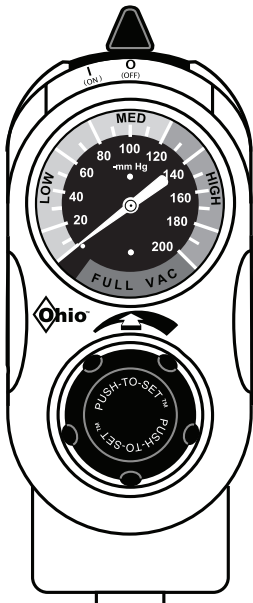
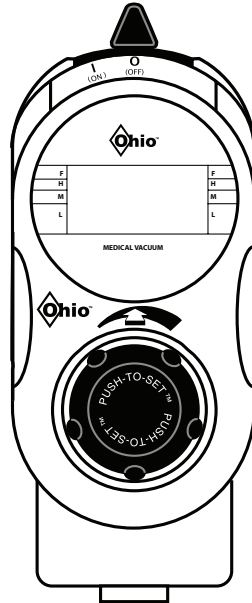


Push-To-Set™ Continuous Vacuum Regulator (PTS-CVR) Instructions for Use



Analog



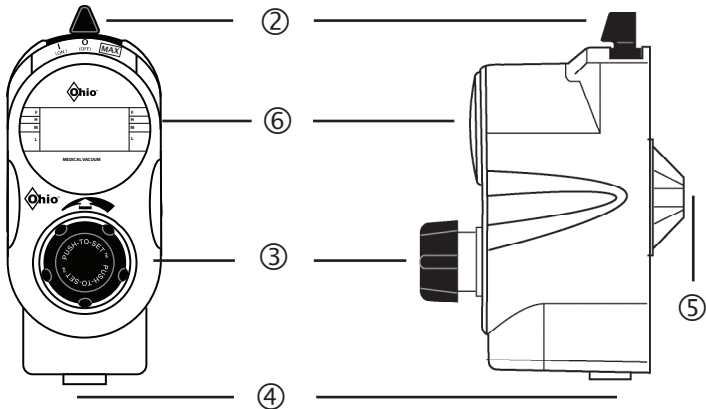
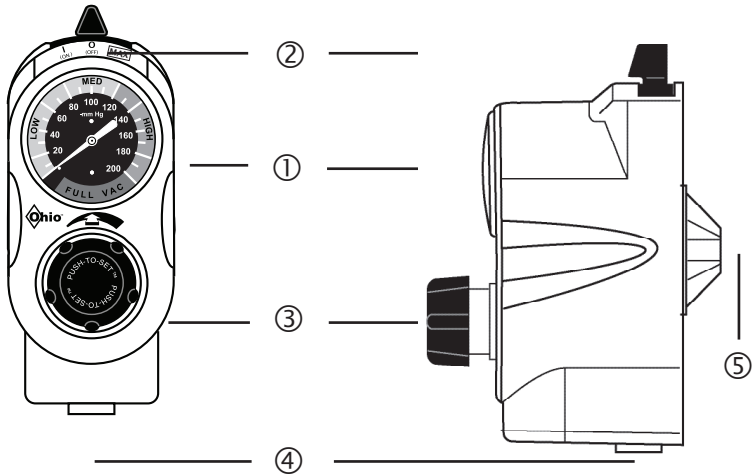
Digital

Regulator Identification

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


1 Figure 1

- ① Vacuum Gauge/Analog
- ② Mode Selector Switch
- ③ Suction Control Knob (Push-To-Set™)
- ④ Fitting Port (inlet)
- ⑤ Probe/Adapter Port (outlet)
- ⑥ Vacuum Gauge/Digital



User Responsibility


IMPORTANT: Federal law in the U.S.A. and Canada restricts this device for sale by or on the order of a licensed medical practitioner.


WARNINGS  This device is to be used only by persons who have been adequately instructed in its use.


 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.

