ACARE

VRF Series - French model

Suction Regulator

OPERATING AND MAINTENANCE MANUAL

IMPORTANT

PLEASE READ THOROUGHLY AND FOLLOW DIRECTIONS CAREFULLY BEFORE OPERATING EQUIPMENT.

CE 2460 FDA **GMP** ISO 13485 CERTIFIED

CAUTION

* The Law (R.O.C.) restricts this devise to be sold to physician or on the order of a physician.

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 model incorrect, do not use it and 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 Acare Warranty, repair of this device is not to be performed by anyone other than an Acare trained professional and done in strict accordance to the to the written instructions provided by Acare. 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. Removing product from storage, allow the product to stand at room temperature for a while. This will ensure the product working at the best condition.

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 for properly trained Acare representatives. DO NOT change, alter or modify intended use of the product.

Suction Regulator Model	*Gauge Range*	*Gauge Accuracy Analog*
High	*0-760 mmHg*	*+/- 3% F.S.*
Standard	*0-400 mmHg*	*+/- 3% F.S.*

Flow rates	*Standard*
Continuous	*0-80 LPM*

Operation

It is very important to keep product 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.
Operation Environmental limits: - 18ºC ~ 50ºC
Recommended Environmental operation limits: 15ºC ~ 29ºC
Storage Environmental limits: -40ºC ~ 60ºC
Humidity: Max 95 % non condensing

Equipment Setup

Depending on the desired location of the regulator, connect the vacuum adapter directly into the wall outlet, or connect one end of a vacuum hose assembly to the supply port of the suction regulator and the other end to 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 Suction Regulator and canister.
To prevent possible contamination of the regulator, a high flow suction filter of an overflow safety trap provided by Acare is recommended between the regulator and the collection canister.

Selecting the Mode

Green: Maximum vacuum is administered to patient

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

Procedures Prior to Use List

WARNING: The following checklist must be done prior to use on each patient. If the Suction 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.
Link the vacuum tubing to block the outlet.
There should be no movement of the gauge needle.

2. Link vacuum tubing and set the vacuum level.

Regulator Setting

Standard: increase the vacuum to - 12kPa (-90 mmHg)
High: increase the vacuum to - 53kPa (-400 mmHg)

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

Standard Continuous and High Vacuum

Please follow steps based on mode type

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

1. Move the selector switch to the “FULL” position. Link the vacuum tubing and ensure that the vacuum gauge is reflecting the maximum suction available.

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

WARNING: Always verify vacuum setting prior to performing any procedure.

CAUTION: When the collection canister is full , Do NOT operate the Suction Regulator.
The WARRANTY WILL BE VOIDED if the canister overflows and contaminates the Suction Regulator.
Always make sure the vacuum level is zero under “REG” position before / after using it.

Setup for Patient Use

1. Ensure that the Procedures Prior to Use List has been completed.
2. Move the selector switch to the “OFF” position and link the vacuum tubing.
3. Set the required vacuum level.
4. Always occlude the regulator when setting the prescribed vacuum level so that the patients do not receive higher vacuum level than required.

⚠ **WARNING:** The vacuum tubing must be linked 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.

Cleaning Instructions

1. Connect the supply port of the Suction Regulator to the patient port of a collection canister.
2. Attach the vacuum port 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 100 cc of a cold sterilant.
4. Fully increase the regulating knob of the Suction Regulator (clockwise).
5. Repeat steps 3,4 & 5 for all modes of the Suction Regulator.
6. Repeat steps 3,4 & 5 using 100cc of isopropyl alcohol to purge the Suction Regulator of the sterilant.
7. 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 Suction Regulator becomes contaminated internally, warranty is voided.
Do not send Suction 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 Suction Regulator with a solution a diluted mild detergent.
2. Make sure all secondary apparatus such as canisters and tuning are thoroughly cleaned.
3. Inspect the bacteria filter. If it has been contaminated replace with a new one.
4. Inspect the overflow safety to make sure the safety trap is free of any restrictions.

MRI WARNING: This product contains magnetic, ferrous material that may affect the result of an MRI, unless the Regulator is ordered as MRI conditional.

DISPOSAL INSTRUCTIONS

Dispose of the Product in accordance with the local regulators.

Please Recycle

⚠ **WARNING**
Product should be cleaned before being disposed of. Potential for Biohazard.

TROUBLESHOOTING

If the Suction Regulator fails to function, consult the Troubleshooting Table below. If problem cannot be solved, consult your Provider.

Problem	Probable Cause	Remedy
No Vacuum at bottom port (gauge at zero)	1. Regulator turned “OFF” 2. Loose connection 3. No vacuum to Regulator 4. Clogged vacuum Port	1. a. Turn selector knob 1. b. Adjust Regulator Knob 2. Tighten connection 3. Connect to a known working vacuum source 4. Disassemble & clean
No vacuum at bottom port (gauge showing vacuum)	1. Clogged Regulator	1. Disassemble & clean
Vacuum at bottom port (No reading on gauge when port is blocked)	1. Defective Gauge	1. Replace Gauge
Gauge will not return to zero	1. Clogged Snubber 2. Damaged Regulator Module 3. Defective Gauge	1. Replace Snubber 2. Replace Regulator Module 3. Replace Gauge
Vacuum Regulator erratic	1. Dirty Regulator Module 2. Defective Regulator Module	1. Disassemble & clean, Lubricate O-ring 2. Replace Gauge
Stiff movement of Selector Knob	1. Dirty Regulator Module and/or Selector Module	1. Disassemble & clean, Lubricate O-ring

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