University of Toronto

Project Requirements

Project STMF – Group #6

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EXECUTIVE SUMMARY

Overeating, the act of consuming excessive amounts of food, is one of the largest contributors to obesity, which has tripled worldwide since 1975. Oftentimes, individuals can overindulge in food before the body can send signals to the brain. To help mitigate this, the client, Professor Nasser Ashgriz from the University of Toronto, has tasked the team with designing a portable, user-friendly device capable of measuring stomach fullness in real time.

Although technology like MRI and sonography can measure stomach fullness, they are far too bulky, complex, and costly for the average person to use. In order for the device to fulfil the current need, the device must provide accurate, real-time data on stomach fullness, helping users to make informed decisions on their eating habits before the brain registers satiety.

The project aims on developing a prototype which uses ultrasonic waves to measure stomach fullness. The design will focus on measuring gastric volume by estimating the cross-sectional area of the distal stomach, specifically the antrum. The antrum was selected not only for the depth of information published on it, but also for its quick response to changes in the stomach. Alternative methods including gastric electrical impedance technology (gEIT) were considered but ultimately ruled out due to their complexity and limited maturity.

The central issue of the project is accurately correlating ultrasound data with changes in real-time gastric volume. The device must not only be accurate, but it must also be safe, comfortable, compact, lightweight, and easy to use for the consumer.

The project must adhere to the development timeline laid out in the MIE491 Capstone Design Course Guide. The team is aiming to complete all major design deliverables, including sensor validation, data collection, and prototype testing, by March 2025.

1. INTRODUCTION

Overeating is the act of consuming excessive amounts of food, above and beyond what is required to reach a state of satiety. Frequent overeating can cause sluggishness, nausea, vomiting, and may eventually lead to obesity [1]. Since 1975, the worldwide rate of obesity has tripled, and in 2018, roughly 63.1% of Canadians over the age of 18 reported to have height and weights that classified them as either overweight or obese [2-3]. Research suggests that the volume or weight of food plays a significant role in fullness, independent of nutritional content [4]. This indicates that overeating is likely linked to excessive food intake relative to the stomach's capacity. Typically, it takes about 30 minutes after eating for the brain to register hormones such as insulin or leptin, which signal satiety [5]. As a result, individuals may unintentionally overeat before these chemical messengers reach the brain.

2. PROBLEM STATEMENT

Despite the availability of medical grade equipment, such as Magnetic Resonance Imaging (MRI) and Ultrasonic Imaging (Sonography), there is currently no consumer available technology to accurately assess gastric volume. Considering this, the client, Professor Nasser Ashgriz from the University of Toronto Department of Mechanical Engineering, has asked the team to develop a device that can accurately measure stomach fullness in real time. By developing an affordable, portable, and user-friendly device, individuals concerned with overeating can access information to help manage their condition.

The main challenge of this project is to develop a reliable and objective method for stomach monitoring, while also considering the various individual differences and conditions present in the stomach. In other words, the device must be able to distinguish between gas, liquid, and solid contents in the stomach, and work on different individuals ranging in age, size, and sex. With respect to the design of the device, a significant complexity lies in accurately translating signals into actionable metrics. Specifically, these metrics would measure the total occupied volume vs the stomach’s total capacity. Thus, the project necessitates the integration of a sensor with advanced data processing techniques to accurately estimate stomach volume.

3. LITERATURE REVIEW

3.1 ANATOMY OF THE STOMACH

The stomach is one of five organs that make up the gastrointestinal (GI) tract [6]. The stomach is located centrally in the upper abdominal area, left of the midline [7]. The stomach’s shape and size can vary based on sex and build, but on average it is 20-30cm long, and can hold roughly 1.5L of food and drink [8].

