Breast Pump for Low-Resource Setting

Prepared by Team 9
Raymond Chen
Anqi Sun
Qi Wang
Yiwen Wu
Undergraduate Engineers, University of Michigan, College of Engineering

Prepared For
Prof. Elijah Kannatey-Asibu
Department of Mechanical Engineering, University of Michigan, College of Engineering

Sponsors
U-M Laboratory for Innovation in Global Health Technology
U-M Institute for Humanitarian Technology
United Nations International Children's Emergency Fund (UNICEF)

Mentors
Prof. Kathleen Sienko
Department of Mechanical Engineering, University of Michigan, College of Engineering
Ms. Leith Greenslade
Office of the UN Special Envoy for Financing the Health MDGs

Executive Summary

The breast pump for low-resource setting project is sponsored by U-M Laboratory for Innovation in Global Health Technology, U-M Institute for Humanitarian Technology, and UNICEF; supervised by Prof. Kathleen Sienko, Ms. Leith Greenslade, and Prof. Kannatey-Asibu.

The goal of this project is to design a low cost, easy to use and clean breast pump that is suitable for use at home and work in low-resource settings.
To design a breast pump for low-resource settings, ten user requirements are addressed by sponsors, potential users, and other stakeholders. The main requirements addressed by our sponsors are easy to use, low-cost, easy to maintain, and efficient. To quantify these requirements, we generated specifications to design a manual pump with no more than 2 parts, with the manufacturing cost less than 5 dollars, and maximum pressure difference higher than 150 mmHg.

After defining the requirements and specifications, concept generation was done. A functional decomposition was generated to describe functions and sub-functions needed for the breast pump. Then, based on the decomposition and challenges, concepts were generated with focus on easy to use, low-cost, easy to clean, and efficient. Selection of the concepts was done, by scoring each concept zero to three on a Pugh chart using Decision-Matrix Method. Each of our team members rated the designs based on this chart, and the score was averaged to lower the selection bias. The six highest scored designs were then chosen, compared, and further evaluated. After much deliberation and discussion, two of the designs were combined to form one final concept. A physical mockup was also created to better demonstrate the design.

The team performed engineering analysis on our three different design drivers. Engineering analysis consisted of theoretical modeling, empirical testing, as well as mockup construction. Initial manufacturing plans, Failure Modes and Effects Analysis, and a mass-manufacturing plan were conducted as well.

The team then finalized the design as well as the prototype. Furthermore, the team completed our testing protocols. Since the team has 17 engineering specifications, the ones with the highest priorities were picked up for the validation testing. There are totally 7 validation tests corresponding to the engineering specifications.

The team 3-D printed a new transparent suction cup and completed validation testing before Design Expo. The prototype together with the report will be delivered to our sponsors, and possibly be tested in Ethiopia in summer.

1. Problem Description And Background

1.1 Problem Description

The Breast Pump for Low-resource Settings project is sponsored by U-M Laboratory for Innovation in Global Health Technology, U-M Institute for Humanitarian Technology, and United Nations Children's Fund (UNICEF). The mentors for this project are Prof. Elijah Kannatey-Asibu, Prof. Kathleen Sienko, and Ms. Leith Greenslade who is a Millennium Development Goals (MDG) Health Alliance Vice Chair in the Office of the UN Special Envoy for Financing the Health MDGs.

Exclusive breastfeeding for the first six months of life is highly recommended by the United Nations Children's Fund (UNICEF) [1] and World Health Organization (WHO) [2] based on its extraordinary range of benefits to both mothers and children. [3] However, only 15% [4] of infants aged 0 to 6 months in some least developed countries such as Nigeria and only 38% [5] of infants worldwide are exclusively breastfed. The low breastfeeding rates are due in large part to a mother's need to return to work [6], where mothers have no access to breastfeeding or expressing breast milk at work [7]. Existing commercial grade and personal-use breast pumps are cost prohibitive [8] and difficult to maintain for mothers in low-resource settings where clean water is a challenge [9] and electricity is not available [10]. Therefore, the goal of this project is to design a cheap, easy to clean, and easy to maintain breast pump for working mothers in low-resource settings.

1.2 Background

Infants who are not breastfed are 15 times more likely to die from pneumonia and 11 times more likely to die from diarrhea than infants who are exclusively breastfed. [11] According to WHO, under-nutrition is associated with 45% of child deaths [12]. At least 800,000 [13] children's lives could be saved each year if they were optimally breastfed, almost 15% of total annual child deaths [14]. Addressing this issue is one of the main focuses of UN Millennium Development Goals [15] and the most effective solution is the usage of breast pumps that help nursing mothers to pump and store breast milk. Benefits of using a breast pump include: 1) providing infants access to breast milk when their mothers are not around, 2) ensuring adequate supply of breast milk by pumping out sufficient amount of milk regularly [16], 3) producing breast milk when infants can not latch well, and 4) relieving breast engorgement [17].

Breast pump market can be divided into three segments: for hospitals, for employers, and for individuals. The first two market segments are not applicable in the context of low-resource settings of this project due to limited accessibility to hospitals [18] and nonexistence of workplace breastfeeding facilities [19]. Personal breast pumps include manual pumps and electric pumps. However, manual pumps are time consuming and unable to pump out sufficient amount of breast milk sometimes while electric pumps are expensive, large, difficult to use, and hard to clean [20]. Therefore, our team is designing a low cost, easy to clean, and easy to maintain breast pump to be used at home and work in low-resource settings where access to clean water and power source is not reliable.

1.3 Benchmarks

1.3.1 Medela Harmony Manual Breast Pump [21]

The Medela Harmony Manual Breast Pump is one of the bestselling manual breast pumps on the market today. The pump uses a unique 2-Phase Expression system. One end of the pump is used for stimulation to get the milk flowing while the other, longer end is used to maximize and extract milk. The main selling points of the system are that it is relatively cheap ($25.99), lightweight, and portable. Additionally there are fewer pieces than other manual breast pumps and all parts are made of plastic for easy cleaning.

Figure 1: Medela Harmony breast pump with two phase expression system and various accessories.

1.3.2 Ameda One Hand Breast Pump [22]

The Ameda One Hand Breast Pump uses dual manual pumps that require a squeezing action. Like the Medela, the Ameda has few parts, is easy to clean, portable, and very quiet. The Ameda is priced a bit higher at $30.99 but is actually smaller in size. One of the main complaints of the product is that the squeezing action is unnatural and is much more tiring than the Medela.

Figure 2: Ameda One Hand breast pump with dual manual pumps.

1.3.3 Philips Avent Manual Comfort Breast Pump [23]

The Philips Avent Manual Comfort Breast Pump uses a soft, cushioned suction cup with five textured petals to provide both a sucking and massaging motion. The cup is intended to mimic a baby's natural sucking pattern. Like the Medela, the Philips is powered with a pushing trigger mechanism. This product is designed the most to mimic actual sucking patterns and based on reviews is the most efficient design. However, this breast pump is expensive compared to the others at ($44.99). Additionally, the pump is not a one size fits all and many features are not found on the base model.

Figure 3: Ameda One Hand breast pump with dual manual pumps.

1.3.4 Hands-free portable breast pump system [24]

The hands-free portable breast pump system includes a breast pump, container, and breast receptor attached to a bra. There are also straps that secure the pumping system and allow the mother to move freely. Tubes connected to the vacuum suction compartment transport the milk from the breasts to the collection container. This system attaches to a bra and is easy to use but must need a battery-operated system to be truly hands free.

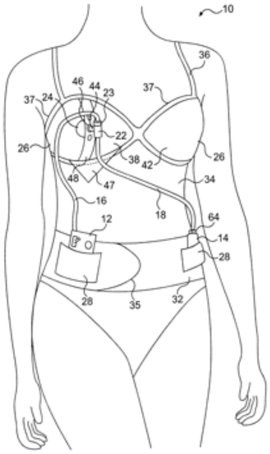

Figure 4: Hands free system that attaches the user and allows the user to continue working.

1.3.5 Suction Cup Technology [25]

Most breast pumps use pulsating negative pressure (lowering pressure by 60-120 mbar at 1-2 Hz) through a diaphragm pump. However, many disadvantages are known to occur such as noise and a large quantity of parts. Current systems attempt to mitigate this noise by using cushioned hollow bodies in the suction cup. This invention uses a flexible funnel that compresses and pumps the breast in order to mimic the natural sucking behavior of an infant.

1.3.6 System and Method for Managing a Supply of Breast Milk [26]

This patent explores systems and methods to monitor, organize, and record the collection/dispensing of breast milk. The system uses codified containers so that software may recognize the size and type of the container. While not feasible for our design, Medela’s research into managing the supply of breast milk may yield new data regarding storage and efficiency.

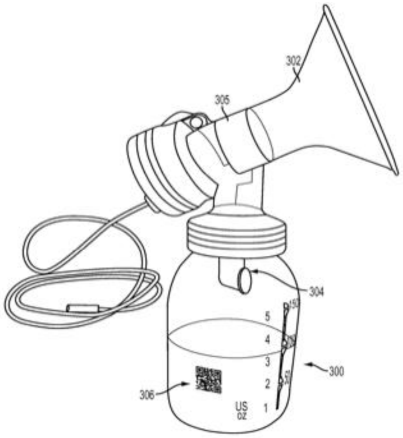

Figure 5: Codefied container that records storage and usage data of breast milk.

2. User Requirements & Engineering Specifications

To identify the user requirements and get more knowledge about breastfeeding, the team interviewed different stakeholders. The team interviewed our mentors Prof. Sienko and Ms. Greenslade from UN. The team interviewed two visiting scholars from Ghana, Dr. Bakari and Dr. Oppong. The team interviewed Ms. Klinke from Business Engagement Center, who is a new mother and currently experiencing breastfeeding. Four of them had experiences of using breast pumps. They helped us identify the user requirements.

2.1 Easy to use

The new design should be easy to use, addressed by Ms. Greenslade and Prof. Sienko. This requirement is our top priority, because our targeting users have little knowledge about breast pumps. The team needs to design a product that they are willing to use, and can be used without much difficulty. The way to achieve this is by designing fewer parts. Fewer parts will allow the user to assemble easily. Furthermore, easy to use also means the design is easy to learn how to operate, and could be learnt peer to peer within a short amount of time.

1. No more than 2 parts
2. No more than 2 steps to operate

First specification is required by Ms. Greenslade and Prof. Sienko. After the team did the benchmarks, this specification would significantly reduce the number of parts for a manual breast pump. A typical manual breast pump has approximately 4-6 parts [21] [22] [23]. The second specification is a proper way to measure how easily the product can be learned to operate.

From a dissertation of Dr. Sarvestani for Ph.D. in Design Science [27], design requirements that can lead to the design of easy to use device for low-resource settings also include: if it reduces the procedure time, if it is low cost, if it is portable, if it is locally manufactured, if it is easy to clean, if it is durable, etc. These detailed requirements overlapped with other user requirements list later on for our design, meaning that if the new design is low-cost, efficient, portable, locally sourced, easy to clean and durable, it would also make the design easy to use. The team would talk about these user requirements and their specifications in the next few parts of the report.

2.2 Low-cost

The second user requirement is affordability, which is also the key requirement for the low-resource setting from Ms. Greenslade. From benchmarks the team did, the current lowest retail price for manual pump is about 25 USD in United States. The team is designing the breast pump for users in the least developed countries and areas. They cannot afford such price. This is definitely a top priority that the team need to cut down the cost of the pump the team designed.

1. Cut down the manufacturing cost to less than 5 USD

Also said by Ms. Greenslade that if the team could cut down the price by half compared with the current retail price, she considered it would make a big difference. And the manufacturing cost is usually a half or one third of the retail price because of other costs, such as transportation, said by a research scientist from Philips during our interview.

2.3 Easy to clean

The product should be easy to clean, addressed by Ms. Greenslade and Prof. Sienko. This requirement has top priority because cleaning and sanitizing would directly affect the health of the baby. Access to clean water is a challenge for some areas. It will affect the sanitization after the use of the pump. About 66% of Africa is arid or semi-arid and more than 300 of the 800 million people in sub-Saharan Africa live in a water-scarce environment, meaning that they have less than 1,000 m^3 per capita per year [28]. The team expects to significantly cut down the number of steps and the water usage for cleaning and sanitizing the breast pump.

1. Have 4 cleaning steps, including disassembling and drying
2. 1 m^3 of water usage per 1000 uses[1].
3. Support sanitation in boiling water for 10 minutes

Washing hands once takes approximately 0.3 gallons of water. The team expects our design can be cleaned as easily as our hands. For our specifications, the water consumption of the breast pump would be approximately 0.1% of the total water used for an Africa mother. Also, being capable of sanitizing in boiling water, our design would save the expense for sanitizer, and provide a more accessible way for sanitation.

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[1] "1000 uses" comes from the calculation in section 2.7, p. 10

2.4 Mechanically powered

Some of the current breast pumps rely on power sources that are not always available in Africa, such as electricity. Ms. Greenslade recommended us to focus our design on manual breast pump for personal use, because electricity might not be always available in our targeting areas.

1. No electrical power source required

Since electrical power is not always available for our targeting users, our design would consider using non-electrical power.

2.5 Efficient

The new design should be efficient for the pumping process. Based on our benchmarks and interviews with two working mothers who had the manual breast pump using experiences, it usually takes 50-60 minutes for a mother to pump both sides with the current manual pump in the market. This leads to one of the common complaints of manual type product, low efficiency. Holding and pressing the pump for such a long time is painful and time consuming. This requirement has top priority because if the design is inefficient, our targeting users in Africa would probably unwilling to use. Pressure and suction frequency are two driving inputs from the breast pump that affects the breast milk generate rate. Considering the difference in power sources between manual breast pump and electric breast pump, the team set the related engineering specifications as the following.

1. Supports 1 or 2 of the milk expression techniques: suction and massage
2. The pressure difference should be greater than 120 mmHg
3. The maximum allowed suction frequency should be greater than 54 cycles/minutes

There are mainly two techniques to express breast milk, suction and massage. From a research done in Stanford University in 2009 [29], massage could significantly increase the efficiency of the milk expression. The specification for the milk flow rate comes from the data that the average breast milk consumption for a baby is 750 ml per day [30]. The team assumes that the mothers use breast pumps 6 times a day, and 30 minutes per use.

2.6 “One Size Fits All”

During our benchmarking, the team found out that a lot of manual pumps on the market have different sizes available for purchase. For our low-resources settings, it would be cost-prohibitive to design and produce different sizes of the breast pumps. Also, our targeting users have limited knowledge about choosing the right breast pump, even if the team designed and produced different sizes. From this perspective, “one size fits all” is a high priority user requirement. Our goal is to produce one size of the pump, and it would fit 90 percent of women in Africa.

1. Fits nipple sizes from 6 mm to 7.5 mm [31]

2.7 Durable

The product should also be durable, from our interview with different users. This requirement has high priority, since back-to-factory maintenance is not available in most of these areas. The lifespan of the product should be for completing lactation period for at least one child. UNICEF and the World Health Organization recommend exclusive breastfeeding for the first six months of life. The team assumes that the average use of the pump is 3 uses/day (once before work, once during work, and once after work).

1. Life time for the breast pump greater than 1000 uses
2. Withstands drops from 1-meter height

2.8 Locally Sourced

During our interview with Dr. Leo and Prof. Sienko who have gone to Africa and have some researches on these low-resource areas, they addressed an issue that the people in low-resource Africa would like to use local materials if possible. This requirement has medium priority, since locally sourced design could potentially decrease the cost, increase the easiness for using, and increase the willingness of our targeting users to use the product.

1. Use at least 1 local material

Noticed that, the local material will not count as parts for our design, it provides more feasibility to both the design and the usage.

2.9 Portable

A portable design is required in the project description from our sponsors. The potential users of this design are working mothers who need to bring the product to daily work. After the interviews, the team found that most mothers have experience using a breast pump at work. But the situation is different in Africa for our low-resource settings. A lot of our targeting users have no jobs. Their work is discontinuous around the home, and they would not leave the child alone for a long time. So this requirement has medium priority. For a portable new design, its size and weigh should be similar with the manual pumps in the current market, and fits in some daily-use handbags.

1. Volume < 3500 cm^3
2. Weight < 300 g

The volume and the weight come from the benchmarks of the current manual pumps on the market [21] [22] [23]. The new product is expected to be able to fit in some daily-use handbags. Besides, the weight of the product should not be a burden.

2.10 Preserves Milk

Freshly expressed breast milk could be kept up 6 hours under room temperature (72°F) [32]. From our interview with sponsors and Prof. Sienko, long-time storage of the breast milk is a good to have feature, but not a must. This requirement has low priority, because a lot of our targeting users have no jobs, as mentioned in section 2.9. Their work is discontinuous around the home, and they would not leave the child alone for a long time.

1. Keep the milk fresh for at least 6 hours under 100°F

The average monthly temperature in Botswana, Africa could be as high as 93°F [33]. Considering even higher possible daily temperature, the team set criteria to be 100°F.

Table 1: User requirements and engineering specifications, with sources and priorities.

Priority	User Requirements	Sources	Engineering Specifications
High Priority	Easy to use	Sponsor	No more than 3 parts to assemble in 30 seconds No more than 2 steps to operate
	Low cost	Sponsor	Manufacturing cost is less than 5 USD
	Easy to clean	Sponsor	No more than 4 cleaning steps 1 m^3 of water usage per 600 uses Sanitation in boiling water for 10 min
	Mechanically powered	Research	No electrical power source required
	Efficient	User	Pressure Difference > 120mmHg Maximum allowed suction frequency > 54 cycles/minute Support suction or/and massage
	"One size fits all"	Research	Fits nipple sizes from 6 mm to 7.5 mm
	Durable	User	Life time is greater than 1000 uses Withstands drops from 1-meter height
Medium Priority	Locally sourced	User	Use at least 1 local material
	Portable	User	Volume < 3500 cm^3 Weight < 300 g
Low Priority	Preserves milk	Research	Keep the milk fresh for at least 6 hours under 100 ℉

3. Concept Generation

3.1 Functional Decomposition

To better define all the target functions that our design needs to realize, our team conducted the functional decomposition with the black box diagram (shown in Figure 7). The blue arrow shows the energy flow of the system, and the green arrow shows the material flow of the system. First step is to attach the pump to the breast, and then it should be able to position the nipple. After that with the external energy, it would create pressure difference/or other ways to pump the breast milk. Then the product is supposed to transport the breast milk and finally store the breast milk. Following concepts are generated mostly focusing on one or more aspects in pumping, transporting, and storing functions, because these three functions are relatively complicated and have more aspects that the team can improve.

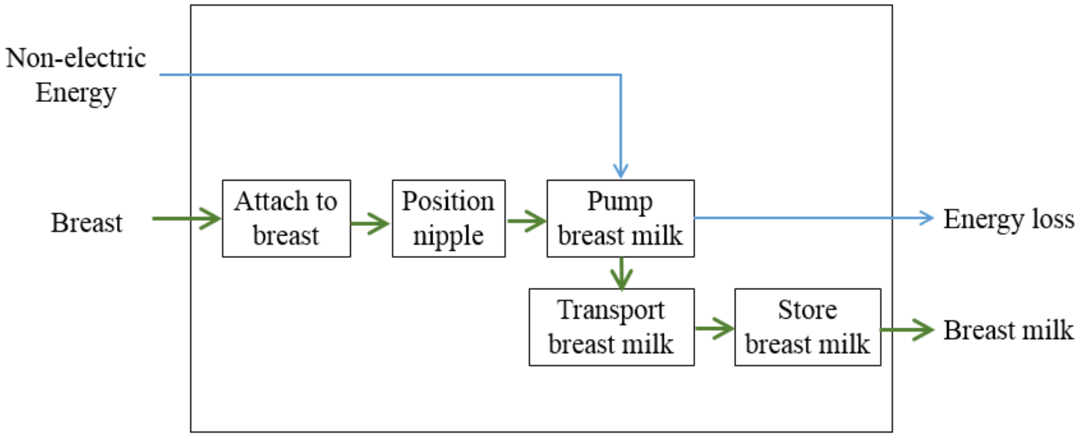


Figure 7. Functional Decomposition

3.2 Concept Drawings

Taking the user requirements and the decomposed sub-functions into consideration, 29 concepts were generated during the brainstorming independently, and all the drawing sketches are shown in Appendix A. Six most representative designs of the twenty-nine concepts are presented in the following sections. Collecting inspirations from soft bottle design, food preservation product, cow and sheep milking device, natural milking procedure and traditional medical treatment, these designs present significantly different ideas.

