TREON® Treatment Guidance System System Manual

Part Number 9680169, revision 10

A Guide to Understanding the TREON® Treatment Guidance System

Read this manual completely prior to using this device.

CE 0123

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Explanation Of Symbols On Package Labeling

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

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.
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.

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 (typically energizes the Isolation Transformer and UPS).

Power off for part of the system.

Freeze caster

Lock caster angle

Use by date specified

Single use only. Do not reuse.

Quantity

Sterilized by ethylene oxide

Non-sterile

Protective Earth (Ground)

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

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

Description of the Treon® Treatment Guidance System

The Treon® Treatment Guidance System is a hardware platform that enables real-time surgical navigation using radiological patient images. The application software reformats patient-specific CT or MR images acquired before surgery and displays them on-screen from a variety of perspectives (axial, sagittal, coronal, oblique). Prior to operating, the surgeon may then create, store, and simulate progression along one or more surgical trajectories. As an aid to visualization, the surgeon may also 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.

If desired, the application software can also show how the actual position and path during surgery relate to the pre-surgical plan, and can help guide the surgeon along the planned trajectory. While the surgeon's judgement remains the ultimate authority, real-time positional information obtained through the Treon® Treatment Guidance System can serve to validate this judgement as well as guide.

This system manual is intended as a reference document for biomedical engineers or other qualified personnel who require familiarity with and details about the Treon® Treatment Guidance System. This manual is not a software usage manual. For complete instructions on using a specific software application, refer to the specific application's instructions for use (pocket guide).

Content of This Manual

This system manual is intended as a reference document for users who require familiarity with and details about the Treon® Treatment Guidance System. This manual is not an application usage manual. For complete instructions on using a specific software application, refer to the specific application pocket guide.

Related Documents

Consult application-specific pocket guides for software application instructions. Consult instrument -specific package inserts for instrument instructions. Consult the Medtronic Navigation Equipment Cleaning and Sterilization sheet (pn 9730713) for equipment and instrument cleaning and sterilization instructions.

Refer to manufacturer's guides for information on peripheral devices.

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.

♦

- Procedures are preceded by diamond symbol at left.
- References to buttons that appear on the system display are enclosed in square brackets. For example:

  Click the **[Edit...]** button.

- References to menu options that appear on the system display are printed in bold letters. For example:

  Choose **Clear** from the list.

- Instructions to click an object on the screen means to tap the object on the touchscreen with your finger or some other blunt object. Alternatively, it means to place the pointer over the object using the system mouse, and depress and release the left mouse button. Click, Select, and Highlight are used interchangeably.
- Right-click means click with the right mouse button instead of the left button.
- Double-click means click twice in rapid succession.

Intended Use

Your Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.

Contraindications

Medical conditions which contraindicate the use of a Medtronic computer-assisted surgery system and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

Warnings and Precautions

⚠ **Warnings:**

- The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained and experienced in performing surgery with Medtronic computer-assisted surgery systems.
- The system and its associated applications should be used only as an adjunct for surgical guidance. They are not a replacement for the surgeon's knowledge, expertise, or judgement.
- If system navigation seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.
- Accessory equipment connected to the analog and digital interfaces of the Medtronic computer-assisted surgery system must be certified according to the respective IEC standards (e.g. IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, contact technical support or your local representative.
- The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide. Position the system at least 25cm from any source of flammable gas.
- Some system components may contain batteries. Do not recharge or disassemble batteries. Do not dispose of batteries in fire. Observe local regulations concerning battery disposal.
- Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.
- There is currently no effective sterilization method for components that are tainted with the infectious agent that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this infectious agent. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.

△ **Precautions:**

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact a technical support representative.
- Verify that all relevant instrumentation has been properly cleaned and sterilized before surgery. Clean and sterilize the components according to the parameters in the Equipment Cleaning and Sterilization sheet (pn 9730713). Clean non-sterilizable equipment according to the parameters in the Non-Sterilizable Equipment Cleaning sheet (pn 9733025).
- The system has been successfully tested against the requirements of IEC 60601-1-2. However, RF interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with an RF barrier, or discontinue use of the system.
- Do not exceed the recommended electrical ratings for the system. Exceeding the ratings could damage the system.
- The system mouse is not designed for sterilization, and may be damaged if sterilization is attempted.
- System components are fragile. Use care when handling system components.
- Before moving the system cart(s), shut down all components, remove any loose items from the top of the cart(s), and dock the carts together (if applicable). To avoid contaminating the inside of the cart(s), clean the power cord(s) before retracting.
- Cart storage drawers have a maximum load capacity of ten pounds each.

Contact Information

Telephone

(800) 595-9709 (technical support)

(720) 890-3200 (general)

(720) 890-3500 (fax)

Regular Mail

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

Medtronic E.C. Authorized Representative

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
NETHERLANDS
Tel. 31 45 566 80 00

World Wide Web

www.medtronicnavigation.com

E-mail

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

System Overview 2

How the System Works

The Treon® Treatment Guidance System creates a **translation map** between all points in the patient images and the corresponding points on the patient anatomy. After establishing this map, whenever the operator touches a point on the patient using a special tracked instrument or pointing device, the computer uses the map to identify the corresponding point on the images. This identification is called **navigation** or **localization**. A localized point is identified on the system display within multiple patient image planes and other anatomical renderings.

Optical System

The system determines the position of the instrument and patient in the operating room by using a camera to track the positions of **optical markers** affixed to them. In the case of instruments, the markers are attached directly to the instrument body. In the case of the patient, the markers are attached to a **dynamic reference frame** which you connect to a support mechanism secured to the patient anatomy.

There are two types of optical markers. Some components may have **LED** optical markers, and others may have **sterile spheres**. LEDs (Light Emitting Diodes) generate and emit infrared light. Sterile spheres reflect infrared light that is emitted by the camera.

The camera (sometimes called the **localizer**) detects the optical markers, determines their spatial positions using the principle of triangulation, and continuously reports this information to the computer. The computer uses this spatial information, in conjunction with information regarding the geometry of the instrument currently in use, to determine exactly where the tip of the instrument is located on the patient anatomy.

Dynamic Referencing

To maintain accuracy, the system must continuously track the position of the anatomy during registration and navigation. This is necessary because you may accidentally or unavoidably move the anatomy or Localizer after patient registration or image acquisition. If the system did not track the position of the anatomy via the dynamic reference frame, any movement of the patient or Localizer after registration or image acquisition would result in inaccurate navigation.

The device that allows you to register and then track the anatomy is called a patient reference frame. The reference frame is of a set of optical markers mounted on a metal frame that can be rigidly positioned with respect to the patient anatomy. Because the reference frame sits in a rigid, fixed position with respect to the anatomy, any movement of the anatomy or the camera results in corresponding movement of optical markers in the camera's field of view. This enables the camera to detect any movement of the anatomy and alert the application software, which updates the registration correlation and thereby maintains accurate navigation.

