stryker

CORE 2 Console

REF 5400-052-000

Instructions For Use

R$_x$ ONLY

$\mathsf{C}\,\mathsf{E}$ 0197

Software Version
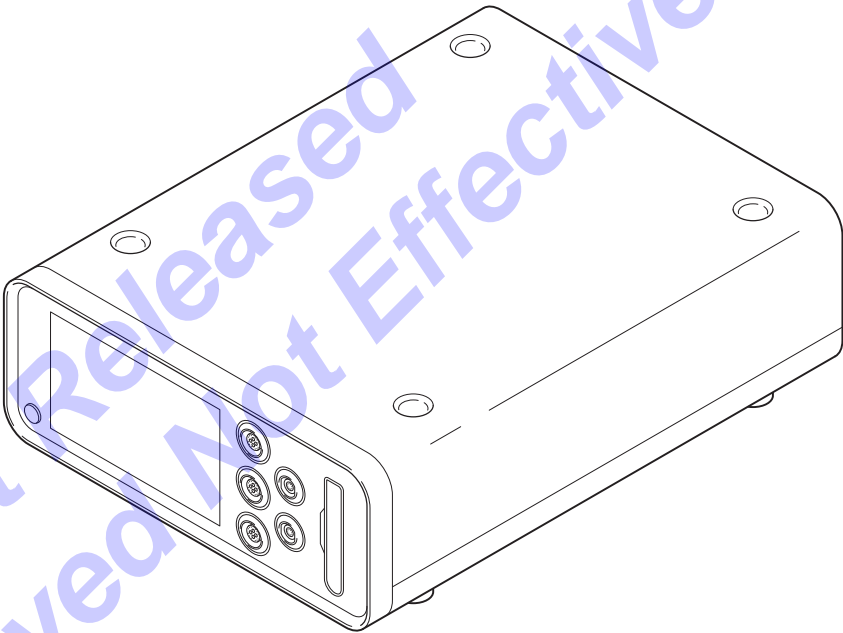
Contents

1 Introduction

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

Keep and consult this manual as necessary.

1.1 Audience

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

1.2 Conventions

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.

- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.

- A **NOTE** supplements and/or clarifies procedural information.

1.3 Contact Information

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

Outside the US, contact the nearest Stryker subsidiary.

NOTE: The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

2 Indications For Use

2.1 United States

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

The CORE 2 Console is also indicated as an accessory to the Stryker Spine Guidance Software for stereotactic surgical procedures on the spine in adult and pediatric (adolescent) patients.

2.2 Rest of World*

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

*NOTE: Product may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Contact your Stryker representative for product availability.

NOTE: For Brazil only, the approved indications are as follows:

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

3 Contraindications

None known.

4 Definitions

The symbols located on the equipment and/or labeling are defined in this section. See the *Symbol Definition Chart* REF 0036-716-000 supplied with the console and the *Global Symbol Glossary* located at ifu.stryker.com for additional definitions.

SYMBOL	DEFINITION
	1Touch
	Accelerate
	Alternating Current
	Back
	Blade (Bone Mill+)
	Brake
	Brightness
	Brightness - Linked
	Brightness - Unlinked
	Cancel
	Cancel Initial Prime
	Cartridge (Bone Mill+)
	Confirm
	Console
	Control Options
	Control Permissions
	Q Guidance System Compatible Motor
	Copy
	Create
	Delete
	Direct Current
	Email
	Edit

SYMBOL	DEFINITION
	Equipotential
	Error
	Export
	Favorite
FIXED	Fixed
	Flush
	Footswitch 1
	Footswitch 2
FWD	Forward
	Fuse
	General Information
	General Settings
	General Warning Sign
	Handpiece
	Handswitch
	Home
	Import
	Initial Prime
	Irrigation
	Keyboard - Backspace
	Keyboard - Capital Letter OFF
	Keyboard - Capital Letter ON
	Keyboard - Spacebar
	Language
	Loading

SYMBOL	DEFINITION
$\frac{mL}{min}$	Milliliters per Minute
	Motor
	Motor Options
	Motor Settings
	Name
	Local Network
	Next
OSC	Oscillating
	Phone
	Power
	Preset/Representative
	Priming
	Q Guidance System
	Quick Access
	Refer to Instruction Manual/Booklet
stryker	Rep Info
	Reset
REV	Reverse
	Roll-out Left
	Roll-out Right
	Save
	Scroll Down
	Scroll Up
	Self-timer (Bone Mill+)

SYMBOL	DEFINITION
	System Information
	System Settings
	Time Based Turn
τ	I.D. Touch (Torque)
	Value - Decrease
	Value - Increase
VAR	Variable
	Volume

5 Supplied Components

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

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

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

6 For Use With

⚠️ **WARNING:** Only use Stryker-approved equipment, unless otherwise specified. Using other electronic components or accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

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

NOTES:

- This equipment is sold separately and may not be available in all markets. To order equipment, contact Stryker.

