

User Manual



*Model 3930
Vacuum Assisted Venous
Drainage Controller w/
WAGD Suction Flowmeter*

BOEHRINGER®

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Phoenixville, PA 19460
800-642-4945**



WELCOME

Congratulations on your purchase of the Boehringer VAVD Regulator. We consider our regulators to be the best in the world. We are confident it will provide you with reliable, trouble-free, safe patient care and low cost of operation. This product is intended for use by clinicians properly trained in the use of vacuum assisted venous drainage for cardiopulmonary bypass. The product is intended for use on the order of a physician. Please read these instructions carefully.

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Definition of Terms and Symbology

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|---|---|
| VACUUM | Air or other gases at a sub atmospheric pressure typically expressed as mmHg. |
| SUCTION | A use of vacuum that causes a fluid or solid to be drawn into an interior space or to adhere to a surface because of the difference between the external and internal pressures. |
|  | Alerts the user to the presence important operating and maintenance instructions in the literature accompanying the device. |
| WARNING | Alerts user to actions or conditions that could result in injury to user or patient. |
| CAUTION | Alerts user to actions or conditions that can cause damage to the device <u>or</u> may result in substandard performance of the device or system. |
| IMPORTANT | Indicates an action that is emphasized to ensure proper operation of equipment. |
| OFF | Supply suction is off and patient circuit is vented to atmospheric pressure. |
| REG | Supply suction is on and regulated output is controlled to prescribed setting. |
|  | <p>Lo Spike: Accuracy of regulation depends primarily on the ability to provide a consistent level of vacuum under changing flow conditions.</p> <p>Involuntary pneumatic biopsy, or tissue damage, can occur when high levels of vacuum are applied to delicate tissue. With a Boehringer regulator, you can depend on very low “spike” compared to our competitor’s models.</p> <p>“Spike” is the variation in indicated suction as flow in the collection circuit changes from a free-flowing condition to an occluded condition. We measure spike as the change in indicated suction from full flow to a no flow condition using a typical collection circuit with a 14 French catheter. To test, set the regulator to 50 mmHg flowing, and then allow occlude the 14Fr catheter. The change in the indicated suction level is “Spike”.</p> <p>Boehringer regulators are checked on the assembly line to meet a specification of less than 10% of the indicated setting, for example 5mmHg spike at a 50 mmHg setting.</p> <p>An evaluation of a regulator’s spike allows one to determine whether the device is truly “regulating”. A safe and reliable regulator should regulate to its set position regardless of variable flow conditions.</p> |
| PARALLAX | Inaccuracy caused by observational position of an indicating element (pointer) to a reference element (scale). |

Indications for Use

This product is intended for use by or on the order of a physician. It is to be used by individuals who are properly trained in the use of Vacuum Assisted Venous Drainage during Cardiopulmonary Bypass.

The Boehringer VAVD Controller was designed to provide accurate control of wall suction for use in vacuum assisted venous drainage and the removal of waste anesthetic gases in cardiac surgery. The VAVD provides a redundant safety device that vents positive pressure and excess negative pressure.

