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GENESIS X

User Guide

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Patents

GenesisX RMN
Manufactured under one or more of the following United States patents:
7,774,046

Navigant
Manufactured under one or more of the following United States patents:
7,516,416; 7,537,570; 7,540,288; 7,540,866; 7,543,239; 7,627,361; 7,630,752; 7,657,075; 7,708,696; 7,751,867; 7,756,308; 7,761,133; 7,769,428; 7,831,294; 7,853,306; 8,024,024; 8,192,374; 8,369,934; 8,721,655; 9,314,222
Manufactured under the following European patent:
EP 1 682 024 issued in Germany, France, and Great Britain; EP 1 769 390, issued in Germany, France, and the United Kingdom

Other patents issued and pending.

Stereotaxis Trademarks

- *GenesisX RMN* and *iCONNECT* are trademarks of Stereotaxis, Inc., registered in the United States.
- *Cardiodrive* and *Navigant* are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, the United Kingdom, and Japan.
- *Odyssey* is a trademark of Stereotaxis, Inc., registered in the United States, the European Community, and the United Kingdom.
- *Odyssey Cinema* is a trademark of Stereotaxis, Inc., registered in the European Community and the United Kingdom.
- *Odyssey Vision* and *MAGiC* are trademarks of Stereotaxis, Inc.

Other Trademarks

- HAT 500 is a registered trademark of Osypka.
- *CARTO* 3 is a trademark of Biosense Webster. *Celsius* and *Thermocool* are registered trademarks of Biosense Webster.
- *Ampere* and *EnSite* are trademarks of Abbott.

All other brand names, product names, and/or trademarks found in this document are the property of their respective owners.

EMC Directive Statement

EMC Directive Compliance	This equipment was tested and found to conform to the Medical Directive 93/42/EEC for electromagnetic compatibility. Compliance with this Directive is based upon compliance with the following harmonized standards:
Emissions:	IEC 60601-1-2 ed 4.0 (2014-02) CISPR11 ed 6.1 (2016-06), Class A (Professional Healthcare Facility Environement)
Immunity:	IEC 60601-1-2 ed 4.0 (2014-02), IEC 61000-4-2 ed 4.0 (2008-12), IEC 61000-4-3 ed 3.2 (2010-04), IEC 61000-4-4 ed 3.0 (2012-04), IEC 61000-4-5 ed 3.0 (2014-05) + AMD:2017, IEC 61000-4-6 ed 4.0 (2014 COR2015), IEC 61000-4-8 ed 2.0 (2009-09), IEC 61000-4-11 ed 2.0 (2004-03) + AMD1:2017 IEC 61000-4-39 ed 1.0 (2017)

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. The *GenesisX RMN* System is designed to be installed and operated in a Professional Healthcare Facility Environment.

Safety Standard Statement

Safety Standard Compliance	This equipment was tested and found to conform to the following IEC 60601-1 Medical Electrical Equipment General Requirements for basic safety and essential performance test specifications:

Standard	CAN/CSA-C22.2 No. 60601-1:14 ANSI/AAMI ES60601-1:2005+A1;A2 *ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]*

Related documents

HDW-0391 *GenesisX* Preventive Maintenance and Service Guide
HDW-0397 Troubleshooting Guide for *GenesisX* with Model S
HDW-0398 *GenesisX* Education and Magnet Safety Manual
HDW-0399 *GenesisX* Automatic Positioner Centering
HDW-0400 *GenesisX* Quick Reference
HDW-0372 *Navigant* User Guide
Respective documentation for compatible devices and/or systems.

Operating conditions

Temperature: 15°C to 30°C
Humidity: 20% to 75%, non-condensing
Atmospheric pressure: 70 kPa to 106 kPa

Storage and transport conditions

Temperature: –10°C to 50°C
Humidity: 20% to 95%
Atmospheric pressure: 70 kPa to 106 kPa

Equipment information

GenesisX, Reference number 001-014000-1
Classification: Class I Medical Electrical equipment

Note: No class B applied parts. Class B limits used for patient leakage. No class BF applied parts.

Degree of protection: IPX0
Mode of operation: Continuous
Electrical ratings:

Cabinet

Voltage rating:	120/230 V ~1N
Current rating:	8/4 A
Frequency:	50 / 60 Hz

Floorbox

Voltage rating:	120/230 V ~1N
Current rating:	6/3 A
Frequency:	50 / 60 Hz

Positioner

Voltage rating:	120/230 V ~1N
Current rating:	10/5 A
Frequency:	50 / 60 Hz

WARNING: No modification of this equipment is allowed. No user-serviceable parts are inside *GenesisX RMN*. The user should not attempt to dissemble any portion of the *GenesisX RMN*.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains that have a protective earth ground.

Operator-accessible disconnect device

Pressing the Model S X-ray E-stop will cause the RMN system to stop.

Disconnection from Mains Supply

To disconnect the positioners, cabinet, and floorbox completely from mains, the input power cable must be disconnected from the power inlet of each subsystem. The input power cable is connected in the back of the positioner, the side of the floorbox, and the front of the cabinet.

Disposal

This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419).

Waste and Recycling

A contractor is responsible for the disposal and recycling of scrap metals and electronics found in the *Cardiodrive* system.
Suggested Contractor: Walch Recycling & Eldelmentalle

Accessories

Accessory	Part Number
Cardiodrive	001-004115-X

Notice to the User and/or Patient

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Cover art

Contents

1. Overview

Introduction

The Stereotaxis GenesisX RMN® (Robotic Magnetic Navigation System) is a medical platform designed for electrophysiological and interventional procedures. *GenesisX RMN* facilitates the control of the distal tip of compatible magnetic devices via magnetic fields. *GenesisX RMN* includes the Stereotaxis *GenesisX RMN* (*GenesisX* System) with Navigant® Workstation (NWS) (*Navigant*) and the Cardiodrive® System. *GenesisX RMN* is an interventional workstation for the intravascular navigation of appropriately equipped, magnetically-adapted devices (e.g., catheters or guidewires) through tissue to designated target sites.

Physicians use computer—controlled permanent magnets, found in the *GenesisX RMN*, to orient or steer the tips of compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart. *GenesisX RMN* integrates with *Navigant* software which determines the direction the magnetic field should be applied and allows the physician to remotely advance and retract compatible, magnetically-adapted devices using *Cardiodrive*.

About This User Guide

The purpose of this user guide is to provide the *GenesisX RMN* user with instructions for operating the equipment. The guide describes basic system information, specific functionality, and emergency operations and troubleshooting. This guide covers the following systems:

GenesisX RMN Reference number 001-014000-1.

Companion Systems

GenesisX RMN may be used with magnetically-compatible devices, such as the following:

- CELSIUS® RMT Catheter
- *CELSIUS* THERMOCOOL® RMT Catheter
- MAGiC™ Catheter (not available in the US)

GenesisX RMN can be used in conjunction with:

- Compatible mapping systems
    - Biosense Webster CARTO™ 3
    - Abbott EnSite™ X
- Compatible RF generators

  - Biosense Webster® Stockert 70 RF Generator
  - *Biosense Webster* SmartAblate™
  - Abbott Ampere™
  - Osypka AG HAT 500® (not available in the US)

- *GenesisX RMN* can communicate with the Stereotaxis Imaging Model S (powered by Omega Imaging)
- *GenesisX RMN* can communicate with the Neusoft F-Model DSA (not available in the US)

The *GenesisX RMN* can integrate with a compatible, digital fluoroscopy system to provide real-time guidance to the physician during an interventional procedure. The fluoroscopy system must be able to operate in the magnetic field environment produced by the magnets.

The *GenesisX RMN* communicates with the Stereotaxis *Cardiodrive* system and iCONNECT™ system found in the laboratory where the *GenesisX RMN* is installed. (The *iCONNECT* system is not available in the US.)

Documentation for companion systems is provided by the manufacturer, not duplicated here.

Indications

In the United States, the following Indications are applicable for the *GenesisX RMN* and *Cardiodrive* systems.

- The *GenesisX RMN* is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart, coronary vasculature, neurovasculature, and peripheral vasculature by orienting the device tip in a desired direction.
- The *Cardiodrive* System is intended to automatically advance and retract compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis MNS.
- The *Cardiodrive* System is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.
- The *Cardiodrive* System is not intended to advance or retract non-compatible catheters and/or other non-compatible devices into the neurovasculature.

In all other geographies, the following Indications are applicable for the *GenesisX RMN* and *Cardiodrive* systems.

- The *GenesisX* System is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart, pericardial space, coronary vasculature, and peripheral vasculature by orienting the device tip in a desired direction.

- The Stereotaxis *Cardiodrive* System is intended for automatically advancing and retracting compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart and pericardial space when used in conjunction with a Stereotaxis RMN.

Intended Patient Population

The intended patient population for the MNS is patients undergoing diagnostic and interventional procedures in the following areas: right and left heart, and the coronary, peripheral, and the neurovasculature.

Intended Users

The GenesisX RMN System should be used only by qualified medical professionals who have been thoroughly trained in its use.

Contraindications

There are no known contraindications.

Clinical Benefits for Patients

Fewer major and minor patient complications during MNS ablation procedure. Reduction of harmful radiation to patients during MNS ablation procedure due to shorter fluoroscopy times. Acute success, long-term success, and procedure times are similar between MNS and manual procedures with no compromise to safety. Potential to treat more complex pathologies due to the precision, reach, and stability of the system.

Clinical Benefits for the Physician and Staff

Reduction of harmful radiation to clinical staff performing and/or participating in MNS ablation procedure due to shorter fluoroscopy times, and system console location outside the x-ray exposure zone. Reduction in orthopedic burden to clinical staff because heavy lead aprons do not have to be worn for the duration of an MNS ablation procedure as compared to manual ablation procedures for which the protective equipment is required. Reduction in posterior subcapsular changes (vision effects) from radiation.

Graphics and Symbols

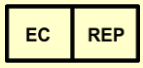
The following graphics and symbols are used in this User Guide:

WARNING		**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION		**CAUTION** indicates a potentially hazardous situation which, if not avoided, could result in injury to patient or operator or damage to the equipment.
Note		**Note** identifies information that could affect the outcome or results of the procedure.

