A USER-CENTERED DESIGN OF A HIP-BRACE TO REDUCE TRENDELENBURG GAIT

APPENDICES

Master thesis | Maxine Rietveld | July 2021
Integrated Product Design | Delft University of Technology

APPENDIX A Project Brief

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME
Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: Rietveld 4739
initials: M. G. J. given name: Maxine
student number:
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): ★ IPD ○ DfI ○ SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: ○ Honours Programme Master
specialisation / annotation: ★ Medisign
○ Tech. in Sustainable Design
○ Entrepeneurship

SUPERVISORY TEAM **
Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Toon Huysmans dept. / section: HCD - AED
** mentor: A.L.M. Minnoye (Sander) dept. / section: SDE - MD
2nd mentor: Bram Sterke
organisation: Erasmus Medical Center
city: Rotterdam country: The Netherlands

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Toon Huysmans date 18 - 02 - 2021 signature Toon Huysmans Digitally signed by Toon Huysmans Date: 2021.02.18 09:25:43 +01'00'

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 40 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 34 EC

List of electives obtained before the third semester without approval of the BoE

★ YES all 1st year master courses passed

NO missing 1st year master courses are:

name C. van der Bunt date 22 - 02 - 2021 signature C. van der Bunt Digitally signed by C. van der Bunt Date: 2021.02.22 12:38:15 +01'00'

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: ★ APPROVED NOT APPROVED

Procedure: ★ APPROVED NOT APPROVED

- also approved for Medisign

comments

name Monique von Morgen date 02 - 03 - 2021 signature

Personal Project Brief - IDE Master Graduation

TU Delft

A user-oriented approach to a hip-brace design for Trendelenburg gait — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 16 - 02 - 2021 — 19 - 07 - 2021 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

The Trendelenburg gait results from weakness of the hip abductor muscles. It can occur due to neural injury in the superior gluteal nerve or from muscular dystrophy. This weakness results in an abnormal gait where the pelvis drops during walking. Without treatment, bone pathologies in the hips and knees can occur.

Patients can wear a hip-brace that will improve their walking gait. These hip braces that are used for such injuries or illnesses are obtrusive and cause shear forces between the brace and the skin of the patient.

The thesis from Vugts (2020) from Precision and Microsystems Engineering describes a conceptual design that is compliant and reduces shear stresses between the legs and the brace, which is important for the patients. However, the design is a proof of concept and consists of a mechanical test setting, unable to test on people. Patients mostly need the hip brace to cover short distances around the house, such as from the couch to the kitchen. For longer distances, patients usually use crutches or a wheelchair.
This context creates a specific use environment, thus specific user needs. It is important to map those needs and translate them into a wearable device that is comfortable and achieves the goal to improve the walking gait of patients with Trendelenburg gait within their home environment.

There are a number of stakeholders that have interests and values concerning the design of the product. The patient suffering from Trendelenburg gait being the largest. Wearing a brace should not obstruct other actions during the day, this means that the brace should fit with daily clothes, or can even be worn underneath. Other important stakeholders are the family and friends. When needed, they should be able to help the patient putting the brace on and off.
The rehabilitation doctor is an important stakeholder since he or she needs to be able to adjust and explain how the brace needs to be worn.

An opportunity in this project arises to allow the brace to fit patients of different ages and sizes.
Fitting the body will be an important aspect so using the 3D scanning and modeling techniques the shape of the brace can be determined. Digital fabrication allows for adjustments to be made easily and offers an iterative approach. The development of digital fabrication techniques for producing hip braces is expected to be of importance. The attachment of the brace to the body is a crucial element of the project, it should have minimal shear forces and not be intrusive. The project will investigate attachment possibilities. Usability factors such as how to put the brace on and take it off, and how much adjustability is required, will be important. It will be researched whether a modular system, personalized option, or a sizable brace would suffice for different users.

As an industrial design engineer, it will be important to clearly map the user needs and requirements to make sure they will be met in the design of the hip-brace. This could imply that Vugts' technology will not play a large role in the design of the brace for the specific home usage environment.

However, it is possible that the working principle of the hip-brace cannot be tested because there is a limited amount of time available for this thesis. It is up to the user research, however, to determine whether a complex working principle is needed for the hip-brace. In the event that a complex system is necessary, I will ensure that all other aspects can be assessed independently of the brace's working principle.

space available for images / figures on next page

Initials & Name M. G. J. Rietveld 4739 Student number 4347862

Title of Project A user-oriented approach to a hip-brace design for Trendelenburg gait

introduction (continued): space for images

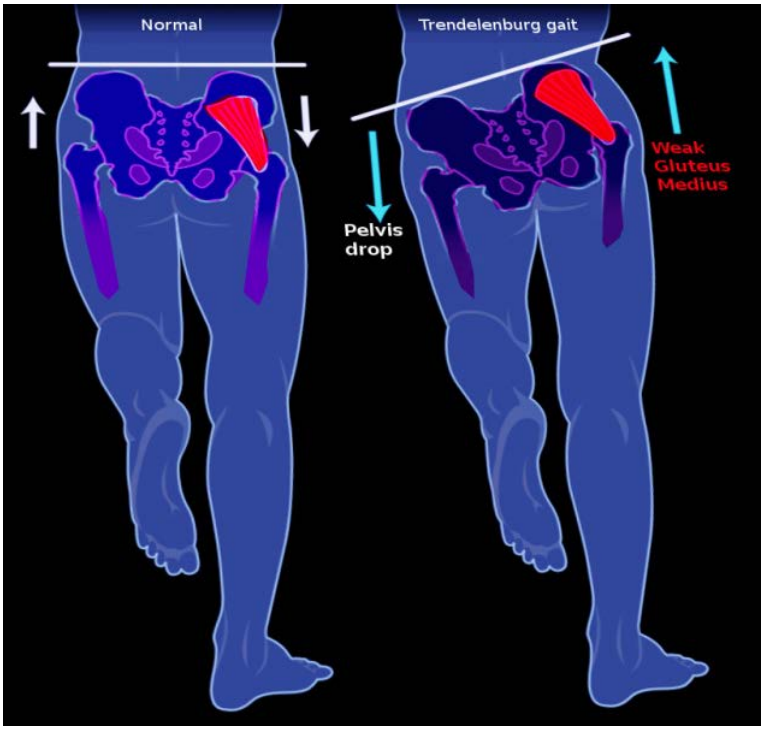


image / figure 1: Image 1: Trendelenburg gait (Bhimji, n.d.)

image / figure 2: Image 2: Braces in the market today (Orthomerica, n.d.)

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

To create a wearable product that is comfortable, provides support, and meets the patients' needs such as an unobtrusive appearance and does not interfere with other activities. Large braces usually don't get worn, since they are inconvenient and obtrusive. The wearable should fit in the desired context. Attention to the attachment to the body is an important aspect, minimal shear stresses between the brace and the skin of the patient

Key aspects from this project include usability, interaction between user and product, the attachment to the body and the overall integration of the product, looking at materials, the frame and shape and how to create a product for different users.

Usability is important since the brace should be worn at home and therefore put on and off by the user themselves or their partners. Creating an understanding of what is important for them in terms of usage and their capabilities will create a product that is comfortable and can be used in the desired situation.

The attachment of the brace will also be a main aspect of this project. The problem of shear forces between braces and the skin of the patients is something that should be avoided. This requires a specific shape of the frame that is attached to the body.

The possibility of implementing a complex working principle will not be included in the scope.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

To create a wearable product that will improve walking gait in the personal environment, taking into account the interaction and the user's needs, focussing on the attachment to the body. The functionality described in Vugts' thesis (2020) is considered as technological background information.

In this project, a brace will be designed using the needs of the user as a starting point. Physical ergonomics and usability will be considered. The product will fit the user's body and reduce shear stresses between the brace and the skin of the patient. It will improve the walking gait in the home environment. Vugts' thesis provides a technological foundation but can be left out if user research proves it unnecessary. The conceptual design is at technology readiness level (TRL) 3; experimental proof of concept. By re-evaluating the relevant drivers in the user environment, I will be able to achieve a higher TRL for certain sub-systems. The sub-systems responsible for putting the brace on and off and the attachment to the body can be aimed at TRL 6; technology demonstrated in relevant environment/context. However, the working principle system of the result can be at a TRL of 3.

The product will be a class I medical device, so appropriate design measures must be documented and tests must be executed in its future development.
The intended outcome of this project will be a model (models) that can be worn or used by people, and its usability aspects will be tested on its functional quality. Comfort and the attachment to the body will be able to be tested with this prototype. Tests will be done with either patients or healthy participants depending on the type of test. The result will be a prototype that validates, comfort and usability and part of the mechanical functional properties. Due to the fact that the brace will be further designed after the end of this project, obtaining a complete, functional, and aesthetically sound prototype may not be feasible, depending on the complexity of the working principle.

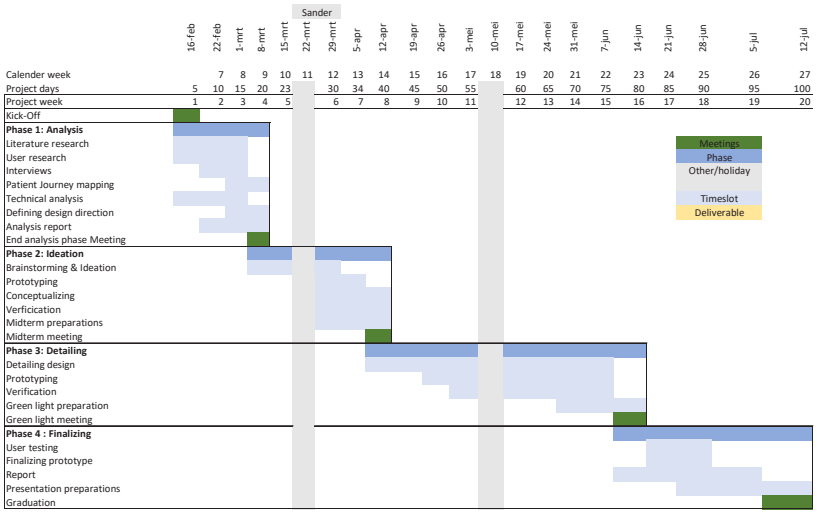
Initials & Name M. G. J. Rietveld 4739 Student number 4347862

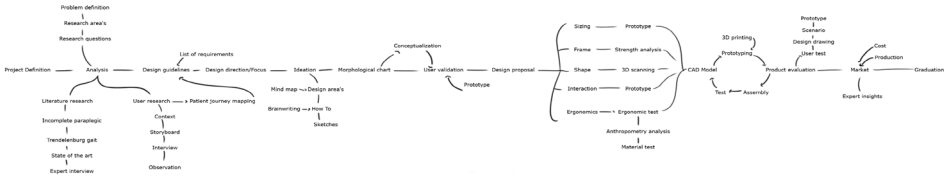
Title of Project A user-oriented approach to a hip-brace design for Trendelenburg gait

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 16 - 2 - 2021 19 - 7 - 2021 end date





The phases represent major activities, but the process itself is not linear. In between activities iteration processes will take place.

In the Gantt chart planning, several activities will be displayed. During the analysis phase, mind maps will be used to identify all the different aspects of the hip-brace. In the user research phase, methods such as interviews and patient journey mapping are used to identify the user needs and the stakeholders' needs. In the ideation phase, methods such as brainstorming and creating a morphological chart will be applied. In between the activities, methods like prototyping and product usability evaluations are used to iterate.

The Gantt chart will also indicate when the deliverables are to be completed.
The activities shown in the gantt chart are meant to accomplish the deliverables. At the end of each activity, a deliverable will be finished.

These deliverables include: insights from literature and user research, interview insights, list of requirements, scenario sketch, patient journey map, design direction, design area's, idea sketches, quick prototypes, morphological chart, concept sketches, models, CAD model, test evaluations, redesign opportunities, user test setup, ethics applications, models, presentations (midterm, green light, graduation) and a graduation report.

Initials & Name M. G. J. Rietveld 4739 Student number 4347862

Title of Project A user-oriented approach to a hip-brace design for Trendelenburg gait

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I have been interested in healthcare for a long time, and my passion for medical design has grown since I graduated from the bachelor of industrial design engineering. I am fascinated by the human body and would like to design a product for people with disabilities or needing rehabilitation to be able to perform their daily tasks again.

In my masters program I focused on translating user desires into feasible and tangible product solutions; for example, to design a game controller for boys with Duchenne muscular dystrophy it was very important to get to know the user.

Other courses have been quite useful such as rules and regulations for designing medical devices. Because this product is a Class I medical device and will need to be tested on patients in the future, it is important to document every step and choice that has been made.

In this project there is a possibility to acquire new competences. Surface modelling will be a competence I will need and want to improve since the brace will have to fit the body properly.
In addition to that, I will analyse the human body in more detail, especially the area of the hip-brace connection. My interest in rehabilitation and design for rehabilitation can come to life in this project.

Due to the COVID regulations, a possible limitation to this project is the difficulty of accessing and testing with patients. However, I will do my best to include patients in the process as best as I can, online or from a safe distance.

References

Bhimji, S. (n.d.). Trendelenburg gait [Image]. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK555987/figure/article-30568.image.f1/

Orthomerica. (n.d.). Newport 3 Hip Orthosis [Image]. Retrieved from https://www.rehabmart.com/product/newport-3-hip-orthosis-40400.html

Physiopedia. (n.d.). Trendelenburg Gait. Retrieved 26 January 2021, from https://www.physio-pedia.com/Trendelenburg_Gait

Vugts, P. (2020). Conceptual design of a compliant hip orthosis for Trendelenburg gait | TU Delft Repositories. Retrieved from https://repository.tudelft.nl/islandora/object/uuid:c9382334-8ff9-49a0-98ee-16d378a010b0

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name M. G. J. Rietveld 4739 Student number 4347862

Title of Project A user-oriented approach to a hip-brace design for Trendelenburg gait

APPENDIX B Anatomical terms

Location

Medial	Near to the median plane of the body
Lateral	Far away of the median plane
Posterior (Dorsal)	Near the back surface of the body
Anterior (Ventral)	Near the front surface of the body
Inferior (Caudal)	Near the soles of the feet
Superior (Cranial)	Near the top of the head
Proximal	Closer to the point of attachment
Distal	Farther from point of attachment
External (Superficial)	Close closer to the surface of the body
Internal (deep)	Farther away from the surface of the body
Bilateral	Paired structures on left and right
Unilateral	Structures on one side of the body
Ipsilateral	Structures occurring on the same side of the body
Contralateral	Structures occurring on opposite sides of the body

Movements

Flexion	Decreasing the angle between parts of the body
Extension	Straightening or increasing the angle between parts of the body
Dorsiflexion	Movement of ankle joint when raising the toes
Plantar flexion	Movement of ankle joint when foot stands on the ground
Abduction	Movement away from the median plane
Adduction	Movement towards the median plane
Circumduction	Circular movement combining: flexion, extension, abduction and adduction
Rotation	Rotation around longitudinal axis
Medial rotation	Rotation towards the medial plane
Lateral rotation	Rotation away from the median plane
Opposition	Movement that brings the pad of the thumb to the pad of another finger
Reposition	Movement from opposition back to anatomical position
protrusion	Anterior movement
Retrusion	Posterior movement
Protraction	Anterior movement of shoulder
Retraction	Posterior movement of the shoulder
Elevation	Raising body part or or superior movement
Depression	Lowering or inferior movement
Eversion	Turning laterally (away from median plane)
Inversion	Turning medially (facing median plane)
Pronation	Movement of forearm that palm faces posteriorly
Supination	Movement of forearm when palm faces anteriorly (towards anatomical position)