Contraindications

This device is designed and sold for use only as indicated

Safety Information

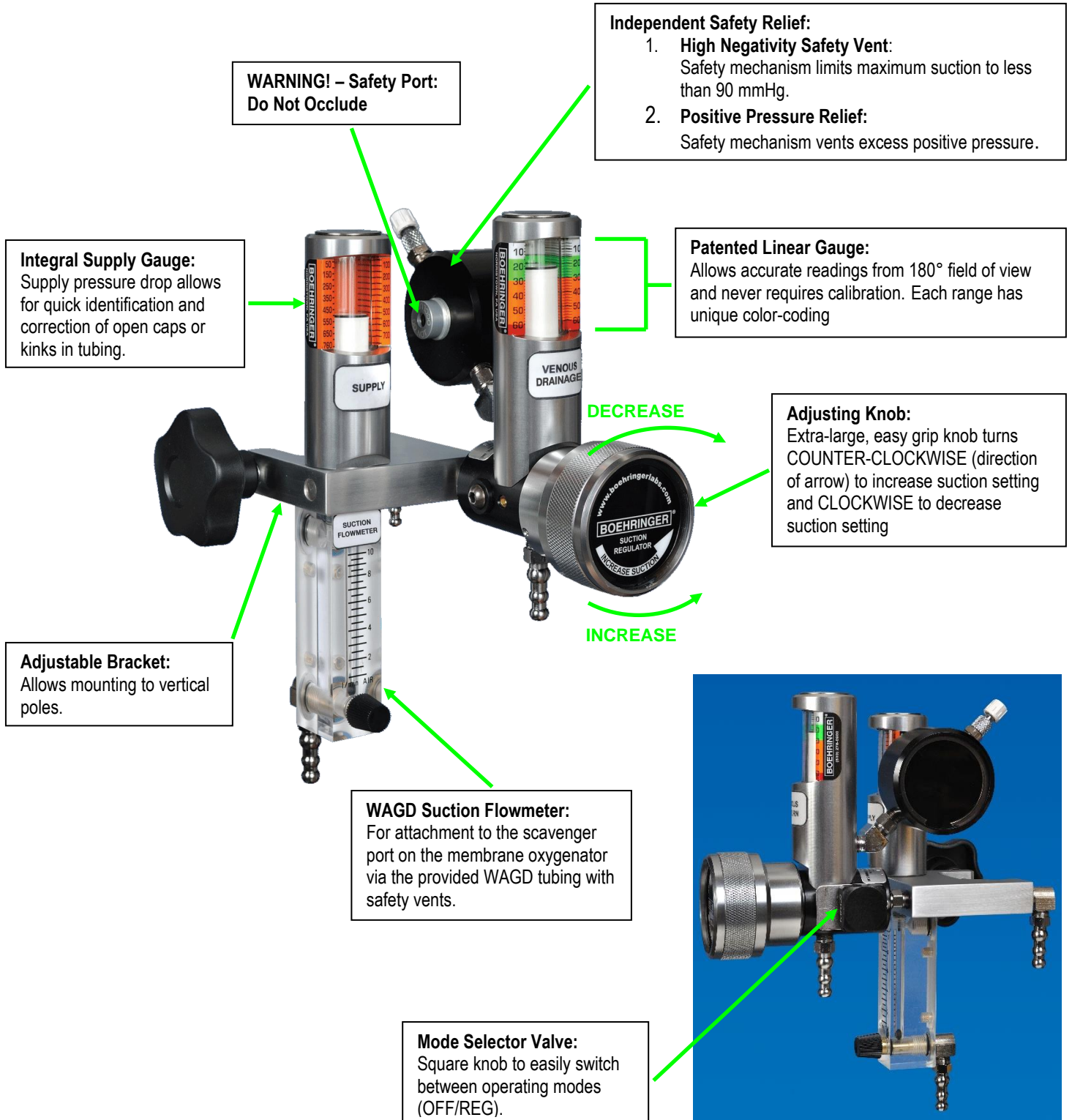
WARNING!

