



Push-To-Set™ Vacuum Regulator Continuous (PTS-CVR)

Service Manual



TWO MODE — ANALOG & DIGITAL — ANSI & ISO



THREE MODE — ANALOG & DIGITAL — ANSI & ISO

Rx Only

User Responsibility

This Product will perform as described in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective product should not be used. Parts that are broken, missing, worn, distorted or contaminated should be replaced immediately. For service advice, Ohio Medical recommends that a telephone request be made to the nearest Ohio Medical Regional Service Center. This product and any of its parts should only be repaired using written instructions provided by Ohio Medical or by Ohio Medical trained personnel. The Product must not be altered without the prior written approval of Ohio Medical's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Ohio Medical.

AAA 12345 This alpha character indicates the year of product manufacture and when the serial number _____ was assigned; "L" = 2007, "M" = 2008, "N" = 2009, etc. "I" and "O" are not used.

Safety Instructions

This manual provides you with important information about the Push-To-Set™ Continuous Vacuum Regulator (PTS-CVR). To ensure the safe and proper use of this device, READ and UNDERSTAND all of the safety and operating instructions. IF YOU DO NOT UNDERSTAND THESE INSTRUCTIONS, OR HAVE ANY QUESTIONS, CONTACT YOUR SUPERVISOR, DEALER OR THE MANUFACTURER BEFORE ATTEMPTING TO USE THE DEVICE.

Intended Use

The vacuum regulator is intended to be used in the medical facility as a means to evacuate media (i.e. fluids) from the body. DO NOT use this vacuum regulator for anything other than its intended use.

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1/Precautions

1.1 DEFINITIONS

WARNING	possible injury to patient or operator				
CAUTION	possible damage to equipment				
Note	provides additional information to clarify a point in the text				
Important	similar to a note but of greater emphasis				
I (ON)	ON	O (OFF)	OFF		Serial Number
	Caution		Consult operating manual		Product Disposal Instructions
	Manufacturer		Device complies with requirements of Directive 93/42/EEC		
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare provider				

ABBREVIATIONS USED IN THIS MANUAL

CCW	Counter-clockwise (decrease)
CW	Clockwise (increase)
CVR	Continuous Vacuum Regulator
MAX	Full Line Vacuum
inHg	Inches of mercury
kPa	Kilopascals (kPa x 7.50 = mmHg)
L/min	Liters per minute
mmHg	Millimeters of mercury (mmHg x 0.133 = kPa)
mL	Milliliters
°C	Degrees Celsius
°F	Degrees Fahrenheit
N-m	Newton-Meter (N-m x 0.737 = ft-lb)
ft-lb	Foot-Pound Force (ft-lb x 1.356 = N-m)
oz	Ounces
DISS	Diameter Index Safety System
OES	Oxequip® Suction
NCG	National Compressed Gases (Chemetron)
NPT	National Pipe Thread (USA)
NPTF	National Pipe Thread Female (USA)
MPTS	Multi-Purpose Therapy Stand
gal	Gallon
PTFE	Polytetrafluoroethylene
PTS	Push-To-Set™
IFU	Instructions for Use

1.2 WARNINGS

This device should be repaired only by qualified Ohio Medical or Ohio Medical-trained, qualified personnel, using only Ohio Medical recommended parts. There are risks associated with using anything other than Ohio Medical parts. Ohio Medical will assume no responsibility for incidents which may occur if the product was not repaired in accordance with procedures authorized by Ohio Medical.

If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure must be performed before using the equipment on a patient.

After patient use, if regulator is contaminated then handle in accordance with you hospital's infection control policy.

To reduce transportation personnel and/or service personnel exposure to hazardous contamination, DO NOT ship any suction equipment that has been contaminated.

Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.

Connection to positive pressure sources such as oxygen and medical air, even momentarily, could injure the patient or operator.

Ohio Medical will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling.

To help prevent aspirate from entering the device, wall outlet and pipeline equipment, a safety trap should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline equipment may impair its operations. The use of the safety trap and suction filter will help prevent this and extend the life of suction equipment.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. No cables, transducers, or accessories are required for operation.

Portable RF communications equipment (including peripherals such as antenna cables and external

antennas) should be used no closer than 30 cm (12 inches) to any part of the Push-to-Set Vacuum Regulator [Amvex Vacuum Regulator]. Otherwise, degradation of the performance of this equipment could result.

1.3 CAUTION

Do not use any Loctite® products or any products which contain Methacrylate Ester as an active ingredient to seal the threads on the adapters/probes and fittings.

Use of lubricants other than recommended may degrade plastic or rubber components.

Do not steam autoclave or liquid sterilize the regulator. Severe impairment to the operation of the regulator will result. Do not use harsh chemical or cleaning solution. Do not spray cleaners directly onto suction regulators. Only use chemical recommended in this manual.

If any evidence of damage is found, repair as necessary or contact your authorized service provider.

Connection to positive pressure sources such as oxygen and medical air, even momentarily, could damage the equipment.

The suction control knob must be completely pushed in to adjust the vacuum level. Failure to do so may damage the vacuum regulator.

Not for transport use: The categories of field and transport user are specifically defined in ISO 10079-3. "Field" means use at accidents or emergencies outside a hospital. "Transport" means use in ambulances, cars and airplanes. These situations may expose the equipment to uneven support, water, dirt, and mechanical shock and temperature extremes. Ohio Medical Suction equipment has not been tested to comply with the specific requirements of these categories.

Note: Ohio Medical requests that parties acquiring this device:

Report the device's purchase, receipt in trade, return after sale, loss, destruction, or retirement.

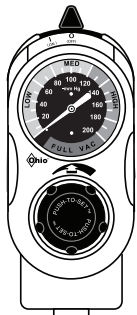
Contact your Ohio Medical customer service representative to obtain manual updates.

Authorized Service Center / Customer Service
Call 1-866-549-6446 or +1 847-855-0500 for service and repair information.

2/Scope

This service manual contains service, maintenance and parts information on all models of the Push-To-Set™ Continuous Vacuum Regulator.

2.1 ANSI Vacuum Regulators (North American)



Analog (1225)
Standard Two Mode
Continuous
Adult



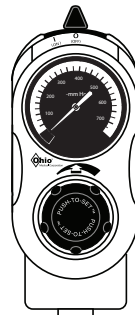
Digital (1325)
Standard Two Mode
Continuous
Adult



Analog (1224)
Standard Three Mode
Continuous
Adult



Digital (1324)
Standard Three Mode
Continuous
Adult



Analog (1330)
High Two Mode
Continuous
Adult



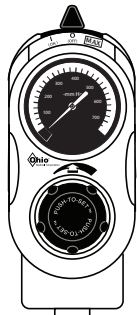
Digital (1430)
High Two Mode
Continuous
Adult



Analog (1227)
Standard Two Mode
Continuous
C.A.S.S.



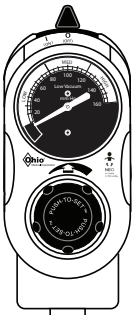
Digital (1327)
Standard Two Mode
Continuous
C.A.S.S.