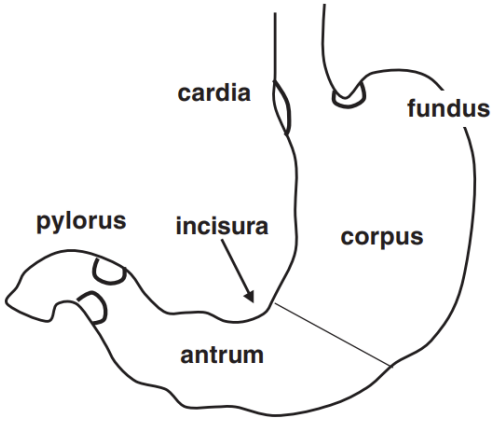

Figure 1 – Regions of the Stomach [9]

The stomach consists of five different regions: the cardia and gastroesophageal junction, the fundus, the corpus, the antrum, and the pylorus [Figure 1]. The cardia is connected to the esophagus and is where food enters the stomach [7]. The fundus and corpus harbor gastric juices which render food particles soluble [9]. Lastly, the antrum holds broken down food until it is passed to the pylorus which empties it to the small intestine [10]. In total, it can take a few minutes for food to reach the antrum after ingestion [11-12].

3.2 STATE OF ART REVIEW

3.2.1 ULTRASONIC TECHNOLOGY

Assessing gastric content and volume via ultrasonic imaging has been widely used in anesthesia practice [13]. It is mainly used to determine the risk of pulmonary aspiration which accounts for up to 9% of all anesthesia-related deaths [14]. One of the main factors for pulmonary aspiration is the presence of gastric contents [14]. It is therefore necessary to accurately determine the presence of solid and liquids prior to surgery.

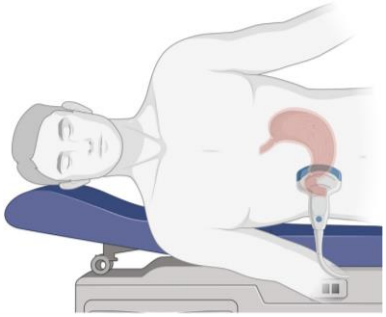

Figure 2 - Right Lateral Decubitus Position [15]

Due to air blocking the visibility of the fundus and body of the stomach, most sonographers use the antrum to determine gastric volume [14]. The patient is placed in the right lateral decubitus position to estimate the cross-sectional area of the antrum [Figure 2]. The formula used to estimate gastric volume has a correlation coefficient $r = 0.86$ and can be seen below.

$$GV\ (ml) = 27.0 + 14.6 * right\text{-}lat\ CSA - 1.28 * age$$

Recent advancements in ultrasound technology have created opportunities for wearable devices that can continuously monitor human physiology in a non-invasive manor [16]. One of those devices is the bioadhesive ultrasound (BAUS). The BAUS has a surface area of just $4cm^2$ and has been used to monitor several different organs, including the stomach [16]. The BAUS uses a 3MHz phased array to generate ultrasonic images and was able to accurately monitor the gradual decrease in antrum cross sectional area due to gastric emptying [16].

Similarly, wearable devices have been developed to monitor the bladder [17]. The ultrasonic patch developed at MIT can monitor bladder volume in real time and was shown to be comparable to standard clinical equipment [17]. The device contains piezoelectric material on both the sagittal and transverse axis to accurately measure the whole bladder [17]. Though the study mainly focused on the bladder, the author's claim the technology is suited for any deep tissue ultrasonography [17].

3.2.2 ELECTRIC IMPEDANCE TECHNOLOGY

Electrical impedance tomography (EIT) is a low-cost non-invasive imaging method [18]. EIT reconstructs images of a specific region in the human body based on the electrical conductivity of the biological tissue [18]. Recent developments in EIT technology have opened the possibility of gastric imaging [19]. The gastric volume is estimated by running an electrical current through several different electrodes to measure their impedance [20]. The data is then fed into a Jacobian matrix and neural network to generate a 3D image of the stomach [20]. The estimated volume determined by the gastric electrical impedance tomography (gEIT) in one study was found to be statistically accurate with a correlation coefficient of $r = 0.88$ [19].

