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Safety Instructions
This manual provides you with important information about the Thoracic Vacuum Regulators. 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, REFER TO THIS SERVICE MANUAL, CONTACT YOUR SUPERVISOR, DEALER OR THE MANUFACTURER BEFORE ATTEMPTING TO USE THE DEVICE.

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 properly trained on the operation of the device. Incorrect use of this device may cause serious injury to a patient.

⚠️ DO NOT operate 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.

⚠️ Thoracic Vacuum Regulator vacuum pressures used should not exceed the recommendations of the Chest Drainage System Manufacturer. Use of excessive vacuum pressure may render the Chest Drainage System ineffective and may result in patient harm.
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. 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 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.

Technical Competence

The procedures described in this service manual should be performed by trained and authorized personnel only. Maintenance should only be undertaken by competent individuals who have a general knowledge of and experience with devices of this nature. No repairs should ever be undertaken or attempted by anyone not having such qualifications.

Genuine replacement parts manufactured or sold by Ohio Medical must be used for all repairs.
Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure.

Abbreviations used in this manual

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>OFF</td>
</tr>
<tr>
<td>I</td>
<td>ON (Regulate)</td>
</tr>
<tr>
<td>CCW</td>
<td>Counter-clockwise (decrease)</td>
</tr>
<tr>
<td>CW</td>
<td>Clockwise (increase)</td>
</tr>
<tr>
<td>in</td>
<td>Inches</td>
</tr>
<tr>
<td>kPa</td>
<td>Kilopascals (kPa x 7.50 = mmHg) (kPa x 10.197 = cmH₂O)</td>
</tr>
<tr>
<td>LPM</td>
<td>Liters per minute</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeters</td>
</tr>
<tr>
<td>mL</td>
<td>Milliliters</td>
</tr>
<tr>
<td>mmHg</td>
<td>Millimeters of mercury (mmHg x 0.133 = kPa ) (mmHg x 1.3595 = cmH₂O)</td>
</tr>
<tr>
<td>cmH₂O</td>
<td>Centimeters of water (cmH₂O x 0.098 = kPa) (cmH₂O x 0.7355= mmHg)</td>
</tr>
<tr>
<td>°C</td>
<td>Degrees Celsius</td>
</tr>
<tr>
<td>°F</td>
<td>Degrees Fahrenheit</td>
</tr>
<tr>
<td>N-m</td>
<td>Newton-Meter (N-m x .737 = ft-lb)</td>
</tr>
<tr>
<td>ft-lb</td>
<td>Foot-Pound Force (ft-lb x 1.356 = N-m)</td>
</tr>
<tr>
<td>oz</td>
<td>Ounces</td>
</tr>
<tr>
<td>NPTF</td>
<td>National Pipe Thread Female (USA)</td>
</tr>
<tr>
<td>MPTS</td>
<td>Multi-Purpose Therapy Stand</td>
</tr>
<tr>
<td>g</td>
<td>grams</td>
</tr>
<tr>
<td>m</td>
<td>meters</td>
</tr>
</tbody>
</table>
1/Precautions

1.1 Definitions

**Note:** A Note provides additional information to clarify a point in the text.

**Important:** An Important statement is similar to a note but of greater emphasis.

⚠️ **CAUTION:** A CAUTION statement is used when the possibility of damage to the equipment exists.

⚠️ **WARNING:** A WARNING statement is used when the possibility of injury to the patient or the operator exists.

1.2 Warnings

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

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

Clean and disinfect all suction equipment before shipment for service to ensure transportation personnel and/or service personnel are not exposed to any hazardous contamination.

Clamping the tubing between the patient and the collection bottle may result in pressure buildup in the catheter and tubing.

When using a disposable chest drainage system, the atmospheric vent at the top of the suction control chamber must be occluded for proper suction regulation with the Thoracic regulator.

The patient port of the regulator must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction levels.

A water seal system must be used with the Thoracic Regulator to prevent atmospheric air from entering the pleural cavity, and to show the presence of air movement into the collection system.

The vacuum relief valve must be tested to ensure compliance with the manufacturer’s specifications before the unit is placed in service. Remove the unit from service if it fails the test, otherwise, excessive suction can cause injury to a patient. Excess Loctite® may seal the steel ball to the seat. This will disable the vacuum relief valve and may allow suction to exceed the pre-set limit.

