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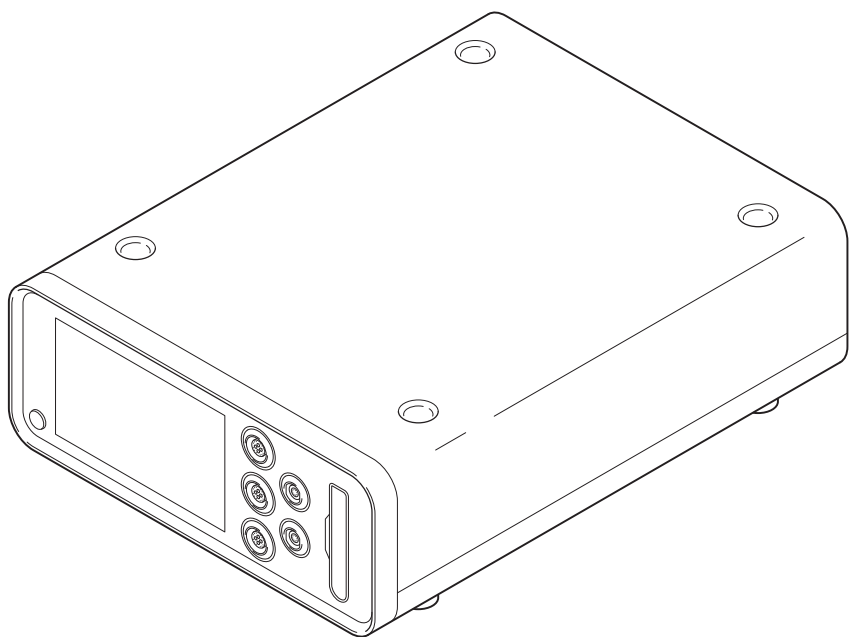
CORE™ 2 Console

REF 5400-052-000

Instructions For Use

R_x ONLY

CE 0197



ENGLISH (EN)



Software Version

1.X.X

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5400-052-700-EN Rev-D

www.stryker.com

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1 Introduction

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

Keep and consult this manual as necessary.

1.1 Audience

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

1.2 Conventions

The following conventions are used in this manual:

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

1.3 Contact Information

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

Outside the US, contact the nearest Stryker subsidiary.

2 Indications For Use






















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

3 Contraindications

None known.

4 Definitions

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

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

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

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

5 Supplied Components

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

| COMPONENT | REF |
|----------------------------|--------------|
| CORE 2 Console | 5400-052-010 |
| Console Power Cord | 0996-851-XXX |
| Symbol Definition Chart | 0036-716-000 |
| Software License Addendum | 5400-052-704 |
| Instructions For Use (IFU) | 5400-052-700 |

NOTES:

- If any component is missing or damaged, contact Stryker for assistance.
- For additional power cord information, see Appendix E: Power Cords.

6 For Use With



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

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

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

| EQUIPMENT | REF |
|--------------------------------------|--------------|
| Accessories | |
| Standard Cord (Keyed) | 5100-004-000 |
| Irrigation Pole | 5100-050-028 |
| CORE Heavy Duty Power Pack | 5400-500-000 |
| Mill Cable | 5400-704-000 |
| ES6 Handpiece Cord | 6292-004-000 |
| Irrigation Cassettes | |
| CORE ESSx/Hummer Irrigation Cassette | 5290-075-000 |
| Disposable Irrigation Cassette | 5400-050-001 |
| Dual Disposable Irrigation Cassette | 5400-050-002 |
| Handswitches | |
| TPS Universal Handswitch | 5100-009-000 |
| CORE Universal Handswitch | 5400-009-000 |
| CORE UHT Drill Handswitch | 5400-111-000 |
| CORE Saber Handswitch | 5400-121-000 |
| CORE Sumex Handswitch | 5400-131-000 |
| RemB Electric Handswitch | 6400-009-000 |