Without dynamic referencing, any movement of the camera after registration would invalidate the registration, since the positions of the optical markers would change in the camera's field of view. So, dynamic referencing also gives you the flexibility to reposition the camera at any time.

Each application has its own unique reference frame. Consult the application's instructions for use (pocket guide) for more information.

⚠ **Warning:** Because the position of the anatomy is defined by the position of the Reference Frame, it is important to ensure that the frame does not move with respect to the anatomy from the time of registration until navigation is complete. Slippage or rotation of the Reference Frame with respect to the anatomy after registration will result in inaccurate navigation.

Camera

The system camera uses two lenses to geometrically triangulate the spatial coordinates of each optical marker on the instrument and Reference Frame. In the case of cabled devices (such as the active registration probe), the camera lenses receive infrared light signals directly from the LEDs on each device. In the case of passive (wireless) devices, the passive spheres on each device reflect light emitted by infrared illuminators on the camera back into the camera lenses. The camera continuously communicates the location of each LED or passive sphere to the system. In order to effectively "see" the LEDs or passive spheres, the camera must be aimed toward the devices and positioned at the proper distance from them.

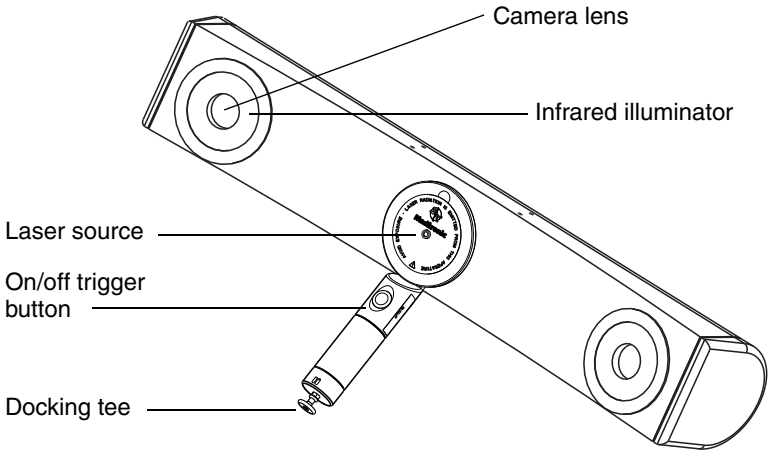


Figure 2-1. *System camera and laser positioning system*

♦ *To dock the camera and its boom:*

1. Rotate the camera boom and arms such that they align with their respective tick marks (the tick marks indicate the "home position" for the joints.
2. Swivel the post until the arm lock audibly clicks into place.
3. Align the docking tee of the laser handle with the camera docking port and snap into place.

Laser positioning system

⚠ **Warning:** The laser positioning system transmits laser radiation. Use caution when operating the device, and never allow the laser beam to enter someone's eye. Laser radiation, even at low levels, can damage the eyes.

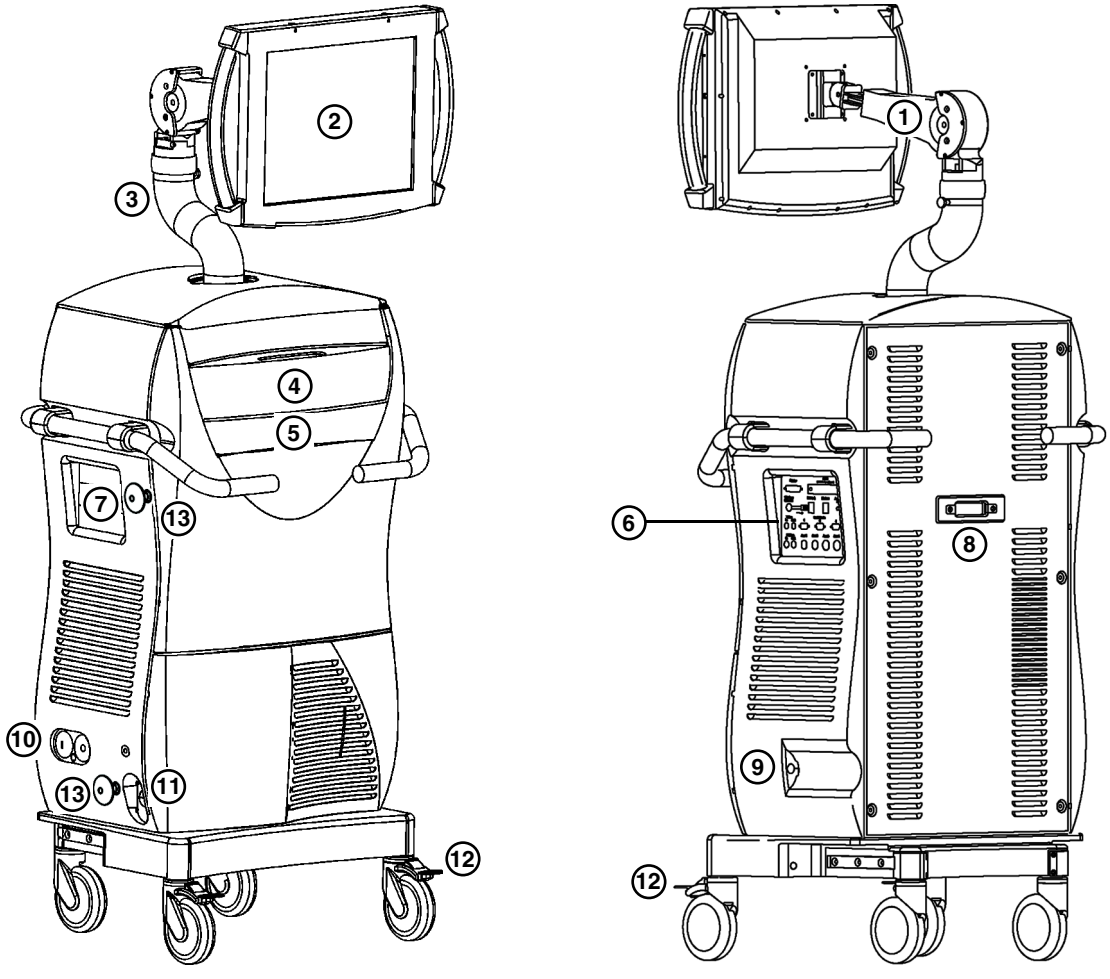
The laser positioning system (located between the camera lenses) helps approximate the correct camera aim by projecting a low-power laser beam along the center of the camera's field of view. The laser is activated by a trigger button in the handle. Depress the on/off trigger button to activate the laser, and release the button to deactivate the laser.

