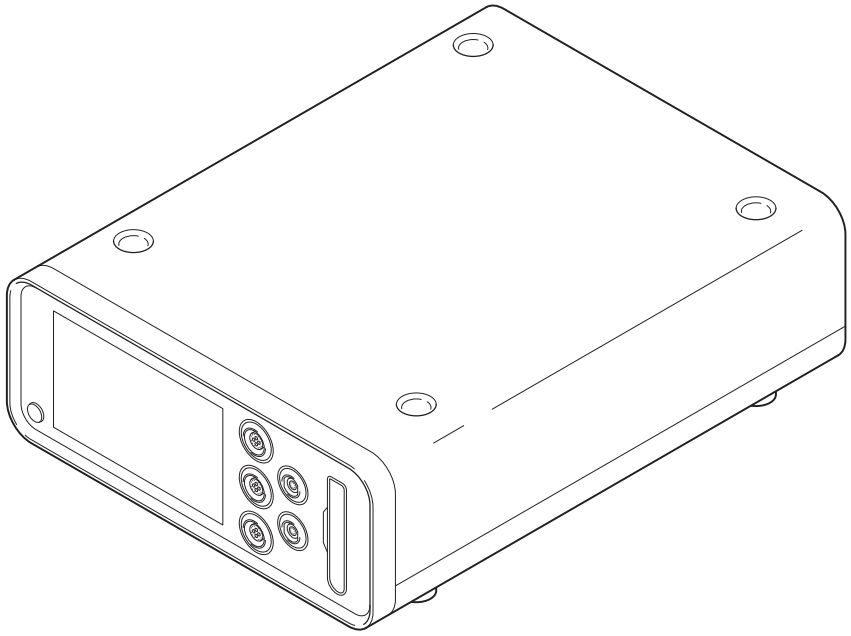
CORE™ 2 Console

REF 5400-052-000

Instructions For Use

R_x ONLY

CE 0197



Software Version

ENGLISH (EN)

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2.X.X

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1 Introduction

This manual contains information intended to ensure the safe, effective, and compliant use of this product.

Keep and consult this manual as necessary.

1.1 Audience

This manual is intended for use by in-service trainers, physicians, nurses, surgical assistants, and biomedical equipment technicians.

1.2 Conventions

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

1.3 Contact Information

For additional information, including safety information, in-service training, or current literature, contact a Stryker Sales Representative or call Stryker Customer Service at 1-269-323-7700 or 1-800-550-7836.

Outside the US, contact the nearest Stryker subsidiary.

2 Indications For Use

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (Ear, Nose, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

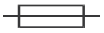
3 Contraindications

None known.

4 Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. Refer to the *Symbol Definition Chart* REF 0036-716-000 supplied with the console.

SYMBOL	DEFINITION
	1Touch
	Accelerate
	Alternating Current
	Back
	Brake
	Brightness
	Brightness - Linked
	Brightness - Unlinked
	Cancel
	Cancel Initial Prime
	Confirm
	Console
	Control Options
	Control Permissions
	Copy
	Create
	Delete
	Direct Current
	Email
	Edit
	Equipotential
	Error
	Export

SYMBOL	DEFINITION
	Favorite
	Fixed
	Flush
	Footswitch 1
	Footswitch 2
	Forward
	Fuse
	General Settings
	General Warning Sign
	Handpiece
	Handswitch
	Home
	Import
	Initial Prime
	Irrigation
	Keyboard - Backspace
	Keyboard - Capital Letter OFF
	Keyboard - Capital Letter ON
	Keyboard - Spacebar
	Language
	Loading
	Milliliters per Minute
	Motor
	Motor Options
	Motor Settings
	Name

SYMBOL	DEFINITION
	Next
	Oscillating
	Phone
	Power
	Preset/Representative
	Priming
	Quick Access
	Refer to Instruction Manual/Booklet
	Rep Info
	Reset
	Reverse
	Roll-out Left
	Roll-out Right
	Save
	Scroll Down
	Scroll Up
	System Information
	System Settings
	Time Based Turn
	I.D. Touch (Torque)
	Value - Decrease
	Value - Increase
	Variable
	Volume

5 Supplied Components

This table identifies supplied components with the purchase of REF 5400-052-000.

COMPONENT	REF
CORE 2 Console	5400-052-000
Symbol Definition Chart	0036-716-000
Software License Addendum	5400-052-704
Instructions For Use (IFU)	5400-052-700-EN

NOTE: If any component is missing or damaged, contact Stryker for assistance.

6 For Use With

WARNING: Only use Stryker-approved equipment, unless otherwise specified.

This table identifies Stryker-approved equipment intended to be used with the console to obtain a safe combination.

NOTES:

- This equipment is sold separately and may not be available in all markets. To order equipment, contact Stryker.
- For additional power cord information, see *Section 18.5 Appendix E: Power Cords*.

EQUIPMENT	REF
Accessories	
Standard Cord (Keyed)	5100-004-000
Console Power Cord	0996-851-XXX
Irrigation Pole	5100-050-028
CORE Heavy Duty Power Pack	5400-500-000
Mill Cable	5400-704-000
ES6 Handpiece Cord	6292-004-000
Irrigation Cassettes	
CORE ESSx/Hummer Irrigation Cassette	5290-075-000
Disposable Irrigation Cassette	5400-050-001
Dual Disposable Irrigation Cassette	5400-050-002
Handswitches	
TPS Universal Handswitch	5100-009-000
CORE Universal Handswitch	5400-009-000
CORE UHT Drill Handswitch	5400-111-000
CORE Saber Handswitch	5400-121-000
CORE Sumex Handswitch	5400-131-000
RemB Electric Handswitch	6400-009-000
Footswitches	
CORE Footswitch	5402-007-000
TPS Two-Pedal	0275-701-400
TPS Uni-Directional Footswitch	5100-007-000
TPS Footswitch	5100-008-000
NSE Footswitch	5400-007-000
Motors	
TPS Small Joint Shaver	0275-601-500
Formula Shaver Foot Control	0375-701-500
Formula Shaver Hand Control	0375-704-500
Formula 180	0375-708-500
TPS Micro Oscillating Saw	5100-031-000
TPS Micro Driver	5100-088-000
TPS XL Oscillating Saw	5100-131-000
Hummer 4 Handpiece	5290-601-100
CORE ESSx Handpiece	5290-601-200
CORE Micro Drill	5400-015-000
CORE Oscillating Saw	5400-031-000
CORE Sagittal Saw	5400-034-000
CORE Reciprocating Saw	5400-037-000
CORE Universal Driver	5400-099-000
CORE U-Drill	5400-100-000
CORE UHT Drill	5400-110-000
CORE Saber Drill	5400-120-000
CORE Modified Saber Drill	5400-120-000S1
CORE Sumex Drill	5400-130-000
CORE Sumex MS1	5400-130-000S1
CORE Impaction Drill	5400-300-000
CORE Mill	5400-700-000
Pi Drive Motor	5407-100-000
Pi Drive Plus Motor	5407-300-000
S2 Drill	5450-400-000
ES6 Single Trigger Rotary Handpiece	6293-000-000
ES6 Dual Trigger Rotary Handpiece	6295-000-000
ES6 Reciprocating Saw	6296-000-000
ES6 Sternum Saw	6297-000-000
ES6 Sagittal Saw	6298-000-000
ES6 Precision Oscillating Tip Saw	6299-000-000
RemB Electric Micro Drill	6400-015-000
RemB Electric Oscillating Saw	6400-031-000
RemB Electric Sagittal Saw	6400-034-000
RemB Electric Reciprocating Saw	6400-037-000
RemB Electric Wiredriver	6400-062-000
RemB Electric Universal Driver	6400-099-000

7 Safety Directives

7.1 General Warnings

WARNINGS:

- ALWAYS be familiar with the Instructions For Use and proper operation of this equipment before use. To request in-service training, contact Stryker.
- ALWAYS consult the Instructions For Use that accompanies motors, footswitches, and attachments for product specific duty cycles and additional information.
- Equipment is limited to professional use within a professional healthcare environment.
- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.
- Healthcare professionals should be thoroughly familiar with the Instructions For Use, handling characteristics, and the indicated and intended uses of this equipment. Contact Stryker for in-service training.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure or technique.
- ALWAYS ensure the console is placed on a sturdy, flat surface near a hospital-grade power outlet and all connections (front and rear) are easily accessible.
- Upon initial receipt and before each use, ALWAYS inspect equipment for damage. DO NOT use any equipment if damage is apparent.
- ALWAYS clean and disinfect the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient and/or healthcare staff injury.
- ALWAYS consult the Instructions For Use that accompanies motors, footswitches, and attachments for product specific cleaning requirements.
- DO NOT touch the screen with any sharp or hard object. Failure to comply may cause breakage and result in healthcare staff and/or patient injury.
- DO NOT disassemble, modify, service, or repair this equipment when using this equipment with a patient.
- DO NOT disassemble, modify, service, or repair any equipment without the authorization of the manufacturer. For assistance, contact Stryker.
- ALWAYS operate this equipment within the specified environmental condition values (*Section 18.9*).
- ALWAYS follow the recommended duty cycle to prevent this equipment from overheating.
- DO NOT stack or place equipment adjacent to the console. If such a configuration is necessary, observe the configuration to ensure that electromagnetic interference does not degrade performance.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the console. Portable and mobile radio frequency (RF) equipment can affect the function of the console.
- DO NOT use the console in an MRI environment. Using the console in an MRI environment could affect the function of the console.
- ALWAYS ensure footswitch placement is in a secure area where inadvertent activation is not possible.
- ALWAYS select the correct irrigation flow rate based on the surgical procedure and/or handpiece requirements to prevent excessive or insufficient irrigation flow. Failure to comply may limit the view of the surgical site and result in patient and/or healthcare staff injury.
- ALWAYS select the correct attachment/reducer when selecting the motor setting to prevent excessive or insufficient motor speed. Failure to comply may cause incorrect information to be displayed and result in patient and/or healthcare staff injury.
- DO NOT place the console within the sterile field.

