According to the United States Census Bureau, approximately 320 million people reside in the United States of America and that number is on the rise.

Historical and recent possibilities of high profile pandemic outbreaks have raised awareness of the acute problem of treating and dealing with mass casualty situations. A pandemic is a disease outbreak, potentially reaching all areas of the world.

One particular issue of great concern is the lack of an adequate way to deal with large groups of people requiring ventilation quickly and effectively. The number of ventilators required to save the lives of people stricken with respiratory failure in a pandemic is far greater than the number of ventilators available.

Of the several major influenza pandemic outbreaks in the 20th century, the 1918 influenza was the most deadly. Killing roughly 50 million people worldwide, this 1918 outbreak eliminated a significant number of the world's population.

During a severe influenza pandemic, many patients with respiratory failure who are able to receive mechanical ventilation may survive, while patients with respiratory failure who do not receive mechanical ventilation are likely to die.

The Center for Disease Control (CDC) assumes that ventilators will be in short supply in many communities prior to or during the peak of a severe influenza pandemic if something is not done.

According to the American Association for Respiratory Care, approximately 62,000 full-feature mechanical ventilators are available in the United States of America. This leaves more than 99% of the United States population without any available form of ventilation in the event of a pandemic outbreak. Current ventilator capacity and usage in the United States is about 75% to 95% utilized with existing cases (COPD, elderly, accident victims, trauma, post surgical, cardiac, etc)

Currently, Endotracheal (ET) intubation is utilized in conjunction with positive pressure ventilation for respiratory support in patients with cardiac or respiratory arrest during emergent situations.

Coupled with the shortage of qualified clinicians capable of managing endotracheal intubation, even with a stockpile of positive pressure ventilators, only a very limited number of patients can be treated.

What will be needed?

- A reliable ventilator that can be produced in a large quantity in a relatively short time.
- The device will not require every feature and ability of existing full function ventilators, but must have the features required to properly ventilate and care for ARDS in a pandemic situation.
- A device that is automated as much as possible to enable clinicians to care for a large number of patients.
- A design of controls and alarms that is intuitive so that other persons can be trained to help support the devices in use.

Biphasic Cuirass Ventilation, by United Hayek provides a real answer to these problems:

- No need for skilled medical staff
- Effective non-invasive ventilation without intubation
- Simplicity of use even when cumbersome protective gear is worn
- Portable - from the field to the medical center with no need for additional equipment

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What is **Biphasic Cuirass Ventilation (BCV)**? BCV is a method of ventilation that works using a non-invasive cuirass or shell, attached to a power unit that actively controls both phases of the respiratory cycle (the inspiratory and expiratory phases), increasing the both the patient's cardiac output and minute ventilation.

