

11.5 Preset Instructions

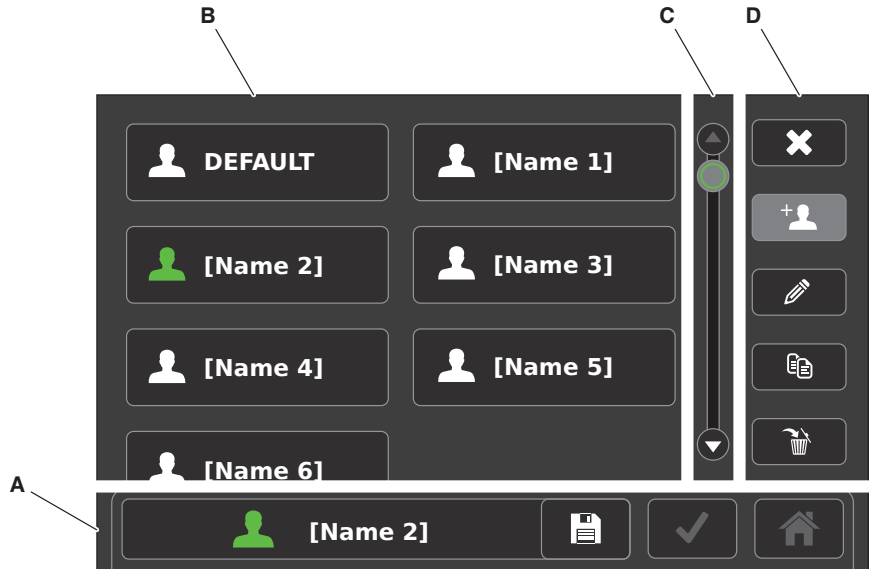


Figure 11 – Preset Screen

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

11.5.1 Create a Preset

1. From (Home) navigate as follows: (Preset)
2. Touch (Create).
3. Enter a preset name, then touch (Next).
4. From the list of motors, touch a motor to add.
5. Manage motor settings as necessary (Section 11.6.7).

11.5.2 Edit a Preset

1. From (Home) navigate as follows: (Preset)
2. In the preset area, touch the preset file to edit.
3. Touch (Edit).
4. From the list of motors, touch the motor to add/edit.
5. Manage motor settings as necessary (Section 11.6.7).

11.5.3 Copy a Preset

1. From (Home) navigate as follows: (Preset)
2. In the preset area, touch the preset file to copy.
3. Touch (Copy).
4. Enter a name, then touch (Next).

11.5.4 Delete a Preset

1. From (Home) navigate as follows: (Preset)
2. In the preset area, touch the preset file to delete.
3. Touch (Delete).
4. Touch (Confirm).

11.5.5 Save a Preset

1. From (Home) navigate as follows: (Preset)
2. Touch the save button (Figure 11).
3. From the Save Current Preset screen, touch Save or Save As.

