Continuous Wave III Arthroscopy Pump

AR-6475

User's Guide

The *Arthrex Continuous Wave III Arthroscopy Pump User's Guide* provides important information for the safe operation of all components of the Arthrex Continuous Wave III Arthroscopy Pump (Model AR-6475), including accessories. Read this *User's Guide* thoroughly prior to using this system and keep it in an easily accessible place for use by all operating personnel. Read and follow all safety warnings, cautions, and precautions.

U.S. Patent No. 5,520,638

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TABLE OF CONTENTS

List of Figures

List of Tables

1.0 Read This First!

1.1 *Important Symbols and Conventions*

The *Continuous Wave III Arthroscopy Pump User's Guide* identifies critical, important, and useful information using these symbols and conventions. Your familiarity with these symbols and conventions is required.

W A R N I N G !

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

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

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

[x] Square brackets that enclose a letter, a number, or a lower-case roman numeral reference a callout on a line drawing. Section 2.2, Product Features, includes line drawings of all products associated with the AR-6475. Each line drawing has its own callout system to identify important elements of each product.

1.2 *Shipping, Unpacking, and Warranty Information*

Prior to use in a surgical procedure, carefully unpack and inspect the components for any sign of damage that may have occurred during shipping. If shipping damage is suspected, notify Arthrex or any authorized Arthrex distributor immediately. Any such damage could compromise patient safety.

If shipping or first-installation damage is not reported within seven business days of receiving the device, the warranty could be rendered void. Refer also to our General Terms of Business.

Arthrex assumes a warranty to the first purchaser for a twelve month period with regard to defects or failure of its medical devices. All defective products covered by the warranty are repaired or replaced free of charge by Arthrex at their discretion. The warranty does not cover any damage caused by unlawful use or improper handling of a product.

The warranty becomes invalid when Arthrex products are changed in any way or repairs are performed by any party other than Arthrex.

Arthrex will answer any questions referring to the quality, reliability and/or shelf life of any product identified in this *User's Guide*.

1.3 *Important Safety Information*

W A R N I N G !

This device is to be used only under the supervision of a trained and licensed physician. This device should not be used by untrained personnel or used for indications other than those described in this *User's Guide*.

⚠ **U.S. Federal Law restricts this device to use only by or on order of a physician.**

⚠ **DO NOT—under any conditions or for any reason—remove the cover of the AR-6475.**

NOTE: Read this User's Guide thoroughly before attempting to operate the device and retain for future reference.

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

2.0 Product Description

2.1 *Functional Description and Intended Use*

The Arthrex AR-6475 Continuous Wave III Arthroscopy Pump is a safe, reliable, user-friendly system that maintains constant, non-pulsed control of intraarticular rinsing and distention pressure throughout all phases of an arthroscopic surgical procedure.

The AR-6475 includes:

- A universal input-grade switching power supply that allows the pump to function automatically at voltage ranges found worldwide;
- Improved displays that combine vacuum fluorescent and dot matrix displays for high contrast and visibility;
- A reprogrammable microcontroller with upgradeable software that supports multilingual messaging;
- Membrane switch overlays for user inputs and easier cleaning; and,

- A FLUSH function for providing elevated pressure to stop bleeding and flow rate to clear joint spaces quickly.

The AR-6475 is intended to provide continuous pulse-free flow that reacts immediately to changes in the intraarticular pressure so that joint distention can be sustained even under high shaver extraction volumes or secondary outflow. The user-defined settings for pressure and flow are adjustable through controls located on the console front panel or on the remote control.

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

1. *Main Pump Tubing Set only*. This tubing, when used alone, must be replaced after each patient.
2. *Main Pump Tubing Set and Extension Tubing combination*. The Main Pump Tubing Set can be reused for an entire surgical day, while the Extension Tubing must be replaced after each patient.
3. *ReDeuce™ Pump Tubing and ReDeuce™ Patient Tubing combination*. The ReDeuce™ Pump Tubing can be reused for an entire surgical day, while the ReDeuce™ Patient Tubing must be replaced after each surgical procedure. The ReDeuce™ system offers a higher flow rate than the Main Pump Tubing Set/Extension Tubing combination.

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

2.2 *Product Features*

2.2.1 Console: Front Panel

Figure 1uses 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

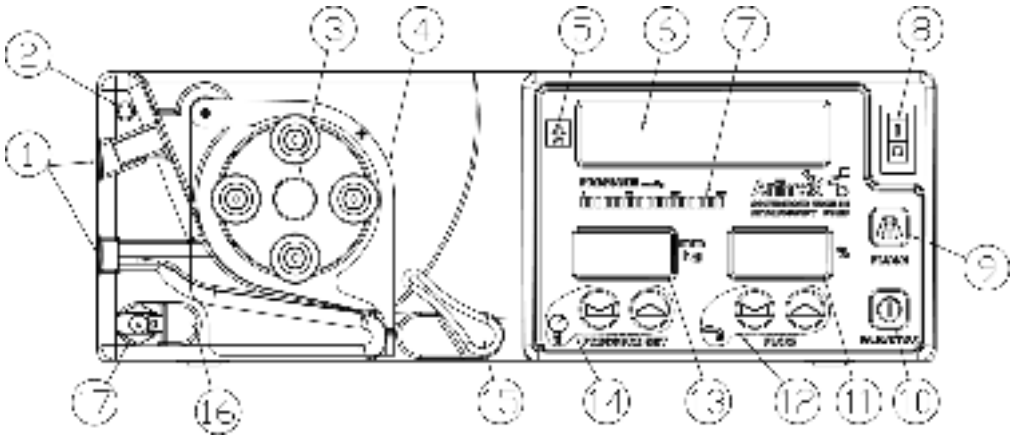


TABLE 1 FRONT PANEL ELEMENTS

ELEMENT NUMBER	ELEMENT NAME
1	Tubing IN Guide (beneath the Green dot)/ Tubing OUT Guide
2	Green dot (for orienting the Pump Tubing)
3	Roller assembly
4	Roller housing door
5	Type "BF" shock hazard symbol
6	Vacuum Fluorescent Display (VFD)
7	Measured pressure bar graph
8	AC mains power toggle switch
9	Activate/Deactivate FLUSH function button
10	Pump motor Enable/Disable button
11	Flow rate in percent
12	Flow buttons and symbol. Increase or decrease maximum fluid flow rate to the joint space by ten percent on a scale of ten to 100 percent.
13	Target distention pressure in mmHg
14	Pressure Set buttons and symbol. Increase or decrease target pressure in the joint space by one mmHg on a scale of zero to 120 mmHg.
15	Locking lever for roller housing door
16	Tubing sensor indicator LED. A steady green LED indicates that the tubing is connected properly. A flashing red LED indicates that the tubing is not present or that it is connected incorrectly.
17	Tubing sensor coupler

2.2.2 Console: Rear Panel

Figure 2 and 3 use an *alphabetic* callout system to identify the main elements of the console's rear panel for both new and old pump versions. These callouts are also listed and labeled in Table 2 and referenced throughout this *User's Guide*.

FIGURE 2 REAR PANEL OF CONSOLE (WITHOUT ACCESS PANEL)

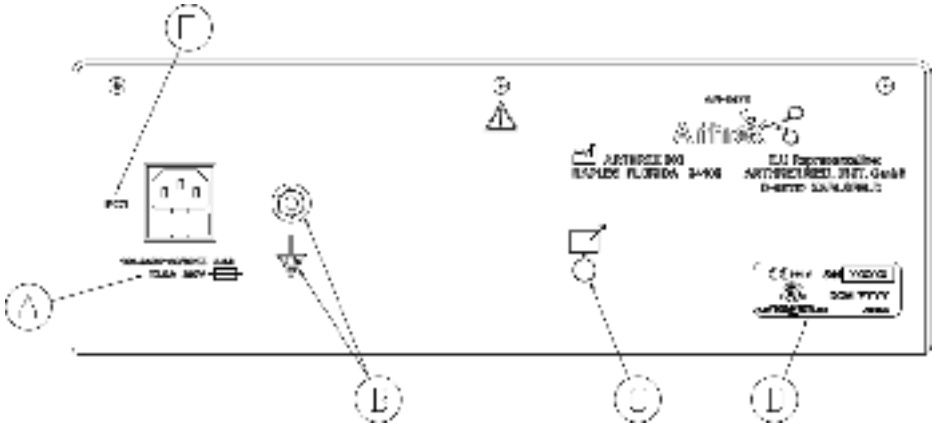


FIGURE 3 REAR PANEL OF CONSOLE (WITH ACCESS PANEL)

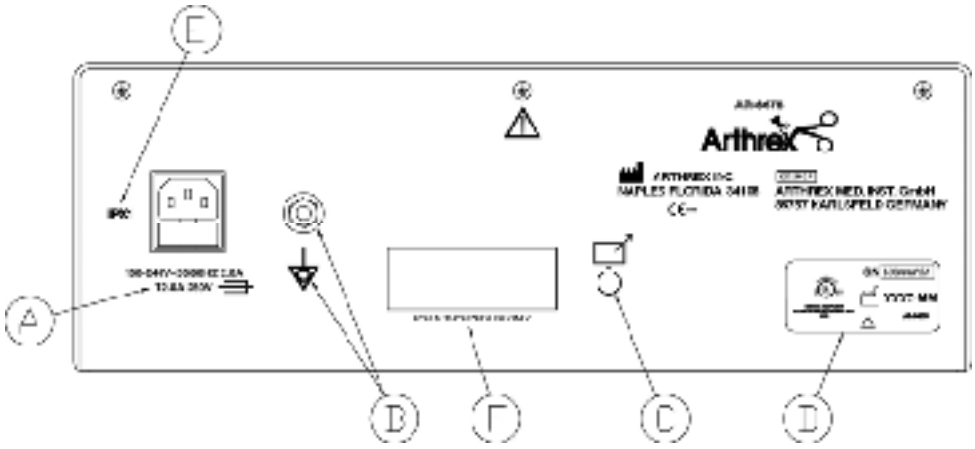


TABLE 2 REAR PANEL ELEMENTS

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

2.2.3 Vacuum Fluorescent Display (VFD): Status and Error Messages

The console's Vacuum Fluorescent Display (VFD) [6] conveys information about the status of the AR-6475 and the LEDs display pressure and flow settings in real time. Table 3 describes each message.

TABLE 3 VACUUM FLUORESCENT DISPLAY MESSAGES

MESSAGE	CAUSE	EXPLANATION
Arthrex AR-6475	Message displayed when the AC mains power is actuated.	Power on message display
Remote	Message displayed when the remote is plugged in and remains a secondary message.	Remote connected
Pressure Set +	Message displayed when the **PRESSURE SET** button is pressed.	Pressure set increase
Pressure Set -	Message displayed when the **PRESSURE SET** button is pressed.	Pressure set decrease
Flow Set +	Message displayed when the **FLOW** button is pressed.	Flow increase
Flow Set -	Message displayed when the **FLOW** button is pressed.	Flow decrease
Flush	Message displayed when the button is pressed for less than one second.	Flush feature enabled
*** Check Tube ***	Message displayed when no tubing is plugged into the Tubing Sensor Coupler [17].	Check tubing installation
*** Door Not Closed ***	Message displayed when the roller housing door [4] is not fully closed.	Roller housing door is not closed
Self Test V X.XX	Displayed prior to running a self-test.	Pump self-test
Power Supplies OK	Displayed after a successful power supply test.	Power supply test passed
*** Over Pressure ***	Displayed when the sensed pressure exceeds over-pressure software limit of 300 mmHg.	Software overpressure condition
Critical Failure	Displayed on the first line of the VFD if one if one of three conditions is met: **Failure Condition 1**: *** Power Failure *** Displayed on line two of the VFD if the power supply self-test fails when the pump is turned on. **Failure Condition 2: * OVP Detect Fail *** Displayed on line two of the VFD if the hardware overpressure diagnostic test fails when the pump is turned on. **Failure Condition 3**: *** Sensor Failure *** Displayed on line two of the VFD if the pump detects a problem with the pressure sensors.	Critical failure, cannot continue operation
*** Power Failure ***	Displayed on line two of the VFD if the power supply self-test fails when the pump is turned on.	Power supply test fails
*** OVP Detect Fail ***	Displayed on line two of the VFD if the hardware overpressure diagnostic test fails when the pump is turned on.	Hardware overpressure diagnostic fails
*** Sensor Failure ***	Displayed on line two of the VFD if the pump detects a problem with the pressure sensors.	Sensor failure

MESSAGE	CAUSE	EXPLANATION
*** Pressure Fault ***	Displayed when the pump is unable to reach a desired set pressure within a specific amount of time. This typically indicates improperly installed tubing set or a split in the tube from continuous use.	Insufficient measured pressure
Pump On	Displayed when the pump motor is running.	Motor on and running
Pump On/Flush	Displayed when the pump is in FLUSH mode.	Motor on and flushing
Pump Off	Displayed when the pump motor is deactivated.	Motor off
Pump Paused	Displayed when the pump is on and the measured pressure exceeds the target pressure.	Motor on but paused
Pump Paused/Flush	Displayed when the pump is in FLUSH mode and the measured pressure exceeds the flush pressure.	Pump flushing but paused

2.2.4 Measured Pressure Bar Graph

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

TABLE 4 MEASURED PRESSURE (±5%) READINGS IN BAR GRAPH

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

2.2.5 Tubing: Configurations

Figure 4 and 5 show the tubing combinations supported by the AR-6475. The following sections describe each configuration in more detail.