APPENDIX C Joints

Hip

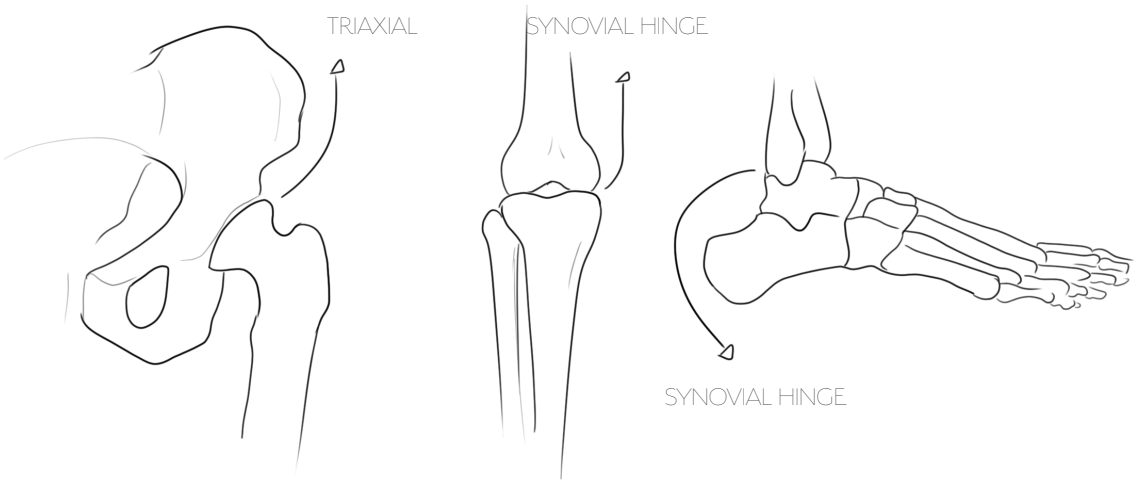
The hip bone consists of three bones, the ilium, ischium and pubis, which together make the left or right innominate bone. The acetabulum is the concave surface of the pelvis. The pubic symphysis acts as a cartilaginous joint. While walking or running it can act as suspension (Akhtaruzzaman et al., 2016). The acetabulum forms a socket that holds the head of the femur, creating the hip joint. The femur is the largest bone in the body. The orientation of the acetabulum has a direct influence on the mobility of the hip. Orientation of the human body is determined by the position and alignment of these two individual bones. The hip joint is a ball and socket or triaxial joint. This means that the hip joint can account for three degrees of freedom. This allows triaxial movement of the lower limbs.These triaxial movements can be categorized by flexion, extension, abduction, adduction, medial rotation, lateral rotation and circumduction.

Knee

The knee joint (tibiofemoral joint) can be described as a synovial hinge joint. It allows only one degree of freedom, flexion and extension of the knee.

Ankle

The ankle joint is also known as a synovial hinge joint. There are three bones at the joint, two from the leg, the fibula and tibia, and one from the foot, the talus. It provides the movement plantar and dorsiflexion. Other joints in the foot provide the movement of inversion and eversion.



APPENDIX D Calculations

Calculations force hip

Calculating rg

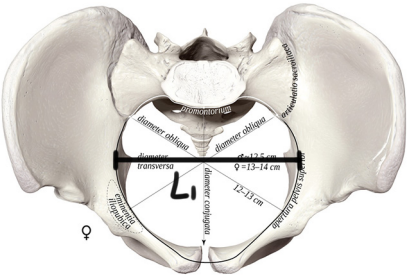
Measurements are taken from from Anatomy Standard 2019–2021 (2020) with for L2 a measurement of 24 cm and for L1 a measurement of 13cm.

$$L2 - L1 = 2x \quad (1)$$

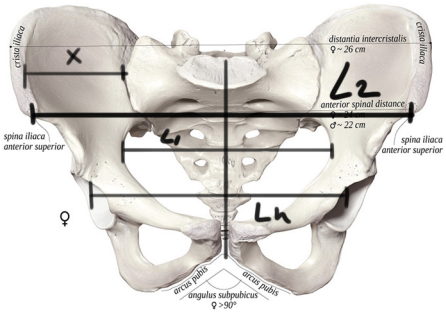
$$L1 + x = Lh \quad (2)$$

$$dh = \frac{Lh}{2} \quad (3)$$

$$rg = \frac{L1}{4} + \frac{L2}{4} \quad (4)$$



Anatomy Standard



Anatomy Standard

The measurement dh is defined as 9,25cm. Since COM shift is approximately 2 mm, rg is defined as 72,5 mm (dh - 2 cm).

Assuming one would be in a balanced single limb stance.

$$\Sigma F = 0 \quad (5)$$

$$\Sigma M = 0 \quad (6)$$

$$F1 \cdot r1 = Fg \cdot rg \quad (7)$$

Example 1

A woman who weighs 58 kilograms and whose r1 measures approximately 73 mm, Fg is approximately 80% of the entire body weight as one leg is still standing on the ground. The height of the application of the force on the body is approximately 15mm, the force needed to keep the pelvis up is 225,8 N.

Example 2

When the height of the application of the force increases for the same women, the force needed to keep the pelvis up is approximately 135,3 N.

r1 = 0.24 m
rg = 0.07 m
F1 = 135, 3 N

APPENDIX E Sensitizing Booklet

Invul 'Boekje'

Afstudeerproject Maxine Rietveld
Technische Universiteit Delft

2

Hallo!

Mijn naam is Maxine en ik studeer Integrated Product Design aan de Technische Universiteit Delft. Ik ben bezig met mijn afstudeerproject. Ik ben erg geïnteresseerd in het ontwerpen van medische producten.

In dit afstudeerproject wil ik een heupbrace ontwerpen die thuis gedragen kan worden. De heupbrace zal bedoeld zijn voor mensen die moeite hebben met lopen door zwakke heupspieren of door een heupoperatie. Maar om een ontwerp te maken dat ook echt werkt en gedragen wordt heb ik meer informatie nodig over jouw dagelijks leven.

Dit is een onderzoeksproject en bevindt zich nog in het beginstadium. Deze informatie kan waardevol zijn voor het ontwerp van de heupbrace, maar er zal meer onderzoek gedaan moeten worden voordat de brace echt ontwikkeld kan worden. Het ontwerp dat uit dit afstudeerproject komt, zal nog niet bruikbaar zijn.

In dit boekje zal ik een aantal vragen stellen en zal ik je vragen om jouw dag te beschrijven. Aan het eind komen er nog wat afsluitende vragen over het gebruik van producten.

Na het invullen van dit boekje zou ik het graag met je willen doornemen en wat laatste vragen stellen.

Mocht er iets niet duidelijk zijn of heb je nog vragen voor mij, stuur mij dan een mailtje!

m.g.j.rietveld@student.tudelft.nl

Hartelijk dank!

Mijn leeftijd: 35 jaar

Mijn werk: Auto verkoper

Mijn hobbies: fietsen, varen, Auto's

Ik woon met:

Waarom ik revalidatie nodig heb:

JOUW DAG

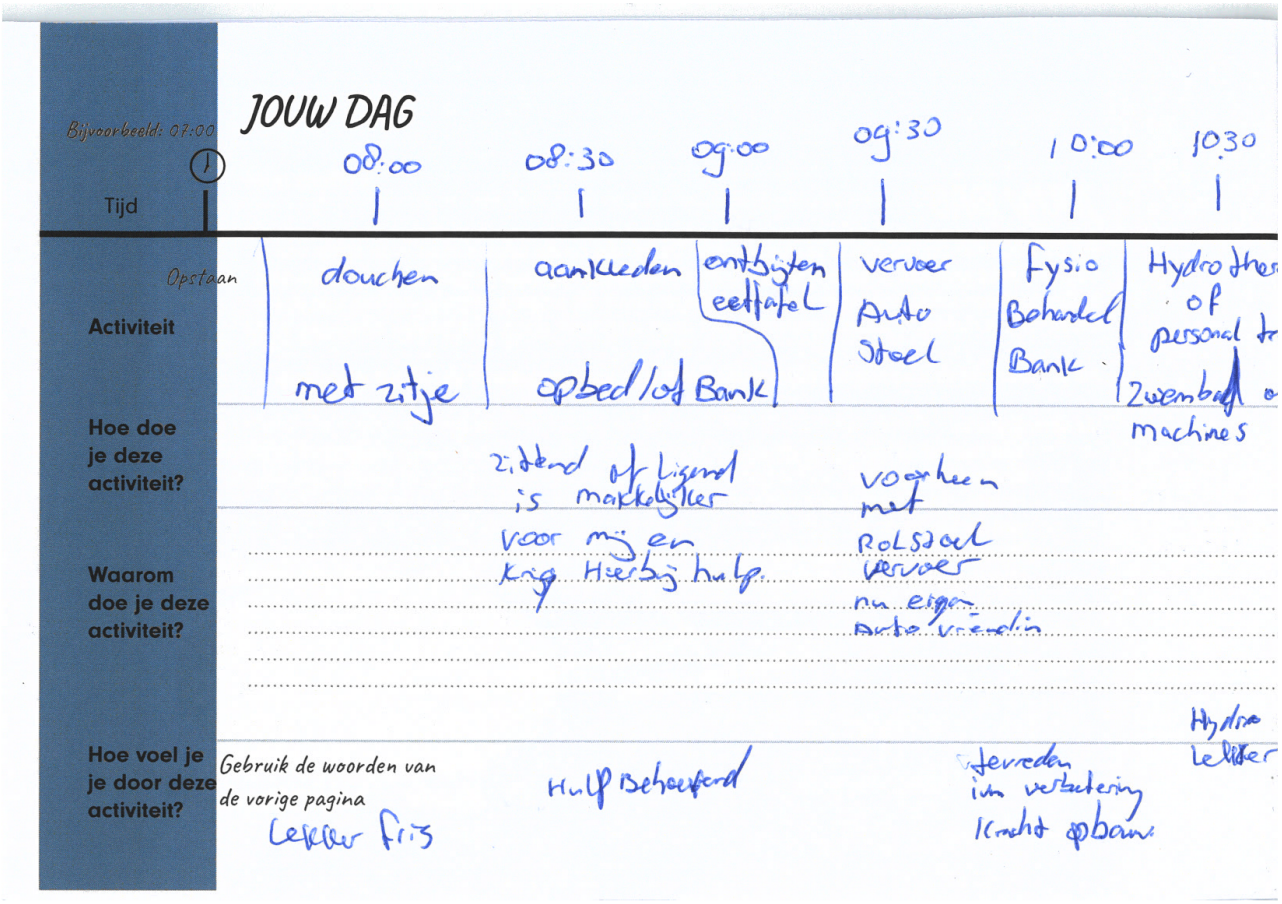
Op de volgende pagina kan je je dag invullen. De lijn die op de pagina staat is de tijdlijn van je dag, met links wanneer je wakker wordt en helemaar rechts wanneer je gaat slapen. Onder deze tijdlijn staat een tabel waar in je een aantal dingen invult. Bij activieiten kan je denken aan, koffie zetten, ontbijt maken, tv kijken, boodschappen doen naar werk gaan, aan bureau zitten, etc.

Als je gister niet veel activiteiten hebt gedaan kies dan een dag waarbij dit wél het geval was.

Vul vervolgens in:
- Van hoelaat to hoelaat je dit doet
- Welke activiteit dit is
- Hoe je deze activiteit doen (staand, zittend, in rolstoel, op de bank of stoel, in de auto, met de bus etc.)
- Waarom doe je deze activiteit
- Hoe voel je je tijdens deze activiteit

Gebruik deze woorden

Trots	Tevreden
Bewondering	Verlangen
Vreugde	Fascinatie
Schaamte	Angst
Minachting	Woede
Verdrietig	Walging
Hoopvol	Verveling


JOUW DAG
Bijvoorbeeld: 07:00
Tijd
08:00
08:30
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Activiteit
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Stoel
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Hoe doe je deze activiteit?
Zittend of Liggend
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met
Rolstoel
vervoer
nu eigen
Auto vervoer
Waarom doe je deze activiteit?
Hoe voel je je door deze activiteit?
Gebruik de woorden van de vorige pagina
Lekker fris
Hulp Behoefte
tevreden
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kracht opbouw
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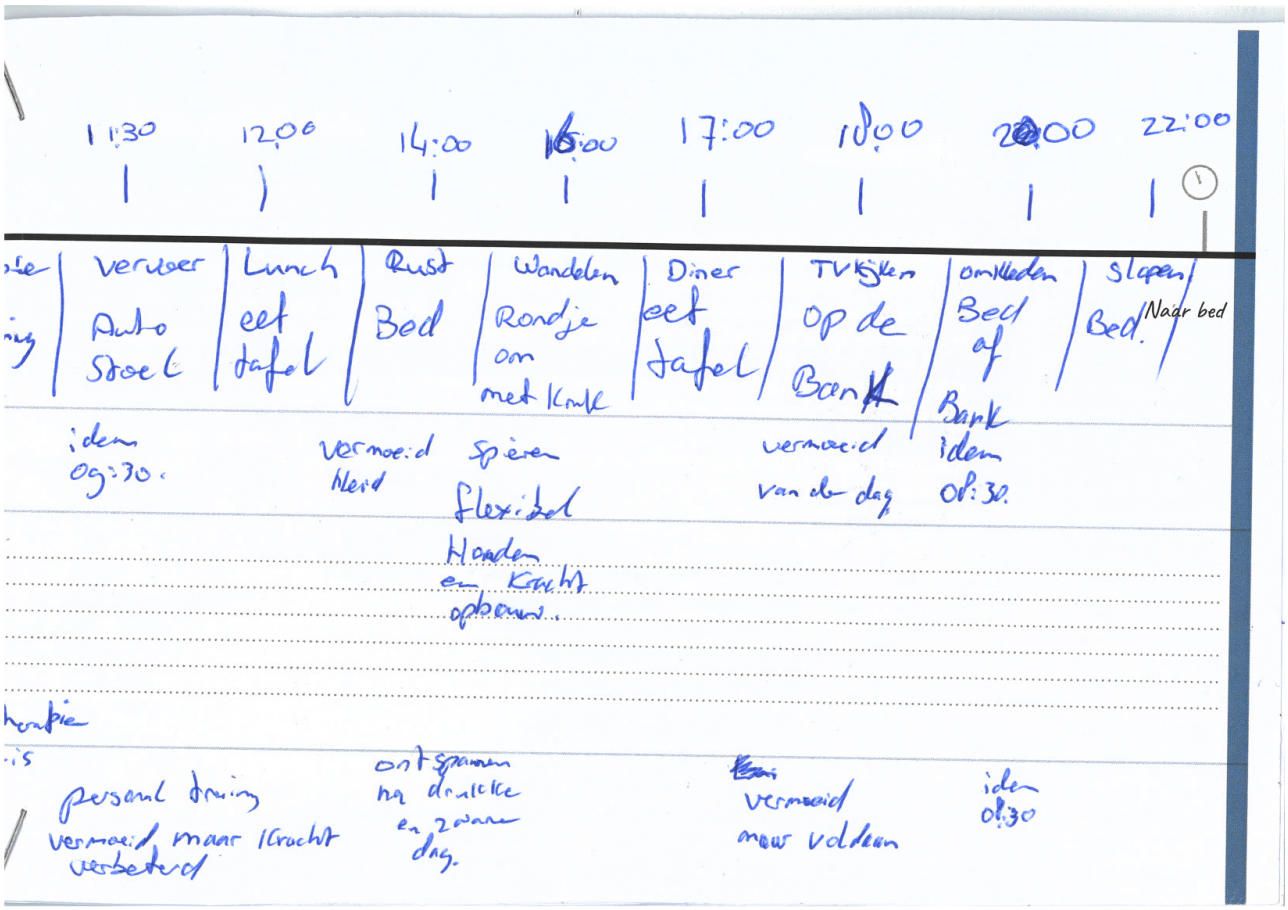
Lekker


11:30
12:00
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om
met Rollat
Diner
eet
tafel
TV kijken
op de
Bank
omkleden
Bed af
Bank
Slapen
Bed
Naar bed
idem
09:30
vermoeid
Moet
Spieren
flexibel
Houden
en Kracht
opbouwen
vermoeid
van de dag
idem
01:30
Therapie
Personal training
vermoeid maar Kracht
verbeterd
ontspannen
na drukke
en zware
dag.
vermoeid
maar voldaan
idem
01:30

Producten

Welke producten gebruik gebruik je in het dagelijks leven?
Vul op de volgende pagina de vakjes in welke producten je gebruikt, denk bijvoorbeeld aan hulpmiddelen zoals krukken, rolstoel, fiets, wandelstok etc.

