Designing a Universal Bag-Valve-Mask

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Abstract

In developing countries, bag valve masks (BVMs) provide a sterile method to resuscitate patients that are not breathing. BVMs are in high demand due to high importation costs. The purpose of this project is to design and construct a low cost BVM with only the necessary components to be manufactured locally in developing countries.

This paper describes the design process of the project from its underlying motivations, the safety and ethical considerations, the fabrication process, and future work. In doing this, the paper creates a rubric for organizations, institutions, or companies to follow so that they can create financially viable BVM production capabilities catering to developing countries.

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

I. 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 [1]. The need for neonatal resuscitation is most pronounced in low-resource countries where the incidence of infant mortality is the highest. The availability of properly-trained and properly-equipped birthing attendants is lowest. According to the 2009 report conducted by the South African-based Saving Newborns Lives foundation, basic neonatal resuscitation could sufficiently be accomplished through the use of a BVM resuscitation device [2]. Resuscitation of this sort could prevent 30% of deaths of full-term babies, as well as 5-10% of deaths due to preterm birth [3]. By reducing the number of neonatal deaths caused by birth asphyxia, which is 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 [4].

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 [3]. The high cost of importing neonatal resuscitation devices makes it difficult to maintain a sufficient supply of BVMs in the developing world. Thus, procurement of the most basic resuscitation device, the BVM, could be facilitated by identifying, and ultimately retrofitting, local manufacturer's capability of BVM 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 BVM 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, BVM 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 this report. The process by which we designed 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 describes the future steps we must take to achieve our goal.

II. Design Research

The number of people in the world that die of preventable deaths is a significant reason why research and development of more cost effective resuscitation devices are necessary. Figure 1 below shows that many neonates could be saved if a cost effective alternative for resuscitation was developed [5].

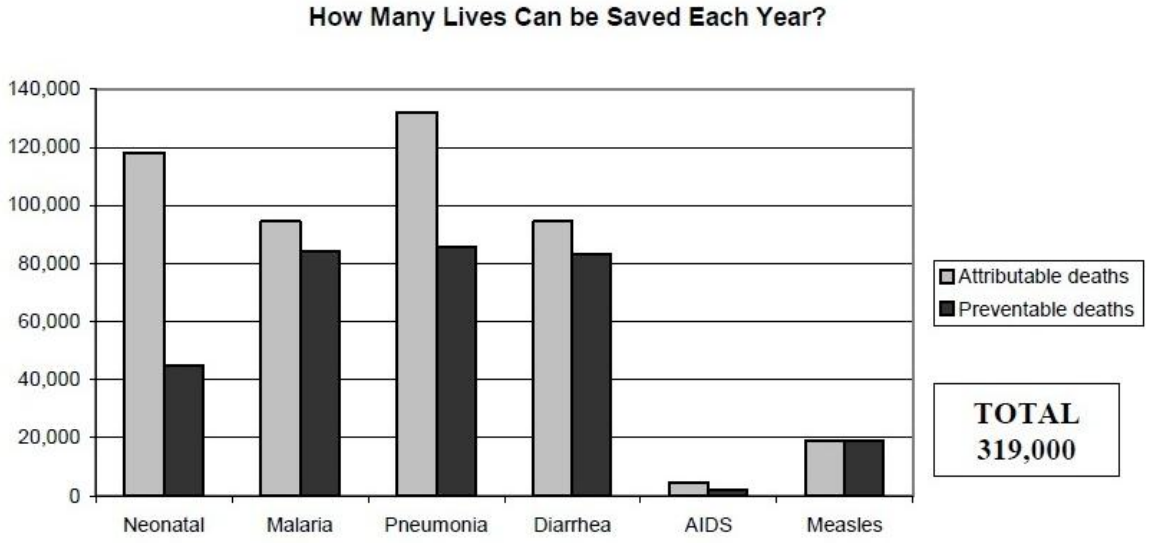
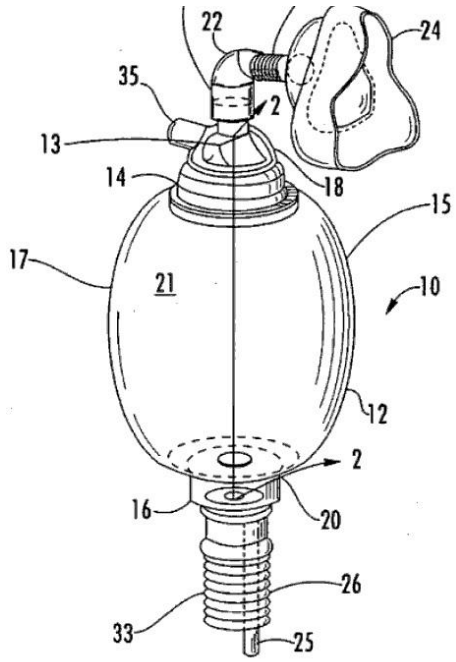


