# Design of a Bag Valve Mask for Developing Countries

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## Abstract

Bag valve masks (BVMs) provide a sterile way to alleviate apnea. In developing countries, BVMs are always in high demand due to the high prices of importing them. Our client, Tiffini Diage, is working with the Ethiopian Ministry of Health toward a long-term goal of implementing medical device manufacturing capabilities in developing countries through investment in injection molding devices. The low cost BVM design will serve as an excellent example of one of the many medical products that can be produced with the molding devices that are to be deployed there.

## Problem Definition

### Background

- 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 highest and the availability of properly-trained and equipped birthing attendants is lowest.

### Project Motivation

Under the guiding supervision of our client Tiffini Diage, founder of Sagean, we aim to design a low-cost, reusable, BVM neonatal resuscitation device which could be manufactured in a developing country such as Ethiopia.

## Problem Statement

- Create a low-cost, reusable, neonatal bag-valve-mask resuscitation device which could be manufactured in a low-resource country.
- Device must adhere to ISO Standards
- Manufacture the bag-valve-mask in country, utilizing resources and labor to enhance production capabilities and avoid high cost of importation.

## Design Criteria

- Reusable up to 50 times
- Comfortably lifted with one hand
- Biocompatible materials for the mask
- Clear plastic (easy to identify blockage)
- Cleanable with glutaraldehyde (CIDEX)
- Cost: Initially 10 USD, eventually 5 USD
- Pressure release accurate to within 5 cm of H20
- Standard attachment for oxygen port
- Universal neck and $O_2$ port for neonatal, pediatric, and adult BVMs

