BSc Creative Technology

Faculty of Electrical Engineering,
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Monitoring of Lymphedema in the Arm after Cancer in the Home Environment

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Abstract

Lymphedema, a chronic condition marked by significant swelling due to lymphatic system damage, impacts millions globally. The challenges of early diagnosis and the costs associated with professional monitoring lead to delayed treatment and worsened health outcomes. This project addresses these issues by developing an accessible tool for accurate lymphedema self-monitoring at home. Following the establishment of specifications, a water displacement-based volumeter was constructed. This tool was evaluated for accuracy and usability by both students and the age group representative of those commonly affected by lymphedema. The home-based volumeter demonstrated accuracy comparable to traditional methods, such as measuring tape, in the sample. The project offers a practical and affordable way to detect lymphedema early, emphasizing the need for new solutions in dealing with long-term illnesses and helping patients take better care of themselves.

Acknowledgment

Completing this thesis was a challenging journey, demanding countless hours of effort. I extend my sincere gratitude to my supervisor, Annemieke Witteveen, and my critical observer, Femke Nijboer, for their invaluable feedback and insightful discussions during our meetings. Their guidance played a crucial role in shaping this project.

I'm thankful to my friends and family for their constant support and encouragement during this period. Their belief in me has helped me overcome obstacles and make significant progress on this project.

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Chapter 1. Introduction

In today's world, cancer stands as a significant health challenge, deeply impacting lives globally. Its prevalence and the mortality it causes underscore the urgent need for ongoing research, as well as effective prevention and treatment strategies. However, cancer treatments can sometimes bring unexpected and lasting challenges to the patients. One of them, is lymphedema (LE), a condition related to the lymphatic system, which is responsible for managing fluids in our body. Lymphedema is characterized by a buildup of proteins and fluids in nearby tissues, causing swelling and inflammation in the affected areas [1]. In this study, the focus is on arm lymphedema specifically. This condition often occurs as a result of cancer treatments like surgery, radiation therapy, or chemotherapy [2]. Due to its progressive nature, lymphedema typically becomes more severe over time, increasing the chances of developing this condition as time passes.

Lymphedema, defined by an increase in arm volume three months after surgery, is a notable complication following cancer treatments [27]. The condition is common, with a reported incidence rate of 6.8% two years following radiation therapy, highlighting its occurrence among cancer survivors [28]. It affects a significant number of breast cancer survivors, with 15-20% of the approximately 2 million survivors experiencing post-treatment lymphedema [3]. These numbers demonstrate how crucial it is to monitor lymphedema as part of the post-cancer treatment continuum [29].

Recent studies highlight the incidence and risk factors associated with lymphedema, particularly following cancer treatment, noting significant prevalence among specific patient groups and various risk factors like the extent of surgery and radiation to lymph nodes [22]. On average, patients diagnosed with lymphedema are typically around 52 to 61 years old, with a notable frequency of symptoms in individuals under 60 years post-breast cancer treatment [12][14]. This highlights the demographic most at risk and underlines the importance of targeted monitoring and management strategies for these patients. The burden of lymphedema for these individuals is significant, encompassing not just physical discomfort and mobility issues, but also psychological impacts due to the chronic nature of swelling and the required ongoing self-care.

Understanding when condition is present depends on distinguishing normal from abnormal arm volumes. According to Karlsson et al. [19], lymphedema was diagnosed when the Lymphedema Relative Volume (LRV) increased by ≥5% to ≤8%, indicating a significant change compared to the unaffected arm. If the arm's volume increases by more than 5% but less than 10%, it suggests that the patient's condition should be watched more closely or that they might need early treatment.

In the present circumstances, arm lymphedema is often diagnosed late because of infrequent monitoring, usually depending on methods like measuring the circumference or volume of the affected arm [3]. To prevent late diagnosis and facilitate early treatment, the circumference method can be employed for self-monitoring. When employing the circumference method, a distinction of 5% is commonly used for diagnosing lymphedema, with anything exceeding a 20% difference being categorized as severe [4]. Nonetheless, it is essential to note that self-monitoring using a measuring tape requires a certain level of self-management skills and the ability to accurately perform measurements. Indeed, a device that enables easy and accurate self-monitoring of arm lymphedema in a home setting is valuable for individuals who prefer or need to stay at home, as it offers a convenient and efficient option for tracking their condition.

Addressing the problem of late diagnosis, this study focuses on the creation of a home-based assessment instrument. The objective is to develop a solution that is not only effective for early diagnosis but also convenient and comfortable for patients, particularly those recovering from breast cancer. This technology intends to fill a gap in existing lymphedema care procedures, which sometimes necessitate numerous hospital visits, adding to the patient's burden. By enabling patients to monitor their condition at home, this technology aims to improve their quality of life and potentially decelerate the progression of lymphedema through early intervention and treatment. This approach emphasizes the importance of patient-centered innovations in healthcare, particularly in managing chronic diseases caused by cancer therapies.

The **research question** is the following:

"How can a user-friendly and reliable lymphedema home-monitoring tool be developed for breast cancer patients?"

Sub-questions:

1. How does the accuracy of the water displacement method in detecting arm volume differences compare to that of the traditional measuring tape technique?
2. What are the differences in the experiences and preferences of users between the newly developed tool and the conventional measuring tape method for monitoring lymphedema?

Chapter 2. Background Research

For background research, a literature review was done where several aspects of lymphedema detection and monitoring had to be examined. The first aspect explores the different conventional methods and technologies available for monitoring lymphedema. The second part focuses on the practicality and feasibility of utilizing these technologies in a home environment. In the third and final section, the analysis delves into the strengths and limitations of these technologies in the context of lymphedema regular monitoringt. This literature review is essential for acquiring knowledge about modern technologies, which facilitated an informed selection for the graduation project.

2.1 Non-technological Approaches

In the realm of lymphedema tracking two primary measurement techniques stand out for their effectiveness and simplicity: the use of a measuring tape for circumference measurement and the water displacement method. Both methods provide alternative approaches to detecting and monitoring changes in limb volume, which is essential for early identification and ongoing observation of lymphedema. Circumference measurement with a measuring tape is a typical approach used in clinical lymphedema assessments. This method involves wrapping a flexible, non-stretch tape around the diseased limb at regular intervals to determine its circumference. This approach has become standard practice for assessing lymphedema because of its simplicity and accessibility, particularly in areas where more complex equipment may not be available. Regularly measuring and comparing circumferences allows for the detection of variations in limb size that show lymphedema development or improvement [17].

In addition to the circumference measurement, the water displacement method offers another effective approach to lymphedema measurement. This technique, based on Archimedes' principle, determines volume by measuring the amount of water displaced by a submerged object. As the arm is immersed, it displaces water equal to its volume. This displacement is then measured, providing a direct indication of the arm's volume. This method is particularly beneficial for lymphedema patients, as it offers a simple, accurate way to monitor changes in limb size, crucial for early detection and handling of the condition [18]. After discussing the primary non-technological methods for lymphedema assessment, the next section will delve into technological solutions, providing a broader view of managing this condition.

In the context of lymphedema detection, the research by Karlsson et al. [19] plays an important role in defining diagnostic criteria. They established that a Lymphedema Relative Volume (LRV) increase between 5% and 8% is indicative of lymphedema, representing a significant change from the unaffected arm's volume.The study further highlights that conventional measures, such as a volume increase exceeding 10% or a circumference change greater than 2 cm, could potentially result in undetected cases of lymphedema. If the arm's volume increases by more than 5% but less than 10%, it suggests that the patient's condition should be watched more closely or that they might need early treatment. The research also points out that commonly used measures, like a volume increase of over 10% or a change in arm circumference greater than 2 cm, may lead to missed lymphedema diagnosis. A small increase in volume, as little as 3% from the patient's initial measurement, is an early indicator of lymphedema, but a 3% to 5% change within three months of surgery indicated a greater risk. These findings are significant for the early detection and treatment of lymphedema since they provide the basis for clinical evaluation using non-technological approaches.

Conversely, Greene et al. [20] propose a broader classification, defining mild lymphedema as a <20% increase in extremity volume, moderate as a 20–40% increase, and severe as a >40% increase. This staging system presents a more generalized assessment of lymphedema severity, which might not be as sensitive in detecting the early stages of the condition as the criteria suggested by Karlsson et al. [19].

Damstra et al. [21] defined diagnostic criteria, which gives a practical approach that can be compared to Karlsson et al. [19]. Damstra et al. [21] recommends starting a comprehensive lymphedema treatment program when there is a volumetric increase of more than 10%, which aligns with Karlsson's warning that rises of more than 10% or changes of more than 2 cm may miss early lymphedema diagnosis. Damstra et al. [21] suggests a lymphedema therapy program for increases ranging from 5 to 10%, which corresponds to Karlsson's prescription for close monitoring or intervention when the arm's volume increases by more than 5% but less than 10%. These different sources highlight how challenging it can be to identify lymphedema and why treatments should be personalized, depending on how much the limb size has changed.

2.2 Technological Approaches

Advanced Technological Methods

In the context of measuring a condition like lymphedema in the upper limbs, various methods and technologies come into play, some of which are highly advanced, while others remain simple. While focusing on advanced technological instruments in this section, it is worth mentioning that the non-technological water displacement approach explained above serves as a reference point.

Kinect Infrared Sensor for Creating 3D Models

Lu et al. [7] compared the effectiveness of a water displacement method to that of a system based on the Kinect Infrared Sensor. Their research revealed that the Kinect application had a strong correlation with the water displacement approach, revealing that the data were in close agreement in most circumstances, with a percentage difference of less than 10% which shows the sensor’s precision. However, despite this connection, the trustworthiness of the IR Depth sensor compared to the water displacement approach may require additional investigation. Noble et al. [6] concur with Lu et al. [7] in their opinion that the Kinect Infrared Sensor is a reliable tool for measuring the volume of the arm and capturing photographs of the arm. Then it is possible to systematically evaluate changes in arm volume. This procedure makes it possible to accurately analyze changes in arm size [6].

Soft Tissue Ultrasonography (STU)

The method described in a publication by Khapaev et al. [8] and tested on patients with upper limb secondary lymphedema, shows soft tissue ultrasonography (STU) as an innovative and accurate instrument for evaluating lymphedema. The STU technique analyzes the tissues of the arm using ultrasound. The researchers advise the patient to lie down with the scanned arm near the torso and one hand on the thigh. By not pressing too hard with the instrument, they ensure a clear picture of the layers and muscles of the arm with no deformation. They also measured soft tissue thickness at four distinct levels on each arm using specific spots on the arm as guidelines [8].

Pressure Sensor

The final technology discussed in this sub-section is a pressure sensor, as investigated by Kato et al. [10]. This device is used for assessing the water content in lymphedema-affected tissues. The key outcome of this study is the establishment of a regression formula for calculating water content in the upper limb. Furthermore, as Kato et al. [10] point out, the tool created shows the potential for future improvements.

Bioimpedance Methods and Perometry

Another two methods are bioelectrical impedance spectroscopy (BIS) and single frequency bioimpedance analysis (SFBIA) which were mentioned in a paper by Kim et al. [1]. Both techniques use bioimpedance (BIA) measurements which determine excess fluid from total limb volume by using electrical currents. Kim et al. [1] suggest that using these technologies could help predict the result of treatment. Still, when compared with clinical data it shows that the measurements of bioimpedance can help to predict how a treatment will go. However, on their own, they do not have a particularly high level of accuracy in predicting treatment results. It is advised to combine bioimpedance measurements with traditional methods a measuring tape or water displacement to increase the accuracy of forecasts.

In his literature review, Rincon et al. [9] compared the two approaches: bioimpedance mentioned above and perometry, as claimed by Gergich et al. [5] it is a tool that utilizes infrared lights. As discussed in Rincon et al.’s [9] review, perometry and bioimpedance analysis (BIA) have a strong correlation. It's important to keep in mind that BIA measures excess water, while perometry offers a more comprehensive evaluation that takes into account changes in fibers, cells, and other limb components.

