DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN–MADISON

Probe-Placement Fixture for Microwave Ablation

Mid-Semester Report

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Team Members

Tej Patel – Team Leader
Kaitlyn Gabardi – Communicator
Tyler Davis – BWIG
Cody Kairis – BPAG
Mitchell Resch – BSAC

Client

Dr. Susan Hagness
University of Wisconsin Philip Dunham Reed Professor of Electrical Engineering

Advisor

Dr. Beth Meyerand
Chair, Department of Biomedical Engineering

Table of Contents

1. Abstract

Microwave ablation is a type of thermal therapy being used to treat the kidney, bone, liver, and lung cancer. Although this process has worked for these types of cancers, it is currently being researched in hopes of being a successful treatment for other types of cancer. Microwave ablation treatment denatures and destroys cancerous cells using the heat generated by

microwaves. The power of microwaves is delivered to the cells through an antenna, and monitored through small temperature probes. This technique, if proven effective, would be a preferred method for future tumor treatments because it prevents many side effects that traditional treatments pose for many patients. The goal of this project is to design a fixture for microwave ablation probe placement that can be easily used by researchers during experimentation. In order to test the design, the probe-placement system will be tested using ex vivo tissue from the liver.

2. Introduction

2.1. Problem Statement

The problem that the client, Dr. Susan Hagness, has presented is that a probe-placement fixture is needed to hold the temperature probes and ablation antenna currently being used to test tissue samples. The current design takes an immense amount of time to set up, and take down. In order for this procedure to be successful, the entire procedure has to be less than 15 minutes, leaving roughly 2-3 minutes to set up our device. Although time is a pressing issue, the other problem is accuracy. In the current design, the antenna is held by a clamp, while the other temperature probes are held up by the tissue conforming around them. Therefore, the probes are unguided while in the tissue and not equally distant from each other.

2.2. Background

2.2.1 What is Microwave Ablation

Microwave ablation uses different intensities of electromagnetic energy to destroy cancer cells [3]. The heat generated by microwaves is transferred through a small antenna that is inserted through the tissue. The antenna is extremely small compared to previous treatments, so that the surgery itself is minimally invasive, and the patient will have a quicker and safer recovery [2]. As the energy is transferred through the antenna into the tissue, the malignant tumor cells are destroyed.

In research studies, different heating patterns were required for different types of cancer. Some tumors required a high frequency of energy, while some cells required a lower frequency [1]. The different frequencies, therefore, have to be monitored for each specific case. Currently, additional research is being performed to monitor this issue.

2.2.2 Implementing Microablation in Breast Cancer

In Dr. Hagness' research, she wanted to explore the possible effects of microablation on various tissue types in hopes of applying it to different types of cancer[4]. She and her team wanted to specifically do research on implementing microablation in breast cancer. As mentioned before, different types of cancers required different types of treatment. Therefore, her team continued to work on this issue.

Her research showed that microablation could possibly be implemented in breast cancer. She discovered that an issue in this treatment was the insertion of the antenna. In order to prevent damage to the tissue, the antenna would have to be small enough to be used to a minimally invasive incision [3]. As a result, the original antenna was made narrower. In order to deliver enough treatment to the cells, a higher frequency of electromagnetic energy was used, and this also proved to deliver the same treatment before; by using a bigger antenna and lower frequency of energy.

After this discovery was made, Dr. Hagness and her team decided that it would be possible to deliver this treatment for breast cancer patients.

2.2.3 Current Procedure for Research

In order for microablation to be implemented in breast cancer, an immense amount of research has to be done. Currently, Dr. Hagness' lab have been working on testing microablation using mastectomy samples.

To monitor the temperature of the tissue, four fiber-optic temperature probes are inserted into the issue [4]. The ablation antenna is inserted into a small hole drilled next to the temperature probes, and is held in place by a clamp connected to a ring stand on the table. The temperature probes are roughly incremented within two centimeter of the ablation antenna.

