



Continuous Wave III Arthroscopy Pump

User's Guide

The *Arthrex Continuous Wave III Arthroscopy Pump User's Guide* provides important safety operation information for all components of the Arthrex Continuous Wave III Arthroscopy Pump (Model AR-6475), and accessories. All Operating Personnel should read this *User's Guide* thoroughly before using this system and follow all safety warnings, cautions, and precautions.

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AR-6475

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1.0 General Warnings and Safety Notices - Read This First

1.1 Important Safety and Conventions Information


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

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

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.

1. Use this device only for purposes described in the User's Guide, under the supervision of a trained and licensed physician.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. No modification of the console (AR-6475) or accessories are allowed.

8. Use this device only under the supervision of a trained and licensed physician. This device should not be used by untrained personnel or used for indications other than those described in this User's Guide.
9. **Do not** open or attempt to service this system, as this may void your warranty. There are no user-serviceable parts inside. Removing the cover may introduce an electric shock hazard by exposing you to dangerous high voltages or other risks. If the system malfunctions, return it for service immediately. 
10. To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAIN with protective earth ground.
11. **Do not** have device in direct contact with patient if high-frequency devices are in use, or if the patient requires defibrillation.
12. To assure that correct pressure monitoring occurs, the pump and operative site **MUST** be in the same horizontal plane.
13. **DO NOT** stack or place equipment adjacent to the AR-6475 console if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.
14. **Use only** Arthrex approved electronic accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Arthrex representative for a complete list of accessories. **DO NOT** modify any accessory. Failure to comply may result in patient and/or operating room staff injury.
15. This equipment is **NOT** suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen rich or nitrous oxide environment
16. Use only Arthrex approved tubing accessories. Other accessories may result in decreased pressure accuracy. Contact your Arthrex representative for a complete list of accessories. **DO NOT** modify any accessory. Failure to comply may result in patient and/or operating room staff injury.
17. The Extension or Patient Tubing must be changed for each patient.
18. 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.
19. If the tubing is disconnected from the pump it must be replaced. **DO NOT** attempt to reconnect the tubing to the pump, as it could lead to unreliable pressure measurements.

20. The safety and effectiveness of the AR-6475 is verified and documented; however, the AR-6475 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)
21. 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.
22. 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.
23. 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.
24. User programmed "Pressure Set" values are increased by as much as 50% to a maximum of 120 mmHg during the FLUSH function. Exercise caution to avoid injury to the patient.
25. The Extension or Patient tubing must be replaced before each new surgical procedure.
26. After autoclaving, the accessory devices are VERY HOT. Handle with care to avoid burns.









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

1. 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.
2. Only use replacement power cords that comply with medical grade standards, IEC 60320-1 Subclause 3.21, Detachable Power Supply Cords or electrical standards for the designated country where the AR-6475 is being used. Contact your Arthrex representative for further information.
3. Avoid positioning the console so that it is difficult to disconnect the coupler or plug from the supply main.
4. Connecting an extension cord to the AR-6475 may result in a reduced level of safety.
5. Always use fuses with the correct values to avoid allowing overcurrent to enter the system.
6. An incorrect fuse may increase the risk of electrical shock or fire hazard.

7. This device may cause interference to other devices in the near vicinity, if not set up and used as Arthrex instructs.
8. Do not attach the remote control during Self Test or the Programming Modes.
9. 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.
10. NEVER use liquid to clean the accessory device connector contacts. Remove dust regularly with dry compressed air.
11. Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.
12. Always comply with the instructions issued by the manufacturer of the the cleaning disinfectant regarding concentration, exposure times, temperature and material compatibility.
13. Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.
14. Refer to the Instructions for Use package insert for detailed remote control (DFU-0144) cleaning and sterilization instructions included with each remote control. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex Representative.
15. After sterilization in the autoclave, let the accessory device cool down slowly. NEVER use cold water to cool the remote control. This will damage the electronic components and seals.

1.2 Symbols Definition

| | | | |
|--|---|---------------------------|---|
| | Authorized Representative in the European Community | R_x ONLY | Caution: Federal Law Restricts this device to sale by or on the order of a Physician. |
| | On / Off (push-push) | | Type BF Equipment |
| | Precaution of Warning Notice | | Fragile |
| | Keep Dry | | This Side Up |
| | 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. | | Temperature Limits for Storage and Transport |
| | Alternating Current | | Pressure Limits for Storage and Transport |
| | Fuse | | Humidity Limits for Storage and Transport |
| | Equipotential [Equipment Potential] | | Protective Earth Ground [Functional] |
| | WEEE [Waste Electronics and Electrical Equipment] Symbol. Regarding European Union End-of-Life of Product. | | RF Symbol. Non-ionizing Electromagnetic Radiation |

| | | | |
|---|----------------------|--|--|
|  | Manufacturer |  | Date of Manufacture; year and month. |
|  | Provided Non Sterile |  | The product meets the essential requirements of Medical Device Directive 93/42/EWG |
| REF | Catalog number |  | Serial Number |
|  | Quantity | | |

[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-6475. 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-6475 Continuous Wave III 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-6475 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.

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 the 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.

The AR-6475 includes:

- A universal medical-grade switching power supply that allows the pump to function automatically at voltage ranges found worldwide.
- Improved displays that combine both vacuum fluorescent and dot matrix displays for high contrast and visibility.
- A reprogrammable microcontroller with upgradeable software that supports multilingual messaging.
- Membrane switch overlays for user inputs and easier cleaning.
- A FLUSH function for providing elevated pressure to stop bleeding and flow rate to clear joint spaces quickly.

The user-defined settings for pressure and flow are adjustable through controls located on the console front panel or on the remote control.

