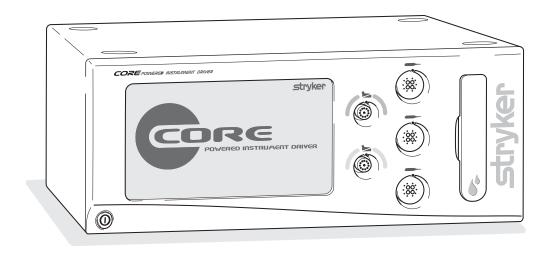


Consolidated Operating Room Equipment (CORE) Powered Instrument Driver

REF 5400-50

Instructions For Use





US Patents: ??? and other patents pending.

stryker° INSTRUMENTS

4100 E. Milham Kalamazoo, Michigan (USA) 49001 1-269-323-7700 1-800-253-3210 **Software Version**





Table of Contents

Important Information	3
Compliance Statements	3
Software License Notice	4
Limited Warranty	4
User/Patient Safety	5
Indications For Use	5
Contraindications	5
System Overview	6
System Block Diagram	6
Hardware Features	7
Accessories	7
Operating Instructions	8
Interconnect Diagram	8
To Connect the Components:	9
Button Definitions	10
Software Menu Map	12
To Power Up:	13
To View Options:	14
To Adjust Handpiece Speed (or Power):	15
To Select Handpiece Direction and Mode:	15
To Adjust Options:	16
To Program Footswitch Options:	17
To Set Handpiece Options:	
To Select a User Preference Favorite:	
To Replace a User Preference Favorite	
To Adjust Irrigation Pump Settings:	
To Adjust the Console Settings: - Standard and Advance User Mode	21
To Manage User Preference Files: - Advance User Mode Only	
To Access Help:	
Troubleshooting Guidelines	
Periodic Maintenance	28
Storage and Handling	
Cleaning and Sterilization Recommendations	
Error Messages	
Messages	30
Specifications	31

Important Information

WARNING - CAUTION - NOTE

Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE carry special meanings and should be carefully reviewed.

WARNING: The personal safety of the patient and user may be involved. Disregarding this information could result in injury to

the patient and/or user.

CAUTION: These instructions point out special service procedures or precautions that must be followed to avoid damaging

the instrument.

NOTE: This provides special information to make maintenance easier or important instructions clearer.

An exclamation point within a triangle displayed on the product is intended to alert the user to the presence of important operating and maintenance instructions in this manual.

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.



User/Patient Safety



WARNINGS:

- Before using any system component, or any component compatible with this system, read and understand the instructions. Pay
 special attention to the important User/Patient Safety information provided in the instruction booklets. Familiarization with the
 system prior to use is important. Failure to comply may result in patient and/or operating room staff injury or damage to
 components.
- The surgeon performing any procedure is responsible to determine the appropriateness of this instrument and the specific technique for each patient. Stryker, as a manufacturer, does not recommend surgical technique.
- Clean and sterilize components before first and every use. See the CORE Cleaning, Maintenance 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.
- Use only Stryker approved accessories. Other accessories may not properly interface with the console. 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, for example burns or damage to tissue.
- 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.
- DO NOT perform footswitch mapping (assign a handpiece port to a footswitch port) while operating a handpiece. 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. (The audible alarm does not warn the user if this event occurs.) Monitor the
 operating time of the handpiece to prevent overheating. Failure to comply may result in patient and/or operating room staff injury.
- Use safety glasses. Failure to comply may result in operating room staff injury.

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

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, Dental and Endoscopic. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices

Contraindications

None.



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. 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. The console provides a common interface for both micro and heavy-duty handpieces. Because options vary among different handpieces, the console will only display those options that are related to the connected handpiece.

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.

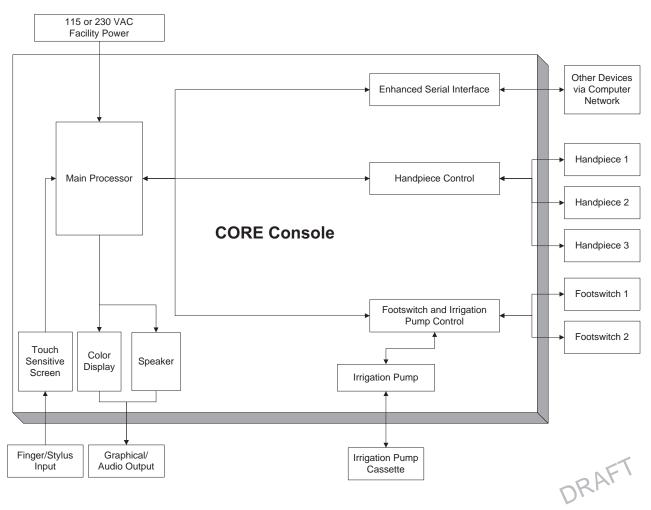
The console's enhanced serial interface provides a serial communications channel between the console and other devices. This feature allows the transfer of data and control information, like run-time data and software upgrades over a computer network.