| EQUIPMENT | REF |
|-------------------------------------|----------------|
| Footswitches | |
| TPS Two-Pedal | 0275-701-400 |
| TPS Uni-Directional Footswitch | 5100-007-000 |
| TPS Footswitch | 5100-008-000 |
| NSE Footswitch | 5400-007-000 |
| Motors | |
| TPS Small Joint Shaver | 0275-601-500 |
| Formula Shaver Foot Control | 0375-701-500 |
| Formula Shaver Hand Control | 0375-704-500 |
| Formula 180 | 0375-708-500 |
| TPS Micro Oscillating Saw | 5100-031-000 |
| TPS Micro Driver | 5100-088-000 |
| TPS XL Oscillating Saw | 5100-131-000 |
| Hummer 4 Handpiece | 5290-601-100 |
| CORE ESSx Handpiece | 5290-601-200 |
| CORE Micro Drill | 5400-015-000 |
| CORE Oscillating Saw | 5400-031-000 |
| CORE Sagittal Saw | 5400-034-000 |
| CORE Reciprocating Saw | 5400-037-000 |
| CORE Universal Driver | 5400-099-000 |
| CORE U-Drill | 5400-100-000 |
| CORE UHT Drill | 5400-110-000 |
| CORE Saber Drill | 5400-120-000 |
| CORE Modified Saber Drill | 5400-120-000S1 |
| CORE Sumex Drill | 5400-130-000 |
| CORE Sumex MS1 | 5400-130-000S1 |
| CORE Impaction Drill | 5400-300-000 |
| CORE Mill | 5400-700-000 |
| Pi Drive Motor | 5407-100-000 |
| Pi Drive Plus Motor | 5407-300-000 |
| S2 Drill | 5450-400-000 |
| ES6 Single Trigger Rotary Handpiece | 6293-000-000 |
| ES6 Dual Trigger Rotary Handpiece | 6295-000-000 |
| ES6 Reciprocating Saw | 6296-000-000 |
| ES6 Sternum Saw | 6297-000-000 |
| ES6 Sagittal Saw | 6298-000-000 |
| ES6 Precision Oscillating Tip Saw | 6299-000-000 |
| RemB Electric Micro Drill | 6400-015-000 |
| RemB Electric Oscillating Saw | 6400-031-000 |
| RemB Electric Sagittal Saw | 6400-034-000 |
| RemB Electric Reciprocating Saw | 6400-037-000 |
| RemB Electric Wiredriver | 6400-062-000 |
| RemB Electric Universal Driver | 6400-099-000 |

7 Safety Directives

7.1 General Warnings



WARNINGS:

- ALWAYS be familiar with the Instructions For Use and proper operation of this equipment before use. To request in-service training, contact Stryker.
- ALWAYS consult the Instructions For Use that accompanies motors, footswitches, and attachments for product specific duty cycles and additional information.
- 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 (Appendix I: Specifications).
- ALWAYS follow the recommended duty cycle to prevent this equipment from overheating.
- DO NOT stack or place equipment adjacent to the console. If such a configuration is necessary, observe the configuration to ensure that electromagnetic interference does not degrade performance.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the console. Portable and mobile radio frequency (RF) communications equipment can affect the function of the console.
- DO NOT use the console in an MRI environment. Using the console in an MRI environment could affect the function of the console.
- ALWAYS ensure footswitch placement is in a secure area where inadvertent activation is not possible.
- ALWAYS select the correct irrigation flow rate based on the surgical procedure and/or handpiece requirements to prevent excessive or insufficient irrigation flow. Failure to comply may limit the view of the surgical site and result in patient and/or healthcare staff injury.
- ALWAYS select the correct attachment/reducer when selecting the motor setting to prevent excessive or insufficient motor speed. Failure to comply may cause incorrect information to be displayed and result in patient and/or healthcare staff injury.
- DO NOT place the console within the sterile field.

7.2 Electrical Warnings



WARNINGS:

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

8 System Overview

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

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

The touch screen provides visual output and serves as an input device when navigating the user interface. The internal speaker provides audio output during operation. See Appendix B: Audio Output for additional information.

The console can store user presets and representative information internally. The presets can be exported from one console and imported to another console with the use of a USB data storage device (Section 11.6.5).

