Intermittent Suction Unit (ISU)
Service Manual

ANSI

ISO
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 malfunctioning Product should not be used. Parts that are broken, missing, plainly worn, destroyed or contaminated, should be replaced immediately. Should such repair or replacement become necessary, Ohio Medical recommends that a telephonic or written request for service advice be made to the nearest Ohio Medical Service Office. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Ohio Medical, or altered without the prior written approval of Ohio Medical’s Safety 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 alterations 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

inHg  Inches of mercury
in  Inch
ISU  Intermittent Suction Unit
kPa  Kilo pascals (kPa x 7.50 = mmHg)
L/min  Liters per minute
mmHg  Millimeters of mercury (mmHg x .133 = kPa)
mm  Millimeters
mL  Milliliters
oz  Ounces
| (CONT)  Continuous (On)
|O|O| (INTER)  Intermittent
O (OFF)  Off
°C  Degrees Celsius
°F  Degrees Fahrenheit
N-m  Newton-Meter (N-m x .737 = ft-lb)
ft-lb  Foot-Pound Force (ft-lb x 1.356 = N-m)
DISS  Diameter Index Safety System
OES  Oxequip Suction
NCG  National Compressed Gases (Chemetron)
BOC  British Oxygen Corporation
NPT  National Pipe Thread (USA)
NPTF  National Pipe Thread Female (USA)
MPTS  Multi-Purpose Therapy Stand
I.D.  Inner Diameter
gal.  gallon
PTFE  Polytetrafluoroethylene
NG  Nasogastric
PED  Pediatric
NFPA  National Fire Protection Association
ISO  International Organization for Standardization
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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

The pre-use checkout procedure (Section 4.4 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 such as oxygen and medical air, even momentarily, could injure the patient or operator.

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

The fitting port of the regulator must be occluded when setting the prescribed suction level. This prevents the patient from receiving higher than required suction levels.

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

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

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

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 the patient.

If the flow control valve is rotated fully clockwise, the ISU will not cycle in the intermittent mode. Drainage will cease.

For the Pediatric ISU, it may be possible to set the vacuum limit to zero. If there is no suction present, rotate the set screw counter-clockwise and/or check Section 6 Troubleshooting.

If the screws on the timing valves are turned all the way clockwise, the ISU will not cycle.
1.3 Cautions

Connect the vacuum regulator to the vacuum source only. Connection to positive pressure sources such as oxygen and medical air, even momentarily, could damage the equipment.

Cleaning the gauge may result in damage.

Do not lubricate any internal components of the regulator module.

Do not over-tighten the timing valve stem; the needle portion of the valve may be damaged.

Do not steam autoclave the ISU. Severe impairment to the operation of the regulator will result.

Do not use any Loctite® products to seal the fitting and adapter/probe port threads (or products which contain methacrylate ester as an active ingredient).

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

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

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.

To help prevent aspirate from entering the regulator, wall outlet and pipeline equipment, an overflow safety trap and/or a high flow suction filter should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline system will impair the operation. The use of the overflow safety trap and/or a high flow suction filter will help prevent this and extend the life of the suction equipment.

To prevent stripping 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 recommended, may degrade plastic or rubber components.

Not for field or transport use**

**The categories of Field and Transport Use are specifically defined in ISO 10079-3. “Field” means use at accidents or emergencies outside a hospital. “Transport” means use in ambulances, cares and airplanes. These situations may expose the equipment to uneven support, water, dirt, mechanical shock and temperature extremes. Ohio Medical suction equipment has not been tested to comply with the specific requirements of these categories.

1.4 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.
2/Scope

2.1 North American (ANSI) Vacuum Regulators
Note: Part numbers given are for vacuum regulators without fittings or adapters/probes.

2.2 International (ISO) Vacuum Regulators
Note: Part numbers given are for vacuum regulators without fittings or adapters/probes.

3.1 Description
⚠ WARNING: Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and possible explosion hazard exists in the presence of these agents.
The ISU is a dual purpose vacuum regulator which provides either intermittent or continuous suction. It can be used for NG (intermittent) or pharyngeal/tracheal (continuous) suctioning throughout the hospital.

On the Pediatric ISU, the maximum vacuum limit is factory present to 135 mmHg (18.0 kPa) and the limit may be adjusted between 80 and 150 mmHg (10.7 and 20.0 kPa). The low gauge and the baby icon on the cover distinguish it from the standard ISU.

Each unit contains a regulator module to regulate and adjust suction, a vacuum gauge which indicates suction supplied, a patented Unilogic Module to silently switch suction on and off, and timing valves which select and adjust the length of the on and off cycles.

In use, the vacuum source is connected through the regulator module which functions as an automatic valve. Rotating the suction control knob adjusts the position of the regulator module and selects a predetermined level of suction.

During use, as the flow requirement increases, the valve automatically opens to maintain suction at the preset 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 to automatically maintain the pre-set suction level.