With the patient tubing occluded, all the bubbling in the water seal system should stop. If bubbling does not stop, check all connections to troubleshoot and eliminate leaks.

When a leak-free collection system connected to a patient is turned on, after initial air in the system is eliminated, only patient air will produce bubbles in the water seal.

Connect the vacuum regulator to the vacuum source only. Connection to positive pressure sources, even momentarily, could injure the patient or operator and damage the equipment.

Always connect the regulator to the vacuum source and check its operation before attaching the patient connection.

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.

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

If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on a patient.

The pre-use checkout procedure (Section 4.2.3 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.

Connect the vacuum regulator to the vacuum source only. Connection to positive pressure sources, even momentarily, could injure the patient or operator and damage the equipment.

Always connect the regulator to the vacuum source and check its operation before attaching the patient connection.

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.

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

If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on a patient.

The pre-use checkout procedure (Section 4.2.3 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.
1.3 Cautions

Cleaning the gauge may cause damage which will result in inaccurate readings.

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

To help prevent aspirate from entering the regulator, the Thoracic Vacuum Regulator should always be used as part of a water seal drainage system. If as a result of misuse, water or aspirate gets into the regulator, it may impair the regulator's operation.

Do not use any Loctite® products, or any products which contain methacrylate ester as an active ingredient to seal the threads on the adapter/probe and fittings.

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

Sterilization with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts. Crazing will be more pronounced when mixtures containing Freon® are used.

Prior to placing the unit back into service, after disassembly or cleaning, perform the service checkout procedure (Section 8 Service Checkout Procedure).

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.

Use care when unhooking the tension spring from the regulator. Excessive tension on the spring can crack the plastic at the base of the mounting post.

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

Use of lubricants other than those recommended may degrade plastic or rubber components (Section 7.1 Service Tools and Equipment).

Not for field or transport use*.

1.4 Intended Use

The Ohio Medical Corporation® Thoracic Vacuum Regulator is a vacuum-powered suction apparatus that is intended for use with Chest Drainage Systems in Thoracic, Cardiovascular, Trauma and Critical Care applications.

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* The categories of Field and Transport Use are specifically defined in ISO 10079-3 (Section 5.1.2). “Field” means use at accidents or emergencies outside a hospital. “Transport” means use in ambulances, cars or 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.
This service manual contains service, maintenance and parts information for four models of the Thoracic Vacuum Regulator.

**Note:** Parts numbers are for vacuum regulators without adapters/probes.

### 2.1 North American Thoracic Vacuum Regulator

![North American Thoracic Vacuum Regulator](image1)

6700-1275-901

### 2.2 International Thoracic Vacuum Regulator

![International Thoracic Vacuum Regulator](image2)

6700-1276-901

### 2.3 French Thoracic Vacuum Regulator

![French Thoracic Vacuum Regulator](image3)

6700-1277-901

### 2.4 Spanish Thoracic Vacuum Regulator

![Spanish Thoracic Vacuum Regulator](image4)

6700-1278-901
3.1 Description

**WARNING:** 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.

The Thoracic Vacuum Regulator is a lightweight, compact unit used throughout the hospital for chest and mediastinal drainage.

Each regulator contains a vacuum gauge which indicates suction supplied by the regulator.

The Thoracic Vacuum Regulator operates only in a regulated vacuum mode. The unit has a diaphragm-type regulator which provides an adjustable vacuum of 0 to 50 cmH₂O (0 to 4.9 kPa). The regulator has a vacuum gauge with increments to 60 cmH₂O (5.9 kPa) and is housed in impact-resistant plastic for durability.

A vacuum limiting valve is incorporated which limits the maximum vacuum between 50 and 60 cmH₂O (4.9 and 5.9 kPa). If positive pressure is applied to the patient port (e.g. patient coughing) a positive pressure relief valve operates to relieve the pressure.

In the | (ON) 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.