Analog (1226)
High Three Mode
Continuous
Adult



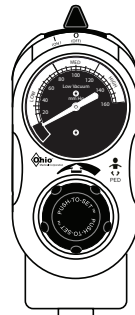
Digital (1326)
High Three Mode
Continuous
Adult



Analog (1231)
Low Two Mode
Continuous
Neonatal



Digital (1331)
Low Two Mode
Continuous
Neonatal

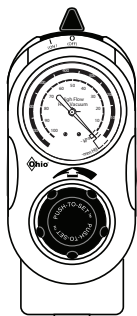


Analog (1234)
Low Two Mode
Continuous
Pediatric



Digital (1334)
Low Two Mode
Continuous
Pediatric

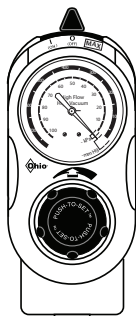
2.2 ISO Vacuum Regulators (International)



Analog (1230)
High Two Mode
Continuous
Adult



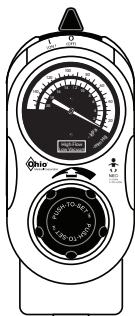
Digital (1337)
High Two Mode
Continuous
Adult



Analog (1229)
High Three Mode
Continuous
Adult



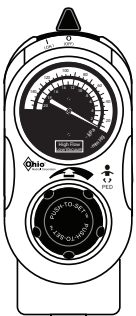
Digital (1329)
High Three Mode
Continuous
Adult



Analog (1232)
Low Two Mode
Continuous
Neonatal



Digital (1332)
Low Two Mode
Continuous
Neonatal



Analog (1235)
Low Two Mode
Continuous
Pediatric



Digital (1335)
Low Two Mode
Continuous
Pediatric

3.1 Description

The PTS-CVR is a lightweight, compact unit used throughout the hospital primarily for pharyngeal/tracheal suctioning (airway management). Various models provide regulated or full-line vacuum for hospital suction procedures.

There are several models of the PTS-CVR. All models contain a vacuum gauge which indicates suction supplied by the regulator. Each has a positive pressure safety relief valve to prevent pressurization by either failed injector vacuum (Venturi®) units or inadvertent cross connection to pressurized gasses. In addition, the Low PTS-CVR models include a vacuum relief valve to limit maximum suction.

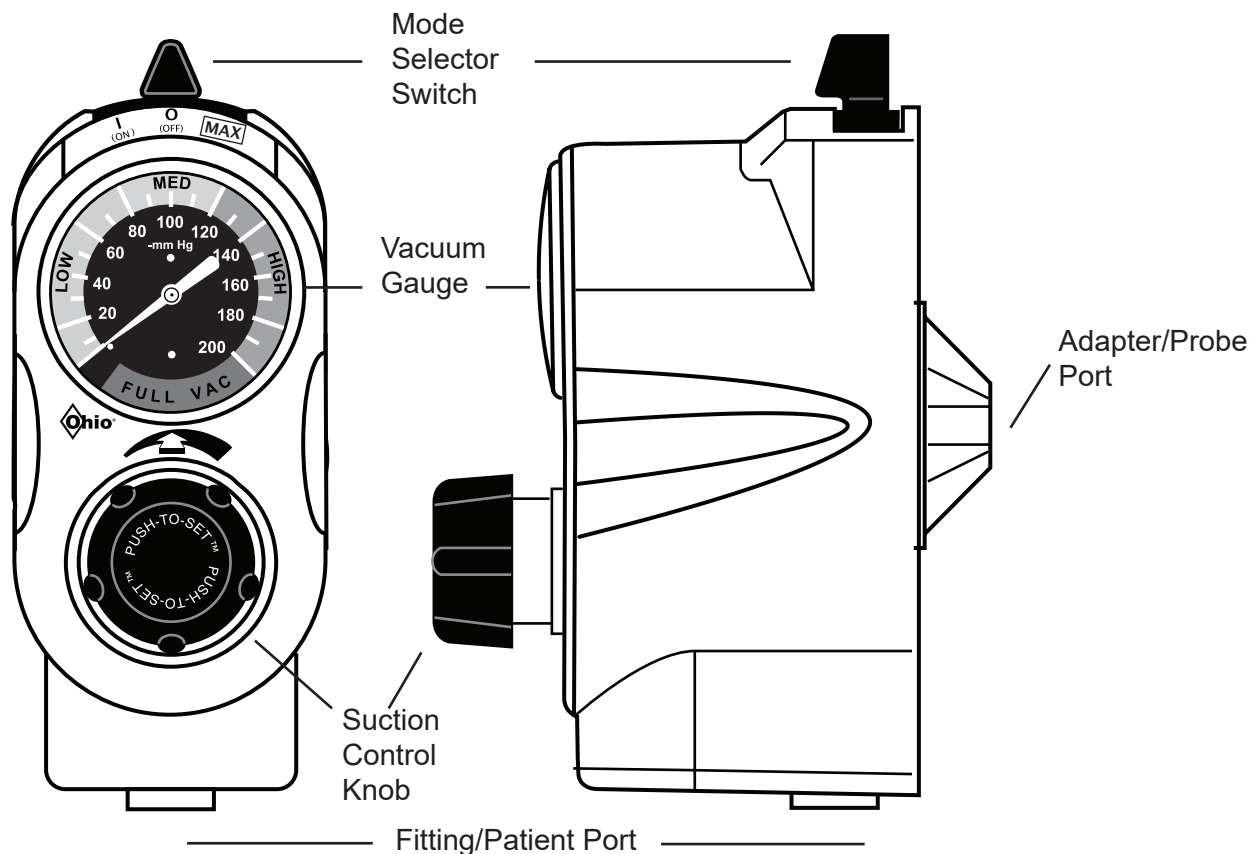
Some models operate in a regulated or non-regulated **MAX** mode. Others operate only in the regulated mode.

In the non-regulated **MAX** mode, the vacuum source is connected directly to the fitting/patient port. The regulator module is bypassed and full-line vacuum is provided.

In the regulated mode, the vacuum source is connected through the regulator module which functions as an automatic valve. Turning the suction control knob adjusts the position of the regulator module and allows selection of a predetermined level of suction when set according to instructions.

During use, as the flow requirement increases, the valve automatically opens to maintain suction at the preset level. When the flow requirement decreases, the valve automatically closes to maintain suction at the preset level. The same mechanism compensates for changes in supply vacuum and automatically maintains the pre-set suction level when set according to instructions.

1. Suction Control Knob - Allows easy adjustment of suction to the patient.
2. Mode Selector Switch - Allows quick and easy mode changes.
 - a. | (ON) - Suction can be adjusted with the suction control knob.
 - b. O (OFF) - No suction is supplied to the patient.
 - c. **MAX** - Maximum full-line vacuum is supplied to the patient.
3. Vacuum Gauge - The suction level to the patient is displayed during use.



3/Description and Specifications

3.2 Specifications

Performance					
	Standard	High	Pediatric	Neonatal	C.A.S.S.
Flow rate ¹	80 L/min	80 L/min	80 L/min	80 L/min	80 L/min
Positive Pressure Safety Relief Valve	Located in the vacuum supply line to prevent pressurization of the patient connection by failed injector vacuum (Venturi) units, or inadvertent cross connection to pressured gases.				
Gauge Accuracy	Gauge Range		Analog ²	Digital ³	
Standard	0-200 mmHg (0-26.7 kPa)		±5% Full-scale	±1% Full-scale	
High	0-760 mmHg (0-101.3 kPa)		±5% Full-scale	±1% Full-scale	
Pediatric	0-160 mmHg (0-21.3 kPa)		±5% Full-scale	±1% Full-scale	
Neonatal	0-160 mmHg (0-21.3 kPa) 0-100 mmHg (0-13.3 kPa)		±5% Full-scale -	- ±1% Full-scale	
C.A.S.S.	0-160 mmHg (0-21.3 kPa)		±5% Full-scale	±1% Full-scale	
Physical					
Dimensions	6.7"H x 2.8"W x 4.8"D (17.02 cm x 7.1 cm x 12.2 cm)				
Weight	1 lb 4 oz (0.57 kg)				
Battery	Two 2/3 AA, 3.6V, 1.6 Ah, lithium				

¹without fittings at full increase setting depending on supply vacuum and open air flow.

