12.3.2 Managing Representative Information

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

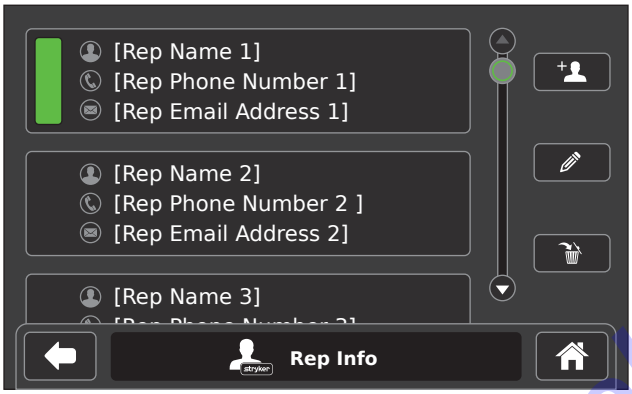

Figure 14 – Representative Information Screen

12.3.3 To Set Control Permissions

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

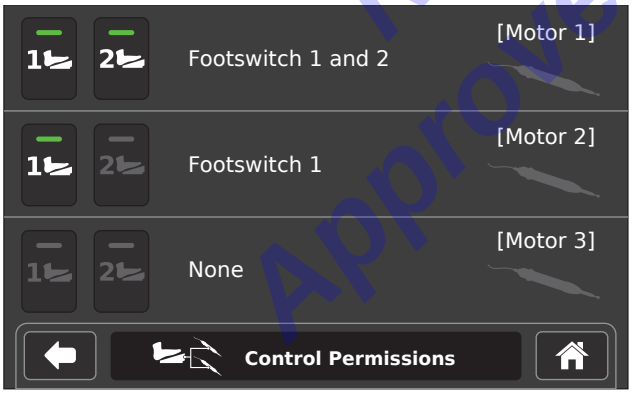

Figure 15 – Control Permissions Screen

12.3.4 To Import and Exporting Preset(s)

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

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

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

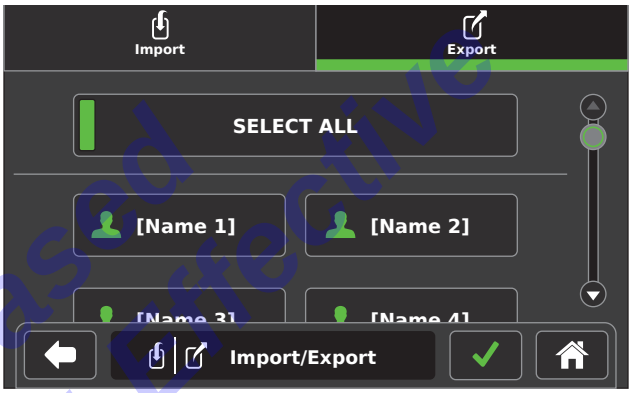

Figure 16 – Import/Export Screen

12.3.5 To Manage Irrigation Settings

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

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

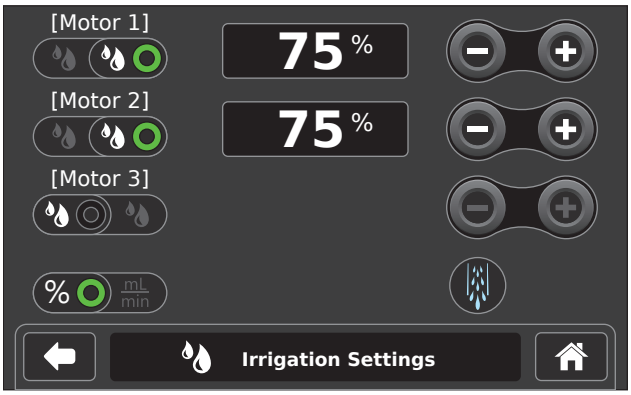

Figure 17 – Irrigation Settings Screen

12.3.6 Preparing the Irrigation Cassette

12.3.6.1 To Prime the Irrigation Cassette

NOTES:

