Product Report
MSc04-ID10 - May 2018

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PEAK

Measuring progress in physiotherapy rehabilitation processes

Title page

Title

'PEAK' Measuring of rehabilitation progress

Project module

Master thesis in Industrial Design

Project period

February 1st - June 31st

Project team

SPÍRA

(M4-ID10)

Supervisor

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Pages

22

Editions

7

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Abstract

This master thesis deals with the development of the design proposal, *Peak,* for measuring functionality and movement quality in physiotherapy rehabilitation processes.

There are a large amount of scientific research on the topic ‘physiotherapy’, and the treatment methods within physiotherapy. However, there are currently little development of more modern assessment tools for the consultation that uses this knowledge in combination with new technology. The fast growing knowledge and development of the field of technology keep giving new possibilities in relation to using the technology in clinical products. This leads to the development of the design proposal; *Peak*.

Peak is a system that by using motion tracking technology can contribute to provide the physiotherapists with accurate objective data on the functionality of the client’s concerning injury (measured in range of motion). This data is converted into velocity, acceleration, and jerkiness, as the first product targeted the market for physiotherapy. These parameters contribute to the clinical picture regarding the quality of movement. *Peak* provides accurate digital objective data mediated through an application in favor of the physiotherapists, the clients, and the insurance companies.

Table of content

Rehabilitation processes

There are many people, who pays a visit to a physiotherapist every year and ends up in a longer rehabilitation process, due to work injuries, sport injuries, accidents, or pain in the back among others. If a person experience pain during movement or has reduced mobility, joint range of motion, can in these cases be a relevant factor to objectively evaluate in relation to see progress in mobility. Today, range of motion is measured with a tool, which can not be applied for measuring all joints. Furthermore, the measurements are questionable due to subjective readings and different ambiguous instructions among other sources of error.

Recent studies in this field show that digital measurements of range of motion can provide more accurate data and can be converted into acceleration and jerkiness, which can tell something about the quality of movement. All factors can contribute to the clinical picture because it can indicate where the pain and/or problem emerge in a movement and therefore help the physiotherapist to make a more detailed and correct training program for the client.

The human body is our most important tool for all physical actions. If the mobility of the body gets affected by an injury or pain, this has consequences as it interferes with our way of living. This can be mentally exhausting, especially in longer rehabilitation processes, where normal/optimal mobility is pursued. In these processes it can be hard to maintain the fighting spirit, which in some cases lead to demotivation.

Problem and opportunity

There has until now not been any objective and accurate assessment methods in the field of physiotherapy for measuring joint range of motion (ROM), where the measurement is not influenced by several errors, and which also has the ability to evaluate the quality of the movement.

Motion tracking is a thorough investigated scientific field and there are several solutions developed for this, but none of these solutions are currently addressed towards physiotherapy and the physiotherapists' needs. These solutions are very complex to utilize and operate, and they are very expensive to acquire.

Because of this, Spíra has developed the assessment tool system 'Peak' in collaboration with a research team with expertise in physiotherapy and pain from Aalborg University. Peak is based on a known technology in the field of motion tracking and can measure joint range of motion, which can be converted into velocity, acceleration, and jerkiness during a movement. Furthermore, it can measure the offset in joint repositioning. It is developed upon the foundation, where it fulfills the needs of the physiotherapists and their clients.

The Peak system is designed to fulfill the need of quick and easy use in a consultation situation, while being easy and fast to clean in between.

Product overview

Peak is a product system consisting of several products and parts:

Measuring unit

The main part of Peak is the measuring unit, which contains the motion tracking technology. The measuring unit has two possibilities of being mounted; stickers or strap. The measuring unit is connected to the chosen mounting method with magnets.

Base and strap

Low practic solution for mounting the measuring unit on the client. Can be used for measurements located on the extremity joints and the neck. The shape and materials make it easy to clean. The strap with holes make it easy to adjust the fitting to each body part and body size.

Application

The Peak system comes with two versions of smartphone applications, one for the physiotherapist and one for the client. The application processes the data from the measuring unit and mediates the data and progress in the rehabilitation process.

Smartphone

The physiotherapist and client are expected to have access to a smartphone.

Stickers

The mounting of the measuring unit can also be performed with disposable stickers, which eliminates the cleaning time between clients. The stickers has a strong adhesiveness, but are yet painless to remove.

PEAK

Peak is a measuring tool system for physiotherapists to measure joint ROM, velocity, acceleration, and jerkiness in relation to the respective ROM movement together with joint repositioning. These factors contribute to the quantification of a client's progress in their rehabilitation process.

Measure the whole body
Peak can be applied for measuring all extremity joints + the back.

Objective documentation
Peak provides objective documentation from measurements and compare them to the previous results to display the rehabilitation progress.

ROM + quality of movement
Peak is currently the only product able to measure ROM together with the quality of the movement in physiotherapy.

Joint repositioning
Peak is currently the only product, developed to measure joint repositioning.

Hygienic
The design of Peak makes it easy and fast to clean between clients.

Accurate digital measurement
Peak is provided with a motion sensor, which is thoroughly tested and programmed to be accurate.

Modular system
Peak consists of a modular mounting system, which makes it possible to fit to every situation.

Adjustable - because every body is different
Peak's mounting system can be adjusted so it fits every person.

Size
The measuring unit of Peak has a small footprint do to its small size.

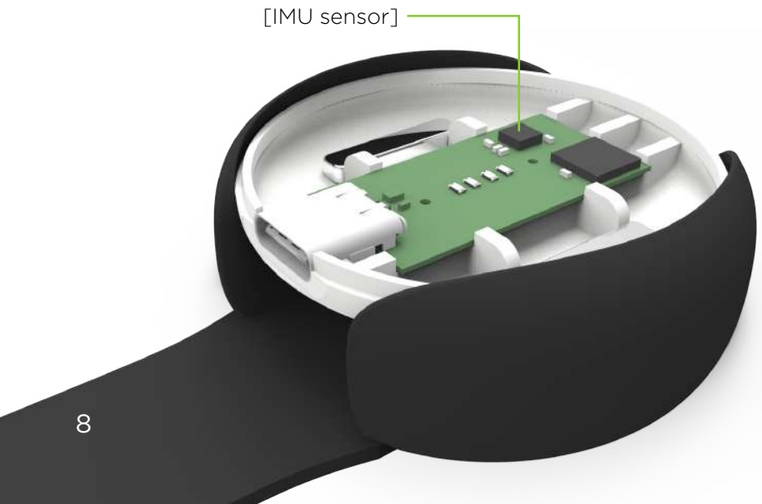
Confined people
Peak can even be applied for bedridden people or people in wheelchair.

Working principle

Peak is based on scientific research and measures the joint mobility in joint range of motion. The quality of movement can from this be derived, which is visualized through graphs of the acceleration and jerkiness of the movement.

Peak's goal is to provide the physiotherapist with objective documentation in relation to joint range of motion, velocity, acceleration, and jerkiness, and thereby be a supportive tool in the treatment process.

Peak's motion tracking technology consists of a 9-axis IMU (inertial measurement unit) sensor, which is located inside the measuring unit. The IMU sensor is quality tested which ensures accurate measurements in coherence with a stable mounting either using the sticker or base unit as instructed.

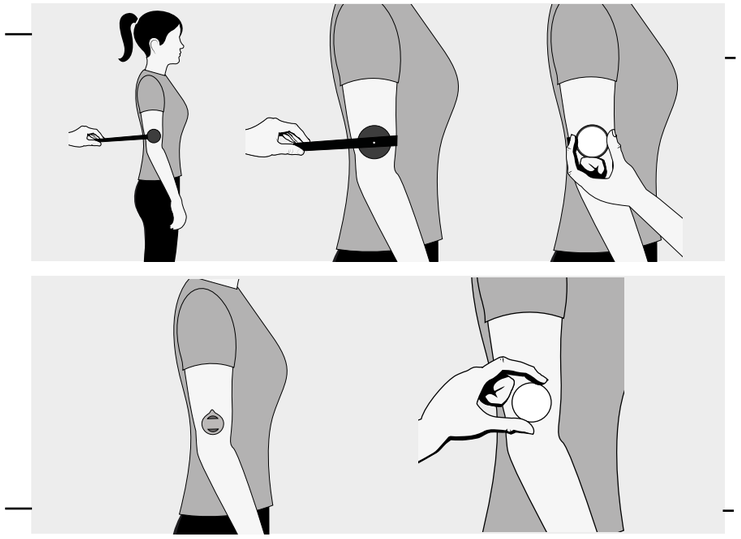


During measurements, the IMU sensor tracks its position in relation to its coordinate system in 3D space. Comparing the values from the start position to the end position results in the joint range of motion.

User guide

The user guide of the product is illustrated below, as are the overall usage effect in the bottom of the spread.

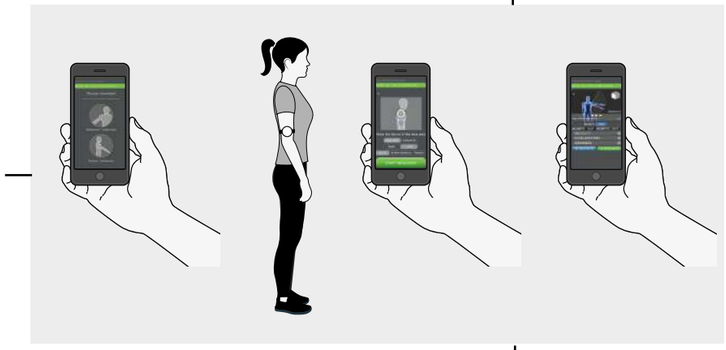
1
- Open application
- Enter ‘Track movement’



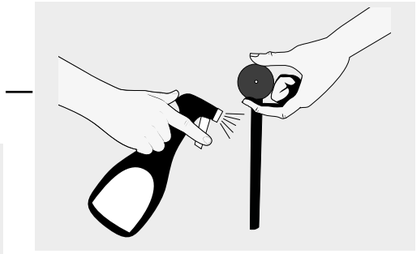
2a
- Place mounting base on the regarding bodypart.
- Adjust the tightness to fit the bodypart, by choosing the suitable hole.
- Place on the measuring unit on the base.

2b
- Remove film from sticker.
- Place the sticker with the pointy tip pointed towards the joint to measure.
- Place the measuring unit on the sticker.

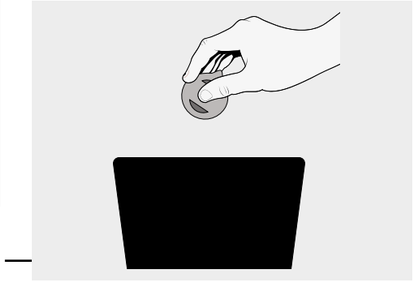
3
- Choose movement type.
- Choose movement settings.
- Ensure that the client is in neutral position.
- Click start measuring.
- After the measuring the data is displayed in the application.



4a
- Afterwards take off the measuring unit and clean with disinfection fluid.



4b
- Afterwards take off the measuring unit and throw away the sticker.



Measure with peak

Read objective data in application

Understand the problem

Create optimal training program

Exercise

Motivating and progressing rehabilitation process

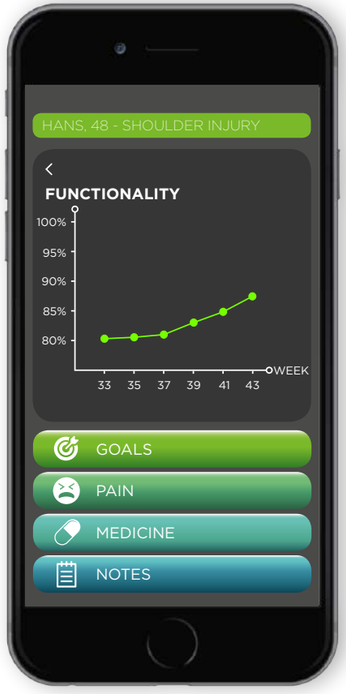
Application - Physiotherapist

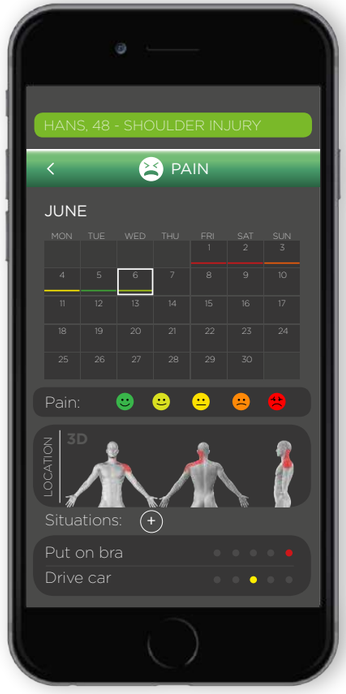
All data is send to the Peak application where it is processed and mediated. The application comes in two versions; the physiotherapist version and the client version.

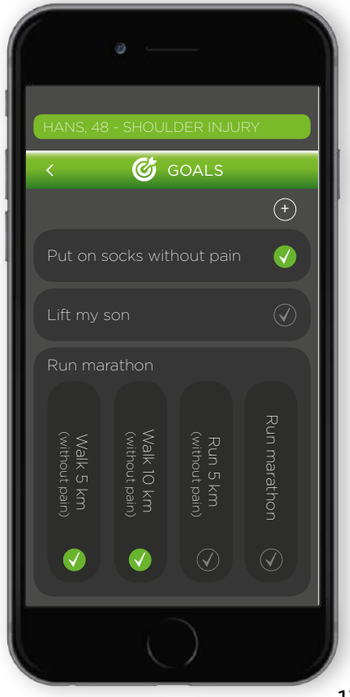
The physiotherapist version provides the possibilities of tracking new movements; Movement extend and quality; joint range of motion, velocity, acceleration, jerkiness, and joint repositioning, where the offset in the front and top plane is mediated. The second option is accessing the data library at all times with all measured movements. All data is visualised with an animation of the movement that gives the opportunity to see the exact movements over time in relation to the measurement data.

Application - Client

The client application provides the client with the possibilities of tracking the rehabilitation progress, based on the previously measured peak measurements. Furthermore, the client has the possibility of entering personal data in relation to pain, pain intensity, personal goals, and medicine intake. This gives the client the best possibility of visually keeping track of the entire rehabilitation progress, which is scientifically proven to contribute as a motivational factor.







Placements

Peak is designed to be able to measure 18 movements, where the placement and mounting of the measuring unit needs to be within the zones as instructed below.

Zone

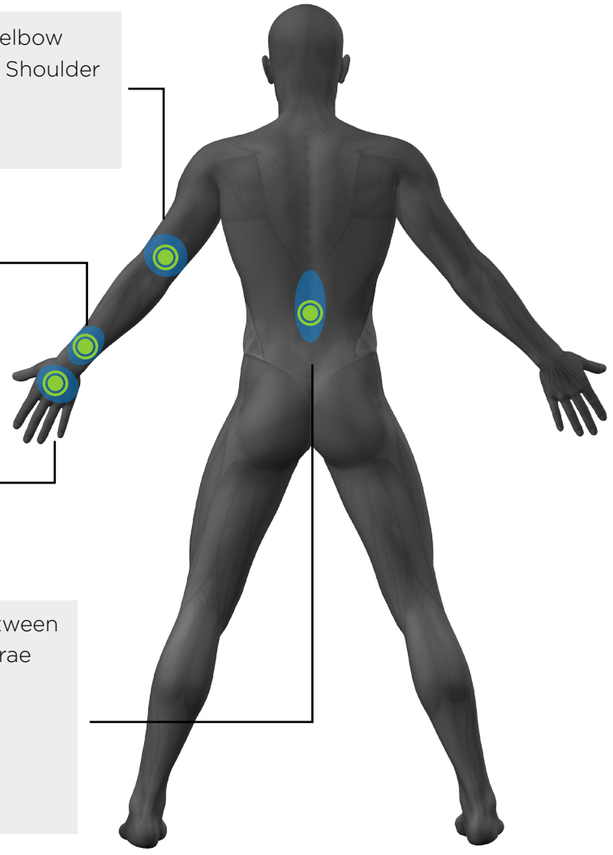
Placement

Placement: Above elbow
For movements in: Shoulder
[Dorsal bending]
[Lateral bending]

Placement: Above wrist
For movements in: Elbow
[Flexion]

Placement: Back of hand
For movements in: Wrist
[Ulnar]
[Radial]
[Flexion]
[Extension]

Placement: Connection between thoracic and lumbar vertebrae
For movements in: Back
[Dorsal bending]
[Lateral bending]
[Flexion]
[Extension]



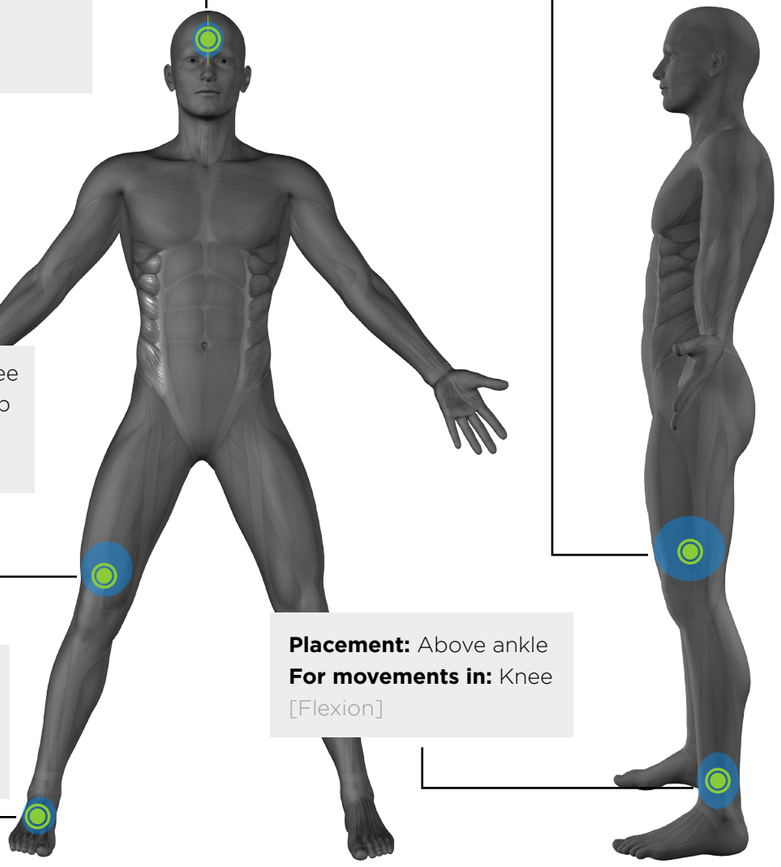
Placement: Forehead
For movements in: Neck
[Dorsal bending]
[Lateral bending]
[Rotation]
[Flexion]
[Extension]

Placement: Above knee on the side
For movements in: Hip
[Flexion]
[Extension]

Placement: Above knee
For movements in: Hip
[Abduction]
[Adduction]

Placement: Foot
For movements in: Ankle
[Dorsal bending]
[Lateral bending]

Placement: Above ankle
For movements in: Knee
[Flexion]



Feedback

Light feedback

The measuring unit is equipped with RGB LEDs, lighting the Peak logo. There are several feedback messages indicated by the logo lights:

- When the 'Track new movement' feature is entered in the Peak application, the logo lights up white, to indicate that the application and measuring unit is connected.
- When the measuring unit is placed correctly in the base or on the sticker, the logo lights up green for 2 seconds.
- When the battery is under 15%, the logo lights up red.
- During the measuring, where data is send from the measuring unit to the application, the logo pulses white, to indicate that the measurement is in progress.

Magnet connection

The connection between the measuring unit and the base and sticker is designed with magnets. The magnets in the measuring unit is placed in an immersion in the surface of the bottom shell of the measuring unit. The same shape as this immersion is raised in the silicone base. Inmoulded in the silicone base is a magnetic stainless steel component. As the magnets attract the metal, while the shapes emerge meanwhile, a tactile feedback is accomplished and the measuring unit can not rotate in the base during measurements.

Exploded view

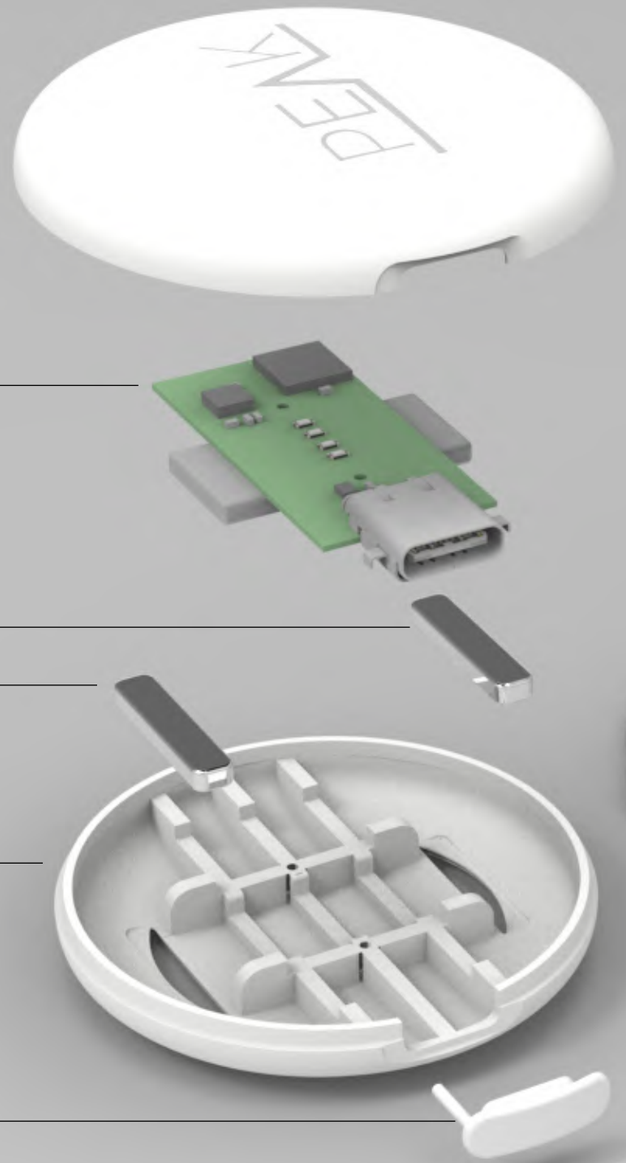
Top shell
(ABS/PC)
[Injection molded]

PCB
- IMU sensor
- MCU with BLE
- RGB LEDs
- Lithium Battery (3,7V, 80mA)
- USB-C

Magnets

Bottom shell
(ABS/PC)
[Injection molded]

Dust cover (USB-C)



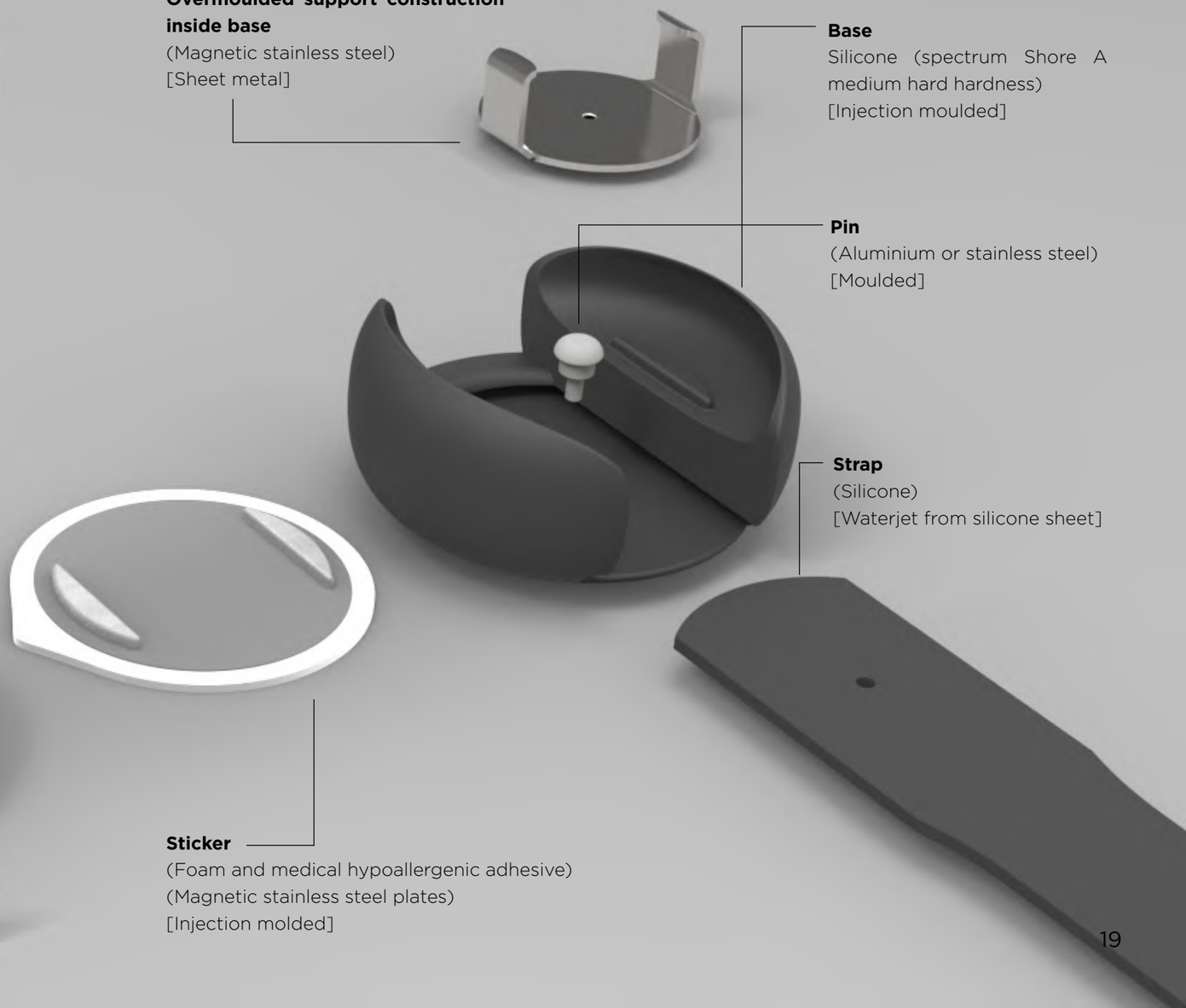
Overmoulded support construction inside base
(Magnetic stainless steel)
[Sheet metal]

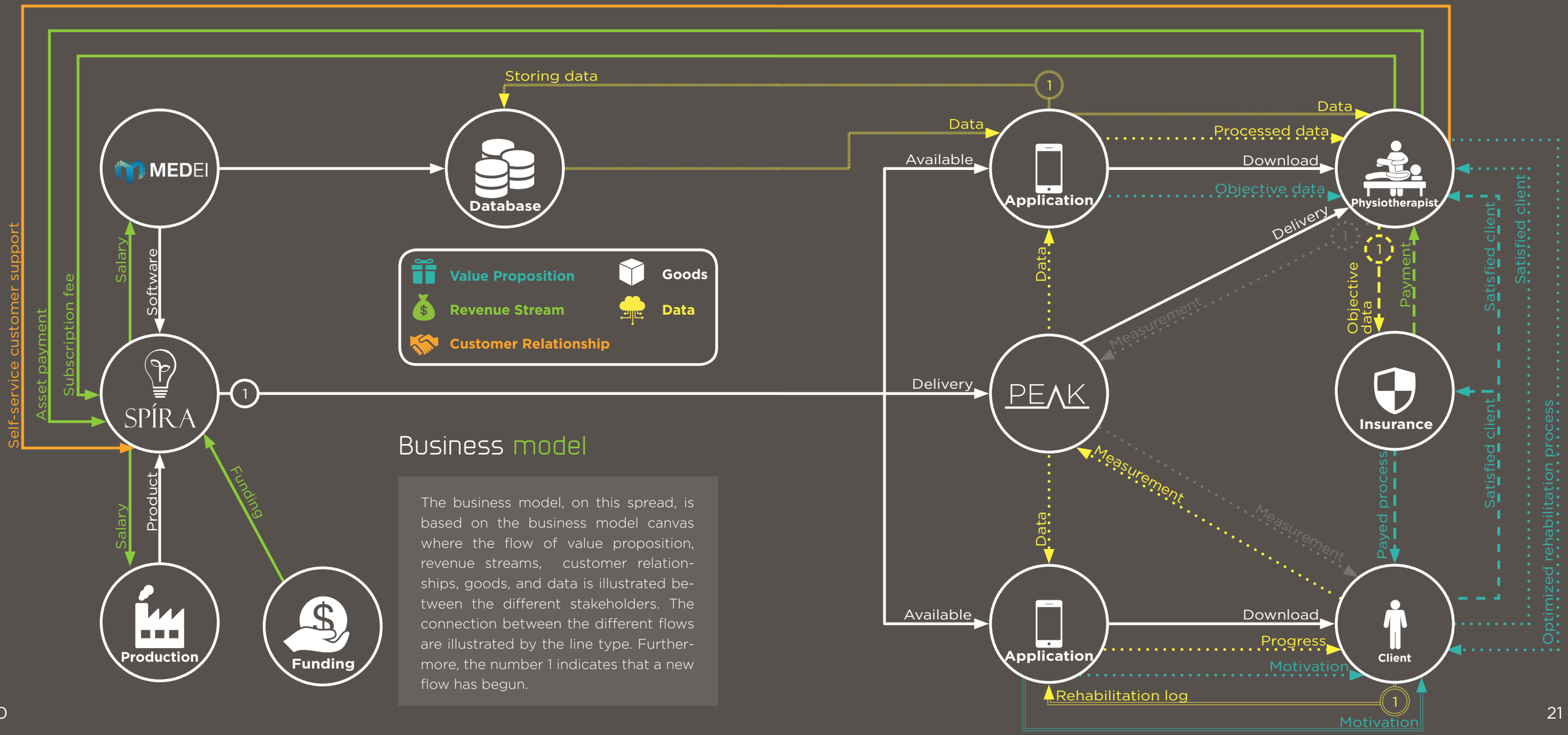
Base
Silicone (spectrum Shore A medium hard hardness)
[Injection moulded]

Pin
(Aluminium or stainless steel)
[Moulded]

Strap
(Silicone)
[Waterjet from silicone sheet]

Sticker
(Foam and medical hypoallergenic adhesive)
(Magnetic stainless steel plates)
[Injection molded]





Business model

The business model, on this spread, is based on the business model canvas where the flow of value proposition, revenue streams, customer relationships, goods, and data is illustrated between the different stakeholders. The connection between the different flows are illustrated by the line type. Furthermore, the number 1 indicates that a new flow has begun.

Budget

Peak production cost (without mould)	DKK
Measuring device, top	3,63
Measuring device, bottom	3,68
Electronics	100,2
Magnets x2	40,0
Anti Dust Plug USB-C	0,20
Assembly	30,00
Silicone base	14,24
Strap	7,00
Pin with thread	2,04
End pin	2,04
Stickers x100	21,00
Total	**224,01**

Application cost	Cost per unit (DKK)
Physiotherapist	32,66
Client	82,20
Total	**214,86**

Total investment	DKK
Moulds	210.400,00
Applications	537.150,00
Prototyping	15.000,00
Total	**762.550,00**

Income per sold unit	DKK
Sales price	995,00
Cost price	529,00
Income	**466,00**

	Pieces sold	Income (DKK)	Profit (DKK)
Year 1	500	454.984,90	-154.015,00
Year 2	2000	1.819.940,00	1.567.940,00
Year 3	3500	3.184.894,00	2.743.894,00

The estimated budget of the product system is calculated.
Salaries for the three team members of this project is not considered. All production will be outsourced.

In relation to the strategy of the future process, the first step is to finish the development of the design proposal with all details, followed by production start. The second step is to start the software development, which is estimated to take 6-9 months. The third step is to make the quality test and documentation of the whole product system to be able to launch it as a medical device.
When the product is ready to be launched on the market, a sales manager is hired to help introducing the product to the market.
From the potential of sales and the business strategy, it is estimated that 500 units will be sold within the first year after entering the market, 2000 units in year 2, and 3500 units in year 3.
This leads to a breakeven achieved in year 2, when 2500 units are sold.

SPÍRA

Process Report
MSc04-ID10 - May 2018

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There are a large amount of scientific research on the topic 'physiotherapy', and the treatment methods within physiotherapy. However, there are currently little development of more modern assessment tools for the consultation that uses this knowledge in combination with new technology. The fast growing knowledge and development of the field of technology keep giving new possibilities in relation to using the technology in clinical products. This leads to the development of the design proposal; *Peak*.

Peak is a system that by using motion tracking technology can contribute to provide the physiotherapists with accurate objective data on the functionality of the client's concerning injury (measured in range of motion). This data is converted into velocity, acceleration, and jerkiness, as the first product targeted the market for physiotherapy. These parameters contribute to the clinical picture regarding the quality of movement. *Peak* provides accurate digital objective data mediated through an application in favor of the physiotherapists, the clients, and the insurance companies.

Preface

The conduction of this master thesis report is performed by team Spíra (MSc04 ID10) from Aalborg University, Industrial Design Engineering, February 1st - May 31st 2018. The project is carried out over four months until the submission with supervisions and status seminars.

Thanks to:

- Supervisor Kaare Eriksen and co-supervisor Ewa Kristiansen for supervision and continuous feedback throughout the design process.

Special thanks to:

- Thorvaldur Skuli Palsson and Steffan Wittrup Christensen, physiotherapists and research team from Department of Health Science and Technology in Aalborg University, for continuous feedback and input.
- Rogerio Pessoto Hirata, Clinical Sports scientist from Department of Health Science and Technology in Aalborg University, for guidance and knowledge regarding 3D camera system and calculations.
- Medei, IT company, for insights in relation to software development of motion tracking.
- Anders Rasmussen, software developer, for help and guidance with software programming, calculations, and GUI set-up.
- Jón Brúnsteð Jóhannesson, mechanical engineer, for help with programming and guidance in relation to production.
- Physiotherapists and clients, who participated in interviews and surveys.
- Nordic Semiconductor for providing us with the development kits, Thingy:52.

Reading guide

The documentation of this master thesis is divided into two parts; product report and process report.
Product report - presentation of the final design proposal
Process report - presentation of the development process of the final design proposal

Additional material:

- Appendix (worksheets)
- Technical drawings
- USB containing worksheets, technical drawings, and the reports.

References are indicated using the Harvard reference method and are listed on p. 95. Illustrations are specified by page numberings and are specified on p. 96.

The process report is divided into seven main chapters, which are corresponding to the phases of the development process.

Barcodes are illustrated in relation to some aspects of the project, where videos exemplifies certain points. These barcodes can be scanned by using a barcode scan application for smartphones and tablets, after which the video will appear. The application called *Free QR Code Scanner - Barcode Scanner* on *GooglePlay* and *QR Reader for iPhone* on *App Store*, is recommended.

Appendix consists of a worksheet list with barcodes on each worksheet, which can be accessed by scanning with the QR application. The worksheets can also be accessed on the usb.

Finding #X

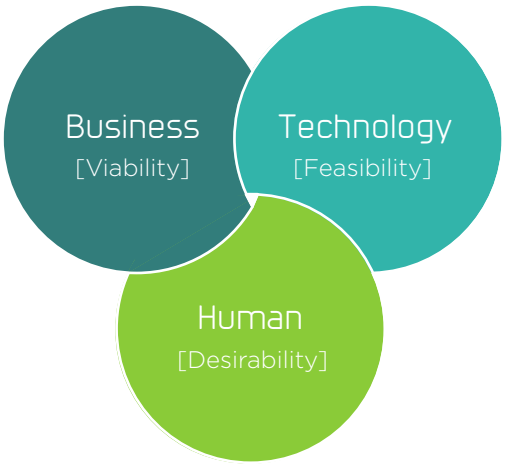
These boxes indicate key insights, which will be used in the entire process. These can contain; key findings/discoveries, part conclusion, decisions made, among others.

