DualWave Arthroscopy Pump

User's Guide

AR-6480

The *Arthrex DualWave Arthroscopy Pump User's Guide* provides safety operation information for all components of the Arthrex DualWave Arthroscopy Pump (Model AR-6480), including accessories. All operating personnel must read this *User's Guide* thoroughly prior to using this system and follow all safety warnings, cautions, and precautions.

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1.0 Read This First

1.1 Important Safety Information

W A R N I N G !

All fluid inflow devices, including gravity assist, may cause fluid extravasations into the surrounding tissues. This extravasation may be mild, moderate or severe. In severe cases, the resulting edema may result in a serious adverse patient event which may include compartment syndrome, nerve compromise or death. Undiagnosed capsular defects will exacerbate fluid extravasation conditions.

When utilizing any fluid management device, the patient (extremity and surrounding area) must be monitored closely by the surgical team for signs of excess fluid buildup. Fluid usage volumes should be monitored and compared to similar surgical procedures. With all arthroscopy pumps, correct set up and proper user operation is required. Always select the lowest possible pressures in order to achieve the required intra-articular distention. All alarms or alerts must be acknowledged and the appropriate troubleshooting procedure followed.

W A R N I N G !

FAILURE TO FOLLOW SET UP INSTRUCTIONS AND/OR CONTINUING TO USE THE PUMP WITHOUT RESOLVING AN ALARM CONDITION COULD RESULT IN A SERIOUS PATIENT ADVERSE EVENT.

Failure to adhere to the set up instructions and use of Arthrex certified tubing may result in inaccurate pressure sensing and monitoring by the device. It is imperative that the user is aware of the potential compromise in patient safety when an alarm on the pump is ignored or silenced incorrectly. NEVER ignore or silence alarms. Follow appropriate troubleshooting procedures and carefully monitor the patient. Only Arthrex certified tubing must be used.

W A R N I N G !

This device is only for use in normal arthroscopic purposes as described in the User's Guide, under the supervision of a trained and licensed physician.

DO NOT—under any conditions or for any reason—remove the cover of the AR-6480.

NOTE: Read this User's Guide thoroughly before operating the device and save it for future reference.

Users of this device are encouraged to contact their Arthrex representatives if they require a more comprehensive surgical technique.

1.2 Important Symbols and Conventions

It is imperative that the symbols and conventions listed below be clearly understood. The *DualWave Arthroscopy Pump User's Guide* identifies critical, important, and useful information using these symbols and conventions.

W A R N I N G !

The WARNING! is the most important safety symbol. It identifies **critical** information that must be followed precisely to avoid injury or death.

Safety Sign Follow Operating Instructions

Power Standby/On

Attention, Consult Accompanying Document

The CAUTION! symbol identifies methods and procedures that must be followed to avoid damaging the device or causing it to malfunction.

NOTE: ***This identifies information that can simplify the setup and operation of this device.***

Type BF Equipment

Electrical Hazard, Dangerous Voltages are Present. Never attempt to repair the equipment. Only Trained Service Personnel may remove the cover, or obtain access to system components.

Alternating Current

Protective Earth [Ground]

Equipotential [Equipment Potential]

WEEE [Waste Electronics and Electrical Equipment] Symbol. Regarding European Union End-of-Life of Product.

RX ONLY

Caution: Federal Law Restricts this device to sale by or on the order of a Physician.

Fragile

Keep Dry

This Side Up

Temperature Limits for Storage and Transport

[x] **Square brackets that enclose a letter, number or lower-case Roman numeral reference a callout on a line drawing. Section 2.2, Product Features, includes line drawings of all products associated with the AR-6480. Each line drawing has its own callout system to identify important elements of each product.**

1.3 Shipping, Unpacking and Warranty Information

Carefully unpack and inspect all components for shipping damage. Any damage could compromise patient safety and should be reported immediately to Arthrex or any authorized Arthrex distributor. Warranty could be voided if shipping or first-installation damage is not reported within 7 business days of receiving the device. Refer also to our General Terms of Business.

A 12 month warranty is provided to the first purchaser for any defects or failure of the medical devices. All defective products will be repaired or replaced at the discretion of Arthrex at no charge. The warranty does not cover damage caused by unlawful use or improper handling of a product.

Warranty is not valid if modifications are made to the product or repairs are completed outside of Arthrex or an authorized Arthrex distributor. Arthrex will answer any questions referring to the quality, reliability and/or shelf life of any product identified in this *User's Guide.*

2.0 Product Description

2.1 Product Description and Intended Use

The Arthrex AR-6480 DualWave Arthroscopy Pump is a system that maintains constant, non-pulsed control of intra-articular rinsing and distention pressure throughout all phases of an arthroscopic surgical procedure. The AR-6480 is intended to provide continuous pulse-free flow that reacts immediately to changes in the intra-articular pressure so that joint distention can be sustained even under high shaver extraction volumes or secondary outflow.

The AR-6480 includes:

- A universal medical-grade switching power supply that allows the pump to function automatically at voltage ranges found worldwide.
- An automatic universal shaver detect feature that allows the device to automatically switch from low cannula suction to high flow shaver suction on demand. Touch panel display for user inputs.
- A Lavage function to provide elevated pressure to stop bleeding and a Rinse function to clear joint spaces quickly.

The user-defined settings for inflow pressure and outflow rates are adjustable through controls located on the touch panel screen or on the remote control.

There are **four pump tubing options** for the AR-6480:

1. *Main Pump Tubing Set only*.
   This tubing, when used alone, must be replaced after each patient.
2. *Main Pump Tubing Set and Extension Tubing combination*.
   The Main Pump Tubing Set can be reused for an entire surgical day, while the Extension Tubing must be replaced after each patient.
3. *ReDeuce™ Pump Tubing and ReDeuce™ Patient Tubing combination*.
   The ReDeuce™ Pump Tubing can be reused for an entire surgical day. The ReDeuce™ Patient Tubing must be replaced after each surgical procedure. The ReDeuce system offers a higher flow rate than the Main Pump Tubing Set/Extension Tubing combination.
4. *Outflow Tubing*.
   When the Outflow tubing is attached to the AR-6480, the pump changes from an inflow-only to an inflow and outflow arthroscopy pump.

The optional *Y-Tubing* connects up to four irrigation bags and can be used with all AR-6480 pump tubing options.

The AR-6480 can be used as an inflow-only irrigation pump or, with the Outflow Tubing attached; it can be used as an inflow/outflow fluid management system.

2.2 Product Features

2.2.1 AR-6480 Console: Front View

Figure 1 uses a *numeric* callout system to identify the main elements of the console's front panel, which are listed and labeled in Table 1. These callouts are referenced throughout this *User's Guide*.

