



# *Cardiodrive* Installation, Operation and Service Manual



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**R<sub>x</sub><sup>Only</sup>**  
**CE 2797**  
Rev J

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## Patents

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Manufactured under one or more of the following patents:

### *United States*

7,066,924; 7,635,342; 7,766,856

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## EMC Directive Statement

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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 60601-1-2:2004 3rd Ed., EN 60601-1-2:2007, EN55011:2007+A2:2007, EN61000-3-2:2006, EN61000-3-3:1995 +A1:2001 +A2:2005
Immunity:	IEC 60601-1-2:2007, IEC 60601-1-2:2004 3rd Ed. EN61000-4-2:1995 + A1:1999 + A2:2001, EN61000-4-3:2006, EN61000-4-4:2004, EN61000-4-5:2005, EN61000-4-6:2007, EN61000-4-8:1993 + A1:2001, EN61000-4-11:2004

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device.

**Related documents**

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HDW-0312 – *Niobe* ES User Guide

**Cover art**

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**Notice**

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Carefully read and understand the instructions, warnings, and precautions presented in this guide and in the Instructions for Use for the *Cardiodrive* unit. Do not attempt to use this device until all procedures described within are thoroughly understood.

## Contents

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<b>1</b>	<b>Introduction .....</b>	<b>6</b>
1.1	About the <i>Cardiodrive</i> system .....	6
1.2	Intended use .....	6
1.3	Companion magnetic navigation system .....	6
1.4	About this user guide.....	6
1.5	Safety .....	7
1.6	Electromagnetic compatibility information.....	8
1.7	Definitions.....	11
1.8	Graphics and Symbols .....	12
<b>2</b>	<b>Configuring the <i>Cardiodrive</i> System.....</b>	<b>13</b>
2.1	System components .....	13
2.2	System interconnection.....	14
2.3	Installing the Controller (030-002046) .....	15
2.4	Installing the Motor (030-005115).....	15
2.5	Installing the User Interfaces (030-002047).....	15
2.6	Installing the Disposable Advancer Unit (001-001751-1).....	15
2.7	Operating the <i>Cardiodrive</i> Unit with Only One User Interface .....	16
<b>3</b>	<b><i>Cardiodrive</i> Instructions for Use .....</b>	<b>17</b>
3.1	Powering up <i>Cardiodrive</i> unit .....	17
3.2	Emergency stop (E-stop) usage.....	17
3.3	Advance and retract joystick operation .....	17
3.4	Advance and retract 1mm button operation .....	18
3.5	Advance and retract 3mm button operation .....	18
3.6	Select user interface operation .....	18
3.7	Powering down <i>Cardiodrive</i> unit .....	18
3.8	Error recovery .....	19
<b>4</b>	<b>CAS User Interface .....</b>	<b>20</b>
4.1	Controls and indicators .....	20
4.2	Performance specifications.....	22
4.3	Additional information.....	22
<b>5</b>	<b><i>Cardiodrive</i> Maintenance .....</b>	<b>23</b>
5.1	Cleaning .....	23
5.2	General safety .....	23
<b>6</b>	<b>Index .....</b>	<b>24</b>
	<b>Appendix A: <i>QuikCAS</i> Device .....</b>	<b>25</b>
	Instructions for Use.....	25

## Figures

---

Figure 1. <i>Cardiodrive</i> Advancer Unit.....	13
Figure 2. <i>Cardiodrive</i> interconnect diagram.....	14
Figure 3. CAS user interface .....	20

## Tables

---

Table 1. Glossary .....	11
Table 2. Graphics and symbols.....	12
Table 3. UI controls and indicators.....	21
Table 4. CAS UI performance specifications.....	22

# 1 Introduction

## 1.1 About the *Cardiodrive* system

The Stereotaxis *Cardiodrive* automated catheter advancement system (CAS) is a tool that provides the physician with the ability and the choice to advance and retract catheters from a control room.

