Master's thesis

NTNU
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Palpation and Prevention: Development of a Breast Cancer Palpation Trainer

Master's thesis in Mechanical Engineering
Supervisor: Martin Steinert
Co-supervisor: Marius Auflem
February 2022

NTNU
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TrollLABS

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Abstract

The World Health Organisation estimates that approximately 685 000 women worldwide died from breast cancer in 2020, with a disproportional part of which were women in developing countries. A great number of these deaths are preventable given raised awareness and early-stage diagnosis.

This master's thesis presents the development process of a palpation trainer prototype based on the novel haptic interface concept of ferrogranular jamming, including research, exploration, prototyping, and testing. Palpation is the medical examination process involving the medical professional using their hands and sense of touch to examine the underlying body part. They look for irregularities and clues such as changes in hardness, texture, and pain points.

The training devices used in the medical field today do not offer the flexibility and adjustability required to deliver a lasting and transferable skill set. Therefore, I developed an adaptive palpation trainer based on the concept of granular jamming, brought from the field of soft robotics to the field of medical simulation. An adjustable pump is used to draw a vacuum in a sealed chamber filled with the magnetic granulate. The granulate can be freely positioned using a magnet, and the user is in total control of the shapes created. The resulting surface can have different texture and hardness characteristics.

An experiment is conducted with 6 participants to test the capabilities of the concept. The experiment assesses the participants' abilities to correctly locate and describe the irregularities constructed. The results from the experiment indicate the prototype's ability to recreate high-fidelity shapes, simulate depth, and teach novices the skills of palpation.

Sammendrag

Verdens helseorganisasjon anslår at omtrent 685 000 kvinner over hele verden døde av brystkreft i 2020, hvorav en uforholdsmessig del var kvinner i utviklingsland. En stor del av disse dødsfallene kan forebygges gitt økt bevissthet og tidlig diagnose.

Denne masteroppgaven presenterer utviklingsprosessen for en prototype av en palpasjonstrener basert på det nye haptiske grensesnittkonseptet av ferrogranulære partikler. Denne prosessen inkluder utforskning, prototyping og testing. Palpasjon er den medisinske undersøkelsesprosessen som involverer medisinsk personell som bruker hendene og følesansen for å undersøke den underliggende kroppsdelen. De ser etter uregelmessigheter og taktile forskjeller som endringer i hardhet, tekstur og smerterespons.

Treningsapparatene som brukes i det medisinske feltet i dag tilbyr ikke fleksibiliteten og justerbarheten som kreves for å levere et varig og overførbart ferdighetssett. Derfor utviklet jeg en adaptiv palpasjonstrener basert på konseptet granulære partikler, brakt fra feltet myk robotikk til feltet medisinsk simulering. En justerbar pumpe brukes til å trekke et vakuum i et forseglet kammer fylt med det magnetiske granulatet. Granulatet kan plasseres fritt ved hjelp av en magnet, og brukeren har full kontroll over formene som lages. Den resulterende overflaten kan ha forskjellige tekstur- og hardhetsegenskaper.

Det gjennomføres et eksperiment med 6 deltakere for å teste konseptets evner. Eksperimentet vurderer deltakernes evne til å korrekt lokalisere og beskrive de konstruerte uregelmessighetene. Resultatene fra eksperimentet indikerer prototypens evne til å gjenskape former med høy presisjon, simulere dybde og lære nybegynnere palpasjonsferdigheter.

Preface

This master's thesis describes the development of a prototype system for advanced palpation training, as requested by Lærdal Medical. It was written to fulfill the requirements of the Product Development and Materials specialization at NTNUs Department of Engineering Design and Materials. I was engaged in this project between August of 2021 and January of 2022. The task was created as a collaboration between Lærdal Medical, and my supporting coach Marius Auflem.

I would like to thank Martin Steinert and Marius Auflem for excellent support and guidance during the span of the project.

Bartosz Jakubowski

Trondheim 02.02.2022

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Chapter 1

Introduction

This thesis describes the research and exploratory development of a haptic palpation training interface, based on the findings in the article by Rørvik et al. (2021). The topic for this project was proposed and encouraged by Lærdal Medical (referred to as Lærdal), a medical simulation equipment provider, specializing in the development of highly immersive and realistic manikins aiming at aiding the learning process of new medical professionals, and honing skills of advanced medical professionals. The prototyping work was carried out at TrollLabs at the Norwegian University of Science and Technology in Trondheim, a research and development laboratory established in the fall of 2014.

1.1 Background

Palpation in medical diagnosis is the process of physical examination with the hand or fingers, by applying pressure to the surface of the patient's body. The goal of such a procedure is to determine the condition of the underlying body part or organ by comparing the size, hardness, texture, or tenderness of the examined part to a description of a normal case. The importance of palpation training can not be undermined, as a correct diagnosis highly depends on the knowledge and experience of the medical professional executing the palpation examination.

Commonly used palpation trainers are custom-made and case-specific. This offers a great safe, and repeatable learning environment for the chosen scenarios, but does not allow for adaptability and can be costly to manufacture. The ideal palpation trainer would be easily adjustable and offer a wider range of simulated scenarios, as well as a haptic feedback system.

The novel concept of using granular jamming of ferromagnetic granules in a 2D environment is a direct continuation of the great work done by Rørvik et al. (2021). The research described is based on the concept of a haptic jamming tactile display (Stanley et al., 2016) and develops a prototype for a highly adjustable and interactive interface surface. In his work, he emphasizes both the potential use cases for this technology, as well as the shortcomings of the tested prototype. This thesis continues the work and describes the development of a prototype system with greater adjustability and an increased range of variables controlled.

1.2 Thesis scope

This project aims to explore the different ways of controlling and manipulating the tactile variables during a palpation examination using the granular jamming of the ferromagnetic granulate method outlined by (Rørvik et al., 2021), as well as to study the trainees' approach to the palpation task. This thesis describes the development process using the new product development methodology, with a focus on tackling one variable at a time in the ambiguous and limitation-free stage of product development.

The work done was technology-driven and focused on the exploration of new ideas. It does not attempt to focus on the ecological validity of the testing environment. The main focus of the thesis is to develop the existing technology in such a way, that it puts the user in control of the variables such as shape, perceived depth, and increased case adjustability.

Chapter 2

Literature and Technology Review

The theory relevant to the execution of this project is described in this chapter. It outlines the methodology used in the process of novel product development, as well as the medical terminology used to describe the task at hand and the limitations of the prototypes.

2.1 Literature Review

2.1.1 Fuzzy Front End and Wayfaring methodologies

The conducted project required insight into medical and technological areas that exceed the scope of typical mechanical engineering. The task at hand has an inherent ambiguity implied to it, and the limited knowledge of the novel solutions tested requires a continuous learning curve. Given this, specific studies have been conducted on the methodology of product development to aid with the process.

Carbone and Tippett (2009) define the Fuzzy Front End as the phase of product development in its earliest stage. It begins with the conception of an idea, a recognition of a need in the market, and follows the uncertain process of continuous testing and rapid prototyping before the product enters the more standardized process of new product development. During the Fuzzy Front End stage the specifications and requirements are loosely defined, and there exist fewer knowns than unknowns, meaning the challenges the researchers are not yet made aware of Kriesi et al. (2016).

Elverum et al. (2016) describe the advantages of using early-stage prototypes as a method of quantitative probing. Every prototype is a new learning opportunity and a guide in the process of need-finding. The focus should be placed on the quantity of single-aspect prototypes, ensuring a greater amount of user feedback, reduced chance of design fixation (Jansson and Smith, 1991), and better opportunities for gathering insight (Leifer and Steinert, 2011).

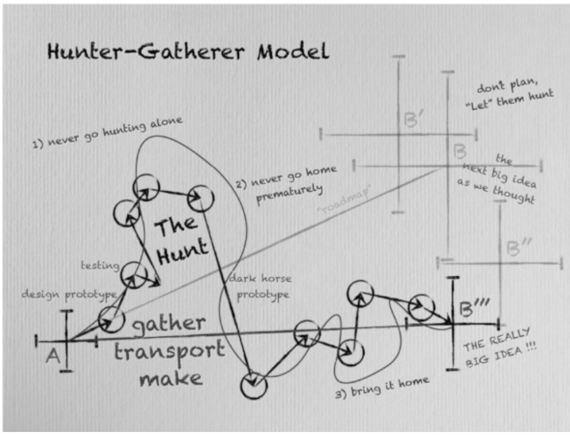


Figure 2.1: From Steinert and Leifer (2012): The Wayfaring Model

This thesis follows the wayfaring method, first described as the Hunter-Gatherer model by Steinert and Leifer (2012), later developed into the wayfaring model by Gerstenberg et al. (2015). The approach of this model is often illustrated as a journey of an explorer, who continuously changes directions based on the environmental feedback until he reaches "The Really Big Idea". The feedback here comes from probing and prototyping, using low fidelity, quick prototypes to test and learn. Every prototype is used to gain more knowledge of the task at hand and produces more concepts and ideas. Using the newly generated knowledge and the experience, the explorer can look in a new direction and see the results as a new opportunity for further probing.

2.2 Technology Review

Palpation is a technique in medical diagnosis, and it refers to the process of examination by hand or fingers. By applying pressure and studying the felt feedback, a lot can be said about the underlying body part or organ. The aspects examined are form, location, hardness, texture, and tenderness.

Form refers to the physical size, as well as the form of the examined object. Correctly identifying an irregular shape can lead to a discovery of an unnatural change in the body.

Location refers to both the depth measured from the surface of the palpated part and the lateral and longitudinal distance from a predetermined landmark position.

Hardness describes the resistance to compression of the examined object and is often evaluated comparatively to the hardness of the surrounding tissue.

Texture defines the roughness of the surface of the examined object. Texture and changes in it can often be correlated to the condition of a body part or organ.

Tenderness is the measure of the pain response recorded in patients during palpation. It is compared to the amount of applied pressure for evaluation of the severity of the condition, and/ or perceived pain level.

The work done by Rørvik et al. (2021) shows how the form and location aspect of palpation can be controlled using granular jamming. It outlines the benefits of the implemented technology by rapidly changing the state of the haptic surface between each experiment, and recording the accuracy achieved by the participants. This thesis focuses on the exploration of the location and hardness aspect of palpation as it theorizes there is a lot we can learn about palpation training as a whole from studying how we approach palpation training devices. As this thesis does not aim to further explore the material choices required for the construction of a palpation trainer, it will not explore the aspect of texture in its research. The aspect of tenderness will also not be of focus as it relies on correlating feedback obtained from the patient undergoing the palpation examination, with the pressure applied.

Hardness is a vague measure to many, and without the proper training, it's highly subjective to each individual. Hardness is relative, and the measure of it by palpation is based on comparing previous experiences to the currently perceived one. The big part of correctly identifying hardness is the muscle memory built over time spent actively practicing. This skill must be regularly maintained to remain consequent. The ability to locate an irregularity in space correlates to both its depth, and the hardness and size. These aspects can feel interchangeable when attempting to describe, thus making for a complex task when trying to simulate a specific irregularity with a two- dimensional tool.

Dynamic palpation trainers improve the tactile experience of palpation compared to static ones. Opposite to the static trainers, dynamic trainers can adapt, and offer more learning opportunities by repetition after the first session. Also, by learning, static trainers increase sensitivity, which increases the rate of false-positive detections Gerling et al. (2003).

Figure 2.2: Lærdal's Abdominal Examination Trainer

Medical trainers involving palpation exercises are a common inclusion in medical practice. They offer a great learning opportunity for students, and a way to upkeep and hone the skills of practicing medical professionals. The main advantage of such a trainer is its repeatability and relative realism. It allows the trainees to get the required muscle memory to correctly diagnose their patients. The trainers are custom-made to represent a certain body part or area and focus specifically on a set of medical diagnoses. If the trainer is built to simulate the different abdominal abnormalities (Figure 2.2), it may include different pre-made inserts intended to simulate an inflamed pancreas or bowel cancer.

A trainer with a focus on breast palpation may include a set of inserts for simulating the different pathologies that can be found inside of the breast tissue as a result of different medical diagnoses. A trainer of this sort is shown in Figure 2.3. This one allows the user to wear it on their body, either to simulate palpation on a patient or to train women how to correctly examine themselves.

Figure 2.3: Lærdal's Advanced Breast Examination Trainer

The two trainers above are a custom build solution provided by Lærdal Medical. The commonality between them is the relative adjustability they achieve using pre-made inserts. This approach offers a simple solution to each problem and is relatively quick to adapt between exercises. The trainers bridge the gap between the real-life exercise using human patients, and the textbook theory. As discussed by Maran and Glavin (2003), simulation in medicine intends to aid and enhance real-life clinical environment learning.

2.2.1 Ecological Validity of a Trainer

This thesis recognizes the studies made in the field of medical simulation regarding ecological validity as a crucial factor in medical task training. Ege et al. (2020) discusses the concept of simulator immersion, where he raises the question about a satisfactory ecological validity in simulation. Ecological validity is a measure of realism in the recreation of the real-life working environment by the simulation. Its four main components are the physical environment, the scenarios used, the tasks performed, and the users involved in the simulation (Kushniruk et al., 2013).

This project is technology-driven as it aims to develop a novel solution of simulating form and hardness in palpation trainers. It will therefore not focus on achieving the necessary immersion required for it to be deemed a satisfactory replacement for real-life exercises.

Chapter 3

Development

Introduction

3.1 Background

The work described in this thesis is heavily inspired by, and a direct continuation of the work done by Rørvik et al. (2021) with their granular jamming prototype. The concept consisted of a granulate made from ground coffee mixed with magnetic paint, crushed to granule size between 1mm and 2.4mm in diameter, and manipulated inside of a vacuum-sealed bag made from polyvinyl-chloride (PVC) film. The prototype rested on a layer of foam to provide a sufficient amount of flexible backing, and an opaque, skin-colored silicone palpation cover.

The focus of the conducted experiment was to establish whether the technique of granular jamming could be used in palpation trainers. The main benefits outlined were the endless adjustability of such a device compared to the standardized trainers currently in use. The findings in the study indicated a strong correlation between trainees' practice with the trainer and increased confidence in the participants' ability to recognize shapes and trust in their sense of touch. This proves how in theory, the concept of granular jamming shows that it has the potential to be the solution to the production of cheap, large, and accurate tactile displays.

The paper thoroughly describes the development and argues for the material choices made in the creation of the prototype. The most important choices with direct rollover to the work done in this thesis are the following:

Open-celled Foam Backing The foam backing with an approximate depth of 50mm is used. This material provides a sufficient amount of give resulting in appropriate palpation depth and consistency of hardness.

Polyvinyl-Chloride Vacuum Chamber Further testing of the different materials proved PVC provided excellent vacuum sealing capabilities, whilst offering an acceptable low level of interference in the process of palpation.

Ferromagnetic Ground Coffee Granulate The granulate chosen proved to exhibit the best characteristics, both when loosely manipulated and when jammed.

3.1.1 Limitations

The work done by Rørvik et al. (2021) is a first step towards the introduction of cheap and highly adjustable palpation trainers into the field of medical practice. It has however its limitations due to the nature of the experiment. The experiment described, involving 28 participants only set out the goal of assessing if granular jamming is a viable option of constructing shapes palpable by the inexperienced user. The authors outline the sensing, user feedback, lack of automation, and ties to a medical context as the aspects their research was most limited on. This thesis sets out to continue their efforts.

3.2 Requirements set for the palpation trainer

This thesis aims to advance the currently possessed knowledge of granular jamming technology by expanding its ability to recreate more nuanced aspects of palpation training. Palpation techniques used to diagnose medical conditions heavily rely on the user being able to correlate the applied pressure to the perceived feeling in the palm or fingers. This relation blends both the ability of the trainer to simulate shapes at specified locations and its ability to simulate depth. By controlling the two aforementioned variables when testing our prototype, we can bring granular jamming trainers closer to the implementation in medical-grade trainers.

Ideally, the fully developed trainer would be able to truthfully recreate a plethora of medical diagnoses, whilst allowing for a rapid and repeatable change of both the simulated irregularities and the palpable silicone covers. The research required to achieve this goal however is a ground for a much more broad thesis and presents enough unanswered questions for multiple research papers. Based on the research done by Rørvik et al. we know that the hardness of the irregularities is one of the aspects we have control over and can be adjusted to the desired level. By introducing depth as a new variable, we can greatly increase the potential for trainers with advanced spatial simulation capabilities.

Setting the scope of the developed trainer in a relevant medical context proved to be challenging, as the number of relevant cases a fully functioning granular jamming prototype would be capable of accurately recreating, is vast. The case chosen for this thesis is female breast cancer. Based on its worldwide prevalence (Gerstenberg et al., 2015), and high survival rates if discovered in its early stages (Ginsburg et al., 2020), breast cancer is a well documented medical diagnosis. Steadily more research focuses on improving the existing treatment for both early- and late-stage breast cancer, as well as the improvement of quality of life of the patients suffering the most severe cases. Despite the great efforts, developing countries experience unproportionally high mortality rates due to the lack of technological and economical development (DeSantis et al., 2015), and would greatly benefit from raised awareness, more readily available tests, and cheap to manufacture training devices.

Breast self-exam (BSE) is an exercise created for women to self-assess their breasts by both visual and palpable inspection. The strength of this exercise lies in its ability to spot changes over time, as this exam is prescribed to be executed at least monthly to be effective. When a visible or palpable irregularity is detected, the patient can seek medical help to better assess the nature of the newly found irregularity. Most women will find lumps of benign nature in their breasts throughout their live, but the exam's focus is to normalize the frequent self-assessment to lower the risk of a cancerous lump developing undetected.

As demonstrated by Gerling et al. (2003), dynamic palpation exercises increase the overall lump detection, reduce the occurrence of false-positive detections, and offer greater skill transfer when tested on static trainers. Most palpation examinations, however, lack any time restrictions on the performed task, thus giving the trainee the freedom of time management. The main requirement is that the trainee feels they are sure about their conclusion and have covered the whole area subjected to examination. This leaves out a lot of potentially important data of how people palpated, what did they find, and how did they react. Even though the participants in palpation exercises are shown the correct techniques beforehand, we can only insinuate about their learning process through their success rates.

