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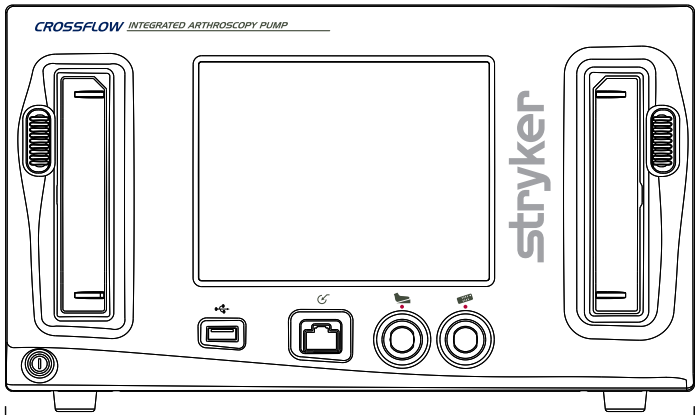
stryker®

CrossFlow™ Integrated Arthroscopy Pump

REF 0450000000



CE 0197 Rx ONLY

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Table of Contents

Please read this manual and follow its instructions carefully. The words warning, caution, and note carry special meanings and should be carefully reviewed:

- **Warning:** Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.
- **Caution:** Indicates risks to the equipment. Failure to follow cautions may result in product damage.
- **Note:** Provides special information to clarify instructions or present additional useful information.

Warnings

Operator Profile

1. Federal (USA) law restricts this device to sale by or on the order of a physician.
2. The operator of the CrossFlow™ system should be a qualified health care professional having complete knowledge of the use of this equipment and awareness of the risks associated with arthroscopic procedures.
3. The operator of the system should be experienced in arthroscopic practices and techniques.
4. The operator of the system should read this manual thoroughly and be familiar with its contents prior to operating the equipment.

Prior to Surgery

1. Carefully unpack the CrossFlow Integrated Arthroscopy Pump and ensure that all components listed in the "Package Contents" section of this manual are accounted for and remain undamaged from shipment. If damage to any component is detected, refer to the standard warranty.
2. Install the system in an operating room that complies with all applicable IEC, CEC, and NEC requirements for safety of electrical devices.
3. Install and use the system according to the information provided in the "Electromagnetic Compatibility" section of this manual.
4. If the pump is installed with other equipment in a stacked configuration, observe the pump to verify normal operation.
5. Portable and mobile RF communications equipment may interrupt system operation. When the pump is in use, the conducted and radiated electrical fields may interfere with other electrical medical equipment. If this occurs, power down all electrical equipment not in use, increase distance of other electrical equipment, and/or connect the pump and other equipment into different outlets.
6. **Place the pump at the same height as the joint to ensure accurate pressure readings.**
7. Ensure the proper connection of the primary power cord of the pump to a grounded receptacle with the correct mains voltage. To prevent the risk of electric shock, do not use extension cords or portable multiple socket outlets that are not a part of a certified hospital cart. The use of a portable multiple socket outlet can lead to a reduced level of safety.
8. Position any cables extending from the pump to avoid contact with the patient, electrodes, other cables, and any electrical leads which provide paths for high frequency current.
9. Do not connect items which are not specified as part of the system. The use of accessories, transducers, and cables other than those specified in this manual may result in increased emissions, decreased immunity of the equipment, or unintended, unsafe operation of the system.
10. Examine all electrical connections to the pump before use. Improper connection may result in malfunction or unintended surgical effects.
11. Do not touch or insert any objects, other than the cassettes, inside of the cassette holders as this may

damage the pressure sensor or cause injury. Place only the cassettes in the cassette holders.
12. Set the alarm volume to a level that is audible in the operating room environment.
13. Ensure the system functions as outlined in this manual prior to a surgical procedure. The system was fully tested at the factory before shipment.

During Surgery

1. Using fluid to distend the joint carries the possibility of fluid extravasation into surrounding tissue. Select the optimal pressure based on the patient profile, including, but not limited to, blood pressure, height, weight, age, and tissue quality. Recommended pressure settings are included in this manual; however, these are only suggestions, and each surgery and each patient may require different parameters.
2. The Wash function may cause high pressure within the joint, which may lead to fluid extravasation. Carefully monitor joint pressure when using this function.
3. The Clear function may cause excessive fluid usage. Monitor the use of this function and the fluid level in the irrigation bags.
4. Use the scope and cannula as selected on the pump. Incorrect scope and cannula use can cause overpressure if it does not match the selected scope and cannula.
5. Start the pump with the inflow tubing outside of the joint, all of the inflow tubing clamps open, and no hardware attached. Failure to remove air from the tubing can cause overpressure in the joint.
6. The pump is only intended for use with flexible fluid containers. Do not use glass containers as they might implode due to the vacuum being generated inside of the container.
7. Do not use this system in the presence of oxidizing agents or flammable materials (e.g. anaesthetics, gases, fluids, skin prepping agents, and tinctures). Observe appropriate fire precautions at all times.
8. Keep the pump dry. If liquid has accidentally leaked into the pump from the cassette(s), change the cassette(s), restart the system, and verify operation.
9. Keep the LCD screen and speaker in the field of view and hearing at all times during use. These are important safety features.
10. Failure of the system may result in an unintended increase or decrease in flow and/or pressure. Carefully the monitor the joint when using the system.
11. Do not allow extended exposure of suction to tissue associated with procedures that require either no or low-flow suction. Always consider the type of tissue associated with the surgical procedure before using this system. Failure to comply may result in severe injury.

After Surgery

1. **Do not remove the cover of the console as this could cause electric shock and product damage.**
2. Disconnect the pump from the electrical output when cleaning, servicing, or inspecting fuses.
3. Do not make any internal repairs or adjustments. Units requiring repair should be returned to Stryker. Decontaminate the pump and accessories prior to returning them to Stryker. Stryker may refuse to carry out repairs if the products are contaminated.
4. Do not use flammable agents for cleaning and disinfecting the system.
5. Do not sterilize the pump.
6. Follow the instructions in the "Disposal" section of this manual to adequately dispose of system accessories.

Cautions

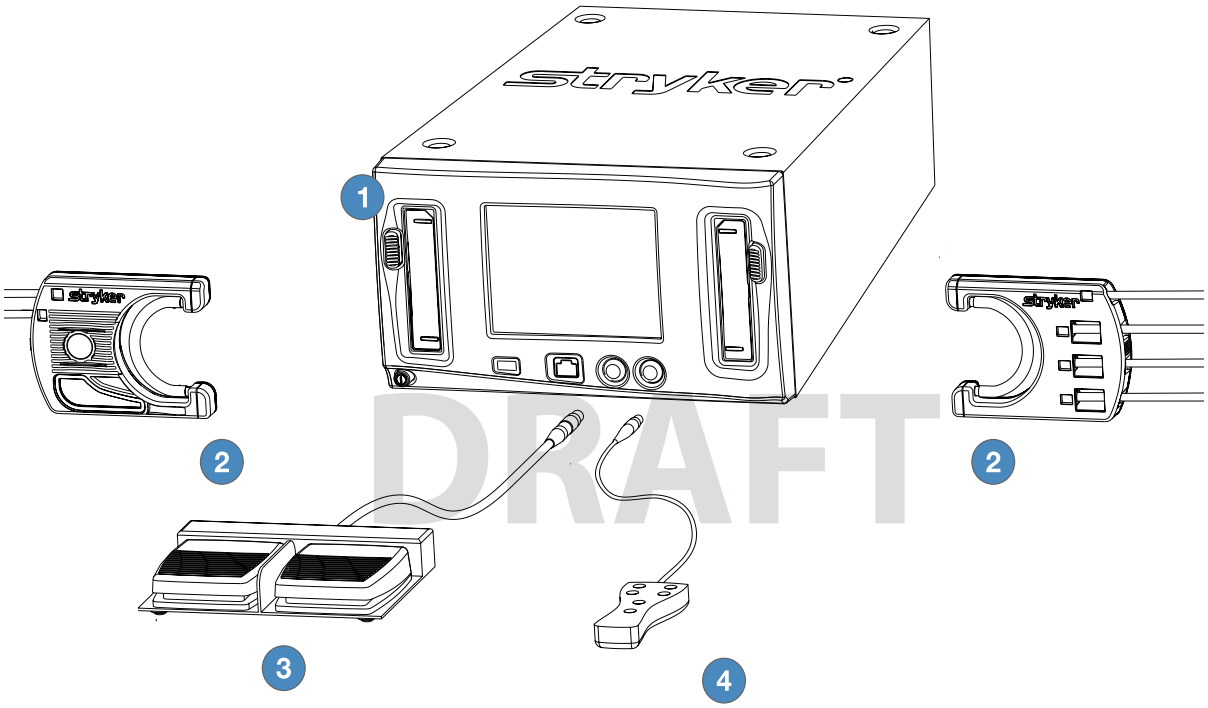
1. No modification of this equipment is allowed.
2. Insert the cassette prior to spiking the saline bag. Failure to do so may damage the pump or the cassette.
3. Do not remove the cassettes while the pump is in use. The pump or the cassette may be damaged. The cassettes can only be removed when the pump is stopped.
4. Stryker does not accept any liability for direct or consequential damages if:
    - the pump or the accessories are used improperly,
    - the instructions and rules in the manual are not followed,
    - the pump or the accessories are improperly connected and maintained,
    - non-authorized persons perform repairs, adjustments, or alterations to the pump or accessories,
    - non-authorized persons open the pump,
    - the prescribed inspection and maintenance schedules are not followed.

The warranty is void if any of these warnings or cautions is disregarded.

About Your Product

Product Description/Intended Use

The Stryker CrossFlow Integrated Arthroscopy Pump is a fluid management system. Illustrated below, the system is composed of a pump console with inflow-only and inflow/outflow modes, disposable cassette tubing, a wired hand control, and a wired footswitch. The system integrates with approved resection consoles.