System Carts

The Treon® Treatment Guidance System has two separate but complementary carts; the **Viewing Cart** and the **Nav Cart**. The carts may be docked together as a single unit, or separated for positional flexibility and convenience during surgery. The system carts are suitable for continuous operation.

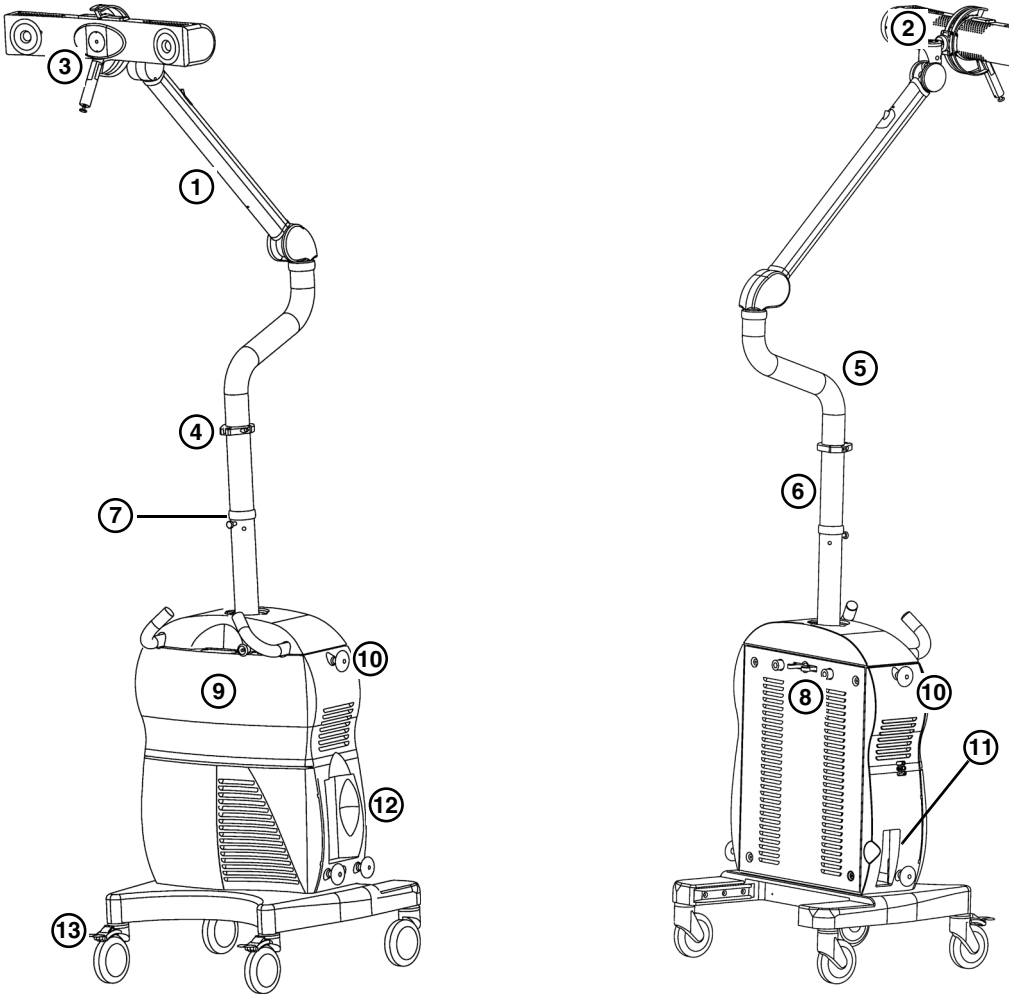
The Viewing Cart contains the power supply, computer, and all related peripheral devices (see Figure 2-2). The Viewing Cart can be used as a stand-alone surgical planning station.

The Nav Cart acts as the base for the camera and contains the Tool Interface Unit (TIU) and a storage drawer. The Nav Cart is connected to the Viewing cart via a communication cable which also supplies the necessary power for the camera and the TIU. See Figure 2-3.



1. Articulating Arm
2. Touchscreen
3. Chicane
4. Storage Drawer
5. Keyboard/Mouse Drawer
6. System Side Panel
7. Media Bays
8. Cart Docking Mechanism
9. Cart Communication Cable Connection
10. On/Off Switch
11. Power Cord Outlet
12. Caster Locks
13. Cable Wraps

Figure 2-2. *Viewing Cart exterior front and back*



1. Camera Boom
2. Camera
3. Laser Pointer
4. Camera Docking Port
5. Chicane
6. Post
7. Post Lock
8. Cart Docking Mechanism
9. Storage Drawer
10. Cable Wraps
11. Cart Communication Cable
12. Breakout Box
13. Caster Locks

Figure 2-3. *Nav Cart exterior front and back*

Input/Output Panel

The right side of the cart contains a side panel with external connection ports for various input and output devices.

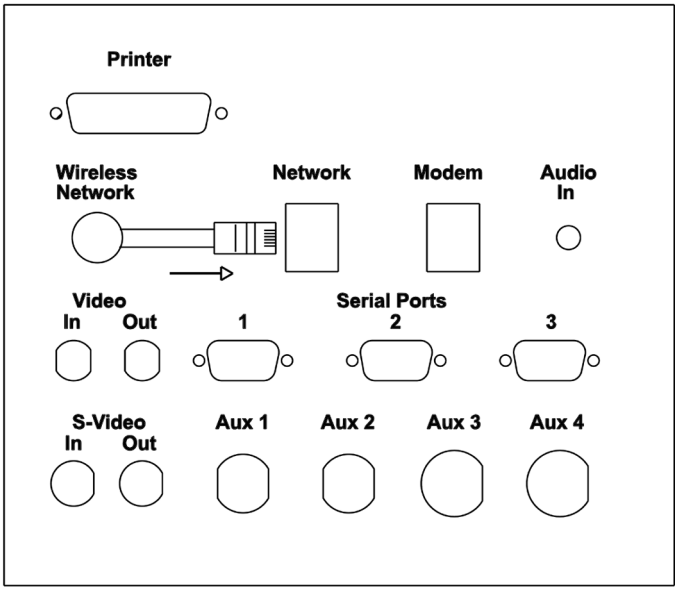


Figure 2-4. *System I/O panel*

Side panel connectors

Printer: Connects the system to a printer.

Network: Connects the system to the site Local Area Network (LAN).

Modem: Connects the system modem to an external telephone line.

Audio In: Connects the system to an audio input device such as a microphone.

Video In: Connects the system video input board to the composite video output of an external source.

Video Out: Connects the system video output to the composite video input of an external source.

