

Portable Manometric Pump

and

Air Compressor

Operating and Service Manual

REF	P3PIP-6-4SS	P3PIP-6-6SS
	P3PIP-6-8SS	P3PIP-6-10SS
	P3PIP-6-12SS	P3PIP-6-14SS
	P3PIP-6-16SS	P3PIP-6-18SS
	P3PIP-6-20SS	P3PIP-6-22SS
	P3PIP-6-24SS	



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145 Traders Blvd. E, Unit #33-34
Mississauga, Ontario, Canada L4Z 3L3
Tel: (905) 890-5525
Toll Free: (800) 303-6611
Fax: (905) 890-3523
Email: mail@muiscientific.com
Web site: www.muiscientific.com

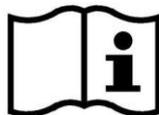
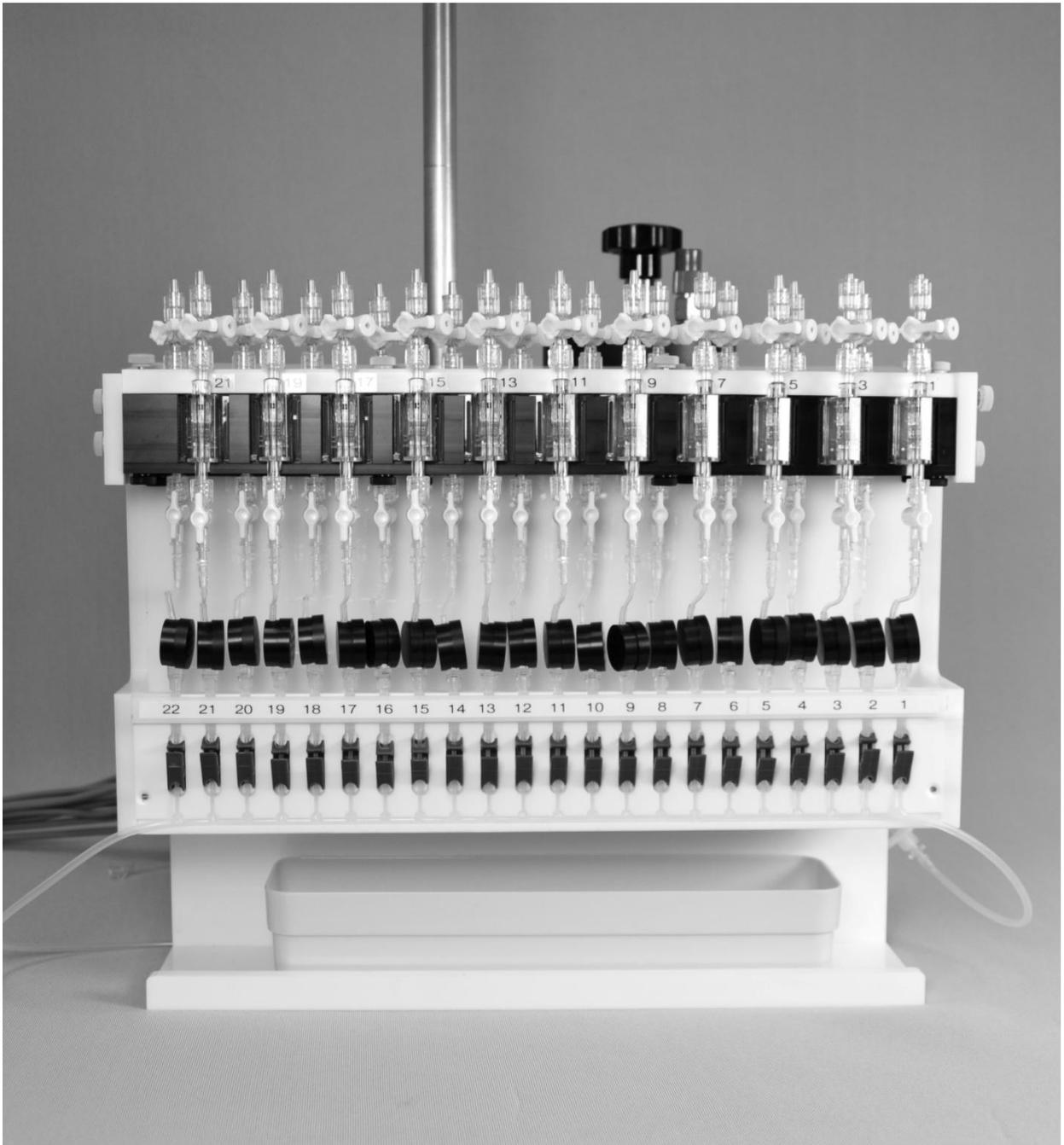


Advena Ltd.
Tower Business Centre, 2nd Floor
Tower Street, Swatar, BKR 4013
Malta



Manual P4-J-201, January 22, 2021

"Federal law (U.S.) restricts the sale of this device to, or by the order of physician."



READ ENTIRE MANUAL
BEFORE OPERATING THIS PUMP

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Section 1 Introduction

1.1 INTRODUCTION

This Portable Manometric Pump is part of the motility system used for intraluminal manometric studies of the gastrointestinal tract, such as pressure measurement of muscular contractions or resting tone inside the esophagus, stomach, bile duct, small intestine, anus, rectum, or colon. Other components of this system include a set of pressure transducers, a manometric catheter, and a computerized data processing system or a chart recorder.

The pump uses regulated compressed air to deliver distilled water through very small bore tubing of resistors to the manometric catheter. The pressurized water from each resistor is connected to a pressure transducer and then passes through one lumen of the multi-lumen catheter to that lumen's single opening into the organ of the patient. The pressure changes in the esophagus are transmitted through this fluid path back to the externally mounted transducer; i.e. the water serves as a pressure - transmission medium. Each lumen of the manometric catheter is connected to its own pressure transducer and all the pressure transducers are connected to a computerized recording system or a strip chart recorder. The pressure profile of the multi-channel tracing provides useful diagnostic data for evaluation of the normal or abnormal motor function of the gastrointestinal tract. Similar applications include pressure measurements for organs such as oropharyngeal, esophageal, stomach, intestinal, colonic, anorectal and biliary manometric studies.

This pump is designed to operate at a constant pressure rather than at a constant flow rate. It maintains a pre-set hydraulic pressure (5-15 psi) at the water reservoir regardless of the flow. At 15 psi (776 mm Hg) the pump provides a high static hydraulic pressure background to ensure a high pressure rise rate as well as recording accuracy and repeatability. It can record fast pressure changes such as in the upper esophageal sphincter. The small bore of the resistor tube also ensures a very low infusion rate. During a motility study, the actual flow rate varies due to the varying amount of obstruction caused by muscle contractions.

The pressure rise rate of the pump, measured as pressure change per unit of time (i.e. mm Hg/sec or cm H₂O/sec), varies directly with the water reservoir pressure. A higher water reservoir pressure will result in a higher pressure rise rate but also a higher flow rate. To achieve measurement accuracy, the pressure rise rate of the recording system must exceed the actual physiological rise rate of the organ. The upper esophageal sphincter has the highest muscular contraction rate of the gastrointestinal tract. A study of this organ requires the highest pressure rise rate of the recording system, 400 mm Hg/sec. The recommended water reservoir pressure of 15 psi (pounds per square inch) will achieve a pressure rise rate of 400 mm Hg/sec. The main purpose of reducing the water reservoir pressure from 15 to 5 psi is to reduce the infusion rate from 0.6 to 0.2 ml/min. The lower water reservoir pressure and lower pressure rise rate still permit reliable measurement accuracy on those organs that have a lower physiological contraction rate. The pump allows the operator to change the water reservoir pressure for different physiological applications in order to optimize the pressure rise rate and flow rate. An infusion rate table (Table 1, Section 4.3) is provided to enable an estimate of the total volume of water infused into the patient in a given period of time.

a) Intended Use

The Manometric Pump is part of the motility system used for intraluminal manometric studies of the gastrointestinal tract, such as pressure measurement of muscular contractions or resting tone inside the esophagus, stomach, bile duct, small intestine, colon, rectum, or anus.