²full scale deflection

³full range at 22°C

ENVIRONMENTAL SPECIFICATIONS

Operating Temperature Range	50 to 104°F (10 to 40°C)
Storage and Transport Temperature Range	-13 to 158°F (-25 to 70°C)
Operating Atmospheric Pressure Range	80 to 106 kPa
Storage and Transport Atmospheric Pressure Range	50 to 106 kPa
Operating and storage Relative Humidity	5 to 95% RH (Non-condensing)
Ingress Protection Rating	IP 20

4.1 Cleaning and Disinfection

WARNING: After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.

CAUTION: Suctioned fluids drawn into a vacuum regulator do not stop in the regulator. They proceed through it into the wall outlet and pipeline system. Failure to clean and disinfect the wall outlet and pipeline system may result in damage to this equipment.

4.1.1 Routine Exterior Cleaning

Routine cleaning of the regulator is recommended as a standard procedure after each use. Wipe all exterior surfaces with a solution of water and mild detergent and/or an approved cleaning solution.

4.1.1.1 Approved Cleaning Solutions

- Sodium Hypochlorite 0.5% (Bleach): Mixture of 13 fl. oz. of bleach to 1 gallon (128 fl. oz.) tap water
- Isopropyl Alcohol 70%
- Hydrogen Peroxide 3%
- Cavicide® Ready to use full strength



4.2 Disposal

Digital Product Only: The batteries and circuit board are not suitable for regular trash disposal.

Follow local guidelines for disposal of other components.

Device may contain bio-hazardous material and should be disposed of properly. Follow local guidelines for disposal of bio-hazardous material.

5/Troubleshooting

SYMPTOM	POSSIBLE CAUSES	POSSIBLE SOLUTION
Unit fails to provide vacuum at patient port in all modes.	Mode Selector Switch is at O(OFF) position	Move mode selector switch [34] to desired mode.
	No Supply Vacuum	Check Hospital vacuum level (should be at least 500 mmHg (66.7 kPa).
	Damaged/Clogged Supply side or Patient side fittings	Replace fittings if damaged/clogged Retighten/Torque if found loose
	Knob fails to return when pushed	Push and rotate the knob [2] if stuck Replace actuator [6], drive gear [5], Regulator Case [3], OTS assembly [10].
	Knob stuck at OFF position (all the way counter clock wise direction)	Push and Rotate Knob [2] to clock wise direction
	Damaged Regulator Module	Regulator Module Assembly [12]
	Clogged external filter	Replace external filter
	Overflow protection device is shut off	Check(Reset float)/Replace Overflow protection device
	Loose or incorrect set-up	Set-up unit correctly without any leak.
	Aspirant draw into unit	Follow your facilities procedures for handling contaminated products. (DO NOT SEND UNIT BACK TO THE MANUFACTURER)
Gauge doesn't respond to changes in suction	Gauge assembly is not properly aligned.	Ensure gauge assembly [6] is properly aligned.
	Missing/Damaged O-Rings	Replace O-Rings [9]
	Gauge assembly is damaged	Replace gauge assembly [6]
	Digital Unit Only: Depleted batteries	Digital Unit Only: Replaced Gauge [6]/Batteries
Suction level cannot be adjusted	Unable to push and rotate knob	Push and rotate knob [2] if stuck Replace actuator [6], drive gear [5], Regulator Case [3], OTS assembly [10].
	Damaged OTS assembly	Replace OTS assembly [10]
	Regulator module is stuck in full OFF or full ON position	Rotate the knob [2] to free the Regulator Module Assembly [12]
	Snap cap separated from regulator module housing.	Reassemble snap cap [28] onto regulator module housing [34] Replace snap cap [28] and/or regulator module housing [34] Replace Regulator Module Assembly [12]
	Damaged/Missing spring inside regulator module assembly	Replace Regulator module assembly [12]
	Damaged/Missing O-ring, Quad-ring on regulator module	Replace O-ring [35] and/or Quad-ring [36]
	Damaged Diaphragm inside regulator module	Replace Diaphragm [30] or regulator module assembly [12]
	Damaged Regulator Module Assembly	Replace Regulator module assembly [12]

5/Troubleshooting

SYMPTOM	POSSIBLE CAUSES	POSSIBLE SOLUTION
Erratic gauge movement resulting from regulator adjustment	Damaged Diaphragm inside regulator module	Replace Diaphragm [30] or regulator module assembly [12]
	Damaged/Missing O-ring, Quad-ring on regulator module	Replace O-ring [35] and/or Quad-ring [36]
	Gauge assembly is damaged	Replace gauge assembly [6]
Knob stuck in full OFF or full ON position	Excessive force applied	Rotate the knob [2] to free the Regulator Module Assembly [12]
Suction level can be adjusted without pushing the knob in	Damaged drive gear	Replace drive gear [5]
	Damaged actuator	Replace actuator occlude-to-set [6]
	Damaged Knob	Replace knob [2]
Gauge won't zero	Damaged gauge assembly	Replace gauge assembly [6]
Whistling/buzzing noise from the unit	Need to apply grease on stem on regulator module	Apply grease on stem [31]
Gauge responds slowly to changes in suction/ failed bleed down test	Blocked bleed hole orifice	Clean bleed hole orifice [32]
	Damaged gauge assembly	Replace gauge assembly [6]
	Damaged/Clogged Supply side or Patient side fittings	Replace fittings if damaged/clogged Retighten/Torque if found loose
Vacuum relief valve activates below specified range {PED and NEO ONLY}	Damaged regulator case	Replace regulator case [3]
	Damaged diaphragm	Replace diaphragm [30]
	Damaged/loose set screw	Replace/Adjust set screw 8700-0007-400.
	Damaged vacuum relief assembly	Replace vacuum relief assembly 6700-0045-700.
Vacuum relief valve does not activate at specified range {PED and NEO ONLY}	Damaged vacuum relief assembly	Replace vacuum relief assembly and follow Section 6.3 suction level limit setting.

6/Service - Disassembly and Assembly

6.1 Service Tools and Equipment

CAUTION: Use of lubricants other than recommended may degrade plastic or rubber components.

The following items should be on hand during any service procedure.

