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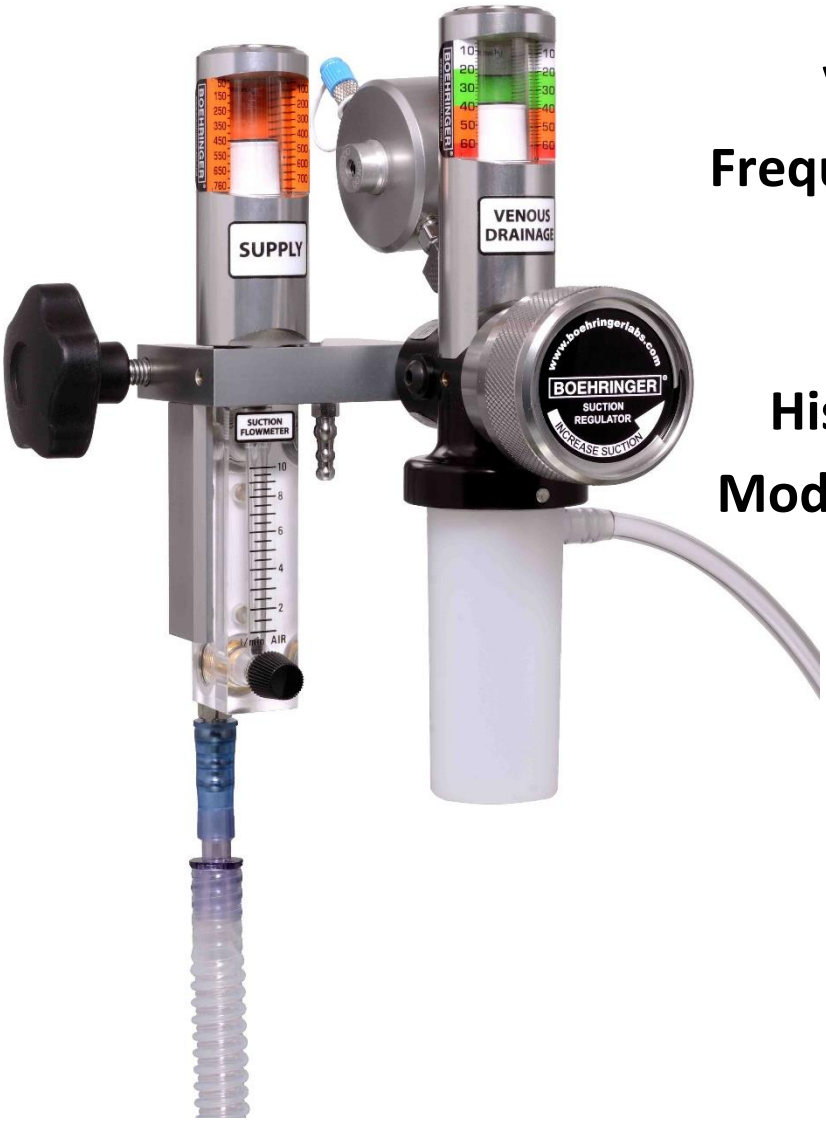


VAVD & VacPac™ Frequently Asked Questions

Historical Perspective & Modern Clinical Application

Contents

VAVD Basics

Acronyms

VAVD- Vacuum Assisted Venous Drainage
WAGD- Waste Anesthetic Gas Disposal
mmHg- Millimeters of Mercury
MGE- Micro Gas Emboli
NFPA- National Fire Protection Association

History / Overview

Traditional Cardiopulmonary Bypass was done with an open circuit; There was no way to accumulate positive or negative pressure in the cardiotomy reservoir. Blood was removed from the patient using a gravity siphon and withdrawn into the venous reservoir. To increase the rate of venous return more 'head height' would be employed, typically by raising the level of the patient in relation to the venous reservoir. In places that rely on gravity drainage you will notice the reservoir is as close to the ground as possible and there are likely stools close at hand for the surgical staff to operate should the table need to be raised. Open circuits have inherent safeties built in. When there is an imbalance of fluid entering and leaving the reservoir, this does not result in a change in pressure in the circuit. Any excess air/liquid entering the circuit is naturally vented. If there is a net deficit in materials entering the circuit, room air will replace the volume. This method is still used by many programs, however, it has limitations, as there is only so much head-height one can feasibly create in an operating room.

