

Automatic Gas-Powered Resuscitators

What Is Their Role in Mass Critical Care?



Automatic gas-powered resuscitators may *seem* like a good choice for ventilating patients in mass critical care situations. But ECRI Institute believes that the respiratory needs of most patients in such scenarios will exceed what these devices can provide. Therefore, stockpiling large quantities of them for disasters may not be the best use of your resources.

In any disaster scenario—whether an earthquake, pandemic, or terrorist attack—at least some of the victims will likely require respiratory support. For certain types of mass casualty events, the need for such support will be widespread. An influenza pandemic, for example, or the release of a chemical or biological agent (whether accidental or intentional) could cause severe and complex lung damage in thousands of victims. To stay alive, these patients will need intense respiratory therapy for days or even weeks.

Ideally, ventilators would be used for all such patients. But communities and healthcare facilities cannot afford to stockpile thousands of ventilators in preparation for an emergency that may or may not occur. Nor is sufficient equipment (or other aid) likely to be available from surrounding communities in the event of a large-scale disaster.

Consequently, as an alternative, some hospitals and communities are considering the purchase of large quantities of automatic gas-powered resuscitators (which



we abbreviate here as AGPRs) to provide respiratory support during mass critical care events. These devices are less expensive than ventilators—some of them considerably less so. They are also smaller and don't have the maintenance requirements of a ventilator. So acquiring a large supply of these devices for mass critical care use might *seem* to be an ideal strategy.

But in ECRI Institute's opinion, this is not the case. AGPRs do not have all the features to provide the sort of respiratory support that is likely to be required by most of the patients suffering from severe lung impairment during mass critical care events. While AGPRs may be useful in a disaster for a small subset of patients, most patients needing respiratory support will require functionality that only ventilators can provide. Consequently, we recommend against stockpiling large numbers of AGPRs for use in a catastrophe.

► This isn't a typical *Health Devices* Evaluation, although it started out as one. See "How We Reached Our Conclusions" on page 248 to learn about the genesis of this article. Also, please note that the opinions expressed in this article pertain only to the use of AGPRs for mass critical care events. We do not address their suitability for other uses, such as routine emergency medical service applications.

Ventilation Requirements of Mass Critical Care Patients

Most victims of biological agent exposure and pandemic influenza will suffer severe lung dysfunction—restricted airways, low lung compliance, and copious secretions—similar to that associated with the most complex respiratory diseases. The onset of these symptoms is likely to take hours or days. Once afflicted, patients are likely to require prolonged mechanical ventilation for at least several days, and possibly a few weeks.

Similar complications can be expected for victims exposed to chemical agents, though their impact will depend on the type and concentration of chemical agent, the exposure time, and the type of treatment provided. For some chemical-exposure cases, for example, victims' survival will depend on administration of an antidote following exposure; if the antidote is effective, the need for respiratory support may be minimal.

UMDNS term. Resuscitators, Pulmonary, Pneumatic [13-366]

A respiratory support device used on patients with these sorts of severe lung injuries must be able to provide adequate and consistent tidal volumes at consistent rates while keeping the lungs open with positive end-expiratory pressure (PEEP). It must be able to accomplish this even in the face of severely compromised or changing lung

VIEWPOINT

Something Isn't Always Better Than Nothing

Boiled down, the recommendations in this article lead to an uncomfortable conclusion: When a massive number of patients have suffered severe lung injuries, it may not be possible to give all of them the mechanical breathing support they need. Ventilators are too expensive to stockpile in sufficient quantity to assist every patient who has been the victim of, for example, a pandemic virus. And obtaining enough of them from other sources (e.g., surrounding communities) may not be feasible.

That's why some observers strongly support the notion that using automatic gas-powered resuscitators (AGPRs) is essential in these cases. They argue that AGPRs can serve as a "bridge" to temporarily provide respiratory support until a ventilator is available and that they should be stockpiled to augment the existing cache of ventilators. While AGPRs may not be ideal, this thinking goes, they are better than nothing.