Table of content

Approach

Design thinking

The *Design Thinking* methodology is the approach utilized in the development process of this project in coherence with *Design Doing*. An approach where insights regarding human behavior makes up a desirable product solution, together with feasible technology, and a viable business case; the three building blocks combined to achieve innovation (Ill. 2.1). Because the affected stakeholders are the experts, the project revolves around them, and they are continually involved in the development process. It is therefore important that both the stakeholders and context are approached with open-mindedness, empathy, and curiosity. For the identification of stakeholder needs, qualitative methods are the main tool. Decisions should be made through testing and experimenting with prototypes as the primary tool in the development process of iterations. Through the whole process; sketches, mock-ups, and illustrations should be utilized as tool of understanding and communicating, to ensure that the whole team is aligned.



Ill. 2.1: Parameters in Design Thinking.

Project management

A task board, adopted from the agile method Scrum, is the primary tool used for managing the process and structuring the project tasks. The task board is digitally administered through the software MeisterTask, which enables the possibility of accessing the task board from everywhere. From the perspective of the team members, this tool contributes to the visibility and tangibility of the development process. This supports the progress of the process by the specification of well-described tasks, which makes it possible to activate all team members at all times, and makes it possible to perform work in parallels and still be on track. Follow-up on tasks, knowledge sharing, and planning of future tasks is done through daily and weekly meetings, which enables a continuous reflection of the project.

Team and resources

The team is composed of members with different sets of professional competencies, which are needed and very valuable in the design process. The intention is to utilize the knowledge and skills of each member. Furthermore, the target is to keep a continuous engagement and motivation for the project through the whole process. If this is complied, the team has the possibility to perform and evolve both on a individual level and to the contribution of the teamwork.

Introduction

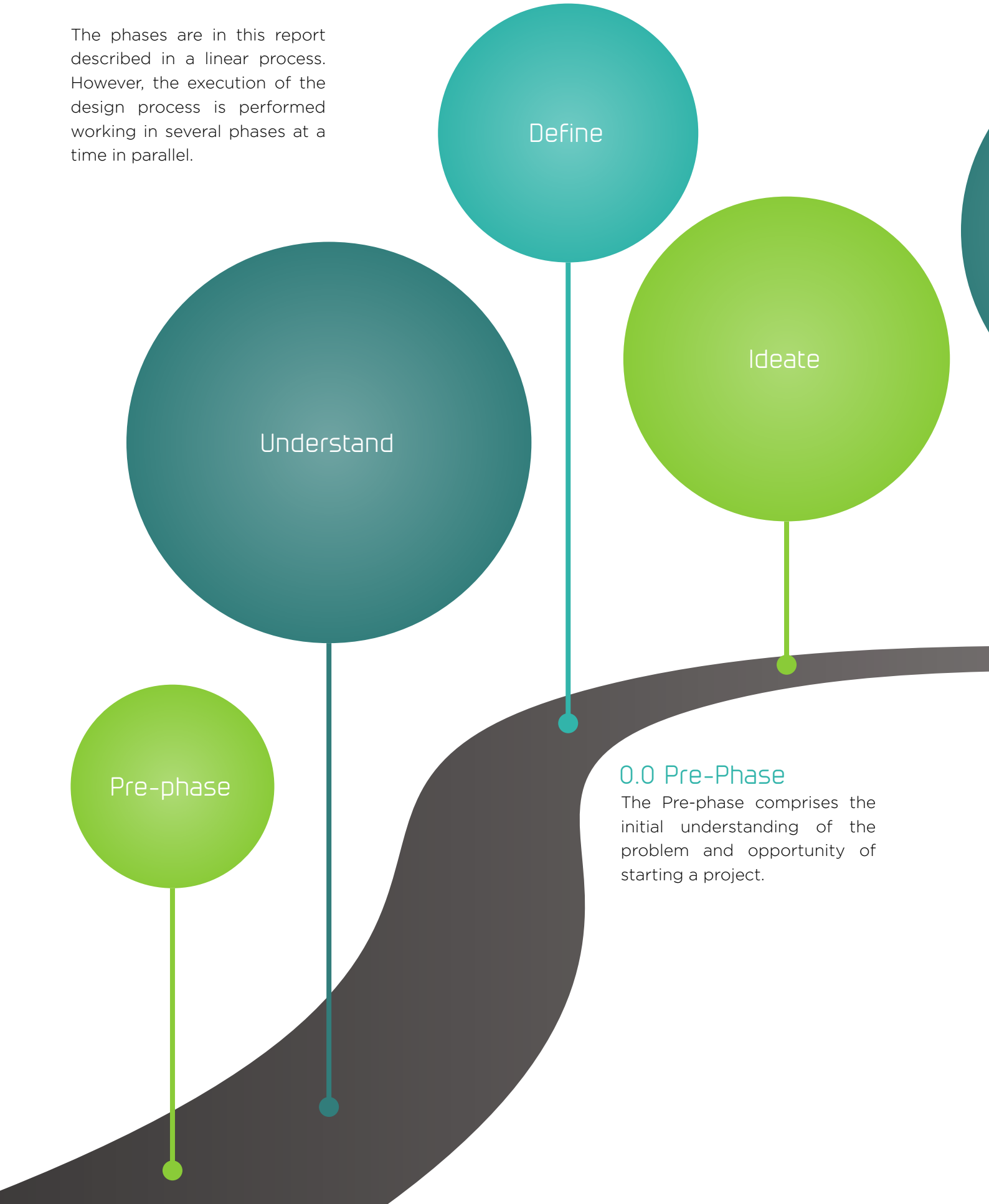
In Denmark many people pay a visit to a physiotherapist each year, and ends up in a longer rehabilitation processes due to work injuries, sport injuries, accidents, or pain in the back among others. If a person experience pain during movement or has reduced mobility, joint range of motion can in these cases be a relevant factor to objectively evaluate in relation to see progress in mobility. Today, joint range of motion is measured with a tool, which can not be applied for measuring all joints. Furthermore, the measurements are questionable due to several different sources of error.
Recent studies in this field show that digital measurements of joint range of motion can provide more accurate data. This in coherence with motion acceleration and jerkiness, which can tell something about the quality of movement. All factors can contribute to the clinical picture because it can indicate where the pain and/or problem emerge in a movement and therefore help the physiotherapist to make a more detailed and correct training program for the client.

The human body is our most important tool for all physical actions. If the mobility of the body gets affected by an injury or pain, this has consequences as it interferes with our way of living. This can be mentally exhausting, especially in longer rehabilitation processes, where normal/optimal mobility is pursued. In these processes it can be hard to maintain the fighting spirit, which in some cases lead to demotivation.

Therefore, the focus of this master thesis addresses the development of a product system for physiotherapy to measure mobility and quality of movements. The design proposal consists of a measuring device for clinical use, which measures the movement, and an application in favor of both the physiotherapist and the client. The physiotherapist application log intermediates the data measured by the device. The client application log intermediates the progress in rehabilitation based on previous measurements. Furthermore, the client has the possibility of entering personal data regarding their injury/pain to keep track of the progress.

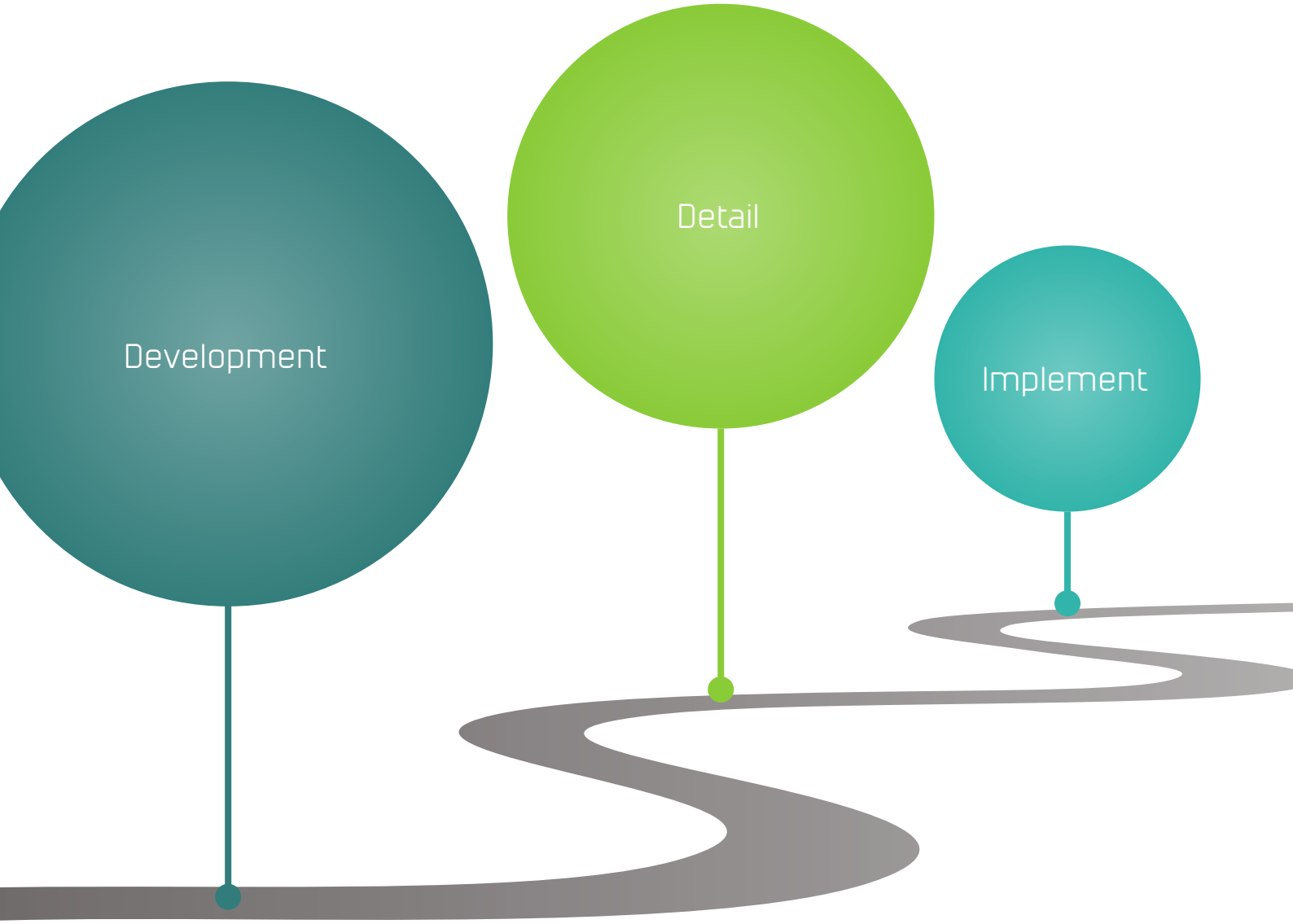
Phase overview

The phases are in this report described in a linear process. However, the execution of the design process is performed working in several phases at a time in parallel.



0.0 Pre-Phase

The Pre-phase comprises the initial understanding of the problem and opportunity of starting a project.



1.0 Understand

In the *Understand* phase, the fields of physiotherapy and rehabilitation are investigated through ethnographic studies; involving the relevant stakeholders in their respective context and through desk research.

2.0 Define

Findings and insights from the research performed in the *Understand* phase are converted into the project frame.

3.0 Ideate

After defining and converging the frame of the project, the solution space is diverged to be able to explore a wide range of possibilities.

4.0 Development

Through prototyping and testing, potential directions are further explored based on the chosen concept and features from the *Ideate* phase.

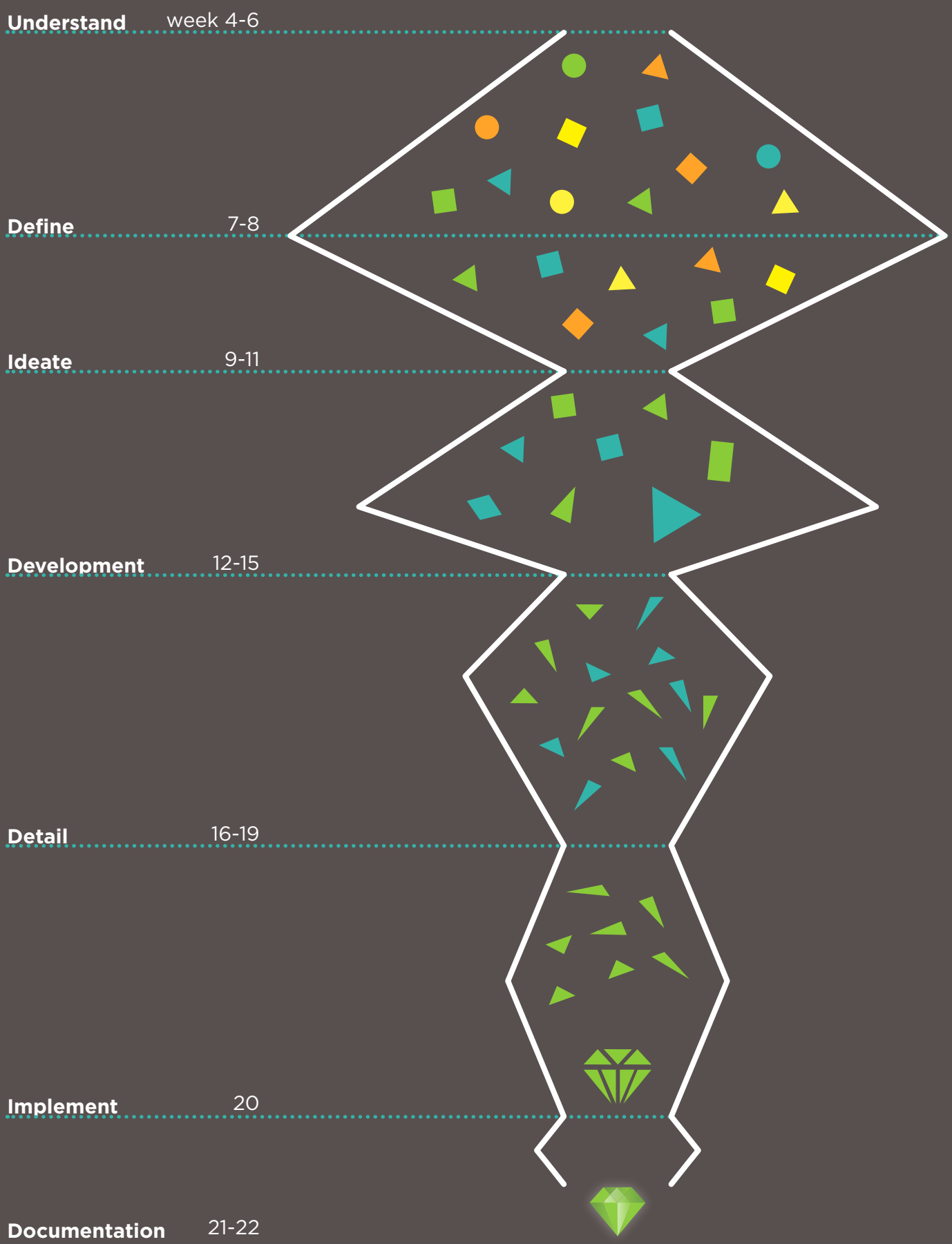
5.0 Detail

The now clear specified concept of the product system are further defined through 3D modelling.

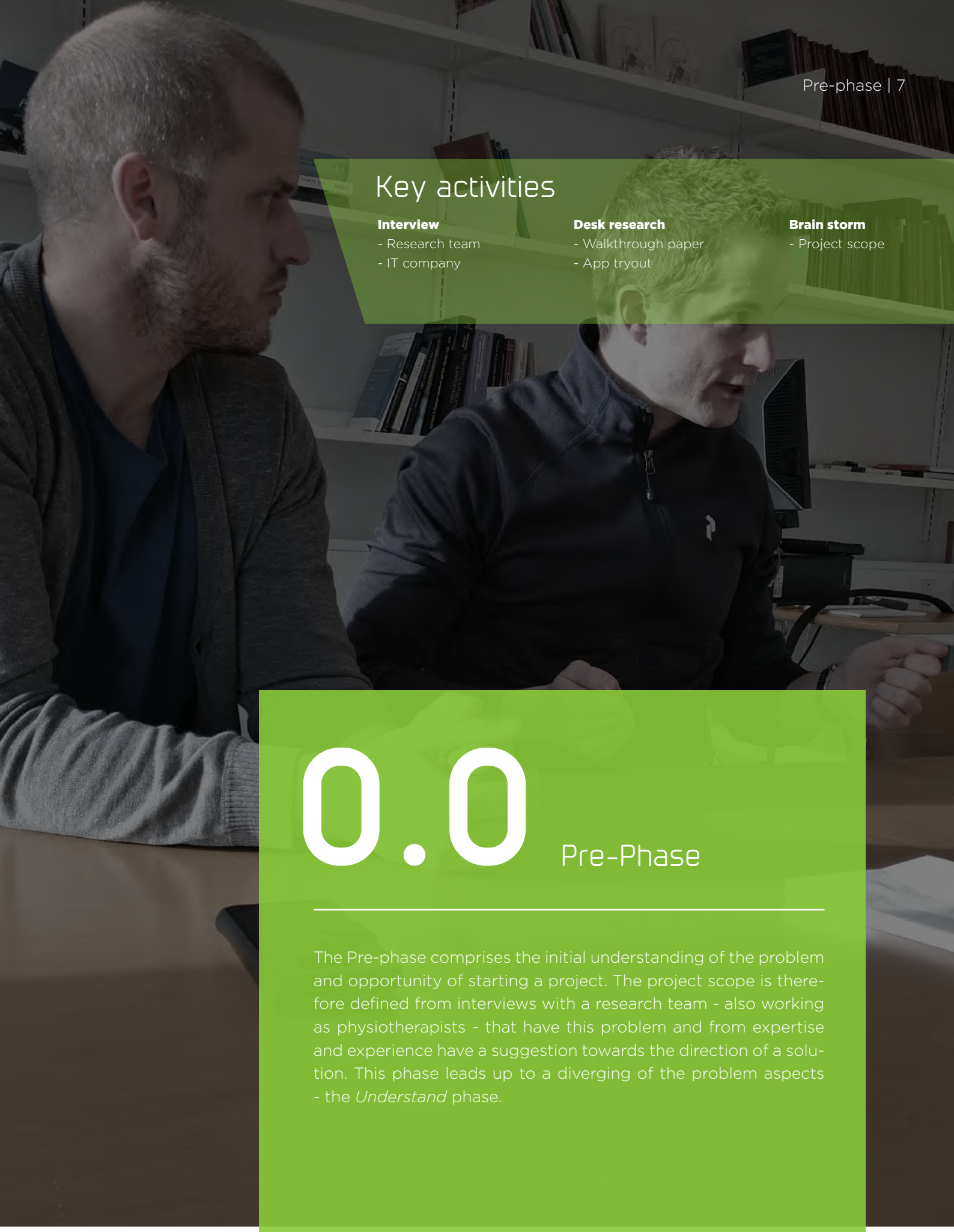
6.0 Implement

The needed business related and strategic actions are described, in relation to realizing and launching the design proposal on the market.

Time planning



Ill. 6.1: Planned diverging and converging in the process.



Key activities

Interview
- Research team
- IT company

Desk research
- Walkthrough paper
- App tryout

Brain storm
- Project scope

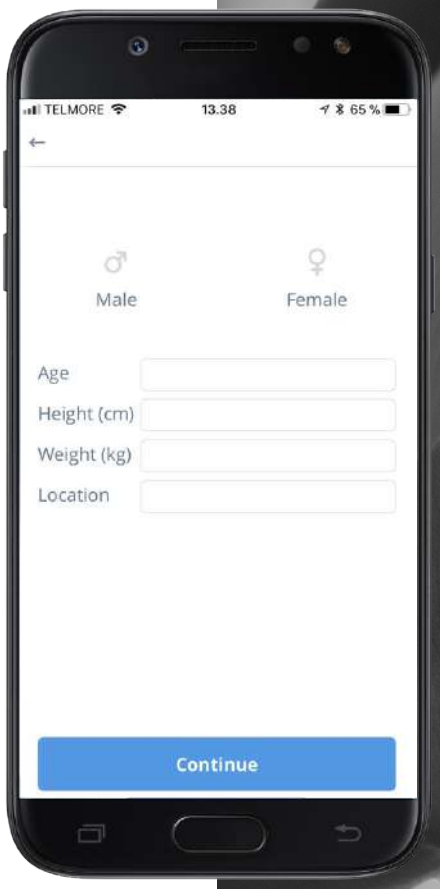
0.0 Pre-Phase

The Pre-phase comprises the initial understanding of the problem and opportunity of starting a project. The project scope is therefore defined from interviews with a research team - also working as physiotherapists - that have this problem and from expertise and experience have a suggestion towards the direction of a solution. This phase leads up to a diverging of the problem aspects - the *Understand* phase.

0.1 Cooperation with research team

This project started by one of the group members being contacted by a relative, working in the IT-company, Medei, that develops medical software for healthcare purposes. His company cooperates with a research team at Aalborg University specialized in physiotherapy. In cooperation they have developed a smartphone application for measuring the rehabilitation progress parameters; joint range of motion, acceleration, and jerkiness of neck movements. The application was tested with a raw prototype mounting method of the smartphone (Ill. 8.1).
To this reason they were interested in the development of a mounting method for a smartphone designed to clinical use, and for more measurement movements than only the neck.

Ill. 8.1: Experimental setup. (Palsson, et al., 2017)



Ill. 8.2: Application used in research.

0.2 Research team

This project is developed in cooperation with a research team at Aalborg University, consisting of Thorvaldur Skuli Palsson and Steffan Wittrup Christensen.

Ill. 9.1: Thorvaldur.

Thorvaldur graduated as physiotherapist in 2003 and is a specialist in musculoskeletal physiotherapy. He works with elucidation and diagnosis of complex problems related to muscles and joints.
In 2014, Thorvaldur finished his PhD about pain from the pelvis and loin.

Ill. 9.2: Steffan.

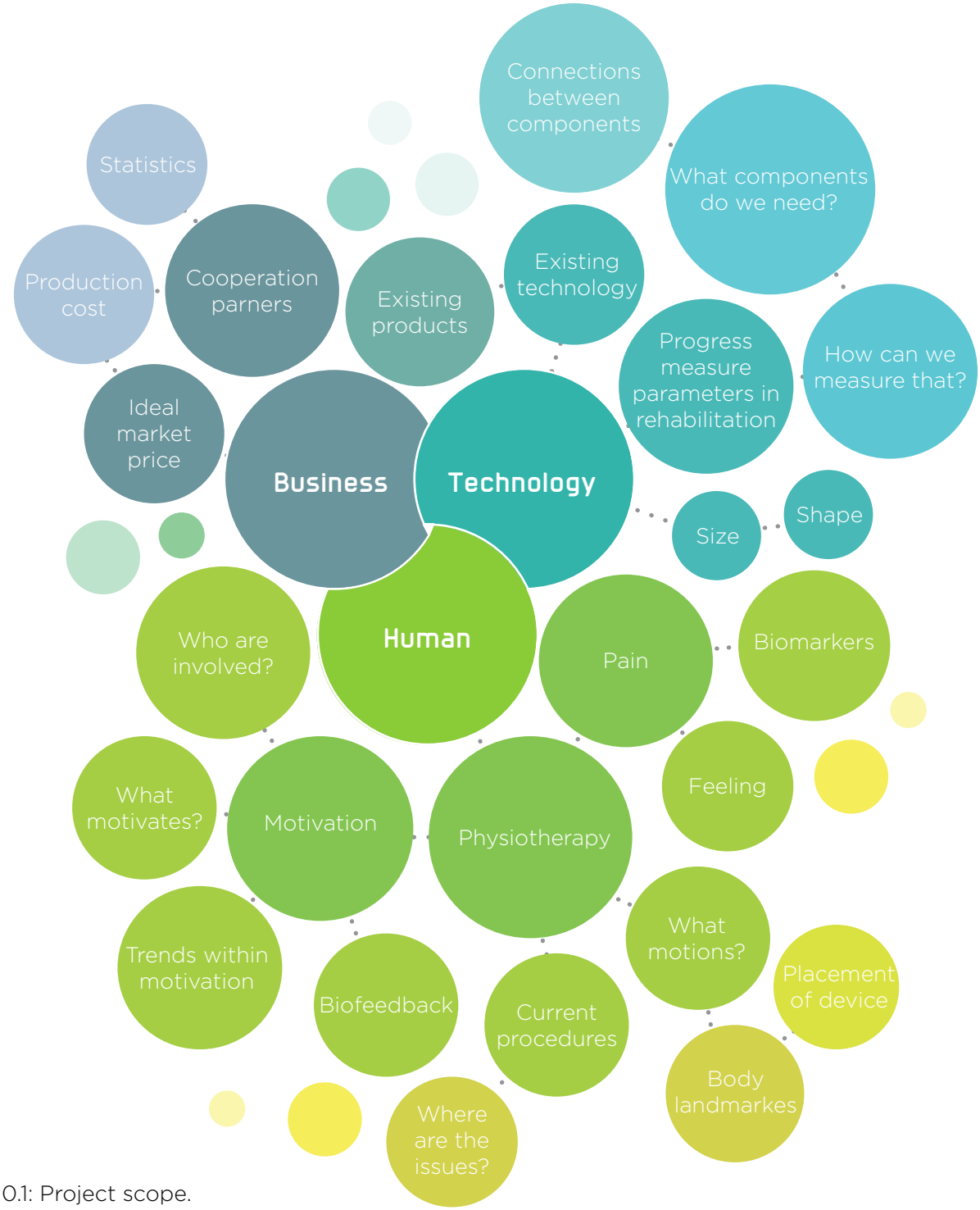
Steffan graduated as physiotherapist in 2005 and is a specialist in musculoskeletal physiotherapy. He works with elucidation and diagnosis of complex problems related to muscles and joints.
In 2017, Steffan finished his PhD about how neck pain influences the muscular function.

Both work at their shared physiotherapy clinic *APEXFYSIO*. On the side they are researching and teaching in the musculoskeletal area.

"*In these years physiotherapy is in a rapid development, where new knowledge just a few years ago is already outdated today. This development contributes to increasing demands for providing evidence-based approaches, which requires continuous professional development. This is necessary in order to implement the latest knowledge in clinical practice.*" - Thorvaldur & Steffan

0.3 Project scope

From an industrial design point of view the concerning topic is investigated from a broader perspective. How to develop a measuring device that can measure the needed parameters, which are necessary, to give the physiotherapist objective data to base and continually evaluate the rehabilitation process and treatment on, are investigated. Furthermore, what are the aspired values from the perspective of the involved stakeholders, and which aspects should be integrated in the design to contribute to the aspired values? What is the potential market of a product like this? How can all these aspects in cohesion lead to a solid business proposal?



Ill. 10.1: Project scope.

Key activities

Desk research
- Physiotherapy
- Motivation
- Business aspects
- Existing products

- Joint range of motion
- Acceleration and jerkiness
- Joint repositioning
- Pain biomarkers

Interview & observation
- Physiotherapists
- Clients
- Insurance company
- IKAS

1.0 Understand

In the Understand phase, the fields of physiotherapy and rehabilitation are investigated. This is performed through ethnographic studies; involving the relevant stakeholders in their respective context, and through desk research; regarding statistics, anatomy, business, existing products, and scientific research concerning motivation, measuring of progress, and pain. During the data collection, the data is analyzed and evaluated, and processed into findings, which makes the foundation of the project focus. These findings are translated into requirements, which forms the frame of the direction and solution space of the product proposal.

1.1 Physiotherapy

Physiotherapy is an activity related to make the human body function as good as possible. The therapy can be used to prevent or treat physical disorders or discomfort. More specifically, the activity especially works with the parts of your body you use when you move; muscles, joints, ligaments, tendons, the nervous system, and the circuit.

There are many causes of going into physiotherapy. The most common is listed in Ill. 12.1. It is different what the treatment is for each injury or discomfort, and the treatment can differ from a few treatment sessions to longer rehabilitation periods. (Corpus Care, 2018)

Back pain	Work injuries	Sport injuries	Accidents
This covers all pain from the neck down to the coccyx (tailbone).	Pain in muscles, joints, and tendons. Typically the cause of bad work posture or heavy lifts.	Can be acute injuries or caused by overload.	Can be a whiplash injury from a car accident e.g.

Ill. 12.1: Causes for going to the physiotherapist.

Statistics

880.000 people in Denmark have low back pain.

570.000 people in Denmark have neck pain.

These two conditions covers **53%** of all visits to the chiropractor and physiotherapist.

(Flachs, et al., 2015)

In 2016 there were reported **42.043** work accidents for the labor inspectorate.

41% of these have suffured under the category *"sprain, joint damage, or similar,"* where physiotherapy could be relevant in the rehabilitation process.

(Arbejdstilsynet, 2016)

There are around **100.000** registered sports injuries in the emergency room a year.

However, the accident register, which registers the sports injuries, estimates the number to be **8** times higher.

(Laursen & Frimodt-Møller, 2002)

There are many types of accidents where physiotherapy can be relevant.

One accident, which is often treated in physiotherapy, is whiplash. It is estimated that **15.000** people in Denmark get whiplash per year.

(Lars Uhrenholt, 2016)

[Worksheet 14 - Statistics]

1.479

physiotherapy clinics in Denmark.

(Danske Fysioterapeuter, 2018)

11.352

physiotherapists in Denmark.

(Danske Fysioterapeuter, 2018)

Back pain is the

8th

biggest pandemics and causes

30%

of all visits to physiotherapists.

(Flachs, et al., 2015)

Neck pain causes

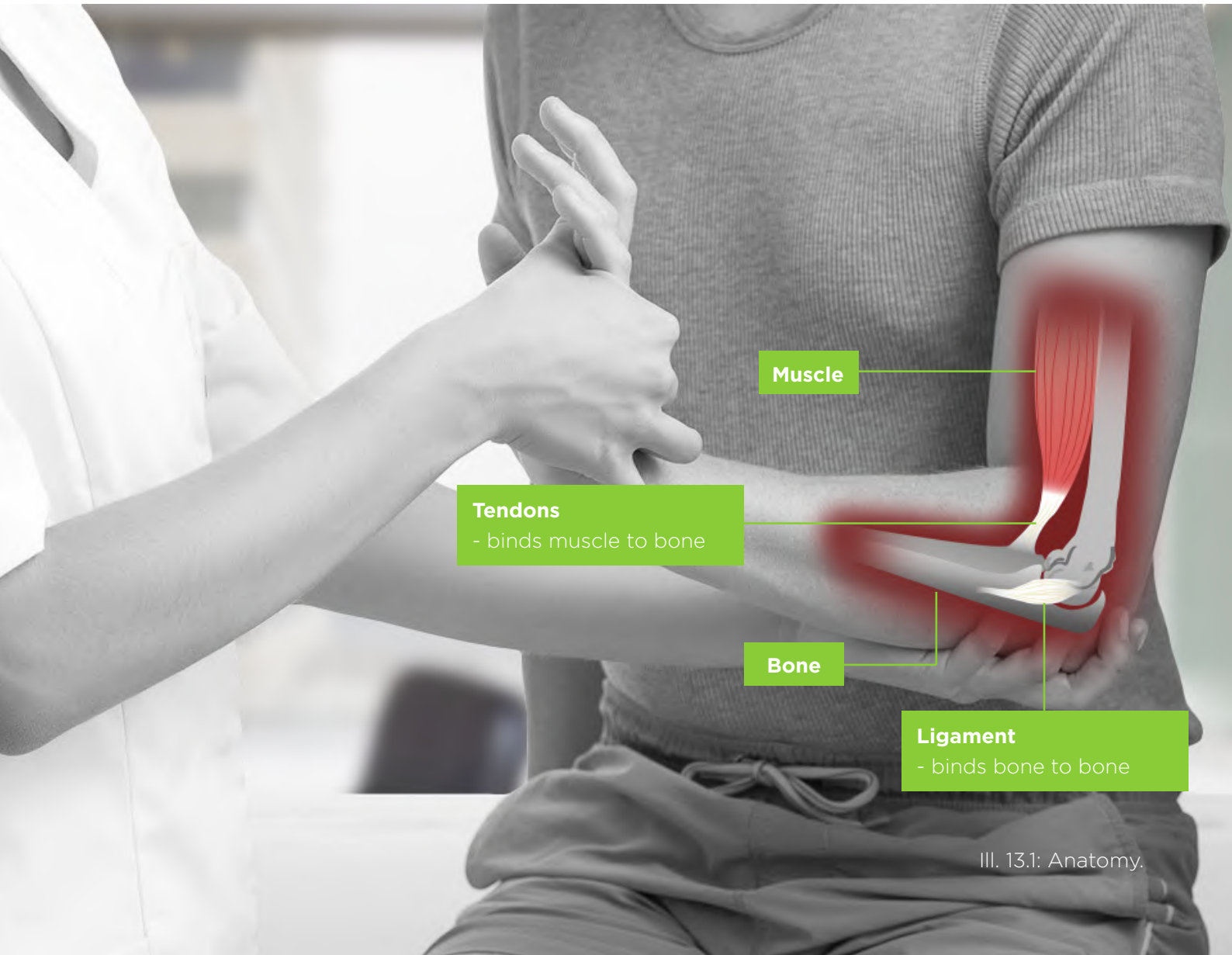
2.1 mio

visits to physiotherapists. This covers

23%

of all visits to physiotherapists.

(Flachs, et al., 2015)

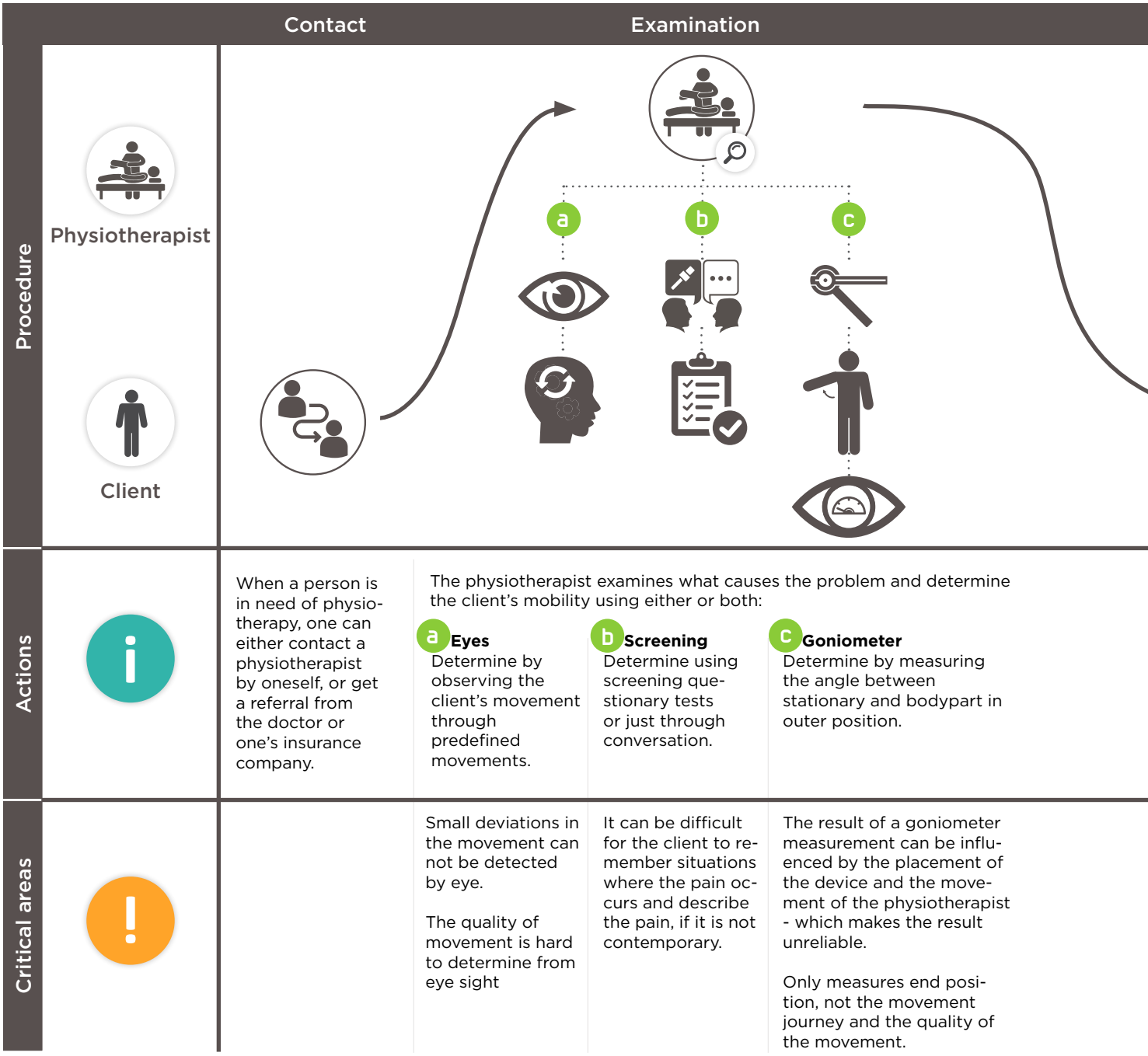


Ill. 13.1: Anatomy.