The increase in minimally invasive surgical techniques created the need for more efficient venous drainage, which came in the form of Vacuum Assisted Venous Drainage (VAVD). VAVD was first proposed as a method to augment venous return independent of the head height (it was described in 1953 by Dr. John Gibbon Jr). To utilize vacuum assist, the cardiotomy reservoir needs to be sealed to consistently apply low levels of vacuum. The first commercially available regulator for VAVD was the Model 7720 which was a joint venture between Baxter/Edwards and Boehringer Laboratories in 1998. Before the introduction of this device perfusionists were forced to try to use standard hospital suction regulators.

Standard hospital suction regulators lack basic features that are needed for VAVD. These regulators do not have vent capability, so when they are turned off, the large cardiotomy reservoir could still be under vacuum as there is no way for it to vent. More dangerously, the lack of a vent also means the sucker pumps could generate positive pressure in the reservoir. The lack of a vent meant perfusionists integrated a Y-connector of tubing. With one leg of the Y-connector open to atmosphere, you were always certain the reservoir was vented. Once you closed the vent, suction was applied to the reservoir. If you are still using a Y-connector today, this is a vestige from clinical practice of more than 20 years ago.

Another early work-around was the integration of a vapor trap. Continuously applying vacuum to a reservoir that contains body temperature blood, means that condensation collects in the suction line. When the suction circuit is vented, the in-rush of room air could force contaminated condensate from the suction regulator into the reservoir. Since suction regulators are not sterile, contaminated condensate returning to the reservoir be very dangerous for the patient. The vapor trap was not intended to protect the suction regulator, it was meant to protect patients.

Vacuum Assisted Venous Drainage regulators and the sealed reservoirs they require add unique risks to the circuit not found in open circuits. In a closed circuit a net increase in air/liquid outside the body results in increased pressure, likewise any deficit would result in decreased pressure.

Vacuum assist also has unique benefits over gravity drainage. Circuit prime volumes can be lower since there is no need to prime the venous return line. Likewise, gross air that is returned from the patient in the venous drainage line can be vented automatically. Vacuum circuits may be much easier to re-prime in an emergent situation than gravity assist.

Clinicians should be mindful of these risks when setting up the circuit and utilizing the safest equipment. In the 1990s the first two dedicated VAVD regulators were designed. One was from Boehringer, the other was from Polystan which would eventually be marketed as Maquet. In the intervening decades since these original units were built, clinical practice improved and better research determined the clinically appropriate range for vacuum during VAVD is 20-40 mmHg, while never exceeding 70 mmHg. In 2011 Boehringer released the Model 3930 which conformed to the best practices. The VAVD unit from Maquet was never updated and withdrawn from the market in 2015. Through market research and evolution, only the Boehringer Laboratories VAVD Model 3931 is available for sale today, which regulates between 0-60 mmHg with redundant safety features to prevent any possibility of circuit pressurization.

In this document, we will go into specific detail about the risks and benefits of VAVD, review the modern standards of vacuum assist and Waste Anesthetic Gas Disposal (WAGD), and answer the most frequently asked questions.

What adds volume to the Reservoir (Generating Positive Pressure)

- Blood from the Venous return line
- Sucker Pumps - - adding both air and blood
- Additional IV fluids.

What removes volume from the Reservoir (Generating Negative Pressure)

- Arterial Pump
- Vacuum Assist Suction Regulator - - removing air from the system

What are the risks of Positive Pressure in the Cardiotomy Reservoir?