**NOTE:** For Save As, enter a new preset name.

4. Touch (Confirm).

11.5.6 Load a Preset

1. From (Home) navigate as follows: (Preset)
2. In the preset area, touch the preset file to load.
3. Touch (Confirm).

11.6 System Settings Instructions

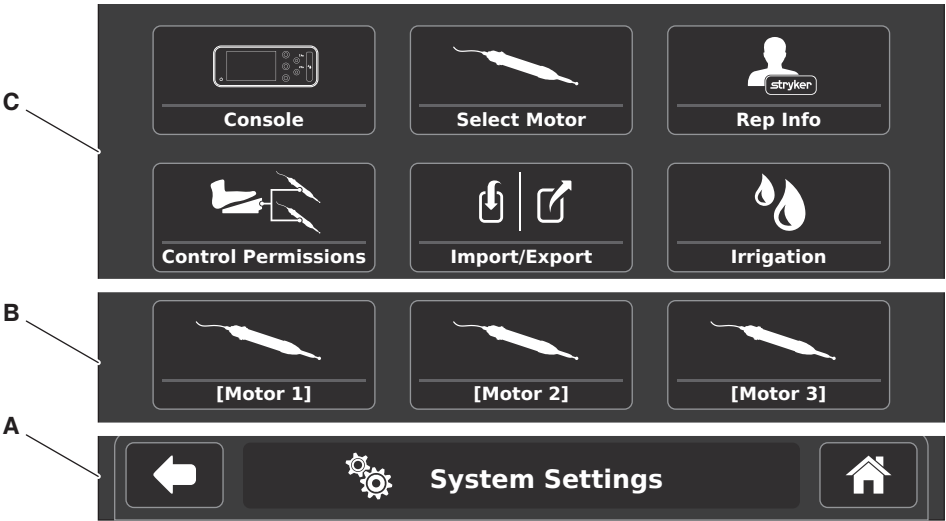


Figure 12 – System Settings Screen

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

11.6.1 Manage Console Settings

- 1. From (Home) navigate as follows:  
 (Settings) > (Console)
- 2. Touch the applicable menu tab to manage console settings as necessary (Figure 13):

| SYMBOL | DEFINITION  | FUNCTION                |
|--------|-------------|-------------------------|
|        | Volume      | Adjust volume           |
|        | Brightness  | Adjust brightness       |
|        | Language    | Set language            |
|        | System Info | View system information |

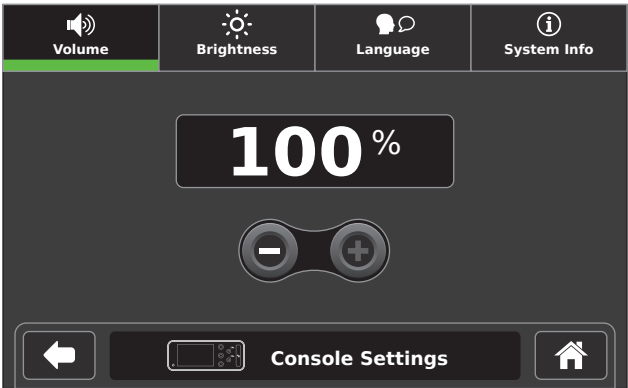


Figure 13 – Console Settings Screen

## 11.6.2 Select a Motor and Edit Settings

1. From  (Home) navigate as follows:  
 (Settings) >  (Select Motor)
2. From the list, touch the motor to edit (Figure 14).
3. Manage motor settings as necessary (Section 11.6.7).

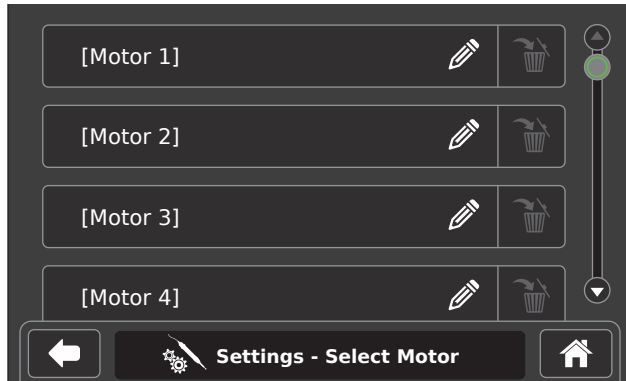


Figure 14 – Select Motor Screen

## 11.6.3 Manage Representative Information

### 11.6.3.1 Create New Rep Info

1. From  (Home) navigate as follows:  
 (Settings) >  (Rep Info)
2. Touch  (Create).
3. Enter a name, then touch  (Next).
4. Enter a phone number, then touch  (Next).
5. Enter an email address, then touch  (Confirm).

### 11.6.3.2 Edit Rep Info

1. From  (Home) navigate as follows:  
 (Settings) >  (Rep Info)
2. Touch the representative information file to edit.
3. Touch  (Edit).
4. Edit the name, then touch  (Next).
5. Edit the phone number, then touch  (Next).
6. Edit the email address, then touch  (Confirm).

