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Portable Device for Breast Volume Measurement

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Abstract

Our client, Dr. Ramzi Shehadi is a reconstructive surgeon interested in developing a device to pre-operatively measure the volume of a patient's healthy breast in order to more accurately perform the Transverse Rectus Abdominus Myocutaneous (TRAM) Flap procedure on the breast that underwent a mastectomy. The device would improve the rate of success of the procedure and the symmetry of the breasts – especially for surgeons lacking significant experience with the procedure. Our three proposed design alternatives feature laser, 3D imaging, and water displacement methods of volume measurement. After assessing the three proposed designs, our final design uses volume displacement principles and incorporates two containers, a valve, and a sliding scale to measure the breast volume. The device was designed to accurately measure breast sizes up to 600 cm³ for the small version, and 1300 cm³ for the large version. This encompassed a small to medium breast size range. It was demonstrated through testing that the device was able to determine volume precisely and with the desired accuracy.

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1.0 Introduction

1.1 Problem Statement

Estimating breast volume is a challenge for any plastic surgeon performing breast reconstruction following mastectomy for cancer. Matching the volume and shape of the contralateral breast intraoperatively, as is the standard at present, is complicated by the swelling induced by the surgery itself. A preoperative accurate assessment of the volume would help the reconstructive surgeon in achieving better symmetry more consistently. A portable device that could take this assessment simply and quickly would be ideal. The device would also be used to estimate the volumes of flaps such as a TRAM flap to achieve better symmetry.

1.2 Background Information

Breast cancer is an extremely widespread disease. In the United States, it is estimated that there will be 288,130 new cases of breast cancer (both invasive and non-invasive) in 2011 alone, claiming the lives of almost 40,000 women ^[1]. Treatment options for breast cancer include chemotherapy, radiation therapy, lumpectomy, and mastectomy. In 2004, 69.8 percent of procedures to remove breast cancer were mastectomies ^[2], with many women pursuing breast reconstruction afterwards. Breast reconstruction is done to permanently regain breast shape, to make the breasts look balanced when wearing a bra, and to avoid the use of an external prosthesis ^[3]. These procedures have a significant impact on not only the health of women with breast cancer, but on their quality of life afterwards.

Breast reconstruction surgery can be performed either immediately after the mastectomy or delayed to a later date; however, to reduce the number of surgeries, it is often recommended that the surgery be done immediately after the mastectomy ^[3]. There are three different types of procedures currently used to reconstruct the breast that is removed. Surgeons and patients may choose between implants, tissue flap procedures, or recently developed artificial tissue support material ^[3]. The most common of the aforementioned procedures, and the one used by the client in this project, is the TRAM flap procedure (a type of tissue flap procedure). The TRAM (transverse rectus abdominis myocutaneous, a section of fat, muscle, and skin in the abdominal region) flap is a procedure that uses muscle, skin, and fat from the abdomen to reconstruct the breast vacancy. Currently, the TRAM flap is the most common form of living tissue used for reconstruction ^[4]. Figure 1 displays an artist's representation of the different steps in the procedure.

There are two types of TRAM flaps that can be used for the breast reconstruction: pedicle flap or free flap ^[3]. The pedicle flap leaves the muscle attached to the original muscle supply, and, in the procedure, the flap is passed under the skin to the point of attachment. Alternatively, the free flap disconnects the muscle from the original blood supply, requiring the surgeon to reattach all capillaries and veins at the new site ^[5]. There are distinct advantages between the two techniques, highlighted by the improved blood supply to the "skin island" (the skin taken to cover the reconstructed breast) that is present in the pedicle flap procedure ^[6]. Bassiouny *et al* also found that the pedicle flap procedure showed significantly less hospital time and blood loss when

compared to the free flap technique ^[7]. The tissue taken in this surgery is very similar to the tissue removed in an abdominoplasty—or 'tummy tuck'—and is another reason for the popularity of this technique.



Figure 1: Representation of the TRAM flap procedure highlighting the location of the TRAM flap (left), the relocation of the muscle, skin and fat (middle), and the desired final result (right). ^[3]

To improve the symmetry of the reconstructed breast, our client wishes to have a device that estimates the volume of the healthy breast before surgery. This estimate will give the surgeon an idea as to how much TRAM flap tissue to remove. Currently, our client does not use any tools to take this estimate and uses his own judgment and experience to estimate the amount of tissue to remove. This technique is limited to surgeons who have years of experience; therefore this device would be tailored to inexperienced surgeons.

