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A Pre-Operative Model for Surgical Practice in Medical Education

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Abstract

In surgery, accuracy and precision are important to prevent potential errors in the operating room. Future surgeons and current medical students therefore need to be comfortable with surgical practice and clinical anatomy. Scalpel training is an area where individuals may wish to enhance their skills. This paper describes a pre-operative model for surgical practice in medical education, with stomach and melanoma tumor models as examples. These two models are important because surgeries involving stomach and tumor removal are commonly performed. We demonstrate the utility of the model kit with a few magnetometers reading data from Arduino Uno, which will then transmit these data points to Python for data visualization. The uniqueness of this model kit lies in its immediate visual feedback of the user's scalpel movements while using realistic 3D organ models. This model kit has a focus on reusability, low manufacturing costs, and clinical relevance. This system is beneficial for those in the medical field who wish to improve their scalpel skills through iterative learning.

Keywords: *Pre-operative Practice, Medical Education, Arduino Uno, Scalpel Accuracy, Magnetometer, Stomach, Melanoma.*

1. Introduction

It has been reported that approximately 310 million patients undergo surgeries per year globally [1]. Of these, 4% of patients die as a result of surgical complications, 15% experience some type of post-operative morbidity, and nearly 8 million patients die annually from surgical procedures [1]. A single mistake during surgery can exacerbate an existing condition or create new complications. To minimize errors, surgeons typically prepare by reviewing and discussing the procedure with medical staff and outlining the steps in advance.

As medical students and future surgeons become more familiar with surgical specialties and clinical anatomy, it is essential to provide effective tools to help them refine their techniques. Scalpel training is one area where individuals may wish to enhance their skills. Therefore, it is crucial to offer tools that provide immediate, comprehensive feedback on scalpel usage. This necessitates the development of training organ models that can offer valuable feedback to medical students while remaining easy to use and efficient.

The Pre-Operative Model for Surgical Practice (Pre-Op Practice) is a model kit and feedback system designed to provide medical students with advanced scalpel training [2]. It features a reusable, realistic 3D organ model for practice that delivers immediate feedback on cuts made. This product offers valuable opportunities for additional practice outside of mandatory classroom sessions. Consequently, all medical schools and teaching hospitals that train students are potential and viable users.

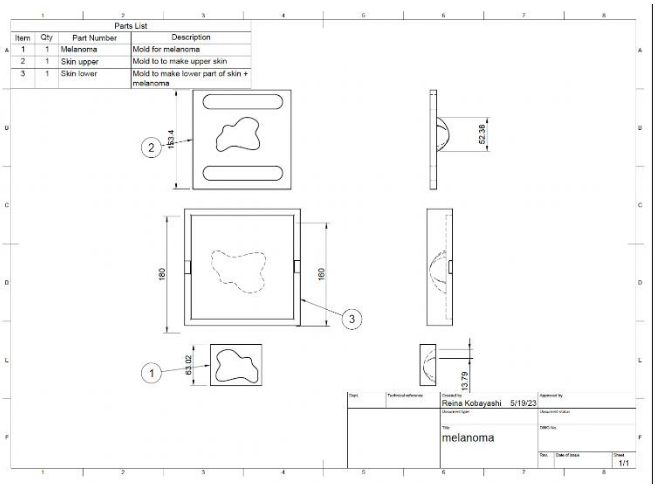
To demonstrate its utility, we have used a stomach model and melanoma tumor model. The stomach model was selected since approximately 17% of all inpatient surgeries in the United States involve the digestive system [3]. The melanoma tumor model was selected because, despite representing only about 1% of diagnosed skin cancers each year, it causes the majority of skin cancer-related deaths [4,5]. Furthermore, surgical removal remains one of the most frequently used treatments, requiring a high degree of precision and accuracy to ensure effective excision and reduce the risk of recurrence [4,5].

This paper presents a low-cost model kit designed to allow users to move a scalpel, visualize its movement, and instantly detect any deviations from a pre-defined path. Currently, the kit is tailored for stomach and melanoma models, but it holds the potential for adaptation to other organ models.