1. Suction Control Knob - Allows easy adjustment of suction to the patient.
2. Mode Selector Knob - Allows quick and easy mode changes.

Note: In the text of this manual, the international graphic symbol for the intermittent mode normally written as: |O|O| will be written as |O|O|.

a. |O|O| (INTER) - Suction is intermittent (cycles on and off) and the suction level can be adjusted with the suction control knob.

When used as an Intermittent Suction Unit, both the “On” and “Off” timing cycles are independently adjustable within a range of 3 to 30 seconds. These are pre-set at the factory at a supply vacuum of 500 mmHg (66.7 kPa) to provide approximately 15 seconds “On” and 8 seconds “Off” for the ISU. If the supply vacuum is different, the timing cycles will vary. Adjustment procedures are outlined in the Operations section of this manual (Section 8.6 Timing Cycle Adjustment).

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

c. | (CONT) - Suction is continuous and can be adjusted with the suction control knob.

3. Vacuum Gauge - The suction level to the patient is displayed during use.
3/Description and Specifications

3.2 Specifications

Gauge: Accuracy: ±5% of full scale deflection

Flow Rates: | (CONT) Mode: 0-80 L/min without fittings at full increase setting depending on supply vacuum and open air flow

|O|O| (INTER): 8 L/min with the suction control knob set to 120 mmHg (16.0 kPa)

Regulated Suction Range: Adult: 0 to 200 mmHg (0 to 26.7 kPa) and up to full wall vacuum Pediatric: 0 to 135 mmHg (0 to 18.0 kPa)

Pre-Set Timing Cycles: On time cycle: 15 seconds ± 3 seconds

Note: The Pre-set timing cycles are set at a supply vacuum of 500 mmHg (66.7 kPa).

Off time cycle: 8 seconds ± 3 seconds

Weight: (Less Fittings) 28 oz (794 grams)

Dimensions: (Less Fittings) Height: 6.6 in (168 mm)

Width: 3.5 in (89 mm)

Depth: 4.8 in (121 mm)

Environmental Specifications

Operating Temperature Range: 40 to 120°F (4 to 49°C)

Storage Temperature Range: 0 to 160°F (-18 to 71°C)

Operating and Storage Relative Humidity: 5 to 95%
4.1 Equipment Set-up

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

⚠ 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.

If the regulator is equipped with an 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. Connect the collection canister or liner’s vacuum port to the regulator’s fitting or overflow safety trap with the appropriate vacuum tubing.

Note: For proper installation of adapters/probes and fittings see appendix (Appendix A-1).

For standard ISU operation, mount the collection canister or liner above the patient.

Connect the collection canister or liner’s vacuum port to the regulator’s fitting port or overflow safety trap with the appropriate suction filter and vacuum tubing.

Hospital supplied suction tubing must be used between the catheter and the collection canister or liner. The recommended minimum inside diameter is 0.25 in (6 mm). Select tubing that is collapse and kink resistant.

An Ohio Medical high flow filter and overflow safety trap should be used between the collection canister or liner and the vacuum regulator to prevent contamination of the regulator, wall outlet and pipeline system.

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

High Flow Suction Filters

Hydrophilic
Pkg of 20 6730-0350-800
Pkg of 200 6730-0351-800

Hydrophobic Filter

Tubing x tubing nipple 1/8” NPT x tubing nipple
Pkg of 3 6730-0570-800 6730-0580-800
Pkg of 10 6730-0571-800 6730-0581-800
Pkg of 50 6730-0572-800 6730-0582-800
4/Operation

4.1.1 Attaching the Overflow Safety Trap (OST)

⚠ CAUTION: To help prevent aspirate from entering the regulator, wall outlet and pipeline system, an overflow safety trap should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline system 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.

**Standard fitting**

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.

**DISS fitting**

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).

4.2 Mode Selection

| O | O | (INTER) - Suction is intermittent (cycles on and off) and the suction level can be adjusted with the suction control knob.

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

| (CONT) - Suction is continuous and can be adjusted with the suction control knob.

4.3 Setting the Suction Level

⚠ WARNING: The fitting port of the regulator must be occluded when setting the prescribed suction level. This prevents the patient from receiving higher than required suction levels.

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

4.4 Pre-use Checkout Procedure

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

Before the vacuum regulator is used, it must be tested for correct operation as outlined below. All tests must be performed with the regulator in its normal (vertical) operating position and with a minimum supply vacuum of 500 mmHg (66.7 kPa).
4/Operation

1. Turn the mode selector knob 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. Unclamp the connective tubing.
5. Turn the mode selector knob to | (CONT).
6. Rotate the suction control knob fully counterclockwise (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 when the tubing is clamped.
10. Turn the mode selector knob to |O|O| (INTER).
11. Clamp the connective tubing.
12. Ensure that the timing cycles are 15 seconds “On” and 8 seconds “Off” both with a tolerance of ± 3 seconds by observing the gauge needle.

Note: The ISU starts in the “Off” cycle.
13. Reduce the suction level to zero and turn the mode selector knob to O (OFF).