- Venous Drainage will be slowed and potentially stopped.
- Air can reverse flow up the venous drainage line to the patient- particularly dangerous for patients with Atrial Septal Defect ASD.
- The cardiotomy reservoir may empty since the fluid returned by the arterial pump is no longer being replenished.
- Gross amounts of air may be moved down the arterial line if the cardiotomy reservoir empties thus depriming the circuit.
- Catastrophic failure of the venous drainage reservoir may occur due to accumulated pressure.

What are the risks of excessive negative pressure in the Cardiotomy Reservoir?

- Increase risk of Micro Gas Emboli (MGE) as suction increases; greater than 60mmHg dissolved gases are removed from solution in the blood but are not given adequate time to resorb before they are pumped back into the patient in the arterial line.
- Decrease in performance of centrifugal arterial pumps as they work against suction applied to their inputs. Their efficiency is typically assumes atmospheric pressure at the pump inlet.
- Catastrophic failure of the cardiotomy reservoir if it implodes under excess suction.
- Depriming of the circuit as air is drawn across the Membrane Oxygenator due to excessive suction pressures applied to the blood circuit.

- Accumulation of large gas emboli under full line suction conditions where most of the dissolved blood gases come out of solution.

Setup / Installation

How do I attach this to my circuit?

The Boehringer Labs VAVD regulator attaches to the wall suction source, or WAGD suction source, via reinforced suction tubing that will be provided with each 3931. The VAVD integrates into your circuit in two locations, with VacPac™ and the Scavenge tubing. The scavenge tubing connects to the bubble barb on the bottom of the flowmeter and fastens to the vent port of the oxygenator for WAGD. The scavenge tubing is corrugated with vents in either end on the blue ports.

VacPac™ is a proprietary connection set with tubing and a vapor trap. The VacPac™ vapor trap, which is the sterile barrier in the kit, is attached to the regulator's circular adapter, located just under the adjustment dial, and connects to the vacuum port of the cardiotomy reservoir. Temperature differences between the blood and the room air causes condensation in the line. The vapor trap is meant to prevent nonsterile condensation from going into the venous drainage reservoir. The vapor trap is not meant to provide vapor protection for the suction controller, since it will always be drawing humidified air through it. The vapor trap does not provide for overflow protection, so in the unlikely event the venous drainage reservoir overflows, the vapor trap will quickly fill before allowing this same fluid to travel to the suction controller. VacPac™ keeps the patient circuit safe from any contaminant that may have formed inside the regulator and prevents movement of the vapor trap. By mounting the vapor trap, you eliminate the possibility of overturning, line kinking due to weigh or positioning, or accidental line obstruction.

Why do you recommend dedicated connection tubing?

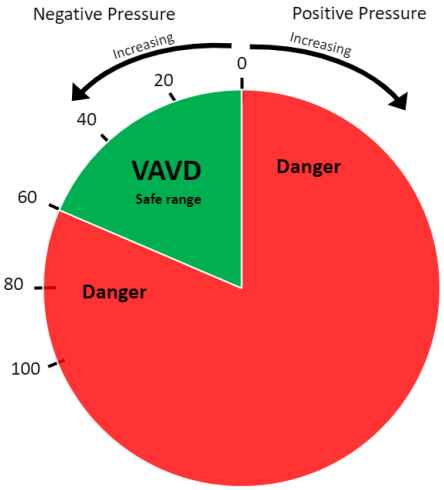
Suction supply pressures need to be a minimum of 20inHg (508mmHg) per NFPA99 code. All too often we have encountered perfusion carts that have been installed via disposable tubing to bring high vacuum from the wall. Under continued exposure to these high levels of vacuum, disposable tubing will slowly collapse greatly decreasing flow. Your 3931 will come from the factory with everything needed for installation, including 20' of reinforced suction tubing and the four most common quick connect wall fittings.

Can you mount the VAVD Controller on a horizontal rail?

Factory manufacturing designs the VAVD Controller to mount onto a vertical downbar and may be placed immediately underneath any of your hung IV Solutions. If you are unsure of a suitable mounting location, please contact your sales representative. There are adaptors to accommodate a horizontal rail (P/N 3944) if required.

Clinical Use

What suction levels are typically used for VAVD?