3.2.1 Dual-use Collapsible Milk Bottle

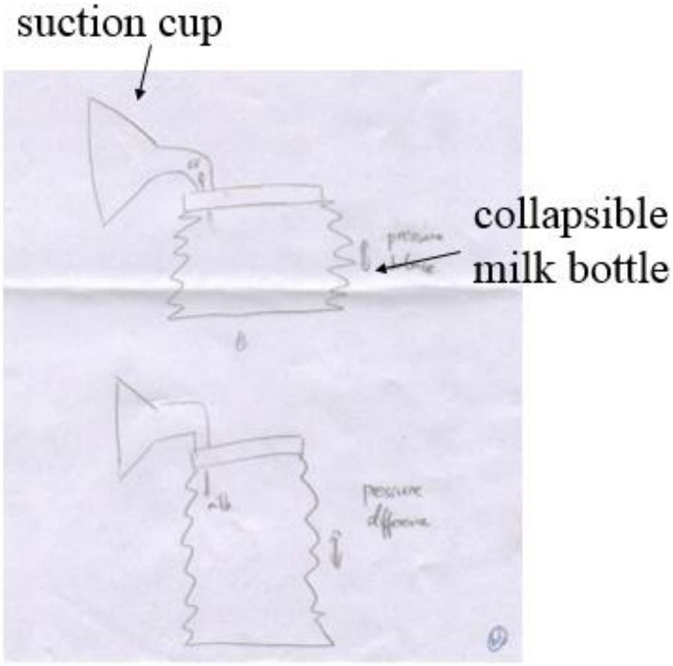


Figure 8. Dual–use Collapsible Milk Bottle

This design utilizes a collapsible bottle, similar to the bending part of a bendy straw, for both pumping and milk storage. After attaching the suction cup to the user’s breast, the user starts pulling the bottle up and down, creating pressure variations like a pump. Breast milk will start flowing and be collected in the bottle. When the breast pump is not in use, it can be folded to a small volume and put into a handbag.

By combining the squeezing pump and the storage bottle to one body, this design has only three simple parts, which makes it an easy-to-use product. Besides, the collapsible structure minimizes the volume of the design and meets the portable requirement. However, wrinkles in the bottle will apparently bring some difficulties in thorough cleaning.

3.2.2 Universal Bottle Assembly

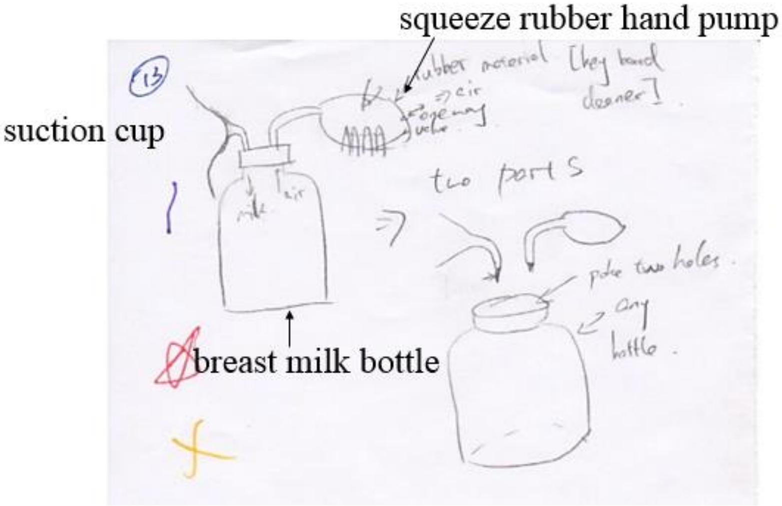


Figure 9. Universal Bottle Assembly

This design consists of only two separate parts: a suction cup with a tube for milk flow and a squeeze rubber hand pump with a tube for airflow. The open ends of the tubes can be connected to any bottles or jars by drilling two holes on the caps. Once connected, the user attaches suction cup to her breast and holds the bottle with one hand, and then starts pumping by squeezing the hand pump. Breast milk will be collected in the bottle or jar attached.

This design is highlighted because of the openness and possibility of universal bottles. Utilizing local material not only reduces the total cost, but also encourages females in fewer developing countries to use it. Besides, the simple design greatly increases the feasibility and is easy to use. The only shortcoming of this design is that a squeeze rubber pump has relatively low efficiency.

3.2.3 Stretchable Silicon Cover

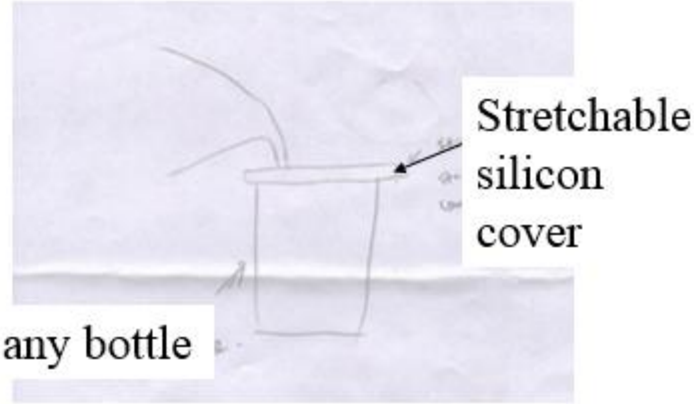


Figure 10. Stretchable Silicon Cover

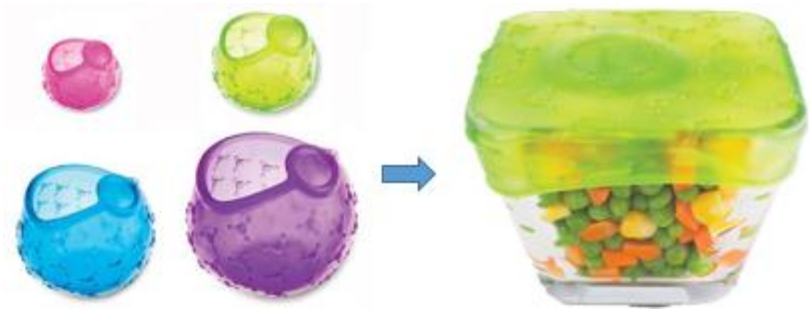


Figure 11. Stretchable Reusable Food Cover [34]

This design mainly emphasizes on the sealing function, and locally sourced requirement. The way to realize this function is utilizing sticky stretchy rubber to connect the pump to any open bottles, jars, or cups. This design is inspired by the stretchable silicon fresh cover on the market, which is accepted to be cheap and easy to clean.

This design simplifies the mechanism of an adjustable lid. Also, it’s intuitive and could reduce the difficulty in promoting breast pump in low resource setting countries.

3.2.4 Squeeze pump inspired by natural milking procedure

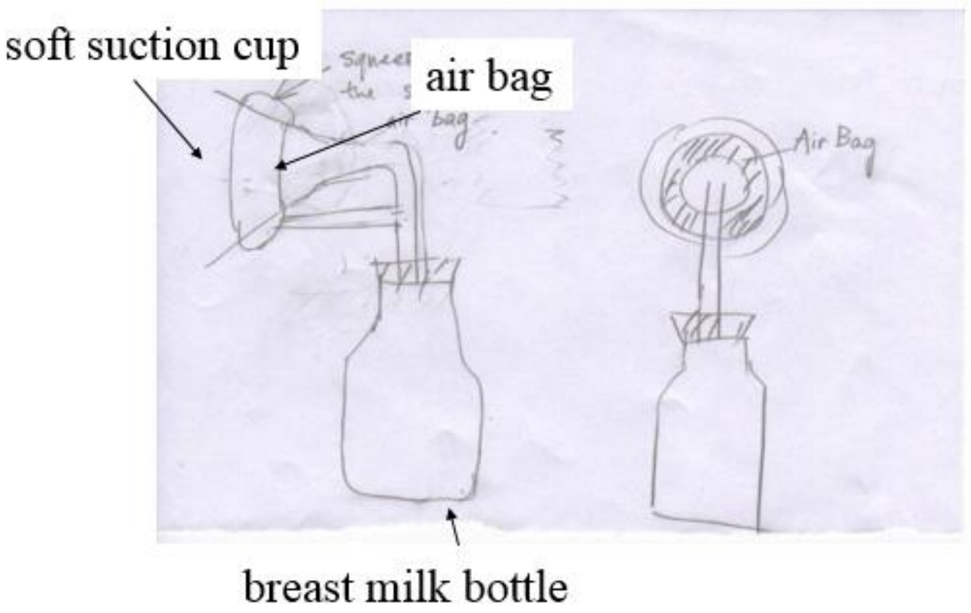


Figure 12. Squeeze pump inspired by natural milking procedure

This design is inspired by the natural milking procedure, where females directly squeeze and massage the breasts to generate milk. In this design, the squeezing mechanism, which is an air bag, is attached to the outside of the soft suction cup. When squeezing the pump, it does not only generate suction in the pump, but also massage the breast to help increase the milking efficiency simultaneously.

This design involves a similar action to the natural milking procedure, which will help moms accept this new tool to their daily life. However, one of the disadvantages in this design is the low durability. The attachment between the soft suction cup and the air bag is relatively unreliable. Besides, cleaning the soft suction cup will be a big issue when clean water is limited.

3.2.5 Foot Pump

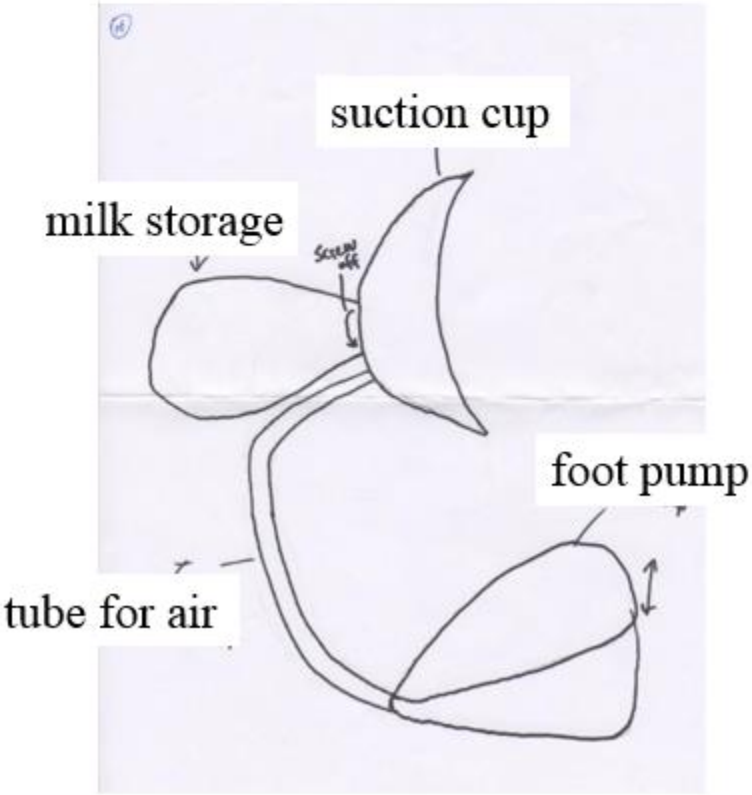


Figure 13. Foot pump

This concept consists of three parts, a suction cup, a milk storage bag and a foot pump. The main purpose of this design is to free the hands. One of the shortcomings mentioned most about a manual breast pump is the tiring and endless pumping process. An average of 30-40 minutes pumping process brings soreness in the arm. Using a foot pump will solve the problem. For our target users, the working moms, hands are freed to continue their work.

However, in the low resource setting regions, the foot pump is supposed to be used on dirty ground or the field. Cleaning the foot pump will be extremely challenging.

3.2.6 Combustion Chamber

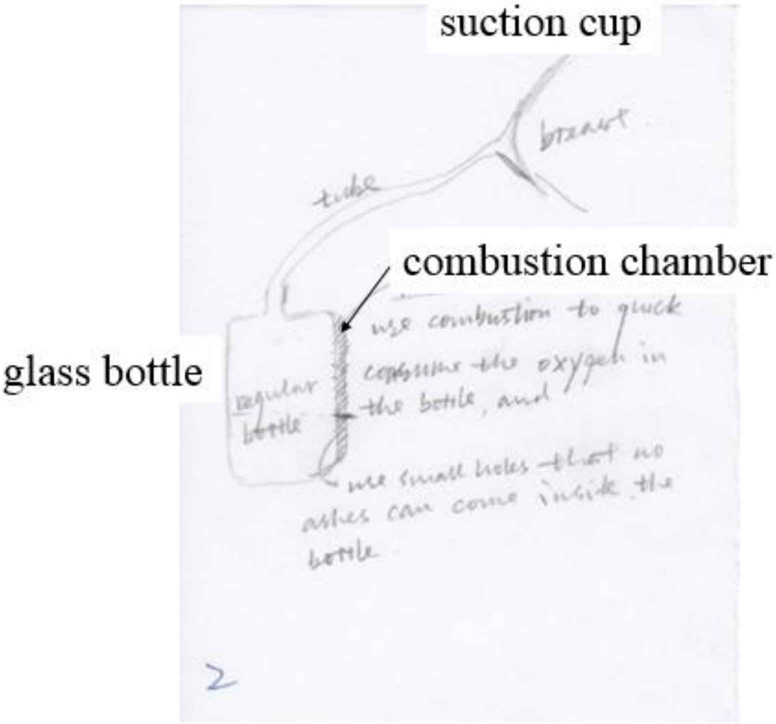


Figure 14. Combustion Chamber

This design was inspired by a traditional medical procedure, “Fire cupping”. First, the user triggers the combustion or chemical reactions to consume the oxygen in the bottle and rapidly heat the bottle, then the bottle cools down to create pressure difference. It saves the labor of pumping and automatically provides suction to the breast.

However, when taking the facts of safety and recyclability into consideration, this fancy idea has a low feasibility.

4. Concept Selection

4.1 Selection Method

After the team had generated a total of 29 concepts, we selected the final concept using the Decision-Matrix Method. The team used the nine user requirements as scoring criteria. Since feasibility is important as well, the team included feasibility as one high priority criterion. The team had totally 10 criteria to evaluate the concepts.

The team gave a weight for each criterion, ranging from 1 to 5. The high-priority user requirements had weights from 4 to 5; the medium-priority user requirements had weights from 2 to 3; and the low-priority requirement had weight of 1. All the criteria, their weights and meanings are shown in Table 2.

There are four criteria that have the weight of 5. “Easy to use”, addressed by our sponsors, is our top priority, because our targeting users have little knowledge about breast pumps. The teams need to design a product that they are willing to use, and can be used without much difficulty; “Low cost” is the key requirement for the low-resource setting from our sponsor. This is definitely a top priority that the team needs to cut down the cost of the pump the team designed; “Easy to clean” also has top priority because cleaning and sanitizing would directly affect the health of the baby. “Efficient” has top priority because if the design is inefficient, our targeting users in Africa would probably unwilling to use.

There are three criteria that have the weight of 4. “Feasible” is very important to consider. It has high priority since the team needs to deliver a fully functional prototype by the end of the project; “One size fits all” also has high priority, since for our low-resources settings, it would be cost-prohibitive to design and produce different sizes of the breast pumps. Also, our targeting users have limited knowledge about choosing the right breast pump, even if the team designed and produced different sizes; “Durable” has high priority because back-to-factory maintenance is not available in most of these areas.

“Locally sourced” has weight of 3. The people in low-resource Africa would like to use local materials if possible. It has medium priority, since locally sourced design could potentially decrease the cost, increase the easiness for using, and increase the willingness of our targeting users to use the product.

“Portable” has weight of 2. It has medium priority, since a lot of our targeting users have no jobs. Their work is discontinuous around the home, and they would not leave the child alone for a long time.

"Preserves milk" has weight of 1. Similar with the reason for portable, long-time storage of the breast milk is a good to have feature, but not a must, because a lot of our targeting users would not leave the child alone for a long time.

For each criterion of each concept, the team assigned a score from 0 to 3 to evaluate its potential performance. 3 means "fully satisfies"; 2 means "substantially satisfies"; 1 means "partly satisfies"; and 0 means "does not satisfy".

For our scoring procedure, the team first evaluated different concepts individually without discussion. The team then multiplied the weight and the score of each criterion of each concept, and added them together as an individual score. Table 2 is an example of our concept scoring system, which is the real numbers when the team evaluated concept 1.

Table 2: Scoring by different people for concept 1

Concept 1	Weight	Anqi Sun	Raymond Chen	Qi Wang	Yiwen Wu	Average
Easy to use	5	2	1	2	1	
Lost cost	5	3	3	2	1	
Easy to clean	5	2	1	1	2	
Efficient	5	2	2	0	3	
Feasible	4	3	1	3	2	
One size fits all	4	1	1	1	1	
Durable	4	2	1	1	2	
Locally sourced	3	1	3	2	2	
Portable	2	3	1	2	1	
Preserve milk	1	0	0	0	0	
Total	114	78	58	55	63	63.5

To lower the decision bias caused by preferences of different teammates, the team evaluated individually, and averaged the score afterwards. The final averaged score for each design is shown in the Table 3 below.

Table 3: The final score for different concepts. The concept numbers are corresponding to the drawings attached in the Appendix A. Highest six concepts are highlighted.

Concept #	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Final Score	63.5	46.25	54	68	54	62.25	59.75	63.25	60.25	56

Concept #	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Final Score	56.5	72.25	85.5	63.5	59.25	57.5	50.5	41	75.5	78.5
Concept #	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	
Final Score	58.5	64.25	66.5	72	55.25	50.25	56.5	51.5	74.5	

After choosing the highest-scored concept 13 as the fundamental design, the team examined five other highest concepts to find if they can be compatible with concept 13. The second highest concept, concept 20 is compatible with the fundamental design, which added a sticky rubber cover that could fit different bottles.

4.2 Chosen Design

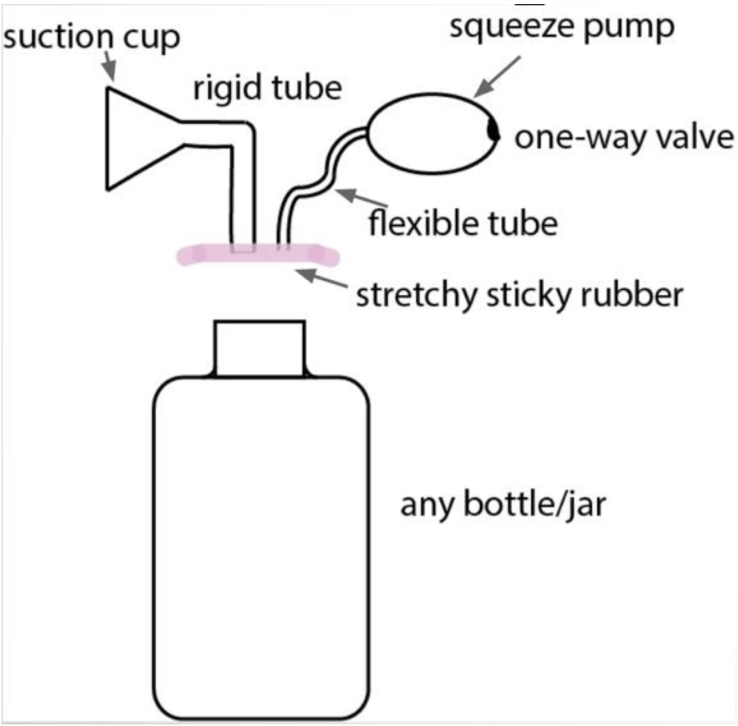


Figure 15. Mechanism of chosen design

The final design combines the key features of two concepts the team generated and consists of three parts: a suction cup with a 90° rigid tube, a squeeze pump with a one-way valve at one end and a flexible tube at the other end, and a stretchy sticky rubber cover that connects the pump and the cup to a bottle or jar of any size. After attaching the suction cup to her breast, the user can start pumping breast milk by manually squeezing the hand pump and the breast milk will be collected in any container that is attached.

The advantages of this design include: easy to use, low cost, easy to clean, mechanically powered, locally-sourced, and portable. The suction cup size is designed to fit most of the breast sizes in Africa. However, this design is not as efficient as some other designs the team generated due to the pumping mechanism and the usage of stretchy rubber might induce durability challenge.

The simple design makes fabrication easy. However, since the design consists mainly rubber and plastic, the connection and sealing during fabrication would be a concern. By constructing a physical design mockup, the team were able to refine identify optimal design dimensions and geometries. The team also used the mockup to brainstorm strategies for connection and sealing.

The team has contacted Dr. Harvey Leo, a research scientist in the Division of Healthy Behavior and Education and Center for Managing Chronic Disease, who is currently conducting research in Ethiopia focused on breast milk banks. He would bring the design prototype with his team to Ethiopia in June 2015 for testing and feedback from key stakeholders to inform further design revisions.

5. Concept Description

The chosen design 3D model is shown in Figure 16. It consists of four parts: a rigid suction cup with rigid curved tube, a squeeze pump with soft tube, a stretchable cover (shown in dark tan), and a duckbill valve (shown in blue).The soft tube is directly connected to the rigid curved tube through the cylinder with rings on the rigid tube to create an air-tight connection shown in Figure 17. This allows a smaller stretchable cover base diameter for compatibility with bottles of smaller lid sizes (e.g. water bottle). The waves of the circular base of the rigid tube provide an air-tight connection between the rigid part and the stretchable cover in use, shown in Figure 17. The duckbill valve is connected to the rigid suction cup via an extended cylinder from the cup to create an air-tight connection, shown in Fig. 18 The duckbill valve acts as a one-way valve to create a constant suction volume. This prevents breast pump performance from variation due to different sizes of bottles connected and increases the breast pump efficiency.
Figure 19 demonstrates how the design can be fit onto a bottle of any lid size.