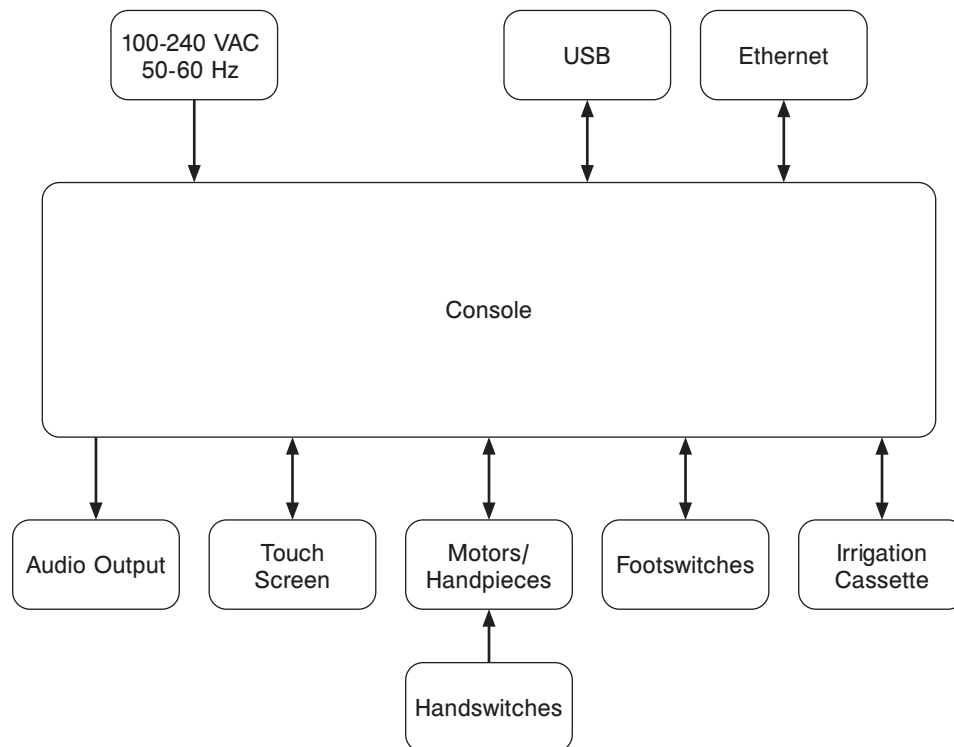


Figure 1 – System Block Diagram

9 Hardware Features

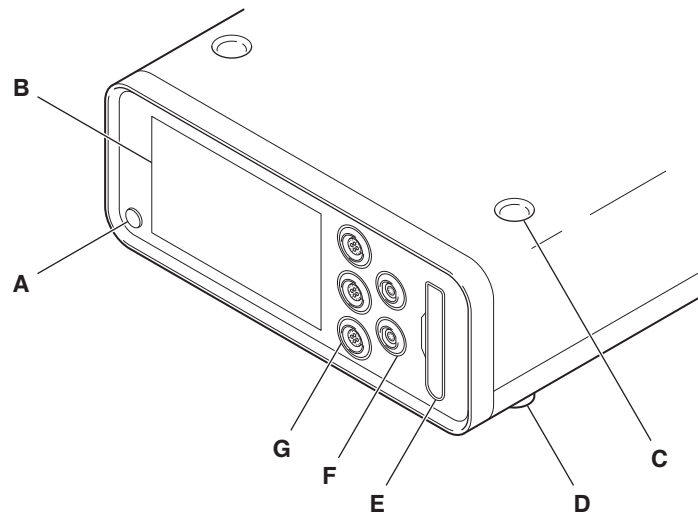


Figure 2 – Console (Front View)

| | |
|---|----------------------|
| A | Power Button |
| B | Touch Screen |
| C | Stacking Inserts (4) |
| D | Stacking Feet (4) |

| | |
|---|--------------------------|
| E | Irrigation Cassette Port |
| F | Footswitch Ports (2) |
| G | Motor Ports (3) |

