University of Tennessee, Knoxville
Trace: Tennessee Research and Creative Exchange

University of Tennessee Honors Thesis Projects
University of Tennessee Honors Program

5-2011

FEASIBILITY OF A TOUCH SENSITIVE BREAST PHANTOM FOR USE IN THE TRAINING OF PHYSICIANS IN CLINICAL BREAST EXAMINATION

Corinne Ashlie Davis
cdavis75@utk.edu

Katherine Lynn Mittura
University of Tennessee - Knoxville, kmittura@utk.edu

Grace Elizabeth Copeland
gcopelan@utk.edu

Erica Martina Hawkins
ehawkin4@utk.edu

Follow this and additional works at: https://trace.tennessee.edu/utk_chanhonoproj

Part of the Biomedical Devices and Instrumentation Commons, and the Systems and Integrative Engineering Commons

Recommended Citation

Davis, Corinne Ashlie; Mittura, Katherine Lynn; Copeland, Grace Elizabeth; and Hawkins, Erica Martina, "FEASIBILITY OF A TOUCH SENSITIVE BREAST PHANTOM FOR USE IN THE TRAINING OF PHYSICIANS IN CLINICAL BREAST EXAMINATION" (2011). *University of Tennessee Honors Thesis Projects.*
https://trace.tennessee.edu/utk_chanhonoproj/1450

This Dissertation/Thesis is brought to you for free and open access by the University of Tennessee Honors Program at Trace: Tennessee Research and Creative Exchange. It has been accepted for inclusion in University of Tennessee Honors Thesis Projects by an authorized administrator of Trace: Tennessee Research and Creative Exchange. For more information, please contact trace@utk.edu.

FEASIBILITY OF A TOUCH SENSITIVE BREAST PHANTOM FOR USE IN THE TRAINING OF PHYSICIANS IN CLINICAL BREAST EXAMINATION

Authors:
Grace Copeland
Corinne Davis
Erica Hawkins
Katie Mittura

Date Published: 9 May 2011

CONTENTS

Page

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

The purpose of this senior design project is to determine the feasibility of a touch sensitive breast phantom for use in the training of medical professionals in clinical breast examination. This project is undertaken at the request of the University of Tennessee Medical Center staff of the Simulation Laboratory and will be completed under the supervision of Drs. William R. Hamel and Mohamed Mahfouz of the Mechanical, Aerospace, and Biomedical Engineering Department. The required sensors and interface electronics will be provided by Mr. Jon Huber, Dr. Mahfouz's PhD student. Using a QFD (Appendix B) to determine the best process to meet the medical center's needs, the group determined that the objective will be best met by attempting to develop a realistic, life-like breast model of a median size, shape, and density that will be set upon a plate of sensors with possible embedded sensors within the model. These sensors shall be capacitive sensors calibrated to detect pressure used and location palpated. The sensors shall interface with the computer through a circuit board supplied by the department and a run report will be generated using MATLAB software. This run report shall provide feedback on the type of pressures used and locations palpated. Additionally an FEA model of the breast shall be created and utilized in the design and fabrication of the phantom and possibly in support of the calibration of the sensors.

1. BACKGROUND

Clinical breast examination (CBE) is performed extensively across the United States and is recommended by the American Cancer Society at least every three years for women in their 20's and 30's and annually for women 40 and older (Saslow, 2004). The purpose of CBE is to visually inspect and palpate the breast to detect abnormalities.

Palpation must examine all breast tissue as well as the nearby lymph nodes and should be systematic in order to be sure no areas are missed. The upper outer quadrant and under the areola and nipple are the most important areas to be searched as they are the most common sites for cancer to arise. It is also essential to use light, medium, and deep pressures during palpation to correspond to the subcutaneous, midlevel, and down to the chest wall (Saslow, 2004).

CBE is a critical part of all assessments of breast lumps, but there is currently no standardization of methodology or performance evaluation for trainees. Medical students and physicians alike report a lack of confidence in their CBE skills owing to the small number of CBEs actually performed, illustrating the limits of current medical school training in the performance of CBE (Saslow). Studies have shown that training with silicone breast models has increased physician's sensitivity to lump detection and decreased false positive detection (Vetto, 2002).

Based on these conclusions about the need for formalized training and the effectiveness of skills learned from a model it is believed that training with a model that gives visual feedback will be a significant improvement. A physician that is able to practice CBE with a touch sensitive breast phantom that interfaces with a computer will be able to self-correct his or her examination or be evaluated on his or her skills. A training system of this type will also allow training supervisors to quantitatively assess a physician's techniques and progression over his or her examination trials.

1.1 PATENT SEARCH

A search of the European Patent Office's Worldwide Database was done in order to do a survey of existing patents related to the project. A group from the University of California holds a patent on a human torso phantom that mimics respiratory and cardiac cycles so that imaging data can be obtained on these processes. The phantom provides a realistic model of the tissues of the human torso.

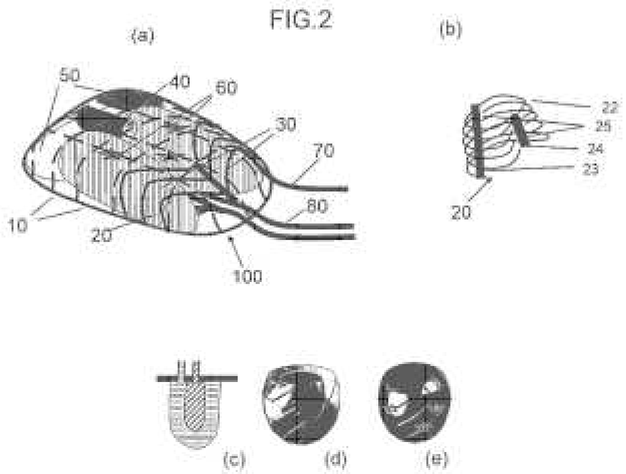


Figure 1: Human torso phantom design

A group from the University of West Virginia has a patent on a computer based instrumentation and sensor for physical examination and training. This system includes a tactile sensor pad commercially available from Tactex Company which is made of a polymer foam and protective membrane. The sensors of this device are arrayed in a rectangular matrix and operate on the principle of deformation of an optical integrating cavity. Any deformation of the foam changes its optical properties and is registered by an optical transducer. The sensor pad is interfaced with a computer based software that provides the user with feedback on the position and amount of pressure used during the examination.

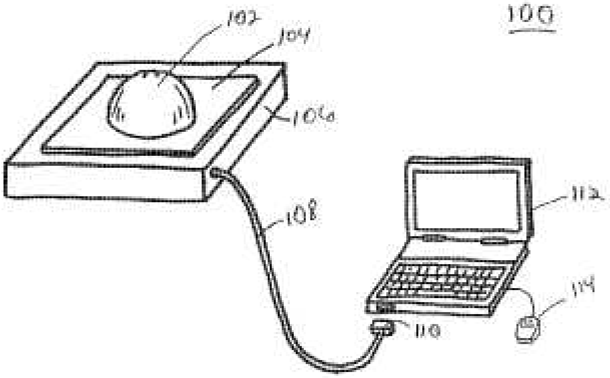


Figure 2: Schematic of UWV's examination system

1.1.1 CONCLUSIONS

The patent search returned items that were related to the design project. The human torso phantom demonstrates that there is existing technology for creating realistic models of human anatomy. The computer based instrumentation system further demonstrated the demand for a product like the intended model of this project. Our phantom is designed with a curved platform to mimic the rib cage for a more life-like examination, and our sensors will be custom built for the model. Additionally our sensor technology will be based on capacitance, not optics.

2. OBJECTIVES

The objective of this project is to develop a model that will aid in the training of physicians to perform effective clinical breast examinations (CBE). The main goal of the research and development done by the group is to determine the feasibility of utilizing external and possibly implanted sensors to increase the utility of a breast model for training. The data from the sensor output should be collected and displayed in order to show progression of the physicians. Figures 3 shows the concept of the design assembly. When the pieces are assembled the sensor mat will be conformed to the contours of the platform, as will the breast phantom.

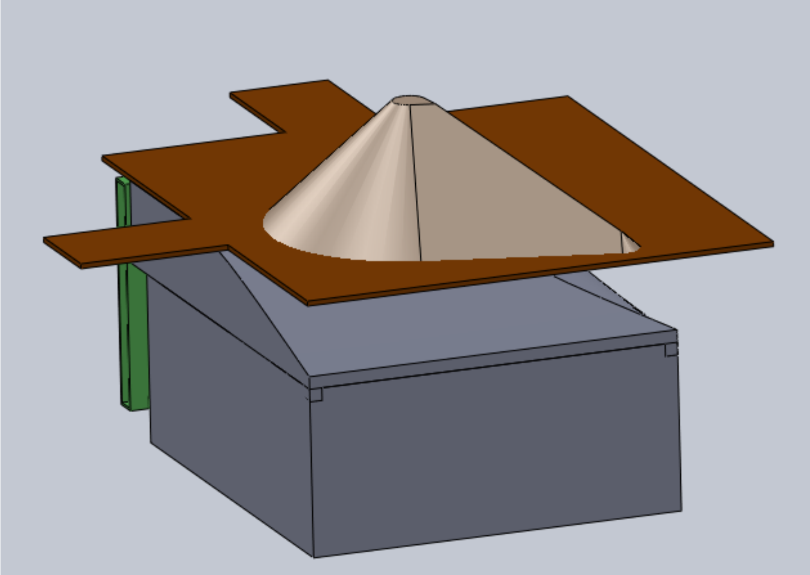


Figure 3: Design concept for the entire assembly

2.1 DETERMINATION OF A SUITABLE MATERIAL FOR REALISTIC MODEL

The model shall be a realistic representation of a human breast. Suitable materials shall be researched and tested such that they will provide similar feeling and mechanical properties as breast tissue (adipose, glandular, and fibrous) as well as an outer tougher covering analogous to human skin for further realism. The material will also be commercially available and long lasting for ease of fabrication and durability of the model.

