

OPERATING AND MAINTENANCE MANUAL

CONTINUOUS / INTERMITTENT VACUUM REGULATORS DIGITAL & ANALOG



CE
0413

Models Include:

VR-CIU2-F2D	VR-CIU2-F2A
VR-I2U2-F2D	VR-I2U2-F2A
VR-PIU2-F2D	VR-PIU2-F2A
VR-PPU2-F2D	VR-PPU2-F2A
VR-NIU2-F2D	VR-NIU2-F2A
VR-NNU2-F2D	VR-NNU2-F2A

(For the above Models: “D” = Digital “A” = Analog)

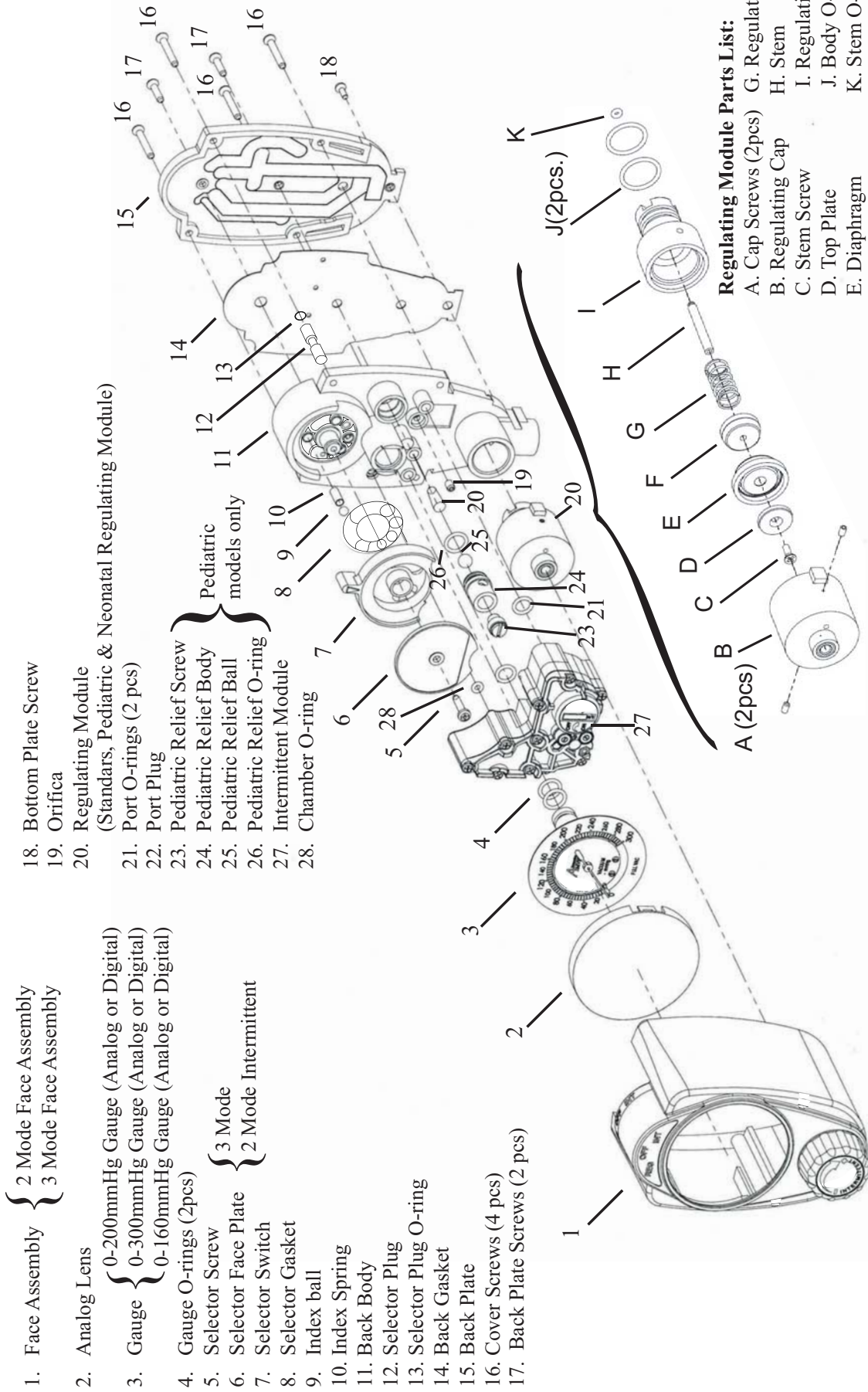
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

