User Manual

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

BOEHRINGER®

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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.

Contents

Definition of Terms and Symbology

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 *or* 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.
	**Lo Spike:** Accuracy of regulation depends primarily on the ability to provide a consistent level of vacuum under changing flow conditions. 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. "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". 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. 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.
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 from 15 - 60 mmHg 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 excess negative pressure > 95 mmHg and positive pressure > 10 cmH_2O.

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 99-2012 (5.1.3.8)

Operation

FEATURES

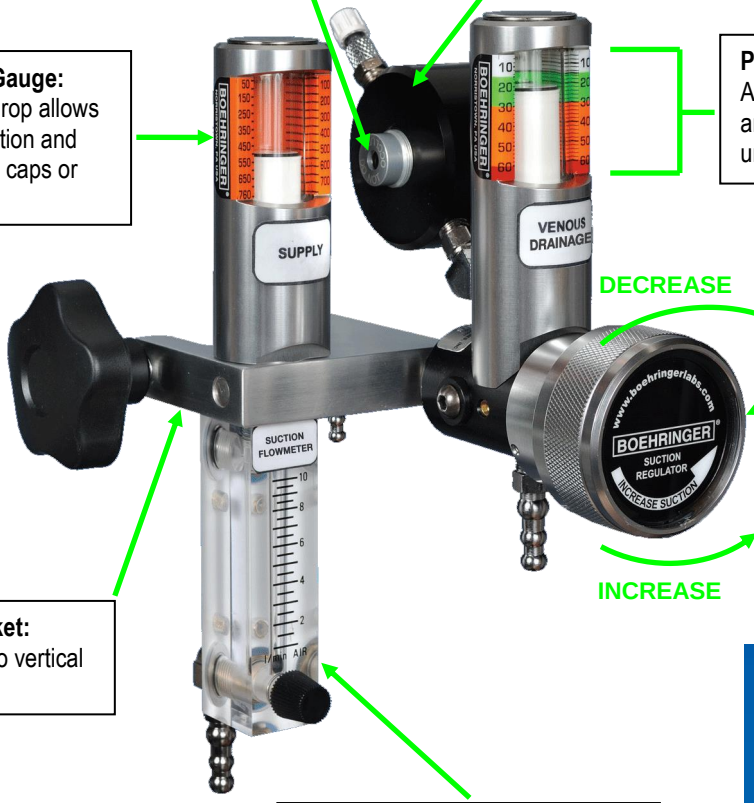
Independent Safety Relief:

1. **High Negativity Safety Vent**: Safety mechanism limits maximum suction to less than 100mmHg.
2. **Positive Pressure Relief:** Safety mechanism vents excess positive pressure.

WARNING! – Safety Port: Do Not Occlude

Integral Supply Gauge: Supply pressure drop allows for quick identification and correction of open caps or kinks in tubing.

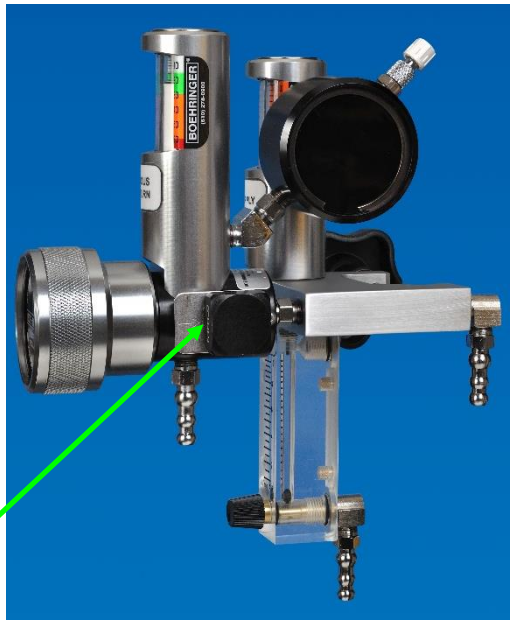
Patented Linear Gauge: Allows accurate readings from 180° field of view and never requires calibration. Each range has unique color-coding



Adjusting Knob: Extra-large, easy grip knob turns COUNTER-CLOCKWISE (direction of arrow) to increase suction setting and CLOCKWISE to decrease suction setting

Adjustable Bracket: Allows mounting to vertical poles.