Figure 1 Front Panel of Console

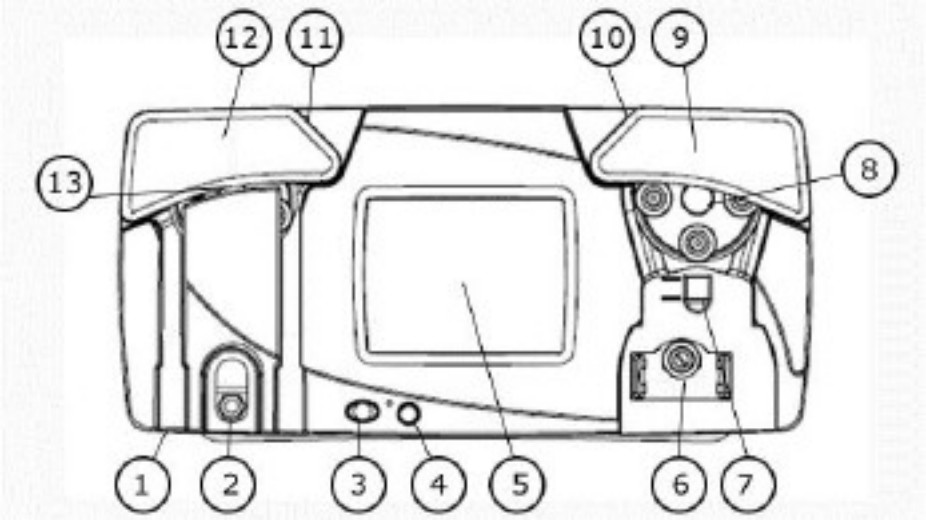

Table 1 Front Panel Elements

1.	Inflow tubing track
2.	Tubing sensor indicator LED. A steady green LED indicates that the tubing is connected properly. A flashing red LED indicates that the tubing is not connected or that it is connected incorrectly
3.	AC mains power switch
4.	Remote control and foot pedal connector
5.	Touch panel visual display (TPVD)
6.	Outflow suction tubing pinch roller
7.	Outflow tubing sensor
8.	Outflow roller assembly
9.	Outflow door
10.	Outflow door locking mechanism
11.	Inflow door locking mechanism
12.	Inflow door
13.	Inflow roller assembly

2.2.2 AR-6480 Console: Rear View

Figure 2 uses a *numeric* callout system to identify the main elements of the console's rear panel, which are listed and labeled in Table 2. These callouts are referenced throughout this *User's Guide*.

Figure 2 Rear Panel of Console

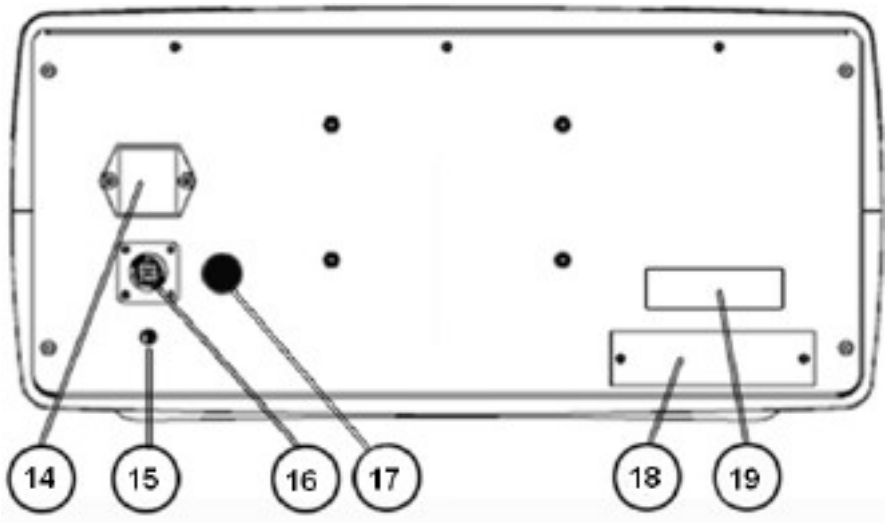

Table 2 Rear Panel Elements

14.	Input line and fuses
15.	Equipotential ground connector and symbol
16.	Shaver Detect power socket
17.	Shaver or Output Fuse
18.	Access panel (For Arthrex authorized use only)
19.	Date of manufacture and serial number label

2.2.3 AR-6480 Display Messages

The console's Touch Panel Visual Display (TPVD) [5] provides information about the status of the AR-6480 and the pressure and flow settings in real time. Table 3 describes each message and button when pump is in ready state.

Table 3 Touch Panel Visual Display Messages AND Iconography

Message	Cause	Explanation
Arthrex DualWave	Message appears when the AC mains power switch is activated.	Power on message display.
** Tubing Out **	Message appears when tubing is not plugged into the Tubing Sensor Coupler [2].	Check tubing installation.
** Door Open **	Message appears when the roller housing door [12] or [9] is open.	Roller housing door is not closed.
** Over Pressure **	Message appears when the sensed pressure exceeds over-pressure software limit of 300 mmHg.	Software overpressure condition.
Critical Failure	Message appears on the first line of the TPVD if one of three conditions is met: **Failure Condition 1: ** Power Failure **** Appears if the power supply self-test fails when the pump is turned on. **Failure Condition 2: ** OVP Detect Fail **** Appears if the hardware overpressure diagnostic test fails when the pump is turned on. **Failure Condition 3: ** Sensor Failure **** Appears if the pump detects a problem with the pressure sensors.	Critical failure, cannot continue operation.
** Power Failure **	Message appears if the power supply self-test fails when the pump is turned on.	Power supply test fails.
** OVP Detect Fail **	Message appears if the hardware overpressure diagnostic test fails when the pump is turned on.	Hardware overpressure diagnostic fails.
** Sensor Failure **	Message appears if the pump detects a problem with the pressure sensors.	Sensor failure.
** Pressure Fault **	Message appears when the pump is unable to reach a desired set pressure within a specific amount of time. This typically indicates an improperly installed tubing set or a split in the tube from continuous use.	Insufficient measured pressure.
Remote Control Icon	Icon appears when the remote is attached.	Remote connected.
Foot Pedal Icon	Icon appears when the foot pedal is attached.	Foot pedal connected,
+ Button	The TPVD displays the pressure reading until PRESSURE (+) button is pressed. Once pressed, the displayed pressure reading will change to the pressure setting. Each subsequent press of the pressure buttons will increase the pressure setting in increments of 5.	Pressure set increase,

Message	Cause	Explanation
- Button	The TPVD displays the pressure reading until PRESSURE (-) button is pressed. Once pressed, the displayed pressure reading will change to the pressure setting. Each subsequent press of the pressure buttons will decrease the pressure setting in increments of 5.	Pressure set decrease.
RUN Button	Button appears when the pump is stopped. Press this button to start the pump.	Motors on.
STOP Button	Button appears when the pump is running. Press this button to stop the pump.	Motors off.
LAVAGE Button	Button appears when the pump is in either inflow only or inflow/outflow mode. Press the button and the pump will increase pressure by a user defined amount and length of time.	Pressure increased for a set time.
RINSE Button	Button appears when the pump is in inflow/outflow mode. Press the button and the pump will increase outflow by a user defined amount and length of time.	Outflow rate and pressure increased for a set time.
BOOST Button	Button appears when the pump is in inflow only mode. Press the button and the user may define the pressure increase when the shaver is activated.	Pressure increased.
CANNULA Button	Button appears when the pump is in inflow/outflow mode. Press the button and the user may define the outflow rate.	Outflow rate change.
SHAVER Button	Button appears when the pump is in inflow/outflow mode. Press the button and the user may define the outflow rate of the shaver and pressure increase. In ASP mode the button is red.	Shaver suction change and pressure increase.
MENU Button	Button appears when the pump is stopped. Press the button and the pump will enter the set-up menu.	User setups displayed.

2.3 Foot Pedal Unit (AR-6483)

The AR-6480 DualWave Arthroscopy Pump can be remotely controlled with the optional Foot Pedal Unit (AR-6483). It provides a Lavage function and a Rinse function. See Figure 3 and Table 4 Foot Pedal Elements (AR-6483).

Do not disconnect the plug of the foot pedal unit by pulling on the cable. Remove the foot pedal unit plug by grasping and pulling on the body of the connector.

