stryker

Consolidated Operating Room Equipment
Powered Instrument Driver
REF 5400-050-000

Instructions For Use

R$_x$ ONLY

$C \epsilon$ 0197
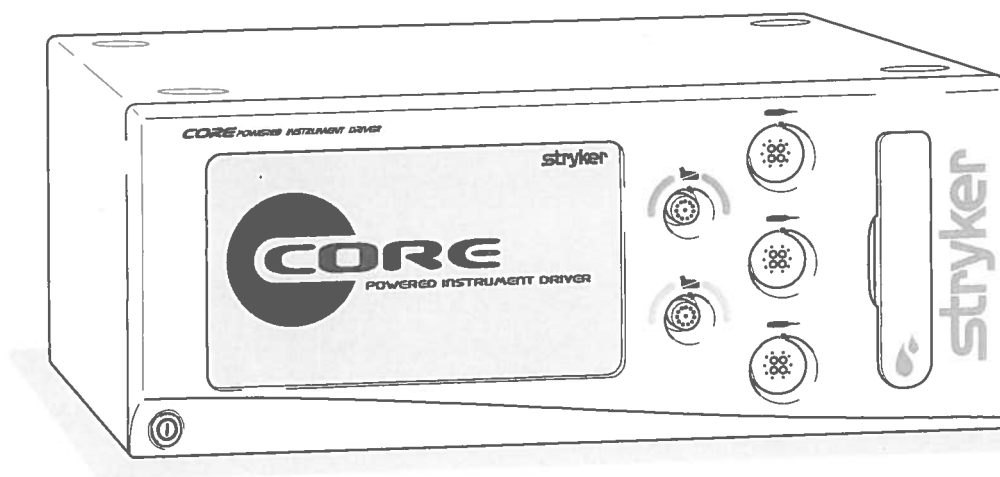
Software Version

8.x

Table of Contents

List of Illustrations

Compliance Statements

Federal Communications Commission (FCC)
FCC ID: Q9R-5400

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: FCC regulations provide that changes or modifications not expressly approved by Stryker Instruments could void your authority to operate this equipment.

Industry Canada (IC)
IC: 4919A-5400

The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

Software License Notice

The Stryker CORE Powered Instrument Driver (console) contains software that is installed by Stryker Corporation ("Stryker"). Stryker owns this software and is licensing it to you, the original CORE Console customer, subject to the following terms and conditions.

Stryker hereby grants you a nonexclusive, nontransferable License to use the software to operate the CORE Console for your own use and to perform maintenance thereon. You hereby agree that you will not copy, alter, modify, translate, disassemble, decompile, reverse engineer, create derivative works of, distribute, sub-license, sell, lease, lend, or otherwise transfer all or any portion of this software, in either original or modified form, except as specifically authorized under this License Agreement. In addition, you agree that you will not use this software in any product other than the Stryker product in which the software was initially installed by Stryker.

EXCEPT FOR ANY WARRANTIES THAT MAY BE EXPRESSLY PROVIDED IN THE STRYKER PRODUCT LITERATURE ACCOMPANYING YOUR CORE CONSOLE OR SOFTWARE, THIS SOFTWARE AND DOCUMENTATION IS PROVIDED "AS IS," AND STRYKER MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

STRYKER WILL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY USE OF THE SOFTWARE OR DOCUMENTATION.

By using this software, you acknowledge and agree that you have read, understood, and agree to be bound by these terms and conditions.

Limited Warranty

In the USA only, products of Stryker Instruments are warranted to the original purchaser for a period of one year from the date of purchase, with exceptions noted below. Products are warranted to be free from defects in material and workmanship. Abnormal wear and tear or damage caused by misuse or by failure to perform normal and routine maintenance as set out in the Maintenance Manual or Operating Instructions, or as demonstrated by an authorized Stryker Instruments representative, is not covered by the warranty. Any effort at field repair or adjustment may invalidate your warranty. Using any accessory that is not a Stryker product will invalidate your warranty.

The warranty extends to all purchasers and is limited to the repair or replacement of the product without charge when returned prepaid to Stryker Instruments. There are no other expressed warranties. This warranty gives you specific legal rights and you may have other rights, which vary by state and municipality.

For selected products.

· Universal Handswitch is warranted for a period of 6 months from date of invoice.

· Handpiece cords are warranted for a period of 6 months from date of invoice.

· Cutting accessories are not warranted.

Important Information

The words WARNING, CAUTION and NOTE have special meaning and should be reviewed.

WARNING: Disregarding WARNING information may compromise the safety of the patient and/or health care staff and may result in injury.

CAUTION: Disregarding CAUTION information may compromise product reliability and may result in damage.

NOTE: NOTE information supplements and/or clarifies procedural information.

⚠ A triangle with an exclamation point alerts the health care professional to read and understand the accompanying instructions, especially the operating, maintenance, and safety information.

Indications For Use

The Stryker Consolidated Operating Room Equipment (CORE™) System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of teeth, bone, bone cement, and other bone-related tissue in a variety of surgical procedures, including but not limited to Neuro, ENT (Ear, Nose, and Throat), Dental and Endoscopic. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

Contraindications

None.

User/Patient Safety*

⚠ **WARNINGS:**

- Only trained and experienced health care professionals should use this equipment. Before using any system component or any component compatible with this system, read and understand the instructions. Pay special attention to WARNING information. Become familiar with system components prior to use. Failure to comply may result in patient and/or operating room staff injury.

- Upon initial receipt and before each use, operate system components and inspect for damage. DO NOT use if damage is apparent. Perform recommended maintenance as indicated in the instructions for use. Only trained and experienced health care professionals should maintain this instrument. Failure to comply may result in patient and/or operating room staff injury.

- Only trained and experienced health care professionals should use this instrument. Health care personnel should be thoroughly familiar with the instructions for use, handling characteristics, and the intended use(s) of this instrument. Contact your Stryker sales representative or Customer Service for in-service training.

- The health care provider performing any procedure is responsible for determining the appropriateness of this instrument and the specific technique for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure.

- Clean and sterilize components before first and every use. See the *CORE Cleaning and Sterilization Recommendations* for specific details.

- DO NOT use this equipment in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

- Prior to each use, operate system components and inspect for damage. DO NOT use if damage is apparent.

- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the CORE console. Install and place the console into service according to the EMC information in this manual. Portable and mobile RF communications equipment can affect the function of the CORE console.

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

- Use only Stryker approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Stryker sales representative for a complete list of accessories. DO NOT modify any accessory. Failure to comply may result in patient and/or operating room staff injury.

- All cutting accessories are intended for single use only. Reuse significantly increases wear on the handpiece and attachment. Failure to comply may result in patient and/or operating room staff injury.

- Always use the appropriate accessory combination with a handpiece. Contact your Stryker sales representative for a complete list of accessories. Failure to comply may result in patient and/or operating room staff injury.

- DO NOT attempt to insert or remove any cutting accessory or attachment while the handpiece is operating. Failure to comply may result in operating room staff injury.

- DO NOT modify the ground connection of the console power cord. Failure to comply may result in patient and/or operating room staff injury.

- DO NOT place a handpiece on a patient. Failure to comply may result in patient injury.

- DO NOT place a handpiece on or near a magnetic pad or tray. A magnetic field can simulate the output of a handswitch or footswitch and may cause the handpiece to operate inadvertently. Failure to comply may result in patient and/or operating room staff injury.

- If power is lost, some of the console's programmed settings, such as the handpiece to footswitch assignment, the footswitch options, and the handpiece operating modes, will revert to their original default configuration or the last selected User Preference configuration. After power is restored, reprogram the console settings as required. Failure to comply may result in patient and/or operating room staff injury.

- Operating a handpiece in the Window Jog mode may increase the temperature of the handpiece. If a handpiece overheats, the console automatically shuts off the handpiece. Monitor the heat response in relation to the type of surgical procedure being performed. Frequently check the distal tip and body until you are familiar with its temperature rise characteristics. Failure to comply may result in patient and/or operating room staff injury.

- Ensure the handpiece speed does not exceed the specified attachment limitations. Failure to do so may result in patient and/or operating room staff injury.

- If operated for extended periods of time, a handpiece may exceed its nominal operating temperature range. A console warning message will appear when the nominal operating range is approached, and again when it is exceeded. Allow the handpiece to cool before restarting.

- Use personal protection equipment. Failure to comply may result in operating room staff injury.

*For further information, contact your Stryker Instruments sales representative or Customer Service at 1-800-253-3210. Outside the USA, contact your nearest Stryker subsidiary.

System Overview

The Stryker CORE Powered Instrument Driver (console) provides an integrated, centrally controlled environment that promotes safe and economical surgical practice.

The console's software provides control over system components including the console, the graphical user interface (GUI), the irrigation pump, and the connected handpieces and footswitches (see figure 1). The software's file management capability allows you to save and store user preference settings and have convenient access to a favorites list of the most frequently used files to improve efficiency.

The color display, with its touch sensitive screen, provides an intuitive graphical user interface that allows you to view multiple system components and set their parameters with the touch of a finger. Changes may be made rapidly, with little to no interruption during surgery.

Multiple handpieces and footswitches may be connected and operated simultaneously from a single console. Because options vary among different handpieces, the console will only display those options that are related to the connected handpiece.

An integral irrigation pump system reliably supplies coolant/irrigation to the cutting site with adjustable flow rates.

Various cutting accessories and irrigation cassettes used with the system are also recognized and identified on the console screen by means of a wireless tag technology.

Console settings, like display brightness and speaker volume, may be easily adjusted. The on board speaker provides audible feedback during operation and configuration.

The console accepts either 100 VAC - 230 VAC input and has the capability to power heavy-duty handpieces.

The Stryker Firewire Backbone (SFB) serial connection provides a serial communications channel between the console and other devices. This feature allows software upgrades over a computer network.
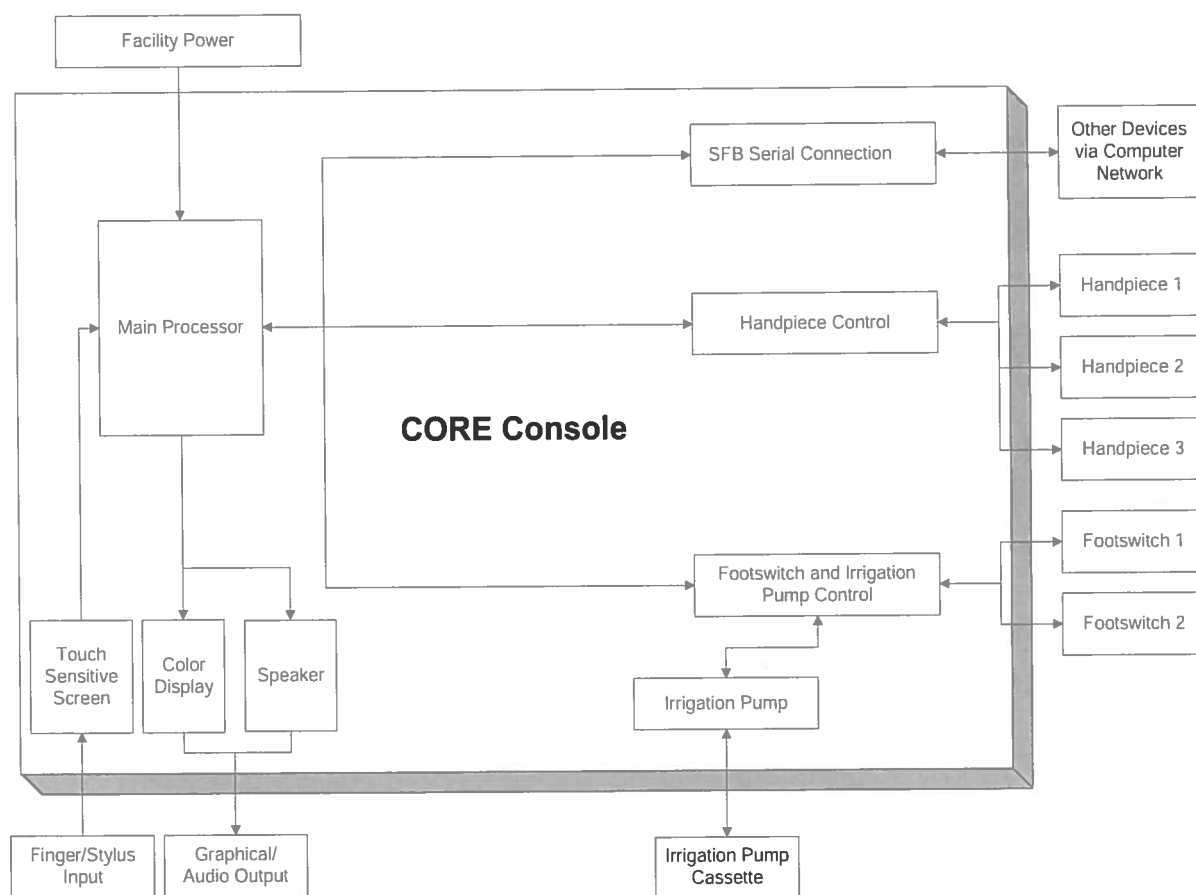

