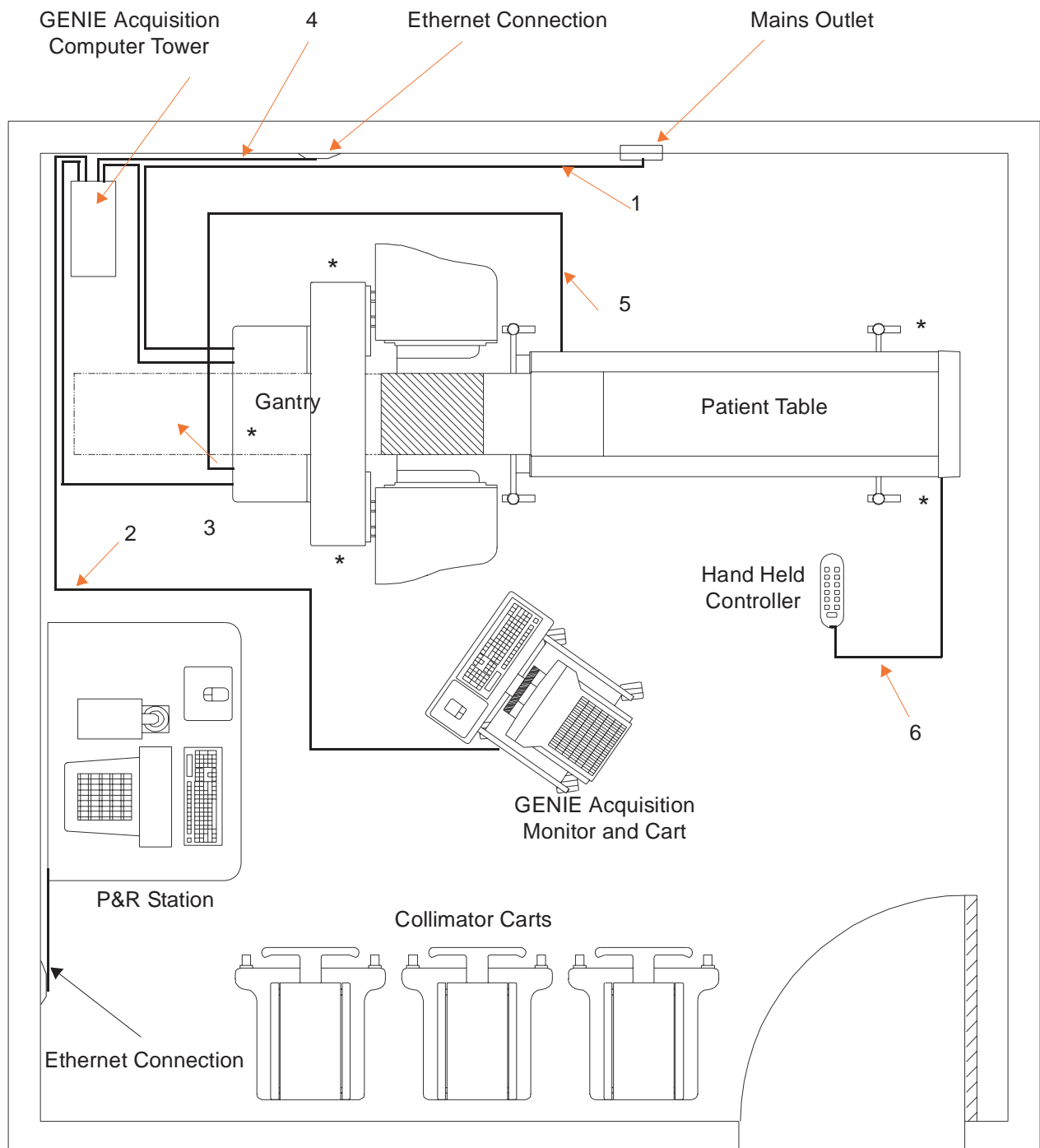


Figure 6-1: Cable Interconnect Map

Chapter 7 - Shipping & Delivery Information

This chapter contains information for shipping environment requirements, shipping packing, and delivery information for the Millennium MyoSIGHT system.

7.1 Shipping Dimensions, Weight And Method

A storage area big enough for the equipment, for installation material and required tools must be defined if the equipment must be stored until the final installation.