3.3 Prototyping stage

3.3.1 Pressure control prototype

Staring where last research left off, there appeared the need for a new pneumatic pressure control system. The previously used pump delivered a set vacuum level of 16inHg (0.46bar or 0.54bar below atmospheric pressure). Any offsets from this pressure were achieved by manually opening a ball valve between the system vacuum, and the surrounding pressure (atmospheric pressure equal to approximately 1.013bar). This solution resulted in limited control over the in-between vacuum levels, as well as an unnecessarily introduced man-made inaccuracy. To combat this a pressure controlling rig was built to set specifications. Firstly the rig has to be able to achieve a vacuum level of at least 0.46bar and hold this indefinitely. Secondly, the rig must offer an easy way of holding a precise level of vacuum between the atmospheric pressure and the lowest achieved pressure.

The first prototype consisted of a 12V DC brushless motor with an integrated pneumatic pump (D2028B, SparkFun Electronics), connected to the PVC vacuum bag with the addition of a ball valve for pressure release, and a pressure gauge for accurate pressure readout. This prototype achieved a stable vacuum of 0.35bar, which coincided with the values advertised by the manufacturer. The system had some inherent leakages that could neither be located nor addressed, so the pump had to continuously operate to maintain the set vacuum level. The variable power supply is capable of delivering between 0 and 30V and scales the current output linearly. Approximately 6.5V was discovered to be the ideal value to both operate the pump with enough current to overcome the vacuum level of 0.35bar, and be reasonably quiet in operation. Although further tests revealed no additional benefit of running the pump at higher voltages than to achieve the wanted vacuum more quickly, the setup was also fitted with an adapter for a 9V battery for better portability.

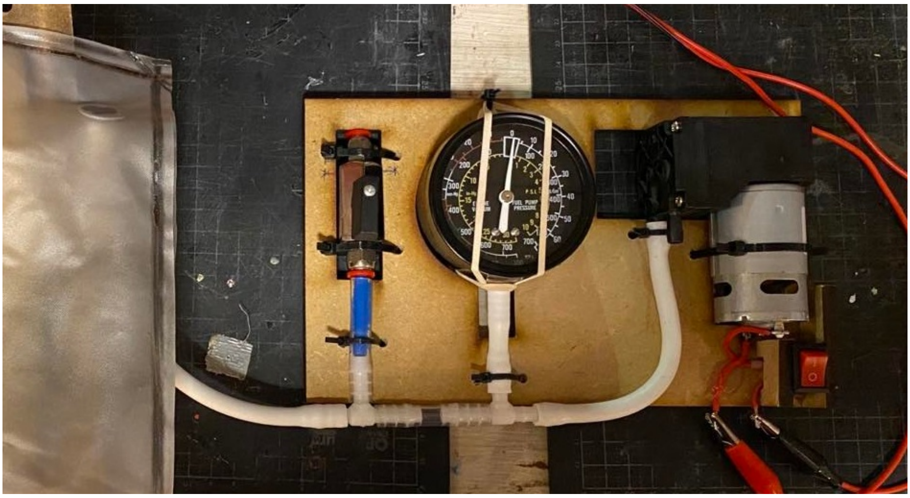
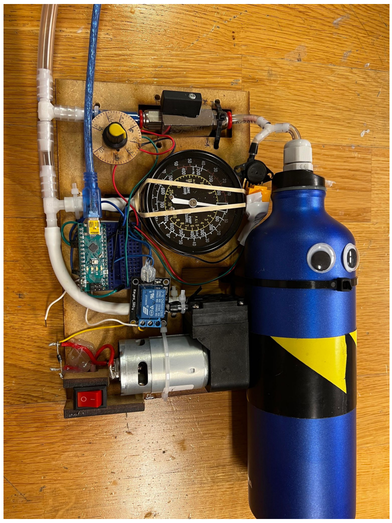


Figure 3.1: First prototype of the vacuum controller

To put the user in fine control over the vacuum, an electronic controller (Adafruit Industries Arduino Micro) was installed and programmed to electrically control the pump to start running when the pressure fell below a set specification, and to turn it off when an adequate pressure was achieved. The controller received accurate pressure data from a pressure sensor (NXP MPX4250AP) connected to the system close to the outlet of the buffer tank. Throughout testing a big disadvantage of the prototype was discovered. Due to the inherent leakages, and the low total air volume in the system, the controller would not be able to switch the pump fast enough, resulting in very inaccurate pressures. To combat this, a buffer air tank made from a metal flask was connected to the system. This solution prolonged both the time it would take to draw the vacuum, but more importantly, it made the pre-existing leakages less effective at increasing pressure thus making it more easily controlled by simply engaging and disengaging the pump. Additionally, an analog potentiometer was installed as user input, and its output value was linearly mapped to the pressure levels between 0.350 and 1.013bar. The code used in this prototype can be found in 6.2.

(a) Vacuum achieved by the prototype rig



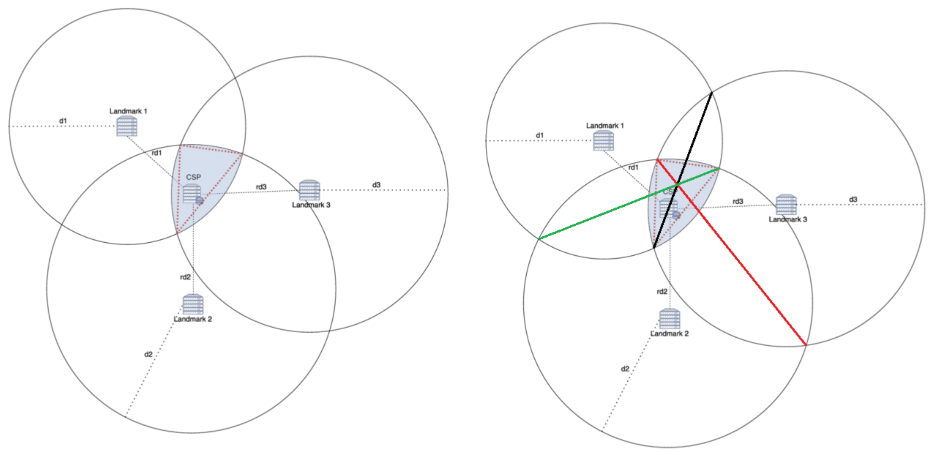
(b) The complete pressure control rig

Figure 3.2: Pressure control prototype

3.3.2 Trilateration prototype

Given the interest in how the users interact with the palpation prototypes, the need of tracking the pressure data was introduced. The idea was to measure where, when, and how hard the different users were palpating the trainer prototype. To extract this data from the test runs, a prototype capable of sensing pressure and its location was necessary. As proposed by Rørvik et al. (2021), a good solution would be a force sensing matrix embedded in the silicone palpable cover, as it is the layer with which the user interacts directly. This concept was evaluated but had to be abandoned due to the lack of a readily available solution that could be implemented in our prototype. As any attempts at producing own versions of such a matrix resulted in a considerably worsened tactile feel to the prototype, this concept was abandoned.

Measuring the position of the palpated area from above the prototype, in general, was abandoned entirely due to the pressure matrix concept not being viable, and the inherent problems with target occlusion when using camera tracking. The solution was to measure the pressure from below the prototype, and this introduced new limitations. The first concept revolved around the use of a high-precision atmospheric pressure sensor (Adafruit Industries BMP280 Pressure Sensor) molded in silicone. This concept was quickly abandoned due to the poor performance of this setup. The pressure measuring capabilities were excellent, but the size of the area measured was significantly too small to be feasible. This setup would require several hundred of said sensors.



(a) From Irain et al. (2017): A multilateration problem

(b) Modified trilateration problem

Figure 3.3: The multilateration problem

During the research on atmospheric pressure sensors, the topic of trilateration, or true-range multilateration, was discovered. Multilateration is a mathematical way of calculating the position of a target using three or more beacons with known locations. Knowing the distance from the target to each respective beacon, we can utilize trigonometry to accurately calculate the position of the target in relation to the beacons (Irain et al., 2017).

The simplest way of implementing multilateration requires three landmark positions, thus making this process trilateration. The modified approach included using the intersection points between the drawn circles to draw lines. The intersection of all three lines indicates the pressure point. A prototype consisting of three loadcells in a triangle was quickly conceptualized. The respective readouts from the three points of measurement could both be the source of the total pressure applied to the prototype, as well as the distances from the point of pressure to each of the loadcells. The output data from the code are the measurements of the position of the pressure point, measured in millimeters along the X-and Y-axis, with the origin point set to the bottom left corner of an equilateral triangle. The calculation and code used in this prototype can be found in 6.3.

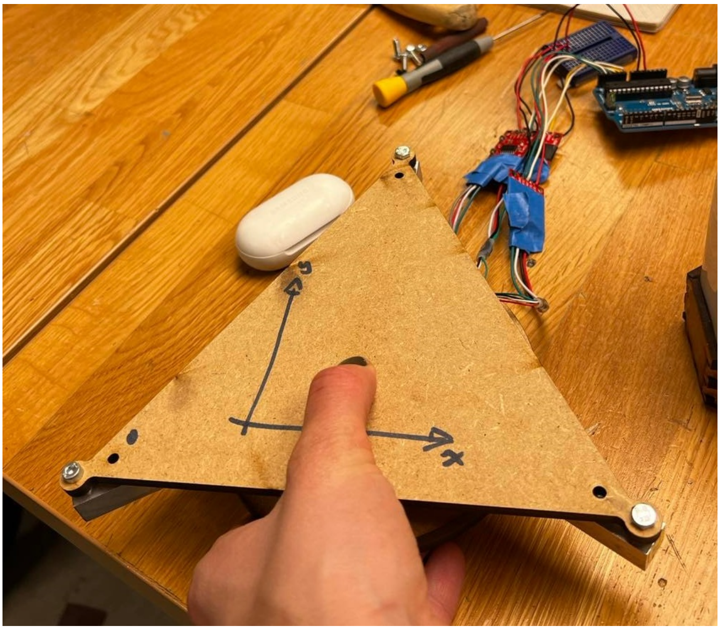


Figure 3.4: First trilateration prototype

To construct the prototype, three loadcells (Flux Workshop BIAA100201) with a measuring capability of up to 5 kilograms were used. To test the capabilities and accuracy of this concept, a small prototype was built using laser-cut medium density fibreboard (MDF), Arduino Uno, the three loadcells, and three signal amplifiers (SparkFun HX711) as seen in Figure 3.4.

The position data from this rig showed to be very repeatable and reasonably accurate with fluctuations from the real-life position between 2-6mm which this thesis deems satisfactory for the intended use case. For a reason this project cannot explain, the data seemed to be altered slightly, making the otherwise straight lines between measuring points (landmarks) appear bent away from the center of the triangle (see Figure 3.5). This is most likely due to the flexibility of the materials used. No alterations in material choice, nor the use of stiffening alleviated the problem. Despite the apparent issue, the trilateration prototype was deemed satisfactory, and a fix for the lens effect was theorized to be simple to implement in the stage of visual post-processing of the data.

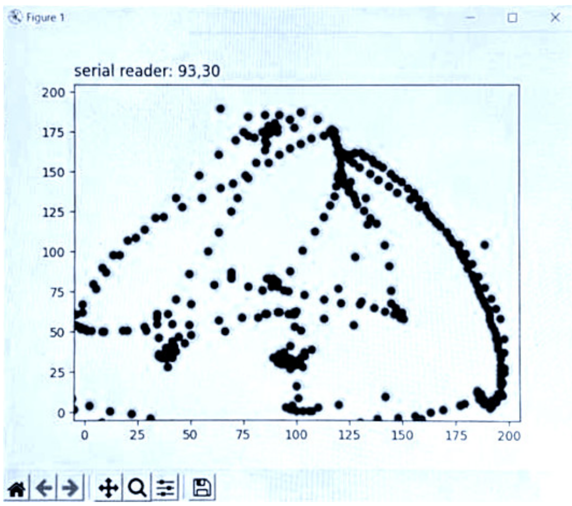
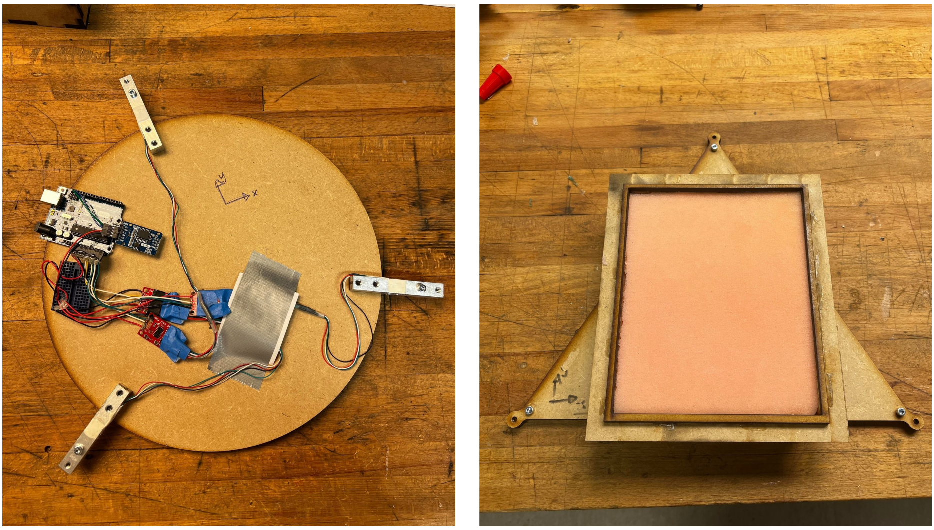


Figure 3.5: Trilateration rig data

A full-scale prototype was built based on the findings from the previous work. Several improvements were made in the construction of the prototype, now also implementing a better design for how the top plate attaches to the base to help reduce the sideways loading on the loadcells, created when dragging the finger over the palpable surface. To both stiffen the construction, and better integrate the different prototypes, the top cover now included a rectangular chamber with the size of 200mm x 160mm, and a wall height of 50mm. The inside of this chamber was filled out with open-celled foam backing described in Section 3.1.

Additionally the micro-controller was equipped with a Real-Time Clock module for accurate time stamps of the outgoing data. The completed setup can be used to accurately track the position and pressure data over time, from any palpation exercise done on top of it. This enables the creation of a heat-map, which is a visualization of how frequently an area was interacted with, and where, as well as the study of the correlation between the results of a palpation exercise and the trainee input.



(a) Trilateration rig base

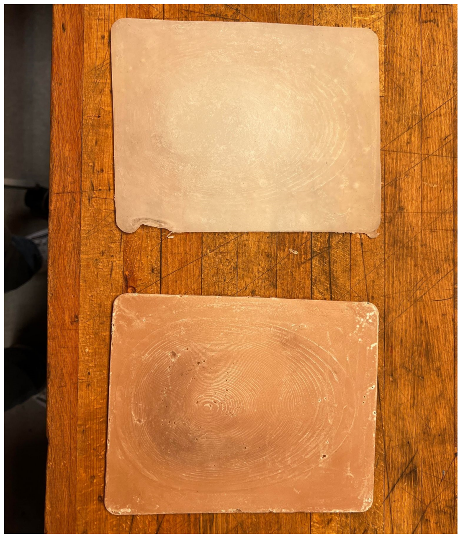
(b) Trilateration rig top cover

Figure 3.6: The trilateration rig

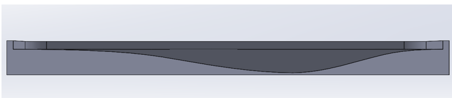
3.3.3 Palpable cover

From the specifications established in Section 3.1.1, the palpable cover had to be manufactured out of soft silicone, with the hardness of that compared to human skin. It also had to resemble the anatomy of a female breast, as that both enables the prototype to explore the depth simulation, as well as ties it to the medical context of breast self-examination and clinical breast examination. This cover does not try to model a realistic nipple to reduce the anxiety in participants, as nearly one-fourth of the participants reported the “intimate/personal nature of the exam” as the leading cause of their anxiety in a similar study (Pugh and Salud, 2007).

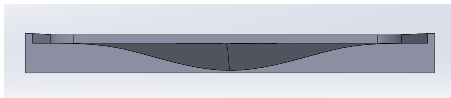
(a) The PLA mold



(c) The palpable silicone covers



(b) Cross-section of the mold, side view



(d) Cross-section of the mold, top view

Figure 3.7: Prototyping of the palpable cover

Throughout the testing period, a set of molds was designed in CAD software and manufactured in PLA plastic using a commercially available 3D printer. This process involved testing and comparison of different combinations of silicone shore hardness and overall thickness of the resulting cover. The goal was to achieve a balance between an end product soft enough to allow the user to feel the granulate at the thickest part of the cover, and firm enough to conceal the trace amounts of the granulate present as a byproduct of handling the granulate when constructing an irregularity with sets of magnets. The resulting silicone cover had a thickness ranging from 4mm at its edges to 15mm at the peak of the areola, and a shore hardness of 00-30 (ASTM D-2240 standard).

Chapter 4

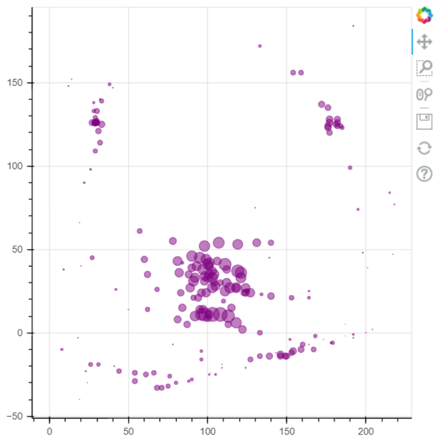
Testing and discussion

4.1 Pilot testing

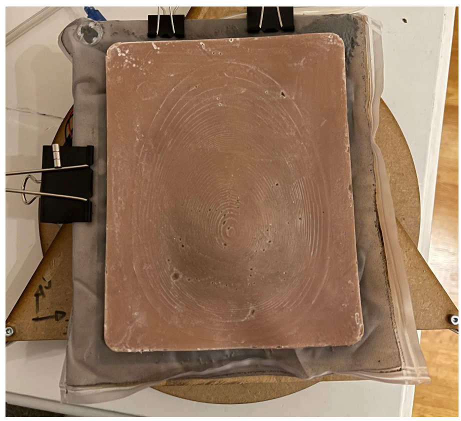
An experiment was designed to evaluate the functionalities of the newly build prototype. The setup of the experiment was constructed during the pilot testing phase, and its design was established after a few iterations with voluntary participants consisting of fellow students at the TrollLabs workshop.