- For additional power cord information, see *Section 18.5 Appendix E: Power Cords*.

DESCRIPTION	REF
Cords, Pole, and Cables	
Standard Cord (Keyed)	5100-004-000
Console Power Cord	0996-851-XXX
Irrigation Pole	5100-050-028
Mill Cable	5400-704-000
ES6 Handpiece Cord	6292-004-000
TPX Cord	7400-004-000
Irrigation Cassettes	
CORE Hummer Disposable Irrigation Cassette	5290-075-000
Disposable Irrigation Cassette	5400-050-001
Dual Disposable Irrigation Cassette	5400-050-002
Handswitches	
CORE UHT Drill Handswitch	5400-111-000
CORE Saber Handswitch	5400-121-000
CORE Sumex Handswitch	5400-131-000
TPX Handswitch	7400-009-000
RemB Electric Handswitch	6400-009-000
Footswitches	
CORE Footswitch	5402-007-000
CORE Q Footswitch (with CORE 2 software version 3.0 or higher)	5502-007-000
TPS Uni-Directional Footswitch	5100-007-000
TPS Footswitch	5100-008-000
NSE Footswitch	5400-007-000
Motors	
TPS Small Joint Shaver	0275-601-500
Formula Shaver Foot Control	0375-701-500
Formula Shaver Hand Control	0375-704-500
Formula 180	0375-708-500

DESCRIPTION	REF
TPX Micro Drill	7400-015-000
TPX Oscillating Saw	7400-031-000
TPX XL Oscillating Saw	7400-131-000
TPX Sagittal Saw	7400-034-000
TPX Reciprocating Saw	7400-037-000
TPX Electric Wire Driver	7400-062-000
TPX Universal Driver	7400-099-000
ESSx Handpiece	5290-601-200
The Mill	5400-700-000
Bone Mill+ Base (with CORE 2 software version 2.4 or higher)	5420-100-000
Pi Drive Motor	5407-100-000
Pi Drive Plus Motor	5407-300-000
Pi Drive 2 Motor (with CORE 2 software version 2.3 or higher)	5407-150-000
Pi Drive 2 Plus Motor (with CORE 2 software version 2.3 or higher)	5407-350-000
S2 Drill	5450-400-000
Pello Microdebrider Handpiece	6290-100-000
ES6 Single Trigger Rotary Handpiece	6293-000-000
ES6 Dual Trigger Rotary Handpiece	6295-000-000
ES6 Reciprocating Saw	6296-000-000
ES6 Sternum Saw	6297-000-000
ES6 Sagittal Saw	6298-000-000
ES6 Precision Oscillating Tip Saw	6299-000-000
Stryker Q Guidance System	
Spine Guidance Software (with CORE 2 software version 3.0 or higher)	6002-810-000

7 Safety Directives

7.1 General Warnings

⚠️ **WARNINGS:**

- ALWAYS be familiar with the Instructions For Use and proper operation of this equipment before use. To request in-service training, contact Stryker.

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

- Equipment is limited to professional use within a professional healthcare environment.

- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.

- Healthcare professionals should be thoroughly familiar with the Instructions For Use, handling characteristics, and the indicated and intended uses of this equipment. Contact Stryker for in-service training.

- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure or technique.

- ALWAYS ensure the console is placed on a sturdy, flat surface near a hospital-grade power outlet and all connections (front and rear) are easily accessible.

- Upon initial receipt and before each use, ALWAYS inspect equipment for damage. DO NOT use any equipment if damage is apparent.

- ALWAYS clean and disinfect the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient and/or healthcare staff injury.

- ALWAYS consult the Instructions For Use that accompanies motors, footswitches, and attachments for product specific cleaning requirements.

- DO NOT touch the screen with any sharp or hard object. Failure to comply may cause breakage and result in healthcare staff and/or patient injury.

- DO NOT disassemble, modify, service, or repair this equipment when using this equipment with a patient.

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

- ALWAYS operate this equipment within the specified environmental condition values (*Section 18.10*).

- ALWAYS follow the recommended duty cycle to prevent this equipment from overheating.

- DO NOT stack or place equipment adjacent to the console. If such a configuration is necessary, observe the configuration to ensure that electromagnetic interference does not degrade performance.

- Take special precautions regarding electromagnetic compatibility (EMC) when using the CORE 2 Console and system components. Install and place this medical electrical equipment into service according to the EMC information contained in this manual. Portable and mobile radiofrequency equipment and high frequency (HF) surgical equipment can affect the function of this medical electrical equipment. See Section 18.11 Appendix K: Electromagnetic Compatibility.

