StealthStation™ S8 System Manual

Read this manual completely before using this device.

Medtronic

6.Symbols

1   *Introduction*

Intended use/indications for use

The StealthStation™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous surgical procedures. The StealthStation™ System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to images 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.

Side effects

The Medtronic computer-assisted surgery system and its associated applications are adjuvant surgical tools and do not independently produce any side effects. When used in conjunction with navigated instruments for surgical procedures, the associated side effects are the same as those for the procedure itself.

Description of the StealthStation™ system

The StealthStation™ System, also known as an Image Guided System (IGS), is comprised of a platform, clinical software, surgical instruments, and a referencing system (which includes patient and instrument trackers). The IGS tracks the position of instruments in relation to the surgical anatomy, known as localization, and then identifies this position on preoperative or intraoperative images of a patient. The StealthStation™ platform supports both optical and electromagnetic (EM) localization. Localization is also called navigation.

Localization is achieved when the system (hardware and software) creates a map between all points in the patient images and the corresponding points on the patient anatomy. After this map has been established, whenever the operator touches a point on the patient with a tracked instrument or pointing device, the computer uses the map to identify the corresponding point on the patient images. A localized point is identified on the system display with multiple patient image planes and possibly other anatomical renderings.

The StealthStation™ platform is made up of one or more carts which contain the key navigation components including the localizers and the computer with the operating system.

System installation

The StealthStation™ S8 system is installed by qualified Medtronic personnel only. If you have any questions about your system installation, contact Medtronic Navigation.

Use profile

The intended user profile for the StealthStation™ system is operating room staff, including surgeons, nurses, surgical technologists, and hospital biomedical engineers.

The intended patient population for the system is patients for whom stereotactic image guided surgery is appropriate.

Conventions

This document employs the following conventions:

- Warnings are preceded by the word **Warning**. Failure to observe a warning may result in physical injury to the patient or operator. Pay special attention to these items.

- Precautions are preceded by the word **Caution**. Failure to observe a precaution could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.

- References to buttons that appear on the system display are enclosed in square brackets. For example:

  Click **[Edit...]**.

- 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 press and release the left mouse button. Instructions to tap an object on the screen means to tap the screen with a finger, a gloved finger, or a capacitive stylus. Click and tap are used interchangeably.

Residual risks

Residual risks related to the use of a Medtronic computer-assisted surgery system and its associated applications are the same as the residual risks for the procedures in which the system is used.

Warnings and precautions

Warnings

Warning: The system hardware and software should be used only by qualified medical professionals who are trained in performing surgery and familiar with image-guided surgery systems.

Warning: If system navigation seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.

Warning: Inspect all visible system components before use including the localizers that accompany your system (that is, the camera, the EM instrument interface, the side-mount emitter, or the flat emitter). If visibly damaged, do not use the system.

Warning: To avoid the risk of electrical shock, do not simultaneously touch the patient and the system input/output panel, mouse, keyboard, or batteries.

Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Warning: Metallic and conductive objects in or near the electromagnetic navigation field can degrade navigational accuracy and the navigation volume. If metallic distortion causes excessive error, navigation may be disabled. To restore navigation, move metallic and conductive objects away from the navigation field.

Warning: Electrical noise in or near the electromagnetic navigation field can degrade navigational accuracy. If electrical noise introduces excessive error, the system may automatically disable navigation. To restore navigation, move devices that produce electrical noise (such as electro-cautery equipment and electric drills) away from the navigation field.

Warning: Prevent fluid from entering any part of the StealthStation™ S8 system. Shut down the system, disconnect the power, and allow the system to dry if you suspect fluids may have entered any part of the system.

Warning: Do not step on the base or legs of the system carts because the carts could tip over and cause injury.

Warning: The system is not suitable for use in the presence of a flammable, anesthetic mixture with air, oxygen, or nitrous oxide.

Warning: Do not modify the StealthStation™ S8 system without prior written consent from Medtronic Navigation, Inc. Prohibited modifications include but are not limited to: altering, repairing, or replacing system components; altering software provided by Medtronic; updating the operating system or drivers; and installing any software that is not provided by Medtronic, including anti-virus software. Secure the system to prevent unauthorized modifications. Unauthorized modifications could render the system unsafe or ineffective for its intended use.

Warning: Follow system component maintenance and care instructions.

Warning: The StealthStation™ S8 system camera cart contains a 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 instructions and warnings prescribed by the manufacturer of the user-provided player.

Precautions

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

Caution: 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 Medtronic Navigation™ technical support representative.

Caution: To avoid interrupting navigation, do not use the StealthStation™ S8 system on battery power alone while the system is in use with a patient.

Caution: Periodically plug in the system to recharge the backup batteries. The backup batteries on the main cart and the camera cart are intended to keep the system operating for a short time if power is lost or disconnected. If the backup batteries are not charged, the system will shut down immediately when power is lost. The backup battery in the camera cart will recharge only when the two carts are connected with the cart-to-cart cable.

Caution: Before surgery, clean the system carts and other non-sterilizable system components according to the parameters in the StealthStation™ S8 cleaning instructions (9735727).

Caution: The system mouse and keyboard are not designed for sterilization and may be damaged if sterilization is attempted.

Caution: System components are fragile. Use care when handling system components.

Caution: Keep the rear storage bin clear of extraneous materials which could block air flow through the perforated panel. Blocking air flow could result in excessive internal cart temperatures, which could degrade the system's performance and longevity.

Caution: Avoid spilling fluids onto casters because fluid may impair the braking ability and the stability of the cart at rest on inclined surfaces.

Content of this manual

This system manual is intended as a reference document for biomedical engineers or other qualified personnel who require familiarity with the StealthStation™ S8 system. This manual is not a software usage manual. For instructions on using specific software, refer to the instructions for use provided with the software.

Related documents

For software instructions, refer to the specific software's instructions for use. For components that interface with the StealthStation™ S8 system, such as instruments, patient reference frames, or intraoperative imaging systems, refer to the component's instructions for use. For instrument cleaning and sterilization instructions, refer to the Medtronic Navigation™ Equipment Cleaning and Sterilization sheet (9730713) or refer to the instructions for use that accompany the instrument. For instructions on cleaning non-sterilizable items, consult the StealthStation™ S8 cleaning instructions (9735727).

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

Contact information

If a serious incident occurs in relation to the use of this Medtronic computer-assisted surgery system, report it to Medtronic Navigation. If a serious incident occurs in the European Union, also report it to the competent authority in the Member State where the incident occurred.

Telephone

Technical support worldwide	+1 720 890 3160
Technical support in the USA	+1 800 595 9709
General	+1 720 890 3200
Fax	+1 720 890 3500

Mailing address

Medtronic Navigation, Inc.

826 Coal Creek Circle

Louisville, Colorado 80027

USA

Medtronic E.C. authorized representative

Medtronic B.V.

Earl Bakkenstraat 10

6422 PJ Heerlen

The Netherlands

Tel. +31 45 566 80 00

Australia

Medtronic Australasia Pty Ltd

5 Alma Road

Macquarie Park, NSW 2113

Australia

Tel. 1800 668 670 (within Australia)

World Wide Web

www.medtronic.com

E-mail

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

2   *System overview*

How the system works

The StealthStation™ S8 system, which is a combination of hardware and software, works in conjunction with special trackable instruments to help guide surgeons during surgical procedures. To achieve this guidance, the system tracks the position of a specialized instrument in relation to the surgical anatomy and transmits that information to the software. The software then displays the instrument's position on diagnostic or intraoperative images of the patient.

The system can track instruments either optically or electromagnetically. Some systems may have one or both of the tracking methods. With optical tracking, a camera (also called a localizer) detects infrared light from optical markers (either reflective spheres or LEDs) on the specialized instrument. The infrared light is either emitted by the camera and reflected off spheres on the instrument or emitted directly by LEDs on the instrument. The camera transmits the instrument's location to the navigation software. Similarly, with electromagnetic tracking, an emitter and an instrument interface work together as a localizer. The emitter emits a low-energy magnetic field with unique characteristics at every point. The electromagnetic instruments contain sensors which allow the navigation software to identify the instrument's location within the electromagnetic field.

For the software to display the instrument's location in relation to images of the patient, you must assist the software by creating a map between points on the patient and points in the images. This process is called registration. After registration is complete, whenever the operator touches a point on the patient using a special tracked instrument, the computer uses the map to identify the corresponding point on the images. This identification is called navigation. A navigated point is identified on the system display within multiple patient image planes and other anatomical renderings.

Precautions

Caution: Portable and mobile RF (radio frequency) communications equipment can affect the StealthStation™ S8 system.

Dynamic referencing

To maintain accuracy, the StealthStation™ S8 system uses dynamic referencing to constantly track the position of the anatomy during registration and navigation. Two devices are necessary for dynamic referencing: a patient reference frame and a localizer. The patient reference frame is rigidly positioned with respect to the anatomy. The localizer, which is either a camera for optical tracking or an emitter and instrument interface for electromagnetic tracking, locates the patient reference frame and reports the frame's position to the navigation software.

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 the reference frame in the localizer's field of view. This enables the localizer to detect any movement of the anatomy by detecting the position of the reference frame, which moves concurrently with anatomy. Then, the system can display the instrument or implant location relative to the patient reference frame, thereby maintaining accurate navigation.

Without dynamic referencing, any movement of the localizer after registration would invalidate the registration because the position of the reference frame would change in the navigation field. Dynamic referencing allows the flexibility to reposition the localizer at any time.

Each tracking method has its own unique reference frames. Optical reference frames feature a set of markers (reflective spheres or infrared LEDs) mounted on a frame. Electromagnetic reference frames include a set of embedded sensors housed within a small module. Consult the software's instructions for use for more information.

Optical localization system

The optical localization system determines the position of the instrument and patient in the operating room by using a camera (a type of localizer) to track the positions of optical markers. The camera's field of view and the software determine 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. The system user connects the patient reference frame to a support mechanism and secures that mechanism in a fixed position in relation to the patient anatomy.

There are two types of optical markers. Some components may have infrared LED optical markers, and others may have reflective spheres. LEDs generate and emit infrared light. Reflective spheres reflect infrared light that is emitted by the camera.

The camera detects the optical markers, determines their spatial positions using the principle of triangulation, and constantly reports this information to the computer. The system constantly re-computes the relative spatial positions and orientations 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 and on optional 3D renderings.

Camera

Warning: The optical system emits (and receives) infrared light and can cause, or be susceptible to, infrared interference.

Caution: Before use, clean the camera lenses according to the StealthStation™ S8 cleaning instructions (9735727). Dirty camera lenses could impair optimal performance of the camera.

Caution: Allow the camera to warm up for 3 minutes after powering on the system because the camera will not track instruments or the patient reference frame until it has warmed up.

The standard infrared camera uses two lenses to geometrically triangulate the spatial coordinates of each optical marker on the instrument and the reference frame. In the case of devices with LEDs (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 reflective spheres on each device reflect light emitted by infrared illuminators on the camera back into the camera lenses. The camera constantly communicates the location of each LED or reflective sphere to the system. In order to effectively localize the LEDs or reflective spheres, the camera must be aimed toward the devices (see Figure 2) and positioned at the proper distance from them, which varies between 1.0 m and 2.4 m (3.3 ft and 7.9 ft) and 1.0 m and 3.0 m (3.3 ft and 9.8 ft) depending on the software application.