1. **CrossFlow Integrated Arthroscopy Pump (featured in this manual)** - Compatible with the Crossfire Console, CrossFlow Footswitch, Autoclavable Hand Control, iSwitch Wireless Universal Foot Control, Stryker firewire-compatible devices, and approved resection consoles.
2. **CrossFlow Cassette Tubing** - Compatible with the CrossFlow Integrated Arthroscopy Pump, 4-bag adapter with inflow cassettes, luer-lock connectors, standard irrigation fluids, suction connectors, and waste management systems. The user may elect to employ one of two modes of operation:
   - **Inflow-Only Mode:** utilizes only the inflow function of the pump via the Inflow Cassette Tubing or the Day-Use Inflow Cassette/Patient-Use Tubing
     - **Inflow Cassette Tubing** - The Inflow Cassette Tubing transmits fluid from saline bags to the inflow cannula at the surgical site and is disposed of after each case.
     - **Day-Use Inflow Cassette/Patient-Use Tubing** - The Day-Use Inflow Cassette Tubing is used for a single day's cases, and the Patient-Use Tubing is connected to the Day-Use Inflow Cassette Tubing for a single case, then removed and discarded.
   - I**nflow/Outflow Mode:** utilizes both the inflow and outflow functions of the pump via the Inflow Cassette Tubing and Outflow Cassette Tubing.
3. **CrossFlow Footswitch (optional)** - Provides remote foot control of pump operation.
4. **Autoclavable Hand Control (optional)** - Provides remote hand control of pump operation.

Indications

The CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, and ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

Contraindications

The use of the CrossFlow Integrated Arthroscopy Pump is prohibited whenever arthroscopy is contraindicated.

Package Contents

Carefully unpack the CrossFlow Integrated Arthroscopy Pump and ensure all components are accounted for and remain undamaged from shipment. If damage to any component is detected, refer to the standard warranty.

- (1) CrossFlow pump
- (1) Hospital power cord
- (2) Approved resection console power cord
- (1) User manual
- (1) Warranty and return policy

Part Numbers and Available Accessories*

The CrossFlow Integrated Arthroscopy Pump is featured in this manual. Refer to individual manuals for all other products and accessories.

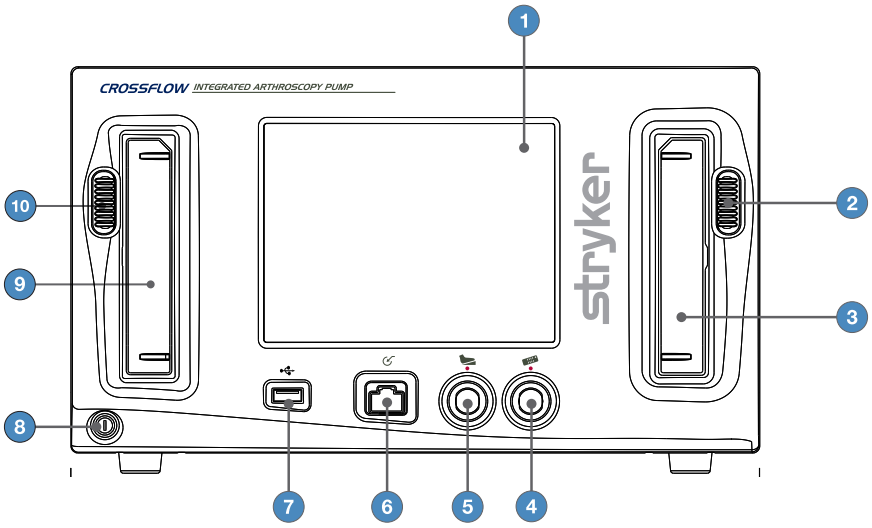
Part Number	Description
0350220000	Autoclavable Hand Control*
0450000000	CrossFlow Integrated Arthroscopy Pump
0450000100	CrossFlow Inflow Cassette Tubing
0450000110	CrossFlow Day-Use Inflow Cassette Tubing
0450000120	CrossFlow Patient-Use Tubing
0450000200	CrossFlow Outflow Tubing
0450000300	CrossFlow Integrated Cassette Tubing
0450000500	CrossFlow Footswitch*

Approved Resection Consoles

The CrossFlow system is compatible with the following consoles. (Contact Stryker Endoscopy for compatibility requirements for any non-approved resection consoles.)

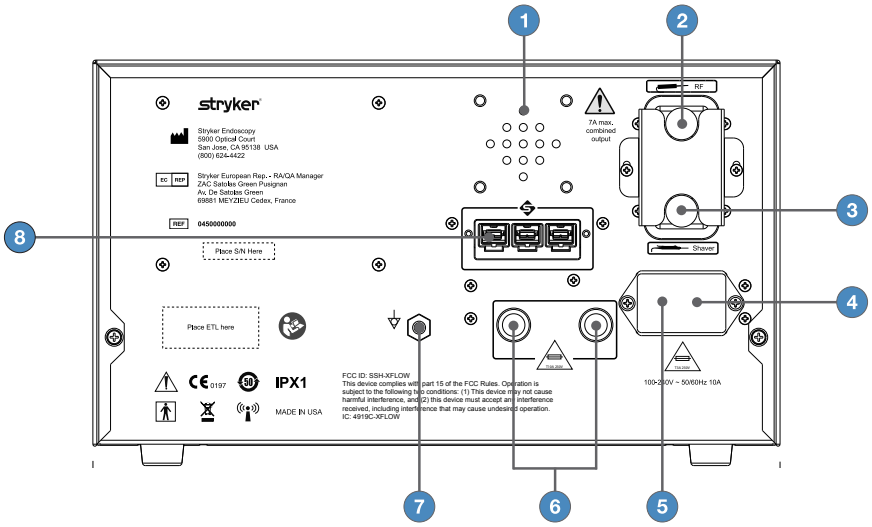
- Arthrex APS II
- Arthrex OPES
- Arthrocare ATLAS
- Arthrocare Quantum
- Arthocare Quantum II
- Dyonics Power
- Dyonics Power II
- Linvatec Advantage
- Mitek VAPR
- Smith and Nephew Vulcan
- Stryker CORE
- Stryker SERFAS
- Stryker TPS

Front Panel



1. LCD Touchscreen
2. Outflow Cassette Ejection Button
3. Outflow Cassette Holder
4. Hand Control Receptacle
5. Footswitch Receptacle
6. Auxiliary Receptacle
7. USB Port
8. Power Button
9. Inflow Cassette Holder
10. Inflow Cassette Ejection Button

Rear Panel



1. Speaker
2. Power Outlet for Approved Resection RF Console
3. Power Outlet for Approved Resection Shaver Console
4. AC Power Inlet
5. Fuse Drawer
6. Global Fuse Holders
7. Equipotentiality Ground Plug
8. SFB Connector Ports

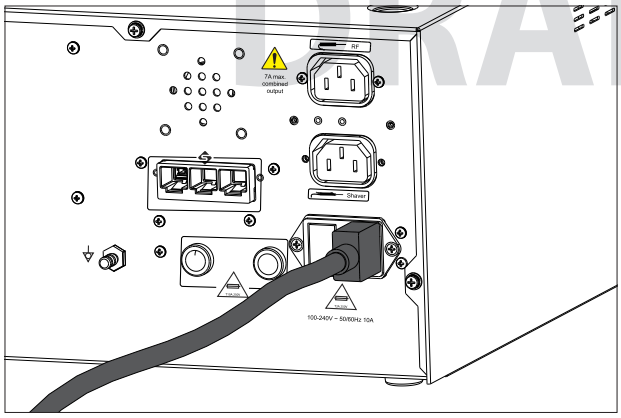
Setup and Device Configuration

Stryker Endoscopy considers instructional training an integral part of the CrossFlow system. Your Stryker Endoscopy representative will perform at least one in-service at your convenience to help you set up your equipment and instruct you and your staff on its operation and maintenance. Please contact your local Stryker Endoscopy representative to schedule an in-service after your equipment has arrived.

1. Choose a location for the CrossFlow pump.
   - Place the pump on a Stryker cart or other sturdy platform near a hospital grade outlet.
   - **Place the pump at the same height as the joint to ensure accurate pressure readings.**
   - Provide at least four to six inches of space around the sides of the pump to ensure proper ventilation and allow access to the power cord.

> ⚠ **Warning**
>
> RF and other mobile communications equipment may affect the normal function of the CrossFlow pump. When placing the pump, follow the instructions located in the "Electromagnetic Compatibililty" section of this manual.

2. Connect the AC power.



   - Connect the provided hospital power cord to the AC inlet on the rear console panel.
   - Connect the other end to a hospital-grade power outlet.

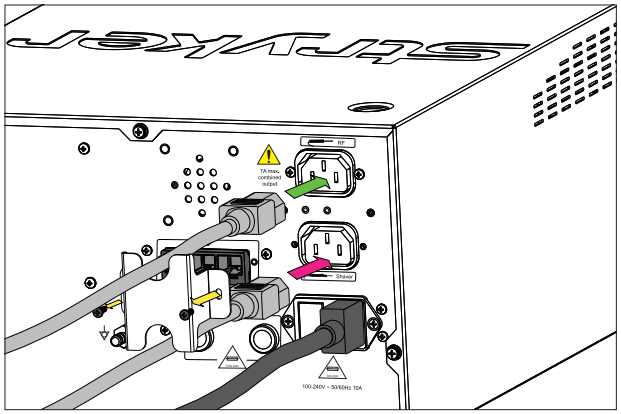
> ⚠ **Warning**
> - Check the device label on the rear of the pump to determine the operating voltage of the device.
> - Check the power cord assembly periodically for damaged insulation or connectors.
> - To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

> **Caution**
> - When connecting or disconnecting a cable, hold the cable by its connector (its plug, not the cord). Failure to comply may result in damage to the cable or pump.
> - Connect the power cords directly to the AC inlet or outlet. Do not connect any of the power cords together.

