StealthStation® i7™ Site Preparation Guide

Part Number 9734449, Revision 4

A guide to preparing for installation of the StealthStation® i7™ System

CE 0123

℞ Only

Explanation Of Symbols On Package Labeling

The following symbols may appear on system equipment, system packaging, or in this system manual.

The device complies with European Directive MDD 93/42/EEC.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL60601-1/CAN/CSA C22.2 NO.601.1-M90.
Control number 87HJ.

Prescription only. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

When found in this reference guide, this symbol means: “Warning! Failure to observe could result in injury or death.” When found on equipment, this symbols means: “Attention: consult accompanying documentation.”

Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.

Consult instructions for use.

Type BF applied equipment, in compliance with IEC60601-1.

Type B applied equipment, in compliance with IEC60601-1.

Fragile contents

Keep upright

Keep dry

Power on. Connect to main power.

Power off. Disconnect from main power.

Power on for part of the system.

Power off for part of the system.

Freeze caster

Lock caster angle

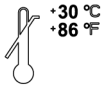
Use by date specified

Single use only. Do not reuse.

Quantity

Non-sterile

Do not allow contact with patient.

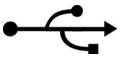


AXIEM™ Emitter must not be used in ambient temperatures greater than 30°C (86°F).

Potential Equalization Conductor

Protective Earth (Ground)

Radio frequency device. Interference may occur in the vicinity of the device.



USB port

Network connection

Modem port

Serial port

Video In

S-Video In

VGA

Spectra Control Unit (SCU) reset switch

LASER radiation emitted from aperture. Do not stare into beam. Class 1 LASER product. Complies with FDA conformance standards for laser products except for deviations pursuant to LASER notice no.50 dated July 26, 2001.

LASER radiation emitted from aperture. Do not stare into beam. Class 2 LASER product. Maximum output 1mW, wavelength 635nm, IEC60825-1 (2001), ANSIZ136 a (2000). Complies with 21CFR104010 and 104011 except for deviations pursuant to LASER notice no.50 dated July 26, 2001.

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

China RoHS compliant. Environmental protection use period of 50 years.
Environmental protection use period of 5 years.

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Introduction 1

What is the StealthStation® i7™ System?

The StealthStation® i7™ System is an integrated version of the StealthStation® image-guided surgical platform. It is designed for installation in a conventional operating room, requiring only minor alterations to the room and minimal interference to the normal OR routine.

The StealthStation® i7™ System reformats patients' CT or MR images acquired before or during surgery and displays them on-screen from a variety of perspectives (axial, sagittal, coronal, oblique). The surgeon may use the system to create, store, and simulate progression along one or more surgical trajectories as well as create and manipulate one or more 3D models of the anatomy. During surgery, the system tracks the position of specialized surgical instruments in or on the patient anatomy and continuously updates the instrument position on these images.

Site Preparation Process

The site preparation process (please see chapter 2) begins when the hospital formally expresses an interest in the StealthStation® i7™ System and consists of three phases: planning, construction, and system installation. A Medtronic site planning specialist works with hospital representatives at all stages of site preparation. The hospital personnel involved in the project include the project manager, architect, general contractor, RF shielding specialist, and the medical staff.

Content of this Site Preparation Guide

This guide aids your organization in preparing for the StealthStation® i7™ System installation and is intended for the project manager, architect, and facilities manager.

Conventions

This document employs the following conventions:

- Warnings are indicated by the symbol at left. Failure to observe a warning may result in physical injury to the patient or operator. Pay special attention to these items.

- Cautions are indicated by the symbol at left. Failure to observe a caution could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.

Contact Information

The StealthStation® i7™ System is marketed, distributed, and supported worldwide by Medtronic Navigation, Inc.

Telephone

- Within the United States:

  (800) 595-9709 (technical support)

  (720) 890-3200 (general)

- Outside the United States, contact your local representative.

Medtronic E.C. Authorized Representative

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6422 PJ Heerlen
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World Wide Web

www.medtronicnavigation.com

Regular Mail

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, CO, U.S.A. 80027

E-mail

E-mail technical support questions to: *rs.navtechsupport@medtronic.com*

E-mail product enhancement requests to: *dl.navsuggestions@medtronic.com*

Site Preparation Process

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The site preparation process is a joint effort involving hospital personnel, a general contractor, subcontractors, and a Medtronic site planning specialist. This chapter describes the major tasks involved in planning, construction, and system installation and specifies the party responsible for each major task.

Overview of Planning and Construction

Preparing an operating room for use with the Medtronic Navigation StealthStation® i7™ navigation system will require the room to be modified from its initial finished design, upgraded from an installed StealthStation® iOR system, or designed from scratch to incorporate an integrated navigation system. Site preparation for the Medtronic StealthStation® i7™ system typically consists of three phases: design, construction, and installation. A Medtronic site planning specialist will work with different team members during all phases of the project. Key hospital personnel and contracted vendors required for the project should include the facilities project manager, architect, general contractor, boom vendor, audio visual vendor, and the surgical staff. When executed correctly, the specifications and requirements described in this document allow installation and operation of the system with minimal interference to the surrounding environment.

Once your hospital has formally expressed an interest in the StealthStation® i7™ system, a Medtronic site planning specialist surveys the proposed location to determine its suitability for the system. The hospital should appoint a project manager once the location has been selected. The site planning specialist and project manager then initiate a joint planning effort involving medical staff, architects, general contractor, and RF shielding specialist (if also installing an intraoperative magnetic resonance imaging system).

This chapter contains the following information.

- The Medtronic StealthStation® i7™ navigation system's effect on the design of the operating room and the surrounding environment.
- A description of the hospital equipment which will need to be interfaced with the StealthStation® i7™ system.
- Requirements for the StealthStation® i7™ system equipment, including electrical, air conditioning/ventilation, and communications requirements.
- Requirements for additional infrastructure involving the hospital's facilities/architectural departments.

Key Definitions

Project – the complete project consisting of three phases: architectural design, physical construction of the defined scope of work, and the installation of the Medtronic StealthStation® i7™ navigation system equipment.

Owner – the hospital which is contracting with the architect, general contractor, and medical vendors.

Facilities project manger – the owner's representative (usually from the facilities department) for the design, construction, and installation phases.

Medtronic site planning specialist – the Medtronic employee who coordinates the clinical navigation functionality with the overall design, construction, and installation of the StealthStation® i7™ system.

Architect – the person who provides all architectural and engineering requirements and drawings to ensure all local and national codes are met. The architect will usually be the responsibility and contracted through the owner.

General contractor – the general contractor provides the scope of work defined by the contract and architectural documents. The general contractor is responsible for general site construction and is contracted by the owner.

Site survey – the site survey is designed to assist the Medtronic site specialist and account manager by gathering pre-purchase information to help identify the owner's surgical and functional needs, which determines the type of equipment required from Medtronic.

Clinical review – the clinical review is a set of parameters that the site specialist and hospital staff use to assist in the coordination of the navigation work flow in the operating room to ensure all required procedures can be easily performed within the operating suite.

Site logistics plan – the site logistics plan is a room layout sketch which the site specialist will create and use to assist in communication with the owner to identify and refine the StealthStation® i7™ system's specifications helping to integrate the system into the architect's overall design.

Boom vendor – the boom vendor provides the ceiling interfacing equipment to support the integrated room's equipment such as the navigation camera and monitor.

AV vendor – the AV (Audiovisual) vendor is responsible for routing video from microscopes, the StealthStation® i7™ system, and imaging systems to wall mounted or boom mounted monitors. The AV vendor may also be responsible for routing video to other rooms in the hospital for teaching and training purposes.

Shielding vendor – the shielding vendor provides the RF interference shielding for the entire operating room including power and communication line filters.