3.4 SELECTED TECHNOLOGY

The two most promising technologies for determining gastric volume are ultrasound and electrical impedance. Considering the scope of this project, the complexity and lack of maturity of electrical impedance technology, the project will focus its efforts on ultrasound technology [18].

4. STAKEHOLDERS

The stakeholders for this device will play a crucial role in the project's success. The primary stakeholders for this project have been compiled in the table below.

Table 1 – Primary Stakeholders

Stakeholder	Rational
Product Users	• The user will be the one wearing the device. The project team will design the device to be: 1. Safe 2. Comfortable 3. Easy to use
Naseer Ashgriz (Client/Supervisor)	• Professor Ashgriz establishes the project expectations, provides constructive feedback, oversight, and helps to ensure the project remains on track.
University of Toronto Department of Mechanical Engineering	• The University of Toronto facilitates the Capstone project and lends out its facilities. The project team must ensure that they are following university guidelines while in and out of the lab.

5. DETAILED REQUIREMENTS

5.1 FUNCTIONS

5.1.1 PRIMARY FUNCTION

The primary function of the device is to accurately measure and display the user's stomach fullness in real time, providing actionable data that helps prevent overeating. This measurement must be consistent and reliable across all users, regardless of variations in waist size, body composition, or stomach capacity.

5.2.2 SECONDARY FUNCTION

The device must function under different food types, digestion rates, and physiological responses. It should be able to handle various states of fullness, accounting for differences in quantity and type of food/liquid.

5.2 OBJECTIVES

The primary objective of this system is to measure stomach fullness in real time, without significant delay. This means that sensor data collection and analysis should be less than thirty minutes to address the lag in satiety [5]. Additionally, the final prototype should prioritize user safety and comfort while being compact, portable, and easy to use in everyday settings.

Given that the product is aimed at improving public health, it must also be inexpensive and simple to set up. The final design should aim to include a user interface to display key measurement metrics on external platforms, such as an Android app. This interface should be intuitive and easy to understand, allowing users to quickly interpret the data and make informed decisions about their eating behavior.

The summary of the objectives and their corresponding metrics are recorded in Table 2.

Table 2 - Objective Metrics

Objective	Metrics
The data collection & analysis time should be fast.	Process time should be less than 30 min [5].
The final prototype should prioritize user safety and comfort.	• Transducer frequency should be between 1 and 20 MHz [23] (see section 5.3.1). • Temperature of the transducer contacting surface should be less than 43°C [25] (see section 5.3.2).
The final product should be inexpensive.	The total cost of the prototype should be less than $1,000.
The measurement results should be easy to read and visualize.	The final product should involve the development of an Android APP to visualize the measurements results.

5.3 HUMAN FACTORS

5.3.1 IMPACT OF DIFFERENT ULTRASOUND FREQUENCIES ON HUMAN BODY

Ultrasound frequencies can have varying effects on the human body, depending on the frequency range and duration of exposure.

Frequencies below 1 MHz primarily affect the body through mechanical and thermal properties. At lower frequencies, ultrasound can cause localized heating, which is often used in therapeutic applications such as physiotherapy to promote tissue healing and relieve pain [21]. However, exposure to airborne ultrasound in this range can also impact the ears, leading to symptoms like temporary hearing threshold shifts, headaches, and nausea [22].

In the 1-20 MHz range, which is commonly used in medical imaging, lower frequencies can penetrate deeper into tissues, making them suitable for imaging organs and other deep structures. Ultrasound transducers operating within this range are considered safe for medical use [23].

Between 500 kHz and 100 MHz, the main biological effect is an increase in tissue temperature. While this effect can be beneficial in therapeutic applications, it may pose risks if not properly controlled, particularly in non-therapeutic contexts [23].

At frequencies above 100 MHz, radiation forces become significant, leading to more pronounced mechanical effects on tissues. Exposure to ultrasound at these high frequencies can result in severe symptoms such as temporary hearing threshold shifts, headaches, nausea, and other discomfort [24].

