

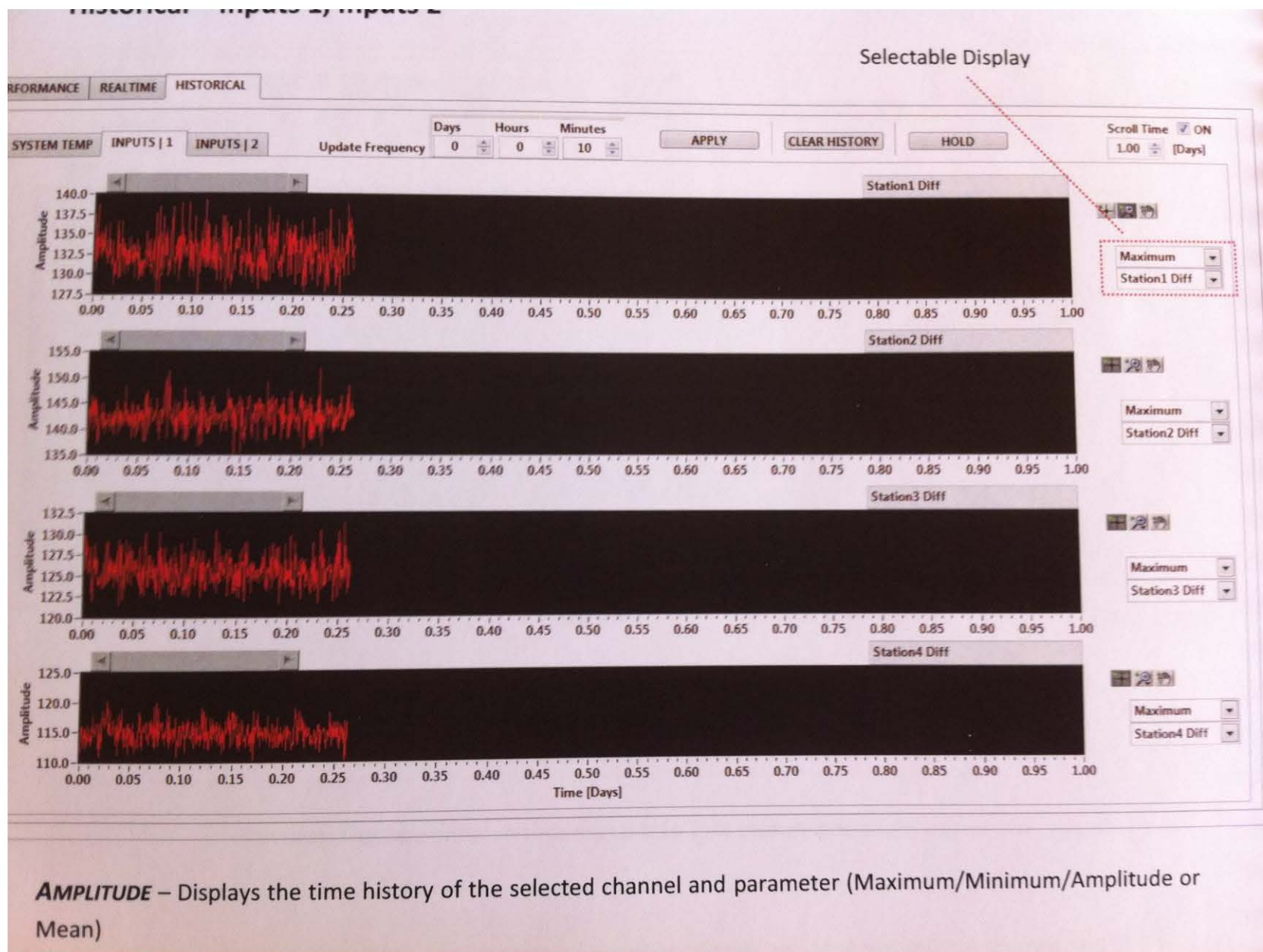


Chart Tools



Click a button in the chart tools to move cursors, zoom, or pan the display. Each button displays a green LED when you enable the button. The chart tools appear with the following buttons, in order from left to right:

CURSOR MOVEMENT TOOL — Moves the cursor on the display. This button applies only to graphs.

ZOOM—Zooms in and out of the display using the following tools:



Box zoom



Fit Vertical



Fit Horizontal



Fit All



Expand



Shrink

PANNING TOOL—Picks up the plot and moves it around on the display.

Configuring Chart X and Y Axes

Right-click the x- or y-scale of a graph or chart and select one of the following shortcut menu options to configure the x- or y-axis.

AUTOSCALE X OR Y — Remove the checkmark next to this option to disable autoscaling. Graphs and charts can automatically adjust their horizontal and vertical scales to reflect the data. By default, autoscaling is enabled for the graph or chart. However, autoscaling can slow performance. Use the Operating tool or the Labeling tool to change the horizontal or vertical scale directly.



SETTINGS

The settings window is used to set parameters that will be used for the test. Channel scaling and names are set through the channel scaling function. Input scale channels and averaging time are set in the Analog Input (AI) Channel Scaling panel and Data Window Average panel respectively. System temperature settings are determined in the Heater Control panel.

Settings - System

SYSTEM

SOFTWARE FILTERING

Filter? ☒ ON

Filter Parameters

Order 10

Cutoff Freq (Hz) 400

DATA WINDOW AVERAGE

Avg Time [s] 1.0

Reset

Window (sec) 1.00

PRESSURE LIMITS

High Limit [mmHg] 700

Low Limit [mmHg] -50

Mean Limit [mmHg] 200

DIFF LOADING ANALYZER

Target [%] 5

Collection Time [s] 2

CHANNEL SCALING

PHYSICAL CHANNELS	SLOPE	OFFSET	ENA	CHANNEL NAMES	ZERO
SCC1Mod1/ai0	20000	-3.015	☒	Pressure 1-	☐
SCC1Mod1/ai1	20000	-3.177	☒	Pressure 1+	☐
SCC1Mod2/ai0	20000	0.703	☒	Pressure 2-	☐
SCC1Mod2/ai1	20000	0.419	☒	Pressure 2+	☐
SCC1Mod3/ai0	20000	0.403	☒	Pressure 3-	☐
SCC1Mod3/ai1	20000	0.129	☒	Pressure 3+	☐
SCC1Mod4/ai0	20000	1.64	☒	Pressure 4-	☐
SCC1Mod4/ai1	20000	0.722	☒	Pressure 4+	☐
SCC1Mod5/ai0	20000	-0.839	☒	Pressure 5-	☐
SCC1Mod5/ai1	20000	-0.342	☒	Pressure 5+	☐
SCC1Mod6/ai0	20000	0.302	☒	Pressure 6-	☐
SCC1Mod6/ai1	20000	-7.219	☒	Pressure 6+	☐
SCC1Mod7/ai0	1	-1.5	☒	System Temp	☐
SCC1Mod7/ai1	1	-11.6	☒	Heater Temp	☐

LOAD | SAVE SCALES

LOAD DEFAULT

LOAD USER

Current Config: Default_Scales.ini

Save As: Default User

SAVE

Channel Scaling

PHYSICAL CHANNELS- Hardware Channel numbers

SLOPE- Scaling Slope

OFFSET - Scaling Offset

ENABLE (On/Off) - Sets the scale to zero. Note that this function does not add or remove a channel from the data acquisition scan. To do this the channel scan order must be modified, see AI channel configuration.

CH NAME - Set the name for the channel, these names will be reflected in the charts and data files

ZERO - Tare the selected channel

Settings - System

STEM

SOFTWARE FILTERING

Filter? ☒ ON

Filter Parameters

Order

Cutoff Freq (Hz)

DATA WINDOW AVERAGE

Avg Time [s]

Reset

Window (sec)

PRESSURE LIMITS

High Limit [mmHg]

Low Limit [mmHg]

Mean Limit [mmHg]

DIFF LOADING ANALYZER

Target [%]

Collection Time [s]

CHANNEL SCALING

PHYSICAL CHANNELS	SLOPE	OFFSET	ENA	CHANNEL NAMES	ZERO
SCC1Mod1/ai0	20000	-3.015	☒	Pressure 1-	Ø
SCC1Mod1/ai1	20000	-3.177	☒	Pressure 1+	Ø
SCC1Mod2/ai0	20000	0.703	☒	Pressure 2-	Ø
SCC1Mod2/ai1	20000	0.419	☒	Pressure 2+	Ø
SCC1Mod3/ai0	20000	0.403	☒	Pressure 3-	Ø
SCC1Mod3/ai1	20000	0.129	☒	Pressure 3+	Ø
SCC1Mod4/ai0	20000	1.64	☒	Pressure 4-	Ø
SCC1Mod4/ai1	20000	0.722	☒	Pressure 4+	Ø
SCC1Mod5/ai0	20000	-0.839	☒	Pressure 5-	Ø
SCC1Mod5/ai1	20000	-0.342	☒	Pressure 5+	Ø
SCC1Mod6/ai0	20000	0.302	☒	Pressure 6-	Ø
SCC1Mod6/ai1	20000	-7.219	☒	Pressure 6+	Ø
SCC1Mod7/ai0	1	-1.5	☒	System Temp	Ø
SCC1Mod7/ai1	1	-11.6	☒	Heater Temp	Ø

LOAD | SAVE SCALES

LOAD DEFAULT

LOAD USER

Current Config:

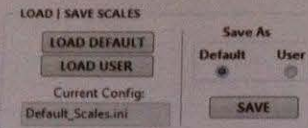
Default_Scales.ini

Save As

Default

User

SAVE



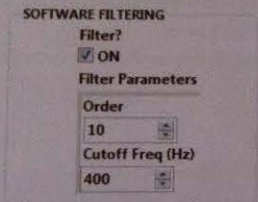
LOAD DEFAULT– Load default settings

LOAD USER– Load user settings

SAVE(DEFAULT/USER) – Save current scale settings to the default or user file

CURRENT CONFIG – Displays the active file name

Software Filter



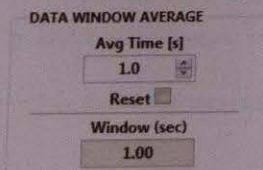
ORDER– Set the filter order (default is 10)

CUTOFF FREQ (Hz)– Set the low pass cutoff frequency (default is 400)



The Statys software employs a digital Butterworth filter to reduce extraneous noise. The default parameters are optimized to reduce environmental noise while maintaining system signal fidelity.

Data Window Average



AVG TIME (sec) – Sets the data averaging time window (must reset to update)

RESET – Updates the averaging time

WINDOW – Displays the current data averaging time window (in seconds)



The window average function looks back over the specified time window and averages the included data. To capture quick events, decrease the average time. For a more stable average, increase the data averaging window time. All plots and indicators reflect window averaged data.

Pressure Alarm

PRESSURE LIMITS

High Limit [mmHg]
700

Low Limit [mmHg]
-50

Mean Limit [mmHg]
200

HIGH LIMIT– Set the global maximum pressure limit, if any active pressure transducer exceeds the limit value the motion will halt and the motors will be disabled

LOW LIMIT– Set the global minimum pressure limit, if any active pressure transducer falls below the limit value the motion will halt and the motors will be disabled

MEAN LIMIT– Set the global mean pressure limit, if any active pressure transducer falls below the limit value the motion will halt and the motors will be disabled



Due to the nature of the dynamic drive system, the system pressure must remain positive while testing. The recommended mean pressure value is 250-300 mm Hg. If the mean pressure falls below 200 mm Hg during testing the system will automatically halt to protect the dynamic drives

DIFF LOADING ANALYZER

Target [%]
5

Collection Time [s]
3

Enable ISO Count? ☒

TARGET [%] – Set the target percentage of the cycle for the differential pressure to be greater than the Threshold

DATA COLLECTION TIME [s] – Set the data collection time (1-5 second range)

ENABLE ISO COUNT? [ON/OFF] – Turn the ISO count on or off. Count values will read 0 when the counter is off.

DATA FILES

The data files window is used to set data collection parameters that control the writing of the data to computer files. The data log function creates a log file, recording data at the specified intervals. The snapshot function allows the user to create a short (0-15 second) high resolution file of the real time data stream (taken at 5khz). Both file types can be opened and analyzed with a variety of programs including Microsoft Excel and Matlab. Data log files are created for each station and can be started and stopped independently. The snapshot file will collect data for all stations simultaneously.