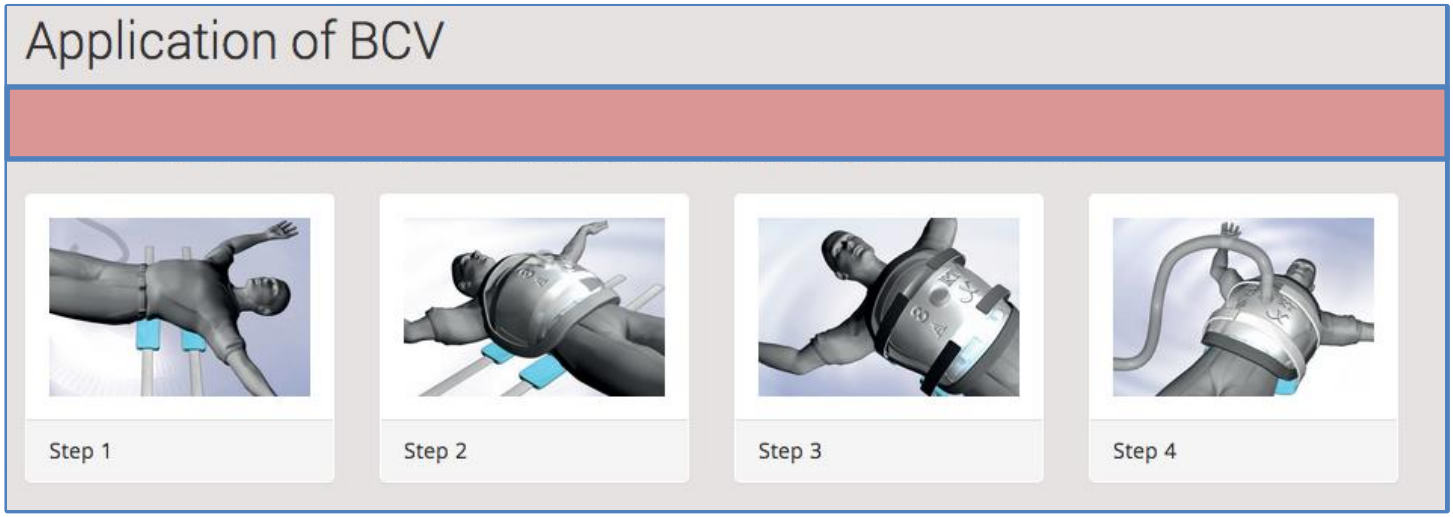
With BCV, it is possible to achieve both higher tidal volumes using negative and positive pressures, higher frequencies -from 6 to 1200CPM, and also for the user to have proper and real control over I:E Ratio, without having to depend on passive recoil of the patients chest.

In addition, the patented technology used for the cuirass and its disposable seal in BCV allows for a comfortable fit and seal of the air within the cuirass. These advantages allow for a much higher minute ventilation to be created and thus making complete ventilation possible, entirely non-invasively.

United Hayek offers user-friendly, fully computerized devices, which have twelve sizes of cuirass shells enabling treatment of adult, pediatric and infant patients.

Compact and lightweight, our devices are ideally suited to ventilate a patient for up to 4- 24 hours on one charge, making United Hayek devices extremely portable and reliable.

United Hayek ventilators provide an efficient and effective method of non-invasive external ventilation and can be a real alternative to traditional forms of ventilation.



United Hayek Offers Ideal Emergency Response Non-invasive Ventilation:

- Provides complete ventilation to patient.
- Is non-invasive.
- Works in a physiological way.
- Works in the way that the lungs work most efficiently by actively controlling both phases of the respiratory cycle.
- Provides even ventilation for patient.
- Improves cardiac output.
- Assists patient to remove secretions which are a symptom of most respiratory diseases, especially in a pandemic outbreak.
- Can begin to provide treatment for patients before their condition deteriorates due to the pandemic.
- Comfortable for the patient.

Consider The Risk Factors; Start Thinking About United Hayek Now:

- United Hayek can provide effective ventilation without intubation.
- Simple to use.
- Can ventilate a patient for up to 24 hours.
- There is strong clinical data to support Biphasic Cuirass Ventilation.
- The MRTX can be applied broadly across any demographic and population.
- No differential access or criteria for special groups.
- Can solve the following issues:
  - Too few ventilators for patients
  - Too few staff for more ventilators
  - Rationing of ventilators needed

BCV - Here's the Proof:

Exhibit A

Application of a Cuirass and initiation of Biphasic Cuirass Ventilation by gear-protected physicians was investigated. In the study, 10 physicians of multiple specialties applied a cuirass shell on an adult patient. Biphasic Cuirass Ventilation was initiated using the Hayek RTX ventilator. ET intubation and manual ventilation of a mannequin were also reasonably evaluated.

In conclusion, physicians wearing full protective gear applied a cuirass shell and instituted Biphasic Cuirass Ventilation much quicker than ET intubation and manual positive pressure ventilation.