If required, connect the pump to a Stryker Firewire-compatible device using one of the SFB connector

ports on each device.
Note: Refer to the manual supplied with each Firewire-compatible device for connection information.

3. If required, connect the approved resection console(s) according to the interconnection diagram.



- Using a #1 Phillips screwdriver, unscrew and remove the power cord bracket.
- Connect the approved resection power cord to the AC inlet on the approved resection console. Refer to the manual supplied with each approved console for connection information.
- Connect the other end to the power cord to the power outlet for the approved resection console on the rear panel of the CrossFlow pump, as marked.
- Using a #1 Phillips screwdriver, attach and secure the power cord bracket.

Note: The pump's screen will display the specific components that are connected when the device is powered on.

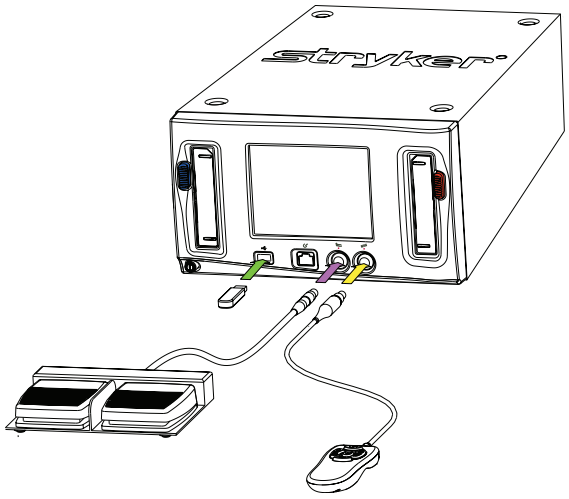
⚠ Warning

When the CrossFlow pump is interconnected with other electrical devices, leakage currents may be additive, resulting in electromagnetic emissions that can interfere with the normal function of electronic medical equipment. To properly control electromagnetic emissions and avoid potential harm to the patient or user, ensure all electrical devices are installed and interconnected according to the requirements of IEC 60601-1-1.

Caution

Ensure the approved resection consoles are connected to the correct power outlets on the rear panel of the pump.

4. If required, connect the hand control, footswitch, and/or USB drive according to the interconnection diagram.
   Note: Stryker recommends using the SIDNE USB 2.0 Flash Disk, 512 MB (P/N 0105-201-529).



Note: The pump's screen will display the specific components that are connected when the device is powered on.

Caution

- Do not connect an ethernet cable to the auxiliary port.
- Turn the connector of the hand control and footswitch so that the red dot points up.
- Do not thread or twist the cable connector for insertion or removal. It is a push/pull connector and may be damaged by twisting it into or out of place.

5. For tubing connection instructions, refer to the CrossFlow Inflow and Outflow Cassette Tubing and the CrossFlow Day-Use Inflow Cassette and Patient-Use Tubing manuals.

Operation

Note: Refer to the "Symbols and Terminology" section in this manual for button and icon definitions and commonly used terms.

Starting a Procedure

To start a procedure, perform the following steps:

1. Power the Pump On and Off
2. Insert the Inflow/Outflow Cassette
3. Select the User Preference File
4. Select the Joint
5. Prime the Inflow Tubing and Operate the Pump

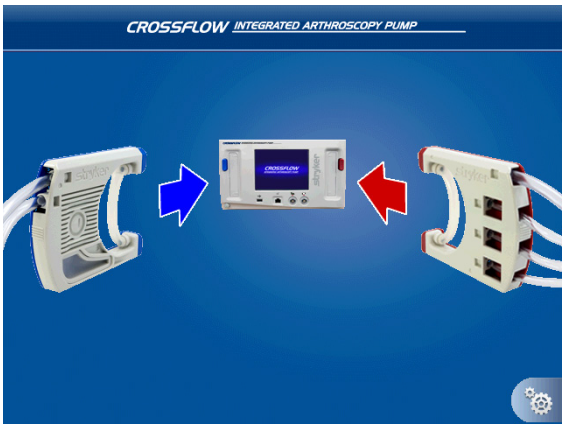
Power the Pump On and Off

1. Press ⏻ located at the bottom left corner of the front panel to power on the pump. When this button is illuminated by a green LED, the system is powered on. The pump will display a splash screen while the software is loading.
2. To power off the system, press ⏻ again.

Insert the Inflow/Outflow Cassette

> ⚠ **Warning**
>
> The choice of irrigation fluid should be determined by the physician, based on the operation method to be employed.

> **Caution**
>
> The cassettes are color-coded. When inserting the cassettes, make sure to insert them as indicated by the color-coding.

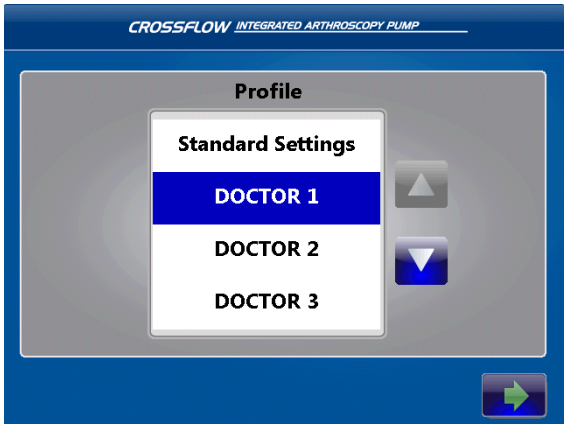


1. Align the colored side of the cassette(s) with the colored button(s) on the pump as depicted in the diagram. The Inflow Cassette is blue and the Outflow Cassette is red.

2. Insert the cassette(s). Push with your thumb until it clicks into place.
   - When the Inflow Cassette is inserted, a green check mark will appear on the cassette, and the screen will advance to the User Preference File Selection screen.
   - When the Outflow Cassette is inserted, "Outflow" will appear at the bottom of the screen. A green check mark will appear on the cassette if it is inserted before the Inflow Cassette (depicted in this scenario).
3. Connect the tubing:
   - For the Inflow and Outflow Cassette Tubing, refer to the instructions in the CrossFlow Inflow and Outflow Cassette Tubing manual.
   - For the Day-Use Inflow Cassette and Patient-Use Tubing, refer to the instructions in the CrossFlow Day-Use Inflow Cassette and Patient-Use Tubing manual.

Select the User Preference File

User preference files can be selected through the CrossFlow Pump interface. Select from "Standard Settings" provided with the pump, or contact your Stryker representative to program your own, including settings for pressure and flow rate and button assignments for the hand control and footswitch.



1. To scroll up and down the user preference file list, press and .
2. Press the name of the desired user preference file to highlight it.
   In this scenario, "Doctor 1" is highlighted.
3. When the desired user preference file is highlighted, press to confirm the selection and advance to the next screen.

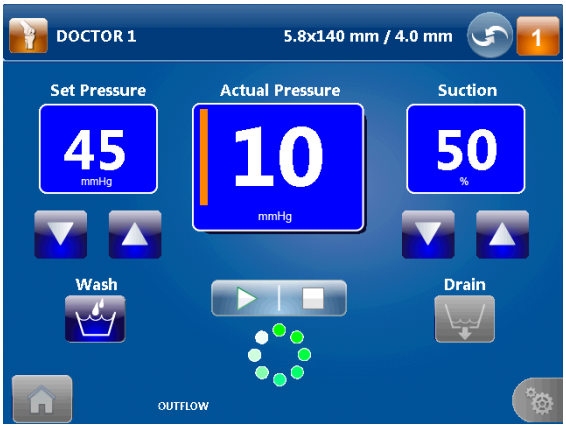
Select the Joint

1. Select the joint:
   - Press to select the shoulder;
   - Press to select the knee;
   - Press to select the hip;
   - Press to select the small joint.
2. When the desired joint is highlighted, the screen will advance to the next screen.
   Note: Press to return to the user preference file selection screen.

Prime the Inflow Tubing and Operate the Pump

> ⚠ **Warning**
>
> - Start the pump with the inflow tubing outside of the joint, all of the inflow tubing clamps open, and no hardware attached. Failure to remove air from the tubing can cause overpressure in the joint.

1. Press to remove air from the inflow tubing.
   Note: This step must be performed each time a new Inflow Cassette is inserted into the pump.



1. Press ▶ | ■ to remove air from the inflow tubing. The ◌ icon indicates that the pump is operating.
   Note: This step must be performed each time a new Inflow Cassette is inserted into the pump.
2. Once the air has been removed and tubing is completely filled with fluid, close the pinch clamps or stopcock.
3. Open the pinch clamps or stopcock to proceed with pump operation.
4. Press ▶ | ■ to start/stop the pump.

During a Procedure

Changing the Pressure and Flow

Note: Follow these instructions to select or change pressure and flow settings if the user preference file does not specify these settings. Adjusting the settings will override the default and user preference file settings.

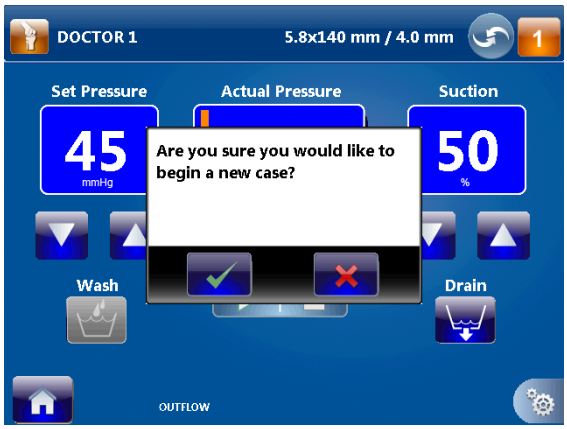
The system will select the following default settings for the following application areas:

Joint	Default Settings
Knee	45 mmHg
Shoulder	50 mmHg
Hip	50 mmHg
Small	35 mmHg

Note: Default pressure settings are only suggestions, and each procedure and each patient may require different parameters. Select the optimal pressure based on the patient profile, including, but not limited to, blood pressure, height, weight, age, and tissue quality.