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

1. **Suction Control Knob** - Allows adjustment of suction to the patient.
2. **Mode Selector Switch** - Allows quick mode changes.
   a. | (ON) - Suction can be adjusted with the suction control knob.
   b. O (OFF) - No suction is supplied to the patient.
3. **Vacuum Gauge** - Displays the suction level to the patient during use.
3/Description and Specifications

3.2 Specifications

3.2.1 Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gauge:</td>
<td>Accuracy ± 3 cmH₂O (± 0.3 kPa)</td>
</tr>
<tr>
<td>Flow Rate:</td>
<td>0 to 40 LPM without fittings at full increase setting depending on the supply vacuum and open air flow</td>
</tr>
<tr>
<td>Positive Pressure Safety Relief Valve:</td>
<td>Located in patient circuit to prevent pressurization of patient chest cavity in excess of 10 cmH₂O (1.0 kPa)</td>
</tr>
<tr>
<td>Regulated Suction Range:</td>
<td>0 to 50 cmH₂O (0 to 4.9 kPa)</td>
</tr>
<tr>
<td>Vacuum Relief Valve:</td>
<td>55 cmH₂O ± 5 cmH₂O (5.4 kPa ± 0.5 kPa)</td>
</tr>
<tr>
<td>Weight:</td>
<td>24 oz (680 g)</td>
</tr>
<tr>
<td>Dimensions (less fittings)</td>
<td></td>
</tr>
<tr>
<td>Height:</td>
<td>7.2 in (185 mm)</td>
</tr>
<tr>
<td>Width:</td>
<td>3.5 in (90 mm)</td>
</tr>
<tr>
<td>Depth:</td>
<td>4.3 in (108 mm)</td>
</tr>
<tr>
<td>Latex tubing</td>
<td>0 to full vacuum</td>
</tr>
<tr>
<td>0.25 in (6.4 mm) ID</td>
<td>Flow dependent on source and set-up</td>
</tr>
<tr>
<td>Disposable tubing</td>
<td>0 to full vacuum</td>
</tr>
<tr>
<td>(available separately in some markets;</td>
<td>Flow dependent on source and set-up</td>
</tr>
<tr>
<td>6 mm ID x 450 mm, 750 mm and 2 m)</td>
<td>to connect regulator and collection bottle</td>
</tr>
<tr>
<td>Disposable Suction Filter:</td>
<td>0 to full vacuum</td>
</tr>
<tr>
<td>0 to 100 LPM @ 650 mmHg (86.7 kPa)</td>
<td></td>
</tr>
</tbody>
</table>

3.2.2 Environmental Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature Range:</td>
<td>40°F to 120°F (4°C to 49°C)</td>
</tr>
<tr>
<td>Storage Temperature Range:</td>
<td>0°F to 160°F (−18°C to 71°C)</td>
</tr>
<tr>
<td>Operating and Storage Relative Humidity:</td>
<td>5 to 95%</td>
</tr>
</tbody>
</table>

3.2.3 Standards

ISO 10079-3 (Section 5.1.2)
4.1 Equipment Set-up

If the regulator is equipped with a adapter/probe for wall outlets, 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 port and the wall outlet.

⚠️ WARNINGS: Always connect the regulator to a vacuum source and check its operation before attaching the patient connection (Section 4.2.3 Pre-use Checkout Procedure).

⚠️ 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 0.25 in. [6 mm]).

An Ohio Medical high flow suction filter and overflow safety trap should be used between the collection container and regulator to prevent contamination of the regulator.

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

Note: A positive pressure relief valve in the Thoracic Vacuum Regulator will prevent pressure buildup in the system if suction is turned off using the mode selector switch.

⚠️ WARNING: Clamping the tubing between the patient and the collection bottle may result in pressure buildup in the catheter and tubing.

⚠️ When using a disposable system, the atmospheric vent at the top of the suction control chamber must be occluded for proper suction regulation with the Thoracic Vacuum Regulator.

Important: Once the atmospheric vent is occluded, the Thoracic Vacuum Regulator controls vacuum level regardless of the presence or amount of water in the suction control chamber.

Note: A positive pressure relief valve in the disposable collection system will prevent pressure buildup in the system if the system is clamped between the vacuum regulator and the collection device.

⚠️ CAUTION: To help prevent aspirate from entering the regulator, the Thoracic Vacuum Regulator should always be used as part of a water seal drainage system. If as a result of misuse, water or aspirate gets into the regulator, it may impair the regulator's operation.
4/Operation

4.1.1 Attaching the Overflow Safety Trap (OST)

**CAUTION**

⚠️ To help prevent aspirate from entering the regulator, 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 operation. The use of the safety trap and suction filter will help prevent this and extend the life of suction equipment.

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 ⤲
   - ① Reg
   - ② Sle

4.2 Operation

4.2.1 Mode Selection

| (ON) - Suction can be adjusted with the suction control knob.

O (OFF) - No suction is supplied to the patient.

