GE HealthCare

MyoSPECT

Pre-Installation Manual

5860425-1EN
Revision 3

Revision History

Revision	Date	Description of Changes
r3	June 2023	**New Items:** • Atmospheric pressures added in 1.3.1.2 Air Pressure Requirements During Transportation on page 19 • MDP photo added in 2.1 Equipment and System Components on page 28 • EStop added to moving components in 2.2 Room Size, Layout and Considerations on page 35 • Interconnection drawings added in Table 2-3 Table Center of Gravity with Different Loads on page 47 2.2.3 Layout Considerations on page 40 • Updated in 2.3.1.2 Floor Loading Requirements on page 44 • Note related to vents direction relative to system added in 4.1 General Guidelines on page 59 • Interconnect drawings for CCTV added in 5.5 System Cable Information on page 68 • UPS-MDP added to cables table in 5.5 System Cable Information on page 68 • Configuration options and drawings added to: ◦ 5.6.2 Primary Power Disconnect on page 72 ◦ 5.6.3 Connection to Power on page 73 • Note related to hospital grade plug supplied by facility added in 5.6.3 Connection to Power on page 73 • Information for CCTV power outlet added in 5.9 Patient Monitoring System (Optional CCTV) on page 76 • MDP information provided in Appendix F Main Disconnect Panel (MDP) (Option) on page 105 **Updated Items:** • Consolidated and updated temperature precautions table, 1.3.1.1 System Temperature Precautions on page 19 • Detector crate weight, table weight and crated gantry measurements updated in 1.3.4 Crated and Uncrated Weights, Measurements and Clearance on page 23 • Minimal room drawing titles updated to improve clarity; index of monitors added to Example Room in 2.2.2 System Layout Drawings on page 36 • Listed line voltages specifically instead of range in 5.2 Power Supply Requirements on page 64 • Updates to 5.3.2 Grounding of System Input Power on page 66 • UPS HCat updated in Appendix E Uninterruptible Power Supply (UPS) Option on page 104
r2	August 2021	Miscellaneous updates

Revision	Date	Description of Changes
r1	June 2020	New manual

Language Policy

DOC0371395 - Global Language Procedure

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Contents

Figures

Tables

Safety Notices

Safety Labels in This Document

This manual addresses the following safety classifications:

⚠ DANGER

Danger is used to identify conditions or actions for which a *specific hazard* is known to exist, which *will cause severe or fatal personal injury* or substantial property damage if the instructions are ignored.

⚠ WARNING

Warnings are used to identify conditions or actions for which a *specific hazard* is known to exist, which *may cause severe or fatal personal injury* or substantial property damage if the instructions are ignored.

⚠ CAUTION

Cautions are used to identify conditions or actions for which a *potential hazard* may exist, which *may cause minor personal injury* or property damage if the instructions are ignored.

Safety-related Information in System Documentation

⚠ WARNING

- Before any attempt is made to use/service the system, the operator and service personnel must be trained, and must read and be acquainted with all *safety-related* information in the relevant documentation.
- This information will prepare all users to operate the equipment safely and correctly in order to ensure the well-being of the patient, operator and service personnel.
- All service safety information that is specific to Pre-Installation and Installation is detailed in the relevant manual, for example: transportation, storage and conveyance precautions are specified in the *Pre-Installation Manual*, while safety details that are relevant only to installation appear in the *Installation Manual*.

Safety-related and general information is available in the manuals provided with the system as follows:

- **Information provided within the Operator Manual Set:**
  - ***Safety and Regulatory Information***
    - Intended use (including medical purpose, patient population and operator profile)
    - General safety warnings and instructions
    - Safety mechanisms and procedures
    - Operator and patient safety during clinical operation
    - Equipment and data safety
  - ***System Description and Specifications***
    - Detailed system description
    - System specifications
    - Startup and shutdown procedures
  - ***Quality Control Operations***
    - Tests and other QC procedures performed by the operator
    - Daily QC
    - Periodical tests and retuning
  - ***Adhesive Labels and Rating Plates***
    - Labels on the exterior of system components

General

Important

The images in this manual are for demonstration only. There may be minor differences that do not affect functionality.

Indications, Terminology and System Names

Indications

The following indications are relevant for all documents in the NM Service documentation.

- The images in this manual are for demonstration only. There may be minor differences that do not affect functionality.
- **General Terminology:**
  - **NM** is an abbreviation for **Nuclear Medicine**.
  - The terms **NM System**, **Gamma camera** and **Camera** are used interchangeably.
  - **SPECT** stands for Single Photon Emission Computed Tomography.

Document Conventions

The following conventions are used throughout the manual:

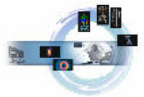
Important

Calls attention to important comments.

NOTE

Contains tips and general comments.

Description	Example
Keys on the operator keyboard, hand-held controller (RCU) or gantry control panels and the gantry	• Press **<SET>** / **<Ctrl>**
Software interface buttons	• Click **[OK]** / **[Apply]** / **[Cancel]**
Names of items in the graphical interface including:	
• Names of dialog boxes, windows, tabs, areas and lists • Menu items • Field and icon labels	• Click **System Setup** (tools icon), then select **Maintenance** > **Utilities** • **To Do List** • **Properties** field
System messages	Press Y to continue.
System parameters whose actual values must be defined by the user	Type-in the **Patient ID**
Hyperlinks	See Figure 1 Sample Image on page 15
File names or paths	root/opt/tacqdb/manuals
References to other documents	*Safety Manual*

Description	Example
Sample Image	**Figure 1 Sample Image** 

Chapter 1 General System Requirements

1.1 Objectives and Overview

This manual provides all information necessary to prepare the site for the installation of the system, taking into consideration the information required for different professionals such as architects, construction engineers, electrical contractors, and all other personnel involved in construction and preparation of the site.

Important

Good site preparation is essential for smooth and efficient installation and for proper functioning of the system. Poor site planning may compromise system efficiency, operator efficiency, operator comfort, and/or patient comfort.

The information provided in this *Pre-Installation Manual* is general in its nature, and must always be used in conjunction with the drawings and specifications prepared specifically for your site.

If the site is considering a future system upgrade, use the pre-installation manual of the intended system type, during site planning. Special attention should be paid to room size, floor requirements, electrical power requirements, cable paths (ducts), and environmental requirements (air conditioning for heat dissipation).

When upgrading a system, the site's power, structure and floor loading requirements must be evaluated for upgrade suitability according to this manual.

Installation Timing

Standard installation takes approximately one week. Mechanical installation is performed during the first two days, and configurations and calibrations are performed during the remaining days. The strength and calibration date of the Co^{57} flood source will directly impact the calibrations. In order to avoid image quality issues, the system's calibrations must be performed **after** the calibration date of the flood source.

Completing the PIM checklist will significantly improve installation efficiency and minimize delays in the installation processes.

1.2 Customer Responsibilities

It is the customer's responsibility to prepare the site in accordance with all the specifications provided in this manual, and in conjunction with the site-specific drawings. It is essential to verify all aspects of the site configuration before construction is started, as subsequent changes can be costly or impractical.

A detailed checklist is provided in Appendix A Customer Checklist on page 79. It is the customer's responsibility to ensure that all requirements in the checklist are fulfilled and the site conforms with all the specifications and requirements in this manual.

The customer is responsible for all aspects of site preparation, including, but not limited to, the following tasks:

- Assigning a project coordinator (see 1.2.2 Project Coordination on page 18)
- Planning and construction or renovations required for installation of the system, in accordance with the specifications included in this manual, including:
  - 2.2 Room Size, Layout and Considerations on page 35
  - Chapter 2 Equipment Description and General Construction Requirements on page 28
  - 3.1 Radiation Protection and Shielding Requirements on page 54
  - Chapter 4 Environmental HVAC Requirements on page 59
  - 5.1 Power Feed on page 63
  - Chapter 6 Network and GE Remote Access Requirements on page 77
- Complying with all national, state, or local regulatory requirements for the country in which the installation occurs, for example:
  - Fire control devices as required by local codes
  - Permits, inspections, radiation licensing etc.
  - Earthquake-related regulations
  - Local regulations for service clearance and egress
- Assuring regulatory compliance for the use of radioactive isotopes and preparation of the required isotopes (see 1.2.1 Using Radioactive Isotopes on page 17)
- Safe storage of the system and auxiliary equipment prior to and during installation
- Floor tile removal and replacement in area of gantry
- Ensuring adequate accessibility for all system components and auxiliary equipment to the site

1.2.1 Using Radioactive Isotopes

Since the system involves the use of radioactive isotopes, compliance with Nuclear Regulatory Commission regulations, or similar regulatory requirements (depending on the country), must be adhered to and all permissions obtained well in advance. It is recommended that regulatory compliance is arranged early in the site planning process.

It is essential that all preparations are completed so that required source materials can be obtained prior to installation, including calibration sources. Take into consideration that these sources may have fairly long delivery lead times, yet may also have a short half life, so that it may not be advisable to store them for long periods of time.

The site must provide a list of isotopes in order to coordinate the calibrations plan prior to installation.

A Co^{57} square flood source with an activity of 20 mCi, to be used for Quality Control and Maps creation, must be pre-ordered at least two months in advance. Since a new Co57 source may contain impurities, it is mandatory that the site will have available for the installation date of the system a flood source that is at least **two months old**, in order for the impurities to decay prior to installation. Approved flood sources include:

- Part number BM55-20 == > 20 millicuries (740 MBq)

  The manufacturer of record with the NRC/FDA for this product is International Isotopes Inc. located in Idaho Falls, Idaho 83401, the ownership, design and engineering is RadQual, LLC

- Catalog number MED3743 - 20 mCi

  Eckert & Ziegler Isotope Products

1.2.2 Project Coordination

The site project coordinator is the primary contact and liaison between GE and all site-related functions, including the purchaser, the construction planners, architects and contractors, and other site administrative personnel.

To ensure a successful installation, it recommended that the site nominates a single site project coordinator, preferably a person familiar with similar medical construction projects, manages the entire project. Ideally, the project coordinator is involved in every phase from pre-installation and installation, from conceptual planning through to system start up, working closely with GE to ensure that the client upholds all requirements in this *Pre-Installation Manual*.

At the end of site preparation, the site project coordinator must verify that:

- The latest **Global Site Readiness Checklist** is being used (available via “GLOBAL HPM LINKS”)
- The checklist has been completed and submitted prior to equipment delivery

1.3 Delivery Requirements

The system is packed for shipment with the minimum number of component packages.

⚠ CAUTION

DAMAGE TO EQUIPMENT

The system components are sensitive to excessive mishandling, including dropping, shock, vibration, tipping or hoisting. Vibration damage to components may not be evident until after system installation is complete.

The system components must **never** be dropped. A drop from a height greater than 1 cm (½") may induce structural damage to the frame or other major components.

To avoid damage to sensitive components, dock-to-dock shipment is recommended. Other methods are acceptable, provided the system is not dropped or otherwise mishandled.

1.3.1 Temperature and Detector Precautions During Transportation and Delivery

1.3.1.1 System Temperature Precautions

Extreme temperatures must be avoided during system transportation and delivery. Ensure that the system is not exposed, for an extended period of time, to temperatures or humidity outside the following specifications. MyoSPECT gantry ships with the detector crate.

	Scan Room	In Transit* (<48 Hours)	In Storage* (>48 Hours)
Temp Range	18°C to 26°C	-40°C to +70°C	5°C - 50°C
Max Temp Change	3°C/Hr	NA	NA
Relative Humidity	30-60%	10-95%	10-85%
Max Humidity Change	5%/Hr	NA	NA
Air Pressure	70 to 106 kPa	52.7 to 101.5 kPa	70 to 106 kPa

* System and detectors (triplets) must be securely closed in original packaging.

NOTE

CZT freezing and unrecoverable damage occur if the system is exposed to temperatures below -18°C (0°F) for a period of longer than two days. Allow a minimum of 12 hours for the system to adjust to ambient room temperature, prior to installation.

1.3.1.2 Air Pressure Requirements During Transportation

Air pressure range is from sea level to 5200 meters.

Air pressure:	101.5 kPa - 52.7 kPa
Altitude:	0 - 5200 m

1.3.1.3 Detector Head Temperature Precautions

⚠ CAUTION

DAMAGE TO DETECTORS

Detector heads are very fragile. Always handle with extra care.

Detector heads are extremely sensitive to sudden changes in temperature.

Failing to comply with the following instructions could cause irreversible damage to the detector heads.

Important

The conveyance path from the unloading area to the temperature-controlled area must be wide enough to allow passage of the detector heads packed in the original containers.

The detector heads must be transported in their original packages, which are designed to provide good mechanical stabilization as well as a certain amount of thermal insulation.

- As soon as the detector heads are unloaded from the transportation vehicles, they must be moved to a temperature-controlled area while still in their original containers, until they are ready to be installed into the system.
- If the temperature in the storage or installation areas differs from that of the delivery route and/or ambient temperature, a stabilization period of 1 hour per 3°C (5.4°F) difference must be allowed.

In order to comply with the strict thermal protection requirements, the detectors with pre-assembled CZT modules are packaged in specially controlled packaging. Make sure to comply with all of the following items:

- CZT detectors can be delivered to the installation site only after confirmation that the site is ready.
- As soon as the detector heads are received from transportation, the lead installation FE must receive them in accordance with the instructions in this section.
- The lead installation FE is responsible as follows:
  - Be present on site and receive the detector packages from transportation.
  - Ensure conveyance of the intact packages (without unpacking) to a controlled environment as follows:
- Before unpacking the detector heads in the temperature-controlled area in the installation room:

- Verify the temperature inside the crate is within 3°C/6°F of the scan room's temperature.
- Confirm thermal stabilization between the ambient temperature and the in-crate temperature, as specified in the *Installation Manual*.

1.3.2 Delivery Unloading Area and Equipment

- The minimal unload area adjacent to the delivery truck is 15m×15m (50'×50'). Make sure that the unloading and storage areas are large enough to maneuver a forklift with crates.
- It is recommended to select the delivery site so as to provide the shortest and smoothest route for component conveyance:
  - If delivered on the installation day, as close as possible to the scan room for installation
  - If delivered prior to the installation day, as close as possible to the storage area
- If a forklift is required in order to unload or move system components:
  - Allocate a forklift capable of lifting more than the maximum weight of the heaviest unit, see **Components and Clearance**: 1.3.4 Crated and Uncrated Weights, Measurements and Clearance on page 23
  - Take into account sufficient floor space to maneuver the forklift near the delivery truck.

1.3.3 Conveyance of Crated System Components Within the Site

Regardless of whether the system is being delivered from the unloading area to storage, from the unloading area to unpacking area for installation or from storage to the installation area, take care to adhere to the following guidelines:

- Ensure that there is a free path, including an elevator if necessary, to wheel the components to the installation area.
- Verify that the route selected has sufficient clearance and load carrying capacity.

  See 1.3.4 Crated and Uncrated Weights, Measurements and Clearance on page 23
- The subsystems may be lifted only with a forklift and only when attached to their original shipping pallets.

⚠ CAUTION

DAMAGE TO SYSTEM COMPONENTS

Lifting of the gantry without its original shipping pallet or using a crane may damage the system and is prohibited.

- If the outer crating is removed after delivery, do not detach the subsystems from their original shipping pallets before they are conveyed to the scan room for installation.

- The center of gravity of each item, including lifting height and position, is marked on the subsystem crate. When conveying the subsystems within the site, and particularly if there are slopes in the delivery path, make sure to take the center of gravity into account.
- Always lower system components at the slowest reasonable rate.
- If the system components are to be transferred from an unloading site outside the building, special facilities must be provided to ensure smooth conveyance.
- Uneven temporary ramps may cause vibrations that could damage some components.
- System components may be moved via flat-bed tow truck or by rolling them across **smooth** sidewalks or other paved surfaces.
- When moving the gantry off a flat-bed tow truck, attach the straps to the lowest point possible on the dolly.

1.3.3.1 Rigging Limitations

Do not lift the gantry assemblies by their dollies. Do not transport the gantry assemblies across any surface by any means other than the dollies provided by GE. The assemblies have no lifting points and are not designed to be lifted by any special rigging attached to the gantry assemblies themselves.

⚠ DANGER

POSSIBLE SEVERE PERSONAL INJURY OR DEATH

The dollies are not designed to be used as an attachment point for any method of lifting the subsystems.

Attaching lifting straps, cables or mechanisms to the dolly handles or any other part of the dolly is strictly prohibited.

NOTE

If it is determined that the subsystems must be lifted by crane or other lifting method the PM or person responsible for local siting of the system shall NOT proceed with the installation without consulting directly with GE Engineering.

Lifting the subsystems by crane or other lifting method should always be avoided. All alternate methods of delivery should be evaluated including the removal of any obstructions, doorways, walls, and windows.

If lifting is still required:

- The entire gantry assembly and both gantry transport side dollies must be placed on a lifting platform. GE does not provide a lifting platform.

- The entire patient table must be lifted while sitting on a lifting platform. The patient table shall be lowered to its transport position so the table base is in contact with the platform.
- The platform must be designed so no lifting straps or cables come in contact with any part of the gantry or table subsystems or its side dollies.
- The lifting platform shall bear the entire load. No part of the subsystem shall bear any load during the lift.

1.3.4 Crated and Uncrated Weights, Measurements and Clearance

The following tables provide you with crate and component measurements, weights and other data, in order to assist you in planning conveyance routes and storage areas. The order of the components in the list constitutes the recommended order of conveyance and delivery to the scan room for installation.