Other components of this system include a set of pressure transducers, a manometric catheter, and a computerized data processing system or a chart recorder.

The pump should be used in a hospital setting under the supervision of a physician who has received professional training in gastrointestinal manometry.

b) Indication for Use

Use of the Manometric Pump together with a manometric catheter is indicated when measurements of gastro- intestinal tract pressures are judged to be useful for determining management of patients with proven or suspected gastro-intestinal motor disorders.

The pressure profile of the multi-channel tracing provides useful diagnostic data for evaluation of the normal or abnormal motor function of the gastrointestinal tract. Similar applications include pressure measurements for oropharygeal, esophageal, stomach, intestinal, colonic, anorectal and biliary motility studies.

The data obtained will assist in the diagnosis and treatment of dysfunction in the GI tract.

c) Contraindication for use

The presence of any stenosis, structural deformity or disease within the gastrointestinal tract, that results in an unacceptably increased risk of distention, perforation, or any other adverse consequence arising from use of this assembly.

d) Warnings

The Manometric Pump must only be used in a hospital setting under the medical supervision of a physician who has received professional training in gastrointestinal manometry.

No electrical equipment should be located beneath the Manometric Pump. Some water from the motility catheter is likely to drip down during the procedure. A danger of electric shock could result.

Use only sterilized irrigation water in the water chamber. Never use tap water as it contains minerals which can cause blockages in tubing and/or can support bacterial growth.

Do not position the unit such that the equipment will be difficult to unplug or that ventilation openings are blocked.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

The Manometric Pump must not be alter or modify in any way. Mui Scientific is not liable for personal injury and damage to property if the original Mui Scientific parts are not being used, if the instruction for use in these operating instructions are not being observed, or if assembly, new settings, alterations, extensions and repairs have been carried out by qualified personnel.

The Manometric Pump has a prescribed lifetime of 10 years.

Section 2 Description of Pump

2.1 PHYSICAL DESCRIPTION

The black hose from the air compressor is connected to the red quick-connect on the back side of the control box of the pump. The pressurized air can be regulated with the manually adjustable pressure regulator located at the front of the control box.

The air compressor pressurizes the water reservoir, which delivers pressurized water to a manifold then up through a set of compact resistors and transducers and then into multi-lumen manometric catheter. The pressurized air is regulated with a manually adjustable regulator. This sets the final pressure in the water reservoir. The Supply Pressure gauge (right side) shows the pressure from the external air supply i.e. air compressor. The Driving Pressure gauge (left side) shows the pressure in the water reservoir. (Refer to Figures 1 and 2 in Section 1.2).

The water reservoir is removable, simply resting between the black pegs, which sits atop the control box. The chamber float acts as a barrier to minimize air absorption into the water. The lid of the water reservoir is removable to facilitate filling and cleaning.

The 2-way stopcock on the Reservoir Outflow Control Device at the bottom of the water reservoir provides the main on/off control of the water flow to the manifold. The outlet of the manifold is connected to the compact resistors which connect to the bottom of the transducers. The 2-way stopcock at the bottom of the transducers function as individual shut-offs for each of the transducers. The pigtails of the manometric catheter are connected to the top of each transducer (Refer to Figure 2 in Section 1.2).

2.2 GENERAL REQUIREMENTS

CAUTION:

- **This pump must only be used in a medical setting under the medical supervision of a physician who has received professional training in gastrointestinal manometry.**

The pump should be positioned at approximately the same height as the patient's bed. The height of the transducers should be level with the height of the patient's stomach. This will minimize the hydrostatic pressure artifact on the transducer and on the recording.

CAUTION:

- **No electrical equipment should be located beneath the pump. Some water from the catheter is likely to drip down during the procedure. A danger of electric shock could result.**
- **Use only sterilized irrigation or distilled water in the water reservoir. Never use tap water as it contains minerals which can cause blockages in tubing and/or can support bacterial growth.**

WARNING:

- **Do not position the unit such that the equipment will be difficult to unplug or that ventilation openings are blocked.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.**
- **The pump must not be altered or modified in any way. Mui Scientific is not liable for personal injury and damage to property if the original Mui Scientific parts are not being used, if the instruction for use in the operating instructions are not being observed, or if assembly, new settings, alterations, extensions or repairs have been carried out by qualified personnel.**

There are no contraindications for this device.

There are no applied parts in this device as defined in IEC 60601-1:2005+C1+C2.

The equipment can be isolated from mains by turning power off or unplugging the unit.

The Manometric Pump does not contain any hazardous goods. The component parts of the pump must be disposed of correctly and the materials are to be separated carefully, according to local regulations.

2.2 GENERAL REQUIREMENTS

Electrical requirements for Air Compressor Unit (if included):

- (a) 115 Volt Model: A grounded, hospital grade, 115 Volt, 60 Hz, 15A electrical outlet is required. The pump is rated at 2A. Hospital grade power cord with IEC plug is included.

- (b) 220 Volt Model: A grounded, hospital grade, 220 Volt, 50 Hz electrical outlet is required. The pump is rated at 2A. Hospital grade power cord with female IEC plug is required.

CAUTION:

- **Duty cycle: Maximum 5 minutes out of 120 minutes.**
- **The inlet pressure rating: 117kPa – 373kPa.**

Ambient Operation Conditions:

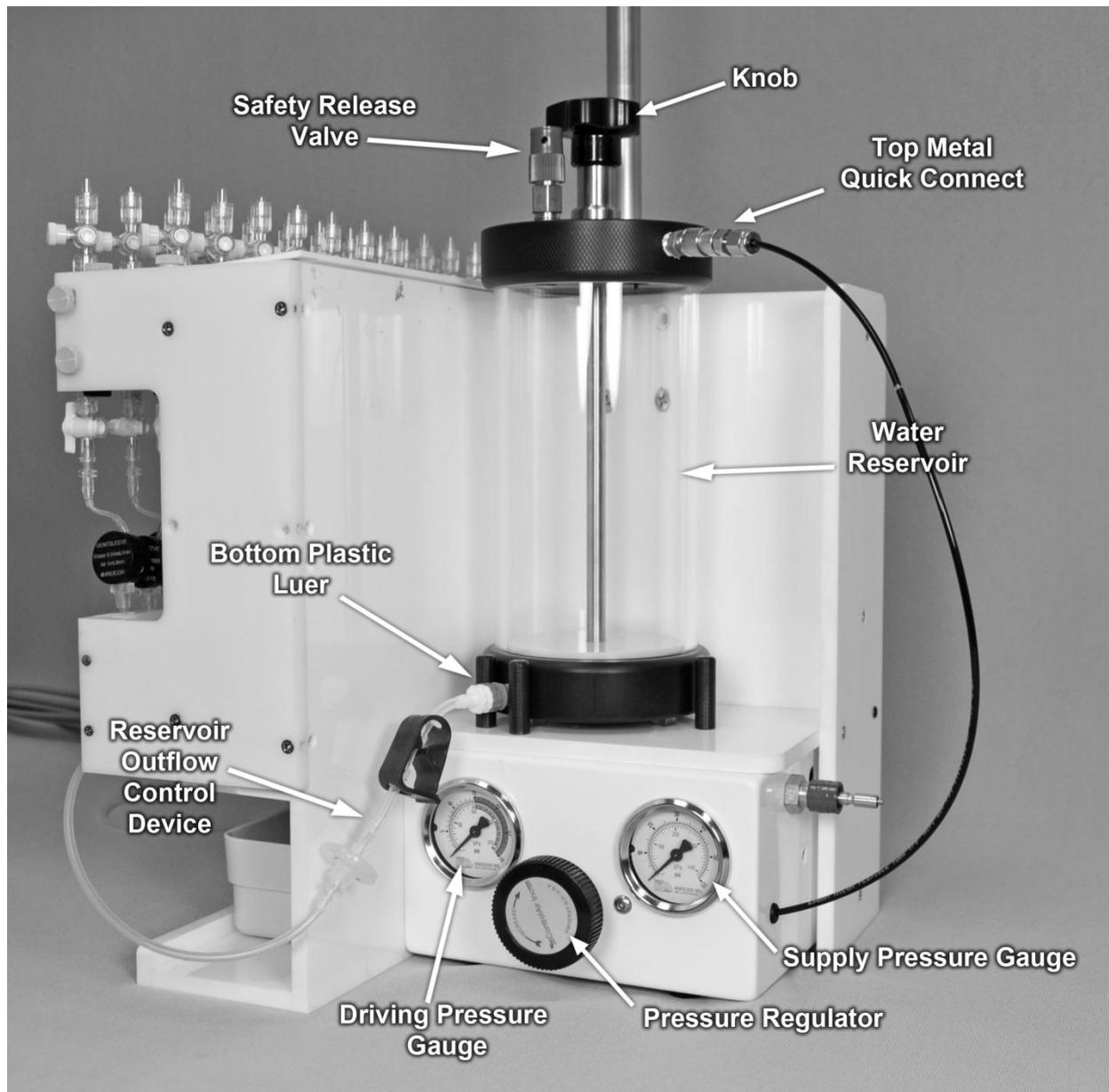
 (Ambient Temperature Range) ----- +10°C To +40°C