4.5 Patient Set-up

1. Make sure the pre-use checkout procedure (Section 4.4 Pre-use Checkout Procedure) has been performed.
2. Clamp the connective tubing and turn the mode selector knob to | (CONT).
3. Set the prescribed suction level.

⚠ WARNING: 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 knob to O (OFF).
5. Attach the patient tubing to the collection canister or liner’s patient port.
6. Turn the mode selector knob to | (CONT) or |O|O| (INTER).

5/Cleaning

5.1 Cleaning

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

5.1.1 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.

5.1.2 Internal Component Cleaning

⚠ CAUTION: Cleaning the gauge may result in damage.
1. 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.
5/Cleaning

5.1.3 Cold Flush Procedure

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 to receive the flush solution. Suction through the vacuum regulator an adequate amount of cold disinfectant to satisfy the infection control requirements of the hospital. Use only approved cleaning/flushing solutions. Make sure those made from concentrates are newly mixed to ensure effectiveness.

Flush both the continuous and intermittent vacuum circuits thoroughly. Adequately aerate both the continuous and intermittent 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.

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

⚠ **WARNING:** Perform the 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 and is not. Body fluids suctioned 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 contamination that contributes to nosocomial infection.
<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Causes</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| A. No gauge indication and no suction in any setting | 1. No supply vacuum  
2. Kinked tube  
3. Poor connection  
4. Blocked wall outlet  
5. Blocked adapter port  
6. Blocked backplate  
7. Loose mounting plate  
8. Bad or missing mounting plate gasket  
9. Regulator module malfunction  
10. Pediatric ISU – Incorrect vacuum limit adjustment  
11. Pediatric ISU – Bad or missing positive pressure relief valves | 1. Correct supply problems  
2. Straighten tube  
3. Check all connections and seals  
4. Unblock outlet  
5. Unblock port  
6. Clean with soap and water and a pipe cleaner  
7. Tighten the 4 mounting screws  
8. Replace/Install gasket  
9. See “Regulator module malfunction” under Problem column in this section of the manual  
10. Reset vacuum limit. (See Section 7.5 Vacuum Limit - Pediatric ISU Only)  
11. Replace/Install positive pressure relief valves |
| B. Regulator module malfunction | 1. O-ring failure or diaphragm rupture  
2. Stem screw loose | 1. Replace rubber components with regulator module replacement kit  
2. Tighten stem screw |
| C. No gauge indication but suction is being delivered | 1. Blocked gauge pressure sensing orifice  
2. Gauge mechanism locked by debris  
3. Gauge mechanism damaged | 1. Unblock orifice  
2. Remove debris  
3. Replace gauge |
| D. Gauge indication but no suction is being delivered | 1. Blocked fitting port  
2. Overflow safety trap shut off  
3. Blocked external filter  
4. Blocked fitting | 1. Unblock port  
2. Reset float/empty overflow safety trap  
3. Replace external filter  
4. Replace fitting |
| E. Suction level cannot be adjusted | 1. Regulator module malfunction | 1. See “Regulator module malfunction” under Problem column in this section of the manual |
| F. Insufficient flow through regulator | 1. Partial blockage in wall supply  
2. Partial blockage in regulator | 1. Confirm wall supply open air flow meets minimum hospital requirements. Unblock if necessary  
2. Perform the Flow Test in Section 8 Service Checkout Procedure of this manual. Clear blockage if necessary |
| G. Inaccurate gauge reading | 1. Damaged gauge | 2. Replace gauge |
## 6/Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Causes</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| **H.** With the fitting port occluded, unable to decrease the suction level and gauge needle does not return to Zero when switched to O (OFF) | 1. Blocked filter and/or orifice  
2. Damaged gauge  
3. Blocked unilogic module filter  
4. Regulator module malfunction | 1. Clear orifice and replace filter  
2. Replace gauge  
3. Replace filter  
4. See “Regulator module malfunction” under Problem column in this section of the manual |
| **I.** Limited suction in any setting and whistling noise from inside the regulator | 1. Selector switch loose or bad selector switch O-rings  
2. Missing internal components | 1. Tighten selector switch and/or replace O-ring  
2. Disassemble regulator and inspect |
| **J.** Suction is delivered in the | (CONT) mode but the | (INTER) will not cycle | 1. Flow control valve blocked or turned full in  
2. Timing valves turned fully in and/or clogged  
3. Unilogic module malfunction/missing  
4. Missing O-ring in selector switch  
5. Blocked backplate | 1. Turn valve counter-clockwise until unit cycles and/or inspect valve seat area  
2. Turn valve counter-clockwise until unit cycles and/or inspect  
3. Replace filters and/or module  
4. Install O-ring  
5. Inspect backplate flow paths and unblock if necessary |
| **K.** Pediatric ISU - Maximum vacuum not limited | 1. Incorrect vacuum limit adjustment | 1. Reset vacuum limit. See Section 7.5 Vacuum Limit - Pediatric ISU Only |
| **L.** Pediatric ISU - Limited suction in any setting and whistling noise from back of regulator | 1. Bad or missing positive pressure relief valves | 1. Replace/Install positive pressure relief valves |
| **M.** Pediatric ISU - Vacuum limit does not remain constant | 1. Loctite on set screw is breaking down | 1. Replace 2.42 Loctite on set screw. See Section 7.5 Vacuum Limit - Pediatric ISU Only |
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: 500 mmHg (66.7 kPa) minimum & 50 L/min open air flow minimum
- Supply vacuum regulator with gauge, 760 mmHg (101.3 kPa) full scale
- Low vacuum calibration gauge, 225 mmHg (30.0 kPa) full scale (Ohio Medical P/N 6700-0352-800)
- 50 L/min flowmeter (Ohio Medical P/N 6700-0355-800)
- 10 L/min flowmeter (Ohio Medical P/N 6700-0354-800)
- Phillips head screwdriver, No. 2
- Flat head screwdriver, 1/4 inch
- Open end adjustable wrench
- Ball hex key wrench, 3/16 inch
- Open end wrench, 11/16 inch
- Pipe cleaner
- Wooden toothpick (O-ring remover)
- Tweezers (filter remover)
- Dow Corning® 111 grease (Ohio Medical P/N 6700-0074-200)
- Tubing clamp
- 1/2 gallon reservoir
- Bubble leak tester
- Stop watch
- Hex key wrench, 1/16 inch (Pediatric ISU only)
- 242 Loctite (Pediatric ISU only)