2.2 DEVELOPMENT OF CAPACITIVE SENSORS

Pressure sensors shall be created to measure the forces applied to the breast model through changes in capacitance. The materials shall be chosen to give the sensor array the desired amount of sensitivity as determined by loads given through an example examination by a physician at UT Medical Center. The capacitive sensors shall be designed to conform to the shape of the breast model and shall deliver capacitance data to the software to be converted into pressure measurements.

2.3 INTERFACE PHANTOM WITH CUSTOMIZED SOFTWARE

The phantom's sensors shall be interfaced with a computer through a custom designed circuit board provided by Jon Huber. The computer will use customized software designed to visually illustrate the effects of the physician's palpations. The software shall create a run report with relevant information that can be printed out or otherwise recorded in order to study and evaluate the performance of the sensor-based phantom.

2.4 DEVELOPMENT OF AN FEA ASSEMBLY

A finite element model shall be created that mimics the size, shape, and material properties of the phantom assembly. It shall be used to aid in the selection of shape and size of the sensor array and to predict how the forces from palpitation will be distributed through the gel and onto the array. Simulations will be run using Autodesk Inventor or ABAQUS in order to improve the design of the model and the efficiency of the design process.

3. METHODOLOGY

3.1 SELECTION OF MATERIALS

In order for the breast phantom materials to comply with the requests of the doctors, certain materials that had similar properties to the skin and tissues in the breast were researched. Currently, different materials have been of great interest such as silicone (gel and rubber), paraffin beads, polyurethane, QM Skin 30, QGel 310, and dragon skin. Each of these materials will be discussed in further detail and an explanation will be given as to why these materials were chosen or discarded. Moreover, in order to get a good idea of which material to use for the breast phantom, research on saline and silicone implants was vital. The scope of the project is not to make our own material, but to find a material that feels similar to human skin and a material that is believable. Since implants are common, it was easier to research breast prosthetics and to observe the design and what materials were used. From the breast prosthetic research, it was discovered that silicone is used by 90% of surgeons who perform breast augmentations; saline makes up the other 10% (Dumitriu, 2001). This information was beneficial because silicone implants have similar viscous properties of the breast, and the body tolerates it well. Even though the breast phantom that is being created will not be implanted into the body, the implant information was useful because it gave a material that had the properties of the breast and gave insight into what is on the market.

Silicone is mostly common in breast implants because of its one advantage; it feels like human tissue. Patients who receive breast augmentations are more concerned about how the implant feels, so silicone is the best option opposed to saline (Replogle, 2008). Also, silicone can be colored and shaped into any configuration or style. It is a good electrical insulator which will be helpful for the sensors, and it can be reused indefinitely. Silicone gel is going to be used in order to mimic the breast tissue, particularly the glandular tissue. Fatty tissue is more liquid at body temperature and fibrous tissue is stiffer. It was advised to make a normal breast since mimicking the tissues of the breast is very complex and would be best for the Generation 2 model. The silicone gel that will be used for this breast phantom is a general purpose silicone that can be lightly cross-linked in order to get the desired texture. QGel 310 is manufactured by Quantum Silicones and has been tested and evaluated to observe which recipe provides the best consistency. The final recipe that was tested was a basic experiment which means the directions from Quantum Silicones were followed; no changes to the measurements were made. The silicone gel showed a good consistency, but the more it cures, the better the results. Also, the samples had air pockets even after being vacuum treated.

QM Skin 30, which is manufactured by Quantum Silicones, was going to be used to mold the breast phantom into the teardrop shape that the medical center requested. However, this "skin" was not the right texture for the breast phantom. Instead, after receiving many different skin samples from Smooth-On Inc., Dragon Skin FX Pro was chosen. The other skin samples were too stiff and the curing time was not as quick. Dragon Skin FX Pro is the ideal skin because of its feel, fast curing time, and versatility. It is marketed as a soft, stable, high performance silicone rubber. It feels like human skin and replaces the silicone rubber that was initially chosen as the shell of the phantom. Moreover, Dragon Skin is selected as the best material because of its skin replication techniques and its appearance. Also, the shore hardness is 2A which is very close to the skin on a breast. Shore hardness gauges the softness or hardness of a given material. The A scale measure soft flexible materials and ranges from 00 to 100 with 00 being the equivalent of human skin and 100 being a car tire. The skin is tacky and needs a coating to cover it. The technical representatives advised the use of baby powder to reduce the tackiness.

Smooth-On Inc. has another material that they manufacture, Slacker Tactile Mutator. The amount of Slacker added depends on the degree of tackiness desired. It is advertised as a one component translucent clear fluid that changes the feel of the Dragon Skin FX Pro to a softer and more flesh-like material. Another product by this same company, Silc-Pig, is a material that changes the dragon skin to a flesh-like hue. It is a silicone color pigment.

3.1.1 MATERIALS NEEDED TO MAKE REALISTIC PHANTOM

The "Breast Shell"

- Printed FEA Model
- Dragon Skin FX Pro
- Vaseline
- Slacker Tactile Mutator
- Silc-Pig

Contents of the breast:

- Silicone Gel (QGel 310)

Chest Wall:

- Dragon Skin FX Pro
- Slacker Tactile Mutator
- Silc-Pig

3.1.2 MATERIAL PROPERTIES

Table 1: Material properties for breast model

Material	Appearance	Viscosity	Specific Gravity (g/cm$^{3)}$	Adhesion	Hardness	Costs
Dragon Skin FX Pro	Translucent	18000cps	1.062	--	2	$30.10 for Trial Size
Slacker Tactile Mutator	Clear	7000cps	1.0	--	--	19.43 for Trial Size
Silc Pig	Flesh-tone	--	--	--	--	$17.88
QMGel310 (Base)	Transparent	1000cps	0.97	Silicone gels have a tacky surface and will form a mechanical bond to most substrates	N/A	*need to get prices from jon*
QMGel310 (Catalyst)	Transparent	1000cps	0.97	-	N/A	_

3.1.3 MIXING AND MOLDING TECHNIQUES

A printed shell of the breast model is made so that the skin can be molded into a specific shape. The skin is mixed with 1:1 Parts A and B of the Dragon Skin FX Pro. Part B is mixed thoroughly before it is added to Part A. About 6ml of Slacker is added to the mixture to give it a softer and life-like feel. Next, a relatively small amount, 1ml, of Silc-Pig is added to change the color. The skin mixture is poured over the printed model and allowed to cure for 45 minutes. Once the skin is ready to be removed from the printed model, it is placed inside of the printed model so that it may be filled with the silicone gel.

The silicone gel is made with 1:1 Parts of A and B. It cures for a full day at room temperature and for one hour at 100 degrees Celsius. Lastly, the chest wall is made by using the same mixing techniques for the breast shell. Once the mixture is completely mixed, it is poured onto wax paper into a thin even layer and allowed to cure for 45 minutes. More Slacker is added to the chest wall which allows it to adhere more closely to the rib cage platform. Two part molding will be the best technique because the breast shell and chest wall have to cure separately. The exact measurements were found through trial and error.

3.1.4 EXCLUDED MATERIALS

Saline was excluded because only 10% of breast implants are saline-filled. Also, saline will not feel like a real breast because it is more viscous; its mostly salt water. Saline for breast prosthetics are becoming rare, and if it is ruptured it leaks quickly.

A novel material which consisted of a solution of polyvinyl alcohol in ethanol and water was one of the materials that could have been used. The material, once mixed, would make a solid, elastically compressible gel (Price et al, 2010). This material required creating it from scratch and it was new, so there had not been much research yet on the effectiveness of the material. Therefore, this material was discarded because it might take unnecessary time to create and it is unfamiliar to the group members. Also, it was not much information on this material.

Parylene was not used because it is just a coating that is mostly used for protection of implant electrodes and implanted electronic circuitry (Ratner, 2004). It is not a good material to go over the "skin" because one of its recent uses was on stainless steel cardiovascular stents. Also, it has a plastic type feel which does not satisfy the requests of the doctors.

Polyurethane has a similar softness and feel of human skin. The advantage of polyurethane is that it can be made into a desired softness or hardness. Smooth-On Inc. has a series of products called Brush-On that is applied with a spatula or brush and it cures with negligible shrinkage to durable rubbers. The skin that was mixed is sticky and needs a coating that does not take away from the feel of the skin and it should be colored since the skin is translucent. This material was not chosen because of the difficulties of mixing and applying it to the mold; it is not as simple as the dragon skin.

3.1.5 DATA TO SUPPORT COMPUTATIONAL MODELING

The data in Table 2 contains values for a general silicone. This data is theoretical since there is not an actual model to test for these values. The company, Quantum Silicones, was contacted in order to get the values for these properties, but none of the messages have been returned as of yet. The values will change once the properties for the materials are known from Quantum Silicones.

Table 2: Material properties needed for computational modeling

Young's Modulus of Elasticity	0.067 ksi
Yield Strength	1500.73 psi
Poisson's Ratio	0.375 ul
Density	0.0451591 lb mass/in^3

3.2 CAPACITIVE SENSORS

Pressure sensors that can detect localized forces through a flexible gel must be created in order to generate a working output that will show the force on the regions being palpated. A number of sensor choices were explored, including thin flexible sensor sheets that would line the outer edge of the phantom and be layered throughout, small wire pressure transducers that would be dispersed throughout the phantom, and a capacitive sensor plate, offered from CMR research, to be laid beneath the phantom. Determination of which type of sensor would be best to use was made based on the criteria for fabrication and incorporation of the sensors with the phantom material, spacing and placement of the sensors, and interfacing the sensor output with an easy-to read report.