Figure 1: Camera, lift arm assembly, and camera handle

①   2 status indicator LEDs   ③   Laser aperture

②   Camera lenses   ④   Laser on/off trigger button
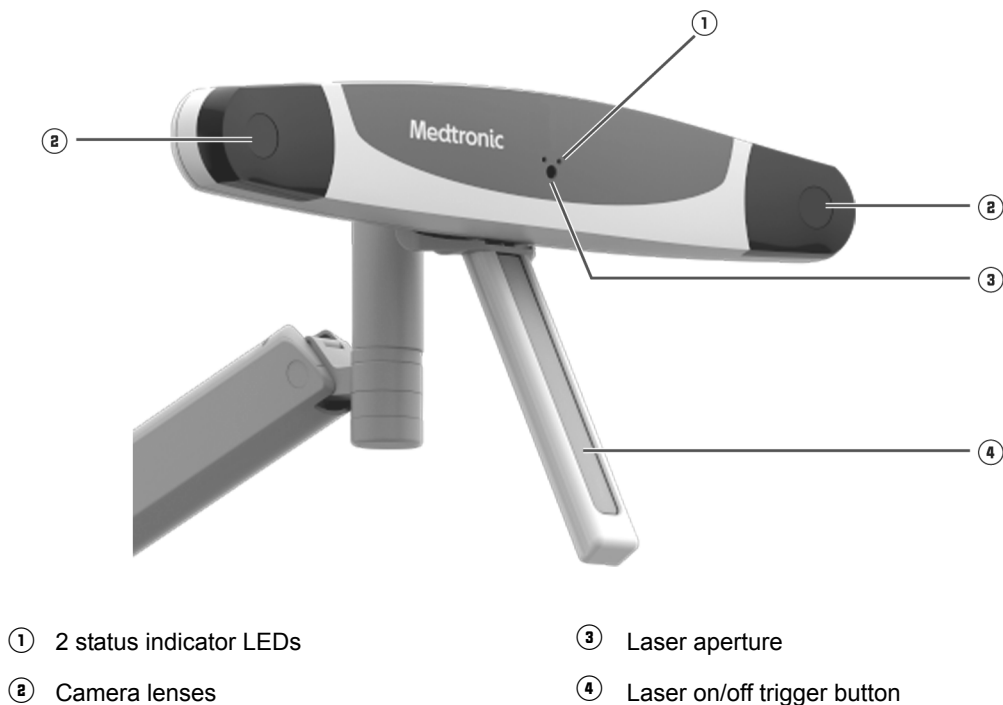
Figure 2: Camera volume
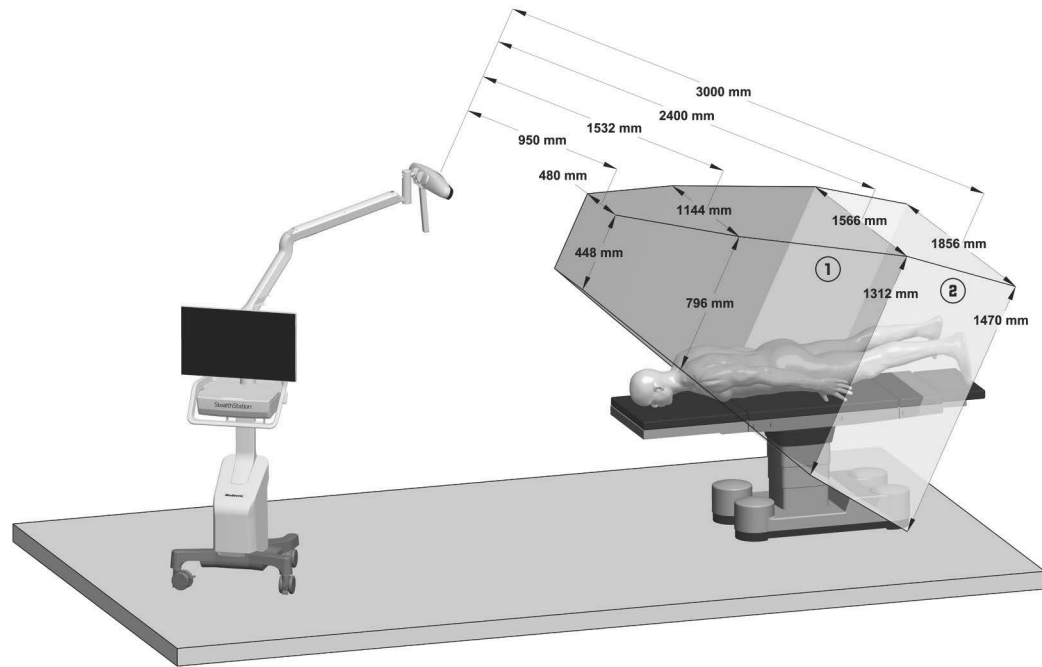
| ① | Standard volume | ② | Extended volume, which is available with some software applications |

Laser aiming system

Warning: The laser aiming system is a Class 2 laser that 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 aiming system (located between the camera lenses, see Figure 1) helps to aim the camera by projecting a low-power laser beam approximately in the center of the camera's field of view. The laser is activated by a trigger button in the handle. Press the on/off trigger button to activate the laser and release the button to deactivate the laser.

Electromagnetic localization system

The electromagnetic (EM) localization system tracks instruments and anatomy simultaneously. An EM emitter is placed near the surgical field, and it generates a low-energy magnetic field, called the navigation field, that encompasses the anatomy of interest. Because every location in the navigation field has unique characteristics, the system can determine the position of a tracked device by measuring the field characteristics at that location. Sensors embedded in the patient reference frame, which is attached to the patient's fixed anatomy, enable the system to identify the location of the anatomy of interest in the EM field. Similarly, sensors embedded in the pointer probe or other instrument enable the system to identify the instrument's position and, for some instruments, the trajectory in the field.

The system constantly 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.

Electromagnetic instrument interface

The main cart houses the electromagnetic localization system components including the EM instrument interface and the emitter. These EM components connect directly to the main cart. The main cart includes a computer, monitor, and all related peripheral devices. The main cart is a platform from which the surgeon or qualified assistant can control the navigation software.

Figure 3: EM instrument interface
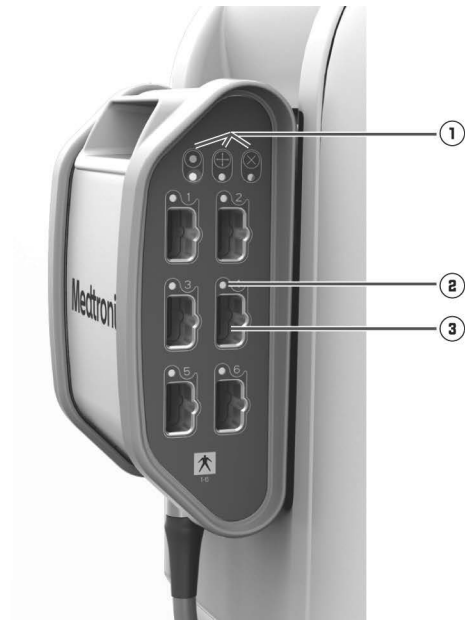
① EM instrument interface status indicator LEDs

② Instrument indicator LED (6 total)

③ Instrument port (6 total)

Connect the patient reference and EM instruments to the instrument ports on the EM instrument interface. The instrument indicator's LED glows green when the instrument is properly connected and functioning normally. For more information about the status indicator colors, see "EM instrument interface status indicator LEDs" on page 68 or "Instrument indicator LEDs" on page 69.

Electromagnetic emitters

The StealthStation™ S8 system supports the use of 2 emitter designs: the side-mount emitter and the flat emitter. You can use only 1 emitter with the system at any given time. Connect the emitter to the EM emitter port on the main cart localization I/O panel (see "Main cart I/O panel connections" on page 29).

Warning: Do not use the side-mount emitter or the flat emitter in ambient (room) temperatures greater than 30°C (86°F). Exceeding this temperature limit could result in navigational inaccuracy or patient or user harm from excessive temperatures.

Warning: Do not place the side-mount emitter in contact with the patient because the emitter temperature may reach 48°C (118°F).

Warning: Do not exceed the maximum weight load of 6.5 kg (14 lbs) on the flat emitter.

Warning: The side-mount emitter, the flat emitter, and the arm assembly that supports the side-mount emitter are not intended for sterile patient contact or interaction. If you place these items in the sterile field, bag or drape them.

Caution: For procedures performed with the flat emitter, a surgical table with a radiolucent table top is recommended. If the surgical table has a metal frame or metal side rails, position the flat emitter at least 5 cm (2 in) away from the metal. Positioning the emitter closer may result in reduced navigational accuracy and volume.

Caution: If the surgical table to be used with the side-mount emitter has a metal frame or metal side rails, position the side-mount emitter at least 25 cm (10 in) away from the metal. Positioning the emitter closer may result in reduced navigational accuracy and volume.

Caution: Procedures performed with the side-mount emitter require a surgical bed featuring side rails because the arm assembly that supports the emitter connects to the side rails.

Side-mount emitter navigation field

The side-mount emitter produces a low-energy magnetic field that encompasses the emitter. Minimize the amount of metal placed in this field. The navigation field, the portion of the magnetic field that is appropriate for navigation, begins 8 cm (3 in) from the emitter face and has a cubical volume of approximately 31.0 cm x 46.0 cm x 46.0 cm (12.2 in x 18.1 in x 18.1 in) (length x width x height). For best results, place the patient in the center of the navigation field. The side-mount emitter may be placed in a holder which is mounted to the operating table or to the main cart. For additional information about setting up the emitter, refer to the emitter setup quick reference guide (9735730).

Figure 4: Side-mount emitter

Figure 5: Side-mount emitter magnetic and navigation fields

① Low-energy magnetic field: Minimize the amount of metal in this field. Metal objects such as instrument stands, equipment carts, surgical lights, and viewing screens in this area will reduce the navigation field size.

② Side-mount emitter

③ Navigation field

Figure 6: Side-mount emitter navigation field
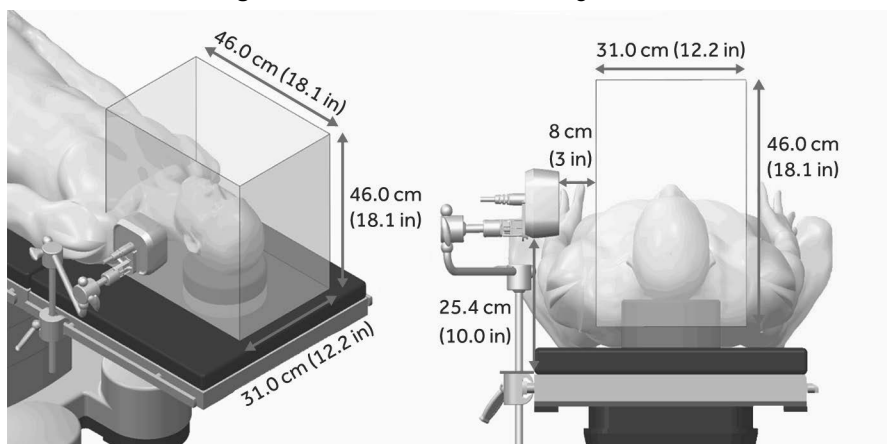
Note: This navigation field size is based on testing with a fluoroscopically radiolucent surgical table with non-magnetic metal rails 3 cm to 6 cm tall by 1 cm to 3 cm wide (1.2 in to 2.4 in tall by 0.4 in to 1.2 in wide) and a 25 cm (10 in) separation between the metal rails and the side-mount emitter.
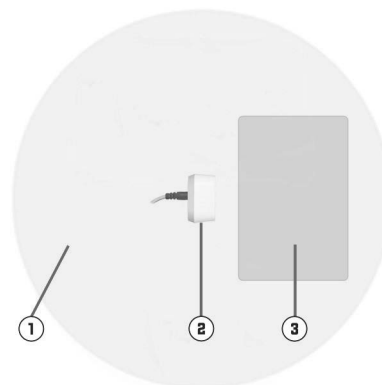
Flat emitter navigation field

The flat emitter produces a low-energy magnetic field that encompasses the emitter. Minimize the amount of metal placed in this field. The navigation field, the portion of the magnetic field that is appropriate for navigation, begins 5 cm (2 in) from the emitter face and extends approximately 40.0 cm x 40.0 cm x 37.5 cm (15.7 in x 15.7 in x 14.8 in) (length x width x height). The flat emitter is intended to be placed on the operating table under the patient's head. For best results, place the patient in the bottom center of the navigation field. Before use, drape the flat emitter. For additional information about setting up and draping the flat emitter, refer to the emitter setup quick reference guide (9735730).

Figure 7: Flat emitter

Figure 8: Flat emitter magnetic and navigation fields
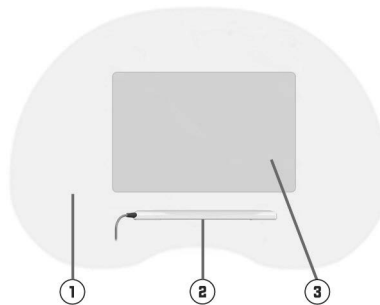
① Low-energy magnetic field: Minimize the amount of metal in this field. Metal objects such as instrument stands, equipment carts, surgical lights, and viewing screens in this area will reduce the navigation field size.

② Flat emitter

③ Navigation field

Figure 9: Flat emitter navigation field
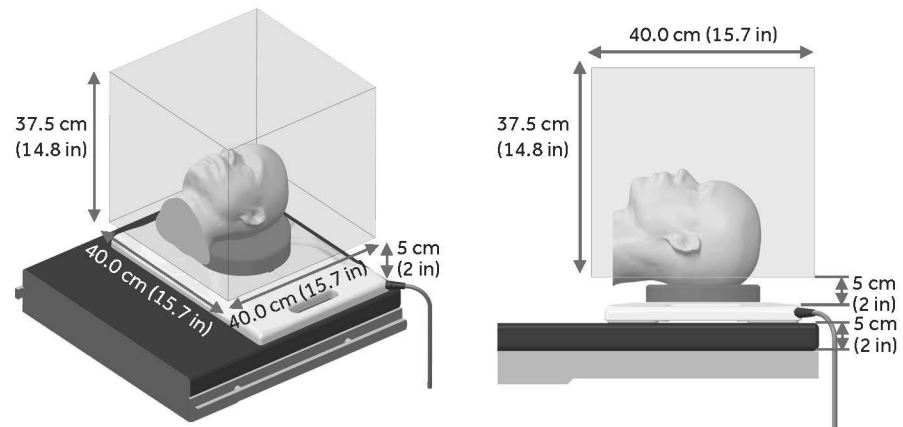
Note: This navigation field size is based on testing with a fluoroscopically radiolucent surgical table with non-magnetic metal rails 3 cm to 6 cm tall by 1 cm to 3 cm wide (1.2 in to 2.4 in tall by 0.4 in to 1.2 in wide) and a 5 cm (2 in) separation between the metal rails and the flat emitter.

