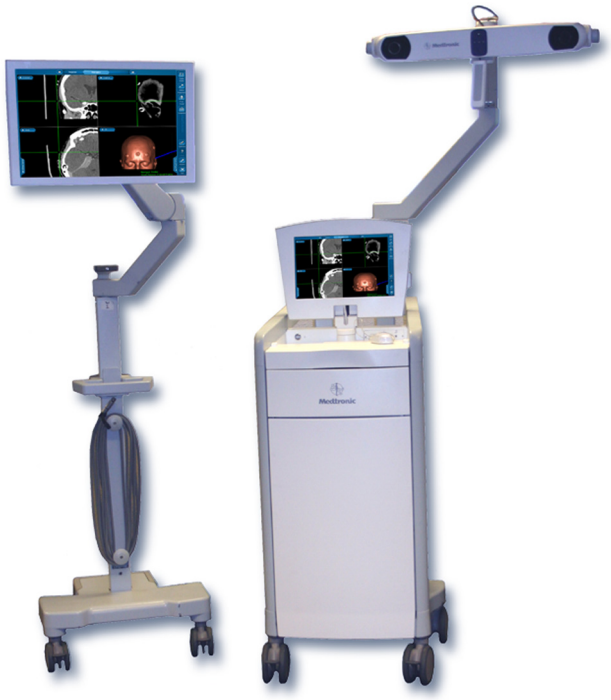
StealthStation® S7®
Treatment Guidance System Manual

Part Number 9733782, revision 14



A Guide to Understanding the StealthStation® S7® Treatment Guidance System

Read this manual completely prior to using this device.

CE 0123

℞ Only

Rev.14
04/2012

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, and IEC60601-1:1988 + A1:1999 + A2:1995.

Control number 87HJ.

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.

For safe use, follow operating instructions.

Consult instructions for use.

Type BF applied equipment, in compliance with IEC/UL60601-1.

Type B applied equipment, in compliance with IEC/UL60601-1.

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.

Use by date specified

Single use only. Do not reuse.

Quantity

Sterilized by ethylene oxide

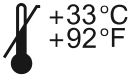
Non-sterile

Do not sterilize

Protective Earth (ground)

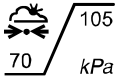
Equipotentiality: identifies the terminal that when connected together, bring the various parts of the equipment or system to the same potential, not necessarily being earth potential (for local bonding).

Do not allow contact with patient. Temperature may exceed limits.



Localizer must not be used in ambient temperatures greater than 33°C (92°F).

Shipping temperature between -29°C and 60°C (-20°F and 140°F)



Shipping pressure between 70kPa and 105kPa.

Do not disassemble

USB port

Network connection

Modem port

Serial port

Video In

S-Video In

VGA

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

Do not transport the carts with monitors in an undocked position. Always dock monitors before moving the carts.

Do not transport the carts with camera in an undocked position. Always dock camera before moving the carts.

Do not transport the carts with drawers in an undocked position. Always dock monitors before moving the carts.

Transport the carts with AXIEM controller docked on its hanger.

No step

Do not push or lean on.

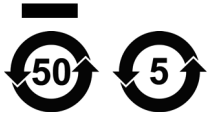
Battery disconnect switch

Remove storage bin to access battery disconnect switch.

Battery disconnect switch location

LASER radiation emitted from aperture. Do not stare into beam. Class 2 LASER product. Maximum output 1 mW, wavelength 635 nm, IEC 60825-1 (2001), ANSI Z136 a (2000). Complies with 21 CFR 1040 10 and 1040 11 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.

Table of Contents

Introduction 1

Description of the StealthStation® S7® Treatment Guidance System

The StealthStation® S7® 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, or fluoroscopic images acquired during 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 StealthStation® S7® System can serve to validate this judgement as well as guide.

Content of This Manual

This system manual is intended as a reference document for biomedical engineers or other qualified personnel who require familiarity with and details about the StealthStation® S7® 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 (procedure pocket guides).

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 (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 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:**

- Do not modify the StealthStation® S7® System.
- 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 Navigation computer-assisted surgery system must be certified according to the applicable IEC standards (e.g., IEC 60601-1 for medical equipment, UL60601-1, and CSA C22.2 No. 601-1-M90). Furthermore all configurations shall comply with the system standard IEC 60601-1-1 or the system requirements of Clause 16 IEC 60601-1: 3rd Edition. 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 or the system requirements of Clause 16 IEC 60601-1: 3rd Edition. If in doubt, contact technical support or your local Medtronic Navigation, Inc. representative.
- The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.
- 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.
- Inspect all instruments before use. If visibly damaged, do not use the instrument.
- Inspect all system components before use. If visibly damaged, do not use the system.
- 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.
- Do not open sterile-barrier packages or containers until surgical use. At time of use, inspect barrier for breach. If the sterile barrier was breached before surgical use, reprocess all devices contained in the package.
- The StealthStation® S7® System is not intended to be operated on battery power alone while instruments are connected to a patient.
- To reduce the potential of electrical shock, the operator should not simultaneously touch the patient and the system input/output panel, mouse, keyboard, or batteries.
- To avoid risk of electrical shock, the StealthStation® S7® System must only be connected to a supply mains with protective earth.
- The StealthStation® S7® System should not be connected to a wired network while in the patient vicinity to avoid electric coupling to non-medical equipment.
- Do not transport the carts in an undocked postion. Carts must be properly placed in the transport position and docked together before moving. To secure the system from unwanted lateral movement (for example, on an incline), lock all the castor wheels of the docked system.
- The StealthStation® S7® System Staff Cart contains a high fidelity stereo system for music playback from a user provided audio player. This system may be capable of sound levels which can lead to permanent hearing loss at high volume. The volume is controlled at the user provided audio player. For hearing safety, follow all warnings prescribed by the user provided player. If these warnings are not available or understood, do not exceed a 50% volume output from the audio player.

△ **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 (9730713). Clean non-sterilizable equipment according to the parameters in the Non-Sterilizable Equipment Cleaning sheet (9733205).
- 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 and stow all components, remove any loose items from the top of the cart(s), and dock the carts together.
- Avoid dripping any fluids into any enclosure on the StealthStation® S7® System. Disconnect the power and allow the system to dry if you suspect fluids may have entered any part of the system.
- The Staff Cart storage drawer has a maximum load capacity of 3.8kg (8lb).

Contact Information

Telephone

(800) 595-9709 (technical support)

(720) 890-3200 (general)

(720) 890-3500 (fax)

Regular Mail

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80027

Medtronic E.C. Authorized Representative

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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 StealthStation® S7® System helps the application software create 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. The system can track instruments either optically or electromagnetically. Some systems may have both or only one of the tracking methods.

△ **Cautions:**

- The StealthStation® S7® System's medical electrical equipment needs special precautions regarding electromagnetic classifications (EMC) and needs to be installed and put into service according to the EMC information included in Chapter 4.
- Portable and mobile RF communications equipment can affect medical electrical equipment, such as the StealthStation® S7® 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 StealthStation® S7® System.

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 patient 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 optical reference frame is a set of optical markers mounted on a metal frame. The AXIEM™ reference frame is a set of embedded sensing coils housed within a small plastic module. Reference frames are 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 localizer results in corresponding movement of optical markers in the camera's field of view. This enables the localizer 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 localizer after registration would invalidate the registration, since the positions of the optical markers would change in the navigation field. Dynamic referencing also gives you the flexibility to reposition the localizer at any time.

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

⚠ **Warning:** Because the position of the anatomy is defined by the position of the patient 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.

Optical Localization System

The optional optical 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. The camera's field of view defines the optical **navigation field**. 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 **patient 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 system continuously re-computes the relative spatial positions of the patient reference frame and instrument in the navigation field, and relates this information to the **patient registration** data in order to identify the location of the instrument on the operative images.

Camera

△ **Cautions:**

- Before use, clean the camera lenses using a camera lens cloth and lens cleaner. Do not apply any chemicals to the camera lenses.
- Allow the camera to warm up for two minutes after powering on the system.
- The optical system emits infrared light and can cause, or be susceptible to, infrared interference.

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.

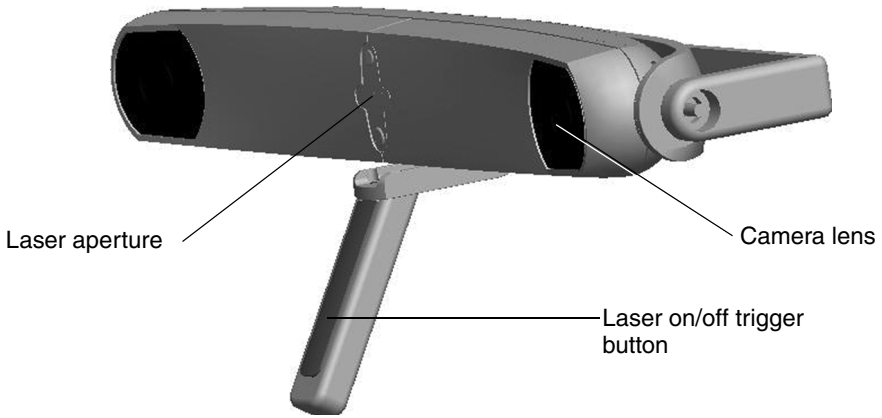


Figure 2-1. *System camera, aiming laser, and yoke assembly*

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.

Electromagnetic (AXIEM™) Localization System

The optional AXIEM™ system employs an electromagnetic (EM) localization system to track instruments and anatomy simultaneously. An **AXIEM™ Emitter** (also called the **localizer**) is placed near the surgical field, encompassing the anatomy of interest in a cubical, low-energy magnetic field called the **navigation field**. Because every point in the navigation field has a unique field strength, the system can determine the position of a tracking device by measuring the field strength at that location. Sensing coils embedded in the **patient reference frame** affixed to the patient's bony anatomy enable the system to identify the location of the anatomy of interest in the electromagnetic field. Similarly, sensing coils embedded in the pointer probe or other instrument enable the system to identify the location of the instrument's position and trajectory in the field.