The screenshot displays the 'DATA FILES' window with three station configurations. Each station has a 'Log Duration' field, 'Initial Motor Count' and 'Initial ISO Count' fields, a 'Test ID#' field, and a 'Write Frequency' table. The 'Write To' field is set to 'New File' for each station. The file paths are as follows:

- STATION 1: C:\Statys VDT\Data Log Files\System 1\Station 1\TEST_P1_2014Jul17.1035AM.xls
- STATION 2: C:\Statys VDT\Data Log Files\System 1\Station 2\TEST_P2_2014Jul17.1035AM.xls
- STATION 3: C:\Statys VDT\Data Log Files\System 1\Station 3\TEST_P3_2014Jul17.1035AM.xls

Station	Log Duration	Initial Motor Count	Initial ISO Count	Test ID#	Write Frequency (Days, Hours, Minutes)
STATION 1	06:20:36	0	0	TEST_P1	0, 0, 10
STATION 2	06:20:36	0	0	TEST_P2	0, 0, 10
STATION 3	06:20:36	0	0	TEST_P3	0, 0, 10

stations simultaneously.

can be started and stopped independently. The snapshot file will collect data for all

STATION 1-3 STATION 4-6

STATION 1

running... click to stop

HOLD

Log Duration

06:20:36

Initial Motor Count

0

Initial ISO Count

0

Test ID# TEST_P1_

Write Frequency

Days

0

Hours

0

Minutes

10

WRITING TO FILE

Write To: ☒ New File ☐ Existing File

C:\Statys VDT\Data Log Files\System 1\Station 1\TEST_P1_2014Jul17.1035AM.xls

STATION 2

running... click to stop

HOLD

Log Duration

06:20:36

Initial Motor Count

0

Initial ISO Count

0

Test ID# TEST_P2_

Write Frequency

Days

0

Hours

0

Minutes

10

WRITING TO FILE

Write To: ☒ New File ☐ Existing File

C:\Statys VDT\Data Log Files\System 1\Station 2\TEST_P2_2014Jul17.1035AM.xls

STATION 3

running... click to stop

HOLD

Log Duration

06:20:36

Initial Motor Count

0

Initial ISO Count

0

Test ID# TEST_P3_

Write Frequency

Days

0

Hours

0

Minutes

10

WRITING TO FILE

Write To: ☒ New File ☐ Existing File

C:\Statys VDT\Data Log Files\System 1\Station 3\TEST_P3_2014Jul17.1035AM.xls

Data Log Settings

Running... click to stop

HOLD

START TEST RUN - Activates the test run and begins data logging to a data file. Ensure all testing and motion parameters are set prior to beginning a test run.

STOP - Pause data logging to file while running a test run.

Write Frequency

Days	Hours	Minutes
0	0	10

WRITE FREQUENCY - Set the data file logging frequency in days, hours and minutes

WRITING TO FILE

Write To: ☒ New File ☐ Existing File

C:\Status VDT\Data Log Files\System 1\Station 1\TEST_P1_2014Jul17.1035AM.xls

HISTORICAL LOG FILE PATH - Shows the data file location

WRITE TO:

- **NEW FILE** - Creates a new data file in the default data logging folder
- **EXISTING FILE** - Appends to an existing data file as specified in the existing file pathway

Test ID# TEST_P1

TEST ID# - Specifies the data file name for new files. Note that a timestamp will be added to the beginning of the file name.

Initial Motor Count	0
Initial ISO Count	0

INITIAL MOTOR COUNT - Input the last motor cycle count when appending to existing data files or new data files

INITIAL ISO COUNT - Input the last ISO cycle count when appending to existing data files or new data files.



If the system loses power or is otherwise stopped during a test run, the initial cycle count should be set to the last value shown in the data log file.

Log Duration

06:20:36

DURATION - Displays the total test time duration

Snapshot File

SNAPSHOT FILE

Manual Mode

Duration [s]

3

CAPTURE

Snapshot ID#

Snapshot File Path

Auto Mode

Countdown

Auto Mode ☐ OFF

Days

0

Hours

1

Minutes

0

SNAPSHOT ID# - Set the name of the data file

SNAPSHOT FILE PATH - Displays the snapshot file location

Manual Mode

DURATION - Sets the snapshot capture duration in seconds (15 second limit)

CAPTURE - Triggers data collection at 5khz for the specified duration

Auto Mode

COUNTDOWN - Sets the snapshot capture frequency in Days, Hours and Minutes

AUTO MODE ON/OFF - Enables/disables auto mode. When enabled a snapshot will be captured at the interval specified in the countdown and with the length set by the Duration control. The snapshot ID# will be added to all files name along with a full timestamp.

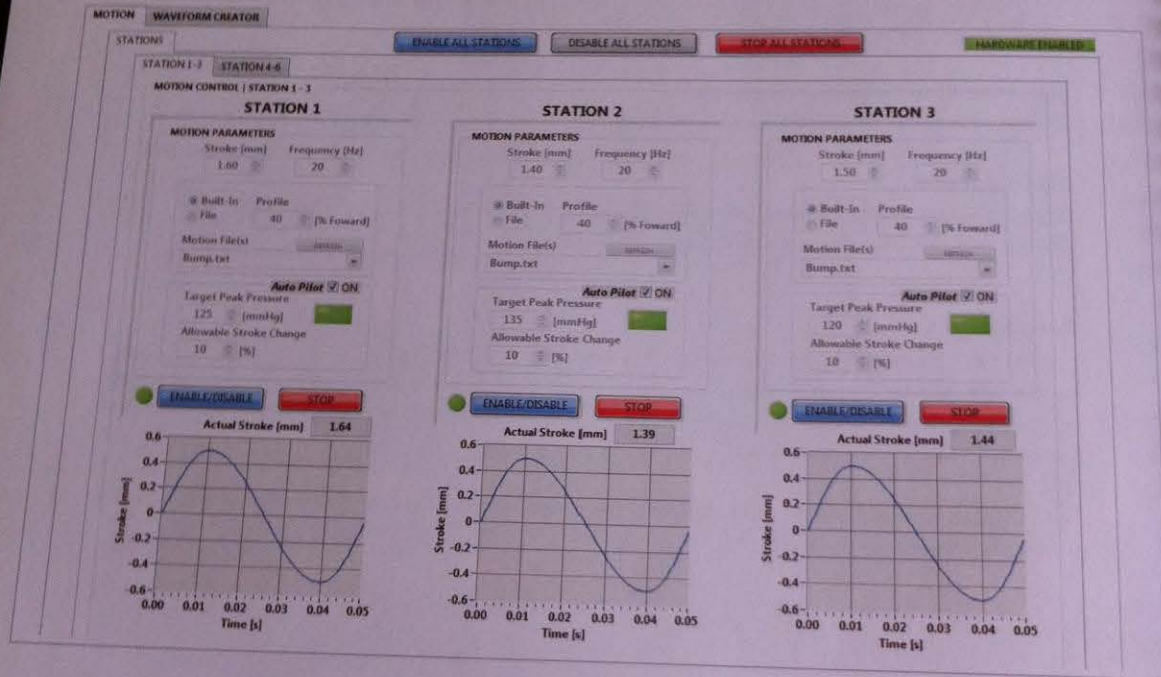


Snapshot data will create a short data file at the data acquisition loop rate (5000 scans/second), which can then be analyzed in Excel or Matlab.

MOTION

The motion window is used to set the oscillatory motion parameters. The motion window is split into two tabs: Stations and Waveform Creator. The motion window allows the user to set motion parameters for Stations 1 through Stations 6. The Waveform Creator (optional) tab allows the user to create and save customized motion waveforms.

STATIONS



STATIONS

MOTION WAVEFORM CREATOR

STATIONS

STATION 1-3 STATION 4-6

MOTION CONTROL | STATION 1-3

ENABLE ALL STATIONS

DISABLE ALL STATIONS

STOP ALL STATIONS

HARDWARE ENABLED

STATION 1

MOTION PARAMETERS

Stroke [mm] 1.60 Frequency [Hz] 20

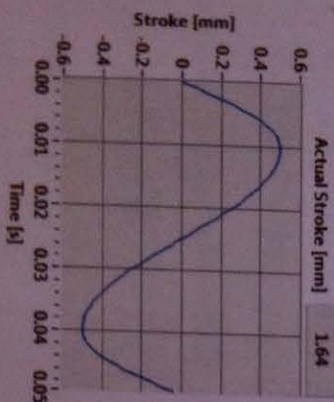
☒ Built-In ☐ Profile
Motion File(s) 40 [% Forward]
Bump.txt

Auto Pilot ☒ ON

Target Peak Pressure 125 [mmHg]
Allowable Stroke Change 10 [%]

ENABLE/DISABLE

STOP



STATION 2

MOTION PARAMETERS

Stroke [mm] 1.40 Frequency [Hz] 20

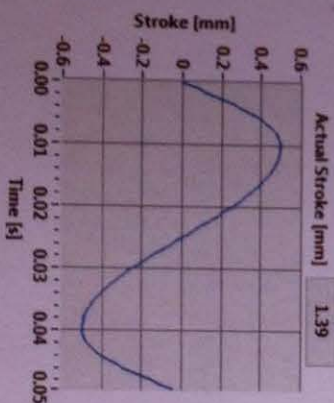
☒ Built-In ☐ Profile
Motion File(s) 40 [% Forward]
Bump.txt

Auto Pilot ☒ ON

Target Peak Pressure 135 [mmHg]
Allowable Stroke Change 10 [%]

ENABLE/DISABLE

STOP



STATION 3

MOTION PARAMETERS

Stroke [mm] 1.50 Frequency [Hz] 20

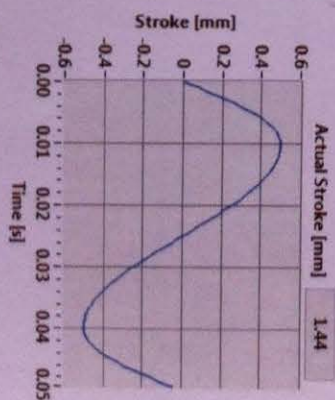
☒ Built-In ☐ Profile
Motion File(s) 40 [% Forward]
Bump.txt

Auto Pilot ☒ ON

Target Peak Pressure 120 [mmHg]
Allowable Stroke Change 10 [%]

ENABLE/DISABLE

STOP



Motion Parameters

Stroke [mm] Frequency [Hz]
 1.00 10

STROKE[MM] – Set the target dynamic drive stroke for the station

FREQUENCY [Hz] – Set the target dynamic drive frequency in Hz (cycles per second) for the station

$\delta f(1-35\text{Hz}) = \pm 1.5\%(\text{measured value})$

$\delta f(35-50\text{Hz}) = \pm 2.5\%(\text{measured value})$

The system test frequency has a maximum experimentally measured uncertainty of $\pm 1.5\%$ from 0-35 Hz and $\pm 2.5\%$ from 35-50 Hz



The stroke and frequency are dependent. The higher the target frequency, the smaller the achievable stroke will be. See Appendix B - Operational Theory for further detail. When starting a test run, it is recommended to start with a small stroke and gradually increase until the desired pressure conditions are achieved.

Waveform Control

BUILT-IN/FILE – Choose between a built in set of motion profiles or a user created waveform (File)

MOTION FILE(S) – Choose the desired waveform

REFRESH – Hit the refresh button if a new waveform is saved to the Waveform folder

% FORWARD – Sets the shape of the sinusoidal motion waveform



The profile shape can be used to adjust the performance of the test valve

Auto Pilot

The Auto Pilot feature allows the system to maintain a target differential loading pressure by adjusting the driving stroke within user specified limits. Once the system has been initially tuned manually to achieve acceptable valve dynamics and differential pressure, the Auto Pilot feature should be switched on. With the Auto Pilot feature enabled, the system will adjust the station drive stroke to maintain the target peak pressure within the specified limits. If the differential pressure is not achievable within the set stroke limits, the drive will stop adjusting and a limit indicator will display.

Auto Pilot ☐ OFF

Target Peak Pressure
120 [mmHg]

Allowable Stroke Change
10 [%]

TARGET PEAK PRESSURE [MM HG] – Target differential loading pressure for the selected station

ALLOWABLE STROKE CHANGE [%] – Allowable displacement change when the Auto Pilot feature is enabled. For example, if the stroke is set at 1mm with a 10% allowable change, the system stroke may vary between 0.9mm and 1.1mm to maintain the target peak pressure.

STROKE CHANGE INDICATOR

- ☐ STROKE WITHIN LIMITS
- ☐ STROKE LIMIT REACHED
- ☐ AUTO PILOT FEATURE IS OFF

Station Motion Controls

ENABLE/DISABLE – Enable or disable the motor

- ☐ MOTOR ENABLED
- ☐ MOTOR DISABLED



The System Enabled switch on the control module must be on to allow the motor to be software enabled, the status of the Hardware Enabled switch is shown in the left pane and on the top of the Motion Tab.



It is recommended that any station not active be disabled in software once the global enable switch (located on the control module) is on.

START/STOP – Start or Stop the Dynamic Drive with the set parameters

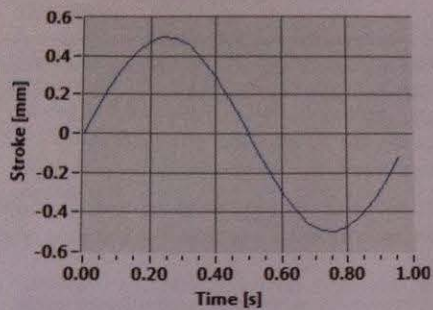


Dynamic Drive Motion Will Result

Actual Stroke [mm]

0.00

ACTUAL STROKE [MM] – Shows the actual stroke achieved by the dynamic drive during operation



PROFILE PREVIEW – Shows the target driver motion profile

Global Motion Controls

The global motion controls allow the user to enable, disable and star/stop all stations simultaneously. The controls are only active if all stations are pressurized and the individual pressure lines are enabled. The controls will be disabled if any pressure input (1-, 1+, 2-, 2+, etc...) is disabled.