Applicable standards for EM fields

Based on the available standards and international guidelines, the StealthStation™ electromagnetic system is considered safe for use in surgical environments. The electromagnetic 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 StealthStation™ electromagnetic 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 occupational exposure basic restrictions recommended by the Institute of Electrical and Electronics Engineers (IEEE), as formally recognized by the American National Standards Institute (ANSI) in the *Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz*. This system also complies with occupational exposure basic restrictions recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), as formally recognized by the World Health Organization (WHO), in the *Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields (1 Hz –100 kHz)*. For occupational exposure, electromagnetic field exposures outside the surface of the side-mount emitter and the flat emitter are below the basic restrictions.

Table 1 outlines the radio frequency wireless operating parameters for the side-mount emitter and the flat emitter.

Table 1: Wireless operating parameters for the side-mount emitter and the flat emitter

	Side-mount emitter	**Flat emitter**
Transmit frequency	3 kHz to 30 kHz Very Low Frequency (VLF) Band	3 kHz to 30 kHz Very Low Frequency (VLF) Band
Power	<30 W This product operates in the VLF band with an RF output power of less than 0.1 mW e.r.p.	<30 W This product operates in the VLF band with an RF output power of less than 0.1 mW e.r.p.
Field strength	<2.10 x (f / 3350) V/m where f is the frequency in Hz from 3 kHz to 5 MHz as set by IEEE Standard C95.1 – 2005	<2.10 x (f / 3350) V/m where f is the frequency in Hz from 3 kHz to 5 MHz as set by IEEE Standard C95.1 – 2005
Volume	The side-mount emitter produces a low-energy magnetic field volume of approximately 31 cm x 46 cm x 46 cm, in front of the emitter face, and with its near side offset 8.0 cm from the face.	The flat emitter produces a low-energy magnetic field volume of approximately 40.0 cm x 40.0 cm x 37.5 cm, in front of the emitter face, and with its near side offset 5.0 cm from the face.

System carts

The StealthStation™ S8 system has two separate but complementary carts; the main cart and the camera cart. The carts may be docked together as a single unit or separated for positional flexibility and convenience during surgery. Your facility may have both carts or only the main cart depending on the localization method and user preferences. For more information about which system components are needed for each localization method, refer to "System configurations" on page 28.

Main cart

The main cart (Figure 10) contains a high-definition touchscreen monitor, computer, system control unit for wired (active) optical instruments (optional), input/output connection ports, power supply, and all related peripheral devices. The optional EM instrument interface is hung on the back of the main cart. The main cart also includes storage locations for the optional side-mount emitter and flat emitter. The cart is intended to be placed near the surgical field so that the surgeon has optimal visibility of the navigation screen. Users interact with and control the system while standing at the main cart or the camera cart touchscreen.

Note: Some images may show components with optional accessories.

Figure 10: Main cart exterior (optical system)
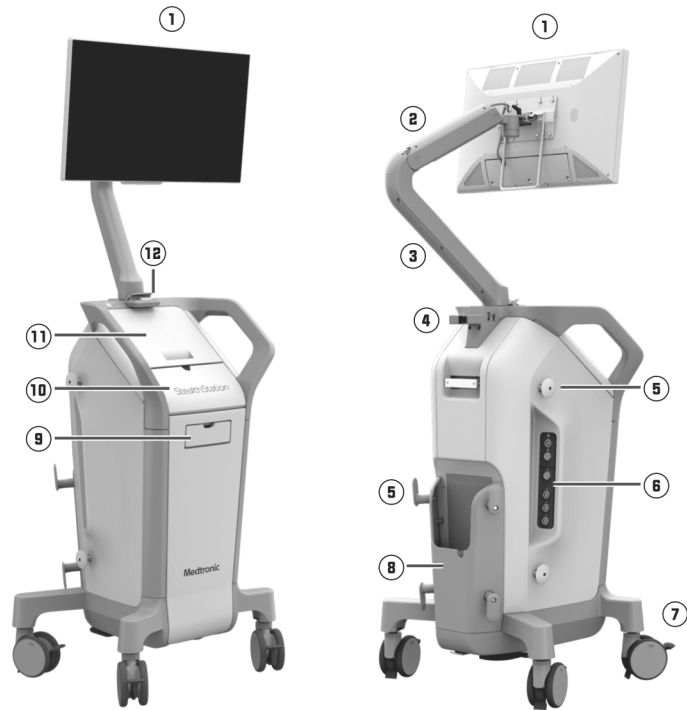
①	Main cart monitor	⑦	Caster locks
②	Monitor lift arm	⑧	Back storage bin
③	Monitor lower arm	⑨	CD/DVD drive and keyboard storage
④	Cart docking coupler	⑩	Front storage bin
⑤	Cable wraps	⑪	Work surface that slides into a horizontal position
⑥	I/O panel for connections to optical instruments and microscopes	⑫	Monitor docking receptacle

Figure 11: Main cart exterior (electromagnetic system with side-mount emitter)

①	Main cart monitor	⑨	Cable wraps
②	Monitor lift arm	⑩	Caster locks
③	Monitor lower arm	⑪	Back storage bin
④	Side-mount emitter	⑫	CD/DVD drive and keyboard storage
⑤	Cart docking coupler	⑬	Front storage bin
⑥	Cord wrap for emitter	⑭	Work surface that slides into a horizontal position
⑦	EM instrument interface	⑮	Monitor docking receptacle
⑧	I/O panel for connections to optical instruments, EM accessories, and microscopes		

Figure 12: Main cart exterior (electromagnetic system with flat emitter)
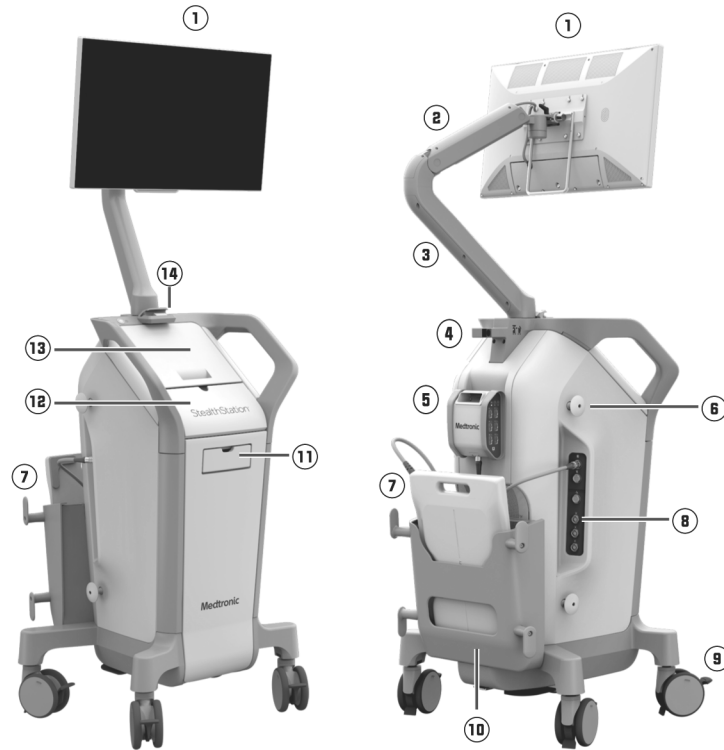
① Main cart monitor

② Monitor lift arm

③ Monitor lower arm

④ Cart docking coupler

⑤ EM instrument interface

⑥ Cord wrap for emitter

⑦ Flat emitter

⑧ I/O panel for connections to optical instruments, EM accessories, and microscopes

⑨ Caster locks

⑩ Storage bin for flat emitter

⑪ CD/DVD drive and keyboard storage

⑫ Front storage bin

⑬ Work surface that slides into a horizontal position

⑭ Monitor docking receptacle

Touchscreen monitor

The touchscreen monitor is a high-resolution, flat panel computer display with built-in speakers. The monitor can be adjusted to a variety of positions to accommodate various operating room configurations and user needs. The capacitive touchscreen interface can be controlled by a finger, gloved finger, or capacitive stylus.

Caution: Do not use a hard object or a sharp object to control the touchscreen interface because the object may damage the screen.

Keyboard and mouse

A wired USB keyboard is provided in the main cart's keyboard storage area. A wired mouse is located in the main cart front storage bin. They are used to control the system, and they can be plugged into either the main cart or the camera cart.

Optical instruments

Instruments designed for use with StealthStation™ systems have a precise instrument geometry and LED or sphere configuration. The specific geometry of each instrument is stored in a file. The computer references that file to determine the instrument tip location relative to the LEDs or spheres.

When you bring an instrument or reference frame into the camera's field of view for the first time, the system expects you to verify that the instrument you have chosen is not compromised. You do this by holding the tip of the instrument in a metal divot on the reference frame. The camera and computer then confirm the condition of the optical markers and that the instrument you are using matches the specifications for the instrument. For instructions on the use of a specific optical 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.

EM instruments

EM instruments designed for use with StealthStation™ systems contain embedded sensors that allow the system to determine their locations in the navigation field. Some EM instruments require the same type of verification as optical instruments. Some EM components are single-use only and may not be reused or resterilized. For instructions on the use of a specific EM 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.

Detachable equipment/applied parts

Refer to the StealthStation™ S8 detachable equipment package insert (9735689) for a list of Medtronic detachable equipment/applied parts that are qualified for use with the StealthStation™ S8 system.

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.

Camera cart

Figure 13 illustrates the camera cart. The camera cart supports the camera and monitor and contains a storage drawer and USB 2.0 ports (for media input/output, keyboard, and mouse connection). The camera cart monitor also contains speakers for music playback. The audio input port for music input devices and the USB 2.0 ports are located at the back of the camera cart work surface.

During use, the camera cart is typically located in the operating room outside the sterile field within 1 m to 3 m (3.3 ft to 9.8 ft) of the operating table. The camera cart monitor is positioned for optimal visibility by the operating room staff, but remains outside the sterile field. Users interact with and control the system while standing at the main cart or the camera cart monitor touchscreen.

Touchscreen monitor

The touchscreen monitor is a high-resolution, flat panel computer display with built-in speakers. The monitor can be adjusted to a variety of positions to accommodate various operating room configurations and user needs. The capacitive touchscreen interface can be controlled by a finger, gloved finger, or capacitive stylus.

Caution: Do not use a hard object or a sharp object to control the touchscreen interface because the object may damage the screen.

Figure 13: Camera cart exterior
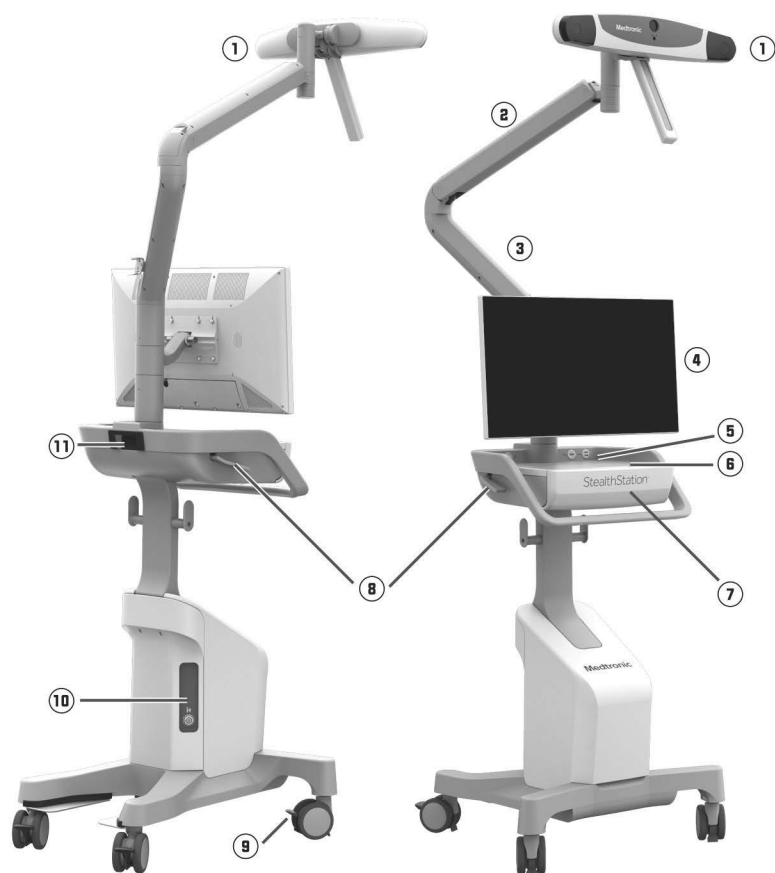
①	Camera	⑦	Storage drawer
②	Camera lift arm	⑧	Docking release lever
③	Camera lower arm	⑨	Caster locks
④	Camera cart monitor	⑩	Cart interconnection panel
⑤	USB 2.0 ports (for media input/output, keyboard, and mouse connection)	⑪	Cart docking mechanism
⑥	Work surface		

System configurations

All of the system components described in this manual may not be included in your system configuration. Some components are required only for optical tracking, and some components are required only for EM tracking. Table 2 lists the components that are required for each tracking method.