2. Materials and Methods

2.1. Design Configuration

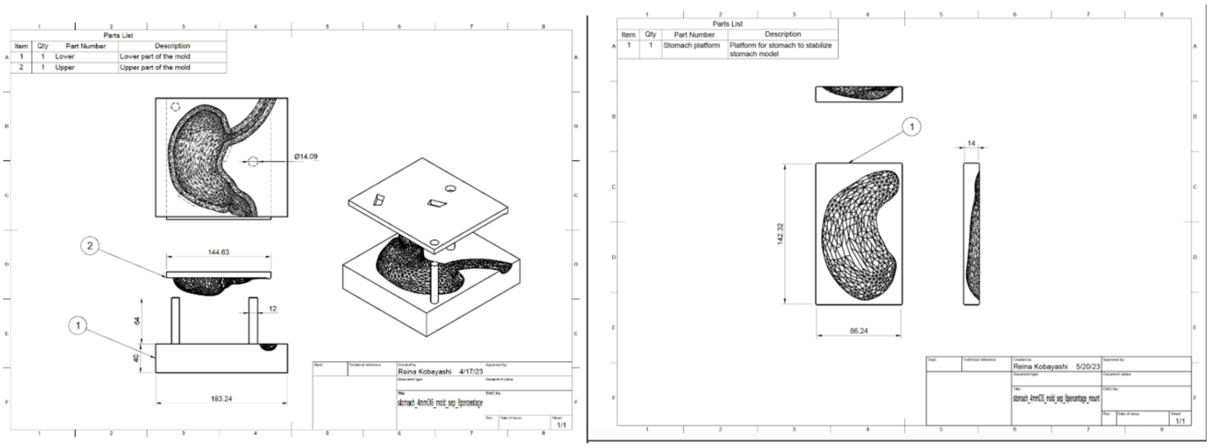
The Pre-Op Practice model kit consisted of three primary components: 1) a 3D-printed cast to silicone mold the 3D organ model, either the melanoma tumor or stomach, 2) a platform for each organ model featuring pegs for stabilization, and 3) an integrated box housing all components. Figure 1 shows the 3D-printed PLA cast for the melanoma tumor model, which includes a tumor (labeled 1), an upper skin layer (labeled 2), and a lower skin layer (labeled 3). Once cast, the melanoma tumor model becomes a solid silicone piece, different colors were used to distinguish the tumor from the surrounding skin layers. The stomach model, on the other hand, was created using a single 3D-printed PLA cast [2].



Item	Qty	Part Number	Description
1	1	Melanoma	Mold for melanoma
2	1	Skin upper	Mold to to make upper skin
3	1	Skin lower	Mold to make lower part of skin + melanoma

Figure 1: Assembly Drawing of Melanoma Tumor Cast.

For each model, a shallow platform is 3D-printed, as illustrated in Figure 2 for the stomach model. This platform elevates the silicone mold above the integration box, ensuring proper positioning during use. Like the other components, this platform was also 3D-printed using PLA [2].

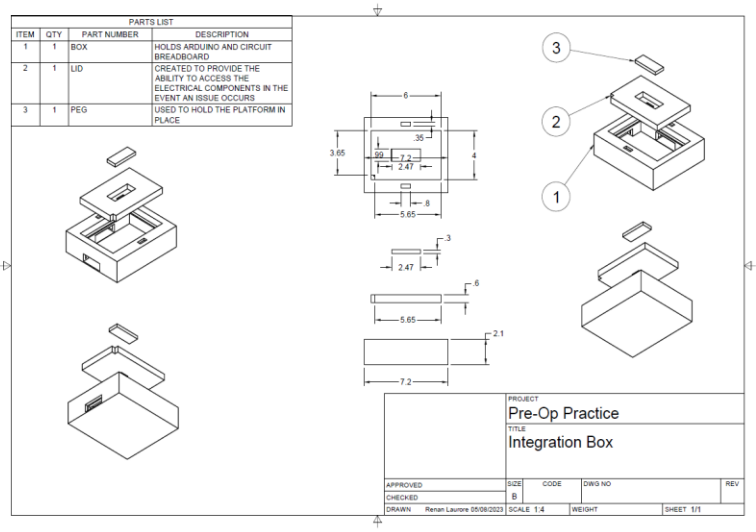


Item	Qty	Part Number	Description
1	1	Lower	Lower part of the mold
2	1	Upper	Upper part of the mold

Item	Qty	Part Number	Description
1	1	Stomach platform	Platform for stomach to stabilize stomach model

Figure 2: Assembly Drawing of the Stomach Cast.

The final structural component of our product is the integration box, which consists of three parts: the box (labeled 1), the lid (labeled 2), and the pegs (labeled 3). The box houses the Arduino and other electrical components. An opening on the side of the box allows for computer connection, enabling power to the Arduino and sensor calibration with the accompanying computer application. Small perforations on the top of the box ensure that the magnetometers function properly while minimizing exposure. The lid provides easy access to the electrical wiring and supports the peg system. The pegs are eventually glued to the platform and offer structural support for the silicone mold during practice.



ITEM	QTY	PART NUMBER	DESCRIPTION
1	1	BOX	HOLDS ARDUINO AND CIRCUIT BREADBOARD
2	1	LID	CREATED TO PROVIDE THE ABILITY TO ACCESS THE ELECTRICAL COMPONENTS IN THE EVENT AN ISSUE OCCURS
3	1	PEG	USED TO HOLD THE PLATFORM IN PLACE

Figure 3: Assembly Drawing of the Integration Box.

To assemble the Pre-Op Practice kit, the user must gather the integration box and separate the pegs. The user should attach the peg(s) to the chosen model platform using tape or super glue. Once secured, the platform should be placed onto the integration box. The realistic 3D organ model should be positioned onto the platform.

2.2. 3D Printing

3D printing is an automated manufacturing process that enables the creation of three-dimensional objects from CAD files, typically using plastic through fused deposition modeling (FDM) [6]. Ultimaker 3D printers were utilized to prototype organ shells and an integration box for molding purposes. These printers, which use fused filament fabrication (FFF), offer a cost-effective and efficient method for producing parts based on our 3D CAD designs. However, to replicate organs, the material properties must closely resemble real tissue. The available 3D-printable materials proved too rigid compared to the native human stomach, as shown in Table 1. As a result, the design team opted to mold silicone to create organ models that more accurately simulated the human stomach. The model was designed with a hollow, tube-like structure to better replicate the sensation of cutting into a real stomach. 3D printing allowed the fabrication of complex parts that would have been otherwise difficult to create.

