Designing a Universal Bag-Valve-Mask

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Abstract

In developing countries, bag-valve-masks are always in high demand due to the high prices of importing them. The purpose of this project is to design and construct a low cost bag-valve-mask with only the necessary components that can be manufactured locally in developing countries.

This paper walks through the design process of the project from its underlying motivations, to the safety and ethical considerations behind the designs created, to fabrication and future work. In doing this, it creates a rubric for organizations/institutions/companies to follow such that they can create financially viable BVM production capabilities catering to a target market.

Keywords: Bag valve mask, resuscitation, pressure release valve, neonatal

Introduction

Problem Statement

Of the 126 million babies born each year, approximately 10 million require assistance to initiate breathing, and 7.5 million require basic neonatal resuscitation. The need for neonatal resuscitation is most pronounced in low-resource countries where the incidence of infant mortality is highest and the availability of properly-trained and properly-equipped birthing attendants is lowest. According to a 2009 report conducted by the South African-based Saving Newborns Lives foundation, basic neonatal resuscitation could sufficiently be accomplished through the use of a bag-valve-mask resuscitation device. Resuscitation of this sort could prevent 30% of deaths of full-term babies, as well as 5-10% of deaths due to preterm birth.[1] By reducing the number of neonatal deaths caused by birth asphyxia—an estimated 904,000 annually—there could be significant progress towards accomplishing the fourth UN Millennium Development Goal: reduce by two-thirds, the under-five mortality rate. [2]

Background

According to the Saving Newborns Lives study, one of the key challenges to reducing neonatal deaths caused by birth asphyxia is making sure that the necessary resuscitation equipment is readily available to health workers and birthing attendants[1]. At the moment, the high cost of importing neonatal resuscitation devices is a major hindrance to adequate availability, particularly in the developing world. Thus, procurement of the most basic resuscitation device, the bag-valve-mask, could be facilitated by identifying, and ultimately retrofitting, local manufacturers capable of bag-valve-mask production. Under this pretext, Sagean, a California-based corporation, was created to specifically address the unmet needs related to medical devices in developing countries. Sagean's mission is to facilitate the identification and/or creation of local infrastructure necessary to manufacture basic medical devices like the bag-valve-mask in areas where low cost is critical and indigenous production of such devices is inadequate.

Project Motivation

Under the guiding supervision of our client Tiffini Diage, founder of Sagean, we aim to create a low-cost, reusable, bag-valve-mask neonatal resuscitation device which could be manufactured in a low-resource country—in this case, Ethiopia. As required by our client, this device must adhere to several criteria which are outlined in the following report. The process by which we design our device to meet the criteria is explicated as well. Furthermore, this report describes some of the challenges we have encountered throughout the design process and, ultimately, describes the future steps we must take to achieve our goal.