### 11.6.3.3 Delete Rep Info

1. From  (Home) navigate as follows:  
 (Settings) >  (Rep Info)
2. Touch the representative information file to delete.
3. Touch  (Delete).
4. Touch  (Confirm).

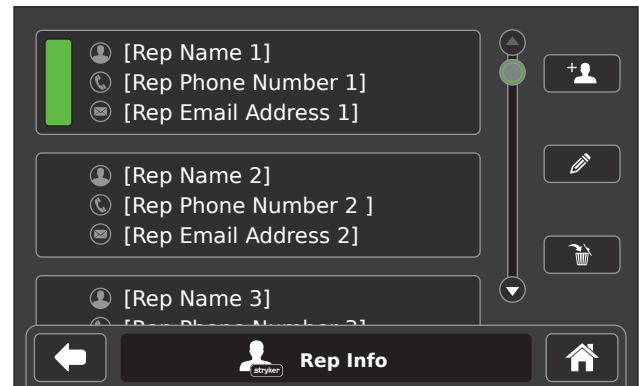


Figure 15 – Representative Information Screen

## 11.6.4 Set Control Permissions

1. From  (Home) navigate as follows:  
 (Settings) >  (Control Permissions)
2. For each connected motor, set control permissions as necessary (Figure 16).

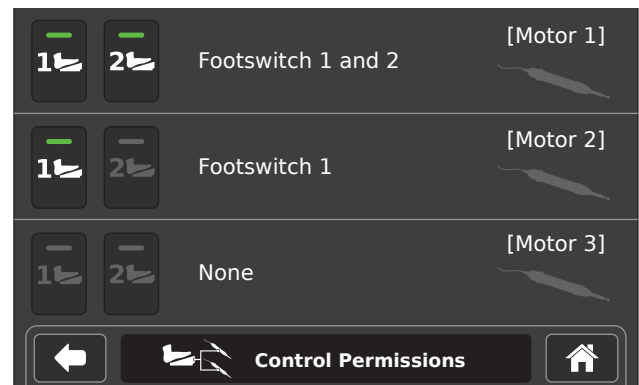


Figure 16 – Control Permissions Screen

### 11.6.5 Import/Export Presets

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

1. From  (Home) navigate as follows:  
 (Settings) >  (Import/Export)
2. Touch the **Import** or **Export** menu tab (depending on required outcome).
3. Touch the **SELECT ALL** button or touch the individual preset file(s) to import/export (Figure 17).
4. Touch  (Confirm).