4.2.2 Setting the Suction Level

1. Clamp the connective tubing to occlude the patient port.
2. Turn the mode selector switch to | (ON).
3. Rotate the suction control knob until the vacuum gauge indicates the required setting.

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

4.2.3 Pre-use Checkout Procedure

The Pre-use Checkout Procedure must be performed before using this equipment on each patient. All tests must be performed with a supply vacuum of 300 mmHg (40.0 kPa) minimum.

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.
4. Turn the mode selector switch to | (ON).
5. Rotate the suction control knob fully counter-clockwise (decrease).
6. Clamp the connective tubing. The gauge needle should not move.
7. With the tubing still clamped, increase the suction to 35 cmH₂O (3.4 kPa).

8. Slowly open and close the clamped tubing to create various flow rates through the regulator. Check that the suction level is maintained when the tubing is clamped.

9. Clamp the connective tubing.

10. Rotate the suction control knob fully clockwise (increase) to verify that the relief valve opens (begins to flow) at 55 cmH₂O ± 5 cmH₂O (5.4 kPa ± 0.5 kPa). As suction is increased, the relief valve should not allow levels of more than 60 cmH₂O (5.9 kPa).

11. Reduce the suction level to zero and turn the mode selector switch to O (OFF).

### 4.2.4 Patient Set-up

1. Make sure the pre-use checkout procedure (Section 4.2.3 Pre-use Checkout Procedure) has been performed.

2. Clamp the connective tubing and turn the mode selector switch to | (ON).

3. Set the prescribed suction level.

⚠️ **WARNING:** The patient port of the regulator must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction levels.

**Important:** Add the 2 cm water seal amount to the level set on the regulator gauge to determine the total suction level.
4. Turn the mode selector switch to O (OFF).

⚠️ WARNING: A water seal system must be used with the Thoracic Vacuum Regulator to prevent atmospheric air from entering the pleural cavity, and to show the presence of air movement into the collection system.

5. Fill the water seal to its designated level.

6. Connect the regulator to a reusable water seal or a disposable system with a water seal.

7. Connect the water seal to the collection bottle’s vacuum port.

8. Attach the patient tubing to the collection bottle’s patient port.

9. Clamp the patient tubing.

10. Turn the mode selector switch to | (ON).

11. After a brief period, all bubbling in the water seal should stop.

⚠️ WARNING: With the patient tubing occluded, all bubbling in the water seal system should stop. If bubbling does not stop, check all connections to troubleshoot and eliminate leaks.

12. Release the clamp on the patient tubing.

⚠️ WARNING: When a leak-free collection system connected to a patient is turned on, and after initial air in the system is eliminated, only thoracic air should produce bubbles in the water seal.
5/Cleaning, Disinfection and Sterilization

5.1 Cleaning and Disinfection

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

⚠️ WARNING: Perform a service checkout procedure (Section 8 Service Checkout Procedure) following cold flushing. Validate the selected cleaning/disinfection procedure. Failure to do so may result in patient use of a product which is assumed to be clean/disinfected but is not.

⚠️ 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.

5.1.1 Routine Exterior Cleaning & Disinfection

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.

5.1.1.1 Approved Cleaning Solutions

• Virex® (Quaternary Ammonium 0.2%): Mixture of 1 fl. oz. of Virex® to 1 gallon (128 fl. oz.) tap water using Virex®128

• Kleenaseptic® Full strength from spray can

• Bleach (Sodium Hypochlorite 0.5%): Mixture of 13 fl. oz. of Clorox household bleach to 1 gallon (128 fl. oz.) tap water

• Betco® TB Plus Mixture of 1 fl. oz. to 1 gallon (128 fl. oz.) tap water

• Glutaraldehyde

• Isopropyl Alcohol 70%

• Hydrogen Peroxide 3%

• Cavicide®: Ready to use full strength

5.1.2 Internal Component Cleaning & Disinfection

⚠️ CAUTION: Cleaning the gauge may cause damage which will result in inaccurate readings.

1. To disassemble the unit, refer to Section 7 Service - Disassembly and Assembly for instructions.

2. All internal components, with the exception of the gauge, may be cleaned with a solution of warm water and mild detergent.

3. Dry all components with a lint free cloth before assembly. Dry internal passages using vacuum flow or compressed air.

4. Perform service checkout procedure (Section 8 Service Checkout Procedure).

5.1.2.1 Approved Flush Solutions

Warm water and mild detergent.

