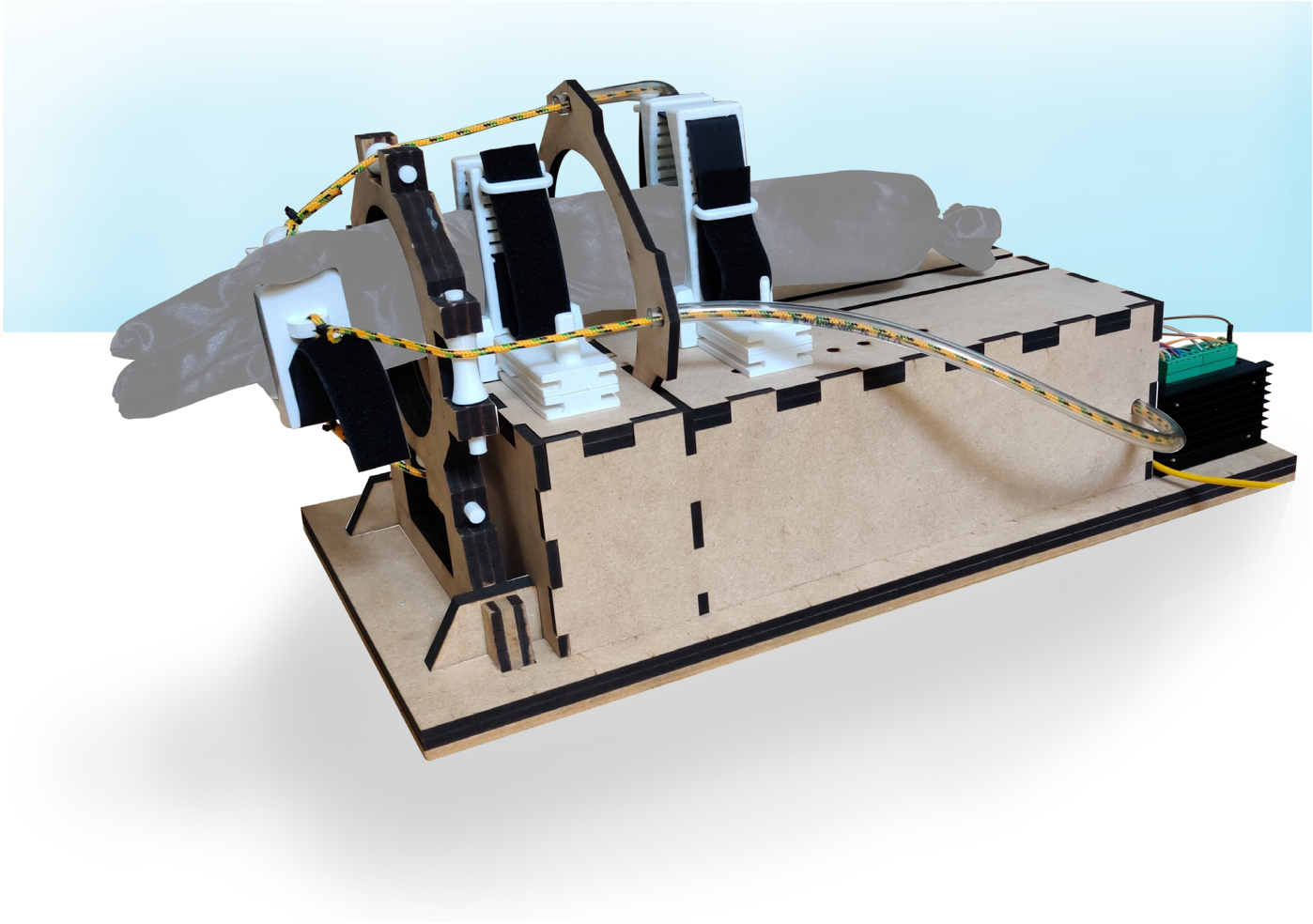
DEVELOPMENT OF AN AUTOMATED PASSIVE WRIST MOVEMENT DEVICE FOR 4D CT SCANS

THESIS REPORT



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Master thesis
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EXECUTIVE SUMMARY

This project is initiated by Stan Buckens, a radiologist from the RadboudUMC, who believes in realizing passive four-dimensional (4D) CT scans for the wrist. At this moment the wrist is mainly scanned and reviewed statically in 3D. However, it is desirable to see what happens on a CT scan during movement (the fourth dimension) of the wrist, as many clinically significant, debilitating and painful wrist pathologies are dynamic in nature and cannot be fully appreciated statically.

Recently it has become technically feasible to have patients actively move their wrists in specific directions (e.g. flexion/extension or ulnar-/radial deviation) to create the fourth dimension, so that the wrist can be reviewed dynamically. However, according to S. Buckens (2019) active movements of the wrist are less desirable than passive movement as patients are typically able to (partly) compensate for wrist instability using forearm muscles, masking potentially significant pathology.

During this project a suitable solution is designed to passively move the patient's wrist in a precise and safe way in the gantry during scanning. Within the analysis phase, a context analysis and state of the art research resulted in six focus areas. Subsequently, in the research phase these focus areas were used to obtain optimal understanding of the product's solution space and to create and evaluate possible solutions for the design problem. For the focus areas market- and literature research was conducted, various experts were consulted and prototypes were developed and tested.

Based on the outcomes of all focus areas a set of design decisions was made throughout the project, eventually leading to the final design of the product. The product makes use of a cable-pulley system in combination with stepper motors which facilitate the desired passive wrist movements. Patients are able to place their arm on top of a standard, where special 3D printed parts (with an integrated adjustment mechanism) are able to fixate their forearm. Additionally, velcro straps are used to account for the variation in arm size. Furthermore, the patient's hand can be fixated by another 3D printed part; again a velcro strap is used to improve fit and fixation. Electronic parts are integrated in the system to automate the movement, while at the same time allowing the radiologist and laboratory technicians to operate the product.

A first evaluation showed that the product is able to facilitate the desired passive wrist movements and is able to fixate both the patient's forearm and hand well. However, concerning future development the product should be improved on several aspects. Therefore, a set of recommendations is given together with a testing- and implementation plan for the hospital.

LIST OF DEFINITIONS

CT scan
A Computed Tomography (CT) scan is a set of two-dimensional (2D) x-ray scans (slices) which offer information about the situation inside the patient. These slices are often combined into one 3D image, hereby generating extensive information about the patient's inside (e.g. the skeleton, organs and tissues). More about this can be read in subchapter 2.2.3.

4D CT scan
While common CT scans are 3D, due to technological developments recently it has become possible to make 4D CT scans. The fourth dimension included in these scans represents time, which is translated to movement on the scans. Eventually the final result of a 4D CT scan would therefore be a video on which the functioning of the patient's inside (or a certain body part or organ) can be analyzed over time. More about this can be read in subchapter 2.2.3.

CT wrist scan
A 3D CT scan specifically made of the wrist, on which the (inside of the) wrist can be analyzed in 3D.

4D CT wrist scan
A 4D CT scan specifically made of the wrist, on which the (inside of the) wrist can be analyzed in 3D over time.

Active movement
Movement of one or multiple body parts where the patients use their muscles to facilitate the desired movements.

Passive movement
Movement of one or multiple body parts where one (or more) actuator(s) facilitates the desired movements, while the patients completely relaxes these body parts.

Active 4D CT wrist scan
In the case of an active 4D CT wrist scan, a CT scan is made while patients are asked to move their wrist into specific directions (explained below). Finally this results in a movie on which the (inside of the) wrist can be seen in 3D while moving into the specific directions.

Passive 4D CT wrist scan
In the case of a passive 4D CT wrist scan, a CT scan is made while one (or more) actuator(s) move the patient's wrist into specific directions. Finally this results in a movie on which the (inside of the) wrist can be seen in 3D while moving into the specific directions.

Flexion/extension and radial-/ulnar deviation
The device has to realize passive movement of the wrist in specific directions, as mentioned above. The movements the device has to be able to facilitate are flexion and extension (figure 1, right) and radial- and ulnar deviation (figure 1, left; also called abduction and adduction respectively).

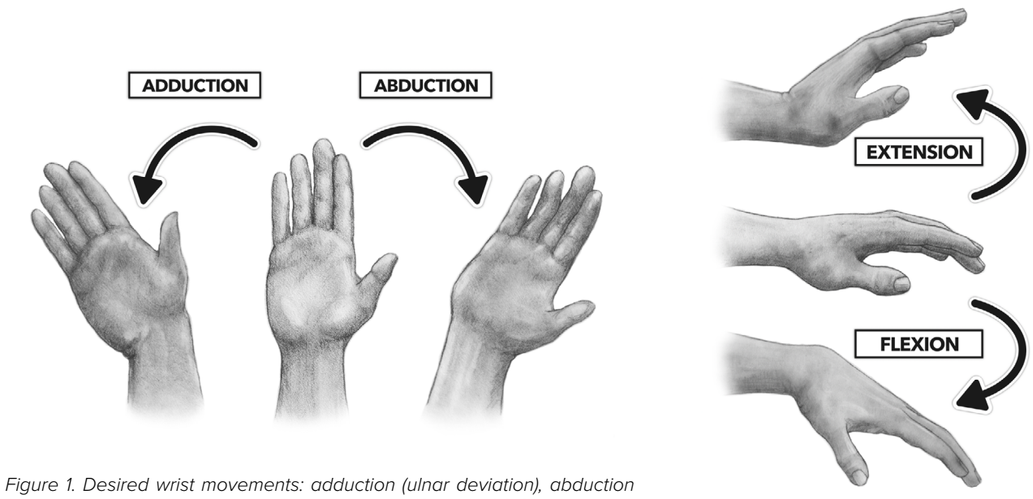


Figure 1. Desired wrist movements: adduction (ulnar deviation), abduction (radial deviation), extension and flexion. Source: (Crossfit, 2019).

Radiation dose
During a CT scan patients are exposed to radiation, which is bad for their health. For example by reducing the scanning time, the radiation dose can be reduced, which is in the end beneficial for the patient's health.

Range of motion (ROM)
The range of motion (ROM) represents the possible movement angle of a muscle or joint. In the case of the different movements of the wrist joint, these movement angles are measured from the neutral position till its maximum.

Patient bed
The bed of the CT scanner on which patients have to lie when a CT scan is made. The bed is movable in all three directions so that the patient can be easily moved into the desired position for the scan.

Gantry
A donut-shaped construction that houses the rotating X-ray source and detector required to produce the scan. The gantry can pivot on the standard underneath, if needed.

Central aperture
The center of the gantry in which patients have to position their body part(s) which is or are about to be scanned.

Detector strip
A grey or silver-like colored strip in the central aperture of approximately 16 [cm] wide. Everything positioned in the area of this strip is scanned. However, radiologists can modify the active area of the detector strip, which is defined from the middle of the strip (center point). For example, a radiologist can set the active detector strip area in a way that only 10 [cm] (5 [cm] to both sides from the middle) is used. Eventually the radiation dose is reduced by this, which is beneficial for the patient's health (also see Appendix Q).

Motion artifacts
Noise on the CT images caused by the patient's body part(s) (which are scanned by the CT scanner) moving too fast. This eventually reduces the quality of the scan and makes it harder to analyze the scan afterwards.

Metal artifacts
Bright areas on the CT images caused by presence of metal parts, blocking visibility of underlying anatomy. The x-ray is not able to penetrate the metal because the latter is so dense (Helmenstine, 2020).

Pathology
A medical specialism which refers to the study of the cause and development of diseases or inuries (Evers, 2013).

Percentiles (e.g. P50)
According to Taylor (2019), percentiles are used to understand and interpret data and are typically written as 'P' with a value ranging from 1-99 behind it. The value behind it indicates the percentage of the population which is below it. For example, in case of a 20-year old male having a stature of 1850 [mm] (which corresponds to a value of P50), 50% of the population has a stature smaller than 1850 [mm].

TABLE OF CONTENTS

01 INTRODUCTION

In this chapter the project is introduced with the use of four subchapters. First, the problem is described which is solved during this project. Then, more information is given about the type of project and a thesis outline is given together with a reading guide. Finally, the focus areas used throughout this entire project are discussed.

Source: Personal photograph

1.1 Problem definition

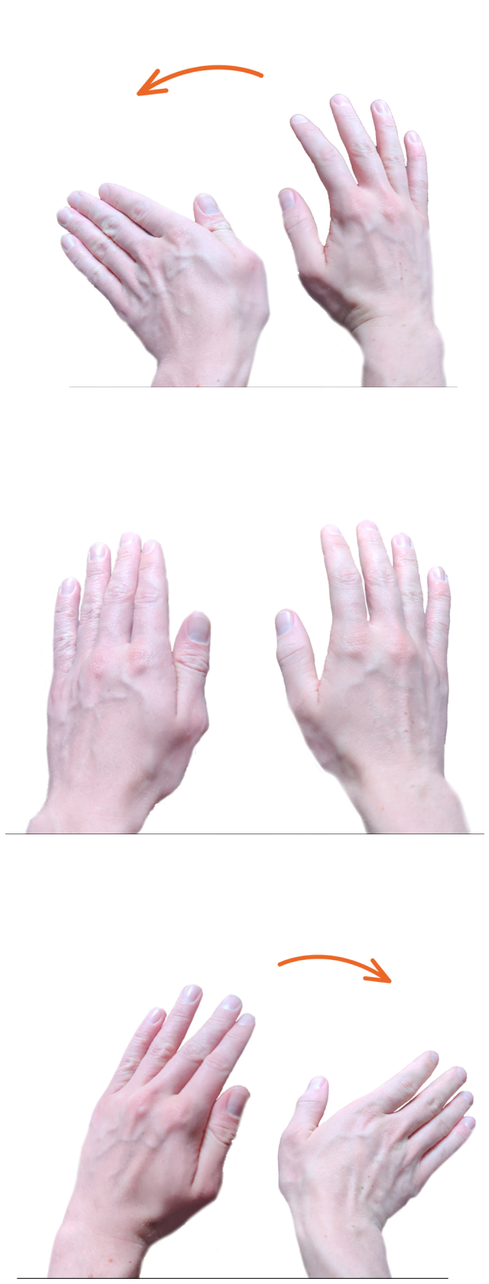
At this moment CT scanning of the wrist is mainly done and reviewed statically in 3D. However, it is desirable to see what happens on a CT scan during movement of the wrist, hence the requirement of the fourth dimension. This is because many clinically significant, debilitating and painful wrist pathologies are dynamic in nature and cannot be fully appreciated statically (S. Buckens, personal communication, September 26, 2019).

Recently it has become technically feasible to have the patient actively move their wrist in specific directions (e.g. flexion/extension or ulnar-/radial deviation) to create the fourth dimension, so that the wrist can be reviewed dynamically in 3D. Radiologist S. Buckens made such a 4D CT scan of his own wrist by standing behind one of the CT scanners (in the Radboud UMC) and stretching his arms into the central aperture (figure 1.1.1). He scanned both his left and right hand during a deviation movement (both ulnar and radial). Three snapshots of the 4D CT scan (and the corresponding positions of the hands) of his hands can be seen in figure 1.1.2.

However, according to S. Buckens, active movements of the wrist are less desirable than passive movement as patients are typically able to (partly) compensate for wrist instability using forearm muscles, masking potentially significant pathology (personal communication, September 26, 2019). Next to this, the desired movement cannot be properly controlled by the patients as they need to hold their arm in free space, while keeping their wrist near the center point of the central aperture. Because of this the movement of the wrist is not controlled and therefore is not proportional and goes too fast. In the scan this results in motion artifacts (red particles in figure 1.1.1), noise on the images which reduces the quality of the scan and makes it harder to analyze the scan afterwards. Furthermore, both the CT scan and the wrist movement should be initiated simultaneously, to prevent scanning of a static wrist and to make sure the entire motion of the wrist is being scanned properly. To conclude, there is currently no way to passively move the wrist in a precise and safe way in the gantry during scanning, leading to the initiation of this project to design a suitable solution.

This solution consists of an automated passive wrist movement device for 4D CT scans. More about how this solution is designed, can be read in subchapter 1.3.

Figure 1.1.1. Standing behind CT scanner and stretching arms into the central aperture of the CT scanner.



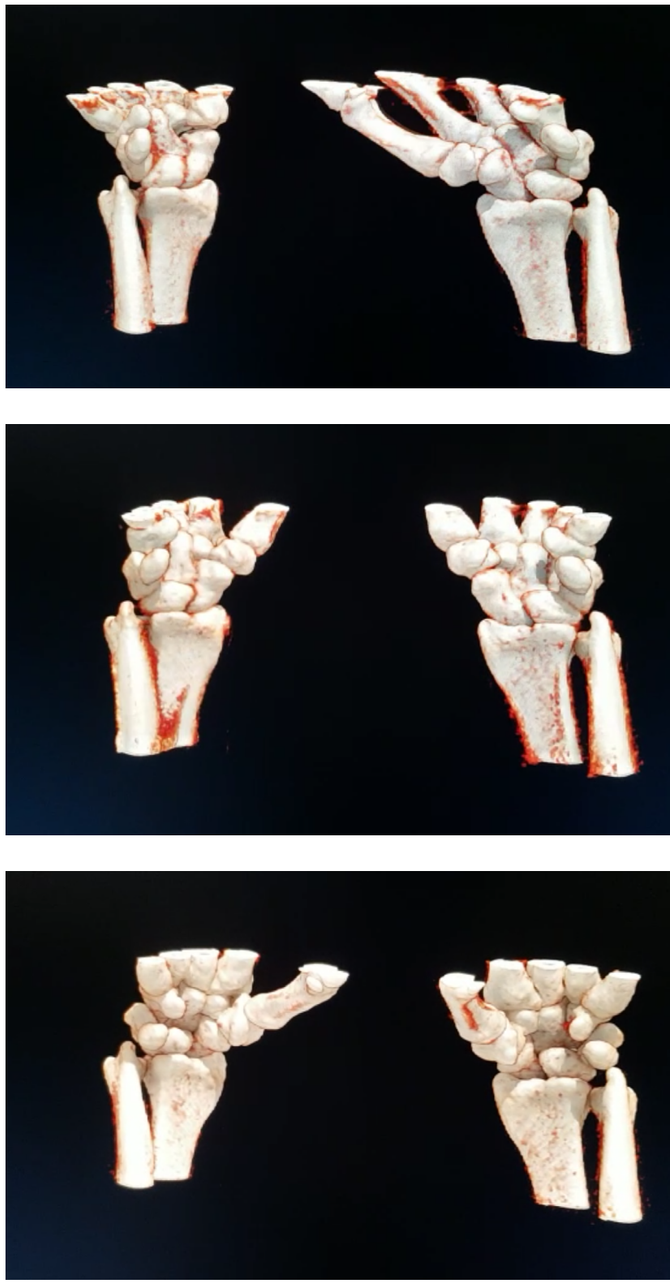


Figure 1.1.2. Snapshots of a 4D CT wrist scan (both hands) with corresponding hand positions: ulnar deviation (top), neutral position (middle) and radial deviation (bottom). The red particales on the snapshots are motion artefacts. Source: (Buckens, 2019).

1.2 Project type

This graduation project is part of a research project about 4D CT wrist scans from the radiology department of the Radboud UMC, led by Stan Buckens (radiologist), Brigitte van der Heijden (hand surgeon) and Stefan Hummelink (technical physician). The overarching goal of the research project is to use 4D CT scans of the wrist as a tool to learn more about the different positions and angles of the wrist joints during movement, related to wrist pathologies (S. Buckens, personal communication, September 26, 2019). The research project can be divided into three stages (figure 1.2.1): 1) the graduation project; 2) scanning of the active and passive movements of the wrist; 3) processing and analysis of the wrist scans, using segmentation and deep learning.

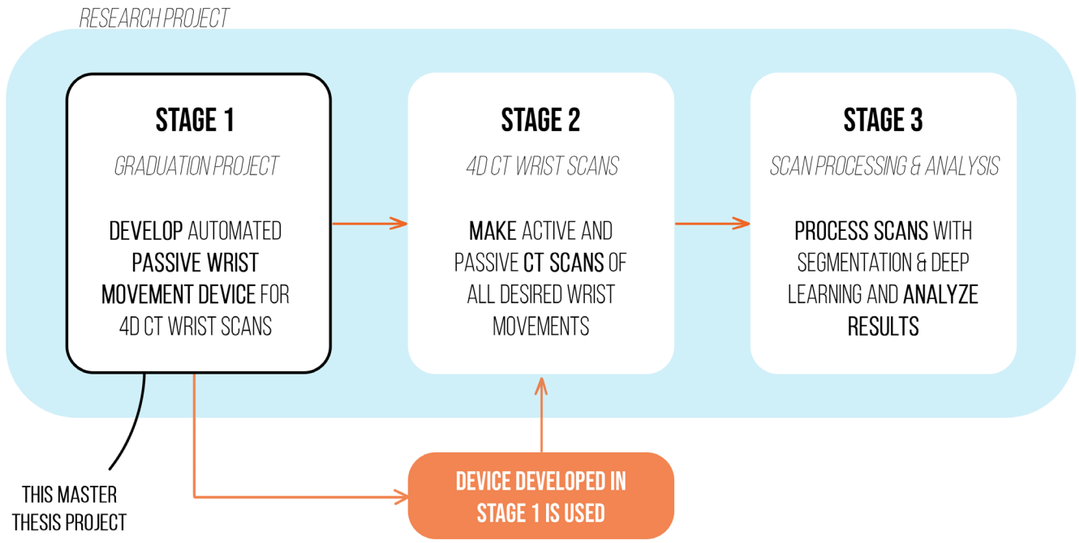


Figure 1.2.1. Three stages of the research project, this graduation project being the first one.

1.2.1 Graduation project

As mentioned above, the first stage of the research project consists of this graduation project. During this graduation project a so-called automated passive wrist movement device (for 4D CT scans) is developed, which can be used in the second stage of the research project.

1.2.2 Wrist scanning

In the second stage of the research project the wrist device (developed in the first stage) is used to make both active- and passive 4D CT scans of patients' wrists.

For the active movements of patients' wrists the device can be used to fixate the forearm of the patients, preventing them from using their forearm muscles to compensate for wrist instability and eventually masking potential pathologies (S. Buckens, personal communication, September 26, 2019).

For the passive movements of patients' wrists the device can be used to fixate the forearm of the patients (for the same reason mentioned above) and to facilitate the desired wrist movements.

For both scenarios applies that in the process of scanning and analyzing the patients' wrists, both static and dynamic CT scans are made. In the beginning a static scan of the wrist is made with a high radiation dose, which results in a high quality scan. Subsequently, the wrist is scanned dynamically (active and passive movement) with a low radiation dose, which results in a low(er) quality scan (S. Buckens, personal communication, November 21, 2019).

1.2.3 Scan analysis

In the third and last stage of the research project the CT scans made in stage 2 are processed and analyzed. The processing is done by using a combination of segmentation and deep learning, the high quality (static) scan of the wrist is used as an overlay for the low quality (dynamic) scans (S. Buckens, personal communication, November 21, 2019). In this way the dynamic movement can be reviewed in high quality, while keeping the radiation dose for the patient relatively low. In the end this allows the radiologist and hand surgeon to effectively analyze the active and passive wrist scans.

Eventually the overarching goal of the research project, learning more about the different positions and angles of the wrist joints during movement, is achieved with this.

1.3 Thesis outline

In this subchapter the structure of the thesis is described, addressing which aspects can be read where in the report. Also, the different design methodologies and tools which are used throughout the project are described.

1.3.1 Structure and lay-out

The structure of the report can be divided according to the different chapters (also see figure 1.3.3). Within each chapter, every subchapter ends with a brief conclusion and possibly a set of design requirements. The brief conclusion (figure 1.3.1) simply sums up the relevant findings of the subchapter, while the design requirements (figure 1.3.2) are important for the design of the final product and are therefore also used in the further design process. In case the reader does not have enough time to read the entire report, only these conclusions can be read to obtain a complete understanding of the project. For each design requirement is indicated which focus area (described in subchapter 1.4), it is related to.

In the report different headers are used to indicate chapters and subchapters. The following lay-out is used (random names are used as an example):

1.3 Final model

1.3.1 Mechanism

Components

Dimensions

Inner dimensions

The content of the different chapters is as follows:

Chapter 2
This chapter provides an analysis of the stakeholders and the context for which the device is designed. Also, existing products which facilitate passive movement of the wrist are analyzed. At the end of the chapter a set of product aspects is described, which are important for the rest of the project.

Chapter 3
In this chapter the focus areas are translated to sub-components of the final product. For each sub-component important design aspects and –decisions are described, together with the different methods and tools which are used to substantiate these. The methods and tools used in this process are described below in subchapter 1.3.2.

Chapter 4
In this chapter all the design requirements for the product are described. The design requirements are arranged according to the focus areas and a few additional categories.

Chapter 5
In this chapter the different sub-components (from chapter 3) are combined into one final product. In the chapter the different aspects like the hardware, software, working and usage are described. Also a future vision for the product is given, concerning styling, materials, production and the price.

Chapter 6
In this chapter the final product (prototype) is evaluated based on a usage test and the program of design requirements.

Chapter 7
In this chapter recommendations are given concerning further development of the product, as well as some limitations of the product. Furthermore, a future test plan is provided, describing how the product has to be tested and eventually can be implemented in the research project and the hospital.

Summary (of subchapter 2.2)

2.2.1
- Relevant information (part 1)
- Relevant information (part 2)

2.2.2
- Relevant information (part 1)
- Relevant information (part 2)

Figure 1.3.1. Overview of relevant findings to summarize the subchapter.

Design requirements

- Design requirement 1 (**focus area**)
- Design requirement 2 (**focus area**)
- Design requirement 3 (**focus area**)
- Etc.

Figure 1.3.2. Overview of design requirements used in further design process.

1.3.2 Methodologies and tools

During the project multiple methodologies and tools are used in order to create and evaluate solutions for the various problems which were encountered.

Concerning methodologies the Basic Design Cycle (as mentioned in the Delft Design Guide) was used in combination with iterative prototyping. The Basic Design Cycle is a process of trial-and-error design, where one cycle of five stages is repeated continuously. The goal of this method is to increase knowledge for both the problem and solution with each cycle (Boeijen et al., 2014). The iterative prototyping is a process of fast prototyping, where techniques as 3D printing and laser cutting are used to create (small) fast but meaningful prototypes. The goal of this method is to be able to make, test, evaluate and iterate quickly on different aspects of the product.

Next to the methodologies mentioned above, there are also multiple tools which are used in the product design process. These tools are: literature- and market research, expert meetings and testing. All of these tools are used to obtain more knowledge about the specific relevant product aspects and to create and evaluate possible solutions for the design problem. Profiles of the experts which were consulted (repeatedly) during the project can be found in Appendix B.

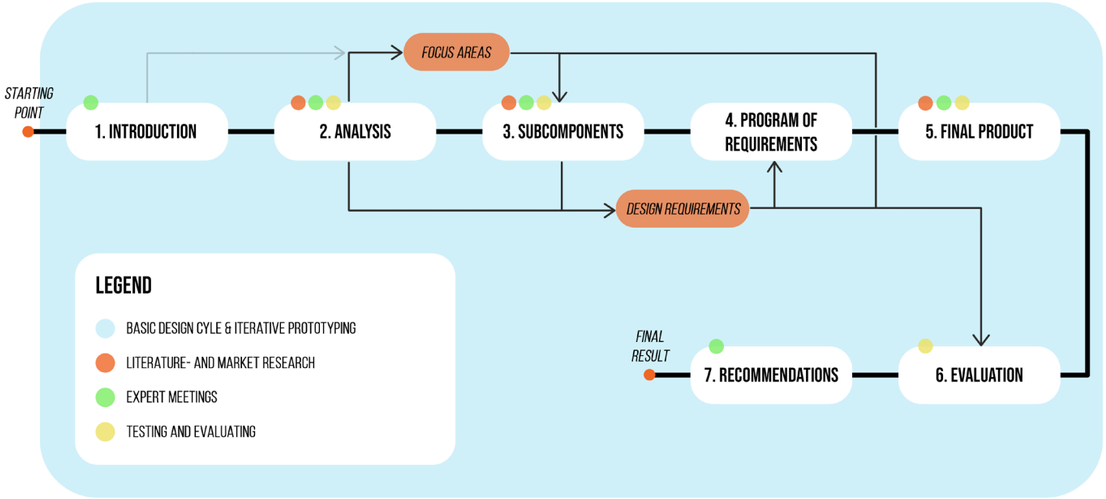


Figure 1.3.3. Report structure with different chapters and methods and tools used throughout the project.

1.4 Focus areas

Within the project there are six variables which are used as focus areas (figure 1.4.1). The focus areas and their background information are based on the analyses and subchapters described in chapter 2. However, the focus areas are already discussed here as the design requirements deriving from the subchapters from chapter 2 are arranged into these focus areas (as mentioned in subchapter 1.3.1).

The focus areas are key factors in the project and important for defining and evaluating the quality and functioning of the product. Therefore they are used as criteria to evaluate the product in different stages throughout the project. Furthermore, the focus areas are used to arrange the majority of the design requirements, which can be found in chapter 4.

Figure 1.4.1. Six focus areas used throughout the project.

1.4.1 Movement

The first focus area is the movement (execution), relating to how well the product is capable of executing the desired passive wrist movements. In total the device has to facilitate four wrist movements: wrist flexion and –extension and radial- and ulnar deviation. These movements are further elaborated in subchapter 2.4.1. Also, more aspects concerning the passive wrist movements are discussed in this subchapter.

1.4.2 Fixation & adjustability

The second focus area concerns the fixation and adjustability of the product, which relates to the possibilities within the product to fixate the patient's forearm and hand and to adapt the product to different arm- and hand sizes of the patients.

The product needs to tightly fixate both the forearm and hand in order to prevent occurrence of motion artefacts and to accurately transfer the movement of the actuators to the hand, resulting in the desired wrist movements in the end. Both fixations need to be adjustable in a way, as mentioned in subchapter 2.1, in order to adapt to the different patients and their different arm- and hand sizes.

1.4.3 Safety

The fourth focus area concerns the safety of the product, which relates to probability of the product causing pain or injuries to the patient when being used. This aspect is applicable in multiple ways, but is especially relevant for the scenario where the wrist is moved into the desired directions by the actuators. As is explained later in subchapter 2.4.1, in the electronic circuit of the product there should be integrated a feedback system which (in a way) monitors the exerted torque the actuator is exerting to eventually facilitate the wrist movement. In the end this feedback system prevents the actuators from moving the patient through their comfortable ROM and possibly even injuring the patient in the end.

1.4.4 Actuation & transmission

The third focus area concerns the actuation and transmission of the product, which relates to the automated part of the product which eventually facilitates the passive movements of the wrist. As mentioned before the patient needs to completely relax their forearm and hand, to make sure none of their muscles are used during the wrist movement. Subsequently, the movement of the product's actuators is transferred to the hand fixation, resulting in execution of the wrist movements.

1.4.5 Usability

The fifth focus area concerns the usability of the product, relating to the level of complexity and effort of using and operating the product by the radiologists (and their team). Naturally, in this case it is preferred for them that the product is easy to use, so that not a lot of extra help or learning is required. Also, when the product's usability is good, it does not require lots of extra time when examining the patients, which will contribute to the time efficiency of the working routine in the hospital. Furthermore, hygiene is something which is related to this. Naturally it is desired that all product parts which are in contact with the patient can either be cleaned easily or are disposable and can simply be replaced. In the end this would have a positive effect on the usability of the product and the time efficiency of the working routine in the hospital.

1.4.6 Comfort

The sixth and last focus area concerns the comfort of the product. As is concluded from the stakeholder research (discussed in subchapter 2.1) the patients, which are one of the direct stakeholders, want the product to be as comfortable as possible. Eventually the patients are the ones fixated in the device. For this period of time it is therefore preferable for them that the parts which make contact with their arm and hand do not irritate, hurt or even injure them. In the end this will have a positive effect on the efficiency of the 4D CT scanning process (of the patient's wrist) and at the same time on the hospital experience of the patient.

02 ANALYSIS

In this chapter the analyses of the main project aspects are described. More information is given about the stakeholders involved in the project, the context of the project, state of the art and the product vision.

Source: Personal photograph

2.1 Stakeholders

In this subchapter the different stakeholders involved in this project are described. For every stakeholder their role in the CT scanning process and their needs concerning the product are described.

2.1.1 The different stakeholders

The main stakeholders in this context (figure 2.1.1) consist of the radiologist who is in lead of the CT scans, their supporting team (principally radiographers and laboratory technicians) who acquire and interpret the imaging, referring physicians (e.g. hand surgeons) who can also act upon the imaging, the patient, the hospital and finally the CT scanner manufacturer (Canon Medical Systems).

Figure 2.1.1. Main six stakeholders involved in this project.

Radiologist

The radiologist wants to be able to acquire the optimal 4D scan of the patient's wrist. In this way he or she is better able to see what is wrong with the patient's wrist and therefore better able to give a diagnosis. For this the radiologist wants a device which is easy to use and clean and can be adapted to the different patients visiting over time (S. Buckens, personal communication, October 15, 2019). In this way the device can be integrated smoothly in the daily working routine of the radiologist, allowing for a similar time schedule during the day.

Supporting team

The team which supports the radiologist with the CT scans acquire and interpret the imaging. From this team especially the laboratory technicians (also referred to as radiographers) are involved in the use of the product, as they for example also help to position the patient correctly in the CT scanner. They might even have to work more with the product than the radiologist, as he (or she) can in that case focus more on the results of the CT scan rather than the CT scanning itself (S. Buckens, personal communication, December 12, 2019). For this the laboratory technicians also want a device which is easy to use and can be easily adapted to different patients over time (S. Buckens, personal communication, October 15, 2019). Also it would be useful if the device had clear indications about how it should be positioned in the CT scanner (W. van der Woude, personal communication, February 20, 2020), as was indicated by a laboratory technician of the Radboud UMC.

Referring physicians

The referring physicians like the hand surgeons also benefit from an optimal 4D scan because it holds the promise of unmasking dynamic wrist pathology, allowing them to better serve and diagnose their patients. This stakeholder has similar needs for the product as the radiologist, as these will also benefit them in the end by providing them with higher quality 4D CT scans.

Patient

The patient has physical problems with his or her wrist and wants these to be solved, hence the patient also benefits from an optimal 4D scan. The patient naturally also benefits from a safe and easy to use (and to clean) device, as this contributes to the hospital experience of the patient. Additionally, as was concluded from a test during the project (see Appendix C) patients have a need for the product to experience as little discomfort as possible when using the device. Finally, it would be helpful if the device looked professional and trustworthy, to ensure that the patients are not scared or confused by the device.

Hospital

The hospital benefits from improving the efficacy of care for hand- and wrist patients. By realizing such a development in the field of radiology and CT-scanning (the wrist in particular), the hospital will also benefit by leading innovation on this topic.

Manufacturer

The last stakeholder, the CT scanner manufacturer, benefits from the development of a novel application for their scanner, increasing its potential utility and marketability.

2.1.2 Conclusion

Looking at the product, of the six stakeholders mentioned above actually only three are directly involved with the use of the product. These are the radiologist (1), their supporting team (2) and the patient (3). As these three stakeholders really have to use and interact with the product, these stakeholders (and their needs) should also be taken into account in the process of designing the product. The design requirements following out of these needs can be seen in the orange rectangle below.

Summary

2.1.1

There are six stakeholders involved in this context: the radiologists, their supporting team, the referring physicians, the patient, hospital and the manufacturer (of the CT scanners).

Design requirements

- The product should be easy to use and operate (1 and 2) (**usability**)
- The product should be adaptable to different patients (1, 2 and 3) (**fixation & adjustability**)
- The product should have clear indications how to be positioned in the CT scanner (2) (**usability**)
- The product should have as little perceived discomfort for the patient as possible during fixation (3) (**comfort**)
- The product should have a professional and trustworthy look (3) (**other**)
- The product should be easy to use and operate (1 and 2) (**usability**)
- The product should be adaptable to different patients (1, 2 and 3) (**fixation & adjustability**)
- The product should have clear indications how to be positioned in the CT scanner (2) (**usability**)
- The product should have as little perceived discomfort for the patient as possible during fixation (3) (**comfort**)
- The product should have a professional and trustworthy look (3) (**other**)

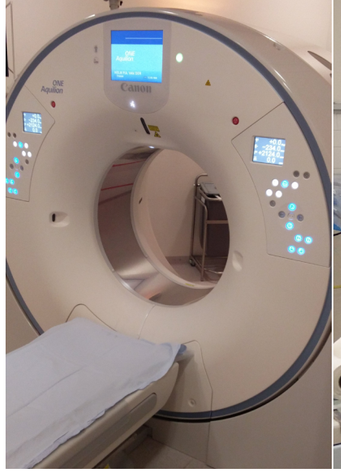


Figure 2.2.1. New Canon CT scanner.

Figure 2.2.2. Different model Toshiba (which is also Canon) CT scanner.

2.2 Context

In this subchapter the different aspects of the context, the CT rooms of the Radboud UMC, are discussed. The different CT scanners and CT rooms are analysed and important aspects are defined. Finally a look is taken at the working of a CT scanner, for both 3D- and 4D scanning.

2.2.1 CT scanners

In the Radboud UMC there are several different models of Canon CT scanners (four in total, see figure 2.2.1 and 2.2.2 for two of them). Both scanners are four-dimensional (4D); more about this is explained later in subchapter 2.1.3. Of each model there are two scanners, adding up to a total amount of four CT scanners. All scanners are from Canon or Toshiba (which later also became Canon). The newest scanner (figure 2.2.1) from Canon is the most recent development within the field of CT scanning and capable of 4D CT scanning. Therefore this scanner and its specific measurements and specifications will be focused on during the project.

Parts

The CT scanner consists of multiple parts (figure 2.2.3). It consists of a movable patient bed, a hollow, donut-shaped gantry with a central aperture in which the patient lies during a CT scan (the hole of the 'donut'). The gantry rests on a mechanical supports that can pivot if needed. The gantry houses the rotating X-ray source and detector required to produce the scan (also see subchapter 2.2.3). The bed is remotely adjustable and can move very precisely in all three directions in order to adapt to every specific patient or situation which is desired for the scan. The patient is always asked to position their body part(s) as close to the center of the central aperture in the gantry (the center point), to ensure the best scanning efficiency and -quality. The detector strip in the gantry, which can be recognized by its grey or silver-like color, is approximately 16 [cm] wide. All body parts held within this range in the gantry are being scanned.

Figure 2.2.3. Different parts of the (Canon) CT scanner.

Projector lines

When taking a closer look at the central aperture, the scanning projector laser lines can be seen (figure 2.2.4). The center point is in the middle where the two red lines cross. On this spot the optimal quality of the scan is reached, which is why this is the optimal position for the patient to position or hold their body parts which are about to be scanned. For the device it is therefore important that the patient's hand can be positioned at (or close to this) point. Indications on the device (as mentioned in the previous subchapter) in combination with the projector laser lines could be used to ease the process of positioning the patient's hand (and thus the device) near the center point.

Patient bed

The device can be placed on the patient bed when it is used to develop 4D CT scans of the wrist. The patient bed is remotely adjustable and can move precisely in all three directions in order to adapt to every specific patient or situation which is desired for the scan. By placing the device on top of the patient bed, also the device can be moved into the desired position.
However, there are two things which have to be taken into account. First of all the bed has something like a cushion (soft material) as a top layer, to increase comfort for the patients when they are being scanned. Because of this the bed is not rigid and stable enough when something is put on top of it. However, this top layer can be removed, as can be seen in figure 2.2.5. The layer underneath consists of hard plastic, which makes it easier to place things on top and keeping them stable. As can be seen in figure 2.2.5, there is also the option to attach objects (using the connection part of figure 2.2.6) to the bed. This could be integrated in the device, to make sure it can be attached to the bed and therefore is stable. However, it may take too much time to apply and set this up. Simply putting the device on top of the bed is easier and saves valuable time. Therefore this should be tested later in the project in order to select the most suitable option. To conclude, for the product it is important to stay stable on the patient bed.
Secondly, the upper surface of the patient bed is mildly shaped as a gutter (figure 2.2.5). This has to be taken into account when placing the product on the patient bed, as the product always needs to stay stable to prevent it from falling.

Figure 2.2.4. Scanning projector (laser) lines in the central aperture.

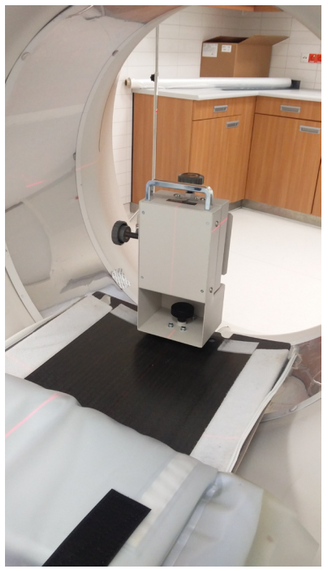


Figure 2.2.5. Top soft layer of bed removed, revealing the hard plastic layer underneath.

Figure 2.2.6. Attachment part.

Dimensions

As the device is going to be placed in the CT scanner (on the CT bed), the inside dimensions of the gantry and the dimensions of the CT bed should be taken into account. The length of the CT bed is in this case not relevant, as it is able to slide through the CT quite far. On the other hand, the width of the CT bed is relevant, as in the end the device is going to be placed on it. This distance was measured (figure 2.2.8) and it turned out to be 465 [mm]. Therefore, the width of the product should not be larger than 465 [mm].

According to S. Buckens (personal communication, December 12, 2019) the diameter of the central aperture is 900 [mm]. This means that the widest and highest points of the central aperture are 900 [mm] away from each other (figure 2.2.7). In the case that the bed is in its normal position and the device is placed along the entire width of the CT bed, the maximum height the device can have to fit in the central aperture is 410 [mm], which was tested in the CT scanner of the Radboud UMC. For the rest of the design process, these measurements are taken into account.

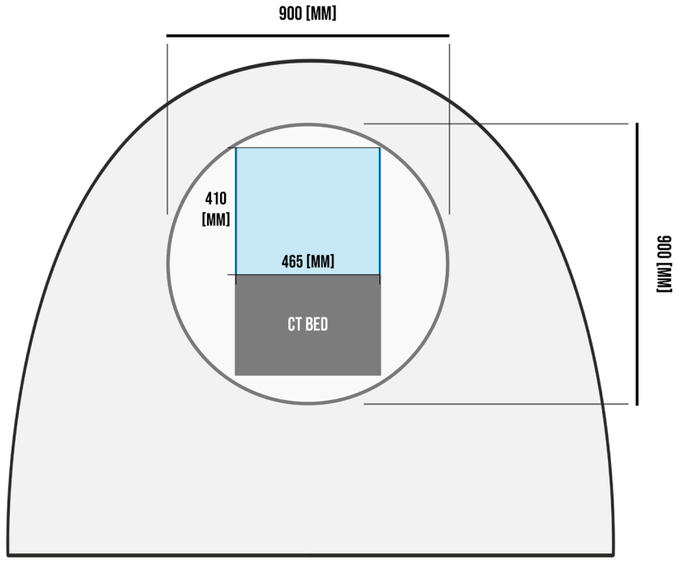


Figure 2.2.7. Device placement in the central aperture.

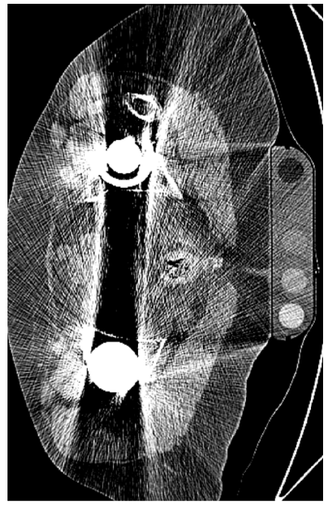


Figure 2.2.8. Metal artefacts on hip prostheses CT scan. [1]

Metal parts

When scanning body parts in a CT scanner there should be no metal parts present in the scanning area (in the central aperture), as this results in metal artefacts (figure 2.2.8) on the CT scans (S. Buckens, personal communication, September 26, 2019). Outside the central aperture it is possible to have metal parts, but still it is preferred to have as little parts as possible and also to have them positioned as far from the central aperture as possible.

[1] *Source: (Isala Klinieken Zwolle, 2015).*

2.2.2 CT rooms

The visit to the radiology department of the Radboud UMC resulted in a set of insights which are important to take into account in the process of designing the device. All the insights are related to aspects in- or of the CT room.

Positioning patient

For the device it is important to determine how it is going to be placed in the CT scanner and, subsequently, how the patient is going to be positioned based on that. When scanning the wrist in the CT scanner the patient cannot lie on the bed of the scanner with their wrist above their head in the 'superman position', as this forces the wrist in a non-neutral position and limits the range of motion (ROM) possible.

Therefore, it is important that in all scenarios the forearm and wrist of the patient are in a neutral position. According to B. van der Heijden (personal communication, November 21, 2019) the neutral position of the hand is the stand in between pro- and supination of the forearm (figure 2.2.9). Seen from the side the fingers of the hand are straight and relaxed (figure 2.2.10).

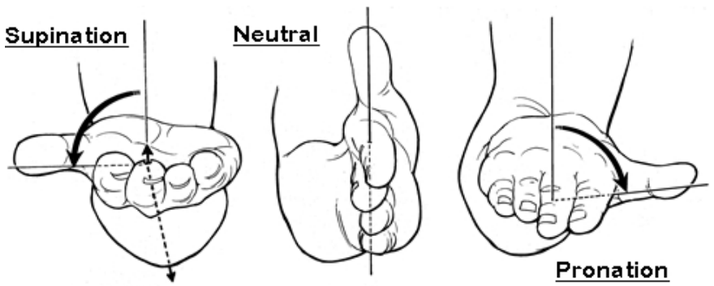


Figure 2.2.9. Positions of the forearm: supination, neutral and pronation. Source: (Enerskin, 2015).

Figure 2.2.10. Relaxed hand and fingers. Source: (Misra, 2015).

According to S. Buckens (personal communication, December 12, 2019) the neutral position of the arm and wrist depends on the position of the shoulder. In the process of abducting the shoulder the neutral position of the arm and wrist changes (figure 2.2.11). This means that if patients have to abduct their shoulders slightly to fit perfectly in the central aperture, the device also has to be tilted with that same angle. This is in order to make sure the orientation of the patient's arm and hand match with the orientation of the device and all passive movements are facilitated correctly.

It may be that in some scenarios patients with smaller arms have to extend their arm somewhat more in order to fit perfectly in the device (figure 2.1.12). According to S. Buckens this is not a problem, as long as the forearm and wrist are in a neutral position in relation to the shoulder abduction mentioned above.

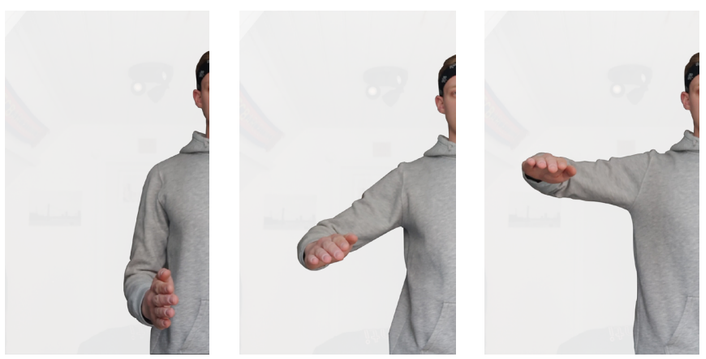


Figure 2.2.11. Neutral arm- and hand position during abduction of shoulder.

Figure 2.2.12. Extension of the arm while holding the forearm and wrist in a neutral position.

Positioning product

When looking at possible positions for patients to place their arm and wrist in the product, there are two possible scenarios.

In the first scenario the patients are asked to sit or stand on the other (rear) side of the CT scanner and position their forearm and wrist in a neutral position inside the CT-gantry (figure 2.2.13).

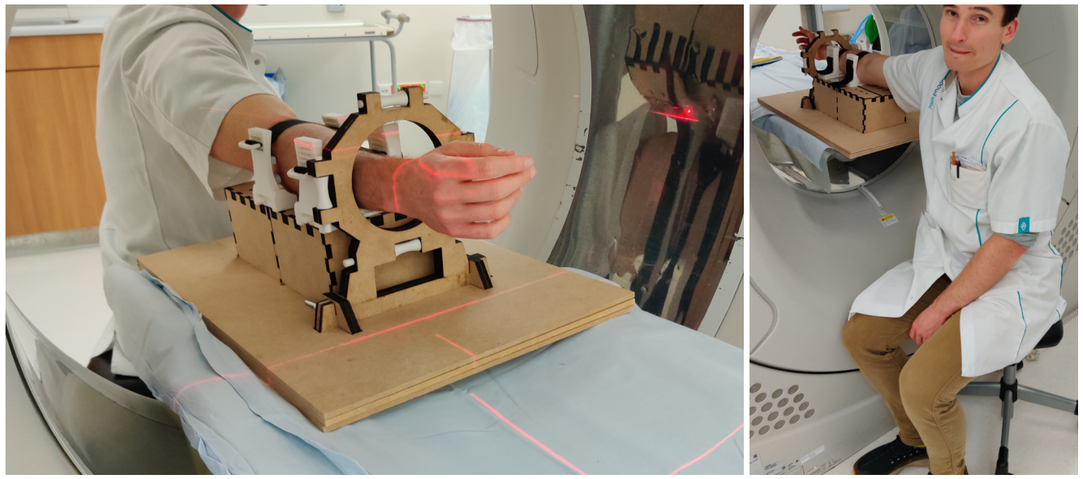


Figure 2.2.13. Patient sitting behind the CT scanner with arm and hand in neutral position in one of the product prototypes: front (left) and rear view (right).

In the second scenario the patients are asked to stand on the front side of the CT scanner, next to the patient bed, and position their forearm and wrist in a neutral position inside the CT gantry (figure 2.2.14).

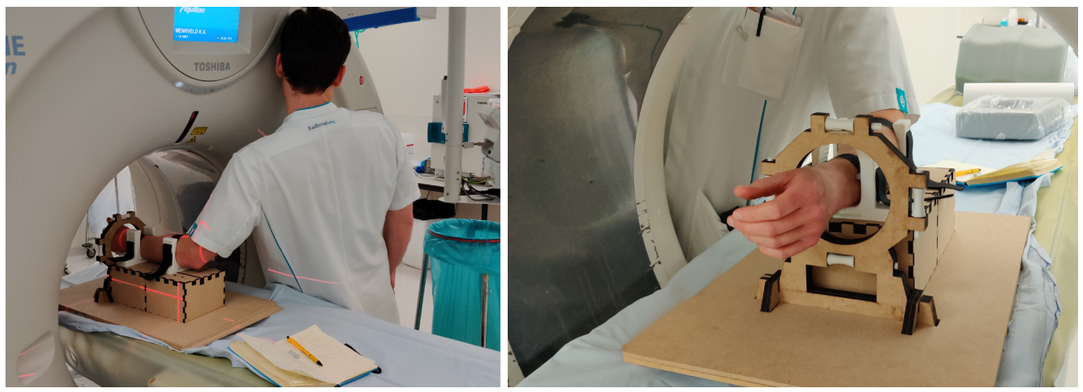


Figure 2.2.14. Patient standing next to the patient bed at the front side of the CT scanner, with arm and hand in neutral position in one of the product prototypes: rear view (left) and front view (right).