During the stage of pilot testing, the integrity, consistency, and efficacy of the prototype was examined to ensure correct data collection. As described in Section 3.3.2, the coordinate data output received from the trilateration module was slightly warped in comparison to the real-life inputs. In all of the testing, this alteration showed to be consistent between the runs. Several material choices were tried to stiffen the construction, but none helped to alleviate the problem. As this data alteration mostly affects the data after the visualization process and is consistent between the recorded experiment runs, it is deemed to be non-disruptive to the experiment.

The readings from the trilateration module were checked to be consistent between the runs, as well as compared to the input data. The calibration process involved a controlled run of the data logger built into the trilateration module, with a user palpating lightly in each corner and at the areola of the palpable silicone cover as seen in Figure 4.1. As previously mentioned, the data output is recognizably warped, as the further, the logged data point is from the center, the bigger offset it has measured from the center of the measured area. Additionally, the vertical axis of the trainer seems to be rotated counterclockwise by about 5 degrees, although this is also consistent between the runs. The consistency of the experiment runs is also ensured by the precision in creating the irregularities. This process will be further described in the following section.



(a) Data output from the calibration process



(b) Prototype calibration reference

Figure 4.1: Calibration of the trilateration module

4.2 The experiment

4.2.1 Participants

The complete system presented in Section 3.3 was tested for portability to ensure it could be deployed at convenience. The described palpation trainer prototype was tested on a group of untrained users. The group consisted of 5 females (83.3%), and 1 (16.7%) male, all healthy students with little to no experience in palpation tasks. Participation was voluntary, and all have given consent to be part of the study.

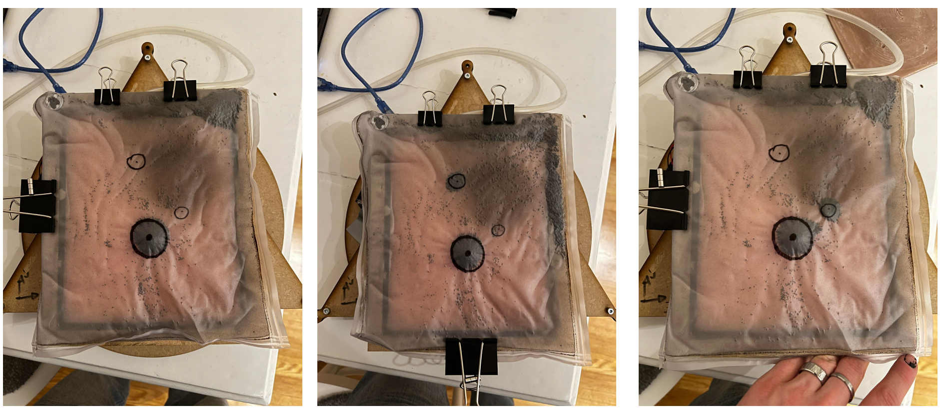
4.2.2 Experimental procedure

All subjects signed a consent form for data collection before participating in the experiment. The necessary preparation of the palpation task was done outside of the participants' view for every task. Each subject performed three palpation tasks (see Figure 4.2) in randomized order:

Baseline, no lump: A large smooth lump placed directly under the areola of the breast present in all of the simulation cases, aims to simulate the mammary gland. Granulate used: 3.2g, pressure: 0.6bar.

Shallow lump: Mammary gland lump with the addition of a lump in the upper regions of the breast. Located under the thinnest part of the palpable cover at a depth of 4mm. Granulate used: 0.5g, pressure: 0.6bar.

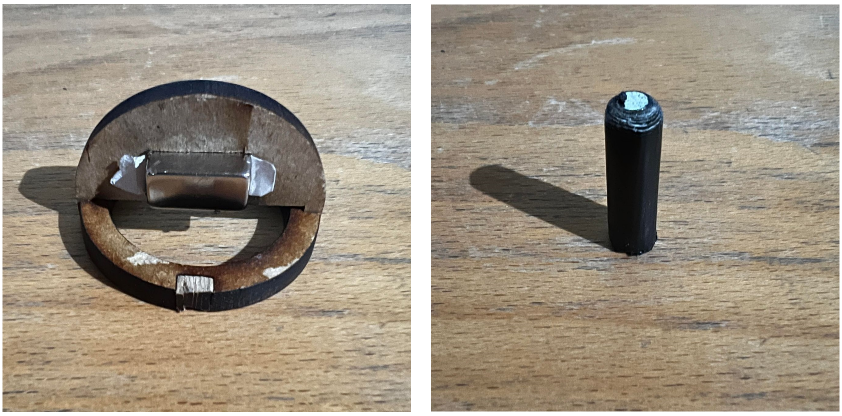
Deep lump: Mammary gland lump with the addition of a lump near the mammary gland. Located very close to the thickest part of the palpable cover at a depth of 10mm. Granulate used: 0.5g, pressure: 0.6bar.



(a) No lump **(b)** Shallow lump **(c)** Deep lump

Figure 4.2: The three palpation task setups

To precisely manipulate the granulate, a set of magnetic tools was developed. The tool used to create the mammary gland consisted of a neodymium magnet with the measurements of 20 x 20 x 10mm, suspended 10mm over the surface of the vacuum bag see Figure 4.3a. The second tool consisted of a stack of cylindrical neodymium magnets with the measurements of 5 x 5 x 5mm, held together with black duct tape, see Figure 4.3b.



(a) The first magnetic tool

(b) The second magnetic tool

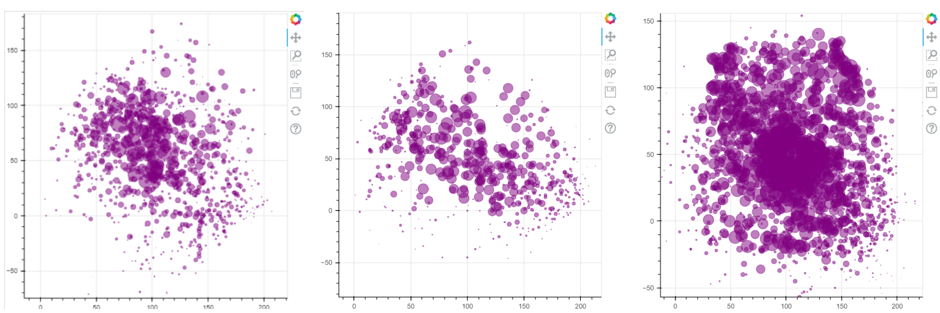
Figure 4.3: Magnetic tools used

To produce the main lump simulating the mammary gland, the first tool was used. Using half of the granulate available in the vacuum bag (approx. 3.2g), the tool was placed at the surface letting the granulate create an indentation in the bag bulging towards the magnet. The underside of the lump remained flat as it was supported by the backing foam. To secure the shape of the lump the vacuum pump was turned on with the magnetic tool still attached to hold the peak of the shape. The smaller lumps were created using the second magnetic tool. In both cases end of the stack of magnets was used to collect a small portion of the granulate (approx. 0.5g). This quantity is considered to be constant as it was the maximal amount of granulate the magnet tool would hold without losses when moving the granulate around to re-position. After placing the center of the granulate lump in the marked position, the magnet tool was removed before drawing the vacuum to let the granulate disperse in the case of the shallow lump, and was held in place when drawing a vacuum to better hold the peak in the case of the deep lump.

4.2.3 Data collection and visualisation

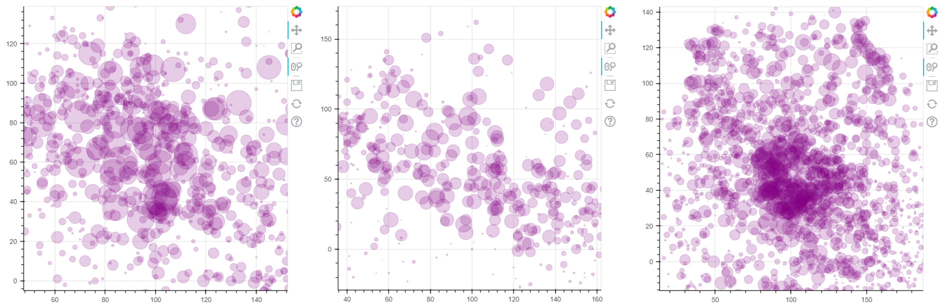
Before the study, each participant was informed bout the presence of the mammary gland and was instructed to palpate for a potential irregularity with the correct technique and to report irregularities if found. The time was recorded and data timestamped, but the participants were told to only end the exercise if they were sure they have covered the entire area and there is no irregularity left undiscovered. If an irregularity was found, the participants were asked to rate the perceived depth of the lump on a scale from 1 to 5, where 1 meant the lump was located just beneath the skin, and 5 meant the lump was located deep at the ribs.

The trilateration module of the prototype was used to record every exercise run, and the data was visualized using the Bokeh Visualisation Library (Contributors) in a custom python script (Appendix 6.4). As every participant had a slightly different approach to the presented palpation task, the amount of pressure applied to the setup and the amount of time spent executing the task varied greatly between the runs, see Figure 4.4. As a result, the data collected could not be treated equally and had to be normalized before being compared. The parameters of the visualization script were adjusted for every participant to result in plots with equally big circles for the hardest respective palpation movement executed in the first run.



(a) Participant 1 **(b)** Participant 2 **(c)** Participant 3

Figure 4.4: Palpation hardness comparison from first exercise



(a) Participant 1 **(b)** Participant 2 **(c)** Participant 3

Figure 4.5: Palpation hardness comparison from first exercise, normalized data

4.3 Results

4.3.1 How many found the irregularity

In the two conditions with an irregularity present, ten (83.3%) exercise runs concluded with an irregularity being discovered. In the baseline condition, one (16.7%) participant found an irregularity despite there not being one. The only participant reporting a false positive was also responsible for one of the two failures to find an irregularity in the non-base condition runs.

The participants were instructed to spend as much time palpating as was needed for them to conclude, and be sure of the discoveries they have made. As the technique and approach to the task varied between the participants, the time spent also had an implied variance. Although the average time spent on the exercises differ between all participants, the time spent on any particular exercise did not differ significantly from their individual averages for all but one participant (16.7%), where the participant spent an additional two minutes going from one exercise to another. This was 42% longer than this participant's average time.

4.3.2 Perceived depth

The participants were asked to rate the perceived depth of the discovered irregularities as they encountered them. All the obtained ratings were given with hesitation, often followed up by the user checking again for own reassurance. The average rating of depth did not differ significantly between the shallow and deep lump, with the rating of 2.4 and 2.9 out of 5 respectively, not counting in the failures of discovery or the false-positive result. As the goal of the two different irregularities was to simulate similar depth, this result is promising.

4.3.3 Position assessment

The participants were asked to point to the irregularity if discovered. The position reported by the participants and the deviation from the real position were both measured using the output data from the trilateration module of the prototype. All participants who correctly identified the presence of an irregularity also reported the correct position. As the two irregularity types were quite small with the diameter of 9mm and 13mm, the observed slight deviation of up to 3mm can be explained by both the participants pointing to the edge of the irregularity where it is easiest to feel and the slight inaccuracy of the trilateration module.

4.3.4 Palpation hardness

The techniques used by the participants varied as a result of their confidence levels, stance, anatomy, and overall physical strength. The resulting palpation hardness was measured to be similar between the different exercises for the same users but varied greatly from one user to another. The most typical pressure applied was around 600 to 1200 grams, with two outliers with an average pressure applied of 2500 grams with peaks of 3500 grams.

4.4 Discussion

4.4.1 Failures of discovery

Two separate participants failed to discover an irregularity in one of their exercises. The first case of failure (Participant 4, run 3, Appendix E 6.5) occurred as the last out of the three tasks and was the shallow lump exercise. Neither the palpation hardness nor the area coverage was in any form less adequate here than the observed average of the other participants. The participant spent nearly three minutes palpating and used the recommended technique utilizing the index and the middle finger of their dominant hand. Interestingly, the same user reported a false positive on the first exercise being the baseline, and correctly identified an irregularity as their second task. We theorize that this subject's low palpation confidence levels can be the leading cause of their worsened success rate.

The second case of failure of detection (Participant 6, run 3, Appendix E 6.5) happened with a different user and occurred in the deep lump case as the first out of the three tasks. This user had an especially forceful technique, achieving double the pressure of the more typical range of around 1000 grams. The examination time for this exercise is of particular interest as it was significantly shorter than the average, coming at one minute and eight seconds. This participant's technique remained equally forceful during the remaining exercises, but the duration of the palpation doubled to around two minutes, and the participant correctly identified the irregularity in the second exercise and did not find any in the third exercise which was the baseline.

4.4.2 The false positive

The only time a false positive was observed during the testing stage (Participant 4, run 1, Appendix E 6.5), it occurred as the participants first run. As commended by several participants, there was a certain mental pressure to find an irregularity. This pressure likely occurs as direct reasoning from the participants thinking they must be palpating wrong if they do not find an irregularity during the span of the exercise. The participant's expectations of how noticeable an irregularity is may have been wrong, and given that this particular test subject have not yet experienced any lumps, their expectations have not yet been corrected

A close examination of the palpation setup post-exercise revealed a possible source of the participant's discovery. The area below where the participant called an irregularity had both minuscule remnants of the granulate left from the process of setting up the irregularities, as well as a slight crease of the vacuum bag resulting from the deformation of the bag.

4.4.3 The observed palpation methods

A point of interest in the research is the different palpation techniques used by the participants. The introductory training given at the beginning of every new participants' first exercise included a short overview of the recommended hand positioning and techniques aiding to ensure full area coverage. This baseline training ensured that the participants had the necessary tools to start their first experiment run.

An overwhelming majority of the participants (83,3%) chose to palpate following the ”vertical strip” method, and one (16,7&) following the ”dial of clock” technique as described by Lohani et al. (2020) (Participant 2, Appendix E 6.5). As both techniques rank high on sensitivity and correct lump detection, subjects choosing the aforementioned approaches was a satisfactory result of the study.

4.4.4 Palpation hardness and success rate

The physical and motoric differences between the participants resulted in a wide range of pressure applied to the palpation prototype throughout the tests. By nature, humans palpate harder the deeper into the tissue they wish to assess, and none of the participants had prior knowledge of the design of the exercise.

A trend was discovered where the first palpation exercise for every participant tended to differ from the second one. Participant 3 (Appendix E 6.5) heavily increased their palpation hardness after the first time they had to estimate the perceived depth of a lump, realizing the deepest point on the scale was ”right over the rib cage”. The output pressure remained constant for the rest of the participants.

Although the palpation pressure was very similar for most of the participants, it is important to point out the outliers. The two failures of detection recorded occurred in an exercise with a participant with either above average or below average palpation hardness. The palpation hardness was measured to an average of 2000 to 2800 grams of pressure, and 400 to 800 grams of pressure respectively, and the first participant failed to detect a ”deep lump” (Participant 6, run 3, Appendix E 6.5), whereas the second one failed to detect the ”shallow lump” (Participant 4, run 3, Appendix E, 6.5).

4.4.5 Palpation hardness and perceived depth

No significant correlation between the palpation hardness and depth rating was recorded. Although an adequate palpation hardness is required to correctly perceive the simulated irregularities, there personal nature of such an assessment of perceived depth makes it hard to spot a trend. This thesis theorizes there might be a correlation but further research is needed to establish this relation.

4.4.6 Time spent and the number of exercises done

As the exercises progressed, a trend of increased confidence was noted. The developed prototype tested was all of the participants' first encounter with a palpation trainer, which contributed to the feeling of uncertainty when interacting with them. The overall high success rate achieved, however, greatly contributed to the participants' heightened confidence levels as the exercises progressed.

Another possible explanation of the increase in confidence might the fact that with more experience with the prototype, the expectations of the participants are adjusted. The ones coming into the experiment with high anxiety, fearing the irregularities will be small and difficult to detect, will learn to trust their abilities better when they first correctly detect an irregularity.

4.4.7 Area coverage and the number of exercises done

Most of the participants tended to stay within proximity to the areola of the breast model in their first exercise. As the experiment progressed, the participants got acclimated to the trainer and expanded their focus more evenly on the entirety of the palpable area. With more consequent exercises, the number of points palpated increased, and the time per singular palpation press decreased resulting in better coverage of the whole area, using less time per any singular spot.

4.4.8 Baseline condition search

The baseline condition proved to be the most troublesome for the participants of the experiment, as it offered no stress relief of successful discovery, present in the two remaining exercises. As commented by Participant 3 in the middle of exercise

3 (Appendix E, 6.5), one does keep palpating actively searching for an irregularity, wishing to discover something even though the lack of an irregularity present is equally likely during the exercise. This anxiety caused by a lack of discovery was noticeably less of an issue in the cases where the baseline condition occurred as the second or third exercise.

4.4.9 Palpation hardness and optimal posture

As mentioned in Section 4.4.4, the palpation technique and approach to the exercises varied based on several factors. One of these differences is the participants' posture and positioning about the palpation trainer. The most noticeable effect this had on the participants' results was in the case of Participants 4 and 5, who were both women with under average height of 162 and 158 cm tall respectively. As the palpation trainer was fixed to the table during the exercises, these participants had a less advantageous line of force when palpating, resulting in a lower palpation pressure. This thesis theorizes that this discovery might have affected the results.