Kies minstens een positief en een negatief product en omschrijf ze aan de hand van de woorden die hier onder staan.

Leg vervolgens uit waarom je zo over dit product denkt en hoe jij denkt dat het product verbeterd kan worden!

Er zijn geen foute antwoorden!

Trots	Tevreden
Bewondering	Verlangen
Vreugde	Fascinatie
Schaamte	Angst
Minachting	Woede
Verdrietig	Walging
Hoopvol	Verveling

Jouw producten

	Product 1	Product 2	Product 3	Product 4
Product	Kruk(ken)	Rolstoel	Brace	~~Krukken~~ electro Step.
Hoe denk je over dit product?	positief tevreden lichte minachting	wisselend positief negatief schaamte	positief + enkele negatieve ervaring	positief fascinatie vreugde
Waarom?	Helpt enorm, makkelijk in te klappen	Helpt zeker enorm bij mee iedereen kijkt je na en soms vragen.	Helpt enorm, om veel afstanden (Klapwiel) enorm in het zicht met korte Broek	enorme Vrijheid Geen minderwaardig gevoel. nog niet Bekend Bij politie Qm Regelgeving
Hoe kan dit product verbeterd worden?	niet is uitbedachten en ontwikkeld mijn Kruk is Licht v.. Carbon en inklapbaar.	Lichter maken ipv zoveel inklapbaar evt. Lichtere.	Denk dat deze uitbedacht is evt iets slimmer?	Denk dat deze uitbedacht is

APPENDIX F List of requirements

1. Functionality
1.1 The brace must be worn
1.2The brace must allow the walking gait
1.3 The brace must allow the user to walk without additional assistance products
1.4 The brace provides pressure on the side of the hip
1.5 The brace reduces the amount of dropping of the pelvis
1.6 The brace must allow hip flexion of 150 degrees
1.7 The brace mst allow hip extension of 15 degrees
1.8 The brace must allow hip abduction for at least 40 degrees
1.9 The brace will prevent adduction of the hip muscles on the affected side
1.10 The brace must keep the pelvis up during ambulation
1.11 The support around the hip and leg can be worn while sitting

2. Performance
2.1 The brace must allow tightening of the support
2.2 The hip support must support at least 23 - 40% of the total body weight (Technology analysis)
2.3 The brace can be attached and detached within 2 minutes (User research)
2.4 Shear forces between the skin and the brace should be as low as possible
2.5 The brace can operate between the temperatures of -10 and 40 degrees Celsius

3. Ergonomics
3.1 Should fit the shape of the body
3.2 The brace must be able to be attached and detached by the user themselves
3.3 The hip support should fit the shape of the hip of the user
3.4 The leg support should fit around the thigh of the user
3.5 The tightness of the hip and leg support must be adjustable by the user
3.6 The brace should not force the user to over-exercise
3.7 The brace should fit the hip and legs of the patient
3.8 The brace should be as light as possible
3.9 The partner/family is able to attach and detach the brace
3.10 The brace should not accumulate moist
3.11 The brace should not apply pressure from a hard surface to a bony surface
3.12 Soft layers on the brace should prevent high pressure on bony surfaces

4. Production
4.1 Should be produced by orthopedic instrument makers

5. Safety (MDR)
5.1 Attaching and detaching the brace must be intuitive and easy to understand
5.2 Adjusting the brace can be done without prior knowledge of usage

6. Size and measurements
6.1 Near moving parts of the body such as the upper arms and inner thigh, the protrusion should not be more than 10mm.

7. Sustainability
7.1 Product materials should be detachable to allow easy reparation
7.2 Materials of the brace should be gained from the Netherlands

8. Product experience
8.1 The aesthetics of the brace should make the user feel empowered
8.2 The brace should not be associated with a medical device
8.3 The aesthetics should invite the patient to wear the brace
8.4 Attaching the brace should fit into the morning routine
8.5 Putting on the brace should feel like putting on a piece of clothing

Wishes
After talking to experts and actual users, user wishes are established. These wishes can be use d in the concept selection process.
- Slim fit
- Comfortable during usage
- Easy to use in the process
- Providing support
- Unobtrusive appearance

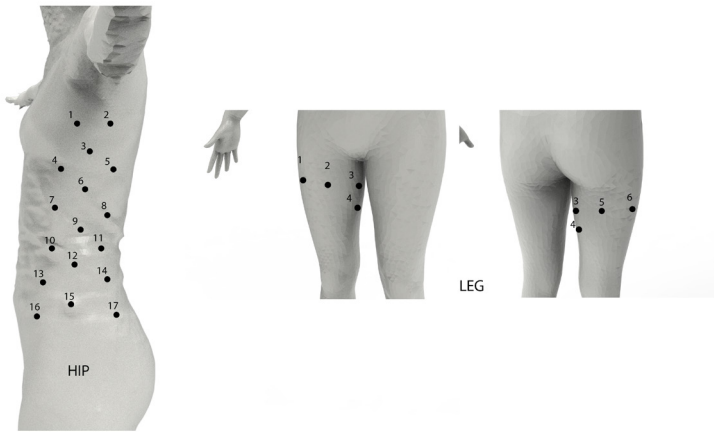
APPENDIX G SENSITIVITY STUDY

Test Plan
Study of the differences in sensitivity around the hip and upper leg

Research questions:
- Is there a relationship between sensitivity and specific body parts?
- Is there a relationship between age and sensitivity?
- What areas are more sensitive than others?
- Is there a relationship between body measurements and sensitivity?

Method
The purpose of this test is to determine the differences in sensitivity around the hip and leg.
To place the force gauge, a shape with holes will be used. The pressure will be increased until the participants experience less comfort.

Apparatus
3D shape of hip support with holes
3D shape of leg support with holes
Force gauge
Laptop
Measuring tape



Participants
A total of 8 participants will be used to evaluate the pressure sensitivity around the hip and leg. 4 female and 4 male with ages between 23 to 60.

Procedure
The participants' informed consent is gathered to be able to collect data. After which the anthropometric data will be collected. The data is stored in an excel file.
The hip support will be placed on the side of the participants' bodies. With velcro strips the support is held into place. The participants are asked to stand. As the force gauge is positioned in the right hole, the pressure will increase. Each point is measured three times due to the habituation effect of the first test as the participant will get used to the pressure.
After measuring three times the leg sensitivity will be measured.

Data collection
The value of the force gauge when the pressure starts to create discomfort is noted in an excel file.
This data will be transferred to the program SPSS.

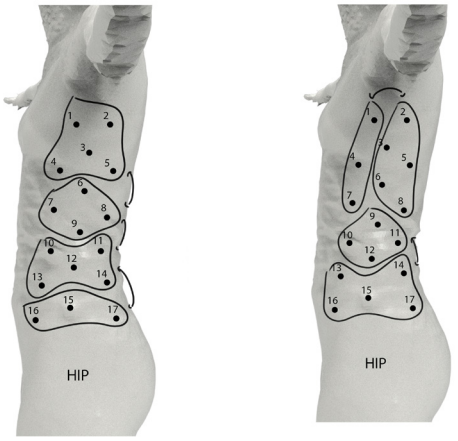
Age
BMI
Anthropometric data
Chest circumference
Hip circumference
Waist circumference
Thigh circumference
Qualitative data about exercise habits

Data analysis
The mean values of the locations are grouped to calculate whether certain areas are significantly more sensitive than others.
Mean values of all locations for each participant to calculate correlations between
anthropometric data and sensitivity
age and sensitivity is also measured.
gender and sensitivity is also measured.

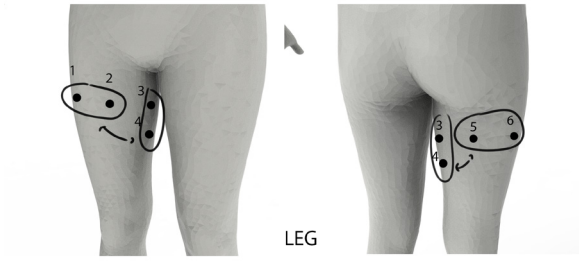
Results
Sensitivity range differences
There was a large difference in range for the experienced (dis)comfort. For a location with relatively high sensitivity, one participant reported

less comfort at 6.1N while for another participant 30.1 N was reported for the same point.

Hip sensitivity
Measurements show that some areas are significantly more sensitive than others. The upper area of the ribs show to be more sensitive than below. The front side of these ribs are also significantly more sensitive than in the back. The area around the pelvis is significantly less sensitive than above (r=0.021).



Leg sensitivity
The medial side of the thigh (inner side) was reported significantly more sensitive than on the lateral side of the leg. r=0.007 for the front and r=0.002 for the back.



Sensitivity and age, gender BMI and exercise habit

The mean of the hip and leg sensitivity values was calculated and the correlation between age was calculated.
There is no significance between the circumference and the sensitivity around the hip or leg.

Relationship between sensitivity and exercise habits
No relationship between sensitivity and exercise habit could be found.

Conclusion
According to the sensitivity test, certain areas, such as around the ribs, are more sensitive than for instance around the pelvis.From the analysis it can be concluded that the ribs and especially on the front side are significantly more sensitive than in the back.
There was significantly less sensitivity in the area surrounding the pelvis. Most of the participants were able to withstand high forces around the pelvis.

Discussion
Due to the low number of participants, the correlations between age, gender, BMI and exercise habit could not be calculated. The correlation calculated is not significant which could be possible, however due to the limited number of participants, this can not be concluded.

The distribution of ages is not a normal distribution. The mean age is 33,5 while the median is 25,5. This means a correlation between age and sensitivity could not be calculated.

The types of clothing the participant wore can have an impact on the amount of sensitivity. In some of the measurements, the participants wore their normal daily clothing such as jeans since they were measured at the faculty of Industrial Design Engineering.

The shape with holes was to make sure the location of pressure was roughly at the same location for all participants. However, the shape fits each body differently which can create a difference in location. Nevertheless, by calculating the means of the areas, an estimation could be made about the significance of sensitivity difference.

Another influence of the test was that the participants were asked to indicate when the

pressure was becoming 'not comfortable'. This is a relative term and hard to measure. Participants had no problem indicating discomfort at the ribs, but the pressure in the stomach could increase significantly, and the participants were not always aware of what they were experiencing. They often felt pushed away rather than uncomfortable.

Despite this, even though these results can not directly indicate what comfortable is, they can provide an idea of which areas are more sensitive and provide useful insights into where pressure can be applied.

APPENDIX H Motion lab test

Goal

Experience

The experience will be tested to gain knowledge on the interaction with the product. The experience will be observed and design characteristics will be defined based on shape and use. The ease of use will be tested and improvements to the design based on the interaction while putting the brace on and taking it off will be outlined.

Fitting

With the use of the markers and the infrared cameras the position of the brace relative to the body can be measured during specific movements. This way the fitting of the brace can be determined when forces act on the brace.

The results of this test will give an indication whether parts need to be redesigned or that they will need to be personalized. Since the design will be based on the measurements of one participant, it can be determined which parts will need to be customised and which parts can be generalized.

(Dis)Comfort

Comfort is an important driver for the design of the brace. A comfort measurement will be used to identify the design improvements that need to be made. As the force being exerted on the hip will be relatively large, it is important that the pressure distributed over the hip is perceived as comfortable. Design improvements will need to be made based on the location of discomfort.

Research questions

Experience

Will the product be used as expected
What are unexpected actions
What behaviour was unexpected
Is the design intuitive

Fitting

How does the brace move relative to the body under pressure
How does the brace move relative to the body when walking
How does the leg support move relative to the body when torque is applied
Which parts need to be personalised
What measurements are necessary
Which parts can be generalised

(Dis)Comfort

Which locations of the brace are described as discomfortable
Why are these locations described as discomfortable
What force is considered uncomfortable

Method

For these tests, one hip brace prototype will be used to measure the experience, fitting and discomfort. A use scenario will be compared to the actual use to evaluate the experience. Markers on the brace and body will measure the fitting of the brace under various circumstances and subjective perceived discomfort is measured after wearing the hip brace.

Apparatus

Storyboard
Hip support
Leg support
Markers
Chair
Laptop
Camera
Questionnaire for perceived discomfort (3 per participant, 2 hip and 1 leg)
Questionnaire for experience
Force gauge

Participants

Four participants with relatively different body shapes will be used. In the test, 2 men and 2 women participate. The participants do not have any walking difficulties due to weakened hip muscles. Prior to the test, measurements such as the stature, hip and waist circumference have been gathered.

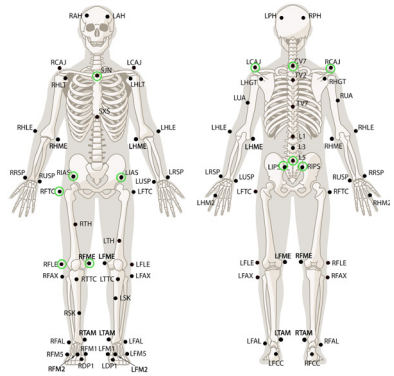
Test protocol

The informed consent is gathered from the participants, additional questions are answered.

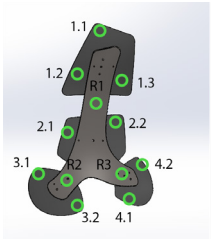
Experience: The participant is asked to put on the brace themselves. One participant is given the brace without further instructions. This is done to evaluate how intuitive the design is. For the other participants, small explanations are given to how

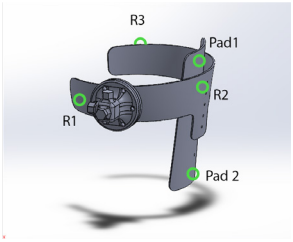
the brace must be worn, however no further help is given when they are putting the brace on.

Fitting: When the brace is correctly worn markers will be placed on the body and brace. The first markers will be placed distal to the trunk of the body to let the participants get used to the touch and to prevent discomfort.



(Biomechanics Markersets - NaturalPoint Product Documentation Ver 2.2, n.d.)





As soon as the countdown has completed, the trigger will be pressed to initiate the video/marker capture.

Capture:

- A pulling force is applied on the wire

Force will be increased until participants indicate that the pressure is becoming uncomfortable. The force is documented.

- Walking

Tightness controlled by the user, tight but comfortable.