Table 2: Components required for optical tracking and EM tracking

Components	Required for optical tracking	Required for EM tracking
Main cart	Yes	Yes
EM emitter (side mount or flat)	No	Yes (You must have either the side-mount emitter or the flat emitter for EM tracking.)
EM instrument interface	No	Yes
Support arm for the side-mount emitter	No	Optional (The support arm is required only if you mount the emitter on the main cart.)
Side arm support bracket	No	Optional (This bracket is required only if you mount the emitter on the main cart.)
I/O panel ports for active (wired) instruments and an active (wired) patient reference frame	Optional (These ports are required only if you use active instruments.)	No
I/O panel ports for the EM emitter and EM instrument interface	No	Yes
Camera cart	Yes	No
Standard camera	Yes	No

3   *Cart Operation*

System Input/Output panels

The main cart and the camera cart contain system input/output panels with external connection ports for various input and output devices. The panels are on the rear of each cart. Both carts also contain external connection ports at the back of their work surfaces.

Warning: Connect only items that are specified as part of the StealthStation™ S8 system or compatible with the system. Connecting incompatible items could render the system unsafe or ineffective for its intended use.

Warning: Accessory equipment connected to the analog and digital interfaces of the StealthStation™ S8 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 avoid the risk of electrical shock, do not simultaneously touch the patient and the system input/output panel.

Main cart I/O panel connections

The following I/O panels are included on the main cart. All of the ports may not be available on your cart. For example, ports A, B, and C shown in Figure 14 are only available on carts configured to support wired (active) optical instruments.

Figure 14: Main cart localization I/O panel

EM instrument interface

EM emitter

Microscope: Connects the system to a surgical microscope.

A: Connects an active, wired patient reference frame to the system.

B: Connects an active, wired ultrasound tracker or microscope bracket to the system.

C: Connects an active, wired patient pointer probe to the system.

Figure 15: Main cart communication I/O panel

SS←	USB 3.0: Connects the system to an external high-speed USB device.
(network symbol)	Network: Connects the system to the site Local Area Network (LAN).
→HDMI	HDMI for video out: Connects the system to an external HD digital video device.
DVI-D →	DVI-D for video in: Connects the system video capture to the composite video output of an external source.
S-VIDEO →	S-VIDEO in: Connects system video capture to the S-video output of an external source.
VIDEO →	VIDEO in: Connects the system video capture to the composite video output of an external source.
(footswitch symbol)	Footswitch: Connects the system to the footswitch.
(camera cart symbol)	Connects the camera cart to the main cart.
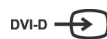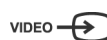
The user assumes responsibility for verifying the output quality of any attached devices that were not supplied for this use by Medtronic.

The following ports are located behind the main cart's work surface.

Figure 16: Main cart ports behind the work surface

SS⬅⤳   High-speed USB 3.0 port for loading patient scans onto the system

⬅⤳   USB 2.0 port for the keyboard and mouse

Camera cart I/O panel connections

Figure 17: Camera cart I/O panel

Connects the camera cart to the main cart.

The following ports are located behind the camera cart's work surface.

Figure 18: Camera cart ports behind the work surface

Connects the system to an external audio device

USB 2.0 port

System security

Good security practices are needed to protect both patient data and the integrity of any network-connected product. The StealthStation™ S8 system includes features and functionality that facilitate management of security. These features work in conjunction with the security practices of hospitals and clinics to provide safe and secure operation of the StealthStation™ S8 system and to protect attached networks and devices.

StealthStation™ S8 system security functionality

The following features and functions help to protect the integrity of the system, the data it contains, and any networks or other devices the system may be connected to:

- **Access control**: The StealthStation™ S8 system has specified user accounts, with the ability to include password protection, for different system user types. User accounts may also be integrated with hospital network privileges. Controlling access to the StealthStation™ S8 system has the ability to prevent unauthorized user access to the system, the data contained on the system, and other devices that may be networked with the system.
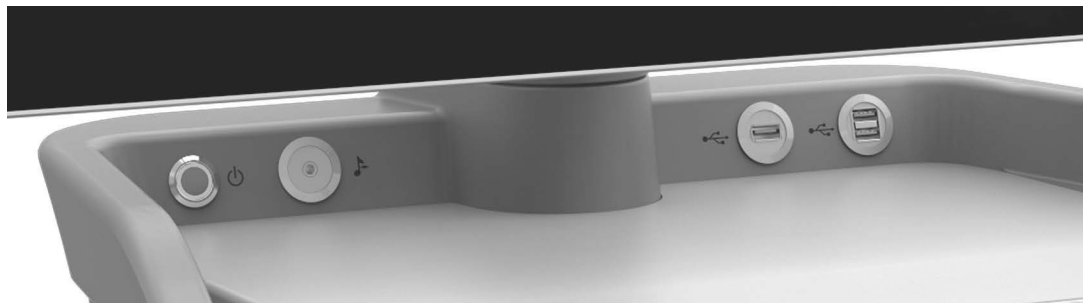
- **Encryption**: The StealthStation™ S8 system encrypts directories containing patient medical images and surgical plan information when the system is not in use. Additionally, data transfer over wireless networks is compatible with hospital network setups for encryption using industry standard protocols.

- **Firewall**: Only predefined connections and information are allowed to be passed to the StealthStation™ S8 system over network communications.

- **Antivirus**: With the antivirus product that is installed on the system by Medtronic, users can update virus definitions and run an on-demand, on-disk antivirus scan to identify potential threats.

Best practices to maintain security of the StealthStation™ S8 system

- Maintain good physical controls over the StealthStation™ S8 system. Keeping the system in a secure location and environment reduces the probability of unauthorized access and unauthorized modifications to the system.

- Only connect the StealthStation™ S8 system to managed, secure networks.

- Only install Medtronic supplied updates and patches for security purposes.

What to do if you suspect the StealthStation™ S8 system has been compromised

If you suspect that the system has been compromised by a security threat, follow these steps:

1. When the system is not in use for a clinical procedure, shut down the system.

2. Disconnect the StealthStation™ S8 system from any networks or other devices.

3. Contact Medtronic Navigation™ technical support for further assistance in troubleshooting potential security threats.

Security for wireless communication

The following standard 802.11 encryption protocols are used to secure information transferred over wireless networks:

- WPA-PSK

- WPA-PSK (Personal)

- WPA2-PSK-TKIP

- PEAP (WPA2 Enterprise)

Network connection information

A network connection is provided on the StealthStation™ S8 system. The network connection is used to transfer data, including patient images and surgical plans, to and from the system. The network connection may also provide the ability for Medtronic Navigation™ technical support to monitor and troubleshoot remotely. The user network must be 10/100/1000 BASE-T to function with the StealthStation™ S8 system.

For network connection, the StealthStation™ S8 system includes an application running in the background that is always checking for DICOM data being pushed to the system. If this application is not running, no data will be accepted. If there is a network failure, a CD/DVD-ROM or a USB drive may be used to transfer images to or from the system. 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.

Connecting the StealthStation™ S8 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 reduce the functionality of the system or introduce new risks, and therefore require additional analysis. The following activities are examples of changes that could change the risk profile and require analysis:

- Changing the network configuration

- Connecting additional items to the network

- Disconnecting items from the network

- Upgrading equipment connected to the network

Wireless networks

Avoid using equipment that is known to share the same wireless communication band, or separate such equipment from the StealthStation™ S8 system because other electronic equipment may interfere with the StealthStation™ S8 system's wireless communications if bandwidths overlap.

Do not use wireless communications outside of the geography of which the system was sold because such use may not comply with local wireless communication standards and regulations.

Table 3 outlines the wireless operating parameters for the StealthStation™ S8 system Wi-Fi components.

Table 3: Wireless operating parameters for the Wi-Fi components

Wi-Fi endpoint This product operates in the frequency bands listed with the RF output powers listed (e.i.r.p.).	Operating frequency	802.11b/g = 2412–2472 MHz 802.11a = 5180–5240 MHz, 5260–5320 MHz, 5500–5700 MHz 802.11n-20M = 2412–2472 MHz, 5180–5240 MHz, 5260–5320 MHz, 5500–5700 MHz
	Transmit power	2412–2472 MHz = 18.5 dBm 5180–5240 MHz = 13.4 dBm 5260–5320 MHz = 14.1 dBm 5500–5700 MHz = 13.4 dBm

Security appliance This product operates in the frequency bands listed with the RF output powers listed (e.i.r.p.).	Operating frequency	Wi-Fi 802.11b/g = 2412–2472 MHz Wi-Fi 802.11n HT20 = 2412–2572 MHz Wi-Fi 802.11 n HT40 = 2422–2462 MHz USA, Europe, China: 2.400–2.483 GHz Japan: 2.400–2.497 GHz
	Transmit power	802.11b = 18.26 dBm (67.0 mW) 802.11g = 12.69 dBm (23.4 mW) 802.11n HT20 = 14.45 dBm (27.9 mW) 802.11n HT40 = 13.45 dBm (22.1 mW)
RFID reader This product operates in the frequency bands listed with the RF output powers listed (e.r.p.).	Operating frequency	125 kHz and 13.56 MHz
	Transmit power	125 kHz = −10.13 dBm (9.7E-2 mW) 13.56 MHz = −31.23 dBm (7.5E-4 mW)

How wireless communication is used

The system uses wireless communication to send and receive data, including patient images and surgical plans. Wireless communications may also provide the ability for Medtronic Navigation™ technical support to monitor and troubleshoot remotely.

Connecting to a wireless network

Follow these steps to connect the StealthStation™ S8 system to a wireless network:

1. At the login screen, select **Other** and then log in using the Stealth Admin username and password.

2. Double-tap **StealthStation Configuration**.

3. Enter the Stealth Admin password and tap **[OK]**.

4. Tap the **WiFi Settings** tab.

5. In the Enable / Disable WiFi section, select **WiFi On**.

   The system starts searching for available wireless networks.

6. In the **Access Points Found** section, select your wireless network.

7. Tap **[Join Selected]**.

   The system fills in information in the Current WiFi Configuration section.

Wired networks

Connecting to a wired network

Follow these steps to connect the StealthStation™ S8 system to a network:

1. Plug in an Ethernet cable.

2. Follow these steps to open the StealthStation Configuration tool.

   a. At the login screen, select **Other** and then log in using the Stealth Admin username and password.

   b. Double-tap **StealthStation Configuration**.

   c. Enter the Stealth Admin password and tap **[OK]**.

3. Select the **Network Settings** tab.

4. Tap **[Configure Network Settings]**.

5. Select DHCP or Static.

   • If you choose DHCP, tap **[OK]**. You do not need to fill in any information.

   • If you choose Static, fill in Static IP, Netmask, Default Gateway, and Primary DNS. Optionally, fill in Secondary DNS and Tertiary DNS. These fields are limited to numbers and periods only. Tap **[OK]**.

   Current Network Configuration information displays.

Configuring user accounts and changing passwords

The StealthStation™ S8 system is configured with 3 accounts: Stealth Admin, Stealth User, and StealthViz User. Each of these 3 accounts has a default password, which can be changed. For assistance with the default passwords for these accounts, contact Medtronic Navigation™ technical support.

Follow these steps to configure accounts for users to log in to the system.

1. At the login screen, select **Other** and then log in using the Stealth Admin username and password.

2. Double-tap **StealthStation Configuration**.

3. Enter the Stealth Admin password and tap **[OK]**.

4. Tap the **System Settings** tab.

5. Tap **[Change Date and Time]**, and then use the drop-down menus to change the date and the time zone. To change the time, type in the time.

   Set the time before connecting to Active Directory so that the time will be associated with the Active Directory server. The time needs to be within 5 minutes of the World Clock time and the Active Directory server time.

6. Tap the **Authentication Settings** tab.

7. Choose either **Local Authentication** or **Active Directory Authentication**.

   • If you choose Local Authentication, then there are 3 password options.