But other observers adamantly disagree. They contend that the limitations of AGPRs will render the devices ineffective—that they can't adequately ventilate patients having the sorts of lung injuries that are likely in mass critical care situations. These individuals believe that communities will be better served by using funds for other aspects of emergency preparedness, such as conducting disaster drills or purchasing antidotes, as well as augmenting their ventilator cache as best as possible with basic ventilators that have the necessary features for these types of lung injury. ECRI Institute agrees with these conclusions.

There's no doubt that the lack of ventilators for emergency mass critical care is a serious problem that needs to be addressed. But we firmly believe that large-scale use of AGPRs is not the answer. ♦

How We Reached Our Conclusions

This article began life as a standard *Health Devices* Evaluation. Because automatic gas-powered resuscitators (AGPRs) have been pegged by some as a suitable solution to the shortage of ventilators that would occur during a mass critical care event, we decided to test these devices to make sure they were, in fact, a good choice for that use.

In keeping with our usual practice, as we started testing these devices, we also spoke with outside experts and reviewed the literature. We wanted to find out what role AGPRs were likely to serve in a disaster.

What we learned was that the complexity of the lung damage that will likely be suffered by most patients during events requiring mass critical care exceeds what AGPR designs are able to support. As we outline in this article, mass critical care victims will require devices that allow the user to set tidal volume, respiratory rate, and positive end-expiratory pressure (PEEP), and that will maintain these values consistently in the presence of changing lung conditions. None of the AGPRs currently on the market can provide all these capabilities.

Our literature searches uncovered no studies supporting the use of AGPRs in mass critical care events. We found neither prospective studies nor retrospective analyses of AGPR use from previous disasters. The literature we did find supported the use of ventilators in such cases—for example, there was a report in which SARS (severe acute respiratory syndrome) patients required 10 days of support on intensive care ventilators,* and another in which anthrax inhalation victims were shown to require ventilators.**

Once we were convinced that AGPRs simply do not provide the features that mass critical care patients would need, we stopped testing the devices. No laboratory testing was needed to confirm the absence of what we believe are essential capabilities. ♦

* Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med* 2006 Feb;13(2):223-9.

** Centers for Disease Control and Prevention, U.S. Update: investigation of bioterrorism-related anthrax and interim guidelines for clinical evaluation of persons with possible anthrax. *MMWR Morb Mortal Wkly Rep* 2001 Nov 2;50(43):941-8. Also available: www.cdc.gov/mmwr/preview/mmwrhtml/mm5043a1.htm.

conditions. Specifically, the device must have controls for setting the following values and must be able to maintain them consistently:

- Tidal volume
- Respiratory rate
- PEEP level

These requirements are in line with the recommendations of the American Association for Respiratory Care and the American College of Chest Physicians; see the box “Meeting Respiratory Needs in a Disaster” on page 249.

How AGPRs Operate

Gas-powered resuscitators deliver positive-pressure breaths via face mask or endotracheal tube to the patient's lungs. They operate on compressed gas at 45 to 80 psi. Depending on the design, the units cycle from inhalation to exhalation either when a set pressure level is reached or when a set tidal volume is delivered.

For devices that operate by controlling pressure, the user adjusts the peak inspiratory pressure (PIP) control; one device has a rate-adjustment control as well. The delivered tidal volume will depend on the PIP setting and

the patient's lung compliance. The patient receives the incoming flow until the set PIP is reached (this is the inhalation phase); then a valve diaphragm opens, releasing the flow into the atmosphere (the exhalation phase). The unit that includes a rate-control knob adjusts the flow rate of the patient's exhaled breath.

For devices that operate by controlling tidal volume, the user sets the tidal volume; when the set volume is delivered, the device releases flow to the atmosphere. The patient's PIP will vary depending on the set tidal volume and the condition of the lungs.

Neither type of device has a control for PEEP. Both types feature an automatic pop-off valve to prevent patients from receiving pressures greater than 60 cm H₂O. They also have oxygen gas inlet fittings, but these may be adapted for air; in addition, some devices can entrain air, thus reducing the consumption of oxygen (which can be in short supply during a disaster).

Limitations of AGPRs

None of the AGPRs on the market provide all three of the features essential to ventilating most mass critical care

patients: control of tidal volume, respiratory rate, and PEEP level. One model has a volume setting; two have pressure settings; none provide user-set PEEP.