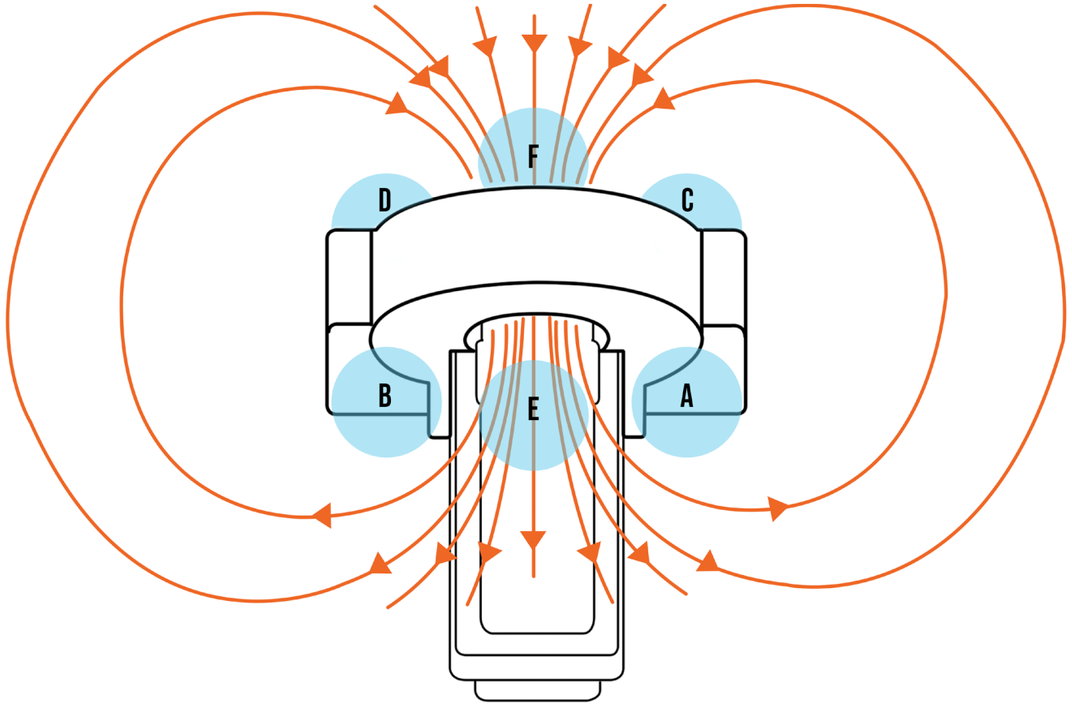


Figure 2.2.15. Radiation field of a CT scanner. Radiation in the areas A – D is significantly lower than in areas E and F.

For both scenarios it should be taken into account how the patient is positioned in relation to the radiation field of the CT scanner (figure 2.2.15). According to S. Buckens (personal communication, February 20, 2020) the amount of radiation close to and next to the CT scanner (areas A – D) is lower than in front of the central aperture (areas E and F). It would therefore be better to position the patient in one of the areas A – D in order to reduce the radiation dose for the patient.

However, if it would be better in the end to position the patient more in the middle of the CT in order to end up with better passive wrist movements and higher quality 4D CT scans, this would be preferred. The same which applied to the speed of the movements applies here: the perfect balance should be found between the CT image quality and the radiation dose for the patients. Also, the patient can be protected from catching too much radiation by placing (or hanging) a lead curtain (figure 2.2.16) between the patient and the CT scanner.

Another option is to give the patient a lead apron (figure 2.2.17) to wear, also to block a part of the radiation (S. Buckens, personal communication, February 20, 2020). More about this can be read in Appendix Q.

Figure 2.2.16. Lead curtain. Source: (MedicalExpo, n.d.).

Unfortunately, during the project the optimal position of the patient and the device in relation to the CT scanner could not be tested. Therefore this is included in the testing- and implementation plan for the product (see subchapter 7.2).

Figure 2.2.17. Lead apron which patients can wear to block the radiation.

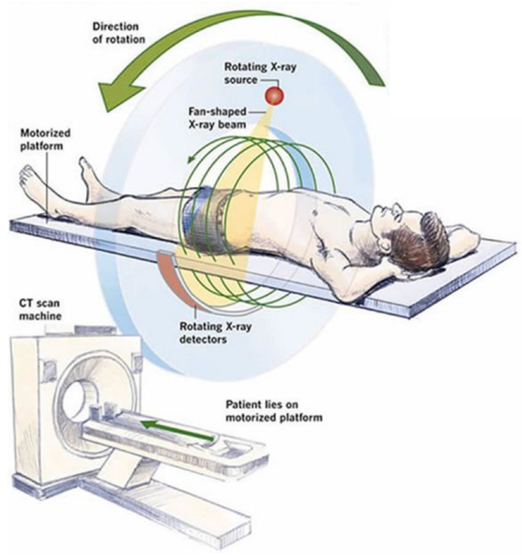


Figure 2.2.18. Working of a 3D scanner. Source: (Omega PDS, 2019).

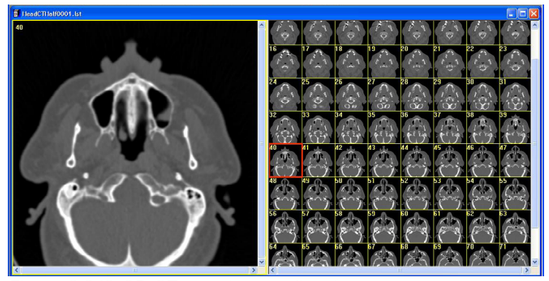


Figure 2.2.19. 2D CT scan image slices.[1]

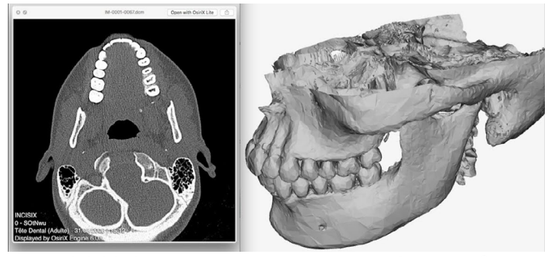


Figure 2.2.20. 2D image slices combined into 3D image.[2]

2.2.3 CT scanning

To get a clear understanding of the context in which this project takes place, it is important to understand how CT scanning works and what the difference is between 3D- and 4D CT scanning.

Three dimensional

First it is important to understand how normal CT (3D) works (figure 2.2.18). A CT scanner makes use of a motorized x-ray source that rotates around the gantry, the hole in the donut. When a CT scan is made, the patient has to lie completely still on the bed of the CT scanner. At the same time the x-ray source rotates around the patient and shoots small beams of x-ray, to the patient, to the opposite side of the gantry. Opposite of the x-ray source, a special digital x-ray detector is positioned. All the x-rays that are shot through the patient, get later on caught by the detectors on the other side. Finally these picked up x-rays get transferred to a computer, which translates the data to images (NIH, 2016).

Using complex mathematical techniques, the computer can develop one 2D image slice with each complete rotation around the patient. When one slice is completed, the bed is moved further into the gantry step-by-step, in order to acquire 2D images of the entire (desired) body part. When the bed is in place, the scanning process described above is repeated to produce more slices, until the required number of slices is developed (NIH, 2016) (figure 2.2.19).

The 2D image slices already offer information about the situation inside the patient. However, most of the time all the 2D image slices are used to be combined into one 3D image by the computer (figure 2.2.20). In this way extensive information about the patient's inside can be realized, for instance the skeleton, organs, tissues. In this 3D image the physician is able to identify any problems or abnormalities, which cannot be detected from the outside. Finally, the 3D image can be rotated in space to take an even closer look at some parts of the scanned body part. This makes it easier to find exact place where the problems or abnormalities might be located (NIH, 2016).

Four dimensional

In comparison with the normal (3D) CT scanning, 4D CT scanning has a new fourth dimension, which is represented by time. With 4D CT scanning multiple 2D images of the body are made over time (and during movement). However, 4D CT scans of the wrist are not officially (with patients) being made yet; at this moment the wrist is mainly scanned and reviewed statically in 3D. According to S. Buckens (personal communication, September 26, 2019) currently there has not been a lot of research into 4D CT scanning, mostly because it is such a novel application that has only recently been unlocked by improvements in CT scanner design and –processing. Furthermore, not all scanner designs are equally suitable for acquiring 4D CT scans; for example Canon's large 16 [cm] detectors are uniquely suited to this application. As such few radiology departments have access to a 4D-CT capable scanner and very few radiology departments have any experience with this technique, the field of making 4D CT scans (of the wrist) is a promising, impactful and novel topic.

Because of these developments in the field of CT scanning, recently it has become technically feasible to have the patient actively move their wrist in specific directions (e.g. flexion/extension or ulnar-/radial deviation) to create the fourth dimension, so that the wrist can be reviewed dynamically. The result of such a 4D CT scan is a video (figure 1.1.1, subchapter 1.1) which can be played back and analyzed in detail by the radiologist, so that physiological processes can be observed and internal movements can be tracked (S. Buckens, personal communication, September 26, 2019). In the CT scanner the same parts and technologies are used as in the normal CT scanner.

[1] Source: (3D-Doctor, n.d.).
[2] Source: (Flynn, 2016).

2.2.4 Conclusion

Summary

2.2.1

- The patients' wrists should always be scanned from the center point of the central aperture of the CT scanner, which is indicated by the projector (laser) lines, to ensure the optimal scanning quality.
- The bed of the CT scanner can be used to position the product (and therewith the arm and wrist of the patient) as close to the center point inside the gantry as possible.
- The patient bed is (mildly) shaped as a gutter, this should be taken into account when placing the product on it.

2.2.2

- The arm, wrist and hand of the patient need to be in a neutral position the whole time, in order to prevent a limit of the possible ROM of the wrist. This neutral position is dependent on the position of the shoulder.
- If patients have to abduct their shoulders slightly to fit perfectly in the central aperture, the device also has to be tilted with that same angle.
- The positioning of the patient in relation to the product and the CT scanner should be a well-considered balance between a high quality of the CT images and a low radiation dose for the patients.

2.2.3

- The fourth dimension in a 4D CT scan is represented by time.
- Recently it has become technically feasible to have patients actively move their wrist in specific directions (e.g. flexion/extension or ulnar-/radial deviation) to create the fourth dimension, so that the wrist can be reviewed dynamically.
- The result of a 4D CT scan is a video which can be played back and analyzed in detail by the radiologist, so that physiological processes can be observed and internal movements can be tracked.

Design requirements

- The product should stay stable on the patient bed (**safety**).
- The product should not be higher than 410 [mm] and not wider than 465 [mm] (**other**).
- The product should not contain any metal parts in the central aperture of the CT scanner (**other**).
- The product should make sure the patient's hand is held in a neutral position during all passive wrist movements (**fixation & adjustability**).
- The positioning of the patient in relation to the product and the CT scanner should be a well-considered balance between a high quality of the CT images and a low radiation dose for the patients (**other**).

2.3.2 Conclusion *(first read 2.3.1)*

Summary

- In most cases the forearm and a part of the hand (often around the metacarpals) was fixated with the use of a hard (rigid) plastic part.
- The majority of the products contained soft (cushion-like) parts around the fixation parts with adjustable straps to optimize comfort and fit of the product for different users.
- One product had molded a silicon-like material around the electronic parts, which made it possible to wash and clean the product without damaging any of the components.
- The functions and working of the W2 Wrist CPM comes closest to the vision of this project's device, which is why its mechanism could be used as inspiration for use and integration.

2.3 State of the art

As mentioned in subchapter 1.1, there is currently no device which can passively move the wrist in a precise and safe way in the gantry during scanning. Therefore, market research was done in order to obtain an idea about how passive movement is facilitated in existing devices. The features and techniques used in these existing products are used for inspiration when designing this project's device.

In the recent years various companies, universities and other institutions have researched passive moment of the wrist. Devices like hand braces or robotic hand exoskeletons were developed, which could facilitate continuous passive movement (CPM) of the wrist. All products which were found, are meant for wrist rehabilitation (i.e. improving range of motion (ROM) of the wrist).

2.3.1 Comparison

Eventually the products were compared based on six different variables (movement, usability, size, adjustability, hygiene and comfort) with the use of the hexagon method. The six criteria were selected as basic product aspects in order to acquire a clear overall view of the product's rating. The method provides a clear visual representation of each of the product's scores on each variable, while at the same time generating one clear overview of the scores of all the products. The hexagon comparisons of all analyzed products can be seen in figure 2.3.1 – 2.3.5. For the full description of all products and more information about the review and the criteria see Appendix D.

KINETEC MAESTRA

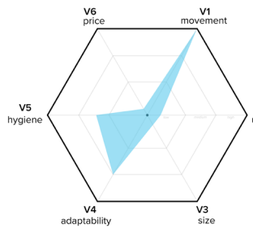


Figure 2.3.1. Kinetec Maestra. Source: (Kinetec, 2016).

6000X WAVEFLEX

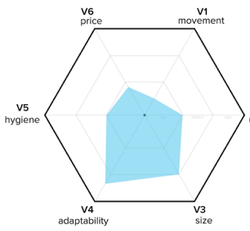


Figure 2.3.2. 6000X WaveFlex. Source: (QAL Medical (b), n.d.).

W2 WRIST CPM

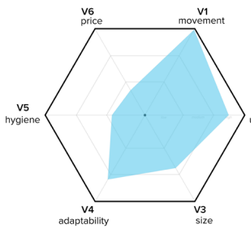
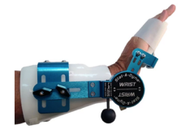


Figure 2.3.3. W2 Wrist CPM. Source: (QAL Medical (a), n.d.).



STAT-A-DYNE

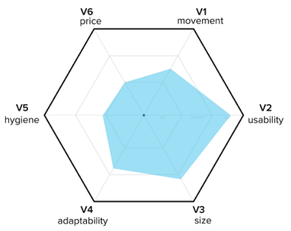


Figure 2.3.4. Stat-A-Dyne. Source: (Lentz Medical, 2013).

Kinetic Maestra CPM

The Kinetec Maestra CPM (figure 2.3.1) is designed for post-operative rehabilitation and provides a solution for every hand and wrist pathology (Kinetec, 2016).

6000X WaveFlex Hand CPM

The 6000X WaveFlex Hand CPM device (figure 2.3.2) consists of an anatomic hand CPM that helps patients to achieve a full composite fist (at 270°) (QAL Medical (b), n.d.).

W2 Wrist CPM

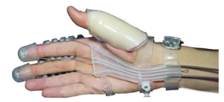
The W2 Wrist CPM device (2.3.3) is a lightweight portable wrist device, designed to increase mobility of the wrist joint in flexion and extension and ulnar- and radial deviation (QAL Medical (a), n.d.).

Stat-A-Dyne Wrist

The Stat-A-Dyne Wrist device (figure 2.3.4) is a product which provides stretch for wrist extension and –flexion, in order to address joint stiffness of the wrist (Lentz Medical, 2013).

Exo-Glove Poly

The Exo-Glove Poly (figure 2.3.5) is a soft wearable robot for the hand, able to help patients move their thumb, index- and middle finger. It comes with a glove that is completely constructed of polymer materials and that operates through tendon-driven actuation for use in spinal cord injury (SCI) (Kang et al., 2019).



EXO-GLOVE POLY

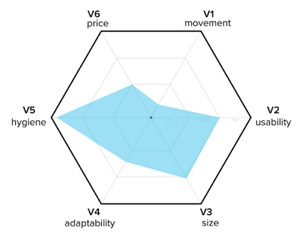


Figure 2.3.5. Exo-Glove-Poly. Source: (Kang et al., 2019).

2.4 Product vision

In this subchapter is described what the final product should be capable of and a set of design requirements resulting out of this.

2.4.1 Key aspects

This list of key aspects is set up based on the insights of two visits to the radiology department of Radboud UMC (26/09/19 and 21/11/2019), where Stan Buckens and Brigitte van der Heijden were spoken with respectively. Not all aspects related to the product are described below, as some aspects are simply less relevant and important for the design of the product. The remaining aspects can therefore be found in Appendix E.

Movement

As mentioned in subchapter 1.2, the goal for the radiologist and hand surgeon is to compare 4D CT scans of active movement with scans of passive movement of the wrist. By reviewing and comparing both of the movements, potential significant pathologies can be discovered. To realize this, the device has to facilitate passive movement of the wrist; in particular flexion and extension (figure 2.4.1, right) and radial- and ulnar deviation (figure 2.4.1, also called abduction and adduction respectively).

In case of CT scanning the scanner has some start-up time at the beginning of every scan. Therefore it is preferred to scan all four wrist movements in one go, in order to reduce the total radiation dose for the patient in the end (S. Buckens, personal communication, November 21, 2019). Whether this is possible is dependent on the available scanning time (how many seconds the scanner can make a consecutive 4D scan in one go) and on the speed of the movement. If the hand is moved too fast by the product, motion artefacts will start to occur (also illustrated in figure 1.1.1.). Therefore it is important that the speed of the passive movements facilitated by the product can be tweaked, in order to find the perfect balance between image quality and radiation dose (for the patient).

Also, for the movements it is important that one of them is executed at the time, so that the radiologists can clearly see what happens inside of the patient's wrist during each specific movement (S. Buckens, personal communication, December 12, 2019). Moving in both planes will result in a combination of the two movements, making it harder for the radiologist to determine the cause of any irregularities in the patient's wrist.

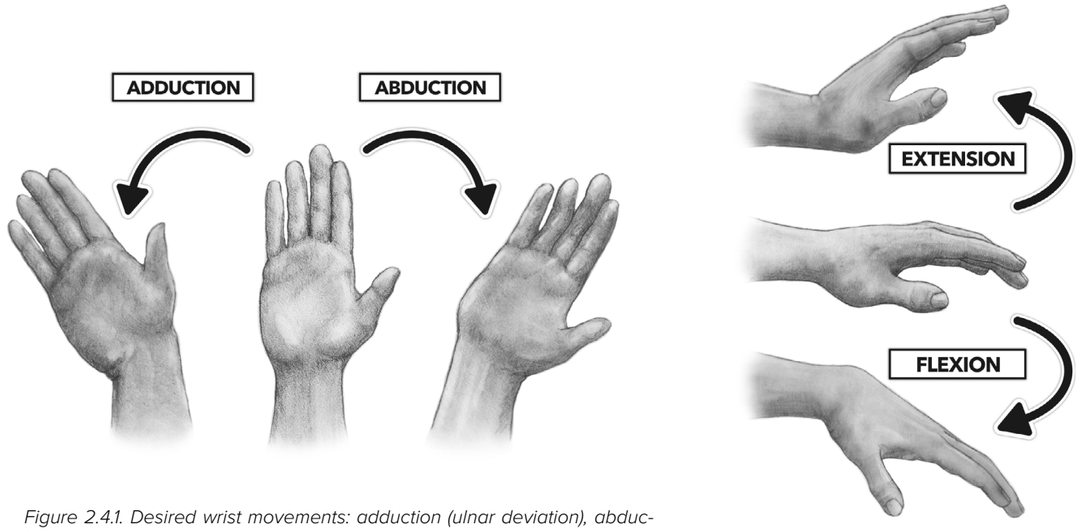


Figure 2.4.1. Desired wrist movements: adduction (ulnar deviation), abduction (radial deviation), extension and flexion. Source: (Crossfit, 2019).

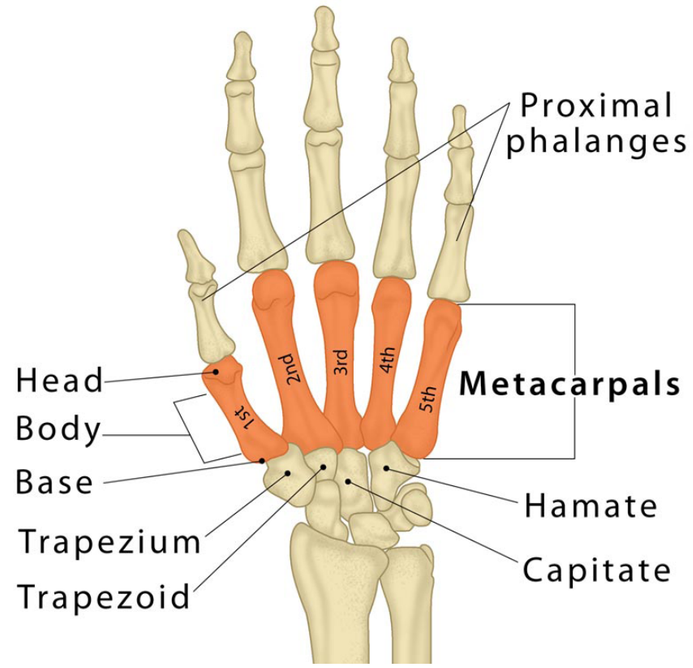


Figure 2.4.2. Metacarpal bones. Source: (TheSkeletalSystem, 2018).

Fixation

In both situations of scanning the wrist (active and passive), the forearm of the patient needs to be fixated. This is because of two reasons. Firstly, if the forearm is still able to move, this can result in motion artefacts on the scan (figure 2.4.3, also see figure 1.1.2 in subchapter 1.1). Secondly, according to S. Buckens, the forearm muscles might be able to (partly) mask potentially significant pathology when actively moving the wrist (personal communication, September 26, 2019). Additionally, the fixation has to be positioned between the wrist and elbow with some free space left at both sides, still allowing the elbow and wrist to move freely (B. van der Heijden, personal communication, November 21, 2019).

In case of passive movement, also the hand of the patient needs to be supported. While the forearm is fixated, the device has to make contact with the hand to eventually move the wrist in the desired direction. This support or fixation of the hand has to be at the metacarpal bones (figure 2.4.2), in order to make sure the hand stays straight and in neutral position during the entire movement (personal communication, B. van der Heijden, November 21, 2019). In subchapter 3.2 this aspect about fixation of both the forearm and hand is researched further.

In the process of scanning and analyzing the patients' wrists, the hands of the patients need to be held in different positions (figure 2.4.4). In this way it can be analyzed on the CT scans if the different stand (and position) of the fingers results in differences inside the wrist or affects the possible movements of the wrist (B. van der Heijden, personal communication, November 21, 2019).

Firstly, the hand needs to rest in a neutral position, where the fingers are stretched out. In this position the hand is then passively- and actively moved. After this, it is also desired that the patient can form a fist with their hand, which is then also lead through the same movements. Still, this fist also needs to be passive, meaning the patient cannot actively keep their fingers in the fist position.

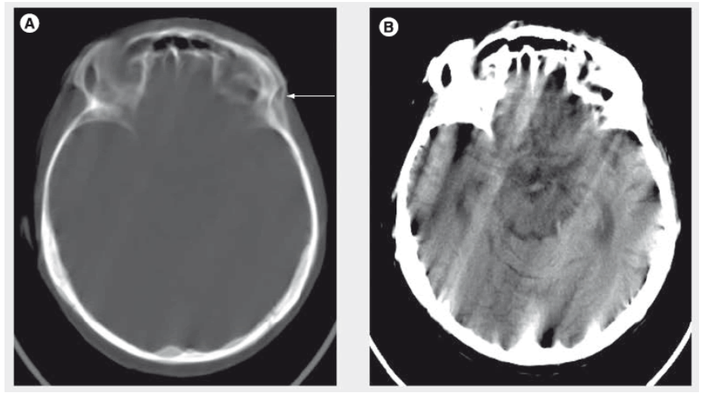


Figure 2.4.3. Two types (A and B) of motion artefacts. Source: (Boas et al., 2012).

Figure 2.4.4. Hand positions during scans: neutral (top) and passive fist (bottom). Source: (Misra, 2015).

Actuation
As the wrist needs to be moved passively, one or more actuators should be used to make sure the patients do not use or compensate with their muscles to make the movement. Regardless which type actuator is used, it is important that the actuator does not injure the patient by forcing them through their possible ROM.

Feedback system
According to S. Hummelink (personal communication, December 12, 2019) there should be integrated a feedback system in the product which is able to measure or calculate how much torque the actuator is delivering to actuate the product and eventually facilitate the wrist movement. This is necessary as the torque of the actuator is not allowed to exceed a certain limit, in order to prevent it from moving the patients through their comfortable ROM and possibly even injuring them in the end.

Symmetrical
The product should be designed symmetrically, so that it does not matter if the left or right arm (and hand) of the patient is scanned. In the process of designing the product it is important to keep in mind that is has to be possible to scan both arms (separately) in the CT scan.

2.4.2 Conclusion

Summary

- There are five key aspects for the product, consisting of: movement, fixation, actuation, feedback system and symmetry.
- All key aspects can be translated to design requirements for the final product.

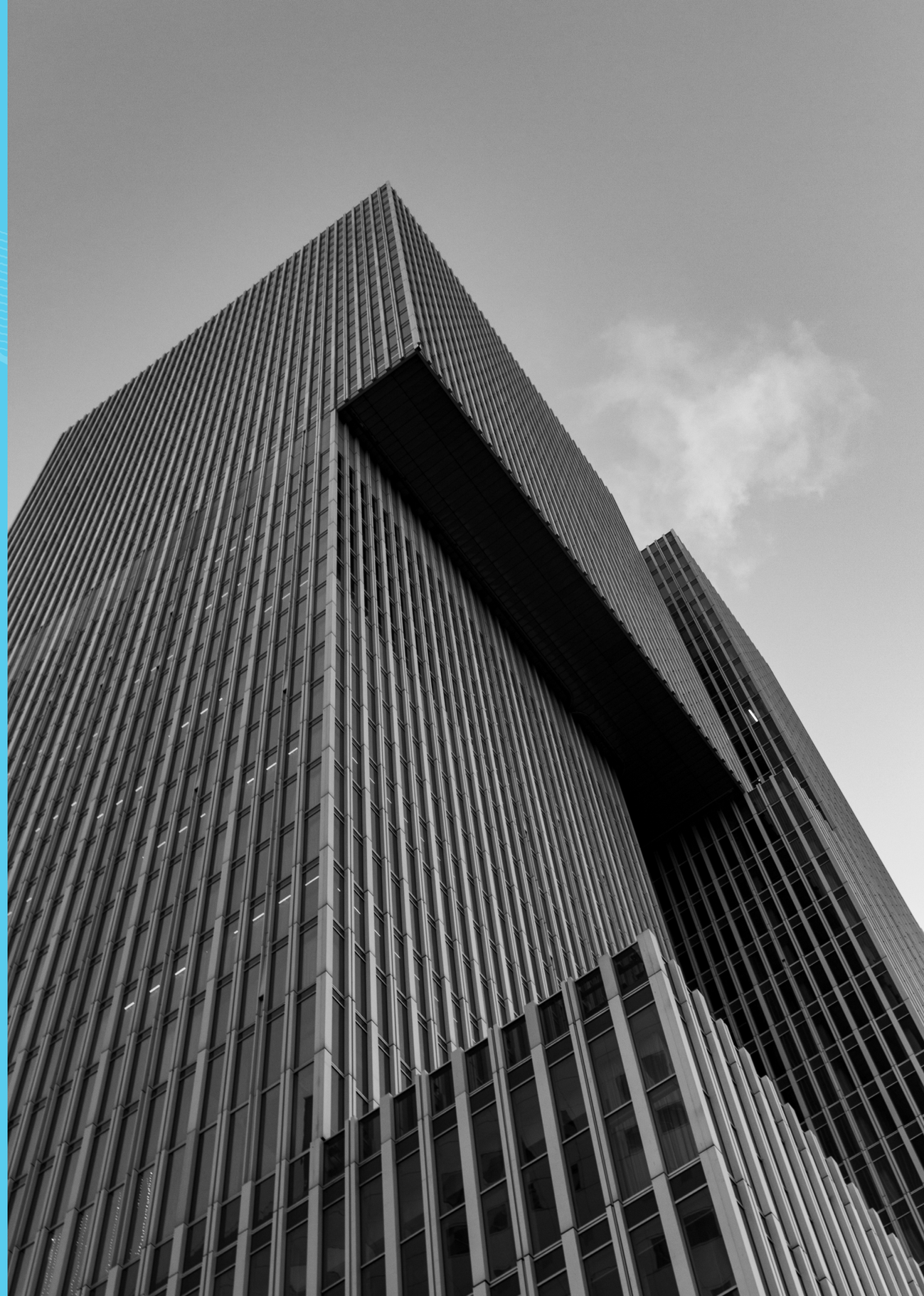
Design requirements

- The product should be able to facilitate all the desired (passive) movements: wrist flexion, wrist extension and radial- and ulnar deviation (**movement**).
- The product should be able to facilitate all desired wrist movements in one go, in order to reduce the radiation dose for the patient (**movement**).
- The product should be able to tweak the speed of the passive wrist movements in order to acquire the perfect balance between image quality and radiation dose (for the patient) (**movement**).
- The product should be able to facilitate one movement at the time and prevent combination of movements, to make sure the radiologist can accurate analyze each specific movement (**movement**).
- The forearm of the patient should be fixated in order to prevent the forearm muscles to compensate during movement and to prevent motion artefacts occurring on the CT scan (**fixation & adjustability**).
- The forearm fixation should be positioned between the wrist and elbow with some free space left at both sides, still allowing them to move freely (**fixation & adjustability**).
- The hand should be fixated as a contact point with the movement mechanism and in order to prevent motion artefacts occurring on the CT scan (**fixation & adjustability**).
- The product should support the hand at the metacarpal bones, in order to make sure the hand stays straight and in neutral position during the entire movement (**fixation & adjustability**).
- The product should allow the patient's hand to be held neutral and in a fist position (**fixation & adjustability**).
- The product should have one or more actuators to facilitate the passive movement (**actuation and transmission**).
- The product should contain a feedback system which can measure or calculate how much torque the actuator is delivering to actuate the product and eventually facilitate the wrist movement (**safety**).
- The product should be designed symmetrically so that both hands (left and right) can be passively moved by the device (**usability**).

03 SUBCOMPONENTS

In this chapter the focus areas discussed in subchapter 2.4 are translated to sub-components of the product. Each component is analyzed, designed, evaluated and iterated using different tools and methods.

Source: Personal photograph



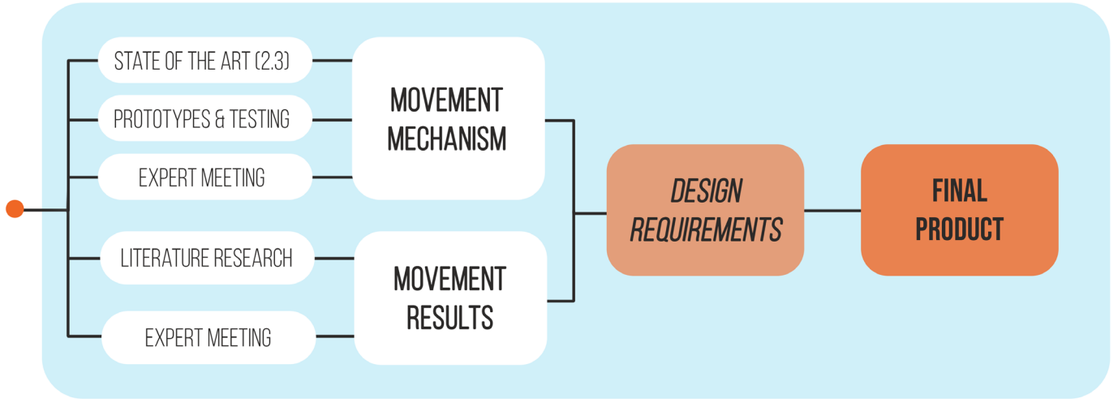


Figure 3.1.1. Overview of activities and outcomes of subchapter 3.1

3.1 Movement

This subcomponent focuses on the execution of the passive movement in the product. For this subcomponent literature research was conducted, prototypes were developed, tested and evaluated and experts were consulted. An overview of the activities and how their outcomes are used can be seen in figure 3.1.1.

3.1.1 Movement results

For each of the wrist movements it is important to consider the movement results. The movement results represents how far (in degrees [°]) people can move their wrist in the desired direction. As the actuators need to realize this movement in the end, it is important that actuators are selected which are able to rotate or move far enough to complete the entire movement for everyone. Therefore the maximum (P95) movement results of each movement should be taken into account in this case, so that all possible scenarios are taken into account.

Method

The range of movement results for each of the wrist movements was defined based on literature research and an expert meeting with B. van der Heijden (personal communication, November 21, 2019), a hand surgeon from the Radboud UMC. The results of both methods can be seen in table 3.1.1 and 3.1.2 respectively.

Table 3.1.1. Measured minimum (P5) and maximum (P95) wrist movement results (Steenbekkers et al, 1998).

Movement	*Minimum (age, gender)*	*Maximum (age, gender)*
Flexion	38 (80+, f)	90 (20-30, f)
Extension	26 (75-79, m)	90 (20-30, f)
Ulnar deviation	28 (80+, m)	62 (60-64, f)
Radial deviation	7 (75-79, m)	36 (55-59, f)

Table 3.1.2. Typical wrist movement results (B. van der Heijden, 2019).

Movement	*Minimum*	*Maximum*
Flexion	60	90
Extension	50	90
Ulnar deviation	20	50
Radial deviation	10	40

Results

Looking at both tables it can be seen that especially the minimum movement results differ quite a lot. However, in this case the maximum movement result is most important as the actuator which is going to be used, needs to be able to realize the full movement results. When it is able to do that, realizing the minimum movement results is of course not a problem anymore.

The maximum movement results are quite close to each other, apart from the one for ulnar deviation. As all scenarios have to be taken into account, an ulnar deviation of 62° is therefore taken into account for the design of the final product.

Considering the fact that the maximum movement results in table 3.1.1 are typical and in table 3.1.2 are for P95, it could still be that some patients who use the device have higher maximum values for the movement results. These people are represented by the percentile values of P96-P99. However, according to B. van der Heijden (personal communication, November 21, 2019) there are almost no people (she has never even encountered one patient) who have larger movement results than the ones mentioned above. Therefore, in the process of designing this product, the movement results mentioned above can be taken into account.

3.1.2 Mechanism

In the end four wrist movements have to be realized, which take place in two planes and in total four directions. As these movements have to be passive, an actuator in combination with a certain mechanism needs to take over the movement. Where normally the muscles and tendons facilitate the movement of body parts, now this mechanism takes over this function.

Concepts

For the movement mechanism eventually three concepts were generated. The concepts were generated with the help of inspiration acquired from the state of the art research (described in subchapter 2.3) and an expert meeting (and brainstorming session) with S. Buckens and S. Hummelink (personal communication, December 19, 2019). The concepts were developed and evaluated by making prototypes and testing them. Below a short description of every concept is given; for an extensive description of all concepts see Appendix F.

Concept 1: Connection arms

The first concept for the movement mechanism is based on the existing CPM devices described in subchapter 2.3. All of these devices realize the wrist movements by having the rotation point of the movement in line of action with the wrist. As the hand needs to be held neutral the entire time this would result in two motors with each their rotation point aligned with the wrist, but in another plane. For flexion and extension (i.e. movement in the horizontal plane, figure 3.1.3) the rotation point of the movement should align from the bottom or top (figure 3.1.2); for radial- and ulnar deviation (i.e. movement in the vertical plane, figure 3.1.5) the rotation point of the movement should align from the side (figure 3.1.4).

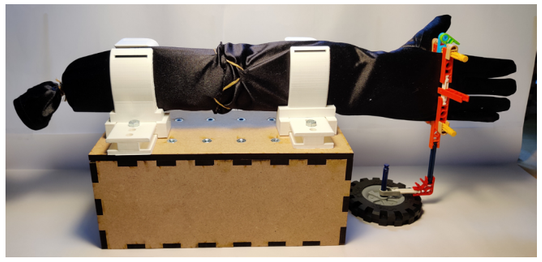


Figure 3.1.2. Rotation point movement aligned from bottom.

Figure 3.1.3. Wrist extension movement (top view).

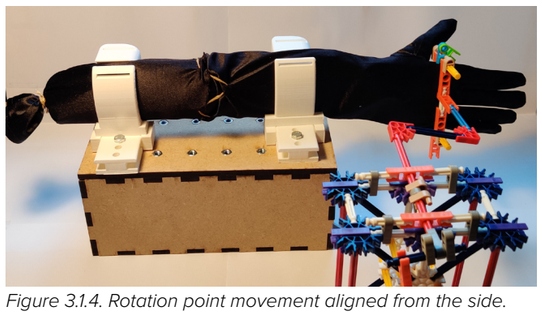


Figure 3.1.4. Rotation point movement aligned from the side.

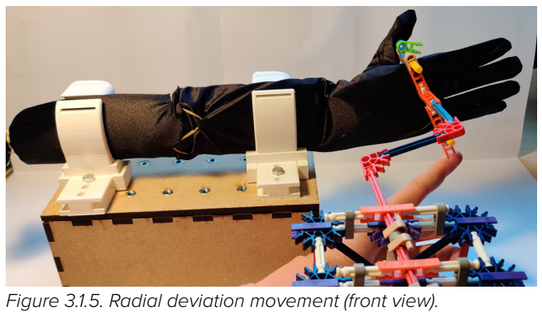


Figure 3.1.5. Radial deviation movement (front view).

Concept 2: Cable-pull

The second concept is based on imitating the functions of the muscles in the human body which usually facilitate the wrist movements. By placing four cables along the length of the arm (figure 3.1.6), the wrist can be moved into the different directions by pulling each of the cables (wrist flexion (and -extension) in figure 3.1.7 and deviation in figure 3.1.8). The mechanism works by having four cables attached to the hand fixation (at the metacarpals): two at both sides of the hand, one at the top and one at the bottom. At the other side the cables are each connected to an actuator, which can take- or let go off the cable (for example by rotation of a shaft on which the cable is wrapped) in order to facilitate the movement in the end.

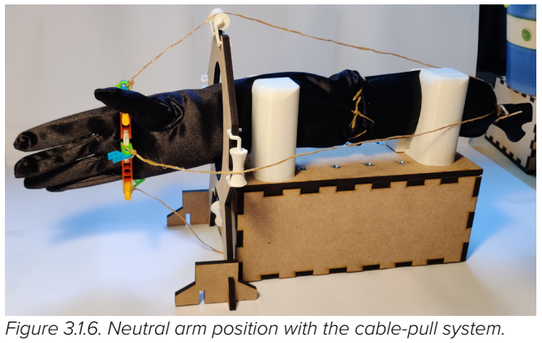


Figure 3.1.6. Neutral arm position with the cable-pull system.

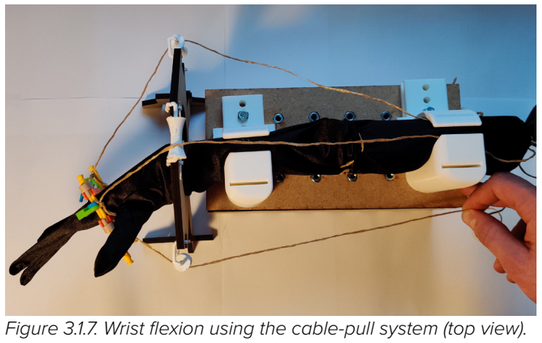


Figure 3.1.7. Wrist flexion using the cable-pull system (top view).

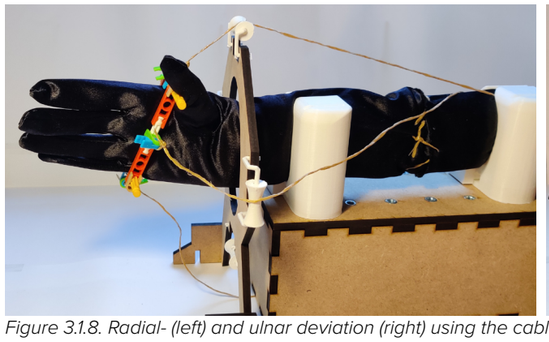


Figure 3.1.8. Radial- (left) and ulnar deviation (right) using the cable-pull system (front view).

Concept 3: Rigid beams

The third and last concept for the movement mechanism comes forward out of combining the two first ideas. Instead of having four cables which pull the hand (and therefore the wrist) in the desired directions, in this system rigid beams are used to facilitate that (figure 3.1.9 and 3.1.10). The same four connection points at the hand fixation are used as in the cable-pull system.

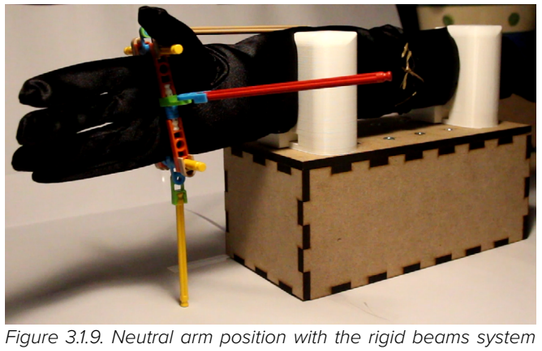


Figure 3.1.9. Neutral arm position with the rigid beams system (front view).

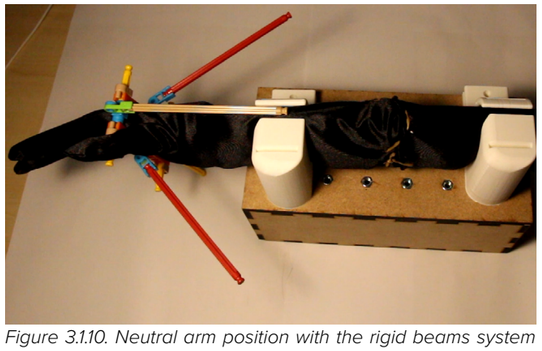


Figure 3.1.10. Neutral arm position with the rigid beams system (top view).

Selection

In order to have a clear comparison between the different concepts, hexagon comparisons were made based on a set of five (instead of six, subchapter 2.3) criteria (figure 3.1.11). All criteria are based (in a way) on the focus areas described in subchapter 1.4. Criteria 1 and 3 relate to usability, criteria 2 to movement, criteria 4 relates to adjustability and criteria 5 relates (partly) to safety. The criteria are not listed in order of importance.

A detailed overview of all positive and negative aspects of each concept and a more extensive explanation on the selection of the movement mechanism can be seen in Appendix G.

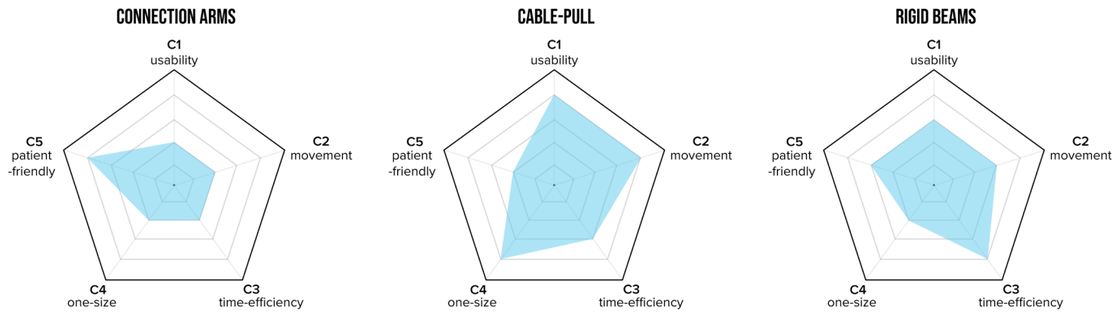


Figure 3.1.11. Hexagon comparison of the three movement mechanism concepts.

Looking at the hexagon comparison, it becomes clear that the 'Connection arm' mechanism scores lowest of the three. This has to do with the fact that the movements executed by this mechanism are not accurately imitated from the human body (more information about this can be found in the next subchapter). Next to this, the rotation points of the arms always have to be adjusted in order to align with the wrist, which takes time and effort. Also, all desired movements cannot be executed all in one go, in between the connection arm needs to changed.

Comparing the 'Cable-pull' and 'Rigid beams' mechanism, they seem to score quite similar at first. The most important difference in this case is that the 'Cable pull' mechanism might take some more time to setup and prepare (calibration), while with the 'Rigid beams' mechanism the execution of the movements will be more difficult, while some movements will even be hindered. As in this case the fact that all movements are executed correctly (as desired) is more important than the time frame in which this is realized, the 'Cable-pull' mechanism is preferred over the 'Rigid beams' mechanism. Because of this reason the 'Cable-pull' mechanism is selected to continue with.

Cable-pull

The selected concept, the cable-pull mechanism, came forward out of an expert meeting with S. Buckens and S. Hummelink (personal communication, December 19, 2019). Both stakeholders from the Radboud UMC mentioned that they preferred the movements to be facilitated as if they were imitated from the human body (muscles). For both flexion and extension (figure 3.1.12) and radial- and ulnar deviation (figure 3.1.13) specific muscles exert forces in order to facilitate the initialized wrist movement. In the concept these different muscles are translated to four cables, where each cable is responsible for one of the four wrist movements. Of course, it is not possible to have these cables inside the arm, which is why they have to be placed outside the arm. Still, it is desired to have them relatively close to the arm, to still imitate the movements as accurate as possible.

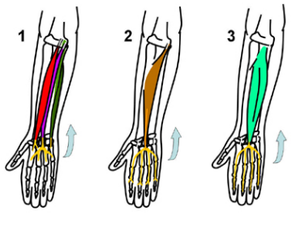


Figure 3.1.12. Active musles during wrist flexion (1) and -extension (3). Source: (PediatricNeuro, 2013).

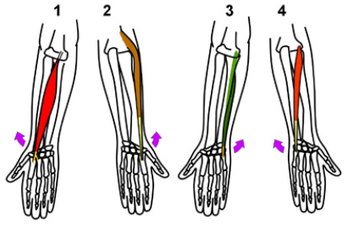


Figure 3.1.13. Active muscles during radial- (1 and 2) and ulnar deviation (3 and 4). Source: (PediatricNeuro, 2013).

Actuation and transmission

The mechanism works by having four cables attached to the hand fixation (at the metacarpals): two at both sides of the hand, one at the top and one at the bottom. At the other side the cables are each connected to a motor, which can take- or let go off the cable (for example by rotation of a shaft on which the cable is wrapped) in order to facilitate the movement in the end. By rotating one of the motors and therefore pulling one of the cables, one of the four wrist movements is facilitated. For instance, assuming the arm and hand are in neutral position, pulling the top cable (attached at the top of the hand) would result in radial deviation of the wrist. The system and its working is clarified in figures 3.1.6 - 3.1.8 (two pages back). In this model the motors are replaced by a hand pulling the cables. The purpose of the MDF standard with the white pulleys at all four sides (and why it is aligned with the wrist) is explained later in “Guidance point”.

Movement

The four movements could be divided into two planes: plane 1 for flexion and extension (x-y) and plane 2 for radial- and ulnar deviation (x-z) (figure 3.1.14). While the patient’s wrist is moved in one plane, the cables responsible for movement in the other plane are locked. This is important to facilitate the desired movement perfectly in its corresponding plane. In the case of flexion or extension that would be a perfect horizontal movement in the x-y plane. In the case of deviation this would be a vertical movement in the x-z plane.

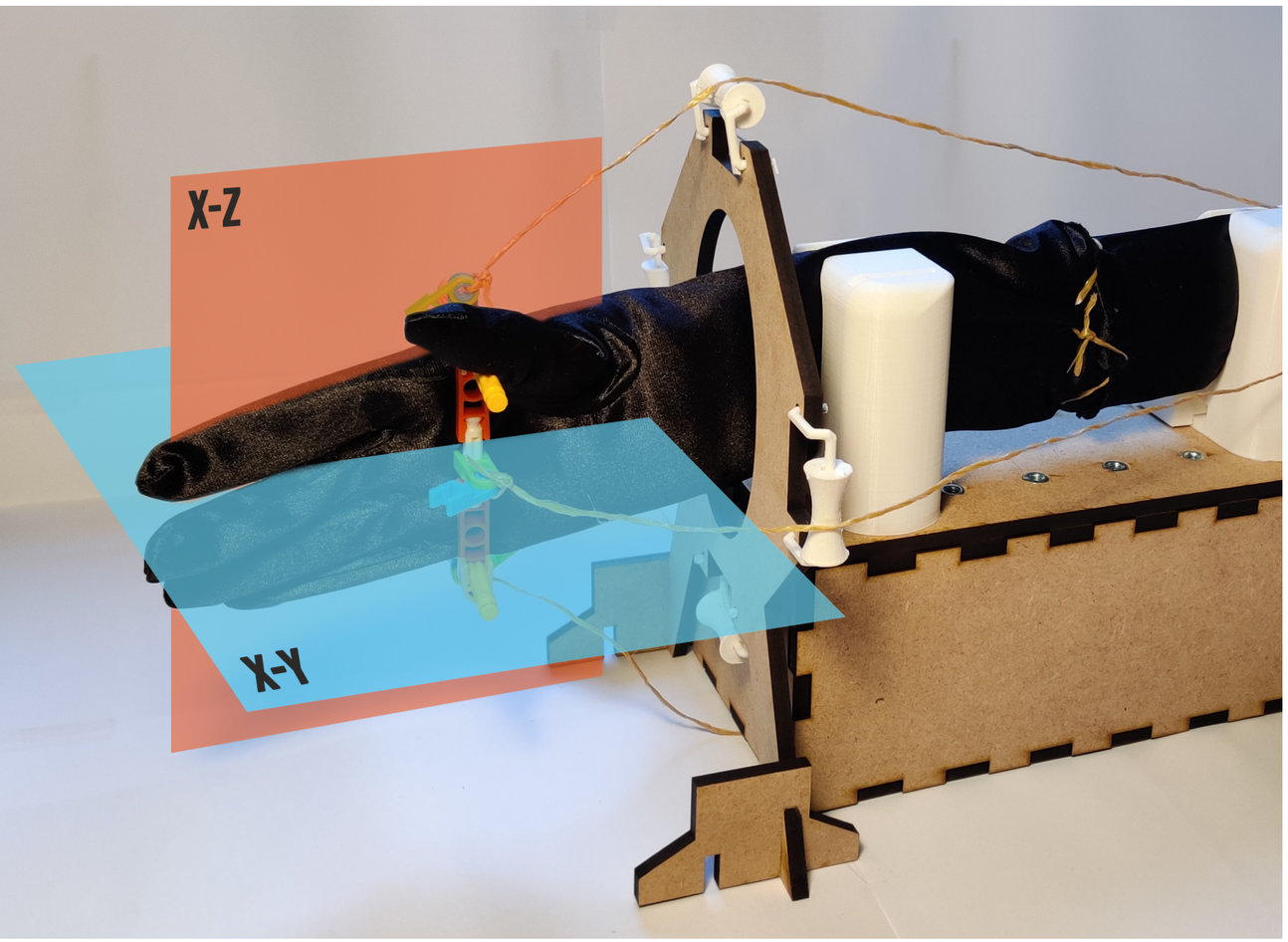


Figure 3.1.14. Movement planes for cable-pull movement mechanism.