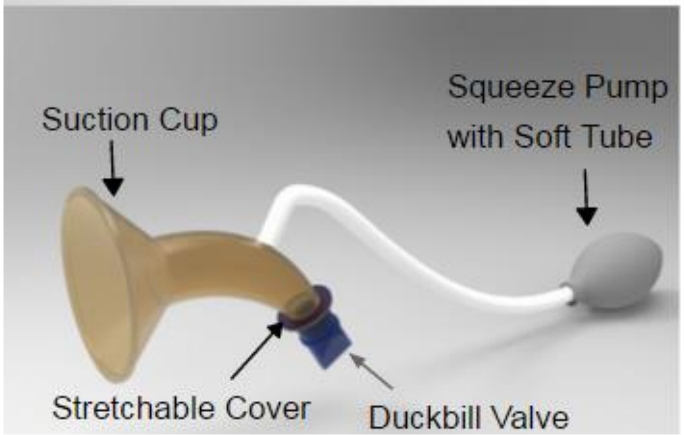


Figure 16: 3D concept of our chosen design.

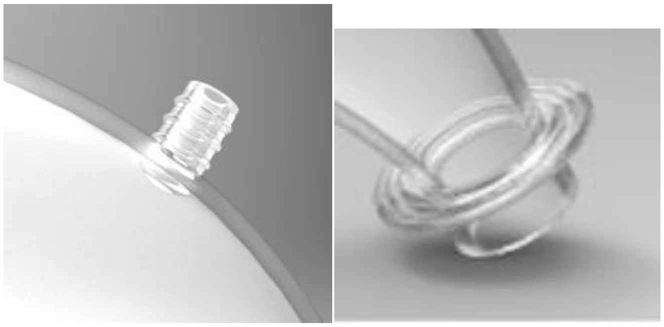


Figure 17: Rings and waves on the connection and cover base to secure silicon cover and ensure air tight connection.

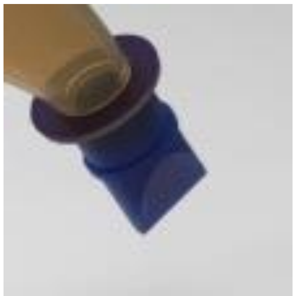


Figure 18: Extended cylinder to connect duckbill valve to secure silicon cover and ensure air tight connection.

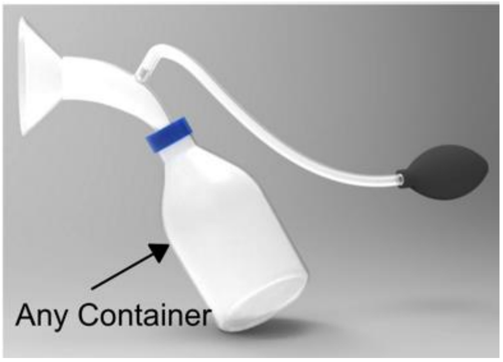


Figure 19: Demonstration of bottle compatibility.

6. Engineering Analysis

The team identified three design drivers: the suction mechanism of the breast pump, the extraction of the breast milk, and storage of the breast milk. The team chose at least one mode of analysis for each design driver, as shown below in Table 4.

Table 4: The modes of analysis used for each of the design drivers identified

Drivers Modes	Suction Mechanism	Extraction of Breast Milk	Storage of the Breast Milk
Theoretical Modeling	☐	☐	
Empirical Testing	☐		☐
Mockup Construction	☐		☐

Since the suction mechanism is the most important part for a working breast pump, the team used all three modes of analysis to demonstrate that the squeeze pump design could generate a periodic pressure difference. The team first used the ideal gas equation to show that the squeeze mechanism could generate pressure difference theoretically. Then the team used empirical testing to demonstrate that the squeeze mechanism could generate not only a one-time pressure difference, but also a periodic pressure difference that simulates the suction of a baby during breastfeeding process. Finally, the team constructed the mock-up to confirm that the squeeze mechanism would work in our particular design.

Extraction of the breast milk is important. Since the team might not have the chance to test the final prototype on users after the project is done, the team needs a relationship between the pressure difference input and the milk flow rate output to verify the efficiency of the pump. This design driver is hard to be analyzed by performing tests on breastfeeding mothers. The team then used theoretical modeling. Also, because of the difficulty of modeling a human breast, the team reviewed papers and found a published model that best fits our interests. The model involves fluids mechanism, solid mechanisms, as well as Anthropometry.

Since the design intends to use the local bottle as the storage of the breast milk, the team was interested in determining the size range of the bottles that could fit the design. The team did testing for difference sizes of bottle caps using the mock-up constructed. The deformation of the stretchable silicon cover involves solid mechanism.

6.1. Suction Mechanism of the Breast Pump

6.1.1. Theoretical Modeling

For the final concept, the team chose a squeeze mechanism to generate pressure difference instead of using a pushing mechanism that is the most common suction mechanism used in the manual pump. This kind of mechanism would potentially decrease the pain when using the breast pump for a long time, but the team needs to justify its feasibility. The squeeze bulb mechanism is shown below in Figure 20.

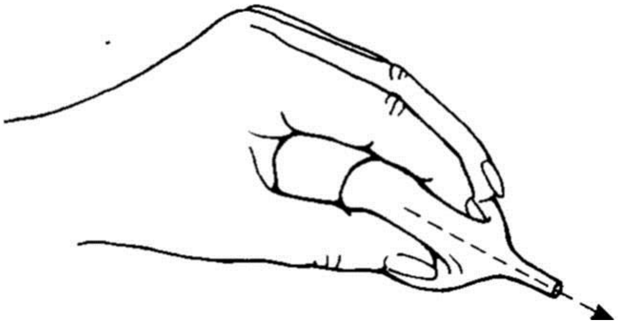


Figure 20. The squeeze bulb mechanism

The team used the ideal gas equation (Eq. 1) as governing equation to generate a simple model, which demonstrates the squeeze mechanism can provide suction inside the tube.

$$PV = nRT \qquad \text{(Eq. 1)}$$

where, P = the pressure of the air inside the system; V = the volume of the system; n = number of moles of the air; R = universal ideal gas constant; T = the temperature of the air in Kelvin. From this equation, the team further defined two states during the pumping process shown in Figure 21.

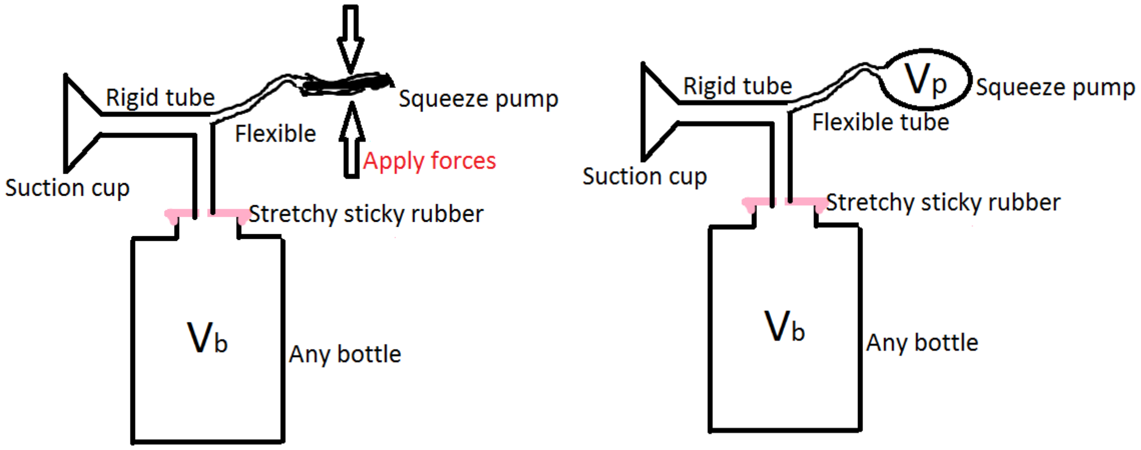


Figure 21. Two states while applied forces to the squeeze pump. Left figure is state 1, when the squeeze pump is compressed; right figure is state 2, when the pump recovers.

The team had the following assumptions before conducting further calculations: 1) the volume of the squeeze pump V_p is much less than the volume of the bottle V_b. 2) All parts are perfectly sealed. 3) Deflection of the bottle and soft tube is negligible. Then directly applying the governing equation (Eq. 1), the following two equations are corresponding to two states.

$$P_1 V_b = nRT \tag{Eq. 2}$$

$$P_2 (V_b + V_p) = nRT \tag{Eq. 3}$$

Combining two equations above, the following results can be found (Eq. 4).

$$P_2 = \frac{V_b}{V_b + V_p} P_1 \tag{Eq. 4}$$

As Eq. 4 shows, the squeeze pump is capable of generating a pressure difference. This laid the foundation for the empirical testing, which would further demonstrate a pressure difference cycle.

6.1.2. Empirical Testing

To further demonstrate that the squeeze mechanism could generate a pressure difference cycle, the team conducted empirical testing. The experimental setup is shown below in Figure 22.

Figure 22. Experimental setup for empirical testing of the suction mechanism

The team used balloons as a simulation of the human breast because the material is soft and there is pressure inside. The storage bottle, connection parts and the suction cup came from the Medela Harmony Manual Breast Pump [21] that we reviewed during the benchmark. The only variable is the suction mechanism, which is a pushing mechanism for Medela pump and a squeeze mechanism for our design. To reach a perfect seal for testing, the team used tape for the connection between the squeeze bulb and the parts from Medela.

The testing procedures are as follows: the team first attached the squeeze pump and sealed it with the tape. Then the team attached the balloon to the suction cup, and made sure that it also sealed perfectly. After that, the team quickly squeezed the pump to its lowest volume then released the pump and waited for it to come back to the initial condition. The team then squeezed it again after it came back to the initial conditions and so on for 30 seconds. The team took pictures and videos while conducting the tests. Finally, the team attached the Medela pushing pump and repeated the same procedures for 30 seconds. Two of the testing pictures are shown below in Figure 23.

Figure 23. The left figure shows that the squeeze pump generated suction inside the suction cup, in comparison with the suction generated using the Medela pump on the right figure.

As shown in the figure, both mechanisms generated pressure differences as the team predicted in the theoretical model. Furthermore, when the team continuously compressed and released in 30 seconds, the squeeze pump could generate a pressure difference cycle. The team used this empirical testing to demonstrate that the squeeze pump is capable of generating periodic pressure difference. More quantitative experiments will be conducted on Medela breast pump and our breast pump with a fake breast and a vacuum pressure gauge in next stage.

However, the period of this cycle takes longer than the cycle for the Medela pump, since the soft material of the squeeze pump would take longer time to come back to the initial state. This empirical testing would potentially influence our decision about the material selection of the pump.

6.1.3. Mockup Construction

After demonstrated that the squeeze mechanism would generate a periodic pressure difference, the team further refined the mockup to test whether the squeeze mechanism would work for the particular design. An updated version of mockup is shown in the Figure 24 below.

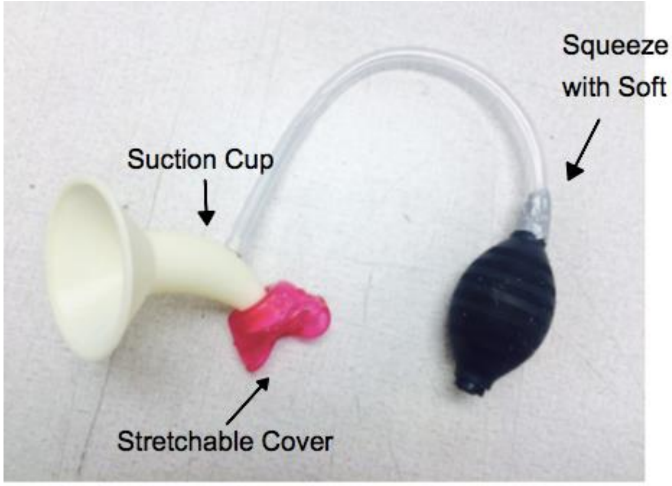


Figure 24. Refined mockup for testing

The rigid suction cup with tube component is 3D printed based on the 3D model introduced earlier. The squeeze pump with soft tube component is constructed using 1/4" ID x 3/8" OD PVC tube and a squeeze duster. The stretchable cover is using the EU/FDA food safe and BPA/Phthalates free sticky rubber.

Since the team 3D-printed the suction cup using ABS, which is not transparent as shown in Figure 23, the team cannot use the same balloon test as introduced in 6.1.2. The team then cut the balloon and attached it directly on the suction cup as shown in Figure 25 below.

Figure 25. Mockup testing setup (left) and results (right)

When the team squeezed the pump, an obvious pressure difference was observed by the deformation of the balloon material surface. When the team continuously compressed and released the pump for 30 seconds, the balloon surface came inside and back out again and again indicating that a pressure difference cycle was generated. The team analyzed this design driver successfully.

More comparison tests on the one-way valve squeeze pump and closed squeeze pump will be conducted later and could potentially influence the final prototype. The team will quantify the pressure difference generated by either type of the squeeze pump, as well as the period for one pressure cycle. Then the team will compare the performance of the two pumps and make a decision about the final prototype.

6.2. Extraction of the Breast Milk:

Extraction of the breast milk is a critical issue since the team needs a relationship between the pressure differences input vs. the milk flow rate as output. The team reviewed different papers, then chose the model described by Christopher Zoppou, Steven L. Barry, and Geoffry N. Mercer in paper [35] and [36], which best fits our interests. The breast model described in the paper [36] are shown as below in Figure 26.

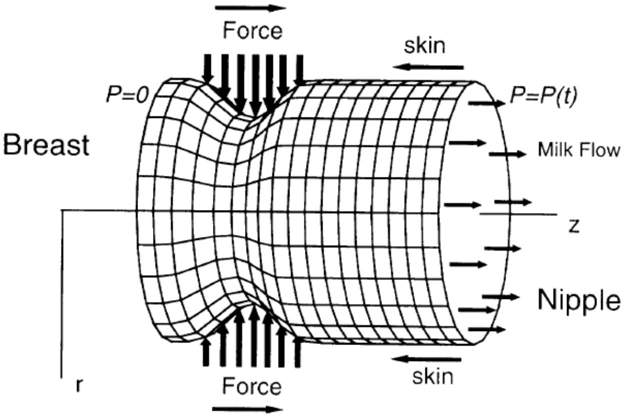


Figure 26. Schematic diagram for the cylinder teat used in the computer model [36]

They modeled the human teat as a porous elastic cylinder. The lactiferous sinuses within the human teat are represented in the computer model as a porous material. At the breast end of the cylinder, they assume that there is a reservoir of milk. Milk is drawn through the porous material by applying a suction at the nipple end of the teat. The application of suction as well as the action of infant suckling deforms the elastic porous material representing the human teat. [36]

Since the porous material is modeled as a continuous binary mixture of solid and fluid phases, the governing equations for this model are from solid mechanism and fluid mechanism. The equations include the conversation of mass (Eq. 5), the momentum equation (Eq. 6), the stress tensors (Eq. 7), the solid contact stress (Eq. 8), the non-dimensionalisation, as well as the appropriate boundary conditions.

$$\frac{\partial \phi^\beta}{\partial t} + \nabla \cdot \left(\phi^\beta \mathbf{v}^\beta\right) = 0 \qquad \text{(Eq. 5)}$$

$$\rho^\beta \left(\frac{\partial \boldsymbol{v}^\beta}{\partial t} + \left(\mathbf{v}^\beta \cdot \nabla\right)\mathbf{v}^\beta\right) = \nabla \cdot \mathbf{T}^\beta + \rho^\beta \square^\beta + \boldsymbol{\pi}^\beta \qquad \text{(Eq. 6)}$$

$$\mathbf{T}^\beta = -\phi p \mathbf{I} + \boldsymbol{\sigma}^\beta, \quad -\boldsymbol{\pi}^s = \boldsymbol{\pi}^f = K(\mathbf{v}^s - \mathbf{v}^f) - p\nabla\phi^s \qquad \text{(Eq. 7)}$$

$$\widehat{\boldsymbol{\sigma}} = \lambda\phi\mathbf{I} + 2\mu\mathbf{e}, \quad \mathbf{e} = \frac{1}{2}\left(\widehat{\nabla}\widehat{\mathbf{u}} + \left(\widehat{\nabla}\widehat{\mathbf{u}}\right)^T\right) \qquad \text{(Eq. 8)}$$

where, ϕ^β = the volume fraction of component β; ρ_T^β = the intrinsic density; $\rho^\beta = \rho_T^\beta \phi^\beta$ is the density of each phase in the mixture; $\mathbf{u}$ = solid displacement vector; $\mathbf{v}^s = \frac{\partial \mathbf{u}}{\partial t}$ is the solid velocity; $\mathbf{T}^\beta$ = the stress tensor for the β phase; $\mathbf{b}^\beta$ = the resultant external body force (neglect here); $\boldsymbol{\pi}^\beta$ = drag force between the constituents representing internal forces due to frictional interaction between the two phases; K = the drag coefficient of relative motion; p = the fluid pressure; $\mathbf{I}$ = the identity tensor; λ, μ = Lame stress constants; $\mathbf{e}$ = the infinitesimal strain tensor; $\phi = \nabla \cdot \mathbf{u}$ is the dilatation [35].

This model can be applied for both manual pump and infant suction. The only thing different would be the boundary conditions to be applied. For the infants, except for the suction cycle illustrated in Figure 27, they will also apply a peristaltic force. For the manual pump on the other side would just apply the suction.

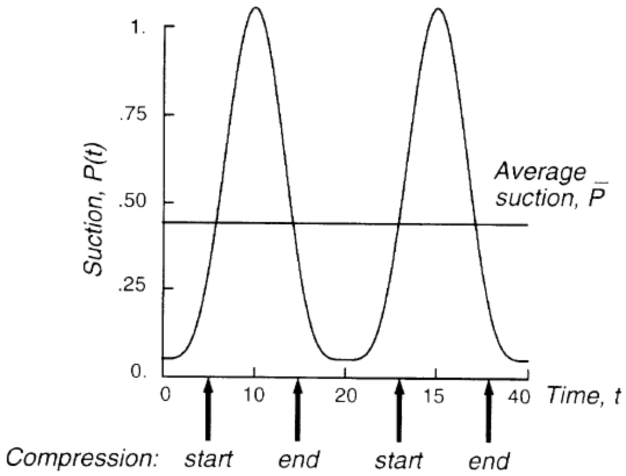


Figure 27. Typical suction cycle (both time and suction are non-dimensional) [36]

More detailed model and parameters used to get numerical solution can be found in the reference [35] and [36]. Here is the result of this model. Figure 28 shows the shape of the teat when only the maximum suction was applied to the teat (no peristaltic force)

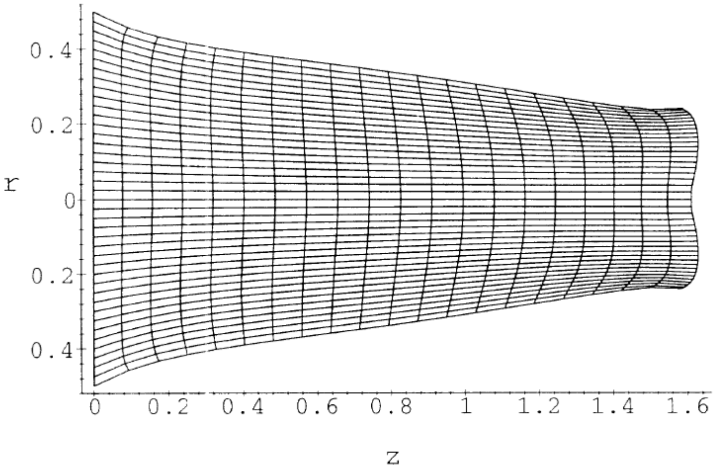


Figure 28. Shape of teat when maximum pressure is applied by a breast pump [35]

More importantly, the model obtained the relationship between average suction and the milk flow. The dimensional result is generated based on our manual breast pump, shown in Figure 29.

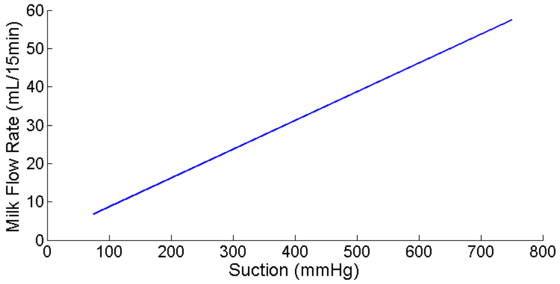


Figure 29. Dimensional relationship between milk flow rate and suction pressure for a manual breast pump[36].

This model would help the team identify whether the suction is enough for efficient breast milk extraction, meaning to identify whether the final prototype generates a reasonable milk flow rate.

6.3. Storage of the Breast Milk

Since the storage container of the breast milk will be the local bottle, the team was interested in finding the sizes range for different bottles that could fit the design. The team did the empirical testing. The experimental setup is the mockup the team constructed (Figure 24). Details of the mockup construction have been included in Section 6.1.3.

The procedures of the empirical testing are as follows: the team stretched the silicon cover to fit different bottles using the mockup the team constructed. After attaching the silicon cover to the bottle, the team tested the quality of the seal with the balloon (Figure 25, Section 6.1.3). For all five common bottles the team could find, the silicon cover could perfectly seal bottles from 1.1 inch to 3.5 inch, as shown in Figure 30 below.