The shipping dimensions for all system units are listed in [Table 7.1](#). Check that sufficient working space exists around all system units for unpacking. Start the unpacking by opening the accessory box. This box contains the handset and power cables (needed if the gantry is to be operated during the installation), tools and information for equipment installation.

Table 7.1: Shipping Information

System Component	Shipping Dimensions L x W x H		Shipping Weight Kg. (Lb)	Shipping Method
	in mm	in inches		
Mobile Cart	571 x 597 x 724	22.5 x 23.5 x 28.5	27.7 (61)	Cardboard box
Monitor	546 x 520 x 584	21.5 x 20.5 x 23.0	25.4 (56)	Cardboard box
Computer Tower	610 x 635 x 381	24.0 x 25.0 x 15.0	16.3 (36)	Cardboard box
Gantry incl. Detectors	1870 x 1260 x 1680	73.6 x 49.6 x 66.1	1580 (3483)	On Dolly Crate
Table	2460 x 1060 x 1200	96.9 x 41.7 x 47.2	610 (1345)	In Wooden Container
IPS	940 x 490 x 800	37.0 x 19.3 x 31.5	82 (181)	Pallet
Collimator Cart incl. Collimators *	910 x 920 x 1500	35.8 x 36.2 x 59.1	Min: 208 (459) Max: 298 (657)	Pallet
Accessories Manuals				Cardboard box

* SET of two collimators for each cart order.

7.2 Installation Equipment

Some system components are shipped on pallets, movable by means of a forklift. The total number of pallets depend on the number of collimator sets ordered (one pallet for each set). These are transported to a place as close as possible to the installation room by using a lifting cart or a forklift. Specifications for the forklift is shown in [Figure 7-1](#).

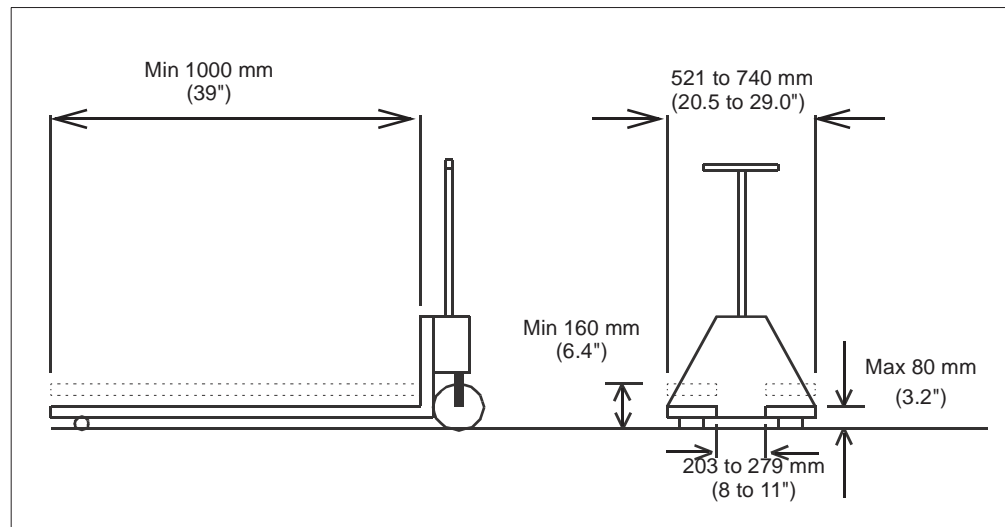


Figure 7-1: Illustration Forklift Specifications

When moving the shipping pallets note the center of gravity sign and place the lifting cart under the pallet in line with the sign.