## 1.2 Intended use

**In the United States and Canada, the following Indications are applicable for the *Cardiodrive* system.**

- The Stereotaxis *Cardiodrive* system is intended for automatically advancing and retracting only compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis magnetic navigation system (MNS).
- The *Cardiodrive* system is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

**In all other geographies, the following Indications are applicable for the *Cardiodrive* system.**

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

## 1.3 Companion magnetic navigation system

The *Cardiodrive* system works in conjunction with a magnetic navigation system. The physician uses the MNS to steer the distal tip of the catheter while the *Cardiodrive* device provides the means for remote advancement or retraction. A companion x-ray system provides real-time guidance for the physician during the interventional procedure as well. The documentation for the MNS and the x-ray system are not duplicated herein.

The Instructions for Use (IFU) for the *Cardiodrive* disposables are provided in appendixes following the body of this guide and are contained in its binder.

## 1.4 About this user guide

The purpose of this guide is to provide the user of the *Cardiodrive* system with instructions for operating the equipment.

The user guide provides information for configuring, powering up, operating, and shutting down the Stereotaxis *Cardiodrive* system (P/N 001-004115). It also provides information on the installation and maintenance of the *Cardiodrive* unit.

## 1.5 Safety

Although the *Cardiodrive* system provides for remote advancement and retraction of compatible devices, it does not replace the physician's knowledge, expertise, or judgment.

### 1.5.1 Warnings



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



**WARNING:** The Stereotaxis *Cardiodrive* system should be used only by physicians trained in electrophysiology, interventional cardiology, and in the use of the *Cardiodrive* device and the Stereotaxis magnetic navigation system.



**WARNING:** The Stereotaxis *Cardiodrive* system should only be used by physicians trained in electrophysiology, interventional cardiology, and in the use of the *Cardiodrive* device and the Stereotaxis magnetic navigation system.



**WARNING:** The "E-stop" on the User Interface shall be "ON" (button pushed in) when the *Cardiodrive* unit is not in use.



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



**WARNING:** Do not remove covers or attempt to service any of the components of the *Cardiodrive* system. Refer all servicing to qualified service personnel.



**WARNING:** Always verify operation of the *Cardiodrive* system before beginning any procedure. Refer to Section 3 of this user guide.

### 1.5.2 Precautions



**CAUTION:** Do not bring the Motor Assembly within 2 feet of the magnet used in the magnetic navigation system.



**CAUTION:** When performing a retrograde approach to the left heart via the ascending aorta, please cross the aortic valve and the mitral valve manually, not by the *Cardiodrive* component of the Stereotaxis MNS.



**CAUTION:** As with manual catheter advancement, when advancing the catheter with *Cardiodrive* system, the catheter speed should be decreased to an appropriate speed when approaching vascular structure (such as pulmonary veins) or coronary artery/vein ostia. As a reminder, the maximum advancement speed of the *Cardiodrive* device is 5.0 cm/second.

## 1.6 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 *Cardiodrive* system.



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

### 1.6.1 Emissions

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

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

Emissions	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The <i>Cardiodrive</i> 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		

### 1.6.2 Immunity—General electromagnetic effects

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

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.




<b>Immunity test</b>	<b>IEC 60601 test level*</b>	<b>Compliance level*</b>	<b>Electromagnetic environment—guidance</b>
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV 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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % 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 % $U_T$ (>95 % 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 <i>Cardiodrive</i> system requires continued operation during power mains interruptions, it is recommended that the <i>Niobe</i> ES System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

### 1.6.3 Immunity—RF interference

The following table provides guidance and Stereotaxis' declaration on **electromagnetic immunity** regarding RF frequency for the *Cardiodrive* system:

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment—guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the <i>Cardiodrive</i> system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the
Radiated RF IEC 61000-4-3	3 V/m 80 kHz to 2.5 GHz	3 V/m	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			<p>transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol :</p> 

**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.

<sup>a</sup> 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 *Cardiodrive* system is used exceeds the applicable RF compliance level above, the *Cardiodrive* 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 *Cardiodrive* system.

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

### 1.6.4 Separation distances

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

Rated maximum output power of transmitter* W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

## 1.7 Definitions

The glossary in **Table 1** defines terms in this user guide.










