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NIOBE®

User Guide

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Patents

Niobe
Manufactured under one or more of the following United States patents:
6,975,197; 7,019,610; 7,161,453; 7,305,263; 7,313,429; 7,495,537; 7,772,950; 7,966,059
Manufactured under the following European patent:
EP 1 488 431 issued in Germany, France, and the United Kingdom

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 the United Kingdom; EP 1 769 390, issued in Germany, France, and the United Kingdom

Other patents issued and pending.

Trademarks

- *Niobe*, *Navigant*, *Vdrive*, and *Cardiodrive* 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, e-Contact, and Vdrive Duo* are trademarks of Stereotaxis, Inc.

Other Trademarks

- *CARTO* 3, SmartAblate, *Navistar*, *Thermocool*, *Celsius*, and *Celsius Thermocool* are registered trademarks of Biosense Webster.
- *AcQMap* is a registered trademark of Acutus Medical.

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 60601-1-2:2007 EN55011, FCC Part 15.109(g), FCC Part 15.107(a) & ICES-003, EN61000-3-2:2006 +A1:2009 +A2:2009, EN61000-3-3:2013
Immunity:	EN 60601-1-2:2015, EN61000-4-2:2009, EN61000-4-3:2006 +A1:2008 +A2:2010, EN61000-4-4:2012, EN61000-4-5:2006, EN61000-4-6:2009, EN61000-4-8:2010, EN61000-4-11:2004

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. The *Niobe* ES 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	ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 CAN/CSA-C22.2 No. 60601-1:14

Related documents 

HDW-0120 *Niobe* ES and *Niobe* II MNS Preventive Maintenance Manual
HDW-0137 *Niobe* Magnetic Navigation System Maintenance and Service Manual
HDW-0228 *Niobe* ES Magnetic Alignment Procedure

HDW-0181 *Niobe* Troubleshooting Guide
HDW-0182 *Niobe* Troubleshooting Guide for Philips
HDW-0061 *Niobe* ES MNS Education and Magnet Safety Manual
HDW-0331 *Niobe* ES *e-Contact* Module User Instructions[1]
DSP-0210 *Niobe* Cover Drape IFU
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

Niobe II, Reference number 001-006000-1

Niobe II, Philips Reference number 001-006100-1

Niobe ES, Model S Reference number 001-006200-1

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:

Voltage rating:	400 V 3N~
Current rating:	20.0 A
Frequency:	50 / 60 Hz

The hospital will provide a disconnect device that removes all power to the *Niobe* ES system when activated.

Operator-accessible disconnect device

In accordance with NEC article 517-72(b), the equipment circuit breaker(s) must be located in a readily operable manner from within the equipment control area. If this is impossible or impractical, a shunt trip circuit breaker with an emergency off push button mounted in the Control Room is acceptable to meet operability requirements.

[1] e-Contact™ Module is only available with *Niobe* Systems in the EU.

Pressing the Control Room Emergency Stop button removes power from the Stereotaxis equipment and activates the Siemens X-ray E-stop.

Note: The hospital facility is responsible for installation of this disconnect device.

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 *Niobe* MNS System.
Suggested Contractor: Walch Recycling & Eldelmentalle

Accessories

Accessory	Part Number
Cardiodrive	001-004115-X
Vdrive	001-002307-1
Vdrive Duo	001-002307-2

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.

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

Cover art

Contents

1. Overview

Introduction

The Stereotaxis Niobe® ES magnetic navigation system (MNS) is a medical platform designed for electrophysiological and interventional procedures. *Niobe* ES MNS facilitates the control of the distal tip of compatible magnetic devices via magnetic fields.

About This User Guide

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

- *Niobe* II, Reference number 001-006000-1
- *Niobe* II, Philips Reference number 001-006100-1
- *Niobe* ES, Model S Reference number 001-006200-1

Companion Systems

The *Niobe* ES system may be used with the following magnetically-compatible devices:

- Biosense Webster Navistar® RMT
- Biosense Webster *Navistar* RMT Thermocool®
- Biosense Webster Celsius® RMT
- Biosense Webster *Celsius* RMT *Thermocool*
- Stereotaxis Helios II
- Pegasus family of magnetic guidewires
- PowerAssert magnetic guidewires

The *Niobe* ES system communicates with:

- Biosense Webster Stockert 70 RF Generator
- Biosense Webster SmartAblate RF Generator

The *Niobe* ES system communicates with a variety of digital fluoroscopy systems:

- Siemens AXIOM™ Artis™ dFC MN
- Siemens *AXIOM Artis* dBC MN
- Siemens *Artis* zee™ Floor MN
- Siemens *Artis zee* Biplane MN

- Philips Allura® Xper FD10C
- Stereotaxis Imaging Model S (powered by Omega Imaging)
- Neusoft F-Model DSA

The *Niobe* ES integrates with a 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 high magnetic field environment produced by the MNS.

The *Niobe* ES system communicates with the Stereotaxis Cardiodrive® system found in the laboratory where the *Niobe* ES system is installed.

The *Niobe* ES and the Biosense Webster CARTO® 3 systems communicate to allow integrated mapping and navigation. The OpenMapping API feature allows communication between the *Niobe* ES system and mapping systems that have been tested to be compatible such as the Acutus AcQMap® High Resolution Imaging and Mapping System.

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

Indications

In Canada, the following Indications are applicable for the *Niobe* ES and *Cardiodrive* systems.

- The *Niobe* ES system is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature and peripheral vasculature by orienting the device tip in a desired direction.
- The Stereotaxis *Cardiodrive* automated catheter advancement system (CAS) is intended for automatically advancing and retracting 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 EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

In the United States, the following Indications are applicable for the *Niobe* ES and *Cardiodrive* systems.

- The *Niobe* System is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature, neurovascular and peripheral vasculature by orienting the device tip in a desired direction.
- The *Cardiodrive* Catheter Advancement System (CAS) 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 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 *Niobe* ES and *Cardiodrive* systems.

- The *Niobe* ES 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* automated catheter advancement system (CAS) 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 MNS.

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 neurovasculature.