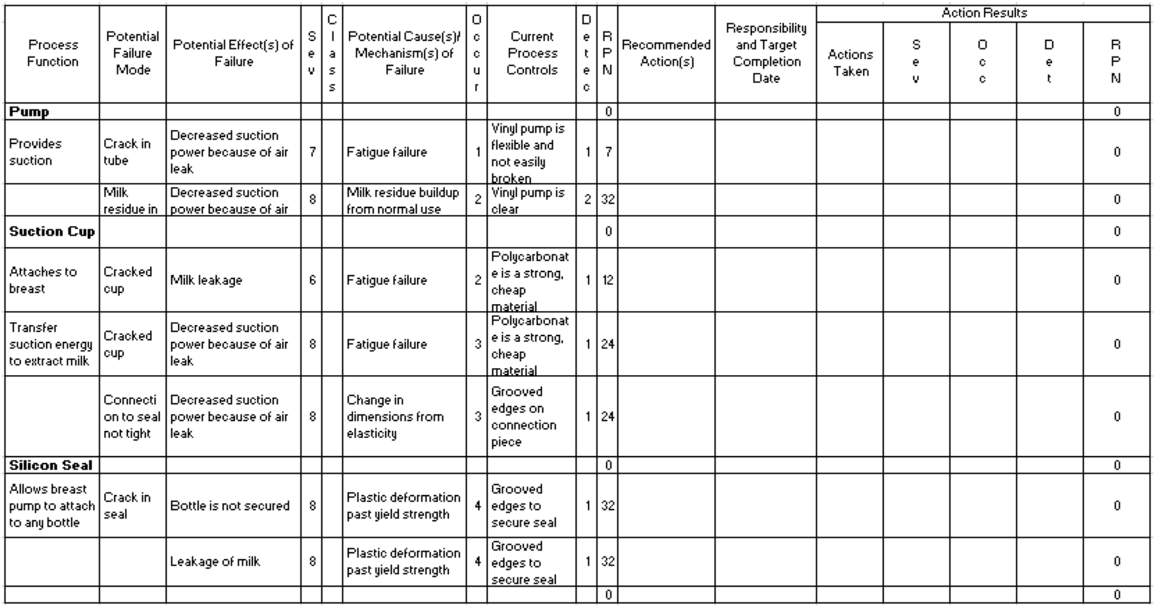
Figure 30. Left figure is the smallest bottle cap size (regular water bottle) that the cover could fit, which is 1.1 inch; right figure is the largest bottle cap size (the coffee cap) the cover could fit, which is 3.5 inch.

More reviews about the common bottle sizes in Africa will be conducted later. This test would potentially influence our final prototype after the team decides whether 1.1 – 3.5 inch bottle cap sizes would be enough for local bottle.

7. Risk Analysis

To assess the risk of the design, our team conducted a Failure Modes and Effects Analysis (FMEA). Our results are shown in Table 5.

Table 5: FMEA for the three different parts of the breast pump (pump, suction cup, silicon seal).



Process Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/ Mechanism(s) of Failure	Occur	Current Process Controls	Detec	RPN	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
												Actions Taken	Sev	Occ	Det	RPN
Pump									0							0
Provides suction	Crack in tube	Decreased suction power because of air leak	7		Fatigue failure	1	Vinyl pump is flexible and not easily broken	1	7							0
	Milk residue in	Decreased suction power because of air	8		Milk residue buildup from normal use	2	Vinyl pump is clear	2	32							0
Suction Cup									0							0
Attaches to breast	Cracked cup	Milk leakage	6		Fatigue failure	2	Polycarbonate is a strong, cheap material	1	12							0
Transfer suction energy to extract milk	Cracked cup	Decreased suction power because of air leak	8		Fatigue failure	3	Polycarbonate is a strong, cheap material	1	24							0
	Connection to seal not tight	Decreased suction power because of air leak	8		Change in dimensions from elasticity	3	Grooved edges on connection piece	1	24							0
Silicon Seal									0							0
Allows breast pump to attach to any bottle	Crack in seal	Bottle is not secured	8		Plastic deformation past yield strength	4	Grooved edges to secure seal	1	32							0
		Leakage of milk	8		Plastic deformation past yield strength	4	Grooved edges to secure seal	1	32							0
									0							0

To calculate the risk priority number (RPN), the team rated each category of severance, occurrence, and detection. The severance of the effect of failure is rated on a 1-10 scale with 1 meaning "no noticeable effect" and 10 meaning "potential failure mode affects safe operation or regulatory requirements, without warning." Next, the occurrence was also rated on a 1-10 scale with 1 meaning "highly improbable" and 10 meaning "failure all but guaranteed." Finally, detection was rated on a 1-10 scale with 1 meaning "almost certain to detect" and 10 meaning "almost no chance of detection prior to release to customers." The RPN is then found by multiplying these scores together. Any score greater than 100 is problematic and failure is almost certain to occur. From our analysis, our highest score was 32 which means that our design will be relatively safe from failure.

8. Initial Manufacturing Plan

8.1 Manufacturing Plan for Prototype Construction

8.1.1 Suction Cup

The suction cup for the prototype component is supposed to be accurate in dimensions, especially the ridges contacting with the tube and the stretchable cover.

In the past week, we built a CAD model and had it printed at the University of Michigan 3D Lab using the Dimension Elite 3D printer. The CAD model and the printed suction cup are shown in Figure 31 and Figure 32. Based on our experiences from the first prototype and the changes we made to the design, we are planning to print Suction Cup 2.0 with the Accura 60 on 3D Systems-SLA 250/50 which has higher accuracy. The details on the printing parameters of the two prototypes are shown in Table 6.

Figure 31. CAD model for Suction Cup 1.0 Figure 32. 3D printed Suction Cup 1.0.

Table 6. 3D printing plan for Suction Cup 1.0 and Suction Cup 2.0

	Suction Cup 1.0	Suction Cup 2.0
Location	University of Michigan 3D lab	G.G.Brown Mechatronics Lab
Equipment	Dimension Elite	3D Systems-SLA 250/50
Material	Acrylonitrile Butadiene Styrene (ABS)	Accura 60
Status	Done	In Progress

Fabricating the suction cup with a 3D printer has many unique benefits. First, 3D printing provides us a rapid prototyping method which is relatively cheap compared with the plastic molding method. Second, a 3D printer can perfectly print out the curves we defined for the suction cup which is impossible to achieve manually.

However, some limitations for 3D printing need to be identified in the prototype construction:

1. A 3d printed model cannot simulate the strength and surface roughness of mass produced plastic components. Since there won't be significantly large force and pressure exerting on the suction cup in either testing or daily usage, the strength and surface roughness will not influence the functionality.

2. The abs material is not waterproof. The layer by layer printed structure is not dense enough to prevent permeation of water. Therefore, to conduct the tests using liquid, the

prototype of the suction cup should be either sprayed with waterproof coat or vapor treated.

3. The ABS material is not transparent. In this case, the suction cycle cannot be observed through the wall of the cup. The problem will be solved when the Accura 60 is used in the second prototype.

To sum up, the disadvantages for 3D printing in our prototype construction could either be ignored or be solved in the future testing and constructions which indicates that 3D printing is overall a proper method for rapid prototyping in this stage.

8.1.2 Stretchable Cover

To assemble the stretchable cover to the suction cup, we are planning to punch a hole at the center of the stretchable cover. To avoid the cover tears during the punch, we will first use the thinnest hex tip screwdriver to poke the center of the cover and then gradually enlarge that whole with larger hex tip screwdrivers.

8.2 Bill of Materials

All materials we are using for the prototype, associated with their model numbers, suppliers, quantity and prices are listed in Table 7. Additional materials may be purchased if any of the following items are proved to be improper in the following tests.

Table 7. Bill of Materials

Item Name	Model Number	Supplier	Quantity	Price	Associated process
CoverBlubber Reusable Stretchable Food Cover	38062-4PK	Fusionbrands	1	10.50	Hole punching on stretchable cover
ABS polymer	-	UM 3D printing lab	-	-	3D printing material for suction cup
Duckbill Valve	N010-5V	Amazon	1	1.70	Duckbill Valve
Dust Blower (from 5-in-1 cleaning kit for cameras)	NS-DCLNKIT	Insignia	1	15.99	Attach pump to soft tube

3/8 in. x 1/4 in x 10 ft. PVC Tubing	SVGE10	The Home Depot	10 ft	3.25	

9. Mass Manufacturing Plan

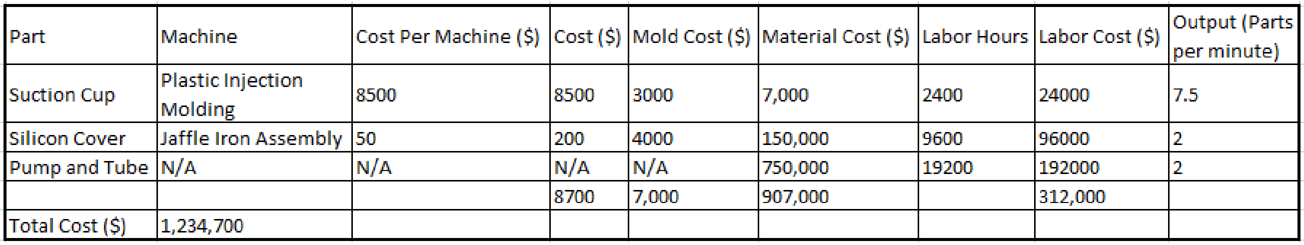
To begin manufacturing our breast pump design on a large scale, certain assumptions will need to be made about our market size. In 2010, the United Nations reported that 36% of the African workforce is comprised of women [37] out of a total of 382 million workers [38]. Out of these workers, 17% of the women are unemployed leaving us with a total of 114 million women in the African workforce at any given time. Africa as a whole has approximately 30 births per 1000 people and approximately 30% of mothers breastfeed [39] leaving us with a market size of 1.02 million mothers per year. Thus we will target one million breast pumps per year. For the purposes of this report we will assume eight hour shifts three hundred days per year.

As seen from Figure 16, our design consists of four producible parts-- the pump, tube, silicon cover, and suction cup. The silicon seal will be manufactured from raw material. Raw silicon costs $7.00 per kilogram [40] and a cast iron mold costs approximately $1,000 [41]. We will need four molds and 1000 kilograms of material. The silicon is then put into a jaffle iron type assembly to be quickly heated and compressed into the cast iron mold shape. A custom jaffle iron costs approximately $50 per unit [42] and has a throughput rate of 30 seconds per unit [43]. We will need four of these units to produce 1,150,200 units per year.

The pump, tube, and duckbill valve will be purchased from local suppliers and connected via loctite and other methods. Eight workers will be needed to achieve an output of 1,150,200 units per year at a rate of 30 seconds per unit [44]. The pump will cost $0.50 per unit [45], the vinyl tube will cost $0.25 per unit [46], and the duckbill valve will cost $0.05 per unit [47].

Additionally, we will use plastic injection molding to produce the suction cup. A mold for plastic injection molding costs anywhere from $1,500 to $8,000 [47] and polycarbonate material costs $1.50 per kilogram [48]. A suction weighs approximately 0.1 kilograms and since our part is simpler, we assume our mold cost to be $3,000. A part can be conservatively estimated to be made every eight seconds [47]. Based on these assumptions we can make 1.08 million suction cups per year. Table 8 below identifies our costs and throughput rates for mass manufacturing. Labor costs are assumed to be $10.00 per hour.

Table 8: Mass manufacturing cost and throughput rates for one year of production.



Part	Machine	Cost Per Machine ($)	Cost ($)	Mold Cost ($)	Material Cost ($)	Labor Hours	Labor Cost ($)	Output (Parts per minute)
Suction Cup	Plastic Injection Molding	8500	8500	3000	7,000	2400	24000	7.5
Silicon Cover	Jaffle Iron Assembly	50	200	4000	150,000	9600	96000	2
Pump and Tube	N/A	N/A	N/A	N/A	750,000	19200	192000	2
			8700	7,000	907,000		312,000	
Total Cost ($)	1,234,700							

Based on the table above, we will produce breast pumps at $1.23 per unit. However, this number does not take into account energy, rent, shipping, training costs, and other costs. These numbers will be calculated once we identify if manufacturing will take place overseas or in the USA.

10. Discussion

10.1 Design Critique

Overall the project was very successful. Out of the sixteen design specifications, thirteen were able to be tested and validated. The three specifications that weren't tested were because we were unable to due to lack of a human subject and material constraints.

From our validation testing we found that that the pump had an efficiency on par or better than pumps on the market. Additionally, we calculated that it will cost approximately $1.23 to produce each pump—well below our target price of $5. Also, the team was able to incorporate local resources in the making of the design. The pump is able to attach to any bottle. Since mothers may want to use their own bottles, the design is able to both satisfy the needs of mothers as well as recycle empty bottles.

One drawback of the design is the fatigue factor involved. Even though the team was able to validate pump frequency, after fifteen minutes fatigue was reported by all who tried the pump.

10.2 Future Work

There are three main points to address in the future. The first is the addition of human testing to acquire breast milk flow rate data and compare our products. Also, it is also very important to get user feedback and lifetime validation. Without an actual user, the team was unable to validate the lifetime durability of the product.

The second problem to address is to decrease operation fatigue. Operation fatigue is one of the biggest deterrents to a good manual breast pump and one of the issues the team wasn't able to fully address. Additional pumping mechanisms should be explored.

Finally, future teams should do more research into milk preservation. Milk preservation is a very important part in providing fresh breast milk to infants. There are many great resources and companies working on this aspect such as PATH.

Appendix A. Concept Drawings Generated

During the brainstorm in Design Review 2, 29 concepts were generated with different emphases. They are numbered from 1 to 29 and scored by each of our teammates.

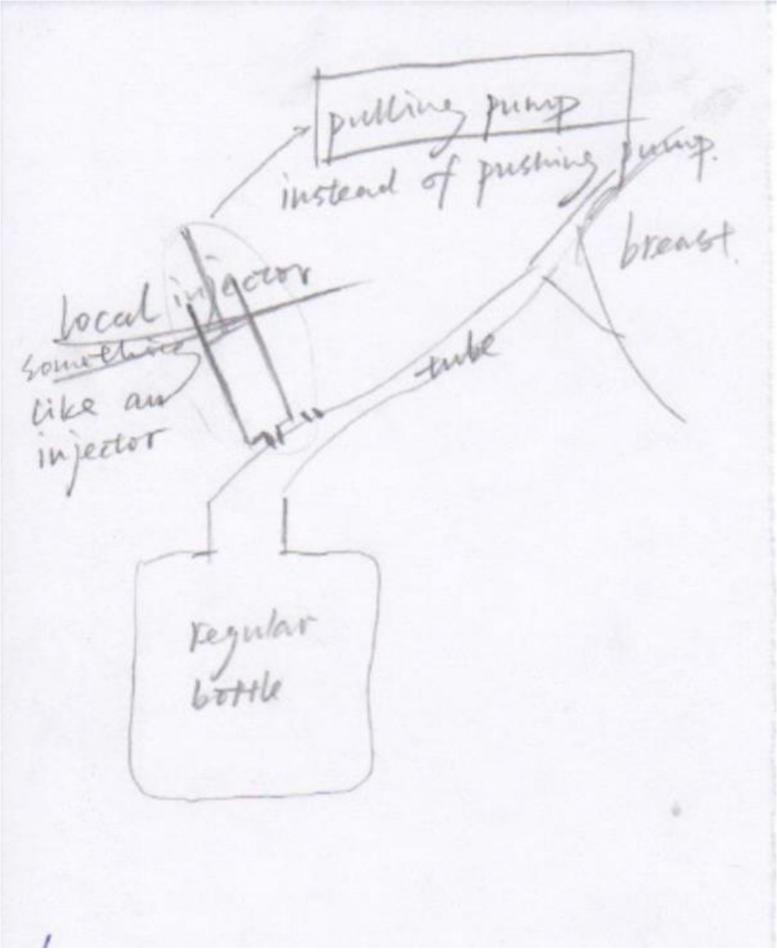


Figure A-1. Pulling pump inspired by injector (Qi)

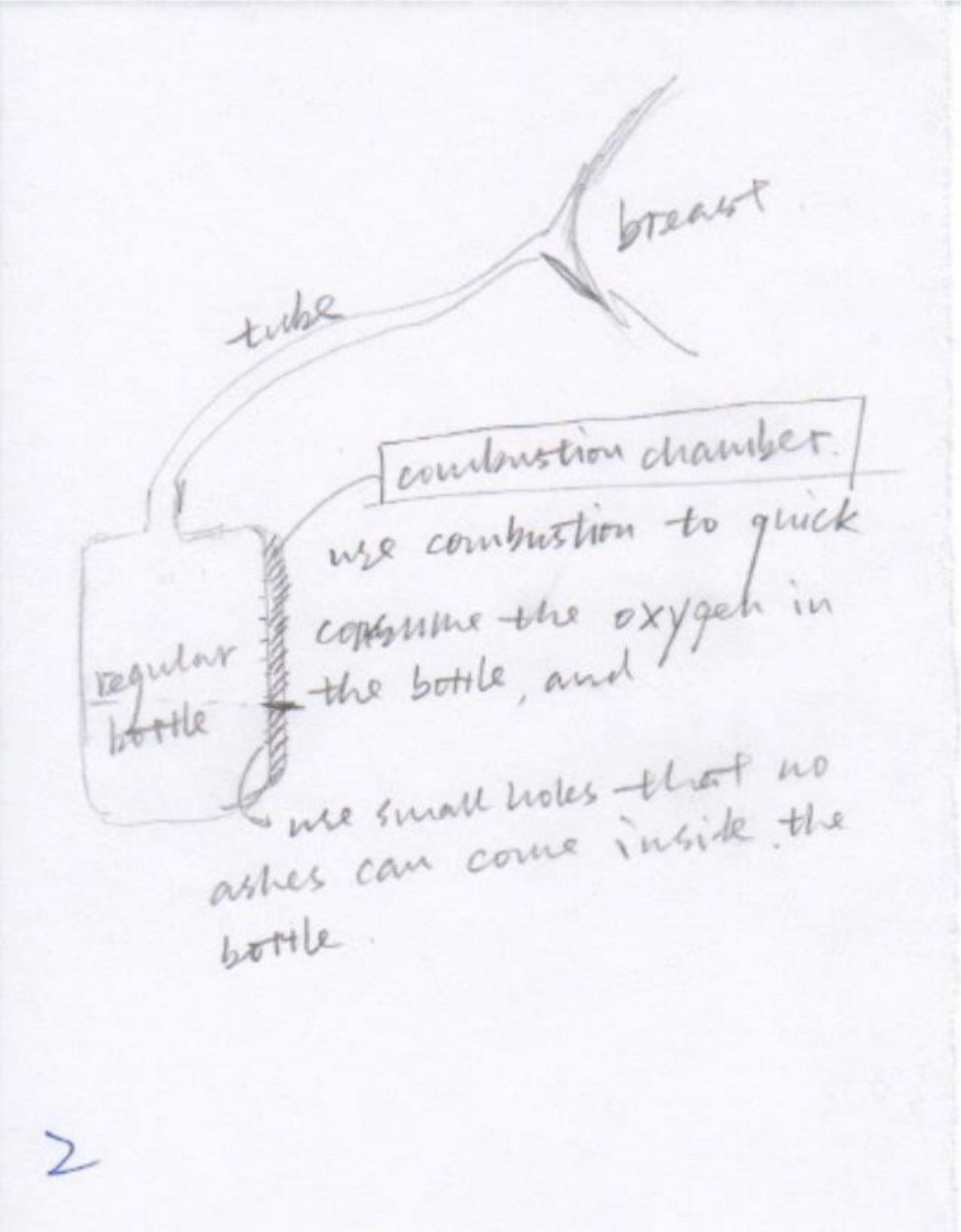


Figure A-2. Suction pump using combustion chamber (Qi)

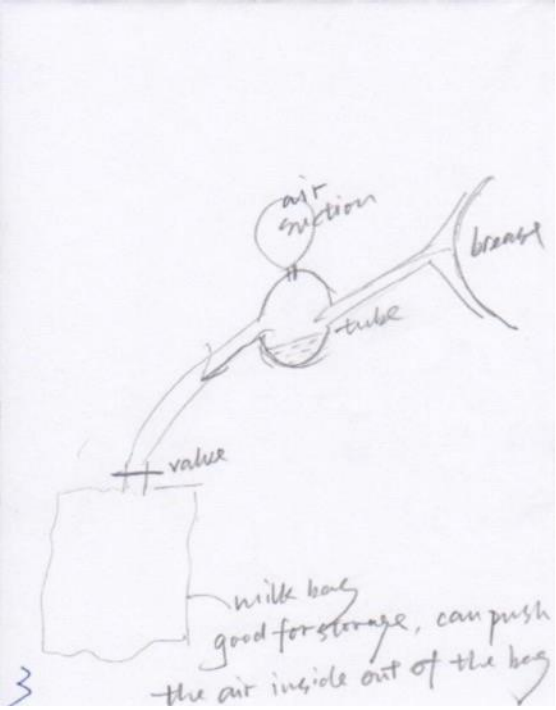


Figure A-3. Squeeze pump with milk bag for storage (Qi)