To summarize, this review has covered a spectrum of techniques for lymphedema assessment, incorporating a variety of technological approaches. To achieve the goal of the graduation project the interest is on the tool that can be employed in the home environment.

2.3 Home Application Feasibility

Patients with lymphedema could significantly benefit from these technologies, particularly if a home applicable monitoring tool becomes available to further improve the monitoring process. It appears that multiple innovative methods are available, including optoelectronic perometry, bioelectrical impedance spectroscopy (BIS), single frequency bioimpedance analysis (SFBIA), soft tissue ultrasonography (STU), pressure sensor, and Kinect Infrared Sensor for creating 3D models. In Nobel et al.'s research [6], it was required that the measuring setup contain four microphones, two cameras, an infrared light source, a Kinect sensor bar, and signal processing equipment. In contrast, Lu et al. [7] claim that their method is automated, relying mostly on a Kinect sensor with extra use of mathematical techniques. However, both research teams agreed that these procedures utilizing the Kinect sensor could be used at home, avoiding the need for external support. Moreover, the study of Kato et al. [10] describes the goal of the research as developing a tool with a pressure sensor for home usage, which was achieved.

When comparing several techniques for measuring home utilization, Lu et al. [7] evaluated perometry as it can be applied in a home setting as mentioned above. They concluded that while perometry, which employs infrared light, has become popular, it is too costly and hence not suitable for self-monitoring. In a paper describing methods to manage lymphedema at the early stages after breast cancer, Gergich et al. [5] agree with Lu et al.'s [7] vision that optoelectronic perometry cannot be used in the home environment which was probably the reason why the research was done in a medical center. Another technology investigated by Khapaev et al. [8] that cannot be used at home by patients is ultrasonography. The ultrasound machine has to be applied at the four different points of an infected arm which is not possible for self-measurement.

In their research, Kim et al. [1] examined BIS and SFBIA measurement methods, noting that they may not be the most practical choice for home use. It was claimed that BIS requires a lot of physical space and is probably not very appropriate for the home setting, whereas SFBIA is small and simple, which makes it ideal for clinic facilities. Additionally, Kim et al. [1] and Lu et al. [7] both had the same opinion on the difficulties involved in self-measurement using BIS and SFBIA. Due to the use of disposable electrode attachments, BIA requires the placing of electrodes at various areas on the limb, which might result in rising expenditures over time.

To conclude, certain measurement techniques are better suited for home implementation, and the following section will look into their benefits and limits, excluding technology unsuited for home usage.

2.4 Advantages and limitations of technological approaches

The above-mentioned new approaches' accessibility, some of which are suited for home usage, comes with benefits and drawbacks worth investigating. Comparing the results of Lu et al. [7] and Noble et al. [6], both studies illustrate the benefits of employing the Kinect Infrared Sensor for lymphedema monitoring. According to Noble et al. [6], it is extremely accurate in detecting even tiny volume changes and has the potential to fix the inaccuracies associated with traditional methods such as the tape measurement approach. Furthermore, it is applicable in the household environment. Its affordability, rapid picture acquisition which is just a few minutes, high precision, and minimum cleanup are also highlighted by Lu et al. [7].

Furthermore, patients can easily conduct these measurements at home for regular monitoring. It can identify early indicators of lymphedema, such as localized swelling. Despite these benefits, the Kinect sensor is not without its faults. Lu et al. [7] point out an important limitation: the sensor's ability to measure accurately decreases for changes larger than 1 cm due to calibration problems, which can lead to significant errors when measuring small volumes. This shows that while the Kinect is very good at picking up small changes in volume, its accuracy drops when dealing with larger changes. Kato et al. [10] also contribute to this discussion by emphasizing the value of precise measurements in self-monitoring technologies, even though they had to manually correct some measurement errors in their study.

Bringing these observations together, it's evident that the Kinect and similar devices offer several benefits for monitoring lymphedema, like being more accessible, accurate, and cost-effective. However, they also come with certain limitations, especially regarding calibration issues that can impact their accuracy in some cases. These technologies represent a significant advance but also underscore the ongoing need for improvement, particularly in enhancing early detection capabilities and reducing measurement errors.

2.5 Conclusion of a literature review

In summarizing the literature on lymphedema measurement techniques, we have assessed both traditional methods and emerging technologies. Reflecting on the efficacy of non-technological approaches in lymphedema measurement, it's clear that both the measuring tape and water displacement methods offer valuable insights for early detection and monitoring of this condition. Building upon this foundation, a wide range of technologies were examined, the investigation revealed several innovative and technologically advanced solutions that showed great potential.

The feasibility of employing these technologies in the house was then investigated. While certain devices, such as the Kinect infrared sensor and pressure sensor, have appealing uses for home monitoring, optoelectronic perometry, bioimpedance (BIA) methods, and ultrasonography are difficult to implement due to their high cost and complexity. It is crucial to emphasize the significance of cost when comparing these methods. Traditional techniques, being more affordable, may remain preferable for widespread use, particularly in settings where cost constraints are a primary concern.

This literature review demonstrates that moving to home lymphedema monitoring can enhance disease regular monitoring. The final section looks at the advantages and disadvantages of various technologies in the context of lymphedema tracking. The Kinect infrared sensor, for example, provides great accuracy and early detection capabilities. However, it cannot avoid limitations, especially errors greater than 1 cm due to calibration. Similarly, pressure sensors may monitor themselves but require professional intervention to fix measurement inaccuracies.

Chapter 3. Methods & Techniques

Creative Technology encompasses various disciplines. The creative technology design process guides the creation of concepts for numerous projects throughout several modules. This approach includes four stages: (1) ideation, (2) specification, (3) realization, and (4) assessment [11]. This chapter comprehensively details all the stages, and each section aligns with a dedicated chapter in the thesis.

3.1 Ideation Phase

In this phase, as mentioned in a paper by Mader and Eggink [11], technology can serve as a starting point. Following an extensive literature review, an informed selection of technology was made by analyzing its advantages, disadvantages, and other crucial factors such as home feasibility. The final decision initially leaned towards utilizing a Kinect Infrared sensor. However, after a more in-depth analysis of the target group, it became apparent that implementing a technological approach, such as the Kinect sensor, might pose challenges due to the age of the users and the associated costs of the sensor. It is important to note that the initial exploration of the technological solution which is the Kinect infrared sensor was a valuable part of the ideation phase. It laid the foundation for critical thinking and ultimately guided the decision towards a non-technological device based on a water displacement approach, ensuring better alignment with the characteristics and preferences of the target demographic.

3.2 Specification

The specification phase discussed the technical criteria for developing efficient lymphedema measuring equipment for home usage, with a focus on post-breast cancer therapy patients. These requirements were divided into Functional and Non-Functional Requirements to ensure that the tool fulfilled its intended function and met user demands and daily usage standards. The chapter also explained the use of the MoSCoW approach for prioritizing features and functionality, which led to the creation of preliminary needs classified as Must Have, Should Have, Could Have, and Won't Have.

3.3 Realization

During this phase, the focus shifted to practical implementation, where the designed lymphedema monitoring system was constructed. Key aspects addressed in the realization phase included the construction of the home arm volumeter using PVC pipes, the creation of a customized cup for severity level indication, the methodology for arm circumference measurement, and the calculation of arm volume using a measuring tape. This phase aimed to translate the theoretical concepts and specifications outlined earlier into tangible prototypes and methodologies for real-world application.

3.4 User Evaluation

The evaluation phase is expected to assess the performance and user interaction of the newly developed tool. The primary objectives include evaluating the accuracy of the volumeter compared to a measuring tape, evaluating its usability in a home environment, and understanding the user experience during operation. The evaluation methods involve recruiting participants for testing, conducting experimental procedures with both the volumeter and measuring tape, and gathering feedback through interviews and surveys. The results of the evaluation will provide insights into the effectiveness and practicality of the volumeter, ultimately informing its potential for improving lymphedema monitoring.

Chapter 4. Ideation

4.1 PACA (People, Activities, Context, and Artefacts) Analysis

The PACA analysis was utilized to make sure that the lymphedema measuring instrument effectively resonates with its intended audience. The framework for a design process is established by this preliminary investigation of the Participants, Activities they participate in, Context of Usage, and the Artifacts they interact with.

4.1.1 People

People undergoing cancer treatments often face the risk of developing lymphedema. If they are at high risk, they could benefit from an effective tool for early detection of lymphedema at home. This tool is designed to effortlessly integrate into patients' daily lives, which is important for two main reasons: firstly, it provides convenience and ease of use right from their homes; secondly, it facilitates the early detection of lymphedema, a condition that individuals might not recognize on their own. By catching lymphedema early with a device that is easy to use and understand, patients can manage their health better and potentially reduce or prevent complications.

In the study of lymphedema following cancer treatment, age is a key factor in its occurrence and management. Research by Zhang et al. [12], including 71 patients found the average age of those with the condition to be 52.14 ± 9.19 years [12]. Meanwhile, a study on a wider age range of participants, from 25 to 79 years, identified an average age of 61 years old [13]. Importantly, an analysis of Armer et al. [14] focusing on post-breast cancer lymphedema showed a more frequent occurrence of symptoms in patients under 60 years. Moreover, studies indicate that older populations often prefer non-technological methods for various activities [15]. This preference can be influenced by factors such as physical and sensory limitations, difficulties in using technology, and a person's absence of interest or fear of technology. Furthermore, there is a common lack of expertise in digital health solutions and a preference for conventional healthcare services [15]. These insights are important for designing a health tool that is user-friendly for older populations, emphasizing the need for simplicity and familiarity in their design.

4.1.2 Activities

The tool is specifically designed for routine usage by individuals who are at risk of developing lymphedema due to cancer treatments, as previously mentioned. It is recommended that users measure their arms with the device at regular intervals, once a week ideally, to monitor for early indicators of lymphedema such as increases in arm volume caused by swelling. This consistent monitoring is crucial for tracking any changes over time. By including measures in a weekly health assessment, a regular monitoring program helps people be aware of their risk for lymphedema and encourages immediate treatment.

4.1.3 Context

The tool is meant to be used at home. It is easy for people to measure themselves, even if they used to get some assistance in a measuring process before. So, people can use it whenever they want, making it a simple part of their daily life. Flexibility in usage is a key feature. It can be used at any time, accommodating users' schedules and removing any pressure associated with specific timing for measurements. Furthermore, the tool's compact design, not exceeding half a meter in length, ensures it fits comfortably in any home setting without occupying much space, enhancing its portability and convenience for regular monitoring.

4.1.4 Artefacts

The tangible components used in the measuring method are the main emphasis of this section. The primary artifact is a water displacement measurement instrument with an accurate and user-friendly design. Additional instruments, such as a measuring tape for comparison reasons, are also necessary. Portability is another key consideration, enabling user convenience without restricting mobility.

4.2 Brainstorming

During the ideation phase, the mind dump ideation technique was used to determine a selection of one final solution. The mind dump approach explained by Bourgeois-Bougrine et al. [30] suggests the researcher to ideate as many ideas as possible without any judgments and overthinking. This technique was selected for its ability to produce a free-flowing creative process, allowing for the exploration of a broad range of ideas without initial constraints. The start was from the topic name, from this central theme, the exploration branched out into sub-topics, each representing a specific aspect or challenge related to the issue. These were then further expanded into more related topics. The first step of this phase is demonstrated in Figure 1. Two major factors led to the selection of base concepts from the variety of generated ideas: researcher interest and feasibility. So, concepts that were judged realistic for execution and fit with the researcher's enthusiasm were prioritized.

From the ideation session, two primary concepts were selected based on criteria such as potential for accurate lymphedema detection, user-friendliness, and cost-effectiveness: a device utilizing a Kinect infrared sensor and a home-based water displacement method for measuring arm volume. Each concept aligns with the research objectives, aiming to provide a user-friendly and efficient solution for early detection and self-monitoring of arm lymphedema. The mind dump approach was efficient in producing a wide range of concepts, allowing for an extensive investigation of potential solutions to the issue. These base concepts will serve as the foundation for the subsequent phases of development and refinement.