- This product is intended for use by or on the order of a physician. It is to be used by individuals who are properly trained in medical suctioning procedures. Please read these instructions carefully.
- A High Flow Bubble Barb fitting is provided to connect the regulator to a central suction source. Braid reinforced tubing must be used to preclude the possibility of suction tubing collapse during extended periods of use. The hose supplying suction to the regulator should have a vertical orientation to reduce the possibility of kinking over time. Any deformation of this tubing may be indicative of a reduction in flow to the suction regulator and accompanying patient circuit.
- Always verify the regulator is attached to an appropriate source of suction, and that suction is present, before attaching a patient collection circuit. This can be verified by turning the control valve to REG and adjusting the control knob to increase suction. The presence of suction can be audibly heard from at the patient port of the regulator.
- Suction regulators must only be attached to vacuum systems. Do not attach to compressed air, nitrogen, or oxygen sources.
- Do not cover, obstruct, or occlude the inlet of the interrupter where it is labeled 'Do Not Occlude Vent'. Do not attempt to calibrate this safety device. Return to the factory for appropriate service.
- When used in conjunction with a venous return reservoir for cardiac bypass surgery: ensure that all air detection and control devices are in proper working order, have all field suction pumps clear and operating and monitor and control the fluid levels in the reservoir to prescribed limits.
- When used for vacuum assisted venous drainage for cardiac surgery, ensure proper placement of cannulae and verify that venous drainage is properly occurring.
- Suction catheters, collection canisters and suction tubing must be carefully evaluated and selected to ensure adequate function for the specific clinical environment and intended field of use.
- Always verify regulator operation (Spike, see page 4 for details) before use on a patient. Verify operation by establishing the desired vacuum level with the collection circuit and suction catheter attached to the regulator. Occlude the suction catheter and note that the indicated vacuum does not rise by more than 10% of the original setting.
- The Suction Flowmeter of the 3930 uses the facility's medical-surgical vacuum source for Waste Anesthetic Gas Disposal (WAGD). As such, flammable anesthetics or other flammable vapors are required to be diluted below the lower flammable limit prior to disposal into the medical-surgical vacuum system per NFPA 99-2018 (5.1.3.8)



Operation

FEATURES



THEORY OF OPERATION

The VAVD regulator incorporates a 2-way selector valve for selecting no suction or a preset level of suction.

REG Mode: With the vacuum regulator attached to the vacuum system and a vacuum capable venous reservoir attached to the vacuum regulator, rotating the control valve on the side of the vacuum regulator will place the vacuum regulator in the **REG** mode. Vacuum can now be regulated from 15-60 mmHg or shut off by turning the knob all the way clockwise.

With the control valve in the **REG** position, wall vacuum may be controlled to a specific level by turning the large adjusting knob in the direction indicated. A spring opposed diaphragm assembly precisely controls the level of suction provided at the lower inlet port of the regulator. This assembly senses changes in the venous return circuit and makes appropriate adjustments to maintain the vacuum level that has been selected. Vacuum level is adjusted by turning the large knob in the direction indicated. Regulated settings are verified with the large, easy to read gauge.

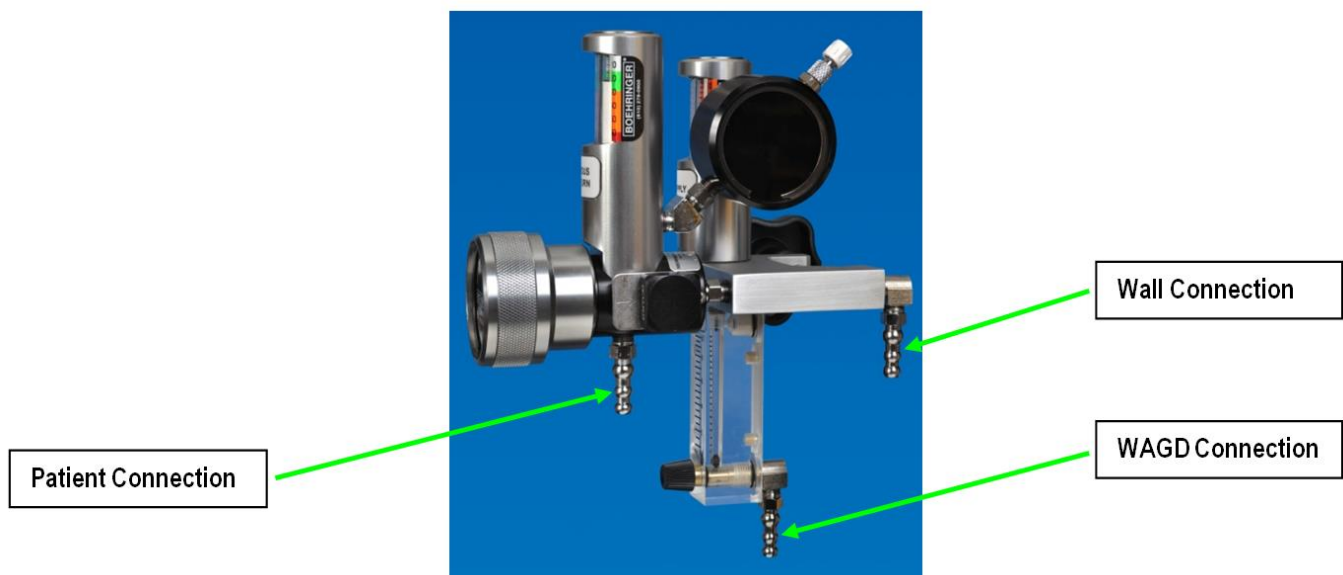
OFF Mode: When the vacuum regulator is on the OFF position, the vacuum return circuit reverts to atmospheric pressure.