FIGURE 4 MAIN PUMP TUBING CONFIGURATION

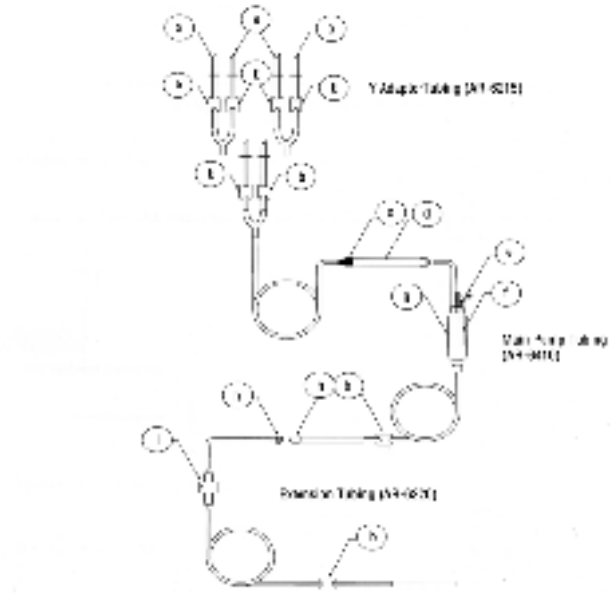


TABLE 5 ELEMENTS OF THE MAIN PUMP TUBING CONFIGURATION

ELEMENT	DESCRIPTION	TUBING SET
a	Bag spikes	Y-Adapter Tubing
b	Tubing clamps	Y-Adapter Tubing Main Pump Tubing Extension Tubing
c	Green connector	Main Pump Tubing
d	Tubing boot	Main Pump Tubing
e	Pressure line connector	Main Pump Tubing
f	Neoprene tube for sensing pressure fluctuations	Main Pump Tubing
g	Sensor chamber	Main Pump Tubing
h	Connector fittings	Main Pump Tubing Extension Tubing
i	Backflow check valve	Extension Tubing

FIGURE 5 REDEUCE™ TUBING CONFIGURATION

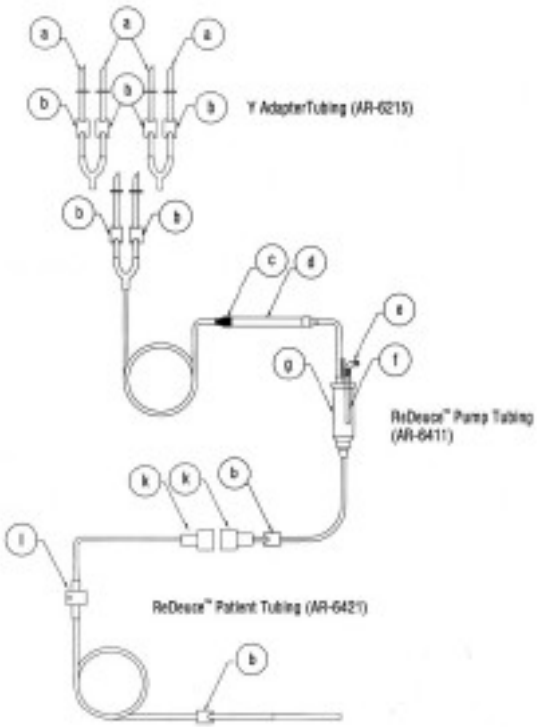


TABLE 6 ELEMENTS OF THE REDEUCE™ TUBING CONFIGURATION

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

2.2.6 Tubing: Main Pump Tubing Set

The Main Pump Tubing Set offers inflow/pressure measurement tubing that, if used alone, must be *completely discarded* following each surgical procedure. It has the following components in each set: bag spikes, drip chamber, flexible boot for pump rollers, and a Luer connector for a scope sheath or other inflow. The Main Pump Tubing is 13 feet (4.0 meters) in length.

NOTE: This User's Guide assumes that you are using either the Main Pump Tubing alone or in combination with the Extension Tubing, below. Refer to the Directions for Use that accompany each tubing set for specific information or contact your Arthrex representative.

2.2.7 Tubing: Extension Tubing System

The unique Extension Tubing System provides the economical option of using the Main Pump Tubing Set for an entire surgical day and replacing only the Extension Tubing Set after each individual surgery. The backflow check valve built into the Extension Tubing System prevents fluid backflow into the Main Pump Tubing, maintaining a closed sterile fluid environment during tubing replacements. The Extension Tubing is 8.5 feet (2.6 meters) in length.

2.2.8 Tubing: ReDeuce™ Pump Tubing

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

2.2.9 Tubing: ReDeuce™ Patient Tubing

The ReDeuce™ Patient Tubing must be used in the first arthroscopic procedure of the surgical day and replaced for each subsequent surgical procedure. It is used in conjunction with the ReDeuce™ Pump Tubing.

2.2.10 Tubing: Y-Adapter Tubing

The optional Y-Adapter Tubing can connect up to four irrigation bags. It can be used with either the Main Pump Tubing/Extension Tubing combination or the ReDeuce™ Pump Tubing/ReDeuce™ Patient Tubing combination.

2.2.11 Remote Control Unit (AR-6476)

The AR-6475 Continuous Wave III Arthroscopy Pump can be remotely controlled with the optional, autoclavable Remote Control (AR-6476). It provides the same controls present on the front panel of the pump, including flow rate and pressure adjustments, a FLUSH function, and the ability to

activate/deactivate the pump motor. The remote control is 9.8 feet (3 meters) in length.

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

Figure 6 uses a *lowercase roman numeral* callout system to identify the main elements on the remote control, which are listed and labeled in Table 7. These callouts are referenced throughout this *User's Guide*.

FIGURE 6 REMOTE CONTROL (AR-6476)

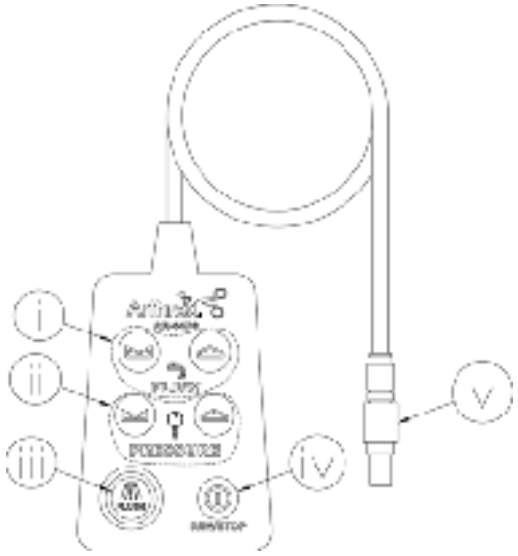


TABLE 7 REMOTE CONTROL ELEMENTS (AR-6476)

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

2.3 *Technical Specifications*

TABLE 8 CONTROL UNIT (AR-6475) SPECIFICATIONS

Width	14.5 inches (36.5 cm)
Height	5.0 inches (12.5 cm)
Depth	12 inches (30 cm)
Weight	18 pounds (8.2 kg)
Maximum Flow rate	1500 ml/minute minimum Measured in percent with a range of 10-100 percent in increments of 10 percent. Default flow rate at power-up is 100 percent
Pressure	0 - 120 mmHg Measured in mmHg in increments of 1 mmHg. Default pressure set at power-up is 0 mmHg
Overpressure control	300mmHg
Pressure control	Continuous pressure checking
Operating mode	Permanent
Water protection	IPX1
Main cable	10 A/250 V
Connector	CEE 7/7
Jack	IEC 320/C13
Power supply	100-240 V, 50/60 Hz, 2A
Fuse	T2.0A 250V
Cleaning	Surface cleaning with mild detergent
Sterilization	Surface disinfection with mild disinfectant

TABLE 9 AMBIENT CONDITIONS FOR OPERATION

Temperature	50° to 104°F (10° to 40°C)
Relative Humidity	0% to 100%, non-condensing
Air pressure	10.15 PSI (700 hPa) to 15.37 PSI (1060 hPa)

TABLE 10 AMBIENT CONDITIONS FOR STORAGE (IN SHIPPING PACKAGING)

Temperature	-40° to 158°F (-40° to +70°C)
Relative Humidity	0% to 100%, non-condensing

TABLE 11 REMOTE CONTROL (AR-6476) SPECIFICATIONS

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

3.0 Setup

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

3.1 *AC Power Safety Considerations*

The AR-6475 is powered by a medically rated universal AC input switching power supply, which allows the console to be connected to any local AC mains outlet provided that you use the appropriate plug and a reliable ground conductor.

Two power cords are supplied by default with the AR-6475: one for the electrical standards of the U.S. and one for the electrical standards of Germany. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.

NOTE: Extension cords must meet local electrical standards.

The console has been designed to meet power-saving guidelines. The console has an AC mains switch on the front panel [8]. When the AC mains switch is OFF, no electrical power is drawn by the console.

When the AC mains switch is ON, the console automatically executes a brief series of self-diagnostic tests. Upon successful completion of these tests, the console displays on the VFD [6] the name and model number, *Arthrex AR-6475*. If the tests discover a problem, an error message will be displayed on the VFD. Refer to Table 3 for a complete list of VFD Messages.

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

W A R N I N G !

If high-frequency devices are in use, or defibrillation of the patient is required, ensure that the device is not in direct contact with the patient.

3.2 *How to Determine if the AR-6475 is Causing Interference to Other Devices*

This device has passed testing for EMI / RFI radiation and susceptibility and EMC compatibility. However, if not set up and used in accordance with the instructions provided by Arthrex, this device may cause interference to other devices in the vicinity.

1. Power OFF the AC mains power switch [8] and then ON again. Try to correct the interference by following one or more of these measures:
2. Reorient or relocate the receiving device.
3. Increase the separation between devices.
4. Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.
5. Consult the manufacturer or field service technician for the receiving device for guidance.

3.3 *Basic Setup Procedure for the AR-6475*

NOTE: Section 4.0, Operation, explains how to use the pump.

1. Place the AR-6475 on a flat, dry surface, such as an arthroscopy equipment cart or a small instrument table.
2. Connect the female end of the power cord for the AR-6475 into the AC socket [A] and the male end to the facility AC mains supply. Turn on the AR-6475 [8].
3. Verify the status of the AR-6475 displayed in the VFD [6].
4. Connect the tubing in accordance with Section 3.4 or 3.5.
5. Close and lock the roller housing door [4, 15].
6. If applicable, attach the Remote Control [v, C].
7. Refer to Section 4.0, Operation, for specific information on how to operate the AR-6475, including pressure and flow settings.
8. Press the  button [10] to activate the pump motor.