Intended Users

The *Niobe* MNS 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

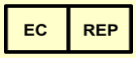
The following graphics and symbols are used in this User Guide:

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 later in this 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 the *Niobe* ES components:

Symbol	Name	Description
	**AC Power**	Indicates the status of the AC power.
REF	**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.

Symbol	Name	Description
	**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.
	**Date of Manufacture**	The date when the medical device was manufactured.
	**E-stop**	Indicates the E-stop button or the E-stop indicator light.
	**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.

Symbol	Name	Description
	**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.
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	Anterior-Posterior.
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).
***CARTO* 3 system**	Biosense Webster system that combines 3D mapping and navigation systems with the Stereotaxis *Niobe* magnetic navigation system.
CAS	*Cardiodrive* catheter advancement system. (*See Cardiodrive* system.)

Term	Description
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.
Fully retracted	Magnet positioners are pivoted toward the patient but 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 magnetic navigation system Procedure Room. The amounts of 5 G and lower are considered safe levels of static magnetic field exposure for the general public. (Named for Johann Carl Friedrich Gauss.)
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.
LAO	Left Anterior Oblique.
MNS	Magnetic navigation system. (See *Niobe* MNS.)
***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 MNS, where the MNS is capable of generating any magnetic field direction at the target magnetic field strength provided by the MNS.
***Niobe* MNS**	A Stereotaxis system consisting of computer-controlled magnets that assist physicians in orienting and steering compatible, magnetically-adapted devices. (The *Niobe* system is available only in magnetic labs.)
***Niobe* 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 *Niobe* System consists of the *Niobe* MNS, *Navigant*, and *Cardiodrive* systems and is available only in magnetic labs.

Term	Description
Pivoted	Magnet position between Navigate AP and Stowed; magnets are pointed away from the patient.
RAO	Right Anterior Oblique.
RF	Radiofrequency.
RMT	Remote magnetic technology. (RMT is often used to refer to the *CARTO* 3 EP navigation system and the integrated *CARTO* 3 / *Niobe* MNS environment).
Tableside Control	Touchscreen controller positioned on the side of the patient table in the Procedure Room.
Tesla (T)	The standard unit of magnetic flux density.

Safety

Warnings

Although the *Niobe* ES 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 *Niobe* ES system should be used only by qualified medical professionals who have been thoroughly trained in its use. The Stereotaxis *Cardiodrive* remote advancement 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 MNS 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 *Niobe* ES system 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 *Niobe* ES computers, other than those specifically called out in the product documentation.

WARNING: There are no user serviceable parts inside the *Niobe* ES magnets. The user should not remove any covers (other than the hand crank 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: The operator must not touch the Procedure Room monitor while also touching the patient.

WARNING: When the *Niobe* ES system displays a graphical representation of the catheter tip and shaft on the *Niobe* ES 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* Catheter Advancement System.

WARNING: The *Niobe* ES system does not track the location or orientation of the catheter. If being used in conjunction with an integrated mapping system, the location and orientation of the catheter tip may be displayed.

WARNING: The graphical representation of the catheter on the *Niobe* ES display 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 to the *Niobe* ES MNS 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: The magnetic navigation system should be used only with magnetic devices and accessories appropriately labeled as compatible with MNS navigation applications.

WARNING: Make sure the patient table pivot is in the central position (centered between the *Niobe* pods) before moving the *Niobe* 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: Advancement of a guidewire is controlled manually by the physician. Always verify guidewire motion using live fluoroscopy images. Stop immediately if resistance is encountered.

WARNING: EP navigation features are only available for use in the EP software. Please refer to HDW-0158 for features available for Interventional Neuroradiology.

WARNING: Do not attempt to use a magnetically compatible guidewire with the Cardiodrive system as the guidewire diameter is too small to engage the drive mechanism.

WARNING: The tip of magnetically compatible guidewires and microwires should only be advanced and manipulated under direct fluoroscopic observation.

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.

WARNING: If there is a cybersecurity breach during a procedure, press the Estop button to stop all device activities. Contact the TeleRobotic Support Team to report the suspicious activity prior to resumption of the procedure

Precautions

CAUTION: If a patient is to receive a permanent pacemaker or internal cardiac defibrillator (ICD) *de novo* in the MNS room, the *Niobe* ES 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, Pivoted, and Navigate positions. An audio signal sounds when magnets have completed their movement. (You may adjust the volume in the Settings → System tab.)

⚠ **CAUTION:** Do not enter the area between the X-ray system and magnet positioner when the magnets are in the Pivoted position or between Pivoted and Stowed.

⚠ **CAUTION:** Due to space constraints in the Procedure Room in the low magnetic field (less than 5 Gauss) area, remove one patient before bringing in another.

⚠ **CAUTION:** The *Niobe* ES MNS 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:

1. Re-register the mapping system to the *Navigant* platform.
2. Re-mark the catheter base.
3. Calibrate the *Cardiodrive* system.

⚠ **CAUTION:** While the magnet system is homing, varying magnetic fields will be applied in the vicinity of the magnets and the patient table.

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

⚠ **CAUTION (Siemens):** The *Niobe* and the Siemens X-ray systems have different emergency stop buttons. Pressing the *Niobe* E-stop will activate the X-ray E-stop (via

a hardware connection), causing the X-ray to stop. Pressing the X-ray system E-stop will cause the *Niobe* ES system to stop (via software).

⚠ **CAUTION (Philips):** With Philips, pressing the X-ray system E-stop will cause the *Niobe* ES system to stop.

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

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

⚠ **CAUTION:** Although the magnetic field is 0.08 to 0.1T (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 the flat front surface of the magnet covers can be as high as 0.7T.
- In the Navigate position, the field strength is less than 0.2T five inches (13 centimeters), or more, in front of the front surface of the magnet cover.
- In the Pivoted and Stowed positions, the field strength is less than 0.2T one inch (3 centimeters), or more, in front of the front surface of the magnet cover.
- Field strengths above, below, behind, and to the sides of the magnets are always less than those on the front surface.

⚠ **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.