1.2 Rehabilitation process

The rehabilitation process varies from client to client. The length of the process can range from a couple of weeks to several years, depending on the severity of the injury. The number of physiotherapy consultations can also vary from a couple of sessions per week to a couple per month. An example of the basic structure of a rehabilitation process is illustrated in the user journey map in Ill. 15.1. This example is based on interviews with physiotherapists (Worksheet 25).

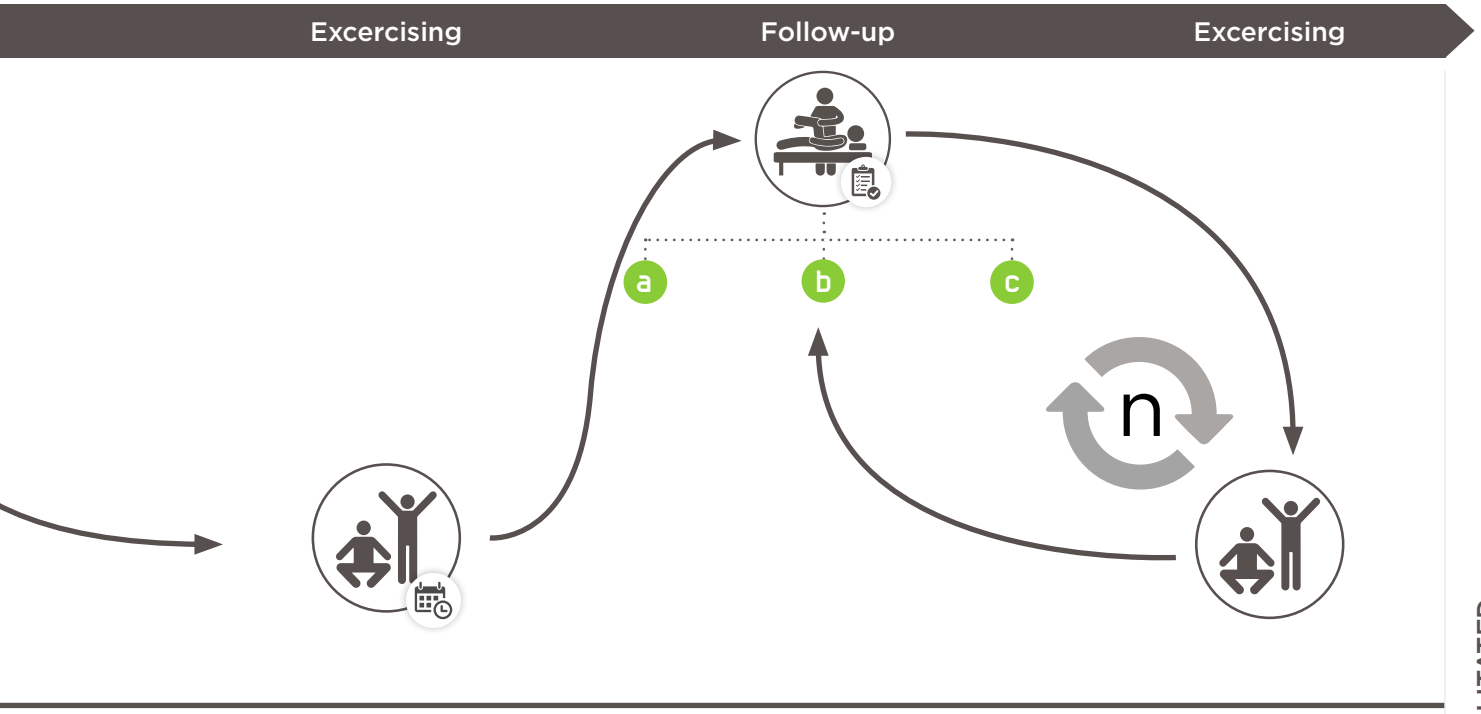
In a rehabilitation process, the main action is the assessment and evaluation of the client's movement and the quality of the movement, in comparison with the treatment the physiotherapist has to provide from that. However, the problem is that this action is characterized by subjective assessment methods as the physiotherapist are



using only their eyes, or equipment (Goniometer). The goniometer has low accuracy due to big margins of error in the execution method of the measuring action, which thereby only can indicate significant measurement differences in relation to the progress.

Goniometer

A goniometer is a protractor used to measure angles of body parts in physiotherapy. This is to determine a client's mobility. The goniometer is one of the most used instruments in physiotherapy regarding mobility measuring.



The client perform rehabilitation excercises at home as provided and demonstrated by the physiotherapist.	Follow-up consultations can take place *n* times. Everytime, the client's mobility is determined by the same assesment method as in the examination phase by the physiotherapist.	The client performs the rehabilitation exercises at home as provided and demonstrated by the physiotherapist.
	Imprecise subjective assesment methods can make it difficult to compare the mobility in each consultation. **a** If the physiotherapist use eye sight to evaluate, it can be difficult to memorize the difference from one session to another. **c** By using goniometer, because the measurement is easily influenced by outer parameters, the tolerance is significant.	It is common that the client loses motivation over time, because they are unable to see any progress.

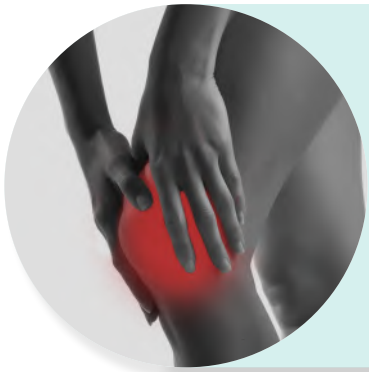
Ill. 15.1: User journey.

1.3 Clients

Camilla: Sports Injury: Two vertebrae jumped out of place; one in the neck and one between the shoulder blades.

"My motivation came when I had accepted that my favorite sport was not an option for me anymore, and when I set a new goal to rebuild my physics through rehabilitation in the fitness center, with the new dream of participating and completing the Nordic Race. "

Ill. 16.1: Vertebrae jumped out of place.



Mia: Sportsinjury: Knee jumped out of the joint and the ligament was ripped apart and a crack occurred in the cartilage in the knee.

"After my operation I was told that I was 12% permanent injured. However, there was a big chance that I could still be physically active, just not on a professional level. However, the process was really mentally hard because it took so long time before I could see the progress."

Ill. 16.2: Knee jumped out of place.

Louise: Pile-up car accident: Whiplash and concussion

"I started with 50% disability regarding rotations in my neck. He evaluated this and following my progress during the process by looking at my movements. It is a tough fight and I am still not completely functional or without pain, but it has improved since. But it motivates me that I can jog again."

Ill. 16.3: Wiplash.

[Worksheet 19]

Finding #1

It motivates the clients when they set their own personal goals.

Finding #2

Goals can often be related to daily life doings.

1.4 Evaluation of session by physiotherapist

Through interviews with ten physiotherapists, it is discovered that the method of assessing, treating, and evaluating the client differs from each physiotherapist. It is not a question of using the correct method, which does not exist, but finding the right combination of tools and methods that is tailored for the individual client and suits their specific problem, pain, rehabilitation period, and rehabilitation goal.
In the interviews the physiotherapists are asked, how they measure the client's progress. The answers were very individual, however, with some repetitions; with goniometer, tests (e.g. BEST-est), by strength, local intensity of pain, with the fingers, by eye, by using the function the client is indicating as a problem, whether it is a simple movement or complex action to evaluate from. All methods and tools used to support the overall clinical picture of the progress (Difference in movement and the quality of movement).

There are separate opinions if this result is satisfying and useful in progress evaluation purposes.

> *Using goniometers etc. can be a bit tricky as there are considerable margins of error which is also the case with visual observation*
> – Physiotherapist (Denmark)

> *Yes, what else is there to work with? The brain is still quicker than a tool ;-)*
> – Physiotherapist (Austria)

> *A goniometer is inaccurate in the measurement and does not measure how good the motion is, which represents the quality of the movement.*
> – Physiotherapist (Iceland)

When we asked them if it could be relevant to get more objective data about the client's movement, both regarding the movement extend (joint range of motion) and the quality of movement (smoothness/jerkiness) for them to evaluate the progress?

10/10 physiotherapists where positive or very positive.

> *Yes - it would be useful to have more precise data and could allow more time for treatment (if done through technology) as well as offering patients more opportunity to see progression*
> – Physiotherapist (Australia)

> *Could be important if this patient is not going to be with the same physiotherapist always, because I can know how one of my patient are improving, but if you don't have objective things to measure it with, it's difficult to give this information to other physiotherapists.*
> – Physiotherapist (Spain and Iceland)

When we asked them if they need a product that could give them these objective informations

9/10 agreed.

When we asked them if this information would give them better possibility of assessing, evaluating, and treating the client

8/10 agreed.

[Worksheet 20]

Finding #3

Physiotherapist are very proud of their profession.

1.5 Motivation

Motivation is investigated as it is an essential part of rehabilitation from the perspective of the client. It is investigated to understand what defines it, which factors can affect it, and to find scientific motivational factors in relation to rehabilitation.

Definition

Motivation is connected to purpose, action, and desire, and can be influenced and stimulated by internal and external factors, which can affect a person's interest or commitment to achieve something (Ryan & Deci, 2000; WebFinance Inc., 2018). Motivation can be elicited because a person finds something valuable, and by interest be urged into doing something (Ryan & Deci, 2000).

Maarten Vansteenkiste describes two parts of motivation as; mustivation and wantivation (Vansteenkiste, 2013), where the mustivation is a controlled motivation, which can be driven by external or internal pressure. Whereas, the wantivation is an autonomous motivation, which can be driven by usefulness, value, or interest. These aspects are a part of the Self-Determination Continuum showed in Ill. 19.1. (Ryan & Deci, 2000)

Motivational factors in rehabilitation

In the scientific research in relation to rehabilitation, agreed goals between the therapists and the client, are an essential motivational factor (Barnes & Ward, 2000). Furthermore, a vital factor in order to have a successful process of rehabilitation is the outcome measurements (Wilson & McLellan, 1997). But the goals that are set today are discussed as being "vague and lacking in precision" (Wilson & McLellan, 1997).

Tracking applications

Looking into the area of health applications, the term e-Health is discovered. This area is explored for relevant aspects in relation to motivation among others. The term e-Health (Electronic Health) application is related to software programs within the field of healthcare. An e-Health application can be providing tools, processes, and/or communication, to complement consultations, evaluations and/or treatments in the healthcare sector (Hairong Yan et at., 2010; Hernandez et al., 2001). m-Health (Mobile Health) is a phenomenon within e-Health, which contains areas as mobile computing, networking, medical sensors, and also communication technologies inside the field of healthcare (Istepanian et al., 2004). Increasingly m-Health is expected to become important in the area of e-Health, and it is also expected that m-Health continuously will play an essential role within healthcare (Norris et al., 2009), as the applications for smartphones has made the healthcare delivery more effective (Vital Wave Consulting, 2009).

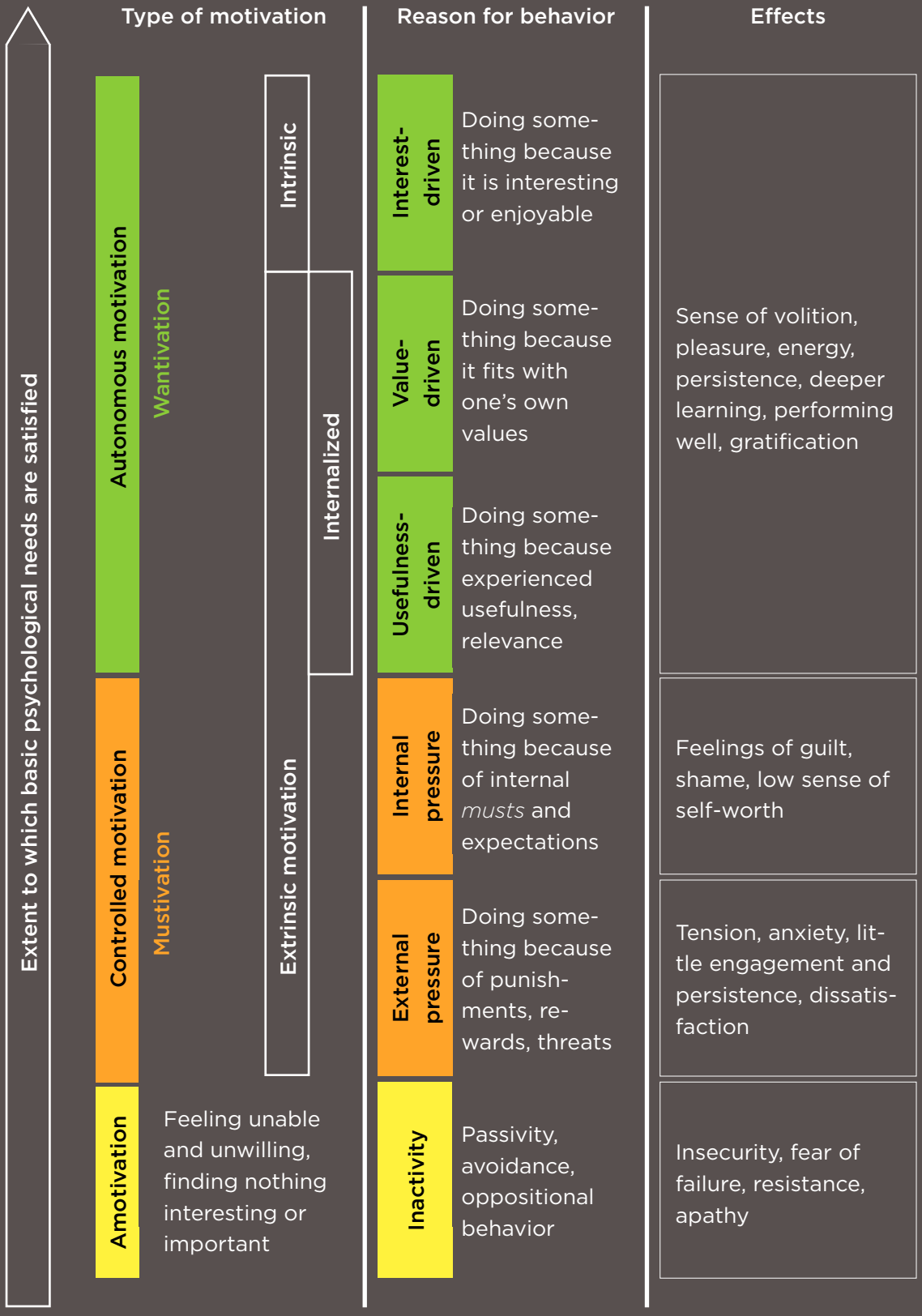
The technology of smartphones benefit its users in relation to healthcare because of its "portability, immediacy, convenience, comparatively low unit cost, and efficiency" (Liu et al., 2011). The technology allows an easy communication between clients and therapists, and m-Health applications can be an effective tool in order to encourage its users to change their lifestyle. A study implies that using 2D or 3D visualization of data in m-Health applications is preferred by the users. Furthermore, the research suggests that m-Health applications compatible with external sensors for data collection could bring the users greater value. (Liu et al., 2011)

Finding #4

If the basic psychological needs are satisfied to the extent of autonomous motivation, the motivation is more likely to be maintained.

Finding #5

2D or 3D visualization of data in m-Health applications is preferred by the users.



Ill. 19.1: Self-Determination Continuum.

1.6 Business

Public, semi-public, and private clinics

There are different types of physiotherapy clinics looking at the financial aspect, which regards if they substantiate a specific agreement, like the Danish public agreement, or if they cooperate with the insurance companies e.g. These different types vary in how much of the treatment payment is patient share, public healthcare insurance share, and private insurance share, if so.

"*There are many insurance companies internationally that require documentation on the rehabilitation progress to continue giving financial subsidies, this requirement could spread to Danish insurance companies*" - Thorvaldur Palsson (physiotherapist and scientist)

Medical equipment

Medical equipment is products that is used within the medical field for either preventing, diagnosing, ease, or treat diseases. To launch a product as a medical device (in Europe), the product needs to have an EU MDR (European Union Medical Device Regulations); certifification through quality tests and documentation.

The advantages of launching a product as a medical equipment is that it reflects the certified quality test, and therefore in terms of quality has very good chances of competing against products that is not certified as medical equipment.

Insurance companies

Talking to TRYG as an insurance example gives insights in the procedure of determining the degree of permanent injury in relation to compensation cases. All depends on each case and which type of insurance the case regards. If it is a private insurance, for example, and the customer has an injury to which they want to apply for compensation, their personal doctor has to perform tests on the person and send the data to the insurance companies. The company has their own doctors associated inhouse, whose job is to evaluate these data and determine in which category of permanent injury the customer belongs in.

The differences in degrees of permanent injury compared to the compensation size varies from type of injury and situation, but only 1% and 2% differences can have large impact on the compensation amount (Arbejdsmarkedets Erhvervssikring, 2016). When it is asked, if they are interested in receiving more objective data in these cases the following is answered:

"*We are interested in making the correct assessment of all cases both in relation to us as an insurance company, but also to provide the customer with the compensation that is required through their insurance. So we always prefer the data that is most correct!*" - Lone Abotts, TRYG

[Worksheet 22, 29, 32]

Finding #6

Launching a product as a medical device gives good chances in relation to competition on the market.

Finding #7

Insurance companies are interested in as correct data as possible to give their customers what they are entitled to by their insurance, and for them as an insurance company not to overcompensate.

1.7 Scientific dissertation of research team

The research investigated the fact that there is a need for assessment methods that can detect discrepancies in the ability to move and the quality of movement. Medei developed software for the research team, where they used smartphone technology for measuring parameters of the quality of movement (joint range of motion, acceleration, and jerkiness). The results showed that the comparison between this method and the gold-standard had excellent agreement in all directions. The scientific approach and results led to important findings derived from the scientific dissertation.
(Palsson, et al., 2017)

Finding #8

There is a need for assessment methods that can detect small discrepancies in the ability to move and the quality of movement, in order to be able to assess the effect of a painful condition.

Finding #9

There is a challenge related to the large variability in the body structure of clients.

Finding #10

3D motion capture analysis is considered as a gold-standard method regarding accuracy. However, the method is not feasible given their cost, necessary technical expertise, and the time required for setup.

Finding #11

Joint range of motion contributes to a greater understanding of the disability regarding the extent of the motion.

Finding #12

The assessment method has to be inexpensive to be attracting for physiotherapists to purchase.

Finding #13

The acceleration and jerkiness in the motion are parameters, which explain how the motion is executed and can help the physiotherapist to understand the client's pain throughout the motion.

Finding #14

Joint repositioning is a sensory-motor, which can contribute to the clinical picture of a client's rehabilitation process.

Finding #15

Jerkiness and other measurements of the quality of movement cannot be detected with the human eye unless there are significant deviations from normal movement.

Finding #16

It is important that the device has a short mounting/set up time.

1.8 Joint range of motion

Definition

Range of motion is defined as the measurement of a movement around a specific joint or body part. The unit used for measuring joint range of motion is degrees. In order for a joint to have a good range of motion, it must have a good flexibility. Factors that can influence a lack in flexibility are pain, swelling, and stiffness in the joints. This can be side effects from diseases as arthritis, rheumatoid arthritis and osteoarthritis, or injuries. Other factors that can affect flexibility are bones, muscles, joint structure, ligaments, tendons, body temperature, activity level, gender, age, and genetics. (AOK, 2018)

Types of movements

There are three types of movement in relation to rehabilitation.

Passive

The range of motion is moved by an external force pushing on the body around a joint.

Active

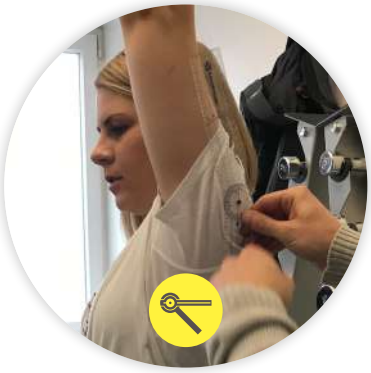
The range of motion is created by the person contracting the muscles around a joint.

Active-assistive

The range of motion is created by the person contracting the muscles around a joint, but with some assistive help e.g. from a strap or band.

1.9 Measurement movements

In physiotherapy to measure joint ROM there is a set of defined movements (Norkin & White, 2003). The focus is on 18 of these movements [Worksheet 3]. The movements are described in the next three pages (Ill. 23-25.1). The movements are performed in the consultations respectively of the client's injury. To measure these movements a goniometer (Ill. 22.1) or Crom device (inclinometer) (Ill. 22.2) can be used.



Ill. 22.1: Goniometer in use.

The goniometer is not optimal to measure any of these movements and to some it is considered impossible. The Crom device is used by some physiotherapists, but is a rather expensive tool. It is marked on the illustration, if the goniometer or Crom device can be applied to measure joint ROM in relation to the specific movement. The marking of the goniometer is performed with advice from physiotherapists [Worksheet 25].

Ill. 22.2: Crom device in use.

1

Flexion

NORMAL

Back

Extension: 25°

Flexion: 90°

Neck

Extension: 60°

Flexion: 50°

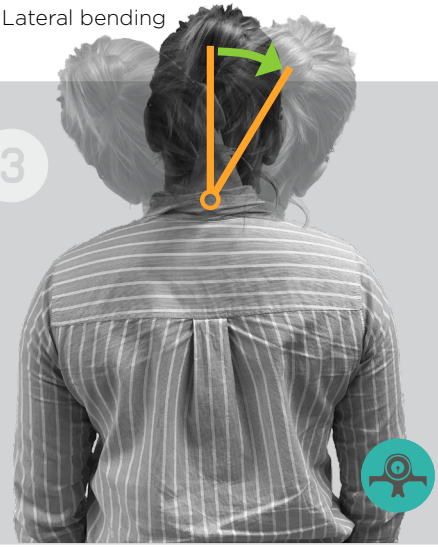
NORMAL

2

Flexion

3

Lateral bending



NORMAL

Neck

Left: 45°

Right: 45°

Neck

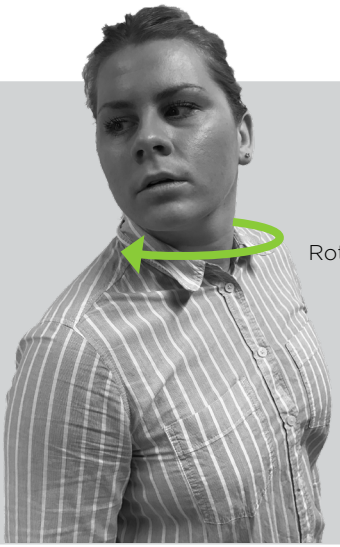
Left: 80°

Right: 80°

NORMAL

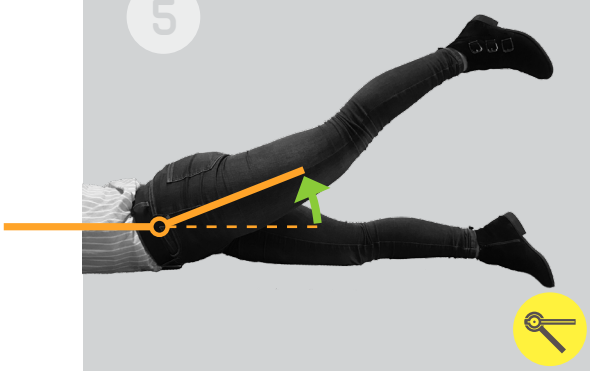
4

Rotation



5

Backward extension



NORMAL

Hip

Left: 45°

Right: 45°

Hip

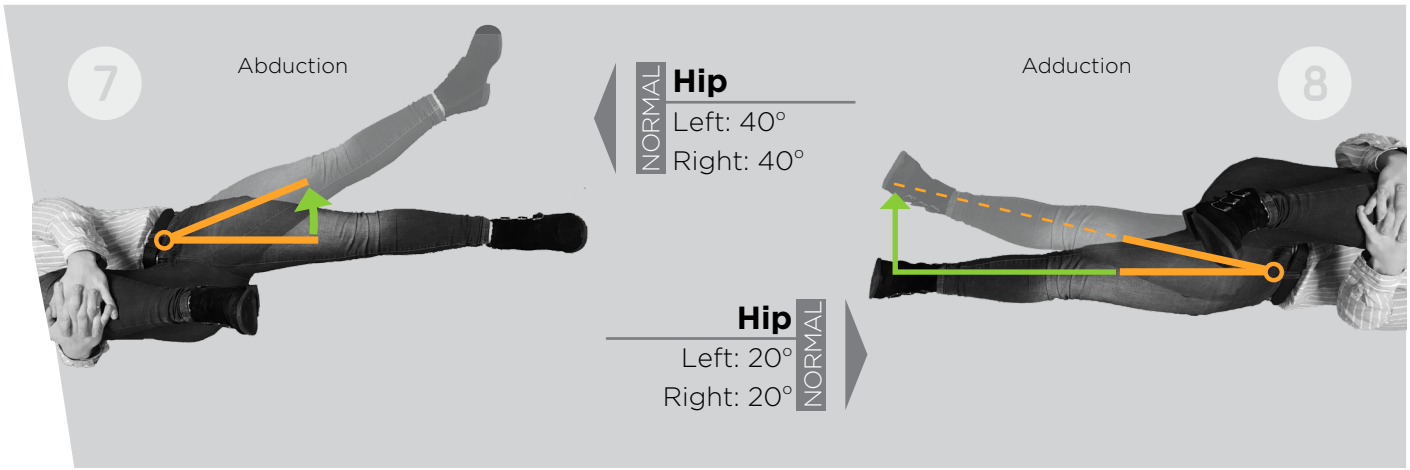
Left: 120°

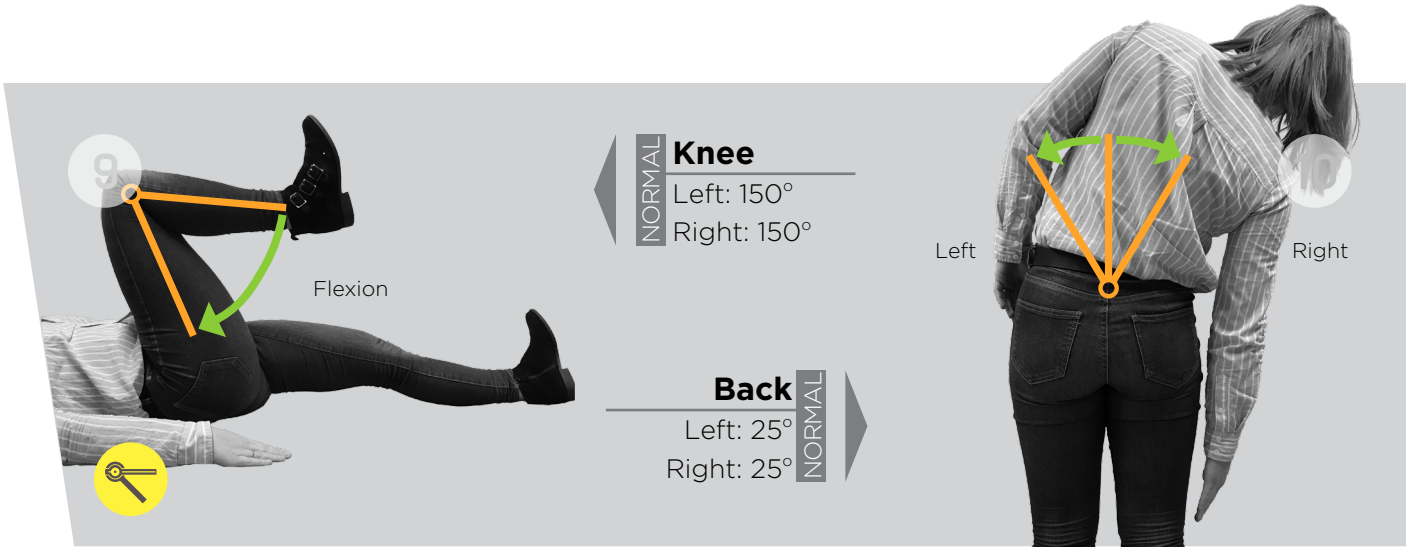
Right: 120°

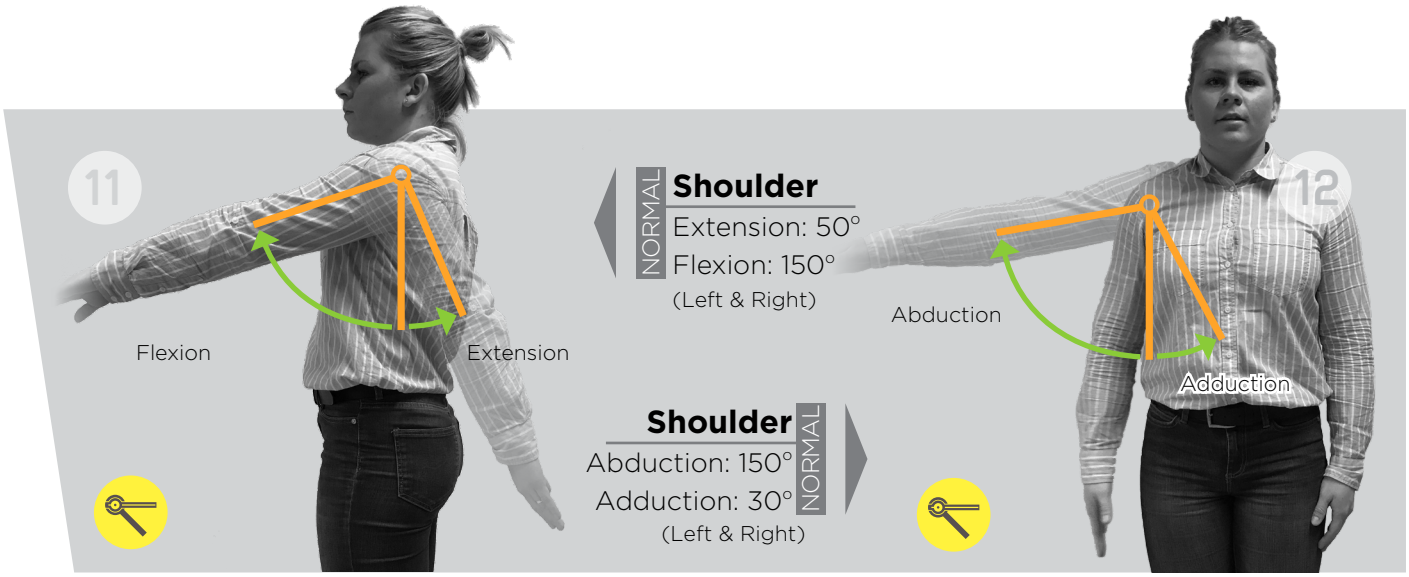
NORMAL

6

Hip flexion with knee flexed 100°

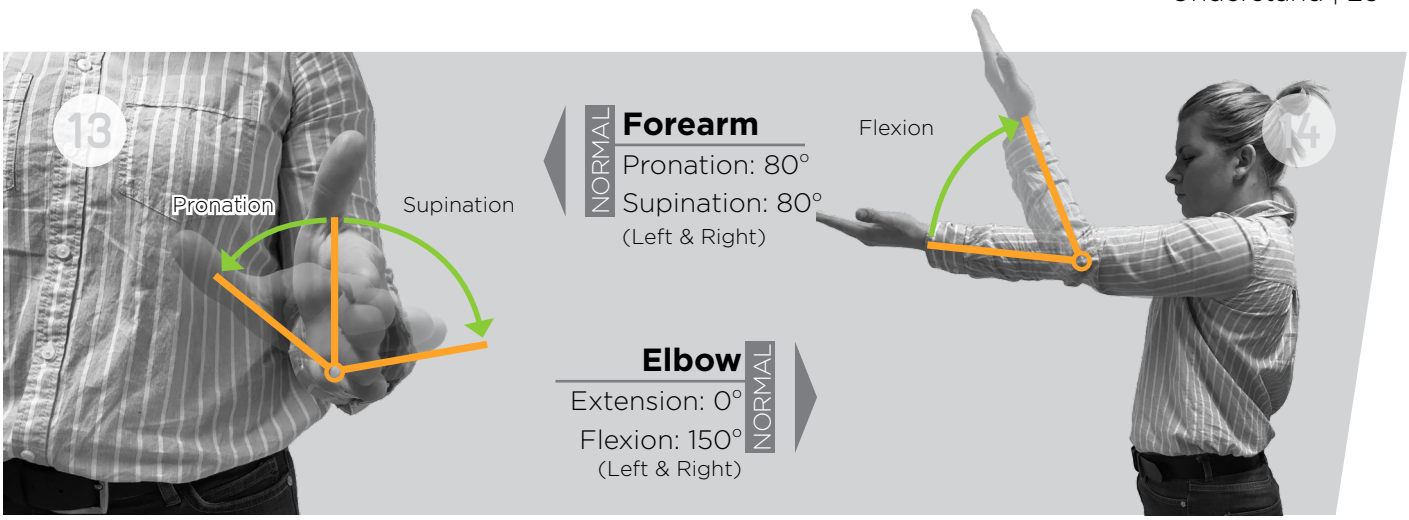


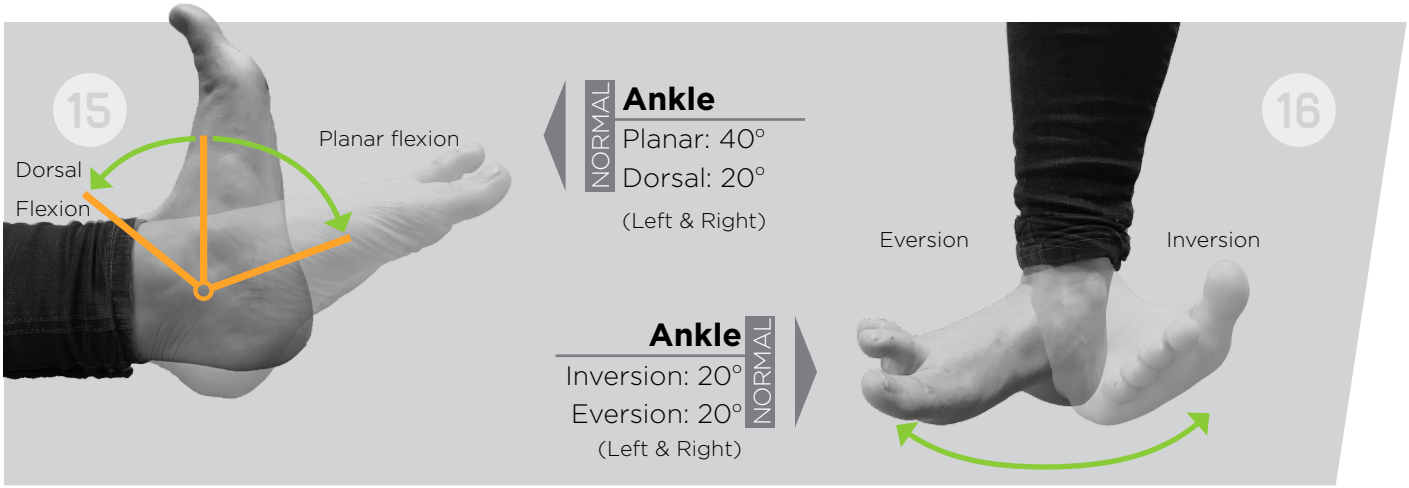


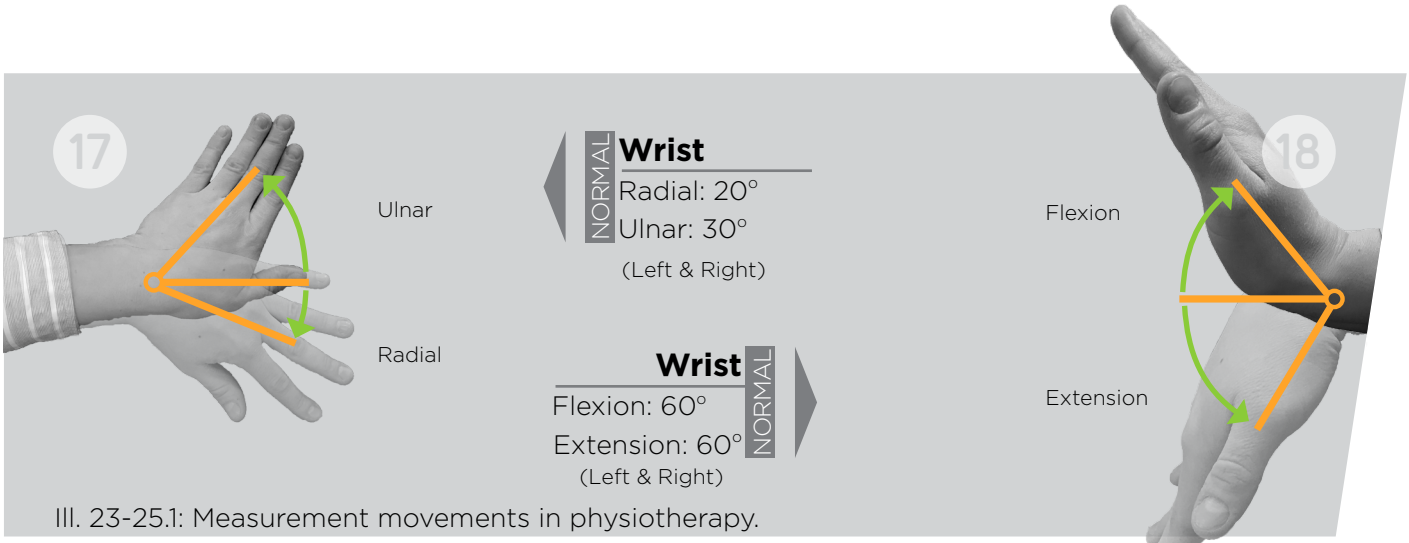


Finding #17

No existing clinical products can measure the neck and back movements, due to complexity, however, pain during these movements are the majority cause of visits to the physiotherapist.