- DO NOT leave the CORE 2 accessories in the surgical site when HF/RF devices are actively in use.

- DO NOT use the console in an MRI environment. Using the console in an MRI environment could affect the function of the console.

- ALWAYS ensure footswitch placement is in a secure area where inadvertent activation is not possible.

- ALWAYS select the correct irrigation flow rate based on the surgical procedure and/or handpiece requirements to prevent excessive or insufficient irrigation flow. Failure to comply may limit the view of the surgical site and result in patient and/or healthcare staff injury.

- ALWAYS select the correct attachment/reducer when selecting the motor setting to prevent excessive or insufficient motor speed. Failure to comply may cause incorrect information to be displayed and result in patient and/or healthcare staff injury.

- DO NOT place the console within the sterile field.

7.2 Electrical Warnings

⚠️ **WARNINGS:**

- ALWAYS connect the console to a hospital-grade, power outlet with protective earth (ground) to avoid the risk of electrical shock.

- Electrical power is present when the console is in standby mode. To completely remove power, disconnect the power cord from either the console or the hospital-grade, power outlet with protective earth (ground) to avoid the risk of electrical shock.

- If power is lost, some of the console's adjustable settings, such as the motor to footswitch assignment, footswitch options, and motor operating modes, will revert to the default configuration or the last selected preset. After power is restored, verify console settings.

8 System Overview

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

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

The Ethernet interface is used to communicate exclusively with other supported Stryker medical devices. The Ethernet interface is not used to communicate with the broader internet or any other unsupported devices.

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

The console can store user presets and representative information internally. The presets can imported and exported with the use of a USB data storage device. For additional information, see *Section 12.3.4 To Import and Exporting Preset(s)*.
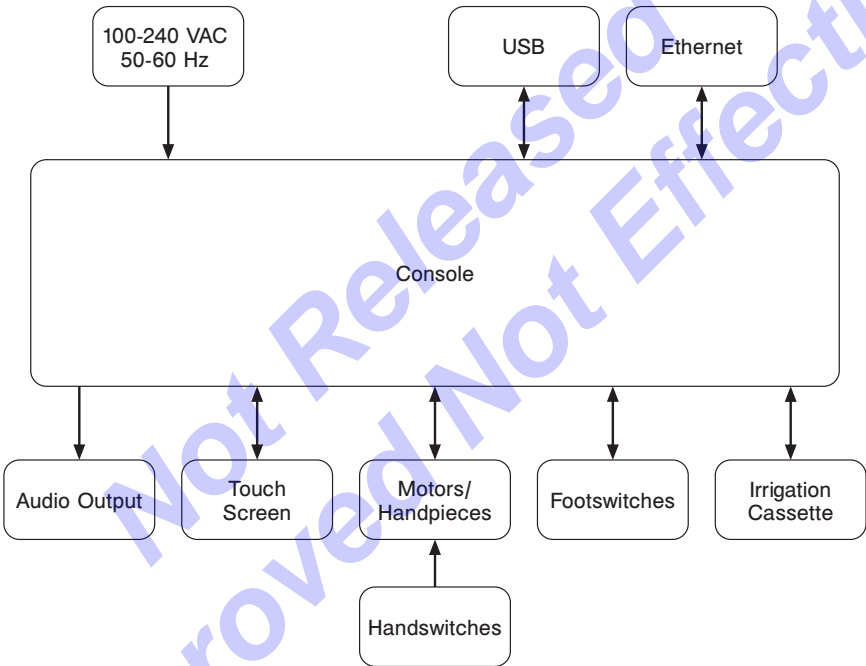
Figure 1 – System Block Diagram