INSTALLATION

The model 3930 regulator is supplied with a high flow bubble barb for attachment to wall suction. Only braided reinforced tubing suitable for suction service should be used when connecting this to a central suction supply. Inappropriate tubing could lead to a reduction in flow and compromise patient safety. The tubing should exit the fitting in a downward vertical orientation to minimize the possibility of kinking the supply tubing over time.

Connect the externally reinforced clear tubing to the WAGD connection (below). This line is meant to conduct waste gases without applying negative pressure to the blood or gas inlet of the oxygenator.

The patient connection must be connected to an appropriate cardiomy reservoir, do not draw patient materials directly into this line, the use of a disposable vapor trap between the suction regulator and the cardiomy reservoir is recommended.

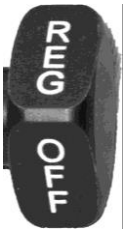


PRE-USE CHECK

1. With the selector valve of the unit in the OFF position and the valve on the suction flowmeter fully closed (clockwise), verify the supply gauge reads > 500 mmHg. If a minimum of 500 mmHg is not available, check the incoming supply tubing, or check the suction inlet to confirm it is compliant with the NFPA 99 standard.
2. Adjust the WAGD suction flowmeter all of the way open (counterclockwise) verify the flowmeter registers the flow and that audible suction can be heard. Ensure the supply gauge registers > 400 mmHg with the suction flowmeter all of the way open. If a minimum of 400 mmHg is not maintained, VAVD may not be effectively applied, resulting in patient risk. Check the incoming supply tubing, or check the suction inlet to confirm it is compliant with the NFPA 99 standard.
3. Connect the VAVD Controller to the cardiotomy reservoir. Turn the control valve to ON and adjust the output to 20 mmHg. Ensure suction can be audibly heard and the unit maintains the 20 mmHg set point.

If the unit is unable to pass the pre-use criteria, please contact Customer Service 800-642-4945 to have the unit returned for needed service / calibration.

MODE SELECTION



OFF: With control valve in the OFF position, suction is off and the collection circuit is returned to atmospheric pressure by an internal vent port, a special feature of the Boehringer design. Any additional positive pressure or negative pressure in excess of 100mmHg will be vented from the patient collection circuit.

REG: With control valve in the REG position, wall suction may be controlled to a specific level by turning the large adjusting knob in the direction indicated. A spring opposed diaphragm assembly precisely controls the level of suction provided at the lower port of the Regulator within the range of the gauge. This assembly "senses" changes in the patient collection circuit and makes appropriate adjustments to maintain the suction level that has been selected. Regulated settings are verified by the large, easy to read gauge.

CAUTION! Use the control knob to discontinue vacuum. The control knob has a dedicated 5mm vent which not only discontinues vacuum, but also rapidly vents the collection circuit. Applying excessive force to the adjustment knob in an attempt to shut off the unit may damage internal components.

CLINICAL USE

Follow venous reservoir manufacturer's instructions regarding proper set up and use.

Ensure that all air detection and control devices are in proper working order. It is recommended that over pressurization and vacuum relief valves are used in conjunction with the venous reservoir. It is recommended that the pressure inside the venous reservoir be monitored by the clinician.

Attach the externally reinforced clear tubing (WAGD Tube Assembly) to the vent port on the membrane oxygenator. The tube is bidirectional and either end may be connected to the vent port as well as the WAGD connection on Suction Flowmeter. Do not block or occlude the vent holes that are at both ends of the tube. Do not modify the tubing in any way. Follow membrane oxygenator manufacturer's recommendation for suction flow settings.