Figure 1. System Block Diagram

Hardware Features and Functions

The hardware feature and functions section provides the location and function of each major feature of the console and may be used during the interconnection of system components (see figure 2).
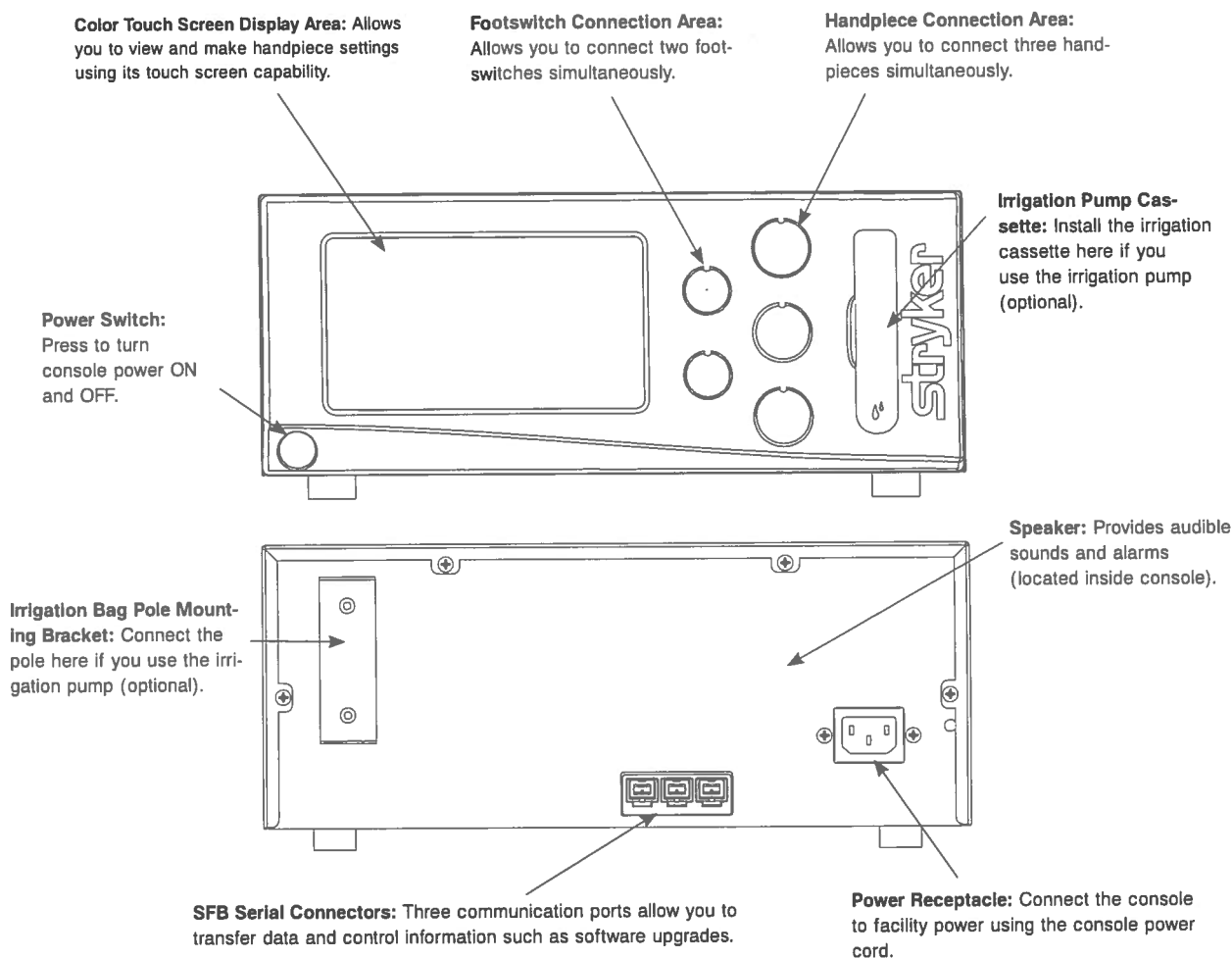
Color Touch Screen Display Area: Allows you to view and make handpiece settings using its touch screen capability.

Footswitch Connection Area: Allows you to connect two footswitches simultaneously.

Handpiece Connection Area: Allows you to connect three handpieces simultaneously.

Irrigation Pump Cassette: Install the irrigation cassette here if you use the irrigation pump (optional).

Power Switch: Press to turn console power ON and OFF.

Speaker: Provides audible sounds and alarms (located inside console).

Irrigation Bag Pole Mounting Bracket: Connect the pole here if you use the irrigation pump (optional).

SFB Serial Connectors: Three communication ports allow you to transfer data and control information such as software upgrades.

Power Receptacle: Connect the console to facility power using the console power cord.

Figure 2. Console Hardware Features and Functions

Accessories*

⚠ **WARNING:** Use only Stryker approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. DO NOT modify any accessory. Failure to comply may result in patient and/or operating room staff injury.

Description	REF
Power Cord	0996-851-010; 0590-100-002
Cable; push-pull type connector with alignment markings and keyed connectors	5100-004-000
TPS Unidirectional Footswitch	5100-007-000
TPS Footswitch	5100-008-000
Irrigation Pole	5100-050-028
NSE Footswitch	5400-007-000
Disposable Irrigation Cassette	5400-050-001
Dual Disposable Irrigation Cassette	5400-050-002

*Contact your Stryker sales representative or Customer Service at 1-800-253-3210 for a complete list of accessories. Outside the USA, contact your nearest Stryker subsidiary.

Operating Instructions

To Connect the Components:

The console interconnect diagram provides the connection sequence of system components. The numbered call outs correspond to the numbered instructions on the next page. See the instructions for use supplied with each component for specific connection information. The illustrated hardware below provides a likeness, but may not be an exact representation of the actual hardware (see figure 3).
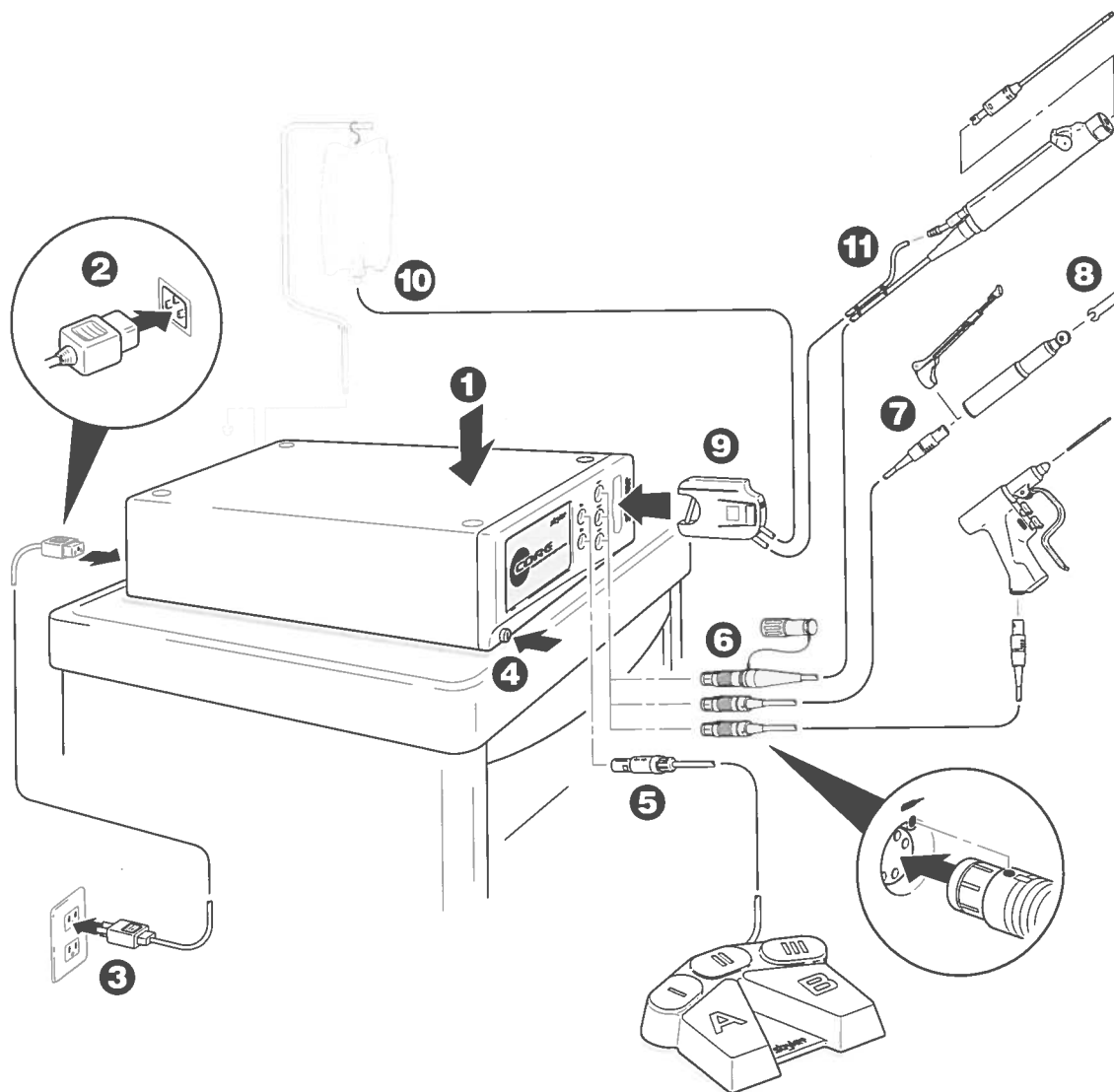
Figure 3. Console Interconnect Diagram

Symbol Definitions

On/Off (push-push)	Footswitch	Handpiece	Irrigation	Type BF Applied Part	SFB Serial Connection	Equipotential

To Connect the Components (cont'd):

NOTE: See figures 2 and 3 while performing the instructions below. See the instructions for use supplied with each component for specific connection information.

1. Place the console on a sturdy, flat surface near a hospital-grade outlet.

2. Install the power cord plug into the power receptacle on the console.

3. Install the other end of the power cord into a hospital-grade wall outlet.

4. Press the power switch to turn the console on. See *To Power Up* and *To Adjust Options* sections for more information.

NOTES:

·   The universal power supply will automatically adjust to match the voltage and frequency of the facility power.

·   As you connect components to the console, the console's screen will change to display the specific components that are connected.

CAUTIONS:

·   DO NOT thread or twist the push/pull connectors on the cords during installation or removal.

·   When connecting or disconnecting a cable(s) to the front of the console, always hold the cable by its connector (the plug, not the cord). Failure to comply may result in damage to the cable or console.

·   Cables that are connected to the front of the console have keyed, push-pull type connectors that lock into place. DO NOT force a connector into a console port. Each connector and port has an alignment mark to indicate proper cable orientation.

5. If using a footswitch, plug the footswitch cable into the console port marked with a FOOTSWITCH PORT symbol. Align the marks and gently push the connectors together. Two footswitches may be connected to the console.

NOTE: A registered wireless footswitch will be overridden and disabled when a wired footswitch is connected and registered to the same color footswitch port.

6. Plug the handpiece cord(s) into the console port(s) marked with a HANDPIECE PORT symbol. Align the marks and gently push the connectors together. Three handpieces may be connected to the console and two handpieces may be operated simultaneously.

NOTES:

·   If using a CORE Universal Handswitch, attach it to the handpiece before you plug the cord into the handpiece.

