

Clarification of Performance Characteristics of the Vortran Automatic Resuscitator

In the December 2007 issue of RESPIRATORY CARE, the article by Mark Babic, Robert Chatburn, and James Stoller asks the worthwhile question of which particular ventilator models are suitable for disaster preparedness in regard to the context of managing large numbers of victims who may need mechanical ventilation.¹ The article focuses on the performance of one brand of device: the Vortran Automatic Resuscitator, which is a pressure-cycled automatic resuscitator. Although their study produced some interesting data, I believe that a different presentation of the information would be helpful in explaining and understanding the results reported by Babic et al.¹ All data included in the present letter were obtained from Table 2 in that report.

The points that need clarification include:

1. Changes in tidal volume (V_T) and respiratory rate associated with changes in lung compliance and airway resistance are a primary operating characteristic of all pressure-cycled ventilators, including the Vortran Automatic Resuscitator, and are normal and desirable.

2. The findings from Babic et al were dependent on the specific Vortran Automatic Resuscitator settings and pulmonary variables chosen for the study, which in some cases were inappropriate for the ventilation mode they used, and changes in device settings were needed.

3. Some meaningful trends in the data were not completely explained.

The Vortran Automatic Resuscitator, as described in the manufacturer's literature, is a pressure-cycled automatic resuscitator and thus is designed to deliver the same maximum inspiratory pressure (MIP) and positive end-expiratory pressure (PEEP) under varying clinical conditions (Fig. 1). The report shows that at a nominal MIP setting at the lowest indicated range (20–30 cm H₂O), the Vortran Automatic Resuscitator automatically adjusts to decreasing compliance by increasing breathing rate and decreasing V_T , with relatively stable minute volume (\dot{V}_E). Important clinical research showed

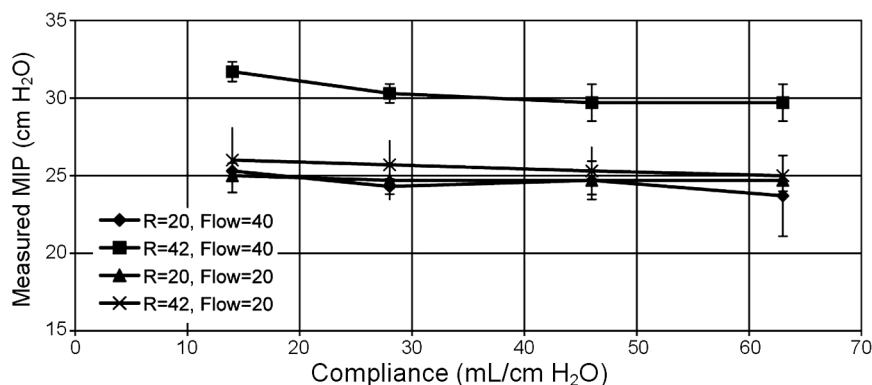


Fig. 1. Measured maximum inspiratory pressure (MIP) versus lung compliance for each of the 4 combinations of airway resistance (R) and set device flow with the Vortran Automatic Resuscitator. The error bars represent one standard deviation. All the measurements were done with the device set at the lowest indicated MIP of 20–30 cm H₂O. As expected, the figure shows that the device provided a MIP of 25 cm H₂O in a wide range of conditions, and that there was a MIP increase with a resistance of 42 cm H₂O/L/s and a set device flow of 40 L/min. (All data in this figure are from Table 2 in Reference 1.)

that a reduction in mortality of acute respiratory distress syndrome patients is associated with a reduced V_T .²⁻⁶ Therefore, the device functioned exactly as intended and expected. However, it is undesirable to allow the V_T to drop close to the volume of the anatomical dead space, as was done in the study by Babic et al.¹ A clinician using any pressure-cycled, flow-controlled device should be prepared to increase the MIP setting upwards if the respiratory rate is above 20 breaths/min, as a way to ensure that the patient is receiving the appropriate V_T .