3.4 *How to Set Up the Pump Tubing*

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

1. Remove the orange cap from the Pump Tubing and insert the connector fitting [e] of the Pump Tubing into the Tubing Sensor Coupler [17]. **This step must be completed first to ensure accurate pressure measurements.**
2. Release the locking lever [15] for the roller housing door [4] and open the door completely. Allow the door to rest against the stop. The roller mechanism is now exposed.
3. Place the green-collared section of the Pump Tubing [c] into the Tubing IN Guide [1] indicated by the green dot [2].
4. Guide the tubing boot [d] over the rollers and insert the output side of the tubing boot into the Tubing OUT Guide [1].

   NOTE: *The Pump Tubing is connected properly when the green connector [c] on the Main Pump Tubing is aligned with the green dot [2] on the front panel of the console.*

5. Close and lock the roller housing door.

   NOTE: The roller housing locking device must seat securely. If the door is not closed securely an internal safety switch prevents the AR-6475 from operating.

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

3.5 *How to Set Up the Two-Piece Tubing System*

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

W A R N I N G !

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

1. The surgical staff removes the sterile Extension or Patient Tubing from its sterile pack and hands the connector [h or k] for the Pump Tubing set to the circulating nurse.
2. The circulating nurse connects the two tubing systems together [h to h in Figure 4 or k to k in Figure 5].

3. Attach the sterile connector cap (supplied with each Extension or Patient Tubing set) to the patient-end of the Pump Tubing.

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

W A R N I N G !

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

3.6 *How to Change the Brightness of the VFD Display*

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

3.6.1 Pumps without a Rear Access Panel

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

   Prog Mode: BRIGHTNESS 1

3. Press the FLOW [12] or FLOW buttons to cycle through the brightness settings. Repeat until the desired brightness setting appears on the console's VFD display.
4. Press to set the brightness.
5. Power OFF the AR-6475.
6. Power ON the AR-6475. The new brightness setting is in use.

3.6.2 Pumps with a Rear Access Panel

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

   ADJUST INTENSITY

3. Press the FLOW [12] or FLOW buttons to cycle through the brightness settings. Repeat until the desired brightness setting appears on the console's VFD display.
4. Press to set the brightness.
5. Power OFF the AR-6475.
6. Power ON the AR-6475. The new brightness setting is in use.

3.7 *How to Change the Language Setting*

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

3.7.1 Pumps without a Rear Access Panel

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

PROG MODE: BRIGHTNESS 1

3. Press and release the button [10] to bypass the Brightness Adjustment Mode and switch to the Language Adjustment Mode. The following message will appear on the console's VFD display:
4. **PROG MODE: LANGUAGE ENGLISH**
1. Press the FLOW [12] or FLOW buttons to cycle through the language settings. Repeat until the desired language appears on the console's VFD display.
2. Press to set the language.
3. Power OFF the AR-6475.
4. Power ON the AR-6475. The new language setting is in use.

3.7.2 Pumps with a Rear Access Panel

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

ENGLISH

3. Press the FLOW [12] or FLOW buttons to cycle through the language settings. Repeat until the desired language appears on the console's VFD display.
4. Press to set the language.
5. Power OFF the AR-6475
6. Power ON the AR-6475. The new language setting is in use.

3.8 *How to Test the Power Supply Voltages and VFD*

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

Self Test V*x.x*

V*x.x* is the version of the firmware self test.

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

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

Power Supplies OK

3.9 *How to Verify Safe Setup and Performance before Use*

3.9.1 Pressure Reading on the Display

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

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

In contrast is the case of the **closed system** (100% impermeable joint and no egress of water whatsoever via the portals; occurs, for example, at a pressure measurement at the end of the applied part.

A dynamic pressure arises here which is increased by a factor of 2.2 (at a setting of 50 mmHg there is thus a max. of 110 mmHg). The pump stops when this value is reached.

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

3.9.2 Pressure Verification Procedure for the AR-6475 Arthroscopy Pump

Pressure verification of the AR-6475 is accomplished in the following manner. For best results, a "quick tips" section follows the procedural information.

1. Set up the AR-6475 as specified on the Directions For Use card contained in the tubing packaging, or as specified in the Operating Instruction Manual on pages 18 and 19.
2. Set the FLOW setting to 10% using either the front panel controls or the AR-6476 Autoclavable Remote Control. Running the pump at a slower flow rate increases accuracy of the pressure meter. The PRESSURE settings will vary throughout the test but should initially be set at 35 mmHg.
3. Prime the tubing set by turning on the pump and running fluid through the tubing until a steady flow of water exits the end of the tubing. Stop the pump by closing the clamp.
4. Attach a pressure meter to the outflow luer fitting and open the clamp. The meter should have the capability to measure up to 300 mmHg. Readings of the meter should be as follows:

Pressure Set (mmHg)	Meter Display (± 10%)
35	77
50	110
75	165
100	220
120	264

The "Pressure Set" figures shown above are arbitrary settings for information only. Recommended test settings are 35 mmHg and 75 mmHg. These two settings cover the lower and upper range of the most commonly used pressures.

As this is a static pressure reading, it is possible for the momentum of the rollers to create a higher pressure than the allowable limit, especially when the test is performed with a high flow rate. The AR-6475 was designed to maintain an average intra-articular pressure equal to the set pressure on the pump face. Without allowing an outflow, as is the case with a static test, an average pressure reading is not possible.

To obtain the best test results, please consider the following tips:

1. Use a new tubing to insure that it is at normal atmospheric pressure before the testing.
2. Follow the pump set-up procedures carefully. This will also prevent pressure from being inadvertently created within the tubing before your test begins.
3. Use the lowest flow setting (10%) when performing the test to minimize the roller momentum.
4. Start at the lowest test pressure setting and increase it to perform additional tests. If the test is started high and then lowered, the pump will not reduce its pressure, and the reading on the meter will remain the same.
5. Use reasonable pressure settings for your test. Most arthroscopies are performed at pressures between 35 and 75 mmHg.

3.9.3 Abnormal Operation

The AR-6475 employs a robust 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 in the VFD [6]. See Table 3 for a complete list of VFD messages and Section 8.0 for troubleshooting information.

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

3.9.4 Overpressure Sensing

The sensing circuitry in the AR-6475 measures the pressure of the fluid in the tubing. The overpressure alarm can be activated when the flow is abruptly interrupted or the joint is suddenly positioned in a way which reduces the joint capsule volume (e.g., bending the knee joint to the "Figure 4" position).

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

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

3.9.5 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.

3.9.6 Tubing Sensor Coupler

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

W A R N I N G !

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

4.0 Operation

There are two modes of operation for the AR-6475: Normal mode and FLUSH mode. Users of this device are encouraged to contact their Arthrex representatives if, in their professional judgment, they require a more comprehensive surgical technique.

4.1 *Initial Pressure Settings*

W A R N I N G !

The safety and effectiveness of the AR-6475 is verified and documented; however, the AR-6475 must be used with an awareness of the risk of extra-articular edemas for patients with pathologically changed articular capsules and for procedures involving an opening of the capsule (e.g. lateral release).

Slight swellings are complications which 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 therefore of the utmost importance that the surgeon monitors both the system and the patient closely whilst 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.

Table 12 specifies the initial pressure settings that are recommended for surgery. The ideal intraarticular pressure depends on the indications for the arthroscopic procedure, bleeding tendency, and the possibility of ischemia.

TABLE 12 INITIAL PRESSURE SETTINGS

Knee arthroscopy	35 mmHg
Shoulder arthroscopy	50 mmHg
Small joint arthroscopy	35 mmHg

All settings are based on the use of a high-flow sheath or secondary inflow portal (suprapatellar, etc.). Normally, pressure settings of 10 mmHg above the patient's diastolic pressure are adequate to control capillary bleeding.

To obtain a clear fluid environment, slowly increase distention pressure beginning with the initial pressure settings in Table 12.

4.2 How to Operate the AR-6475 in Normal Mode

W A R N I N G !

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

1. After adjusting the required pressure using the Pressure Set buttons [14 or ii], remove the cap from the patient end of the tubing.
2. Open all appropriate tubing clamps.
3. Activate the pump motor by pressing  [10 or iv].
4. Fill the entire length of the tubing with fluid to remove any air bubbles.

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

5. After the air has been purged from the tubing, close the clamp at the patient end of the tubing. The rollers [3] should stop turning. This is a safety check to ensure that the sensor system is working properly.

   - If the rollers do not stop, ensure clamp is firmly closed.
   - If the rollers turn continuously, the connector fitting [e] may not be functioning properly. Replace the Pump Tubing.

6. Connect the tubing to the inflow cannula.

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

7. Open the clamp on the tubing to release the flow.

   Once the set pressure is reached, the pump will reduce flow to maintain the set pressure. When the pressure drops, the flow automatically increases until the set pressure is achieved. If the set pressure cannot be attained, (i.e. no fluid restriction at the end of distal-end of tubing) flow will not exceed the user setting [11].

8. When the procedure is completed, close all clamps and disable the pump motor [10].

4.3 *How to Operate the AR-6475 in FLUSH Mode*

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

W A R N I N G !

User programmed "Pressure Set" values are increased by *fifty percent to a maximum of 120 mmHg* during the FLUSH function. Exercise caution to avoid injury to the patient.

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

   Pump On/Flush

2. Press and hold the  button for continuous FLUSH operation. The FLUSH function only operates while the button is pressed. When in FLUSH mode, the pump maximum flow rate increases to 100 percent and the pressure increases by fifty percent to a maximum of 120 mmHg.

   Release the  button [9 or iii] to disable this function and return to Normal Mode with the pre-FLUSH pressure and flow settings.

5.0 Cleaning and Sterilization

5.1 *Console (AR-6475)*

The AR-6475 is provided ***non-sterile*** and should not be sterilized.

The AR-6475 console can be cleaned/disinfected using commercially available surfactants/surface disinfectants. Always comply with the instructions issued by the manufacturer of the surfactant/disinfectant. The AR-6475 must not be submersed in any liquid.

⚠ **NEVER use liquid to clean the remote control connector contacts on the rear panel of the pump. Remove dust regularly with dry compressed air.**

5.2 *Remote Control (AR-6476)*

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

The Remote Control can be autoclaved for sterilization.

Gravity displacement cycles:

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

250° F (121° C): exposure time 60 minutes

Prevacuum cycle:

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

Sterilizers vary in design and performance characteristics. Cycle parameters and load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled after being removed from the sterilizer. Do not touch the device during the cooling process. Do not place the device on a cold surface or immerse it in a cold fluid.

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

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

5.3 *Tubing*

W A R N I N G !

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

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

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

6.0 Maintenance

Other than keeping the console and remote control clean (see Section 5.0), there is *no recommended maintenance schedule*. If the AR-6475 should malfunction, contact an Arthrex representative or Arthrex Technical Support.

7.0 Technical Support

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

7.1 *How to Display the Software Version*

Technical Support may request the software version of the pump. These instructions explain how to display the software version.

1. Power OFF the AC mains power switch [8] on the AR-6475.
2. While pressing the FLOW button [12], power ON the AC mains power switch. The software version of the AR-6475 will be displayed on the VFD [6].

8.0 Troubleshooting

Arthrex Technical Support should be informed immediately in the event of any damage or malfunction of the equipment. Attempt the remedies listed in Table 13 *in the order in which they are presented*.

TABLE 13 COMMON PROBLEMS AND REMEDIES

PROBLEM	SOLUTION
*** Check Tube ***	1. Tubing sensor indicator not seated. 2. Ensure that the tubing pressure plug is seated completely. 3. Change tubing. 4. Return to Arthrex for repair.
Console fails Self Diagnostic Test	1. Ensure no tubing is connected to the pump during power on sequence. 2. Return to Arthrex for repair.
Console won't power up	1. Check AC mains power cord. 2. Try alternate power outlet. 3. Check AC mains fuses. 4. Return to Arthrex for repair.
Distention liquid bloody or cloudy	1. Increase outflow. 2. Increase pressure.
Doesn't pump when activated	1. Open all tubing clamps and shut-off valves. 2. Ensure actual pressure is below target pressure. 3. Check if the tubing is pinched, kinked, or blocked. 4. Check whether the pressure sensor plug is seated completely and correctly. 5. Return to Arthrex for repair.
*** Door Not Closed ***	1. Roller Housing not secured – ensure locking lever is properly secured. 2. Return to Arthrex for repair.
Inadequate pressure	1. Increase pressure. 2. Reduce outflow. 3. Use high-flow cannulas.
No (or inadequate) flow	1. Check that all tubing clamps are open. 2. Check the settings for flow and pressure. 3. Check if the tubing is pinched, kinked or blocked. 4. Secure the roller housing door. 5. Check that tubing seats correctly over the rollers. 6. Verify use of high-flow cannulas. 7. If failure remains, return to Arthrex for repair.
*** Overpressure ***	1. Increase outflow. 2. Manipulate joint to stress-free position.
*** Pressure Fault ***	1. Ensure adequate fluid supply. 2. Decrease outflow. 3. Check tubing for damaged and if it is pinched, kinked or blocked. 4. Check tubing for proper connections. 5. Replace tubing. 6. If failure remains, return to Arthrex for repair.