·   If using CORE console software version 6.1 or later, a Heavy Duty Power Pack (power pack) may be used to allow either a Stryker System 4 or 5 Heavy Duty Handpiece to operate with the console. If a power pack is connected to the console, the associated heavy duty handpiece will take priority over other attached, inactive handpieces. Only one heavy duty handpiece may be operated using the power pack with the console. No other connected handpieces will be allowed to operate. See instructions for use supplied with the Heavy Duty Power Pack for connection information.

7. Plug the other end of the handpiece cord(s) into the handpiece(s). See instructions for use supplied with each handpiece for connection information.

⚠ **WARNING:** Use only Stryker approved cutting accessories.
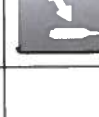
8. Attach the cutting accessory to the handpieces. See the instructions for use supplied with each handpiece or attachment for cutting accessory installation information.

    NOTE: If using the console irrigation pump (optional), install the Irrigation Pole REF 5100-050-028 (optional, may use equivalent irrigation pole) to the mounting bracket on the back of the console. Hang the irrigation bag from the pole.
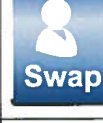
9. If required, install the irrigation cassette into the console port marked with a IRRIGATION PUMP CASSETTE symbol.

10. If required, connect the irrigation tubing to the irrigation bag.

11. If required, attach the irrigation clips to the handpiece(s) and connect the tubing. Connect the irrigation tubing to the handpiece. See the instructions for use supplied with each handpiece for connection information.

12. Test all the system components to ensure that they are performing properly before surgery. Refer to the Button Definitions and Software Menu Map sections when using the graphical user interface.

Button Definitions:

The button definitions section provides a complete list of the buttons as they appear on screens within the software interface.

BUTTON	NAME	DEFINITIONS	BUTTON	NAME	DEFINITIONS
	HOME	Access the HOME screen to view and adjust handpieces and system settings		OSCILLATE	Set default mode of handpiece to OSCillate
	HELP	Access task-oriented HELP related to screen and button functionality		FORWARD	Set default mode of handpiece to rotate in the Forward (clockwise) direction
	BACK	Return to the previous screen		REVERSE	Set default mode of handpiece to rotate in the Reverse (counterclockwise) direction
	UP	Scroll up		LOW	Set default mode of handpiece to operate in the low RPM range mode
	INCREASE	Increase the value of a setting		HIGH	Set default mode of handpiece to operate in the high RPM range mode
	DOWN	Scroll down		ADJUST OPTIONS	Adjust handpiece and footswitch options
	DECREASE	Decrease the value of a setting		FIXED SPEED	Set the default run mode of the handpiece speed to operate at the set speed only
	OK	Accept inputs, changes or selections and return to previous screen		VARIABLE SPEED	Set the default run mode of the handpiece speed to respond to the degree of pressure applied to the handswitch or footswitch
	ESC	Close (ESCape) a pop-up or screen without accepting inputs, changes or selections and return to previous screen		ONE TOUCH	Set the default run mode of the handpiece activation to respond to one touch of a handswitch or footswitch
	FACTORY DEFAULT	Apply original factory default settings		PROGRAM FOOTSWITCH	Program the footswitch pedals and pads based on the handpiece capabilities
	DISABLE BUTTONS	Disable all four NSE Footswitch pads		ASSIGN FOOTSWITCH TO HANDPIECE	Assign a specific footswitch port to a specific handpiece port
	SWITCH FOOTSWITCH	Toggle between the NSE Footswitch Options screen and the TPS Footswitch Options screen			

Button Definitions: (cont'd)

BUTTON	NAME	DEFINITIONS	BUTTON	NAME	DEFINITIONS
	SET HANDPIECE OPTIONS	Select specific handpiece options and assign them to a particular handpiece button		SAVE CURRENT SETTINGS	Save current console settings to the selected file in the user preference favorites list
	MANAGE USER PREFERENCES	Create and modify user preference folders and files		ADJUST CONSOLE OPTIONS	Adjust console options in the standard or advanced mode
	DELETE	Delete a folder, file or handpiece from a user preference file		ADJUST VOLUME AND SCREEN	Adjust console volume, brightness and contrast
	CREATE FILE	Create a new user preference file		SELECT LANGUAGE PREFERENCE	Select the language to be displayed on the console screen
	COPY CURRENT SETTINGS	Copy the current active user preference settings to a new file		SELECT ADVANCED CONSOLE SETTINGS	Select network settings
	CREATE FOLDER	Create a new user preference folder		ACCESS ADVANCED MODE	Access user preference options
	OPEN AND MODIFY	Open a user preference folder and modify the file(s) as required		SELECT USER PREFERENCE FAVORITE	Select one of five favorite user preference files as the console default
	NAVIGATE UP	Navigate up one directory		SWAP USER PREFERENCE FAVORITE	Replace one of the five favorite user preference files with another preference file
	ACCESS HANDPIECE SCREEN	Access the Add Handpiece screen		ACCESS ADVANCED HANDPIECE OPTIONS	Access advanced handpiece options
	ADD HANDPIECE	Add handpiece to a user preference file		SYSTEM INFORMATION	Access to System Information screen to view hardware and software information
	VIEW/EDIT SETTINGS	View and edit the user preference file settings of a selected handpiece		ADJUST IRRIGATION PUMP SETTINGS	Adjust and apply an irrigation flow rate to a handpiece cutting accessory
	EDIT SETTINGS	Change user preference file settings			

Button Definitions: (cont'd)

Button	Name	Definitions
FLUSH	FLUSH TUBING SET	Provide a continuous irrigation flow rate to flush the tubing set
AUTO PRIME	AUTO PRIME TUBING SET	Prime the tubing set to the irrigation tip
(S icon)	SELECT NETWORK CONNECTIONS	Select specific network connections
English	SELECT ENGLISH LANGUAGE	Select English as console screen language
Deutsch	SELECT GERMAN LANGUAGE	Select German as console screen language
Français	SELECT FRENCH LANGUAGE	Select French as console screen language
Español	SELECT SPANISH LANGUAGE	Select Spanish as console screen language
Italiano	SELECT ITALIAN LANGUAGE	Select Italian as console screen language

To Power Up:

This screen is momentarily displayed while the console powers up. Note the software version is displayed in the lower right corner of the screen (see figure 4).

Figure 4. Power Up Screen

If no handpieces or cords are connected to the console during initial power up, the following screen will appear (see figure 5):
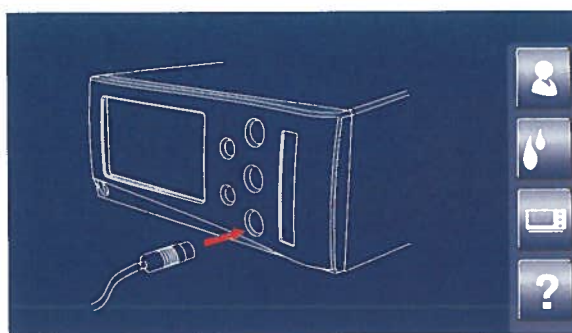
Figure 5. Plug In Handpiece Cable Screen

Software Menu Navigation

The software menu map is a visual representation of how the software is structured and is designed to facilitate navigation (see figure 6). The map also provides the sequence of screen information provided in this manual, top down and left to right. The icons used in this map are button icons used in the software and also reside near header information in this manual. The screen illustrations used in this manual provide a likeness, but may not be an exact representation of the actual console screens.
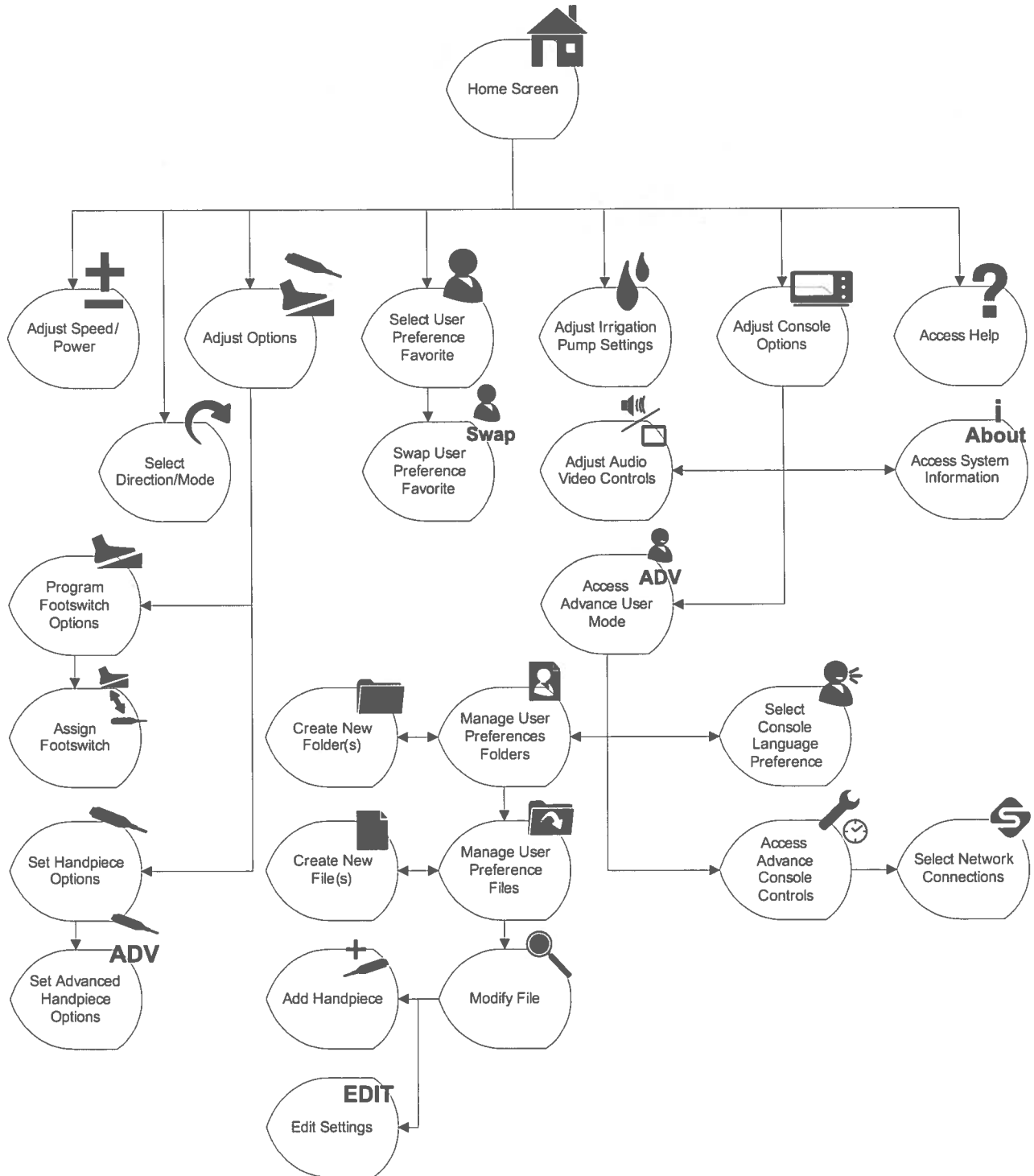
Figure 6. Console Software Menu Map

To Select Settings:

The HOME screen is where most user interaction will take place (see figure 7). Up to three handpieces may be displayed on the screen simultaneously. When the console is initially turned on, the console settings are factory default settings until a user preference file is selected or the settings are manually modified.

NOTE: If the console screen is touched in two places simultaneously, unintended button activation may result.

Handpiece Operating Area
View and modify key handpiece settings.

View User Preference File Name
View name of file that contains handpiece settings for a specific procedure, for example, ACL (Anterior Cruciate Ligament) surgery.

Console Operating Area
Access key console functions.

Attached Handpieces
Three handpieces may be attached to the console and two may be operated simultaneously.

View Handpiece Name
View name of active handpiece. Three handpieces may be connected and displayed. Two powered handpieces may be operated from the same console, simultaneously.

View Option Settings
View option settings such as irrigation, footswitch control, and fixed or variable RPM (revolutions per minute). All of these settings may be modified.

View Cutting Accessory or Attachment Name
View cutting accessory or attachment name if the handpiece, accessory and/or attachment have been selected or have recognition capability.

Figure 7. Home Screen - Overview

2011/02

+ —   **To Adjust Handpiece Speed (or Power):**

From the HOME screen, touch the plus and minus buttons to adjust the handpiece speed or power set point in RPMs or percentage of power (see figure 8).