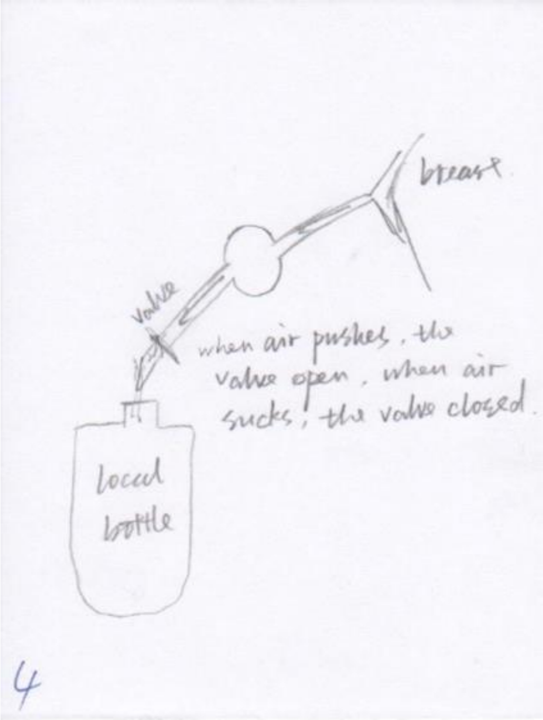


Figure A-4. Squeeze pump using local bottle (Qi)

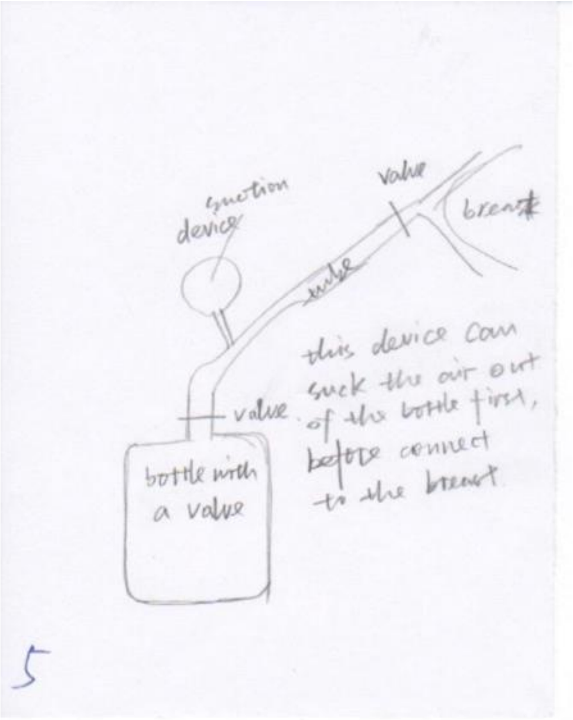


Figure A-5. Squeeze pump with valves (Qi)

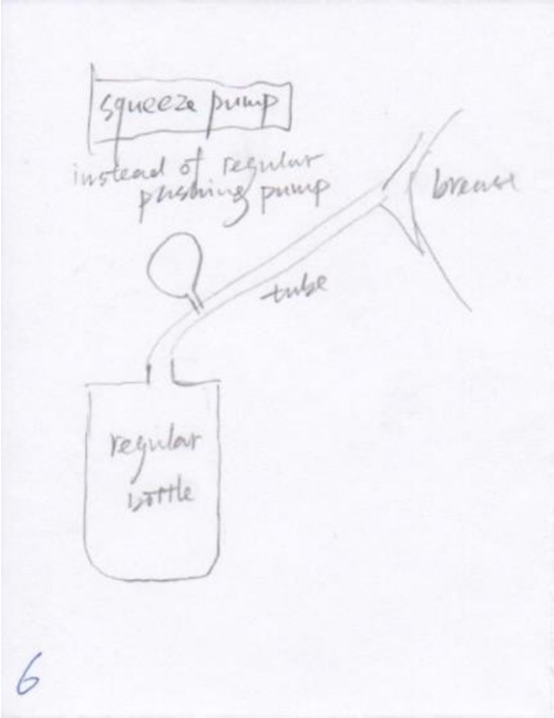


Figure A-6. Squeeze pump (Qi)

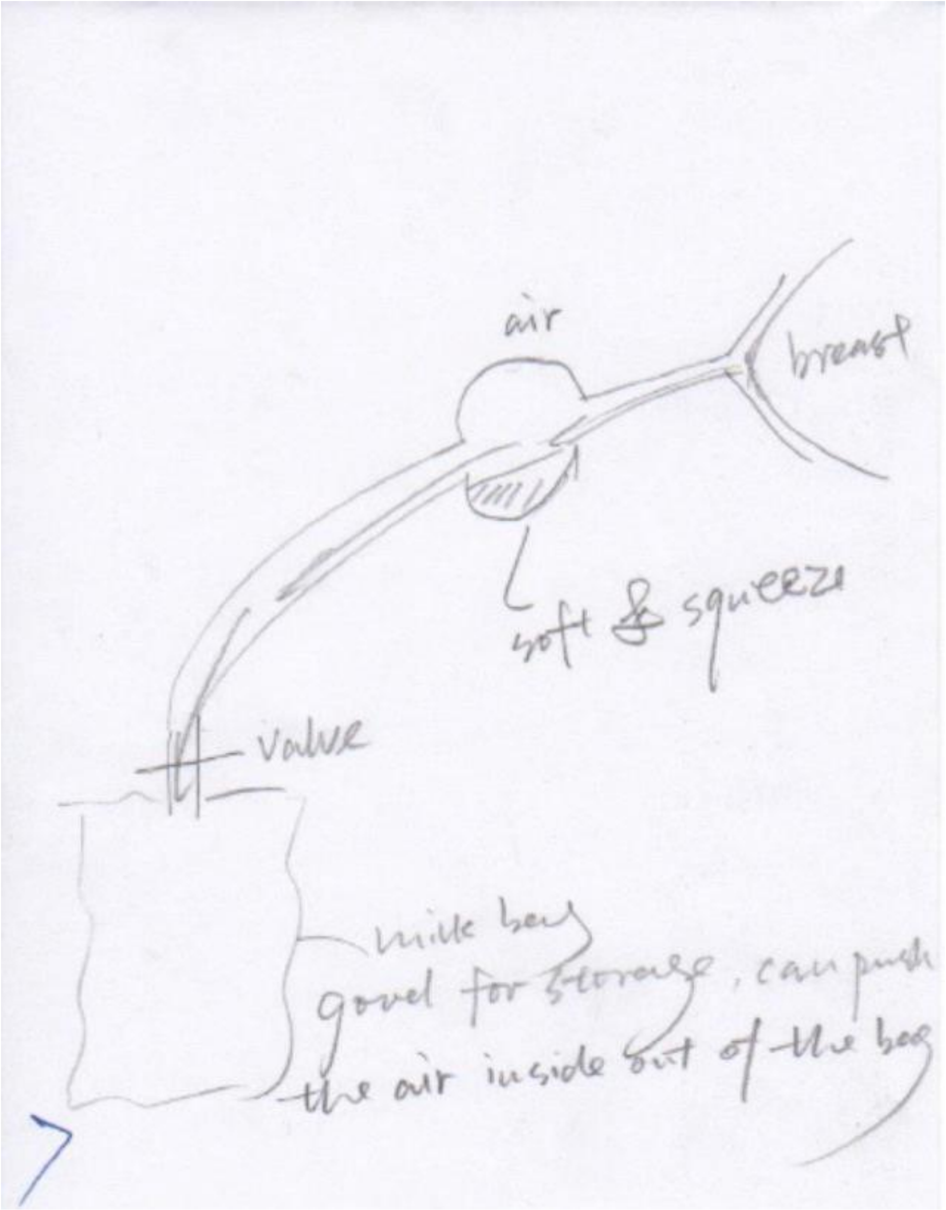


Figure A-7. Squeeze pump using milk bags for storage (Qi)

Figure A-8. Water bottle cap for standard attachment (Ray)

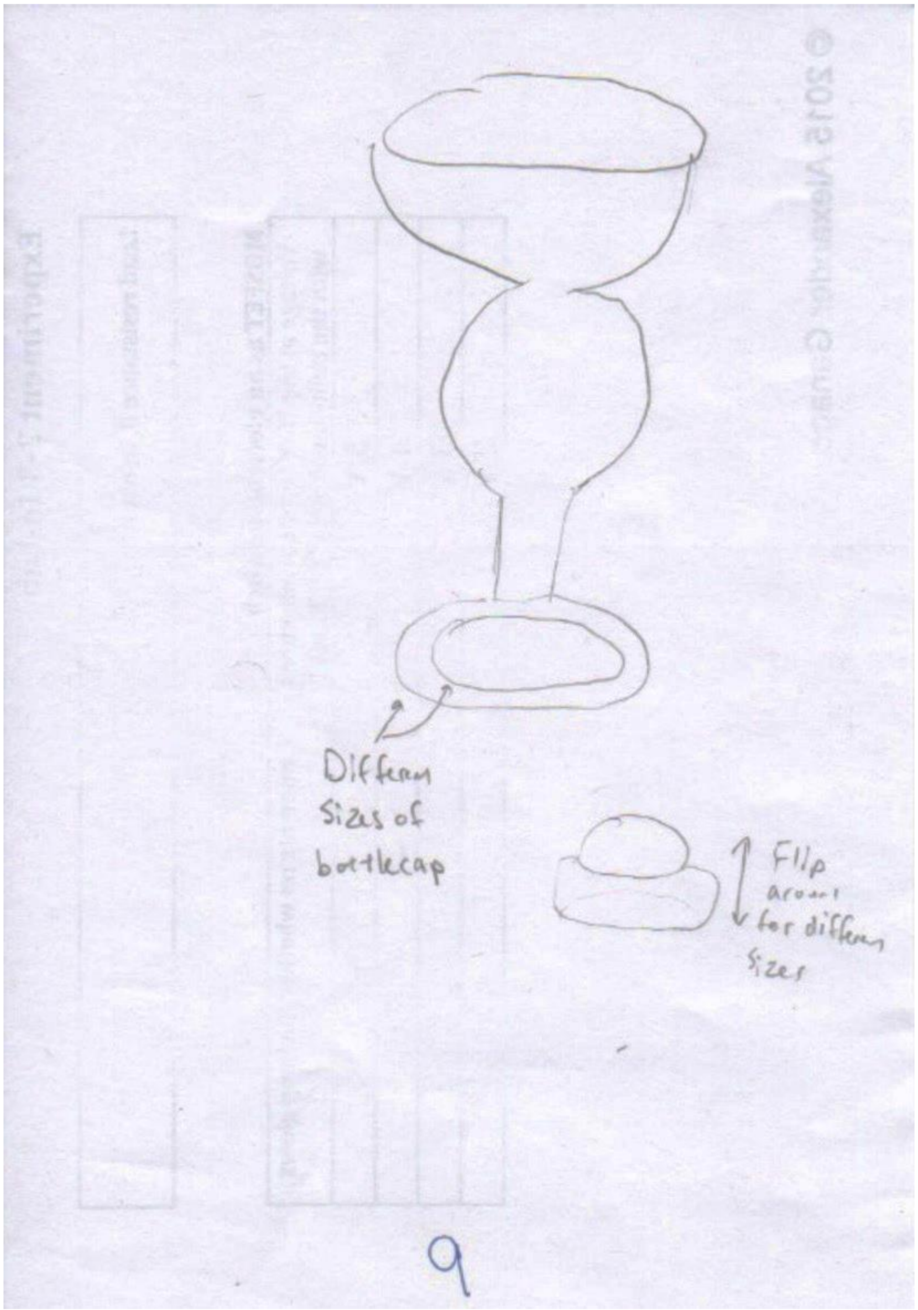


Figure A-9. Two-directional cap that attaches to two different size storage containers (Ray)

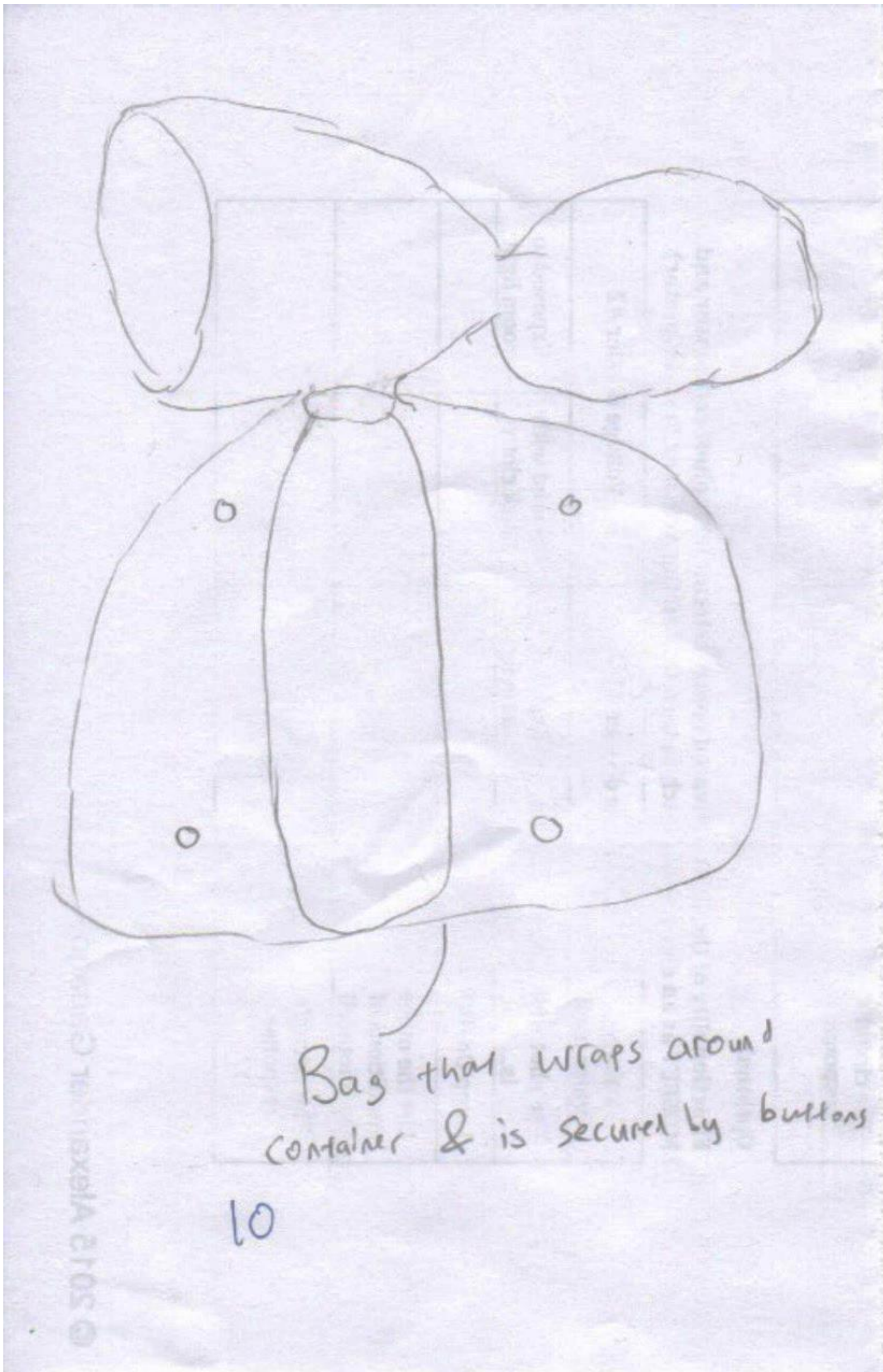


Figure A-10. Bag that wraps around storage container with squeezing mechanism (Ray)

Figure A-11. Bag that wraps around storage container with scissor mechanism (Ray)

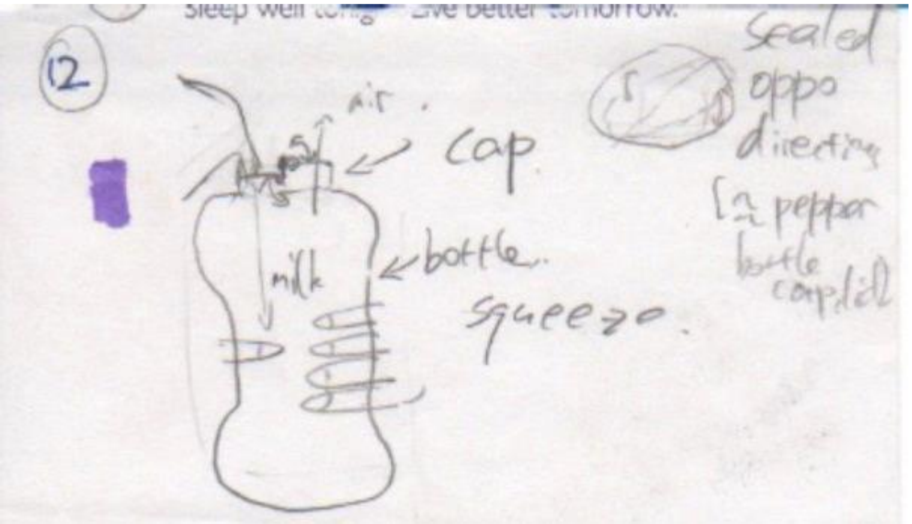


Figure A-12. Squeeze bottle for pumping and milk storage (Yiwen)

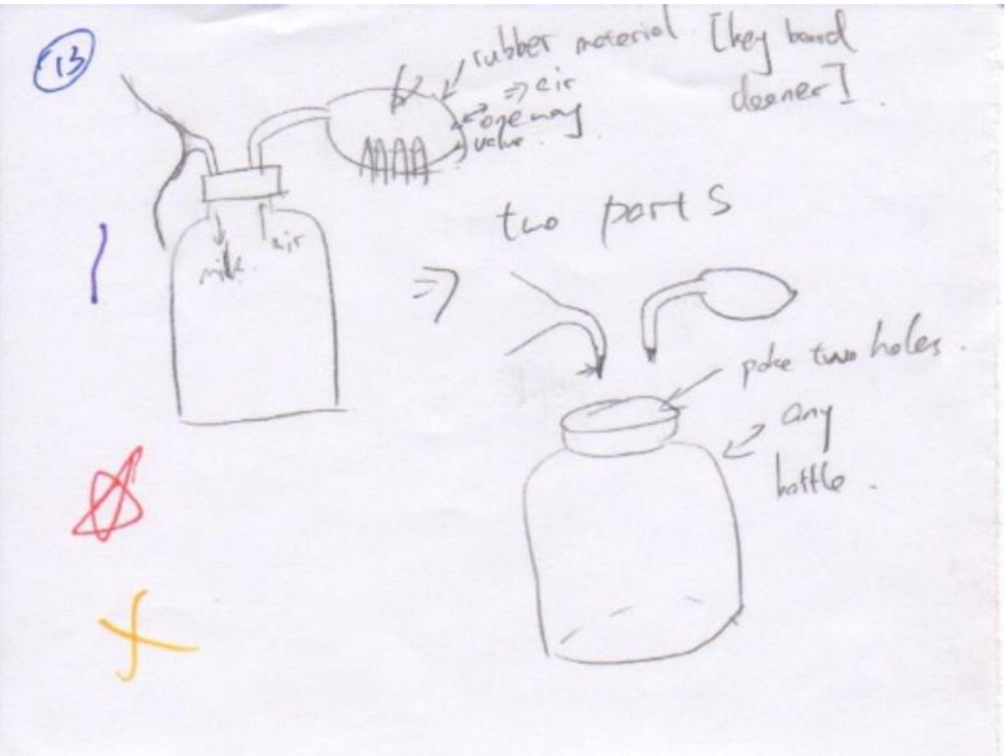


Figure A-13. Modular suction cup and squeeze pump for any bottles (Yiwen)

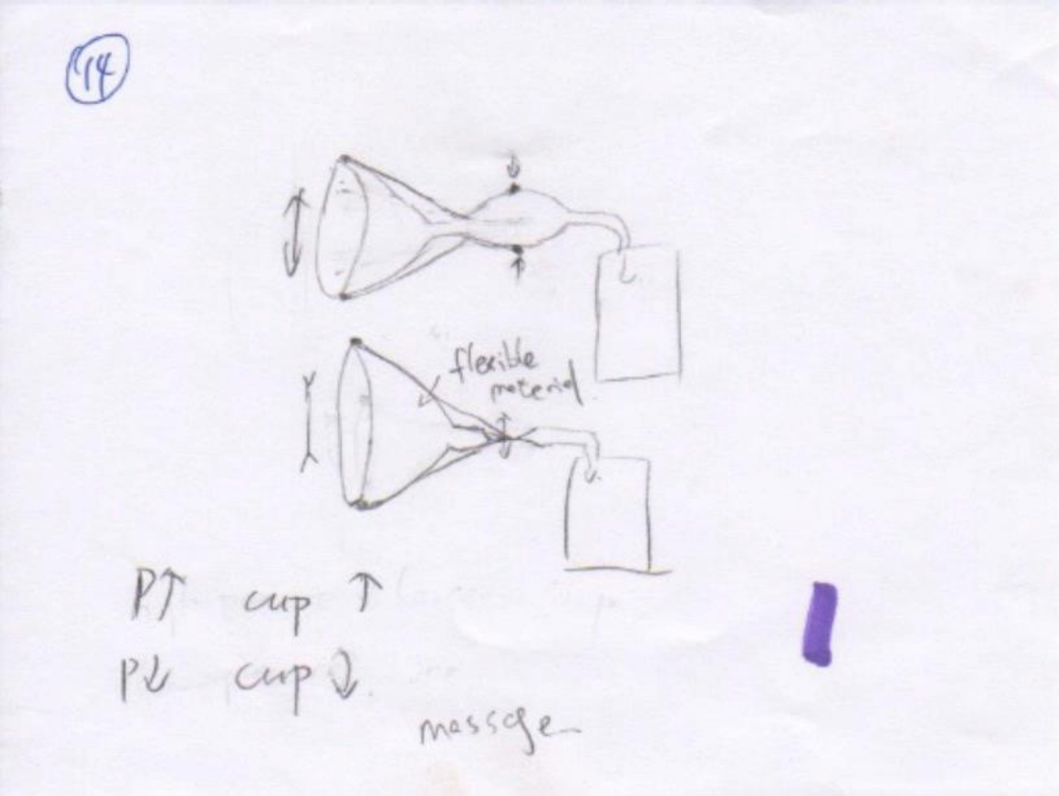


Figure A-14. Massage and suction for milk expression (Yiwen)