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

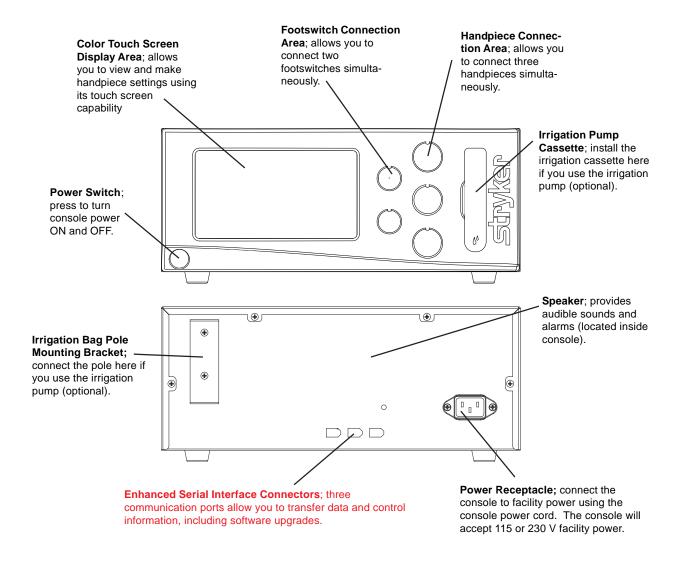
Console settings, like display brightness and speaker volume, may be easily adjusted. The on board speaker provides audible feedback during operation and configuration.

The console accepts either 115 VAC or 230 VAC input and has the capability to power heavy-duty handpieces.

System Block Diagram



Hardware Features



Accessories



WARNING: Use only Stryker approved accessories. Other accessories may not properly interface with the CORE Console. 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.

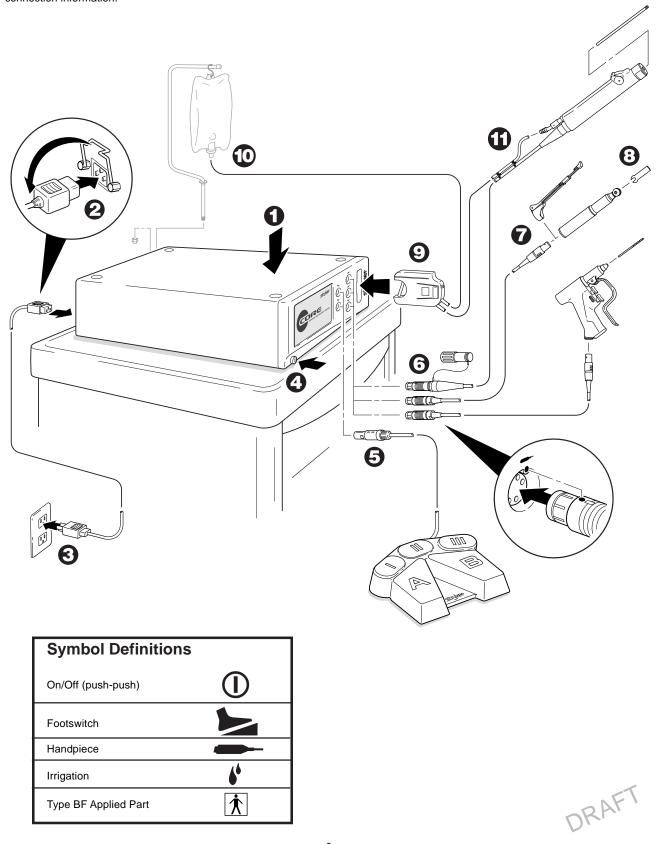
<u>Description</u>	<u>REF</u>
Power Cord	0996-851-010
Cable; push-pull type connector with alignment markings and keyed connectors	
Footswitch	5100-008-000
Disposable Irrigation Cassette	5400-050-001



Operating Instructions

Interconnect Diagram

The interconnect diagram provides the connection sequence of CORE system components. The diagram's numbered callouts correspond to the numbered instructions on the next page. See the instructions for use supplied with each component for specific connection information.