Design Research

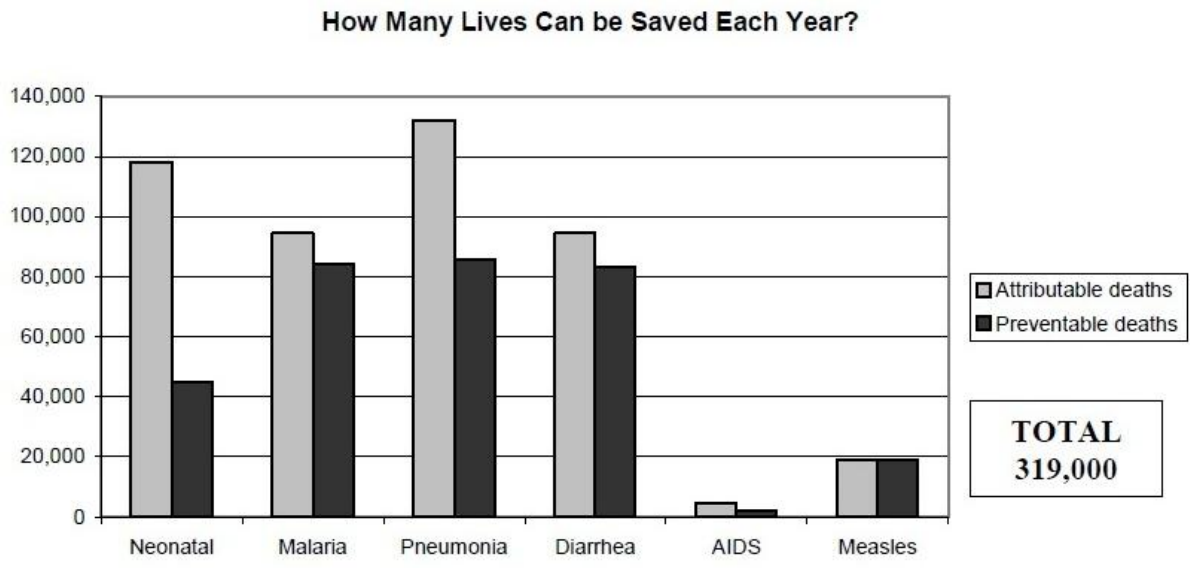
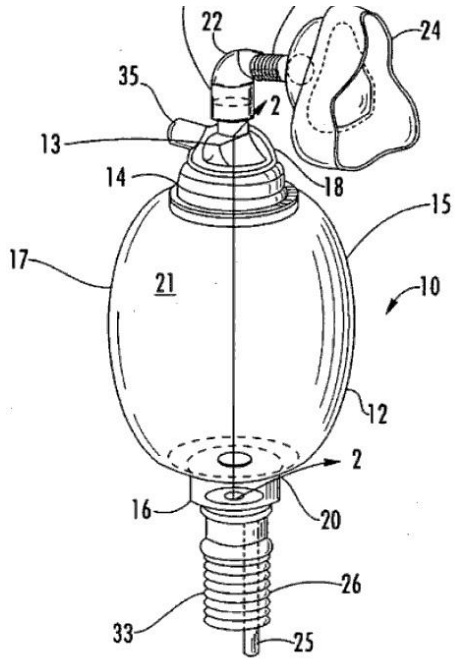


Figure 1: The data above was based on the 5% of deliveries that take place in facilities in Ethiopia. It may be anticipated that the percentages of death due to prematurity would be higher in communities. Since, asphyxia, infection, and tetanus account for an even larger proportion of deaths due to limited resources and technical skills.

Bag-Valve-Masks are in high demand in developing countries. Because of the high cost of importation, it is cheaper to manufacture the bag-valve-mask in country utilizing its resources and labor to enhance production capabilities. With a greater supply of essential resuscitation devices, like bag-valve-masks, in Ethiopian Hospitals, more deaths will be preventable [3]. The goals of this design project are to create a reusable, low-cost bag-valve-mask for a budget-strained African nation to meet the high demand of this emergency medical device.

Resuscitation describes an exerted effort to assist in restoring the breaking of a patient whose natural breathing has become impaired or ceased. This involves forcing air or oxygen under the appropriate pressure to the patient's airway system. One medical device that delivers artificial air is bag-valve-masks (BVM). These hand-held, emergency devices allow health-care providers to deliver air from the atmosphere or pure oxygen from a supplemental system to the patient[4].



21: Self-inflating oblong bag

20: One-way inlet valve

16: Inlet Port

35: Exhalation Valve

24: Mask

18: Outlet Valve Assembly

14: Outlet Port

33: Optional entrainment reservoir for external source gas

Figure 2. A self-inflating resuscitation system. US Patent 20060060199, March 23 2006.

The main components for bag-valve-masks are shown in figure 2. Having a self-inflating bag and two one-way valves allows the device to be non-rebreathing. Non-rebreathing means that a patient does not breathe the air he or she exhales and allows for a flow of high oxygen concentration. The patient-device interface is the mask, which can be designed to fit the face in different manners. The importance of the mask is to create a seal over the patient's face[5]. When doctors were surveyed, they preferred round masks over masks shaped to cover the chin and the bottom of the nose. This is because they found the round masks achieved a better seal with the patient's face and were more easily cleaned. The bag is an air chamber that is attached to the face mask. When the bag is squeezed, air is expelled into the lungs and when the bag is released, it self-inflates form the opposite end and allows ambient air (room air) or oxygen from a supplemental source in. This mechanism allows the lungs to deflate[6].

Block Diagram

Figure 3 a block diagram of our bag valve mask design showing each of the eleven components of the design and their approximate locations. Arrows between blocks indicate interactions between individual components.

