Operation and Maintenance Manual for GENTEC® Model 881VR Continuous/Intermittent Digital Suction Regulators

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CAUTION: United States Federal law restricts this device to sale by or on the order of a physician.

IMPORTANT SAFETY INSTRUCTIONS.

READ AND UNDERSTAND THESE INSTRUCTIONS COMPLETELY BEFORE OPERATING THIS EQUIPMENT.

If you do not understand any of these instructions, or if you have any questions regarding the use of this product, please contact your facility's training manager, your supervisor, the medical equipment dealer from whom the product was purchased, or the manufacturer before operating the equipment.

Do not attempt to repair this device if you have not been properly trained. Doing so may create a hazardous situation that may result in death or serious injury. Attempted repair by anyone other than a duly authorized repair/service center of Genstar Technologies Co., Inc. voids any and all warranties, express or implied.

Carefully inspect and test this product before each use to ensure proper operation. Do not use the product if there are signs of damage or if it does not pass the initial suction test.

Should this product require repair or service that will require shipping the product to another location, bear in mind that United States Federal law restricts the shipping of contaminated products. Refer to DOT regulations for additional information.

Genstar Technologies Co., Inc. (GENTEC®) manufactures continuous/ intermittent digital suction regulators in two ranges, 0 to 160mmHg (881VR-160) and 0 to 300mmHg (881VR-300). These suction regulators provide three modes: CONT (continuous regulated vacuum), OFF (no vacuum) and INT (intermittent regulated vacuum). Please take a few minutes to familiarize yourself with the product by reviewing Figure 1 on the next page.

The mode is selected by moving the lever at the top of the regulator to the left (CONT) for continuous suction, the center (OFF) to turn off the regulator, or the right (INT) for intermittent suction.

The **CONT** mode provides continuous regulated suction levels as set by the user. The suction level is set by occluding the suction tubing, then adjusting the regulator knob on the front of the suction regulator to achieve the desired suction level, up to the designed range. Suction is increased by turning the regulator knob clockwise, decreased by turning it counter-clockwise.

The **OFF** mode turns off the suction regulator, allowing no suction at the tubing. The **INT** mode provides intermittent regulated suction levels as set by the user. The suction level is set by occluding the suction tubing, then making sure the

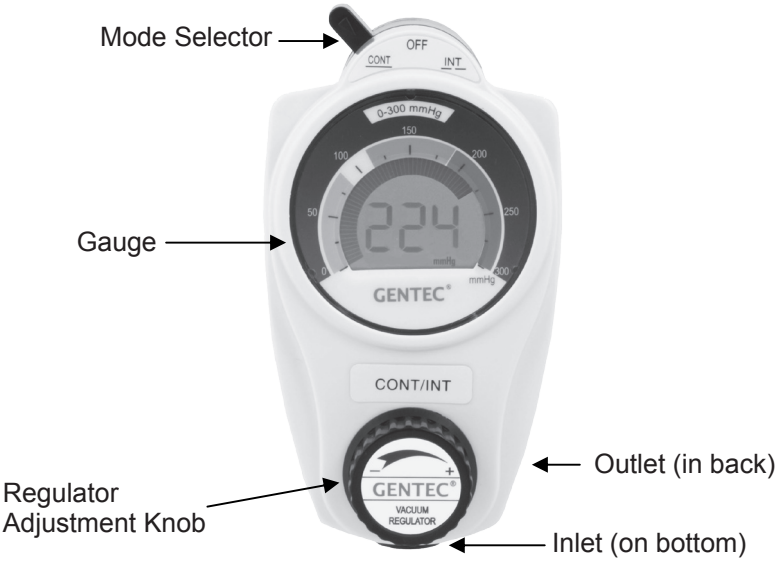


Figure 1 - Main Features

regulator is in the ON cycle. This could take up to 10 seconds. When the regulator begins the ON cycle, adjust the regulator knob on the front of the suction regulator to achieve the desired suction level, up to the designed range. Suction is increased by turning the regulator knob clockwise, decreased by turning it counter-clockwise.

A suction filter or vacuum trap assembly (GENTEC catalog #880VT) should be used to prevent aspirate from entering the suction regulator. Typically, the suction catheter is connected to the suction tubing, which is then connected to the inlet fitting on the suction canister.

The canister can be connected directly to the suction regulator via DISS connection, or, as is recommended, connected to a filter or vacuum trap, which is then connected to the suction regulator via direct, threaded connection, suction tubing, or DISS connector (see Figure 2).

The appropriate outlet connector (located on the back of the suction regulator) must be used for connection to the wall inlet. The use of converting adapters (e.g., DISS connection to Ohio connection) should be avoided. If the suction regulator is connected via tubing or hose assembly to the wall inlet (as occurs when the suction regulator is attached to a mobile stand), a minimum inside hose diameter(ID) of 5/16” (7.9mm) should be used to prevent loss of flow.

DO NOT connect the suction tubing directly from the patient to either the vacuum trap assembly or the suction regulator. Doing so may permanently damage the suction regulator and void any and all warranties, express or implied.