ENABLE ALL STATIONS

DISABLE ALL STATIONS

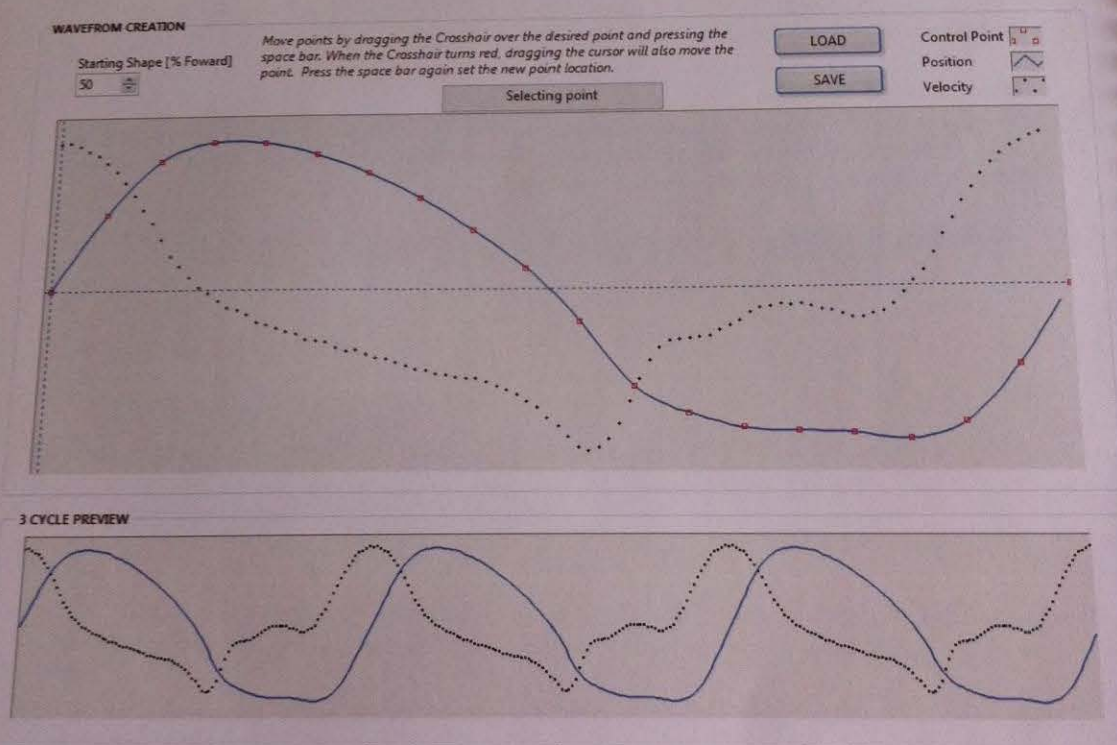
STOP ALL STATIONS

WAVEFORM CREATOR (OPTIONAL)

The waveform creation module enables the user to generate and save customized motion waveforms. These wave shapes can then be loaded and run by the station motor, allowing the user to optimize the opening and closing performance for the particular test valve. A starting shape is selected and loaded into the software interface. A series of control points can be selected and dragged to change the wave shape.

OPERATION

Move points by dragging the Crosshair over the desired point and pressing the space bar. When the Crosshairs turns red, dragging the cursor will also move the point. Press the space bar again to set the new point location.

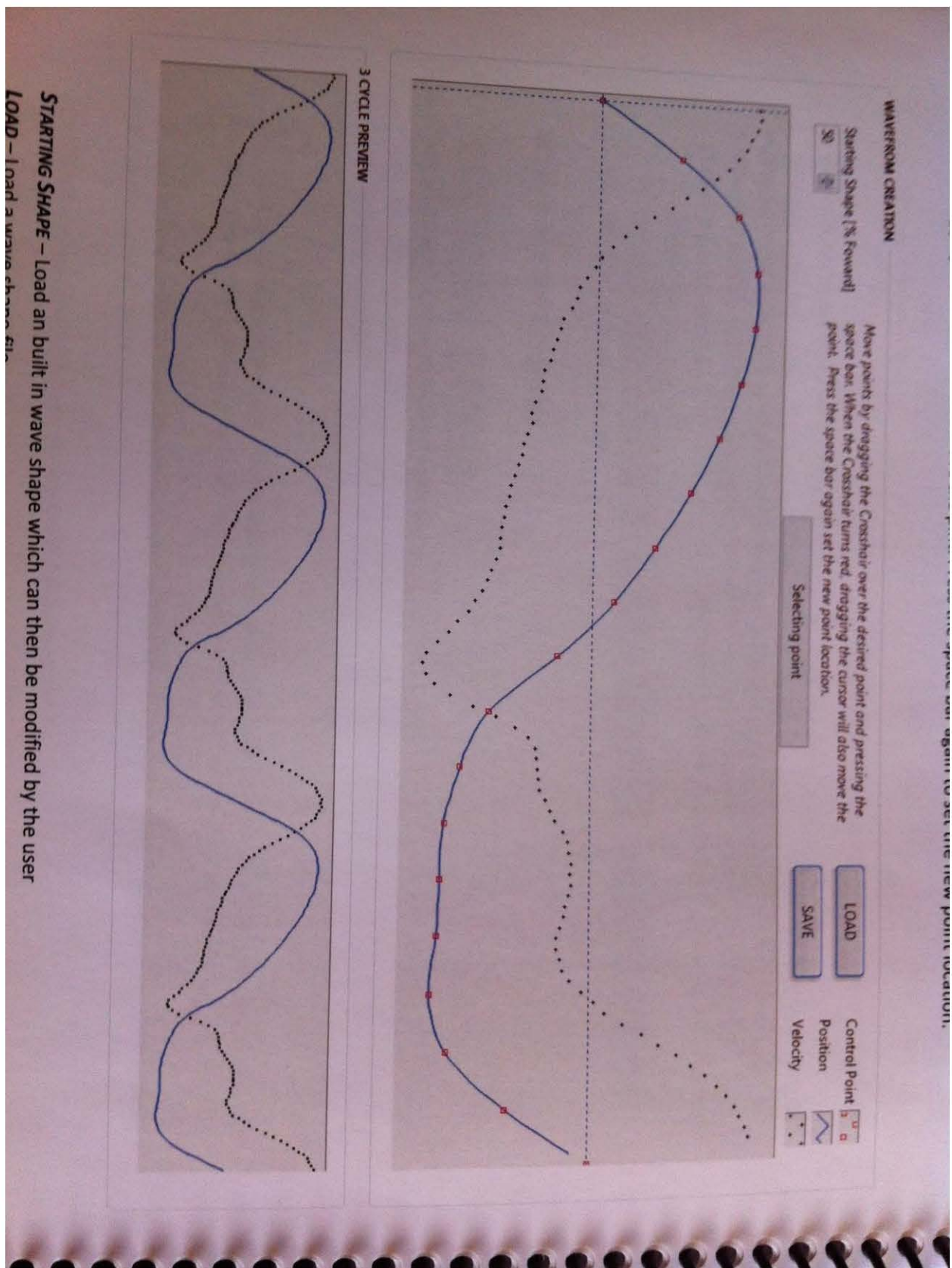


STARTING SHAPE – Load an built in wave shape which can then be modified by the user

LOAD – Load a wave shape file

SAVE – Save a wave shape file

3 CYCLE PREVIEW – Shows three waveform cycles plotted consecutively, position is shown in blue, velocity in dashed black



ALARMS

The alarms window allows the user to define critical testing parameter bounds based on minimum and maximum values from the system input and motion channels. Each channel has a maximum and minimum target value with a tolerance. If the system deviates from these values while running an alarm will be generated and motion will stop on the station with the active alarms. A temperature alarm will stop all stations. Alarms remain active until cleared. To quickly start the system without disabling all input alarms the override function can be used to ignore alarm conditions.

SINGLE ENDED ALARMS

CHANNEL	MEAN	TARGET	TOLERANCE	ENABLE MAX?	ALARM?
System Temp	35.8	0	0	☐	☐
Heater Temp	38.1	0	0	☐	☐

DIFFERENTIAL ALARMS

CHANNEL	MAX	TARGET	TOLERANCE	ENABLE MAX?	ALARM?
Station1 Diff	133.7	120	40	☐	☐
Station2 Diff	142.5	120	40	☐	☐
Station3 Diff	123.6	120	40	☐	☐
Station4 Diff	113.2	120	40	☐	☐
Station5 Diff	137.5	120	40	☐	☐
Station6 Diff	137.8	120	40	☐	☐

LOAD | SAVE SETTINGS

Current Config

User_Alarms.ini

Save As

☒ Default
 ☐ User

LAST ALARM

CLEAR ALL ALARMS

ALARM OVERRIDE

Alarm Configuration

CHANNEL – Lists the channel name as defined in Settings – System tab

MAX/MEAN – Displays the averaged maximum or mean channel value over the windowed time

MAX/MEAN LIMIT – Set the maximum or mean limit for the specified channel

TOLERANCE – Set the limit tolerance for the specified channel

ENABLE MAX? (On/Off) – Activate maximum value alarm

ALARM? (On/Off) – Indicates that an alarm has been triggered (Red)



To protect the system and samples from overheating, alarms should always be set on the temperature input channels during a test

values from the system input and motion channels. Each channel has a maximum and minimum target value with a tolerance. If the system deviates from these values while running an alarm will be generated and motion will stop on the station with the active alarms. A temperature alarm will stop all stations. Alarms remain active until cleared. To quickly start the system without disabling all input alarms the override function can be used to ignore alarm conditions.

SINGLE ENDED ALARMS

CHANNEL	MEAN	TARGET	TOLERANCE	ENABLE MAX?	ALARM?
System Temp	35.8	0 	0 		
Heater Temp	38.1	0 	0 		

DIFFERENTIAL ALARMS

DIFFERENTIAL ALARMS				ENABLE	
CHANNEL	MAX	TARGET	TOLERANCE	MAX?	ALARM?
Station1 Diff	133.7	120  	40  		
Station2 Diff	142.5	120  	40  		
Station3 Diff	123.6	120  	40  		
Station4 Diff	113.2	120  	40  		
Station5 Diff	137.5	120  	40  		
Station6 Diff	137.8	120  	40  		

LOAD | SAVE SETTINGS

LOAD DEFAULT

LOAD USER

Current Config

User Alarms.ini

Save As

Default

User

SAVE

LAST ALARM

CLEAR ALL ALARMS

CLEAR

ALARM OVERRIDE

OVERRIDE

Alarm Configuration

LAST ALARM

CLEAR ALL ALARMS

CLEAR

ALARM OVERRIDE

OVERRIDE

LAST ALARM – Displays the current state of the alarms. Any active alarms will be displayed in the log along with a time stamp showing alarm occurrence details

ALARM OVERRIDE – Allows the user to override all alarms without disabling them. Since all alarms are ignored when the override is on, it is not recommended to be used for an extended period of time.

CLEAR ALL ALARMS – Clears all latched alarms.



System alarms are latching and halt motion. Motion can only be activated if the alarms are first cleared.

LOAD | SAVE SETTINGS

LOAD DEFAULT

LOAD USER

Current Config

Default_Alarms.ini

Save As

Default

User

SAVE

LOAD DEFAULT– Load default settings

LOAD USER– Load user settings

SAVE (DEFAULT/USER) – Save current scale settings to the default or user file

CURRENT CONFIG – Displays the active file name

SPECIFICATIONS

VDT-3600i Test System		
International System Power Requirements		
VDT-3600i System (heater included)	230 5	VAC A
Heating System	230 2	VAC A
Main Fuse	250VAC	6.3A
Heater Fuse	250VAC	2.5A
Controller Fuse	250VAC	2.5A
Motor Fuse	250VAC	6.3A
US System Power Requirements		
VDT-3600i System (heater included)	120 9	VAC A
Heating System	120 4.1	VAC A
Main Fuse	250VAC	10A
Heater Fuse	250VAC	5A
Controller Fuse	250VAC	5A
Motor Fuse	250VAC	6.3A
Pressurized Air Requirements		
Adjustable Regulated Air	0-10 psi	
Volumetric Requirements		
Fluid Reservoir Volume	10 2.5	L Gal
Working Fluid	Water, PBS, Blood Analog	
VDT-3600i Dynamic Drive		
Displacement ¹	0-6	mm
Stroke Volume	0-14	ml
Waveforms	Sine and Modified Sine	
Working Fluid	Water or PBS	
Frequency ¹	1-50	Hz
Maximum Differential Pressure	500	mm Hg
Mean Pressure	500 Max 200 Min	mm Hg

¹ Frequency dependent upon system pressure and target displacement

BDC Laboratories

VDT-3600i Test System		
<i>Dimensions – VDT-3600i Test System</i>		
Height	38.9	cm
	15.3	in
Width	83.8	cm
	33.0	in
Depth	61.2	cm
	24.1	in
Weight	68.0	kg
	150	lb
<i>Dimensions – VDT-3600i Control Module</i>		
Height	22.3	cm
	8.8	in
Width	41.1	cm
	16.2	in
Depth	42.4	cm
	16.7	in
Weight	13.6	kg
	30	lb

PATENT INFORMATION

Protected by US Patents: 8,627,708 and 8,584,538



DECLARATION OF CONFORMITY

We,

Biomedical Device Consultants and Laboratories
4060 Youngfield St.
Wheat Ridge, CO 80033 USA

Declare under our sole responsibility that the product:

VDT-3600i

To which this declaration relates, are in conformity
with the following standards:

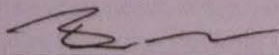
In accordance with EC Directive 2004/108/EC (EMC Directive)

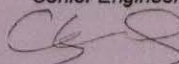
EN61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 55011: 2003	Industrial, Scientific, and Medical (ISM) Radio Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement Group 1, Class A
EN 61000-3-2: 2006 A1/A2 2009	Electromagnetic Compatibility (EMC) - Part 3-2: Limits for harmonic current emissions
EN 61000-3-3: 2008	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems

In accordance with EC Directive 2006/95/EC (Low Voltage Directive)

EN 61010-1:2010	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use
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Biomedical Device
Consultants and
Laboratories
September 16, 2013