There are **three Applied Part pump tubing options** for the AR-6475:

1. *One piece tubing only.*
This tubing, when used alone, must be replaced after each patient.
2. *One piece tubing and Extension Tubing combination.*
The AR-6410 can be reused for an entire surgical day, while the AR-6220 must be replaced after each patient.
3. *Two piece tubing combination.*
The pump tubing can be reused for an entire surgical day. The patient tubing must be replaced after each surgical procedure.

The optional *Y-Tubing* connects up to four irrigation bags and can be used with all AR-6475 pump tubing options.

Optional Accessory:

- Remote Control

2.2 Product Features

2.2.1 AR-6475 Console: Front View

Figure 1 and Figure 2 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 AR-6475 CWIII Front Panel of Console

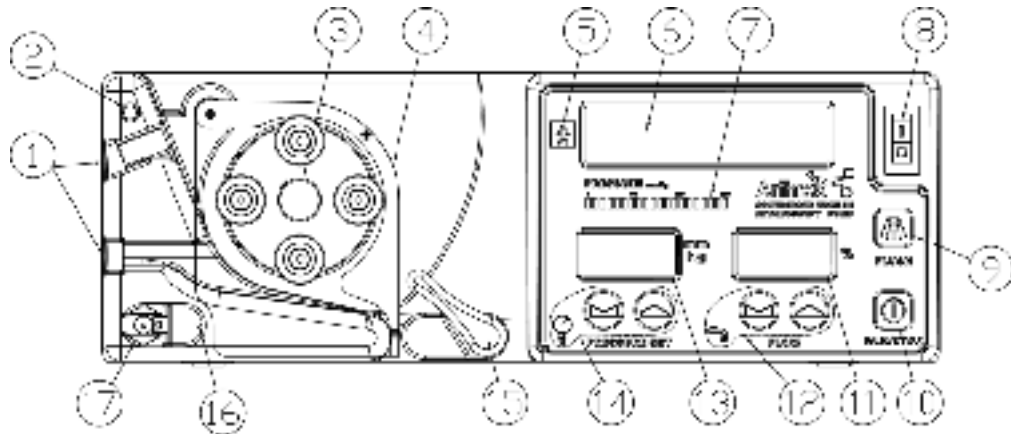


Figure 2 AR-6475 Synergy CWIII Front Panel of Console

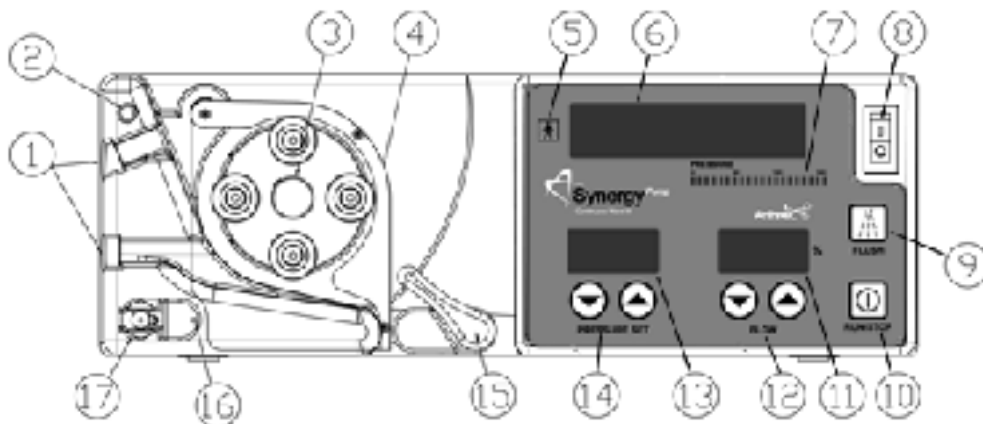


Table 1 Front Panel Elements

| | |
|----|---|
| 1 | Tubing IN Guide (beneath the Green dot)/ Tubing OUT Guide |
| 2 | Green dot (for orienting the Pump Tubing) |
| 3 | Roller assembly |
| 4 | Roller housing door |
| 5 | Type "BF" shock hazard symbol |
| 6 | Vacuum Fluorescent Display (VFD) |
| 7 | Measured pressure bar graph |
| 8 | AC mains power toggle switch |
| 9 | Activate/Deactivate FLUSH function button |
| 10 | Pump motor Enable/Disable button |

| | |
|----|---|
| 11 | Flow rate in percent |
| 12 | Flow buttons and symbol. Increase or decrease maximum fluid flow rate to the joint space by ten percent on a scale of ten to 100 percent. |
| 13 | Target distention pressure in mmHg |
| 14 | Pressure Set buttons and symbol. Increase or decrease target pressure in the joint space by one mmHg on a scale of zero to 120 mmHg. |
| 15 | Locking lever for roller housing door |
| 16 | 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 present or that it is connected incorrectly. |
| 17 | Tubing sensor coupler |

2.2.2 AR-6475 Console: Rear View

Figure 3 and Figure 4 uses an *upper case letter* 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 3 AR-6475 Rear Panel OF Console (Without Access Panel)