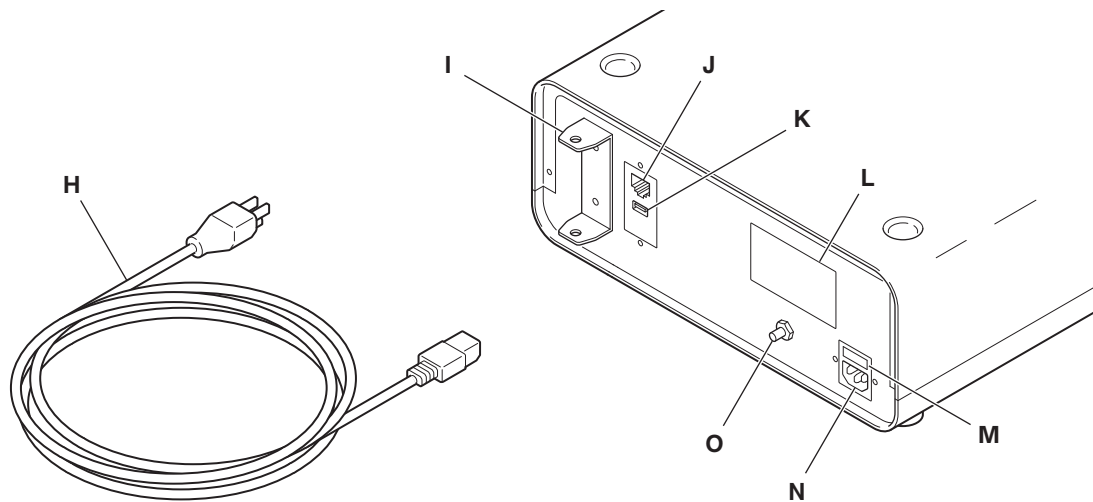


Figure 3 – Console (Rear View)

| | |
|---|---------------|
| H | Power Cord |
| I | Pole Bracket |
| J | Ethernet Port |
| K | USB Port |

| | |
|---|---------------------|
| L | Specification Label |
| M | Fuse Holder |
| N | Power Receptacle |
| O | Equipotential Lug |