The system continuously re-computes the relative spatial positions of the patient reference frame and instrument in the navigation field, and relates this information to the **patient registration** data in order to identify the location of the instrument on the operative images.

AXIEM™ System Controller

The AXIEM™ system controller houses the electromagnetic localization system components. The AXIEM™ system connects directly to the Staff Cart. The Staff Cart includes the computer, monitor, and all related peripheral devices and is the platform from which the surgeon or qualified assistant controls the AXIEM™ software.

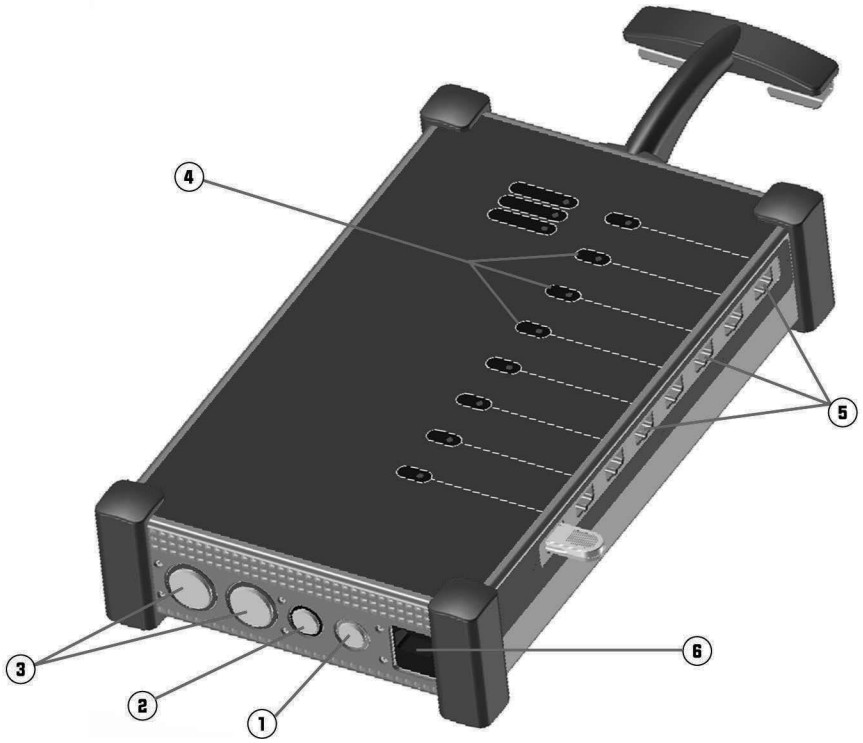


Figure 2-2. *AXIEM™ System Controller*

No.	Component	No.	Component
①	Medtronic® CAS system communication port	④	Instrument indicator LEDs (8 total)
②	Footswitch port	⑤	Instrument ports (8 total)
③	Mobile Emitter port	⑥	Power cord port

Connect the patient reference and AXIEM™ instruments to the instrument ports on the AXIEM™ system controller. The instrument indicator's LED glows green when the instrument is properly connected and functioning normally. Connect the Mobile Emitter and footswitch to their respective ports on the AXIEM™ system controller.

AXIEM™ Mobile Emitter

The Navigation Field

The Mobile Emitter produces a low-energy magnetic field volume of approximately 600mm x 600mm x 400mm, in front of the emitter face, and with its near side offset 50mm from the face. The emitter may be placed in a holder which is mounted to the operating table or held by an assistant.

Ferrous and conductive metals can interfere with the navigation field and degrade the system accuracy. Accuracy is maintained as long as the metal is at least six inches (about 150mm) away from the Mobile Emitter and AXIEM™ system instruments.

⚠ **Warning:** Do not use the Mobile Emitter in ambient (room) temperatures greater than 33°C (92°F).

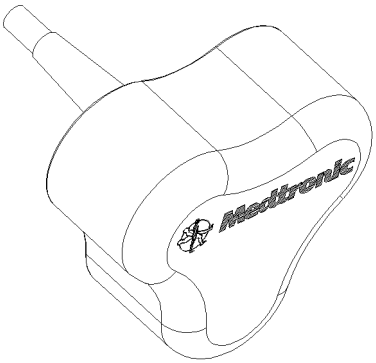


Figure 2-3. *AXIEM ™Mobile Emitter*

Applicable Standards for EM Fields

Based on the available standards and international guidelines the AXIEM™ system is considered safe for use in surgical environments. The AXIEM™ system has been successfully tested against the requirements of IEC 60601-1 *General Requirements for Basic Safety and Essential Performance*, and the associated Part 2 Collateral Standard, *Electromagnetic Compatibility.*

Guidelines for exposure to electromagnetic fields are not addressed as part of the above certifications, and no single definitive source exists for demonstration of safety. The AXIEM™ system is in compliance with the recommended guidelines for EMF exposure as outlined by a number of U.S. and international bodies.

The system complies with guidelines from the American National Standards Institute (ANSI) / Institute of Electrical and Electronic Engineers (IEEE) in C95.1 *Standard for Safety Levels with Respect to Human Exposure to Radio-Frequency Electromagnetic Fields*. For "Persons in a Controlled Environment", all electromagnetic fields in the navigation region are below the recognized limits.

The system complies with limits recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), as formally recognized by the World Health Organization (WHO), in the standard Guidelines for Limiting Exposure to Time-varying Electric, Magnetic and Electromagnetic Fields. For occupational exposure, all electromagnetic fields in the navigation region are below the recognized limits.

△ **Caution:** The field strength directly at the face of the Emitter, outside of the navigation region, may exceed limits for occupational exposure according to the ICNIRP and for the General Public per ANSI/IEEE. Limit the duration of operator and patient contact with the stronger magnetic fields at the face. Specifically, do not allow the Emitter to directly contact the patient for the duration of a procedure.

System Carts

Staff Cart

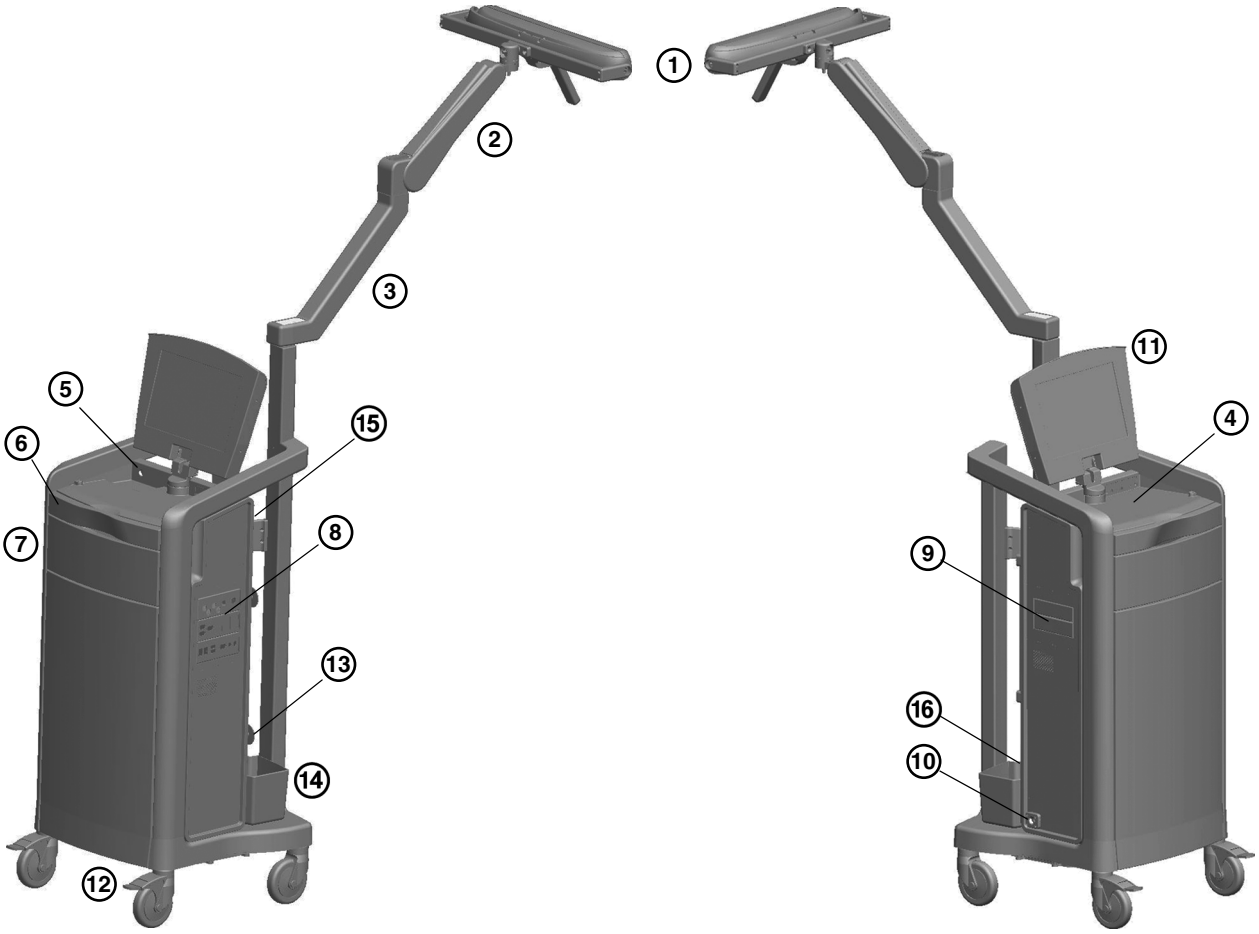
The StealthStation® S7® System has two separate but complementary carts; the **Surgeon Cart** and the **Staff Cart**. The carts may be docked together as a single unit, or separated for positional flexibility and convenience during surgery.

The Staff Cart contains the computer, system control unit, power supply, and all related peripheral devices. Figure 2-4 illustrates a typical optical system and Figure 2-5 illustrates a typical AXIEM™ only system. The Staff Cart acts as the base for the camera and contains the keyboard drawer, a storage drawer, input/output connection ports, media input/output bays, and a monitor. The Staff Cart contains a high fidelity stereo system for music playback. The connection port for music input devices is located on the cart deck. The optional AXIEM™ system controller is hung on the back of the Staff Cart.