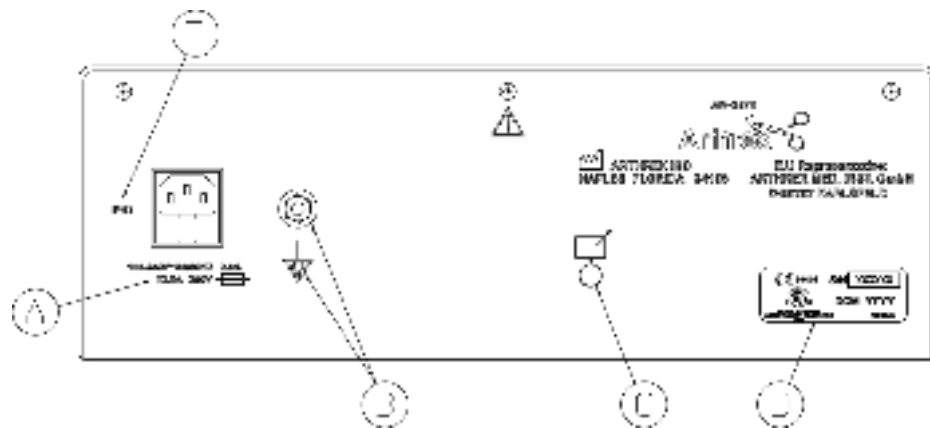


Figure 4 AR-6475 Rear Panel of Console (With Access Panel)

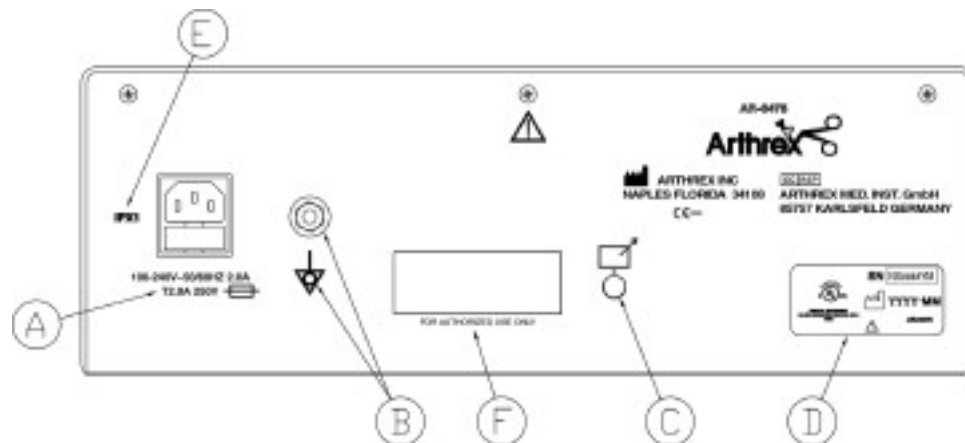


Table 2 Rear Panel Elements






| | |
|----------|---|
| A | AC mains power plug socket and ratings |
| B | Equipotential ground connector and symbol |
| C | AR-6476 Remote Control connector and symbol |
| D | Date of manufacture and serial number label |
| E | Water ingress protection rating (IPX1) |
| F | Access panel (on some units) |

2.2.3 AR-6475 Vacuum Fluorescent Display Messages

The console's Vacuum Fluorescent Display (VFD) [6] provides information about the status of the AR-6475 and the pressure and flow settings in real time. Table 3 describes each message and button when pump is in ready state.

Table 3 Vacuum Fluorescent Display Messages AND Iconography

| Message | Cause | Explanation |
|---------------------|--|--|
| Arthrex AR-6475 | Message displayed when the AC main power switch is activated. | Power on message display |
| * Check Tube * | Message appears when tubing is not plugged into the Tubing Sensor Coupler [17]. | Check tubing installation |
| * Door Not Closed * | Message appears when the roller housing door [4] 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 VFD 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. |

| Message | Cause | Explanation |
|-------------------|--|--------------------------|
| Remote | Message appears when the remote is plugged in and remains a secondary message. | Remote connected |
| Pressure Set + | Message appears when the PRESSURE SET  button is pressed. | Pressure set increase |
| Pressure Set - | Message appears when the PRESSURE SET  button is pressed. | Pressure set decrease |
| Flow Set + | Message appears when the FLOW  button is pressed. | Flow increase |
| Flow Set - | Message appears when the FLOW  button is pressed. | Flow decrease |
| RUN/STOP Button | Message appears when the RUN/STOP button is pressed. | Motors on / Motors off |
| Flush | Message appears when the  button is pressed for less than one second. | Flush feature enabled |
| Pump On | Message appears when the pump motor is on. | Motor on and running |
| Pump On/Flush | Message appears when the pump is in FLUSH mode. | Motor on and flushing |
| Pump Off | Message appears when the pump motor is off. | Motor off |
| Pump Paused | Message appears when the pump is on and the measured pressure exceeds the target pressure. | Motor on but paused |
| Pump Paused/Flush | Message appears when the pump is in FLUSH mode and the measured pressure exceeds the flush pressure. | Pump flushing but paused |
| Self Test V X.XX | Message appears prior to running a self-test. | Pump self-test |
| Power Supplies OK | Message appears after a successful power supply test. | Power supply test passed |

2.2.4 Measured Pressure Bar Graph

The console's Measured Pressure Bar Graph [7] uses twenty colored LEDs that illuminate to display the sensed pressure information in real time. Table 4 summarizes the segments, their colors, and the corresponding sensed pressure ranges.

