# DualWave™ Arthroscopy Pump

## *User's Guide*

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* for version 1.7 or higher thoroughly prior to using this system and follow all safety warnings, cautions, and precautions.

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# 1.0 General Warnings and Safety Notices - Read This First

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.

## 1.1 Important Safety Conventions

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

**W A R N I N G !**

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

1. 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.
2. **Failure** to follow the setup instructions and/or continuing to use the pump without resolving an alarm condition could result in a serious patient adverse event.
3. **Failure** to adhere to the setup 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 that patient safety may be compromised 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
4. This device is only for use in normal arthroscopic procedures as described in the User's Guide, 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.
5. 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 setup 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.
6. **No** modification of the console (AR-6480) or accessories is allowed.

**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 dangerously high voltages or other risks. If the system malfunctions, return it for servicing immediately.

7. To avoid the RISK of electric shock, this equipment must only be connected to a MAINS POWER SUPPLY with a protective earth terminal.
8. **Do not** have the device in direct contact with the patient if high-frequency devices are in use, or if the patient requires defibrillation.
9. To ensure that correct pressure monitoring occurs, the pump and operative site **MUST** be in the same horizontal plane.
10. **DO NOT** stack or place equipment adjacent to the AR-6480 console, if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.
11. **Use only** Arthrex approved 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 injury to the patient and/or operating room staff.
12. 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.
13. **Do not** use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide, oxygen, or endogenous gases. All oxygen connections must be leak free for the duration of the surgical procedure.
14. 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.
15. The extension, patient, and/or outflow tubing must be replaced before each new patient and/or procedure.
16. 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 ensures its safe operation throughout the entire surgical day.
17. 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.
18. 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).

19. 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.
20. 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.
21. 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.
22. 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.
23. After autoclaving, the accessory devices are VERY HOT. Handle with care to avoid burns.
24. Caution: Federal law restricts this device to sale by or on the order of a physician.
25. This device is intended to be used by a trained medical professional
26. Detailed instructions on the use and limitations of this device should be given to the patient.
27. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
28. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

**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 or foot pedal unit by pulling on the cable. Remove it 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-6480 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 mains power supply.

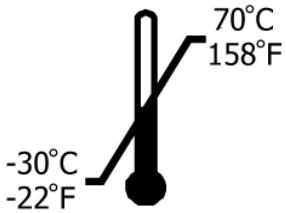
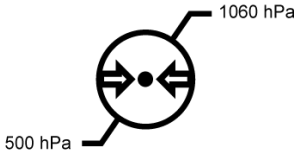
4. To prevent electrical shock do not use extension cords or two-prong/three-prong adaptors.
5. Always use fuses with the correct values to avoid allowing overcurrent to enter the system.
6. An incorrect fuse may increase the risk of electrical shock or fire hazard.
7. This device has passed testing for EMI / RFI radiation and susceptibility, and EMC compatibility. This device may cause interference with other devices in the near vicinity if not set up and used as instructed by Arthrex.
8. Do not attach the remote control or the foot pedal during the Self Test or Programming Modes.
9. NEVER use liquid to clean the accessory device connector contacts. Remove dust regularly using dry compressed air.
10. Liquid on the cable connector of the accessory device can damage the device. Before connecting the cable, ensure the receptacles are clean and dry.
11. Always comply with the instructions issued by the manufacturer of the cleaning disinfectant regarding concentration, exposure times, temperature, and material compatibility.
12. Never allow the console receptacles to come into contact with liquids. If there is dust or moisture on the receptacles, remove using dry compressed air. ONLY dry connectors should be plugged into the console.
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 (DFU-0144-XX) for detailed remote control 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. Refer to the Instructions for Use package insert (DFU-0140-XX) for detailed tubing cleaning and sterilization instructions included with each tube set. Additional copies of this insert can be obtained from the Arthrex website at www.arthrex.com, or by contacting your local Arthrex representative.
16. The foot pedal is NOT suitable to be cleaned and disinfected in a thermo washer disinfector.
17. 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.
18. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.

- **In CE accepting Countries:** Procedures carried out using these devices may be used on the general population.

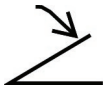
- **In CE accepting Countries:** The clinical benefits associated with the use of these devices outweigh the known clinical risks.
- **In CE accepting Countries:** There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

## 1.2 Symbols Definition

All of the symbols used on the labeling along with the title, description and standard designation number may be found on our website at **www.arthrex.com/symbolsglossary**.

| | | | |
|---|---|---|---|
|  | **Safety Sign**<br>**Follow operating instructions** | $R_x$ ONLY | **Caution: Federal law restricts this device to sale by or on the order of a physician.** |
|  | **On/Off (push-push)** |  | **Type CF Defibrillator Proof** |
|  | **Caution** |  | **Fragile, handle with care** |
|  | **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** |  | **Atmospheric pressure limitation** |
|  | **Fuse** |  | **Humidity limits for storage and transport** |

| | |
|---|---|
|  | **Equipotential [equipment potential]** |
|  | **Electrical waste** |
|  | **Manufacturer** |
|  | **Non sterile** |
| REF | **Catalog number** |
|  | **Quantity** |
|  | **Remote control connection** |
|  | **Do not use if package is damaged** |
| IP22 | **International protection marking** |
| **USB** | **Universal serial bus [for use ONLY with Arthrex approved thumb drive]** |

| | |
|---|---|
|  | **Protective earth terminal** |
|  | **RF symbol. Non-ionizing electromagnetic radiation** |
|  | **Date of manufacture; year and month.** |
| CE<br>2797 | **The product meets the essential requirements of Medical Device Directive 93/42/EWG** |
| SN | **Serial number** |
| EC REP | **Authorized representative in the European Community** |
|  | **Foot pedal connection** |
|  | **No user-serviceable parts inside**<br><br>**Electrical hazard** |
| **RS-232** | **Serial port [Arthrex integration]** |

[x] **Square brackets that enclose a letter, number, or Roman numeral reference a callout on a line drawing. Section 2.2, Product Features, includes drawings of 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. The warranty could be voided if shipping or first-installation damage is not reported within seven business days of receiving the device. Refer also to our General Terms of Business.

