11.5 Preset Instructions

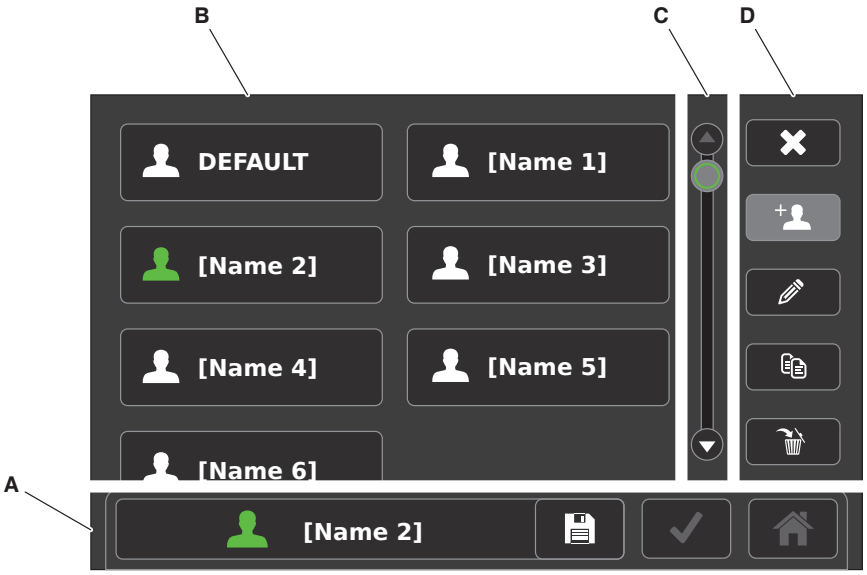

Figure 11 – Preset Screen

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

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11.6 System Settings Instructions

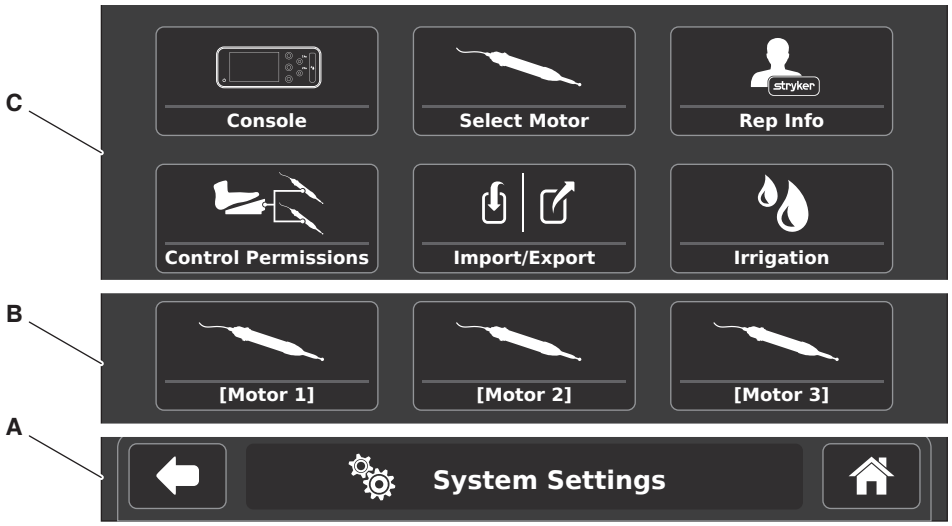

Figure 12 – System Settings Screen

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

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

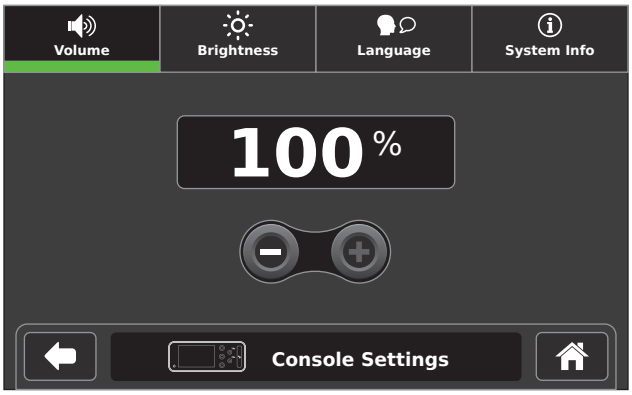

Figure 13 – Console Settings Screen

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).