WAGD Suction Flowmeter: For attachment to the scavenger port on the membrane oxygenator via the provided WAGD tubing with safety vents.



Mode Selector Valve: Square knob to easily switch between operating modes (OFF/REG).

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.

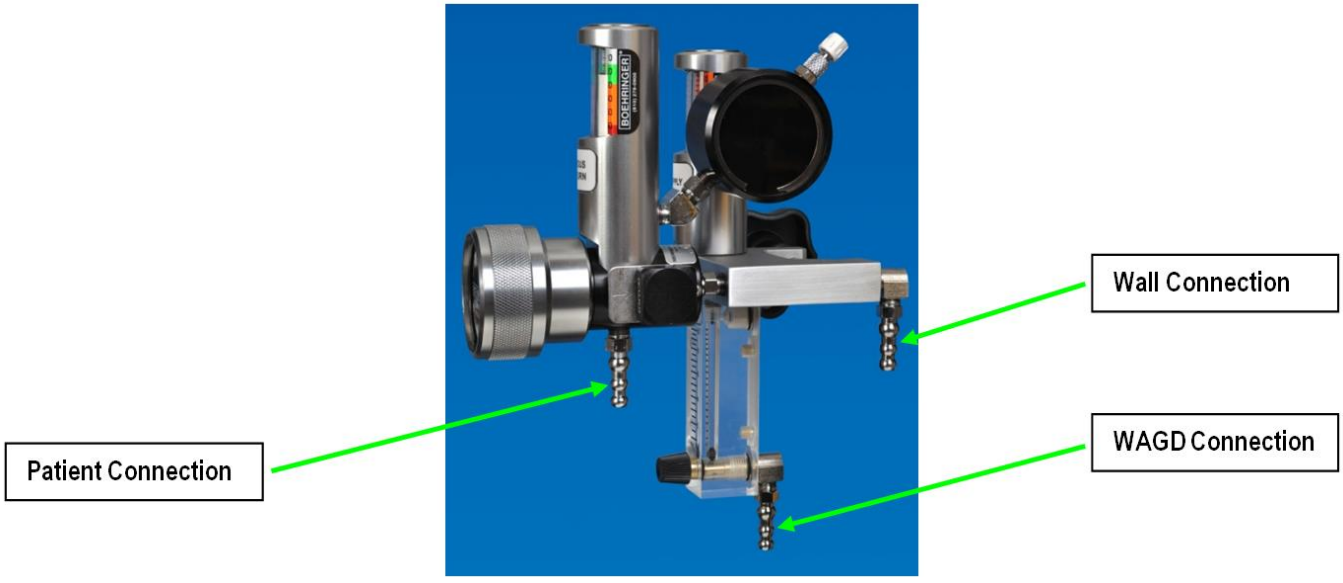
OFF Mode: When the vacuum regulator is on the OFF position, the vacuum return circuit reverts to atmospheric pressure.

INSTALLATION

The model 3930 regulator is supplied with a high flow bubble barb for attachment to wall suction. Only braid 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 cardiotomy reservoir, do not draw patient materials directly into this line, the use of a disposable vapor trap between the suction regulator and the cardiotomy reservoir is recommended.

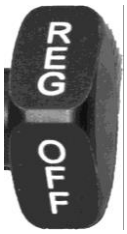


PRE-USE CHECK

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. 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 and calibration may be performed on this unit.