1. If necessary, press ▲ and ▼ to increase or decrease the Set Pressure (adjust in increments of 5 mmHg from 15–150 mmHg) and Flow or Suction (adjust in increments of 10% from 0–100%).
   In this scenario, the pump is operating in Inflow/Outflow mode. The Set Pressure is set at 45 mmHg, and the Suction is set at 50%.
   Note: A green box will surround the suction/flow value when the pump reaches the flow limit. The pump is operating in constant flow mode. Once the flow limit is reached, it will operate in constant flow mode. (The pump will attempt to operate at the set pressure until the flow limit is reached.)

Changing the User Preference File or Joint Selections



1. If the pump is running, press to stop the pump.
2. Press in the lower left-hand corner of the screen.
3. Press to return to the user preference file selection menu. Press to return to the Run Screen.
4. Follow the instructions in the "Select the User Preference File" and "Select the Joint" section to change the user preference file and/or joint.

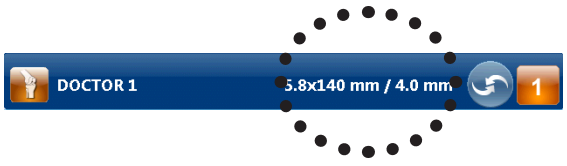
Changing the Hardware Combination Selections

Note: Adjusting the settings will override the default and user preference file settings.

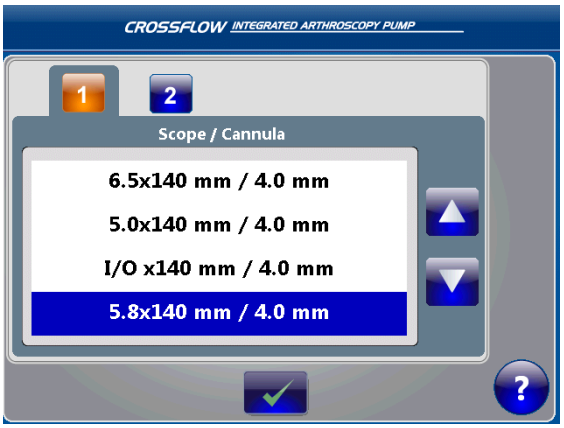
The system will select the following default hardware combination if "Standard Settings" is selected:

Hardware option	Joint	Default combination
1	Knee	Stryker 5.8 mm x 140 mm cannula with 4.0 mm scope
	Shoulder	Stryker 5.8 mm x 140 mm cannula with 4.0 mm scope
	Hip	Stryker 5.0 mm x 165 mm cannula (bridge) with 4.0 mm scope
	Small	Stryker 4.0 mm x 75 mm cannula with 2.7 mm scope
2 3 4	—	None
Alternate hardware combination selections		**Cannula diameter - scope diameter = x**
Low Flow		$x \leq 1$
Medium Flow		$1 > x \geq 2$
High Flow		$x > 2$

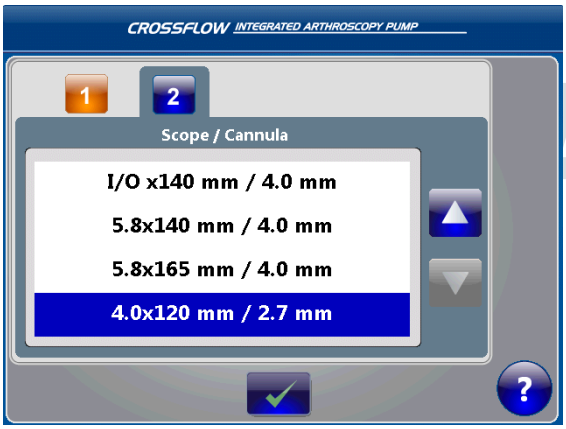
Note: If the user preference file does not specify a hardware combination, follow these instructions to change a hardware combination.



1. If the pump is running, press to stop the pump.
2. Press the hardware combination selection to return to the hardware combination selection menu.



3. Select the scope/cannula combination for option 1 ; to scroll up and down the hardware combination list, press ▲ and ▼ .
4. Press the desired hardware combination to highlight it.
   In this scenario, "5.8 mm x 140 mm cannula with 4.0 mm scope" is highlighted. (Select Low, Medium, or High Flow if the desired hardware combination does not appear on the list.)
5. If no other hardware combination options are required, proceed to step 6.
6. If necessary, press 2 , 3 , and/or 4 to view the available scope/cannula combinations for these options.
   Note: Hardware 3 and 4 are only enabled if the hip joint is selected.



7. Repeat steps 3 and 4 to select the scope/cannula combination for options 2 , 3 , and/or 4 .
   In this scenario, "4.0 x 120 mm cannula with 2.7 mm scope" is highlighted for option 2 .
8. When the desired hardware combinations are highlighted, press ✓ to confirm the selections and advance to the Run screen.

Swapping Between Hardware Combination Selections During the Case

The "Hot Swap" function allows the user to switch the cannula through which the inflow tubing is attached without requiring recalibration. Depending on the surgical site, up to four cannulas can be utilized by this function.

> ⚠ **Warning**
>
> Use the scope and cannula as selected on the pump. An incorrect scope and cannula selection may cause overpressure in the joint.

1. Press to change to option 2 . A green box will briefly appear displaying the new hardware combination selection.
2. Ensure the correct hardware combination is displayed. If the incorrect hardware combination selection is displayed, or to change the hardware combination selection, follow the instructions in the "Change Hardware Combination Selections" section.
3. Press to change to hardware combination 1 .

Performing the Wash Function

The Wash function increases the set pressure and flow limit by a user-specified percentage over a user-specified duration (for Inflow-only mode), or increases set pressure and suction by a user-specified percentage over a user-specified duration (for Inflow/Outflow mode).

1. While the pump is running, press to perform the Wash function. Follow the instructions in the "Program the Wash and Clear Function Settings" section to adjust the default settings.
2. Press to repeat or stop the Wash function.

Performing the Drain Function

The Drain function is only available in the Inflow/Outflow mode. It operates the outflow pump to remove fluid from the surgical site for 30 seconds or until the user stops the pump.

1. Press to stop the pump.
2. Press to remove fluid from the joint.
3. Press to repeat or stop the Drain function.

After a Procedure

Remove the Cassettes

Caution

- Do not remove the cassettes while the pump is in use. The pump or the cassette may be damaged. The cassettes can only be removed when the pump is stopped.
- Do not attempt to remove the Outflow Cassette if it gets stuck as it may damage the pump or the cassette. Follow the instructions in the "Troubleshooting" section in this manual to resolve this problem.

1. Press to stop the pump.
2. Close all pinch clamps.

3. Refer to the CrossFlow Day-Use Inflow Cassette and Patient-Use Tubing and the CrossFlow Inflow and Outflow Cassette Tubing manual on instructions on how to disconnect and discard the tubing. Always maintain a sterile technique.
4. Press the Inflow Cassette Ejection button (blue) and/or the Outflow Cassette Ejection button (red) on the front panel of the pump to eject the cassette(s).
5. Discard the cassettes and tubing appropriately.

Menu Features

Opening and Closing the Main Menu

1. If the pump is running, press to stop the pump.
2. Press to open the Main Menu.
3. Press to close the Main Menu.

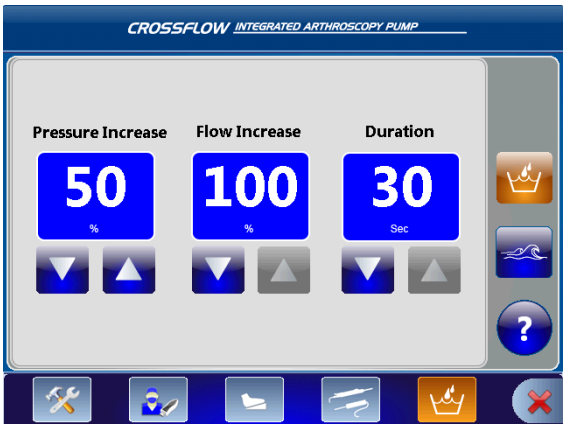
Programming the Wash and Clear Functions Settings

Note: Adjusting the settings will override the default and user preference file settings.

1. Press to open the Main Menu.
2. Press to open the Wash and Clear Settings Menu.

Setting	Function
Wash	• Inflow-only mode: Increases set pressure and flow limit by user-specified percentage over user-specified duration. By default, the set pressure will increase by 50% of the current setting, and the flow limit will increase by 100% of the current setting for 30 seconds. • Inflow/Outflow mode: Increases set pressure and suction by user-specified percentage over user-specified duration. By default, the set pressure will increase by 50% of the current setting, and the suction will increase by 100% of the current setting for 30 seconds.
Clear	• Inflow-only mode: Increases flow limit by user-specified percentage over user-specified duration. By default, the flow limit will increase by 100% of the current setting for 30 seconds. • Inflow/Outflow mode: Increases suction rate by user-specified percentage over user-specified duration. By default, the outflow will increaseby 100% of the current setting for 30 seconds.

Wash Function Settings



1. Press to program the settings for the Wash function.
2. Press and to adjust the Pressure, Flow, or Duration.
   In this scenario, the pressure will increase by 50% and the flow will increase by 100% for 30 seconds.

Clear Function Settings

1. Press to program the settings for the Clear function.
2. Press and to adjust the Flow or Duration.
   In this scenario, the flow will increase by 100% for 30 seconds.

Programming the Resection Integration Settings

Note: Adjusting the settings will override the default and user preference file settings.

1. Press to open the Main Menu.
2. Press to open the Resection Integration Settings Menu.

Shaver Console Settings

1. Press to specify the shaver console:
   - Press CROSSFIRE to select the CrossFire console;
   - Press OTHER DEVICES to select an approved resection console;
   - Press NONE if no shaver console is in use.