Clinical Information

SUMMARY OF CLINICAL INFORMATION

Data from four clinical studies involving 511 patients who underwent catheter ablation using the Stereotaxis Magnetic Navigation System (MNS) are summarized. The Magnetic Navigation System includes the *Niobe* System, the *Navigant* software, the *Cardiodrive* catheter advancement system (CAS) and either the Stereotaxis Helios Ablation catheter, or the BWI *Navistar Thermocool* RMT ablation catheter. Collectively, the data in these studies demonstrates the safety and effectiveness of the Magnetic Navigation System for catheter ablation.

Study Design

All four studies were prospective in nature and included safety and efficacy endpoints. Data from all four studies were used to support regulatory approvals. Evaluation of 7 day major adverse

events for safety, and acute procedural success was measured in all studies. Three studies reported long-term (90 day) success.

Study Results

Acute procedural success was achieved in 473/498 (95.0%) of subjects who underwent catheter ablation using the Stereotaxis Magnetic Navigation System.

Long-term success (90-day success) was achieved in 278/288 (96.5%) of subjects who completed the predefined follow-up visit.

Adverse Events

The overall 7-day major complication rate for all four studies was 20/511 (3.9%) Major adverse complications that occurred within 7 days post procedure included:

- 1 cardiac tamponade related to right sided catheter
- 1 cardiac tamponade related to the transseptal puncture
- 1 new focal wall abnormality
- 1 change in LVEF (60% to 45-50%)
- 2 vena cava thrombi
- 1 groin complication
- 1 chest soreness
- 1 prolonged hospitalization for grogginess
- 1 pseudoaneurysm
- 1 bleeding
- 1 anemia
- 1 dementia
- 1 pericardial effusion
- 1 heart block requiring pacemaker
- 2 pulmonary embolisms
- 1 AV fistula
- 2 arrhythmia recurrence (per protocol requirement)

Conclusion

The data in this summary supports the reasonable assurance of safety and effectiveness of the Stereotaxis Magnetic Navigation System for cardiac ablation procedures.

Technical Details

The *Niobe* system generates a directional 0.08T or 0.1T magnetic field within the patient's heart. The navigation volume is 6 inches (15 centimeters) in diameter centered at X-ray isocenter.

Mechanical Performance Testing

Mechanical performance testing of the compatible catheters included anatomical and deflection target testing. Deflection testing included six separate deflection directions and was performed at five separate positions around the navigation volume. Acceptable performance was reaching anatomical targets and all deflection targets.

Deflection Testing Positions

Pos A - Isocenter
Pos B – Posterior 2 inches (5 centimeters) from A
Pos C – Inferior 2 inches (5 centimeters) from A
Pos D – Patient right 2.5 inches (6 centimeters) from A
Pos E – Patient left 2 inches (5 centimeters) from A

Catheter	Anatomic	Pos A	Pos B	Pos C	Pos D	Pos E
Navistar RMT	Success	Success	Success	Success	Success	Success
Navistar Thermocool RMT	Success	Success	Success	Success	Success	Success
Celsius RMT	Success	Success	Success	Success	Success	Success
Celsius Thermocool RMT	Success	Success	Success	Success	Success	Success
Helios II	Success	Success	Success	Success	Success	Success

Fluoroscopy Exposure

Patients and operators will be exposed to fluoroscopy during procedures performed with the *Niobe* ES system. 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.

Cybersecurity

Please note the following important information concerning cybersecurity:

- Cybersecurity controls operate in the background in the *Niobe* MNS with *Navigant* Workstation (NWS). No user actions are required to maintain the security of the system, but any suspected cybersecurity incidents should be reported the Stereotaxis Telerobotic Support Team (TST).
- Only trusted users should be allowed physical access to the *Niobe* 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 *Niobe*. Independent virus scanning is recommended before insertion or connection to the system.

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 *Niobe* MNS.

Images acquired during C-Arm or table movement cannot be transferred to *Niobe* MNS.

C-Arm collision with magnet considerations

When both are powered up, the MNS and the X-ray system are "aware" of each other and their current location. The user will neither be able to move the magnet 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 (Siemens): Siemens collision avoidance is disabled by design when not communicating to the *Niobe* ES system unless the system sees the *Niobe* ES magnet is in the Stowed position (via hardware signal). When collision avoidance is disabled, the C-Arm will only move very slowly, but it is possible to hit the magnets at this slow speed.

CAUTION (Model S): Model S collision avoidance is disabled by design when not communicating to the *Niobe* ES system unless the system sees the *Niobe* ES magnet is 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.

Note: What is referred to as the C-Arm in Siemen and Model S systems is referred to as the L-Arm in Philips systems. To eliminate confusion, this document will reference the device as ***C-Arm***.

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 *Niobe* ES system.

WARNING: The *Niobe* ES system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the *Niobe* ES system 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 includes the following information:

WARNING: This equipment has been tested for radiated radiofrequency (RF) immunity only at selected frequencies, and use of nearby emitters at other frequencies could result in improper operation.

Following are the frequencies and modulations used to test the Immunity of the ME Equipment or ME System:

- 52.5Mhz
- 144Mhz
- 433MHz
- 467Mhz
- 2.4GHz

Emissions

The *Niobe* ES system is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the *Niobe* ES system should ensure that it is used in such an environment.

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *emissions*** for the *Niobe* ES system:

Emissions	Compliance	Electromagnetic environment—guidance
EN55011 FCC Part 15.109(g) FCC Part 15.107 (a) ICES-003	Group 1	The *Niobe* ES 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.

Emissions	Compliance	Electromagnetic environment—guidance
EN55011 FCC Part 15.109(g) FCC Part 15.107 (a) ICES-003	Class A Complies	
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Immunity—General electromagnetic effects

The following table provides guidance and Stereotaxis' declaration on **electromagnetic *immunity*** regarding general electromagnetic effects for the *Niobe* ES system:

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
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	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 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 *Niobe* ES system requires continued operation during power mains interruptions, it is recommended that the *Niobe* ES 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 *Niobe* ES system:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 mHz to 2.7 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *Niobe* ES system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance*** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol : 

Note 1: At 80 MHz and 800 MHz, 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.

a 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 *Niobe* ES system is used exceeds the applicable RF compliance level above, the *Niobe* ES system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Niobe* ES system.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation distances

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *Niobe* ES system, including cables specified by Stereotaxis, Inc.

