05/26/2017

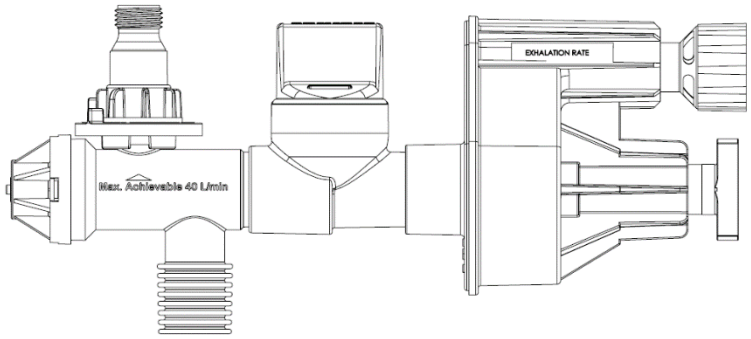
USER'S GUIDE

GO_2VENT™

VORTRAN® Automatic Resuscitator with Manometer

Unique single patient, multiple-use disposable emergency resuscitator

VORTRAN® GO_2VENT™ for patient body weight of 10 kg and above



Model 6123

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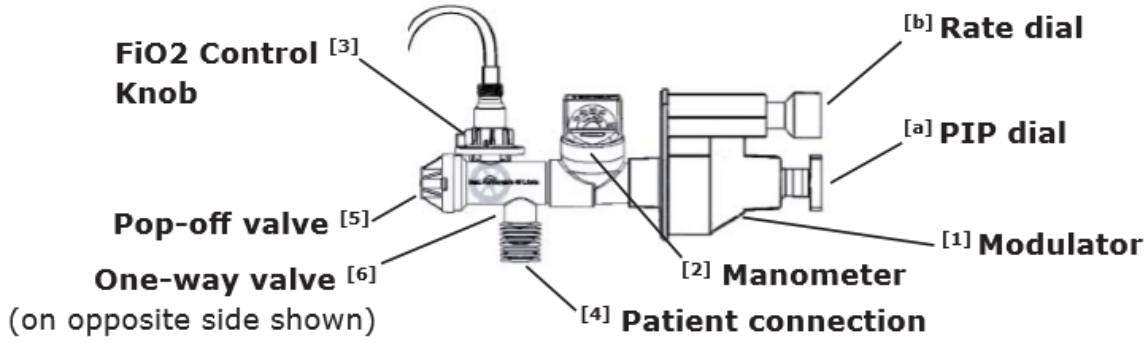
I. Functional and Operational Characteristics

The gas-powered GO_2VENT™ provides constant flow, pressure cycled automatic ventilatory support for both breathing and non-breathing patients. The primary working mechanism of the GO_2VENT™ (refer to Figure 1) is the [1] modulator with [a] peak inspiratory pressure (PIP) and the [b] breathing rate adjustment dials, which includes an exhalation valve that opens at one pressure (PIP) and closes at another lower pressure (PEEP). The remaining components of the GO_2VENT™ consist of the [2] pressure manometer, [3] FiO_2 Control Knob, [4] patient connection port, [5] redundant pressure pop-off valve, and [6] one-way valve for entraining additional air.

The pulmonary modulator provides the actual ventilatory support. The primary working mechanism of the pulmonary modulator is the diaphragm. The diaphragm is spring loaded, designed like a pressure pop-off valve except the spring force is adjustable (the [a] PIP Dial).

Figure 1

GO_2VENT™ Component Description



OPERATIONAL CHARACTERISTICS	
Recommended body weight	10 Kg and above
Ventilatory frequency	Auto-adjusting to lung capacity
Adjustable PIP range	10 to 45 cm H_2O
PEEP	1/5th of PIP (2 to 9 cm H_2O)
Inspiratory resistance	3 ± 1 cm H_2O / L/ sec
Expiratory resistance	3 ± 1 cm H_2O / L/ sec
Dead space	4 ± 3 mL
Operating environmental limits	-18 to 50 ^oC
Storage environmental limits	-40 to 60 ^oC
Patient connection	Ø15 mm female, Ø22 mm male
Gas inlet	DISS gas connection
Oxygen delivery	>85% O_2 when supplied with 100% O_2

II. Clinical Considerations

The GO_2VENT™ provides short term, pressure cycled, and constant flow ventilatory support for either breathing or non-breathing patients. This allows the patient to receive consistent and reliable ventilatory support. Because the GO_2VENT™ is pressure cycled, changes in the patient's lung compliance will cause a change in the patient's breathing rate. The GO_2VENT™ is positional sensitive. **Final adjustments should be made with the GO_2VENT™ in its secured operating position.** The GO_2VENT™ is pressure cycled on inhalation and exhalation (PIP and PEEP) which minimizes the possibility of gas trapping. During inhalation, exhalation will not start until PIP is reached. During exhalation, inhalation will not begin until pressure drops to PEEP. For the spontaneously breathing patient, the rate dial of the GO_2VENT™ is set so the baseline pressure is above the intrinsic PEEP allowing the patient to initiate inhalation by drawing the baseline pressure down to the set PEEP. Because the GO_2VENT™ is a constant flow pressure cycled device, changes in patient compliance will result in changes in the respiratory rate (stiffer or smaller compliances produce faster rates). The advantage of this minimizes the danger of barotrauma. It should be emphasized that the GO_2VENT™ is to be used only by trained personnel who continuously monitor the patient. The GO_2VENT™ is not an ICU stand-alone ventilator with multiple monitoring features.

Setup and use of the GO_2VENT™ is simple (refer to Setup Instructions in Section III on page 7). Set desired flow (**Q**), adjust PIP pressure dial to obtain desired inspiratory time ($\mathbf{t_{insp}}$) to attain tidal volume ($\mathbf{TV = Q \times t_{insp}}$ see Tidal Volume Table 1). The gas flow, patient's lung compliance, and PIP settings control the inspiratory time and tidal volume. Then adjust rate dial to obtain desired breathing rate.

Table 1 – Estimated Tidal Volume (mL) Delivered at Various Flow (L/min) and Inspiratory Time (Seconds)

Flow (L/min)	Inspiratory Time (Seconds)					
	0.5	1	1.5	2	2.5	3
15	125	250	375	500	625	750
20	167	333	500	667	833	1000
25	208	417	625	833	1042	1250
30	250	500	750	1000	1250	1500
35	292	583	875	1167	1458	1750
40	333	667	1000	1333	1667	2000

II. Clinical Considerations (continued)

The GO_2VENT™ runs on a continuous gas flow (inspiratory flow) of 6 to 40 L/min depending on patients' inspiratory flow demand. When connected to a 50 PSIG gas source, the GO_2VENT™ will automatically deliver 40 L/min (667 mL/second) per ASTM Guideline[1]. Delivered tidal volume may be determined by multiplying the flow in mL/second and the inspiratory time in second, or by using the estimated tidal volume table.

The rate dial controls exhalation time (t_{exhl}), and when dialed down enough will cause the GO_2VENT™ to stop cycling automatically (infinite exhalation time). Under these circumstances, the GO_2VENT™ is delivering pressure supported ventilatory support and the patient must trigger the GO_2VENT™ to begin subsequent full inhalations. If the patient is apneic or pressure control ventilation is desired, restart automatic cycling of the GO_2VENT™ by adjusting the rate dial counterclockwise until cycling begins again. Whenever the GO_2VENT™ stops cycling, the first step in the absence of obvious clinical factors, is to check if it is in pressure support mode by rotating the rate dial counter clockwise (out). If rotating the rate dial counter clockwise substantially (3 or 4 turns) does not start automatic cycling, the patient's airway may be occluded or a very large leak exists.

The PIP may be adjusted from 10 and 50 cm H_2O. The PEEP is intrinsic to the device which ranges from 2 to 9 centimeters and is directly proportional to the set PIP. Inspiratory time and rate are adjustable over a wide range. Changes in the PIP setting or flow will also affect the respiratory rate. It is important to check all settings when making a change to any of these three variables (flow, PIP and rate). For example: reducing the PIP setting may cause the GO_2VENT™ to go into spontaneous breathing mode. Adjust the rate dial out (counter-clockwise) to restart automatic cycling.

The GO_2VENT™ is equipped with an air entrainment valve which allows the patient to entrain additional air and respond to the demands of the patient. Patient entrainment of outside air is normally audibly detectable and the percent oxygen delivered to the patient will be reduced. Specific concentrations of oxygen may be delivered to the patient with the use of an oxygen blender.

Although the design of the modulator is similar to that of a pop-off valve and is inherently safe, the GO_2VENT™® is also equipped with a redundant pop-off valve that relieves pressure at 60 cm H_2O. When the pop-off valve is activated, the pop-off valve piston will be seen to open slightly and excess pressure released.