- Supply vacuum: 500 mmHg \pm 10 mmHg (67 kPa \pm 1.3 kPa) & 80 L/min open air flow minimum
- Supply Vacuum Regulator with Gauge, 760 mmHg (101.3 kPa) Full Scale
- High Vacuum Calibration Gauge, 760 mmHg (101.3 kPa) Full Scale* recommend Dwyer® Series DPG-100 Digital Pressure Gauge or equivalent (Dwyer Instruments)
- 80 L/min Flowmeter
- Phillips Head Screwdriver, No. 2
- Flat Head Screwdriver, 1/4 inch
- Tubing Clamp
- Bubble Leak Tester
- Tweezers (Filter Remover)
- Wooden Tooth Pick (O-ring Remover)
- Phillips head screwdriver No.1
- Dow Corning® 111 grease (Ohio Medical P/N 6700-0074-200)
- Loctite® 242 removable thread locker (Ohio Medical P/N 0220-5016-300)
- Stop watch
- Open end adjustable wrench
- 10 L/min flowmeter

(*) Accuracy: \pm 1% of full scale deflection

6.2 Continuous Vacuum Regulators (All Models)

6.2.1 Disassembly

WARNING: If the Vacuum Regulator is repaired or disassembled in any manner, the Service Checkout Procedure must be performed before using the equipment on a patient.

WARNING: Clean and disinfect all suction equipment if contaminated before disassembly to ensure service personnel are not exposed to hazardous contamination.

WARNING: When servicing a Low Vacuum Regulator, perform the Vacuum Relief Valve Adjustment and Low Vacuum Limit Setting Procedure.

CAUTION: The gauge assembly must be handled with

utmost care to retain its precision. If the lens is removed, do not rest the gauge on its face.

Note: See Section 9.1 Illustrated Parts

1. Remove the four cover screws from the back of the regulator.
2. With regulator facing up, carefully pull the cover assembly off the back body.
3. To remove the gauge assembly, grasp the assembly and pull straight out. The snap-fit lens can also be removed (if applicable) for replacement.
4. Remove actuator and PTS assembly.
5. To remove the regulator module from the manifold assembly, rotate the regulator module clockwise.
6. Using tweezers, remove the filter. Replace with a new filter.
7. Grasp the positive pressure safety relief valve, and pull it from the back body.
8. Remove the mounting screws from the actuator support bracket and remove the support bracket, detent plate and selector switch.
9. Low models ONLY: Grasp the vacuum relief valve and pull it from the back body.

6.2.2 Assembly

CAUTION: To prevent stripping the plastic threads, place the screw in the hole and turn counter-clockwise until it drops into the original thread, then tighten the screws.

1. Place the positive pressure safety relief valve in position and push onto the back body.
2. Low models ONLY: Lubricate the vacuum relief valve O-ring and install it in the valve housing.
3. Lubricate switch with a thin coat of Dow Corning 111 on the overmolded area. Place in manifold with grease side down.
4. Add detent plate making sure the fingers are on either side of the switch shaft and pointing down.
5. Place O-ring on post coming up through center of detent plate and set actuator support bracket over O-ring. Tighten down with 4 screws.
6. Place cylindrical white filter in corresponding cavity.
7. Screw regulator module counter-clockwise into manifold.
8. Place PTS assembly in manifold directly below regulator module.

9. Set actuator in brackets of the actuator support bracket and rest the loop on the top of the PTS assembly.
10. Place gear over regulator post and rest it on the actuator.
11. Place lens on gauge with single tab at the top and the two tabs at the lower portion of the gauge and set gauge into support bracket.
12. Place cover strip in curved slot inside case.
13. Mate the cover with the manifold. With both thumbs positioned just below the lens, press firmly to snap the lens in.
14. Install the 4 cover screws.

6.3 Suction Level Limit Setting (PED/NEO/C.A.S.S. Models ONLY)

WARNING: This Low Vacuum Limit Setting Procedure must be followed when repairing Low Vacuum Regulators. Failure to do this may result in suction exceeding the prescribed level.

6.3.1 Vacuum Relief Valve Adjustment

1. Remove the cover (see Section 6.2.1 Disassembly).
2. Connect the supply vacuum to the adapter/probe port.
3. Connect an external vacuum test gauge to the patient port.
4. Move the mode selector switch to | (ON).
5. Slowly rotate the regulator module to increase the vacuum level. Note the suction level at which the relief valve opens. The relief valve should open at 140 mmHg \pm 5 mmHg (18.7 kPa \pm 0.7 kPa) on the external test gauge.
6. If adjustment is required, grip the vacuum relief valve firmly with pliers and rotate the screw about 1/8 turn with a screwdriver. Repeat the previous step and check the suction level at which the valve opens.
Note: Clockwise rotation will increase the suction level at which the relief valve opens. Counter-clockwise rotation will decrease it.
7. Lock the adjusting screw with a drop of removable thread locker such as Loctite 242. Repeat step 5 to verify the vacuum relief valve setting.
8. Re-attach the cover (see Section 6.2.2 Assembly).

WARNING: Excess Loctite® may seal the steel ball to the seat. This will disable the vacuum relief

valve and may allow suction to exceed the preset limit.

CAUTION: When Loctite is used on the vacuum relief safety valve, ensure that it only contacts the metal parts. Loctite causes many plastic parts to deteriorate.

6.3.2 Vacuum Limiting Set Screw Adjustment (PED and NEO Units ONLY)

6.3.2.1 Pediatric Unit

1. Adjust the regulator until the unit's gauge reads 135 mmHg (18.0 kPa).
2. Rotate the set screw located above the regulator knob clockwise until it stops against the regulator module and then place one drop of Loctite 242 onto the set screw.
3. Turn the regulator counter-clockwise then clockwise until it stops against the set screw. Ensure that the gauge reads 135 mmHg \pm 5 mmHg (18.0 kPa \pm 0.7 kPa) and that the relief valve does not activate. For the digital unit, ensure that the gauge reads 135 mmHg \pm 2 mmHg (18.0 kPa \pm 0.3 kPa).

6.3.2.2 Neonatal Unit

1. Adjust the regulator until the unit's gauge reads 100 mmHg (13.3 kPa).
2. Rotate the set screw located above the regulator knob clockwise until it stops against the regulator module and then place one drop of Loctite 242 onto the set screw.
3. Turn the regulator counter-clockwise then clockwise until it stops against the set screw. Ensure that the gauge reads 100 mmHg \pm 5 mmHg (13.3 kPa \pm 0.7 kPa) and that the relief valve does not activate. For the digital unit, ensure that the gauge reads between 99 mmHg and FULL (13.2 kPa and FULL).

6.4 Regulator Module

CAUTION: Do not lubricate any internal components of the regulator module.

CAUTION: The cap screws can strip the regulator module housing threads if they are screwed in too tight.

6/Service - Disassembly and Assembly

6.4.1 Disassembly

1. Remove the quad-ring from the piston stem and the O-ring from the housing. Lubricate or replace if needed.
2. Lift and pull tabs to pry off and remove the cap.
3. Peel the diaphragm from the piston head.
4. With the piston head facing down, lift the housing to separate.
5. Remove springs from the piston stem.

6.4.2 Assembly

1. With the piston head facing down, place the springs on the piston stem.
2. Place the housing over the piston and slide the piston stem into the housing.
3. Place the quad-ring on the tip of the piston stem.
4. Place the O-ring on the housing.
5. Fold the diaphragm and place it on the piston head.
6. Place the cap on the housing and press until it snaps into place.

6.5 Digital Gauge

Note: Both batteries are positioned with the positive side facing up relative to the display.

6.5.1 Removal of Batteries

1. Remove digital gauge as described in Section 6.2.1 Disassembly.
2. Using a small flat head screwdriver, push batteries out at a 45° angle.