Chapter 5

Limitations and future Work

5.1 Limitations

5.1.1 Limitations of the prototypes

This thesis describes the research and development of a novel palpation trainer prototype, and thus carries the inherent uncertainties of unproven technology. One limitation of the tested prototype is the limited guarantee of repeatability. As the exercises are hand-built by the user and are not automated, the possibility of human error is introduced. This concerns mostly the process of handling the ferromagnetic granulate when constructing the irregularities. A possible solution for this problem would be to implement an automated, computer-controlled process of handling the granulate in between the different exercises, as well as an improvement in material choices regarding the vacuum bag, which in this prototype tends to deform over time.

Another point of possible improvement lies within the trilateration rig as its reliability can be questioned given the not-infrequent appearance of extreme data points. These data entries can be attributed to a poor calibration process, inherent inaccuracies in the load cell hardware, elastic deformation in the supporting structure of the module, or a lack of adequate computational power in the micro-controller responsible for the calculation of the position. The fidelity of the received data can also be a factor in any inaccuracies present.

5.1.2 Limitations of the testing setup

The experiment setup utilized in testing the described prototype was designed to extract data regarding depth perception and hardness. There are many aspects of palpation we still are unsure of that could be researched utilizing the prototype constructed during the making of this thesis.

The limitations of the aforementioned experiment setup lay in the simplicity of the experiment runs, and the low participant count. There is still much to learn about how newcomers to the palpation trainers interact with the hardware and what mental barriers hinder the average user from achieving better results. An interesting question to ask would be how knowledge and skill retention obtained on an adaptive trainer compares to a similar training regime utilizing a static trainer.

This thesis also recognizes the low number of participants as a limitation of the experiment. An experiment with a low participant number will not generate the correct statistical values needed to draw a definite conclusion. The results from the experiment, however, can be used as a good indication of how successful the prototype has been at challenging the participants, and how viable of an option granular jamming is for use in the medical training field.

An important consideration when making a medical palpation trainer is the comparative realism of the prototype required to allow the skills taught on the trainer to transfer to a real-world situation. No input from medical professionals was received throughout the development process, which greatly reduces the risk of the trainer not being a valuable training device. As stated in the introduction of this thesis, the work done is technology-focused, and thus it does not try to replicate a realistic situation, in favor of better data collection.

5.2 Future Work

5.2.1 Untested concepts

Several promising concepts and technologies were discovered throughout the development phase of this thesis, most of which offer a great improvement to the performance of the existing prototype.

One promising concept was described by Rørvik et al. (2021) and involves the use of a capacitive sensor layer to sense the location and pressure data. One advantage of such a system is that it is directly embedded into the palpable cover, collecting data from the directly affected part of the trainer. This has the potential to output data of better quality and fidelity, as it is not separated from the hands of the trainees by multiple layers which position we cannot always guarantee. Additionally, the bigger advantage of this system is the ability to register movement and pressure in three-axis, as the capacitive layer would be embedded in the outermost layer of the palpable cover, thus following the curvature of the silicone cover.

The lack of any kind of feedback from the prototype is also outlined in the work done by Rørvik et al.. The authors describe the problematics of a non-reactive trainer as one of the biggest problems when implementing such a trainer in the field of medical training. A big aspect of palpation is tenderness, the measure of reaction received from a patient given the applied palpating pressure. A great way of enhancing the trainer experience would be to implement a feedback loop, either by playing sounds of painful patient gasps or by having control over the real-time placement of an irregularity and position of the trainer about the trainee to simulate a pain response.

5.2.2 Ecological Validity

This thesis recognizes the importance of ecological validity in medical training, as the lack of adequate realism reduces the benefits of such an exercise (Ege et al., 2020). Although the benefits of increased realism when testing a prototype of this sort are clear, the measure of ecological validity was not considered when developing the described prototype.

Chapter 6

Conclusion

This thesis contributes to the development of a medical palpation trainer utilizing ferrogranular jamming as the haptic interface. The inspiration for this project was the great work done by Rørvik et al. (2021), bringing the technology of granular jamming into the palpation trainer field. The requirements for the developed prototype have been for it to be able to control the position, shape, and hardness of any desired irregularity, as well as to collect position and pressure data from the user experiments. The final prototype was built and tested on 6 participants, and the findings and insight from these tests have been summarized in this thesis.

Additionally, the importance of prototyping in new product development was highlighted. This thesis followed the Wayfaring model in its development, which uncovered previously unknown requirements and possibilities. This approach allowed the development to quickly adapt to the emerging needs.

In conclusion, a low-cost palpation trainer with high accuracy has been developed based on early granular jamming palpation interface concepts.

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Appendix

6.1 Appendix A: Project Thesis

NTNU
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PROJECT THESIS

Technologies to control the arms of patient simulators

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June 2021
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Supervisor: Martin Steinert
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TrollLABS

Summary

This task identifies, analyzes and conceptualizes different technologies to simulate manikin limb movement and its importance in healthcare simulation manikins. The project outlines the techniques for controlling the mechanical arm in a realistic fashion, as well as explores what it takes to achieve a realistic behavior.

A number of prototypes for reenactment of human-like movement is conceptualized and judged. By directly reading the movement from the operator, the final concept is able to accurately replicate the planar movement of the arm in real-time. Several concepts for improving the system are proposed, and the future possibilities for the implementation of the concept in medical simulators are outlined. These concepts use

The final prototype proposed is simply the current iteration of the product development, and is far from a perfect solution to the proposed problem. It has however a great potential, and depending on further work and optimization, can be developed into a practical system that can be implemented into a medical simulation manikin.

Preface

This project thesis describes the development of a prototype system for actuation and control of arms in health care simulators, as requested by Lærdal Medical. It was written to fulfill the requirements of the Product Development and Materials specialization at NTNUs Department of Engineering Design and Materials. I was engaged in this project between January and June of 2021. The task was created as a collaboration between Lærdal Medical, and my supporting coach Marius Auflem.

I would like to thank Martin Steinert and Marius Auflem for excellent support and guidance during the span of the project.

Bartosz Jakubowski

Trondheim 30.06.2021

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Chapter 1

Introduction

1.1 Background

The topic of research for this project was proposed by Lærdal Medical, a company specializing in the production and development of high realism medical training devices. Lærdal Medical (from now on referred to as Lærdal) is a manufacturer of advanced patient simulators such as the SimMan or Resusci Anne manikins. Manikins are life-sized human-like mannequins with the purpose of giving students, healthcare givers, and doctors a safe environment to practice their skills and simulate realistic scenarios without the use of a real patient. The various modules installed inside of these manikins can accurately simulate medical conditions that either occur too rarely or are too life-threatening to the patient to be allowed to be practiced on by someone inexperienced. The functionalities and the outputs of the manikin can be controlled by a trained instructor during the staged scenario simulation.

The project was carried out at TrollLabs at Norwegian University of Science and Technology in Trondheim, a research and prototyping laboratory, established in the fall of 2014. It aims to investigate and improve the development process of the early fuzzy front end in cases of engineering design.

1.2 The Task

This project aims to explore the different ways of increasing the realism and immersion of the simulations by implementing autonomous manikin body movement during several specific scenarios. A big obstacle in the medical simulation is ensuring the adequate immersion and workload on the trainee to make the simulation sufficiently realistic, Lærdal wishes to advance their simulators in that regard. During various training scenarios, the realistic outcome would be for the manikin to move by itself, give feedback to physical push, and overall be more life-like by exhibiting recognizable human body movement during a variety of medical procedures. This project will mostly focus on the involuntary arm movement, as it can be implemented in and vastly increase the realism of, a wide range of simulation scenarios. With the use of current manikins, these cases are difficult to simulate realistically without the involvement of a human actor. With the use of a manikin, the feedback received from the patient often has to be conveyed from a third party during the simulation, and not from the patient/ manikin itself.

A desirable outcome of the increased realism and motion capabilities of the manikin would also be an improved human-robot interaction between the trainee and the simulation robot. In the simulated scenarios, the patients are rarely unconscious and lay stationary, rather they are fully or partially mentally present. To ensure a sufficient amount of physical and mental strain and accurately simulate a medical scenario, a feedback loop between the patient and the trainee is required. The manikin should respond to trainee inputs and be safe to work with, so as to not hurt anyone by an uncontrolled movement. In addition to autonomous limb movement, a very important requirement for the finished product is for the solution to be able to be implemented alongside the modules already installed throughout the manikin's body to conserve space.

Chapter 2

Literature and Technology Review

2.1 Literature Review

This project was started with no prior experience in the field of medical simulation and limited knowledge of the specific medical cases to be involved. A project of this scale, involving high amounts of uncertainty, required continuous ingenuity and acceptance of a steep learning curve to be completed. The underlined obstacles of this task such as specification ambiguity and an unknown scope of implementation, are a common occurrence in the field of research and development. To combat this, several studies have been conducted on the methodology of product development.

According to Carbone and Tippett (2009), this project falls into the category of ”Fuzzy Front End”, the phase of product development in its earliest stages. They describe it as the unpredictable starting stage in which the product concept is still very fresh, the period between idea conception and the start of the subsequent and much more standardized new product development. The great advantage of this stage is its relatively low development cost and effort. The specifications in this stage are loosely defined and there are more unknowns than knowns, meaning hidden problems that the researcher is not aware of as of yet Kriesi et al. (2016).

Taking advantage of the described benefits of the Fuzzy Front End this project exists in, the focus can shift towards a quantitative probing method as proposed in Elverum et al. (2016). Using prototyping as a learning opportunity rather than an early proof of concept ensures a valuable learning opportunity for each cycle. The focus should be placed on the speed and quantity of the prototypes, ensuring rapid feedback cycles, reduced design fixation , and better learning loops Leifer and Steinert (2011).

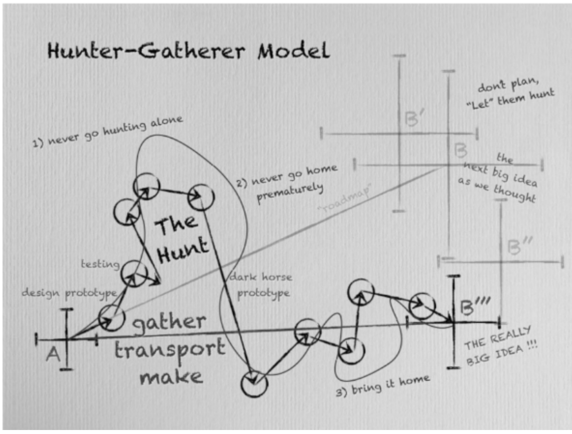


Figure 2.1: From Steinert and Leifer (2012): The Wayfaring Model

This project closely follows the Wayfaring method as a development from the Hunter-Gatherer Model described by Steinert and Leifer (2012), later developed into the wayfaring model by Gerstenberg et al. (2015). This model can be illustrated as a journey where the desired direction changes continuously based on the environmental feedback, where the feedback is gained by probing, and the desired direction is the discovery of ”The Really Big Idea”. It emphasizes the use of rapid, low fidelity prototyping, as opportunities for testing and learning, with every prototype expanding the knowledge of the task at hand. This is an iterative process that divides the progress into a series of probing stages. The proposed probing starts with building a low fidelity prototype trying to test a concept or idea. Using the newly gained knowledge and experience, more ideas and concepts can be generated. The probing stage ends with a converging phase, where the new ideas are filtered and converted into new prototypes.

2.2 Technology Review

The simulator at focus is the SimMan 3G (figure 2.2). Currently, it is equipped with modules for medically accurate simulation of IV injections, cardiopulmonary resuscitation, procedures involving airways, and more. It also has built-in features such as pupil dilating, blinking, and sweating/ secretion. Utilizing different combinations of the existing modules, the manikin is capable of simulating a wide range of conditions. The SimMan doll can be controlled remotely by a trained technician throughout the duration of the simulation to tune it to the required specification, as well as to help to crate variation between the scenarios, and to lower the chances of experiment learning.

Figure 2.2: SimMan 3G PLUS

The SimMan 3G is targeted for the training of medical professionals such as ambulance workers, nurses, medical students, and other first responders. Its main advantage is its repeatability and safety of training. It ensures an accurate representation of medical cases that either occur too rarely to reliably offer a training opportunity or are too threatening to the patient's life to allow any untrained medical staff to train on. As described by Maran and Glavin (2003), simulation in medicine does not intend to replace learning in a real-life clinical environment, but to enhance it by integrating both methods. It is there to let those still in training practice uncommon conditions and allows professional practitioners to maintain their skills.

2.2.1 The dimensions of a simulation

The benefits of medical simulation are clear as discussed in 2.2, but there is a spectrum to the fidelity of the simulators used. It encompasses everything from a part-task trainer for ”mock drills”, to a computer-driven, high fidelity integrated manikin. Simulated patients are undoubtedly the training tools with the highest fidelity used in simulation today. Together with a realistically recreated working environment, it makes for a powerful learning experience. Additionally, the mentioned simulations help the trainees to focus on the social aspects such as team working, interpersonal communication, and task management, all the non-technical skills needed to perform well as a group as described by Maran and Glavin (2003).

Simulation as a technique works best when it achieves full immersion for the participants. In their research, Maran and Glavin highlight the importance of the dimension of stress in the medical simulation. They describe the absence of it as the ”adrenaline gap”, and argue how this shortcoming of today's simulators affects how well we can assess the performance of the trainees. The concept of simulator immersion is also discussed by Ege et al. (2020), where the question about a satisfactory ecological validity is raised. Ecological validity is a measure of realism in the recreation of the real-life working environment by the simulation. Its four main components are the physical environment of the simulation, the scenarios used, the performed tasks, and the users involved (Kushniruk et al., 2013). This project aims to discover the potential of increased simulation realism by the addition of limb movement. It theorizes that the added dimension of visual and physical feedback will result in enhanced simulation experience and increased ecological validity.

There is a clear need for improvement in several areas of medical simulation. This project outlines a selection of specific medical cases where the added limb movement would be advantageous to the overall realism of the simulation. Presented in order of which they are considered to be the most advantageous to least advantageous to implement:

Tonic-Clonic Seizures Often evoked by an underlying condition like epilepsy, it is one of the most intricate cases to recreate realistically given how the movement is the most unpredictable from patient to patient. Currently simulated almost exclusively with the use of an actor, a healthy human playing a role written based on the experience of medical professionals.

Strokes Highly relevant health condition that is commonly hard to simulate. Currently, the training involves teaching the recognition of a series of traits in the movement of a patient, as well as testing for mobility in the limbs on both the left and the right side of the patient's body. This training also utilizes a human actor.

Pain Response The commonly used Glasgow Coma Scale is a system developed for patient evaluation. Using a series of tests involving increasingly more stimulating pressure points to get feedback from the patient after a trauma or in an inebriated state, it assesses the patient's level of consciousness.

This project will mainly focus on the physiology and recreation of Tonic-Clonic seizures as it is a medical scenario that the SimMan manikin cannot simulate with its current build, as well as it heavily relies on arm movement which can later be adapted to help simulate a number of other conditions.

2.2.2 Safety concerns

An accurate recreation of the medical conditions described in 2.2.1 would require a technologically capable manikin with potentially very powerful actuation methods that could present a safety concern. Creating an actuation system for limb movement will therefore require several safety measures to be implemented. The measures could be a force sensor measuring the resistance on the limbs to sense when it is hitting/pushing something, or a predetermined software limit for end tip velocity, ensuring the movement could never be considered to be dangerous to the trainees.

Chapter 3

Development

Introduction

Early insights revealed that the state of current simulation is in a need of an improvement. The technology available is sufficient to create a viable solution, yet the problem remains largely unsolved. This project will mainly focus on the development of an advanced actuation system which can accurately recreate the human motion in the case of a Tonic-Clonic seizure. Although the goal is to develop a high fidelity training device, this project recognises the existence of a number of low cost solutions developed in the recent years, that can be implemented on low fidelity manikins, as showed by QuEST (2019) or Baily (2019). These will always stay relevant as they offer a good enough immersion factor at an extremely low cost.

One of the main challenges this project encountered was the study of the human motion itself. The big unanswered question was: What makes the patients motion recognisable and distinctively human, and how can we truthfully replicate it? The research suggests that even with real-life examples, the seizures can go overlooked if not spotted by a trained eye, so a lot of research will have to be conducted in order to fully understand all of the important yet subtle cues of a Tonic-Clonic seizure (Spray, 2015).

Tonic-Clonic seizures is what most people think of when they think of *seizure* and *Epileptic seizure*. As the name implies, said seizures have both the characteristics of a tonic and a clonic seizure. Tonic means stiffening, and clonic means rhythmical jerking. A typical seizure of this kind typically develops as described by Kiriakopoulos and Osborne (2017):

Tonic phase:

The tonic phase comes first. All the muscles stiffen. Air being forced past the vocal cords causes a cry or groan. The person loses consciousness and falls to the floor. A person may bite their tongue or inside of their cheek. If this happens, saliva may look a bit bloody.

Clonic phase:

After the tonic phase comes the clonic phase. The arms and usually the legs begin to jerk rapidly and rhythmically, bending and relaxing at the elbows, hips, and knees. After a few minutes, the jerking slows and stops.

The person's face may look dusky or a bit blue if they are having trouble breathing or the seizure lasts too long. The person may lose control of their bladder or bowel as the body relaxes. Consciousness, or a person's awareness, returns slowly. These seizures generally last 1 to 3 minutes. Afterwards, the person may be sleepy, confused, irritable, or depressed.

3.1 Consultations with medical staff

This project seeks to keep the needs of the user in focus, so as a means of acquiring data several medical professionals were contacted. Their role was that of a consultant and an extreme user. Extreme users in this context mean the users with disproportionately more experience with the clinical cases discussed than an average health worker. Their involvement ensures both an important insight into the state of current training, and valuable feedback on the accuracy of the findings and assumptions made in this project.

After the consultations with nurses from St. Olavs hospital in Trondheim and

Helse Fonna hospital in Haugesund, it was clear that the current training is not sufficient. They described their limited experience learning about seizures and how most of it consisted of lecture-style training with a few picture examples. The few nurses who have witnessed a Tonic-Clonic seizure have seen those for the first time in a work environment, and a large portion of them was alone when this occurred. This makes the first encounter extremely stressful to the nurses, and potentially dangerous to the patient due to the lack of any prior practical experience.