7.2 Electrical Warnings

WARNINGS:

- ALWAYS connect the console to a hospital-grade, power outlet with protective earth (ground) to avoid the risk of electrical shock.
- Electrical power is present when the console is in standby mode. To completely remove power, disconnect the power cord from either the console or the hospital-grade, power outlet with protective earth (ground) to avoid the risk of electrical shock.
- If power is lost, some of the console's adjustable settings, such as the motor to footswitch assignment, footswitch options, and motor operating modes, will revert to the default configuration or the last selected preset. After power is restored, verify console settings.

8 System Overview

The CORE 2 Console has three handpiece ports, two footswitch ports, and one irrigation cassette port. The console supplies power to a variety of devices including small and large bone drills, small and large bone saws, small and large bone drivers, large joint and small joint shavers, ENT shavers, bone mills, and various footswitches. Additionally, the console supports the use of irrigation. For a complete list of equipment that can be used with the console, see *Section 6*.

When a device is connected to the console, the console automatically detects the connected device and will only display options and settings that are available for the connected device.

The touch screen provides visual output and serves as an input device when navigating the user interface. The internal speaker provides audio output during operation. For additional information, see *Section 18.2*.

The console can store user presets and representative information internally. The presets can imported and exported with the use of a USB data storage device. For additional information, see *Section 12.3.4*.

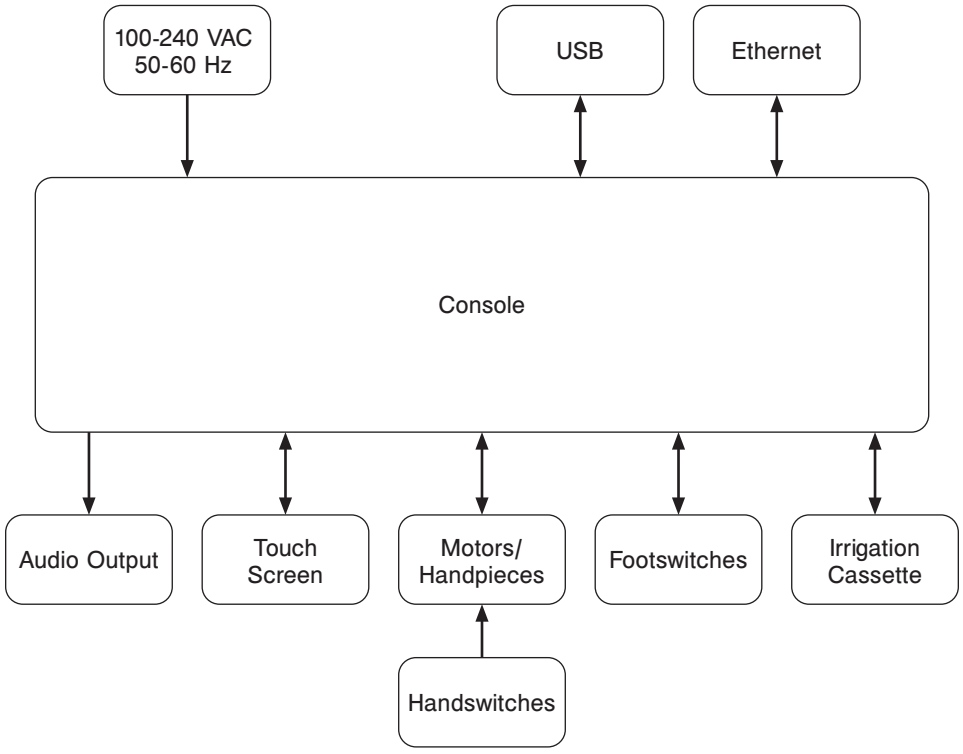


Figure 1 – System Block Diagram

8.1 Hardware Features

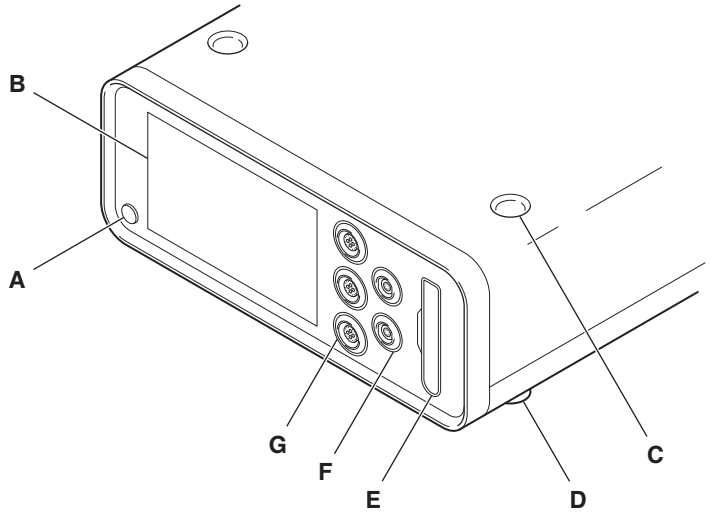


Figure 2 – Console (Front View)

A	Power Button
B	Touch Screen
C	Stacking Inserts (4)
D	Stacking Feet (4)
E	Irrigation Cassette Port
F	Footswitch Ports (2)
G	Motor Ports (3)

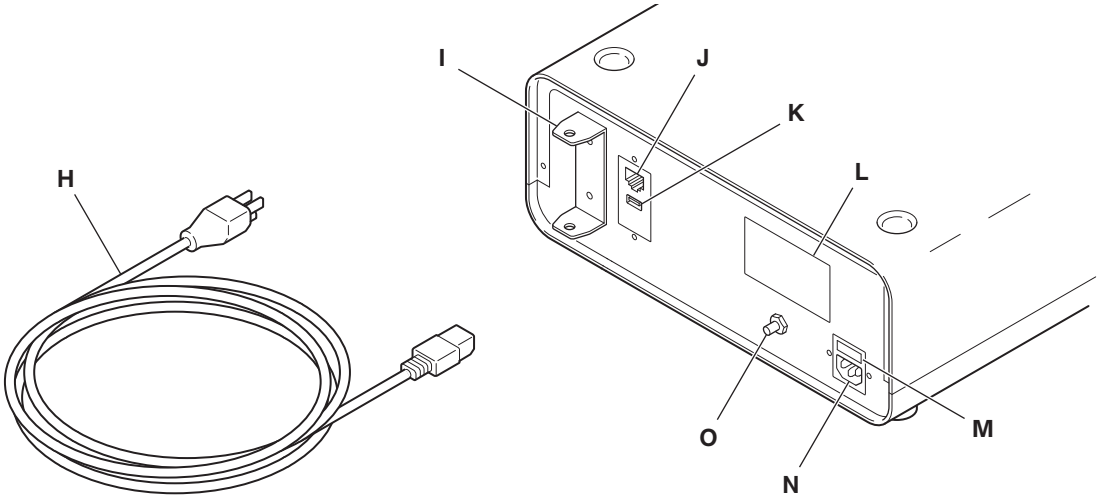


Figure 3 – Console (Rear View)

H	Power Cord
I	Pole Bracket
J	Ethernet Port
K	USB Port
L	Specification Label
M	Fuse Holder
N	Power Receptacle
O	Equipotential Lug

8.2 Software Features

NOTE: Only the Home screen and Irrigation screen can be viewed while the motor is activated. If the motor is activated from any other screen, the Home screen will automatically be displayed.