Figure 3 Foot Pedal Unit (AR-6483)

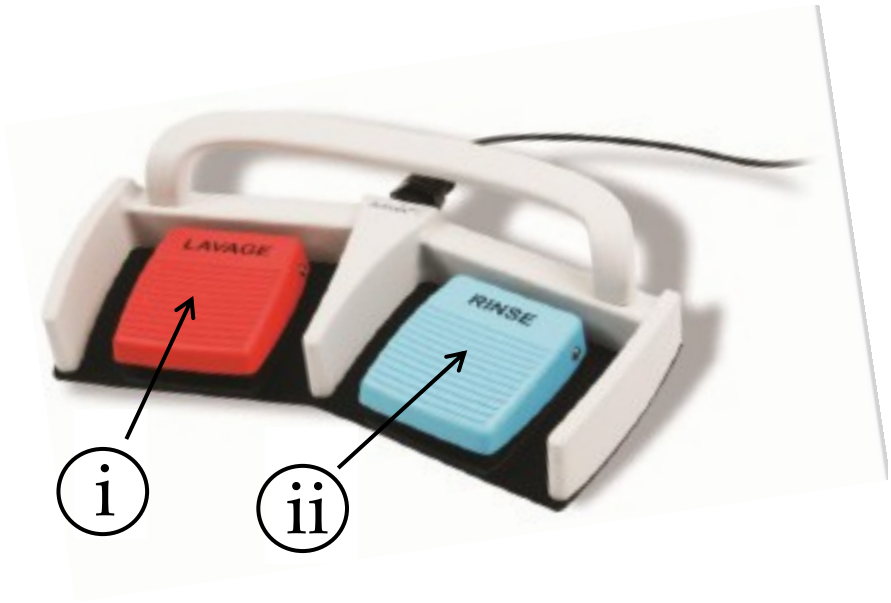

Table 4	Foot Pedal Elements (AR-6483)
i.	**LAVAGE.** Increases the pressure by a percentage and time selected by the user.
ii.	**RINSE.** Increases the outflow rate and pressure by a rate and time selected by the user. The Pump can also enter Alternative Suction Pathway (ASP) Mode if pressed while shaver is activated and the ASP mode is enabled via the Outflow Shaver menu.

2.4 Remote Control Unit (AR-6482)

The AR-6480 DualWave Arthroscopy Pump can be remotely controlled with the optional, autoclavable Remote Control Unit (AR-6482). It provides the ability to control pressure adjustments; a Lavage function; a Rinse function; shaver suction controls; and the ability to activate and deactivate the pump motor. The remote control unit's cable is 9.8 feet (3 meters) in length.

Do not disconnect the plug of the remote control unit by pulling on the cable. Remove the remote control unit plug by grasping and pulling on the body of the connector.

Figure uses an *uppercase Roman numeral* callout system to identify the main elements on the remote control, which are listed and labeled in Table 5. These callouts are referenced throughout this *User's Guide.*

Figure 4 Remote Control Unit (AR-6482)

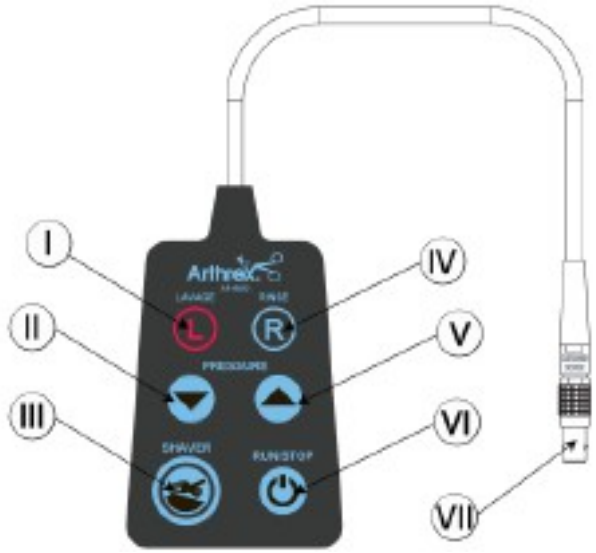

Table 5 Remote Control Unit Elements (AR-6482)

I.	**Lavage**. Increases the pressure by a percentage and time selected by the user.
II.	**Pressure Decrease**. Decreases target pressure by five mmHg.
III.	**Shaver Suction**. Cycles through shaver suction settings.
IV.	**Rinse**. Increases the outflow rate and pressure by a rate and time selected by the user. The Pump can also enter Alternative Suction Pathway (ASP) Mode if pressed while shaver is activated and the ASP mode is enabled via the Outflow Shaver menu.
V.	**Pressure Increase**. Increases target pressure by five mmHg.
VI.	**Run/Stop.**
VII.	**Lemo Connector**. Attaches to the corresponding plug on the front panel [4] of the AR-6480

2.5 Tubing

2.5.1 Tubing Configurations

Figure 5, Figure 6 ReDeuce Tubing Configuration, and Figure 7 Outflow Tubing Configuration show the tubing combinations supported by the AR-6480.

Figure 5 Main Pump Tubing Configuration

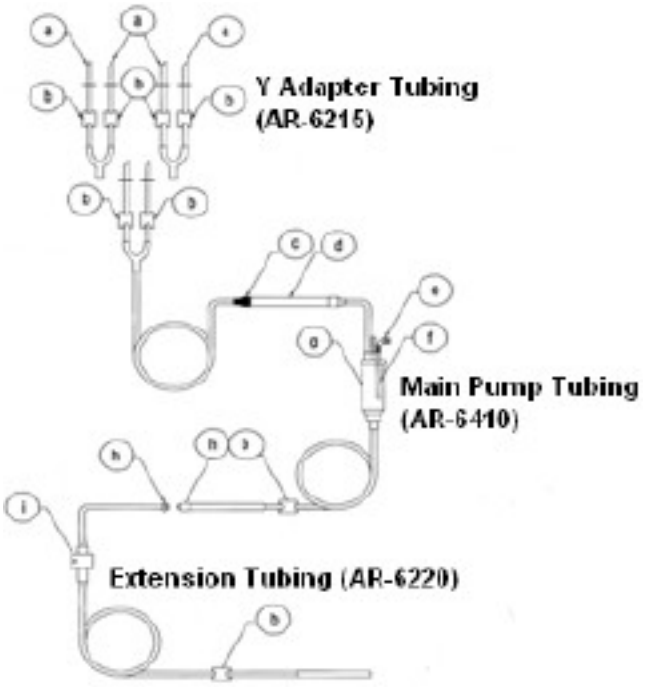

Table 6 Elements of the Main Pump Tubing Configuration

Element	Description	Tubing Set
a.	Bag spikes	Y-Adapter Tubing
b.	Tubing clamps	Y-Adapter Tubing Main Pump Tubing Extension Tubing
c.	Green connector	Main Pump Tubing
d.	Tubing boot	Main Pump Tubing
e.	Pressure line connector	Main Pump Tubing
f.	Neoprene tube for sensing pressure fluctuations	Main Pump Tubing
g.	Sensor chamber	Main Pump Tubing
h.	Connector fittings	Main Pump Tubing Extension Tubing