S-Video In: Connects system video input to the S-VHS video output of an external source.

S-Video Out: Connects system video output to the S-VHS video input of an external source.

Serial Ports 1-3: Connects the system to external serial devices.

AUX 1-4: These ports are accessory ports for system expansion and are normally empty.

Wireless Network: Feature pending future development. When enabled, will connect the system to the site wireless network (where applicable). A network jack protruding from the Wireless Network Port connects to the Network connector. If the wireless network connection is interrupted, simply remove the Wireless Network jack and plug the Local Area Network into the Network connector.

Touchscreen Monitor

The touchscreen monitor is a high-resolution, flat panel computer display with built-in speakers. The display is visible at angles up to 80° from perpendicular. When placed in the surgical field, the touchscreen allows the physician to control the system without the need for an assistant, keyboard, or mouse. To select an item on the screen, tap the item with the sterilized stylus. For any software fields that require text entry, a virtual keyboard will appear on-screen with buttons that can be touched like a typewriter.

♦ *To dock the monitor:*

1. Adjust (push down) the articulating arm such that the arm button is in the lock position. There will be an audible click when the arm locks.
2. Adjust the monitor arm such that it is in the lock position. The lower elbow of the chicane will be at its closest point to the back of the system cart.
3. Rotate the monitor such that the face is pointing down.
4. Push the monitor down toward the back of the cart.

Keyboard and Mouse

Although the touchscreen eliminates the need for a keyboard and mouse, a keyboard and mouse are provided in the cart's lower storage drawer for use in certain circumstances. The drawer also features a built-in mouse tray.

Breakout Box

The Breakout Box acts as a junction box for various hardware devices, like the footswitch, reference frame, 3-marker probe, and 4-marker probe. The breakout box does not contain any user-serviceable parts.

Figure 2-5. *Breakout box*

The breakout box can hook onto the operating room bed rail or the Nav Cart. During transportation and storage, attach the breakout box to the lower right hand side of the Nav Cart.

♦ ***To attach the breakout box to the Nav Cart:***

1. Align the posts on the breakout box with the slots on the side of the cart.
2. Firmly push the posts into the slots.

Optical Instruments

Instruments designed for use with the Treon® Treatment Guidance System have a precise instrument geometry and LED/sphere configuration. The specific geometry of each instrument is stored in a file to which the computer refers to determine where the tip of the instrument is located in relation to the instrument LEDs or spheres. Before you begin navigating, you must tell the computer which instrument you have chosen to use.

When you select the instrument you will use from the probe list in the application software, the system will expect you to **verify** that the instrument you have chosen is not bent or otherwise damaged. You do this by placing the tip of the instrument into a metal divot on the reference frame and pressing the footswitch. The camera and computer then confirm that the instrument you are using matches the specifications for the instrument you have selected in the software.

System Specifications

The specifications listed apply to system operation under typical conditions.

Table 2-1. *StealthStation Equipment Specifications*

	United States	International	Japan
Operating Temperature	64° to 92°F	18° to 33°C	18° to 33°C
Shipping and Storage	-40° to 150°F	-40° to 65°C	-40° to 65°C
Input Voltage	110 to 120 VAC	220 to 240 VAC	100 VAC
	50 Hz to 60 Hz	50 Hz to 60 Hz	50 Hz to 60 Hz
Maximum Current Allowed	5 A	2.5 A	5 A
Typical Power Dissipation	500 V-A	500 V-A	500 V-A
UPS	5 minutes autonomy	5 minutes autonomy	5 minutes autonomy
Relative Humidity	10% to 80% Non-Condensing	10% to 80% Non-Condensing	10% to 80% Non-Condensing
Monitor Dimensions	15.5”H x 22.5”W x 4.25”D	39.5 cmH x 57 cmW x 11 cmD	39.5 cmH x 57 cmW x 11 cmD
Monitor Weight	20 lbs	9 kg	9 kg
Monitor Display *	Screen pitch = 0.28 mm, resolution = 1280 x 1024 dpi, 60 Hz		
Navigation Cart Footprint	24” x 28”		61 cm x 71 cm
Navigation Cart Weight	180 lbs		82 kg
Viewing Cart Footprint	23” x 23”	58.5 cm x 58.5 cm	58.5 cm x 58.5 cm
Viewing Cart Weight	330lbs	150 kg	150 kg

* Additional monitors connected to the system which are not provided by Medtronic, must meet a minimum resolution requirement of 1280 x 1024 dpi. The user assumes the responsibility of verifying that the visual quality of the attached monitor is equivalent to or better than the monitor(s) supplied by Medtronic.

System Classifications

Table 2-2. *General StealthStation® System Classifications*

Agency	System Rating
European Medical Device Directive 93/42/EEC	Class IIa according to Rule 6, Annex IX
FDA Medical Device 21 CFR 882.4560	Class II
Electrical Safety Classification IEC 60601-1/UL 60601-1/ CAN/CSA-C22.2 No. 601.1-M90+S1 (1994)+A2 (1998)	Class I, continuous operation with BF applied parts
Electromagnetic Emissions Compatibility, IEC 60601-1-2	Class A, Group 1

Table 2-3. *Water Ingress Classifications*

Component	Water Ingress Classification
System (both carts)	IPX0 (not protected)
AxiEM™ System box	IPX0 (not protected)
Breakout box	IPX0 (not protected)
Camera	IPX0 (not protected)
Footswitch	IPX8 (water tight)

System Electromagnetic Emissions and Immunity Declarations

Table 2-4. *Guidance and Manufacturer's Declaration - Cables, Transducers, and Accessories*

The listed cables, transducers, and accessories have been determined by Medtronic to be compliant with the emissions and immunity requirements of IEC 60601-1-2: 2001.			
Medtronic Part Number	**Description**	**Max. Possible Length (m)**	**Shielded (Y/N)**
System Equipment			
9680159	Camera, Position Sensor Unit (PSU)	NA	NA
9731117, 9732610, 9732611, 9731118, or 9732309	Monitor, 19”	NA	NA
1130700120	Monitor and Camera Ferrite	NA	NA
9680129	Keyboard	NA	NA
9680144	Mouse	NA	NA
9731332 or 9680162	Laser Pointer	NA	NA
9660651	AxiEM™ System Box	NA	NA
Cables			
9680280	Power Cable	15 ft	No
9680177	Break-out Box with Cable	25 ft	No
9731736	Footswitch with Cable	10 ft	No
9680165	Power and Communication Cable	25 ft	Yes
9680141	Modem Cable	25 ft	No
9680142	Ethernet Cable	10 ft	No
9730750	Printer Cable	15 ft	No
Generic	Audio Cable	12 ft	No
963-809	BNC Video Cable (2x)	25 ft	No
Generic	S-Video Cable (2x)	12 ft	No
9731516	Calibration Target Cable	15 ft	No
9680232	Touchsite External Monitor Cable	18 ft	Yes