To Connect the Components:

NOTE: Refer to the Interconnect Diagram 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. Pull the bracket over the plug to secure it within the power receptacle.
- 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 reflect the various 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.
- 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 operated simultaneously.

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

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.

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 5100-50-28 (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 CORE 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

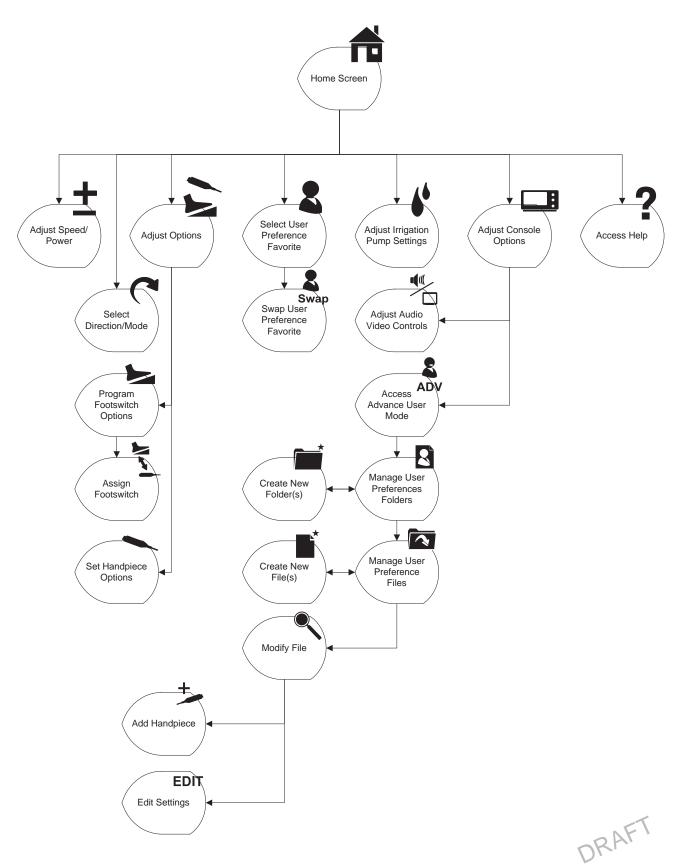
Button	Name	Definitions	Button	Name	Definitions
	HOME	View and adjust handpieces and system settings		OSCILLATE	Set default mode of handpiece to oscillate
?	HELP	Access task-oriented HELP related to screen and button functionality	F	FORWARD	Set default mode of handpiece to rotate in the forward (clockwise) direction
—	BACK	Return to the previous screen	R	REVERSE	Set default mode of handpiece to rotate in the reverse (counterclockwise) direction
	UP	Scroll up	Low	LOW	Set default mode of handpiece to operate in the low rpm range mode
+	INCREASE	Increase the value of a setting	High	HIGH	Set default mode of handpiece to operate in the high rpm range mode
	DOWN	Scroll down		ADJUST OPTIONS	Adjust handpiece, footswitch and console options
	DECREASE	Decrease the value of a setting	FIXED	FIXED SPEED	Set the default run mode of the handpiece speed to operate at the set speed only
ОК	ОК	Accept inputs, changes or selections and return to previous screen	\^\\\\VAR	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	ESC	Close a pop up or screen without accepting inputs,	ONE	ONE TOUCH	Set the default run mode of the handpiece activation to respond to one touch of a handswitch or footswitch
Factory	FACTORY	changes or selections and return to previous screen		PROGRAM FOOTSWITCH	Program the footswitch pedals and pads based on the handpiece capabilities
Default	FACTORY DEFAULT	Apply original factory default settings		ASSIGN FOOTSWITCH TO HANDPIECE	Assign a specific footswitch port to a specific handpiece port
					DRAFT