 (Relative Humidity Range) ----- 30% To 75%

 (Atmospheric Pressure Range) ----- 86 kPa To 106 kPa

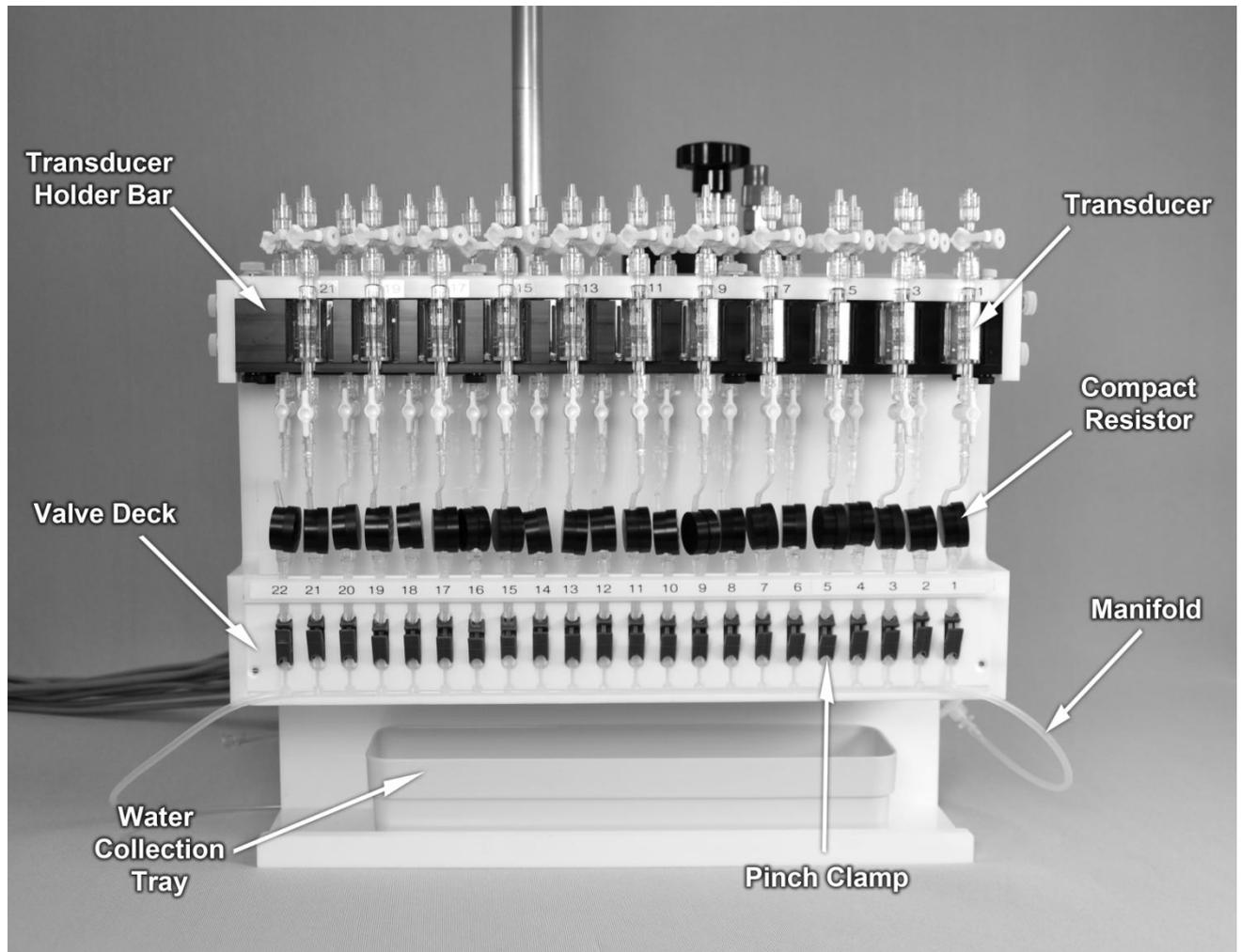
2.3 DIAGRAM OF FEATURES

Figure 1 – Front View



2.3 DIAGRAM OF FEATURES

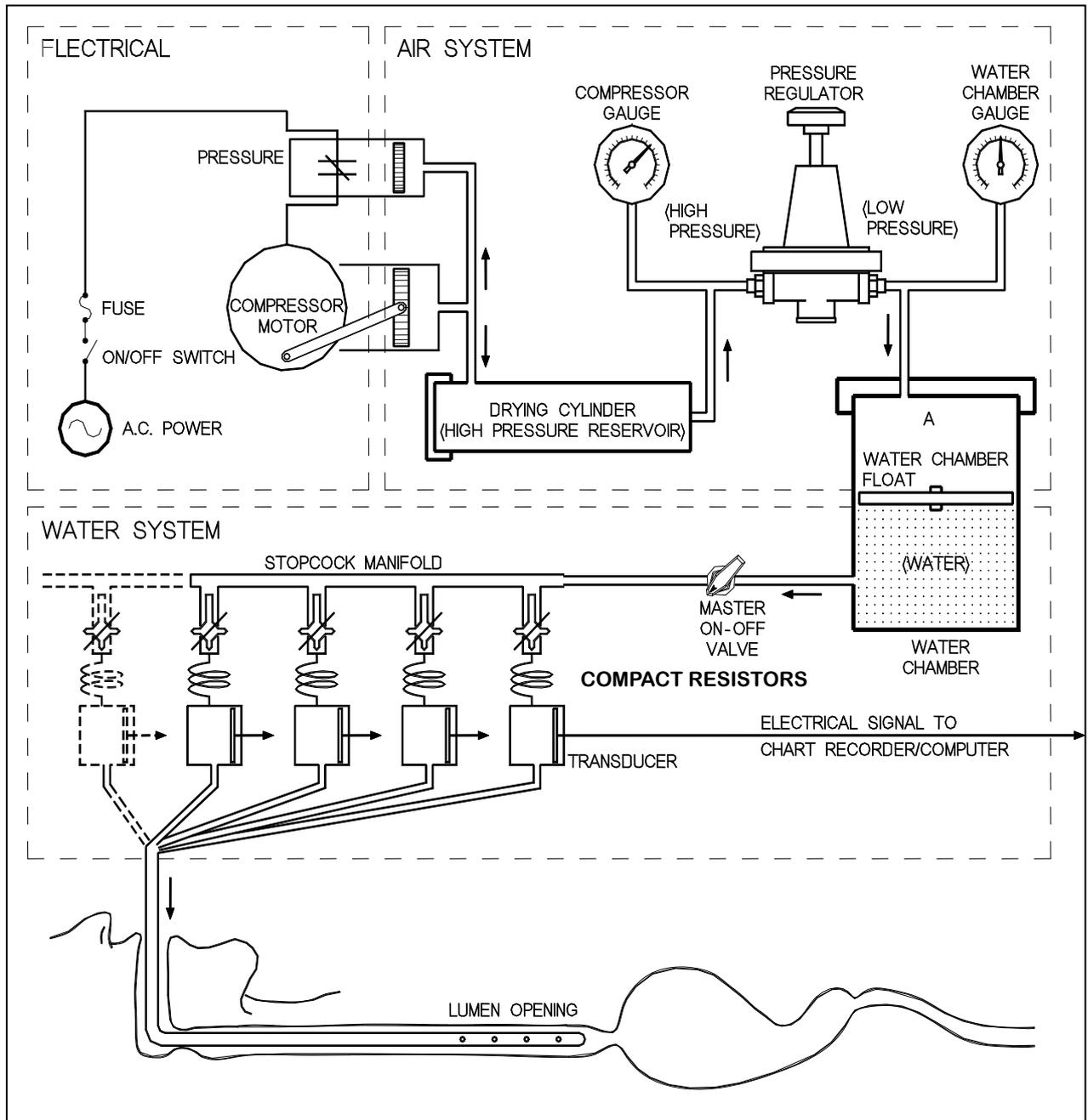
Figure 2 – Side View



*Pump shown in picture is the 22-Channel Portable pump

2.3 DIAGRAM OF FEATURES

Figure 3 – Block Diagram of Manometric Pump



2.4 APPLICABLE STANDARDS AND WARNING STATEMENTS

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019*	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1:General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN 60601-1:2015/A1:2013	Medical electrical equipment — General requirements for basic safety and essential performance
EN 60601-1-2:2014	Electromagnetic disturbances requirements and tests (EMC)
IEC 60601-1-6: 2013	General requirements for basic safety and essential performance: Usability
ISO 17664:2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices

Equipment Classification

Class I with respect to protection from electric shock.

Type BF with respect to degree of protection from electric shock.

Ordinary degree of protection against ingress of liquids.

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with nitrous oxide.

Mode of operation: Max 5 minutes ON per 2 hours.

2.4 CERTIFICATION, CLASSIFICATION, AND WARNING STATEMENTS

Warning Statements and Warning Symbols



TYPE BF APPLIED PART

DANGER: EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE

DO NOT PERFORM SERVICE OR MAINTENANCE WHILE EQUIPMENT IS IN USE

GROUND RELIABILITY CAN ONLY BE ACHIEVED WHEN THE EQUIPMENT IS CONNECTED TO A RECEPTACLE MARKED "HOSPITAL ONLY" OR "HOSPITAL GRADE"



REFER TO INSTRUCTION MANUAL/BOOKLET



ATTENTION; CONSULT ACOMPANYING OPERATING INSTRUCTIONS



CAUTION; TO REDUCE THE RISK OF ELECTRIC SHOCK DO NOT REMOVE COVERS. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL



REPLACE FUSE AS MARKED (250V, T2A)

Note: All models (115v, 220v) require 2 fuses:
5 x 20 mm, 250v, T2A, 35A breaking capacity.



SEE INSTRUCTION MANUAL



DO NOT USE IF PACKAGE IS DAMAGED



NON STERILE



NON-DEHP

Environmental Conditions for Storage or Transport

When packed for transport from factory, equipment will withstand



AMBIENT TEMPERATURE RANGE -40°C TO +70°C



RELATIVE HUMIDITY RANGE 10% TO 100%



ATMOSPHERIC PRESSURE RANGE 86 KPA TO 106 KPA

Section 3 Initial Installation

3.1 INITIAL UNPACKING

Remove any remaining packing material. Place the main pump assembly on a table. Unpack the following:

- Calibration rod (with 2 tubes and 2 thumb screws)
- Water collection tray
- Water reservoir
- Reservoir outflow control device

Note: Calibration rod is only included, if customer ordered it with the pump.

3.2 ASSEMBLY OF PUMP

Attach the accessories in the following order (refer to Figures 1 & 2 in Section 1.2):

Calibration Rod (If ordered):

- Place the calibration rod against the left back of the pump and secure the rod to the pump using the 2 thumb screws provided. Slide the calibration tubes onto the upper and lower holders on rod.

Water Collection Tray:

- Place the water collection tray in the bottom tray holder.

Transducers:

Transducers are already connected in assembly of new unit. Follow the instructions below to replace or reconnect the transducers:

- Remove the channel number label strip from the top of each transducer bar by unscrewing the 4 thumb screws on top.
- Slide a transducer downward into each transducer holder, folding the cord upwards behind the transducer to fit in the groove of the transducer bar and hang over the top into the cable box.
- Secure transducers in place by replacing the channel number label strip and securing with the thumb screws on top.
- Connect the cord from each transducer to the cables that leads to your computer motility system.
- Attach the compact resistors to the bottom of the transducers (female luer) and to the top of the water manifold (male luer).

Water Reservoir:

- Place the water reservoir onto the top housing of the pump so the bottom plastic luer sits in between the two pegs on the left.
- Connect the reservoir outflow control device from the connector at the bottom of the water reservoir to the right end of the water manifold.
- Connect the black hose from the pressure regulator to the metal quick-connect on the lid of the water reservoir. Push the two metal fittings together until they snap into the latched position.
- Connect the air lead black hose for air compressor to the red quick-connect on the back side of the pump. Push the two metal fittings together until they snap into the latched position.

Section 4 Preparation Procedures

4.1 FILLING THE WATER RESERVOIR

Ensure that the 2-way stopcock on the reservoir outflow control device is in the OFF position.

Ensure the 2-way stopcocks below the transducers are open.

Follow the steps below in given sequence:

- Unscrew the knob of the water reservoir and remove the lid and round float by tipping the water reservoir on its side.
- Ensure that the inside of the water reservoir is clean. Fill three-quarters full with sterilized irrigation or sterilized distilled water only.
- Place the reservoir float back in the water reservoir to avoid any bubbles being trapped under the float.