Table 2-4. *Guidance and Manufacturer's Declaration - Cables, Transducers, and Accessories*

The listed cables, transducers, and accessories have been determined by Medtronic to be compliant with the emissions and immunity requirements of IEC 60601-1-2: 2001.			
Medtronic Part Number	**Description**	**Max. Possible Length (m)**	**Shielded (Y/N)**
9732300	Surgeon Monitor External Cable	35 ft	Yes
9733017	Treon AxiEM™ Cable	1 ft	Yes
9660865	AxiEM™ System Communication Cable	20 ft	Yes
9731203 or 9660182 or similar***	AxiEM™ Emitter with Cable	20 ft	Yes
9660204 or similar **	AxiEM™ Instrument	10 ft	No
963-719 or similar *	Optical Instrument	12 ft	No
9731086	ORTHOsoft, Inc. Footswitch	17 ft	No
9731085	ORTHOsoft, Inc. Keypad	15 ft	No
960-730, 960-486, 961-415, 960-442, 960-418, or similar****	Microscope Cables	25 ft	Yes
Accessories			
963-750, 963-781, 963-741, or 9730259	Calibration Target	NA	NA
9732316	Wireless Surgeon Mouse	NA	NA
9732313	USB Wireless Antenna	NA	NA
* Any active or wireless active optical instrument has been qualified to IEC 60601-1-2: 2001			
** Any AxiEM™ instrument has been qualified to IEC 60601-1-2: 2001			
*** Any AxiEM™ Emitter has been qualified to IEC 60601-1-2: 2001			
**** For use with Zeiss, Leica, Moller or Olympus microscopes			

Table 2-5. *Guidance and Manufacturer's Declaration - Electromagnetic Emissions IEC 60601-1-2: 2001, Table 201*

The Treon® Treatment Guidance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Treon® Treatment Guidance System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The Treon® Treatment Guidance 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	The Treon® Treatment Guidance System is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Table 2-6. *Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 202*

The Treon® Treatment Guidance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Treon® Treatment Guidance System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV Air	± 6 kV contact ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential Mode ± 2 kV Common Mode	± 1 kV Differential Mode ± 2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% Dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% Dip in UT) for 5 sec	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% Dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% Dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Treon® Treatment Guidance System requires continued operation during power mains interruptions, it is recommended that the Treon® Treatment Guidance System be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power Frequency Magnetic Fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Table 2-7. *Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 204*

The Treon® Treatment Guidance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Treon® Treatment Guidance System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Treon® Treatment Guidance System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d=1.2^* \sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d=1.2^* \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	$d=2.3^* \sqrt{P}$ 800 MHz to 2.5 GHz 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.** Interference may occur in the vicinity of equipment marked with the following symbol: 

* 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 Treon® Treatment Guidance System is used exceeds the applicable RF compliance level above, the Treon® Treatment Guidance System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Treon® Treatment Guidance System.

Table 2-7. *Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 204*

The Treon® Treatment Guidance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Treon® Treatment Guidance System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Notes:

- At 80 MHz and 800 MHz, 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.

Table 2-8. *Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Treon® Treatment Guidance System IEC 60601-1-2: 2001, Table 206*

The Treon® Treatment Guidance System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Treon® Treatment Guidance System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Treon® Treatment Guidance System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2 * \sqrt{P}$	$d = 1.2 * \sqrt{P}$	$d = 2.3 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- At 80 MHz and 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.

△ **Cautions:**

- The Treon® Treatment Guidance System medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the EMC tables.
- Portable and mobile RF communications equipment can affect medical electrical equipment, such as the Treon® Treatment Guidance System.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Medtronic as replacement parts for internal components, may result in increased emissions or decreased immunity of the Treon® Treatment Guidance System.

System Set Up

⚠ **Warnings:**

- For electrical safety reasons, disconnect any local area network (LAN) cables from the Treon® Treatment Guidance System before proceeding with system set up.
- Prevent fluid from entering any part of the Treon® Treatment Guidance System. If you suspect fluid has entered any part of the unit, allow adequate dry time before connecting the system to power.

♦ ***To set up and start the system:***

1. Connect the communication cable from the Nav Cart to the Viewing Cart.
2. Plug the system power cord into an electrical outlet.
3. Connect the footswitch to the **Button** port on the breakout box.
4. Press and briefly hold down the green power on button on the left side of the Viewing Cart.

   The system will power-up and the login screen will appear when all boot-up diagnostics are complete.
5. Double-click the application icon to launch the software.

Inside the Cart

3

Component Locations

Because the Treon® Treatment Guidance System contains no user-repairable parts, the interior of the system is normally inaccessible. However, it may occasionally be necessary for a qualified service person to remove system panel(s) and access interior components. For example, it is necessary to remove cart panels in order to troubleshoot a connection problem or perform routine cleaning and maintenance.

Remove the lower front panel of the Viewing Cart to access the isolation transformer and power strip. Remove the upper front panel to access the video splitter and power supply ports for system accessories. Remove the back panel to access the A/V ports of the computer, modem, uninterruptible power supply (UPS), and system cooling fan. Remove the right side panel to access the rear panel of the computer.