Table 1: Tensile modulus and ultimate tensile strength for human stomach and different materials. Green corresponds to material used in FDM 3D printers, blue corresponds to molding materials.

	Tensile modulus	**Ultimate tensile strength**
Human stomach	1.92 kPa	0.7 MPa (axial) 0.5 MPa (transversal)
TPU	12 MPa	26 MPa
Flexible 80A	–	3.7 MPa
Elastic 50A	–	1.61 MPa
Silicone	–	70 - 10,300 kPa
Polyurethane	0.621 - 5.50 GPa	28 - 96 MPa

2.3. Silicone Molding Process

The process for molding the stomach and melanoma (skin) models is outlined in Figure 4. The user begins by following a general set of steps, then selects a specific method depending on whether they are molding a melanoma (skin) or stomach model. An account of the entire procedure, including all attempts for this project, is documented in the design history file [2].

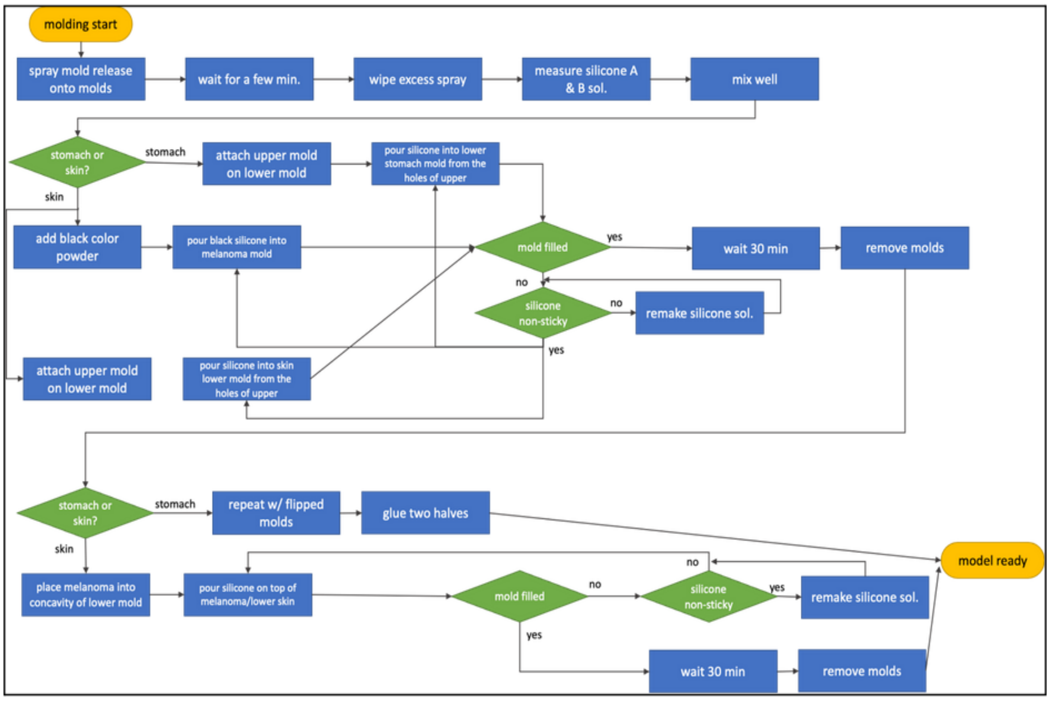


Figure 4: Flowchart of molding stomach and melanoma model.

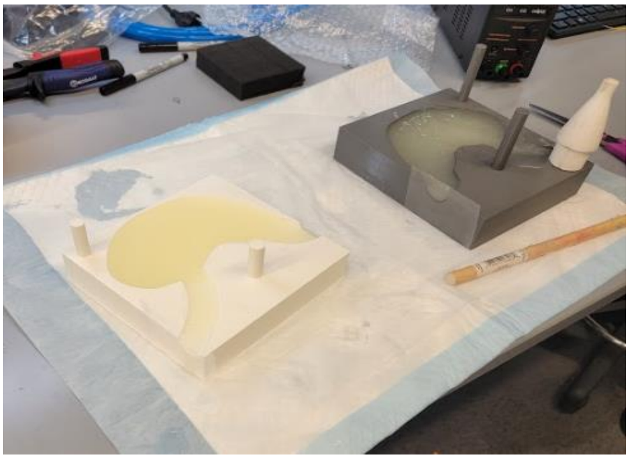


Figure 5: Creating two silicone molds through 3D-printed shell.

2.4. Hardware Description

The final circuit schematic is shown in Figure 4. The Arduino Uno currently requires a computer for power. The magnetometer's circuitry is relatively straightforward, consisting of five main pins: Vin, 3V, GND, SCL, and SDA. In Pre-Op Practice, connecting a single magnetometer to the Arduino involves linking Vin to the 5V power source, GND to the Arduino ground, and SCL and SDA to their respective pins on the Arduino. The SCL is the 'serial clock pin' that presents clock data in an interval, and the SDA is the 'serial data pin' that sends data between devices. Future iterations could involve connecting multiple magnetometers, which would necessitate a more complex circuit design. The current tlv493d triple-axis magnetometer is described in further in section 2.5 Magnetometer.