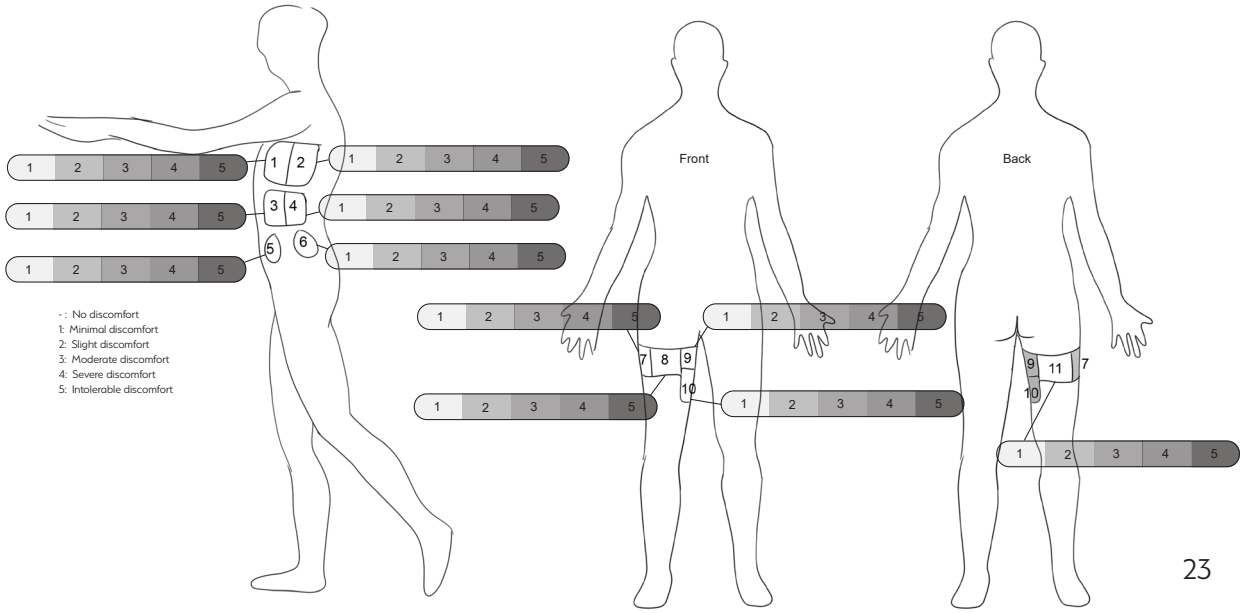
- Participant sitting on chair and pulling the wire with force gauge

Until the participant indicates that holding the spine straight is too difficult, that it requires too much back force.

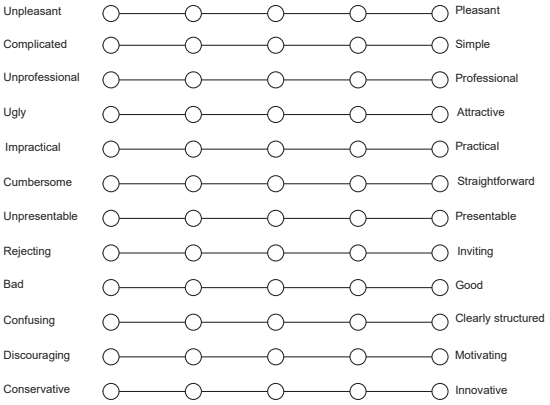
- Torque applied on leg support

Once the recording is done, the markers are removed from the brace and body.

Discomfort: After each recording / measurement (pulling, walking and torque), participants fill out a questionnaire with a visual-analogue scale to indicate their level of discomfort. The level of discomfort at each location for every situation will be rated. A visual-analogue scale will be used.



Experience:
After taking off the brace, the participants are asked to fill out a questionnaire concerning the experience of putting on, adjusting and taking off the brace.
The method that is used for this evaluation is based on the Attrakdiff questionnaire. This method has been chosen because it can evaluate how the users or potential users experience the product or prototype. Since ease of use is a design driver for this project, it is important to know what kind of experience the product gives the user at this moment.