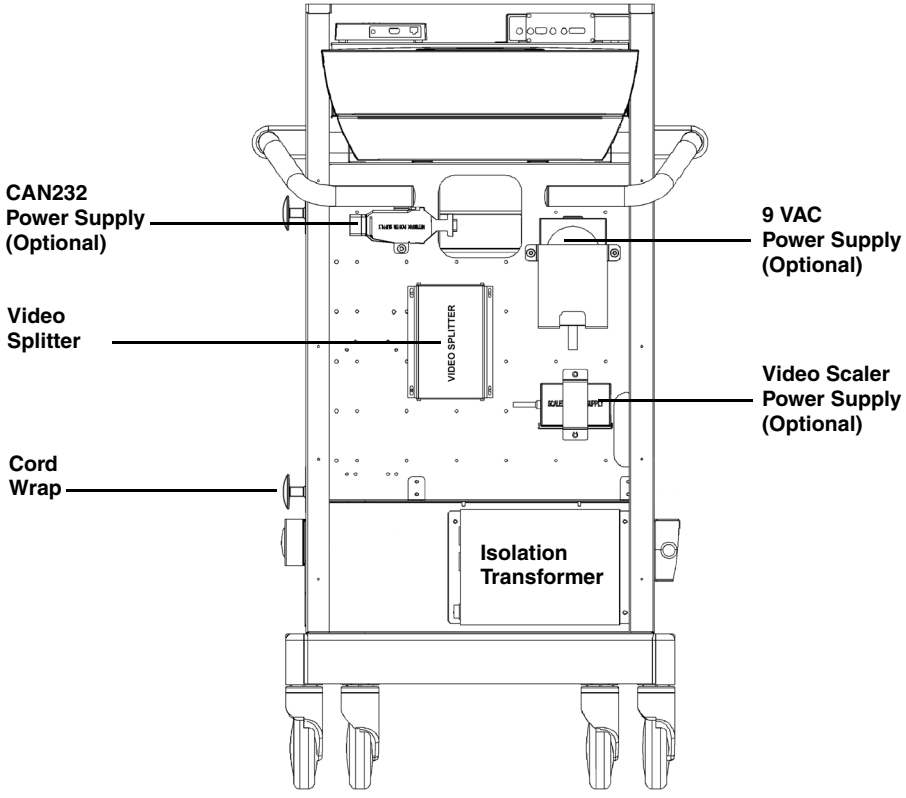


Figure 3-1. *Interior of Viewing Cart (front)*

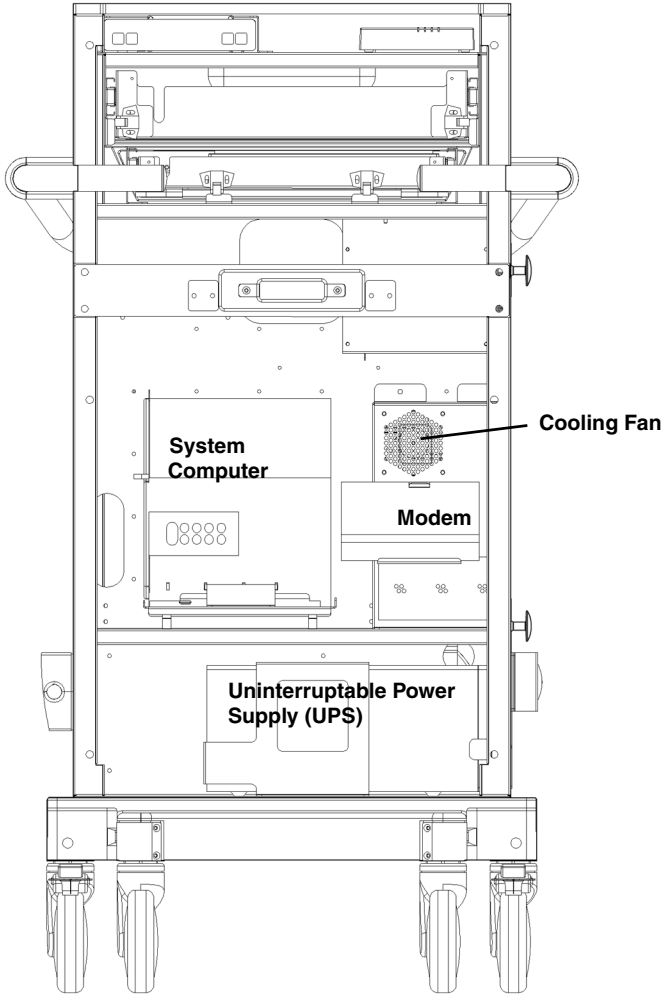


Figure 3-2. *Interior of Viewing Cart (back)*

Remove the lower front panel of the Nav Cart to access the Tool Interface Unit. The Tool Interface Unit powers the active emitters (LEDs) and communicates positional information from the active probes to the system computer.

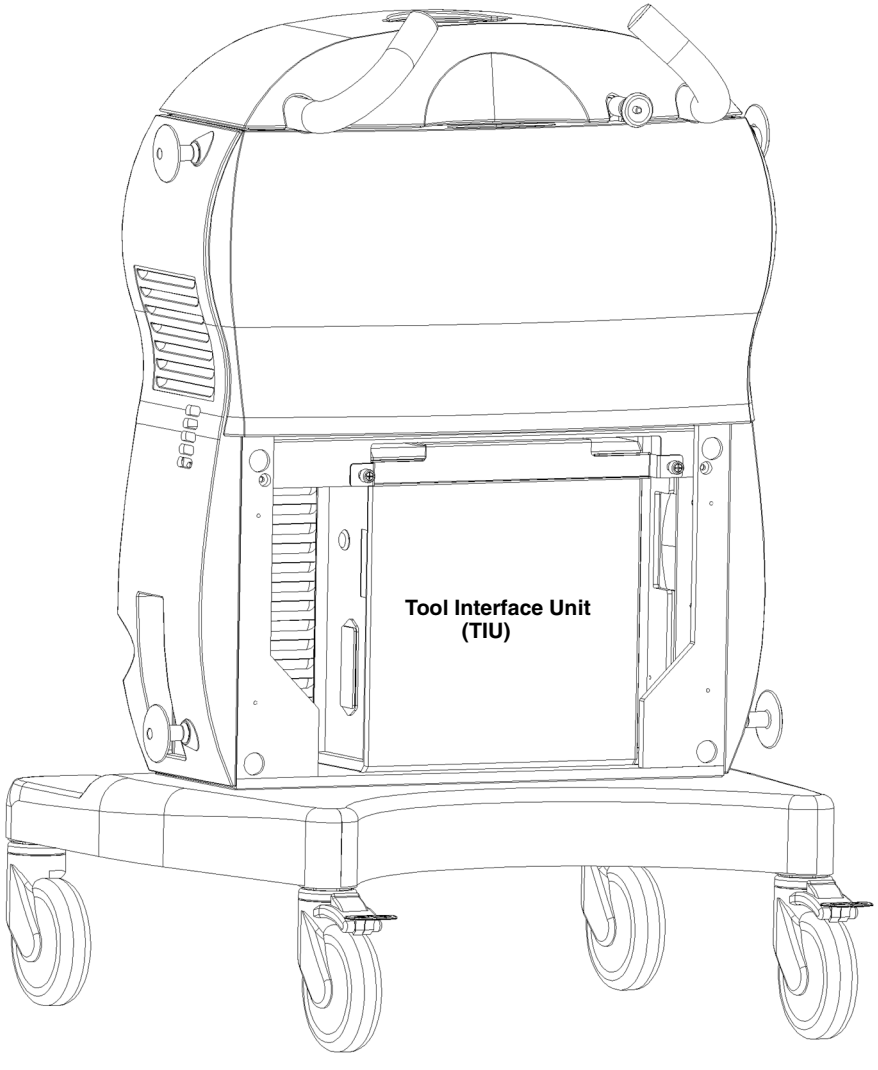


Figure 3-3. *Interior of Nav Cart (front)*

Opening the Viewing Cart

To access the interior of the Viewing Cart, you must remove the appropriate cart panels. The front of the cart has a lower panel below the storage drawer and is held in place by ball stud connectors. The back of the cart has one single panel and is held in place by six Phillips head screws.