Connect the reservoir connection port to the venous reservoir. It is highly recommended to use a disposable vapor trap between the vacuum regulator and the venous reservoir

MAINTENANCE

Your VAVD Controller has been designed with the highest quality materials and to the strictest production tolerances. Unlike common hospital suction regulators, the VAVD controller has precision low suction output and redundant safety features to limit excess negative pressure and positive pressure. Given the critical nature of the clinical interventions for which the VAVD Controller is employed, and the inherent risk involved in applying unregulated suction during these procedures, only factory service may be performed on this unit.

Factory calibration is recommended - -

- Any time contaminated or biological fluid has entered the VAVD Controller.
- Any time there is physical damage noted to VAVD Controller.
- Any time the VAVD Controller fails a pre-use test.

A biennial inspection is recommended every 24 months. This may be performed at the factory or may be performed locally using the techniques below. This inspection ensures the excess vacuum relief and positive pressure relief circuits are functioning within specification.

Biennial Inspection Equipment List and Requirements:

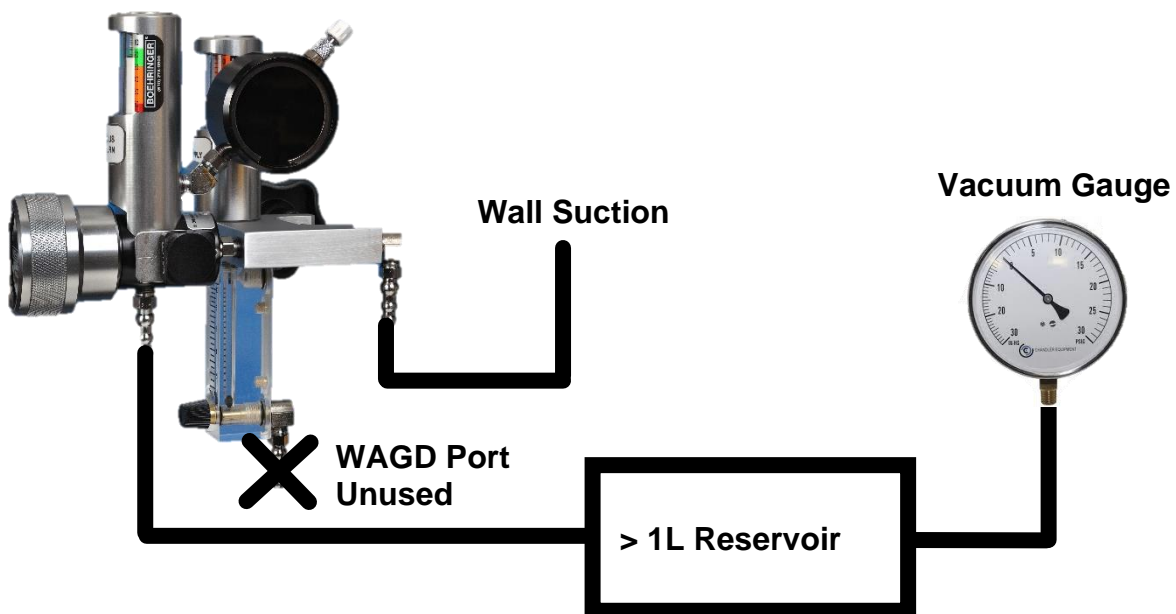
- **Flowmeter:** An adjustable ball flowmeter with a range of at least 0-10 LPM must be used in the test circuit (Ex. Dwyer® VISI-FLOAT® Model VFA-24-SSV, Dwyer® RATE-MASTER® Model RMA-21-SSV, etc.).
- **Vacuum Gauge:** The range maximum must be > 100 mmHg.
- **Pressure Gauge:** The range maximum must be > 30 cmH₂O.
- **Reservoir:** Volume must be > 1L. If using a suction cannister as the reservoir, ensure that it is unused or that the internal filter is removed before use in the test circuit.
- **Tubing:** The minimum inner diameter (ID) of the flow pathway must be ≥ 0.236" (6 mm) – this includes both the tubing and any connectors used between circuit components. Maximum tubing length should not exceed 10' between the flowmeter and VAVD patient port.
- **Source/Wall Suction:** Must be a National Fire Protection Association (NFPA) 99 qualified suction source. Portable pumps are not acceptable for use in maintenance testing.
- **NOTE:** Test circuit must be leak free for valid maintenance test results.