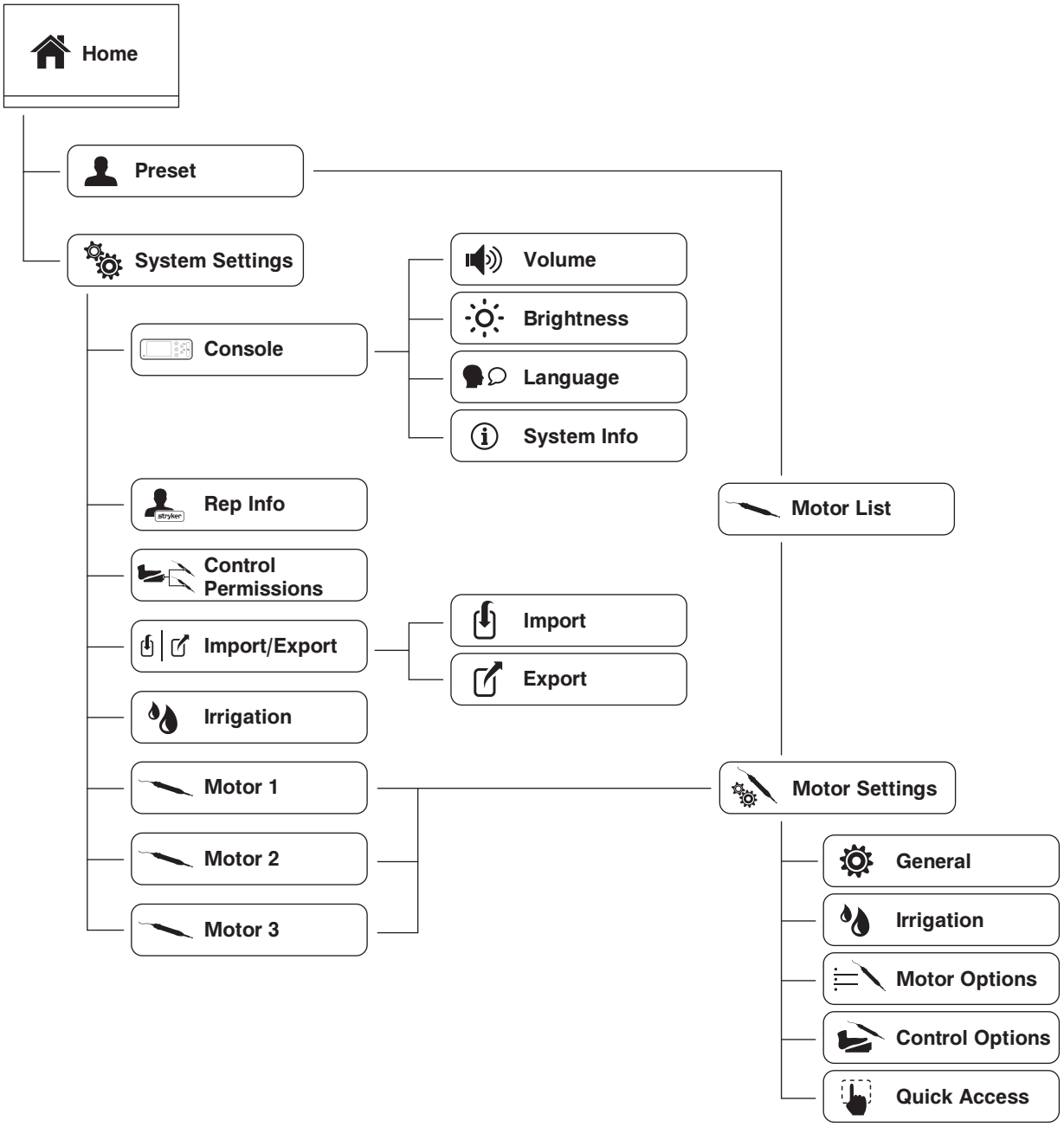


Figure 4 – Screens and Menu Tabs Map

WARNING: Before using this equipment, or any compatible equipment, read and understand the Instructions For Use. Pay particular attention to safety information. ALWAYS become familiar with the equipment before use.

9 Before the Procedure

1. Verify the console is placed on a sturdy, flat surface.
2. Verify the console is not within the sterile field.
3. Verify the following items are connected; connect as necessary (*Figure 5*):
   - (Optional) Equipotential cable
   - Power cord
4. Verify the equipment is clean and not damaged.
5. Connect the following devices as necessary:
   - Motor(s) (*Figure 6*)
   - Footswitch(es) (*Figure 7*)
6. Press ⏻ to power the console on.
7. (Optional) Prepare the console for irrigation as follows:

WARNING: DO NOT use an irrigation bag that can hold more than 1000 ml of irrigation fluid.

   7.1. If required, install an irrigation pole (*Figure 5*).

   7.2. Insert an irrigation cassette (*Figure 8).*

   7.3. Attach the irrigation sleeve/clip onto the motor and connect the tubing to the irrigation bag.

   7.4. Prepare the irrigation cassette (*Section 12.1.1*).
8. Manage presets as necessary (*Section 12.2*).
9. Manage system settings as necessary (*Section 12.3*).

10 During the Procedure

- Connect and disconnect devices as necessary.
- Refer to the following sections for guidance during the procedure as necessary:
  - *Section 12.1 Home Screen Guidance*
  - *Section 12.2 Preset Screen Guidance*
  - *Section 12.3 System Settings Screen Guidance*

11 After the Procedure

1. Remove power from the console as follows:

   1.1. Press ⏻ to set the console in standby mode.

CAUTION: Some power cords have a locking mechanism, press the colored tab prior to disconnection.

   1.2. Disconnect the power cord.

   1.3. If used, disconnect the equipotential cable.
2. If irrigation was used, perform the following:

   2.1. Detach the irrigation sleeve/clip from the motor and disconnect the tubing from the irrigation bag.

   2.2. Remove the irrigation cassette (*Figure 9).*
3. Disconnect the following devices as necessary:
   - Motor(s) (*Figure 6*)
   - Footswitch(es) (*Figure 7*)
4. Clean and disinfect the console (*Section 13.2*).
5. Inspect the equipment for damage.

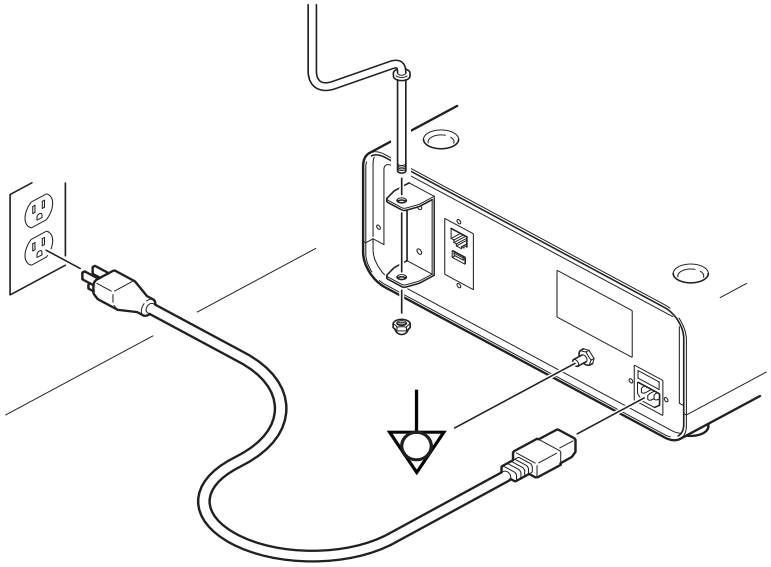


Figure 5 – Console (Rear View)