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

⚠ 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 10.1 Illustrated Parts

1. Remove all fittings from the regulator and ensure that the mode selector knob is in the O (OFF) position.
2. Remove the three cover screws from the back of the unit.
3. Rotate the suction control knob counter-clockwise (decrease) until it is free from the regulator module. Carefully pull the cover and knob assembly off of the backplate.
4. To remove the gauge assembly, grasp the dial mounting bracket and pull straight out. The snap-fit lens cover can also be removed (if applicable) for replacement. Replace gauge O-rings if required.
5. To remove the regulator module, grasp and pull it from the backplate.

⚠ WARNING: 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 the patient.

Note: To disassemble the regulator module, refer to Section 7.3 Regulator Module.

6. Remove the unilogic module by carefully pulling the module away from the backplate. This releases the tubing connections. Replace beige and green filters and silastic tubes if required.

Pull down plastic tab with right index finger while holding gauge frame with left hand

Snap-fit Lens Removal
7. Remove the timing valves by pulling the valve stem out of the backplate. Replace the filters if required.

   **Note:** To disassemble the timing valves, refer to Section 7.4 Timing Valves.

8. If the mode selector switch needs service, carefully unscrew the center retaining screw while holding the main valve body. Remove the washers, detent plate, ball bearings, and valve body. Replace O-rings if required.

9. Remove the gauge bleed hole filter from the backplate. Replace if required.

10. Remove the flow control valve by turning counterclockwise until it is out of the backplate.

11. For the Adult ISU - Remove the ISU mounting plate by removing the four screws and pulling the plate and gasket from the backplate. Replace gasket if required.

12. For the Pediatric ISU
   a. Remove the Pediatric ISU mounting plate by removing the four screws and pulling the plate and gasket from the backplate.
   b. Replace gasket if required. Use Pediatric ISU gasket ONLY (6700-0221-500)
   c. To remove valves, grasp top of valve and pull. Replace positive pressure relief valves if required.
   d. Under the suction control knob there is a brass stud and a retaining ring. DO NOT remove these parts from the cover assembly.

### 7.2.2 Assembly

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

1. Lubricate all O-rings and the gasket with a small amount of Dow Corning® 111 grease before assembly.

2. For the Adult ISU - Place the lubricated mounting plate gasket onto the holes and install the mounting plate onto the backplate. Ensure the protruding posts on the mounting plate align in to the backplate properly.

3. For the Pediatric ISU - Install new positive pressure relief valves by pulling tail of valve through the small hole on the mounting plate. When installed, the three other vent holes should be covered. After valve is installed, clip the tail. Place the lubricated mounting plate gasket onto the backplate. Ensure the protruding posts on the mounting plate align into the backplate properly.

4. Install the flow control valve into its proper location. Use the proper tool to rotate the valve clockwise approximately 3 full turns, taking extra care to ensure that the threads are engaged properly.

5. Place the gauge bleed hole filter into its proper location. Push until it bottoms on the backplate.

6. **Mode Selector Switch Assembly**
   a. Place the four selector switch O-rings into their proper location on the backplate.
   b. Install the main valve body on the backplate post with the protruding ear at the 3 o’clock position. Ensure the valve body seats on the four O-rings.
   c. Place the four ball bearings on top of the valve body. Place the detent plate on top of the four ball bearings (smooth side down). Place the spiral spring washer on top of the detent plate. Place the flat washer on top of the spiral spring washer.
   d. Install the screw through the washer and into the backplate post. Tighten the screw.

