



Cardiodrive Installation, Operation and Service Manual

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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 15.107(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.

Related documents

HDW-0312 – Niobe ES User Guide

HDW-0358 – Genesis User Guide

Cover art

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Notice

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

1	Introduction	1
1.1	About the <i>Cardiodrive</i> system	1
1.2	Intended use	1
1.3	Companion magnetic navigation system	1
1.4	About this user guide.....	1
1.5	Safety	2
1.6	Electromagnetic compatibility information	3
1.7	Definitions.....	6
1.8	Graphics and symbols	7
2	Configuring the <i>Cardiodrive</i> System.....	8
2.1	System components	8
2.2	System interconnection.....	9
2.3	Installing the Motor Assembly mounting hardware	10
2.4	Installing the Motor (030-005115).....	10
2.5	Installing the User Interface (030-002047)	10
2.6	Installing the Disposable Advancer Unit (001-001751-1).....	11
3	<i>Cardiodrive</i> Instructions for Use	12
3.1	Powering up <i>Cardiodrive</i> unit	12
3.2	Emergency stop (E-stop) usage.....	12
3.3	Advance and retract joystick operation	12
3.4	Advance and retract 1mm button operation	13
3.5	Advance and retract 3mm button operation	13
3.6	Powering down <i>Cardiodrive</i> unit	13
3.7	Error recovery	13
4	CAS User Interface	15
4.1	Controls and indicators	15
4.2	Performance specifications.....	17
4.3	Additional information	17
5	<i>Cardiodrive</i> Maintenance	18
5.1	Cleaning	18
6	Optional <i>Cardiodrive</i> Two-User Interface Kit	18
6.1	Select user interface operation	18
7	Index	19
	Appendix A: <i>QuikCAS</i> Device	20
	Instructions for Use	20

Figures

Figure 1. <i>Cardiodrive</i> Advancer Unit.....	8
Figure 2. <i>Cardiodrive</i> interconnect diagram.....	9
Figure 3. Motor Assembly mounting hardware installation	10
Figure 4. CAS user interface	15

Tables

Table 1. Glossary	6
Table 2. Graphics and symbols.....	7
Table 3. UI controls and indicators.....	16
Table 4. CAS UI performance specifications.....	17

1 Introduction

1.1 About the *Cardiodrive* system

The Stereotaxis *Cardiodrive* 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 EN55011	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 EN55011	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


Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV 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>Cardiodrive</i> 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:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF	3 Vrms	3 V	Portable and mobile RF communications equipment should

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
IEC 61000-4-6 Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 3 V/m 80 kHz to 2.5 GHz	3 V/m	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 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 where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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 *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.

^b 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
Advance	Forward direction of travel of device being controlled
Advancer Unit	Disposable component that attaches <i>Cardiodrive</i> unit to device to be advanced or retracted
CAS	<i>Cardiodrive</i> catheter advancement system
E-stop	User interface component that controls power to motor
EP	Electrophysiology
IFU	Instructions for Use
MNS	Magnetic Navigation System
Motor	<i>Cardiodrive</i> component that provides the mechanical force to move device
Retract	Backward direction of travel of device being controlled
UI	User interface – <i>Cardiodrive</i> (CAS) component that allows physician control of 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
	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.
	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 Motor Assembly (030-005115)

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

2.1.2 User Interface (030-002047)

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

2.1.3 Disposable 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.

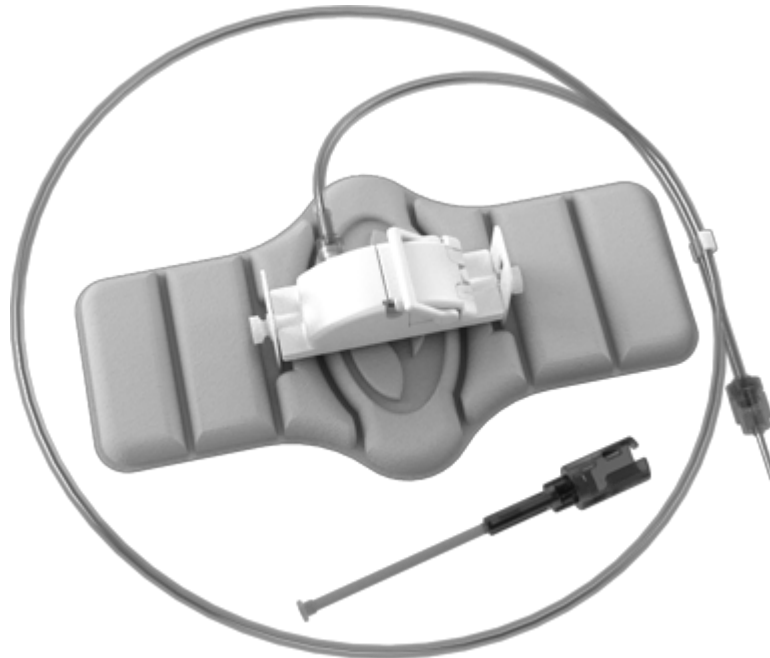


Figure 1. *Cardiodrive* Advancer Unit



WARNING: Do not connect *Cardiodrive* components together while power is applied. Power down the MNS 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. 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 Unit itself. **Figure 2** displays the interconnection diagram for the *Cardiodrive* system.