One of the main flaws with this procedure is the accuracy of the probes, and the time the procedure requires [4]. Currently, the procedure takes a long time setting up and taking everything down, and the temperature probes are not equal distance from each other or parallel to the antenna. Another requirement given by the client was that the temperature probes need to be at a certain depth within the tissue to give accurate data. It is important that the procedure does not take over 15 minutes, because having the tissue sample out in room temperature for that amount of time could damage the tissue. As seen from Figure 1 below, the temperature probes are not held by anything, other than the tissue itself.

For this project, these issues were important to solve in order to be successful in having accurate results, and overall safety of the issue during research.

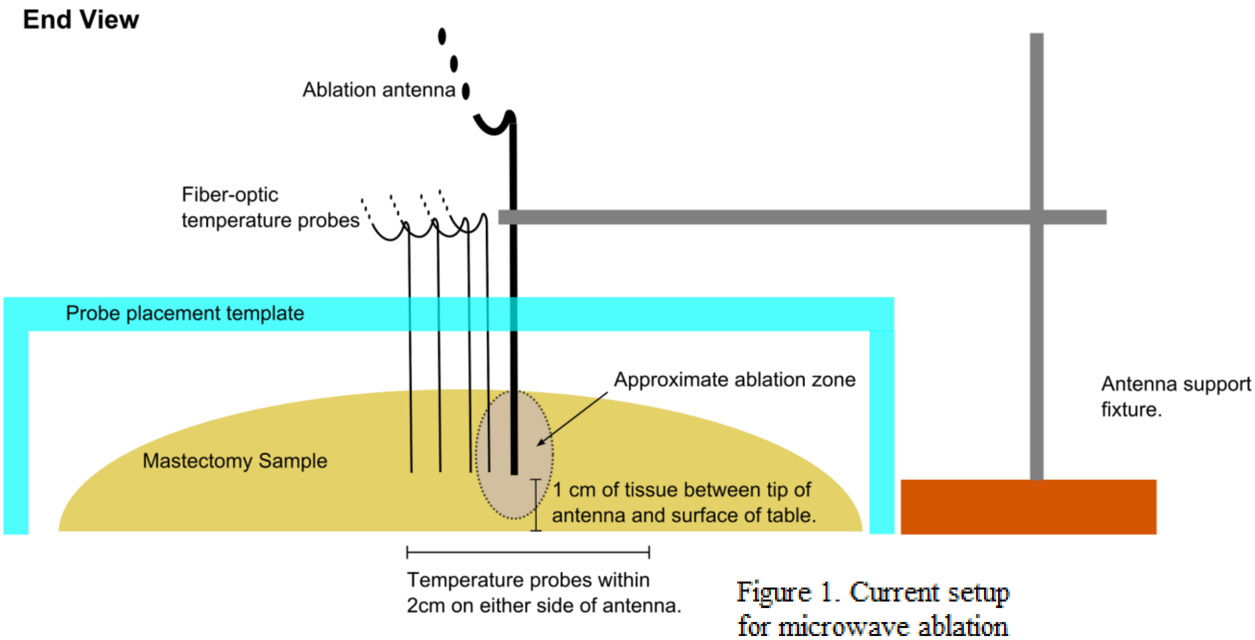

Figure 1. Current setup for microwave ablation

2.3. Product Design Specifications

The client for this project, Dr. Susan Hagness, wanted the team to develop a fixture for placement of temperature probes to be used in microwave ablation. The temperature probes must be at known distances from the antennae (~0.5cm increments and all within 2cm). The probes must be parallel to the ablation antenna and inserted at known depths within the mastectomy sample. The design must also not interfere with the the tissue sample undergoing ablation. The design should be easily set up and taken down, as the time frame for the ablation is limited. Achieving these goals will allow researchers to accurately measure the temperature induced by microwave ablation. Ultimately, accurate temperature readings ensure that the exposed tissue is not damaged.

2.4. Design Possibilities

The team explored three possible designs to fix the temperature probes at a known distance. It was suggested to use 3D printing or table top supports would be used to insert the temperature probes at known distances. The next section outlines the possible designs that the team explored.

