Continuous Wave™ 4 Arthroscopy Pump

User's Guide

The *Arthrex Continuous Wave™ 4 (CW4) Arthroscopy Pump User's Guide* provides safety operation information for all components of the Arthrex CW4 arthroscopy pump (model AR-6485), including accessories. All operating personnel must read this *User's Guide* for version 1.9 or higher thoroughly prior to using this system and follow all safety warnings, cautions, and precautions.

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This is not a warranty document. For all warranty information, including disclaimers, exclusions, terms, conditions and related provisions, refer to the "Arthrex U.S. Product Warranty" section of the Arthrex, Inc. website, found at www.arthrex.com whose provisions are incorporated herein by reference.

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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 *CW4 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. 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.
3. **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.
4. **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.
5. 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.
6. **No** modification of the console (AR-6485) or accessories is allowed.

7. **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.

8. To avoid the RISK of electric shock, this equipment must only be connected to a MAINS POWER SUPPLY with a protective earth terminal.
9. **DO NOT** have the device in direct contact with the patient if high-frequency devices are in use, or if the patient requires defibrillation.
10. To ensure that correct pressure monitoring occurs, the pump and operative site **MUST** be in the same horizontal plane.
11. **DO NOT** stack or place equipment adjacent to the AR-6485 console, if possible. If such a configuration is necessary, carefully observe the configuration in question to ensure that electromagnetic interference does not degrade performance.
12. **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.
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 and/or patient 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-6485 is verified and documented; however, the AR-6485 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%, but not to exceed a pump pressure of 120 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-6485 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.

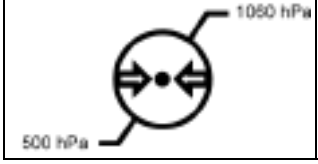
4. To prevent electrical shock do not use extension cords or two-prong/three-prong adaptors.
5. Always use fuses with the correct values to avoid allowing overcurrent to enter the system.
6. An incorrect fuse may increase the risk of electrical shock or fire hazard.
7. This device has passed testing 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.

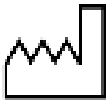
- **In CE Accepting Countries:** Procedures carried out using these devices may be used on the general population.

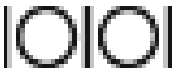
- **In CE Accepting Countries:** The clinical benefits associated with the use of these devices outweigh the known clinical risks.
- **In CE Accepting Countries:** There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

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** **Follow operating instructions**	R_x ONLY	**Caution: Federal law restricts this device to sale by or on the order of a physician.**
	**Stand-by power switch (push-push)**		**Type BF Equipment**
	**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]**		**Protective earth terminal**
	**Electrical waste**		**RF symbol. Non-ionizing electromagnetic radiation**
	**Manufacturer**		**Date of manufacture; year and month.**
	**Non sterile**		**The product meets the essential requirements of Medical Device Directive 93/42/EEC**
	**Catalog number**		**Serial number**
	**Quantity**		**Authorized representative in the European Community**
	**Remote control connection**		**Foot pedal connection**
	**Do not use if package is damaged**	IP22	**International protection marking**

USB	**Universal serial bus [for use ONLY with Arthrex approved thumb drive]**		**Serial IO [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-6485. 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-6485 CW4 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-6485 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-6485 includes:

- A universal medical-grade switching power supply that allows the pump to function automatically at voltage ranges found worldwide.
- An automatic Shaver Detect feature that allows a pressure boost to be created to adjust for high flow shaver suction on demand.
- There is an operator display for user inputs.
- A Lavage function to provide elevated pressure to stop bleeding.

The user-defined settings for inflow pressure are adjustable through controls located on the operator display or on the remote control.

There are **three Applied Part pump tubing options** for the AR-6485:

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 adapter* is intended to be used with Arthrex inflow tubing sets/system combinations to connect up to four irrigation bags.

The AR-6485 is an inflow-only irrigation pump.