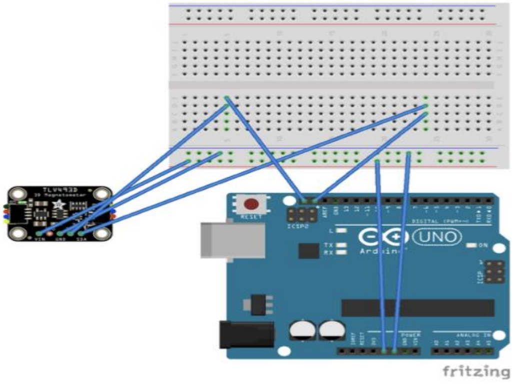


Figure 6: Arduino Circuitry Schematic.

The bill of materials, including key components, is detailed in Table 2. The estimated cost for the model kit is approximately $109.21 for manufacturers. This is considered a low-cost estimate, assuming access to 3D printing and silicone molding materials, as noted in the design history file (non-recurring costs) [2].

Table 2. The cost of producing 1 Pre-op Practice Device.

Part	Part No.	Quantity	Price/Unit	Source	Total Cost
Scalpel Set	-	1	$8.99	Amazon	$8.99
Adafruit TLV493D Triple-Axis Magnetometer - STEMMA QT / Qwiic	4366	3	$5.95	Adafruit	$17.85
Arduino Uno	A000066	1	$27.60	Design Lab*	$27.60
Jumper Wire Male to Male 6.00" (152.40mm) 28 AWG	1528-1967-ND	1	$1.95	Design Lab*	$1.95
Circuit Breadboard	1286-1185-ND	1	$5.99	Design Lab*	$5.99
3D-printed PLA Integration Box (Main box, lid, and peg)	-	1	$27.59	Ultimaker Cura	$27.59
3D-printed stomach platform	-	1	$5.00	Ultimaker Cura	$5.00
3D-printed melanoma platform	-	1	$3.80	Ultimaker Cura	$3.80
USB Cable	62	1	$2.95	Adafruit	$2.95
Packaging	-	1	$0.39	Uline	$0.39
Final Assembly	-	1	$7.10**	Employee	$7.10**
Total	-	-	-	-	$109.21

*Indicates that item was found in the design lab, but it would have been purchased off Digikey if it was not available in the lab.

2.5. Magnetometer

A key technology used in this project is the magnetometer, a device that measures magnetic fields or magnetic dipole moments. The magnetometer employed here is a magnetoresistive device, composed of thin metal strips whose electrical resistance changes in response to an externally applied magnetic field. Leveraging this property, the magnetometer calculates the 3D location of magnets by determining their distance from the point of the strongest magnetic field [7]. Magnetoresistive devices have a defined axis of sensitivity, enabling relatively precise 3D mapping [7]. Additionally, these devices can be mass-produced at low cost and scaled down to the size of an integrated circuit. They also offer rapid response times of less than 1 ms and a resolution of 0.1°.

These characteristics made magnetometers crucial to the development of our project. The TLV493D triple-axis magnetometer was utilized in this design, as shown in Figure 7. While magnetometers have been extensively used in industries ranging from oil exploration to space exploration, to our knowledge, this project is the first to apply them in an educational context for surgery. Surgical scalpels are pre-magnetized, allowing the magnetometer to detect the 3D location of the magnetic source (i.e., the scalpel). The triple-axis magnetometer we used detects only nearby magnetic fields, enabling accurate scalpel tracking while ignoring interference from Earth's magnetic field or other magnetic objects. The calibration process was through a simple calibration program which averages the first magnetic field recordings to account for any offset, and then subtract subsequent measures with the average value calculated. A small magnet can also be attached to the scalpel to enhance magnetic field detection.