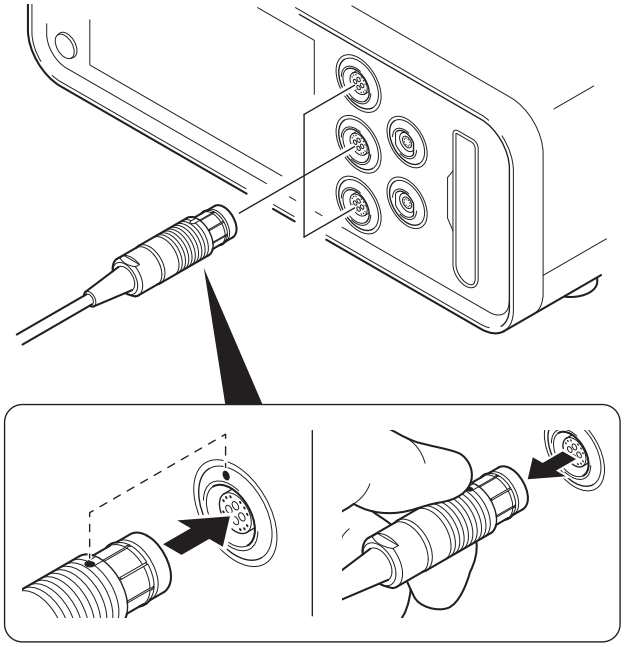


Figure 6 – To Connect/Disconnect a Motor

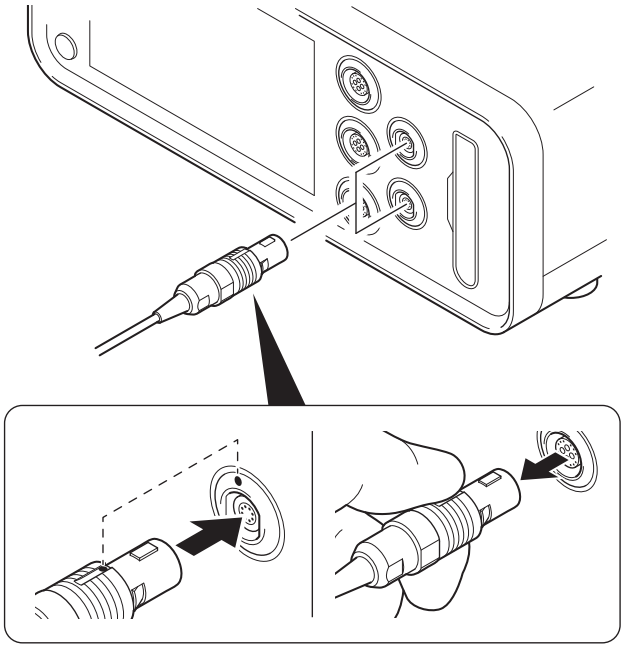


Figure 7 – To Connect/Disconnect a Footswitch

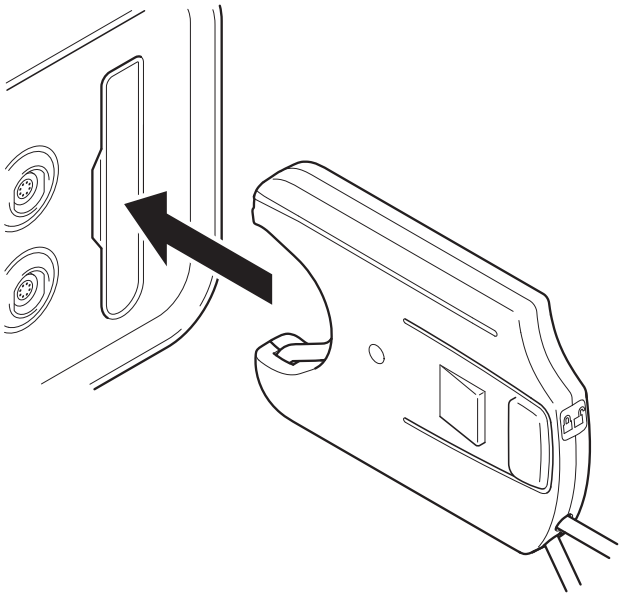


Figure 8 – To Insert an Irrigation Cassette

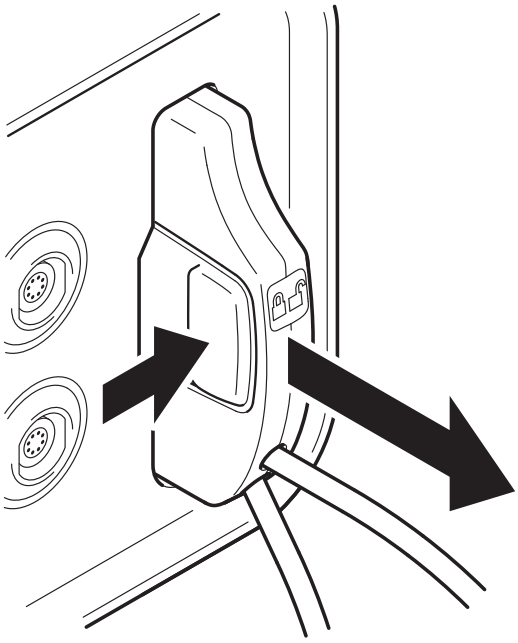


Figure 9 – To Remove an Irrigation Cassette

12 User Guidance

12.1 Home Screen Guidance

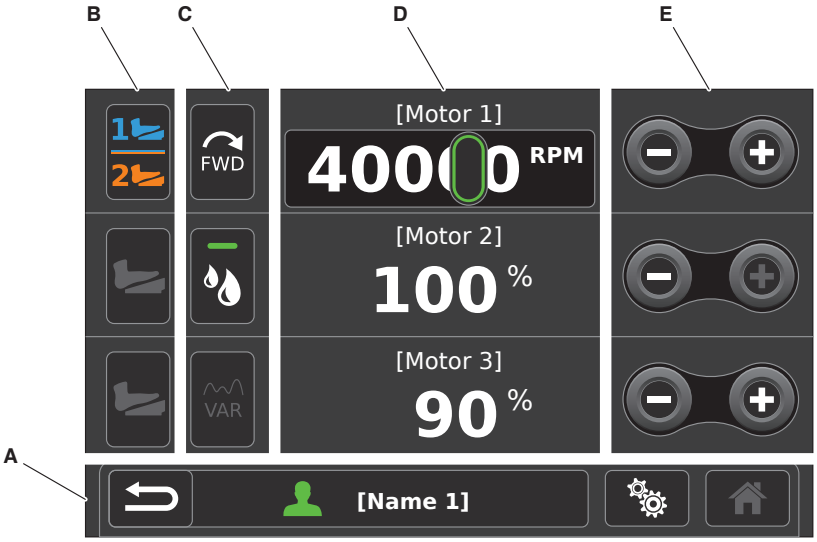


Figure 10 – Home Screen

A	**Navigation Bar Area** – Provides navigational buttons and displays the active preset. **NOTE:** The reset button will appear within this area if the active preset has been modified. Press the reset button to undo changes.
B	**Footswitch Assignment Area** – Provides a graphical representation of the current footswitch assignment. These buttons can be touched to toggle footswitch assignment.
C	**Quick Access Area** – Allows the user to set features such as direction, irrigation, mode, or I.D. Touch (torque) to be accessible from the Home screen. These buttons can be set to accommodate the user's preference, see *Section 12.3.7.5*.
D	**Motor Settings Value Area** – Displays the connected motor(s) name and value setting. Touch the motor value to access the slider bar to adjust the motor value setting.
E	**Decrease/Increase Area** – From here, the user can use the decrease and increase buttons to adjust the motor value setting.

12.1.1 Accessing Screens

NOTE: The Home screen is where most user interaction will occur and allows access to the preset and settings screens.

SYMBOL	DEFINITION	FUNCTION
	Home	Use this button to access the Home screen.
	Preset	Use this button to access the Preset screen.
	Settings	Use this button to access the System Settings screen.

12.2 Preset Screen Guidance

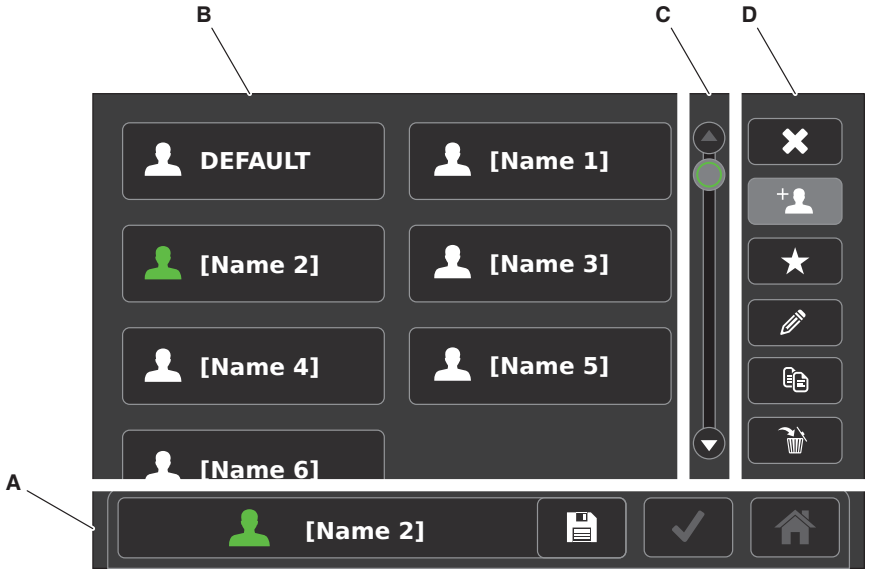


Figure 11 – Preset Screen

A	**Navigation Bar Area** – Provides navigational buttons and displays the active preset. **NOTE:** The save button will appear within this area if the active preset has been modified.
B	**Preset Area** – Contains the DEFAULT preset and created (or imported) presets.
C	**Vertical Slider Bar Area** – Contains a vertical slider bar used to scroll up and down.
D	**Preset Options Area** – Contains the following buttons: Cancel, Create, Favorite, Edit, Copy, and Delete

12.2.1 Managing Presets

SYMBOL	DEFINITION	FUNCTION
	Create	Use this button to create a new preset.
	Favorite	Use this button to identify a preset to load when the console is powered on. **NOTE:** Only one favorite can be selected at a time.
	Edit	Use this button to edit a preset.
	Copy	Use this button to copy a preset.
	Delete	Use this button to delete a preset.
	Save	Use this button to save changes to a preset.

12.2.2 To Activate a Preset

1. Access the Preset screen.
2. In the preset area, touch the preset file to activate.
3. Touch ✓ (**Confirm**).

12.3 System Settings Screen Guidance

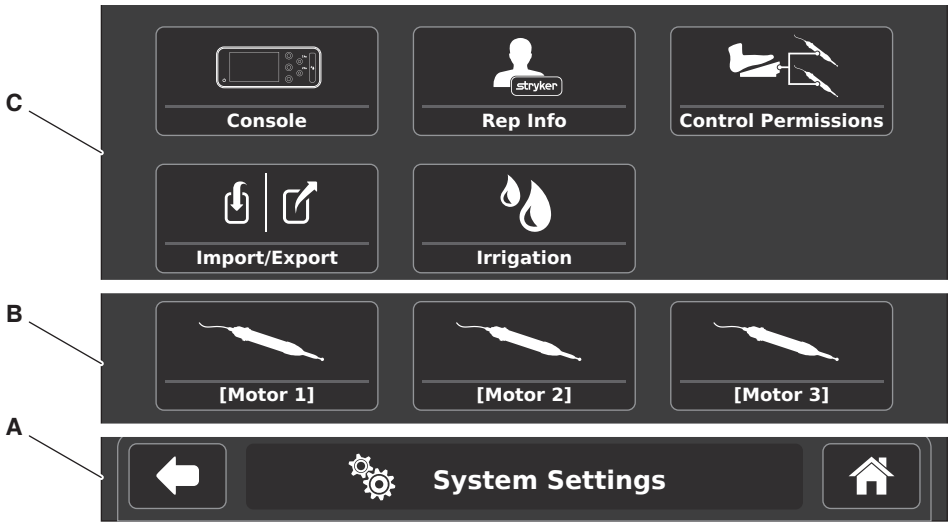


Figure 12 – System Settings Screen

A	**Navigation Bar Area** – Provides navigational buttons and displays the current screen name.
B	**Connected Motor(s) Area** – Provides access to the connected motors.
C	**System Settings Area** – Contains the following buttons: Console, Rep Info, Control Permissions, Import/Export, and Irrigation

12.3.1 Managing Console Settings

SYMBOL	DEFINITION	FUNCTION
	Volume	Use this menu tab to adjust the volume level.
	Brightness	Use this menu tab to adjust the screen or port brightness.
	Language	Use this menu tab to set the console language.
	System Info	Use this menu tab to access the system information.