Clinically appropriate vacuum levels are 20mmHg to 40mmHg. Levels greater than 60mmHg decrease the efficiency of the arterial pump and put the patient at greater risk of MGE's. Pediatric suction equipment is not adequately range limited for VAVD. Even though units are advertised at 0-100mmHg, they often have no fixed upper limit and can deliver in excess of 200mmHg. Only the 3931 has a clinical range which is appropriate for this application and the needed safety mechanisms. Likewise, any positive pressure also presents dangers for the circuit and the patient.

How does the excess negative pressure relief work in the VAVD?

Attached directly to the vacuum gauge of the unit is an entirely redundant suction regulator that serves as a dedicated high vacuum safety. The redundant safety relief has the same fiber reinforced diaphragm and precision ground stainless steel spring found in the main regulator and vents the circuit starting at 85mmHg. Under no circumstances will it allow the circuit to exceed 100mmHg, even with a 10lpm high suction flow on the circuit. An audible sound from the port it is an indication the safety relief has been activated. This is an indication to immediately investigate and correct the cause of the excess suction.

At the heart of this safety device is a 1.5" diameter diaphragm that multiplies vacuum forces in the reservoir to precisely vent the circuit. There are some disposable vacuum connection circuits that employ a high vacuum vent, but these competitive devices rely on a small ball and spring to vent the circuit. Given the small effective area of the ball and the metal to metal seat contacts, these designs may be prone to fouling with corrosion or foreign materials. The small effective areas mean that they may have only 2% of the opening force of the large diaphragm of the 3931.

How does the positive pressure safety relief compare to others I have seen?

The positive pressure safety built in to your cardiotomy reservoir is likely a tiny duckbill valve in the lid of the device. You will often see these packaged with a toothpick sized pin in it to make sure it is open from the factory. As a general rule, duckbill valves have a very low cracking pressure (this is the positive pressure at which they will allow air to escape). The problem with these small duckbill valves is they are not intended to have high airflow through them, so if you set up multiple sucker lines, or you have the speed on your suckers turned up, it is very easy to get your reservoir to exceed 20mmHg of positive pressure (even though your small duckbill is trying its best to vent). The positive pressure safety relief built into the VAVD is not only more sensitive, but it is capably of venting the positive pressure created by multiply suckers running at high RPM.

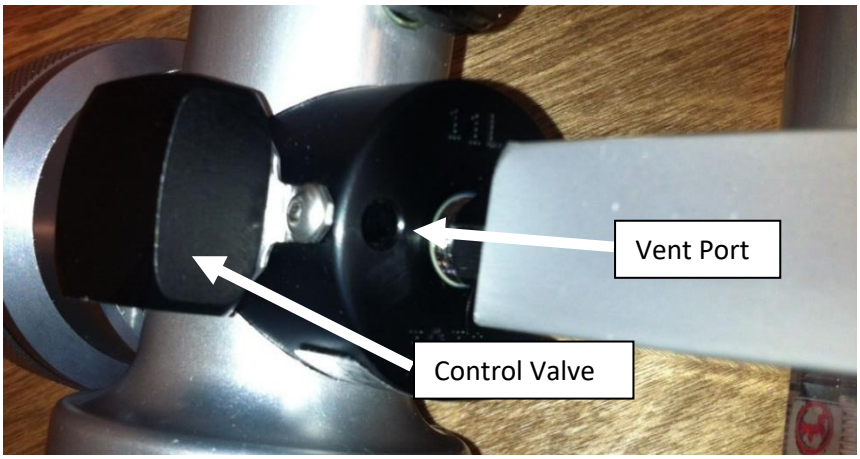
What are some of the risks of a vapor trap?

Vapor traps frequently use a silicone line to attach to the venous reservoir. Without proper support they are prone to bending and kinking. A kink in this line would essentially close the circuit causing positive or excess negative pressure in the cardiotomy reservoir. The VacPac™ connection set is designed to eliminate the risk of kinking.

What are the inherent risks of a Y-Connector? How are these mitigated?