Other optional accessories:

- Remote control
- Foot pedal
- Synergy integration cable

2.2 Product Features

2.2.1 AR-6485 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

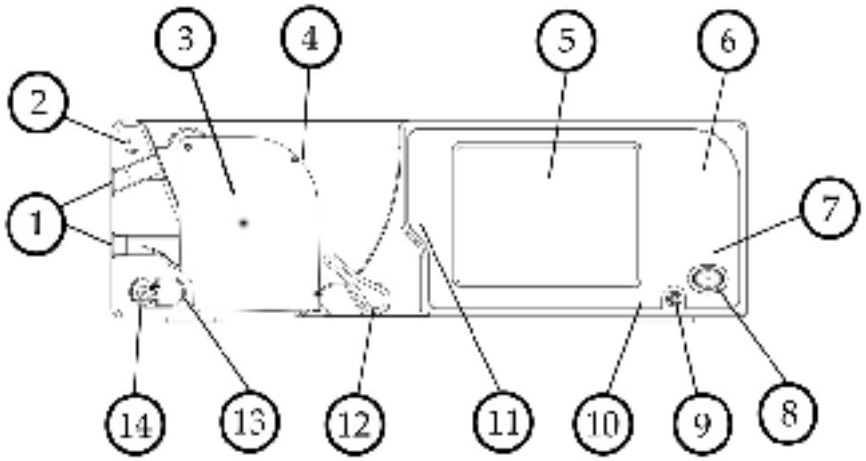


Table 1 Front Panel Elements

1.	Inflow tubing track
2.	Inflow tubing alignment marker
3.	Inflow roller assembly
4.	Inflow roller housing door
5.	Operator display
6.	Synergy Product Logo
7.	Power Switch IEC 60417-5009 symbol (Stand-by)
8.	Stand-by power switch
9.	Remote control or foot pedal connector
10.	Remote control or foot pedal symbols
11.	Type BF Symbols (Electric Shock Protection)
12.	Inflow door locking mechanism
13.	Tubing sensor coupler 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
14.	Tubing sensor coupler