5.1.3 Cold Flush Procedure

⚠️ CAUTION: Unit failure due to cold flushing is not the responsibility of Ohio Medical and may invalidate the warranty. Failure to adequately dry the product following a cold flush may damage the working parts which are designed for pneumatic air-flow only. Failure to disassemble to check O-ring and filter status may render the unit inoperative.

If desired, the vacuum regulator can be cold-flushed as part of a cleaning or disinfecting procedure. Set up a collection canister or liner between the vacuum source and the adapter/probe port of the vacuum regulator to receive the flush solution. To satisfy the infection control requirements of the hospital, suction an adequate amount of cold disinfectant through the vacuum regulator. Use only approved flushing solutions. Make sure solutions that are made from concentrates are newly-mixed to ensure effectiveness.

Flush the vacuum circuits thoroughly. Allow the specified time required for your cold solution to elapse to achieve disinfection. Adequately aerate the circuits with vacuum flow or compressed air until all internal channels, switches, gauge ports and regulating mechanisms are dry. Disassemble to check O-rings for adequate lubricant and filters for proper function following any cold flush procedure. Perform service checkout procedure (Section 8 Service Checkout Procedure).

5.2 Sterilization

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

⚠️ WARNING: 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 130°F (54°C). Follow your hospital sterilization procedure.

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

⚠️ CAUTION: Sterilization with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts. Crazing will be more pronounced when mixtures containing Freon® are used.

Note: The vacuum regulator should only be sterilized if it is contaminated or maintenance is to be performed.
<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. No gauge indication but suction is being delivered</td>
<td>1. Blocked gauge pressure sensing orifice and/or gauge tubing 2. Dust in gauge mechanism 3. Gauge mechanism jammed</td>
<td>1. Clean orifice and/or gauge tubing 2. Gently blow out dust 3. Replace gauge</td>
</tr>
<tr>
<td>E. Insufficient flow through regulator</td>
<td>1. Partial blockage in wall outlet 2. Partial blockage in regulator</td>
<td>1. Remedy: i. Confirm wall supply open air flow meets minimum hospital requirements ii. Clean if necessary 2. Remedy: i. Perform the flow test in the service checkout procedure section of this manual (Section 8.2 Flow Test) ii. Clear blockage if necessary</td>
</tr>
<tr>
<td>F. Inaccurate gauge reading</td>
<td>1. Damaged gauge</td>
<td>1. Replace gauge</td>
</tr>
<tr>
<td>Note: All gauge needles should come to rest at the stop pin when no suction is being supplied.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G. No suction in any setting and whistling or vibrating noise from inside the regulator</td>
<td>1. Vacuum relief valve failure 2. Positive pressure safety relief valve failure</td>
<td>1. Replace rubber sleeve and ensure that the steel ball is present and clean 2. Replace positive pressure safety relief valve</td>
</tr>
</tbody>
</table>
7/Service - Disassembly and Assembly

7.1 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: 300 mmHg (40.0 kPa) minimum with 80 LPM open air flow minimum.
- Bubble leak tester
- 50 LPM flowmeter (6700-0355-800)
- Water manometer or calibrated vacuum gauge, 0 to 70 cmH₂O (± 1 cmH₂O)
- Water manometer or calibrated pressure gauge, 0 to 70 cmH₂O (± 1 cmH₂O)
- Dow Corning No. 111 lubricant (6700-0074-200)
- Pliers
- Loctite® 242 removable thread locker (6600-0058-300)
- 1/4 inch flathead screwdriver
- No. 2 Phillips screwdriver
- Internal snap ring pliers
- 5/16” and 9/16” open end wrenches
- Positive pressure source delivering 10 LPM open flow
- Toothpick (O-ring removal)

7.2 Disassembly

⚠️ **WARNINGS:** If the vacuum regulator is repaired or disassembled in any manner, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on a patient.

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

⚠️ **To reduce service personnel exposure to hazardous contamination, clean and disinfect all suction equipment before disassembly.**

⚠️ **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.

1. Remove the four cover mounting screws and lift off the front cover.

2. Pull the knob off of the control shaft, as well as the washer and plastic spacer on the shaft under the knob.

3. Gently slide the gauge out of its mounting and disconnect from tubing.

   **Note:** The plastic gauge lens should remain attached to the gauge.

4. Remove the connecting tube with the restricting orifice from the regulator assembly.

5. Unhook the tension spring (if present) from the mode selector switch.

⚠️ **CAUTION:** Use care when unhooking the tension spring from the regulator. Excessive tension on the spring can crack the plastic at the base of the mounting post.

