Introducing BostonVent

Born of the COVID-19 pandemic, BostonVent is a ventilator developed to:

1. Provide increased access to ventilators in poorer countries. While it's estimated that US hospitals have more than 70,000 full-featured ventilators, 41 African countries have a total of 2,000 units between them. Ten countries have no ventilators at all[1].
2. Support the stockpiling of ventilators in richer countries in case of widespread future need, such as a new wave of COVID-19 cases or another future pandemic.

What sets BostonVent apart from other low-cost ventilators developed in response to the COVID-19 crisis is its appropriateness for use beyond initial resuscitation, at all stages in a respiratory illness. It is designed to be inexpensive, safe, effective, readily manufactured from commonly available parts, easy to service, highly transportable, and usable in adverse environments. The electronics, software, and mechanical designs are all open-sourced and freely usable. BostonVent will be produced under a business model (described later) that is designed to minimize pricing while enabling long-term manufacturing, distribution, and support.

Figure 1: BostonVent CAD Model

Pricing

Through the use of commonly available commodity components, BostonVent is expected to have a selling price of $4,000 or less. Current hospital-grade ventilators with the same core features sell for $20,000 and up.

Effectiveness

To help ensure that BostonVent is clinically effective and fit for purpose, the BostonVent development team includes anesthesiologists and critical care physicians with deep expertise in patient ventilation. Unlike most ventilators developed in response to the COVID-19 pandemic, BostonVent supports the major features expected in a contemporary Intensive Care Unit (ICU) ventilator. Additional (and less-often-used) features that are available on higher-priced devices can be added in the future, largely through software updates. However, it may be advantageous to support only the current core features in order to simplify its use and cognitively unburden clinicians.

Ventilation Modes

There are two basic ventilator modes:

[1] Ruth Maclean and Simon Marks, "10 African Countries Have No Ventilators. That's Only Part of the Problem.," *The New York Times*, April 18, 2020, sec. World, https://www.nytimes.com/2020/04/18/world/africa/africa-coronavirus-ventilators.html.

- *Mandatory* ventilation, in which the ventilator performs *all* breathing for the patient, and
- *Supported* ventilation, in which the ventilator *supports* (supplements) a patient's spontaneous breathing during long-term care and "weaning" off of ventilation.

The vast majority of "COVID-19-designed" ventilators use electromechanical mechanisms that squeeze bags of air (technically known as "bag valve mask" devices, or BVMs) which are supplemented with oxygen. The BVMs themselves are not designed for this purpose; they are produced for short-term *manual* use (periodic manual squeezing by a provider) when an automatic ventilator is not available. For example, in the setting of emergency resuscitation outside of a hospital or for short within-hospital transport of a non-critical patient. Simply substituting automated squeezing simplifies ventilator design, but at the expense of important features and reliability; in particular, these "automatic bag squeezers" provide only *mandatory* ventilation mode, whereby the ventilator performs all breathing for the patient. While this is normally useful in the early resuscitation phase of critical care, it is inappropriate for patient who are destined to recover from their illness, breathe on their own, and ultimately be liberated from a ventilator. Also, as BVM bags are designed for short-term emergency use, meaningful data have not been developed around the reliability of their long-term use.

By contrast, BostonVent provides ventilation using compressed air and oxygen, which are ubiquitous in hospitals. This more sophisticated approach enables both *mandatory and supported* ventilation, from the early resuscitation phase through to the critical support of a patient's spontaneous breathing during long-term care and weaning off of ventilation.

In short, BostonVent currently offers all the core features needed for most ventilation scenarios, which cannot be provided by BVM-based ventilators.

FiO2

BostonVent can deliver a tightly controlled oxygen concentration (FiO2) of up to 100%, as is often needed for ventilated patients. In contrast, FiO2 in bag squeezers is loosely controlled, and they frequently cannot achieve 100% oxygen delivery.

Suctioning

BostonVent has a maximal flow rate adequate to maintain ventilation and preserve positive end expiratory pressure (PEEP) while suctioning the patient's airways, a procedure that is vital for ICU care. This is technically nearly impossible with the use of BVMs without adding considerable complexity.

Safety

Safety is of utmost importance in a medical device. The BostonVent team includes engineers with substantial experience in developing regulated (e.g., FDA) life-critical medical devices. BostonVent implements the safety features expected in these critical devices – for example, it contains two independent computer systems to ensure that the failure of one is detected and can be handled properly by the other.

FDA clearance will be sought for BostonVent under the FDA's 510(k) submission process. More than 95% of medical devices are cleared via the 510(k) process, and the average time from submission to clearance is less than 6 months. Our medical device engineers have played a key role in developing more than a dozen devices that have been submitted for 510(k) clearance, and 100% of these were cleared.

Manufactured from Commonly Available Components

One key to BostonVent's low cost, high reliability, and ease of maintenance and repair is the careful use of off-the-shelf components, rather than the highly customized components typically used in medical devices. Off-the-shelf components are typically much less expensive than their customized equivalents.

Another important advantage of off-the-shelf components is that they oftentimes have been in use for many years and in perhaps millions of installations, so their reliability is well understood. By comparison, the reliability of custom components (in particular, electromechanical ones like valves used in ventilators) can be challenging to accurately determine before going to market.

The components used in BostonVent have been carefully assessed to assure that they meet relevant regulatory standards and are appropriate for medical device use.

The use of commodity parts also makes BostonVent easy to service – diagnosing malfunctions can be performed using standard tools, and replacement parts may be ordered from vendors throughout the world. Additionally, by using standard pneumatic and electrical connections, component replacement is modular and trivial to perform.