Figure 1: The data above was based on the 5% of deliveries that take place in facilities in Ethiopia. It may be anticipated that the percentages of death due to prematurity would be higher in communities. Since, asphyxia, infection, and tetanus account for an even larger proportion of deaths due to limited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

The BVM masks are in high demand in developing countries. Because of the high cost of importation, it might be cheaper to manufacture the BVM in country utilizing its resources and labor to enhance production capabilities. With a greater supply of emergency resuscitation devices, such as BVMs, in Ethiopian Hospitals, more deaths will be preventable [6]. The goal of this design project is to create a reusable, low-cost BVM 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 breathing 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. A BVM is one medical device that delivers oxygen via positive pressure to a patient in need. These hand-held, emergency devices allow health-care providers to deliver 21% oxygen from the atmosphere or pure oxygen from a supplemental system to the patient [7].



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 BVMs are shown in Figure 2 above. Having a self-inflating bag and two 1-way valves allows the device to be non-rebreathing. Non-rebreathing means that fresh air is always directed to the patient during inhalation and the exhaled air is released to the atmosphere[8]. 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 [9]. When doctors were surveyed, they preferred round masks over other masks shaped to cover the chin and the bottom of the nose [7]. This is because they found the round masks achieved a better seal with the patients' 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) [8] or oxygen from a supplemental source in. This mechanism allows the lungs to deflate [10].

In addition to these basic BVM components, we also discussed many other potentially useful components. Designs containing an adjustable volume self-inflating bag were considered. Another contains a filter to clean contaminated air, and a final design contained a flow control valve [11]. Additionally, patents exist for nebulizer attachments to deliver medication to patients[12]. Due to the need for the most simple, yet functional BVM, it was decided that these additional components were not necessary for our design. Pressure release valves, which prevent pneumothorax and gastric distension, were deemed necessary a necessary component due to its safety implications.

III. Block Diagram

The block diagram below shows all eleven components of our design and the arrows between blocks indicate interactions between the individual components.