6. Remove the mounting screw and spring washer from the center of the mode selector switch. Lift the switch from the unit and unplug its connecting line to the regulator assembly. Use a toothpick to remove the O-ring from its recess in the back plate.

7. Unbolt the adapter/probe connector from the back plate. Use a toothpick to remove the O-ring.

8. Pull the vacuum relief valve off its mounting vent (cup your hand under the valve to catch the ball as it falls out while unscrewing the adjustment screw).

9. Remove the regulator assembly mounting screws and lift the assembly off the back plate.

10. Take the diaphragm off the back plate.

   **Note:** The metal disc at the center of the diaphragm may be removed for further cleaning if necessary.

11. Separate the regulator assembly and remove the large O-ring seal.

12. Unscrew the patient port fitting from the regulator assembly, and remove the O-ring.

13. Using the snap ring pliers, remove the snap ring that retains the control shaft in the regulator assembly. Pull out the control shaft, and remove the spring, nut and O-ring.

   **Note:** The spring button and piston should be left assembled in the baffle guide plate.
7.2.1. Part Numbers

1. Control Knob ........................................ 0212-0806-100
2. Bent Metal Washer ................................ 0202-3042-300
3. Plastic Spacers (2) ............................... 0202-0063-300
4. Cover Mounting Screws (4) .................... 0142-4113-108
5. Restrictor tubes and orifice kit
   (Includes items 6, 7, and 8) ...................... 6700-0429-850
6. Restrictor Mounting Tube
7. Restrictor Orifice
8. Tube
9. Gauge kit (Includes items 10, 11, and 12)
   Domestic ............................................. 6700-0430-850
   International ...................................... 6700-0431-850
10. Barbed Fitting
11. Vacuum Gauge
12. Lens Cover ...................................... 6700-0087-500
13. Label
   Domestic ............................................. 0205-4366-300
   International ..................................... 6700-0224-100
14. Front Cover
   English .............................................. 6700-0155-400
   French .............................................. 6700-0155-401
   Spanish .............................................. 6700-0155-402
1. Vacuum Tube ........................................0211-0072-300
2. Adapter/probe Mounting Screws (2) .... 0140-6624-108
3. Adapter/probe connector ............... 0206-5149-300
4. O-ring ............................................. 6700-0131-500
5. Nuts (2) .......................................... 6700-0175-400
6. O-ring ............................................. 6700-0131-500
7. Mode Selector switch
   (International – I/O) ..................... 6700-0092-701
   (Domestic – ON/OFF) .................... 6700-0092-700
8. Spring washer .................................. 0202-3030-300
9. Screw ............................................. 6700-0208-400
1. Vacuum Relief Adjustment Kit
   (Includes items 2 and 3) 6700-0432-850
2. Vacuum Relief Adjustment Screw
3. Vacuum Relief Body
4. Ball 6700-0248-400
5. Patient port fitting 0204-9046-535
6. O-ring 6700-0130-500
7. Diaphragm 0210-7300-100
8. Disc 0214-3212-300
9. Backplate - English 6700-0643-850
   French 6700-0633-850
   Spanish 6700-0634-850
   German 6700-0635-850
   Italian 6700-0636-850
   Swedish 6700-0637-850
   Japanese 6700-0638-850
   Russian 6700-0639-850
   Greek 6700-0640-850
   Dutch 6700-0641-850
   Portuguese 6700-0642-850
10. Rubber Sleeve 0211-0719-500
11. Screws (4) 0140-6124-112
1. Snap ring ...............................................0203-5213-300
2. O-ring ....................................................6700-0131-500
3. O-ring ....................................................6700-0132-500
4. Brass nut ...............................................0402-1659-500
5. Spring ....................................................0203-3054-300
6. Spring Button ........................................0212-0800-100
7. Spring Case Cover ................................0221-6365-300
8. O-ring ....................................................0210-0527-300
10. Piston ....................................................6700-0099-400
11. O-ring ....................................................0210-0527-300
12. Flapper Valve ........................................0211-1451-100
13. Control Shaft .......................................0221-6351-500
7.3 Assembly

Before reassembling the unit, sparingly lubricate all of the O-rings with Dow Corning® No. 111.