Moreover, most models are pressure-cycled—they deliver flow until the set pressure is reached, then open a valve to release pressure. This can pose a problem with patients whose lungs start to lose function (for example, because of fluid accumulation or bronchospasm) and grow stiff. As lung compliance decreases, the resuscitator's set pressure is reached more quickly, shortening the inhalation phase. If adequate PEEP cannot be provided, the lungs may begin to collapse, making breaths increasingly inadequate.

AGPRs have other drawbacks as well. One is that they need compressed gases to operate. Since an E-cylinder of compressed gas can operate a device for only approximately 25 minutes (depending on the settings and lung compliance), obtaining adequate cylinder supplies for a disaster in which hundreds or even thousands of victims may require ventilation for several days or more is daunting at best. (Note, however, that air compressors or the hospital's compressed-gas system could be used as an alternative in some situations.)

Another drawback is that most AGPRs do not have alarms to warn clinicians of device malfunction or of failure to deliver adequate ventilation (e.g., because of disconnections or changes in patient lung conditions). This is particularly concerning because it is unlikely that each patient will be able to receive continuous individual care, given the severe staffing shortages expected during mass critical care events.

Because of these limitations, AGPRs are likely to serve, at best, a minor role during disasters. (See the table on page 250.) They may be useful for situations in which victims need respiratory support but otherwise have normal lungs—for example, in cases of CO₂ poisoning, botulinum toxin exposure, chemical inhalation (after antidote administration), or secondary effects such as heart attack. Using these devices for these patients may free up ventilators for patients who need them.

Therefore, having a small number of AGPRs on hand may be useful, as long as you are aware of their limitations and carefully select the patients on whom you use them. But in most mass critical care events, the number of victims who can be effectively ventilated using AGPRs will be small, and stockpiling large numbers of these devices will not be the best use of resources.

Meeting Respiratory Needs in a Disaster: AARC and ACCP Recommendations

Two organizations have issued materials outlining ventilator-support requirements during mass critical care events: the American Association for Respiratory Care* and the American College of Chest Physicians.**

This is a list of the principal ventilator requirements recommended by both groups:

- Independent controls for each of the following settings: tidal volume, respiratory rate, inspired oxygen concentration, and positive end-expiratory pressure (PEEP). Also, the ability to accurately deliver a prescribed minute ventilation when patients are not breathing spontaneously.
- Alarms for loss of power source (gas and/or electricity), low pressure, high pressure, and disconnect, as well as apnea, circuit disconnect, low gas source, low battery, and high peak airway pressures.
- Ability to operate across a wide range of patient populations (infants to adults).
- Easy, safe operation.
- Minimal maintenance.
- Ability to operate for four to six hours when electric and gas supplies are unavailable. Battery operation might include internal and external batteries.

In addition, current literature on the subject (e.g., Branson and Rubinson 2006, Daugherty et al. 2007, Hick et al. 2006, Rubinson et al. 2008) supports recommendations similar to the above. ♦

* American Association for Respiratory Care. Guidelines for acquisition of ventilators to meet demands for pandemic flu and mass casualty incidents [online]. 2006 May 22 [cited 2008 Jul 8]. Available from Internet: www.aarc.org/resources/vent_guidelines.pdf.

** Rubinson L, Hick JL, Hanfling DG, et al. Definitive care for the critically ill during a disaster: a framework for optimizing critical care surge capacity: from a Task Force for Mass Critical Care Summit meeting, January 26-27, 2007, Chicago, IL. *Chest* 2008 May;133(5 Suppl):18S-31S.

See the update at the bottom of this PDF.

What Are the Alternatives?

If AGPRs aren't the answer, what is? Unfortunately, there's nothing currently on the market that is both inexpensive and able to meet the needs for this application. We encourage manufacturers to develop products that have alarms, an internal gas source (compressor, turbine), and an internal battery, in addition to being able to control tidal volume, respiratory rate, and PEEP.