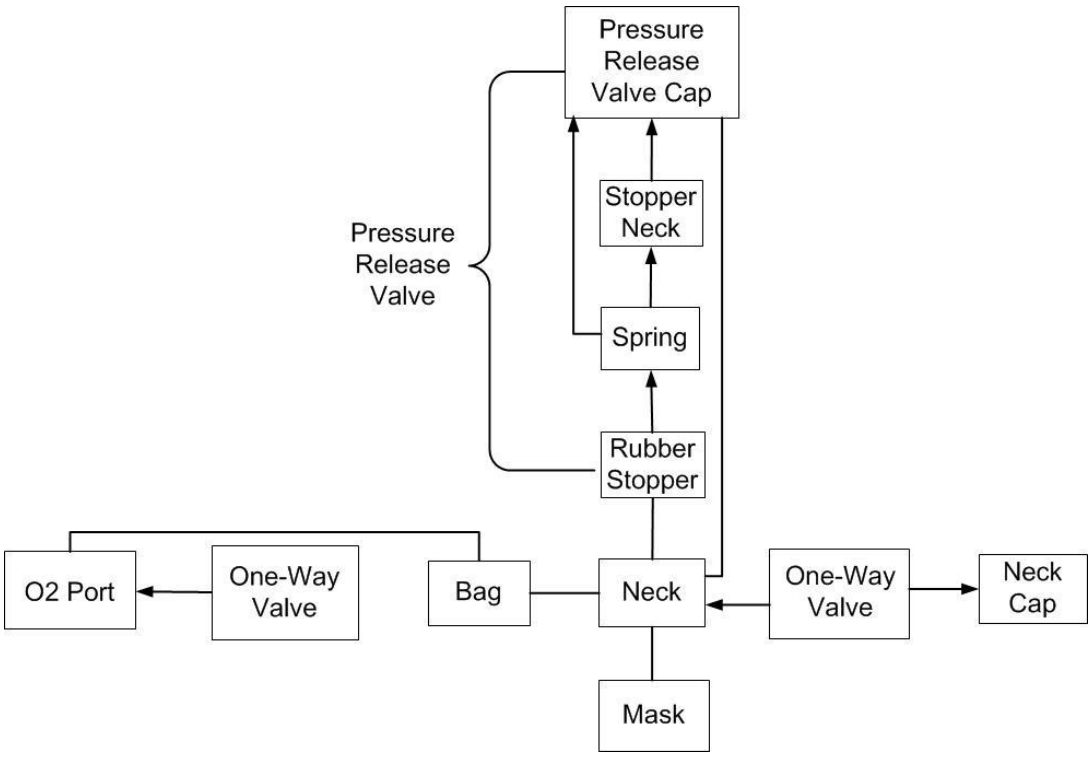


Figure 3. The above block diagram describes the interaction of the components of our BVM design. Components interact with each other mechanically: an arrow indicates that a component exerts a force on another component, and lines indicate physical connections between components.

Description

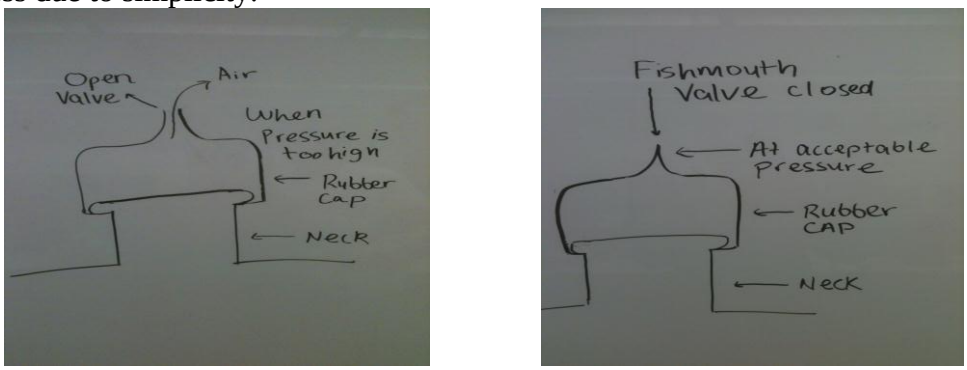
If the oxygen port is connected to a supplemental oxygen source, oxygen flows from the oxygen port through a 1-way valve into the bag. When the bag is squeezed, if the air pressure produced by squeezing the bag exceeds 45 cm H_2O for an infant less than 10 Kg or 60 cm H_2O for any other patient, the air flows through the pressure release valve, reducing the pressure delivered to the patient. Otherwise, air flows from the bag into the neck, through a 1-way valve, and into the patient's lungs via the mask [11]. The amount of pressure delivered by a self-inflating bag is dependent on how hard the user squeezes the bag. Any leak that may be present between the mask and the patient's face as well as the tolerance of the pressure release valve will also affect the pressure delivered to the patient [1]. The 1-way valves utilized in this device allow airflow in only one direction: if oxygen is supplied from an external source, oxygen presses against the 1-way valve, which will open and let air into the bag. Similarly, near the neck, the 1-way valve will open when air is pushed from the neck into the mask but will close if the patient breathes into the mask. Rather, the air leaves through a separate channel through the neck cap, which allows for non-re-breathing [8].

IV. Design

Design Alternatives – Pressure Release

One of the most important parts of a BVM is the pressure release valve. The pressure release valve is set to ensure that the patient does not receive more than 45 cm H_2O pressure for an infant less than 10 Kg or 60 cm H_2O for an adult. 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 patient's airway or the BVM [6].