A Corporation
AMVEX

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INTERMITTENT VACUUM REGULATOR PART IDENTIFICATION



- 1. Face Assembly { 2 Mode Face Assembly
3 Mode Face Assembly

- 2. Analog Lens
- 3. Gauge { 0-200mmHg Gauge (Analog or Digital)
0-300mmHg Gauge (Analog or Digital)
0-160mmHg Gauge (Analog or Digital)
- 4. Gauge O-rings (2pcs)
- 5. Selector Screw { 3 Mode
- 6. Selector Face Plate { 2 Mode Intermittent
- 7. Selector Switch
- 8. Selector Gasket
- 9. Index ball
- 10. Index Spring
- 11. Back Body
- 12. Selector Plug
- 13. Selector Plug O-ring
- 14. Back Gasket
- 15. Back Plate
- 16. Cover Screws (4 pcs)
- 17. Back Plate Screws (2 pcs)

- 18. Bottom Plate Screw
- 19. Orifixa
- 20. Regulating Module (Standards, Pediatric & Neonatal Regulating Module)
- 21. Port O-rings (2 pcs)
- 22. Port Plug
- 23. Pediatric Relief Screw { Pediatric models only
- 24. Pediatric Relief Body
- 25. Pediatric Relief Ball
- 26. Pediatric Relief O-ring
- 27. Intermittent Module
- 28. Chamber O-ring

- Regulating Module Parts List:**
- A. Cap Screws (2pcs)
 - B. Regulating Cap
 - C. Stem Screw
 - D. Top Plate
 - E. Diaphragm
 - F. Support Plate
 - G. Regulating Spring
 - H. Stem
 - I. Regulating Body
 - J. Body O-rings (2 pcs)
 - K. Stem O-ring

IMPORTANT: SAFETY INSTRUCTIONS

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, DEALER OR THE MANUFACTURER BEFORE ATTEMPTING TO USE THE APPARATUS.

⚠ WARNING: Indicates a potentially hazardous situation, if not avoided, could result in death or serious injury.

ATTENTION: Indicates a potentially hazardous situation, if not avoided, could result in minor or moderate injury.

CAUTION: Indicates a potentially hazardous situation, which, if not avoided could result in property damage.

Receiving Inspection

Remove product from package and inspect for damage. Verify that the model received is in working order. If product is damaged, or incorrect do not use. Contact your dealer, equipment provider or manufacturer.

User Responsibility

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

This product performs as explained in this manual. 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 damage or defects 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 malfunction 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. DO NOT change, alter or modify intended use of the product.

Vacuum Regulator Model	Gauge Range	Gauge Accuracy	
		Analog	Digital
Continuous / Intermittent:	0 - 300 mmHg 0 - 200 mmHg	+/- 3% F.S. +/- 3% F.S.	+/- 1% F.S. at 22°C +/- 1% F.S. at 22°C
Pediatric Continuous / Intermittent	0 - 160 mmHg	+/- 3% F.S.	+/- 1% F.S. at 22°C
Neonatal Continuous / Intermittent	0 - 100 mmHg	+/- 3% F.S.	+/- 1% F.S. at 22°C

Flow rates	Standard	Pediatric & Neonatal
Continuous:	0-80 LPM	0-40 LPM
Intermittent:	8 LPM	2.5 LPM

Operation Instructions

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

The operating and storage temperature for the regulator should reflect typical environmental conditions of a medical facility environment.