The thin flexible sensor sheets (*FlexiForce*® Sensors Model: A201, $117 for 8-pack of 7.75 in. sensors) were not chosen because they could have been detected during an examination, and the group was concerned about the accuracy of the measurement since the placement of the sensors would be shifted during an examination. This type of sensor would also have to be cut, and possibly reshaped, to fit the design of the phantom. The small wired pressure transducers (MicroStrain®, Inc. Model: AIFP4, $1,705 per one-unit system and Model: AIFP6, $1805 per one-until system; Precision Measurement Co. Model: 105, $215 each and Model: 060 $245 each) were not chosen because the exact placement and positioning of the sensors in the phantom material would have been very difficult to do while the material was being molded, and the group was not sure if the sensors would be able to function inside a silicon gel material. The transducers were very expensive compared to the flexible sheets and the materials need to build a plate. The capacitive sensor plate provided by Dr. Mahfouz's graduate student was selected as the most effective way to measure the force of palpation because it was the cheapest option and could be made exactly to the specifications desired. These sensors must be calibrated to determine the applied force through the change in capacitance experienced during the examination.

The capacitive sensors will easily track the applied forces during the examination. During an examination, light, intermediate, and heavy forces are applied to certain areas of the breast. Dr. Huffstutter will demonstrate the examination for the group to determine the range of acceptable forces. These sensors work by measuring the change in capacitance caused by a force over a specific area. Creating a plate of capacitive sensors will allow the pressure produced during an examination to be monitored and recorded. A certain change in capacitance:

Equation 1: Capacitance

$$C = \frac{\varepsilon_0 \varepsilon_r A}{d}$$

will produce a number for that sensor (Baxter, 1997). This number can be calibrated by applying a known force and determining the change in capacitance created using an Instron testing machine with a known force. Testing will be done a number of times to ensure the accuracy of the capacitance readings.

3.2.1 DETERMINATION OF SENSOR ARRAY

After determining that buying pressure sensors would be more expensive than building them and would be more difficult to embed in the material, the group has decided that building a plate with capacitive sensors will the best decision in producing the desired result. The plate could be customized to fit the exact specifications of the breast model. As specified by UT Medical, the model should distinguish palpation over the four quadrants of the breast, as well as the portion above the outside of the breast where the lymph nodes are found. The shape of the phantom is a nearly symmetrical teardrop, which has been divided into the four quadrants of the lower portion and an additional section for the tip. In order to accommodate all areas of the phantom with the greatest sensitivity, an array of 256 1.0 x 1.0 cm square sensors was designed. Figure 4 shows the conceptual design for the sensor array.

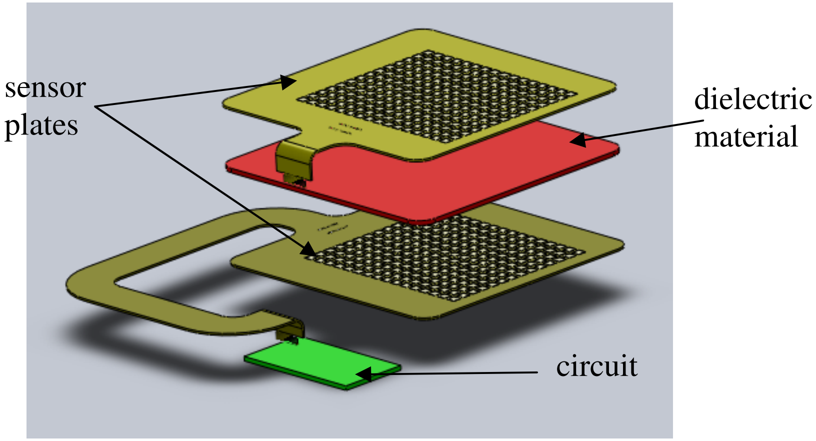


Figure 4: Conceptual design for the sensor array and hardware

3.2.2 SENSOR DESIGN AND INTERFACE

The final sensor design was created by using photolithography to make two sheets of sixteen 25 cm by 1 cm rows of copper sensor regions on polyester material, as shown in Figure 5. By turning the sheets perpendicular to one another, up to 256 sensors can be created. At each cross-section of the strips, a square 1 cm by 1 cm sensor is created. Polyurethane was selected as the non-conductive, dielectric material to use between the two plates. Smooth-on skin, neoprene and polyurethane were tested with the Instron machine to compare their capacitive ability. Smooth-on skin was ruled out because of the difficulty of fabricating a layer with the exact thickness throughout. Polyurethane was chosen over neoprene because its capacitance readings were more precise when tested on the Instron machine.

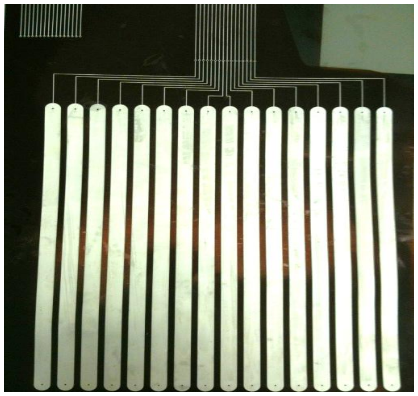


Figure 5: Single sheet with 16 copper sensor regions on polyester material

Instead of creating a sensor plate shaped like the breast phantom, the final plate is a 20 cm by 17.5 cm rectangle made of an array of 224 1 cm by 1 cm sensors. The sensor plate lays on a mounting that resembles the chest wall, and the breast phantom sits on top, shown in Figure 6. Since the plate and breast phantom are different shapes, the sensors that lay outside of the phantom can be turned off to avoid excess readings. The advantage to using a rectangular plate will allow UT Medical Staff to use multiple phantoms on the same sensor, and each will fit.

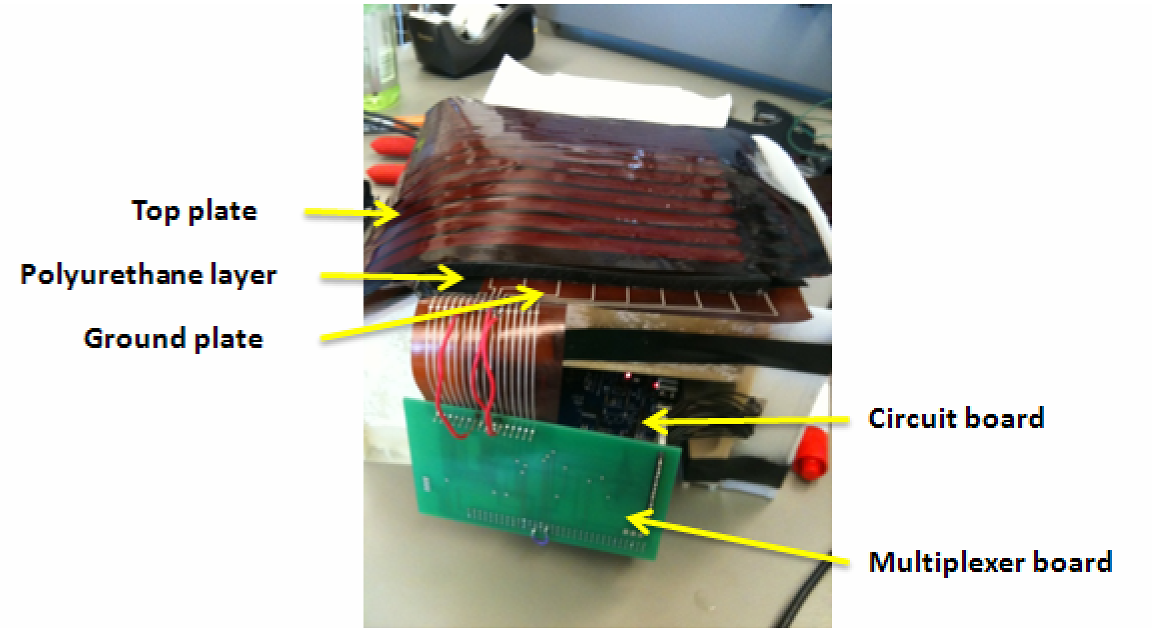


Figure 6: Final design of sensor assembly

3.2.3 DESIGN OF PLATFORM FOR ASSEMBLY

In order to assemble the examination system consisting of the phantom, the sensor array, and the electronic hardware, a platform was designed to hold all components in the desired configuration. The platform was designed to mimic the shape of a human rib-cage/chest wall, with the left edge of the structure simulating the curvature of the second through seventh ribs (LeBlond et al., 2009). The platform also was built with a hollow space underneath for the microcontroller and printed circuit board to reside where they would be protected from the environment. This space has a drawer-like covering that can be opened for easy access to the controls if necessary. The platform (Figures 7 and 8) was designed in SolidWorks and consists of a hollow structure printed in ABS plastic that was then filled with plastic foam and the edges coated with epoxy for protection and solidity without the heavy weight and high cost associated with printing a solid block.