We developed three different designs for the pressure release valve through brainstorming and research. The simplest one was a slit in a rubber cap that could be placed over the BVM neck opening. In theory, the rubber would not let any air out until a specific pressure, under which the rubber will deform and release the pressure. For this design, we would need to test various materials with regard to thicknesses 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 are that the rubber could deform or stretch over time, changing the release pressure, or even allowing air to escape. However, the advantages to this design include cost-effectiveness due to simplicity.



(a) **(b)**

Figure 4. The photographs (a) and (b) represent the simplest design showing a one piece pressure release valve. Photograph (a) shows the one piece pressure release valve in its opened state while photograph (b) shows the pressure release valve in its closed state.

Our second design was modeled after the Laerdal BVM given to us by Dr. Laura Houser[13]. This design is regulated by a spring, which compresses when the pressure exceeds the ISO standards for pressure referenced in the block diagram description[14]. It has four pieces: the cap, the spring, the rubber stopper, and the stopper neck. This particular design has shown up in multiple designs in our research and consistently provides accurate pressure release. We considered this an advantage since the patient's safety is of the utmost importance.

Figure 5. The photograph shows the second design which is a simple four piece design.

Our third and final design is another permutation of our second design. It was designed to allow the user to adjust the pressure release threshold by twisting the top, which would adjust the compression of the spring. The third design would consist of five parts because it would need a piece that could move up and down the stopper neck to adjust the spring compression. This design eliminates the need for two separate pressure release valves for neonatal and pediatric/adult BVMs. However, we also considered that it could be set to the wrong release point accidently, which could be dangerous to the patient.

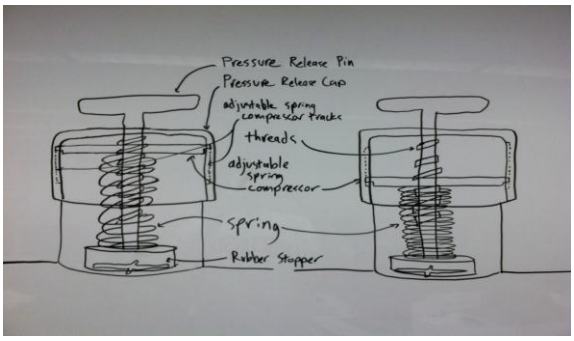


Figure 6. Photograph shows the third design with an adjustable spring.

Table 1. Pressure release valve decision matix is shown with designs across the top row and assessment considerations in the left column.

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

Table 1 shows all of the considerations our group used to assess which pressure release valve would be best for our design. Accuracy and cost were considered the most important criteria. In order to create an affordable BVM, the cost must remain low but still provide the correct amount of oxygen to the patient. In addition to these two criteria, ease of assembly and manufaturabilty were important criteria. For manufacturing of BVMs in Ethiopia to occur, the process must be as simple as possible because of the lack of manufacturing capacity. Additionlly, ease of assembly is an important criterion because it allows the devices to be distributed with reduced training and instruction.

After giving weights to each of our categories, 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 well. The largest risk associated with the third design is the consistency at which the tidal volume would be delivered to the patients. This is important for the safety of the patient because if the pressure of the oxygen delivered to the patient is inappropriate according to ISO standards, death can result[14].

Oxygen Port

After research and brainstorming, we came up with the two designs for our oxygen port shown in Figure 7. Figure 7 (b) shows a single piece design and (a) shows a two piece design. The one piece design would be simpler to manufacture but more difficult to make as a prototype with our current shop abilities. 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, which is 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 provided by (a) was unnecessary.