7.2.1 List Of Tools Required For Installation

Table 7.2: Tool List

Field Provided
Pallet Lifting Cart (As detailed in this chapter)
Power Extension Cable
Impact Drill Motor (with 0.5 inch chuck)
Spirit Level
Vacuum Cleaner
Standard Tool Kit
Force Meter Gauge (GE Part Number 46-308109P1 currently used by NM)
1/2" Drive Socket Wrench (for raising/lowering shipping dollies)

Table 7.3: Regionally Held Tools

Item Description	Part Number
NEMA Kit	2146256
NEMA Resolution Phantom (Rectangular)	2146254
NEMA Resolution Phantom Case (Rectangular)	2146255
Linearity Kit	2146273
Linearity Phantom (Rectangular)	2146260
Linearity Phantom Case (Rectangular)	2146261
Source Holder and Tripod	2146262

Table 7.4: Shipped With System

Item Description	Part Number
Jumper Plug (J6 on IPS)	CBL000480
Jumper Plug (J5)	CBL000481
14 mm Hex Allen Head Bit (for 1/2 "socket drive wrench)	ZT830014127
Masonry Drill 15mm	ZT830015160
Masonry Drill 1/4"	ZT011304127

7.3 Storage Temperature/Humidity Range

The equipment must be stored, still crated under cover in a dry, dust free environment. The temperature and humidity must be maintained within the limits:

- Temperature range: 7° C (45° F) to 40° C (104° F)
- Max. temperature change: 3° C/Hr (5° F/Hr)
- Humidity maintained at: 20% - 80% no condensing.



CAUTION

Temperature and mechanical shock can cause permanent damage to the imaging detector. The detector must remain wrapped up during storing.



CAUTION

The imaging detectors should remain wrapped up and at a room temperature between 7° C (45° F) to 40° C (104° F) temperature for at least 24 hours before unpacking

Chapter 8 - Pre Installation Checklist

8.1 Purpose

This chapter contains a general checklist form to be used by the site planner to ensure that all site preparation has been done according to the agreements with the customer.

8.2 General

This section contains a general checklist form to be used by an installation planner to ensure that all site preparation agreements with the customer are understood.

The customer is to prepare the site before any equipment is installed. Installation must take place according to technical, environmental specifications.

8.3 Checklist

The following checklist should be completed by both the customer and a representative. Mark each **Yes** or **No** box. The checklist should then be signed.

At this point, the pre-installation phase is completed.

Table 8-1. Checklist

Arrival/Installation Check List				Comments	
Equipment Arrival/ Installation	Site Name: _____ When will the equipment arrive? _____ Date: _____ When will the equipment be installed? _____ Date: _____				
Site Preparation Check List			Yes	No	Comments
Contact Persons	Is primary field engineer identified ? Is primary field engineer trained, on the equipment ? Is sales representative identified ? Is customer system administrator identified ? Is customer facility coordinator identified ?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Corridor/ Elevator Requirements	Is the route to the installation room clear, are corridor / elevator requirements met ?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>		
Room Power Requirements	Is the room lighting adequate ? Are system power devices (1 phase) installed and is power available ? Must suppresser/filter be installed prior to start of the installation ? Is minimum one wall outlet available for power tools ? Is power available along the delivery route ?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Room Layout	Is facility space identified by customer ? Is room layout approved by customer ? Are final room layout drawings signed by customer ? Are final room layout drawings forwarded to GEMS ? Does the room layout leave a free working space of 61cm (2'0") around the equipment for service ?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Room Environments	Does the room meet GEMS environmental specifications for minimum size, HV AC system, telephone, network, temperature and humidity ? Is room construction complete and are room and adjacent corridors dirt and dust free ? Are walls and ceiling support structures installed and painted? Is the floor installed to levelness specifications ? Has the necessary cable routing/trunking been completed ?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Equipment Receiving	Is the receiving dock defined ? Is a pallet truck available locally ? Is a pallet truck supplied by forwarder ? Are customer and neighbors notified of need to use hammer drill (noise issue) ? Is the equipment delivery route defined and accepted by GEMS and customer ? If necessary, is temporary storage area defined ? Are all conveying means and architectural changes required to facilitate equipment delivery done ?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Radiation License	Is a radiation site license obtained and will a radiation source be available for calibration of the equipment ?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>		
Waste Packing	Is there facility for the disposal of empty wooden cases, foam blocks and large cardboard boxes ?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>		
Networking	Are network site name, hostname and IP address established ? Are network cabling and hardware installation complete or has contractor been scheduled to complete work as required? This work must be completed prior to the delivery of the system and IP address communicated to FDO administrator to generate license before system ships. Is a phone line installed for the InSite modem?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Completion Sign Off	Pre-installation completed: _____ Date: _____ Customer: _____ System Vendor Representative: _____				

Appendix A – EMC COMPLIANCE

This system complies with IEC60601-1-2 (2nd Edition - 2001) EMC standard for medical electrical equipment.