NOTE: When you install a cutting accessory with cutter recognition capability or select an attachment, the system will automatically override the selected speed setting in each mode to the speed settings that are appropriate for the installed cutting accessory.

While the handpiece is running, the display shows the actual handpiece speed. If the handpiece is not running, the default or selected speed is displayed.

The default speed is displayed for each handpiece until you adjust the speed set point based on the handpiece capability or modify the speed in a user preference file.
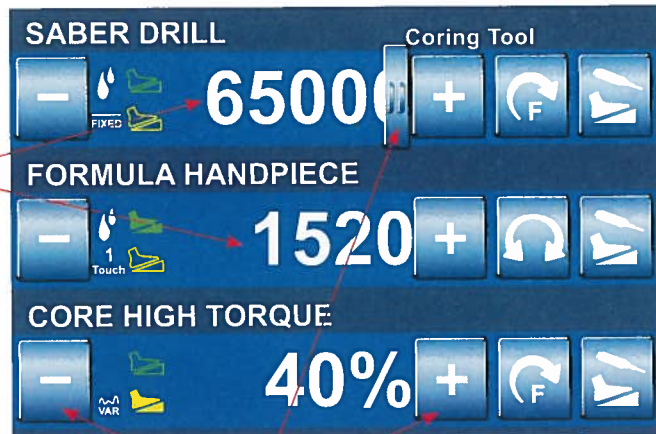
Touch the adjustment buttons (or slider bar that becomes visible when touching the speed value) to increase or decrease the speed (power) set point.

Figure 8. Home Screen - Speed (or Power)

To Select Handpiece Mode and Direction:

From the HOME screen, touch the Select Direction/Mode button to adjust the handpiece direction and mode (see figure 9).

NOTE: The available handpiece options, including handpiece direction and mode, will depend on the type of handpiece that is identified at the top of the screen.

REVERSE: Touch to cause the handpiece cutting accessory to rotate in the reverse (counterclockwise) direction.

FORWARD: Touch to cause the handpiece cutting accessory to rotate in the forward (clockwise) direction.

Direction Options Select the direction of the cutting accessory.

OSC: Touch to cause the handpiece cutting accessory to OSCillate.

Mode Options Select the mode of handpiece operation.

HIGH: Touch to cause the handpiece to operate in the high RPM range mode.

LOW: Touch to cause the handpiece to operate in the low RPM range mode.

Figure 9. Select Mode/Direction Screen

To Adjust Options:

From the HOME screen, touch the Adjust Options button to adjust the handpiece options (buttons and trigger, such as handswitch). The available handpiece options will depend on the type of handpiece that is identified at the top of the screen (see figure 10).

NOTE: To program the footswitch pedals and pads, touch the Footswitch Options button.

Adjust Acceleration

- Touch the plus and minus buttons or slider bar to adjust the percent of acceleration [0 to 100%].

- At 100%, the handpiece speed accelerates quickly. Acceleration slows as the setting approaches zero percent.

Select Run Mode

- **FIXED:** handpiece runs at the full set speed or power. Varying pressure on the handswitch (or trigger) will not vary the handpiece speed or power.

- **VARIABLE:** handpiece speed responds to the degree of pressure applied to the handswitch (or trigger).

- **ONE TOUCH:** Handpiece activation responds to one touch of a trigger device (handswitch) and continues to run when the trigger device is released. Handpiece is deactivated by touching any trigger device. In this mode, the handpiece operates at constant set-point speed/power level.
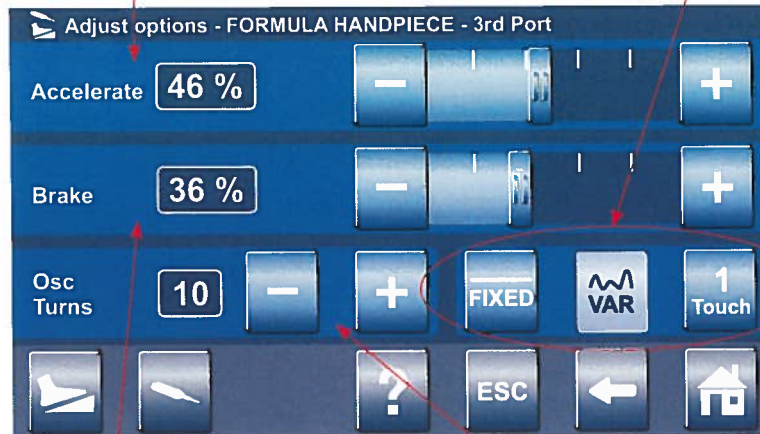
Adjust Braking

- Touch the plus and minus buttons or slider bar to adjust the percent of braking [0 to 100%].

- At 100%, the handpiece stops abruptly. The amount of deceleration decreases as the setting approaches zero percent.

Adjust Oscillate Turns

- Touch the plus and minus buttons to select the number of turns per direction when running a handpiece in the oscillate mode.

- Touch the minus button until the TIME-BASED icon is visible to operate in a TIME-BASED mode where the number of turns are based on the speed of the handpiece.

Figure 10. Adjust Options Screen

To Program Footswitch Options:

From the Adjust Options screen, touch the Program Footswitch button to program the footswitch pedals and pads based on the capabilities of the connected handpiece (see figure 11). Two footswitches may be connected to and simultaneously operated from the same console. However, two footswitches cannot be used to control the same handpiece at the same time.

TPS Footswitch Options Screen

View Handpiece Port
Indicates the assigned handpiece port for which the footswitch is programmed.

Assign Specific Option
Select a footswitch pad [I, II or III] or pedal [A, B or NSE Footswitch] and assign a specific option.

Touch the arrow buttons to scroll through the footswitch options. The available options are handpiece specific. Touch the OK button to select the option.

NSE Footswitch Options Screen

Figure 11. Footswitch Options Screens

To Program Footswitch Options:

⚠️ **WARNING:** Read and understand the appropriate Stryker handpiece instructions for use.

NOTES:

· Footswitch options will override individual handpiece settings unless the footswitch is programmed with default settings.

· The following is a generic list of footswitch pedal and pad options that are available if the connected handpiece supports the option:

TPS Footswitch Pedals [A and/or B] and NSE Footswitch Pedal Options:

Direction:

- **DEFAULT**: will cause the handpiece to operate according to the HOME screen settings. These settings may be factory default settings of the connected handpiece or user programmed settings. Specific default settings vary based on how the handpiece was programmed at the factory or Home screen.

- **FORWARD [FWD]**: pressure on the pedal will cause the handpiece to rotate in the forward (clockwise) direction.

- **REVERSE [REV]**: pressure on the pedal will cause the handpiece to rotate in the reverse (counterclockwise) direction.

- **DISABLE**: will disable the footswitch pedal.

Operating Mode:

- **DEFAULT**: will cause the handpiece to operate according to the factory default setting of the connected handpiece. Specific default settings vary based on how the handpiece was programmed at the factory.

- **HIGH**: pressure on the footswitch pedal will cause the handpiece to operate in the high-speed range or mode.

- **LOW**: pressure on the footswitch pedal will cause the handpiece to operate in the low speed range or mode.

- **OSC**: pressure on the footswitch pedal will cause the handpiece to OSCillate.

Run Mode:

- **DEFAULT**: will cause the handpiece to operate according to the factory default setting of the connected handpiece. Specific default settings vary based on how the handpiece was programmed at the factory (DEFAULT will cause the handpiece to operate in the specific RUN mode selected in the Adjust Options screen).

- **VARIABLE**: varying pressure on the footswitch pedal will cause the handpiece speed to vary.

- **FIXED**: pressure on the footswitch pedal will cause the handpiece to operate at a constant speed as set on the HOME screen.

- **1 TOUCH**: acting like an on/off toggle, tap the footswitch pedal to operate the handpiece at the maximum speed. Tap the footswitch pedal again to stop the operation.
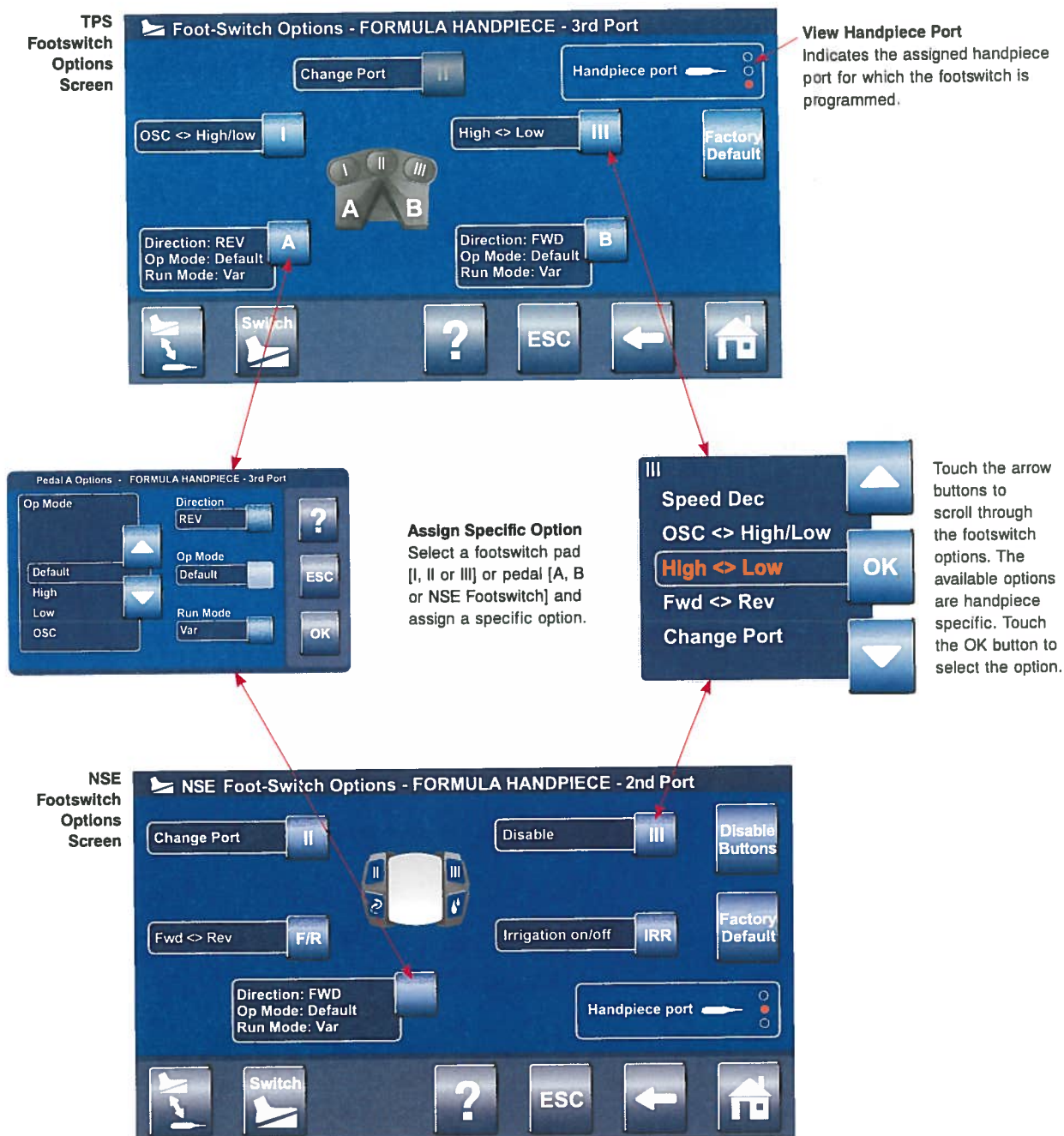
Footswitch Pads [I, II, and/or III] Options:

NOTE: The **IRRIGATION ON/OFF** and **FWD<>REV** stand-alone buttons on the NSE Footswitch can not be programmed to any footswitch pad options other than **DISABLE**.

- **SPEED INCREMENT [INC]**: pressure on the pad will increment the set point speed.

- **SPEED DECREMENT [DEC]**: pressure on the pad will decrement the set point speed.

- **IRRIGATION INCREMENT [INC]**: pressure on the footswitch pad will increment the pump flow set point and increase irrigation to the handpiece cutting accessory.

- **IRRIGATION DECREMENT [DEC]**: pressure on the footswitch pad will decrement the pump flow set point and decrease irrigation to the handpiece cutting accessory.