Table 1-1 Components and Clearance

	Crated		Uncrated					
Component name	**Crate size (cm) (without dollies) (H×W×L)**	**Weight (kg)**	**Minimal dimensions (cm)**[*1]					**Weight (kg)**
			Door width	**Corridor / elevator width**	**Corridor / elevator length**	**Width of corridors w.90° turns**[*2]	**Height**	
NM gantry with dollies	191.5×90×148	~900	91	91	200	152	170[*3]	815[*4]
Detector Crate	105×80×56.5	52	80	80	105	any	any	<20
Table	140×90×300	562	91	91	230	152	any	377
Acquisition station	80×60×60	30	any	any	any	any	any	<20
Peripherals and accessories[*5]	80×190×140	up to 400	any	any	any	any	any	up to 300
Optional Items								
NM UPS	May vary but not more than 60×40×80	May vary but not more than 80	any	any	any	any	any	May vary but not more than 60
• Xeleris • Monitors	May vary but not more than 80×80×80	May vary but not more than 15	any	any	any	any	any	<13

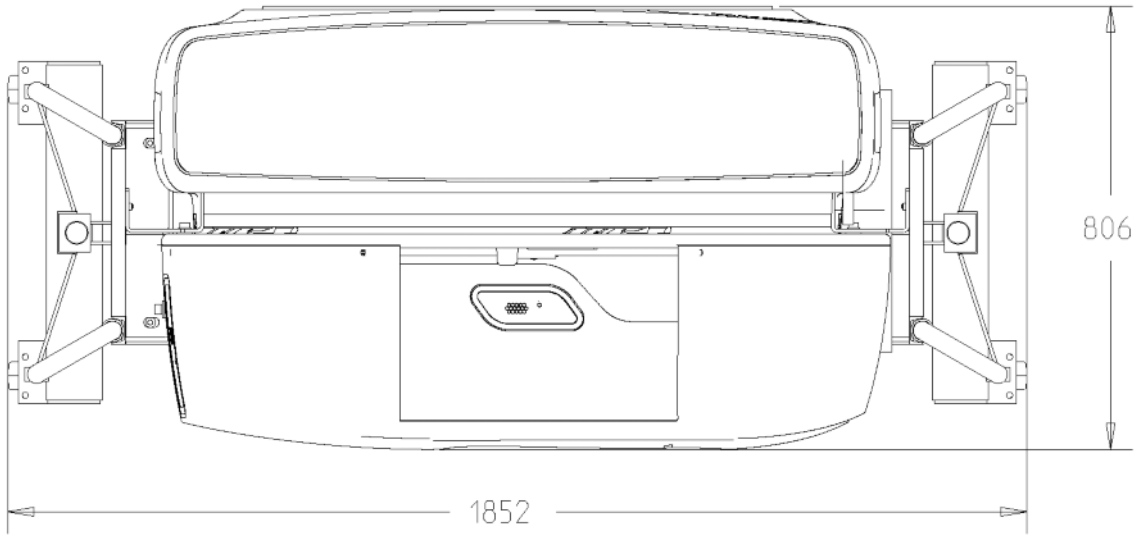
[*1] The minimum door width required in order to bring the system components into the scan room also depends on the width of the corridor leading to the room. When planning or measuring the width of the scan room door, use the graphs provided in Figure 1-2 Door Opening vs Corridor Width for 90° Turn of NM Sub-system on page 26 in order to verify that the measurements comply with the requirements.

Table 1-1 Components and Clearance (Table continued)

	Crated		Uncrated					
Component name	**Crate size (cm) (without dollies) (H×W×L)**	**Weight (kg)**	**Minimal dimensions (cm)**[*1]					**Weight (kg)**
			Door width	**Corridor / elevator width**	**Corridor / elevator length**	**Width of corridors w.90° turns**[*2]	**Height**	
[*2] The corridor width required in order to move the system components from the unloading area to the scan room depends on the angles of turns on the corridor. For the required width when the angle is 90°, see Figure 1-2 Door Opening vs Corridor Width for 90° Turn of NM Sub-system on page 26.								
[*3] 10 mm clearance above the floor								
[*4] Weight of gantry without dollies and after CZT triplets are installed (clinical configuration)								
[*5] The standard system is available in two basic configurations - with a single monitor or with dual monitors and a choice of options. Therefore the system components weight is approximate and may vary according to the options specified.								

The following figures provide you with crate and component measurements, weights and other data, in order to assist you in planning conveyance routes and storage areas.

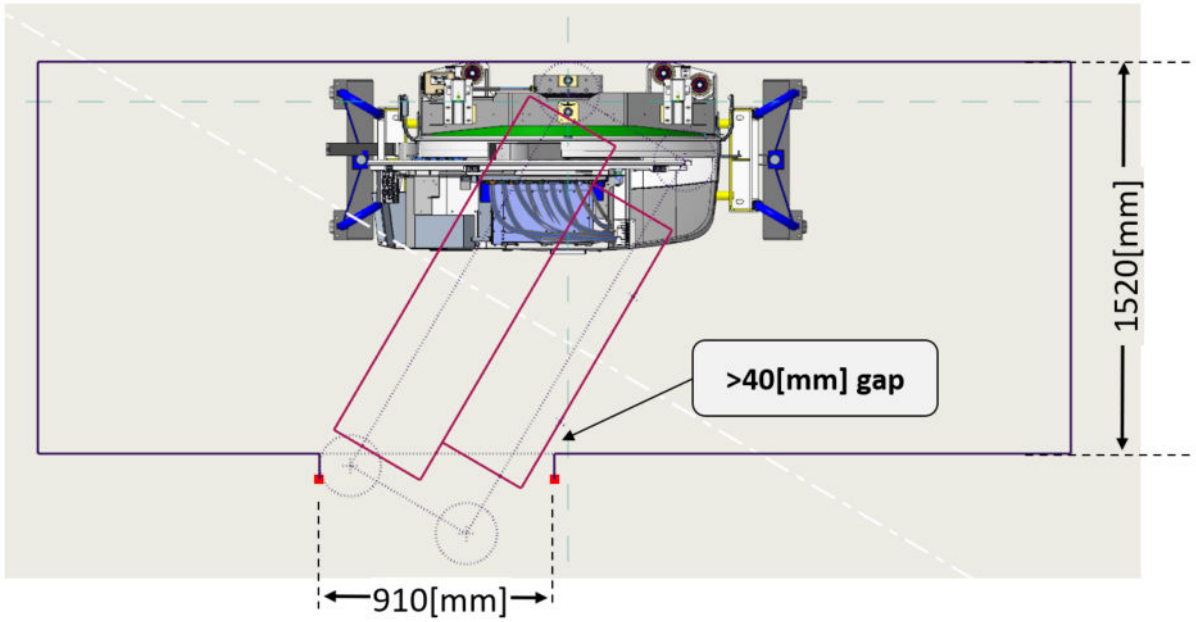
Figure 1-1 NM Gantry on Dolly Measurements



NOTE

Measurements are in mm

Figure 1-2 Door Opening vs Corridor Width for 90° Turn of NM Sub-system



Legend

A: Minimum door opening required to convey sub-systems into the room from corridor when 90deg turn is required (NM Gantry)

1.4 Product Storage and Handling Requirements

All components must be stored in their original crating.

Important

The storage requirements in this section are not relevant for the CZT detectors. For detector storage requirements, see 1.3.1.1 System Temperature Precautions on page 19.

If the system is to be stored before installation, store in a temperature and humidity controlled environment, and protect from weather, dirt and dust. Storage longer than 12 months is not recommended. Meeting these requirements prevents rust and corrosion from forming on bearing surfaces due to condensation.

⚠ CAUTION

DAMAGE TO DETECTORS

Component freezing occurs if the system is exposed to temperatures below -18°C (0°F) for a period of longer than two days.

Gradually adjust the system to ambient room temperature prior to installation, with a change of no more than 3°C (5.4°F) per hour.

Chapter 2 Equipment Description and General Construction Requirements

This chapter provides the following:

- 2.2 Room Size, Layout and Considerations on page 35

  Provides guidelines for determining the size and layout of the and of the above components, including example layouts of typical rooms, illustrating the position and dimensions of the components.

- 2.3 Room Structural Requirements on page 43

  Provides floor, ceiling and wall requirements, and acoustic and vibration specifications for the scan room.

- Seismic Requirements

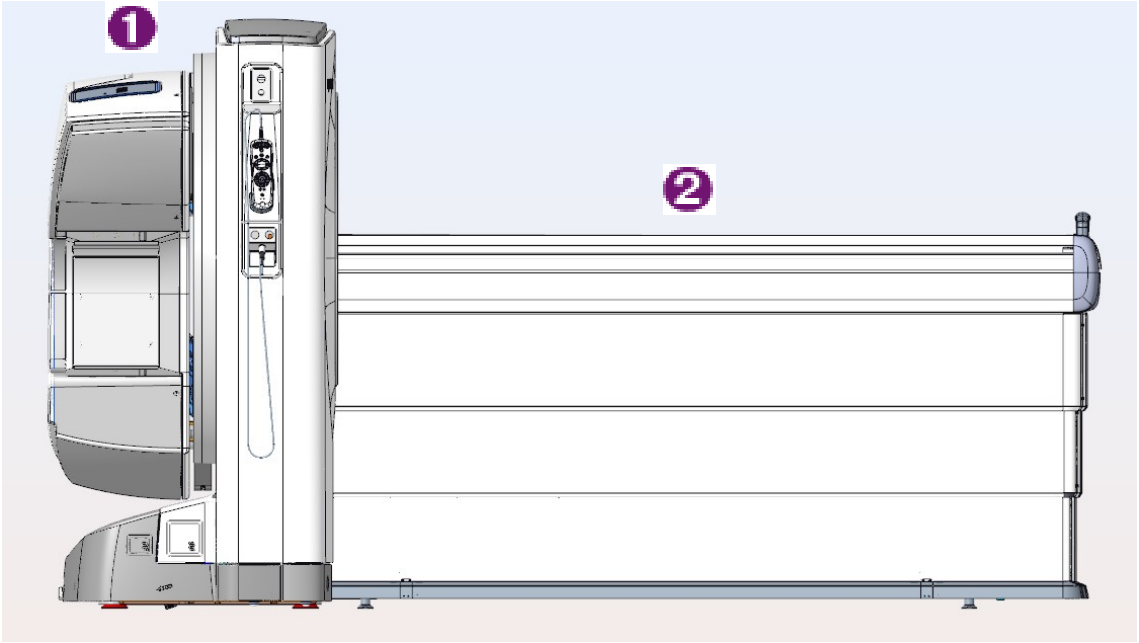
  Provides center of gravity information for the different system components.

2.1 Equipment and System Components

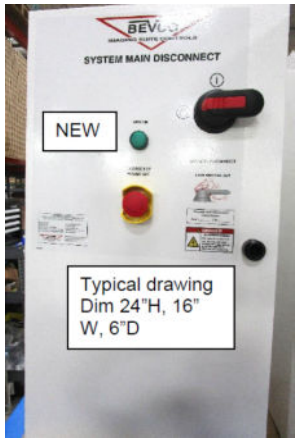
The following figures illustrate the different system components:

- Scan Room Fixed Components - Figure 2-1 Scan Room Fixed Components on page 29
- Scan Room Moving Components - Figure 2-2 Scan Room Moving Components on page 31
- Gantry - Figure 2-4 Gantry on page 33
- Table Views - Figure 2-5 Table Views on page 34

Figure 2-1 Scan Room Fixed Components



5



4

3

6

7

8

Legend

(1) Gantry and detector	(5) EMO (wall mounted) and Emergency Stop buttons
(2) Patient table	(6) Acquisition station computer*1
(3) NM UPS (optional)	(7) Xeleris workstation*1
(4) Main Disconnect Panel (optional)	(8) Patient monitoring system (optional)

*1 Can be placed in an adjacent operator room

Figure 2-2 Scan Room Moving Components

Legend

(1) Acquisition station cart with monitor, keyboard, mouse	(4) Gantry display monitor (optional)
(2) QC Source holder	(5) E-Stop button
(3) Patient table accessories	

Figure 2-3 Operator Room Components – optional configuration

Legend

(1) Processing station such as Xeleris (can be located in a remote location such as a reading room)	(3) Acquisition station monitor, keyboard, mouse and
(2) E-Stop button	(4) Acquisition station computer

Figure 2-4 Gantry

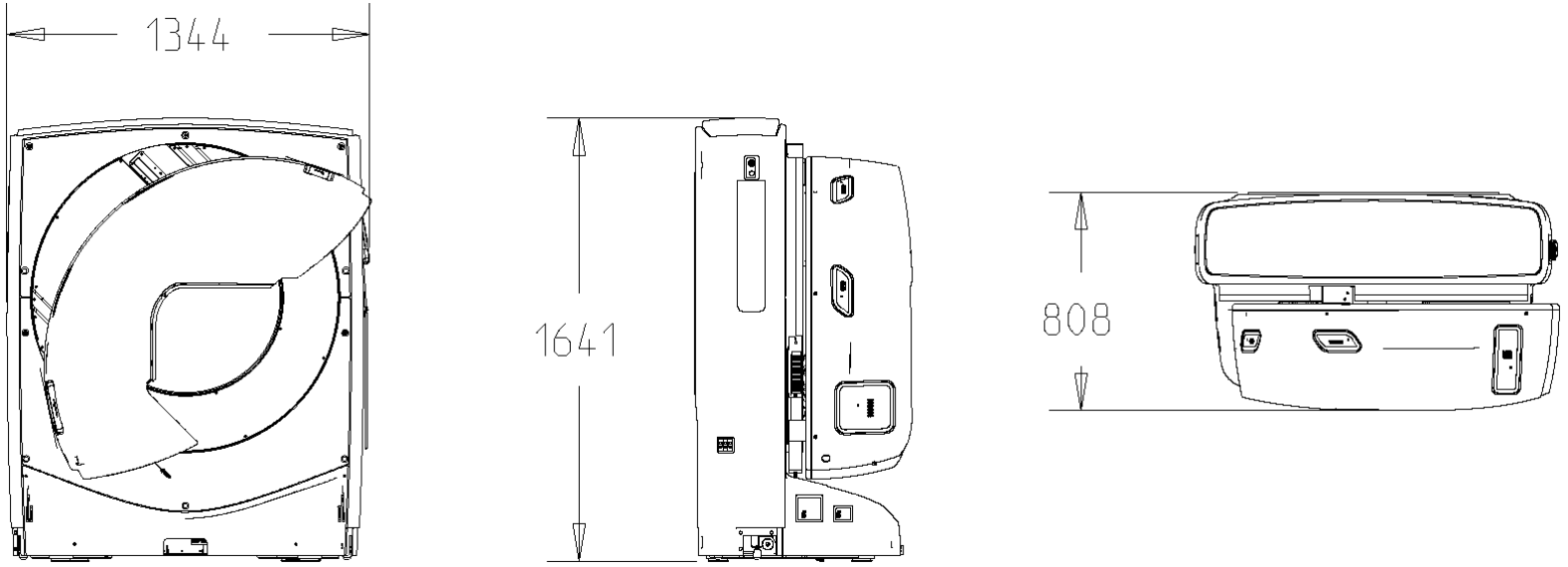
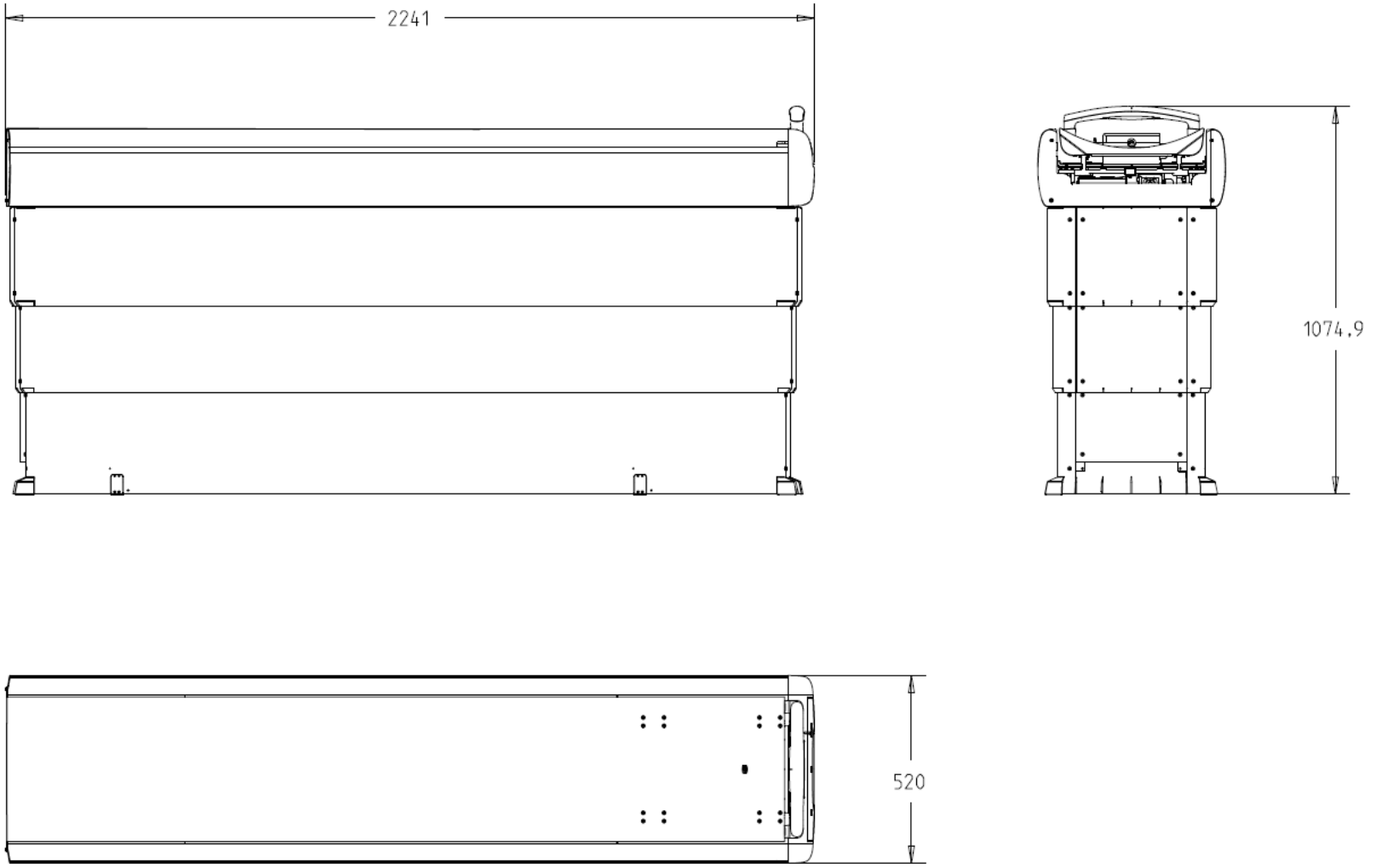


Figure 2-5 Table Views



2.2 Room Size, Layout and Considerations

The system requires a main Scan room that at its basic configuration contains all sub-systems, including the operator console , on a mobile cart. If otherwise required, the operator console can be located in an adjacent operator room.

Table 2-1 Components in Scan Room

Fixed Components (see Scan Room Fixed Components on page 29)	**Moving Components** (see Scan Room Moving Components on page 31)
NM gantry	Acquisition station cart*1
Patient table	Monitor cart*2
NM UPS (optional)	Patient Positioning accessories (optional)
Main Disconnect Panel (optional)	QC source holder
EMO (wall mounted)*3	E-Stop*4
NM Acquisition station	
Xeleris workstation*5	
Gantry display monitor (optional)	
Patient monitoring closed circuit display (optional)	

*1 Unless installed on a desk or in a separate operator room

*2 (optional, to extend the display from the acquisition station when installed in an operator room)

*3 Recommended to mount on the wall and near the door the technician's will use most often.

*4 Can be mounted on a mobile cart, on the wall in the scan room or placed in an adjacent operator room.

*5 Can be installed on a desk in the scan room or placed in an adjacent operator room.