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.

The warranty is not valid if modifications are made to the product or repairs are carried out 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.

**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 setup 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 THE SETUP 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 setup 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 that patient safety may be compromised 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 procedures as described in the User's Guide, 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.

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. There is a 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 Applied Part pump tubing options** for the AR-6480:

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.
4. *Outflow tubing*.
   When the *Outflow Tubing Set* is attached to the AR-6480, the DualWave Arthroscopy Pump changes from an inflow-only pump to an inflow/outflow fluid management system.

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

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.

Other optional accessories:

- Remote control
- Foot pedal
- Shaver Detect cord
- Synergy integration cable

## 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**

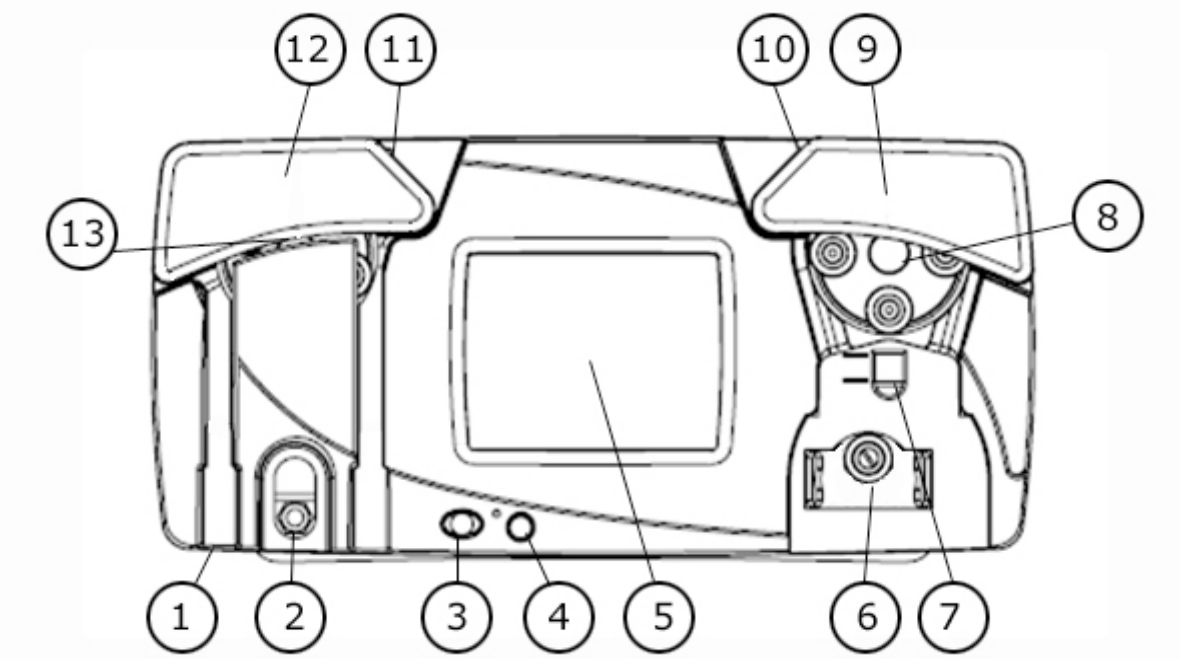



**Table 1 Front Panel Elements**

| | |
|---|---|
| 1. | Inflow tubing track |
| 2. | Tubing sensor coupler with 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 or foot pedal connector |
| 5. | Operator display |
| 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**

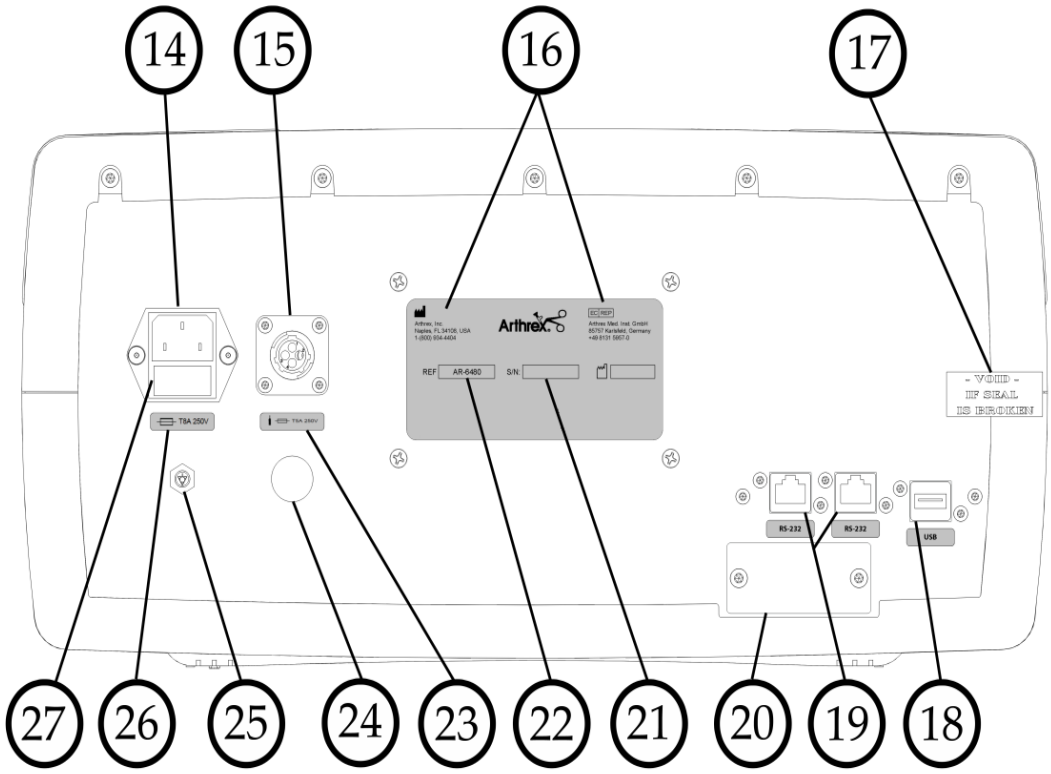



**Table 2 Rear Panel Elements**

| | |
|---|---|
| 14. | AC mains power input plug |
| 15. | Shaver Detect power socket |
| 16. | Address |
| 17. | Void seal sticker |
| 18. | USB port (For use **ONLY** with an Arthrex approved thumb drive) |
| 19. | Serial ports for Arthrex integration (refer to IFU 950-0052-00) |
| 20. | Access panel (for Arthrex authorized use only) |
| 21. | Serial number label |
| 22. | Model number label |
| 23. | Shaver or output fuse label |
| 24. | Shaver or output fuse |

| | |
|---|---|
| 25. | Equipotential ground connector and symbol |
| 26. | Main power input - Fuse label |
| 27. | Main power input - Fuse holder |