1.3 Motivation

A device for accurately measuring volume of a breast would produce more accurate surgeries, thereby reducing the need for further surgeries. This will save both time, money, and work for the surgeon as well as improving the patient's overall experience. The current techniques that are available for measuring breast volume pre-surgery are either very expensive or inaccurate. 3-D imaging devices that are currently on the market and are able to calculate volume accurately can be priced as high as \$30,000^[8]. This is much too high for most hospitals and the goal of this project is create a device that is under \$500. This way it will be marketable to all hospitals, small or large. Other methods include the comparison of the breast to prosthetics of a known volume. This method is inaccurate because it does not account for the individuality of the various breasts that it will have to measure. This method also leads to variability between

surgeons who may choose one prosthetic over another. A surgeon who is more experienced at the TRAM flap procedure will be able to make a much more accurate assessment of the breast which leads to a steep learning curve for inexperienced surgeons. A cheap and accurate device will lead to more efficient surgeries and therefore a lower cost for both surgeon and patient.

2.0 Design Specifications

The device must be able to determine the volume of a breast with little work done by the surgeon. A simple, portable device is the most convenient and effective approach to take to designing this type of device. Portability is an important requirement of the device because it must be able to be used in a clinic setting. This means that the device must have the ability to perform its task in a relatively small room and be easily transported into other exam rooms prior to surgery. Along with this, the device must take up a small amount of space when stored. The device must be easy to use in the sense that a surgeon who has little to no knowledge in the engineering or computer science fields will be able to learn how to use it very quickly. The accuracy of the device is also a necessity. The volume that is determined by the device will be of little importance unless it is within a reasonable degree of accuracy for any type of breast. Breasts that are large, small, uneven, or contain any other complication will have to be taken into account in order for the device to be useful. The cost of this device is also of much importance. There are devices currently available on the market that can determine the volume of 3D objects, but they are quite expensive. The device should be under a \$500 budget so that it is affordable to all types of clinical settings. A safe device is always important when it is going to be used on patients. This entails that the device must be sterilizable or covered with a sterile material without losing its ability to perform its function (Appendix 9.1).

3.0 Design Alternatives

In order to perform most efficiently in breast reconstruction surgery, the surgeon must have an idea of the volume that the breast needs to be. This is difficult to determine without a device. In order to determine a solution for the problem along with meeting the design specifications mentioned in the previous section, three design alternatives were considered. One of the design alternatives used volume displacement while the other two used laser technology and 3-D sensing technology in order to determine the volume. The designs are described below.

3.1 Lasers

The first design utilizes laser technology that is able to calculate and store the distance between the origin of the laser and the first solid material that the laser comes in contact with. The general design behind this idea consists of an adjustable stand and two lasers that are supported at the top of this stand (Fig. 2). The lasers at the top of this stand would have to be adjustable in order to compensate for breasts of different width. It was determined that in order to accurately measure the volume of a breast, at least three measurements would have to be taken ^[9]. The three measurements would be at the crown of the breast and slightly to the right and left of this

measurement. These measurements could be taken most efficiently with the use of two lasers. The third measurement would simply be taken by the same laser that took the measurement of the crown of the breast after adjustment to the right or left. These distances that are recorded by the lasers would have to be subtracted from the known distance of the lasers from the sternum of the patient in order to get the height of the breast at that particular point. These calculations can be done directly on the lasers ^[10]. These heights would then be used with the known lengths between the measurements taken in order to from a rough curve that would fit the curvature of the breast. Assuming symmetry of the top and bottom of the breast, the curve could then be rotated about an axis and the volume of the breast could be estimated. The mathematics involved in this design would be done by a computer program, but the values of the heights and lengths that must be recorded for this calculation must be typed into this computer program by the person operating the device. This involves much more human interaction than is desired by the client and therefore is not as easy to use as would be preferred. This technique is also rather inaccurate for breasts that are not uniform in size and could not be optimized as a symmetrical mound. This design would be rather portable and would also be safe and sterilizable.



Figure 2: The second design with two lasers that can translate horizontally with a stand that can adjust up and down.

