Design of a Low-cost BVM
Product Design Specification Report

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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