### 2.2.3 AR-6480 Operator Display Messages and Iconography

The console's operator display [5] provides information about the status of the AR-6480 modes, pressure, and flow settings in real time. Table 3 describes each message or button, cause and explanation when the pump is in the ready state.

**Table 3 AR-6480 Operator 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 [9] or [12] 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 operator display if one of three conditions is met:<br>**Failure Condition 1: ** Power Failure **** Appears if the power supply self-test fails when the pump is turned on.<br>**Failure Condition 2: ** OVP Detect Fail **** Appears if the hardware overpressure diagnostic test fails when the pump is turned on.<br>**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 improperly installed tubing or a split in the tube from continuous use. | Insufficient 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 operator display shows the pressure reading until the PRESSURE (+) button is pressed. Once | Pressure set increase. |

| Message | Cause | Explanation |
|---|---|---|
| | pressed, the displayed pressure reading will change to the pressure setting. Each subsequent press of the pressure button will increase the pressure setting in increments of 5. | |
| – Button | The operator display shows the pressure reading until the PRESSURE (-) button is pressed. Once pressed, the displayed pressure reading will change to the pressure setting. Each subsequent press of the pressure button 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 (Alternative Suction Pathway), 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 setup 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.

**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 uses a *lowercase Roman numeral* callout system to identify the main elements on the foot pedal unit, which are listed and labeled in Table 4. These callouts are referenced throughout this *User's Guide.*

**Figure 3 Foot Pedal Unit (AR-6483)**

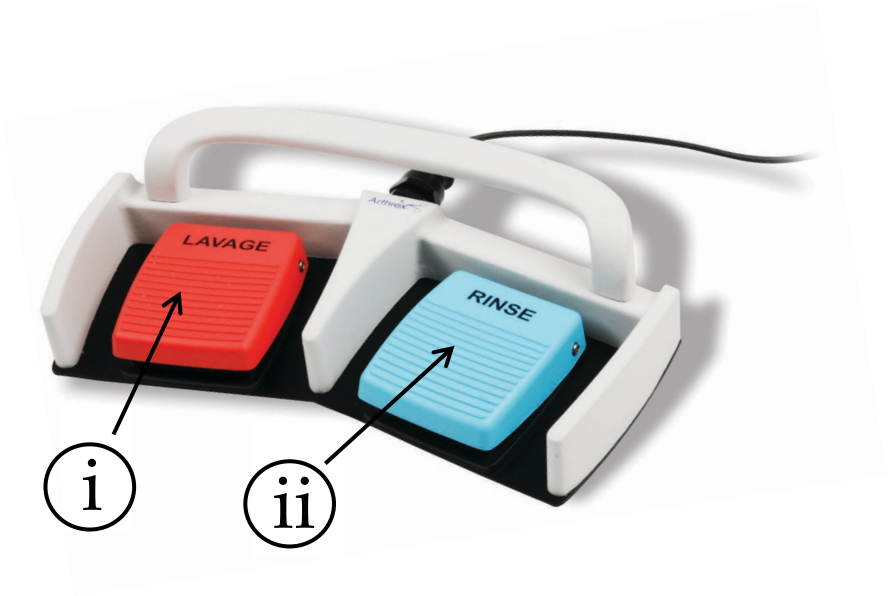



**Table 4 Foot Pedal Elements (AR-6483)**

| | |
|---|---|
| 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) if pressed while the 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 3 meters (9.8 ft.) 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 4 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)**

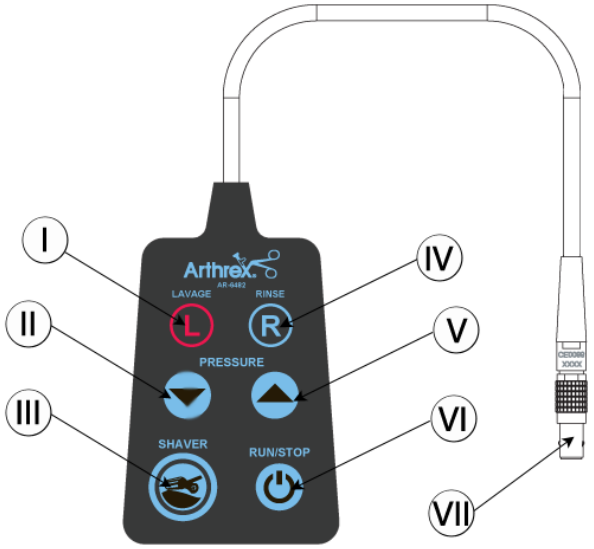



**Table 5 Remote Control Unit Elements (AR-6482)**

| | |
|---|---|
| I | **Lavage** - Increases the pressure by a percentage and time selected by the user. |
| II | **Pressure Decrease** - Decreases target pressure in increments of five. |
| 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) if pressed while the shaver is activated and the ASP mode is enabled via the outflow shaver menu. |
| V | **Pressure Increase** - Increases target pressure in increments of five. |
| 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, and Figure 7 show the tubing combinations supported by the AR-6480.