3. Designs

3.1 Design 1 – Table Top Stand

The first design is modeled after a table. We chose four legs for this design to give the table sturdiness and prevent as much tipping as possible. With dimensions of 20 cm wide, 30cm long, and 15 cm high the table design would allow for the mastectomy sample to sit underneath the table without the legs of the table touching the material. This is important because if the tissue is touched by anything other than the needles, antennae, and temperature probes, the tissue

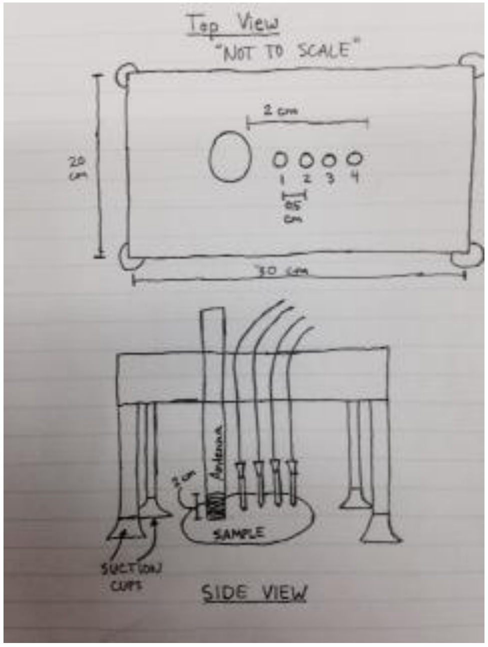

Figure 2. Table Top Stand

will not be able to be used again. Suction cups will be added to the feet of the table to stop the table from sliding or tipping over onto the the mastectomy sample and ruining its integrity for future research.

The top of the table design would be machined with one larger guide hole for the antenna, and four smaller holes with a diameter of 1.3 mm that serve as rough guides for needle insertion and hold the needles once they have been removed from the tissue. Our client will simply need to place the larger hole for the antennae over ablation point, and then use the guide to place the antenna. They will then have to place the needles for the temperature probes by threading the fiber optic cable through the smaller holes. Unfortunately, the needles that puncture the holes for the temperature probes will still be placed by hand. The needles must be removed from the tissue to avoid false temperature readings. The smaller holes in the table top are to hold the needles once they are removed from the tissue.