Ben McCloskey
Senior Engineer


Craig Weinberg
President

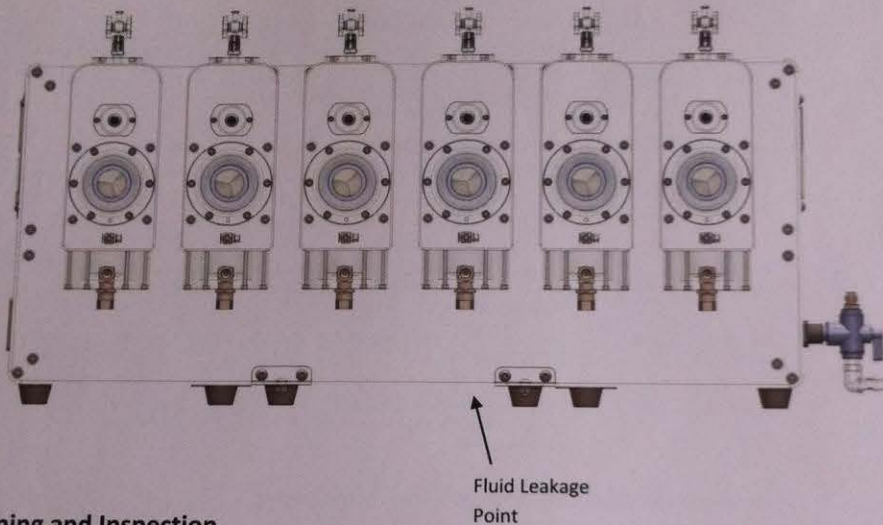
BDC Laboratories

MAINTENANCE

CLEANING AND INSPECTION

INTERVAL: WEEKLY

1. Clean exterior of system using a with soapy water mixture
2. Inspect test system for signs of dynamic diaphragm leakage
 - a. When a dynamic drive diaphragm begins to leak, fluid will collect around the bottom of the system.
At this point the diaphragm should be replaced



Cleaning and Inspection

INTERVAL: POST TEST

1. Clean exterior of system using a with soapy water mixture
2. Inspect test system for signs of dynamic diaphragm leakage
 - a. When a dynamic drive diaphragm begins to leak, fluid will collect around the bottom of the system.
At this point the diaphragm should be replaced
3. To remove bacteria, the test system must be flushed with a cleaning agent and then distilled water, see pg. 15 for system filling and draining procedure
 - a. The cleaning agent must be compatible with acrylic



Flushing the system will prevent salt crystal build-up with evaporation which can potentially damage the motor diaphragm

MOTOR DIAPHRAGM LEAK TEST

INTERVAL: EVERY APPROXIMATE 100 MILLION MOTOR CYCLES (OR AS DESIRED)

The motor diaphragm leak test can be used to determine if a leak is present on any active station during a test. The leak test should be run over 1-2 hours on a station of interest.

1. Move the Station Fluid Valve to the CLOSED position (this can be done while the station is active)
2. Record the inflow (-) and outflow (+) station mean pressures from the data table
3. Allow the system to run for between 1 and 2 hours
4. Record the inflow (-) and outflow (+) station mean pressures from the data table
5. If the inflow (-) or outflow (+) pressures have dropped at a rate greater than **5 mm Hg per hour**, a leak may be present in the motor diaphragm.
6. If no leak is detected, return the Station Fluid Valve to the RUN position



It should be noted that a high rate of pressure drop as described above (>5 mm Hg) may also result from a leak in the compliance chamber diaphragm. If excessive fluid is noted in the compliance chamber, the compliance diaphragm should be inspected prior to investigation of the motor diaphragm.



Due to normal permeation through the compliance diaphragm, a slow decrease in mean pressure (~ 2 mm Hg / hr) is normal.

MOTOR DIAPHRAGM REPLACEMENT

INTERVAL: EVERY 600 MILLION MOTOR CYCLES (OR WHEN A LEAK IS DETECTED)



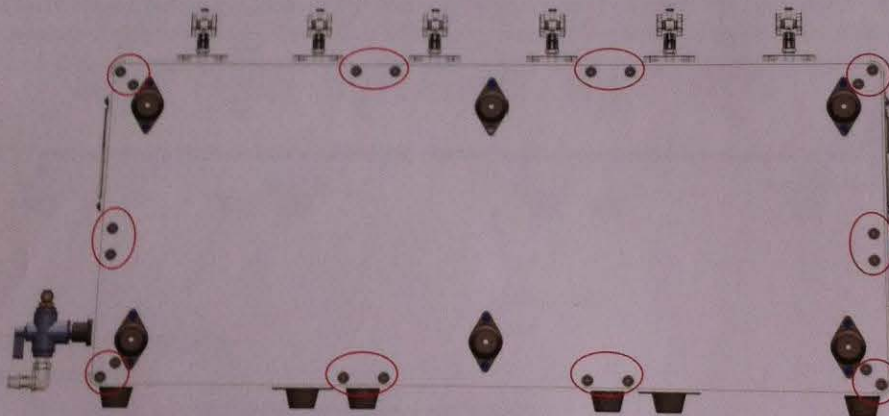
Hazardous voltages exist within the system; Ensure power has been removed before proceeding



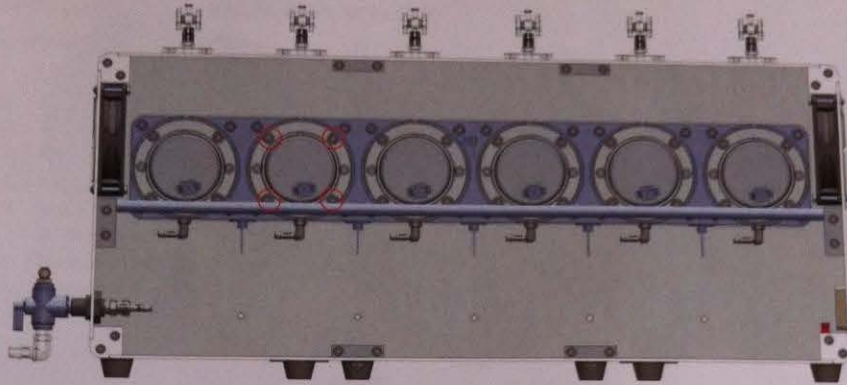
Failure to maintain system pressure and fluid leakage around the diaphragm housing indicate a diaphragm failure. If these occur, a replacement diaphragm should be promptly installed.

NOTE: The actual cycle life of the motor diaphragm is dependent upon the specific test conditions being run and therefore, may be less than or greater than 600 million cycles.

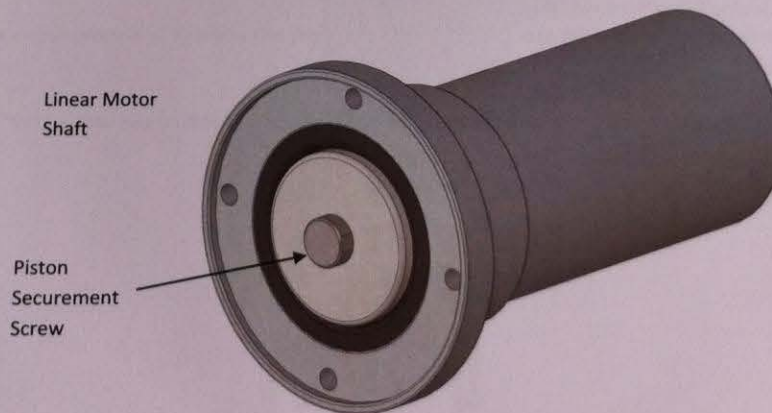
1. Turn off System power and disconnect power cord from the power outlet
2. Perform System Drain (See pg. 15)
3. If necessary, place the system in the horizontal configuration
4. Remove the VDT-3600i Rear Panel by loosening and removing the 20X ¼-20 panel screws with a 3/16" hex key



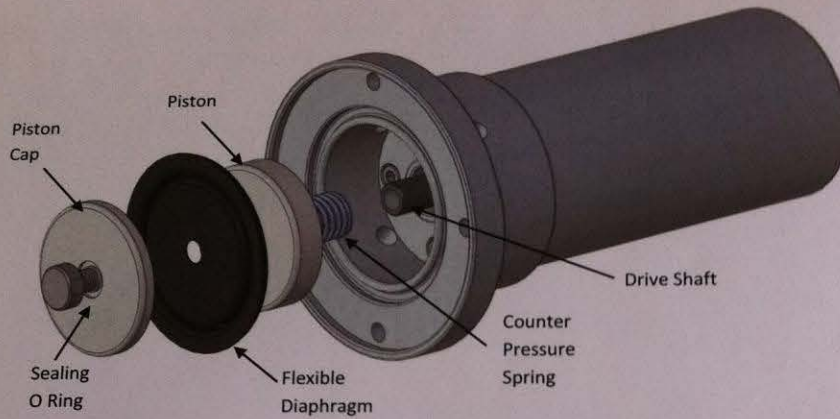
5. Remove the dynamic drive assembly by loosening and removing the 4X ¼-20 panel screws with a 3/16" hex key



6. With the dynamic drive removed, loosen and remove the piston securement screw from the drive with a 15mm open ended wrench. Apply some counter pressure to the piston when removing the securement screw as the piston is spring loaded and will pop out of place.



7. The piston assembly will now disconnect as shown below. Replace the used flexible diaphragm with a new diaphragm installing in the same inverted orientation as the original.

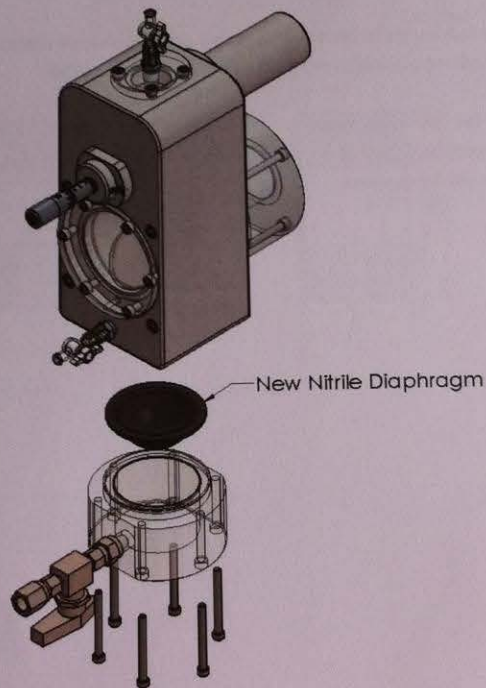


8. Inspect the Sealing O Ring for signs of wear and replace if necessary, apply a small amount of lubricant to the Sealing O Ring
9. Group the Piston Cap, Flexible Diaphragm, Piston and Counter Pressure Spring together and place on the drive shaft.
10. While maintaining pressure on the assembly to compress the spring, install the Piston Securement Screw. Ensure the Sealing O Ring is installed and well seated.
11. Reinstall the Dynamic Drive assembly onto the VDT-3600i test system, secure the 4X ¼-20 panel screws with a 3/16" hex key
12. Repeat the procedure on the other Test Stations as necessary
13. Replace the VDT-3600i Rear Panel by installing and securing the 20X ¼-20 panel screws with a 3/16" hex key

COMPLIANCE DIAPHRAGM REPLACEMENT

INTERVAL: AS NECESSARY

1. De-pressurize and drain sample station
2. Remove acrylic compliance chamber by removing 6X screws with 9/64" hex key
3. Remove damaged Diaphragm
4. Install New Nitrile Diaphragm in the orientation shown
5. Replace acrylic compliance chamber with 6X screws with 9/64" hex key, tightening in a star pattern to 10 in*lb torque
6. The system should be run with the diaphragm in neutral position. The diaphragm should not stretch during operation



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TROUBLESHOOTING

MOTION WILL NOT START

1. Check System Enable Switch on Control Module front panel
2. Check that the Station drive is enabled
3. Check alarms
 - a. If alarm is active, clear alarms or override
4. If steps 1-3 do not resolve the situation, re-start the computer and control module