**Figure 5 One-Piece Tubing Configuration**

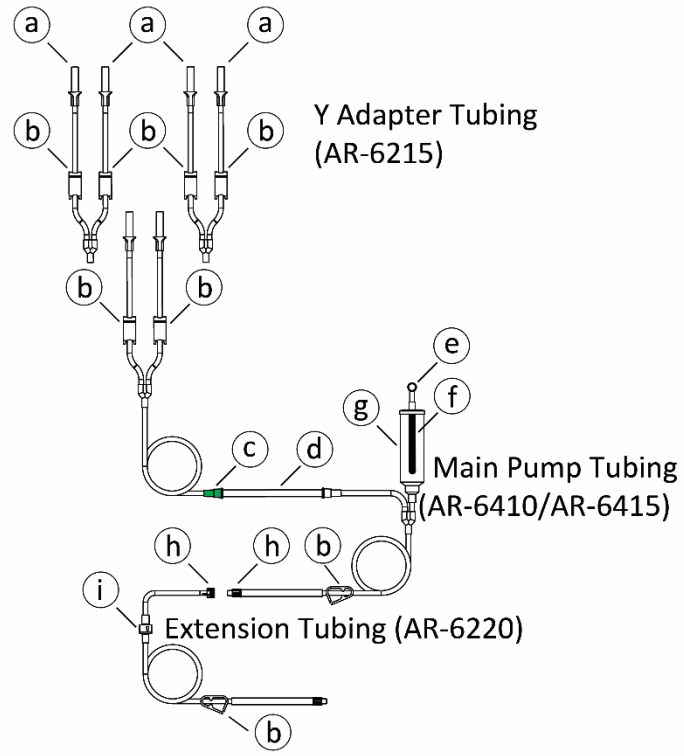



**Table 6 Elements of the One-Piece Tubing Configuration**

| Element | Description | Tubing Set |
|---|---|---|
| a | Bag spikes | AR-6215 |
| b | Tubing clamps | AR-6215<br>AR-6410/AR-6415<br>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 |

| Element | Description | Tubing Set |
|---|---|---|
| h | Connector fittings | AR-6410/AR-6415<br>AR-6220 |
| i | Backflow check valve | AR-6220 |

**Figure 6 Two-Piece Tubing Configuration**

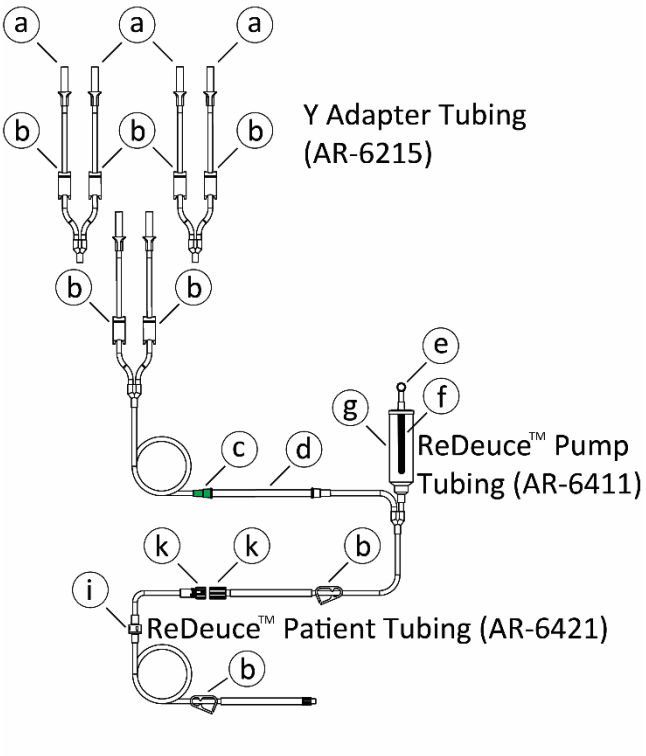



**Table 7 Elements of the Two-Piece Tubing Configuration**

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

**Figure 7 Outflow Tubing Configuration (AR-6430)**

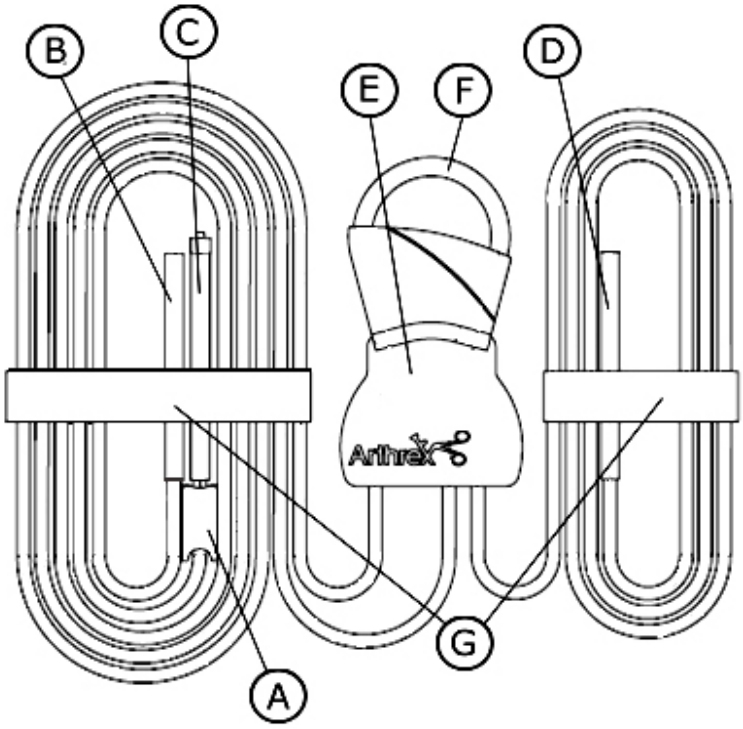



**Table 8 Elements of the Outflow Tubing Configuration**

| Element | Description | Tubing Set |
|---|---|---|
| A | Tubing clamp | AR-6430 |
| B | Shaver attachment | AR-6430 |
| C | Cannula attachment | AR-6430 |
| D | Waste egress | AR-6430 |
| E | Outflow cassette | AR-6430 |
| F | Tubing loop for outflow roller | AR-6430 |
| G | Paper retaining strap | AR-6430 |

### 2.5.2 Main Pump Tubing Set (AR-6410: Region A)

The *Main Pump Tubing Set* offers inflow and pressure sensing tubing. If used alone, the tubing must be *completely discarded* following each surgical procedure. From the pump, the tubing is 4 meters (13 ft.) 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 tubing set, refer to the Directions for Use that are included with each set or contact your Arthrex representative.*

### 2.5.3 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 sensing tubing. It is not intended to be used as a stand-alone product. 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 0.5 meters (1.7 ft.) in length.