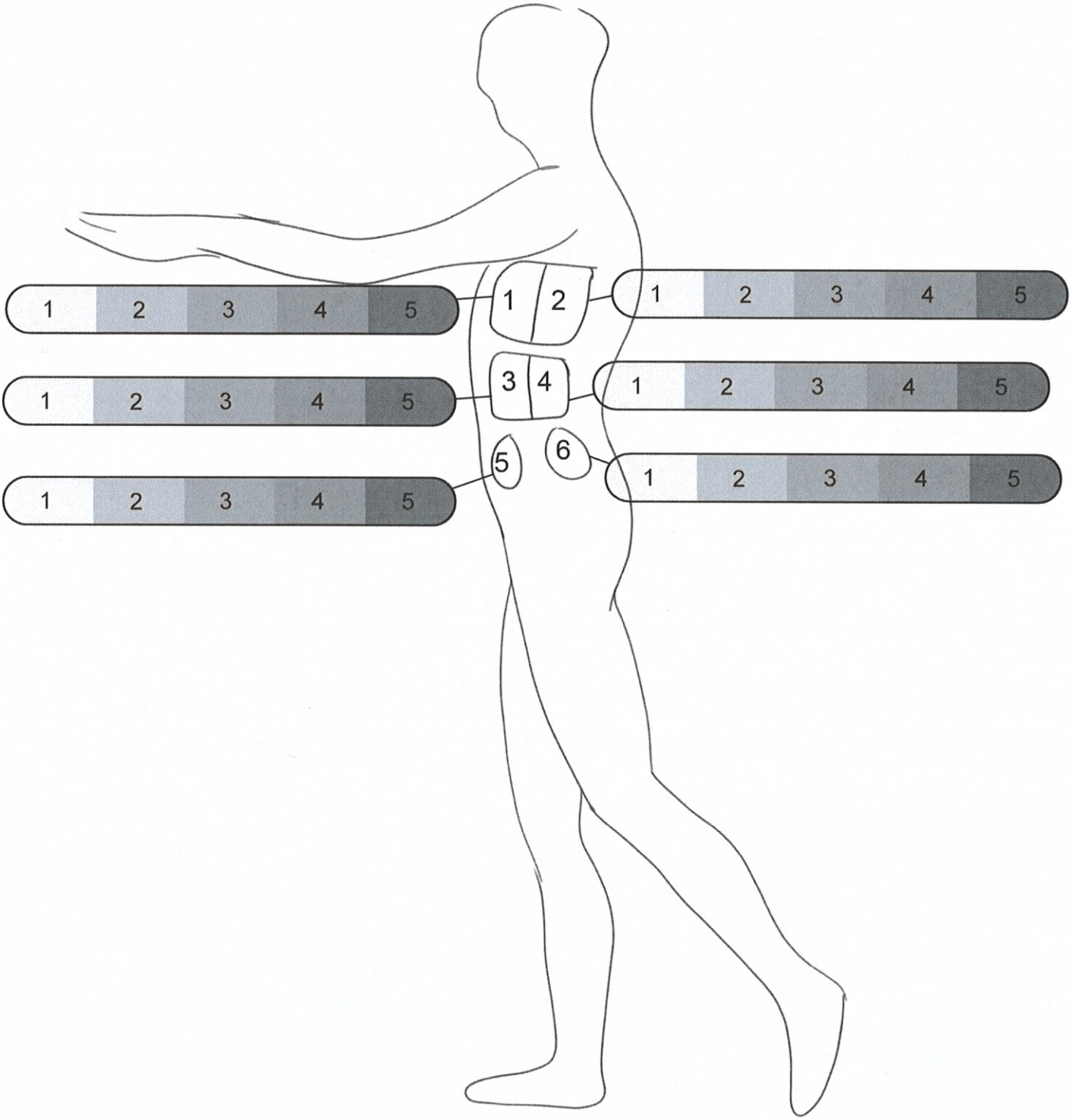


Results

Comfort

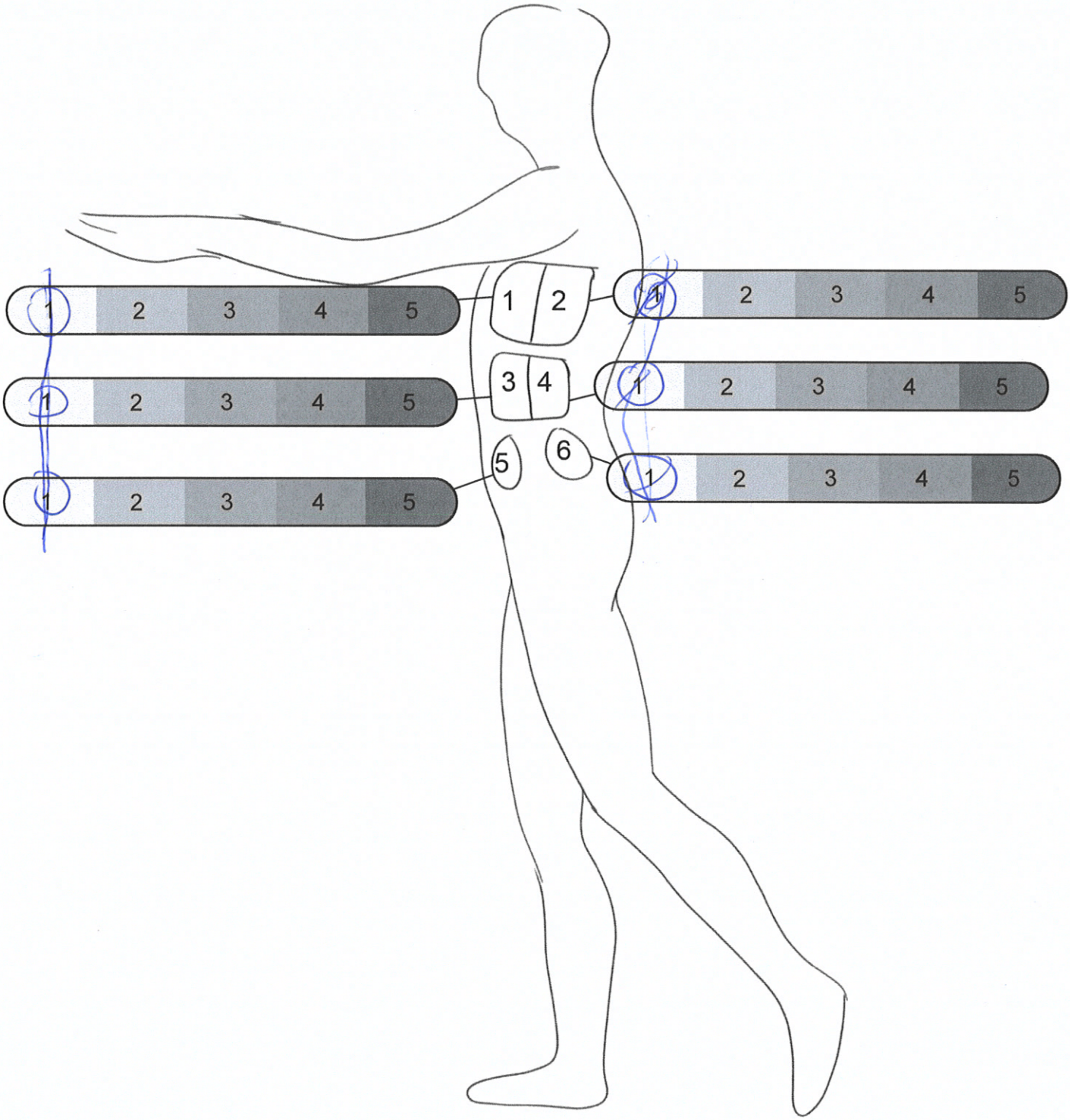
P1 - 7

- 0: No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



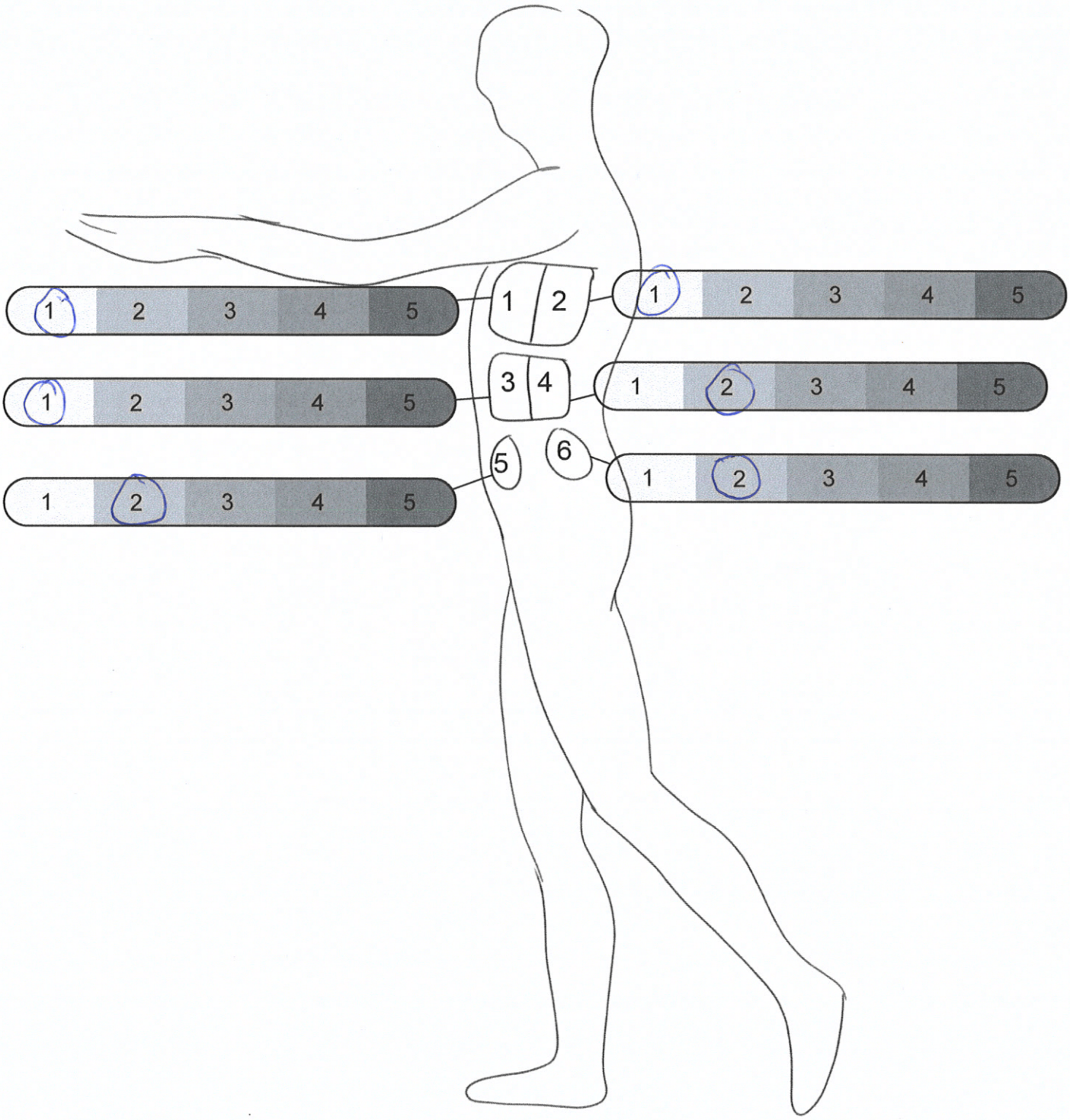
P2- 1

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



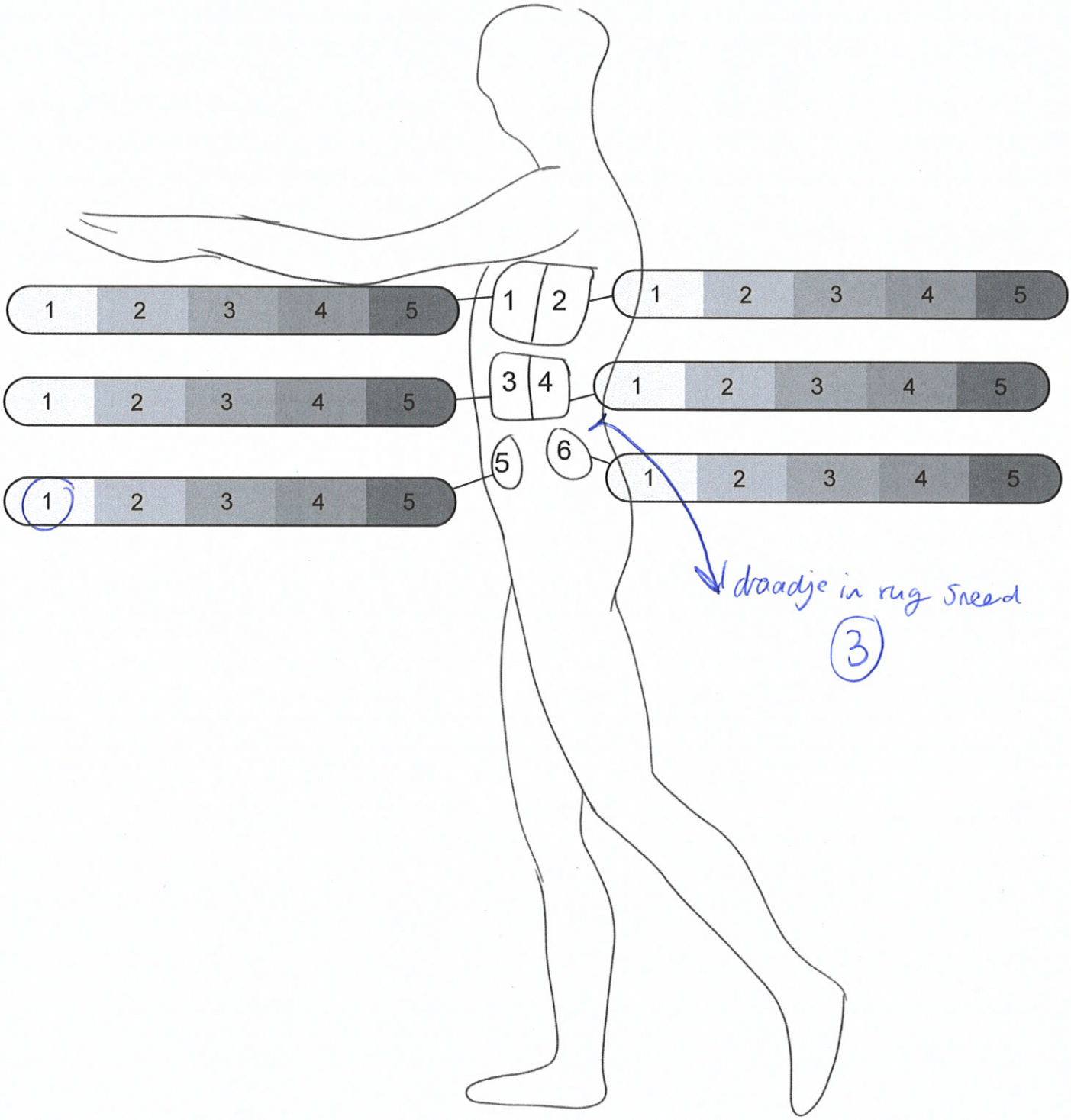
P3 -1

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



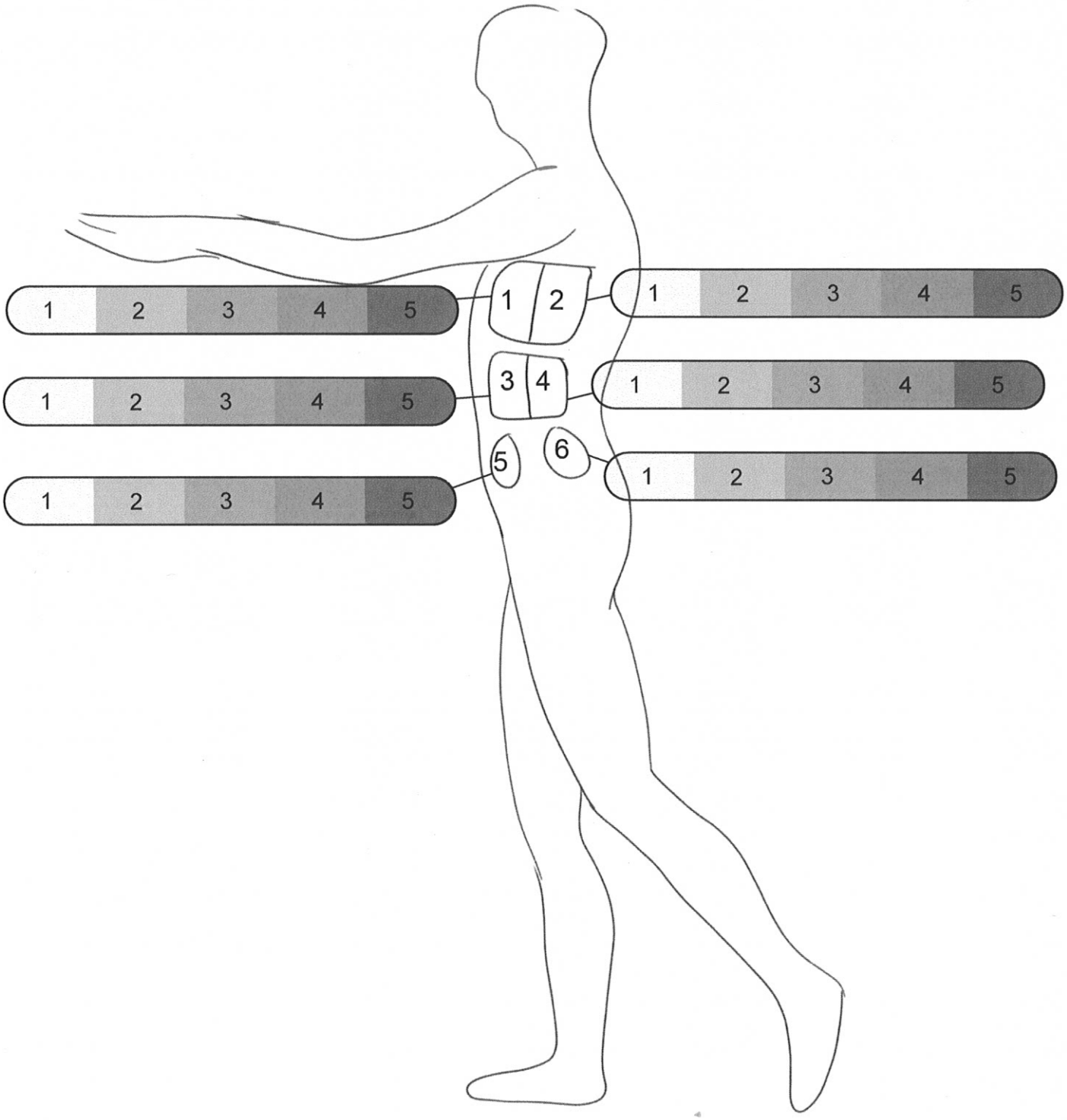
P4 - 1

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



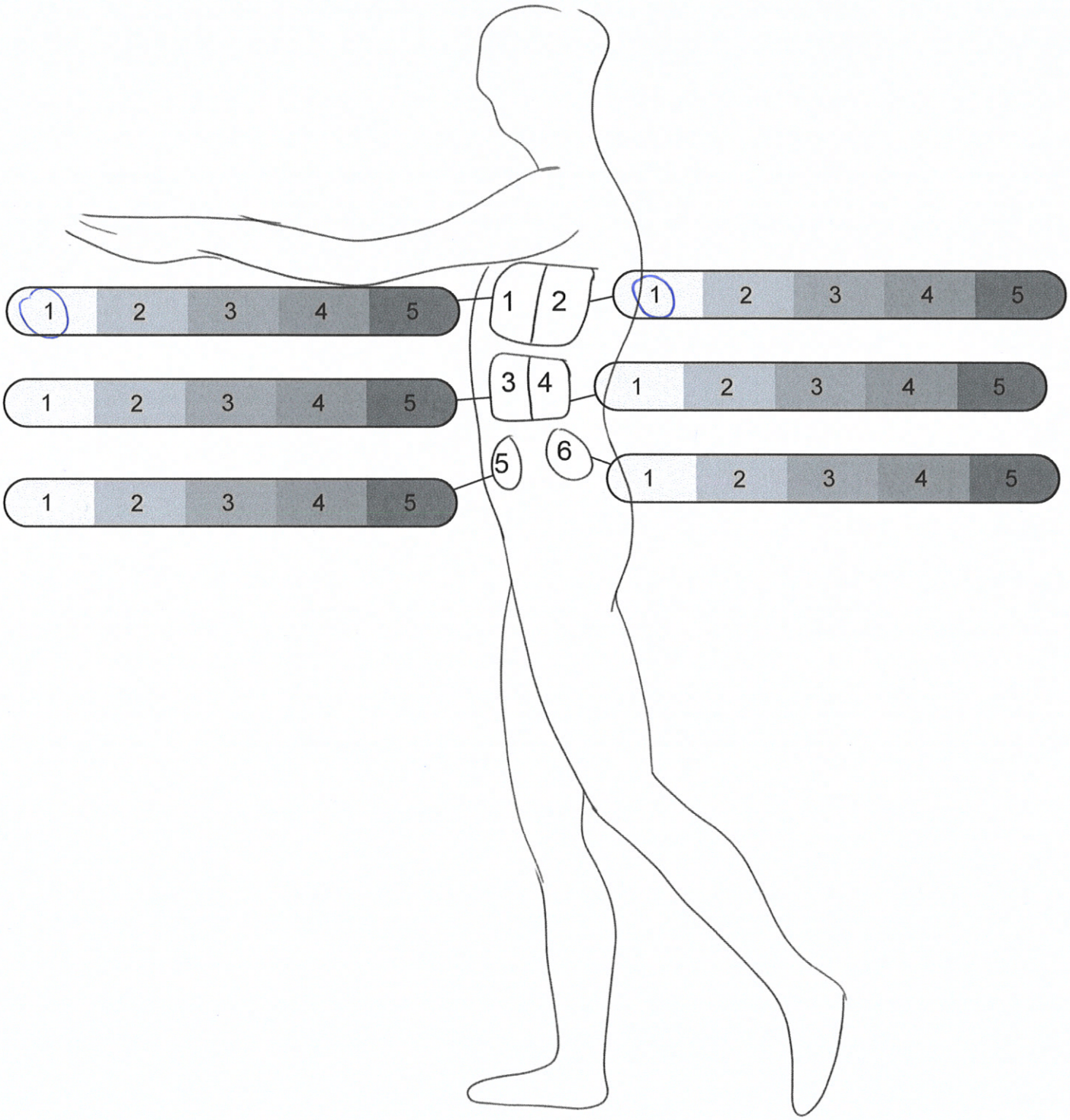
P1 -2

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



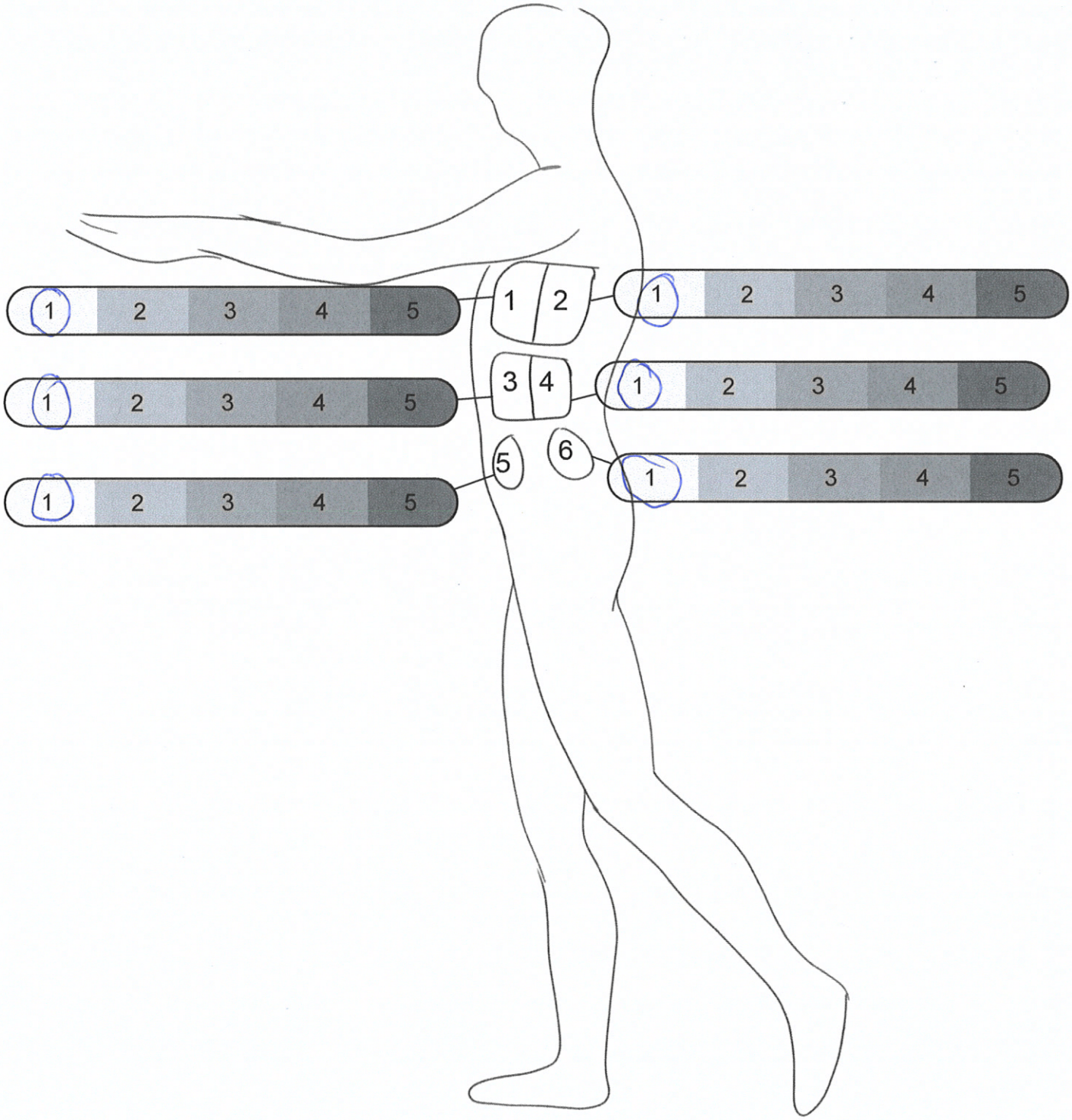
P2-2

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



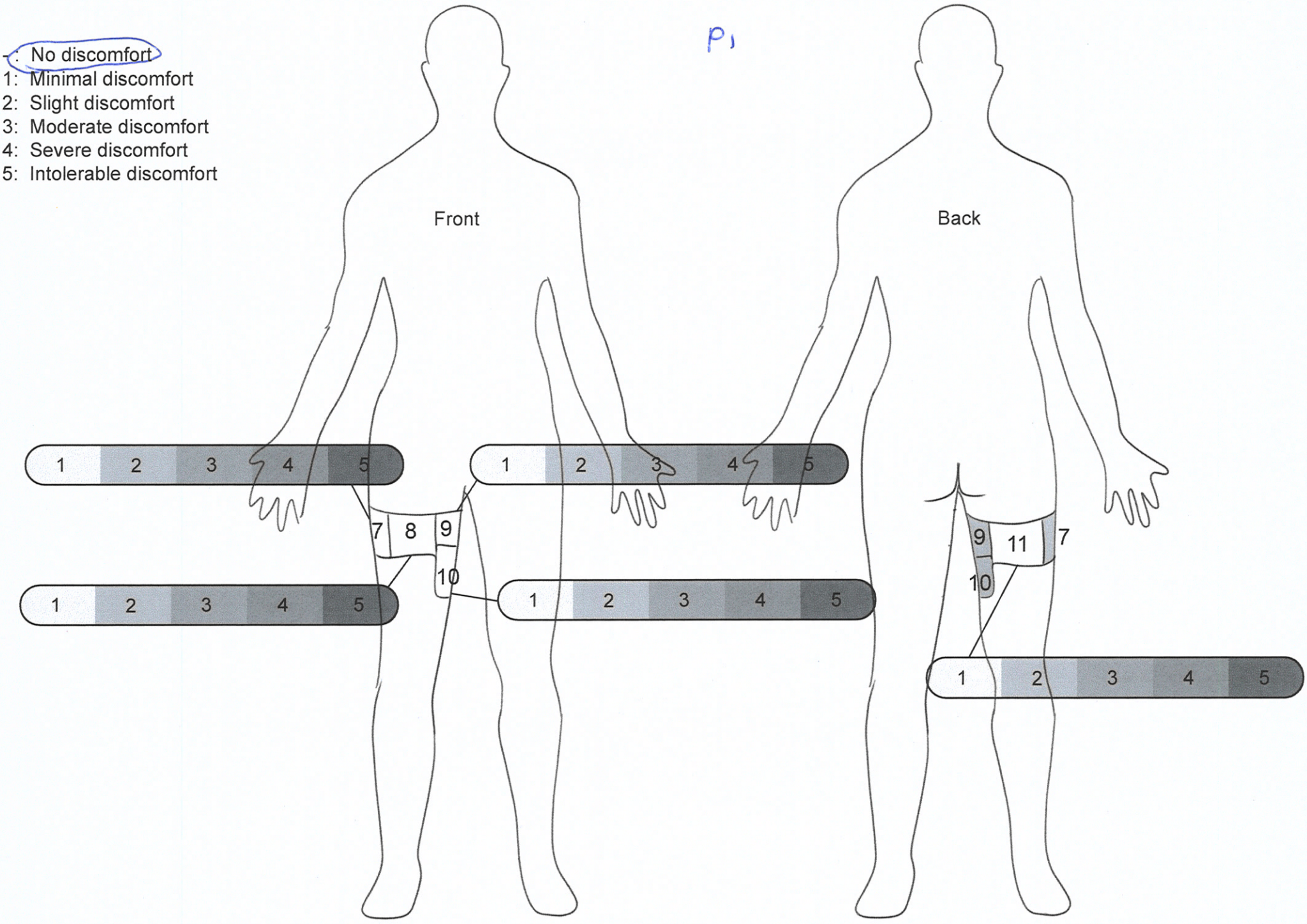
P3 - 2

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



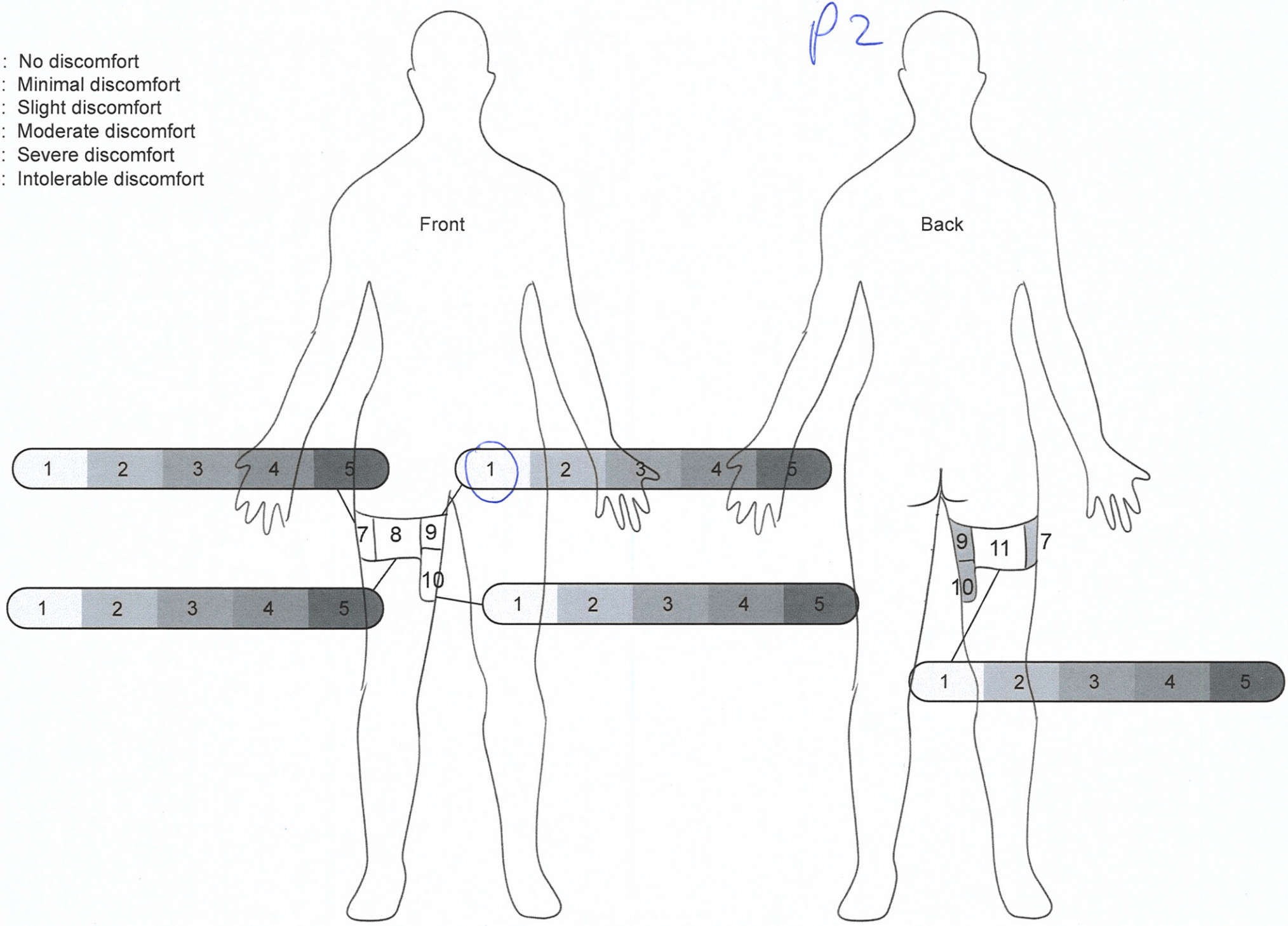
P1

-: No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



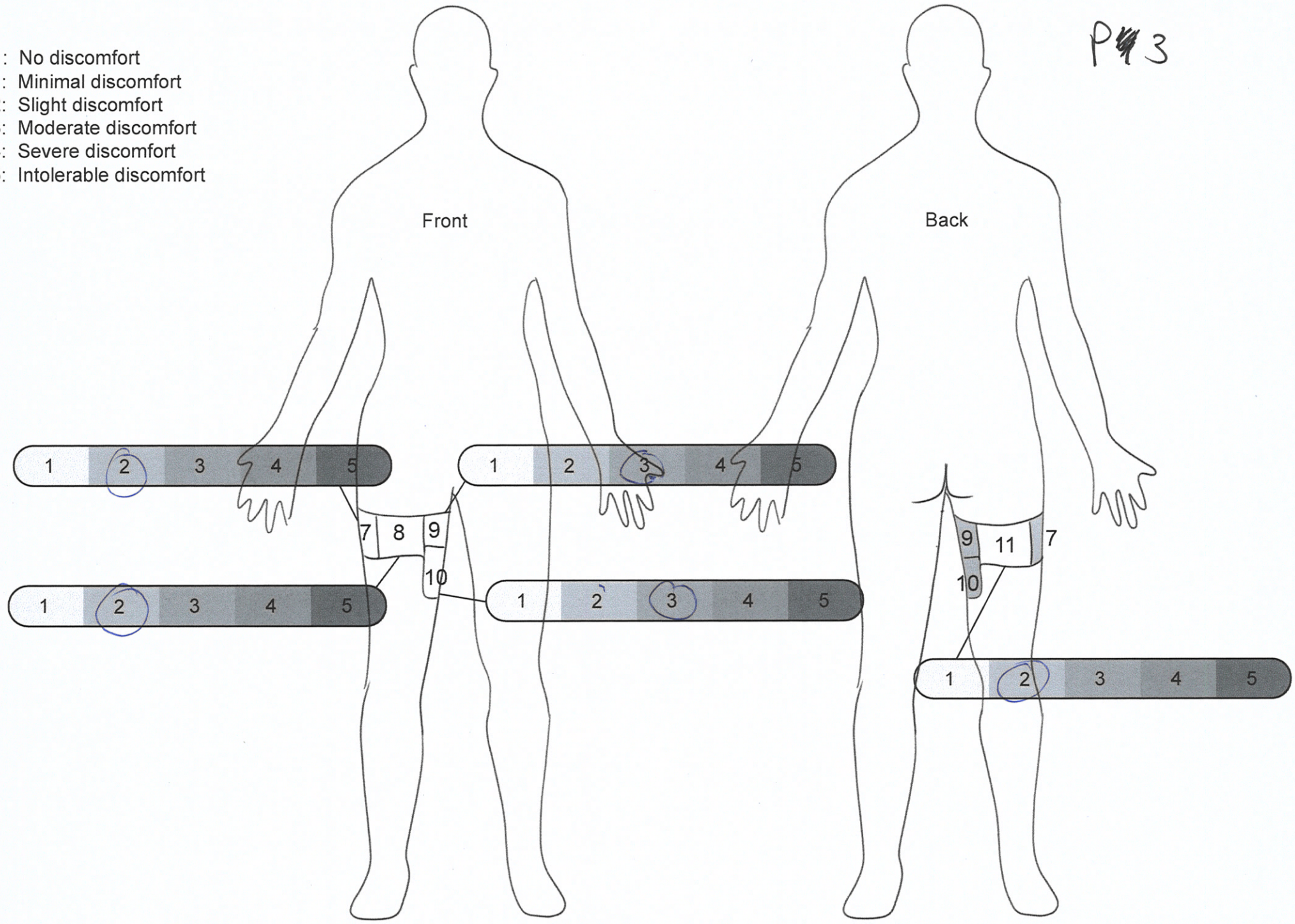
P2

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



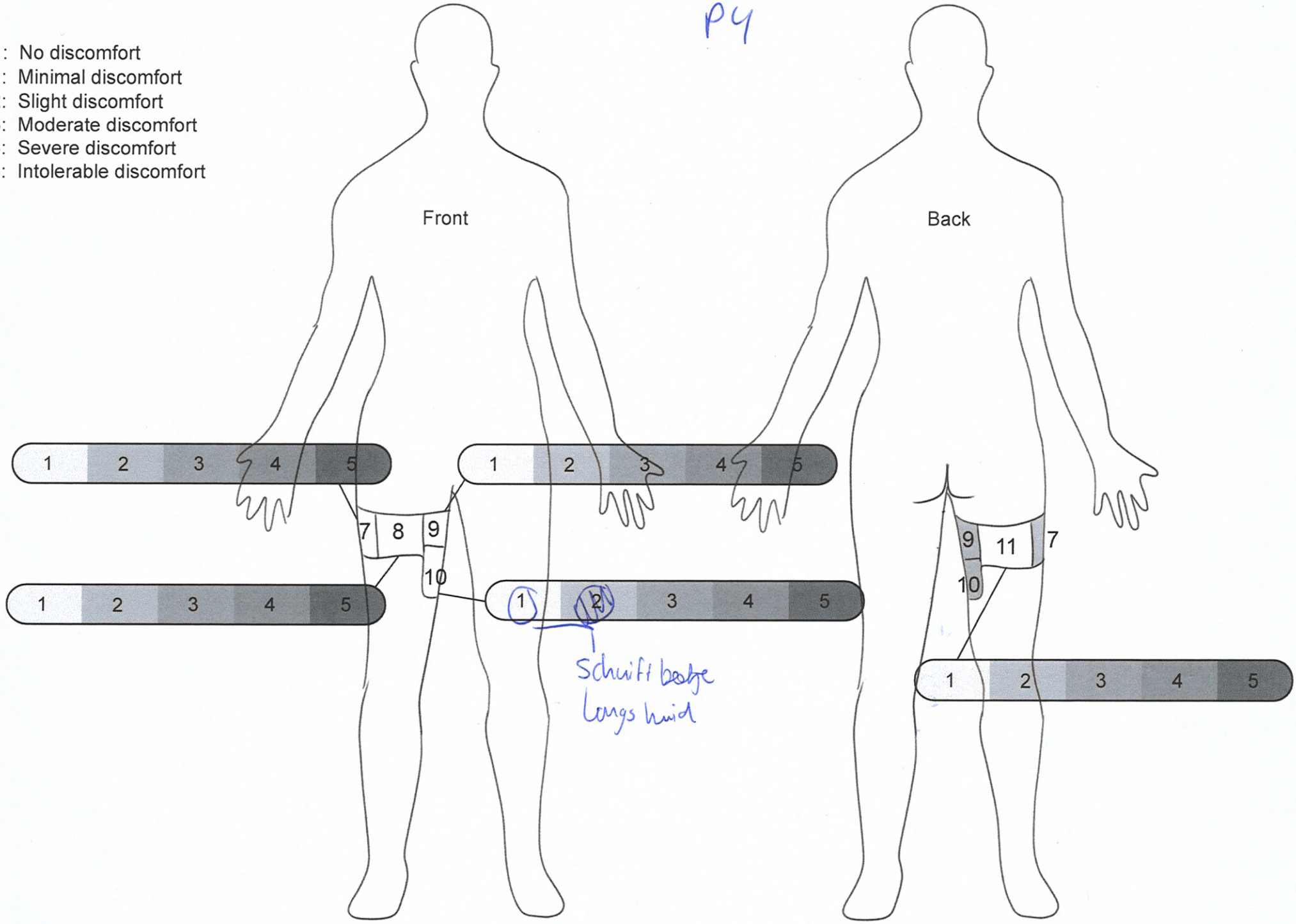
P#3

- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



P4

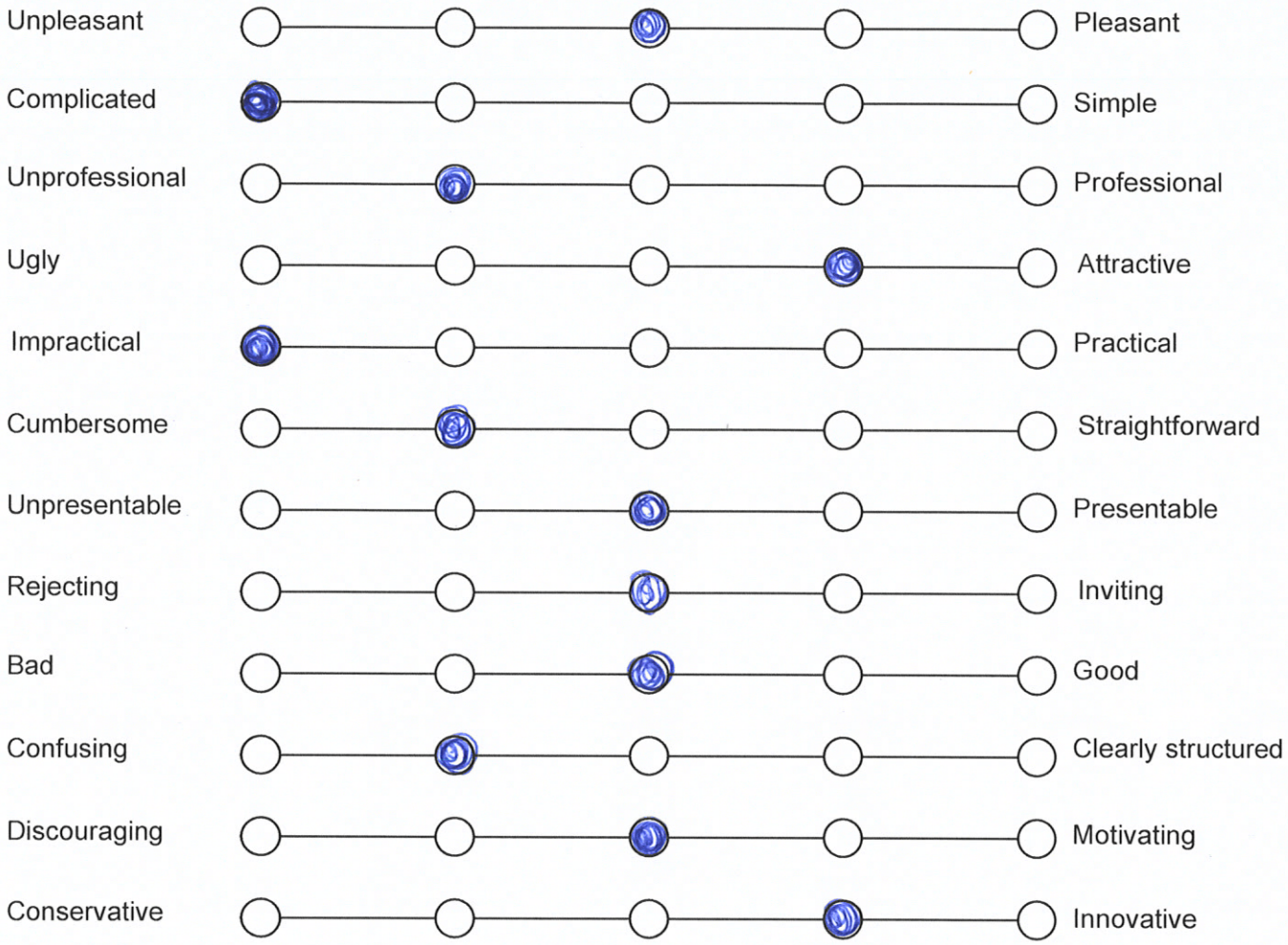
- : No discomfort
1: Minimal discomfort
2: Slight discomfort
3: Moderate discomfort
4: Severe discomfort
5: Intolerable discomfort



P1

Results
Experience

P2


Unpleasant
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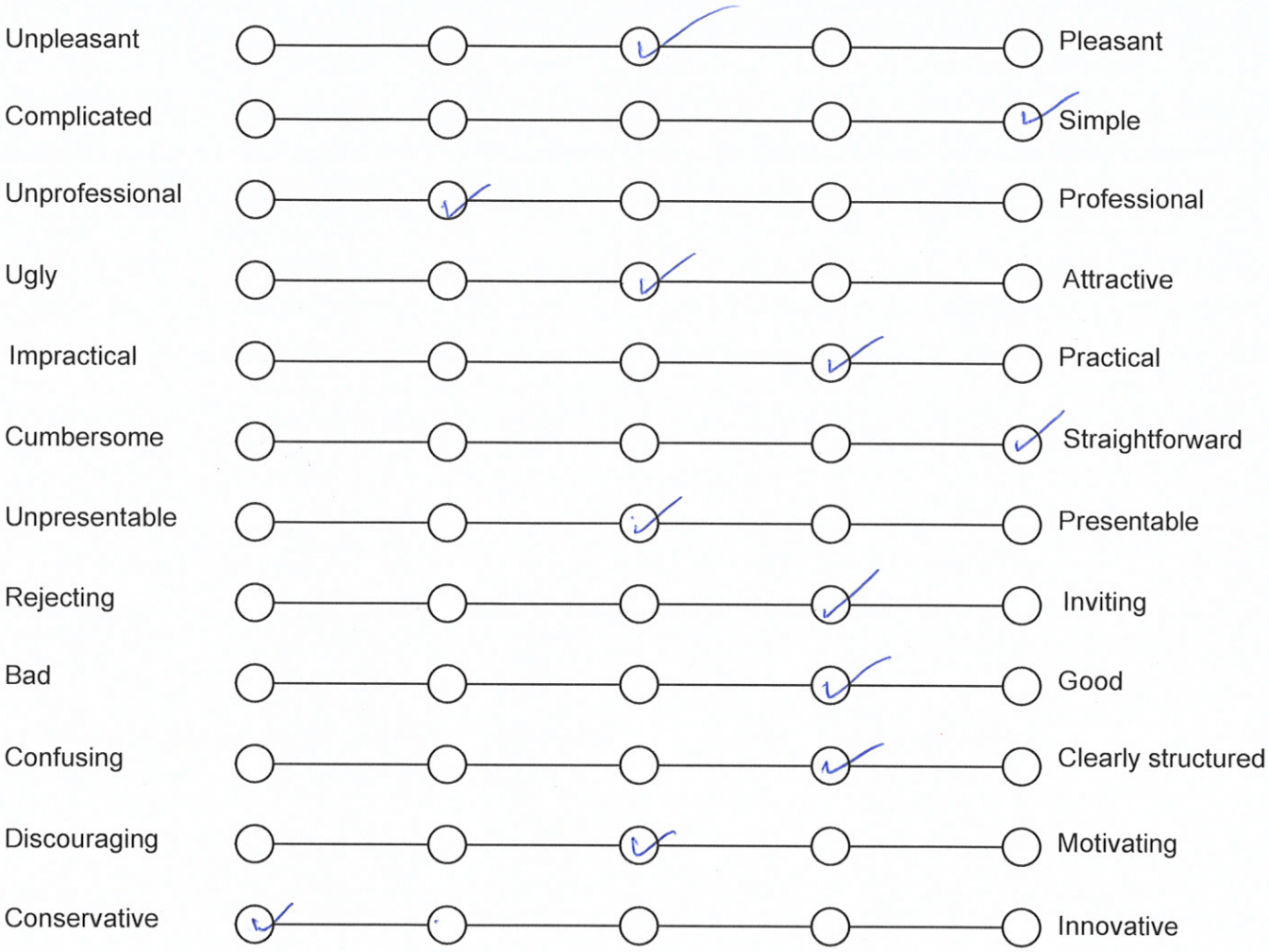
Complicated
Simple
Unprofessional
Professional
Ugly
Attractive
Impractical
Practical
Cumbersome
Straightforward
Unpresentable
Presentable
Rejecting
Inviting
Bad
Good
Confusing
Clearly structured
Discouraging
Motivating
Conservative
Innovative

P#3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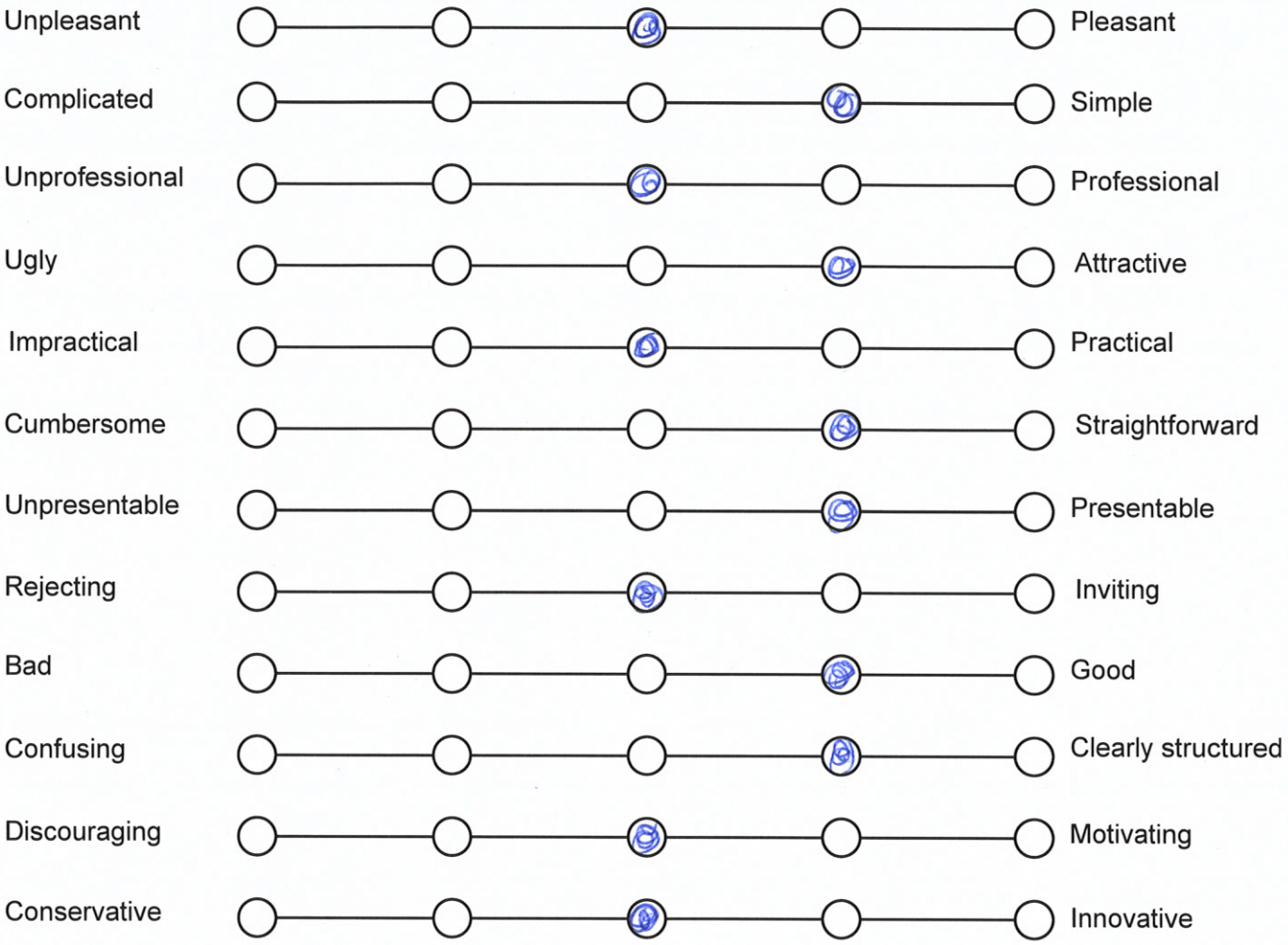
Innovative

P 4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Fitting

Angle differences

Table 1 Angle differences between participants

	P1	**P2**	**P3**	**P4**
Pulling guide wire				
Pad1	1,89	1,034	2,001	0,793
Pad 2	1,112	0,116	1,335	4,413
Pad 3	0,229	1,55	2,678	4,616