[1] Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans, ASTM Designation: F 920 – 93.

II. Clinical Considerations (continued)

Although peak pressures are listed on the side of the pressure dial, they are only approximate. Clinicians using the GO_2VENT™ are still required to use good clinical judgment and monitor the patient appropriately. A manometer may be connected between the modulator and the patient connector tee.

The GO_2VENT™ is pressure cycled on PEEP as well as PIP. In the pressure control mode, there is no prolonged stage where the flow of exhalation gas stops for a significant duration of time (in the pressure support mode, exhalation time is determined by the patient). This occurs because the exhalation time is set with the rate dial by varying the exhalation resistance so the patient just finishes exhalation with the beginning of the subsequent inhalation. The volume of gas with which the patient's lungs are inflated when reaching PEEP is the same as with any other means of obtaining PEEP. As with all ventilatory support modes, short exhalation times on patients with high airway resistance may lead to gas trapping which is not detectable in the patient's external airways. Upon occlusion of the patient's airways, the GO_2VENT™ will stop cycling or may sometimes cycle rapidly.

The GO_2VENT™ will work with any mask that provides a good seal with the patient. All clinicians should receive adequate training on the GO_2VENT™ with a mask prior to use. In the presence of a small leak, the GO_2VENT™ will still cycle between PIP and PEEP. Noticeable changes in the presence of a leak are increased inspiratory times and decreased expiratory times. The GO_2VENT™ works very well with an endotracheal tube.

Inhalation may be initiated by briefly removing the mask from the patient or briefly disconnecting the modulator from the patient adapter tee. In either event, inhalation begins because pressure has dropped down to PEEP and the GO_2VENT™ is pressure cycled.

Upon contamination of the GO_2VENT™ with vomitus, it may be cleared by disconnecting the modulator from the patient connector tee (see enclosed instructions) and tapping out vomitus on a hard surface. Additionally, if needed, the rate dial may also be removed to facilitate removal of vomitus from modulator. This operation should take less than 20 seconds, and in a lab setting has consistently been shown to take approximately 11 seconds. Alternatively, upon contamination with vomitus, the clinician may choose to discard the device and use a new one.

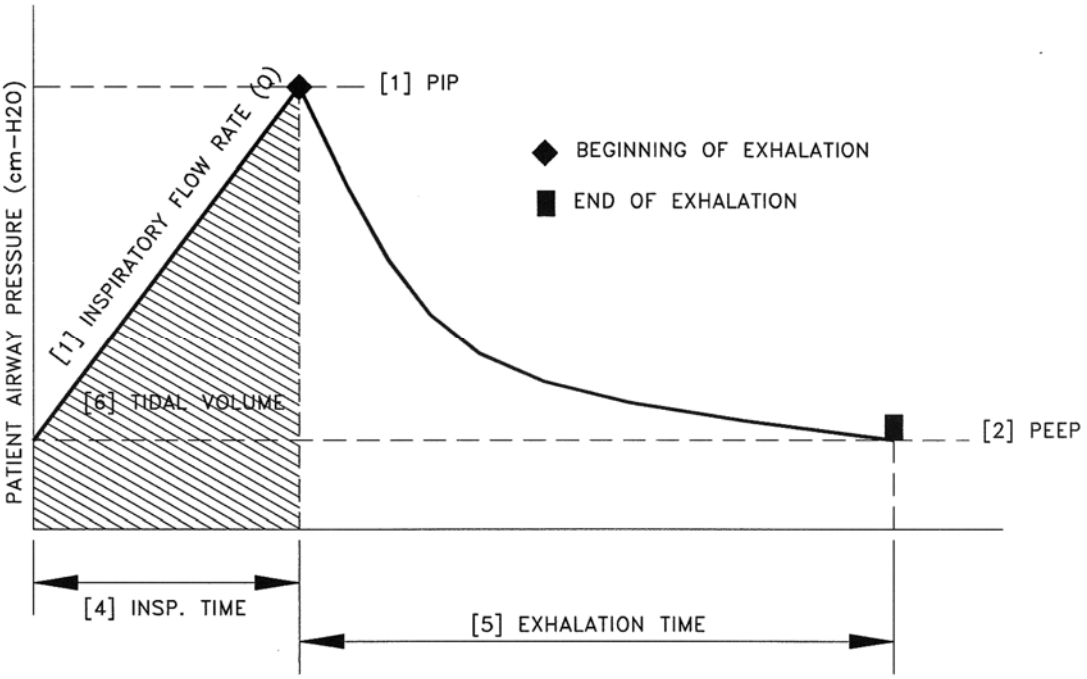
Inhalation and exhalation are audibly detectable and easily recognizable during operation of the GO_2VENT™.

II. Clinical Considerations (continued)

The GO_2VENT™ may be controlled remotely by connecting any length of 22-mm corrugated tubing between the patient connector tee and the modulator. The attached tubing will not increase the dead space, the modulator is an exhalation control valve, and inspiratory gas is delivered through the patient connector tee.

The primary advantage of the GO_2VENT™, as compared to manual resuscitators, is the ability to deliver consistent, reliable, and hands free resuscitation. Manual resuscitators may have adverse effects on patients as a result of inconsistent ventilation (see Clinical Reference in Section VII).

Figure 2
Airway Pressures - PIP & PEEP



1 PIP – Set by **PIP DIAL**, controls INSPIRATORY TIME ($\mathbf{t_{insp}}$)
2 PEEP – Approximately 1/5th of PIP setting
3 INSPIRATORY FLOW RATE (Q) – Maximum 40 L/min (= 667 mL/sec)
4 INSPIRATORY TIME ($\mathbf{t_{insp}}$) – Time required to reach PIP
5 EXHALATION TIME ($\mathbf{t_{exhl}}$) – Time required to drop from PIP to PEEP
6 Tidal Volume = Q x $\mathbf{t_{insp}}$
7 RESPIRATORY RATE (RR) = 60 / ($\mathbf{t_{insp}}$ + $\mathbf{t_{exhl}}$)
8 RATE DIAL – Set exhalation resistance and change RR

III. Protocol: Setup Instructions - GO_2VENT™

Policy Number:	Institution:	Department:
Date Adopted:	Date Received:	Date Reviewed:
Approved by:	Name:	Title:

1.0 POLICY STATEMENT:

This policy/protocol is intended for use with patients requiring short-term ventilatory support while being monitored by a clinician trained in the use of mechanical ventilation.

2.0 PURPOSE:

To provide clinically appropriate recommendations and guidelines for the use of the GO_2VENT™ device, including clinical indications, device set-up, bedside application, potential hazards, and documentation.

3.0 DESCRIPTION:

The GO_2VENT™ provides short term, constant flow, pressure cycled ventilatory support in either pressure control or pressure support modes on patients weighing 10kg and above. In the pressure support mode, the rate dial of the GO_2VENT™ is set so that the baseline pressure is above the set PEEP allowing the patient to initiate inhalation by drawing the baseline pressure down to the set PEEP. The device includes the pulmonary modulator (an exhalation valve that opens at PIP and closes at PEEP) and a patient connector tee to supply gas flow, entrain additional air, and provides a redundant pop-off valve for patient care. The working mechanism of the GO_2VENT™ consists of a moving diaphragm which adds or subtracts spring force when it is moved from a horizontal to a vertical position, the addition or subtraction of spring force will affect the PIP setting by 1~3 cm-H_2O. The GO_2VENT™ will function in any position as long as the final adjustments are made in a secured position (strapped or taped to the patient).

4.0 PROCEDURE:

4.1 INDICATIONS

4.1.1 Patients in need of emergency, short term, constant flow, pressure cycled ventilatory support.

4.1.2 Patients unable to maintain an adequate acid-base status during unassisted ventilation.

4.2 CONTRAINDICATIONS

4.2.1 None.

III. Protocol: Setup Instructions - GO_2VENT™ (continued)

4.3 HAZARDS/PRECAUTIONS

4.3.1 The GO_2VENT™ should be used only by individuals who have adequate training in CPR techniques and the operation of gas-powered resuscitators.

4.3.2 Do not use grease or oil on the GO_2VENT™ for any reason.

4.3.3 Do not use the GO_2VENT™™ in oxygen deficient atmospheres or near open flames.

4.3.4 Do not smoke while using the GO_2VENT™ or any other oxygen equipment.

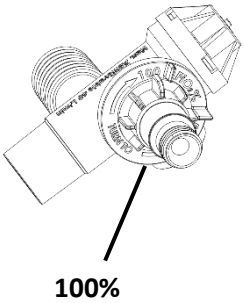
4.3.5 Do not dismantle or attempt to remove any components other than those required for routine operations. Any tampering with the GO_2VENT™ may cause the unit to malfunction, and will automatically void the warranty.