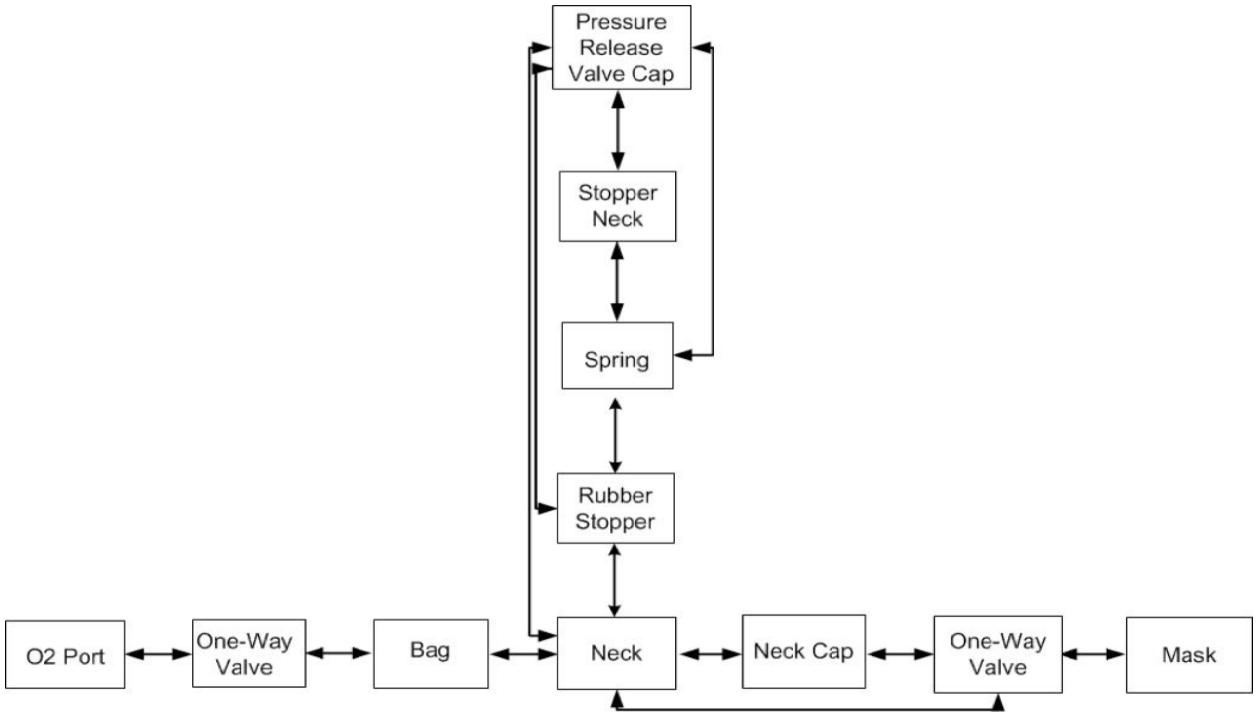


Figure 3. Block Diagram describing the interaction of the components of our bag valve mask design. Components interact with each other mechanically: an arrow could indicate that a component rests on another component, air travels through one component to the next, or that a component exerts a force on another component.

Description

If the oxygen port is connected to a supplemental oxygen source, oxygen flows from the oxygen port through a one-way valve into the bag. When the bag is squeezed, if the air pressure produced by squeezing the bag is not too high, air flows from the bag into the neck, through the neck cap, through a one-way valve, and into the patient's lungs via the mask. If the pressure in the neck is too high, the force of the air will push the rubber stopper and the pressure release valve cap upwards, releasing air through a hole under the pressure release valve cap[7]. The one-way valves utilized in this device allow airflow in only one direction: if the oxygen port is used, oxygen presses against the one-way valve, which will open and let air into the bag. Similarly, near the neck, the one-way valve will open when air is pushed from the neck cap into the mask but will close if the patient breathes into the mask. Rather, the air leaves through a separate channel[8]. This allows for non-rebreathing.

Design

Design Alternatives – Pressure Release

One of the most important parts of a bag valve mask is the pressure release valve. The pressure release valve is set to ensure that the patient does not receive too high of pressure upon delivery of the tidal volume. This is a significant safety concern because if not dealt with properly it could cause gastric inflation or pneumothorax (lung collapse)[6]. Gastric inflation can lead to vomiting, which could leave vomitus blocking the BVM airway[6].

