

Continuous Vacuum Regulators Instructions for Use

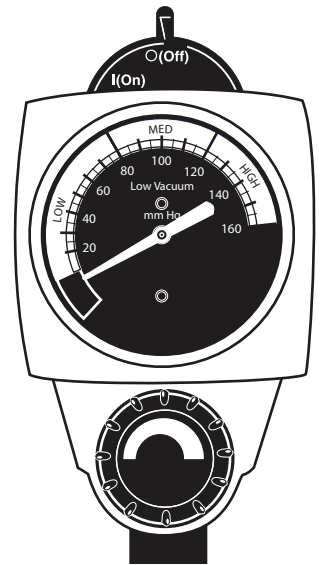
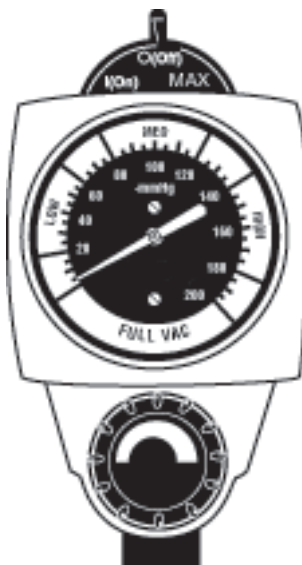
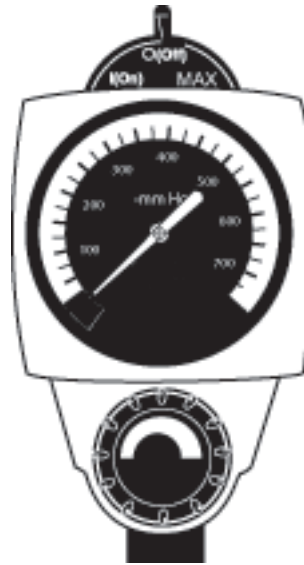
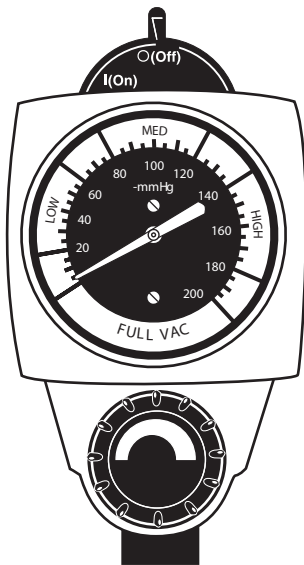


Table of Contents

Safety Instructions	2
Intended use	2
Receiving/Inspection	2
User Responsibility	2
Definitions	3
Regulator Identification	3
Operation	4
Cleaning	8
Troubleshooting	8
Warranty	9

Safety Instructions

This manual provides you with important information about the Continuous Vacuum Regulators (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.

Receiving / Inspection:

Remove product from package and inspect for damage. If product is damaged, DO NOT USE and contact your dealer or equipment provider.

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.**

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, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, Ohio Medical recommends that a telephone or written request for service advice 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 and 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.

Definitions

⚠ Detailed information for more extensive repairs is included in the service manual solely for convenience of 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, “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.