Medtronic Components

System Rack

The StealthStation® i7™ system rack contains the navigation system computer and other crucial components on a series of two shelves. The components consist of but are not limited to the computer, power supply, modem, UPS, optical input and output drives, video splitters, fiber optic transceivers, power sequencer, interface connection panel, cooling fans, and power strips. The cabinet shelves are designed to unbolt and allow access to these components for service and installation. The shelves can also be integrated into an existing equipment rack without the need for the supplied system rack shell. See Appendix B for proposed specifications.

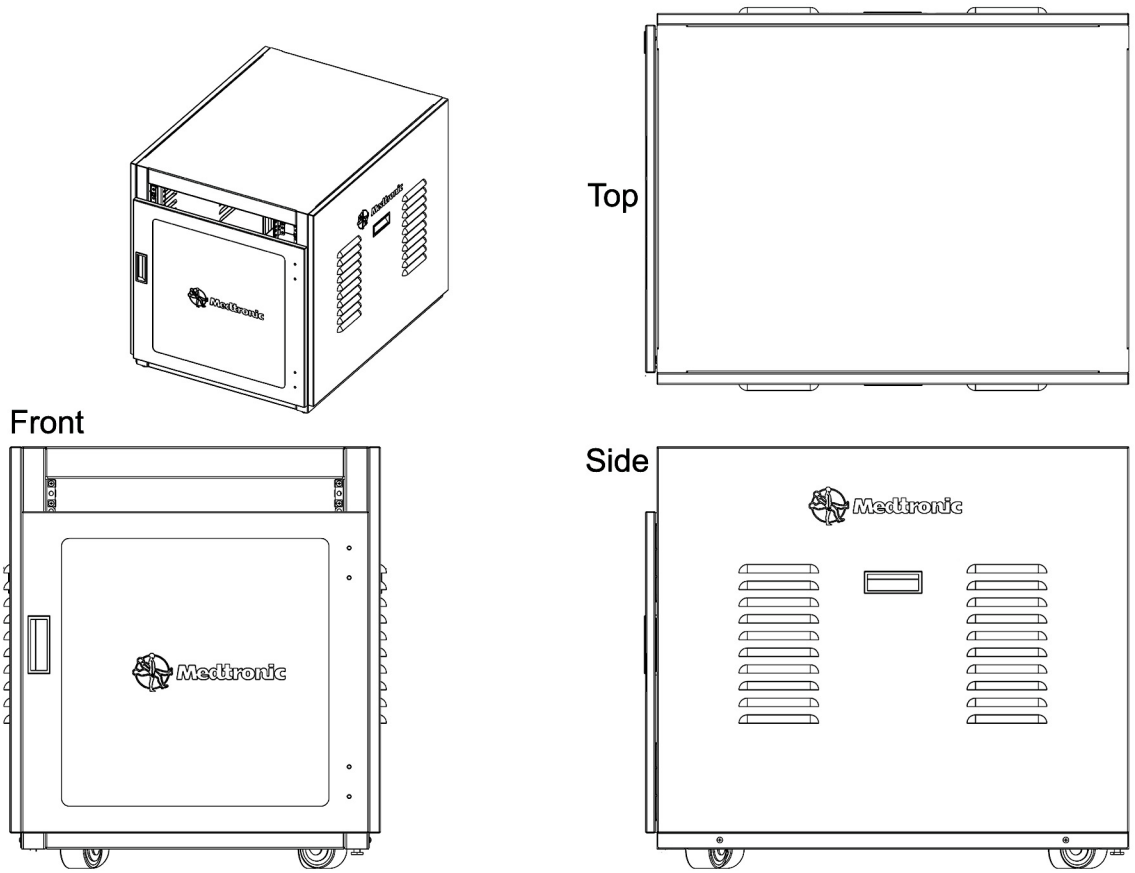

Figure 2-1. *StealthStation® i7™ system rack*

Dimension	Navigation Rack	
Width	24 in	61 cm
Height	27 in	69 cm
Depth	31 in	79 cm
Weight	~175 lbs	~78 kg

The Site Specialist will assist with the selection of the final location of the StealthStation® i7™ system rack inside the operating room, in an adjacent control room, or in an adjacent equipment room. The final location is determined by:

- the architect's overall design for the operating room
- the maximum fiber optic cable length that connects the system rack to the other navigation components located throughout the operating room (100 ft maximum)
- the preferred operating room work flow defined by the surgical staff

A designated power circuit must be supplied to provide power to the system rack. The architect's design should specify that the power outlet be installed directly behind the proposed location of the system rack. Power input specifications are given in the table below.

Input Voltage	**U.S.A.**	**International**
	110 to 120 VAC	220 to 240 VAC
	50 Hz to 60 Hz	50 Hz to 60 Hz
Maximum current allowed	5 A	2.5 A

⚠ **Warning:** Electrical design must meet the national and local electrical codes and final electrical design shall be provided by the owner's engineering consultant.

A designated telephone line should be supplied to allow remote diagnostic service of the navigation system. The architect's design should locate the telephone jack directly behind or adjacent to the designated location for the system rack.

A network connection should be supplied so that the StealthStation® i7™ system can import patient imaging data from the hospital's local PACS system. The architect's design should locate the network connection directly behind or adjacent to the designated location for the system rack.

A conduit raceway system is required to be included in the architect's construction documents to supply the fiber optic connections from the system rack to the Navigation Interface Unit and the touchscreen monitor located in the operating room. The raceway should terminate behind the system rack in a 4 inchx 4 inch (10.2cm x 10.2cm) junction box (or similar) and should daylight adjacent to the identified booms which will house the Navigation Interface Unit and touchscreen monitor. These specifications are identified in a typical architectural layout located in Chapter 3.

The Medtronic StealthStation® i7™ navigation system is designed to integrate into an intraoperative magnetic resonance imaging (iMRI) suite. All StealthStation® i7™ system cabling penetrating the shielded room is fiber optic cable. The fiber optic cable will not distort or create RF interference in iMRI images; however, the shielding vendor is responsible for the installation of any wave guides or other special filters for all penetrations into the iMRI suite. The overall design of the integrated suite should be coordinated with the architect, shielding vendor, iMRI vendor, boom vendor, AV vendor, and Medtronic.

Navigation Touchscreen Monitor

The touchscreen monitor is typically boom mounted and strategically placed to meet the operating room workflow when using navigation. It is a high resolution, flat panel computer display with built in speakers. When placed in the surgical field the touchscreen monitor allows the physician to control the Medtronic StealthStation® i7™ navigation system without the need for an assistant, keyboard, or mouse. The Medtronic site specialist coordinates planning with the surgical staff, architect, and boom vendor to ensure that monitor placement will meet the surgical team's expectations for all navigation procedures. Monitor specifications are given below.

Dimension	**Touchscreen monitor**	
Width	32.5 in	82.5 cm
Height	15.5 in	39.5 cm
Depth	4.25 in	11 cm
Weight	16 lbs	7 kg
Specifications	Screen pitch = 28mm, resolution = 1920 x 1200 dpi, 60 Hz	

The monitor is connected to the StealthStation® i7™ system rack using fiber optic cable which is terminated on site by Medtronic engineers. The fiber optic cable requires a conduit raceway which is installed by the owner. The raceway should be designed in conjunction with the architect, boom vendor, and site specialist. The raceway specifications are identified in a typical architectural layout located in Chapter 3 and in the conduit schedule located on page 3-4. Cable placement to and from the monitor must be performed by certified Medtronic engineers on site and in conjunction with the boom vendor. It is important to contact the site specialist and boom vendor for installation coordination before attempting to run fiber optic and power cabling through the monitor boom.

The touchscreen monitor can interface with a variety of booms. See Appendix A for compatible boom vendors. A 100 mm VESA monitor mount attachment is supplied with the Medtronic StealthStation® i7™ touchscreen monitor, and careful coordination is required with the boom vendor and the site specialist for installation requirements. The touchscreen monitor requires power cables to be run within the boom and installation should be coordinated by the architect, boom vendor, and site specialist. Power requirements for the monitor are listed below.