9.0 Repair Policy

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

10.0 Contact Information

Arthrex, Inc.
Naples, Florida 34108-1945 USA
Tel: +1 239-643-5553
Fax: +1 239-643-6218
Toll-Free Technical Support: +1 888 420-9393, Monday through Friday, 9:00 AM – 5:00 PM ET.
Website: www.arthrex.com

EC REP

Arthrex Med. Inst. GmbH
85757 Karlsfeld, Germany
Tel: +1 49 81 31 59 57 29 0
Fax: +1 49 81 31 59 57 63 1
Website: www.arthrex.de

10.1 *Compliance Information*

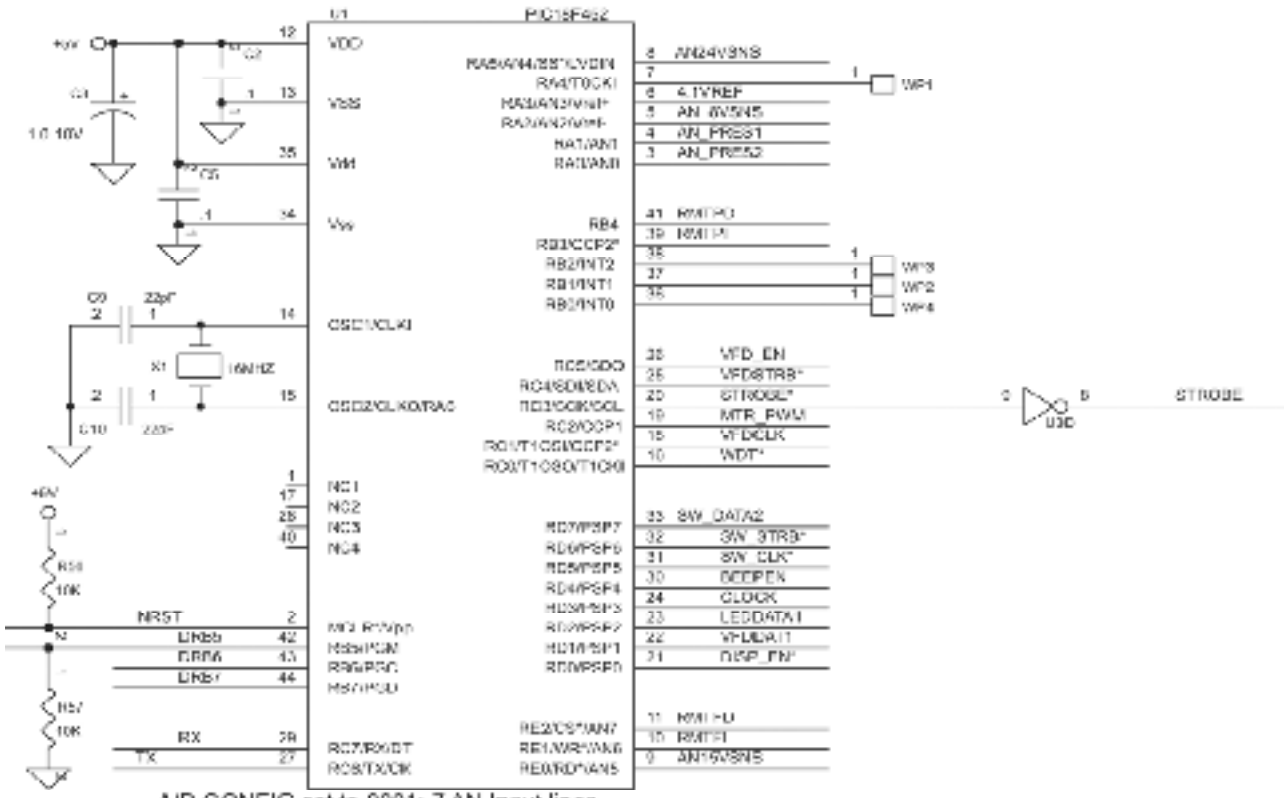
The Continuous Wave III Arthroscopy Pump (AR-6475) is designed and tested in accordance with 60601-1.
According to 60601 this device is Type BF, Class 1, IPX1 rating.
According to MDD93/42/EEC, Annex IX, Rule 11, this device is classified as a Class IIa device.
EN-55011B (EMC 89/336/CEE): Emission Standards
IEC-60601-1 (73/23/CEE): Medical electrical equipment, General Requirements for Safety
UL 544: Standard for Safety, Medical and Dental Equipment, being replaced by UL-2601-1
UL 2601-1: Medical Electrical Equipment, General Requirements, US
CUL-2601.1: Medical Electrical Equipment, General Requirements, Canada

10.2 *Related Documents*

LAI6302, *Pump Stand and Assembly*
LM0602, *Arthrex Continuous Wave III Arthroscopy Pump – Set Up and Operation and Troubleshooting*
AR-6475 Block Diagrams