CAUTION:

- **Never use the pump without the float in the water reservoir. Air bubbles will form at the transducer and will reduce the pressure rise rate and the accuracy of measurement.**
- Replace the lid and screw the knob back on and tighten securely.
- Ensure the bottom plastic luer located at the bottom of the water reservoir is connected.
- Ensure the top metal quick-connect located on the lid of the water reservoir is connected by pushing the two metal fittings together until they snap into the latched position.

4.2 CONNECTING AIR COMPRESSOR

- Attach the black extension tube from the compressor to the red quick-connect on the back side of the pump.
- Push the two metal fittings together until they snap into the latched position.
(NOTE: pump will not be pressurized until air compressor is turned ON)

4.3 ADJUSTING WATER RESERVOIR PRESSURE

To select water reservoir pressure for optimal recording accuracy of pressure rise rate for your recording site or organ, refer to Table 1 and adjust the water reservoir pressure accordingly.

CAUTION:

- **Do not set water reservoir pressure higher than 15 psi. Patient will receive excessive water.**

Table 1: Water Reservoir Pressure Selection vs Infusion Rate/Pressure Rise Rate

RECORDING SITE (ORGAN)	APPROXIMATE INFUSION RATE WITH COMPACT RESISTORS ml/min	RECOMMENDED WATER RESERVOIR PRESSURE pound/square inch (kPa)	MINIMUM PRESSURE RISE RATE AT CATHETER OPENING mm Hg/sec
UES	0.6	15 (103)	400
Esophagus	0.6	15 (103)	400
Stomach	0.6	15 (103)	400
Small Bowel	0.3	5 (35)	60
Bile Duct	0.3	5 (35)	60
Colon	0.3	5 (35)	60

Table 2: Pressure Conversion Chart

Psi	cm of H₂O	mm of Hg	kPa
20	1408	1034	138
15	1056	776	103
5	352	259	35

4.4 FILLING PUMP AND TRANSDUCERS WITH WATER

- Ensure the water collection tray is placed underneath water manifold such that it can catch any water dripping out.
- Ensure or 2-way stopcock on the reservoir outflow control device is in the OFF position.
- Ensure all 2-way stopcocks below the transducers are open.
- After the water reservoir pressure has been adjusted to the desired level (usually 15 psi), turn ON the 2-way stopcock on the reservoir outflow control device leading into the right side of the water manifold.
- Allow 2-3 minutes for the water pressure to purge any air inside the compact resistors.
- Ensure the water is flowing out of the top of all the transducers and no trapped air bubbles are in the transducers.
- Connect the manometric catheter by attaching each pigtail to its' respective transducer.
- Fill the catheter with water and flush out any remaining air bubbles.
- The pump system is now filled with water and ready for a functional check.

4.5 CALIBRATION OF RECORDING SYSTEM

Refer to the manufacturer's instructions for your computerized data processing system.

Follow the recommended calibration procedure.

Use of Hydrostatic Calibration System (0-50 cm H₂O or 0-68 cm H₂O)

- With pump ON and water dripping, slide catheter into the bottom calibration tube. The bottom calibration tube is fixed to the same height as the transducers. This position simulates 0 cmH₂O or 0 mmHg pressure. Select low calibration on computer or adjust baseline on recorder to 0 cmH₂O or 0 mmHg position for each channel.
- Slide catheter into the top calibration tube. This position generates 68 cmH₂O pressure or 50 mmHg (or 50cm H₂O). Select high calibration on computer, or adjust the recorder to 68 cmH₂0 or 50 mmHg (or 50cm H₂O) for each channel.
- The pump is now calibrated and in stand-by mode ready for a study.

4.6 FUNCTIONAL CHECK- PINCH TEST

It is recommended to perform this pinch test routinely at the beginning of each motility study.

This test confirms that the entire system is functioning properly, including the pump, the transducers, and the recording system, and gives a permanent record of the functional performance of the system. This pinch test can also be useful during a study whenever the clinical tracing is abnormally inactive and the performance of the system is in question.

- Run the recording program as you normally would for a motility study.
- Set the recording system pressure amplitude as you would for a study.
- Firmly pinch the manometric catheter for several seconds at a point immediately above the transducer and release it. The pressure tracing should respond immediately with a virtually vertical rise to the full-scale pressure amplitude as set. This response confirms

that the entire system is functioning properly, with no leakage or major trapped air bubbles in the system.

- If poor response, troubleshoot before beginning study. Refer to Section 5.1 – Functional Troubleshooting with the Pinch Test, for detailed explanations of unsatisfactory pressure tracings, and to Section 5.2 for Calculation of Pressure Rise Rate.
- Repeat this test for all channels.
- The pump is now in standby mode ready for calibration.

4.7 NORMAL OPERATION BEFORE AND DURING THE STUDY

- Check that there is sufficient water in the reservoir to complete the study. Refill the water reservoir if necessary.
- The Driving Pressure or Water Reservoir Pressure gauge should be set at the desired level (usually 15 psi).
- The manometric catheter should be firmly attached to the stopcocks on the top of the transducers and all air bubbles should have been flushed out.
- Calibrate the recording system if necessary (Refer to Section 4.5 – Calibration of Recording System, and see instructions from the manufacturer of the computer system). Make sure that all the tracings are at zero pressure (baseline position).
- Run the computer as for a motility study.
- Set the baseline tracing to 0. This establishes the true hydrostatic baseline pressure to zero.
- With the pump ON, all tracings should show an increase from the baseline of 2-10 mm Hg. This is known as the infusion artifact. It is caused by friction and restriction of the water flow passing through the catheter. If an abnormally high infusion artifact occurs, blockage may have occurred within the manometric catheter. (Refer to Figure 3 below).
- Set the infusion baseline tracing to 0 again. This is the infusion baseline, the baseline pressure with the infusion artifact removed. This is the baseline to be used for the study.
- Pinch Test: Pinch the manometric catheter immediately above the transducer and observe a sharp rise in the tracing. Repeat the pinch test for all channels.
- If the tracing does not rise sharply full-scale (refer to Figure 4 below), the pump and/or computerized recording system are not functioning properly. Troubleshoot the problem before proceeding with the study (Section 5.1 – Functional Troubleshooting with the Pinch Test).
- If the tracings are acceptable, the manometric catheter can be placed into the holding tray directly below the water manifold until the patient is ready for insertion, or it can be immediately inserted into the patient.
- You can repeat the pinch test again, or start the motility procedure according to your protocol.