### 2.5.4 ReDeuce Patient Tubing Set (AR-6421: Region A)

The *ReDeuce Patient Tubing Set* 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* Set 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 2.4 meters (8 ft.) in length.

### 2.5.5 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 2.4 meters (8 ft.) in length.

### 2.5.6 One-Piece Tubing Set System (AR-6415/AR-6415CL: Region B)

The *One-Piece Tubing System* offers inflow and pressure sensing 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.

### 2.5.7 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 sensing tubing. It is not intended to be used as a stand-alone product. The *Main Pump Tubing Set* may be used for an entire surgical day, 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.

### 2.5.8 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 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.

### 2.5.9 Outflow Pump Tubing Set (AR-6430)

The *Outflow Pump Tubing* is intended to be used with all the Arthrex tubing sets while in inflow/outflow mode to provide precisely-controlled outflow from the shaver and a cannula (optional) to multiple waste consumption devices. When the *Outflow Tubing Set* is attached to the AR-6480, the DualWave Arthroscopy Pump changes from an inflow-only pump to an inflow/outflow fluid management system.

### 2.5.10 Outflow Tub set with ReDeuce Tubing System (AR-6435: Region A)

A combination tube set with both outflow tubing (AR-6430) and ReDeuce Patient Tubing (AR-6421) is packaged together in one tray. For customers who are currently purchasing both the AR-6430 and the AR-6421, the AR-6435 will save preparation time by reducing the number of fluid management items that have to be opened prior to surgery.

### 2.5.11 Y-Adapter Tubing (AR-6215)

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

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

**Table 9 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 as a stand-alone product or in conjunction with the AR-6220 Extension Tubing Set) | AR-6415<br>AR-6415CL * | One-Piece Tubing System<br>One-Piece Tubing System with CareLock bag spikes (used as a stand-alone product) |
| AR-6220 | Extension Tubing Set (can be used in conjunction with the AR-6410 Main Pump Tubing Set as an additional extension) | AR-6220 | Not sold in region B. |
| AR-6411 | ReDeuce Tubing Set (MUST be used with the AR-6421 ReDeuce Patient Tubing Set) | AR-6420<br>AR-6420CL * | Main Pump Tubing Set<br>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-6430 Outflow Tubing Set | | | |
| AR-6435 | Combination tube set with the AR-6430 Outflow Tubing and AR-6421 ReDeuce Patient Tubing packaged together. | AR-6435 | Not sold in region B. |
| AR-6215 Y-Tubing Adapter | | | |

* CL = CareLock: Tubing spike used mainly for Fresenius fluid bags.

CareLock tubing does not work with AR-6215.

# 3.0 Technical Specifications

## 3.1 Console

| Table 10 | Control Unit (AR-6480) Specifications |
|---|---|
| Width | 42 cm (16.5 in.) |
| Height | 19 cm (7.5 in.) |
| Depth | 35.5 cm (14 in.) |
| Weight | 12.25 kg (27 lbs.) |
| Maximum flow rate | ≥ 1500 ml/minute |
| Pressure | 10 – 120 increments of 5. |
| Overpressure control | 300 mmHg ± 5 |
| 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, 6.5A |
| Mains fuse | T8LA250V (5 x 20 mm) |
| Shaver supply fuse | T5AL250VP (5 x 20 mm) |
| Applied part type | CF |
| Cleaning | Surface cleaning with mild detergent |
| Sterilization | Surface disinfection with mild disinfectant |

| Table 11 | Ambient conditions for operation |
|---|---|
| Temperature | 10° to 40 °C (50° to 104 °F) |
| Relative Humidity | 20% to 75%, non-condensing |
| Barometric pressure | 700 hPa (10.15 PSI) to 1060 hPa (15.37 PSI) |

| Table 12 | Ambient conditions for storage (in shipping packaging) |
|---|---|
| Temperature | -30° to +70°C (-22° to 158°F) |
| Relative Humidity | 10% to 90%, non-condensing |
| Barometric pressure | 500 hPa (7.25 PSI) to 1060 hPa (15.37 PSI) |

## 3.2 Foot Pedal

| Table 13 | Foot Pedal Unit (AR-6483) Specifications |
|---|---|
| Width | 330 mm (13 in.) |
| Height | 178 mm (7 in.) |
| Depth | 76 mm (3 inches) |
| Weight | 2.766 kg (6.1 lbs.) |
| Cable length | 3 m (9.8 ft.) |
| Cleaning | Surface cleaning with mild detergent |
| Sterilization | No |

## 3.3 Remote Control

| Table 14 | Remote Control Unit (AR-6482) Specifications |
|---|---|
| Width | 63.5 mm (2.5 in.) |
| Height | 95.3 mm (3.8 in.) |
| Depth | 22.2 mm (0.9 in.) |
| Weight | 0.23 kg (0.5 lbs.) |
| Cable length | 3 m (9.8 ft.) |
| Cleaning | Surface cleaning with mild detergent |
| Sterilization | Autoclave |

## 3.4 Safety, EMC, and Regulatory Requirements

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. For all other accessories refer to the accompanying DFUs for more information.

Refer to section 13.0 for further details on EMC certification.

# 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 Europe 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.

**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-6480 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 mains supply.**

**To prevent electrical shock do not use extension cords or two-prong/three-prong adaptors.**

*NOTE: If required by local codes, connect the console to the hospital equalization connector with an equipotential cable. Connect the power cord to a wall outlet with the correct voltage. Otherwise, the product may be damaged.*

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.