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

The table provides **recommended separation distances** between portable and mobile RF communications equipment and the *Niobe* ES 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 $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
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 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.

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 *Niobe* system, please contact Stereotaxis Service. Otherwise, there are no specific service requirements to maintain *Niobe* ES EMC integrity.

2. Basic Information

Niobe System Magnet Information

The arrangement of the magnetic Procedure Room is fairly standard among institutions. The major difference is the X-ray system present. **Figure 1** describes the main Procedure Room components without the X-ray system.

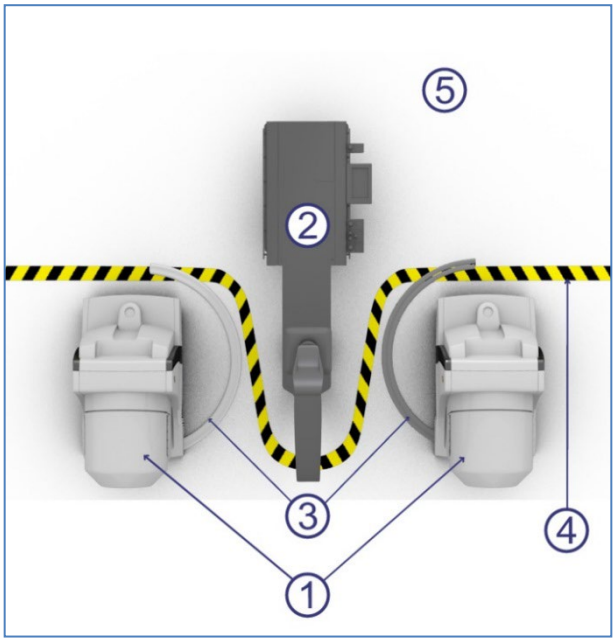


Figure 1. Drawing of Procedure Room components

Procedure Room component guide (Figure 1)

① ***Niobe* system magnet positioners.** Also called pods, the magnet positioners contain the *Niobe* system magnets.

② **Patient table.**

③ ***Niobe* system magnet positioner floor tracks.** The floor tracks support the magnet positioners as they swing in and out.

④ **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.

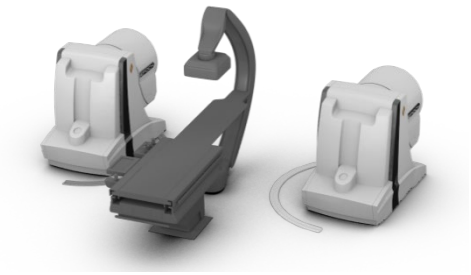
⑤ **Five Gauss zone.** The zone that is less than 5 G (the table side of the room) within which individuals should remain when magnets are stowed.

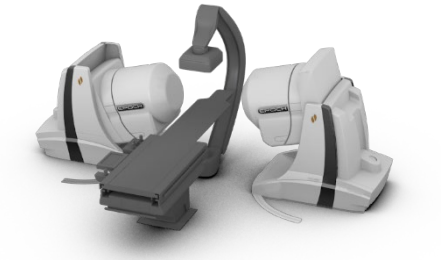
Niobe System Magnet Positions

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, Navigate AP, Navigate RAO, or Navigate LAO. The magnets are moved by pressing buttons on the Tableside Controller. The following table and **Figure 2** through **Figure 6** describe each of the positions and list when the various positions are used in a procedure.

Position	Position description	When position is used
Stowed	 **Figure 2. 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
Pivoted	 **Figure 3. Magnets in Pivoted position**	• When greater patient access is needed • To allow increased imaging angle flexibility
Retracted	Magnets are pointed toward patient, but cover-to-cover distance is larger than what is necessary to enable magnetic navigation. Whenever magnets are retracted the maximum distance from patient, the system is considered to be in fully Retracted position.	• 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

Position	Position description	When position is used
Navigate AP	 **Figure 4. Magnets in Navigate AP**	During magnetic navigation procedure with C-Arm angulation centered with respect to patient
Navigate RAO	 **Figure 5. Magnets in Navigate RAO**	During magnetic navigation procedure with C-Arm angulation on right side of patient
Navigate LAO	 **Figure 6. Magnets in Navigate LAO**	During magnetic navigation procedure with C-Arm angulation on left side of patient

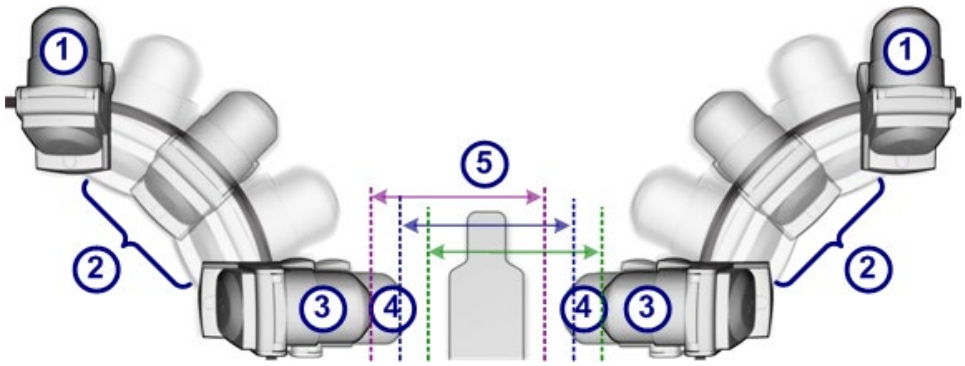


Figure 7. Magnet position options

Magnet positions guide (Figure 7 — Figure 9)

① **Stowed**

② **Pivoted**

③ **Fully retracted**

④ **Fully extended**

⑤ **Cover-to-cover distance**
Magnetic field strength determines the cover-to-cover distance. A force of 0.1 Tesla requires a distance of 23.5 inches (60 centimeters), while 0.08 T requires 26.5 inches (67 centimeters). The offset is variable: If the table is not centered and one cover comes too close to the table, the cover will automatically retract and the opposite cover will extend to maintain the same cover-to-cover distance.