Feedback system

As was mentioned in subchapter 2.4.1, it is important to have some sort of a feedback system to see how much torque the actuator is exerting to make its rotation and eventually the wrist movement. In this system this feedback could be acquired differently, by using the tension on the cables. In the beginning the arm and hand need to be held in a neutral position by tensioning the cables. This is called calibrating, where the required tension on each cable in order to keep the arm and hand in their neutral position, is measured. During the movements the tension on the cables is only allowed to exceed this calibration tension with a certain percentage (which needs to be tested and can be built in the software code), in order to prevent the system from pulling the wrist through its comfortable ROM and therewith injuring the patient.

The measurement of this tension could for example be done by using a strain gauge (figure 3.1.15) attached to each of the cables. For this the strain gauge should be attached to a rigid plate (which is fixed at one side), as in this way the strain gauge is able to measure the deflection of the plate and therewith the cable tension (figure 3.1.16). Measuring of this deflection works with a strain sensitive pattern in combination with two terminals (figure 3.1.17). In case of tension the area narrows and the resistance increases, while in case of compression the opposite occurs (Electrical4U, 2012).

It is still important to pay attention to the resistance range of the strain gauge, as this has to be in proportion to the actual tension on the cables (M. Verwaal, personal communication, December 16, 2019). Of course, it should not happen that the resistance of the strain gauge is already exceeded when calibrating the cables.

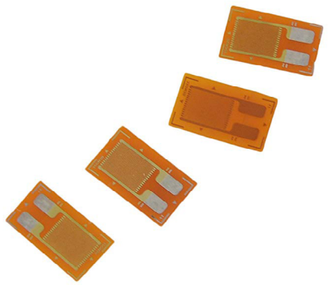


Figure 3.1.15. Strain gauges. Source: (Amazon, 2017).

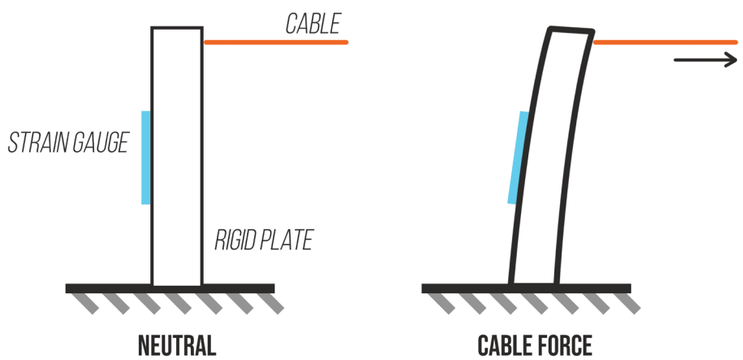


Figure 3.1.16. Strain gauge setup with cable attached to rigid plate (which is fixed at one side).

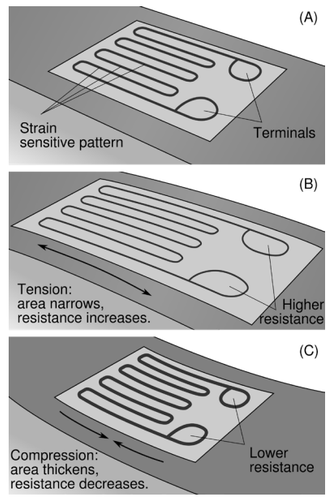
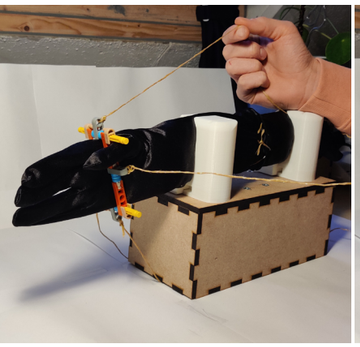


Figure 3.1.17. Measuring of deflection with strain sensitive pattern and two terminals. Source: (Electrical4U, 2012).



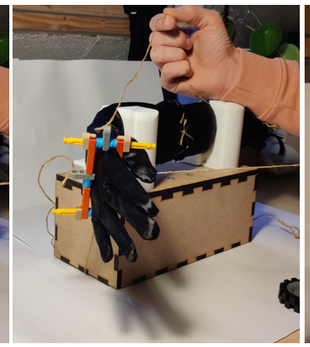
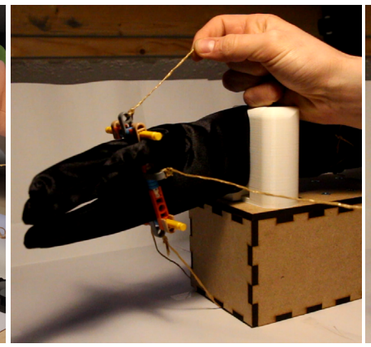


Figure 3.1.18. Wrist flexion using the cable-pull system, guidance point of the cable behind the wrist.



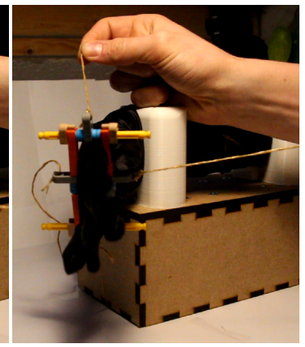


Figure 3.1.19. Wrist flexion using the cable-pull system, guidance point of the cable aligned with the wrist.

Guidance point

The MDF standard with the white pulleys (mentioned above), plays a major role in the execution of the wrist movements. By testing the system in different ways it became clear that having a guidance point of the cable aligned with the wrist (like the rotation points of the 'connection arms' which were also aligned with the wrist) is important to be able to keep the calibration tension on the cables. This is demonstrated in figure 3.1.18 and 3.1.19.

In figure 3.1.18 the guidance point of the cables is positioned behind the wrist. When pulling the cable responsible for flexion of the wrist, the wrist is flexed. However, in this process the tension on the top cable (responsible for radial deviation of the wrist) decreases, as can be seen on the right. Because of this the wrist, the more it is flexed (or extended in the other scenario), will fall downwards due to the effect of gravity. This will result in the movement not being executed as desired, as it now, besides the x-y plane, also acts in the x-z plane.

In figure 3.1.19 the guidance point of the cables is positioned in line with the wrist. The same process is traversed as above, only now it can be seen that the tension on the top cable remains the same. Because of this the movement will be executed as desired, being only in the x-y plane.

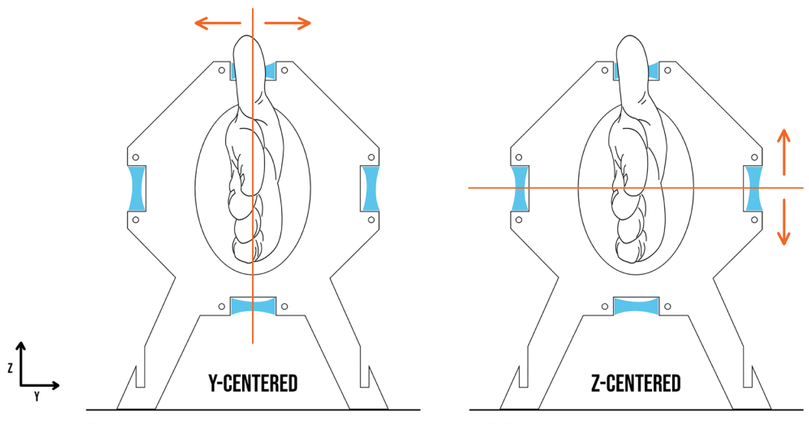


Figure 3.1.20. Hand (and wrist) alignment with MDF (pulley) standard (y- and z-axis).

Centered wrist

Next to the fact that the wrist needs to be aligned with the MDF standard (with the pulleys) in the x-direction, the wrist (and hand) also need to be centered in the width (y-axis) and height (z-axis) of the standard (figure 3.1.20). This is to make sure the movements are being executed symmetrically. To have the hand centered in the y-axis, the middle of the hand needs to be aligned with the middle of the two (upper and lower) pulleys. To have the hand centered in the z-axis, the middle finger of the hand needs to be aligned with the middle of the two side pulleys. According to S. Buckens (personal communication, December 18, 2019) centering in the z-axis can simply be done by choosing approximately the correct height for all the components (arm standard, wrist standard and forearm fixation) in order for the patient's middle finger to end up around the side pulleys of the wrist standard. There is only a small variation in the height of the hand for different patients (also see paragraph 2.5.2), which is why one fixed z-position (in height) should be sufficient to position all hands correctly in relation to the wrist standard.

According to S. Buckens (personal communication, December 18, 2019), in that case the correct movements of the hand and wrist are facilitated and the hand is moved in the two desired planes (x/y-plane and x/z-plane). Otherwise the hand will be moved slanted, causing it to move in more than one plane at a time. In that scenario a combination of for example flexion and ulnar deviation occurs, which is something not desired by the radiologist and referring physicians as it is in that case harder to accurately review the wrist's movements (S. Buckens, personal communication, December 18, 2019).

COMPONENTS

01 00 BASEPLATE
02 00 ARM STANDARD
03 00 WRIST STANDARD
04 00 FOREARM FIXATIONS
05 00 HAND FIXATION
06 00 ACTUATION (+TRANSMISSION)
07 00 CONTROL PANEL

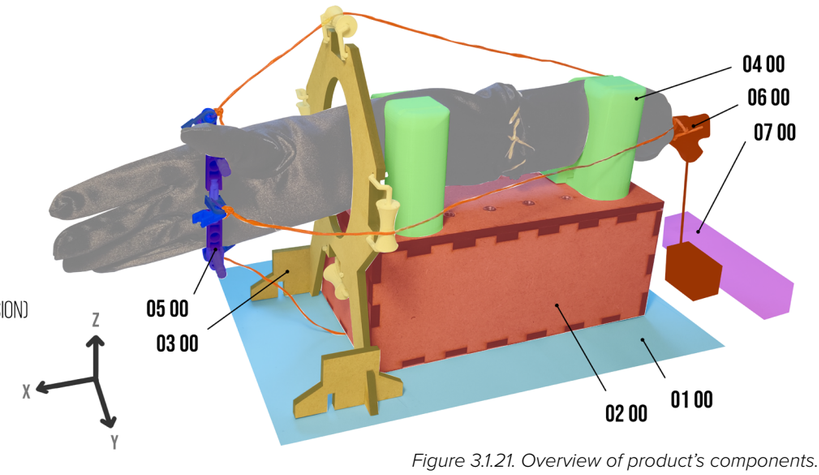


Figure 3.1.21. Overview of product's components.

Product overview

In order to have a clear idea of the cable-pull mechanism and its components for the rest of the project, an overview of the different components which can be present in the model is given below (figure 3.1.21). This overview and component list is used during the rest of the project.

In subchapter 5.1 the final version of each of the seven components is shown, including part specifications and main dimensions. For each component multiple prototypes were made, continuously iterating and improving on the previous version. This results in a series of prototypes for each component, which all can be seen in Appendix H. Here all modifications per version and the improvements leading to the final prototype of each component are elaborated.

3.1.3 Conclusion

Summary

3.1.1

- The following movement results for flexion, extension, radial- and ulnar deviation are taken into account respectively: 90°, 90°, 62° and 36°.

3.1.2

- Three movement mechanism concepts were generated; the cable-pull mechanism was selected to use and integrate in the product (also see Appendix G).
- The mechanism has four cables (connected to the hand fixation) positioned along the length of the arm; the wrist can be moved into the different directions by pulling each of the cables.
- The mechanism has a feedback system using strain gauges to measure the cable tension in order to prevent the actuators from pulling the wrist through its comfortable ROM and therewith injuring the patient.
- The wrist standard should always be aligned as closely with the wrist as possible, to make sure the cable tension on the other cables (which are blocked) remains the same.
- The middle of the wrist (y-axis and z-axis) should always be centered with the center axes of the wrist standard, to make sure all movements are executed symmetrically.
- The product can roughly be divided into seven components, with each components consisting of multiple (smaller) parts.

Design requirements

- The product should be able to facilitate passive wrist flexion of at least 90° (**movement**).
- The product should be able to facilitate passive wrist extension of at least 90° (**movement**).
- The product should be able to facilitate passive radial deviation of at least 40° (**movement**).
- The product should be able to facilitate passive ulnar deviation of at least 62° (**movement**).
- The product should facilitate the passive wrist movements as if they imitate the working of the muscles in the human body (**movement**).
- The product should have the cable-pull mechanism integrated as a movement mechanism to facilitate all wrist movements optimally (**movement**).
- The product should allow for optimal positioning (alignment) of the patient's wrist in relation to the wrist standard (**movement**).
- The product should be able to position the middle of the wrist (y-axis and z-axis) always centered with the center axes (y and z) of the wrist standard, to make sure all movements are executed symmetrically (**movement**).

3.2 Fixation & adjustability

This subcomponent focuses on the possibilities within the product to fixate the patient's forearm and hand and to adapt the product to different arm- and hand sizes of the patients. For this subcomponent literature- and market research was conducted, prototypes were developed, tested and evaluated and experts were consulted. An overview of the activities and how their outcomes are used can be seen in figure 3.2.1.

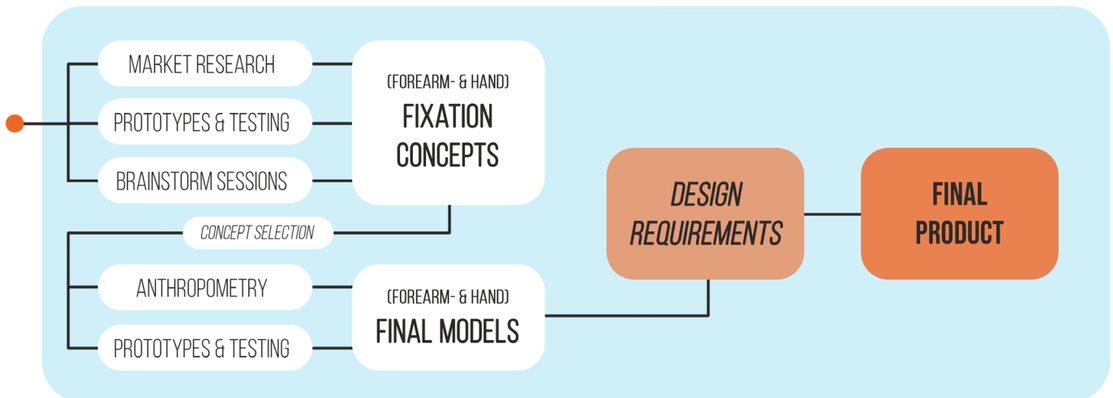


Figure 3.2.1. Overview of activities and outcomes of subchapter 3.2.

3.2.1 Market research

For the fixation parts of the product market research was conducted in order to get an idea about existing types of fixations. Later this output is used as inspiration for designing both the forearm- and hand fixations.

Existing products

In subchapter 2.3 a couple existing CPM devices were analyzed regarding fixation. In this subchapter other existing products containing some sort of a fixation are analyzed. All of these products (figure 3.2.2), of which a summary is given below, can be used for inspiration for the design of the final product. The full description and evaluation of all products can be found in Appendix I.

Existing products which fixate the forearm typically consist of three parts: a splint, a glove and straps or elastic bands. The splint is rigid and is used to fixate the body part, so movement of that particular body part is minimized or even impossible. The splint goes partly or completely around the body part which has to be fixated.

The glove-part is used around the splint, covers it and thereby optimizes fit and comfort for the users. Typically these gloves are made of Cordura, neoprene, nylon or leather, which are all durable materials. In the glove an extra padding can be integrated to increase comfort; this could be done using EVA foam.

In every splint straps are used for tightening and adaption to different user sizes. Typically these are velcro straps (nylon) or elastic straps (rubber).

Figure 3.2.2. Overview of existing products with some sort of fixation. Sources: 1. (Mercado Libre, 2018); 2. (DJO, n.d.); 3. (Allen Medical, n.d.); 4. (Walmart, n.d.); 5. (Human Protection, n.d.); 6. (Amazon, n.d.).

Figure 3.2.3. Phone holder. Source: (MobileFun, 2015).

Figure 3.2.4 (1). Helmet adjustment mechanism. Source: (Team Obsidian, 2016).

Other fixation types

Besides the fixations mentioned above, there are still other possibilities to fixate the arm and hand. One of these options is discussed in this subchapter. A description of the rest of the possibilities can be found in Appendix J, as these turned out to be irrelevant.

Clamping mechanism

A clamping mechanism can be used to fixate something with the use of two (or more) movable clamps. This mechanism is used in phone holders for cars (figure 3.2.3), but the same principle is also used in the adjustment mechanism of helmets (figure 3.2.4 (a)). The two clamps (at the sides) will always move simultaneously and symmetrically (figure 3.2.4 (b)). This mechanism could also be used to fixate the arm. With the use of for example movable clamps the different sizes of the forearm can be fixated. The integration of this mechanism can be seen in subchapter 3.2.2.

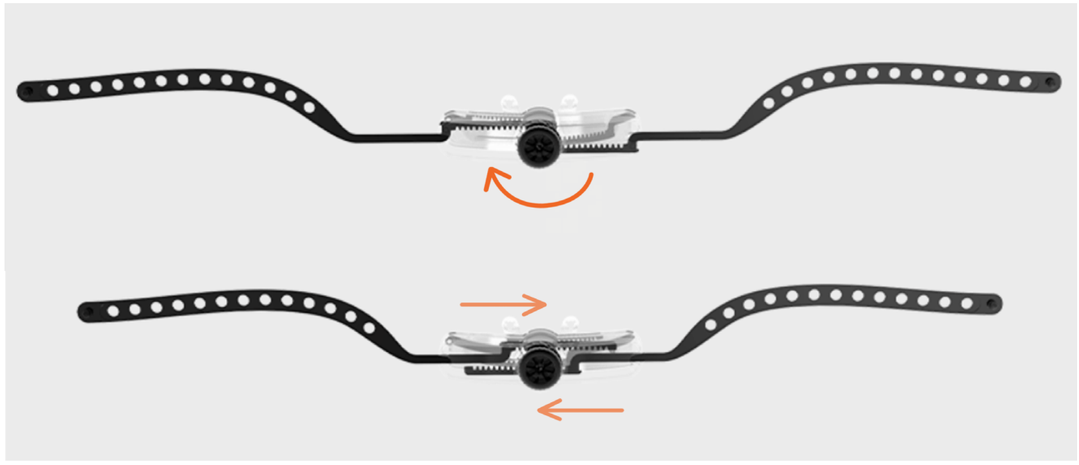


Figure 3.2.4 (2). Working of the helmet adjustment mechanism.

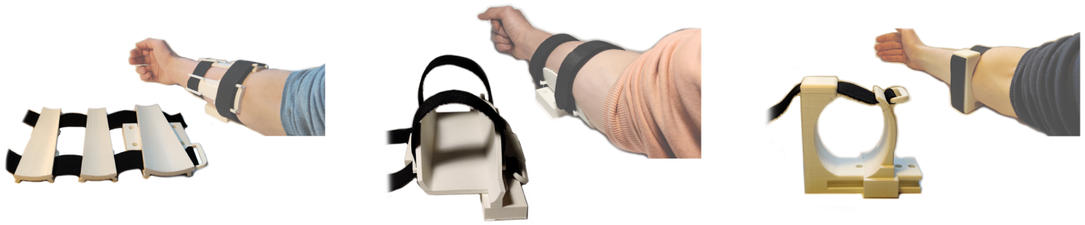


Figure 3.2.5. Forearm fixation concepts.

3.2.2 Forearm fixation

As mentioned in subchapter 2.4.1, the patient's forearm has to be fixated. In this subchapter the different aspects concerning the forearm fixation are shown, consisting of the different concepts, the mechanism, main dimensions and adjustability.

Concepts

For the forearm there were multiple options to fixate it (Appendix K), which in the end also lead to different concepts for the forearm fixation (figure 3.2.5). The concepts were generated based on the market research described above and a brainstorming session and further developed and optimized by making and testing prototypes. Below a short description of each of the concepts can be read.

Concept 1

This concept consists of three parts (one larger; two smaller). The forearm rests on the bottom part, while the two smaller parts are used to enclose the forearm from the top. Two straps are used to tighten the parts against the forearm and fixate it in the end.

Concept 2

This concept consists of two large parts, which cover a large surface of the forearm. The two parts are able to slide into each other, hereby able to account for the variation in arm size. Two straps are used to fix the parts' position and to fixate the forearm.

Concept 3

This concept consists of four parts, two pairs of a 'body' and a 'slider' part. One pair fixates the forearm near the elbow, while the other fixates the forearm near the wrist. Each of the pairs covers a small surface of the forearm. The 'slider' part is able to slide over the body, hereby able to account for the variation in arm size. Per combination one strap is used to fix the body's- and slider's position and to fixate the forearm.

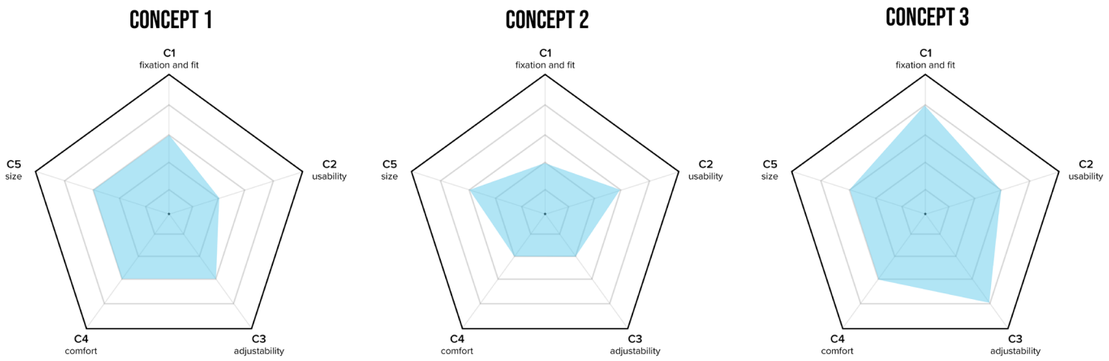


Figure 3.2.6. Hexagon comparison of the forearm fixation concepts.

Selection

Eventually, one concept was selected based on a discussion with S. Buckens (personal communication, December 12, 2019) and on a comparison where the different forearm fixation concepts were evaluated on multiple relevant criteria. Hexagon comparisons were made based on a set of five criteria (figure 3.2.6). Most criteria are based on the focus areas defined in subchapter 1.4; C5 is simply a relevant criteria when comparing the concepts. Looking at the focus areas, C1 and C3 relate to fixation and adjustability, C2 to usability and C4 relates to comfort. The criteria are not listed in order of importance.

A more extensive description of the different concepts and the selection process can be found in Appendix L. In the end the choice was made to use and integrate concept 3 in the product to fixate the forearm. The main reasons why this concept was chosen was because it: 1) was better able to fixate and offered a better fit for the different sizes of forearms; 2) was easy and fast to use. Also, this choice was made as it is hard to cover a large surface of the forearm with one fixation part, as the length of patients' forearms differs (more about this can be read in 'Main dimension') and the shape (cross-section) of the forearm changes along the length (see figure 3.2.7). Furthermore, in this way one fixation part can be positioned closer towards the wrist, hereby more effectively preventing pro- and supination (rotation) of the forearm (S. Buckens, personal communication December 12, 2019).

Final model

Eventually, multiple iterations were made by making prototypes and testing these, leading to the final model of the forearm fixation (figure 3.2.10). An important iteration was that the inside curve of the sliders for the elbow region was made more rounded (figure 3.2.8), while the inside curve of the sliders for the wrist region was made more oval-shaped (figure 3.2.9). This was done because the cross-section of the forearm changes along the length of it (figure 3.2.7). Also, a new mechanism had to be integrated in order to be able to center the arm in the y-direction. More about this can be read in the next subchapter. For an overview of the iterations and different prototypes see Appendix H.

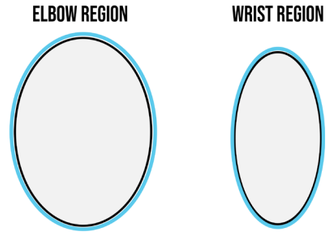


Figure 3.2.7. Different cross-sections for the forearm.

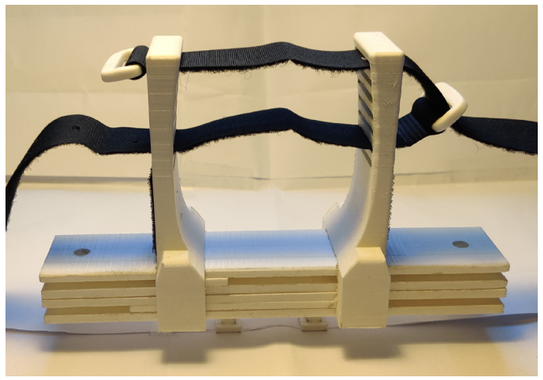


Figure 3.2.8. Fixation for elbow region (left, more rounded).

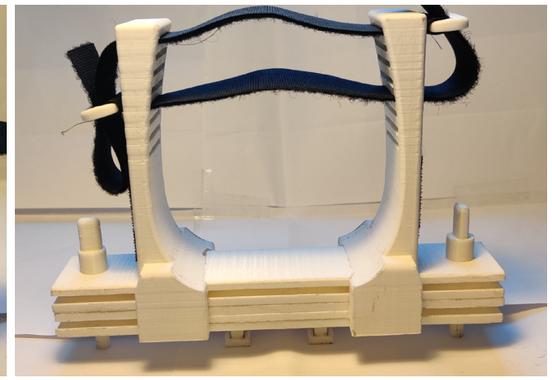


Figure 3.2.9. Fixation for wrist region (right, less rounded).

Mechanism

As was described in subchapter 3.1.2, the forearm needs to be centered (in the y-direction) on the arm standard and in relation to the wrist standard, to make sure all wrist movements are executed symmetrically.

As was concluded out of a product usability test with potential patients (Appendix C), with the initial mechanism this was not possible. Therefore, to meet this requirement, the selected concept for the forearm fixation (mentioned above) needed to be modified. A new mechanism had to be integrated which could facilitate symmetrical movement of the two sliders, resulting in a centered arm in every case. Eventually a new mechanism (figure 3.2.9, based on the clamp mechanism mentioned in the previous subchapter) was designed and integrated, resulting in a new concept for the forearm fixation (figure 3.2.10 and 3.2.11).

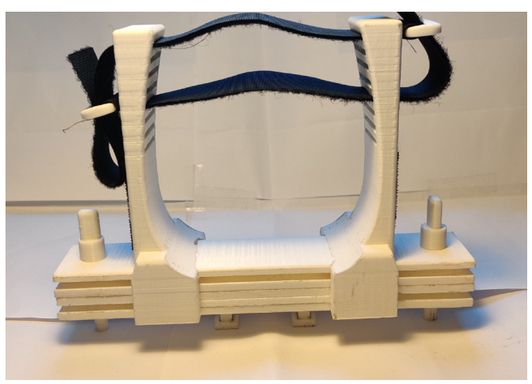


Figure 3.2.10. Final model forearm fixation (elbow) with straps and small pins (open).

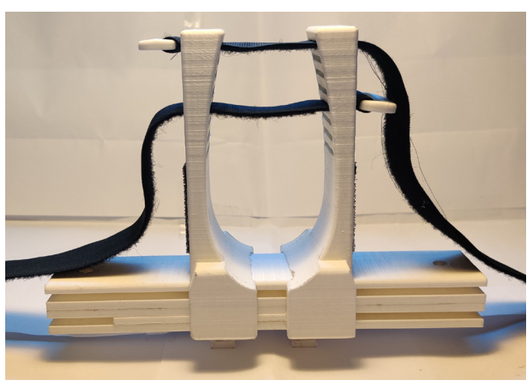


Figure 3.2.11. Final model forearm fixation (elbow) with straps (closed).

In the middle a spur gear is integrated in the body (figure 3.2.12), while both sliders have a rack gear attached to it. While one slider moves over the rails of the body, its rack gear moves the spur gear, also causing the other rack gear (of the other slider) to move towards it. Hereby the symmetrical movement is facilitated.

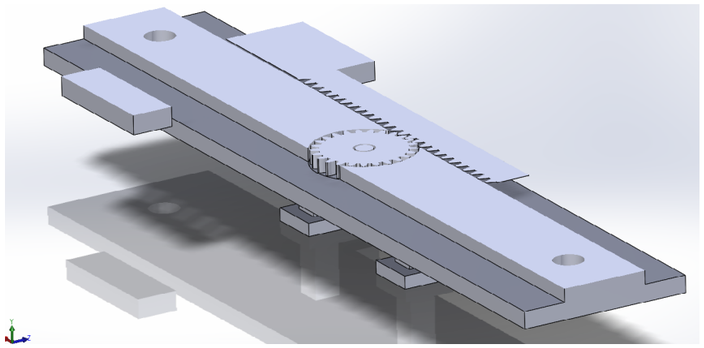


Figure 3.2.12. Bottom half of lower body part with slider (and rack gear) and spur gear.

Main dimensions

To help define the dimensions of the forearm fixation, research was done and measurements were conducted in relation to relevant body parameters (figure 3.2.13). The definition of all parameters can be found in Appendix M; the measurements and variation of the body parameters can be found in Appendix N. More about the dimensions of the forearm fixations can be read in chapter 5.1.4.

For defining the length of the forearm fixation, the variation of the length of the forearm was used. This length ranged from 103 [mm] (P5) to 160 [mm] (P95), resulting in a total variation of 57 [mm]. As all arms need to fit in the fixation, the maximum length would be 103 [mm], as otherwise larger arms would not fit or the fixation had to be adjustable. Eventually, in the final model two smaller parts are used to fixate the forearm, whose lengths are in total (80 [mm]) even less than 103 [mm]. In this way the forearms of all patients fit in the fixations, without making it adjustable.

For defining the width and height of the forearm fixation, the variation of the forearm circumference (near the elbow and wrist) was used. The circumference of the forearm near the elbow ranged from 210 [mm] (P5) to 285 [mm] (P95), while for near the wrist it ranged from 145 [mm] (P5) to 180 [mm] (P95). These values were used in the iterative prototyping process of developing the forearm fixations. Eventually, the variation in forearm width was solved by making it adjustable, with the use of the sliders. For the height of the fixation the P95 values of both forearm circumferences (elbow and wrist) were used, as this was necessary for the double slider adjustment system (also see the next subchapter).

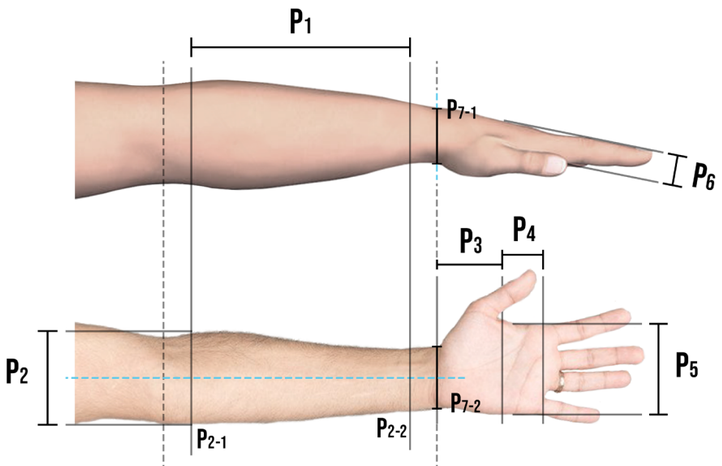


Figure 3.2.13. Important parameters for the arm and hand.

Adjustability

Size

As mentioned in the previous subchapter, two smaller parts are eventually used to fixate the patient's forearm.

For the width and height of the forearm fixation, which relate to the circumference of the forearm, the measurements were only used to give an indication of the required sizes. In the end, the variation of the circumference of the forearm is compensated by using a system with two velcro straps.

As was concluded out of a product usability test with potential patients (Appendix C) the velcro attachment system with one strap did not work as desired. When fastening the strap and fixating the patient's forearm (figure 3.2.14), it seemed to be fixated tightly at first. However, when the forearm applied pressure downwards the sliders were still able to move slightly away from each other, resulting in space for the arm to move and eliminating the fixation (figure 3.2.15).

Because of this reason there has been added an extra velcro strap with which the arm can be fixated tightly. In this system (figure 3.2.10) the upper strap is used to keep the sliders on the same position in relation to each other and to fixate the patient's forearm from the sides (figure 3.2.16). This strap does not touch the arm but goes straight over it. The lower strap is used to fixate the patient's forearm from the top, to prevent rotation and movement upwards of the arm.

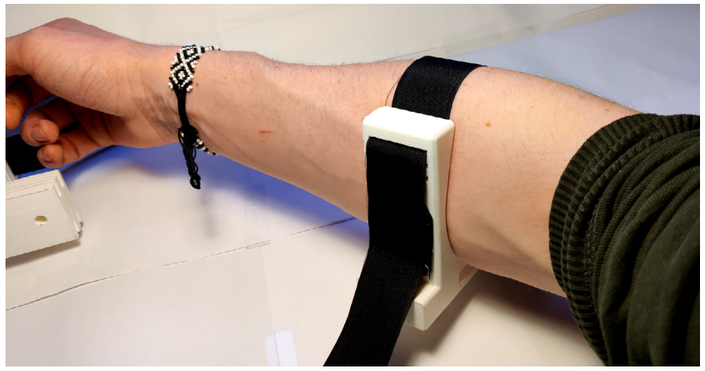


Figure 3.2.14. One strap velcro attachment fastened.

Figure 3.2.15. One strap velcro attachment loosened after applying pressure downwards.

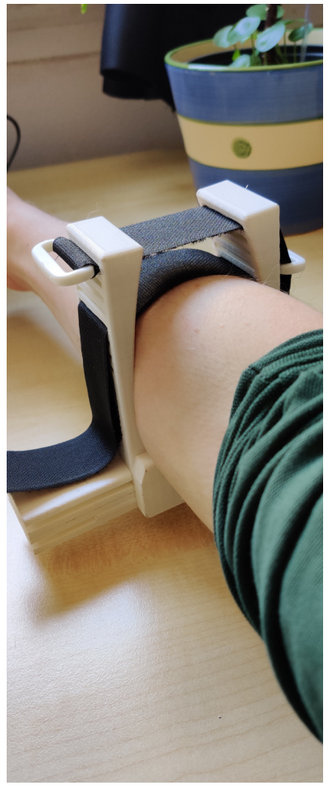


Figure 3.2.16. Double strap attachment system.

Position
As was described in subchapter 3.1.2, the forearm fixation needs to be adjustable in both the x- and y-direction (figure 3.2.17). There is only a small variation in the height of patients' hands (26 [mm], see Appendix N), which is why it was decided to take a fixed z-position (in height). According to S. Buckens (personal communication, February 20, 2020) this should work to position all hands correctly in relation to the wrist standard.

For the y-position, it was eventually decided to integrate the (new) clamping mechanism described previously. This mechanism could facilitate symmetrical movement of two sliders, resulting in a centered arm in every case.

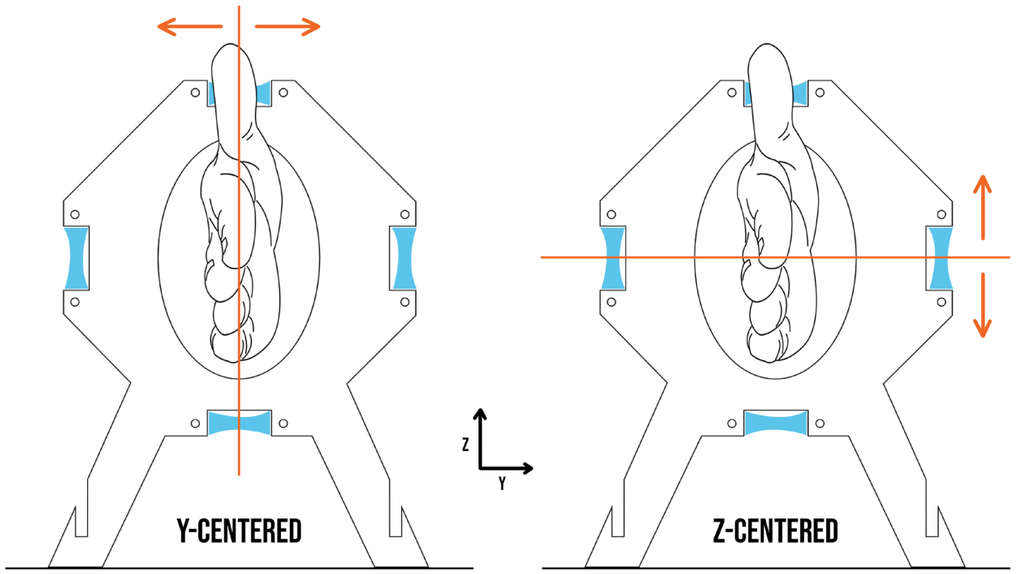


Figure 3.2.17. Hand (and wrist) alignment with wrist standard.

Then finally concerning the x-direction, the patient's wrist needs to be aligned with the wrist standard. In the end this influences the x-position of the forearm fixation.

When a shorter arm is fixated with the wrist aligned with the wrist standard, the forearm fixation should be pushed forward more in order to be able to fixate the arm properly (figure 3.2.18). The same (but the other way around) applies to the case of fixating a larger arm; then the forearm fixation needs to be pushed more towards the back.

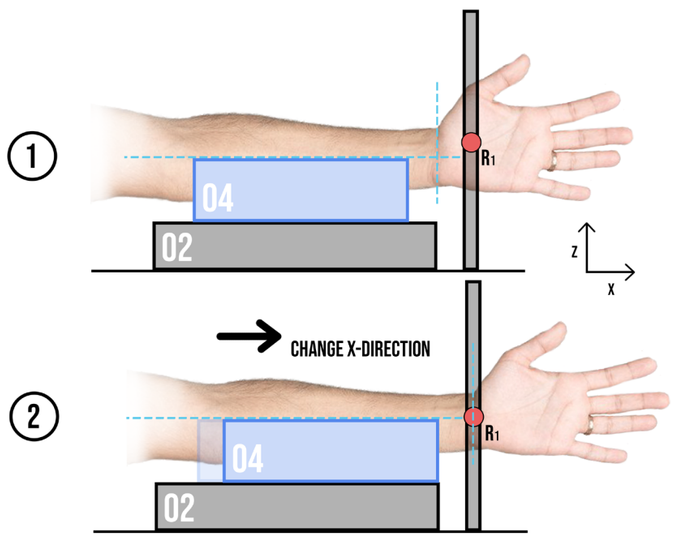


Figure 3.2.18. Forearm fixation adjustment x-position (short arm).

Figure 3.2.19. Hand fixation concepts.

3.2.3 Hand fixation
As mentioned in subchapter 2.4.1, the patient's hand has to be fixated. In this subchapter the different aspects concerning the hand fixation are shown, consisting of the attachment points, the different concepts, main dimensions and adjustability.

Concepts
For the hand there were multiple options to fixate it (Appendix O), which in the end also lead to different concepts for the hand fixation (figure 3.2.19). The concepts were generated with the use of a brainstorming session and further developed and optimized by making and testing prototypes. Below a short description of each of the concepts can be read.

Concept 1
This concept consists of a U-profile, where the hand is enclosed from the sides and supported at the bottom.

Concept 2
This concept of an L-profile, where the hand is supported at one side and supported at the bottom.

Concept 3
This concept consists of two parts, a so-called 'body' part and a 'slider' part. The slider is used to account for the variation in hand thickness, enclosing the hand from both sides and supporting it at the bottom.

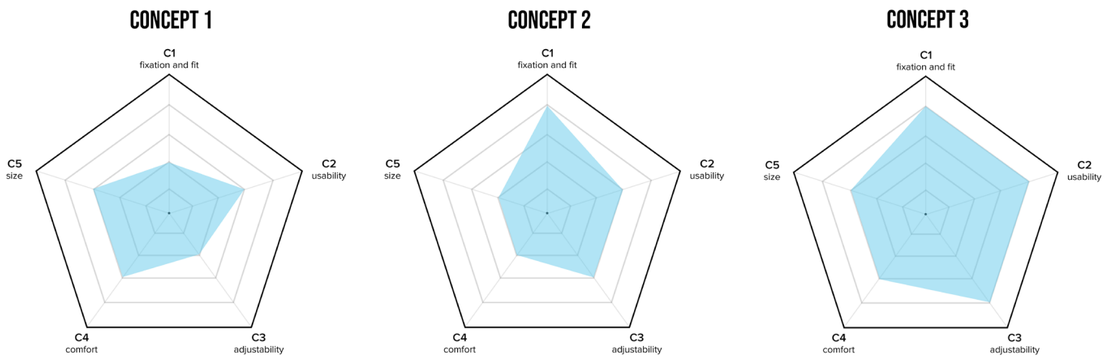


Figure 3.2.20. Hexagon comparisons of hand fixation concepts.

Selection
A more extensive description of the different concepts and the selection process can be found in Appendix P. In the end the choice was made to use and integrate concept 3 in the product to fixate the forearm. The main reasons why this concept was chosen was because it: 1) was better able to fixate and offered a better fit for the different sizes of hands; 2) was easy and fast to use.

On the other hand concept 1 could not fixate different hand sizes well, as its width was not adjustable. Comparing concept 2 and 3, the latter was simply easier and faster to use. The velcro strap of concept 2 was in this case significantly easier to use than the rigid slider part of concept 3.

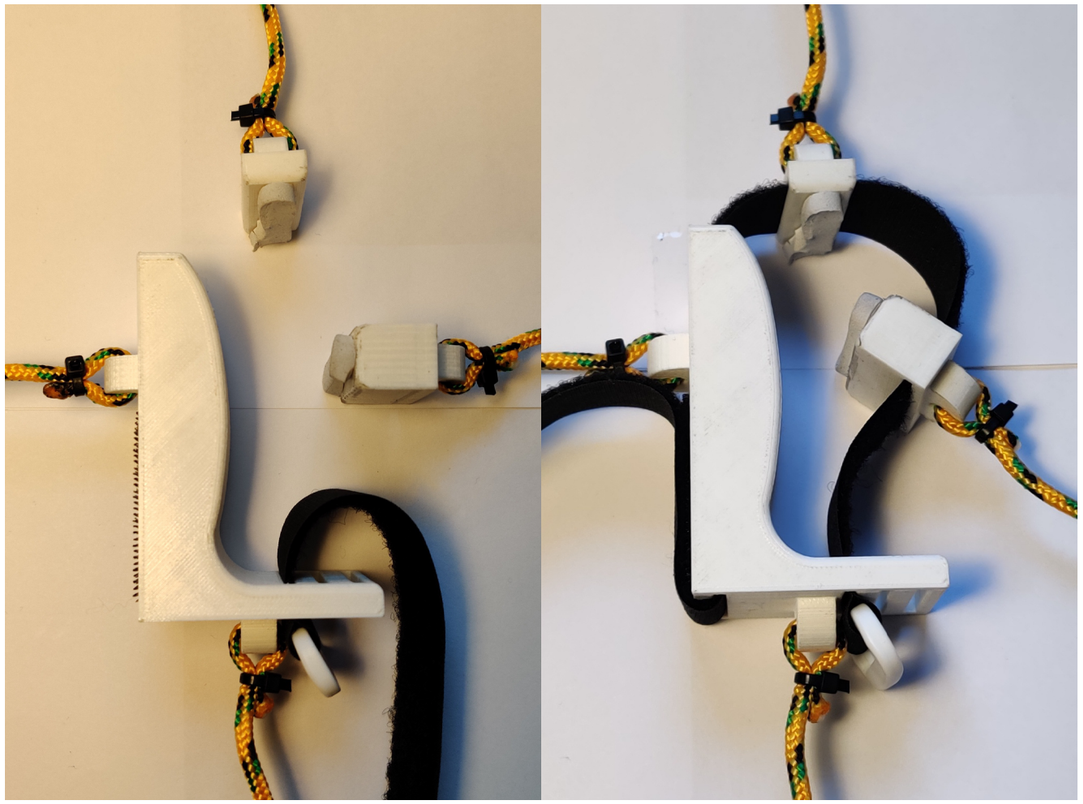


Figure 3.2.21. Final model hand fixation with sliders and strap loose (left) and fastened (right).

Final model

Eventually multiple iterations were made leading to the final model for the hand fixation (figure 3.2.21). For an overview of the iterations and different prototypes see Appendix H.

Attachment points

As also mentioned in subchapter 2.4.1, the contact region of the product with the hand should be at the metacarpal bones (B. van der Heijden, personal communication, November 21, 2019). For the two movements (flexion/extension and radial-/ulnar deviation) the hand fixation has different contact points (figure 3.2.22). The red dots represent the points where the hand fixation should be pulled for deviation; the blue dots for flexion and extension.

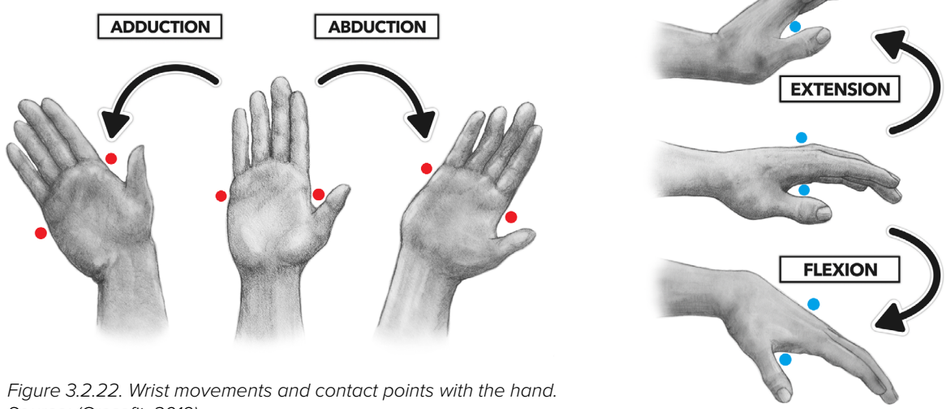


Figure 3.2.22. Wrist movements and contact points with the hand. Source: (Crossfit, 2019).

Concerning the facilitation of the desired wrist movements, these contact points mentioned above can be translated into attachment points for the hand fixation in order to connect with all of the four cables of the cable-pull movement mechanism (figure 3.2.23). These attachment points should be aligned both horizontally (P1 and P2) and vertically (P3 and P4), to ensure symmetrical execution of all wrist movements. According to S. Buckens (personal communication, January 16, 2020) the horizontal attachment points should align with the middle finger of the hand, while the vertical attachment points should simply align with the middle of the hand (seen from above).

Next to the fact that the attachment points need to be aligned, they should also be positioned at a similar distance from the hand (figure 3.2.24). This is also to ensure that all movements are executed perfectly symmetrical.

The position of the attachment points is defined taking into account the variation of hand sizes. The values for P50 are used in order to ensure optimal fit for the largest part of the population. For the horizontal attachment points the average (P50) height of the bottom of the hand to the (middle of the) middle finger is used. According to Dined (2020), the P50 for thickness of the hand (both male and female, 20-60 years old) is 26 [mm]. Therefore, the vertical attachment points should be positioned at a distance of 13 [mm] from the contact surface of the hand (distance ‘x’ in figure 3.2.24).

For the vertical attachment points the average (P50) distance from the bottom of the hand to the (middle of the) middle finger is used. This distance can be calculated by using the (average) width of the hand and subtracting one and a half times the (average) width of the forefinger. According to Dined (2017), the P50 for the width of the hand (‘Dutch adults 20-60, mixed’) is 85 [mm]. In the same database, the P50 for the forefinger width is 17 [mm]. This results in the horizontal attachment points being positioned at a distance of: 85 – 17 – (17/2) = 60 [mm] from the bottom of the hand ((distance ‘y’ in figure 3.2.24).

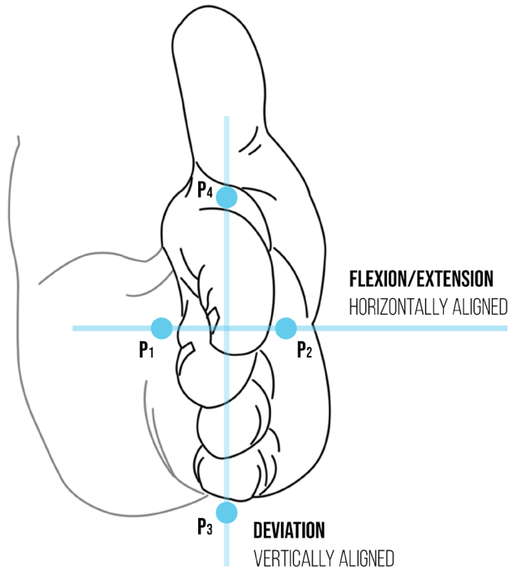


Figure 3.2.23. Attachment points of the hand fixation (pairs of two points per movement plane).

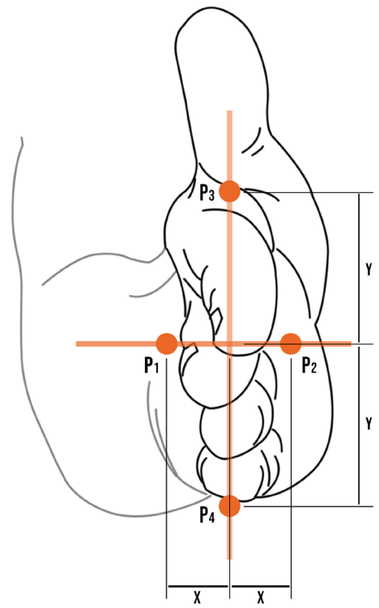


Figure 3.2.24. Symmetrical placement of attachment points (per plane) of the hand fixation.

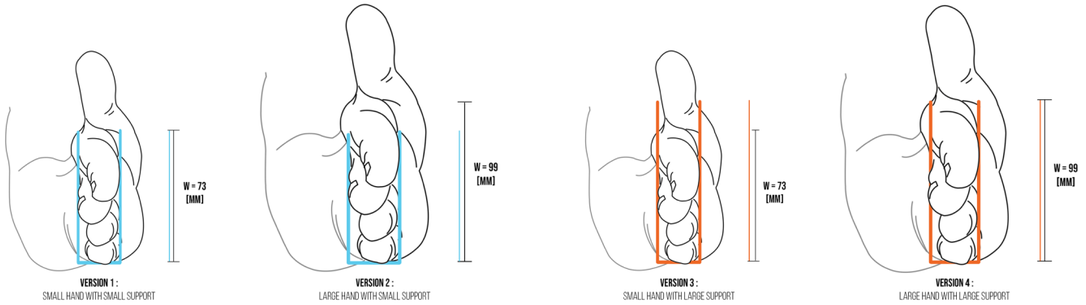


Figure 3.2.25. Different heights for hand fixation (both small- and large hands).