8.1 Hardware Features
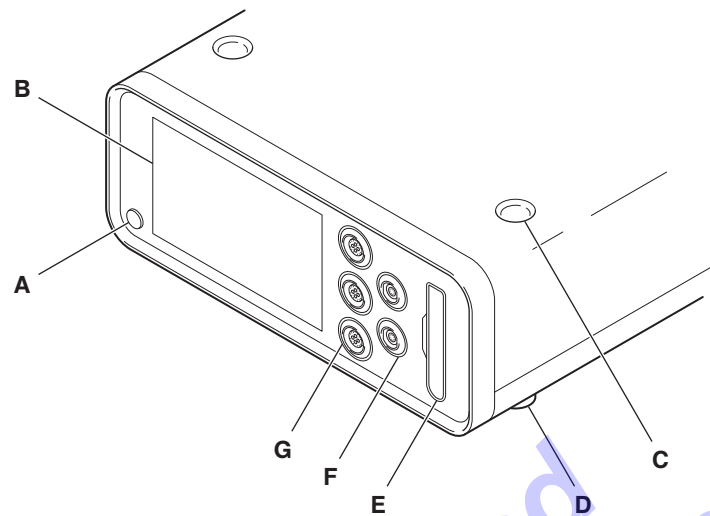
Figure 2 – Console (Front View)

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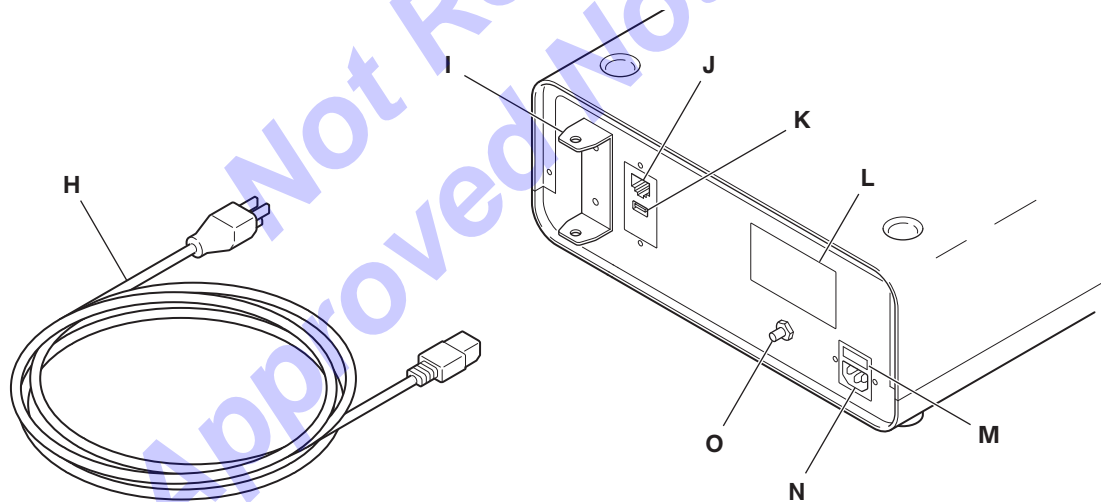
Figure 3 – Console (Rear View)

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

8.2 Software Features

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

Figure 4 – Screens and Menu Tabs Map

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

9 Before the Procedure

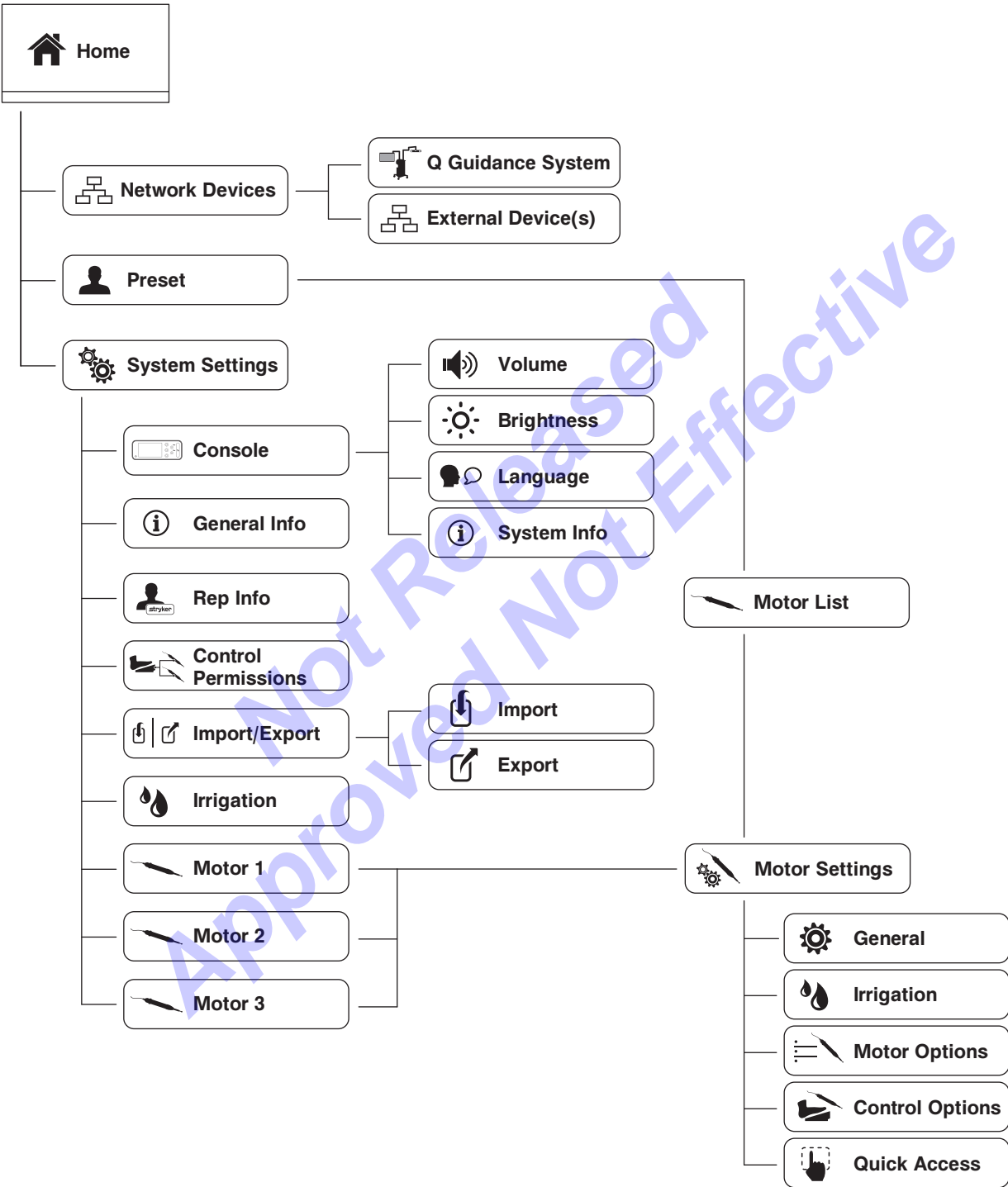1. Verify the console is placed on a sturdy, flat surface.