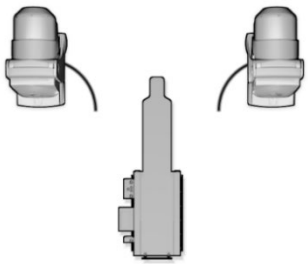


Figure 8. Stowed positions

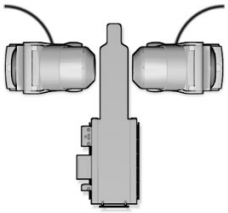


Figure 9. Navigate positions

When changing the Navigate position, the magnets are first moved to the Retracted position prior to tilting.

Note: The magnets can be tilted **only** when the *Niobe* MNS is not in navigation mode.

The magnets move in close proximity to the patient table and the imaging system C-Arm.

The user may move the patient table off center to optimize visualization of the desired anatomy for magnetic navigation. When the **Navigate AP**, **RAO**, or **LAO** button is pressed on the Tableside Controller, the magnets will automatically calculate the table position and the cover-to-cover distance required. The user may also manually move each magnet independently to accommodate the change in table position. For example, if the right magnet is moved away from the patient, the left magnet needs to be moved toward the patient until the message ***Magnets in Navigate Position*** is displayed on the *Niobe* ES screen.

The cover positions for each of the last achieved positions (Navigate AP, Navigate RAO, and Navigate LAO) are stored by the system. Subsequent moves of the magnets to one of these positions will result in their movement to the stored position. The stored positions will be adjusted if the table is moved, or a new procedure is started.

The approximate time the magnet takes to move between any two positions is listed below. Up to an additional 5 seconds variation may occur in movements from the Navigate position depending on the magnet position inside the covers:

- Stowed to/from Retracted: 15 seconds
- Retracted to/from Navigate: 5 seconds
- Stowed to/from Navigate: 20 seconds
- Navigate RAO or LAO to/from Retracted: 7 seconds

Figure 10. Pinch hazard areas (red shading)

Notes:

- To prevent collision, all accessories and cables should be clear of magnet movement.
- Magnets pivot on tracks that are mounted in the floor. User should exercise caution when working in the floor track area due to risk of stumbling.
- User should note areas labeled for potential pinch hazard as shown in **Figure 10**.

CAUTION: Do **not** use the Tableside Controller to move magnets when hand crank cover is off. See ***Moving Magnets Manually*** for manual hand crank operation.

Tableside Magnet Controller

The Tableside Magnet Controller allows the user to physically move the magnets and controls various other system functions.

Note: Keep accessories clear of the magnet movement zone to prevent collision with magnets.

In the Procedure Room, the *Niobe* ES magnets are controlled using the Tableside Controller. The configuration of the Controller varies based on the X-ray and *Niobe* ES systems (**Figure 11**).

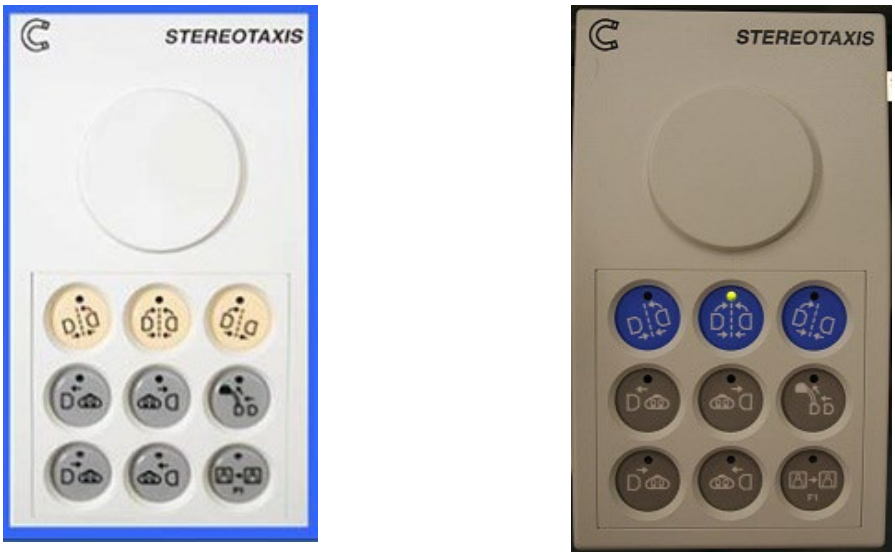


Figure 11. Tableside Controllers: Philips and Model S (left); Siemens and Neusoft (right)

Niobe ES Tableside Controller buttons

Niobe ES buttons are dark yellow and light gray for the Philips and Model S X-ray systems, and blue and gray for the Siemens X-ray system. The button images (in Philips/Model S colors) are displayed in **Figure 12.**

Panel	Buttons and names		
	 Navigate RAO	 Navigate AP (Also used for homing)	 Navigate LAO

Panel	Buttons and names		
	 Retract – Patient right side*	 Retract – Patient left side*	 Stowed
	 Advance – Patient right side*	 Advance – Patient left side*	 Image transfer (Also used for override moves)

Figure 12. Niobe ES Tableside Controller buttons and descriptions

*** Applies to patients in head-first supine position**.

To perform a move in override mode, press and hold the **Image Transfer** button, and then press the button of the desired movement. During an emergency or other exceptional situation, Override mode enables the user to override the safety precaution restraints on individual controller buttons. For example, the mode enables the user to immediately stow the magnets regardless of the X-ray C-Arm and table position.

WARNING: Use of the Override feature may result in a *Niobe* magnet collision with the C-Arm or table.

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

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. Clear and clean the magnet positioner floor tracks.
4. 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 13.**).