2.2.2 AR-6485 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

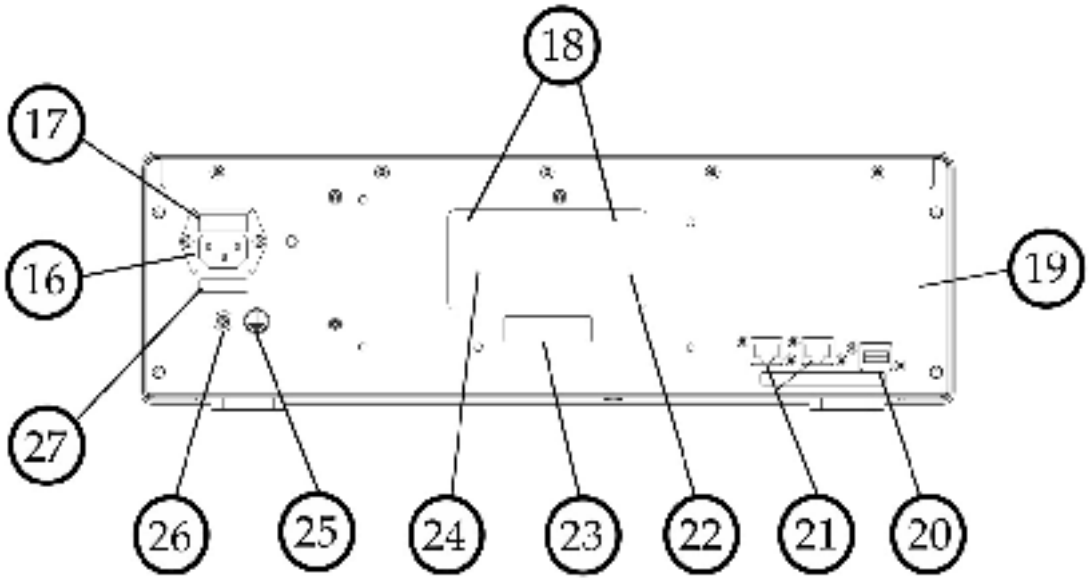


Table 2 Rear Panel Elements

16.	AC mains power input plug
17.	Main power input - Fuse holder
18.	Address
19.	Void seal sticker
20.	USB port (For use **ONLY** with an Arthrex approved thumb drive)
21.	Serial IO for Arthrex integration (refer to IFU 950-0052-00)
22.	Serial number label
23.	Software label
24.	Model number label
25.	Equipotential ground symbol
26.	Equipotential ground connector
27.	Main power input - Fuse label

2.2.3 AR-6485 Operator Display Messages and Iconography

The console's operator display [5] provides information about the status of the AR-6485 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-6485 Operator Display Messages and Iconography

Message	Cause	Explanation
Arthrex CW4	Message appears when the power stand-by switch is activated.	Power on message display.
** Tubing Out **	Message appears when tubing is not plugged into the tubing sensor coupler [14].	Check tubing installation.
** Door Open **	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 operator display 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 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 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.	Pressure set increase.
– 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.

Message	Cause	Explanation
RUN Button	Button appears when the pump is stopped. Press this button to start the pump.	Motor on.
STOP Button	Button appears when the pump is running. Press this button to stop the pump.	Motor off.
LAVAGE Button	Button appears when the pump is in run 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.
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.
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-6485 CW4 arthroscopy pump can be remotely controlled with the optional foot pedal unit (AR-6483). It provides a Lavage 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)

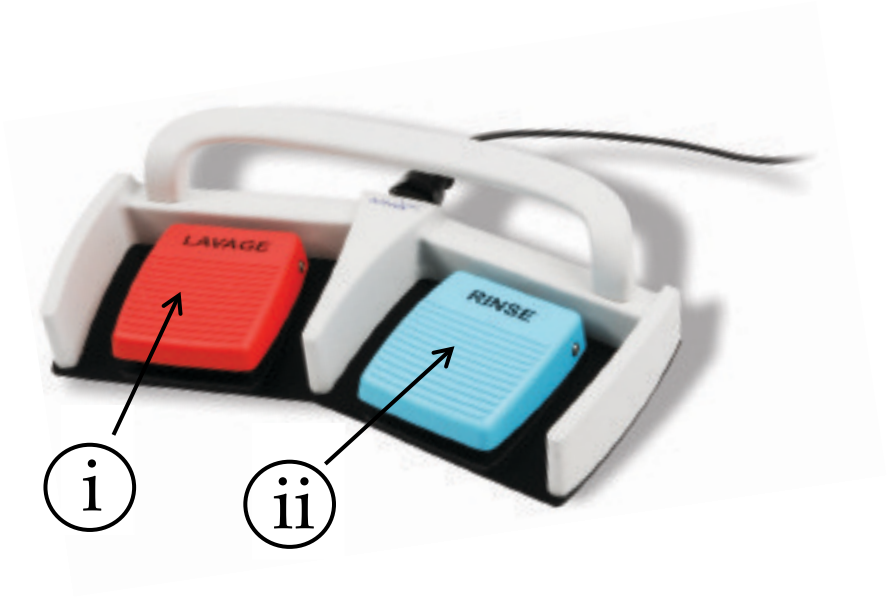


Table 4 Foot Pedal Elements (AR-6483)

i	**Lavage** increases the pressure by a percentage and time selected by the user.
ii	**Rinse** is for use only with an inflow outflow pump.