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

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

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

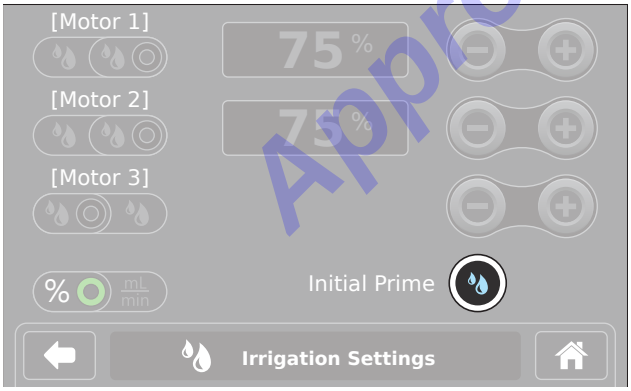

Figure 18 – Irrigation Settings (Initial Prime)

12.3.6.2 To Flush the Irrigation Cassette

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

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

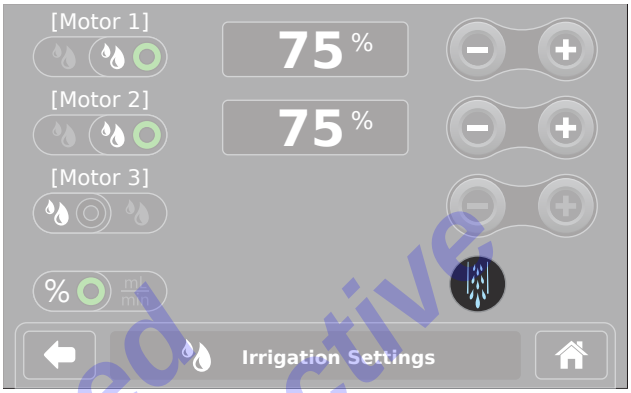

Figure 19 – Irrigation Settings (Flush)

12.3.7 To Access General Information

NOTE: The General Info screen provides URLs and QR codes to access electronic versions of the Instructions For Use and Open Source Software disclosures for the console (*Figure 20*).