Table 4 Measured Pressure ($\pm 5\%$) Readings in Bar Graph

| SEGMENTS | COLOR | MEASURED PRESSURE RANGE DISPLAYED |
|--------------|--------|-----------------------------------|
| 1-13 | Green | 8 mmHg to 98 mmHg |
| 14-16 | Yellow | 105 mmHg to 120 mmHg |
| 17-20 | Red | 128 mmHg to 150 mmHg |

2.3 Remote Control Unit (AR-6476)

The AR-6475 Continuous Wave III Arthroscopy Pump can be remotely controlled with the optional, autoclavable Remote Control Unit (AR-6476). It provides the ability to control pressure adjustments; flow adjustments; Flush; 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 5 uses a *lowercase 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 5 Remote Control Unit (AR-6476)

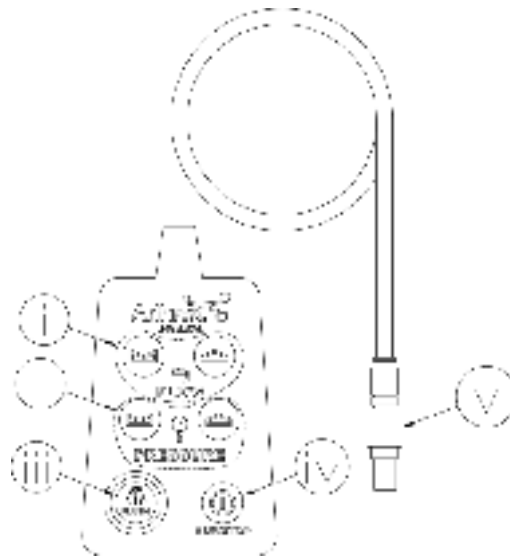


Table 5 Remote Control Unit Elements (AR-6476)

| | |
|------|--|
| i. | Flow buttons and symbol. Increase or decrease maximum fluid flow rate to the joint space by ten percent on a scale of ten to 100 percent. |
| ii. | Pressure Set buttons and symbol. Increase or decrease target pressure in the joint space by one mmHg on a scale of zero to 120 mmHg. |
| iii. | Activate/Deactivate FLUSH function. |
| iv. | Pump motor Enable/Disable switch. |
| v. | Lemo connector to attach to the corresponding plug on the rear panel [C] of the AR-6475. |

2.4 Tubing

2.4.1 Tubing Configurations

Figure 6 and Figure 7 show the tubing combinations supported by the AR-6475.

Figure 6 One Piece Tubing Configuration

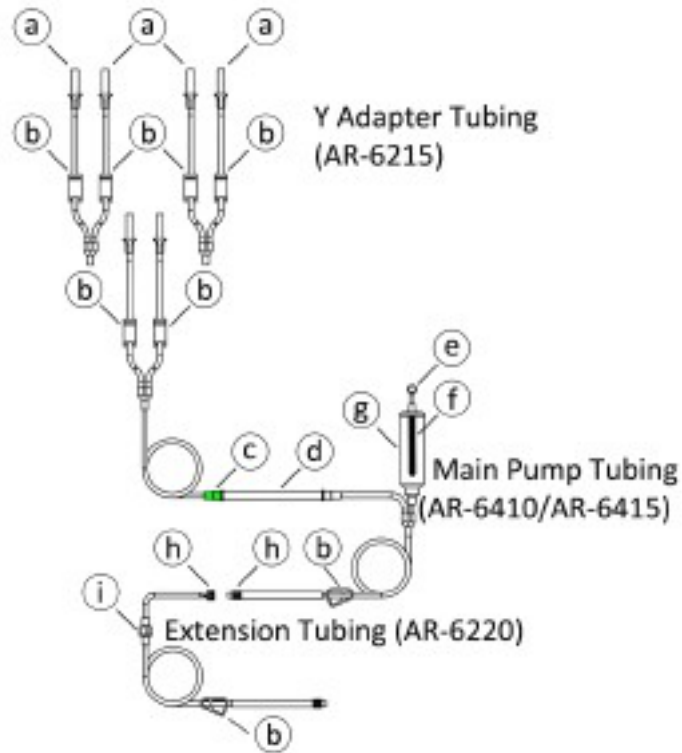


Table 6 Elements of the One Piece Tubing Configuration

| Element | Description | Tubing Set |
|---------|---|---------------------------------------|
| a. | Bag spikes | AR-6215 |
| b. | Tubing clamps | AR-6215 AR-6410/AR-6415 AR-6220 |
| c. | Green connector | AR-6410/AR-6415 |
| d. | Tubing boot | AR-6410/AR-6415 |
| e. | Pressure line connector | AR-6410/AR-6415 |
| f. | Neoprene tube for sensing pressure fluctuations | AR-6410/AR-6415 |
| g. | Sensor chamber | AR-6410/AR-6415 |
| h. | Connector fittings | AR-6410/AR-6415 AR-6220 |
| i. | Backflow check valve | AR-6220 |