In the meantime, we are aware that certain hospitals are taking some or all of the following steps:

- Purchasing as many transport or portable ventilators as their budgets permit
- Planning to pool resources with other local hospitals (though this may be of limited use during a region-wide or nationwide disaster)
- Planning to triage the allocation of ventilators based on established guidelines

Also, keep in mind that the U.S. Centers for Disease Control and Prevention operates the Strategic National Stockpile, which has about 4,000 ventilators on hand to be deployed as needed—although, in a pandemic, these are likely to be resourced out very quickly.

We welcome suggestions for solutions to this crucial problem.

Ratings for the Available Products

As discussed in “How We Reached Our Conclusions” on page 248, we had originally intended a comprehensive Evaluation of AGPRs. But we stopped after performing only limited testing, having recognized that, regardless of how well they operate, these devices lack the functionality that ECRI Institute believes is needed for most patients in mass critical care scenarios (see the table on this page

ECRI Institute Rating: Not Recommended

for support of patients with the sort of complex lung damage that is likely during mass critical care events

None of these devices offer the ability to set and maintain consistent tidal volume, consistent respiratory rate, *and* consistent PEEP level. Therefore, we recommend against stockpiling large quantities of them for use in mass critical care scenarios. ♦

Usefulness of Automatic Gas-Powered Resuscitators for Respiratory Support in Mass Critical Care Events

During a mass critical care event, a small number of patients may be suitable candidates for AGPRs—specifically, patients with normal lung function who are suffering other problems that require ventilator support. Such problems might include secondary effects such as heart attack. Support could be required at the scene, during transport, and during hospitalization while compressed-gas supplies are available.

The following are examples of mass critical care scenarios. A check mark (✓) indicates scenarios in which AGPRs are likely to be useful for most victims. Judgments are based on the likely symptoms of patients in each scenario.

BIOLOGICAL (e.g., influenza pandemic, attack)	
Anthrax	—
Botulinum toxin	✓
Bubonic plague	—
Influenza pandemic (e.g., avian flu)	—
CHEMICAL (accidental or deliberate release)	
Carbon monoxide	✓
Chlorine	—
Cyanides	—
Mustard/lewisite	—
Nerve agent (for the few victims requiring ventilator support after administration of antidote)	✓
Phosgene	—
OTHER (events in which most victims will not have severe lung injuries or dire lung conditions)	
Earthquake	✓
Tsunami/hurricane	✓

and the table on page 251). Therefore, our rating for these products is not based on our testing, but on the units' basic capabilities.

Ambu Ambumatic

Supplier information. Ambu Inc. [104479], Glen Burnie, Maryland (USA); +1 (800) 262-8462, +1 (410) 768-6464; www.ambuusa.com

Description. The Ambumatic is a pneumatically powered reusable, time-cycled device in which the user sets tidal volume on a calibrated slide control. It operates on a high-pressure gas source (39 to 94 psi of compressed oxygen); it also has a control for air entrainment. Respiratory rate is dependent on the tidal-volume setting. It has an optional pressure manometer.

Cost. Approximately \$1,750.

Note. Ambu Inc. has discontinued this product and no longer offers an automatic resuscitator. The Ambumatic may be available from some third-party vendors, but quantities may be limited, and you may not be able to supplement your inventories in the future.

Availability of AARC-Recommended Features on Automatic Gas-Powered Resuscitators

The following features are recommended by the American Association for Respiratory Care for ventilation during mass critical care events. A check mark (✓) indicates availability of these features on the systems we looked at.

Features	Ambu Ambumatic	Lifesaving Systems Oxylator EMX	Vortran VAR-Plus and VAR RC
Basis for our rating			
Tidal volume setting	✓	—	—
Respiratory rate setting	—	—	See footnote*
PEEP setting	—	—	—
Additional features			
Oxygen setting	—	—	—
Alarms	—	—	See footnote**

* The VAR has a nonquantitative rate setting—a “faster/slower” dial without graduations or numerical indicators.

** ECRI Institute has been provided with documentation of premarket clearance for a version of the VAR that will alarm when the unit stops cycling. We have not examined this version.