2.4 Remote Control Unit (AR-6482)

The AR-6485 CW4 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; 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)

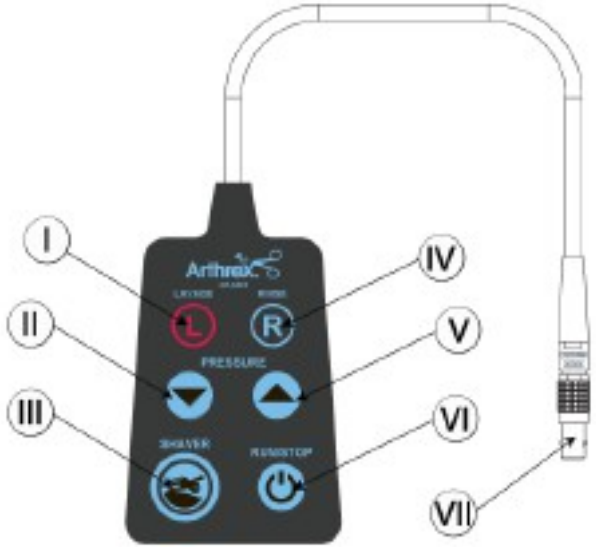


Table 5 Remote Control Unit Elements (AR-6482)

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 (for use with inflow outflow pump).
IV	**Rinse** – For use only with an inflow outflow pump.
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 [9] of the AR-6485.

2.5 Tubing

2.5.1 Tubing Configurations

Figure 5, Figure 6, and Figure 7 show the tubing combinations supported by the AR-6485.

Figure 5 One-Piece Tubing Configuration

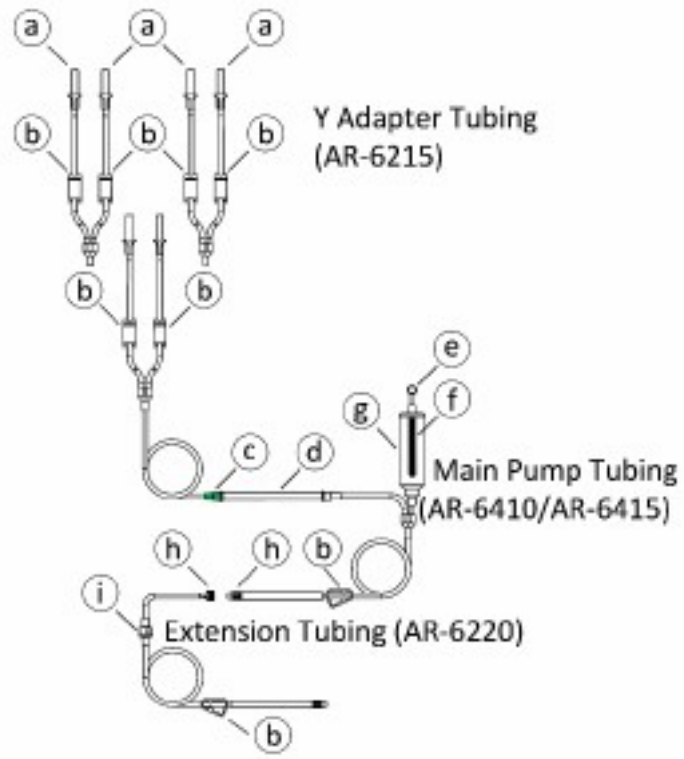


Table 6 Elements of the One-Piece Tubing Configuration

Element	Description	Tubing Set
a	Bag spikes	AR-6215
b	Tubing clamps	AR-6215 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 6 Two-Piece Tubing Configuration