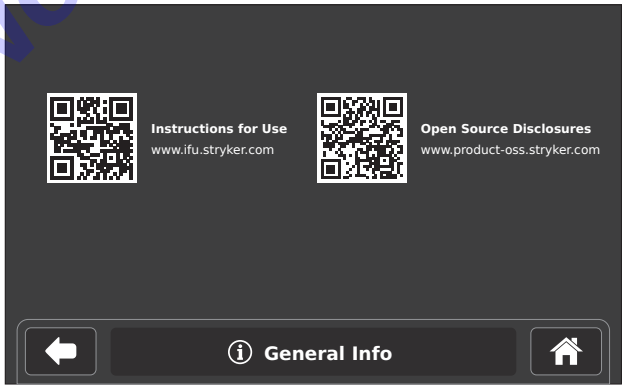

Figure 20 – General Info Screen

12.3.8 Managing Motor Settings

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

12.3.8.1 General (Motor Settings)

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

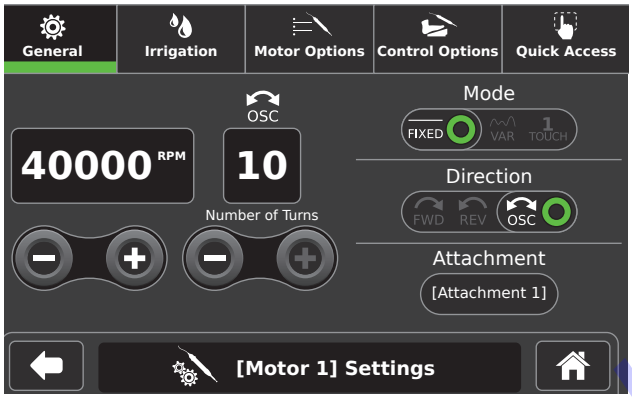

Figure 21 – General Menu Tab

12.3.8.2 Irrigation (Motor Settings)

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

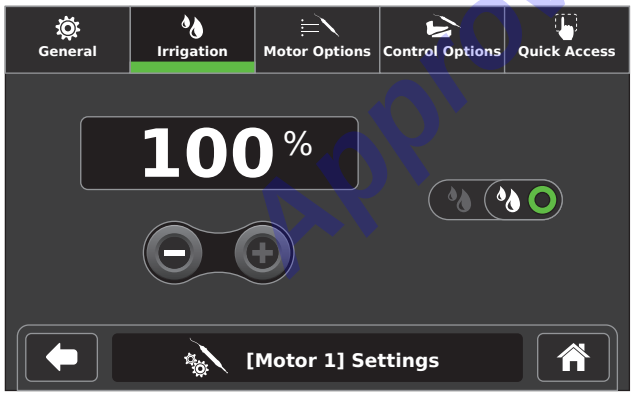

Figure 22 – Irrigation Menu Tab

12.3.8.3 Motor Options (Motor Settings)

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

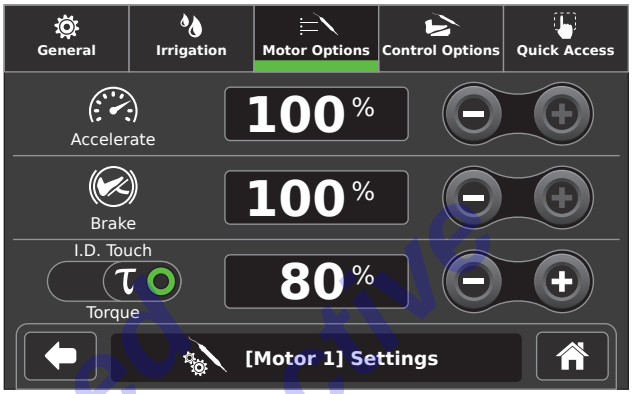

Figure 23 – Motor Options Menu Tab

12.3.8.4 Control Options (Motor Settings)

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

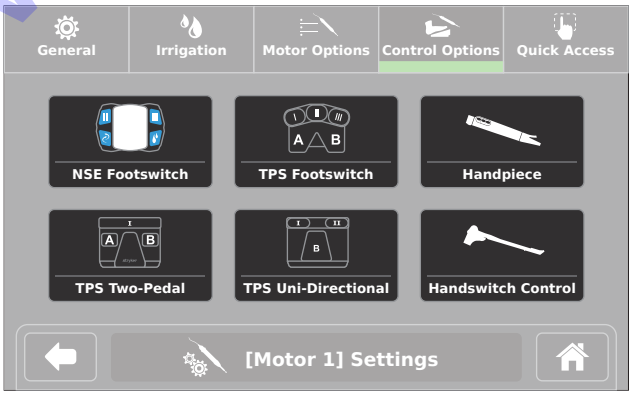

Figure 24 – Control Options Menu Tab

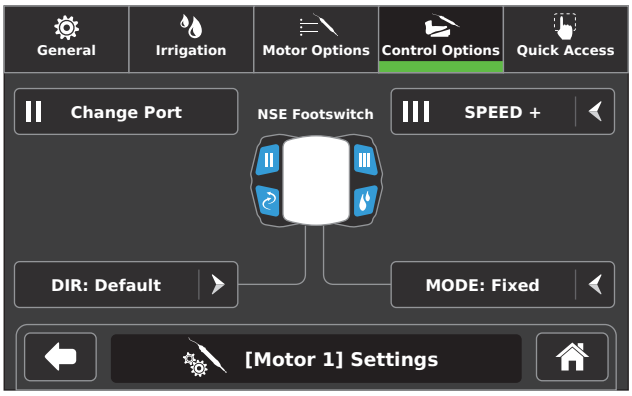

Figure 25 – NSE Footswitch Control Options

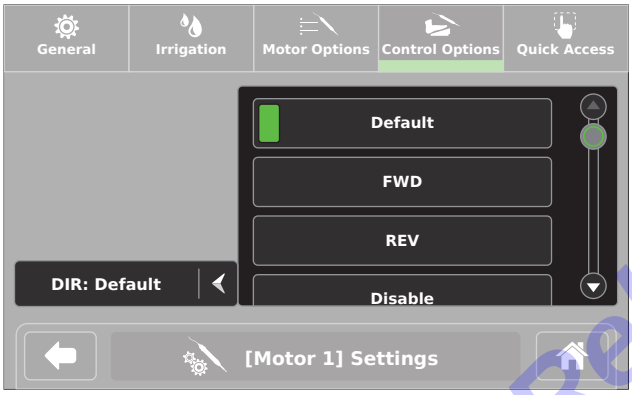

Figure 26 – Direction Options List

12.3.8.5 Quick Access (Motor Settings)

SYMBOL	DEFINITION	FUNCTION
	Quick Access	Use this menu tab to set direction, irrigation, mode, or I.D. Touch (torque) to be accessible from the Home screen. Choosing the No Quick Access option will remove the quick access button from the Home screen. The PREVIEW area displays a glimpse of the quick access area on the Home screen (*Figure 27*).

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

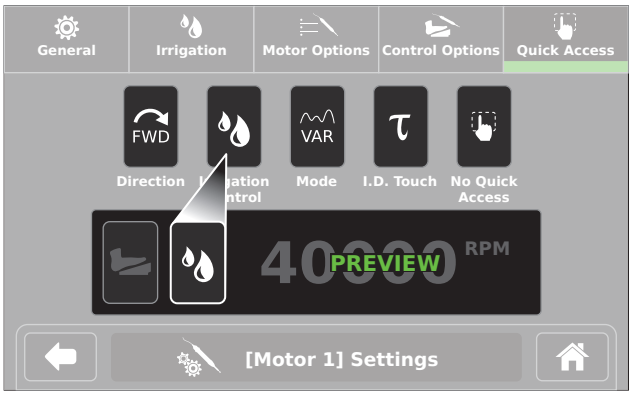