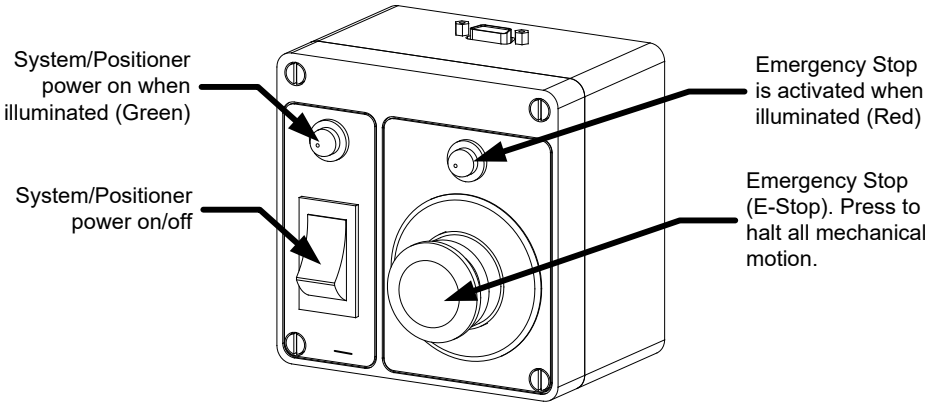


Figure 13. Power Box in Control Room

5. Home the system by pressing and holding the **Navigate AP** button on the Tableside Controller. Hold the button until the message ***Homing Complete*** displays in the bottom-left corner of the *Niobe* ES screen. Homing takes up to 60 seconds.
6. Retract magnet positioners back to Stowed position by pressing the **Stow** button on the Tableside Controller to aid in patient loading.

Note: In case of a voltage interruption, the *Niobe* ES system may shut down, necessitating a system restart.

Note: Tableside Controller button colors differ according to the X-ray system in use. Philips and Model S systems have dark yellow and gray buttons while Siemens and Neusoft systems have blue and gray buttons.

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. Individuals should stay on the table side of the 5 Gauss line when the magnets are stowed.

WARNING: The *Niobe* ES system 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.

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 HDW-0372 *Navigant* User Guide for 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 14**) except when performing a femoral or tibial procedure. For femoral and tibial cases, the patient should be feet-first supine (**Figure 15**).

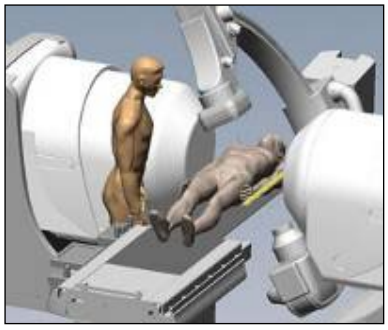


Figure 14. Head-first supine position

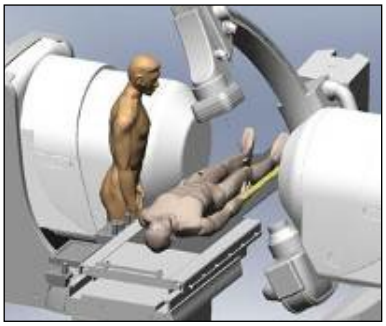


Figure 15. Feet-first supine position

Positioning Patient Guide (Figure 14 and Figure 15)

The patient is loaded feet first for femoral and tibial cases; however, the user must **register the patient "head-first, supine"** for some **Philips** and **Siemens X-ray systems** to ensure proper image transfer. Refer to the X-ray system user guide for instructions regarding feet-first cases.

1. Place the patient on the table in a supine position.
2. Center the patient on the tabletop laterally. Aligning the patient too far off center can interfere with successful automatic positioning of the *Niobe* magnet covers.
3. Secure the patient's legs.
4. Secure the patient's arms. Ensure no part of the arms is below the tabletop to avoid pinching when the magnet positioners move toward the table.
5. Make sure no excess table padding protrudes outside the edge of the tabletop.

Cover-Force Sensor

The magnet covers contain cover-force sensors that detect when the face of the cover is pressing against the patient. 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 movement button. The *Niobe* ES system automatically retracts the individual cover that is contacting the patient slightly and advances the opposite cover to continue movement to the Navigate position.

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 *Niobe* ES system adjusts the Navigate position center based on this new location and displays the following status message: ***Magnets in Navigate Position.***

Automatic positioner centering

The *Niobe* ES system 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 the Tableside Controller and fluoroscope, center the patient relative to the X-ray isocenter.
2. Press one of the **Navigate** buttons on the *Niobe* controller and hold it down. The *Niobe* ES system calculates the target position, including an offset based on the lateral and vertical 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 *Niobe* ES 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:
    - The operator did not hold down the **Navigate** button until the system reached the Navigate Position. In this case, the operator may continue to the Navigate Position by pressing and holding one of the **Navigate** buttons on the Tableside Controller.
    - Both cover-force sensors have activated. The *Niobe* ES 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 cover cannot achieve the position because of a potential collision with the table or X-ray system**.**
- The cover cannot achieve the 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 ***Recommended Patient Loading Procedure***.
2. Prepare the patient per hospital procedure and apply a sterile drape over the tableside user interface.
3. Insert the magnetic catheter or guidewire and advance it to the desired anatomy. You can advance the device manually or with the *Cardiodrive* system (for approved catheters).
4. Place the X-ray system in the AP, head-side position.
5. Press one of the **Navigate** buttons on the Tableside Controller. Release the button and press it again to move the magnets to the Navigate or Navigate AP position.
6. Perform the procedure.
7. When the procedure is complete, move the magnets to the Stowed position by pressing the **Stow** button on the Tableside Controller. Hold the button until the message ***Magnets in Stowed Position*** displays in the bottom-left corner of the window.

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 MNS, 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 *Niobe* ES system 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 16**). 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.