Warnings and Cautions precede the text and any procedure involving a clear risk to the operator(s), the patient, or the equipment. General warnings are listed in the Warnings and Precautions summary, which can be found in the *Safety* section. Pay close attention to the instructions that accompany the warnings, notes, and symbols.

The following graphical symbols are used in this document and/or on system components:

Symbol	Name	Description
	**AC Power**	Indicates the status of the AC power.
	**Catalogue Number**	Catalogue/part number.
	**Caution**	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot be presented on the medical device.
	**Caution: Risk of Electric Shock**	Identifies equipment, such as a power source, that has a risk of electric shock.
	**CE Marking**	Product conforms to European Medical Directive 93/42/EEC and meets applicable healthy, safety, and environmental requirements. If the mark is accompanied by a number, conformity is valid.
	**Consult Instructions**	See the Operating Instructions for additional information or instruction.

Symbol	Name	Description
	**Date of Manufacture**	The date when the medical device was manufactured.
	**E-stop**	Indicates the E-stop button or the E-stop indicator light for the Model S x-ray.
	**European Representative**	Name and address of the authorized representative in the European Community.
	**Importer**	Name and address of the entity importing the medical device into the locale.
	**Magnet Present**	Indicates a magnet is present in the equipment.
	**Manufacturer**	Name and address of the manufacturer of the product.
	**Medical Device**	Indicates the item is a medical device.
	**Pinch Point**	Indicates location of a pinch point.
	**Prescription Only**	Caution: Federal law restricts this device to sale by or on the order of a physician.
	**Recycle: Electronic Equipment**	Product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC/EU Directive for recycling of electronic equipment.
	**Refer to Instruction Manual/Booklet**	The instruction manual or booklet must be read.

Symbol	Name	Description
SN	**Serial Number**	The manufacturer's serial number so a specific medical device can be identified.
UKRP	**UK Responsible Person**	A person established in the United Kingdom (UK) who acts on the behalf of a non-UK established manufacturer in relation to the manufacturer's obligations under UK regulations.

Glossary

The following terms appear in this document:

Term	Description
2D	Two-Dimensional.
3D	Three-Dimensional.
5 Gauss line	See Gauss.
AP/LAO	Anterior-Posterior/Left Anterior Oblique
C-Arm	An X-ray image intensifier that produces live X-ray images displayed on a monitor and named because of its configuration, with the top part of the C extending over the patient and the bottom extending under.
***Cardiodrive* System**	The Stereotaxis tool that provides the physician with the ability to advance and retract catheters from a Control Room. The full name is *Cardiodrive* Catheter Advancement System (CAS).
CAS	*Cardiodrive* Catheter Advancement System. (See *Cardiodrive* System.)
CRT	Cardiac Resynchronization Therapy.
EMC	Electromagnetic compatibility.
EP	Electrophysiology.
Fluoro	Fluoroscopic, or Fluoroscopy.
Fluoroscope	An X-ray image intensifier that produces live X-ray images displayed on a monitor. Also called X-ray or C-Arm.

Term	Description
Fully retracted	Magnet positioners are pivoted toward the patient and at the farthest distance from the patient.
Gauss (G)	The centimeter-gram-second (cgs) unit of magnetic flux density. A 5 Gauss line is marked on the floor of the Procedure Room. < 5 G of static magnetic field exposure for the general public is considered safe.
GenesisX System	A medical platform that enables physicians to more effectively navigate catheters, guidewires and other magnetic interventional devices through the blood vessels and chambers of the heart to treatment sites and then to effect treatment. The *GenesisX* System consists of the *GenesisX RMN*, *Navigant*, and *Cardiodrive* systems and is available only in magnetic labs.
***GenesisX Robotic Magnetic Navigation* (RMN) System**	A Stereotaxis system consisting of computer-controlled magnets that assist physicians in orienting and steering compatible, magnetically-adapted devices.
IC	Interventional, or Intracardiac, Cardiology.
Isocenter	In X-ray technology, the isocenter is the point in space through which the central ray of the radiation beams pass.
Mapping System	System that combines 3D mapping and navigation systems with the Stereotaxis GenesisX MNS.
Move button	Upon selecting a magnet position on the UTSC, the user will hold down the Move button to move the magnets into the selected position.
***Navigant* software**	A platform of software applications designed to simplify clinical workflows. The *Navigant* Workstation (NWS), excluding the *Odyssey* add-on, provides enhanced integration of catheterization and electrophysiology labs and improved automation during magnetic navigation of medical devices. (Available only in magnetic labs.)
Navigation volume	Spatial volume defined for RMNS, where the RMNS is capable of generating any magnetic field direction at the target magnetic field strength provided by the RMNS.
RAO	Right Anterior Oblique.
RF	Radiofrequency.
RMN	Robotic Magnetic Navigation System (*e.g., GenesisX RMN*)
RMT	A remote magnetic technology. (RMT is often used to refer to the integrated third-party / *GenesisX* RMN environment incorporating 3D mapping and navigation and magnetic maneuvering of compatible devices).

Term	Description
Tesla (T)	The standard unit of magnetic flux density.
UTSC	Universal Tableside Controller. Touchscreen controller positioned on the side of the patient table in the Procedure Room.

Safety

Warnings

Although the *GenesisX* System provides skill amplification and an automated means of steering the distal tip of catheters and guidewires, these features do not replace the physician's knowledge, expertise, or judgment.

WARNING: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING: The Stereotaxis *Cardiodrive* System should only be used by physicians trained in the use of these systems, with a thorough understanding of angiography and percutaneous interventional procedures.

WARNING: The *GenesisX RMN* has permanent magnets that **always produce** a strong magnetic field. The field cannot be turned off. This field could cause metal objects in the Procedure Room to become airborne projectiles if not kept sufficiently isolated from the magnetic field. The magnetic field is present in the vicinity of the magnets at all times. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant before entering the Procedure Room. Serious injury may result.

Refer to the "Reference Manual for Magnetic Resonance Safety, Implants & Devices" published by Biomedical Research Publishing Group for details on the types of objects and medical implants compatible with magnetic environments.

Individuals near the magnet should remove from their person items that could be affected by magnetic fields, including items with magnetic stripes on them (credit cards, employee badges), wristwatches with mechanical movements, cell phones, and magnetic media such as floppy disks and ferrous materials.

WARNING: The *GenesisX RMN* magnets produce a strong magnetic field, which is always on. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant before entering the Procedure Room. Serious injury may result.

WARNING: The user should not attempt to upgrade, configure, or run any other software programs on the *GenesisX* System computers, other than those specifically mentioned in the product documentation.

WARNING: There are no user serviceable parts inside the *GenesisX RMN* magnets. The user should not remove any covers or guards or attempt to disassemble any portion of these magnets.

WARNING: All equipment brought into the Procedure Room (for example, IV poles, patient monitoring equipment, oxygen tanks, etc.) must be safe in a magnetic environment. All equipment that is "MRI compatible" meets these criteria.

WARNING: When a graphical representation of the catheter tip and shaft on the *GenesisX* System display screen, the graphical representation is a display of the calculated catheter shape, based on the initial location and orientation of the catheter base and distance of catheter shaft advancement (or retraction) by the *Cardiodrive* System.

WARNING: *GenesisX RMN* does not track the location or orientation of the catheter. (If the user purchases a compatible mapping system, the location and orientation of the catheter tip can be displayed.)

WARNING: The graphical representation of the catheter on the *GenesisX* System display screen represents an approximate location and orientation of the catheter inside the patient's heart after the user acquires a new fluoro image and subsequently transfers it from the X-ray using the "Transfer Image" button.

WARNING: Exercise caution with moving parts of the system to prevent inadvertent contact or damage to the patient, operator, or equipment. Movable items include both magnet positioners, the accompanying fluoroscopy system's C-Arm, and the patient table.

WARNING: *GenesisX RMN* should be used only with magnetic devices and accessories appropriately labeled as compatible with *RMN* applications.

WARNING: Make sure the patient table pivot is in the central position (centered between the magnet pods) before moving the *GenesisX RMN* pods out of the Stowed position toward the Navigate position.

WARNING: The operator should always confirm device location using a live fluoroscopic image.

WARNING: If the device is moved manually instead of using the *Cardiodrive* System, the *Cardiodrive* display, and any previously stored position data may become invalid. The physician should remove all previously set markers after moving the device manually.

WARNING: Always verify catheter motion using live fluoroscopy images. Stop immediately if catheter motion can no longer be verified.

WARNING: Ablation system foot pedal should not be connected to the RF generator in the Procedure Room. It is intended for use only in the control room.

WARNING: If unexpected catheter motion occurs during ablation, stop RF energy delivery.

Precautions

CAUTION: If a patient is to receive a permanent pacemaker or internal cardiac defibrillator (ICD) *de novo* in the Procedure Room, the system magnets must be moved and kept in the Stowed position. The magnets should stay in their Stowed positions during the entire period starting from the moment the ICD or pacemaker is brought inside the Procedure Room, and ending when the patient (with the ICD or pacemaker implanted) is moved out of the Procedure Room. Proper functioning of ICDs and pacemakers should be verified following the removal of the patient from the Procedure Room.

CAUTION: During patient loading and unloading, there is a collision risk for individuals in the vicinity of the magnet positioners and the X-ray system. All individuals should make sure they are not in this vicinity when the magnets are moving between the Stowed and Navigate positions. An audio signal sounds when magnets have completed their movement. (Volume may be adjusted in Settings → System tab.)

CAUTION: Do not enter the area between the X-ray system and magnet positioner when the magnets are moving from the Stowed to Navigate position.

CAUTION: Due to space constraints in the Procedure Room in the low magnetic field (< 5 gauss) area, remove one patient before bringing in another.

CAUTION: The *GenesisX RMN* uses a magnetic field to orient the tip of the catheter to the desired intracardiac orientation.

CAUTION: The points on the *CARTO* 3 System screen are for reference only. Always confirm orientation of the catheter location with localization methods—fluoroscopy, for example—in addition to the electrograms.