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 of the canister, as well as, between the outlet port of the vacuum regulator and canister.

To prevent possible contamination of the regulator, a high flow suction filter or an overflow safety trap provided by Amvex is recommended between the regulator and the collection canister.

Selecting the Mode:

REG:  Allows degree of vacuum to be adjusted by use of the regulating knob.

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

INT:  Vacuum in intermittent (cycling between “on” and “off”). Degree of vacuum can be adjusted with the regulating knob.

NOTE: REG mode is only available on the 3 mode models

Procedures Prior to Use List:

⚠ WARNING: The following checklist must be done prior to use on each patient. If the vacuum regulator does not pass one or more of the following tests outlined on the checklist, the regulator must be removed and 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 switch to the “OFF” position. Turn the regulator knob one complete turn in the clockwise direction. Kink the vacuum tubing to block the outlet. There should be no movement of the gauge needle (or in case of a digital gauge, no change in display).
2. Move the selector switch 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 a digital gauge, no change in display).
3. Kink vacuum tubing.

Regulator Setting:

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

Pediatric & Neonatal: increase the vacuum to -5 kPa (-40 mmHg)

4. 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.
5. Move the selector switch to “INT”.
6. Kink vacuum tubing.
7. Timing cycles are approximately 16 seconds on and 8 seconds off.

NOTE: The intermittent unit starts in the off cycle.

8. Decrease the vacuum level to zero and move the selector switch to the “OFF” position.

Pediatric & Neonatal:

9. In the “REG” position, kink the vacuum tubing and turn the regulator control knob fully in the clockwise direction to ensure that the vacuum level does not go over -21 kPa (-160 mmHg) for Pediatric and -13 kPa (-100mmHg) for Neonatal.

NOTE: This feature is only present in the Pediatric and Neonatal models.

10. Decrease the vacuum level to zero and move the selector switch to the “OFF” position.

⚠ WARNING: Always verify vacuum setting prior to performing any procedure. Vacuum levels set in the “REG” mode will remain the same when switched to the “INT” mode; and vacuum levels set in the “INT” mode will remain the same when switched to the “REG” mode.

CAUTION: When the collection canister is full DO NOT operate the vacuum regulator. The WARRANTY WILL BE VOIDED if the canister overflows and contaminates the vacuum regulator.

Setup for Patient use:

Setting the Level of Vacuum for Patient use:

1. Ensure that the Procedures Prior to Use List has been complete.
2. Move the selector switch to the “REG” position
3. Kink the vacuum tubing.
4. 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.

5. Move the selector switch to the “OFF” position.
6. Attach the vacuum tubing to the vacuum canister.



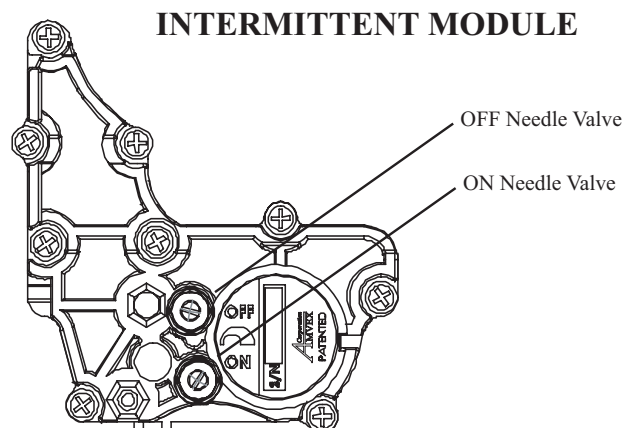
Instructions for Setting the Intermittent Timing:

1. Remove the four cover screws [16] located at the back of the Vacuum Regulator and pull the Face Assembly [1] from the Back Body [11].
2. Connect the Supply Port of the Vacuum Regulator to a vacuum source.
3. Occlude the Patient Port.
4. Switch the Vacuum Regulator to “INT” mode.
5. The Intermittent Module [25] must be held firmly against the Vacuum Regulator body during timing.