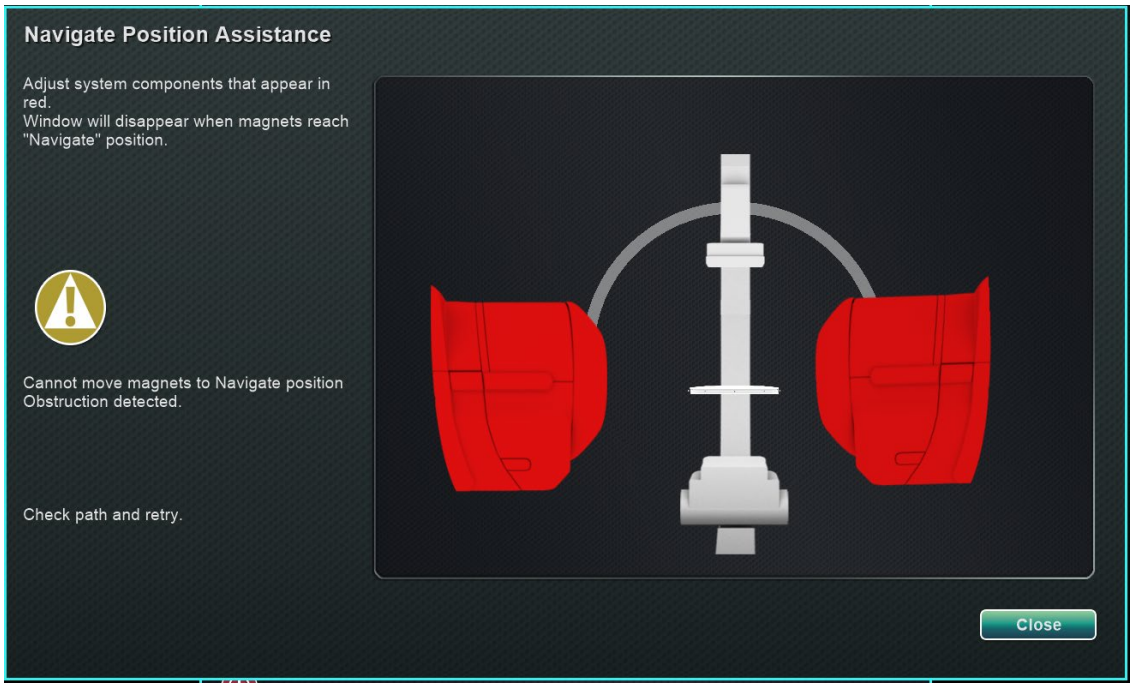


Figure 16. Magnet collision risk message

Once the collision risk has been eliminated, press and hold the **Navigate** button on the Tableside Controller. 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 17**, 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 18**, 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.

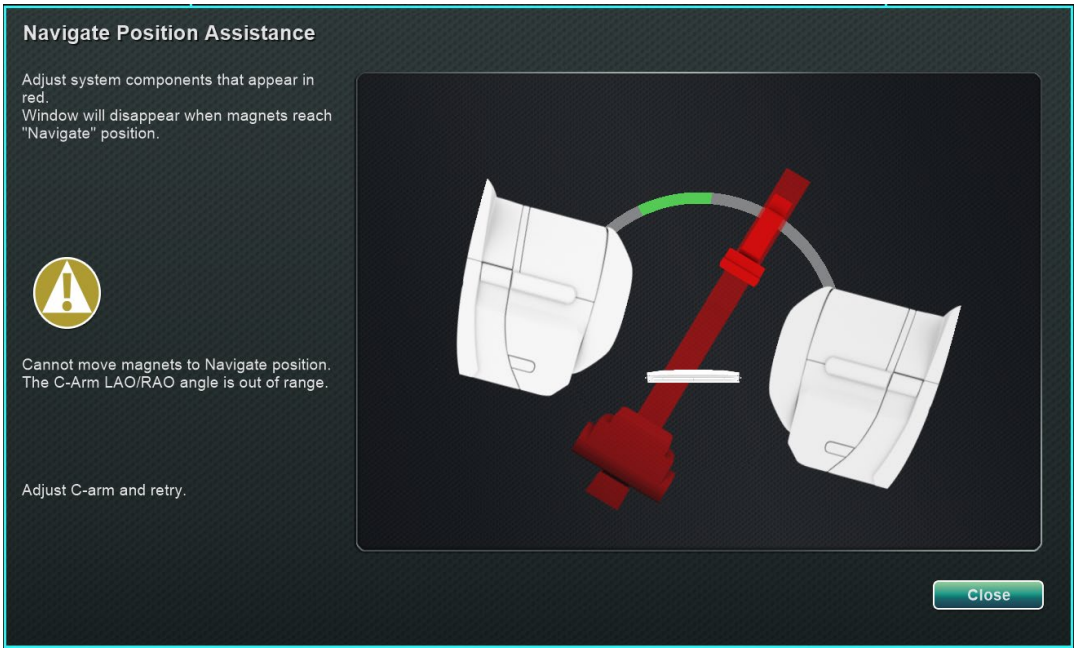


Figure 17. C-Arm collision risk message

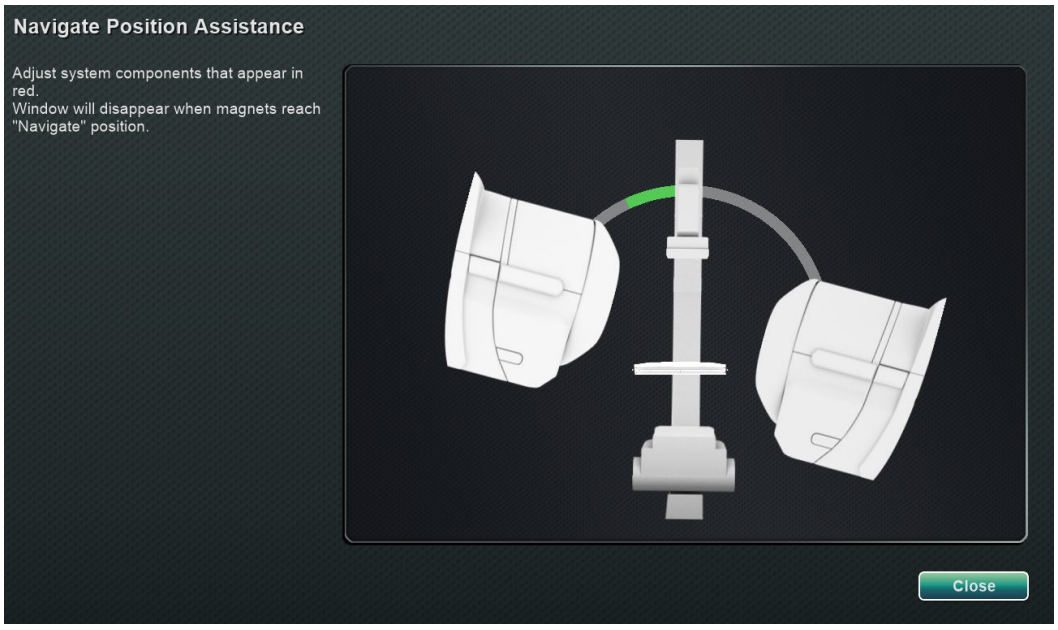


Figure 18. C-Arm graphic after C-Arm has been adjusted

In **Figure 19**, 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.