CAUTION: The *CARTO* 3 System points and catheter tip location displayed on the *CARTO* 3 screen can be transferred to the *Navigant* screen. The catheter tip displayed on the *Navigant* screen is used only as a visual reference to aid navigation, not to identify the location of the catheter tip in the heart. Always confirm orientation of the catheter location with localization methods—fluoroscopy, for example—in addition to the electrograms.

⚠ **CAUTION:** If the physician believes the catheter may be in the wrong location, the physician should refresh the fluoroscopy image. If a discrepancy occurs, the physician should reregister the mapping system to *Navigan*t, remark the catheter base, and recalibrate the *Cardiodrive* System.

⚠ **CAUTION:** Do not enter the area between the C-Arm and magnet when the magnets are in the pivoted position.

⚠ **CAUTION (Model S):** With Model S, pressing the X-ray system E-stop will cause the *GenesisX RMN* System to stop.

⚠ **CAUTION:** If the *GenesisX RMN* is operated with interlocks overridden (as described in the Emergency Operations section), a collision between the *GenesisX RMN* and the X-ray system is possible. Closely monitor the magnet movement, and be ready to release the Move button if a collision is imminent. Failure to heed this caution may cause damage to the equipment.

⚠ **CAUTION:** Although the magnetic field is 0.05T (Tesla) in the navigation volume at isocenter, it is stronger than this in regions closer to the front of the magnets:

- In the Navigate position, the field strength at any surface of the magnet covers can be as high as 0.55T.
- In the Navigate position, field strength is 0.1T at five inches (13 centimeters) away from the front surface of the magnet cover, and at more than five inches away from the front surface of the magnet cover the field strength is less than 0.1T.
- In the Stowed position, the field strength is less than 0.05T one inch (3 centimeters), or more, in front of the front surface of the magnet cover.

⚠ **CAUTION:** Do not set anything on the keypad or flip the keypad over. This will prevent a key from being held down causing unwanted repetitive motion.

⚠ **CAUTION: T**he external power strip is not to be loaded with anything other than the intended accessories.

Magnet Safety Sign

For the outside entrance doors to a *GenesisX* procedure room, a magnet safety sign is affixed to them advising personnel of the health and safety dangers of the magnets. **Figure 1** shows an example of the provided sign. Below is a detailed explanation on the sign and its symbols.

Because of the nature of the *GenesisX*'s magnetic field, there are potential risks to the health and safety of personnel coming into contact with the magnetic field, so the only people who should be inside the room with the *GenesisX* are authorized personnel trained in health and safety risks associated with the device's magnets and means to secure the room are recommended.

Indicates there is a strong magnetic field from within the procedure room housing the *GenesisX* that is always on.

Indicates that people who have cardiac pacemakers, implantable cardioverter defibrillators (ICDs), or any other metallic, electronic, magnetic, or mechanical implants, devices, or objects should not be brought into the area of the *GenesisX* and its magnetic field due to what the magnetic field could do to any of those items/devices and how it could harm anyone with them. Additionally, someone shouldn't enter the area beyond the sign if they are unsure about the safety of their implant, device, or object in the magnetic area; they should consult an MRI Technologist or Radiologist first if they have any questions.

Indicates that loose, metal objects made of ferrous materials shouldn't be taken near the area of the *GenesisX* magnetic field due to the potential risks of serious injury or property damage. Additionally, electronic objects (such as hearing aids, cell phones, beepers, etc.) shouldn't be brought into the area due to those objects being at risk of damage or destruction because of the magnetic field's interference.

Figure 1. Magnet Safety Sign Listing Magnet Health and Safety Risks

Technical Details and System Testing

The *GenesisX RMN* generates a directional 0.05T magnetic field within the patient's heart. The navigation volume is 6 inches (15 centimeters) in diameter centered at X-ray isocenter.

Impedance Measures When Using *iCONNECT*

When used with the optional *iCONNECT* system, the impedance readings from the catheter can be displayed if the operator chooses. Cardiac impedance values are a useful means to help understand contact with the tissue and assess changes over time.

With impedance values, there is significant variability between patients as to baseline impedance values for blood and heart tissues. Because of this, it is not an actual numerical impedance value that is of significance but rather the measured changes that occur between these tissues and blood as the catheter is moved and over time as therapies are delivered. The *iCONNECT* measures of impedance are designed to be of sufficient accuracy and precision for assessing these changes.

The *iCONNECT* system when used with Genesis is designed to provide an impedance measure as follows:

Channels	2 (E1-E3 and E2-E4)
Calibrated Range	120 to 340 ohms
Accuracy	<2.5%
Precision	≤1 ohm

Fluoroscopy Exposure

Patients and operators will be exposed to fluoroscopy during procedures performed with the *GenesisX RMN*. Operators may experience less exposure because they will be remotely performing the procedure in the control room. Clinical trials using previous versions of magnetic navigation systems reported mean fluoroscopy times ranging from 10.64 minutes to 16.91 minutes.

General Notes

- Always verify the fluoroscopy images match the current patient.
- Before ablation, verify the field is applied to ensure proper device functionality.
- Images electronically zoomed and/or panned cannot be transferred to *GenesisX* System.
- Images acquired during C-Arm or table movement cannot be transferred to *GenesisX* System.

C-Arm collision with magnet considerations

When both are powered up, the *GenesisX RMN* magnets and the X-ray system are "aware" of each other and their current location. The user will neither be able to move the magnets into an area where the C-Arm is located, nor move the C-Arm into an area where the magnets are located. If the user attempts to do this, a warning message will appear and the controls will be locked out.

The X-ray C-Arm and magnets must **never** physically contact each other, for several reasons:

- The magnetic tube shield around the X-ray tube would stick to the magnet.
- The C-Arm could sustain physical damage.
- The cosmetic covers could sustain physical damage.

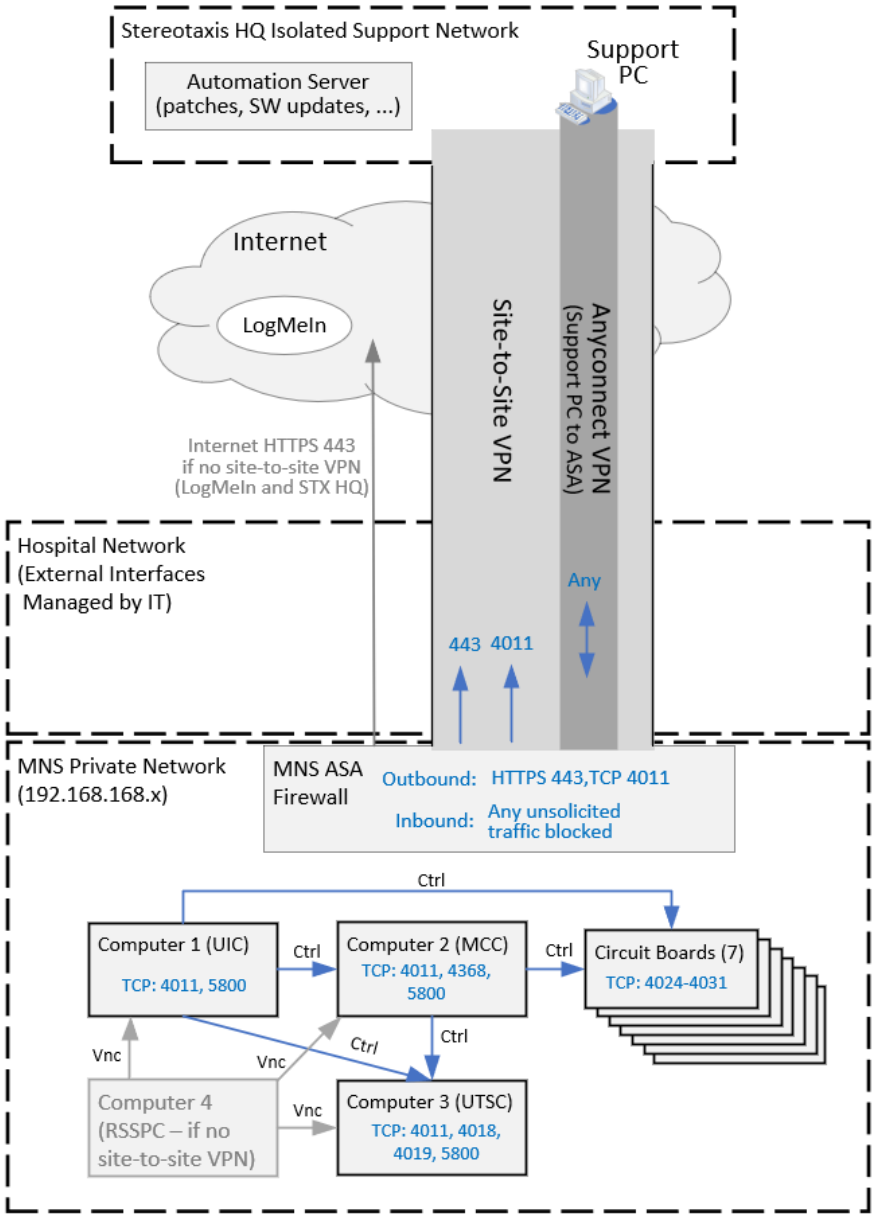
⚠ **CAUTION (Model S):** Model S collision avoidance is disabled by design when not communicating with the *GenesisX RMN* unless the Model S System sees that the *GenesisX RMN* magnets are in the Stowed position (via hardware signal). When collision avoidance is disabled, the C-Arm will allow movement to only the AP position and table height movement will be restricted.

Cybersecurity Information

Please note the following important information concerning cybersecurity:

- Cybersecurity controls operate in the background of *Navigant* Workstation. No user actions are required to maintain the security of the system, but any suspected cybersecurity incidents should be reported to the Stereotaxis Telerobotic Support Team (TST).
- During the site-planning process hospital IT and Stereotaxis IT/security should coordinate to establish a secure networking solution that allows the device to securely access a Stereotaxis server for software and security updates.
- Only trusted users should be allowed physical access to the *GenesisX* System.
- Confidentiality of system passwords should be maintained. Only trusted users should have access to them.
- Caution should be used when using removable media, e.g., CD, DVD, Blu-ray disks, flash drives, USB hard drives, with *GenesisX* System. Independent virus scanning is recommended before insertion or connection to the system.