Appendix A: Block Diagrams for AR-6475 without a Rear Access Panel

Diagram 1: Microcontroller



A/D CONFIG set to 0001: 7 AN Input lines

Pins 3, 4, 5, 8, 9, 10, 11; 1 Vref Pin 6

Diagram 2: DC Power

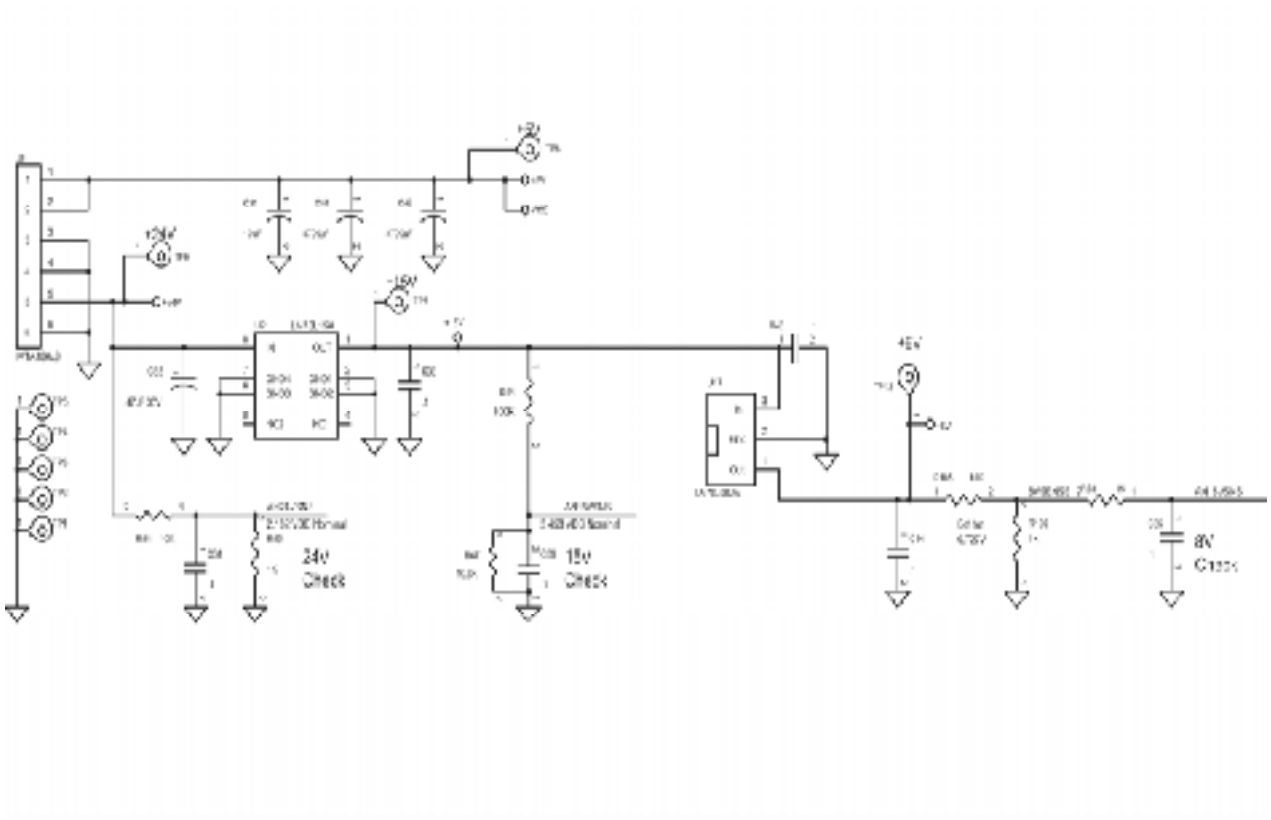


Diagram 3: Pressure Display

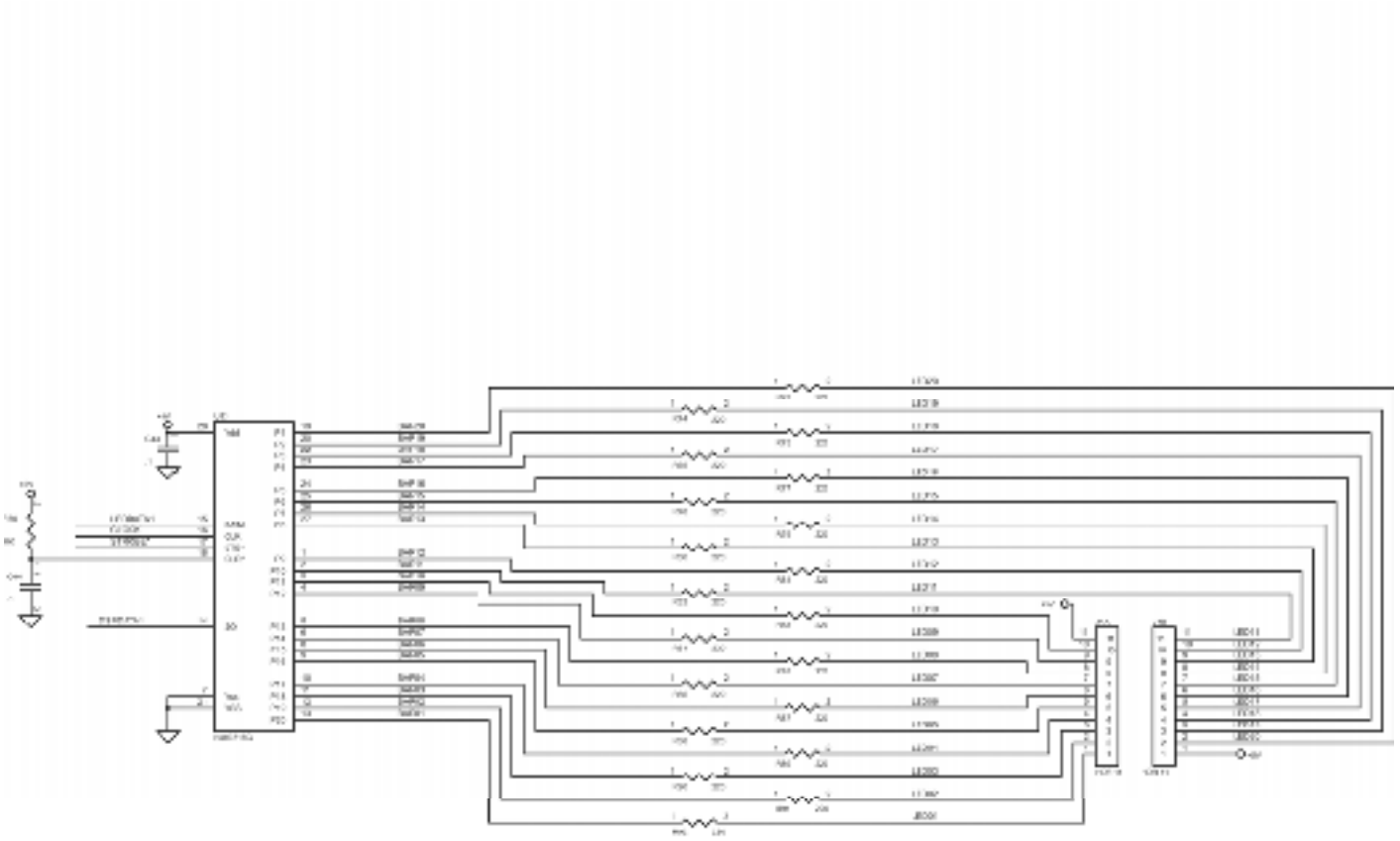


Diagram 4: VFD Outputs

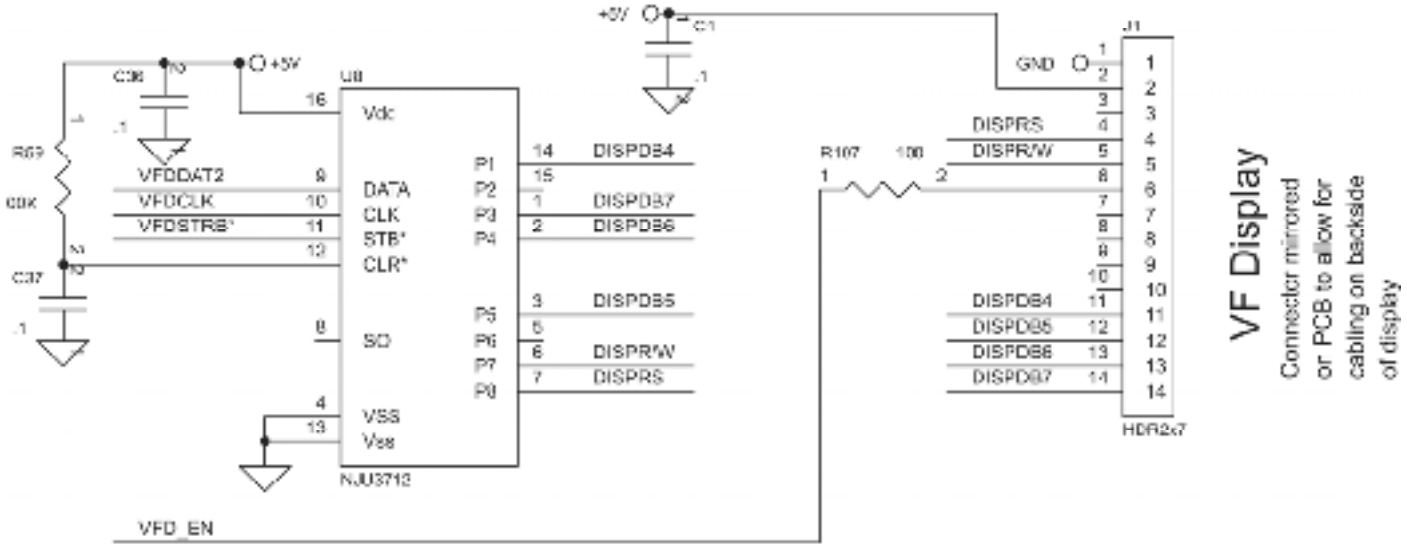


Diagram 5: Motor Drive, Discrete Outputs, Switch Registers, and Remote Interface