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

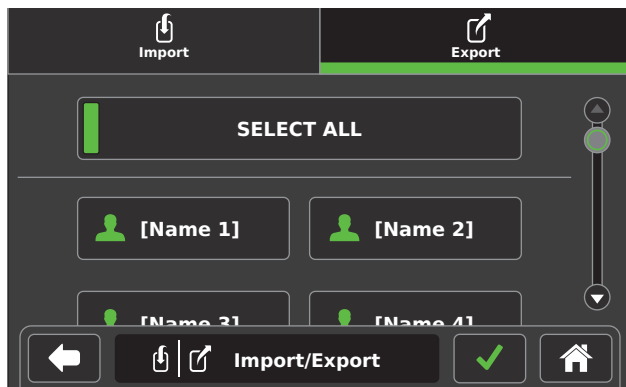


Figure 17 – Import/Export Screen

### 11.6.6 Manage Irrigation

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

1. From  (Home) navigate as follows:  
 (Settings) >  (Irrigation)
2. Adjust settings as necessary (Figure 18).

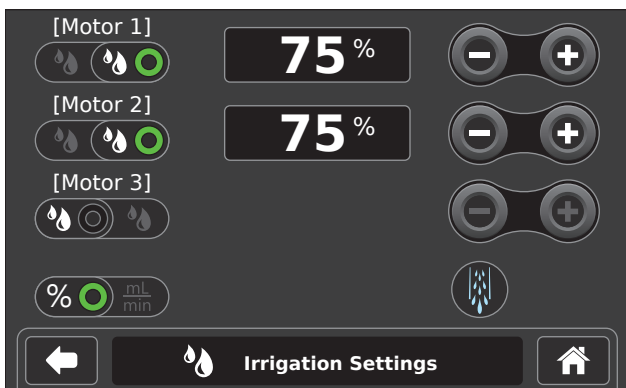


Figure 18 – Irrigation Settings Screen

#### 11.6.6.1 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) From  (Home) navigate as follows:  
 (Settings) >  (Irrigation)
2. Touch  (Initial Prime) to prime the irrigation cassette (Figure 19).

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

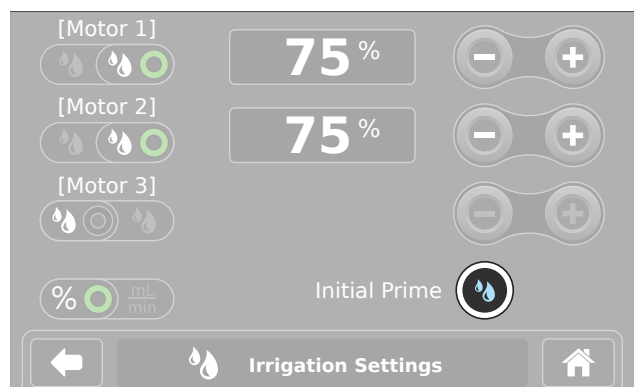


Figure 19 – Irrigation Settings (Initial Prime)

#### 11.6.6.2 Flush Irrigation Tubing

**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.

1. From  (Home) navigate as follows:  
 (Settings) >  (Irrigation)
2. Touch and hold  (Flush) until lodged debris is removed (Figure 20).

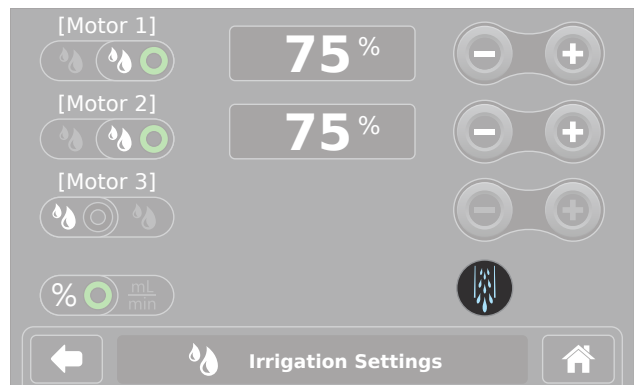


Figure 20 – Irrigation Settings (Flush)

## 11.6.7 Manage Motor Settings

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

### 11.6.7.1 Adjust General (Motor Settings)

- From  (Home) navigate as follows:  
 (Settings) >  (Motor Name)
- Adjust settings as necessary (Figure 21).

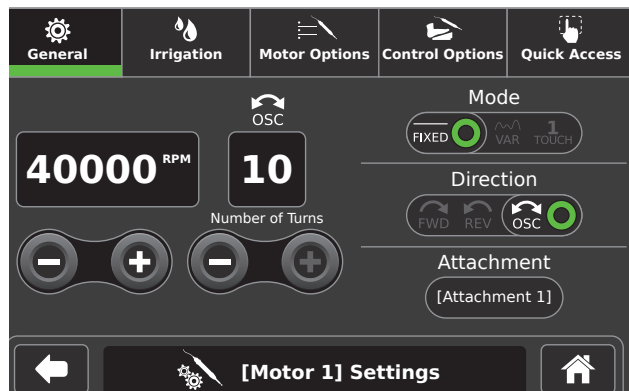


Figure 21 – General (Motor Settings) Screen

### 11.6.7.2 Adjust Irrigation (Motor Settings)

- From  (Home) navigate as follows:  
 (Settings) >  (Motor Name)
- Touch  (Irrigation).
- Adjust settings as necessary (Figure 22).