**Table 1.** Glossary

Term	Explanation
<b>Advance</b>	Forward direction of travel of the device being controlled
<b>Advancer Unit</b>	Disposable component that attaches <i>Cardiodrive</i> unit to the device to be advanced or retracted
<b>CAS</b>	<i>Cardiodrive</i> catheter advancement system
<b>Controller</b>	<i>Cardiodrive</i> component that controls motor operation
<b>E-stop</b>	User interface component that controls power to the motor
<b>EP</b>	Electrophysiology
<b>IFU</b>	Instructions for Use
<b>MNS</b>	Magnetic navigation system
<b>Motor</b>	<i>Cardiodrive</i> component that provides the mechanical force to move the device
<b>Retract</b>	Backward direction of travel of the device being controlled
<b>UI</b>	User interface – <i>Cardiodrive</i> (CAS) component that allows physician control of the device

## 1.8 Graphics and Symbols

The following graphics and symbols (**Table 2**) are used in this guide and/or on the *Cardiodrive* components.

**Table 2.** Graphics and symbols

Symbol	Name	Description
	<b>WARNING</b>	<b>WARNING</b> indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	<b>CAUTION</b>	<b>CAUTION</b> indicates a potentially hazardous situation which, if not avoided, could result in injury to patient or operator or damage to the equipment.
	Consult Instructions	See the Operating Instructions for additional information or instruction.
	Power	Indicates the power status of the component or system.
	Manufacturer	Name and address of the equipment manufacturer
	European Representative	Name and address of the authorized representative in the European Community.
	Reference	Part Number
	Lot Number	
	Expiration Date	

## 2 Configuring the *Cardiodrive* System

### 2.1 System components

The *Cardiodrive* system consists of three main components:

#### 2.1.1 Controller (030-002046)

The Controller contains the power supply for the motor as well as the Control Interface circuit card assembly.

#### 2.1.2 Motor Assembly (030-005115)

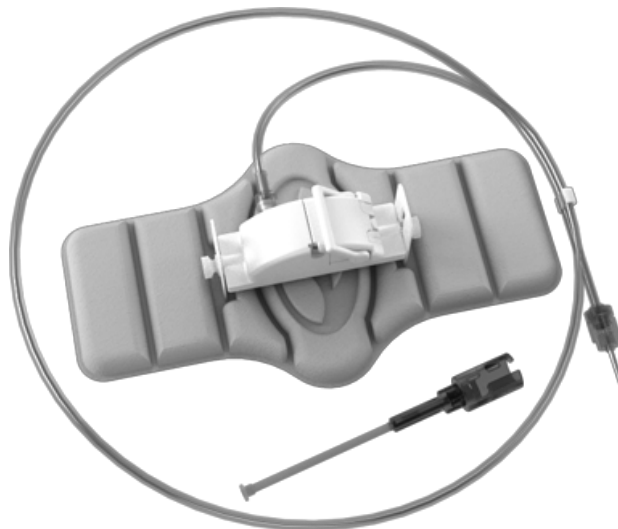
The Motor Assembly contains the motor, which turns the flexible drive cable that connects to the disposable catheter Advancer Unit.

#### 2.1.3 One (Standard) or Two (Optional) User Interfaces (030-002047)

Each UI contains a joystick and button controls for physician use of advancing or retracting the catheter during the procedure.

#### 2.1.4 Advancer Unit (001-001751-1)

The *Cardiodrive* system is used with the disposable Advancer Unit (**Figure 1**), which contains the drive assembly for the catheter. The catheter is placed inside the Advancer Unit (also known as the *QuikCAS* device) before the procedure.