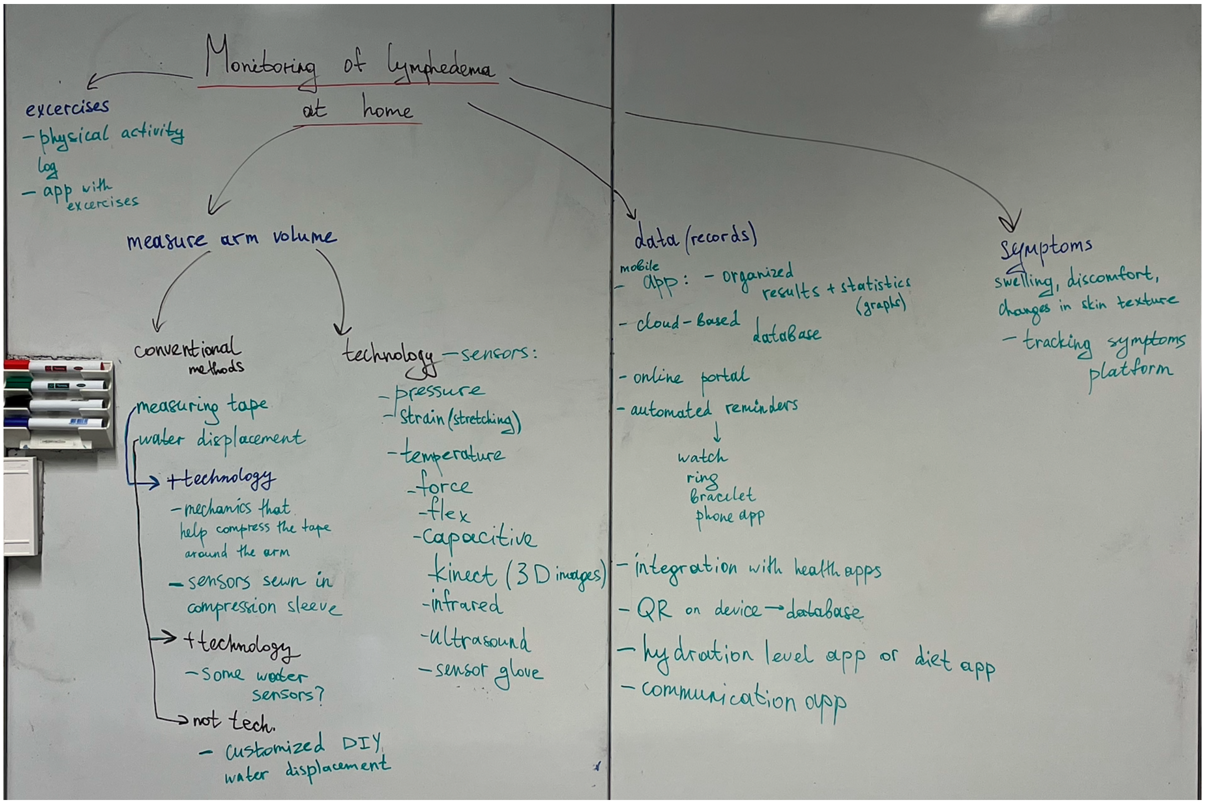


Figure 1. ‘Mind dump’ ideas method which helped to generate 31 ideas

4.3 Preliminary concept

As mentioned in section 4.1, the brainstorming session led to two ideas selected by the researcher. The two ideas selected at the end of that phase were the Kinect sensor device and the method based on water displacement that can be implemented in the home setting. The literature review gave some background about this type of sensor that can take depth maps of the object, in the context of the project is an arm, which later can be used in creating 3D images of the object, and then the measurements can be done. In a paper by Lu et al. [6], which compares technological and traditional methods of estimating lymphedema, the patients who tested the proposed technique had to manually hold the Kinect camera and rotate the sensor around the affected arm, maintaining a distance of 80 cm to ensure the most accurate results. One potential solution to enhance this process is the development of a device that automatically rotates the Kinect sensor, eliminating the need for users to do so themselves. In a flash of inspiration, the sketch of the possible device was drawn and shown in Figure 2.

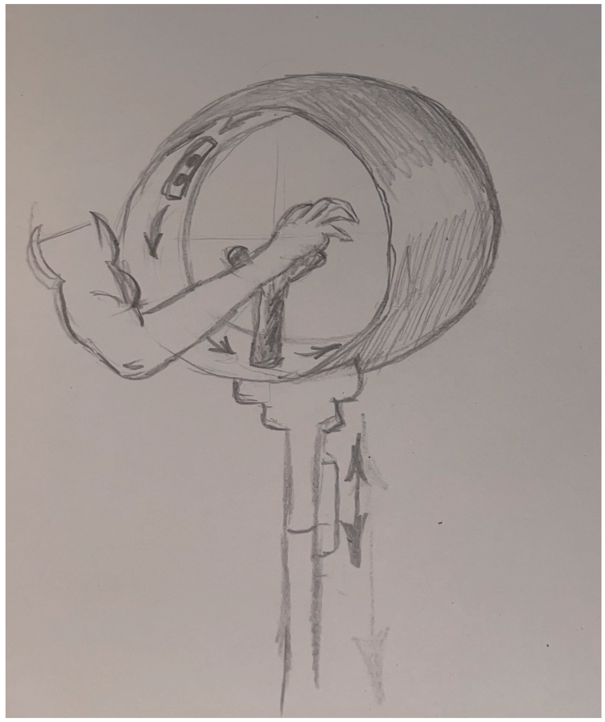


Figure 2. The sketch of the first product idea after the Ideation step

It is a cylindrical tube with a Kinect sensor inside that rotates automatically around the arm. Introducing a hand holder can enhance the user experience by minimizing arm fatigue and providing a more comfortable alternative for supporting the raised arm. To enable the sensor to identify and initiate the scanning process, clear instructions or visual cues on the holder can guide users in positioning their hands correctly.

This technology appears complex, raising questions about its suitability for the intended older user group. As highlighted in sub-section 4.1.1 and supported by the study conducted by Lisa Gualtieri et al. [15], older adults may face challenges with digital health technologies due to varying levels of digital literacy. These challenges include difficulties in downloading apps, setting up devices, and understanding technical jargon. This study emphasizes the importance of providing user-friendly solutions that fit the needs and comfort levels of senior citizens. As a result, directing the project toward a more conventional, non-technological approach is an essential requirement for assuring the tool's use and acceptability by its core users. Moreover, the required setup space adds to the complexity, especially since the sensor needs to be 80 cm away from the user to work properly. This space requirement may not fit well in smaller home environments, making the technology less suitable for everyday use. This further supports the shift towards simpler, more space-efficient solutions that cater to the practical limitations and preferences of the intended users, it will be further discussed in the following section.

4.4 Final Concept

The final concept is grounded in the principle of water displacement shown in Figure 3, a method proven effective in related study [16]. This tool includes a set of pipes designed to measure changes in arm volume, a key indicator of lymphedema. The interaction with it is straightforward: the user inserts their arm into a water-filled pipe. As the arm displaces the water, the tool measures the change in water level, which correlates to the volume of the arm.

This method, inspired by traditional water displacement techniques is suitable for the target demographic as it employs a more conventional approach that aligns with their preference for non-technological methods. The design emphasizes simplicity and ease of use. Clear, visual instructions guide the user through the measurement process, ensuring that even those with limited technological experience can operate the device confidently. Its interface offers real-time feedback on measurements, enabling users to monitor changes over time and notify their healthcare provider if needed, as detailed in the following section 4.4.1. This final concept combines the reliability of proven scientific methods with user-friendly design and accessibility.

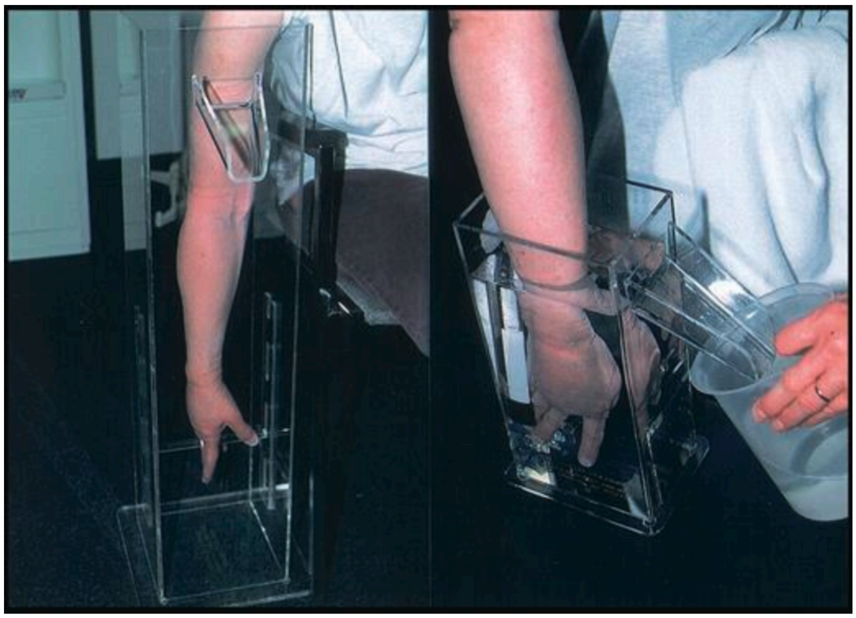


Figure 3. Water displacement method of measuring lymphedema [26]

4.4.1 Personalized cup

The addition to the final concept, created for the lymphedema monitoring system, was a personalized cup. A tool designed to indicate the severity of lymphedema based on the volume of displaced water. This cup is ingeniously segmented into three distinct zones - green, orange, and red - each representing different levels of arm volume and, consequently, the severity of lymphedema. The addition to the final concept, created specifically for the lymphedema monitoring system, was a personalized cup.

Green: This zone indicates either normality or a negligible shift in arm volume. When the volumeter's displaced water falls inside the cup's green region, the user's arm volume is within normal bounds which is less than 5% as discussed in section 2.1. This reassures the user by implying that there are no significant lymphedema-related issues.

Orange: The cup's orange area signifies the warning level. The presence of water in this region could point to the beginning of lymphedema. This intermediate zone suggests an apparent increase in arm volume, but maybe not to a crucial degree. Individuals whose measurements are in the orange zone are recommended to keep a careful eye on their condition and may want to seek early intervention advice from medical specialists.

Red: The red region is alert. If there is more water displaced here, there is likely an urgent lymphedema issue present since it signals a considerable rise in arm volume. The user should get medical help right away based on this obvious indicator. Water in the red zone is a crucial indicator that you need to get expert assistance to successfully manage the disease.

Chapter 5. Specification

5.1 Technical requirements

To build effective lymphedema measurement equipment for home use, particularly for patients who have completed breast cancer treatment, a set of technical specifications must be defined. Functional and Non-Functional Requirements are the two main categories into which these requirements are separated.

1. Functional Requirements

Measurement Capacity: The tool should accurately measure differences in arm volume.

Measurement Outcomes: This function interprets the measurement outcomes, using the cup's color-coded zones.

Alert System: It should be capable of alerting the user if measurements fall outside normal parameters, suggesting a potential risk of lymphedema. The severity level is displayed on personalized cup with green, orange, and red colors.

2. Non-Functional Requirements

Usability: The tool must be user-friendly, especially for the target group, and with clear instructions.

Reliability: High accuracy in measurements and consistent performance over time.

Safety: The tool must be safe to use, with no risk of harm to the user.

Portability: The tool is designed to be compact, ideally not exceeding half a meter in length, to fit easily in a home environment without taking up much space, enhancing its portability and convenience for regular use.

Durability: The tool, constructed with durable PVC pipes, is designed to last for at least 5 years under regular use, offering longevity and resistance to wear and tear in a home environment.

Maintenance: Requires minimal maintenance and is easy to clean and care for.