NOTE: The off time must be adjusted prior to the on time.

6. The unit will begin in the off mode of the intermittent cycle. To increase the off time, turn the OFF Needle Valve clockwise. To decrease the off time, turn the OFF Needle valve counterclockwise.
7. After the off time has been adjusted to the desired timing the on time may be adjusted. To increase the on time, turn the ON Needle Valve clockwise. To decrease the ON time, turn the ON Needle Valve counterclockwise.
8. Once the desired cycle time has been reached, slide the Face Assembly [1] back on the Back Body [11] and re-insert the four Cover Screws [16].
9. Complete the procedures prior to use list to assure Vacuum Regulator is operating correctly.

CAUTION: To prevent stripping of the plastic threads first turn the screw counterclockwise until it drops into its original threading. Now the screw may be turned clockwise and tightened.



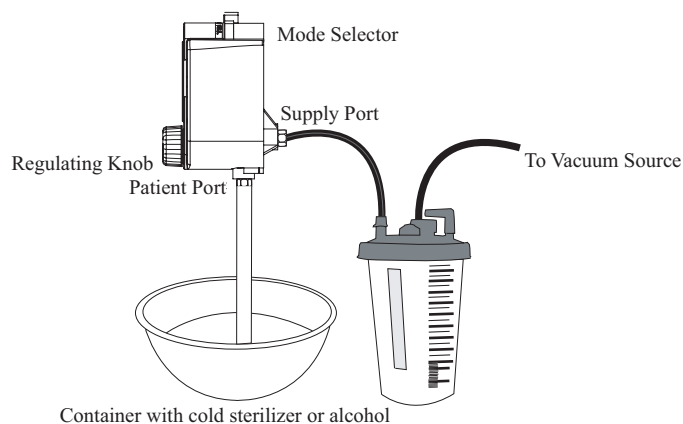
Cleaning Instructions

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 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 steps 3,4 & 5 for all modes of the Vacuum Regulator.
7. Repeat steps 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. in each mode with its patient port open to atmosphere to dry internal parts.

CAUTION: 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 the 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.



Recommended Maintenance:

The following are recommended maintenance steps that should be taken after each patient:

1. Clean the exterior of the vacuum regulator with a solution of a diluted mild detergent.
2. Make sure all secondary apparatus such as canisters and tubing are thoroughly cleaned.
3. Inspect the bacteria filter. If it has been contaminated replace with a new one.
4. Inspect the overflow safety trap to make sure it is free of any restrictions.

Replacement Parts

- VR-AG-100MM-WL Analog Gauge with Lens 100mmHg
- VR-AG-160MM-WL Analog Gauge with Lens 160mmHg
- VR-AG-200MM-WL Analog Gauge with Lens 200mmHg
- VR-AG-300MM-WL Analog Gauge with Lens 300mmHg
- VR-DG-100MM Digital Gauge with Lens 100mmHg
- VR-DG-160MM Digital Gauge with Lens 160mmHg
- VR-DG-200MM Digital Gauge with Lens 200mmHg
- VR-DG-300MM Digital Gauge with Lens 300mmHg
- VR-MOD-160MM Regulating Module Assembly for 0-160mmHg
- VR-MOD-300MM Regulating Module Assembly for 0-300mmHg
- VR-ORING-KIT-PI 1 Set of O-rings, Gaskets and Filters for all Pediatric & Neonatal Models. (PI, PP & NI, NN)
- VR-ORING-KIT-CI 1 Set of O-rings, Gaskets and Filters for Continuous/ Intermittent Models (CI & I2)

WARRANTY

Durring the term of your warrantry: 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.

The 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 INCLUSIVE 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.

Authorized Representative
in the European Union:



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