2. Verify the console is not within the sterile field.

3. Verify the following items are connected; connect as necessary (*Figure 5*):
   - (Optional) Ethernet cable
   - (Optional) Equipotential cable
   - Power cord

4. Verify the equipment is clean and not damaged.

5. Connect the following devices as necessary:
   - Motor(s) (*Figure 6*)
   - Footswitch(es) (*Figure 7*)

6. Press ⏻ to power the console on.

7. (Optional) Prepare the console for irrigation as follows:

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

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

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

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

   7.4. Prepare the irrigation cassette (*Section 12.1.1*).

8. Manage presets as necessary (*Section 12.2*).

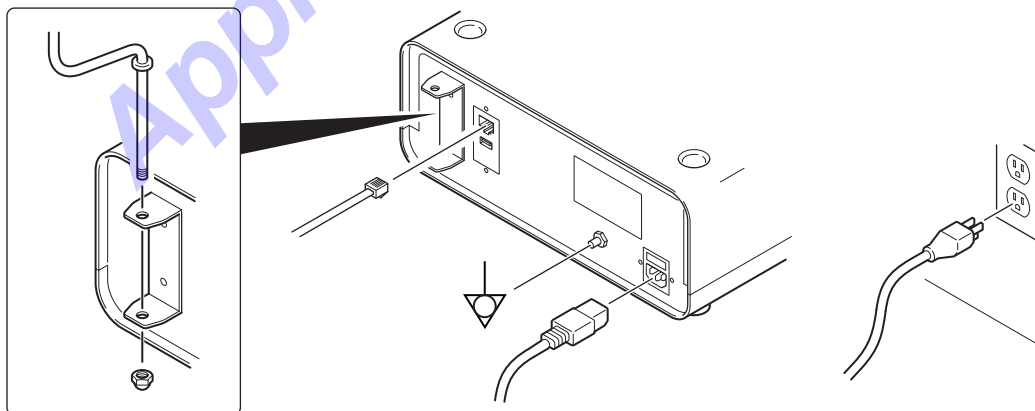9. Manage system settings as necessary (*Section 12.3*).

10 During the Procedure

- Connect and disconnect devices as necessary.

- Refer to the following sections for guidance during the procedure as necessary:
   - *Section 12.1 Home Screen*
   - *Section 12.2 Preset Screen*
   - *Section 12.3 System Settings Screen*