During use, the Staff Cart is typically located in the operating room outside the sterile field within 1 - 2 meters of the operating table. The surgeon monitor is positioned for optimal visibility by the surgeon, but remains outside the sterile field. Users interact and control the system while standing in front of the Staff Cart or the optional surgeon monitor touchscreen. The system is transported and stored with both the Staff Cart and Surgeon Cart docked together in the labeled transport position.

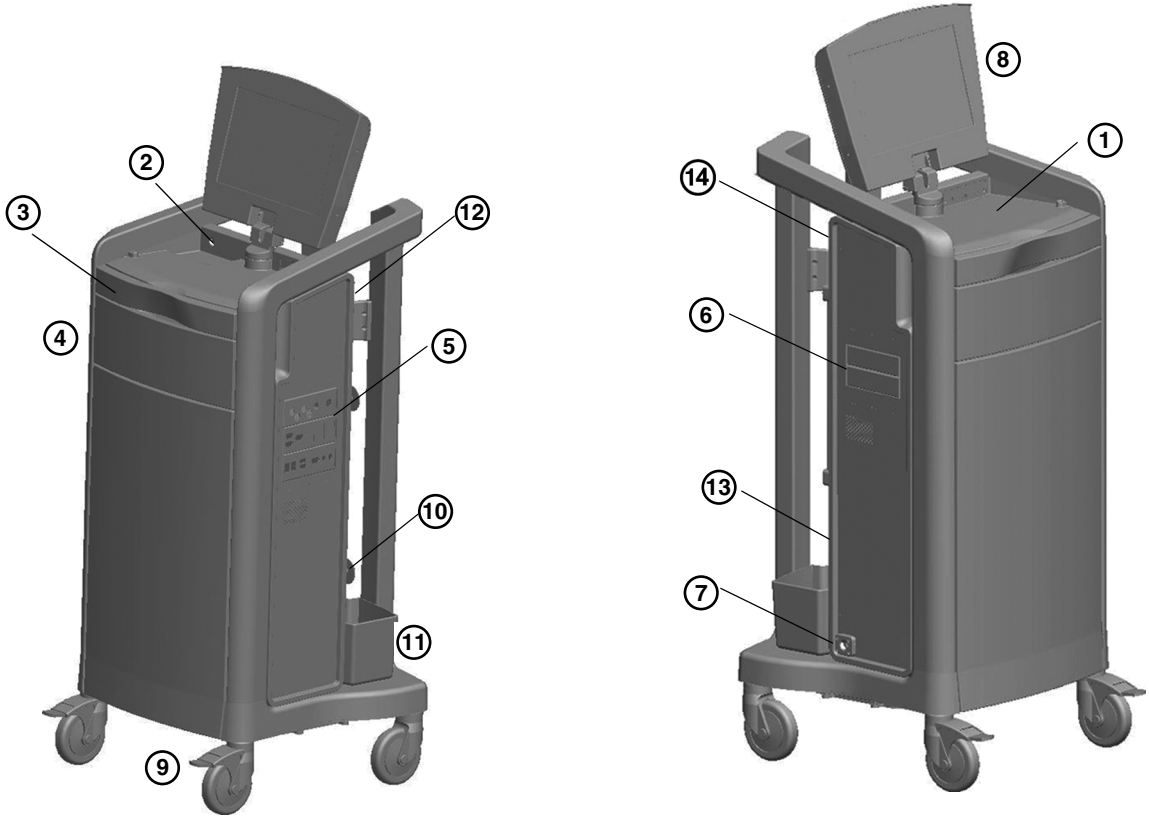
Staff Monitor

The Staff Cart monitor is located on the Staff Cart deck. The monitor is a high-resolution, flat panel liquid crystal display. The monitor folds down into a stowed position for transportation and storage.



1. Camera
2. Upper articulating arm
3. Lower articulating arm
4. Deck
5. On/Off switch
6. Keyboard drawer
7. Storage drawer
8. System input/output side panel
9. Media bays
10. Cart power cable outlet
11. Staff monitor
12. Caster locks
13. AXIEM™ controller cable wraps
14. Storage bin
15. Surgeon monitor cable connection
16. Battery disconnect switch (behind storage bin)

Figure 2-4. *Staff Cart exterior (optical system)*



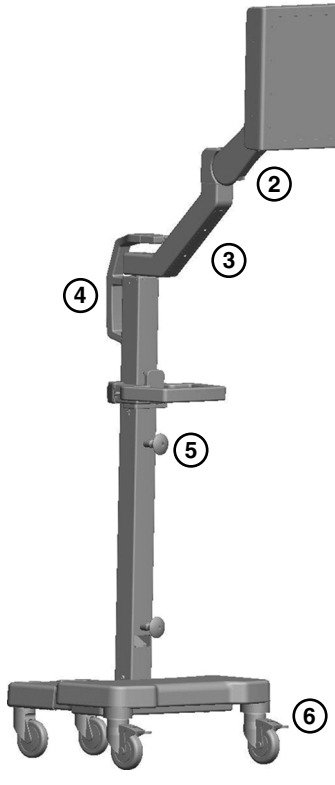
1. Deck
2. On/Off switch
3. Keyboard drawer
4. Storage drawer
5. System input/output side panel
6. Media bays
7. Cart power cable outlet
8. Staff monitor
9. Casters and caster locks
10. AXIEM™ controller cable wraps
11. Storage bin
12. Surgeon monitor cable connection
13. Battery disconnect switch (behind storage bin)
14. AXIEM Controller rack (rear of cart)

Figure 2-5. *Staff Cart exterior (AXIEM™ System)*

Surgeon Cart

The Surgeon Cart (see Figure 2-6) is the base for a high definition monitor. The cart is placed near the surgical field so that the surgeon has optimal visibility of the navigation screen. During storage and transport, the monitor is protected by a folding cover.

The Surgeon Cart monitor is a high-resolution, flat panel liquid crystal display with built-in speakers. The display is visible at angles up to 80° from perpendicular.



1. Surgeon monitor and cover
2. Upper articulating arm
3. Lower articulating arm
4. Cart docking mechanism
5. Cable wraps
6. Caster locks

Figure 2-6. *Surgeon Cart*

Optional Touchscreen Surgeon 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. The touchscreen interface can be controlled by finger, gloved finger, or other smooth object such as the touchscreen stylus. The touchscreen comes with two touchscreen styluses and two stylus holders that can be mounted to the side of monitor.

Before using the touchscreen, verify acceptable touchscreen functionality. If the touchscreen is not functioning properly, continue the procedure using alternative input methods (mouse, keyboard). Call Medtronic Navigation, Inc. to report touchscreen functionality issues.

Keyboard and Mouse

A keyboard is provided in the Staff Cart's top drawer. A wired mouse is located on the Staff Cart deck. They are used to control the system from the Staff Cart. The Staff Cart deck is designed as a working surface for the system mouse. The system can also be controlled with an optional wireless mouse.

Optical Instruments

Instruments designed for use with the StealthStation® S7® 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.

AXIEM™ System Instruments

AXIEM™ system instruments designed for use with the StealthStation® S7® System contain embedded sensing coils that allow the system to determine their locations in the navigation field. Some AXIEM™ system instruments require the same type of verification as optical instruments. Some AXIEM™ system components are single-use only, and may not be re-used or re-sterilized. For instructions on the use of a specific AXIEM™ system instrument or accessory, refer to the package insert which accompanied the item or follow the instructions provided in the application software's instructions for use (pocket guide).

Detachable Equipment/Applied Parts

The following Medtronic detachable equipment/accessories are qualified for use with the StealthStation® S7® System. The listed accessories have been determined by Medtronic to be compliant with the safety, emissions, and immunity requirements of IEC60601-1/UL60601-1/CAN/CSA C22.2 NO.601.1-M90.

△ **Caution**: Prior to use, examine accessory components for damage, deterioration, deformation, and abuse. Do not attempt to use any accessory that appears to be bent or otherwise damaged.

- Microscope brackets (Zeiss Pentero, Zeiss Vario, Zeiss NC-4, Leica, Moller)
  - Microscope brackets are not rated for patient contact.
  - Microscope brackets must be installed and calibrated by Medtronic personnel only.
- Footswitch
  - Footswitches are not rated for patient contact.
- AXIEM™ system controller
  - The AXIEM™ system controller is not rated for patient contact.
- AXIEM™ emitter
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).
- AXIEM™ENT patient tracker, AXIEM™ ENT instrument tracker
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).

- AXIEM™ cranial resection instruments
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).
- AXIEM™ VP shunt instruments
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).
- AXIEM™ pointers
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).
- Rotatable Fusion™ Blades (TRICUT - 13CM, RAD 12, RAD 40)
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).
- Optical spine and cranial navigation probes, patient reference frames, and instrument trackers (fighters)
  - Patient applied part (BF rated per IEC60601-1 2nd and 3rd edition).
- Wireless optical C-arm trackers
  - Patient applied part (B rated per IEC60601-1 2nd and 3rd edition).

Cart Operation

3

System Input/Output Panel

The Staff Cart contains a system input/output panel with external connection ports for various input and output devices. The panel is flush mounted and located on the right side of the of the cart.

⚠ **Warning:** Accessory equipment connected to the analog and digital interfaces of the Medtronic Navigation computer-assisted surgery system must be certified according to the applicable IEC standards (e.g., IEC 60601-1 for medical equipment, UL60601-1, and CSA C22.2 No. 601-1-M90). Furthermore all configurations shall comply with the system standard IEC 60601-1-1 or the system requirements of Clause 16 IEC 60601-1: 3rd Edition. 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 or the system requirements of Clause 16 IEC 60601-1: 3rd Edition. If in doubt, contact technical support or your local Medtronic Navigation, Inc. representative.

⚠ **Warning:** To reduce the potential of electrical shock, the operator should not simultaneously touch the patient and the system input/output panel.