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

kPa

= Kilopascal

mL

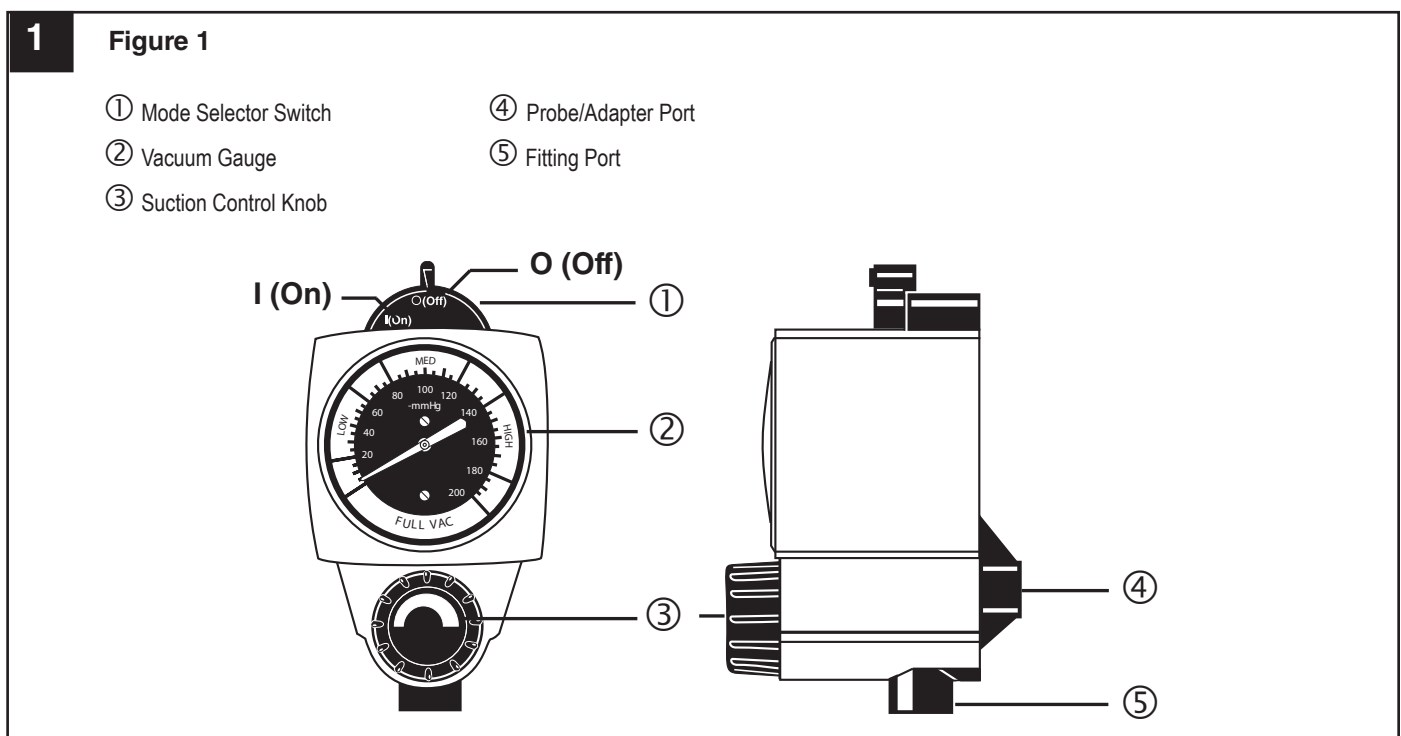
= Milliliter

mm

= Millimeter

Regulator Identification

Continuous Vacuum Regulator



Operation

Equipment Set-up

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

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

⚠ **CAUTION:** Connection to positive pressure sources such as oxygen and medical air, even momentarily, could 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 overflow safety trap and high flow suction filter should be used between the collection container and regulator to prevent contamination of the regulator. Hospital-supplied suction tubing must be used between the catheter and the collection bottle. Recommended minimum inside diameter is 0.25 in (6 mm).

ISO 10079-3 (section 5.1.2) states that "the usable volume of the collection container shall not be less than 500 mL."

High Flow Suction Filters

Hydrophilic		Hydrophobic	Tubing x tubing nipple	1/8" NPT x tubing nipple
Pkg of 20	6730-0350-800	Pkg of 3	6730-0570-800	6730-0580-800
Pkg of 200	6730-0351-800	Pkg of 10	6730-0571-800	6730-0581-800
		Pkg of 100	6730-0572-900	6730-0582-800

Attaching the Overflow Safety Trap (OST)

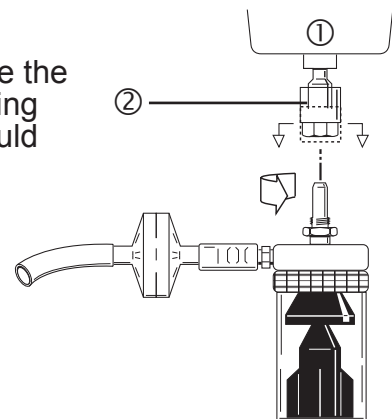
CAUTION ⚠ To help prevent aspirate from entering the regulator, wall outlet and pipeline equipment, an overflow safety trap should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline equipment may impair their operation. The use of the overflow safety trap and suction filter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