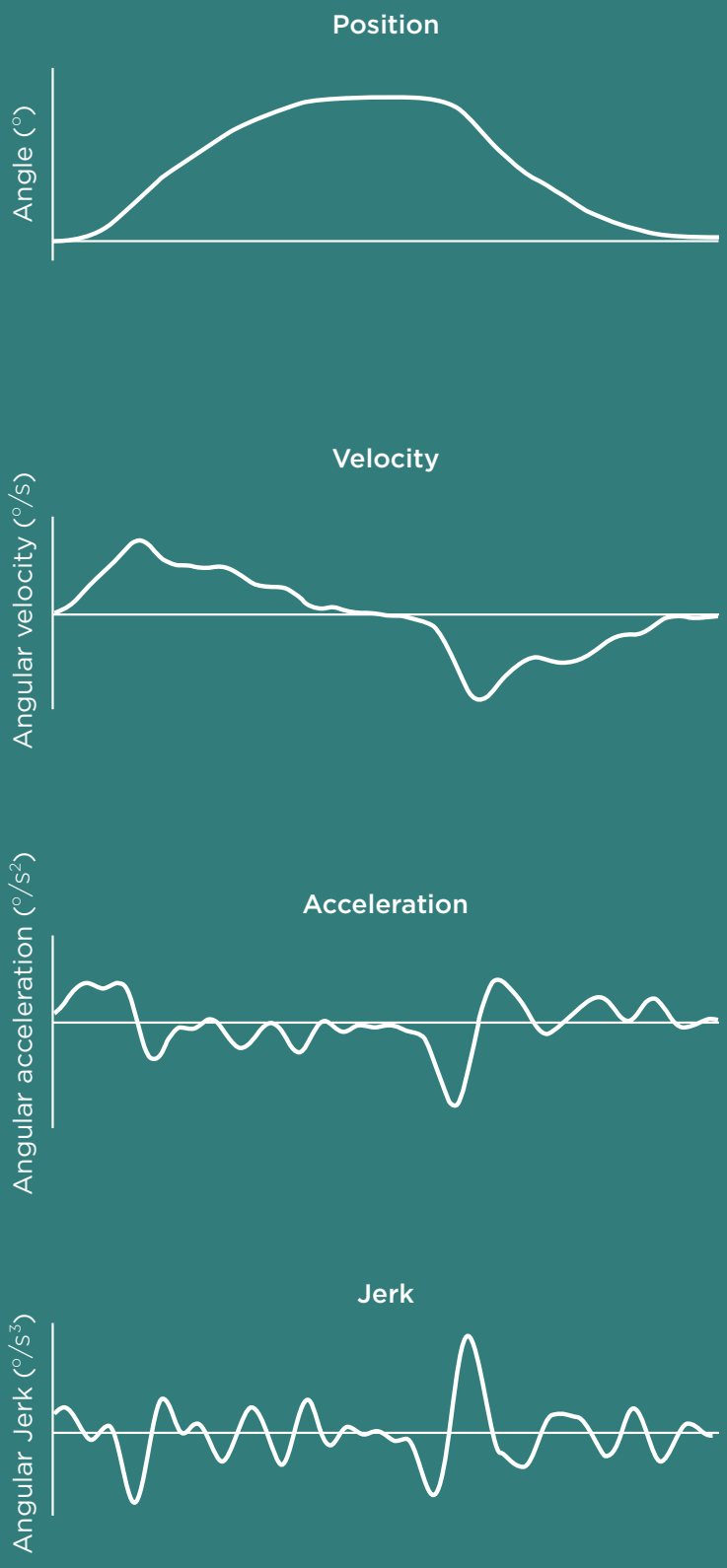


Ill. 23-25.1: Measurement movements in physiotherapy.

Finding #18

Movements 1-18 regards all key joints where objective data could be relevant.

1.10 Acceleration and jerkiness



Ill. 26.1: Example of graphs on a movement showing position, velocity, acceleration, and jerk over time.

Acceleration

The Acceleration is defined as the change in velocity with respect to time.

$$\frac{\Delta v}{\Delta t}$$

Jerkiness

A jerk is defined as the change in acceleration with respect to time. The greater the change is, the larger the jerk is. (Eager, et al., 2016)

$$\frac{\Delta a}{\Delta t}$$

In physiotherapy the jerk or jerkiness tells the physiotherapist how smooth the client's movement is. If there is jerk in the movement it can indicate that the client is in pain. By showing how big the jerk is and exactly when and where in the movement the jerk appears, the physiotherapist can possibly gain a greater understanding of what the problem is and more precisely where the injury is located and which bones, muscles, tendons, and ligaments is affected by the injury.

[Worksheet 2]

1.11 Joint repositioning

Joint repositioning can be performed with all measurement movements (Section 1.9 Measurement movements). The exercise of joint repositioning starts with the client positioned properly for the movement soon to be carried out. The client has to close their eyes to avoid that the sight is making disturbance in the repositioning offset result. The following steps carries out:

Step 1: The physiotherapist places the related body part and ensures the neutral position.

Step 2: The physiotherapist places the related body part in a position. (Hold for 5 seconds)

Step 3: The physiotherapist places the related body part back in neutral position.

Step 4: The client has to move the related body part back to the position.

The offset in joint repositioning can tell something about the client's proprioceptive sense (joint sense), which can be pain-related or influenced by other factors, and can contribute to the identification of the disturbances in the postural control system that causes the pain and/or disability (Treleaven, Jull, & LowChoy, 2006). [Worksheet]

Especially related to neck pain the joint repositioning offset is tested greater within clients, who have whiplash related injuries, compared to controls, and is often characterized by dizziness also. (Treleaven, Jull, & Sterling, 2003)

Step 1

Step 2

Step 3

Ill. 27.1: Joint repositioning.

Step 4

1.12 Pain biomarkers

What is pain?

Pain comes in many sizes and shapes depending of the reason and the person who feels it - but what is common for all types is that it hurts. But why do we feel pain? To protect our most important physical tool - the human body. If you feel pain, you will typically stop doing what caused the pain. It is a way of your brain telling you that what you are doing is harmful and you need to stop.

Two types of pain:

Acute pain is a short-term pain, which usually is from some sort of accident or injury. Once the injury has healed the pain is gone.

Chronic pain is persistent pain, which can be caused by conditions/diseases like arthritis. This pain is difficult to treat, because there is no cure. However, therapy can help the person with the pain to manage their pain differently, and trying to prevent the pain from getting worse. (Rodriguez, 2013)

What is a biomarker?

Biological markers - biological measures of a biological state. A characteristic that is objectively measured and evaluated as an indicator of normal biological processes. (Mandal, 2014)

The question is - are there any relevant validated pain biomarkers that can be integrated in the product system, to provide the physiotherapist with more pain evaluation factors, to contribute to the greater clinical picture of the rehabilitation?

Scientific research

Many studies have investigated potential pain biomarkers in many different fields of pain study. Amongst some substances in liquids like blood, urine or spit or neuroimaging. The conclusion on this is that there are some implications and/or indications in the results of the studies, that can give useful insight, however, not strong enough to be validated as clinical measurable pain biomarkers. Though, a common finding in many studies is that self-reporting is the most reliable and accurate method of evaluating pain and the intensity of pain and continues as a clinically vital [Worksheet 16].

The conclusion is that there are no other validated pain biomarkers relevant in relation to this project, expect from the already found potential indicator of pain - jerkiness in movement.

Biofeedback

Biofeedback is a training technique that gives a person feedback on a certain unconscious element, and makes you able to voluntarily control autonomic body functions.

Example: A person with heart problems or similar has electrical sensors on the body that measures the heart rate and gives you feedback, if the heart rate is getting to high (the boundary is manually determined).

Potential project case example: The client/physiotherapist gets feedback during the movements every time there is a significant jerk, or if there is a too big amount of jerk over the movement time period. This could be a potential information for the client/physiotherapist, which could contribute to a coping strategy exercise to prevent the jerk.

Finding #19

Self-reporting is the most reliable and accurate method of evaluating pain and the intensity of pain and continues as a clinically vital.

Finding #20

Biofeedback could be relevant to provide to the client/physiotherapist with realtime feedback on jerkiness in a movement.

1.13 Existing products

Ill. 29.2: Goniometer displacement.

Ill. 29.1: Goniometer.

Goniometer

A goniometer is a protractor, which measures range of motion in rehabilitation physiotherapy.
The physiotherapist places the goniometer at the respective joint, holds one of the rulers with the stationary body part and moves the other ruler with the moving body part where he reads the angle in the end position.

+

- Small and simple in use.
- Short setup time.

−

- Low accuracy in use, the placement of the device and how the therapist moves it is a key factor in the measurement (tolerance 7 degrees).
- Active-assistive movements can not be measured - physiotherapist's hands are engaged in measuring with the device.
- Only measures joint range of motion.

Ill. 29.3: Halo.

Ill. 29.4: Halo displacement.

Halo

Halo is a digital goniometer, which measures range of motion. Like the goniometer the physical therapist places the device and moves it with the movement.

+

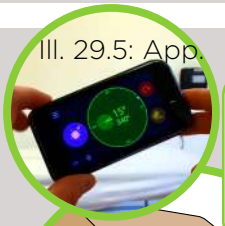
- Small and simple in use.
- Short setup time.

−

- The technique has a high accuracy, but in use the accuracy is lower because of the error source, that the measurement is depending on the physiotherapist's movements and not the client's.
- Can be difficult to secure correct movement, because at least one hand is used to hold the device.
- Only measures joint range of motion.

Goniometer Pro

Goniometer Pro is an application that can be downloaded on your smartphone.



Ill. 29.5: App.

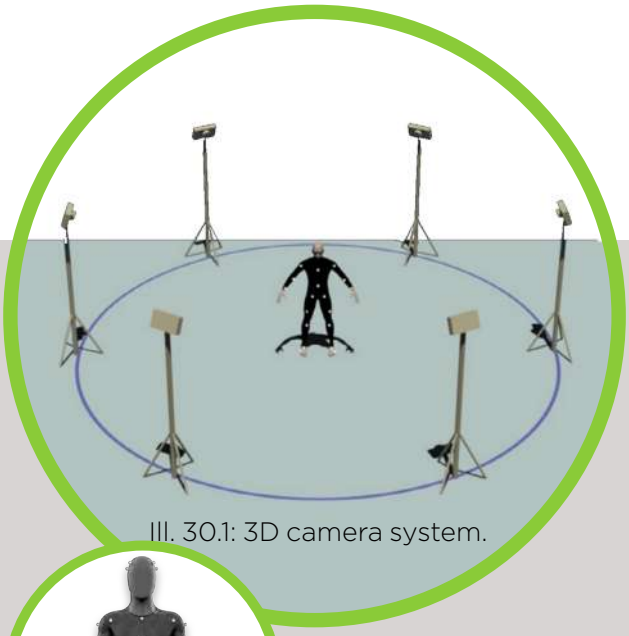
Ill. 29.6: Phone displacement.

+

- Integrated into a device that everybody have on them.
- Simple in use and does not fill up space.
- Short setup time.

−

- The technique has a high accuracy but in use the accuracy is lower because of the error source, that the measurement is depending on the physiotherapist's movements and not the client's.
- Active-assistive movements can not be measured - physiotherapist's hands are engaged in measuring with the device.



Ill. 30.1: 3D camera system.

Ill. 30.2: 3D suit.

3D camera system (Gold standard)

A 3D camera system setup consists of many cameras and a suit with marks. The pictures from the cameras are processed in relation to the purpose, and can show very specific motion data.

+

- The data has high measurement accuracy in use.
- Can process the marker data to get many different outcome factors. (Physiotherapy relevant: joint ROM, acceleration, jerkiness)

−

- Large footprint.
- High complexity (Setup and software) and over qualified in relation to this project.
- Long setup time.

MVN Awinda

Full body motion analysing system that have multiple sensors on the body and a wireless data link station.

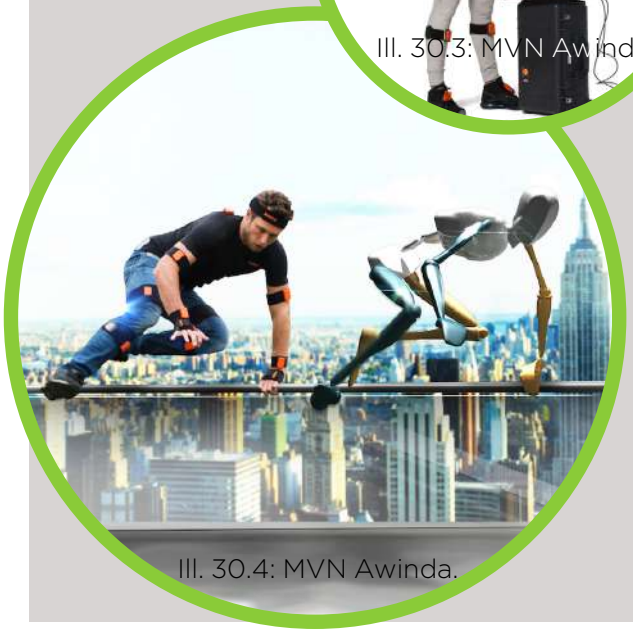
+

- The device has high measurement accuracy in use.

−

- High complexity (Setup and software) and over qualified in relation to this project.
- Long setup time.

Ill. 30.3: MVN Awinda.



Ill. 30.4: MVN Awinda.

Finding #21

The physiotherapist needs to be able to use both hands for making sure the movement is done correct, and can therefore not be interacting with the device during measurement.

Comparison

The investigated existing products are compared with one another (Ill. 31.1). This is to get an overview of which of the important aspects they each fulfill or not. This method makes it clear that there are currently no existing products on the market, which fulfill these discovered aspects in order to fit into the context of measuring progress in physiotherapy.

Functions/features available:	Goniometer	Halo	Goniometer pro app	3D camera system	MVN Awinda
Measure acceleration	✗	✗	✗	✓	✓
Measure joint range of motion (angle)	✓	✓	✓	✓	✓
Joint repositioning feature	✗	✗	✗	✓	✓
Digital data	✗	✓	✓	✓	✓
Save user data	✗	✗	✗	✓	✓
Can measure more than one joint at a time	✗	✗	✗	✓	✓
Accurate (Correlation >0,75 compared to gold standard)	✗	✗	✗	✓	✓
Result is not influenced in relation to how it is measured from time to time.	✗	✗	✗	✓	✓
Average physiotherapist can use it	✓	✓	✓	✗	✗
Can be used for bedridden people	✓	✓	✓	✗	✗
Biofeedback	✗	✗	✗	✓	✓
Set up time under 3 min	✓	✓	✓	✗	✗
Can be moved around without adding to setup time	✓	✓	✓	✗	✗
The setup fills same or less than a human	✓	✓	✓	✗	✗
Can fit into 30 L backpack when not in use	✓	✓	✓	✗	✓

Ill. 31.1: Comparison of existing products. ✓ means that the technology has the capability to measure these factors, but software needs to be developed in order to process and extract this data.

1.14 Evaluation

There are several types of injuries that can vary in disability, pain intensity, and complexity. However, all injuries acquire a set of proper assessment and evaluation methods for the physiotherapist to base the right rehabilitation program on.

Existing assessment methods are subjective only. By lacking the objective data where small discrepancies are identifiable, clients in longer rehabilitation processes can get demotivated.

It can be motivational for the clients to make their own goals visible and keep track of the progress in relation to them.

Several physiotherapists think their existing coping strategies are unsatisfying, and 10/10 think that it could be relevant to get more objective data on the rehabilitation progress. 9/10 have a need of a product that can provide them with these objective data, and 8/10 think that it would give them better possibilities of assessing, evaluating, and treating the client.

Motivation is a large influence factor in rehabilitation progress, because motivated clients tend to give greater results as they struggle to get better. In m-Health applications 2D or 3D visualizations of the data is preferred by the users.

It is different who covers the sale costs of a product, dependent on the type of organisation who is purchasing the product. However, products launched as medical equipment has a much higher chance of success because of the certified quality. Small differences in functionality can have huge impact in the compensation size in cases with permanent injury. It is in the insurance companies interest that such cases are assessed on as correct data as possible.

Scientific research show that it is possible to make accurate measuring with motion tracking technology, which is an essential need in the field of physiotherapy. Joint range of motion, acceleration, jerkiness, and joint repositioning can contribute to the clinical picture. For a product to contain these factors, it is important that the user scenario is designed to be quick and easy to use and to be cleaning friendly.

Regarding pain and how to evaluate pain, no biomarkers are available based on existing research and the most reliable and accurate method of evaluating pain and the intensity of pain is by self-reporting.

The existing products addressed for physiotherapy can either only measure joint range of motion manually or digital. None of them logs the data. However, the sources of errors in use are many, and the measurements are therefore questionable, which reflects in the fact that none of them are being used as clinical equipment.
Motion tracking technology has proven to be very accurate, but is, in the existing product systems on the market, demanding and has a high complexity, both in relation to setup, but also the translation of data. They are used for purposes like making animations in films and similar. None are addressed for physiotherapy and the needs this user scenario deals with.

Key activities

- Target group
- Value mission
- Problem statement
- Mission statement
- Paradoxes
- Requirements
- Project focus

2.0 Define

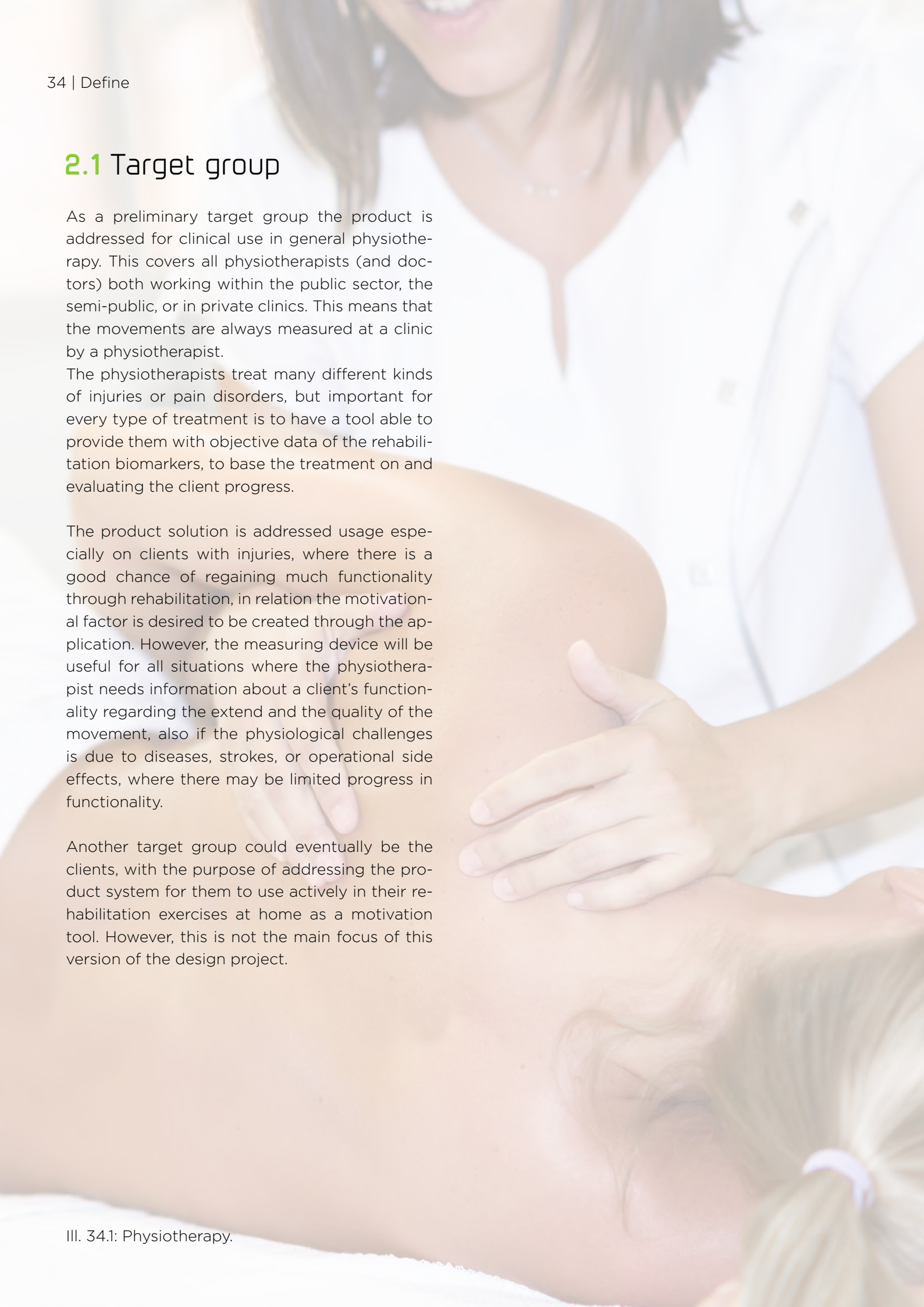
Findings and insights from the research performed in the *Understand* phase are converted into the project frame, which includes problem statement, value mission, mission statement, requirements, and paradoxes. This project frame will work as guidelines throughout the entire design process, and will be the evaluation factor for the final design proposal.

2.1 Target group

As a preliminary target group the product is addressed for clinical use in general physiotherapy. This covers all physiotherapists (and doctors) both working within the public sector, the semi-public, or in private clinics. This means that the movements are always measured at a clinic by a physiotherapist.
The physiotherapists treat many different kinds of injuries or pain disorders, but important for every type of treatment is to have a tool able to provide them with objective data of the rehabilitation biomarkers, to base the treatment on and evaluating the client progress.

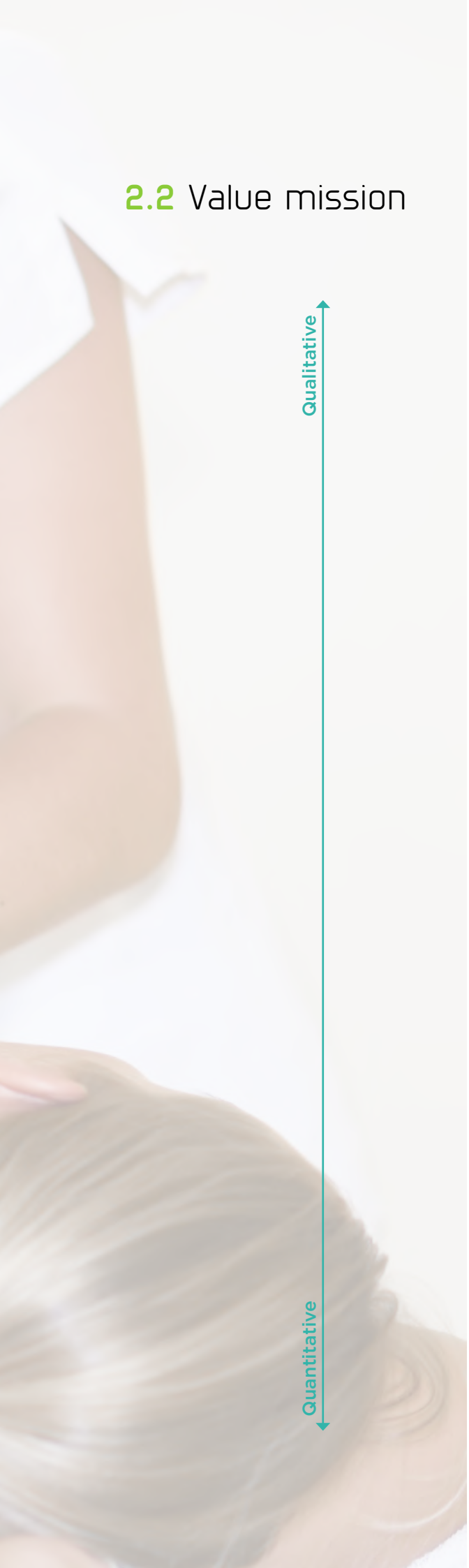
The product solution is addressed usage especially on clients with injuries, where there is a good chance of regaining much functionality through rehabilitation, in relation the motivational factor is desired to be created through the application. However, the measuring device will be useful for all situations where the physiotherapist needs information about a client's functionality regarding the extend and the quality of the movement, also if the physiological challenges is due to diseases, strokes, or operational side effects, where there may be limited progress in functionality.

Another target group could eventually be the clients, with the purpose of addressing the product system for them to use actively in their rehabilitation exercises at home as a motivation tool. However, this is not the main focus of this version of the design project.



Ill. 34.1: Physiotherapy.

2.2 Value mission



Physiotherapist (+ doctor)

By providing the physiotherapist with correct qualitative data of the client's rehabilitation progress, the basis for developing the ideal treatment and evaluate the progress improves. This means that the physiotherapist is able to make a qualified clinical opinion based on objective data. Furthermore, the progress data can function as evidence of treatment effectiveness, which can promote the therapist.

Client

By providing the client with available specific rehabilitation progress data, the mission is to motivate the client by being able to see the progress, even if the progress is limited. This would make each progress a success experience.

SPÍRA

Have a product to start building the company portfolio and enter the market to initiate building a brand on creating value for others.

Insurance company

The value for the state/insurance companies is to receive proof of the progress in the physiotherapy treatment and compensation cases, which they are supporting financially. To potentially reduce costs of rehabilitation processes.

2.3 Problem statement

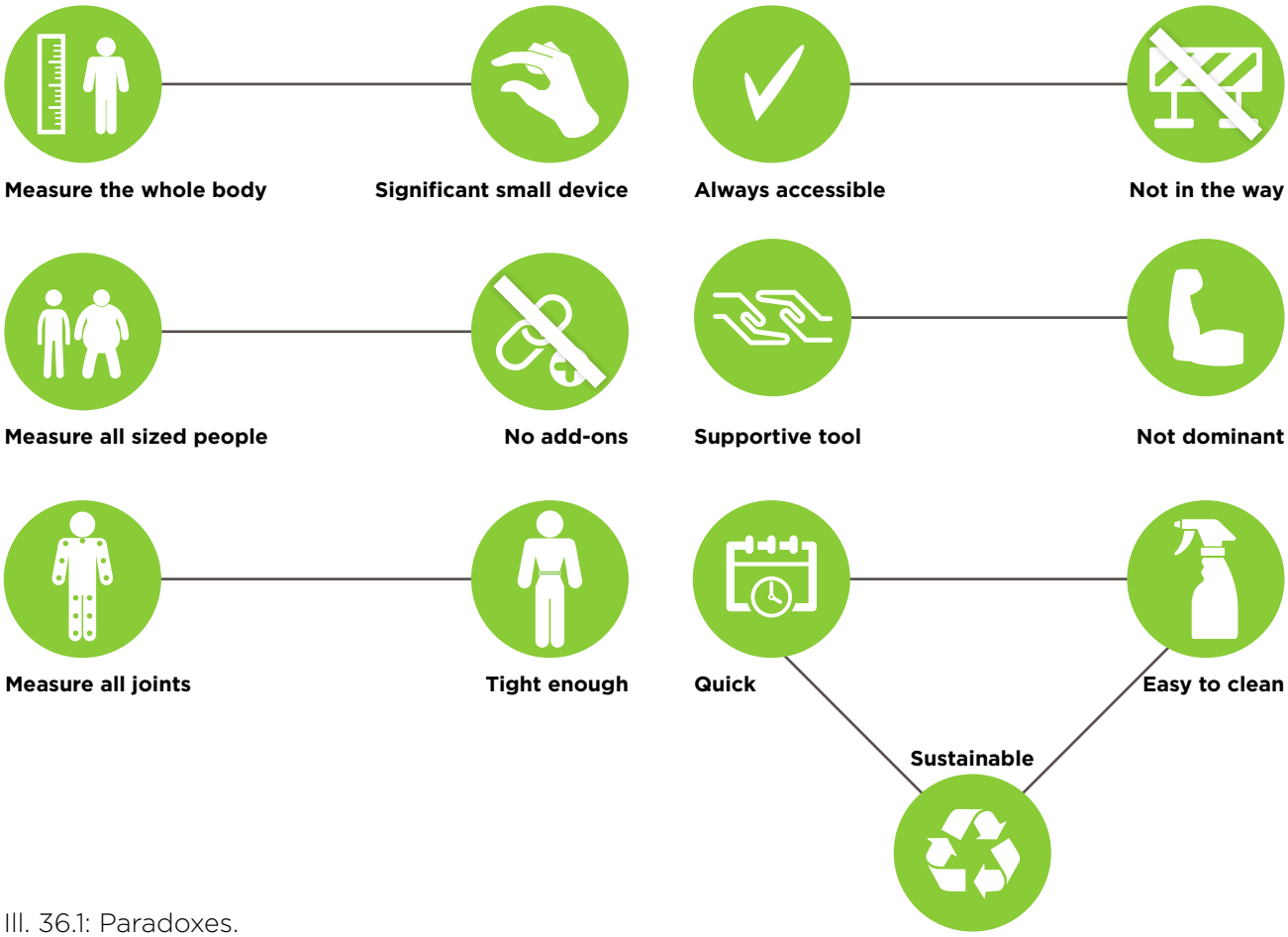
How can progress in a rehabilitation process be measured and processed to provide objective data to...

...make the physiotherapist able to structure a more solid treatment process, and be able to evaluate the progress objectively?
...increase the motivation of the client to insure a successful rehabilitation process?

2.4 Mission statement

The mission is to develop a product system with a device to measure the rehabilitation progress using gyroscope, accelerometer, and compass technology together with a software system that processes the data mathematically in order to receive calculated values; joint range of motion, acceleration, jerkiness, and joint repositioning off-set. The device should be designed to fulfill the needs in the user scenario. Furthermore, the mission is to develop this product system in a way that motivates the client in the rehabilitation process.

2.5 Paradoxes



Ill. 36.1: Paradoxes.

2.6 Requirements

The following requirements are the result of the findings found during the problem unfolding in the Understand-phase. They represent the first iteration of the requirements that form the direction of the product system. All requirements are equally important to meet in the final design proposal. The process consist of many iterations and specifications of the requirements. Throughout the rest of the process more detailed and technical requirements is listed, as they are found in the associated work. The full requirement specification is available on the Appendix list.

2.7 Project focus

The project focus is to develop a product system consisting of a physical measuring device, software that processes the data and mediates the data in an application. However, the main focus lies in developing the measuring device, with all the aspects it contains.
Secondary focus lies on developing a concept for the application in relation to the features integrated, the basic structure, and how to make an intuitive interface.

The project is delimited from developing the application software. However, the product system coherence will be clarified, and a basic understanding of how the raw sensor data is transformed to the desired mediated factors in the application will be illuminated.

Ill. 38.1: Project focus.

Key activities

Desk research
- Principles

Development
- Problem dismantling
- Interaction process
- Systematic sketching
- Exploring principles

Prototype & Act-it-out
- Function mock-ups
- Showcase of concepts

3.0 Ideate

After defining and converging the frame of the project, the solution space is diverged to be able to explore a wide range of possibilities. Ideas are unfolded through systematic idea generation, for then to be evaluated in relation to the requirements together with the opinion of interviewed physiotherapists. This leads to the identification of potential directional solution frames for the future product system.

3.1 Diverging

Ideation

The purpose of diverging is to unfold the interaction process to find the different areas/categories that needs to be investigated in terms of existing principles. From that ideate within the frame of the product in coherence with the requirements. Due to the technology being locked at this point, the ideation lies in the interaction scenario space.