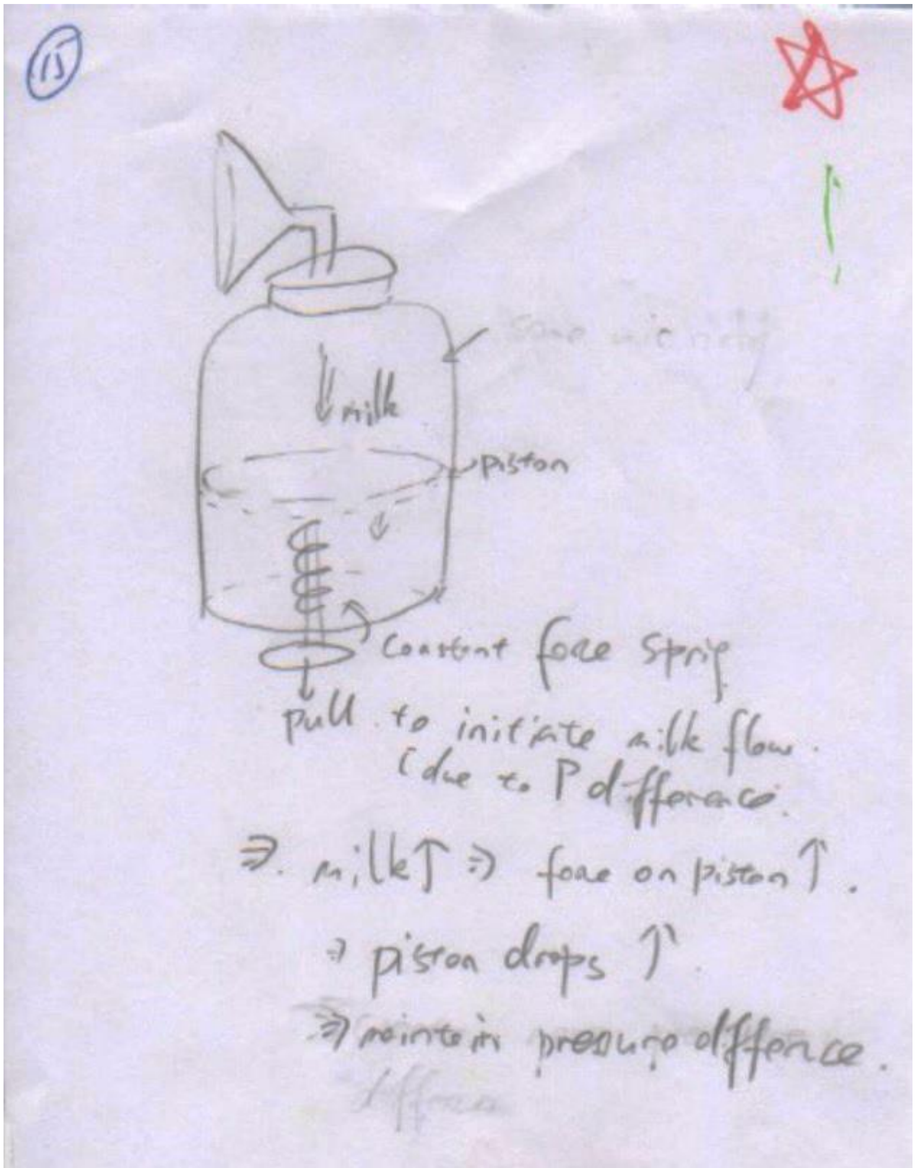


Figure A-15. Spring-loaded syringe bottle (Yiwen)

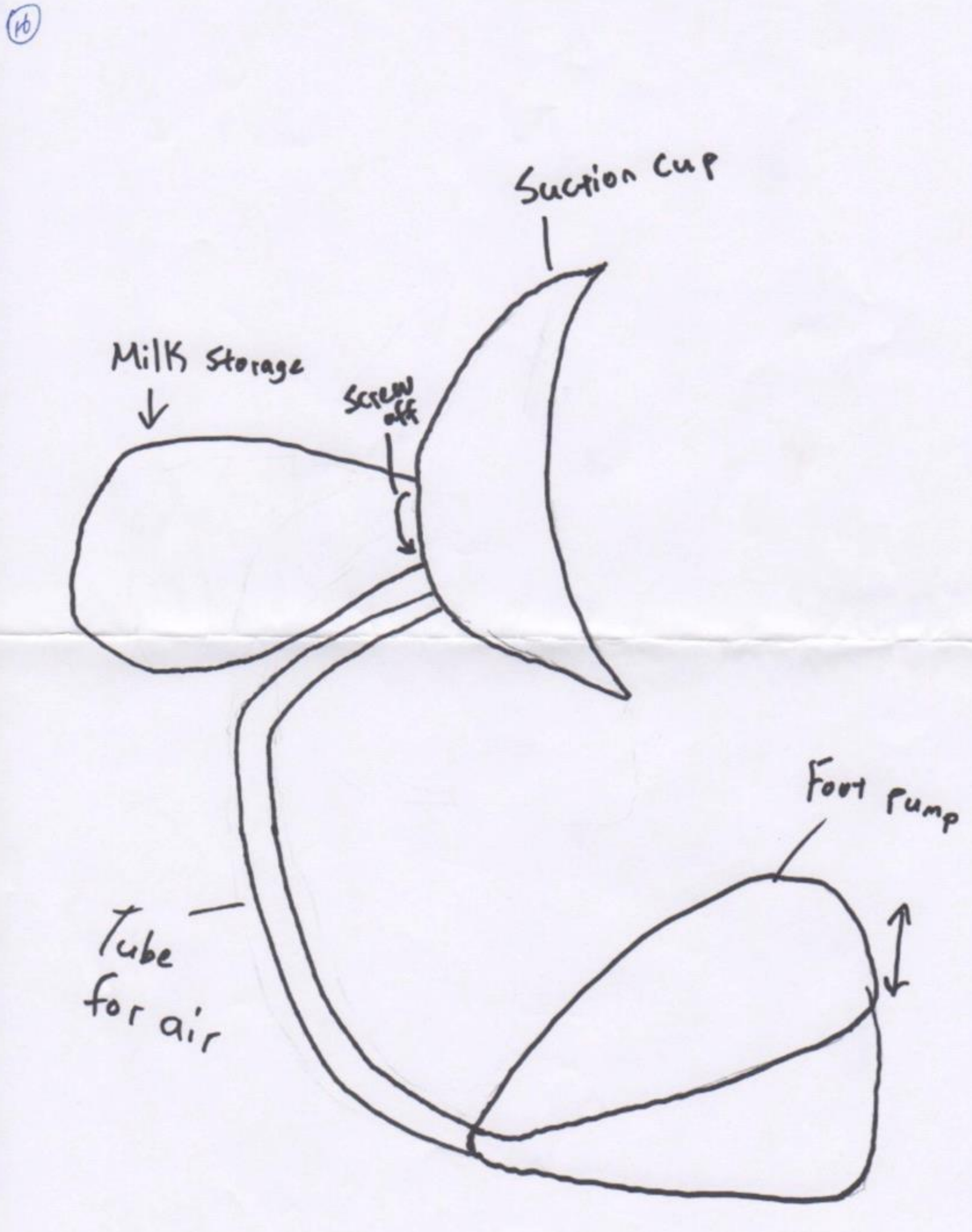


Figure A-16. Foot pump with suction and storage attached (Ray)

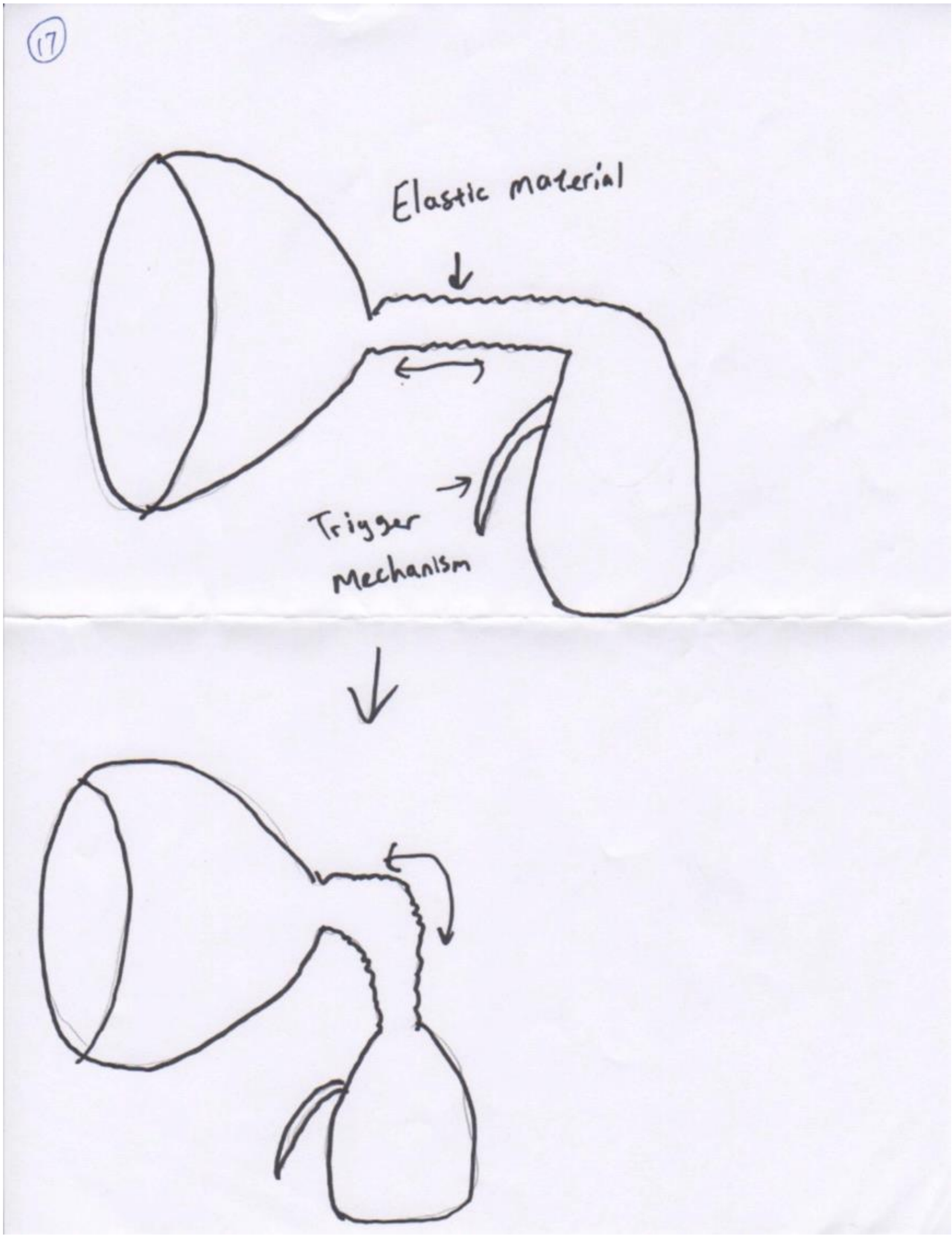


Figure A-17. Straw mechanism to adjust pump orientation (Ray)

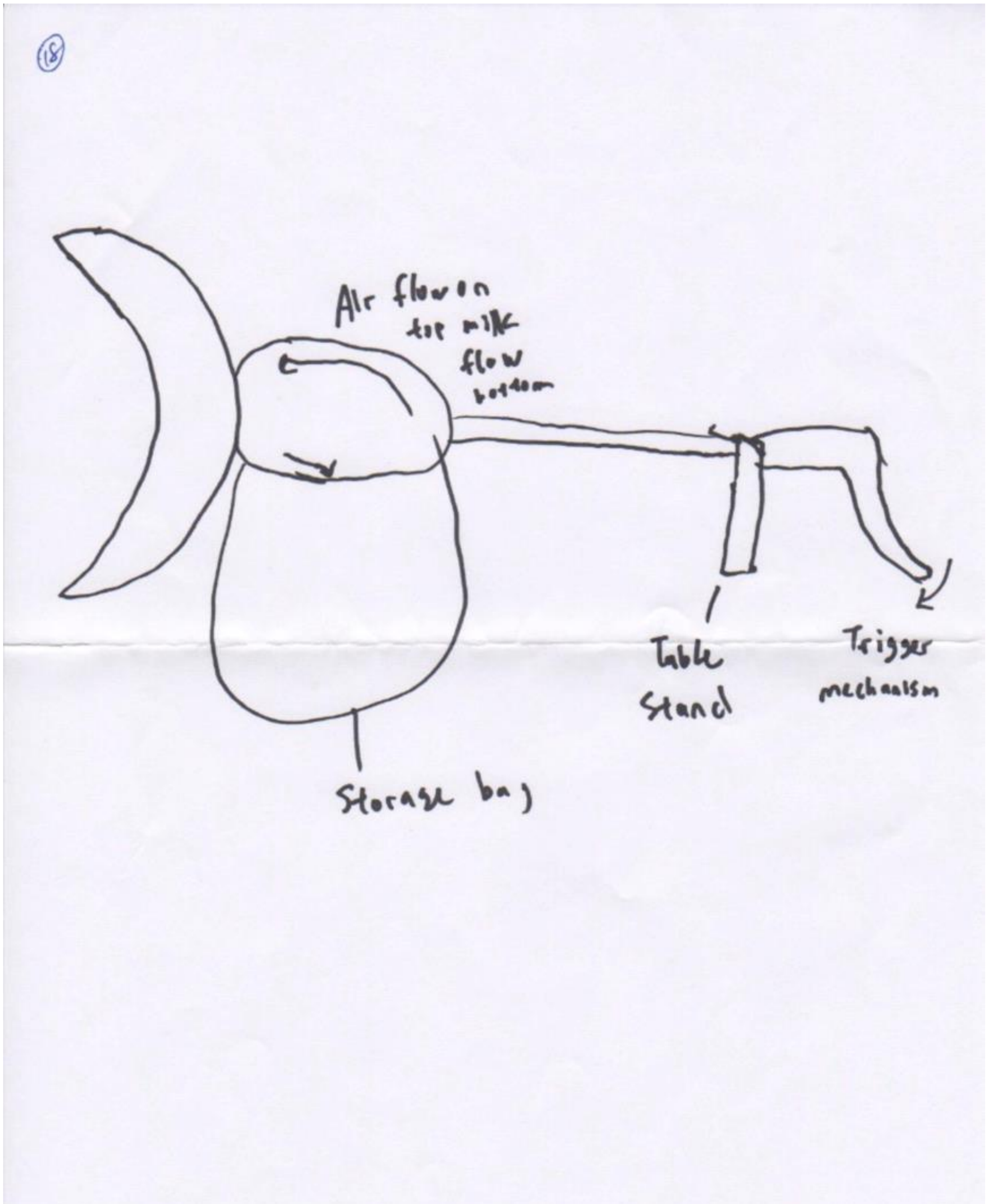


Figure A-18. Design for optimized use on a table (Ray)

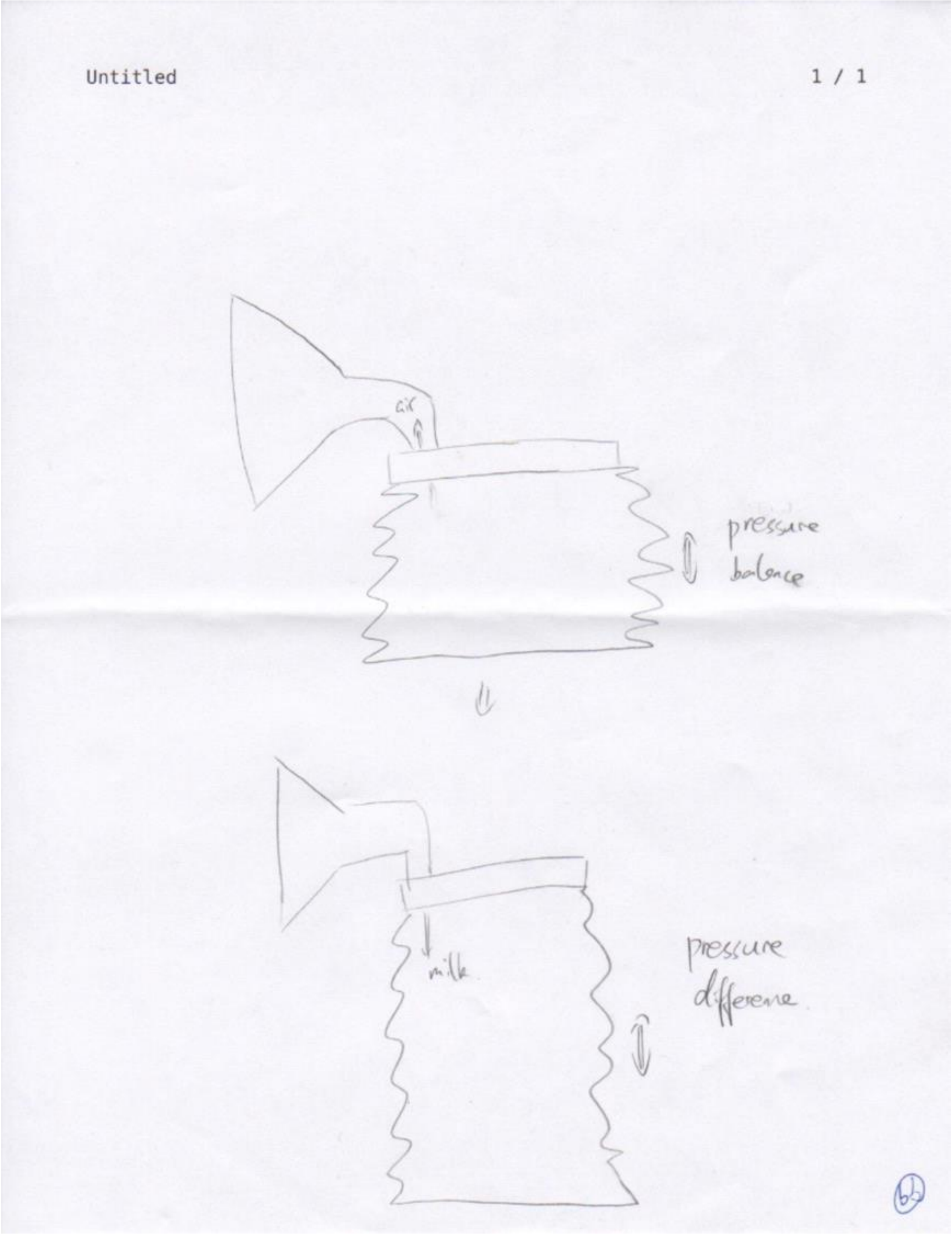


Figure A-19. Collapsible bottle for pumping and milk storage (Yiwen)

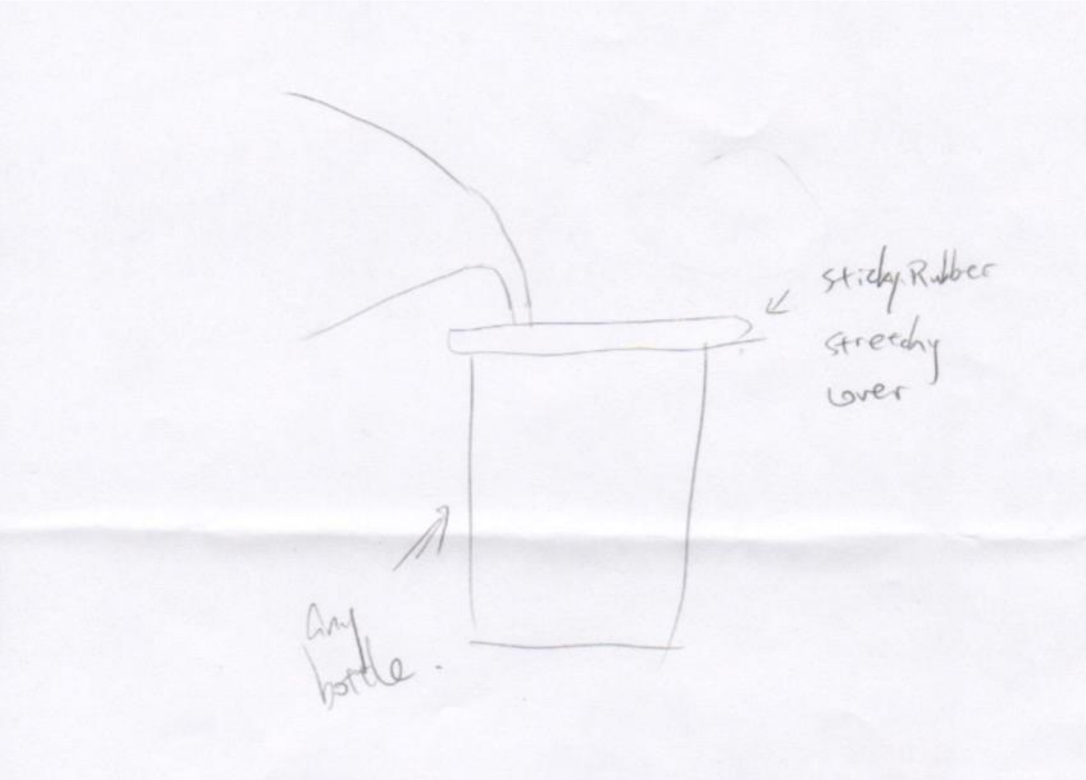


Figure A-20. Stretchable sticky rubber cover for any bottles (Yiwen)