Figure 27 – Quick Access Menu Tab

12.4 Network Devices Screen

NOTE: The Network Devices screen displays connected external devices. Only Stryker supported devices will appear after successfully connecting with the CORE 2 Console. For example, this screen is used to confirm the Q Guidance System is connected (*Figure 28*).

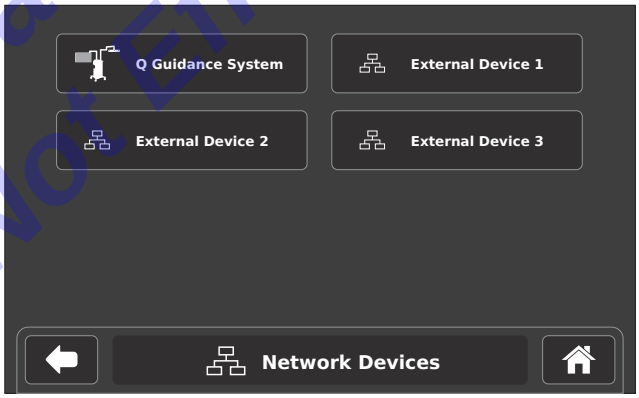

Figure 28 – Network Device Screen

13 Cleaning and Disinfection

WARNINGS:

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

CAUTIONS:

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

13.1 Recommended Materials

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

13.2 Clean and Disinfect Procedure

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

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

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

14 Troubleshooting

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

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

15 Maintenance

15.1 Fuse Replacement

WARNINGS:

- ALWAYS disconnect the power cord from the console before replacing the fuses. Failure to comply may cause an electrical shock hazard.
- ALWAYS use the same type and rated fuse when replacing fuses. Failure to comply may cause a fire hazard. See *Section 18.10 Appendix J: 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 17 Disposal/Recycle* for disposal information.
5. Install two new fuses into the fuse holder (*Figure 29*).
6. Securely install the fuse holder into the console.