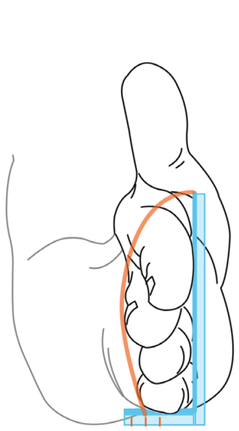
Main dimensions

To help define the dimensions of the forearm fixation, research was done and measurements were conducted in relation to relevant body parameters (figure 3.2.13). As was mentioned before, the definition of all parameters can be found in Appendix M; the measurements and variation of the body parameters can be found in Appendix N. More about the dimensions of the hand fixation can be read in chapter 5.1. The main dimensions of the hand fixation are: 40 (L) x 35 (W) x 73 (H) [mm].

For defining the length of the hand fixation, the variation of the length of the metacarpals was taken into account. This length ranged from 40 [mm] (P5) to 50 [mm] (P95), resulting in a total variation of 10 [mm]. Considering the fact that the patients also need to form a fist with their hand (as mentioned in subchapter 2.4.1) the length of the hand fixation should not be too large, as otherwise smaller hands are not able to make a fist anymore. By taking the smallest measurement for the length of the hand fixation (40 [mm]), all the other measurements automatically also fit in.

For defining the height of the hand fixation, the variation of the hand width (without thumb) was taken into account (figure 3.2.25). This length ranged from 73 [mm] (P5) to 99 [mm] (P95), resulting in a total variation of 26 [mm]. Having a (large) fixation of 99 [mm] high does not work well, as then smaller hands cannot be fixated tightly from the top (figure 3.2.25, version 3). With a hand fixation of an averag height (86 [mm] high) this problem still applies to approximately half of the hands (the smaller ones). On the other hand, in the case of having a (small) fixation of 73 [mm] high, all hands easily fit and can be fixated tightly. For larger hands, the remaining (open) space at the top of the hand can be fixated with the use of the strap. Because of this reason, a height for the hand fixation of 73 [mm] is used.

For the width of the hand fixation, the variation of the hand thickness was taken into account. This length ranged from 19 [mm] (P5) to 35 [mm] (P95), resulting in a total variation of 16 [mm]. For the hand thickness this is quite some difference, which is why the maximum width was taken and it was made adjustable to ensure that all hands can be fixated tightly (also see the next subchapter).



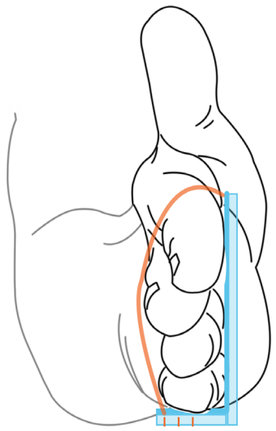


Figure 3.2.26. Strap attachment system to account for variation in hand thickness.

Figure 3.2.27. Different strap slots on hand fixation to account for variation in hand thickness.

Adjustability

As was mentioned previously, the hand fixation is made adjustable to ensure that all hands are fixated tightly and stay still during the movement, which prevents occurrence of motion artefacts.

In the final model for the hand fixation the required adjustability has been solved by using a strap in combination with an L-profile (figure 3.2.26 and 3.2.27). In this case different strap slots for the strap (orange rectangles at the bottom of the hand fixation) could account for the variation in width of the hand and the thickness of the hand at the same time.

3.1.3 Conclusion

Summary

3.2.1

- Existing products which fixate the forearm typically consist of three parts: a splint, a glove and straps or elastic bands. The splint is rigid and is used to fixate the body part. The glove-part around the splint covers it and optimizes fit and comfort for the users. In every splint straps are used for tightening and adaption to different user sizes.
- The helmet mechanism (with movable clamps) can be used and integrated to fixate forearms.

3.2.2

- Three concepts for the forearm fixation were generated; concept 3 was selected to use and integrate in the product (better fit and fixation and faster and easier to use).
- The selected forearm fixations consists of two pairs of two sliders: one for near the elbow region and one for near the wrist region.
- The helmet mechanism (3.2.1) is integrated in the forearm fixation to ensure symmetrical positioning of the forearm on the arm standard.
- Dimensions of the forearm fixations is done by taking into account the variation of the forearm circumference (near elbow and wrist) and the forearm length.
- The adjustability in size of the forearm fixation is facilitated with a double strap system, where the upper strap fixes the position of the sliders while the lower strap fixates the forearm.
- The position of the forearm fixations is adjustable in the x-direction, in order to account for the variation in forearm length.

3.2.3

- Three concepts were generated; concept 3 was elected to use and integrate in the product (better fit and fixation and faster and easier to use).
- For the four wrist movements the hand fixation has different contact points which can be translated to attachment points.
- Dimensions of the hand fixation and positioning of the attachment points is done by taking into account the variation of the hand thickness, hand width (without thumb) and the length of the metacarpals.
- Adjustability of the size of the hand fixation is facilitated with a velcro strap which can be inserted through different strap slots.

Design requirements

- The length of the forearm fixation should not exceed 103 [mm] (**fixation & adjustability**).
- The x-position of the forearm fixation should be adjustable in order to be able to position the patient's arm and hand properly in relation to the wrist standard (**fixation & adjustability**).
- The size of the forearm fixation should be adjustable to optimize comfort and fit for the different patients (**fixation & adjustability**).
- The hand fixation should have four attachment points (two for flexion/extension; two for deviation) to connect with all of the four cables of the cable-pull movement mechanism (**fixation & adjustability**).
- The two pairs of attachment points of the hand fixation should be aligned (horizontally for flexion/extension; vertically for deviation) to ensure symmetrical movement execution (**fixation & adjustability**).
- The attachment points of the hand fixation should be positioned at a similar distance from the hand, to ensure symmetrical movement execution (**fixation & adjustability**).
- The vertical attachment points should be positioned at a distance of 13 [mm] from the contact surface of the hand (with the hand fixation) (**fixation & adjustability**).
- The horizontal attachment points should be positioned at a distance of 60 [mm] from the bottom of the hand (where it makes contact with the hand fixation) (**fixation & adjustability**).
- The length and height of the hand fixation should be 38 [mm] and 73 [mm] respectively (**fixation & adjustability**).
- The width of the hand fixation should be adjustable (with a strap) to account for the variation in hand width (**fixation & adjustability**).

3.3 Safety

This subcomponent focuses on the safety of the product, which relates to probability of the product causing pain or injuries to the patient when being used. Three different aspects of the product related to safety are described, which are: the feedback system, sharp edges and corners and the replacement of parts. Aspects concerning radiation dose are not particularly important for the product, but they are for the process of CT scanning. More about this can be read in Appendix Q.

For this subcomponent literature research was conducted and experts were consulted. An overview of the activities and how their outcomes are used can be seen in figure 3.3.1.

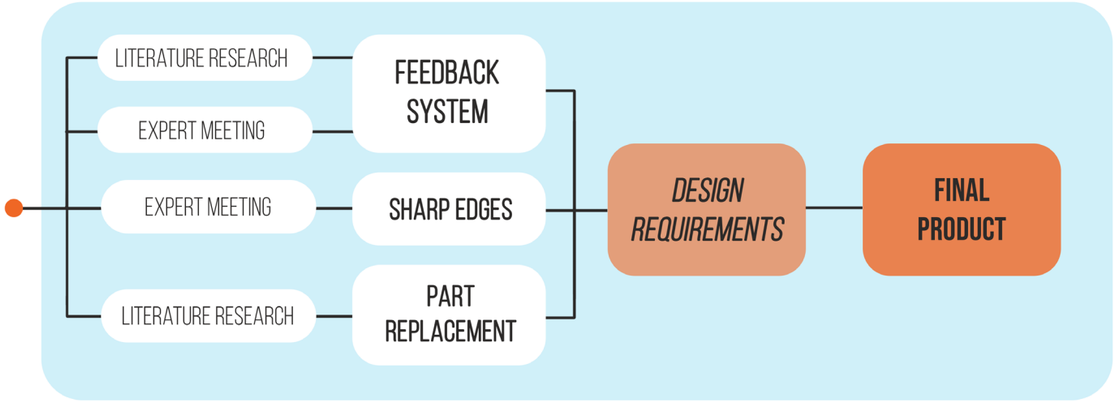


Figure 3.3.1. Overview of activities and outcomes of subchapter 3.3.

3.3.1 Feedback system

As also mentioned in paragraph 2.4.1, there should be integrated a feedback system in the cable-pull mechanism which is able to measure or calculate how much torque the actuator is exerting to facilitate the wrist movement, to prevent the actuator from pulling the patients through their comfortable ROM and possibly even injuring them in the end.

Strain gauge

At first it was assumed that the measurement of this tension could for example be done by using a strain gauge setup (figure 3.3.2) where the strain gauges have to be attached to a small rigid plate. Subsequently, the two sensors have to be soldered onto cables and connected with an amplifier (which is in the end connected to an Arduino).

However, as was stated by M. Verwaal (personal communication, January 21, 2020), it takes too much effort and expertise to use these strain gauges and integrate them in such a feedback system. According to Verwaal, even experienced electronic experts could still have a hard time completing these steps. This is why he recommended to use load cells instead, which are significantly easier to use and integrate in the feedback system, as in these components strain gauges are already implemented. More about these sensors can be read in the next subparagraph.

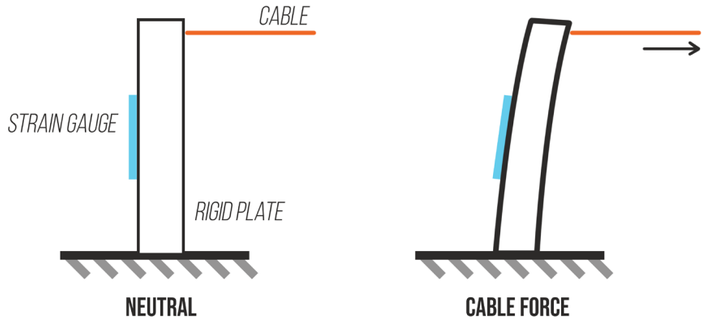


Figure 3.3.2. Strain gauge setup in cable pull mechanism.

Load cell

A load cell (figure 3.3.3) is a force transducer, which converts a force (e.g. pressure, torque, compression or tension) into a measurable electrical signal (Omega, 2018). The working of the load cell is quite simple: if the force applied to it increases, the electrical signal also increases (proportionally). There are many different kind of force sensors, but these strain gauge load cells are the ones most commonly used.

There are different versions of the load cells, each one representing a different maximum amount of kilograms they are able to withstand. The one on the picture for example is able to carry a maximum load of 1 [kg]. For the product the load cell version should also be considered, as it needs to be able to carry all forces working on it caused by the cable tension. Also, selecting a load cell which is able to carry for example a load of 50 [kg] would not be suitable, as the measurement range is not proportional with the actual forces working on the load cell.

Based on the weight distribution of the human body (Tözeren, 2006), the database of Dined (2020) and the advice of M. Verwaal (personal communication, January 21, 2020) a load cell able to carry a load of 5 [kg] was selected to use and integrate in the product. More information about this calculation can be found in Appendix R.

In order to use such a load cell in combination with an Arduino, an HX711 amplifier sensor (figure 3.3.3) (or comparable) has to be used. This sensor is used to amplify the electrical signal from the load cell so that it can be accurately read out by the Arduino in the end (M. Verwaal, personal communication, January 21, 2020).

As can be seen in figure 3.3.3, the load cell can be attached by using one of the screw holes. By fixating the load cell at one side and pulling or pushing at the other side, tension or compression can be measured respectively. Eventually the load cell is used to measure the cable tension on the cables used to move the wrist into the desired directions. More about how this load cell can be integrated into the device is explained later in subchapter 3.4.5.

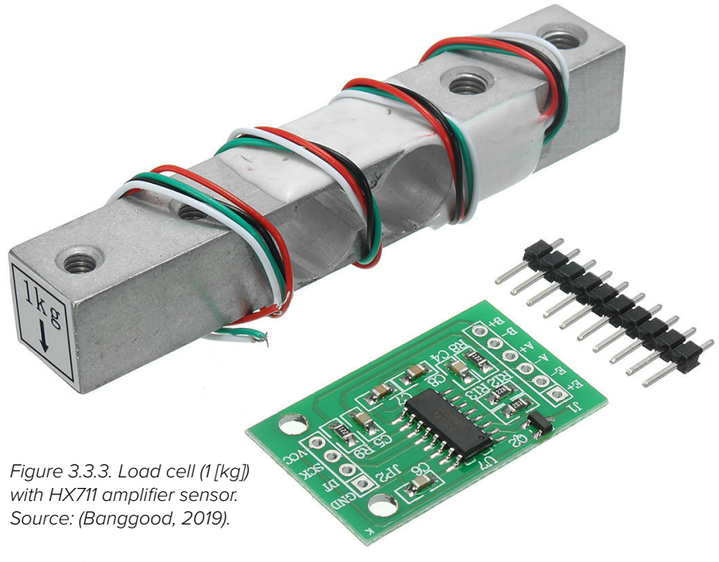


Figure 3.3.3. Load cell (1 [kg]) with HX711 amplifier sensor. Source: (Banggood, 2019).

3.3.2 Sharp edges

During usage of the product the radiologist, laboratory technician and the patient come in direct contact with several parts of the product. The radiologist and laboratory technician come in contact with all parts, while the patient mainly comes in contact with the forearm- and hand fixation. As was concluded out of a discussion with S. Buckens and S. Hummelink (personal communication, December 12, 2019), these parts cannot have sharp edges or corners or a rough surface, as this may result in pain or even small wounds for either one involved. Especially for the patient this is important, as this could in the end also negatively influence their hospital experience and even result in legal action.

Because of this reason, any edges or corners of the parts the patient comes in direct contact with should be rounded. Additionally, any rough surfaces of these parts should be sanded.

3.3.3 Part replacement

In the scenario where the device is being used for multiple times per day, the different parts of the product might deteriorate after a certain amount of time (Ríos et al., 2018). Obviously this reduces the quality of the parts and this could affect the safety and the life span of the product. For example, in a worst-case scenario the cable which is attached to the hand fixation might snap during passive movement of the patient's wrist, causing the hand to fall and possibly even result in an injury for the patient.

According to Ríos et al. (2018) a solution for this problem would be to design the product in a way that the product can be disassembled and the different parts can be replaced. In this case any deterioration of parts has to be monitored regularly to determine if the part should be replaced or not. Next to this, it is also important to carefully select the materials of all parts, for them to be as durable as possible. In this way all parts of the device can last for a long period of time, while they also have to be checked less regularly.

Looking at the system, there are two parts which tend to deteriorate fastest during usage. On the one hand the cables which are connected to the hand fixation and the operating system tend to deteriorate relatively a lot. During usage of the device there is always tension on these cables, causing them to wear out, become less strong and possibly even elongate over time. For the product it is therefore important that cables are selected to be integrated in the product which are strong and durable to minimize the deterioration.
On the other hand the attachment systems of the fixations is something which tends to deteriorate relatively fast. During usage of the product the attachment systems are fastened and loosened more than ten times per day. Here also applies that it strongly depends on which kind of attachment system is chosen, how severe and fast the deterioration is. For example, a ratchet attachment mechanism (e.g. also used in skates) will suffer these effects significantly less than a velcro strap attachment. Because of this reason in the product there should be used a high quality and durable attachment system to minimize the deterioration.

2.4.2 Conclusion

Summary

3.3.1

- Instead of strain gauges, one or more load cells can be used to measure the cable tension on the cables responsible for executing the wrist movements. Load cells have strain gauges already implemented and are therefore easier to use and integrate in the product.
- A 5 [kg] load cell is selected to integrate in the product to measure the cable tension.
- The electric signal from the load cells has to be amplified using the HX711 sensors.

3.3.2

- Any edges or corners of the parts the radiologist, laboratory technician(s) and patients comes in direct contact with should be rounded. Additionally, any rough surfaces of these parts should be sanded.

3.3.3

- The product parts tend to deteriorate after a certain amount of time of daily usage. Therefore vulnerable parts (e.g. cables and straps) should be supervised.
- Making the product modular allows the parts to be replaced rather easily.

Design requirements

- The product should use one or more load cells (5 [kg], in combination with HX711 amplifier sensors) as a feedback system to measure the cable tension on the cables (of the cable-pull mechanism) used to facilitate the wrist movements (**safety**).
- The product should not have sharp corners or edges or rough surfaces in order to prevent the radiologist, laboratory technician(s) and patients hurting themselves (**safety**).
- The product should be designed in a modular way, making it easier to disassemble and replace parts (**safety**).
- For the different parts of the product, high quality and durable materials should be selected, in order of the product to last for a long period of time (**safety**).

3.4 Actuation & transmission

This subcomponent focuses on the actuation and transmission of the product, which relates to the automated part of the product which eventually facilitates the passive movements of the wrist. For this subcomponent literature research was conducted, prototypes were developed, tested and evaluated and experts were consulted. An overview of the activities and how their outcomes are used can be seen in figure 3.4.1.

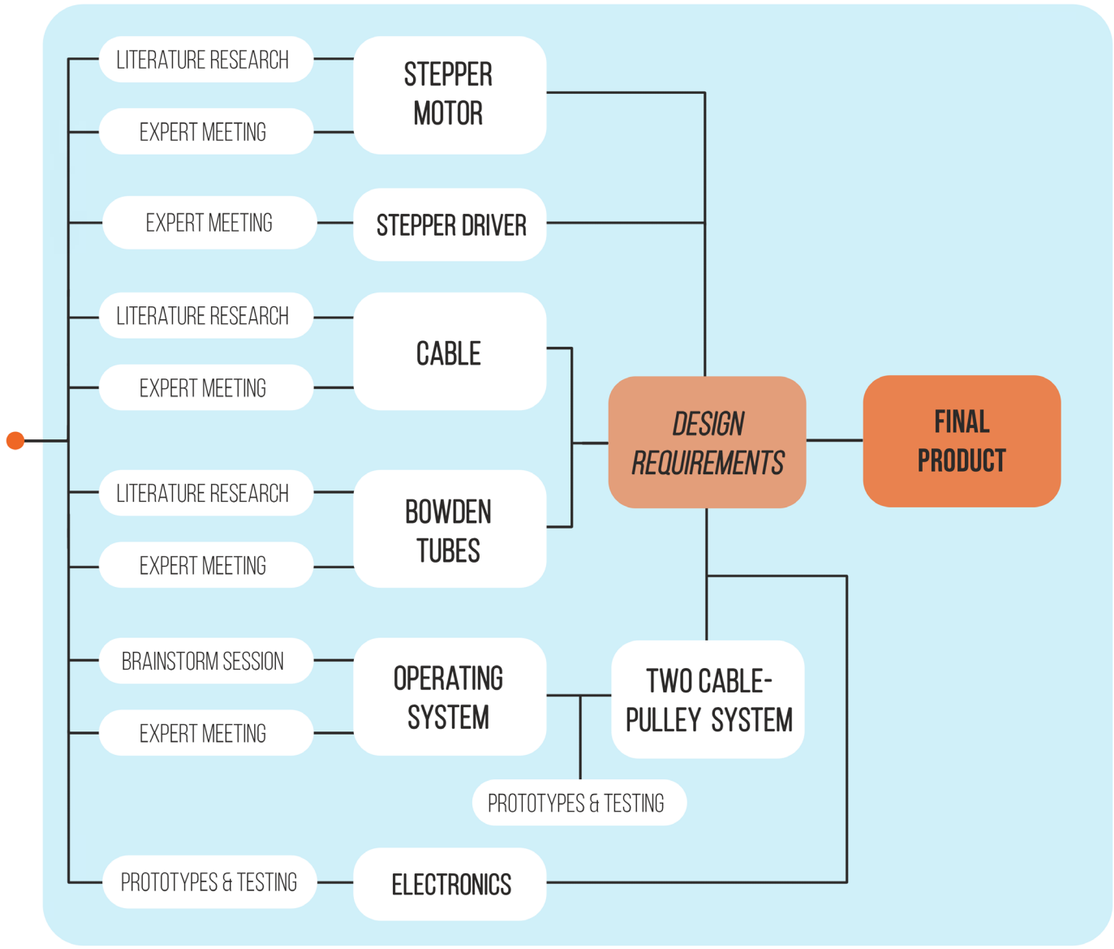


Figure 3.4.1. Overview of activities and outcomes of subchapter 3.4.

3.4.1 Stepper motor

As mentioned in subchapter 2.4.1 one or more actuators need to be used and integrated in the product in order to facilitate the passive wrist movements. Based on literature research it was concluded that an electric actuator was most suitable for the product in terms of hygiene, performance and costs (see Appendix S).

Based on literature and an expert consultation with electronics expert M. Verwaal (personal communication, January 21, 2020) from the IDE faculty, the specific electric actuator was selected (see Appendix T). Out of the different electric actuators (servo motor, stepper motor and RC servo motor) the stepper motor was in this case the most suitable option, as these motors are affordable, durable and allow for slow- and high precision movements. Servo motors on the other hand are more expensive and a better choice for systems requiring high speed, high acceleration, and high accuracy (The Green Book, 2013).

Based on advice from M. Verwaal (peronal communication, January 21, 2020) the stepper motors from the NEMA-series were selected to continue with as they are widely used in professional projects. Additionally, the motors are safe, reliable and durable and come in different versions, mainly varying in the maximum current, voltage, rotating torque and price.

Initially the NEMA 17 (figure 3.4.2) was bought as this motor is affordable and the most commonly used stepper motor. Subsequently, this motor was used and integrated in electronic prototypes and eventually tested to see if this motor was strong enough to facilitate all wrist movements through their entire ROM (see Appendix U). During testing it became clear that the NEMA 17 stepper motors were powerful enough to move the participants' hands in all directions. Therefore, in the product NEMA 17 stepper motors should be used as the actuators to facilitate the passive wrist movements.

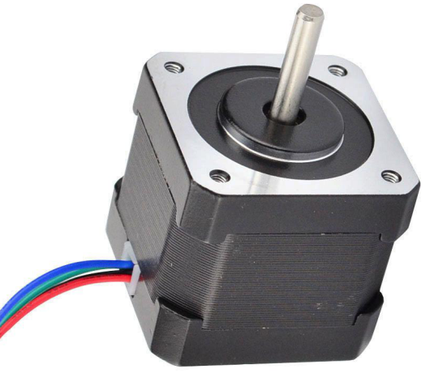


Figure 3.4.2. NEMA 17 stepper motor with cable. Source: (Kehan, 2003).

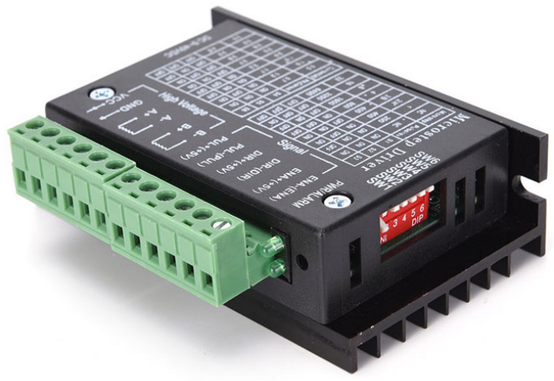


Figure 3.4.3. TB6600 stepper driver. Source: (Makerlab, n.d.).

3.4.2 Stepper driver

In order to be able to control and operate a stepper motor with Arduino, a stepper driver should be used. More information about the working of a stepper driver can be found in Appendix V.

Based on a consultation with electronics expert M. Verwaal (personal communication, January 21, 2020) from the IDE faculty, the most suitable stepper driver was selected. In this process three different stepper drivers were compared on aspects like size, price and features (see Appendix V).

Eventually the TB6600 stepper driver was selected out of these three drivers for a few reasons. First of all the driver simply offers more microstep resolutions, meaning the stepper motors can be controlled more precise with this driver. Secondly, the current the smaller drivers can deliver is simply too low for the motor's function in the product. The motors might have to work quite hard in order to reach the full ROM of the patient's wrist, also requiring a higher current.

Thirdly, in this product's context (hospital) a more professional operating unit is required. When using one of the two cheaper drivers the chances are high the drivers get overheated (fast). As this product is going to be used multiple times per day and it has to function within a clean and safe environment, overheating is something which is simply not tolerated in the usage process.

3.4.3 Cable

As mentioned in subchapter 3.1.2, in the cable-pull mechanism four cables are used to pull the wrist into the four desired directions. In this first prototype a simple twine rope (figure 3.4.4) was used as cable, to simply demonstrate the working principle of the mechanism. However, this rope was not strong enough to withstand the forces working on it as a result of facilitation of the passive movements. Also, the different threads of the rope fell apart quite quickly, causing the rope to disintegrate.

Based on advice from S. Hummelink (personal communication, December 12, 2019) and J. Molenbroek (personal communication, January 13, 2020) eventually a nylon cable (4 [mm] thick) was selected to use and integrate in the product (3.4.5). This cable can carry more weight and has a more professional look. Also this cable tended to disintegrate at the ends (figure 3.4.6, left), but in the prototype this was solved by burning the ends to solidify them (figure 3.4.6, right). In the final product for implementation in the hospital this has to be solved in a more professional (and cleaner) way,

for example with the use of a plastic rope clamp (figure 3.4.7). Also, when applying forces to the ca-ble it tends to elongate. This elongation was tested and turned out to be 4.11 [mm] for a P95 male hand (weight) (see Appendix W). With the use of a test with the product it became clear that this elongation did not have any negative influence on the facilitation of the passive wrist movements. Still this has to be investigated further to make sure this cable elongation has no negative effect on the functioning of the product (also see chapter 7.2).

Figure 3.4.4. Simple twine used as cable for demonstration of the cable-pull mechanism.

Figure 3.4.5. Nylon cable as optimization of twine rope.

Figure 3.4.6. Disintegrated (left) and solidified end of the cable (right).

Figure 3.4.7. Plastic rope clamp. Source: (Nautiline, n.d.).

3.4.4 Bowden tubes

As mentioned in subchapter 3.1.2, from the points where they are attached to the hand fixation the cables need to be maneuvered over the wrist standard to the back of the product where they are connected to the stepper motors. In this process it has to be made sure the cables do not interfere with other parts of the product, requiring the cables to be maneuvered freely and in an organic way.

However, the cables need to be tight and under tension all the time. This would mean that the cables could only be guided towards the back in straight lines and by using guiding pieces (i.e. pulleys). Based on an expert meeting with D. Bosboom (personal communication, January 16, 2020) Bowden tubes (figure 3.4.8 and 3.4.9) were used and integrated in the product to solve this problem. With these Bowden tubes the cables can make smooth turns and can be guided to every preferred spot quite easily. Next to that, the tubes protect the cables from wearing out (D. Bosboom, personal communication, January 16, 2020).

Transparent rubber Bowden tubes of different sizes (figure 3.4.8 and 3.4.9) were tested regarding how fluently the cable was able to flow through. Eventually the optimal diameter (outside: 10 [mm]; inside: 7 [mm]) was selected (figure 3.4.10), as with this the optimal balance between tube size and cable movement freedom was acquired. In case when the cables suffer from friction inside the tube, Teflon spray could be used to counteract this (D. Bosboom, personal communication, January 16, 2020).

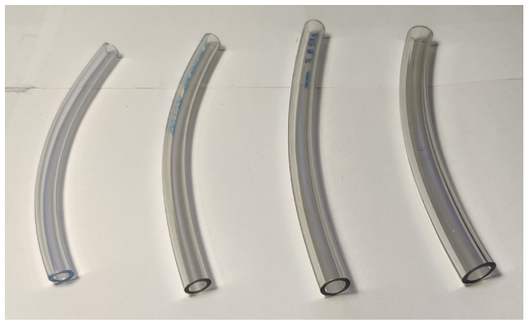


Figure 3.4.8. Multiple sizes for the rubber tube Bowden tubes (top view).

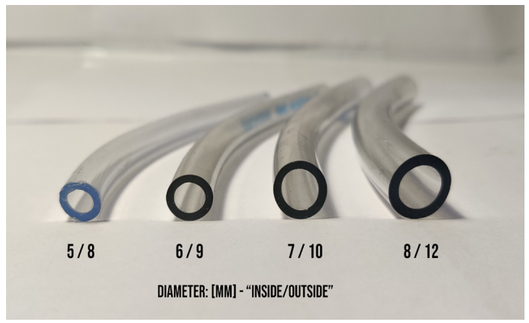


Figure 3.4.9. Multiple sizes for the rubber tube Bowden tubes (front view).

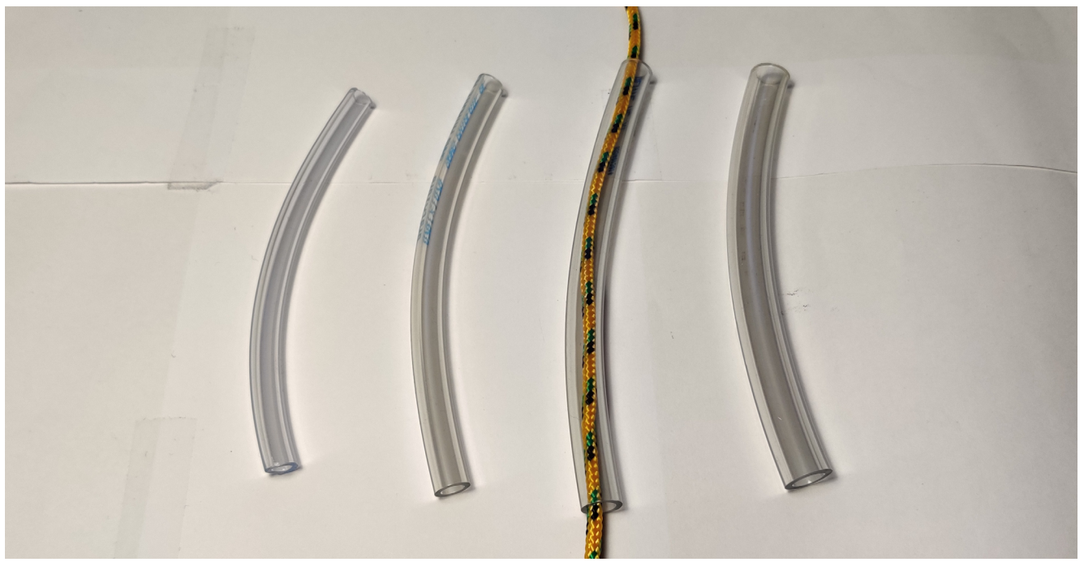


Figure 3.4.10. Selected rubber tube as Bowden tube with nylon cable through it.

3.4.5 Operating system

In subchapter 3.1.2 the movement mechanism was selected, resulting in the cable-pull mechanism being integrated in the product. Still, when looking at this mechanism, there are multiple possibilities concerning how the cables are driven, how the cables are connected to the motors and how the tension on the cables is measured. In this subchapter three concepts are described and compared, of which one is selected to continue with.

Concepts

For the operating system eventually three concepts were generated. The concepts were generated with the help of inspiration acquired from a private brainstorm session and an expert meeting with S. Buckens and D. Bosboom (personal communication, March 12, 2019). The concepts were developed and evaluated by making fast prototypes and testing them. Below a short description of every concept is given; for more information see Appendix X.

Concept 1: Four cable system

The first concept makes use of four cables which are all connected to 'their own' motor. Each of the four attachment points of the hand fixation is connected to one cable; every cable is at the back connected to one motor and one load cell (figure 3.4.11). From the hand fixation, eventually every cable is lead downwards to the back, at the correct height in relation to the stepper motor. This can be done with the use of bowden cables. In the system every cable is operated separately and the cable tension is therefore also measured on every cable separately.

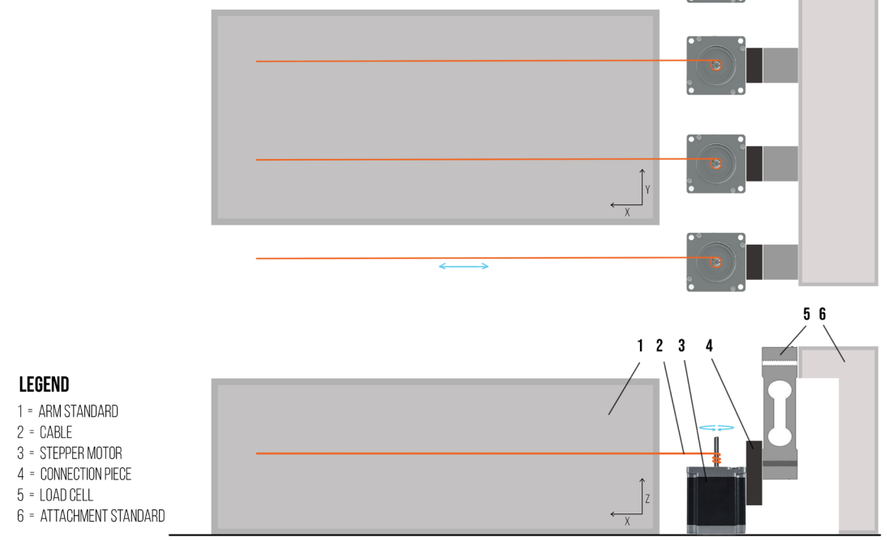


Figure 3.4.11. Setup four cable system: top view (top) and front view (bottom).

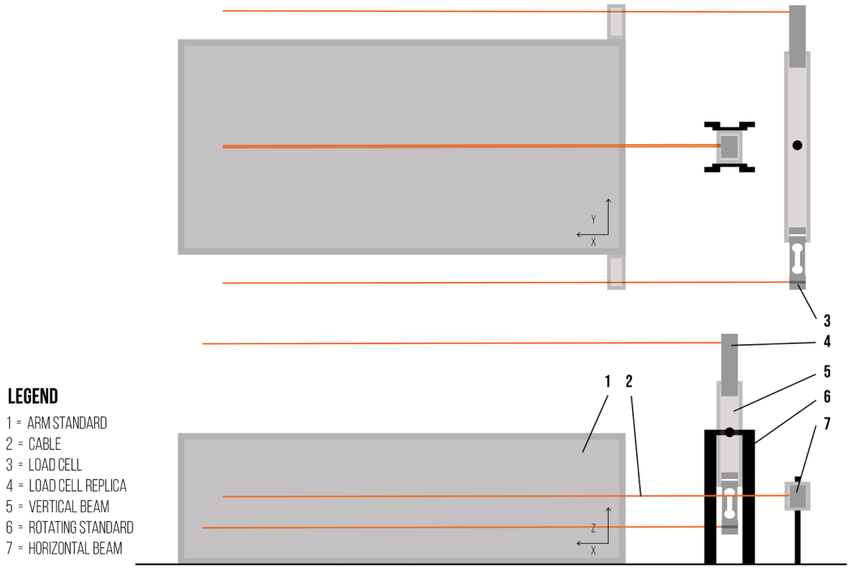


Figure 3.4.12. Setup two cable-lever system: top view (top) and front view (bottom).

Concept 2: Two cable-lever system

The second concept makes use of four cables which are (in pairs of two) connected to one motor. For movement in each plane there are two pieces of cable, one motor and one load cell, meaning there are four pieces of cable, two motors and two load cells in total. At the back of the device there is something like a lever (or puppet) system, where two cables are connected to both ends of a beam (figure 3.4.12). Both beams are driven by their own motor, however this is not visualized in this figure. The horizontal beam facilitates the horizontal (flexion and extension) movement, while the vertical beam facilitates the vertical (radial- and ulnar deviation) movement.

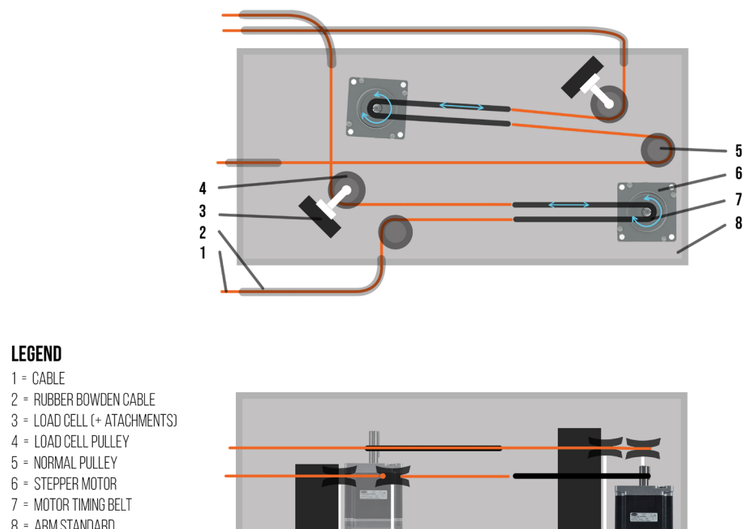


Figure 3.4.13. Setup two cable-pulley system: top view (top) and front view (bottom).

Concept 3: Two cable-pulley system

The third concept makes use of two cables which are each connected to one motor. For movement in each plane there is one cable, one motor and one load cell. In the box of the arm standard there is a pulley system (figure 3.4.13) which connects the side cables (for flexion and extension and the upper and lower cable (for radial- and ulnar deviation) to each other.
From the hand fixation, eventually every cable is lead downwards to the desired spot in the back, at the correct height in relation to the stepper motor. This can be done with the use of Bowden tubes. In the system the cables for flexion and extension are positioned slightly lower than the cables for deviation, to create space for the cables to pass each other.

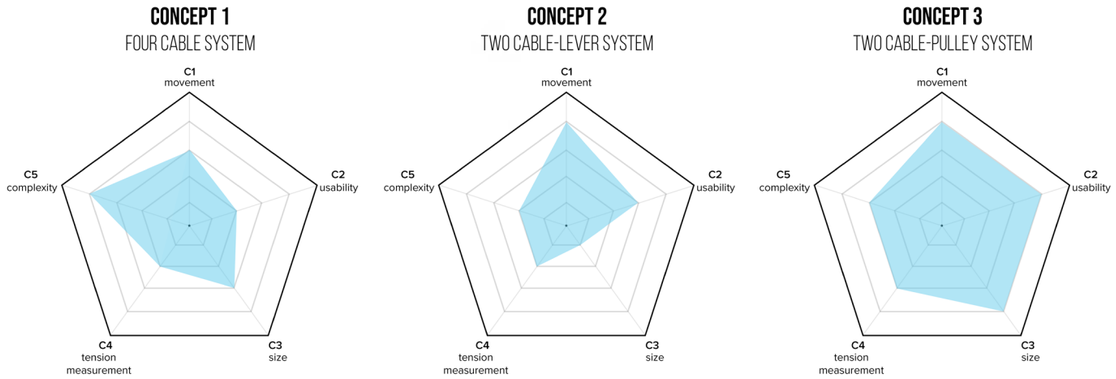


Figure 3.4.14. Hexagon comparison of operating system concepts.

Selection

In order to have a clear comparison between the different concepts, hexagon comparisons were made based on a set of five (instead of six, subchapter 2.3) criteria (figure 3.4.14). Most criteria are based on the focus areas defined in subchapter 1.4, but two (C3 and C5) are simply a relevant criteria when comparing the concepts. Looking at the focus areas, C1 relates to movement, C2 to usability and C4 relates to safety. The criteria are not listed in order of importance.

A detailed overview of all positive and negative aspects of each concept and a more extensive explanation on the selection of the movement mechanism can be seen in Appendix Y.
Looking at the hexagon comparison it becomes clear that concept 3 scores significantly higher (especially on criteria 2 and 3) than the other two concepts. The concept is easier to use and requires significantly less space to work. Concept 3 scores slightly higher on C4 because the setup with the load cell and the calculation of the cable tension on the pulley (and the resulting force) is an easier and more accurate way to measure the cable tension. Concept 3 scores slightly lower on C5 because it is still a bit complex to integrate all components into the arm standard. To ease this process, the arm standard's dimensions have to be increased.

Still, concept 3 scores significantly higher (overall) than concept 1 and 2; because of this reason this concept is selected to continue with.

Two cable-pulley system

Components

As mentioned above, this concept makes use of two cables which are each connected to one motor. For movement in each plane there is one cable, one motor and one load cell. In the box of the arm standard there is a pulley system which connects the side cables (for flexion and extension (figure 3.4.15)) and the upper and lower cable (for radial- and ulnar deviation) to each other. Deviation works practically the same as flexion and extension. Rotation of the motor and movement of the cables to one side results in radial deviation, while the opposite movement results in ulnar deviation.

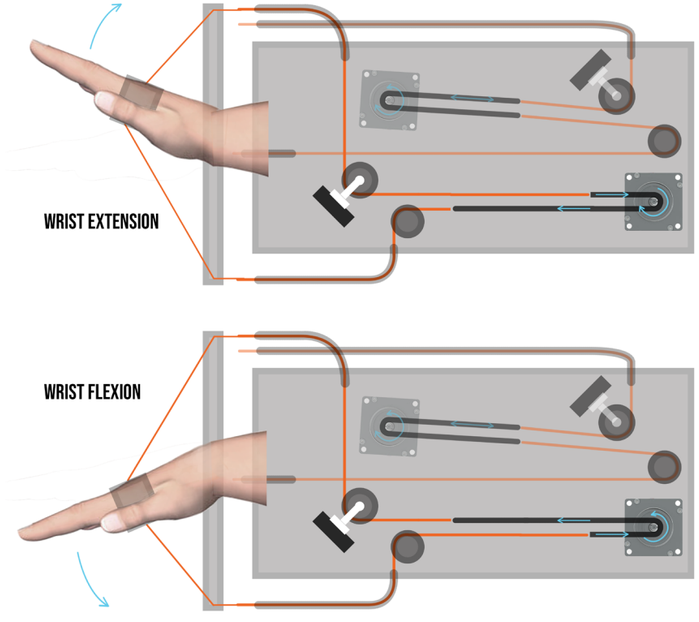


Figure 3.4.15. Wrist flexion- and extension by two cable-pulley system.

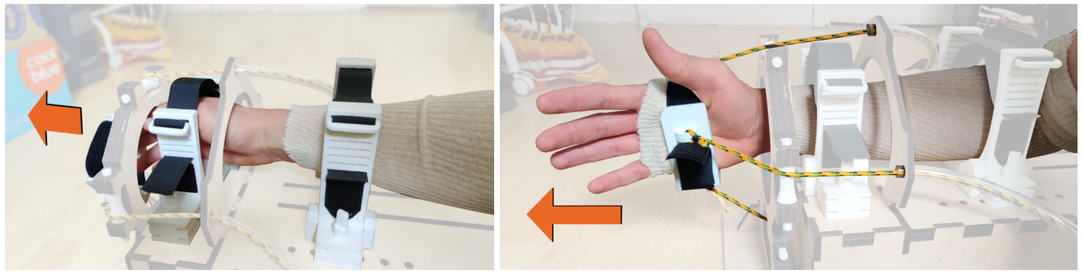


Figure 3.4.16. Patient's arm pushed forward through the fixations in order to acquire desired cable tension.

Cable length

In this concept the cables have a fixed length, which are perfectly adjusted so that the hand fixation is positioned in the correct starting position (i.e. in the middle of both planes). For the patient to start in the correct position with the right amount of tension on the cables, it is important to push their arm and hand far enough through the forearm fixations and wrist standard (figure 3.4.16). The radiologist and laboratory technician will in this case define if the patient's arm is pushed far enough through and if the desired cable tension is reached.

However, there exist differences between people in their distance from wrist to the metacarpals (where the hand fixation is positioned). This distance was measured among people from the faculty (same study as in subchapter 3.2.2 and 3.2.3, see Appendices M and N). The variation for this length ranged from 60 [mm] (minimum) to 75 [mm] (maximum), resulting in a total difference of 15 [mm].

According to S. Buckens (personal communication, March 12, 2020) this distance is too small to integrate an adjustable feature with which the entire length range can be realized. Thus, one value had to be selected, which is why different possible scenarios were compared (figure 3.4.17).

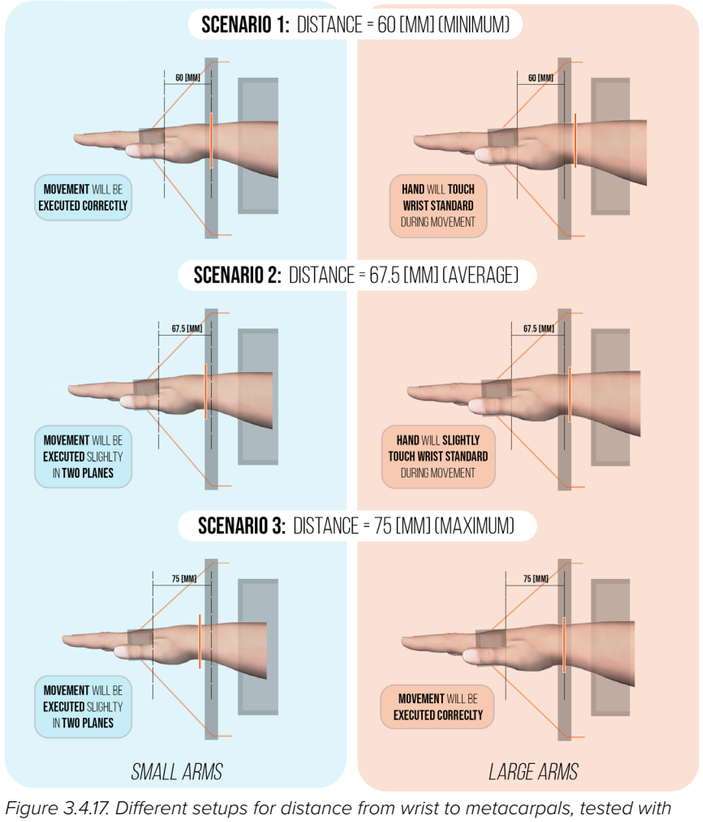


Figure 3.4.17. Different setups for distance from wrist to metacarpals, tested with small and large patients (arms and hands).

In scenario 1 a distance from wrist to the metacarpals of 60 [mm] is taken. This works perfect for the smallest arms, but not for all arms larger than these. The wrists of these arms will be positioned not far enough through the wrist standard, eventually causing the hand to touch the wrist standard during movement.

In scenario 2 an average distance of 67.5 [mm] is taken. This works perfect for the average arms, but not for the other half of the arms (both smaller and larger). The smaller arms will be positioned too far through the wrist standard, slightly causing movement in two planes (as described in subchapter 3.1.2). The larger arms will still be positioned not far enough through the wrist standard, again causing the hand to touch the wrist standard during movement.

Finally, in scenario 3 the maximum distance of 75 [mm] is taken. This works perfect for the larger arms, but not really for the smaller arms. The arms will be positioned too far through the wrist standard, slightly causing movement in two planes. However, this effect will still only occur slightly as the wrist is only positioned 15 [mm] in front of the wrist standard (worst-case scenario). Also this weighs up to the drawback of the wrist hitting the wrist standard during movement (S. Buckens, personal communication, March 12, 2020).

To conclude, for the final cable length it is best to use the maximum value for the distance of the wrist to the metacarpals (beginning of the hand fixation): 75 [mm]. The distance from the beginning of the hand fixation to the attachment point of the cables has to be taken into account here as well, as this is the point where the cable force acts on and which eventually causes the hand (and wrist) to move. This distance turned out to be 20 [mm] (also see subchapter 3.2.3 and subchapter 5.1.5).

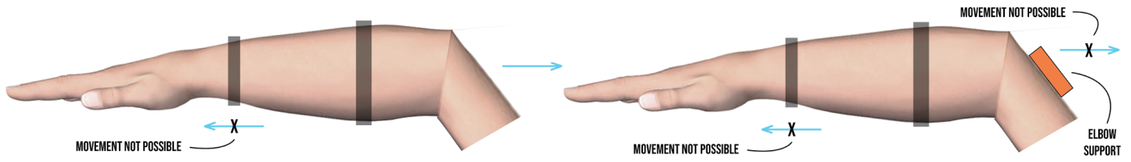


Figure 3.4.18. Elbow support at the back of the arm to prevent moving backwards.

Elbow support

While facilitating the passive movements, it is important that the patient's arm stays in this position the entire time, in order to keep the right amount of tension on the cables. Because of this, an elbow support should be integrated in the concept. This component should be positioned at the back of the upper arm of the patient (around the elbow) (figure 3.4.18). The support prevents the arm from sliding backwards and therefore keeps it in the correct initial position. Moving forwards is already impossible, as the circumference of the arm increases towards the back and therefore won't fit through the forearm fixations. This part is not further developed during this project, which is why it should still be tested whether this elbow support is required in the product (see subchapter 7.2).

Tension measurement

In this system there are two load cells, one connected to each cable. The load cell itself is, via a connection piece, connected to the pulley where the cable is running over (figure 3.4.19).

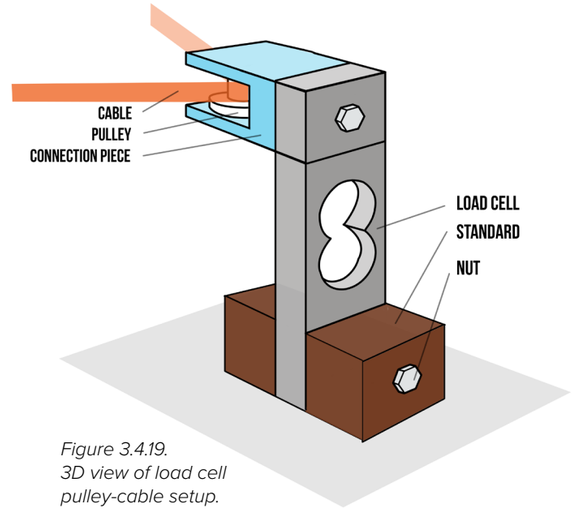


Figure 3.4.19. 3D view of load cell pulley-cable setup.

In this process the cable tension is translated to a force working on the pulley (figure 3.4.20). In step 1, the forces working on the pulley (caused by the cable running over it) are shown. In step 2, the resulting force working on the pulley is shown. The same resulting force is working on the attachment part, at both sides in order to have an equilibrium (step 3). In the last step (4) the resulting force working on the load cell can be seen. Subsequently, this resulting force can be measured.

One thing which has to be taken into consideration is the angle of the load cell in relation to the cables. The load cell always has to be positioned perpendicular to the middle of the angle (between the two cables), as the forces can then be calculated symmetrically. In this scenario this angle (α) is 45°, meaning the measured force (by the load cell) should be translated to one of the cable forces. This can be done by simply using the cosines function (figure 3.4.20).

In the process of calculating the cable tension threshold, also the friction working on the cable (caused by the rubber Bowden tubes) needs to be taken into account. More about this is discussed in subchapter 7.3. More information about assumptions which are made for the cable tension measurement can be read in Appendix Z.