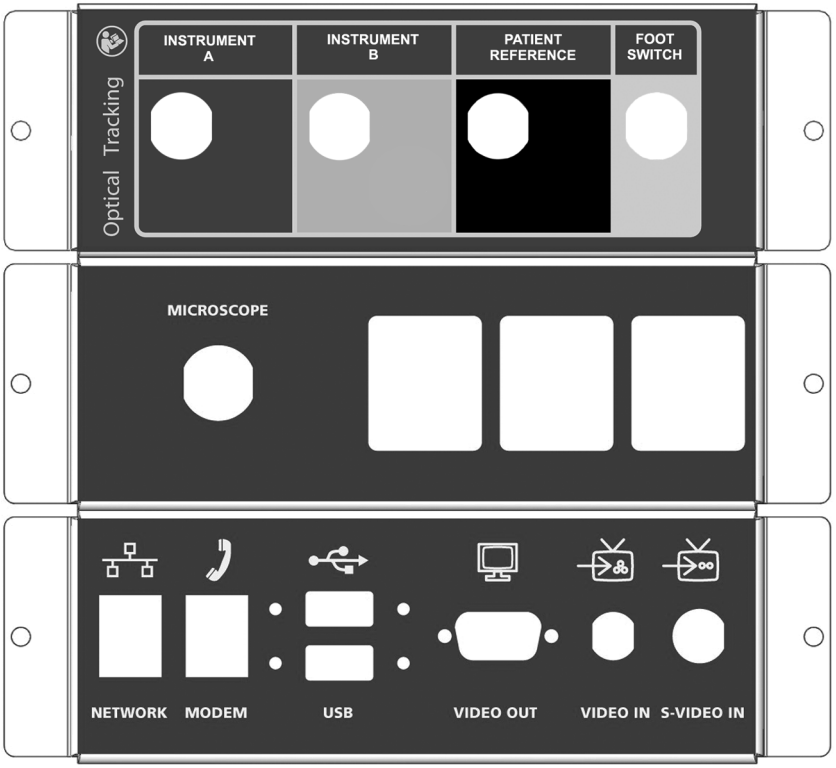


Figure 3-1. *System I/O panels*

Optical tracking panel

INSTRUMENT A: Connects the system to a wired (active) instrument.

INSTRUMENT B: Connects the system to a wired (active) instrument.

PATIENT REFERENCE: Connects the system to wired patient reference frame.

FOOTSWITCH: Connects the system to the footswitch.

Microscope panel

MICROSCOPE: Connects the system to a surgical microscope.

Standard system I/O connectors

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

MODEM: Connects the system modem to an external telephone line. The modem connection is provided for system maintenance only and is not intended for use during surgical procedures.

USB: Connects the system to an external USB device.

VIDEO OUT: Connects the system to an external analog video device.

VIDEO IN: Connects the system video input board to the composite video output of an external source.

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

Network Connection Information

A network connection is provided on the StealthStation® S7® System. The purpose of the network connection is to provide a means of image and data transfer. The user network must be 10/100/1000 baseT to function with the StealthStation® S7® System. The StealthStation® S7® System supports auto negotiated, full duplex and half duplex network connections.

For network connection, the StealthStation® S7® System requires an active application seeking data, or no data will be accepted. StealthStation® S7® System information is limited to image and data transfer. If there is a network failure, navigated procedures may be delayed while alternate media is used for image transfer, or navigation may be aborted if alternate image transfer media is unavailable.

Connection of the StealthStation® S7® System to an IT Network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. Users should identify, analyze, evaluate and control these risks. Subsequent changes to the network could introduce new risks and require additional analysis. These changes may include:

- changing the network configuration,
- connecting additional items to the network,
- disconnecting items from the network,
- or upgrading equipment connected to the network.

System Set Up

⚠ **Warnings:**

- For electrical safety reasons, disconnect any local area network (LAN) cables from the StealthStation® S7® System before proceeding with system set up.
- Prevent fluid from entering any part of the StealthStation® S7® System. If you suspect fluid has entered any part of the unit, turn the system off immediately using the steps in "System Set Up" on page 3-6. and allow adequate drying time before powering the system back on.
- To reduce the potential of electrical shock, the operator should not simultaneously touch the patient and the system mouse, keyboard, or batteries.

Separate the Carts

Make sure the system is on a level surface before attempting to separate the carts.

1. Disconnect and store any loose cables.
2. While standing behind the Surgeon Cart, pull the docking lever located on the Surgeon Cart towards you.
3. Separate the carts with a gentle tug.

Connect and Start the System

1. Unwrap the communication cable on the Surgeon Cart, and connect it to the Surgeon Cart cable connection located on the Staff Cart.
2. Unwrap the power cord from the Staff Cart and plug it into an electrical outlet.
3. Press and hold the blue LED power switch located on the Staff Cart deck for one second. The system powers up and the login screen appears when all computer bootup diagnostics are complete.

Connect Either the Optical or the AXIEM™ Hardware to the Staff Cart

For Optical Localization, Connect the Optical Hardware

1. Connect the wired (active) instruments to the **INSTRUMENT A** or **INSTRUMENT B** port.
2. Connect the Patient Reference Frame cable to the **PATIENT REFERENCE** port.
3. Connect the footswitch to the **FOOTSWITCH** port.

For Electromagnetic Localization, Connect the AXIEM™ Hardware

1. Connect the AXIEM™ controller to the AXIEM cable which is hard wired into the Staff Cart.
2. Connect the AXIEM™ Mobile Emitter cable to the emitter port on the AXIEM controller.
3. Connect the footswitch to the footswitch port on the AXIEM controller.
4. Connect the AXIEM™ instruments to any open instrument port on the AXIEM controller.

Launch the Software

There are two ways to launch Medtronic Navigation software.

1. From the login screen, use the mouse to double click the desired software icon.
2. From the login screen, use the mouse to click the appropriate software icon, then click **[Launch]** at the bottom of the screen.

System Shutdown

Exit the Software

1. Click the exit button at the bottom right corner of the software screen. Click Yes to confirm that you want to exit.

   Note: The software saves exam data continuously. No information is lost upon exit, and there is no save function.

Shut Down the System

There are three ways to shut down the system. Use method #3 only if the first two methods fail to shut down the system. After the system shuts down, pull the power plug out of the electrical outlet.

1. After exiting the software, click the Shutdown icon located on the login screen. the system will fully shut down.
2. Press the blue LED power switch located on the Staff Cart deck. The system will fully shut down.
3. Press and hold the blue LED power switch located on the Staff Cart deck for eight seconds. The system will fully shut down.

Transport Position

Follow the instructions below to configure the carts into the transport position. Transport the carts only when in the transport position.

Wrap Cords

1. Pull the power plug out of the electrical outlet.
2. Clean the cord, and wrap it around the cord wraps located on the side of the Staff Cart.
3. If present, hang the AXIEM™ controller on the hanger on the rear of the Staff Cart and wrap the cord on the cord wraps located on the rear of the cart.

4. Disconnect and store any cables and instruments.

Close All Cart Drawers

1. Close all cart drawers.

Dock the Camera (Optical System):

1. Rotate the camera yoke and articulating arms such that they are generally in line with the cart.
2. Fold down the upper articulating arm so that it is positioned next to the lower articulating arm.
3. Swivel the camera yoke into a vertical orientation.
4. Guide the docking tee on the rear of the yoke assembly into the port located at the base of the lower articulating arm.
5. Swing the handle around into the docking port located in the center of the lower articulating arm.

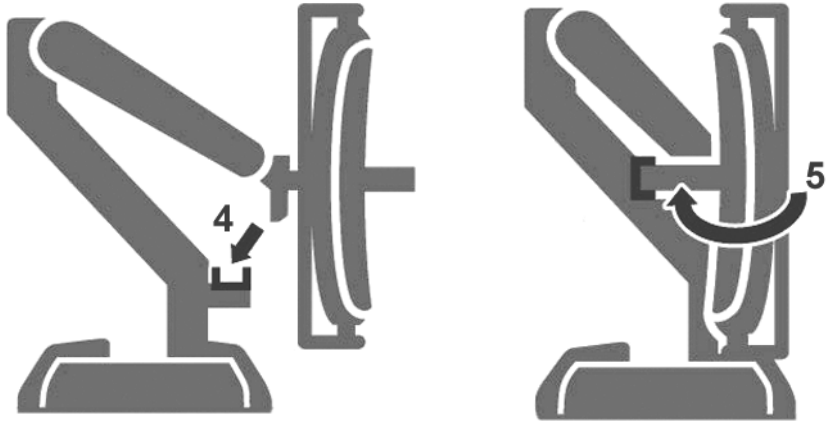


Figure 3-2. *Camera docking steps 4 and 5*

Dock the Surgeon Monitor:

1. Rotate the monitor and articulating arms such that they are generally in line with the cart.
2. Fold down the upper articulating arm so that it is positioned next to the lower articulating arm.

3. Swing the articulating arms 90° so that they are perpendicular to the front of the cart, and the monitor is parallel to the front of the cart.
4. Gently guide the docking tab on the bottom of the monitor into the port located at the base of the lower articulating arm.

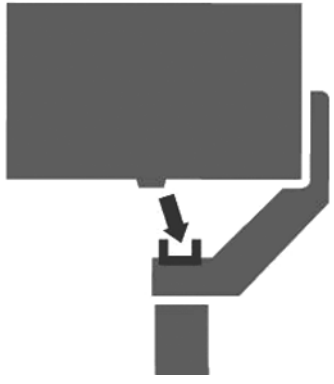


Figure 3-3. *Docking the surgeon monitor*

Dock the Carts:

1. On a level surface, orient the Staff Cart and the Surgeon Cart so that the rear of the Staff Cart faces the front of the Surgeon Cart.
2. Move the Surgeon Cart between the Staff Cart casters.
3. Slowly push the two carts together until you hear a click from the latch mechanism.

System Specifications 4

System Specifications

The specifications listed apply to system operation under typical conditions.