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	EDIT	EDIT SETTINGS	Change user preference file settings
8	MANAGE USER PREFERENCES	Create and modify user preference folders and files	Current	SAVE CURRENT SETTINGS	Save current console settings as a new user preference file
L	NAVIGATE UP ONE LEVEL	Navigate one directory level up		ADJUST CONSOLE OPTIONS	Adjust console options in the standard or advanced mode
	DELETE	Delete a folder or file		ADJUST VOLUME AND SCREEN	Adjust console volume, brightness and contrast
*	CREATE FILE	Create a new user preference file	ADV	ACCESS ADVANCED MODE	Access user preference options
	COPY	Copy a user preference file or folder	8	SELECT USER PREFERENCE FAVORITE	Select one of five favorite user preference files as the console default
	CREATE FOLDER	Create a new user preference folder	Swap	SWAP USER PREFERENCE FAVORITE	Replace one of the five favorite user preference files with another preference file
	OPEN AND MODIFY	Open a user preference folder and modify the file(s) as required	65	ADJUST IRRIGATION PUMP SETTINGS	Apply an irrigation flow rate to a handpiece cutting accessory
+	ADD HANDPIECE	Add a handpiece to a user preference file	FLUSH	FLUSH TUBING SET	Provide a continuous irrigation flow rate to flush the tubing set
	SAVE CHANGES	Save changes to the handpiece settings of a user preference file	AUTO	AUTO PRIME TUBING SET	Prime the tubing set from the pump head to the irrigation tip clip
	VIEW/EDIT SETTINGS	View and edit the user preference file settings of a selected handpiece			
UNDO	UNDO CHANGES	Undo the last changes made			DRAFT

Software Menu Map

The software menu map is a visual representation of the menu structure and its hierarchy. 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 the same icons used on buttons in the software and are also used with the header information in this manual.



To Power Up:

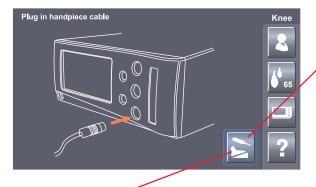
Power Up Screen

This screen is momentarily displayed while the console powers up. Note the software version is displayed in the lower right corner of the screen.



Plug in Handpiece Cable Screen

If no handpieces or cords are connected to the console during initial power up, the following screen will appear:



If the Adjust Options button is pressed before any cords or handpieces are connected, the following screen will appear. At this time, console options that are not handpiece specific may be set up before the sterile handpieces are brought into the operating room and plugged into the console.

Adjust Options



The subdued portions of these screens will become available once a handpiece is plugged into the console. These screens do not depend on whether a footswitch is plugged into the console.





To View Options:

HOME screen

The HOME screen is where most user interaction will take place. 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.

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 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. 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 recognition capability.



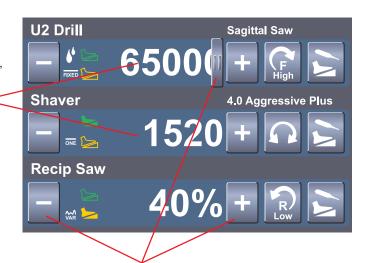
To Adjust Handpiece Speed (or Power):

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.

NOTE: When you install a cutting accessory with cutter recognition capability, 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.

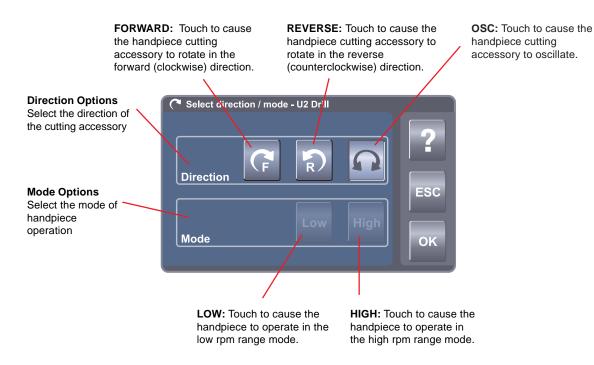


Touch the adjustment buttons (or slider bar that becomes visible when touching the speed value) to increase or decrease the speed (power) set point.



To Select Handpiece Direction and Mode:

From the HOME screen, touch the Select Direction/Mode button to adjust the handpiece direction and mode.



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.





To Adjust Options:

From the HOME screen, touch the Adjust Options button to adjust the handpiece and footswitch options. The available handpiece options will depend on the type of handpiece that is identified at the top of the screen.

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.

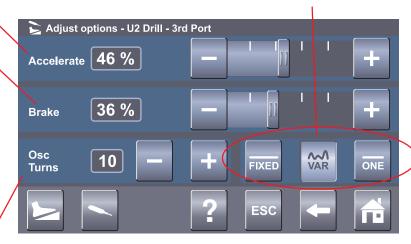
Select Run Mode

- FIXED: handpiece speed runs at the maximum setting only. Varying pressure on the footswitch or handswitch will not vary the handpiece speed.
- VARIABLE: handpiece speed responds to the degree of pressure applied to the footswitch or handswitch.
- ONE TOUCH: Handpiece activation responds to one

touch of a trigger device (footswitch, 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 setpoint 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.