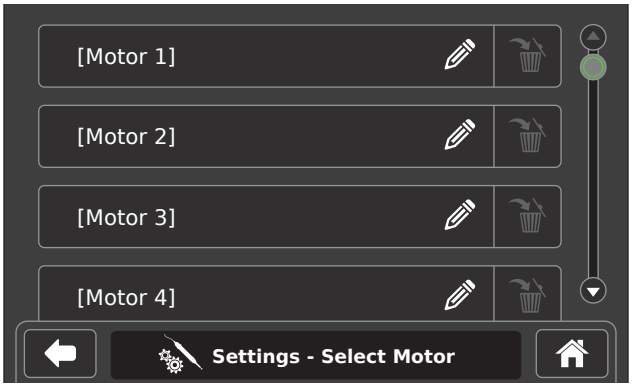

Figure 14 – Select Motor Screen

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**).

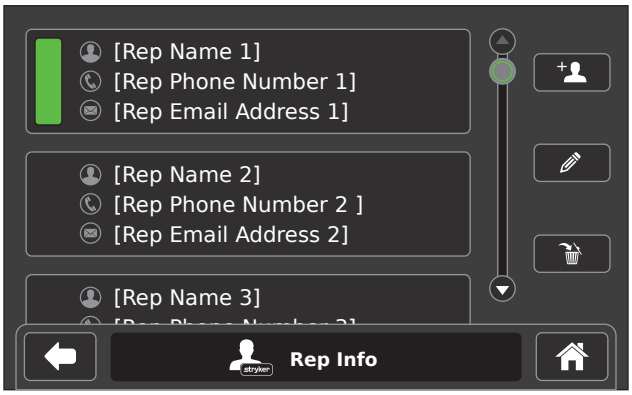

Figure 15 – Representative Information Screen

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.

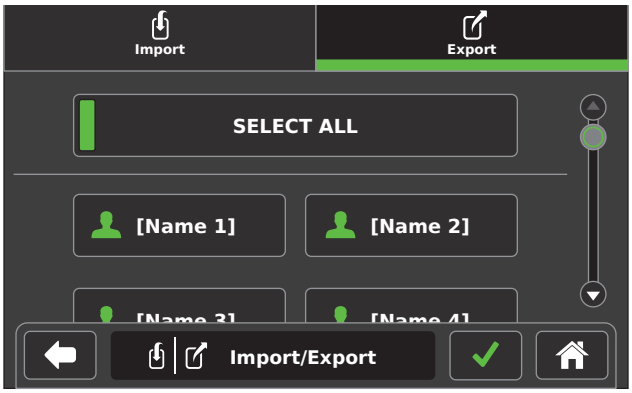

Figure 17 – Import/Export Screen

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).

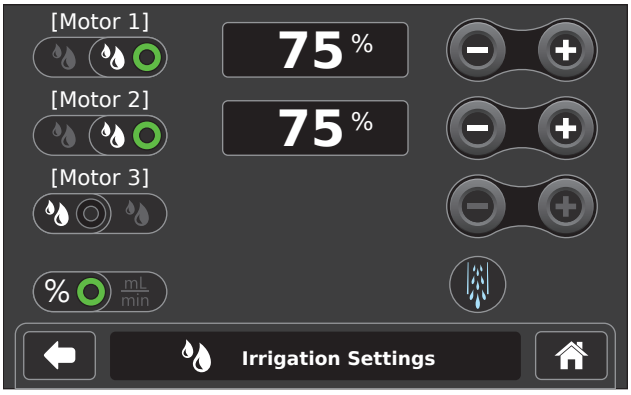

Figure 18 – Irrigation Settings Screen

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.

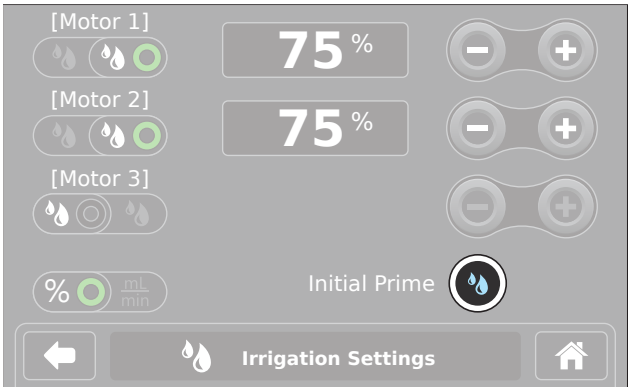

Figure 19 – Irrigation Settings (Initial Prime)

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).