4.4 SET-UP INSTRUCTIONS

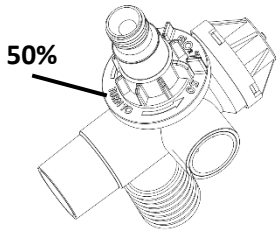
4.4.1 The GO_2VENT™ is suitable for patients weighing 22 pounds or 10 kilograms.

4.4.2 Select desired FiO2 delivery.

[a] If 100% FiO_2 is to be delivered to the patient, connect tubing to the white gas connector with the DISS thread connection on the patient tee. Ensure that the green knob is turned **clockwise** until it comes to a stop.



[b] If 50% FiO2 is to be delivered to the patient, connect tubing to the white gas connector with the DISS thread connection on the patient tee. Ensure that the green knob is turned **counterclockwise** until it comes to a stop.

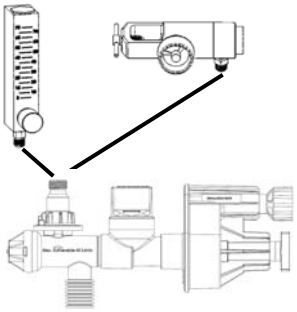


ENTRAINED FLOWCHART

50% connector		Total delivered flow (L/min)
Supply flow (L/min)	Entrained flow (L/min)	
6	14	20
8	17	25
10	20	30
12	23	35
15	25	40

III. Protocol: Setup Instructions - GO_2VENT™ (continued)

4.4.3 **STEP [1]**: **Set flow to 10-25 L/min**



Remove the GO_2VENT™ from package and connect the supply tubing to either an appropriate cylinder or wall source. A good starting point is 10 L/min. Adjust as needed. See **ENTRAINED FLOWCHART** for "Total delivered flow" requirements. The GO_2VENT™ is designed to automatically deliver 40 L/min when connected directly to a 50 PSIG gas source.

Note: For better flow control, a flowmeter capable of 40 L/min is preferred. The flow controls the inspiratory time – the higher the flow, the shorter the i-time; the lower the flow, the longer the i-time.

Note: If using an orifice-type flow regulator that is common to most cylinders, you will only be able to provide as much flow as the regulator indicates. If the regulator being used has a high flow port connection and you connect the GO_2VENT™ to this port, you will automatically get 40 L/min.

Note: The GO_2VENT™ is completely gas driven, requiring no electrical power and will deliver 100% oxygen to a patient.

Note: The duration of an "E" cylinder when using the GO_2VENT™ will depend on the flow. An "E" cylinder contains 625 L of gas. At 40 L/min, 625 L will last up to 15 minutes; at 20 L/min, 625 L will last up to 30 minutes. 15 L/min orifice type flowmeters used on many "E" cylinders will not be able to deliver more than 15 L/min. When clinicians decide that 15 L/min is not sufficient flow, the GO_2VENT™ can be attached to a regulator that has a high flow port (50PSIG) to deliver 40 L/min. The length of use for various sizes of compressed oxygen tank (D, E, M & H) is a function of supplied oxygen flow from 6 to 40 L/min to GO_2VENT™ (see Table 1 below).

TABLE 1 - LENGTH OF USE FOR COMPRESSED OXYGEN TANKS

Tank	D	E	M	H
(Liters)	387	662	3028	6905
Flow (L/Min)	Length of use (minutes)			
6	65	100	500	1150
8	50	80	380	860
10	40	60	300	690
12	30	50	250	570
15	25	40	200	460
20	20	30	150	340
25	15	25	120	270
30	13	20	100	230
35	11	18	80	190
40	10	16	70	170

III. Protocol: Setup Instructions - GO_2VENT™ (continued)

4.4.4 STEP [2]: Verify PIP ~25 cm-H2O

The second step in setting up the GO_2VENT™ is to set the patient's Peak Inspiratory Pressure, or PIP. Verify PIP pressure at approximately 25 cm-H2O (factory pre-set). Adjust pressure dial to achieve desired peak pressure. Adjust the pressure dial to the desired setting.

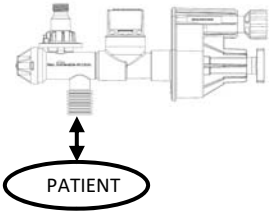
Note: Indicated pressures are approximate and may vary depending on conditions and settings. Verify with a manometer.

Note: Indicated peak pressure is printed on the pressure dial. PEEP is about 1/5th of set PIP. Indicated pressures are approximate and depend on conditions and settings. Verify with a manometer by connecting between modulator and patient connector. I-time is counted off manually (1-1000, 2-1000, ...) or with a watch.

PIP Label

Note: Typical required supply pressure is 45 to 55 PSIG. Supply pressures from 39 to 80 PSIG may be used if the flow is adjusted to 40 L/min ± 10%. The GO_2VENT™ will deliver 40 L/min against a patient pressure of 20 to 40 cm-H2O when connected directly to a 50 PSIG source. Lower flows are obtainable with flowmeter adjustment. Use minimum flow of 10 L/min for best results.

4.4.5 STEP [3]: FUNCTION CHECK - CONNECT TO PATIENT

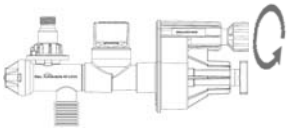


Once your flow and pressure have been set, perform a function check on the unit before connecting it to the patient. This is accomplished by occluding the patient connection port and verifying that the modulator opens and the pressure does not exceed 60 cm-H_2O.

Note: It is very important to be trained in the correct application of the face mask before any attempt is made to use the GO_2VENT™.

Note: For use with a mask, clear mouth and airway of visible foreign bodies and use accepted techniques to ensure correct position of airway. Hold mask firmly against face ensuring a tight seal while keeping head in correct position. For use with endotracheal tube, connect patient adaptor directly to endotracheal tube.

4.4.6 STEP [4]: ADJUST RATE



Adjust rate dial to achieve desired respiratory rate. The GO_2VENT™ may be set in a spontaneous pressure support mode by

III. Protocol: Setup Instructions - GO_2VENT™ (continued)

adjusting rate dial clockwise until mandatory rate stops. To return to automatic cycling, rotate rate dial counterclockwise until desired respiratory rate is achieved.

Note: Observe rise and fall of the chest corresponding to patient's inhalation and exhalation. Listen for expiratory flow from modulator. Listen to chest sounds.

Note: If patient vomits, disconnect patient adaptor from modulator and remove rate dial if necessary. Tap out vomitus on hard surface to dislodge and reassemble. Clear patient's airway and reconnect. Clearing procedure should take less than 20 seconds. Check that inhalation and exhalation occur without obstruction.

Note: The GO_2VENT™ is pressure limited and is equipped with a redundant pressure pop-off valve which will activate at a maximum of 60 cm-H_2O.

Note: Changes in patient's lung compliance will result in respiratory rate changes. In such an event, make appropriate clinical changes.

Note: If patient draws air through entrainment port or device is set to FiO_2 of 50%, oxygen concentration delivered to patient may differ from concentration at gas inlet of patient connector.

Note: Perform a FUNCTIONAL CHECK by occluding patient port with supply gas flowing and verify that pressure DOES NOT EXCEED 60 cm-H_2O.

Note: Gas supply source must be capable of delivering up to 40 L/min. Typical required supply pressure is 50 ± 5 PSIG. Supply pressures from 12 to 80 PSIG may be used if the flow is adjusted between 6 to 40 L/min (±10%).

Note: The GO_2VENT™ will deliver 40 L/min against a patient pressure of 20 to 40 cm-H_2O when the green knob is turned all the way clockwise and is connected directly to a 50 PSIG source. Lower flows are obtainable with flowmeter adjustment.

Note: The GO_2VENT™ will deliver FiO2 of 50% (±10%) when the green knob is turned all the way counterclockwise and is supplied with oxygen flow from 6 to 15 L/min with resulting output flow of 20 to 40 L/min respectively (see "ENTRAINED FLOWCHART").

4.4.7 STEP [5]: Adjust Flow, PIP and Rate

Observe the rise and fall of the chest corresponding to inhalation and exhalation of patient. Listen for expiratory flow from modulator. Listen to breath sounds of patient. There is no substitute for a good clinical assessment.

IV. CAUTIONS AND WARNINGS

CAUTIONS
Federal law restricts the use of this device to sale by or on order of a physician (or properly licensed practitioner).