7. Grasp the main valve body and rotate the switch in all three positions. Ensure that the protruding ear is near the 3 o’clock position after testing the switch.

8. Install the timing valves into their proper locations and push fully in so that the O-rings seats in the backplate.

9. Install the Unilogic Module by aligning the silastic tubes with the ports on the backplate and push fully in.

10. Install the regulator module into its proper location. Rotate the module so that the protruding ears are at the 5 o’clock and 11 o’clock positions.

11. Install the snap-fit lens by placing one of the retaining tabs over the edge of the gauge face, and then pressing lightly until the other tab snaps onto the gauge face. Rotate the lens to confirm proper installation. If the lens is not the snap-fit type, simply place the lens onto the gauge ensuring it rotates easily and is resting properly.

12. Install the gauge assembly into its proper location so that the O-rings seat fully. Ensure the gauge is properly aligned. For the Pediatric ISU Only - The suction control knob is NOT lockable.
13. Place and align the cover and knob assembly onto the backplate with the mode selector knob in the O (OFF) position. Rotate the suction control knob clockwise (increase) until the cover is flush with the backplate.

14. Install the three cover screws.

15. Install all fittings.

Note: For proper installation of adapters/probes and fittings see Appendix A-1.

7.3 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.

### 7.3.1 Disassembly

1. Remove the cap screws (2) and remove the cap.
2. Remove the O-rings (2).
3. Observe the position of the diaphragm convolution to aid in assembly.
4. Withdraw the diaphragm/stem assembly from the housing.
5. Remove the spring.
6. Grasp the stem with your fingers and unscrew the stem screw.
7. Remove the retainer, diaphragm and piston from the stem.

---

**Pediatric ISU Regulator Module**

Note: The pediatric regulator cap is different from that of the standards ISU - shape and material (aluminum). Only use the cap pictured above on the Pediatric ISU

---

**Parts and Descriptions**

1. O-ring, Stem
2. O-ring
3. Housing
4. Stem
5. Spring
6. Piston
7. Diaphragm
8. Retainer
9. Stem Screw
10. Cap
11. Cap Screw
7/Service - Disassembly and Assembly

7.3.2 Assembly
1. Return the diaphragm to its original position (convoluted), with the molded number facing the retainer.
2. Assemble the diaphragm onto the retainer by lining up the center holes as shown in the diagram.
3. Insert the piston into the diaphragm and ensure that the retainer mates with the recess in the piston.
4. Insert the stem through the piston.
5. Holding the retainer/diaphragm/piston/stem as an assembly with your fingers, insert the stem screw and tighten.
6. Place the spring in the housing.
7. Insert retainer/diaphragm/piston/stem assembly through the spring and into the cavity in the housing. Fit the diaphragm bead into the groove in the housing.
8. Install the cap and the two cap screws.
9. Apply a small amount of Dow Corning® 111 grease to the O-rings only.
10. Install O-rings onto the stem and housing.

7.4 Timing Valves

⚠ CAUTION: Do not over-tighten the timing valve stem. Needle portion of the valve may be damaged.

7.4.1 Disassembly
1. Remove the O-rings from the valve base and replace if required.
2. Rotate the valve stem counter-clockwise until it is removed from the valve base.
3. Inspect the needle and O-ring. Replace O-ring if required.

7.4.2 Assembly
1. Install all O-rings and apply a small amount of Dow Corning® 111 grease to the O-rings.
2. Carefully insert the valve stem into the valve base and rotate clockwise approximately 5 full turns. The final valve stem position will be set in Section 8 Service Checkout Procedure.

7.5 Vacuum Limit - Pediatric ISU Only

This step is only necessary if the vacuum limit is not holding steady over time.

1. Remove the cover by removing the three cover screws from the back of the unit.
2. Remove the screw, washer, and black plastic cam from the suction control knob.
3. Place 1/16” hex key wrench through hole in stud to engage with the internal adjusting set screw.
4. Hold suction control knob in place and turn the set screw clockwise to remove it out the back. Note: Set screw can not be removed by turning it counter-clockwise.
5. Place a small drop of 242 Loctite® on the threads near the head end of the set screw.
6. Assemble set screw back into the stud. Insert the hex key wrench through knob and stud and engage head end of set screw. From knob site, turn hex key wrench counter-clockwise to start threads. Continue to assemble by turning counter-clockwise until the end of the set screw is only protruding a small amount.
7. Assemble screw, washer, and black plastic cam on suction control knob.

8. Assemble cover onto unit. See Section 7.2.2 Assembly, Step 13.


⚠ WARNING: 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 the patient.

Important: This entire procedure must be performed in numerical order.