Therefore, an ultrasound transducer frequency range of 1 to 20 MHz is selected to ensure safe and effective detection while minimizing the risk of adverse effects on the human body.

5.3.2 THERMAL LIMIT OF THE HUMAN BODY

According to international standards, the maximum temperature the human body can safely tolerate from an ultrasound probe in contact with the skin is 43°C. This threshold is set to prevent thermal damage to tissues [25]. To ensure the product remains safe for users, the team will conduct thorough testing and configurations to ensure the contact area of the device does not approach this temperature limit.

Additionally, the team has decided to use pulsed signals rather than continuous waves, as this approach significantly reduces the risk of prolonged heating. Pulsed excitation minimizes the thermal impact on the transducer and enhances energy efficiency, while still providing the necessary signal strength for accurate measurements [26]. This method is effective in maintaining safe temperature levels and preventing potential tissue damage.

By implementing these strategies, the team will ensure that the final product remains a safe and reliable medical device.

5.4 CONSTRAINTS

The project is constrained by an initial budget of $1,000, which must cover all components and testing costs. As the final product will be a wearable device, any solution that will cause harm to the user must be immediately disqualifying.

6. SOLUTION METHOD

The project's strategy focuses on two key areas: signal processing and wearable design. For signal processing, ultrasonic transducers will be used to record reflected waves from the human stomach at varying levels of fullness. By examining these signals, using gathered data, and calibrating to account for individual differences, the team hopes to predict fullness levels

Choosing the proper ultrasonic frequency is critical since it requires balancing penetration and resolution. Ultrasound in radiology is primarily based on longitudinal waves, which are represented by the 2D wave equation.

$$v = \lambda f$$

where v is the velocity of the wave in meters per second (m/s), λ is the wavelength in meters (m), and f is the frequency in hertz (Hz).

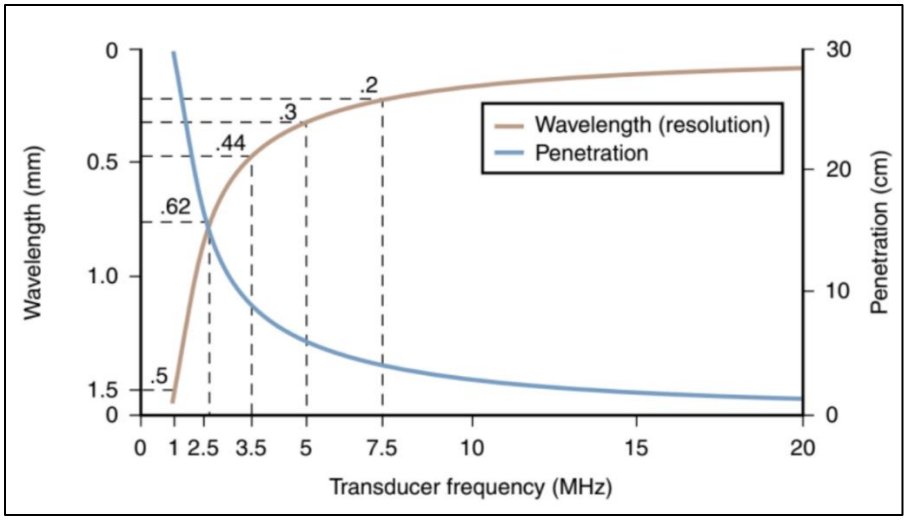

Figure 3 - Transducer frequency vs wavelength and penetration of ultrasound signal in soft tissue [29]

It should be noted that the average speed of sound (v) in human tissue is 1540 m/s and the desired penetration, i.e., stomach depth, is relatively constant [27]. Thus, to select an ultrasound transducer, we can utilize the equation above and the relationship graph [Figure 3]. Therefore, an optimal transducer frequency is 2 – 3 MHz can give us 10 – 15 cm penetration and a millimeter range resolution. Individuals have varying levels of subcutaneous fat and muscle thickness. A 10-15 cm penetration allows the ultrasound to reach deeper organs and tissues. This ensures that ultrasound waves can bypass these layers and still provide enough information regardless of body type.