SYSTEM WILL NOT HEAT

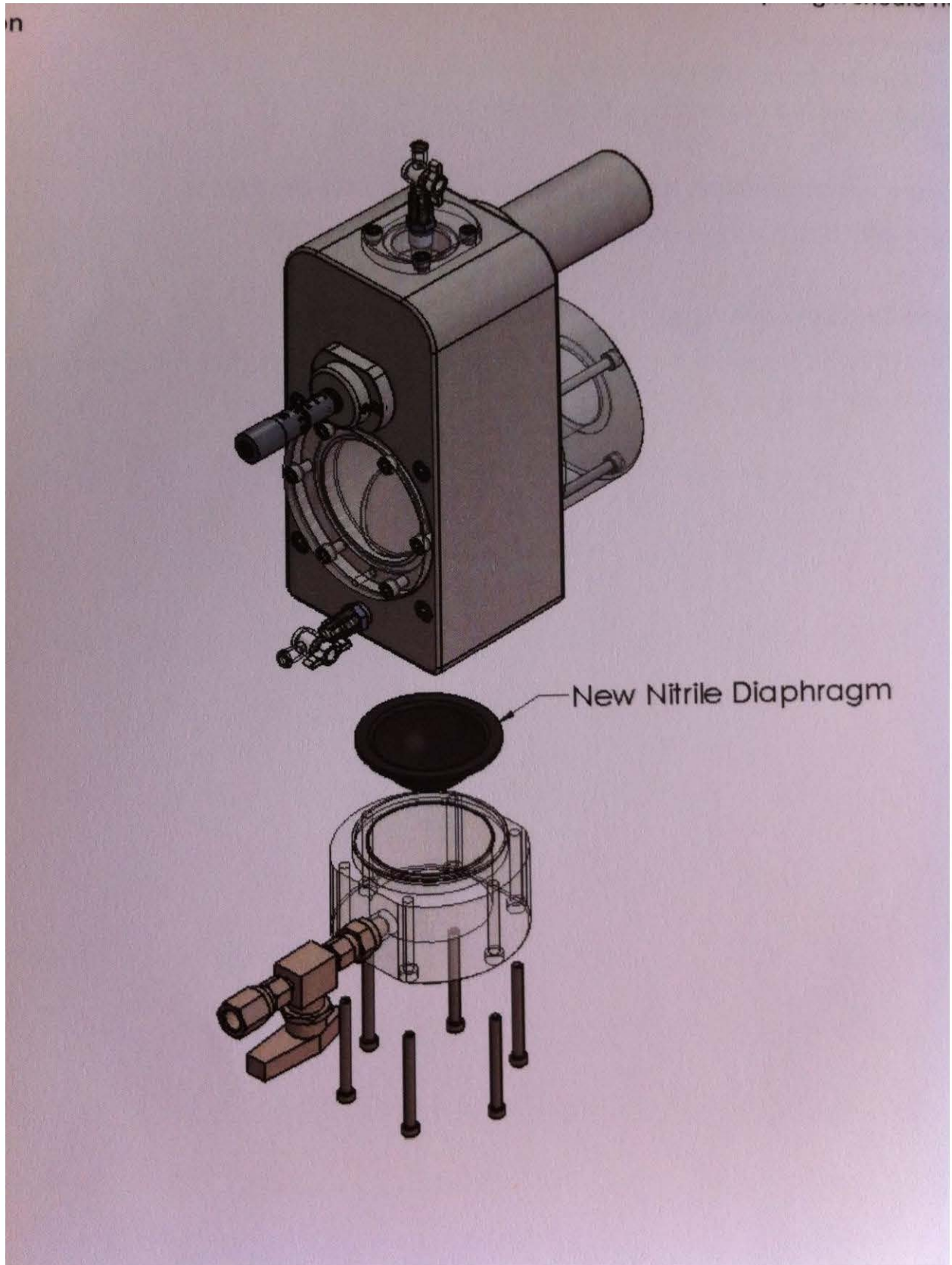
1. Check temperature alarm
 - a. If alarm is active, clear alarms or override
2. Check temperature and heater fuses in the rear panel

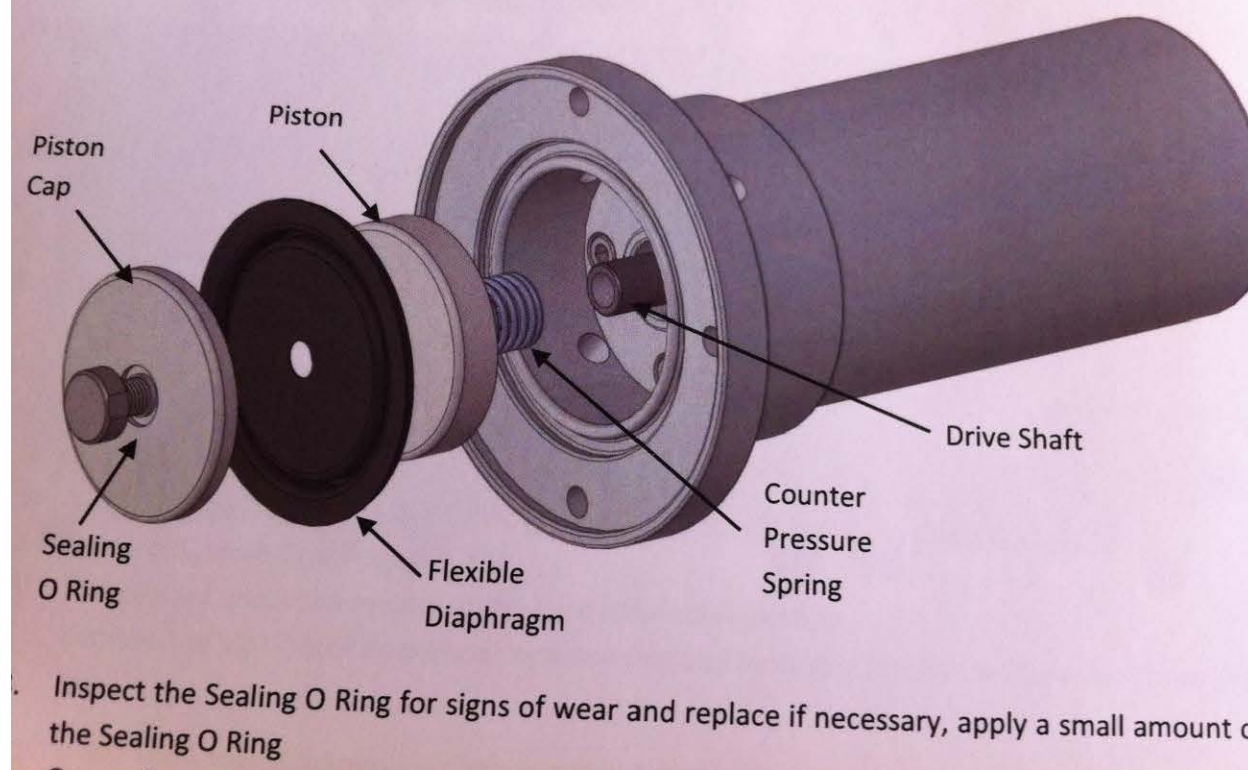
SYSTEM WILL NOT MAINTAIN PRESSURE OR FLUID IS LEAKING AROUND BASE OF SYSTEM

1. The system diaphragm needs to be replaced, see maintenance pg. 56

AIR BUBBLES OCCUR IN THE TEST CHAMBERS

1. To prevent cavitation, increase the system mean pressure. With higher frequencies and strokes, a higher mean pressure will be required.





TROUBLESHOOTING

MOTION WILL NOT START

1. Check System Enable Switch on Control Module front panel
2. Check that the Station drive is enabled
3. Check alarms
 - a. If alarm is active, clear alarms or override
4. If steps 1-3 do not resolve the situation, re-start the computer and control module

SYSTEM WILL NOT HEAT

1. Check temperature alarm
 - a. If alarm is active, clear alarms or override
2. Check temperature and heater fuses in the rear panel

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1. The system diaphragm needs to be replaced, see maintenance pg. 56

AIR BUBBLES OCCUR IN THE TEST CHAMBERS

1. To prevent cavitation, increase the system mean pressure. With higher frequencies and strokes, a higher mean pressure will be required.

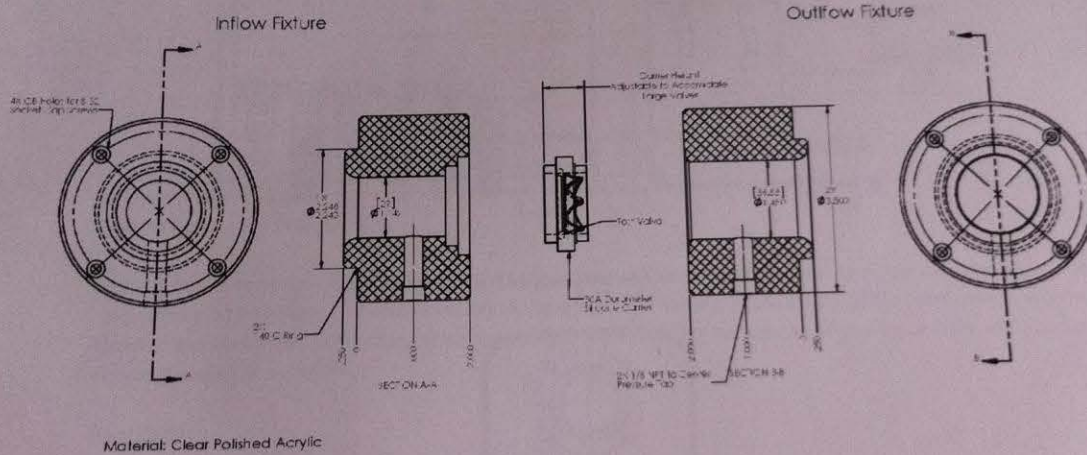
APPENDIX

A - FIXTURES

The first step in implementing a successful test is the design of appropriate test fixtures. Valve fatigue tests generally entail pressure cycling a test sample of known geometry. Test samples are affixed to testing fixtures specifically designed to accommodate the sample. These testing fixtures are then attached to the VDT-3600i test system.

Test samples can be mounted in a variety of ways; however, the most common method is to clamp the test sample and device in a two part fixture. An example fixture is shown.

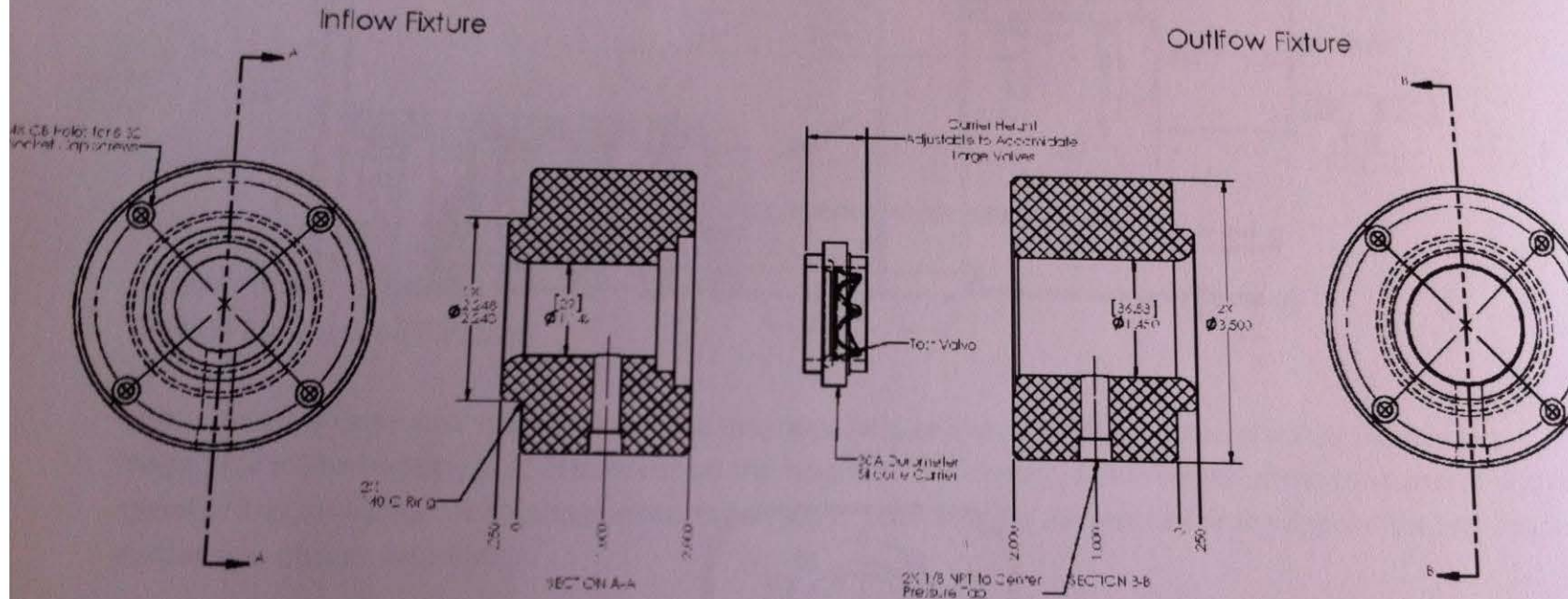
Standard Fixture Configuration



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or device in a two part fixture. An example fixture is shown.