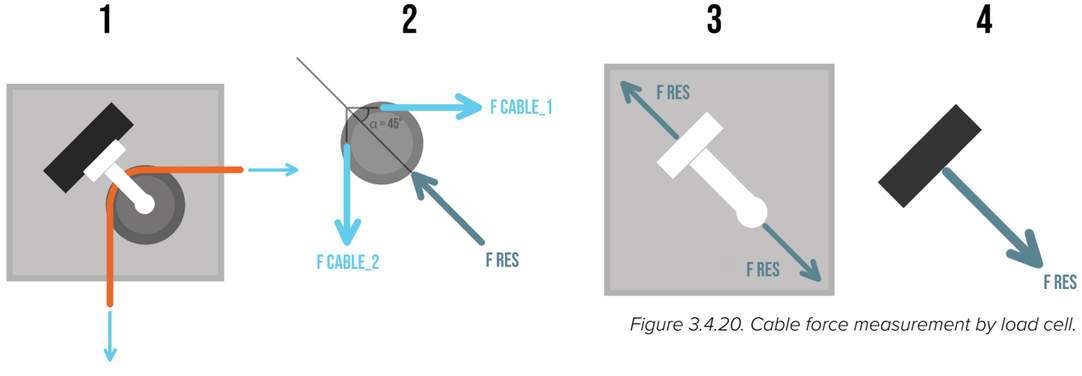


Figure 3.4.20. Cable force measurement by load cell.

Driving

As mentioned before, each of the two cables are driven by one motor. With this concept the motor functions as the drive and a pulley at the same time. In order to prevent slipping of the cable over the motor shaft, a timing belt (figure 3.4.21) is used in combination with a special drive belt gear (figure 3.4.22). These parts are also used in 3D printers to precisely move the print head. In the system the middle of the timing belt should be positioned at the motor shaft when the hand is in the neutral (starting) position (black line, figure 3.4.23), so that both movements can be completely facilitated by the timing belt.

The timing belt should be long enough to be able to complete the full ROM of all wrist movements (of which 90° is largest for wrist flexion- and extension). Based on a test where the amount of cable required for full wrist flexion was measured (see Appendix AA), the required length for the timing belt was defined to be 300 [mm] (150 [mm] to both sides, figure 3.4.23). For the setup of all the components of the cable-pulley system, see next page.

Figure 3.4.21. Timing belt. Source: (RS, n.d.).

Figure 3.4.22. Drive belt gears. Source: (HobbyKing, 2018).

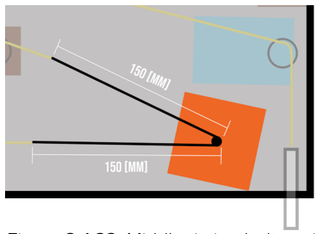


Figure 3.4.23. Middle timing belt positioned at motor (orange block) shaft.

Control

Controlling the cables of this system is done with the control panel (figure 3.4.25). The design of this control panel is selected out of multiple concepts. More about the concepts and the selection of this specific design can be read in subchapter 3.5.3.

In the system pairs of two cables are connected to a motor (and each other) and therefore responsible for movement in one plane (figure 3.4.24). Maneuvering the hand fixation in all four directions can be done with the positioning buttons, these are used in the beginning when the patient's hand needs to be maneuvered in the right starting position (which is straight in both the x-y- and x-z-plane). The movement sequence can be started and stopped with the 'start'- and 'stop' button respectively. When the movement sequence is started the cable tension limit is set (based on the most recent value which was measured by the load cell) and the movements are facilitated in the following order: flexion, extension, radial- and ulnar deviation. Each movement is facilitated up up until the point that the cable tension (measured by the load cell) exceeds the pre-set limit. When the limit is reached, the hand automatically returns to the starting position, after which the following movement is facilitated.

More information about the control panel needed to facilitate this control of the product can be read in subchapter 3.5.3. The different steps of usage and the working of the product can be read in subchapter 5.3.

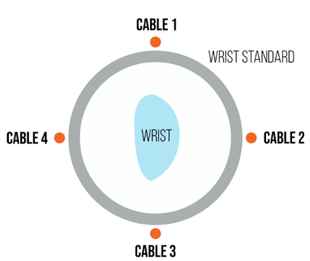


Figure 3.4.24. Cable motor connection and corresponding movements.

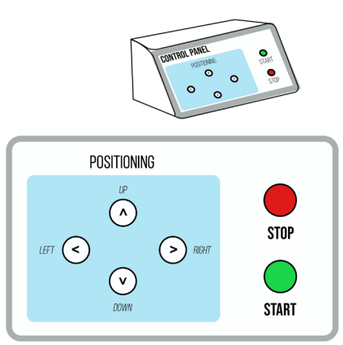


Figure 3.4.25. Cables and control panel.

Setup

For the multiple components of the operating system, the optimal setup had to be defined. This was done by making (scaled) representations of the components in Photoshop and making different setups with them. Three things had to be taken into account in this process: 1) components with metal parts should be positioned as far away from the left side of the arm standard (metal artefacts on CT scan); 2) components should be positioned as far away from each other as possible (to make sure the full ROM of the wrist movements can be facilitated); 3) the spots where the Bowden tubes 'enter' the arm standard should be optimal (so that they do not have to make sharp turns).

In the end this resulted in two versions (figure 3.4.26). Eventually, version was selected because: 1) in this setup there was more space between the different components; 2) the positions of the Bowden tubes were better (less sharp turns had to be made).

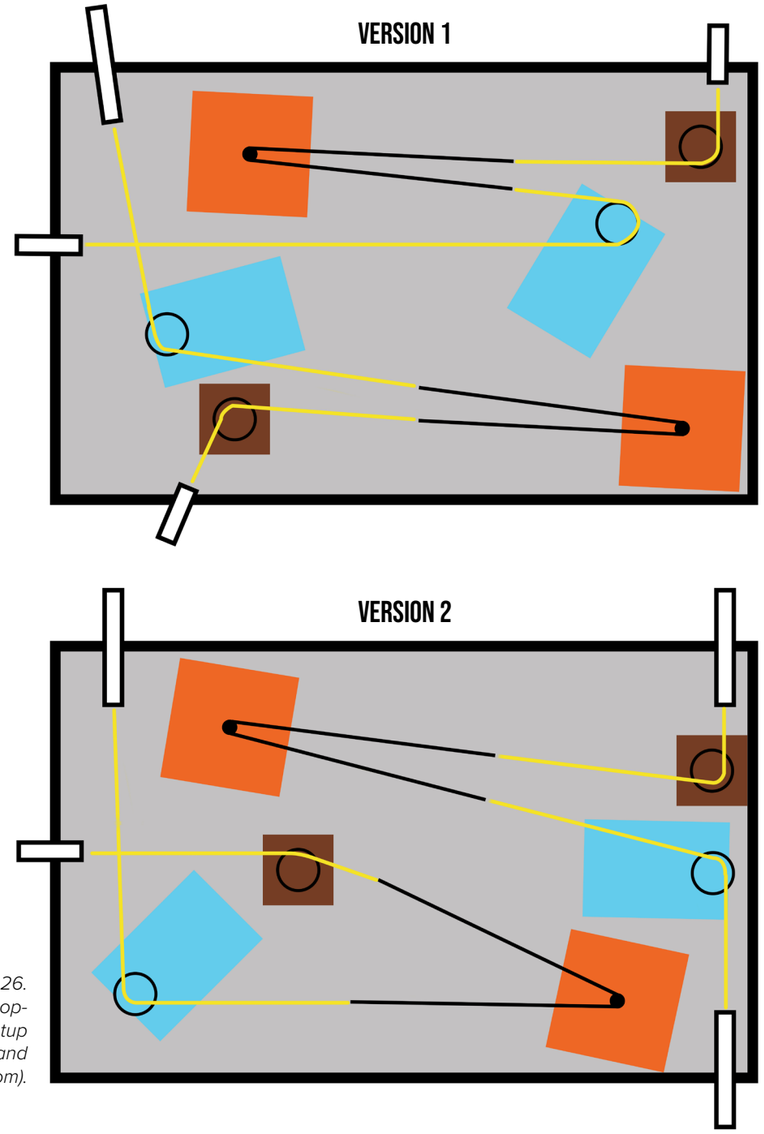


Figure 3.4.26. Two cable-pulley operating system: setup version 1 (top) and version 2 (bottom).

3.4.6 Electronics

Now that the operating system of the product is selected and elaborated, there still needs to be made a connection from the actuators to the control panel. This connection enables the users (the radiologist or the laboratory technician) to control and operate the product in the end. To facilitate this connection, electronic components have to be integrated which are operated by programming software. For this part of the product Arduino was selected to use, as this is an open-source electronic prototyping platform for both beginners and experienced people, which is widely used (also during the bachelor and master program on the faculty of IDE) to create interactive electronic prototypes (Arduino, n.d.).

Based on the choice of movement mechanism and operating system there are eleven different components which are needed to make the working electronic prototype. This list of components is also based on the working of the product, described in subchapter 3.4.5 (Two cable-pulley system – Control). The components which are needed in the prototype can be seen below in table 3.4.1. The NEMA 17 stepper motor, the TB6600 stepper driver, the load cell and the amplifier sensor were already discussed in this subchapter. The remaining components can be seen in figure 3.4.27.

Table 3.4.1. Components needed for electronic prototype: name, quantity and purpose.

Component	Quantity	Function
Arduino Mega	1	Connect and control all electronic parts
NEMA 17 stepper motor	2	Facilitate desired wrist movements
TB6600 stepper driver	2	Operate and control stepper motors
Load cell (5 [kg])	2	Measure real-time tension on cables
HX711 amplifier sensor	2	Amplify load cell signal for Arduino Mega
Push button	6	Input for stepper motor control
Jumper cables	50+	Connect different electronic parts
Breadboard	1	Connect different electronic parts
USB 2.0 connection cable (type B to type A)	1	Connects computer to the Arduino Mega to transfer the software code
External 9V adapter	1	Power stepper motors with 9V
Female DC power adapter	1	Connect 9V adapter to Arduino

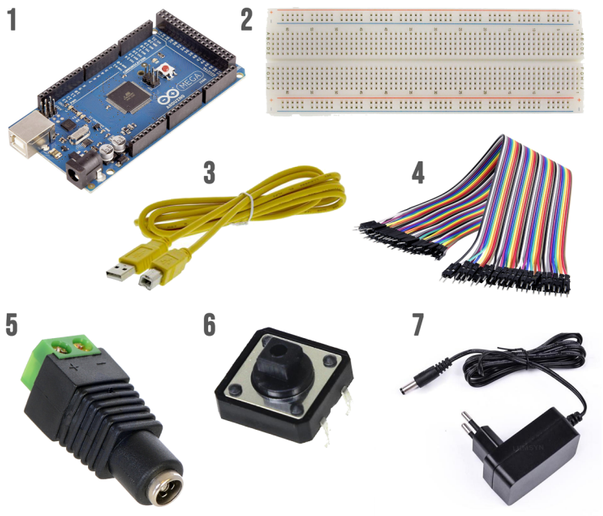


Figure 3.4.27. Remaining components: 1) Arduino Mega; 2) breadboard; 3) USB connection cable; 4) jumper wires; 5) female DC power adapter; 6)) push button; 7) external 9V power adapter. Sources: 1) (Conrad, 2012); 2) (Solarbotics, 2018); 3) (RS, n.d.); 4) (Conrad, 2015); 5) (Polulu, n.d.); 6) (Grandado, 2015); 7) (Lumsyn, 2017).

The external 9V adapter was used based on advice from M. Verwaal (personal communication, January 21, 2020). Without this external power supply it would be difficult to provide the two stepper motors with enough power via the USB cable (which gives 5 [V]). This adapter on the other hand, which has to be plugged in a socket, is able to supply both stepper motors with up to 9 [V] of power. The female DC power supply has to be connected to the external 9V adapter. Finally, two jumper wires can be used to connect the positive- and negative pin to the rest of the electronic system (5V and ground respectively).

With these components the final working (electronic) prototype has to be made, where the entire movement sequence can be facilitated automatically by the device. Unfortunately, during the project there was not enough time to fully develop the working prototype. Two prototypes have been made which served as preparation for the final working model (Appendix BB). With the first prototype the rotation direction of a stepper motor could be controlled with push buttons. Pressing the left button resulted in clockwise rotation of the motor shaft, while pressing the right button resulted in counter-clockwise rotation. With the second prototype the load cells, required for measurement of the cable tension, were calibrated. This was necessary to make sure both load cells measure the same value and can therefore be used in the same system, as advised by M. Verwaal (personal communication, January 21, 2020).

Eventually a part of the desired working prototype was made (see subchapter 5.2 – Electronics).

3.1.3 Conclusion

Summary

3.4.1

- Based on literature research and an expert meeting the choice was made to use and integrate a NEMA 17 stepper motor in the product as the actuator.

3.4.2

- A stepper motor driver is necessary to be able to control and operate the stepper motor with Arduino.
- Based on a comparison of three different stepper motor drivers and an expert meeting, the TB6600 driver was selected to be integrated in the product.

3.4.3

- A nylon cable (4 [mm] thick) was used as an optimization of the simple twine rope. The nylon cable had a more professional look and was stronger.

3.4.4

- From the hand fixation the cables can be maneuvered over the wrist standard to the back of the product (stepper motors) with rubber Bowden tubes. This improves the movement freedom and protects the cables from wearing out.
- With the use of a test the optimal diameter of the Bowden tubes was defined: 10 [mm] (outside diameter) and 7 [mm] (inside diameter).

3.4.5

- For the operating system three concepts were generated; the two cable-pulley concept was selected to use and integrate in the product because it is easier to use and requires significantly less space to work.
- The concept makes use of two cables which are each connected to one motor. For movement in each plane there is one cable, one motor and one load cell. In the arm standard there is a pulley system which connects the side cables (flexion/extension) and the upper and lower cable (deviation) to each other.
- The cable tension is measured and calculated using a setup with a load cell, a pulley and the cable. The force working on the pulley is eventually translated to the cable tension.
- To prevent slipping of the cable over the motor shaft, a timing belt is used in combination with a special drive belt gear.
- Controlling the cables of this system is done with the control panel (with six different buttons).
- The optimal component setup of the operating system was selected out of two versions.

3.4.6

- The connection between the actuators and the control panel, to enable the users to control and operate the product, is facilitated by electronic components which are integrated and operating by programming software (Arduino).
- There are eleven different electronic components which are required to facilitate the desired connection (which is based on the described control of the product) between the actuators and the control panel.

Design requirements

- The product should use NEMA 17 stepper motors as actuators to facilitate the passive movement (**actuation & transmission**).
- The product should use TB6600 stepper motor drivers to control and operate the (NEMA 17) stepper motors with Arduino (**actuation & transmission**).
- The product should use nylon cables to make the connection between the hand fixation and the operating system and the actuators (**actuation & transmission**).
- The product should use rubber Bowden tubes to maneuver the cables to every preferred spot (**actuation & transmission**).
- The product should have the two cable-pulley operating system integrated as the operating system to facilitate all wrist movements optimally (**actuation & transmission**).
- The product should measure the cable tension with the use of a load cell setup where the force working on the pulley is eventually translated to the cable tension (**actuation & transmission**).
- A timing belt should be used to prevent slipping of the motor pulley (**actuation & transmission**).
- With the operating system the middle of the timing belt should be positioned at the motor shaft when the hand is in the neutral (starting) position, so that both movements can be driven by the timing belt (**actuation & transmission**).
- The product should use an Arduino Mega, breadboard, jumper wires and push buttons to facilitate the desired connection between the actuators and the control panel (**actuation & transmission**).
- The product should use an external 9 [V] power supply in combination with a female DC power adapter to be able to power both stepper motors (**actuation & transmission**).

3.5 Usability

This subcomponent focuses on the usability of the product, which relates to the level of complexity and effort of using and operating the product by the radiologists (and their team). For this subcomponent literature research was conducted, prototypes were developed, tested and evaluated and experts were consulted. An overview of the activities and how their outcomes are used can be seen in figure 3.5.1.

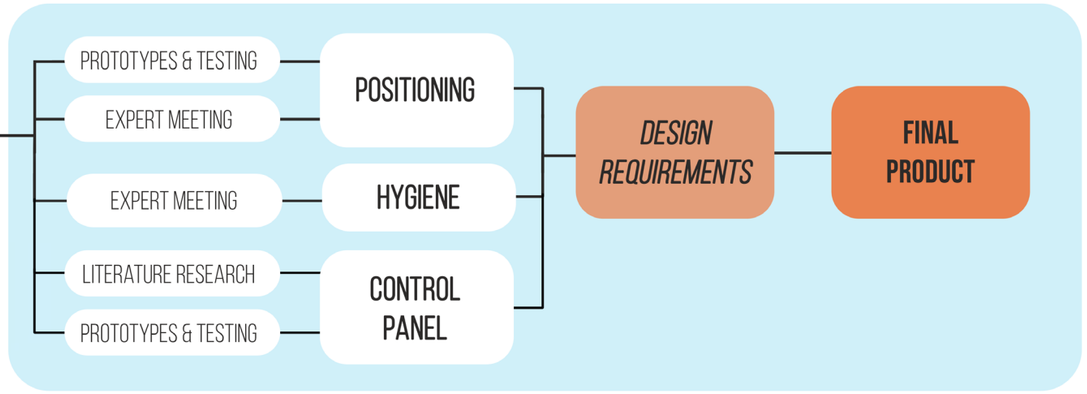


Figure 3.5.1. Overview of activities and outcomes of subchapter 3.5.

3.5.1 Positioning

As was also mentioned in subchapter 2.2.1, for the product it is important to position it perfectly in the central aperture so that the patient's wrist is aligned with the center point (indicated with laser lines). Based on a discussion with a laboratory technician from the Radboud UMC the decision was therefore made to add markings on the baseplate which could be used to align the baseplate with the laser lines of the CT scanner (W. van der Woude, personal communication, February 24th, 2020). In this way the baseplate can be positioned correctly faster and easier on the CT bed by the laboratory technicians.

The marking lines (figure 3.5.2 and 3.5.3) are drawn on the baseplate on the exact location where the laser lines of the CT scanner should align. At this point the markings are black, but it might be that another (brighter) color works better as it stands out more. Unfortunately during this project it did not work out to test this. Therefore this still has to be tested in the future to see if these marking lines are positioned correctly and if they are clear enough for the laboratory technicians to understand and use. More about this can be read in subchapter 7.2 (Testing and implementation).

Figure 3.5.2. Baseplate (v4) configuration without arm- and wrist standard.

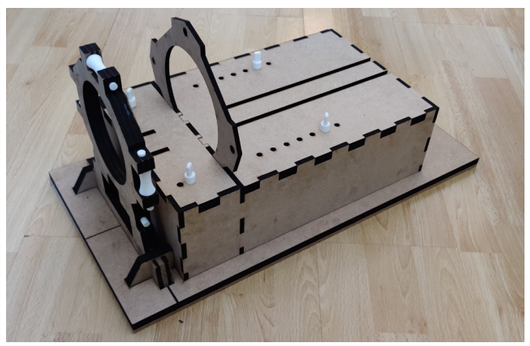


Figure 3.5.3. Baseplate (v4) configuration with arm- and wrist standard.

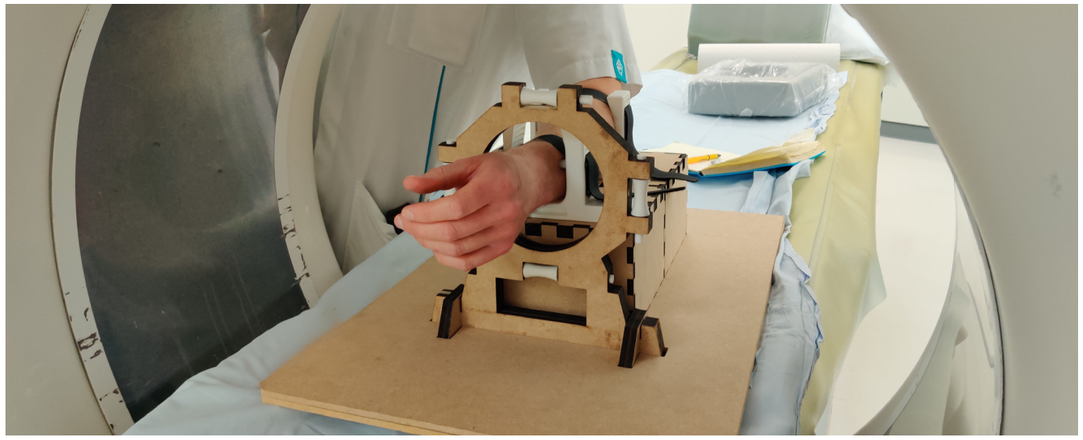


Figure 3.5.4. Product (older prototype) stays stable on the patient bed.

As was concluded from a small test conducted in the CT room of the Radboud UMC (also see Appendix CC) the device can stay stable on the patient bed without having to be attached to it (figure 3.5.4). Because of the weight of the product it does not move or slide away and because of the baseplate it does not fall over.

3.5.2 Hygiene

As was also mentioned in the focus area of usability (subchapter 1.4.5) it is desired that all product parts which come in contact with the patient can either be cleaned easily or are disposable and can simply be replaced. In the end this can have a positive effect on the usability of the product and the time efficiency of the working routine in the hospital. In this subchapter this issue is analyzed and a suitable solution is selected.

Product parts

Looking at the ideal usage scenario of the product, the patients only come in direct contact with the parts of the forearm- and hand fixation. However, the chances are high that in the entire scanning process the patients accidentally touch other parts of the product as well (i.e. the arm standard). Therefore, the hygiene measures have to be taken where all product parts are taken into account.

Measures

The hygiene measures can be divided into two things: prevention of direct contact and cleaning of the product after direct contact. Direct contact, in this case, represents the patient touching the product with their bare skin.

Prevention

On the one hand, preventive hygiene measures are taken by using first aid stockings. According to B. van der Heijden (personal communication, November 21, 2019) making direct contact of the patient with both the forearm fixations and the hand fixation can simply be solved by using a first aid stocking (figure 3.5.5 and 3.5.6). Before putting their arm and hand into the device, the patients get a stocking around their forearm and their hand (at metacarpal level).

In the picture the forearm stocking is too long (rolled up near the elbow), which is why the stockings might have to be cut in smaller pieces in order to reduce waste. For defining the required length of the stocking the maximum length of the forearm (160 [mm]) can be used (Appendix N); in this way the stocking is long enough for every patient. For the hand stocking also smaller pieces should be cut; for this piece the maximum length of the metacarpal region (50 [mm]) can be used (Appendix N).

Figure 3.5.5. First aid stocking around hand.

Figure 3.5.6. First aid stocking around forearm.

When the stockings are attached to the patient's arm and hand, they can be fixated in the device (figure 3.5.7 and 3.5.8). After the passive CT scans, the arm and hand can be loosened, removed from the device and the stockings can be removed and thrown away (figure 3.5.9). In the end, the forearm- and hand fixations (and also the arm standard) do not need to be cleaned, as they did not have come in contact with the patient's skin.

While the first aid stocking serves as a protective hygiene layer for the product parts, it also serves as a thin damping layer which could decrease the discomfort for the patients while they are being fixated in the device. The stockings are usually made of a soft fabric-like material, which could in that way decrease the pressure of the fixations applied on the patients' arms (and thereby decreasing the patient's discomfort). This is further analyzed in subchapter 3.6 (Comfort).

Figure 3.5.7. Forearm fixated with first aid stocking around it.

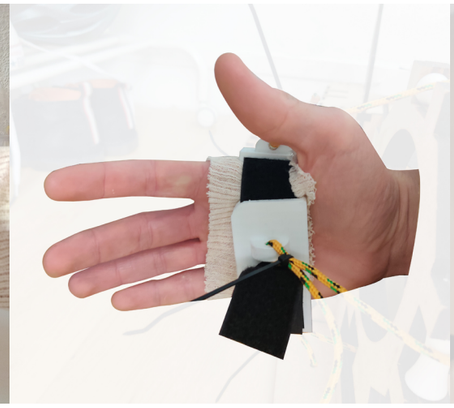


Figure 3.5.8. Hand fixated with first aid stocking around metacarpals.

Figure 3.5.9. Throw away used first aid stocking(s).

Cleaning

In case when the patient accidentally touches one of the product parts with their bare skin, these parts need to be cleaned afterwards. According to S. Buckens (personal communication, April 22, 2020) this is done with the use of disinfectant wipes (figure 3.5.10). These wipes are fast and easy to use and can simply be thrown away after cleaning. For the product this means that its parts should be made of materials which can be cleaned with these disinfectant wipes (and are not damaged by it).

Figure 3.5.10. Disinfectant wipes used to clean product parts which have come in direct contact with the patient.

3.5.3 Control panel

As described in subchapter 3.1.2, the product has a control panel which is used by the radiologist and laboratory technicians to control and operate the product. The design and configuration of the control panel is important, as it influences how easy it is for the user to operate and control the product. In the hospital this can affect the time needed to scan and help the patient.

According to the usage scenario described in subchapter 3.4.5 (Two cable-pulley system – Control), the different aspects required for the control panel can be defined. Four buttons are needed in order to move the hand fixation into the four directions (left, right, up and down). In this way it is made sure that the patient's hand starts in the correct position, centered in both the x/y- and x/z-plane. Furthermore, one button is used to set the cable tension threshold and at the same time initiate the movement sequence. The sixth and last button is used as an emergency button to stop the movement sequence in case something happens (e.g. if the patient feels pain).

For the configuration of the control panel a theory called 'dual coding' is used, as was advised by J. Molenbroek (personal communication, March 9, 2020). The theory uses different attributes (e.g. position, color and tag) to describe or indicate the working of a button (TeacherToolkit, 2019). Therefore, in the configuration of the control panel, the functions of the buttons are clarified using the following attributes: position, color, tags (position and style) and size. The color and size of the buttons are defined based on literature research, while the other attributes are defined based on a test.

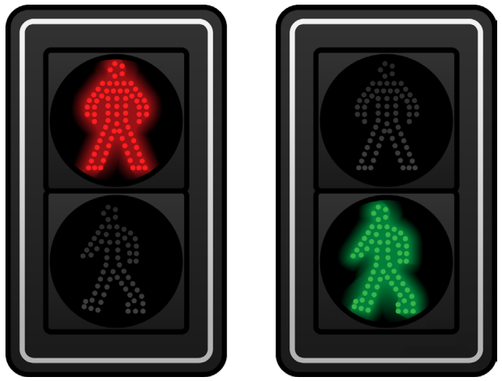


Figure 3.5.11. Pedestrian light with red (stop) and green (go) light. Source: (CI, 2017).

Figure 3.5.12. Different buttons: size and priority. Source: (Anthony, 2018).

Color

The colors used in the control panel are based on other color applications in products. For the 'start' and 'stop' button the example of a traffic light (figure 3.5.11) is taken. When the traffic light turns green the pedestrians are allowed to cross the road, while they have to wait if the traffic light is red. This can be translated to the device: when the movement sequence can be facilitated the green 'start' button can be pressed; if, in any case, the movement has to be stopped, the red 'stop' button can be pressed.

In this case the 'positioning' buttons are used to maneuver the hand to set it in the correct starting position. Therefore, behind the 'positioning' buttons a blue background has been used, as this color is often used for push buttons meant to set up or reset something (Bouchery, 2018).

Size

The size of the buttons is based on a study of Jin et al. (2007), where the optimal size of buttons was investigated. The study found that when having multiple buttons, it is important to arrange them based on their priority (figure 3.5.12). In this case the 'start' and 'stop' button can be considered being high priority, as this starts and stops the movement sequence respectively and thereby represents the main function of the product. On the other hand, the 'positioning' buttons can be defined as medium priority.

Related to the priority of the different buttons, the study also found that different button sizes resulted in a different touch accuracy. A button size of 42 – 72 pixels represented the highest accuracy, which is why all buttons should have a size somewhere in between this range. As can be seen in figure 3.5.12, the button size can be determined based on the priority arrangement. Therefore, the 'start' and 'stop' button should have a size (diameter) of 19 [mm] and the 'positioning' buttons a size of 16 [mm].

Position

For the position of the buttons different concepts were made (figure 3.5.13), which were in the end tested with the radiologist and technical physician. More about the different concepts and the test can be read in Appendix DD. Based on the preference of both participants, concept 3 was selected to use for the control panel. This layout was preferred because it feels more intuitive. Also, it is typical to have a 'start' and 'stop' button above each other. However, in this case it would be even better to have the 'start' button at the bottom and the 'stop' button at the top. Finally, with this layout the product can be easily operated with two hands: the left hand for the 'positioning' buttons and the right hand for the 'start'/'stop' button.

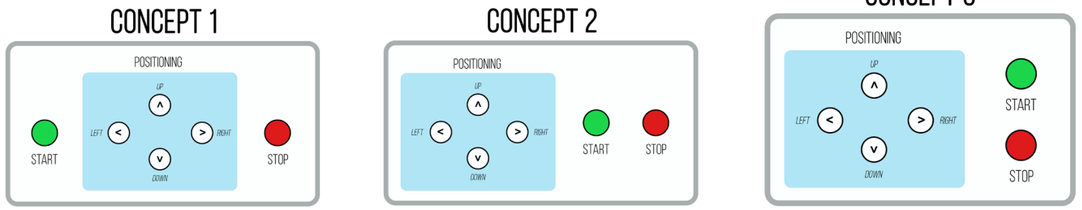


Figure 3.5.13. Different concepts for category 1: button position.

Tags

For the tags of the buttons also different concepts were made (figure 3.5.14), which were tested in the same test described above (also see Appendix DD). Based on the preference of both participants, concept 2 was selected to use for the control panel. This layout was preferred by both participants because it simply felt more intuitive, having the buttons somewhat closer to each other in this way.

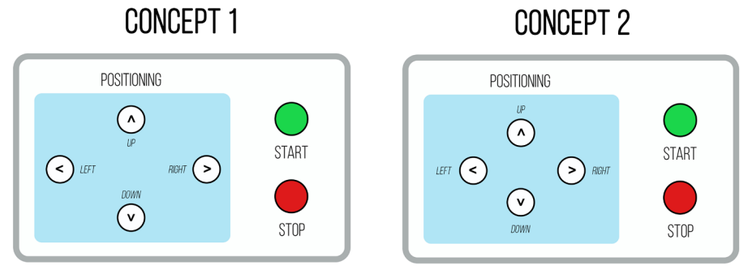


Figure 3.5.14. Different concepts for category 2: buttons and tags.

Text style

For the text style of the control panel also different concepts were made (figure 3.5.15), which were tested in the same test as described above (also see Appendix DD). Based on the preference of both participants, concept 1 was selected to use for the control panel. This layout was preferred because in this way the 'positioning' text (which is semi bold) functions as a header for its buttons. Also, the 'start' and 'stop' button are more important and therefore have to be bold to attract more attention.

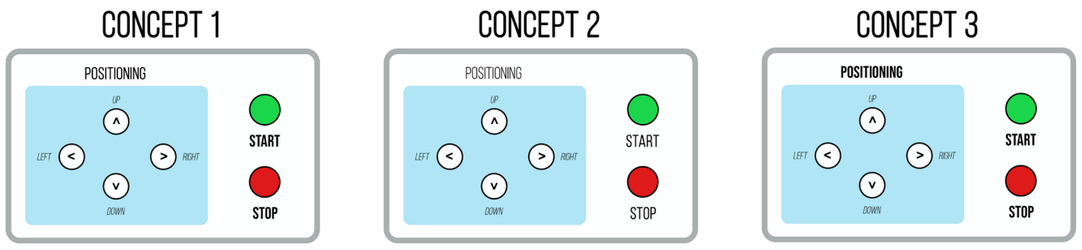
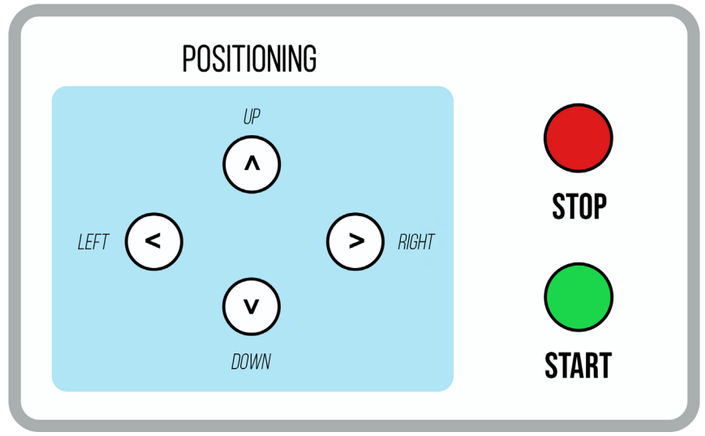


Figure 3.5.15. Different concepts for category 3: text style.

Figure 3.5.16. Final layout for control panel.



In the end this resulted in a final layout for the control panel (figure 3.5.16). More about further development of the control panel can be read in subchapter 7.1.

3.1.3 Conclusion

Summary

3.5.1

- It is important to position the product perfectly in the central aperture so that the patient's wrist is aligned with the center point (to ensure optimal scanning quality)
- Markings are added on the baseplate so that it can be positioned correctly faster and easier in the central aperture by the laboratory technicians, using the laser lines of the CT scanner.
- As was concluded from a small test conducted in the CT room of the Radboud UMC, the device can stay stable on the patient bed without having to be attached to it.

3.5.2

- It is desired that all product parts which come in contact with the patient can either be cleaned easily or are disposable and can simply be replaced.
- Prevention of direct contact is realized by using first aid stockings for both the forearm and hand. The stockings need to be cut in smaller pieces in order to reduce waste.
- After usage the stockings can simply be removed and thrown away.
- In case when the patient accidentally touches one of the product parts with their bare skin, these parts can be cleaned with disinfectant wipes.

3.5.3

- The product has a control panel which is used by the radiologist and laboratory technicians to control and operate the product. The design and configuration of the control panel is important, as it influences how easy it is for the user to operate and control the product.
- 'Dual coding' is used for the configuration of the control panel. In the control panel configuration, the functions of the buttons are clarified using: color, size, position, tags and text style.
- The attributes color and size are based on literature research, while the remaining attributes are defined based on a (small) test conducted with a radiologist and a technical physician.

Design requirements

- The product should have markings on the baseplate which can be used (with the laser lines) to correctly position the device faster and easier in the central aperture (usability).
- During usage of the product, first aid stockings (cut to size) should be used for the forearm and hand to prevent direct contact of the patient with the fixations (usability).
- The product's parts should be made of materials which are cleanable with disinfectant wipes (and are not damaged by it) (other).
- The 'start' and 'stop' button should be green and red respectively (traffic light) (usability).
- The buttons of the control panel should be arranged according to their priority: the 'start'- and 'stop' button are high priority and therefore 19 [mm]; the 'positioning' buttons are medium priority and therefore 16 [mm] (usability).
- Based on the user test, for the position the 'start'- and 'stop' button should be positioned above each other (usability).
- Based on the user test, the tags should be positioned at the outside of the buttons (usability).
- Based on the user test, the text style of 'positioning' should be semi-bold; for the 'start'- and 'stop' button this should be bold (usability).

3.6 Comfort

This subcomponent focuses on the comfort of the product, which relates to how comfortable it is for the patients to be fixated in the forearm- and hand fixation. For this subcomponent market research was conducted, different materials were tested and compared and a comfortability test was conducted. An overview of the activities and how their outcomes are used can be seen in figure 3.6.1.

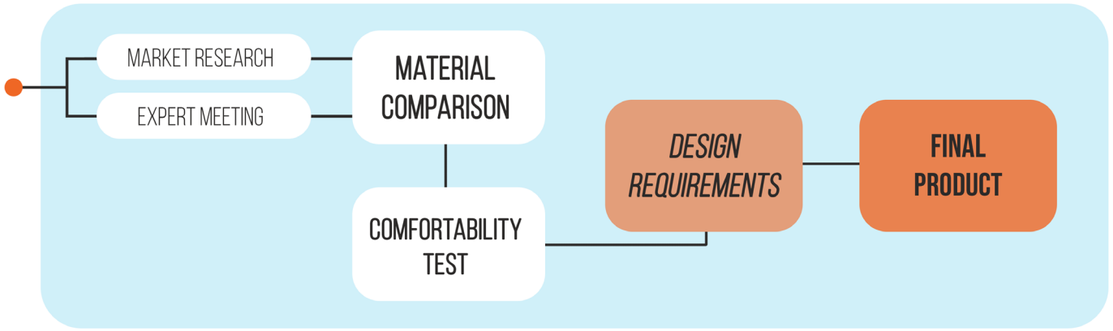


Figure 3.6.1. Overview of activities and outcomes of subchapter 3.6.

3.6.1 Market research

For the required comfort of the product market research was conducted in order to get an idea about existing solutions. Later this output is used to select multiple potential materials.

For increasing comfort of both the forearm- and hand fixation in this product there is merely focused on foam (rubbers). As was concluded from research of existing products (subchapter 3.2.1) and mentioned by Q. Spoon (personal communication, March 25, 2020), this is a relatively affordable and durable material and works easily to increase comfort for the user and is therefore widely used in products. In this subchapter three new existing products (figure 3.6.2 – 3.6.4) were analyzed in terms of their application of foam to increase comfort.

A more extensive description of the market research can be found in Appendix EE. According to Q. Spoon (personal communication, March 25, 2020) the ethylene-vinyl acetate (EVA) foam used in the EXO-L has a closed cell structure, which is easier to clean as it does not absorb water. He recommended to use a foam with a closed cell structure in this product, as this is easier to clean and therefore beneficial concerning hygiene aspects. On the other hand, hardness of the foam is also relevant. This is because the foam is often also used to improve fit and comfort of the product for the user, by facilitating a soft layer between the product and the user (Alyko Medical, 2015).

To conclude, when selecting the most suitable material for increasing comfort of the fixations, the hardness and cell structure of the material are important. Therefore, these two variables are also used in the material comparison.

Figure 3.6.2. EXO-L with the (hard plastic) shell (blue) and the EVA foam layer (grey). Source: (EXO-L, 2017).

Figure 3.6.3. Encore protective glasses with foam. Source: (Innova, n.d).

Figure 3.6.4. Hockey shin protection. Source: (GoHockey, n.d.).

3.6.2 Material comparison

Eventually five different materials (figure 3.6.5) were compared on two criteria: hardness and cell structure. An extensive description of the material comparison can be found in Appendix FF.

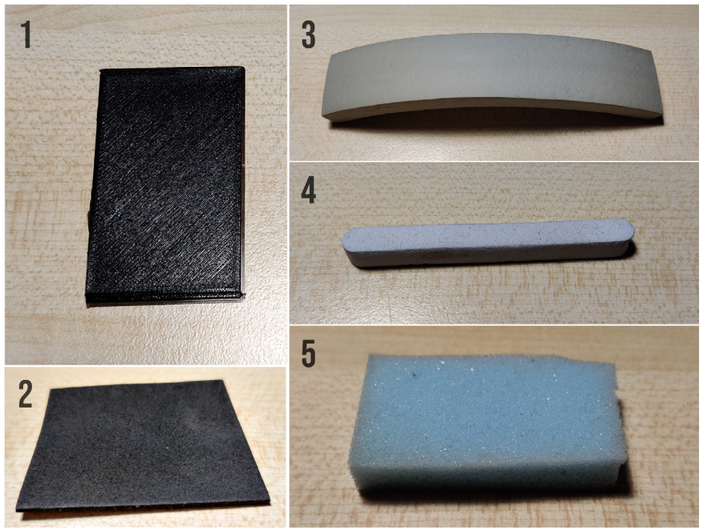


Figure 3.6.5. Five different materials used for material comparison: 1) TPU; 2) EVA foam; 3) moss foam rubber; 4) 'single-cell foam'; 5) polyether (SG35).

Table 3.6.1. Overview of foam types and criteria. The criteria 'hardness' is defined using a scale ranging from 1 (very soft) to 7 (very hard).

Type of foam	Hardness score	Cell structure
TPU	7	-
Single-cell foam	2	Open cell structure
Polyether (SG35)	1	Open cell structure
Moss foam rubber	3	Both (inside: open; outside: closed)
EVA	3	Closed cell structure

For the selection of the most suitable foam for use and integration in the product, an overview (table 3.6.1) has been made concerning all types of foam and the two criteria mentioned above. Concerning the two criteria, a suitable midway has to be found. Regarding the hardness, the material should not be too hard (uncomfortable for the patient), nor too soft (offers no damping thus no comfort to the patient). Regarding the cell structure, a cell foam which is closed is preferred, as this is easier to clean and therefore beneficial concerning hygiene aspects (as was also recommended by Q. Spoon, mentioned above).

Looking at table 3.6.1, the TPU and polyether fall off as these materials are simply too hard and soft respectively. Furthermore, the single-cell foam falls off as it has an open cell structure. This resulted in two materials (EVA foam and moss foam rubber) remaining to choose from. These materials are tested in a comfortability test, which is described in the next subchapter.

3.6.3 Comfortability test

In order to define which of the two remaining materials (material comparison) was most suitable to use and integrate in the product, the materials were tested with potential patients.

In this test the participants were fixated in the forearm fixation with a first aid stocking (as described in subchapter 3.5.2) around their arm, to imitate the actual situation (figure 3.6.6).

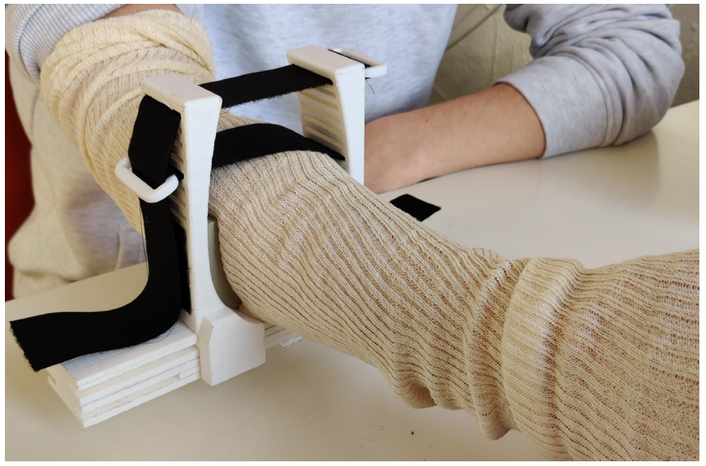


Figure 3.6.6. Fixation with first aid stocking around forearm.

For the EVA foam two thicknesses were tested: 1) equally thick as the moss (rubber) foam (EVA (6)); 2) half as thick as the moss foam rubber (EVA (3)). Also, the comfortability was tested without any of the materials (indicated with a '-'), to see how this was perceived in comparison with the materials. In total this resulted in four tests; per test the participant was fixated for one minute. After one minute they were asked to rate the comfortability of the fixation using a scale ranging from 1 (very uncomfortable) to 7 (very comfortable). After all tests the participants were allowed to revise their scores as at that point they were better able to compare all the situations. For the results of the test see table 3.6.2.

Markings were used on the fixation to indicate the position of the material (figure 3.6.7), to ensure similar positioning of the different materials.

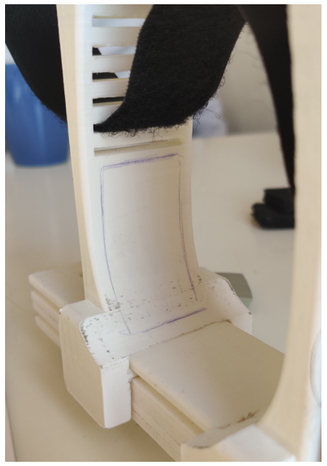


Figure 3.6.7. Markings on fixation to indicate position of material.

Looking at table 3.6.2, it becomes clear that the comfortability scores of the test without any of the materials are highest. In other words, the participants experienced the fixation with only the first aid stocking around their forearm as most comfortable. According to the participants, this was caused by the fact that without any of the materials the forces working on the forearm are acting on a larger surface of the forearm. In the case of having small pieces of foam, the forces of the fixations are merely acting on the small surfaces where the foam pieces touch the arm.

Table 3.6.2. Results of comfortability test. Scores represent the perceived comfortability, ranging from 1 (very uncomfortable) to 7 (very comfortable).

	Material			
Participant	*EVA (3)*	*EVA (6)*	*Moss foam rubber*	-
1	5	4	3	6
2	3	4	2	5
3	5	4	3	5

Another benefit of fixation without the foam pieces was that the forearm was fixated better, as there was significantly less free space for the forearm to move (figure 3.6.8).

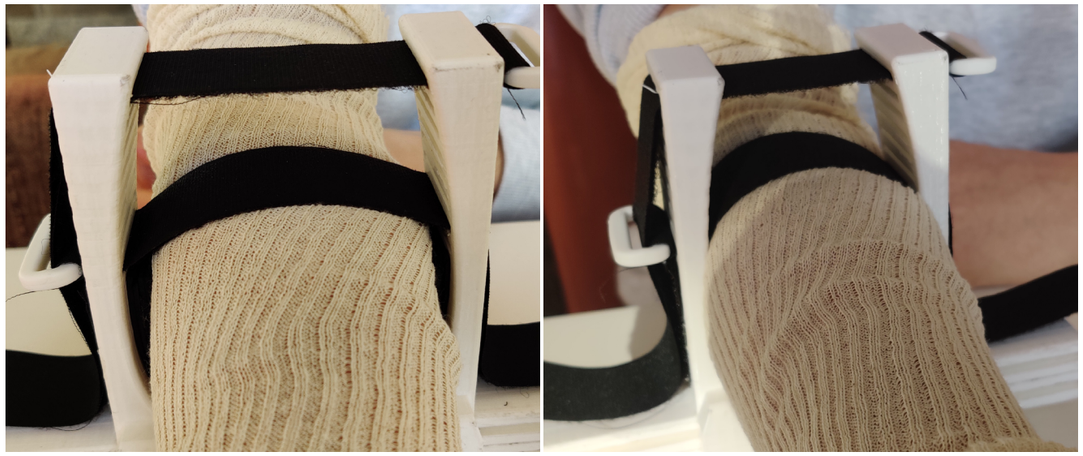


Figure 3.6.8. More free space for the forearm to move with material (left) than without (right).

Based on the results of this comfortability test, the choice was made to not use any of the foam materials to increase comfort (and fit) for the patient. In the end fixation without any foam appeared to have a positive effect on both the comfort and fit.

As this test was done with the forearm, there still needed to be looked further into adding foam to the hand fixation. As was mentioned in subchapter 3.2.3, the attachment points of the hand fixation should be positioned at a similar distance from the hand, to ensure symmetrical movement execution. When adding foam to the inside of the hand fixation, this will result in the attachment points not being positioned symmetrically anymore. Also, a similar test (but smaller) was conducted with the hand fixation as the one described above (see Appendix GG) and it turned out that the first aid stocking again (already) provided damping and increased the overall comfort.

Because of these two reasons, for the hand fixation the choice was also made to not use any of the foam materials to increase comfort.

3.6.4 Conclusion

Summary

3.6.1

- Market research was conducted in order to get an idea about existing solutions regarding comfort in products; later this output is used to select potential materials for the product.
- When selecting the most suitable material for increasing comfort of the fixations, the hardness and cell structure of the material are important (thus used in the comparison).

3.6.2

- Five different materials were compared on two criteria: hardness and cell structure.
- Regarding the hardness the material should not be too hard (uncomfortable for the patient), nor too soft (offers no damping thus no comfort to the patient).
- Regarding the cell structure, a cell foam which is closed is preferred, as this is easier to clean and therefore beneficial concerning hygiene aspects.
- Based on the material comparison only the EVA foam and moss foam rubber remained; later the comfortability of these materials was tested with the (forearm) fixation of the product.

3.6.3

- In order to define which of the two materials was most suitable to use and integrate in the product, the materials were tested with potential patients.
- The forearm of the participants was fixated in total four times for one minute: 1) with EVA (3); 2) EVA (6); 3) moss foam rubber; 4) nothing.
- The choice was made to not use any of the foam materials to increase comfort (and fit) for the patient. In the end fixation without any foam appeared to have a positive effect on both the comfort and fit. This applies to both the forearm- and the hand fixation.

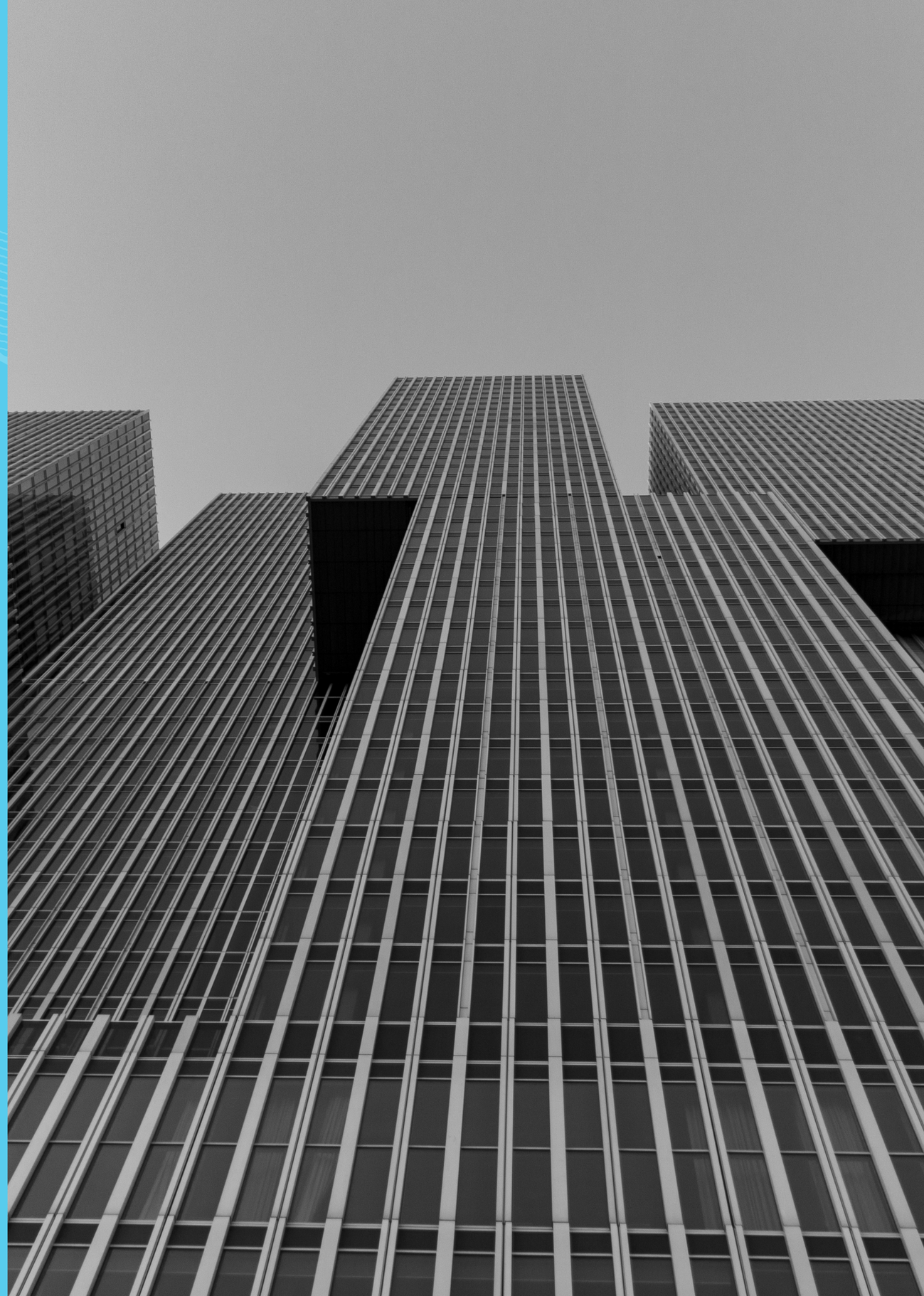
Design requirements

- The product should not use any additional material on the inside of both the forearm- and hand fixations to increase comfort for the patients (**comfort**).