Element	Description	Tubing Set
l.	Backflow check valve	Extension Tubing

Figure 6 ReDeuce Tubing Configuration

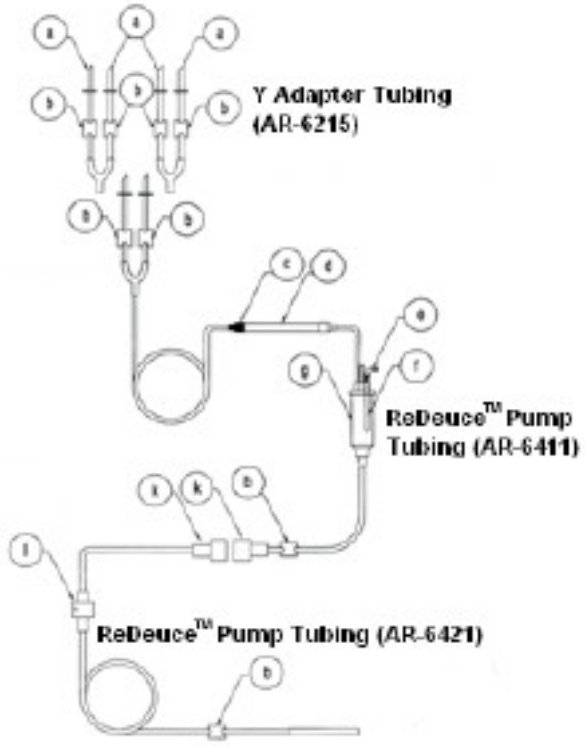

Table 7 Elements of the ReDeuce Tubing Configuration

Element	Description	Tubing Set
a.	Bag spikes	Y-Adapter Tubing
b.	Tubing clamps	Y-Adapter Tubing ReDeuce Pump Tubing ReDeuce Patient Tubing
c.	Green connector	ReDeuce Pump Tubing
d.	Tubing boot	ReDeuce Pump Tubing
e.	Pressure line connector	ReDeuce Pump Tubing
f.	Neoprene tube for sensing pressure fluctuations	ReDeuce Pump Tubing
g.	Sensor chamber	ReDeuce Pump Tubing
k.	High flow, dual lumen connectors	ReDeuce Pump Tubing ReDeuce Patient Tubing
l.	Backflow check valve	ReDeuce Patient Tubing

Figure 7 Outflow Tubing Configuration (AR-6430)

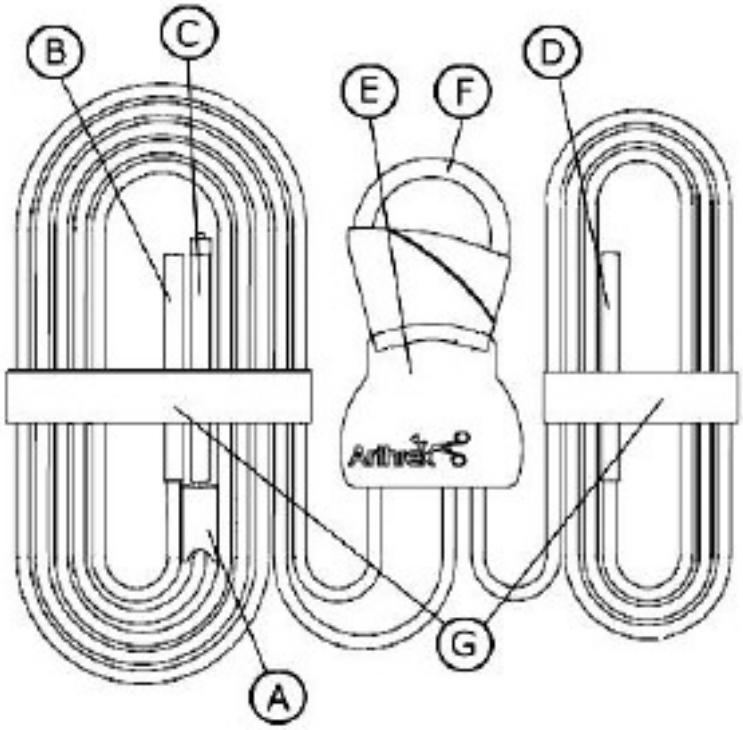

Table 8 Elements of the Outflow Tubing Configuration

Element	Description	Tubing Set
A.	Tubing clamp	Outflow
B.	Shaver attachment	Outflow
C.	Cannula attachment	Outflow
D.	Waste egress	Outflow
E.	Outflow Fixture	Outflow
F.	Tubing loop for Outflow roller	Outflow
G.	Paper retaining strap	Outflow

2.5.2 Tubing: Main Pump Tubing Set (AR-6410)

The Main Pump Tubing Set offers inflow and pressure measurement tubing. If used alone, the tubing must be *completely discarded* following each surgical procedure. The Main Pump Tubing is 13 feet (4.0 meters) in length.

NOTE: This User's Guide assumes that either the Main Pump Tubing is used alone or in combination with the Extension Tubing, described below.

For specific information about each tubing set, refer to the Directions for Use that are included with each set or contact your Arthrex representative.

2.5.3 Tubing: Extension Tubing System (AR-6220)

The unique Extension Tubing System allows use of the Main Pump Tubing Set for an entire surgical day. Users replace only the Extension Tubing Set after each individual surgery. The backflow check valve built into the Extension Tubing System prevents fluid backflow into the Main Pump Tubing. This maintains a closed, sterile fluid environment during tubing replacements. The Extension Tubing is 8.5 feet (2.6 meters) in length.

2.5.4 Tubing: ReDeuce Pump Tubing (AR-6411)

The ReDeuce Pump Tubing provides an alternative to complete replacement of the irrigation tubing after each patient. The backflow check valve of the ReDeuce Patient Tubing prevents contaminated fluid from reaching the ReDeuce Pump Tubing and permits its use for the entire surgical day. The ReDeuce Pump Tubing must be used with the ReDeuce Patient Tubing.

2.5.5 Tubing: ReDeuce Patient Tubing (AR-6421)

The ReDeuce Patient Tubing must be used in the first arthroscopic procedure of the surgical day and replaced after each surgical procedure. It is used in conjunction with the ReDeuce Pump Tubing. The backflow check valve of the ReDeuce Patient Tubing prevents contaminated fluid from reaching the ReDeuce Pump Tubing and permits its use for the entire surgical day.

2.5.6 Tubing: Y-Adapter Tubing (AR-6215)

The optional Y-Adapter Tubing can connect up to four irrigation bags. It can be used with the Main Pump Tubing or the ReDeuce Pump Tubing.

2.5.7 Tubing: Outflow Tubing (AR-6430)

The optional Outflow Tubing can be used with either the Main Pump Tubing or the ReDeuce Pump Tubing. It provides precisely controlled outflow from the shaver and a cannula (optional) to a waste container.

2.5.8 Tubing: Outflow with ReDeuce Patient Tubing (AR-6435)

A combination tube set with both Outflow tubing (AR-6430) and ReDeuce Patient Tubing (AR-6421) is packaged together in one tray. See sections 2.5.5 and 2.5.7 for more information about each tube set.

3.0 Technical Specifications

3.1.1 Console

Table 9	Control Unit (AR-6480) Specifications
Width	16.5 inches (42 cm)
Height	7.5 inches (19 cm)
Depth	14 inches (35.5 cm)
Weight	27 pounds (12.25 kg)
Maximum Flow rate	1500 ml/minute
Pressure	0 – 120 increments of 5 mmHg.
Overpressure control	300 mmHg
Pressure control	Continuous pressure checking
Protection	IP22
Main cable	10 A/250 V
Connector	CEE 7/7
Jack	IEC 320/C13
Power supply	100-240 V, 50/60 Hz, 4A
Fuse	T8.0A 250V
Cleaning	Surface cleaning with mild detergent
Sterilization	Surface disinfection with mild disinfectant

Table 10	Ambient conditions for operation
Temperature	50° to 104°F (10° to 40°C)
Relative Humidity	30% to 75%, non-condensing
Air pressure	10.15 PSI (700 hPa) to 15.37 PSI (1060 hPa)

Table 11	Ambient conditions for storage (in shipping packaging)
Temperature	-22° to 158°F (-30° to +70°C)
Relative Humidity	10% to 90%, non-condensing

3.1.2 Foot Pedal

Table 12	Foot Pedal Unit (AR-6483) Specifications
Width	13 inches (330 mm)
Height	7 inches (178 mm)
Depth	3 inches (76 mm)
Weight	6.1 lbs (2.766 kg)
Cable length	10 ft feet (3 m)
Cleaning	Surface cleaning with mild detergent
Sterilization	No

3.1.3 Remote Control

Table 13 Remote Control Unit (AR-6482) Specifications

Width	2.5 inches (63.5 mm)
Height	3.8 inches (95.3 mm)
Depth	0.9 inches (22.2 mm)
Weight	0.5 lbs. (0.23 kg)
Cable length	9.8 feet (3 m)
Cleaning	Surface cleaning with mild detergent
Sterilization	Autoclave

4.0 Setup

4.1 How to Set Up the Console

Users are encouraged to contact their Arthrex representative if they require a more comprehensive surgical technique.