3.2 Exploration

The first stages of research focused on finding a baseline for what the finished product would aim to replicate. A meticulous study of publicly available real-life seizure footage was done. The aim was to generalize the movement and to highlight the biggest similarities between cases, as well as the scope of the differences observed. Seizures of this kind can vary greatly between cases and can be both perceived and interpreted differently by the users. Therefore a big goal of this process was to describe the movement mathematically to avoid vague statements in the judgment of the results.

The research identified several common movement cues and described them. If replicated correctly, these had a chance to realistically convey a Tonic-Clonic seizure simulation. The findings show that for the tonic phase the elbow joint experiences the biggest range of motion of between 10 and 90 degrees of relatively slow rotation (two to three seconds to travel through the full range of motion). The shoulder joint experiences a much smaller range of movement. Both tend to lock up in one position after a couple of seconds, and the elbow tends to do so in an extreme position. The wrist and fingers tend to curl up, yet the fingers often stay semi-relaxed despite the tension in the wrist.

During the clonic phase, the observations showed that the elbow was the joint experiencing the fastest rotational speed as expected. The movement was rapid, twitchy, and repetitive, and the range of motion could be both relatively small (10-15 degrees) and as big as 70 to 90 degrees. The shoulder joint experienced movements as big as 90 degrees in both of its rotational axis (X: along the body to reached over the head, Y: with the elbow bent to 90 degrees, from it pointing forwards to it pointing in towards the other side of the body). The wrist movement is either minimal in comparison, or hard to perceive due to the angular velocity of the elbow (the hands are hard to focus on given the speed of the arm movement). Most of the movement observed was equally twitchy as in the elbow, either actuated by the wrist or carried over from the elbow given the springiness of the system (arm).

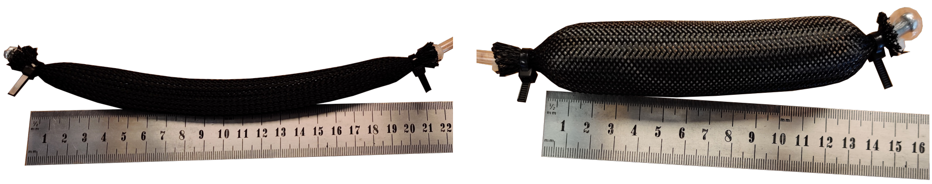
3.3 Prototyping

One of the main physical obstacles in the prototyping process was the choice of an actuation method. What are the advantages and disadvantages of the different methods, and how would the choice affect the realism of the finished solution? The methods chosen for testing were the following:

Direct drive of the joints: A system composed of motors installed directly in the joint itself. This system allows the control of the joints to be simplified as the ratio of input to desired output is 1:1. Additionally, it allows for greater precision of control as there is a direct connection between the actuator and the limb. This method however required the motor to have great torque and to be very compact. The weight of the motor itself was also an obstacle. Early testing excluded this actuation method as it did not produce very favorable results, and the increase in precision provided by the method was negligible.

Cable and pulley system: A centralized actuation system using a system of cables and pulleys to transfer the linear motion of a cable to a rotation of a joint. The main advantage of this system is the possibility to separate the actuation system from the arm itself for lighter construction. Additionally, the cables have very high strength and do not require a lot of internal space. The early testing of this method showed promising results and the research on the method will be expanded upon in later sections.

McKibben muscles: Pneumatic artificial muscles were invented in the 1950s for use in artificial limbs. They consist of an inflatable bladder encapsulated in a woven shell. The muscle contracts and broadens as the bladder is filled and lengthens as the air is let out and the muscle is stretched. Home-made McKibben muscle built from a braided cable sleeve, silicone tube, a condom, and a couple of zip ties can be seen in figure 3.1. Advantages include anatomically correct expansion of the actuator, lightweight construction, and good elasticity. The early testing of this method showed promising results.



(a) Home-made McKibben muscle deflated **(b)** Home-made McKibben muscle inflated

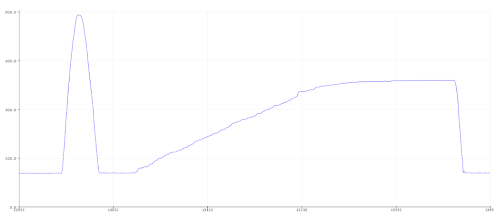
Figure 3.1: The operation of a home-made McKibben muscle

3.3.1 Prototype: Small Scale Elbow Joint

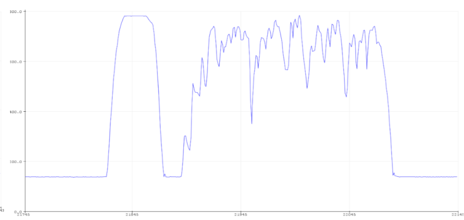
The first prototype built was a simple elbow joint that consisted of two wooden stirring sticks with a pivot joint connecting them. Its purpose was to serve as a simple model of a human arm on which the different actuation types could be compared. Its construction was very lightweight and it had no fastening mechanism which could be used for fixing it in place. The prototype was tested with both string actuation, and a set of McKibben muscles, as shown in figure 3.2. All actuation methods tested were controlled manually and could be prone to human error, however, this stage of testing focused simply on discovering the potential of the proposed actuation systems.

Figure 3.2: First prototype using McKibben muscles

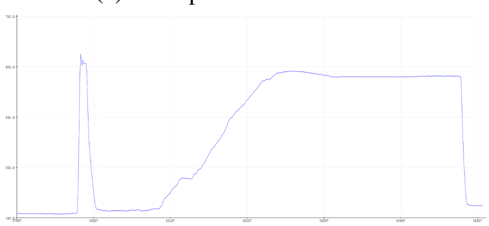
During this preliminary testing, a potentiometer was fitted to the elbow joint in order to accurately measure the angle. The two most promising actuation methods were tested for ease of use and actuation speed by trying to accurately recreate the elbow movement during a generalized Tonic-Clonic seizure. The test were plotted with the elbow angle on x-axis, and time in milliseconds on y-axis (figure 3.3). Each test started with a calibration movement starting with the arm fully extended, then quickly flexed to its maximum flexion, and then released back to fully extended. This was done in order to reference the joints entire range of motion. Both methods showed promising results. The cable method showed to be the one easier to control precisely, as well as the one allowing for the fastest angular acceleration. McKibben muscle showed to be harder to control accurately but inhibited an interesting behavior of resonance. Because of the elastic materials it's made of, this actuator has a natural frequency that can be taken advantage of. If agitated non synchronously with the frequency, it acts as a brake for the swings in the system. If however agitated synchronously with its natural frequency, the swings achieved in the system can be of greater frequency than what can be achieved using a cable and pulley system. This behavior is advantageous for the rapid and twitchy movement in the clonic phase, but it also dampens any big swings that are equally vital for a realistic simulation.



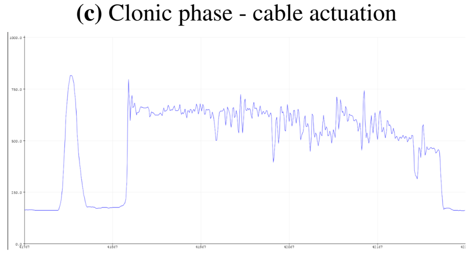
(a) Tonic phase - cable actuation



(c) Clonic phase - cable actuation



(b) Tonic phase - McKibben actuation

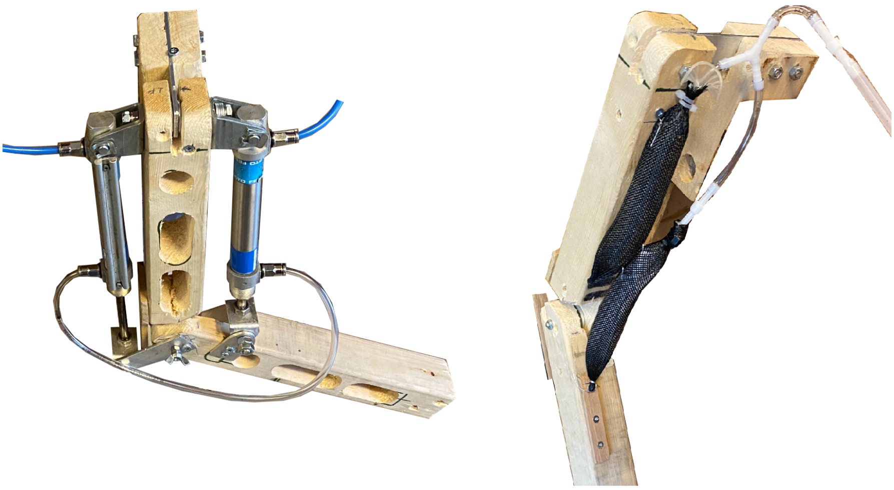


(d) Clonic phase - McKibben actuation

Figure 3.3: Tonic-Clonic seizure simulated using cables and air muscles

3.3.2 Prototype: Full Scale Wooden Arm

Building on the knowledge gathered in the testing of the previous prototype, the need for a bigger prototype arose. Having tested the actuators in an artificially simple environment the next step was to create a full-scale arm. The prototype was built using wooden planks with a rectangular cross-section of 5 cm by 5 cm, aluminum plates, and M6 bolts and nuts. The wooden parts were hollowed out for weight reduction. This prototype featured two joints, the elbow joint, and a simplified one-axis shoulder joint (figure 3.4).



(a) Full scale prototype with pneumatic actuators **(b)** Full scale prototype with McKibben actuators

Figure 3.4: Prototype: Full Scale Wooden Arm

Testing this setup quickly unveiled a number of problems. When testing the elbow joint, the pneumatic actuators were considerably stronger than the air muscles at the same pressures. They were rated to handle pressures up to 4 bar, whereas the air muscles ruptured if pressurized above approximately 1.2 bar. The air muscles were also not strong enough to lift the wooden forearm of the prototype even when fastened up to 7 cm away from the joint axis. The shoulder joint showed to be more troublesome to test than anticipated, as the air muscles proved to be even weaker at lifting the arm at the higher joint, and the pneumatics were too cumbersome to install without adding an excessive amount of bulk to the design.

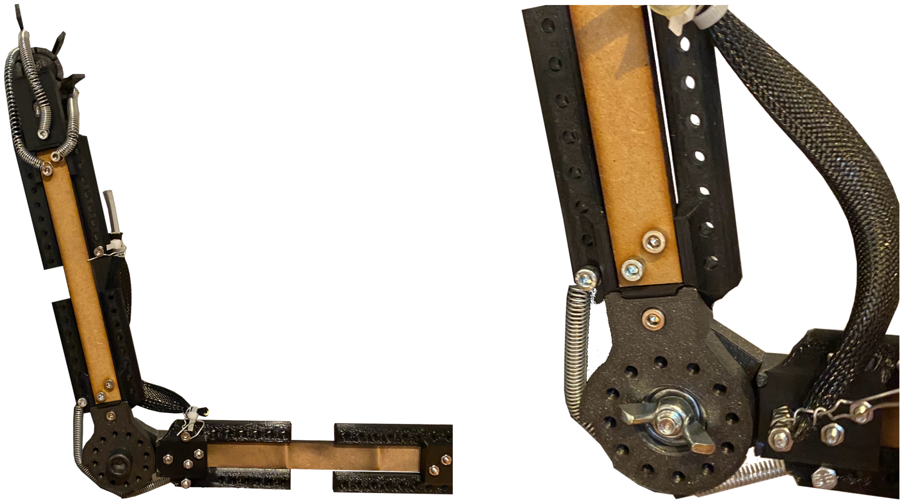
Even though the pneumatic actuators were more than strong enough, they were excessively heavy and bulky to work with and would not fit inside of the manikin's arm very easily. This could possibly be combated using a thinner actuator. The McKibben muscles on the other hand performed noticeably worse but did not add nearly as much weight as the metal pneumatic actuators. The biggest shortcoming of the used McKibben muscles is the low-pressure design of the bladder, as it is made from a condom and would easily rupture if over-pressurized or incorrectly inserted. A number of alternatives can be tested to find a more suitable material for the inner sleeve.

3.3.3 Prototype: Lightweight Modular Arm

The previous prototype had shown the importance of a lightweight design as the self-weight could be attributed to the general failure of both of the designs. As a way of combating the problem, a new modular arm design was introduced (figure 3.5). Featuring 3D printed ball socket shoulder joint, 3D printed elbow joint with slots for ball bearings for frictionless operation, and a skeleton structure made from laser-cut Medium-Density Fibreboard (MDF). A big focus point of this design was the modularity and a broad selection of attachment points for testing of different configurations. With length measurements equal to the previous one, this prototype weighed only 1100 grams compared to the old weight of 3500 grams.

For testing purposes the movement of the elbow joint was controlled solely with one air muscle, using a set of sprints as a counterforce. This proved to be a challenge as the homemade air muscles simply were not strong enough to overcome the force of springs, and barely strong enough to lift the forearm of the new model without any added resistance. The ball socket of the shoulder also proved to be troublesome as it required a lot of balancing to stabilize in a satisfactory position, and the springs added an immense amount of resistance rendering both air muscles and any cable and pulley system too weak to lift it. For future prototypes, a universal joint would be preferred as it separates the movement into two distinct axes and allows for independent control.

The modular prototype was a good proof of concept, as well as a good testing ground for the actuators chosen for the comparison. Its modularity proved



(a) Lightweight modular prototype with air muscles attached

(b) Closeup of the prototype

Figure 3.5: Prototype: Lightweight Modular Arm

to be a great strength for quickly adapting to new ideas when testing, but also its biggest setback as the high complexity introduced many new obstacles. The lessons learned will be useful in the making of a full-scale prototype further down the road.

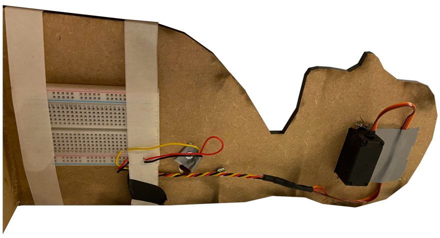
3.3.4 Prototype: Humanoid Testing Rig

For this setup, a human-like side profile cutout made from a laser-cut MDF board was used as mounting for the components (figure 3.6). This structure would serve as both a convenient mounting solution and a visual aid for increasing the realism of the arm movement. The human profile model measures 96 cm in length and can be considered to be a 1:2 scale model of a 192 cm tall human. This size was chosen to conserve materials and to enable the prototype to use weaker actuators. This prototype did not need to be life-sized, as it would not be directly interacted with and would instead be used to record short videos of Tonic-Clonic seizure cases. This will be discussed in 3.4.

Because of the simplicity of implementation and small footprint, the actuation

Figure 3.6: The silhouette of the humanoid prototype

method chosen for this prototype was a system of servos and cables. This system will be used in the prototypes from this point forward. The servos used were hobby grade HK15328D High Torque Servos. At 5V of voltage they were run at, the torque output was 1.03 Nm. A spool of mono-filament nylon fishing line was used for the cable material as it had negligible elastic deformation at the loads tested. Powering the prototype was an Arduino DUE.



(a) Servo and electronics mounting

(b) Prototype overview

Figure 3.7: Prototype: Humanoid Testing Rig

As mentioned earlier, the pulley and cable system had a number of crucial advantages that fit the project. First of which was the reduced system complexity, as a system of air muscles would require a bigger power supply unit and an air pump, both of which would introduce new physical points of failure. Secondly, the pulley and cable system could in theory be placed far away from the point of actuation, making it the ideal candidate for a centralized system for powering the movement of the entire manikin from one hub.

The testing of the new prototype showed a significant increase in the perceived realism of movement. The new human-like silhouette and hidden actuators contributed greatly towards making the test rig look more natural, and the lack of distracting mechanisms made it possible to get feedback from a wider audience. The elbow joint was wired to a potentiometer allowing the user to input desired motion in real-time.

Figure 3.8: Elbow joint actuation system

Following the promising results of one joint prototype, the shoulder pivot point was replaced by a second servo making the entire arm fully controllable. A second potentiometer was added for full simultaneous control of both joints. During testing this proved to be of a great challenge as the chaotic nature of a Tonic-Clonic seizure made it nearly impossible to accurately steer both joints. No satisfactory reenactment of a seizure could be done using this control system.

Improving the control system, a new idea was introduced. As the prototype was intended to perform the human-like motion, the best way of controlling the rig was to mimic the user's arm movement literally. The idea of tracking the exact human movement has been used for many decades, mostly in animated motion pictures and in the creation of video games where the motion data would be put directly into a computer-modeled model. This idea inspired the creation of an exoskeleton with built-in potentiometers for direct control of the humanoid prototype as shown in figure 3.9.

The last iteration of the Humanoid Test rig was equipped with two servo motors and an advanced control system. Leveraging this setup a new study was conducted. This study aimed to determine which parts of the movement during a simulated seizure were the most important to include for the simulation to remain convincing. The easiest way of solving this project would have been to re-purpose an advanced 7 degrees-of-freedom robot arm and program it to follow the movement recorded from a real patient. This however is not feasible in most cases and would have increased the cost by a factor of one hundred to one thousand. The im-

(a) Exoskeleton attached to the operators arm

(b) Exoskeleton controlling the prototype

Figure 3.9: The exoskeleton design

portant question this project undertakes is exactly: How can we achieve a realistic simulation in the simplest way possible?

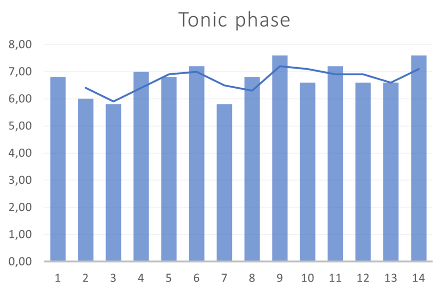
3.4 Online Survey

Using the newly constructed rig, a series of 14 videos was recorded, 9 using both servo motors, and 5 utilizing only the one controlling the elbow. The videos were short and included a 15-second simulation of the tonic phase, followed up by a 15-second clonic phase for an approximate 30 second total run time. The recordings were showed in the order of increasing motion fidelity and included bigger and more rapid rotations as the fidelity increased. The participants were asked to watch the videos one after another. After each video, they were asked to rate the realism of the tonic and the clonic stages separately, on a scale from 1 to 10.