5.2 Requirements

After conducting research on background information and the user domain, preliminary requirements can be established. The use of the MoSCoW technique in the device for monitoring arm lymphedema helps in the prioritizing of features and functionality.

Must Have	• Accurate volume measurement • User-friendly design • Intuitive user interface • Hygienic materials • User feedback mechanism
Should Have	• Real-time data visualization of arm volume trends • Durability and longevity (materials)
Could Have	• Integration with wearable technology • Connection to Bluetooth or WiFi • Reminders to encourage regular monitoring
Won't Have	• High-cost materials and components

Table 1. Preliminary requirements for home-based arm volume monitoring tool

Table 1 demonstrated essential specifications for the home-based arm volume monitoring tool, categorized into four groups: Must Have, Should Have, Could Have, and Won't Have. The researcher concentrated on meeting all essential Must-Have requirements. Subsequently, the focus shifted to exploring additional Should-Have functionalities. Furthermore, the researcher would have assessed the possibility of incorporating Could-Have features if time had allowed, but it was not feasible. By clearly identifying Won't-Have aspects, practical constraints were established.

Chapter 6. Realization

6.1 Construction of the Home Arm Volumeter

The home arm volumeter, a key tool in lymphedema measurement, is constructed using common polyvinyl chloride (PVC) plumbing pipes.

Parts required for building an installation:

- A PVC pipe with a diameter of approximately 12.5 cm (4,9 inches), is cut to a length equal to the arm's length.
- A PVC pipe with a diameter of approximately 11 cm (4,4 inches), is cut to a length of about 23 cm (9 inches).
- An asymmetric "Y" PVC connector is designed to join a 12.5 cm (4,9-inch) pipe
- A PVC 45-degree elbow for connecting pipes of approximately 11 cm (4,3 inches) in diameter.
- A PVC cap for sealing the volumeter, designed for a 12.5 cm (4,9-inch) diameter pipe.
- PVC solvent glue for assembly.

After having all the parts, 4 steps have to be done. They are measuring arm length, cutting and gluing, then fitting and preparing.

1. **Measuring Arm Length**

The arm length of the researcher was measured first. With the hand extended, the measurement was taken from the inner fold of the armpit to the tip of the middle finger. This measurement indicates the necessary length for cutting the main PVC pipe. Anthropometric data specific to the Netherlands revealed that the average arm length for both males and females is 71.6 cm [22].

2. **Cutting and Gluing**

- The 12.5 cm diameter PVC pipe is cut to a length that matches the arm's measured length.

Based on these findings, the initial prototype's 2-meter PVC pipe was cut to 76 cm to align with the average arm length found. The 2-meter PVC pipe is shown in Figure 4. However, for a personalized evaluation before user testing, the researcher created a second version of the prototype measuring 69 cm in length, suiting their arm dimensions. Figure 5 showcases the two prototype versions developed for the project, one with a pipe length of 72 cm, aligning with the average arm length in the Netherlands, and the other with a length of 69 cm, tailored to the researcher's specific arm measurements.

Figure 4. PVC pipe, original length

Figure 5. Two PVC pipes of 69 cm and 72 cm

- A section of PVC pipe, which has an opening measuring 11 cm in diameter, was cut to create a segment that is 23 cm in length.

- From the bottom of the connector end that fit the 12.5 cm diameter pipe, a distance of 13 cm was measured upwards as shown in Figure 6. This measurement was marked on the Y-connector as point A. Next, the ridge on the Y-connector was found, and a point just above this ridge was marked as point B. A straight line was then cut from point A to point B. A smooth, curving lip was produced by sanding the cut edge. This step was illustrated in Figure 7.

Figure 6. Point A marked

Figure 7. Connection between points A&B

- The 12.5 cm cap was glued to one end of the 12.5 cm diameter pipe, closing the bottom of the volumeter.

- The asymmetric Y-connector was then attached to the other end (on top) of the 12.5 cm diameter pipe.

3. **Fitting**

In the fitting stage, the 10 cm diameter pipe was connected to one end of the elbow. This elbow was then attached to the asymmetric Y-connector. This process formed the spout of the volumeter, which also serves as a handle for transporting the device. The result of this stage is depicted on Figure 8.

Figure 8. Assembled prototype

4. **Preparation**

   Every component has been properly cleaned. Next, an internal and external inspection was performed on the volumeter. To guarantee safety, all sharp edges were filed and sanded down. To provide hygienic conditions, a bleach solution was used to clean and disinfect the volumeter. Also, some blue lines were painted to hide the connecting parts.

Figure 9. Prototype with all edges sanded and some design details added

6.2 Customized cup

In the creation of the lymphedema monitoring system's customizable cup, the choice of defining the different severity levels was guided by the study findings presented in section 2.1 on non-technological ways of lymphedema assessment. One of the most important parts of the system is the cup, which has three different zones on it: green, orange, and red. These zones correspond to different ranges of arm volume changes, which indicate differing degrees of lymphedema severity, as described in section 4.4.1.

So the process is the following:

1. Water displaced by the arm flows into the personalized measuring cup.
2. This cup is marked with a scale for easy reading.
3. Given that the density of water is close to 1 gram per cubic centimeter at standard conditions with temperature 20°C, milliliters to milligrams can be equated.

Interpreting the Cup Levels:

- If the percentage increase is up to 3%, the water level in the personalized cup will fall within the green zone.
- If the increase is between 3% and 10%, it will be in the orange zone.
- If the increase is more than 10%, it will reach the red zone.

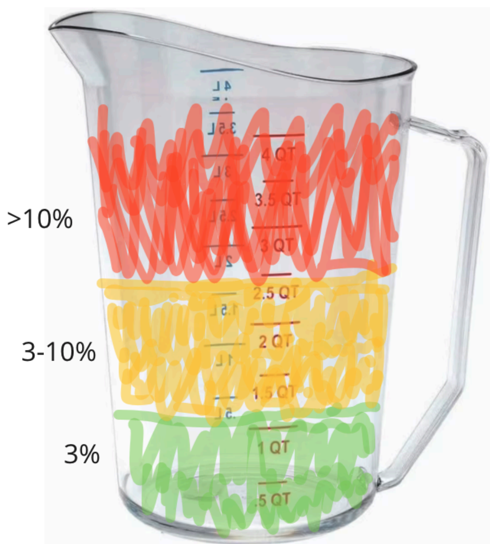
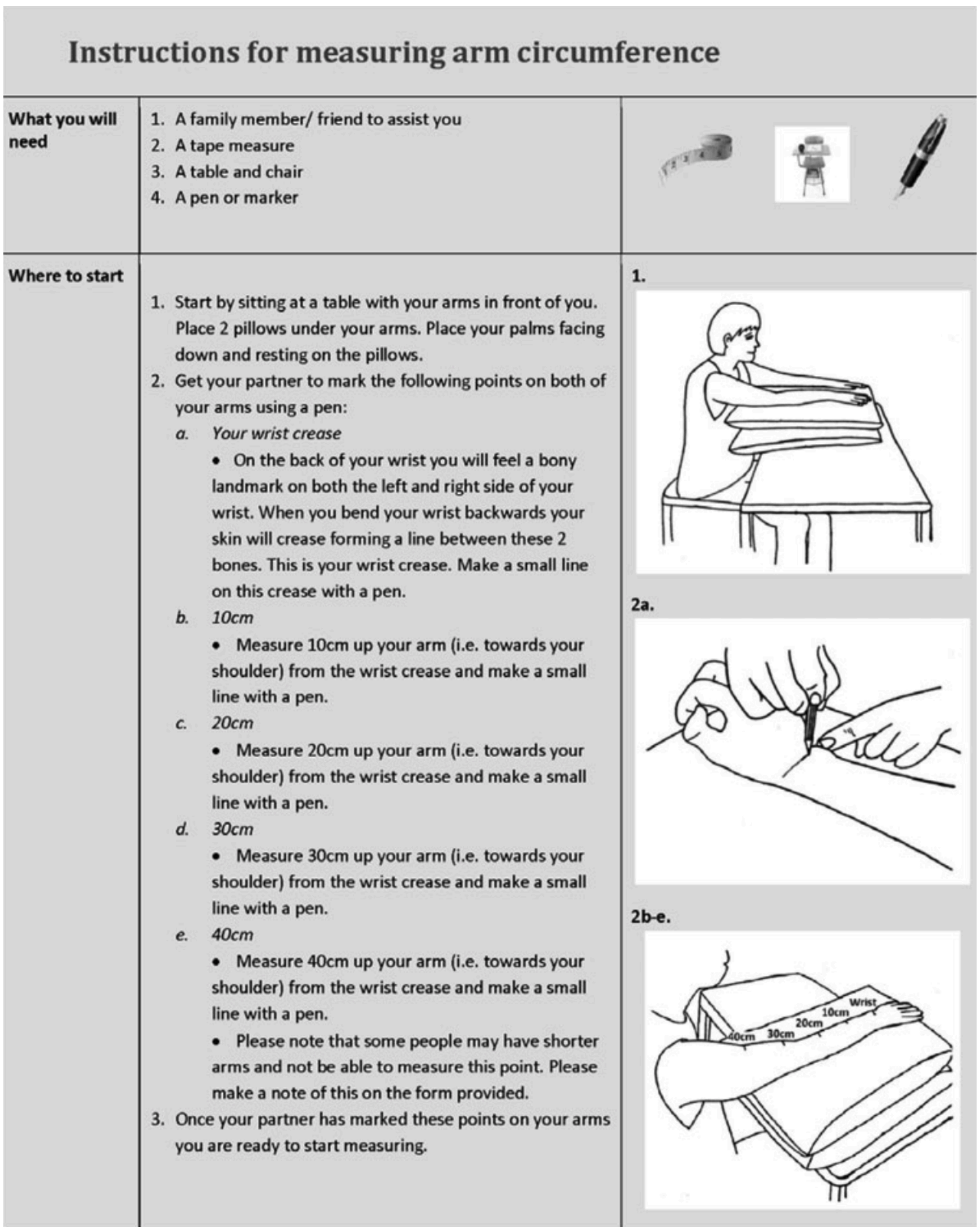


Figure 10. Representational sketch of a customized cup

6.3 Arm Circumference Measurement Methodology

For monitoring potential lymphedema, arm circumference measurements must be accurately captured. The participant should sit with their arms completely extended on a table, supported by pillows. Marks should be made at the wrist, then at 10-centimeter intervals up the arm to the shoulder. The measuring tape should fit easily around the arm without being too tight. Each measurement should be carefully recorded with the participant identification number. Illustrative images on Figure 11 and 12 are provided to guide the step-by-step measurement process.



Instructions for measuring arm circumference

What you will need	1. A family member/ friend to assist you 2. A tape measure 3. A table and chair 4. A pen or marker	
Where to start	1. Start by sitting at a table with your arms in front of you. Place 2 pillows under your arms. Place your palms facing down and resting on the pillows. 2. Get your partner to mark the following points on both of your arms using a pen: *a. Your wrist crease* • On the back of your wrist you will feel a bony landmark on both the left and right side of your wrist. When you bend your wrist backwards your skin will crease forming a line between these 2 bones. This is your wrist crease. Make a small line on this crease with a pen. *b. 10cm* • Measure 10cm up your arm (i.e. towards your shoulder) from the wrist crease and make a small line with a pen. *c. 20cm* • Measure 20cm up your arm (i.e. towards your shoulder) from the wrist crease and make a small line with a pen. *d. 30cm* • Measure 30cm up your arm (i.e. towards your shoulder) from the wrist crease and make a small line with a pen. *e. 40cm* • Measure 40cm up your arm (i.e. towards your shoulder) from the wrist crease and make a small line with a pen. • Please note that some people may have shorter arms and not be able to measure this point. Please make a note of this on the form provided. 3. Once your partner has marked these points on your arms you are ready to start measuring.	1. 2a. 2b-e.