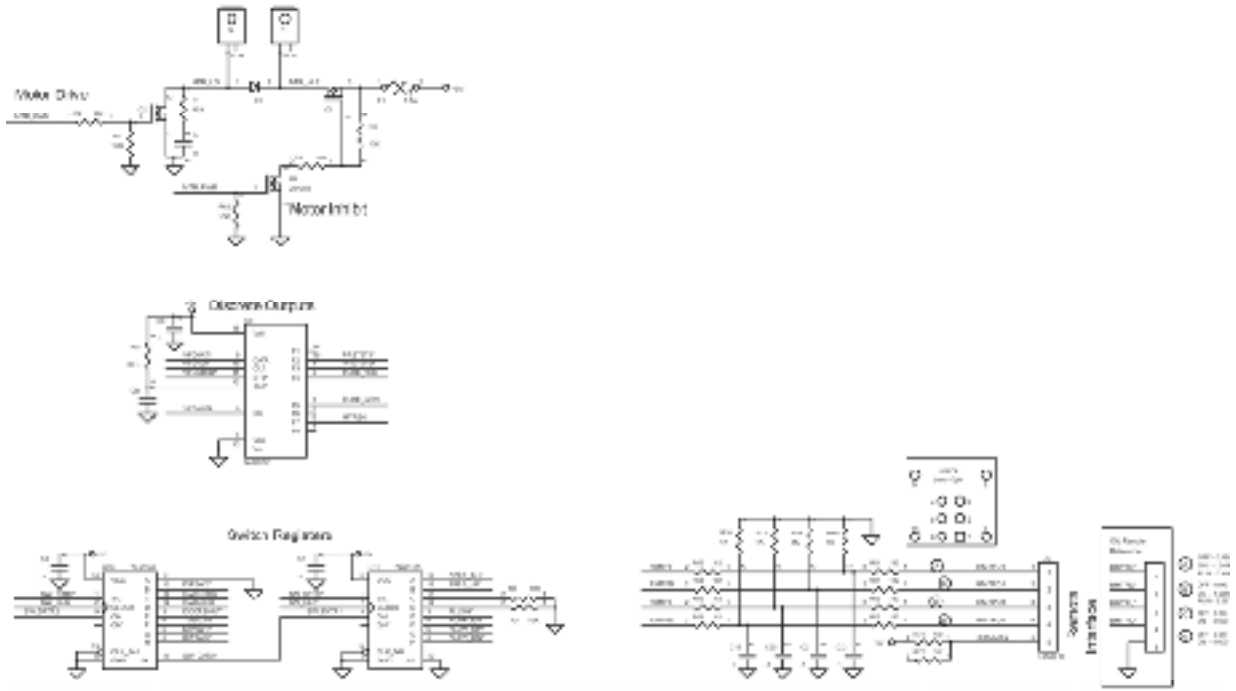


Diagram 6: Sensor Test, Failure and Overpressure Detect

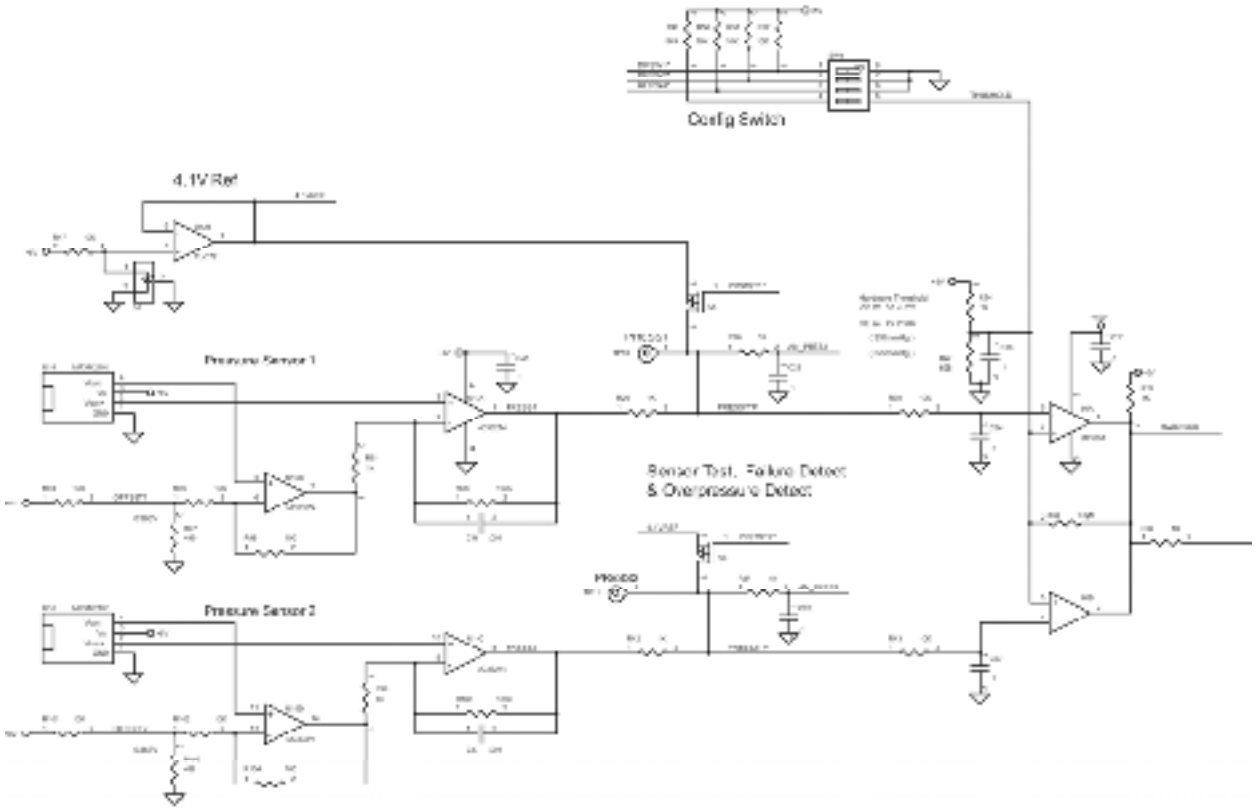


Diagram 7: Hardware Failsafe

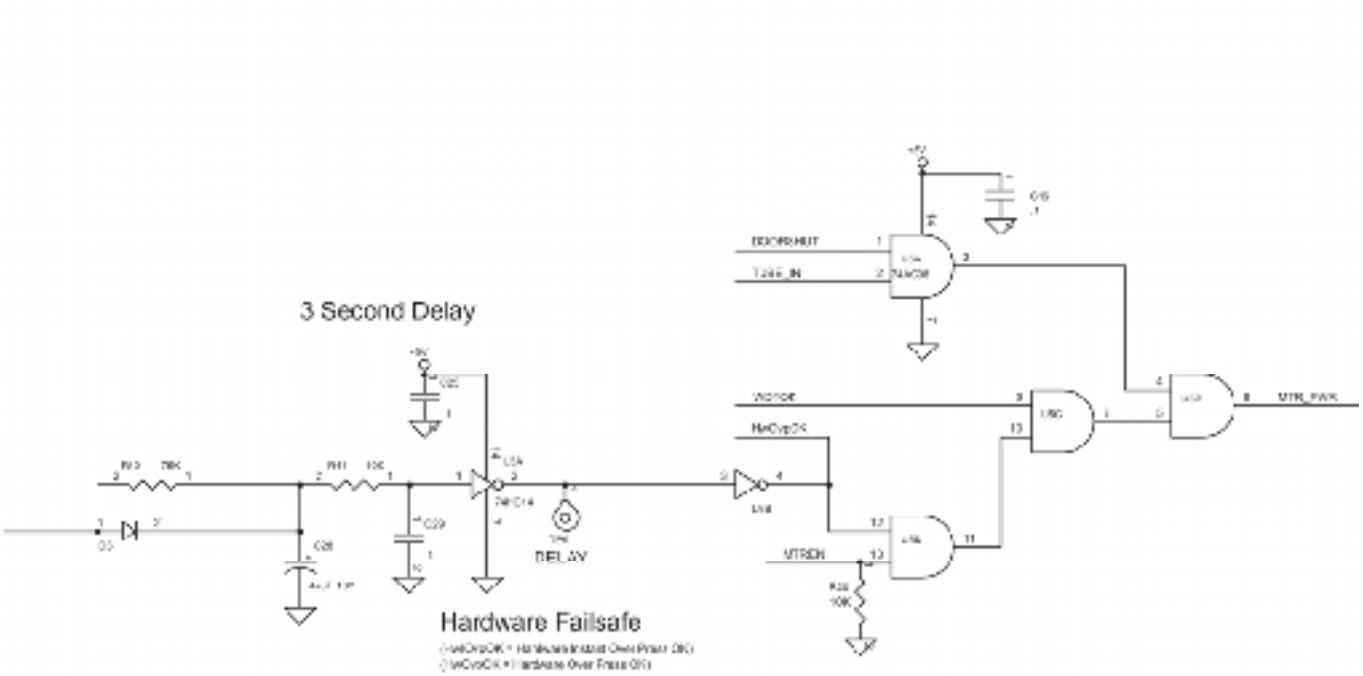


Diagram 8: Communication

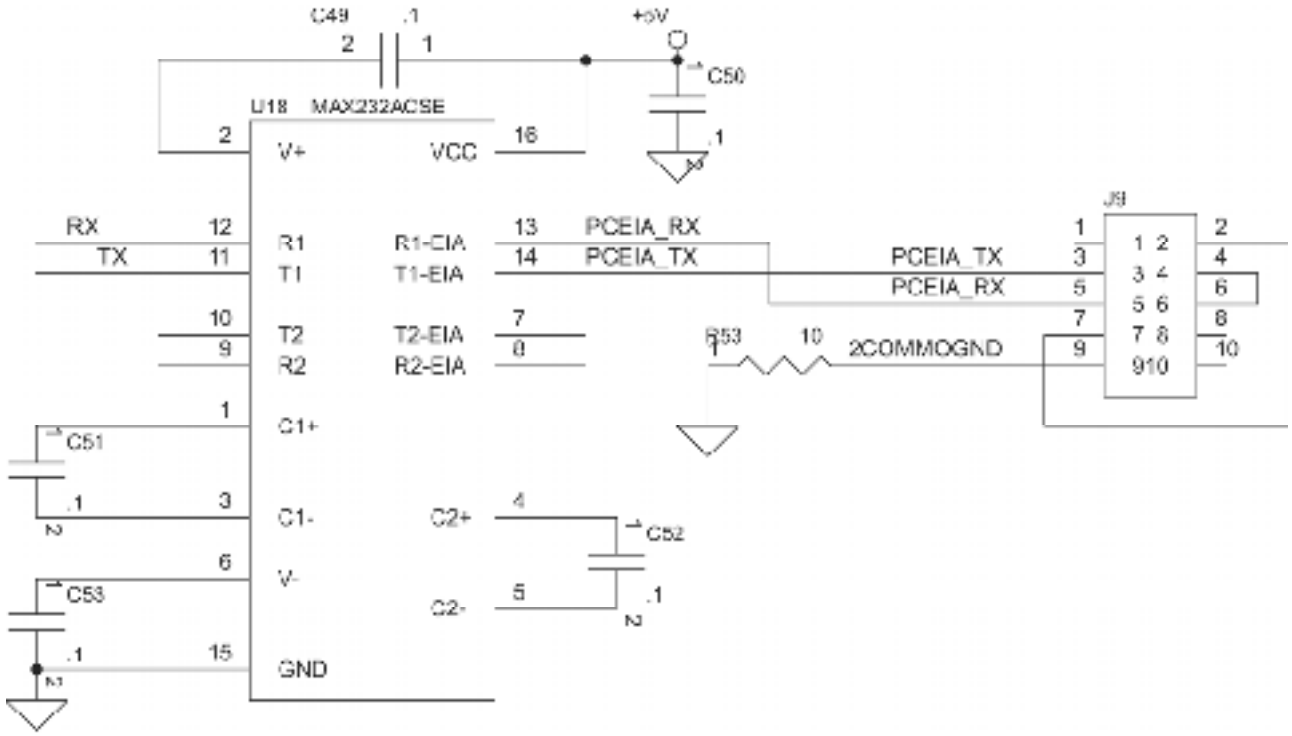
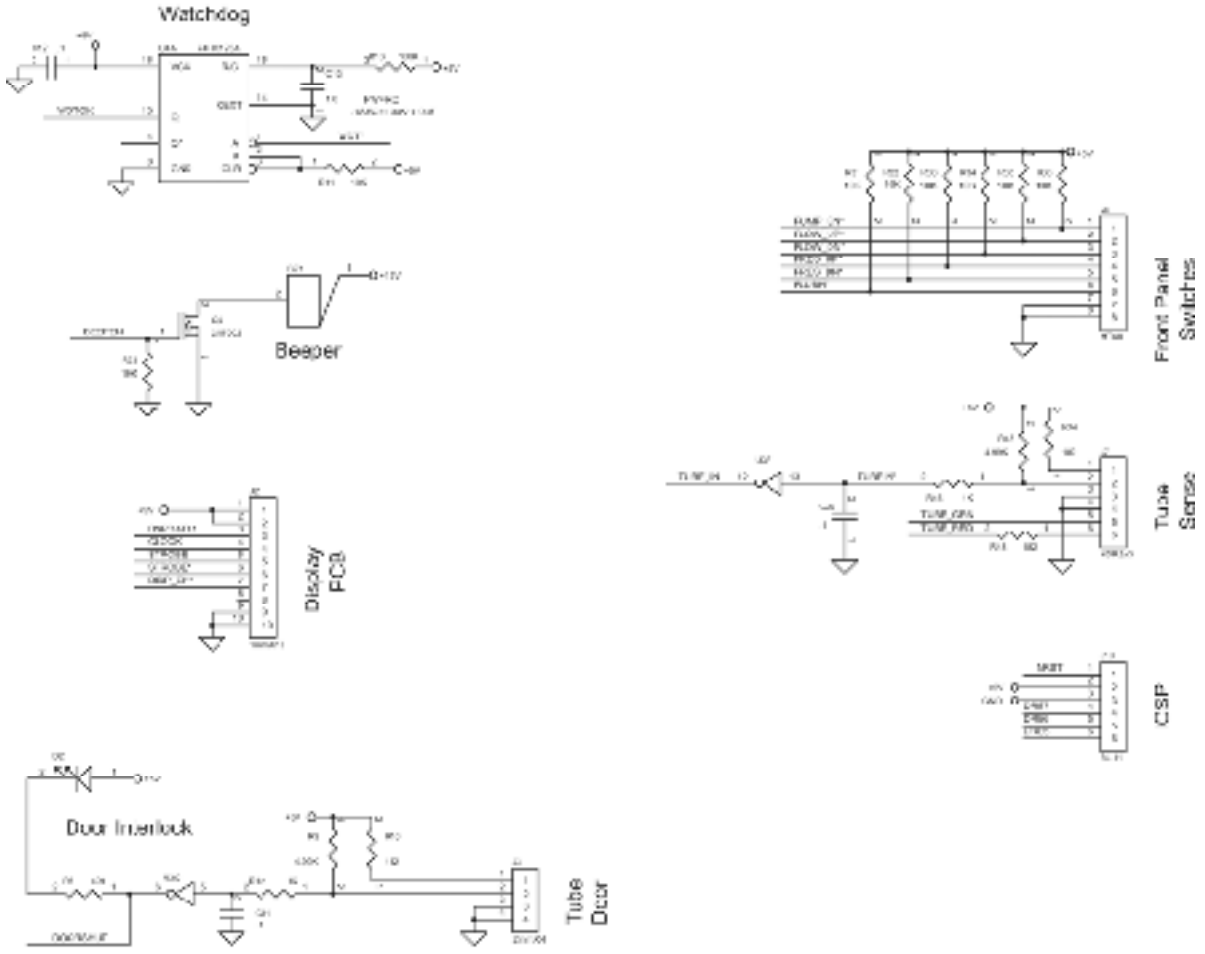


Diagram 9: Watchdog, Beeper, Display PCB, Door Interlock, Front Panel Switches, Tube Sense, ICSP