10 Screens and Menu Tabs

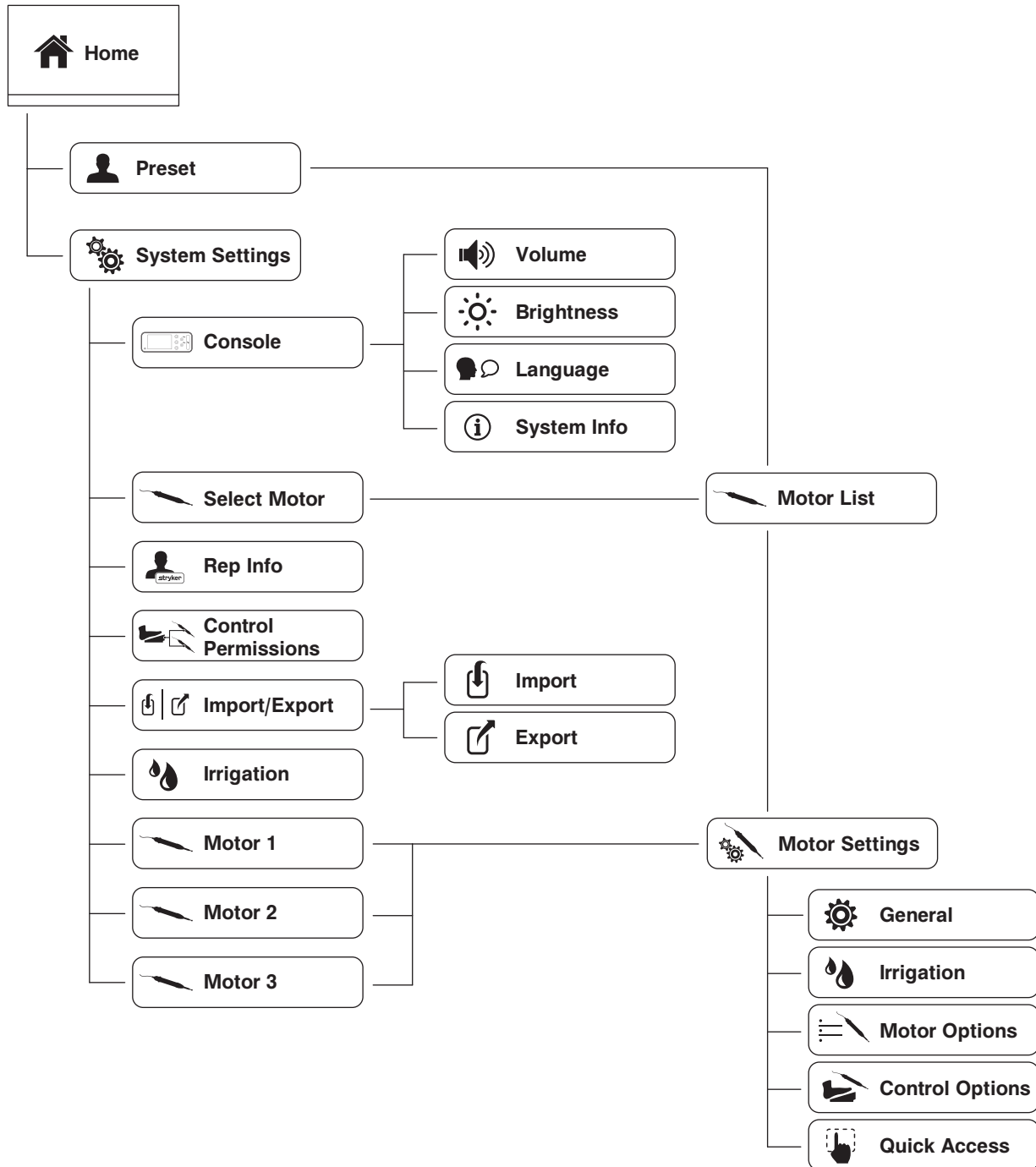



Figure 4 – Screens and Menu Tabs Map

11 Instructions

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.

11.1 Before the Procedure


1. Verify the console is placed on a sturdy, flat surface.
2. Verify the console is not within the sterile field.
3. Verify the following items are connected; connect as necessary (Figure 5):
 - (Optional) Equipotential cable
 - Power cord
4. Verify the equipment is clean and not damaged.
5. Connect the following devices as necessary:
 - Motor(s) (Figure 6)
 - Footswitch(es) (Figure 7)
6. Press  to power the console on.
7. (Optional) Prepare the console for irrigation as follows:
 - 7.1. If required, install an irrigation pole into the pole bracket on the rear of the console (Figure 5).
 - 7.2. Insert an irrigation cassette (Figure 8).
 - 7.3. Attach the irrigation clips onto the motor and connect the tubing to the irrigation bag.
 - 7.4. Prime the irrigation cassette (Section 11.6.6.1).
8. Manage presets as necessary (Section 11.5).
9. Manage system settings as necessary (Section 11.6).

11.2 During the Procedure

- Connect and disconnect devices as necessary.
- If using irrigation, flush irrigation tubing as necessary (Section 11.6.6.2).
- Refer to the following sections for guidance during the procedure as necessary:
 - Section 11.4 Home Screen Instructions
 - Section 11.5 Preset Instructions
 - Section 11.6 System Settings Instructions

11.3 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 clips 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 12).
5. Inspect the equipment for damage.

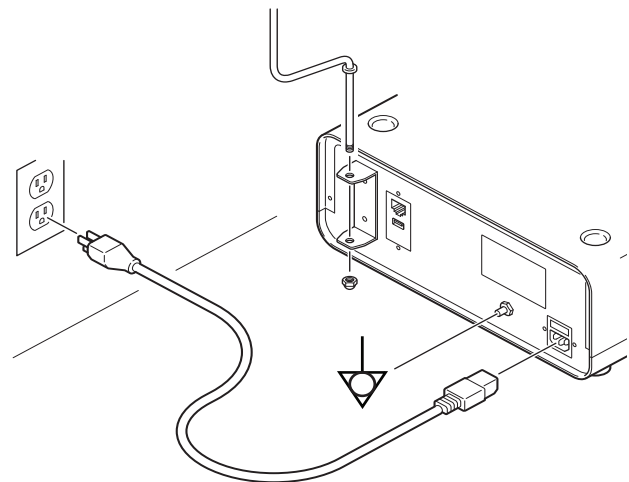


Figure 5 – Console (Rear View)