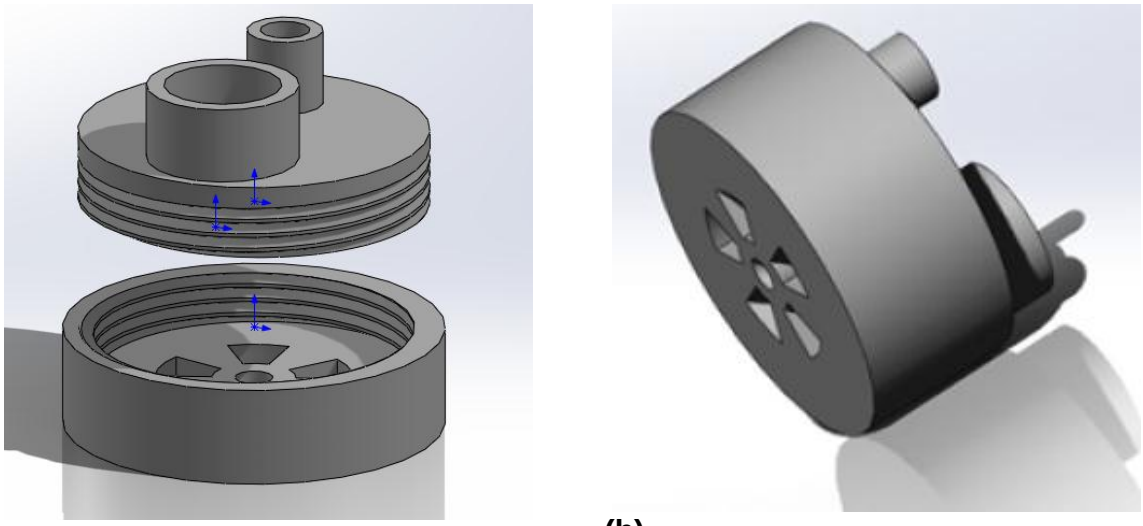


Figure 7. (a) Current commercial products have two-piece oxygen ports (b) Our new one-piece oxygen port designed to reduce complexity.

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 as shown in Figure 8. This eliminates the need for three different sized necks and three different sized oxygen ports. The universal connection will save money in production as well as simplify our calculations to make our bag size work with the correct tidal volumes.

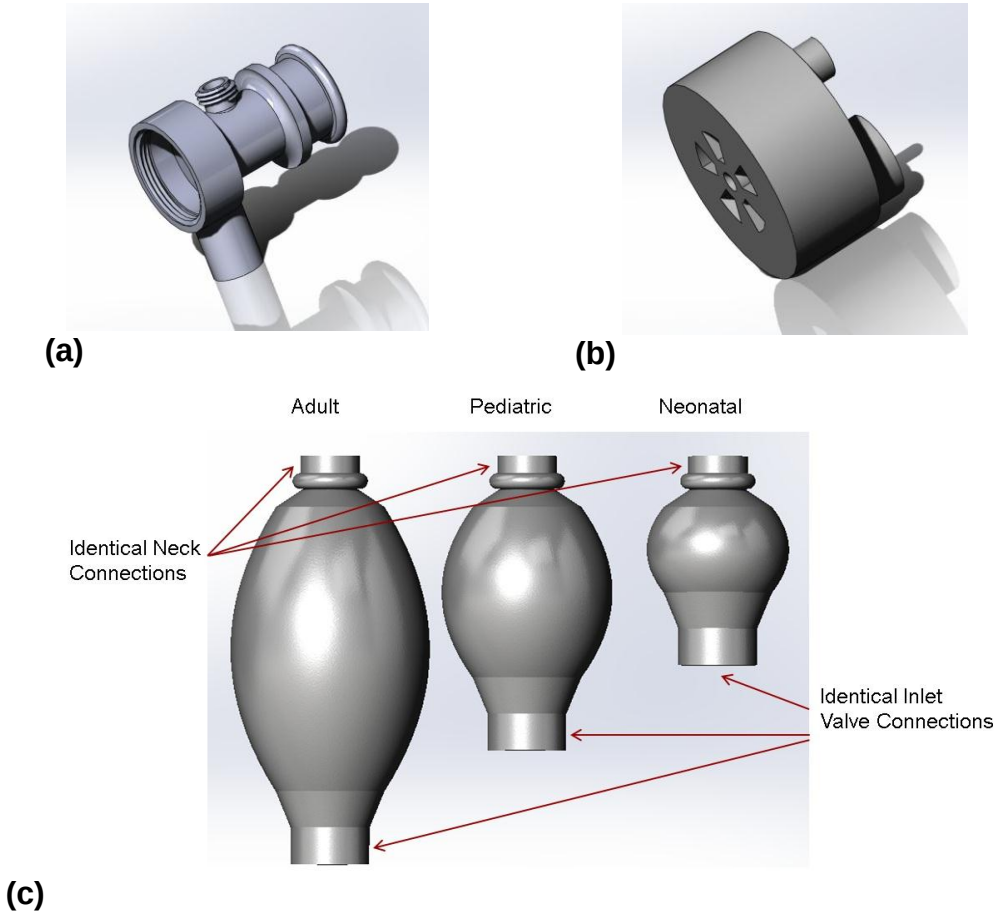


Figure 8. (a) Our neck design with a universal bag connection. (b) Our oxygen port design with a universal bag connection. (c) Our bag design with a univeral connection for our neck and oxygen port.