Figure 11. Detailed instruction on the usage of measuring tape [24]

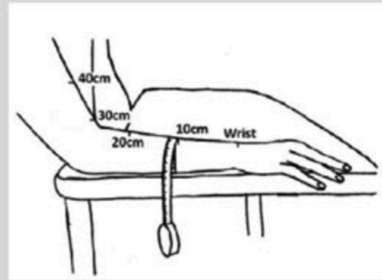
Completing the measurements	1. Start with your RIGHT arm. 2. Use the tape measure to measure the distance around your wrist at the wrist crease. Ensure that you do not pull the tape measure too tight around your arm. An average measurement for this position would be somewhere between 14cm and 20cm. Please double check your measurement prior to recording it. 3. Record your measurement on the form provided, being careful to write it in the correct position corresponding to the right arm. 4. Continue up your arm measuring the circumference at the 10cm, 20cm, 30cm and 40cm marks you made earlier. Generally your measurements should get larger as you move up the arm; however, this is not always the case. 5. Repeat steps 2-4 to measure your left arm.	
Important points to remember:	• All measurements are in centimeters. • When recording your measurements on the form provided, please double check that the measurements for your right arm are recorded in the space for the right arm on the form, and similarly for the left arm. • Please include your study identification number in the area provided at the bottom of the form.	

Figure 12. Detailed instruction on the usage of measuring tape [24]

6.4 Calculated Volume using measuring tape

To establish a standard for comparison in arm volume measurement, the study employed a mathematical model using the measuring tape as a reference. The arm volume was calculated using the following formula derived from the geometry of a truncated cone:

$$V=\frac{1}{3} \times \pi \times h \times (r_1^2 + r_2^2 + r_1 \times r_2)$$

Formula 1. Volume of a truncated cone

where V represents the volume of the arm segment, h is the height (distance between measurement points), and r_1 and r_2 are the radii at the ends of the arm segment. In this study, h was consistently maintained at 10 cm.

To ascertain the radius of the arm, the circumference (C) was measured with a measuring tape, and the radius was derived using the relationship between circumference and radius:

$$C = 2\pi r \Rightarrow r = \frac{C}{2\pi}$$

Formula 2. Circumference formula rearranged for radius

Then, the arm was divided into segments (10-20 cm, 20-30 cm, 30-40 cm), and the volume for each segment was calculated independently. The total volume of the arm was then determined by summing the volumes of these individual segments.

The Python code (in Appendix B) was written to facilitate the arm volume calculation based on circumference measurements. By inputting the circumference values at different segments of the arm and the distance between those points, the total volume of the arm has been calculated. This was done to make the calculation process faster.

Chapter 7. Evaluation

7.1 Evaluation Objectives

The evaluation of the newly developed lymphedema monitoring tool is designed to assess its performance and user interaction. There are three primary objectives: to evaluate the tool's accuracy in measuring arm volume changes, to examine its usability in a home environment, and to understand the user experience during its operation. The ethical committee has reviewed and accepted the request for conducting the study (application number 230682).

Accuracy: The evaluation determines the accuracy of the volumeter by comparing its readings with those from a measuring tape, which is a standard and reliable tool for measuring limb volume. The goal was to confirm that the volumeter's measurements are as accurate as those taken with a measuring tape. This comparison is important to ensure the volumeter can be trusted for regular use.

Usability: Usability is the second key parameter, with a focus on the tool's design, which incorporates readily available materials, durability, and ease of handling. The simple-measurement volumeter was built of non-fragile materials and is lightweight, making it easy for the target audience to operate without the need for special assistance.

User Experience: The user experience includes the general engagement with the device, as well as the simplicity with which the customized cup's findings may be understood and interpreted. The objective was to ensure that the tool not only fits effortlessly into the user's daily routine but also promotes self-monitoring.

7.2 Evaluation Methods

7.2.1 Recruitment Process

For the user evaluation, two rounds of testing were conducted. The first round included at least five university students, following Lazar et al.'s [31] guidance to identify key system issues. Participants were required to be healthy, at least 18 years old, and fluent in English. Exclusion criteria encompassed any serious medical disorders, medication or substance usage that could influence the results, and sensory impairments. Recruitment took place through the university's participation website (https://www.utwente.nl/onderzoek/meedoen/) and the researcher's network.

The second phase focused on older individuals, aiming to recruit at least one person over the age of 55 who spoke English. Similar exclusion criteria as in the first round were applied. This phase concentrated on an age range that closely aligns with the typical age of individuals affected by breast cancer, ensuring the study's relevance. Recruitment for this phase also relied on the participation website and personal connections.

7.2.2 Experimental Procedure

Before introducing the device to participants, a preliminary test was conducted by the researcher to ensure its safety and readiness for evaluation as shown on Figure 13. This first testing step is important for making certain the tool works as intended, provides no safety issues, and is ready for the evaluation by the participants.

There were two testing conditions:

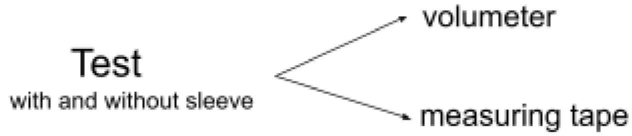


Figure 13. Preliminary safety check by the researcher

First Round: University Students

Participants first received and reviewed consent forms and informational brochures to ensure informed participation. After, they were introduced to the newly developed volumeter designed for arm volume measurement. With detailed instructions, participants initially used the tool to measure their arms without any additional equipment, ensuring a baseline volume is established.

Participants then put on a sleeve from bubble wrap (Figure 14) that follows the proportions of the arm. It was designed to imitate increased arm volume before taking a second measurement with the volumeter. This method enables the monitoring of any variations caused by the additional sleeve. To provide a 'golden standard' for comparison, the researcher measured the subjects' arm volume with a measuring tape with a sleeve on and without. This comparison methodology aims to validate the precision of the created instrument against the standard measuring tape method. Following the measurement procedure, semi-structured interviews was carried out to obtain qualitative feedback on the device's usability and user experience. Participants were questioned about their comfort level with the instrument, the simplicity with which the findings may be interpreted, and any ideas for improvements. Moreover, the study utilized a within-subject design, where the same participants used both the newly developed tool and the traditional measuring tape, allowing for a direct comparison.

Figure 14. Bubble wrap sleeve

Second Round: Older Participants

The second round's approach is similar to the first, but it is tailored particularly for older participants, to ensure that the tool's applicability within the context of the intended user group. After reviewing the consent forms and brochures, participants were guided through the use of the volumeter on their unaltered arms and encouraged to self-measure with a measuring tape. The user had to do: volumeter measurements with and without a bubble wrap sleeve and measuring tape measurements with and without a sleeve. This comparison methodology aims to determine which method is preferable in terms of user experience. This approach will help identify the most effective and user-friendly tool for monitoring arm volume, especially for those at risk of developing lymphedema.

Following the testing phase, users were asked to complete a survey questionnaire that incorporates the System Usability Scale (SUS) to evaluate the tool's usability. Open-ended questions were also provided to gather specific feedback on their experiences with the volumeter and measuring tape. This technique collects both quantitative and qualitative data.

7.2.2 Data Analysis

The first stage of testing with university students were focused on comparing the accuracy of the new water displacement instrument to the standard measuring tape. In this comparison, participants measured their arm volumes with and without a sleeve, using both methods. The goal was to use the Wilcoxon signed-rank test to statistically examine the percentage changes in volume and circumference to determine the new tool's accuracy. The second round of testing shifted focus to older individuals, who are more representative of the tool's target demographic. The second round of testing was primarily evaluate user experience, evaluating participants' comfort, ease of use, and preference for the water displacement tool versus the measuring tape.

7.3 Results of evaluation

7.3.1 Comparative analysis

The study aimed to compare the accuracy of a new volumeter for arm volume measurement to the classic measuring tape approach. Arm volumes were assessed using both devices in a within-subject design, with individuals wearing a sleeve made from bubble wrap designed to simulate increased arm volume. Percentage differences in arm volume were calculated using the formula:

$$\text{Percentage increase} = \frac{(subsequent\ volume - baseline\ volume)}{baseline\ volume} \times 100\%$$

Where baseline volume - arm volume without additional clothing in milliliters
subsequent volume - arm volume when the individual wears a bubble wrap sleeve

This measure served as the basis for subsequent statistical comparisons discussed in section 7.3.2. The screenshot of spreadsheet with measurement data is in the Appendix A.

The research included six participants, with ages ranging from 18 to 58 years. Five of the participants were students above the age of 18, representing a younger population, while the sixth participant was 58 years old, who matches the age group affected by lymphedema. This age range helps to assess the new tool's usability and accuracy across a wider range of potential users.

Figure 15 and Figure 16 below provide a visual comparison of baseline and subsequent arm volumes for six participants. Both graphs illustrate the changes in arm volume with and without the influence of bubble wrap, enabling an evaluation of the volumetric variations identified by two techniques. When the two graphs are compared, it is clear that both the measuring tape and the volumeter instruments detected changes in arm volume when bubble wrap was applied, imitating an increase similar to lymphedema.

Figure 15 shows that the volumeter was especially effective at picking up changes in the arms of participants P2 and P3. Because these participants had bigger arms then all other participants, wrapping them in bubble wrap added more volume compared to smaller arms. The volumeter, which works by seeing how much water is pushed aside by the arm, noticed a bigger volume increase for these larger arms. Essentially, even a small increase in the size of a larger arm results in a significant volume change, showing that the volumeter is really effective at detecting volume differences in bigger limbs.

For the others, P1, P4, P5, and P6, with smaller arms, the measuring tape seemed to be more sensitive. This might be because it's easier to see changes in the arm's circumference with a tape, especially when the overall volume is less.

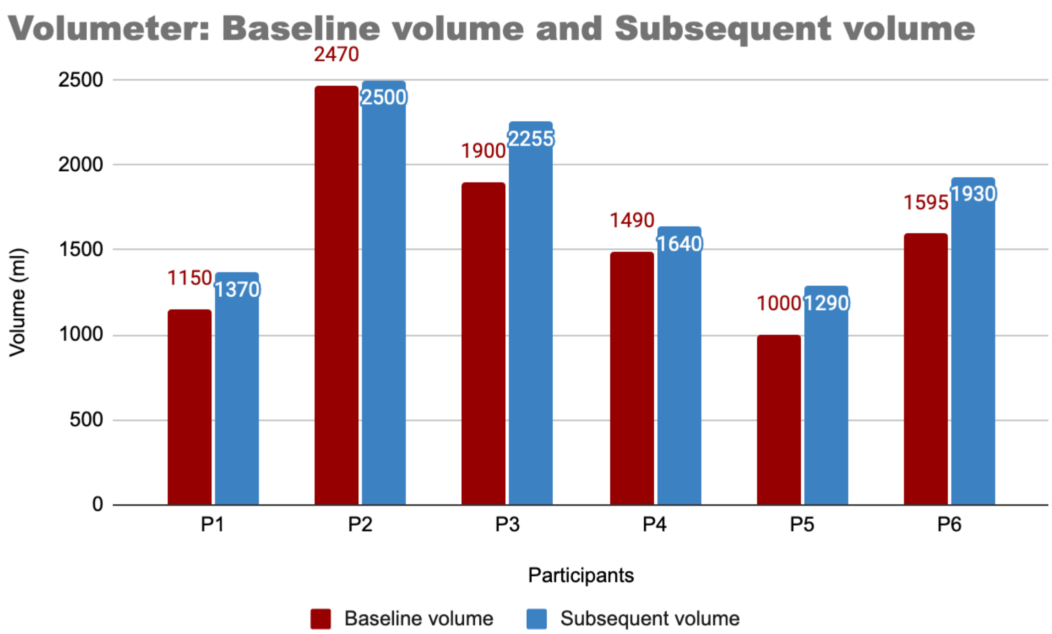


Figure 15. Comparison of baseline and subsequent (with bubble wrap) arm volumes for six participants, as measured with a home-based volumeter tool