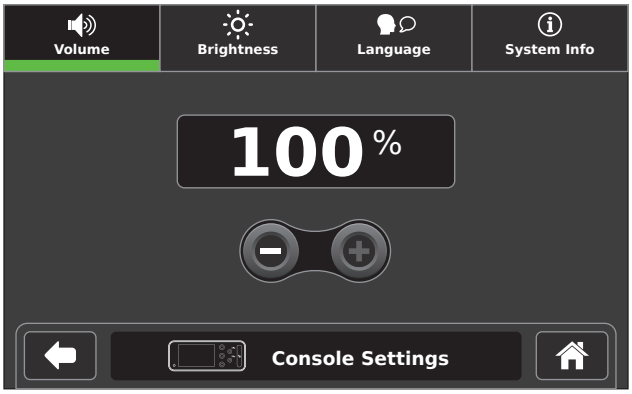


Figure 13 – Volume Menu Tab (Console Settings)

12.3.2 Managing Representative Information

SYMBOL	DEFINITION	FUNCTION
	Create	Use this button to create a new representative information profile.
	Edit	Use this button to edit a new representative information profile.
	Delete	Use this button to delete a new representative information profile.

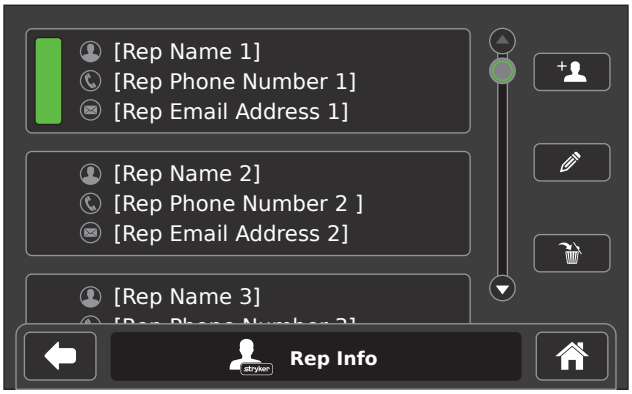


Figure 14 – Representative Information Screen

12.3.3 To Set Control Permissions

1. Access the Control Permissions screen.
2. For each connected motor, set control permissions as necessary (*Figure 15*).

Figure 15 – Control Permissions Screen

12.3.4 To Import and Exporting Preset(s)

NOTE: A USB data storage device must be inserted into the USB port to access the Import/Export screen.

1. Access the Import/Export screen.
2. Touch the **Import** or **Export** menu tab (depending on required outcome).
3. Touch the **SELECT ALL** button or touch the individual preset(s) to import/export (*Figure 16*).
4. Touch ✓ (**Confirm**).

NOTE: A pop-up message will appear upon completion.

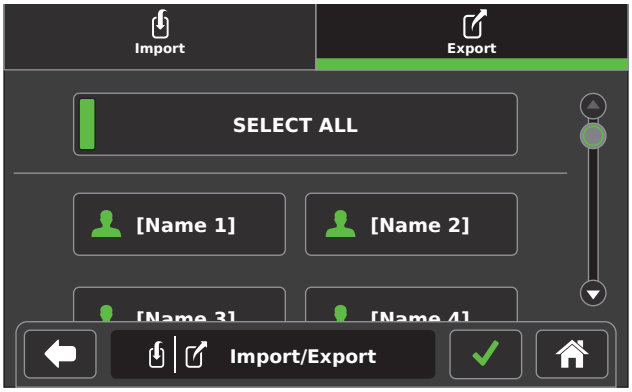


Figure 16 – Import/Export Screen

12.3.5 To Manage Irrigation Settings

NOTE: An irrigation cassette must be inserted into the irrigation port to access the Irrigation Settings screen.

1. Access the Irrigation Settings screen.
2. Adjust settings as necessary (*Figure 17*).

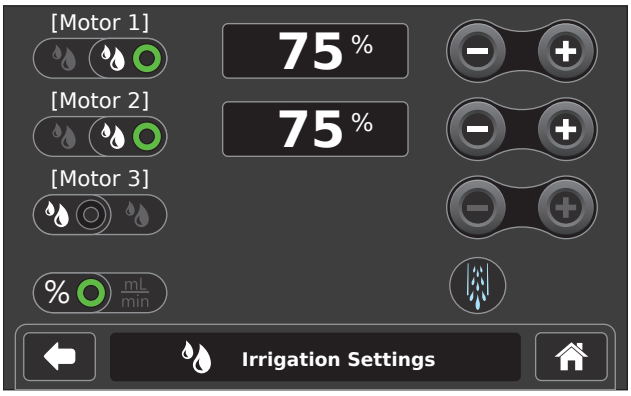


Figure 17 – Irrigation Settings Screen

12.3.6 Preparing the Irrigation Cassette

12.3.6.1 To Prime the Irrigation Cassette

NOTES:

- The prime feature is used to fill the irrigation tubing with sterile fluid and remove air pockets.
- After inserting an irrigation cassette, the Irrigation Settings screen will automatically be displayed.

1. (If required) Access the Irrigation Settings screen.
2. Touch (**Initial Prime**) to prime the irrigation cassette (*Figure 18*).

NOTE: A pop-up message will appear upon completion.

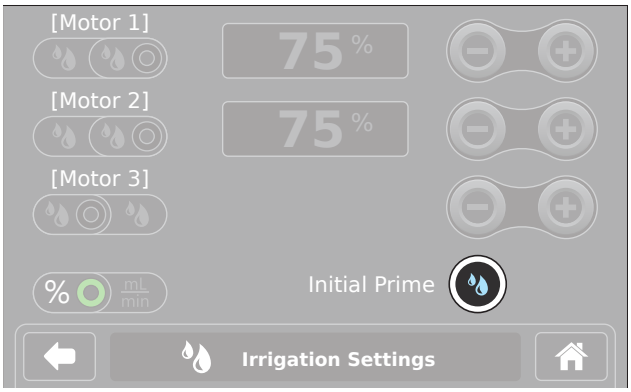


Figure 18 – Irrigation Settings (Initial Prime)

12.3.6.2 To Flush the Irrigation Cassette

NOTE: The flush feature is only available if the irrigation cassette has been primed and is used to maximize fluid flow through the irrigation tubing to remove lodged debris.

3. Touch and hold (**Flush**) until lodged debris is removed (*Figure 19*).

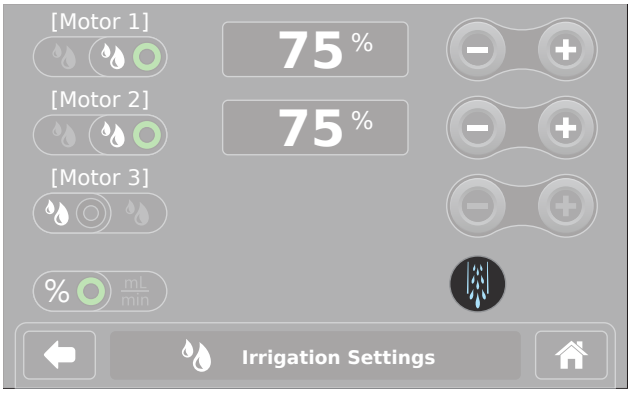


Figure 19 – Irrigation Settings (Flush)

12.3.7 Managing Motor Settings

NOTE: Available motor settings may vary. The console will only display settings that are available for the connected device.

12.3.7.1 General (Motor Settings)

SYMBOL	DEFINITION	FUNCTION
	General	Use this menu tab to adjust various motor settings.

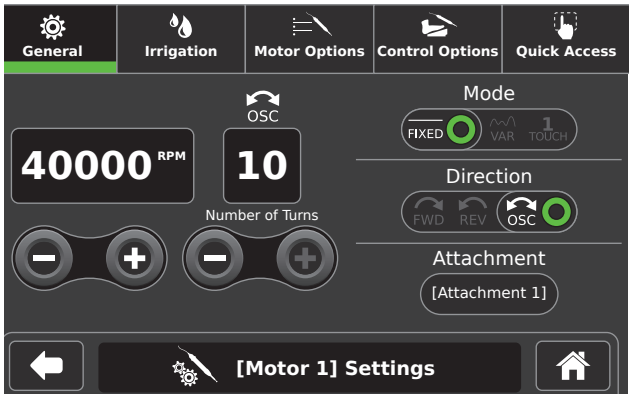


Figure 20 – General Menu Tab

12.3.7.2 Irrigation (Motor Settings)

SYMBOL	DEFINITION	FUNCTION
	Irrigation	Use this menu tab to adjust various motor irrigation settings.