6.5.2 Inserting Batteries

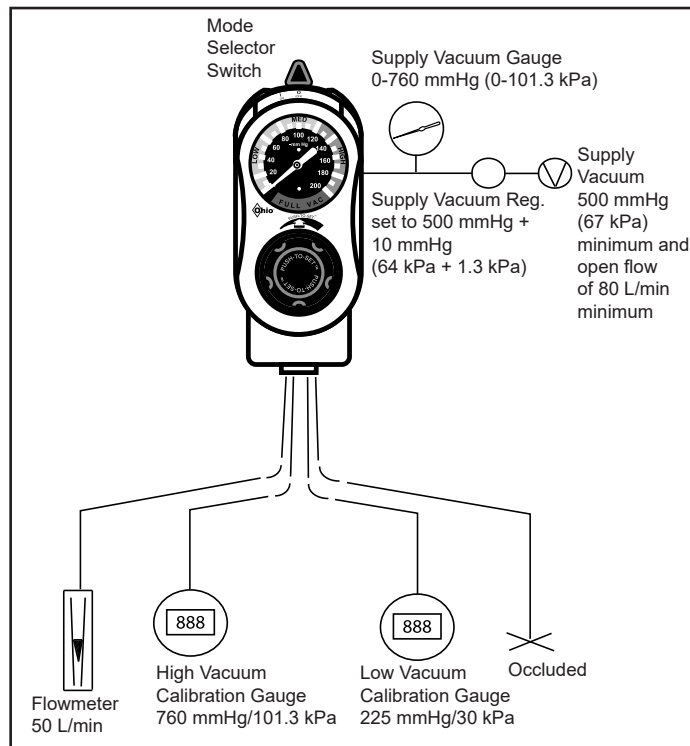
1. Place negative side of battery into battery slot first (battery will be at an angle).
2. Then using a flat head screwdriver, gently push in positive battery contact while sliding battery in place.

WARNING: If the Vacuum Regulator is repaired or disassembled in any manner, the Service Checkout Procedure must be performed before using the equipment on a patient.

Important: This entire Service Checkout Procedure must be performed in numerical order.

7.1 Set-up

1. Verify that there is 500 mmHg \pm 10 mmHg (66.7 kPa \pm 1.3 kPa) vacuum on the supply gauge.
2. The supply open flow must be 80 L/min minimum.
3. Connect the supply vacuum to the adapter/probe port.



7.2 Push-To-Set™ Test

1. Connect the 10 L/min flowmeter to the patient port.
2. Move the mode selector switch to | (ON).
3. Set 200 mmHg (26.6 kPa) on the gauge and keep the knob pushed in. For the pediatric unit set at 135 mmHg (18.0 kPa), for the neonatal unit set at 100 mmHg (13.3 kPa) and for the C.A.S.S. unit set at 140 mmHg (18.7 kPa)
4. Make certain leakage at the patient port connection is no more than 1 L/min.
5. While observing the flowmeter with the knob still pushed in, rotate the knob. Leakage should be no more than 1 L/min. Release the knob and move the mode selector switch to O (OFF).

7.3 Gauge Test

Note: Analog gauges are supplied with an accuracy of $\pm 5\%$ of full scale deflection throughout their range. See step 4 of Section 7.4 Regulation Test.

Note: Digital gauges are supplied with an accuracy of $\pm 1\%$ of full range at 22°C.

Note: All gauge needles should come to rest within the zero range bracket or return to the stop pin when no suction is being supplied. Gauges which do not comply may be out of calibration. Digital gauge should read “0” when no suction is applied. No calibration required on digital gauges.

Note: When checking the accuracy of the gauge on the analog unit, be sure that the calibration gauge has an accuracy of 1% of full scale deflection or better.

7.3.1 High Vacuum Gauges ONLY

1. Connect the regulator’s fitting/patient port to the high calibration gauge with tubing.
2. Move the mode selector switch to | (ON).
3. Ensure that the gauge is in agreement with the high vacuum calibration gauge within the ± 38 mmHg (± 5.1 kPa) tolerance. Recommended test points are 100, 300, and 450 mmHg (13.3, 40.0 and 60.0 kPa).
4. Push and rotate the suction control knob fully clockwise and ensure that the vacuum calibration gauge reads at least 450 mmHg (60.0 kPa).
5. Three mode models ONLY: Move the mode selector switch to **MAX** and ensure that the vacuum calibration gauge reads at least 450 mmHg (60.0 kPa).
6. Push and rotate the suction control knob fully counter-clockwise (decrease) and verify the gauge reading decreases to zero.

7.3.2 Standard and PED/NEO/C.A.S.S. Vacuum Gauges ONLY

1. Connect the regulator’s fitting/patient port to the low calibration gauge with tubing.
2. Move the mode selector switch to | (ON).
3. Ensure that the gauge is in agreement with the low vacuum calibration gauge within ± 10 mmHg (± 1.3 kPa) for the standard model. For the PED/NEO/C.A.S.S. models, ensure that the calibration gauge is within ± 8 mmHg (± 1.1 kPa). Recommended

7/Service Checkout Procedure

test points are 40 and 80 mmHg (5.3 and 10.7 kPa) for the standard/PED/NEO/C.A.S.S. models and 140 mmHg (18.7 kPa) for standard model only.

4. For the standard model ONLY: Push and rotate the suction control knob fully clockwise. Ensure that the vacuum calibration gauge reads at least 450 mmHg (60.0 kPa) and that the gauge on the unit is in the FULL VAC range.
5. Push and rotate the suction control knob fully counter-clockwise (decrease) and verify the gauge reading decreases to zero.

7.4 Regulation Test

1. Remove any equipment attached to the patient port.
2. If using a high vacuum regulator, set its gauge to 300 mmHg (40.0 kPa). If using a standard/PED/NEO/C.A.S.S. vacuum regulator, set its gauge to 100 mmHg (13.3 kPa).
3. Open and close the fitting/patient port several times to create various flow rates through the regulator.
4. With the fitting/patient port occluded, the gauge should return to the setting listed in step 2 within the following tolerances:
 - For analog units, the gauge should return to ± 10 mmHg (± 1.3 kPa) for the standard model, ± 8 mmHg (± 1.1 kPa) for the PED/NEO/C.A.S.S. models, and ± 38 mmHg (± 5.1 kPa) for the high model.
 - For digital units, the gauge should return to ± 2 mmHg (± 0.3 kPa) for the standard/PED/C.A.S.S. models, ± 1 mmHg (± 0.1 kPa) for the NEO model, and ± 8 mmHg (± 1.0 kPa) for the high model.

7.5 Maximum Vacuum Test (PED/NEO/C.A.S.S. Models ONLY)

1. Occlude the fitting/patient port.
2. Rotate the suction control knob fully clockwise (increase).
3. Verify that the suction delivered does not exceed 100 mmHg ± 5 mmHg (13.3 kPa ± 0.7 kPa) for the NEO model, 135 mmHg ± 5 mmHg (18.0 kPa ± 0.7 kPa) for the PED model, and 140 mmHg ± 5 mmHg (18.7 kPa ± 0.7 kPa) for the C.A.S.S. model.

Note: For setting the suction level limit, refer to Section 6.3 Suction Level Limit Setting (PED/NEO/C.A.S.S. Models ONLY).