     – New Stealth Admin Password

     – New Stealth User Password

     – New StealthViz User Password

     To reset a password, enter the password and tap **[Reset]**.

- If you choose Active Directory Authentication, obtain information from the hospital IT administrator to fill in all fields, and then tap **[Join Domain]**.

  – If joining the domain is successful, tap **[OK]**. Then tap **[Change Password]** to change one of the 3 passwords.

  – If joining the domain fails, tap **[Show Details]** to display additional information that you can provide when you call Medtronic Navigation™ technical support.

Configuring antivirus scan settings

An antivirus product is installed on the StealthStation™ S8 system. The default setting is to scan the root directory (/). To select a different directory to scan or to exclude directories or files from antivirus scans, follow these instructions.

Note: For instructions on updating antivirus definitions, see "Updating antivirus definitions" on page 39.

1. At the login screen, select **Other** and then log in using the Stealth Admin username and password.

2. Double-tap **StealthStation Configuration**.

3. Enter the Stealth Admin password and tap **[OK]**.

4. Tap the **Antivirus Settings** tab.

5. Choose the directory to scan.

6. Choose directories or files to exclude from scans.

7. Tap **[Configure]**.

   If the **Enter Directory to Scan** field is empty or if any directories or files are invalid, an error message appears.

Updating antivirus definitions

An antivirus product is installed on the StealthStation™ S8 system. Follow hospital IT policies regarding how frequently to update the antivirus definitions and scan the system according to these instructions:

1. At the login screen, select **Other** and then log in using the Stealth Admin username and password.

2. Double-tap **StealthStation Self-Test**.

3. Make sure that the StealthStation™ S8 system is connected to the Internet.

4. Tap the **Antivirus Status** tab.

   - To update antivirus definitions, tap **[Update Antivirus Definitions]**.

   - To scan the system, tap **[Scan]**.

     The default setting is to scan the root directory (/). To select a different directory to scan or to exclude directories or files from antivirus scans, see "Configuring antivirus scan settings" on page 39.

– If antivirus definitions have never been updated, a message displays in the **Last Antivirus Definition Update** field, and the **[Scan]** button is disabled. To enable scanning, update antivirus definitions.

– If the scan fails, tap **[Details]** to display additional information that you can provide when you call Medtronic Navigation™ technical support.

Remote Presence

Remote Presence provides an enhanced level of support capability by enabling a secure, high speed connection to Medtronic Navigation™ systems in the field. Remote Presence uses Axeda™ Corporation's ServiceLink™ application to connect securely.

The **Remote Support** tab in the **StealthStation Configuration** tool provides information so that a Medtronic technical support representative who logs in to the system remotely can verify that he is connected to the correct system.

The serial number is required for a Remote Presence connection. The other information is optional but helpful for technical support.

System set up

Warning: Prevent fluid from entering any part of the StealthStation™ S8 System. If you suspect fluid has entered any part of the unit, turn the system off immediately using the steps in "System shutdown" on page 45, disconnect from electrical power, and allow adequate drying time before powering the system back on.

Warning: Moving parts may create pinch points. Use care to maintain control over the object that you are moving and be aware of potential pinch points when moving arm joints, docking the carts, docking the main monitor, docking the camera, locking and unlocking casters, and opening and closing storage compartments.

Warning: Do not damage the cart-to-cart cable or roll heavy equipment over the cable to minimize the risk of degrading system functionality.

Use care when transporting the carts, setting up in the operating room, or maneuvering other equipment to avoid contact or a collision that could damage the monitors, the camera, or exterior cart panels.

Separating the carts

Separating the carts is optional. The carts may be docked together as a single unit or separated for positional flexibility and convenience during surgery.

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

1. Disconnect and store any loose cables.

2. While facing the camera cart drawer, pull up on one or both of the docking release levers located under the handle on both sides of the camera cart.

   Warning: Keep fingers clear of the space between the camera cart handle and the docking release paddles when disengaging carts to avoid potential injury.

Figure 19: Cart docking lever

①   Cart docking release lever

3. Separate the carts with a gentle tug.

Positioning the main cart monitor

1. Grasp the sides of the monitor, and pull the monitor toward the front of the cart to release it from its stowed state.

2. Move the monitor to the desired position.

Connecting and starting the system

1. If you are using the camera cart in addition to the main cart, connect the carts with the cart-to-cart cable before you start the system.

Unwrap the cart-to-cart cable on the camera cart and connect it to the cart cable connections located on the camera cart I/O panel and on the main cart communication I/O panel.

2. Unwrap the power cord from the main cart and plug it into an electrical outlet.

When positioning the main cart, be sure to maintain easy access to the power outlet in case it becomes necessary to unplug the system quickly.

3. Press and hold the LED power switch located on either the main cart deck or the camera cart deck for one second.

The power switch illuminates blue when the system is on.

When the carts are connected by the cart-to-cart cable, pressing the power button on either cart powers up both carts. The system powers up and the login screen appears when all system bootup diagnostics are complete. If the carts are disconnected and the main cart is powered up, you can connect the camera cart and then press the power button on the camera cart to power it up.

Positioning the camera

1. Pull the camera handle away from the plastic clip to release the camera from its stowed state.

2. Move the camera to the desired position.

   Caution: Maintain a clear line of sight from the camera to the patient reference frame and instruments during a procedure so that the system software can track the position of the patient and the instruments.

Connect either the optical or the EM hardware to the main cart

For optical localization, connect the optical hardware

1. If you have a wired (active) patient reference frame, connect the cable to the A port on the main cart localization I/O panel.

2. If you have a microscope bracket or an ultrasound tracker, connect the cable to the B port on the main cart localization I/O panel.

3. If you have wired (active) instruments, connect them to the instrument C port on the main cart localization I/O panel.

4. Connect the footswitch to the footswitch port on the main cart communications I/O panel (left side).

For electromagnetic localization, connect the EM hardware

1. Connect the EM instrument interface to the EM instrument interface port on the main cart localization I/O panel.

2. Connect the flat emitter or side-mount emitter cable to the emitter port on the main cart localization I/O panel.

3. Connect the footswitch to the footswitch port on the main cart communications I/O panel.

4. Connect the EM instruments and the EM patient reference frame to any open instrument port on the EM instrument interface.

Launching the software

Warning: Before using the system in a clinical procedure, verify monitor functionality (for example, make sure that images display and the touchscreen responds to touch).

If the touchscreen is not functioning properly, use alternative input methods (mouse and keyboard). Call Medtronic Navigation™ technical support to report touchscreen functionality issues.

1. Type in your username and password to log in to the system (if required at your facility).

   The **SELECT PROCEDURE** screen appears.

2. To launch the Medtronic Navigation software, tap the desired software icon.

Setting up external video

Overview of setting up external video

Connecting the system to external video displays is optional. Hospital monitors have a variety of inputs, connectors, and circuitry between a video plug and the actual monitor. Not all monitors will work or work well with the HDMI signal from a StealthStation™ S8 system. If you plan to use external video, it is recommended that you provide sufficient time before starting a case to configure an external video port for use with the StealthStation™ S8 system.

The StealthStation™ S8 system can send video to external monitors via an HDMI port. This section describes how to connect the system to external displays.The StealthStation™ S8 system external video port is an HDMI digital video output port on the main cart communication I/O panel and is disabled by default. In order to output video to an external display, you must complete the following steps:

1. Turn on the external display option in the software.

   For detailed instructions, see "External video port setup" on page 44.

2. Log out of the StealthStation™ S8 system.

3. Connect and power on the external video display device.

   For detailed instructions, see "Connecting to the external display device" on page 44.

4. Log back in to the StealthStation™ S8 system.

   The StealthStation™ S8 system sends a signal to the external display device for a video setting only once upon login. Always plug the external video display device into the StealthStation™ S8 system before starting a case.

Supported external video display resolutions

The StealthStation™ S8 system supports external display resolutions up to 4k when utilizing an HDMI connection directly. The StealthStation™ S8 system will also automatically scale its video signal to support external displays with different aspect ratios. Some example video signals that have been tested with the StealthStation™ S8 system include:

• 3840x2160 @30Hz (4k; 16:9)

• 2560x1440 @60Hz (1440p; 16:9)

• 1920x1200 @60Hz (1200p; 16:10)

• 1920x1080 @60Hz (1080p; 16:9)

• 1280x720 @60Hz (720p; 16:9)

External video port setup

Before plugging in the external display device, enable the external video port in the clinical software application. Once enabled, this feature will remain turned on.

1. Tap the menu button.

2. Tap **[About this Stealth]**.

3. Slide the **External Video Port** switch to the on position.

Figure 20: External Video Port switch
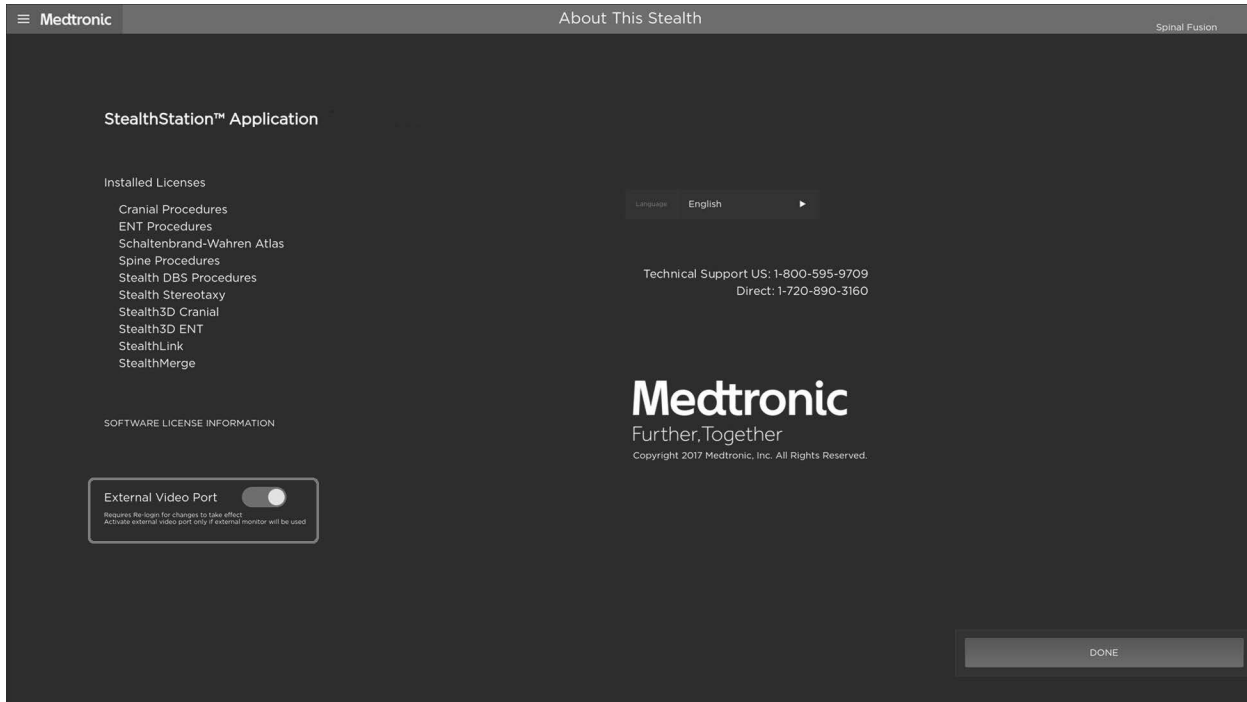
4. Log out of the StealthStation™ S8 system.

   a. Tap the menu button at the upper left corner of the software screen.

   b. Tap **[Log Out]**.

   The **Login** screen displays.

Connecting to the external display device

1. Connect an HDMI cable from the external display device to the StealthStation™ S8 system HDMI video out port on the main cart communication I/O panel. See Figure 21.

   Note: The HDMI video out port is the only video out port for the entire system. All other ports on the main cart communication I/O panel are video in connections for external devices to display video within the StealthStation™ S8 software. See "Main cart I/O panel connections" on page 29 for more information on device connections.

   Note: Newer external video displays with an HDMI connection may work by simply plugging the device into the StealthStation™ S8 system (hot plug).

Figure 21: HD External video display device plugged into the StealthStation™ S8 system

2. Power on the external display device.

3. Log back in to the StealthStation™ S8 system.

   Note: When you log in, the system attempts to establish optimal resolution with the connected monitor. This process only works with a fully digital connection. In the case of a conversion to an analog signal, such as on a VGA cable, the system selects a default resolution.

   Attaching additional equipment between the StealthStation™ S8 system and the external display may alter the output on the external display. You cannot adjust the HDMI external display options from the StealthStation™ S8 system. If needed, you may be able to adjust video output settings on the external display device. Do not change the display settings on the monitors of the StealthStation™ S8 system.