Test 1: Calibration Testing

Test Procedure:

1. Connect the VAVD to wall suction and set the unit to REG.
2. Connect the bubble barb directly below the Adjusting Knob (Patient Connection) to the vacuum gauge, with the reservoir in line.
3. Test the VENOUS DRAINAGE gauge accuracy at 10, 30, and 60 mmHg by using the Adjusting Knob to set the pressure.

Acceptance Criteria: The VENOUS DRAINAGE gauge and vacuum gauges read within 3 mmHg of one another at all three test pressures. If the difference is > 3 mmHg, send in for factory calibration.

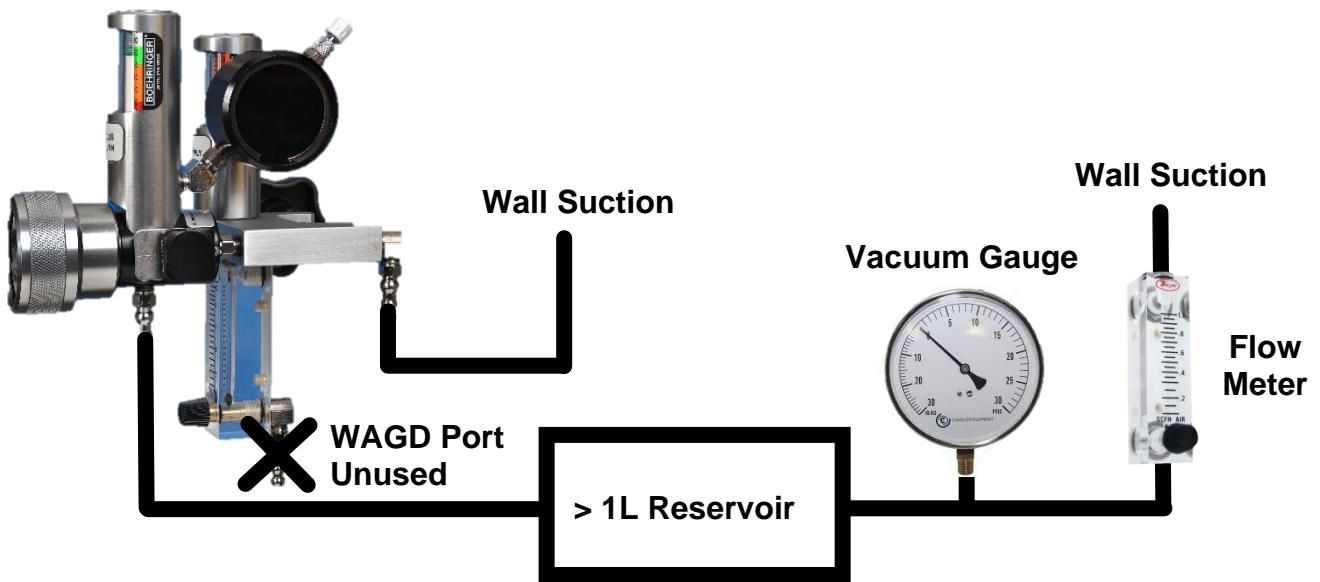


Test 2: Excess Vacuum Relief Testing

Test Procedure:

1. Connect the VAVD to wall suction and set the unit to REG.
2. Connect the bubble barb directly below the Adjusting Knob to the reservoir. Then connect the reservoir to wall suction with the vacuum gauge, and flowmeter in line.
3. Use the Adjusting Knob to set the VENOUS DRAINAGE gauge to 40 mmHg.
4. Adjust the flowmeter to 8 LPM.