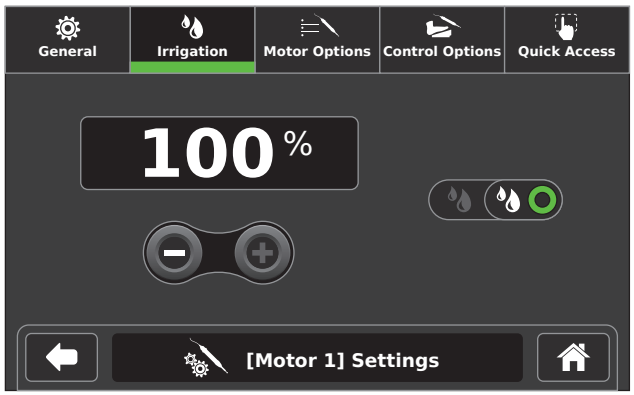


Figure 21 – Irrigation Menu Tab

12.3.7.3 Motor Options (Motor Settings)

SYMBOL	DEFINITION	FUNCTION
	Motor Options	Use this menu tab to adjust various motor options.

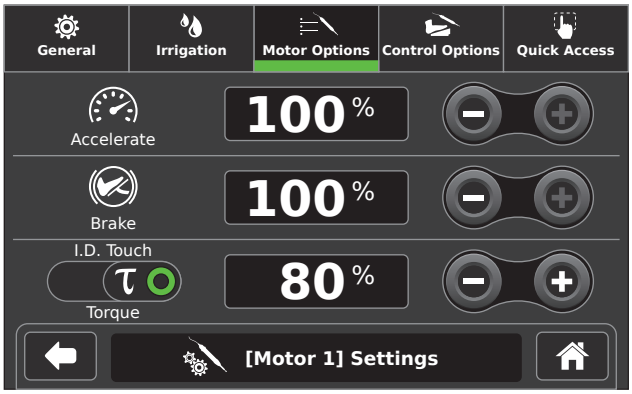


Figure 22 – Motor Options Menu Tab

12.3.7.4 Control Options (Motor Settings)

SYMBOL	DEFINITION	FUNCTION
	Control Options	Use this menu tab to adjust various control options.

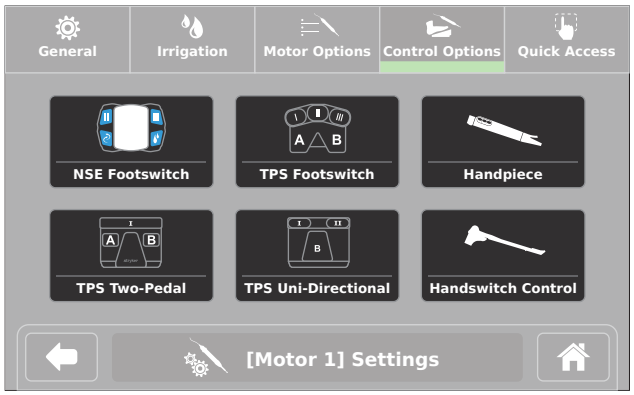


Figure 23 – Control Options Menu Tab

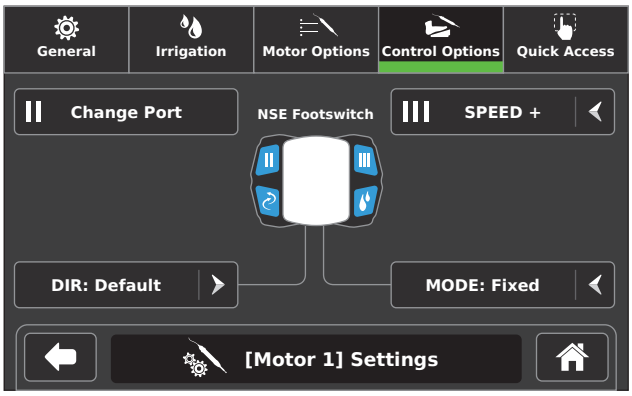


Figure 24 – NSE Footswitch Control Options

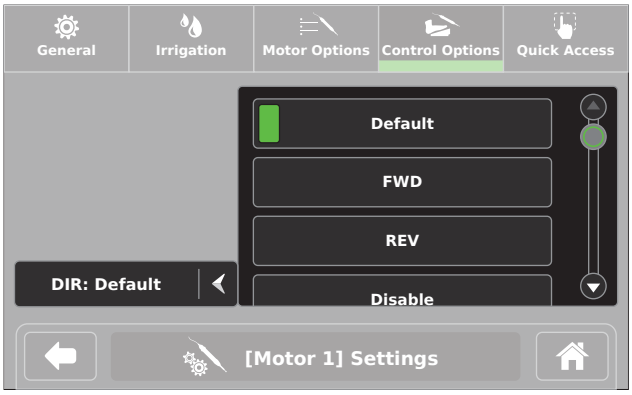


Figure 25 – Direction Options List

12.3.7.5 Quick Access (Motor Settings)

SYMBOL	DEFINITION	FUNCTION
	Quick Access	Use this menu tab to set direction, irrigation, mode, or I.D. Touch (torque) to be accessible from the Home screen. Choosing the No Quick Access option will remove the quick access button from the Home screen. The PREVIEW area displays a glimpse of the quick access area on the Home screen (*Figure 26*).

NOTE: In *Figure 26*, the Irrigation Control option was touched and appears in the PREVIEW area.

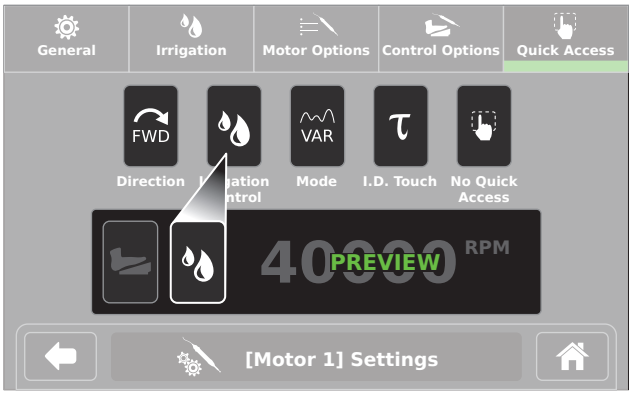


Figure 26 – Quick Access Menu Tab

13 Cleaning and Disinfection

WARNINGS:

- ALWAYS clean and disinfect the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient or healthcare staff injury.
- ALWAYS consult the Instructions For Use that accompanies motors, footswitches, and attachments for product specific cleaning requirements.

CAUTIONS:

- DO NOT immerse the equipment in liquid. DO NOT allow liquids or moisture to enter any electrical connection.
- DO NOT sterilize the console.
- DO NOT use solvents, lubricants, or other chemicals, including glutaraldehyde or similar chemical cleaners, unless otherwise specified.
- Use of unapproved disinfectants may cause damage to equipment.

13.1 Recommended Materials

- PPE as recommended by the disinfectant manufacturer
- Soft, lint-free cloth
- Brushes
- United States Environmental Protection Agency (US EPA) registered disinfectant with a claim for activity against Hepatitis B. The following disinfectants have been validated for use on the exterior surfaces of the Stryker CORE 2 Console:
  - Quaternary Ammonium Based - CaviCide® Disinfectant (EPA Registration #46781-6)
  - Sodium Hypochlorite Based - Clorox® Clean-Up® Disinfectant Cleaner with Bleach (EPA Registration #67619-17)

13.2 Clean and Disinfect Procedure

1. Lightly wipe all external surfaces of the console and power cord with a soft, lint-free cloth moistened with a non-abrasive, hospital disinfectant prepared according to the manufacturer's instructions. Clean surfaces until all visible soil is removed.
2. Wipe critical areas such as the area around the power button, irrigation cassette door, and any other areas that may have become soiled. Use appropriate brushes to remove soil from difficult to clean locations on the console that could not be thoroughly cleaned by wiping alone.
3. After removing all visible gross soil, use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the Instructions For Use supplied by the disinfectant manufacturer.
4. Remove any excess disinfectant solution using a soft, lint-free cloth moistened with water if required by the instructions supplied by the disinfectant manufacturer.

CAUTION: DO NOT use an aerosol spray directly on the console screen.

5. Apply glass cleaner to a soft, lint-free cloth and clean the console screen.

14 Troubleshooting

WARNING: DO NOT disassemble, modify, service, or repair any equipment without the authorization of the manufacturer. For assistance, contact Stryker.

PROBLEM	CORRECTIVE ACTION
Console powers OFF unexpectedly.	Verify the power cord is connected properly.
Console powers OFF due to elevated temperature.	Disconnect the console power cord from the hospital-grade power outlet for a minimum of five minutes before attempting to use the console again.
Console does not recognize a device.	Verify the device is connected properly. If necessary, remove and replace the device cord.
Electrical interference is experienced.	Turn off all equipment not in use in the operating room. Verify equipment is not placed too close to the console.

15 Maintenance

15.1 Fuse Replacement

WARNINGS:

- ALWAYS disconnect the power cord from the console before replacing the fuses. Failure to comply may cause an electrical shock hazard.
- ALWAYS use the same type and rated fuse when replacing fuses. Failure to comply may cause a fire hazard. See *Section 18.9* for fuse information.
- DO NOT use the console if a fuse immediately fails after replacement. For assistance, contact Stryker.

1. Remove power from the console as follows:

CAUTION: Some power cords have a locking mechanism, press the colored tab prior to disconnection.

   1.1. Disconnect the power cord from the console.

   1.2. If used, disconnect the equipotential cable.

2. Using a small flat blade screwdriver, gently pry open the cover of the fuse holder.
3. Remove the fuse holder from the console.
4. Remove the two fuses from the fuse holder and properly dispose of the fuses. See *17* for disposal information.
5. Install two new fuses into the fuse holder (*Figure 27*).
6. Securely install the fuse holder into the console.