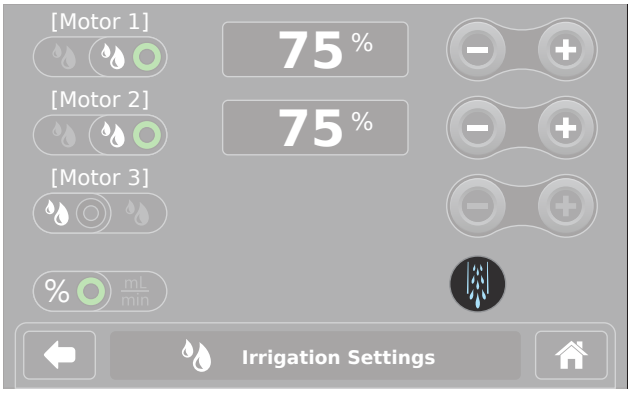

Figure 20 – Irrigation Settings (Flush)

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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)

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

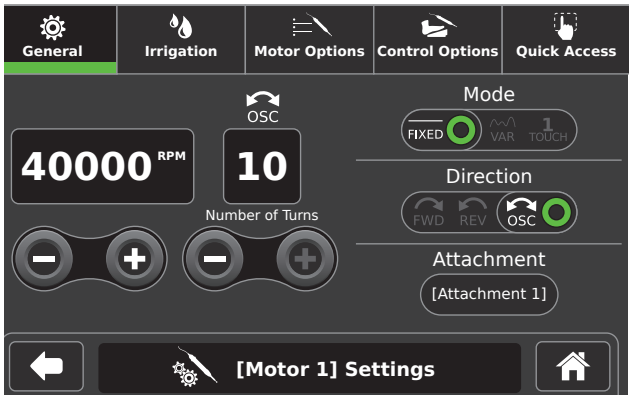

Figure 21 – General (Motor Settings) Screen

11.6.7.2 Adjust Irrigation (Motor Settings)

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

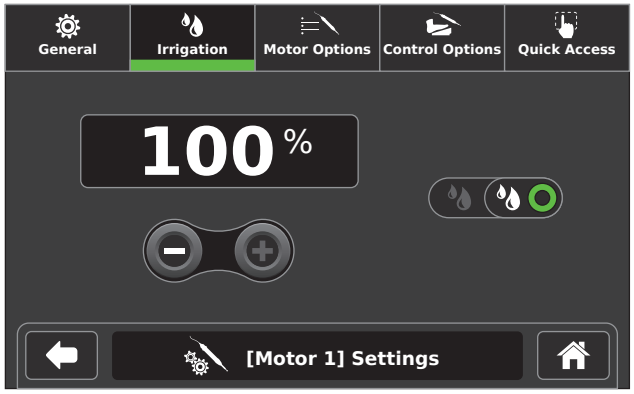

Figure 22 – Irrigation Screen

11.6.7.3 Adjust Motor Options

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

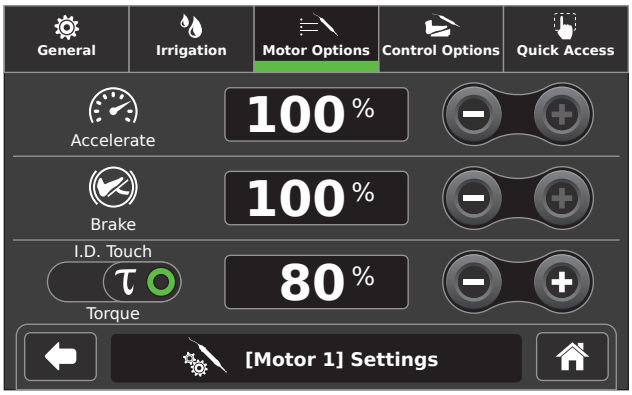

Figure 23 – Motor Options Screen

11.6.7.4 Adjust Control Options

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

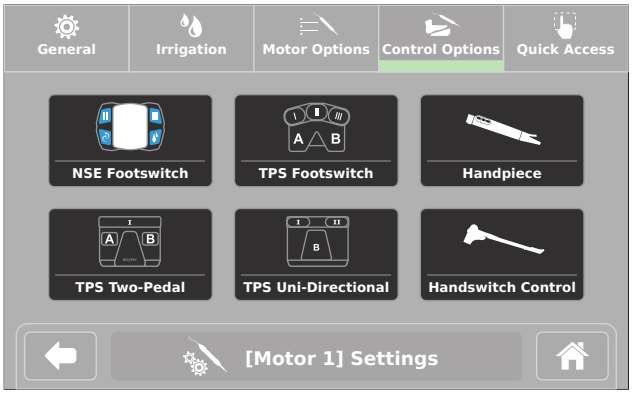

Figure 24 – Control Options Screen