Network Ports



The following ports will send/receive data in/out of the MNS system's private network through approved endpoints:

Outbound from MNS if Site-to-Site VPN is used for support:

- Https 443 or Http 4011 to Automation Server at STX HQ for support (e.g. software/patch downloads)
- Any ports when support PC connects to ASA using Anyconnect VPN (i.e. VPN within the VPN).

Outbound from MNS if Site-to-Site VPN is not used for support:

- Https 443 to Automation Server at STX HQ for support (e.g. software/patch downloads)
- Https 443 to LogMeIn to provide remote control service.

Inbound to MNS:

Any unsolicited traffic is blocked by the MNS ASA firewall.

Responding to Cyber Incident

The *GenesisX* system operates as a self-contained system with all necessary communications for normal clinical use occurring within its internal network, protected by a dedicated hardware firewall. No additional networking or encryption infrastructure is required from the hospital to support standard clinical operation. The system functions independently and does not rely on an external network for its primary functionality.

For remote support only, an external network connection is required. This connection may be established via a site-to-site VPN or a cloud-based remote access solution (e.g., LogMeIn). The configuration and security of these remote-access connections must be coordinated between Stereotaxis and the hospital's Information Technology (IT) personnel to ensure a secure and reliable connection that aligns with cybersecurity best practices and institutional cybersecurity policies.

If you need further clarification or specific technical guidance on secure network deployment and servicing, please contact Stereotaxis TeleRobotic Support Team.

> ⚠ **WARNING:** If there is a cybersecurity breach during a procedure, press the E-stop button to stop all device activities. Contact the Emergency call center to report the suspicious activity prior to resuming the procedure.

Software Bill of Materials (SBOM)

To support effective cybersecurity risk management and asset tracking, a **machine-readable Software Bill of Materials (SBOM)** is available for this device (PM11-041 PM11 Software Bill of Materials and NWS-472 Navigant SBOM). The SBOM provides a structured inventory of software components, including open-source and third-party dependencies, to help users assess potential vulnerabilities and apply appropriate security measures.

The SBOM is provided in **CycloneDX v1.3 JSON** format and can be requested as needed for security assessments, compliance purposes, or vulnerability management. To obtain the latest SBOM for this device, please contact the Stereotaxis TeleRobotic Support Team.

User Involvement in Software Updates

To ensure the security, performance, and reliability of this device, all software updates and patches are managed directly by Stereotaxis. No user action is required to install updates; however, users may need to provide support when field service technicians visit for scheduled maintenance.

- **Automated Updates**: Operating system security patches and antivirus updates are automatically downloaded and installed as part of the device's built-in maintenance process. These updates help protect against cybersecurity threats and ensure continued compliance with security best practices. When the update downloads to the computer, the user is presented with the following message window when they close their procedure. It is important that the system is left on with the procedure closed as the update's installation occurs overnight.

- **Field Service Updates**: Updates to clinical software and other critical system components are performed on-site by authorized field service technicians. If access or coordination is required during a service visit, users will be notified in advance.

For questions regarding software updates or to schedule a service visit, please contact Stereotaxis TeleRobotic Support Team.

System Response to Anomalous Events

The device continuously monitors for potential security threats and system anomalies to ensure safe and reliable operation. When an anomalous condition is detected, the system responds as follows:

- **Malware Detection**: If malware is detected on the system, a real-time alert is automatically sent to **Stereotaxis's TeleRobotic Support Team**. The event is also recorded in system log files for further analysis. No user action is required, but support personnel may reach out if additional assistance is needed.
- **Compromised Device Communication**: If the system detects any compromise in communications between internal components, a real-time alert is sent to the call center. This ensures that any potential security risks or operational disruptions are promptly addressed. The event is also logged in system files for diagnostic purposes.

If users observe any other unexpected behavior or suspect an issue not covered by the automated monitoring system, they should promptly contact the Stereotaxis call center for further assistance.

System Protective Features

The system is designed with multiple layers of cybersecurity protections to ensure the confidentiality, integrity, and availability of critical operations. These measures help safeguard the system against unauthorized access, tampering, and potential cybersecurity threats.

- **Protected Private Network**: All communication between system components occurs within a **dedicated private network** that is isolated from external networks using a **hardware ASA firewall**. This prevents unauthorized access from outside sources.
- **Firewall Protections**: The **ASA firewall blocks all unsolicited incoming traffic**, ensuring that only necessary and explicitly allowed communication can occur. Outbound traffic is restricted to a **limited set of service-related ports** to minimize exposure.
- **Encrypted Communication**: Even within the **secure private network**, communications between system components are **encrypted** to prevent data tampering, eavesdropping, and replay attacks, further securing critical operations.
- **Endpoint Security**: All Windows-based system components have **Windows Defender and Windows Firewall enabled**, with **real-time scanning** to detect and mitigate potential malware or unauthorized activity.
- **System Backup & Recovery**: To ensure **rapid restoration** in the event of a failure or compromise, **disk images are created** at the time of installation and updated during preventive maintenance visits by authenticated authorized users. These backups provide a reliable means of recovery.
- **Multi-Factor Authentication (MFA)**: **Administrative access to system computers requires MFA**, adding an additional layer of security to prevent unauthorized access to system settings and sensitive functions.

These protections work together to ensure the system remains secure, reliable, and resistant to cybersecurity threats. For additional security-related inquiries, please contact the Stereotaxis TeleRobotic Support Team.

User-Configurable Changes

Secure Configuration of the System

The system is shipped **fully configured** with all cybersecurity protections enabled to ensure a secure operational state from installation. **No user configuration is required** to maintain or enhance cybersecurity protections. The following security measures are pre-configured and enforced:

- **Hardware Firewall Configuration**: The ASA firewall is preconfigured to **block all unsolicited inbound traffic** and restrict outbound traffic to essential service ports only, preventing unauthorized access.
- **Account Security**: User accounts and permissions are pre-set to enforce **role-based access contro**l, with **Multi-Factor Authentication (MFA)** required for administrative accounts.
- **Cryptographic Protections**: Encryption keys for secure communication between system components are **pre-installed** and managed internally, ensuring data integrity and confidentiality.

- **Anti-Malware and Software Firewall**: Windows Defender is **enabled with real-time protection**, and the Windows Firewall is configured to allow only required services while blocking unauthorized network access.
- **Security Event Logging**: The system is configured to **log security events**, including malware detection and communication anomalies, which are **automatically reported to the manufacturer's call center** for monitoring and response.
- **Backup and Recovery**: Disk images are created at installation and updated during preventive maintenance visits to ensure **quick restoration** if needed by authenticated authorized users.
- **Physical Security Protections**: System access is restricted to authorized personnel, with **administrator credentials managed securely** and changed as needed to maintain security.

User-Configurable Settings and Potential Security Risks

Since the system is fully secured at shipment, **no user-configurable changes** are required for cybersecurity. Any unauthorized modifications to system security settings—such as disabling the firewall, modifying cryptographic settings, or altering administrative accounts—**could compromise the security and integrity of the device**. Users should not attempt to make changes to system security settings and should contact the Stereotaxis TeleRobotic Support Team if modifications or access adjustments are necessary.

Capturing of Forensic Evidence

Forensic Evidence and Security Event Logging

The system maintains detailed log files to capture forensic evidence of system activity, including security events such as **malware detection and communication anomalies**. These logs provide valuable insights for troubleshooting, incident response, and security monitoring.

Log File Capture and Storage

- **Event Logging**: Almost all system actions are recorded in log files, including security-related events.
- **Security Event Logs**: **Malware detection events** and **communication anomalies** are logged and **reported in real time** to the Stereotaxis support center for immediate response and investigation.
- **Windows Event Logs**: In the event of a security incident or system compromise, **Windows Event Logs** can be examined to provide additional forensic evidence, including system activity, login attempts, and security alerts.
- **Log File Location & Format**: Logs are stored locally on system components in **standard text-based log file formats**, compatible with manual review and automated analysis tools. Log files are uploaded daily for diagnostics purposes (no PHI is in the logs).

- **Retention & Recycling**: Log files are **automatically rotated** to maintain storage efficiency. Historical logs may be archived for forensic analysis as needed.

Forensic Analysis & Automated Consumption

- **Manufacturer Monitoring**: Security event data is sent to the Stereotaxis TeleRobotic Support Team, allowing for **real-time monitoring and response**.
- **Windows Event Log Analysis**: In case of a suspected compromise, Windows Event Logs can be reviewed by authorized personnel to trace system activity and identify potential security incidents.
- **No IDS or SIEM Integration**: The system does not integrate **with Intrusion Detection Systems (IDS)** or **Security Information and Event Management (SIEM)** solutions. However, logged events are structured to allow for external review if necessary.

For assistance with log file analysis or forensic investigation, users should contact the Stereotaxis TeleRobotic Support Team.

Decommissioning

If a component containing sensitive data needs to be removed or replaced, or for system removal, contact the Stereotaxis TeleRobotic Support Team for the appropriate steps to be taken.
The expected lifetime of the GenesisX RMN is defined as at least ten (10) years from the date of manufacture, based on technology and part obsolescence. Stereotaxis regularly monitors devices, parts, and components (including software/firmware) for potential End of Life (EOL) and End of Service / Support (EOS). If a component is declared EOL/EOS, Stereotaxis will update the device to a supported version or alternative supported component to prevent premature device EOL/EOS. When a Stereotaxis device is declared EOL/EOS, direct customer notification will be sent to the applicable personnel according to the relevant Service Contracts / Records. Please contact the Stereotaxis TeleRobotic Support Team for further information on device lifecycle and EOL/EOS.

Electromagnetic Compatibility Information

WARNING: The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by Stereotaxis, Inc., may result in increased emissions or decreased immunity of the *GenesisX RMN*.

WARNING: The *GenesisX RMN* should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the *GenesisX RMN* should be observed to verify normal operation in the configuration in which it will be used.