Table 4-1. *StealthStation® System Specifications*

	United States and Canada	International ~220V - ~240V	International ~100V - ~120V
Operating Temperature	65° to 91°F	18° to 33°C	18° to 33°C
Operating Pressure	70 kPa (700 - 1050 mbar)	70 kPa (700 - 1050 mbar)	70 kPa (700 - 1050 mbar)
Operating Altitude	3000m (9842 ft) maximum	3000m maximum	3000m maximum
Shipping Temperature	-20° to 140°F	-29° to 60°C	-29° to 60°C
Storage Temperature	-4° to 140°F	-20° to 60°C	-20° to 60°C
Input Voltage	~100 to ~120 V	~220 to ~240 V	~100 to ~120 V
	50 Hz to 60 Hz	50 Hz to 60 Hz	50 Hz to 60 Hz
Maximum Current Allowed	9 A	4.5 A	9A
Typical Power Dissipation	600 V-A	600 V-A	600 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
Surgeon Monitor Dimensions	15”H x 23”W x 2.75”D	38 cmH x 58 cmW x 7 cmD	38 cmH x 58 cmW x 7 cmD
Surgeon Monitor Weight	16 - 20lbs	7 - 9kg	7 - 9kg
Surgeon Monitor Display *	Resolution = 1920 x 1200 dpi, 60 Hz		
Staff Monitor Dimensions	13”H x 15”W x 1.75”D	33 cmH x 38 cmW x 4.5 cmD	33 cmH x 38 cmW x 4.5 cmD
Staff Monitor Weight	7 lbs	3 kg	3 kg
Staff Monitor Display *	Resolution = 1440 x 900 dpi, 60 Hz		
Staff Cart Footprint	23” x 24”	58 cm x 61 cm	58 cm x 61 cm
Staff Cart Weight	325 lbs	148 kg	148 kg
Surgeon Cart Footprint	23” x 24”	58 cm x 61cm	58 cm x 61cm

Table 4-1. *StealthStation® System Specifications*

	United States and Canada	International ~220V - ~240V	International ~100V - ~120V
Surgeon Cart Weight	230lbs	104kg	104kg

* Additional monitors connected to the system which are not provided by Medtronic, must meet a minimum resolution requirement of 1920 x 1200 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 4-2. *General StealthStation® System Classifications*

Agency	System Rating
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 (all applied parts are of a single function), equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
IEC 60601-1: 2005	Pollution Degree 2 Overvoltage Category II
Electromagnetic Emissions Compatibility, IEC 60601-1-2	Class A, Group 1

Table 4-3. *Water Ingress Classifications*

Component	Water Ingress Classification
System (both carts)	IPX0 (not protected)
AXIEM™ System Controller	IPX0 (not protected)
Camera	IPX0 (not protected)
Footswitch	IPX8 (water tight)

AXIEM™ System Controller Specifications and Classifications

The following tables outline the environmental and physical specifications of the AXIEM™ system controller.

Table 4-4. *AXIEM™ System Controller Specifications*

	United States	International	Japan
Operating Temperature	64° to 92°F	18° to 33°C	18° to 33°C
Shipping and Storage Temperature	-20° to 140°F	-29° to 60°C	-29° to 60°C
Atmospheric pressure	500 to 1060 mbar	500 to 1060 mbar	500 to 1060 mbar
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	2.0 A	2.0 A	2.0 A
Nominal Power Dissipation	100 Watts		
Humidity	10% to 80% non-condensing		
Dimensions	22 x 9.3 x 3.3 (in)	560 x 236 x 84 (mm)	560 x 236 x 84 (mm)
Weight	10.5 lbs	4.8 kg	4.8 kg
Maximum Operating Altitude	9842 ft	3000 m	3000 m

Table 4-5. *AXIEM™ System Controller Classifications*

Standard	Classification
European Medical Device Directive 93/42/EEC	Class IIa according to Rule 6, Annex IX
FDA Medical Device CFR part 21 882.4560	Class II
Electrical Safety Class EN60601-1/UL 60601-1 CAN/CSA-C22.2 No 601.1-M90	Class I, continuous operation with BF applied parts
Electromagnetic compatibility emissions EN6060-1-2 *	Class A, Group 1
IEC 60601-1: 2005	Pollution Degree 2 Overvoltage Category II

* All information regarding emissions testing (subsection of the 60601-1-2 emissions standard) for the CE labeling of the product is only applicable to the AXIEM™ system controller, model number (9660651). This information does not apply to the AXIEM™ system controller, model number (9660650).

System Electromagnetic Emissions and Immunity Declarations

Table 4-6. *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.			
Medtronic Part Number	**Description**	**Max. Possible Length (m)**	**Shielded (Y/N)**
System Equipment			
9733437	Spectra Position Sensor Unit (PSU)	NA	NA
9733622	Staff Monitor	NA	NA
9733623	Widescreen 24” Surgeon Monitor	NA	NA
9734686	Surgeon Monitor with Touch (Touchscreen)	N/A	N/A
9733779	Keyboard	NA	NA
9733670	Mouse	NA	NA
9660651	AXIEM™ System Controller	NA	NA
Cables			
Generic	Power Cord	15ft (4.6m) maximum	No
9733624	Footswitch with Cable	10 ft	No
9733597	AXIEM™ Power and Communication Cable	25 ft	Yes
9680141	Modem Cable	25 ft	No
9680142	Ethernet Cable	10 ft	No

Table 4-6. *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.			
Medtronic Part Number	**Description**	**Max. Possible Length (m)**	**Shielded (Y/N)**
Generic	Audio Cable	12 ft	No
963-809	BNC Video Cable	25 ft	No
Generic	S-Video Cable	12 ft	No
9731516	Calibration Target Cable	15 ft	No
9733571	Widescreen Surgeon Monitor External Cable	35 ft	Yes
9733017	AXIEM™ Cable	1 ft	Yes
9731203 or 9660182 or similar***	AXIEM™ Mobile Emitter with Cable	20 ft	Yes
9733821, 9733822, 9733823, 9733824, 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
9660204 or similar **	AXIEM™ Instrument	10 ft	No
963-719 or similar *	Optical Instrument	12 ft	No
* 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, or Moller microscopes			

Table 4-7. *Guidance and Manufacturer's Declaration - Electromagnetic Emissions IEC 60601-1-2, Table 1*

The StealthStation® S7® Treatment Guidance System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation® S7® AXIEM™ System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The StealthStation® S7® AXIEM™ 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 StealthStation® S7® AXIEM™ 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 4-8. *Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2, Table 2*

The StealthStation® S7® AXIEM™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation® S7® AXIEM™ 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 StealthStation® S7® AXIEM™ System requires continued operation during power mains interruptions, it is recommended that the StealthStation® S7® AXIEM™ 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 4-9. *Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2, Table 4*

The StealthStation® S7® AXIEM™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation® S7™ 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 StealthStation® S7® AXIEM™ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d=1.2* $\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	d=1.2* $\sqrt{P}$ 80 MHz to 800 MHz 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 StealthStation® S7® AXIEM™ System is used exceeds the applicable RF compliance level above, the StealthStation® S7® AXIEM™ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the StealthStation® S7® AXIEM™ System.

Table 4-9. *Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2, Table 4*

The StealthStation® S7® AXIEM™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation® S7™ 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 4-10. *Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the StealthStation® S7® AXIEM™ System IEC 60601-1-2, Table 6*

The StealthStation® S7® AXIEM™ System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the StealthStation® S7® AXIEM™ System Treatment Guidance System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the StealthStation® S7® AXIEM™ 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.			

Electromagnetic Emissions and Immunity Declarations

Note: The AXIEM™ system has been tested for compatibility with Medtronic® implantable cardiac device families. Interference testing indicates that the AXIEM™ system does not adversely affect the function of these devices and does not constitute a patient hazard.

△ Cautions

△ **Caution:** Portable and mobile RF communications equipment can affect medical electrical equipment, such as the AXIEM™ system.

△ **Caution:** 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.

△ **Caution:** In the U.S.A., operation of this system at 220-240 VAC, 50/60 Hz requires power supplied by a center-tapped transformer. For 120VAC operation, no special considerations are required.

△ **Caution:** The AXIEM™ 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.

△ **Caution:** The use of accessories, transducers and cables other than those specified, with the exception of transducers, and cables sold by Medtronic Navigation as replacement parts for internal components, may result in increased emissions or decreased immunity of the AXIEM™ system.

△ **Caution:** All information regarding emissions testing (subsection of the 60601-1-2 emissions standard) for the CE labeling of the product is only applicable to the AXIEM™ system, model number (9660651). This information does not apply to model number (9660650).

Troubleshooting 5

Cart Separation

Difficulty separating the Staff Cart and the Surgeon Cart

Check that the carts are not positioned on a slope. The docking mechanism will bind if the floor is not completely level. Move the carts to a level surface before attempting to separate them.

Opening the Staff Cart

Because the StealthStation® S7® 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 Staff Cart panels in order to troubleshoot a connection problem or perform routine cleaning and maintenance.

To access the interior components of the Staff Cart, you must remove the appropriate cart panels. The front of the cart has a panel below the storage drawer that is held in place by captive screw at the top. Each side panel is held in place by four ball stud connectors. The back of the cart has one single panel and is held in place by four Phillips quarter-turn fasteners.

♦ ***To remove the front panel:***

1. Open the front drawer and locate the captive screw that is between the drawer and the front panel (mid-line of cart).
2. Loosen the screw (the screw will not fall out).
3. Grasp the front panel and pull it off the ball studs.
4. Lift the panel up and away from the cart.

♦ ***To remove the side panels:***

1. Remove visible screws.
2. Place the flat end of a standard screwdriver between the panel and the cart frame at the access slots. Use the tool as a lever to pry the panel corner off of the connecting ball stud.

3. Grasp the top of the panel and pry the upper left corner off of the connecting ball stud.
4. Pry the lower panel corners off of the connecting ball studs.
5. Lift the panel up and away from the cart.

Note The fans attached to the right lower panel may need to be disconnected in order to completely remove the panel.

♦ *To remove the back panel:*

1. If present, remove the AXIEM™ controller.
2. Remove the storage bin.
3. Quarter turn (counter clockwise) the two screws at the bottom of the panel using a Phillips head screwdriver.
4. Quarter turn (counter clockwise) the two screws at the top of the panel using a Phillips head screwdriver. Support the panel weight to prevent panel or screw damage.
5. Lift the panel up and away from the cart.