- **IRRIGATION ON/OFF**: pressure on the footswitch pad will toggle the irrigation pump on and off.

- **OSC<>HIGH/LOW**: pressure on the pad will toggle the operating mode of the handpiece.

- **HIGH<>LOW**: pressure on the pad will toggle the operating mode of the handpiece speed.

- **FWD<>REV**: pressure on the pad will toggle the direction of handpiece rotation.

- **CHANGE PORT**: pressure on the footswitch pad will change the footswitch assignment to another assigned handpiece.

- **FLUSH**: pressure on the pad will turn the irrigation pump on at the flush rate [300%].

- **CHANGE ATTACHMENT**: pressure on the footswitch pad will toggle through the list of attachments that are available for the handpiece. Available attachments are handpiece dependent.

- **DISABLE**: will disable the footswitch pad.

- **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.

To Program Footswitch Options: (cont'd)

⚠️ **WARNING:** When a footswitch is connected or disconnected from the console, the handpiece to footswitch assignment will change. Verify the handpiece to footswitch assignment is correct before using a handpiece in a procedure. Failure to comply may result in patient and/or operating room staff injury.

Assign Footswitch to Handpiece Port

The Assign Footswitch to Handpiece screen will appear automatically when connecting two footswitches and two or more handpieces to the console (see figure 12). This screen will also appear when a footswitch is plugged into an unassigned footswitch port.
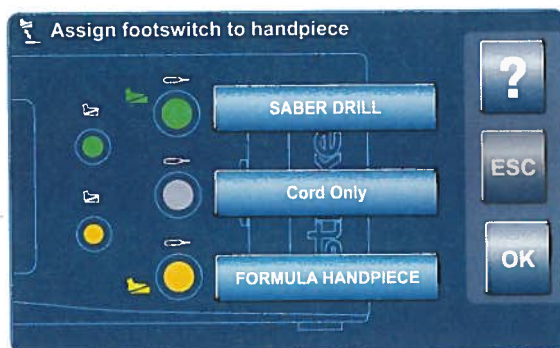
Figure 12. Assign Footswitch Screen - Automatic

Access the Assign Footswitch to Handpiece screen manually as follows (see figure 13):
1. From HOME screen, press Adjust Options button
2. From Adjust Options screen, press Program Footswitch button
3. From Program Footswitch screen, press Assign Handpiece to Footswitch button
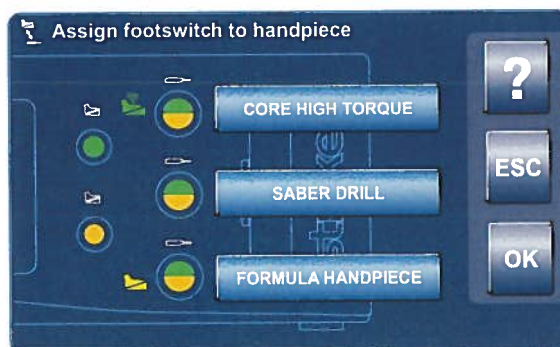
Figure 13. Assign Footswitch Screen - Manual

The color options above indicate the default setting for two connected footswitches and three connected handpieces. Touch the handpiece name button to toggle through the four color options. Each color indicates a footswitch to handpiece port assignment as described below:

Green indicates the top (green) footswitch is assigned to the handpiece port.

Filled green icon indicates which handpiece will be operated when the associated footswitch is actuated.

Yellow indicates the bottom (yellow) footswitch is assigned to the handpiece port.

Filled yellow icon indicates which handpiece will be operated when the associated footswitch is actuated.

Green/Yellow combination indicates both footswitch are assigned to the handpiece port.

Filled green icon with waves indicates which handpiece will be operated when the associated wireless footswitch is actuated.

Gray indicates no footswitch is assigned to the handpiece port.

Filled yellow icon with waves indicates which handpiece will be operated when the associated wireless footswitch is actuated.

To Set Handpiece Options:

⚠ **WARNING:** Read and understand the appropriate Stryker handpiece instructions for use.

From the Adjust Options screen, touch the Set Handpiece Options button to select specific handpiece options and assign them to a particular handpiece button (see figure 14). Options are handpiece dependent and may not be available if the handpiece does not support them. Handpiece attachments may also be selected, if supported. If selected, the console will display the correct attachment information and set speed value for the handpiece.

Select Handpiece Attachment

- Select specific attachment based on the handpiece capability.

- Touch arrows to scroll through and highlight a handpiece attachment.

Program Handpiece Buttons

- Touch numbered button to assign an option.

- Select specific options and assign them to a particular handpiece button based on handpiece capability.

- Touch arrows to scroll through and highlight an option. Touch OK to select option.

Figure 14. Set Handpiece Options Screen

NOTE: The following is a generic list of handpiece button options that are available if the connected handpiece supports the option:

- **MAIN TRIGGER:** button actuation will cause the handpiece to operate according to the factory default settings for direction and mode. Specific default settings vary based on how the handpiece was programmed at the factory.

- **FORWARD [FWD]:** button actuation will cause the handpiece to rotate in the forward (clockwise) direction.

- **REVERSE [REV]:** button actuation will cause the handpiece to rotate in the reverse (counterclockwise) direction.

- **OSCILLATE [OSC]:** button actuation will cause the handpiece to OSCillate.

- **DISABLE:** will disable the handpiece button.

- **SPEED INCREMENT [INC]:** button actuation will increment the set point speed.

- **SPEED DECREMENT [DEC]:** button actuation will decrement the set point speed.

- **OSC<>HIGH/LOW:** button actuation will toggle the operating mode of the handpiece.

- **HIGH<>LOW:** button actuation will toggle the operating mode of the handpiece speed.

- **FWD<>REV:** button actuation will toggle the direction of handpiece rotation.

- **JOG:** button actuation will cause the cutting accessory to rotate at a very low speed to position the cutting edge within the cutting window.

To Set Advanced Handpiece Options:

From the Set Handpiece Options screen, touch the Advanced Handpiece Options button to select specific advanced handpiece options and assign them a value (see figure 15). Options are handpiece dependent and may not be available if the handpiece does not support them.

ADV

Set Handswitch Control Button

Press the button to toggle the handswitch control function to ON or OFF.
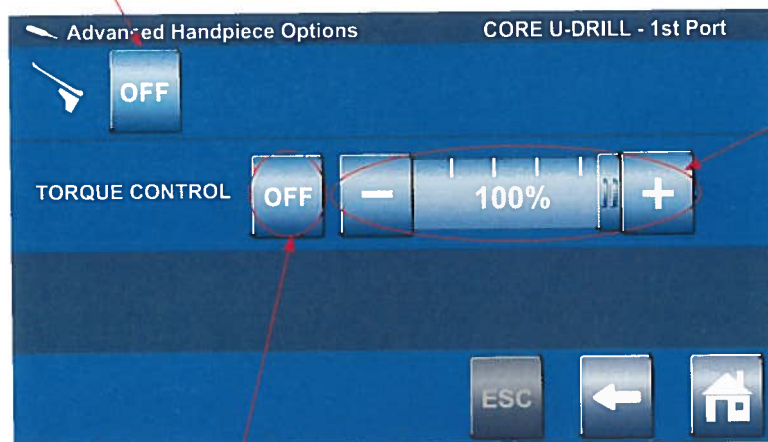
Adjust Torque Control Setting

Touch the slide bar or plus/minus buttons to adjust the percentage of torque control [0 to 100%] of the handpiece.

Torque Control ON/OFF Toggle Button

- Touch the button and select OFF to set the torque control to the default setting of 100%.

- Touch the button and select ON to allow the torque control to be adjusted between 0% and 100%.

Figure 15. Set Advanced Handpiece Options Screen

To Select a User Preference Favorite:

From the HOME screen, touch the Select a User Preference Favorite button to select a favorite user preference file or replace an existing one (see figure 16). Five favorite files are available. Each file contains specific handpiece(s) settings for a particular procedure.

NOTE: To create or modify a user preference file, see *To Adjust Console Options* and *To Manage User Preferences* sections.

Default File: Any file loaded to the default location will be active at console start up.

Touch to select one of the five favorite user preference files.
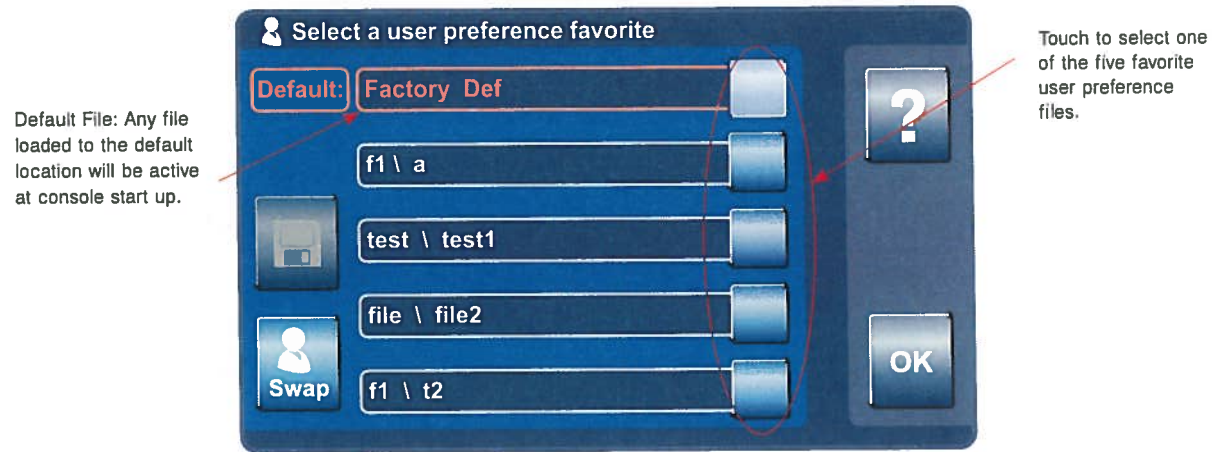
Figure 16. Select User Preference Favorite Pop-up

To Replace a User Preference Favorite:

Swap

From the Select a User Preference Favorite pop-up, touch any of the five User Preference Favorite buttons to make the Swap button active (see figures 17, 18, and 19). Once active, touch the Swap button to select a new favorite preference file.

Save Current Settings - Touch to save current console settings to the selected file in the user preference favorites list.
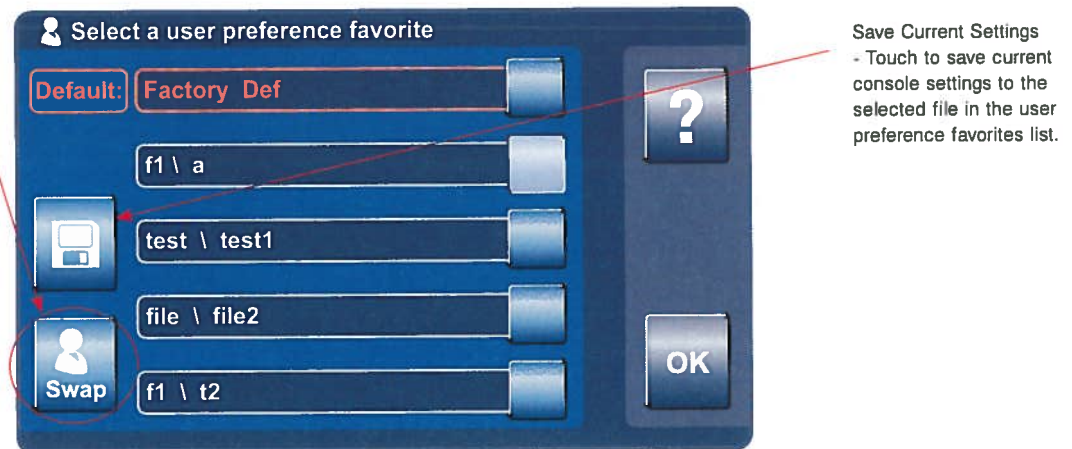
Figure 17. Swap (replace) User Preference Favorite Pop-up

Swap

To Replace a User Preference Favorite (cont'd)

Touch to highlight and select the desired folder.
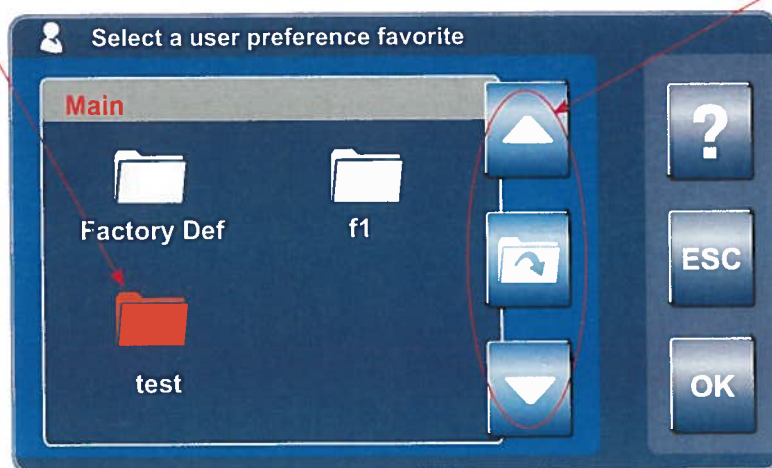
Touch arrow buttons to scroll through and view the available folders. Select a folder and touch the Open Folder button to access the files.