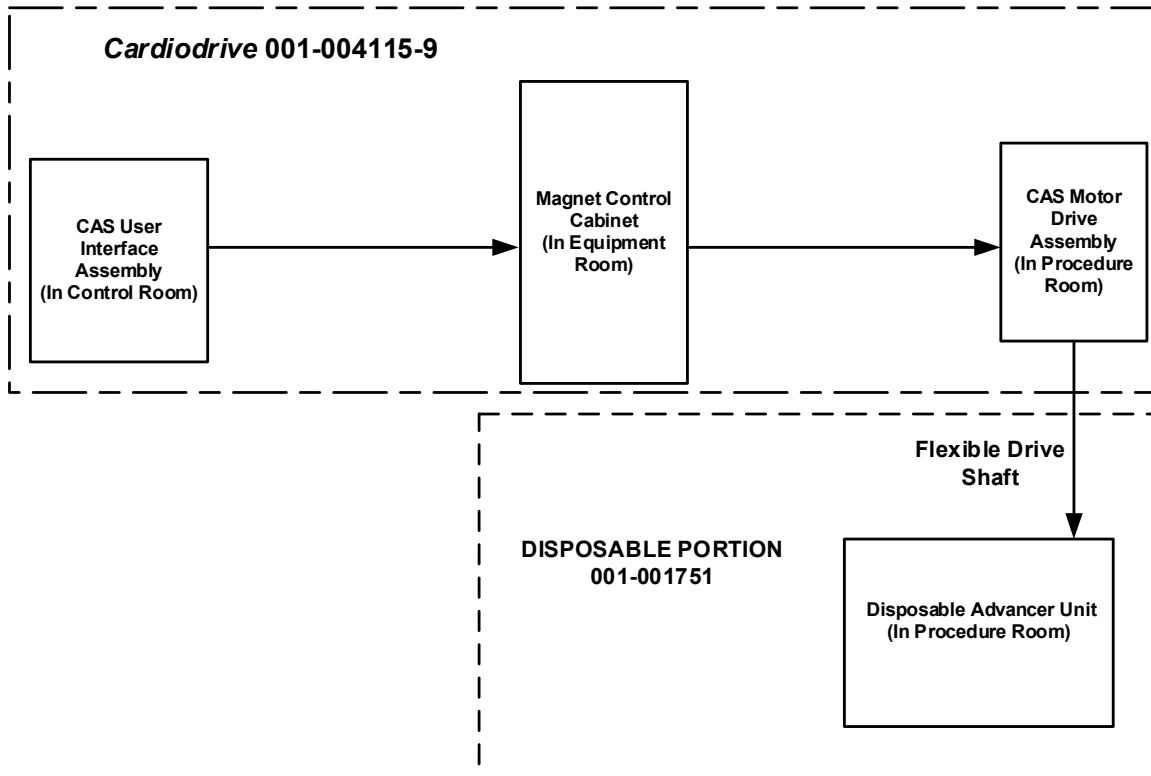


Figure 2. *Cardiodrive* interconnect diagram

2.3 Installing the Motor Assembly mounting hardware

- Push the clip in on the Motor Assembly and install on the mounting hardware.
- Attach the Motor Assembly and mounting hardware to the patient table rail as shown in **Figure 3**.

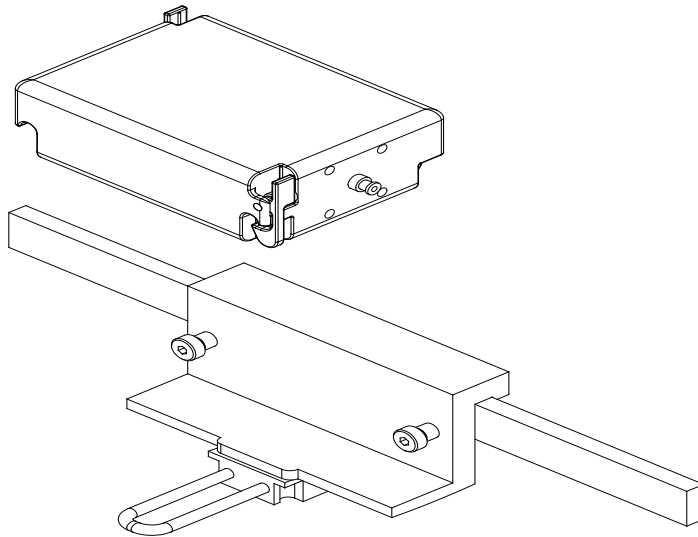


Figure 3. Motor Assembly mounting hardware installation

2.4 Installing the Motor (030-005115)

- Attach the Motor Assembly to the patient table rail:
 1. Attach the assembly to the rail 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 Interface (030-002047)

- Verify the 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 *Cardiodrive* 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.