Application of a Cuirass and Institution of Biphasic Extra-Thoracic Ventilation by Gear-Protected Physicians

Table 1. Endotracheal Tube Insertion and Cuirass Application (see text, mean ± SD)

	Endotracheal Intubation	Cuirass Application
Time to successful application (s)	177 ± 31*	102 ± 8.7
Failure during 1st attempt (n)	4	1
Failure during 2nd attempt (n)	2	0

*$P < .01$ *v.* the cuirass value.

Exhibit B

In another study Comparing the MRTX ventilator to positive pressure ventilation (PPV) in OP (paraoxon) poisoned pigs, three study groups were examined:

- Control – no ventilatory support
- PPV – using an airbag ventilation (more abundant measure; technical difficulty)
- Biphasic ventilation Using the MRTX

There were a total of 23 animals – two were used as controls to establish the specific respiratory insult model, seven in every other group. Each animal was exposed to *1.2*LD50 of paraoxon IM Atropine was given IM eight minutes post exposure. After ventilation was stopped, the MRTX group started to breath freely and independently, in contrast to the PPV and control groups. Survival Rate in each group:

- 33% of Control group survived with no ventilatory support
- 28% of the PPV group survived using an airbag ventilation
- <u>100% of the Biphasic ventilation group using the MRTX survived.</u>

Exhibit C

The effect of BCV for acute respiratory failure through the patient of pandemic A (H1N1) influenza infection was examined. BCV (Continuous Negative Mode: CNEP) was used as respiratory management in 4 cases, and BCV (Secretion Clearance Mode: SC) was used as airway clearance in 8 cases. All 4 BCV (CNEP) cases had pneumonitis, respiratory distress and severe hypoxia. In 3 cases using BCV (CNEP), atelectasis was present. BCV (SC) with BCV (CNEP) was used to clear their airway 3 or 4 times a day. The patients recovered without intratracheal intubation.

Overall, BCV was effective for pandemic A (H1N1) influenza. Especially, the direct effects that BCV (CNEP) provided from early respiratory distress, and as a result prevented serious illness. BCV (SC) prevented obstruction of the airways, and also aided patient's to recover from marked obstructions (plastic bronchitis).

BCV – It's the Only Alternative

Considerable costs are associated with stockpiling, maintaining reserve ventilators, and funding the training of personnel needed to operate and maintain ventilators skillfully and safely. The major need for skilled medical staff is eliminated when using BCV, therefore delivering a significant cost reduction.

During a severe influenza pandemic and declared public health emergency there may be a severe shortage of healthcare professionals skilled in providing intensive care. With BCV, the goal of increasing the number of individuals trained or cross-trained to manage ventilator-dependent patients is easily achieved.

In pediatrics, BCV has been used to successfully ventilate infants with respiratory failure. It should be noted that of the 62,000 available full-feature mechanical ventilators in the United States, less than 50% of those ventilators can be utilized in a pediatric population. With the appropriate cuirass shell, BCV can be used on mostly anyone, regardless of his or her age.

Positive pressure ventilation techniques, as well as invasive mechanical ventilation, have a lengthy list of adverse effects, which BCV does not. Some potential adverse physiologic effects of positive pressure ventilation (PPV) are:

1. Decreased cardiac output
2. Unintended respiratory alkalosis
3. Increased intracranial pressure
4. Gastric distension
5. Impairment of hepatic and renal function

Perhaps the most feared complications occurring during mechanical ventilation include:

1. Pneumothorax
2. Brochopleural fistula
3. Development of nosocomial pneumonia

The use of positive pressure ventilation can lead to barotrauma, volutrama and possible development of a pneumothorax. These complications can be entirely avoided with the use of BCV.

BCV offers effective, even and natural ventilation without risk to the patient and can be applied by virtually anyone with minimal training.

BCV will also facilitate the clearance of secretions in contrasts to PPV, which compounds secretions.

BCV provides the only real solution to the complexities encountered in delivering life saving ventilation in such events.