⚠️ **CAUTIONS**: To prevent stripping of the plastic threads, place the screw in the hole and turn counter-clockwise until it drops into the original threads, then tighten the screw.

⚠️ Over-tightening of the screws may result in stripped threads.

When installing the diaphragm, orient it with its metal section towards the metal piston of the regulator assembly. The rim of the diaphragm should fit over the outside of the diaphragm seat for a good seal. Do not lubricate the diaphragm. Tighten the regulator assembly mounting screws in an “X” pattern to prevent warpage (do not over tighten the screws).

Before placing the front cover on a reassembled unit connect it to a functioning vacuum source and adjust the vacuum relief valve. Refer to Section 8.5 Vacuum Limit Test.

⚠️ **WARNING**: The vacuum relief valve must be tested to ensure compliance with manufacturer’s specifications before the unit is placed in service. Remove the unit from service if it fails the test, excessive suction can cause injury to a patient.

Ensure that the conductive wire (if present) between the adapter/probe connector and the patient port fitting is properly connected.

⚠️ **WARNING**: If the vacuum regulator is repaired or disassembled, the service checkout procedure (Section 8 Service Checkout Procedure) must be performed before using the equipment on a patient.

**Important**: This entire Service Check-out Procedure MUST be performed in numerical order.
8.1 Set-Up
1. Verify that there is a minimum of 300 mmHg (40.0 kPa) vacuum on the supply gauge.
2. The supply open flow must be at least 80 LPM.
3. Connect the supply vacuum to the adapter/probe port of the regulator.

8.2 Flow Test
1. Connect the regulator’s patient port to the flowmeter with tubing. Use the shortest tubing possible with an inside diameter of 0.25 in (6 mm) or larger.
2. Rotate the suction control knob fully clockwise (increase).
3. Turn the mode selector switch to | (ON) and verify that the flow rate is at least 40 LPM.
4. Turn the mode selector switch to O (OFF) and disconnect the flowmeter.

8.3 Gauge Test
Note: All Ohio Medical gauges are supplied with an accuracy of ± 5% of full scale deflection throughout their range.
Note: All gauge needles should come to rest at the stop pin when no suction is being supplied. Gauges which do not comply may be out of calibration.

When checking gauge accuracy, be sure that the calibration gauge has an accuracy of ± 1 cmH₂O (± 0.1 kPa) or better.

1. Connect the regulator’s patient port to the calibration gauge with tubing.
2. Turn the mode selector switch to | (ON).
3. Check that the regulator gauge is in agreement with the vacuum calibration gauge within the ± 3 cmH₂O (± 0.3 kPa) tolerance. Recommended test points are 15, 30, and 45 cmH₂O (1.5, 2.9, and 4.4 kPa).

8.4 Regulation Test
1. Disconnect the calibration gauge and occlude the patient port.
2. Set the vacuum level on the gauge to 30 cmH₂O (2.9 kPa).
3. Open and close the patient port several times.
4. With the patient port occluded, the regulator gauge should return to the setting listed in step 2 within a tolerance of ± 3 cmH₂O (± 0.3 kPa).

8.5 Vacuum Limit Test
1. Occlude the patient port of the regulator.
2. Turn the suction control knob fully counter-clockwise (full decrease).
3. Slowly increase the vacuum and observe the gauge.
4. The vacuum relief valve should open at 55 cmH₂O ± 5 cmH₂O (5.4 kPa ± 0.5 kPa). The gauge needle may oscillate, but the vacuum should not increase beyond 60 cmH₂O (5.9 kPa) as the suction control knob is turned further clockwise.
5. 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 the suction level at which the relief valve opens.
6. When the desired limit is reached, lock the screw with a drop of removable thread locker Loctite® 242.

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 pre-set limit.

7. Repeat the steps one through four if the relief valve does not open within the specified range.
8/Service Checkout Procedure

8.6 Positive Pressure Relief Test

1. Set the mode selector switch to O (OFF).
2. Connect the positive pressure source and calibrated pressure gauge to the patient port of the regulator with tubing (see diagram on page 20).
3. Apply a positive pressure (at 10 LPM open flow) and observe the calibrated pressure gauge.
4. The reading on the pressure gauge should not exceed 10 cmH₂O (1.0 kPa).