Figure 3 - Infusion Artifact

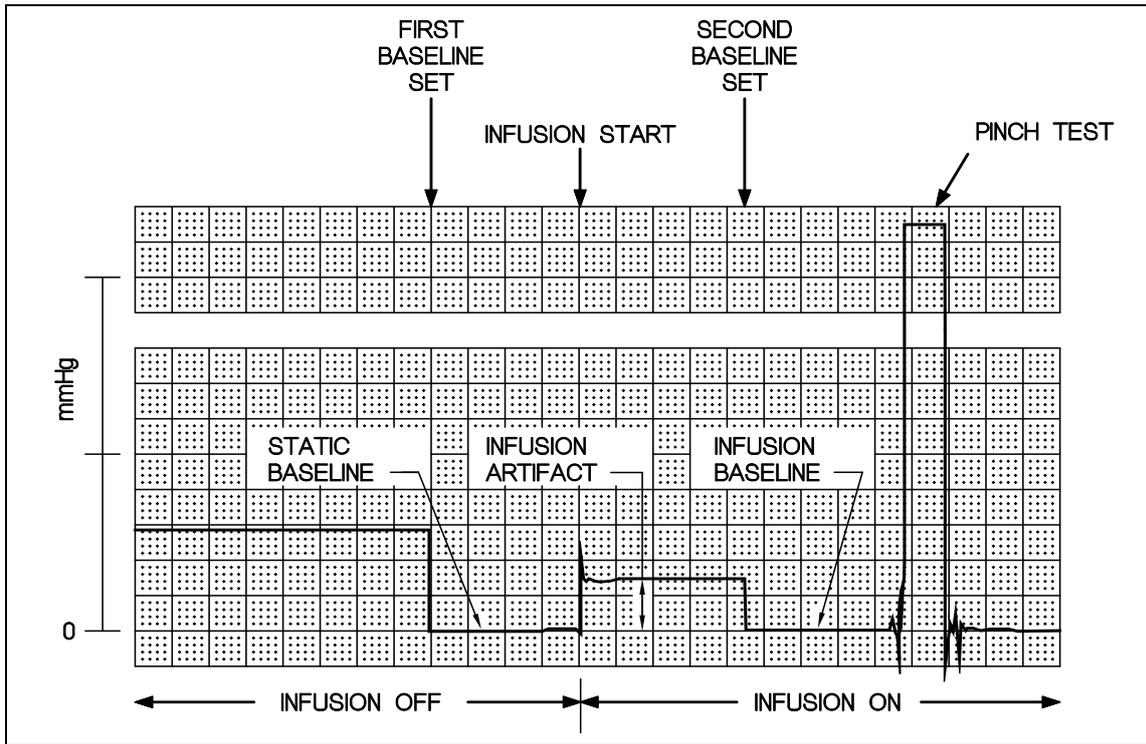
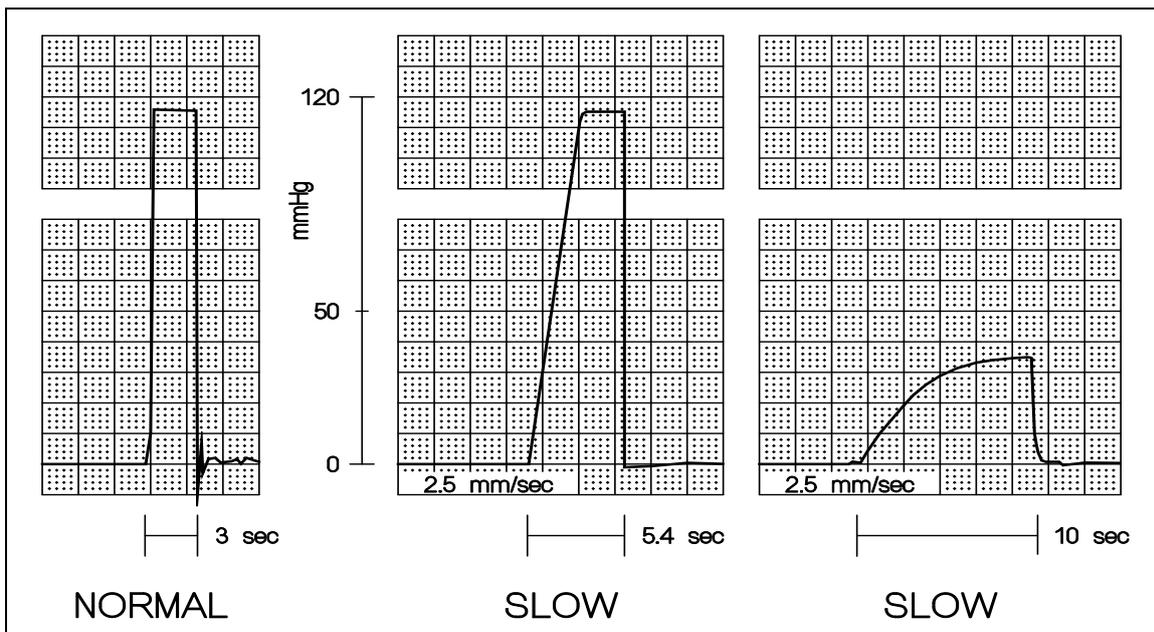


Figure 4 – Pinch Test: Normal and Slow Pressure Rise Rate



4.8 POST STUDY: DAILY BLOW-DRY SHUT-DOWN PROCEDURE

- Release all pressure in the pump system by using the pressure release valve located at the control box above the pressure regulator knob until the pressure in both gauges on the control box (and the gauge on the compressor, if included) drops to zero.
- Remove all the water from the water reservoir.
- Reconnect the empty water reservoir and pressurize by reconnecting the metal quick-connect on the water reservoir lid.
- Open all valves and stopcocks.
- Flush the whole system with air for 5 minutes or until no more water is dripping out of the transducers.
- Depressurize the pump system till both the high and low pressure gauge are at 0 psi using the pressure release valve.
- Remove empty water reservoir. Store dry with lid off.
- Store pump system dry with all stopcocks and valves open.

CAUTION:

- **Do not leave any water in the pump system or water reservoir overnight. Retained water in the pump system may cause the growth of bacteria to unacceptable potable water standards.**

SERVICE MAINTENANCE

According to clinical standards, the water in the water reservoir has to meet the acceptable levels of potable water. The proven method to keep bacterial levels down is to store the pump tubing system dry when not in use. The drying protocol alone can maintain the daily sterilized irrigation water within acceptable potable water standards.

Section 5 Troubleshooting

5.1 FUNCTIONAL TROUBLESHOOTING WITH THE PINCH TEST

When the tracing following the pinch test does not rise sharply to full-scale deflection, the system is not functioning properly. If only one tracing is affected, the problem is most likely to be in the individual compact resistor, the transducer, or the manometric catheter. If all channels are affected, then the problem is probably with the water reservoir, or the recording system.

A. No pressure rise in recording – Possible causes:

- Supply Pressure or Driving Pressure is abnormal:
 - If the Supply Pressure gauge is zero, check the connection of the black hose, and ensure that the compressor is turned ON.
 - Check that the Driving Pressure gauge reads 15 psi (or the desired setting)
 - Top quick-connect to water reservoir is disconnected or water reservoir is not pressurized:
 - Ensure that the metal quick-connect on the side of the water reservoir lid is connected properly. Push the metal connector together hard, until it snaps.
 - Bottom plastic luer to water reservoir is disconnected:
 - Reconnect the bottom plastic luer.
 - The 2-way stopcock on reservoir outflow control device to water manifold, compact resistor/transducer/manometric catheter is closed:
 - Ensure that 2-way stopcock is at “open” position to fix the problem
 - Transducer malfunction:
 - If any individual channel has a poor or no response rate, then there could be a transducer malfunction.
 - Interchange the transducer of a poor response channel, with one from a channel that is responding properly to confirm malfunction.
- Note: Refer to section 3.2 of this manual for replacing transducers
- Recording system malfunction:
 - If all channels have no response, then the possible cause is a recording system malfunction.
 - Troubleshoot by following manufacturer’s instructions for the computer system.