Acceptance Criteria: The vacuum gauge reads ≥ 65 and ≤ 100 mmHg. If the reading is outside the required range, send in for factory calibration.

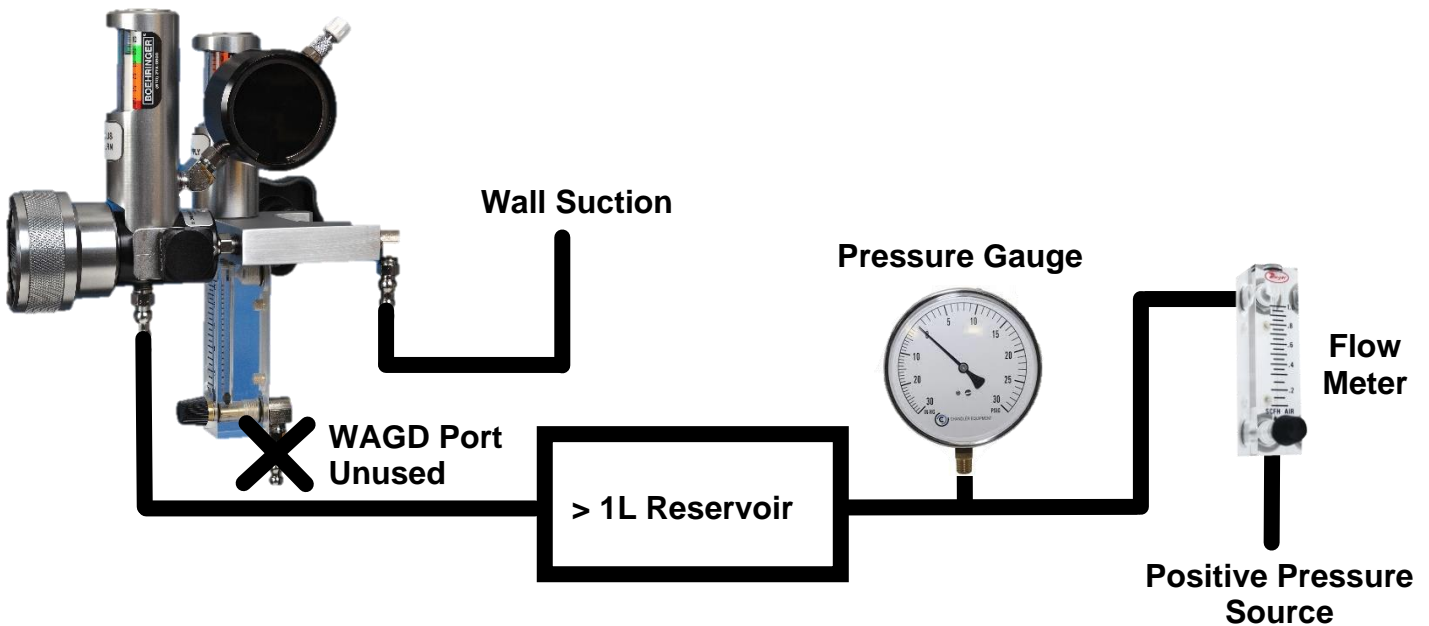


Test 3: Positive Pressure Relief Testing

Test Procedure:

1. Set the VAVD to REG and turn the Adjusting Knob clockwise until it is all the way down.
2. Connect the bubble barb directly below the Adjusting Knob to the reservoir. Then connect the reservoir to a positive pressure source with the pressure gauge, and flowmeter in line.
3. Adjust the flowmeter to 10 LPM.

Acceptance Criteria: The pressure gauge reads ≥ 10 and ≤ 30 cmH₂O (note the units). If the reading is outside the required range, send in for factory calibration.



Accessories

WAGD Tube Assembly (Model 3947) - -

It is recommended to replace the WAGD Tube Assembly every (3) three months or sooner if it has any sign of being damaged or visibly contaminated. Additional WAGD Tube Assemblies (Model 3947) are available for purchase.

