

Setup for Patient Use

1. Ensure that the Procedures Prior to Use List has been complete.
2. Move the selector valve to the "REG" position and kink the vacuum tubing.
3. Set the required vacuum level.

WARNING: The vacuum tubing must be kinked to ensure that the patient is not exposed to a higher level of vacuum than what is required.

4. Move the selector valve to the "OFF" position.
5. Attach the vacuum tubing to the vacuum canister.

Cleaning & Troubleshooting

1. Connect the supply port of the Vacuum Regulator to the patient port of a collection canister.
2. Attach the vacuum port of the collection canister to a vacuum source.
3. Connect a hose from the patient port of the Vacuum Regulator to be cleaned and place the other end into a container containing 100cc of a cold sterilant.
4. Fully increase the regulating knob of the vacuum regulator (clockwise).
5. Turn on the Vacuum Regulator to the "REG" mode. Wait until all of the cold sterilant is passed through the regulator.
6. Repeat step 5 for all models of Vacuum Regulators.
7. Repeat step 3, 4 & 5 using 100cc of isopropyl alcohol to purge the Vacuum Regulator of the sterilant.
8. The Regulator should be run for 30 sec with its patient port open to dry its internal components.

NOTE: Ethylene oxide is not recommended. Sterilization using an ethylene mixture may cause small surface cracks to some of the plastic parts. If you decide to clean with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the plastic material.

CAUTION: Do not steam autoclave, immerse in liquid or gas sterilize Amvex suction regulators. This may cause damage to the unit.

CAUTION: If vacuum regulator becomes contaminated internally, warranty is voided. Do not send vacuum regulator back to the manufacturer. Follow your facilities procedures for handling contaminated products.

WARRANTY

Amvex Corporation warrants its Medical Vacuum Regulator to be free from defects in material and workmanship for a period of Three (3) years for the analog version and Five (5) years for the digital version from the date of shipment. Within the first twelve (12) months from date of shipment Amvex will repair or replace any part which is proven to be defective at Amvex's cost. After the first twelve (12) months, Amvex will send the parts to the customer free of charge, but the shipping and installation will be borne by the Customer.

This warranty is valid only when the product has been properly installed according to Amvex specifications, used in a normal manner and serviced according to factory recommendations. It does not cover failures due to damage which occurs in shipments or failures which resulted from accidents, misuse, abuse, neglect, mishandling, alteration, misapplication or damage that may be attributable to acts of God.

AMVEX CORPORATION DOES NOT HONOR VERBAL STATEMENTS CONCERNING THE WARRANTY.

The distributor and/or dealer are not sanctioned to create verbal warranties about the product described in this agreement. Any statements will not be honored or be made part of the agreement of sale. This document is the final, complete and exclusive terms of the agreement.

THIS WARRANTY IS EXCLUSIVE AND REPLACES ALL OTHER WARRANTIES.

Amvex Corporation shall not, under any circumstances, be liable for incidental or consequential damages including, but not limited to, profit loss, loss of sales or injuries to person(s) or property. Correction of non-compliances as noted above will result in completion of all liabilities of Amvex Corporation whether based on agreement, neglect or otherwise. Amvex Corporation reserves the right to stop manufacturing any product or change materials, designs or specifications without notice.

All claims for warranty must first be approved by Amvex's Service Department: (support@amvex.com or 905-764-7736). A valid Return Goods Authorization (RGA) number must be obtained from Amvex prior to commencement of any warranty claim.

OPERATING AND MAINTENANCE MANUAL

CONTINUOUS VACUUM REGULATORS DIGITAL & ANALOG



MODELS INCLUDE:

VR-C2U2-F2A	VR-C2U2-F2D
VR-C3U2-F2A	VR-C3U2-F2D
VR-CHU2-F2A	VR-CHU2-F2D
VR-P2U2-F2A	VR-P2U2-F2D

(For the above models: "A" = Analog; "D" = Digital)

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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IMPORTANT SAFETY INSTRUCTIONS

WARNING

READ AND UNDERSTAND ALL THE SAFETY AND OPERATING INSTRUCTIONS CONTAINED IN THIS BOOKLET. IF YOU DO NOT UNDERSTAND THESE INSTRUCTIONS, OR HAVE ANY QUESTIONS, CONTACT YOUR SUPERVISOR OR DEALER BEFORE ATTEMPTING TO USE THE APPARATUS.