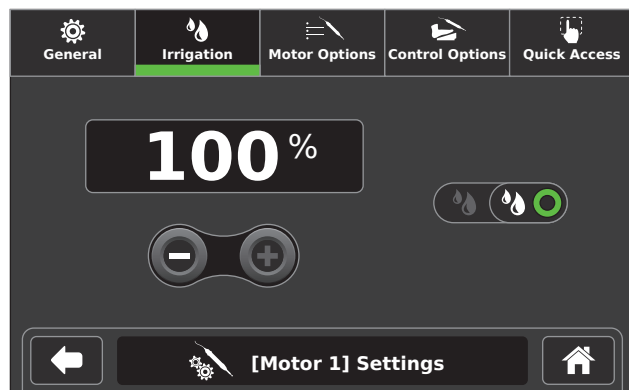


Figure 22 – Irrigation Screen

### 11.6.7.3 Adjust Motor Options

- From  (Home) navigate as follows:  
 (Settings) >  (Motor Name)
- Touch  (Motor Options).
- Adjust settings as necessary (Figure 23).

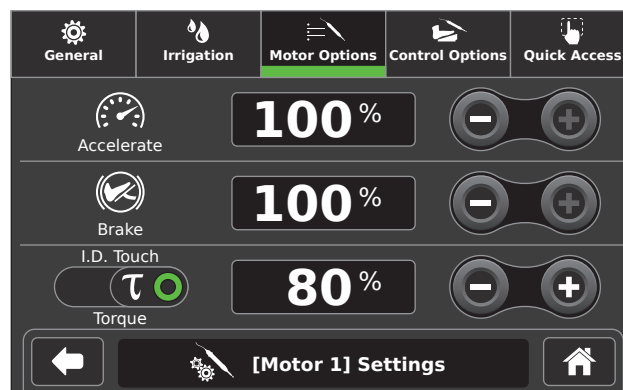


Figure 23 – Motor Options Screen

### 11.6.7.4 Adjust Control Options

- From  (Home) navigate as follows:  
 (Settings) >  (Motor Name)
- Touch  (Control Options).
- Touch the control device button to adjust options for that specific device (Figure 24).

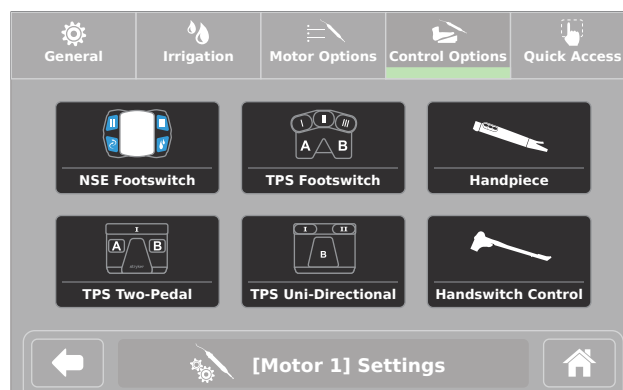


Figure 24 – Control Options Screen

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

- Adjust control options as necessary (Figure 25 and Figure 26).