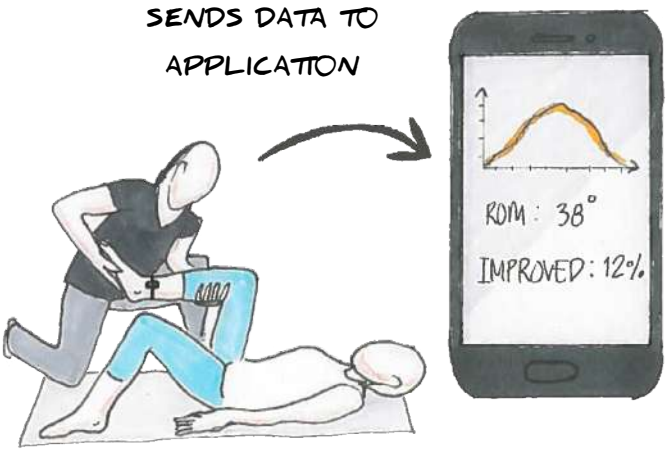
Initial ideas

The first step in the ideate phase is to empty the heads from ideas occurred during the previously phases, which also has the effect of kickstarting the ideation mindset. This step originates from the basis that no rules are determined.

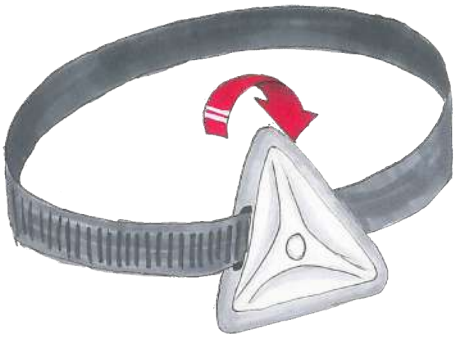
Interactions and possibilities

The next step lies in understanding the process in details in terms of which interactions are required and need to be attended. This opens the different interactions areas that frames the space of the part solutions and the different categories. The categories unfold many different possibilities, where some are investigated and tested.
These are listed in Ill. 44-45.1.

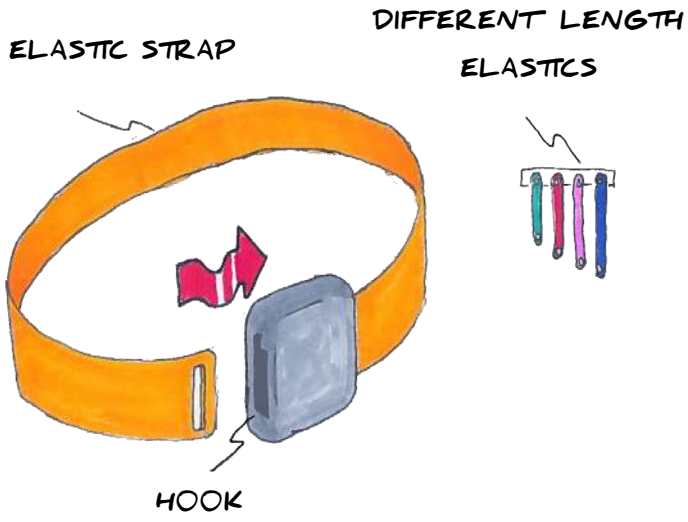
Inital ideas



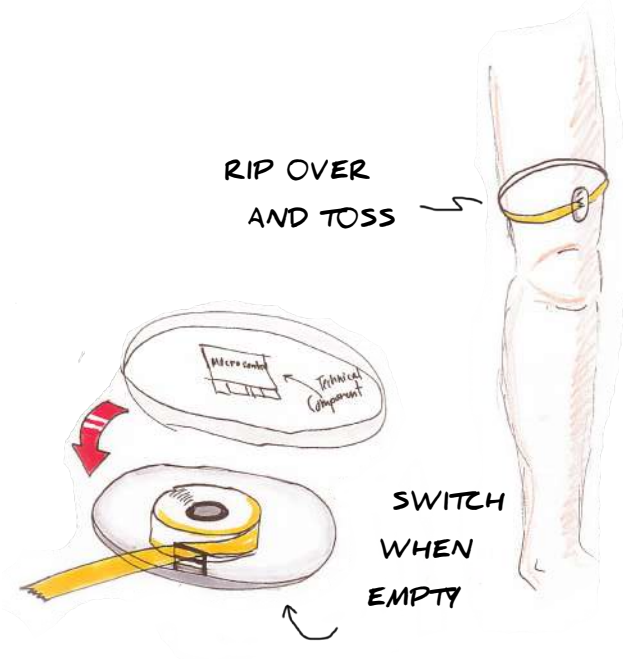
Ill. 41.1. Shows the product system. Data is send from measuring unit during movement to the application where it is processed and illustrated.



Ill. 41.3. Fine adjustment by rotation - integrated in measuring unit.



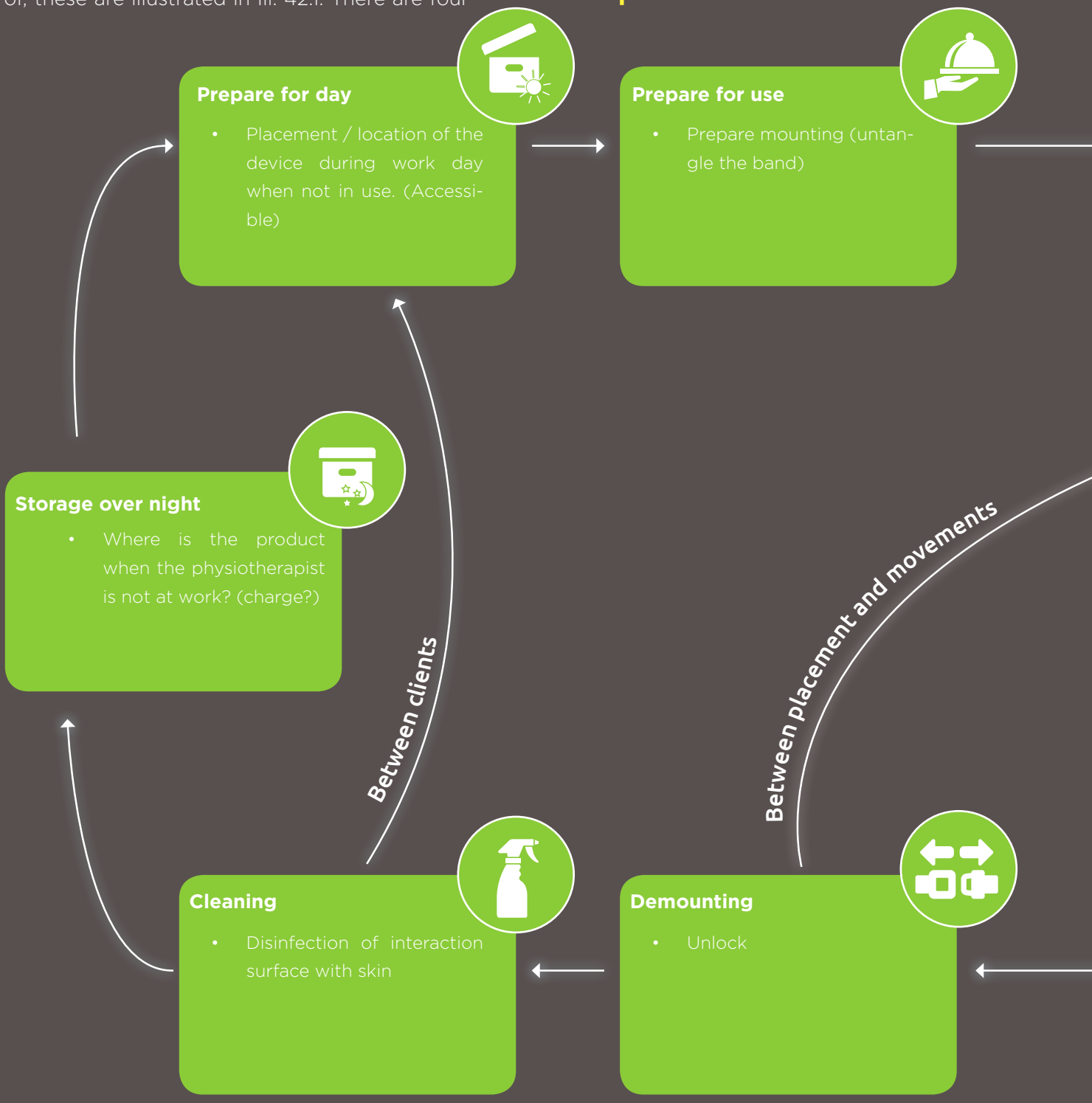
Ill. 41.2. Low tech mounting by using an elastic strap with a hole and py placing it on a hook on the measuring unit.



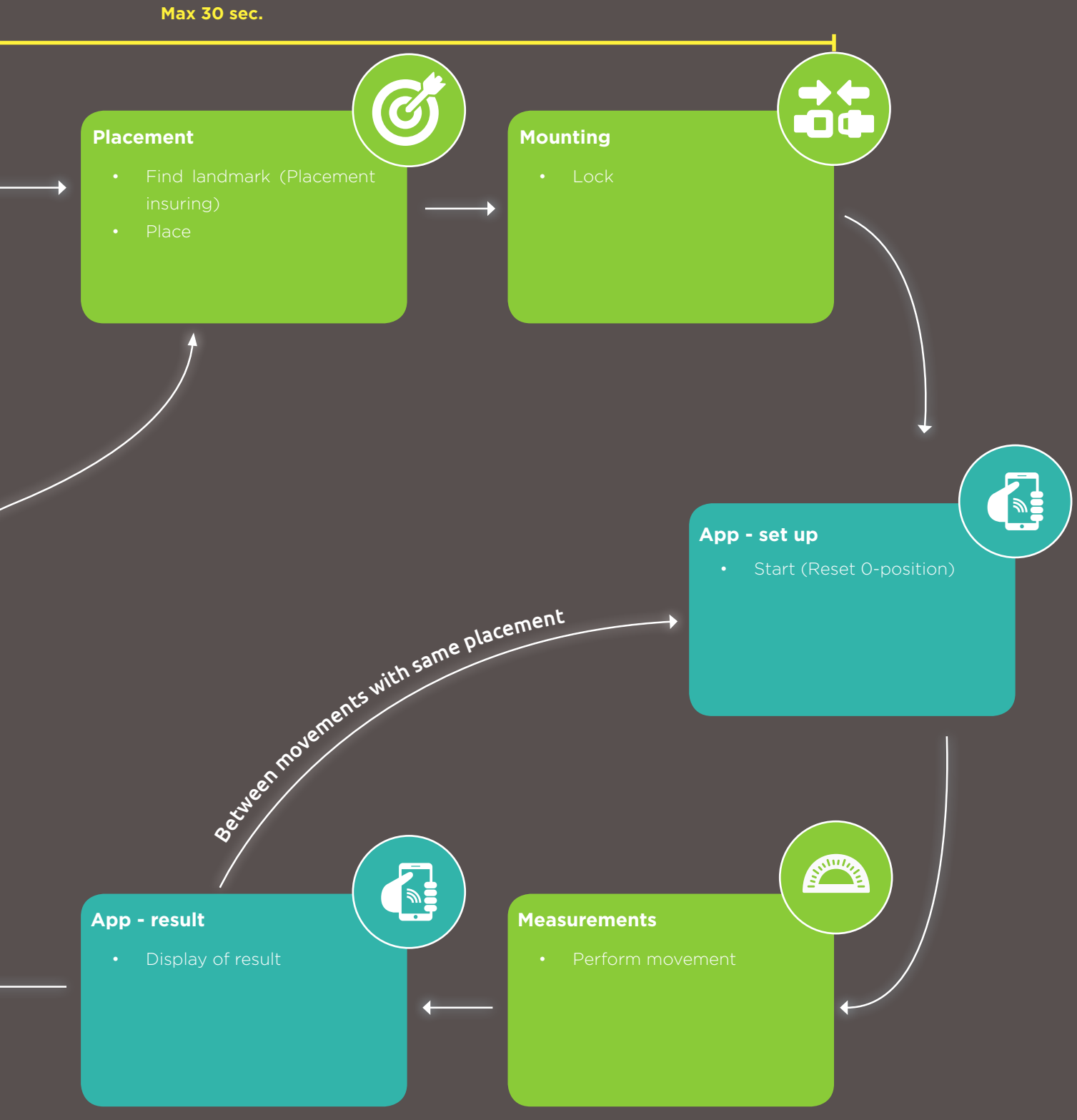
Ill. 41.4. Use replaceable disposable tape.

Interaction process

The future product solution will be included in the physiotherapist's existing work process and be a tool to support the physiotherapist in assessments and evaluations of the clients' conditions. To get an overview of the different situations the product solution is anticipated to be a part of, these are illustrated in Ill. 42.1. There are four overall loops of interactions the product will be included in during a day, depending on if it is the beginning of the day, switching between clients, switching placement for different movements on the same client, or between movements with the same placement on the same client.



Ill. 42.1: Interaction process.


Max 30 sec.
Placement
Find landmark (Placement insuring)
Place
Mounting
Lock
App - set up
Start (Reset 0-position)
Between movements with same placement
Measurements
Perform movement
App - result
Display of result

Category unfolding

Principles unfold in categories of the solution parameters. Used for diverging the solution space.

Mounting

[Worksheet 26]

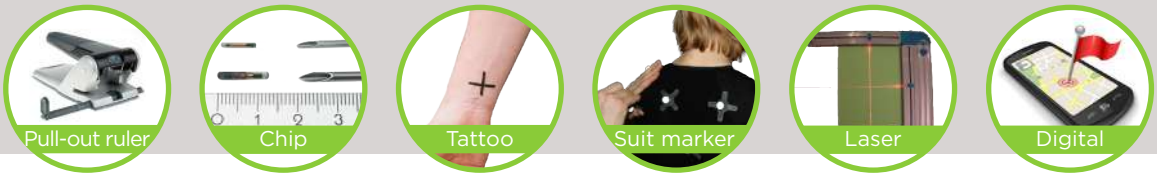
Fine adjustment

[Worksheet 26]

Fits all (Bodyparts & size)

Placement ensuring

[Worksheet 27]



Storage when not in use

Visual feedback log (rehabilitation progress)

Realtime feedback (during movement)

Ill. 44-45.1: Category unfolding.

Exploring principles

In order to explore the feasibility in the principles, some of them are tested out.

Disposable electrodes

Disposable stickers with the same properties as the disposable electrodes from *Ambu* with strong adhesiveness, which make it stay in place even with applied force, but are still painless to remove.

Ill. 45.2: Test with disposable electrode.

Roll-up mechanism

A spring attached to a band represents an automatic roll-up mechanism, as in a measuring tape. This enables the possibility of having an adjustable band, where the band is not in the way.

Ill. 45.3: Study of measurement tape.

[Worksheet 33]

Concepts

Measuring unit

The concepts showcased in the following pages is a composition of ideas emerged during ideation and through investigating the existing principles in the different categories. The concepts will show diversity within the categories; mounting, fits all, and business. Furthermore, the visual feedback log category will be represented in all concepts, however, the specific principle is the same in all four concepts and will be unfolded in the section following the concepts.
The remaining categories will be further developed and specified in later phases.

Application:

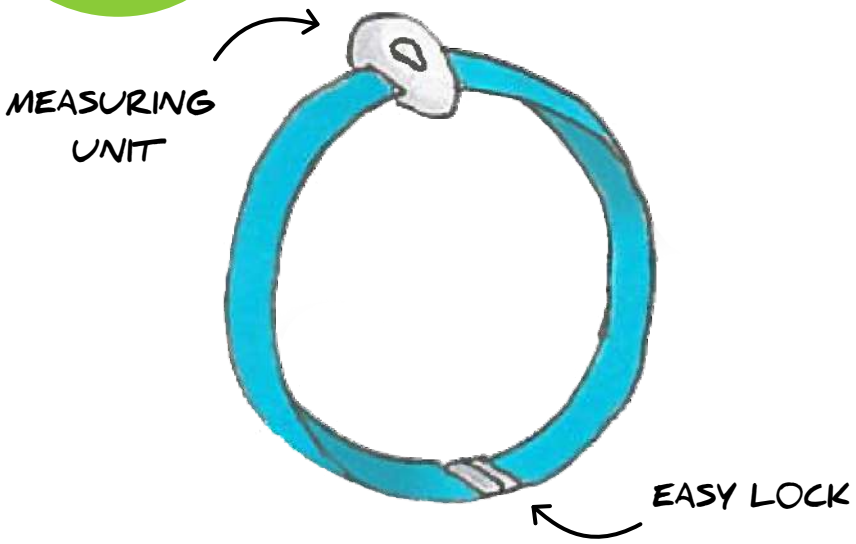
The application concept is as well an iteration of different ideas, features, and interfaces, combined with research on existing tracking applications and other healthcare applications.

3.2 Converging: four concepts

CONCEPT 1

Roll-up | Adjustable | Application | Asset sale

Mounting | Fits all | Visual feedback log | Business



Place

Pull around

Close

Tighten+lock

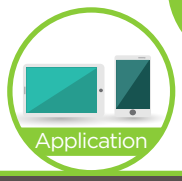
*Application will be elaborated in later section

Ill. 46.1: Concept 1.

CONCEPT 2

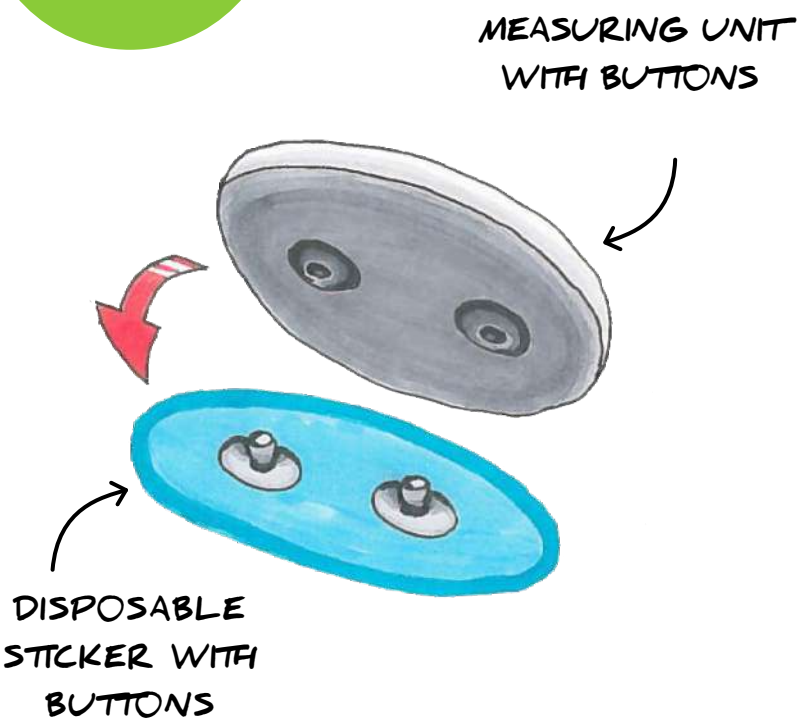
Mounting

Fits all



Visual feedback log

Business



*Application will be elaborated in later section

Ill. 47.1: Concept 2.

Grab sticker

Place sticker

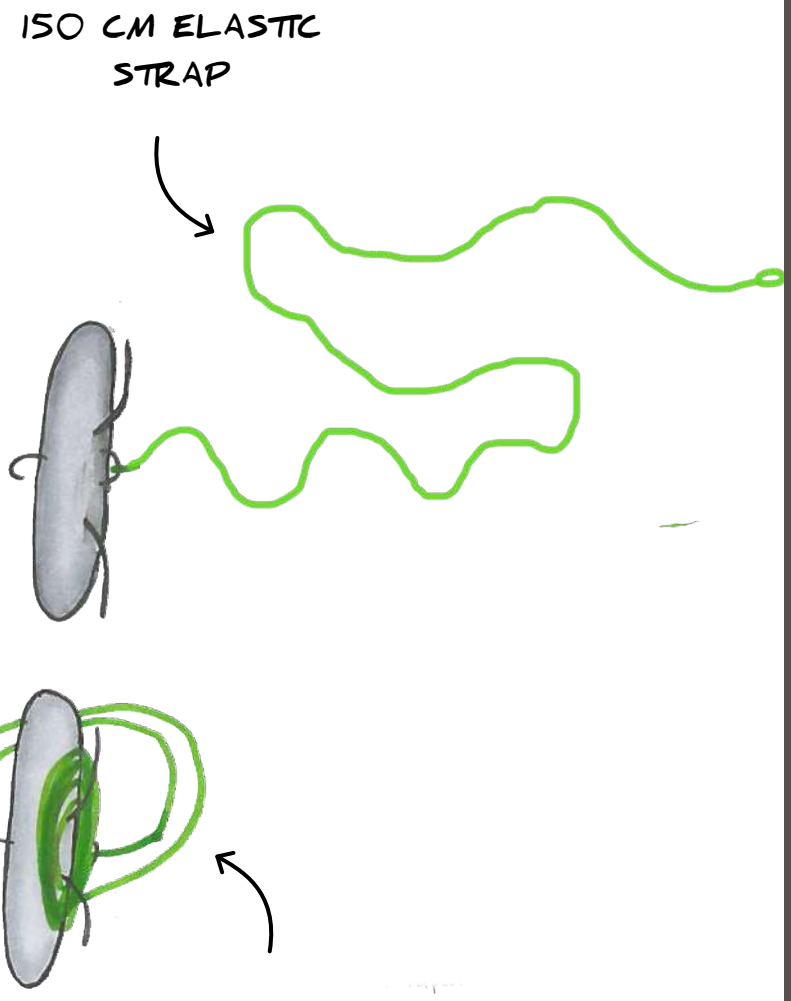
Grab measuring unit

Click on sticker

CONCEPT 3

Knot | Long strap | Application | Asset sale

Mounting | Fits all | Visual feedback log | Business



Unwrap

Place

Wrap

Lock with end strap

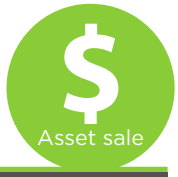
*Application will be elaborated in later section III. 48.1: Concept 3.

CONCEPT 4

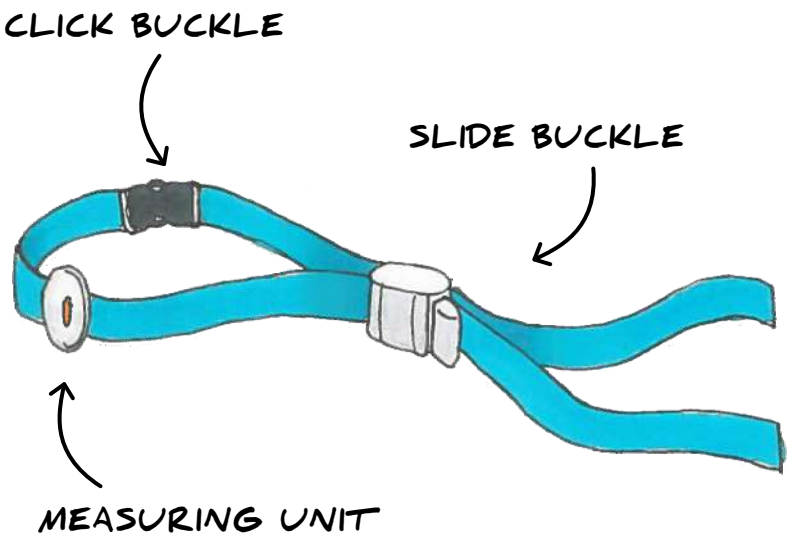
Mounting

Fits all

Visual feedback log



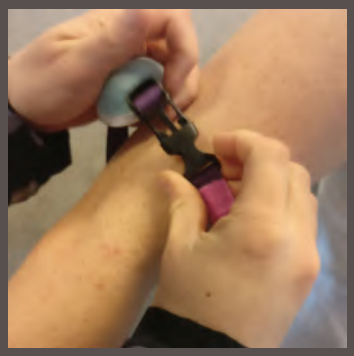
Business



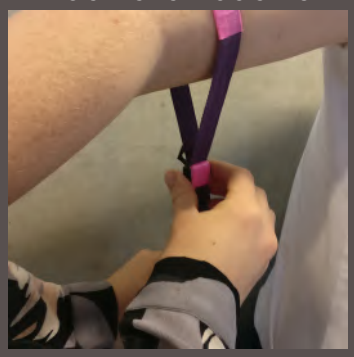
TOTAL LENGHT OF STRAP = 160 CM

*Application will be elaborated in later section

Unlock click buckle



Lock click buckle

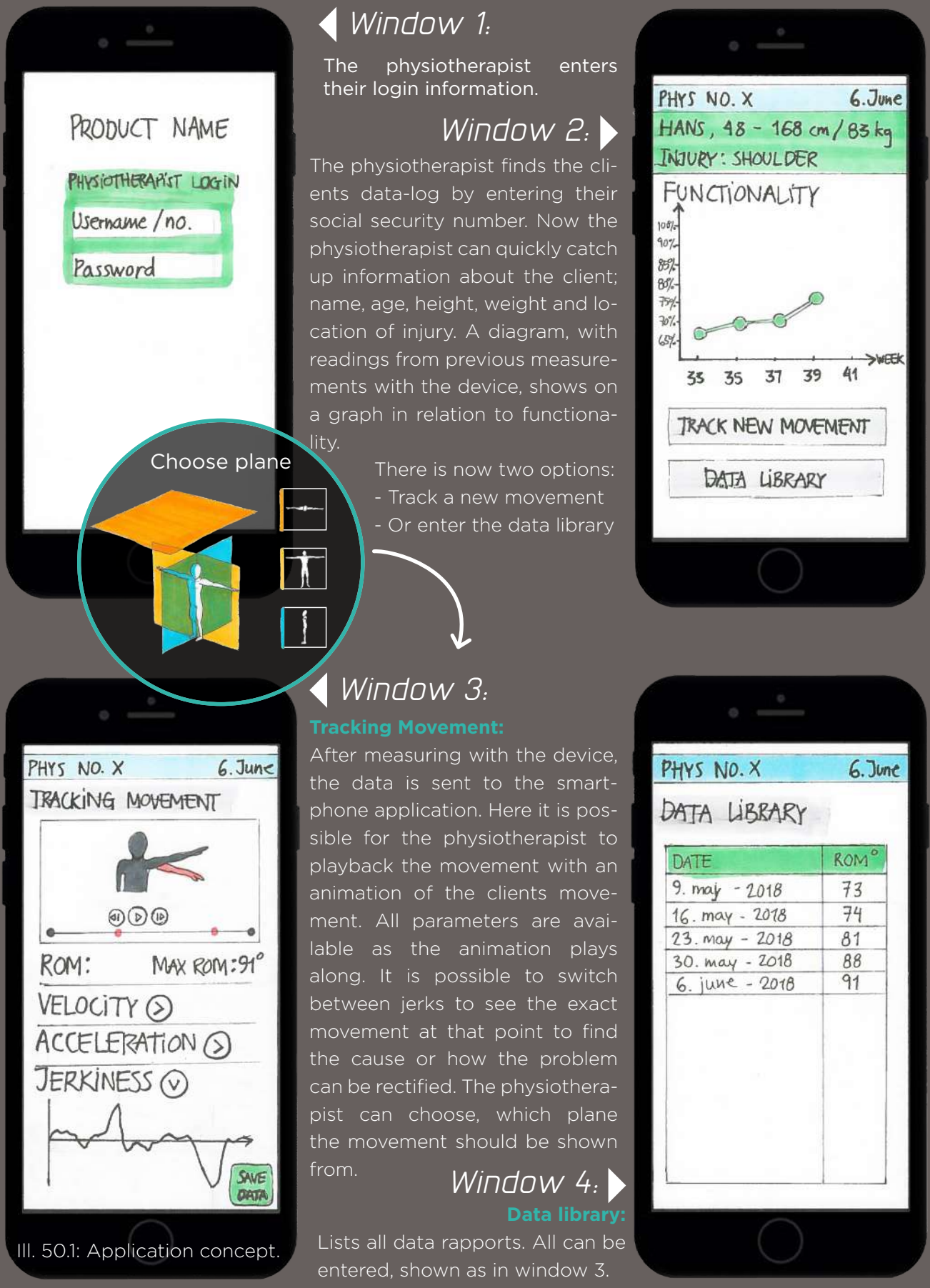


Tighten

Correct unit

Ill. 49.1: Concept 4.

3.3 Application concept - Physiotherapist and client



III. 50.1: Application concept.

Window 1:

The physiotherapist enters their login information.

Window 2:

The physiotherapist finds the clients data-log by entering their social security number. Now the physiotherapist can quickly catch up information about the client; name, age, height, weight and location of injury. A diagram, with readings from previous measurements with the device, shows on a graph in relation to functionality.

There is now two options:
- Track a new movement
- Or enter the data library

Window 3:

Tracking Movement:

After measuring with the device, the data is sent to the smartphone application. Here it is possible for the physiotherapist to playback the movement with an animation of the clients movement. All parameters are available as the animation plays along. It is possible to switch between jerks to see the exact movement at that point to find the cause or how the problem can be rectified. The physiotherapist can choose, which plane the movement should be shown from.

Window 4:

Data library:

Lists all data rapports. All can be entered, shown as in window 3.

It is optional for the client if they want to use the application and to which extend.

Window 1:

The client enters their login information. (social security number)

Window 2:

The client can now, outside the clinic, get an overview on the functionality graph based on the measurements, and have the possibility to insert or access previously inserted goals, pain reportings, medicine reportings, and personal notes.

Window 3:

Goals:

Here the client can insert personal goals and keep track of the progress, which can motivate the client to keep training. It is also possible to add defined goals, where a goal is split in four part goals.

Window 4:

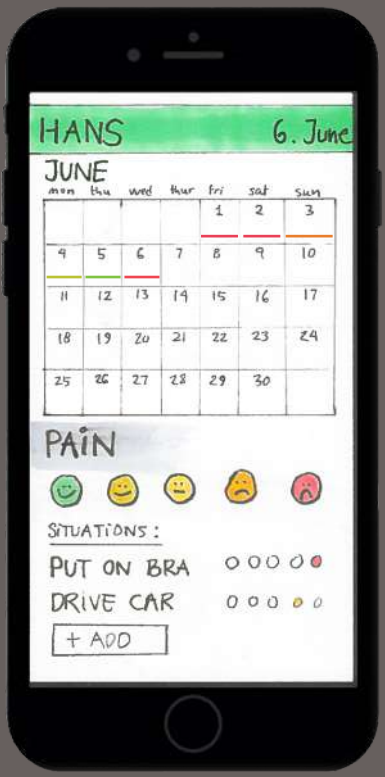
Pain:

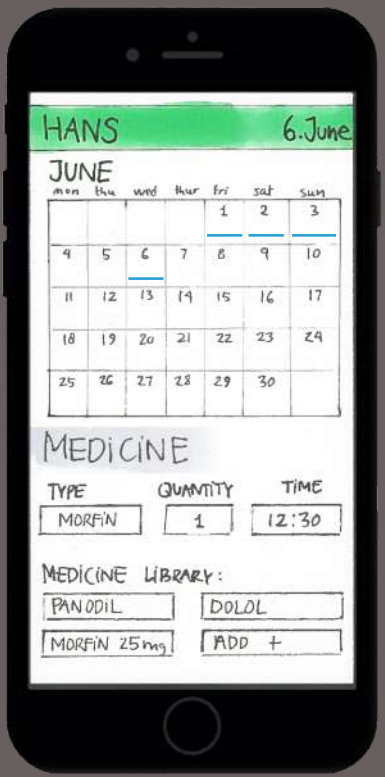
Here the client has the opportunity to register their pain in relation to intensity, and also related to the situations where the pain occurs. This can be for personal use, but also for later conversation with the physiotherapist at a consultation. The information can help the physiotherapist to get a better understanding of the physiological problem.

Window 5:

Medicine:

Here the client has the opportunity to register which type of medicine they take, how much, and how often.





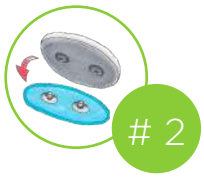
3.4 Concept evaluation

Measuring unit concepts

The concepts are evaluated by several physiotherapists and tested especially on the requirements related to the usage scenario because this is where the concepts show diversity. The table in illustration 52.1 shows the assembled data and some of their suggestions. [Worksheet 35 and 36]

Application concepts

The application concept is evaluated by constructive feedback and suggestions from both the physiotherapist and the client, in relation to the integrated features and intuitive interface.

	 # 1	 # 2	
Mounting (Mounting time < 30 seconds)	+ Average mounting time 12-15 seconds*	+ Average mounting time 15-16 seconds* + Impossible to slide and rotate during movement - Can be a challenge on people with much body hair, regarding if it is possible to stabilize attachment to the skin.	
Adjustability	- Roll-up mechanism can get loose due to fatigue in spring coil.	+ Adjustability regarding body part and size plays no role.	
Cleaning (Cleaning time < 25 seconds)	+ Average cleaning time 14 seconds. + Possibility of cleaning the straps before unlocking the roll-up mechanism, only cleaning the part that interacted with the client. - Difficult/impossible to clean mechanism inside	+ Cleaning not necessary	
Low cost product	- High complexity construction compared to other concepts	+ Low complexity construction	
Other		+ Looks appealing	
Comments/ suggestions		Important to never be able to run out of stickers. Stickers has to be cheap.	

Ill. 52.1: Concept evaluation table.

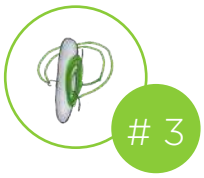
* Two average times - average time mounting on both arm and head.

Feedback and suggestions - Application concept:

Nice and simple - easy to decode

Integrate the feature total movement time. People with pain makes movements slower than without the pain, so it is a factor where it is interesting to follow the progress.

Could be nice if normative values where visible next to ROM, to be able to see the difference.



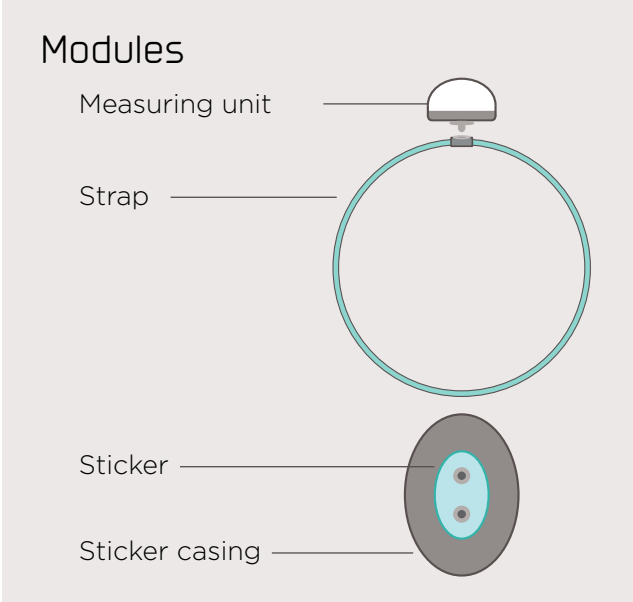
	+ - Average mounting time 23-32 seconds* - Possibility of tightening too much so it is uncomfortable, due to lack of fine adjustment. + The strap is replaceable.	+ Average mounting time 12-14 seconds* + The strap is replaceable
	- Straps can get tangled. + The strap lenght not in use, can be wrapped around the device during measuring. - The excess strap can be long, and can take much time to tie.	- The excess strap can possibly be annoying.
	+ Average cleaning time 20 seconds. - Necessary to clean all strap length after use.	+ Average cleaning time 21 seconds. - Necessary to clean all strap length after use.
	+ Low complexity construction	+ Low complexity construction
	- The excess strap can look unappealing.	- The excess strap can look unappealing.
	Positive feedback on concept by all physiotherapists, however, not with wrapping principle. Instead with holes in strap and pin on unit.	

3.5 Category closing

What was important for all physiotherapists was the simplicity in use, and the possibility to choose the most simple method, in relation to the given situation.
The concept chosen for further development is to this reason a combination of previously presented concepts with a product architecture that combines the features in modules.

It consists of the modules; a measuring unit, a strap, a sticker, and a sticker dispenser.