Input Voltage	U.S.A.	International
	110 to 120 VAC	220 to 240 VAC
	50 Hz to 60 Hz	50 Hz to 60 Hz
Maximum current allowed	5 A	2.5 A

⚠ **Warning:** Electrical design must meet the national and local electrical codes and final electrical design shall be provided by the owner's engineering consultant.

Camera

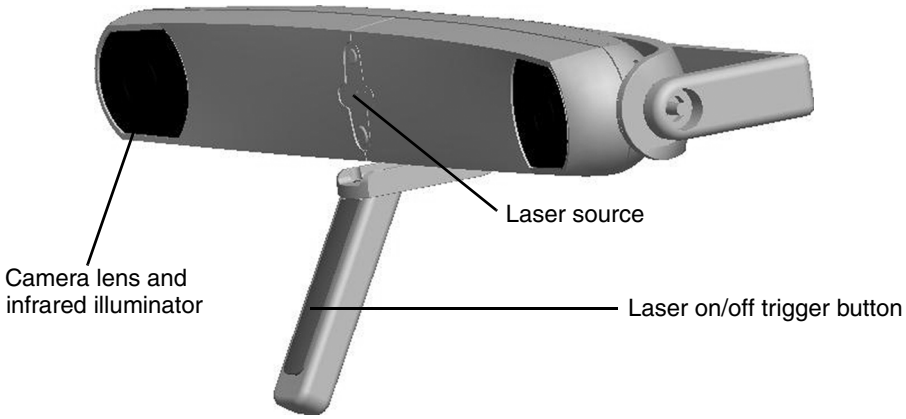

Figure 2-2. *System camera and laser positioning system*

The navigation system camera is boom mounted and strategically placed to maximize operating room work flow while using navigation. The camera emits infrared light to locate reference points required for navigation and the camera's line of sight needs to be considered during the planning stages of the project. Inadequate distance between the camera and the reference points or a diminished line of site may compromise navigation. Collaboration between the site specialist, surgical staff, and boom vendor is required to ensure that camera placement will provide adequate infrared coverage to achieve all of the procedures desired by the hospital staff. Camera weight is given below.

	Camera	
Weight without laser pointer and spindle adapter	~8 lbs	~3.6 kg
Weight with laser pointer and spindle adapter	~18 lbs	~8.2 kg

The camera can interface with a variety of booms. See Appendix A for compatible boom vendors. A specialized boom/camera spindle yolk is supplied with the Medtronic StealthStation® i7™ system. The camera requires connectivity with the Navigation Interface Unit which is typically located on the equipment boom. A conduit raceway is required to be run from the camera boom to the equipment boom containing the Navigation Interface Unit. The raceway should be included in the architectural drawings designed by the architect and site specialist. The raceway should be designed in conjunction with the architect, boom vendor, and site specialist. The raceway specifications are identified in a typical architectural layout located in Chapter 3 and in the conduit schedule located on page 3-4. Cable placement to and from the camera must be performed by certified Medtronic engineers on site and in conjunction with the boom vendor. It is important to contact the site specialist and boom vendor for installation coordination before attempting to run fiber optic and power cabling through the camera boom.

Navigation Interface Unit

Figure 2-3. *Navigation Interface Unit*

The Navigation Interface Unit (NIU) powers active optical instrumentation and communicates positional information about tracked instruments and patient reference frames to the system computer. The Navigation Interface Unit is typically placed on an equipment boom shelf and requires connectivity to the system rack (located in the equipment room) and the Navigation Relay Unit (located above the ceiling in the operating room).

A conduit raceway located in the interstitial space of the operating room is required from the boom supporting the Navigation Interface Unit to the system rack (max 100ft) and the Navigation Relay Unit. The Navigation Relay Unit must be placed within 3 feet of the boom supporting the NIU for connectivity. The raceway specifications are identified in a typical architectural layout located in Chapter 3 and in the conduit schedule located on page 3-4. Cable placement to and from the NIU must be performed by certified Medtronic engineers on site and in conjunction with the boom vendor. It is important to contact the site specialist and boom vendor for installation coordination before attempting to run fiber optic, signal, communication, and power cabling through the equipment boom.

The NIU is normally always on, but it must be powered off during intraoperative MRI scans. The power switch is located on the rear panel of the NIU. An SCU (Spectra Control Unit) reset switch is also located on the rear panel of the NIU. Push the reset switch to reset the system camera.

Dimension	Navigation Interface Unit	
Width	15.25 in	38.7 cm
Height	4.25 in	11 cm
Depth	17.5 in	44.5 cm
Weight	~18 lbs	~8.2 kg

Navigation Relay Unit

The Navigation Relay Unit (NRU) houses an isolation transformer and is the power supply for the Navigation Interface Unit (located on the equipment boom). The NRU is typically mounted above the operating room's ceiling on a support supplied by the owner and requires two Medtronic engineers for installation. Refer to the NRU installation guide (9734408) for complete installation instructions.

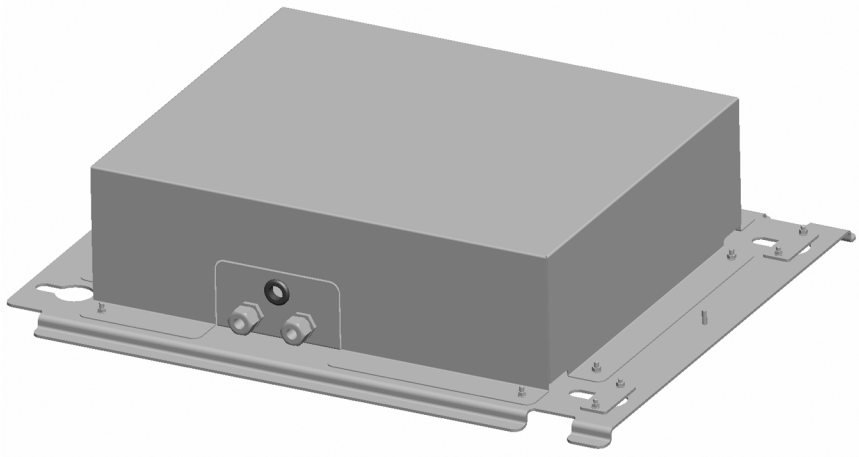

Figure 2-4. *Navigation Relay Unit*

Dimension	Navigation Relay Unit	
Width	22.5 in	57 cm
Height	6.75 in	17.2 cm
Depth	27 in	69 cm
Weight	~74 lbs	~33.6 kg

The architect must design ceiling access adequate for the installation and service of the Navigation Relay Unit (minimum 2 feet x 2 feet (60cm x 60cm)). Prior to the installation of the NRU, the interstitial space must be prepared to accept mounting of the unit. This entails the installation of proper infrastructure to support the additional weight in the ceiling using backing/unistrut designed by the owner's structural engineers and detailed in the architect's design. All backing/unistrut material is the responsibility of the owner and must be designed to meet the Navigation Relay Unit's connection plate specifications. The NRU connection plate (see Figure 3-2 for further details) is designed to attach to 1- 5/8 inches x 1- 5/8 inches (38.5mm x 38.5mm) unistrut channel and the Medtronic StealthStation® i7™ system is supplied with the proper channel nuts containing springs (1/2 inch (12.7 mm) thread size), bolts, and washers required for the installation.

The Navigation Relay Unit is not to be permanently attached to the backing/unistrut suspension. It is to slide over keyholes and install with safety latches to keep it secure to the backing/unistrut.