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

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

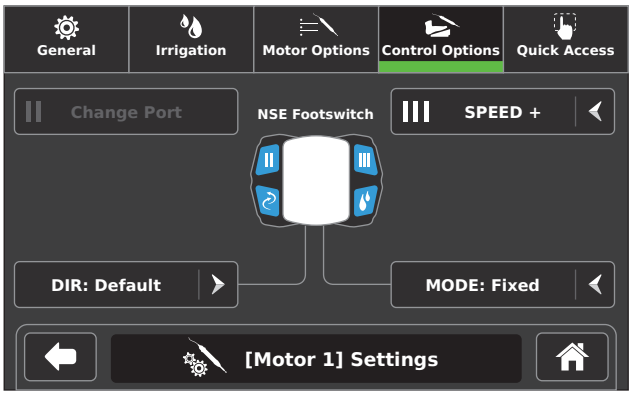

Figure 25 – NSE Footswitch Control Options Screen

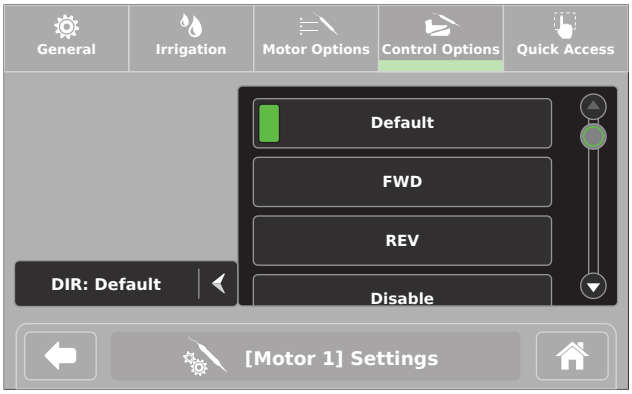

Figure 26 – Options List

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).

1. From (**Home**) navigate as follows:
   (**Settings**) > (**Motor Name**)
2. Touch (**Quick Access**).
3. 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.

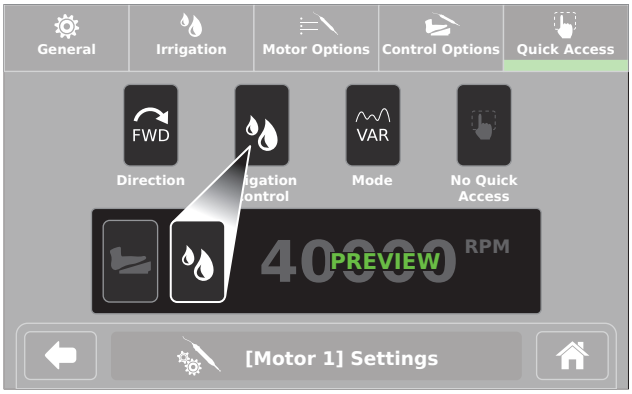

Figure 27 – Quick Access Screen

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.

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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.

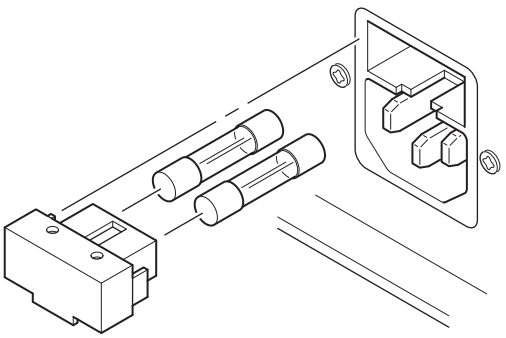

Figure 28 – Fuse Replacement

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.