Trap fitting

2 Figure 2

1. Raise the sleeve and insert the trap 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



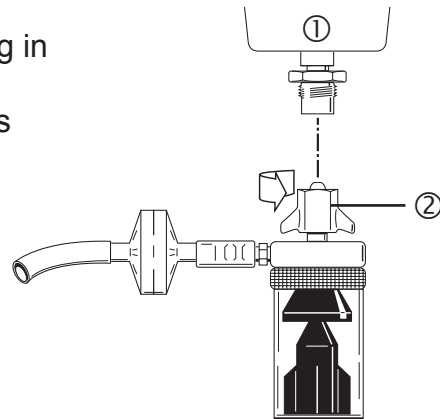
Operation

DISS fitting

3 Figure 3

1. Insert trap 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



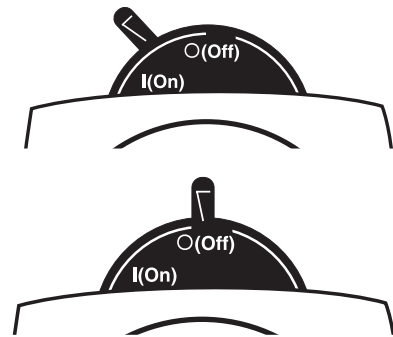
Mode Selection

4 Figure 4

2 Mode Continuous

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

O (Off) - No suction supplied to the patient.

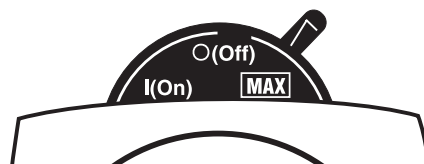


5 Figure 5

3 Mode Continuous

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

Note: Available on Three-mode vacuum regulators ONLY.



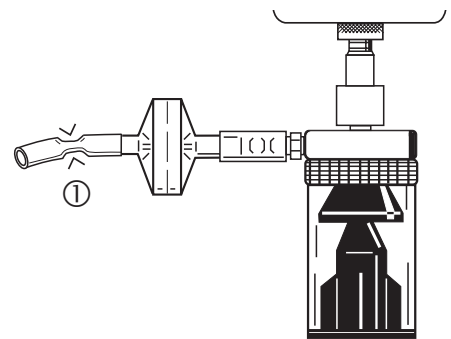
Operation

Setting the suction level

6 Figure 6

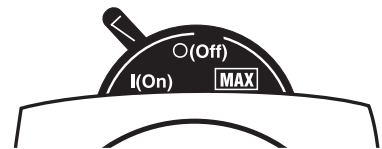
1. Clamp the connective tubing to occlude the fitting port

① Clamp



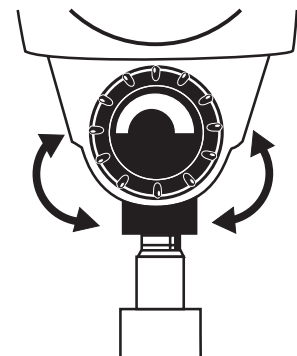
7 Figure 7

2. Turn the mode selector switch to I (On).



8 Figure 8

3. Rotate the suction control knob until the vacuum gauge indicates the required setting.



WARNING ⚠ The regulator fitting port or patient connector must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.

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 the regulator in its normal (vertical) operating position, with a minimum supply vacuum of 500 mmHg (66.7 kPa).

1. Turn the mode selector switch to O (Off).
2. Rotate the suction control knob one full turn clockwise (increase).
3. Clamp the connective tubing to occlude the fitting port. The gauge needle should not move.

Operation

4. Unclamp the connective tubing.
5. Turn the mode selector switch to I (On).
6. Rotate the suction control knob fully counter-clockwise (decrease).
7. Clamp the connective tubing. The gauge needle should not move.
8. With the connective tubing clamped, increase the suction to 90 mmHg (12.0 kPa).
9. Slowly open and close the clamped tubing to create various flow rates through the regulator. Check that the suction level is maintained at $\pm 5\%$ of full scale deflection when the tubing is clamped.

For Standard Two Mode Continuous, go to step 11

10. High and Standard Three Mode Continuous ONLY

- a. Turn the mode selector to MAX.
- b. Clamp the connective tubing and check that the gauge needle indicates the maximum available suction.
- c. Turn the mode selector to | (On).

11. Low Continuous ONLY

Clamp the connective tubing and rotate knob fully clockwise (increase) to verify the suction level does not exceed 135 mmHg \pm 5 mmHg (18.0. kPa \pm 0.7 kPa).