Issues discussed by Babic et al¹ concerning the appropriateness of the ventilation provided by the device were not the result of a defect of the device (which might be inferred by some readers) but were more a question of the ventilation mode chosen, the device settings (MIP of only 20–30 cm H₂O), and the pulmonary variables chosen for the experiment (compliances of 14–63 mL/cm H₂O, resistances of 20 and 42 cm H₂O/L/s). Figures 1 and 2 show the measured MIP values and the calculated alveolar \dot{V}_E values, respectively. Although the Vortran Automatic Resuscitator is relatively stable over most compliance settings, the very low compliance of 14 mL/cm H₂O with the MIP setting of only 20–30 cm H₂O yields a poor level of alveolar ventilation, associated with a highly elevated respiratory rate

(> 40 breaths/min).¹ In such a situation a trained clinician observing a respiratory rate > 20 breaths/min can increase the MIP setting up to 50 cm H₂O, which would increase MIP and PEEP to compensate for this serious lung condition. If necessary, an auxiliary PEEP controller may be useful in the most serious cases.

Although no measurements were made of alveolar \dot{V}_E or P_{aCO_2} , the report¹ estimated expected values under the assumed clinical conditions (Fig. 3). Alveolar \dot{V}_E and P_{aCO_2} are important because they represent the quality of ventilation provided to the patient, along with total \dot{V}_E , V_T , and MIP. As expected and shown in Figures 2 and 3, alveolar \dot{V}_E drops off and P_{aCO_2} increases with decreases in lung compliance and a constant nominal MIP setting of 20–30 cm H₂O. That result is expected as a result of the decreasing V_T and the increasing respiratory rate, and may be corrected simply by adjusting the MIP upward to maintain a clinically appropriate V_T and respiratory rate. The statement by Babic et al that the “calculated P_{aCO_2} was never in the normal range” is misleading because the values ranged from low to high for the chosen settings in the study, and values in the normal range could be achieved by adjusting the Vortran Automatic Resuscitator's operating conditions.

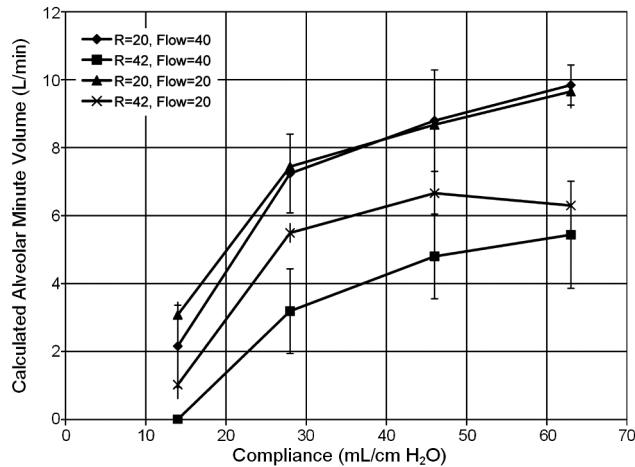


Fig. 2. Calculated alveolar minute volume versus lung compliance for each of the 4 combinations of airway resistance (R) and set device flow with the Vortran Automatic Resuscitator. The error bars represent one standard deviation. All the measurements were done with the device set at the lowest indicated maximum inspiratory pressure of 20–30 cm H₂O. The figure shows a drop in calculated alveolar minute volume due to expected decreasing tidal volume and compliance associated with high respiratory rates (> 40 breaths/min). (All data in this figure are from Table 2 in Reference 1.)

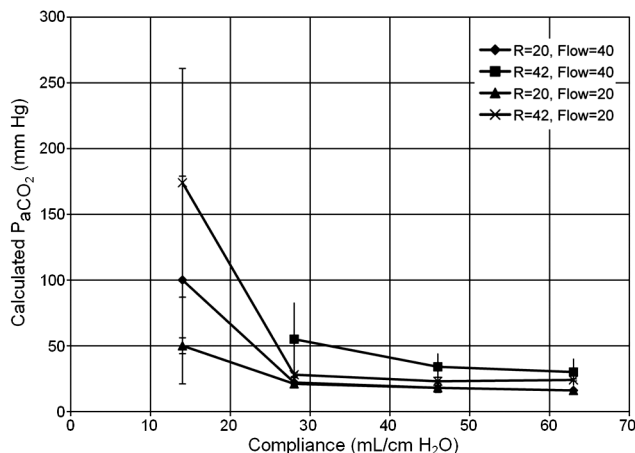


Fig. 3. Calculated P_{aCO₂} versus lung compliance for each of the 4 combinations of airway resistance and set device flow with the Vortran Automatic Resuscitator. The error bars represent one standard deviation.¹ All the measurements were made with the device set at the lowest indicated maximum inspiratory pressure of 20–30 cm H₂O. The figure shows that the device was able to provide sufficient ventilation, provided that the tidal volume was not too low (the predictable result of a low maximum-inspiratory-pressure setting of 20–30 cm H₂O and a compliance of only 14 mL/cm H₂O). (All data in this figure are from Table 2 in Reference 1.)