This section provides guidelines for determining the size and layout of the and of the above components, and example layouts of typical rooms, illustrating the position and dimensions of the components.

The room layouts provided take into consideration all aspects of operation, operator and patient requirements and service clearance requirements.

Egress

The room layouts, diagrams and dimensions in this manual provide the required clearances for proper equipment operation and service only. The customer/purchaser is responsible for compliance with federal, state and/or local codes regarding facility egress and related facility requirements (see Appendix D Regulatory Clearances on page 99).

2.2.1 Room Dimension Requirements

NOTE

The minimal and standard system layouts described in this manual may not comply with specific local/regional/country/state requirements (such as OSHA in the USA).

Take into consideration the local regulations in force when planning room dimensions and layout (see Appendix D Regulatory Clearances on page 99).

Minimal scan room size, without operator room (L × W × H)

3.96 m × 2.51 m × 2.25 m (13' × 8.2' × 7.4')

2.2.2 System Layout Drawings

This section provides typical sample layouts, illustrating the position and dimensions of the scan/operator room and the system components.

The room layout dimensions take into consideration all aspects of operation, operator and patient requirements and service clearance requirements (see 2.2.3 Layout Considerations on page 40).

Sufficient regulatory and service clearances must be maintained around the equipment for full operation, service, and safety.
In addition, a system footprint is provided to facilitate site planning. This illustration does not contain information regarding service clearance areas around the system.

Figure 2-6 Minimal scan room size for Single Monitor Configuration

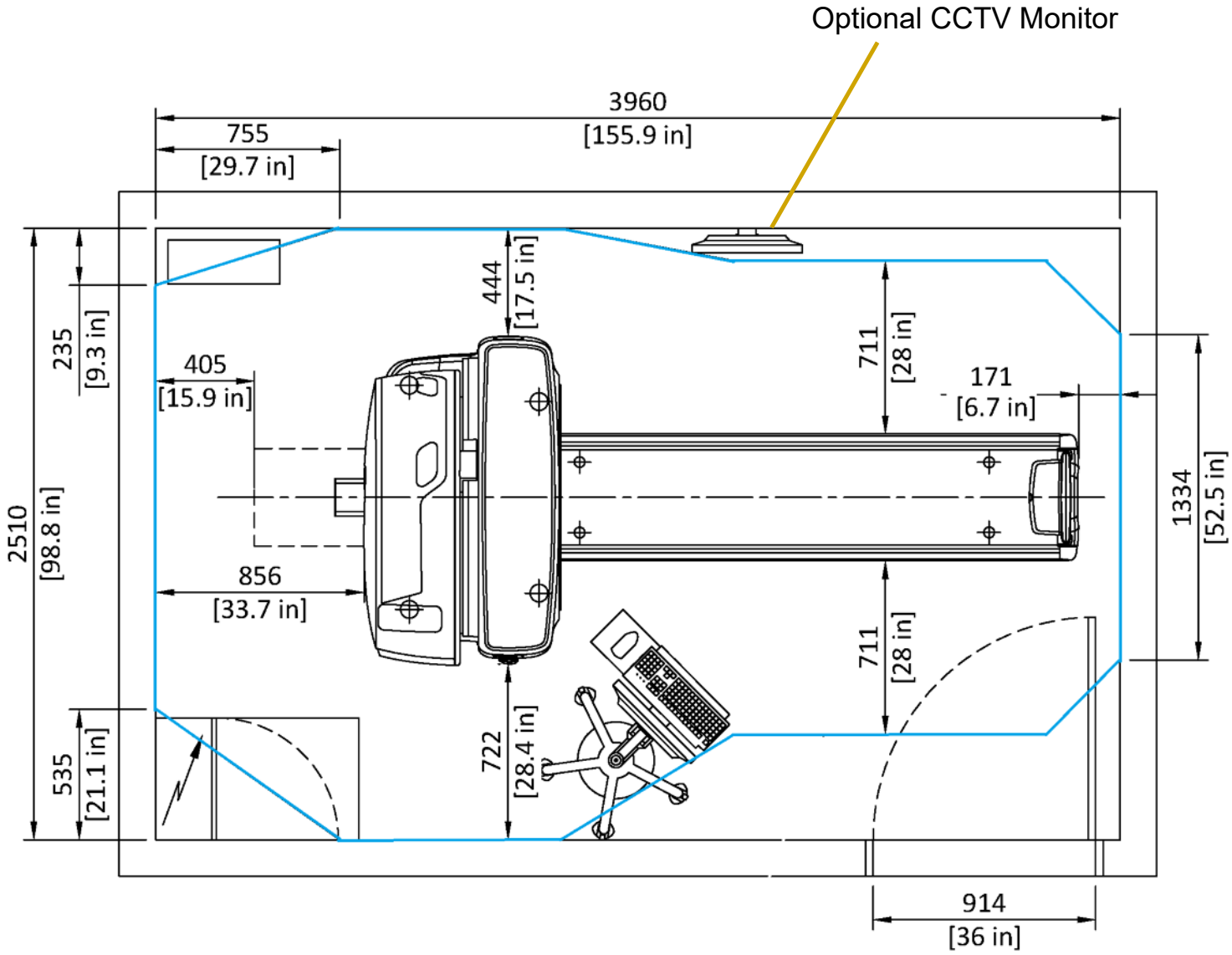


Figure 2-7 Minimal scan room size for Dual Monitor Configuration

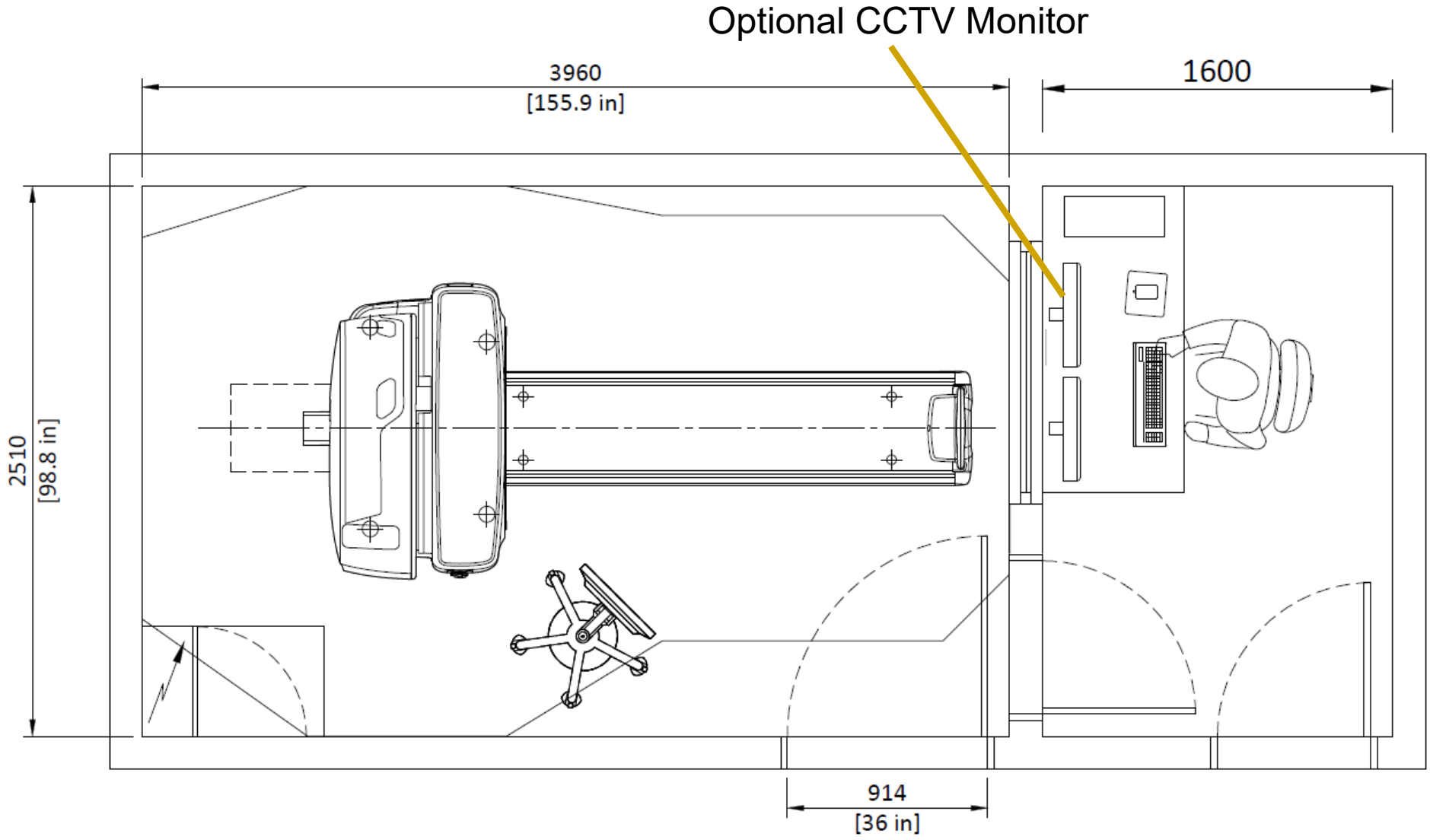
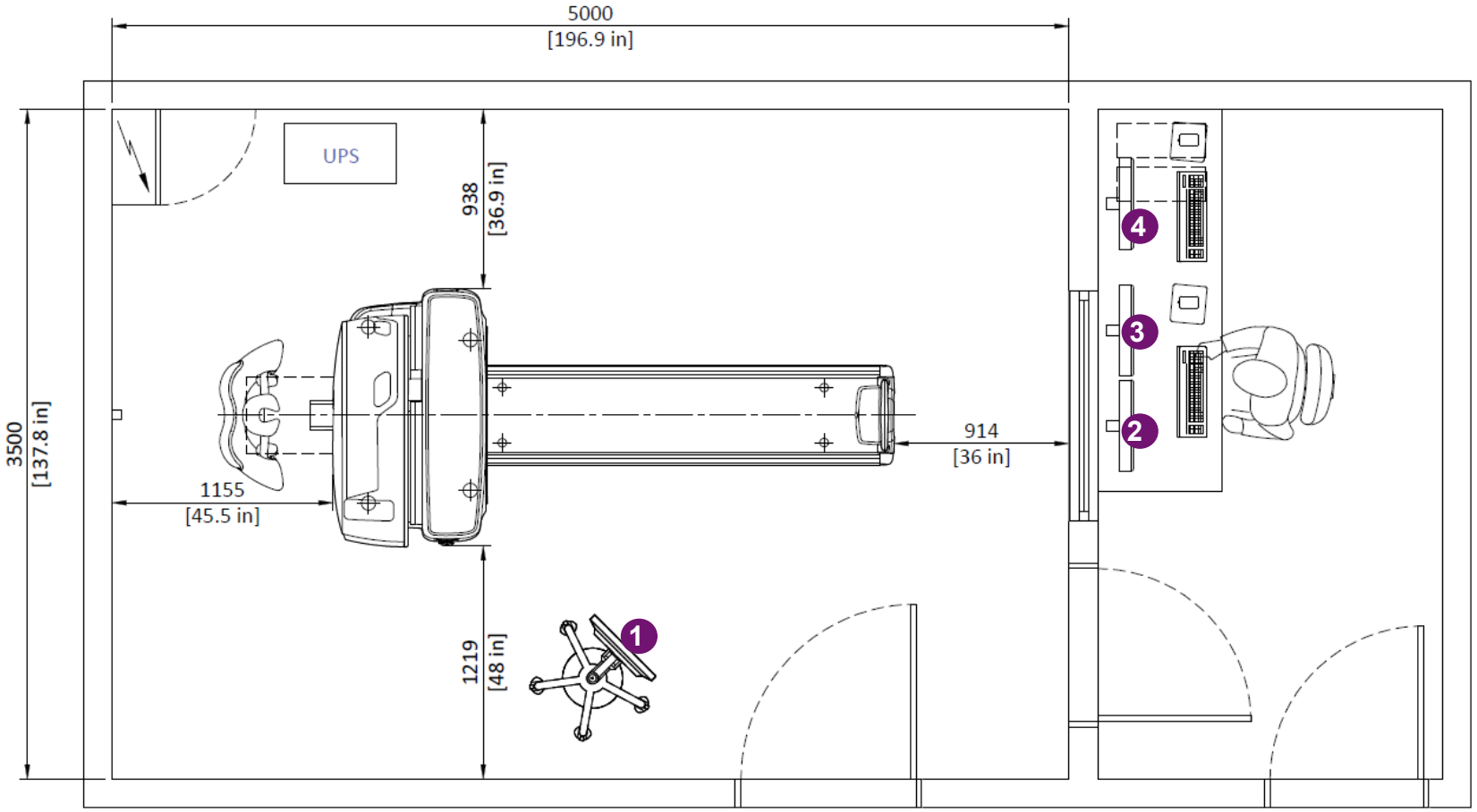


Figure 2-8 Example of Room Layout



1. Gantry Display Monitor | 2. Acquisition Station Monitor | 3. CCTV Monitor | 4. Xeleris Monitor

Notes to figures:

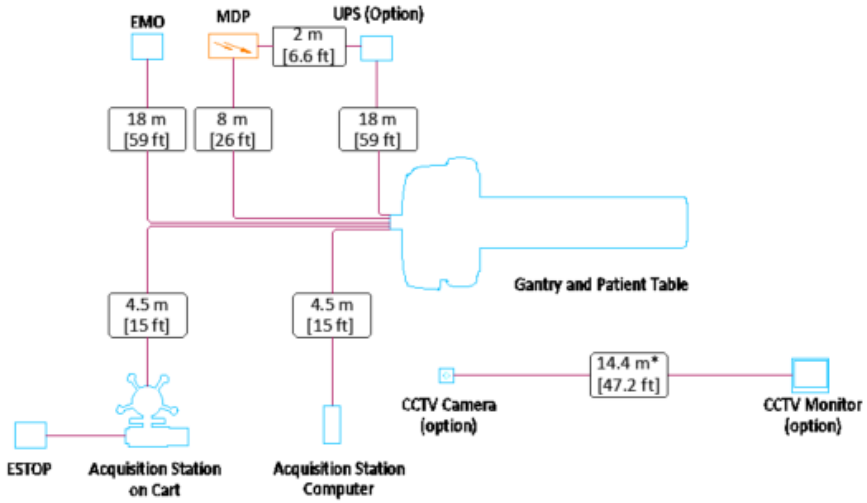
- Dimensions are in mm [in]
- Does not take into account local requirements

- Radiation shielding regulations differ from one country or state to another.
  It is the customer's responsibility to ensure that radiation protection and shielding comply with such regulations and requirements during site preparation, system installation, operation and service.
- The blue line indicates the service clearance area
- The gantry display monitor is optional

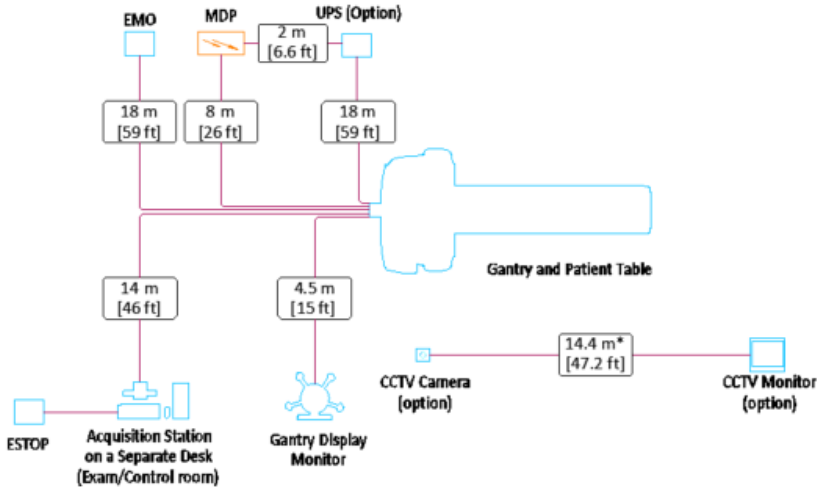
2.2.3 Layout Considerations

This section describes the considerations you must take into account when selecting a site and planning the room size and layout. In addition, it is the responsibility of the customer to ensure that all aspects of the scan and operator rooms conform with the local requirements.

Interconnection Options



with station on cart



with station on separate desk

Room Dimensions and System Placement

The room size and shape and the placement of the system components must enable optimal functional and working conditions, including the best possible relative positioning of the gantry and acquisition console in operator room, including:

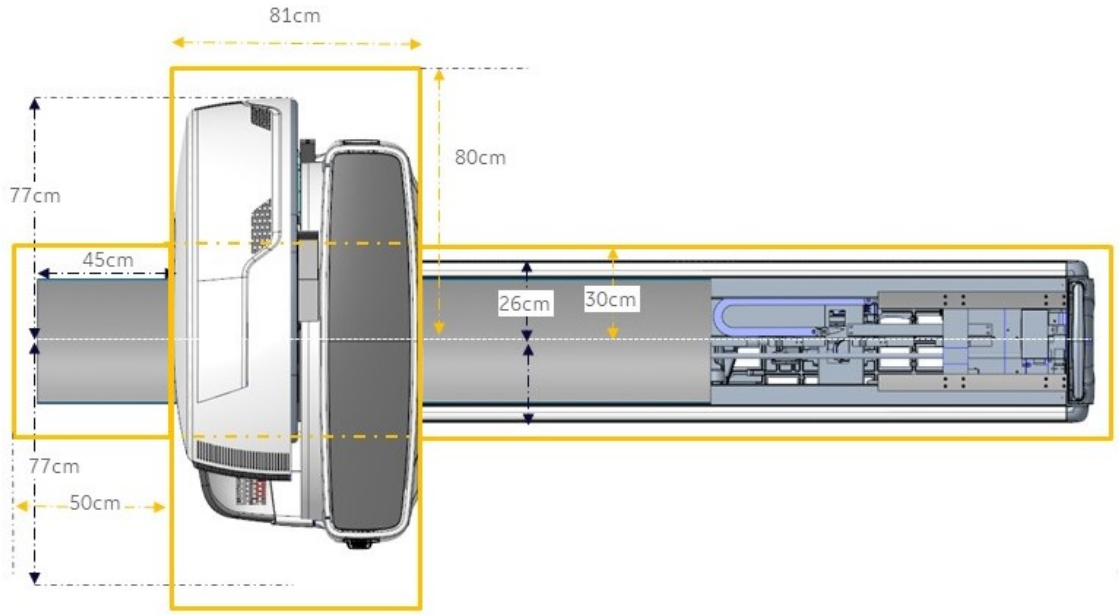
- **Operator access in scan room**, around the gantry in order to:

- Assist patient positioning
- Perform examination routines
- Act efficiently and quickly in case of an emergency, including easy access to emergency switch

- **Upgrade considerations:**
  - If a system upgrade is planned or possible, the requirements for the larger system should be assessed to avoid unnecessary future rework:
    - Room dimensions
    - Power requirements
    - HVAC requirements
    - Floor loading and anchoring requirements
- **Safety zone considerations**

  The safety zone is designated by tape on the floor, usually yellow (can also be differentiated by a change in floor coloring). This designates the area that must be free of obstructions to avoid a collision during automatic motion.