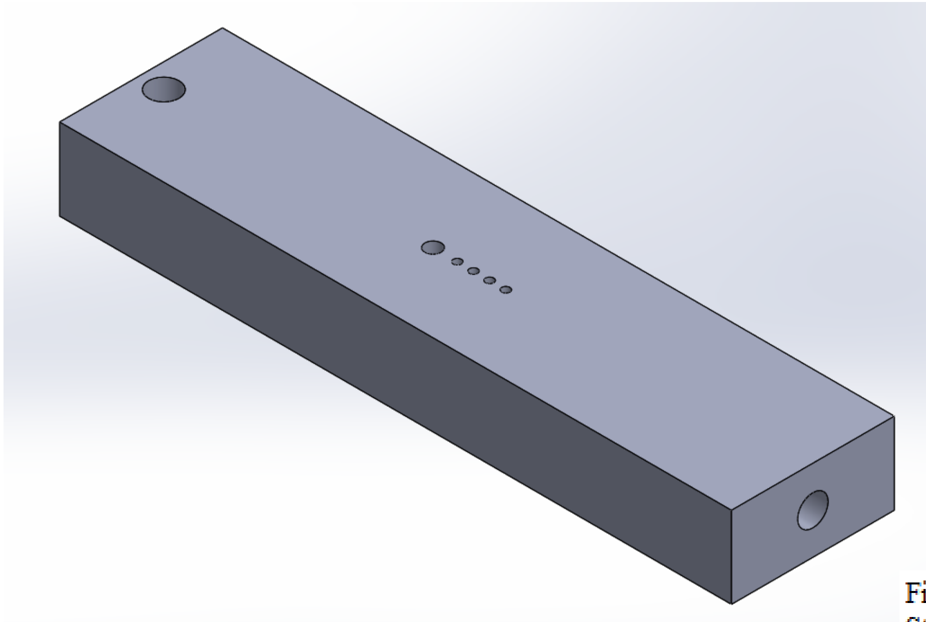

Figure 3. Clamp Stand Probe Fixture

3.2 Design 2 – Clamp Stand Probe Fixture (3D-printed)

The second design is an accessory for common lab clamp stand. The hole located on the bottom right of the drawing will be threaded for a metal rod to be placed inside it. The rod will then be slid into a clamp on the clamp stand. After the measuring device is secured to the clamp stand, the device will sit over top of the tissue sample with the help of a support rod/level bar that will be in the hole on the far left of the drawing. The hole will be threaded, allowing for easy adjustability of the rod. The level bar can be adjusted to control the depth of the needle and the antenna in the sample since the dimensions of the tissue sample will be unknown until the procedure.

Once the clamp stand is set in place so the antenna guide (the larger hole) is over the site the ablation will occur and the level bar is set so the probes and the antenna will reach the correct depth in the tissue, the placement of the ablation antenna and the temperature probes can begin. First the researcher will place the needle needed into the large hole to make a guide hole for the ablation antenna. The ablation antenna can then be put into place.

After the ablation antenna is in place, the needles for the temperature guides can be placed into the guide holes. The fiber optic cable with the temperature probes on the end can then be threaded through the hollow needle into the tissue sample. The needles can then be removed from the tissue sample to avoid tampering with the temperature readings. Once the needles have been removed, the procedure can begin.

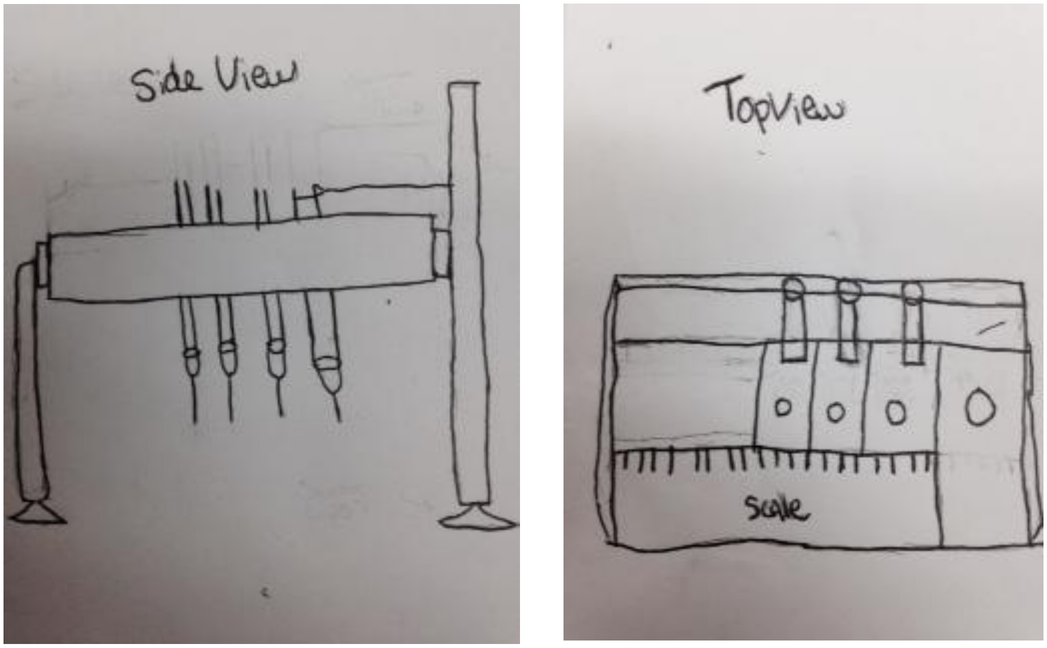

Figure 4. Bridge Probe Guide

3.3 Design 3 – Bridge Probe Guide

The final design is similar to the first design, but implements some new ideas to increase accuracy.