11 After the Procedure

1. Remove power from the console as follows:

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

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

   1.2. Disconnect the power cord.

   1.3. If used, disconnect the equipotential cable.

2. If irrigation was used, perform the following:

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

   2.2. Remove the irrigation cassette (*Figure 9*).

3. Disconnect the following devices as necessary:
   - Motor(s) (*Figure 6*)
   - Footswitch(es) (*Figure 7*)

4. Clean and disinfect the console (*Section 13.2*).

5. Inspect the equipment for damage.

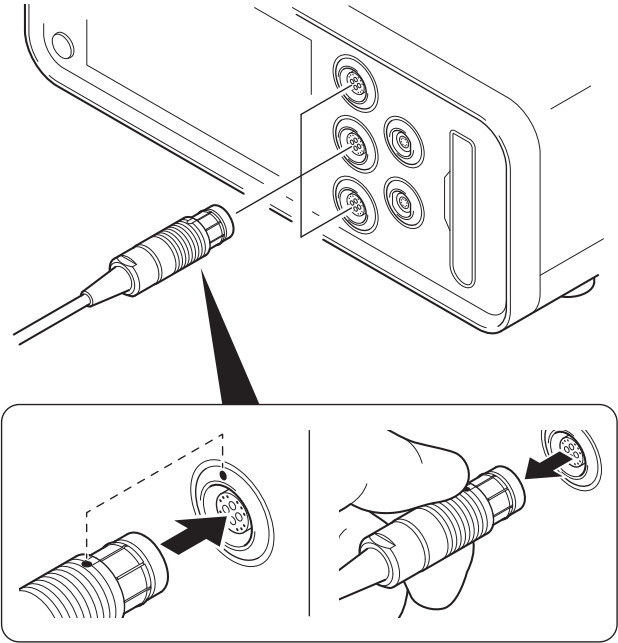**Figure 5 – Console (rear view) Connection/Disconnection Interface**

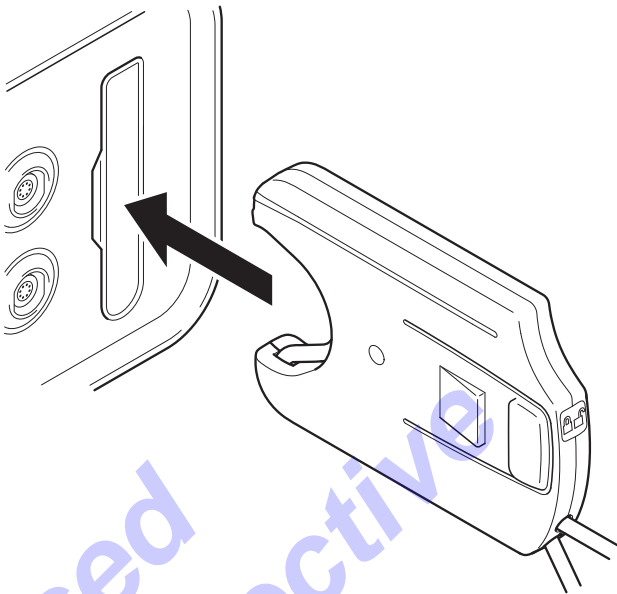**Figure 6 – To Connect/Disconnect a Motor**

Figure 8 – To Insert an Irrigation Cassette
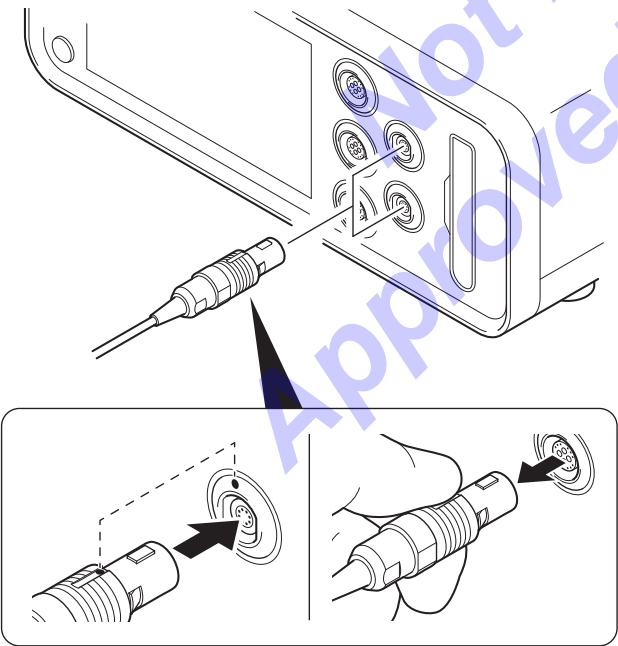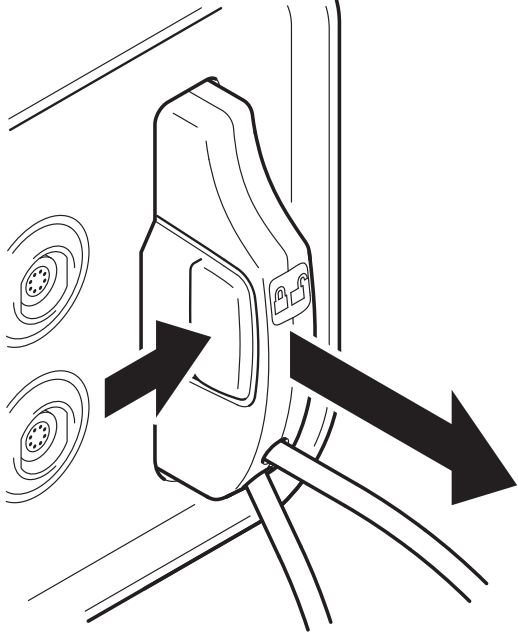