04 PROGRAM OF REQUIREMENTS

In this chapter the program of requirements is presented, which is based on the research and test results of chapters 2 and 3.

Source: Personal photograph



As stated in the Delft Design Guide, the Program of Requirements represents the important characteristics that a design must meet in order to be successful (Boeijen et al., 2014). All the design objectives are concretely described and can be used to select the most promising ideas and design proposal(s) or combinations of proposals.

For setting up the program of requirements Pugh's checklist was used (Appendix GG). This checklist consists of 24 design-related categories which makes it easier to generate design requirements relevant for the final product. The final list of design requirements can be found below.

The majority of the design requirements is divided into the focus areas mentioned in subchapter 1.4. The remaining requirements, which are described at the end, are divided into other categories, which were presumed to be relevant. After each design requirement the subchapter in which it was initially described, is stated.

4.1 Movement

- 1.1 The product should be able to facilitate all the desired (passive) movements: wrist flexion, wrist extension and radial- and ulnar deviation (**2.4.1**).
- 1.2 The product should be able to facilitate all desired wrist movements in one go, in order to reduce the radiation dose for the patient (**2.4.1**).
- 1.3 The product should be able to tweak the speed of the passive wrist movements to acquire the perfect balance between image quality and radiation dose (for the patient) (**2.4.1**).
- 1.4 The product should be able to facilitate one movement at the time and prevent combination of movements, to make sure the radiologist can accurate analyze each specific movement (**2.4.1**).
- 1.5 The product should be able to facilitate passive wrist flexion of at least 90° (**3.1.1**).
- 1.6 The product should be able to facilitate passive wrist extension of at least 90° (**3.1.1**).
- 1.7 The product should be able to facilitate passive radial deviation of at least 40° (**3.1.1**).
- 1.8 The product should be able to facilitate passive ulnar deviation of at least 62° (**3.1.1**).
- 1.9 The product should facilitate the passive wrist movements as if they imitate the working of the muscles in the human body (**3.1.2**).
- 1.10 The product should have the cable-pull mechanism integrated as a movement mechanism to facilitate all wrist movements optimally (**3.1.2**).
- 1.11 The product should allow for optimal positioning (alignment) of the patient's wrist with the wrist standard, to make sure the cable tension on the other cables (which are blocked) remains the same. Because of this the facilitated wrist movement is executed in one plane, as desired (**3.1.2**).
- 1.12 The product should be able to position the middle of the wrist (y-axis and z-axis) always centered with the center axes (y and z) of the wrist standard, to make sure all movements are executed symmetrically (**3.1.2**).

4.2 Fixation & adjustability

- 2.1 The product should be adaptable to different patients (**2.1.1**)
- 2.2 The product should make sure the patient's hand is held in a neutral position during all passive wrist movements (**2.2.2**).
- 2.3 The forearm of the patient should be fixated in order to prevent the forearm muscles to compensate during movement and to prevent motion artefacts occurring on the CT scan (**2.4.1**).
- 2.4 The forearm fixation should be positioned between the wrist and elbow with some free space left at both sides, still allowing them to move freely (**2.4.1**).
- 2.5 The hand should be fixated as a contact point with the movement mechanism and in order to prevent motion artefacts occurring on the CT scan (**2.4.1**).
- 2.6 The product should support the hand at the metacarpal bones, in order to make sure the hand stays straight and in neutral position during the entire movement (**2.4.1**).
- 2.7 The hand fixation should allow the patient's hand to be held both neutral and in a fist position (**2.4.1**).
- 2.8 The length of the forearm fixation should not exceed 103 [mm] (**3.2.2**).
- 2.9 The x-position of the forearm fixation should be adjustable in order to be able to position the patient's arm and hand properly in relation to the wrist standard (**3.2.2**).
- 2.10 The size of the forearm fixation should be adjustable to optimize comfort and fit for the different patients (**3.2.2**)
- 2.11 The hand fixation should have four attachment points (two for flexion/extension; two for deviation) to connect with all of the four cables of the cable-pull movement mechanism (**3.2.3**).
- 2.12 The two pairs of attachment points of the hand fixation should be aligned (horizontally for flexion/extension; vertically for deviation) to ensure symmetrical movement execution (**3.2.3**).
- 2.13 The attachment points of the hand fixation should be positioned at a similar distance from the hand, to ensure symmetrical movement execution (**3.2.3**).
- 2.14 The vertical attachment points should be positioned at a distance of 13 [mm] from the contact surface of the hand (with the hand fixation) (**3.2.3**).
- 2.15 The horizontal attachment points should be positioned at a distance of 60 [mm] from the bottom of the hand (where it makes contact with the hand fixation) (**3.2.3**).
- 2.16 The length and height of the hand fixation should be 38 [mm] and 73 [mm] respectively (**3.2.3**).
- 2.17 The width of the hand fixation should be adjustable (with a strap) to account for the variation in hand width (**3.2.3**).

4.3 Safety

- 3.1 The product should stay stable on the patient bed (**2.2.1**).
- 3.2 The product should contain a feedback system which can measure or calculate the torque the actuator is delivering to actuate the product and facilitate the wrist movement (**2.4.1**).
- 3.3 The product should use one or more load cells (5 [kg], in combination with HX711 amplifier sensors) as a feedback system to measure the cable tension on the cables (of the cable-pull mechanism) used to facilitate the wrist movements (**3.3.1**).
- 3.4 The product should not have sharp corners or edges or rough surfaces in order to prevent the radiologist, laboratory technician(s) and patients hurting themselves (**3.3.2**).
- 3.5 The product should be designed in a modular way, making it easier to disassemble and replace parts (**3.3.3**).
- 3.6 For the different parts of the product, high quality and durable materials should be selected, in order of the product to last for a long period of time (**3.3.3**).

4.4 Actuation & transmission

- 4.1 The product should have one or more actuators to facilitate the passive movement (**2.4.1**).
- 4.2 The product should use NEMA 17 stepper motors to facilitate the passive movement (**3.4.1**).
- 4.3 The product should use TB6600 stepper motor drivers to control and operate the (NEMA 17) stepper motors with Arduino (**3.4.2**).
- 4.4 The product should use nylon cables to make the connection between the hand fixation and the operating system and the actuators (**3.4.3**).
- 4.5 The product should use rubber Bowden tubes to maneuver the cables to their preferred spot (**3.4.4**).
- 4.6 The product should have the two cable-pulley operating system integrated as the operating system to facilitate all wrist movements optimally (**3.4.5**).
- 4.7 The product should measure the cable tension with the use of a load cell setup where the force working on the pulley is eventually translated to the cable tension (**3.4.5**).
- 4.8 A timing belt should be used to prevent slipping of the motor pulley (**3.4.5**).
- 4.9 The middle of the timing belt should be positioned at the motor shaft when the hand is in the neutral (starting) position, so that both movements can be driven by the timing belt (**3.4.5**).
- 4.10 The product should use an Arduino Mega, breadboard, jumper wires and push buttons to facilitate the desired connection between the actuators and the control panel (**3.4.6**).
- 4.11 The product should use an external 9 [V] power supply in combination with a female DC power adapter to be able to power both stepper motors (**3.4.6**).

4.5 Usability

- 5.1 The product should be easy to use and operate for both the radiologist and their supporting team (laboratory technicians) (**2.1.1**)
- 5.2 The product should be designed symmetrically, working for left and right arms (**2.4.1**).
- 5.3 The product should have markings on the baseplate which can be used (with the laser lines) to correctly position the device faster and easier in the central aperture (**3.5.1**).
- 5.4 During usage of the product, first aid stockings (cut to size) should be used for the forearm and hand to prevent direct contact of the patient with the fixations (**3.5.2**).
- 5.5 The 'start' and 'stop' button should be green and red respectively (traffic light) (**3.5.3**).
- 5.6 The buttons of the control panel should be arranged according to their priority: the 'start'- and 'stop' button are high priority and therefore 19 [mm]; the 'positioning' buttons are medium priority and therefore 16 [mm] (**3.5.3**).
- 5.7 Based on the user test, for the position the 'start'- and 'stop' button should be positioned above each other (**3.5.3**).
- 5.8 Based on the user test, the tags of the 'positioning' buttons should be positioned at the outside of the buttons (**3.5.3**).
- 5.9 Based on the user test, the text style of 'positioning' should be semi-bold; for the 'start'- and 'stop' button this should be bold (**3.5.3**).

4.6 Comfort

- 6.1 The product should have as little perceived discomfort for the patient as possible during fixation (**2.1.1**)
- 6.2 The product should not use any additional material on the inside of both the forearm- and hand fixations to increase comfort for the patients (**3.6.3**).

4.7 Other

- 7.1 The product should have a professional and trustworthy look (**2.1.1**).
- 7.2 The product should not be higher than 410 [mm] and not wider than 465 [mm] (**2.2.1**).
- 7.3 The product should not contain any metal parts in the central aperture of the CT scanner (**2.2.1**).
- 7.4 The positioning of the patient in relation to (the product and) the CT scanner should be a well-considered balance between a high quality of the CT images and a low radiation dose of the patients (**2.2.2**).
- 7.5 The product's parts should be made of materials which are cleanable with disinfectant wipes (and are not damaged by it) (**3.5.2**).

05 FINAL PRODUCT

In this chapter the final product (prototype) is described and shown. The different components, the mechanical and electronic working of the product and the usage are extensively explained. Furthermore, attention has been paid to a future vision regarding styling, materials, production and the price.

Source: Personal photograph

5.1 Components

In this subchapter the different components of the final product are highlighted and explained. For each component its functions, its different parts (if any), the main dimensions and the modifications (of the iteration steps) are elaborated on. Detailed information about the different iteration steps for each of the components can be found in Appendix H.

In subchapter 3.1.2 the initial prototype of the product and its different parts was shown, below in figure 5.1.1 an updated overview of the final product (prototype) and its components can be seen.

01 00 BASEPLATE
02 00 ARM STANDARD
03 00 WRIST STANDARD
04 00 FOREARM FIXATIONS
05 00 HAND FIXATION
06 00 ACTUATION (+TRANSMISSION)
07 00 CONTROL PANEL

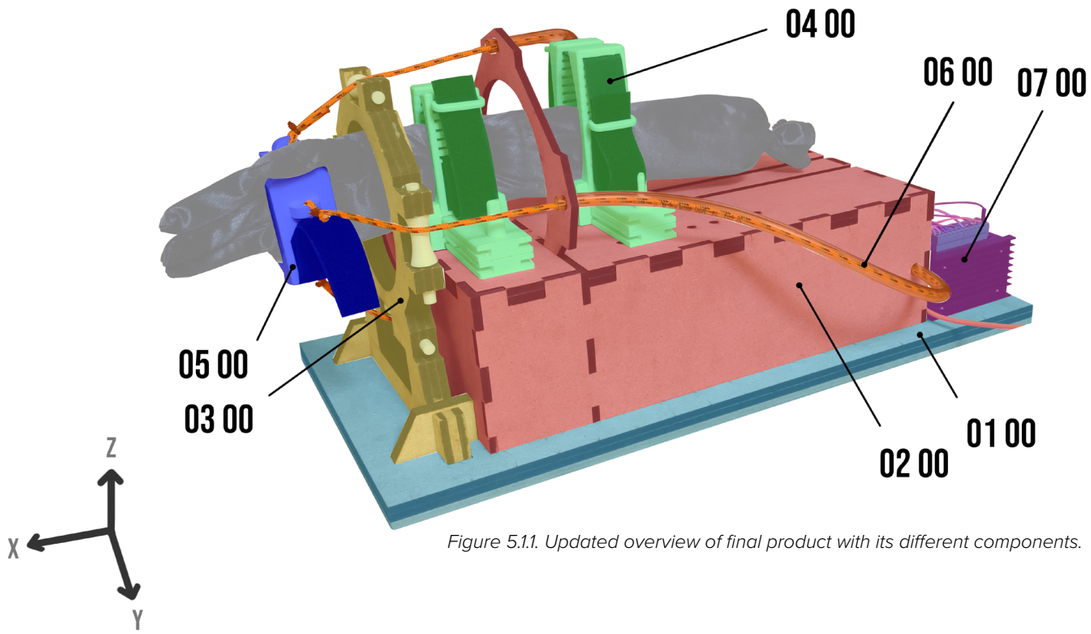


Figure 5.1.1. Updated overview of final product with its different components.

5.1.1 Baseplate (01 00)

The baseplate (figure 5.1.2 and 5.1.3) is used as an underlay for the rest of the prototype. In this subparagraph its functions, parts and dimensions are described.

Functions
The baseplate has two functions:

1) Firstly, the cutouts in the plates are meant to fix the position of two of the components (the arm- and wrist standard). In this way the correct (desired) position of these components is fixed, while at the same time preventing movement of the components (and hereby preventing motion artefacts).

2) Secondly, the baseplate has marking lines which can be used to align the baseplate with the laser lines of the central aperture of the CT scanner. It is desired that the wrist (and thus the wrist standard) is aligned with the center of the central aperture, to ensure the optimal scanning quality.

Figure 5.1.2. Baseplate (01 00) version 4 (without arm- and wrist standard).

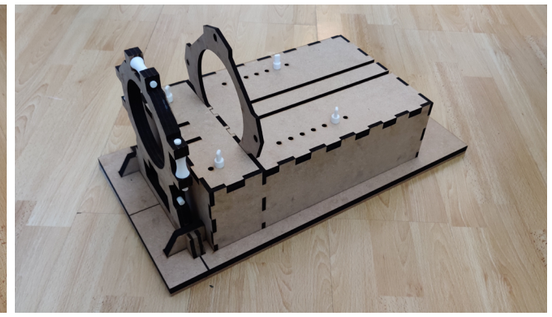


Figure 5.1.3. Baseplate (01 00) version 4 (with arm- and wrist standard).

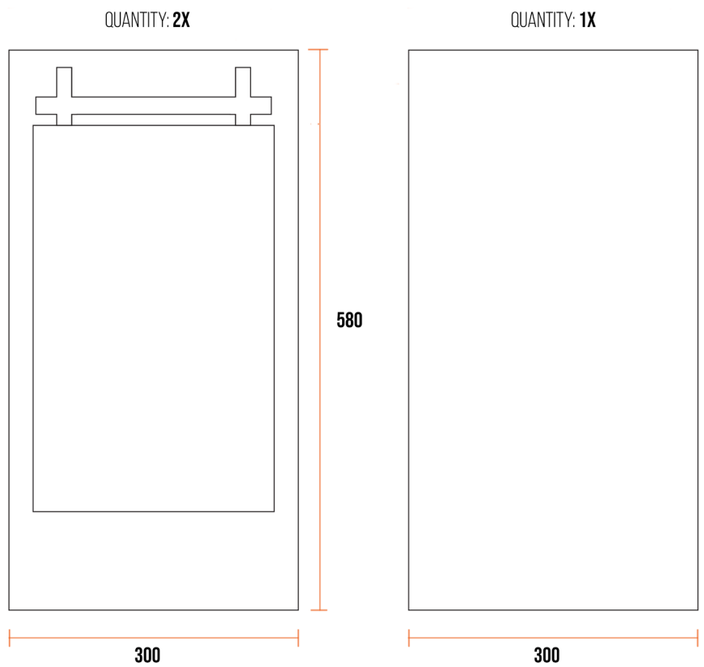


Figure 5.1.4. Baseplate parts and their main dimensions (in [mm]).

Parts
The baseplate consists of three laser cut plates of 6 [mm] MDF in total (figure 5.1.4). Two of these plates have cutouts and one (the bottom plate) does not. The three different plates are glued on top of each other to make sure they cannot be released from each other.

Dimensions
The outer dimensions of the baseplate are: 580 (L) x 300 (W) x 18 (H) [mm]. The main (outer) dimensions of the different parts of the baseplate can be seen in figure 5.1.4. The thickness of the baseplate is 18 [mm]. The specific dimensions can be found in Appendix II.

Modifications
Throughout the different iteration steps multiple modifications are made to the baseplate in order to improve it. These modifications are:

- Wrist standard positioned closer to the arm standard.
- Baseplate smaller in order to reduce product size.
- Marking lines on baseplate for easy- and fast positioning in CT scanner.

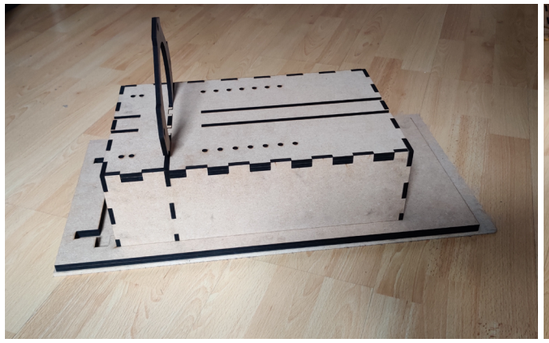


Figure 5.1.5. Arm standard (v5) front view (on baseplate).

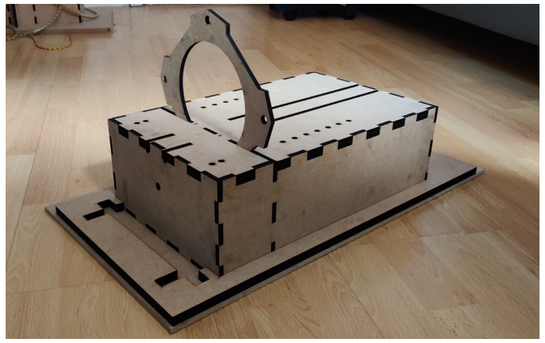


Figure 5.1.6. Arm standard (v5) 3D-view (on baseplate).

5.1.2 Arm standard (02 00)

The arm standard (figure 5.1.5 and 5.1.6) is a box which is used to let the patients rest their arm on. In this subparagraph its functions, parts and dimensions are described.

Functions

The arm standard has three functions:
1) The forearm fixations, the components who fixate the forearm in the right position, are placed on top of this box. On top of the box there are designated holes (and trails) for these forearm fixations to be positioned. The arm of the patient gets fixated in these fixations.

2) The standard houses the parts of the operating system which is part of the actuation and transmission of the product. The different components of that system are integrated in the inside of the arm standard (see subchapter 5.1.6).

3) The standard has an integrated part which guides the cables (with the use of Bowden tubes) towards the wrist standard, from which they are directed to the hand fixation.

Parts

The arm standard consists of seven different laser cut parts (of 6 [mm] MDF) which are in the end all integrated into one box (figure 5.1.7). Some parts are used multiple times in the arm standard, such as the parts for the top and the side.

Dimensions

The outer dimensions of the arm standard are: 400 (L) x 250 (W) x 283 (H) [mm]. The main (outer) dimensions of the parts of the arm standard can be seen in figure 5.1.8. The specific dimensions for each part can be found in Appendix II.

Modifications

Throughout the different iteration steps multiple modifications are made to the arm standard in order to improve it. These modifications are:

- Increase size to provide more space for the arm to rest on.
- Adjusted top layer with rails and holes for adjustment- and fixation of forearm fixations.
- Small holes for rubber Bowden tubes and cables.
- Extra round (high) panel to guide rubber Bowden tubes and cables.

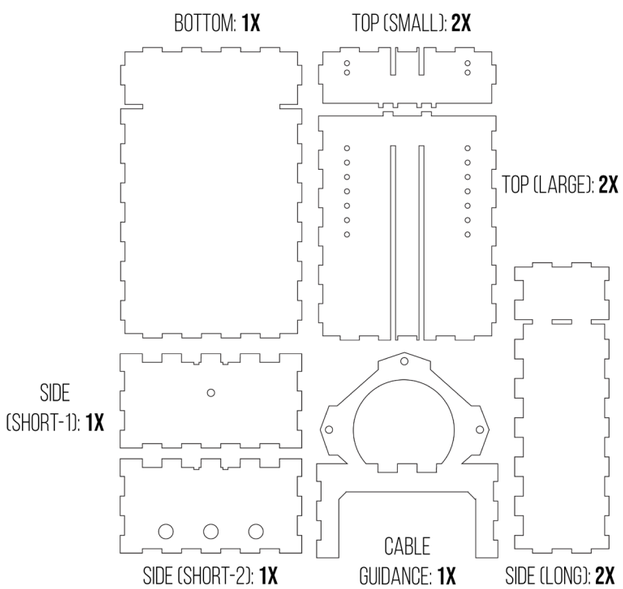


Figure 5.1.7. Arm standard parts: name and quantity.

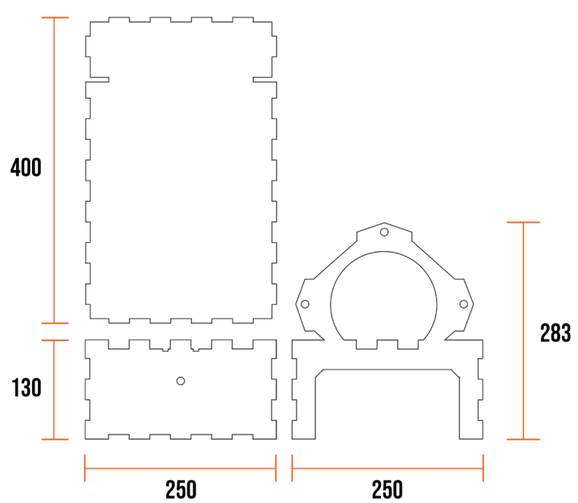


Figure 5.1.8. Main outer dimensions of the arm standard (in [mm]).

5.1.3 Wrist standard (03 00)

The wrist standard (figure 5.1.9 – 5.1.12) is a standard which is aligned with the patient's wrist. In this subparagraph its functions, parts and dimensions are described.

Functions

The wrist standard has two functions:
1) The wrist standard guides the cables of the movement mechanism in order to ensure correct movement execution. When the standard is aligned with the patient's wrist, the cable tension is kept equal, also allowing for accurate cable tension measurement.
2) The pulleys of the standard facilitate some movement space for the cables to move sideways when they are blocked. For example in the case of flexion and extension, the upper and lower cable can move sideways slightly in order to smoothen the movement.

Figure 5.1.9. Wrist standard (v3) front (3D) view.

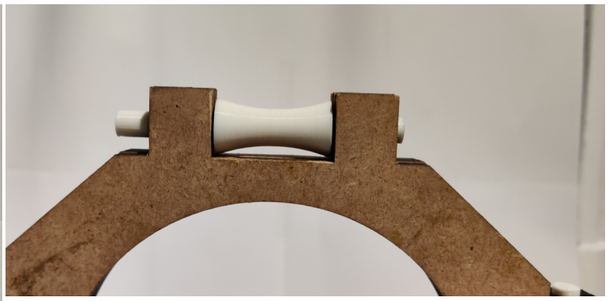


Figure 5.1.10. New pulley with axle integrated into wrist standard (v2).

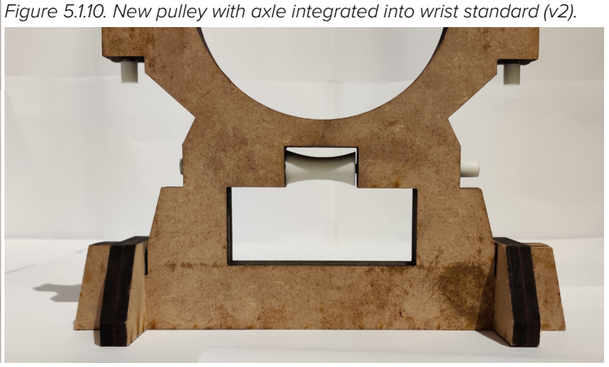


Figure 5.1.11. Wider wrist standard with supports more to the sides.

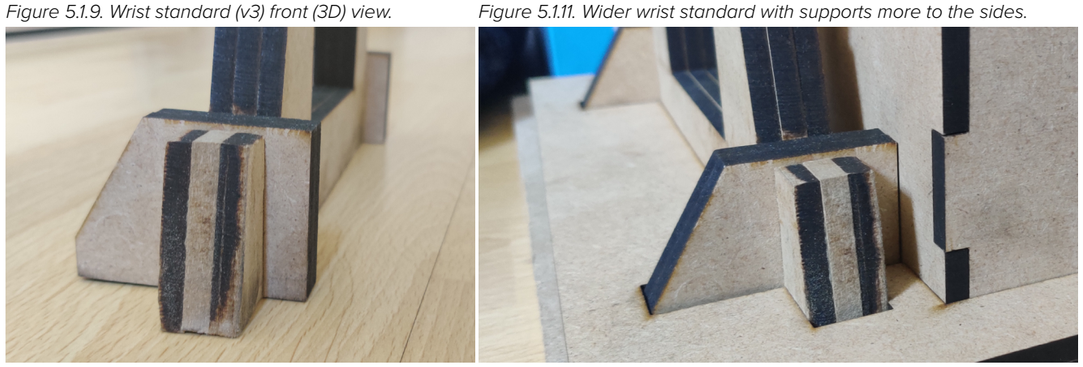


Figure 5.1.12. New (shorter) support pieces for the wrist standard: outside (left) and inside the baseplate (right).

Parts
The wrist standard consists of seven parts, of which two are for the standard and five are for the pulley system (figure 5.1.13). The parts for the standard are laser cut and made of 6 [mm] MDF; the parts for the pulley system are 3D-printed and made of polylactic acid (PLA).

Dimensions
The outer dimensions of the wrist standard are: 243 (L) x 60 (W) x 261 (H) [mm]. The main (outer) dimensions of the arm standard and the parts of the pulley system can be seen in figure 5.1.13. All specific dimensions for each part can be found in Appendix II.

Modifications
Throughout the different iteration steps multiple modifications are made to the wrist standard in order to improve it. These modifications are:
- Larger and thicker standard (18 [mm] instead of 6 [mm]) with optimized support pieces.
- Optimized pulleys and axes, integrated into the standard.
- Adjusted shape of standard (due to integration of pulleys and axes in the standard).
- Larger (and more rounded) middle hole (more space for hand to move).

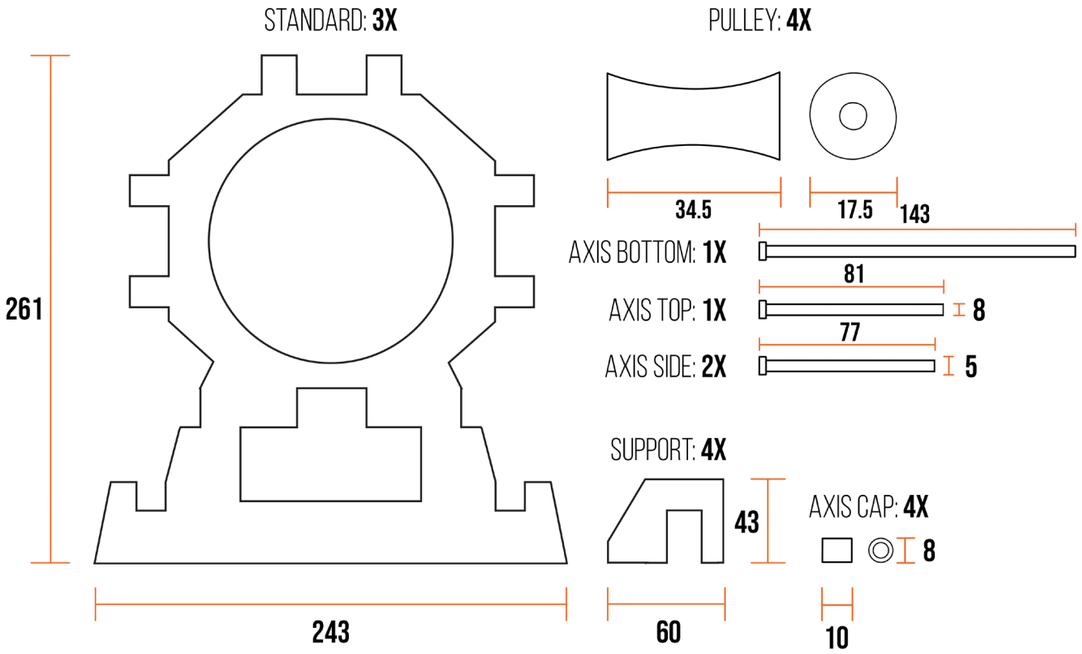


Figure 5.1.13. Wrist standard parts: name and main dimensions (in [mm]).

5.1.4 Forearm fixation (04 00)
The forearm fixation is the part with which the forearm of the patient is fixated.

Functions
The forearm fixation (figure 5.1.14 and 5.1.15) has two functions:

1) The forearm fixations can fixate the patient's forearm on the arm standard so that it is held in the desired position and cannot move. In the end this prevents occurrence of motion artefacts and possible influence of the forearm muscles during movement of the wrist.

2) The forearm fixations are adjustable in size and position to account for the variation in arm sizes among the different patients.

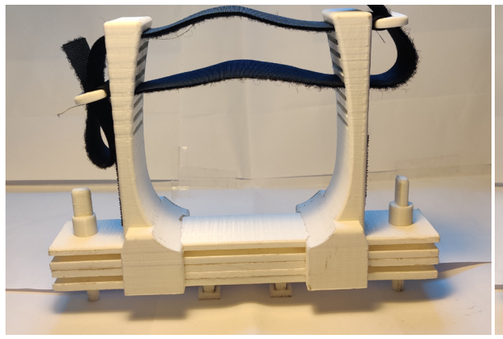


Figure 5.1.14. Concept 4 (v1) prototype (elbow) with straps and attachment pins.

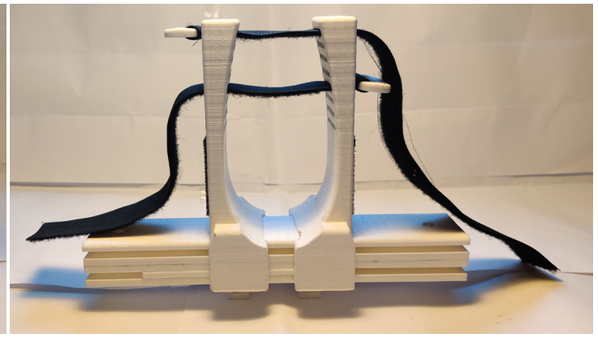


Figure 5.1.15. Concept 4 (v1) prototype (wrist) with straps.

Parts
Looking at the forearm fixation, there is an elbow (region) fixation and a wrist (region) fixation. The sliders for the elbow fixation are somewhat larger and shaped slightly different, as the forearm is larger here and more rounded (near the wrist the forearm is smaller and more shaped like an oval). Looking at both forearm fixations together it consists of eight parts (figure 5.1.16). Some parts are used multiple times in the fixations, such as the sliders and the Velcro straps. Besides the Velcro straps all parts are 3D-printed and made of PLA.

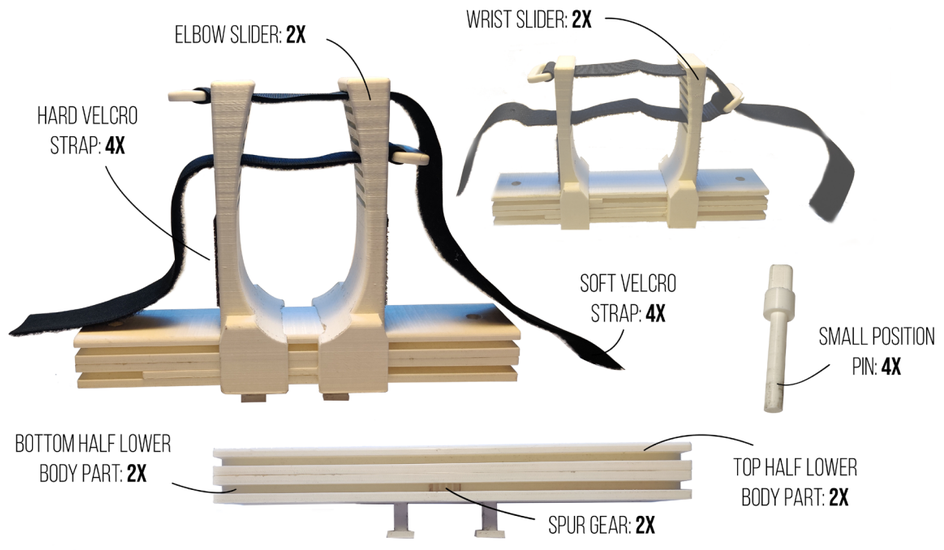


Figure 5.1.16. Forearm fixation parts: name and quantity.

Dimensions
The outer dimensions of the forearm fixations are: 200 (L) x 60 (W) x 150 (H) [mm]. The main (outer) dimensions of the forearm fixations (elbow and wrist) and its parts can be seen in figure 5.1.17. All specific dimensions for each part can be found in Appendix II.

Modifications
Throughout the different iteration steps multiple modifications are made to the forearm fixations in order to improve it. These modifications are:

- New integrated mechanism with double sliders to center the patient's arm and hand on the arm standard.
- Different inside curve for elbow- and wrist sliders (because of different arm cross-section).
- Larger body part and -sliders to create more space for larger arms to be fixated.
- Double velcro adjustment system to fixate the sliders' position and the patient's forearm.
- Added holes and blocking pieces to body for position adjustment and –fixation.

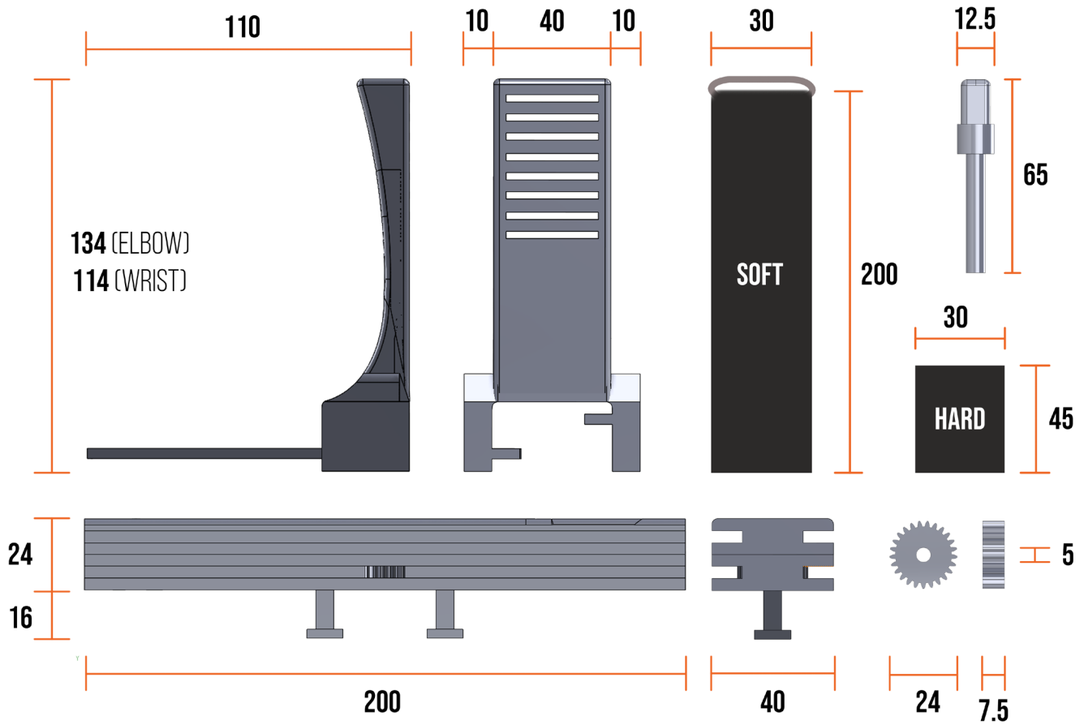


Figure 5.1.17. Main outer dimensions of the parts of the forearm fixation (in [mm]).

5.1.5 Hand fixation (05 00)
The hand fixation (figure 5.1.18) is the part with which the hand of the patient is fixated.

Functions
The hand fixation has three functions:

1) The hand fixation can fixate the patient's hand at the metacarpals in order to make sure the hand stays straight and in neutral position during the entire movement and cannot move. In the end this prevents occurrence of motion artefacts.

2) The hand fixation functions as a contact point with the mechanism and actuation of the device which eventually moves the wrist into the desired directions.

3) The hand fixations is adjustable in width to account for the variation in hand thickness among the different patients.

Parts
Looking at the hand fixation there are five parts to be identified (figure 5.1.19). Besides the velcro straps all parts are 3D-printed and made of PLA. The foam pieces on the sliders can be ignored in this picture, as this was a temporary solution for increasing comfort for patients.

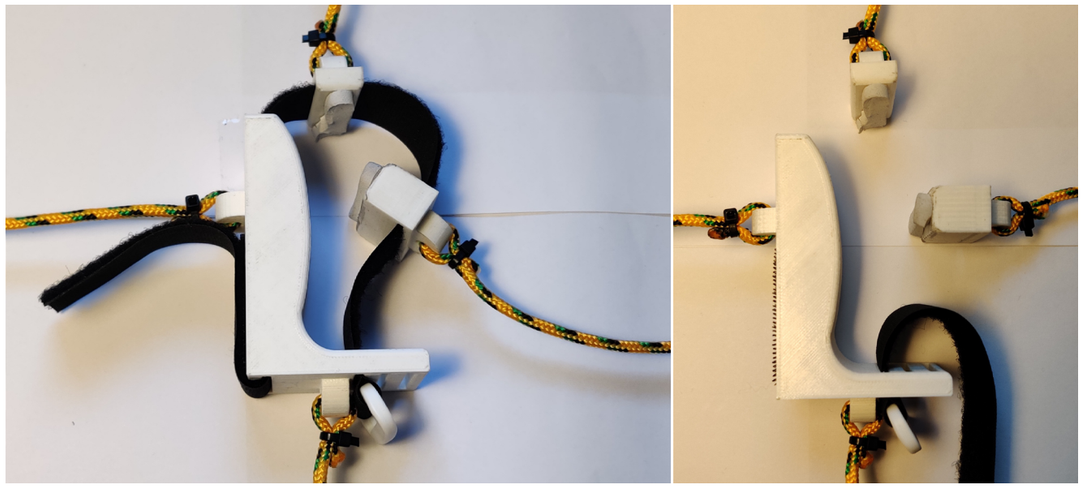


Figure 5.1.18. Concept 2 – V4 prototype with sliders and strap loose (left) and fastened (right).

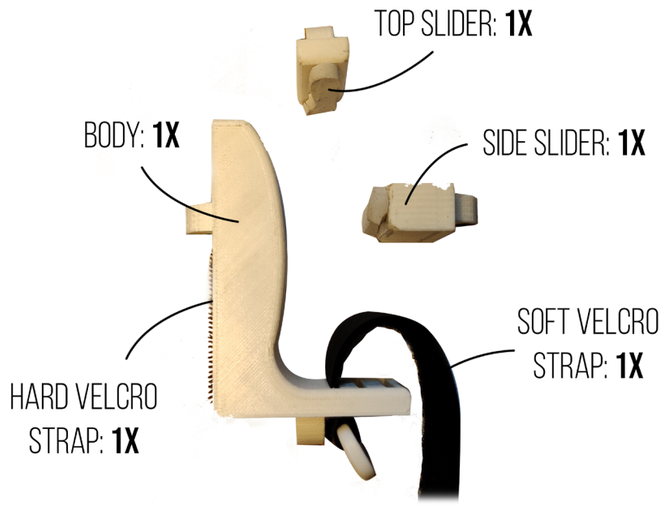


Figure 5.1.19. Hand fixation parts: name and quantity.

Dimensions
The main (outer) dimensions of the hand fixation are: 62 (L) x 40 (W) x 90 (H) [mm]. The main (outer) dimensions of the hand fixation and its parts can be seen in figure 5.1.20. All specific dimensions for each part can be found in Appendix II.

Modifications
Throughout the different iteration steps multiple modifications are made to the hand fixation in order to improve it. These modifications are:

- Strap slots to fixate hand and account for variation in hand thickness.
- Attachment points added at the body and sliders to establish the cable connection.
- More rounded edges to prevent discomfort.
- Different thickness for sliders to ensure symmetrical position of attachment points in relation to the hand (ensuring symmetrical execution of the movements).

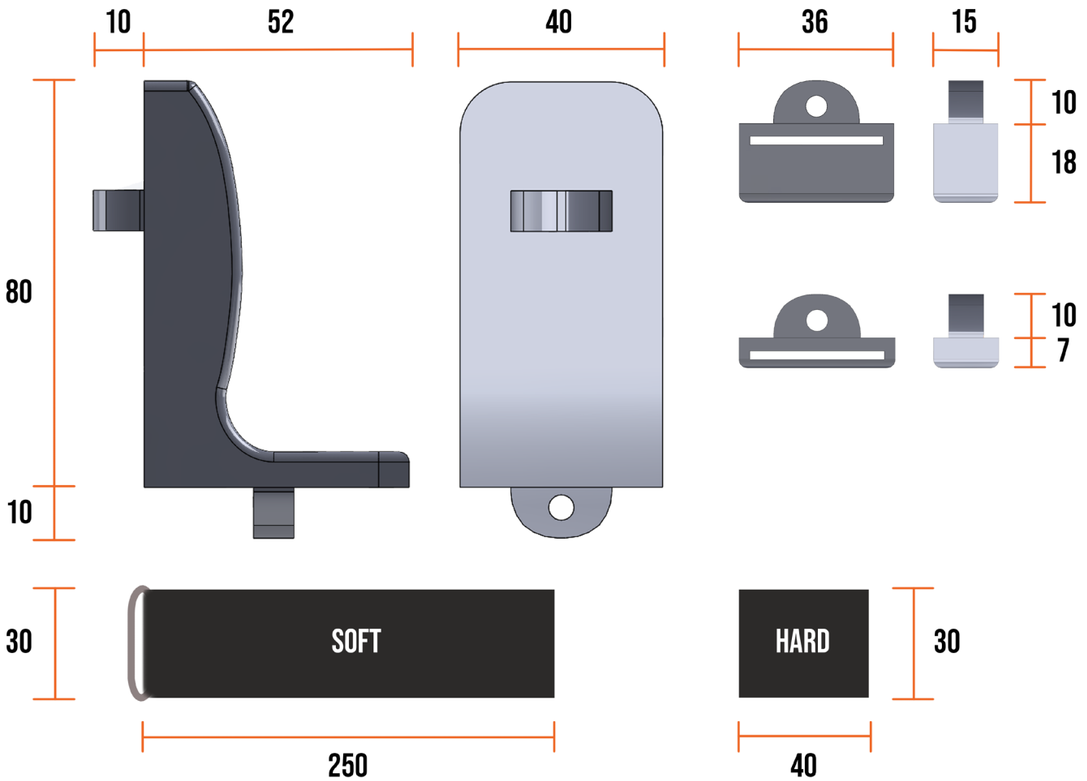


Figure 5.1.20. Main outer dimensions of the parts of the hand fixation (in [mm]).

5.1.6 Actuation & transmission (06 00)

The actuation and transmission of the product (figure 5.1.21) is the part which transfers the actuation movement towards the desired wrist movements. In this case only the operating system (including the cables and Bowden tubes) are taken into account, and described. Electronic parts, although being a part of the actuation and transmission of the product, are not taken into account here; these are described in the next subchapter (5.2).

Functions
The actuation and transmission part of the product has three functions:

1) The system facilitates the automated movements of the patient's wrist, transferred from the actuators through the cables and operating system to the hand fixation. Eventually this transfer results in the desired wrist movements.

2) The Bowden tubes allow the cables to be moved freely to (almost) every preferred spot near the product, which is beneficial for the setup of the operating system.

3) Together with the electronic setup (e.g. the load cells) the operating system is responsible for measuring and calculating the cable tension and its associated threshold.

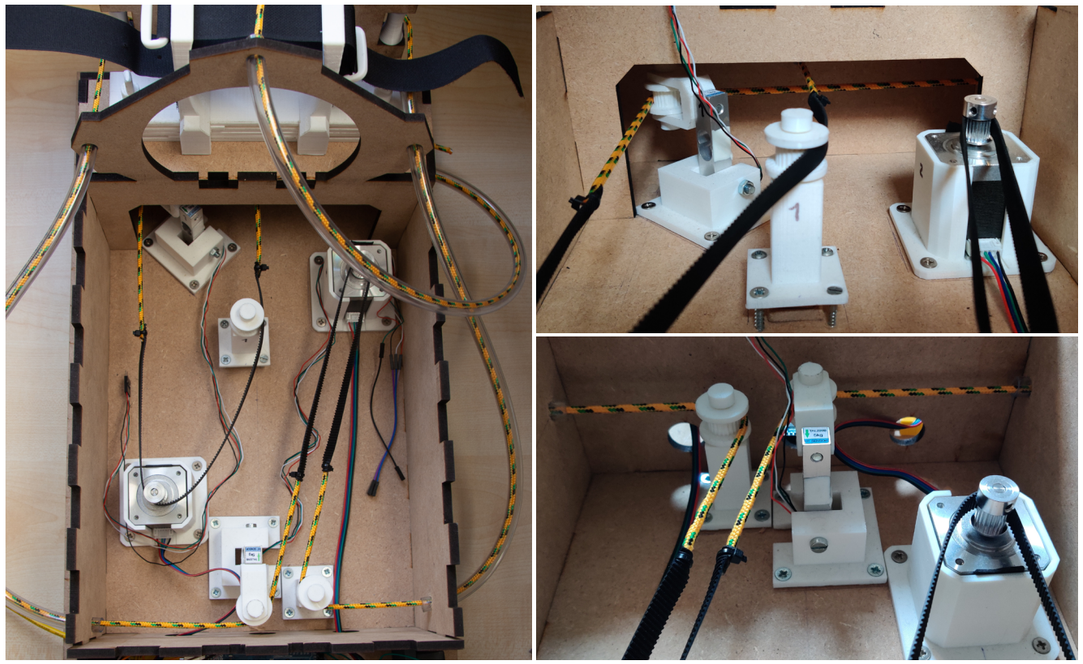


Figure 5.1.21. Actuation and transmission of the product.

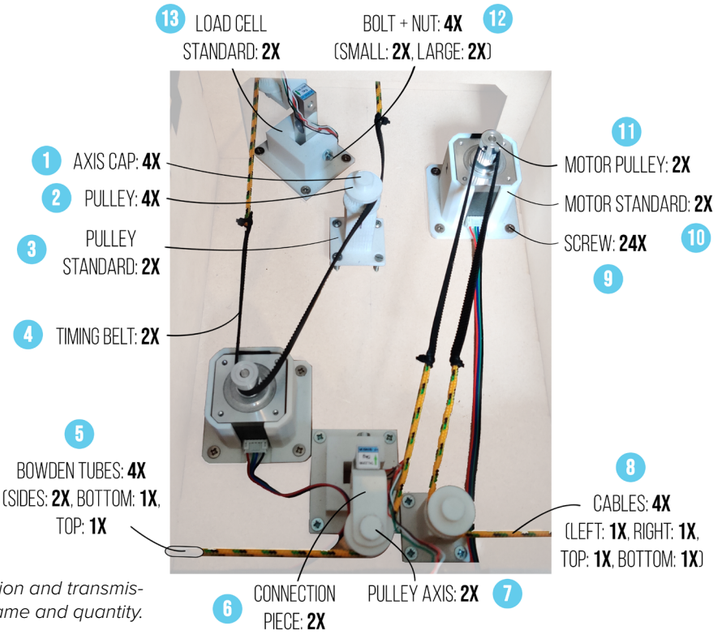


Figure 5.1.22. Actuation and transmission parts: name and quantity.

Parts

For the actuation and transmission of the product there are thirteen parts (figure 5.1.22). The cables, Bowden tubes, screws, bolts and nuts, timing belts and the motor pulleys are purchased parts. Of these parts the cable, Bowden tubes and timing belt still need to be cut to the correct size. The rest of the parts are 3D-printed.

Dimensions

The main (outer) dimensions of the different parts of the actuation and transmission can be seen in figure 5.1.23 (3D printed parts) and 5.1.24 (purchased parts). For the specific dimensions of all parts, see Appendix II.

Modifications

Regarding the actuation and transmission of the product no modifications have been made. Instead, the two cable-pulley system was selected out of (in total) three concepts, to use and integrate in the product. More about this is discussed in subchapter 3.4.5.

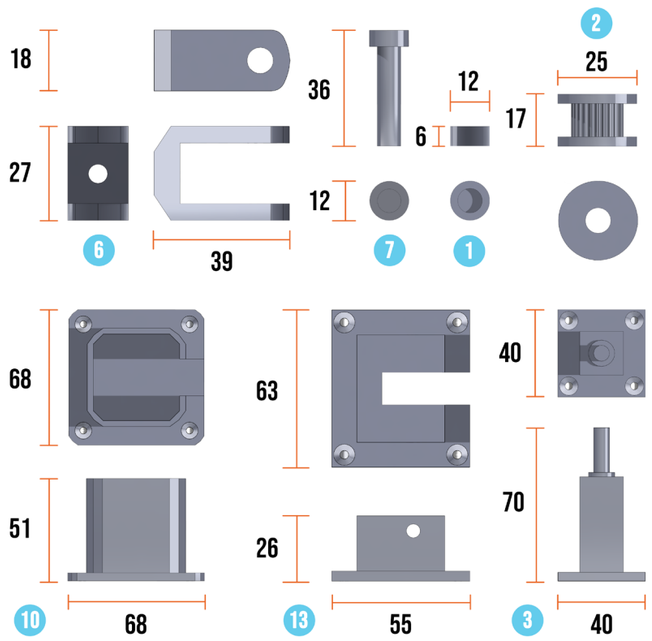


Figure 5.1.23. Main outer dimensions of the 3D printed parts (in [mm]).

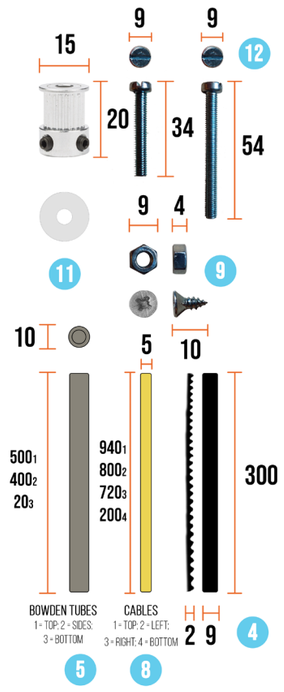


Figure 5.1.24. Main outer dimensions of purchased parts (in [mm]).