WARNINGS
1. The GO_2VENT™ should be used only by individuals who have adequate training in CPR techniques and in the operation of gas powered resuscitators. 2. Do not reuse - Risk of cross-contamination. 3. Do not use grease or oil on the GO_2VENT™ for any reason. 4. Spontaneously breathing patients may entrain ambient air. 5. Supply pressure of 39 to 80 PSIG must be adjustable to 40 L/min. 6. Redundant pop-off valve is set at 60 cm-H_2O. 7. Do not use the GO_2VENT™ in oxygen deficient atmospheres or near open flames. 8. Do not smoke while using the GO_2VENT™ or any other oxygen equipment. 9. Do not dismantle or attempt to remove any components other than those required for routine operations. Any tampering with the GO_2VENT™ may cause the unit to malfunction and will automatically void the warranty. 10. US FDA restricts the use of this device by sale by or on order of a physician (for properly licensed practitioner).

PRECAUTIONS
1. Patients connected to this device are to be monitored continuously by persons having adequate training. **Do not leave patients unattended.** 2. When ventilating an intubated patient, higher pressure release settings may be required. Select a pressure setting of 35 cm-H_2O to start and adjust if necessary. 3. An audible, rapid clicking sound and rapid movement of the diaphragm in the modulator indicates airway obstruction. Clear the airway and resume the ventilation procedure. 4. Positive End Expiratory Pressure (PEEP) is intrinsic to this device. PEEP is usually 1/5th PIP and will range from 2 to 9 cm-H_2O depending on pressure settings. Verify actual PEEP with a manometer. 5. For a minute ventilation of 10 L/min and an I:E ratio of 1:1: [a] at 100% FiO_2 setting - the GO_2VENT™ will operate for 30 minutes (± 10%) with an output and supply flow rate set at 20 L/min on an "E" cylinder volume of 625 liters, [b] at 50% FiO_2 setting - the GO_2VENT™ will operate for 100 minutes (± 10%) with an output flow rate of 20 L/min and supply flow rate set at 6 L/min on an "E" cylinder volume of 625 liters. 6. Please review and follow the instructions and observe the warnings before using the GO_2VENT™. 7. If the use or operation of the GO_2VENT™ is unclear, contact your distributor or dealer for clarification. 8. GO_2VENT™ is a resuscitation management system and should not be used as an unattended automatic ventilator.

V. GO_2VENT™ COMPETENCY

How to set up your ventilator dependent patient using the GO_2VENT™, a fully automatic disposable ventilator that operates with compressed gas.

Objectives

1. To be able to set up the GO_2VENT™.
   a. Setting the required flow for FiO_2 100% or 50%
   b. Getting the PIP and PEEP from the manometer
   c. Adjusting the respiratory rate
   d. For non-breathing and spontaneous breathing patient

2. 2. To be able to troubleshoot and correct any problem that may arise with the use of the GO_2VENT™.
   a. Gas consumption during use
   b. What is happening if it stops cycling while adjusting the rate dial

Troubleshooting

1. I can set a constant respiratory rate and tidal volume with the GO_2VENT™.

   [ ] True [ ] False

2. With the GO_2VENT™, compliance has a direct effect on the respiratory rate and volumes being delivered to your patient.

   [ ] True [ ] False

After completion of the GO_2VENT™ competency, the practitioner should be able to set up the GO_2VENT™and troubleshoot problems that may arise with its use.

Name:	Institution:
Department:	Date Completed:

VI. FAQ (Frequently Asked Questions)

Question	Answer
1. Nomenclatures	E-time: Exhalation time in seconds I-Time: Inspiratory time in seconds L/min: Flow of gas in liters per minutes Manometer: Pressure gauge PIP: Peak inspiratory pressure PEEP: Positive end-expiratory pressure
2. How does the GO_2VENT™ function during inhalation and exhalation?	The GO_2VENT™ is a small automatic gas-powered resuscitator intended to provide pressure-limited, flow controlled ventilatory support for short-term emergency ventilatory support for both breathing and non-breathing patients while being monitored by a clinician or trained operator. The GO_2VENT™ is a single patient, multiple use device. • During inhalation, exhalation will not start until the desired peak inspiratory pressure (PIP) is reached. • During exhalation, inhalation will not begin until pressure drops to the controlled positive end-expiratory pressure (PEEP).
3. What is the definition of "pressure control" mode (mandatory breathing) and "pressure support" mode (assisted breathing) when used with GO_2VENT™?	For non-breathing patients - the mode of ventilation is called pressure control because no effort is required by the patient to initiate inhalation (mandatory breathing). For patients taking spontaneous breaths requiring assisted breathing - If the rate dial has been adjusted to a position that the continuous flow of gas creates more pressure than the set PEEP, then the GO_2VENT™ will not go into inhalation until the patient draws the baseline pressure down to PEEP. Again, because the GO_2VENT™ is cycled on both set PIP and PEEP, inhalation will not start until pressure reaches the set PEEP value. This mode of ventilation is called pressure support because the GO_2VENT™ only delivers ventilatory support when initiated by the patient.
4. How do I set the GO_2VENT™ in pressure control or pressure support mode?	Which mode the GO_2VENT™ is in is simply a function of where the rate dial has been adjusted. Turn the rate dial clockwise until it is in pressure support (assisted breathing) mode. For pressure control (mandatory breathing) mode, turn the rate dial counter clockwise.
5. What does the rate dial do?	The rate dial is a variable resistor which controls the rate at which gas may escape. When the rate dial has been adjusted to a position where the continuous flow of gas does not create more pressure than the set PEEP (set PEEP is approximately $1/5^{th}$ of the set PIP), upon completion of exhalation, the GO_2VENT™ will automatically cycle into inhalation because it cycles on both the set PIP and PEEP.
6. Does the gas supplied to the GO_2VENT™ flow continuously during exhalation and inhalation?	Yes

VI. FAQ (Frequently Asked Questions) (continued)

Question	Answer
7. Does the GO_2VENT™ work with a mask or an endotracheal tube (Combitube® Dual Lumen Airway)?	The GO_2VENT™ works well with most endotracheal tubes or masks. When the GO_2VENT™ is used with a mask, clinicians must have proper training to be aware of the increased mortality associated with aspiration when vomitus occurs. If there is a small leak around the mask, the GO_2VENT™will still cycle between PIP and PEEP, but inspiratory times will increase and expiratory times will decrease. In the event of a larger leak, the GO_2VENT™ will stop cycling because it cannot compensate for the leak.
8. What is the sensitivity or pressure drop required to trigger the GO_2VENT™ into inhalation?	The GO_2VENT™ is pressure cycled on PIP and PEEP. Therefore, as soon as the patient's pressure drops to PEEP, inhalation will start whether this occurs because exhalation has been completed or the patient draws a breath. Compared to time cycled ventilators, the sensitivity would be zero in the pressure control mode. In the pressure support mode, the sensitivity may be set as light as 1 cm H2O or less; therefore, the patient's work of breathing will be minimal. If greater effort by the patient is desired, it may be increased by turning the rate dial clockwise. Be sure to use a manometer when performing this procedure.
9. When adjusting the rate dial on the GO_2VENT™, it sometimes stops cycling. What is happening?	The GO_2VENT™ rate dial controls rate by controlling the exhalation time. Once the PIP and inspiratory flow (L/min) have been set, inspiratory time is also set. The only way to control respiratory rate is by controlling the exhalation time. In the pressure control mode, this is done with the rate dial which is actually a variable flow resistor. Depending on the patient and flow conditions used, it is possible to set the rate dial so that the continuous flow of gas always creates more pressure across the variable flow resistance than what the modulator is set to cycle at for PEEP. This means the GO_2VENT™ is currently in the pressure support mode. In this condition, the patient's airway pressure will remain slightly above set PEEP just as in a variable resistance PEEP valve and the GO_2VENT™ will not cycle. When pressure control is the mode of ventilation (which is required), the situation is easily corrected by dialing out the rate dial (counterclockwise) until the it starts cycling, thus reducing the variable resistance so the patient's pressure is allowed to drop below PEEP and cycle the modulator automatically. In the pressure support mode, it is the patient who initiates inhalation by drawing the baseline pressure down to the set PEEP value. Therefore, if it is not cycling, chances are the patient is not spontaneously breathing or the rate dial has been adjusted too far down, creating a baseline pressure which is too high above the set PEEP value for the patient to be able to initiate inhalation (the sensitivity is too high). In either event, turn the rate dial counterclockwise until the sensitivity is low enough for the patient to trigger inhalation. Otherwise the GO_2VENT™ will go into the pressure control mode.