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. 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.

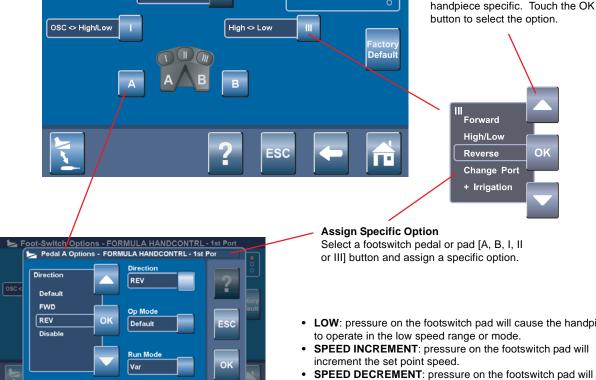
Handpiece port

View Handpiece Port

Change Port

Indicates the handpiece port that the footswitch is programmed for.

Foot-Switch Options - FORMULA HANDCONTRL - 1st Port



Based on handpiece capabilities, options may include:

- FORWARD: pressure on the pad or pedal will cause the handpiece to rotate in the forward (clockwise) direction.
- REVERSE: pressure on the pad or pedal will cause the handpiece to rotate in the reverse (counterclockwise) direction.
- +OSC TURNS: pressure on the footswitch pad will cause the handpiece to oscillate; increase number of turns.
- -OSC TURNS: pressure on the footswitch pad will cause the handpiece to oscillate; decrease number of turns.
- **ON**: pressure on the footswitch pad or pedal will make the port active, for example it will provide input to the assigned handpiece.
- OFF: pressure on the footswitch pad or pedal will make the port inactive, for example it will not provide input to the assigned handpiece.
- **HIGH**: pressure on the footswitch pad will cause the handpiece to operate in the high-speed range or mode.

LOW: pressure on the footswitch pad will cause the handpiece

Touch the arrow buttons to scroll through the footswitch options. The available options are

OK

- SPEED INCREMENT: pressure on the footswitch pad will
- SPEED DECREMENT: pressure on the footswitch pad will decrement the set point speed.
- **IRRIGATION INCREMENT**: pressure on the footswitch will increment the pump flow set point and increase irrigation to the handpiece cutting accessory.
- **IRRIGATION DECREMENT**: pressure on the footswitch will decrement the pump flow set point and decrease irrigation to the handpiece cutting accessory.
- IRRIGATION ON/OFF: pressure on the footswitch will toggle the irrigation pump on and off. If pressed and held, the irrigation pump can be turned on without running the handpiece. Once started, the irrigation pump can be stopped by pressing the pad again or by starting the handpiece.
- **PUMP FLUSH**: pressure on the footswitch will turn the irrigation pump on at the flush rate. Once started the irrigation pump may be stopped by pressing the pad again or by starting the handpiece.
- **CHANGE PORT**: pressure on the footswitch pad will change the footswitch assignment to another active handpiece.
- ONE TOUCH: acting like an on/off toggle, tap the footswitch pad to operate the handpiece at the maximum speed. Tap the footswitch pad again to stop the operation.
- VARIABLE: varying pressure on the footswitch pad will cause the handpiece speed to vary.
- FIXED: pressure on the footswitch pad will cause the handpiece to operate at a constant speed as set on the HOME DRAF



To Program Footswitch Options:



WARNING: DO NOT perform footswitch mapping (assign a handpiece port to a footswitch port) while operating a handpiece. Failure to comply may result in patient and/or operating room staff injury.

Assign Handpiece Port to a Footswitch Port

The Assign Handpiece to Footswitch screen will appear automatically when connecting two footswitches and two or more handpieces to the console.





Access the Assign Handpiece to Footswitch screen manually as follows:

- 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



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 port is assigned to the handpiece port.



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



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



Gray indicates no footswitch port is assigned to the handpiece port.



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



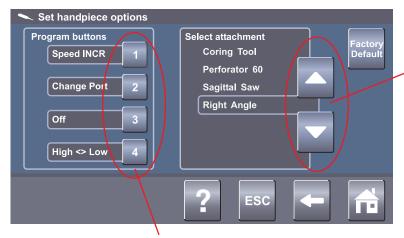


To Set Handpiece Options:



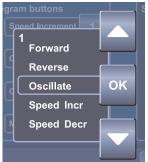
WARNING: Read and understand the appropriate Stryker handpiece instructions for use.