User Responsibility

WARNING: *This device is to be used only by people that have been properly trained on the operation of this device. Operation of this device is not to be done if flammable anesthetics are present due to the possibility of explosion caused by the static charge.*

This product performs as explained in this manual and all accompanying labels and inserts. This holds true as long as the assembly, use, repair and maintenance are properly followed according to our instructions. Periodic review of this device is recommended. If any broken, damaged or defective parts are present, the product should not be used. This includes parts that may have been altered, become contaminated, and are worn or missing. If any of the above are noted, immediate repair/replacement is required. In compliance with the Amvex Warranty, repair of this device is not to be performed by anyone other than an Amvex trained professional and done in strict accordance to the written instructions provided by Amvex. If this device is subject to improper maintenance, repair, use and or abuse leading to inoperation of the device, replacement is the sole responsibility of the user.

ATTENTION: Service of this device should only be performed by properly trained individuals.

This manual and all other labels and inserts are strictly for the ease of operators that have proper tools and knowledge in the repair of this device, and properly trained Amvex representatives.

Operation

It is very important to allow product to remain in original packaging for 12-24 hours to acclimatize to room temperature before use

Equipment Setup:

Depending on the desired location of the regulator, connect the vacuum adapter directly into the wall outlet, or connect one end of an Amvex Corporation vacuum hose assembly onto the supply port of the suction regulator and the other end onto the vacuum source (i.e.: wall outlet).

Suction tubing, provided by the hospital, is required between the patient and patient port, as well as, between the outlet port and canister.

To prevent possible contamination to the regulator, a high flow suction filter provided by Amvex is recommended between the regulator and the collection jar.

Selecting the Mode:

Model: 2 Mode Continuous

REG: Allows vacuum to be adjusted by use of the control knob

OFF: Vacuum is no longer on or being supplied to patient

Model: 3 Mode Continuous

Same options as above, as well as:

FULL: Maximum vacuum is administered to patient.

NOTE: This option is only available on the 3 mode model.

Setting the level of vacuum:

1. Move the selector valve to the "REG" position
2. Kink the vacuum tubing to allow no passage of suction while setting the regulation.
3. Turn the regulator control knob until the desired vacuum setting is reached.

WARNING: *The vacuum tubing must be kinked when setting the vacuum level to ensure that the patient is not exposed to a higher level of vacuum than what is required.*

Procedures Prior to Use List:

WARNING: *The following checklist must be completed prior to use on each patient. If the regulator does not pass one or more of the following tests outlined on the checklist the regulator must and be repaired by personnel with qualified training.*

The following tests must be done with a minimum supply vacuum of -53 kPa (-400 mmHg):

1. Move the selector valve to the "OFF" position.
Turn the regulator knob one complete turn in the clockwise direction.
Kink the vacuum tubing to block the adapter port. There should be no movement of the gauge needle (or in case of digital gauge, no change in display).
2. Move the selector valve to the "REG" position.
Turn the regulator knob fully in the counter-clockwise direction.
Kink the vacuum tubing; again, there should be no movement of the gauge needle (or in case of digital gauge, no change in display).
3. Kink vacuum tubing.

Regulator Setting

Standard: increase the vacuum to - 12 kPa (-90 mmHg)

High: increase the vacuum to - 40 kPa (-300 mmHg)

Pediatric: increase the vacuum to - 13 kPa (-100 mmHg)

Open and close the kinked vacuum tubing slowly to reach various vacuum rates. Ensure that the level of vacuum is staying consistent when the vacuum tubing is kinked.

Standard Continuous and High Vacuum:

2 Mode

Decrease the vacuum to zero and move the selector valve to the "OFF" position.

3 Mode

Move the selector valve to the "FULL" position. Kink the vacuum tubing and ensure that the vacuum gauge is reflecting the maximum suction available.

Move the selector valve to the "REG" position.

Decrease the vacuum to zero and move the selector valve to the "OFF" position.

Pediatric Continuous:

Kink the vacuum tubing and turn the regulator knob fully in the clockwise direction to ensure that the vacuum level does not go over -21 kPa (-160 mmHg)

Note: This feature is only present in the pediatric model.

Decrease the vacuum level to zero and move the selector valve to the "OFF" position.