VI. FAQ (Frequently Asked Questions) (continued)

Question	Answer
10. If I connect to a 15 L/min flowmeter and dial it all the way up, what flow will I get through the GO_2VENT™?	Orifice type flowmeters like those which are commonly used on "E" cylinders will flow a maximum of what is indicated on the gauge. Timeter and other flowmeters using a floating ball as an indication of flow are capable of being adjusted to flows above what is indicated. If connecting to a flowmeter and adjusting the dial all the way open, the float will be slightly above the 15 L/min flow mark but 40 L/min will actually be flowing through the GO_2VENT™. As long as the hospital gas supply and cylinder regulators are adjusted to 50 PSIG, which is the standard, the flow going through the GO_2VENT™ will never exceed 40 L/min.
11. What kinds of compressed gas source can I use with the GO_2VENT™?	You can use any breathing gas from the hospital wall outlet or gas cylinder.
12. All I have are 15 L/min orifice type flowmeters with my "E" cylinders. 15 L/min of inspiratory flow is not enough flow for my patient. What can I do?	Some cylinder regulators equipped with an orifice type 15 L/min flowmeter are also equipped with a high flow (power take-off) port. If you connect the GO_2VENT™ to this port, you will automatically get 40 L/min. If 40 L/min is too much flow or you don't have a high flow port, you will need to use a different flowmeter. If you use the GO_2VENT™ at 50% FiO_2 setting, you can operate the GO_2VENT™ at 6-8 L/min, which on an H tank can last up to 14 hours.
13. How long will my "E" cylinder last with the GO_2VENT™?	It depends on the flow rate. There are 625 L in an "E" cylinder so at 40 L/min it will last approximately 15 minutes; at 20 L/min it will last 30 minutes; at 10 L/min it will last approximately 60 minutes.
14. What is the FiO_2 delivered to my patient?	The GO_2VENT™ can be used to deliver an air-O_2 mixture of 50% FiO_2 and extend oxygen cylinder functional time.
15. May I connect any DISS connector to the patient tee connector threaded gas inlet fitting?	Yes
16. How can I measure tidal volume when using the GO_2VENT™?	Tidal volume may be estimated by using the tidal volume chart included with the instructions. The GO_2VENT™ runs on a continuous fixed flow rate of gas (inspiratory flow) of up to 40 L/min (667 mL/second) when connected to a 50 PSIG gas source with associated flowmeter and control valve. Tidal volume is the inspiratory time multiplied by the flow rate (example: 1 second i-time X 667 mL/second = 667 mL tidal volume).

VI. FAQ (Frequently Asked Questions) (continued)

Question	Answer
17. PIP ranges are indicated on the pressure dial, but what is the expected PEEP?	PEEP setting on the GO_2VENT™ is automatically set at about 1/5th of the selected PIP. It is good clinical practice to use a manometer to verify any pressure setting. PIP indications on the pressure dial are approximate only and ranges between 15 and 50 cm H_2O, and PEEP ranges between 2 and 9 cm H_2O respectively.
18. How do I connect a pressure manometer to the GO_2VENT™?	A manometer may be connected to the GO_2VENT™ by placing a 22 mm fitting between the modulator and patient connector tee (see enclosed instructions). Although the pressure dial indicates typical PIP and PEEP is about 1/5$_{th}$ of PIP, a manometer is recommended because it provides valuable information to the clinician on what is occurring with the patient.
19. Is it possible to override the pop-off valve (high pressure relief valve)?	No, the GO_2VENT™ is a pressure cycled automatic resuscitator which has a maximum setting of 45 cm H_2O. It includes an inspiratory pressure relief valve that opens automatically at approximately 60 cm H_2O (preset and non-adjustable) and has a distinctive and easily recognized warning sound.
20. Can I deliver aerosol treatment while the patient is connected to the GO_2VENT™?	Yes. NOTE: Deposition of medicine residue may cause the GO_2VENT™ to stick if it dries for an extended period of time. Always perform a functional check per instructions before reconnecting the patient.
21. Is the GO_2VENT™ MRI safe?	Yes. The GO_2VENT™ has been tested and is MR Conditional and can be used in the MRI environment according to the following conditions: 1) Static magnetic field of 3-Tesla or less; and 2) Spatial gradient magnetic field of 10,000-gauss/cm (extrapolated) or less.
22. Can I do CPR (closed- chest compression) with conventional automatic gas-powered resuscitators?	Yes. The cardiopulmonary resuscitation (CPR) guidelines and American Society for Testing and Materials caution against the use of automatic gas-powered resuscitators during CPR closed chest compression because the compression process may interfere with lung ventilation and airway resistance may prevent adequate ventilation.
23. Can I use the GO_2VENT™ with CPR?	Yes. The GO_2VENT™ is ideal for use in CPR. Studies (by Otto Raabe, Ph.D. et. al) have shown that the GO_2VENT™ is safer than manual resuscitation using a BVM. The GO_2VENT™ should not cause baro-trauma, as the unit will not exceed the set peak inspiratory pressure and will automatically cycle at the end of each compression. In the case of manual bagging, medical personnel must be careful not to bag and compress the patient simultaneously in order to avoid high PIP. Manual bagging can cause pressures that can exceed 60 cm-H_2O.

VI. FAQ (Frequently Asked Questions) (continued)

Question	Answer
24. Is the GO_2VENT™ safe when used with CPR?	Because the GO_2VENT™ responds to thoracic pressure variations, it appears to provide the maximum ventilation possible during closed chest compression and responds with a full inhalation at high flow rate as soon as the compression ends. Because of its audible and visual indications of inhalation-exhalation cycling, elevated airway resistance or low tidal volume is readily observed by the rescuer.
25. How about the caution statement?	These results suggest that there is no contraindication associated with performing CPR closed chest compression while utilizing the GO_2VENT™ as a ventilatory resuscitator. Further, the results suggest that such use would be beneficial. A revision of CPR guidelines and ASTM 920-93 should be considered.
26. What are some of the other commonly used devices for providing patient ventilatory support?	The GO_2VENT™ is classified as an "automatic pressure-cycled, gas-powered resuscitator" per ASTM resuscitator guideline (F920-93). There are "operator-powered resuscitators" such as Bag-Valve-Mask (BVM); "manually-cycled, gas-powered resuscitators" such as Demand Valves; "automatic-time cycled, gas-powered resuscitators" and "volume-cycled, gas-powered resuscitators" such as the emergency transport ventilators.
27. Why should I use the GO_2VENT™ when I am use to BVM?	"Operator-powered resuscitator" – Bag-Valve-Mask (BVMs) are the most commonly used devices for emergency short term ventilator support. They are typically disposable and are used extensively in the pre-hospital and inter-hospital markets. Manual resuscitators are labor intensive and are unable to deliver consistent ventilatory support. When used with a mask or endotracheal tube, they require the clinician to use both hands. They do not require being connected to a gas supply to provide ventilatory support but are almost always used in conjunction with compressed oxygen to increase the patient's FiO_2. Although they appear easy to use, many studies have shown that they all deliver insufficient tidal volume and often deliver respiratory rates which are too high, resulting in significant adverse effects on the patients (refer to Clinical References in Section VII). Nevertheless, many clinicians, when questioned about the use of manual resuscitators, feel certain that they deliver a consistent tidal volume of 750 mL per breath and that the ventilatory support they deliver is superior because of the feel they get through their hands when squeezing the bag.
28. What does automatic-cycled resuscitator do?	There are many automatic resuscitators that are gas or battery powered and non-disposable. All require some type of regular cleaning and are sold with some type of associated disposable products. Most are constant flow, time-cycled devices with no high-pressure relief valve which puts the patient in danger of a pneumothorax if there is an unexpected decrease in lung compliance. These devices have no monitoring or alarm features and have a minimum list price of $1,000.

VI. FAQ (Frequently Asked Questions) (continued)

Question	Answer
29. What is the least expensive automatic-cycled resuscitator cost?	The Oxylator EM-100 is a gas-powered automatic resuscitator which provides constant flow, pressure-cycled ventilatory support just like the GO_2VENT™. Unlike the GO_2VENT™, the Oxylator EM-100 is relatively heavy, non-disposable, and is not equipped with a pop-off valve. The cost is considerably higher than the GO_2VENT™
30. What are the advantages of the transport ventilators?	Transport ventilators are equipped with sophisticated monitoring and alarm functions. They are usually able to provide several modes of ventilatory support and provide more versatile ventilation than the GO_2VENT™. Because they are very complicated, significant training is needed. They are used in conjunction with disposable products and can cost as much as $2,000 to $5,000.

VII. Clinical Reference

A. Berthieaume, Dave Swift RRT, Evaluation of the Vortran Automatic Resuscitator and the Vortran Airway Pressure Monitor in the MRI Environment. Respiratory Care, Vol. 8. 2 - April-May 2013

INTRODUCTION: The magnetic resonance imaging (MRI, 3 Tesla strength) scanner creates a unique electromagnetic environment that allows high fidelity images of patients. With critically ill patients requiring mechanical ventilation, this environment produces some unique challenges in management of ventilation and monitoring of ventilation. Currently, there are a limited number of ventilatory devices that can provide mechanical ventilation in the MRI environment.