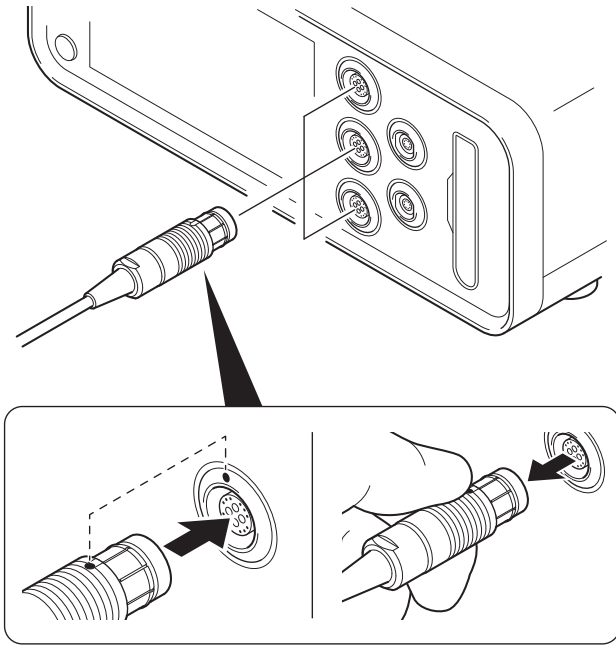


Figure 6 – To Connect/Disconnect a Motor

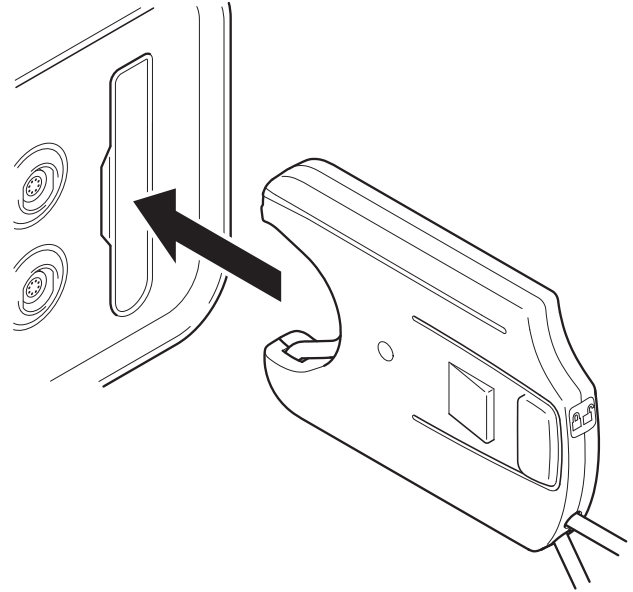


Figure 8 – To Insert an Irrigation Cassette

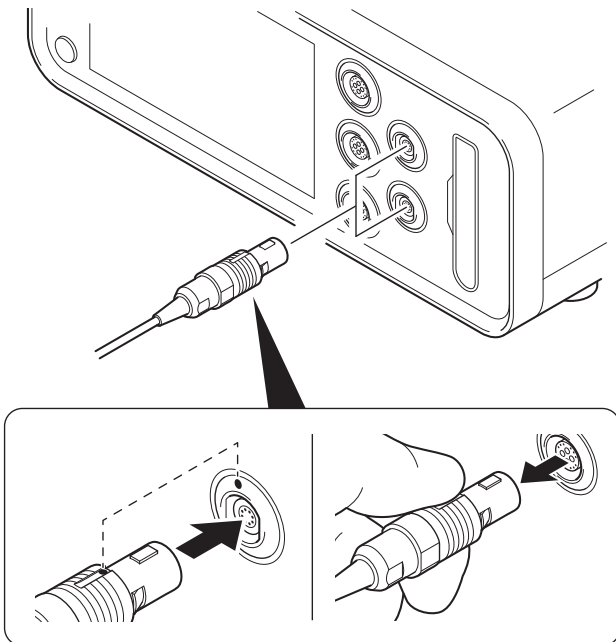


Figure 7 – To Connect/Disconnect a Footswitch

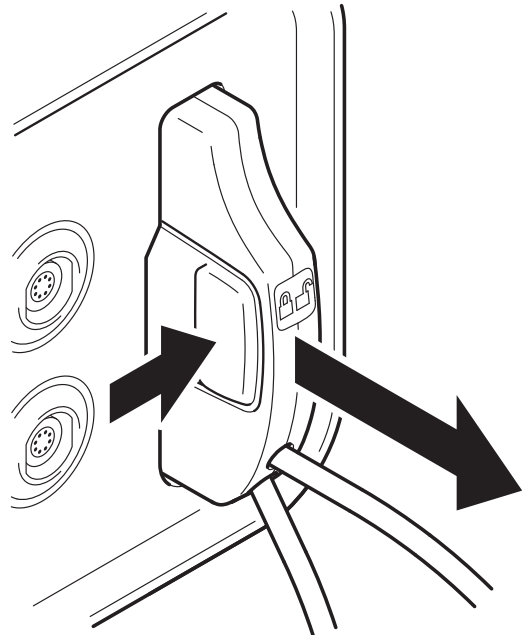


Figure 9 – To Remove an Irrigation Cassette

11.4 Home Screen Instructions

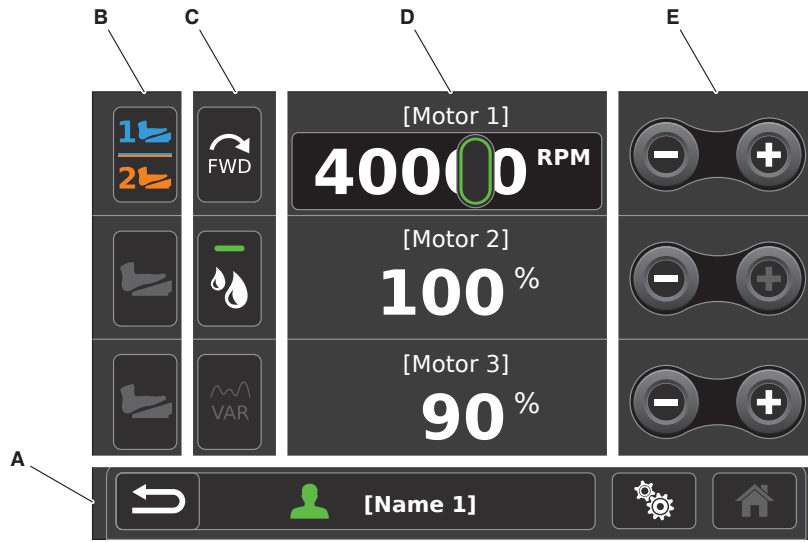



Figure 10 – Home Screen

| | | | |
|-----------------|--|-----------------|---|
| <p>A</p> | <p>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.</p> | <p>D</p> | <p>Motor Settings Value Area – Displays the connected motor(s) name and value setting. Touch the motor value to access the slider bar to adjust the motor value setting.</p> |
| <p>B</p> | <p>Footswitch Assignment Area – Provides a graphical representation of the current footswitch assignment. These buttons can be touched to toggle footswitch assignment.</p> | <p>E</p> | <p>Decrease/Increase Area – From here, the user can use the decrease and increase buttons to adjust the motor value setting.</p> |
| <p>C</p> | <p>Quick Access Area – Allows the user to set features such as direction, irrigation, and mode on the Home screen. These buttons can be set to accommodate the user’s preference (Section 11.6.7.5).</p> | | |

11.4.1 Manage Connected Devices



NOTE: When navigating the software, touch  (Home) to return to the Home screen.

1. Access the Home screen.
2. For each connected device, set the following as necessary (Figure 10):
 - Motor settings value
 - Footswitch assignment
 - Quick access

11.4.2 Access Other Screens

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

From the Home screen:

- Touch  (**Preset**) to access the preset screen.
- Touch  (**Settings**) to access the system settings screen.