5.1.7 Control panel (07 00)

The control panel of the product (figure 5.1.25) is used by the radiologist and laboratory technicians to control and operate the product. Unfortunately, during the project it did not work out to finish and make the control panel. In the end the prototype could be controlled by the push buttons mounted on the breadboard, which is shown in this subchapter.

Functions

The actuation and transmission part of the product has one function:

1) The control panel facilitates the connection between the hardware and software of the product (the operating system and the electronic parts respectively) on the one hand, and the user on the other hand. In other words, it enables the radiologist and laboratory technician to control and operate the product.

Parts

Looking at the (unfinished version of the) control panel of the product there are four parts to be identified. These parts are the four 'positioning' buttons, which are used to position the hand fixation (and therewith the patient's hand) into the correct starting position (as described in subchapter 3.5.3).

As mentioned before the control panel could not be prototyped completely in the end. Because of this reason the subchapters 'Dimensions' and 'Modifications' are left out. More about what the control panel should look like in the end, can be read in subchapter 5.4. More about what still needs to be integrated in the control panel is discussed in subchapter 7.1.

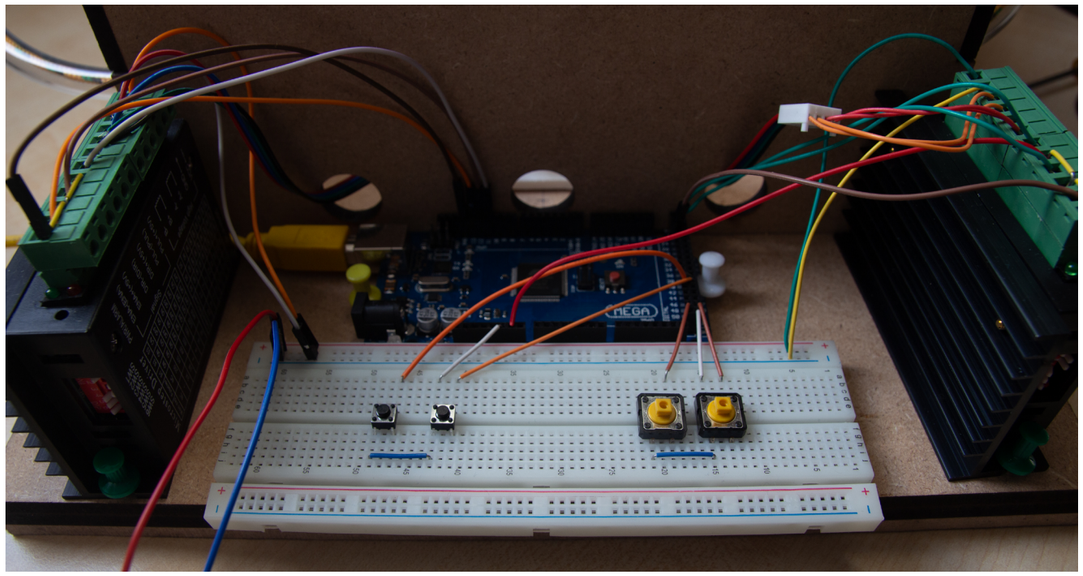


Figure 5.1.25. Control panel in latest prototype.

5.1.8 Conclusion

Summary

5.1.1 - 5.1.7

- The product is divided into seven components: the baseplate (01 00), arm standard (02 00), wrist standard (03 00), forearm fixation (04 00), hand fixation (05 00), actuation and transmission (06 00) and the control panel (07 00).
- For each of the components their function, different parts, (outer) dimensions and the modifications are described.
- Each component has been improved during the project within an iterative prototyping process.

5.2 Electronics

In this paragraph the different electronic components of the product are described and elaborated on.

5.2.1 Components

As was also mentioned in subchapter 3.4.6, for the electronic part of the product there are eleven different components that have to be used. Below all components and their dimensions (figure 5.2.1) and the required quantity and their function (table 5.2.1) can be seen.

In the current prototype an external 9V adapter is used to power the device. However, as was later advised by M. Verwaal (personal communication, March 10, 2020), the device can also be powered wirelessly by using a 9V battery (with a battery clip). In this case the device would not be needed to be plugged into a socket. More about this can be read in subchapter 7.1. Also, when the device has the most recent (correct) version of the software uploaded to it, also the USB cable is not needed to connect the device to a pc. Because of this, the dimensions of both the external 9V adapter and the USB cable are not relevant, and are therefore not taken into account in figure 5.2.1.

Table 5.2.1. Electronic components, quantity and purpose.

No.	Component	Quantity	Function
1	Arduino Mega	1	Connect and control all electronic parts
2	NEMA 17 stepper motor	2	Facilitate desired wrist movements
3	TB6600 stepper driver	2	Operate and control stepper motors
4	Load cell (5 [kg])	2	Measure real-time tension on cables
5	HX711 amplifier sensor	2	Amplify load cell signal for Arduino Mega
6	Push button	6	Input for stepper motor control
7	Jumper cables	50+	Connect different electronic parts
8	Breadboard	1	Connect different electronic parts
(9)	USB 2.0 connection cable (type B to -A)	1	Connects computer to Arduino Mega to transfer software code
(10)	External 9V adapter	1	Power stepper motors with 9V
11	Female DC power adapter	1	Connect 9V adapter to Arduino

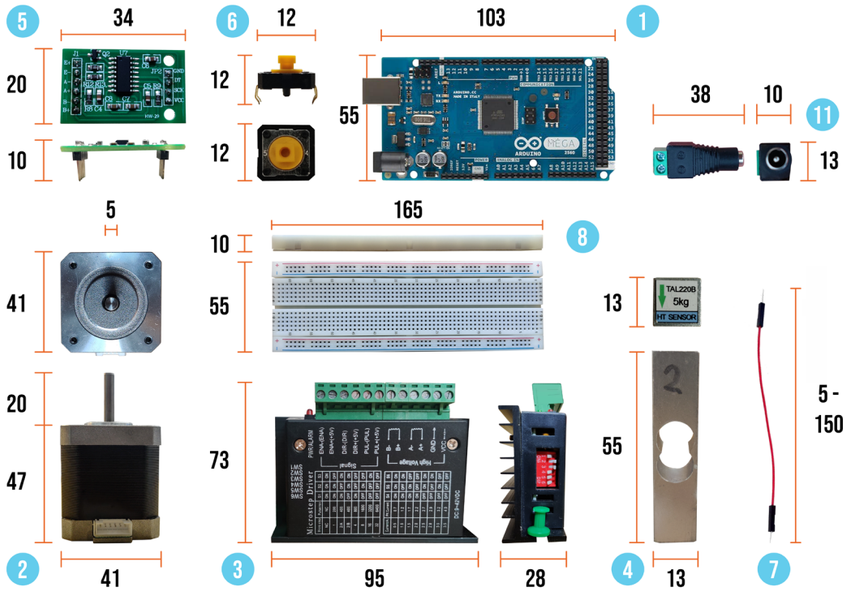


Figure 5.2.1. Electronic parts: number and dimensions (in [mm]).

5.2.2 Hardware

For the final product it was desired that it could automatically facilitate all passive movements by pressing only one (the 'start') button. With the use of the load cells which could measure and calculate the cable tension, each movement would be facilitated up until the point that the cable tension threshold was reached. In the final prototype of the project the passive movements could be facilitated, but only manually by the user pressing the four 'positioning' buttons. Therefore, to finish the electronic system of the prototype, two things still had to be integrated:

1) The HX711 amplifier sensors, which are (in combination with the load cells) used to facilitate the measurement of the cable tension, have to be connected to the load cells and the rest of the electronic system. In the current prototype the load cells are already integrated.

2) The 'stop' button, which can be used to stop the passive movement at any time in case something goes wrong, has to be integrated and connected to the rest of the electronic system.

More information about what exactly needs to be added and improved for the electronic system, see subchapter 7.1. For pictures of the electronic setup of the current prototype, see figure 5.2.2 and 5.2.3. The dip switches in figure 5.2.3 are used to set the current the motors receive and the amount of pulses per revolution (which regulates the speed of the motor). These dip switch settings still have to be finetuned. For a schematic overview of this hardware setup see figure 5.2.4. An overview of the desired hardware setup can be found in Appendix JJ.

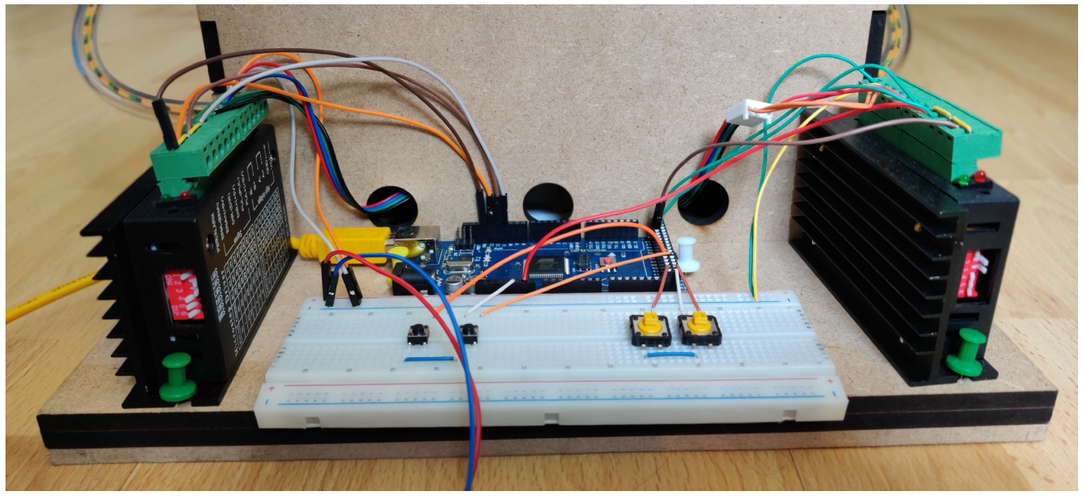


Figure 5.2.2. Electronic setup of current prototype.

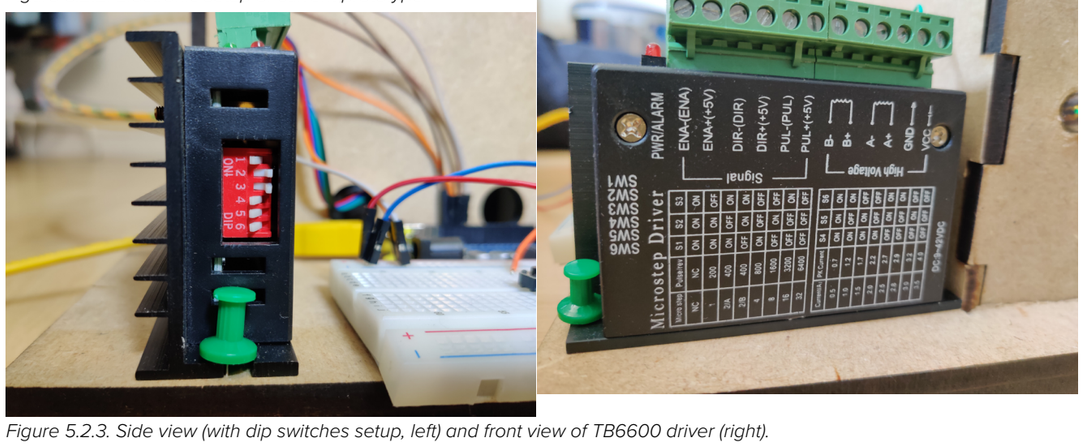


Figure 5.2.3. Side view (with dip switches setup, left) and front view of TB6600 driver (right).

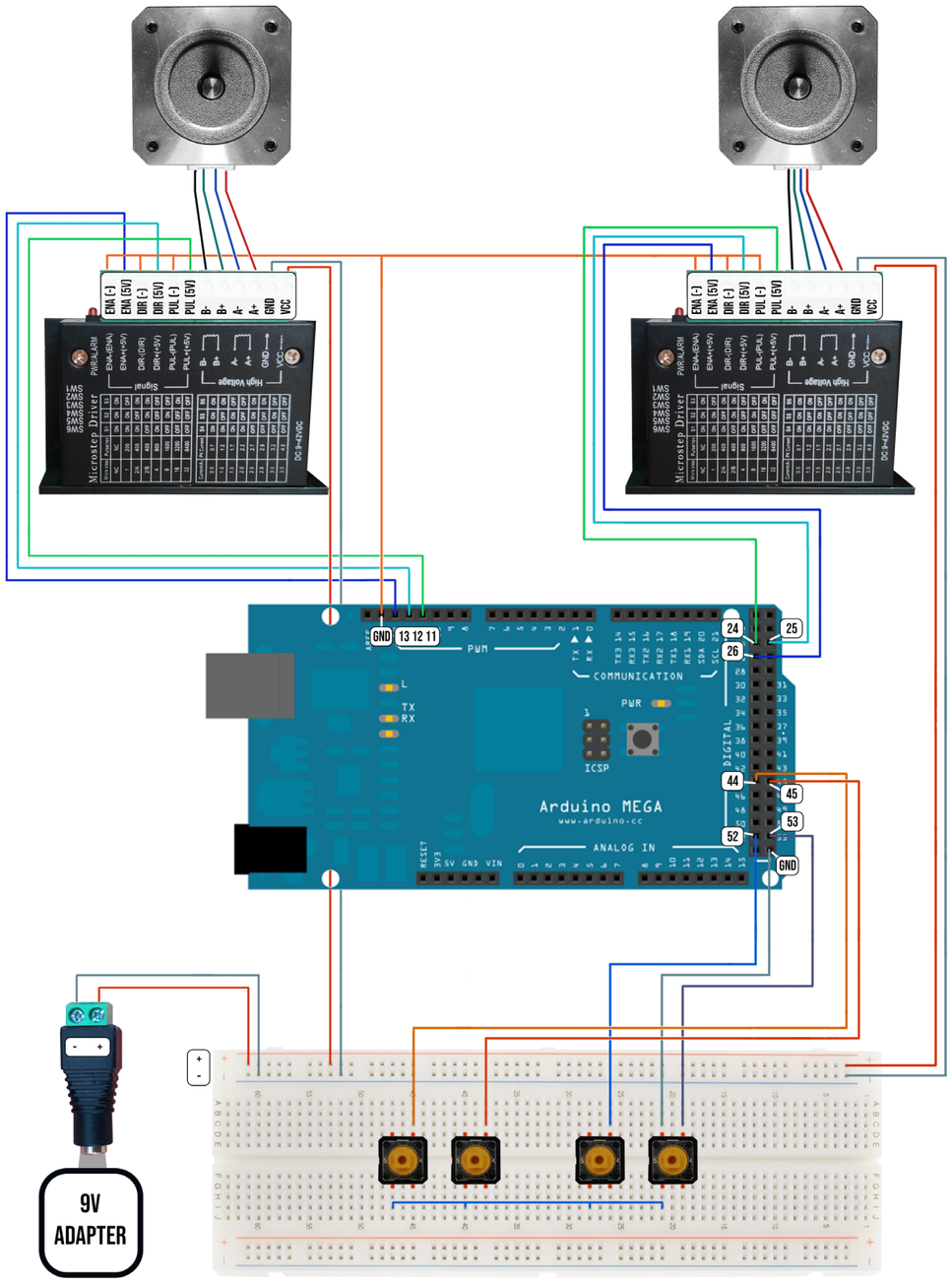


Figure 5.2.4. Overview of hardware setup of current prototype.

5.2.3 Software

The hardware shown in the previous subchapter is operated by an Arduino software code. In this code the different electronic components are introduced and their desired actions are programmed. Below the different parts and their function are described.

First, the pin numbers of the motor connections and the push buttons are defined (figure 5.2.5). Motor 1 facilitates deviation (controlled by buttons 1 and 2), while motor 2 facilitates flexion and extension (controlled by buttons 3 and 4).

Secondly, the beginning state of the buttons is set at zero, letting the system know that in the beginning none of the buttons is pressed (figure 5.2.6).

Thirdly, all the pins and buttons (which were introduced in step 1) are defined as either an input or an output (figure 5.2.7). As the push buttons are used to control the device, these have to be defined as inputs. On the other hand, the movement of the motors (and therewith the movement of the wrist) is the desired outcome and goal of the device, which is why the motor pins are defined as outputs.

STEP 1: DEFINE PIN NUMBERS

```
// MOTOR PINS
  // Motor 1
   const int dirPin_Motor1    = 12;
   const int stepPin_Motor1   = 11;
   const int enaPin_Motor1    = 13;

  // Motor 2
   const int dirPin_Motor2    = 24;
   const int stepPin_Motor2   = 25;
   const int enaPin_Motor2    = 26;

// PUSH BUTTONS
  // Deviation
  const int Button1 = 44;
  const int Button2 = 45;

  // Flexion
  const int Button3 = 52;
  const int Button4 = 53;
```

MOTOR CONNECTIONS (ENA+, DIR+, PUL+)

PUSH BUTTONS

Figure 5.2.5. Software code part 1: define pin numbers.

STEP 2: DEFINE BUTTON STATE

```
//BUTTON STATES

int buttonStateB1 = 0;         // current state of the button

int buttonStateB2 = 0;         // current state of the button

int buttonStateB3 = 0;         // current state of the button

int buttonStateB4 = 0;         // current state of the button
```

BUTTONS 1 - 4

Figure 5.2.6. Software code part 2: define button state.

STEP 3: SET PINS AS INPUTS/OUTPUTS

```
void setup() {

  Serial.begin(9600);

  // Sets the button pins as OUTPUTS
  pinMode(Button1, INPUT_PULLUP);
  pinMode(Button2, INPUT_PULLUP);
  pinMode(Button3, INPUT_PULLUP);
  pinMode(Button4, INPUT_PULLUP);

  // Sets the two motor pins of each motor as OUTPUTS
    // Motor 1
    pinMode(stepPin_Motor1,OUTPUT);
    pinMode(dirPin_Motor1,OUTPUT);

    pinMode(enaPin_Motor1,OUTPUT);
    digitalWrite(enaPin_Motor1,LOW);

    // Motor 2
    pinMode(stepPin_Motor2,OUTPUT);
    pinMode(dirPin_Motor2,OUTPUT);

    pinMode(enaPin_Motor2,OUTPUT);
    digitalWrite(enaPin_Motor2,LOW);
```

PUSH BUTTONS AS **INPUTS**

MOTOR 1 PINS AS **OUTPUTS**

MOTOR 2 PINS AS **OUTPUTS**

Figure 5.2.7. Software code part 3: set pins as in- or outputs.

STEP 4: BUTTON DIGITAL SIGNAL

```
void loop() {
  buttonStateB1 = digitalRead(Button1);
  buttonStateB2 = digitalRead(Button2);
  buttonStateB3 = digitalRead(Button3);
  buttonStateB4 = digitalRead(Button4);
```

DIGITAL SIGNAL DEFINES BUTTON STATE

Figure 5.2.8. Software code part 4: button digital signal.

STEP 5: MOTOR 1 CONTROL WITH PUSH BUTTONS

```
// Button 1

  if (buttonStateB1 == HIGH) {
    digitalWrite(dirPin_Motor1,HIGH);
    digitalWrite(stepPin_Motor1, LOW);
  }
  if (buttonStateB1 == LOW) {

    digitalWrite(stepPin_Motor1, HIGH);
  }
  delayMicroseconds(500);

// Button 2

  if (buttonStateB2 == HIGH) {
    digitalWrite(dirPin_Motor1,LOW);
    digitalWrite(stepPin_Motor1, LOW);
  }
  if (buttonStateB2 == LOW){
    digitalWrite(stepPin_Motor1, HIGH);
  }
  delayMicroseconds(500);
```

IF **BUTTON 1** IS **NOT PRESSED** > **MOTOR 1** DOES **NOT WORK**
IF **BUTTON 1** IS **PRESSED** > **MOTOR 1** DOES **WORK**

CLOCKWISE ROTATION

IF **BUTTON 2** IS **NOT PRESSED** > **MOTOR 1** DOES **NOT WORK**
IF **BUTTON 2** IS **PRESSED** > **MOTOR 1** DOES **WORK**

COUNTER-CLOCKWISE ROTATION

Figure 5.2.9. Software code part 5: motor 1 control with push buttons.

Subsequently, in the fourth step the button states of each of the four buttons are based on their digital signal picked up by the Arduino (figure 5.2.8). Normally, the button not being pressed would result in a 'LOW' signal and in this case no rotation of the motor. However, for some reason the push buttons gave a 'HIGH' signal while they were not being pressed. Therefore, in the code the motors are programmed in a different way: the push button giving a 'HIGH' signal results in no motor rotation; the push button giving a 'LOW' signal results in motor rotation. This can also be seen in step 5.

Finally, in step 5 the motors are controlled based on the digital signal of the push buttons (figure 5.2.9) (described in step 4). In this case motor 1 is shown, which is controlled by buttons 1 and 2. Not pressing any of the buttons results in no rotation of the motor. On the other hand, pressing button 1 results in clockwise rotation and pressing button 2 results in counter-clockwise rotation. The same applies for motor 2, only this motor is controlled by buttons 3 and 4.

As mentioned before, the part of the load cells and HX711 amplifier sensors is not integrated yet in the code. This is further discussed in subchapter 7.1.

5.2.4 Conclusion

Summary

5.2.1

- There are eleven different electronic components that have to be used in the product. For all parts their name, quantity, function and main dimensions are described.
- At this point the prototype is powered with an external 9V adapter; in the future it could also be powered wirelessly with a 9V battery.

5.2.2

- In the final prototype of the project the passive movements could be facilitated, but only manually by the user pressing the four 'positioning' buttons.
- The device still has to be finished; more about this can be read in chapter 7.

5.2.3

- The hardware shown in subchapter 5.2.2 is operated by an Arduino software code. In this code the electronic components are introduced and their desired actions are programmed.

5.3 Working & usage

In this paragraph the working and usage of the product is explained. The usage of the product is elaborated with the use of a scenario (storyboard) (figure 5.3.1). Next to that, the working is elaborated with a small flowchart (figure 5.3.2), indicating how (and when) the different buttons of the product are used.

In total three different stakeholders are involved in the scenario: the radiologist, the laboratory technician and the patient. Per step of the scenario is highlighted (with a color) in the top left corner which stakeholders are involved. The radiologist is indicated with blue, the laboratory technician with green and the patient with orange. When the device is involved in a step, for example in the case of facilitating the passive movements, it is indicated with a yellow color. In general, the roles of the different stakeholders can be described as follows:

Radiologist

- In control of the patient check-up
- Controls and operates the device
- Checks positioning of both the device and the patient
- Communicates with the control room
- Defines CT scanning settings
- Starts CT scan and device (passive) movement

Laboratory technician

- Positions the device correctly in the CT scanner
- Positions the patient correctly in the device
- Fixates (and loosens) the patient's forearm and –hand in the device
- If necessary, cleans device with disinfectant wipes

Patient

- Follows instructions of both the radiologist and laboratory technician
- Indicates if he or she is okay

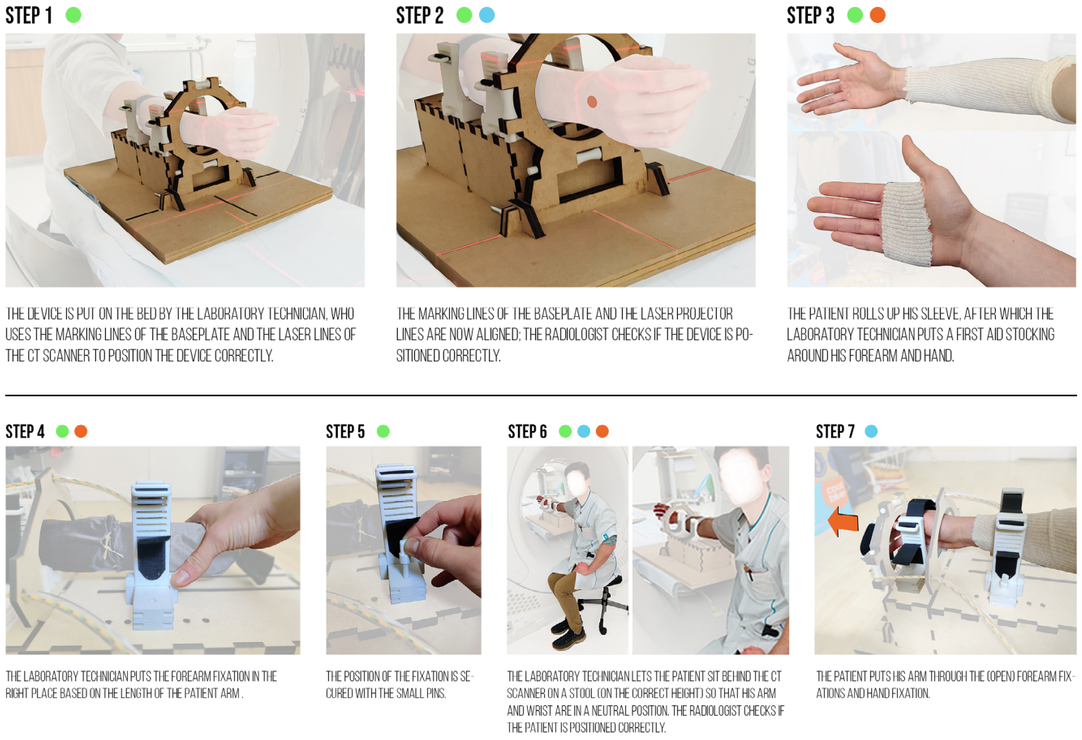
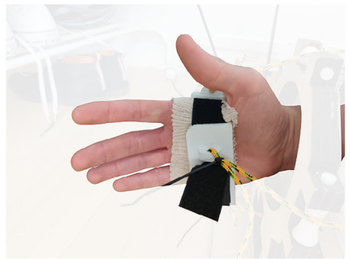


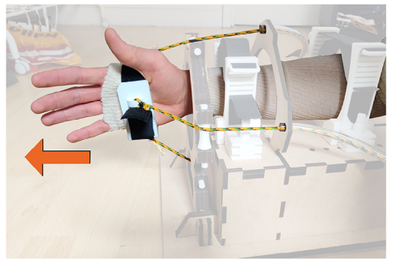
Figure 5.3.1. Product usage scenario involving radiologist, laboratory technician and patient (1/3).

STEP 8



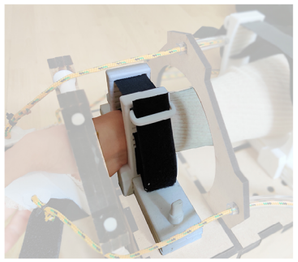
THE HAND FIXATION IS POSITIONED CORRECTLY AT THE (METACARPALS OF THE) PATIENT'S HAND AND FIXATED USING THE STRAP.

STEP 9



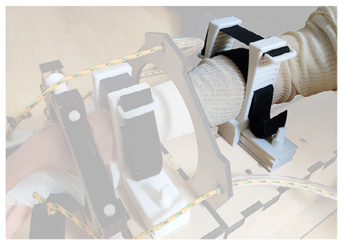
SUBSEQUENTLY, THE FOREARM IS PUSHED FURTHER FORWARD IN ORDER TO ACQUIRE THE DESIRED TENSION ON THE CABLES AND TO ALIGN THE WRIST WITH THE WRIST STANDARD.

STEP 10



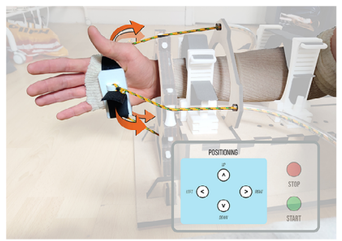
WHEN THIS TENSION IS ACQUIRED, THE FOREARM FIXATION NEAR THE WRIST IS FIXATED FIRST BY THE LABORATORY TECHNICIAN USING THE STRAPS.

STEP 11



THEN, THE FOREARM FIXATION NEAR THE ELBOW IS FIXATED USING THE STRAPS, AGAIN BY THE LABORATORY TECHNICIAN.

STEP 12

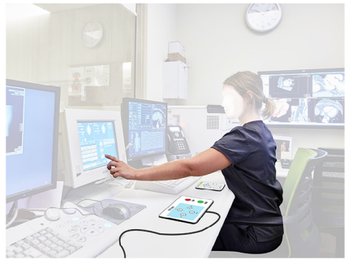


IF NEEDED, THE RADIOLOGIST USES THE 'POSITIONING' BUTTONS TO MANEUVER THE PATIENT'S HAND INTO THE CORRECT STARTING POSITION.

STEP 13

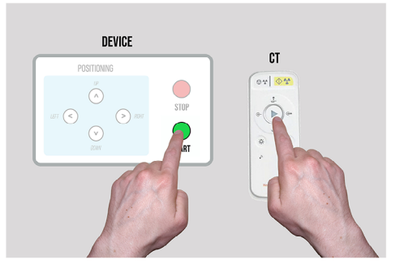
WHEN EVERYTHING IS GOOD TO GO, THE RADIOLOGIST AND LABORATORY TECHNICIAN GO OUTSIDE THE ROOM, TO PREVENT CATCHING RADIATION.

STEP 14



THE CONTROL PANEL IS CONNECTED VIA A LONG WIRE AND CAN THUS BE TAKEN WITH THEM.

STEP 15

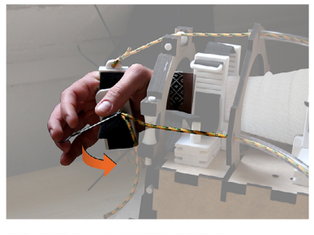


AT EXACTLY THE SAME TIME THE CT SCAN AND THE MOVEMENT SEQUENCE OF THE DEVICE ARE STARTED. A LABORATORY TECHNICIAN STARTS THE CT SCANNER AND THE RADIOLOGIST PUSHES THE GREEN 'START' BUTTON OF THE DEVICE.

STEP 16

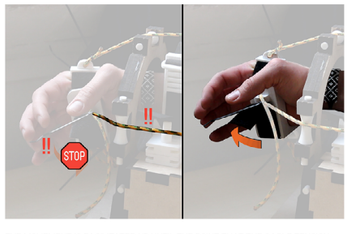
AT THE MOMENT THE 'START' BUTTON IS PRESSED, THE CABLE TENSION THRESHOLD IS DEFINED BY THE SYSTEM BASED ON THE CABLE TENSION ON THE MOMENT THE BUTTON WAS PRESSED.

STEP 17



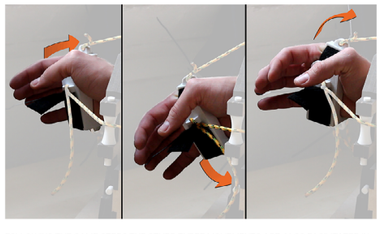
FIRST, WRIST FLEXION IS FACILITATED BY THE DEVICE.

STEP 18



THE MOVEMENT IS FACILITATED UP UNTIL THE POINT THAT THE CABLE TENSION THRESHOLD IS REACHED. AT THIS POINT THE MOVEMENT AUTOMATICALLY STOPS AND THE HAND RETURNS TO THE STARTING POSITION.

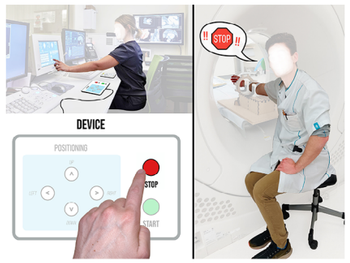
STEP 19



FOLLOWING THE SAME STEPS THE OTHER THREE MOVEMENTS ARE ALSO FACILITATED IN THE FOLLOWING ORDER: WRIST EXTENSION, RADIAL DEVIATION AND ULNAR DEVIATION.

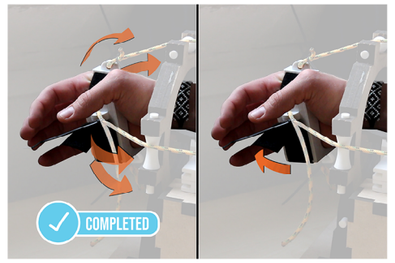
Figure 5.3.1. Product usage scenario involving radiologist, laboratory technician and patient (2/3).

STEP 20



DURING THE PASSIVE MOVEMENTS THE PATIENT CAN ALWAYS INDICATE WHEN HE IS FEELING PAIN OR UNCOMFORTABLE. IN THIS SCENARIO THE RED 'STOP' BUTTON CAN BE USED TO CANCEL THE PASSIVE MOVEMENT.

STEP 21

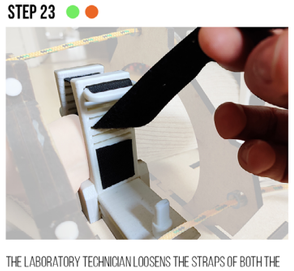


AFTER THE MOVEMENT SEQUENCE IS COMPLETED, THE HAND IS RETURNED INTO THE STARTING POSITION.

STEP 22

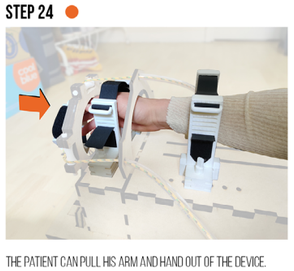
THE RADIOLOGIST AND LABORATORY TECHNICIAN RE-ENTER THE CT ROOM.

STEP 23



THE LABORATORY TECHNICIAN LOOSENS THE STRAPS OF BOTH THE FOREARM FIXATIONS AND THE HAND FIXATION.

STEP 24

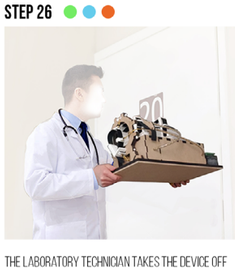


THE PATIENT CAN PULL HIS ARM AND HAND OUT OF THE DEVICE.

STEP 25

THE FIRST AID STOCKINGS AROUND THE PATIENT'S FOREARM AND HAND ARE TAKEN OFF AND THROWN AWAY.

STEP 26



THE LABORATORY TECHNICIAN TAKES THE DEVICE OFF THE CT BED AND STORES IT SOMEWHERE. THE RADIOLOGIST FINALIZES THE CHECKUP WITH THE PATIENT.

Figure 5.3.1. Product usage scenario involving radiologist, laboratory technician and patient (3/3).

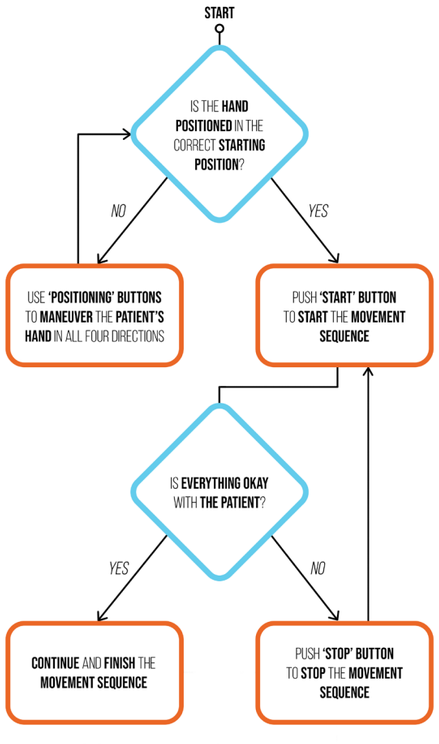


Figure 5.3.2. Flowchart of product working.

5.4 Product vision

In this subchapter a vision is given for the product regarding its styling, the materials and production and its price. This vision can be used for future development of the product. For each of the subchapters the method and results are explained.

5.4.1 Styling

The styling of the future product is based on the appearance and styling of both existing and futuristic medical products. In this way a decent balance could be found between current (topical) and futuristic design. A collection of images of these products was made (figure 5.4.1), providing a set of aspects which could be used in the future design vision of the product.

Looking at the different products there are three overarching aspects to be identified. First of all, all products are designed quite organic with fluent shapes and rounded corners and edges. Still, straight lines and shapes can also be seen, like with number 1, 4 and 5. In the end this results in a more simplistic and clean look.

Secondly, obviously a lot of white is used in all the products; black and (light) blue are also recurring in multiple products.

Thirdly, there can be seen lots of parting lines in all products. The lines are quite minimalistic, but provide the products with a bit more detailing.

Figure 5.4.1. Collection of medical products. Sources: 1. (BusinessWire, 2016); 2. (Cornelissen, 2013); 3. (Borsoï, 2012); 4. (IF Design, 2016); 5. (F/P Design, 2016); 6. (Cadcrowd, n.d.).

Based on the overarching aspects described above, the styling vision of the product is realized (figure 5.4.2). The product has been given a more professional, clean and futuristic look. The white and blue colors are used to give the product a modern 'hospital' look, while the orange is used for detailing and usecues.

Both the forearm- and hand fixation have been optimized in terms of appearance as well. Rounded shapes and corners in combination with the use of colors makes the parts look more aesthetically pleasing.

Looking at the product body, the baseplate is not integrated as this would draw too much attention. The arm- and wrist standard are connected so that there is more cohesion within the product. Also, the extra panel of the arm standard (used as a guidance point for the Bowden tubes) is integrated better into the sides of the arm standard.

Finally, the control panel has been transformed into a remote control. The remote can be clicked into place at the back of the product (e.g. when storing the product somewhere).

However, when the product is in use and the radiologist wants to operate it from the control room, the remote can be disconnected and taken with him.

For the product's materials and production (5.4.2) and the product's price (5.4.3) the current prototype has been taken into account. This model is simply not realistic when looking at development within the first couple years.

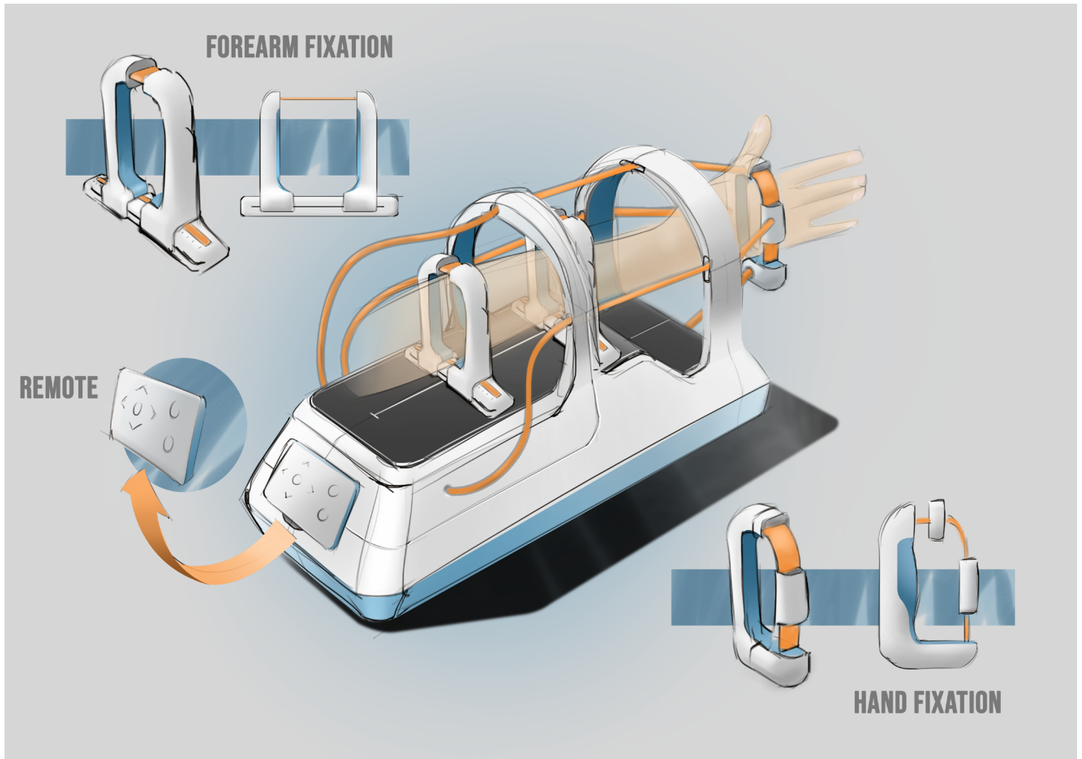


Figure 5.4.2. Future styling vision of product. Source: (Osseweijer, 2020).

5.4.2 Materials & production

The materials and production method(s) which are used in the future product are dependent on the batch size. Having a relatively large batch size makes it possible to make use of more expensive production methods which are able to produce large quantities within a short period of time, like injection molding (Worth, 2018).

Batch size

The batch size of the product was based on a discussion with S. Buckens (personal communication, April 29, 2020) about possible distribution and implementation of the product in the future. For now the product first has to be further developed and tested before it can be implemented (more about this is discussed in subchapter 7.2). Therefore, there is merely focused on the Netherlands for the first couple years; later distribution to other countries in Europe (and possibly even the rest of the world) could be an option.

Scenario 1

According to Buckens, the product can only be used in combination with a special 4D CT scanner with a high scanning frequency, in order to capture the fourth dimension of the CT scan (movement). Besides the Radboud UMC, only four other hospitals in the Netherlands have such a CT scanner. These are hospitals in Rotterdam, Amsterdam, Amersfoort and Den Bosch. This results in a batch size of five products.

Scenario 2

However, as was mentioned by Buckens as well, it could be that the product could be made useful for 'normal' CT scanners (which capture images with a lower frequency) as well. The product then has to be adjusted so that the passive movements are facilitated significantly slower, to cope with the lower scanning frequency. In the end this would result in a batch size which could add up to 100. However, as it is far more likely for scenario 1 to take place, this scenario is not taken into account further.

Figure 5.4.3. Scenario 1 for the batch size.

Materials and production

Because of the small batch size the production methods which are used for this prototype can also be used for the other four products. An overview of the production methods and materials can be seen in figure 5.4.4.

3D printed parts

The forearm fixations and hand fixation, the parts for the wrist standard (pulleys etc.) and the operating system can still be 3D printed. For the current prototype PLA was used as printing material, as this was the standard material used for (free) 3D printing in the faculty. In the scenario where the 3D printers of the faculty could still be used to 3D print for free, naturally PLA would be used for the prints.

Otherwise ABS would also be an option as the material costs are equal to PLA, which is approximately €20 per spool (Giang, n.d.). Furthermore, both materials have their benefits. On the one hand PLA is a safer material which gives more precise prints and aesthetic quality (Hesse, 2018). On the other hand ABS is a stronger material with a higher impact resistance (Hesse, 2018). To conclude, PLA seems as the most suitable material as its benefits seem more relevant to the hospital context. Also, the 3D printed parts do not need to be really strong, as the forces working on them are relatively small.

Laser cut parts

Also, the parts for the baseplate, arm standard and wrist standard can still be laser cut. However, as was advised by T. Essers (personal communication, February 24, 2020) it might be better to use acrylate instead of MDF. Acrylate is easier to clean and also looks cleaner and more professional compared to MDF. A drawback of this material is that it is significantly more expensive than MDF. According to Laserbeest (2017), an MDF plate (1000x1000x6 [mm]) costs €6.43, while a white acrylic plate (1000x1000x3 [mm]) costs €41.22. In this case the acrylic plate is also even half as thick as the MDF plate. The costs for both materials are calculated in subchapter 5.4.3.

Purchased parts

Finally, of course the electronic parts (stepper motors and –drivers, load cells, etc.) and some parts of the operating system (motor pulleys and normal pulleys) can still be purchased.

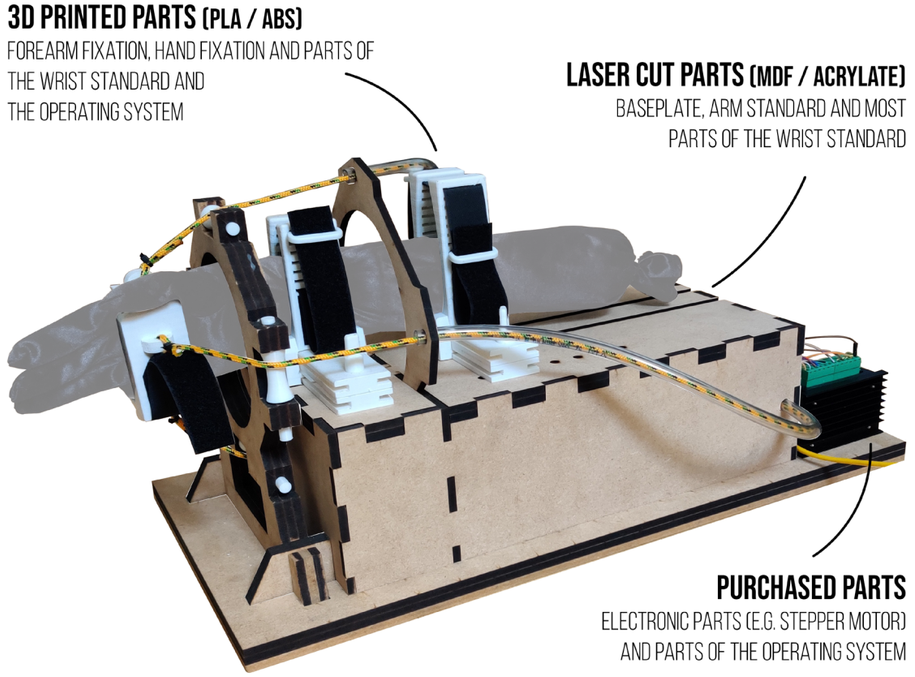


Figure 5.4.4. Product production methods and materials.

5.4.3 Price

The cost price of the product is based on the choice of materials and production method for the product parts mentioned in subchapter 5.4.2. During the projects all 3D printed and laser cut parts were made for free, as the facilities of the faculty were used. However, for this cost estimation it is assumed that none of the parts can be made for free, in order to come up with a realistic cost estimation of the product for the hospital. Any post-processing is not taken into account for the cost calculation.

3D printed parts

In total for four components of the product there are parts which have to be 3D printed: the forearm- and hand fixation, the wrist standard and the operating system.

In order to determine the costs for these 3D printed parts, a quotation was requested at a 3D printing company (3D hubs, 2020) (also see Appendix KK). In table 5.4.1 the costs per part (of every component) can be seen to 3D print it. Both 3D printing time and material costs are included. An infill density of 20% and a layer height of 200µm were assumed, as these are considered common settings used for 3D printing (Siber, 2019).

As can be seen in table 5.4.1, the total costs for the 3D printed parts of five products would result in €574.50; per product this would result in €114.90.

For all parts applied that the price per piece decreased if more pieces were ordered (bulk pricing (3Dhubs, 2020). In this case it was assumed that five entire products needed to be made, based on scenario 1 mentioned above. In the end this results in a quantity of all required 3D printed parts (for one product) times five. For example, the 'body (bottom half)' part of the forearm fixation is needed two times per product. For five products this would results in: 5*2 = 10 parts. Of course it would be useful if more parts were ordered to serve as spare parts. This would also decrease the costs per piece because of the bulk pricing. However, this is not taken into account in the cost calculation.

Table 5.4.1. Costs of 3D printed product parts. Source: (3D hubs, 2020).

Component	Part	Quantity/product	Quantity total	Costs/piece [€]	Subtotal [€]
Forearm fixation	Body (bottom)	2	10	7.11	71.10
	Body (top)	2	10	7.70	77.70
	Spur gear	2	10	0.86	8.60
	Elbow slider	2	10	8.32	83.20
	Wrist slider	2	10	6.60	66.00
	Small position pin	4	20	0.88	17.60
Hand fixation	Body	1	5	6.45	32.25
	Top slider	1	5	1.51	7.55
	Side slider	1	5	1.75	8.75
Wrist standard	Pulley	4	20	0.90	18.00
	Axis bottom	1	5	1.91	9.55
	Axis side	2	10	1.01	10.10
	Axis top	1	5	1.52	7.60
	Axis cap	4	20	0.77	15.40
Operating system	Pulley standard	2	10	2.41	24.10
	Motor standard	2	10	4.82	48.20
	Load cell standard	2	10	3.12	31.20
	Connection piece	2	10	1.34	13.40
	Pulley axis	2	10	0.88	8.80
	Axis cap	4	20	0.77	15.40
			Total (5 products)		574.50
			Total (1 product)		114.90

Laser cut parts

In total there are three components of the product which have to be laser cut: the baseplate and the arm- and wrist standard. The costs for these laser cut parts consist of the material costs, file preparation time and laser cutting time.

Material

By taking the different parts and their dimensions, it was defined that approximately 1.5 [m2] of MDF was needed in total to laser cut all parts (Appendix LL). This would result in: 1.5*6.43 = €9.65 of material costs. For acrylate this would result in: 1.5*41.22 = €61.83 of material costs.

File preparation time

Rates for file preparation time are approximately €18.00 (Laserbeest, n.d.), which has to be paid only once. Within this time the files which are delivered are checked, adjusted if needed and prepared for the laser cut machine.

Laser cutting time

The laser cutting time required for all parts was determined in discussion with a laser cut expert from the faculty of Industrial Design Engineering (personal communication, April 21, 2020). Based on his experience the laser cutting time for all parts is defined at 45 minutes. Hourly rates for laser cutting are approximately €72 (Laserbeest, n.d.), which results in: 0.75*72 = €54.

Total costs

The total costs for the laser cut parts can be seen in table 5.4.2. As can be seen there is quite a large difference between the costs for MDF and acrylate: €51.18. To reduce this costs difference also only a few parts could be made of acrylate, while still keeping the majority of the parts of MDF.

Table 5.4.2. Total costs laser cut parts.

Description	Costs MDF [€]	Costs Acrylate [€]
Material	9.65	61.83
File preparation time	18	18
Laser cutting time	54	54
Total	81.65	133.83

Purchased parts

For the parts which can be purchased an overview is given, containing the name, quantity, price and supplier (table 5.4.3). For all parts the most affordable option was selected, which is why AliExpress is the supplier for all parts.

Table 5.4.3. Overview costs of purchased parts, including part name, quantity, price and supplier. Source: (AliExpress, n.d.).

Component	Part	Quantity	Costs [€]	Subtotal [€]	Supplier
Electronics	Arduino Mega + USB cable	1	5.15	5.15	AliExpress
	NEMA 17 stepper motor	2	2.80	5.60	
	TB6600 stepper driver	2	3.73	7.46	
	Load cell (5 [kg]) + HX711 sensor	2	1.88	3.76	
	HX711 amplifier sensor	2	-		
	Push button	6	0.92	5.52	
	Jumper cable	50+	0.93	0.93	
	Breadboard	1	0.35	0.35	
	USB 2.0 connection cable	1	-		
	External 9V adapter	1	0.58	0.58	
	Female DC power adapter	1	0.29	0.29	
Operating system	Motor pulley	6	0.23	1.38	AliExpress
	Velcro straps	4	0.46	1.84	
			Total	32.86	

Total costs

In table 5.4.4 the total costs for the product can be seen, which are based on the costs for the different production methods described above. As for the laser cut parts the materials MDF and acrylate were compared, both materials are also taken into account in the total costs calculation.