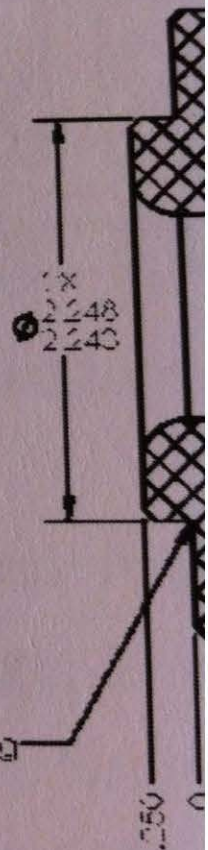
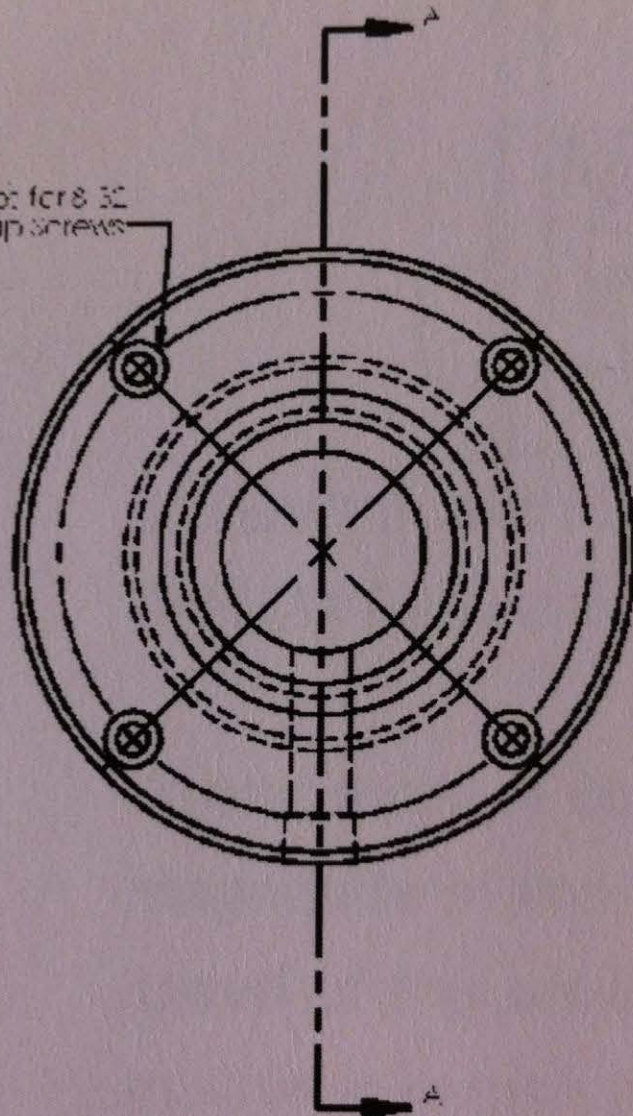
Standard Fixture Configuration