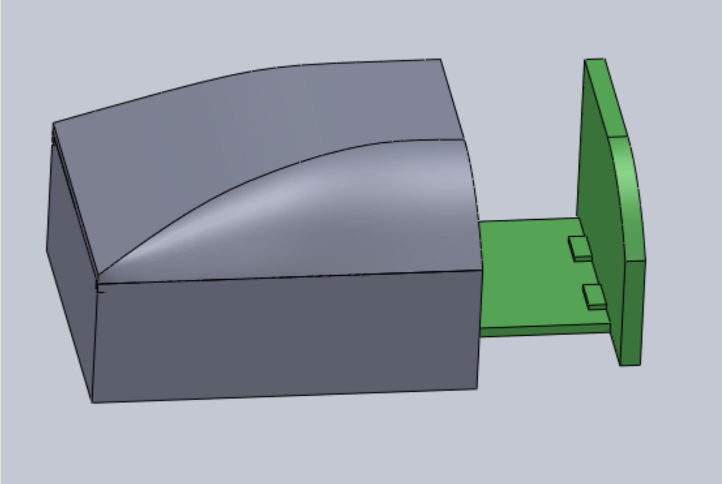


Figure 7: Side view of the platform showing curvature representing ribs 2 through 7

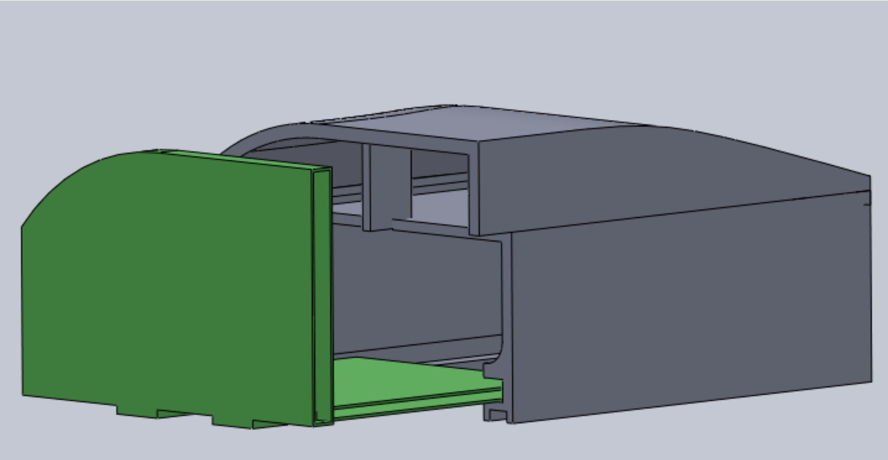


Figure 8: End-view of platform showing the hollow space for the hardware to reside

3.3 FINITE ELEMENT ANALYSIS

Finite element analysis (FEA) modeling is important because it predicts how the phantom will respond to forces applied to the surface. The modeling approach will involve both point forces as well as pressure distributions on the surface of the model to demonstrate forces the phantom will undergo when a resident performs a breast examination. The modeling forces will include light, medium, and hard forces to demonstrate various reactions. The force distribution is incredibly important in the sensor layout and design. The FEA allows for the prediction of how the phantom medium will distribute the palpated forces across the sensor plate, as well as the depth of the forces.

3.3.1 MODEL

One of the important goals was to create a CAD breast model that could be printed and used as a mold for the silicone as well as the 3D computer image for the FEA modeling. Designing the desired curvatures on separate planes and then allowing the loft feature to connect the curvature of the planes created using a loft function in Autodesk Inventor the new breast phantom model was created. This was different than previous attempts using a revolved extrusion in Autodesk Inventor. Two molds were printed using a 3D printer. The first mold was too shallow as viewed in Figure 9 (left), therefore the second mold was created to correct for the depth, Figure 9 (right). Additional models were created for the replication of the silicone material property testing as well as a model of the polyurethane that was selected for use as a dielectric material. The silicone model was made in a cup shape to mimic the testing conditions. The polyurethane was modeled as a square with the appropriate thickness.

Figure 9: Side-by-side view of the two iterations of the computer-modeled breast printed for a phantom mold

The CAD models were then exported to a .IGES file format so they could be imported using ABACUS. One imported into ABACUS each model was meshed to create a nodal system for the analysis and the material properties that were obtained from the testing were applied. The material properties of interest were the density, Poisson's Ratio, and the Young's Modulus. Next loads were created in increments from 5 to 35 N in accordance with the material testing procedure. These loads were applied for steps for the models to run and then the models were run. Models were run for the silicone sample, the breast phantom, and the polyurethane.

4. RESULTS

4.1 MOLDING OF BREAST PHANTOMS

Many breast phantoms were made in order to get the optimal results that the doctors requested. The first breast phantom was made with Steri-Drape which is a plastic sheet that is used to cover the body during surgery. Quantum Silicones donated samples of their silicone gel and skin which were used for this first trial model. The mold was a circular glass dish because the printed FEA model had not been completed. The silicone gel was mixed at a 1:1 ratio of the base A and catalyst B. The samples cured for a full day at room temperature and for one hour at 100 degrees Celsius. The silicone gel samples were placed in plastic cups and vacuumed in order to remove the air bubbles. Once this was done, the Steri-Drape with the QM Skin 30 was placed into the circular dish. The silicone gel was poured into the dish, on top of the QM Skin 30 and Steri-Drape, and vacuumed again in order to remove the air bubbles that were created from the pouring. The trial model was left to cure at ambient temperature for 7 days. There were many issues with the trial model, Figure 10. The skin was folded in the packaging which contributed to the lines on the mold. Some of the silicone gel leaked from under the Steri-Drape and the material upturned at the corners of the model which made the silicone gel seep through even more. However, the silicone gel was excellent and it was decided that it was the best material for the phantom.

Once more samples and donations from other companies such as Smooth-On were received, more phantoms were made. The FEA model was printed which allowed the phantom to have a breast shape. It was difficult in finding the right skin for the application because many of the samples sent were too hard or too soft. After talking to some of the technical representatives at Smooth-On, they recommended Dragon Skin FX Pro which has a shore hardness of 2A. The shore hardness is important because it gauges the softness or hardness of a given material. It has a range from 0 to 100. Human skin has a shore hardness of 0 to 20, and the Dragon Skin FX Pro falls into that range. Furthermore, the dragon skin is marketed as a stable, soft, high performance rubber. It was the ideal skin because of its feel, fast curing time, and adaptability. Smooth-on also has a material that changes the tackiness of the dragon skin. Slacker Tactile Mutator is advertised as a one component translucent fluid that changes the "feel of the silicone rubber to a softer and more 'flesh-like' material".

The breast phantom recipe outlined in the Mixing/Molding Techniques gives in depth detail as to how the mixtures were made. Some challenges arose when an effective chest wall was not being made. At first, a skin mixture was made to pour over the silicone, but this left the back of the phantom uneven and disfigured in certain areas. In order to rectify this situation, the skin mixture for the chest wall was poured onto wax paper into an even thin layer. This changed proved to be the most effective because it adhered very well to the rib cage platform. The chest wall and breast shell were attached with skin since the skin cures to itself. The final model is shown in Figure 11.

Figure 10: Trial model

Figure 11: Final breast phantom created using Dragon Skin and silicone gel

4.2 TESTING OF MATERIALS AND CALIBRATION OF SENSOR DESIGN

Testing has been done on many materials of many different shapes and sizes. The first tests were done on which type of non-conductive, dielectric material should be used for the sensors. The materials tested included: neoprene, smooth-on skin (which was also used for the skin of the breast phantom), and polyurethane. A small sample of each was cut and made into a single capacitive sensor using aluminum foil as the sensor plates. Using the Instron machine, each sensor was tested by adding a known load and measuring the displacement necessary to reach that load. The sensors were also connected to the circuit board, and the number of counts produced under each load was measured as well. A single count is a tiny reduction in capacitance. The number of counts of each load is correlated to the total capacitance the material produces. The differences between each material for counts per load are shown in Figure 12. The counts under an equal load were more precise for polyurethane, than neoprene. From the figure, the average counts per load, as the load increased, also increased for polyurethane and smooth-on skin. This increase was not seen in the neoprene. The polyurethane produced a smaller change in counts per load for each load as well. The range of counts per load for polyurethane was about 1,000 counts. For neoprene, the range was closer to 2,000 counts.

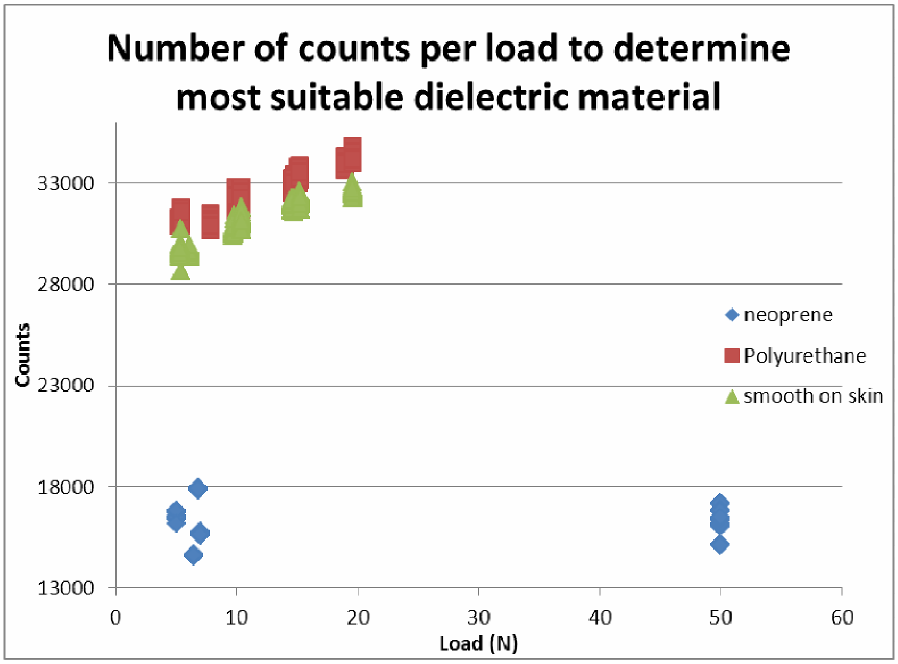


Figure 12: Relationship of counts per load for each material tested to determine most suitable dielectric material

Once polyurethane was chosen, a stress-strain curve was produced, shown in Figure 13, to find the Elastic modulus to use for capacitance calculations and the FEA model. The slope of the comparison of stress and strain is the experimental elastic modulus of the material. The slope was found to be 1.986 MPa. We are confident in this number after comparing it to the known range of the elastic modulus of rubber. The polyurethane chosen was the softest available, so our reading correlates with the lowest acceptable modulus for rubber.