Figure 7 Two Piece Tubing Configuration

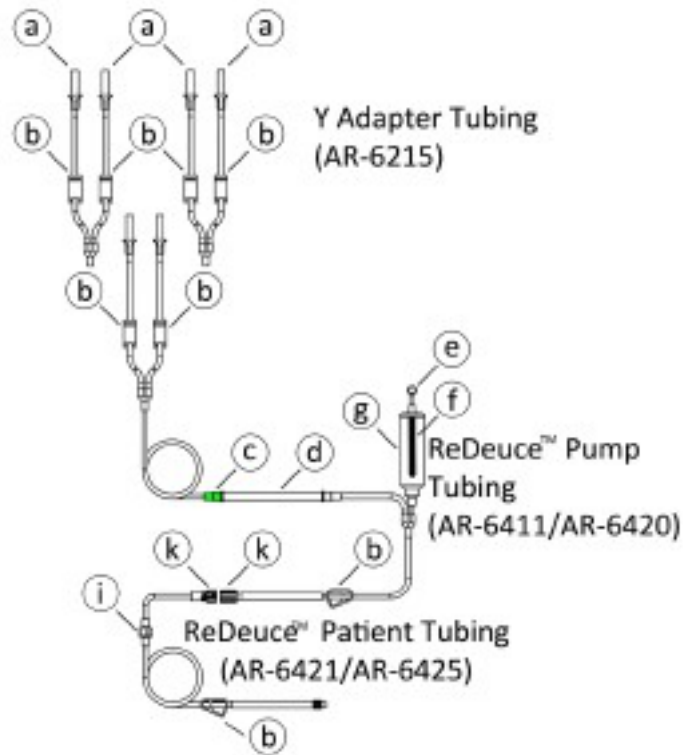


Table 7 Elements of the Two Piece Tubing Configuration

| Element | Description | Tubing Set |
|---------|---|---|
| a. | Bag spikes | AR-6215 |
| b. | Tubing clamps | AR-6215 AR-6411 or AR-6420 AR-6421 or AR-6425 |
| c. | Green connector | AR-6411 or AR-6420 |
| d. | Tubing boot | AR-6411 or AR-6420 |
| e. | Pressure line connector | AR-6411 or AR-6420 |
| f. | Neoprene tube for sensing pressure fluctuations | AR-6411 or AR-6420 |
| g. | Sensor chamber | AR-6411 or AR-6420 |
| k. | High flow, dual lumen connectors | AR-6411 or AR-6420 AR-6421 or AR-6425 |
| i. | Backflow check valve | AR-6421 or AR-6425 |

2.4.2 **Main Pump Tubing Set (AR-6410: Region A)**

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 pump tubing is 13 feet (4.0 meters) in length.

NOTE: *This User's Guide assumes that the AR-6410 is used alone or in combination with the AR-6220, described below. For specific information about each tube set, refer to the Directions for Use that are included with each set or contact your Arthrex representative.*

2.4.3 **Extension Tubing System (AR-6220: Region A)**

The *Extension Tubing System* is intended to be used in conjunction with the *Main Pump Tubing Set* (AR-6410) to allow the *Main Pump Tubing Set* to be used for an entire surgical day, while only replacing the *Extension Tubing System* after each individual surgery. The *Extension tubing* is 8 feet (2.4 meters) in length.

2.4.4 **ReDeuce™ Pump Tubing Set (AR-6411: Region A)**

The *ReDeuce Pump Tubing Set* is intended to be used in conjunction with the *ReDeuce Patient Tubing Set* (AR-6421) to offer inflow and pressure measurement tubing. It is not intended to be used stand-alone. The *ReDeuce Pump Tubing Set* may be used for an entire surgical day, unless sterility is compromised in any way. From the pump the tubing is 1.7 feet (0.5 meters) in length.

2.4.5 **ReDeuce Patient Tubing (AR-6421: Region A)**

The *ReDeuce Patient Tubing* is intended to be used in conjunction with the *ReDeuce Pump Tubing Set* to allow the use of the *ReDeuce Pump Tubing Set* for an entire surgical day, while replacing only the *ReDeuce Patient Tubing* after each individual surgery. The backflow check valve built into the *ReDeuce Patient Tubing Set* prevents contaminated fluid from back-flowing into the *ReDeuce Pump Tubing Set*, maintaining a closed sterile fluid environment during tubing replacements. The patient tubing is 8 feet (2.4 meters) in length.

2.4.6 **One Piece Tubing Set System (AR-6415/AR-6415CL: Region B)**

The *One Piece Tubing System* offers inflow and pressure measurement tubing. The *One Piece Tubing System* is intended to be used for ONLY one procedure and must be replaced after each patient.

The only difference between the AR-6415 and the AR-6415CL model is that the bag spikes on the "CL" model are CareLock spikes which are used specifically with Fresenius fluid bags.

2.4.7 **Main Pump Tubing Set (AR-6420/AR-6420CL: Region B)**

The *Main Pump Tubing Set* is intended to be used in conjunction with the *Patient Extension Tubing System* (AR-6425) to offer inflow and pressure measurement tubing. It is not intended to be used stand-alone.

The *Main Pump Tubing Set* may be used for an entire surgical day when used in conjunction with the *Patient Extension Tubing System* (AR-6425), unless sterility is compromised in any way.

The only difference between the AR-6420 and the AR-6420CL model is that the bag spikes on the "CL" model are CareLock spikes which are used specifically with Fresenius fluid bags.

2.4.8 **Patient Extension Tubing System (AR-6425: Region B)**

The *Patient Extension Tubing System* is used in conjunction with the *Main Pump Tubing Set* (AR-6420/AR-6420CL) to allow the *Main Pump Tubing Set* to be used for an entire surgical day, while only replacing the *Patient Extension Tubing System* after each individual surgery. The *Patient Extension Tubing System* is intended to be used in conjunction with the *Main Pump Tubing Set* (AR-6420/AR-6420CL) to allow the use of the *Main Pump Tubing Set* for an entire surgical day, while replacing only the *Patient Extension Tubing System* after each individual surgery. The backflow check valve built into the *Patient Extension Tubing System* prevents contaminated fluid from back-flowing into the *Main Pump Tubing Set*, maintaining a closed sterile fluid environment during tubing replacements.


2.4.9 **Y-Adapter Tubing (AR-6215)**

The optional *Y-Adapter Tubing* is intended to be used with all the Arthrex tubing sets/system combinations to connect up to four irrigation bags).

For more details on which tubing configuration are available in each your area, contact your Arthrex representative.

NOTE: Refer to the *Instructions for Use* package insert for detailed tubing (DFU-0140/DFU-0140G) instructions included with each tubing set. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex Representative.