Note: In addition to the requirements of 7.9.3 of the general standard for Permanently Installed Large Medical Electrical (ME) Equipment and Large ME Systems for which the

exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used, this technical description include s the following information:

WARNING: This equipment has been tested for radiated radiofrequency (RF) immunity at selected frequencies, and use of nearby emitters at other frequencies could result in improper operation. Improper operation may consist of (1) prevention of patient treatment, (2) uncontrolled motion of magnets, and (3) uncontrolled motion of the *Cardiodrive* System.

Emissions

The *GenesisX RMN* is intended for use in the electromagnetic environment specified in the following tables. The user of the *GenesisX RMN* should ensure that it is used in such an environment.

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *emissions*** for the *GenesisX RMN*:

Emissions	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The *GenesisX RMN* System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A Complies	
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

WARNING: The EMISSIONS characteristics of this equipment make it suitable for use in industrial and hospital (CISPR 11 class A) settings. 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.

Immunity—General electromagnetic effects

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *immunity*** regarding general electromagnetic effects for the *GenesisX RMN*:

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
			Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8 & 15 kV air	± 8 kV contact ± 2, 4, 8 & 15 kV air	
Electrical fast transient/burst I EC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (100 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (100 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *GenesisX RMN* System requires continued operation during power mains interruptions, it is recommended that the *GenesisX RMN* System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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.

* U_T is the a.c. mains voltage before application of the test level.

Immunity—RF interference

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *immunity*** regarding radiofrequency for the *GenesisX RMN*:

Immunity test	IEC 60601 test level	Compliance level [a]
Conducted RF IEC 61000-4-6	**3 Vrms** 150 kHz to 80 MHz **6 Vrms** ISM & Amateur Radio Bands	**3 Vrms** **6 Vrms**
Radiated RF EM Fields and Proximity Fields from RF Wireless Communications IEC 61000-4-3	**27V/m** 380-390MHz **28V/m** 430-470MHz 800-960MHz 1700-1990MHz 2400-2570MHz	**19V/m** 1200MHz **22V/m** 902-904MHz 925-927MHz **23V/m**

Immunity test	IEC 60601 test level	Compliance level [a]
	9V/m 704-787MHz 5100-5800MHz	2.412-2.462GHz 5.47-5.85GHz **26V/m** 144-148MHz 222-225MHz 420-450MHz **27V/m** 130-170MHz 430-450MHz

[a] Testing was completed using licensed transmitters and their corresponding modulations. These compliance levels shown should be used when calculating recommended distance from transmitters expected to be in the vicinity of the system. Further guidance on separation distances can be found in the section below.

Separation distances

WARNING: Portable and mobile RF communications equipment should be used no closer to any part of the GenesisX RMN System, including cables, than the required separation distance calculated using the formula below. The minimum separation distance of any such RF communication equipment to any part of the GenesisX system is 30 cm (12 inches).

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

Separation distance:

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 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. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 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 theoretically predicted 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 GenesisX RMN is used exceeds the applicable RF compliance level above, the GenesisX RMN should be observed to confirm normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GenesisX RMN or contacting the TeleRobotic Support Team.

Interference may occur in the vicinity of equipment marked with the following symbol:

The table provides **required separation distances** between portable and mobile RF communications equipment and the *GenesisX* System.

Rated maximum output power of transmitter* W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz t0 2.5 GHz** $d = 2.3\sqrt{P}$
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

* For transmitters rated at a maximum output power not listed above, the required 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.

Note 1: At 80 MHz and 800 MHz, separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note: If there are Electromagnetic Compatibility (EMC) issues with the *GenesisX* System, contact Stereotaxis TeleRobotic Support Team. There are no specific service requirements to maintain EMC integrity.

2. Basic Information

GenesisX RMN Magnet Information

The arrangement of the magnetic Procedure Room is fairly standard among institutions. The major difference is the X-ray system present. **Figure 2** describes the main Procedure Room components with the X-ray system.

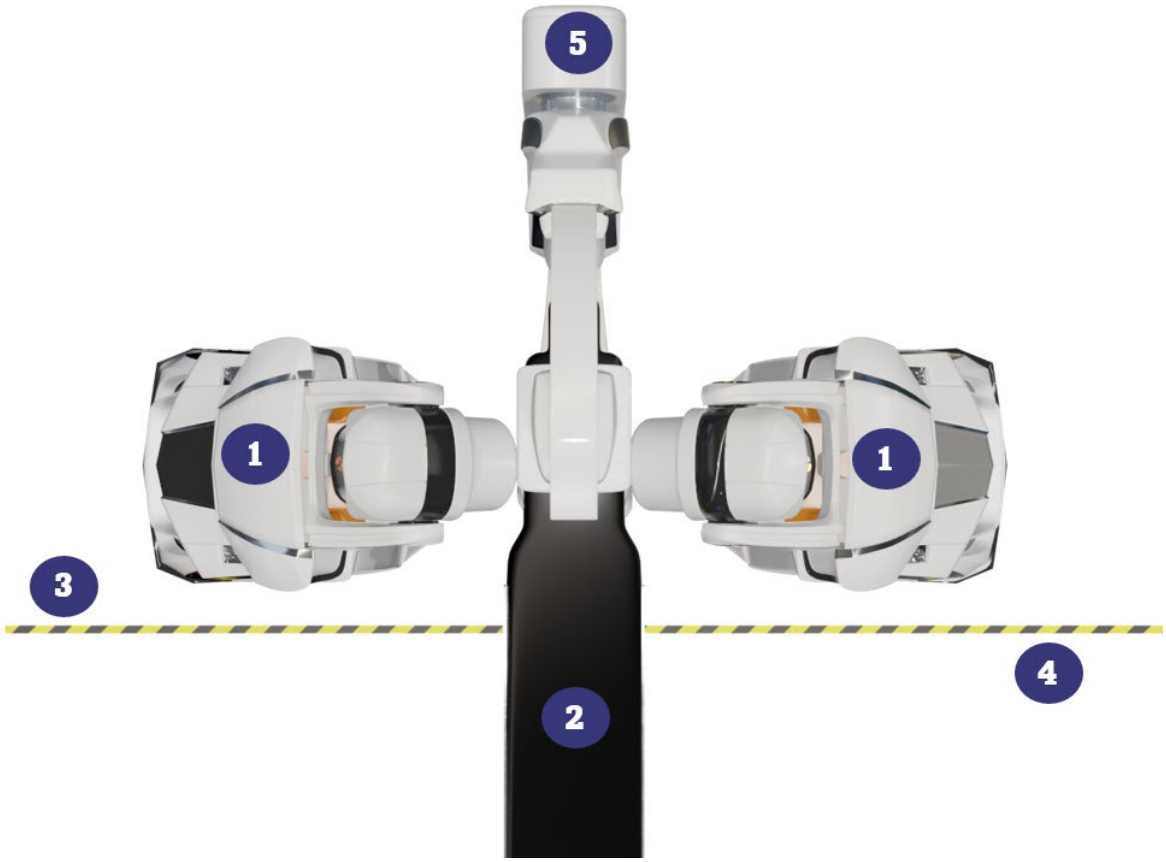


Figure 2. Procedure Room components

Procedure Room component guide (Figure 2)

① **GenesisX RMN magnet positioners.** Magnet positioners or *pods* contain system magnets.

② **Patient table.**

③ **Five Gauss line.** The dividing line between the zones that are less than 5 G and more than 5 G when the magnets are stowed. Institutions indicate this division in various ways.

④ **Five Gauss zone.** The zone that is less than 5 G (the table side of the room) within which individuals should remain when magnets are stowed.

⑤ **X-ray system.** The compatible digital fluoroscopy system in use.

GenesisX RMN Magnet Positions

System positions define the locations of the magnets relative to the patient.

System positions

At any given time, the magnets are in one of the following positions: Stowed, Pivoted, Retracted, or Navigate AP, Navigate RAO, or Navigate LAO. The magnets are moved by pressing buttons on the Universal Tableside Controller (UTSC). The following table describes each of the positions and lists when the various positions are used in a procedure.

Position	Position description	When position is used
Stowed	*GenesisX* is in this position when it is furthest away from the patient along its constrained movement pattern and Shielded.  **Figure 3. Magnets in Stowed position**	• When no procedure is being performed • During non-magnetic procedures • To allow increased imaging angle flexibility • When greater patient access is needed • When field beyond Physician Access Line needs to be less than 5 G • To move *GenesisX* out of the way and to enable standard lab procedures to be performed.
Shielded	The state of the *GenesisX* system when both positioners have the pod placed within the magnetic shielding frame of the base.  **Figure 4. Magnets in Shielded position**	• When greater patient access is needed • To allow increased imaging angle flexibility

Retracted	This is an array of positions when the pod cover location is beyond what is necessary to enable magnetic navigation but is not Stowed or Shielded. The system shall be considered to be in the Fully Retracted position when pods are a maximum distance from the patient while the Base is nearest the patient.  **Figure 5. Magnets in Fully Retracted RAO (Top) & LAO (Bottom) Positions**	• When field needs to be reduced • To allow increased imaging angle flexibility without having to wait for magnets to pivot away from patient • When greater patient access is needed

Navigate RAO	The position when the pod cover position is within a range to enable magnetic navigation. Positioners are moved to the Navigate position to begin navigating devices.  **Figure 6. Magnets in Navigate RAO**	During magnetic navigation procedure with C-Arm angulation on right side of patient
Navigate AP/LAO	 **Figure 7. Magnets in Navigate AP/LAO**	During magnetic navigation procedure with C-Arm angulation on left side of patient

Universal Tableside Controller (UTSC)

The UTSC allows the user to physically move the magnets and controls various other system functions. In the Procedure Room, the user controls the *GenesisX RMN* magnets using the UTSC (**Figure 8**). Once the *GenesisX RMN* icon is selected (**Figure 9**), more UTSC buttons display as well as a **Transfer Image** button.