3.2 3D Imaging

The second design alternative involves using pre-existing technology. In 2010, Microsoft released Xbox Kinect, a motion sensing input device that is capable of creating a 3D image (Fig. 3). The 3D sensing technology used in Kinect comes from the company Primesense and consists of 3 parts: a chip (PrimeSense PS1080 SoC), depth sensors (IR light source and CMOS image sensor), and a RGB color camera ^[11]. The Kinect works by first allowing the chip to acquire a depth image by infrared lights. Then, in a stage called light coding, the CMOS image sensor reads the coded light back from the scene. After light coding, the chip uses an algorithm to

process data from the CMOS image sensor and creates a 3D image of the scene ^[12]. The second part of the design would involve writing a computer program that would use the raw data obtained from the Kinect to calculate the volume of the breast. Essentially, the Xbox Kinect would be on an adjustable stand and the patient would be positioned in front of the stand such that their breast aligns with the Kinect. A 3D image of the breast would be produced and the data from the Kinect would be transferred to a computer, via a USB cable, and the computer program would be used to process the data and calculate the volume of the breast.



Figure 3: The 3D depth sensors and RGB camera on the Xbox Kinect help create a 3D image of a scene.^[13]

3.3 Volume Displacement

The final design alternative would use Archimedes' Principle (or volume displacement) in order to determine breast volume ^[14]. The design would include different sizes of primary containers, an external container, an adjustable scale, and a valve (Fig. 4). The scale would fit around the external container so that it could be read like a graduated cylinder. The scale would also be calibrated so that the number that corresponds to each water level would be the volume of the breast in the primary container (Appendix 9.2). Since the calibration of the scale depends on the size of the primary container, a scale would be needed for each primary container. The primary containers would have a plastic membrane sealed onto the rim so that it fits loosely into the container and creates a "pouch". The breast would be inserted into this pouch, not necessarily stretching or filling the pouch. The potential extra room in the pouch is eliminated as the known volume in the external container is allowed to flow through the valve into the primary container. The volume continues to flow until all of the empty space in the primary container is filled, and the membrane is tight against the breast. Once the water has stopped flowing into the primary container, the number on the scale that corresponds to the water level is the calculated volume of the breast. With this design, some complications arise with reusability and creating a water-tight system. The design would have to be reset, so that no volume is in the primary container and the external container has its starting amount of volume. Also, the seal of the membrane to the primary container could be one area with a high potential of allowing volume to escape.



Figure 4: A SolidWorks representation of the final design. The design features two containers, primary and secondary, that are joined via threaded valve connections. The scale is on the secondary container.

4.0 Design Matrix

In order to choose a final design, a design matrix was created (Table 1). The following categories were chosen for the design matrix (in order from most important to least important): Cost, accuracy, portability, ease of use, maintenance, speed, patient comfort, and safety. Cost was determined to be the most important part of the design. This was not only because the client stressed the importance of a low cost design, but also because of the availability of current expensive devices that could measure the volume of a breast in our application. The water displacement design received the highest point value in the cost category because the cost to manufacture the design will be under our budget of \$500. The laser and 3D imaging design were given lower point values in the category of cost because they will likely exceed our \$500 budget.

Accuracy and portability were the next two most important categories. Our client would like the volume of the breast to be accurate in order to know how much muscle, skin, and fat from the abdomen must be used during the TRAM flap procedure. The integration programs that would be used to calculate the volume of a breast in the laser and 3D imaging designs assume symmetry of the breast which would lead to a less accurate volume measurement. For the design matrix, we predicted that the water displacement design would give the most accurate volume of a breast because it simply uses Archimedes' Principle. Our client would also like the device to

be portable so it can be carried to different rooms. Because both the laser and the 3D imaging design would require stands, they would be less portable than the water displacement design.

Ease of use and maintenance of the device were the next most important categories. The device should be simple enough to use such that a person with little training on the device would be able to accurately determine the volume. The water displacement design got a relatively high score compared to the laser device because it only requires the user to firmly place the device against the skin around the breast, to open the valve and pressure-releasing screws, and to read the scale at the meniscus of the water. The laser device would involve a lot of user manipulation and orientation of the lasers on the stand, the stand's distance relative to the patient, and the angle of the lasers to the breast. Also, the laser distance measurements would have to be entered into a program manually. The 3D imaging device would connect directly to a computer and a program would output a volume number without any user input, making this design's ease of use score the highest. Next, the device will be used in a hospital setting so it must be easy to clean and sterilize. Since the laser and 3D imaging design don't actually touch the patient, they would be easier to clean than the water displacement design.