Figure 18. Select User Preference Favorite - Folder

Touch to select the desired file.
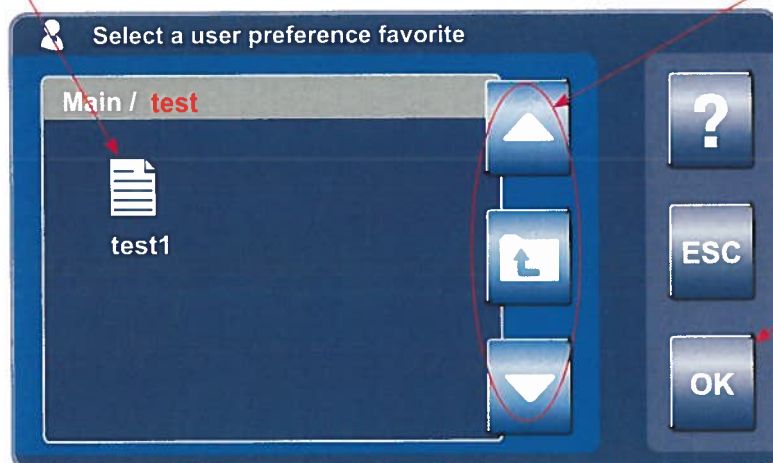
Touch arrow buttons to scroll through and view the available files. Touch the Navigate Up button to return to folder directory.

Touch OK button to replace one of the favorite preference files.

Figure 19. Select User Preference Favorite - File

To Adjust Irrigation Pump Settings:

NOTE: If using the irrigation pump, assemble the irrigation pole to the mounting bracket located on the back of the console. Hang the irrigation bag from the pole. Install the irrigation cassette into the console pump. Attach the irrigation clips onto the handpiece and connect the tubing.

From the HOME screen, touch the Adjust Irrigation Pump Settings button to adjust and apply an irrigation flow rate to a handpiece cutting accessory (see figure 20). AUTO PRIME and FLUSH options are also provided.

Adjust Irrigation % Setting

- Touch the slide bar or plus/minus buttons to adjust the flow rate percentage of irrigation [0 to 100%] to the cutting accessory of the handpiece.

- At 100%, irrigation to the handpiece is set to maximum flow rate. The rate decreases as the setting approaches zero.
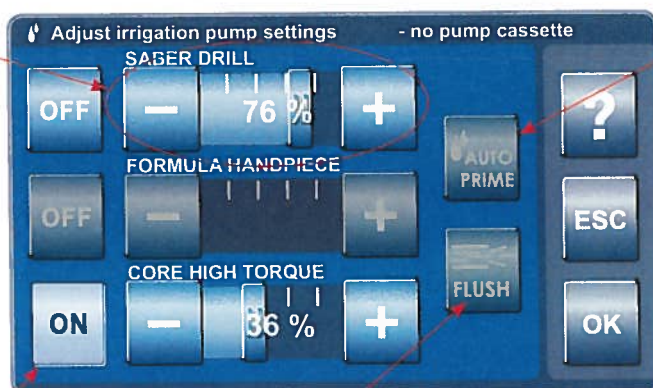
AUTO PRIME Tubing Set

- Touch to activate the priming sequence of the installed irrigation cassette.

- The tubing will be primed from the pump head to the irrigation tip.

FLUSH Tubing Set - Touch and hold to provide a continuous flow rate of 300 mL/min with no irrigation clip and a minimum pressure of 30 psi when the tubing is blocked.

Select Handpiece

- Touch one or all of the handpiece buttons to allow activation of the irrigation pump. If no buttons are selected, the pump will not operate.

- Activation will apply an irrigation flow rate to the handpiece cutting accessory.

- The flow rate will depend on the type of handpiece.

- Activating a handpiece will gain control of the console irrigation. While the first activated handpiece is running, activating another handpiece will not change pump flow, but may reduce irrigation to the first handpiece if a dual disposable irrigation cassette REF 5400-050-002 is used. To gain complete control of console irrigation, stop the first handpiece and activate the other handpiece.

Figure 20. Adjust Irrigation Pump Settings Screen

To Adjust the Console Options: - Standard and Advance User Mode

From the Adjust Options screen, touch the Adjust Console Options button to access console adjustments and settings (see figure 21).

To Adjust Audio/Video Controls - Standard Mode

Touch the button to adjust the console controls.

Adjust Volume

Touch the slide bar or plus/minus buttons to adjust the percent of console volume [0 to 100%].

Adjust Brightness

Touch the slide bar or plus/minus buttons to adjust the percent of console display brightness [0 to 100%].

Adjust Contrast

Touch the slide bar or plus/minus buttons to adjust the percent of console display contrast [0 to 100%].
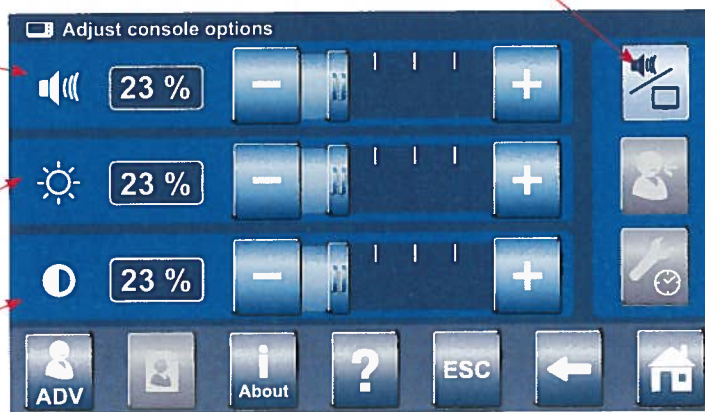
Figure 21. Adjust Console Options Screen - Standard User Mode

To Adjust the Console Options: - Standard and Advance User Mode

To Access Advance User Mode

From the Adjust Console Options screen, touch the ADV button to gain access to the ADVance User Mode and the User Preference file management system (see figures 22, 23, 24, 25, 26 and 27). An Access Advance User Mode pop-up will appear to confirm your request. Once confirmed, the Manage User Preference button will become active.
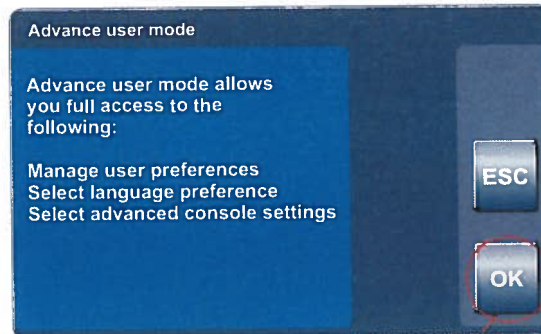
Figure 22. Access Advance User Mode Pop-up
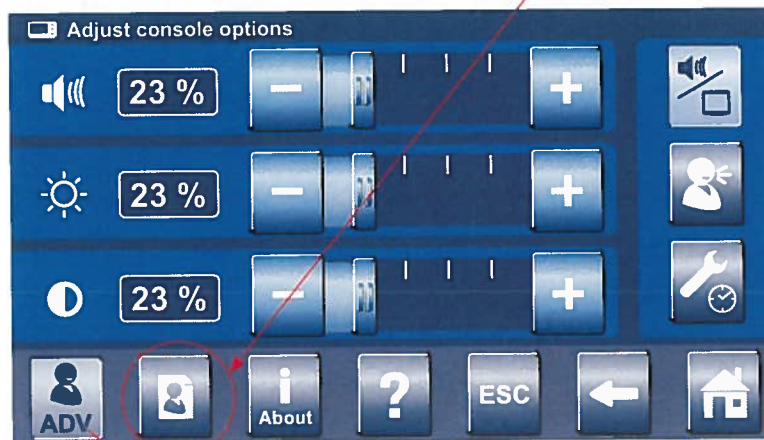
Figure 23. Adjust Console Options Screen - Advanced User Mode

To Return to Standard User Mode

To exit the ADVance user mode, touch the ADV button again. Touch the OK button if you want to return to the standard user mode.
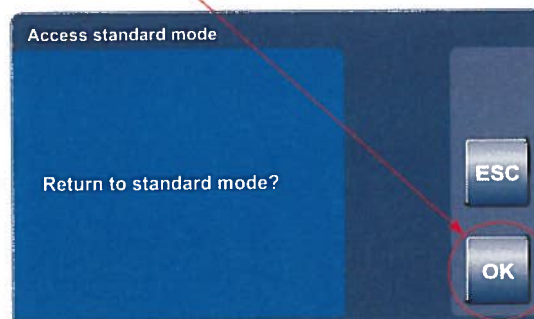
Figure 24. Return to Standard User Mode Pop-up

To Adjust the Console Options: - Advance User Mode

To Select Console Language Preference - Advance User Mode Only

Touch the button to select the appropriate console language.

Touch the button to select the console language preference.

Touch the arrow buttons to scroll through the list of languages: English, German, French, Spanish, and Italian.
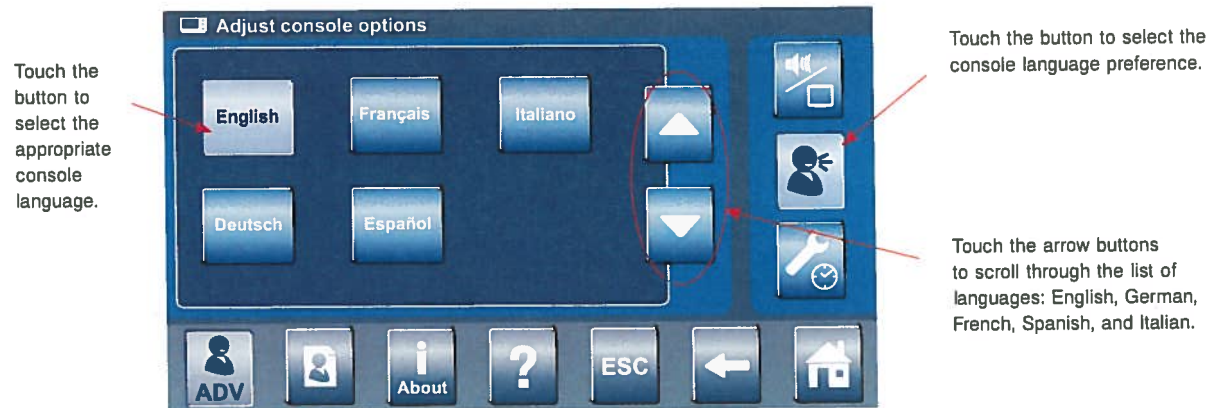
Figure 25. Select Language Preference Screen - Advance User Mode

To Select Advance Console Settings - Advance User Mode Only

Touch the button to select network connections.

Touch the button to select the console advance settings.

Figure 26. Select Advance Console Settings Screen - Advance User Mode

To Adjust the Console Options: - Advance User Mode

To Select Network Connections - Advance User Mode Only

Touch the button to toggle network control ON and OFF.

Touch the button to assign a wireless device to a specific footswitch port.

Figure 27. Select Network Connections Screen - Advance User Mode

To Manage User Preference Folders: - Advance User Mode Only

NOTE: You must be in the Advance User Mode to manage user preferences. See *To Adjust Console Options* section for details.