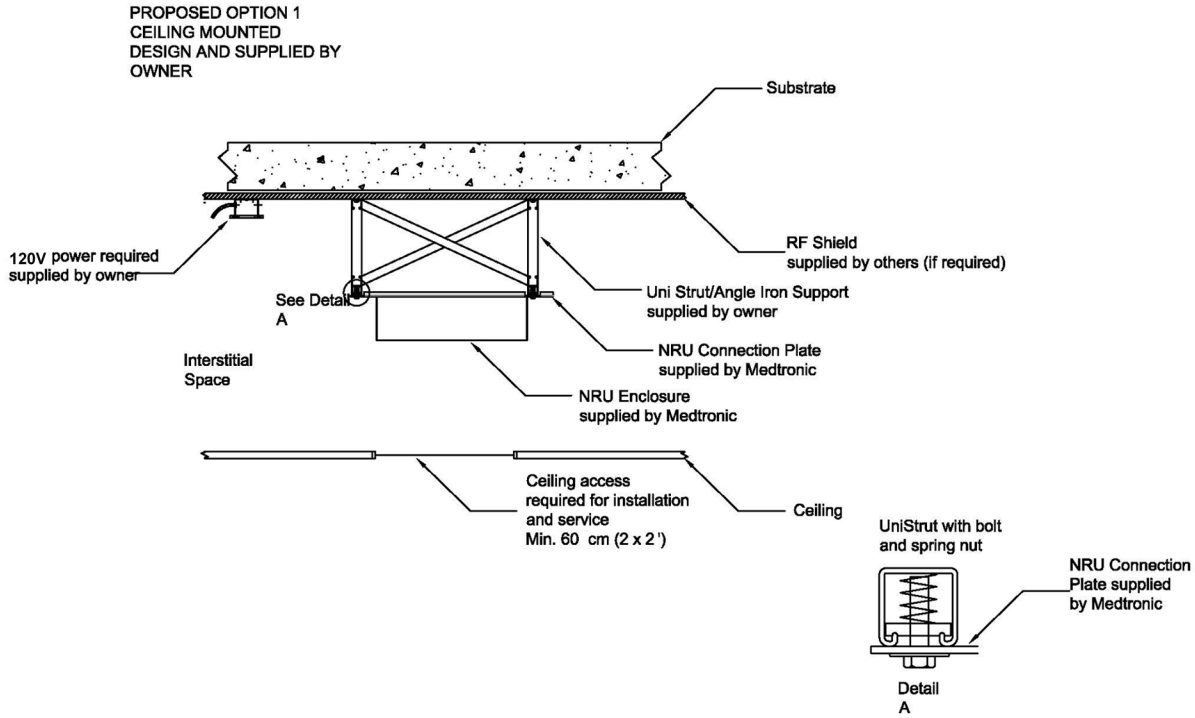

Figure 2-5. *Proposed detail for unistrut horizontally mounted NRU*

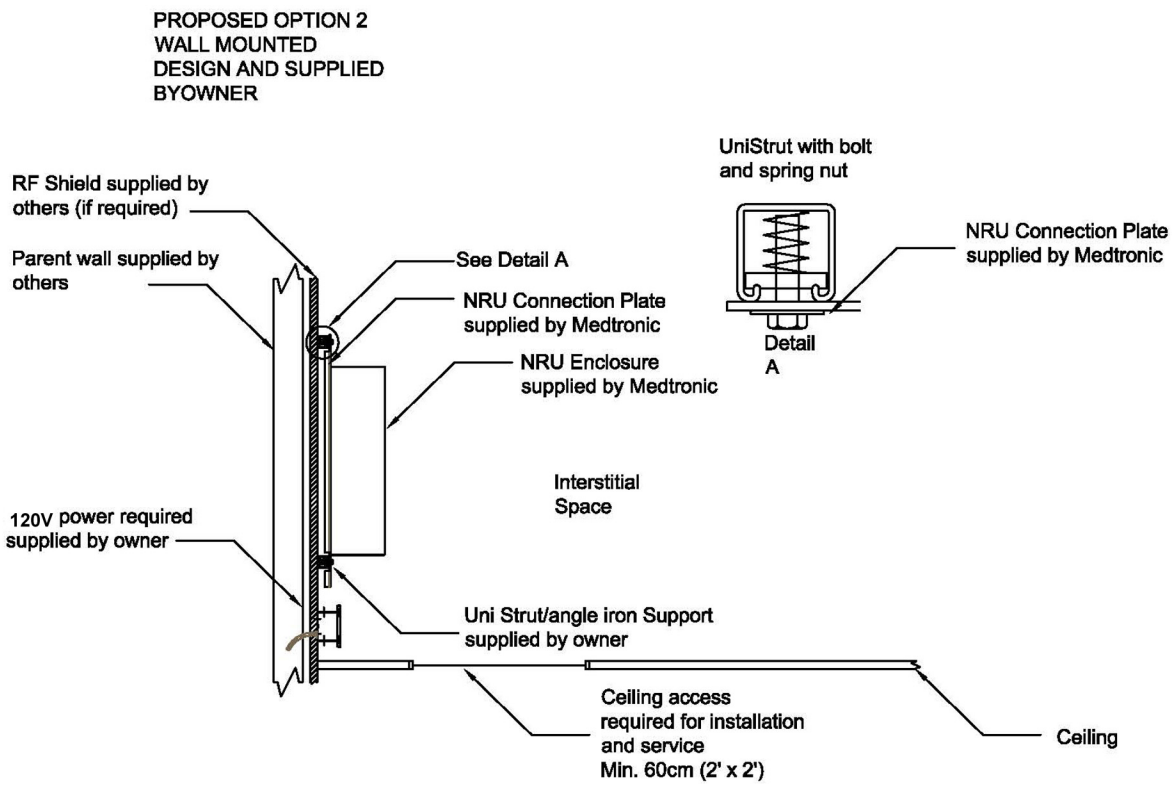

Figure 2-6. *Proposed detail for unistrut vertically mounted NRU*

A designated power circuit should be supplied to power the Navigation Relay Unit. The NRU must be located within 3 feet of the boom supporting the NIU to meet cable restrictions. The architect's design should place the power outlet in the interstitial space adjacent to the relay unit. In some cases to help meet the local codes, the StealthStation® i7™ system is supplied with a field wiring compartment and cabling kit containing a single gang box with1/2 inch (12.7mm) conduit connectors so that the owner's electrician can deliver power to the system. Power input specifications are given in the table below.

Input Voltage	**U.S.A.**	**International**
	110 to 120 VAC	220 to 240 VAC
	50 Hz to 60 Hz	50 Hz to 60 Hz
Maximum current allowed	5 A	2.5 A

⚠ **Warning:** Electrical design shall meet the national and local electrical codes and final electrical design shall be provided by the owner's engineering consultant.

The Navigation Relay Unit requires connectivity to the camera and Navigation Interface Unit. The cabling from the Navigation Relay Unit will require a conduit raceway supplied by the owner. The conduit raceway should be supplied to feed the connectivity from the Navigation Relay Unit to the boom that supports the camera (30 feet max.). The raceway should be coordinated with the architect, boom vendor, and site specialist. The raceway specifications are identified in a typical architectural layout located in Chapter 3 and in the conduit schedule located on page 3-4. Cable placement to and from the NRU must be performed by certified Medtronic engineers on site and in conjunction with the boom vendor. It is important to contact the site specialist and boom vendor for installation coordination before attempting to run fiber optic and power cabling through booms.

Desktop Monitors (optional)

The system computer (located in the Navigation Rack) has an additional video output allowing an additional Medtronic desktop monitor, keyboard, and mouse to be installed. Possible locations include operating suites designed with a nurse's work station (located inside the operating room) or an adjacent control room where the OR staff will perform surgical planning. The Medtronic site specialist will help the site to determine the optimum installation location of additional monitors.

The desktop monitor requires a power supply and a fiber optic raceway/conduit from the monitor's location to the Navigation Rack. The maximum distance between the Navigation Rack and the additional monitor is 70 feet (21.3m).