From the Adjust Options screen, touch the Set Handpiece Options button to select specific handpiece options and assign them to a particular handpiece button. 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 maximum speed values 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.

Based on handpiece capabilities, options may include:

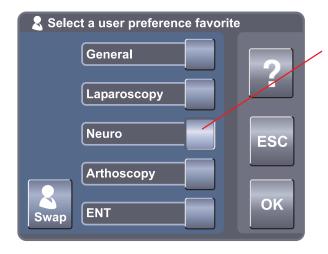
- FORWARD: option will rotate cutting accessory in the forward (clockwise) direction.
- REVERSE: option will rotate cutting accessory in the reverse (counterclockwise) direction.
- +OSC TURNS: option will increase the number of oscillate turns.
- -OSC TURNS: option will decrease the number of oscillate turns.
- **HIGH**: option will operate handpiece in the high-speed mode.
- LOW: option will operate handpiece in the low speed mode.
- CHANGE PORT: option will change the button assignment to another active handpiece.
- +IRRIGATION: option will increase irrigation to the handpiece cutting accessory.
- -IRRIGATION: option will decrease irrigation to the handpiece cutting accessory.
- WINDOW JOG TRIGGER: option will rotate the cutting accessory at a very low speed to position the cutting edge
 within the cutting window.

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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. Five favorite files are available. Each file contains specific handpiece(s) settings for a particular procedure.



Touch to select one of the five favorite user preference files.



To Replace a User Preference Favorite

From the Select a User Preference Favorite pop up, make a file selection via the arrow buttons and OK button, then touch the Swap button to replace an existing favorite file.



Touch arrow buttons to scroll through the list and highlight one of the preference files. Touch OK button to replace one of the favorite preference files.





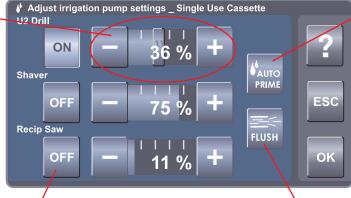
To Adjust Irrigation Pump Settings:

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 apply an irrigation flow rate to a handpiece cutting accessory. 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 [1 to 100% or OFF] 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 clip within 20 seconds.
- The button will remain depressed during the timed operation.

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 a second or third handpiece will not
 change pump flow, but may reduce irrigation to the first handpiece if a Y-splitter
 is used. To gain control of console irrigation using a second or third handpiece,
 activate the second or third handpiece while the first handpiece is not running.

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

From the Adjust Options screen, touch the Adjust Console Options button to adjust the volume, brightness and contrast.



Adjust Audio/Video Controls - Standard Mode

Adjust Volume

Adjust the percent of console volume [0 to 100%] by touching the slide bar or the plus, minus buttons

Adjust Brightness

Adjust the percent of console display brightness [0 to 100%] using the slide bar or the plus, minus buttons

Adjust Contrast

Adjust the percent of console display contrast [0 to 100%] using the slide bar or the plus, minus buttons



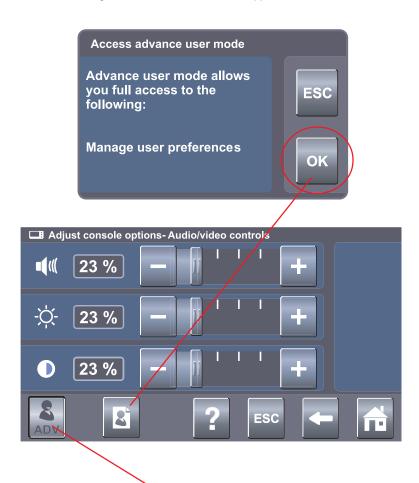


To Adjust the Console Settings: - Standard and Advance User Mode



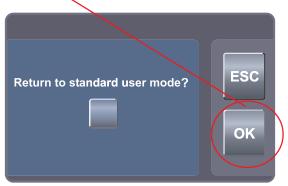
Access Advance User Mode

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. A pop up will appear to confirm your request. Once confirmed, the Manage User Preference button will appear.



Return to Standard User Mode

After managing user preference files in the advance user mode, touch the ADV button to return to the standard 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.