As Babic et al correctly stated, it is important that the Vortran Automatic Resuscitator be used under the supervision of a trained clinician who can evaluate the appropriateness of the settings and make adjustments as needed to the operating conditions to optimize the respiratory conditions to the patient's needs. In patients with severely limited lung compliance and/or high airway resistance, higher MIP may be indicated and a higher pressure setting can be used than the low setting that Babic et al

chose in their study, and in the worst cases an auxiliary PEEP controller may be desirable.

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S David Piper PE works for Piper Medical and is the inventor of the Pulmonary Modulation Technology on which the Vortran Automatic Resuscitator Model RTM is based. Vortran Medical Technology has the exclusive right to

manufacture and market the Vortran Automatic Resuscitator model RTM, based on a licensing agreement between Piper Medical and Vortran Medical Technology, for which Piper Medical receives periodic payment. The author reports no other conflicts of interest related to the content of this paper.

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The authors respond:

We appreciate the opportunity to respond to Mr Piper's "clarification" of our study.¹ We are mindful that our paper and its abstract captured the attention of financial beneficiaries of the Vortran Automatic Resuscitator, and we commend Mr Piper for articulating his questions about the study in a scientific forum.

As we read Mr Piper's letter, he makes 3 contentions that he suggests "clarify" the findings in our paper.

First, he contends that the Vortran Automatic Resuscitator's variable tidal volume (V_T), which, as he states "automatically adjusts to decreasing compliance by increasing breathing rate and decreasing V_T , with relatively stable \dot{V}_E ," is a benefit of its use

in patients with acute respiratory distress syndrome (ARDS). Implicit in his comment is that, in the context of the results of the ARDS Network trial,² which showed that a V_T of 6 mL/kg was associated with better survival in patients with ARDS, decreasing the V_T in response to decreasing compliance is beneficial and recommended. We believe that that contention, though broadly correct, overlooks the essential finding of the ARDS Network (in which our institution participated), that a specific V_T of 6 mL/kg is recommended, not a varying V_T , and not a V_T that exceeds 6 mL/kg, even if V_T decreases as the lung stiffens. Furthermore, in endorsing a maximum inspiratory pressure up to 50 cm H₂O, the “clarification” overlooks the target of a plateau pressure of < 30 cm H₂O in the ARDS Network trial,² which would probably be exceeded by a maximum inspiratory pressure of 50 cm H₂O in the absence of increased airway resistance (depending, of course, on the inspiratory flow rate). Furthermore, Mr Piper’s comment about the device’s automatic adjustment seems to imply that there is some intelligence in the adjustment process, which, of course, there is not. The adjustment is simply a mechanical response to a changing respiratory-system time constant. The only ventilators that make “intelligent” changes to the delivered V_T are much more sophisticated devices.³

The most important issue regarding “automatic” changes in ventilatory parameters is that, unlike any other ventilatory device, setting a “rate” on the Vortran device does not guarantee a preset number of *mandatory* breaths per minute, because the breaths are not time-triggered independent of the patient’s respiratory-system mechanics (ie, resistance, compliance, and muscle activity). On the contrary, *spontaneous* breaths are pressure-triggered according to the interaction of the Vortran’s internal leak flow (set by the “rate” knob) and the patient’s inspired V_T and expiratory time constant. Indeed, the “rate” knob should be thought of not as a frequency control but rather as a trigger-sensitivity control. What the operator is really doing (with a passive patient) is setting the ventilator to auto-trigger, much like a standard ventilator will do when there is a leak in the system.

The second contention is that our choosing a compliance of 14 mL/cm H₂O as a working condition in the study¹ was imprudent and cast the device’s performance in an unfavorable light. As we stated, our

goal was to examine the device’s performance under 2 mass-casualty conditions that would simulate those in which a portable, inexpensive device might be considered desirable, such as poisoning causing neuromuscular paralysis (in which the lung compliance would be expected to be normal) and acute lung injury/ARDS (in which the lung compliance would be decreased). Still, patients with ARDS have been reported to have average compliances as low as 37 mL/cm H₂O, with a standard deviation of 23 mL/cm H₂O, so compliance values in the teens would be expected in perhaps 30% of patients.⁴ In that context our choice of compliance values under which to simulate the use of the device seems defensible and appropriate.