B. Slow pressure rise in recording – Possible causes:

- Air bubbles in fluid path:
 - carefully inspect for air bubbles in system. Flush the system thoroughly to ensure the absence of bubbles.
- Leakage in fluid path:
 - carefully inspect all luer connections for leakage of water. Tighten all connections; replace any components that leak. Wipe all luer connections to dry.
- Supply Pressure gauge too low, i.e. 1-2 psi:
 - if the Driving Pressure is less than 15 psi (or desired setting), turn the pressure regulator control knob clockwise to increase the pressure output from the regulator to the water reservoir.
 - if the pressure on the Supply Pressure gauge is less than 15 psi (or desired setting of Driving Pressure), ensure the air hose is properly connected and that there is proper air flow through the system.
- Blocked compact resistor (in channels with slow rise rate):
 - remove any blocked compact resistors, attach the flush support tool (if available) around the silicone luer, and flush them using a 1cc syringe filled with sterilized irrigation water. If any compact resistors are still blocked repeat flushing with isopropyl alcohol, or replace them.
 - check that the 2-way stopcocks on the bottom of the transducers are in fully open position.
 - disconnect the catheter from the transducers. Observe water dripping from each transducer.
- Leaking or blocked catheter:
 - connect the catheter to the transducer and lay it horizontally on top of the transducers.
 - the artifact should be similar for all channels.
 - any channel that has an unusually low infusion artifact is likely to have a leaking lumen or valve connection. Repair or replace leaking component.
 - any channel that has an unusually high infusion artifact is likely to be blocked in that lumen of the catheter. Remove the catheter, place it in a basin of hot water, and flush the channel with a small syringe and hot water until the channel is cleared.

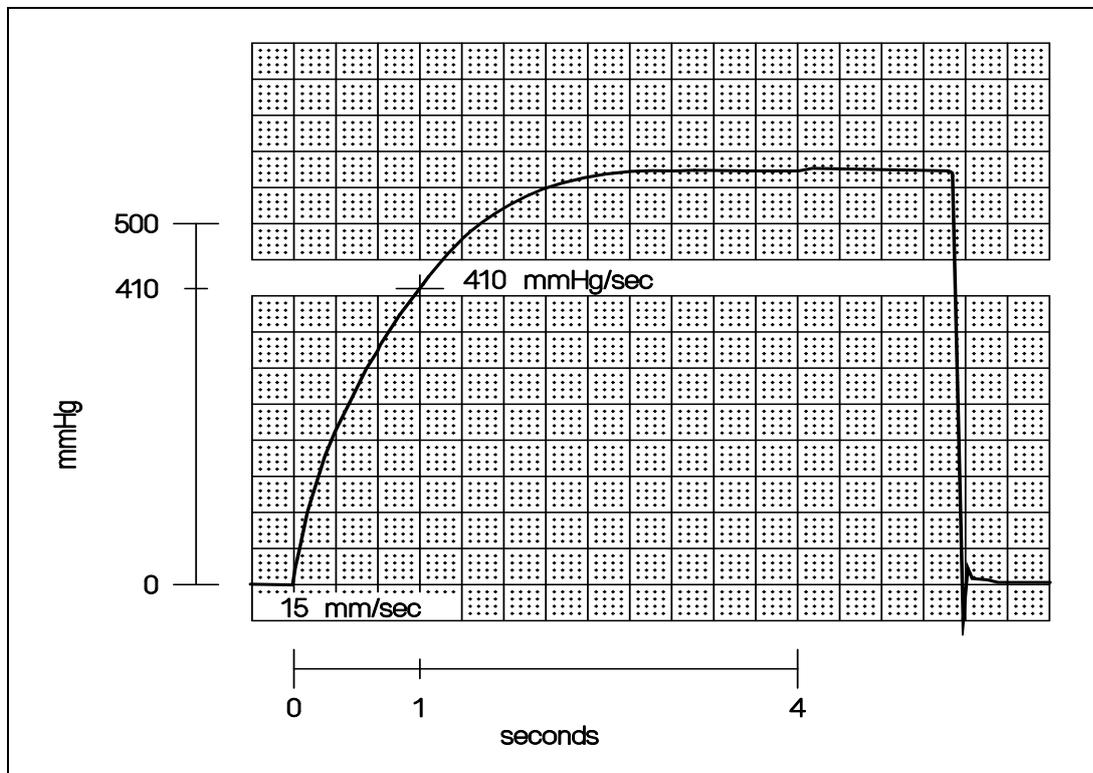
If user unable to resolve problem with the Manometric Pump, they are to contact the manufacturer directly.

5.2 CALCULATION OF PRESSURE RISE RATE

The pressure rise rate is defined as the pressure rise rate in mmHg or cmH₂O per second.

- Run the recording system at a high speed such as 15 mm/sec in order to capture a one-second slope.
- With infusion on, block the opening of the manometric catheter with your finger to create a rise in pressure.
- The pressure tracing in the figure rises from 0 mmHg at the beginning of the rise to 410 mmHg at the 1-second mark. The pressure rise rate is therefore $(410)/(1)=410$ mmHg/sec.

Figure 5 - Calculation of Pressure rise rate



Section 6 Service: Maintenance

6.1 DISINFECTION

*Disinfection of the pump should be done at regular intervals – **monthly is recommended** – or prior to Biliary motility.*

CAUTION:

- **Do not use alcohol to clean the water reservoir. Alcohol may cause cracks in the water reservoir material.**
- **Do not use any disinfectant or solution in the fluid path of the pump which is incompatible with the following materials: silicone, acetal, acrylic, Buna-N, epoxy adhesive, polycarbonate, high-density polypropylene, polyurethane, TFE, Brass-Nickel, PEEK, polyvinylchloride.**

Confirm compatibility of the disinfectant with the disinfectant manufacturer before use. Mui Scientific is not liable for any damage to the pump, or harm to patients or personnel, caused by improper use of a disinfectant or procedure.

Clinical evaluations have verified the following disinfectants for use:

- Cidex OPA
- Sporox II
- Korsolex Extra

A disinfectant which is compatible with flexible endoscopes will be compatible with this portable manometric pump.

Disinfecting Procedure

Step 1: Purge system with air

(Skip Step 1 when starting with a dry pump)

- Depressurize system using the pressure release valve located at the control box until the pressure in both gauges on the control box (and the gauge on the compressor, if included) drops to zero.
- Empty the water reservoir.
- Reconnect the empty water reservoir and reconnect the metal quick-connect to the water reservoir lid to pressurize.
- Purge the whole system with 15 psi air for 5-10 minutes, or until no more water is dripping out of the ends of the resistors.

Step 2: Fill system with disinfectant

- Ensure that the system is fully depressurized. Use the pressure valve located on the control box to remove all the pressure from the unit.
- Fill water reservoir 1/2 full with disinfectant and swirl within water reservoir to rinse all surface area (including underside of lid)
- Replace lid and reconnect water reservoir to outflow control device, and to top quick-connect to pressurize.
- Perfuse at 20 psi through pump tubing system for the time indicated in the chart below, allowing the disinfectant to drip out through the ends of the resistors into the water collection tray.

Resistor Part #	Flow (ml/min)	Perfusion Time
P4HREC080	.80	15 mins.
P4HREC060	.60	20mins.
P4HREC045	.45	25 mins.
P4HREC030	.30	30mins.
P4HREC020	.20	45 mins.
P4HREC015	.15	60mins.

* Please contact Mui Scientific directly for disinfection protocol of any resistors not listed above.

- Allow the disinfectant to sit within the system for the additional length of time recommended by the disinfectant manufacturer

Step 3: Rinse system with sterilized irrigation water

- Depressurize system using the pressure release valve located at the control box until the pressure in both gauges on the control box (and the gauge on the compressor, if included) drops to zero.
- Remove water reservoir. Rinse with sterilized irrigation water,
- Fill water reservoir 1/2 with sterilized irrigation water.
- Replace lid and reconnect water reservoir to outflow control device, and to top metal quick-connect and pressurize the system.
- Perfuse at 20 psi for the same amount of time as indicated in the chart above to rinse disinfectant.

Step 4: Repeat Step 3 (to ensure all disinfectant has been rinsed out of system.)