**Figure 1.** *Cardiodrive* Advancer Unit

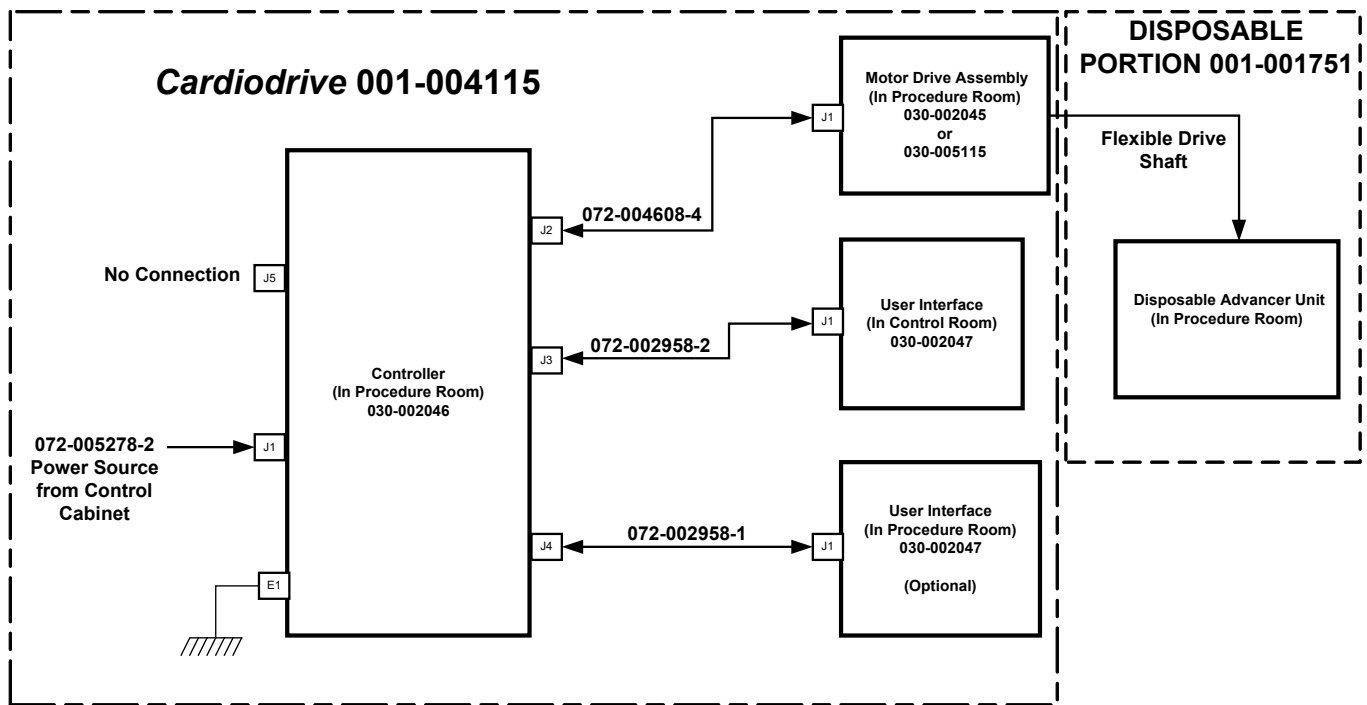


**WARNING:** Do not connect *Cardiodrive* components together while power is applied. Turn off the power switch on the Controller before connecting the *Cardiodrive* system.

## 2.2 System interconnection

The *Cardiodrive* system is to be configured so the Motor Assembly is mounted to the patient table rail. The User Interface (UI) resides in the Control Room. If the second (optional) user interface is used, it also goes at the patient table. The Controller unit is placed in an area near the patient table. The disposable Advancer Unit is attached to the patient’s leg. The flexible drive cable is installed between the Motor Assembly and the Advancer Unit. The catheter is installed inside the disposable advancer itself. Having one UI in the Procedure Room and one UI in the Control Room, the physician can control the catheter from either location.

**Figure 2** displays the interconnection diagram for the *Cardiodrive* system.



**Figure 2.** *Cardiodrive* interconnect diagram

## 2.3 Installing the Controller (030-002046)

- Depending on the facility power, the Controller will operate from a 230Vac/60Hz or a 230Vac/50Hz single-phase power source. Verify the power cord is correct for the facility power source and securely installed into the J1 connector of the Controller.
- Verify the grounding stud, E1, is connected to the facility equal potential ground.
- Verify the correct fusing is installed into the AC power inlet. Refer to 985-004663.
- Verify the cable (072-004608-4) is securely installed between the J2 connector of the Controller and the J1 connector of the Motor Assembly.
- Verify the cable (072-002958-2) is securely installed between the J3 connector of the Controller and the J1 connector of the UI in the Control Room.
- Verify the cable (072-002958-1) is securely installed between the J4 connector of the Controller and the J1 connector of the UI in the Procedure Room.