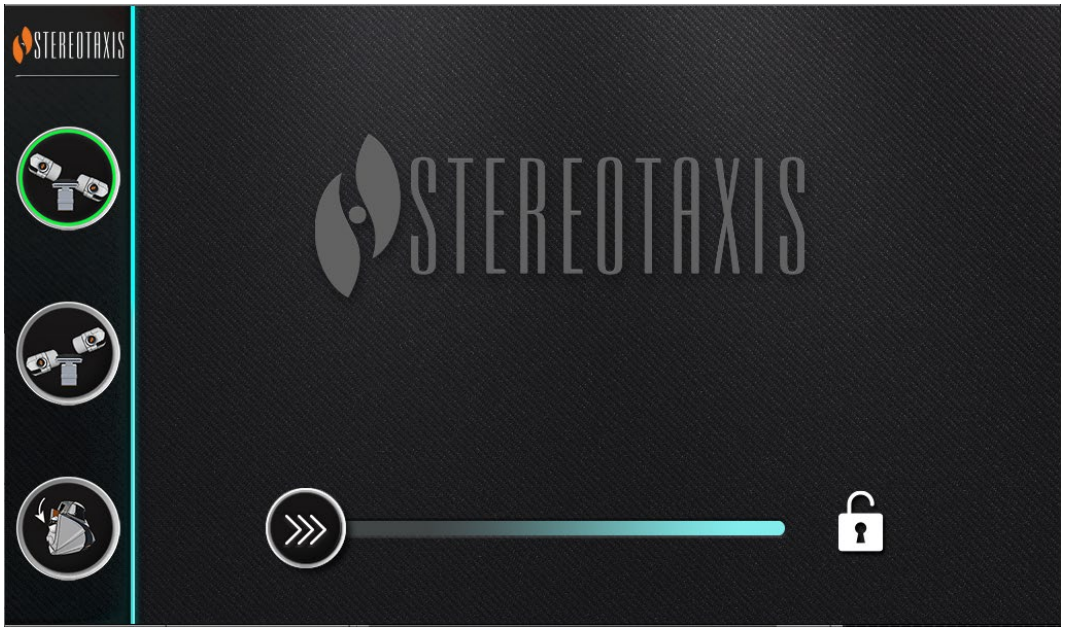


Figure 8. UTSC buttons (*left*)

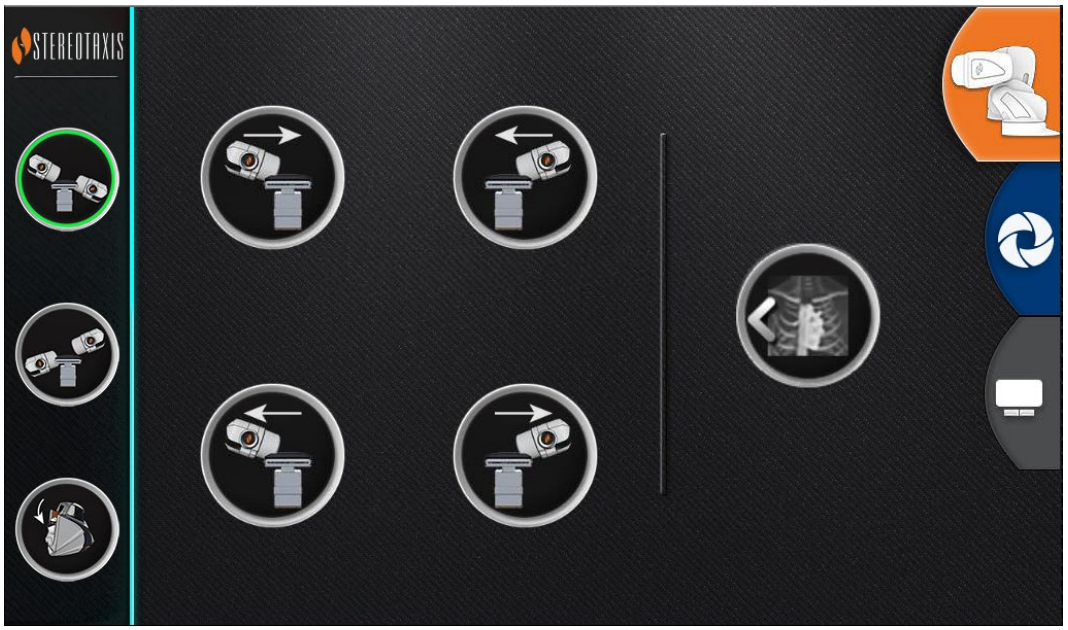


Figure 9. *GenesisX RMN* icon selected (right), more UTSC buttons display

Table 1 details the magnet positions that correspond with the UTSC buttons (**Figure 8** and **Figure 9**). The user must select a magnet position on the UTSC and hold down the **Move** button (**Figure 12**) to move the magnets into the desired position.

Table 1. UTSC buttons and descriptions

	**Navigate AP/LAO**		**Advance Patient Right Side***
	**Navigate RAO**		**Advance Patient Left Side***
	**Stowed**		**Retract Patient Right Side***
			**Retract Patient Left Side***

* Applies to patients in head-first supine position.

System Power Up

Preparing for patient's entry

Follow these steps before bringing the patient into the Procedure Room:

1. Ensure no ferrous objects (objects magnets could attract) are in the area.
2. Ensure objects magnets could damage are not in the area, such as credit cards, watches, floppy disks, cell phones, beepers, and hearing aids.
3. Power up the system. On the remote power panel (located in Control Room), hold the toggle switch in the **ON** ("I") position for approximately 1 second until the green power lamp illuminates (**Figure 10**).
4. If not already positioned, retract magnet positioners to Stow by pressing the **Stow** button on the UTSC and the **Move** button (**Figure 12**) to aid in patient loading.

Figure 10. Power Box in Control Room

Note: In case of a voltage interruption, *GenesisX RMN* may shut down, requiring a system restart.

Recommended Patient Loading Procedure

This section outlines the basic steps and precautions for generic and peripheral magnetic navigation procedures.

Magnetic safety precautions

The intent of this procedure is to keep the patient and attending medical staff in a low magnetic field (less than 5 G) while the patient is transferred into and out of the Procedure Room. The 5 Gauss line is marked on the floor. The user should move the magnets into the Stowed position using the UTSC, and move the tabletop back, away from the X-ray system and magnets. Individuals should stay on the tableside of the 5 Gauss line when the magnets are stowed.

WARNING: The *GenesisX RMN* produces a strong magnetic field that is always on. Patients and operators with pacemakers, internal cardiac defibrillators (ICD), neurostimulators, or magnetic sensitive or ferromagnetic implants should contact the manufacturer of their respective implant **before** entering the Procedure Room. Serious injury may result if no precautions are taken.

Patient Table

The patient should be centered laterally on the table so the magnets on either side of the table can move toward the patient equally. The table can be moved vertically to adjust the height. See Error! Reference source not found. HDW-0372 *Navigant* User Guide for Error! Reference source not found.specifics regarding the adjustment of table height to match the isocenter height.

The position of the patient on the table depends on the type of procedure performed. Patients should be in a head-first supine position (**Figure 11**) except when a femoral or tibial procedure is performed.

Figure 11. Head-first supine position

Cover-Force Sensor

The magnet covers contain cover-force sensors that detect when the face of the cover is pressing against the patient or padding. When a cover-force sensor is activated, the magnet positioner pauses, then retracts slightly and stops.

If a single cover-force sensor is activated, the operator may choose to continue holding the **Move** button. The system automatically retracts the individual cover that is contacting the patient slightly and advances the opposite cover to continue movement to the Navigate position.

Figure 12. Move button

If the second cover-force sensor is activated before the positioner reaches Navigate position, the Navigate Position Assistance dialog appears. If the second positioner has enough room to reach Navigate position, the *GenesisX RMN* adjusts the Navigate position center based on this new location and displays the status message, "***Magnets in Navigate Position***."

Automatic positioner centering

The *GenesisX RMN* can automatically center the magnet positioners in the Navigate position, based on the patient table's lateral and vertical positions. To understand this, it is important to first understand the Navigate position and cover-force sensor.

1. Using fluoroscope images, center the patient (region of interest) relative to the X-ray isocenter.
2. Press one of the **Navigate** buttons (the ring around the button will light) on the UTSC. Then press the **Move** button. The system calculates the target position based on the position of the patient table and begins moving to that position.
3. If motion stops and the message ***Magnets in Navigate Position*** displays in the bottom-left corner of the monitor, the automatic positioner centering has been successful. The system also emits an audio signal that the system is in Navigate position. (The user may adjust the volume in the Settings → System tab.)
4. If the cover contacts the patient and activates the cover sensor, the cover will stop and retract slightly. The other cover's position will adjust to try to reach the Navigate position.
5. If motion stops before the system reaches the Navigate position, one of these conditions has occurred:
    - After selecting one of the **Navigate** buttons, the operator did not hold the **Move** button down until the system reached the Navigate Position. The operator may continue to the Navigate Position by pressing and holding the **Move** button.
    - Both cover-force sensors have activated. The system displays a message in the bottom-left corner of the monitor and emits an audio signal if the system does not reach Navigate position because of cover-force sensor activation.
    - The covers cannot achieve the position because of a potential collision with the table or X-ray system.
    - The covers cannot achieve this position because the patient is not centered laterally on the table and one cover is fully extended.

Navigation Procedure Tasks

1. Place the patient on the table as described in

2. ***Recommended Patient*** Loading Procedure.
3. Prepare the patient per hospital procedure and apply a sterile drape over the tableside user interface.

4. Insert the magnetic catheter or guidewire and advance it to the desired anatomy. The user can advance the device manually or with the *Cardiodrive* System (for approved catheters).
5. Place the X-ray system in the AP, head-side position.
6. Select one of the **Navigate** buttons on the UTSC. Then press and hold the **Move** button to move the magnets to the Navigate or Navigate AP position.
7. Perform the procedure.
8. When the procedure is complete, move the magnets to the Stowed position by pressing the **Stow** button on the UTSC. After which, press and hold the **Move** button until the message ***Magnets in Stowed Position*** displays.

Note: The system was designed with a safety feature that requires pressing the Navigate button multiple times to give the user an opportunity to double-check patient positioning and safety before moving the magnets.

Note: If the system is unable to reach Navigate position due to a possible collision with the X-ray system or table, a Navigate Position Assistance dialog will display indicating which system components are at risk for a collision.

When the magnetic field direction is defined with the use of any single plane X-ray system, similar to the one employed with the *GenesisX RMN*, the views are acquired simultaneously. However, when two X-ray views are employed, the views are not acquired simultaneously.