METHODS: To determine if the Vortran Automatic Resuscitator (VAR Plus model) can be safely utilized in the MRI environment. To evaluate, if the Vortran Airway Pressure Monitor (VAPM) can deliver accurate monitoring capability within the MRI environment. The VAR-Plus performance was verified in a bench top setting, within the MRI core (with and without extension lines) and outside of the MRI core (with and without extension lines). The VAPM was used in parallel to verify the VAR-plus performance.

RESULTS: The VAR-plus consistently delivered the RATE (within one bpm) and pressure set using a static lung compliance & resistance model. The VAPM unit consistently monitored the set rate. However the unit's ability to monitor the inspiratory time was limited by rounding up at the 0.05 mark (ex. Ti of 0.56 displays as 0.6 and 0.45 displays as 0.4). The VAPM (Vortran Airway Pressure Monitor) is not designed to be used within the immediate magnetic field of the MRI machine. The magnetic field interferes with its operation and the authors recommend that it not be used within the magnetic field - it does provide effective remote monitoring capability for the VAR-plus.

CONCLUSION: The VAR-plus can effectively function, according to established performance characteristics, within the MRI environment. The unit is not impacted by the electromagnetic field of the MRI scanner. The VAPM provides an effective remote monitor for ventilation within the MRI environment (outside of the magnetic field) for adult and pediatric populations not requiring very low inspiratory times.

Robert Kohler, EMT-P, The Control of End Tidal CO2. Respiratory Therapy, Vol. 7 No. 2 - April-May 2012

INTRODUCTION: Pre-hospital care can be defined as efforts to achieve or maintain homeostasis. The ability to monitor and control CO2, a key component of the buffering system, is an essential means to that end. Because of CO2, a key component of the buffering system, has a direct effect on the pH of the body, the ability to monitor and control End Tidal CO2 (ETCO2), is essential in order to maintain homeostasis.

Recently the American Heart Association has issued new guidelines defining a narrow range of optimal oxygen saturation for many situations. Based on these recommendations proper patient care mandates that we have the ability to control both components of ventilation. This pilot study examines the feasibility of controlling the End Tidal CO2 during 911 ground ambulance operations.

MATERIAL AND METHODS: There were 2 ventilation adjuncts available, the choice of either was not defined or dictated by the protocol and was the clinician's choice.

The control: an adult bag valve mask (BVM) as manufactured by Life Support Products #L770 with a bag volume of 1488 ml, valve dead space of 7.8 mil (not including mask) and a patient connection of 22 mm outside diameter, 15 mm inside diameter with no pop off valve.

The study: An oxygen powered disposable PIP cycled automatic resuscitator that regulated: Respiratory Rate, Tidal Volume, Peek Inspiratory Pressure (PIP). Peak End Expiratory Pressure was variable at 20% of the selected PIP. The VAR-Plus model PCM (VORTRAN Automatic Resuscitator) was used.

In December of 2009 Stamford EMS Paramedics began a program of training using manufacturer's competency requirements and guidelines from FCCS course curriculum. Clinical targets were FiO2 of 100% at a rate of 10-12 bpm and a PIP range from 20-25cm/H2O. Paramedics were not restricted to these targets and were instructed to vary settings to meet the patient's needs. ETCO2 was monitored via Side Stream filter line capnography as manufactured by Microstream and available on the Lifepak 12s currently in use. January through September of 2010, 152 intubated patients were reviewed. 46 met the criteria of any patient greater than 10 kg with an intrinsic pulse and in respiratory arrest whether idiopathic or clinician induced as an example from Rapid Sequence Induction. One patient was excluded due to a metabolic aberration. The remaining cases were split, with 1,012 specific ETCO2 samplings evenly distributed over 23 cases using a BVM (as the control) and with 1,270 specific ETC) 2 samplings evenly distributed over 22 cases using the VAR. The first 4 minutes of data records from all cases were excluded to compensate for procedural anomalies experienced while securing the airway. Data for all cases in each group were combined for the calculation of standard deviation (Sd). The Sd was also calculated for each individual case. The difference in the quantity of records had no statistical significance on results in a test analysis.

RESULTS: After 9 months, ETCO2 values in the control group reflected a Standard deviation of 16.97 while the test group ventilated with the VAR reflected as standard deviation of 14.09. In addition the study group trended lower as time progressed while the control group did not.

CONCLUSION: Although data is still being collected, these initial values show that despite the dynamic environment of the pre hospital setting, with a minimum of additional training the pre-hospital provider can more accurately control ETCO2 with a disposable PIP cycled respirator than with a Bag Valve Mask.

Dave Swift, RRT, RRCP - Senior Therapist Ottawa Hospital, Ottawa, Ontario, Canada, Preparing for Mass Casualties & Mechanical Ventilation Alternatives, presented at 48th AARC International Respiratory Congress in Tampa, FL, Oct 5-7, 2002.

The March 1995 Tokyo, Japan terrorist attack using the nerve agent Sarin sounded a wakeup call to health care workers. The intentional release of this neurotoxin resulted in 11 dead and five thousand exhibiting toxic symptoms. The health care system was rapidly overwhelmed.[1]

The National Capital Region of Ottawa is home to embassies of many nations and is viewed as a very high risk for a terrorist attack. As the sole Respiratory Therapist representative on the Chemical, Biological, Radiation and Nuclear Committee, it became rapidly apparent that there was a serious discrepancy between the number of ventilators available and the actual ventilator resources available. This finite limit was determined to be both unacceptable and avoidable. To avoid compromising patient care a cost effective method for treating the largest number of patients had to be determined.

It was determined that a pneumatic, automatic resuscitator offered the best clinical options. As it was not dependent on a/c power, was highly portable and relatively easy to use it seemed the most appropriate, cost effective choice.

The units were tested using the following clinical simulations: increased resistance, decreased compliance, increased compliance and with an air leak present. All units performed as advertised when faced with increased compliance, with delivered volumes decreasing and rates increasing with increased resistance and compliance. Serious clinical problems would be encountered with air leaks present and would need prompt medical intervention. Although all three units performed as advertised, each unit had individual characteristics that would have to be evaluated by the potential user as suitable for their own clinical applications.

The Vortran Automatic Resuscitator offered the capabilities of managing the largest number of patients at the most financially responsible cost. In addition, the unit has the advantage of ease of use and that the equipment offered a simple solution to the handling of contaminated units from a biological or terrorism incident, it is disposable. The costs of the other units prohibited one time use and would result in a lengthy and expensive decontamination process, which might also pose a hazard to hospital staff charged with decontamination.

Characteristics	**AMBUMATIC**[2]	**GENISIS II**[3]	**VORTRAN AUTOMATIC RESUSCITATOR**[4]
Patient Type	Pediatric (>3 yrs) & adult	Pediatric (>3 yrs) & adult	Pediatric (>3 yrs) & adult
Power source	pneumatic	pneumatic	pneumatic
Portability	<1.5 lb.	<2 lb.	<1 lb.
Pressure cycled	yes	no	yes
Volume cycled	yes	yes	no
Rates	12 or 20	8 - 12	0->40
Antisuffocation valve	yes	yes	yes
Pressure relief	yes	yes	yes
Pressure monitoring	yes (optional)	no	yes (optional)
Alarms	audible blowoff	audible blowoff	audible blowoff
FiO2 control	60 or 100%	100%	50 or 100%
PEEP	intrinsic	intrinsic	intrinsic
Single/multiple use	multiple pts	multiple pts	single
Cost CDN (0.62US$)	>$500	<$400	<$45
Replacement parts	yes (valves, etc)	no	no
Required & CT scan/ MRI compatibility	Not certified for CT Scan or MRI use	Not certified for CT Scan or MRI use	Certified for CT Scan or MRI use

Characteristics Required In A Mass Casualty Ventilator/Resucitator:

1 Brackett D.W., Holy Terror, Armageddon in Tokyo, New York:Weatherhill, Inc. 1996

2 Ambumatic , Manufacturer: Ambu Inc. Linthicum, MD, USA

3 GenisisII, Manufacturer: O2 Systems Inc., Mississauga, Ontario, Canada

4 VAR (Resp. Tech Pro), Manufacturer: VORTRAN Medical Technology, Sacramento, California, USA

Steven J. Weiss, Todd Filbrun, Chad Augustin, Ray Jones and Amy Ernst. UC Davis Medical Center: Sacramento, CA, Sacramento City Fire/EMS: Sacramento, CA. ABSTRACT: An Automatic Transport Ventilator (ATV) vs. Bag Valve Mask (BVM) for Ventilation during EMS Transport. Academic Emergency Medicine Volume 11, Number 5 592, May 2004.

ABSTRACT:

OBJECTIVES: The hypothesis of this study was that paramedics (EMTPs) perceived that use of automatic transport ventilator (ATV) was better than BVM for managing ventilation during patient transport.