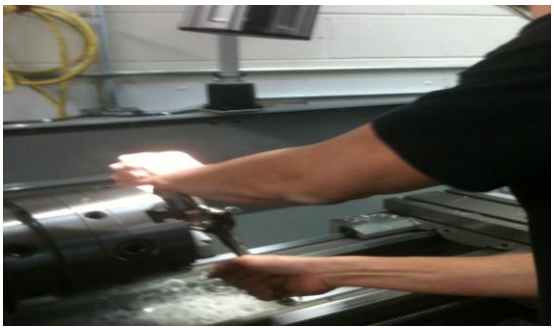
V. Fabrication

An initial prototype was developed from a cylinder of high density polyethylene. It serves 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 valve from an infant Laerdal BVM are used in the prototype because these required parts are difficult to fabricate. The prototype design was modified from the SolidWorks design to allow for use of the readily available components. The oxygen port, neck, and neck screw-in were machined in the College of Engineering (CoE) machine shop. All of the parts are round and were machined with an engine lathe and mill. The team decided to machine the prototype because there is a need for high precision in interacting components and the precision of the rapid prototype does not meet these needs.

The team 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 is 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 was 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 were made separately and later connected to the rest of the neck.

Further prototypes will be fabricated using injection molding to increase both the precision of the device and the efficiency of creating the prototype. The material used should be clear, so that it is possible 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.

(a)



(b)

Figure 9. The photographs (a) and (b) show the fabrication work completed at the Student Shop.

VI. Safety Concerns

Ethical considerations

A major ethical consideration is the decision of cost versus accuracy. The pressure release must occur at 45 cm H_2O for an infant less than 10 Kg or 60 cm H_2O for a child or an adult. If reducing the cost significantly decreased the accuracy of the pressure release valve, then reducing the cost would be unethical. However, more precision usually results in a higher production cost. Furthermore, the more pieces a design incorporates, and the higher the quality of the material of which it is made, the more expensive it becomes. 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 likely to die whether or not our device is used, so resuscitation should not be attempted.

Health concerns regarding neonates

The major health concern regarding neonates is apnea, which 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 neonate's life is threatened [1]. In order to save the neonate's life, intervention is needed to assist the neonate in breathing. Resuscitation is completed most often using a resuscitation device such as a BVM. This intervention ideally occurs within a minute after the first sign of apnea [1]. Apnea occurs most often in premature births [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]. The number of preventable deaths that occur because of apnea in economically disadvantaged parts of the world is high due to a lack of resources and devices such as BVMs. The aim of this project is to help prevent the number of deaths that can be attributed to apnea in areas of the world which are economically disadvantaged.

VII. 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 BVMs. The standards and regulations below are found in the ISO standards 10651-4[14].

Table 2. ISO standards and regulations for BVMs

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

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
Pediatric:70 mL @ 30 breaths/ min and
Adult: 600 mL @ 20 breaths/ min
Adult: 600 mL @ 20 breaths/ min
Pressure Release Valve
Infant, Pediatric: within +/- 5 cm H2O of target
Resuscitator Dead Space
< 5 mL + 10% of minimum delivered volume

Toxicity/Biocompatibility/Sterility

Biocompatibility of Mask
Patient contacting materials must meet test requirements for limited duration contact with intact skin and mucosal membranes

Table 2 describes the ISO regulations for BVMs regarding performance, safety, limits and tolerances and toxicity/biocompatibility/sterility**.**

VIII. Testing

We performed tests which measured the assembly and disassembly times of our prototype compared with the assembly and disassembly times of the Laerdal model. We decided that assembly and disassembly times are good indicators of simplicity of the product. The lower the assembly time, the more simple the device is, and therefore is associated with less likelihood for user error in assembly. Assembly and disassembly were defined as the components as state of the components to be cleaned in. This means that the pressure release unit consisting of the cap, stopper, spring, and pin are removed from the neck but maintained as one. Both assembly time and disassembly time were lowered with the prototype among the four subjects. Assembly time was the improved the most. Among the four subjects it improved from 87.7 s (SE = +/- 8.5) to 54.6 s (SE = +/- 3.3).