## 2.4 Installing the Motor (030-005115)

- Attach the Motor Assembly to the patient table rail:
  1. Attach the assembly to the rail that is on the patient's left side (while the patient is lying on his or her back).
  2. Attach the assembly so the motor shaft points toward the patient's head (not toward the feet).
- The motor can be slid along the rail as needed. Its exact position should be adjusted with each patient to take the slack out of the flexible drive cable. This position along the rail varies from patient to patient. Attempt to place it as far toward the patient's feet as practical.

## 2.5 Installing the User Interfaces (030-002047)

- Attach the UI connected to the 072-002958-1 cable to the patient table rail.
- Verify the other UI is sitting on a flat, secure surface in the Control Room, free of any obstacles that may fall on it.

## 2.6 Installing the Disposable Advancer Unit (001-001751-1)

- Refer to the Advancer Unit IFU (**Appendix A: QuikCAS Device**) for installation of the disposable.
- Slide the motor along the patient table rail (toward the patients head or feet) as necessary to take out slack in the flexible drive cable and keep it as straight as

possible for a given patient. Attempt to place it as far toward the patient's feet as practical.

## **2.7 Operating the *Cardiodrive* Unit with Only One User Interface**

The *Cardiodrive* system is capable of operating with only one UI installed (the standard configuration). However, if you have the two-interface option but wish to operate with just one UI installed, you must install the Control Shunt (030-002990) on either the J3 or J4 connector of the Controller.

If the UI connected to J3 is not being used, the shunt is installed on the J3 connector. If the UI connected to J4 is not being used, the shunt is installed on the J4 connector.



## 3 **Cardiodrive Instructions for Use**

### 3.1 **Powering up Cardiodrive unit**

- Ensure the power switch labeled I/O next to the J1 connector on the Controller is in the “Off” position.
- Verify all cables are securely fastened to their appropriate connectors.
- Verify both E-stops are “Off” (pulled out) on the UIs.
- Turn on the AC power switch labeled I/O next to the J1 connector on the Controller.
- Verify the green power indicator becomes illuminated on each UI when it is selected.
- Test all of the following operations to ensure proper device functioning *before* each use in a surgical procedure.

### 3.2 **Emergency stop (E-stop) usage**

- When the E-stop is in the “On” (pushed in) position, all catheter movement is disabled. To enable catheter movement via the UI controls, ensure the E-stop is in the “Off” (pulled out) position.
- To verify the functionality of both E-stops, proceed to the next step.
- Verify that both E-stops are “Off” (pulled out) on the UIs.
- On the currently selected UI, verify its Power indicator is illuminated, and then press its E-stop button.
- Verify the green Power indicator is off. Once the E-stop button is depressed, twist it and pull it back out to enable the *Cardiodrive* catheter movement. Verify the green Power indicator is on.
- Select the other UI and verify its Power indicator is on. Press its E-stop button.
- Verify that the green Power indicator is off. Once the E-stop button is depressed, twist it and pull it back out to enable the *Cardiodrive* catheter movement. Verify the green Power indicator is on.

### 3.3 **Advance and retract joystick operation**

- On the UI with the Power indicator illuminated, press and hold the enable button on the joystick as it is moved forward. The catheter moves forward at a continuous rate until the enable button on the joystick is released.
- The Advance indicator illuminates when the joystick is being used to advance the catheter.

- On the UI with the Power indicator illuminated, press and hold the enable button on the joystick as it is moved backward. The catheter moves backward at a continuous rate until the enable button on the joystick is released.
- The Retract indicator illuminates when the joystick is used to retract the catheter.

### 3.4 Advance and retract 1mm button operation

- On the UI with the Power indicator illuminated, verify the Step selection switch is pointing to the 1mm setting.
- Press and release the Advance push button switch once. The catheter moves forward by a 1mm step.
- The Advance indicator illuminates when the Advance button is pressed.
- On the UI with the Power indicator illuminated, press and release the Retract pushbutton switch once. The catheter moves backward by a 1mm step.
- The Retract indicator illuminates when the Retract pushbutton is pressed.

### 3.5 Advance and retract 3mm button operation

- On the UI with the Power indicator illuminated, verify the Step selection switch is pointing to the 3mm setting.
- Press and release the Advance pushbutton switch once. The catheter moves forward by a 3mm step.
- The Advance indicator illuminates when the Advance button is pressed.
- On the UI with the Power indicator illuminated, press and release the Retract pushbutton switch once. The catheter moves backward by a 3mm step.
- The Retract indicator illuminates when the Retract pushbutton is pressed.