1.9.4

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

Savitestavimo sistema kiekvieną kartą įjungus;

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 the default settings when the 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 MAINS POWER SUPPLY with a protective earth terminal.

**W A R N I N G !**

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

## 4.3 Replacing the Fuses

The main fuse is replaced with T8LA250V (5 x 20 mm) 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 outward.
3. Replace the fuses with T8LA250V (5 x 20 mm) Line Fuses as noted on the rear panel.
4. Push the fuse holder back into the AC inlet.
5. Ensure that the fuse holder is fully seated and that the tabs snap back.

The shaver supply fuse is replaced with T5AL250VP (5 x 20 mm) as follows:

1. Disconnect the device from the AC mains.
2. Open the fuse holder in the shaver supply, by rotating counter clockwise with a flathead screwdriver.
3. Replace the fuses with T5AL250VP (5 x 20 mm) Line Fuses as noted on the rear panel.
4. Push the fuse holder back into the AC inlet.
5. Ensure that the fuse holder is fully seated by rotating clockwise with a flathead screwdriver.

**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-6480 console incorporates a universal AC input power supply. A voltage selection switch is not required.*

## 4.4 Electromagnetic Compatibility (EMC)

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

The AR-6480 has been designed to accept EMC from other devices within the limitations as described in section 13.0.

To determine if the AR-6480 is causing interference with other devices, power the AC mains power switch [3] OFF 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 distance between the devices.
3. Connect the device to an outlet on a different circuit than the other device(s) are connected to.
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 ensure 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 console.*

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 mains power socket [14] and the plug end to the facility AC mains supply.
3. Connect the Synergy System Integration Cable (if Synergy Integration is used, skip to step 5).

*NOTE: For more on Synergy Heads-Up Display, see IFU 950-0052-00.*

4. Connect the Shaver Detect cord (if Shaver Detect is desired, otherwise skip to step 6).

*NOTE: For more on Shaver Detect, see section 4.6.*

5. Power on the shaver system.
6. Turn on the AR-6480 [3].

7. Verify the status of the AR-6480 displayed in the operator display [5].
8. Connect the tubing in accordance with section 4.8 or 4.9
9. Close the roller housing doors.
10. Attach the remote control unit or foot pedal unit [4], if applicable.
11. Refer to section 5.0, Operation, for specific information on how to operate the AR-6480, including pressure and flow settings.
12. Press the Run/Stop button [Table 3 or VI] to activate the pump motor.

**W A R N I N G !**

**DO NOT** stack or place equipment adjacent to the AR-6480 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 the remote control or the foot pedal during the Self Test or Programming Modes.**

**W A R N I N G !**

Use **ONLY** Arthrex approved 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 injury to the patient and/or operating room staff.

**W A R N I N G !**

**Do not** use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide, oxygen, or endogenous gases. All oxygen connections must be leak free for the duration of the surgical procedure.

**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 Shaver Detect

~~The AR-6480 detects when a shaver handpiece has been activated. The Shaver~~ Detect feature operates differently, depending on if an AR-6430 Outflow Tube Set is installed on the DualWave. Shaver Detect can be set up in three different ways.

*NOTE: The Shaver Detect feature will function as described in sections 4.6.3 – 4.6.4.*

### 4.6.1 Shaver Detect, Synergy System Connection

For correct operation of Shaver Detect when connecting with a Synergy System Integration Cable (AR-3200-1040):

1. Ensure the Synergy System Integration Cable is properly connected between the Synergy Resection Console and the DualWave.
2. Attach the shaver handpiece and footswitch (if used).
3. Turn on the Synergy Resection Console.
4. Turn on the DualWave.

*NOTE: For use only with DualWave software version 1.8 or greater and Synergy Resection Console version 2.3 or greater. Refer to IFU 950-0052-00 for more information.*

*NOTE: It is recommended that the Shaver Detect Power Cable not be connected when using the Synergy System Integration cable for Shaver Detection.*

NOTE: The Shaver Detect feature will function as described in sections 4.6.3 – 4.6.4.

### 4.6.2 Shaver Detect, Shaver Power Cable

The Shaver Detect 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 when connecting with the Shaver Interface Cable:

1.5.6 p.d.

1. Ensure the Shaver Detect Power Cable is properly connected between the Shaver console and the DualWave.
2. Attach the shaver handpiece and footswitch (if used).
3. Turn on the Shaver Console.
4. After the Shaver Console sequence, turn on the DualWave.

NOTE: The Shaver Detect feature will function as described in sections 4.6.3 – 4.6.4.

NOTE: The Shaver Detect settings adjustments are described in section 4.6.5.

### 4.6.3 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 the shaving device.

The pressure will automatically change to the preset BOOST values, and can be noted on the operator display [5]. The BOOST button will change to a dark blue color when the shaver is activated.

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

### 4.6.4 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 the shaver being activated, 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.

### 4.6.5 Adjusting the Shaver Detect

*NOTE: Only adjust when using the Shaver Detect Power Cable.*

Users can adjust the Shaver Detect function for optimal interfacing performance. To change the settings, press these buttons in this sequence:
MENU → DEFAULTS → Shaver Detect. The screen displays and allows changes to the settings for 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 needs. 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 detect 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 ($1/10^{th}$ 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 the 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 Shaver 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." During the baseline capture, do not activate the shaver.

**Cautions to the 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 as if 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 value 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 DualWave's Shaver Detect function has been verified to function properly with the Arthrex Adapteur II Shaver Console and Arthrex Synergy Resection Console. It is the responsibility of the user facility to evaluate third-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 Synergy Heads-Up Display

1. First obtain the Synergy System Integration Cable Kit (AR-3200-1040).
2. Connect the Synergy System Integration Cable between the rear panel of the DualWave [19] and the rear of the Synergy Imaging Console communication connections labeled RS-232.
3. Turn on the DualWave and Synergy Imaging Console.

*NOTE: Refer to IFU 950-0052-00 for more information.*

## 4.8 How to Set Up Pump Tubing

*NOTE: These instructions describe the procedure for setting up the AR-6410, AR-6415, AR-6411, or AR-6420.*

1. Remove the clip 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 sensing**.
2. Open the inflow door [12] 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 mark.
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 mark on the front panel of the console.*

5. Close the inflow door [12].

*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 to the unused spike.