From the Adjust Console Options screen, touch the Manage User Preferences button to create and modify user preference folders and files (see figures 28 and 29). Each folder may contain multiple files and each file may contain the settings for multiple handpieces used for a specific procedure and/or physician.

View Address Bar

View the directory file path (folder/file name) to help with navigation.

Open (and Modify) Folder

Touch arrow buttons to scroll through and view the folders. Touch a folder and the Open Folder button to open and modify file(s) as required.

Create New Folder

Touch to create a new folder.
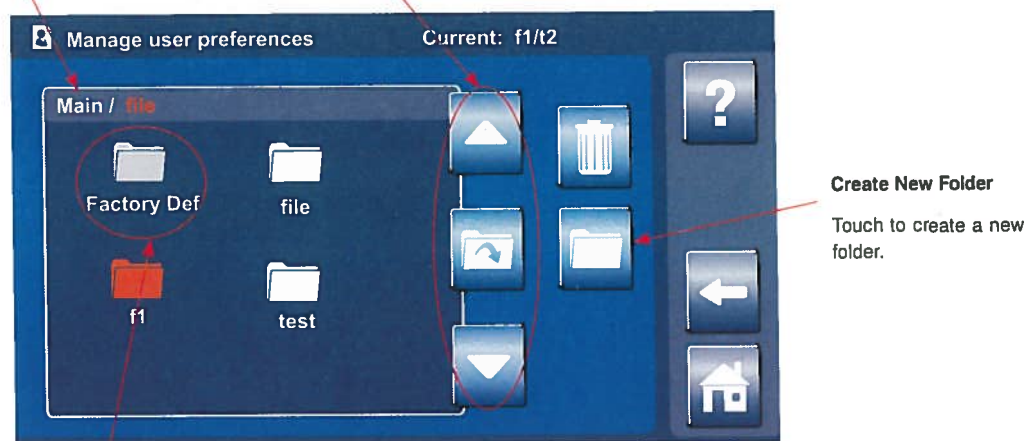
Factory Default Folder

A factory default file resides in this folder that cannot be selected or edited.

Figure 28. Manage User Preferences Screen - Folders

To Manage User Preference Files: - Advance User Mode Only

Open (View and Edit) File

Touch arrow buttons to scroll through and view the files. Touch a file and the Open File button to view and edit the user preference file settings of a file.

Create New File

Touch to create a new file.

Copy Current Settings

Touch to copy the current active user preference settings to a new file.
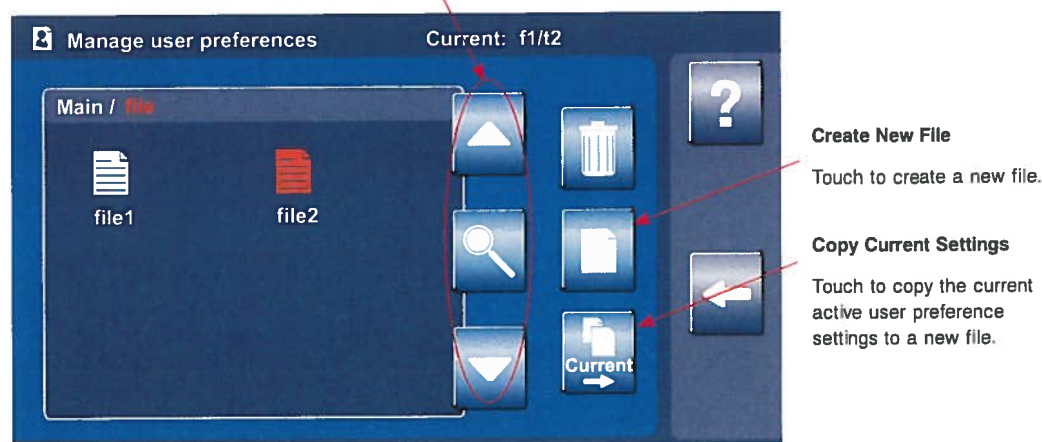
Figure 29. Manage User Preferences Screen - Files

To Manage User Preference Folders and Files: - Advance User Mode Only

To Create a New Folder or File

From the Manage User Preferences screen (folder or file screen), touch the Create New Folder or File button to create a new preference folder or file using a keyboard screen (see figure 30).

Enter a Folder or File Name

Touch key buttons to enter a folder or file name.

BACKSPACE

Touch to delete keystrokes.

ENTER

Touch to create folder or file.

SHIFT Lock/Unlock

Touch to toggle between upper and lower characters.

SPACE

Touch to create a space between characters and numbers.

Figure 30. Keyboard Screens

To Manage User Preference Folders and Files: - Advance User Mode Only

To Modify a File

View and Edit Settings

Touch the ADD Handpiece button to add a handpiece to the file (see figure 31). Once handpieces are added to a file, touch the arrow buttons to scroll through and highlight a handpiece. Touch the magnifying glass button to create or edit handpiece settings.
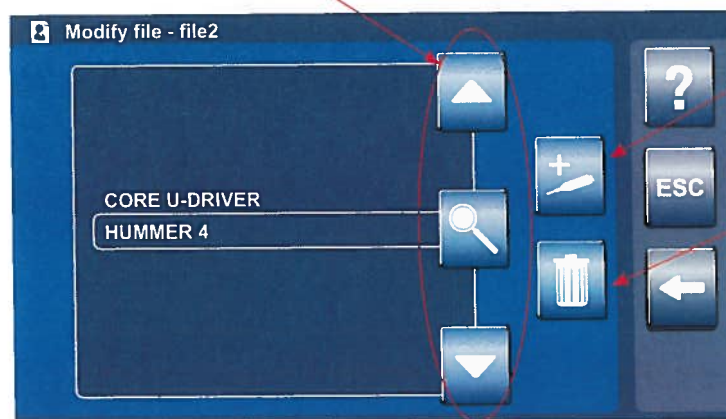
Add Handpiece

Touch to add a handpiece to the preference file.

Delete Handpiece

Touch to delete a handpiece from the preference file.

Figure 31. Modify File Screen

To Add a Handpiece

From the Modify File screen, touch the Add Handpiece button to add a handpiece to the preference file from a list of available handpieces (see figure 32).
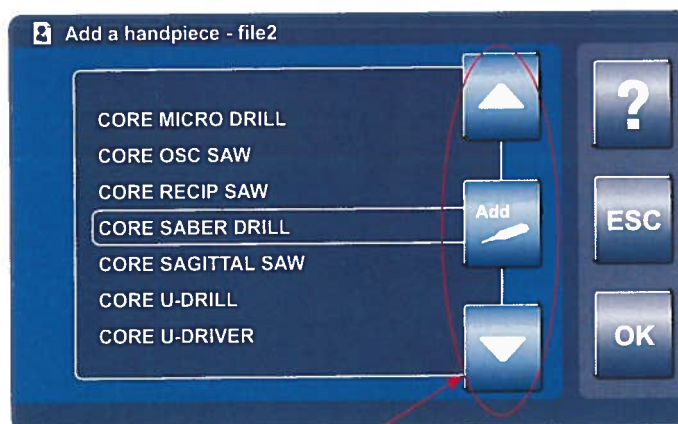
View and Add a Handpiece

Touch arrow buttons to scroll through and highlight a handpiece. Touch the ADD button to add a handpiece to the user preference file.

Figure 32. Add Handpiece Screen

To Manage User Preference Folders and Files: - Advance User Mode Only
To View Settings

From the Modify File screen, touch the View (magnifying glass) button to view the preference settings of a selected handpiece within a user preference file (see figure 33).
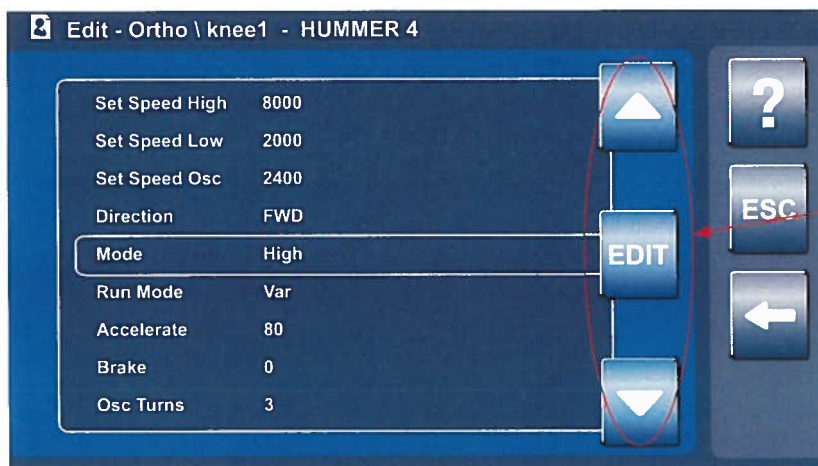
Edit Settings

Touch arrow buttons to scroll through and highlight a handpiece setting. Touch EDIT button to change the setting.

Figure 33. View Handpiece Settings Screen

EDIT

To Edit Settings

From the Edit screen, touch the EDIT button to modify the setting within the user preference file only (console defaults remain unchanged). See figure 34.
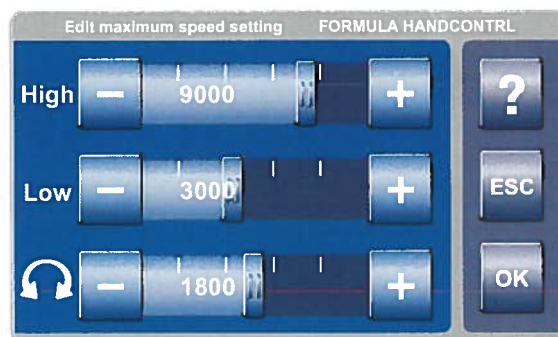
Figure 34. Typical Edit Setting Screen

To Edit Settings - Radio Frequency Identification (RFID) Handpiece and Cutters

NOTE: Before you begin, you must create a user preference file, load the file into the User Preference Favorites list and select the file. You must also be in the Advanced User Mode. For specific screen information, see the relevant sections of *To Manage User Preference Files - Advanced User Mode Only* and *Replace and Select a User Preference Favorites.*

1. Once you have selected the file to be edited in the User Preference Favorite screen, connect a RFID-enabled handpiece, for example a Formula Shaver, to the console.

2. Respond to any pop-ups as required.

3. Plug in an RFID-enabled cutter and verify the cutter is recognized. The cutter name should appear on the HOME screen.

4. Edit speed set points for all directions and operating modes, as well as acceleration, brake, number of oscillating turns, and run mode.

5. Remove the cutter from the handpiece.

6. Repeat steps 3 through 5 for any additional cutters up to 30 cutters maximum.

7. From the User Preference Favorite screen, touch the SAVE CURRENT SETTINGS button to save all the cutter settings to the selected user preference file.

8. Return to HOME screen and proceed as required.

i
About

To Access System Information:

From the Adjust Console Options screen, touch the i About button to obtain specific hardware and software information. Relevant information includes reference part numbers and current revision levels (see figure 35).

Screen Summary - A description of the hardware and software information.

OK Button - Touch to exit the screen.

Figure 35. System Information Screen

?

To Access Help:

From any screen, touch the Help button to obtain specific screen and button information (see figure 36). Each Help screen is divided into two columns. The right column contains a summary of the screen's overall function. The left column provides a list of all the screen buttons and their function.

Screen Summary - A description of a screen's overall functionality.
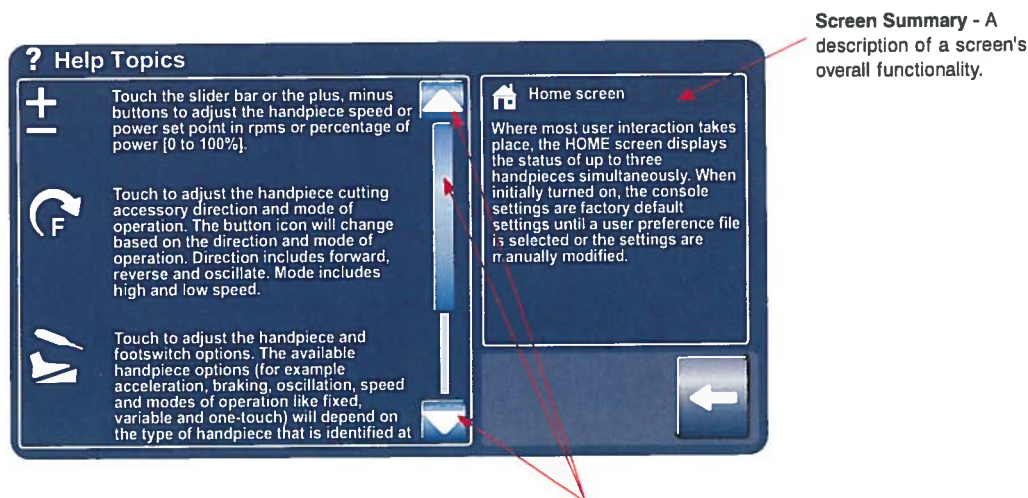
View Help Topics - Touch the arrow buttons or slider to scroll through and view help topics related to button functions on a specific screen.