"The majority of measurements are going to be on the extremity joints (limb joints + neck)." - Physiotherapist



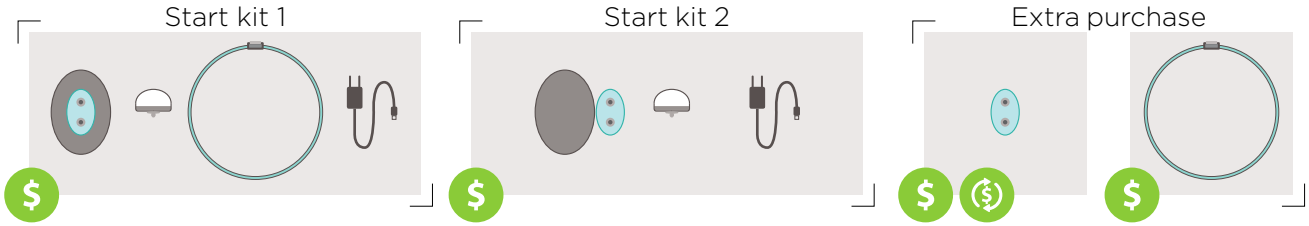
Strap

The extremity joint with the largest circumference, in relation to where the measuring unit has to be located, is the head. The biggest head size is 63 (63 cm), and the strap has to this reason only have to be 70 cm. The problem with unappealing and disturbing/demanding long excess strap is therefore minimized.

Usage

The physiotherapist have the possibility of using the module measuring unit on both the low tech strap with male/female locking mechanism, and the disposable stickers as a mounting method. However, it is possible to only use the stickers for all movements if desired.

Business



There are two start kits available. One with the measuring unit, the strap, stickers, and a sticker container. The second start kit is without the strap. Following it is possible to purchase a new strap, if the old breaks and also new stickers by subscription payment.

This is a result of statements being taken into consideration, which points in the direction that it differs from public/private clinics in relation to which budget they have to follow, which traditions and what habits they have regarding purchasing and use of products - Hence having two mounting possibilities. Furthermore, the rules regarding hygiejne from the State Serum Institute is in January 2019 going to be a part of the control of clinics by IKAS (the Danish Institute for Quality and Accreditation in Healthcare) [Worksheet 34].

Key activities

Research & Development
- 9-axis IMU sensor
- Software calculations
- Scale priority tool
- 3D modelling of expression

Prototyping & test
- Test-program
- Placement insurance
- Function modelling
- Expression modelling

Interview & Act-it-out
- Clinical sports scientist
- Showcase of function
- Showcase of expression

4.0 Development

Through prototyping and testing potential directions are further explored based on the chosen concept and features from the Ideate phase. The end users are involved through this phase to evaluate different parameters, which continually will be developed, investigated, and evaluated through visualizations and models iteratively until the objectives for the detailing are reached.

4.1 Diverging

This phase unfold the concept in relation to the different directions possible. Through prototyping, tests, and evaluations the directions are investigated for the purpose of converging to the goal of the final detailing.
In the following sections, the possible directions at this time in the process are showcased.

Placement ensuring

It is important to test if accurate persistent placement plays a crucial part for the measurement, both regarding the distance of the measuring device in relation to the joint, the rotation around the body part, and the rotation around the device itself.

If the placement plays a crucial part for the measurement - how are we going to ensure the placement, taking a reference in the placement ensuring category unfolded in Ill. 44-45.1 at page 44-45.

Mounting

From the feedback at the concept evaluation, good ideas and important consideration were illuminated. This leads to prototyping and testing of the concept, and different solutions within the concept frame, for the purpose of finding the detailed specifications of the product in relation to mounting and adjusting.

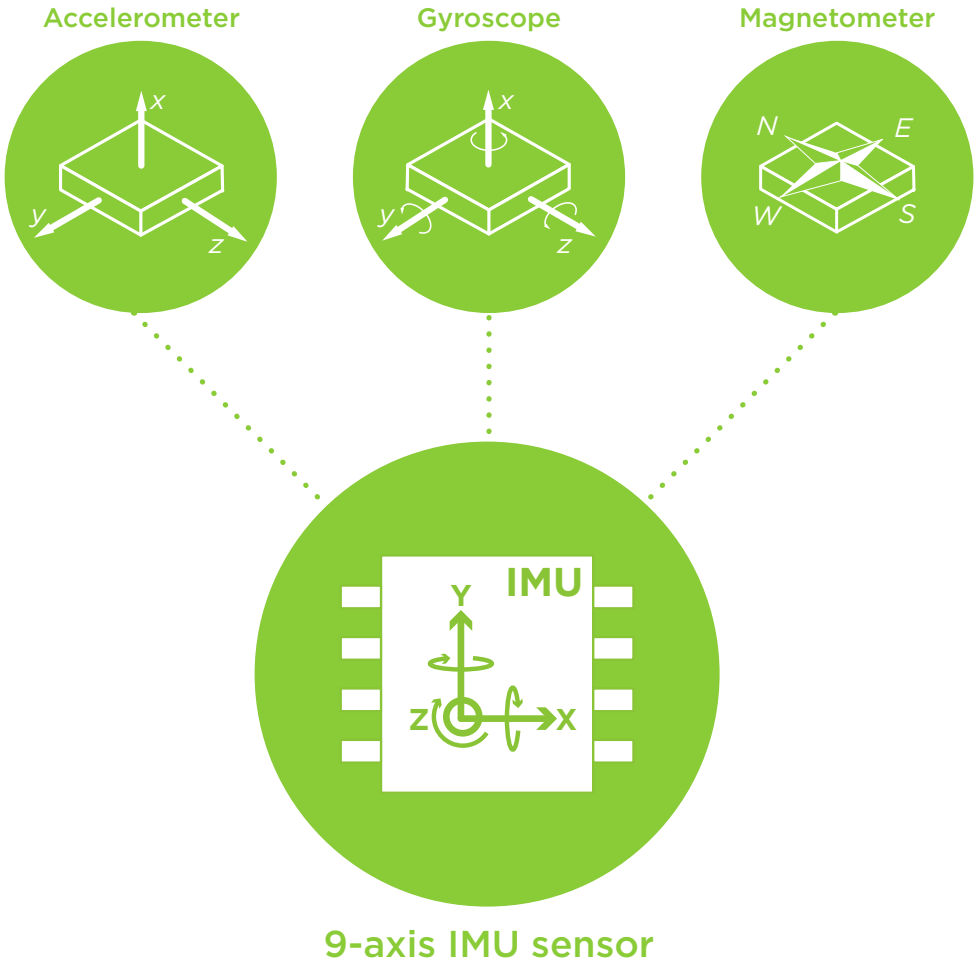
Product aesthetics

Which styles are preferred regarding the interactions, the context, and the purpose. How can these styles be integrated in the design of the product. The scale priority tool is used to get closer to the suitable aesthetic expression in the final design proposal.

4.2 Main element - 9-axis IMU sensor

To be able to measure angle [°], velocity [°/s], acceleration [°/s²], and jerkiness [°/s³] in relation to the defined movements, a 9-axis IMU (inertial measurement unit) sensor is chosen to be the most efficient technology for this purpose. The sensor is cheap compared to other solutions, for example a 3D-camera system, and it has the possibility to measure complex movements - how complex depends on the software development. It is a small sensor, which means it has a small footprint and measures a movement locally. The sensor is used in various applications, which benefits from object motion tracking in 3D space; tracking of movement, object orientation, navigation among others (Emotiv, 2018).

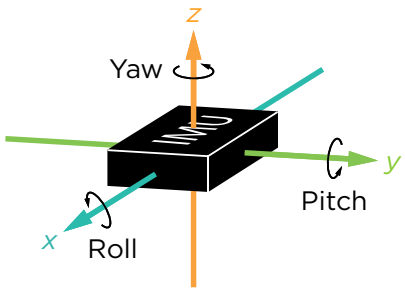
A 9-axis IMU sensor consists of a 3-axis gyroscope, a 3-axis accelerometer, and 3-axis magnetometer. Gyroscope and accelerometer together register their own motion in a 3D space; accelerations along each axis [*m/s²*] and gyration (rotation) [*rad/s*] around all the three axes. Furthermore, the accelerometer is affected by gravity, and the direction to the center of the Earth can therefore be derived. The magnetometer provides information about what direction the sensor points according to the magnetic North Pole and South Pole of the Earth [*μT*]. The combination of these three sensors can therefore register the IMU's motion in a 3D space defined by the magnetic poles and center of the Earth. (CH Robotics, 2018 and Emotiv, 2018)



Ill. 57.1: 9-axis IMU sensor consisting of accelerometer, gyroscope, and magnetometer.

4.3 Software calculations

When making use of the 9-axis IMU sensor, it is discovered that Euler angles can be used to measure the joint range of motion. Time is spent on developing another method to calculate joint range of motion [Worksheet 30], but is left in advantage of using Euler angles, which will be described in this section. Furthermore, the remainder calculations that has to be performed in the software will also be described.



Ill. 58.1: 9-axis IMU coordinate system.

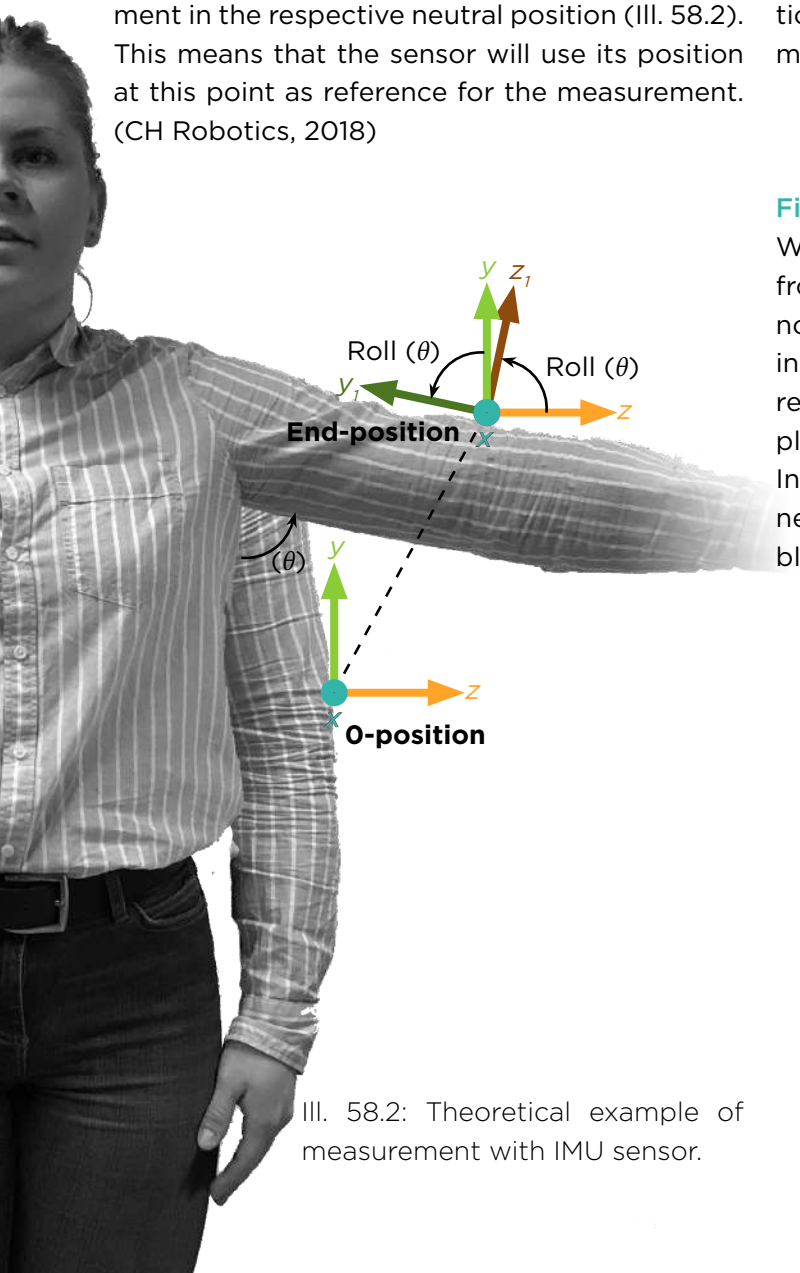
Euler angles (joint ROM)

Euler angles can be described as each angle between two corresponding axes in two different frames (coordinate systems). The two frames share the same origin. In the case of this project, the sensor will be reset before every movement in the respective neutral position (Ill. 58.2). This means that the sensor will use its position at this point as reference for the measurement. (CH Robotics, 2018)

To get more knowledge about Euler angles in motion tracking, a Clinical Sports scientist from Aalborg University, with expertise in motion tracking, is contacted. With his advice in relation to error correction using Euler angles, a correction vector should be applied to the rotation matrix in case of rotations around two axis.

Filtering

When using an IMU-sensor, the sensor output from the gyroscope is influenced by errors; noise and drift. Noise is consistent, where drift increases over time. These errors can be corrected by filtering. Average filtering can be applied to the correction of noise (Phidgets, 2017). In relation to drift, the accelerometer and magnetometer should be used to correct this problem by resetting the errors (Gowda, 2018).



Ill. 58.2: Theoretical example of measurement with IMU sensor.

Acceleration [°/s²]

The acceleration of the movement is extracted by differentiating the velocity of the angle [°/s].

Jerkiness [°/s³]

Jerkiness is then extracted by differentiating the acceleration [°/s²].

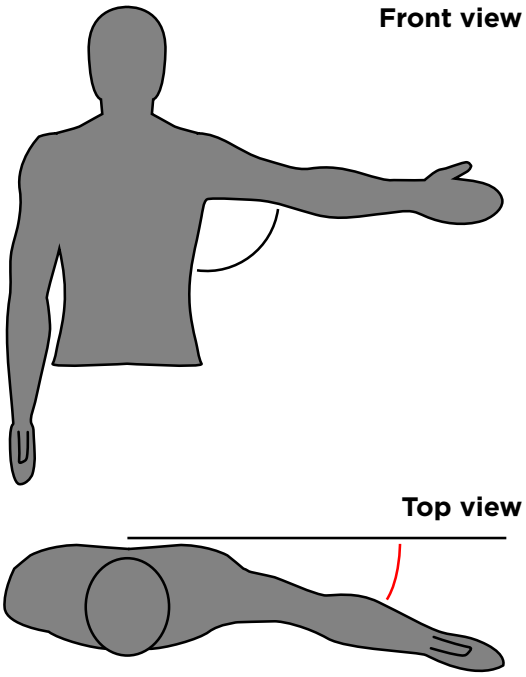
Joint repositioning off-set

For the feature of measuring joint repositioning, Euler angles should also be applied. Here it is important to measure the angle in relation to two plans, as there can be an off-set from the plan, where the movement is performed (Ill. 59.1).

Mock-up software

The software is not developed in this project period, but a version for test purposes is developed. Two *Thingy:52* development kits from *Nordic Semiconductor* (Ill. 59.2) are acquired for testing the technology. These development kits have various sensors for different purposes; measurement of temperature, pressure, humidity, air quality, color intensity, and also it can give feedback in form of light and sound. Furthermore, it has a 9-axis IMU sensor with a preprogrammed system for processing the sensor data to Euler angles.

The software system developed for this project can only perform a reset of the IMU sensor and read the values of roll, pitch, and yaw.



Ill. 59.1: Joint repositioning off-set.

Ill. 59.2: Thingy:52 development kit from Nordic Semiconductor.

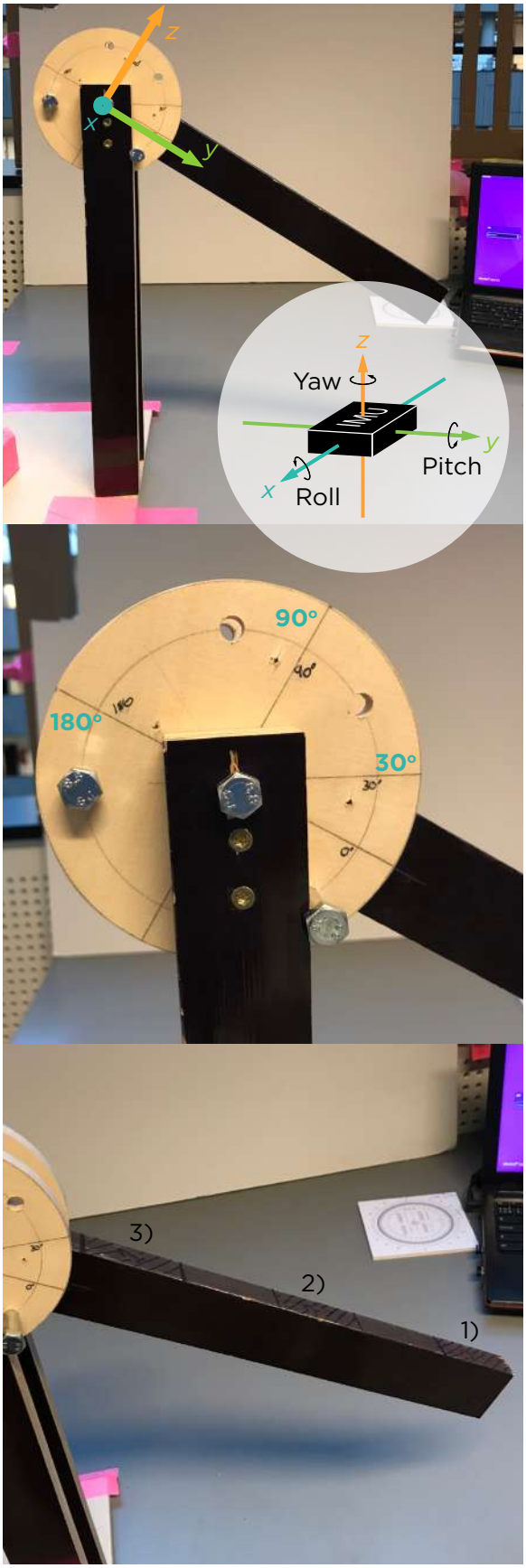
4.4 Test - Placement insurance

The working principle of measuring joint range of motion using a 9-axis IMU sensor and Euler angles is tested out. Four tests are carried out to see, if they have an influence on the accuracy of the measurement; distance between the IMU sensor and the joint, rotation around and to the body part, and rotation around the IMU itself. All tests are fully explained in worksheet 37.

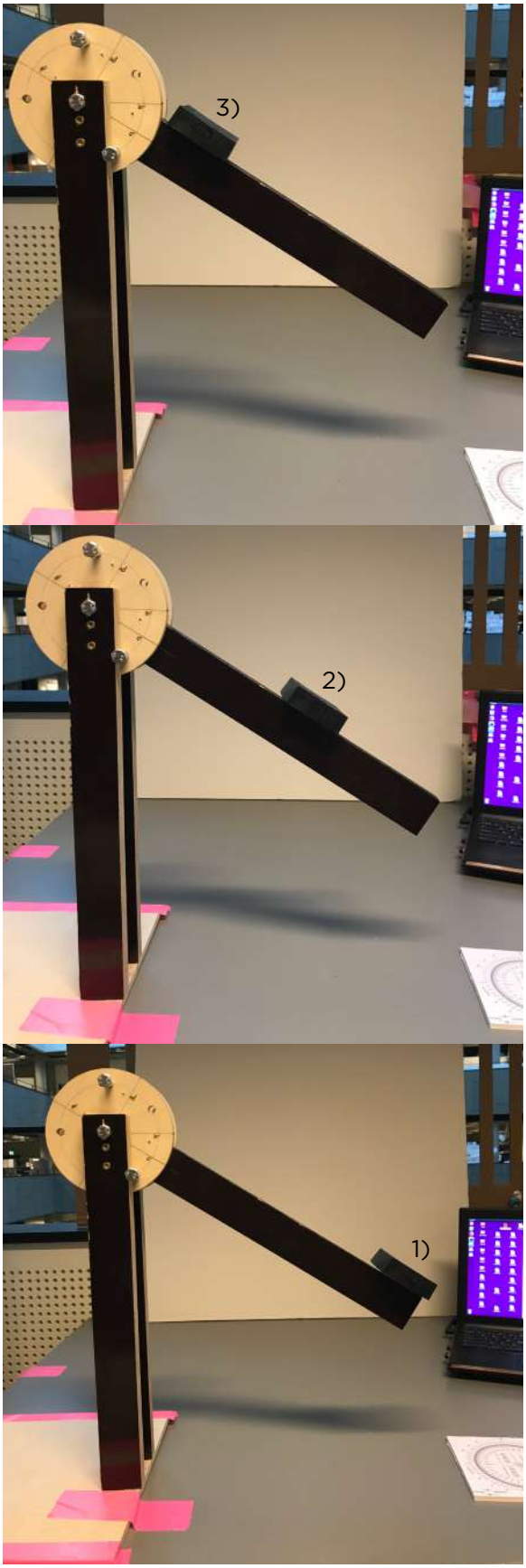
Test setup

A controlled test environment is created with an artificial arm with one joint, which is mounted to a table (Ill. 60.1), the Thingy:52 as the 9-axis IMU sensor, and the test-program. The arm can be adjusted to be rotated **30°**, **90°**, and **180°**. The communication between the sensor and the software is via Bluetooth.

It is taken into consideration that there can be some errors due to the material of the arm - in this case wood, which can have some flexibility that can affect the measurement with some degrees. Furthermore, the arm is handmade, and the mounting of the Thingy is done with duct tape, which both can have an effect on the test results.



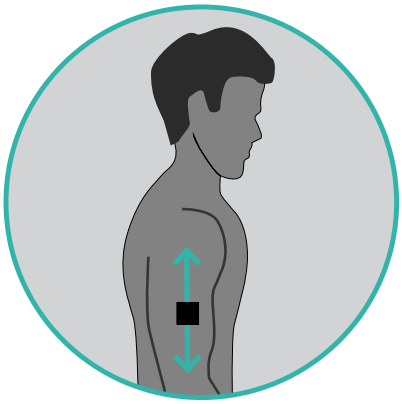
Ill. 60.1: Test setup.



Ill. 61.1: Test: Distance to joint.

Distance to joint

The first test is to investigate, if a further distance from the moving joint to the IMU has an impact on the accuracy of the measurement. The Thingy is tested in three different distances to the joint; 3) 7,5 cm, 2) 20 cm, and 1) 32,5 cm - and in three different angles (position of the arm); **30°**, **90°**, and **180°**. Every combination is performed three times. An off-set tolerance on **+/- 2°** is chosen to be acceptable, although the great amount of errors in the test.



Results:

Distance 3) at **30°** has an off-set on **0°**, **90°**; **+/- 1°**, and at **180°**; **-3°**. Distance 2) **30°**; **-1°**, **90°**; **-1°**, and **180°**; **-2°**. Distance 1) **30°**; **-1°**, **90°**; **-2°**, and **180°**; **-2°**. The off-set is listed with the maximum off-set in all three cases.

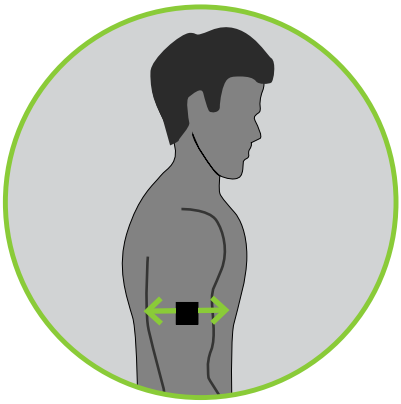
The results of the test show that the distance to the joint do not have an impact of the measurement. The **3°** off-set is 1 out of 27 measurements and is on the shortest distance, therefore, this measurement is considered irrelevant.

Discovery

Distance to joint do not influence the measurement - no placement insurance needed.

Rotation around body part

In the second test it is investigated, if the IMU rotated around the axis parallel with the body part has an impact on the measurement. The Thingy:52 is tested in three different rotations on the arm (Pitch); 0°, 30°, and 75° - and in the three angles (Roll); 30°, 90°, and 180°. All measurements are performed with a distance of 32,5 cm to the joint. An off-set tolerance on **+/- 2°** is chosen to be acceptable.



Results:

Rotation on 0° (Pitch) at 30° (Roll) has an off-set of **0°**, 90° (Roll); **0°**, and 180° (Roll); **+1°**. Pitch rotation on 30° at 30° (Roll) is **0°** off-set, 90°; **0°**, and 180°; **+1°**. Rotation 75° (Pitch) at 30° (Roll); **-1°**, 90°; **0°**, and 180°; **0°**.

Rotation of the device around the axis parallel with the body part does not influence the measurement.

Discovery

Pitch do not influence the measurement - no placement insurance needed.

Ill. 62.1: Test: Rotation around body part.

Rotation around the device itself

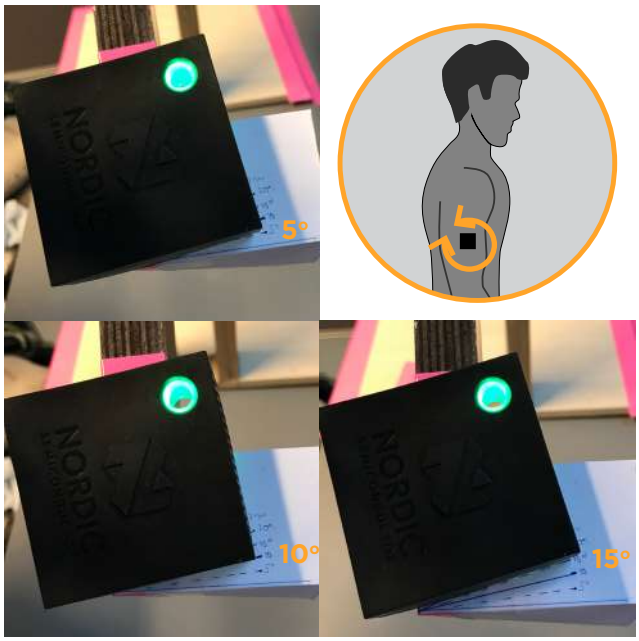
The third test is investigated to get an understanding of the importance of placement insurance in relation to rotation around the last axis (Yaw). This test is performed twice as the first attempt shows drifting in the digital readings of yaw, which make them inaccurate. Therefore, in the second attempt, the yaw angle is specified; 0°, 20°, and 30°. They are tested at 30°, 90°, and 180° (Roll). All measurements are performed with a distance of 32,5 cm to the joint. An off-set tolerance on **+/- 2°** is chosen to be acceptable.

Results:

Yaw = 0° at roll = 30°; off-set = **-1°**, 90°; **0°**, and 180°; **0°**. Yaw = 20° at 30°; **-3°**, 90°; **-8°**, and 180°; **+1°**. Yaw = 30° at 30°; **-5°**, 90°; **-4°**, and 180°; **0°**. With these large off-sets, the test is performed again at yaw = 5°, 10°, and 15°.

Results:

Yaw = 5° at 30° (Roll); **0°**, 90°; **0°**, and 180°; **+2°**. Yaw = 10° at 30°; **-1°**, 90°; **-1°**, and 180°; **0°**. Yaw = 15° at 30°; **-2°**, 90°; **-3°**, 180°; **+1°**.



Ill. 63.1: Test: Rotation around device itself.

Discovery

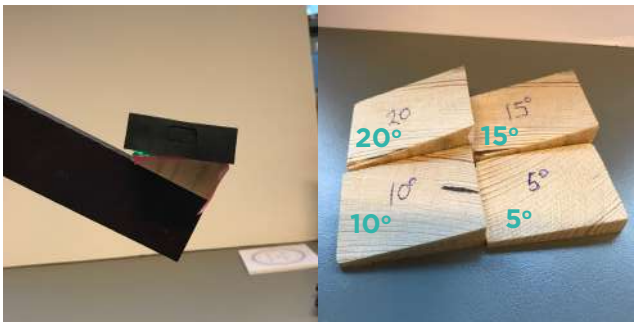
Yaw **> 10°** influence the measurement - correction vector needed for this error.

Angle to body part

The last test is performed to understand the impact, if the IMU-sensor has an angle to the respective body part in relation to different body curves. The Thingy:52 is tested at 5°, 10°, 15°, and 20°. All measurements are performed with a distance of 32,5 cm to the joint. An off-set tolerance on **+/- 2°** is chosen to be acceptable. All measurements are performed three times.

Results:

5° at 30°; **+1°**, 90°; **0°**, 180°; **-1°**. 10° at 30°; **0°**, 90°; **0°**, 180°; **-1°**. 15° at 30°; **+/-1°**, 90°; **+/-1°**, 180°; **-1°**. 20° at 30°; **0°**, 90°; **+1°**, 180°; **-1°**.



Ill. 63.2: Test: Angle to body part.

Discovery

Angle to the body part do not influence the measurement

Conclusion:

With this specific IMU sensor, only rotation around the z-axis is influenced. This error can be corrected in the software by applying a correction vector to the rotation matrix. These tests is only performed in 2D, similar tests should be performed in 3D and in this case, it is likely that more correction is needed. Another IMU sensor can be influenced by other errors on other axes, but it is common to influence the z-axis.

The Thingy:52 has already preprogrammed firmware, for the real system the programming of the firmware and processing program needs to be performed. In this case, it could be beneficial to make use of an open source software for IMU sensors.

4.5 Development of strap and sticker

At this point in the design process, the concept specifications are: having a module measuring unit that is able to be mounted with two module mounting methods; a sticker and a strap.
The sticker needs to be able to stick on all people and needs to have a connection method for connecting with the measuring unit. This needs to be the same connection method placed on the strap base.
The strap has to be 70 cm long and has to have a low practical and simple mounting and adjusting solution.

Sticker

It is desired that the interaction - connecting the measuring unit on the sticker or strap base, activates the device, and likewise deactivates the device when disconnecting the measuring unit. Furthermore, it is desired that the device gives visual feedback when turned on, and gives visual feedback when connected correctly to the mounting method.

Test with hair

A concern from the physiotherapists regarding the stickers is, if the device would be connected to the skin and stay in place, if the client had much body hair. This is investigated with a test using the mockup, consisting of a heavy measuring unit due to mockup material, and two types of stickers (blister sticker bandage and sticker for mounting electrodes on the body for clinical purposes). The test is performed on a test person with much body hair, and the mounting during and after the movement is noted. Furthermore, the test person is asked if it hurts when the sticker is taken off. As a safety precaution regarding the results, the testperson is asked to perform intense movement, which is extreme in relation to the measuring movements in a consultation.
The test results are clear. The hair does not affect the mounting of the sticker during movement, and does not contribute to pain when being pulled off.


Ill. 64.1: Test with hair.

Connection methods

There are different methods of connecting the measuring unit with either the strap or sticker. The following methods are unfolded, as are their pros and cons. Furthermore, they are holded against the desired interactions.

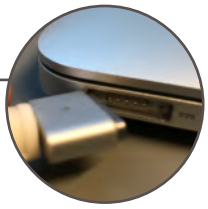
Snap button


Ill. 64.2: Button

Pros:
- Simple
- Cheap
- Known technique - used in stickers in other situations like connecting electrodes on skin.
- Conductive
- Connection gives tactile and auditory feedback

Cons:
- Difficult to clean inside female button

Magnet


Ill. 64.3: Magnet

Pros:
- Easy to clean
- Conductive

Cons:
- Not stainless

Micro velcro


Ill. 64.4: Velcro

Pros:
- Simple
- Cheap

Cons:
- More difficult to clean
- No feedback if the device is attached correctly
- Difficult to integrate switch in method for turn on/off device.

The cons of the micro velcro weighs too much in relation to the cleaning requirements and is to this reason excluded. The metal button and magnets are both optimal choices for a connection in this product system. However, there are no arguments for choosing one over the other at this time in the process. It is therefore decided later in the process, when other design factors can impact the choice.

Strap

The solution space is unfolded within the strap specification at this point, which leads to three solutions. The solutions are built as mock-ups, tested, and evaluated. The three solutions are unfolded below an the feedback is showcased. [Worksheet 39]

Solution 1

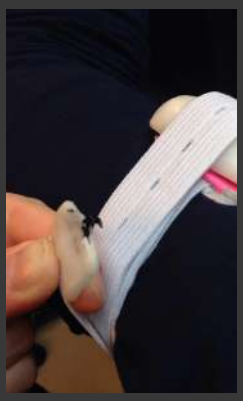
This mounting and adjusting happens with tightening the elastic strap and locking it by pushing the fitting hole on the button. It is possible to wrap and mount the excess strap with a simple hook, if desired. The interaction steps are showed in Ill. 65.1.

Interaction steps

The device is placed and wrapping starts.

Wrapped while adjusting tightness and push hole on button.

Wrap around, above measuring unit.



Place hook in hole.

Ill. 65.1: Solution 1

Feedback

- Unwieldy mounting because the button is not fixed in relation to anything.
- Button is too flat compared to the holes size.
- Feels and looks unappealing to wrap the strap over the measuring unit, if the mounting is on a body part where the excess strap will occur.
  (Tip: if so it would be a good idea to indicate this in the design/styling of the measuring device)
- The measuring unit complicates the mounting, regarding the placement of the button in relation to the measuring unit.
  (Tip: The button has to be further from the measuring unit to not be inconvenient.)
- + Simple hook to mount the excess strap.

Solution 2

This mounting and adjusting happens with first locking a buckle, tightening the elastic strap and locking the strap in the buckle. It is possible to wrap and mount the excess strap with a simple hook, if desired. The interaction steps are showed in Ill. 66.1.

Interaction steps

The device is placed.

The buckle is locked.

The strap is tightened by pulling, and locks by itself.

Excess strap is wrapped and mounted with hook.

Ill. 66.1: Solution 2

Feedback

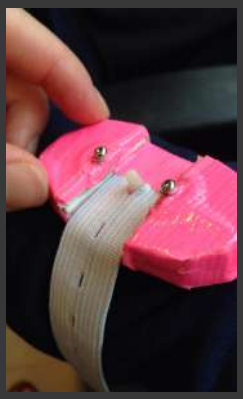
- (+) The click feels nice and gives a nice feedback sound.
- (+) The adjustment, pulling the strap, feels appealing.
- (+) It is a controlled interaction because you hold two components and connects them with a click
- (-) When adjusting by pulling the strap, the measuring unit rotates slides a little around the body part in the direction of the pull, if you do not hold the measuring unit with the other hand.
- (-) Feels and looks unappealing to wrap the strap over the measuring unit, if the mounting is on a body part where the excess strap will occur. (Tip: if so it would be a good idea to indicate this in the design/styling of the measuring device)
- (+) Simple hook to mount the excess strap.
- (-) Difficult to clean buckle inside

Comment: The buckle seems needless compared to that a knob, like in solution 3, can do the job.

Solution 3

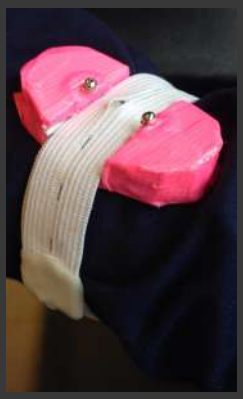
This mounting and solution happens with tightening the elastic strap locking it by pushing the fitting hole on the pin integrated in the base component. What is different from solution 1 is that the wrapping is done first, and the measuring unit is clicked on afterwards to prevent the strap from going over the measuring unit. The interaction steps are showed in Ill. 67.1.

Interaction steps



The base with strap is placed.

Wrapped while adjusting tightness and push hole on pin.



Excess strap is wrapped and mounted with hook.

Measuring unit is clicked on the base.

Ill. 67.1: Solution 3

Feedback

- \+ Very simple solution
- \+ Nice design.
- \+ The strap is wrapped in the base, and not over the measuring device.
- \+ Simple knob, easy to mount strap on and take off.
- \+ Simple hook to mount the excess strap.
- \- The construction deforms when tightened. (Tip: Material with higher strength could solve this problem.)