Y-connector sets are a vestige from the days of old, before dedicated vacuum regulators designed for vacuum assist. When use properly, y-connectors can mitigate the risks of using traditional vacuum regulators, however with multiple positions that may be clamped and with not dedicated labeling or safeties, they actually introduce new risks to the circuit. There are two safe positions to clamp the Y-connector and two unsafe ways of using this.

The problem with standard suction equipment is that it is not intended to vent high flow positive pressure in the off position. This could mean that even though the suction supply is turned off, the reservoir would continue to be charged with Vacuum, or in a worse case, positive pressure could develop. The control valve design of the Boehringer 3931 makes the use of a Y-Connector redundant. In a single turn vacuum is applied to the circuit, and once it is turned to the 'OFF" position the suction supply is interrupted as well as the system will now passively vent. One vent port, and the control valve are shown below.



What should I do if fluid intrudes my units?

Units which have been intruded by fluid should be returned to the factory for service due to the intricate nature of the safety mechanisms on these devices. Service can be arranged by calling 800-642-4945. Typical turnaround time is five days.

Can VAVD and the 3931 be used with a closed Bag System?

The 3931 could provide vacuum for a closed system utilizing a bag. A system such as the V-Bag by Circulation Technologies (www.cirtec.com) allows for the use of a closed system with the application of vacuum assist. These 'Bag in a Box' circuits have unique features not found in traditional bag or hardshell systems, but please consult their manufacturer for specific use instructions.

Suction Flowmeter and Waste Anesthetic Gas Disposal

What should the suction flowmeter be set at?

We recommend the suction flowmeter be set between 8 and 10 Liters per Minute (lpm) to give a visual indication that waste gas is being removed. Additional flow beyond the oxygenator sweep is made up by room air drawn in through the vents in the distal end of the tubing. Some facilities have enacted protocols whereby the WAGD flowmeter is set at 1-2lpm above the sweep, this can be done at the discretion of the facility, however, for proper WAGD removal the flowmeter must be set higher than

the effective sweep. The suction flowmeter is factory limited to 12lpm so as to allow sufficient supply for VAVD uses. The suction flowmeter can be used independent of the VAVD control, and vice versa.

Can the Suction Flowmeter Affect the Airflow / Saturation of the Circuit?

The suction flowmeter will not impart more than 0.5cmH20 pressure on the oxygenator. The inclusion of a passive vent immediately proximal to the oxygenator helps ensure negative pressure is not applied to the oxygenator. The suction flowmeter will not impart a pressure differential on the oxygenator, so it cannot affect flow or saturation levels in the circuit. Always use the provided WAGD tubing for scavenging as it has factory calibrated vents to maintain zero pressure differential across your oxygenator membrane.

Why can't I feel suction in the scavenger line?

The suction flowmeter tubing is also called the scavenger line. The inclusion of a passive vent immediately proximal to the end of the line ensures that in a static condition the unit cannot deliver more than 0.5cmH20 to the vent port of the oxygenator. This low level of suction is meant to remove waste gas in a laminar flow and not the typical high flow fashion you would normally attribute to a suction circuit.

Can the suction flowmeter degrade performance of the VAVD circuit?

The manifold bracket of the 3931 ensures that even if the suction flowmeter were turned to its maximum setting, only 15lpm could be delivered to the oxygenator and removed from the available supply for the VAVD circuit. Per the NFPA99 standard, the supply line to the 3931 should be capable of 89lpm of flow, so the suction flowmeter at most could remove 11% of the available flow, leaving more than adequate static pressure and flow to power the VAVD circuit.

Can I alter the scavenge line?

Do not alter the scavenge line, and do not cut/modify the piece that attaches to the oxygenator. This has a special fitting modified to function as a passive vent. In the event someone shuts off the suction flowmeter, the system will vent passively. By having this passive vent immediately proximal to the oxygenator we lessen the possibility the tubing could be bent or kink. The tubing itself is corrugated, and its full length is required to allow for proper evaporation of any water vapor buildup.

Can Waste gas be run into the central suction system?