Looking at table 5.4.4, one entire new product manufactured with the production methods described above, costs either €229,41 (laser cut parts of MDF) or €281,59 (laser cut parts of acrylate). The difference in costs is only caused by the difference in material costs for MDF and acrylate, which is: €52.18.

Eventually the hospital is responsible for making the choice which material is going to be used and therefore how much the product is going to cost. My advice would be to focus on higher quality for the product concerning appearance, hygiene and usability. These benefits significantly outweigh the relatively small difference in costs. In other words, choose the more expensive option with the acrylate rather than the (slightly) cheaper option of MDF.

Table 5.4.4. Total product costs.

Description	Costs MDF [€]	Costs Acrylate [€]
3D printed parts	114.90	114.90
Laser cut parts	81.65	133.83
Purchased parts	32.86	32.86
Total	**229.41**	**281.59**

5.4.4 Conclusion

Summary

5.4.1

- The styling of the future product is based on the appearance and styling of both existing and futuristic medical products.
- Looking at the different products there are three overarching aspects to be identified: organic and fluent shapes, the combination of black, white and blue colored parts and the presence of parting lines.
- Based on the aspects described above, the styling vision of the product is realized; it has been given a more professional, clean and futuristic look.

5.4.2

- A batch size of five has been defined, based on the product being used in five hospitals in Netherlands (which posses a special compatible 4D CT scanner).
- In total two production methods are used: 3D printing and laser cutting. For 3D printing the material PLA is used; for laser cutting MDF or acrylate can be used. Some parts can also simply be purchased on AliExpress.

5.4.3

- The cost price of the product is based on the choice of materials and production methods for the product parts.
- 3D printing the parts for one product costs €114.90; laser cutting the parts costs either €81.65 (MDF) or €133.83 (acrylate). The purchased parts cost €32.86 in total.

06 EVALUATION

In this chapter the product is evaluated on two aspects: a small usage test and the program of requirements. Both evaluations result in points of improvement, which are discussed in subchapter 7.1 (Recommendations).

Source: Personal photograph

6.1 Usage test

With the latest prototype, described in subchapters 5.1 and 5.2, a small usage test is done in order to find out if there are aspects of the product which have to be improved for further development. During the usage test both a fake (figure 6.1.1) and a real arm (with hand) were used to test the product usage. The arm and hand were fixated, the hand was moved (passively) into the four directions by using the 'positioning' buttons. Finally, the arm and hand were loosened out of the fixations.

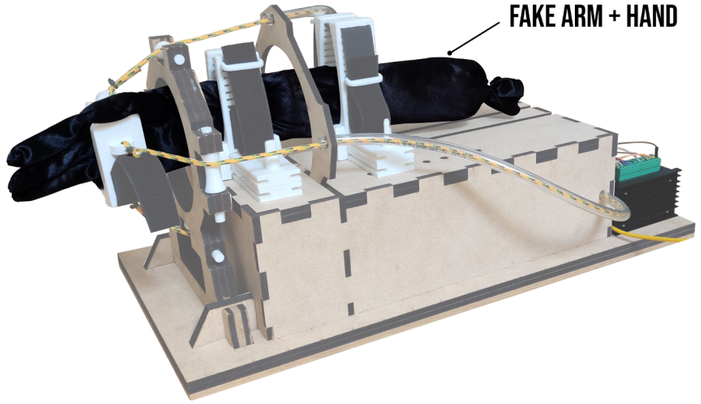


Figure 6.1.1. Latest prototype with fake arm (and hand).

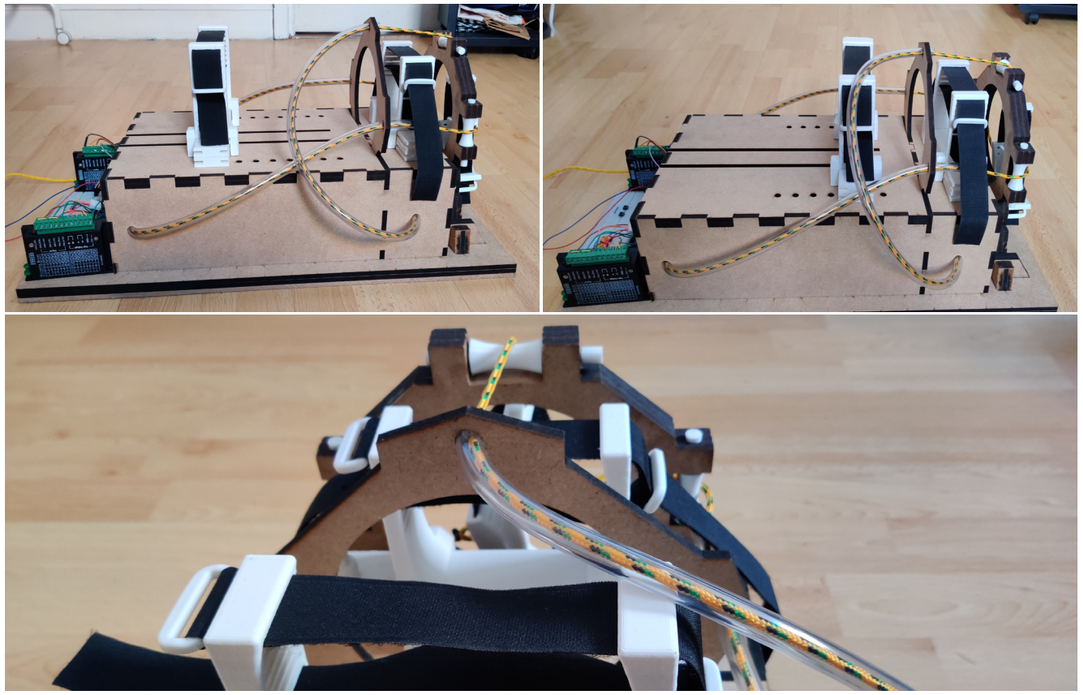


Figure 6.1.2. Top Bowden tube is in the way of the forearm fixation (when it is moved forward).

There were multiple things which became clear after this product usage test. These things are described below and can be translated to points of improvement for the product. These improvements are also discussed in subchapter 7.1.

6.1.1 Bowden tube

First of all, when fixating a relatively small forearm (near the elbow) the top Bowden tube is in the way of the forearm fixation (figure 6.1.2). The Bowden tube hangs in the region where the forearm fixation is positioned. In an improved prototype the top Bowden tube should be guided to its target spot in a different way, so that it does not block the forearm fixation.

6.1.2 Velcro strap

Secondly, the velcro straps used for the two forearm fixations and the hand fixations are still quite long. As can be seen clearly in figure 6.1.3, a large part of the strap of the hand fixation hangs loose and actually has no function. Also, large parts of both velcro straps of the forearm fixations hang loose because they are too long. In an improved prototype the velcro straps should be made shorter, so that they exactly have the required length to fixate all patients' arms and hands.

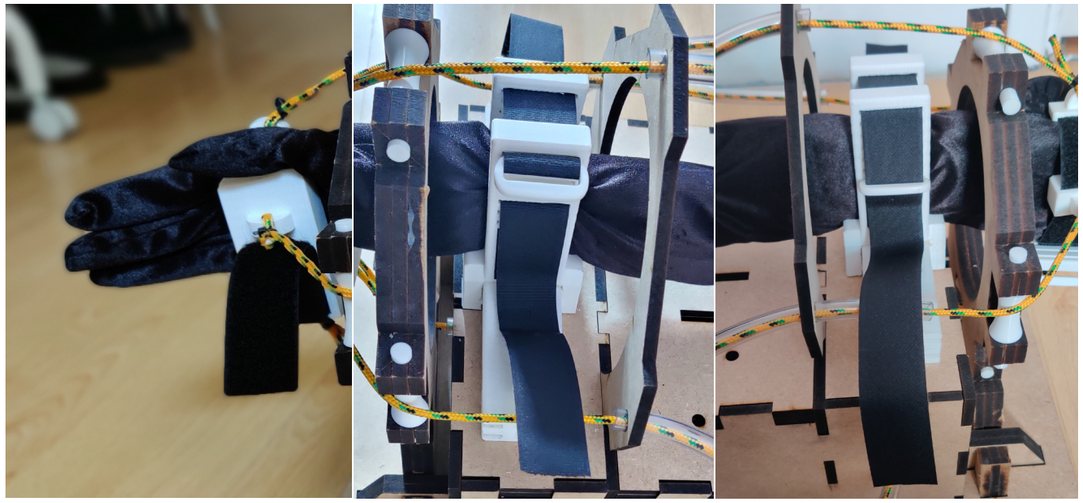


Figure 6.1.3. Velcro straps of the hand fixation (left) and forearm fixation (middle, right) hang loose.

6.1.3 Hand fixation

Thirdly, in the current prototype only right hands can be fixated properly. The way the hand fixation is positioned now is specifically suited for the curve of right hands (figure 6.1.4). Left hands, on the other hand, do not fit perfectly in the fixation and thus cannot be fixated perfectly as well (figure 6.1.5). To solve this the hand fixation should be rotated 180° so that it perfectly fits the left hand as well. However, in this prototype the attachment of the cables to the attachment points of the hand fixation is facilitated with a cable tie (figure 6.1.6). This makes it impossible to loosen them, rotate the hand fixation and fasten them again. Therefore, in an improved prototype a small plastic snap hook (figure 6.1.7) (or comparable) should be used at the end of each cable to attach it to the attachment points of the hand fixation. Eventually this allows the hand fixation to be rotated to ensure perfect fit for both left and right hands.

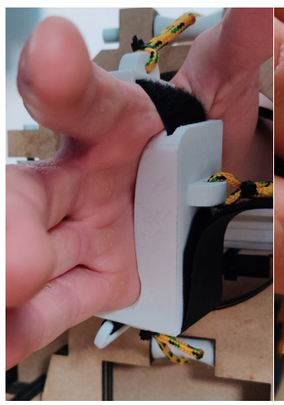


Figure 6.1.4. Hand fixation perfectly fits curve of right hand.

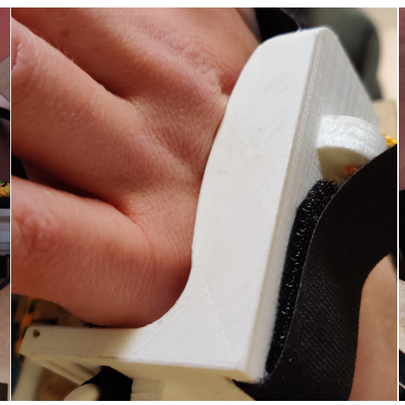


Figure 6.1.5. Hand fixation does not perfectly fit curve of left hand.

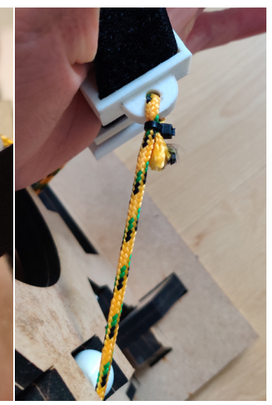


Figure 6.1.6. Cable tie attachment to hand fixation.

Small plastic snap hook. Source: (Bosin Hardware, 2013).

6.1.4 Height arm

As a fourth point it was observed that the patient's arm is actually positioned too high in relation to the middle hole of the wrist standard (figure 6.1.8). The patient's wrist should be positioned in the middle of this hole, to ensure symmetrical execution of all wrist movements (as described in subchapter 3.1.2). To solve this, in an improved prototype either the arm standard should be made lower or the wrist standard should be made higher.

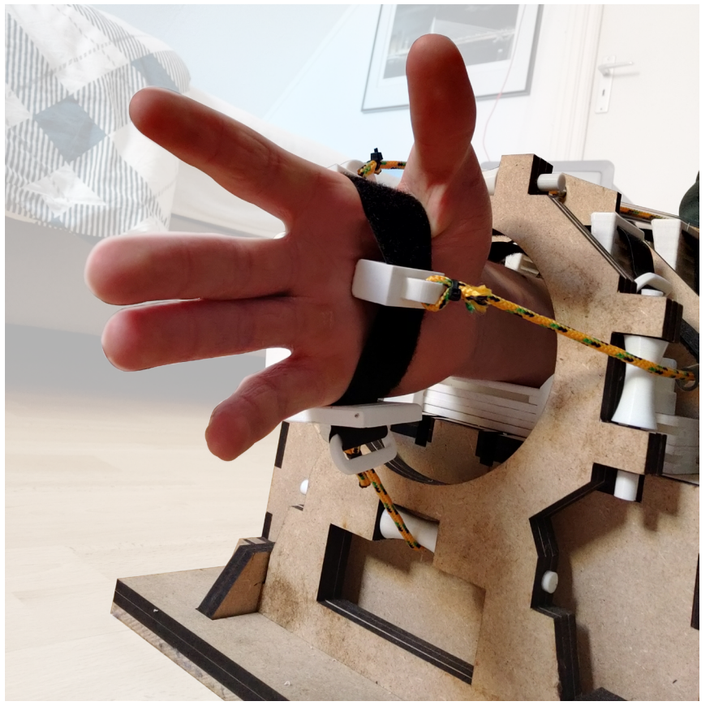


Figure 6.1.8. Patient's arm positioned too high in the wrist standard's middle hole.

6.1.5 Cable tension

Finally, it became clear that when the hand fixation hangs loose (figure 6.1.9, left), the cable tension decreases (figure 6.1.9, right), sometimes even causing the cable to come off the pulley (figure 6.1.11). When this happens the mechanism does not work anymore and the passive movements cannot be facilitated anymore. Therefore it is desired that at all times the hand fixation is held under tension (figure 6.1.10, left), so that the cables remain under tension as well (figure 6.1.10, right).

When looking closely at the four cables, it became clear that only the tension on the lower cable decreased significantly. Also, the cable coming off the pulley occurred only with that cable. Therefore, it has to be prevented that the lower cable loses its tension (figure 6.1.12), to make sure it stays on the pulley and the mechanism keeps working. This could be solved by applying something like a hook at the bottom of the middle hole of the wrist standard, which can be used to secure the lower cable (figure 6.1.13).

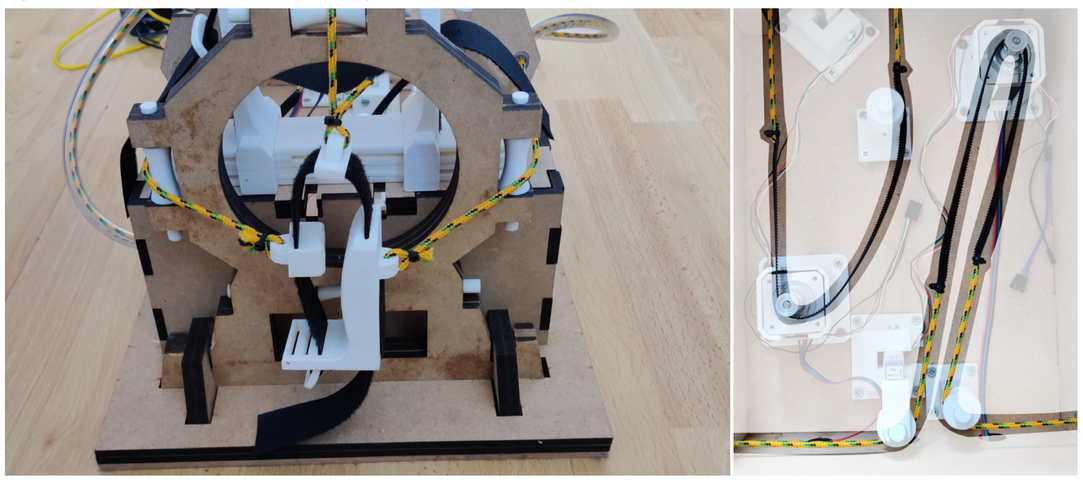


Figure 6.1.9. Hand fixation hangs loose (left), causing the cable tension to decrease (right).

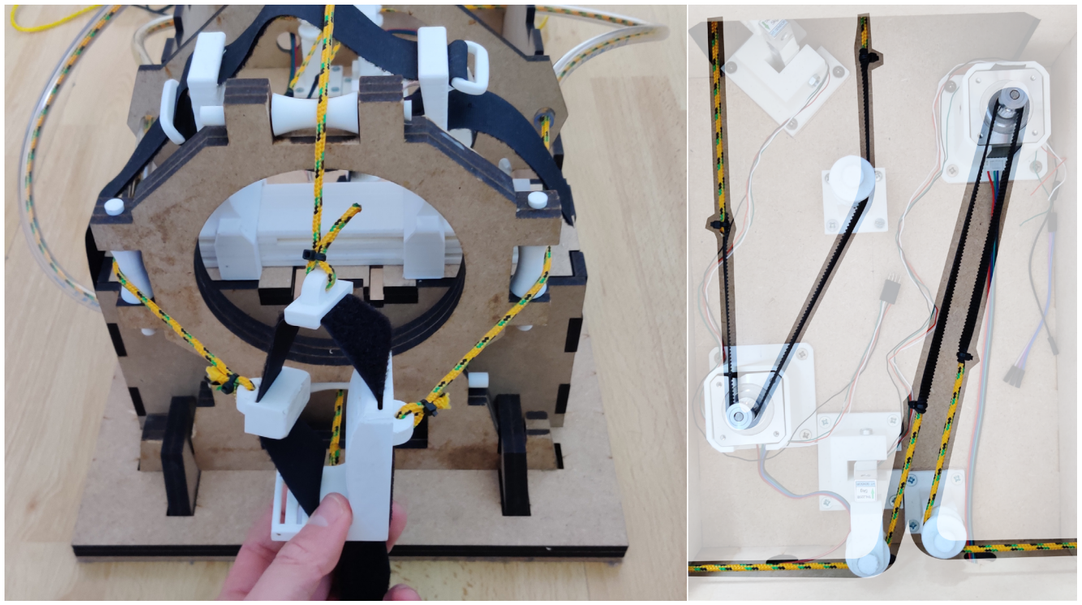


Figure 6.1.10. Hand fixation held under tension (left) causing the cables to remain under tension (right).

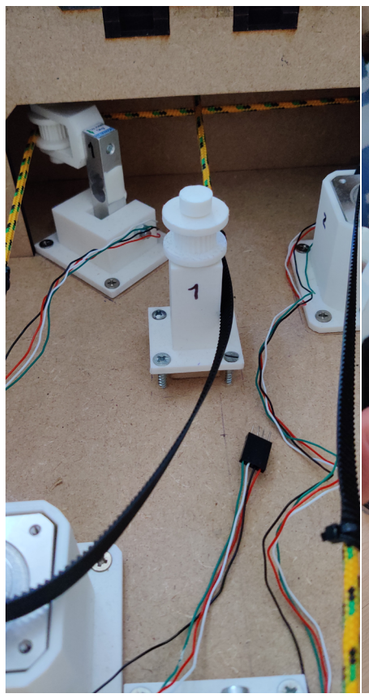


Figure 6.1.11. Lower cable coming off the pulley.

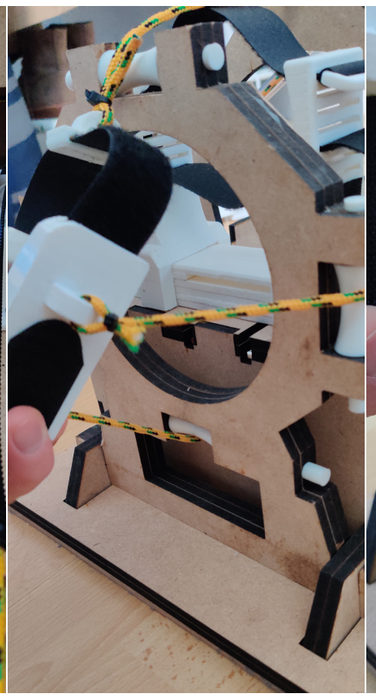


Figure 6.1.12. Keep lower cable under tension.

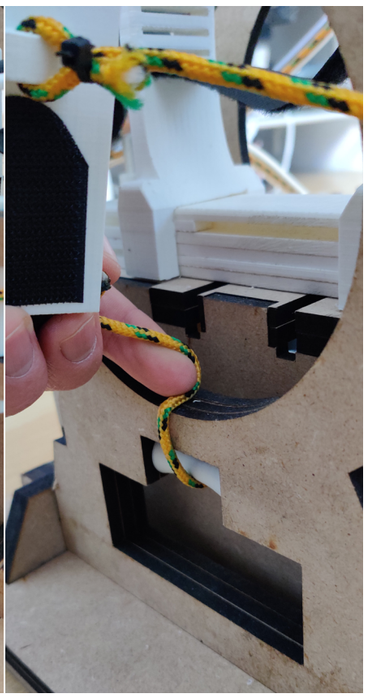


Figure 6.1.13. Keep lower cable under tension by securing cable behind hook (represented by finger).

6.1.6 Conclusion

Summary

6.1.1 - 6.1.5

- With the latest prototype, described in subchapters 5.1 and 5.2, a small usage test is done in order to find out if there are aspects of the product which have to be improved for further development.
- In total five problems were encountered: 1) the top Bowden tube has to be guided differently as it is in the way of the forearm fixation; 2) the velcro straps are too long; 3) the hand fixation attachment should be improved to make it symmetrical; 4) the arm standard should be made lower or the wrist standard higher in order to position the patient's arm on the correct height (middle of wrist standard); 5) the cable tension on the lower cable needs to remain equal in order to prevent the timing belt from falling off the pulley.

6.2 Program of Requirements

By defining which requirements are met by the product and which are not, an idea can be obtained about how the product scores on the different focus areas.

Evaluating the product on the design requirements (described in chapter 4), it becomes clear that the product does not yet meet all of them. In the subchapters below for every category (specified in chapter 4) is indicated if there are still design requirements which are not met by the product. In subchapter 7.1 all these shortcomings of the product are translated to recommendations for further development.

6.2.1 Movement

For this focus area there are three design requirements which are not yet met by the product:

1.2 "The product should be able to facilitate all desired wrist movements in one go, in order to reduce the radiation dose for the patient."

As mentioned before the 'start' button and the entire automatic movement sequence is not yet integrated, as the load cells are also not integrated yet. Therefore the product is not yet able to facilitate all desired wrist movements in one go.

1.5 "The product should be able to facilitate passive flexion of the wrist up till an angle of at least 90°."

At this point there is not enough space for the hand to be flexed or extended 90°. As can be seen in figure 6.2.1, the hand fixation tends to touch the pulley of the wrist standard. A solution for this would be to increase the size of the wrist standard or to slightly move the patient's forearm forward. With the second solution it has to be kept in mind that the hand cannot be moved too far forwards, as otherwise this will result in movements in two planes at the time (which is not desired, as mentioned in subchapter 2.4.1).

1.6 "The product should be able to facilitate passive extension of the wrist up till an angle of at least 90° (3.1.1)."

See requirement 1.5 above.

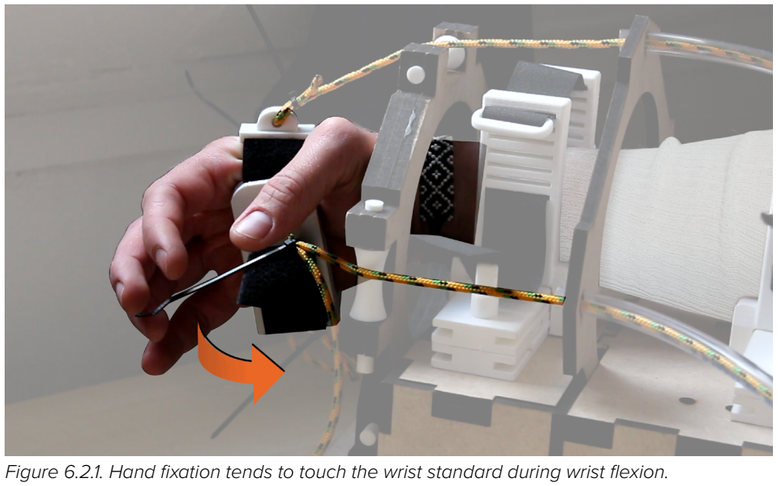


Figure 6.2.1. Hand fixation tends to touch the wrist standard during wrist flexion.

6.2.2 Fixation & adjustability

For this focus area all design requirements are met by the product.

6.2.3 Safety

For this focus area there are three design requirements which are not yet met by the product:

3.2 "The product should contain a feedback system which can measure or calculate how much torque the actuator is delivering to actuate the product and eventually facilitate the wrist movement."

The load cells and HX711 amplifier sensors still have to be integrated in the system. The load cells were already calibrated in a separate prototype, using the HX711 amplifier sensors. To finalize the feedback system these calibrated load cells (and HX711 sensors) should be connected to the electronic system and the software code should be supplemented.

3.4 "The product should not have sharp corners or edges or rough surfaces in order to prevent the radiologist, laboratory technician(s) and patients hurting themselves."

In the final prototype there are still some parts which have a few 90° edges, such as the arm- and wrist standard. However, the final prototype was mainly intended as a prototype to test the working and usage. In a next prototype these edges should be sanded in order to smoothen them, to prevent anyone hurting themselves to them.

3.6 "For the different parts of the product, high quality and durable materials should be selected, in order of the product to last for a long period of time."

The PLA which is used for the 3D prints is a durable material and is able to last for multiple years. However,

on the other hand the MDF from the baseplate (and arm- and wrist standard) and the velcro straps from the fixations are less durable. Therefore, replacements have to be found for these materials; this is described in subchapter 7.1.

6.2.4 Actuation & transmission

For this focus area there is one design requirement which is not yet met by the product:

4.7 "The product should measure the cable tension with the use of a load cell setup where the force working on the pulley is eventually translated to the cable tension."

For this requirement the same comment applies as given with requirement 3.2 (6.2.4 – Safety).

6.2.5 Usability

For this focus area there is one design requirement which is not yet met by the product:

5.1 "The product should be easy to use and operate for both the radiologist and their supporting team (laboratory technicians)."

At this point it is still unknown if the product is easy to use and operate for the radiologist and laboratory technician, because the current (working) prototype is not tested with them. However, an idea was acquired about how easy it is for an 'ordinary' person to use the product, as this was tested in a small usage test. Some interesting things were noticed and translated to possible improvements for the product (see subchapter 6.1). However, the product still has to be tested with the radiologist and laboratory technician; more about this can be read in subchapter 7.2.

5.2 "The product should be designed symmetrically, working for both left and right arms."

As also became clear from the usage test (subchapter 6.1.3), in the current prototype the hand fixation cannot be used for both left and right hands. Therefore, special (plastic) snap hooks should be used at the end of the cable which can be fastened and loosened from the attachment points of the hand fixation. In this way the hand fixation can easily be detached, rotated and fastened again.

6.2.6 Comfort
For this focus area all design requirements are met by the product.

6.2.7 Other
For this focus area there are three design requirement which are not yet met by the product:

7.1 "The product should have a professional and trustworthy look."

The final product consists of a working prototype, whose main function is to demonstrate the usage and working of the product. Because it is a prototype, it also does not look professional and trustworthy. Also, according to S. Buckens (personal communication, March 12, 2020), in this stage of the research project it is not important what the product looks like. If the radiologist and the laboratory technician say the product works and is safe, the patient will believe them. Still, as described and illustrated in subchapter 5.4.1, in the end the product's appearance is based on both existing and futuristic medical products. This will result in a professional and trustworthy look, smoothly blending in into the hospital context.

7.3 "The product should not contain any metal parts in the central aperture of the CT scanner."

The final product has metal parts inside the central aperture of the CT scanner. However, they are not positioned within the active area of the detector strip. According to S. Buckens (personal communication, April 29, 2020) approximately 8-10 [cm] of the detector strip (which is 16 [cm] in total) will be used to make 4D CT scans of the wrist. Seen from the wrist standard, which is supposed to be aligned with the patient's wrist, the nearest metal parts (screws used to attach the load cell standard) are further away than 5 [cm]. This means that these metal parts will not have a negative effect on the CT scan.

7.4 "The positioning of the patient in relation to (the product and) the CT scanner should be a well-considered balance between a high quality of the CT images and a low radiation dose of the patients."

As mentioned in subchapter 2.2.2, the optimal position of the patient in relation to (the product and) in relation to the CT scanner could not be tested during this project. Therefore, this still needs to be researched further (see subchapter 7.2).

6.2.8 Conclusion

Summary

6.2.1 - 6.2.7

- By defining which requirements are met by the product and which are not, an idea can be obtained about how the product scores on the different focus areas.
- Evaluating the product on the design requirements (described in chapter 4), it becomes clear that the product does not yet meet all of them.
- For the focus areas "Fixation & adjustability" and "Comfort" all requirements are met by the product. For the remaining focus areas there are still product aspects which have to be improved.
- In subchapter 7.1, these product aspects are translated to recommendations for further development.

07 FUTURE DEVELOPMENT

In this chapter aspects are discussed concerning further development of the product. For the product recommendations are given, a test- and implementation plan is composed. Finally, limitations of this project are described, which have to be taken into account for further development of the product.

Source: Personal photograph

7.1 Recommendations

Based on the product evaluations described in chapter 6 there is a list of recommendations for future development of the product. In this subchapter these recommendations are described. The recommendations arise from three different sources: 1) the product evaluation usage test; 2) the product evaluation on the program of requirements; 3) other product aspects mentioned throughout the report which are not finished yet. An overview of all the recommendations for the product can be seen in figure 7.1.1.

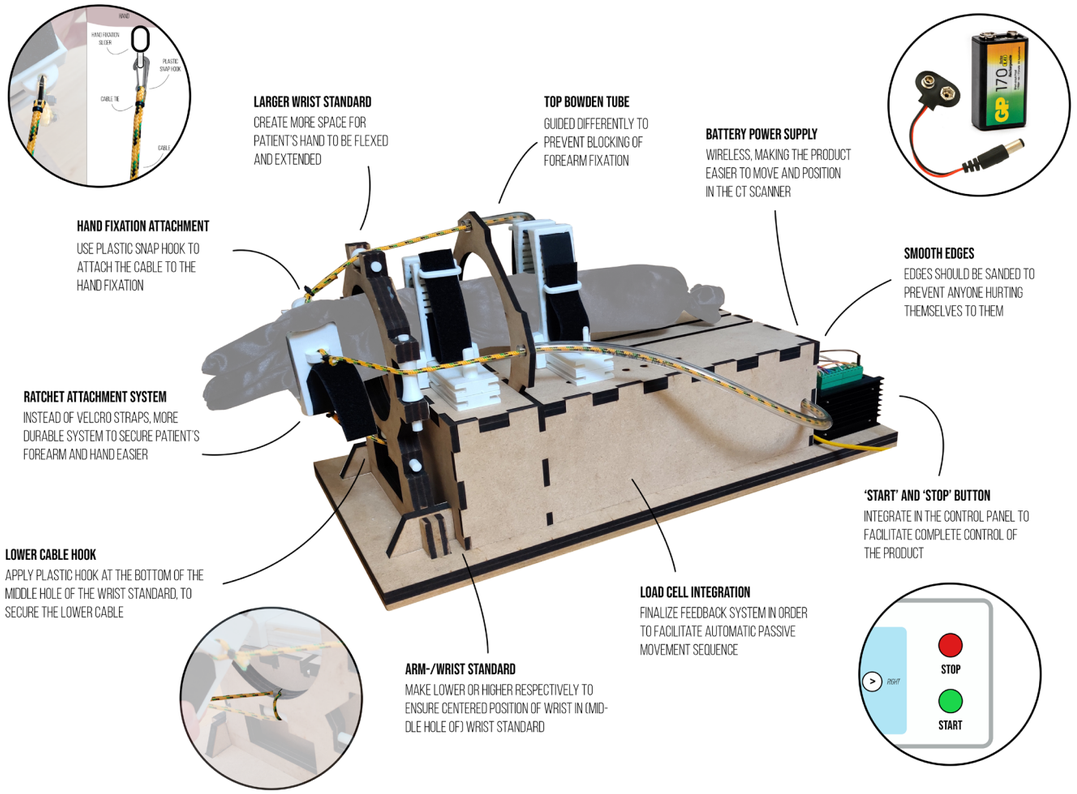


Figure 7.1.1. Overview of all recommendations for the product.

7.1.1 Usage test

In this subchapter product recommendations are given based on the outcomes of the usage test described in subchapter 6.1.

Bowden tube

In an improved prototype the top Bowden tube should be guided to its target spot in a different way, so that it does not block the forearm fixation (figure 7.1.2).

Velcro strap length

In an improved prototype the velcro straps should be made shorter, so that they exactly have the required length to fixate all patients' arms and hands. However, it is also desired that a more qualitative attachment system (e.g. a ratchet mechanism) is used to secure the patient's forearm and hand (see subchapter 7.1.2 – Durable materials).

Hand fixation

In an improved prototype a small plastic snap hook (figure 7.1.3) (or comparable) should be used at the end of each cable to attach it to the attachment points of the hand fixation. Eventually this allows the hand fixation to be rotated to ensure perfect fit for both left and right hands.

Figure 7.1.2. Top Bowden tube is in the way of the forearm fixation (when it is moved forward).

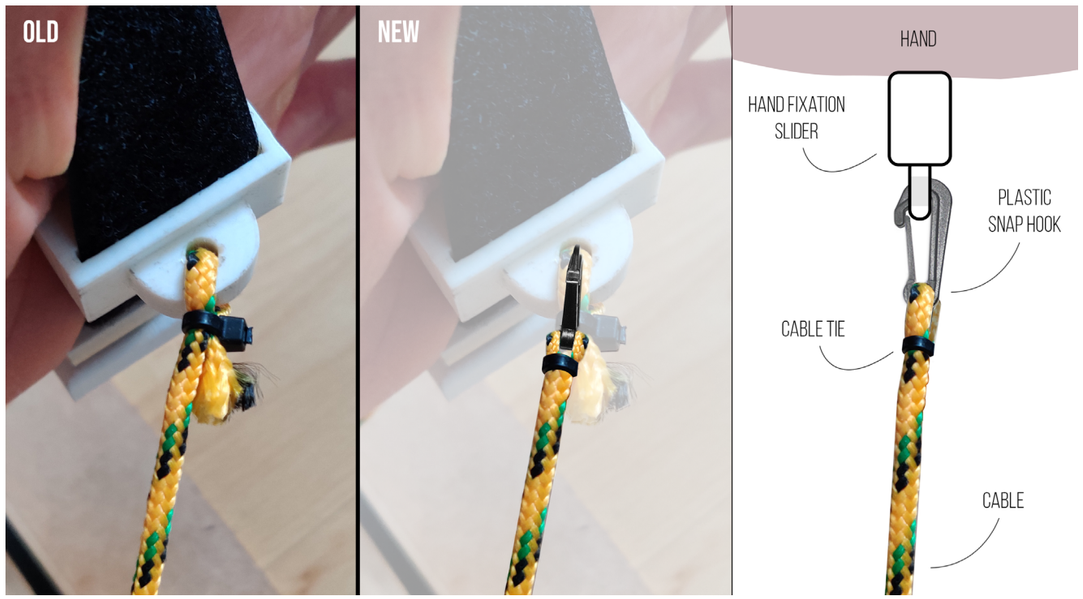


Figure 7.1.3. Old cable attachment with cable tie (left); new cable attachment with plastic snap hook (and cable tie) (right).

Height arm- and wrist standard
In an improved prototype either the arm standard should be made lower or the wrist standard should be made higher. This is to ensure that the patient's wrist is positioned in (or close to) the middle of the middle hole of the wrist standard, to ensure symmetrical execution of all wrist movements in the end.

Lower cable hook
When the hand fixation is not pushed forward (e.g. before the patients push their arm forward through the fixations), the cable tension of the lower cable decreases and the cable tends to come off the pulley (also see in subchapter 6.1.5). Therefore, something has to be added which makes sure the cable tension (of the lower cable) remains equal. This can be solved in two ways. Option 1 is to apply a small plastic hook at the bottom of the middle hole of the wrist standard, which can be used to secure the lower cable (figure 7.1.4). In this way the lower cable is held in its place, preventing the cable to come off the pulley.

Option 2 is to place a low-friction bar (or roller) directly below the lower pulley which can be pushed towards the cable (figure 7.1.5). In position 1 the cable still has enough space to freely move over the pulley, while in position 2 the roller is pushed towards the cable to block it and prevent it from sliding back into the arm standard. Additionally, such a bar (or roller) could be added at all four pulley positions to improve the stability of the device (S. Buckens, personal communication, May 15, 2020).

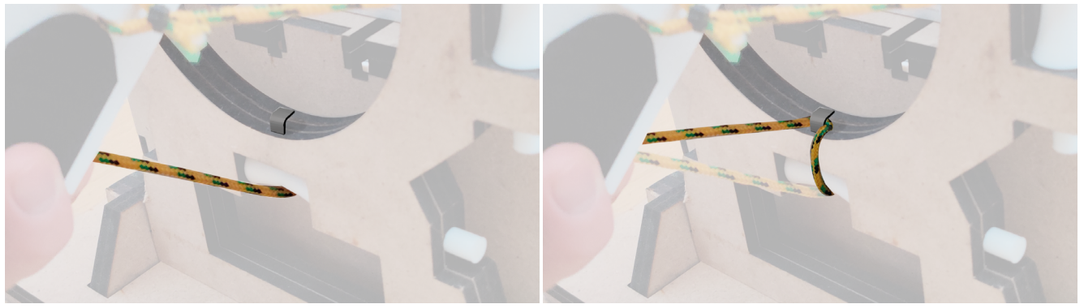


Figure 7.1.4. Small plastic hook used to secure the lower cable.

Figure 7.1.5. Roller underneath pulley and cable which can be pushed against cable to block it.

7.1.2 Program of requirements
In this subchapter product recommendations are given based on the outcomes of the evaluation of the product on the program of requirements, described in subchapter 6.2.

Load cell integration
To finalize the feedback system of the product the calibrated load cells (and HX711 sensors) should be connected to the rest of the electronic system. Also the software code should be supplemented in order to acquire the automatic movement sequence in which movements are stopped when the cable tension threshold (continuously measured by the load cells) is reached.

Larger wrist standard
At this point there is not enough space for the hand to be flexed or extended 90°. The hand fixation tends to touch the pulley of the wrist standard, which is why the size of the wrist standard has to be increased. If needed, the patient's arm could also be moved slightly forward.

Smooth edges
In a next prototype all edges should be sanded in order to smoothen them, to prevent anyone hurting themselves to them.

Durable materials
As was mentioned in subchapter 6.2.3, the MDF used in the laser cut parts (baseplate and arm- and wrist standard) and the velcro straps used in the fixations are not that durable. As was discussed in subchapter 5.4.2, acrylate would be a good replacement for the MDF as it is easier to clean and also looks cleaner and more professional compared to MDF. Also, instead of using velcro straps there should be integrated something like a ratchet mechanism (e.g. also used in snowboard bindings, figure 7.1.6) to keep the sliders of the forearm fixations in place and to secure the patient's forearm and hand. This adjustment mechanism is easier to use and provides a higher quality and –durability (J. Molenbroek, personal communication, February 24, 2020).

Figure 7.1.6. Snowboard binding with ratchet mechanism. Source: (AlzaShop, n.d.).

Figure 7.1.7. 9V battery. Source: (WPI, 2015).
Figure 7.1.8. Battery clip with DC jack. Source: (Makerlab Electronics, 2017).

7.1.2 Program of requirements
In this subchapter two last product recommendations are given. The two recommendations are based on two product aspects which were not fully developed yet in the product (prototype).

Finish control panel
As mentioned in subchapter 5.1.7, the final prototype of the control panel did not contain all the elements yet. The 'start' and 'stop' button were not integrated yet, which was mainly due to the fact that the feedback system (with the load cells) was not integrated yet as well. Therefore, after integrating the feedback system, the control panel can be finalized by adding the 'start' and 'stop' button.

For the control panel it would also be useful if it could be connected to the device with a long cable. In this way the control panel can be taken to the control room of the CT, enabling the device to be operated from a distance. This also allows both the CT scanner and the device to be started at exactly the same time, for example in order to prevent scanning of a static wrist.

Battery power supply
In the current prototype an external 9V adapter is used to power the device. However, as was later advised by M. Verwaal (personal communication, March 10, 2020), the device can also be powered wirelessly by using a 9V battery (figure 7.1.7) with a special clip with DC jack (figure 7.1.8). In this case the device would not be needed to be plugged into a socket, making it easier to move and position in the CT scanner. In a later prototype this battery supply should therefore be integrated instead of the external 9V adapter.

7.2 Testing & implementation

In order to get a clear idea about the future development of the product and how it is going to be used and integrated in the CT scanning routine of the hospital, a testing- and implementation plan (figure7.2.1) has been composed. The plan is composed based on a discussion with S. Buckens (personal communication, April 29, 2020).

In this plan the different steps concerning development-, evaluation-, testing- and implementation of the product are described. The plan concerns the transition from stage 1 to stage 2 of the research project as described in subchapter 1.2.

7.2.1 Summary

Looking at the plan it can be divided into two main phases, with a checkpoint moment in between:

1) The product development and – evaluation phase (6 months).
In this phase the product is tested and evaluated on multiple aspects which could not yet be tested during the graduation project. Based on these results the product is improved and further developed. Finally, the product's hardware and -software and its documentation (e.g. containing technical details) are finalized.

Checkpoint for product approval (1 month).
After phase 1 there is a moment where the product needs to be tested and approved by an internal commission of the Radboud UMC. In this way it is made sure the product is safe, cannot harm patients or cause permanent injuries. As a result the product receives a certificate, allowing it to be used with patients within the hospital. Also, the product is insured by the hospital, in case something happens.

2) The testing- and implementation phase (6-12 months).
In this phase the product is used to conduct (4D CT) tests with small groups of patients (5-10). First, only the radiologist (Stan) and the main laboratory technician (Willem-Jan) are involved in this. Based on these tests the working process is evaluated and optimized and a protocol (about how the product should be used and operated) is set up. Later, more laboratory technicians are involved with the use of the protocol, information dissemination during so-called clinical lessons and small training sessions. Finally, the product is fully implemented and tests are conducted with larger groups of patients (20+). After this phase the product can be used (officially) for the research project, which was described in subchapter 1.2.

See subchapter 7.2.2 fora more extensive explanation of each of the steps within phase 1 and 2.

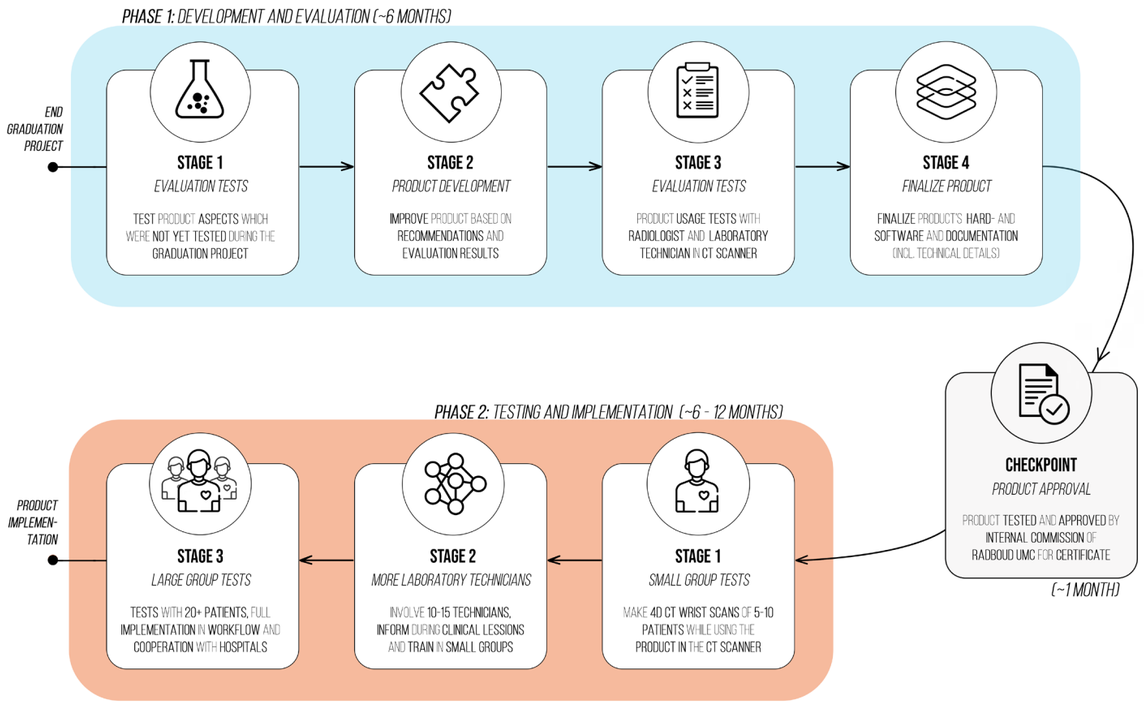


Figure 7.2.1. Testing- and implementation plan for product.

7.2.2 Specific steps

In this subchapter all specific steps of the testing- and implementation plan are elaborated.

Phase 1
Stage 1
In this stage the product is tested and evaluated on multiple aspects which could not yet be tested during the graduation project. For all different aspects, which are listed down below, is determined what their influence or effect is on the product and if it should be improved or integrated.

- Influence of the cable elongation on the passive movements (subchapter 3.4.3).
- Ease of use of the product for the radiologist and laboratory technician (subchapter 6.2.5).
- Best position of patient in relation to product and CT scanner (subchapter 2.2.2).
- Understandability and effectivity of markings on baseplate (subchapter 3.5.1).
- Need for elbow support to prevent arm from sliding backwards (subchapter 3.4.5).

Stage 2
Based on the recommendations (described in subchapter 7.1) and the results of the product evaluation test described above, the product is improved and further developed.

Stage 3
After the product is improved and further developed, it is tested with only the radiologist and laboratory technician, being some sort of second product evaluation test. The outcomes of this last evaluation are used to optimize and finalize the product.

Stage 4
In the last stage of the first phase the product is fully developed: the product's hardware and -software and its documentation (e.g. containing technical details) are finalized. In the documentation is described and proven that the product is safe and not able to harm patients or permanently injure them.

Checkpoint
See description in subchapter 7.2.1.

Phase 2
Stage 1
In this stage the product is used to conduct (4D CT) tests with small groups of patients (5-10). First, only the radiologist (Stan) and the main laboratory technician (Willem-Jan) are involved in this. Based on these tests the working process with the product is evaluated and optimized. Eventually a protocol is set up, describing how the product should be used and operated.

Stage 2
Later, more laboratory technicians are involved in the project (about 10-15). During so-called clinical lessons they acquire more information about the product and how it should be used (protocol). With the use of training sessions small groups of laboratory technicians get more experienced working with the product.

Stage 3
Finally, the product is fully implemented and tests are conducted with larger groups of patients (20+). Eventually there can be cooperated with other hospitals on this topic to exchange knowledge and experience and to realize a promising future for 4D CT wrist scans.

7.3 Limitations

In this subchapter the limitations of this project are described. There are a few limitations which have to be taken into account when using these project's outcomes for further development and/or implementation.

7.3.1 Participants

During the project multiple and various tests have been conducted. However, for the majority of these tests only a small amount of participants was used. Therefore, the outcomes of the tests might be less reliable. As an example, the comfortability test described in subchapter 3.6.3 was conducted with only three participants (including myself). Therefore, the outcomes of this test could be different when conducting it with fifteen or even more participants. Because of this, some parts of the product might turn out to be different than they are now. Because of this reason it is recommended to test and evaluate the product extensively, as described in the test- and implementation plan (subchapter 7.2).

7.3.2 Prototype

The final prototype delivered at the end of the project is, as mentioned before, not finished and should still be further developed and optimized. Due to a lack of time and financial resources available the prototype is not as far developed as it could have been. However, as discussed in subchapter 7.2, there is still time to realize this in the future.

7.3.3 Testing

Unfortunately, during the project the prototype could never been tested in the hospital with actual patients. This is due to the strict ethical regulations of the Radboud UMC, where the product could not comply with yet at that point. Therefore it is extremely important that the product is going to be tested extensively with patients, before fully implementing and using it in the research study, which is also included in the test- and implementation plan (subchapter 7.2).

7.3.4 Cable tension measurement

For measuring the cable tension with the load cell setup there are multiple assumptions which have been made (Appendix Z). However, there are multiple factors which are of influence. For example there occurs friction of the cable within the rubber Bowden tube, which should somehow be taken into account in the calculation of the cable tension. Therefore, by testing and tweaking the measurement and calculation of the cable tension, this part of the product has to be optimized and integrated, to make sure it works as desired.

PERSONAL REFLECTION

At the beginning of this project I defined three personal learning objectives. These objectives were:

1) Manage a relatively large design project on my own, taking into account all stakeholders and involving them into the design process.

2) Learn more about prototyping, electronics and coding.

3) Develop a working prototype which can be adapted to different users (patients).

Concerning the first learning objective, this was something I really looked up to. Working in teams is something I prefer over working individually. However, I think that exaclty because of this reason this project has been a good learning experience for me, as it forced me to kind of step out of my comfort zone. Eventually I think that I succeeded in managing the project, while at the same time keeping in account and involving all stakeholders. Keeping the stakeholders from the Radboud UMC involved was sometimes hard because of their busy schedules and the fact that Delft and Nijmegen are simply quite far from each other. Still, every time visiting the Radboud made clear to me how important it is to keep the stakeholders involved; our brainstorm sessions and their feedback really helped me throughout the project to keep iterating and improving my prototype.

Secondly, during the project I wanted to step out of my comfort zone as well by striving to learn more about prototyping, electronics and coding. This was something which I remembered from the bachelor, but never actually put to use within design projects. Also, for prototyping normally my approach would have been to do this near the end of the project. However, for this project I challenged myself to to make at least one prototype every week. With the help of my chair (Johan) and mentor (Tessa) and Martin Verwaal (Applied Labs) my knowledge and skills concerning (fast) prototyping and electronics and coding have grown significantly. Eventually it became clear to me how helpful prototypes, even really quick and small ones, can be for evaluations or validations of the product. Instead of spending hours of desk research, one quick prototype often has an even more valuable outcome. Also, I learned a lot more about the working of electronics and the possibilities and applications of it within product design. I feel that this skill set which I acquired during this project, is something I can use in the rest of my future career.

Thirdly, ending the project with a working prototype is something I wanted quite desperately. Most of my previous projects simply ended up with some visuals of a product proposal, which is still quite vague. With this project I felt that a working prototype was achievable, especially when putting more effort and time into the prototyping aspect. By prototyping from the beginning and striving to achieve the second learning objective, I am glad that I ended this project with a partly working prototype. As this was something completely new to me, the moment my model worked automatically (with the integrated electornics) was one of the most special ones during th entire project. Next to this, I feel that I succeeded in making the product adaptable to different patients. For example, the integrated mechanism in the forearm fixations with which every forearm could be centered, was something I was satisfied with. To conclude, this project has allowed me to both apply the skills I already had, while at the same time learning me new things which I can take with me and use in the rest of my future design career.

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