♦ *To remove the lower front panel:*

1. Place the flat end of standard screwdriver between the upper right corner of the panel and the cart frame. Use the tool as a lever to pop the panel corner off of the connecting ball stud.
2. Grasp the top of the panel and pop the upper left corner off of the connecting ball stud.
3. Pop the lower panel corners off of the connecting ball studs.
4. Lift the panel up and away from the cart.

♦ *To remove the back panel:*

1. Remove the two screws at the bottom of the panel using a Phillips head screwdriver.
2. Remove the two screws at the middle of the panel using a Phillips head screwdriver. Support the panel weight to prevent panel or screw damage.
3. Lift the panel up and away from the cart.

Opening the Nav Cart

- ***To remove the front panel:***

  1. Place the flat end of standard screwdriver between the upper right corner of the panel and the cart frame. Use the tool as a lever to pop the panel corner off of the connecting ball stud.
  2. Grasp the top of the panel and pop the upper left corner off of the connecting ball stud.
  3. Pop the lower panel corners off of the connecting ball studs.
  4. Lift the panel up and away from the cart.

Docking and Separating the Carts

The Treon® Treatment Guidance System carts can be docked together for transportation and storage.

- ***To dock the carts:***

  1. On a level surface, orient the Nav Cart and the Viewing Cart with their back panels facing each other.
  2. Move the Nav Cart between the Viewing Cart feet.
  3. Slowly push the two carts together until you hear the click from the latch mechanism.

- ***To separate the carts:***

  1. Disconnect and stow any loose cables.
  2. Push the button on the head of the docking lever located on the Nav Cart, and simultaneously pull the docking lever straight out from the cart.
  3. Separate the carts with a gentle tug.

Component Connections

System malfunctions are sometimes the result of loose or disconnected cables. This section shows the connection ports on the system computer and how the internal system components are connected. This information may be useful when you work with technical support to diagnose or fix a malfunction. Do not disconnect any cables unless instructed to do so by a Medtronic SNT technical support representative.

System Computer

Refer to the following diagrams for device connection locations on the system computer. The back of the system computer faces the right side of the View Cart.

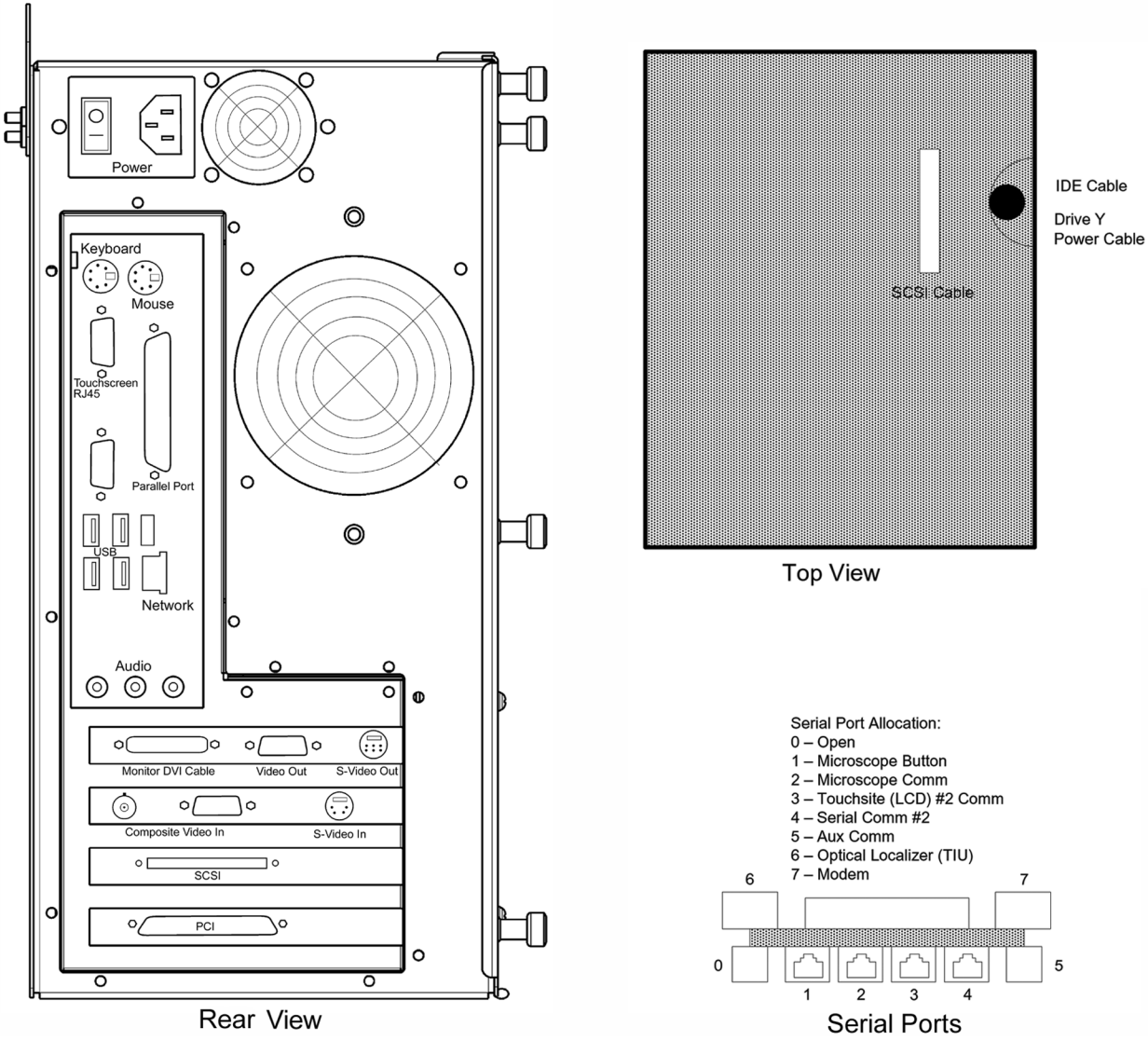


Figure 3-4. *Computer ports*

Device Connectivity Diagrams

Complete device connectivity diagrams are provided on the following pages.