NOTE: To minimize the effects of hydrostatic pressure differences on the actual joint pressure, both the pump and joint must be in the same horizontal plane.

4.2 AC Power Safety Considerations

The AR-6480 is powered by a medically rated universal AC input switching power supply. This power supply allows users to connect the console to any local AC mains outlet. Please use the appropriate plug and a reliable ground conductor.

Arthrex supplies separate power cords for the U.S. and Germany (CEE 7/7) with the AR-6480. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.

NOTE: Extension cords must meet local electrical standards.

The console is designed to meet power-saving guidelines. The console has an AC mains switch on the front panel [3]. When the AC mains switch is OFF, no electrical power is drawn by the console.

When the AC mains switch is ON, the console executes a series of self-diagnostic tests. Upon successful completion of these tests, the console displays on the TPVD [5] the name and model number, Arthrex DUALWAVE. If the tests discover a problem, an error message shows on the TPVD. Refer to Table 3 for a complete list of TPVD Messages.

In the event of an AC power interruption, the console can run continuously without fault for up to 10 milliseconds. If an AC power failure lasts longer than 10 milliseconds, the system will reset to default settings when AC power is restored.

W A R N I N G !

Do not have device in direct contact with patient if high-frequency devices are in use, or defibrillation of the patient is required.

4.3 Replacing the Fuses

Replace the 250v 6.3A mains fuse as follows:

1. Disconnect the device from the AC mains.
2. Open the fuse tray in the AC inlet, by pinching the tabs and pulling outwards.
3. Replace the fuses with 250V 6.3A Line Fuses as noted on the rear panel.
4. Push the fuse holder back into the AC inlet.
5. Ensure that fuse holder is fully seated and that the tabs snap back.

Always use fuses with the correct values to avoid allowing overcurrent to enter the system.

NOTE: The AR-6480 console incorporates a universal AC input power supply. A voltage selection switch is not required.

4.4 Electromagnetic Compatibility

This device has passed testing for EMI / RFI radiation and susceptibility and EMC compatibility. This device may cause interference to other devices in the near vicinity, if not set up and used as Arthrex instructs.

To determine if the AR-6480 is causing interference to other devices, power OFF the AC mains power switch [3] and then ON again.

Try to correct the interference by following one or more of these measures:

1. Reorient or relocate the receiving device.
2. Increase the separation between devices.
3. Connect the device to an outlet on a different circuit than the other device(s) are connected.
4. Consult the manufacturer or field service technician for the receiving device for guidance.

4.5 Basic Setup Procedure for the AR-6480

W A R N I N G !

To assure that correct pressure monitoring occurs, the pump and operative site MUST be in the same horizontal plane.

NOTE: Section 5.0, Operation, explains how to use the pump.

1. Place the AR-6480 on a flat, dry surface in the same horizontal plane as the operative site, such as the AR-6481 Arthrex Arthroscopy pump cart.

2. Connect the receiver end of the power cord for the AR-6480 into the AC socket [14] and the plug end to the facility AC mains supply.
3. Connect the shaver power cord (If shaver detection is desired, otherwise skip to step 5).

NOTE: For more on shaver detection, see 4.6 Shaver Detection.

4. Power on the shaver system.
5. Turn on the AR-6480 [3].
6. Verify the status of the AR-6480 displayed in the TPVD [5].
7. Connect the tubing in accordance with Section 4.7 or 4.8
8. Close the roller housing doors.
9. Attach the Remote Control Unit or Foot Pedal Unit, if applicable.
10. Refer to Section 5.0, Operation, for specific information on how to operate the AR-6480, including pressure and flow settings.
11. Press the Run/Stop button [Table 3] to activate the pump motor.

4.6 Shaver Detection

The AR-6480 detects when a shaver handpiece has been activated. The shaver detection feature operates differently, depending on if an AR-6430 Outflow Tube Set is installed on the DualWave.

The Shaver detection feature depends on the differential of current draw from the shaver system when it is powered on in a static state and when the shaver handpiece is activated.

For correct operation of Shaver Detect:

1. Insure Shaver Detect power cord is properly connected between the Shaver console and the DualWave.
2. Attach shaver handpiece and foot pedal (if used).
3. Turn on Shaver Console.
4. After Shaver Console sequence, turn on DualWave.

NOTE: Shaver detect feature will function as described in 4.6.1 – 4.6.2.

4.6.1 Shaver Detect, Inflow only

During inflow only (No outflow tube set) when the shaver is activated the DualWave activates BOOST mode for increased pressure to compensate for the loss of distention from the vacuum used with shaving device.

The pressure will automatically change to the preset BOOST values, and can be noted on the TPVD. The BOOST button will change to a dark blue color when the shaver is activated.

If the LAVAGE mode is ON prior to the shaver activation, the LAVAGE mode will be overridden except when LAVAGE mode causes a larger pressure increase.

4.6.2 Shaver Detect, Inflow/Outflow

During Inflow/ Outflow operation (Outflow tube set present), the DualWave responds to shaver activation by closing the cannula suction tube and opening the shaver suction tube for fluid egress. The level of suction will automatically change to either the preset shaver suction value, or to the user defined level.

If LAVAGE mode or RINSE mode are activated during or prior to shaver being, both modes will be overridden except when LAVAGE mode causes a larger pressure increase.

When the shaver is deactivated, the DualWave automatically closes the shaver suction tube, opens the cannula suction tube, and reverts to the preset outflow rate.

4.6.3 Adjusting the Shaver Detect

Users can adjust the Shaver Detect function for optimal interfacing performance. To change the settings press these buttons in this sequence:
MENU → DEFAULTS → SHAVER. The screen displays and allows changes to the settings for Shaver Suction and Shaver Detect.

There are four Shaver Detect Presets that offer various levels of sensitivity. The user may select from the four presets preloaded into the DualWave or adjust each preset according to individual need. This can be done by pressing the EDIT button after a preset has been selected.

There are three settings inside each preset that are changeable by the user:

1. THRESHOLD is the level of sensitivity that the DualWave uses to detects the incoming signal from the Shaver Console. This ranges from 1 to 100.
2. DELAY controls the amount of time the Shaver Detect Circuit examines the incoming signal from the Shaver Console before it activates the pinch roller mechanism. This ranges from 0 - 10 (1/10ths of a second).
3. DRIFT TRACKER controls whether or not the DualWave will constantly adjust the stored shaver current baseline reading. This can be turned on or off.

Once the necessary adjustments have been made, press the DONE button to save the changes to the selected preset.

Note to User:

- Select the highest THRESHOLD that will allow detection of the shaver when used at typical RPMs.
- Increase the DELAY setting to filter out noisy electrical conditions.
- All four presets can be reset by pressing the RESET DEFAULTS button on the MENU screen.

- The Shave Console must be completely powered up before powering on the pump.
- A new baseline is captured when pressing the RUN button which characterizes a NOT ACTIVATED condition. The screen will display a message reading, "ACQUIRING SHAVER BASELINE". During the baseline capture, do not activate a shaver.