This Product will perform in conformity with the description thereof contained 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, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, see the Ohio Medical service manual for service or repairs to this product. For service advice, Ohio Medical recommends that a telephone request be made to the nearest Ohio Medical Regional Service Center. This product or any of its parts should not be repaired other than in accordance with 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 A 12345 This alpha character indicates the year of product manufacture and when the serial number was assigned; "Y" = 1995, "Z" = 1996, "A" = 1997, etc. "I" and "O" are not used.




CAUTIONS  Only competent individuals trained in the repair of this equipment should attempt to service it.

 Detailed information for more extensive repairs is included in the service manual for users having proper knowledge, tools and test equipment, and for service representatives trained by Ohio Medical.

 Not for field or transport use.*


* The categories of Field and Transport Use are specifically defined in ISO 10079-3 (BS 7259: Part 2) "Field" means accidents or emergencies outside the hospital. "Transport" means use in ambulances, cars and airplanes. These situations may expose the equipment to uneven support, dirt, water, mechanical shock and temperature extremes. Ohio Medical suction equipment has not been tested to comply with the specific requirements of these categories.

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
	= Attention. Alerts you to a warning or caution in the text.
MAX	= maximum
High Flow High Vacuum	= high flow, high vacuum
High Flow Low Vacuum	= high flow, low vacuum
I (On)	= on
O (Off)	= off
	=  European Union Representative

Equipment Setup

Insert the adapter/probe into the vacuum wall outlet. If the regulator is mounted elsewhere, connect a vacuum supply hose between the regulator's adapter/probe and the wall outlet.

WARNING  **Connection to pressure sources, even momentarily, could injure the patient or operator and damage the equipment.**

Use hospital-supplied suction tubing between the end piece and the collection container, and between the patient port and the patient (minimum inside diameter is 6 mm [0.25 in.]).

An Ohio Medical Hydrophobic or Hydrophilic Filter and/or Overflow Protection Device (OPD) should be used between the collection container and regulator to prevent contamination of the regulator, wall outlet and pipeline system.

ISO 10079-3 (BS 7259: Part 2, section 5.1.2) states that "the usable volume of the collection container shall not be less than 500 ml."


Suction Filters

Hydrophilic:		Hydrophobic:		
	Nipple		Nipple	Threaded
20 Pack	6730-0350-800	3 Pack	6700-0570-800	6700-0580-800
200 Pack	6730-0351-800	10 Pack	6700-0571-800	6700-0581-800
		50 Pack	6700-0572-800	6700-0582-800

Note: For proper installation of adapters/probe and fittings, see page 9.

Operation

Attaching the Overflow Protection Device (OPD)

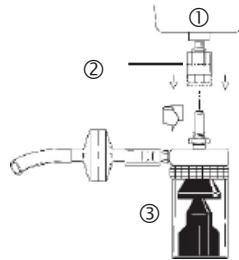
CAUTION  To help prevent aspirate from entering the regulator as a result of misuse, an OPD should be attached prior to its use. Aspirate in the regulator may impair its operation. The use of the OPD and suction filter will help prevent this and extend the life of suction equipment.

Locking Gland Fitting

2 Figure 2

1. Raise the sleeve and insert the OPD into the regulator fitting.
2. Turn the trap clockwise about one and a half turns to engage the threads. The trap does not need to be screwed tight; an O-ring in the regulator fitting provides a vacuum seal. The trap should rotate freely to allow the desired tubing positioning.
3. Lower sleeve to lock trap in position.

- ① Regulator
- ② Sleeve
- ③ OPD

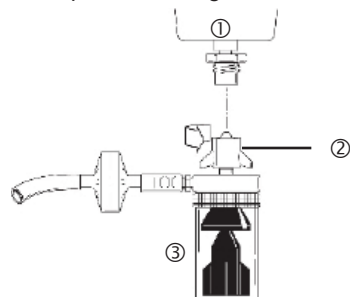


DISS fitting

3 Figure 3

1. Insert the OPD into the regulator fitting. Situate the tubing in the desired position.
2. Turn the DISS wing nut clockwise to engage threads and tighten (there is no O-ring, so the vacuum seal depends on a tight connection).