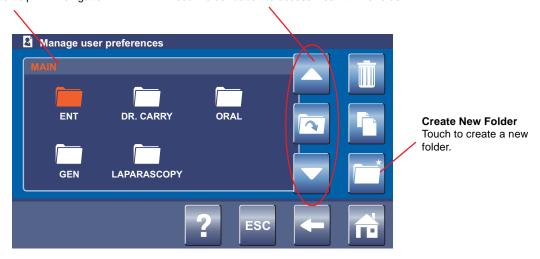
From the Adjust Console Options screen, touch the Manage User Preferences button to create and modify user preference folders and files. Each folder may contain multiple files and each file may contain the settings for multiple handpieces used for a specific procedure and/or physician.

View Address Bar

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

Open Folder

Touch arrow buttons to scroll through and highlight a folder. Touch folder button to access files within a folder.

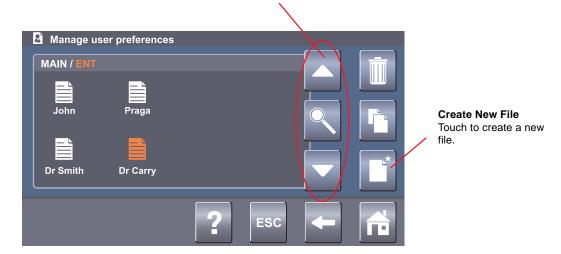




To Manage User Preference Files: - Advance User Mode Only

Open File

Touch arrow buttons to scroll through and highlight a file. Touch Modify button to open and modify a file.







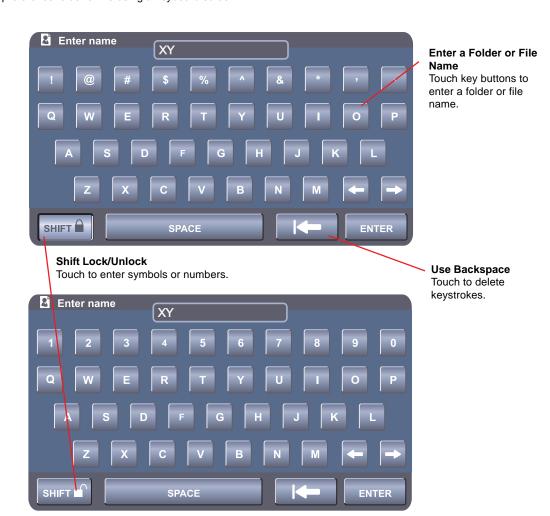
To Manage User Preference Folders and Files: - Advance User Mode Only



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.









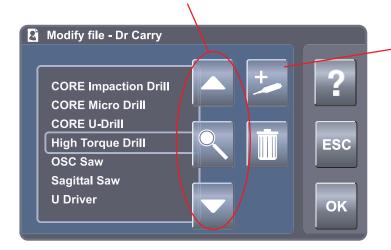
To Manage User Preference Folders and Files: - Advance User Mode Only



Modify File

View and Edit Settings

Touch the ADD Handpiece button to add a handpiece to the file. 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.

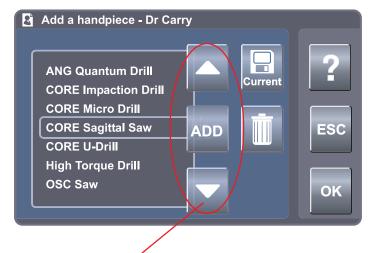


Add Handpiece Touch to add a handpiece to the preference file.



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.



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.



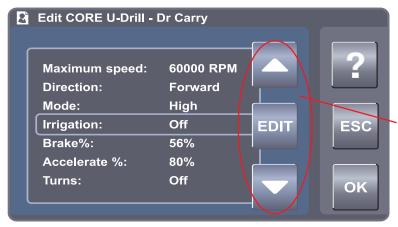


To Manage User Preference Folders and Files: - Advance User Mode Only

View and Edit Settings

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

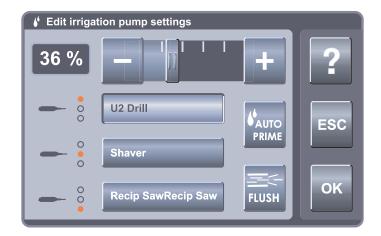




View and Edit Settings
Touch arrow buttons to scroll
through and highlight a handpiece
setting. Touch EDIT button to
change the setting.

EDIT Edit Settings

From the Edit screen, touch the EDIT button to modify the setting within the user preference file only (console defaults remain unchanged). Notice that the user preference Edit screen below (typical example) has a light blue background color to differentiate it from a console default Edit screen (dark blue).