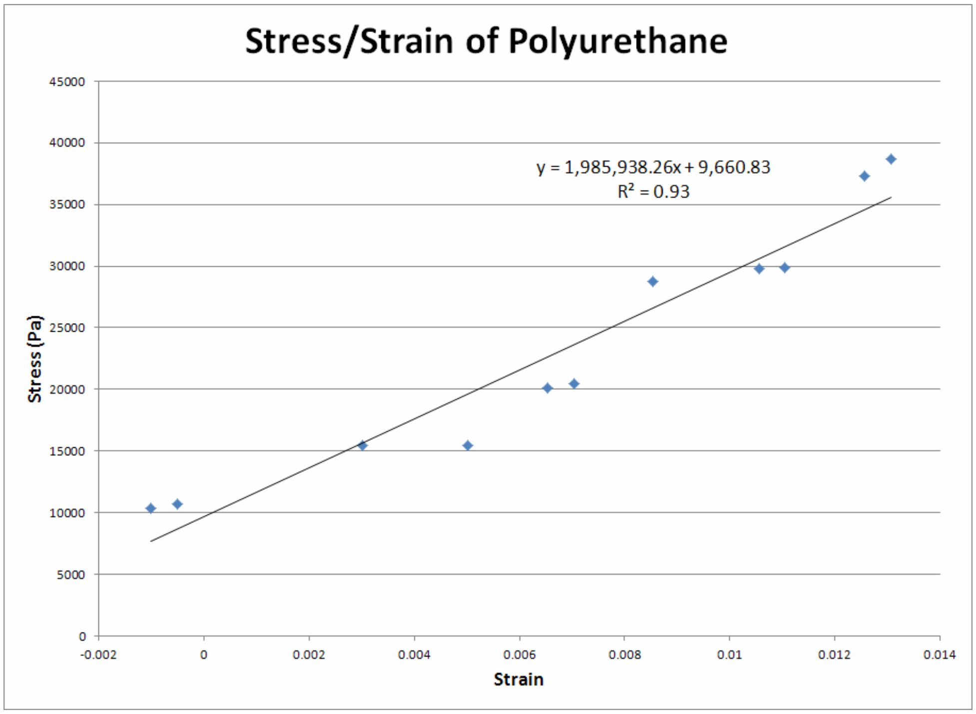


Figure 13: Stress-Strain comparison of polyurethane to find the Young's modulus

The sensor was next calibrated through a series of calculations to find the relationship between the number of counts and the actual force being added. Using the capacitance equation, Equation 1, the theoretical capacitance was found based on the known thickness, d, of the polyurethane. To determine the change in capacitance, the change in thickness was considered, as well as the force creating the change. See Appendix D for complete calculations. A 50µF capacitor was also connected to the circuit board, and true readings of counts and capacitance changes are known. The counts produced by the known 50µ capacitor and our readings for the polyurethane capacitor showed less than a 10 percent difference, giving us confidence in the calculations. From these tests, we can determine the force produced when a certain number of counts are reached. The capacitance calculations were compared against the counts readings for specific loads tested with the Instron. This information is shown in Figure 14. The slopes of the capacitance calculations and counts are very close to the same, showing that a specific load produces a certain amount of counts that directly correlates to the capacitance. The small difference in the slope of the first readings is due to the sensor plates settling. Once enough force was applied to the sensor to smash the plate into the polyurethane, the slopes are more accurate. The counts and capacitance increase because the distance between the two plates decreases after the initial settling.

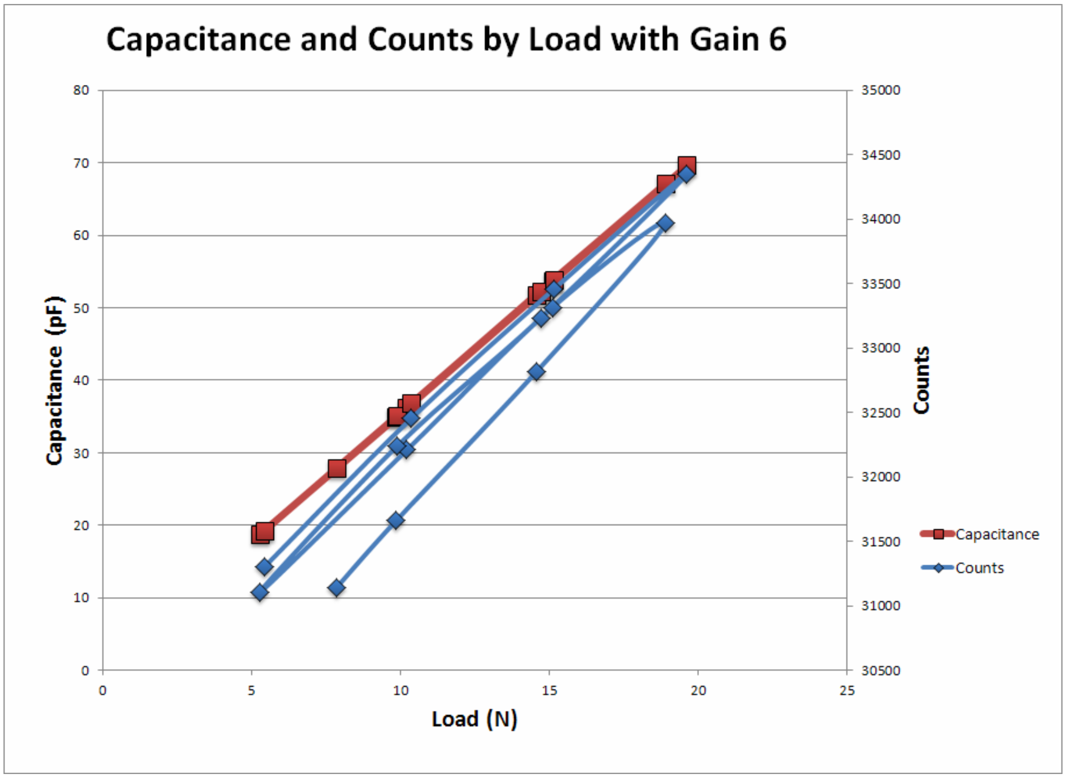


Figure 14: Capacitance and counts comparison at the same load

After the testing and calculations, a mock sensor was created and taken to UT Medical Center, where Dr. Huffstutter demonstrated light, intermediate, and deep forces. The forces created by Dr. Huffstutter were about 4 lb, 7 lb, and 13lb, as the light, intermediate, and deep forces, respectively. These forces appear to be good readings for the amount of force applied. From these, we can see that the sensors are able to detect changes as small as half a pound, which is necessary for performing a breast examination.

4.3 FEA MODELING

The results of the models run on the polyurethane, silicone, and the breast sample display displacement as well as maximum stress data. This data is displayed below in Table 3. The FEA results also demonstrate using a color map to show both the stress dispersion as well as the displacements. Red indicates the highest displacement and blue indicates the smallest. Figure 15 illustrates the stresses on the silicone sample. Figure 16 illustrates the deformation on the silicone sample as seen in a cross-sectional view. Figure 17 demonstrates the maximum stresses on the breast in a cross-sectional view. Figure 18 shows the displacement of the breast due to a 35 N force in a cross-sectional view. Figure 19 displays the displacement of the polyurethane due to a 15 N force applied at its center.

Table 3: FEA Load/Displacement compared to testing results

Model	Load (N)	Displacement (cm)	Test Data Displacement (cm)
Silicone	35	2.9	2.7
Polyurethane	15	1.5	2.0
Breast Phantom	35	2.92	2.7