8.1 Set-up

1. Verify that a minimum of 500 mmHg (66.7 kPa) vacuum exists at the supply vacuum gauge.

2. The supply open flow must be 50 L/min minimum.

8.2 Leak Test - Supply Side

1. Connect the supply vacuum tubing to port “A” of the bubble leak tester.

2. Connect port “B” of the bubble leak tester to the regulator adapter/probe port.

3. Set the supply vacuum to 500 mmHg ± 10 mmHg (66.7 kPa ± 1.3 kPa) on the supply vacuum gauge.

4. Turn the mode selector knob to O (OFF). Allow the fitting port to be open to air.

5. Wait 5 seconds.

6. No more than 5 bubbles should appear in the bubble leak tester for the next 10 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 adapter/probe port of the vacuum regulator.
8/Service Check Out Procedure

8.3 Flow Test

1. Remove the bubble leak tester from the supply vacuum connection and connect the supply vacuum directly to the regulator adapter port.
2. Set the supply vacuum to 500 mmHg ± 10 mmHg (66.7 kPa ± 1.3 kPa) on the supply vacuum gauge.

8.3.1 Continuous Mode Flow Test

1. Connect the regulator fitting port to the 50 L/min flowmeter.
2. Turn the mode selector knob to | (CONT).
3. Rotate the suction control knob fully clockwise (increase).
4. Verify that the flow rate exceeds:
   - Adult ISU: 40 L/min
   - Pediatric ISU: 25 L/min

8.3.2 Intermittent Mode Flow Test

1. Pull the nameplate wrench from the front of the regulator to access the flow control valve.
2. Occlude the regulator fitting port.
3. Turn the mode selector knob to | (CONT).
4. Set 120 mmHg (16.0 kPa) on the regulator gauge.
5. Turn the mode selector knob to O (OFF).
6. Connect the regulator fitting port to the 10 L/min flowmeter.
7. Turn the mode selector knob to |O|O| (INTER).
8. Locate the flow control valve in the regulator.
9. The flow rate must be adjusted during the “On” cycle of the intermittent mode. Using the proper tool, either a Phillips head screwdriver or a ball hex key wrench, adjust the flow control valve to produce a flow rate of 8 L/min. To increase the flow rate, turn the valve counter-clockwise. To decrease the flow rate, turn the valve clockwise.
**8.4 Gauge Test**

**Note:** All Ohio Medical gauges are supplied with an accuracy of ±5% of full scale deflection throughout their range. The ISU vacuum gauges have an accuracy of:

<table>
<thead>
<tr>
<th>Gauge Range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-200 mmHg (0-26.7 kPa)</td>
<td>± 10 mmHg (± 1.3 kPa)</td>
</tr>
<tr>
<td>0-760 mmHg (0-101.3 kPa)</td>
<td>± 38 mmHg (± 5.1 kPa)</td>
</tr>
<tr>
<td>0-160 mmHg (0-21.3 kPa)</td>
<td>± 8 mmHg (± 1.1 kPa)</td>
</tr>
</tbody>
</table>

**Note:** All gauge needles should return to 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% of full scale deflection or better.

1. Connect the regulator fitting port to the low vacuum calibration gauge with tubing.
2. Turn the mode selector knob to | (CONT).
3. Ensure that the regulator gauge is in agreement with the low vacuum calibration gauge within the tolerances listed above. Recommended test points are:
   - Adult ISU: 40, 80, 140 and 200 mmHg (5.3, 10.7, 18.7 and 26.7 kPa)
   - Pediatric ISU: 40, 80 and 120 mmHg (5.3, 10.7, and 16.0 kPa)
4. Adult ISU Only - Rotate the suction control knob fully clockwise (increase) and verify the gauge’s reading is in the FULL VAC range.
5. Rotate the suction control knob fully counter-clockwise (decrease) and verify the gauge’s reading decreases to zero.

**8.5 Regulation Test**

1. Disconnect the low vacuum calibration gauge from the regulator fitting port.
2. Occlude the fitting port.
3. Set 90 mmHg (12.0 kPa) on the regulator gauge.
4. Open and close the fitting port several times.
5. Check that the regulator gauge reads between:
   - Adult ISU: 80 mmHg (10.7 kPa) and 100 mmHg (13.3 kPa) when the regulator fitting port is occluded.
   - Pediatric ISU: 82 mmHg (10.9 kPa) and 98 mmHg (13.1 kPa) when the regulator fitting port is occluded.

**8.6 Timing Cycle Adjustment**

⚠ **WARNING:** If the screws on the timing valves are turned all the way clockwise, the ISU and the Pediatric ISU will not cycle.

**Factory Settings:**

- “On” Cycle: 15 seconds ± 3 seconds
- “Off” Cycle: 8 seconds ± 3 seconds

To set the timing cycles, perform the following procedure.