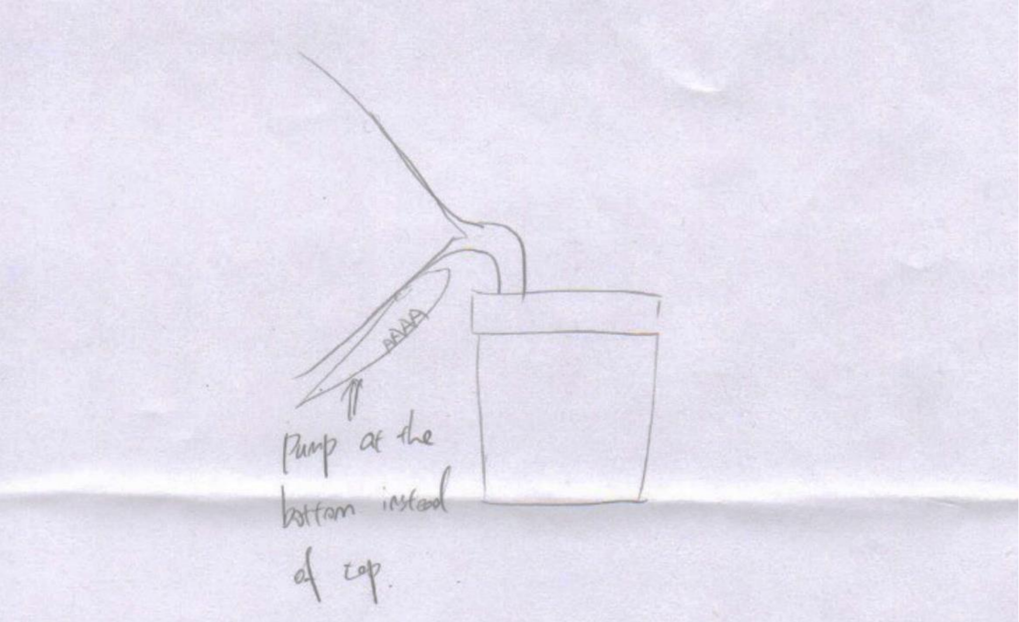


Figure A-21. Inverse pump (Yiwen)

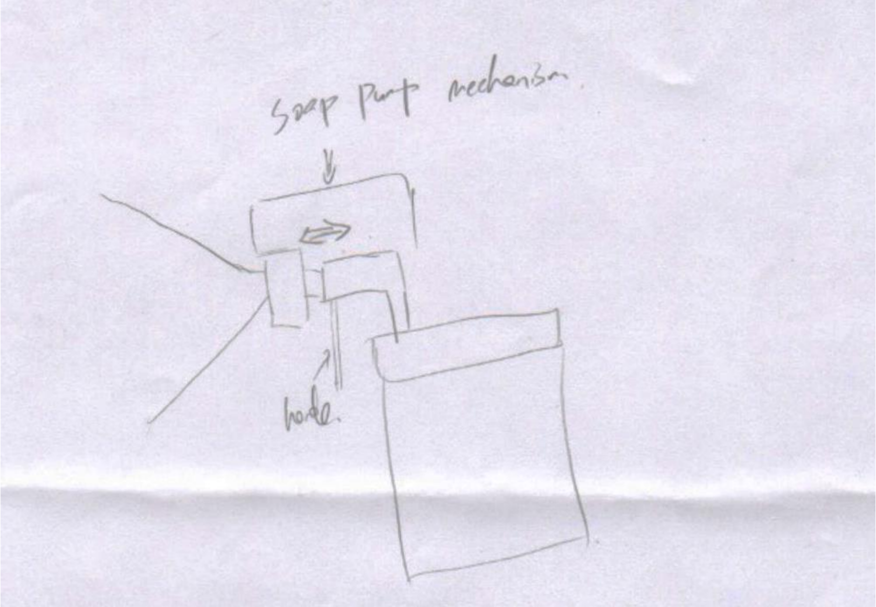


Figure A-22. Soap pump mechanism (Yiwen)

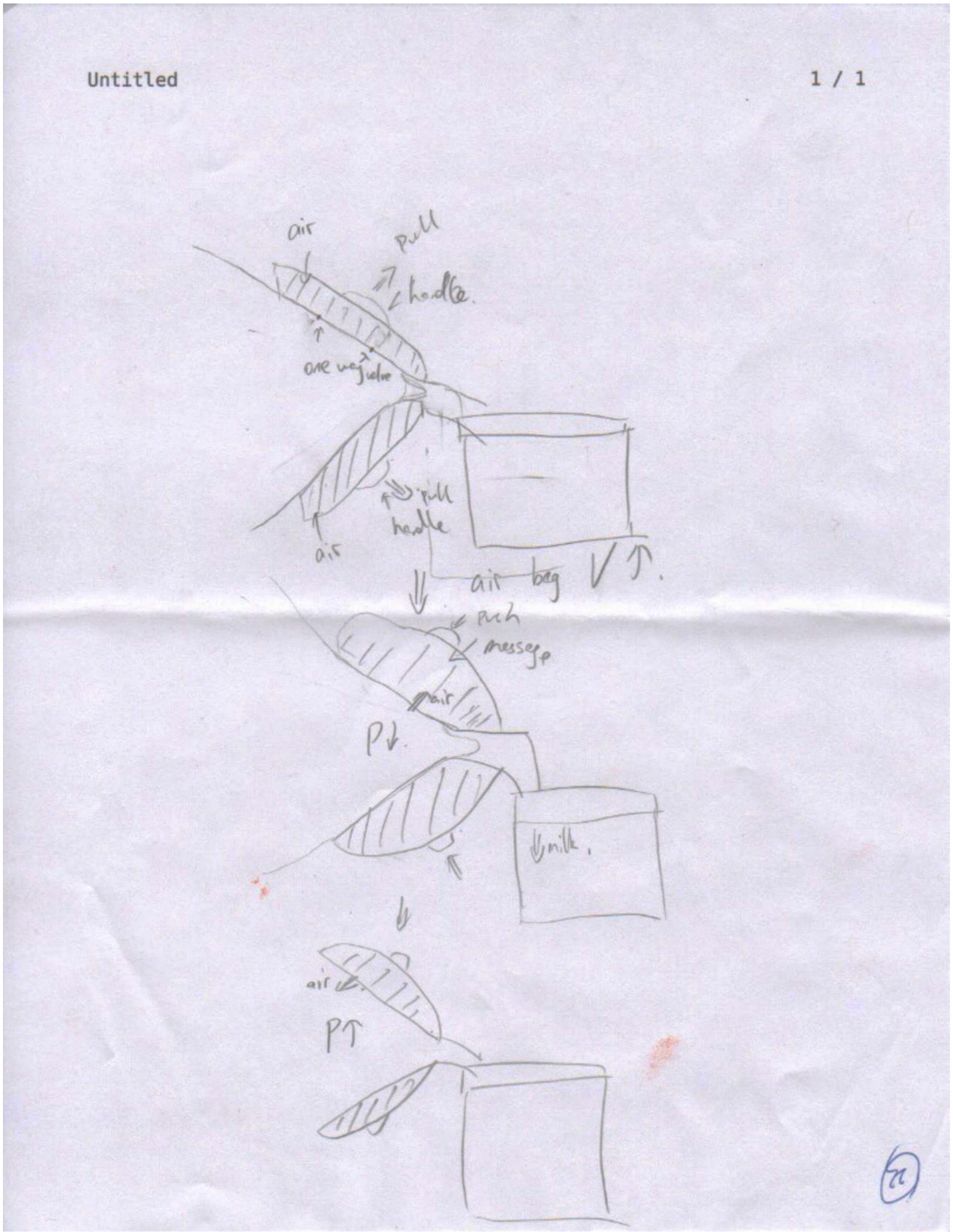


Figure A-23. Flexible suction cup with airbag attached for suction and massage (Yiwen)

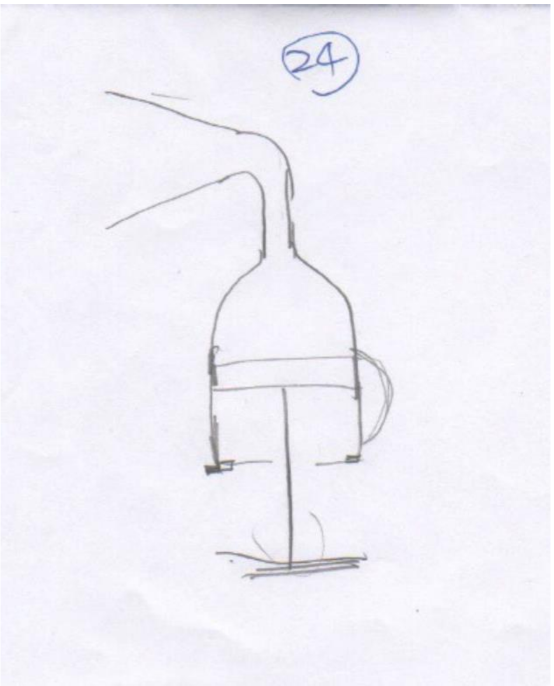


Figure A-24. Piston storage bottle (Anqi)

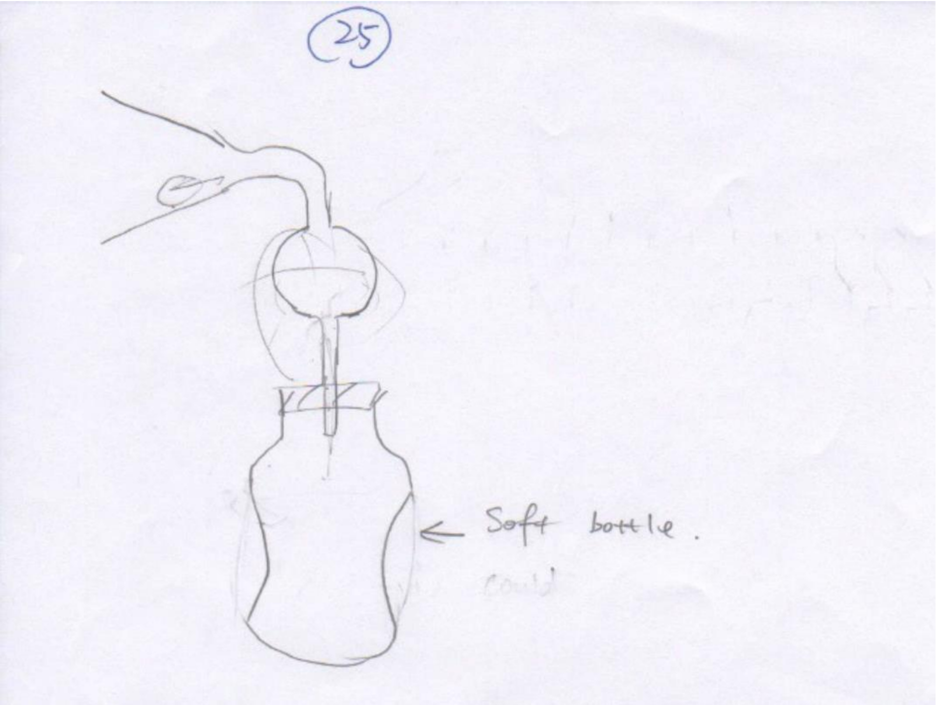


Figure A-25. Soft bottle with temp storage in tube (Anqi)

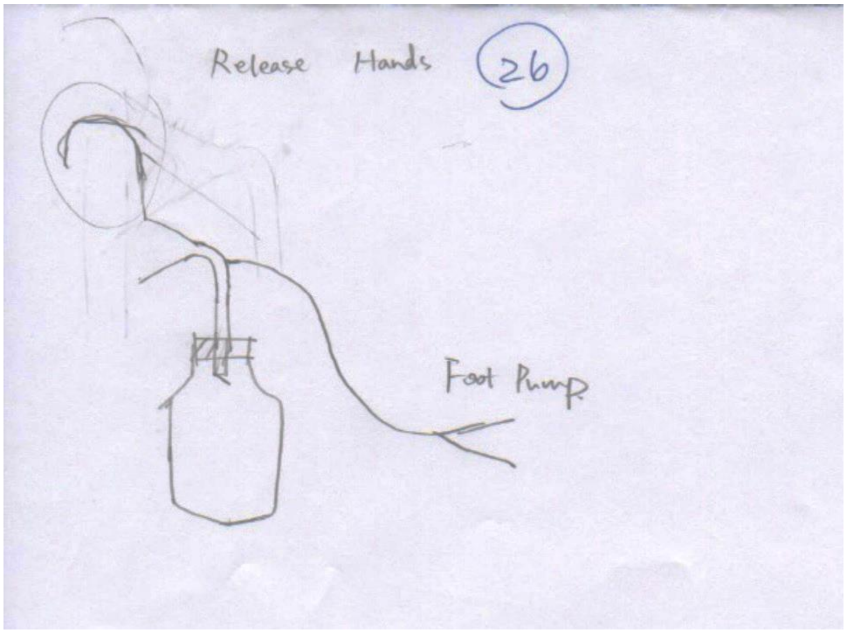


Figure A-26 Foot pump with belts to hang on the shoulder (Anqi)

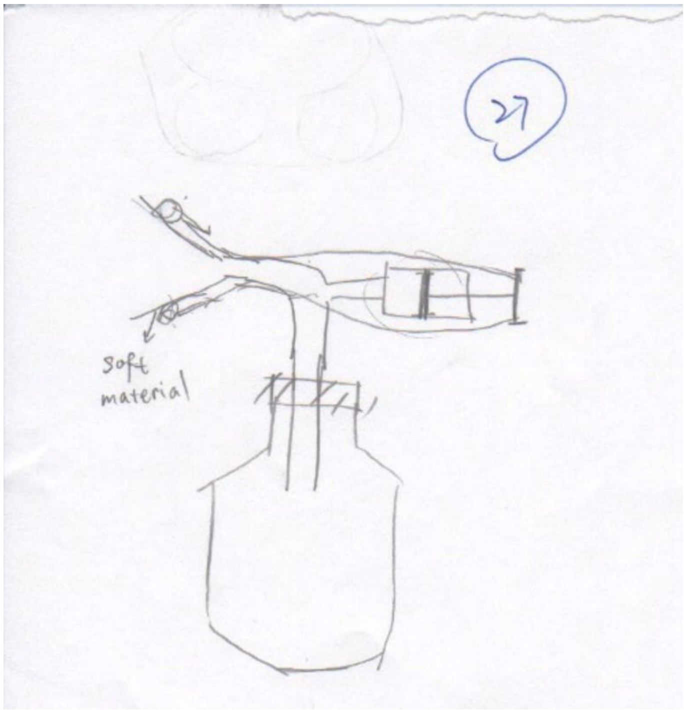


Figure A-27. Hand pump inspired by injectors (Anqi)

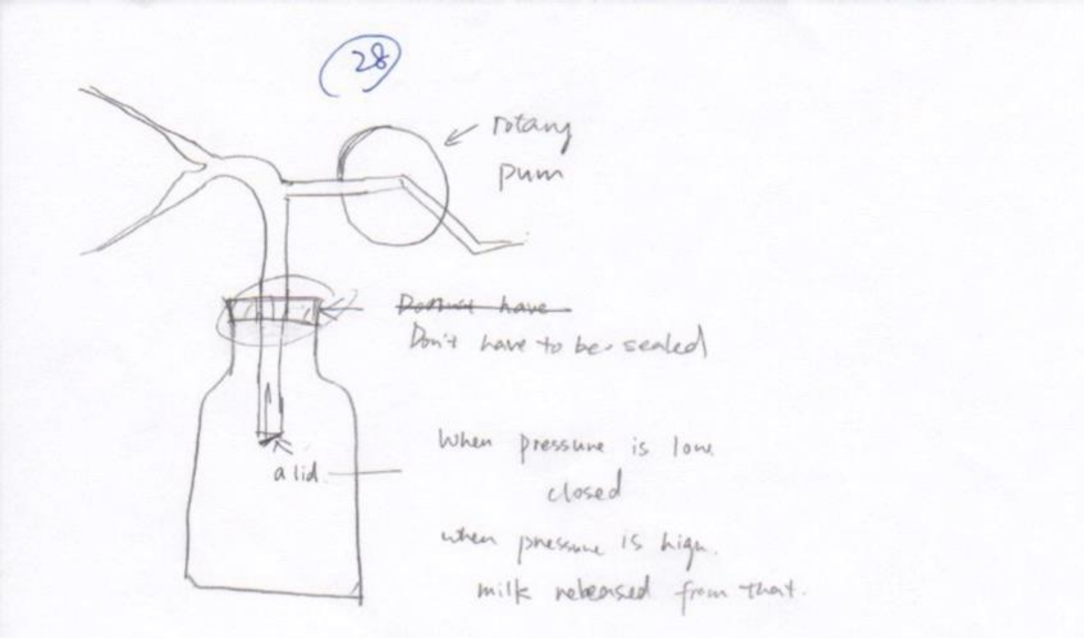


Figure A-28. Rotary pump (Anqi)

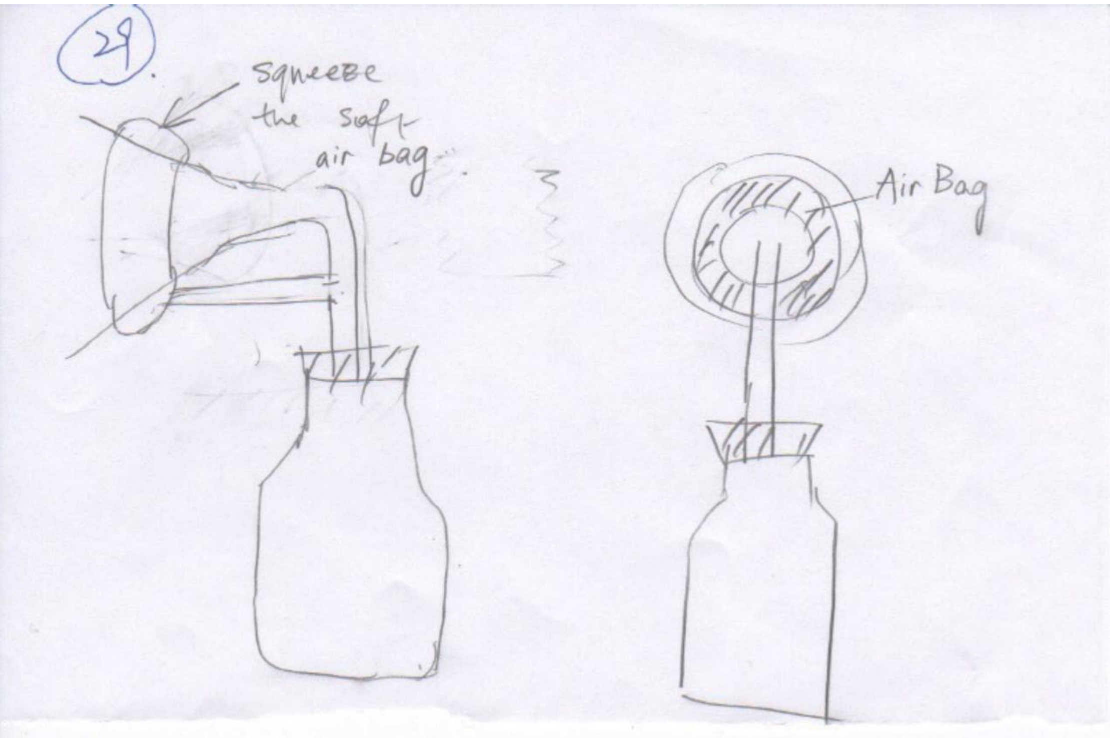


Figure A-29. Squeeze pump inspired by natural milking procedure (Anqi)

Appendix B. Validation Protocol Expectations

Since the team has 17 engineering specifications, the ones with the highest priorities were picked up for the validation testing. There are totally 7 validation tests corresponding to the engineering specifications and the team has already done some of them: 1) the efficiency validation, 2) the “easy to use” validation, 3) the “easy to clean” validation, 4) the portability validation, 5) durability validation, 6) the bottle compatibility validation

Appendix B.1. Efficiency Validation

The efficiency validation includes two tests, the pressure difference test, as well as the pumping frequency test. From the literature [35][36], the pressure difference (suction) below 100 mmHg is considered inefficient. And the pressure difference above high 200’s mmHg often causes pain. So our testing value is good between 100 mmHg and 250 mmHg. The other test is the pumping frequency test. An infant usually sucks breast 60 times per minute, and the maximum for the breast pump is 54 times per minute. We are aiming at the results higher than the current manual pump.