The final two categories were safety and patient comfort, both of equal importance. All three designs would be safe to use and would not harm the patient. The patient should also feel comfortable while the device is functioning. Because both the 3D imaging design and the laser design do not physically touch the patient, they were given a higher point value in the category of patient comfort.

Category	Lasers	Water Displacement	3D Imaging
Cost (25)	10	25	15
Accuracy (20)	5	15	10
Portability (15)	7	12	7
Ease of Use (15)	5	12	14
Maintenance (10)	9	5	9
Speed (5)	1	4	4
Patient Comfort (5)	5	3	5
Safety (5)	5	5	5
Total (100)	47	81	69

 Table 1: Design matrix for the different designs to measure breast volume.

5.0 Final Design

The design that was chosen to pursue further was the Volume Displacement design. This design scored the highest in the design matrix with a total score of 81 out of 100 (Table 1). This was because of the design's high portability, low cost, and high relative accuracy compared to the other design alternatives. The laser design was dismissed from final design consideration, as it received a low score of 47. This was because of a high cost, low ease of use, and relatively low accuracy. The 3D imaging design was also dismissed, receiving a score of 69. This was due to its low portability and insufficient accuracy.

The design team concluded that the volume displacement design was indeed the best alternative of the three. The cost is under budget, it is highly portable, and is expected to maintain an acceptable degree of accuracy.

The prototype for the final design can be seen in Figure 5. There are two primary containers, each PVC caps (schedule 40) that could hold a volume of 700 mL (small) and 1450 mL (large). The external container is made of 3 inch acrylic tube fitted with an acrylic cap on the top and an aluminum piece on the bottom. The scale fits around this external container. This scale was rapid prototyped with ABS and has measurements every 50 mL. In order to save on costs, the scale has two sets of labels, one for the small primary container and one for the large primary container. Each cap has a bleed valve (threaded screw) that needs to be released when there is water flow in order to provide a means for the air to escape the tube as the water enters. During measurement, the top bleed valve must be open to the air and during refilling of the secondary container the bottom bleed valve must be opened. The bottom aluminum cap was machined to thread into the valve connecting the two containers. The membrane, made of LDPE, was joined and sealed to the primary container with a hose clamp and then covered with a nitrile band. All the threaded connections had Teflon tape applied and all seals were made with waterproof silicon. Table 2 contains a cost analysis of the prototype. The most expensive portions of the prototype were the two containers that were used. This cost could be decreased by buying the materials in bulk as opposed to specific dimensions. Overall, the prototype was comfortably beneath the proposed budget of \$500.



Figure 5: The final prototype with the scale for the small primary container (left) and large primary container (right).

Part of Design	Specific Material	Cost	
Primary Container	$4\frac{1}{2}$ inch diameter PVC Slip Cap	\$7.71	
Membrane	Dual-layered LDPE Sheet	\$2.40	
Membrane Attachment	4⅓ – 7 inch Steel Hose Clamp	\$1.72	
Membrane Attachment Cover	12 x 12 inch, 1/32 inch think, Nitrile	\$10.36	
Valve	¼ inch end, Male x Female threaded, Chrome-plated, Brass Ball Valve	\$7.90	
External Container (Bottom)	1 inch thick, 3½ inch diameter, High-strength, Aluminum disk	\$19.71	
External Container (Sides)	12 inch long, 3 inch inside diameter, ¼ inch thick wall, Acrylic cylinder	\$22.03	
External Container (Top) 44 inch thick, 3 inch diamet Acrylic disk		\$6.64	
Scale	Scale ABS (Rapid Prototyped)		
		Total Cost = \$135.51	

Table 2: Cost analysis of the prototype with part, material, and individual parts.

6.0 Testing

To assess the functionality of the prototype and whether it met the desired design specifications, tests were run checking for accuracy, repeatability, and ease of use. Human testing would have been the most realistic assessment of the device, but female volunteers were not readily available and the volume of the tested breast or object must be known to quantify the results. Therefore, objects of known volume were used.