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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*.

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17.5 Appendix E: Power Cords

17.5.1 Power Cord General Specifications

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

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.

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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.

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

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

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

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17.9 Appendix I: Specifications

Model:	CORE 2 Console
REF:	REF 5400-052-000
Dimensions:	
Width:	13.0 inch [330.2 mm]
Height:	5.4 inch [137.2 mm]
Depth:	17.4 inch [442.0 mm]
Weight:	17.3 lb [7.8 kg]
Equipment Type:	Class 1  Type BF Applied Part
Power Supply:	Input voltage: 120 V ~ 60 Hz, 6.0 A 100 V ~ 50-60 Hz, 6.0 A 240 V ~ 50-60 Hz, 3.0 A Motor port output voltage: 40 V ⎓ Footswitch port output voltage: 5 V ⎓
Fuse Type, Rating, and Breaking Capacity:	2 x 6.3 A, 250 VAC, 5 x 20 mm, (F) Fast-Acting, (L) Low Breaking Capacity 63 A at 250 VAC, IEC 60127
Enclosure (Ingress) Protection:	IPX0
Ground Type:	 Protective Earth (ground); when connected to facility power
Mode of Operation:	Continuous operation with intermittent loading
Duty Cycle:	See the duty cycle times defined in the Instructions For Use supplied with the motor and/or accessories.
Product Safety Certification:	 **CSA International** **Canadian Standards Association (CSA)** *CAN/CSA-C22.2 No. 60601-1:14, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; (IEC 60601-1:2005+A1:2012, MOD)* **American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)** *ANSI/AAMI ES60601-1:2005/(R) 2012, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; Consolidated Reprint (2009/(R) 2012); Amendment 2 (2010/(R) 2012); Amendment 1 (2012)*

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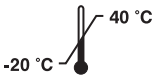
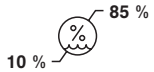
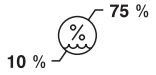
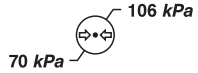
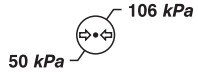
Product Safety Compliance:	**International Electrotechnical Commission (IEC)**
	IEC 60601-1:2005, Ed: 3.1, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; Corrigendum 1 (2006); Corrigendum 2 (2007); Amendment 1 (2012)
	IEC 60601-1-2:2007 Ed: 3, 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**
Temperature:		
Humidity Limitation:		
Atmospheric Pressure Limitation:		

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

Guidance and manufacturer's declaration - electromagnetic immunity			
The CORE 2 Console is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE 2 Console should assure that the console is used in such an environment. NOTE: The values provided in the table below have changed due to 60601-1-2 4th Edition requirements.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±6, ±8 kV Contact ±2, ±4, ±8, ±15 kV Air	±2, ±4, ±6, ±8 kV Contact ±2, ±4, ±8, ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T (100% dip in U_T) for 1 cycle at 0˚ 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚ <5% U_T (>95% dip in U_T) for 5 s 0% U_T (100% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T (100% dip in U_T) for 1 cycle at 0˚ 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚ <5% U_T (>95% dip in U_T) for 5 s 0% U_T (100% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CORE 2 Console requires continued operation during power mains interruptions, it is recommended that the CORE 2 Console be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m at 50 and 60 Hz	3 A/m, 30 A/m at 50 and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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

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

6 Vrms 150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz</td><td rowspan="2">IEC 60601-1-2 3rd Edition:

Portable and mobile RF 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.

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

IEC 60601-1-2 4th Edition:

⚠ WARNING: Portable RF 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.

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b].

Interference may occur in the vicinity of equipment marked with the following symbol:

 

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

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CORE 2 Console is used exceeds the applicable RF compliance level above, the CORE 2 Console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CORE 2 Console.

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

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 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 transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.7 GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

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5400-052-700-TR
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Stryker Instruments
4100 E. Milham
Kalamazoo, Michigan
(USA) 49001
1-269-323-7700
1-800-253-3210

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