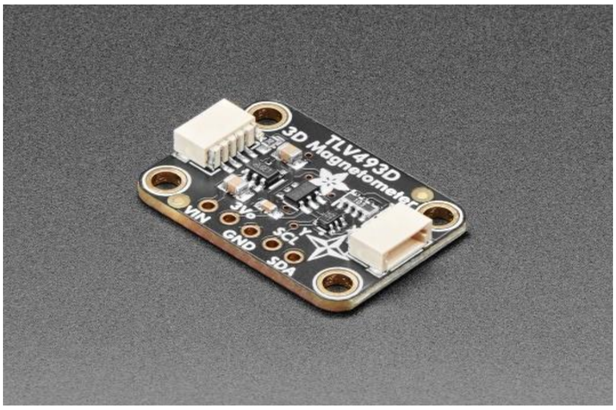
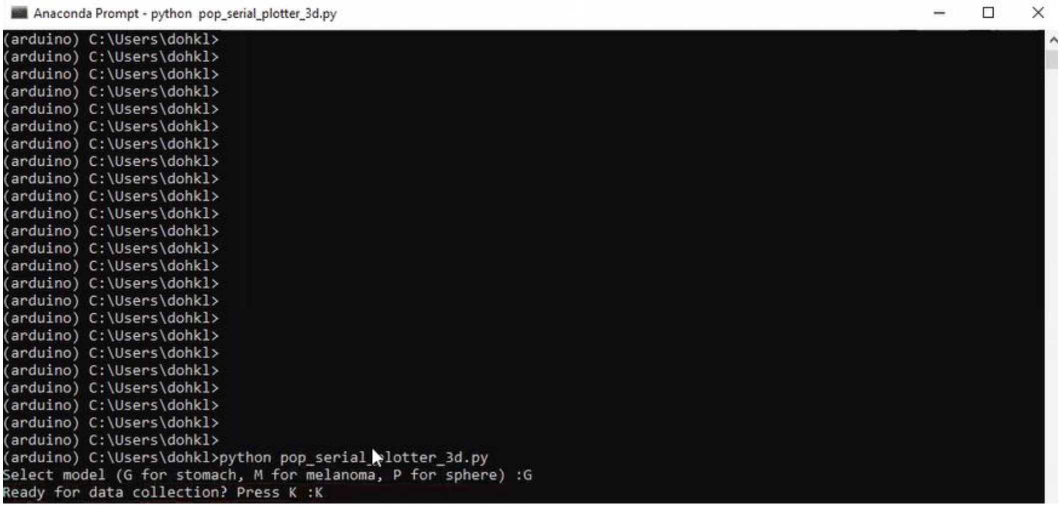


Figure 7: The TLV493D triple-axis magnetometer from adafruit [8].

2.6. Software Description

The Arduino Uno, an open-source microcontroller, processes both analog and digital inputs and outputs through its pins. In this project, it served to capture signals from the magnetometer and present a user-friendly interface. The program enables users to select an organ model and prompts them to press a key when ready to initiate data collection, as illustrated in Figure 8. Before data collection, users can interchange the silicone-modeled organs within the integration box, selecting from options like a stomach model or melanoma/tumor model. Once a model is chosen, the user receives both real-time data from the magnetometers and predefined data mapped in 3D space, based on the magnetometer's detection of the magnetic field. Additionally, users can select various modes tailored to the specific surgical model. Programming code and additional information are documented in the design history file [2].