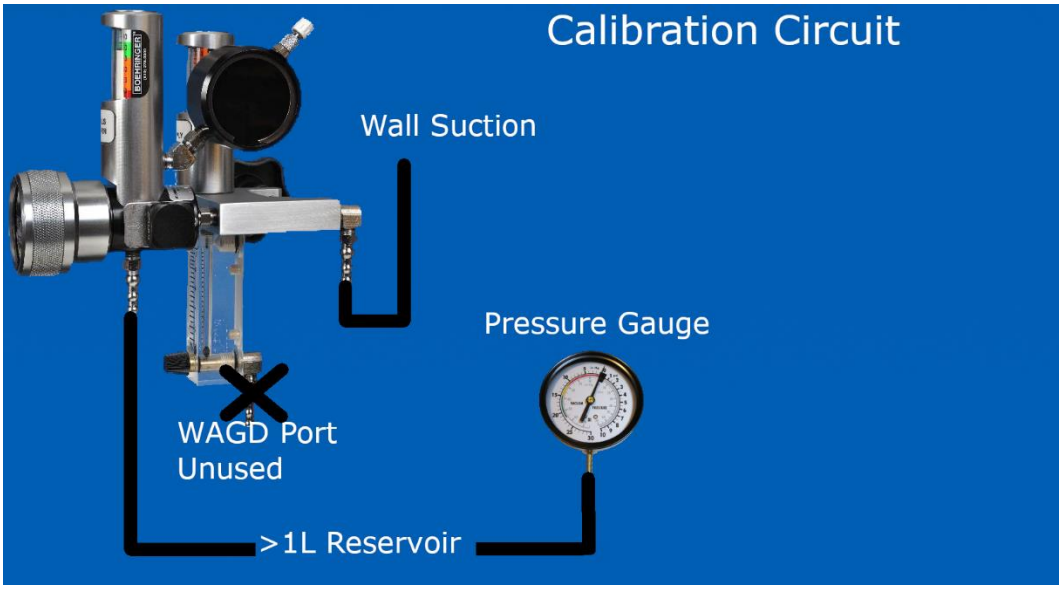
Factory calibration is recommended - -

- Any time 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 minimum of every 24 months.

While biennial factory calibration is strongly recommended, at minimum, the calibration, excess vacuum relief, and positive pressure relief must be tested every other year to ensure the VAVD Controller remains in proper working order.