Please call Customer Service at 800-642-4945 to obtain an RMA prior to return or to order additional WAGD Tube Assemblies (Model 3947). Once the unit has been received you will be contacted with an estimate of any service charges. Units will be serviced within five days of receipt of charge authorization.

Cleaning & Disinfection

After patient use, wipe all exterior surfaces of the VAVD Controller with an appropriate surface disinfectant. Appropriate disinfectants are:

- 3M Quat®
- Cavacide®

TROUBLESHOOTING

Your VAVD regulator has been designed for years of trouble-free service. Should you experience difficulty that is not the result of damage to the instrument, the most likely cause is aspiration of dirt and/or fluids into the Regulator.

| Symptom | Probable Cause | Solution |
|--|--|---|
| Instrument fails to provide suction at the patient port. | The supply or patient fittings are clogged, or the incoming suction tubing is collapsed or kinked. | Replace or clean the fittings. Replace the incoming suction line. |
| Gauge doesn't respond to changes in suction (via control valve or adjustment knob) | Gauge diaphragm is improperly sealed on the gauge piston and/or view tube | Reference Boehringer Tech Bulletin 3700.051. |
| Gauge piston is discolored. | Material has entered the inside of the device. | Instrument is contaminated. Please return to the factory for service. |
| Instrument will not shut off or exhibits high spike. | Dried fluids may have cut the quad ring seal. | Please return to the factory for service. |
| Instrument fails to regulate suction | Piston/Stem surface is binding with foreign matter | Please return to the factory for service. |
| Audible sound coming from safety port on safety interrupter | Material has entered the inside of the device. | Instrument is contaminated. Please return to the factory for service. |

SPECIFICATIONS

- Inlet and outlet fittings: 1/8 NPT, High Flow Bubble Barb (P/N 2469)
- Gauge accuracy ANSI Class B, $\pm 5\%$ FS (± 3 mmHg)
- Regulation Accuracy: $\pm 10\%$ FS from full flow to zero flow with 14 FR catheter attached.
- Materials: polycarbonate, hard-anodized aluminum, stainless steel, Buna rubber, Acetal copolymer.

| Model | Regulation Range | User Selectable Modes | Wt. (lb.) * | H x W x D (in) |
|-------|------------------|-------------------------|-------------|--|
| 3930 | 15 - 60 mmHg | Off & Regulated Control | 3.40 lbs. | 10 ¹ / ₄ " x 7 ¹ / ₂ " x 8 ¹ / ₂ " |

Operating and Storage Limits

We recommend that Boehringer Suction regulators be operated and stored at controlled conditions that typically reflect the medical facility environment.

Warranty and Repair

Boehringer Laboratories, Inc. guarantees your VAVD regulator for FIVE years from the date of manufacture. Boehringer Laboratories, Inc. warrants to the original purchaser, new suction regulators purchased directly from Boehringer Laboratories, Inc. or from an authorized dealer or representative. This warranty guarantees the suction regulators to be free from functional defects in materials and workmanship. We also guarantee that our suction regulators will meet our published specifications.

All regulators returned for repair shall be clean and free from contamination prior to shipment. This requirement is for the safety of our employees as well as to comply with Federal Law prohibiting the shipment of unmarked biohazard materials. If units are returned contaminated, a cleaning charge may result.

A service charge may be assessed on any unit returned that shows evidence of gross abuse.

Boehringer Laboratories, Inc. is the only authorized warranty service center for your VAVD regulator.

This warranty excludes acts of God, fire, flood and acts of war, terror or insurrection.

Boehringer Laboratories' sole and exclusive remedy under this warranty is limited to repairing and/or replacing the suction regulator. There are no other express or implied warranties beyond these warranties set forth above. At Boehringer Laboratories, we are committed to lowering your suction regulator costs of operation!

A Return Material Authorization Number (RMA) must be obtained prior to returning a unit for service. Please contact Customer Service at

Boehringer Laboratories, LLC

800-642-4945

info@boehringerlabs.com

300 Thoms Dr.

Phoenixville, PA 19460

www.boehringerlabs.com

See our full list of patents here:

www.boehringerlabs.com/our-patents