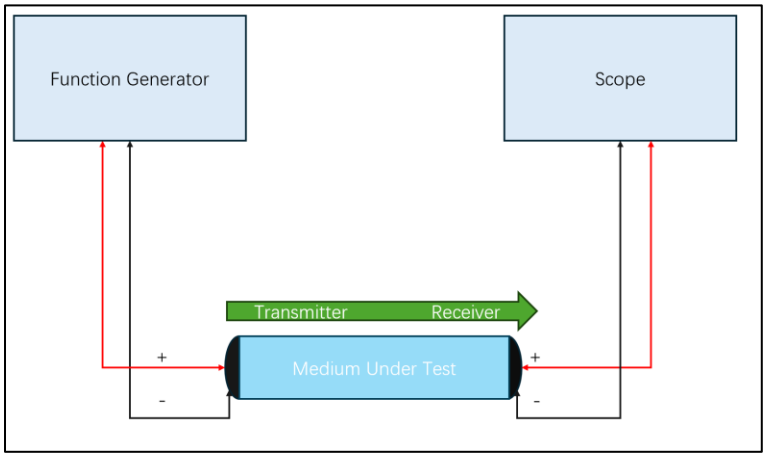

Figure 4 - Test Setup Diagram

Ultrasound applications are generally divided into two types: continuous and discontinuous. To prevent energy buildup and overheating, the team will focus on using the discontinuous method, which sends short pulses (in microseconds) and waits for the reflected waves. Due to the small surface diameter of the transducer (20 mm), receiving signals on the same side as the transmitter is challenging. This is because the tissues and organs within the human body have varied geometries, causing the waves to reflect at different angles. As a result, the setup will use two transducers: one positioned at the front and the other at the back. In a test setup, the function generator would be connected to the

transmitting transducer, while the receiving transducer would be linked to an oscilloscope for testing. [Figure 4]

In a functional system, the transmitter would be controlled by the microcontroller's PWM digital output, and the receiver would be connected to the analog input of the microcontroller (see Figure 5).

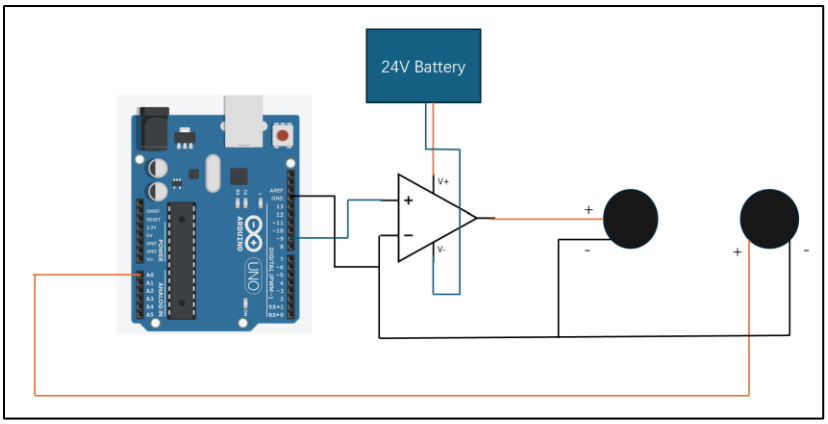

Figure 5 – Working Setup Diagram

To send pulses periodically, we can set the pulse frequency in Hz (pulses per second), also termed as pulse repetition frequency (PRF), then measure the time it takes for the echoes to return [28]. By analyzing changes in the echo amplitude and duty cycle, we can correlate these variations with different fullness levels. We can achieve this by measuring changes in the transmitter (TX) and receiver (RX) signals on scope to determine the stomach's fullness level. To avoid signal aliasing using the Nyquist limit, it's important to sample at least twice the wavelength, or ½ of the PRF. For example, if a 2 MHz transducer is used, the PRF limit is 1 MHz, therefore a sampling rate of 500kHz or even lower is appropriate.