Figure 2-9 Safety Zone Marking



- **Operation-related considerations**:
  - Enable access for hospital beds, including maneuvering and positioning the bed.
  - For ease of use, it is highly recommended to orient the camera so that its left side faces the direction from which technologists will enter the room. It is also highly recommended for the RCU and cart to be kept on the left side of the system, where the operator can clearly see the camera for patient positioning.
  - Installation and service considerations:
    - Location of power connections
    - Access to communication lines (Ethernet, external hardcopy device)
    - Floor loading capacity and weight of system components, including storage
    - Service clearance areas (see Appendix D Regulatory Clearances on page 99)
    - Storage cabinet for storage of operator and service tools (optional). Depending on the room layout, it is recommended that sufficient area is allocated for a cabinet.

- Patient path from entry door to table should be without any floor hazards such as a table floor puck, conduit or cables.

- **Operator room** (if applicable)
  - Operator field of view, enabling direct view of patient in bore, or taking into consideration viewing via remote closed-circuit camera in the scan room and screen in the operator room
  - Space, power and network connections for additional equipment such as PACS workstation, archiving devices, etc.
- **Proximity of scan room to other utilities**
  - Avoid detrimental influences from surrounding rooms and activities, such as:
    - Radioactive or magnetic sources
    - A local wireless environment
    - Vibrations
    - Transformers from elevators, compressors, or other high power devices.
  - Plan the optimal proximity of the scan room to related utilities. In addition to patient comfort, take into consideration that background radiation activity from such utilities could negatively affect image quality and system calibration. These utilities include:
    - Waiting/injection areas, toilets
    - Viewing and processing rooms
    - Radionuclide storage and preparation area
    - Office facilities
    - Smoke detectors that use/have radioactive activity

2.3 Room Structural Requirements

Room requirements consist of the following:

- 2.3.1 Floor Requirements on page 44, including floor strength, levelness and flatness, vibration and conductivity
- Floor Loading Requirements
- 2.3.2 Ceiling Requirements on page 52
- 2.3.3 Wall Requirements on page 52
- 2.3.4 Acoustic Specifications on page 52

- 2.3.5 Vibration Specifications on page 52

2.3.1 Floor Requirements

Important

It is the customer's responsibility to have appropriate tests performed and to obtain a construction engineer’s assessment of the floor’s suitability to meet the requirements of this section.

2.3.1.1 Floor Strength

The floor must be capable of supporting the weight of the equipment and accessories described in this section.

For seismic installations, in order to enable system mounting using the supplied floor anchors, concrete floors must have a minimum cube strength of f'c = 4350 psi (30 MPa) at 28 days (curing time) for 25/30 concrete.

NOTE

- Concrete strength is determined by the “Cylinder Test” (used in the USA) or “Cube Test” (used in Europe), where a cylinder or cube of concrete is cast, cured for the appropriate time and then compressed between two parallel faces until failure. The stress at the failure is taken to be the compressive strength of the concrete. The 25/30 concrete required for the system installation is concrete with a strength of 25 in the cylinder test (resulting 3625 psi), or strength of 30 in the cube test (resulting 4350 psi).
- If the system is expected to be upgraded in the future, the floor strength requirements for the larger model should be used.

It is the customer’s responsibility to have appropriate tests performed to determine and measure concrete strength, and to obtain a construction engineer’s assessment of the floor load capability.

2.3.1.2 Floor Loading Requirements

Table 2-2 Weight of Components

Component	Weight (kg)	Weight (lb)	Load Distribution	Comments
NM gantry	815	1797	4 pads, Ø 90 mm each: • 225 kg each on front pads • 183 kg each on rear pads	
Patient table (without patient)	377	831	The front of the table is permanently connected to the gantry and the back of the table is supported by two pads.	Weight of table without patient

Table 2-2 Weight of Components (Table continued)

Component	Weight (kg)	Weight (lb)	Load Distribution	Comments
NM acquisition station	11.25	25		
Personnel and patient	< 500	< 1102	Variable	Normally 3-4 people in room during scan/service operations
NM UPS (optional)	May vary, no more than 60	May vary, no more than 130	4 feet	
Xeleris workstation	(insignificant)			

Figure 2-10 NM Gantry Center of Gravity Points

NM gantry CoG weight: 815 Kg (1797 lb)

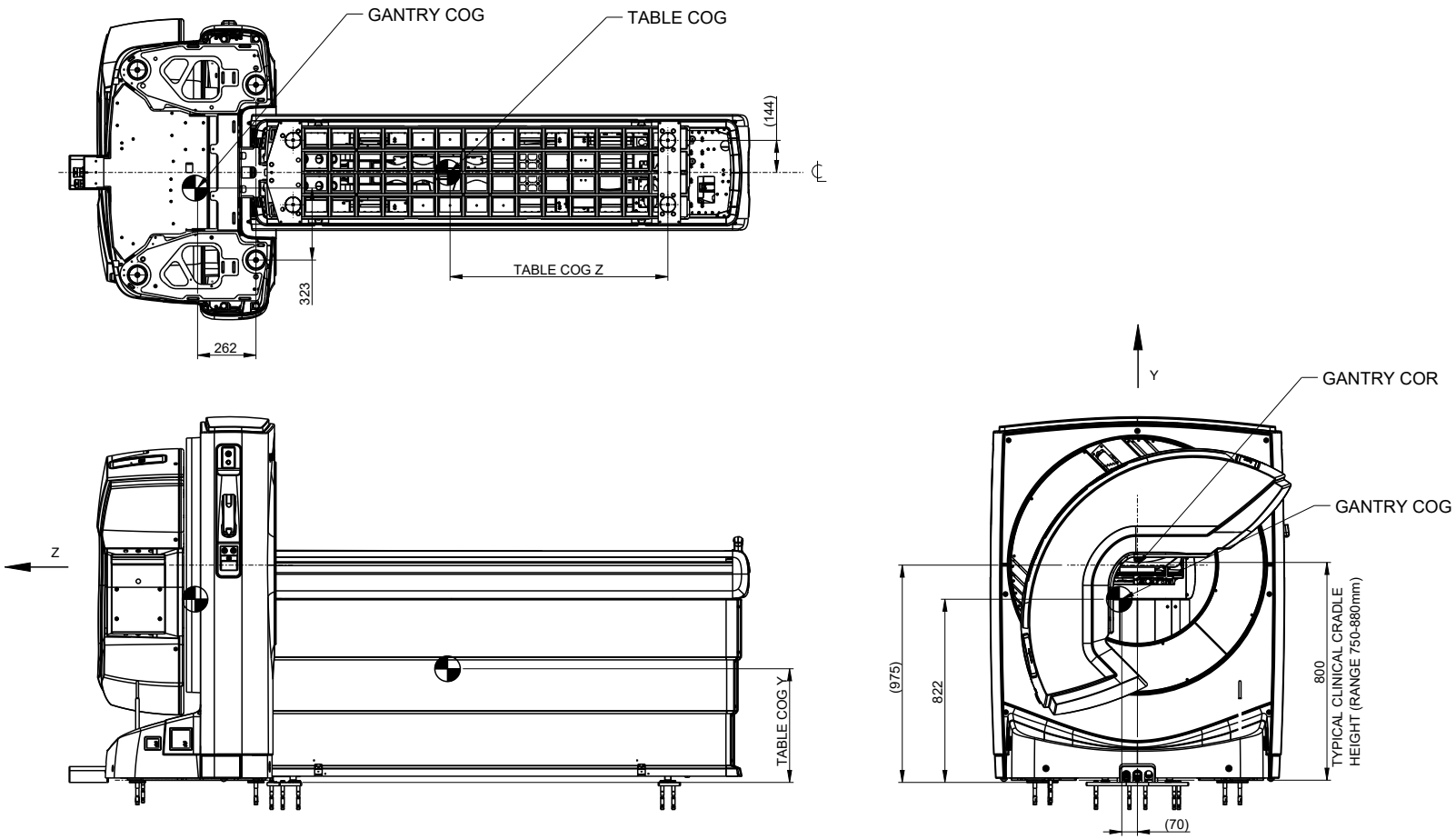


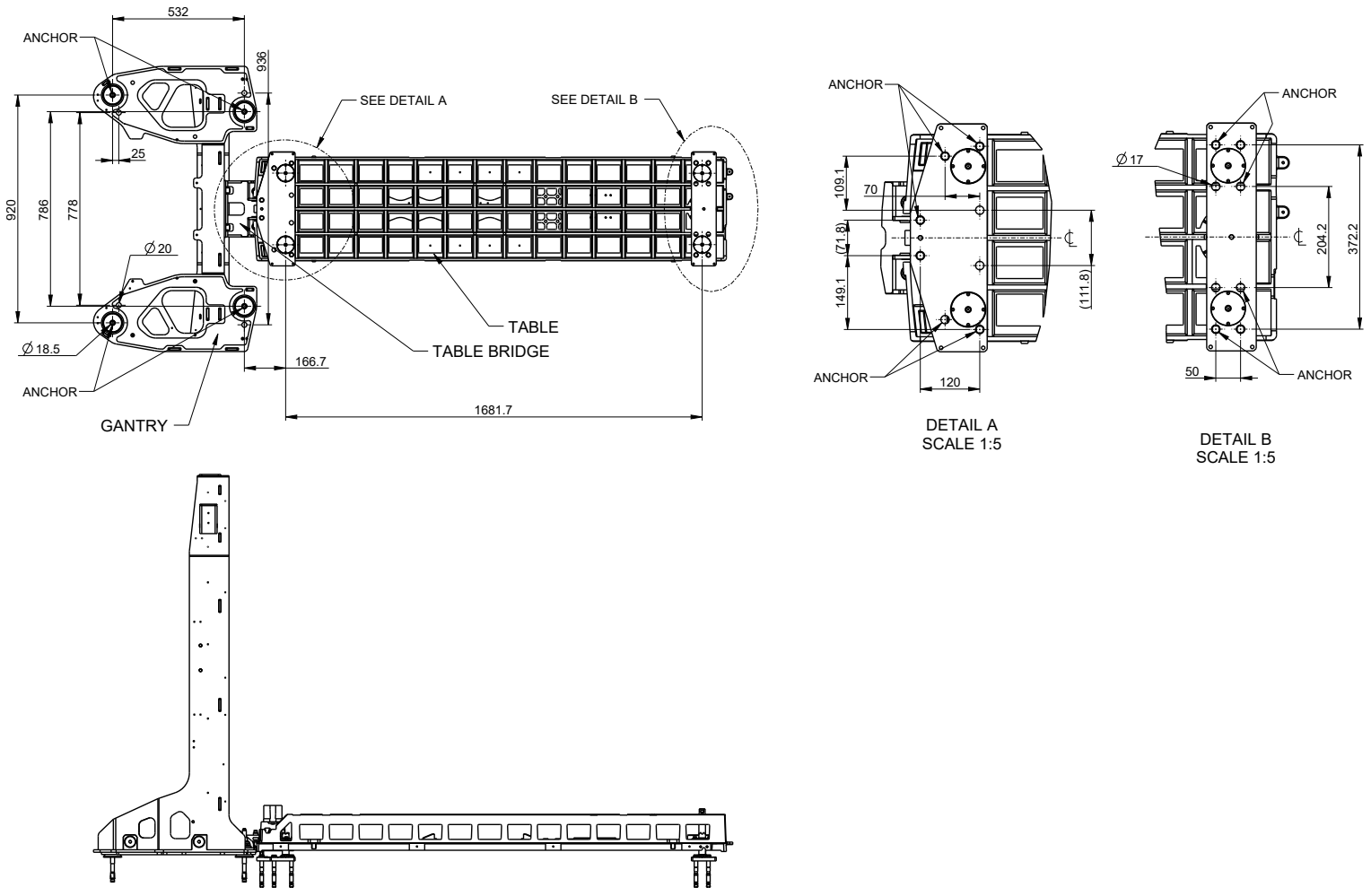
TABLE COG Y	NO PATIENT	TABLE IS LOADED WITH 350LB PATIENT	TABLE IS LOADED WITH 500LB PATIENT
TABLE HEIGHT 540[mm] (min)	232[mm]	328[mm]	352[mm]
TABLE HEIGHT 880[mm] (clinical max)	377 [mm]	535[mm]	629[mm]
TABLE HEIGHT 1000[mm] (MAX)	429[mm]	607[mm]	653[mm]

TABLE COG Z	CRADLE RETRACTED	CRADLE EXTRACTED (1130[mm])
NO PATIENT	958[mm]	958[mm]
TABLE IS LOADED WITH 350LB PATIENT	964[mm]	1317[mm]
TABLE IS LOADED WITH 500LB PATIENT	966[mm]	1409[mm]

Table 2-3 Table Center of Gravity with Different Loads

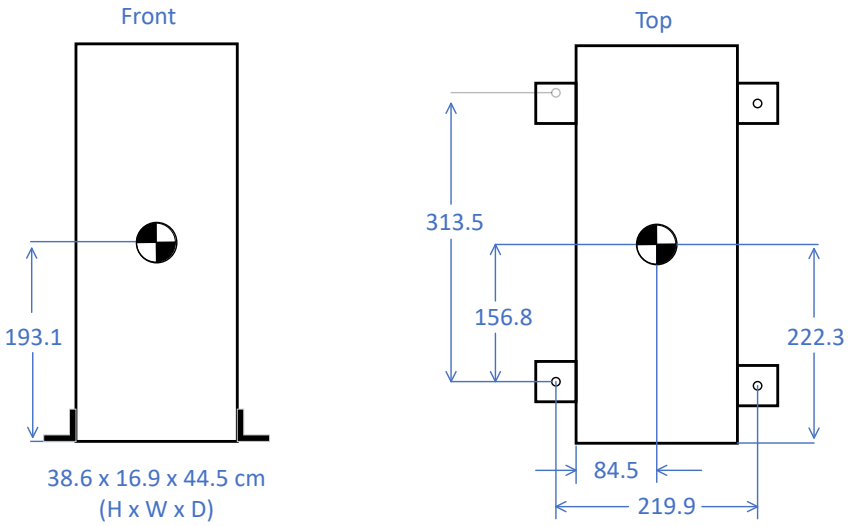
CoG Y, Z Coordinates	No Patient 0 kg/lb			Typical Load 159 kg (350 lb)			Max Load 227 kg (500 lb)		
Table Height (mm)	**CoG Y**	**CoG Z** Min Cradle (0mm)	**CoG Z** Typical Cradle (1130mm)	**CoG Y**	**CoG Z** Min Cradle (0mm)	**CoG Z** Typical Cradle (1130mm)	**CoG Y**	**CoG Z** Min Cradle (0mm)	**CoG Z** Typical Cradle (1130mm)
Minimum Height 540 mm	232 mm	958 mm	958 mm	328 mm	964 mm	1317 mm	352 mm	966 mm	1409 mm
Clinical Max Height 880 mm	377 mm	958 mm	958 mm	535 mm	964 mm	1317 mm	629 mm	966 mm	1409 mm
Maximum Height 1000 mm	429 mm	958 mm	958 mm	607 mm	964 mm	1317 mm	653 mm	966 mm	1409 mm

Figure 2-11 Floor Loading and Center of Gravity Points for Gantry and Table



Gantry rear pads: 183 kg load per pad	Gantry center of gravity 915 kg
Gantry front pads 225 kg load per pad	Table center of gravity 377 kg load (distributed on 4 pads)

Figure 2-12 NM Acquisition Computer Center of Gravity Points



2.3.1.3 Floor Levelness and Flatness

The scan room floor must be leveled, and its surface must be smooth.

It is recommended that the floor in the entire scan room is leveled and flattened. If this is not possible, it is a minimum requirement for the gantry installation area to be level and flat.

The floor levelness requirement is essential for proper alignment of the gantry, which affects accurate patient positioning and other aspects of system functionality. For more details, see Appendix B Measuring Floor Flatness on page 86.

⚠ CAUTION

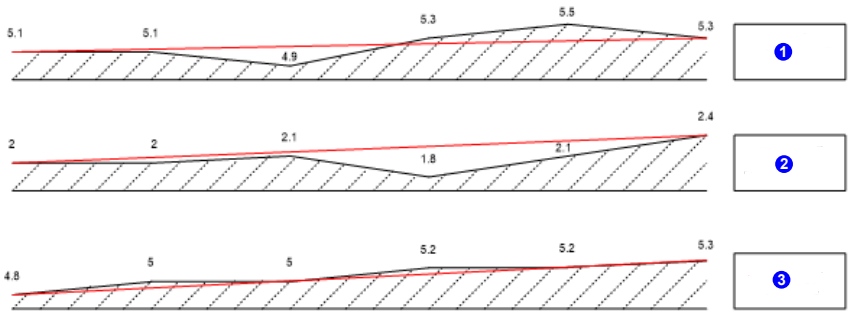
FLOOR LEVELING REQUIRED

- The use of floor shims is not suitable to achieve floor levelness.
- Do not use fill material to compensate for holes or depressions in the floor surface.
- Thin fill areas under load will crack and deteriorate over time causing issues with system leveling that may lead to image quality problems. If necessary, level and flatten the entire floor area.

Table 2-4 Floor Leveling Specifications

Item	Requirement
Floor leveling area	290 cm×150 cm (9.5' × 4.9') (covering the entire planned area of table and gantry installation, depending on room layout)
Slope	**30 mm over 4300 mm**
Floor surface	A single poured surface.

Table 2-4 Floor Leveling Specifications (Table continued)

Item	Requirement
Flatness	The surface must be smooth and without significant valleys or peaks. The entire surface area must have an overall flatness of 5 mm over 1500 mm in any direction (see Appendix B Measuring Floor Flatness on page 86 for measurement procedure).  **Legend** Example (1): The slope (red line) = Pass; the flatness (black line) = Fail Example (2): The slope (red line) = Fail; the flatness (black line) = Fail Example (3): The slope (red line) = Fail; the flatness (black line) = Pass

2.3.1.4 Floor Vibration

Floor vibration requirements are included in the general vibration requirements (see 2.3.5 Vibration Specifications on page 52).

2.3.1.5 Floor Conductivity Recommendations

The purpose of this section is to measure the electrical conductivity of the floor surface to the 'GND' (Ground).

- The surface of the conductive floor shall provide a patch of electrical conductivity between all persons and equipment making contact with the floor.
- Using a DVM, measure the impedance between the upper surface of the floor – where the NM gantry is planned to be positioned, and the system power supply GND terminal in the room. The readout should be <35 M Ohm.