Table 8 Tubing Set Correlation and Comparisons

| Region A Tubing Set Part Number | Region A Tubing Set Description | Region B Tubing Set Part Number | Region B Tubing Set Description |
|---|---|---------------------------------------|---|
| AR-6410 | Main Pump Tubing Set (Can be used stand-alone or in conjunction with the AR-6220 Extension Tubing Set) | AR-6415 AR-6415CL * | One Piece Tubing System One Piece Tubing System with CareLock bag spikes (Used stand-alone) |
| AR-6220 | Extension Tubing Set (Can be used in conjunction with the AR-6410 Main Pump Tubing Set as an additional extension) | | |
| AR-6411 | ReDeuce Tubing Set (MUST be used with the AR-6421 ReDeuce Patient Tubing Set) | AR-6420 AR-6420CL * | Main Pump Tubing Set Main Pump Tubing Set with CareLock bag spikes (MUST be used with the AR-6425 Patient Extension Tubing Set) |
| AR-6421 | ReDeuce Patient Tubing (MUST be used with the AR-6411 ReDeuce Tubing Set) | AR-6425 | Patient Extension Tubing Set (MUST be used in conjunction with the AR-6420/AR-6420CL Main Pump Tubing Set) |
| AR-6215 Y-Tubing Adapter | | | |
| * CL = CareLock: Tubing spike used mainly for Fresenius fluid bags. | | |  |

3.0 Technical Specifications

3.1 Console

| Table 9 Control Unit (AR-6475) Specifications | |
|--|---|
| Width | 14.5 inches (36.5 cm) |
| Height | 5.0 inches (12.5 cm) |
| Depth | 12 inches (30 cm) |
| Weight | 18 pounds (8.2 kg) |
| Maximum Flow rate | 1500 ml/minute |
| Pressure | 10 – 120 mmHg increments of 5 mmHg. |
| Overpressure control | 300 mmHg |
| Pressure control | Continuous pressure checking |
| Protection | IPX1 |
| Main cable | 10 A/250 V |
| Connector | CEE 7/7 |
| Jack | IEC 320/C13 |
| Power supply | 100-240 V, 50/60 Hz, 6.5A |
| Mains Fuse | T2.0A 250V |
| Applied Part Type | BF |
| 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 |

3.2 Remote Control

| Table 12 Remote Control Unit (AR-6476) 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-6475 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 Europe CEE 7/7 with the AR-6475. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.



Only use replacement power cords that comply with medical grade standards, IEC 60320-1 Subclause 3.21, Detachable Power Supply Cords or electrical standards for the designated country where the AR-6475 is being used. Contact your Arthrex representative for further information.



Avoid positioning the console so that it is difficult to disconnect the coupler or plug from the supply main.

NOTE: Extension cords must meet local electrical standard. Extension cords are not recommended to be used with the AR-6475.



Connecting an extension cord to the AR-6475 may result in a reduced level of safety.

The console is designed to meet power-saving guidelines. The console has an AC mains switch on the front panel [8]. 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 VFD [6] the name and model number, Arthrex CONTINUOUS WAVE III. If the tests discover a problem, an error message shows on the VFD. Refer to Table 3 for a complete list of VFD 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 !

To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAIN with protective earth ground.

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

Main fuse replaced with T2.0A 250V as follows:

1. Disconnect the device from the AC mains.
2. Open the fuse tray in the AC inlet, by pulling on the tabs.
3. Replace the fuses with T2.0A 250V 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.



An incorrect fuse may increase the risk of electrical shock or fire hazard.

NOTE: The AR-6475 console incorporates a universal AC input power supply. A voltage selection switch is not required.

4.4 Electromagnetic Compatibility



This device may cause interference to other devices in the near vicinity, if not set up and used as Arthrex instructs.

AR-6475 has been designed to accept EMC from other devices within the limitations.

To determine if the AR-6475 is causing interference to other devices, power OFF the AC mains power switch [8] 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-6475

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-6475 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-6475 into the AC socket [A] and the plug end to the facility AC mains supply.
3. Turn on the AR-6475 [8].
4. Verify the status of the AR-6475 displayed in the VFD [6].
5. Connect the tubing in accordance with Section 4.6 or 4.7
6. Close the roller housing door and locking lever [4, 15].
7. Attach the Remote Control Unit, if applicable [v, C].
8. Refer to Section 5.0, Operation, for specific information on how to operate the AR-6475, including pressure and flow settings.
9. Press the Run/Stop  button [10 or vi] to activate the pump motor.

W A R N I N G !

DO NOT stack or place equipment adjacent to the AR-6475 console if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.



Do not attach remote control during Self Test or the Programming Modes.

W A R N I N G !

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

W A R N I N G !

This equipment is **NOT** suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen rich or nitrous oxide environment.

W A R N I N G !

Use only Arthrex approved tubing accessories. Other accessories may result in decreased pressure accuracy. Contact your Arthrex representative for a complete list of accessories. **DO NOT** modify any accessory. Failure to comply may result in patient and/or operating room staff injury.

4.6 How to Set Up Main Pump Tubing

NOTE: These instructions describe the procedure to set up the AR-6410, AR-6415, AR-6411 or AR-6420.

1. Remove the orange clip from the Pump Tubing and insert the Pressure Line Connector [e] of the Pump Tubing into the Tubing Sensor Coupler [17]. **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 Pump Tubing is aligned with the green dot [2] 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-6475 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.

4.7 How to Set Up the Two-Piece Tubing System

NOTE: *These instructions describe the procedure to set up the AR-6421, AR-6425 or AR-6220.*

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 6 or k to k in Figure 7].
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.