Finally, Mr Piper found our statement about calculated P_{CO_2} misleading. We absolutely agree that only actual blood gas data from patients will settle the issue and allay concerns, but our experience in this study makes us reluctant to undertake actual clinical testing to resolve this.

Overall, we stand by our suggestions that, “The variable performance under changing load along with the lack of alarms should prompt caution in using the Vortran Automatic Resuscitator for emergency ventilatory support in situations where patients cannot be constantly monitored by trained and experienced operators.”¹ As evidence that truth in science is replication of findings, we point out that conclusions from other groups echo our concerns about the device.⁵

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The authors report no conflicts of interest related to the content of this letter.

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More Environmental Prevention of Gram-Negative Infections Needed

I appreciated the excellent review article¹ by Robert Siegel on emerging antibiotic resistance of Gram-negative bacteria. Gram-negative bacteria account for a large percentage of the estimated 99,000 annual United States deaths due to hospital-acquired infections. Better antibiotic management and the development of new antibiotics are important for controlling Gram-negative bacteria. However, many environmental interventions exist that can prevent Gram-negative infections, but are often overlooked in hospital practice.

Hand-washing is the most important single step in preventing the spread of Gram-negative infections. Various studies have reported that viable bacteria are commonly found on the hands of health care providers; these include *Pseudomonas* (found on 1.3–25% of provider hands), *Acinetobacter* (3–15%), *Klebsiella* (17%), and vancomycin-resistant enterococcae (41%).² An intervention to increase the use of alcohol-based hand rub and gloves reduced Gram-negative infections by 60% and Gram-positive infections by 60% ($p < 0.001$ for each comparison) in a neonatal intensive care unit.³

An intervention that involved education of hospital cleaning staff was associated with a 64% reduction in vancomycin-resistant enterococcae infection (95% confidence interval 0.19–0.68).⁴ Portable high-efficiency-particulate-air (HEPA) filters significantly reduce hospital airborne *Pseudomonas*.⁵ Siegel¹ cited several sources that reported that better disinfection and man-

agement of respiratory equipment can reduce the spread of Gram-negative bacteria.¹ Meta-analyses have found that many non-pharmacologic interventions can significantly reduce the rate of ventilator-associated pneumonia; these include kinetic bed therapy, subglottic secretion drainage, heat-and-moisture exchangers (rather than heated humidifiers), and oral decontamination with chlorhexidine.⁶

Environmental controls can prevent a large percentage of hospital-acquired bacterial infections. Fewer nosocomial infections will reduce overall antibiotic use, which should reduce the risk of creating bacterial antibiotic resistance and improve the efficacy of antibiotics given to patients who do acquire infections. Much more research is needed on the prevention and antibiotic treatment of Gram-negative infections.

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The author reports no conflicts of interest related to the content of this letter.

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The author responds:

Dr Curtis emphasizes some very important environmental issues that are frequently overlooked and some measures that can decrease the incidence of nosocomial infections. Organisms, such as *Acinetobacter*, that can persist for long periods on surfaces easily spread from patient to patient via hospital personnel (eg, radiology technicians and respiratory therapists) and equipment (eg, electrocardiographs, ultrasound machines, thermometers).

Improvements in intensive care unit design may reduce the risk from environmental surfaces that become colonized with pathogenic organisms. Curtains used for patient privacy may harbor organisms such as *Clostridium difficile* spores, and should be replaced with alternatives, such as E-glass or double glass plates with embedded shades

or blinds. Those surfaces are easy to clean and might help prevent infections by preventing colonization. Seamless intensive care unit floors and fabrication of environmental surfaces from materials that inhibit bacterial growth, such as copper, might also be effective. Research on those subjects is underway and may lead to new concepts and designs that provide a hospital milieu hostile to bacteria (personal communication, Neil A Halpern MD, Memorial Sloan-Kettering Cancer Center, New York, New York, April 28, 2008).

As Dr Curtis pointed out, subglottic suctioning decreases ventilator-associated pneumonia. Another strategy is silver-coated endotracheal tubes, which get less bacterial colonization.¹ We clearly need to look at innovations that can prevent infections, because they are not only cost-effective but will reduce the development of resistant microorganisms, decrease the need for antibiotics, and save lives.

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