## 4.9 How to Set Up the Two-Piece Tubing System

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

**W A R N I N G !**

The extension, patient, and/or outflow tubing must be changed for new each patient and/or procedure.

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. At the end of each case, detach the extension or patient tubing set and 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 ensures its safe operation throughout the entire surgical day.

## 4.10 How to Set Up the Outflow Tubing

1. Open the 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 the 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.

## 4.11 How to Change the Language Setting

The AR-6480 supports English, French, German, Italian, Russian and Spanish. The default language is English. To change the language setting for operator display 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 the desired language.
5. Press ok. The language is now stored in the memory.

## 4.12 How to Test the Power Supply Voltages

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

## 4.13 Safe Setup and Performance

### 4.13.1 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 operator display [5]. See Table 3 for a complete list of operator display messages and section 10.0 for troubleshooting information.

*NOTE: If abnormal console operation cannot be corrected, disinfect the pump, repackage in the original shipping materials, and return to Arthrex, accompanied by a brief description of the malfunction. Prior to shipping, it is necessary to obtain a return authorization number from Arthrex.*

### 4.13.2 Overpressure Sensing

The sensing circuitry in the AR-6480 detects 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.

### 4.13.3 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.

### 4.13.4 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.

**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.

## 4.14 Shutdown Procedure

The AR-6480 can be safely shut down at any time by powering down the console. All tubing accessories must be discarded as biohazardous 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-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 operator display. The pressure presets can be adjusted by entering the MENU, then Defaults, then Presets. Selecting "done" will save the adjusted preset in the memory until it is changed.

Table 15 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 15 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 the distention pressure beginning with the initial pressure settings in Table 15.

**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 patient and/or 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 the clamp is firmly closed.
   - If the rollers turn continuously, the pressure line connector [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 the distal end of the 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, patient, and/or outflow tubing must be replaced before each new patient and/or procedure.

1. Follow the steps as outlined in section 5.2.
2. Add the outflow tube set to the AR-6480.
3. The sensor will detect that the outflow tubing has been added and change the controls and icons on the operator display to signify INFLOW/OUTFLOW mode.
4. The red waste tubing end should be attached to a waste bag or suction device/container.
5. The end of the clear tubing labeled SHAVER should be attached to the shaver suction port.
6. The end of the blue 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 or set cannula suction to off.*

## 5.4 How to Operate the AR-6480 in LAVAGE Mode

The AR-6480 pump has a LAVAGE function for hemostatic 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, i or I] to enable this function. The LAVAGE button should turn dark blue in 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, ii 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 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. ASP mode changes the suction pathway from the shaver suction pathway to the cannula suction pathway while shaving. The shaver suction level will be maintained while the shaver is activated.

1. Turn ON ASP MODE in the OUTFLOW SHAVER default menu.
2. Press the RINSE button on the remote control [IV] or foot pedal [ii] 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. 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 [IV] or foot pedal [ii] while the shaver is activated.

# 6.0 Cleaning and Disinfection

## 6.1 Console (AR-6480) and Foot Pedal Control Unit (AR-6483)

This device is provided non-sterile and must **not** be sterilized. Each device must be adequately cleaned and disinfected prior to use or re-use.


To clean and disinfect, use a disinfecting towelette or a clean, low-linting cloth dipped in disinfectant solution and gently wipe down all surfaces of gross contamination from the device. Using a second (fresh) towelette or cloth, thoroughly wet the surface of the device and ensure it remains visibly wet for the contact time recommended by the disinfectant manufacturer. The use of additional towelettes or cloths may be used to ensure the surface remains visibly wet for the entire contact time. If required by the disinfectant manufacturer, rinse per instructions; otherwise, allow to air dry. If gross contamination remains, repeat the procedure and re-inspect.

Always place the main power switch in the "Off (O), position" and disconnect the power before cleaning the AR-6480 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.**

**These devices are NOT suitable to be cleaned and disinfected in an automated washer/disinfector.**

## 6.2 Remote Control Unit (AR-6482)

**Refer to the Instructions for Use package insert (DFU-0144-XX) for detailed remote control 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-6482) is supplied **non-sterile**.


The remote control unit can be autoclaved for sterilization.

## 6.3 Tubing

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

**Refer to the Instructions for Use package insert (DFU-0140-XX) for detailed tubing cleaning and sterilization 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.**

**W A R N I N G !**

The extension, patient, and/or outflow tubing must be replaced before each new patient and/or 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 ensure 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 (DFU-0144-XX) for detailed remote control 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.

## 7.1 Transmissible Spongiform Encephalopathy Agents

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 disinfection and sterilization processes. 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. Refer to AAMI ST79 for further information.

# 8.0 Maintenance

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

Recommended care and handling of the DualWave 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, foot pedal, remote control, cable, connectors, and display before each use.

Your authorized Arthrex service department is extremely knowledgeable about the Arthrex Medical DualWave Arthroscopy Pump, tubing and/or foot pedal and remote control and will provide a competent and efficient service. Any services and/or repairs carried out by any unauthorized repair facility may result in reduced performance of the instruments or instrument failure.

## 8.1 Periodic Maintenance

The product should be inspected prior to and after each use to ensure that the foot pedal, remote control, cable, strain relief, overmold, connector contacts, and display are not damaged or worn. If it becomes necessary to return the foot pedal and/or remote control to Arthrex for service, please sterilize the remote control before shipping. If fluid or particles splash on the display, clean with a microfiber cloth by gently wiping in a circular motion.

# 9.0 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; or at +49 89 90 90 05 8800 or techsupport@arthrex.de from 8:00 AM to 5:00 PM CET.

## 9.1 How to Display the Software Version

Technical Support may request the pump's software version. 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 operator display during the power-up sequence.

## 9.2 Additional Technical Information

Contact your Arthrex representative if you require more comprehensive technical information. The pressure verification or other information will be provided upon request by Arthrex APPROVED SERVICE PERSONNEL.