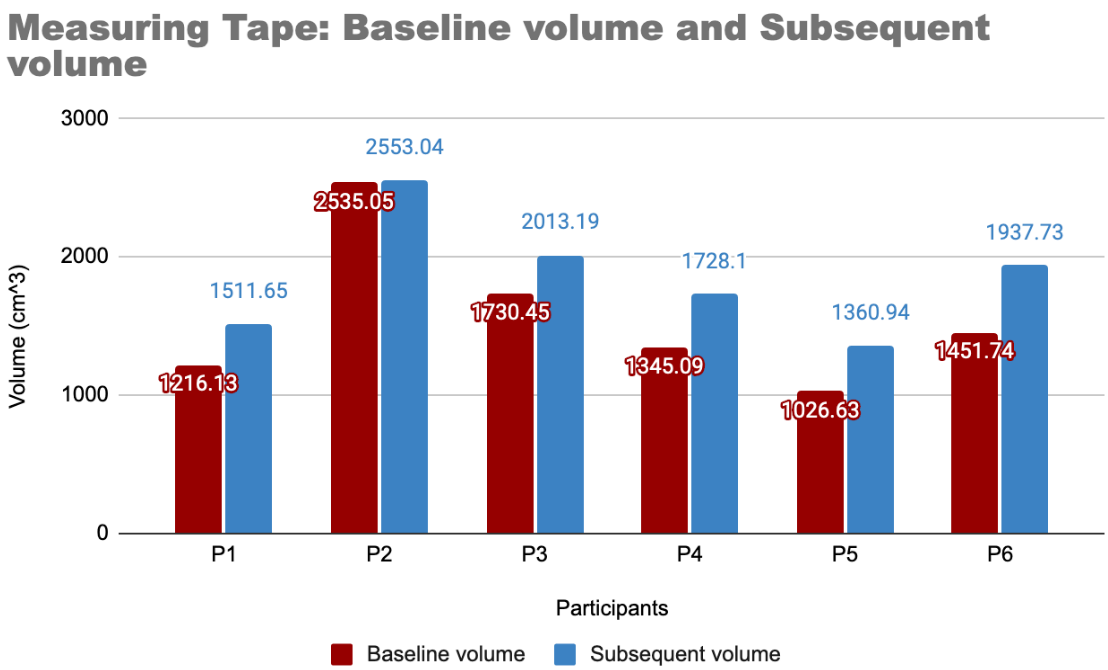


Figure 16. Comparison of baseline and subsequent (with bubble wrap) arm volumes for six participants, as measured with a measuring tape

The volumeter's effectiveness was determined by calculating the percentage increase in arm volume after the application of bubble wrap, in contrast to using a conventional measuring tape. These calculated percentages are shown in Table 2. The visual representation of these results is demonstarated in Figure 17, which sshows the differences between the two methods for each participant.

Participant Number	Percentage difference when using a measuring tape (%)	Percentage difference when using a volumeter (%)
1	24.30	19.13
2	0.71	1.21
3	16.34	18.68
4	28.47	10.07
5	32.56	29.00
6	33.48	21.00

Table 2. Summarized results of the percentage increase in arm volume while testing 2 methods: measuring tape and volumeter

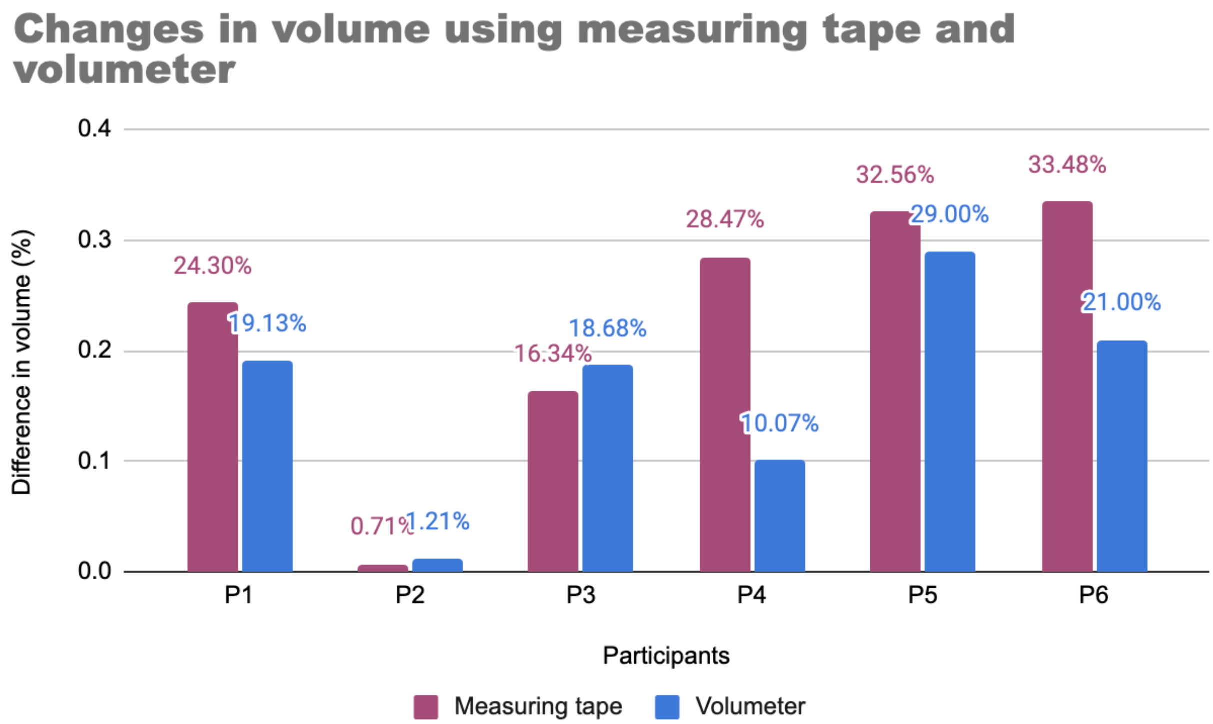


Figure 17. Percentage difference in volume measurements for six participants, comparing the results obtained using a traditional measuring tape (shown in red) and a new volumeter (shown in blue)

In the comparative analysis of arm volume measures as demonstrated in Figure 17, a group of younger participants, specifically Participants P1, P2, P3, and P5, showed only minimal differences between the old measuring tape and the volumeter. The findings from Participant P2 represent a unique situation within the study's framework. While the bubble wrap sleeve was used to increase arm volume, the difference observed for this individual was minimal. This observation could indicate a possible issue with the application of the bubble wrap sleeve for P2, potentially due to improper fitting or placement, which resulted in a less increase in volume compared to other participants. Despite the possibility of a problem with Participant P2's bubble wrap sleeve, the two techniques' measurements remain consistent. The minute 0.5% difference in their case indicates a high level of agreement between the traditional and novel measurement techniques.

Participant P4's results showed a big difference between the measuring tape and volumeter readings, unlike what was seen with other participants. This suggests something went wrong during P4's measurement. The correct method for using the volumeter involves placing the arm in a pipe so that the middle finger reaches the bottom, ensuring the right amount of water is displaced for an accurate measurement. P4's arm was too short to reach the bottom, leading to a potential misreading by the volumeter.

Participant P6, age target group representative, showed a larger difference in volume increase between the two methods, with the volumeter indicating a 33% increase versus 21% from the measuring tape. This participant self-measured their arm with the tape, which is more difficult and less trustworthy than measures performed by a researcher as was done with other participants. Participant P6 experienced difficulties keeping the tape steady and questioned the accuracy of their own measurements. These concerns show that self-measurement using a tape may be unreliable in older persons, emphasizing the need for more user-friendly instruments for accurate self-assessment.

7.3.2 Statistical analysis

The Wilcoxon signed-rank test's applicability was decided by the measurement data's non-normal distribution, which required a non-parametric technique for paired sample analysis. The findings of this test are critical in supporting or denying the null hypothesis (H_0), which suggests there is no significant difference between the percentage increases in arm volume evaluated by the two techniques.

Null Hypothesis (H_0): There is no significant difference in the percentage increase of arm volume measurements obtained from the traditional measuring tape and the newly developed volumeter. This means that the volumeter is just as accurate as the measuring tape in detecting changes in arm volume.

Alternative Hypothesis (H_1): There is a significant difference in the percentage increase of arm volume measurements obtained from the traditional measuring tape and the newly developed volumeter. This means that the measurements obtained from the volumeter differ from those obtained from the measuring tape, indicating a possible discrepancy in accuracy.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The median of differences between MeasuringTape and Volumeter equals 0.	Related-Samples Wilcoxon Signed Rank Test	,225	Retain the null hypothesis.

a. The significance level is ,050.

b. Asymptotic significance is displayed.

Figure 18. SPSS Statistics output showing the result of Wilcoxon Signed Rank Test

The Wilcoxon signed-rank test, as illustrated in Figure 18, has a significance level (p-value) of 0.225, which is larger than the standard alpha level of 0.05 with confidence interval 95%. This finding indicates that there is insufficient evidence to reject the null hypothesis. As a result, the null hypothesis is retained, which claims that there is no significant difference in the percentage rise in arm volume measurements acquired using standard measuring tape vs the newly created volumeter. Based on the sample data examined the test shows that developed tool is statistically equal in accuracy to the measuring tape for assessing changes in arm volume. There is no significant statistical evidence to suggest that the measurements from the volumeter differ from those of the measuring tape. This outcome supports the volumeter's potential use as a reliable tool for measuring arm volume in the studied group.

7.3.3 Feedback Analysis

During the initial round of testing with students, the qualitative feedback on the new volumeter device was gathered through semi-structured interviews. The participants, all students, provided their insights on several aspects of the device's usability and user experience.

The device was generally well-received, with all participants reporting that it was comfortable to use. However, P1 highlighted the need to stand as a discomfort. After that, the chair was provided to the next participants. The intuitive nature of the device varied among participants. Participants P1 and P4 specifically mentioned that clear instructions were crucial for them to understand that the arm must be submerged in the water-filled section of the volumeter. In contrast, other participants did not require such guidance and found the process of using the volumeter to be intuitive. Interpreting the results was straightforward for all individuals. P3 found it particularly easy to understand the implications of the measurements for lymphedema stages. Comments on the build quality were positive, with specific praise for some colored blue stripes mentioned by P2 and the overall functionality noted by P4. When it came to possible enhancements, P1 expressed worry mostly about the need to stand while measuring. P3 recommended improving the device's portability.

Satisfaction levels were determined from semi-structured interviews conducted after the testing, in which participants rated their satisfaction with the volumeter. A key question asked was how satisfied they were with the volumeter as a tool for measuring arm volume. The responses revealed high satisfaction, with all participants expressing a preference for the volumeter over traditional measuring tape due to its speed, ease, and the convenience it offers for regular volume monitoring. The students appreciated the volumeter's quickness and user-friendly approach, especially in comparison to the tape measure. The feedback provided by the students suggests that the volumeter was well-received and might be a more useful tool for measuring arm volume during routine monitoring.

The second round of usability testing incorporated an age target group representative (P6), providing valuable insights into the user experience of the volumeter for a demographic that can benefit from such a device. Following the testing part, the participant completed a survey adapted from the System Usability Scale (SUS) [25], as well as two open-ended questions to gather more nuanced feedback. Based on the information provided in the survey results image, the participant's responses to the SUS questions indicate a positive user experience, with strong agreement on the system's ease of use and confidence in using it. The results in a survey were transferred by the researcher to the template provided by Brooke [25] for better representation and represented on Figure 19.