Component Locations

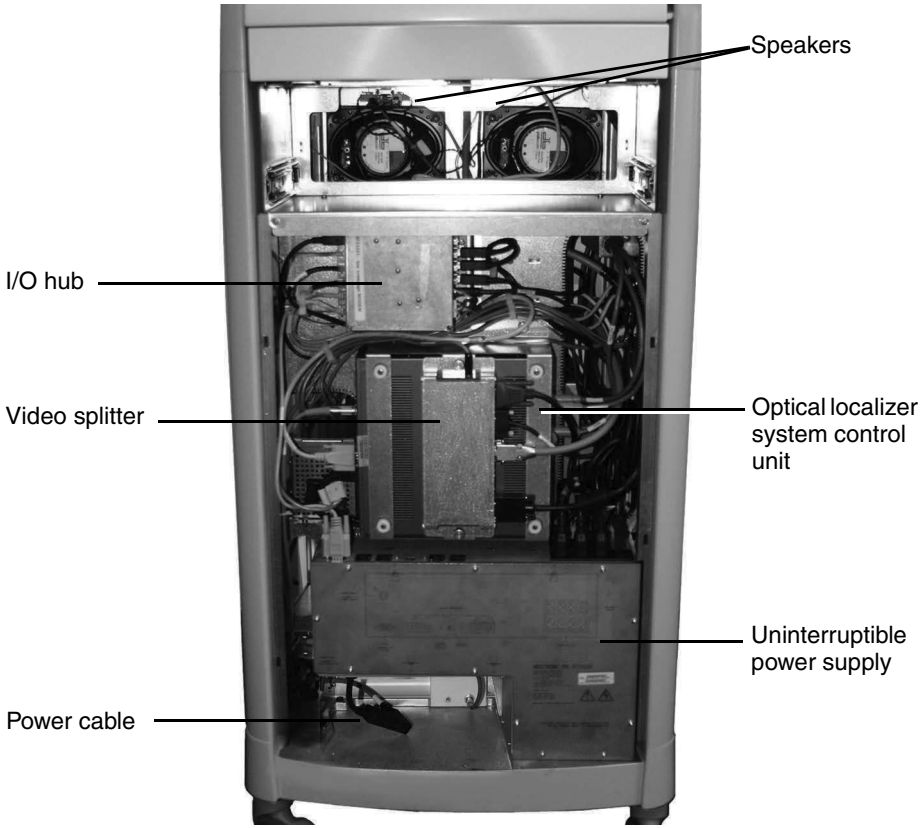


Figure 5-1. *Interior of Staff Cart (front)*

- Remove the front panel of the Staff Cart to access the system control unit, video splitter, input/output hub, and the uninterruptible power supply (UPS).
- Remove the rear panel to replace the system computer.

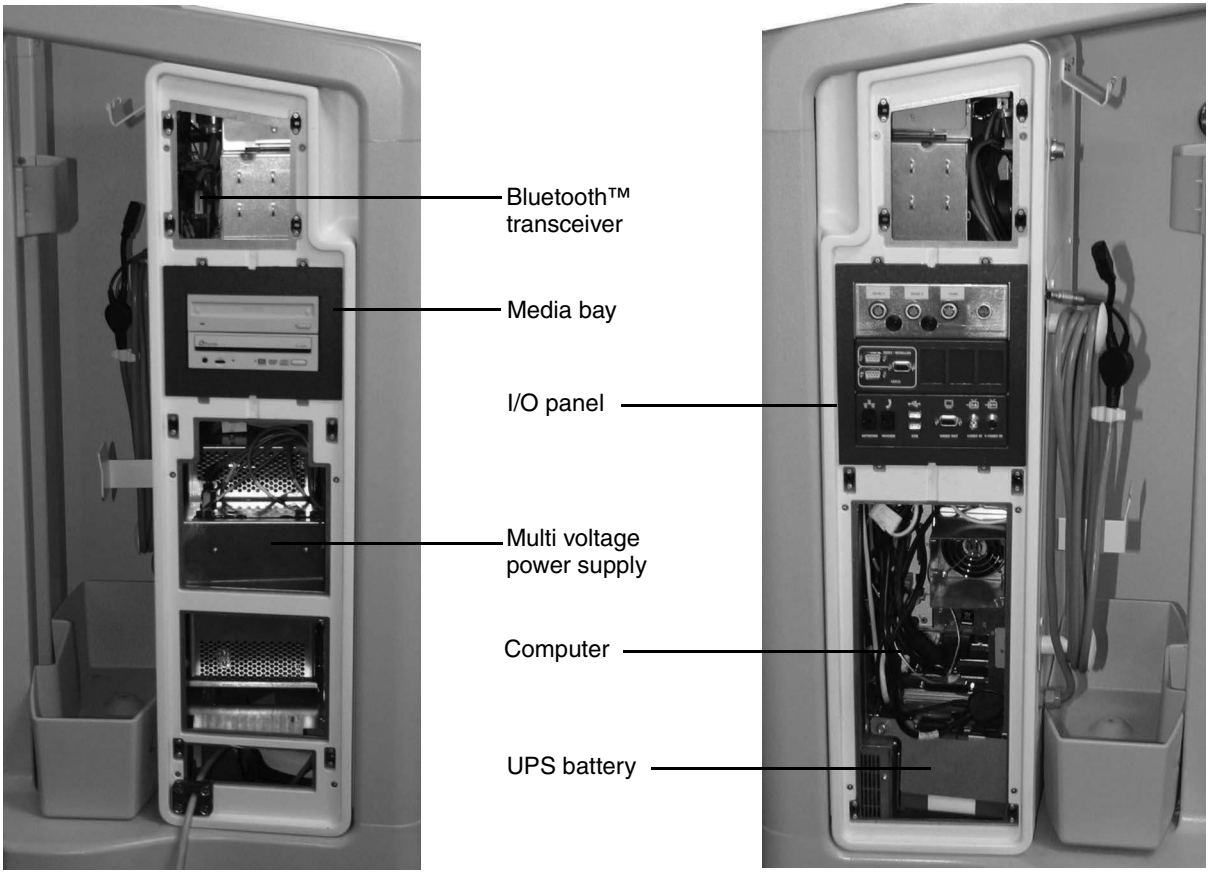


Figure 5-2. *Interior of Staff Cart (left and right)*

- Remove the cart drawers and the remove the upper side panels to access the keyboard and storage drawer rear assembly and the high fidelity speakers.
- Remove the lower left side panel to access the multi voltage power supply.
- Remove the lower right side panel to access the system computer connection panel and the UPS battery pack.
  - The UPS battery is not a user-serviceable item. It can be replaced with Medtronic part number 9733627.

    ⚠ Warning: Do not recharge or disassemble batteries. Do not dispose of batteries in fire. Observe local regulations concerning battery disposal.

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 Navigation, Inc. technical support representative.

⚠ **Warning**: Do not disconnect or remove any cables while the system is powered on.

♦ *To shut down all power to the Staff Cart:*

Note: Use the battery disconnect switch only when servicing interior connections or during emergency situations.

1. Follow the instructions in "System Shutdown" on page 3-8.
2. If present, remove the AXIEM™ controller.
3. Remove the storage bin.
4. Turn the battery disconnect switch to the off position. The battery disconnect switch is located on the rear of the Staff Cart in the lower left corner (behind the storage bin).