   In this scenario, the CrossFire console is selected.
2. Press and to increase or decrease the Suction (adjust in increments of 10% from 0–100%).
   In this scenario, the Suction is set at 50%.

RF Console Settings

1. Press to specify the RF console:
   - Press CROSSFIRE to select the CrossFire console;
   - Press OTHER DEVICES to select an approved resection console
     (Press "Suction" if the RF probe is a suction probe.);
   - Press OFF if no RF console is in use.

   In this scenario, an approved resection console with a suction probe is selected.
2. Press and to increase or decrease the Suction (adjust in increments of 10% from 0–100%).
   In this scenario, the Suction is set at 50%.

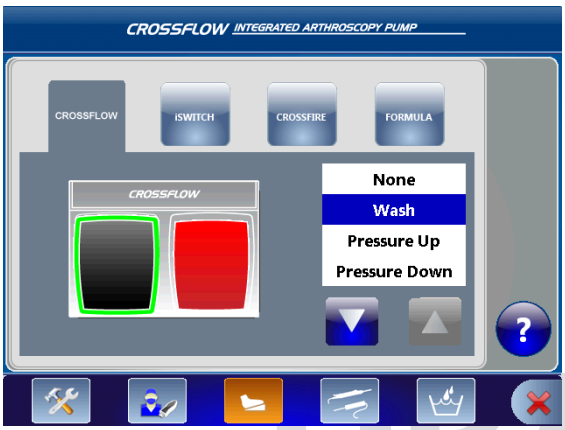
Programming the Footswitch and Formula Shaver Settings

1. Press to open the Main Menu.
2. Press to open the Footswitch/Formula Shaver Settings Menu.

Setting	Function
Wash	• Inflow-only mode: Increases set pressure and flow limit by user-specified percentage over user-specified duration. • Inflow/Outflow mode: Increases set pressure and suction by user-specified percentage over user-specified duration.
Clear	• Inflow-only mode: Increases flow limit by user-specified percentage over user-specified duration. • Inflow/Outflow mode: Increases the suction by user-specified percentage over user-specified duration.
Drain	• Operates the outflow pump to remove fluid from the surgical site for 30 seconds or until the user stops the pump.

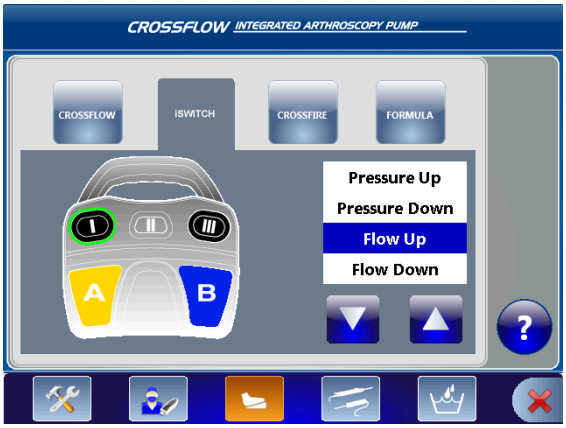
Pressure Up/Down	• Increases/decreases the set pressure.
Hot Swap	• Switches between selected arthroscope/cannula combinations.
Start/Stop	• Starts/stops the pump.
Flow Up/Down	• Inflow-only mode: Increases/decreases the flow limit. • Inflow/Outflow mode: Increases/decreases suction.
None	• No function.

CrossFlow Footswitch



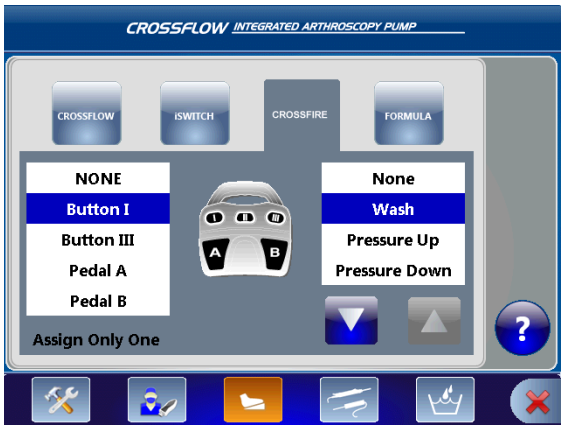
1. Press the CrossFlow button to program settings for the CrossFlow Footswitch.
2. Press the black foot pedal (highlighted with green border) to select its function.
3. Press and to scroll up and down the function list.
4. Press the function of choice to assign the function to the pedal.
   In this scenario, the "Wash" function is selected.
5. Repeat steps 2–4 to program the red foot pedal.

iSwitch Footswitch



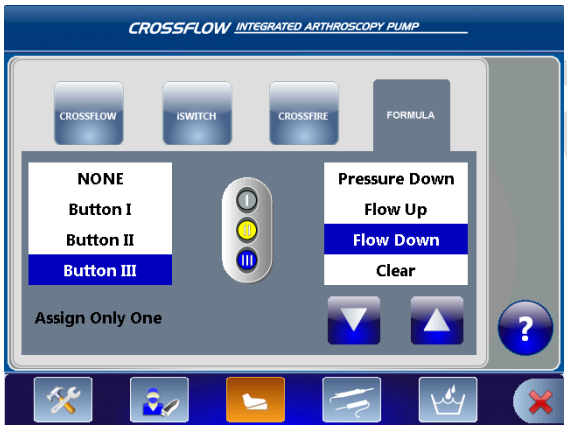
1. Press the iSwitch icon to program settings for the iSwitch Footswitch.
2. Press the appropriate button/pedal (highlighted with green border) to select its function.
3. Press and to scroll up and down the function list.
4. Press the function of choice to assign the function to the button/pedal.
   In this scenario, the "Flow Up" function is selected for Button I.
5. Repeat step 2–4 to program each button/pedal.

Crossfire Footswitch



1. Press the Crossfire icon to program settings for the Crossfire Footswitch.
2. Select a button/pedal in the left-hand menu to program it.
   Note: Only one button or pedal may be assigned a function.
3. Press and to scroll up and down the function list.
4. Press the function of choice to assign the function to the button/pedal.
   In this scenario, the "Wash" function is selected for Button I.

Formula Shaver

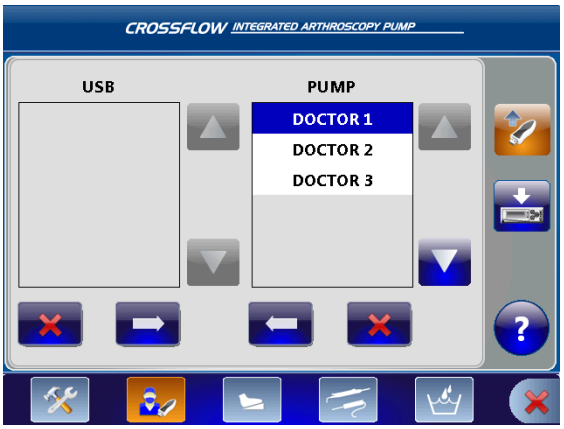


1. Press the Formula icon to program settings for the hand control.
2. Select a button in the left-hand menu to program it.
   In this scenario, Button III is selected.
   Note: Only one button or pedal may be assigned a function.
3. Press and to scroll up and down the function list.
4. Press the function of choice to assign the function to the button/pedal.
   In this scenario, the Flow Down is selected for Button III.

Loading User Preference Files

1. Press to open the Main Menu.
2. Press to open the User Preference Menu.

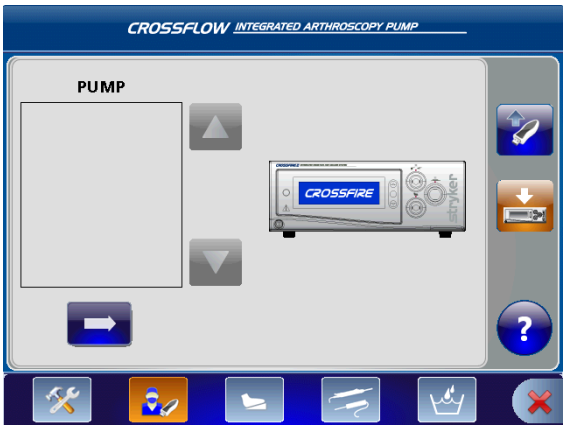
Transferring Files to/from a USB drive



1. Press to upload/download files to/from a USB drive.
2. Connect the USB drive according to the instructions in the "Setup and Device Configuration" section.
3. Press and to scroll up and down the file list.
4. Select the file to transfer or delete.
   In this scenario, the "Doctor 1" file is selected.

5. Press and to transfer files to/from the USB drive to/from the pump.
6. Press below the USB or pump list to delete the selected file.
7. To delete the selected file, press . To cancel the operation, press .

Transferring Files to the Crossfire System



1. Press to transfer a user preference file to the Crossfire system.
2. Press and to scroll up and down the file list.
3. Select the file to transfer.
   Note: Only preference files containing Crossfire settings will appear in this menu.
4. Press to transfer the file to the Crossfire system.