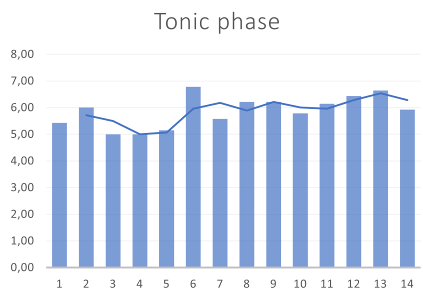
The goal of the online survey was to reach more relevant participants than what a process of personally scheduling meetings would allow for. This was done during the Covid-19 pandemic, and the access to medical professionals was very limited. For ease of use, the survey divided the participants into two groups, medical professionals and others. The survey also gave the chance to specify any other relevant experience. The survey in its entirety can be seen in Appendix B (8.2).

3.4.1 Survey Results

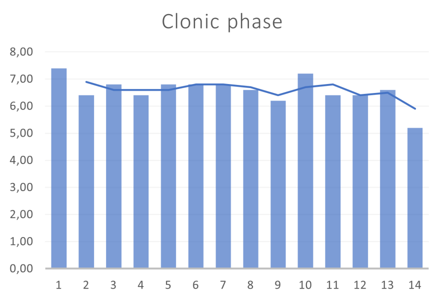
The survey was distributed not only to hospitals but also among students, nurses, and some faculty staff in hopes of reaching medical professionals. The resulting 19 participants were divided into two groups, the first of which included four medical professionals and one first aid instructor, and the second one consisting of 15 non-medical professionals. This was done to separate the opinions of participants with very little background knowledge and participants with a visual experience of what a Tonic-Clonic seizure looks like.



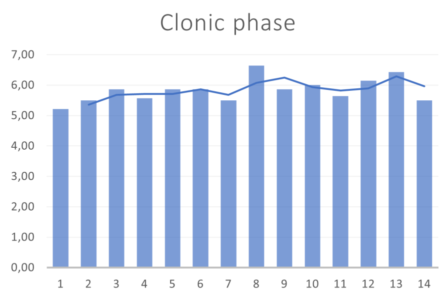
(a) Tonic phase - medical professionals



(c) Tonic phase - non-medical professionals



(b) Clonic phase - medical professionals



(d) Clonic phase - non-medical professionals

Figure 3.10: The online survey results

Analyzing the results proved to a challenge of its own. All results depend on the setup of the survey and there are some caveats to be aware of. Firstly the survey does its own judgment of what it considers to be the most realistic and high-fidelity and presents the videos in that order. Secondly, the fidelity itself does not have to have a lot of influence on the results, as this project theorizes there are certain movements which if performed, will drastically increase the realism of the scenario, no matter the overall fidelity. These movements are what the survey aims to uncover. Additionally, the goal is to compare the movements to real-life Tonic-Clonic seizure occurrences, as certain movements might not be realistic, but be what the over-dramatized medical movies and TV series use to portray a seizure.

There can be seen a vague pattern of an increased score as the fidelity increases, but this does not always hold, and for all but one video the score of the most detailed animation is considerably lower than the second most detailed one (see 3.10). As explained earlier this is what was expected of the outcome as the movements in the most high-fidelity scenarios were allowed to have the most speed and detail, which is especially important in portraying the clonic phase with its jerky motion. No more trends were observed in the results of this survey.

Because of the nature of a study of this size, it was challenging to spot trends in the collected data. A very real possibility is also that the prerecorded videos were deficient and therefore interfered in the data collection. As a means of extracting more insights from the results, the top two rated scenarios in each category were compared and analyzed. The QR codes for all videos can be found in Appendix C (8.3).

The top two rated tonic phases in the medical professionals' group, video 9 and video 14, had two things in common; they both utilized a slow opening shoulder motion at the start of the simulation and had a slight but continuous elbow movement throughout the tonic phase. Even though the tonic phase is characterized as the phase where motion seizes up, a slight motion helps to convey that this is a living human struggling, and not a doll simply holding a position. The top-rated tonic phases in the non-medical group were videos 6 and 13, both of which had similar characteristics to the two previously mentioned recordings, with the difference of added twitch at the start. It would be expected for the group with less visual experience to rate a more violet motion higher as this is how it is usually portrayed in movies.

The two top-rated clonic phase videos for the medical professionals' group were the number 1 and 10. This was surprising as it was the only time a video utilizing just the elbow motion was included. Upon closer inspection, it was revealed that this was not the case, and video 1 features very slight but noticeable movement in the shoulder. This seemed almost involuntary and might be exactly what was perceived as realistic by the participants. Combined with video 10, a few common movements can be highlighted. In both cases, the shoulder movement seemed particularly chaotic, with nuanced motions throughout the simulation, with sudden big jumps every couple of seconds. This motion of a sudden shoulder flexion combined with the elbow flexion, followed by an outwards twitch of the elbow makes for a very powerful visual aid.

Comparing the two top-rated clonic reenactments from the non-medical professional group, videos 8 and 13, some similarities can be spotted. In both cases, the movement seems slower than what the medical professionals rated as most realistic, but the movements were grander in scale, making every swing more pronounced. The common motion both videos include is the punching movement when the shoulder flexes as the elbow extends. These sharp movements seem very involuntary and show a sort of vulnerability in the simulated patient. Although the movements were otherwise very similar to the previously mentioned simulations, these traits are special to videos 8 and 13.

What ties all the results together are the micro-movements of the simulations, the most nuanced and easily overlooked details that can give a lasting impression. The field of these micro-movements, or micro-expressions as they are often called, is a very well researched one (Yan et al., 2013). It aims to find the true human motion and to combat the Uncanny Valley effect, which is the sudden dip in perceived realism as one approaches a simulation indistinguishable from a real human motion (Brenton et al., 2005). This is an exciting new direction for this project, and much research would have to go to reliably implement motions of this kind into the simulation of Tonic-Clonic seizures or any other medical cases one would wish a manikin to perform.

This online survey has given a good insight into the inner workings of the human motion simulation and the specifics around perceived realism of a Tonic-Clonic seizure reenactment, yet it has its issues. The survey proved to be challenging to perform, and some concerns can be raised about the structure of the experiment, as human error can easily be present. It can be theorized how the simplicity of the test rig was a distraction by itself, and how that could have affected the rating received from the participants.

Computer Vision

As the human factor can prove to be unreliable when collecting data on the motion of the rig, computer vision could be implemented as an impartial way of rating the motion instead. An open-source computer vision Python script was repurposed for this project to help in the data collection (MediaPipe, 2020). The pose estimation script used can be seen in its entirety in Appendix A (8.1). The implementation of a computer vision script is something left for future work.

Chapter 4

Discussion and Future Work

As this project deals with new problems and uncommon grounds for a mechanical engineer student, the exploratory way of approaching this task was proved effective. The use of rapid prototyping and wayfaring quickly grants new knowledge and uncovers new, previously unknown obstacles and opportunities. The insights gained from each prototype can be leveraged in future work as this project continuously proves to find itself in the fuzzy front end of innovation. This inclination towards an exploration of concepts is what has lead this task down this new path, rather than following a predetermined trajectory. The big obstacle working in this fashion is the emerging need for deeper studies and more invested prototypes as the project progresses.

This task deals with the issues of correct mentioning, motion study, uncanny valley, and realism in medical simulation. The challenge of quickly creating new prototypes is the low fidelity of each outcome, which over time renders incapable of giving satisfactory results as the need for higher fidelity studies emerges. There is a clear need for a bigger, more encompassing study in the area of mimicking human motion.

The results from the online study showed promising results in spotting the important clues of what makes the simulated movement recognizable and inherently human. In order to improve the potential knowledge advancements, a full-scale model with a bigger scope of movement would need to be constructed.

4.1 Future Work

A number of future points of interest and new obstacles have been identified during the course of this project. The solution to these newly discovered challenges could prove to be groundbreaking in the field of medical simulation and lead to innovation in several neighboring fields of science. This project aims to expand our understanding of the requirements for a successful simulation and aims to share the findings which might prove to be valuable to other researchers.

4.1.1 Ecological Validity

The sufficient ecological validity requirements were not met during the testing of the prototypes as the desired target audience could not be reached. The need for testing with the right users is crucial for the development of this project as it progresses. This project describes the phase focused simply on data collection and furthering our understanding of the task at hand, as well as uncovering the unknown requirements and tackling the technical challenges.

4.1.2 Future Work

Building upon the insights and knowledge gained from the work conducted in this project, several topics and designs could be explored. For the master thesis it is recommended to explore these concepts and ideas:

Human Scale Manikin Implementation: The current humanoid test rig proved to be useful, yet it had its limitations. To truly test the concepts involved in this project, a full-scale manikin with an updated actuation system should be constructed. This would both benefit the understanding of the technical requirements for the actuation system, expand the motion from planar motion to a full three-dimensional one, and could finally be used for user testing as it could be interacted with. This would greatly improve the ecological validity of the test setup.

Force Sensing: As the user testing is introduced, a layer of safety will have to be introduced. The manikin needs to be able to have safety measures implemented, as to not hurt any of the participants. One way of ensuring user safety is to implement a clutch-like behavior with force sensors. This would sense excessive resistance in the joints and both hinder the chance of injuring the users, and the chance of undesired wear of the actuators.

Hand Motion: The current model does not place a lot of focus on hand movement. The implementation of a technician-controlled hand would beneficial, as the big discovery of testing mentioned setup is the importance of the micro-movements, which is especially present in the observed hand and finger motion during a real-life Tonic-Clonic seizure. This could greatly improve the perceived realism of the simulation as a whole, and open up a range of new medical scenarios to be simulated such as strokes and pain response simulations.

Soft Robotics: As the project involves creating a human-like manikin and the interaction with the model is necessary, the implementation of soft sensors could prove beneficial. An area of interest could be the use of soft sensors in the gathering of feedback for use in smart adaptive simulations.

Chapter 5

Conclusion

This project was based on a task provided by Lærdal Medical, an international manufacturer of medical training and simulation equipment. The goal for this project was to explore the different ways of implementing movement into the existing SimMan 3G manikin as Lærdal wishes to expand its simulation capabilities to new areas. In this project thesis, The Wayfaring method has been utilized in order to quickly test new concepts and gain valuable knowledge and understanding of the challenge.

The main focus of this project has been to map out the human movement during a Tonic-Clonic seizure and to realistically recreate its most important cues to convey the state of the simulated patient. Throughout the testing process, new requirements emerged, and the assessment of ecological validity and the uncanny valley effect was necessary to take into consideration.

Some interesting user feedback has been gathered during the surveying period. This has provided important insight into the predicaments of this task. All concept and prototype testing have been documented and the results have been discussed. The shortcomings and results of the conducted work are underlined and will be beneficial for future work.

The work started in this project will be continued in the master thesis. This will hopefully lead to the development of a fully working system that solves the previously stated problem.

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Appendix

8.1 Appendix A: Python Computer vision code

```
import cv2
import mediapipe as mp
import numpy as np
mp_drawing = mp.solutions.drawing_utils
mp_pose = mp.solutions.pose

def calculate_angle(a,b,c):

    a = np.array(a)
    b = np.array(b)
    c = np.array(c)

    radians = np.arctan2(c[1]-b[1], c[0]-b[0]) - np.arctan2(a[1]-b
        [1], a[0]-b[0])
    angle = np.abs(radians * 180.0/ np.pi)

    if angle > 180.0:
        angle = 360 - angle

    return np.around(angle, 2)

# Video feed
cap = cv2.VideoCapture(0)

# Setup mediapipe instance
with mp_pose.Pose(min_detection_confidence=0.5,
    min_tracking_confidence=0.5) as pose:
    while cap.isOpened():
        ret, frame = cap.read()

        # Recolor image to RGB
        image = cv2.cvtColor(frame, cv2.COLOR_BGR2RGB)
        image.flags.writeable = False
```

```
        # Make detection
        results = pose.process(image)

        # Recolor back to BGR
        image.flags.writeable = True
        image = cv2.cvtColor(image, cv2.COLOR_RGB2BGR)

        # Extract landmarks
        try:
            landmarks = results.pose_landmarks.landmark

            l_shoulder = [landmarks[mp_pose.PoseLandmark.LEFT_SHOULDER.value].x, landmarks[mp_pose.PoseLandmark.LEFT_SHOULDER.value].y]
            l_elbow = [landmarks[mp_pose.PoseLandmark.LEFT_ELBOW.value].x, landmarks[mp_pose.PoseLandmark.LEFT_ELBOW.value].y]
            l_wrist = [landmarks[mp_pose.PoseLandmark.LEFT_WRIST.value].x, landmarks[mp_pose.PoseLandmark.LEFT_WRIST.value].y]
            l_hip = [landmarks[mp_pose.PoseLandmark.LEFT_HIP.value].x, landmarks[mp_pose.PoseLandmark.LEFT_HIP.value].y]

            r_shoulder = [landmarks[mp_pose.PoseLandmark.RIGHT_SHOULDER.value].x, landmarks[mp_pose.PoseLandmark.RIGHT_SHOULDER.value].y]
            r_elbow = [landmarks[mp_pose.PoseLandmark.RIGHT_ELBOW.value].x, landmarks[mp_pose.PoseLandmark.RIGHT_ELBOW.value].y]
            r_wrist = [landmarks[mp_pose.PoseLandmark.RIGHT_WRIST.value].x, landmarks[mp_pose.PoseLandmark.RIGHT_WRIST.value].y]
            r_hip = [landmarks[mp_pose.PoseLandmark.RIGHT_HIP.value].x, landmarks[mp_pose.PoseLandmark.RIGHT_HIP.value].y]


        except:
            pass
```

```
        # image = cv2.flip(image, 1)

        # Calculate angle
        l_elbow_angle = calculate_angle(l_shoulder, l_elbow, l_wrist)
        l_shoulder_angle = calculate_angle(r_shoulder, l_shoulder, l_elbow)

        r_elbow_angle = calculate_angle(r_shoulder, r_elbow, r_wrist)
        r_shoulder_angle = calculate_angle(l_shoulder, r_shoulder, r_elbow)


        # Visualise
        cv2.putText(image, str(l_elbow_angle),
                        tuple(np.multiply(l_elbow, [640, 480]).astype(int)),
                        cv2.FONT_HERSHEY_SIMPLEX, 0.5, (255, 255, 255), 2, cv2.LINE_AA
                    )

        cv2.putText(image, str(l_shoulder_angle),
                        tuple(np.multiply(l_shoulder, [640, 480]).astype(int)),
                        cv2.FONT_HERSHEY_SIMPLEX, 0.5, (255, 255, 255), 2, cv2.LINE_AA
                    )

        cv2.putText(image, str(r_elbow_angle),
                        tuple(np.multiply(r_elbow, [640, 480]).astype(int)),
                        cv2.FONT_HERSHEY_SIMPLEX, 0.5, (255, 255, 255), 2, cv2.LINE_AA
                    )

        cv2.putText(image, str(r_shoulder_angle),
                        tuple(np.multiply(r_shoulder, [640, 480]).astype(int)),
```

```
                        cv2.FONT_HERSHEY_SIMPLEX, 0.5, (255, 255,
                            255), 2, cv2.LINE_AA
                    )


        # Render detections
        mp_drawing.draw_landmarks(image, results.pose_landmarks,
            mp_pose.POSE_CONNECTIONS,
                                mp_drawing.DrawingSpec(color
                                    =(245,117,66), thickness=2,
                                    circle_radius=2),
                                mp_drawing.DrawingSpec(color
                                    =(245,66,230), thickness=2,
                                    circle_radius=2)
                                 )

        cv2.imshow("Mediapipe Feed", image)

        if cv2.waitKey(10) & 0xFF == ord("q"):
            break

    cap.release()
    cv2.destroyAllWindows()
```

8.2 Appendix B: Google Forms Questionnaire

Tonic-Clonic seizure simulation

This test aims to collect data on simulation of arm movement during a tonic-clonic seizure. Its findings will support the development of a medical trainer that is a part of a project thesis at NTNU in Trondheim.

During the test, you as the participant will be briefed on the necessary terms and background knowledge about tonic-clonic seizures to ensure correct data collection. You will be asked to rate a set of recorded simulation videos from 1 to 10, according to how believable said simulations were. Each scenario lasts around 30 seconds, 15 seconds of tonic and 15 seconds of clonic phase. The simulations will be done on a human-like doll with movable shoulder and elbow joints. The goal is not to recreate it perfectly but to make it recognisable and unmistakably a tonic-clonic seizure.

As described by the Epilepsy Foundation of America:

This type of seizure (also called a convulsion) is what most people think of when they hear the word "seizure." An older term for this type of seizure is "grand mal." As implied by the name, they combine the characteristics of tonic and clonic seizures. Tonic means stiffening, and clonic means rhythmical jerking.

-The tonic phase comes first.
- •All the muscles stiffen.
- •Air being forced past the vocal cords causes a cry or groan.
- •The person loses consciousness and falls to the floor.
- •A person may bite their tongue or inside of their cheek. If this happens, saliva may look a bit bloody.

-After the tonic phase comes the clonic phase.
- • The arms and usually the legs begin to jerk rapidly and rhythmically, bending and relaxing at the elbows, hips, and knees.
- • After a few minutes, the jerking slows and stops.

-The person's face may look dusky or a bit blue if they are having trouble breathing or the seizure lasts too long.

-The person may lose control of their bladder or bowel as the body relaxes.

-Consciousness, or a person's awareness, returns slowly.

-These seizures generally last 1 to 3 minutes. Afterwards, the person may be sleepy, confused, irritable, or depressed.

(epilepsy.com)

A seizure of this type includes a wide range of clues, but this test focuses only on the arm movement, keep this in mind.

1. Are you a medical professional?

Markér bare én oval.