Figure 7 – To Connect/Disconnect a Footswitch

Figure 9 – To Remove an Irrigation Cassette

12 Graphical User Interface Overview
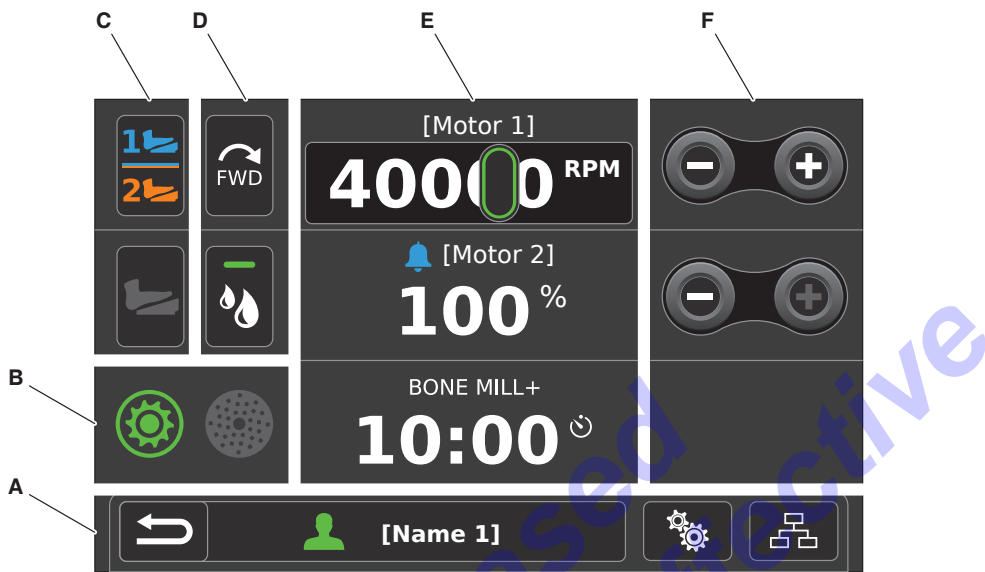
12.1 Home Screen

Figure 10 – **Home Screen**

A	**Navigation Bar Area** – Provides navigational buttons and displays the active preset. **NOTE:** The reset button will appear within this area if the active preset has been modified. Press the reset button to undo changes.
B	**Bone Mill+ Disposables Status Area** – Displays the connected Bone Mill+ status of the cartridge and the blade. See the instructions for use supplied with the Bone Mill+ Base.
C	**Footswitch Assignment Area** – Provides a graphical representation of the current footswitch assignment. These buttons can be touched to toggle footswitch assignment.
D	**Quick Access Area** – Allows the user to set features such as direction, irrigation, mode, or I.D. Touch (torque) to be accessible from the Home screen. These buttons can be set to accommodate the user's preference, see *Section 12.3.8.5 Quick Access (Motor Settings)*.

E	**Motor/Bone Mill+ Value/Status Area** – Displays the connected motor(s) name and value setting. Touch the motor value to access the slider bar to adjust the motor value setting. Displays the connected Bone Mill+ Base name and value settings for the attached disposable component: self-timer for cartridge (as shown), or % power for blade. **NOTE:** Displays the Q Guidance System Compatible Motor symbol if the Navigation function is activated and enabled and the motor is Q Guidance System compatible.
F	**Decrease/Increase Area** – From here, the user can use the decrease and increase buttons to adjust the motor value setting.

12.1.1 Accessing Screens

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

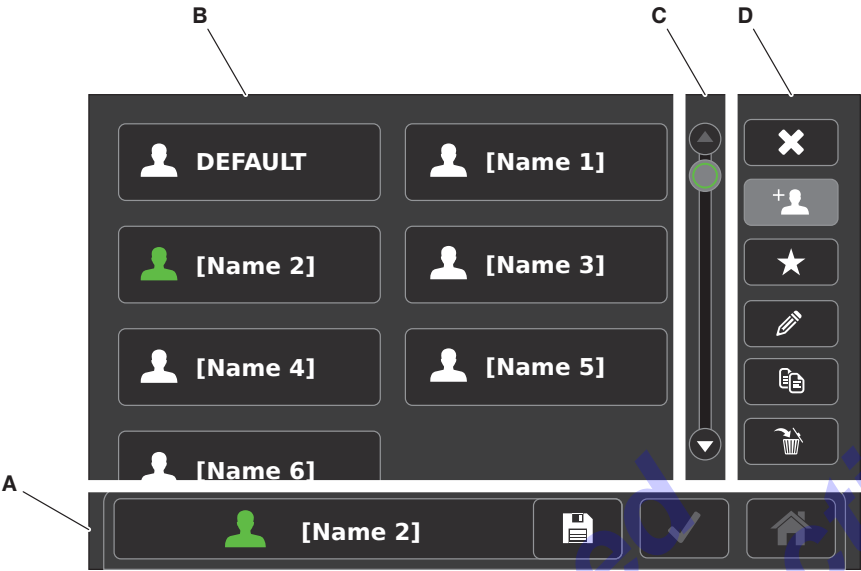| SYMBOL	DEFINITION	FUNCTION
🏠	Home	Use this button to access the Home screen.
🖧	Local Network	Use this button to access the Network Devices screen.
👤	Preset	Use this button to access the Preset screen.
⚙	Settings	Use this button to access the System Settings screen.