System shutdown

Exiting the software

1. Tap the menu button at the upper left corner of the software screen.

2. Tap **[Log Out]**.

   The **Login** screen displays.

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

Shutting down the system

Follow these steps to shut down the system.

Note: If you are using both carts of the StealthStation™ S8 system, leave the carts connected with the cart-to-cart cable and initiate the shut down sequence. Disconnect the cart-to-cart cable after both monitors have turned off and the systems have shut down. If the cart-to-cart cable is disconnected before both carts shut down, the camera cart transitions to battery power and must be shut down by holding the power button on the camera cart.

1. At the login screen, tap the power button in the upper right corner of the screen to access the drop-down menu.

2. Tap **[Shut Down]**.

   The system will fully shut down.

3. After the system shuts down, remove the power plug from the electrical outlet.

   Alternatively, leave the system plugged into the electrical outlet to charge the backup batteries. The system will continue charging the batteries as long as it is plugged in to the electrical outlet. The backup battery in the camera cart will recharge only when the two carts are connected with the cart-to-cart cable.

Emergency shutdown

If you need to shut down the system quickly in an emergency, or if you are not able to exit the software, follow this procedure:

1. Press and hold the blue LED power switch located on either the main cart or the camera cart deck until the blue LED light turns off (approximately 8 seconds).

   When the systems are connected, pressing the power button on either cart shuts down both carts. The system will fully shut down.

2. After the system shuts down, remove the power plug from the electrical outlet.

Cleaning the system

For instructions on cleaning the system, refer to the StealthStation™ S8 cleaning instructions (9735727).

Transport position

Warning: Before transporting the system carts, shut down the system and stow all components, dock the monitors, dock the camera on the camera cart, close all storage compartments, and remove any loose items from the top of the carts.

Warning: Keep fingers clear of articulating arm joints, neighboring components, monitor or camera docking mechanisms, cart docking mechanism mating components, and the space between carts to avoid potential injury.

Use the dedicated cord wraps to neatly stow power and accessory cables and to keep the cables clear of casters, cart legs, and docking components. Store accessories and components within the confines of storage compartments so that all storage and docking mechanisms can operate freely and are clear of obstructions. Make sure that the EM instrument interface, if used, is fully seated on the mounting rail. Make sure that arms are folded and stowed in their home position.

Follow the instructions below to configure the carts into the transport position.

Cord wrapping locations

Use care to wrap cords neatly as shown in Figure 22.

Figure 22: Cord wrapping locations
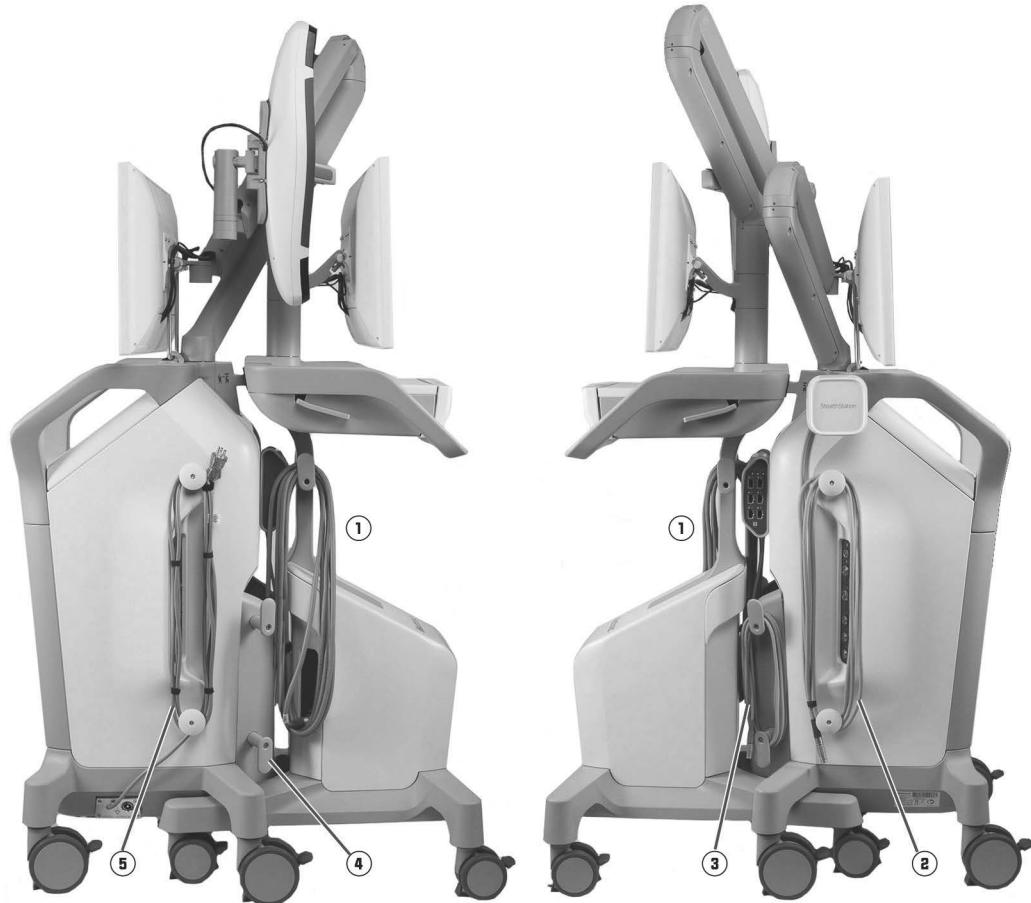
The following cable wrapping locations are recommended:

①	Cart-to-cart cable: Wrap this cable in a large loop and hang it on the top cord wrap on one side of the camera cart.
②	Side-mount emitter cable: Use the cord wraps on the left side of the main cart.
③	EM instrument interface cable: Use the cord wraps on the left rear of the main cart.
④	Footswitch and cable (not shown): Use the cord wraps on the right side of the main cart: that is, either the wraps that contain the power cord or the wraps on the back storage bin.
⑤	Power cord: Use the cord wraps on the right side of the main cart.
Not shown	Flat emitter cable: Use the cord wraps on the flat emitter storage bin or the cord wraps on the right side of the cart.
Not shown	Ethernet cable: Bundle the cable neatly with a cable wrap and then place it in the main cart back storage bin.

# *Wrapping cords and closing all storage compartments*

Follow these instructions to wrap cords and close all storage compartments to prepare the system for docking before transport.

1. Remove the power plug from the electrical outlet.

2. Wrap the power cord around the cord wraps located on the side of the main cart where the cord connects to the cart.

3. If you are using the cart-to-cart cable, wrap the cable in a large loop and hang it on the top cord wrap on one side of the camera cart.

4. If you are using electromagnetic hardware, complete the following steps:

   a. Hang the EM instrument interface on the mounting rail on the rear of the main cart and wrap the cord on the cord wraps located on the rear of the cart.

   b. Store the emitter.

   - Store the side-mount emitter on the upper rear bracket of the main cart and wrap the cord on the cord wraps located on the side of the cart.

   - Store the flat emitter in the rear storage bin on the main cart. Wrap the cord around the cord wraps on the side of the main cart (preferred) or around the cord wraps on the rear storage bin.

5. Disconnect and store any cables and instruments.

6. Close the camera cart drawer.

7. Unplug the keyboard cable from the USB port.

8. Remove the keyboard cable and store it in the front storage bin.

9. Place the keyboard in the keyboard storage compartment.

10. Unplug the mouse cord from the USB port.

11. Place the mouse in the main cart front storage bin.

Docking the camera (optical system)

1. Fully lower the camera lift arm so that it is positioned next to the lower camera arm.

2. Orient the camera arms relative to the cart as shown in Figure 23.

3. Rotate the camera into a vertical orientation.

4. Insert the camera handle into the docking clip located on the camera's lower arm.

Figure 23: Docked camera
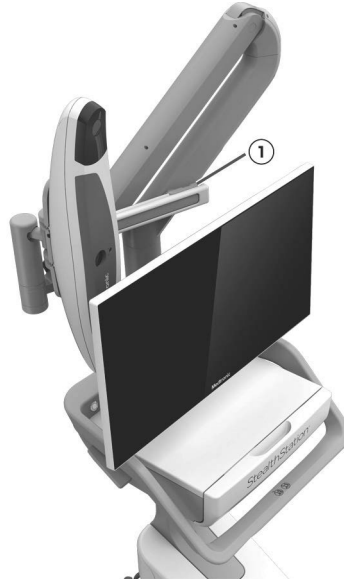
①   Camera docking clip

Docking the main cart monitor

1. Fully lower the monitor lift arm so that it is positioned next to the lower arm.

2. Orient the monitor arms relative to the cart as shown in Figure 24.

3. With the monitor approximately vertical, push the monitor toward the rear of the cart until the monitor's docking bar engages with the docking latch.

4. Align the dot on the lower part of the arm with the dot on the back of the cart.

Figure 24: Main monitor docked
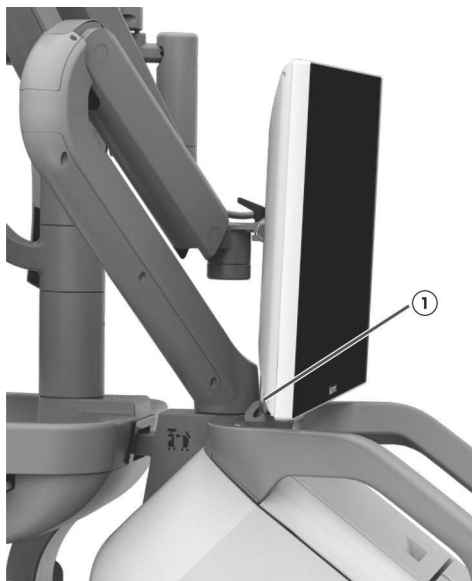
①   Monitor docking latch

Docking the camera cart monitor

1. Rotate the monitor to face the front of the camera cart.

2. When the monitor is aligned with the front of the cart, you will feel it click into its docked position.

Docking the carts

1. On a level surface, orient the camera cart and the main cart so that the rear of the camera cart faces the rear of the main cart.

2. Guide the camera cart legs between the main cart's casters and align the docking coupler with the docking mechanism.

   Warning: Keep fingers clear of docking mechanism mating components and clear of the space between carts to avoid potential injury.

3. Slowly push the two carts together until you hear a click from the latch mechanism.

Figure 25: Cart docking mechanism and coupler
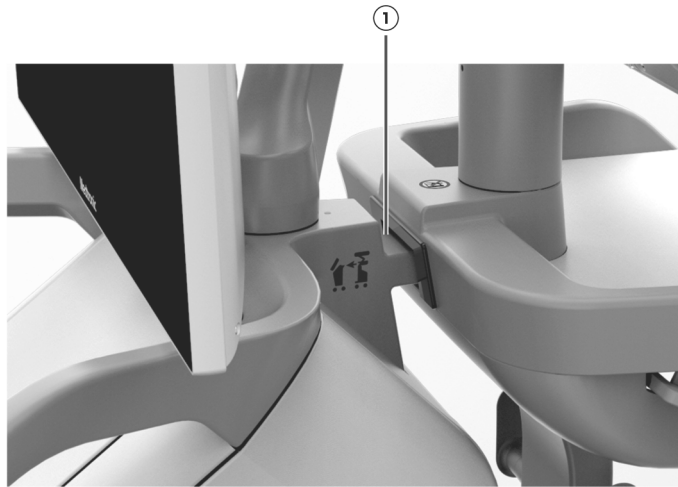
①   Cart docking mechanism and coupler

Transporting the carts

Additional effort and care may be required when pushing carts across thresholds. For optimal maneuverability of the docked carts, push the heavier main cart.

Warning: Avoid crossing raised thresholds that are higher than 10 mm (0.4 in.) because the carts could become unstable and cause injury.

Warning: Do not exceed the weight limits of cart storage compartments. The camera cart drawer has a weight limit of 3.6 kg (8.0 lb). Exceeding this weight limit could cause the cart to tip over if it is on a sloped surface.

* The following items are intended to be stored in the main cart storage compartments: flat emitter, footswitch, mouse, keyboard, software product use instructions, system quick reference guides, 5 DVD-Rs and their associated jewel cases, and a single 5 pack of reflective spheres.

* The following items are intended to be stored in the camera cart drawer: 1 Vertek™ articulating arm, a non-sterile cranial patient reference frame, 2 non-sterile registration instruments, and software product use instructions.

Caution: Do not use the carts to open doors or impact stationary objects during transport because the impact could damage the carts.

Storing the carts

When the carts are not in use, store them in their docked, transport position with all cables neatly wrapped and stowed. Store the carts in an environment within the following temperature and humidity ranges:

Storage temperature	15° to 30°C (59° to 86°F)
Relative humidity	10% to 80% Non-condensing

4 *System specifications*

System specifications

The specifications listed apply to system operation under typical conditions.