2.3.1.6 Additional Floor Requirements

The floor finish must take into consideration magnetic field and EMI considerations (see 3.5 EMI Considerations on page 56).

2.3.2 Ceiling Requirements

Scan room height must be at least 2.25 meters (7.4') meters .

2.3.3 Wall Requirements

Operator room window

If there is an operator room, the operator must be able to view the patient from the operator room during a scan. The location of the window depends on the position of operator room relative to the scan room. It is recommended that the window is positioned in front of the console so that the operator can look down the length of the bore.

The recommended patient viewing window dimensions are approximately 120 cm wide by 110 cm high (48"×42").

Consult a qualified radiological health physicist for radiation protection requirements for the window glass (lead content and thickness), in accordance with 3.1 Radiation Protection and Shielding Requirements on page 54 and with local requirements.

Radiation protection

For details on wall, door and window radiation protection, see 3.1 Radiation Protection and Shielding Requirements on page 54.

Other

Verify that all walls conform with local regulations, such as washability.

2.3.4 Acoustic Specifications

The system creates acoustic noise. In compliance with IEC 601-1-1 standard the measured noise (at 1m distance away from the system) is less than 70 db. It is recommended that the wall and ceiling surface is of a sound dampening material to avoid noise reverberation and amplification.

2.3.5 Vibration Specifications

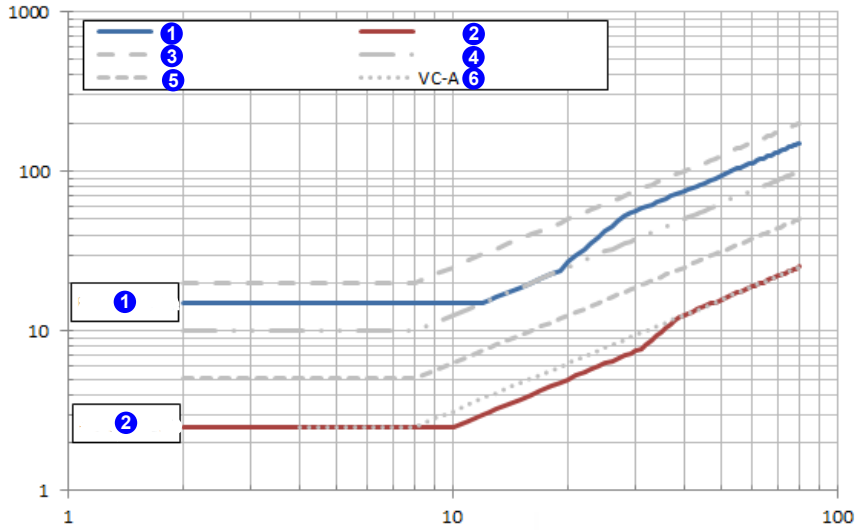
The system components are sensitive to vibration in the frequency range of 0.5 to 20 Hz, depending on the amplitude of the vibration. It is the customer’s responsibility to contract a vibration consultant or qualified engineer to verify that these specifications are met and implement an appropriate solution.

To minimize vibrations, the system must be installed on a solid floor, as far as possible from the following vibration sources:

Outside building	Inside building	Other
• Parking lots • Roadways • Subways • Heliports • Trains	• Hallways • Elevators	• Hospital power plants containing pumps, motors, air handling equipment and air conditioning units

Figure 2-13 Acceleration Profile Specifications mm/s^2

X = Frequency [Hz] / Y= Acceleration RMS [s^2 per 1/3 octave band]



Legend

Blue – NM Velocity curve
Red – Hybrid NM/CT Velocity curve

Chapter 3 Special Construction Requirements

3.1 Radiation Protection and Shielding Requirements

⚠ CAUTION

RADIATION HAZARD

Specific room shielding requirements should be determined by local regulatory considerations, facility policy and if available, the facility physicist.

Radiation shielding regulations differ from one country or state to another. It is the customer's responsibility to ensure that radiation protection and shielding comply with such regulations and requirements during site preparation and system installation and operation.

The system involves the use of radionuclides. Appropriate barriers such as walls, lead-shielded glass, lead shields, etc. can be installed to protect staff from unnecessary exposure to radiation.

Patients become significant sources of radioactivity; therefore consideration should be given to maximize the distance between the patient and operator during the uptake and acquisition phases of scan procedures.

Scatter-room shielding requirements must be reviewed by a qualified radiological health physicist taking into consideration:

- Scatter radiation levels within the scan room
- Equipment placement
- Weekly projected workloads
- Materials used for construction of walls, floors, ceilings, doors and windows
- Access to surrounding scan room areas
- Equipment in surrounding scan room area (for example: film developer, film storage)

3.2 Background Radiation

When the system is calibrated, background radiation from surrounding areas may adversely affect calibration. Therefore all radiation sources must be suitably shielded, including:

- Waiting/Injection areas
- Radionuclide storage and preparation area (sometimes known as “hot lab”)

As a general guideline, if the anticipated background radiation in the Scan Room will be higher than 0.1mR/h (1microGy/h), then appropriate additional shielding should be installed.

If radioactive gases are used in the scan room or in nearby rooms, for example gases used during ventilation lung scans; there must be mitigations to keep the gases away from the detectors. Some gases can settle on the floor while other gases can be drawn into the detector via the cooling fans. A detector's recovery from a gas contamination will depend on the half life of the radioactive gas. Negative room pressure and other air flow mitigations should be considered if radioactive gases are expected to be present in the department.

3.3 Scan Room Shielding

Shielding of the Scan Room includes walls, lead-shielded glass, lead shields, etc. and must be sufficient to protect staff from unnecessary exposure to radiation. The shielding requirements must be determined by a qualified radiological health physicist, taking into consideration:

- Local regulatory requirements
- Facility policy
- Patient location and level of radiation from patients after intake of radionuclides
- Equipment placement
- Materials used for construction of walls, floors, ceiling, doors, and windows
- Weekly projected work-loads
- Access to areas surrounding the Scan Room
- Equipment in areas surrounding the Scan Room (for example: film developer, film storage)
- Protection of operator room, included leaded window, walls and door

3.4 Magnetic Field Considerations

The ambient static magnetic field in the system location must be less than 10^{-4} tesla (1,000 milligauss). The ambient AC magnetic fields must be below the 10^{-6} tesla (10 milligauss) peak.

Low Frequency Magnetic Field

N/A

Static Magnetic Field Limits

In order to avoid interference on the system, the static field limits from the surrounding environment must be less than 1 Gauss in both the scan and the operator rooms.

3.5 EMI Considerations

3.5.1 Electrostatic Discharge Environment & 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.

3.5.2 Electro-Magnetic Interference (EMI) System Placement

NOTE

If power sub-stations exist under or above the scan room, or near the operator room, consider EMI testing to determine if your proposed room meets the published acceptable EMI room limits. This also includes high voltage lines under the scan or operator room floor.

EMI Reduction

If fields of excessive EMI are known or suspected to be present, consult GE Sales & Service for recommendations. Consider the following if you attempt to reduce EMI:

- External field strength decreases rapidly with distance from source of magnetic field.
- External magnetic field leakage of a three-phase transformer is much less than that of a bank of three single phase transformers of equivalent power rating.

- Large electric motors are a source of substantial EMI.
- High-powered radio signals are a source of EMI.
- Ensure sufficiently good screening of cables and cabinets.
- Consider and measure EMI fields of sites with main facility power running under the floor or within the walls or ceilings of the scan room.
- Pay special attention to power substations or high-voltage power lines in proximity to the scan facility.
- If any concerns remain regarding excessive EMI fields, be sure to measure to confirm that your site meets all required specifications.

Table 3-1 Electro-Magnetic Interference (EMI) Constraints

Component	Ambient magnetic fields		System attributes affected	Comments
	Static	AC		
Gantry	< 10^{-4} tesla (1,000 milligauss)	< 10^{-6} tesla (10 milligauss) peak	Imaging performance	
Color Monitor	< 10^{-3} tesla (10,000 milligauss)	NA	Color purity and display geometry	The gantry produces an electromagnetic field that radiates outward in all directions. The UPS provides a consistent power supply in normal conditions and during a site-wide power outage. The UPS and gantry are not classified as sensitive electronics.
Console / Computer Equipment	< 10^{-3} tesla (10,000 milligauss)	NA	Data integrity	
Magnetic Media	< 10^{-3} tesla (10,000 milligauss)	NA	Data integrity	

3.5.3 Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified in Appendix C EMC Compliance on page 92. The customer must assure that the system is installed and used in such an environment.

The system should not be used adjacent to or stacked with other equipment. If adjacent/stacked use is necessary, the system should be observed to verify normal operation.

3.5.4 Recommended Separation Distances

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer 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.

NOTE

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

For transmissions between 150 kHz and 2.5 GHz, adhering to the recommended distance separation 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. For example, in order to avoid image interference risks, a 1 W mobile phone (800 MHz to 2.5 GHz carrier frequency) must be placed 2.3 meters away from the system.

See also Table C-4 Separation Distances for Portable and Mobile RF Communications Equipment on page 97.

3.5.5 Cable Shielding and Grounding

All interconnect cables to peripheral devices must be shielded and properly grounded, except when technologically prohibited. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference. GE Healthcare is not responsible for any interference caused by using other than recommended interconnect cables or panels, or by unauthorized changes or modifications to this equipment.

Unauthorized changes or modifications could void the users' authority to operate the equipment.

Electromagnetic Emission

This equipment complies with IEC 60601-1: 2: 2004, IEC 60601-1: 2: 2007 and IEC 6061-1-2: 2014; EMC standards for medical devices.

NOTE

This system complies with the EMC standard when used with supplied cables. If cables of different lengths are required, contact your PM. Cables cannot be cut, shortened, lengthened, or spliced.

The system is suitable to be used in an electromagnetic environment, in compliance with the limits and recommendations provided in Table C-5 Electromagnetic Compliance on page 98.

Chapter 4 Environmental HVAC Requirements

⚠ WARNING

IMPEDED SYSTEM OPERATION / IMAGE QUALITY

Ratings and duty cycles of the system apply only if site environment meets the standards of this section. If environmental specifications are not respected, system operation and image quality may be affected.

The environmental conditions listed in this chapter are essential to maintain proper cooling for the system. These conditions must be maintained at all times, including overnight, weekends and holidays. Only when the system is shut down, for example for major repair, may the air conditioning also be shut down.

Failure to adhere to these requirements can lead to image quality issues.

⚠ WARNING

OVERHEATING

If air conditioning is not functioning correctly, the system must be shut down.

4.1 General Guidelines

Maintaining constant temperature and humidity levels is essential in order to ensure system stability over time.

Overheating or underheating, or changes in humidity that exceed the requirements provided in this section can cause technical difficulties and system failures and can cause damage to system components. You must conform to the requirements in Table 4-1 Requirements for Ambient Temperature, Humidity and Altitude on page 60 both during system storage and in as long as the system is operational after installation.

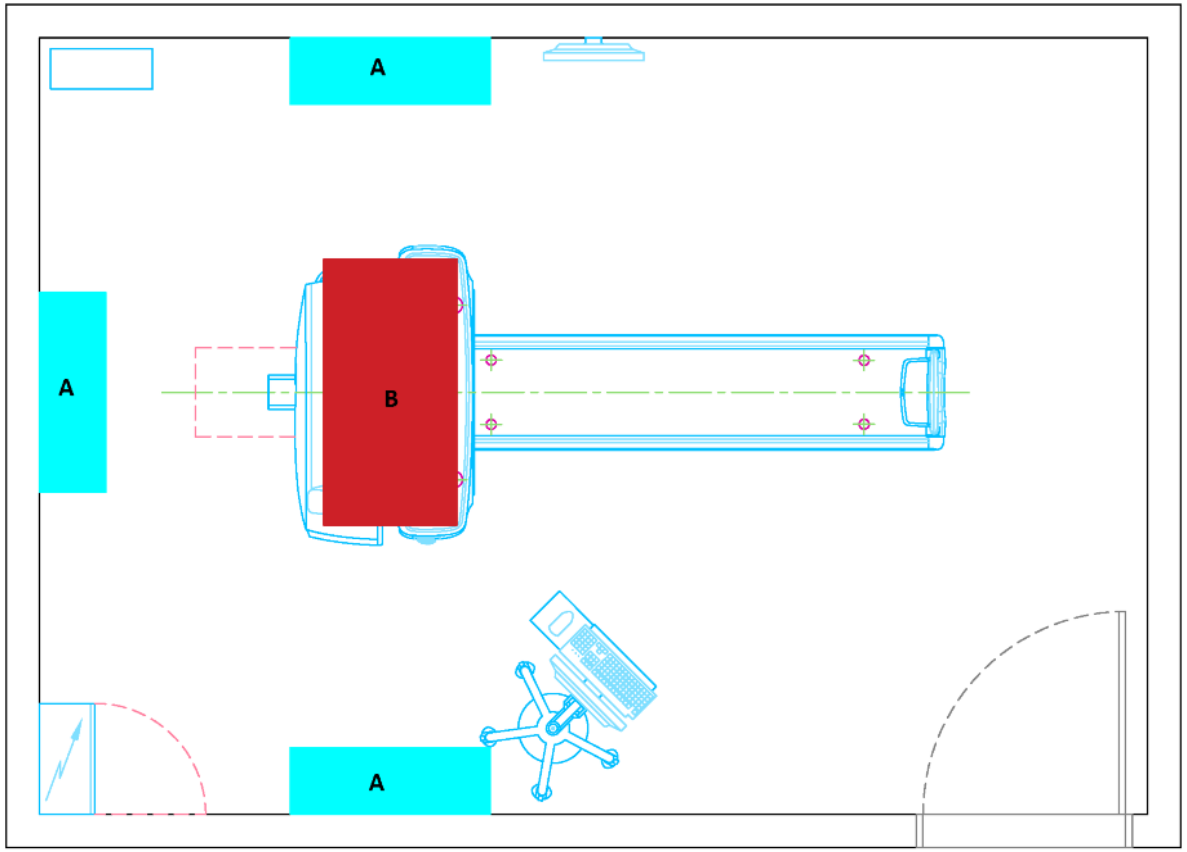
Cooling requirements do not include cooling for room lighting, personnel or other equipment.

Locate a wall air-conditioning vent at floor level beside and behind gantry to meet gantry cooling needs and to provide patient comfort. Do not locate any cooling vents directly above the gantry or such that they will blow directly on the detector. Air returns above the gantry are recommended.

Table 4-1 Requirements for Ambient Temperature, Humidity and Altitude

	Maximum	Minimum	Recommended	Maximum rate of change
Temperature	26°C (79°F)	18°C (64°F)	22°C (72°F)	3°C/hr (5°F/hr)
Humidity	60% non- condensing relative humidity	30% non- condensing relative humidity		5%/hr
Altitude	3000 m (9,843 ft.)	-150 m (-492 ft.)		

Figure 4-1 Air-conditioning Ducts



Legend

(A) Must plan to flow air towards the rear and sides of the gantry. It is important that vents do not blow directly on the detector.

(B) Ceiling area for “Air Returns” above gantry. No cooling vents in this area.

4.2 Heat Output

Table 4-2 Heat Output in Scan Room

System Component	BTU/hr	Watt	Comments
Gantry	2,390	700	
Table	682	200	
Recommended subtotal	3,072	700	
Acquisition station	512	150	(computer only)
Recommended subtotal without options	512	150	
SYSTEM TOTAL	**3,583**	**1,050**	**Cooling requirements do not include cooling for room lighting, personnel or other equipment**
NM UPS (optional)	< 1500	< 440	

4.3 Air Quality

The system is especially sensitive to the presence of sulfide, chloride and nitrate contaminates, with sulfur being the most damaging element. If high levels of contaminates exist, it is recommended that appropriate air filtration systems are installed.

Chapter 5 Electrical Requirements

5.1 Power Feed

A dedicated feeder run from the facility main isolation transformer is recommended to power the system. If the system must be powered from an existing distribution transformer and secondary feeder, such as the equipment distribution panel of an x-ray department, installation with other x-ray equipment that uses rapid film changers should be avoided. These changers use a large number of high powered, closely spaced exposures, which may coincide with the scan and produce image artifacts. If a dedicated distribution transformer is provided for the scanner, the minimum recommended transformer size is as follows, rated 2.4% regulation at unity power factor:

1.9 kVA

In all cases, qualified personnel must verify that the transformer and feeder, at point of take-off, plus the run to the system, meet all the requirements provided in this document.

Table 5-1 System Power Characteristics

Maximum power demand	1.4 kVA
Continuous (average) power demand at maximum duty cycle	0.6 kVA
Maximum allowable total power source regulation	6%
Minimum recommended transformer size	1.9 kVA

The following tables, and Table 5-3 Power Supply Requirements on page 64) are based on the use of copper wire, rated 75 C and run in steel conduit. The current rating (ampacity) is determined in accordance with the National Electrical Code (NFPA 70), Table 310-16 (2002).

NOTE

Ampacity, or Current Rating, is the RMS current which a device can carry within specified temperature limitations in a specified environment, depending upon: a) temperature rating, b) power loss, c) heat dissipation.

The ampacity for a power cable depends on properties of the conductor and the insulation and on environmental conditions adjacent to the cable.

The minimum feeder size is determined by the current rating (ampacity) of the circuit protection device listed below. In some cases a larger size may be necessary in accordance with local regulations for total source.

The Minimum Feeder Wire Size is 12 AWG (4 mm^2).

Table 5-2 Nominal Power Line Ranges

The nominal line voltage must fall within one of the ranges listed below					
Nominal line voltage (Volt)	110	120	220	230	240
Hi-Line Limit, +10% (Volt)	121	132	242	253	264
Lo-Line Limit, -10% (Volt)	99	108	198	207	216
Continuous line current (Amp)	6	5	3	3	2.5
Maximum line current (Amp)	13	12	7	7	6
Minimum recommended circuit protection rating (Amp)	16	16	8	8	8

5.2 Power Supply Requirements

The system must receive its power supply via a dedicated feeder run from the nearest Main Distribution Panel (MDP).

NOTE

The system is designed to operate on a Single phase (Line + Neutral), three wires power source.

Table 5-3 Power Supply Requirements

	Characteristics	Comments		
Line voltage specifications	110/120/220/230/240 VAC			
Line frequency specifications	50-60 Hz ± 3 Hz			
Measured kVa load characteristics	1.4 kVA	Maximum power demand	1.4 kVA	
		Average (continuous) power demand	0.6 kVA	At maximum duty cycle
Line Impedance	0.4 Ohm			
Fuse or Circuit Breaker Ratings	8 to 16 Amps	According to input voltage		

Table 5-3 Power Supply Requirements (Table continued)

	Characteristics	Comments
Power requirements for equipment not powered from the system	In scan room and in operator room: 2 one-phase regular power outlets for service tools (such as vacuum cleaner, electric drill, soldering iron etc.)	For service activities
Power stability (transient etc) requirements	Maximum transient voltages should be limited to 1500 V peak	Sags and surges of the power line must not exceed the absolute range limits shown in the **Nominal Power Line Ranges** table in 5.1 Power Feed on page 63.
Inrush current	Can withstand up to x10 of the recommended Circuit Breaker Ratings that could be reached during system power up, due to the system main transformer.	Circuit breaker Type D or similar is recommended to avoid breaker tripping upon system power up.