Comment: I like that you mount the strap and base first, and then click on the measuring unit afterwards. Then you are not as afraid of dropping the measuring device when mounting the strap.

Conclusion

Through testing and feedback from the test panel solution 1 is excluded due to unwieldy interactions. Both solution 2 and 3 have good feedback response. However, it is decided of the design team to go with solution 3, because the interaction is the simplest. Furthermore, the buckle from solution 2 is harder to clean inside, which is a small minus.

Decision

Solution 3 is chosen for further development.

4.6 Product aesthetic

The product aesthetics are a combination of form, material, colors, texture, composition, and first of foremost, how all these are combined in a cohesion that contributes and supports the interactions intended with the product. Through the design process, many iterations containing these aspects has been carried out through ideas and concepts with no clear directions or boundaries. However, to create boundaries, the method scale priority tool has been utilized.

Scale priority tool

This method consists in creating style tiles that consists of a style name and 2-4 pictures of products that express this style. Afterwards, the tiles are used in conversation with the stakeholders that has an opinion regarding the purchase/usage of the product in development. You can e.g ask them about, which style they want the product to contain, where after the stakeholder has the style tiles to speak from and with, being able specify what they say, from aesthetic aspects on the pictures on the tile. Style and aesthetics are very subjective, and it can be hard for non-designers to express only through imagination and words. That is why this tool is a great method of making something intangible - more tangible.

Purpose

The purpose of the scale priority tool exercise in this project, is to ask the stakeholders what style they find motivating - not in relation to anything, then what they find motivating in relation to physiotherapy, which styles they would scale as how they see the physiotherapy clinics look now, and which styles they would find interest in to be at physiotherapy clinics in the future.

Fabric

Robust

Geometric

Grey on grey

Mesh

Neutral and bright color

Grey on grey

Wood and neutral color

Style tiles

From the results of the exercise, five tiles are repeated to be perceived appealing regarding what is motivating in relation to physiotherapy, and which style is desired in the future physiotherapy clinic; All white, Hightech aluminium, White and black highgloss, and Color layer and Light feedback. Comments from the stakeholders during this exercise, are illustrated on the below.

All white

Black and white high gloss

Hightech aluminium

Color layer

Light feedback

> “
>
> Picking a neutral expression (not too sparkly) makes it look as a medical device that is trustworthy.

> “
>
> Double curves makes it blend in with the body curves and are easy to clean.

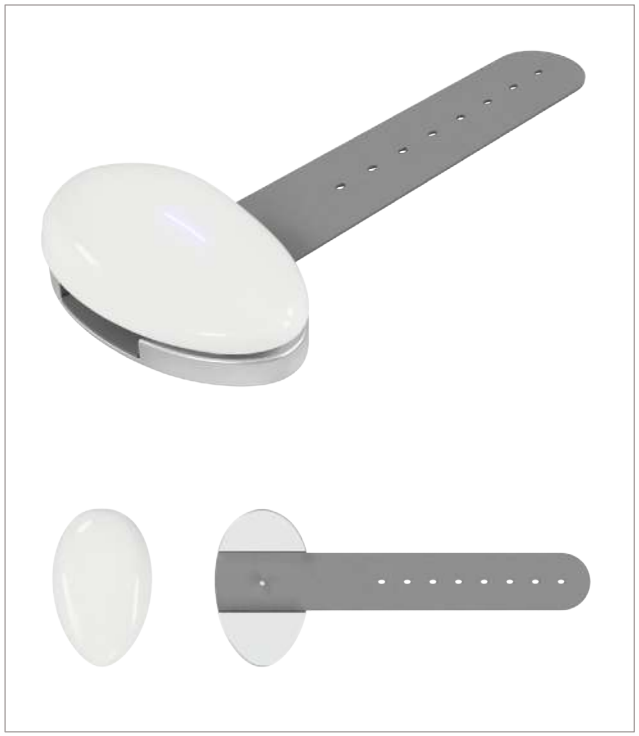
> “
>
> Lights look motivating

Ill. 69.1: Created style tiles.

Six expressions

From the chosen style tiles six expressions are developed with a mix of two or more of the style tiles and their aesthetic characteristics. The six expressions are modelled in CAD, and printed in 3D. Furthermore, materials are added on CAD model renderings to get different expressions, within the tile characteristics. Both renderings and 3D printed models are presented to the stakeholders to get feedback.

Expression 1

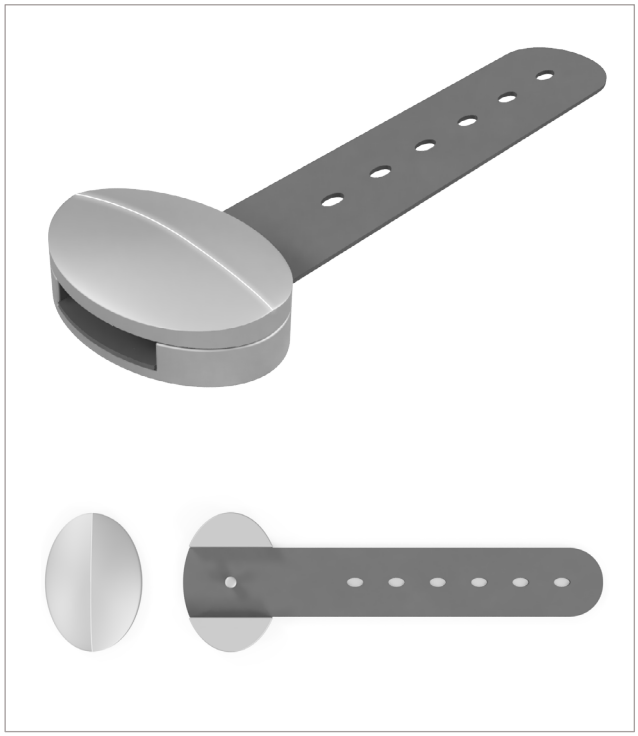


Expression 2

Expression 3

Expression 4

Expression 5



Expression 6

Ill. 71.1: Expressions.

"The circular shapes indicate that it can measure rotation"

"Colors make it look unprofessional and not as a medical equipment"

"Making the measuring unit integrated in the base gives clear indications on how to connect the two"

Product aesthetics

From the feedback and the team's own intentions regarding aesthetics, following guidelines/ requirements are extracted:

Demands:

- Expression that integrates the base and measuring unit
- No colored materials
- Include round or ellipse shapes
- Be symmetric in at least one plane
- Light feedback through logo
- Size within boundary box of approx. 55x55x12mm

4.7 Test - Mounting for all movements

In relation to the defined movements (Section 1.9 Measurement movements), placement of the measuring unit is specified according to these movements (Ill. 72.1). The placements are specified with guidance from physiotherapists. All placements, except for neck and back, are located after the joint, where the measurement takes place, and before the next joint. For example placement C is located after the shoulder, which is the joint for measuring, and before the elbow. This ensure that the IMU sensor is only reading one joint movement. The placements are marked with a point and a placement zone, the measuring unit should be placed within this zone.

A (forehead) is the placement of the unit for all three neck movements; dorsal bending (2), lateral bending (3), and rotation (4). With this placement the strap solution have a risk of interfering with the client's hair, but this can be avoided using a sticker.

B (between thoracic and lumbar vertebrae) is the placement for measuring back movements; dorsal bending (1) and lateral bending (10). In this case, the physiotherapist should use the navel as reference.

C (above elbow) is the placement for measuring shoulder movements; dorsal bending (11) and lateral bending (12).

D (above wrist) is the placement for measuring elbow movement (14) and movement of the forearm (13). In situations where the client is wearing a watch or bracelet, they have to remove this during the movement.

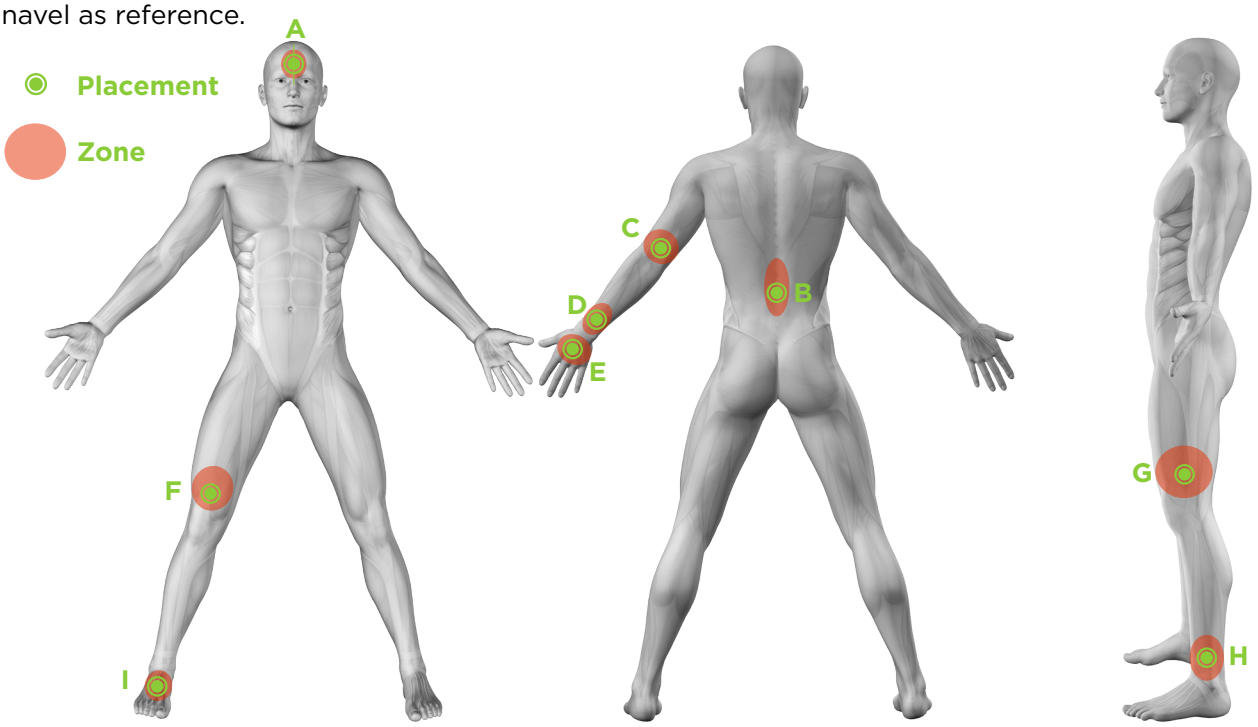
E (back of hand, above fingers) is the placement for measuring wrist movements ulnar-radial (17) and flexion-extension (18).

F (above the knee, front) is the placement for measuring hip abduction (7) and adduction (8).

G (above knee, side) is the placement for measuring hip extension (5) and flexion (6).

H (ankle, side) is the placement for measuring knee movement (9).

I (foot) is the placement for measuring ankle movements; dorsal bending (15) and lateral bending (16).



Ill. 72.1: Placement locations.

4.8 Development of sticker dispenser

For the product system always to be quick and easy to use, the system includes a sticker dispenser, which can be mounted on the physiotherapist's clothes with a magnet; always accessible. This aspect together with the possibility of mounting the measuring unit onto the dispenser, when it is not in use, is included in three developed concepts of the sticker dispenser. The three concepts differ in the interaction of dispensing the stickers. The evaluation and selection will take place on a later state.

Solution 1

Dispenser on physiotherapist.

The container is opened and a sticker is picked.

The measuring unit is removed from the dispenser and applied to the sticker.

Ill. 73.1: Solution 1.

Solution 2

Dispenser on physiotherapist.

A sticker is slided up.

The measuring unit is removed from the dispenser and applied to the sticker.

Ill. 73.2: Solution 2.

Solution 3

Dispenser on physiotherapist.

The measuring unit on the sticker is slided up.

The measuring unit is already applied to the sticker.

Ill. 73.3: Solution 3.

4.9 Summary

With the knowledge on how the 9-axis IMU sensor works in cooperation with the development of a simple software program, the limitations of the sensor was explored. The results of the placement insurance test showed that the accuracy of the physical placement of the measuring unit was only influenced by rotation on more than 10° around the z-axis (with this specific IMU sensor). But with guidance from a Clinical Sports scientists, it is assured that errors caused by such influences can be corrected in the software.

The further development of the mounting solutions resulted in the strap solution, where there is a possibility to roll up the excess strap without the strap going over the measuring unit. The attachment between the measuring unit and the mounting solutions is narrowed down to either a type of snap buttons or magnets. This will be specified in the next chapter.

The next chapter will also unfold a second iteration in relation to the styling of the product as a follow up from the results from the first test of the developed aesthetic expressions. In the next chapter the preferred characteristics will be combined into new aesthetic expressions.

From the standardized movements ideal placement location of the measuring unit was chosen with advice from physiotherapists. All locations were tested out with the product solution to identify any problems there could be with these placements.

Lastly, the sticker dispenser was further developed. The evaluation and selection will take place in the next chapter as the sticker dispenser is depending on the final shape of the measuring unit and the final attachment between the measuring unit and the mounting solutions.

Key activities

Detailling
- Application
- Hardware
- Software
- Aesthetics

- Construction
- Dimensioning
- Materials
- Production methods

Specification
- Quality verification

5.0 Detail

The now clear specified concept of the product system are further defined through 3D modelling. The aspects of dimensioning and construction are integrated into the final product system together with materials and production methods.

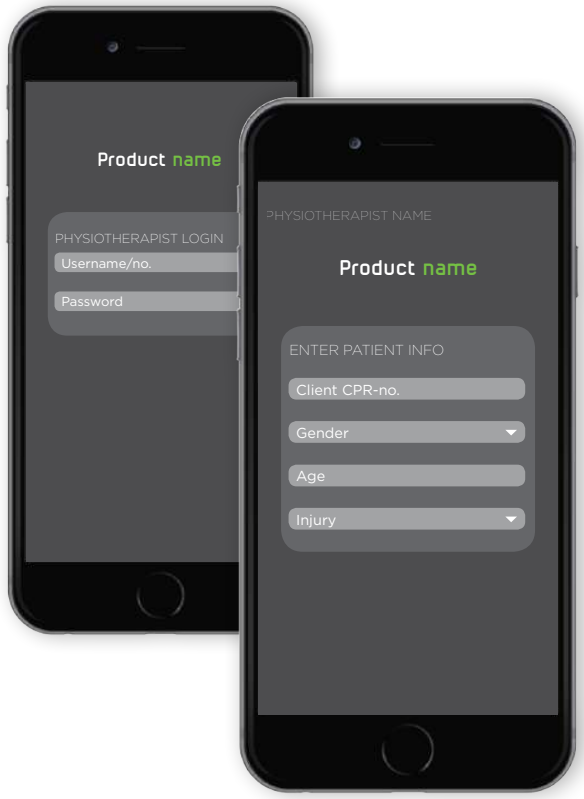
5.1 Detailing of application

From the ideation of the application, small changes are made by adding some features and developing a layout that makes it easy to decode the different menus and the navigation between them.

The application is setup in a mockup program called Invision that allows the interactions with the application and the navigation between menus, to be close to reality to test if the construction is intuitive and the mediated data easy to understand.

The application mockup is presented to the physiotherapists - who find it easy to understand also in relation to navigating between the menus.

Below and inside the foldout, the application menus and navigation are showcased.

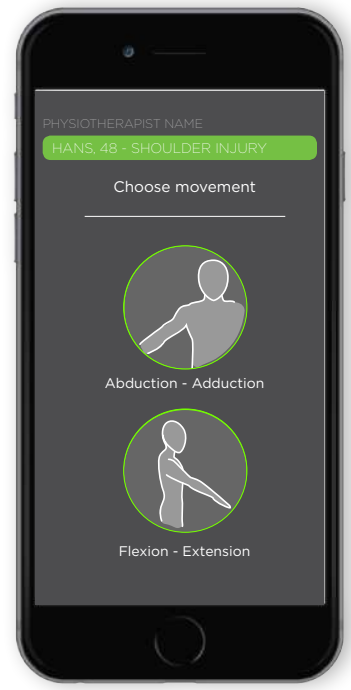


1 Physiotherapist login and access client profile.

[Physiotherapist log]

2 The head menu illustrates the client's progress in the rehabilitation process, and provides the physiotherapist with the options of entering the data library or tracking a new movement.

3 Choose exercise to measure



4a Choose type of movement, within the injury spectrum. (In this case shoulder)

5a Instructions for placing the device is illustrated - choose measurement settings.

Instruction steps are showcased in between

EXERCISE IS PERFORMED BY THE CLIENT

4b Read the offset movement when repositioning the concerning body part with offset in the front and top plane.

6a Read measurements; velocity, acceleration, jerkiness, and range of motion according to the movement over time. Change perspective to explore the movement and movement data. Furthermore, see the maximum ROM and the normative ROM to compare.

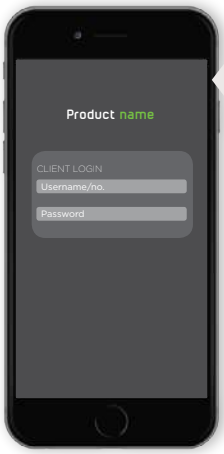
All data is saved and always accessible in data library where date, exercise type, and movement data is visible in a table.

New motion data is saved in the data library

III. 76.1: Physiotherapist log interfaces

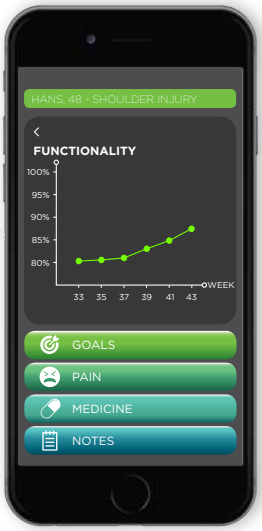
[Client log]

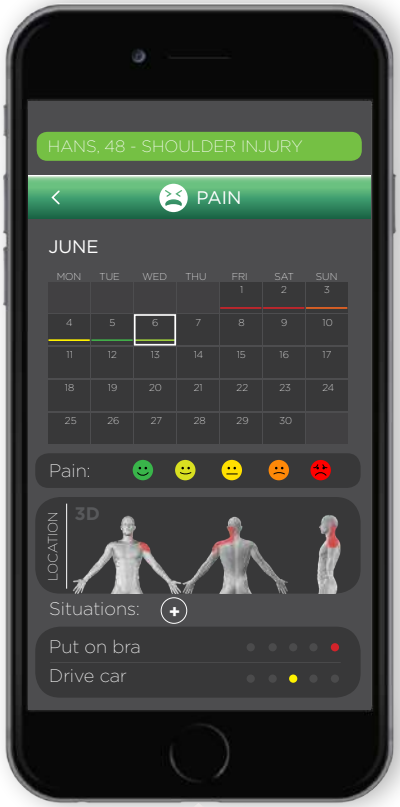
The client application log is developed for the client to be able to see the progress in functionality. Furthermore, it gives the client the possibility to gather all information related to the injury in one place.



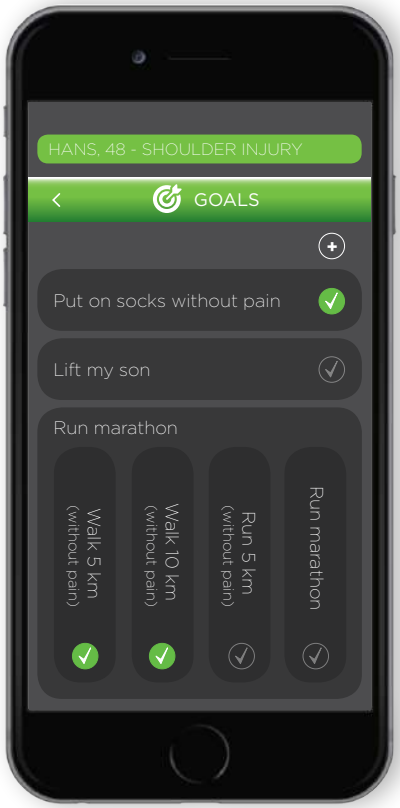
1 The client logs in with social security number.

2 The progress in functionality is illustrated in a graph. Four log menus are now available for the client to enter if desired.

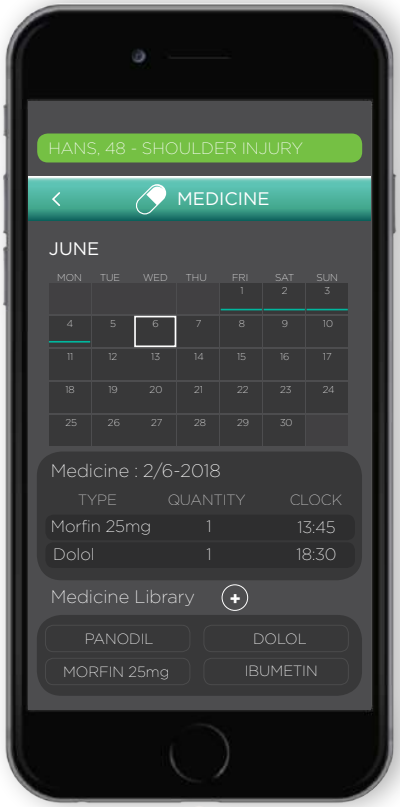




In the PAIN log menu, the client has the possibility to enter and keep track of their pain, the location of the pain, and the situations where pain occur, all according to the intensity of pain. These parameters are used in physiotherapy consultations, to give the physiotherapist an insight in what the problem is and how the exercises are working. Furthermore, it is a great way for the client to see progress in pain relieve.



In the GOAL log menu, the client has the possibility to enter and keep track of goals, whether they refer to small daily activities or bigger goals defined in several part goals.
To keep the motivation in the progress it can help to be able to see that things that were impossible in the beginning has become possible due to the progress.



In the MEDICINE log menu the client has the possibility to enter and keep track of their medicine intake.

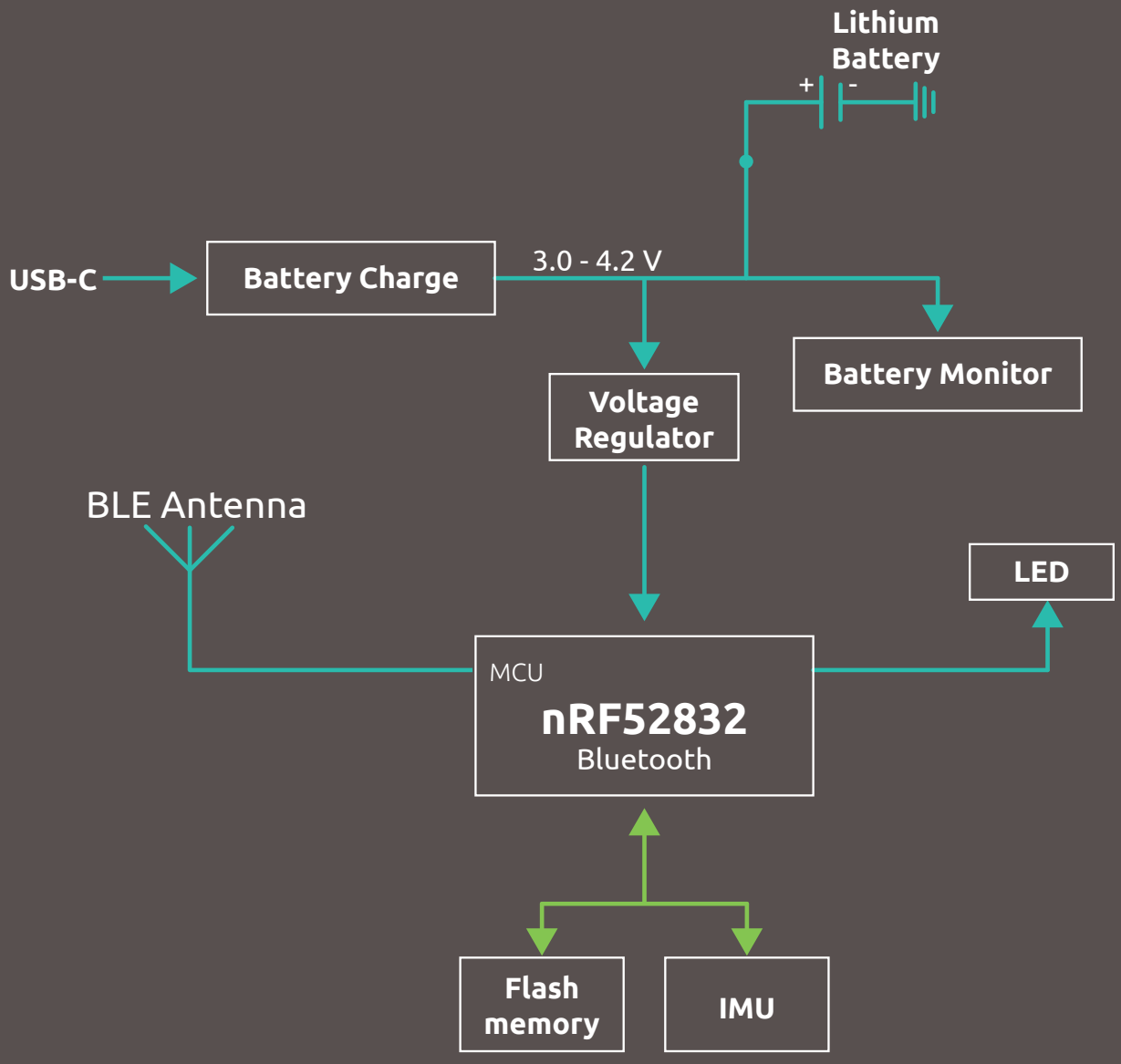
Ill. 77.1: Client log interfaces

Comment

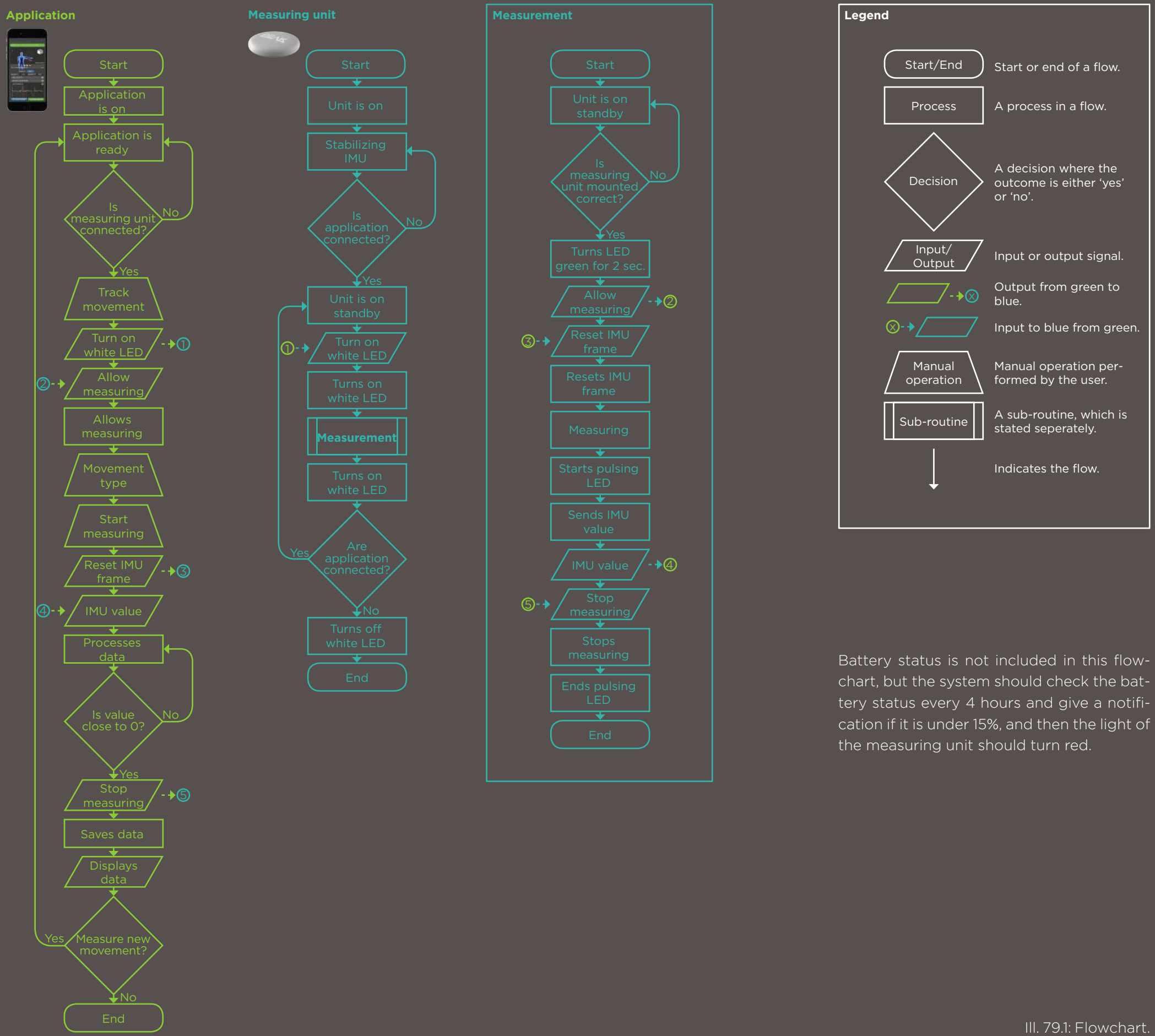
With digital measurements, it is possible to build up a database platform for all physiotherapists. (Without identity data)

5.2 System and software

In relation to give an overview of the required electric components and the connections between them, a block diagram is created (Ill. 78.1). The system consists of a microprocessor, nRF52832, which is an ultra low power type of microprocessor. It has BLE (Bluetooth Low Energy) included, which will be used as wireless connection between the smartphone application and the measuring unit. Required in the system is also a 9-axis IMU sensor, consisting of 3-axis accelerometer, 3-axis gyroscope, and 3-axis magnetometer. For power supply, a rechargeable lithium battery on 3,7V and 80mA could be an ideal candidate. Because this product system is intended to be a business start-up, the charging is chosen to be with USB-C as this is a cheap standard solution. Furthermore, the system should contain flash memory and RGB LED for light feedback. On the diagram the data flow is indicated with green.



Ill. 78.1: Block diagram.



Battery status is not included in this flowchart, but the system should check the battery status every 4 hours and give a notification if it is under 15%, and then the light of the measuring unit should turn red.

Ill. 79.1: Flowchart.

Flowchart

A flowchart is developed to describe the overall software process, when performing a measurement (Ill. 79.1). The flowchart is divided into two parts; one showing the process in the application, which controls the measuring unit, and one showing the process in the measuring unit. The legend (behind this fold-out) describes the definitions of the different symbols in the flowchart.

To perform a measurement the application is opened and prepared for the respective client. Likewise, the measuring unit is attached and mounted as instructed with either the sticker or the strap. The application will at this point check if it is connected to the measuring unit. The measuring unit is always turned on, except if it is out of battery. It will, like the application, check if it is connected to the application. When the physiotherapist enters 'Track movement', the LED on the measuring unit will turn on with white light. If the measuring unit is correct attached to a mounting unit, it will allow the possibility to enter 'Movement type' and afterwards allow the physiotherapist to click 'Start measuring'. When 'Start measuring' is pressed, the application will send a command to the measuring unit to reset the reference frame in its current position. Here the physiotherapist has ensured that the client is positioned in the 0-position. When the frame is reset, the measuring starts, and the LED is pulsing with white light during the measuring. The measuring data is sent to the application, which process the data (calculate angle, velocity, acceleration, and jerkiness) until the received value is close to the 0-position (this tolerance is not specified); then the application sends a command to the measuring unit to stop measuring. The LED lights constant white again. The application saves and display the data. If the measuring is still attached and has connection to the application, the system is ready to perform the next measurement.

5.3 Detailing the aesthetics

From the aesthetic requirements extracted from the previously expression test round, six new expressions are developed. The expressions are CAD modelled and rendered with intended materials.

[Aesthetic 1]

[Aesthetic 2]

[Aesthetic 3]

[Aesthetic 4]

[Aesthetic 5]

[Aesthetic 6]

Ill. 80-81.1: Aesthetics.

A mix between quantitative and qualitative feedback are gathered from different test participants.

Following comments were repeated:

- White high gloss contributes to the product being perceived as a medical device.
- Model 2 and 6 have an appealing expression because of the contrasts and the transition between the modules.

Considering comments and opinions expressed by the test participants, and the personal opinions of the team members, model 2 is chosen to be fully developed and defined in relation to materials, construction, and dimensioning.

Product aesthetics

Requirements

Measuring unit:

- Round shape in white material with high gloss surface.

Base unit:

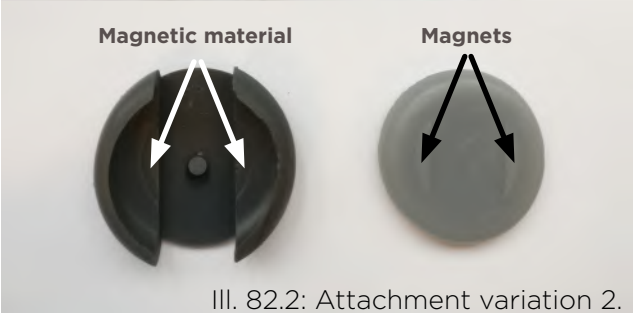
- In medium hard material that allows the measuring unit to be pushed into the inside shape, with an expression of rubber like/matt silicone surface.

5.4 Construction and dimensioning

With clear demands regarding aesthetics, the construction, dimensioning, and materials can be specified. The measuring unit and the two mounting solutions; disposable sticker and strap solution, will be specified. The sticker dispenser is discarded because at this state of its development, the thickness of it would be 40 cm if it should contain 10 stickers inside. This could be dealt with by redesigning the dispenser, but because the business of this product system is thought of as being a start-up, it is decided not to. Furthermore, it is decided not to develop a docking station for charging. This will be done using USB-C as mentioned in the block diagram.

For attachment between the measuring unit and mounting solutions it is chosen to use magnets. Two variations of attachments with magnets are developed. Both variations are with magnets on the measuring unit and magnetic material on the mounting parts. The first variation is with one magnet inside the bottom center of the measuring unit and the corresponding male part as the head of the mounting pin (Ill. Ill. 82.1). The second variation with two magnets on the bottom of the measuring unit and the corresponding female part in the mounting solution (Ill. 82.2). It is decided to develop the second variation further, as the first one makes more demands to the pin. In the second variation the pin is shorter and the interaction surface, which contribute to the stabilization of measuring unit, is larger and distributed to two points instead of one. Though, it is chosen to reverse the male and female part, which means that the magnets will be inside the bottom of the measuring unit, and the magnetic material is extruded out of the mounting units.

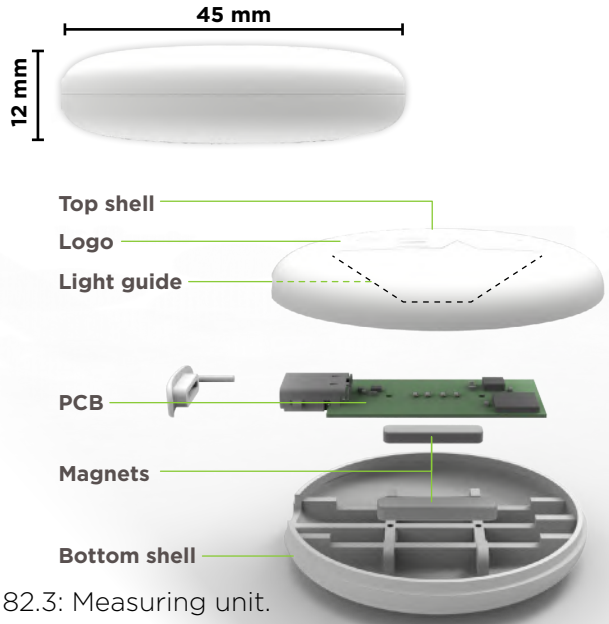
Ill. 82.1: Attachment variation 1.