- Yes
- No
- Andre: ______________________

2. Have you witnessed a tonic-clonic seizure in real life?

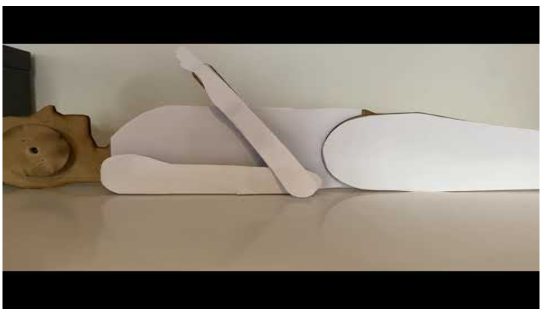
Markér bare én oval.

- Yes
- No
- Andre: ______________________

Simulation examples

You will now be asked to rate the believability of the motion of the prototype simulator.

One joint example 1



http://youtube.com/watch?v=SdFXFxEYN4w

3. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

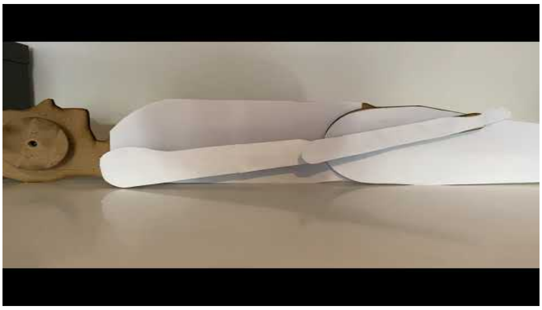
1	2	3	4	5	6	7	8	9	10

4. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

One joint example 2



http://youtube.com/watch?v=ozn9kVZtijQ

5. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

6. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

One joint example 3

http://youtube.com/watch?v=kdiYfABkIJ4

7. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

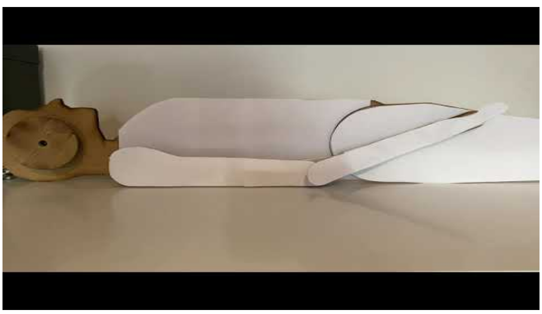
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

8. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

One joint example 4



http://youtube.com/watch?v=-_isXrO_qjo

9. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

10. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

One joint example 5

 http://youtube.com/watch?v=eGvQWY2JdVA

11. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

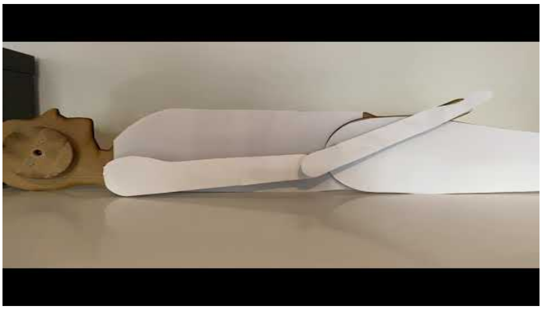
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

12. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 1



http://youtube.com/watch?v=vwK_5ljZL1A

13. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

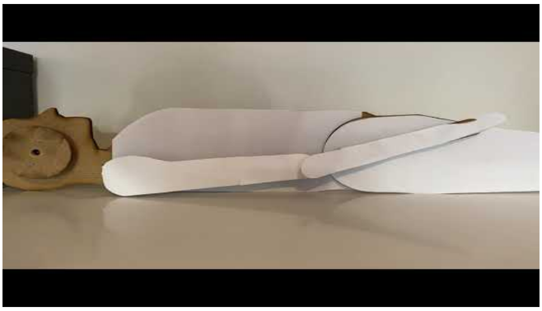
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

14. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 2

 http://youtube.com/watch?v=vsSC5Z31Zvs

15. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

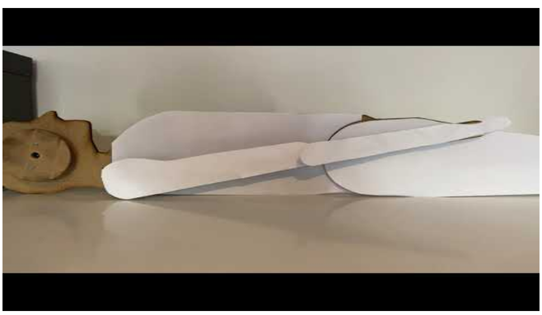
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

16. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 3

 http://youtube.com/watch?v=6Pg0-Deqnxo

17. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

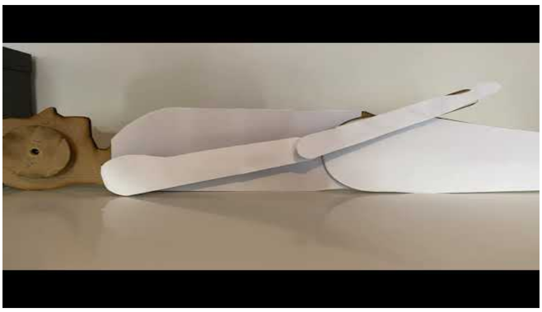
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

18. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 4



http://youtube.com/watch?v=ywBhkt-MrjM

19. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

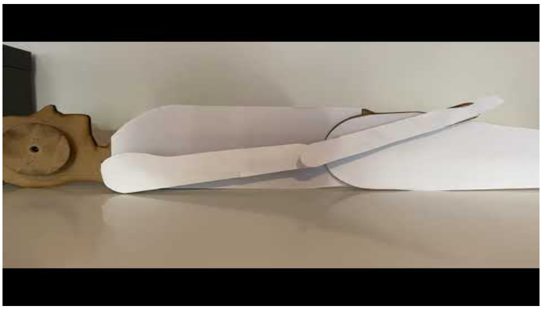
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

20. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 5



http://youtube.com/watch?v=GGq0fAxEon4

21. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

22. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 6

 http://youtube.com/watch?v=lRoNY0nHt8M

23. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

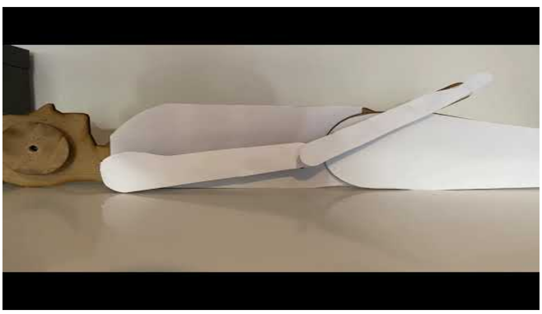
1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

24. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 7

 http://youtube.com/watch?v=xiR4S2VU0-U

25. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

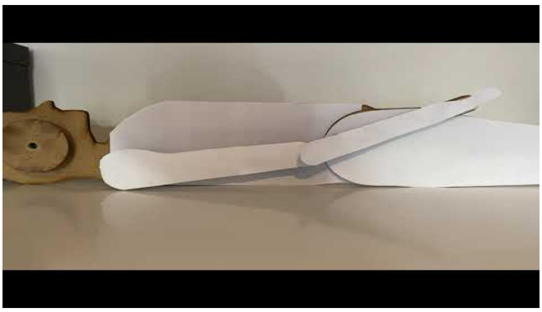
	1	2	3	4	5	6	7	8	9	10
	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

26. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

	1	2	3	4	5	6	7	8	9	10
	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 8

 http://youtube.com/watch?v=_3kZIEKhEXs

27. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

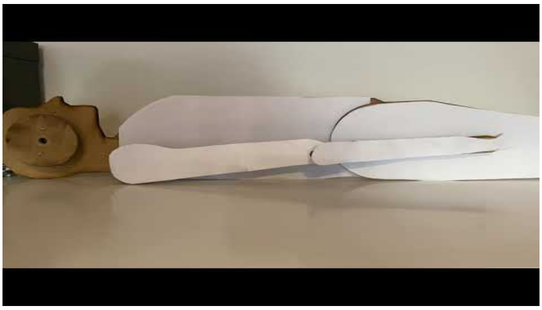
	1	2	3	4	5	6	7	8	9	10
	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

28. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

Two joints example 9



http://youtube.com/watch?v=leMRg9OBp0I

29. On a scale of 1 to 10 how realistic/ life-like was the tonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

30. On a scale of 1 to 10 how realistic/ life-like was the clonic phase?

Markér bare én oval.

1	2	3	4	5	6	7	8	9	10
⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭	⬭

31. Was the simple nature of the simulation (2D with simple shapes) an obstacle in judging the realism of each scenario?

Markér bare én oval.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree

32. Was the lack of other stimuli such as sound or face expressions an abstacle in judging the realism of each scenario?

Markér bare én oval.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree

33. Were the simulations missing anything important that compromised realism/believability of the scenarios? If yes, what was it, and what could be improved?

34. Do you have any questions or suggestions after completing the survey?

35. Would you like to receive invitations to any follow up surveys on this project? If yes, please fill in the email address you would like the invitation to be sent to:

8.3 Appendix C: Survey Video QR Codes

Video 1
Video 2
Video 3
Video 4
Video 5
Video 6
Video 7
Video 8
Video 9
Video 10
Video 11
Video 12
Video 13
Video 14

Figure 8.1: QR codes for the respective videos used in the online survey

8.4 Appendix D: Risk assessment

NTNU		Utarbeidet av	Nummer	Dato
HMS	Kartlegging av risikofylt aktivitet	HMS-avd.	HMSRV2601	30.06.2021
		Godkjent av	Side	Erstatter
		Rektor		

Enhet: Department of Engineering Design and Materials **Dato:** 30.06.2021

Linjeleder: Torgeir Welo

Deltakere ved kartleggingen (m/ funksjon): Bartosz Jakubowski - student, Martin Steinert - Ansv. Veileder, Marius Auflem - medveileder

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Kort beskrivelse av hovedaktivitet/hovedprosess: Prosjektoppgave student Bartosz Jakubowski. Lærdal Medical - "Technologies to control the arms of patient simulators"

Er oppgaven rent teoretisk? *(JA/NEI)* NEI *"JA" betyr at veileder innestår for at oppgaven ikke innholder noen aktiviteter som krever risikovurdering*

Dersom "JA": Beskriv kort aktiviteten i kartleggingskjemaet under. Risikovurdering trenger ikke å fylles ut.

Signaturer: *Ansvarlig veileder:* Martin Steinert *Student:* Bartosz Jakubowski

ID nr.	Aktivitet/prosess	Ansvarlig	Eksisterende dokumentasjon	Eksisterende sikringstiltak	Lov, forskrift o.l.	Kommentar
1	Bruk av TrollLABS workshop eller maskinverksted	BJ	Romkort	Romkort		
1a	Bruk av roterende maskineri	BJ	Maskiners brukermanual, Maskinkort	Maskinkort, Sikringskabinett	Ukjent	
1b	Bruk av laserkutter	BJ	Maskiners brukermanual, Maskinkort	Maskinkort, Avtrekkskabinett	Ukjent	
1c	Bruk av 3D printer	BJ	Maskiners brukermanual, Maskinkort	Ukjent	Ukjent	
1d	Bruk av skjæreverktøy	BJ	Ukjent			
1e	Bruk av sammenføyningsmidler (lim og lignende)	BJ	Produktets brukermanual og datablad	Datablad	Ukjent	
1f	Eksperimentelt arbeid	BJ	Produktets brukermanual og datablad	Personlig verneutstyr, ventilering	Ukjent	
2	Tilstedeværelse ved arbeid utført av andre	Andre	Andres risikovurdering	Andres risikovurdering	Prosessavhengig	

NTNU		Utarbeidet av	Nummer	Dato
HMS /KS	Risikovurdering	HMS-avd.	HMSRV2603	30.06.2021
		Godkjent av	Side	Erstatter
		Rektor		

Enhet: Department of Engineering Design and Materials **Dato:** 30.06.2021

Linjeleder: Torgeir Welo

Deltakere ved risikovurderingen (m/ funksjon): Bartosz Jakubowski - student, Martin Steinert - Ansv. Veileder, Marius Auflem - medveileder

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Risikovurderingen gjelder hovedaktivitet: Prosjektoppgave student Bartosz Jakubowski. Lærdal Medical - "Technologies to control the arms of patient simulators"

Signaturer: *Ansvarlig veileder:* Martin Steinert *Student:* Bartosz Jakubowski

ID nr.	Aktivitet/prosess fra kartleggingsskjemaet	Mulig uønsket hendelse	Vurdering av sann-synlighet (1-5)	Vurdering av konsekvens: Menneske (A-E)	Ytre miljø (A-E)	Øk./ materiell (A-E)	Om-dømme (A-E)	Risiko-verdi (menn-eske)	Kommentarer/ status Forslag til tiltak
1	Bruk av TrollLABS workshop eller maskinverksted								
1a-i	Bruk av roterende maskineri	Stor kuttskade	2	D	A	A	D	D2	Sørg for at roterende deler er tilstrekkelig sikret/dekket. Vær nøye med opplæring i bruk av maskineri.
1aii		Liten kuttskade	3	B	A	A	A	B3	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iii		Klemskade	2	D	A	A	C	D2	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iv		Flygende spon/gjenstander	3	C	A	A	B	C3	Bruk øyevern og tildekk hurtig roterende deler (fres og lignende).
1a-v		Feil bruk - ødelagt utstyr	3	A	A	C	A	A3	Vær nøye med opplæring i bruk av maskineri.
1b-i	Bruk av laserkutter	Klemskade	2	D	A	A	C	D2	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1b-ii		Brannskade	3	B	A	A	A	B3	Vær nøye med opplæring i bruk av maskineri. Bruk hansker ved håndtering av varme materialer.
1b-iii		Øyeskade - laser	2	D	A	A	C	D2	Bruk øyevern. Skru av laser ved oppsett av maskinen.
1b-iv		Brannskade	2	B	A	D	C	B2	Vær nøye med opplæring i bruk av maskineri. Ha slukkeutstyr tilgjengelig. Folat ikke maskinen under bruk.
1c-i	Bruk av 3D printer	Brannskade	3	B	A	A	A	B3	Vær nøye med opplæring i bruk av maskineri.
1c-ii		Feil bruk - ødelagt utstyr	3	A	A	C	A	A3	Vær nøye med opplæring i bruk av maskineri.
1d-i	Bruk av skjæreverktøy	Stor kuttskade	2	D	A	A	D	D2	Bruk skarpe verktøy, riktig skjæreunderlag og personlig verneutstyr.
1d-ii		Liten kuttskade	3	B	A	A	A	B3	Bruk skarpe verktøy, riktig skjæreunderlag og personlig verneutstyr.
1e-i	Bruk av sammenføyningsmidler (lim og lignende)	Eksponering på øyet	2	D	A	A	B	D2	Bruk øyevern, ha datablad tilgjengelig.

Risikoverdi = Sannsynlighet (1, 2 ...) x konsekvens (A, B ...). Risikoverdi A1 betyr svært liten risiko. Risikoverdi E5 betyr svært stor og svært alvorlig risiko.

Sannsynlighet: Verdi	Kriterier	Konsekvens: Gradering		Menneske	Ytre miljø: Vann, jord og luft	Øk/materiell	Omdømme
1	**Svært liten**:1 gang pr 50 år eller sjeldnere	E	Svært alvorlig	Død	Svært langvarig og ikke reversibel skade	Drifts- eller aktivitetsstans >1 år.	Troverdighet og respekt betydelig og varig svekket
2	**Liten**: 1 gang pr 10 år eller sjeldnere	D	Alvorlig	Alvorlig personskade. Mulig uførhet	Langvarig skade. Lang restitusjonstid	Driftsstans > ½ år, aktivitetsstans opptil 1 år	Troverdighet og respekt betydelig svekket
3	**Middels**: 1 gang pr år eller sjeldnere	C	Moderat	Alvorlig personskade.	Mindre skade og lang restitusjonstid	Drifts- eller aktivitetsstans < 1 mnd	Troverdighet og respekt svekket
4	**Stor**: 1 gang pr måned eller sjeldnere	B	Liten	Skade som krever medisinsk behandling	Mindre skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1uke	Negativ påvirkning på troverdighet og respekt
5	**Svært stor** :Skjer ukentlig	A	Svært liten	Skade som krever førstehjelp	Ubetydelig skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1dag	Liten påvirkning på troverdighet og respekt

MATRISE FOR RISIKOVURDERINGER ved NTNU

	Svært alvorlig	E1	E2	E3	E4	E5

KONSEKVENS						
	Alvorlig	D1	D2	D3	D4	D5
	Moderat	C1	C2	C3	C4	C5
	Liten	B1	B2	B3	B4	B5
	Svært liten	A1	A2	A3	A4	A5
		Svært liten	Liten	Middels	Stor	Svært stor
		SANNSYNLIGHET				

Prinsipp over akseptkriterium. Forklaring av fargene som er brukt i risikomatrisen.

Farge	Beskrivelse
Rød	Uakseptabel risiko. Tiltak skal gjennomføres for å redusere risikoen.
Gul	Vurderingsområde. Tiltak skal vurderes.
Grønn	Akseptabel risiko. Tiltak kan vurderes ut fra andre hensyn.