Pad4	0,058	0,02	0,96	2,23
Walking	x	x	x	x
Leg	x	x	x	x
Pad	5,13375	x	x	4,75604

** boxes marked with an 'x' indicates that the data was unavailable for processing.*

Discussion

As can be seen in Table 1, the angle differences are highest for participant 4. This would indicate that the brace fitted participant 4 the least and participant 2 the best. However since the forces pulling on the wire was different for each participant this cannot directly be concluded.

However, participant 1 did also receive a pulling force of 130 N, this resembles the 134 N that participant 4 received. This means that participant 4 and 1 can be compared.
Most angle differences occur in pad 2 and 3. As these did not touch the skin without force, this could make sense. Therefore, the fitting was not correct.

Since the fitting was designed to fit participant one it is not unsurprising that the brace did not fit the other participants properly. The height of the brace was the main issue between all participants.

Impact: 0 N

Impact: 134 N

PARTICIPANT 4 HIP WIGGLE																	
Force	0				X	Y	Z			134				X	Y	Z	
	Spine R	100,00%	##	M	832,10	-20,50	1065,50	0,37		Spine R	######	##	Me	839,50	18,70	1070,10	0,37
	Spine M	100,00%	##	M	864,40	-63,50	1063,00	0,45		Spine M	######	##	Me	872,00	-24,30	1069,40	0,41
	Spine L	100,00%	##	M	888,40	-114,20	1072,10	0,55		Spine L	######	##	Me	898,80	-73,30	1081,40	0,38
	Shoulder R	100,00%	##	M	708,90	9,10	1547,60	1,49		Shoulder R	######	##	Me	711,10	50,50	1556,20	1,59
	Shoulder L	100,00%	##	M	869,60	-239,50	1535,80	1,05		Shoulder L	######	##	Me	883,70	-189,80	1538,80	1,14
	Rig3	100,00%	##	M	878,70	-254,10	1091,30	0,15		Rig3	######	##	Me	883,20	-212,50	1112,30	1,09
Reference point	**Rig1**	100,00%	##	M	819,30	-273,50	1204,40	1,37		**Rig1**	######	##	Me	825,90	-217,90	1226,20	0,88
	R2	100,00%	##	M	763,60	-283,90	1076,00	0,59		R2	######	##	Me	767,30	-232,30	1099,20	0,45
	Pelvis R	100,00%	##	M	637,30	-37,60	1030,60	0,54		**Pelvis R**	######	##	Me	643,40	-0,30	1037,10	1,29