Appendix B: Block Diagrams for AR-6475 with a Rear Access Panel

Diagram 1: Microcontroller

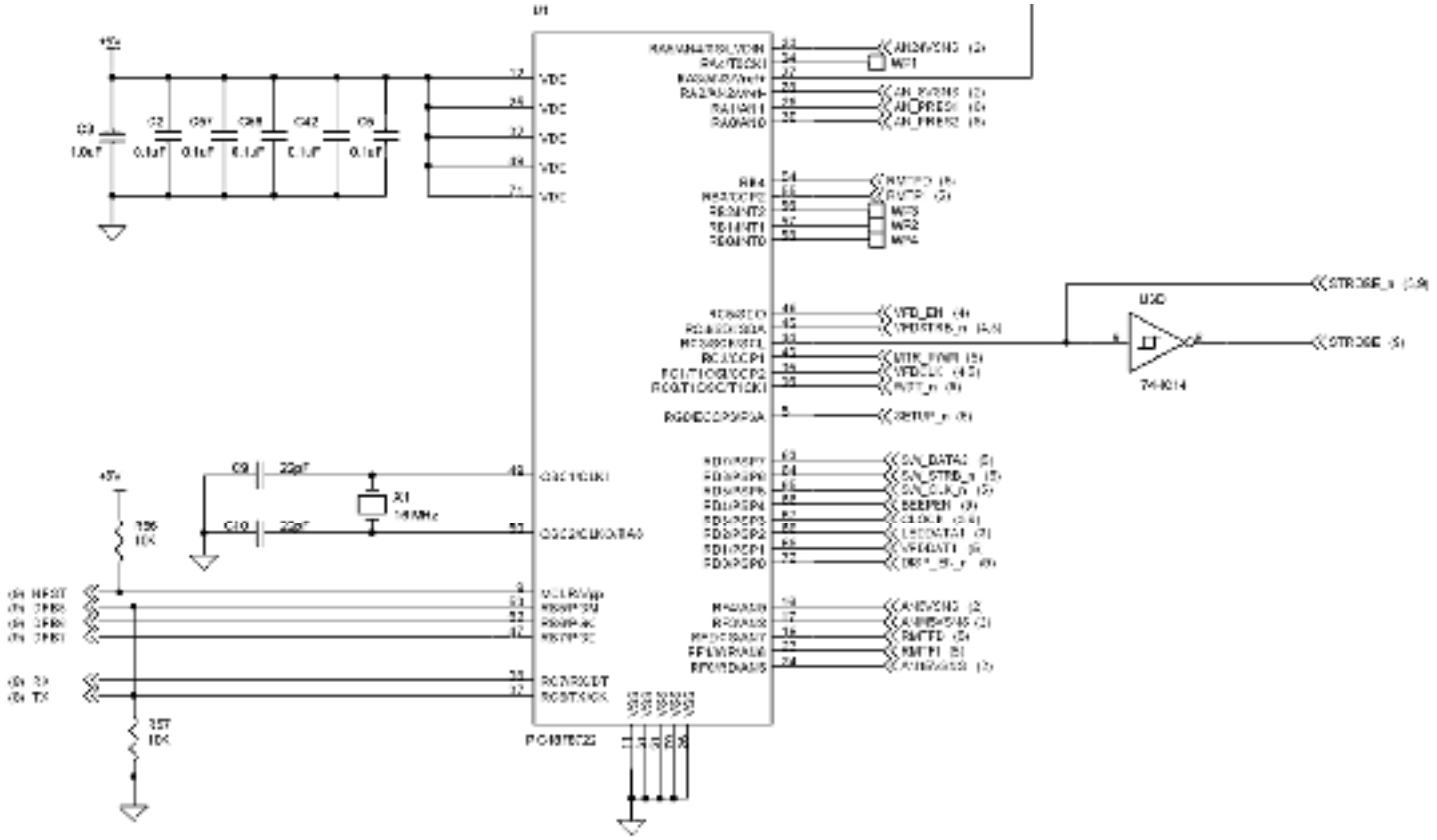


Diagram 2: Power

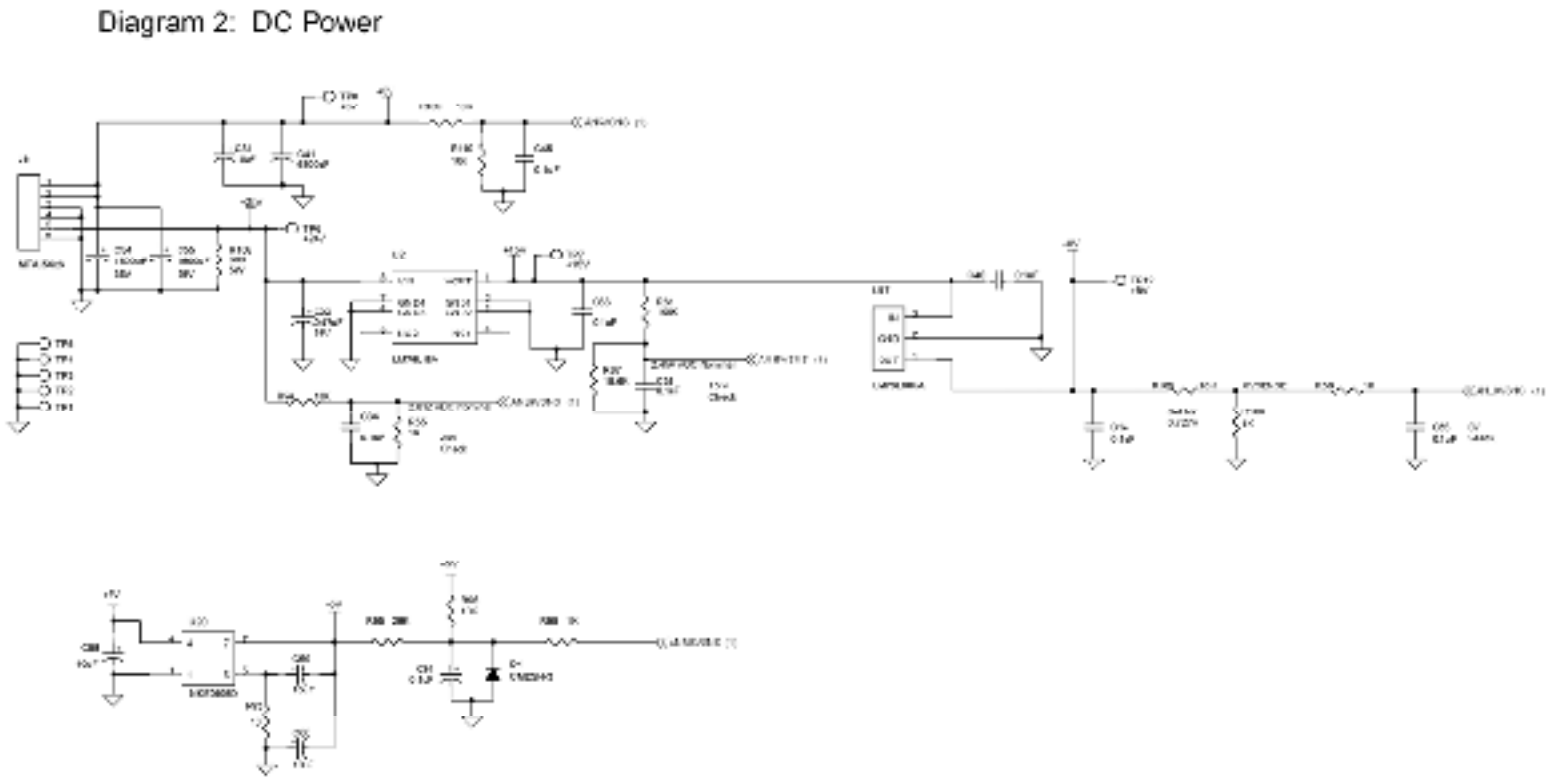


Diagram 3: Pressure Display

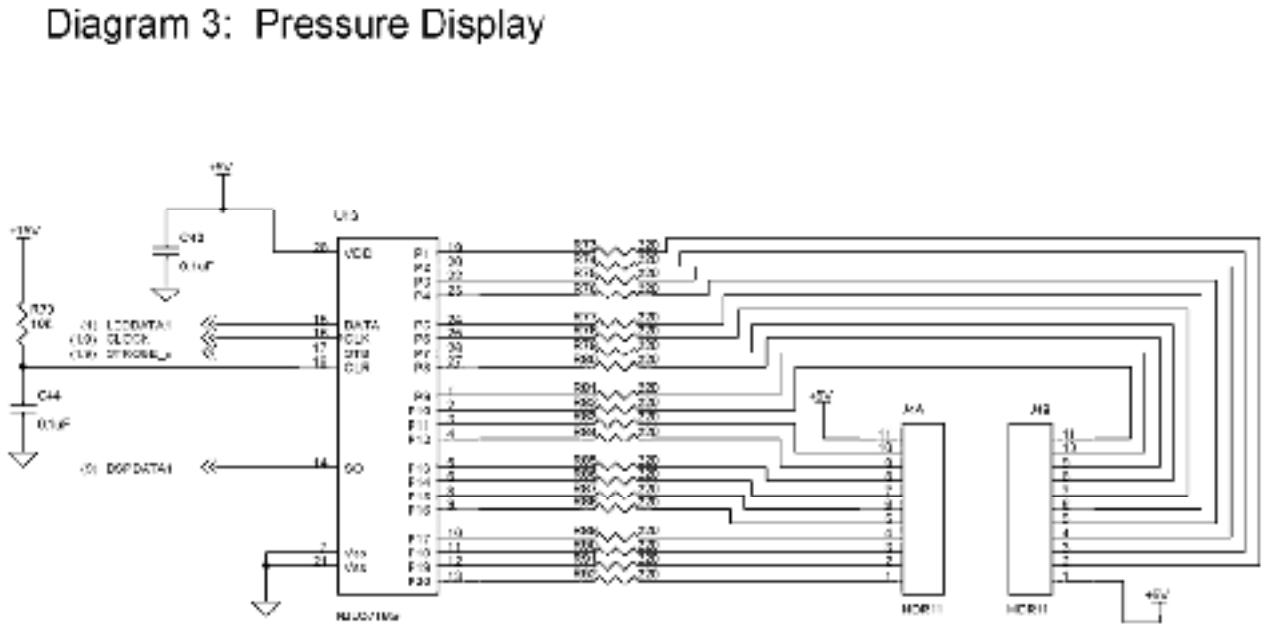


Diagram 4: VFD Outputs

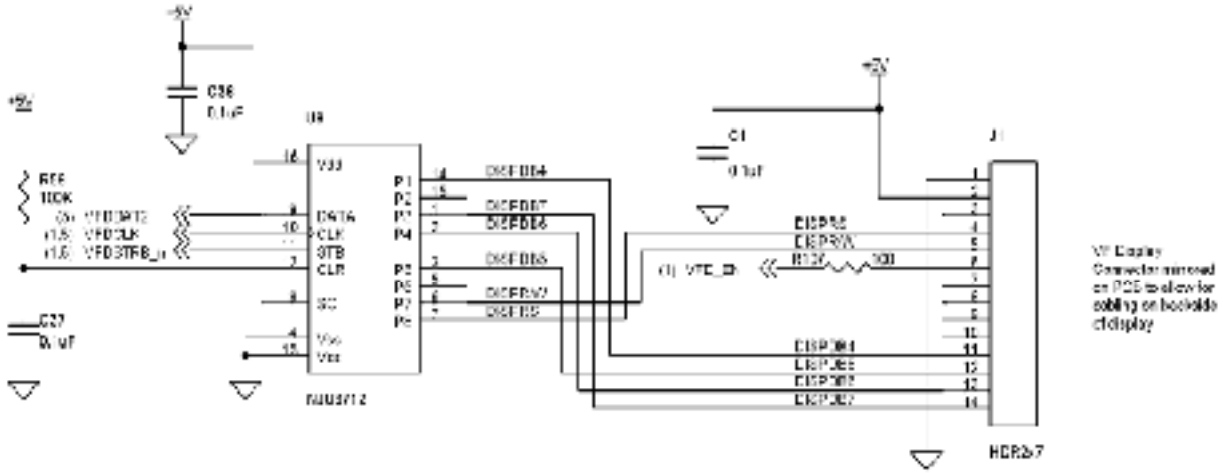


Diagram 5: Motor Drive, Discrete Outputs, Switch Registers, and Remote Interface