Instead of being a table, this design is called the bridge because it only has two legs. The tissue sits underneath the bridge the same way as it did with the table, keeping it safe. The suction cups are added to the base to help avoid tipping and to counteract the unstable nature of the two legged bridge. Once the probe is placed in the proper position for the procedure, the suction cups can be pushed tight to the table to lock the bridge in place.

The top view shows the adjustability of the probe placement. The holes for the temperature probes are machined through block that lie on sliders. The sliders can be slid along a rail system and clipped into place by weld clamps so they will not move when the needles are being placed. The scale will fixed on the structure so the researchers know which distance the probes are placed if they are adjusted. This adjustability allows for the researchers to collect different sets of data if they choose.

The needle insertion for the temperature probes will be guided. The researcher will place the guide needle for the ablation antenna through the guide hole for the antenna, remove the needle and replace it with the antenna just like with the table. The guide needles for the temperature probes will be placed into the tissue using the guide hole. The needles will be attached to hollow guide rods, similar to a gutted mechanical pencil. The guide rods ensure the temperature probes are placed parallel to the ablation antenna. The fiber optic cables can then be threaded through the needles to be placed into the tissue. Once the probes are in place, the needles can be removed and the researchers can begin their data collection.

3.4 Design Matrix

Design Criteria	Design 1 Table Top Support	Design 2 Clamp Stand Device	Design 3 Bridge Probe Guide
Efficacy and Accuracy (30)	10	30	20
Safety of Tissue (20)	18	16	12
Ease of Use/Set Up Time (20)	20	14	16
Adjustability (15)	1	10	8
Ease of Fabrication (10)	6	8	2
Cost (5)	5	2	3
Totals (100)	60	80	61

Figure 5. Design Matrix. This is the design matrix for the three different stands. The winners for each respective criterion are highlighted in blue and the overall winner is highlighted in green.

A design matrix (Figure 5) was created with the three aforementioned designs. Designs were ranked based on six categories in order of decreasing weight: efficacy and accuracy, safety of tissue, ease of use/set up time, adjustability, ease of fabrication, cost.

Efficacy and Accuracy was evaluated based on whether or not the temperature probes could be inserted at proper distances in the tissue. It was determined to be the highest weighted category, as the location of each temperature probe relative to the antennae needs to be precise. Specifically, the temperature probes need to be incremented at 0.5 cm intervals in the tissue sample. The Clamp Stand Device won this category with a maximum score, since it incorporates a level bar that ensure the probes are inserted at the proper depth (as well as location in the tissue). The Bridge Probe Guide finished with the second highest score in this category, as it contains guides that ensure the proper placement of the temperature probes relative to the antennae. However, the Bridge design does not include a method for fixing the depth, thus it scored lower than the Clamp Stand Device. Finally, the Table Top device scored the lowest in this category, as it does not ensure that the temperature probes are placed at proper distances from the ablation antennae.

Safety of tissue was determined to be the second highest priority, and was gauged on whether or not the probe fixture device would interfere with the tissue sample. This category is relatively high in weight because the client requested that tissue samples not be contacted. In addition, contact with the tissue sample may cause any data obtained from testing to be skewed. The Table Top Support device scored the highest in this category, as this fixture is positioned high enough over the samples such that it would not contact it. In addition, the design features suction cups to keep the stand in place, thus preventing the device from sliding/falling into the tissue. The Clamp Stand probe fixture scored the second highest in this category. The Clamp Stand fixture would be secured via a screw to the clamp stand on one end, and by a measuring/support bar on the other. However, the clamp stand needs to be moved to the proper height, and could come in contact with the tissue if the operator is not careful. Lastly, the Bridge Probe Guide design score the lowest in this category, as it only contains two legs of support, causing it to be prone to fall over.

Ease of use/Set up time was determined to be of equal importance to the safety of the tissue. This is because the entire microwave ablation procedure takes about 15 minutes, thus leaving on 2-3 minutes for setup and takedown before the tissue is damaged. The Table Top Support design scored the highest in this category, as the setup includes placing the fixture device over the sample and inserting the antennae/probes into the sample. The second highest scoring device was the Bridge Probe Guide probe holder. This design requires slightly more time to set up: the device needs to be placed over the tissue, the probe holes need to be slide to the desired location and locked, and the antennae/probes inserted into the tissue through the guide holes. The lowest scoring design in this category was the Clamp Stand design. This design requires the highest amount of setup time: the fixture needs to be attached to the clamp stand, the clamp stand needs to be set to the proper height, and the probes/antennae need to be inserted into the tissue.