Total load regulation as measured at the input terminals must not exceed 6%. The capacity of the facility transformer and the size and length of feeder wires directly affect the load regulation presented to the system.

NOTE

- The electrical rating is described on the system rating label attached to the gantry.

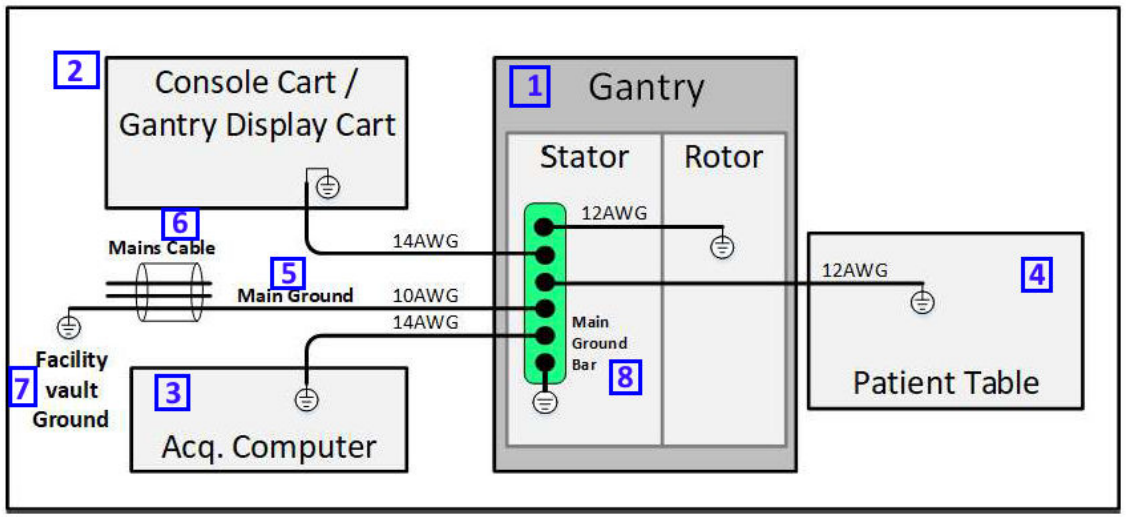
5.3 Grounding

5.3.1 Grounding Requirements

The system has been designed to use an equal potential grounding system. The required ground system is shown below.

The primary grounding point is located at the gantry base. All exposed metal surfaces in the patient vicinity are grounded to the reference ground point.

Figure 5-1 System Grounding Map



Legend:

(1) Gantry (Stator/Rotor)

(2) Console cart/gantry display cart

(3) Acquisition station

(4) Patient table

(5) Mains ground

(6) Mains cable

(7) Facility vault ground

(8) Main ground bar

NOTE

Shield/signal grounds are not shown.

5.3.2 Grounding of System Input Power

Make sure to comply with the following grounding requirements:

- Connect the grounding wire to the gantry base.
- Connect the metal conduit, raceway, or the armor of the armored cable used to the power the system, to the system gantry ground.
- Run a dedicated 10AWG (6 mm^2) or larger insulated copper ground wire with the phase wires from the main distribution panel to the main facility ground.

Important

When the system is installed using a detachable plug, or when a UPS is used, a dedicated ground wire is required from the gantry to the facility's vault ground. A ground cable (PN 5835625) is supplied with all systems for this purpose. This is necessary to ensure grounding when:

- The UPS power is disconnected from the facility but the UPS is still supplying power (via batteries) to the system.

or

- The detachable plug for the system mains power is disconnected.

- Connect the ground wire to the facility vault ground through which it passes, in accordance with local codes.
- Ensure that the resistance between the gantry ground and the facility earth ground does not exceed 0.5 Ω. Measure with an ohm meter and a piece of wire.
- Ensure that the total resistance between the gantry ground and earth does not exceed 2 Ω. The system's ground conductor must be in the same conduit as the system phase conductors. This ground conductor must be bonded to the main facility ground.

NOTE

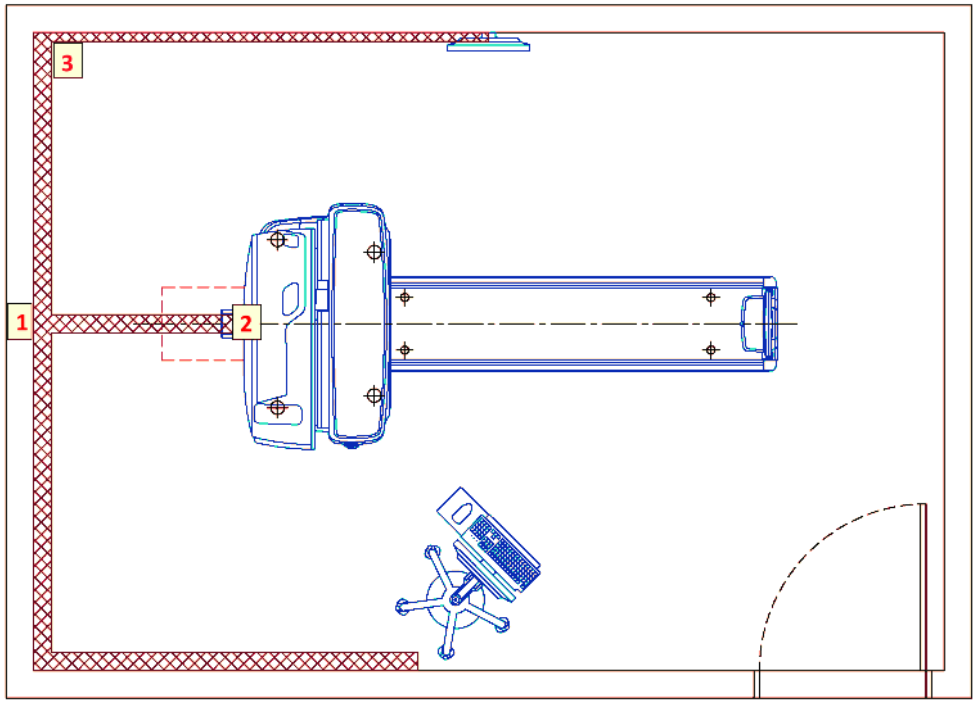
The shield or armor of armored cable is not sufficient for this purpose.

5.4 Interconnections

It is recommended that all cables are run inside ducts or conduits, as illustrated below.

Ensure adequate duct or conduit sealing to prevent penetration of liquids or other objects that may damage the cables.

Figure 5-2 Example of Suggested Cable Ducts Routing



Legend

(1) Recommended duct width 140 mm × height 45 mm

(2) Cable entry is located in middle back of gantry

(3) Optional: Patient monitoring system. If installed, ducts are recommended. Size: 34 mm diameter tubing

5.5 System Cable Information

This section provides technical information regarding system cables connecting different sub-systems, in order to facilitate the planning of cable routing.

Figure 5-3 Single Monitor Interconnects

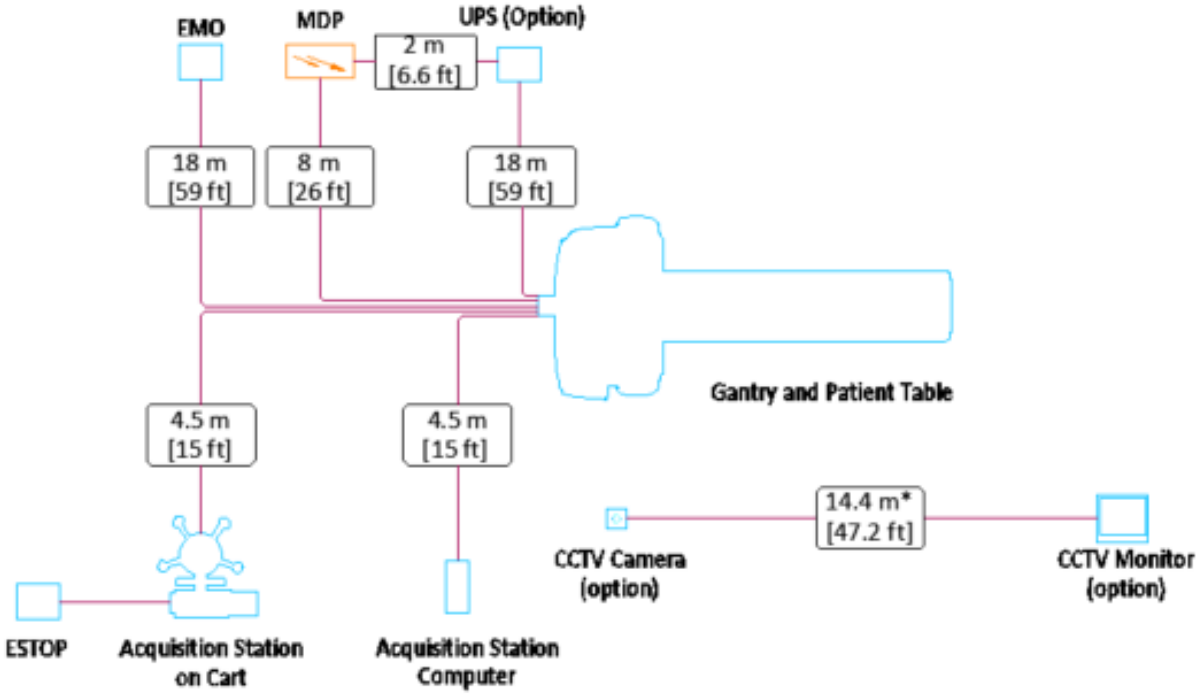


Figure 5-4 Dual Monitor Interconnects

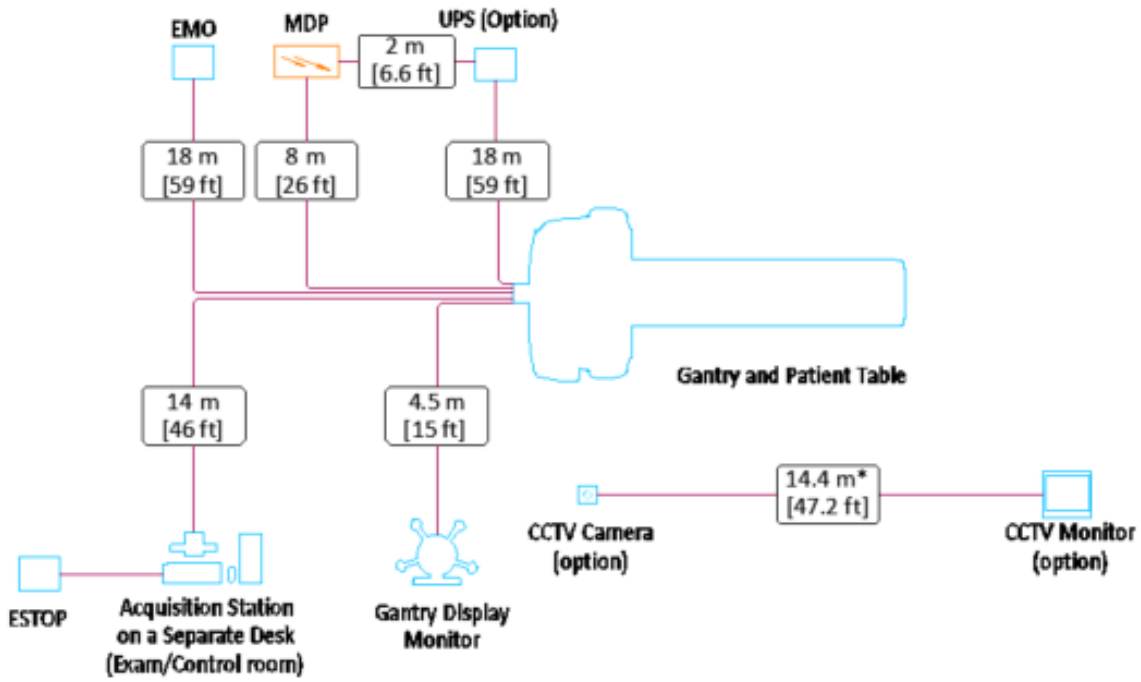


Table 5-4 Inter-connection Cables

	Start/Destination		H/V Separation (Yes/No)	Cabling Diameter (Conduit Size)	Total Usable Length	Description
System Configuration	**From**	**To**				
Single monitor, acquisition station located in scan room	MDP (Wall)	Gantry	Y	34 mm	8m (26 ft.)	MyoSPECT mains power cable
	EMO unit	Gantry	N	8 mm	18m (59 ft.)	MyoSPECT EMO unit cable
	Acquisition station cart	Gantry	N	34 mm	4.5m (15 ft.)	MyoSPECT in-room cart bundle
	Computer	Gantry	N	34 mm	4.5m (15 ft.)	MyoSPECT in-room computer bundle
	UPS	MDP (wall)	Y	34 mm	2 m (6.5 ft)	MyoSPECT UPS power cable

Table 5-4 Inter-connection Cables (Table continued)

	Start/Destination		H/V Separation (Yes/No)	Cabling Diameter (Conduit Size)	Total Usable Length	Description
System Configuration	**From**	**To**				
Dual monitors, acquisition station located outside scan room	Wall	Gantry	Y	34 mm	8m (26 ft.)	MyoSPECT mains power cable
	EMO unit	Gantry	N	8 mm	18m (59 ft.)	MyoSPECT EMO unit cable
	In-room monitor cart	Gantry	N	34 mm	4.5m (15 ft.)	MyoSPECT in-room monitor bundle
	Acquisition station in other room	Gantry	N	34 mm	14m (46 ft.)	MyoSPECT acquisition station computer bundle
	UPS	MDP (wall)	Y	34 mm	2 m (6.5 ft)	MyoSPECT UPS power cable

Connector Sizes

The table below shows information about the largest connector size for each sub-system interconnect cable bundle.

Table 5-5 Connectors

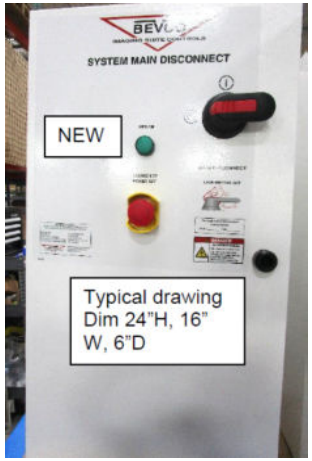
Connect to	Largest Connector Size	Image
Acquisition station	35mm	
Gantry	45mm	
In-room monitor (optional)	45mm	

5.6 Typical Customer Supplied Cables and Wiring

5.6.1 MDP (A1)

For the convenience and safety of service, it is recommended for a lockout-tagout (LOTO) compatible Main Disconnect Panel (MDP/A1) be installed in the room with the gantry.

For details on an MDP unit available from GE HealthCare Accessories, see Appendix F Main Disconnect Panel (MDP) (Option) on page 105



A UPS is highly recommended. See Appendix E Uninterruptible Power Supply (UPS) Option on page 104 for details.

5.6.2 Primary Power Disconnect

MDP with lockout /tagout (LOTO)

In order to safely install and service the system, it is recommended to have a lockout /tagout (LOTO) compatible Main Disconnect Panel (MDP) installed in the room.

The MPD and the lockout /tagout must be visible when servicing the system.

The customer must ensure that all cables and wiring specified in this section are prepared in advance. These cables and wiring components are not supplied with the system.

Figure 5-5 MDP Wiring (No UPS)

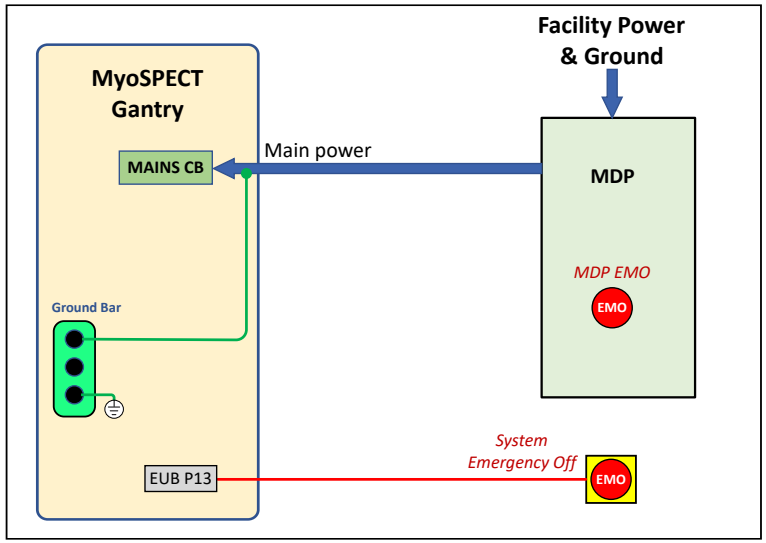
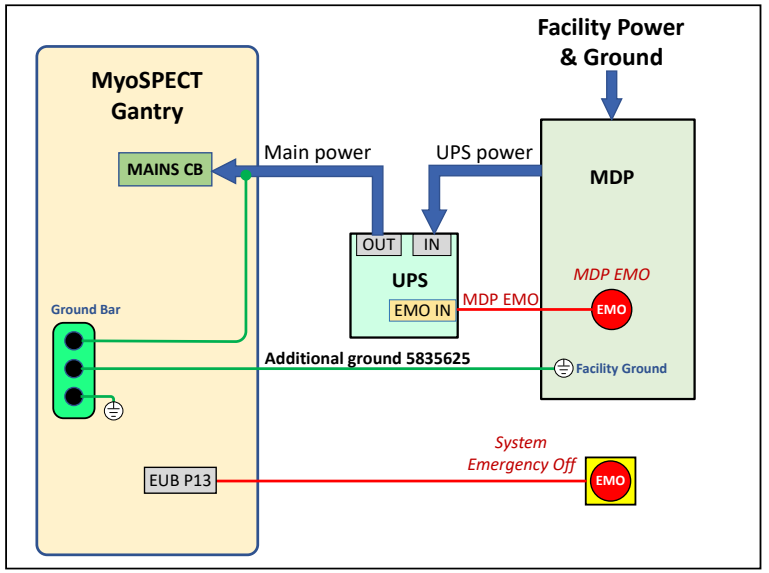


Figure 5-6 MDP Wiring with UPS



5.6.3 Connection to Power

The site electrician shall supply the connection to the power supply and any required hardware. A hard-wired connection (MDP) is preferred. The hard-wired connection should be done by an Electrician.