Once the sensor is validated and functional, the next step is to collect enough data to link the level of fullness with changes in duty cycle/amplitude during ultrasound exposure. This can be done using either an animal stomach or a phantom model. By feeding different levels of fullness and recording the reflected wave's duty cycle, we'll use this data to build our mathematical model. This model will allow us to quickly determine the level of fullness based on changes in duty cycle.

The final step is to integrate the sensor and microcontroller into a wearable belt with a real-time UI to monitor fullness levels. We can apply the 3D printing and machining skills we learned in our second year and utilize the Myhal Fabrication Centre to prototype the frame for the device.

7. PROJECT PLAN

The project team expects the client to give timely feedback (within the week) on design deliverables, and in turn, the team will give the client a clear and transparent communication schedule.

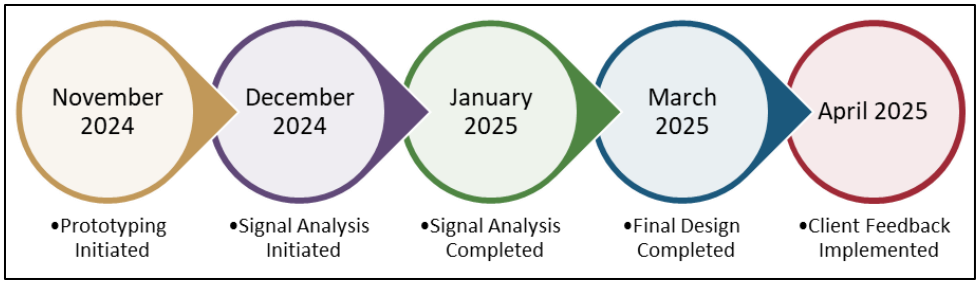

Figure 6 – Project Timeline

There are three stages to the design process. Stage of sensor validation: by the end of November 2024, the client should be able to anticipate that the team will have sent and received a reflected signal on the scope. At the data collecting stage, the client can anticipate that the team will demonstrate a relationship between the output level of stomach fullness and the duty cycle change of PRF. By January 17, 2025, the team will modify its modelling methodology based on the client's input. The client would give sufficient feedback for the team to finalize the design before the showcase date (April 03, 2025), and the prototype of the design would be ready by March 23, 2025 (before the Final Design Specification). The timeline of the design workflow can be seen in Figure 6.

8. CONCLUSION

The team has proposed a portable, real-time stomach fullness measurement device aimed at helping individuals manage overeating. Drawing on advancements in ultrasonic technology, the design focuses on providing a cost-effective, user-friendly, and non-invasive solution that can be worn comfortably and operate under various conditions. The device is intended to overcome limitations of existing medical tools, such as ultrasound machines, which are bulky, expensive, and inaccessible for everyday use.

By leveraging real-time data collection and analysis, this design will address the delay in satiety signaling, offering users critical feedback to help prevent overeating before it occurs. Our solution integrates safety measures, including the use of safe ultrasonic frequencies and temperatures, ensuring that the device meets medical safety standards while maintaining user comfort.

Moving forward, the project timeline outlines the development phases, including sensor validation, data collection, and the final prototype construction, with the aim to deliver a fully functional and tested device by March 2025. Once complete, this wearable device has the potential to empower individuals with the tools they need to make more informed eating decisions, contributing to the broader goal of improving public health and reducing the incidence of obesity-related conditions.

The success of this project relies on continued collaboration with our client and stakeholders, alongside rigorous testing and refinement to meet all performance, safety, and usability requirements. With the final design, the team hope to introduce a new standard in wearable medical technology for managing overeating and promoting healthier lifestyles.

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10. ATTRIBUTION TABLE

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