6.2 Appendix B: Pressure control script

```
float mapped;
float target;
bool pump = false;

void setup() {
  Serial.begin(115200);
  pinMode(3,OUTPUT);
  pinMode(A1,INPUT);
  digitalWrite(3,LOW);
}

void loop(){
  int sensor = analogRead(A0);

  mapped = map(analogRead(A1),0,1023,34,101);
  target = (mapped)/100;

  float pressure = 1+(sensor-360)/385.7;
  Serial.println(pressure);
  Serial.println(target);
  Serial.println(pump);
  delay(100);

  if (pressure>(target+0.01)){
    if (pump == false){
      pump = true;
      digitalWrite(3,HIGH);
    }
    else
      return;
  }
  else if (pressure<(target-0.01)){
    if (pump == true){
      pump = false;
      digitalWrite(3,LOW);
    }
    else
      return;
  }
```

```
  else
    return;

  delay(100);
}
```

6.3 Appendix C: Trilateration script

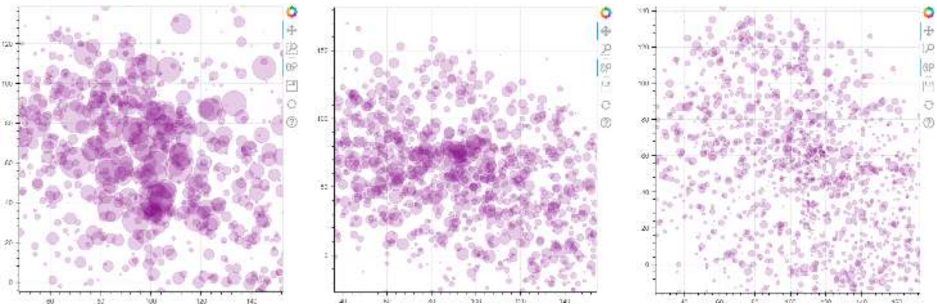
```
#include "HX711.h"

long previousMillis = 0;
unsigned long sec = 0;
unsigned long mts = 0;
unsigned long hrs = 0;

const int LOADCELL1_DOUT_PIN = A0;
const int LOADCELL1_SCK_PIN = A1;
const int LOADCELL2_DOUT_PIN = A2;
const int LOADCELL2_SCK_PIN = A3;
const int LOADCELL3_DOUT_PIN = A4;
const int LOADCELL3_SCK_PIN = A5;

float a, b, c;
float r_1, r_2, r_3;

int weight;
int x_pos, y_pos;

HX711 scale1, scale2, scale3;

void setup() {
  Serial.begin(115200);

  scale1.begin(LOADCELL1_DOUT_PIN, LOADCELL1_SCK_PIN);
  scale2.begin(LOADCELL2_DOUT_PIN, LOADCELL2_SCK_PIN);
  scale3.begin(LOADCELL3_DOUT_PIN, LOADCELL3_SCK_PIN);
  scale1.set_scale(375.f);
  scale2.set_scale(375.f);
  scale3.set_scale(375.f);
  scale1.tare();
  scale2.tare();
  scale3.tare();
}

void loop() {

  a = scale1.get_units();
```

```
  c = scale2.get_units();
  b = scale3.get_units();

  weight = a + b + c;

  r_1 = 200*((weight-a)/weight);
  r_2 = 200*((weight-b)/weight);
  r_3 = 200*((weight-c)/weight);

  x_pos = ((r_1 * r_1) - (r_2 * r_2))/400 + 100;
  y_pos = x_pos/1.732051 - ((r_3 * r_3) - (r_2 * r_2))/346.4101616;

  unsigned long currentMillis = millis();
  unsigned long diff = currentMillis - previousMillis;

  if(diff > 976) {
    previousMillis = currentMillis;
    sec +=1;

    if (sec >= 60) {
      sec = 0;
      mts +=1;
    }
  }

  char text1[40];
  sprintf(text1, "%d,%d,%d,%lu,%lu,%lu", x_pos, y_pos, weight, mts, sec, diff);

  char text2[40];
  sprintf(text2, "%d,%d,%d,%lu,%lu,%lu", 0, 0, 0, mts, sec, diff);

  if (weight>15){
    Serial.println(text1);
  }
  else{
    Serial.println(text2);
  }
}
```

6.4 Appendix D: Python visualisation script

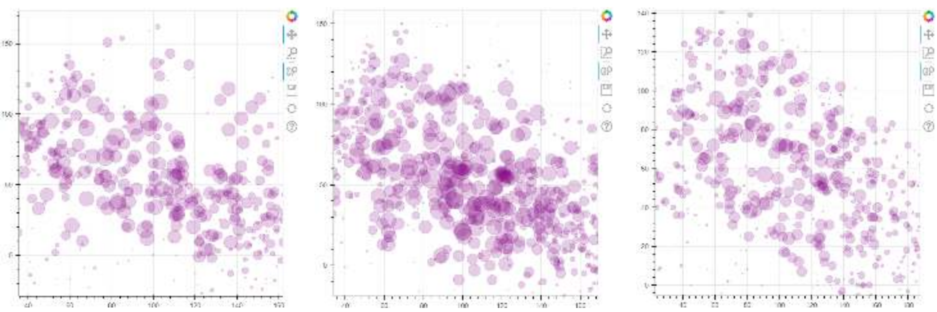
```python
import pandas as pd
import numpy as np
import itertools

from bokeh.layouts import column, row
from bokeh.models import Select, ColorBar, ColumnDataSource
from bokeh.palettes import Turbo256 as palette
from bokeh.plotting import figure, output_file, show
from bokeh.transform import linear_cmap, log_cmap

data = pd.read_csv('13deep.txt', sep=",", header=None)
data.columns = ["x", "y", "weight", "m", "s", "ms"]

T = np.arange(len(data))
T2 = np.round(T, -1)
data['t'] = T2

# output to static HTML file
output_file("13deep.html")

p = figure(width=500, height=500)

# add a circle renderer with a size, color, and alpha
p.circle(data.x, data.y, size=data.weight/100, color='purple',
    alpha=0.2)

#p.line(data.x, data.y, line_width=1)
#p.ellipse(x=[100], y=[30], width=180, height=180, color='red',
    alpha=0.05)
#p.ellipse(x=[100], y=[0], width=200, height=150, color='red',
    alpha=0.05)
# show the results
show(p)
```

6.5 Appendix E: Heatmaps gererated the python script in 6.4



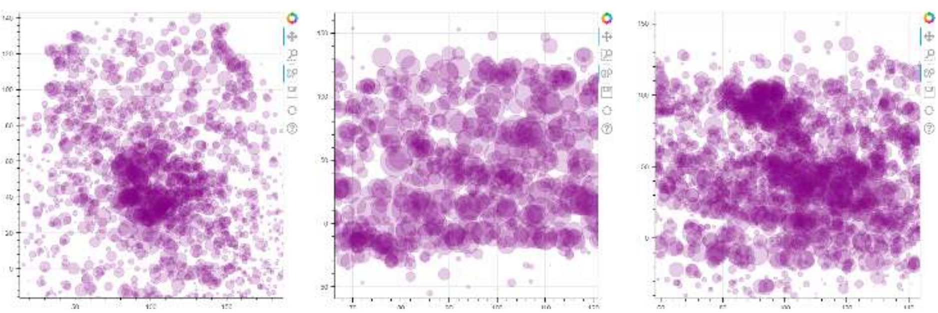
(a) 1: Shallow lump **(b)** 2: Baseline **(c)** 3: Deep lump

Figure 1.1: Participant 1



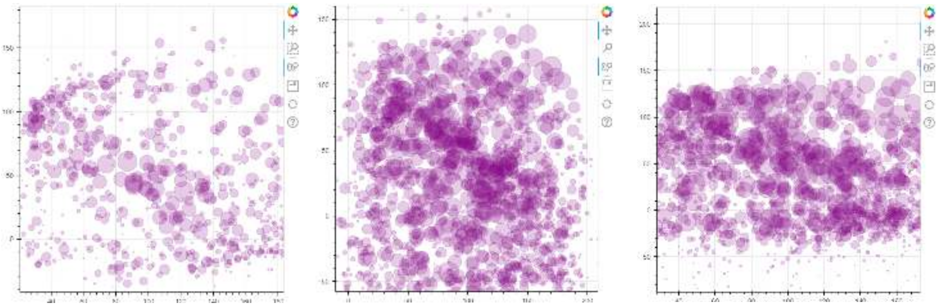
(a) 1: Baseline **(b)** 2: Shallow lump **(c)** 3: Deep lump

Figure 1.2: Participant 2



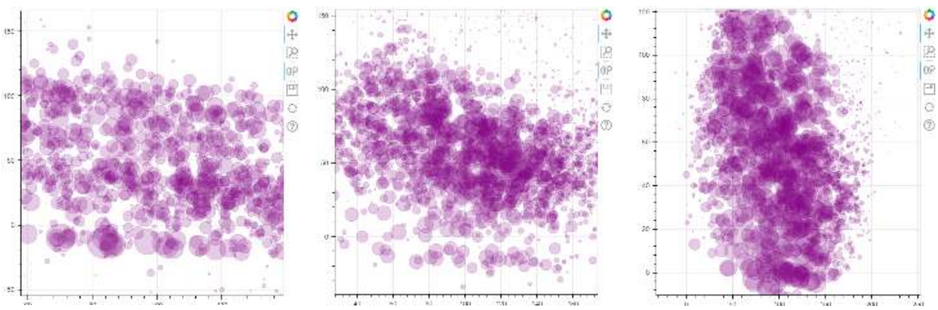
(a) 1: Deep lump **(b)** 2: Baseline **(c)** 3: Shallow lump

Figure 1.3: Participant 3



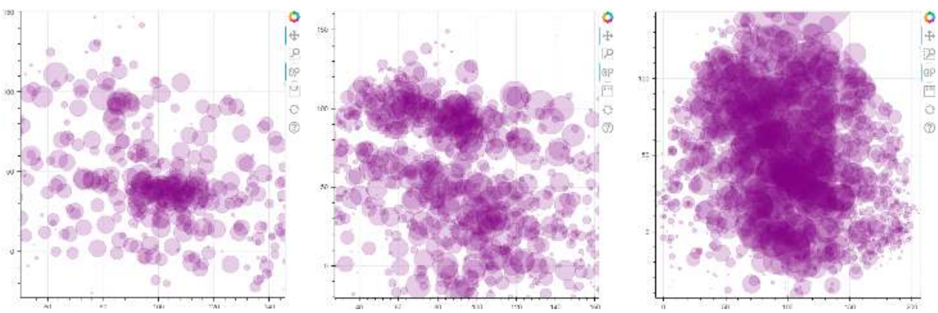
(a) 1: Baseline **(b)** 2: Deep lump **(c)** 3: Shallow lump

Figure 1.4: Participant 4



(a) 1: Shallow lump **(b)** 2: Deep lump **(c)** 3: Baseline

Figure 1.5: Participant 5



(a) 1: Deep lump **(b)** 2: Shallow lump **(c)** 3: Baseline

Figure 1.6: Participant 6

6.6 Appendix F: Risk assessment

NTNU	Kartlegging av risikofylt aktivitet	Utarbeidet av	Nummer	Dato
HMS		HMS-avd.	HMSRV2601	30.06.2021
		Godkjent av	Side	Erstatter
		Rektor		

Enhet: Department of Engineering Design and Materials **Dato:** 30.06.2021

Linjeleder: Torgeir Welo

Deltakere ved kartleggingen (m/ funksjon): Bartosz Jakubowski - student, Martin Steinert - Ansv. Veileder, Marius Auflem - medveileder

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Kort beskrivelse av hovedaktivitet/hovedprosess: Prosjektoppgave student Bartosz Jakubowski. Lærdal Medical - "Technologies to control the arms of patient simulators"

Er oppgaven er rent teoretisk? *(JA/NEI)* NEI *"JA" betyr at veileder innestår for at oppgaven ikke inneholder noen aktiviteter som krever risikovurdering*

Dersom "JA": Beskriv kort aktiviteten i kartleggingskjemaet under. Risikovurdering trenger ikke å fylles ut.

Signaturer: *Ansvarlig veileder:* Martin Steinert *Student:* Bartosz Jakubowski

ID nr.	Aktivitet/prosess	Ansvarlig	Eksisterende dokumentasjon	Eksisterende sikringstiltak	Lov, forskrift o.l.	Kommentar
1	Bruk av TrollLABS workshop eller maskinverksted	BJ	Romkort	Romkort		
1a	Bruk av roterende maskineri	BJ	Maskiners brukermanual, Maskinkort	Maskinkort, Sikringskabinett	Ukjent	
1b	Bruk av laserkutter	BJ	Maskiners brukermanual, Maskinkort	Maskinkort, Avtrekkskabinett	Ukjent	
1c	Bruk av 3D printer	BJ	Maskiners brukermanual, Maskinkort	Ukjent	Ukjent	
1d	Bruk av skjæreverktøy	BJ	Ukjent			
1e	Bruk av sammenføyningsmidler (lim og lignende)	BJ	Produktets brukermanual og datablad	Datablad	Ukjent	
1f	Eksperimentelt arbeid	BJ	Produktets brukermanual og datablad	Personlig verneutstyr, ventilering	Ukjent	
2	Tilstedeværelse ved arbeid utført av andre	Andre	Andres risikovurdering	Andres risikovurdering	Prosessavhengig	

NTNU	Risikovurdering	Utarbeidet av	Nummer	Dato
HMS /KS		HMS-avd.	HMSRV2603	30.06.2021
		Godkjent av	Side	Erstatter
		Rektor		

Enhet: Department of Engineering Design and Materials **Dato:** 30.06.2021

Linjeleder: Torgeir Welo

Deltakere ved risikovurderingen (m/ funksjon): Bartosz Jakubowski - student, Martin Steinert - Ansv. Veileder, Marius Auflem - medveileder

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Risikovurderingen gjelder hovedaktivitet: Prosjektoppgave student Bartosz Jakubowski. Lærdal Medical - "Technologies to control the arms of patient simulators"

Signaturer: *Ansvarlig veileder:* Martin Steinert *Student:* Bartosz Jakubowski

ID nr.	Aktivitet/prosess fra kartleggingsskjemaet	Mulig uønsket hendelse	Vurdering av sann-synlighet (1-5)	Vurdering av konsekvens: Menneske (A-E)	Ytre miljø (A-E)	Øk./materiell (A-E)	Om-dømme (A-E)	Risiko-verdi (menn-eske)	Kommentarer/ status Forslag til tiltak
1	Bruk av TrollLABS workshop eller maskinverksted								
1a-i	Bruk av roterende maskineri	Stor kuttskade	2	D	A	A	D	D2	Sørg for at roterende deler er tilstrekkelig sikret/dekket. Vær nøye med opplæring i bruk av maskineri.
1aii		Liten kuttskade	3	B	A	A	A	B3	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iii		Klemskade	2	D	A	A	C	D2	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iv		Flygende spon/gjenstander	3	C	A	A	B	C3	Bruk øyevern og tildekk hurtig roterende deler (fres og lignende).
1a-v		Feil bruk - ødelagt utstyr	3	A	A	C	A	A3	Vær nøye med opplæring i bruk av maskineri.
1b-i	Bruk av laserkutter	Klemskade	2	D	A	A	C	D2	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1b-ii		Brannskade	3	B	A	A	A	B3	Vær nøye med opplæring i bruk av maskineri. Bruk hansker ved håndtering av varme materialer.
1b-iii		Øyeskade - laser	2	D	A	A	C	D2	Bruk øyevern. Skru av laser ved oppsett av maskinen.
1b-iv		Brannskade	2	B	A	D	C	B2	Vær nøye med opplæring i bruk av maskineri. Ha slukkeutstyr tilgjengelig. Folat ikke maskinen under bruk.
1c-i	Bruk av 3D printer	Brannskade	3	B	A	A	A	B3	Vær nøye med opplæring i bruk av maskineri.
1c-ii		Feil bruk - ødelagt utstyr	3	A	A	C	A	A3	Vær nøye med opplæring i bruk av maskineri.
1d-i	Bruk av skjæreverktøy	Stor kuttskade	2	D	A	A	D	D2	Bruk skarpe verktøy, riktig skjæreunderlag og personlig verneutstyr.
1d-ii		Liten kuttskade	3	B	A	A	A	B3	Bruk skarpe verktøy, riktig skjæreunderlag og personlig verneutstyr.
1e-i	Bruk av sammenføyningsmidler (lim og lignende)	Eksponering på øyet	2	D	A	A	B	D2	Bruk øyevern, ha datablad tilgjengelig.

Risikoverdi = Sannsynlighet (1, 2 ...) x konsekvens (A, B ...). Risikoverdi A1 betyr svært liten risiko. Risikoverdi E5 betyr svært stor og svært alvorlig risiko.

Sannsynlighet		Konsekvens					
Verdi	Kriterier	Gradering		Menneske	Ytre miljø: Vann, jord og luft	Øk/materiell	Omdømme
1	**Svært liten**:1 gang pr 50 år eller sjeldnere	E	**Svært alvorlig**	Død	Svært langvarig og ikke reversibel skade	Drifts- eller aktivitetsstans >1 år.	Troverdighet og respekt betydelig og varig svekket
2	**Liten**: 1 gang pr 10 år eller sjeldnere	D	**Alvorlig**	Alvorlig personskade. Mulig uførhet	Langvarig skade. Lang restitusjonstid	Driftsstans > ½ år, aktivitetsstans opptil 1 år	Troverdighet og respekt betydelig svekket
3	**Middels**: 1 gang pr år eller sjeldnere	C	**Moderat**	Alvorlig personskade.	Mindre skade og lang restitusjonstid	Drifts- eller aktivitetsstans < 1 mnd	Troverdighet og respekt svekket
4	**Stor**: 1 gang pr måned eller sjeldnere	B	**Liten**	Skade som krever medisinsk behandling	Mindre skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1uke	Negativ påvirkning på troverdighet og respekt
5	**Svært stor** :Skjer ukentlig	A	**Svært liten**	Skade som krever førstehjelp	Ubetydelig skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1dag	Liten påvirkning på troverdighet og respekt

MATRISE FOR RISIKOVURDERINGER ved NTNU

	Svært alvorlig	E1	E2	E3	E4	E5

KONSEKVENS						
	Alvorlig	D1	D2	D3	D4	D5
	Moderat	C1	C2	C3	C4	C5
	Liten	B1	B2	B3	B4	B5
	Svært liten	A1	A2	A3	A4	A5
		Svært liten	Liten	Middels	Stor	Svært stor
		SANNSYNLIGHET				

Prinsipp over akseptkriterium. Forklaring av fargene som er brukt i risikomatrisen.

Farge	Beskrivelse
Rød	Uakseptabel risiko. Tiltak skal gjennomføres for å redusere risikoen.
Gul	Vurderingsområde. Tiltak skal vurderes.
Grønn	Akseptabel risiko. Tiltak kan vurderes ut fra andre hensyn.

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