The wall outlet connection option requires Hospital grade connectors and plugs when the system is not hard-wired and are to be supplied by the facility.

The customer should supply a grounded type B (NEMA 5-15) power outlet.

Figure 5-7 Wall Outlet Wiring (No UPS)

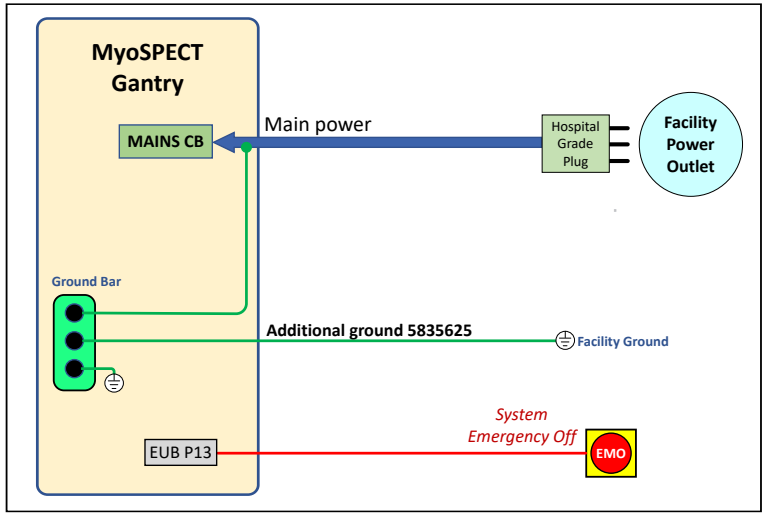
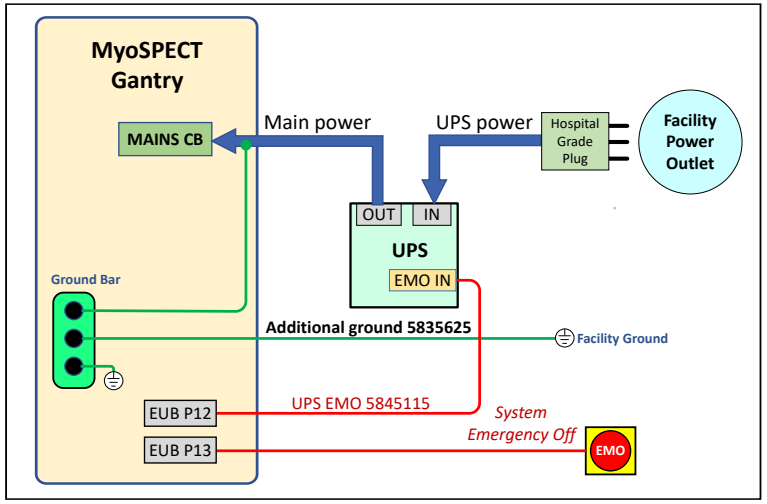


Figure 5-8 Wall Outlet with UPS



5.7 Lighting Specifications

5.7.1 Scan Room Lighting

The lighting should be planned so there is sufficient light for:

- Scan preparation
- Scan setup
- Patient unloading
- Working light for service and maintenance activities

The lighting should be designed so that it can be dimmed or otherwise changed in order to minimize discomfort for patients lying supine for extended periods with the ceiling in view.

NOTE

- Scan room lighting above the gantry and patient area should consist of fluorescent lights only (no direct sunlight or direct bright light from filament light bulbs).

- During system servicing in the scan room, a relatively bright light is required in the area behind and around the gantry.

5.7.2 Operator Room Lighting

NOTE

Applicable if a separate operator room is planned.

The lighting should be planned taking into account that operators will be working with computer monitors and reading digital images during much of the day. Reflections in monitors should be avoided, and other ergonomic factors taken into account.

The operator room lighting must also take into account that relatively bright light is required while servicing the acquisition station.

5.8 Power Line Outlets for Service

It is recommended to install at least two standard power outlets in the scan room and in the operator room, to be used for electrically powered service tools. The exact location of these outlets should be defined according to regulatory and service clearances around the system.

5.9 Patient Monitoring System (Optional CCTV)

The Patient Position Monitor option includes a wall mounted, miniature video camera and a display screen. The monitor provides a live view of the camera and patient from the rear.

This is a stand-alone option. The facility must provide a power outlet near the video camera and one near the LCD monitor locations. The kit includes IEC C-13 to NEAM 5-15 power cables. If the outlets do not support this connection, the facility must provide two IEC C-13 to local AC power cables. If conduit is desired to hide cabling, the facility must provide it. The conduit must support 45mm video connectors.

Chapter 6 Network and GE Remote Access Requirements

6.1 Network Requirements

The system requires the following network connections:

- Broad-Band Network Connection (BBNC) (required): broad-band network connection wall jack, located within 1 m (40") of the operator computer location, for internal hospital networking and GE remote broadband connectivity.
- Local Area Network (LAN) (required)
  - LAN connections are usually required in the operator room for:
    - Xeleris workstation
    - DICOM LAN printer (optional)

      The LAN and WAN Networks sockets/outlets (minimum) must be available in the operator room within a distance of 1 m (40") of the operator computer location, processing workstations (Xeleris) and LAN printer installed in the operator room.
  - In the scan room it is recommended to have one LAN socket/outlet available in close proximity to the gantry for service engineer activities actions.
- Wide Area Network (WAN) (optional)

6.2 RSVP Requirements

The system requires internet connectivity as follows:

- The system allows for DNS configuration or Proxy server connection to the internet.
- If replacing an existing system that has a remote GE connection, the current internet connection supporting GE remote access (InSite) connection can be reused.
- Proxy configuration for internet access may also include authentication credentials (user name and password). Local IT contact must be able to provide these details if required.
- If the site would like to whitelist only certain URLs, the following addresses can be used for RSVP connectivity. All service traffic is via port 443:

    - RSVP Servers:
        - https://insite.gehealthcare.com
        - https://insite-eu.gehealthcare.com
        - https://as1-insite.gehealthcare.com
        - https://as2-insite.gehealthcare.com
    - Flexera Servers:
        - https://gehealthcare-ns.flexnetoperations.com
        - https://download.flexnetoperations.com
- It is not recommended to route the connection over an existing VPN tunnel. If the customer requires the use of a VPN tunnel, a case must be escalated to the local connectivity team.

Appendix A Customer Checklist

The checklist must be completed by the customer and delivered to GE prior to installation.

Important

This checklist is general in nature and is intended to assist the customer in verifying site preparation. The checklist does not cover all details in this manual, and it is the customer's responsibility to fully prepare the site, taking into account all details and specifications set out in this manual.

Site Information	Contact Information	Contact Persons	Name	Telephone	email
Site name		Site project coordinator			
Department		System administrator			
Street		Chief technologist			
City, State, Zip		Facilities engineer			
Country		Shipping / Receiving			
Telephone		Physician			
Fax		Other			
Safety Declaration					
I hereby confirm that the relevant site personnel have read the *Safety and System Overview Manual*, in conjunction with this Pre-Installation Manual.			Name		
			Position		
			Signature		
Completion Sign Off					
I hereby confirm that pre-installation is complete and that I have examined and confirmed all items in the Pre-Installation Customer Checklist			Name		
			Position		
			Signature		

Table A-1 Deviation from Specifications in Site Preparation Manual

Description		Personal Details	
Floor and anchoring	I hereby confirm that the site takes full responsibility for the floor and anchoring methods differing from the specifications in this manual	Name	
		Position	
		Signature	

Table A-2 Site Preparation Timetable

Description		Status	See	Comments
Scheduling	Project schedule verified with GE			
	3rd party vendors scheduled			
	Can meet the committed site ready date			
	Construction completion date matches delivery date			
	System delivery date scheduled for			
	Detectors delivery date scheduled for			
	Installation dates scheduled for			
	Applications/Training date scheduled for			
	Site Ready date scheduled for			
	First Use date scheduled for			

Table A-3 Room Preparation

Description		Status	See	Comments	
Pre-construction	Site layout drawings completed and approved				
	Radiologist health physician has reviewed the room layout				

Table A-3 Room Preparation

Description		Status	See	Comments	
	3rd party vendors identified: _____ _____ _____				
Post-construction: Room measurements and layout	• Length				
	• Height				
	• Width				
Servicing clearance	Meets all requirements, including local codes and local regulatory requirements as detailed in Appendix D Regulatory Clearances on page 99. No grounded walls are present in the regulatory clearance areas.				
Egress	Sufficient egress space per local regulatory requirements				
Structural and floor preparation	Floor tolerates specified loads				
	Floor meets thickness requirements or alternate anchoring has been specified and is available from the customer's structural engineer				
	Floor meets leveling requirements				
	Floor meets flatness requirements				
	Floor meets vibration requirements				
Ducts	Ducts installed in floor, according to approved room layout				
	Ducts meet requirements (size, depth, sealing, high voltage separation)				
Electricity requirements	Main Distribution Panel (MDP (A1)) meets requirements and is installed				

Table A-3 Room Preparation (Table continued)

Description		Status	See	Comments	
	Wall outlets are live and available for installation and service tools				
	Environmental conditions	Ample working light is available for service			
Air-conditioning meets requirements for system thermal loads					
Air-conditioning meets humidity requirements					
Magnetic field in camera room is < 1 Gauss					
Room is clean and free of dust, ready for installation					
Room shielding	Shielding of scan room meets requirements				
	Shielding of operator room meets requirements				
Safety	Planned location of emergency button in scan room is easily accessible by operator				
	Interlock system installed				

Table A-4 Unloading, Conveyance and Storage

Description		Status	See	Comments
Temporary storage	System will be delivered on first install day **or** Some or all crated components will be stored until installation date			
	Site has sufficient storage area			

Table A-4 Unloading, Conveyance and Storage (Table continued)

Description		Status	See	Comments
Staging area	If a staging area is required, its size and all environmental conditions meet the system's requirements.			
Loading dock	Is a loading dock with 112 cm (44") truck-height available?			
	Full-size truck can access loading dock **or** Site will arrange for short truck delivery			
Unloading by forklift	Site has forklift with weight capacity to lift a fully crated gantry **or**			
	Site will arrange for appropriate forklift			
Rigging (required if halls/ elevator/doors access is not available)	Rigging company details: Name: _____ Contact person: _____ Phone: _____			
	Rigging company has insurance policy			
	Insurance policy of rigger company is attached			
Pallet truck	Site has pallet truck **or** Site will arrange for pallet truck			
Delivery route	Delivery route is defined by site and meets requirements			
	Delivery route is tested by site			
Installation room	Room can be locked during installation			
Suitability of halls, elevators and doors for conveyance of all components, when mounted on moving kit/wheels **Note:** All items must refer to conveyance as follows:	All door openings, hallways are large enough			
	Pathways can tolerate weight			

Table A-4 Unloading, Conveyance and Storage (Table continued)

Description		Status	See	Comments
- From truck to installation room (crated or uncrated) or - From truck to storage (crated) and from storage to installation room (crated or uncrated)	Elevator openings and size are large enough			
	Elevator can tolerate weight			
	Gantry can clear all corners			
	Inclines on the route to the camera room are suitable (weight, size and incline angle)			
	State the incline angle			
	There are delicate carpets or tiles along the conveyance route			
	Floor protection is supplied for delicate surfaces			
Waste materials	Site has arranged for disposal of empty wooden cases, foam blocks and large cardboard boxes after installation			

Table A-5 Network Preparation

Description		Status	See	Comments
Local networking or IT Contact information	Info provided			
Network cabling and hardware	Installation complete			
Broadband	Installed and tested			
Network definitions and testing	Acquisition station site name, hostname and IP address defined and tested			
	Xeleris workstation site name, hostname and IP address defined and tested			

Network Definition Details					
Item	Hostname	IP	Wired (Y/N)	DICOM Port	AE Title

Network Definition Details					
NM Acquisition Station					
Processing host					
Hardcopy host					
LAN Net Mask					
Gateway to other networks					

Table A-6 Radioactive Isotopes for System Calibration

Description		Status	See	Comments
Basic calibration	Site has license for Tc^{99m}			
	Tc^{99m} will be available during installation			

Appendix B Measuring Floor Flatness

The floor must meet strict flatness specifications. The information in this appendix is provided as a tool for accurate measurement of the floor flatness.

Required Tools

- Self-leveling fan beam laser tool (self-leveling for at least 3 degrees)
- Masking tape
- Chalk line
- 1 m (3') level with minimum 1 mm (1/16") gradations (alternatively, use a tape measure securely taped to a spirit level)

1. Map the floor as follows:

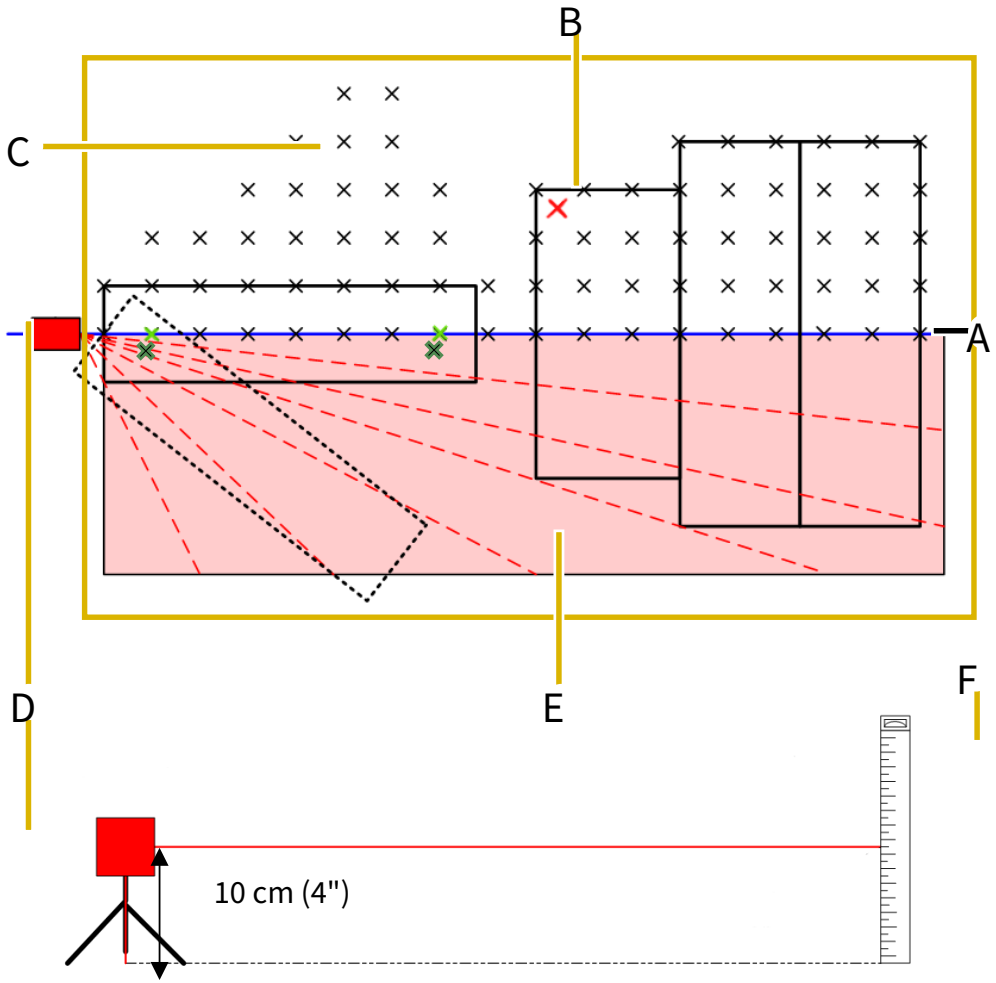
   NOTE

   In the following graphic:

   The "interest area" that needs to be checked (marked with two green X markers in the diagram) differs depending on the system type. This example demonstrates the area for 870 and D670 systems.

   The "interest area" for table installation is indicated by the two green X marks.

   Maximum height of laser: 10 cm (4")



2. Place the laser (D) at the end of the center line.

   The laser must be high enough for the fan beam to be visible over the entire footprint area (E), but no more than 10 cm (4") high (the closer to the floor the more accurate).

   a. Using a chalk line, mark the center line (A) (refer to site drawings or proposal for exact location).

   b. Using masking tape, place × marks at 30 cm (1 ft) intervals along the center line.

c. Add × marks at 30 cm (1 ft) intervals from center line, so that the system footprint is covered with a grid of × marks (C).

d. Place the level flat on the floor and move it around the footprint area. Visually inspect the floor for any significant highs/lows, and add × marks (B) to identify them.

3. Keeping the measuring stick (F) exactly perpendicular to the floor, at each tape mark record the height at which the laser hits the ruler.

4. Record the measurements in a table that represents the system footprint. Add notes for any significant high/low measurements found in between the grid locations.

The table provides a visual contour of the floor, where each cell in the grid represents 30 cm (1 ft). Compare to the system specifications to determine whether the floor meets the requirements.

Table B-1 Floor Flatness Conforming with 0.5 cm over 150 cm Specs (0.5 Deviation) on page 88 shows a floor that meets the specification of 0.5 cm over 150 cm: there is no deviation greater than 0.5 between any 5 cells in the grid.
Table B-2 Floor Flatness Outside 0.5 cm over 150 cm Specs (1.1 Deviation) on page 89 shows a floor with three areas out of specification.