Highly Transportable, Usable in Adverse Conditions, and Designed to be Stockpiled

The BostonVent's enclosure may not win awards for beauty: when folded down, it looks and carries like a sturdy suitcase. In fact, its enclosure *is* a sturdy suitcase - BostonVent is built into a commercially available hardened plastic case that is certified to US and NATO military specifications. This construction makes BostonVent suitable for use in harsh conditions, and its size and shape are ideal for minimizing the space occupied by a stockpile (i.e., stackable with very little wasted space). Provisions have been made in the design to ensure that the devices remain ready for immediate deployment while in long-term storage by periodic stroke testing, a feature not commonly found on any ventilator. For situations without access to electricity and/or piped air and oxygen, the unit may be operated using two standard car batteries and readily available resources, such as portable bottled air or oxygen, an oxygen concentrator, and/or an air compressor.

Open Source Design

In an unprecedented move for a sophisticated medical device, we have chosen to make BostonVent's electronics, software, and mechanical designs open source (i.e., freely available to all). We believe that this offers several important advantages relative to proprietary designs:

1. It will result in reduced costs. Multiple manufacturers can build BostonVent and compete on price. Whether in the US or other countries, BostonVent can be manufactured locally from readily available parts. In addition, governments, healthcare providers, and non-governmental organizations (NGOs) potentially can build their own devices at the lowest cost.
2. It will increase safety by allowing engineers, physicians, and others to review its design. While our own team has substantial experience and expertise, we will actively solicit reviews from experts at the finest hospitals and engineering institutions around the globe.

3. It will support innovation by allowing others to extend our design with new developments. It is much easier to update an existing device than to create a new one from scratch. For example, if a biomedical engineer has a great idea for adding a helpful feature, she can add that feature to the BostonVent design. Of course, to use it commercially, relevant regulatory authorities (e.g., FDA) must approve the change. However, this approval process is much easier by piggybacking off of an existing, approved design.

BostonVent Business Model

BostonVent's business model is designed to:

- Maximize access to devices, and
- Maintain income to fund an operation that can provide adequate long-term technical support.

We will either create or partner with a non-profit foundation, which will hold the intellectual property for BostonVent and commence manufacturing.

1. The designs themselves – electronics, software, and hardware – will be free and open source for any entity, commercial or non-commercial.
2. The (voluminous) detailed design and test *documentation* necessary for acceptance by FDA and similar international regulatory bodies (i.e., requirements, specifications, test reports, and so forth) will be copyrighted and held by the foundation. Licenses will be granted to non-commercial entities at a low cost (or perhaps no cost), while commercial entities may license these for a fee. In principle, commercial entities can, since they have the design, create this documentation on their own, but it is a large and challenging task that requires a highly specialized group of experts.
3. The foundation will partner with a small set of contract manufacturers to produce devices using processes that are fully approved by the FDA and other international agencies. Anyone may purchase these units, which will carry a modest markup to fund the foundation's expenses. Non-commercial entities will pay a reduced price.

Team Personnel

BostonVent was initially developed and prototyped as an open-source design by a team of engineers and doctors at Imperial College London, with whom we are partnered. Our US team is dedicated to developing this innovative prototype into a finished medical device that conforms to the design and manufacturing requirements set forth by the FDA and similar international bodies. The US team is Boston-based, and currently consists of ten active volunteers with experience that is deep and relevant, among them:

- Two anesthesiologists/intensivists affiliated with Harvard Medical School (Massachusetts General Hospital and Brigham and Women's Hospital), with extensive ICU as well as pre-hospital care experience.
- Four engineers who work at entities affiliated with Harvard Medical School or MIT.
- Two medical device engineers with more than 35 years of combined experience in developing commercial FDA-regulated devices, many of them life-sustaining. One is the author of a popular

book on developing technology products from design through to manufacturing, published by O'Reilly Media.
- A former IBM software manager.

Supporting BostonVent

The BostonVent team has produced a prototype that is highly functional but does not yet implement all functionality or meet the rigorous documentation, safety, and testing standards that the FDA (and our team members) require for a medical device. We are seeking funding in two phases that cumulatively fund product completion:

1. Completion of additional, fully-functional prototypes.
2. Extensive testing that will lead to production.
3. Generation of the substantial documentation required by the FDA to convincingly demonstrate safety and efficacy.
4. Obtaining FDA clearance.
5. Initiating marketing activities.

We feel that a two-phase approach will enable important short-term efforts via a smaller investment, while we are pursuing longer-term and higher-dollar efforts (e.g., larger grants, donations, etc.). Fundraising activities for this second phase are currently underway.

Phase 1: Fully-Functional Prototypes

We are currently seeking funding totaling $35,000 in donations and grants for Phase 1 work to enable the rapid creation of advanced prototypes. These prototypes will be used to support clinical validation of core functionality, i.e. they will support key functions within ventilation modes to demonstrate that our concept is sufficiently sound for clinical use. Phase 1 funds will be used solely to purchase the materials and services needed to create and test these prototypes. Our design and documentation will be submitted to FDA under the Emergency Use Authorization (EUA) program.

Phase 2: Commercialization

In Phase 2, we will complete BostonVent's design and documentation in preparation for production. We believe that this effort will require $850,000 and eight months of effort once funding is secured. FDA clearance is expected to take an additional six months. Depending on the level of support we receive and other circumstances, there is the possibility of substantially compressing this timeline.

Phase 2 funds will be used to:

- Obtain extensive third-party testing and create the documentation needed for FDA clearance.
- Prepare for factory production (creating molds, securing supply chains, etc.).
- Initiate efforts to create awareness of BostonVent among prospective customers.
- Begin production of FDA-approved devices.
- Compensate those members of our team who spend substantial time in completing productization

We are also seeking partners, such as NGOs and distributors, to help ensure that these ventilators are available to all medical facilities with an unmet need.