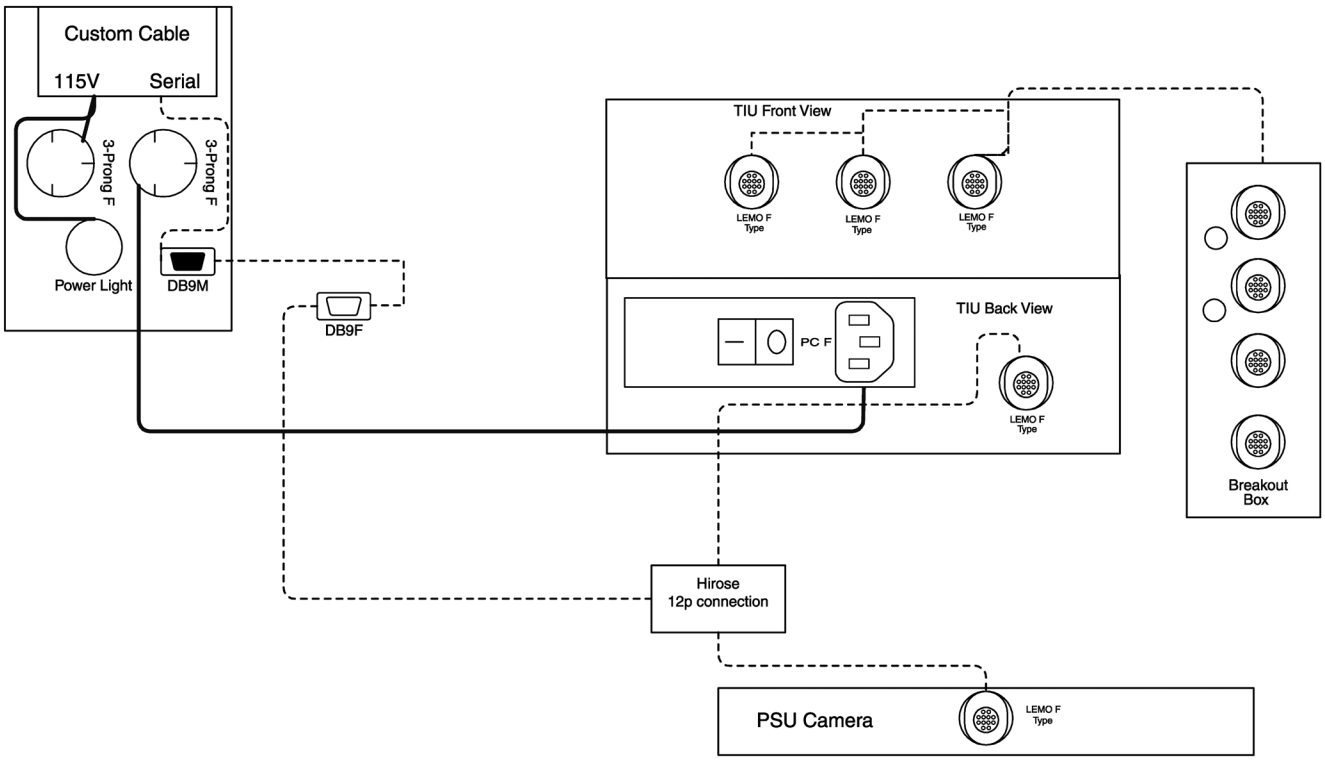


Figure 3-5. *Nav Cart connectivity*

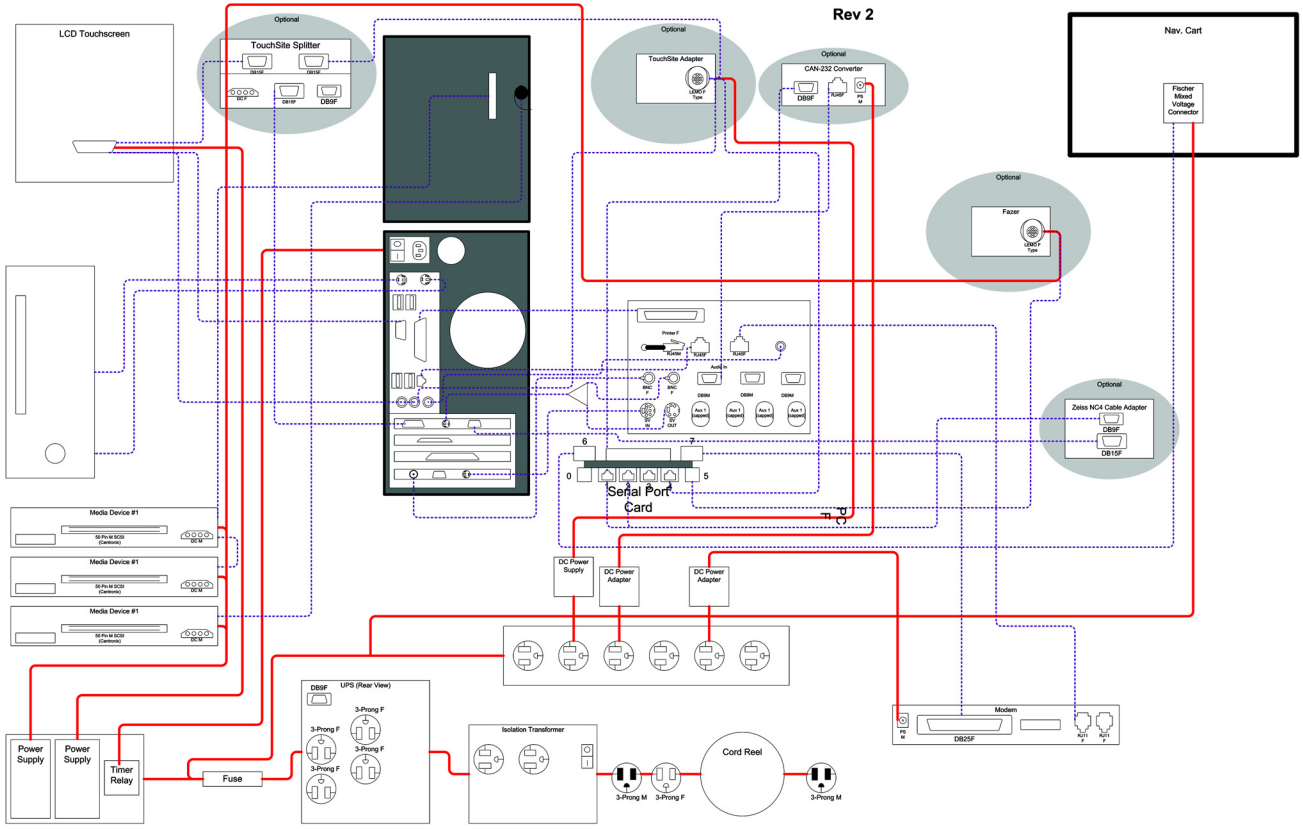


Figure 3-6. *View Cart connectivity*

Medtronic Navigation
826 Coal Creek Circle
Louisville, Colorado 80027
USA

Main 720.890.3200
Fax 720.890.3500

Technical Support 1.800.595.9709

www.medtronicnavigation.com

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
Netherlands

Tel 31.45.566.80.00

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