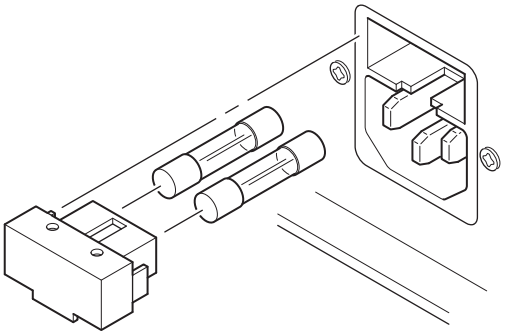


Figure 27 – Fuse Replacement

16 Storage and Handling

CAUTIONS:

- ALWAYS save the original packaging container for reuse. Failure to comply may result in damage during transport to the Stryker Service Center.
- ALWAYS store the equipment within the specified environmental condition values (*Section 18.9*).

17 Disposal/Recycle

WARNING: ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment.

To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, this device should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling.

Infected units should be decontaminated before they are sent for recycling. If it is not possible to decontaminate the unit for recycling, the hospital should not attempt to remove the batteries from waste equipment. Continued disposal of small amounts of portable batteries to landfill and incineration is allowed under Directive 2006/66/ EC and Member State regulations.

廢電池請回收

18 Appendices

18.1 Appendix A: Acronyms

ACRONYM	DEFINITION
DIR	Direction
EMC	Electromagnetic Compatibility
ENT	Ear, Nose, Throat
ES6	Electronic System 6
FWD	Forward
I.D.	Identification
IRR	Irrigation
MRI	Magnetic Resonance Imaging
OSC	Oscillating
PPE	Personal Protective Equipment
REV	Reverse
RF	Radio Frequency
RFID	Radio Frequency Identification
RPM	Rotations Per Minute
TPS	Total Performance System
UHT	Universal High Torque
UI	User Interface
USB	Universal Serial Bus
VAR	Variable

18.2 Appendix B: Audio Output

TYPE	DESCRIPTION
Button Press	A quick low pitched beep to denote actuation of a button.
Footswitch Mapping	
Volume Change	A quick low pitched beep to denote volume of a button press.
Confirm	Slightly elongated chime to denote completion of a task.
Motor Reverse	Two tone set of beeps to indicate the motor is rotating in reverse (counterclockwise).
Notice	Two tone ascending beep to indicate a notification.
Error	High two tone descending beep to indicate an error.
Prohibited	Low two tone descending beep to denote prohibited actions.

18.3 Appendix C: Colors

18.3.1 User Interface Colors

COLOR	DEFINITION
	Selected/Active
	Disabled/Inactive/Inaccessible

18.3.2 Power Button Illumination Colors

COLOR	DEFINITION
	Console On
	Console Standby Mode

18.4 Appendix D: Equipotential Bonding

Equipotential bonding involves the joining together of all metalwork and conductive items that are in the same potential (voltage) everywhere and is an important countermeasure in reducing the risk of equipment damage and personal injury. For additional information, refer to *IEC 60601-1 Clause 16*.

18.5 Appendix E: Power Cords

18.5.1 Power Cord General Specifications

Current Rating:	10 A
Voltage Rating:	250 VAC minimum
Frequency Rating:	50/60 Hz
Copper Conductor Size Rating:	3 X 1.00 mm^2 ≤ Conductor Size < 3 X 1.50 mm^2
Connector Type:	IEC 60320 C13
Cord Lengths:	3.0 m, 2.5 m **NOTE:** The 2.5 m cord is not for use in Canada or the US.
Temperature Rating:	0 °C to 70 °C minimum
Flammability Rating:	UL 94 V-2 minimum, IEC 60332-1
Cord Type:	SJT, H05VV-F, HVCTF, RVV or equivalent (unshielded)
Dielectric Withstand:	1500 VAC for 60-seconds between Line/Neutral and Protective Earth
Mains:	Plug shall have a ground/ earthing pin
Certification:	All applicable in-country medical electrical requirements

18.5.2 Additional Power Cord Requirements

The Canadian and US power supply cord shall have a tag or label in English and French indicating that “GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED ‘HOSPITAL ONLY’ OR ‘HOSPITAL GRADE’ “ or equivalent wording.

Agency Approval: CSA Certified for Canada and US or UL Recognized for Canada and US.

18.6 Appendix F: Intellectual Property

18.6.1 Software Licensing

Refer to the *Software License Addendum* REF 5400-052-704 supplied with the console.

18.6.2 Trademarks

Trademarks not the property of Stryker Corporation are the property of their respective owners.

18.7 Appendix G: Footswitch Pedal/Pad Options

WARNING: ALWAYS consult the Instructions For Use that accompanies motors, footswitches, and attachments for product specific duty cycles and additional information.

NOTE: Available options may vary. The console will only display options that are available for the connected device.

18.7.1 Footswitch Pedal Direction Options

OPTION	FUNCTION
Default	These settings may be factory default settings of the connected motor or user programmed settings.
Disable	Disables the footswitch pedal.
Forward (FWD)	Pressure on the pedal will cause the motor to rotate in the forward (clockwise) direction.
Reverse (REV)	Pressure on the pedal will cause the motor to rotate in the reverse (counterclockwise) direction.
Oscillate (OSC)	Pressure on the footswitch pedal will cause the motor to oscillate.
(OSC <> FWD)	Pressure on the pedal will cause the motor to oscillate when in the oscillate operating mode and forward (clockwise) direction when in normal operating mode.
(OSC <> REV)	Pressure on the pedal will cause the motor to oscillate when in the oscillate operating mode and reverse (counterclockwise) direction when in normal operating mode.

18.7.2 Footswitch Pedal Mode Options

OPTION	FUNCTION
Default	Causes the motor to operate according to the factory default setting of the connected motor. Specific default settings vary based on how the motor was programmed at the factory.
Variable	Varying pressure on the footswitch pedal will cause the motor speed to vary.
Fixed	Pressure on the footswitch pedal will cause the motor to operate at a constant speed as set on the Home screen.
1Touch	Press and release the footswitch pedal to activate the motor to operate at a constant speed as set on the Home screen. Press and release the footswitch pedal again to deactivate the motor operation.

18.7.3 Footswitch Pad Options

NOTE: The IRR On/Off and FWD<>REV buttons on the NSE Footswitch cannot be programmed to any footswitch pad options.

OPTION	FUNCTION
Disable	Disables the footswitch pad.
SPEED +	Pressure on the pad will increment the set point speed.
SPEED -	Pressure on the pad will decrement the set point speed.
IRR +	Pressure on the footswitch pad will increment the pump flow set point and increase irrigation to the motor cutting accessory.
IRR -	Pressure on the footswitch pad will decrement the pump flow set point and decrease irrigation to the motor cutting accessory.
IRR On/Off	Pressure on the footswitch pad will toggle the irrigation pump on and off.
Change Port	Pressure on the footswitch pad will change the footswitch assignment to another assigned motor.
Flush	Pressure on the pad will turn the irrigation pump on at the flush rate (300%).
OSC<>Normal	Pressure on the pad will toggle the operating mode of the motor.
FWD<>REV	Pressure on the pad will toggle the direction of the motor rotation.
Change Attachment	Pressure on the footswitch pad will toggle through the list of available attachments for the motor.
Jog	Pressure on the footswitch pad will cause the cutting accessory to rotate at a very low speed to position the cutting edge within the cutting window.

18.8 Appendix H: Errors and Notifications

NOTE: Items within [brackets] in the following table are variables. For assistance, contact Stryker.

CODE	TITLE	CORRECTIVE ACTION
00000005	Motor Actuation Error	The console only allows two motors to operate simultaneously.
00000006	Motor Actuation Error	Connected motors cannot operate simultaneously.
00000007	Motor Actuation Error	[Motor] has multiple active inputs. Only the first input detected is used. If the motor is inactive, release all inputs and try again.
00001000 00001001	Motor Functional Error	[Motor] or cord connected to Port [port] requires service. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00001002	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00001003	Motor Actuation Error	Reset [motor] actuation. Release the motor button, trigger, or handswitch lever to reset. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00001004	Motor Compatibility Error	Motor connected to Port [port] is not supported. See the For Use With section of the Instructions For Use provided with the equipment.
00001005	Motor/Console Functional Error	Error detected with [motor] connected on Port [port]. Remove [motor] from Port [port]; use a different motor. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00001007	Motor Functional Error	Error detected with [motor] connected to Port [port]. Remove [motor] from Port [port]. If the error is resolved, return [motor] and cord to Stryker. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00001008	Motor Temperature Error	[Motor] connected to Port [port] has reached an elevated operating temperature. Allow handpiece to cool before restarting.
00001009	Motor Temperature Error	[Motor] or cord connected to Port [port] requires service. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
0000100A	Motor Service Requirement	[Motor] requires service. Return handpiece to Stryker for service. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
0000100B	Motor Stall Error	Excessive load detected on Port [port]. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
0000100E	Cutter Speed Notification	Ensure [motor] speed does not exceed specified attachment limitations. Failure to do so may result in user and/or patient injury.
00002000 00002001	Footswitch Functional Error	Footswitch connected to port [port] requires service. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00002002	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00002003	Footswitch Actuation Error	Reset Footswitch [port] actuation. Release the footswitch button or pedal to reset the actuation. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.