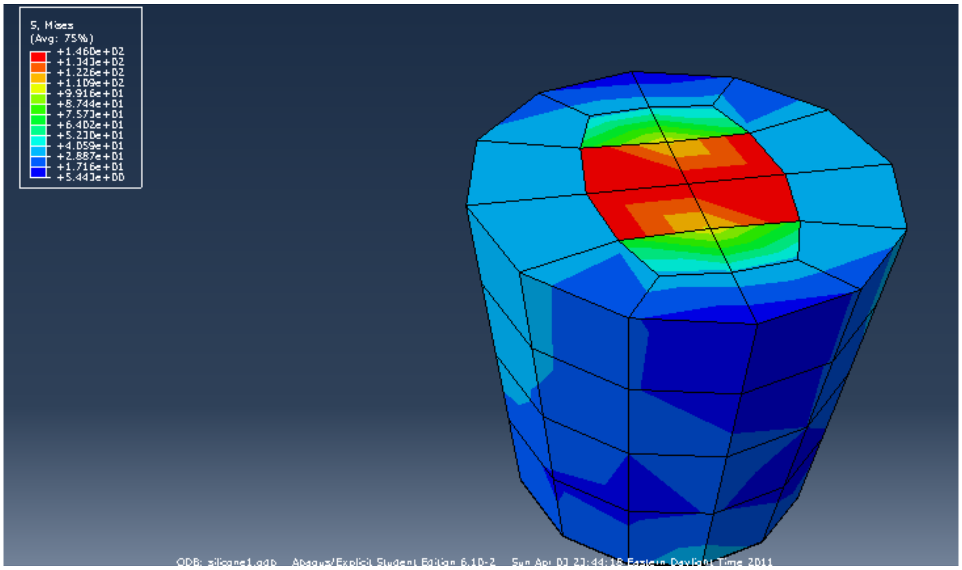


Figure 15: Maximum stresses on the Silicone sample

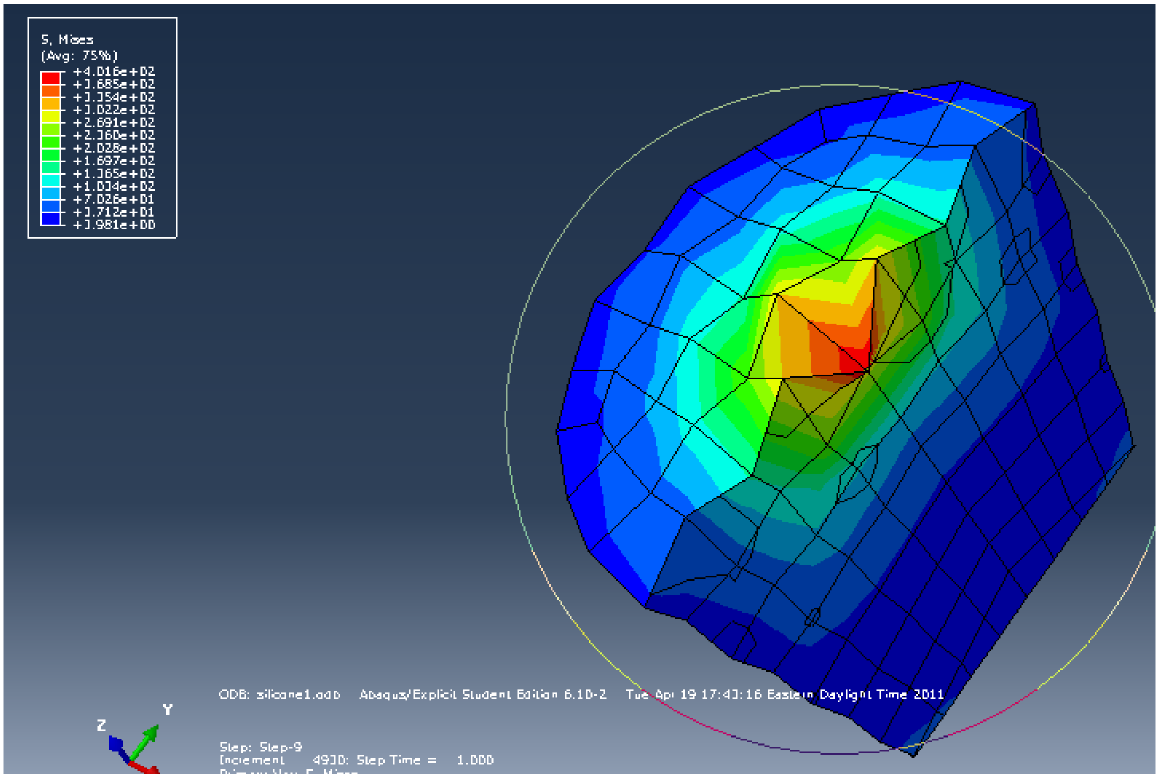


Figure 16: Cross-section of deformation on Silicone sample in plastic cup

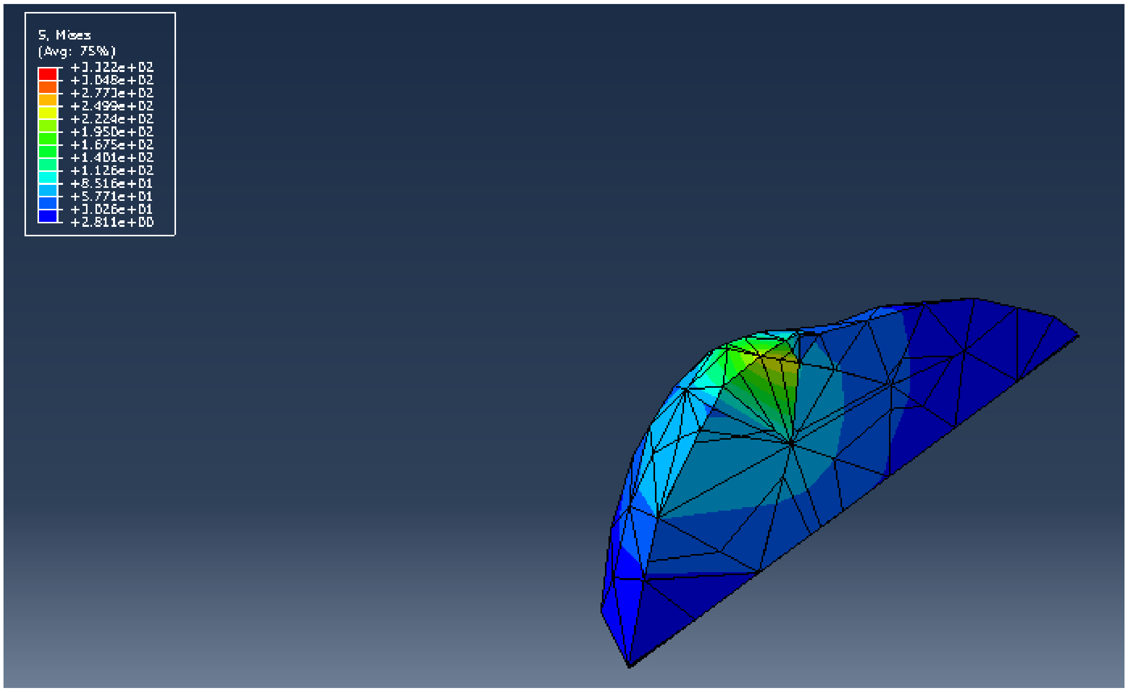


Figure 17: Cross-section of maximum stresses on breast phantom

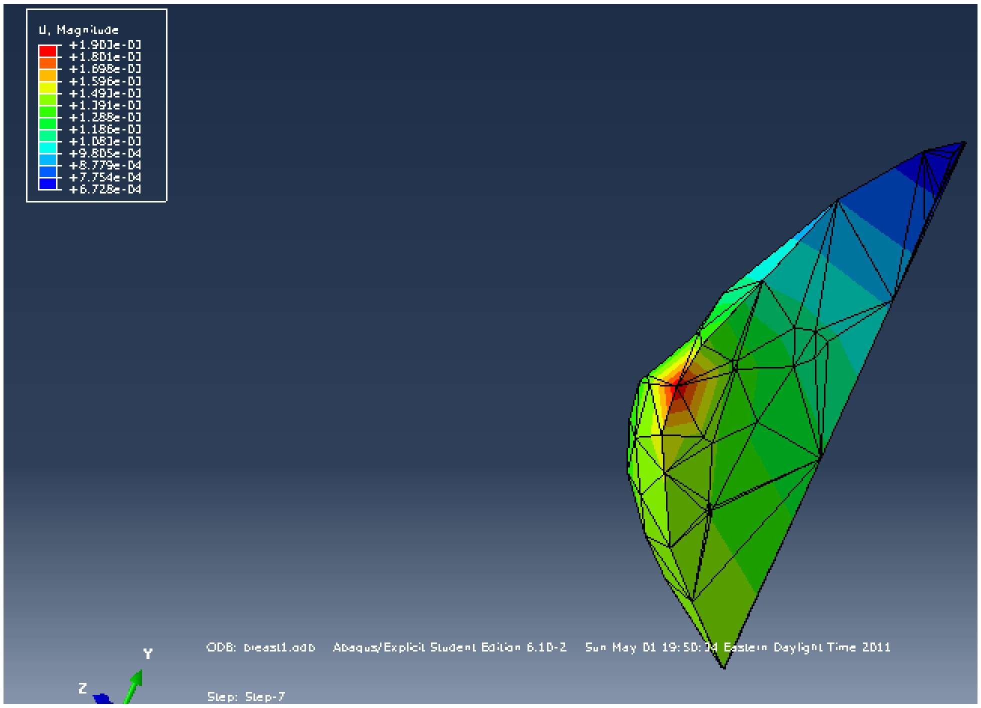


Figure 18: Cross-sectional view of breast phantom displacement due to 35 N force

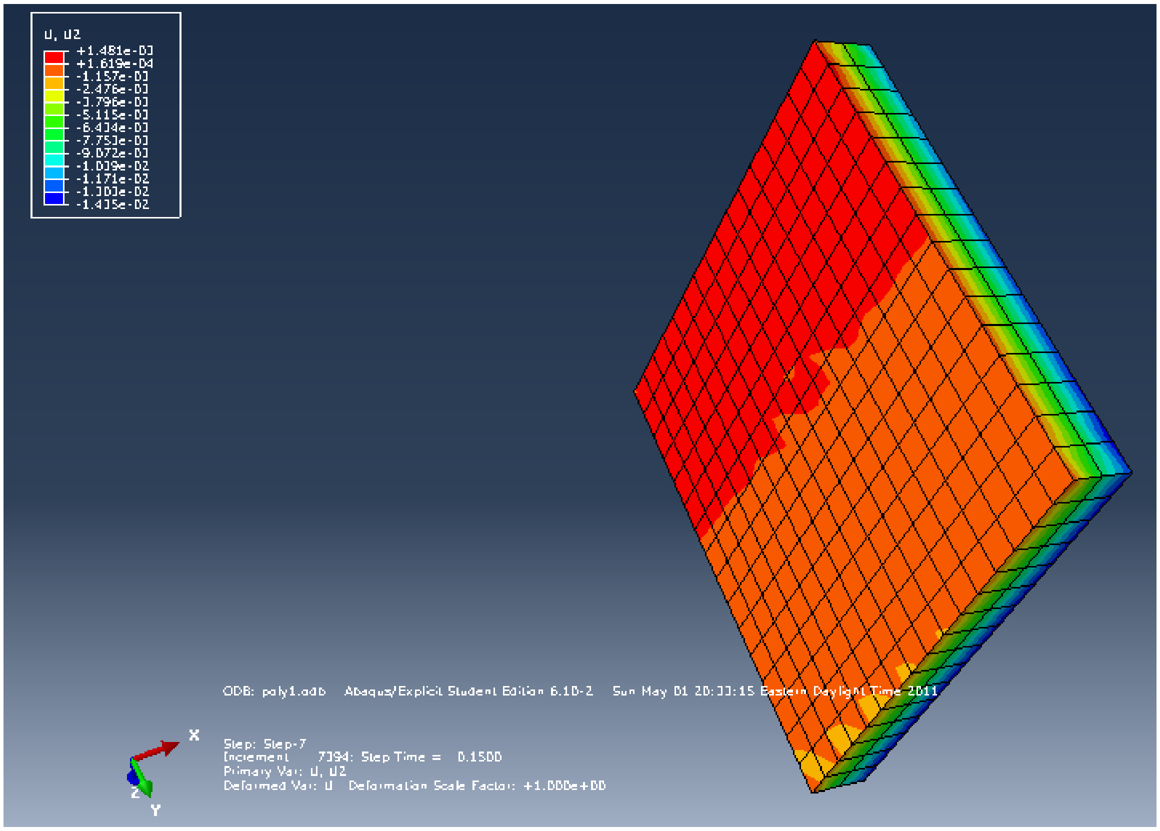


Figure 19: Displacement of Polyurethane due to a 15 N force applied at its center

The displacements for both the breast and the silicone cup were very similar as reported by the FEA analysis; however they are both slightly smaller than the displacement of the silicone sample during testing. This is likely accounted for because the silicone sample was contained in a hard plastic cup and therefore could only be displaced along the Y-axis. Therefore since the FEA allowed for the silicone to displace in multiple dimensions rather than one the displacement in the Y-direction is expected to be smaller. The density of the silicone sample was obtained from the manufacturer and our sample could have been mixed incorrectly as well causing the manufacturer density to be too high which would also cause for the displacement to be too low. Another possibility would be improper calibration of the Instron machine used for testing.