We came up with three different designs for the pressure release valve through brainstorming and research. The simplest one was a slit in a rubber cap you could put over the BVM neck opening. In theory, the rubber would not let any air out until a specific pressure, when it will deform and release the pressure. For this design, we would need to do a lot of testing on different materials, thicknesses of that material, and length of the slit in order to determine the correct combination to create an accurate pressure release valve. A couple potential problems with this design would be that the rubber could deform/stretch over time, changing the release pressure, or even allowing air to escape. However, this was somewhat offset by the fact that it was only one piece.

Our second design we modeled after our laerdal BVM given to us by Dr. Laura Houser. This design is regulated by a spring, which compresses when the pressure exceeds a certain point. It has four pieces, the cap, the spring, the rubber stopper, and the stopper neck. This particular design has shown up in multiple design in our research and has consistently provided accurate pressure release. We considered this a very big advantage since the patient's safety is the utmost importance.

Our third and final design is another permutation of our second design. It was designed to allow for adjusting the pressure release point by twisting the top, which would adjust the compression of the spring. This would be five parts since it would need a piece that could move up and down the stopper neck to adjust the spring compression. This eliminates the need for two separate pressure release valves between neonatal and pediatric/adult BVMs. However, we also considered that it could be set to the wrong release point on accident, which could be dangerous to a neonatal, or not provide enough pressure to pediatrics/adults.

Design Trait	Multiplier	Slit in Rubber (one piece)	Spring with rubber stopper (four pieces)	Adjustable spring and rubber stopper (five pieces)
Cost	4	4	3	2
Ease of Assembly	3	5	5	3
Accuracy	5	2	4	4
Manufacturability	2	5	4	2
Totals		51	55	41

After giving weights for our categories from accuracy, to cost, to ease of assembly, to manufacturability, we ranked each design. Our second design ended up with the most points since we ranked accuracy as more important than the ease of manufacturability of our first

design. Our third design was too complicated and included too many risks for the patient, so it did not score as well.

Oxygen Port

After research and brainstorming we came up with two designs for our oxygen port shown in figure 4. We had one design that was a single piece, and another that had two pieces that could screw together. One piece would be simpler in manufacturing, but more difficult to make as a prototype with our current shop abilities. We would have to make two pieces and glue them together in order to get the space in the middle, which would not be a problem for extrusion molding (our end manufacturing goal). The two-piece design made for easier access to the inside of the port. However, since this piece is meant to be cleaned in liquid Cidex (the common cleaning agent in Ethiopia), and the oxygen port never comes in direct contact with the patient or the patient's exhaled air, we decided that the easy access was not necessary.

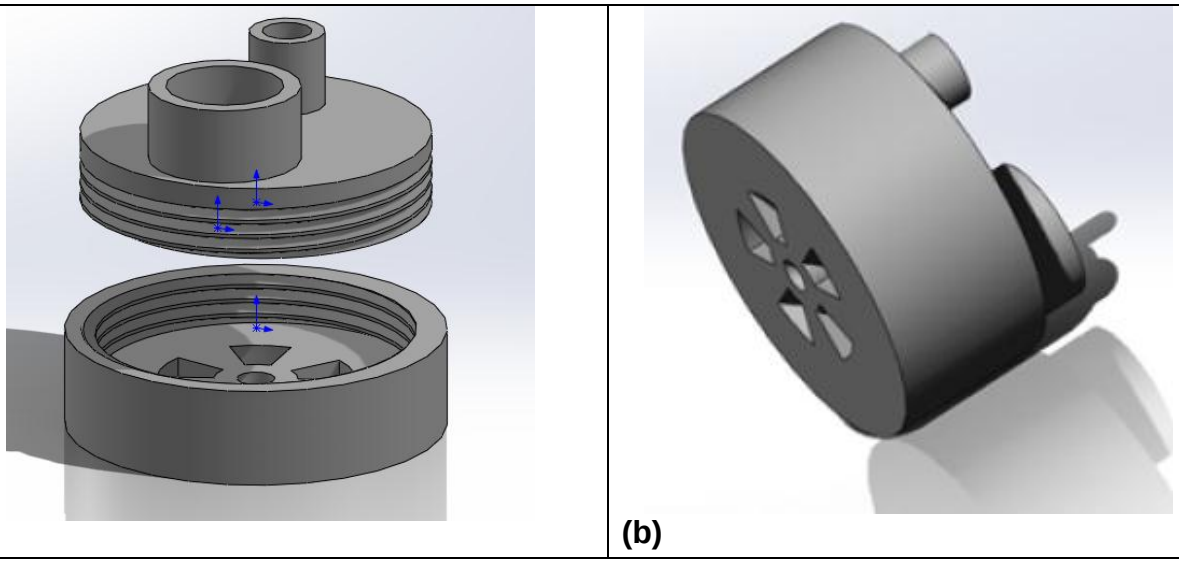


Figure 4. (a) Current commercial products have two-piece oxygen ports (b) Our new one-piece oxygen port design to reduce pieces