Table 4: StealthStation™ S8 System specifications

Operating temperature	18° to 30°C (64° to 86°F)
Operating pressure	101.3 kPa to 69.7 kPa
Operating altitude	-50 m (-164 ft) minimum 3000 m (9842 ft) maximum
Shipping temperature	-29° to 60°C (-20° to 140°F)
Storage temperature	15° to 30°C (59° to 86°F)
Input voltage	~100–~230 V
Input frequency	50–60 Hz
Fuse rating	10 A
Maximum power	900 VA
Typical power dissipation	400–600 VA
UPS	5 minutes autonomy
Relative humidity	20% to 80% Non-condensing
Monitor dimensions	389 mm high by 648 mm wide by 63 mm deep (15.3 in high by 25.5 in wide by 2.5 in deep)
Monitor weight	7.5 kg (16.5 lb)
Monitor display	Resolution = 2560 x 1440 pixels, 60 Hz
Camera cart footprint	68 cm wide by 69 cm deep (26.9 in wide by 27.1 in deep)
Camera cart weight	75 kg (165 lb)
Main cart footprint	69 cm wide by 52 cm deep (27.3 in wide by 20.4 in deep)
Main cart weight without EM components	113 kg (250 lb)

Main cart weight with EM components and the side-mount emitter	118 kg (260 lb)
Main cart weight with EM components, the side-mount emitter, and the flat emitter	125 kg (275 lb)

System classifications

Table 5: General StealthStation™ S8 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. 60601-1: 14	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: 3rd Edition	Pollution Degree 2 Overvoltage Category II
Electromagnetic Emissions Compatibility, IEC 60601-1-2	Class A, Group 1

Table 6: Water Ingress Classifications

Component	Water Ingress Classification
System (both carts)	IPX0 (not protected)
Electromagnetic instrument interface	IPX0 (not protected)
Side-mount emitter	IPX0 (not protected)
Flat emitter	IPX2 (protected against dripping water when tilted up to 15 degrees)
Camera	IPX0 (not protected)
Footswitch	Equal to or better than IPX6

System electromagnetic emissions and immunity declarations

Table 7: Guidance and Manufacturer's Declaration - Cables, Transducers, and Accessories

Medtronic Part Number	Description	Length	Shielded (Y/N)
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.			
System Equipment			
9735821	Standard camera	NA	NA
9735795	Cart monitors	NA	NA
9735828	Keyboard	NA	NA
9735829	Mouse	NA	NA
9735824	EM controller	NA	NA
9735825	EM instrument interface	NA	NA
Cables			
Part number varies by geography	Power cord	4.6 m (15 ft)	No
9735800	Footswitch with cable	4.6 m (15 ft)	Yes
9735825	EM instrument interface cable	4.6 m (15 ft)	Yes
Generic	Composite video cable	1.8 m (6 ft)	Yes
Generic	USB cable	2.0 m (6 ft 6 in)	Yes
Generic	Ethernet cable CAT6	3.0 m (10 ft)	No
Generic	Audio cable	1.5 m (5 ft)	Yes
Generic	DVI cable	3.0 m (10 ft)	Yes
Generic	HDMI cable	1.8 m (6 ft)	Yes
Generic	S-video cable	2.3 m (7 ft 6 in)	Yes
9733752	Cable on the flat emitter	4.6 m (15 ft)	Yes
9735521	Cable on the side-mount emitter	4.6 m (15 ft)	Yes
9735772	Cart-to-cart cable	11.0 m (36 ft)	Yes
9733822, 9733823, 9733939 or similar***	Microscope cables	9.2 m (30 ft 2 in)	Yes
Accessories			
963-750, 963-741, 9730259, 9732222, or 9732247	Calibration target	NA	NA
9660204 or similar **	Electromagnetic instrument	3.0 m (10 ft)	No
963-719 or similar *	Optical Instrument	3.7 m (12 ft)	No
* Any active or wireless active optical instrument has been qualified to IEC 60601-1-2			

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**	**Length**	**Shielded (Y/N)**
** Any electromagnetic instrument has been qualified to IEC 60601-1-2			
*** For use with Zeiss or Leica microscopes			

Table 8: Guidance and Manufacturer's Declaration - Electromagnetic Emissions IEC 60601-1-2

The StealthStation™ S8 System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation™ S8 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™ S8 System uses RF energy only for its internal function and local area communication. 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™ S8 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 9: Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2

The StealthStation™ S8 System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation™ S8 System should assure that it is used in such an environment. Test Level values are from the 3rd edition of the standard; 4th edition values, if they differ, are shown in brackets ([ ]).			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV [±8 kV] contact ±8 kV [±15 kV] Air	±6 kV [±8 kV] contact ±8 kV [±15 kV] Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines [100 kHz repetition frequency]	±2 kV for power supply lines ±1 kV for input/output lines [100 kHz repetition frequency]	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	<5% UT (>95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the StealthStation™ S8 System requires continued operation during power mains outages, it is recommended that the StealthStation™ S8 System be powered from an uninterruptible power supply.
	40% UT (60% Dip in UT) for 5 cycles	40% UT (60% Dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 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 5 sec	
[Voltage dips IEC 61000-4-11]	[0% UT for 0.5 cycle 0% UT for 1 cycle and 70% UT for 25/30 cycles]	[0% UT for 0.5 cycle 0% UT for 1 cycle and 70% UT for 25/30 cycles]	**Note:** 25/30 cycles means 25 periods at 50 Hz or 30 periods at 60 Hz.
[Voltage interruptions IEC 61000-4-11]	[0% UT for 250/300 cycles]	[0% UT for 250/300 cycles]	**Note:** 250/300 cycles means 250 periods at 50 Hz or 300 periods at 60 Hz.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m [30 A/m]	3 A/m [30 A/m]	Power Frequency Magnetic Fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Table 10: Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2

The StealthStation™ S8 System is intended for use in the electromagnetic environment specified below. The customer or the user of the StealthStation™ S8 System should assure that it is used in such an environment. Test Level values are from the 3rd edition of the standard; 4th edition values, if they differ, are shown in brackets ([ ]).			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz [6 Vrms in ISM bands between 0.15 MHz and 80 MHz]	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the StealthStation™ S8 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz [80 MHz to 2.7 GHz] [80% AM at 1 kHz] [Additional proximity fields from RF wireless communications equipment per Table 9 of IEC 60601-1-2: 2014.]	3 V/m	$d = 1.2* \sqrt{p}$ $d = 1.2* \sqrt{p}$ 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: ((•)) [The product has been certified to 60601-1-2 4th edition, which specifies that the product should be kept a minimum of 30 cm (12 in) from portable and mobile RF communications equipment.]
* 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™ S8 System is used exceeds the applicable RF compliance level above, the StealthStation™ S8 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™ S8 System.			
** 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 11: Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the StealthStation™ S8 System IEC 60601-1-2

The StealthStation™ S8 System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the StealthStation™ S8 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the StealthStation™ S8 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)		

Rated Maximum Output Power of Transmitter (W)	150 kHz to 80 MHz $d = 1.2 * \sqrt{p}$	80 MHz to 800 MHz $d = 1.2 * \sqrt{p}$	800 MHz to 2.5 GHz $d = 2.3 * \sqrt{p}$
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.

Note: In addition to the recommendations from 60601-1-2, separate technologies that emit low frequency RF, such as RFID emitters, from the StealthStation™ S8 electromagnetic system.

Note: The emissions characteristics of the StealthStation™ S8 System make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic emissions and immunity declarations

Note: The StealthStation™ S8 System has undergone coexistence testing and, in expected use conditions, is unlikely to impact other systems or devices.

To allow use of devices that are sensitive to electromagnetic fields during a procedure with the StealthStation™ S8 system, the StealthStation™ S8 software includes a button to temporarily turn off the emitter. Live navigation with the software is disabled while the emitter is turned off. For more information about turning off the emitter, refer to the specific software application's instructions for use.

Warnings and precautions

Warning: RF emitters typically found in an operating room can affect medical electrical equipment, such as the StealthStation™ S8 electromagnetic system.

Warning: The system has been successfully tested against the requirements of IEC 60601-1-2. However, RF interference, including RFID or other low frequency technologies, 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 StealthStation™ S8 electromagnetic system medical electrical equipment needs special precautions regarding EMC (electromagnetic classifications) and needs to be installed and put into service according to the EMC information provided in the EMC tables. The StealthStation™ S8 system has been certified to 60601-1-2 4th edition, which specifies that portable and mobile RF communications equipment should be used no closer than 30 cm (12 in) from any part of the system including the system cables specified in Table 7.

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 StealthStation™ S8 electromagnetic system.

5 *Troubleshooting*

Cart Separation

Difficulty docking or separating the main cart and the camera cart

Check the following items and then attempt to dock or separate the carts:

- Check that the carts are not positioned on a slope or on uneven or soft floor surfaces. The docking mechanism may bind if the floor is not level. Move the carts to a level surface before attempting to dock or separate them.

- If difficulty is encountered during docking, unlock all casters. Use care to keep casters clear of cables and obstructions. Readjusting the position of the carts will often resolve any caster interference.

- Check that the power and accessory cables are stowed on the dedicated cord wraps and that the cables are clear of casters, cart legs, and docking components.

- Check that accessories and components are within the confines of storage compartments so that all storage and docking mechanisms can operate freely and clear of obstructions.

- Make sure that the EM instrument interface, if used, is fully seated on the mounting rail.

- Make sure that arms are folded and stowed in their docked position.

Component connections

System malfunctions are sometimes the result of loose or disconnected cables. Do not disconnect any cables unless instructed to do so by a Medtronic Navigation™ technical support representative.

Running the self-test tool

Follow these steps to test whether system components are properly connected and configured.

Note: The StealthStation™ S8 system is available in multiple configurations. All of the system components listed in this section may not be included in your system configuration. Therefore, "Unavailable" status for certain components may be normal in some system configurations.

1. Open the StealthStation Self-Test tool.

   a. At the login screen, select **Other** and then log in using the Stealth Admin username and password

   b. Double-tap **StealthStation Self-Test**.

2. Tap the **Internal Network Status** tab to view the connection status of components in the main cart and camera cart.

   Green "Connected" status indicates proper connection.

   Red "Unavailable" status indicates a connection problem. If a component has red status, take the following actions:

   • Close the StealthStation Self-Test tool and then reopen the tool.

   • If red status remains, check external cable connections related to the component.

   If the problem persists, contact Medtronic Navigation™ technical support.

3. Tap the **Software Information** tab to view the status of operating system services, the UPSs, and user input devices such as the footswitch, keyboard, mouse, and touchscreens.

   Green "Connected" status indicates proper connection.

   Red status indicates a connection problem. If a user input device has red status, take the following actions:

   • Check cable connections.

   • Plug the device in to a different port.

4. Tap the **Internal Component Firmware** tab to display the firmware version and the connection status for some or all of the following items (depending on the system configuration): PC Over IP Host Card, the main cart UPS, Firewall/Router, WiFi Client Endpoint, Network Switch, PC Over IP Zero Client, and the camera cart UPS.

   Red status indicates a connection problem. If a component that is included in your system configuration has red status, take the following actions:

   • Close the StealthStation Self-Test tool and then reopen the tool.

   • If red status remains, shut down the system, wait 10 seconds, and then turn the system power back on.

   If the problem persists, contact Medtronic Navigation™ technical support.

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 supplies power? Test the outlet with a multi meter or a wall power circuit tester. 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. Contact Medtronic technical support to replace any damaged cables. If necessary, power down the system and re-connect all external cables and devices (carts, instruments, footswitch) and turn the system power back on.

- If your system includes a camera cart, pay attention to the communication tones when turning on the system power. 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.

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

Power switch

The power switches located on the main cart and camera cart decks contain 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.

| LED state	System power status	Troubleshooting
On/steady	The system is powered on by the external AC power supply.	
Slow flashing	The system is being powered by the internal uninterruptible power supply (battery backup).	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.
Rapid flashing	The system is being powered by the internal uninterruptible power supply (battery backup), but the battery is running low on power.	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, contact Medtronic Navigation™ technical support to schedule a battery replacement. The batteries can be replaced with Medtronic part number 9735773 (main cart) and 9735771 (camera cart).

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)	Error LED (amber)	Camera Status
Flashing	Any state	Camera is warming up.
On/steady	Off	Camera is ready for use.
On/steady	Flashing	Major fault. Call Medtronic Navigation for technical support.
On/steady	On/steady	Minor fault. Call Medtronic Navigation for technical support.
Off	On/steady	Camera is not functioning and must be returned for service.
Off	Off	No power.

Camera motion is too tight or too loose

Follow these steps to increase or decrease resistance in camera motion about the roll and yaw axes. You will need a 1/2 in. socket and driver and a small flathead screw driver.