1. Occlude the fitting port.
2. Turn the selector mode knob to | (CONT).
3. Set 120 mmHg (16.0 kPa) on the regulator gauge.
4. Turn the mode selector knob to |O|O| (INTER) with the fitting port still occluded.
5. Wait 20 seconds.
6. If the regulator does not cycle “On,” use a flat-head screwdriver to rotate the “Off” timing valve stem counter-clockwise until the regulator cycles “On.”
7. Wait 20 seconds.
8. If the regulator does not cycle “Off,” use a flat-head screwdriver to rotate the “On” timing valve stem counter-clockwise until the regulator cycles “Off.”
9. Once the regulator has completed an “On” and “Off” cycle, fine tune each cycle to the desired time by adjusting the corresponding valve. To increase the time, turn the timing valve stem clockwise. To decrease the time, turn the timing valve stem counter-clockwise.
8/Service Checkout Procedure

8.7 Vacuum Build-up/Bleed-down Test - Intermittent Mode

1. Connect the regulator fitting port to the 1/2 gallon reservoir.

2. During the “On” cycle, check that the suction increases to the preset 120 mmHg (16.0 kPa) on the regulator gauge in 5 seconds or less.

3. During the “Off” cycle, check that the suction decreases to zero on the regulator gauge (zero stop pin) in 5 seconds or less.

4. If the regulator fails either of the build-up or bleed-down tests, replace the regulator module.

8.8 Bleed Test

1. Turn the mode selector knob to | (CONT).

2. Occlude the regulator fitting port and set the vacuum level to 120 mmHg (16.0 kPa).

3. Turn the mode selector knob to O (OFF) and observe the gauge needle. It must return to zero within 10 seconds.

8.9 Leak Test - Patient Side

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

2. Connect the regulator fitting port tubing to port “A” of the bubble leak tester.

3. Rotate the suction control knob fully counter-clockwise (decrease).

4. Turn the mode selector knob to | (CONT).

5. Wait 5 seconds.

6. No bubbles should appear in the bubble leak tester for the next 10 seconds.

8.10 Vacuum Limit Adjustment - Pediatric ISU Only

⚠ WARNING: It may be possible to set the vacuum limit to zero. If there is no suction present, rotate set screw counter-clockwise and/or check Section 6 Troubleshooting.

To set the vacuum limit, perform the following procedure.

1. Occlude the regulator fitting port.

2. Remove the screw, washer and black plastic cam from the suction control knob.

3. Turn the mode selector knob to | (CONT).

4. Turn suction control knob until desired vacuum limit is reached. Factory set to 135 mmHg ± 10 mmHg (18.0 kPa ± 1.3 kPa).

Note: Internal adjusting set screw may need to be rotated counter-clockwise to reach desired vacuum limit; See Step 6.

5. Place 1/16” hex key wrench through hole in stud to engage with set screw.

6. Hold suction control knob in place and tighten set screw (clockwise) until the end of it bottoms out on the inside of the cap bore.

7. Turn suction control knob counter-clockwise and then back to the vacuum limit to test the limit setting.

8. Assemble screw, washer and black plastic cam on suction control knob.

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8/Service Checkout Procedure

Bubble Leak Test - Patient Side

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6700-0082-000 (Rev. 7) 08/2020
9.1 General Maintenance of Suction Equipment

⚠ **WARNING:** The pre-use checkout procedure (Section 4.4 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:** Clean and disinfect all suction equipment if contaminated before disassembly, to ensure service personnel are not exposed to hazardous contamination.

Protection of the vacuum piping system is as important as maintenance of the suction equipment. The use of collection canister 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. 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 canister for correct operation.
7. Perform the pre-use checkout procedure (Section 8 Service Checkout Procedure).

9.2 Recommended Maintenance

In addition to the Pre-use Checkout Procedure, the following periodic maintenance should be performed.

1. Periodically inspect the overall condition of the vacuum regulator. Test gauge accuracy (Section 8.4 Gauge Test) and perform the pre-use checkout procedure. If the regulator does not pass, refer to troubleshooting (Section 6 Troubleshooting).
2. Determine a maintenance schedule based on data from your periodic inspections. Following the guidelines below.

<table>
<thead>
<tr>
<th>Item</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform Service Checkout Procedure</td>
<td>If the regulator does not pass, refer to troubleshooting (Section 6 Troubleshooting). Repair as needed.</td>
</tr>
<tr>
<td>Check elastomeric parts, O-rings, gaskets, diaphragms, positive pressure safety relief valves (Pediatric ISU ONLY), internal filters.</td>
<td>Cleaning, lubrication and replacement interval depends on hours of usage and environmental conditions. Replace and repair as needed.</td>
</tr>
</tbody>
</table>
9.3 Repair Policy

⚠️ WARNING: Clean and disinfect all multiple use suction equipment before shipment to ensure transportation personnel and/or service personnel are not exposed to any hazardous contamination.