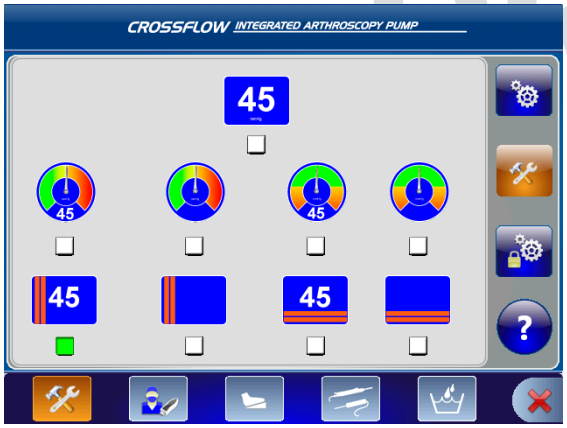
Navigating to the Settings Menu

1. Press to open the Main Menu.
2. Press to open the Settings Menu.

Adjusting the Volume, Brightness, and Language, and Upgrade Software

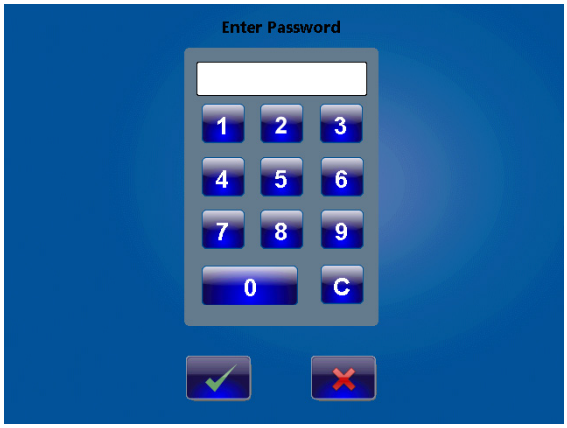
1. Press to open the General Settings Menu.
2. Adjust the Volume .
3. Adjust the Brightness .
4. Press and to select the language preference.
5. To upgrade the software:
   - Connect the USB drive according to the instructions in the "Setup and Device Configuration" section. The current software version appears in the box. In this scenario, version 00.02.10 is installed.
   - Press to upgrade the software. The system will automatically restart once the software is succesfully upgraded.

Adjusting the Actual Pressure Display



1. Press to open the Actual Pressure Display selection menu.
2. Select the desired display icon. The selection will be highlighted with a green box.

Accessing the Stryker Settings Menu (For Stryker use only)



Only authorized Stryker representatives have access to this menu.

1. Press to open the Stryker Settings Menu.
2. Enter a password.
3. To confirm, press . To cancel, press .

Navigating to the Help Menu

1. Press ? to open the Help Menu on any screen.

System Feedback

Audible Feedback

Audible Feedback	Event	Implication
Three high-tone beeps	Fault error	Refer to "Error Messages"
Three high-tone beeps, pause, two beeps	Lockdown error	Refer to "Error Messages"
One medium-tone beep	Accessory connection	Refer to "Connect the Components" and "Insert the Inflow/Outflow Cassette"
Two medium-tone beeps	Accessory removal	Refer to "Connect the Components" and "Insert the Inflow/Outflow Cassette"
One low-tone beep	Touchscreen/Hand control/ Footswitch operation	N/A
Three (medium, low, high-tone) beeps	Hot swap	Refer to "Swap between Hardware Combination Selections"

Error Messages

The words caution, fault, and lockdown carry special meanings and should be carefully reviewed:

- **Caution:** Visual popup error is displayed for five seconds; user may clear the message when the problem is resolved.
- **Fault:** The pump will stop; user may clear the message when the problem is resolved.
- **Lockdown:** The pump will stop; reboot system.

Error Message	Cause	Possible Solution
CAUTION	Cassette about to expire (two hours left before expiration).	• Replace the cassette.
CAUTION	Preventative Maintenance required; the unit has reached its recommended service interval.	• Contact your Stryker representative.
CAUTION	Inflow/Outflow RFID read failure: The Inflow or Outflow RFID tag cannot be detected while the pump is stopped.	• Ensure the Inflow or Outflow Cassette is fully inserted. • If the problem persists, replace the cassette. • If the problem persists, contact your Stryker representative.
FAULT	Priming Error: No fluid in the tubing after ten seconds.	• Ensure the pinch clamps on the saline bags are open. • Ensure the Inflow Cassette is fully inserted.

Error Message	Cause	Possible Solution
FAULT	Instrument recognition error: The stopcock on the cannula is closed, the lower clamp on inflow tubeset is closed, or no hardware is attached to the tubing.	• Check the inflow tubing from the bags to the joint and ensure the hardware is properly attached. • Open any closed clamps or stopcocks. • Repeat the priming step.
FAULT	Inflow and/or Outflow Cassette not fully inserted.	• Remove and reinsert the cassette until it clicks into place.
FAULT	Cassette is expired (after 24 hours of use).	• Replace the cassette.
FAULT	The connection to the Crossfire console or approved resection console is lost.	• Ensure the consoles are properly connected to the pump. Follow the instructions in the "Setup and Device Configuration" section in this manual. • Reboot the system. • If the problem persists, contact your Stryker representative or return the console for repair.
FAULT	The Crossfire console is specified in the user preference file, but it is improperly or not connected to the pump.	• Ensure the console is properly connected to the pump. Follow the instructions in the "Setup and Device Configuration" section in this manual. • Reboot the system. • If the problem persists, contact your Stryker representative or return the console for repair.
LOCKDOWN	Hardware fault detected	• Reboot the system. • If the problem persists, contact your Stryker representative or return the console for repair.
LOCKDOWN	Motor defective	• Reboot the system. • If the problem persists, contact your Stryker representative or return the console for repair.
LOCKDOWN	Pressure Transducer out of calibration: If the pressure is at a value greater than 20 mmHg for five seconds when no cassette is inserted.	• Reboot the system. • If problem persists, contact your Stryker representative.
LOCKDOWN	Possible Overpressure: The pressure is sustained at 750 mmHg for more than one second, or a hardware failure or pressure transducer malfunction has occurred.	• Reboot the system. • If the problem persists, contact your Stryker representative or return the console for repair.

Troubleshooting

Problem	Cause	Possible Solution
The pump does not power on (no approved resection console(s) are attached to the pump).	The pump is not plugged in, or the global or main fuses are out.	• Ensure the pump is plugged in to the main outlet. • Inspect the all fuses. • Replace the fuse if it is out of service.
The pump does not turn on (approved resection console(s) are attached and turn on).	There is a power supply failure, or the main fuses are out.	• Inspect the main fuses in the fuse drawer. • Replace the fuses if it is out of service. • If the problem persists, contact your Stryker representative.
The pump turns on, but approved resection console(s) do not.	There is a problem with the approved resection console(s).	• Inspect the approved resection console(s). • If the problem persists, contact your Stryker representative or return the console for repair.
Neither the pump or approved resection consoles turn on.	The pump is not plugged in, or the main fuses are out.	• Ensure the pump is plugged in to the main outlet. • Inspect the main fuses in the fuse drawer. • Replace the fuses if they are out of service.
The pump is plugged in, the fuses are functional and/or have been replaced, and the pump still does not turn on.	A hardware error occurred.	• Plug the pump in to a different main outlet. • If the problem persists, contact your Stryker representative.
The cassette(s) are inserted, but the Run Screen does not appear, and the pump does not start.	The Inflow or Outflow RFID tag cannot be detected.	• Ensure the Inflow or Outflow Cassette is fully inserted. • If the problem persists, replace the cassette. • If the problem persists, contact your Stryker representative.
The pump turns on, but there is no image on the screen or the screen is frozen.	A hardware error occurred.	• Reboot the system. • If the problem persists, contact your Stryker representative.
The hand control or the footswitch are plugged in, but are not activating.	The devices are improperly connected to the pump.	• Ensure the devices are properly connected according to the instructions in the "Setup and Device Configuration" section of this manual.
	The settings in the Footswitch/Formula Shaver Settings Menu are set to "None."	• Check the settings in the Footswitch/Formula Shaver Settings Menu. • Reset the settings to the Default settings.
	The device(s) have reached their expected lifetime.	• Replace the device(s).

There are abnormal pressure or flow rate fluctuations.	There is a pressure sensor error. A hardware fault is detected.	• Reboot the system. • If the problem persists, contact your Stryker representative, or return the console for repair.
The pump stops pumping fluid, and the pressure indicator continues to blink.	The pressure is too high. The actual pressure exceeds 200 mmHg for 15 seconds or greater than 250 mmHg for five seconds.	• Open the valve at the outflow tube, the drainage tube, or the stopcock on the instrument to reduce the pressure.
The pinch valves are not engaging.	There is a pinch valve or hardware error.	• Examine the pinch valves to ensure they are functioning properly. • Reboot the system.
Bubbles appear in the joint.	There is no more irrigation fluid.	• Replace or add additional saline bags. • Ensure the pinch clamp is open on the irrigation tube, or the stopcock is open.
	The tubing connection is loose.	• Ensure the tubing is securly connected. • If the problem persists, replace the tubing.
	A priming error occurred.	• Ensure the pinch clamps on the saline bags are open. • Ensure the Inflow or Outflow Cassette is fully inserted. • Remove the hardware from the tubing and repeat the priming step. • If the problem persists, replace the cassette.
	The suction level is set too high.	• Decrease the suction level.
The pump cannot achieve the set pressure.	There is a hardware setup error, the flow limit is set too low, or the suction level is set too high.	• Verify the luer-lock is tightly closed, the correct hardware is selected and properly connected, and the dual stopcock cannula is properly set up. • Increase the flow limit or the set pressure setting. • Decrease the suction level. • Press Run/Stop to restart the pump.
There is insufficient pressure in the surgical site.	An irrigation problem exists.	• Check the stopcock on the arthroscope and the clamps under the saline bags.
	The hardware set up is incorrect.	• Ensure the hardware is properly selected and set up.
There is no suction while the pump is running.	The approved resection consoles are improperly connected. The tubes on the Outflow Cassette are improperly connected.	• Ensure the consoles and the tubes are properly connected according to the instructions in Setup and Device Configuration section of this manual.
Unable to upload files to/from USB drive.	A hardware fault occurred.	• Ensure the USB drive is functioning properly and the correct files are on the drive. If the drive is not functioning properly, replace the USB drive. • Reboot the system.