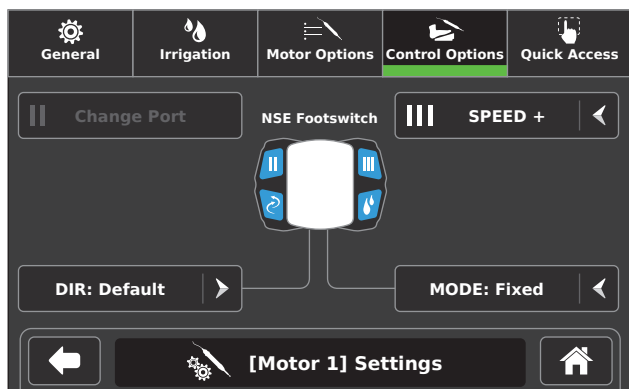


Figure 25 – NSE Footswitch Control Options Screen

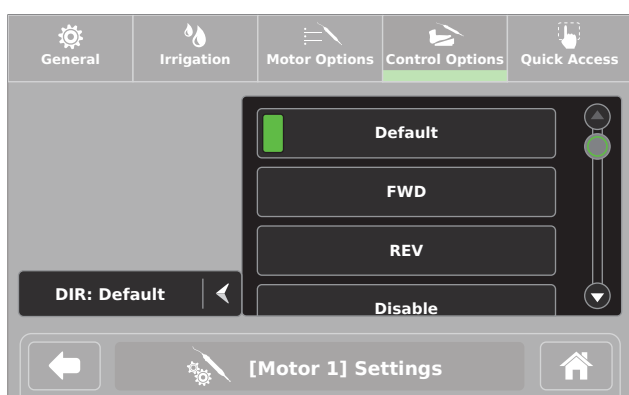


Figure 26 – Options List

#### 11.6.7.5 Set Quick Access

##### NOTES:

- From the Quick Access menu tab, the user can choose to set direction, irrigation, or mode 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 27).

- From **Home** navigate as follows:  
 ⚙️ (**Settings**) > 🗑️ (**Motor Name**)
- Touch **Quick Access**.
- Touch the applicable option (Direction, Irrigation Control, Mode, or No Quick Access) to set as the quick access button (Figure 27).

**NOTE:** In Figure 27, the Irrigation Control option was touched and appears in the PREVIEW area.

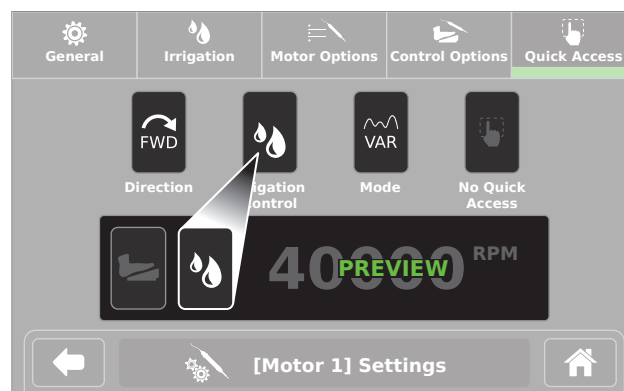


Figure 27 – Quick Access Screen

## 12 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.

### 12.1 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)

### 12.2 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.

## 13 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.                                |

## 14 Maintenance

### 14.1 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 Appendix I: Specifications 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 Section 16 for disposal information.
5. Install two new fuses into the fuse holder (Figure 28).
6. Securely install the fuse holder into the console.

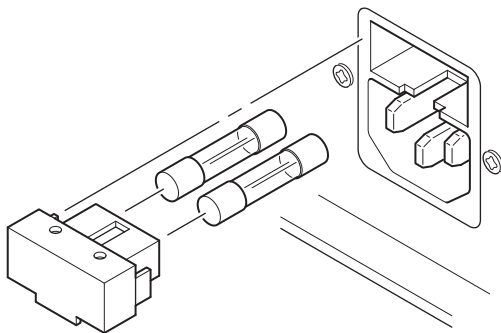


Figure 28 – Fuse Replacement

## 15 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 (Appendix I: Specifications).

## 16 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

## 17 Appendices

### 17.1 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                       |

### 17.2 Appendix B: Audio Output

| TYPE          | DESCRIPTION                                                                            |
|---------------|----------------------------------------------------------------------------------------|
| Button Press  | A quick low pitched beep to denote actuation of a button.                              |
| 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.                             |