A collection canister (reusable or disposable) **MUST** be used between the patient and the suction regulator or vacuum trap, if used. If a vacuum trap is not used it is recommended that a disposable hydrophobic bacterial filter be used between the suction canister and the suction regulator to prevent overflow of the canister into the suction regulator. Use of these filters may also prevent build up of aerosolized particulate inside the suction regulator, thus reducing maintenance requirements and extending the life of the unit.

VERIFYING REGULATOR OPERATION

NOTE: The proper operation of the suction regulator must be verified prior to each use. Should the regulator not operate in accordance with the following, it must be repaired by authorized personnel.

1) Ensure that the Mode selector is in the OFF (center) position.
2) Connect the regulator to a vacuum source (normally the wall-mounted inlet).
3) Occlude the regulator inlet, and turn the adjustment knob one full turn clockwise.
4) Verify that the gauge needle does not move from the “0” position.
5) Move the Mode selector to the “CONT” position.
6) Occlude the regulator inlet, and turn the adjustment knob counter-clockwise until the gauge needle is at 0.
7) Keeping the inlet occluded, turn the adjustment knob clockwise. The gauge needle should move in a clockwise direction, indicating an increase in the vacuum level. Turning the adjustment knob counter-clockwise should reduce the vacuum level, with the gauge needle moving counter-clockwise.
8) Occlude the regulator inlet. The regulator should begin the ON cycle within 10 seconds, and the gauge needle should read the same as the previous setting.
9) The unit should remain the ON cycle for 14-18 seconds, then turn OFF for 6-10 seconds, then back on for 14-18 seconds. Verify one complete cycle.
10) Move the Mode selector to the “OFF” position. The needle should return to 0.

If the regulator passes all of the above, it is ready for patient use. Failure of any of the above requires that the unit be serviced by authorized personnel.

Once the operation of the regulator has been verified, it can be prepared for patient use as follows:

1) Connect the regulator to the wall inlet, ensuring proper latching.
2) Move the Mode selector to “CONT” or “INT”.
3) Occlude the inlet or tubing.
4) Adjust the regulator knob to achieve the desired level of vacuum.
5) Attach the suction catheter and proceed.

NOTE: the suction regulator should always be turned OFF when not in use. This will prevent placing undo demands on the facility’s central vacuum system.

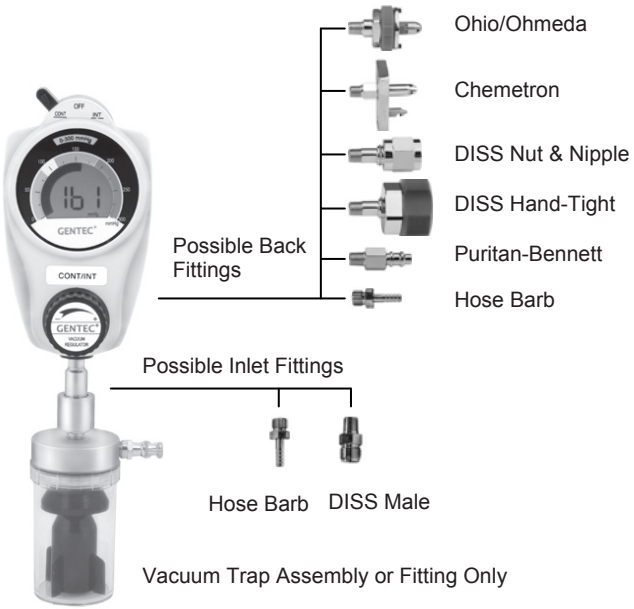


Figure 2 - Suction Regulator Configurations

DO NOT connect suction tubing directly to the vacuum trap, filter or suction regulator!

881VR Disassembly Instructions:

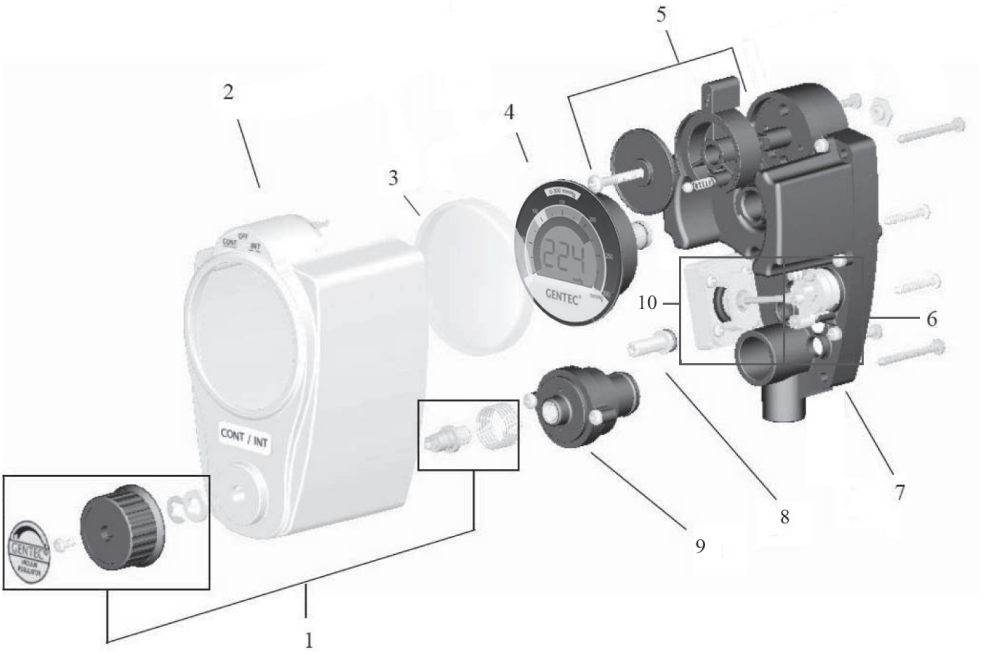
1) Disconnect the 881VR from the suction source.
2) Sterilize the suction regulator using ETO or autoclave, for self-protection.
3) Remove the four screws marked by arrows on the back of the unit.
4) Turn the regulator adjustment knob counterclockwise to release the faceplate.
5) The gauge can be gently lifted out of the socket.
6) The regulator can be gently lifted out of the socket.
7) One screw holds the Mode selector lever in place.

Reassembly is accomplished by performing the above steps in reverse order. DO NOT OVERTIGHTEN THE SCREWS WHEN REPLACING.

The timing of the intermittent mode can be adjusted by removing the T_0 and T_1 - T_2 covers. The T_0 valve controls the OFF time, and the T_2 valve controls the ON time. These timers should only be adjusted by authorized personnel, at the direction of a physician. Refer to GENTEC publication #881VR-TIMING for additional information regarding timing adjustment.

The regulator can be cleaned by wiping the outside surfaces with disinfectants, Virox (accelerated hydrogen peroxide), Clorox (sodium hypochlorite), and Cavi-wipes. The internal flow path can be cleaned by suctioning a cold sterilant through the unit, then allowing the unit to run for 30-45 minutes to dry the interior.

Repair assemblies can be purchased from your Authorized GENTEC distributor, refer to the exploded view on page 5 for the parts list. All parts are sold in kits of 6.



No.	Part No.	Description	Qty/Kit
1	881VR-K01	Adjustment Knob Assembly	6
2	881VR-K02	Front Cover	6
3	881VR-K04	Lens	6
4	881VR-K05	Gauge, 881VR-K05-D160	6
	881VR-K05A	Gauge, 881VR-K05-D300	6
5	881VR-K07	Selector Knob Assembly	6
6	881VR-K09	Drive Plate Assembly	6
7	881VR-K10	Back Body	6
8	881VR-K06	Relief Valve, 0-160 mmHg	6
	881VR-K06A	Relief Valve, 0-300 mmHg	6
9	881VR-K03	Regulator Assembly, 0-160 mmHg	6
	881VR-K03A	Regulator Assembly, 0-300 mmHg	6
10	881VR-K08	Timer Assembly	6
Not Shown	881VR-K11	Timing Needle Valve Assembly (2 per suction regulator)	6
Not Shown	881VR-K12	Timer Cap, T_0	6
Not Shown	881VR-K13	Timer Cap, T_1, T_2	6

#	Problem	Probable Cause		Corrective Measures
1	The vacuum gauge needle does not move off “0” when regulator is connected to vacuum source.	The regulator is in the “OFF” mode, or is not fully in the “CONT” or “INT” position.		Move the mode selector to the “CONT” or “INT” position.
		The suction regulator is in the “INT” position, and has started in the “OFF” cycle.		Wait 8-10 seconds for the “ON” cycle to start.
		The adjustment knob is in the fully counter-clockwise, closed, position.		Turn the adjustment knob clockwise to open.
		The collection bottle or suction tube is leaking.		Check the collection bottle and tubing for leaks.
2	The vacuum regulator gauge shows a reading but there is no suction at the tubing.	The collection bottle is too full, causing the float to shut off the suction.		Empty the collection bottle.
		The filters or suction tubing are clogged.		Change the filters and tubing.
3	Under the regulator cannot reach the specified suction level (i.e., 120mmHg or 240mmHg, depending upon model).	Suction source cannot provide sufficient suction.		Increase source equipment vacuum settings.
		Regulator Internal Problems	Relief valve (F) is damaged.	Replace relief valve.
			O-ring on vacuum gauge (B) is damaged.	Replace o-ring.
			O-ring in regulator assembly (E) is damaged.	Replace o-ring.
			Regulator assembly (E) is damaged.	Replace regulator assembly.
			Mode selector assembly (H) is loose.	Tighten or replace mode selector assembly.
4	Under REG mode the suction is too strong and cannot be reduced	Gas assist port (6) is clogged.		Clean gas assist port.

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Form No. 9-OM-881VR/0812