Material: Clear Polished Acrylic

Inflow Fixture

4x CB Hole for 8-32
socket cap screws

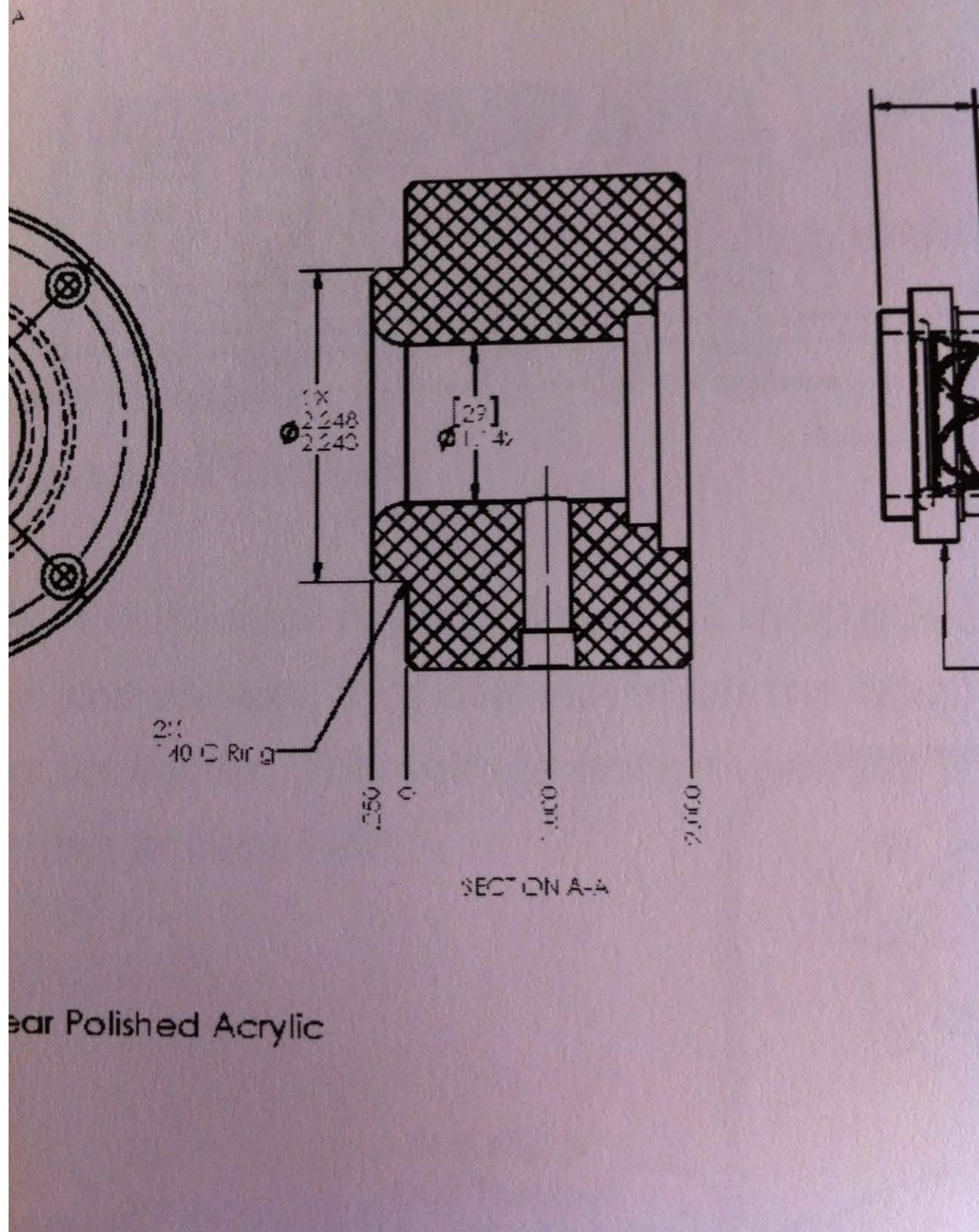


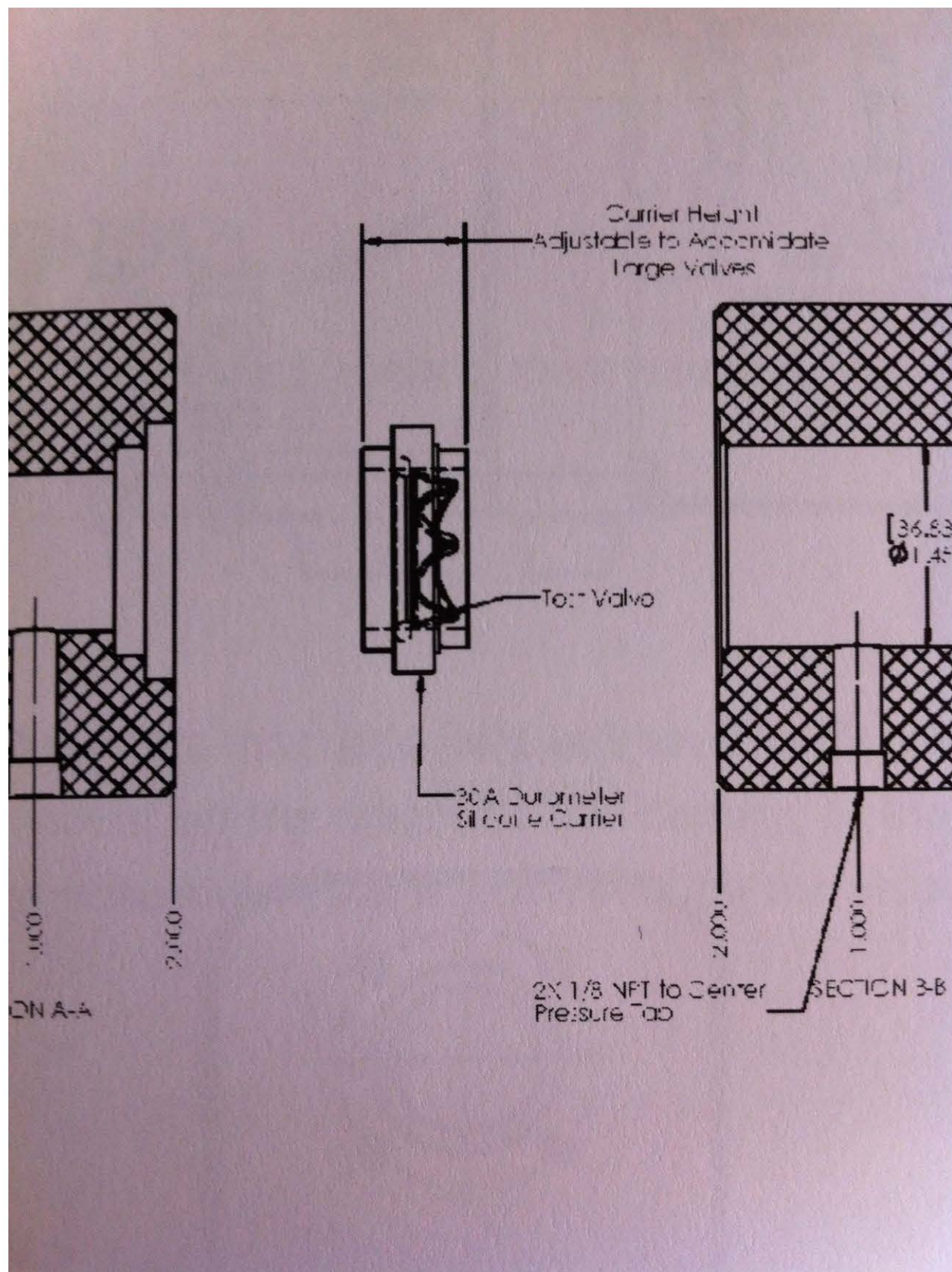
2x
1/40 ID Ring

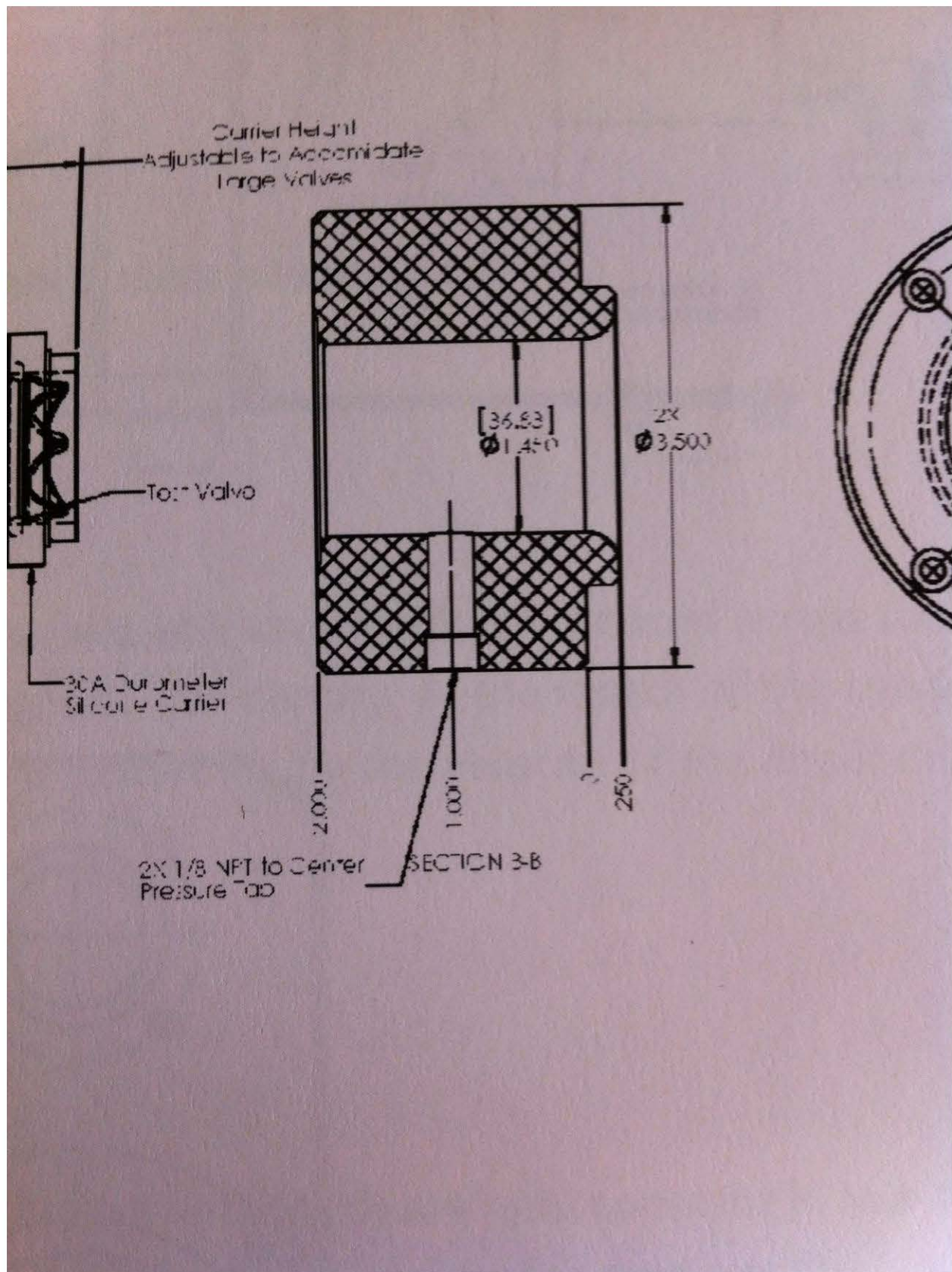
0.50

Material: Clear Polished Acrylic

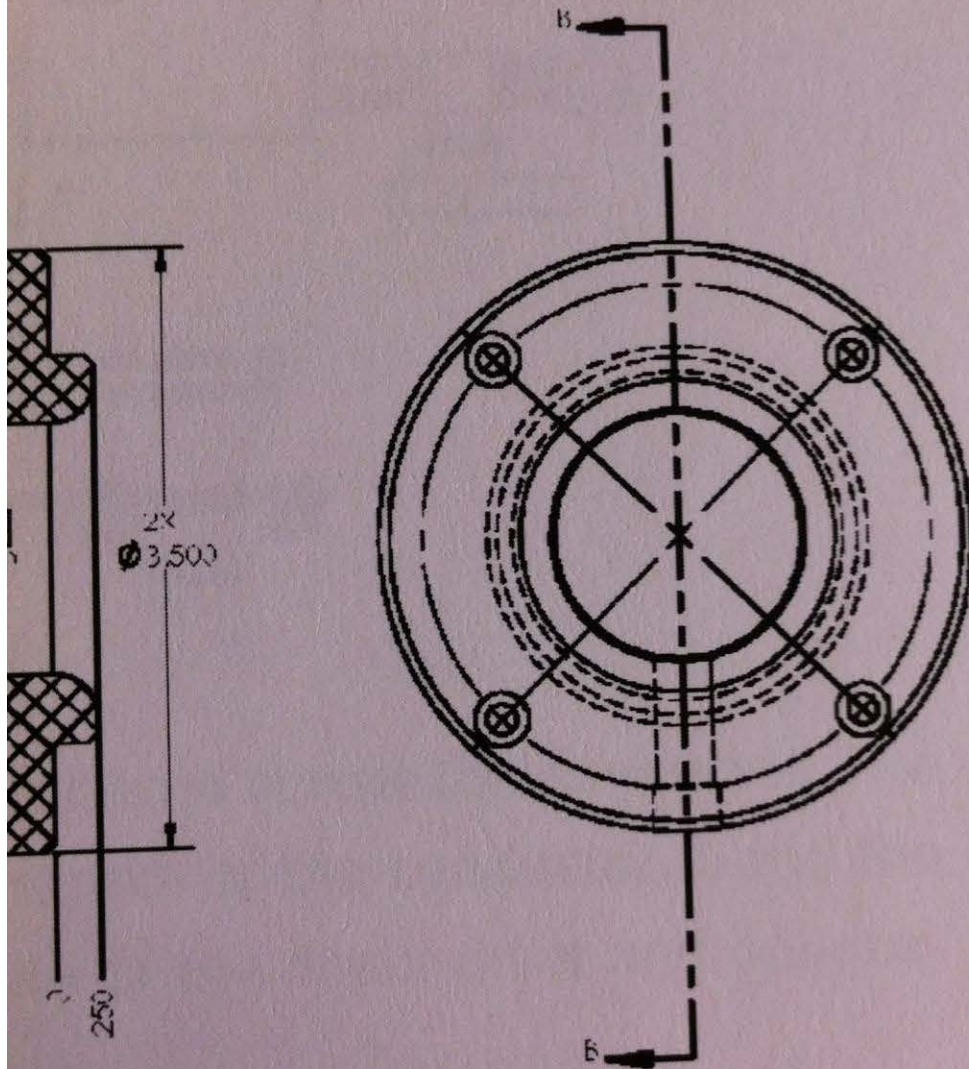
Inflow Fixture





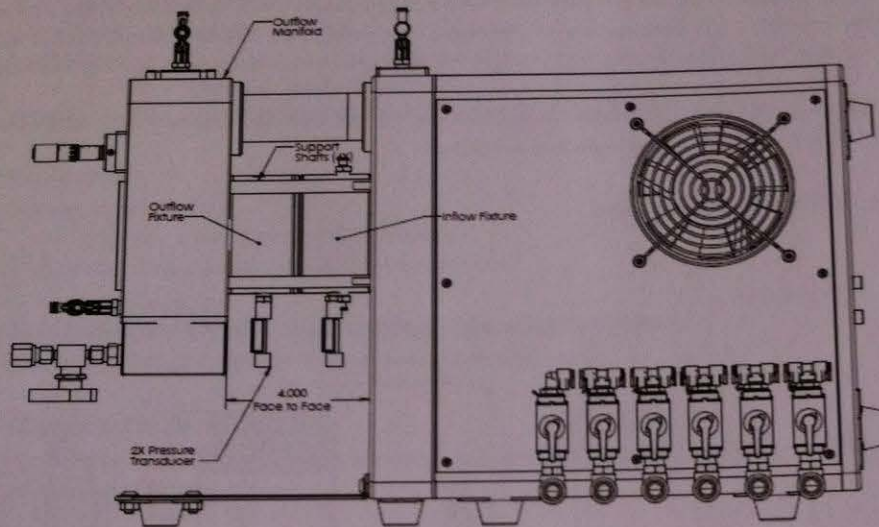


Outflow Fixture

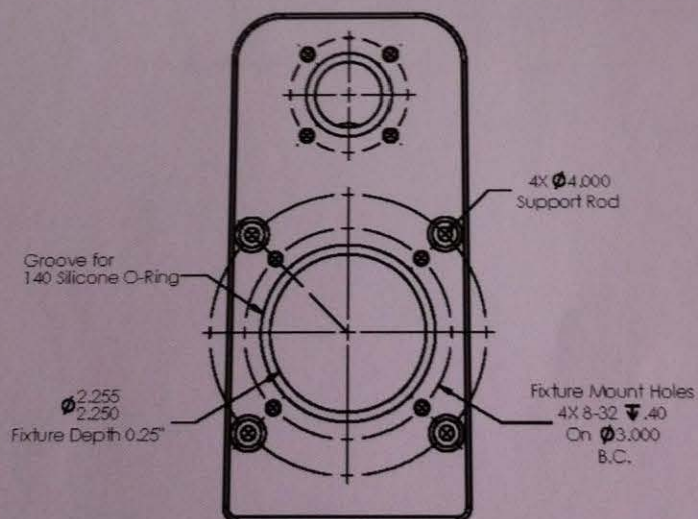


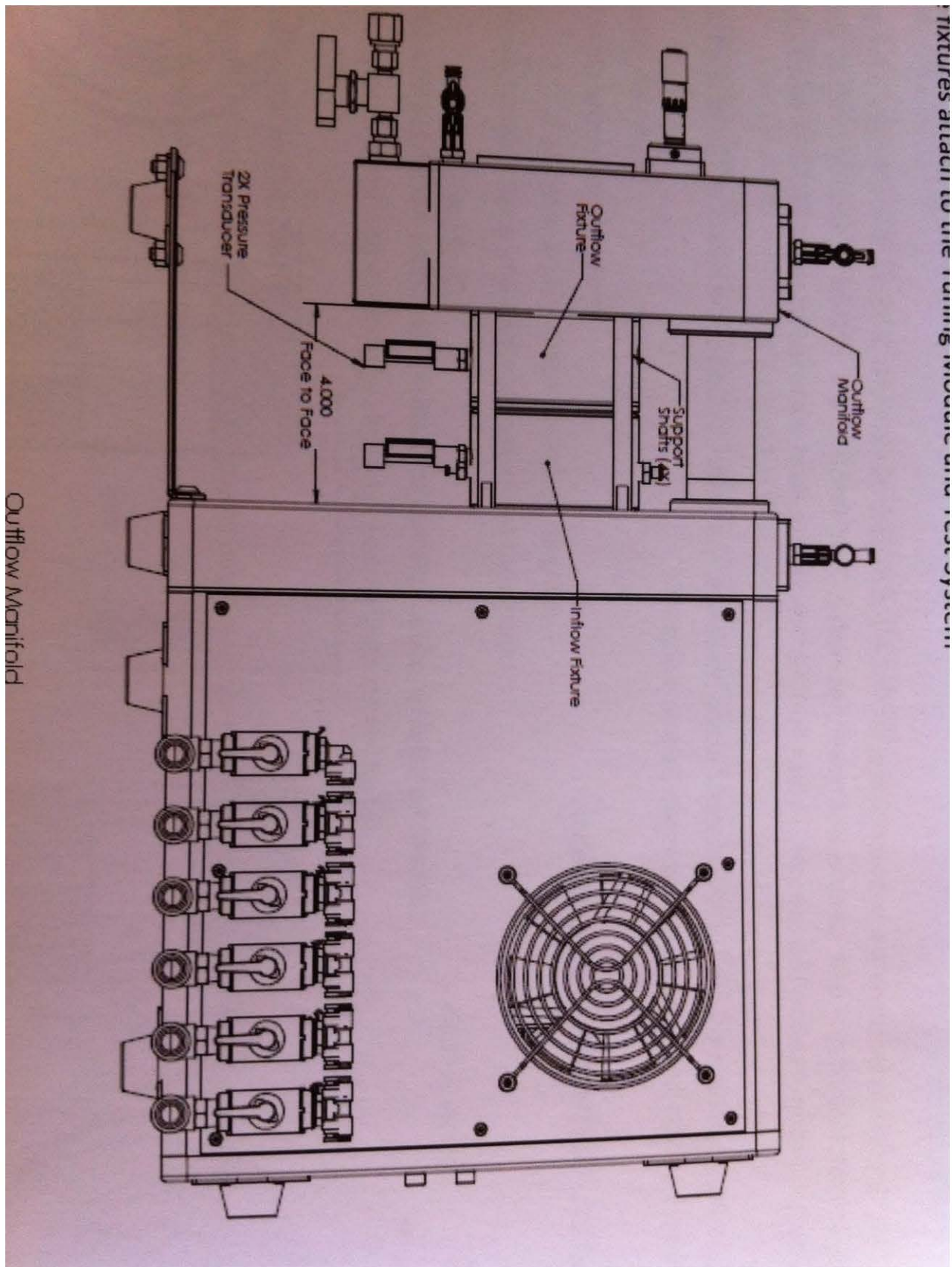
System Mounting

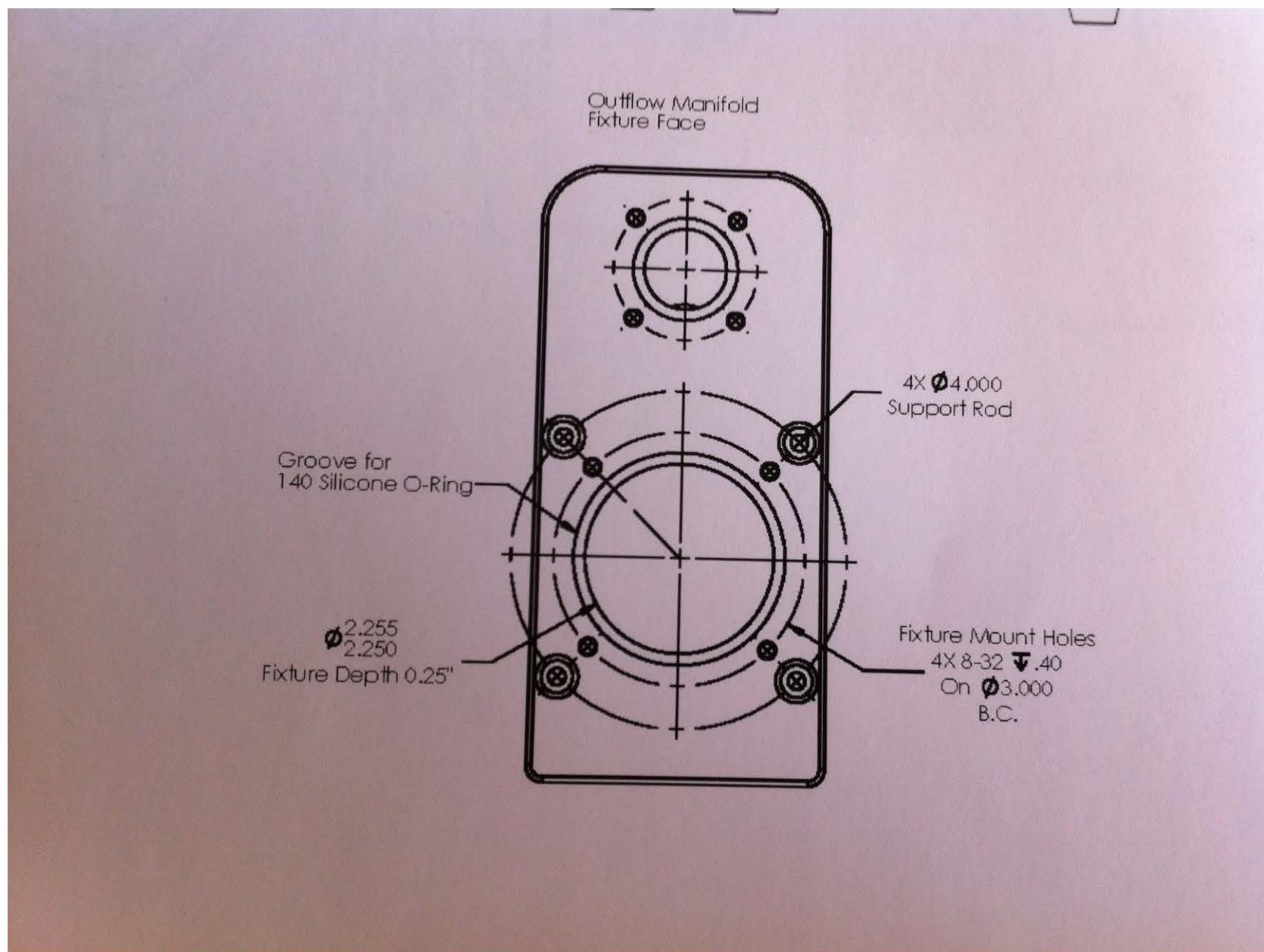
These fixtures attach to the Tuning Module and Test System



Outflow Manifold
Fixture Face







B - OPERATIONAL THEORY

LINEAR DRIVE THEORY

Electromagnetic actuators are direct drive, limited motion devices that utilize a permanent magnet field and coil winding to produce a force that is proportional to the current applied to the coil. The conversion of electrical energy to mechanical is governed by the Lorentz Force Principle. This principle states that if a current carrying conductor is placed in a magnetic field, a force F will act upon it. The magnitude of this force is proportional to the current I , magnetic flux density B and the total number of conductors N of length L .