As a result, the overlay on the X-ray views is an approximate representation of the magnetic field direction relative to the heart's location. This is because the two X-ray views may have been acquired at different phases in the patient's respiratory and cardiac cycle.

When changes are made to the magnetic orientation of the device tip, confirm the orientation of the device tip with localization methods such as fluoroscopy and electrograms (if using a catheter). If the device tip is not at the desired orientation, update the magnetic field direction and repeat the magnetic navigation procedure if desired.

CAUTION: The *GenesisX RMN* uses a magnetic field to orient the tip of the catheter to the desired intracardiac orientation.

Navigate Position Assistance

The position of equipment (e.g., the table and X-ray arm) in the Procedure Room may interfere with magnet movement. If the system detects a collision risk while the magnets are moving, a Navigate Position Assistance dialog will be displayed. Warning messages associated with the collision risks will be displayed in the dialog. These messages show the system component in red that needs to be adjusted. In the case of a cover sensor activation, either of the magnetic pods will be shown in red (**Figure 13**). After the appropriate adjustment is made to resolve the

collision risk, the associated component will be shown in gray. In some cases, adjustments of multiple components may be required to resolve the collision.

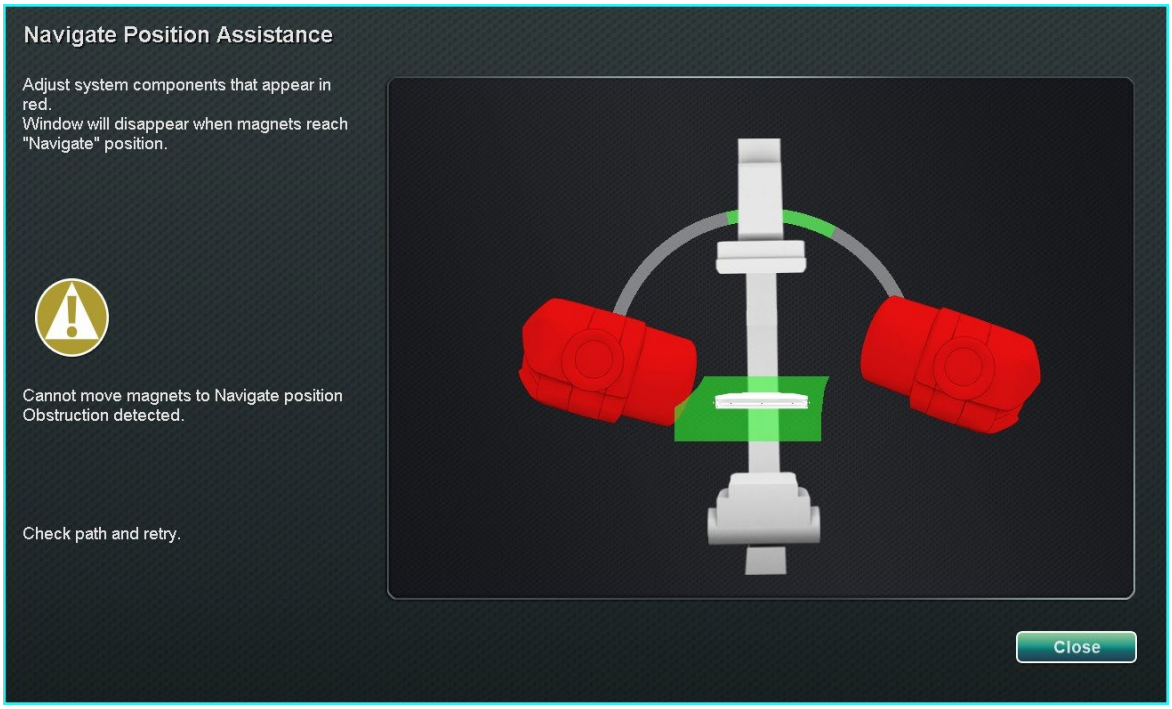


Figure 13. Magnet collision risk message

Once the collision risk has been eliminated, press and hold the **Navigate** button on the UTSC. The dialog automatically disappears after reaching Navigate position. The user is now able to proceed. If it is determined that there are no collision risks, the user may press the **Close** button to remove the dialog.

The green zones in the Navigate Position Assistance dialogs represent regions where the C-Arm or table should be positioned to eliminate the collision risks. In **Figure 14**, the C-Arm is shown in red and needs to be adjusted until it reaches the green zone. Until the C-Arm collision risk is eliminated, the magnets will not move.

In **Figure 15**, the C-Arm has been adjusted into the green zone and is shown in gray. The user may now proceed as there is no collision risk.

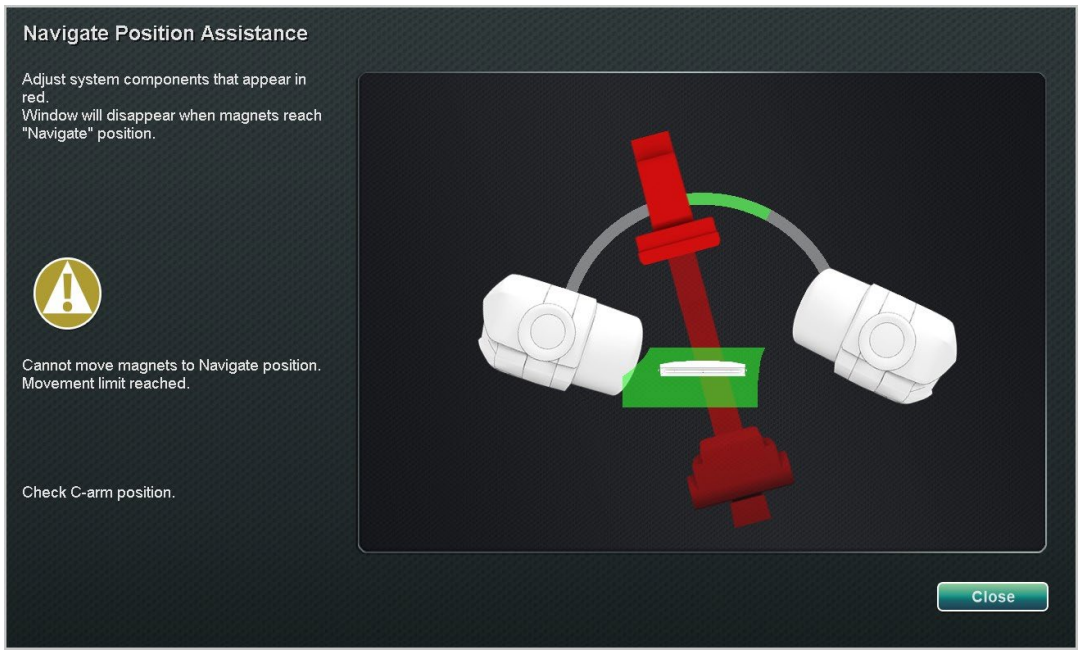


Figure 14. C-Arm collision risk message

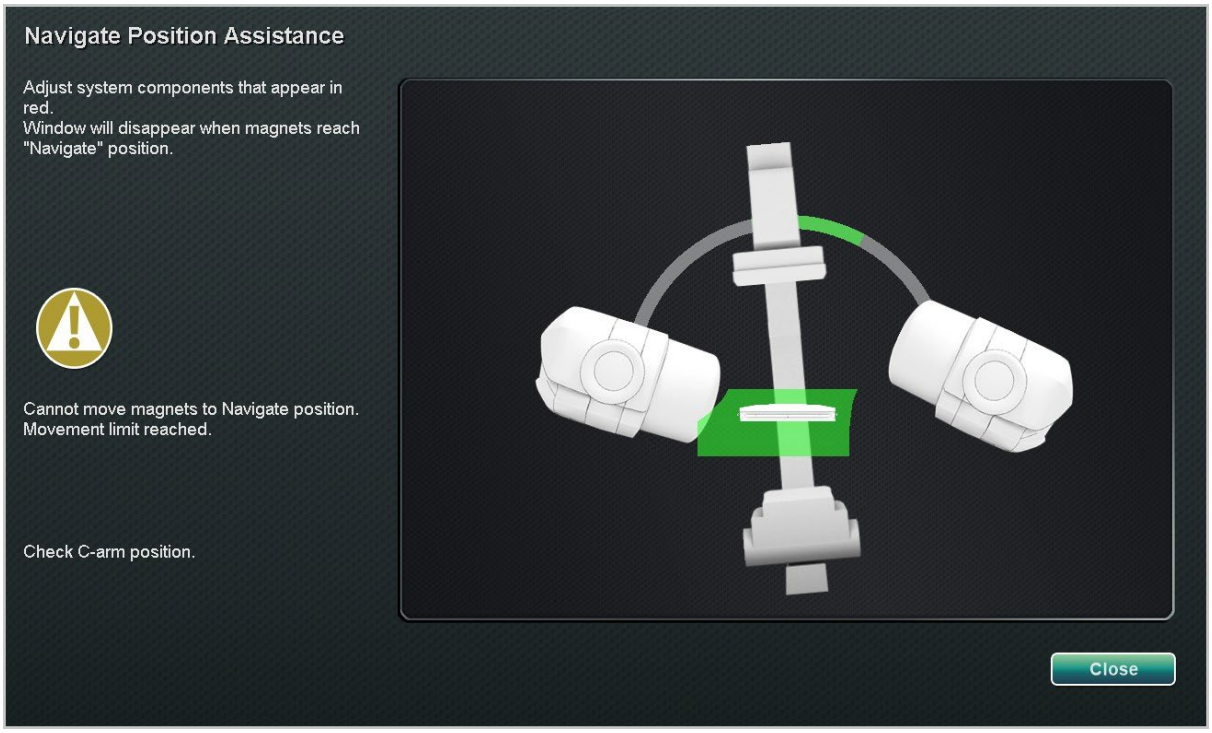


Figure 15. C-Arm graphic after C-Arm has been adjusted

In **Figure 16**, the table is shown in red. Before proceeding, adjust the table laterally until it is in the green zone and displays as gray. Once the table is shown in gray, it is safe to proceed as the collision risk has been eliminated.