Cable Specifications

The StealthStation® i7™ system contains a series of fiber optic cables, power cables, and signal cables. Many of the cables will need to be pulled through the boom arms that are attached to the StealthStation® i7™ components. Installation is a collaborative effort between the general contractor, boom vendor, and the Medtronic site specialist. Medtronic's cable placement to and from the StealthStation® i7™ components must be performed onsite by certified Medtronic engineers in conjunction with the boom vendor. All field terminations are inspected and verified at the time of installation.

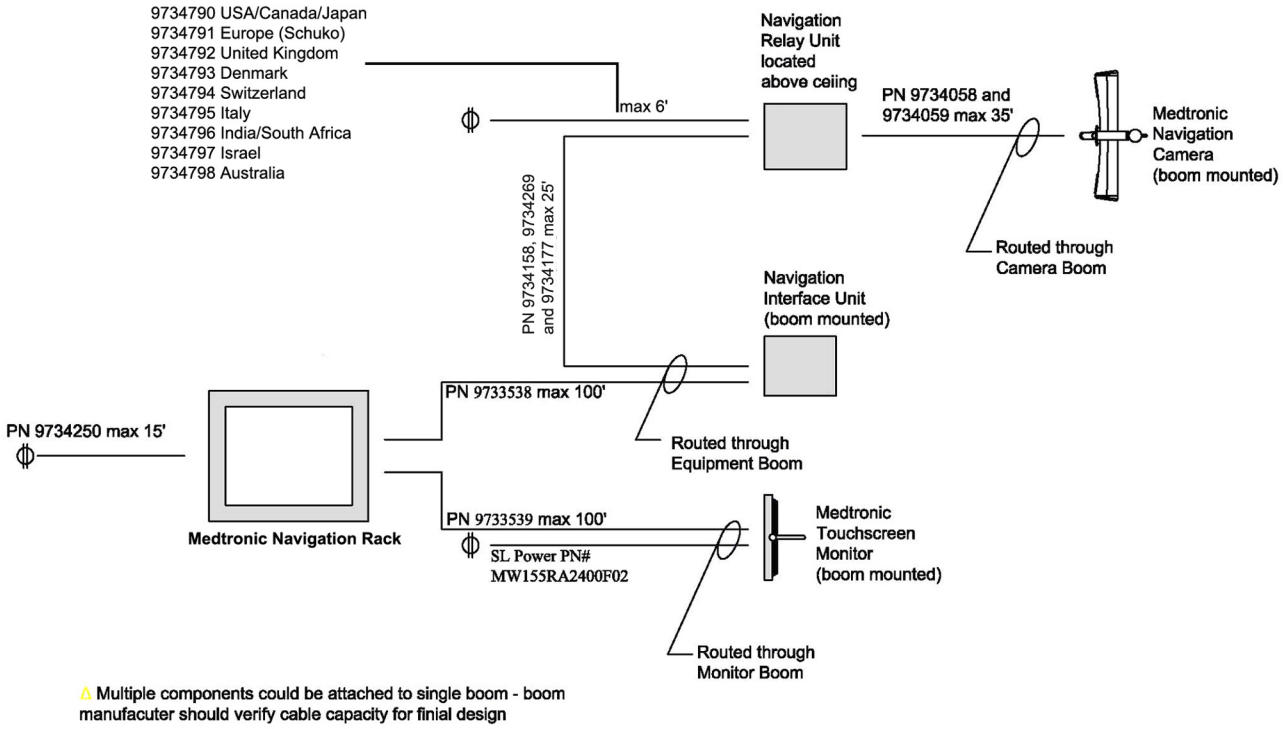

Figure 2-7. *Proposed cabling plan*

Cable Part Number	Maximum Length	Description
9734250	15ft (4.6m)	Power cable connects power input to the isolation transformer located in the system rack
9733538	100ft (30.5m)	Optical fiber provides signal connectivity from the system rack to the boom-mounted Navigation Interface Unit
9734158, 9734269, and 9734177	25ft (7.6m)	Signal, communication, and power cables provide connectivity to boom mounted Navigation Interface Unit and ceiling mounted Navigation Relay Unit
9734790 - 9734798	6ft (1.8m)	Power cable connects power input (located above ceiling) to the isolation transformer located in the Navigation Relay Unit
9734058 and 9734059	35ft (10.7m)	Signal cable provides signal connectivity from ceiling mounted Navigation Relay Unit to boom mounted navigation camera (PSU)
9733539	100ft (30.5m)	Optical fiber connects the system rack to the boom mounted navigation touchscreen monitor
SL Power PN# MW155RA2400F02	6ft (1.8m)	Power cable connects power input located on the boom (coordinate with boom vendor) to the boom mounted navigation touchscreen monitor

Site Requirements

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During the site planning process, the Medtronic site specialist works with the owner (hospital) to determine which requirements must be supplied for the proper installation of the StealthStation® i7™ system. This chapter describes some of the more common owner requirements.

Electrical

The Owner is required to provide the following power supplies:

- 120V for the Navigation Rack
  - Located immediately adjacent to the Navigation Rack
  - Connected to an emergency battery or backup generator power
  - Special image acquisition power requirements and/or filtering may be necessary for iMRI and should be coordinated with iMRI and shielding vendors
- 120V for touchScreen monitor
  - Power should be located above ceiling adjacent to the touchscreen monitor boom
  - Special image acquisition power requirements and/or filtering may be necessary for iMRI and should be coordinated with iMRI and shielding vendors
- 120V for the Navigation Relay Unit
  - Power should be located above ceiling adjacent to the Navigation Relay Unit
  - Ceiling access must be designed into the construction documents to ensure proper access for installation and service
  - Special image acquisition power requirements and/or filtering may be necessary for iMRI and should be coordinated with iMRI and shielding vendors
- 120V for desktop monitor (optional)
  - Power should be located adjacent to the monitor's location
  - Special image acquisition power requirements and/or filtering may be necessary for iMRI and should be coordinated with iMRI and shielding vendors

⚠ **Warning:** Electrical design shall meet the National and local electrical codes and final electrical design shall be provided by owner's engineering consultants.

Communication

Ethernet network connectivity is required for the navigation computer located in the Navigation Rack. The hospital will provide an IP address and enable a DICOM connection with the hospital's PACS system. A dedicated phone line should be made available for remote diagnostics. All connections should be installed directly behind the system rack for easy installation and service.

Ventilation

The navigation components should be ventilated to maintain an operating temperature between 64° - 84°F (17.8° - 28.9°C).

The StealthStation® i7™ system rack must have a 3 inches (7.6cm) minimum clearance from adjacent walls or other equipment to maintain proper computer ventilation and cable protection.

Cable Management

The owner is required to supply the appropriate conduit/raceways to supply the StealthStation® i7™ system's connectivity requirements throughout the operating suite. Specifications should be included in the architect's final design. Conduit should be a minimum of 1.5 inches (3.8cm) diameter with sweeping elbows only.