Cautions to User:

- As the THRESHOLD value decreases, so does the DualWave's ability to prevent false detections of shaver activation. This condition makes the DualWave behave like the shaver handpiece is activated when it is not. This is characterized by sporadic movement of the pinch roller between the Shaver and Cannula tube ends. Conversely, as the THRESHOLD value increases, so does the likelihood of the DualWave not recognizing shaver activation. This can result in failure of the DualWave to provide for aspiration through the shaver blade and result in retention of heat within the blade.
- As the DELAY values decreases the DualWave will have less time to analyze the information received through the shaver detect circuit. This action can result in a false detection. Increasing the DELAY value should alleviate this condition. As the DELAY value increases, the accuracy of the determination of the shaver handpiece state will improve, but at the highest levels, the DELAY time may result in a perceived lag before the DualWave responds to the shaver activation.
- The shaver detect function of the DualWave has been verified to function properly with the Arthrex Adapteur II shaver console. It is the responsibility of the user facility to evaluate 3rd party shaver consoles to determine the correct operating parameters and any potential hazards of utilizing the DualWave with an alternate shaver console.

4.7 How to Set Up the Pump Tubing

NOTE: These instructions describe the procedure to set up the Main Pump Tubing or the ReDeuce Pump Tubing.

1. Remove the orange cap from the Pump Tubing and insert the Pressure Line Connector [e] of the Pump Tubing into the Tubing Sensor Coupler [2]. **This step must be completed first to ensure accurate pressure measurements**.
2. Open the inflow door completely. Allow the door to rest against the stop. The roller mechanism is now exposed.
3. Place the green-collared section of the Pump Tubing [c] into the Inflow Tubing Track [1] indicated by the green dot.

4. Guide the tubing boot [d] over the rollers and insert the output side of the tubing boot into the Tubing OUT Guide.

NOTE: The Pump Tubing is connected properly when the green connector [c] on the Main Pump Tubing is aligned with the green dot [1] on the front panel of the console.

5. Close the inflow door.

NOTE: The inflow door locking device must be secure. If the door is not closed securely an internal safety switch prevents the AR-6480 from operating.

6. Puncture the fluid bags with the spikes on the tubing. If only one fluid bag is being used, seal the second fluid line by closing the clamp nearest the unused spike.

4.8 How to Set Up the Two-Piece Tubing System

*NOTE: These instructions describe the procedure to set up the **Extension Tubing or ReDeuce™ Patient Tubing**.*

W A R N I N G !

The Extension or Patient Tubing must be changed for each patient.

1. The surgical staff removes the sterile Extension or Patient Tubing from its sterile pack and hands the connector [h or k] for the Pump Tubing set to the circulating nurse.
2. The circulating nurse connects the two tubing systems together [h to h in Figure 5 or k to k in Figure 6].
3. **Attach the sterile connector cap (supplied with each Extension or Patient Tubing set) to the patient-end of the Pump Tubing**.

*NOTE: **Following each surgery, detach and discard the Extension or Patient Tubing Set**.*

W A R N I N G !

The sterile connector cap must be used to cover the Pump Tubing Set connector after each surgical procedure. This maintains sterility of the Pump Tubing and assures its safe operation throughout the entire surgical day.

4.9 How to Set Up the Outflow Tubing

1. Open outflow door completely.
2. Place looped tubing around the roller assembly.
3. Pull Outflow Fixture [E] down until it slides into the outflow tubing receiver.

4. If pump is on, the pump should now detect the tubing and change the pump setting to inflow and outflow controls.
5. Close the outflow door.

4.10 How to Change the Language Setting

The AR-6480 supports English, French, German, Italian, and Spanish. The default language is English. To change the language setting for TPVD messaging, follow these instructions.

1. Power ON the AC mains power switch [3] on the AR-6480.
2. Press the Menu button.
3. Press the Language button.
4. Select desired language.
5. Press ok. The language is now stored in memory.

4.11 How to Test the Power Supply Voltages

1. Performed automatically as a part of the power-up sequence.

4.12 Safe Setup and Performance

4.12.1 Abnormal Operation

The AR-6480 employs a dual-pressure sensor design. Microcontroller-based internal circuitry monitors the sensors, as well as other circuit parameters, to ensure that the pump remains within normal operating limits. In the event of a fault, the pump motor is automatically disabled and an error message is displayed on the TPVD [5]. See Table 3 for a complete list of TPVD messages and Section 11.0 for troubleshooting information.

NOTE: If abnormal console operation cannot be corrected, disinfect the pump, re-package in the original shipping materials, and return to Arthrex, accompanied by a brief description of the malfunction. Prior to shipment, it is necessary to obtain a Return Authorization Number from Arthrex.

4.12.2 Overpressure Sensing

The sensing circuitry in the AR-6480 measures the pressure of the fluid in the tubing. The overpressure alarm can be activated when the flow is abruptly interrupted or the joint is suddenly positioned in a way which reduces the joint capsule volume (e.g., bending the knee joint to the "Figure 4" position).

If an overpressure event occurs (300 mmHg), a warning message reading ***Over Pressure*** will flash on the TPVD and an audible alarm will sound. The pump motor is automatically disabled until the pressure returns to the set range.

To reduce the pressure in a joint, open an outflow and/or manipulate the joint to a stress-free position.

4.12.3 Roller Housing

The pump motor automatically deactivates when the roller housing door is opened. A locking mechanism prevents access to the rotating parts while the device is operating.

4.12.4 Tubing Sensor Coupler

The pump motor automatically deactivates when the tubing is disconnected from the pump. If the tubing is disconnected during a surgical procedure it must be replaced by new tubing. Do not reconnect the tubing to the pump as it could lead to unreliable pressure measurements.

W A R N I N G !

If the tubing is disconnected from the pump in the middle of a procedure it must be replaced. Do not attempt to reconnect the tubing to the pump as it could lead to unreliable pressure measurements.

5.0 Operation

Users of this device should contact their Arthrex representative if they require a more comprehensive surgical technique.

5.1 Initial Pressure Settings

W A R N I N G !

The safety and effectiveness of the AR-6480 is verified and documented; however, the AR-6480 must be used with an awareness of the risk of extra-articular edemas for patients with pathologically changed articular capsules and for procedures involving an opening of the capsule (e.g. lateral release).

Slight swellings have been observed and described in the literature in cases where roller pumps are used in arthroscopy. This build-up of fluid can lead to postoperative swellings and pathological changes in patients. It is of the utmost importance that the surgeon monitors both the system and the patient closely while the roller pump is in operation.

Always start with the lowest possible pressure to achieve the desired joint distention. Continue to increase distention pressure until a clear liquid medium is obtained.

After the DualWave power-up sequence has finalized, the user will be able to select from four preprogrammed pressure settings for the knee, shoulder, small joint, and hip joint spaces. Once the icon for the selected joint space has been pressed, the DualWave will display the appropriate controls and readings on the TPVD. The pressure presets can be adjusted by entering the MENU, then Defaults, then Presets. Selecting "done" will save the adjusted preset in memory until it is changed.

Table 14 specifies the initial pressure settings that are preprogrammed for surgery. The ideal intra-articular pressure depends on the indications for the arthroscopic procedure, bleeding tendency, and the possibility of ischemia

Table 14 Initial Pressure Settings

Knee arthroscopy	35
Shoulder arthroscopy	50
Small joint arthroscopy	40
Hip arthroscopy	45

All settings are based on the use of a high-flow sheath or secondary inflow portal (suprapatellar, etc.).

To obtain a clear fluid environment, slowly increase distention pressure beginning with the initial pressure settings in Table 14.

W A R N I N G !

The initial pressure settings are recommendations, it is always appropriate and prudent to use the lowest possible pressure setting to minimize extravasation and any other pressure related injury to the patient.

5.2 How to Operate the AR-6480 in INFLOW ONLY Mode

W A R N I N G !

The Extension or Patient Tubing must be replaced before each new surgical procedure.