Sporadic electrical interference is affecting the pump.	Electrical, RF, and/or mobile communications equipment is affecting the normal function of the pump.	• Power down all electrical equipment not in use. • Increase the distance of other electrical equipment. • Connect the pump and other equipment into different outlets.
The touch screen is unresponsive or inaccurate.	Touch screen is not properly calibrated for the user.	• Reboot the system. • If the problem persists, contact your Stryker representative or return the console for repair.
	A hardware or software error occurred.	
A user preference file was accidentally deleted from the pump.	Unintentional deletion of a user preference file.	• Transfer the user preference file from a USB drive to the pump according to the instructions in the "Transfer Files to/from a USB drive" section of this manual.
The pump is stopped, but the Outflow Cassette is stuck and cannot be ejected.	The pinch valves do not retract.	• Do not attempt to remove the cassette as it may damage the pump or the cassette. • Reboot the system. • If the problem persists, contact your Stryker representative.
"Service Pump Soon"	The pump is 95% through the current maintenance period.	• Contact your Stryker service representative.

Cleaning, Maintenance, and Disposal

⚠ Warning

- **Do not remove the cover of the console as this could cause electric shock and product damage.**
- To avoid electric shock and potentially fatal injury, unplug the pump from the electrical outlet before cleaning.

Caution

To prevent product damage:

- when cleaning the pump, do not spray cleaning liquid directly onto the pump; spray on the cloth before wiping the pump,
- do not immerse the pump in any liquid,
- do not use corrosive cleaning solutions to clean the pump,
- do not sterilize the pump.

Clean the Components

Pump

Should the pump need cleaning:

1. Spray cleaning liquid onto a dry, sterile cloth. Avoid excess liquid or drips.
2. Wipe the pump.
3. Take extra care when cleaning the front LCD screen. Excess liquid or drips that enter the bottom of the screen may result in product damage.

Footswitch

⚠ Warning

Clean the footswitch prior to first use and after every subsequent use.

Consult the footswitch manual (P17862) for cleaning instructions.

Hand control

⚠ Warning

Clean and sterilize the hand control prior to first use and after every subsequent use to minimize risk of infection.

Consult the hand control manual for cleaning and reprocessing instructions.

Replace the Fuses

1. Disconnect the pump from the electrical output and remove the power cord from the rear of the pump.
2. Remove the appropriate fuse holder; with a straight blade screwdriver, unlatch the fuse drawer, or turn the global fuse holders in a counter clockwise direction until the spring pushes out.
3. Remove the fuse(s).
4. Replace the fuse(s) with a fuse of the same value and rating as indicated on the rear of the pump.

5. Follow these steps in reverse for assembly.
    - Push in the the fuse drawer until it clicks into place.
    - Turn the global fuse holders in a clockwise direction until they are fully pushed in and secure in their original position.

Perform Annual Inspection

Stryker recommends inspections of the system on an annual basis. These inspections evaluate whether the product currently or in the near future may fail in a manner that affects device performance.

Safety Test

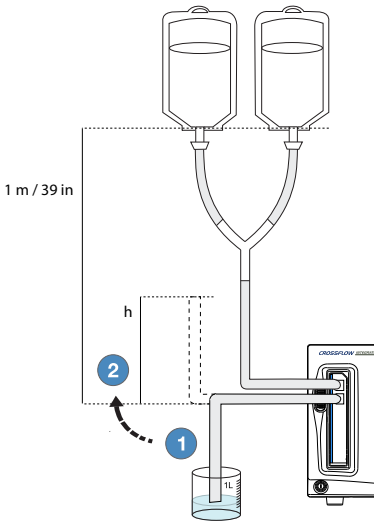
Visually inspect the device and its components to ensure the:

- fuses correspond with the specifications on the pump,
- labels and device markings are legible,
- mechanical condition of the system (wires, hardware, etc.) allows for its safe use, and
- the system is clean for safe and proper use.

Basic Function Test

Perform a basic function test to analyze the features, displays, and performance of the system.

1. **Power**
    - Power on the pump according to the instructions in "Power the CrossFlow Pump On and Off" section of this manual. The power button will be illuminated by a green LED, indicating the system has powered on.
2. **Stepper motor**
    - Insert the cassettes according to the instructions in "Insert the Inflow/Outflow Cassette" section of this manual.
    - Visually inspect the stepper motors located in the cassette holder; they will be disengaged.
    - Remove air from the inflow tubing according to the instructions in "Prime the Inflow Tubing" section of this manual.
    - Visually inspect the stepper motors; two motors will be engaged.
    - Stop the pump.
    - Visually inspect the stepper motors; they will be disengaged.
    - Remove the cassettes according to the instructions in "Remove the Cassettes" section of this manual.
3. **Device Detection**
    - Connect the components (for example, the hand control, footswitch, CrossFire system, etc.) according to the instructions in "Connect the Components" section of this manual.
    - Ensure the console displays the icon in the bottom of the screen of each component that is connected when the device is powered on.
4. **Pressure Sensor**



- Gather the following equipment:
  - disposable Inflow Cassette tube set
  - container filled with water
  - fluid bag (3 L)
- Follow the instructions in this manual to power on the pump, insert the Inflow Cassette, select a preference file, and select a joint.
- Suspend a fluid bag 1 m/39 in on its holder and connect the bag to the tubing according to the diagram.
- Discard the protective cap on the tubing (if needed), and immerse the end of the tubing into a container filled with water. 1
- Set the Pressure to 50 mmHg and Flow to 20%, according to the instructions in the "Set the Pressure and Flow" section of this manual.
- Remove air from the inflow tubing according to the instructions in the "Prime the Inflow Tubing" section of this manual.
- Press ▶ | ■ to start the pump. Allow the tubing to completely fill with fluid.
- Press ▶ | ■ to stop the pump. The actual pressure display will show approximately 0–5 mmHg.
- Remove the tubing from the container and hold it at a given water column height (h) indicated in the table below. Ensure the tubing in the water column is completely filled with fluid. 2
- Read the actual pressure displayed on the pump. The test has been successfully completed if the actual pressure on the pump is within the range indicated in the table below for a given height of the water column.

Height of water column (h)		Acceptable actual pressure (mmHg)
Inches	Centimeters	
12	30	20–25
18	45	30–35
24	60	40–45
46	90	65–70

5. **Inflow Flow Rate**
   - Gather the following equipment:
     - disposable Inflow Cassette tube set
     - fluid bag (3 L)
     - stopwatch
     - one 1 L measuring cup
   - Follow the instructions in this manual to power on the pump, insert the Inflow Cassette, select a preference file, and select a joint.
   - Suspend a fluid bag 1 m/39 in on its holder and connect the bag to the tubing according to the diagram.
   - Discard the protective cap on the tubing (if needed), and place the end of the tubing into a container filled with water. 1
   - Set the pressure to 150 mmHg and flow to 50%.
   - Remove air from the inflow tubing according to the instructions in the "Prime the Inflow Tubing" section of this manual.
   - Clamp off the tubing in the measuring cup without stopping the pump.

- Empty the measuring cup.
- Unclamp the tubing and place it in the cup. Start the stopwatch once the tubing is placed back in the cup.
- Once the measuring cup is filled with 1 liter of fluid, press  to stop the pump.
- The test has been successfully completed if the time it takes to fill the measuring cup with 1 liter of fluid is within the range specified in the table below.

Flow (%)	Time (seconds)
50	70

Perform Preventive Maintenance and Calibration

Caution

Stryker does not accept any liability for direct or consequential damages if:
- the pump or the accessories are improperly prepared and maintained,
- non-authorized persons perform repairs, adjustments, or alterations to the pump or accessories,
- non-authorized persons open the pump,
- the prescribed inspection and maintenance schedules are not followed.

When the pump is 95% through the current maintenance period, a "Service Pump Soon" notification will appear on the screen. An authorized Stryker service technician must inspect and service the device according to the maintenance and calibration schedule below to maintain product functionality.

Component	Maintenance/Calibration Period
Motors	2 years
Pinch valves	2 years
Pressure transducer	2 years

Expected Life

Equipment	Expected Life
Console	Five years
Footswitch	Three years
Hand Control	One year
Inflow, outflow, patient-use tubing	Single-use
Day-use cassette	Ten cases, eight hours of active use, or 24 hours after point of first use

Disposal

This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately in accordance with applicable national or institutional related policies relating to obsolete electronic equipment.
Dispose of any system accessories and irrigation fluid according to normal institutional practice relating to potentially contaminated items.

Technical Specifications

Equipment Information

Size	**Pump Dimensions:** • 12.528 in. (318.2 mm) width • 7.025 in. (178.4 mm) height • 16.990 in. (431.6 mm) depth **Pump Weight:** 24 lbs. (10.9 kg) **Hospital power cord:** (p/n 0105-033-001) 2 m **Approved resection console power cord:** (p/n P17275) 2 m
Power Connection	**Input Voltage:** 80–275 V **Inlet Fuse:** 10 A, 250 V
Frequency	47–63 Hz
Power/Current Consumption	Maximum power consumption: 269 W Maximum current consumption: 80 V: 3.4 A; 275 V: 0.98 A Motor output maximum speed: 650 RPM RF output waveform: 13.56 MHz (ISO15693)
Electrical Safety Classification	Class I equipment Type BF Part Water ingress protection, IPX1 Continuous Operation
Environmental Specifications	Operating Temperature: 5 – 40°C Operating Humidity: 30 – 95% RH (non-condensing) Shipping Temperature: -18° – 60°C Shipping Humidity: 15 – 90% RH
Safety and EMC Compliance	• UL 60601-1: 2006 • IEC 60601-1-2: 2007 • IEC 60601-1-4: 2000 • IEC 60601-1-6: 2010 • IEC 60601-1-8: 2006 • IEC 62304: 2006 • IEC 62366: 2007 • CAN/CSA-C 22.2 No. 601.1-M90: 2003 • CAN/CSA 22.2 No. 60601-1: 2002 • AS/NZS 3200.1.0: 1998 • IEC 60601-1: 2005 + Corr 2006 + Corr 2007 • IEC 60601-1-1: 2005 + Corr 2006 + Corr 2007 • CAN/CSA-C 22.2 No. 60601-1-2: 2003 + A1: 2006
Pump Capacity	3.0 L/min
Pressure range	0-150 mm Hg
Max suction by pressure relief	500 mm Hg
Measuring accuracy	Pressure: ≤2% Flow: ±10%
Display/Color Touch Screen	160° viewing angle 6.5 inch diagonal active LCD Resolution 800 (horizontal) x 480 (vertical) 12:8 aspect ratio 16-bit color Dimensions: 153 mm (width) x 118 mm (height)
Volume Adjustment	0-85 dBA

Connections	Wired Hand Control Wired Footswitch USB 1.1 port Stryker Firewire Backbone (SFB)

Electromagnetic Compatibility

Like other electrical medical equipment, CROSSFLOW INTEGRATED ARTHROSCOPY PUMP requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), CROSSFLOW INTEGRATED ARTHROSCOPY PUMP must be installed and operated according to the EMC information provided in this manual.