7.6 Bleed Test

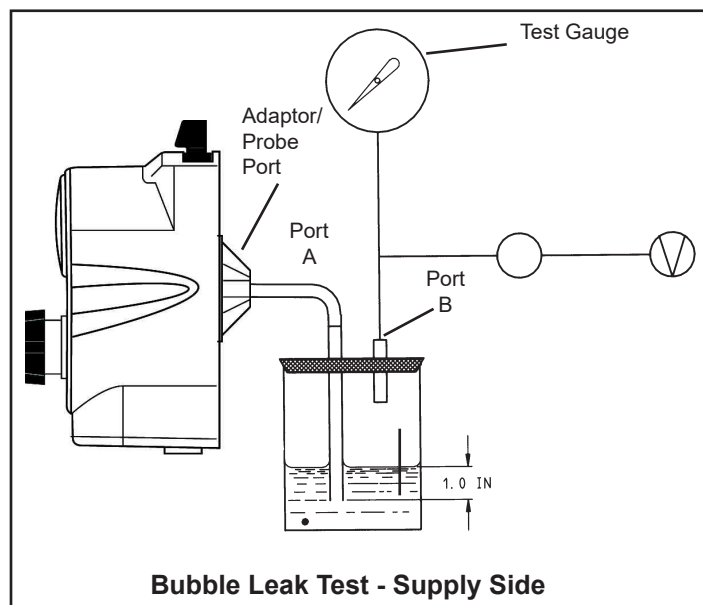
1. Occlude the fitting/patient port and set the vacuum level to 100 mmHg (13.3 kPa).
2. Move the selector switch to O (OFF) and observe the gauge needle. It must return to the zero range bracket or stop pin within 10 seconds (digital gauge will return to "0").

7.7 Leak Test

7.7.1. Supply Side

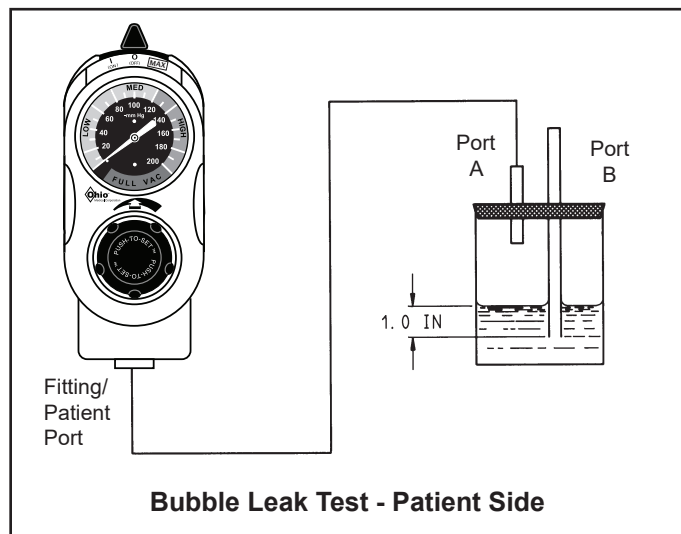
1. Connect the adaptor/probe port to port "A" of the bubble leak tester. Allow the fitting/patient port to be open to air.
2. Move the mode selector switch to O (OFF).
3. Connect port "B" of the bubble leak tester to the supply vacuum regulated to 500 mmHg (66.7 kPa).
4. Wait 20 seconds. No more than 6 bubbles should appear in the next ten seconds.

Important: Prior to venting port "A" of the bubble leak tester to atmosphere (i.e. turning the supply regulator off), ensure the tubing from port "B" has been disconnected from the adaptor/probe port of the vacuum regulator.



7.7.2 Patient Side

1. Connect the supply vacuum tubing to the adapter/probe port.
2. Connect the fitting/patient port to port "A" of the bubble leak tester with tubing. Allow port "B" of the bubble leak tester to be open to air.
3. Rotate the suction control knob a minimum of one full turn clockwise (increase). No bubbles should appear in the next ten seconds.
4. Rotate the suction control knob fully counter-clockwise (decrease).
5. Move the mode selector switch to | (ON). No bubbles should appear in the next ten seconds.



7.8 Flow Test

Note: All PTS-CVR models should produce a minimum of 25 L/min from the patient port given the following conditions:

- The supply open flow is 80 L/min minimum.
- The supply vacuum pressure is 500 mmHg \pm 10 mmHg.
- The unit has fittings on the fitting/patient and adapter/probe ports with minimum inner diameters of 0.140".
- The unit is either directly connected to the vacuum source, or connected with a tube no more than 4" in length with a minimum inner diameter of 0.25".
- The unit is connected to a flowmeter with a tube no more than 4" in length with a minimum inner diameter of 0.25"

- The unit is set to 100 mmHg \pm 5 mmHg (12.7 kPa \pm 0.7 kPa) in | (ON) mode.
 - Adult/High models ONLY: the unit should produce a minimum of 40 L/min at maximum vacuum in | (ON) mode.
1. Connect the fitting/patient port to the 50 L/min flowmeter.
 2. Move the mode selector switch to | (ON).
 3. Set the unit to 100 mmHg \pm 5 mmHg (12.7 kPa \pm 0.7 kPa).
 4. Release the suction control knob and verify that the flow rate exceeds 25 L/min.
 5. Adult models ONLY: Push and rotate the suction control knob fully clockwise.
 6. Release the suction control knob and verify that the flow rate exceeds 40 L/min.

8/Maintenance

8.1 General Maintenance of Suction Equipment

WARNING: The Pre-use Checkout Procedure must be performed before using this equipment on each patient. If the regulator fails any part of the Pre-use Checkout Procedure, it must be removed from service and repaired by qualified service personnel.

WARNING: If the unit has been contaminated, clean and disinfect all suction equipment before disassembly.

Protection of the vacuum piping system is as important as maintenance of the suction equipment. The use of collection canisters with reliable shut-off valves, overflow safety trap assemblies and disposable suction filters will protect the regulator, wall outlet, and piping system.

Routine maintenance and inspection are important to the performance of suction equipment. The following is a recommended list for care of suction equipment after each patient use.

1. Keep connecting tubing, fittings and adapters/probes clean.
2. Wipe all exterior surfaces with a solution of water and mild detergent or approved cleaning solutions.
3. Perform a careful visual inspection of the vacuum regulator.
4. Check that the high flow disposable suction filter is clean and in good condition.
5. Check that all tubing is in good condition and connected securely to the correct ports.
6. Check the floats in the Overflow Protection Device and collection canister for correct operation.
7. Perform the Pre-use Checkout Procedure.

8.2 Recommended Maintenance

We recommend the following to determine maintenance appropriate for each facility:

1. Periodically inspect the overall condition of the vacuum regulator. Test gauge accuracy (Section 7.3 Gauge Test) and perform the pre-use checkout procedure (See PTS-CVR Instructions for Use for the Pre-use Checkout Procedure). If the regulator does not pass, refer to troubleshooting (Section 5 Troubleshooting).
2. Determine maintenance based on data from your periodic inspections. Follow the guidelines below.

Item	Comments
Perform Service Checkout Procedure	If the regulator does not pass, refer to troubleshooting (Section 5 Troubleshooting). Repair as needed
Check elastomeric parts, O-rings, gaskets, diaphragms, internal filters	Cleaning, lubrication and replacement interval depends on hours of usage and environmental conditions. Replace, lubricate, and repair as needed

8.3 Repair Policy

WARNING: To reduce transportation personnel and/or service personnel exposure to hazardous contamination, clean and disinfect all suction equipment before shipping for service.