4.8 How to Change the Brightness of the VFD

The VFD supports four levels of brightness. The brightest setting is 1, which is the default. The dimmest setting is 4. To change the brightness of the VFD, follow these instructions:


4.8.1 Pumps without a Rear Access Panel

1. Power OFF the AC main power switch [8] on the AR-6475.
2. Press and hold—simultaneously—the PRESSURE SET  [14] and FLOW  [12] buttons while powering ON the AC main power switch [8]. The following message will appear on the console's VFD [6]:

Prog Mode: BRIGHTNESS 1


3. Press the FLOW  [12] or FLOW  buttons to cycle through the brightness settings. Repeat until the desired brightness setting appears on the console's VFD [6].





4. Press  [10] to set the brightness.
5. Power OFF [8] the AR-6475.

6. Power ON [8] the AR-6475. The new brightness setting is in use.


4.8.2 Pumps with a Rear Access Panel

1. Power OFF the AC main power switch [8] on the AR-6475.
2. Press and hold the PRESSURE SET  [14] button while powering ON the AC main power switch [8]. The following message will appear on the console's VFD [6]:

ADJUST INTENSITY

3. Press the FLOW  [12] or FLOW  buttons to cycle through the brightness settings. Repeat until the desired brightness setting appears on the console's VFD [6].





4. Press  [10] to set the brightness.
5. Power OFF [8] the AR-6475.
6. Power ON [8] the AR-6475. The new brightness setting is in use.

4.9 How to Change the *Language Setting*


The AR-6475 supports English, French, German, Italian, and Spanish. The default language is English. To change the language setting for VFD messaging, follow the instruction below:

4.9.1 Pumps without a Rear Access Panel



1. Power OFF the AC main power switch [8] on the AR-6475.
2. Press and hold—simultaneously—the PRESSURE SET  [14] and FLOW  [12] buttons while powering ON the AC main power switch [8]. The following message will appear on the console's VFD [6]:

PROG MODE: BRIGHTNESS I




3. Press and release the  button [10] to bypass the Brightness Adjustment Mode and switch to the Language Adjustment Mode. The following message will appear on the console's VFD [6]:

PROG MODE: LANGUAGE ENGLISH


4. Press the FLOW  [12] or FLOW  buttons to cycle through the language settings. Repeat until the desired language appears on the console's VFD [6].





5. Press  [10] to set the language.
6. Power OFF [8] the AR-6475.

7. Power ON [8] the AR-6475. The new language setting is in use.


4.9.2 Pumps with a Rear Access Panel

1. Power OFF the AC main power switch [8] on the AR-6475.
2. Press and hold the PRESSURE SET  [14] button while powering ON the AC main power switch [8]. The current language will appear on the console's VFD [6]:


ENGLISH

3. Press the FLOW  [12] or FLOW  buttons to cycle through the language settings. Repeat until the desired language appears on the console's VFD [6].



4. Press  [10] to set the language.
5. Power OFF [8] the AR-6475.
6. Power ON [8] the AR-6475. The new language setting is in use.

4.10 How to Test the Power Supply Voltages and VFD

1. Power OFF [8] the AR-6475.
2. Press and hold the FLOW  [12] button while powering ON the AC main power switch [8]. The following message will appear on the console's VFD[6]:

Self Test Vx.x

Vx.x is the version of the firmware self test.

The self test is comprised of two parts. The first test checks the VFD by illuminating all of the pixels and then displaying a series of digits. The VFD must be visually inspected to verify that all characters are legible and of the same brightness.

The second test verifies that the power supply voltages are within tolerance and that the hardware overpressure protection circuit is running as a backup to the software protection. The following message will appear on the console's VFD after successful completion of the tests:

Power Supplies OK

4.11 Safe Setup and Performance

4.11.1 Pressure Reading on the Display

The pump runs as an **open system** in nearly all applications. This means inflow and outflows are open (the outflow on the sheath or the outflow over the optical and working portals).

Under this system, the 50 mmHg shown on the display corresponds to the actual pressure in the joint. If there is a fall in pressure, the pump increases pressure up to 50 mmHg and then stops.

In contrast, a **closed system** has a 100% impermeable joint and no egress of water through the portals. For example, at a pressure measurement at the end of the applied part a dynamic pressure arises here which is increased by a factor of 2.2 (at a setting of 50 mmHg, the maximum is 110 mmHg). The pump stops when this value is reached.

| Joint | Pressure reading on display | Actual pressure in open systems | Theoretical maximum pressure in closed systems |
|---------------------|-----------------------------|---------------------------------|--|
| <i>Knee</i> | 35 – 60 mmHg | 35 – 60 mmHg | 77 – 132 mmHg |
| <i>Hip</i> | 35 – 60 mmHg | 35 – 60 mmHg | 77 – 132 mmHg |
| <i>Shoulder</i> | 60 – 80 mmHg | 60 – 80 mmHg | 132 – 176 mmHg |
| <i>Small joints</i> | 50 – 70 mmHg | 50 – 70 mmHg | 110 – 154 mmHg |
| <i>Overpressure</i> | 136 mmHg | 136 mmHg | 300 mmHg |

4.11.2 Abnormal Operation

The AR-6475 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 VFD [6]. See Table 3 for a complete list of VFD 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.*

4.11.3 Overpressure Sensing

The sensing circuitry in the AR-6475 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 VFD 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.

4.11.4 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.

4.11.5 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 it must be replaced. Do not attempt to reconnect the tubing to the pump as it could lead to unreliable pressure measurements.

4.12 Shutdown Procedure

The AR-6475 can be safely shut down at any time by powering down the console. All tubing accessories must be discarded as a biohazards waste.

5.0 Operation and Frequently Used Functions

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-6475 is verified and documented; however, the AR-6475 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 Continuous Wave III 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. Normally, pressure settings of 10 mmHg above the patient's diastolic pressure are adequate to control capillary bleeding.

The ideal intra-articular pressure depends on the indications for the arthroscopic procedure, bleeding tendency, and the possibility of ischemia.