## Final Design

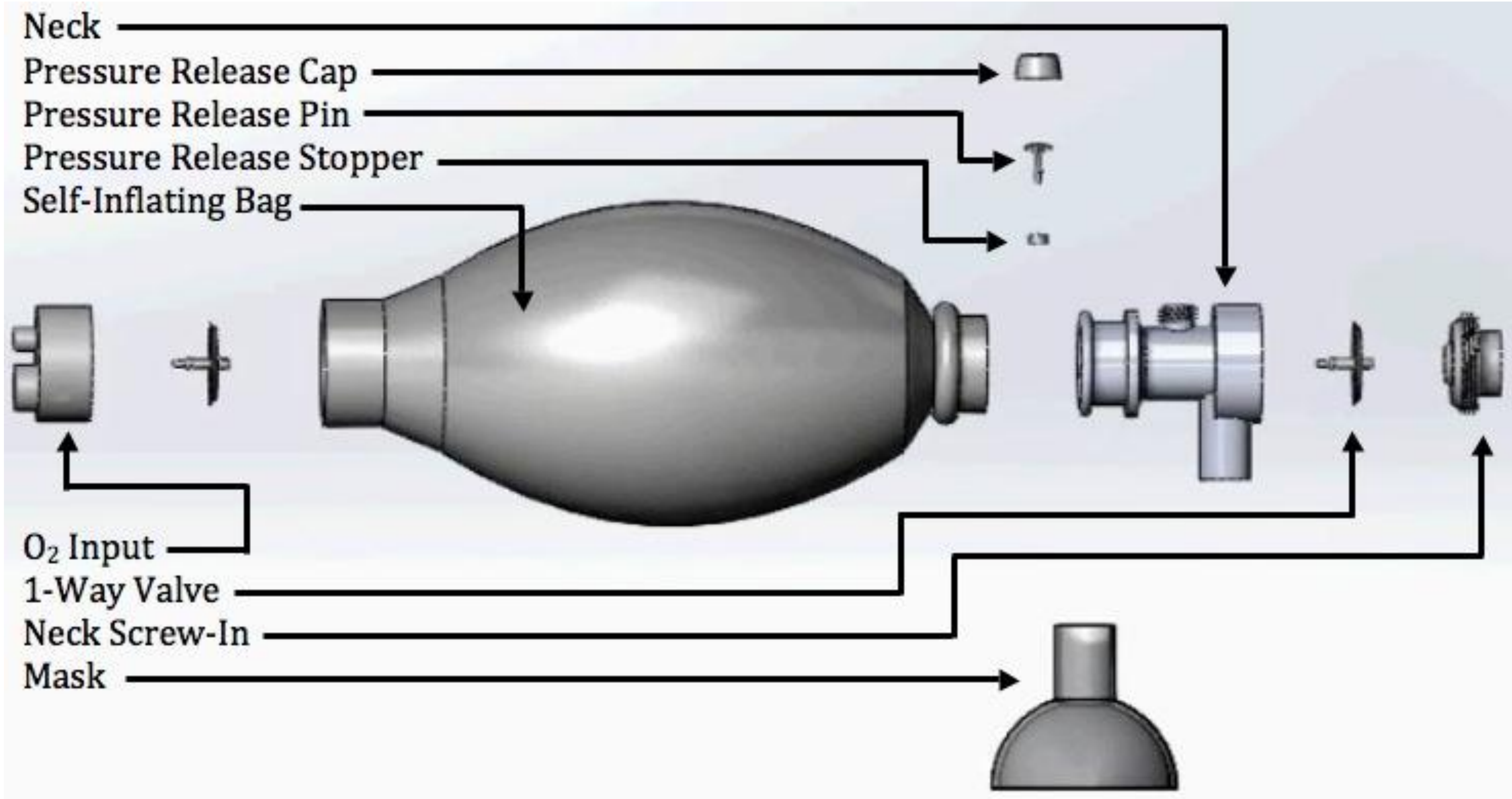


**Figure 1:** Above is shown a SolidWorks model of the final design with all of the pieces disassembled.

## Testing and Analysis

### Assembly Time

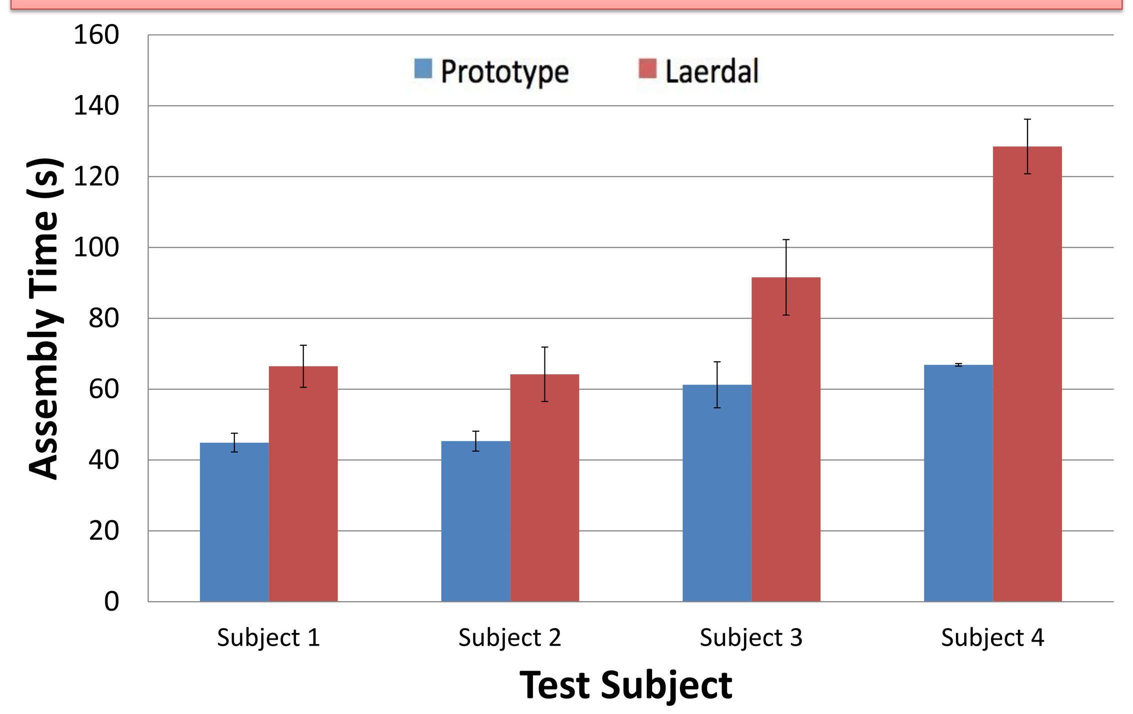


**Figure 2:** The average assembly time of the device for each subject among three trials. Blue refers to the prototype while red refers to a current Laerdal© device. The total average time among all four subjects is significantly lower for the prototype (54.6 s) than for the Laerdal (87.7 s). One standard error is shown above and below the mean.