CAUTION: Do not steam autoclave or liquid sterilize the PTS-CVR. Severe impairment to the operation of the regulator will result.

CAUTION: Only competent individuals trained in the repair of this equipment should attempt service.

Do not use malfunctioning equipment. Make all necessary repairs. Have the equipment repaired by qualified service personnel or by Ohio Medical. After repair, perform the Service Checkout Procedure to ensure that the product is functioning properly, and complies with the manufacturer's published specifications.

8.4 Technical Assistance

If technical assistance is required, contact Ohio Medical technical support at +1 857-855-0500 or toll free at 866-549-6446.

8.5 Return Instructions

1. Clean and disinfect the vacuum regulator.
2. Package securely for protection, preferably in the original container.
3. Include a letter describing in detail any difficulties experienced with the product. Include the person, title, and telephone number to contact for functional questions.
4. If the vacuum regulator is covered under warranty, include the warranty information that came with the device and a copy of the invoice.
5. Call toll free 866-549-6446 or +1 847-855-0500 and ask customer service for an RMA number to include with your shipment.
6. Ship the vacuum regulator prepaid. Write your return address and billing address information on the package or letter that comes with the package.

For Warranty and non-warranty repairs, mail the package to

Ohio Medical, LLC
1111 Lakeside Drive
Gurnee, IL 60031 USA
RMA # _____

In other locations contact your nearest Ohio Medical office or authorized Ohio Medical distributor.

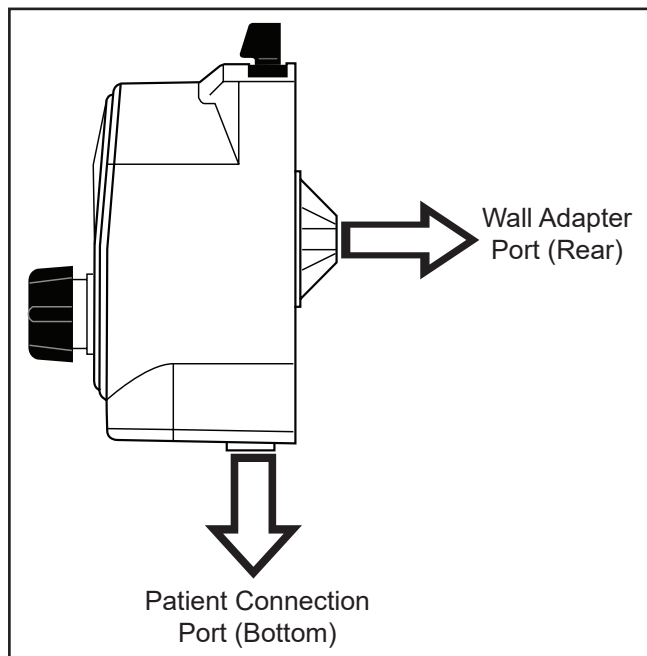
8.6 Installation Procedure for Adapters/Probes and Fittings

CAUTION: Do not use any Loctite® products or any products which contain Methacrylate Ester as an active ingredient to seal the threads on the adapters/probes and fittings.

All Ohio Medical regulators are supplied with 1/8" NPT female ports. The standard port facilitates simple adaptation to any quick disconnect system. Fittings are available from Ohio Medical to adapt to your quick connect system. We recommend you purchase the appropriate fittings with your regulator at the time of purchase. The fittings will then be factory installed prior to shipping.

In the event that you must assemble or disassemble fittings, please follow these instructions:

1. Prior to installing the fittings wrap the thread with Teflon tape Ohio Medical P/N 6700-1987-800 or equivalent.
2. Apply appropriate torque 4.0 ft-lb (5.4 N-m) minimum to 10.0 ft-lb (13.6 N-m) maximum.
3. Adapters/Probe and fittings which are not keyed for specific orientation, should be torque approximately 6.0 ft-lb (8.1 N-m).
4. Adapters/Probes and fittings that are keyed to specific orientation, must be torque initially to 4.0 ft-lbs (5.4 N-m). Additional torque is applied only until orientation is correct.
5. Make sure wall adapter are installed to specific orientation so that they are mount straight on wall.
6. The regulator is now ready to be place in service on your suction system.