	Pelvis L	100,00%	##	M	763,70	-266,40	1021,10	1,73		Pelvis L	######	##	Me	767,50	-226,00	1043,30	1,58
	Pad4,2	99,90%	##	M	894,10	-225,70	1105,00	1,07		Pad4,2	99,90%	##	Me	902,10	-183,20	1123,90	0,63
	Pad4,1	100,00%	##	M	883,50	-250,60	1071,10	0,97		Pad4,1	######	##	Me	890,00	-211,80	1093,10	0,61
	Pad1,2	100,00%	##	M	781,40	-272,30	1236,40	1,01		Pad1,2	######	##	Me	788,30	-212,30	1259,10	0,37
	Pad1,1	100,00%	##	M	839,80	-285,30	1310,20	1,32		Pad1,1	######	##	Me	844,60	-223,60	1331,90	0,59
	Pad 3,2	100,00%	##	M	756,80	-287,50	1041,40	0,67		Pad 3,2	######	##	Me	759,70	-239,60	1068,00	1,11
	Pad 3,1	100,00%	##	M	714,50	-254,90	1099,80	0,85		Pad 3,1	######	##	Me	720,90	-196,30	1120,30	1,74
	Pad 2,2	100,00%	##	M	857,10	-259,60	1175,20	0,94		Pad 2,2	######	##	Me	863,40	-210,10	1196,40	0,85
	Pad 2,1	100,00%	##	M	768,00	-271,50	1150,60	0,64		Pad 2,1	######	##	Me	773,60	-214,80	1172,20	0,61
	Pad 1,3	100,00%	##	M	866,90	-257,90	1236,00	1,40		Pad 1,3	######	##	Me	874,40	-204,40	1256,20	1,40
	Neck F	100,00%	##	M	723,50	-146,70	1479,60	1,89		Neck F	######	##	Me	734,50	-102,70	1485,00	1,19
	Neck B	100,00%	##	M	844,30	-73,10	1545,90	0,93		Neck B	######	##	Me	850,60	-25,50	1552,70	0,92

Angle moment 1

Difference reference location and pad location

Angle difference

Angle moment 2

Rig1 -Pelvis - 3.1	36,00647334		-182,00	235,90	-173,80		**4,615529**	31,39094442		-182,50	217,60	-189,10	
Verschil			-104,80	18,60	-104,60					-105,00	21,60	-105,90	
Rig1 -Pelvis - 2.1	41,67693103		-182,00	235,90	-173,80		**4,413475**	37,2634561		-182,50	217,60	-189,10	
			-51,30	2,00	-53,80					-52,30	3,10	-54,00	
Rig1 -Pelvis - 1.2	84,57089466		-182,00	235,90	-173,80		**0,793087**	83,77780789		-182,50	217,60	-189,10	
			-37,90	1,20	32,00					-37,60	5,60	32,90	
Rig1 -Pelvis - 4.2	71,03654961		-182,00	235,90	-173,80		**-2,22657**	73,26311886		-182,50	217,60	-189,10	
			74,80	47,80	-99,40					76,20	34,70	-102,30	

APPENDIX I Measurements brace

It will be necessary to make the brace fit a large number of people. In order to fit this group of individuals, a sizing system was developed.