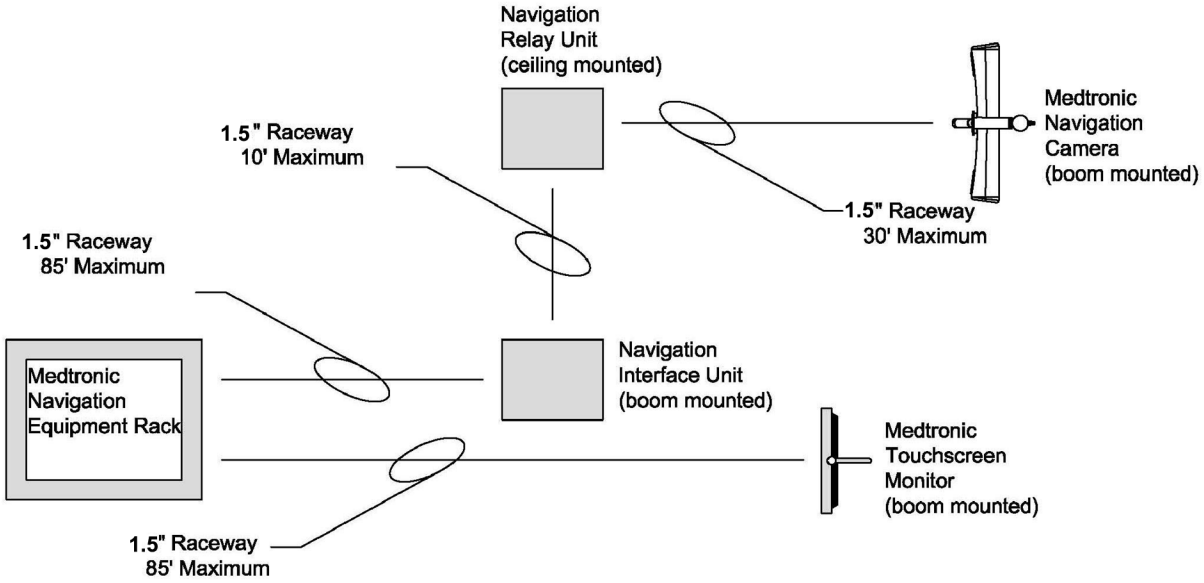

Figure 3-1. *Proposed conduit routing*

Item	Size	Conduit Schedule	Termination
1	1.5in (3.8cm)	Conduit should be installed between the location of the Navigation Rack and boom mount for the Navigation Interface Unit	From gang box located behind Navigation Rack (16 inches (40.6cm) O.F.F.) to daylight within 16 inches (40.6cm) of the boom mount for the NIU with insulated bushings
2	1.5in (3.8cm)	Conduit should be installed between the location of the Navigation Rack and the boom mount of the touchscreen monitor	From gang box located behind Navigation Rack (16 inches (40.6cm) O.F.F.) to daylight within 16 inches (40.6cm) of the boom mount for the touchscreen monitor with insulated bushings
3	1.5in (3.8cm)	Conduit should be installed between the location of the Navigation Relay Unit and boom mount for the camera	Daylight from 16 inches (40.6cm) of Navigation Relay Unit to within 16 inches (40.6cm) of the boom mount for the camera with insulated bushings
4	1.5in (3.8cm)	Conduit should be installed between the location of the boom mount for the Navigation Interface Unit and the Navigation Relay Unit	Daylight from 16 inches (40.6cm) of boom mount for the Navigation Interface Unit to within 16 inches (40.6cm) of the Navigation Relay Unit located in the ceiling

If the Medtronic StealthStation® i7™ system is going to be integrated with an intraoperative magnetic resonance imaging machine, any penetration through the RF shielding should be designed by the shielding vendor. The shielding vendor is responsible for any wave guides or special filtering for required power or penetrations entering the shield room. The design of the integrated navigation system within the iMRI suite should be coordinated with the architect, general contractor, shielding vendor, iMRI vendor, boom vendor, AV vendor, and the Medtronic site specialist.

Structural Support for the Navigation Relay Unit

The owner is required to supply the appropriate support structure for the Medtronic StealthStation® i7™ system's Navigation Relay Unit. The NRU is typically located in the interstitial space above the operating room ceiling. The StealthStation® i7™ components include a connection plate (Figure 3-2) that requires a support structure (typically unistrut). Specifications for NRU placement design and installation should be identified in the architectural construction documents.

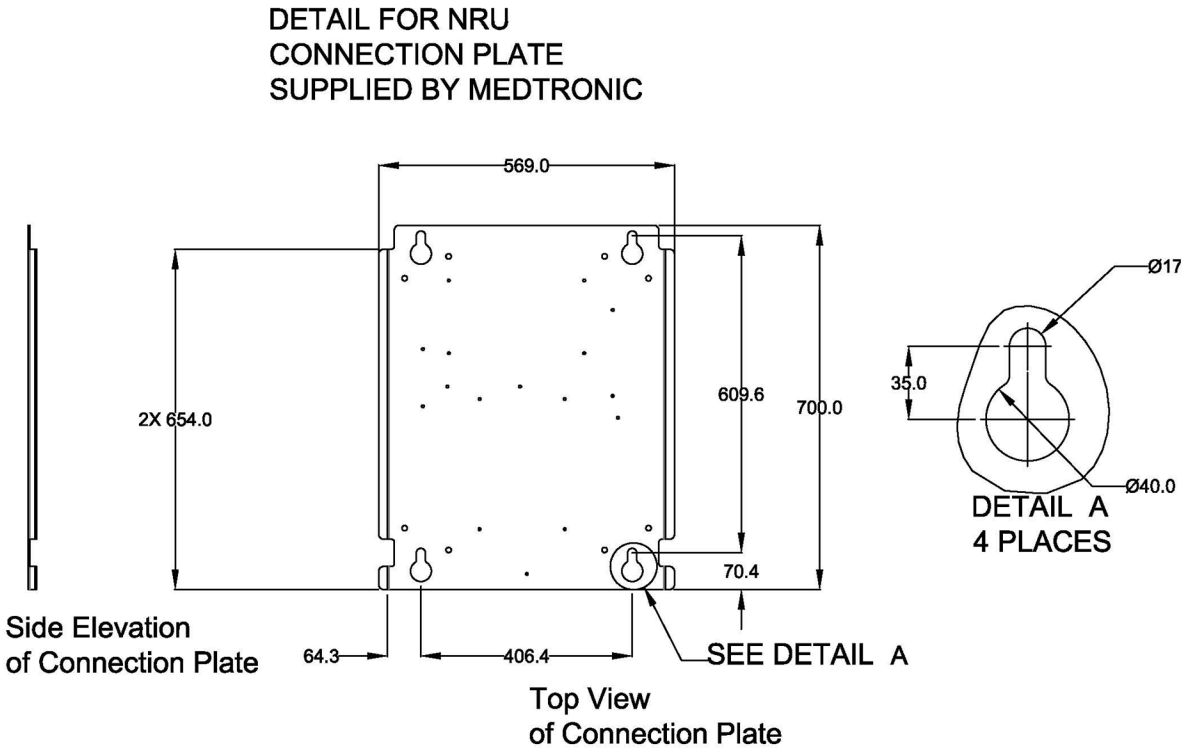

Figure 3-2. *NRU Connection plate details (units in mm)*

The Navigation Relay Unit is designed to accommodate a unistrut support structure for horizontal (Figure 3-3) or vertical (Figure 3-4) placement. The final design for the NRU's placement is dictated by the interstitial environment and the layout of the operating room. The NRU support structure placement design and installation is coordinated with the architect, general contractor, and the Medtronic site specialist.