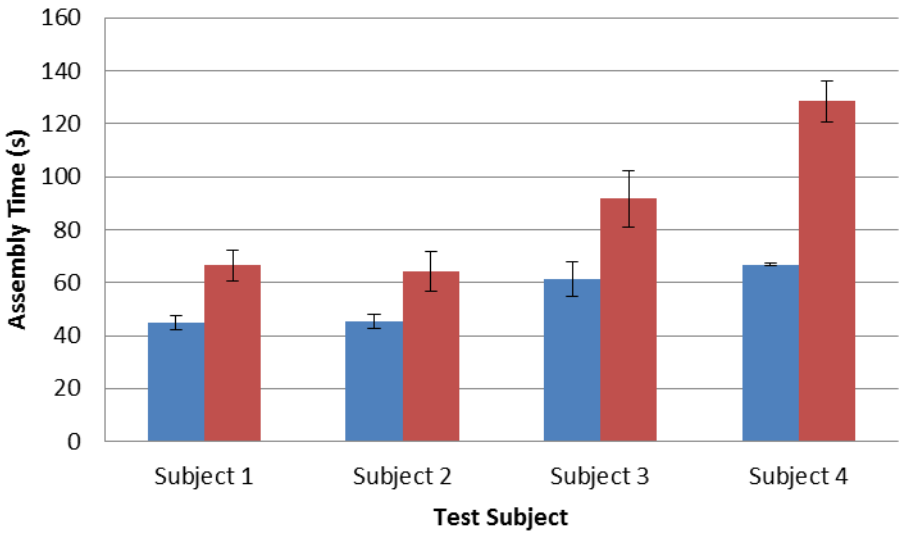


Figure 10. Shown are the assembly times for each subject among three trials. Blue represents our prototype and red represents the Laerdal BVM. Average assembly time was less for each subject. One standard error is shown above and below the mean.

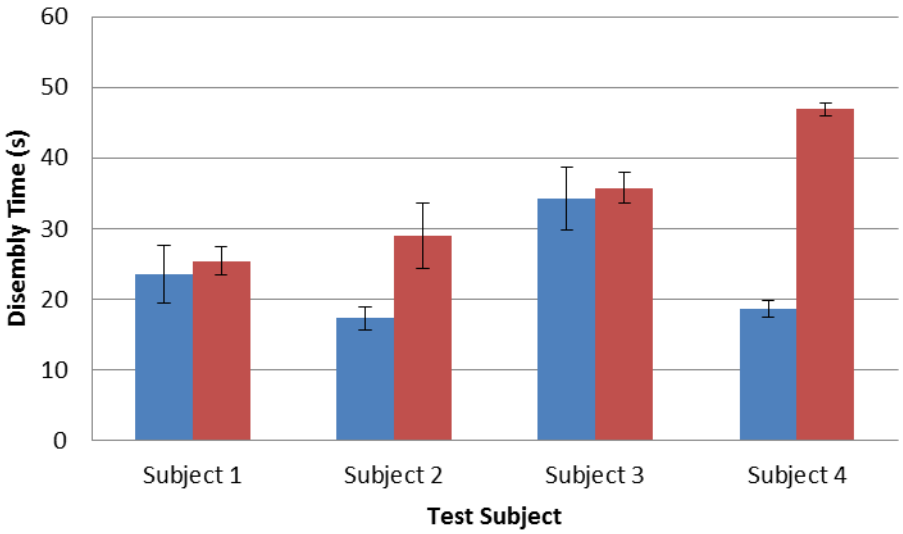


Figure 11. The graph shows the dissasembly times for each subject. Blue represents our prototype and red represents the Laerdal BVM. The average time was lower for all subjects for the prototype, however, only significant for subjects 2 and 4. One standard error is shown above and below the mean.