The CROSSFLOW INTEGRATED ARTHROSCOPY PUMP has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Caution: Portable and mobile RF communications equipment may affect the normal function of the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP.

Caution: Do not use cables or accessories other than those provided with the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

Caution: If the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP is used adjacent to or stacked with other equipment, observe and verify normal operation of the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP in the configuration in which it will be used prior to using it in a surgical procedure. Consult the tables below for guidance in placing the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
CROSSFLOW INTEGRATED ARTHROSCOPY PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of CROSSFLOW INTEGRATED ARTHROSCOPY PUMP should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	CROSSFLOW INTEGRATED ARTHROSCOPY PUMP 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 CISPR 11	Class A	CROSSFLOW INTEGRATED ARTHROSCOPY PUMP is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
CROSSFLOW INTEGRATED ARTHROSCOPY PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of CROSSFLOW INTEGRATED ARTHROSCOPY PUMP should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Electrostatic Discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±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 IEC61000-4-4	±2 kV for power supply lines ±1 kV 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 IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 IEC61000-4-11	<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 CROSSFLOW INTEGRATED ARTHROSCOPY PUMP requires continued operation during power mains interruptions, it is recommended that CROSSFLOW INTEGRATED ARTHROSCOPY PUMP 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration--Electromagnetic Immunity			
The CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system is intended for use in the electromagnetic environment specified below. The user of the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system should ensure 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 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 that 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 CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system is used exceeds the applicable RF compliance level above, the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP unit. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP System			
The CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CROSSFLOW INTEGRATED ARTHROSCOPY PUMP system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power (W) of transmitter	**Separation distance (m) according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 kHz to 800 MHz $d = 1.2\sqrt{P}$	800 kHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
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.			

Regulatory Information

Federal Communications Commission (FCC)

FCC ID: SSH-XFLOW
Trade Name: CrossFlow Integrated Arthroscopy Pump
Type or Model: 0450000000

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

- this device may not cause harmful interference, and
- 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 Endoscopy could void your authority to operate this equipment.

Frequency of transmission: 13.56 MHz
Type of frequency / characteristics of the modulation: 10% ASK
Subcarrier: 423.75 kHz, Manchester coding
Effective radiated power: 50 µW

Industry Canada (IC)

IC: 4919C-XFLOW
Trade Name: CrossFlow Integrated Arthroscopy Pump
Type or Model: 0450000000

This device complies with Industy Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

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

R&TTE Declaration of Conformity

We,

Name of company: Stryker Endoscopy
Address: 5900 Optical Court, San Jose, CA 95138
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: CrossFlow Integrated Arthroscopy Pump
Trade Name: CrossFlow Integrated Arthroscopy Pump
Type or Model: 0450000000
Relevant Supplementary Information: None

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: EN 60601-1
EMC: EN 60601-1-2
Radio Spectrum: EN 300 330-1 V1.5.1
Supplementary information: none
Notified body involved: TÜV Rheinland Product Safety (GmbH)
Technical file held by: Stryker Endoscopy
Place and date of issue (of this DoC): San Jose, CA USA, DATE

Signed by or for the manufacturer:

Name: Mike Hilldoerfer
Title: Associate Director, Regulatory Affairs

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

Symbols and Terminology

This device and its labeling contain symbols that provide important information for the safe and proper use of the device. These symbols are defined below.

Warning


Warning/Caution: See Instructions for Use


General warning sign, Multiple socket-outlet, maximum allowed continuous output

Front Console


Power


USB port


Auxiliary receptacle


Footswitch receptacle


Hand control receptacle

Rear Console


Complies with CSA C22.2 No. 601.1, UL 60601-1


Emits RF radiation


Equipotential ground plug - connects to potential equalization conductor. The resulting medical electrical system shall follow all applicable IEC 60601-1 requirements.


Stryker Firewire - enables firewire connection with Stryker firewire devices (Crossfire, iSwitch, SDC3)


Fuse rating


Type BF Applied Part


Probe

Shaver


Alternating Current

RoHS 50 years

IPX1
Protection against vertically falling objects


Follow instructions for use


This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately.

Packaging/Labeling


Manufacturer


Date of manufacture

EC REP
Authorized representative in the European community


Consult instructions for use

SN	Serial Number	REF	Catalog number
CE 0197	Fulfills requirements of the European Medical Device Directive 93/42/EEC	NON STERILE	Non-Sterile
Made in USA	Made in USA		

Interface

Icon	Name/Term	Description
	OPEN MAIN MENU	Accesses the Main Menu
	CLOSE MAIN MENU	Closes the Main Menu
XF	CROSSFIRE	Indicates the Crossfire is attached
	FOOTSWITCH	Indicates the footswitch is attached
	HAND CONTROL	Indicates the hand control is attached
	AUXILIARY DEVICE	Indicates the auxiliary device is attached (currently there are no approved auxiliary devices for use)
	SHAVER	Indicates an approved resection shaver console is attached
	RF PROBE	Indicates an approved resection RF console is attached
—	OUTFLOW	Indicates the Outflow Cassette is inserted
DAY-USE	DAY-USE CASSETTE	Indicates the Day-Use Cassette is inserted
	UP	Scrolls up
	DOWN	Scrolls down
	FORWARD	Advances to the next screen
	BACK	Returns to the previous screen
	SHOULDER JOINT	Selects the shoulder joint
	KNEE JOINT	Selects the knee joint
	HIP JOINT	Selects the hip joint
	SMALL JOINT	Selects the small joint
	HARDWARE COMBINATION SELECTION	Hardware combination selection (3 and 4 are only available if the hip joint is selected)

Icon	Name/Term	Description
	PRESSURE	Displays the current pressure setting
	FLOW/SUCTION	Displays the current flow/suction setting
	START/STOP	Starts/stops the pump
	IN PROGRESS	Indicates the pump is operating
	HOT SWAP	Toggles between hardware combination selections
	WASH FUNCTION	Increases the set pressure and flow limit by a user-specified percentage over a user-specified duration (for Inflow-only mode)
		Increases the set pressure and suction by a user-specified percentage over a user-specified duration (for Inflow/Outflow mode)
	DRAIN FUNCTION	Removes excess fluid from the joint at the end of a case (Outflow mode only)
	HOME	Retuns to the user preference file selection screen
	DELETE	Deletes a file
	CANCEL	Rejects an action
	CONFIRM	Accepts an action
	HELP	Accesses task-oriented help related to screen and button functionality
	WASH MENU	Navigates to the Wash menu to adjust the Wash and Clear function settings
	CLEAR FUNCTION	Increases the flow limit by a user-specified percentage over a user-specified duration (for Inflow-only mode)
		Increases the suction by a user-specified percentage over a user-specified duration (for Inflow/Outflow mode)
	RESECTION INTEGRATION	Navigates to resection integration settings menu
	RF PROBE	Selects an approved resection RF console
	SHAVER	Selects an approved resection shaver console
	CROSSFIRE	Selects the Stryker Crossfire console
	APPROVED RESECTION CONSOLE	Selects an approved resection console
	NONE	Indicates no RF/shaver console is selected
	FOOTSWITCH/FORMULA SHAVER OPTIONS	Programs footswitch and hand control options for Crossflow, iSwitch, Crossfire, and Formula shaver

Icon	Name/Term	Description
	CROSSFLOW FOOTSWITCH	Programs the settings for the CrossFlow footswitch
	iSWITCH FOOTSWITCH	Programs the settings for the iSwitch footswitch
	CROSSFIRE FOOTSWITCH	Programs the settings for the Crossfire footswitch
	FORMULA SHAVER.	Programs the settings for the Formula Shaver
	USER PREFERENCE	Loads User Preference files
	USB UPLOAD	Uploads/saves user preference settings from/to USB drive
	RIGHT ARROW	Moves a file to the right screen
	LEFT ARROW	Moves a file to the left screen
	SEND PREFERENCE FILE TO CROSSFIRE	Sends a preference file to the Crossfire system
	SETTINGS	Navigates to the Settings screens
	GENERAL SETTINGS	Adjusts the volume, brightness, and language
	VOLUME	Adjusts the volume of pump
	BRIGHTNESS	Adjusts the monitor brightness
	SOFTWARE UPGRADE	Loads new software upgrades from a USB drive
	ACTUAL PRESSURE DISPLAY ICON SELECTION	Selects the Actual Pressure Display icon
	STRYKER SETTINGS	Password-protected settings, for Stryker use only
—	FLOW	The fluid entering and exiting the joint; keeps the joint space clear by removing loose tissue, debris, and fluid from the joint.
—	FLOW LIMIT	The maximum flow rate.
—	FLOW RATE	The speed at which fluid enters and exits the joint; measured as volume over time, or liters per minute (L/min).
—	PRIME	To remove air from the inflow tubing prior to pumping fluid through the tubing.
—	SUCTION	The force required to pull loose tissue, debris, and fluid from the joint.

DRAFT

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