Table 13 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 13.


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-6475 in *Normal* 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 [14 or ii], remove the cap from the patient end of the tubing.
2. Open all appropriate tubing clamps.
3. Activate the pump motor by pressing  [10 or iv].
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 [3] 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 pressure line connector [e] or sensor chamber [g] 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 [10].


5.3 How to Operate the AR-6475 in FLUSH Mode

The AR-6475 pump has a FLUSH function for hemostatic purposes.

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 and hold down the  button [9 or iii] for one second to enable this function. The following message will be displayed on the VFD [6]:

Pump On/Flush



2. Press and hold the  button for continuous FLUSH operation. The FLUSH function only operates while the button is pressed. When in FLUSH mode, the pump maximum flow rate increases to 100 % and the pressure  increases by 50% to a maximum of 120 mmHg. Release the  button [9 or iii] to disable this function and return to Normal Mode with the pre-FLUSH pressure and flow settings.

6.0 Cleaning and Disinfecting

6.1 Console (AR-6475)

The AR-6475 console is provided non-sterile and must not be sterilized.



The AR-6475 console can be cleaned/disinfected using a cloth and commercially available surfactants or surface disinfectants only. Use a commercially available cleaning disinfectant for surfaces. Alkaline agents with a pH value > 8 are to be avoided. The AR-6475 must not be submersed in any liquid.

Always place the Main Power Switch [8] to “Off (O), position” and disconnect the power before cleaning the AR-6475 console.



Always comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature and material compatibility.



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.



Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.

6.2 Remote Control Unit (AR-6476)



Refer to the Instructions for Use package insert for detailed remote control (DFU-0144) cleaning and sterilization instructions included with each remote control. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex Representative.

The Remote Control Unit (AR-6476) is supplied **non-sterile**.

The Remote Control Unit can be autoclaved for sterilization.



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 accessory device connector contacts. Remove dust regularly with dry compressed air



Do NOT clean the device with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device.

6.3 Tubing

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

W A R N I N G !

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

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.



Refer to the Instructions for Use package insert for detailed Remote Control (DFU-0144) cleaning and sterilization instructions included with each remote control. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex Representative.



After sterilization in the autoclave, let the accessory device cool down slowly. NEVER use cold water to cool the remote control. 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 ST79: Good Hospital Practice: Steam sterilization and sterility assurance.

9.0 Maintenance

Regular and proper maintenance of your Continuous Wave III Arthroscopy Pump is the best way to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the Continuous Wave III Arthroscopy Pump includes proper day-to-day operation, cleaning, and sterilization which are extremely important to ensure safe and efficient operation. It is important to visually inspect the tubing, remote control, cable and connectors before each use.

Your authorized Arthrex service department is the most knowledgeable about the Arthrex Continuous Wave III Arthroscopy Pump, tubing and remote control and will provide competent and efficient service. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the instruments or instrument failure.

9.1 Life Expectancy

The standard warranty for this product is twelve months.

9.2 Periodic Maintenance

The product should be inspected prior to and after each use to ensure that the remote control, cable, strain relief, overmold, or connector contacts are not damaged or worn. If it becomes necessary to return the remote control to Arthrex for service, please sterilize the remote control before shipping.

10.0 Technical Support

For assistance in using the products identified in this *User's Guide*, contact an Arthrex representative or contact the **Arthrex Technical Support Hotline** at 1-(888) 420-9393, Monday through Friday from 9:00 AM to 5:00 PM EST; at +49 8131 5957 803 or techsupport@arthrex.de from 8:00 AM to 5:00 PM CET.

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 [8] on the AR-6475.
2. The software version is displayed on the VFD [6] during the power-up sequence.

10.2 Additional Technical Information

Contact your Arthrex representative if you require more comprehensive technical information. Pressure Verification Procedure, Circuit diagrams, component part lists, descriptions, calibration instructions, or other information can accessed at: www.Arthrex.com or will be provided upon request by Arthrex APPROVED SERVICE PERSONNEL.

11.0 Troubleshooting

Refer to Table 14 for device troubleshooting if problems occur after cleaning, transporting or changing operating staff.

Table 14 Troubleshooting: Faults, their Causes and Solutions

| Message | Cause |
|--|--|
| * Critical Failure * | 1. Return to Arthrex for repair. |
| * Door Not Closed * | 1. Roller Housing not secured – ensure locking lever is properly secured. 2. 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. |
| * 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. |
| * Check Tube * | 1. If tubing sensor indicator's LED is red then tubing is not properly connected. 2. Ensure tubing sensor coupler [17] is open not seated. 3. Ensure that the tubing pressure line connector [e] is seated completely. 4. Change tubing. 5. 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. |
| 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. |
| Inadequate distention, liquid bloody or cloudy | 1. Increase pressure. 2. Activate Flush mode. 3. Reduce outflow. 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. |

If the problems persist, disinfect the Continuous Wave III Arthroscopy Pump and send in to Arthrex using the original packaging. Always send the corresponding console together with the tubing and remote control. Please enclose a brief explanation of the detected malfunction. Refer to Section 13.0 for more information.

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 End of Life, Environmental Directives

WEEE Directive [2002/96/EC] on Waste Electrical and Electronic Equipment



The Directive on Waste Electrical and Electronic Equipment obliges manufacturers, importers, and/or distributors of electronic equipment to provide for recycling of the electronic equipment at the end of its useful life.

Do not dispose of WEEE in unsorted municipal waste.

The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your medical endoscopic video equipment at the end of its useful life for recycling, please contact Arthrex Customer Service Department.

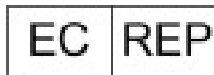




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