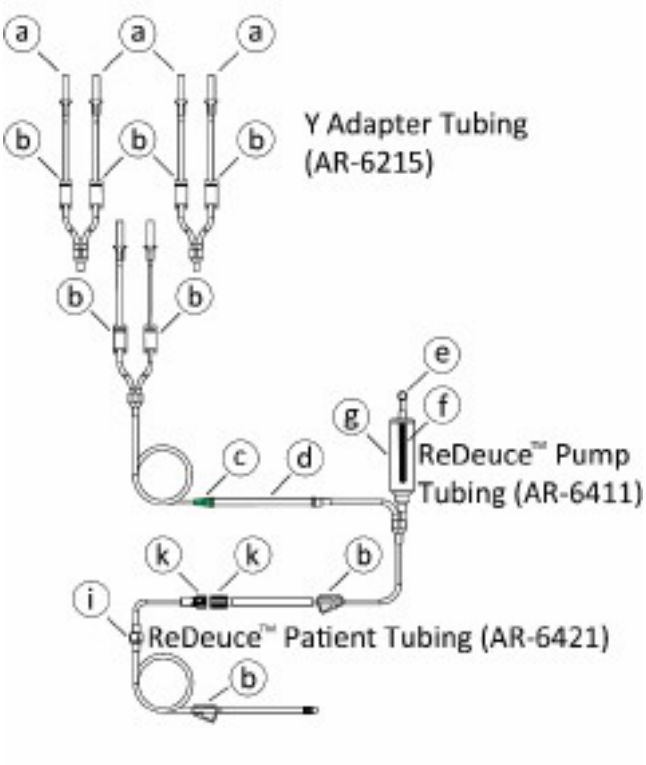


Table 7 Elements of the Two-Piece Tubing Configuration

Element	Description	Tubing Set
a	Bag spikes	AR-6215
b	Tubing clamps	AR-6215 AR-6411/AR-6420 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 AR-6421/AR-6425
i	Backflow check valve	AR-6421/AR-6425

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 Care-Lock®* spikes which are used specifically with Fresenius Kabi 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 pumping 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 Care-Lock spikes which are used specifically with Fresenius Kabi 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 Y-Tubing Adapter (AR-6215)

The optional *Y-tubing adapter* 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 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 as a stand-alone product or in conjunction with the AR-6220 extension tubing set)	AR-6415 AR-6415CL *	One-piece tubing system One-piece tubing system with Care-Lock 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 AR-6420CL *	Main pump tubing set Main pump tubing set with Care-Lock 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 = Care-Lock: Tubing spike used mainly for Fresenius Kabi fluid bags.

Care-Lock tubing does not work with AR-6215.

3.0 Technical Specifications

3.1 Console

Table 9	Control Unit (AR-6485) Specifications
Width	42 cm (16.5 in.)
Height	13.5 cm (5.3 in.)
Depth	29.2 cm (11.5 in.)
Weight	6.24 kg (13.75 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
AC mains power input plug	IEC 60320 C13/C14
AC Input	100-240 V, 50/60 Hz, 1.5A Max/100VAC, 0.7A Max/240VAC
Mains fuse	T2AH250V (5 x 20 mm)
Applied part type	BF
Cleaning	Surface cleaning with mild detergent
Sterilization	Must not be sterilized

Table 10	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 11	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 12	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 13	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 CW4 arthroscopy pump (AR-6485) is designed and tested in accordance with:

EN 60601-1/A1:2014

AAMI ES 60601-1 3rd Edition + A1:2012

CAN/CSA-C22.2 No. 60601-1:2014

According to 60601 this device is Type BF, 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-6485 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-6485. 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-6485 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 a stand-by power switch [8] on the front panel. When the stand-by power switch is in stand-by, electrical power is still drawn by the console. To eliminate electrical power drawn by the console, disconnect the rear mains power cable from the AC mains power input plug [16].

When the stand-by power 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 CW4. 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.

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 requires defibrillation.

4.3 Replacing the Fuses

The main fuse is replaced with T2AH250V (5 x 20 mm) as follows:

1. Disconnect the device from the AC mains.
2. Open the fuse tray [17] in the AC inlet by pinching the tabs and pulling outward.
3. Replace the fuses with T2AH250V (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.

⚠ **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-6485 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-6485 has been designed to accept EMC from other devices within the limitations as described in section 13.0.