Figure 36. Typical Help Screen

Troubleshooting Guidelines*

PROBLEM	ACTION
Sporadic electrical interference is experienced.	Turn off all electrical equipment not in use in the operating room. Relocate electrical equipment; increase spatial distance. Plug the console and other operating room equipment into different outlets.

*The console is not field repairable. In case of operating difficulties, return this product to Stryker Instruments for repair. For more information, contact your Stryker sales representative or Customer Service at 1-800-253-3210.

Periodic Maintenance

INTERVAL	ACTIVITY
Prior to Use.	Inspect console for damage or signs of wear. DO NOT use if damage is apparent.

Storage and Handling

To ensure the longevity, performance, and safety of this equipment, package in original package materials when storing or transporting.

Disposal/Recycle

Follow the current local regulations governing environmental protection to recycle or dispose of the console at the end of its useful life.

Cleaning Recommendations

Console, Power Cord, Cable(s) and Footswitch Cleaning Instructions

CAUTIONS:
- DO NOT sterilize the console or power cord.
- DO NOT allow moisture in any console opening, power cord, handpiece cable, and footswitch electrical connection.
- DO NOT use an aerosol spray directly on the console display.

1. Lightly wipe the console, power cord, and footswitch surfaces with a soft cloth dampened with a non-abrasive, hospital disinfectant or mild detergent and water.
2. Apply glass cleaner to a soft cloth and wipe the console display.

Messages*

TYPE	MESSAGE	ACTION TO TAKE
WARNING	Ensure handpiece speed does not exceed specified attachment limitations. Failure to do so may result in user and/or patient injury.	N/A
WARNING	Handpiece temperature has exceeded its nominal operating range and may result in injury.	N/A
WARNING	Handpiece temperature has exceeded its operating range. Allow to cool before restarting.	N/A
WARNING	Wireless Footswitch: Override wireless [green/yellow] footswitch?	Press OK; or unplug footswitch.
WARNING	The handpiece has experienced a serious fault condition (0x13000001) and may unpredictably activate. Contact the Stryker Service Center as soon as possible to schedule maintenance for the handpiece and cable. See the instructions for use supplied with the console. Failure to comply may result in patient and/or healthcare staff injury.	A beep will be heard when the WARNING appears. Press OK. Return the handpiece and cable to Stryker for service as soon as possible. If service is not obtained immediately, a beep will be heard each time the same serious fault condition occurs indicating the handpiece may unpredictably activate.
CAUTION	Handpiece has reached recommended service interval. Please return for service at earliest convenience.	Press OK; return handpiece to Stryker for service.
CAUTION	Power supply temperature has exceeded its nominal operating range. Performance may be affected.	N/A
CAUTION	Power supply temperature has exceeded its operating range. Allow to cool before restarting.	N/A
ERROR	Console hardware fault detected.	Turn the unit off and on again. If the problem persists, contact your Stryker representative; or Return console to Stryker for repair.
ERROR	Flash Bad Data Error	Please contact your Stryker representative.
ERROR	Footswitch 1 Micro Communication Fault	Please contact your Stryker representative.
ERROR	Footswitch 2 Micro Communication Fault	Please contact your Stryker representative.
ERROR	Handpiece 1 Micro Communication Fault	Please contact your Stryker representative.
ERROR	Handpiece 2 Micro Communication Fault	Please contact your Stryker representative.
ERROR	Handpiece 3 Micro Communication Fault	Please contact your Stryker representative.
ERROR	Main Board EEPROM (I2C bus) Communication Error	Please contact your Stryker representative.
ERROR	Motor Controller DSP Communication Fault	Please contact your Stryker representative.
ERROR	NOVRAM Micro Communication Fault	Please contact your Stryker representative.
ERROR	Pump Micro Communication Fault	Please contact your Stryker representative.
ERROR	RFID Micro Communication Fault	Please contact your Stryker representative.
ERROR	Communication Error	Please contact your Stryker representative.
ERROR	Touch Screen CODEC Communication Error	Please contact your Stryker representative.
ERROR	Main Board EEPROM Bad Data Error	Please contact your Stryker representative.
ERROR	Display Controller Software Rev Error	Please contact your Stryker representative.
ERROR	Footswitch 1 Micro Software Rev Error	Please contact your Stryker representative.
ERROR	Footswitch 2 Micro Software Rev Error	Please contact your Stryker representative.
ERROR	Handpiece 1 Micro Software Rev Error	Please contact your Stryker representative.
ERROR	Handpiece 2 Micro Software Rev Error	Please contact your Stryker representative.
ERROR	Handpiece 3 Micro Software Rev Error	Please contact your Stryker representative.

* For more information, contact your Stryker sales representative or Customer Service at 1-800-253-3210. Outside the USA, contact your nearest Stryker subsidiary.

Messages* (cont'd)

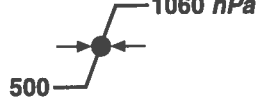| TYPE	MESSAGE	ACTION TO TAKE
ERROR	Motor Controller DSP Software Rev Error	Please contact your Stryker representative.
ERROR	NOVRAM Micro Software Rev Error	Please contact your Stryker representative.
ERROR	Pump Micro Software Rev Error	Please contact your Stryker representative.
ERROR	RFID Micro Software Rev Error	Please contact your Stryker representative.
ERROR	Software Error Bootup Initialization Error	Please contact your Stryker representative.
NOTE	Handpiece requires additional console hardware.	Please contact your Stryker representative; or See manual, press OK to clear.
NOTE	Handpiece requires additional console software.	Please contact your Stryker representative; or See manual, press OK to clear.
NOTE	Footswitch requires additional console hardware.	Please contact your Stryker representative; or See manual, press OK to clear.
NOTE	Footswitch requires additional console software.	Please contact your Stryker representative; or See manual, press OK to clear.
NOTE	Identical folder name already exists. Please enter a different name.	N/A
NOTE	Handpiece has reached its recommended service interval.	Please contact your Stryker representative.
NOTE	Cutter has reached its recommended usage period.	Please contact your Stryker representative.
NOTE	Irrigation Cassette has reached its recommended usage period.	Please contact your Stryker representative.
NOTE	A non-programmable footswitch has been connected. The pedals and buttons of both footswitch ports will now operate according to the non-programmable footswitch defaults.	N/A
NOTE	The network connection has been lost.	N/A
NOTE	The network connection has been established.	N/A
NOTE	The maximum number of data records has been reached. Delete unnecessary User Preference files to make storage space available.	N/A
QUESTION	Identical file name already exists. Do you want to save over this file?	N/A
QUESTION	Are you sure you want to delete this file?	N/A
QUESTION	Are you sure you want to delete this folder and all its contents?	N/A

* For more information, contact your Stryker sales representative or Customer Service at 1-800-253-3210. Outside the USA, contact your nearest Stryker subsidiary.

Specifications*

Model:	REF 5400-050-000 CORE Powered Instrument Driver (console)
Size:	12.5 in. [317.5 mm] width
	5 in. [127 mm] height
	17 in. [431.8 mm] depth
Weight:	20 lbs. [9.1 kg]
Equipment Type:	Class I, Type BF Applied Part
Power Supply:	Input voltage: 100-120 V ~, 50-60 Hz, 6.0 A
	230 V ~, 50/60 Hz, 3.0 A
Enclosure Protection:	IPX0 Ordinary Equipment
Protective Earth Ground:	
Duty Cycle:	Continuous operation with intermittent loading
	See cycle times defined in handpiece instructions for use
Display/Color Touch Screen:	Wide 65° minimum viewing angle;
	6.5 inch diagonal active LCD;
	resolution 800 (horizontal) x 480 (vertical);
	16:9 aspect ratio;
	16-bit color;
	dimensions 3.19 in. [81.0 mm] height
	5.67 in. [144.0 mm] width
Volume Adjustment:	0 dBA to 81 dBA
Approval:	CSA International
	UL 60601-1
	CAN/CSA-C22.2 No. 601.1 M90
	IEC 60601-1
	AS/NZS 4268: 2008
	N 17693

Environmental Conditions:	Operation	Storage and Transportation
Temperature:	40°C / 10	40°C / -20
Relative Humidity:	75% / 30	75% / 10
Atmospheric Pressure:	1060 hPa / 700	1060 hPa / 500

*Specifications listed are approximate and may vary slightly from unit to unit or by power supply fluctuations.

Stryker and CORE are trademarks and/or registered trademarks of the Stryker Corporation.

Specifications

Guidance and manufacturer's declaration - electromagnetic emissions		
The CORE Console REF 5400-050-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE Console REF 5400-050-000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CORE Console REF 5400-050-000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class A	The CORE Console REF 5400-050-000 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Specifications

Guidance and manufacturer's declaration - electromagnetic immunity			
The CORE Console REF 5400-050-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE Console REF 5400-050-000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2, ±4, ±6 kV contact ±2, ±4, ±8 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 for power supply lines ±1kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±0.5 and ±1 kV line(s) to line(s) ±0.5, ±1, ±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 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CORE Console REF 5400-050-000 requires continued operation during power mains interruptions, it is recommended that the CORE Console REF 5400-050-000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Specifications

Guidance and manufacturer's declaration - electromagnetic immunity			
The CORE Console REF 5400-050-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CORE Console REF 5400-050-000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the CORE Console REF 5400-050-000, 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 2.5 GHz 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 meters (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:
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 Console REF 5400-050-000 is used exceeds the applicable RF compliance level above, the CORE Console REF 5400-050-000 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 Consol REF 5400-050-000.			
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Specifications

Recommended separation distances between portable and mobile RF communications equipment and the CORE Console REF 5400-050-000		
The CORE Console REF 5400-050-000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CORE Console REF 5400-050-000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CORE Console REF 5400-050-000 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 2.5 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.

R&TTE Declaration of Conformity (DoC)

We,   **Name of company:** Stryker Instruments
     Address: 4100 East Milham Avenue, Kalamazoo, Michigan 49001-6197
     Authorized Representative: Jean-Yves Carentz
     Contact Detail of Authorized Representative: Stryker France, ZAC Satolas Green Pusignan,
     Av. de Satolas Green, 69881 MEYZIEU Cedex, France

declare under our sole responsibility that the product:
     Product Name: Consolidated Operating Room Equipment (CORE) System
     Trade Name: Stryker Instruments
     Type or Model: 5400-50 CORE Powered Instrument Driver (console)
     Relevant supplementary information: EN/IEC 60601-1-2:2001 & EN 301-489-3:EN 300 330-2 v1.1.1

to which this declaration relates is in conformity with the *essential requirements and other relevant requirements* of the R&TTE Directive (1999/5/EC).
The product is compliant with the following standards and/or other normative documents:

SAFETY (art 3.1.a): IEC 60601-1:1995 Medical Electrical Equipment

EMC (art 3.1.b): EN 301 489-3 v1.3.1 Specific Conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz.

SPECTRUM (art 3.2): EN 300 330-2 v1.1.1 Harmonized EN Covering Essential Requirements Under Article 3.2 of the R&TTE Directive

OTHER: ANSI C95.1 Safety Levels with Respect to Human Exposure to RF Electromagnetic Fields 300 kHz to 300 GHz

     Supplementary information: None
     Notified Body involved: TUV Rheinland Product Safety (GmbH)
     Technical file held by: Stryker Instruments
     Place and date of issue (of this Doc): Kalamazoo, Michigan USA, March 2005

     Signed by or for the manufacturer:

     Name (printed):   Jason Allen
     Title: Director, Regulatory Affairs, Quality Assurance

Hereby, Stryker Instruments, declares that this Short Range Device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

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

| EC | REP |

Stryker France
ZAC Satolas Green Pusignan
Av. de Satolas Green
69881 MEYZIEU Cedex
France

stryker®