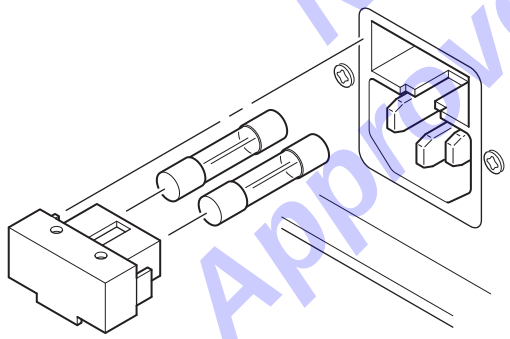

Figure 29 – Fuse Replacement

16 Storage and Handling

CAUTIONS:

- ALWAYS save the original packaging container for reuse. Failure to comply may result in damage during transport to the Stryker Service Center.
- ALWAYS store the equipment within the specified environmental condition values (*Section 18.10*).

17 Disposal/Recycle

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

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

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

廢電池請回收
(Taiwan - Recycle Waste Batteries)

18 Appendices

18.1 Appendix A: Acronyms

ACRONYM	DEFINITION
DIR	Direction
EMC	Electromagnetic Compatibility
ENT	Ear, Nose, Throat
ES6	Electronic System 6
FWD	Forward
I.D.	Identification
IFU	Instructions For Use
IRR	Irrigation
MRI	Magnetic Resonance Imaging
OSC	Oscillating
OSS	Open Source Software
PPE	Personal Protective Equipment
QR	Quick-response Code
REV	Reverse
RF	Radio Frequency
RFID	Radio Frequency Identification
RPM	Rotations Per Minute
TPS	Total Performance System
UHT	Universal High Torque
UI	User Interface
URL	Uniform Resource Locator
USB	Universal Serial Bus
VAR	Variable

18.2 Appendix B: Audio Output

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

18.3 Appendix C: Colors

18.3.1 User Interface Colors

COLOR	DEFINITION
	Selected/Active
	Disabled/Inactive/Inaccessible

18.3.2 Power Button Illumination Colors

COLOR	DEFINITION
	Console On
	Console Standby Mode

18.4 Appendix D: Equipotential Bonding

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

18.5 Appendix E: Power Cords

18.5.1 Power Cord General Specifications

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

18.5.2 Additional Power Cord Requirements

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

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

18.6 Appendix F: Ethernet Cables

18.6.1 Ethernet Cable General Specifications

Connector Type:	RJ45
Cable Type:	CAT6 (shielded or unshielded)
Cable Length:	Up to 5 meters maximum

18.7 Appendix G: Intellectual Property

18.7.1 Software Licensing

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

18.7.2 Trademarks

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

18.8 Appendix H: Footswitch Pedal/Pad Options

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

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

18.8.1 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.

18.8.2 Footswitch Pedal Mode Options

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

18.8.3 Footswitch Pad Options

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

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

18.9 Appendix I: 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 *Section 1.3 Contact Information* to contact Stryker.
00001002	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00001004	Motor Compatibility Error	Motor connected to Port [port] is not supported. See *Section 6 For Use With*.
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 *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
0000100A	Motor Service Requirement	[Motor] requires service. Return handpiece to Stryker for service. See *Section 1.3 Contact Information* to contact Stryker.
0000100B	Motor Stall Error	Excessive load detected on Port [port]. Report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00002002	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00002004	Footswitch Compatibility Error	Footswitch connected to Port [port] is not supported. See *Section 6 For Use With*.