Universal connections

In order to further simplify our design, we made our neck and oxygen port able to connect with infant, pediatric, and adult self-inflating bags (see figure 5). This eliminates the need for three different sized necks and three different sized oxygen ports. The universal connection will theoretically save money in production as well as simplifying our calculations to make our bag size work with the correct tidal volumes.

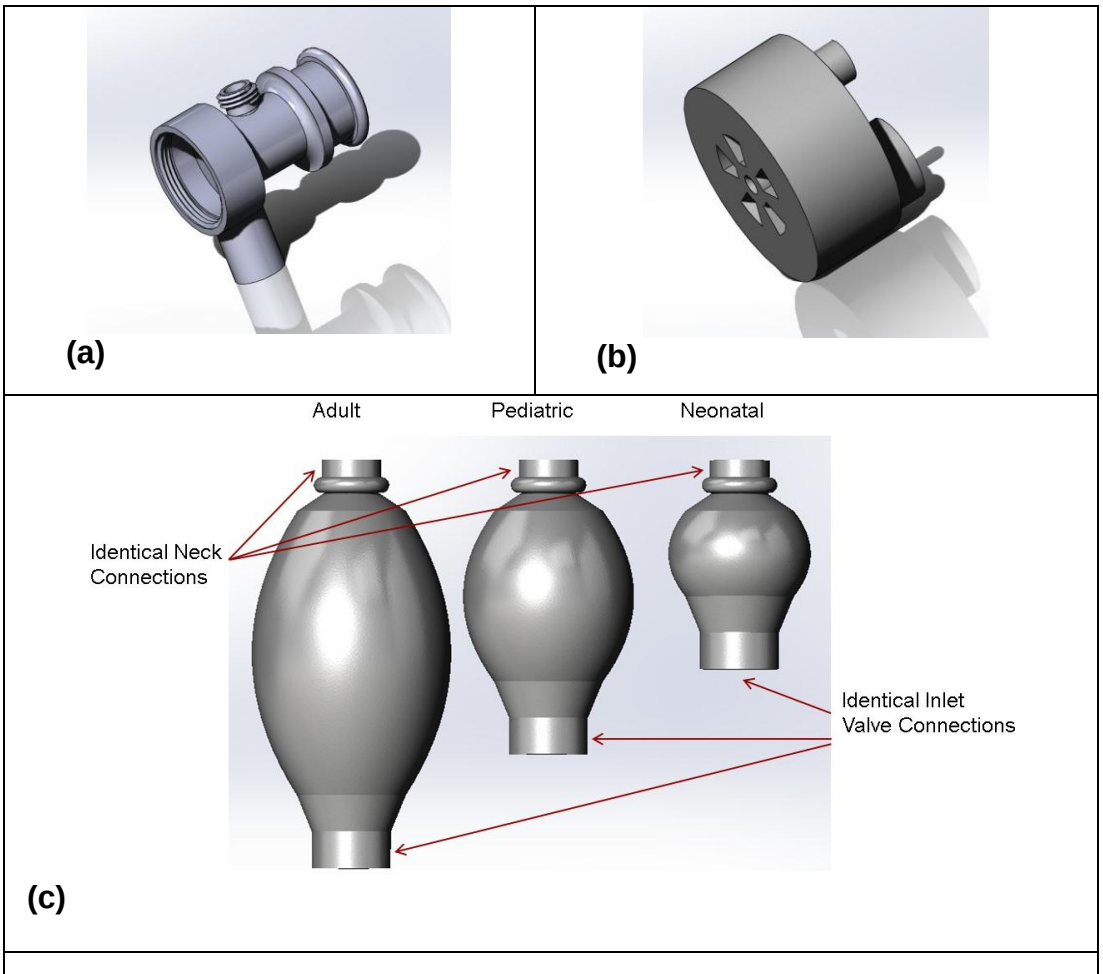


Figure 5. (a) Our neck design with a universal bag connection. (b) Our oxygen port design with a universal bag connection. (c) Our bag design with a univeral connection for our neck and oxygen port.