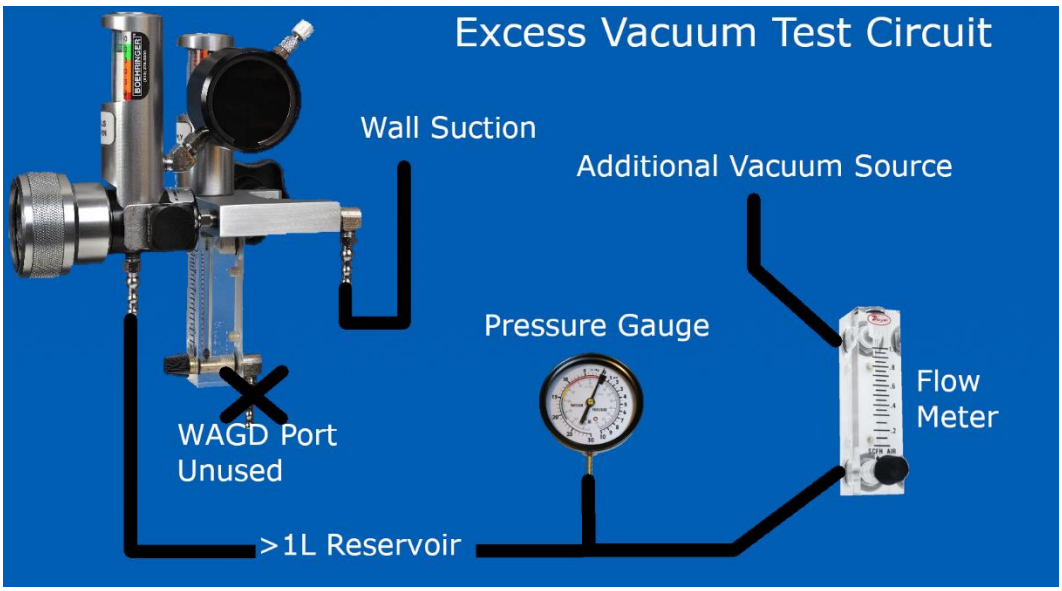
Calibration Testing

1. Attach the unit to a vacuum source which can achieve at least 400 mmHg of vacuum.
2. Connect the patient port to a mock circuit with a >1L reservoir, and a test gauge with a minimum of 0.25% Full Scale accuracy.
3. Turn the unit to REG.
4. Test VENOUS DRAINAGE gage accuracy at 10, 30, and 60 mmHg with the patient circuit fully occluded. The unit and test gages should read within 3 mmHg of one another at all three points.
    i. If the difference between the two readings is greater than 3 mmHg, send for factory calibration.



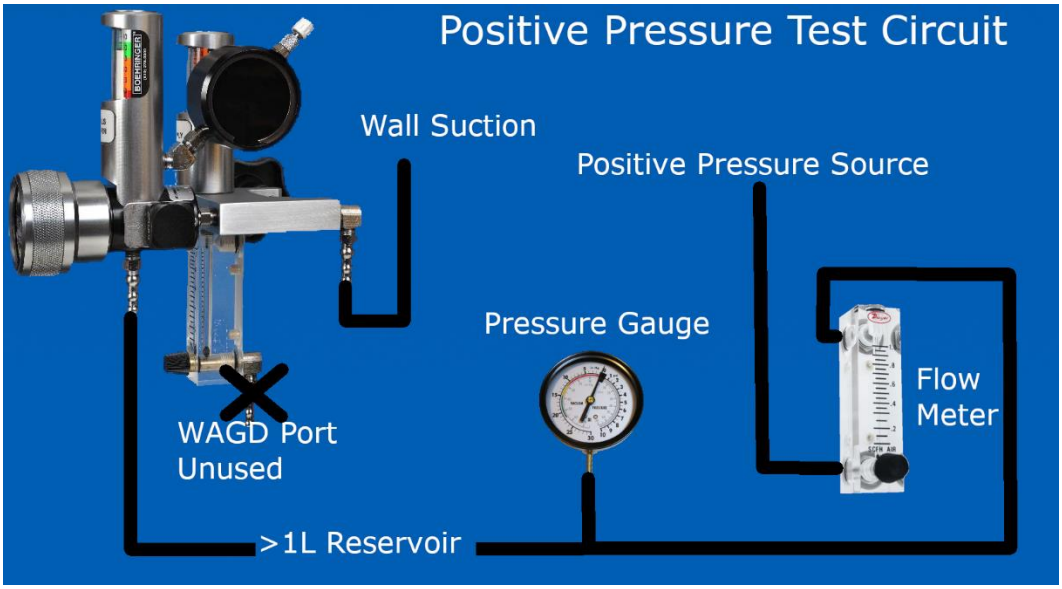
Excess Vacuum Relief Testing

1. Set the VAVD to REG and 40 mmHg.
2. Apply 10 LPM of excess suction to the mock patient circuit.
3. The test gage should read between 75 and 90 mmHg.
    i. If the reading is outside this range, send for factory calibration



Positive Pressure Relief Testing

1. Disconnect the mock circuit from the patient port.
2. Set the VAVD to REG, and screw the diaphragm housing all the way in.
3. Connect a positive pressure source to the patient port of the device with a flow meter and pressure gage in line.
4. Use the flow meter to adjust to 10 LPM of flow through the VAVD.
5. The pressure gage should read between 16 and 25 cmH_2O (note the different units)
    i. If the reading is outside this range, send for factory calibration



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 3700.044.
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, ± 5% FS (± 3 mmHg)
- Regulation Accuracy: ±10% FS from full flow to zero flow with 14 FR catheter attached.
- Leak rate in OFF position: less than 1 cc/min
- 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 7½" 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

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