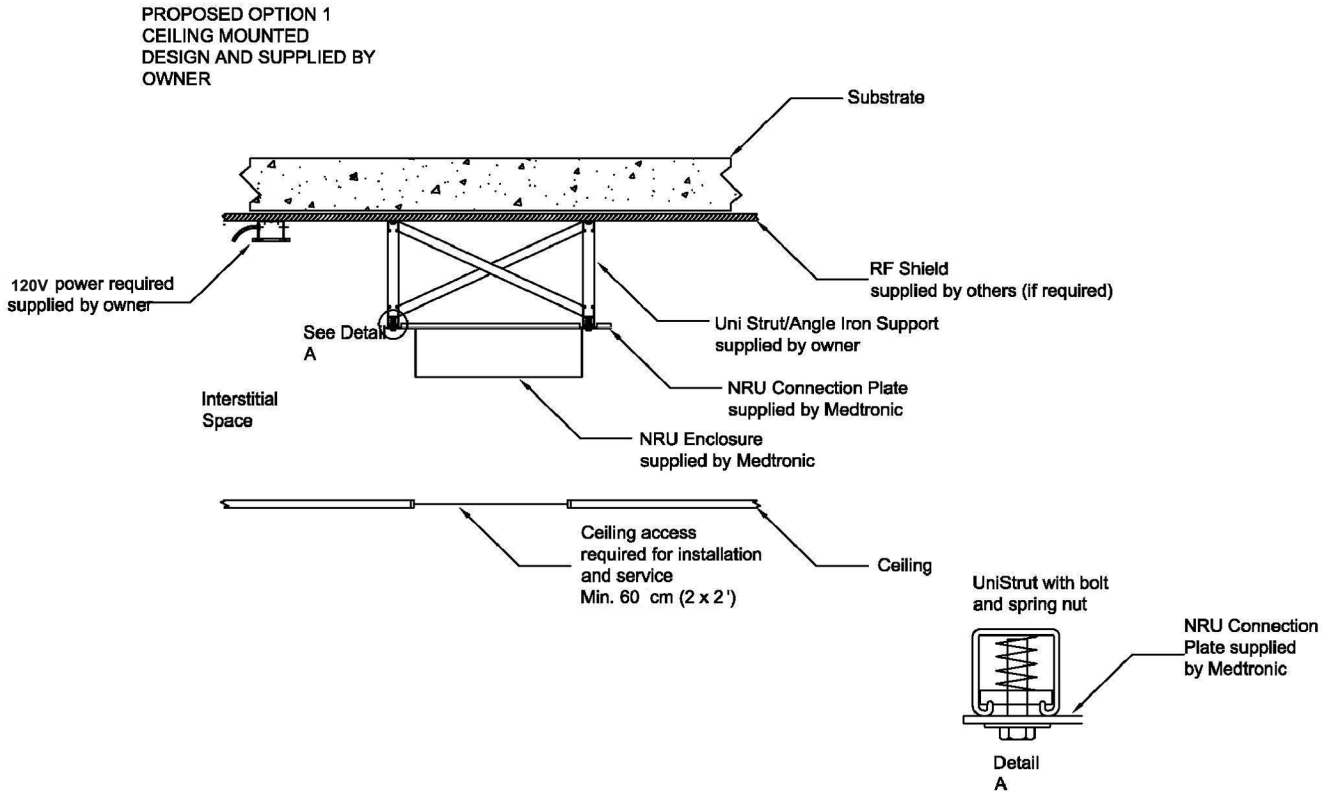

Figure 3-3. *Proposed detail for NRU horizontally mounted support*

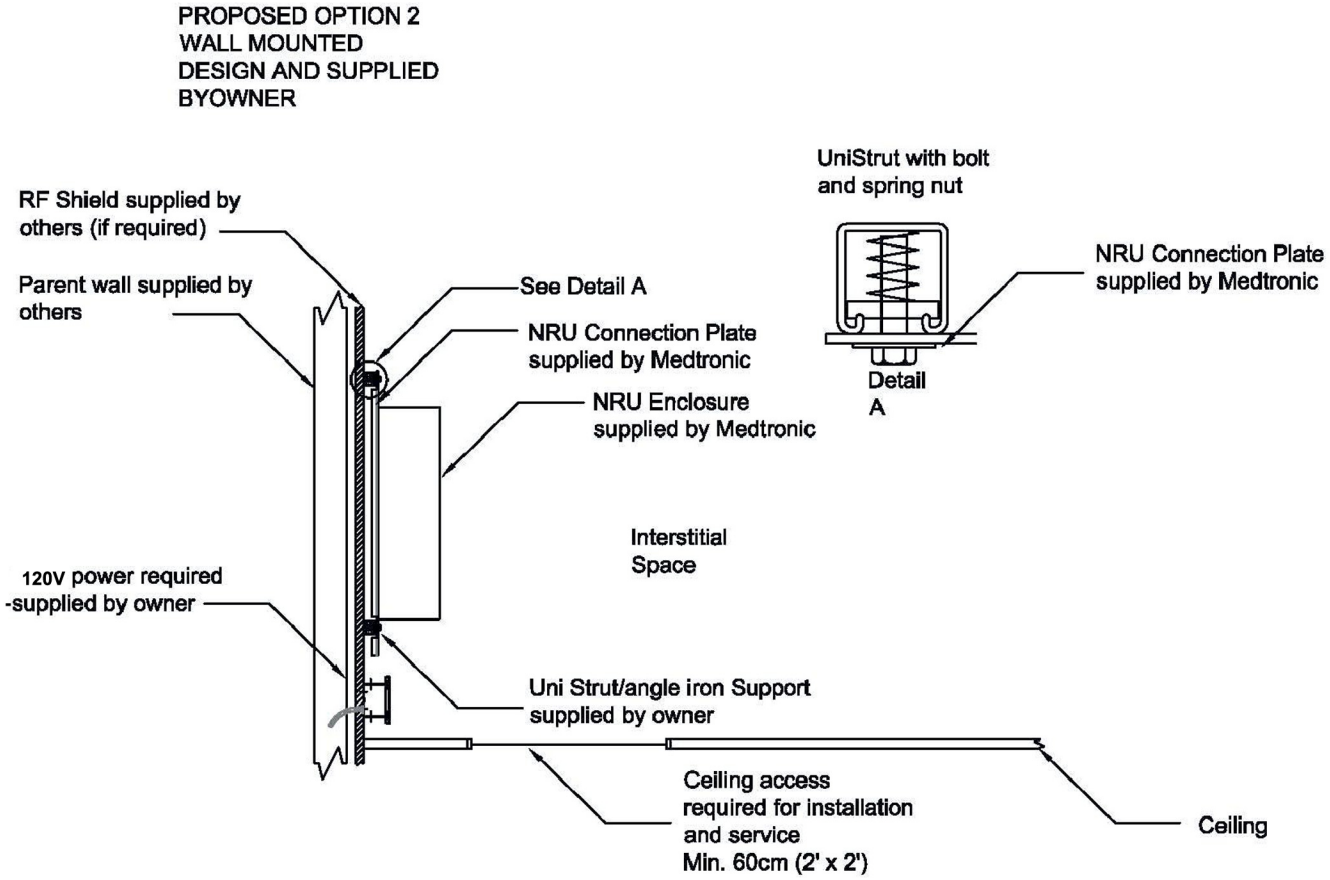

Figure 3-4. *Proposed detail for NRU vertically mounted support*

Typical Architectural Layout for StealthStation® i7™ Components

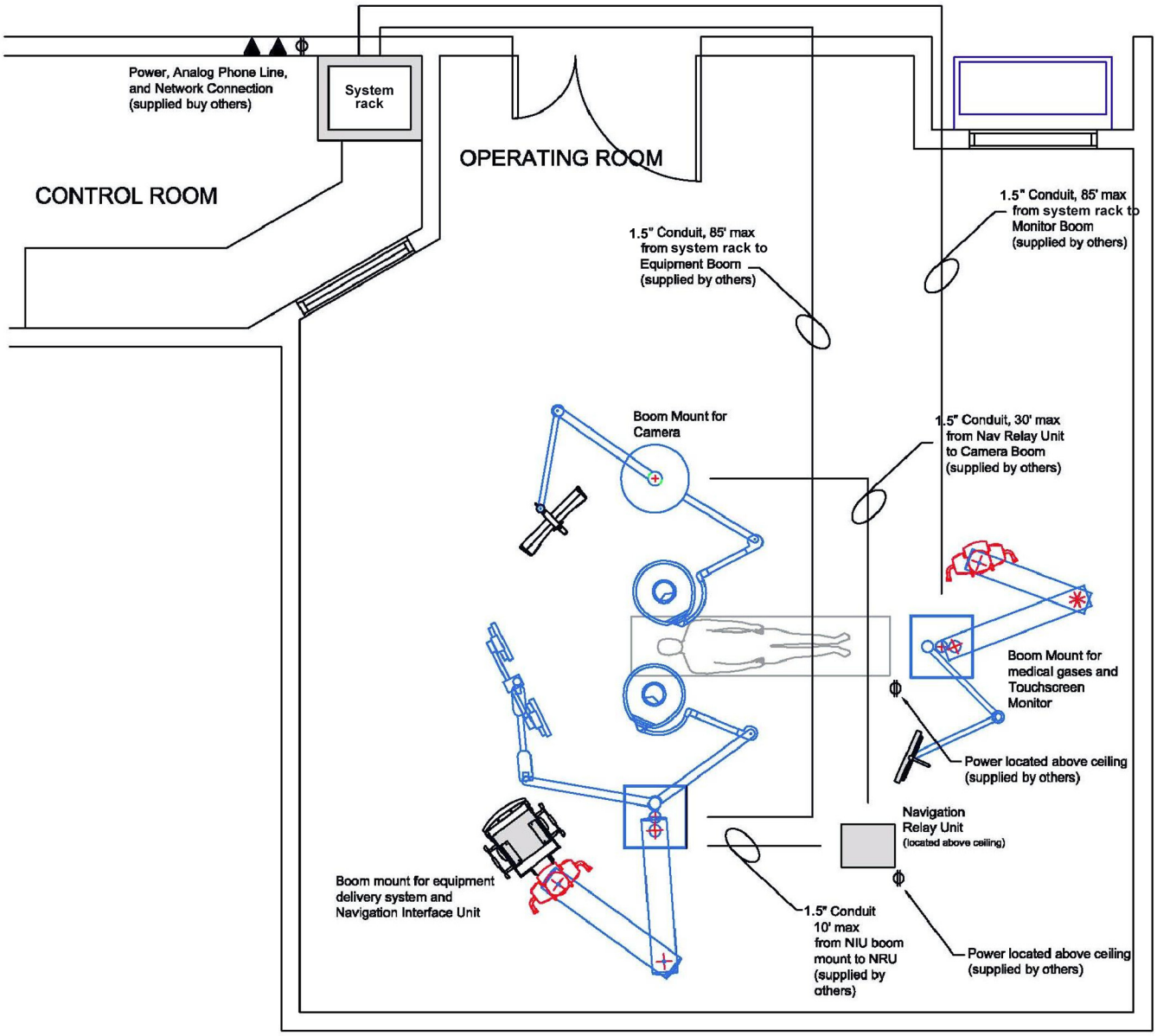

Figure 3-5. *Generic architectural layout*

Navigation Component Swing Radius

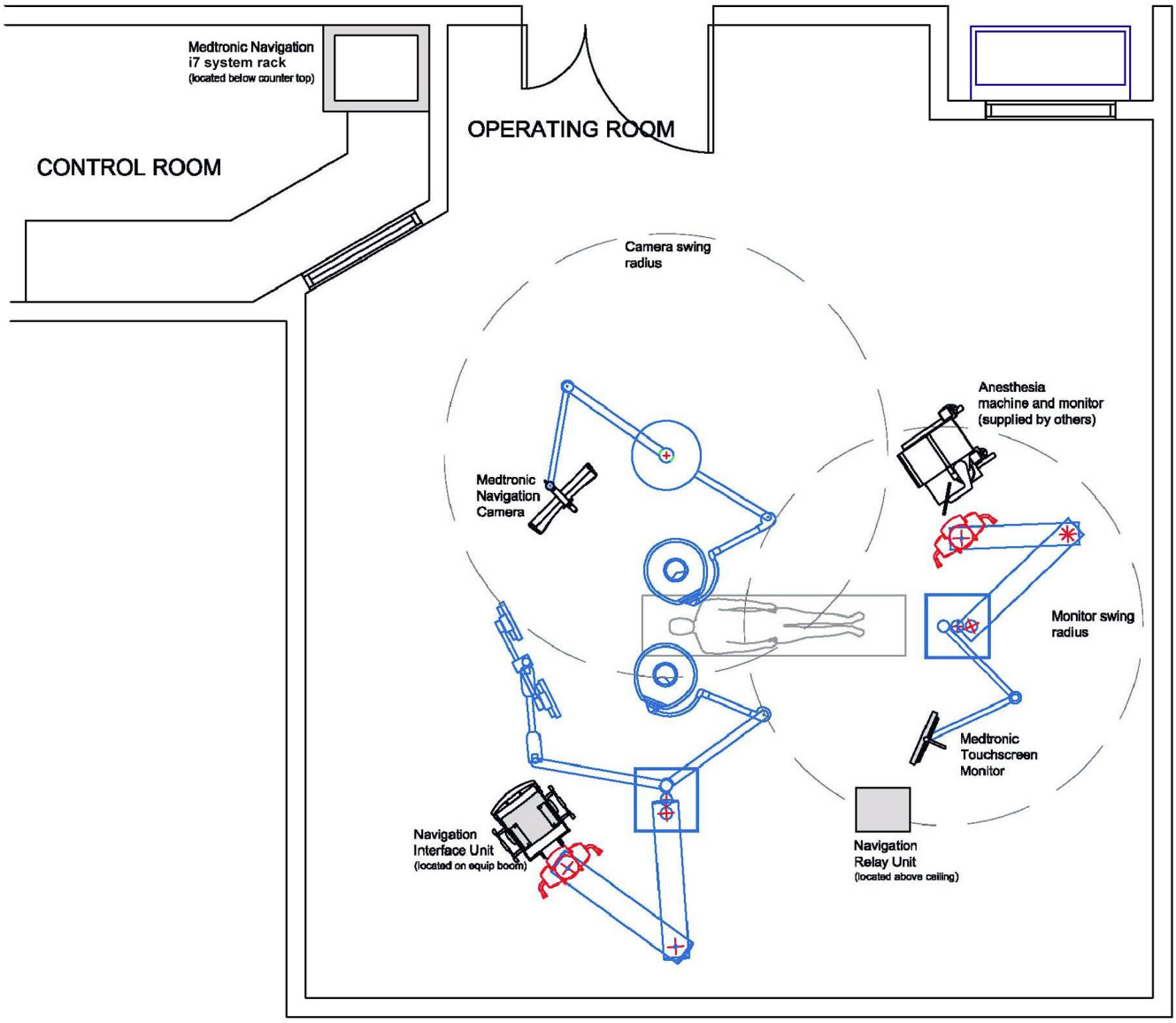

Figure 3-6. *Generic layout with component swing radii*

Boom Vendors

A

Boom Vendors

Booms manufactured by the following companies have been qualified for use with StealthStation® i7™ system navigation system components.

- BERCHTOLD Corporation
  www.berchtoldusa.com
- KLS-Martin, L.P.
  www.klsmartin.com
- SKYTRON® Corporation
  www.skytron.us
- STERIS® Corporation, LC and LA
  www.steris.com
- Stryker Corporation
  www.stryker.com
- TRUMPF Medical Systems, Inc.
  www.trumpf.com
- Draeger Medical, Inc.
  www.draeger.com
- Maquet Inc. (Getinge Group)
  www.maquet.com

Rack Options

B

Rack Options

Proposed Specifications for an Owner-Supplied Equipment Rack Cabinet Shell for the StealthStation® i7™ System Computer Components

The hospital has an option to supply the equipment rack cabinet shell or shelves if they choose to utilize an existing cabinet, are required to match existing cabinets, or the overall floor plan requires a double rack configuration if two StealthStation® i7™ systems will be located in the same equipment room. If the hospital chooses to provide the computer rack shell or shelves, then the space must meet the following specifications.

- For a single StealthStation® i7™ computer system configuration, the cabinet space must meet the specifications for, or be an approved equivalent of Middle-Atlantic MRK-XX31 (rack must be at least 31" in depth and have 12 consecutive spaces available.

  http://www.middleatlantic.com/enclosure/gang/mrkg.htm

- For a double-stacked StealthStation® i7™ computer system configuration, the cabinet space must meet the specifications for, or be an approved equivalent of Middle-Atlantic MRK-2431 (rack must be at least 31" in depth and have 24 consecutive spaces available.

  http://www.middleatlantic.com/enclosure/gang/mrkg.htm

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