Fabrication Progress

An initial prototype is being developed from a cylinder of high density polyethylene. It will serve to act as a physical working model of our design and aid the team in stepwise refinement of problems with the design. Additionally it serves to motivate the project and be the first step in transforming it from an idea and a three dimensional software model to a tangible product. The self-inflating bag, mask, one way valves, and pressure release rubber stopper from an infant Laerdal BVM are going to be used in the prototype because these required parts are difficult to make. The prototype design was modified from the actual design to allow for use of the readily available components. The oxygen port, pressure release cap, pressure release stopper, neck, and neck screw-in are being machined in the COE machine shop. All of the parts are round and are being machined with an engine lathe and mill. The spring for the pressure release is to be purchased. The team decided to machine the prototype because there is a need for high precision in interacting components and the precision of the rapid prototyper does not meet these needs.

The team has had a few minor setbacks in prototyping because some design aspects of the device lie outside of the capabilities of the COE shop. For example, the design for the threads of the pressure release cap are in metric units, but the shop only has threading devices in US units. Therefore we had to increase the diameter of the pressure release neck to compensate for the different thread size. In addition the neck must be made by adhering three separate parts because the design of the neck does not allow it to be turned on the lathe as one piece. The mask connection and the pressure release connection must be made separately and connected to the rest of the neck.

Further prototypes are planned to be made using CNC machining to increase precision and require less of an investment of time. We would like it to be made of a clear material so that it is possible for one to observe and analyze the mechanical function of the valves. This would allow us to spot and make improvements on internal problems with the design in its fully assembled and functional form.

Safety Concerns

Ethical considerations

A major ethical consideration is the decision of cost versus accuracy. This always comes into play because everything relates back to business. More precision usually implies a higher cost. Furthermore, the more pieces a design incorporates, and the higher the quality of the material it is made of, the more expensive it becomes due to manufacturing costs. However, patient safety is of the utmost importance. A balance must be achieved where patient safety is ensured, but costs are minimized.

Another consideration is the use of resuscitation in premature neonates. Our device is made to save the lives of neonates who have trouble breathing, however, certain conditions may make it unethical to save our patient's life. For example, it may be ethical to forgo resuscitation in cases where delivering food and fluids to the patient is impossible[3]. In this example, the patient is very likely to die whether or not our device is used, which is an issue we must confront before we release our product to the world.

Health concerns regarding neonates

The major health concern regarding neonates is apnea. Apnea is the suspension of external breathing (apnea is common in neonates and in cases in which the time of suspended breathing exceeds 30-40 seconds the neonates life is threatened)[1]. In order to save the neonates life outside intervention is needed to assist the neonate in breathing. Resuscitation is completed most often using a resuscitation device such as a Bag-Valve mask (this intervention ideally occurs within a 1 minute after the first sign of apnea)[1]. A major cause of apnea occurs in neonates when neonates are born prematurely[3]. This happens because premature neonates lungs are not fully developed. Other health concerns regarding neonates that require intervention include a lack of oxygen flow during birth, an unsafe level of fluid in the lungs of a neonate, or a puncture wound to the lungs of a neonate[3].

Standards and Regulations

The regulations regarding medical devices in Ethiopia are virtually nonexistent and decisions regarding the approval of a specific medical device for use in Ethiopia are directed through the Ethiopian Ministry of health. Our group will refer to the ISO regulations regarding bag valve masks. The standards and regulations below are found in the ISO standards 10651-4.

