

Portable Device for Breast Volume Assessment  
Product Design Specifications (PDS)

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**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 sterilizable 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.