Figure 26: Locations of camera adjustment nuts
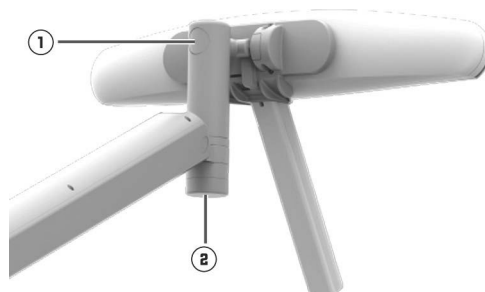
①   Cap concealing the camera roll adjustment nut

②   Location of the camera yaw adjustment nut

Figure 27: Camera yaw and roll

①   Camera yaw

②   Camera roll

Adjusting resistance in camera roll

1. Pry off the plastic cap that covers the roll adjustment nut on the camera bracket.

Retain this cap for reinstallation.

2. Turn the 1/2 in. nut clockwise to increase resistance or counter-clockwise to decrease resistance.

3. Replace the cap over the adjustment nut.

Align the cap so that the relief cuts on the cap align as closely as possible with the scalloped opening. Replacing the cap in this way makes removal easier for future adjustments.

Contact Medtronic Navigation™ technical support if the adjustment does not resolve the issue.

Adjusting resistance in camera yaw

1. Place a 1/2 in. socket on the adjustment nut.

2. Turn the 1/2 in. nut clockwise to increase resistance or counter-clockwise to decrease resistance.
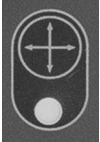
   Contact Medtronic Navigation™ technical support if the adjustment does not resolve the issue.

EM system LED definitions and issues

EM instrument interface status indicator LEDs

When you select an EM procedure in the Cranial software or any procedure in the ENT software, the EM instrument interface receives power from the system. Refer to the following table for information about each status indicator.

Note: When the EM instrument interface first receives power, some or all of the LEDs may light up briefly.

LED symbols	LED descriptions	Actions to take if the LED is not lit
	Green power LED: Indicates when the system is supplying power to the EM instrument interface.	• Make sure that the cart is powered on. • Make sure that the EM instrument interface cable is connected to the cart. • Make sure that an EM procedure has been selected in the Cranial or ENT software.
	Green navigation LED: Indicates when the EM system is in the navigation mode.	• Make sure that the EM instrument interface cable is connected to the cart. • Make sure that an EM procedure has been selected in the Cranial or ENT software. • Make sure that the emitter is turned on in the software. The emitter is turned on by default, but the tracking details area in the software includes a button to turn the emitter off. Refer to the Cranial or ENT software instructions for more information.
	Yellow fault LED: Indicates, when lit, that the system has encountered a fault. Check the software for more diagnostic information.	If the fault LED is not lit, the system has not encountered a fault. No action is required.

Instrument indicator LEDs

The instrument status LED color relays real time information about EM instruments and the StealthStation™ EM system controller. When you plug in an EM instrument, the LED color is orange until the system is ready to track the instrument. When the system is ready to track the instrument, the LED turns green.

Indicator LED color	Actions to take
Green - Indicates that the instrument is properly connected and can be tracked by the system.	No action needed
Orange - Indicates that the system has detected the instrument, but the system is not ready to track the instrument. When the system is ready, the indicator turns green.	Instrument initialization can take several seconds. If the problem persists, plug the instrument in to a different port, or plug in a different instrument.
Not lit - Indicates that no instrument has been detected. Either no instrument is plugged in, or a failure has occurred.	Plug in an instrument, or if an instrument is already plugged in, make sure that the instrument connector is properly seated in the port. If the problem persists, plug the instrument in to a different port, or plug in a different instrument.

Main cart 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 display on the monitor is distorted*

- The contrast settings are incorrect in the software. Adjust the Level (brightness) and Width (contrast) settings for images using the on-screen controls in the application software.

- If adjusting Level and Width does not resolve the problem, shut down and reboot the system.

- If the problem persists, call Medtronic Navigation for technical support.

# *Main cart monitor motion is too tight or too loose*

Follow these steps to increase or decrease resistance in monitor motion about the pitch and yaw axes. You will need a 1/2 in. socket and driver to adjust yaw.

Figure 28: Locations of monitor adjustment lever and nut
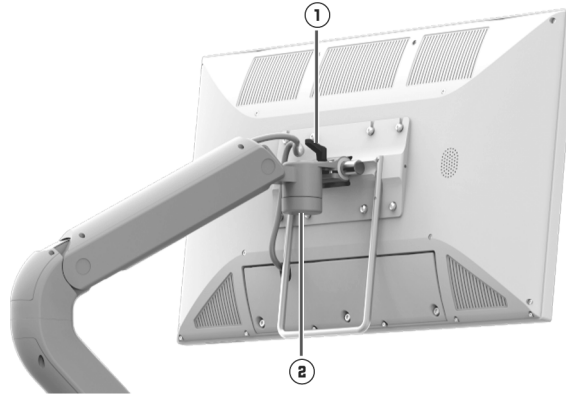
① Main monitor pitch adjustment lever

② Location of the main monitor yaw adjustment nut

Figure 29: Monitor yaw and pitch
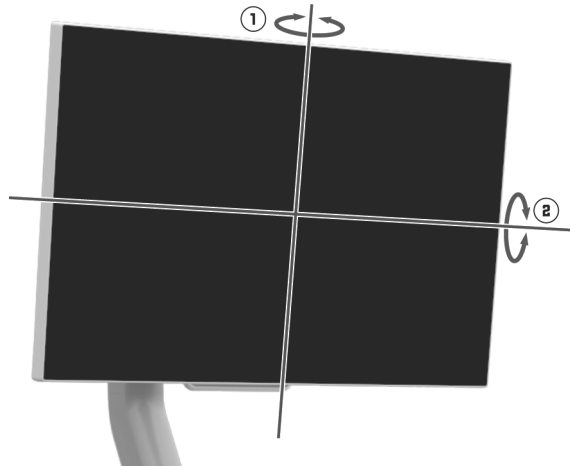
① Monitor yaw

② Monitor pitch

Adjusting resistance in monitor pitch

A black plastic lever on the back of the main cart monitor bracket controls monitor pitch resistance.

• Turn the lever clockwise to increase resistance.

• Turn the lever counter-clockwise to decrease resistance.

Contact Medtronic Navigation™ technical support if the adjustment does not resolve the issue.

Adjusting resistance in monitor yaw

1. Place a 1/2 in. socket on the adjustment nut.

2. Turn the 1/2 in. nut clockwise to increase resistance or counter-clockwise to decrease resistance.

   Contact Medtronic Navigation™ technical support if the adjustment does not resolve the issue.

Camera cart monitor

Camera cart monitor motion is too tight or too loose

Follow these steps to increase or decrease resistance in monitor motion about the pitch axis. You will need a 4 mm Allen wrench.

1. Locate the two 4 mm Allen screws at the base of the monitor bracket, below the hinge.

2. Turn both screws an equal number of turns clockwise to increase resistance or counter-clockwise to decrease resistance.

   Contact Medtronic Navigation™ technical support if the adjustment does not resolve the issue.

Mouse and keyboard

The mouse and keyboard are optional input devices. If a mouse or a keyboard is connected to a USB port on the system, and the system is not responding to input from the device, follow these troubleshooting instructions.

- 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 a system USB port and reboot the system.

- If the keyboard is not operational, the keyboard may have been disconnected at start up. Reconnect the keyboard to a system USB port 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.

- Check the connection between the footswitch and the cart. Reboot the system.

- 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 wired instruments are connected to the correct ports (port B or port C) on the main cart localization I/O panel.

- Make sure that the Patient Reference Frame is connected to the correct port (port A) on the main cart localization I/O panel.

- Use software to diagnose optical instrument tracking problems.

Recommended maintenance

Because the StealthStation™ S8 system contains no user-repairable parts, the interior of the system is normally inaccessible. However, it may occasionally be necessary for a qualified Medtronic service person to remove system panels and access interior components.

Warning: Do not perform any service or maintenance that requires removing the system covers while the system is in use with a patient.

The StealthStation™ S8 system contains no user-serviceable components and no material that is consumed during operation. Under normal operation, detachable parts are not subject to deterioration.

The StealthStation™ S8 system and its associated components require cleaning as needed and annual inspection and testing. Annual inspection and testing should be completed by a Medtronic-authorized and trained service person. Please contact Medtronic Navigation, Inc. (see page 9) to schedule a full maintenance and system check appointment.

Inspection should include:

- Inspect cables for damage, cuts, or connector wear.

- Inspect the following items for damage, wear, or unexpected behavior: carts, casters, monitor, monitor arm, monitor latching mechanism, camera arm, and camera latching mechanism.

Testing should include:

- Verify full functionality of keyboard, mouse, computer, and monitor.

- Verify full functionality of navigation including image load, image settings, registration, and navigation of all instruments and all cable ports.

Verifying system electrical safety (per tests specified in Electrical Safety Tests document 9736044 or equivalent) is an optional annual test. These electrical safety tests may be performed by a hospital biomedical engineer.

Replacing the power cord

If the power cord is damaged, contact Medtronic Navigation™ technical support to schedule a power cord replacement. Power cord replacement must be performed by a qualified Medtronic service person.

Removing and reattaching the back storage bin on the main cart

For cleaning, you may need to remove the back storage bin on the main cart. The storage bin is held in place by 4 reclosable ball stud pins. No tools are required to remove or reattach the storage bin.

- To remove the bin, pull it straight out with a gentle tug.

- To reattach the bin, align the 4 ball pins with their holes and then push the bin straight in until the pins snap securely in place.

System disposal

Warning: Some system components contain batteries. Do not recharge or disassemble batteries that have been removed from system components. Observe local regulations concerning battery disposal.

Do not dispose of the StealthStation™ S8 system or system components 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.

6 *Symbols*

Explanation of symbols on package labeling

The following symbols may appear on system equipment, on system packaging, on accessories used with the system, or in this document.

$C\epsilon$	The device complies with European Directive MDD 93/42/EEC.
TÜVRheinland	cTUVus Mark certifies the product meets the requirements of a Nationally Recognized Testing Laboratory for compliance with IEC 60601-1 and CAN/CSA-C22.2 No. 60601-1:14.
$R_{\!x}$ Only	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
⚠	Caution
📖	Follow instructions for use.
📖i	Consult instructions for use.
🧍	Type BF applied part, in compliance with IEC/UL60601-1.
🧍	Type B applied part, in compliance with IEC/UL60601-1.
⊘	Single use only. Do not reuse.
⧖	Use by date
LOT	Batch code
SN	Serial number
REF	Catalog number
⚖	Quantity

75

Symbols
Explanation of symbols on package labeling

STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
NON STERILE	Non-sterile
(STERILIZE)	Do not sterilize.
2 STERILIZE	Do not resterilize.
	Manufacturer
EC REP	Authorized representative in the European Community
	Date of manufacture
	Keep dry.
	Do not use if package is damaged.
	Fragile, handle with care.
	Keep upright.
	Do not stack.
	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
	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.

+30°C
+86°F
Localizer must not be used in ambient temperatures greater than 30°C (86°F).

Storage temperature between 15°C and 30°C (59°F and 86°F)

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

MR Conditional. Certain accessories that may be used with the system are MR Conditional. Refer to the labeling for those devices for additional instructions on MR conditional use.

Do not disassemble.

USB 2.0 port

High-speed USB 3.0 port

Network connection

HDMI for video out

DVI-D for video in

S-VIDEO in

Composite VIDEO in

Footswitch

Connects the camera cart to the main cart

EM instrument interface

EM emitter

Microscope

A: Connects an active, wired patient reference frame to the system.

B: Connects an active, wired ultrasound tracker or microscope bracket to the system.

Symbols
Explanation of symbols on package labeling

C: Connects an active, wired patient pointer probe to the system.

Line level input for an external audio device

Cart docking location

Placement of the side-arm support bracket

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

Protect from heat and radioactive sources

Do not transport the camera cart with camera in an undocked position. Always dock camera before moving the camera cart. Use the handle to push the cart.

Do not push the cart from the back of the cart or from the labeled or adjacent surfaces.

LASER radiation emitted from aperture. Do not stare into beam. Class 2 LASER product. Maximum output <1 mW, CW, 640–670 nm, IEC 60825-1 (2014), ANSI Z136.1 (2014). Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to LASER notice no. 50 dated June 24, 2007.

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.

Open here

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027
USA
Main 720 890 3200
Fax 720 890 3500
Technical Support
U.S. 1 800 595 9709
International 1 720 890 3160
www.medtronic.com

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Telephone 31 45 566 80 00

Australia
Medtronic Australasia Pty Ltd
5 Alma Road
Macquarie Park, NSW 2113
Australia
Telephone 1800 668 670

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