5. DISCUSSION AND CONCLUSIONS

For this project the product will not be a commercial grade teaching tool, but rather a prototype that will be used to assess the feasibility of the development of such a teaching tool for breast exams. After fabrication and testing of the many components of the device the group has determined some strengths and weaknesses of the design that will affect the way the project is carried on in the future.

5.1 FEASIBILITY ASSESSMENT

The molding technique for the breast phantom itself is particularly successful. The skin molds smoothly to the 3D printed models and is able to mimic the shape of the mold extremely well. The silicone gel chosen gives a realistic feel of adipose and glandular tissue found in a normal, healthy breast, as well as conforming to the shape of the molded skin without loss of integrity even after deep palpations. The group is confident that with more iteration, an extremely realistic breast can be created using the techniques discussed.

The main drive of this project was to determine if capacitive sensors could be used to measure forces put on a breast phantom during an examination and provide feedback to physicians. The largest issue that the group ran into was that of residual capacitance from the environment, including the examiner. If the sensors are touched with a bare finger, the software will read many thousands of "pounds" of force because the force calculations are based off a range of capacitance measured by the sensors and calibrated to represent pounds of force to the observer through the software. Since the human body holds roughly 200 pF of capacitance, and the system is measuring capacitance somewhere around 40 or 50 pF, the touch of a person affects the readings quite a bit. This residual capacitance, as well as that from the environment leads to an unfavorable signal to noise ratio. There is a lot of noise in the system, and unfortunately the current sensor array has a weak signal. Since the capacitance of our circuit is so high to start out with (it is a large system + residual capacitance) we are limited in how much we can amplify the signal before the needle is off the scale, so to speak. Though these problems seem daunting, they are not impossible to fix, and therefore the design of the system is definitely feasible. With more time all of these issues have possible solutions, which will be discussed in the recommendations for future work.

5.2 RECOMMENDATIONS FOR FUTURE WORK

5.2.1 FABRICATION OF THE BREAST MODEL

The doctors would like for the breast phantom to have masses. This particular request was outside of the scope of the project, so implanting masses that will show up on an ultrasound and will feel like tumors should be achieved in the future. A mass that is chosen has to have a dielectric constant two to three times greater than the components of the breast. A more exaggerated nipple is needed to make it look more life-like and help the students identify the different quadrants of the breast. Moreover, more iterations of the printed model are needed so that the axillary tail is more realistic. Currently, it is too wide and thick which is not a good representation of an actual tail on the breast. The phantom that was made is composed mostly of material that feels like glandular tissue and neglects to mimic the softer adipose and denser fibrous tissues of the breast. Emulating the different tissues of the breast is a more difficult task because another material in addition to silicone gel needs to be used.

5.2.2 SENSOR ARRAY AND INTERFACE

The sensors designed this semester were 256 1 cm by 1 cm squares, however not all of these squares fit underneath the phantom, due to the shape of the model and the size of the array. In order to develop more sensitivity, a different geometry with smaller sized sensors should be developed. However this also means that another microcontroller must be connected in a multiparallel array so that more than 256 sensors can be read at a time. Additionally for more sensitivity the problem of residual capacitance needs to be solved by shielding the system from capacitance from the examiner and the surrounding environment. Steps to do this could include using a non-conductive material to rest the platform on, and possibly coating the outside of the phantom with some sort of insulator. If the capacitance of the system can be reduced, then the signal can be amplified much more, improving the ability of the device to register even the lightest pressures with ease. Finally, the sensor array is currently only reading lines at a time instead of one sensor at a time. This problem stems from the fact that the microcontroller's sensor "ground" is not separated from the multiplexer's electrical "ground". Hence all 16 channels on that plate are going to the micro controller's ground whether they're switched on or off, and the microcontroller cannot tell the difference between the active channel and the remaining channels. This can be corrected by separating the ground for the multiplexer so that all the channels not being used can go to ground without interfering with the microcontroller's readings.

This device is designed to simulate the examination of a patient that is lying supine, with the breast tissue distributed evenly against the chest wall. In order to produce repeatable results for comparison, a standard examination procedure was developed (Appendix C) that should be used with all physicians when the device is implemented. This procedure will allow for checkpoints to be developed in the software that will show that the physician has palpated all areas of the breast. Using this checkpoint procedure as well as the "save data" feature of the interface will allow for the teacher to evaluate the student effectively.

5.2.3 FEA MODELING

A more realistic breast phantom could be designed using a CAD program using a more complex loft structure. A professional version of ABACUS could also potentially be used since the student version only allows for the mesh to contain 1000 nodes. More nodes create a much more complex model that takes much longer to run, however the results are superior.

6. REFERENCES

Baxter, Larry K. *Capacitive Sensors: Design and Application.* New York, NY: IEEE Press, 1997

El-Zaim H.S., and J.P. Heggers. “Silicones for Pharmaceutical and Biomedical Applications”. *Polymeric and Biomaterials, 2^{nd} Edition.* Marcel Dekker Inc. New York: 2002. pp. 81-82.

Hong, Nung-Pyo, Byung-Ki Song, Soo-Won Lee, Won-Chul Kim, Pil-Gyu Im, Jin Woong Hong. “The Electrical Properties of Silicone Gel due to Curing Condition.” IEEE International Conference. 1998.Web. 16 Oct. 2010.

LeBlond, R. F., DeGowin, R.L., Brown, D.D. *DeGowin’s Diagnostic Examination: Ninth Edition,* pp. 435-443. McGraw-Hill Companies, 2009.

Marotta, J. S., Widenhouse, C. W., Habal, M. B. and Goldberg, E. P. (1999), Silicone gel breast implant failure and frequency of additional surgeries: Analysis of 35 studies reporting examination of more than 8000 explants . Journal of Biomedical Materials Research, 48: 354–364.

Matsumura, K. and Yamaguchi, H. (2010), Elastic modulus of viscoelastic magnetic silicone gel body. Polymer Engineering & Science, 50: 857–862.

Miller, P. and S. Astley. Classification of Breast Tissue by Texture Analysis. 258-265.

Price, B. D., A. P. Gibson, L. T. Tan and G. J. Royle. “An Elastically Compressible Phantom Material with Mechanical and X-Ray Attenuation Properties Equivalent to Breast Tissue.” *Physics in Medicine and Biology* 55 (2010): 1177-1188. Print.

Ratner, Buddy D., et al. *Biomaterials Science.* San Diego: Academic Press, 2004. Print.

Replogle, Scott L. " Breast Implants: Silicone or Saline- Which is Better?" drdonnica.com. n.p. n.d. Web. 14 Nov. 2010

Saslow, D., Hannan, J., Osuch, J., Alciati, M. H., Baines, C., Barton, M., Bobo, J.K., Coleman, C., Doleman, M., Gaumer, G., Kopans, G., Kutner, S., Lane, D.S., Lawson, H., Meissner, H., Moonman, C., Pennypacker, H., Pierce, P., Sciandra, E., Smith, R., Coates, R., “Clinical Breast Examination: Practical Recommendations for Optimizing Performance and Reporting”. *CA: A Cancer Journal For Clinicians.* 54.2004 (6): 327-344. Published Online.

Severian Dumitriu. *Polymeric Biomaterials.* New York: CRC Press, 2001. Print

University of California. (2010). Human Torso Phantom for Imaging of Heart with Realistic Modes of Cardiac and Respiratory Motion. USA, US2010167251.

University of West Virginia. (2002). Computer based instrumentation for physical examination training. USA, WO0213164.

Vetto, John T., Petty, John K., Dunn, Nancy, Prouser, Nancy C., Austin, Donald F., “Structured clinical breast examination (CBE) training results in objective improvement in CBE skills”. *Journal of Cancer Education.* 17.2002 (3): 124-127. Print.

Vranjesevic, D., Schiepers, C., Silverman, D.H., Quon, A., Villalpando, J., Dahlbom, M., Phelps, M.E., Czernin, J. (2003). "Relationship Between F-FDG Uptake and Breast Density in Women with Normal Breast Tissue". *Journal of Nuclear Medicine.* 44 (8): 1238-1242.

Weintraub, Steven. "Demystifying Silica Gel." 2002. Web. 16 Oct. 2010.

"Learn About Silicon and Silicone." Silicon-Silicone. 2006. Web. 16 Oct. 2010.

"Material Safety Data Sheet." Cole-Parmer. 2010. Web. 25 Oct. 2010

"Silicone Breast Implants." JustBreastImplants. 2010. Web. 18 Oct. 2010

"Silicone Gels." Quantum Silicones. 2009. Web. 25 Oct. 2010

"What is Breast Cancer." Susan G. Komen for the Cure. 2010. Web. September 24, 2010.

.

.

APPENDIX A.

FUNCTIONS AND REQUIREMENTS DOCUMENT

APPENDIX A: FUNCTIONS AND REQUIREMENTS DOCUMENT

1. Scope

The purpose of this project is to assess the feasibility of a breast examination simulator that incorporates internal sensors that measure the physician's palpations. The project will include the development of a life-like model breast with a suitable array of embedded sensors. The variable capacitance pressure sensors will be used to quantify the location and applied pressure of each examination point. Ultimately the data from the sensors could be recorded in order to evaluate the progression of medical residents. If the feasibility is established, a follow-on project shall develop a complete simulator that could be used routinely in the Graduate School of Medicine Simulation Lab. The feasibility project must be completed by May 2011.