To determine if the AR-6485 is causing interference with other devices, power the stand-by power switch [8] to stand-by and unplug the power cord. Once verified reconnect the power cable and power 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-6485

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-6485 on a flat, dry surface in the same horizontal plane as the operative site, such as the AR-6481 arthroscopy pump cart.
2. Connect the receiver end of the power cord for the AR-6485 into the AC mains power plug [16] and the plug end to the facility AC mains supply.
3. Connect the Synergy system integration cable.

NOTE: For more on Synergy Heads-Up Display feature heads-up display feature, see IFU 950-0052-00.

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

4. Power on the shaver system.
5. Turn on the AR-6485 [8].
6. Verify the status of the AR-6485 displayed in the operator display [5].
7. Connect the tubing in accordance with section 4.8 or 4.9
8. Close the roller housing door [4].
9. Attach the remote control unit or foot pedal unit [9], if applicable.
10. Refer to section 5.0, Operation, for specific information on how to operate the AR-6485, including pressure and flow settings.
11. 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-6485 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-6485 detects when a shaver handpiece has been activated.

NOTE: The Shaver Detect feature will function as described in section 4.6.2.

4.6.1 Shaver Detect, Set-up

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$^{\text{Resection™}}$ console and the CW4 [21].
2. Attach the shaver handpiece and footswitch (if used).
3. Turn on the Synergy$^{\text{Resection}}$ console.
4. Turn on the CW4.

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

4.6.2 Shaver Detect, Activation

While the CW4 is running and the shaver is activated the CW4 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.

4.7 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 CW4 [21] and the rear of the Synergy Imaging Console communication connections labeled IOIOI.
3. Turn on the CW4 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 [14]. **This step must be completed first to ensure accurate pressure sensing**.
2. Open the inflow door [4] 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 [2].
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 [2] on the front panel of the console.

5. Close the inflow door [4].

NOTE: The inflow door locking device must be secure. If the door is not closed securely an internal safety switch prevents the AR-6485 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 and/or patient tubing must be changed for each new 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 Change the Language Setting

The AR-6485 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 stand-by power switch [8] on the AR-6485.
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.

4.11 How to Test the Power Supply Voltages

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

4.12 Safe Setup and Performance

4.12.1 Abnormal Operation

The AR-6485 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.

4.12.2 Overpressure Sensing

The sensing circuitry in the AR-6485 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 operation display [5] and an audible alarm will sound. The pump motor is automatically disabled until the pressure returns to the set range.

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

4.12.3 Inflow Roller Housing [4]

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

4.12.4 Tubing Sensor Coupler [14]

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.

4.13 Shutdown Procedure

The AR-6485 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-6485 is verified and documented; however, the AR-6485 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 CW4 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 CW4 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 14 specifies the initial pressure settings that are preprogrammed for surgery. The ideal intra-articular pressure depends on the indications for the arthroscopic procedure, bleeding tendency, and the possibility of ischemia.

Table 14 Initial Pressure Settings

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

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

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

W A R N I N G !

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

5.2 How to Operate the AR-6485

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 [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 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-6485 in LAVAGE Mode

The AR-6485 pump has a LAVAGE function for hemostatic purposes.

W A R N I N G !

User-programmed "Pressure Set" values are increased by as much as 50%, but not to exceed a pump pressure of 120 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.

5.4 How to Operate the Flow Control on the AR-6485

The AR-6485 has a flow control setting with in the default menu that allows for the maximum fluid flow rate to the joint space to be increased or decreased by a 10 percent on a scale of 50 percent to 100 percent.

6.0 Cleaning and Disinfection

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.

NEVER use liquid to clean the accessory device connector contacts. Remove dust regularly using dry compressed air.

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

6.1 Console (AR-6485) 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 stand-by power switch in Stand-by position and disconnect the power cable before cleaning the AR-6485 console.

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 and/or patient 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 CW4 arthroscopy pump is the best way to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the CW4 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 CW4 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-(800) 934-4404, 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 stand-by power switch [8] on the AR-6485.
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 procedure, circuit diagrams, component part lists, descriptions, calibration instructions, or other information will be provided upon request by Arthrex APPROVED SERVICE PERSONNEL.