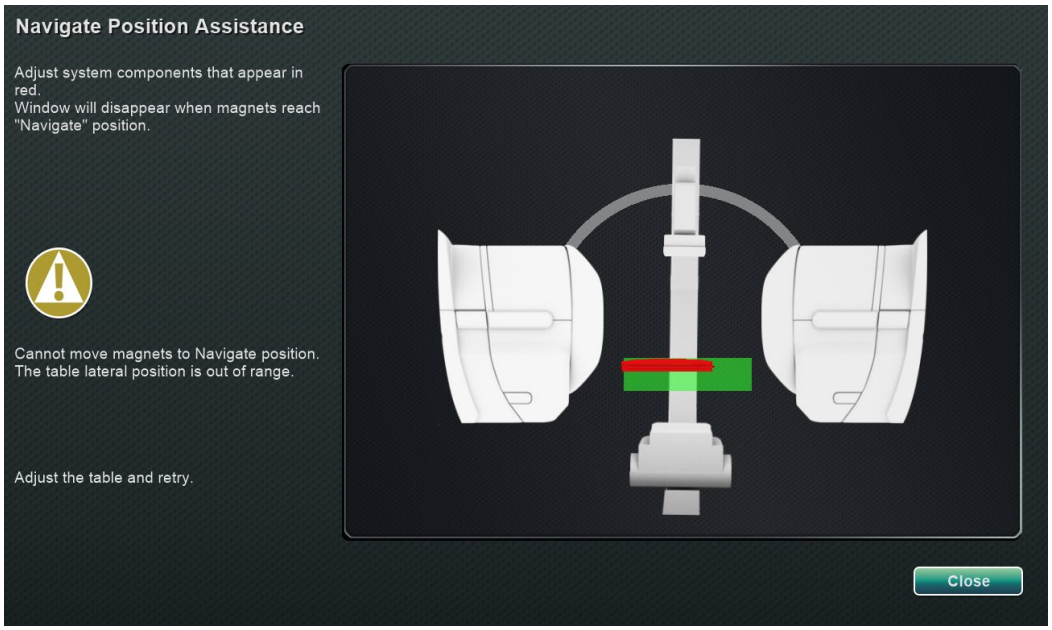


Figure 19. Table collision risk message

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 *Niobe* system, pivot the system between the Stowed and Navigate positions with the Tableside Controller.

Cleaning the *Niobe* system

The *Niobe* system can be wiped clean between each case. The cleaning solutions used should be a pH neutral hospital-grade, EPA-registered germicidal solution (e.g., CIDEX® Activated Dialdehyde).

Niobe ES system drapes can be purchased to cover the magnetic navigation system and maintain a sterile field on the front of the pods to keep them clean throughout the procedure. Please contact your Account Manager to purchase *Niobe* drapes as needed.

3. Emergency Operations

Emergency Patient Retraction

To move the magnets out of the way for an emergency patient retraction, press the **Stow** button on the Tableside Control. Note that the magnets do not have to swing to the full 90° and lock in the Stowed position. The user can release the button whenever the magnets are sufficiently out of the way. If a power or other failure occurs that keeps the magnets from moving, see **Figure 21** for manual movement of the magnets.

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 by pressing and holding the **Transfer Image** and the button of the desired movement on the Tableside Controller illustrated in **Figure 12.**

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 movement buttons if a collision is imminent. Failure to heed these warnings may cause damage to equipment.

Moving Magnets Manually

A manual hand crank allows the user to manually move the magnets in the event of a facility power failure, or if a mechanical or electrical failure renders the system unable to move normally.

WARNING: When using the manual hand crank, **EXTREME CAUTION** must be taken to ensure proper patient table, C-Arm, and magnet positioning clearance. Ensure that no one attempts to use the Tableside Control while manually moving the magnets. Failure to heed these warnings may cause an unsafe condition resulting in personal injury and/or damage to equipment.

To manually move the magnets, first remove the side cover by pushing on the button and pulling off the cover (**Figure 20**). Next, follow the steps outlined in **Figure 21**. When power is restored and the Tableside Control is again used, the interlocks will automatically re-engage.

Figure 20. *Niobe* ES cover for emergency manual pod movement

① Set side cover aside.

② Remove hand crank bar from clip.

③ Insert bar in to hand crank hole. Make sure hand crank bar is ***fully*** inserted.

④ Turn hand crank to pivot magnet on curved floor track.

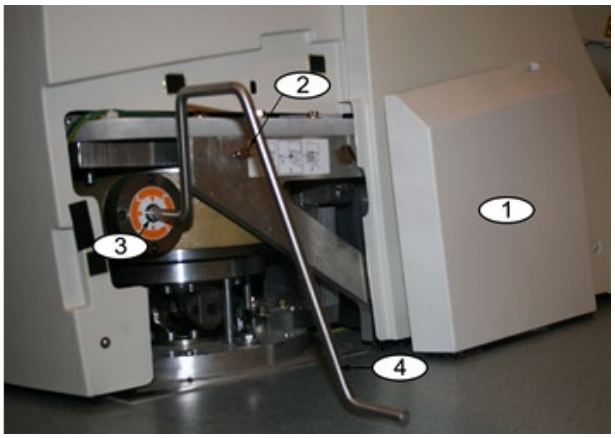


Figure 21. Niobe ES manual hand crank

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 instructions 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-0120 *Niobe* ES and *Niobe* II MNS Preventive Maintenance Manual
HDW-0137 *Niobe* Magnetic Navigation System Maintenance and Service Manual
HDW-0228 *Niobe* ES Magnetic Alignment Procedure
HDW-0181 *Niobe* Troubleshooting Guide
HDW-0182 *Niobe* Troubleshooting Guide for Philips

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

Facility breakers

If the *Niobe* facility breakers have switched or turned off, contact one of the following areas:

- The hospital in-house Facilities Department
- Stereotaxis main number
  - 314-678-6100
- Stereotaxis TeleRobotic Support Team:
  - 314-678-6200
  - 1-866-269-5268 (US only)

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