### 17.3 Appendix C: Colors

#### 17.3.1 User Interface Colors

| COLOR                                                                              | DEFINITION                     |
|------------------------------------------------------------------------------------|--------------------------------|
|  | Selected/Active                |
|  | Disabled/Inactive/Inaccessible |

#### 17.3.2 Power Button Illumination Colors

| COLOR                                                                             | DEFINITION           |
|-----------------------------------------------------------------------------------|----------------------|
|  | Console On           |
|  | Console Standby Mode |

### 17.4 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*.

## 17.5 Appendix E: Power Cords

### 17.5.1 Power Cord General Specifications

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

### 17.5.2 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.

## 17.6 Appendix F: Intellectual Property

### 17.6.1 Software Licensing

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

### 17.6.2 Trademarks

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

## 17.7 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.

### 17.7.1 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.                                |

### 17.7.2 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. |

### 17.7.3 Footswitch Pad Options

**NOTES:**

- The IRR On/Off and FWD<>REV buttons on the NSE Footswitch cannot be programmed to any footswitch pad options.
- Button II cannot be programmed to any footswitch pad options for any of the footswitches.

| 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. |

## 17.8 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<br>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<br>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                                                 | 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.                                                                                                       |
| 00003005                                                 |                                      |                                                                                                                                                                                                                                                                                           |
| 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<br>00003008<br>00003009<br>0000300A<br>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<br>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<br>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<br>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<br>00003109<br>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<br>00004002<br>00004003<br>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<br>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<br>0000400A<br>0000400B<br>0000400C<br>00004101<br>00004102<br>00004103<br>00004104<br>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.                                                                                                                                       |

## 17.9 Appendix I: Specifications

|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Model:</b>                                    | CORE 2 Console                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>REF:</b>                                      | REF 5400-052-000                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Dimensions:</b>                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                  | <b>Width:</b> 13.0 inch [330.2 mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                  | <b>Height:</b> 5.4 inch [137.2 mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                  | <b>Depth:</b> 17.4 inch [442.0 mm]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Weight:</b>                                   | 17.3 lb [7.8 kg]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Equipment Type:</b>                           | Class 1  Type BF Applied Part                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Power Supply:</b>                             | Input voltage: 120 V ~ 60 Hz, 6.0 A<br>100 V ~ 50-60 Hz, 6.0 A<br>240 V ~ 50-60 Hz, 3.0 A<br><br>Motor port output voltage: 40 V ===<br>Footswitch port output voltage: 5 V ===                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Fuse Type, Rating, and Breaking Capacity:</b> | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Enclosure (Ingress) Protection:</b>           | IPX0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Ground Type:</b>                              |  Protective Earth (ground); when connected to facility power                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Mode of Operation:</b>                        | Continuous operation with intermittent loading                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Duty Cycle:</b>                               | See the duty cycle times defined in the Instructions For Use supplied with the motor and/or accessories.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Product Safety Certification:</b>             |  <b>CSA International</b><br>C US<br><b>Canadian Standards Association (CSA)</b><br><i>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)</i><br><b>American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)</b><br><i>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)</i> |

**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 dBμA/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 |
|-----------------------------------------|-----------|----------------------------|
| <b>Temperature:</b>                     |           |                            |
| <b>Humidity Limitation:</b>             |           |                            |
| <b>Atmospheric Pressure Limitation:</b> |           |                            |