Lifesaving Systems Oxylator EMX

Supplier information. Lifesaving Systems Inc., Roswell, Georgia (USA); +1 (866) 699-5283; www.lifesavingsystemsinc.com

Description. The Oxylator is a reusable pneumatically powered, pressure-cycled device. It requires an input flow of at least 30 L/min of oxygen or air from a compressed-gas source of 35 to 80 psi. The user sets the pressure level by rotating a selector sleeve. The device has a manual mode that allows the users to initiate and terminate breaths.

Cost. \$850 to \$950.

Vortran VAR-Plus and VAR RC

Supplier information. Vortran Medical Technology 1 [156127], Sacramento, California (USA); +1 (800) 434-4034; www.vortran.com

Description. Both devices are disposable, pressure-cycled units. The VAR-Plus and the VAR RC are similar but intended for different patient populations; the former is intended for patients 10 kg or greater and the latter for patients 40 kg or greater. They operate on 20 to 40 L/min oxygen or air from a compressed-gas source of 39 to 80 psi. The user sets a PIP range and a “faster/slower” respiratory rate (with no graduations or indication of rate setting) independently using manual dial controls.

Cost. \$60.70.

Notes. During our testing, some of the VAR units spontaneously stopped functioning. However, we are not aware of any reports of this occurring clinically. For more details, see our December 2007 Hazard Report, “Vortran VAR Gas-Powered Resuscitators (Also Referred to as the Surevent) May Spontaneously Stop Delivering Breaths.”

Also, a version of the VAR that will alarm when the unit stops cycling is now being marketed. ECRI Institute has not tested this version but has been provided with documentation of premarket clearance for it.

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EVALUATION UPDATES

New Information on Recent Studies

Radio-Frequency Surgical Sponge Detection

In our July 2008 issue, we presented our Evaluation of radio-frequency (RF) surgical sponge detection systems (“Radio-Frequency Surgical Sponge Detection: A New Way to Lower the Odds of Leaving Sponges [and Similar Items] in Patients”). In this article, we discussed the two sponge detection systems currently on the market, ClearCount Medical’s SmartSponge System and RF Surgical Systems’ RF Surgical Detection System. Both systems are designed to reduce the risk of surgical sponges being retained in patients after surgical procedures, but in different ways: The SmartSponge System detects and uniquely identifies each sponge while simultaneously maintaining a running count of the sponges as a redundancy to manual counts, whereas the RF Surgical Detection System only detects the sponges.

Each system had a similar per-procedure cost (approximately \$55, based on 35 RF-tagged sponges); however, the SmartSponge System also included an initial added cost of \$19,000 for the associated equipment. Therefore, in the Evaluation, we stated that the RF Surgical Detection System should be given first consideration due to its overall lower cost and simpler approach compared to the SmartSponge System.

Since the publication of the article, ClearCount Medical has informed us that it has altered the pricing structure for its system. Now, the cost per procedure is approximately \$50, which includes the cost of all associated equipment. This new structure eliminates the \$19,000 initial equipment charge, making the revised cost of the SmartSponge System comparable to the cost

of the RF Surgical Detection System. Therefore, we believe that both systems should be given equal consideration as a means to reduce the number of retained surgical sponges, and facilities should purchase the system that best meets their needs. And with costs now being equal, some facilities may find the redundancy in sponge counting offered by the SmartSponge System appealing.

In addition, ClearCount Medical has discontinued the SmartMat—a disposable mat embedded with RF tags used before the start of the procedure to verify that the system is working properly in detecting RF tags through the patient. The SmartMat has been replaced with the SmartTag, a smaller version of the mat that has the same functionality.

Automatic Gas-Powered Resuscitators

After publishing our August Evaluation “Automatic Gas-Powered Resuscitators: What Is Their Role in Mass Critical Care?” we received a question regarding our use of the term “pressure-cycled” to describe some of the evaluated products. We reexamined our wording and decided that, because it may be unclear that these devices are controlled by setting a specific inspiratory pressure, the term “pressure-controlled” is probably better for describing their function. This term indicates that these devices end the inspiratory phase when the set pressure level is reached, and that exhalation is passive. The exhalation time depends on the patient’s compliance and resistance, and these devices do not apply negative pressure during exhalation. ♦