System Computer

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

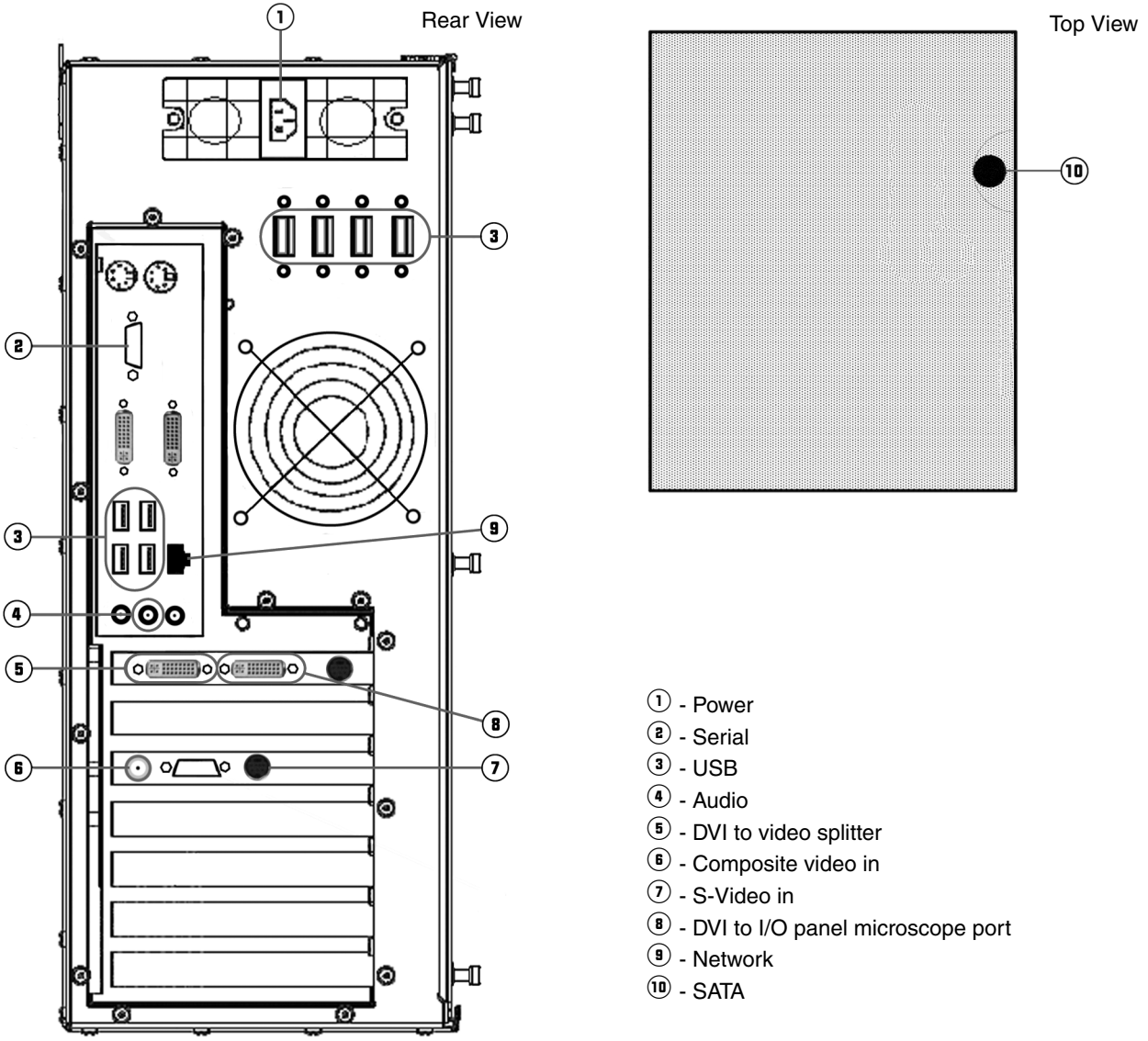


Figure 5-3. *Ports for computer A*

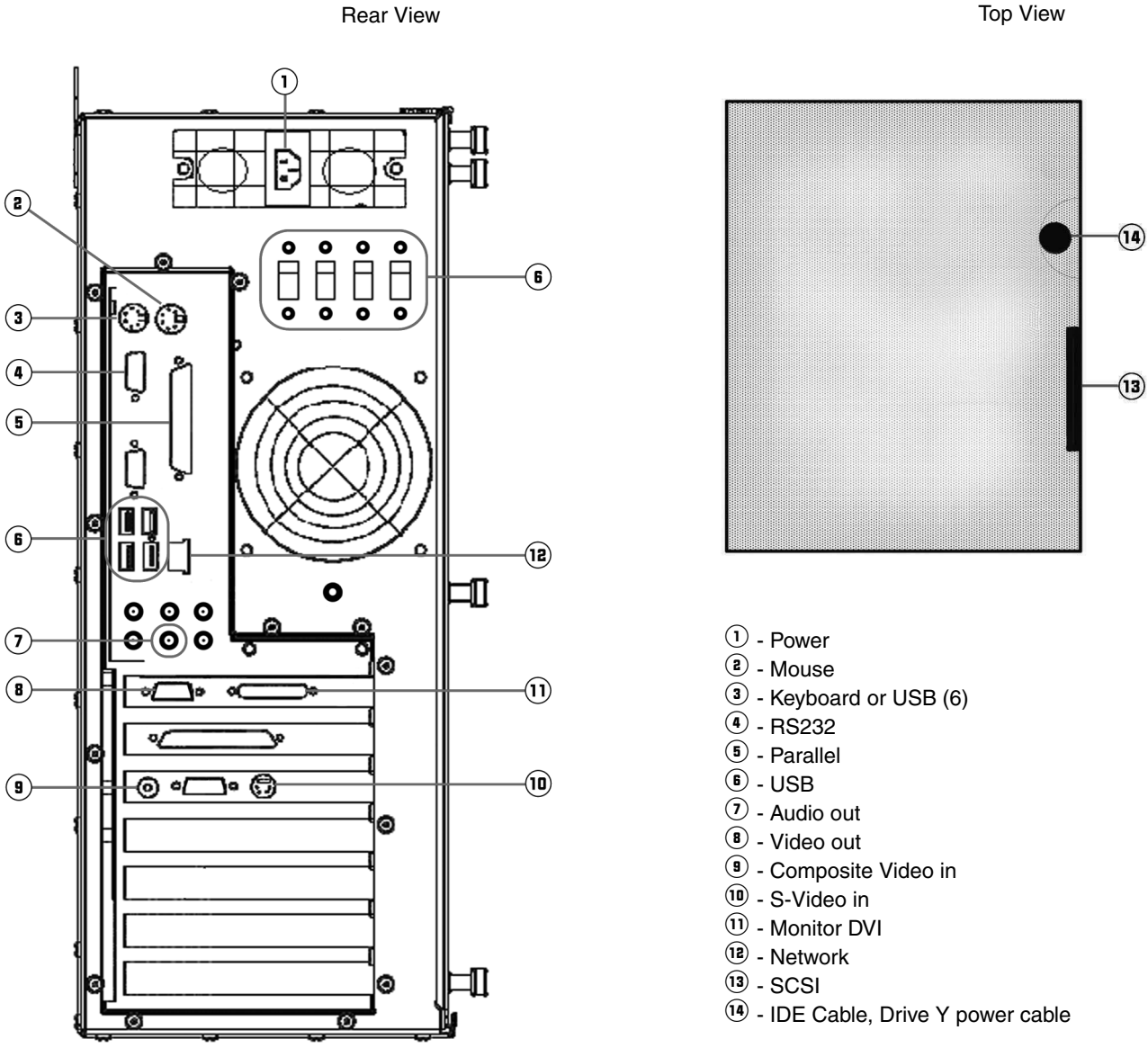


Figure 5-4. *Ports for computer B*

Device Connectivity Diagram

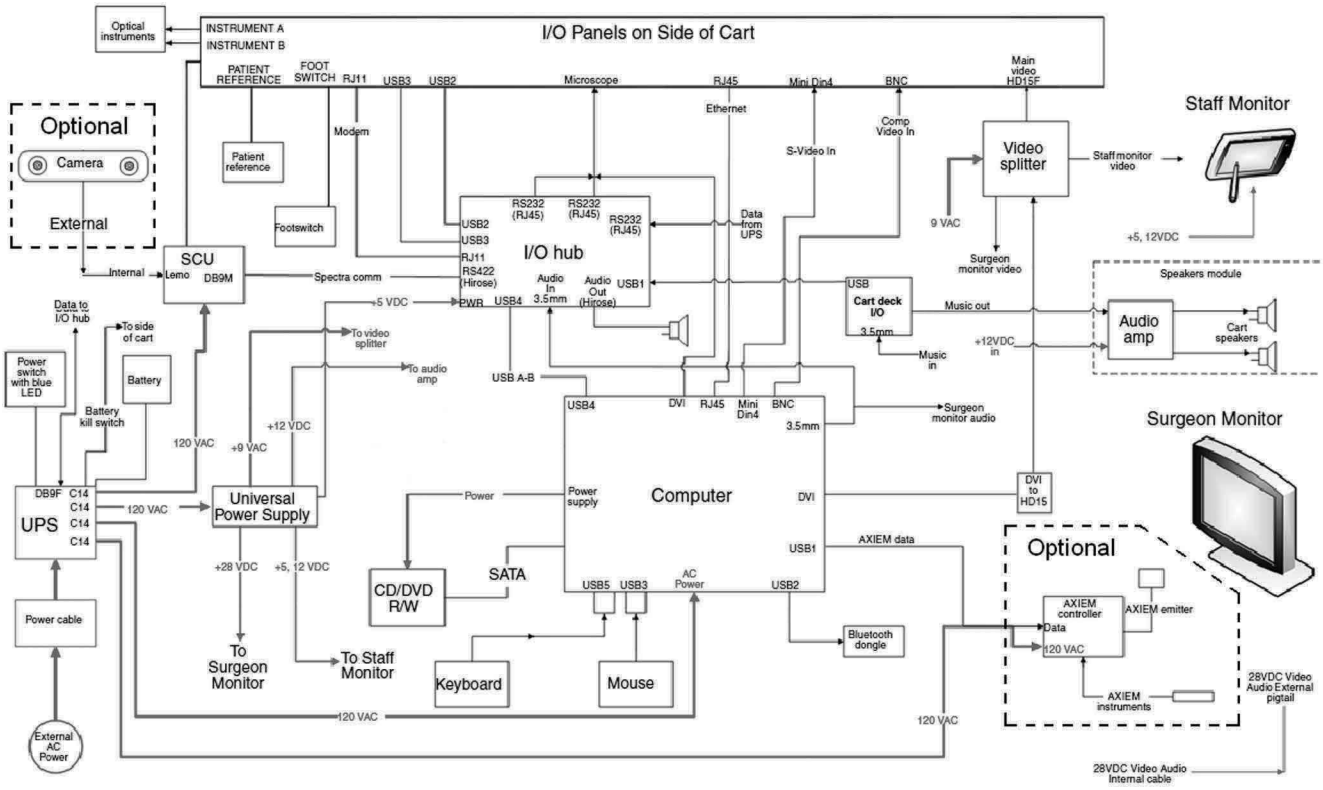


Figure 5-5. *Component connections (computer A)*

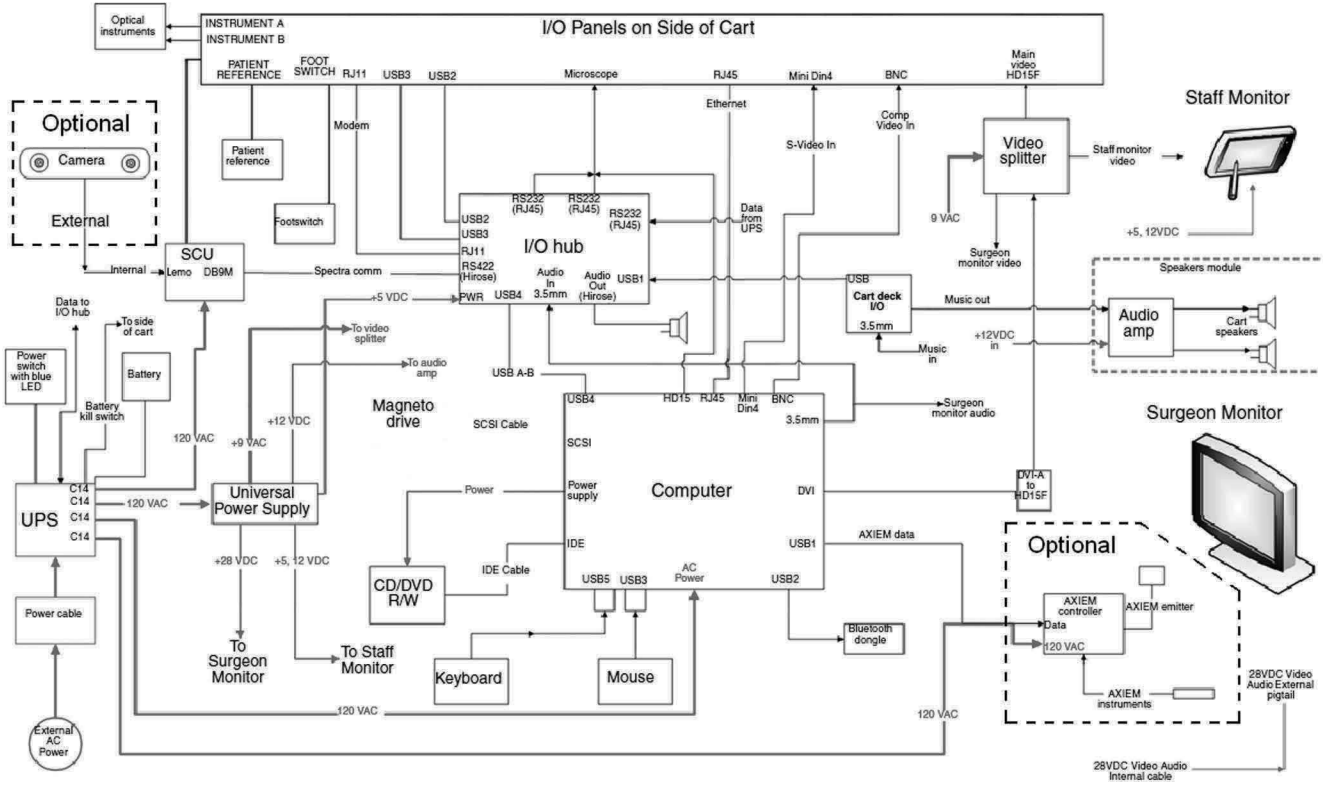


Figure 5-6. *Component connections (computer B)*

System Power

No power to system

- Is the system plugged in to an electrical power outlet? If not, plug the power cord into an electrical power outlet.
- Is the system plugged into a power outlet that actually supplies power? Test the outlet with a multi meter or a portable lamp or electronic device. If there is no power, use an electrical power outlet that is supplying power.
- Check all system connections. Check cables for crimps or damage. Check connector housing and pins for bent or broken components. Replace damaged cables. If necessary, power down the system and re-connect all external cables and devices (carts, touchscreen, instruments, footswitch, camera) and turn the system power back on.
- When turning on the system power, pay attention to the communication tones. Make a note of the different tones emitted by the system during a problem start-up. Normal response is an initial beep from the camera after turning system power on.

Power up	One short beep
Program start	One beep followed by two short beeps
Fault detected	Three or more short beeps

The power supply is making a beeping noise.

- There is no electrical voltage coming from the outlet, or the system is not plugged in. Check the power cable, the power switch, and the electrical power outlet.
- The electrical voltage is out of range. Test the voltage coming from the electrical power outlet.
  - If input voltage is in normal range, the batteries in the UPS may be low. The UPS batteries are recharged when the unit is connected to input power. The UPS batteries are not a user-serviceable item. If the problem continues after supplying AC power, the batteries can be replaced with Medtronic part number 9733627.

  △ Precautions:

  - If battery chemicals or corrosion are present, do not remove battery, contact Medtronic technical support.

- Disconnect cart power plug from outlet, turn off system power, and turn battery disconnect switch off before removing battery.
- Do not touch exposed battery contacts. Do not remove wiring from battery.

Power Switch

The system power switch located on the Staff Cart deck contains a blue LED. The state of the LED indicates the current system power status. Use the following information as a guide for determining current system power status.

On/steady	The system is powered on by the external AC power supply.
Slow flashing with a slow beep	The system is powered on by the internal uninterruptible power supply (battery backup).
Rapid flashing with a rapid beep	The system is powered on by the internal uninterruptible power supply (battery backup), but the battery is running low on power.

System Camera

The system camera contains an array of LEDs near the laser aperture. The state of the LEDs indicates the current camera status. Use the following information as a guide for determining the current camera status.

Power LED (green)	Status LED (green	Error LED (amber)	Camera Status
Flashing	Any state	Any state	Camera is warming up.
On/steady	On/steady	Off	Camera is ready for use
On/steady	On/steady	Flashing	Minor fault. Call Medtronic Navigation for technical support.
On or off/steady	On/steady	On/steady	Major fault. Call Medtronic Navigation for technical support.
On/steady	Off	On/steady	Camera is not functioning and must be returned for service.
Off	Off	Off	Voltage is out of range.

AXIEM™ System Power LED Definitions and Issues

	LEDs	LEDs not Lit
	**Power LED –** Indicates when power is being supplied to the unit.	▪ Check the power cable. ▪ Check the fuses on the power entry module.
	**Navigation LED –** Indicates when the system is in the navigation mode.	▪ Check that the communication cable is connected. ▪ Check that the AXIEM™ application software is running.
	**Fault LED –** Indicates, when lit, when the system has encountered a fault. ▪ Check the application software for further diagnostic information.	▪ No fault indicated.

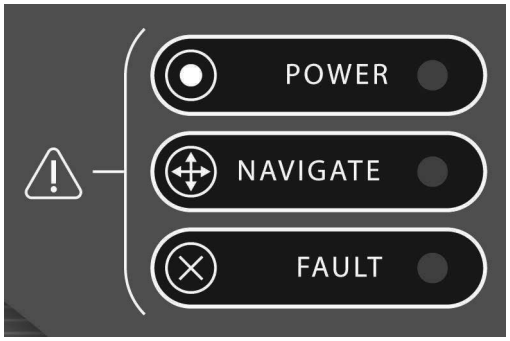


Figure 5-7. *AXIEM™ system LED label*

Controller Status LED

A status LED display is located on the back of the StealthStation® AXIEM™ system controller. Medtronic Navigation service representatives may ask for the number code displayed in this LED during a service call.