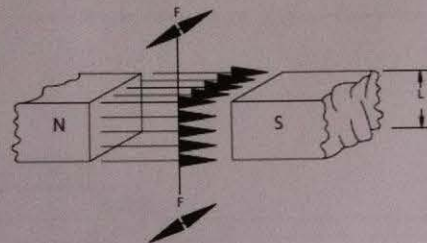


FIGURE 1: LORENTZ FORCE PRINCIPLE

LORENTZ FORCE PRINCIPLE

$F = kBLIN$ (where k is a constant)

Furthermore, a conductor moving through a magnetic field will have a voltage induced across the conductor. The magnitude of the voltage, E , is dependent on the magnetic flux density, B , the length of the conductor, L and the speed of the conductor. This voltage potential which is generated by the velocity of the linear drive and opposes motion is known as back EMF.

BACK EMF

$$E = kBLvN$$

Since the magnetic flux density, total number of conductors and length are held constant in this system, the force produced by the linear motor is directly proportional to the current. In a similar manner, the back EMF is directly proportional to the drive velocity. These physical laws limit the force, displacement and operational frequencies available on the test system.

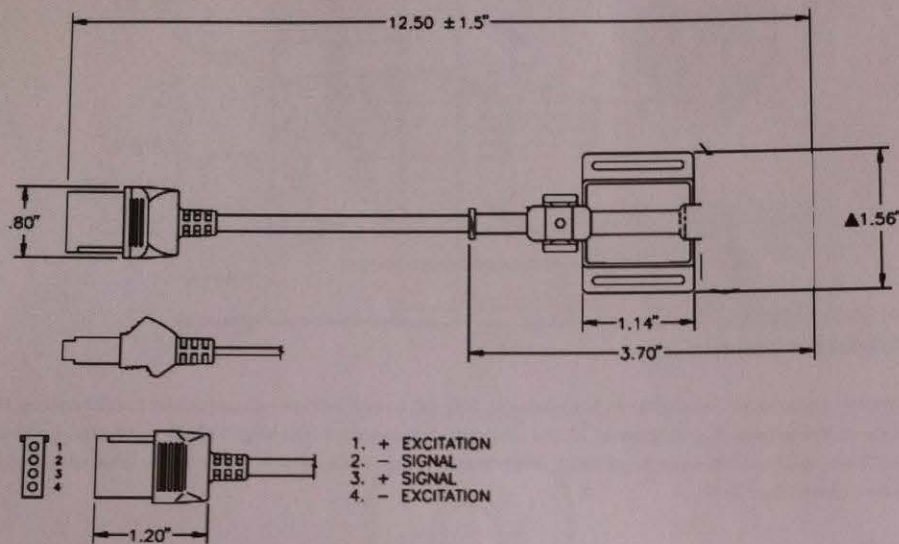
C – SENSOR SPECIFICATIONS

PRESSURE TRANSDUCERS

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PN: PT-U

*Sensor may not include an integrated stopcock and flush device



Detail	Specification
Accuracy	Better than $\pm 2\%$ of reading in the range of 0 to 310 mm Hg Better than $\pm 3\%$ of reading in the range of 310 to 1551 mm Hg In range of 1551 to 3102 mm Hg typically better than $\pm 5\%$ of reading
Pressure Range	-362 to 3878 mm Hg
Frequency Response	1200 Hz
Biocompatibility	All materials in contact with product fluid path meet USP Class VI requirements
Manufacturing Environment	FDA Registered, ISO 13485 certified facility; class 100,000 clean room
Operating Temperature	15 °C to 40 °C (other ranges with process qualification)
Storage Temperature	-25 °C to 65 °C
Input/Output impedance	270 to 400 Ohms
Excitation Voltage	2.5 to 10 VDC
Connector	Custom molded water-tight 4 pin connector; signal $\pm$ and excitation $\pm$

PRESSURE CALIBRATION OUTLINE

- 1) Set the scale at 1000 with an offset of 0 (this will scale the sensor output to mV)
- 2) Apply pressure to the transducer and record the pressure (from a calibrated pressure gauge) and output at various steps (i.e. 0, 100, 200, 300 mm Hg etc..)
- 3) Input the data into excel and create a linear regression [use commands $\text{SLOPE}(X,Y)$ and $\text{INTERCEPT}(X,Y)$]. Convert the mV output back to V when creating the slope and offset
- 4) Input the slope and offset into the Statys Software
- 5) Verify the slope and offset by applying a static pressure (i.e. 200 mm Hg)

TEMPERATURE TRANSDUCER

Omega Engineering

Sensor Contains a Precision 100 Ohm Class A DIN Platinum Element

- Temperature Coefficient (Alpha) = .00385 ohm/ohm/°C
- 3-Wire Configuration with PFA Insulated and Jacketed Lead Wire (Heater RTD Probe)
- 4-Wire Configuration with PFA Insulated and Jacketed Lead Wire (System RTD Probe)

Accuracy for Standard OMEGA RTDs

Temperature °C	Ohms	°C
-200	±0.56	±1.3
-100	±0.32	±0.8
0	±0.12	±0.3
100	±0.30	±0.8
200	±0.48	±1.3
300	±0.64	±1.8
400	±0.79	±2.3
500	±0.93	±2.8
600	±1.06	±3.3
650	±1.13	±3.6
700	±1.17	±3.8
800	±1.28	±4.3
850	±1.34	±4.6

Accuracy for Standard OMEGA RTDs

Temperature °C	Ohms	°C
-200	±0.56	±1.3
-100	±0.32	±0.8
0	±0.12	±0.3
100	±0.30	±0.8
200	±0.48	±1.3
300	±0.64	±1.8
400	±0.79	±2.3
500	±0.93	±2.8
600	±1.06	±3.3
650	±1.13	±3.6
700	±1.17	±3.8
800	±1.28	±4.3
850	±1.34	±4.6

D – STROKE VOLUME TABLES

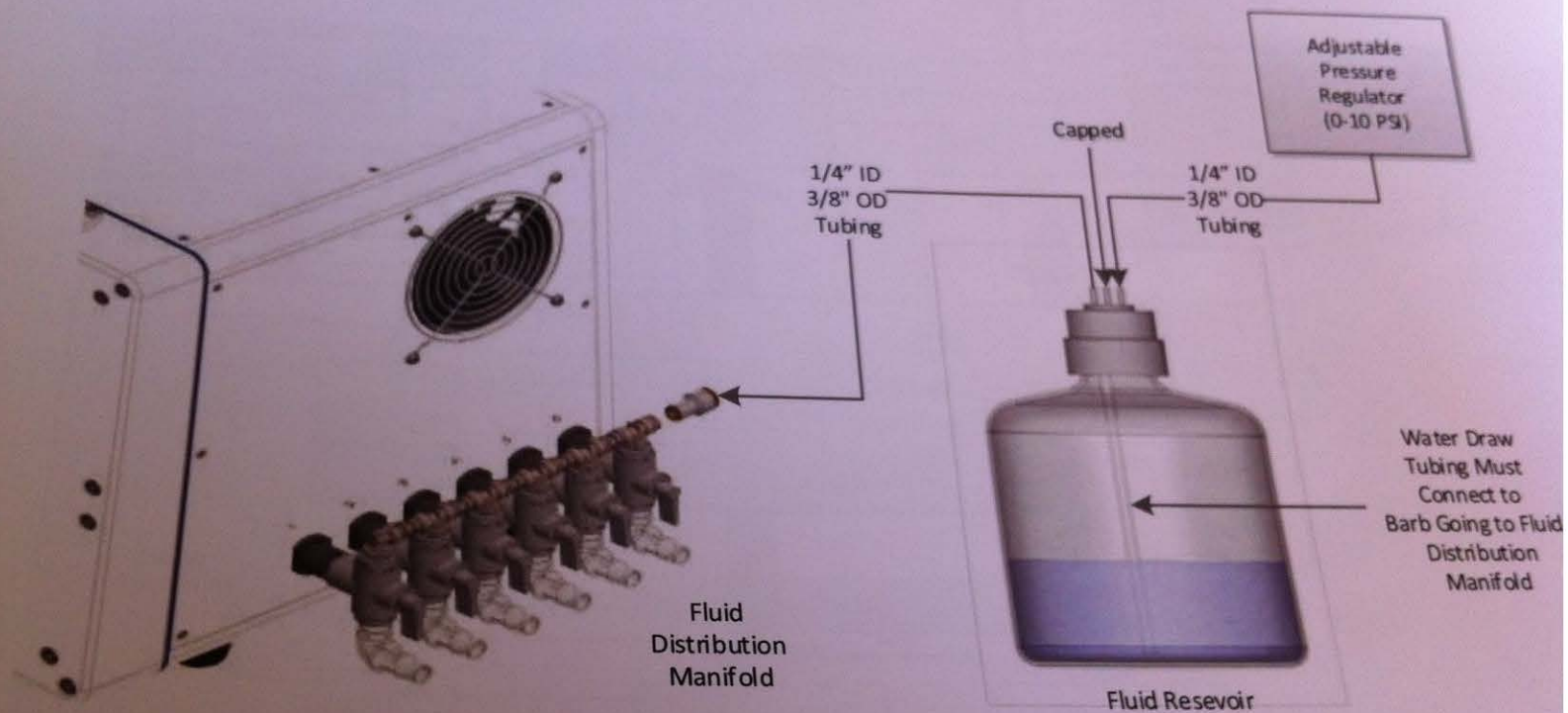
Drive Size [in]	Effective Pressure Area [in ²]	Effective Pressure Area [cm ²]
2.25	3.64	23.48

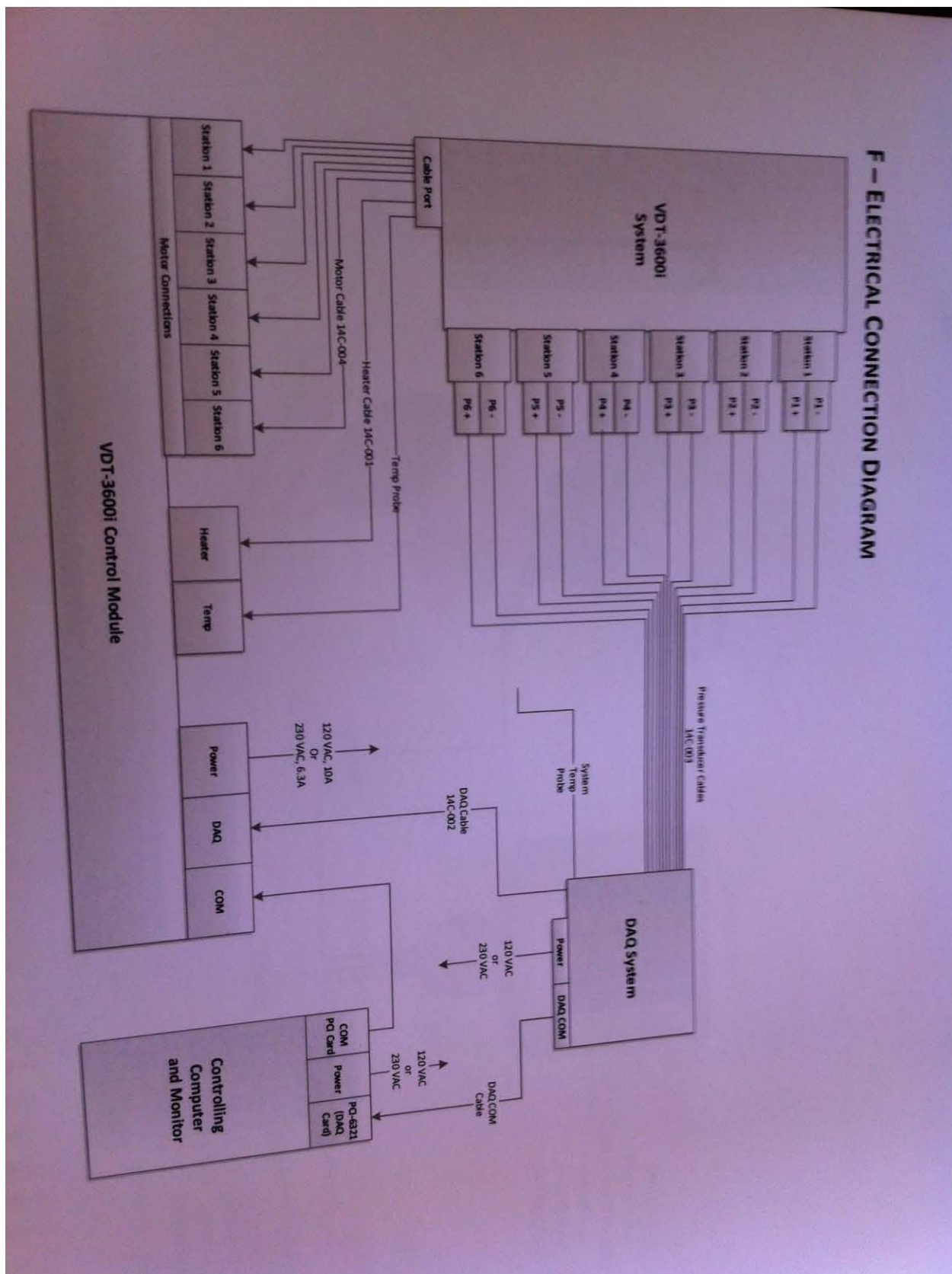
Stroke [mm]	Volumetric Displacement [ml]
	Drive Size [in]
	2.5
0.5	1.17
1	2.35
1.5	3.52
2	4.70
2.5	5.87
3	7.05
3.5	8.22
4	9.39
4.5	10.57
5	11.74
5.5	12.92
6	14.09

*Volumetric displacements are approximate.

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E — GENERIC FLUID CONNECTION DIAGRAM





G – SYSTEM ADJUSTMENT FLOW CHART