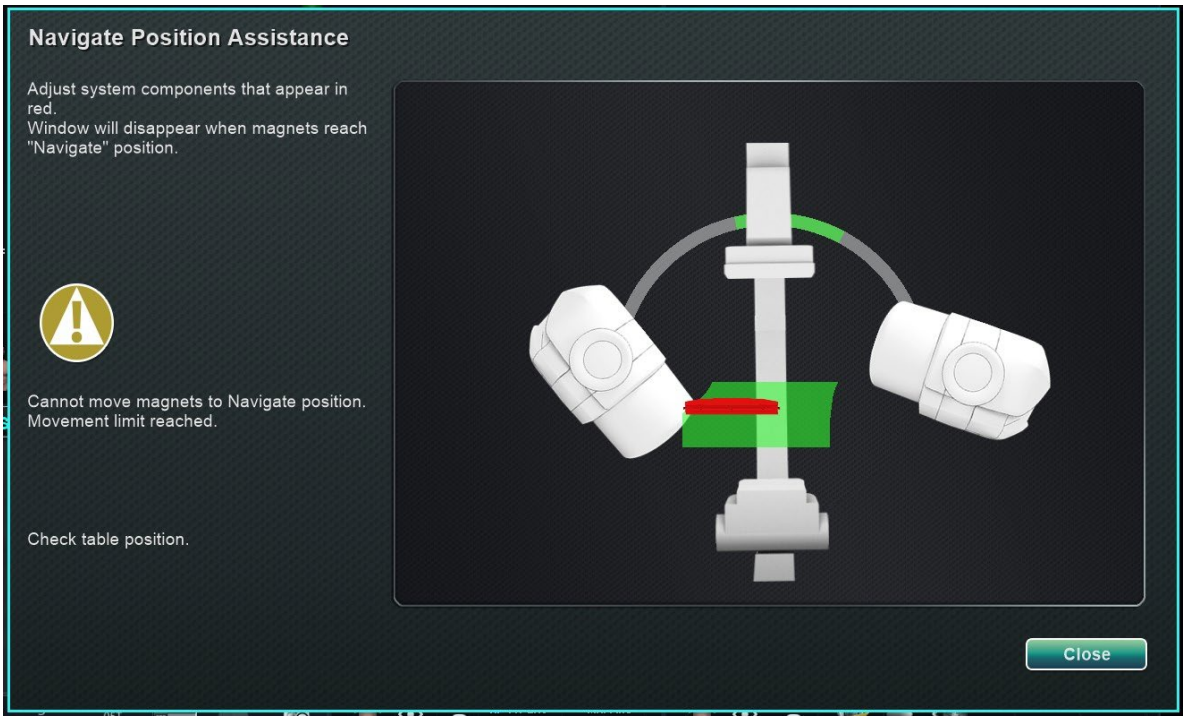


Figure 16. Table collision risk message

Cleaning Instructions

Cleaning the lab

Because the magnetic field in a Stereotaxis lab is always on, caution must be taken while cleaning the lab. MRI-compatible cleaning equipment is recommended, such as mops and brooms without ferrous material in their construction.

To clean the floor under the *GenesisX RMN* pivot the system between the Stowed and Navigate positions using the UTSC.

Cleaning the *GenesisX* System

The *GenesisX* System can be wiped clean between cases. The cleaning solutions used should be a pH neutral hospital-grade, EPA-registered germicidal solution (e.g., Super Sani-Cloth® Germicidal Disposable Wipe).

Drapes can be purchased to cover the *GenesisX RMN* and maintain a sterile field on the front of the pods to keep them clean throughout the procedure. Account Managers can assist in purchasing drapes as needed.

3. Emergency Operations

Emergency Patient Retraction

To move the magnets out of the way for an emergency patient retraction, press the **Stowed Position** button on the UTSC and press and hold the **Move** button. The user can release the **Move** button whenever the magnets are sufficiently out of the way.

Overriding Magnet Interlocks

System software interlocks prevent the magnet from moving into and colliding with the X-ray system components. The user can override this interlock and move the magnets by simultaneously pressing the **Stow Position** button on the UTSC and pressing and holding the **Move** button. While the **Move** button is held, the magnets are moving and the UTSC will display the message seen in **Figure 17.**

Figure 17. Interlock Override UTSC Message

WARNING: When using the interlock override, visually ensure magnet and X-ray system components will not physically collide. Closely monitor the magnet movement and be ready to release the **Move** button if a collision is imminent. Failure to heed these warnings may cause damage to equipment.

Removing Item Stuck to Magnet

If all safety precautions are followed, ferrous items should never be near the magnet. An incident of something being attracted to and becoming stuck to a magnet should never occur.

However, if an item does become stuck to a magnet, please review the following before attempting removal.

1. The permanent magnets are always "on" and cannot be turned "off."
2. The larger the mass of the item stuck to the magnet, the harder it will be to remove.
3. Use work gloves or other protective equipment around hands to prevent injury (e.g., skinned or scraped knuckles) when removing large items from a magnet.
4. The magnetic forces are strongest at the front (flat) face of the magnet.
5. The force decays rapidly with increased distance from the front face of the magnet.
6. If the item is sharp, consider potential damage to oneself or others if the user or the item slips, or is re-attracted to the magnet during removal.
7. The general strategy should be to **slide** the item (on the surface of the cosmetic cover) away from the front face of the magnet, and then **quickly and firmly** pull the item away **without hesitation**.
8. Sliding an item toward an outside corner of the cosmetic cover before making the "pull off" attempt over the edge of the cover is most effective.
9. Be aware that the forces around the magnet change. If an item becomes stuck to the magnet and one attempts to move the magnet from the Navigate to the Retracted or Stowed position, the field will change, and the item could fall on its own (or become stuck even firmer).
10. **DO NOT** remove cosmetic magnet covers in an attempt to remove a stuck item. If contacted, the magnet (which the covers protect) could be irreversibly damaged.
11. Contact Stereotaxis TST for assistance if unable to easily, or safely remove an item stuck to a magnet.

4. Troubleshooting

When troubleshooting, the following documents may be referenced:

- HDW-0391 GenesisX Preventive Maintenance and Service Guide
- HDW-0398 GenesisX Education and Magnet Safety Manual
- HDW-0399 GenesisX Automatic Positioner Centering
- HDW-0400 Quick Reference for GenesisX
- HDW-0397 Troubleshooting Guide for GenesisX with Model S

In the event a Positioner becomes inoperable, the Bypass button can be pressed to return the Positioner to the Stowed location. The Bypass button can be accessed via the access door shown in the figure below.

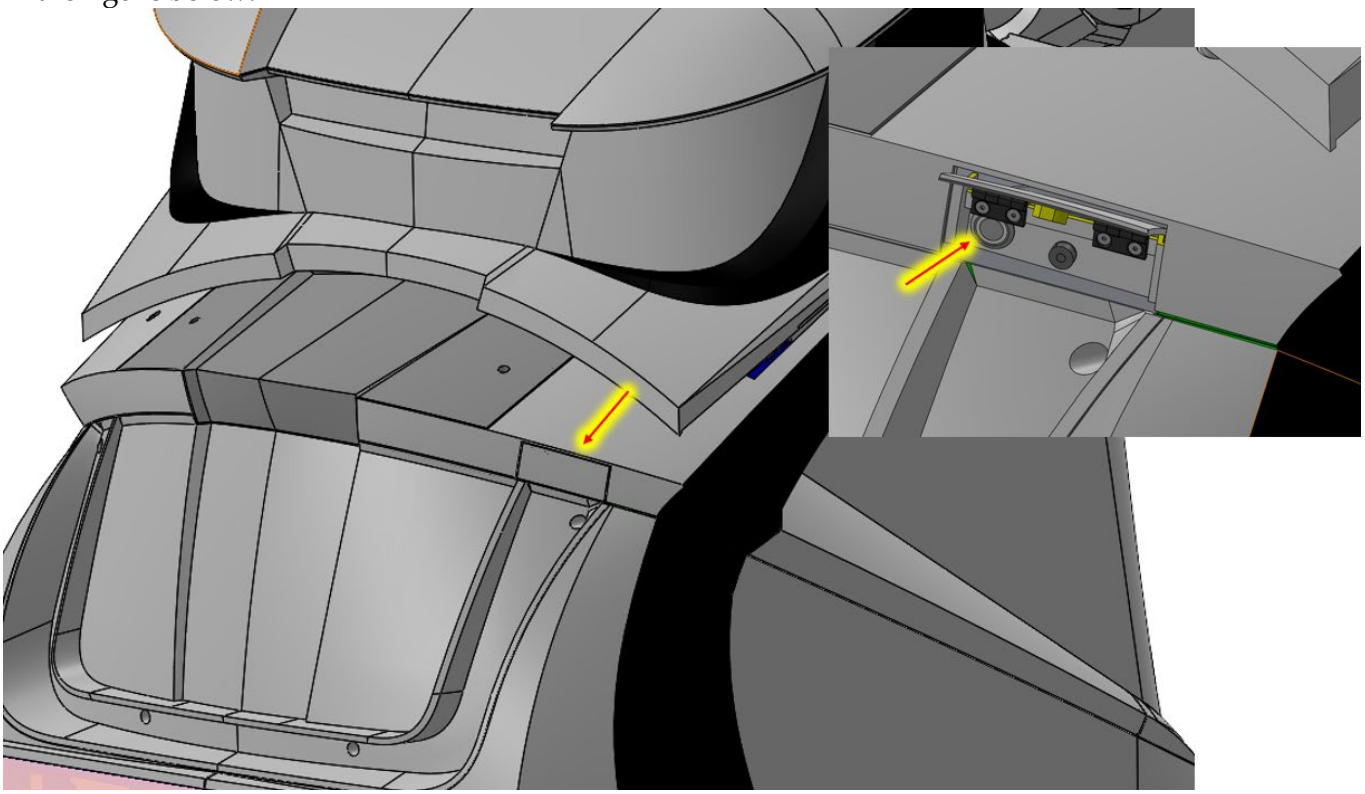


Figure 18. Bypass Button for Positioner

If further assistance is needed, call the **TeleRobotic Support Team (TST)** at 1-314-678-6200 or 1-866-269-5268.

Index