Table B-1 Floor Flatness Conforming with 0.5 cm over 150 cm Specs (0.5 Deviation)

Measurements in CM					Center						Notes
	1.3	1.2	1.1	1.1	1	1.1	0.9	0.9	1		Greatest Deviation: 1.4 - 0.9 = 0.5
	1.2	1.1	1.1	1.1	1	1	1	0.9	1		
	1.2	1	1	1	1	1	1	1	1		
	1.1	1	1	1	1	1	1.1	1.1	1.1		
	1	1	1	1	1	1	1.1	1.2	1.2		
	1	1	1	1	1	1	1.2	1.2	1.3		
	1.1	1.1	1.1	1	1	1.1	1.2	1.3	1.3		
		1.1	1.1	1.1	1.1	1.1	1.2	1.3			
		1.2	1.2	1.1	1.1	1.1	1.2	1.2			
		1.2	1.2	1.2	1.1	1.1	1.2	1.2			
				1.2	1.2	1.2					
		1.2	1.2	1.2	1.2	1.2	1.2	1.2			
1.3	1.3	1.2	1.2	1.2	1.3	1.3	1.2	1.2	1.1	1	
1.3	1.3	1.2	1.2	1.2	1.3	1.3	1.2	1.2	1.1	1	
	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.1		

Table B-1 Floor Flatness Conforming with 0.5 cm over 150 cm Specs (0.5 Deviation) (Table continued)

Measurements in CM					Center						Notes
		1.2	1.3	1.3	1.3	1.3	1.3	1.3			
			1.3	1.4	1.3	1.3	1.3				
				1.4	1.4	1.3					

Table B-2 Floor Flatness Outside 0.5 cm over 150 cm Specs (1.1 Deviation)

Measurements in CM					Center						Notes
	5.2	5.3	5.4	5.4	5.4	5.4	5.4	5.4	5.5		Greatest Deviation: 5.9 - 4.8 = 1.1
	5.3	5.4	5.4	5.3	5.4	5.4	5.4	5.4	5.4		
	5.4	5.4	5.3	5.2	5.2	5.3	5.1	5.3	5.4		
	5.3	5.3	5.2	5.1	5.1	5.2	5	5.3	5.6		
	5.4	5.4	5.4	5.2	5	5.1	5.2	5.2	5.3		
	5.3	5.3	5.3	5.1	5	5	5.1	5.2	5.2		
		5.1	5.1	5	5	5.1	5.3	5.3			
		5	5	5.1	5.1	5.3	5.4	5.6			
		4.8	4.9	5.1	5.2	5.4	5.6	5.9			
				5.1	5.2	5.3					
		5.1	5.2	5.2	5.2	5.3	5.4	5.5			High spot between orange blocks = 4.8
5.1	5.1	5.1	5.2	5.2	5.3	5.3	5.5	5.6	5.8	5.9	
5	5.1	5.2	5.2	5.3	5.4	5.4	5.5	5.6	5.8	5.9	
	5.2	5.2	5.3	5.4	5.5	5.5	5.6	5.6	5.7		
		5.3	5.4	5.5	5.6	5.6	5.6	5.7			
			5.5	5.6	5.7	5.6	5.7				
				5.7	5.8	5.7					
	5.2	5.3	5.4	5.4	5.4	5.4	5.4	5.4	5.5		

Table B-3 Blank Table for Measurements

Measurements in CM					Center						Notes
											Greatest Deviation:

Table B-3 Blank Table for Measurements (Table continued)

Measurements in CM					Center						Notes

Appendix C EMC Compliance

This equipment complies with IEC60601-1-2 Edition 4 EMC Standard for medical electrical equipment.

The system is suitable to be used in an electromagnetic environment, in compliance with the limits and recommendations provided in the following tables:

- Emission compliance level and limits
- Immunity compliance level and recommendations to maintain equipment clinical utility

Table C-1 EMC Emission Declaration

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	
Harmonic emissions IEC 61000-3-2	NA	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 61000-3-2	NA	

Table C-2 Immunity Guidance and Declaration

Immunity Test	EC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air ±8 kV contact ±15 kV air	[Edition 2 and 3] • ±6 kV contact ±8 kV air [Edition 4] • ±8 kV contact • ±15 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%.

Table C-2 Immunity Guidance and Declaration (Table continued)

Immunity Test	EC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100 Khzrate ± 1 kV for input/ output lines 100 Khzrate	[Edition 2 and 3] • ±2 kV for power supply lines, 100Khz rate • ±1 kV for input/ output lines, 100Khz [Edition 4] • ±2 kV for power supply lines, 100Khz rate • ±1 kV for input/ output lines, 100Khz rate	Mains power quality should be a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line-line ±2 kV line-earth	[Edition 2,3, and 4] • ±1 kV line-line • ±2 kV line-earth	Mains power quality should be a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 5 sec	[Edition 2 and 3] • < 5 % UT (>95% dip in UT) for 5 sec [Edition 4] • 0% UT for 5 sec	Mains power quality should be a typical commercial or hospital environment. lf the user of the system requires continued operation during power mains interruptions, it is recommended that the system is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m 30 A/m	[Edition 2 and 3] • 3 A/m [Edition 4] • 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT equals the alternating current mains voltage prior to application of the test level.			

Table C-2 Immunity Guidance and Declaration (Table continued)

Immunity Test	EC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 Mhz	[Edition 2, 3, and 4] • 3 Vrms • 150 kHz to 80 MHz [Edition 4] • 6 Vrms in ISM bands • 150 kHz to 80 Mhz	Do not use portable and mobile RF communications equipment closer to any part of the system, including cables, than the recommended separation distance (d) calculated from the equation appropriate for the frequency of the transmitter. Recommended Separation Distance (d): $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ See Table C-4, 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) . Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*1, should be less than the compliance level in each frequency range.*2 Interference may occur in the vicinity of equipment marked with the following symbol: 

Table C-2 Immunity Guidance and Declaration (Table continued)

Immunity Test	EC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF Fields / Proximity Fields from Wireless Transmitters IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM 1 kHz 9V/m to 28 V/m Spot frequencies 385 / 450 / 710 / 745 / 780 / 810 / 870 / 930 / 1720 / 1845 / 1970 / 2450 / 5240 / 5500 / 5785 MHz PM 18 Hz or 217 Hz (50% duty cycle) See Table C-4 for details.	[Edition 2 and 3] • 3 V/m • 80 MHz to 2.5GHz • 80%AM 1 kHz [Edition 4] • 3 V/m • 80 MHz - 2.7 GHz • 80%AM 1 kHz [Edition 4] • 9 V/m to 28 V/m • spot frequencies 385 / 450 / 710 / 745 / 780 / 810 / 870 / 930 / 1720 / 1845 / 1970 / 2450 / 5240 / 5500 / 5785 MHz • PM 18 Hz or 217 Hz • (50% duty cycle) See Table C-4 for details.	Do not use portable and mobile RF communications equipment closer to any part of the system, including cables, than the recommended separation distance (d) calculated from the equation appropriate for the frequency of the transmitter. Recommended Separation Distance (d): $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ $d = \left[\frac{7}{3}\right]\sqrt{P}$ See Table C-4 , 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) . Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.*2 Interference may occur in the vicinity of equipment marked with the following symbol: 

*1 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 reorienting or relocating the system.

*2 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table C-3 Spot Frequencies

Spot Frequency (Mhz)	Band (Mhz)	Service	Maximum Power (Watts)
385	380-390	TETRA 400	1,8
450	430-470	GMRS 460 FRS 460	2,0
710	704-787	LTE Band 13, 17	2
745			
780			
810	800-960	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	2
870			
930			
1720	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UTMS	2
1845			
1970			
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	2
5240	5100-5800	WLAN 802.11 a/n	0,2
5300			
5785			

Table C-4 Separation Distances for Portable and Mobile RF Communications Equipment

Rated Max Output Power (P) of Transmitter (Watts)	Separation distance according to frequency of transmitter (meters)			Comments
	150 kHz to 80 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{3}\right]\sqrt{P}$	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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[*1], should be less than the compliance level in each frequency range.[*2] Interference may occur in the vicinity of equipment marked accordingly.
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	11.7	11.7	23.3	

[*1] 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, and 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 relocation the system.

[*2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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 power (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

- At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. As an example, keep a 1 W mobile phone (800 MHz to 2.7 GHz carrier frequency) at least 2.3 m from the NM/CT system (to avoid image interference risks).

Limitations Management: Adhering to the distance separation recommended in (150 KHz to 2.7 GHz) reduces disturbances recorded at the image level, but may not eliminate all disturbances. However, when installed and operated as specified, the system maintains its essential performance by continuing to acquire, display, and store diagnostic quality images safely.

Table C-5 Electromagnetic Compliance

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 not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	When installed in such a shielded location, the scanner 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	N/A	N/A
Voltage fluctuation/ flicker emissions IEC 61000-3-2	N/A	N/A

Appendix D 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):

is a map of clearance requirements for U.S. regulatory compliance. See 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. See D.5 Service Clearances on page 102 for additional information.

D.1 Regulatory Code Description

Egress: 29 CFR 1910 Subpart E (OSHA) and NFPA 101 (Life Safety Code) define the minimum requirements for means of egress. The requirement most applicable to equipment installation and room layout is minimum width of exit access. Under OSHA 1910.37(f)(6), the minimum width of exit access shall in no case be less than 28 in. from any potentially occupied point in the room.

Under NFPA 101 (2006 edition) 7.3.4.1, the minimum width of any means of egress is 36 in. However, NFPA allows this to be reduced to 28 in. around furniture or equipment, provided that a 36 in. clearance would otherwise be available without moving permanent walls.

Electrical Clearance: 29 CFR 1910 Subpart S (OSHA) and NFPA 70E (Standard for Electrical Safety in the Workplace) define minimum clearance requirements for the workspace around electrical equipment. Under both OSHA 1910.303(g)(1) and NFPA 70E (2004 edition) 400.15, a minimum clear space of 36" depth (with minimum 30" width and 78" height) must be provided in front of electrical equipment with parts operating at 600 volts or below and likely to require examination, adjustment, servicing, or maintenance while energized.

This safety clearance requirement applies to all GEHC equipment. Although 36 in. is the minimum clearance for most installations, the standards require an increased minimum clearance distance where parts operate above 150 volts (but still below 600 volts) under the following circumstances:

- If the wall or surface directly facing the electrical equipment is grounded (for example: brick, concrete, or tile) or includes grounded protrusions (such as medical gas ports, metal door or window frames, water sources and metallic sink structures, metallic cabinetry, electrical disconnects or emergency off panels, air conditioners or vents), then a 42" clearance depth is required.
- If the possibility exists of exposed and unguarded live parts on both sides of the workspace (for example if a power distribution unit were positioned on the wall directly facing the GEHC equipment), then a 48" clearance depth is required.

D.2 Regulated Minimum Working Clearance by Major Subsystem

Requirements apply to equipment operating at 600V 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, distances are measured from the enclosure, not the finish covers.

Table D-1 Gantry Subsystem

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access (all sides)		If exposed live parts of 151 - 600 volts are present, 1219 mm (48 in.) on both sides of workspace with the operator between is required. If the opposite wall is grounded and exposed live parts of 151-600 volts are present, 1067 mm (42 in.) is required.
Service access width (left-right of workspace)	762 mm (30")	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required.

Table D-2 UPS Subsystem

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access (front of UPS)	914.4 mm (36")*	There are no exposed live part hazards with the cover in place. This component is typically serviced from the front with access to the rear. • If exposed live parts of 151 - 600 volts are present, 1219 mm (48 in.) is required on both sides of the workspace with the operator between. • If the opposite wall is grounded and exposed live parts of 151 - 600 volts are present, 1067 mm (42 in.) is required.
Service access width (right side and length of UPS)	762 mm (30")	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required
Head clearance	1981 mm (78")	This is the height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s). A minimum of 1981 mm (78 in.) or the height of the equipment, whichever is greater, is required.

Table D-3 MDP (A1) Disconnect Subsystem

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access (front of MDP/A1)	914.4 mm (36")*	There are no exposed live part hazards with the cover in place. This component is typically serviced from the front with access to the rear. • If exposed live parts of 151 - 600 volts are present, 1219 mm (48 in.) is required on both sides of the workspace with the operator between. • If the opposite wall is grounded and exposed live parts of 151 - 600 volts are present, 1067 mm (42 in.) is required.
Service access width (right side and length of MDP/A1)	762 mm (30")	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required.
Head clearance	1981 mm (78")	This is the height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s). A minimum of 1981 mm (78 in.) or the height of the equipment, whichever is greater, is required.

D.3 Terms and Definitions

Egress: The path of exit from within any room, constituting a continuous and unobstructed space, without trip hazards along the path of exit.

Workspace: 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. Additional conditions can increase the minimum dimension requirement. GE defines this as the envelope of the component superstructure with the external covers in place.

Service Access Width: The width of the workspace in front of the equipment. A minimum of 762 mm (30"), or the width of the equipment, whichever is greater.

Head Clearance: The height dimension of the workspace. The height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s). 1981.2 mm (78"), or the height of the equipment, whichever is greater.

Grounded Wall: Any wall that can be electrically conductive to earth ground. Masonry, concrete, and tile are considered conductive. Additional commonly found aspects of a wall should also be considered grounded.

The following is not an all-inclusive list:

• Medical gas ports and plates • Metal doors and window frames • Water sources and metallic sink structures • Metallic wall-mounted cabinetry • MDP (A1) • Equipment Emergency OFF panels • Industrial equipment (such as air conditioners and vents) • Expansion joints • Surface raceway • Exposed wall conduits • Floor outlets boxes	The following are not considered as grounded elements of a common wall: • Standard wall outlet • Light switches • Telephones • Communication wall jacks • Ceiling tile grids

D.4 Additional Regulatory Clearance Information

D.4.1 Regulatory Caution

Site prints are required for all system installations including relocation and moves. The room layout, as shown on your site print, shall meet all regulatory requirements as described in the installation manual. Additional room components, such as cabinets, reduce room size. Equipment not shown on the site print may void the caution statement, making the room non-compliant. Actual site measurements before installation will be taken to determine room size and compliance.

D.4.2 Egress Clearance

Egress requires a clear, unobstructed route out of the room.

Exceptions: Small rooms require construction to meet the minimum requirements. The design center or your GE PMI may have additional recommendations for your room size.

D.5 Service Clearances

Servicing of the system can be safely performed within the regulatory envelopes defined in Appendix D Regulatory Clearances on page 99; however sufficient space must be maintained to remove the covers from the system.

To achieve clearance for the gantry, clear space must be available to maneuver the gantry covers. One Service Engineer can accomplish this.

Appendix E Uninterruptible Power Supply (UPS) Option

The Uninterrupted Power Supply (UPS) is an option intended to provide emergency power to operate the system for a short period of time.

Only the camera system should be plugged into the UPS.

- Place the UPS as close as possible to the system.
- Avoid locations near heat sources or in direct sunlight.
- It is important that ventilation air can move freely around and through the unit.
- Do not block the air vents.

The UPS is powered from a fixed connection box.

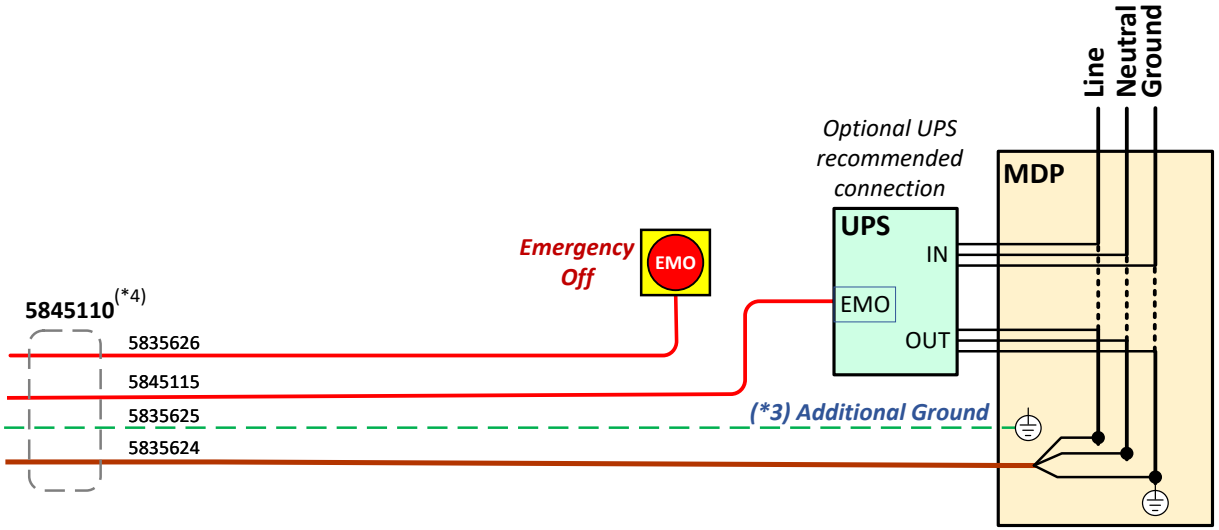
Options include:

Operating Voltage	GE ECAT	Name	Region
110-120 VAC	E4502KV	Powercom VGS-2000 2kVA	USA, Japan
220-240 VAC	E45971ND	ABB UPS PowerValue 11RT 3kVA	EMEA

Appendix F Main Disconnect Panel (MDP) (Option)

The Main Disconnect Panel (MDP) is an imaging system panel that serves as the main power disconnect between the facility 110, 120, 220, 230, or 240V single phase power source and the imaging system.

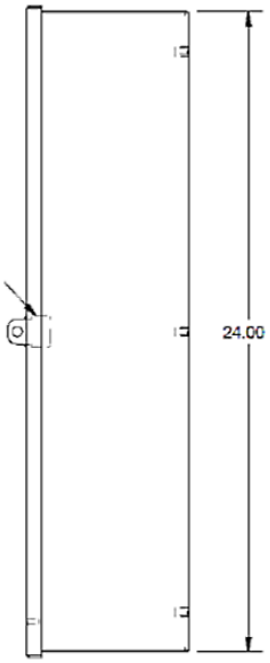
The panel provides emergency shut down, service LOTO and over-current protection.



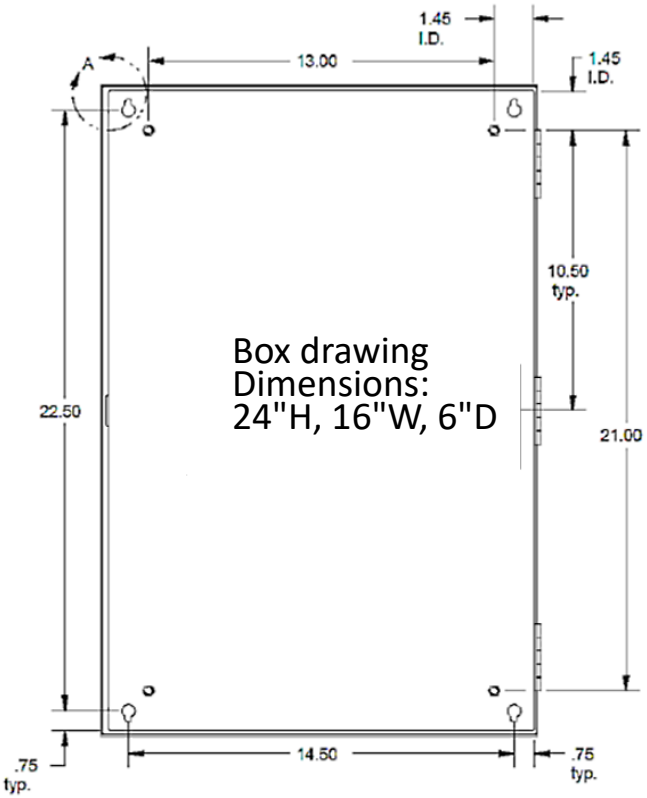
Recommended Panel

Bevco MyoSPECT Main Disconnect 20A single phase E4502AJ

This panel is UL, cUL, OSHPD* and CE labeled for compliance with NEC article 100, 110.2 and 110.3. The surface is semi-flush, mounted with 2 guarded remote Emergencies OFF pushbuttons and flush steel wall plates.



Right Side View



Rear View

GE HealthCare

www.gehealthcare.com