# 10.0 Troubleshooting

**Refer to Table 16 for device troubleshooting if problems occur after cleaning, transporting, or changing operating staff.**

**Table 16 Troubleshooting: Faults, their Causes, and Solutions**

| Message | Cause |
|---|---|
| ** Critical Failure ** | 1. Return to Arthrex for repair. |
| ** Door Open ** | 2. Roller housing is not secured – ensure the locking lever is properly secured.<br>3. If the failure persists, return to Arthrex for repair. |
| ** Overpressure ** | 1. Increase or open the outflow.<br>2. Manipulate the joint to a stress-free position.<br>3. If the failure persists, return to Arthrex for repair. |
| ** Pressure Fault ** | 1. Ensure adequate fluid supply.<br>2. Decrease the outflow.<br>3. Check the tubing for damage or pinches, kinks, or blockages.<br>4. Check the tubing for the proper connections.<br>5. Replace the tubing.<br>6. If the failure persists, return to Arthrex for repair. |
| ** Tubing Out ** | 1. If the tubing sensor indicator's LED is red, the tubing is not properly connected.<br>2. Ensure the tubing sensor coupler [2] is open, not seated.<br>3. Ensure that the tubing pressure line connector [e] is seated completely.<br>4. Change the tubing.<br>5. If the failure persists, return to Arthrex for repair. |
| Console fails Self Diagnostic Test | 1. Ensure no tubing is connected to the pump during the power on sequence.<br>2. If the failure persists, return to Arthrex for repair. |
| Console will not power up | 1. Check the AC mains power cord.<br>2. Try an alternate power outlet.<br>3. Check the AC mains fuses.<br>4. If the failure persists, return to Arthrex for repair. |
| Does not pump when activated | 1. Check for error messages.<br>2. Open all tubing clamps and shut-off valves.<br>3. Ensure the actual pressure is below the target pressure.<br>4. Check the tubing for pinches, kinks, or blockages.<br>5. If the failure persists, return to Arthrex for repair. |
| Inadequate distention, liquid bloody or cloudy | 1. Increase the pressure.<br>2. Activate Lavage mode.<br>3. Reduce the outflow.<br>4. Use high-flow cannulas.<br>5. If the failure persists, return to Arthrex for repair. |
| No (or inadequate) flow | 1. Check for error messages.<br>2. Check that all tubing clamps are open.<br>3. Check the settings for flow and pressure.<br>4. Check the tubing for pinches, kinks, or blockages.<br>5. Check that the tubing seats correctly over the rollers.<br>6. Verify use of high-flow cannulas.<br>7. If the failure persists, return to Arthrex for repair. |

| Message | Cause |
|---|---|
| No Shaver Detect | Synergy Shaver Detection<br>1. Verify DualWave software is at least 1.8.<br>2. Verify Synergy Resection Console is at least 2.3.<br>3. Ensure the Synergy cable is connected.<br>4. Press stop and then run on the DualWave while the Synergy Resection Console is on.<br>5. Replace cable.<br>6. If the failure persists, return to Arthrex for repair. |
| | Universal Shaver Detection<br>1. Ensure the universal shaver cable is connected.<br>2. Turn DualWave on and off while the shaver system is powered on.<br>3. Adjust the DELAY and/or THRESHOLD settings.<br>4. Isolate the power source.<br>5. If the failure persists, return to Arthrex for repair. |

If the problems persist, disinfect the DualWave Arthroscopy Pump and send to Arthrex using the original packaging. Always send the corresponding console together with the tubing, foot pedal, and remote control. Please enclose a brief explanation of the detected malfunction. Refer to section 11.0 for more information.

## 10.1 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 the devices.
- Connect the device to an outlet on a different circuit than the other device(s) are connected to.
- Consult the manufacturer or field service technician for the receiving device for assistance.

# 11.0 Repair Policy

Contact Arthrex for a return authorization number and instructions prior to returning the device.

# 12.0 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 electronic equipment at the end of its useful life for recycling, please contact Arthrex Customer Service Department.

# 13.0 Electromagnetic Emissions

**Table 17 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 ensure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment – guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The AR-6480 DualWave Arthroscopy Pump uses RF energy only for its internal function. Therefore its RF emissions are very low and 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 18 System Cables**

| Type | Use | Shielded | Ferrite | Maximum Length |
|---|---|---|---|---|
| Power Cords | Supply line power to the console | No | No | 3.048 m (10 ft) |
| Universal Shaver Detect Cord | Supply line power to the shaver console from the DualWave console | No | No | 2.438 m (8 ft) |
| Synergy System Integration Cable Kit | System integration cables | No | No | 2.438 m (8 ft) |

**Table 19 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<br>± 8 kV air | ± 6 kV contact<br>± 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<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 | <5 % Uτ<br>(>95 % dip in Uτ)<br>for 0.5 cycle<br>40 % Uτ<br>(60 % dip in Uτ)<br>for 5 cycles<br>70 % Uτ<br>(30 % dip in Uτ)<br>for 25 cycles<br><5 % Uτ<br>(>95 % dip in Uτ)<br>for 5 sec | <5 % Uτ<br>(>95 % dip in Uτ)<br>for 0.5 cycle<br>40 % Uτ<br>(60 % dip in Uτ)<br>for 5 cycles<br>70 % Uτ<br>(30 % dip in Uτ)<br>for 25 cycles<br><5 % Uτ<br>(>95 % dip in Uτ)<br>for 5 sec | 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 19 Guidance and Manufacturer's Statement - Electromagnetic Immunity (cont'd)**

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<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz<br><br>3 V/m 80 MHz to 2.5 GHz | 3 Vrms<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Model AR-6480, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = [3.5 / V1]\sqrt{P}$ = 1.2 $\sqrt{P}$<br>$d = [3.5 / V1]\sqrt{P}$ =1.2 $\sqrt{P}$ 80 MHz to 800 MHz<br>$d = [7 / E1]\sqrt{P}$ = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz<br>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).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range. [b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model AR 6480 is used exceeds the applicable RF compliance level above, the Model AR-6480 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model AR-6480

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

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