8.7 Leak Test

1. Connect the patient port to port “A” of the bubble leak tester with tubing (see diagram below).
2. Set the mode selector switch to O (OFF) and check that the suction control knob is set approximately in the middle of its range.
3. Observe the bubble leak tester. No bubbles should appear within 10 seconds.
4. Rotate the suction control knob fully counter-clockwise (decrease) and turn the mode selector switch to | (ON).
5. Observe the bubble leak tester. No bubbles should appear within 10 seconds.
9.1 General Maintenance of Suction Equipment

⚠️ WARNINGS: The pre-use checkout procedure (Section 4.2.3 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.

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

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

Vacuum regulators should be kept in use or used on a rotating basis. Internal parts of unused equipment may tend to deteriorate.

Maintenance 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. The flow rate at the wall outlet should be checked on a yearly basis and suitable cleaning of the outlets should be performed as needed. The flow rate measurement should meet NFPA®99 and/or ISO® standards.

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. Perform a thorough cleaning by washing all bottles, tubing, metal connectors, etc, and removing all residue.
2. Wipe all exterior surfaces with a solution of water and mild detergent.
3. Perform a careful visual inspection.
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 safety trap and collection bottle for correct operation.
7. Perform the pre-use checkout procedure.

9.2 Recommended Maintenance Schedule

In addition to the pre-use checkout procedure, the following periodic maintenance should be performed.

9.2.1 Maintenance Schedule

<table>
<thead>
<tr>
<th>Item</th>
<th>Minimum Frequency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service Checkout</td>
<td>Every 4 months</td>
<td>If the regulator does not pass the service checkout procedure (Section 8 Service Checkout Procedure), refer to Section 6 Troubleshooting section of this manual. Repair as necessary.</td>
</tr>
<tr>
<td>Elastometric Components</td>
<td>Inspect every 4 months; Replace every 24 months</td>
<td>Replace as necessary to minimize in-use failures.</td>
</tr>
<tr>
<td>• Positive pressure safety relief (flapper) valve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Switch O-ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Low vacuum relief valve sleeve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Control shaft O-rings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient port O-ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Adapter/probe connector O-ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Flow Disposable Suction Filter</td>
<td>Replace after each patient use</td>
<td>Replace more frequently if flow deteriorates</td>
</tr>
</tbody>
</table>
9.3 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.

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

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

Do not use malfunctioning equipment. Make all necessary repairs. Have the equipment repaired by qualified service personnel or by Ohio Medical. Parts listed in this service manual may be repaired or replaced by a competent, trained person who has experience in repairing devices of this nature. After repair, perform the service checkout procedure (Section 8 Service Checkout Procedure) to ensure that the equipment is functioning properly, and complies with the published specifications.

9.4 Technical Assistance

If technical assistance is required, contact Ohio Medical technical support or field operations listed on the back cover.

9.5 Return Instructions

1. Call for a Return Material Authorization (RMA) number before sending any items for warranty and/or non-warranty repair. (1-866-549-6446)

2. Clean and disinfect the vacuum regulator.

3. Package the vacuum regulator securely for protection, preferably in the original container.

4. Include a letter describing in detail any difficulties experienced with the vacuum regulator. Include the person, title, and telephone number to contact for questions.

5. If the vacuum regulator is covered under warranty, include the warranty information that came with the device and a copy of the invoice.

6. Include a purchase order to cover repair of a regulator not under warranty.

7. 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 Corporation
1111 Lakeside Drive
Gurnee, IL 60031 USA
RMA #_____________

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

9.6 Installation Procedure for Adapters/Probes

All adapters/probes should be sealed and installed properly to prevent leaks and to support the equipment when mounted. The adapter/probe port is a 1/8-27 NPTF tapered pipe thread. It is important to note that adapters/probes seal on the thread and may have threads exposed after they have been tightened properly.

Prior to installing the adapter/probe, seal the thread with Teflon® (PTFE) tape or one of the following lubricants:
Dow Corning® 111 (6700-0074-200)

⚠️ CAUTION: Do not use any Loctite® products, or products which contain methacrylate ester as an active ingredient, to seal the adapter/probe threads.

The torque range for installing adapters/probes is 4.0 ft-lb (5.4 N-m) minimum to 10.0 ft-lb (13.6 N-m) maximum.

Adapters/probes which are not keyed for specific orientation, should be torqued to approximately 6.0 ft-lb (8.1 N-m).

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

9.7 Disposal Instructions

Dispose of vacuum regulator in accordance with local regulations.