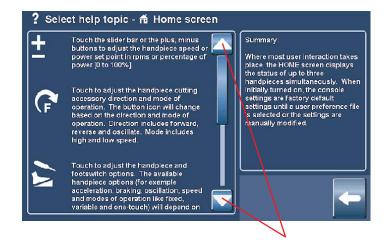


?

To Access Help:

From most screens or pop ups, touch the Help button to obtain specific screen and button information. 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.

Select Help Topic Screen



View Help Topics - Touch the arrow buttons to scroll through and view help topic information.



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.

Periodic Maintenance

<u>Interval</u> <u>Activity</u>

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.

Cleaning and Sterilization Recommendations



WARNINGS:

- Clean and sterilize handpieces before first and every use.
- Cutting accessories are single use only. Sterile only if package is unopened and undamaged. DO NOT resterilize or reuse.

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

CAUTIONS:

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



^{*}The CORE 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.

Error Messages*

<u>Message</u>	Action to Take
Error xxx. Console hardware fault is detected.	Contact your Stryker service representative. Turn the console off and on again. If the problem persists, return the console to Stryker for repair.
Error xxx. Footswitch fault is detected; the right pedal is disabled.	Contact your Stryker service representative. Unplug the footswitch from the console and plug it into the console again. If the problem persists, return the footswitch to Stryker for repair.
Error xxx. Footswitch fault detected, left pedal is disabled.	Contact your Stryker service representative. Unplug the footswitch from the console and plug it into the console again. If the problem persists, return the footswitch to Stryker for repair.
Error xxx. Footswitch is not detected or fails to be recognized by the console.	Contact your Stryker service representative. Unplug the footswitch from the console and plug it into the console again. If the problem persists, return the footswitch to Stryker for repair.
Error xxx. Handpiece fault is detected, handpiece trigger is disabled.	Contact your Stryker service representative. Unplug the cord from handpiece and plug the cord into the handpiece again. If the problem persists, return the handpiece to Stryker for repair.
Error xxx. Handpiece is not detected or fails to be recognized by the console.	Contact your Stryker service representative. Unplug handpiece from console and plug in again. If problem persists, return handpiece Stryker for repair.
Error xxx. Handpiece requires additional console hardware.	Contact your Stryker service representative.
Error xxx. Cutting accessory requires additional console hardware.	See the instructions for use supplied with the cutting accessory.

^{*} For more information, contact your Stryker sales representative or Customer Service at 1-800-253-3210.

To Be Determined



Messages*

Message

Delete all the surgeon's user preferences?

Change the name of all the surgeon's user preferences?

If You Select OK to a Question

The surgeon ID and all user preferences will be deleted.

User preferences listed under the surgeon will be moved under the current surgeon's name.

Identical record found.

Maximum number of records exceeded. Please delete inactive records.

Initializing console hardware. Please wait.

Handpiece has reached recommended service interval. Please return for service at earliest convenience.

Handpiece does not support the selected preference. Default handpiece setting will be used.

Handpiece temperature has exceeded its nominal operating range and may cause burning.

Handpiece temperature has exceeded its operating range. Allow to cool before restarting.

Procedure name unspecified.

DO NOT allow the handpiece speed to exceed specified attachment limitations. Failure to comply may result in user and/or patient injury.

Cutter/bur is not compatible with the current handpiece.

Cutter/bur has exceeded its life. Please replace with a new cutter/bur.

To Be Determined



Specifications*

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Model:	REF 5400-50 CORE 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: 120V, 60Hz, 6.0A Output voltage: 40V ± 0.25 V Output power: 200 W continuous, 400 W peak			
Enclosure Protection:	IPXO Ordinary Equipment	IPXO Ordinary Equipment		
Protective Earth Ground:				
Duty Cycle:	Peak power - 10 A, 400 W 50% duty cycle for 10 seconds Sustained power - 5 A, 100% duty cycle for three minutes continuous			
Display/Color Touch Screen:	Wide 65° minimum viewing angle; 6.5 inch diagonal active LCD; resolution 800 (horizontal) x 480 (ve 16:9 aspect ratio; 16-bit color; dimensions 3.19 in. [81.0 mm] heigl 5.67 in. [144.0 mm] width			
Volume Adjustment:	0 dBA to 81 dBA			
Environmental Conditions:	Operation	Storage and Transportation		
Temperature:	10——40°C	-20——40°C		
Relative Humidity:	30—75%	10—75%		
Atmospheric Pressure:	1060 hPa	1060 hPa		

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



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