METHODS: ATVs and BVMs were randomized on 5 City Fire Department Paramedic Units. At the conclusion of each patient transport, using a 5-point Likert scale, EMTPs rated the modality used (ATV vs. BVM) on ease of use, time of setup, expedition of transport, additional tasks completed, documentation, overall patient care, and patient comfort. Pulse, oxygen saturation, respiratory rate, and end tidal CO2 were collected every 5 seconds. Statistical analysis was performed on results of the Likert scale using a Mann-Whitney U rank sum test. Results were significant if $p < 0.05$. The power of the study was 80 percent to show a difference of 1.0 on the Likert scale.

RESULTS: 28 patients were entered into the study, 14 BVM and 14 ATV. The reason for device use was assisted ventilation in 7/28 (25%) cases and CPR in 21/28 (75%) cases. There were no significant differences in the EMS perceptions of ease of use ($p = 0.08$), time of setup ($p = 0.14$), expedition of transport ($p = 0.27$), or overall patient care ($p = 0.59$). There were significant differences in favor of the ATV in ability to accomplish additional tasks ($p = 0.01$), ability to document ($p = 0.04$), and ability to provide patient care ($p = 0.03$). The data collector stored ongoing physiologic data on 15/28 (54%) patients during EMS transport.

CONCLUSIONS: EMTPs perceived that they were able to accomplish more tasks, document more completely, and provide better patient care with the use of the ATV. The data collector time marked data and stored the data for subsequent retrieval in a majority of cases.

Nates, Joseph L. MD, FCCM, Combined external and internal hospital disaster: Impact and response in a Houston trauma center intensive care unit*. Critical Care Medicine. 32(3):686-690, March 2004.

ABSTRACT: OBJECTIVE: To increase awareness of specific risks to healthcare systems during a natural or civil disaster. We describe the catastrophic disruption of essential services and the point-by-point response to the crisis in a major medical center.

DESIGN: Case report, review of the literature, and discussion.

SETTING: A 28-bed intensive care unit in a level I trauma center in the largest medical center in the world.

CASE: In June 2001, tropical storm Allison caused >3 feet of rainfall and catastrophic flooding in Houston, TX. Memorial Hermann Hospital, one of only two level I trauma centers in the community, lost electrical power, communications systems, running water, and internal transportation. All essential hospital services were rendered nonfunctional. Life-saving equipment such as ventilators, infusion pumps, and monitors became useless. Patients were triaged to other medical facilities based on acuity using ground and air ambulances. No patients died as result of the internal disaster.

CONCLUSION: Adequate training, teamwork, communication, coordination with other healthcare professionals, and strong leadership are essential during a crisis. Electricity is vital when delivering care in today's healthcare system, which depends on advanced technology. It is imperative that hospitals take the necessary measures to preserve electrical power at all times. Hospitals should have battery-operated internal and external communication systems readily available in the event of a widespread disaster and communication outage. Critical services such as pharmacy, laboratories, blood bank, and central supply rooms should be located at sites more secure than the ground floors, and these services should be prepared for more extensive performances. Contingency plans to maintain protected water supplies and available emergency kits with batteries, flashlights, two-way radios, and a nonelectronic emergency system for patient identification are also very important. Rapid adaptation to unexpected adverse conditions is critical to the successful implementation of any disaster plan.

Otto G. Raabe, Ph.D. and Mario Romano, RCP, Comparison of RespirTech PRO™ and Ambu® SPUR Resuscitators During Simulated CPR.

BACKGROUND: The cardiopulmonary resuscitation (CPR) guidelines and American Society for Testing and Materials warn against the use of automatic pulmonary resuscitators during CPR closed chest compression because the compression process may interfere with lung ventilation and airway resistance may prevent adequate ventilation. However, appropriately designed pressure-cycled, pressure-controlled (rather than pressure-cycled, time-controlled) mechanical ventilators should be able to automatically respond to pulmonary pressure changes to provide air or oxygen to the lung at high flow rate upon demand and alert the rescuer of ventilatory problems. This evaluation was conducted to investigate ventilatory factors associated with the use of either the portable RespirTech PRO™ (RTP) gas-powered automatic resuscitator or a typical manually operated self-inflating bag-valve resuscitator.

METHODS: Thirty tests, 17 with the RTP and 13 with the bag resuscitator, were conducted using the resuscitator connected to a commercial test lung modified for automatic simulated chest-compression following standard compression rates as timed with an electronic metronome. The test system was designed to be totally mechanical to avoid operator effects.

RESULTS: Both resuscitators provided appropriate ventilation without excessive lung pressures following the chosen 5:1 compression-ventilation ratio. Overall, the RTP (at 25 L/min) and bag-valve resuscitator minute ventilation values were about the same with means of 6.3±0.5 SE liters and 6.2±0.6 SE liters, respectively. The RTP automatically responded to pulmonary pressure variations, rapidly delivering short breaths between compressions and a full inhalation during the pause without serious pressure extremes. The highest observed intrapulmonary pressures (>80 cm H_2O) occurred with the bag-valve resuscitator operated during uninterrupted ("seamless") chest compressions without inhalation synchronization.

DISCUSSION: Both devices worked well following the standard protocol for CPR. Because the RTP inhalation-exhalation cycling is visually and audibly obvious, indications of possible airway resistance or low tidal volume are readily observed by the rescuer.

CONCLUSIONS: The RTP may be used safely as an automatic resuscitator during CPR. Revision of CPR guidelines and ASTM 920-93 for use of pressure-controlled resuscitators should be considered.

Michael Rossini, M.D., Barry Hickerson, EMT-P, Preliminary Evaluation of a Lightweight, Disposable Emergency Transport Ventilator in the Aeromedical Setting

INTRODUCTION: Recent evidence suggests patients receiving pre-hospital ventilation benefit from the use of emergency transport ventilators (ETV). This evidence is supported by the fact manual ventilation using a bag-valve-mask type device has substantial variations in rate and volume. These variations occur during initial treatment and transport even by well-trained EMS crews. Proper tidal volume, airway pressures and respiratory rate are critical components of emergency ventilatory support and variations can impact mortality and morbidity on a wide range of patients suffering from illness or injury.

METHODS: The purpose of the evaluation was to determine the practicality and ease of use of a new ETV, the "RespirTech PRO" manufactured by VORTRAN Medical Technology 1, Inc. and identify any shortcomings during the initial phases of patient treatment, transport and emergency room care. The ETV was placed into service on our single BK 117-B2 hospital-based helicopter program. A Registered Nurse and Licensed Paramedic staff Air Med Team, which is based in Modesto, California. The majority of scene transports are flown to our base hospital, Doctors Medical Center also in Modesto, California. We gathered data on 12 patients from October 1999 to July 2000 that received ventilatory support from the ETV. Vitals signs during and post transport, arterial blood gases post transport and subjective data regarding ease of use, set-up and controls where gathered on all 12 patients.

RESULTS: Twelve patients received on-scene and in-flight ventilatory support from the ETV without complications. All 12 adult patients were intubated by ground EMS personnel or the Air Med Team and placed on the ETV. The two manual settings, pressure and rate were set without difficulty and facilitated by the use of continuous end-tidal CO2 monitoring. The oxygen source for the ventilator was a 15-25 liter per minute fitting that allowed operation without difficulty in all 12 cases. Blood gas analysis and review of vital signs during and post transport indicated all patients had been adequately ventilated during initial treatment and transport.

CONCLUSION: The RespirTech PRO proved to be an easy-to-use and reliable ETV that lends itself to a range of patients requiring prehospital ventilation. Ventilation is a key factor in the outcome of many types of injury and illness and this ETV should be considered for on-scene or transport use in a variety of prehospital settings.

Mario Romano, RCP, Otto G. Raabe, Ph.D, William Walby, MS and Timothy E. Albertson, MD, Ph.D., The Stability of Arterial Blood Gases During Transportation of Patients Using the RespirTech PRO™, American Journal of Emergency Medicine, May 2000.

PURPOSE: The transportation of critically ill patients requiring mechanical ventilation is recognized as a high risk and expensive procedure. Approaches have included using manual bag-type valve resuscitators and expensive portable transport ventilators. This study evaluated the effectiveness of the inexpensive portable RespirTech PRO (RTP) gas-powered automatic resuscitator during intra-hospital transport of critically ill mechanically ventilated patients.

BASIC PROCEDURES: Twenty medical intensive patients on stable mechanical ventilator settings had arterial blood gas and vital sign determination before routine transport out of the intensive care unit. Repeat measurements were made during transport approximately 30 minutes after being placed on the RTP portable pressure-cycled automatic resuscitator using an FiO2 of 100%.