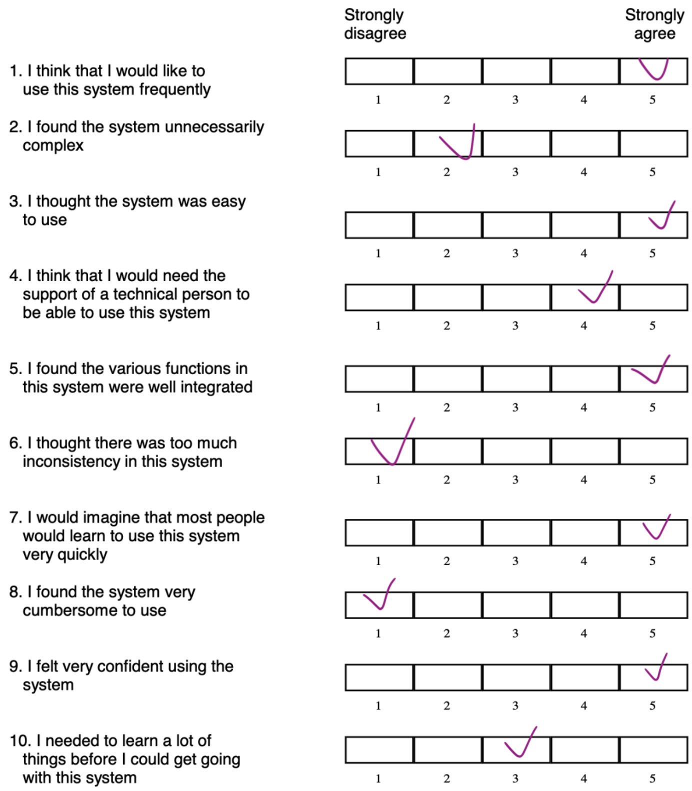


Figure 19. SUS responses of Participant 6

The calculated System Usability Scale score for the P6's responses is 82.5. This score is out of a possible 100 and is considered above average, indicating that the participant found the volumeter to be a usable and satisfactory tool. Generally, a SUS score above 68 is deemed to be above average, and scores above 80 are considered an indication of excellent usability. Therefore, this score suggests that the participant found the system to be quite usable and user-friendly.

In the open-ended responses, the participant expressed a preference for the volumeter over measuring tape, emphasizing the difficulty of self-measurement. The tape's tendency to slip and the difficulty in keeping it in place around the arm raised concerns about the quality of the measurements, according to the individual. It was noted that using the volumeter was more time efficient and user-friendly. Their decision was influenced by the simplicity of use without assistance and the speed with which the measurement was completed. This choice highlights the practical benefits of the volumeter in self-monitoring circumstances.

Chapter 8. Discussion

8.1 Strengths and Limitations

This section aims to provide an overview of the positive aspects that support the research findings, as well as the constraints that may have influenced the interpretation of the results.

8.1.1 Strengths

The study benefits from the use of within-subject design to assess users, a method discussed by Lazar et al. [32]. Within-group designs have several benefits, particularly in reducing the necessary sample size (in this case, 6 participants were tested). This design allows for a direct comparison of participants' performances under different conditions, which helps isolate the effects of individual differences. Another strength of the study lies in the gathering of both quantitative and qualitative data. Quantitative data were acquired through measurements, providing numerical insights. These measurements included various metrics such as arm volume, which was deteremined using both the developed tool and traditional measuring tape for comparison purposes.

The addition of a personalized cup to the monitoring system enhances its usability and effectiveness by providing visual indicators of lymphedema severity. A significant advantage of the system is its ability to provide immediate feedback on measurements. This tool allows users to notify their healthcare providers if needed. By providing real-time feedback, the system encourages proactive self-care, allowing users to actively monitor their health and take control of their well-being. Furthermore, a significant advantage is that the final concept is based on the well-established principle of water displacement, which has been proven effective in related studies. This foundation adds credibility and reliability to the developed tool.

8.2.2 Limitations

The study's participant sample, which consists primarily of university students and one age target group representative, does not represent a wide range of demographic characteristics. Individuals with diverse backgrounds, socioeconomic status, and gender are absent. The research cannot sufficiently assess how various groups use and interact with the monitoring tool. A more diversified participant pool would provide a more comprehensive view of the tool's use and efficacy across several demographics. Another limitation arises from not measuring the speed difference between using the volumeter tool and a measuring tape. Although participants preferred the volumeter for its quickness, precise timing data between the two methods were not gathered.

Another limitation is that, although all the "must-have" requirements identified through the MoSCoW method were successfully implemented, the aspect of an intuitive user interface was not fully addressed. During testing, 2 out of 6 participants required guidance on using the system. This indicates a potential lack of user-friendliness in the interface. However, due to time constraints, the design aspect was not prioritized in the study.

8.2 Future Work

The current lymphedema monitoring tool serves as a practical, high-fidelity prototype. However, further investigation might improve its comprehensiveness by taking into account some recommendations. In future work, there are key areas to focus on improving the lymphedema monitoring tool. Firstly, it's important to broaden user testing. Engaging a more diverse participant pool will provide useful insights about the tool's usability, functionality, and user experience across various demographics. Additionally, testing the instrument on post-cancer patients who have already experienced different measuring techniques can offer valuable comparisons with other methods and assess the volumeter's effectiveness.

Secondly, improving the design and appearance of the tool can minimize the need for instructions. Intuitive features such as visual cues, like arrows indicating where to place the hand, or implementing step-by-step audio instructions can enhance user experience. Furthermore, including speed measures in further research is necessary. Quantifying the time difference between the volumeter tool and standard measuring tape will provide insight into practical efficiency, enhancing the equipment's usability.

Expanding research to include a broader range of age groups among lymphedema patients could provide a better understanding of the condition and its monitoring. While many studies concentrate on older individuals, examining the experiences of younger patients, like children or young adults, is important for meeting the needs of all patient groups.This approach ensures inclusivity and may reveal insights that benefit minority populations within the lymphedema community.

Chapter 9. Conclusion

This chapter summarizes the findings and insights gained throughout this bachelor thesis, which aimed to develop a user-friendly and reliable lymphedema home-monitoring tool for breast cancer patients.

Research Question:

"How can a user-friendly and reliable lymphedema home-monitoring tool be developed for breast cancer patients?"

The literature review provided a comprehensive overview of various methods for measuring lymphedema, ranging from non-technical to technological approaches. Additionally, it explored the possibility of integrating these methods into a home setting, considering their individual strengths and limitations.

After the PACA analysis, the focus transitioned to a non-technological method. The specification phase helped establish the necessary requirements. Subsequently, the prototype developed for this study was constructed using PVC pipes and employed the water displacement method commonly utilized in clinical settings. An innovative addition to the main equipment is a personalized cup, serving as a visual indicator to determine the severity of lymphedema or its absense. Evaluation of the prototype demonstrated minimal differences in arm volumes between the traditional measuring tape and the volumeter. The high System Usability Scale (SUS) score of 82.5 indicates a significant level of user satisfaction with the prototype.

Statistical analysis, including the Wilcoxon signed-rank test, demonstrated that the volumeter is as accurate as the measuring tape in the sample studied. Qualitative feedback confirmed the tool's effectiveness, with participants indicating clear interpretations of results and no issues, aside from initial concerns regarding standing position, which were swiftly addressed. The preference for the volumeter over the measuring tape among all participants suggests promising potential for the developed product. Their choice was influenced by the ease of use and the speed with which measurements were completed.

In conclusion, the developed lymphedema monitoring tool demonstrates significant potential in meeting the needs of breast cancer patients, as evidenced by the research findings. The results of the Wilcoxon signed-rank test support the reliability of the volumeter, while qualitative feedback validates its user-friendly nature. These findings directly address the research question of this study, confirming the effectiveness of the developed tool in providing accurate and accessible monitoring for lymphedema patients.

Appendix

During the preparation of this work, the author used ‘Grammarly’ for proofreading and grammar checking. After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the content of the work.
During the preparation of this work, the author used ‘ChatGPT’ in order to correct the grammar, punctuation marks and the language itself. After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the content of the work.

A. Arm measurements data

A	B	C	D	E
Participants	**Baseline Volume (cm^3)**	**Subsequent Volume (cm^3)**	**Baseline Volume (ml)**	**Subsequent Volume (ml)**
P1	1216.13	1511.65	1150	1370
P2	2535.05	2553.04	2470	2500
P3	1730.45	2013.19	1900	2255
P4	1345.09	1728.1	1490	1640
P5	1026.63	1360.94	1000	1290
P6	1451.74	1937.73	1595	1930

Figure A1. Calculated volumes of six participants when using the volumeter and the measuring tape

MEASURING TAPE				
Without a sleeve				
	10 cm	20 cm	30 cm	40 cm
P1	17.6	22.8	23	25.7
P2	21	28.2	30.5	32.4
P3	20.6	26.6	27.7	31.5
P4	18.9	24	23.7	27.6
P5	16.4	20.7	21.9	22.4
P6	22	24	25.1	27.5
With a sleeve				
P1	21.5	25	26	27.2
P2	25	32	34.5	37.2
P3	22.6	28.5	30.1	33.6
P4	22.6	26	27.8	30.7
P5	20.6	23.5	25	25.4
P6	26	27.4	29.5	30.9

% difference MT	
P1	0.2430003371
P2	0.007096506972
P3	0.1633910255
P4	0.2847467456
P5	0.3256382533
P6	0.3347638007

% difference VM	
P1	0.1913043478
P2	0.01214574899
P3	0.1868421053
P4	0.1006711409
P5	0.29
P6	0.210031348

Figure A2. Measurements taken at every 10 cm of the participant’s arm without bubble wrap sleeve and with; calculated percentage difference between baseline volume and subsequent volume

B. Code

```
import math
```

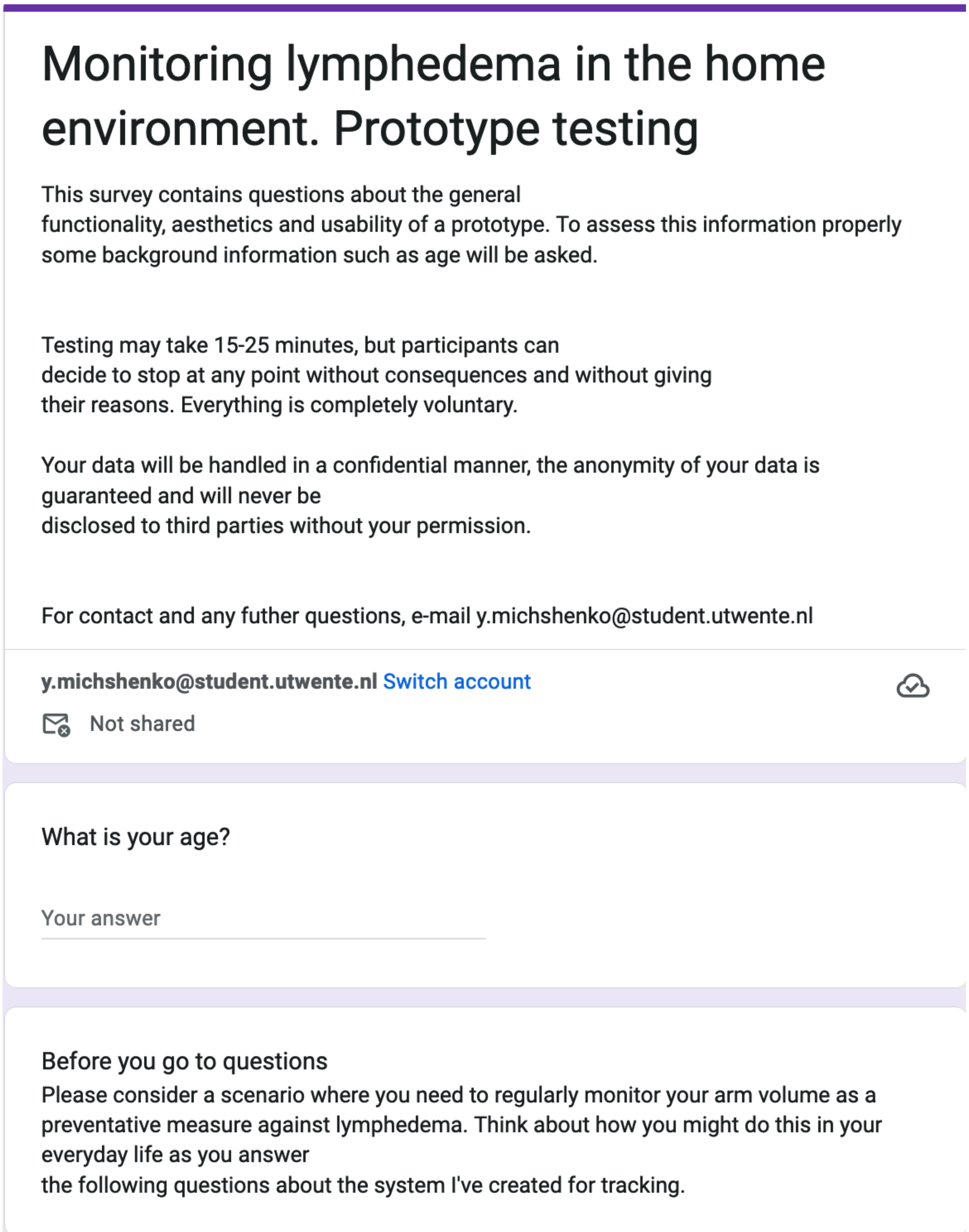
```
# Circumference measurements at every 10 cm

circumferences = [26, 27.4, 29.5, 30.9]  # in cm


# Convertion of circumferences to radii

radii = [c / (2 * math.pi) for c in circumferences]


# Heights of each segment (distance between points)

heights = [10, 10, 10]  # in cm, as the measurements are taken every
10 cm


# Calculation of a volume of each segment individually and sum them

volumes = []

for i in range(len(heights)):

   r1 = radii[i]

   r2 = radii[i + 1]

   h = heights[i]

   volume = (1/3) * math.pi * h * (r1**2 + r2**2 + r1*r2)

   volumes.append(volume)


# Individual volumes for each segment and the total volume

volumes_per_segment = {f"{10*(i+1)}-{10*(i+2)} cm segment": volumes[i]
for i in range(len(volumes))}

total_volume = sum(volumes)


# Printing radii and volumes
```

```
print("Radii:", radii)

print("Volumes per segment:", volumes_per_segment)

print("Total volume:", total_volume)
```