10.0 Troubleshooting

Refer to Table 15 for device troubleshooting if problems occur after cleaning, transporting, or changing operating staff.

Table 15 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. 3. If the failure persists, return to Arthrex for repair.
** Overpressure **	1. Increase or open the outflow. 2. Manipulate the joint to a stress-free position. 3. If the failure persists, return to Arthrex for repair.
** Pressure Fault **	1. Ensure adequate fluid supply. 2. Decrease the outflow. 3. Check the tubing for damage or pinches, kinks, or blockages. 4. Check the tubing for the proper connections. 5. Replace the tubing. 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. 2. Ensure the tubing sensor coupler [14] is open, and tubing isn't connected. 3. Ensure that the tubing pressure line connector [e] is seated completely. 4. Change the tubing. 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. 2. If the failure persists, return to Arthrex for repair.
Console will not power up	1. Check the AC mains power cord. 2. Try an alternate power outlet. 3. Check the AC mains fuses [17]. 4. If the failure persists, 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 the actual pressure is below the target pressure. 4. Check the tubing for pinches, kinks, or blockages. 5. If the failure persists, return to Arthrex for repair.
Inadequate distention, liquid bloody or cloudy	1. Increase the pressure. 2. Activate Lavage mode. 3. Reduce the outflow. 4. Use high-flow cannulas. 5. If the failure persists, 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 the tubing for pinches, kinks, or blockages. 5. Check that the tubing seats correctly over the rollers. 6. Verify use of high-flow cannulas. 7. If the failure persists, return to Arthrex for repair.

Message	Cause
No Shaver Detect	Synergy Shaver™ detection 1. Verify CW4 software is at least 1.8. 2. Verify Synergy[Resection] console is at least 2.3. 3. Ensure the Synergy cable is connected. 4. Press stop and then run on the CW4 while the Synergy[Resection] console is on. 5. Replace cable. 6. If the failure persists, return to Arthrex for repair.

If the problems persist, disinfect the CW4 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 16 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The AR-6485 CW4 arthroscopy pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-6485 CW4 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-6485 CW4 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-6485 CW4 arthroscopy pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 17 System Cables

Type	Use	Shielded	Ferrite	Maximum Length
Power Cords	Supply line power to the console	No	No	3.048 m (10 ft)
Synergy System Integration Cable Kit	System integration cables	No	No	2.438 m (8 ft)

Table 18 Guidance and Manufacturer's Statement - Electromagnetic Immunity

The AR-6485 CW4 arthroscopy pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-6485 CW4 arthroscopy pump should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 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 (>95 % dip in Uτ) for 0.5 cycle 40 % Uτ (60 % dip in Uτ) for 5 cycles 70 % Uτ (30 % dip in Uτ) for 25 cycles <5 % Uτ (>95 % dip in Uτ) for 5 sec	<5 % Uτ (>95 % dip in Uτ) for 0.5 cycle 40 % Uτ (60 % dip in Uτ) for 5 cycles 70 % Uτ (30 % dip in Uτ) for 25 cycles <5 % Uτ (>95 % dip in Uτ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the AR-6485 CW4 arthroscopy pump requires continued operation during power mains interruptions, it is recommended that the AR-6485 CW4 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-6485 CW4 arthroscopy pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AR-6485 CW4 arthroscopy pump should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Model AR-6485, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [3.5/V1]\sqrt{P}$ = 1.2 $\sqrt{P}$ $d = [3.5/V1]\sqrt{P}$ =1.2 $\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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-6485 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-6485

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 20 Guidance and Manufacturer's Statement – Recommend Separation Distance between portable and mobile RF communications equipment and the Model AR-6485

Recommended separation distances between portable and mobile RF communications equipment and the Model AR-6485

The Model AR-6485 Synergy Continuous Wave 4 arthroscopy pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model AR-6485 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model AR-6485 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

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