MAIN FINDINGS: During use of the RTP for transport, there were no statistically significant variations observed in mean arterial blood pressure [82 ± 11 SD (range 65-112) mm Hg before transport versus 85 ± 14 SD (range 59-110) mm Hg during transport], heart rate [94 ± 16 SD (range 74-127) beats/min) before versus 96 ± 17 SD (range 69-132) beats/min during], arterial pH [7.41 ± 0.07 SD (range 7.31-7.58) before versus 7.42 ± 0.05 SD (range 7.37-7.52) during], and PaCO2 [43 ± 10 SD (range 26-65) mm Hg versus during 43 ± 10 SD (range 27-61 mm Hg) during]. Because the FiO2 before transport was 63 ± 26 SD (range 30-100%) versus 100% during transport using the RTP, the mean PaO2 was significantly increased from 124 ± 86 SD (range 57-367) mm Hg before transport to 297 ± 168 SD (range 65-537) mm Hg during ($P<0.001$). No transportation associated clinical adverse events were noted.

DISCUSSION: Several previous investigations have shown that portable ventilators are safe and effective in intra-hospital transport of mechanically ventilated patients. This study demonstrated that the portable pressure-cycled RTP also allows safe transportation of mechanically ventilated ICU patients. By analogy, the RTP is potentially useful as an automatic resuscitator for emergency medical care.

PRINCIPAL CONCLUSION: This RTP is a disposable resuscitator/ventilator device that provides an inexpensive alternative for transporting ventilator-dependent patients

Mario Romano, RCP, COMPATIBILITY OF THE RESPIRTECH PRO IN THE MRI UNIT, presented at 46th AARC International Respiratory Congress in Cincinnati, OH, October 7-10, 2000.

BACKGROUND: Because most medical facilities do not have MRI compatible ventilators, MRI studies on intubated patients are frequently delayed until the patient is extubated. Although there are mechanical ventilators that are MRI compatible, the cost for purchasing them for MRI use only is impractical, especially in light of the limited number of intubated patients needing an MRI. This paper examines the RespirTech PRO, a single patient use fully automatic resuscitator, and how it functioned during an MRI study in a General Electric 1.5 MRI unit.

METHODS: One clinically stable 72-year old male patient in need of an MRI of his head was placed on the automatic resuscitator with extension kit. The patient was set in a control mode of 16 BPM with a ventilating pressure of 25 cm-H2O and a liter flow of 40 LPM at a FiO2 of 100%. The patient was placed in a General Electric 1.5 MRI unit, and the device functioned without incident. No attraction to the magnet was noted. Image artifact was minimal and was limited to the patient tee area, allowing for a clear picture of the head. The patient tolerated ventilation well, and his vital signs are summarized in the graph below.

RESULTS: Patient Vital Signs:

Tx	HR	BP	O_2 Sat.	FiO_2 Set
Pre MRI	85	98/51	98%	100%
During MRI	77	102/54	96%	100%

DISCUSSION: No significant changes in vital signs or O_2 saturation were noted with the use of the automatic resuscitator. The patient appeared to tolerate the procedure with no adverse affects. No attraction to the MRI magnet was noted and artifact was limited to the patient tee area.

CONCLUSIONS: The RespirTech PRO can be a safe and cost effective ventilator for use in the MRI room without the need to purchase capital equipment. More experience with the use of this automatic resuscitator in transporting patients to other areas of the hospital can establish it as a safe and cost effective transport.

VIII. Coding Information

HCPCS - HCFA (Health Care Financing Administration) Common Procedure Coding System

PRODUCT	GO_2VENT™ (Automatic Resuscitator)
CODE	K0533 / E0471
DESCRIPTION	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
INSTRUCTIONS	Coverage issue, CIM 60-9

CPT - Current Procedure Terminology (American Medical Association)

PRODUCT	GO_2VENT™ (Automatic Resuscitator)
CODE	94656
DESCRIPTION	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; first day.
CODE	94657
DESCRIPTION	Subsequent

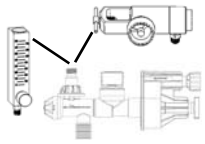
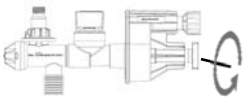
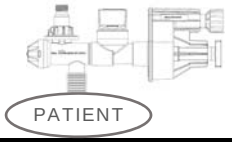
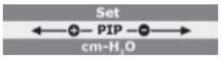
IX. Product Information

Product Name:	GO_2VENT™
Order Number:	6123
Case Quantity:	10
O2 Tubing:	10' Length
Flex Hose:	6' Length
Manometer:	Included
Entrainment:	Included

X. Troubleshooting

• GO_2VENT™ stops cycling	1. Leak in circuit / look for pressure leak at gas connections, gas supply, patient airway, ET tube cuff, etc. 2. Compliance change / change in patient's lung compliance may affect breathing rate, adjust rate dial accordingly. 3. Increased gas flow / an increase in supply gas flow will elevate PEEP. Adjust rate dial out (counter-clockwise) accordingly. 4. Out of gas / replace oxygen cylinder or connect to other gas source. 5. Assisted breathing mode / the GO_2VENT™ is waiting for patient to trigger the inspiration.
• Breathing (exhalation) rate is too fast	1. High supply flow / reduce supply gas flow. 2. Low PIP setting / increase PIP as needed. 3. Compliance too high (stiff lung) / change mode of ventilation. 4. Low exhalation resistance / set rate dial down (clockwise)
• Breathing (exhalation) rate is too slow	1. Low supply flow / increase supply gas flow. 2. High PIP setting / decrease PIP as needed. 3. Compliance too low (soft lung) / change mode of ventilation. 4. High exhalation resistance / adjust rate dial out (counter-clockwise).
• Inspiratory time is too long	1. Supply gas flow too low / increase supply gas flow. 2. High PIP setting / lower PIP setting as appropriate. 3. Compliance too low / change mode of ventilation.
• Inspiratory time is too short	1. Supply gas flow too high / decrease supply gas flow. 2. Low PIP setting / increase PIP setting as appropriate. 3. Compliance too high / change mode of ventilation.
• Reading on pressure manometer increases or decreases	1. PIP increase / look for airway occlusion or kinked ET tube, change in patient's lung compliance, verify PIP setting. 2. PIP decrease / look for change in patient's lung compliance, verify PIP setting on GO_2VENT™.
• Flow on my regulator does not go to 40 L/min	1. GO_2VENT™ can operate at flows as low as 15 L/min 2. Maximum flow is 40 L/min per ASTM guideline 3. If you have a 15-16 L/min flowmeter connected to a 50 PSIG piped-in gas source, the maximum flow to GO_2VENT™ is self-limited to 40 L/min when you flush open the flowmeter.
• Maximum flow 40 L/min is not enough	1. Maximum flow is 40 L/min per ASTM guideline. 2. Patient can entrain additional room air through the one-way valve to meet their inspiratory flow demand for spontaneously breathing patient.
• What is the tidal volume delivered?	1. Tidal volume delivered is a function of flow rate (liters per minute) over inspiratory time (seconds). 2. GO_2VENT™ delivers gas until the set PIP is reached.

XI. Quick Guide

1	**Set flow to 10-25 L/min** Step 1: Set the flow to approximately 25 liters per minute with a flowmeter from a suitable gas source. Adjust flow as needed.	
2	**Verify PIP ~25 cm-H_2O** Step 2: Verify the PIP on the pressure dial. Adjust PIP as needed. Each GO_2VENT™ is factory tested and pre-set to 25 cm-H_2O.	
3	**Function check - Connect to patient** Step 3: Before connecting to the patient, perform a function check. Connect the GO_2VENT™ to the patient and then verify the PIP with a pressure manometer.	
4	**Adjust rate** Step 4: Adjust the breathing rate with the rate dial. Refer to the rate dial label. 	
5	**Adjust Flow, PIP and Rate** Step 5: Re-adjust flow, PIP and rate for the patient's clinical situation. There is no substitute for a good clinical assessment.	
*	**Use of extension tubing in MRI or CT** NOTE: Position modulator away from patient tee using extension tubing and verify patient cycling whenever modulator is repositioned.	

This Quick Guide is intended to help you gain a general understanding of the GO_2VENT™ product. Please be certain to read, understand, and follow the information listed in this User's Guide before using this product.

Brief Device Description

The GO_2VENT™ provides constant flow, pressure-cycled ventilatory support in either pressure control or pressure support modes on patients weighing 10kg and above. The device includes the pulmonary modulator (an exhalation valve that opens at PIP and closes at PEEP) and a patient connector tee to supply gas flow, entrain additional air, and provide a redundant pop-off valve for safety. The working mechanism of the GO_2VENT™ consists of a moving diaphragm which adds or subtracts spring force when it is moved from a horizontal to a vertical position, the addition or subtraction of spring force will affect the PIP setting by 1~3 cm-H_2O. The GO_2VENT™ will function in any position as long as the **final adjustments are made in a secured position** (strapped or taped to the patient).