3 *Cardiodrive* Instructions for Use

3.1 Powering up *Cardiodrive* unit

- Verify all cables are securely fastened to their appropriate connectors.
- Verify the E-stop is “Off” (pulled out) on the UI.
- Power up the *Cardiodrive* unit by powering up the MNS system. Refer to the User Guide for this procedure. Verify the MNS E-stop is “Off.”
- 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, verify the E-stop is in the “Off” (pulled out) position. Catheter movement is also disabled if the MNS E-stop is “On.”

- To verify the functionality of the E-stop, proceed to the next step.
- Verify the E-stop is “Off” (pulled out) on the UI.
- On the UI, press the 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.

3.3 Advance and retract joystick operation

- On the UI, 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, 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, verify the Step selection switch is pointing to the 1mm setting.
- Press and release the Advance pushbutton switch once. The catheter moves forward by a 1mm step.
- The Advance indicator illuminates when the Advance button is pressed.
- On the UI, 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, 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, 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 Powering down *Cardiodrive* unit

To power down the *Cardiodrive* unit, power down the MNS system. Refer to the User Guide for this procedure.

3.7 Error recovery

If the UI does not appear to be working (i.e., controlling the catheter movement), verify the Power indicator is illuminated.

- If the Power indicator is not illuminated, check that the E-stop is “Off.” Also check that the MNS E-stop is “Off.”
- If the motor is not operational, check that the E-stop is “Off.” Also check that the MNS E-stop is “Off.”
- 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 disposable Advancer Unit 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 Unit.
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 the system controls and indicators you will encounter on the *Cardiodrive* (CAS) user interface (UI).

4.1 Controls and indicators

Figure 4 and its associated numbered areas below describe the UI controls, the particular usage relative to the catheter's movement, and their corresponding indicators.



Figure 4. 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 MNS 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 4** 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 4 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 joystick movement	5.0 cm/sec, maximum
Velocity for remote controlled movement	2.0 cm/sec, maximum
Power supply (supplied by the MNS system)	24 Volts DC -0%/+10%

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 procedure 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.

6 Optional *Cardiodrive* Two-User Interface Kit

6.1 Select user interface operation

If you have the 020-005854-1 option, the *Cardiodrive* Two-User Interface Kit contains a manual switchbox located in the Control Room. The UI with the Power indicator illuminated has control of the motor. Only one UI can control the motor at any particular time.

- To obtain control for the UI in the Control Room, turn the knob on the manual switchbox to the “A” position. The Power indicator will turn on to indicate the Control Room UI now has control. The Power indicator on the remote UI will go off, indicating it no longer has control.
- To obtain control for the UI in the remote location, turn the knob on the manual switchbox to the “B” position. The “Power” indicator will turn on to indicate the remote UI now has control. The “Power” indicator on the Control Room UI will go off, indicating it no longer has control.

7 Index

A

About user guide	i
Advance and retract button operation	16
Advancer Unit.....	v, 6, 8, 9, 11, 13, 14

B

Button operation.....	13
-----------------------	----

C

<i>Cardiodrive</i> system	
About.....	i
Components	8
Configuring.....	8
Electromagnetic compatibility information ...	3
Intended use	i
Maintenance	18
Safety.....	2
CAS.....	6
Cleaning components.....	18
Companion system.....	i
Contact Stereotaxis	ii
Contents	iv

D

Definitions	6
-------------------	---

E

EC Representative	ii
Electromagnetic compatibility information	3
Electromagnetic immunity	3
EMC Directive Statement	ii
Emergency stop	See E-stop
Emissions	3
E-stop.....	6, 15, 16
Usage.....	12

F

Figures	v
---------------	---

I

IFU	See Instructions for Use
Instructions for Use	iii, i, 6, 12, 13, 14, 20

J

Joystick	15, 16
----------------	--------

Advance and retract operation	12
Button.....	15

M

Magnetic navigation system.....	i
Motor Assembly	v, 2, 8, 9, 10, 16

P

Patents.....	ii
Powering down <i>Cardiodrive</i> unit	13
Powering up <i>Cardiodrive</i> unit	12
Precautions	2

Q

<i>QuikCAS</i> device	8, 11, 20
-----------------------------	-----------

R

Related documents.....	iii
Requesting information.....	17
RF interference immunity.....	4

S

Safety	2
Select button	15, 16
Separation distances.....	5
Single step buttons	16
Step size.....	15, 16
Symbols.....	7
System components	8
System interconnection.....	9

T

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

U

User Interface	2, 6, 8, 9, 15, 18
Controls and indicators	15
Error recovery.....	13
Installing	10
Optional Two-User Kit	18
Performance specifications	17

W

Warnings.....	2
---------------	---

Appendix A: *QuikCAS* Device

Instructions for Use