NFPA99 requires that waste anesthetic gas be diluted below flammable levels before introduction into the central suction system. The Boehringer VAVD Controller has been designed in a single manifold with both VAVD and Waste Anesthetic Gas removal functions. In addition, an auxiliary vent port on the distal end of the suction flowmeter brings room air into the suction flowmeter. The combination of these features allows the anesthetic gas to be diluted appropriately before introduction into the hospital suction system. If there are any questions, please have your facilities engineer contact the Boehringer factory engineers.

Why isn’t the WAGD Scavenge line sterile?

This tubing does not come in contact with the blood side of the patient circuit or any patient materials. By connecting to the vent port on the oxygenator, it pulls off waste anesthetic gases, but has multiple layers (hollow fiber membranes) between that chamber and any patient materials. At the Suction Flowmeter on the VAVD Controller, waste gases and air/vapor from the cardiotomy reservoir are safely pulled out of the circuit, and appropriately introduced into the hospitals central suction system.

How often do I need to change the Scavenge line? What happens if it gets dirty or there is water in it?

The scavenge line is designed to last three months but should be changed more frequently if damaged or soiled. Sanitation wipes may be used on the exterior. If condensation builds up in the tubing, either hang it vertically to drain out, or attach to the Suction Flowmeter with 10lpm of airflow. If there is blood or other material inside of the Scavenge line, it should be replaced, as cleaning solutions will damage the material.

Safety

Why have a 0-60mmHg Operation Range?

Clinical literature shows increased risk of air embolism over 60mmHg. The control knob on the front of the Boehringer Model 3931 is calibrated to limit the maximum suction. Boehringer is the only manufacturer of suction equipment that factory limits the maximum of our suction controls, eliminating the need to rely on auxiliary safety devices. By having a narrower pressure range on the regulator, we are able to provide greater precision at the low pressures used for VAVD than a 0-100mmHg regulator.

Jones, Timothy, Deal Dwight, et al. "Does Vacuum-Assisted Venous Drainage Increase Gaseous Microemboli During Cardiopulmonary Bypass?." *Ann Thorac Surg*. 74. (2002): 2132-2137

Kiyama, Hiroshi, Yasushi Katayama, et al. "Vacuum-assisted venous drainage in single-access minimally invasive cardiac surgery." *J Artif Organs*. 6. (2003): 20-24.

Wilcox, Timothy, Simon Mitchell, and Des Gorman. "Venous Air in the Bypass Circuit: A Source of Arterial Line Emboli Exacerbated by Vacuum-Assisted Drainage." *Ann Thorac Surg*. 68. (1999): 1285-1289.

How does the Vent Mechanism Work?

All Boehringer suction regulators utilize a single piece machined control valve to make a seal, without the need for easily damaged rubber gaskets or O-Rings. This means that you can be confident that you will always have control of your suction when you need it and -just as importantly- when you don't need it. The Boehringer design has large 5mm vent ports that open the circuit to atmosphere when suction is shut off. This assures that the reservoir returns to atmospheric pressure when suction is shut OFF.

Why is an Independent Negative Pressure Relief needed on the regulator?

The addition of a safety relief device is intended to ensure that circuit pressures are maintained below 100mmHg. These controls begin to vent at 85+/- 5mmHg in order to keep your patient safe.

How much Positive Pressure is Vented?

The same device on your 3931, which provides for negative pressure relief also vents excess positive pressure. While applying suction to the circuit, any positive pressure would be eliminated by the suction. When the unit is off, the large 5mm vent will relieve any pressure. If the unit is in the REG mode, and the control knob is turned down until the output is zero, the 3931 would not be applying suction and the 5mm vent is not open. In this scenario, the unit begins to vent positive pressure at 1.5cmH20 (~1mmHg) and even with 10lpm of air entering the reservoir (as would occur if two or more sucker pumps are running at maximum capacity) the circuit will not exceed 25cmH20 of positive pressure (18mmHg). The in-line positive pressure relief valves found in most disposable circuits have low cracking pressures but are easily overpowered with high flow through the circuit. Many disposable valves will allow pressure to exceed 20mmHg with only 5lpm of flow applied to the circuit.