C. Semi-structured interview questions

1. **Usability and User Experience:**
    - Did you encounter any difficulties while using the device? Explain
    - Did you find the device comfortable to use?
    - How intuitive did you find the process of using the volumeter?
2. **Interpretation of Results:**
    - How easy was it to understand and interpret the results provided by the volumeter?
3. **Design and Physical Aspects:**
    - What are your thoughts on the build quality of the volumeter?
    - Are there any changes you would suggest for the physical design of the device?
4. **Overall Satisfaction:**
    - Overall, how satisfied are you with the volumeter as a tool for measuring arm volume?
    - Would you prefer using this volumeter over a traditional method like measuring tape for regular monitoring? Why?

D. Survey questions with System Usablity Scale (SUS) and open-questions



Monitoring lymphedema in the home environment. Prototype testing

This survey contains questions about the general
functionality, aesthetics and usability of a prototype. To assess this information properly some background information such as age will be asked.

Testing may take 15-25 minutes, but participants can
decide to stop at any point without consequences and without giving
their reasons. Everything is completely voluntary.

Your data will be handled in a confidential manner, the anonymity of your data is guaranteed and will never be
disclosed to third parties without your permission.

For contact and any futher questions, e-mail y.michshenko@student.utwente.nl

y.michshenko@student.utwente.nl Switch account

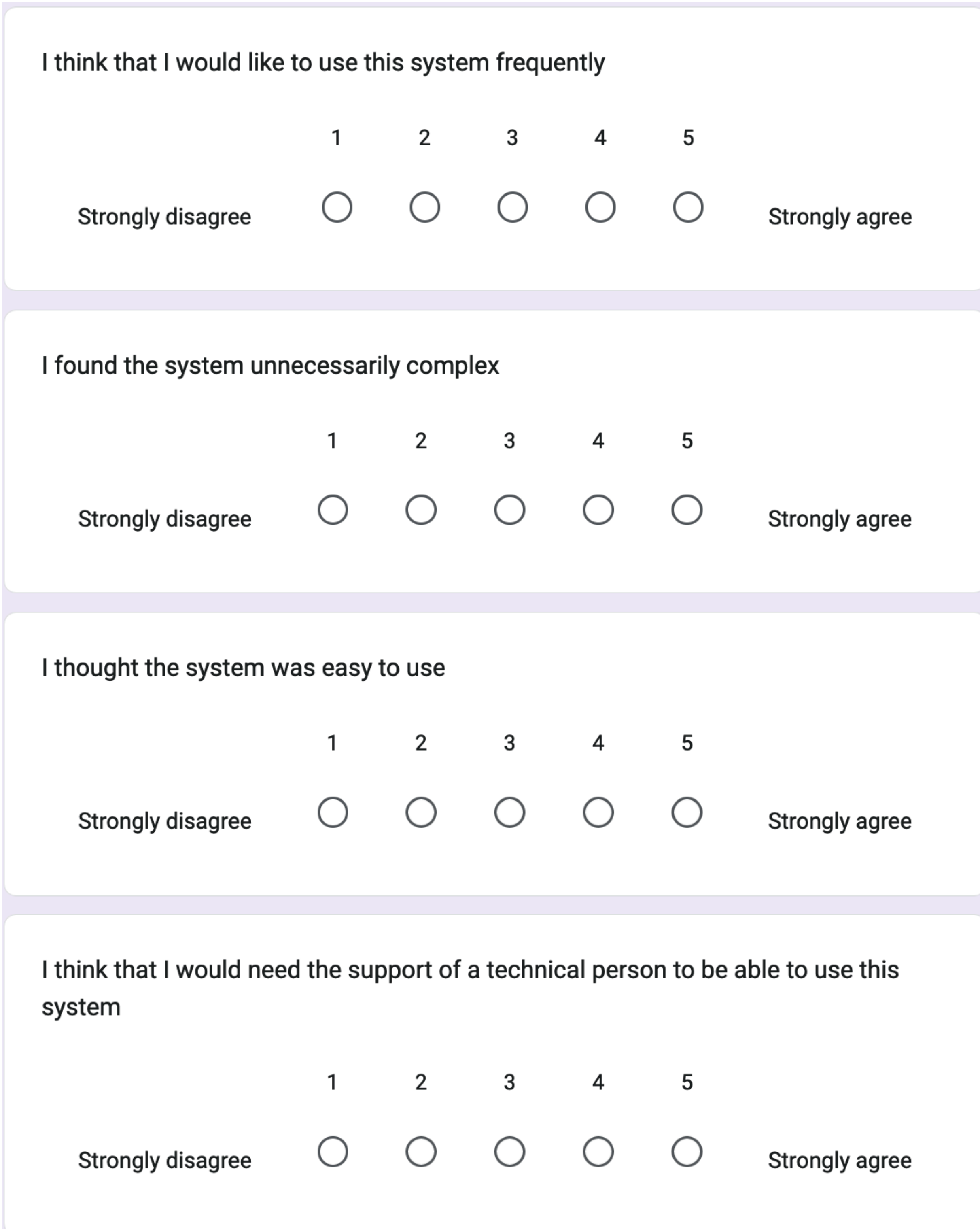
Not shared

What is your age?

Your answer

Before you go to questions
Please consider a scenario where you need to regularly monitor your arm volume as a preventative measure against lymphedema. Think about how you might do this in your everyday life as you answer
the following questions about the system I've created for tracking.

Figure D1. Survey questions



I think that I would like to use this system frequently

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

I found the system unnecessarily complex

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

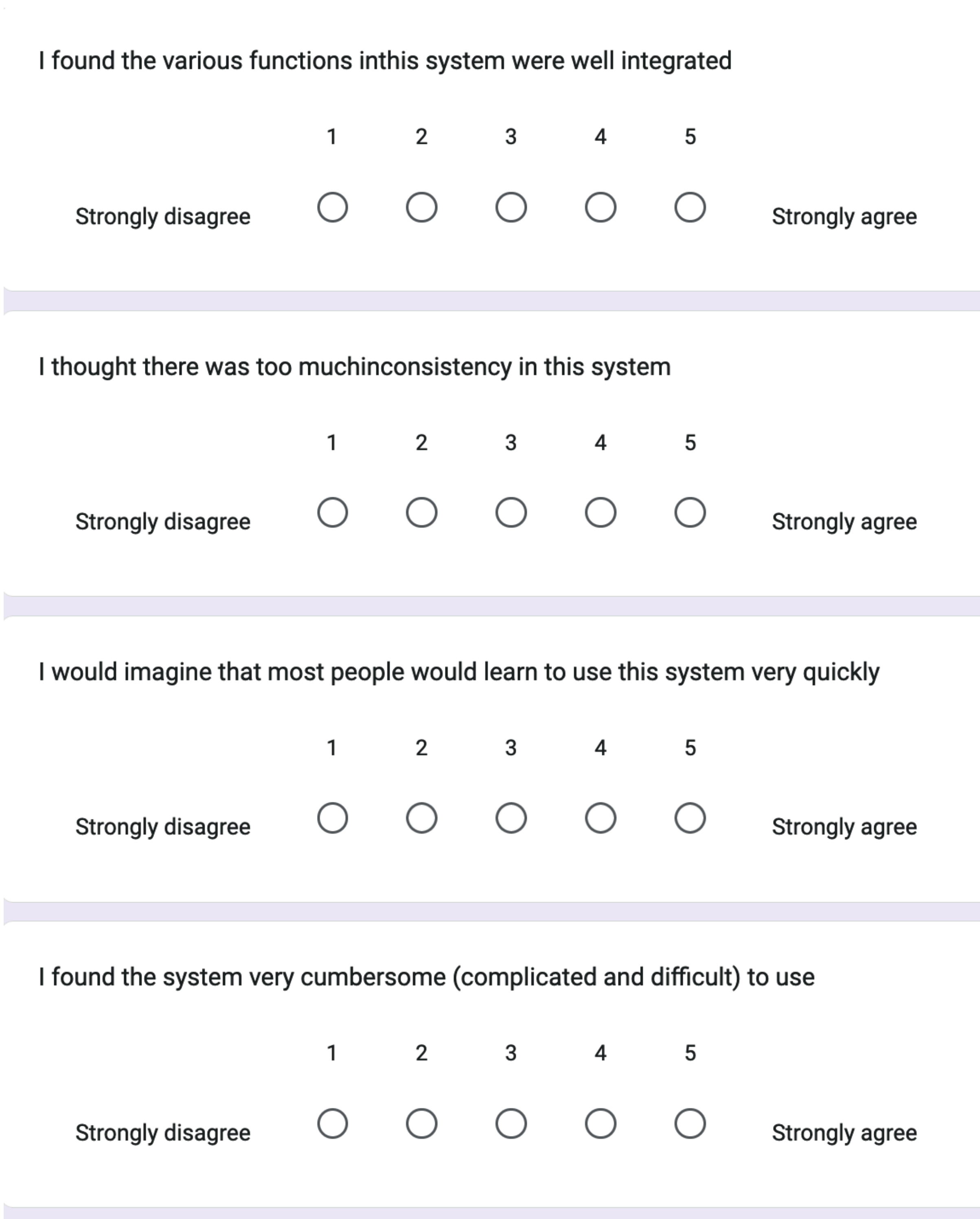
I thought the system was easy to use

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

I think that I would need the support of a technical person to be able to use this system

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

Figure D2. Survey questions



I found the various functions inthis system were well integrated

Strongly disagree 1 2 3 4 5 Strongly agree

I thought there was too muchinconsistency in this system

Strongly disagree 1 2 3 4 5 Strongly agree

I would imagine that most people would learn to use this system very quickly

Strongly disagree 1 2 3 4 5 Strongly agree

I found the system very cumbersome (complicated and difficult) to use

Strongly disagree 1 2 3 4 5 Strongly agree

Figure D3. Survey questions

I felt very confident using the system

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

I needed to learn a lot of things before I could get going with this system

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

What method (developed volumeter or measuring tape) would you prefer for regular monitoring? Why?

Your answer

What would you improve about the system?

Your answer

Figure D4. Survey questions

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