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(arduino) C:\Users\dohkl>
(arduino) C:\Users\dohkl>python pop_serial_plotter_3d.py
Select model (G for stomach, M for melanoma, P for sphere) :G
Ready for data collection? Press K :K
```

Figure 8. Pyserial prompting user to select organ model.

3. Results

The final configuration of the stomach model kit is presented in Figure 11, comprising both the organ model (Figure 9) and the associated circuit (Figure 12). Only one magnetometer was used, with the second one kept as a spare in case the first became damaged. Due to time constraints, the stomach model was the only one fully tested with the magnetometers during the project.

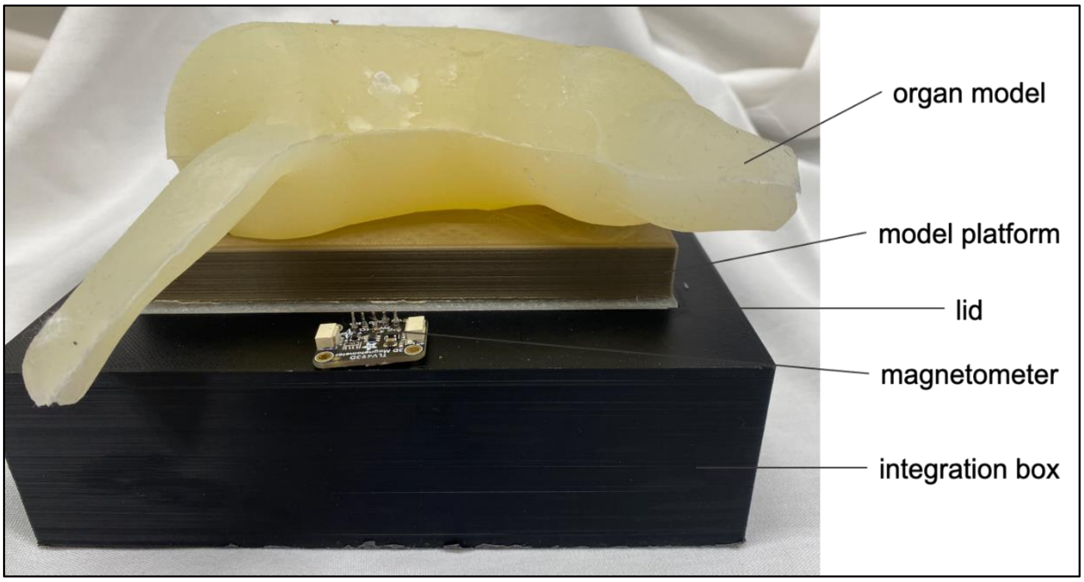

Figure 9: Labeled side view of the organ model with main components.

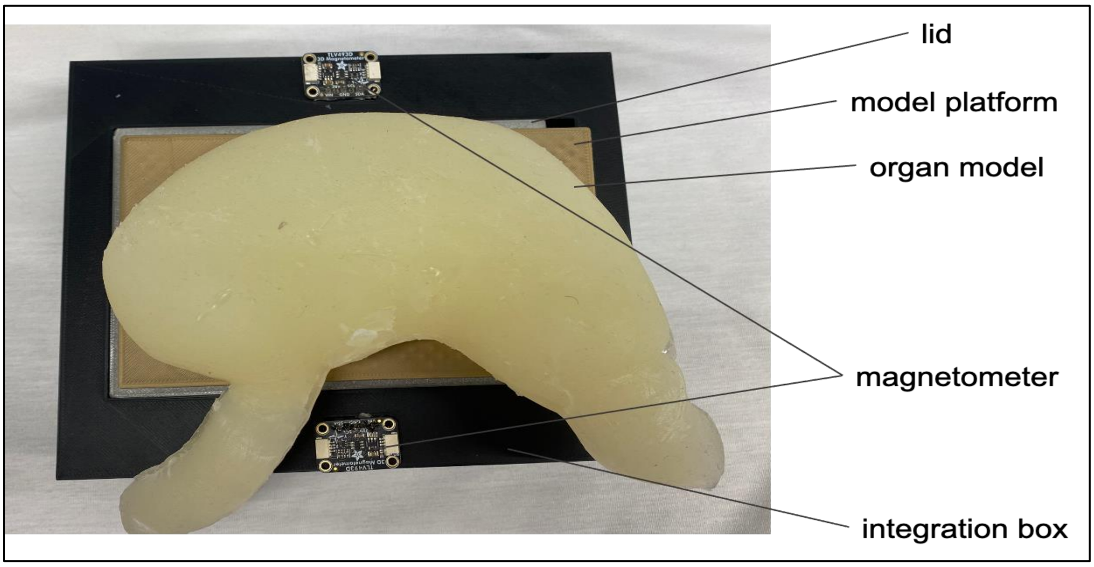

Figure 10. Full side and top view of stomach model kit.

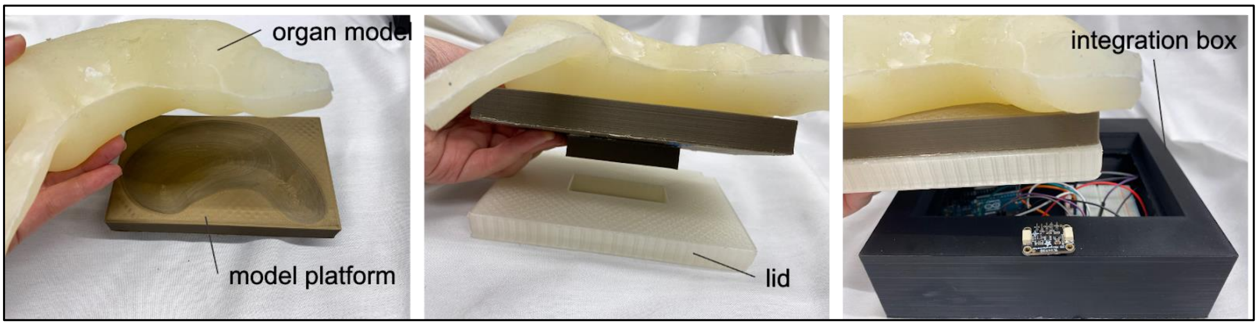

Figure 11: Three layers structures of stomach model kit.

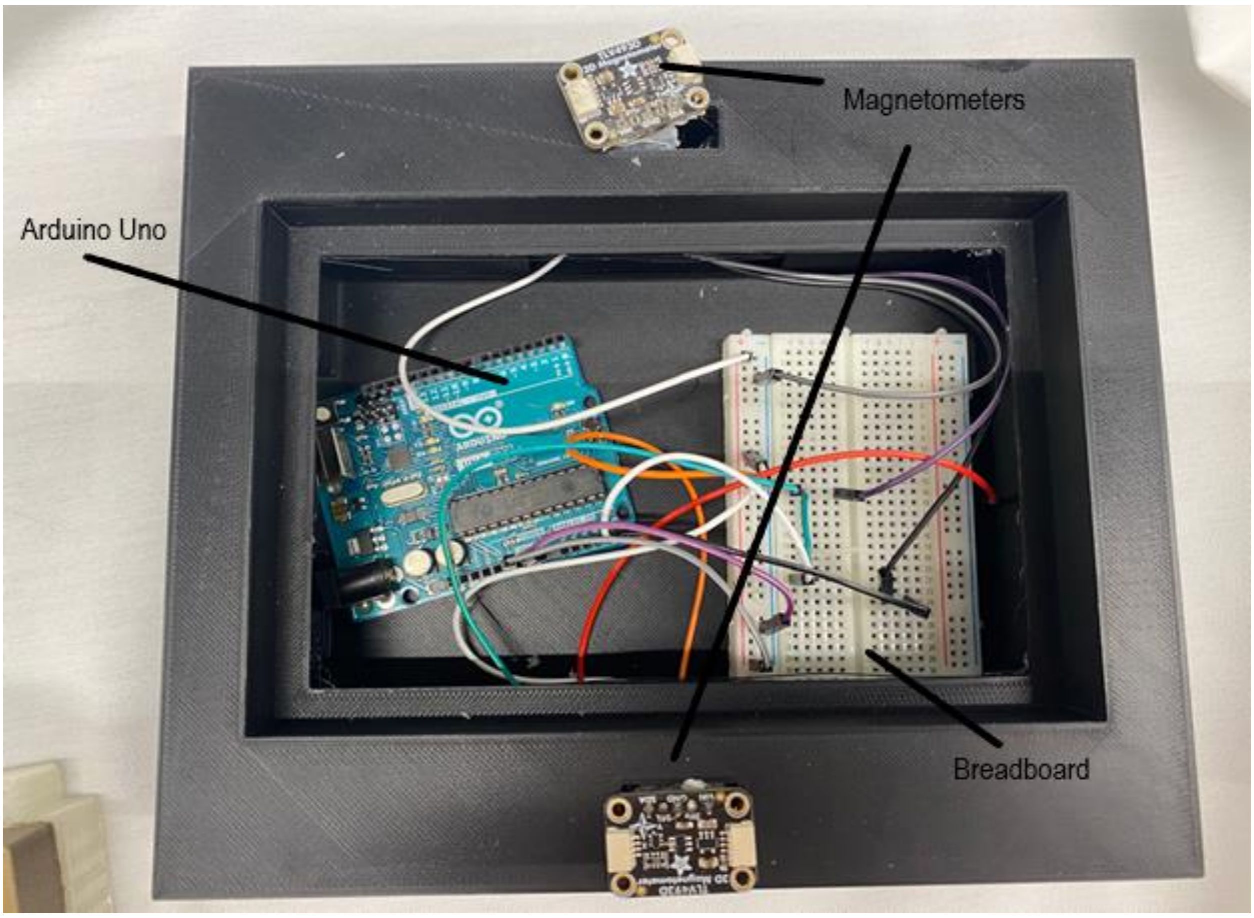

Figure 12: Circuit inside the integration box.

The final test involved collecting data from the Arduino and transmitting it to Python for visualization. The stomach model was programmed with a predetermined path, which was then compared to the actual data path. Although minor deviations and errors were observed in following the predetermined path, the overall geometry of the data closely matched the intended trajectory, as shown in Figures 13 and 14.

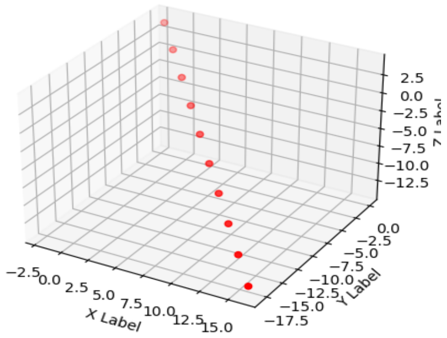

Figure 13: Predetermined Path of Cut for the stomach model

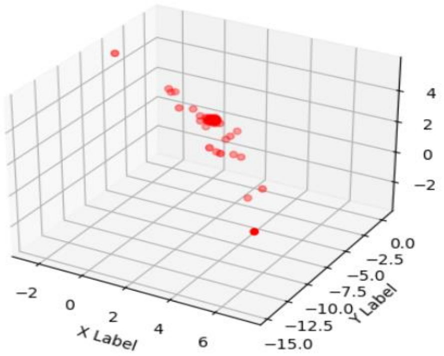

Figure 14: Actual Path of Cut for the stomach model

4. Conclusion/ Discussion

The main purpose of the project was to develop a pre-operative model for surgical practice in medical education with a stomach model and melanoma tumor model as examples. The two organ models were silicone molded from a 3D-printed cast. The organ models were then transferred to an integration box that held electrical components that were connected to a computer using Arduino Uno. The model kit's uniqueness lies in its ability to acquire scalpel tracing using an XYZ-coordinate system, and then present a pre-determined path and 'actual' path of movement. The model kit used a magnetometer for detection.

Although the organ selection mode and data visualization were functional as shown in Figure 8, the system's aesthetics could be enhanced by incorporating features like subplots. Additionally, improvements could be made by installing magnetometers with a broader detection range, allowing for more accurate interpretation of complex cut geometries and pathways. Furthermore, the integration of advanced data analysis or other quantitative feedback mechanisms—such as 3D correlation of clustered data points or time-interval markers—could significantly enhance the user experience by providing more detailed insights and checkpoints throughout the process. The python and Arduino code provided a useful way to record data points and transmit these data points for data visualization. The program could be improved by automatically saving data after the user uses the device compared to having the user manually save the data.

The design team opted to produce two identical silicone molds of the stomach model to verify consistency in the manufacturing process. Upon completion, both molds were nearly identical, demonstrating a reliable and consistent method for creating the silicone molds throughout the design phase. Finally, both molds were cut and inspected to ensure there were no noticeable differences between the separately produced molds.