Almany, Daniel, and Joseph Sistino. "Laboratory Evaluation of the Limitations of Positive Pressure Safety Valves on Hard-Shell Venous Reservoirs." *Journal of the American Society of Extra-Corporeal Technology*. 34. (2002): 115-117.

Design Considerations

Is the Boehringer VAVD Controller tolerant to fluid intrusion?

The patented Self-Clearing™ control mechanism found in Boehringer 3800 & 3900 series controls ensures the device will continue to function after it has been intruded with fluid. Once the case is complete, and the blood dries, it will affect the functionality of the device. The device should be disassembled, cleaned, disinfected and retested at the factory. Do not attempt to do this at your facility. Please call into our Customer Service line, 800-642-4945 for return instructions.

Can the Boehringer VAVD Controller handle humidity and aerosol?

The internal control mechanisms are stainless steel, and tolerant to humidity and aerosols.

What is the use of the supply gauge?

The VAVD Controller was designed to work with a suction supply compliant to the National Fire Protection Association code (NFPA99). It is recommended you use the VAVD connection kit which includes the proper fittings and reinforced supply tubing. The supply gauge serves a two-fold purpose. Per NFPA99, your suction supply pressure should be a minimum of 20inHg (508mmHg). NFPA99 also requires there is a minimum suction flow of 89lpm. Should anything compromise your supply such as a hose disconnection, line kink, or equipment running over the supply hose, you will readily see a decrease in supply. If there is any excess circuit demand on vacuum, possibly due to a dislodged cap on the venous reservoir, you will likewise see a decrease in the supply gauge. The suction flowmeter will impart a slight draw on the supply of the system. When fully open, on a compliant outlet, the suction flowmeter will reduce supply pressure less than 100mmHg.

How does the control valve work?

In one action, the ON/OFF control valve will control both suction application and circuit venting. When the valve is in the OFF position, a large 5mm vent is opened to the circuit. Other suction equipment does not actively vent the circuit, necessitating the use of a Y-Connector to vent the circuit. The inclusion of a Y-connector allows for additional risks to your circuit and patient. (see the FAQ's on the Y-Connector).

Why is high flow important?

Sucker pumps can generate upwards of 5lpm of air flow. Multiple sucker pumps could pump 10 Liters of air per minute into the venous reservoir. If your suction control is not able to keep up, your circuit is at risk of becoming positively pressurized despite the application of vacuum. The high flow nature of the Boehringer VAVD controller, ensures that if suction is turned on, you can safely remove air captured by the sucker pumps and maintain vacuum on the circuit.

Self-Clearing Control Surfaces

The Boehringer 3800 & 3900 series controls use a patented design that provides for a dedicated air-curtain of fresh air to flush over the control surfaces preventing liquids and aerosols from fouling the controls mechanism even under the most grueling conditions. Without this feature, aerosols and liquids may inhibit proper functioning of suction controllers, causing them to regulate inconsistently or even jam. A jammed regulator results in either no suction at all or unlimited application of wall suction to your patient circuit.

Patented Linear Gauge

Boehringer utilizes a patented linear gauge that is elegant in design, extremely accurate, and tolerant to many common forms of abuse. Traditional dial gauges have 35-40 internal parts making them delicate and prone to damage.

Dial gauges also rely on a micro-orifice as small as 0.1mm to dampen the motion of the needle. Any internal debris or liquid can clog this orifice, preventing the function of the gauge. Our linear gauge has a large 5mm orifice in its base allowing entrained material to more easily exit the gauge.

Digital gauges depend on the same inaccurate underlying control mechanism found in older generation suction controls, require corrections for Zero and Span readings, and may drift as batteries are drained.

100% American Made Craftsmanship

Boehringer Laboratories was founded in 1972 by John Boehringer in his home in Wynnewood, Pennsylvania. All Boehringer Controls are proudly designed, assembled, and tested here in the United States at our facility just outside of Philadelphia.

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