6.1 Procedure

The final design was tested using objects of known volume. The external container was first filled with water while the valve was closed. The scale was then set to the water level according to the size of the primary container being used. In order to be as near to the actual volume as possible, the object of known volume was held up to the flat chest of a male volunteer. The primary container was then placed over this object, on the chest of the volunteer so that the object was completely encompassed by the primary container. Once the device had been comfortably fitted onto the volunteer, the pressure-releasing screw on the top of the external container was removed and the valve between the containers was opened to allow the water to flow from the external container into the primary container. Then, the water was allowed to settle, and the volume of the object was found by reading the number on the scale that was closest to the water level. Each procedure was timed and performed five times for each of the three objects tested.

6.2 Results

The observed volume of each test was recorded as well as the accepted volume for each object. The mean and standard deviation was then calculated for each set of five tests. Timing of the procedure showed that it took an average of 30 seconds to achieve the observed volume.

Object	Test Number	Accepted Volume (mL)	Observed Volume (mL)
Container cap	1	260	275
Container cap	2	260	300
Container cap	3	260	275
Container cap	4	260	275
Container cap	5	260	275
Top half of a bottle	1	150	200
Top half of a bottle	2	150	175
Top half of a bottle	3	150	200
Top half of a bottle	4	150	150
Top half of a bottle	5	150	175
Applesauce Cup	1	125	150
Applesauce Cup	2	125	150
Applesauce Cup	3	125	175
Applesauce Cup	4	125	175
Applesauce Cup	5	125	150

Table 3: Displays the results of tests for the container cap, top half of bottle, and applesauce cup. Observed volume and accepted volume are reported.

Table 4: The mean and standard deviation for the three objects are shown in comparison to the accepted volume of the object.

Object Number	Object	Accepted Volume (mL)	Mean Volume (mL)	Standard Deviation (mL)
1	Container Cap	260	280	11.18033989
2	Top half of a bottle	150	180	20.91650066
3	Applesauce Cup	125	160	13.69306394



6.3 Discussion

An analysis of our results shows that the device was repeatable and reasonably accurate. The standard deviation can be explained by the fact that the scale was only accurate to the nearest 25 Since each of our standard deviations was less than the increments on the scale, the mL. differences between the observed volumes were small. Therefore, it could be concluded that the device is repeatable due to its ability to produce the same results consistently. The mean volumes found were above the accepted value by no more than 35 mL. The deviation from the accepted value can be partially explained by the inaccuracy of the scale, but also for other reasons. The abnormal corners of the objects that were measured most likely resulted in a larger observed volume. This particular complication would not be present while measuring a smooth breast. The device was able to determine the volume in a short 30 seconds which is desired. Inversion of the device was quick and simple, allowing the water to flow back into the external container. This resets the device and allows it to be used again immediately. The device was slightly difficult to use due to the pressure needed to be applied in order to keep it tightly on the patient's chest. Another difficulty that arose while using the device was unscrewing the air holes to release the pressure inside the device.

7.0 Future Work

Although the prototype produced adequate results, this device is not ready for the clinical setting. The most important steps in making this prototype a product are improving the ease of use of the device, creating different sizes for the primary container, and developing a better and more reliable seal between the containers, membrane, and valve. To improve the ease of use of the device and to minimize human error, our client suggested using a digital readout of the volume of the breast instead of reading the scale. This could be achieved by using more sophisticated volume measurement devices and projecting the volume on an LED screen ^[15]. Another large improvement in making the device more user-friendly would be to incorporate a pump to facilitate the exchange of water between the primary and secondary container ^[16]. To expand on the range of sizes of measurable breasts, more primary containers could be made to

accommodate larger or smaller sizes ^[17]. Also, to improve the seals in the device and to ensure that the patient does not get wet, we would want to make the entire external container (including the aluminum piece) out of one solid piece of acrylic. This would eliminate the main source of leakage found during the construction and testing of the device.

After making the aforementioned changes, this device would need to be tested on human breasts to confirm its potential for the clinical setting. Hopefully, the device will be deemed effective enough to be implemented into the client's hospital. From there, the team and client may come to the decision that the design is marketable and may move to try to patent and/or mass-produce the device. There are many inexperienced reconstructive surgeons around the United States that could benefit and be interested in such a device.