Ill. 82.2: Attachment variation 2.

Measuring unit

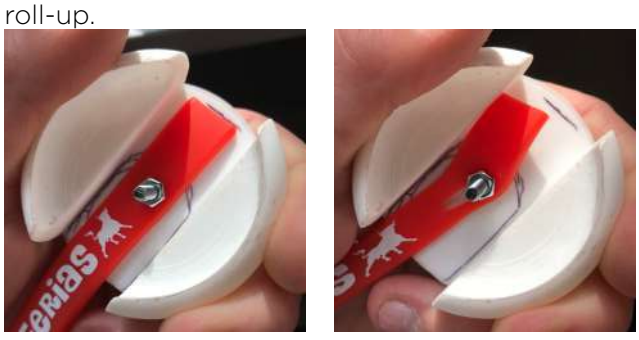
The measuring unit consists of a top and bottom shell, where it contains the PCB and magnets inside. Both shells should be made in ABS, PC, or a combination of those two, as the shells should have a high gloss surface. ABS and PC both have a good chemical resistance and strength. The shells should be injection moulded with the plastic in transparent, which afterwards should be painted white on the inside and outside of the shells. The reason for this is that the product logo is intended to be on the top shell of the measuring unit, where light feedback is supposed to light through the logo. Here a light guide should be moulded inside (Ill. 82.3.), to be able to distribute the light equally. It is taken into consideration that there is a risk of immersion on the outer shell, this would be corrected in the moulding machine settings. The shells will be assembled with a click mechanism.



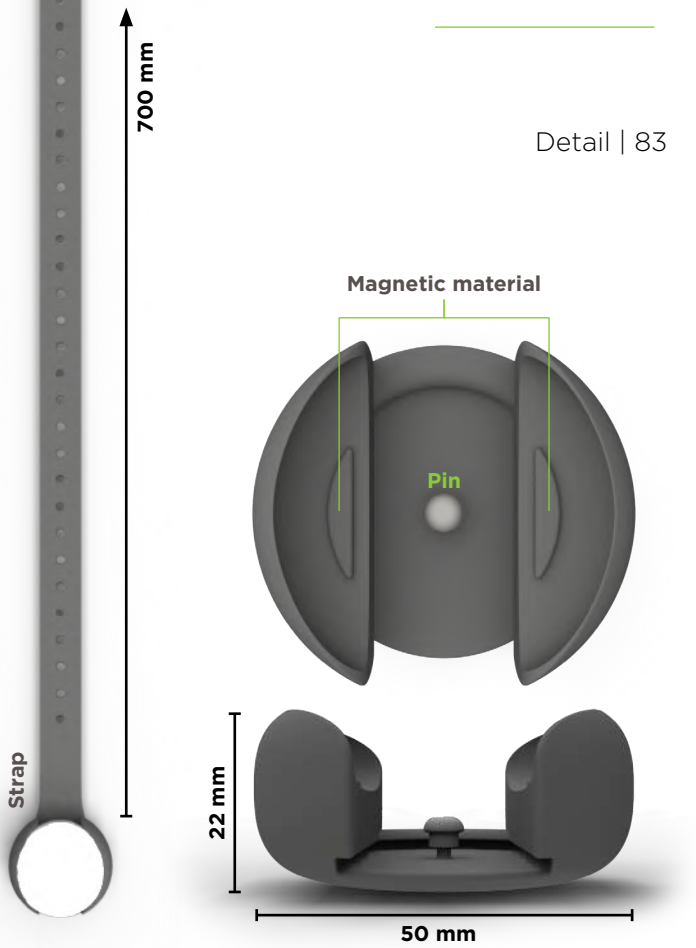
Ill. 82.3: Measuring unit.

Mounting strap

The strap solution (Ill. 83.2) consists of a base with the mounting pin and a strap. Both the base unit and the strap should be in silicone in the spectrum Shore A medium hard hardness [Worksheet 38], but this should be tested before specifying it further. The silicone of the base unit should be overmoulded a magnetic stainless steel support construction, to reinforce the bottom of the base unit. This support construction makes it possible to mount the pin afterwards and is also the magnetic material for the measuring unit to be attached to. The magnet's strength depends on how magnetic the magnetic stainless steel is, when it is overmoulded. The pin should be made in either stainless steel or aluminium. As a start-up business it is prefered to rent an already existing mould for a standardized pin, which will lower the cost compared to buying a new mould. In the case of using an existing mould, the design should be adjusted to fit this pin. Because the strap is chosen to be a separate part, it is possible to waterjet it from a silicone sheet, which is cheaper than injection moulding. The strap is mounted to the base unit with the pin, and the edge of the strap, which is touching the base unit, is inside a groove to cover any deformations as seen in Ill. 83.1. The length of the pin is shortened in relation to the original length. This is because, it is discovered through a test that when mounting on a small body part, the strap gets tighter and tighter, when the excess strap is rolled up, when the pin have to go through a hole in the strap everytime it is rolled a round (Ill. 83.3). Therefore, the length of the pin should only fit at least one round of roll-up.



Ill. 83.1: Strap deformation.



Ill. 83.2: Mounting strap solution.

Ill. 83.3: Tightening.

Ill. 83.4: Disposable sticker.

Disposable stickers

The disposable sticker solution exist as a standard component; disposable electrodes, which comes in either cloth or foam. Foam is selected as this is tested to be less painful to remove. The adhesive should be medical hypoallergenic. The stickers comes in various shapes and sizes; drop shape is chosen to be ideal as this one has a pointy end, which can work as a placement indicator. The stickers usually comes with a snap button for electrical conduction for electrodes. These has to be exchanged for two deep drawn male parts that fit in the female parts of the measuring unit (Ill. 83.4), these should be made in magnetic stainless steel like the inner frame in the base unit. The mounting of the male part will be the same method as the original snap buttons.

5.5 Quality verification

To accommodate the requirement of the measuring unit having a correlation on > 0,75 compared to the gold standard (3D camera system), the measuring unit needs to be tested on three parameters and pass. The three parameters that can affect the accuracy is the accuracy of the specific IMU sensor, the software, and the mounting of the measuring unit. This is also some of the tests that are required for the product system to be approved as a medical device.

IMU sensors are built differently and, therefore, have different accuracy. In order to quality test the IMU sensor, the specific IMU sensor should first be tested in a controlled environment to be able to discover its errors. This test could be performed similar to the placement insurance test done in this project, but with much less errors in the physical part of the test. Afterwards, the software should be developed with implemented correction of the IMU's errors and be tested in the controlled environment until there are no significant errors. Then the measuring unit should be tested in relation to all the specified movements and the software modified in relation to any errors. Lastly, the IMU and software should be tested in comparison with the 3D camera system to verify the accuracy in the IMU and software.

In relation to the mounting method, its construction and materials can affect the ability of keeping the measuring unit in place during the movements and measurements. Therefore, the thorough tested IMU and software should be tested with the developed mounting method versus the gold standard.

Key activities

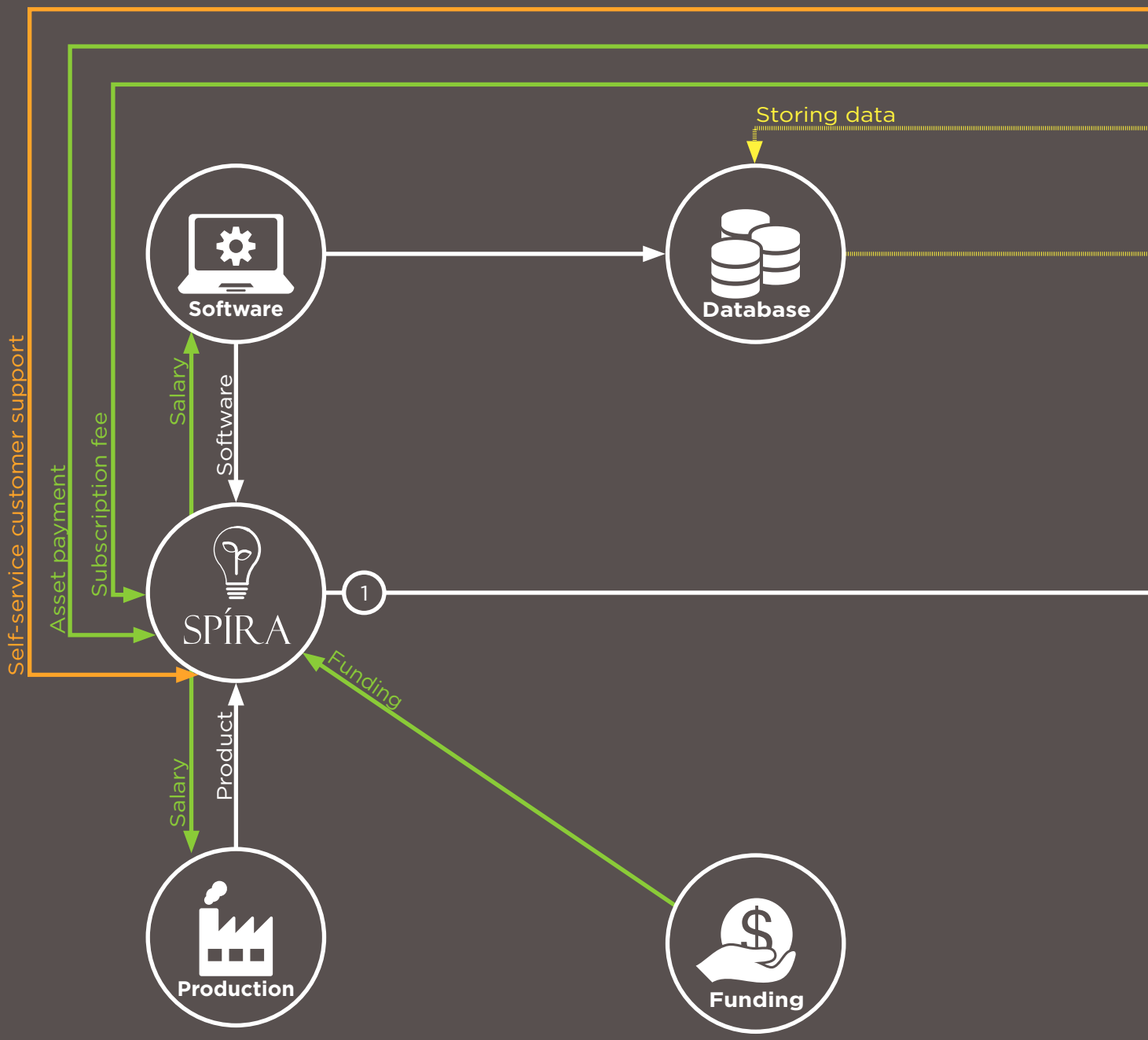
Development
- Business model
- Budget

6.0 Implement

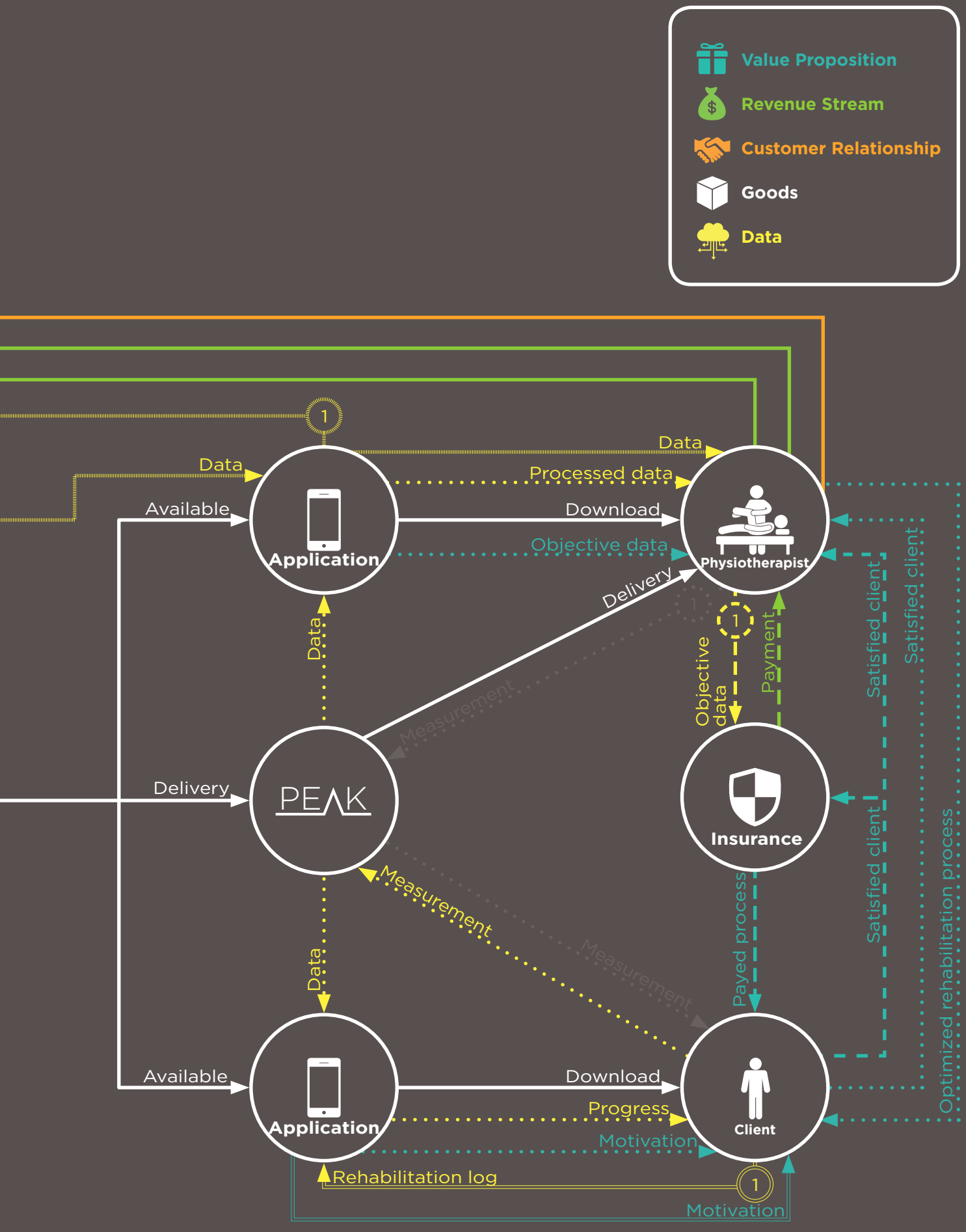
The process of implementing the developed product system is specified in continuation of the Detail-phase. The needed business related and strategic actions are described, in relation to realizing and launching the design proposal on the market.

6.1 Business model

A business model (Ill. 86.1) is developed with inspiration from the Business Model Canvas (Osterwalder, et al., 2014). In the business model, Spíra is the main establishment, where external suppliers such as manufacturing and software production are the Key Partnerships. These three instances, together with the developed product system, and the Customer Segments; physiotherapist, insurance company, and client are included in the business model. Between them, the flow of Value Proposition, Revenue Stream, Customer Relationship, Goods, and Data (Measurement data from the device) are shown. *PEAK* is the product system. The number 1 in illustration 86.1 refers to a new flow, which originates from a certain action. The line types corresponds to the coherence between the different factors.



Ill. 86.1: Business model.


Value Proposition
Revenue Stream
Customer Relationship
Goods
Data
1
Data
Data
Processed data
Available
Download
Application
Objective data
Physiotherapist
Delivery
Data
Measurement
1
Objective data
Payment
Satisfied client
Satisfied client
Delivery
PEAK
Insurance
Measurement
Measurement
Payed process
Satisfied client
Optimized rehabilitation process
Data
Available
Download
Application
Progress
Motivation
Client
Rehabilitation log
1
Motivation

As Spíra are not in possession of internal production facilities, all production related activities are outsourced to external partners. The positions of sales and marketing are required internal in the company. In relation to the software development, which Spíra does not possess the competencies of making, a cooperation agreement,with Medei, with expertise in the field of medical devices, should be established. Medei developed the application for the research team's scientific research. This company already has the knowledge of processing these data and also has the expertise in the development of databases, which is also an asset for further development of this product system.

In relation to the two different main customer segments (physiotherapist and client) there are different sets of value proposition. The physiotherapist is the financial buyer of the product system. To reach this customer segment there are several channels to make use of. Every year a number of physiotherapy conferences are held around the world. Introducing the product system on such conference will reach a great amount of physiotherapist from all over the world, for then to be channeled into a larger network. To reach credibility, this introduction could be performed by practicing physiotherapists, who get the product system sponsored in return. Another way of being noticed on the market is to sell the product via the online physiotherapy retail shops, where they sell equipment for measuring, rehabilitation, and training. Furthermore, to get the product system implemented as a permanent part of the physiotherapy, it should be introduced in the physiotherapy education programme. In relation to this, the insurance companies should be made aware of this product system and its possibilities of providing objective documentation for both compensation cases and cases where they cover physiotherapy consultations expenses.

Spíra has the advantage of being the first mover within this market segment; in this context with this technology. Furthermore, the product system will be verified as medical equipment, which makes it more attractive as it is quality tested. Spíra's competency strengths lie in the dedication of performing thorough implementation research, which minimize the risk of significant adjustments in the product system after the system has been launched. Furthermore, a part of Spíra's competitiveness is in the communication of all the data through the application together with the great opportunity of developing other product systems in the medical field for other applications.

A second business model could be that Spíra sells the project and rights to an external company for a one time payment. The factors around the product system will be the same. However, the company might have internal software department and productions.

A third business model could be that team Spíra gets employed by an external company to execute the project until it is up and running, and sell the rights in return of royalties per sold product.

A forth business model could be that Spíra as a startup company contacts an insurance company with the offer of starting a partnership, where they fund the project in favor of owning a part of the company. Furthermore, they change their policy requirements to demand objective functionality progress data in relevant cases. This to determine compensation cases and to determine which physiotherapists they can make referrals to and support financially, in relation to the physiotherapists treatment effect. This will also contribute to a higher level of competition amongst the physiotherapists.

6.2 Budget

Starting this business as a start-up, a budget and a plan for implementation is created. The budget is made from the angle of cooperating with Medei and the research team. The full budget is available in worksheet 43. Salary for the three team members of this project is not considered.

The first step is to finish the product system to be prepared for production. The production will be outsourced. The moulds for plastic and silicone injection should be a Class 104 (100.000 cycles), both the injection moulding and waterjet cutting of the strap could be performed at the production company Protolabs. For metal injection moulding (for the pins), the mould should be a higher class, which is also more expensive. Therefore, an existing mould for a standardized pin should be rented. The total mould investment is 210.400 DKK (Ill. 89.3). Standard components, such as the stickers and magnets, can be provided from many different suppliers. All electrical components that should be mounted to the PCB will be ordered assembled. E.g. this could be through the company PCBCart. Salary for a production employee, who should be hired to assemble the measuring unit and the base unit, is taken into account in the budget. The expenses per piece are 224 DKK (Ill. 89.1). The expenses and mould investment divided on 2500 pieces are 308 DKK per piece.

Parallel with the final specification of the product system, the quality testing and documentation will be performed to get the product system verified as a medical device. This will be in collaboration with the research team and will approximately last 8 months. During the quality verification, the software development of the applications will be performed. This will be done by software developers from Medei, who already have the competencies in relation to the needed calculations. Medei estimates the development time to be around 6-9 months and cost approximately 332.000 DKK for the physiotherapist version, and 205.500 DKK for the client version. Overall this is 215 DKK per piece, when Spíra and

Peak production cost (without mould)	DKK
Measuring device, top	3,63
Measuring device, bottom	3,68
Electronics	100,2
Magnets x2	40,0
Anti Dust Plug USB-C	0,20
Assembly	30,00
Silicone base	14,24
Strap	7,00
Pin with thread	2,04
End pin	2,04
Stickers x100	21,00
Total	**224,01**

Ill. 89.1: Peak production cost (without mould).

Application cost	Cost per unit in house (DKK)	Cost per unit out house (DKK)
Physiotherapist	32,66	436,32
Client	82,20	262,80
Total	**214,86**	**699,12**

Ill. 89.2: Application cost.

Total investment	DKK
Moulds	210.400,00
Applications	537.150,00
Prototyping	15.000,00
Total	**762.550,00**

Ill. 89.3: Total investment.

Medei is cooperating (Ill. 89.2). If the development expenses are too high, the client application can be left out as a start and only focus on the physiotherapist version. In the budget, 63.000 DKK is marked for design of the interface. This job could be performed by the three members of this project, which will lower the price. Including the applications in the price per piece divided on 2500 pieces, the cost price is 523 DKK per piece. Including 15.000 DKK for prototyping the price is 529 DKK per piece. The total investment on 752.500 DKK (Ill. 89.3) is 305 DKK per piece, which is returned when 2500 pieces are sold.

The estimated use of the disposable stickers is around 100 per month per unit. It is considered that half of the physiotherapists, who have bought the product system, will use this amount of stickers. There is a 75% markup on the stickers (Ill. 90.3).

With a sales price on 995 DKK subtracted the production expenses give approximately a 50% markup.

After finished development, a marketing and sales person would be hired to manage the marketing and sales aspects, he/she is expected to have a salary on 35.000 per month. Including the facility expenses, break even will happen in year 2, and in exit year 2 the profit is 1.567.940 DKK (Ill. 90.4), when 2500 pieces are sold. But there are still only one marketing and sales employee in the company, and the team has worked without salary. The operation costs will increase, when the team is getting payed. Likewise, more investment is needed, if there should be a further development and updates of the applications.

Income per sold unit	DKK
Sales price	995,00
Cost price	529,00
Income	**466,00**

Ill. 90.1: Income per sold unit.

Expenses per year	DKK
Marketing/sales employee	420.000,00
Utilities	126.000,00
Total	**546.000,00**

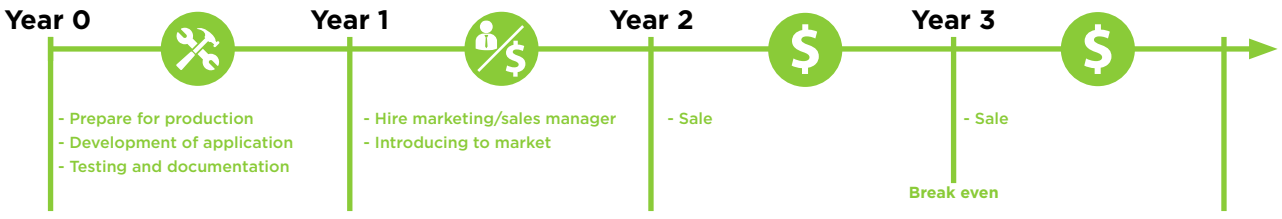
Ill. 90.2: Expenses per year.

Box with 100 stickers	DKK
Production cost	21,00
Sales price	95,00
Income	**74,00**

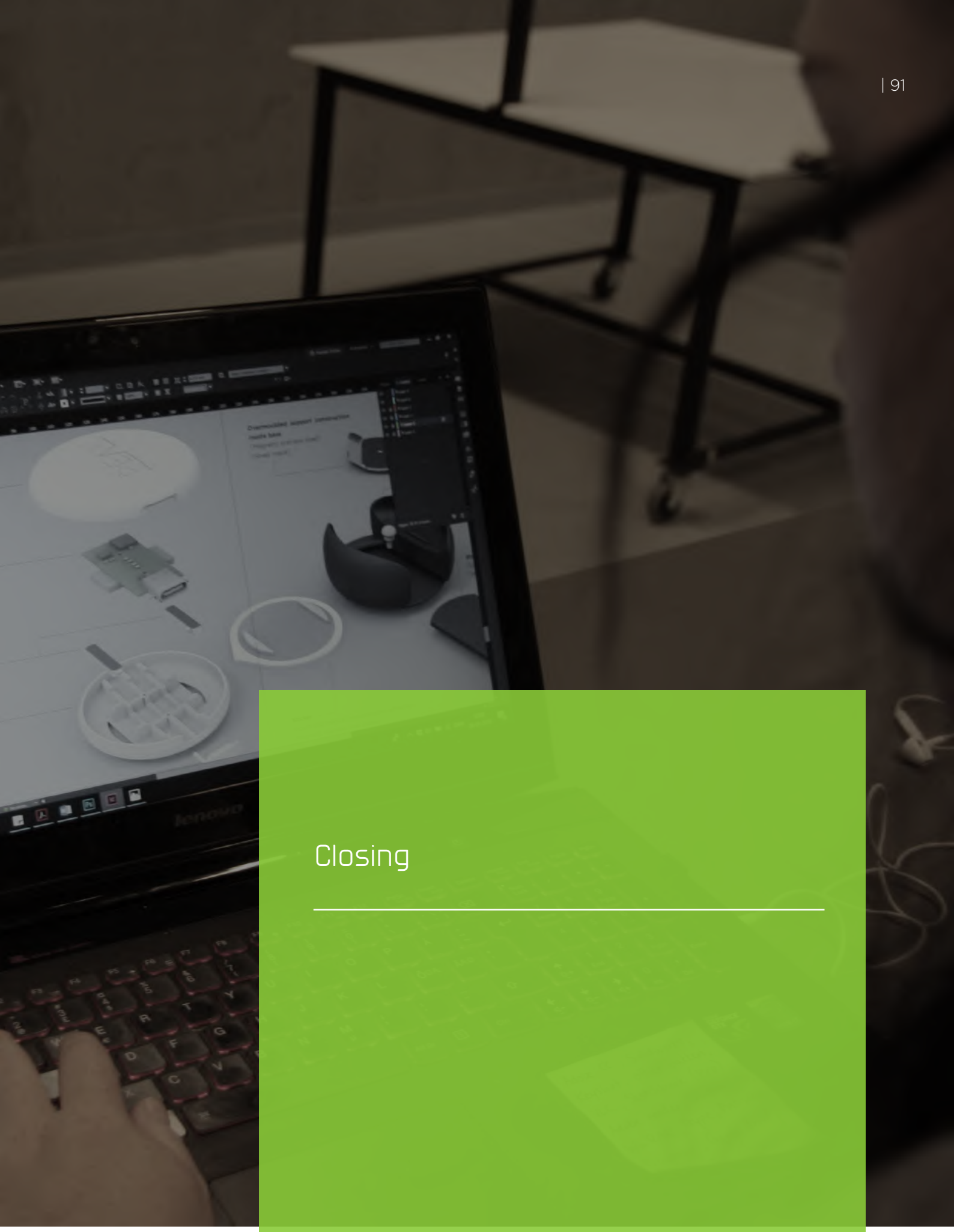
Ill. 90.3: Box with 100 stickers.

	Pieces sold	Income (DKK)	Profit (DKK)
Year 1	500	454.984,90	-154.015,00
Year 2	2000	1.819.940,00	1.567.940,00
Year 3	3500	3.184.894,00	2.743.894,00

Ill. 90.4: Financial business plan.



Ill. 90.5: Implementation-plan.



Closing

Conclusion

The mission of this project is to develop a product system that can provide accurate objective functionality and movement quality data and mediate the data so it is easy to understand both for the physiotherapists and the clients.
The final design proposal is Peak - a medical equipment for rehabilitation physiotherapy that can measure and mediate accurate movement data through the Peak application.

Evaluation of the demands

The final design proposal is evaluated from the requirements listed at p. 37.

Peak is able to measure joint range of motion, acceleration, jerkiness, and joint repositioning, as research show that these can contribute to the clinical picture of an injury, which can lead to a greater treatment. Furthermore, the objective data is digital and is saved on a database always accessible for the physiotherapist, which makes it easy and fast to compare measurements to be able to see the progress.

In relation to achieving a measurement with high accuracy, a 9 axis IMU sensor is chosen as the measuring technology. Tests performed with the development kit lead to insights regarding the accuracy of the measurement. Noise and drift will always appear on IMU sensors. Where they occur and to which extend needs testing. However, these tests will lead to a clear picture of the sensors weaknesses, and can therefore be corrected in the software. It is therefore possible to develop the software on this basis and make the measurements pass the test of having a correlation of higher that 0,75 compared to the gold standard camera system.

By having a modular system with two mounting methods, Peak is able to measure all the movement exercises, and can be adjusted to fit every body part in every size. The stickers are disposable which requires no cleaning and the strap base and the measuring unit is shaped with soft curves and designed in the materials; silicone and hard plastic, which is easy to clean with a wipe within the required timespan of 25 seconds.

The measurement is performed by technology, and to this reason the device is not interacting with the physiotherapist during the measurements. This gives them the opportunity to observe more closely and help the client if necessary. That makes the mounting time the only active action when using the product which is possible to do within the timespan of 30 seconds, only having the interaction steps of mounting the sticker or strap base, and placing the measuring unit.

The data is send to the application, where it is processed and mediated. The application is developed on a concept basis and presented to the physiotherapists to get feedback on, if it is easy to decode. The feedback was very positive, however, the development of the final application will need more testing in relation testing if it is easy to the decode.
The client log contains the possibility of seeing the rehabilitation progress and entering personal goal and pain, as research show that having the possibility to visually see the progress can have a motivational effect.

Regarding the price, production cost including the development of the software for the application is estimated on a price of 529 DKK. The decided sales price is set on 995 DKK, which means that the profit is approximately on 50%. This fulfills the requirement of a sales price under 1000 DKK.

Quality of evaluation

The evaluation of the requirements are hard to completely verify, as some have to be evaluated on a later stage. This, when the final design proposal is carried into reality both regarding software development, production and testing of the final prototype all in relation to the total experience. Tests of the whole product system in the future will therefore create a firmer basis of evaluating the requirements.

Reflection

Product

With much discussion with the scientist physiotherapists in the end of the project, doubts are made whether measurements of the back would be realistic to perform in order to use the data actively. As they point out, back movement is a complex movement that involves many joints, muscles, tendons, and ligaments. To this reason, it is impossible to measure just one joint because back movement also can include movement in the hip. The only back movement where measurements could be relevant is flexion and extension. Also back pain is often not proportional to the functionality, which means that you can have back pain with good functionality, and no back pain with little functionality.

In the beginning of the project it was desired to develop a solution that only consisted of one physical measuring product that could measure all movements. However, all data points that the diversity amongst physiotherapists in relation to preferences, conviction, and budget, amongst some, has different requirements to the solution, as the future cleaning regulations. To this reason, a compromise is made with having two mounting solutions in favor of the ability to measure all movements and meeting the different requirements.

Process

Much time is utilized in the Understand phase because it is in the teams conviction that it is important for a design project like this to have scientific evidence to backup the part solutions in relation to avoid blind spots that could be a deal breaker for the project in the future. Especially, when the product is intended to be launched as a medical device, where evidence regarding the quality of measurement is crucial to the design's survival.

Throughout the design process, mockups is used to test different aspects of the design, which has been an important tool for the development of the design as the models have created insights or problems that has lead to different directions than initially intended.

Work performed in the Detail phase of the development could have had deeper documentation in how they are executed. However, this is deprioritized compared to other important tasks to get the project ready for submission in time.

In relation to exploring the different types of methods for mediating the data, the decision to mediate data through an application was quickly chosen as the method that was most suitable for the project, before thoroughly exploring the alternative methods. From the beginning, the project was based on the foundation that the business strategy should be launching the product as a startup company. Therefore, it was important to choose a solution that required as little as possible in relation to number of items in the product system and the complexity of the development. Furthermore, the product only addresses use in the physiotherapy consultations, where the importance lies in the physiotherapist to focus on the client, and the client to focus on making the movement. Therefore, the mediation of the data should be more discrete and not realtime.

User involvement

From the project start it was desired to put together a user group consisting of variations of physiotherapists and clients. This desire has not been carried into reality to the wanted extend. The survey results represents a wide range of physiotherapists, however, only two physiotherapists have been involved in all iterations of the project. It is a future wish to receive feedback on the final design proposal before examination.

The client perspective has been second priority in the development of the design proposal. Interviews in the beginning pointed that motivation was an important aspect to integrate in a rehabilitation process. Scientific research within this field has lead to features that supported

these overall motivational aspects, not going into detail with the different types of motivation and ideate how to tricker them in the application concept. It is a wish to receive feedback on the client log and design proposal before examination.

Project

The choice of measuring with use of IMU sensor technology was a decision made early in the design process based on the research team's scientific dissertation, where the technology was tested to be accurate, in coherence with an analysis of existing solutions, their setup, cost, functionality, and footprint. This has lead to a fast converging in the solution space, which has resulted in more time and resources released for other aspects of the project. Especially the mounting solution, software testing, and the aesthetic aspects are developed with several iterations within each aspect.

Choosing to develop a measuring device that can measure all movements was risky, because the risk of ending up with a design proposal that was inadequate, due to the huge variety in movements, was present. However, the vision of developing a device with this ability overshined the risk of failing. This is why much time is spend on developing and redeveloping the mounting solution, which ended up with a modular solution, to meet this desire.

Cooperating with both the research team and Medei has created a professional evaluation on the design proposal in its many stages in coherence with guidance when needed. However, the project planning and decisions are based only from the interest of the design team Spíra, in spite of the cooperation partners convictions and opinions.

Perspectivation

This project has focused on the development of a measuring device addressed for physiotherapy rehabilitation, as a medical equipment tool for them to use during consultations. However, there are several possibilities and potential of development in the future. This could be:

- Developing a database that saves all measurement data from all physiotherapists using the product, also normative data from healthy people. This in the attempt to keep all functionality and mobility data, in general, renewed from consultation data and not from research tests only, which are comprehensive to plan and execute. This is of course only an option if the design proposal, when carried into reality, has passed the quality test and can be verified as medical equipment.
- Developing an add-on to the client application, with training program matching their stage in their rehabilitation process. This could be by showing the exercises suitable for their injury, how the exercises are performed and similar.
- Looking in a wider perspective, this technology can be used for all actions where there is a need of tracking a motion. This could be in other scenarios where the requirements of the user scenario is much different. The possibility of this potential in development then leads to finding these scenarios, analyzing the needs to be able to develop a solution that suits these needs.

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Illustrations

2.1	Own illustration
6.1	Own illustration
8.1	Palsson, T., Christensen, S., Thomsen, M. & Hirata, R., 2017. Assessment of Neck Range Motion: Correlation Between a Smartphone-based Application and Gold standard.
8.2	Own illustration (MSKExact Beta)
9.1	https://apexfysio.dk/fysioterapeut-thor-valdur-skuli-palsson/
9.2	https://apexfysio.dk/fysioterapeut-stef-fan-wittrup-christensen/
10.1	Own illustration
12.1	Own illustration
13.1	Own illustration
15.1	Own illustration
16.1	Own illustration
16.2	Own illustration
16.3	Own illustration
19.1	Own illustration
22.1	Own illustration
22.2	https://iaom-us.com/2017/11/14/the-reliability-of-the-cervical-relocation-test-on-people-with-and-without-a-history-of-neck-pain/
23-25.1	Own illustration
26.1	Own illustration
27.1	Own illustration
29.1	https://www.fab-ent.com/evaluation/range-of-motion/baseline-plastic-goniometers/
29.2	Own illustration
29.3	http://halomedicaldevices.com/home/#halo
29.4	Own illustration
29.5	https://www.youtube.com/watch?v=6j9AujM-jLjw
29.6	Own illustration
30.1	https://optitrack.com/motion-capture-movement-sciences/
30.2	https://optitrack.com/motion-capture-movement-sciences/
30.3	http://www.animationmagazine.net/tech-reviews/april-2017-tech-reviews/
30.4	https://bmslab.utwente.nl/fullbodymocap/
31.1	Own illustration
34.1	https://www.freepik.com/free-photo/professional-female-physiotherapist-giving-shoulder-massage-to-blonde-woman_1318976.htm
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