1. After adjusting the required pressure using the Pressure Set buttons [Table 3, II or V], remove the cap from the patient end of the tubing.
2. Open all appropriate tubing clamps.
3. Activate the pump motor by pressing RUN [Table 3 or VI].
4. Fill the entire length of the tubing with fluid to remove any air bubbles.

NOTE: It is not necessary to remove the air within the Sensor Chamber [g] on the Pump Tubing Set.

5. After the air has been purged from the tubing, close the clamp at the patient end of the tubing. The rollers [13] should stop turning. This is a safety check to ensure that the sensor system is working properly.
   - If the rollers do not stop, ensure clamp is firmly closed.
   - If the rollers turn continuously, the connector fitting [e] may not be functioning properly. Replace the Pump Tubing.
6. Connect the tubing to the inflow cannula.

NOTE: ***A high-flow arthroscope sheath should be used for optimum flow when rinsing through the inflow cannula****.*

7. Open the clamp on the tubing to release the flow.
   Once the set pressure is reached, the pump will reduce flow to maintain the set pressure. When the pressure drops, the flow automatically increases until the set pressure is achieved. If the set pressure cannot be attained, (no fluid restriction at the end of distal end of tubing) flow will not exceed the user setting.
8. When the procedure is completed, close all clamps and disable the pump motor.

5.3 How to Operate the AR-6480 in INFLOW/OUTFLOW Mode

W A R N I N G !

The Extension or Patient Tubing must be replaced before each new surgical procedure.

1. Follow steps as outlined in 5.2.
2. Add Outflow tube set to AR-6480.
3. The sensor will detect that the outflow tubing has been added and change the controls and icons on the TPVD to signify INFLOW/OUTFLOW mode.
4. The waste tubing end should be attached to a waste bag or suction device/container.
5. The end of the tubing labeled SHAVER should be attached to the shaver suction port.
6. The end of the tubing labeled CANNULA can be attached to an outflow cannula, working cannula, or left unutilized.

NOTE: If the CANNULA tubing end is not used, leave unclamped.

5.4 How to Operate the AR-6480 in LAVAGE Mode

The AR-6480 pump has a LAVAGE function for haemostatic purposes. The LAVAGE mode is accessible in INFLOW ONLY and INFLOW/OUTFLOW MODE.

W A R N I N G !

User programmed "Pressure Set" values are increased by as much as 50% to a maximum of 120 mmHg during the LAVAGE function. Exercise caution to avoid injury to the patient.

1. Press the LAVAGE button [Table 3 or I] to enable this function. The LAVAGE button should turn color and begin a countdown. The pressure will be increased to the factory default of a 50% increase for 120 seconds or to the user defined parameters.
2. The LAVAGE mode will stop when the countdown reaches zero, or if the user presses the LAVAGE button a second time.

5.5 How to Operate the AR-6480 in RINSE Mode

The AR-6480 pump has a RINSE function for irrigation purposes. The RINSE MODE is only accessible in INFLOW/OUTFLOW MODE.

1. Press the RINSE button [Table 3 or IV] to enable this function. The RINSE button should turn color and begin a countdown. The Outflow will be increased to the factory default of a 300mL/min with a

pressure increase of 30% for 60 seconds or to the user defined parameters.

2. The RINSE mode will stop when the countdown reaches zero, or if the user presses the RINSE button a second time.

5.6 Alternative Suction Pathway (ASP) Mode

The AR-6480 pump has an ASP function for minimizing clogging issues. The ASP MODE is only accessible in INFLOW/OUTFLOW MODE. In ASP Mode changes the suction pathway from the shaver suction pathway to the cannula suction pathway at the shaver suction level.

1. Turn ON ASP MODE in OUTFLOW SHAVER default menu.
2. Press the RINSE button on the Remote control or Foot Pedal [iv] while the shaver is activated to enable this function. The Shaver button will turn Red. The suction pathway will change from the shaver suction pathway to the cannula suction pathway.
3. The ASP mode will stop when the shaver is deactivated or by exiting ASP mode when the user presses the RINSE button a second time on the Remote Control or Foot Pedal [IV] while the shaver is activated.

6.0 Cleaning and Disinfecting

6.1 Console (AR-6480)

The AR-6480 console is provided non-sterile and should not be sterilized.

The AR-6480 console can be cleaned/disinfected using a cloth and commercially available surfactants or surface disinfectants only. The AR-6480 must not be submersed in any liquid.

Always comply with the instructions issued by the manufacturer of the disinfectant.

NEVER use liquid to clean the remote control connector contacts. Remove dust regularly with dry compressed air.

6.2 Remote Control Unit (AR-6482)

The Remote Control Unit (AR-6482) is supplied **non-sterile**.

The Remote Control Unit can be autoclaved for sterilization.

See Section 7.0 for sterilization information.

The Remote Control Unit can be cleaned/disinfected using commercially available surfactants or surface disinfectants. Always comply with the instructions issued by the manufacturer of the surfactant or disinfectant. It is not designed to be submersed in Gluteraldehyde, Steris®, or Sterrad® disinfectants.

NEVER use liquid to clean the connector contacts of the remote control unit connector. Remove dust regularly with dry compressed air.

6.3 Footswitches Control Unit (AR-6483)

Clean the footswitch with an enzymatic cleaner without subsequent acid neutralization.

Rinse the footswitch thoroughly after cleaning.

After cleaning, disinfect the footswitch with a commercially available surface disinfectant.

Thoroughly rinse the footswitch under lukewarm water.

Always comply with the instructions issued by the manufacturer of the disinfectant.

NEVER allow the console receptacles to have any contact with liquids. If there is dust or moisture on the receptacles, remove with dry compressed air. ONLY dry connectors should be plugged into the console.

6.4 Tubing

W A R N I N G !

The Extension, Patient, and/or Outflow tubing must be replaced before each new surgical procedure.

The tubing is supplied pre-packaged **sterile** by EO sterilization. **Do not re-sterilize.**

Every Extension or Patient Tubing Set is supplied with a sterile connector cap for the Pump Tubing Set connection. Use this connector cap to cover the Pump Tubing Set connector after each surgical procedure to maintain sterility and assure safe use throughout the entire surgical day.

7.0 Sterilization

Sterilization capabilities, cleaning, disinfecting, handling, and storage of instrumentation are the responsibility of qualified facility and/or user personnel. Qualified personnel must still properly clean and disinfect the instruments prior to sterilization.

Reusable accessories that are provided non-sterile may be sterilized by one of the following methods:

Gravity displacement cycles:

- 270° F to 275° F (132° C – 135° C): exposure time 18 minutes
- 250° F (121° C): exposure time 60 minutes

Prevacuum cycle:

- 270° F – 275 °F (132° C – 135° C): 5 minutes

Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration being used. It is recommended that the user perform appropriate validation tests.

- Drying - It is recommended to use a dry-cycle of a minimum of 4 minutes.
- Cooling – Once removed from the sterilizer, the device must be adequately cooled.

⚠ **After sterilization in the autoclave, let the accessory device cool down slowly. NEVER use cold water to cool the handpieces. This will damage the electronic components and seals.**

⚠ **Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.**

W A R N I N G !

After autoclaving, the accessory devices are VERY HOT. Handle with care to avoid burns.

8.0 Transmissible Spongiform Encephalopathy (TSE)

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy (TSE) Agents.

The agents for transmission of Creutzfeldt-Jakob disease are believed to be resistant to normal processes of disinfection and sterilization. Therefore, the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk.

In general, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, take particular precautions when handling instruments that have been used on known, suspected, or at risk patients.

References:

ANSI/AAMI ST46: Good Hospital Practice: Steam sterilization and sterility assurance.

9.0 Maintenance

There is no recommended maintenance schedule. Follow instructions listed in Section 6.0 for cleaning the console and remote control units. If the AR-6480 should malfunction, contact an Arthrex representative or Arthrex Technical Support.