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9.0 Appendix

9.1 PDS

Problem Statement

Estimating breast volume is a challenge for any plastic surgeon performing breast reconstruction following mastectomy for cancer. Matching the volume and shape of the contralateral breast intraoperatively as is the standard at present is complicated by the swelling induced by the surgery itself. A preoperative accurate assessment of the volume will help the reconstructive surgeon in achieving better symmetry more consistently. The device would also be used to estimate the volumes of flaps such as a TRAM flap also to achieve better symmetry.

Client Requirements:

- Must be portable
- Must be light in weight
- Must accurately and consistently measure the volume of a breast
- Must easily communicate with the surgeon
- Must be reasonable in cost

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements

The portable device for breast volume assessment must measure the volume of a breast in a timely manner. The device must be accurate, precise, and give consistent measurements.

b. Safety

The device will not harm or hurt the patient while recording the volume of a breast. The device will not expose the patient to harmful electromagnetic radiation that could cause complications in the future. The device must be sterializable or be able to be covered while in use.

c. Accuracy and Reliability

The device must be accurate to +/-10% of the actual breast volume. The device must be reliable for consistent results.

d. Life in Service

The device must last at least 5 years.

e. Operating Environment:

Our device would be used in a clinical setting. It will be used in a preoperative appointment and potentially be used during surgery. It should be capable of estimating the volume of any size breast.

f. Ergonomics:

The device should be extremely user friendly. Any plastic surgeon with basic training should be able to easily and effectively use the device. The device should be easily used by one person.

g. Size:

The device must easily be used with two hands. Also, the device must be portable and fit inside of a case.

h. Weight:

The weight of the device should easily be held with two hands. In order to accommodate this request, the device will weigh no more than 10lbs.

i. Materials:

The external container of the device will be made out of acrylic. The primary container will be made out of polyvinyl chloride (PVC) and must accurately measure the volume of the water displaced. In between the external and primary containers will be a mating piece machined out of aluminum which threads the valve into the primary container. The membranous material that provides a water-tight seal must be elastic and will be nitrile or a material with similar properties to nitrile. A metal hose clamp will also be used to attach the membrane to the primary container. The scale will be rapid prototyped in ABS plastic.

j. Aesthetics, Appearance, and Finish:

It is preferred that the device will be aesthetically appealing for patient comfort; however, function and accuracy of the device are more important.

2. Production Characteristics

a. Quantity: 1 deliverable.

b. Target Product Cost: the client proposed an initial budget of \$500.

3. Miscellaneous

a. Customer: Dr. Ramsey Shehadi

b. Patient related concerns: N/A

c. *Competition*: There are other devices on the market that measure the volume of 3-D objects; however, these devices can cost up to \$30,000. No current device is available in our price range.

9.2 Calculations

Calculations for the calibration of the scale

Volume of External container $V = \pi r^2 h$ $r = 3.81 \text{ cm} h = 30.48 \text{ cm} V = 1390 \text{ cm}^3$

Known Volume of Primary containers

 $P_1 = 700 \ cm^3$ and $P_2 = 1450 \ cm^3$

- Each notch will be for 50 mL and $1 mL = 1 cm^3$
- Distance between each notch = $d = \frac{50 \text{ mL}}{\pi r^2} = 1.0964 \text{ cm}$

Scale for P₁

$$P_{1Top} = 700 \ mL \qquad P_{1Bottom} = 0 \ mL$$

$$\frac{700 \ mL}{50 \ mL} = 14 \ not ches in scale for P_1$$

Length of scale for P_1

14 notches * 1.0964 $\frac{cm}{notch}$ = 15.3496 cm = Length of scale for P_1

Scale for P₂

$$P_{2Top} = 1450 \ mL \qquad P_{2Bottom} = 300 \ mL$$

- Bottom of scale cannot be 0 due to size of external container
- All breasts under 300 mL can be measured using smaller size

Total amount of volume on scale $P_{2Top} - P_{2Bottom} = 1150 \text{ mL}$ $\frac{1150 \text{ mL}}{50 \text{ mL}} = 23 \text{ notches in scale for } P_2$

Length of scale for P_2

23 notches * 1.0964 $\frac{cm}{notch}$ = 25.2172 cm = Length of scale for P_2