- ① Regulator
- ② Wing nut
- ③ OPD

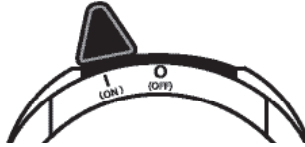


Operation

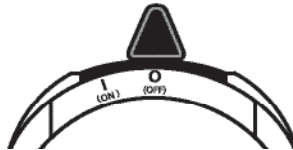
Mode Selection

4 Figure 4 - 2 Mode Continuous

I (On) - Suction can be applied with the suction control.



O (Off) - No suction supplied to the patient



5 Figure 5 - 3 Mode Continuous

MAX - Maximum, full-line vacuum is supplied to the patient

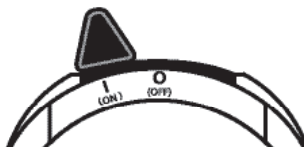


Note: Available on Three-Mode Vacuum Regulators ONLY

Setting the suction level

6 Figure 6

1. Turn the mode selector switch to I (ON).

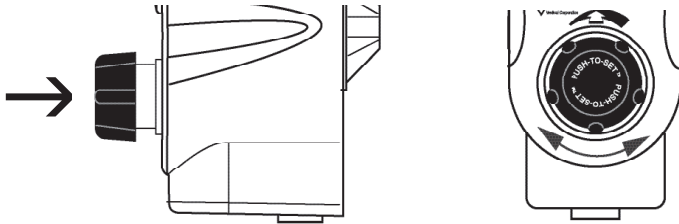


Operation

7

Figure 7

2. Push the suction control knob and rotate the suction control knob until the vacuum gauge indicates the required setting.



CAUTION

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

Pre-Use Checkout Procedure



WARNING

The Pre-Use Checkout Procedure must be performed before using the 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.

All tests must be performed with supply vacuum of 500 mmHg (67 kPa) minimum.

1. Turn the mode selector switch to O (OFF).

Push and rotate the suction control knob one full turn clockwise (increase).

Release. The gauge needle should not move.

2. Move the mode selector switch to I (ON). The gauge should indicate vacuum.

Push and rotate the suction control knob fully counter-clockwise (decrease) until it stops and release.

The gauge needle should move to zero and remain there.

Operation

3. Push suction control knob and set the following:

REGULATOR(Type)	SETTING
-----------------	---------

Standard:	Increase the suction to 90 mmHg (12 kPa)
High:	Increase the suction to 300 mmHg (40 kPa)
Low:	Increase the suction to 100 mmHg (13 kPa)

4. Slowly release and push the suction control knob to create various flow rates through the regulator. Check that the suction level is maintained when the knob is fully pushed in.
5. Move the mode selector knob to **MAX** on three mode units.
6. Push knob and release
7. Check gauge to insure maximum suction is applied.

Push the suction control knob and reduce the suction to zero. Set the mode selector to O (OFF).

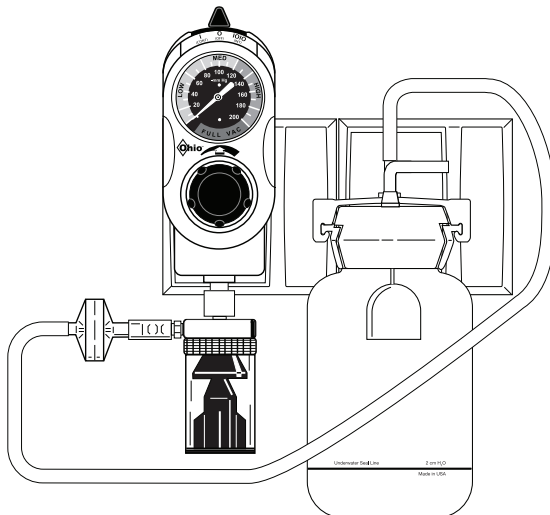
Patient Setup

1. Make sure the Pre-Use Checkout Procedure has been performed.


8

Figure 8

2. Move the mode selector switch to I (ON) and push suction control knob.
3. Set the prescribed suction level.



Cleaning/Troubleshooting

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


4. Move the mode selector switch to O (OFF).
5. Attach tubing to the vacuum port of the collection container.

Cleaning


Cleaning the regulator is recommended as a standard procedure after each use.