CODE	TITLE	CORRECTIVE ACTION
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 *Section 1.3 Contact Information* to contact Stryker.
00002006	Footswitch Functional Error	Footswitch connected to port [port] requires service. Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00002007	CORE Q Footswitch Functional Error	Footswitch connected to port [port] requires service to enable haptic features. Confirm the error to continue using the footswitch without haptic or Q Guidance System compatibility. See *Section 1.3 Contact Information* to contact Stryker.
00002008	CORE Q Footswitch Functional Error	Footswitch connected to port [port] requires service to enable haptic features. Confirm the error to continue using the footswitch without haptic or Q Guidance System compatibility. See *Section 1.3 Contact Information* to contact Stryker.
00002009	CORE Q Footswitch Functional Error	Footswitch connected to port [port] requires service to enable haptic features. Confirm the error to continue using the footswitch without haptic or Q Guidance System compatibility. See *Section 1.3 Contact Information* to contact Stryker.
00003001	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003002	Console Functional Error	Irrigation pump is nonfunctional. Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003003	Console Functional Error	RFID is nonfunctional. Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003004 00003005	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003006	Console Functional Error	Port illumination error occurred. Continue without illumination or report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003007 00003008 00003009 0000300A 0000300B	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
0000300D	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00003011	Irrigation Cassette Error	Use a Stryker approved irrigation cassette. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003012 00003013	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003014	Console Functional Error	Error with audio function. Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.

CODE	TITLE	CORRECTIVE ACTION
00003016	Console Functional Error	Power supply temperature sensor error. Report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00003101	Console Functional Error	Irrigation pump is nonfunctional. Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003102	Console Functional Error	RFID is nonfunctional. Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003103 00003104	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003105	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003106	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003107	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00003108 00003109 0000310A 0000310B	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00004001 00004002 00004003 00004004	Console Functional Error	Reset console. If the error persists, report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00004006	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* 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 *Section 1.3 Contact Information* to contact Stryker.
00004009 0000400A 0000400B 0000400C 00004101 00004102 00004103 00004104 00004105	Console Functional Error	Report error code to Stryker. See *Section 1.3 Contact Information* to contact Stryker.
00005001	Q Guidance System Connection Error	Q Guidance System timed out. Check the Ethernet connection to the Q Guidance System. Press Confirm to try and reconnect.

CODE	TITLE	CORRECTIVE ACTION
00005002	Q Guidance System Connection Error	CORE 2 Console has had too many reconnection attempts. Check the Ethernet connection to the Q Guidance System and restart the CORE 2 Console.
00005003	Q Guidance System Connection Error	Q Guidance System unexpectedly disconnected. Check the Ethernet connection to the Q Guidance System. Press Confirm to try and reconnect.
00005004	Q Guidance System Compatibility Error	The version of software on the CORE 2 Console is incompatible with the current Q Guidance System. Report error code to Stryker. See the *Contact Information* section of the Instructions For Use provided with the equipment to contact Stryker.
00005005	Q Guidance System Functional Error	Q Guidance System experienced an unexpected error. Check the Ethernet connection to the Q Guidance System and restart the CORE 2 Console.
00005006	Q Guidance System Functional Error	CORE 2 Console experienced a timing error. Restart the CORE 2 Console to re-enable the Q Guidance System.

18.10 Appendix J: 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]
Material:	In accordance with the European REACH regulation and other environmental regulatory requirements, components within the product contain the following substances: Diboron Trioxide, CAS No. 1303-86-2 Lead Monoxide (Oxide), CAS No. 1317-36-8 Lead Titanium Trioxide, CAS No. 12060-00-3
Equipment Type:	Class 1  Type BF Applied Part
Power Supply:	Input voltage: 100-240 V ~ 50/60 Hz, 6-3 A Motor port output voltage: 40 V ⎓ Footswitch port output 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:	C SA US	CSA Group certification mark for United States and Canada. These products were tested and meet medical electrical equipment certification requirements, including compliance with applicable 60601 series standards. For additional information, contact Stryker.
		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.
Four (4) Channel RFID Module:		
Frequency of Operation:	13.56 MHz	
RF Bandwidth:	13.553 MHz- 13.567 MHz	
Modulation:	ASK	
RF Field Strength:	67.92 dBµV/m at 3 m	
Touch Screen:	7 inch [177.8 mm] (800 x 480), 24-bit color, wide viewing angle: 170˚	
Adjustable Volume:	0 dBA to 52 dBA	
Environmental Conditions:	**Operation**	**Storage and Transportation**
Temperature:	10 °C – 27 °C	-20 °C – 40 °C
Humidity Limitation:	10 % – 85 %	10 % – 75 %
Atmospheric Pressure Limitation:	70 *kPa* – 106 *kPa*	50 *kPa* – 106 *kPa*