Adjustability was rated based on a device's capability to allow vertical flexibility. Since the horizontal distances to the probe are small, a device's adjustability in that direction was not as important. The device that rated the highest in this category was the Clamp Stand design. The Clamp Stand design can be adjusted via screw to best suit the tissue. In addition, this design includes an adjustable measuring bar, which allows control of the depth of the temperature probes. The Bridge Probe Guide design scored the second highest, as it allows the temperature probe holes to slide horizontally. However, this horizontal adjustability is not as important as the vertical adjustability of the Clamp Stand design. Finally, the Table Top Support design scored the lowest in the adjustability category as it contains no adjustable parts.

Ease of fabrication was the second lowest weighted category. Ease of fabrication basically measured how easily a device could be constructed. The highest scoring device in this category was the Clamp Stand design. The Clamp Stand design implements 3D printing in the manufacturing of the design, thus it does not require a high level of fabrication knowledge and skill. The second highest rated device in this category was the Table Top Support design. This design would require some level of machining of the guide holes, as well as insertion points for the legs. The suction cups would have needed to be attached to the legs as well. The lowest rated design in this category was the Bridge Probe Guide Design. This device scored the lowest mainly due to its implementation of rails and locks for the holes. While this is possible to construct, it is beyond the capabilities of a majority of the group members.

Cost was determined to be of the least importance in this experiment, as the budget of $150 would be an ample amount to create a device to fix the temperature probes. The design that scored the best in this category was the Table Top support design. This device requires a small amount of material to be used for the guide part of the design, as well as four legs and suction cups to hold the design in place. Since the amount of material required would be rather small, this design would not cost very much to construct. The next highest scoring design was the Bridge Probe Guide design. While this design is similar to the Table Top design, it would also require guides for the probes to be inserted, as well as clamps and a rail system for the adjustable holes. Finally, the Clamp Stand design scored the lowest, largely in part to the 3D printing aspect. The clamp stand and measuring/support bar would be rather inexpensive, however; we predicted that 3D printing would cost more than assembling the two other designs.

4. Future Work

The team plans on narrowing in the design specifications by getting exact diameters of the new temperature probes being used by their client. With this information they can 3D model the device more precisely and get closer to their eventual goal of using a 3D printer to create the probe placement device. Upon 3D printing the model, the team plans on adding on the measurement/level bar that assures the device user that each probe and the ablation antenna are the desired depths within the mastectomy sample.

Once the device is constructed, the team could work with research teams to implement the device in microwave ablation experiments. Ultimately, the team hopes that this device allows the furthering research of microwave ablation in breast tissue.

5. Conclusion

The team has been approached by Dr. Susan Hagness to develop a temperature probe fixture device to be used in microwave ablation research. In order to perform valid research on the effects of microablation on the tissue, the temperature sensors must be inserted into the tissue at known distances. However, there is no available device that allows for the insertion of temperature probes at known distances from the antennae. Having a temperature-probe fixture device is a must if microwave ablation research wants to make any progress.

Specifically, the device needs to be able to fix four temperature probes at 0.5 cm increments from an antennae delivering energy to the tissue. The probe fixture needs to be setup and taken down quickly, as the timeframe for the entire microablation experiment is fifteen minutes. The current method of approximating the distances by eye has proven to be inaccurate and ineffective in research. Thus, the team must design and fabricate a temperature probe fixture to ensure accurate tissue temperature readings.

6. Acknowledgements

The team would like to thank: Our advisor, Dr. Meyerand, for her guidance thus far in our design process, our client, Dr. Susan Hagness for submitting the project and being open and helpful throughout the design process, graduate assistants Owen Mays and Luz Neira for their input during the brainstorming phase of the design, and finally, the entire BME department for providing helpful resources and the opportunity to work on these design projects.