Although the 3D-printing and silicone modeling process was successful, several improvements could be implemented. The organ models are currently made from skin-safe silicone, which was the closest material available to mimic the texture and mechanical properties of human organs during the design process. However, it is not ideal, as the silicone proved too sticky and stiff for scalpel cutting, and the consistency of the molded organs was not sufficiently uniform. Moving forward, we will explore other options, including different medical-grade silicones, as well as materials like gelatin and collagen. In addition to texture and mechanical performance, material costs will also be carefully evaluated.

As outlined in the estimated manufacturing cost section in the design history file, skin-safe silicone has accounted for the majority of our non-recurring production expenses [2]. It would be better to explore lower-cost materials or negotiate with suppliers to reduce costs. Additionally, expanding the variety of organ models will enhance the range of practice scenarios. This versatility, achieved by simply swapping out the single-use organ model attachments, will offer users diverse and realistic practice experiences.

Throughout the design process, we adhered to ISO 13485 and ISO 9001 standards. ISO 13485 focuses on quality management for medical devices, ensuring that organizations involved in any stage of the device life cycle meet the necessary quality requirements [9]. For example, Section 4 of ISO 13485 emphasizes the documentation of a quality management system, including policies, objectives, a quality manual, procedures, and records, which must be maintained throughout the design process.

ISO 9001 outlines the requirements for a quality management system that ensures an organization consistently provides products and services that meet customer and regulatory requirements, while also aiming to enhance customer satisfaction through continuous improvement [9].

For this project, the design team did not develop specific quality assurance procedures. However, we have ensured compliance by researching relevant engineering standards and maintaining thorough design documentation [2]. The design team conducted verification and validation testing to evaluate the effectiveness of our device.

One of the key standards for medical electrical devices is IEC 60601, which is also a requirement for medical device registration under the FDA. A medical electrical device is defined as one intended by the manufacturer for diagnosing, treating, or monitoring patients, or compensating for or alleviating disease, injury, or disability [10]. While the model kit did not fall into these categories, and we are not required to follow this standard, IEC 60601 provides valuable guidelines for general safety requirements.

Of particular importance is IEC 60601-1, which specifies general requirements for the basic safety and essential performance of medical electrical equipment, including risk management, and electrical, mechanical, and software safety [10]. Given that the magnetometer is a key sensor in our product, it is especially critical to address electromagnetic compatibility.

Another relevant standard is IEC 62304, which outlines life cycle requirements for medical device software, including safety, detailed design, validation, verification, and maintenance [11]. While our product is not classified as a medical device, this standard offers a useful benchmark for software quality control, particularly since our system processes, visualizes, and analyzes scalpel traces.