Performance

Mask

- Infant- Shape of mask circular
- Pediatric/Adult- Shape of mask oblong

BVM to mask connection

- 15 mm female and 22 mm male coaxial connector

Face mask to BVM connection

- 15 mm male or 22 mm female coaxial connector

Bag Volume

- Infant:240 mL
- Pediatric: 650 mL
- Adult: 1500 mL

Safety

Pressure Tollerance

- Infant (<10Kg): Max=45 cm H2O
- Pediatric and Adult (>10Kg): Max- 60 cm H2O

Limits and Tolerances

Minimum Tidal Volume

- Infant: 20 mL @ 60 breaths/ min and
  70 mL @ 30 breaths/ min and
  600 mL @ 20 breaths/ min
- Adult: 600 mL @ 20 breaths/ min

Pressure Release Valve

- Infant, Pediatric: within +/- 5 mm H2O of target

Resuscitator Dead Space

- < 5 mL + 10% of minimum delivered volume

Toxicity/Biocompatibility/Sterility

Cleanable with Cidex (gluteraldehyde)

- All components able to withstand gluteraldehyde exposure and function properly

Biocompatibility of Mask

- Patient contacting materials must meeting test requirements for limited duration contact with intact skin and mucosal membranes

Human Factors

Ergonomic Bag

- All bags sized appropriately to allow one average sized hand to employ minimum required tidal volume

Ergonomic Facemask

- Allows one person to both hold facemask to patient and employ minimum required tidal volume

Future Work

Testing

Testing will begin after completion of the first prototype. The test involving resistance and tidal volumes will be conducted using a "Michigan Lung" (which is an automated lung to mimic breathing conditions). In addition to the required tests for the device a determination of the spring constant (k) for the spring inside the pressure release valve will be determined using the equations $P = F/A$ and $F = -kx$ because our design has been modified from a standard BVM purchased in the United Sates from companies such as Lerdal or Ambu. The pressure at which air needs to be released is given for neonates, pediatrics and adults along with these values based on our design the cross sectional area A of the rubber stopper is given and the displacement x is also specific to our design. The pressure release valve will then be tested for the releasing pressure.

Required Tests for Device:

- Bag refill valve connectors: measure internal diameter of connector using 32 mm male gauge
- Dismantling and reassembly: functional test has been provided to test operation and reassembly
- Valve function after contamination with vomitus: simulated vomitus
- Drop Test: begin by stabilizing the resuscitator at the minimum functioning temperature recommended by manufacturer then drop the resuscitator from a height of 1 m onto a concrete floor in the worst case orientation (repeat 6 times)
- Immersion in water: drop from 1 m into the water reservoir then take out after 10 s and remove water for not more than 20s, finally begin ventilating the test lung
- Expiratory resistance : Patient is able to expire without significant resistance
- Inspiratory resistance : Patient is able to inspire without significant resistance

Cost

The target price of our product will be in the $5-10 USD after manufacturing is established in country. Our target price is based on implementing manufacturing capabilities

within Ethiopia because of the cost associated with importing BVM's currently is economically not feasible for the majority of Ethiopian health clinics.

Manufacturability

Our goal is to fabricate a prototype and create an instructional manual for assembly. Using this instruction manual and our clients goal of establishing manufacturing in Ethiopia the distribution of the BVMs to local health centers will be a streamline process for minimizing cost and easing assembly. The goal is to use a type of extrusion molding to produce the high density plastic components needed for a number of the parts and utilize local sources (if possible) for the rubber needs as well as the spring for the pressure release valve. Ultimately there should be 10 separate parts for the BVM that will simplify assembly and manufacturing.

References

[1] S. N. Wall, A. Cc, S. Niermeyer, M. English, W. J. Keenan, W. Carlo, Z. A. Bhutta, A. Bang, I. Narayanan, I. Ariawan, and E. Joy, "UKPMC Funders Group Neonatal resuscitation in low-resource settings : What , who , and how to overcome challenges to scale up?," vol. 107, no. Suppl 1, pp. 1–35, 2010.

[2] F. Sheet and Q. Facts, "FACT SHEET GOAL 4: Reduce child mortality," no. September, pp. 4–5, 2008.

[3] G. S. W., Richard;Black E., Robert; Bhutta A., Zulfigar; Morris S., Saul;and the Bellagio Child Survival Study Jones and Group, "How many child deaths can we prevent this year?," *The Lancet*, 2003. [Online]. Available: http://www.who.int/maternal_child_adolescent/documents/pdfs/lancet_child_survival_prevent_deaths.pdf. [Accessed: 21-Oct-2012].

[4] N. N. Finer, W. Rich, a Craft, and C. Henderson, "Comparison of methods of bag and mask ventilation for neonatal resuscitation.," *Resuscitation*, vol. 49, no. 3, pp. 299–305, Jun. 2001.