Step 5: Purge system with air again (for storage or immediate use)

- Depressurize system using the pressure release valve located at the control box until the pressure in both gauges on the control box (and the gauge on the compressor, if included) drops to zero.
- Empty water reservoir.
- Reconnect empty water reservoir to outflow control device, and top metal quick-connect.
- Purge tubing system with 20 psi air until no more water is dripping out of the compact resistors.
- Remove all the pressure from the unit using the pressure release valve.
- Disconnect water reservoir metal quick-connect.
- Replace used transducers with new transducers.
- Reconnect compact resistors to new transducers.

For storage: Remove empty water reservoir and store dry with lid off.

For immediate use: Fill water reservoir with fresh sterilized irrigation water and continue with start-up procedure.

6.2 CARE AND CLEANING OF THE PUMP

- Use a soft cloth moistened slightly with water and mild soap to wipe down any spots that may accumulate on the outside of the pump. Wipe off any soap residue with sterilized irrigation water.
- Rinse out the water reservoir with fresh clean water and wipe out using a soft cloth.
DO NOT USE ALCOHOL.

Section 7 Air Compressor

7.1 AIR COMPRESSOR FIGURES

Figure 9 – Front view of Air Compressor

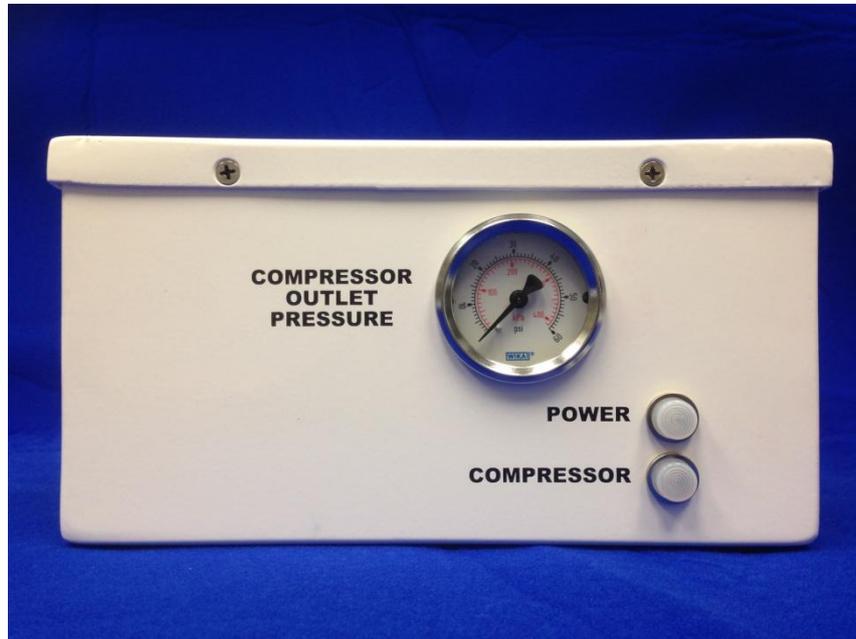


Figure 10 – Back view of Air Compressor



Figure 11 – Interior of Air Compressor



7.2 DRYING THE DESICCANT

If the color of the entire drying cylinder is dark green, it indicates that the desiccant has absorbed excessive amounts of moisture from the air, and it must be regenerated.

The length of time before the desiccant needs to be regenerated will vary, depending on the operating environment and the frequency of pump use. The desiccant may last several years before regeneration is needed.

To Regenerate Desiccant:

- Remove the lid of the air compressor housing.
- Remove the drying cylinder from the air compressor.
- Unscrew the cylinder cap by hand, or using the black plastic wrenches provided.
- Pour out the granules on a tray and spread evenly, one granule deep.
- Heat the granules for 5 hours at 125°C (250° F) in a conventional oven.
When all the water has been driven out, the granules will be orange again.
To ensure maximum effectiveness of desiccant, do not regenerate more than five times.
- Cool the desiccant in a tight container before refilling the drying cylinder.
- Pre-dry the felt filters at 100 °C for 30 minutes before assembly of the drying cylinder.
- Reassemble the drying cylinder and connect to the air compressor. Pressurize the air compressor and check that the cap of the drying cylinder is on tightly, with no leakage.
- Reconnect to the pump.

7.2 TROUBLESHOOTING THE COMPRESSOR MOTOR

A. Compressor motor does not run:

- Check that the power cord is plugged in to the supply
- Check that power switch is turned ON (the white power light should be illuminated).
- Check that the fuses are not blown. Two fuses (5 x 20 mm, 250v, T2A) are located next to the power ON/OFF switch.
- If the motor has been running continuously, the thermal protection switch may have shut off the compressor. Turn off the power, and let the motor cool down for at least 30 minutes, then turn ON the power again. Compressor motor should run without any barrier.

B. Compressor motor runs too often or does not shut off at all:

- Disconnect the air lead hose from portable pump, and let it stay connected to the air compressor.
- Plug in the power supply and turn ON the power switch. Check that the pressure gauge on compressor shows pressure increase as the motor is running.
- If the compressor motor does not stop at cut-off pressure, or it does not reach cut-off pressure; the defect has been caused in the air compressor itself. It could be electrical or mechanical defect - please contact Mui Scientific (by phone: 905-890-5525/ by email: mail@muiscientific.com).
- If the compressor motor runs smoothly during above process, this implies that defect or leakage may have occurred in main housing of portable pump.

Troubleshoot by following these steps:

- Connect the air lead hose to the metal quick connector at the control box. Check that air lead hose is connected properly to the metal quick female connector located at the back side of air compressor.
- Check the pressure release valve on air control box is closed. Ensure all the connections are tightened enough.
- Turn ON the power switch to pressurize the system. Turn OFF the power switch when compressor motor shuts down at cut off pressure. Mark the place the of the needle gauge, and observe for 1 hour if pressure drops.
- If pressure drops, use soapy solution to find the leak at any connections. Try to reconnect all the connections to ensure no leakage.
- If the problem still persists, please contact Mui Scientific (by phone: 905-890-5525/ by email: mail@muiscientific.com).

If user unable to resolve problem with the Manometric Pump, they are to contact the manufacturer directly.

Section 8 Parts List

8.1 PUMP PARTS LIST

Description	Part Number
Compact Resistor	P4HRECO60
Reservoir – 1000ml with fittings	P4-A-RES1
Outflow Control Device	P4-B-602
Silicone Water Manifold	P4-C-310
Water Collection Tray (Large)	P4-D-401
Calibration system (0-50 cm H ₂ O)	P4-H-631
Calibration system (0-68 cm H ₂ O)	P4-H-620
Air Compressor (115V)	P4-F-210
Air Compressor (220V)	P4-F-211
Regulator Control Box	P4-CONBOX
Drying Cylinder Subassembly	P4-F-411
Desiccant Orange (1 pack)	P4-F-435
PVB Transducer	P4-D-222T
Water Reservoir – 500mL with fittings	P4-A-RES
Open-Flow Male Connect with O-Ring	P4-C-551
Silicone Reservoir outflow Main Tube Assembly	P4-B-601
2-Way Stopcock	P4-C-601
Flushing Connecting Tube – 3 Transducers	P4-H-304
Reservoir Draining Tube with 2-Way Stopcock	P4-H-306
Silicone Reservoir Outflow Main Tube Only	P4-B-601X
Water Filter – 20 Microns	P4-C-545X
C-clamp for IV Pole	P4-P-503
Water Collection Tray (Medium)	P4-D-400