## 17.10 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<br>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<br>CISPR 11                                                                                                                                                                                 | Class A    | <p>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:</p> <p> <b>WARNING:</b> 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.</p> |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                                      | Class A    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Voltage fluctuations/<br>flicker emissions<br>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)<br>IEC 61000-4-2                                                                                                                                                           | ±2, ±4, ±6, ±8 kV Contact<br>±2, ±4, ±8, ±15 kV Air                                                                                                                                                                                                                                                                                                                                                                                    | ±2, ±4, ±6, ±8 kV Contact<br>±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/<br>burst<br>IEC 61000-4-4                                                                                                                                                     | ±2 kV at 100 kHz repetition frequency for power supply lines<br>±1 kV at 100 kHz repetition frequency for input/output lines                                                                                                                                                                                                                                                                                                           | ±2 kV at 100 kHz repetition frequency for power supply lines<br>±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<br>IEC 61000-4-5                                                                                                                                                                                   | ±0.5, ±1 kV line(s) to line(s)<br>±0.5, ±1, ±2 kV line(s) to earth                                                                                                                                                                                                                                                                                                                                                                     | ±1 kV line(s) to line(s)<br>±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<br>IEC 61000-4-11                                                                                                   | $<5\% U_T$<br>(>95% dip in $U_T$ )<br>for 0.5 cycle<br>$0\% U_T$<br>(100% dip in $U_T$ )<br>for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br>$0\% U_T$ (100% dip in $U_T$ )<br>for 1 cycle at 0°<br>$40\% U_T$ (60% dip in $U_T$ )<br>for 5 cycles<br>$70\% U_T$<br>(30% dip in $U_T$ )<br>for 25 & 30 cycles at 0°<br>$<5\% U_T$<br>(>95% dip in $U_T$ )<br>for 5 s<br>$0\% U_T$<br>(100% dip in $U_T$ )<br>for 5 s | $<5\% U_T$<br>(>95% dip in $U_T$ )<br>for 0.5 cycle<br>$0\% U_T$<br>(100% dip in $U_T$ )<br>for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°<br>$0\% U_T$ (100% dip in $U_T$ )<br>for 1 cycle at 0°<br>$40\% U_T$ (60% dip in $U_T$ )<br>for 5 cycles<br>$70\% U_T$<br>(30% dip in $U_T$ )<br>for 25 & 30 cycles at 0°<br>$<5\% U_T$<br>(>95% dip in $U_T$ )<br>for 5 s<br>$0\% U_T$<br>(100% dip in $U_T$ )<br>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<br>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.

| 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. |                                                                                                                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Immunity test                                                                                                                                                                                            | IEC 60601 test level                                                                                                                | Compliance level                                                                                                                    | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                                            | 3 Vrms 150 kHz to 80 MHz outside ISM bands<br>80% AM at 1 kHz<br><br>6 Vrms<br>150 kHz to 80 MHz in<br>ISM bands 80% AM at<br>1 kHz | 3 Vrms 150 kHz to 80 MHz outside ISM bands<br>80% AM at 1 kHz<br><br>6 Vrms<br>150 kHz to 80 MHz in<br>ISM bands 80% AM at<br>1 kHz | <p>IEC 60601-1-2 3rd Edition:</p> <p>Portable and mobile RF communications 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.</p> <p>Recommended separation distance</p> $d = 1.17 \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$ $d = 1.17 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.33 \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ <p>IEC 60601-1-2 4th Edition:</p> <p> <b>WARNING:</b> Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CORE 2 Console including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  <p>(Non-ionizing electromagnetic radiation)</p> |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                             | 3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz                                                                                             | 3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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.

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

## 17.11 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.

| IEC 60601-1-2 3rd Edition: Recommended separation distances between<br>portable and mobile RF communications 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 communications equipment (transmitters) and the CORE 2 Console as recommended below, according to the maximum output power of the communications equipment. |                                                                       |                                       |                                        |
| Rated maximum output power of<br>transmitter<br><b>W</b>                                                                                                                                                                                                                                                                                                                                                                                             | Separation distance according to frequency of transmitter<br><b>m</b> |                                       |                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 150 kHz to 80 MHz<br>$d=1.17\sqrt{P}$                                 | 80 MHz to 800 MHz<br>$d=1.17\sqrt{P}$ | 800 MHz to 2.7 GHz<br>$d=2.33\sqrt{P}$ |
| 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.

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