To align with these standards, we have documented the roles of the developers responsible for software development and the technical resources used in IEC 62304 [12]. We also performed validation and verification procedures, which are detailed in the design history file [2].

One of the most important standards, ISO 10993: Biological Evaluation of Medical Devices [13], provides guidelines for assessing a device's biocompatibility—its ability to function as intended without causing harm to biological tissues. Although our device does not come into direct contact with human tissues, it is still important to comply with ISO 10993, particularly for the organ model, as our device is designed to mimic human tissues and may come into contact with users' skin [13]. Our organ model meets ISO 10993 standards because the silicone used is certified as skin-safe [14].

The model kit described in this paper offers a realistic 3D organ model for practice and immediate feedback on cuts made. Currently, we offer a large tumor model, mimicking a melanoma, and a stomach model, both in a 1:1 size ratio to human anatomy, with materials optimized to replicate the feel of real organs. Current competitors, as discussed in the design history file (appendix: Patent Analysis and Appendix: Competition Analysis), often lack real-time feedback or provide it weeks or months after practice [2]. This delay prevents users from immediately applying corrections, which is crucial for improving surgical precision.

Our model kit is scalable, with the potential to expand to additional organs and surgical tools, ultimately enhancing scalpel skills through consistent and effective practice. The integration box and Arduino components are separate from the 3D organ model, allowing users to switch between different models, such as from the stomach to the tumor, without needing to rebuild or reconnect components. This flexibility gives users autonomy and enables practice in various environments.

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Conflict of Interest: The authors have no conflict of interest.

Author contributions: **Ave** was also in charge of the electrical aspect of the project, working with circuitry, pyserial, arduino IDE, and python to maximize the functionality of the magnetometers, create the different predetermined paths, and program the tracking of the scalpel onto a 3D space. **Elyona** was responsible for assisting in the development of the feedback system as well as maintaining the weekly deliverables - work orders, invoices, generating timelines, purchase request forms and project reports. **Reina** focused on building organ models including researching the right material for models, designing the updated models for molding with CAD, assisting with 3D-printing parts, and molding silicone. **Renan** was in charge of the mechanical aspect of the project, emphasizing on the product development aspect through designing the CAD models, 3D printing, and assisting with fabricating the silicone-molded models. **Renan** worked on finalizing the CAD models that would end up being utilized as the shells for the silicone-molded models. **Renan** was in charge of creating the design of the integration box on Fusion 360 and performing most of the 3D printing for all of the models, replacing the materials and monitoring the models as they printed. **Ave**, **Renan**, **Elyona, and Reina** contributed to study conception and design, and assisted with interpretation of the results. **Ave** wrote the initial manuscript draft. **Renan** revised the manuscript for clarity and critically important intellectual content.

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