12. Reduce the suction level to zero and set the mode selector switch to O (Off).

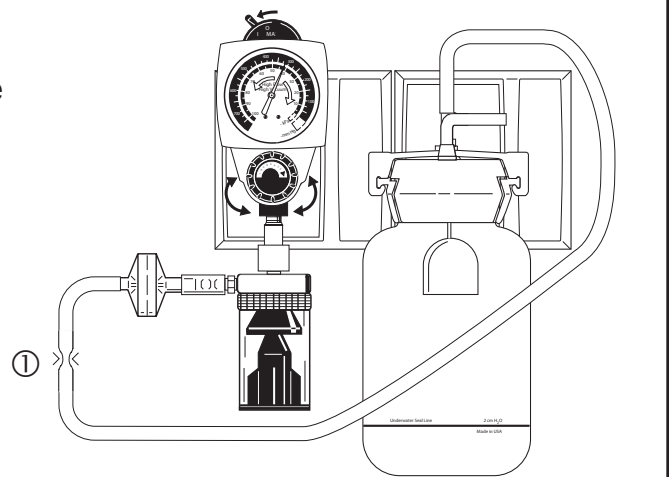
Patient Setup

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

9 Figure 9

2. Clamp the connective tubing and turn the mode selector switch to I (On).

① Clamp



3. Set the prescribed suction level.

WARNING \triangle The regulator must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.

4. Turn the mode selector switch to O (Off).
5. Attach the connective tubing to the vacuum port of the collection container.
6. Turn the mode selector switch to | (On).

Important: The Low models do not deliver suction in excess of 135 mmHg \pm 5 mmHg (18.0. kPa \pm 0.7 kPa).

Cleaning/Troubleshooting

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.

Should misuse occur resulting in accidental flooding of the regulator, the regulator may be sterilized using ethylene oxide (ETO). See section 5.2 (Sterilization) of the regulator service manual. After sterilization follow the service checkout procedures in section 8 (Service Checkout Procedure) of the regulator service manual.

CAUTION ⚠ Do not steam autoclave or liquid sterilize the regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

WARNINGS ⚠ **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). Follow your hospital sterilization procedure.**

⚠ 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.

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.

Problem	Possible Cause	Remedy
No suction	Mode selector is in the O (Off) position or between positions	Switch to I (On)
	Leak in system	Check that lid is secure on the collection container Check tubing connections
	Suction control knob at full decrease	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 to CVR service manual or refer servicing to qualified service personnel.

Warranty

This Product is sold by Ohio Medical, LLC (the “Company”) under the express terms of the warranty set forth below.

For a period of SIXTY (60) MONTHS from the date the Company ships this Product to the customer, but in no event for a period of more than five years from the date of original delivery by the Company to an authorized dealer, this Product, other than its expendable parts is warranted to be free from functional defects in materials and workmanship and to conform in all material respects to the description for the Product contained in this operation manual, if this Product is properly operated under conditions of normal use, regular periodic maintenance and service is performed and repairs are made in accordance with this operation manual. The warranty period for all expendable parts of the Product is sixty (60) days from the date the Company ships the Product to the customer.

The Company’s sole and exclusive obligation and customer’s sole and exclusive remedy under the above warranty is limited to repair or replacement, at the Company’s option, of the defective Product.

The foregoing warranty shall not apply if the Product has been repaired or altered by anyone other than the Company or an authorized dealer; or if the Product has been subjected to abuse, misuse, negligence, or accident.

The Company reserves the right to stop manufacturing any product or change materials, designs, or specifications without notice.

This warranty is extended to only the initial customer with respect to the purchase of this Product directly from the Company or an authorized dealer as new merchandise. Dealers are not authorized to alter or amend the warranty of any Product described in this agreement. Any statements, whether written or oral, will not be honored or be made part of the agreement of sale.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE COMPANY SHALL NOT BE LIABLE FOR INCIDENTAL, COLLATERAL, CONSEQUENTIAL, OR SPECIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, OR LOSS OF USE. THE COMPANY’S LIABILITY, IN THE AGGREGATE, SHALL NOT EXCEED THE PURCHASE PRICE OF THE PRODUCT.

In order to file a warranty claim, customer is required to return Product prepaid to the Company at 1111 Lakeside Drive, Gurnee IL, 60031 USA. As determined at the sole discretion of the Company, Products which qualify under the warranty will be repaired or replaced, at the Company’s option, and returned to customer via ground delivery at the Company’s expense.

All claims for warranty must first be approved by Ohio Medical Customer Service Department. For US Domestic customer returns: customer.service@ohiomedical.com or 1-800-662-5822 (Option 3). For International customer returns: intl.customerservice@ohiomedical.com or 1-800-662-5822 (Option 3). Upon approval the customer service department will issue a Return Goods Authorization (RGA) number. An RGA must be obtained prior to commencement of any warranty claim.



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