### 3.6 Select user interface operation

Each *Cardiodrive* UI contains a Select indicator and pushbutton. The UI with the Select indicator illuminated has control of the motor. Only one UI can control the motor at any particular time. To obtain control, press the Select button on the UI with the Select indicator extinguished. The Select indicator turns on, indicating this UI now has control. The Select indicator on the other UI goes off, indicating it no longer has control.

### 3.7 Powering down *Cardiodrive* unit

To power down the *Cardiodrive* unit, turn off the AC power switch labeled I/O next to the J1 connector on the Controller. When powering the *Cardiodrive* unit back up, repeat the steps defined in Section 3.1.

## 3.8 Error recovery

If the UI does not appear to be working (i.e., controlling the catheter movement), verify the Select and Power indicators are illuminated.

- If the Select indicator is not illuminated, refer to Section 3.6.
- If the Power indicator is not illuminated, check that both E-stops are “Off.”
- If the UI still does not have the Power indicator illuminated, cycle power at the Controller.
- If the motor is not operational, check that both E-stops are “Off.”
- If one of the UIs continues to be troublesome, refer to Section 2.7 (Operating the *Cardiodrive* Unit with Only One User Interface).
- If the motor stops moving and does not respond to the UI, the motor may be detecting a high mechanical resistance in the system and automatically shutting down. To resolve this:
  1. First physically verify the disposable drive cable and advancer assembly are still positioned as originally set up on the patient.
  2. Disconnect the disposable drive cable from the motor assembly.
  3. Press the red button on the UI in, and then twist the button so it pops back up (i.e., cycle power to the motor). Then use the joystick to advance. Cycling power resets the motor.
  4. Listen to the motor to determine if it sounds like the motor is turning. If the motor is turning, replace the disposable advancer.
  5. If the motor is not turning, the motor requires service.
  6. Refer to the disposable Instructions for Use for disposable component identification.

## 4 CAS User Interface

This section describes each of the system controls and indicators you will encounter on the User Interface.

### 4.1 Controls and indicators

**Figure 3** and its associated numbered areas below describe the UI controls, the particular usage relative to the catheter's movement, and their corresponding indicators.



**Figure 3.** CAS user interface

- ① **E-stop.** Disconnects power to the motor assembly. Push the red button to quickly shut down power to CAS. When the button is pressed, power is off and the green light is off. To restore power, twist the button clockwise; the green light should turn on. (However, if the *Niobe* E-stop is on, the CAS E-stop green light will not turn on.)
- ② **Selection button.** Push this button to enable CAS (to determine that the UI is in control of the motor assembly). When CAS is enabled (the UI is in control of the motor), the green light is on (indicator is "On"). Also use this button to take control from the Procedure or Control room.
- ③ **Joystick button.** Press and hold this button to activate the joystick. **Figure 3** shows a top view of the joystick with the button outlined by the dashed orange circle.
- ④ **Joystick.** Tilt the joystick forward (toward the +) to advance the catheter and back (toward the -) to retract it. The motion is slower as you approach the joystick's center and speeds up as you tilt the joystick farther in either direction.
- ⑤ **Step size controller.** This button controls the discrete 1mm / 3mm step movement of the catheter in either Advance or Retract direction. Twist the button counterclockwise to point it to the 1mm setting and clockwise for the 3mm setting.

Each button has a corresponding indicator that lights when the catheter movement is set in that direction.

- ⑥ **Single step buttons.** Press these buttons to advance (+) or retract (-) CAS one step at a time (1mm or 3mm). Or double-press these buttons to advance the set distance (2mm or 6mm).



**Note:** When the + indicator is “On,” the catheter movement is in the Advance direction by either the joystick or the Advance step size button. When the – button is “On,” the catheter movement is in the Retract direction by either the joystick or the Advance step size button.

Another way to view the explanations of the controls and indicators on the UI is shown in **Table 3**.