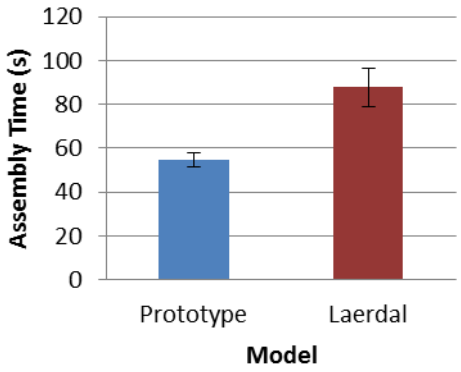


Figure 12. The graph shows the average assembly time. Blue represents our prototype and red represents the Laerdal BVM. The total average time among all four subjects was significantly lower for the prototype (54.6 seconds) than for the Laerdal (87.7 seconds). One standard error is shown above and below the mean.

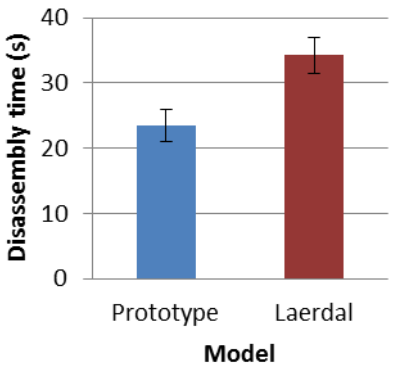


Figure 13. The graph shows the average dissasembly time. Blue represents our prototype and red represents the Laerdal BVM. The total average time among all four subjects was significantly lower for the prototype (23.4 seconds) than for the Laerdal (34.3 seconds). One standard error is shown above and below the mean.

The ISO standard drop test, which involved dropping the prototype three times from a height of one meter and observing any changes was also performed [15]. No changes in the structure of the prototype were observed during any part of the drop test. Further, the ISO standard immersion test was performed [15]. The prototype was dropped into a resevoir full of water and left there for ten seconds. Then, the water was removed from the prototype for twenty seconds. Finally, resuscitation on a test dummy was attempted. Since resuscitation was successful, the prototype passed the immersion test.

IX. Future Work

Testing

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 (1) and (2) because our design has been modified from a standard BVM purchased in the United Sates from companies such as Laerdal and Ambu. The pressure at which air needs to be released is given for neonates, children, and adults. 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.

$P = F/A$ *(1)*

$F = -kx$ *(2)*

Required Tests for Device

Table 3. ISO 10651-2:2004 Tests for lung ventilators for basic safety and essential performance are outlined below.

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

Table 3 describes the necessary tests to be performed on our protoype. After these tests have been performed, it will show that our product is valid for clinical use.

Cost

The target price of our product will be in the range of $5-10 USD after manufacturing is established in country. Our target price is based on implementing manufacturing capabilities within Ethiopia, because the cost associated with importing BVMs is currently economically unfeasible 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 client's goal of establishing manufacturing in Ethiopia, the distribution of the BVMs to local health centers will be a streamlined process for minimizing cost and simplifying assembly. The goal is to use a type of injection molding to produce the plastic components needed for a number of the parts and to utilize local resources needed for the rubber components as well as the spring for the pressure release valve. Ultimately, there should be ten separate parts for the BVM that will simplify assembly and manufacturing.

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XI. Appendix

Design of a Low-cost BVM
Product Design Specification Report

Team Members
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Problem Statement

Unfortunately, due to limits and delays in importation and expense of bag valve masks (BVMs), 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 a set of reusable BVMs for adults, children, and infants that costs less than $5 USD. This device will include a pressure release valve to ensure that the pressure delivered to the patient does not exceed the ISO value. Additionally, this device should be composed of materials available in Ethiopia and must one day be manufactured in country, but importation of resins may be needed. 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*: Reusable up to ten times. Eventually an oxygen supply attachment.
   b) *Safety*: Manufactured 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 pressure exceeds 45 cm H_2O for infant less than 10 Kg or 60 cm H_2O for adults.
   c) *Accuracy and Reliability*: accurate pressure around 45 cm of H_2O. Pressure release valve that releases at 60 cm of H_2O.
   d) *Life in Service*: Up to ten 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 capable 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