Wipe all exterior surfaces with a solution of water and mild detergent.

Should misuse occur resulting in accidental flooding of the regulator, the regulator may be sterilized after cleaning using ethylene oxide (ETO). See section 5 of the regulator service manual. After sterilization follow the service checkout procedures in section 8 of the regulator service manual.

WARNINGS  **Clean and sterilize all suction equipment before shipment to ensure transportation personnel and service personnel are not exposed to any hazardous contamination.**

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

 **Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 54°C (130°F).**

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

Troubleshooting

If the regulator does not operate and you have performed the Pre-Use Checkout Procedure, the following procedures may be used to attempt to correct the problem.

<u>Problem</u>	<u>Possible Cause</u>	<u>Remedy</u>
No suction	Mode selector is in the O (Off) or between positions	Switch to I (ON) or MAX position

Troubleshooting

Problem	Possible Cause	Remedy
No Suction	Leak in system	Check lid is secure on the collection container Check tubing connections
	Suction control knob at full decrease	Push and rotate the suction control knob in the increase direction (clockwise)

Important: If the above actions do not correct the problems or other problems exist, refer servicing to qualified service personnel.

Installation Procedure for Adapters/Probes and Fittings

All adapters/probes and fittings should be sealed and installed properly to prevent leaks and to support the equipment when mounted. Both vacuum regulator ports are 1/8-276 NPTF tapered pipe threads. It is important to note that adapters/probes and fittings seal on the thread and may have threads exposed after they have been tightened properly.

Prior to installing the adapter/probe or fitting, seal the thread with ¹Teflon® (PTFE) tape or one of the following lubricants:

²Dow® 111 (Ohio Medical P/N 6700-0074-200)

³Ball Vac-Kote (37951M) (Ohio Medical P/N 0220-0091-300)

CAUTIONS  Do not use any Loctite® products to seal the threads (or product which contain Methacrylate Ester as an active ingredient).

The torque range for installing adapters/probes and fittings is 4.0 ft-lb (5.4 N-m) minimum to 10.0 ft-lb (13.6 N-m) maximum. Adapters/probes and fittings which are not keyed for specific orientation, should be torqued to approximately 6.0 ft-lb (8.1 N-m).

Adapters/probes and fittings that are keyed to specific orientation, must be torqued initially to 4.0 ft-lbs. Additional torque is applied only until orientation is correct.

¹Teflon is a registered trademark of the DuPont Company.

²Dow is the registered trademark of the Dow Chemical Corporation.

³Ball Vac-Kote is a registered trademark of the Ball Aerospace Systems Division.

®Loctite is a registered trademark of Loctite Corporation.

Warranty

Warranty

This Product is sold by Ohio Medical under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this Product directly from Ohio Medical or Ohio Medical's Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for purpose of resale.

For a period of One hundred and twenty (120) months from the date of original delivery to Buyer or to Buyer's order, but in no event for a period of more than two years from the date of original delivery by Ohio Medical to an Ohio Medical Authorized Dealer, this Product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the Product contained in this operation manual and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided*. This same warranty is made for a period of thirty (30) days with respect to the expendable parts. The foregoing warranties shall not apply if the Product has been repaired other than by Ohio Medical or not in accordance with written instructions provided by Ohio Medical, or altered by anyone other than Ohio Medical, or if the Product has been subject to abuse, misuse, negligence, or accident.

Ohio Medical's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at Ohio Medical's option, a Product, which is telephonically reported to the nearest Ohio Medical Regional Service Office and which, if so advised by Ohio Medical, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty, to the designated Ohio Medical Service Office during normal business hours, transportation charges prepaid, and which, upon Ohio Medical's examination, is found not to conform with the above warranties. Ohio Medical shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. Ohio Medical makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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