9/Ordering Information

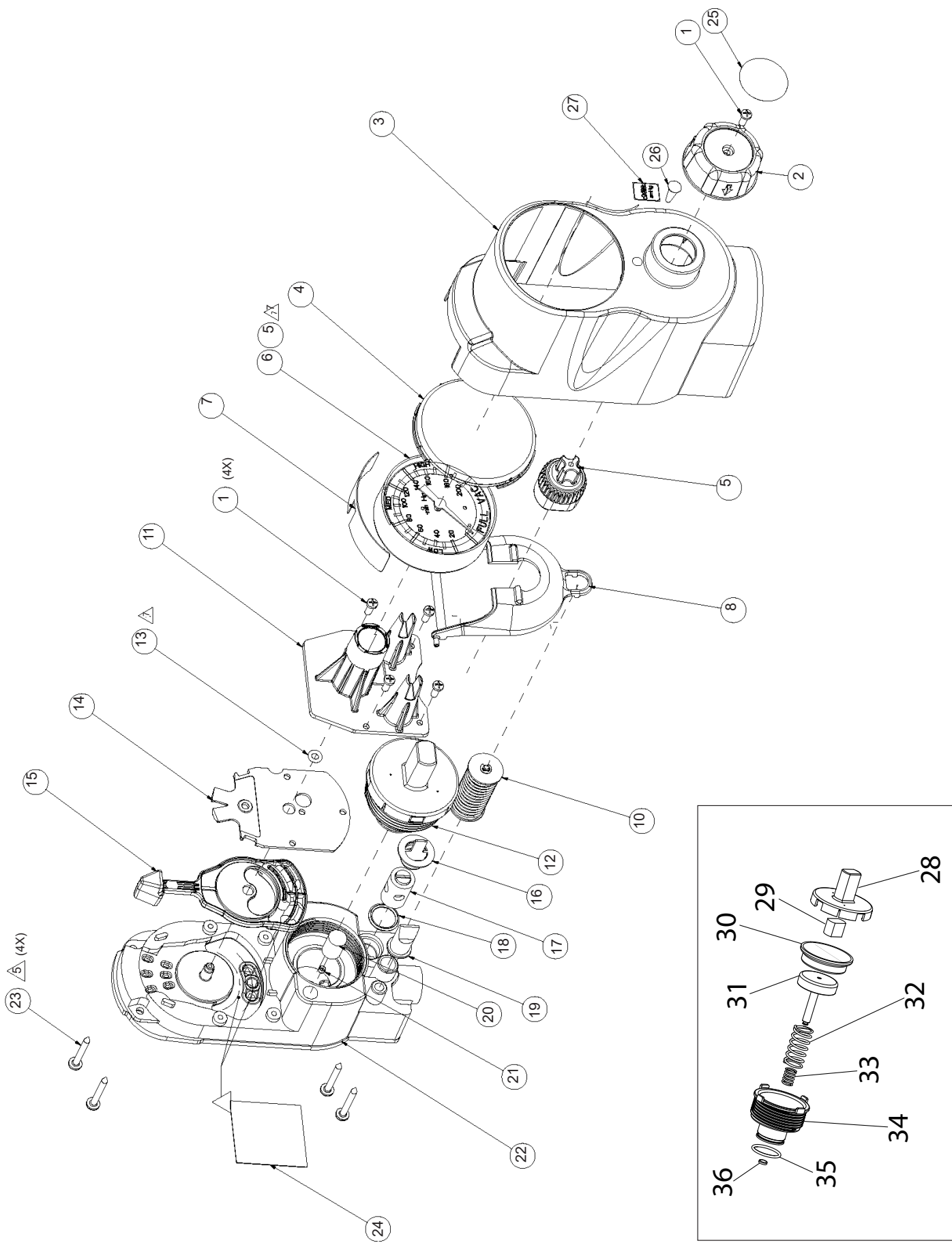
9.1 Illustrated Parts

Item	Part Number	Description	Qty	Item	Part Number	Description	Qty
1.	6700-0078-400	Screw, PHH PNH, 4-20 Plastite	5	20.	0206-5159-300	Plug, Filter	1
2.	8700-0017-500	Knob	1	21.	6700-0121-400	Orifice, Continuous Vacuum Regulator	1
3.	See Table	Case, Regulator	1	22.	8700-0009-700	Manifold Assembly	1
4.	8700-0041-500	Gauge Lens	1	23.	6700-0151-400	Screw, Self Tap, #6 Pan Head	4
5.	8700-0021-500	Drive Gear, Occlude-To-Set	1	24.	8700-0016-100	Serial Number Label	1
6.	See table below	Gauge, Vacuum	1	25.	8700-0005-100	Knob, Label	1
7.	8700-0038-500	Cover Strip, Switch	1	26.	8700-0056-500	Plug	1
8.	8700-0015-500	Actuator, Occlude-To-Set	1	27.	See table below	Label	1
9.	6700-0175-500	O-Ring, 2-013 Nitrile	1	28.	8700-0006-500	Cap	1
10.	8700-0002-700	OTS Assembly	1	29.	8700-0046-500	Cap Plug	1
11.	8700-0043-500	Support Bracket, Actuator	1	30.	8700-0008-500	Diaphragm	1
12.	8700-0001-700	Assembly, Reg Mod	1	31.	8700-0007-500	Piston with stem	1
13.	0210-0525-300	O-Ring, 9.32 OD x 5.32 IS x 1/16 W	1	32.	8700-0011-400	Spring, 0.475" ID	1
14.	8700-0040-500	Plate, Detent	1	33.	8700-0012-400	Spring, 0.246" ID	1
15.	8700-0016-500	Selector Switch, Overmolded	1	34.	8700-0005-500	Housing	1
16.	See table below	Plug, Pull Tab	1	35.	8700-0023-500	O-Ring, -018 Nitrile	1
17.	See table below	Vacuum Relief Assembly	1	36.	8700-0024-500	Quad-Ring, -006 Nitrile	1
18.	See table below	O-Ring, 2-014, Nitrile, Buna-N	1		8700-0006-000	PTS-CVR Service Manual	1
19.	6700-0115-400	Relief Valve, Positive Pressure	1				

Model #	Item 3 Case, Regulator	Item 6 Gauge, Vacuum Analog (ANSI) / Digital	Item 6 Gauge, Vacuum Analog (ISO)
1224/1324	8700-0012-500	8700-0002-400 / VR-DGP-200MM	X
1225/1325	8700-0022-500	8700-0002-400 / VR-DGP-200MM	
1226/1326/1229	8700-0012-500	8700-0022-400 / VR-DGP-760MM	8700-0023-400
1231/1331/1235	8700-0053-500	8700-0024-400 / VR-DGP-160MM	8700-0025-400
1234/1334/1232	8700-0053-500	8700-0024-400 / VR-DGP-160MM	8700-0025-400
1330/1430/1230	8700-0022-500	8700-0022-400 / VR-DGP-760MM	8700-0023-400

Model #	Item 16 Plug, Pull Tab	Item 17 Vacuum Relief Assembly	Item 18 O-Ring, 2-014, Nitrile, Buna-N	Item 27 Label
1224/1324	8700-0039-500	N/A	N/A/	N/A
1225/1325	8700-0039-500	N/A	N/A	N/A
1226/1326	8700-0039-500	N/A	N/A	N/A
1231/1331	N/A	6700-0045-700	6700-0135-500	8700-0036-102
1234/1334	N/A	6700-0045-700	6700-0135-500	N/A
1330/1430	8700-0039-500	N/A	N/A/	N/A

Color Case for Digital Regulators Only (Item 3)	2-Mode and C.A.S.S.	3-Mode	Pediatric	Neonatal
Purple	8700-0065-500	8700-0092-500	8700-0108-500	8700-0124-500
Red	8700-0066-500	8700-0093-500	8700-0109-500	8700-0125-500
Blue	8700-0067-500	8700-0094-500	8700-0110-500	8700-0126-500
Yellow	8700-0068-500	8700-0095-500	8700-0111-500	8700-0127-500
Lt. Blue	8700-0069-500	8700-0096-500	8700-0112-500	8700-0128-500
Pink	8700-0070-500	8700-0097-500	8700-0113-500	8700-0129-500



9/Ordering Information

9.3 ACCESSORIES

Suction Filters and Tubing

Description	Part Number		
Disposable Hydrophilic Filter	6730-0350-800 20 Pack	6730-0351-800 200 Pack	
Disposable Hydrophobic Filter Tubing x Tubing nipple	6730-0570-800 3 Pack	6730-0571-800 10 Pack	6730-0572-800 50 Pack
Disposable Hydrophobic Filter 1/8 NPT x Tubing nipple	6730-0580-800 3 Pack	6730-0581-800 10 Pack	6730-0582-800 50 Pack
Tubing	6700-0005-300		

Reusable Overflow Safety Traps

Description	Part Number
Overflow Safety Trap – with locking gland connection	6700-0365-901
Overflow Safety Trap - Hand-I-Twist (HIT)	6702-0365-901
Overflow Safety Trap - DISS Wing Nut & Gland	6703-0365-901


Sure-Trap™ Overflow Safety Traps

Description	Part Number
Sure-Trap (1/8 NPT) (Box of 12)	7725-0365-912
Sure-Trap (1/8 NPT) (Box of 25)	7725-0365-925
Sure-Trap (1/8 NPT) (Box of 50)	7725-0365-950

10/Electromagnetic Compatibility Declarations for PTS Digital

10.1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The PTS Digital is intended for use in the electromagnetic environment specified below. The user of the PTS Digital should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The PTS Digital uses RF energy only for its internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class A	The PTS Digital is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The PTS Digital is intended for use in the electromagnetic environment specified below. The user of the PTS Digital should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV Contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV Air	±8kV Contact, ±2 kV, ±4 kV, ±8 kV, and ±15 kV Air	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with this symbol: 
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PTS Digital is used exceeds the applicable RF compliance level above, the PTS Digital should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PTS Digital.			

10/Electromagnetic Compatibility Declarations for PTS Digital

10.2

IMMUNITY to Proximity Fields from Radio Frequency Wireless Communication Equipment						
In addition to the Radiated RF IEC 6100-4-3 as shown in the table above, the PTS Digital has been tested as specified in the table below.						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN, 802.11 b/g/n, RFID	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						



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