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

⚠️ CAUTION: 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 it is functioning properly and complies with the manufacturer’s 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. Clean and disinfect the vacuum regulator.
2. Package the vacuum regulator securely for protection, preferably in the original container.
3. Include a letter describing in detail any difficulties experienced with the vacuum regulator. Include the person, title, and telephone number to contact for functional questions.
4. Include a purchase order to cover repair of a regulator not under warranty.
5. 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

In other locations contact your nearest Ohio Medical office or authorized Ohio Medical distributor.
### 10.1 Illustrated Parts

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
<th>Qty/Pak</th>
<th>Multi-Paks</th>
<th>Kits*</th>
</tr>
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<tbody>
<tr>
<td>1. Gauge Assy. (Includes O-rings and Lens)</td>
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<td>North American Std, 0-200 mmHg</td>
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<td>0211-5867-300</td>
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<td>International Std, ccw, 0-200 mmHg</td>
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<td>2. Gauge Lens</td>
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<td>3. O-ring, 2-012 Buna-N</td>
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<td>4. Screw</td>
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<td>5. Retaining Washer</td>
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<td>6. Spiral Spring Washer</td>
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<td>7. Detent Plate</td>
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<td>8. Ball</td>
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<td>9. Switch Main Valve Body</td>
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<td>10. O-ring, 2-010 Buna-N</td>
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<td>13. Screw, 4-40, Ph. Hd</td>
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<td>14. Diaphragm</td>
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<td>15. O-ring, 2-016 Buna-N</td>
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<td>17. Gauge Filter</td>
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<td>18. Flow Control Valve</td>
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<td>19. O-ring, 2-011 Buna-N</td>
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<td>23. Filter</td>
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<td>26. Filter, Beige</td>
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<td>27. Tube</td>
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<td>28A. Backplate Assy. with Mount Plate</td>
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<td>29. Cover Screw</td>
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<td>30. Nameplate Wrench</td>
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<td>34. Mounting Plate, Std ISU</td>
<td>6700-0053-400</td>
<td>4</td>
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<tr>
<td>Standard Model</td>
<td>6700-0252-400</td>
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<tr>
<td>Pediatric Model (order item 3B)</td>
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<tr>
<td>35. Gasket</td>
<td>6700-0030-500</td>
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<td>Standard Model</td>
<td>6700-0221-500</td>
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<tr>
<td>Pediatric Model (order item 3B)</td>
<td>6700-0151-400</td>
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<tr>
<td>36. Screw</td>
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<td>37. Positive Pressure Relief Valves</td>
<td>6700-0687-850</td>
<td>4</td>
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<td>(Pediatric ISU Only)</td>
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<td>38. Pediatric Mounting Plate</td>
<td>6700-0689-850</td>
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<tr>
<td>Assembly Only</td>
<td>6700-0199-700</td>
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<td>39. Service Manual</td>
<td></td>
<td>2</td>
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</table>

*Kits contain the noted quantities of items in the corresponding rows.
10/Ordering Information

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
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<tbody>
<tr>
<td>1. Mounting Plate, ISU</td>
<td>6700-0053-400</td>
</tr>
<tr>
<td>2. Gasket</td>
<td>6700-0030-500</td>
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<tr>
<td>3. Serial Number Label</td>
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<tr>
<td>4. Screw (4 or 5)</td>
<td>6700-0151-400</td>
</tr>
<tr>
<td>10. Backplate Assembly</td>
<td>6700-0043-500</td>
</tr>
</tbody>
</table>

(*)These parts are available as service kits. See section 10.2.

10.2 Service Kits

1. Regulator Module Replacement Kit ............................................. 6700-0030-700
   Includes the following parts:
   O-ring, Stem
   O-ring
   Diaphragm
   Stem Screw
   Cap Screw (2)
   These parts are available only in kit form. If other parts are needed for replacement, the entire Module must be ordered. (6700-1225-800)

2. Complete Filter and O-ring Replacement Kit ......................... 0221-5887-300
   Includes all O-rings (16) and Filters (5) for servicing the regulator

3. Complete O-ring Replacement Kit ........................................... 0210-0474-870
   Includes all O-rings (16) for servicing the regulator

4. Complete Filter Replacement Kit ........................................... 0221-5884-870
   Includes all Filters (5) for servicing the regulator

5. Mode Selector Knob Replacement Kit ................................... 0221-5897-300
   Includes the following parts:
   Mode Selector Knob
   Extension
   Hardware

6. Suction Control Knob Replacement Kit .................................. 0221-5898-300
   Includes the following parts:
   Suction Control Knob
   Threaded Stud
   Hardware

7a. ISU Backplate Replacement Kit, North American ................. 6700-0002-700
   Includes the following parts:
   Backplate Assembly
   Gasket
   ISU Mounting Plate
   Screw (4)

7b. ISU Backplate Replacement Kit, International .................. 6700-0003-700
   Includes the following parts:
   Backplate Assembly
   Gasket
   ISU Mounting Plate
   Screw (4)
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 1/8-27 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 Teflon® (PTFE) tape or one of the following lubricants:

Dow Corning® 111 (Ohio Medical P/N 6700-0074-200)
Ball Vac Kote® (27951M) (Ohio Medical P/N 0220-0091-300)

⚠ CAUTION: Do not use any Loctite® products to seal the threads (or products 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.