18.10.1 Essential Performance

The CORE 2 Console on its own does not have Essential Performance. See the user manual supplied with the Spine Guidance Software (see *Section 6 For Use With*) for any Essential Performance related to the use of the CORE 2 Console at the medical electrical system level.

18.11 Appendix K: 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:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as shielding, relocating or reorienting the equipment.
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.			
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 10%.
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.

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 IEC 61000-4-6	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	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	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz 27 V/m 385 MHz Pulse modulation 18 Hz, Maximum power 1.8 W 28 V/m 450 MHz, FM ± 5 kHz deviation, 1 kHz sine, Maximum power 2 W 9 V/m 710, 745, 780, 5240, 5500, 5785 MHz, Pulse modulation 217 Hz, Maximum power 0.2 W 28 V/m 810, 870, 930 MHz, Pulse modulation 18 Hz, Maximum power 2 W 28 V/m 1720, 1845, 1970, 2450 MHz, Pulse modulation 217 Hz, Maximum power 2 W	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz 27 V/m 385 MHz Pulse modulation 18 Hz, Maximum power 1.8 W 28 V/m 450 MHz, FM ± 5 kHz deviation, 1 kHz sine, Maximum power 2 W 9 V/m 710, 745, 780, 5240, 5500, 5785 MHz, Pulse modulation 217 Hz, Maximum power 0.2 W 28 V/m 810, 870, 930 MHz, Pulse modulation 18 Hz, Maximum power 2 W 28 V/m 1720, 1845, 1970, 2450 MHz, Pulse modulation 217 Hz, Maximum power 2 W	**WARNING:** Portable RF equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CORE 2 Console including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. 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)
Proximity magnetic fields IEC 61000-4-39	65 A/m 134.2 kHz, pulse modulation 2.1 kHz 7.5 A/m 13.56 MHz, pulse modulation 50 kHz	65 A/m 134.2 kHz, pulse modulation 2.1 kHz 7.5 A/m 13.56 MHz, pulse modulation 50 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.

[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.

18.12 Appendix L: 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.

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

Contains 4 Channel RFID Module
FCC ID: Q9R-5400052020 or Q9R-5400052000
IC: 4919A-5400052020 or 4919A-5400052000

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.

18.12.2 Hazardous Materials Statement (China Only)

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

5400-052-700-DA	5400-052-700-NO
5400-052-700-DE	5400-052-700-PL
5400-052-700-ES	5400-052-700-PT
5400-052-700-FI	5400-052-700-SV
5400-052-700-FR	5400-052-700-TR
5400-052-700-IT	5400-052-700-ZH
5400-052-700-JA	700002939929 (RO)
5400-052-700-KO	700002940095 (RU)
5400-052-700-NL	700003015473 (EL)

Stryker Instruments
1941 Stryker Way
Portage, Michigan 49002 USA
(269) 323-7700 (800) 253-3210

EC REP

Stryker European Operations Limited
Anngrove, IDA Business & Technology Park
Carrigtwohill, Co Cork
T45 HX08 Ireland

Stryker EMEA Supply Chain Services B. V.
Frans Maasweg 2
Venlo 5928 SB, The Netherlands

UK Responsible Person
Stryker UK Ltd,
Stryker House,
Hambridge Road,
Newbury,
Berkshire,
RG14 5AW