[5] C. P. F. O. Donnell, P. G. Davis, and C. J. Morley, "Positive pressure ventilation at neonatal resuscitation : review of equipment and international survey of practice," pp. 583–588, 2004.

[6] L. M. Jacobs, "The importance of airway management in trauma.," *Journal of the National Medical Association*, vol. 80, no. 8, pp. 873–9, Aug. 1988.

[7] S. B. Ainsworth, R. Humphreys, and L. Stewart, "The pressure is on! The danger of a broken blow off valve on a bag valve mask.," *Archives of disease in childhood. Fetal and neonatal edition*, vol. 91, no. 3, p. F233, May 2006.

[8] J. A. and M. D. Dorsch, *Understanding Anesthesia Equipment: Construction, Care and Complications*. Lippincott Williams & Wilkins, 1975.

Appendix

Design of a Low-cost BVM
Product Design Specification Report

Team Members
Nick Glattard: Team Leader
Brandon Jonen: Bwig
Becky Eastham: Bsac
Samuel Jensen: Communicator
Adjunct Team Members
Padraic Casserly: Graduate Leader
Betsy Hose: Project Reporter

Problem Statement

Unfortunately, due to limits and delays in importation and expense of bag-valve-masks, budget-strained African nations, such as Ethiopia, have an inability to meet the high demand of these life-saving devices. Our goal is to create set of reusable set of bag-valve-masks for adults, pediatrics, and infants that costs less than $5 USD. This device will include a pressure release one-way valve to ensure pressure does not exceed a certain value. Additionally, ideally this device will be composed of materials available in Ethiopia and must one day be manufactured in country, but importation of resins may be needed if feasible. Finally, a set of instructions, taking into consideration, cultural appropriateness, must be developed. The design should serve as an example of the potential that molding machinery has in producing medical goods in developing countries.

Client requirements

- Low cost ($5 USD)
- Manufactured in Ethiopia

Design requirements:

1) **Physical and Operational Characteristics**
   a) *Performance requirements*: single use, disposable. Eventually an oxygen supply attachment.
   b) *Safety*: Manufactured sterile. Not stored sterile. Instruction manual with pictures (low literacy rate in Ethiopia) intended to prevent problems such as gastric distension, cross contamination, and rupturing of the lungs if under too much pressure.
   c) *Accuracy and Reliability*: accurate pressure around 25 cm of H2O. Pressure release valve that releases at 45 cm of H20.
   d) *Life in Service*: Up to 50 uses. Should be able to supply breaths for at most an hour.

e) *Shelf Life*: Should last one year "on shelf" in an environment between 0 and 40 degrees Celsius
f) *Operating Environment*: Ideally this would be in a hospital setting. The temperature range our BVM will be able to handle will be decided by the material we choose. The container the BVM comes in should be sealed enough so that insects, dirt, and dust cannot touch the product.
g) *Ergonomics*: To be used by anyone capable of lightly squeezing the bag and maintaining tight seal of the patient to the mask.
h) *Size*: Volume to be delivered should be a maximum of 50 ml (5-7 ml/kg with babies weighing between 2.5 and 4 kg at birth comes out to a theoretical maximum of 28 ml). Volume is larger because it is better to have excess. Physical bag should be small enough to be squeezed by a smaller person's hand comfortably. Will be transported and kept in a non sterile container.
i) *Weight*: Very easily lifted in one hand.
j) *Materials*: Face mask must be biocompatible. Possibly Latex since allergy rates are extremely low in developing countries. PVC and rubber.
k) *Aesthetics, Appearance, and Finish*: Ideally would like to use a clear hard plastic for the neck so it is easier to see if/where blockages occur.

2) Production Characteristics

a) *Quantity*: Pilot production: 25-50, eventually 1000/year is a good start.
b) *Target Product Cost*: Initially 10 USD. Eventually 5 USD.

3) Miscellaneous

a) *Standards and Specifications*: FDA approval not required. FDA equivalency in Ethiopia for drugs but not for manufacturing of devices. Will not be worrying about regulations unless the Ethiopian Ministry of Health asks us to. Need to show that as a group we are competent of producing safe medical devices.
b) *Customer*: The initial goal is for the device to be used for medical professionals (the Ministry of Health) and then eventually to be used by health extension workers.
c) *Patient-related concerns*: Needs a pressure release valve since it is easy to damage neonates.
d) *Competition*: See commercial products ie: Laerdal, Ambu