12.2 Preset Screen

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.	**C**	**Vertical Slider Bar Area** – Contains a vertical slider bar used to scroll up and down.
B	**Preset Area** – Contains the DEFAULT preset and created (or imported) presets.	**D**	**Preset Options Area** – Contains the following buttons: Cancel, Create, Favorite, Edit, Copy, and Delete

12.2.1 Managing Presets

SYMBOL	DEFINITION	FUNCTION
$^+\!\!\perp$	Create	Use this button to create a new preset.
★	Favorite	Use this button to identify a preset to load when the console is powered on. **NOTE:** Only one favorite can be selected at a time.
✎	Edit	Use this button to edit a preset.
⎘	Copy	Use this button to copy a preset.
🗑	Delete	Use this button to delete a preset.
💾	Save	Use this button to save changes to a preset.

12.2.2 To Activate a Preset

1. Access the Preset screen.

2. In the preset area, touch the preset file to activate.

3. Touch ✔ (**Confirm**).
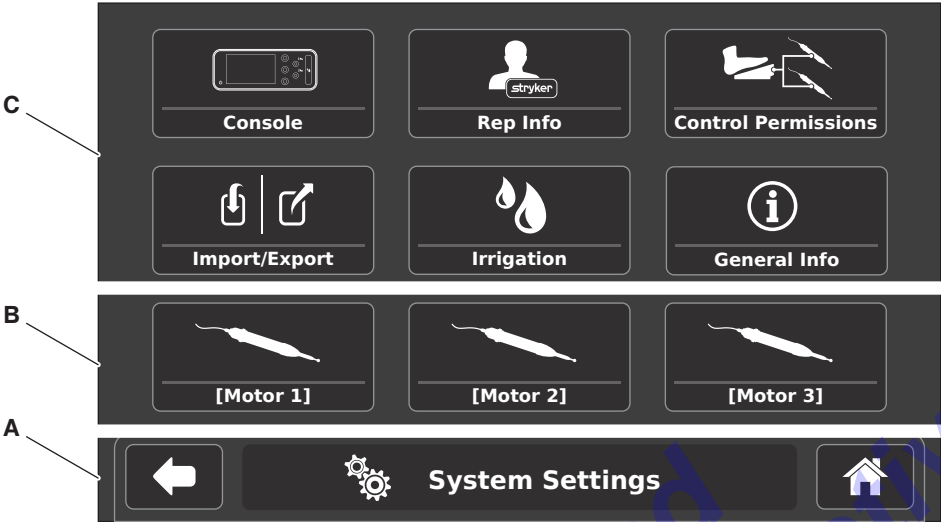
12.3 System Settings Screen

Figure 12 – System Settings Screen

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

12.3.1 Managing Console Settings

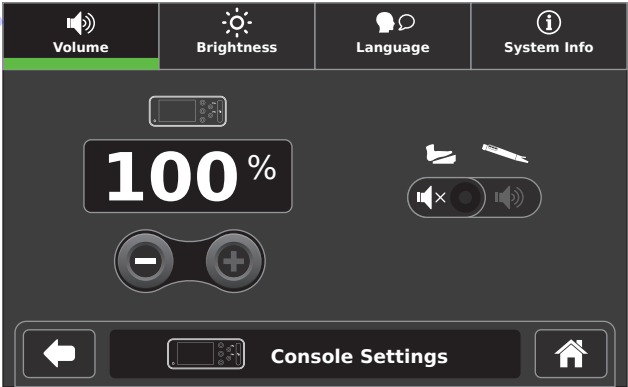| SYMBOL	DEFINITION	FUNCTION
🔊	Volume	Use this menu tab to adjust the console volume level. Use the toggle option (off is default) to turn on extra footswitch and motor sounds.
☀	Brightness	Use this menu tab to adjust the screen or port brightness.
🗣💬	Language	Use this menu tab to set the console language.
ⓘ	System Info	Use this menu tab to access the system information.

Figure 13 – Volume Menu Tab (Console Settings)