2. System Components

1. Pressure Sensors, based on previously studied variable capacitance sensors will be fabricated by the project team based on specifications provided by Dr. Mahfouz's research group. All of the sensor signal conditioning and computer interfacing electronics will be provided by Dr. Mahfouz's research group.
2. Real-time or near real-time software to acquire and display sensor output data will be provided by Dr. Mahfouz's research group.
3. Breast model. The skin and internal materials shall be determined upon proper investigation of the physical and mechanical properties of the human breast. The model will be fabricated by the project team in conjunction with the Simulation Lab staff.

3.Functional Requirements

For the feasibility model to address the ultimate desire of the University of Tennessee Medical Center, certain functional requirements must be met. The life-like breast model must track and graphically show the amount of pressure applied at any point on the breast model by use of a finite element model. The model should have similar mechanical and physical properties of an actual breast.

4. Technical Requirements

In order to achieve the functional requirements of the project, it is the responsibility of the group to determine the technical aspects necessary to carry out the design and fabrication of the project. Listed below are the technical requirements required to create a practical model:

4.1 The model is to be life-like, and resemble an actual breast by sight and touch.
  4.1.1 The physical and mechanical properties of each part of the breast will be researched and measured, including, but not limited to elastic modulus, dielectric constant, density, and texture.
  4.1.2 The material selection process will determine which material has the most comparable physical and mechanical properties of an actual breast, including, but not limited to: elastic modulus, dielectric constant, density, and texture.
4.2 Pressure sensors shall be fabricated to measure the breast simulator response to forces applied to the breast model through changes in capacitance.
  4.2.1 The capacitor plates shall have a specific shape, area and distance between plates selected to give the best results in resolving palpation location and strength.
  4.2.2 A dielectric material shall be selected to be used between the plates of each capacitor in order to provide the degree of capacitive sensitivity needed to

register the palpations of a physician.

4.3 The pressure sensors shall be designed and calibrated for a measurement range suitable for the overall model configuration and procedures used during a breast examination.
    4.3.1 A calibration apparatus shall be designed and fabricated that will allow the response of the overall model to be calibrated across all sequences of palpation (magnitude and location.
        4.3.1.a The apparatus will allow a specific palpation to be repeated with 5% accuracy in location and strength
    4.3.2 The capacitors shall have a capacitance calibrated from the acceptable forces, to be determined by the medical staff.
        4.3.2.a The capacitors will be calibrated with known weights.
        4.3.2.b The output data feed from the changes in capacitance will be calibrated by known forces.

4.4 The pressure sensors shall be integrated into the overall model such that they are not palpable by the medical resident during the examination.
    4.4.1 Different sensor array positions will be tested with the material for the model to ensure that the sensors are not detectable.

4.5 A FEA model of the entire breast simulator, including the sensor array, will be developed
    4.5.1 Predictive techniques will be explored using the FEA model to refine the definition of a specific palpation in terms of location and strength given a specific sensor array output.

4.6 The data from the simulator shall be collected into a database to be used for comparing medical resident's progression throughout testing.

5. Demonstration Plan

The model will be presented with an explanation of how it works, as well as the techniques used to create it. The model will be tested to ensure that the calibration of the capacitors shows an accurate pressure based on the amount of force applied to a specific area.

6. Final Deliverables

6.1 Notebook tracking all research, design, fabrication, and testing

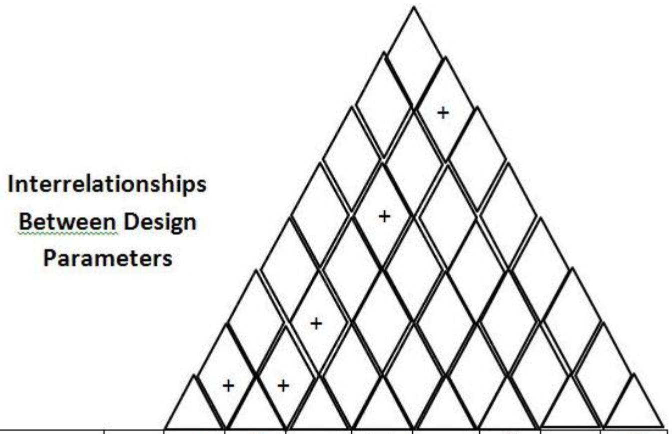
6.2 Oral presentations at the end of each semester

6.3 Detailed technical project reports at the end of each semester (Preliminary design and results; Final design and results)

6.4 Demonstration of breast model simulation

APPENDIX B.
QUALITY FUNCTION DEPLOYMENT

APPENDIX B: QUALITY FUNCTION DEPLOYMENT (QFD)



Design Parameters	Importance (%)	Wireless Transfer	Fast Reaction Time	Phantom Material	Dielectric Material	Run Report	Real-time Software	FEA Data	Sensor Distribution
Realistic Examination Simulation	25	++	++	+++	+			+	+++
Ease of Use	15	+	++			+			
Durability	10	+		--	-		--		+
Quantitative Output	15		++		+				
Low Cost	10	--	-				--		
Repeatability	25		+		++	+++	+	+	

Figure 20: QFD

The QFD was used to determine the importance of design parameters with respect to the different needs of the medical center. The most important deliverables were a realistic examination simulation and repeatability of results, so the design parameters the group focused the most energy on were a fast reaction time, a way to save data and develop a run report, and an effective sensor distribution.

APPENDIX C.
BREAST EXAMINATION PROCEDURE

APPENDIX C: BREAST EXAMINATION PROCEDURE

This device is designed to simulate the look and feel of the breast tissue of a patient that is lying supine, with the breast tissue evenly distributed against the chest wall.

1. Begin the exam at the axilla (near the armpit, see **Figure 21**), palpating with the pads of the middle three fingers in small, overlapping circular motions.
2. The exam should continue down the midaxillary line to the 5th or 6th rib [1], continuing the circular motions of the fingers and varying the pressure from light to medium to deep at each point. A vertical strip pattern should be used, where the palpations continue in a line down the body towards the feet and then back up toward the head in slightly overlapping passes [2] (See **Figure 22**). This is currently the most validated pattern for detecting masses [1], [3]. Laterally the exam must be continued all the way to the left sternal border and then up the lateral edge of the sternum to the clavicle and back across to the midaxillary line.
3. The nipple must also be palpated thoroughly but not squeezed. [1]

Figure 21: Starting point and finger placement

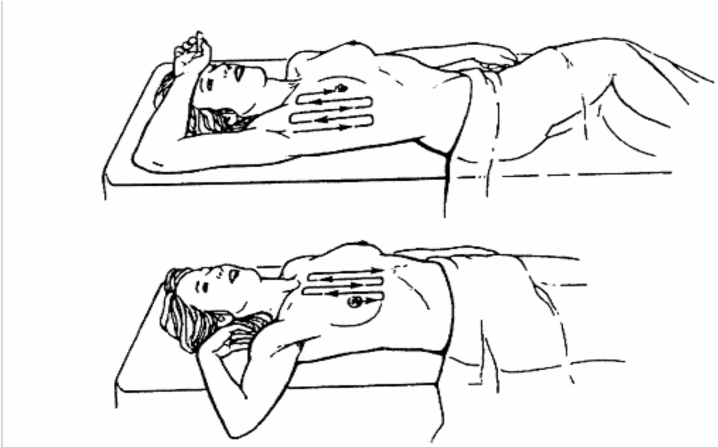


Figure 22: Examination Pattern

References

1. Saslow, D., Hannan, J., Osuch, J., Alciati, M. H., Baines, C., Barton, M., Bobo, J.K., Coleman, C., Doleman, M., Gaumer, G., Kopans, G., Kutner, S., Lane, D.S., Lawson, H., Meissner, H., Moonman, C., Pennypacker, H., Pierce, P., Sciandra, E., Smith, R., Coates, R., "Clinical Breast Examination: Practical Recommendations for Optimizing Performance and Reporting". *CA: A Cancer Journal For Clinicians.* 54.2004 (6): 327-344. Published Online.
2. LeBlond, R. F., DeGowin, R.L., Brown, D.D. *DeGowin's Diagnostic Examination: Ninth Edition,* pp. 435-443. McGraw-Hill Companies, 2009.
3. "Breast and Axillae: Examining Female Breasts."Bates' Visual Guide to Physical Assessment 9th Edition, Volume 6.

APPENDIX D.
CALCULATIONS

APPENDIX D: CALCULATIONS

Beginning capacitance: $C = \frac{\varepsilon_o \varepsilon_r A_{int}}{d_o}$

A_{int} is the area of intersection of the capacitive plates

ε_o is the electric constant (8.854×10^{-12} F m^{-1})

ε_r is the relative dielectric constant. For polyurethane, it is about 3.5 mV for 1kHz

d_o is the thickness of the dielectric material with no change in displacement.

Once a force is placed on the sensor, a change in the thickness, Δd, occurs: $\Delta d = d_o - d'$

d' is the thickness during the force.

Now that the change is d is known, it must be compared to the stress that is causing the displacement. By definition, $\varepsilon_z = \frac{d_o - d\prime}{d_o}$.

ε_z is the strain in the z-direction

$\varepsilon_z d_o = d_o - d' = \Delta d$

$\Delta d = \varepsilon_z d_o$

Also by definition, $\sigma\varepsilon = E$.

σ is the stress applied over a certain area in the z-direction.

E is the Young's modulus.

For our calculations, $\varepsilon_z = \frac{E}{\sigma_z}$.

σ_z is the stress applied by the Instron machine over an area of 0.00127 m^2.

E is the Young's modulus found from the preliminary testing of the polyurethane.

The stress in the z-direction was calculated by the force exerted on the sensor by the Instron machine over its known area of 0.00127 m^2: $\sigma_z = \frac{F}{A}$.

Finally, the change in capacitance can be found by substituting each of these values:

$$\Delta C = \frac{\varepsilon_o \varepsilon_r A_{int}}{d_o\left(\frac{E}{\sigma_z}\right)}.$$