**Table 3.** UI controls and indicators

Control or Indicator	Figure 3 Identifier	Usage
E-stop	1	Disconnects power to Motor Assembly. When indicator is On, motor is powered up; when Off, motor is powered down.*
Select	2	Pushbutton that determines UI’s control of motor assembly (when On, UI is in control of motor).
Joystick	3 & 4	Controls movement of catheter in both Advance and Retract directions.
Step size	5	Pushbutton that controls discrete 1mm/3mm step movement of catheter (twist counterclockwise for 1mm setting and clockwise for 3mm setting).
Advance/Retract	6	Pushbuttons that initiate 1mm or 3mm step movement of catheter in either Advance (+) or Retract (-) direction.

\* The Power indicator is next to the symbol to the right of the E-stop.

## 4.2 Performance specifications

Table 4 summarizes the performance specifications for the *Cardiodrive* unit.

**Table 4.** CAS UI performance specifications

Parameter	Specification
Velocity for 1mm / 3mm discrete movement	2.0 cm/sec, maximum
Velocity for joystick movement	5.0 cm/sec, maximum
Velocity for <i>Navigant</i> -controlled movement	2.0 cm/sec, maximum
Acceleration for all movement	6.25 cm/sec <sup>2</sup> , maximum

## 4.3 Additional information

Upon request, Stereotaxis will make available circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist the user's appropriately qualified technical personnel in repairing the parts of the *Cardiodrive* unit designated by Stereotaxis as repairable.

## **5 Cardiodrive Maintenance**

This section outlines the basic procedures for maintenance of the *Cardiodrive* system.

### **5.1 Cleaning**

Do not autoclave any of the *Cardiodrive* components. The *Cardiodrive* electrical equipment is designed to be wiped down with a cloth or swab dampened in common hospital disinfectants. Never submerge any components of the *Cardiodrive* system.

### **5.2 General safety**

The *Cardiodrive* unit is designed to accept power from a single-phase power source of nominally 230 VAC at 60Hz or 230 VAC at 50Hz. To prevent electrical hazards to all personnel, properly ground the *Cardiodrive* unit. The grounding stud (E1) on the Controller has been provided for this protection.

## 6 Index

### A

About user guide .....	6
Advance and retract button operation .....	21
Advancer Unit.....	11, 13, 14, 15

### B

Button operation.....	18
-----------------------	----

### C

<i>Cardiodrive</i> system	
About.....	6
Components .....	13
Configuring .....	13
Electromagnetic compatibility information ...	8
Intended use .....	6
Maintenance .....	23
Safety.....	7
With one user interface .....	16
CAS.....	11
Cleaning components.....	23
Companion system .....	6
Contact Stereotaxis .....	ii
Contents .....	iv
Controller .....	13
Installing .....	15

### D

Definitions .....	11
-------------------	----

### E

EC Representative .....	ii
Electromagnetic compatibility information .....	8
Electromagnetic immunity .....	8
EMC Directive Statement .....	ii
Emergency stop.....	<i>See</i> E-stop
Emissions .....	8
E-stop.....	11, 20, 21
Usage.....	17

### F

Figures .....	v
---------------	---

### G

General safety .....	23
----------------------	----

### I

IFU .....	<i>See</i> Instructions for Use
Instructions for Use .....	iii, 6, 11, 17, 19, 25

### J

Joystick.....	20, 21
Advance and retract operation .....	17
Button.....	20

### M

Magnetic navigation system.....	6
Motor Assembly .....	7, 13, 14, 15, 21

### P

Patents.....	ii
Powering down <i>Cardiodrive</i> unit .....	18
Powering up <i>Cardiodrive</i> unit.....	17
Precautions .....	7

### Q

<i>QuikCAS</i> Device.....	13, 15, 25
----------------------------	------------

### R

Related documents.....	iii
Requesting information.....	22
RF interference immunity.....	9

### S

Safety .....	7
Select button .....	20, 21
Separation distances.....	10
Single step buttons .....	21
Step size .....	20, 21
Symbols.....	12
System components .....	13
System interconnection.....	14

### T

Tables.....	v
Trademarks .....	ii

### U

User Interface .....	13, 20
Controls and indicators .....	20
Error recovery.....	19
Installing .....	15
Performance specifications .....	22
Select operation .....	18

### W

Warnings.....	7
---------------	---



## **Appendix A: *QuikCAS* Device**

### **Instructions for Use**