A.1 GENERAL SCOPE

The System is suitable to be used in the electromagnetic environment, within the limits & recommendations shown in the following tables:

- [Table A-1 – Emission Declaration on page A-3](#)
- [Table A-2 – Immunity Declaration on page A-4](#)

Note

This system complies with above-mentioned EMC standard when used with the standard supplied cables.

A.2 ELECTROMAGNETIC EMISSION

See [Table A-1 – Emission Declaration on page A-3](#).

A.3 ELECTROMAGNETIC IMMUNITY

See:

- [Table A-2 – Immunity Declaration on page A-4](#)
- [Table A-3 – Immunity Declaration \(continued\) on page A-5](#)
- [Table A-4 – Separation Distances on page A-6](#)

A.3.1 LIMITATIONS MANAGEMENT

Adhering to the distance separation recommended in [Table A-4](#), between 150KHz & 2.5GHz, will reduce disturbances recorded at the image level but may not eliminate all disturbances. However, when installed and operated as specified herein, the system will maintain its essential performance by continuing to acquire, display, and store diagnostic quality images safely.

A.4 LIMITATIONS of USE

A.4.1 External Components

In order to minimize interference risks, the requirements listed below apply.

A.5 INSTALLATION REQUIREMENTS and ENVIRONMENT CONTROL

In order to minimize interference risks, the requirements listed below apply.

A.5.1 Cable Shielding and Grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interfer

A.5.2 Radiated Emissions

This product complies with the radiated emission specifications CISPR11 Group1 Class A standard limits.

The System is predominantly intended for use, in non-domestic environments, and not directly connected to the Public Mains Network. The System is predominantly intended for use (e.g. in hospitals) with a dedicated supply system, as described in the site preparation manual.

A.5.3 Power Supply Distribution - Subsystem and Accessories

All components, accessories subsystems, systems which are electrically connected to the System, must have all the AC power supplied by the same power distribution panel and line.

A.5.4 Stacked Components and Equipment

The System should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the System should be observed in order to verify normal operation in the configuration in which it will be used.

A.5.5 Static Magnetic Field Limits

In order to avoid interference on the System system, static field limits from the surrounding environment are specified below.

Static field must be less than <1 Gauss in Examination room, and in the Control Area.

Static field must be less than <3 Gauss in the Technical Room.

A.5.6 Electrostatic Discharge Environment and Recommendations

In order to reduce electrostatic discharge interference, install a charge dissipative floor material to avoid electrostatic charge buildup. The relative humidity shall be at least 30 percent.

The dissipative material shall be connected to the system ground reference, if applicable.

Table A–1: Emission Declaration

EMC Emissions Guidance & Declaration for the System		
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.
Harmonic emissions IEC 61000-3-2	Not applicable	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.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	


Table A–2: Immunity Declaration

EMC Immunity Guidance & Declaration for System			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should verify that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 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 atleast 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-line ± 2 kV line-earth	± 1 kV line-line ± 2 kV line-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% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 5 sec	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 a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note

U_T is the a.c. mains voltage prior to application of the test level.

Table A–3: Immunity Declaration (continued)

EMC Immunity Guidance & Declaration for System			
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should verify that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RFI EC 61000-4-6 Radiated RF IEC 61000-4-3 (alternative method: IEC 61000-4-21)	3 V _{RMS} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V _{RMS} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	<p>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 appropriate for the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = \left[\frac{3.5}{3} \right] \sqrt{P}$ <p>(see Table A–4)</p> $d = \left[\frac{3.5}{3} \right] \sqrt{P}$ <p>80 MHz to 800 MHz (see Table A–4)</p> $d = \left[\frac{7}{3} \right] \sqrt{P}$ <p>80 MHz to 2.5 GHz (see Table A–4)</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p>^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.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Note

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table A-4: Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System			
The System is intended for use in an 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 (P) of Transmitter Watts (W)	Separation Distance According to Transmitter Frequency		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{3} \right] \sqrt{P}$	$d = \left[\frac{3.5}{3} \right] \sqrt{P}$	$d = \left[\frac{7}{3} \right] \sqrt{P}$
	Separation Distance (meters)	Separation Distance (meters)	Separation Distance (meters)
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

Note

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.