1. Pressure difference: 100 – 250 mmHg
2. Pumping frequency > 54 times per minute

Appendix B.1.1. Pressure Difference Test

The inner pressure difference of the breast pump when sucking the breast can be measured using the fake breast and the vacuum gauge that the team purchased. The experimental setup is shown in the Figure B-1 below:

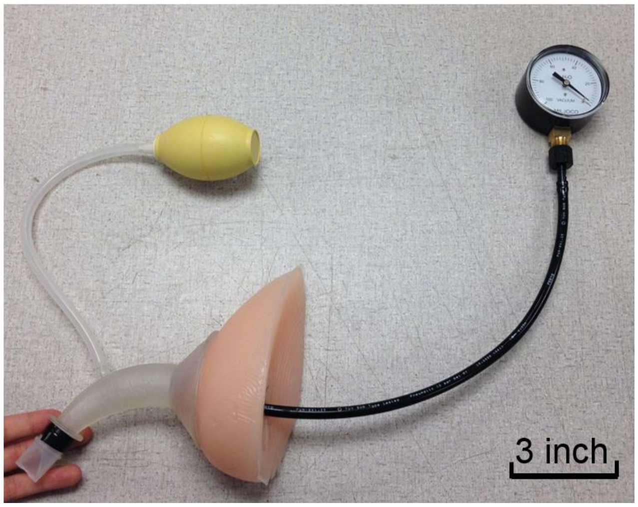


Figure B-1. The experimental setup for the pressure difference test

Testing involves the following steps:

1. Drill a hole through the back of the fake breast to the nipple.
2. Put the vacuum gauge through the hole.
3. Perfectly seal the hole with the tape.
4. Attach the prototype onto the fake breast
5. Operate the breast pump several times and read the maximum pressure difference shown on the gauge.
6. Record the readings and repeat 3 times.
7. Repeat steps 1-6 for the Medela manual pump, obtain the result for comparison

After the data was obtained, the team will average the pressure difference for multiple measurements. Then the team will compare the prototype with the Medela manual pump, as well as the literature value mentioned above.

Validation Results:
The maximum inner pressure difference generated by the pump is 178 ± 6 mmHg, which is within the pressure range in specifications and is higher than the Medela Harmony Manual breast pump.

Appendix B.1.2. Pumping Frequency Test

The pumping frequency will be tested in continuous 15 minutes for one person. The team will invite different kinds of people for testing to minimize the human factor bias.

1. Operate the prototype naturally for 1 minute, and count the number of complete pumping times.
2. Record the data as [number] times per minute
3. Repeat steps 1-2 immediately for a total of 15 minutes
4. Repeat steps 1-3 for at least 5 people

After obtained the data, we will use the average times per minute for 15 minutes of one person. Then we will average the results for different people to obtain the pumping frequency for our own prototype.

Validation Results:
The testing result shows that for all the experiment participants, the pumping frequency trended to be stable around a certain value in the last five minutes. The average stable pumping frequency is 72 ± 4 times per minute, which meets the specification of 54 cycles/minute.

Appendix B.2. "Easy to Use” Validation:

To quantify our "easy to use" requirement, we timed the assembly and disassembly time of our design and compared the times with the Medela Harmony manual pump. The purpose of these tests is to prove that there are no more than three steps to assemble the pump and that it may be assembled in 30 seconds or less. We will need a stopwatch, our breast pump, the Medela breast pump, and a sample bottle for this test. This test will be conducted with many different individuals ranging from mothers to classmates to faculty and staff. The range in test subjects is to ensure that we have users from a broad range of experience.

Validation Results:
Among the eight participants, the average assembly time is 27.8 ± 6.1 seconds.

Figure B-2. The experimental setup for the assembly time test

Appendix B.3. "Easy to Clean” Validation:

The “easy to use” validation includes two tests, the disassembly test as well as the water consumption test.

Appendix B.3.1. Disassembly Time Test

To quantify our "easy to clean" requirement, we will time the disassembly time of our design. This is because the user will need to disassemble the pump in order to clean the individual parts. We will need a stopwatch, our breast pump, a sample bottle, and the Medela breast pump for this test. Similar to the "easy to use" validation, we will need test subjects from a broad range of experience. It will be ideal to have the same subjects conduct both the "easy to use" and "easy to clean" validation tests.

Validation Results:
Among the eight participants, the average disassembly time is 10.3 ±3.1 seconds.

Appendix B.3.2. Water Consumption Test

Next, to quantify the water required to clean the pump, we will measure the volume of water needed to completely submerge the breast pump. This is done because the breast pump will be cleaned with boiling water and the volume of water needed to submerge the breast pump is the minimum viable amount to fully clean the pump.

Validation Result:
The experiment result shows that a minimum of 1.8 L water is needed to submerge the prototype. The total water consumption of 600 uses is 0.65 m^3, which meets the requirement of less than 1 m^3 per 600 uses.

Appendix B.4. Portability Validation

The portability validation includes two tests, the weight, as well as the volume test. As discussed in previous section, the product is designed for working mothers who need to bring the pump to work place. Two variables are selected to evaluate the portability. Based on the engineering specifications on portability, the volume of the design is supposed to be smaller than 3500 cm^3, and the weight of the design is supposed to be less than 300g. These two properties will be validated with the following methods.

Appendix B.4.1. Volume

Since the main part of the prototype is 3D printed based on our CAD model, the volume of the prototype should strictly follow the dimension in SolidWorks. Therefore, the volume of the prototype will be measured in SolidWorks.

1. Fold the tubes and replace the pump beside the suction cup.
2. Measure the diameter of the suction cup, which is the maximum thickness of the product, recorded as H.
3. Measure the maximum width and length of the design, recorded as W and L.

The volume of the product is

$$V = W \times L \times H$$

Validation Result:

The volume of the product is 951 $cm^{3.}$

Appendix B.4.2. Weight

The weight of the prototype can be measured with the scale in Assembly room with a resolution of 1 gram.

1. Put the suction cup on the scale, recorded as W1.
2. Put duckbill valve, stretchable cover and the squeeze pump on the scale, recorded as W2.
3. Measure the weight and repeat 3 times.
4. Repeat step 1 and 2 for fully assembled Medela Manual Pump as a reference.

Since the material of the prototype is not the exact material in mass production. The reading value of the suction cup will be converted based on the density of the ABS plastic and the PVC plastic. The density of ABS plastic is 1.04g/cm^3 while the density PVC is 1.42 g/cm^3 [49][50]. Therefore, an estimation of the total weight of the product is:

$$\mathrm{W} = \mathrm{W}_2 + \frac{1.42}{1.04} W_1 = W_2 + 1.37W1$$

Result:

The calculated weight of the breast pump is 116.9g.

Appendix B.5. Durability Validation

The durability was validated by dropping the prototype from a height over 1 meter. A meter scale was set beside the table as a reference. The experimental setup is shown in Figure B-3.

1. Setup a meter scale by the table.
2. Lift the prototype above the 1-meter height.
3. Drop the prototype and check the functionality.
4. Repeat Step 1 to 3 for three times

Figure B-3. Experimental setup for dropping test

Based on our experiment results, the breast pump remained functional after the dropping test, which indicated that the durability of dropping from 1 meter is validated.

Appendix B.6. Bottle Compatibility Validation

Since the storage container of the breast milk will be the local bottle, the team was interested in finding the sizes range for different bottles that could fit the design. The procedures of the validation testing are as follows:

1. The team stretched the silicon cover to fit different bottles using the prototype.

2. After attaching the silicon cover to the bottle, the team tested the quality of the seal with the balloon

For all five common bottles the team could find, the silicon cover could perfectly seal bottles from 1.1 inch to 3.5 inch, as shown in Figure B-4 below.

Figure B-4. Left figure is the smallest bottle cap size (regular water bottle) that the cover could fit, which is 1.1 inch; right figure is the largest bottle cap size (the coffee cap) the cover could fit, which is 3.5 inch.

To sum up, out of the sixteen design specifications, thirteen were able to be tested and validated. All validation results are shown in Table B-1. Since the human testing and long-term durability testing are outside the scope of the course, the team were not able to validate the lifetime of the breast pump. Besides, with the available resources, the sanitation level after boiling is not able to be tested. Also, because of the limitation of time in this semester and the advice from the sponsor, technology of preserving milk is not in the scope in this semester.

Table B-1: Engineering specifications and validation results

User Requirements	Engineering Specifications	Validation results
Easy to use	≤ 30 seconds to assemble	27.8 ±6.1 seconds
	≤ 2 steps to operate	2 steps
Low cost	Manufacturing cost ≤ 5 USD	Around 1.23 USD
Easy to clean	≤ 4 cleaning steps	4 cleaning steps
	≤ 1 m^3 of water usage per 600 uses [21]	0.65 m3 of water usage per 600 uses
	Sanitation in boiling water for 10 min	Not Tested
Mechanically powered	No electrical power source required	Validated
Efficient	Pressure Difference > 150mmHg [22]	Pressure difference is 178 ±
	Max allowed frequency > 54 cycles/minutes [23]	6 mmHg
	Support suction or/and massage [29]	Support suction function
"One size fits all"	Fits nipple sizes from 6 mm to 7.5 mm [24]	Validated
Durable	Life time is greater than 1000 uses	Not Tested
	Withstands drops from 1 meter	Validated
Locally sourced	Use at least 1 local material	Use local bottles
Portable	Volume ≤ 3500 cm^3 [25] [26] [27]	951 cm^3
	Weight ≤ 300 g [25] [26] [27]	116.9 g
Preserves milk	Keep the milk fresh for at least 6 hours under 100 ℉ [28][29]	Not Tested

Appendix C. Ethical Design Statements

Appendix C.1. Raymond Chen’s Statement

The Code of Ethics for Mechanical Engineers has been applied to our design process. Our project is designed to be used by low-income mothers so that they may breast feed their children. The breast pump opens up a whole new market for engineering development and saves the lives of many children along the way. The final proposed design was very centered around the experience of the user. Our four main design points were easy to use, easy to clean, efficient, and low-cost. The goal of this project is to make the breast pump as accessible as possible to mothers. Also, we have picked materials so that the breast pump is comfortable and sanitary for the mother.

Appendix C.2. Anqi Sun’s Statement

In this project, the team is supposed to design a breast pump for low resource settings. It is a product that directly touches the skin of breastfeeding moms and the breast milk, which is the food of infants. Code of Ethics is applied through our entire design process, especially in the concept selection stage.

In the concept generation stage, we came up with many fancy idea which may have higher efficiency than our current design, such as heating the bottle to a relative high temperature and cool it down to generate a high pressure difference, or exhaust oxygen in the bottle using some chemicals to generate the pressure difference. However, when coming to the selecting stage, we put safety above the efficiency criteria. Any designs that may cause light burns on skin, or mixing chemicals into the breast milk when the bottle is leaking.

Besides the safety concern, another code that leads our design process is the limitation of our competence, which indicates that we should only perform services only in areas of our competence. Another reason for abandoning the chemical idea is that as a group of mechanical engineers, chemical study is out of our competence. We could not evaluate and predict the long-term performance of certain chemical in safety and sustainable development aspect.

To sum up, the Code of Ethics was applied to our design process as a mandatory requirement and an orientation in design.

Appendix C.3. Qi Wang’s Statement

The team has been carefully following Code of Ethics for Mechanical Engineers through our design process. We are designing a breast pump for low-resource settings, and we realized that a lot of children died every year because of malnutrition, while breastfeeding in the first six month of newborns would significantly decrease the number of death. There is no better time to let Code of Ethics lead our design process.

Our sponsors are UNICEF, UM Laboratory for Innovation in Global Health Technology, and UM Institute for Humanitarian Technology. They value the ethical design very much. The team interviewed sponsors multiple times for user requirements. After the interviews, the team communicated with our sponsors very often through emails, phone calls, meetings and interviews. The team made sure that every time a design decision was made, we notified our sponsors.

Not only the team communicated with sponsors, the team also kept in touch with several other stakeholders. The team interviewed breastfeeding mothers, visiting scholars from low-resource area as well as doctors from University hospitals to generate more precise user requirement, confirm design process as well as validate our design. We kept in mind that all of these shareholders are the people we were designing for, and they are the best people to help our ethical design.

There is one particular example I would like to bring up for our ethical design process. For a breast pump, food safety is our top concern. After the team decided to use the stretchable silicon cover, the team reviewed papers, products and patterns for several days to find the material not only cheap in price but also food-safe. We followed Code of Ethics for Mechanical Engineers in every detail of our design.

Appendix C.4. Yiwen Wu’s Statement

My team has been following the Code of Ethics for Mechanical Engineers throughout our design process. Sponsored by UNICEF, UM Laboratory for Innovation in Global Health Technology, and UM Institute for Humanitarian Technology, we consider the safety, health and welfare of not only our potential users but also the public as our top priority. Thus, we interviewed professors, visiting scholars, experts, and other stakeholders to better understand the design challenges and concerns.

From our research, we realized that 800,000 children die each year from mal-nutrition. Therefore, as engineers, we’ve been trying our best to address the problem and save those

800,000 children’s lives using our engineering expertise while collaborating with other experts in fields such as nursing and medical. We’ve been researching and consulting throughout our design process, which not only helped the development of the product but also the development of ourselves as better engineers.

With weekly sponsor meetings, my team makes sure that sponsors approve our design direction and progress in order to avoid any possible conflicts of interest. The four members in our team work collaboratively throughout the design process because my team strongly believes that great designs are created through collaboration rather than competition. With the same idea in mind, we’ve been collaborating with industry partners (e.g. Philips and Medela), Nonprofits (e.g. UNICEF and PATH), and other academic institutes (e.g. MIT) to address the breastfeeding issue.

In order to create an objective and truthful design report, my team has been interviewing breastfeeding mothers for user feedbacks, which are crucial to the success of our design because those feedbacks are unbiased user feedbacks compared to feedbacks from anyone without breastfeeding experience. A UM professor who will be working on setting up a breast milk bank in Ethiopia this summer has also agreed to bring the prototype with him to obtain more objective feedbacks.

Appendix D. Environmental Impact Statement

Appendix D.1. Raymond Chen's Statement

As far as environmental impact is concerned, one of the main features of our design is the reusability of bottles. Because mothers in low resource settings may use bottles of many different sizes, our breast pump will be able to attach to any bottles that the mother may have. Additionally, the materials used for the rest of our pump are readily accessible and cheap. Silicon and plastic is available in low-resource countries. The parts will be plastic injection molded and produced in a volume such that the parts are very cheap. Since our breast pump is entirely manual, there are no emissions. Finally, when a user is done using the product, our design is modular such that the next generation may use it as well. We have designed our parts to be durable enough for 1000 uses. Other than the suction cup and duckbill valve (which may be sanitized), all other parts do not come in contact with the breast or milk. Those parts may be recycled and the materials may ultimately be used for new breast pumps as well.

Appendix D.2. Anqi Sun's Statement

One special design we made to reduce both environmental impact and the cost is the stretchable cover, which can make use of local bottles. For a regular manual breast pump, besides the pump itself, there usually is a bottle coming with the pump, besides, to store the milk in the bottle, there also has be a lid to fit the bottle. With our design, moms in low resource setting countries can use their own bottles are lids. When the bottle is broken, just use another bottle instead.

Besides, there are some benefits since our design simplified most manual breast pump products on market. First, with simpler structures, our design uses less material than current products. Second, because of the conciseness of the design, much assembling labor is saved during the mass production.

In our design for mass production, the suction cup and the tube are made of PVC, which is a non-degradable material. A possible solution is to replace with a biodegradable material, which has good heat tolerance, similar strength and low cost. Considering the fabrication of the suction cup, plastic casting is not an energy-saving mode of production. Researches are done to reduce the energy cost in plastic manufacturing process. For example, minimize the idle time on machines can reduce over 52% of the energy count of full molding consumption. Also, optimizing machine routing and mold allocation decisions also greatly decreases the energy consumption since 59% of energy was consumed in machinery [51].

Since our product is specially designed for low resource settings, the cost is a major limitation on the material selection. Some of the recommendations mentioned above were rejected because of this reason. Those recommendations may become more practical when the cost of these environment friendly procedures and materials are decreased in the future.

Appendix D.3. Qi Wang's Statement

The team has carefully considered the environmental impact for each design decision, manufacturing process and disposal of the material.

For design decision, starting from generating the user requirement, the team listed "easy to clean", "mechanically powered", and "durable" as our first priority user requirement. The team aimed to design a manual breast pump with minimum water consumption and maximum durability. The team also listed "locally sourced" as our medium priority user requirement, which allows local people using local resources. Following in the concept selection, the team chose the concept that could allow user to use local bottle as the storage of the breast milk, which reduced the manufacturing components. Finally to finalize the prototype, the team reviewed papers, products and patterns for several days to find the material for stretchable silicon cover to be not only cheap in price but also food-safe.

The team also considered the environmental impact when determining the mass-manufacturing plan. The team concerned about the disposal of the pump. All the material used is recyclable, and the squeeze pump is reusable even if the suction cup breaks.

Within the design target and budget, the team has carefully considered environmental impact as a high priority factor when making design decisions.

Appendix D.4. Yiwen Wu's Statement

Besides ethical concerns, environmental impact is another important consideration to the team. Even though we cannot eliminate all negative environmental impact of the product, we purposefully selected materials that are more eco-friendly and durable than regular materials. The suction cup is made of BPA (Bisphenol A) free polycarbonate plastic and the stretchable cover is made of food safe and BPA free sticky rubber. These materials also have less energy consumptions and carbon emissions during production.

Furthermore, we have engineered our design to be a durable that mothers can use the breast pump, with a 6 months breastfeeding cycle, for more than one child. However, due to safety and sanitary concerns, most mothers are not willing to share breast pumps with other mothers, resulting the disposal of used breast pumps before their life times end. However, the materials we used in the design are all recyclable and the storage bottles used can be any existing bottles that mothers have, leading to a significantly lowered environmental impact than some of the existing products.

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Biography

Raymond Chen

My name is Raymond Chen, a senior majoring in mechanical engineering and minoring in multidisciplinary design. I have lived in the Midwest my entire life with my hometown being Troy, Michigan. Outside of class I really enjoy activities such as tennis and mountain biking. In the future I wish to have a career as a product designer and will go on to complete a master's degree.

Anqi Sun

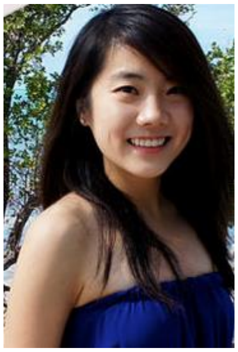
My name is Anqi Sun, a senior student major in mechanical engineering, and dual degree in electrical and computer engineering in Shanghai Jiao Tong University. I grew up in Harbin, China, an ice city in the northeast of China. My area of interest in ME is manufacturing, nonlinear dynamics, and system control. My interest in mechanical engineering blossomed during my second year in high school, when I first watched the video of a CNC machine designed and produced by DMG Corporation. I was shocked by the beauty of the accurate and flowing actions of the drilling and milling tools. Therefore, I transferred to U of M to start my journey in Mechanical Engineering.

I once worked as a temp research assistant with Prof. Dawn Tilbury and Prof. Kon-well Wang on physiological signal processing and nonlinear vibrations inspired by trees, respectively. My research experience also firms my desire to continue graduate study. Holding the belief that development of engineering skills in graduate school will make me more competitive in industry. I finally decided to pursue master degree.

Qi Wang

My name is Qi Wang, a senior student major in Mechanical Engineering expecting to graduate in May. I transferred to UMich on my junior year from Shanghai Jiao Tong University. Back in China, my major is Electrical and Computer Engineering. I was born in Jiuquan, where the earliest Chinese space vehicle launch facility, Jiuquan Satellite Launch Center (JSLC) was built. I watched the rockets live since I was a child. My interests in engineering were inspired at that time. Because of my multi-disciplinary academic background, I enjoy the research areas that can combine my electrical and coding skill with mechanical knowledge. Currently, I am working with Prof. Jianping Fu on 3-dimensional bio-printing stage, and with Prof. Angela Violi on the Stochastic Nanoparticle Simulator (SNAPS) in combustion.

Yiwen Wu



I'm Yiwen Wu, born and raised in Shanghai, China and currently a fourth year undergraduate student majoring in Mechanical Engineering at the University of Michigan. I've always been intrigued not only by the beauty of machines, but more importantly, by how technologies empower people to realize their dreams. Through my education and various design experiences, I became increasingly passionate about combining technology and human concerns to create desirable, feasible, and viable designs. I aspire to realize people's desires through the power of human-centered design. I am also a passionate baker and traveler! Feel free to explore this site and hope you enjoy my story!