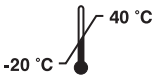
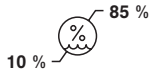
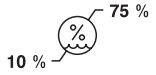
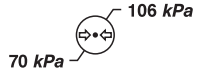
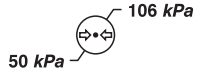
CODE	TITLE	CORRECTIVE ACTION
00002004	Footswitch Compatibility Error	Footswitch connected to Port [port] is not supported. See the For Use With section of the Instructions For Use provided with the equipment.
00002005	Footswitch/ Console Functional Error	Error detected with footswitch on Port [port]. Remove the footswitch from Port [port]; use a different footswitch. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00002006	Footswitch Functional Error	Footswitch connected to port [port] requires service. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003001	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003002	Console Functional Error	Irrigation pump is nonfunctional. Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003003	Console Functional Error	RFID is nonfunctional. Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003004 00003005	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003006	Console Functional Error	Port illumination error occurred. Continue without illumination or report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003007 00003008 00003009 0000300A 0000300B	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
0000300C	Motor/Console Functional Error	Error detected with [motor] on Port [port]. Remove [motor] and cord from Port [port]; use a different motor or cord. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
0000300D	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
0000300E	Console Functional Error	Ensure irrigation cassette is installed properly.
00003010	Motor Attachment Error	Use a Stryker approved cutter. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003011	Irrigation Cassette Error	Use a Stryker approved irrigation cassette. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003012 00003013	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003014	Console Functional Error	Error with audio function. Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003015	Console Functional Error	Power supply over temperature. This may result from excessive use of motor duty cycle. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.

CODE	TITLE	CORRECTIVE ACTION
00003016	Console Functional Error	Power supply temperature sensor error. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003017	USB Error	Unrecognized USB device connected.
00003018 00003019	Console Functional Error	RFID is nonfunctional. Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003101	Console Functional Error	Irrigation pump is nonfunctional. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003102	Console Functional Error	RFID is nonfunctional. Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003103 00003104	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003105	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003106	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003107	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00003108 00003109 0000310A	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00004001 00004002 00004003 00004004	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00004005	Motor/Console Functional Error	Disconnect all motors and reset the console. If the error is resolved, return the motors and cords to Stryker. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00004006	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00004007 00004008	Motor/Console Functional Error	Disconnect all motors and reset the console. If the error is resolved, return the motors and cords to Stryker. If the error persists, report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.
00004009 0000400A 0000400B 0000400C 00004101 00004102 00004103 00004104 00004105	Console Functional Error	Report error code to Stryker. See the Contact Information section of the Instructions For Use provided with the equipment to contact Stryker.

18.9 Appendix I: Specifications

Model:	CORE 2 Console
REF:	REF 5400-052-000
Dimensions:	
Width:	13.0 inch [330.2 mm]
Height:	5.4 inch [137.2 mm]
Depth:	17.4 inch [442.0 mm]
Weight:	17.3 lb [7.8 kg]
Equipment Type:	Class 1  Type BF Applied Part
Power Supply:	Input voltage: 100-240 V ~ 50/60 Hz, 6-3 A Motor port output voltage: 40 V ⎓ Footswitch port output voltage: 5 V ⎓
Fuse Type, Rating, and Breaking Capacity:	2 x 6.3 A, 250 VAC, 5 x 20 mm, (F) Fast-Acting, (L) Low Breaking Capacity 63 A at 250 VAC, IEC 60127
Enclosure (Ingress) Protection:	IPX0
Ground Type:	 Protective Earth (ground); when connected to facility power
Mode of Operation:	Continuous operation with intermittent loading
Duty Cycle:	See the duty cycle times defined in the Instructions For Use supplied with the motor and/or accessories.
Product Safety Certification:	 **CSA International** **Canadian Standards Association (CSA)** *CAN/CSA-C22.2 No. 60601-1:14, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; (IEC 60601-1:2005+A1:2012, MOD)* **American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)** *ANSI/AAMI ES60601-1:2005/(R) 2012, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; Consolidated Reprint (2009/(R) 2012); Amendment 2 (2010/(R) 2012); Amendment 1 (2012)*

Product Safety Compliance:	**International Electrotechnical Commission (IEC)**
	IEC 60601-1:2005, Ed: 3.1, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; Corrigendum 1 (2006); Corrigendum 2 (2007); Amendment 1 (2012)
	IEC 60601-1-2:2007 Ed: 3, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Compatibility
	IEC 60601-1-2:2014 Ed: 4, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Disturbances
	IEC 60601-1-6:2010+ A1:2013 Ed. 3.1, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Usability
	IEC 62366-1:2007+ A1:2014 Ed 1.1, Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
	IEC 62304:2015 Ed: 1.1, Medical Device Software – Software Life Cycle Processes
	European Committee for Electrotechnical Standardization (CENELEC)
	EN 60601-1:2006+A12:2014, Ed: 3.1, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011); IEC Amendment 1 (2013); IEC Corrigendum 3 (2014); CENELEC Amendment A12 (2014)
	The Regulatory Compliance Mark (RCM) is a visible indication of a product's compliance with all applicable ACMA regulatory arrangements, including all technical and record-keeping requirements.
RFID Module:	
Frequency of Operation:	13.56 MHz
RF Field Strength:	67.92 dBµV/m at 3 m
Touch Screen:	7 inch [177.8 mm] (800 x 480), 24-bit color, wide viewing angle: 170˚
Adjustable Volume:	0 dBA to 52 dBA

Environmental Conditions:	**Operation**	**Storage and Transportation**
Temperature:		
Humidity Limitation:		
Atmospheric Pressure Limitation:		

18.10 Appendix J: Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic emissions		
The CORE 2 Console is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE 2 Console should assure that the console is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The CORE 2 Console uses RF energy only for the internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The CORE 2 Console is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. Mitigation measures may be necessary, such as reorienting or relocating the CORE 2 Console or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The CORE 2 Console is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE 2 Console should assure that the console is used in such an environment. NOTE: The values provided in the table below have changed due to 60601-1-2 4th Edition requirements.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±6, ±8 kV Contact ±2, ±4, ±8, ±15 kV Air	±2, ±4, ±6, ±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 IEC 61000-4-4	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±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 0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T (100% dip in U_T) for 1 cycle at 0˚ 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚ <5% U_T (>95% dip in U_T) for 5 s 0% U_T (100% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T (100% dip in U_T) for 1 cycle at 0˚ 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚ <5% U_T (>95% dip in U_T) for 5 s 0% U_T (100% 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 CORE 2 Console requires continued operation during power mains interruptions, it is recommended that the CORE 2 Console be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m at 50 and 60 Hz	3 A/m, 30 A/m at 50 and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The CORE 2 Console is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE 2 Console should assure that the console is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz outside ISM bands 80% AM at 1 kHz

6 Vrms 150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz</td><td>3 Vrms 150 kHz to 80 MHz outside ISM bands 80% AM at 1 kHz

6 Vrms 150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz</td><td rowspan="2">IEC 60601-1-2 3rd Edition:
Portable and mobile RF equipment should be used no closer to any part of the CORE 2 Console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = 1.17\sqrt{P}$ 150 kHz to 80 MHz
$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 800 MHz to 2.7 GHz

IEC 60601-1-2 4th Edition:
⚠ WARNING: Portable RF 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 CORE 2 Console including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 metres (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:
 
(Non-ionizing electromagnetic radiation)</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz</td><td>3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz</td></tr>
</table>

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 CORE 2 Console is used exceeds the applicable RF compliance level above, the CORE 2 Console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CORE 2 Console.

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

IEC 60601-1-2 3rd Edition: Recommended separation distances between portable and mobile RF equipment and the CORE 2 Console			
The CORE 2 Console is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CORE 2 Console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF equipment (transmitters) and the CORE 2 Console as recommended below, according to the maximum output power of the equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.7 GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the 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.

18.11 Appendix K: Compliance Statements

The CORE 2 Console creates and uses radio frequencies and may cause interference with other medical equipment. If interference occurs, see the information contained within this appendix.

Federal Communications Commission (FCC) & Industry Canada (IC)

Contains RFID Module: 4 Channel RFID Module
FCC ID: Q9R-5400052020
IC: 4919A-5400052020

This device complies with FCC Part 15 and Industry Canada license exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Changes or modifications not expressly approved by Stryker Instruments could void your authority to operate the equipment.

Hazardous Materials Statement (China Only)

Hazardous Substances						
Part Name	**Lead (Pb)**	**Mercury (Hg)**	**Cadmium (Cd)**	**Hexavalent Chromium (Cr (VI))**	**Polybrominated Biphenyls (PBB)**	**Polybrominated Diphenyl Ethers (PBDE)**
Front Bezel	X	O	O	O	O	O
Motor Controller PCBA	X	O	O	O	O	O
Irrigation Pump Controller PCBA	X	O	O	O	O	O
Main Controller PCBA	X	O	O	O	O	O
IMX53 SOM PCBA	X	O	O	O	O	O
Power Supply	X	O	O	O	O	O
This table is prepared in accodance with the provisions of SJ/T 11364.						
O: Indicates that said haxardous substance contained in all of the homogeneous materials for this part is below the limit requirement of GB/T 26572.						
X: Indicates that said hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement of GB/T 26572.						
Enterprises may further provide in this box technical explanation for marking “X” based on their actual circumstances.						

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