7. References

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[3] S. Gordon. (2014, October 15) *Novel antenna breaks down barrier in tumor ablation technology* [Online]. Available: htttp://www.engr.wisc.edu/news/archive/2014/oct15-novel-antenna-ablation.html

[4] S. Hagness, private communication, September 2015

8. Appendix

8.1. Product Design Specifications

Function:

Microwave ablation is a type of thermal therapy being used to treat the kidney, bone, liver, and lung cancer. Although this process has worked for these types of cancers, it is currently being researched in hopes of being a successful treatment for other types of cancer. Microwave ablation treatment denatures and destroys cancerous cells by using the heat generated by microwaves. The power of microwaves is delivered to the cells through an antenna, and monitored through small temperature probes. This technique, if proven effective, would be a preferred method for future tumor treatments because it prevents many side effects that traditional treatments pose for many patients.

The goal of this project is to design a fixture for microwave ablation probe placement that can be easily used by researchers can during experimentation. In order to test the design, the probe-placement system with be tested using ex vivo tissue from the liver.

Client Requirements:

- Operate quickly and efficiently due to the clients 15 minute time limit with the tissue sample.
- Must be able to easily maneuver and insert the temperature probes and antenna efficiently into the tissue sample.
- The mastectomy sample must remain in good condition after the experiment.
- Each probe has to be equally 0.5 cm apart, and 2 cm from the antenna in parallel. If possible, would like the option to make the distance variable.
- The probes perpendicular from the mastectomy sample, but would like the potential in from different angles is desired if possible.
- Maximum Diameter should be 20 cm to hold all of the temperature probes.

Design Requirements:

1. **Physical and Operational Characteristics**

a. Performance requirements: The device must be able to insert a microwave ablation probe and fiber optic temperature probes into a mastectomy. The device must also be able to position the temperature probes an accurate distance from the ablation probe, while remaining at the same depth and parallel to the ablation probe.

b. *Safety:* Our device must be functionally stable so it avoids all contact with the tissue. The mastectomy must remain intact and testable after the experiment is completed.

c. *Accuracy and Reliability:* Design must function in a way that it can be used for numerous experiments to provide consistent and accurate results for the research assignment.

d. Life in Service: Probe positioning device must be continuously effective throughout its implementation.

e. Shelf Life: The probe positioning device must last for multiple years.

f. Operating Environment: The device will be operated on a small lab table held at standard atmospheric conditions and temperature. The device will be positioned 10-25 cm above the mastectomy sample during the 15 minute procedure.

g. Ergonomics: The device must be easy to use after a quick briefing. It must also be quickly assembled and disassembled.

h. Size: The probe placement device must be able to fit on a small lab table approximately 120 cm by 120 cm and be no more than 10-25 cm above the mastectomy sample.

i. Weight: The maximum weight of the device should not exceed five kilograms.

j. Materials: The probe fixture must be sterilizable. Have access to sample antennas and fiber-optic probes.
k. Aesthetics, Appearance, and Finish: Aesthetics and appearance of the design is not of particular importance.

2. Production Characteristics:

a. Quantity: One fully operational probe-placement fixture will be produced.
b. Target Product Cost: The budget is $150.

3. Miscellaneous:

a. Standards and Specifications: No standards or approvals are required.
b. Customer: The research team conducting the experiments must be able to use the device.
c. Patient-related Concerns: The device must be sterilizable.
d. Competition: There are currently no devices in the market that act as a probe placement fixture for microwave ablation.

2. Production Characteristics:

a. Quantity: One fully operational mite trap device will be produced.
b. Target Product Cost: The budget for this product is set at $1000.

3. Miscellaneous:

a. Standards and Specifications: No standards or approvals are required.
b. Customer: Primarily students and researchers in Drosophila labs.
c. Patient-related Concerns: The ability to be sterilized is prefered (not required).
d. Competition: There are many different ways to kill or segregate mites such as freezing them, autoclaving them, or using pesticides, present in the market today. However, there has not been a mite trap or passive removal technique designed specifically for use in an incubator.