### Disassembly Time

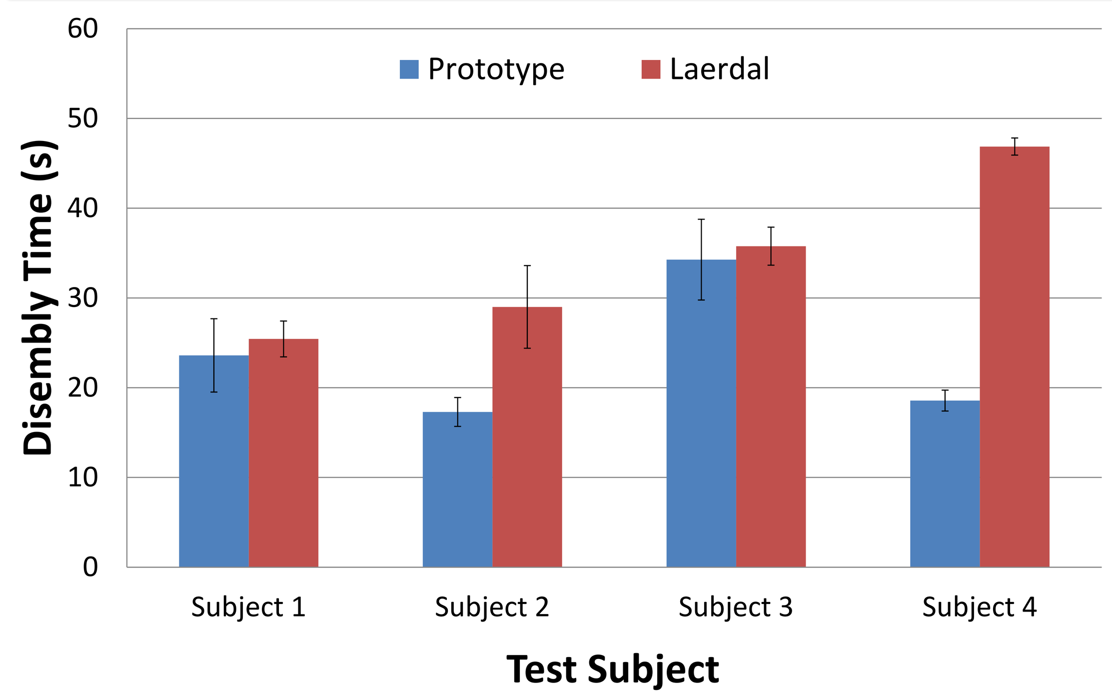


**Figure 3:** The average disassembly time required for cleaning. Average time was smaller for all subjects for the prototype, however only significant for subjects 2 and 4. Total average time for the prototype (23.4 s) was less than that of the Laerdal (34.3 s). One standard error is shown above and below the mean.

### International Standards Testing

Table 1: Two required tests we performed for Lung Ventilation devices as outlined in ISO 10651-4

| Test | Description | Results |
|---|---|---|
| Immersion in water | Drop from 1 meter into water reservoir then take out after 10 seconds. Remove from water and test for successful ventilation no more than 20 seconds after removal. | Successful Ventilation |
| Drop Test | Drop the device in the most break-prone position from one meter onto concrete repeat six times. Record changes to device. | Device did not yield or fail and was fully functional |

## Component Descriptions

**One piece $0_2$ input**: Reduces manufacturing cost and simplifies the cleaning process
**One way valves:** Both are identical to increase simplicity of cleaning/assembly
**Bag:** Connections to neck and $0_2$ input identical for all three sizes
**Mask:** Neonatal, pediatric, and adult sizes
**Neck screw-in:** Provides a quick mechanism to allow for quick cleaning
**Neck:** Non-rebreathing function implemented with least pieces possible and a standard mask connector
**Pressure release unit:** A three piece unit plus spring (infant 45 $cmH_2$ 0, adult 60 $cmH_2$ 0). That is not to be taken apart when cleaned

## Prototype Manufacturing

- Used lathe and end mill to construct hard plastic components of the design ($0_2$ input, neck, and neck screw-in) from a cylinder of high density polyethylene.
- Had to deviate from the design slightly in order to incorporate components that we were unable to manufacture in the shop. Certain sizes of tools were unavailable and so required deviation from the initial design.

## Future Work

Design Modifications
- Simplify pressure release for fewer parts.
- Create an instruction booklet with pictures
- Design bags, masks, and pressure release valves for adult and child sized BVMs.

Manufacturing
- Hire SMC to injection mold our second prototype.

Testing
- Additional tests with more subjects.
- Test new prototype: volume delivered to lungs, speed with which volume is delivered, pressure of air delivered, etc.

International
- Client will demonstrate new, injection-molded prototype to doctors in Ethiopia.

## Acknowledgements

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## References

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

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