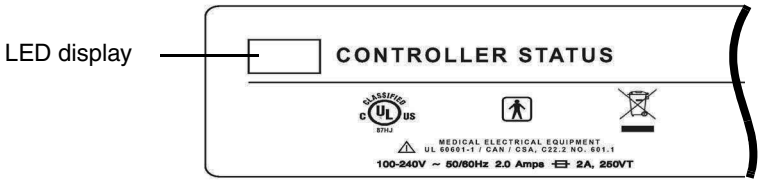


Figure 5-8. *AXIEM ™ system controller status label and LED*

Instrument Indicator LEDs

The instrument status LED color relays real time information about AXIEM™ instruments and the StealthStation® AXIEM™ System controller.

Indicator LED Color	Function
Green – Indicates that instrument is properly connected and can be tracked by the system.	▪ Normal

Orange – Indicates that instrument port is ready.	▪ Plug in an instrument and proceed with the procedure.
Blinking Orange – Indicates that the StealthStation® AXIEM™ system controller is not booting successfully.	▪ Disconnect the StealthStation® AXIEM™ system controller for 30 seconds and then reconnect it to the system. ▪ Remove all instruments and try disconnecting and reconnecting the StealthStation® AXIEM™ system controller.
Not lit – Indicates that the StealthStation® AXIEM™ system controller has failed.	▪ Disconnect the StealthStation® AXIEM™ system controller for 30 seconds and then reconnect it to the system. ▪ Check the application software for further diagnostic information.

Surgeon Monitor

The monitor screen is blank.

- The system is off or the monitor power is off. Verify that both the system and monitor are receiving power. The monitor is turned on and receiving a signal if you can hear a hum emanating from the back of the monitor.
- The monitor cable is loose. Check both ends of the cable (going to the Staff Cart and on the monitor). Make sure all connection pins are straight and the cable is securely connected.

The display on the monitor is distorted.

- The monitor cable is loose. Check both ends of the monitor cable. Make sure all connection pins are straight and the cable is securely connected.
- The contrast settings are incorrect in the software. Adjust the Level (brightness) and Width (contrast) settings using the on-screen controls in the application software.
- Shut down and reboot the system.
- There is a faulty monitor cable or faulty video card. Call Medtonic Navigation for technical support.

Mouse and Keyboard

- If the cursor does not move on the screen, the computer is not responding. Reboot the system.
  - Turn the system power off, wait 10 seconds, and turn the system power back on.
- If the mouse buttons are not operational, the mouse may have been disconnected at start up. Reconnect the mouse to the system computer and reboot the system.
- If the keyboard is not operational, the keyboard may have been disconnected at start up. Reconnect the keyboard to the system computer and reboot the system.

Footswitch

The system does not recognize the footswitch.

- Make sure that the footswitch is connected to the correct port on the system I/O panel.
- There is a loose connection. Check the connection between the Footswitch and the cart. Reboot the system.
- Make sure the System Control Unit (SCU) power switch is in the On position.
- Verify the expected footswitch mode in the application (update continuously or Update while footswitch is pressed). Change if necessary.

Optical Instruments

The system does not recognize the optical instruments.

- Make sure that the instruments are connected to the correct ports (INSTRUMENT A or INSTRUMENT B) on the system I/O panel.
- Make sure that the Patient Reference Frame is connected to the correct port (PATIENT REFERENCE) on the system I/O panel.
- Use software to diagnose optical instrument tracking problems.

Recommended Maintenance

The StealthStation®S7® System contains no user-serviceable components and no material which is consumed during operation. Under normal operation, detachable parts are not subject to deterioration. However, the StealthStation®S7® System and its associated components require cleaning as needed and annual inspection and testing.

Inspection should include:

- Inspect cables for damage, cuts or connector wear.
- Inspect cart, castors, monitor and monitor arm, and camera arm for damage or wear.

Testing should include:

- Verify full functionality of keyboard, mouse, computer, monitor, and fans.
- Verify full functionality of navigation including image load, image settings, registration, and navigation of all instruments and all cable ports.
- Verify system electrical safety (per tests spcecified in Electrical Safety Tests document 9732380 or equivalent).

Please contact Medtronic Navigation, Inc. (see page 1-9) to schedule a full maintenance and system check appointment.

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