10.0 Technical Support

For assistance in using the products identified in this *User's Guide*, contact an Arthrex representative or call the **Arthrex Technical Support Hotline** at 1-888-420-9393, Monday through Friday from 9:00 AM to 5:00 PM EST

10.1 How to Display the Software Version

Technical Support may request the software version of the pump. Follow these instructions to display the software version.

1. Power On the AC mains power switch [3] on the AR-6480.
2. The software version is displayed on the TPVD during the power-up sequence.

10.2 Additional Technical Information

Contact your Arthrex representative if require more comprehensive technical information or consult the DualWave Service Guide. Information related to the Pressure Verification Procedure for the AR-6480 can be accessed at: www.Arthrex.com. or can be requested in writing from your Arthrex representative.

11.0 Troubleshooting

Contact Arthrex Technical Support immediately in the event of any damage or malfunction of the equipment. Attempt the remedies listed in Table 15, in the order in which they are presented.

Table 15 Common Problems and Remedies

Message	Cause
** Tubing Out **	1. Tubing sensor indicator not seated. 2. Ensure that the tubing pressure plug is seated completely. 3. Change tubing. 4. If failure remains, return to Arthrex for repair.
Console fails Self Diagnostic Test	1. Ensure no tubing is connected to the pump during power on sequence. 2. If failure remains, return to Arthrex for repair.
Console will not power up	1. Check AC mains power cord. 2. Try alternate power outlet. 3. Check AC mains' fuses. 4. If failure remains, return to Arthrex for repair.
Inadequate distention, liquid bloody or cloudy	1. Activate Lavage mode. 2. Increase pressure. 3. Decrease outflow. 4. If failure remains, return to Arthrex for repair.
Does not pump when activated	1. Check for error messages. 2. Open all tubing clamps and shut-off valves. 3. Ensure actual pressure is below target pressure. 4. Check if the tubing is pinched, kinked, or blocked. 5. If failure remains, return to Arthrex for repair.
** Door Open **	1. Roller Housing not secured – ensure locking lever is properly secured. 2. If failure remains, return to Arthrex for repair.
Inadequate pressure	1. Increase pressure. 2. Activate Lavage mode. 3. Reduce outflow. 4. 4. Use high-flow cannulas. 5. If failure remains, return to Arthrex for repair.
No (or inadequate) flow	1. Check for error messages. 2. Check that all tubing clamps are open. 3. Check the settings for flow and pressure. 4. Check if the tubing is pinched, kinked or blocked. 5. Check that tubing seats correctly over the rollers. 6. Verify use of high-flow cannulas. 7. If failure remains, return to Arthrex for repair.
** Overpressure **	1. Increase or open outflow. 2. Manipulate joint to stress-free position. 3. If failure remains, return to Arthrex for repair.

Message	Cause
** Pressure Fault **	1. Ensure adequate fluid supply. 2. Decrease outflow. 3. Check tubing for damaged and if it is pinched, kinked or blocked. 4. Check tubing for proper connections. 5. Replace tubing. 6. If failure remains, return to Arthrex for repair.
No Shaver Detect	1. Ensure Universal shaver cable is connected. 2. Turn On and Off DualWave while the shaver system is powered on. 3. Adjust the DELAY and/or THRESHOLD settings. 4. Isolate the power source. 5. If failure remains, return to Arthrex for repair.

11.1 Troubleshooting Interference with Other Devices

Try one or more of the following to correct interference:

- Reorient or relocate the receiving device.
- Increase the distance between devices.
- Connect the device to an outlet on a different circuit than the other device(s).
- Consult the manufacturer or field service technician for the receiving device for assistance.

12.0 Limited Warranty

For a period of one (1) year after delivery of the Equipment and subject to the terms hereof, Arthrex warrants the Equipment to be free from manufacturers' defects in material and craftsmanship under normal use and service. The Warranty does not apply to any Equipment that has been repaired, serviced or altered outside of the manufacturer's or Arthrex's facility or to Equipment that has been subjected to abuse, misuse, neglect, accident or negligence in use, storage or handling. Arthrex's obligation, and the Customer's sole and exclusive remedy, is limited to the replacement or repair of any Equipment which Arthrex's examination shall disclose, in its sole discretion, to be defective or inoperative, and will be conditioned upon Arthrex's receiving written notice of any alleged nonconformity or defect during the applicable warranty period and the return of defective products to Arthrex, F.O.B. Arthrex's facility. If Arthrex determines that any product or service is not defective or that Arthrex is not liable for the defect, the Customer will be notified; thereafter, Arthrex will repair or replace such product upon the Customer's written consent and at prevailing prices. Arthrex may, in its discretion, provide reasonable use of loaner Equipment while repair or replacement is underway. This warranty applies only to the original Customer and is not transferable except at the discretion of Arthrex. Repairs and replacements made under this warranty are not warranted beyond the remainder of the warranty period. ARTHREX'S LIABILITY SHALL BE LIMITED SOLELY, AT ARTHREX'S OPTION, TO REPAIR OR REPLACEMENT OF THE GOODS OR COMPONENT PARTS NOT MEETING THE QUALITY AND SPECIFICATIONS WARRANTED. THERE ARE NO WARRANTIES, IMPLIED OR STATUTORY (INCLUDING THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR INTENDED USE, NON-INFRINGEMENT, OR ARISING OUT OF A COURSE OF PERFORMANCE, DEALING OR TRADE USAGE) THAT EXTEND BEYOND THIS EXPRESS WARRANTY. IN THE EVENT THAT APPLICABLE LAW PREVENTS THE DISCLAIMER OF ANY IMPLIED WARRANTIES, THEN SUCH IMPLIED WARRANTIES SHALL BE LIMITED TO THE CONTENTS AND DURATION OF THIS EXPRESS WARRANTY.

13.0 Repair Policy

Contact Arthrex for a Return Authorization Number and instructions prior to returning the device.

14.0 Electromagnetic Emissions

Table 16 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The AR-6480 DualWave Arthroscopy Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-6480 DualWave Arthroscopy Pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1	The AR-6480 DualWave 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 with nearby electronic equipment.
RF emissions CISPR 11	Class A	The AR-6480 DualWave 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 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 17 Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-6480 DualWave Arthroscopy Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-6480 DualWave 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) IEC 61000-4-2	± 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 IEC 61000-4-4	± 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Surge IEC 61000-4-5	± 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 IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40% UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	95% Reduction (10ms) 60% Reduction (100ms) 30% Reduction (500ms) 95% Reduction (5s)	Mains power quality should be that of a typical commercial or hospital environment. If the AR-6480 DualWave Arthroscopy Pump requires continued operation during power mains interruptions, it is recommended that the AR-6480 DualWave Arthroscopy Pump be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Table 18 Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-6480 DualWave Arthroscopy Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-6480 DualWave Arthroscopy Pump 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	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the AR-8305 Synergy Resection System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17P^{1/2}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.17P^{1/2}$ 80 MHz to 800 MHz $d = 2.33P^{1/2}$ 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). Interference may occur in the vicinity of equipment marked with the following symbol: 

15.0 Contact Information

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Naples, FL 34108-1945 USA

Tel: +1 239-643-5553

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Toll-Free Technical Support: +1 888 420-9393,
Monday through Friday, 9:00 AM – 5:00 PM ET.

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15.1 Compliance Information

The DualWave Arthroscopy Pump (AR-6480) is designed and tested in accordance with:

EN 60601-1/A2:1995

UL 60601-1:2003

CAN/CSA-C22.2 No. 601.1-M90

According to 60601 this device is Type CF, Class 1, IP22 rating.

According to MDD93/42/EEC, Annex IX, Rule 11, this device is classified as a Class IIa device.