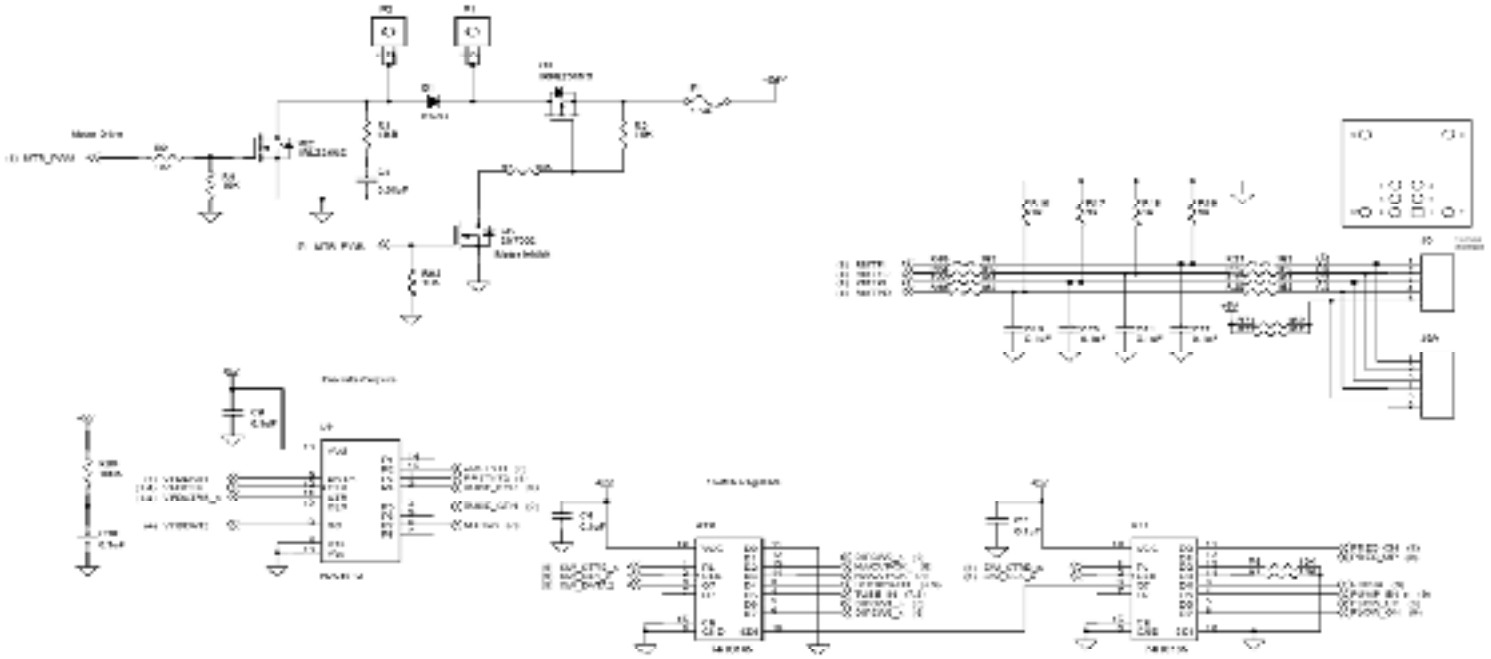


Diagram 6: Sensor Test, Failure and Overpressure Detect

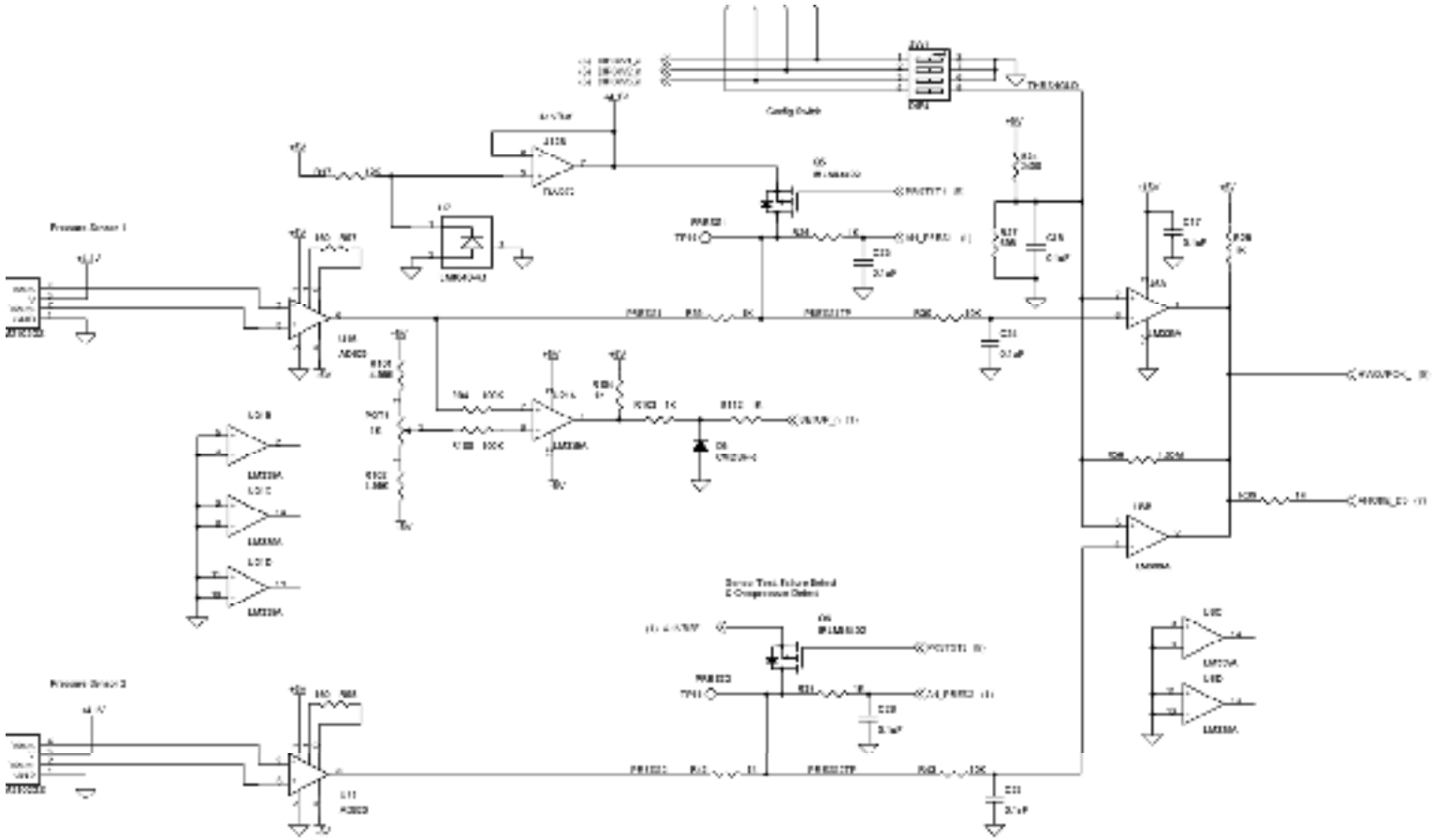


Diagram 7: Hardware Failsafe

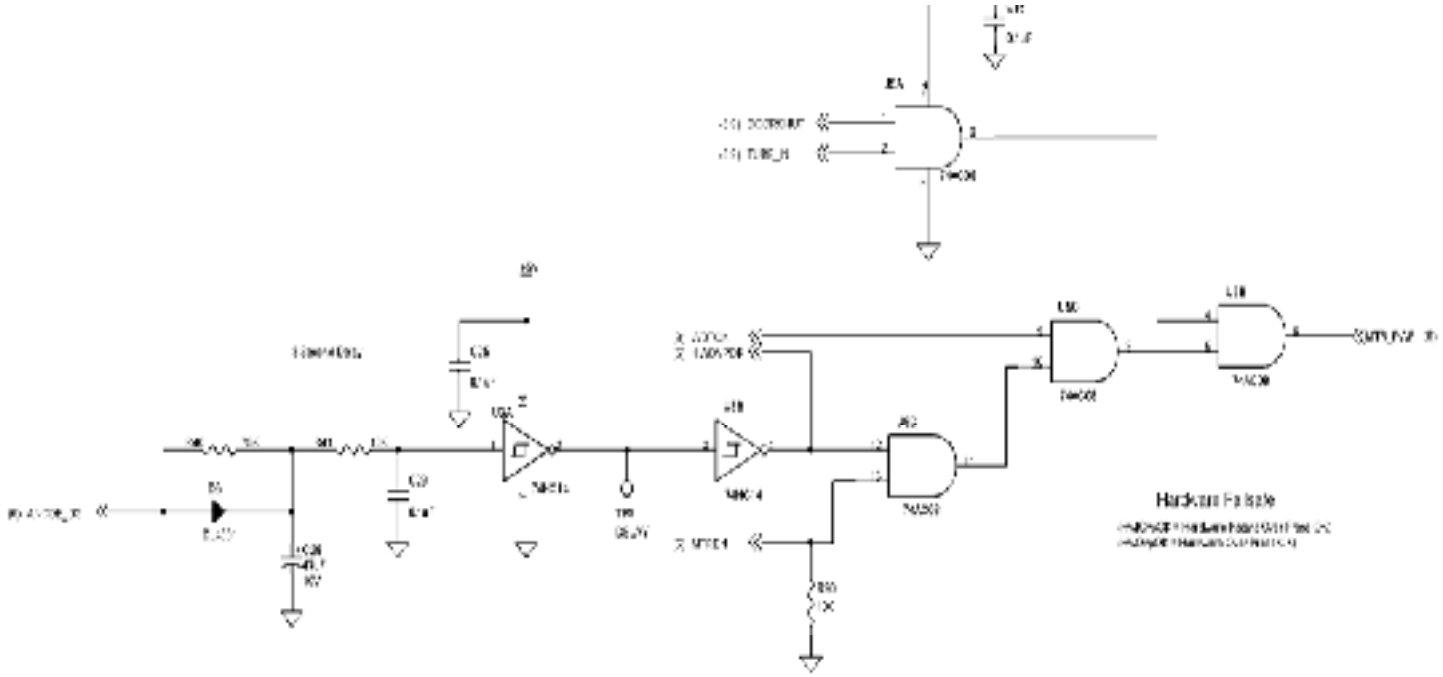


Diagram 8: Communication

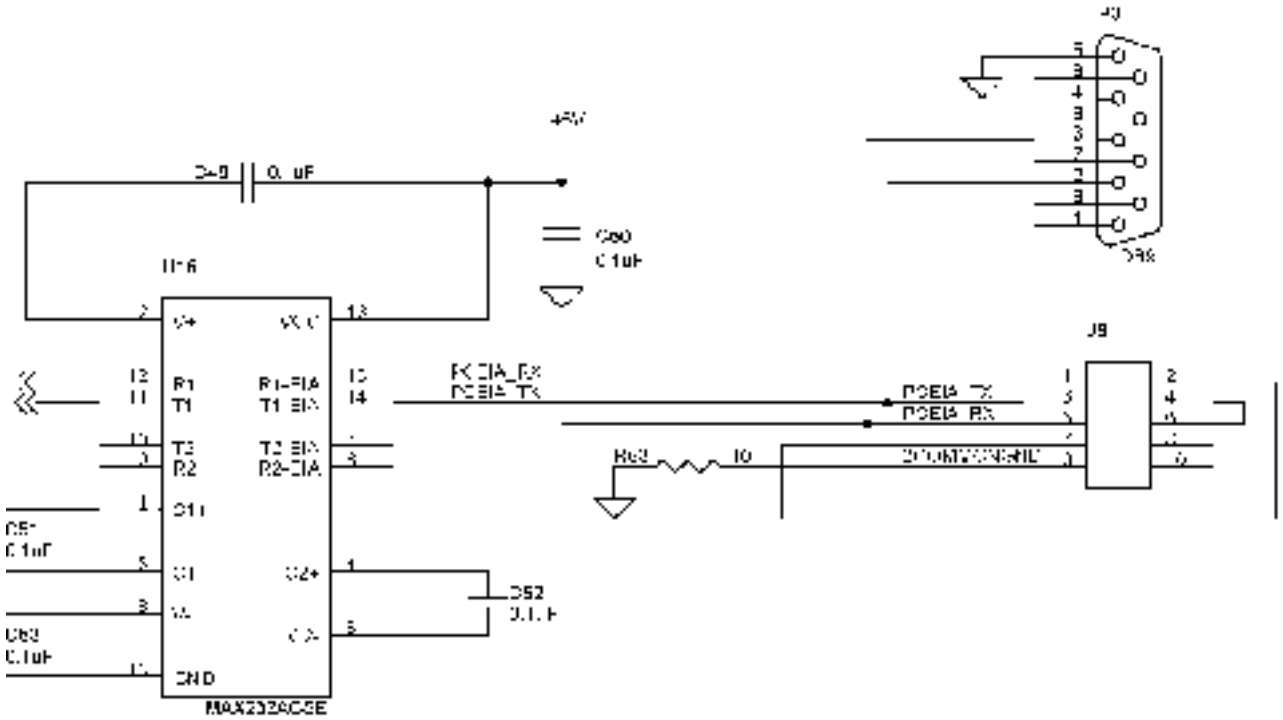


Diagram 9: Watchdog, Beeper, Display PCB, Door Interlock, Front Panel Switches, Tube Sense, ICSP

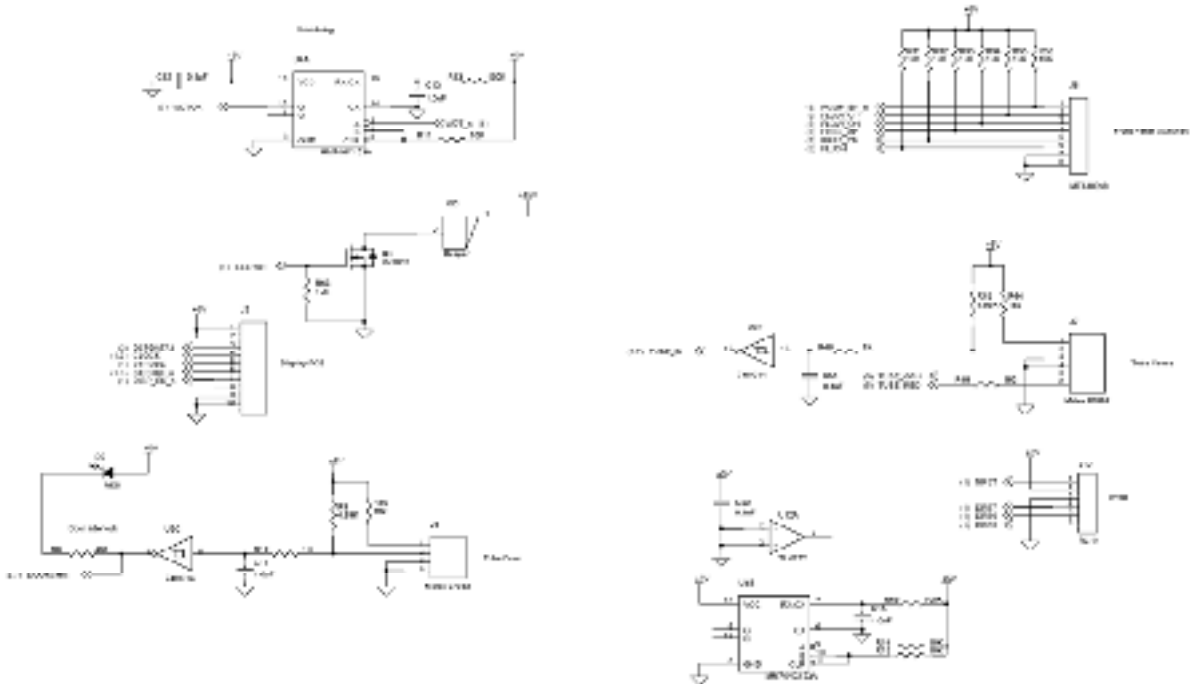


Diagram 10: LED Display