DINED was used to make a mixed gender mannequin measuring stature, waist and hip circumference between ages 30 - 51. The age group reflects the average age of someone with paraplegia. Defining the exact distance from pelvis to axillary is difficult to measure from the mannequin.To define what the maximum and minimum distances are, solidworks have been used to estimate a distance. For the P95, the pelvis to axillary distance is 401 mm, while for the P5, it is 314 mm. The length needed is approximately 20% of the height of both mannequins.The shells are spaced 17mm apart. By doing so, the steps increase in length consistently.

Three options are available in the small version, and three options in the large version.

Lengths for the small structure can be 315, 332 or 349 mm. The large structure lengths are 366, 383 or 400 mm. By doing so, the increments between each option are consistent. Similar options are given to the location of the middle pad. For the pads around the pelvis only two options for placement are given.

400mm
Suitable for P95
measurements

315 mm
Suitable for P5
measurements

APPENDIX J Cost estimation

The costs of the bolts and buckles have not been taken into the estimation of the costs. The material costs have been extracted from the CES EduPack software.

Materials
4x shells - LTTP PS (1,71 €/kg)
4x foam - Flexible polymer foam (2,52 €/kg)
Hip structure - HTTP (PE-copolymer)(1,46 €/kg)
Leg structure - HTPS (PE-copolymer)(1,46 €/kg)
Leg foam - flexible polymer foam (1,71 €/kg)

Cost per part
Shells: 1(20.29g), 2(16,13g), 3(4.63g), 4(7,06g),
= 48,11 g = € 0.08
Foam: 1(85,12), 2(68,46), 3(20.78), 4(30.03), 5(leg) (191,71 g)
= 386,1 g = € 0.97
Structure: hip(28,99) leg(106,48)
= 135,47 g = € 0.20

Total: 1,25 €

Parts
Nylon-covered stainless steel strands (€ 1,71)
Boa lacing system € 19,95 eur (Partnering with boafit recommended)

Total : € 21,66

Approximately material costs are: € 22,91 for one brace excluding the working principle. Based on the type of mechanism this will increase the price.

Average monthly salary of an instrument maker is approximately 2800 €/month (Nationale Beroepengids, n.d.), with an average of 17,50 €/ hour. Based on the steps made in the prototyping phase an estimation of the production time can be made. To create the high temperature thermoplastic parts, a mold needs to be made. This increases the costs.

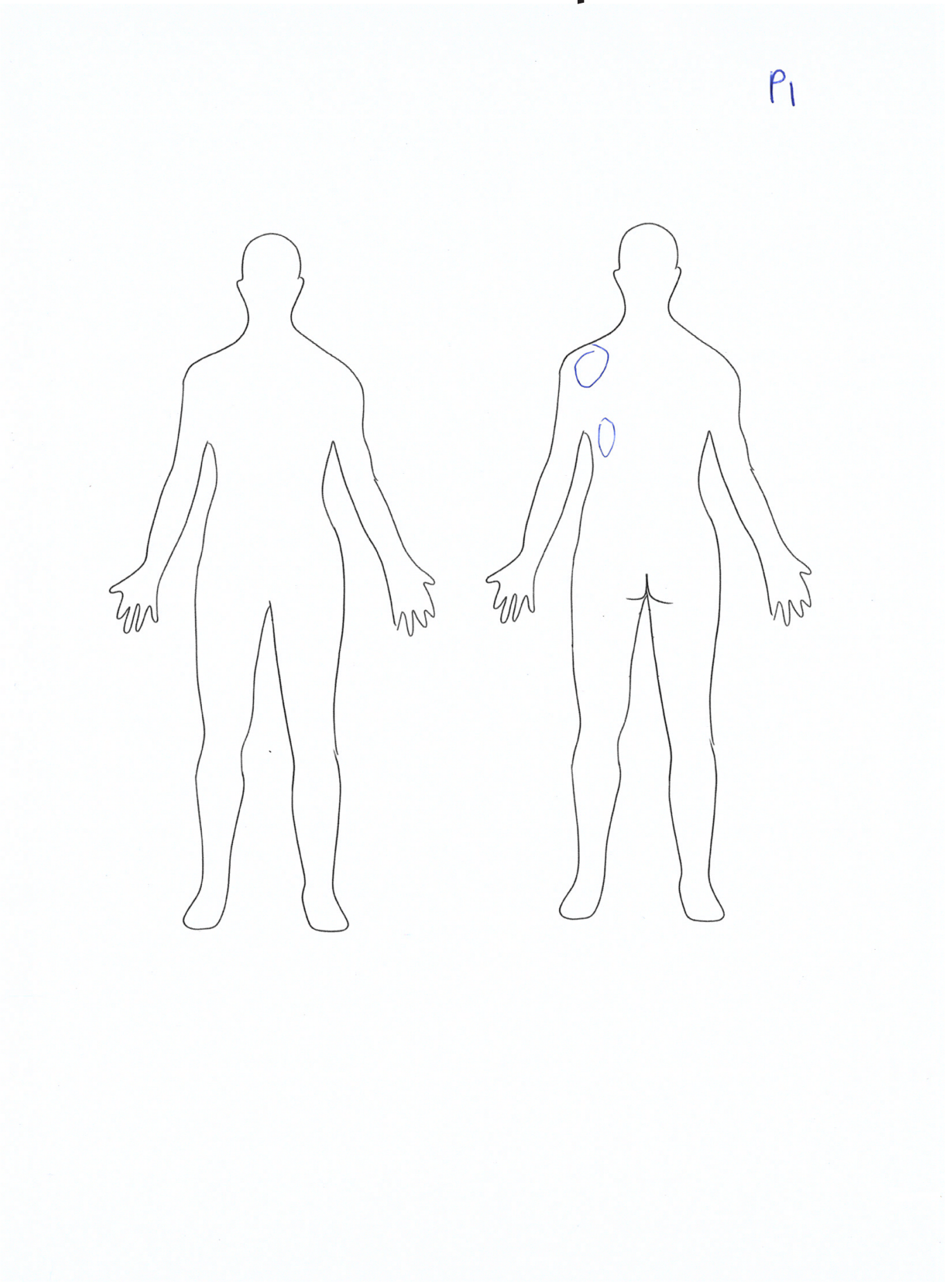
Steps of the production process
Cutting the HTTP in right shape: 5 min
Creating a positive plaster mold (shells, hip support, leg support) : 1 hour
Forming the HTTP in convection or infrared oven: 4 min
Drape HTTP over the positive mold : 10 min
Let product cool down on the mold for 24 hours
Polishing edges and add accessories : 30 min
Hot bending LTTP for the shells : 10 minutes
Assembly of all parts together with the patient to adjust the right size: 30 min

Approximately the production time of the brace is 173 minutes without taking into account the waiting time to let the product cool down.

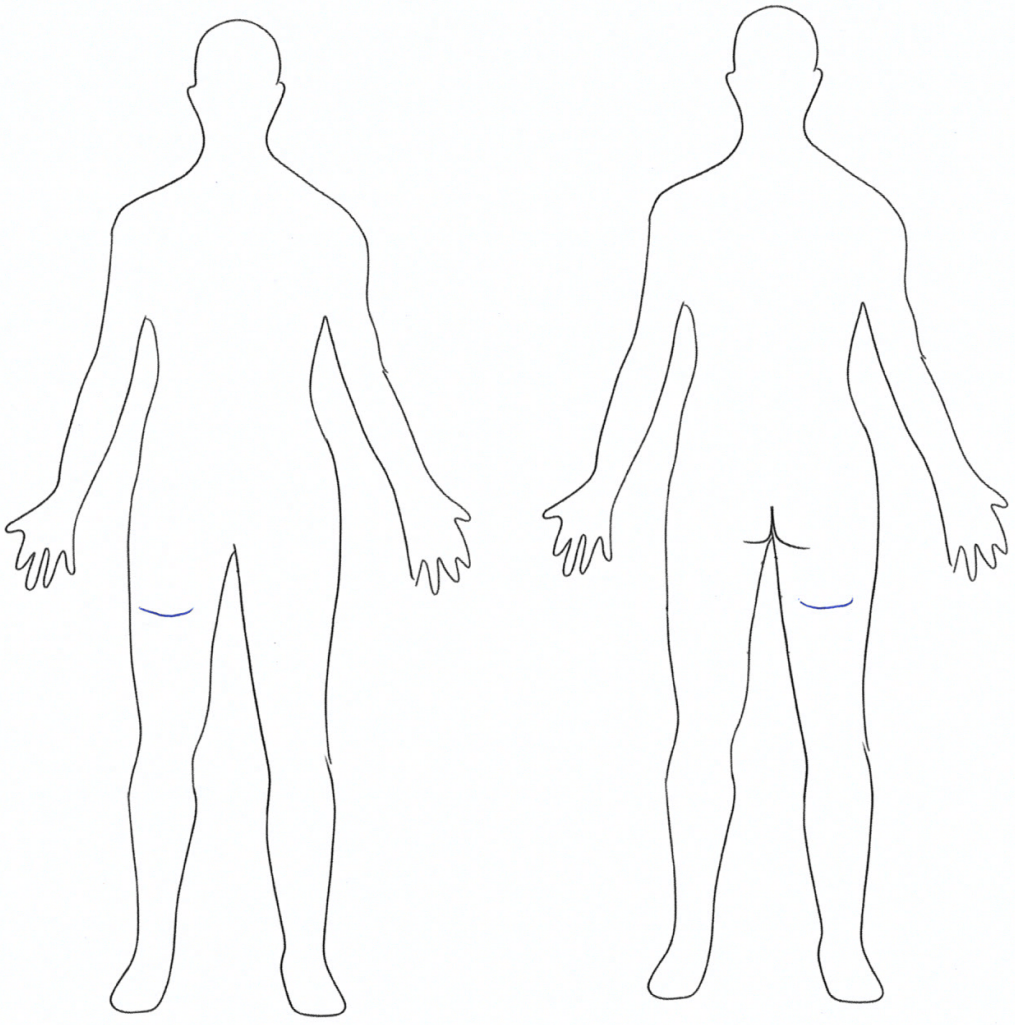
Creating a total of assembly costs of approximately € 50,46. Once the HTTP is removed from its mold it is recommended to let it sit for 24 hours to cool down. This thermoforming process is usually less expensive than the option of injection molding. Mold costs of thermoforming are less expensive than mold costs for injection molding. Since the brace is still in its development phase and monitoring with the patient is necessary to ensure its effectiveness as a medical device, thermoforming or drape forming is a viable solution as a production method, this way during its development changes can still be made to find the right shape to apply to the largest group of people. Since there is flexibility in the brace, it allows it to be fitted for more than one user.

Orthotics that are designed for people with a disability fall under the 9% rate (VAT) in the netherlands. There will be additional costs besides materials and production costs.

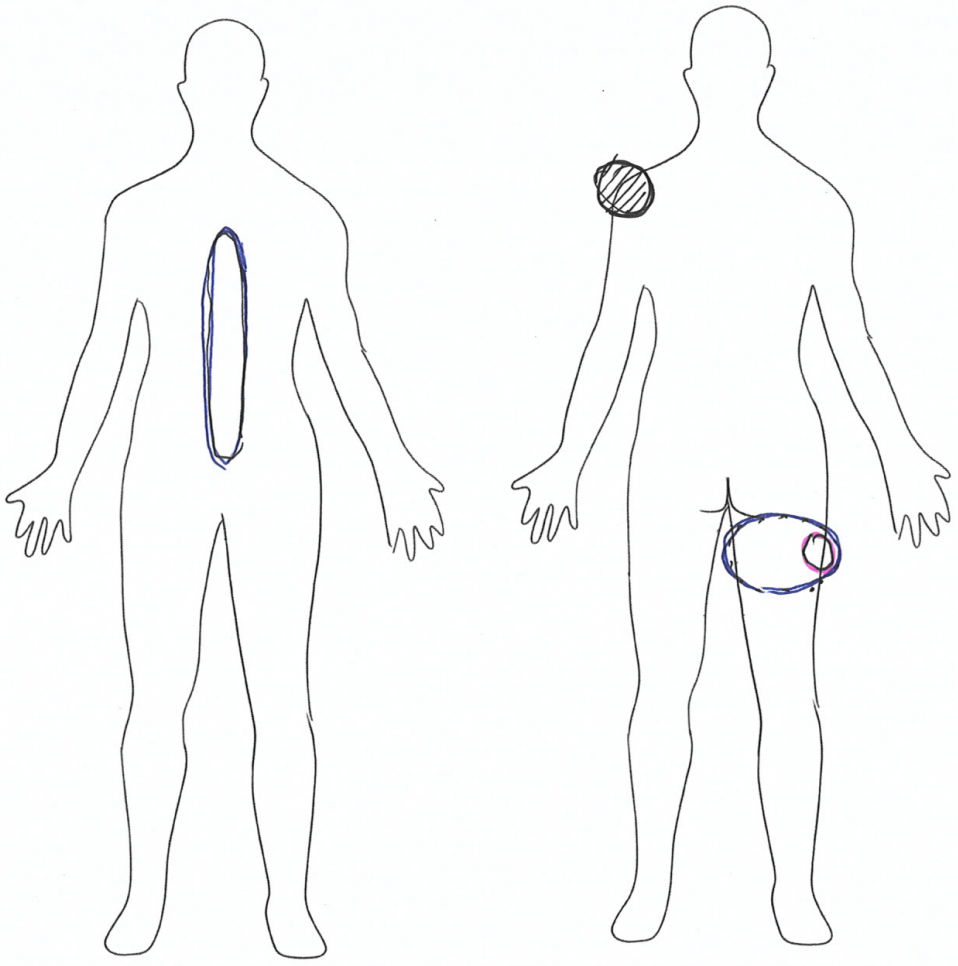
APPENDIX K Discomfort maps



P2



P3

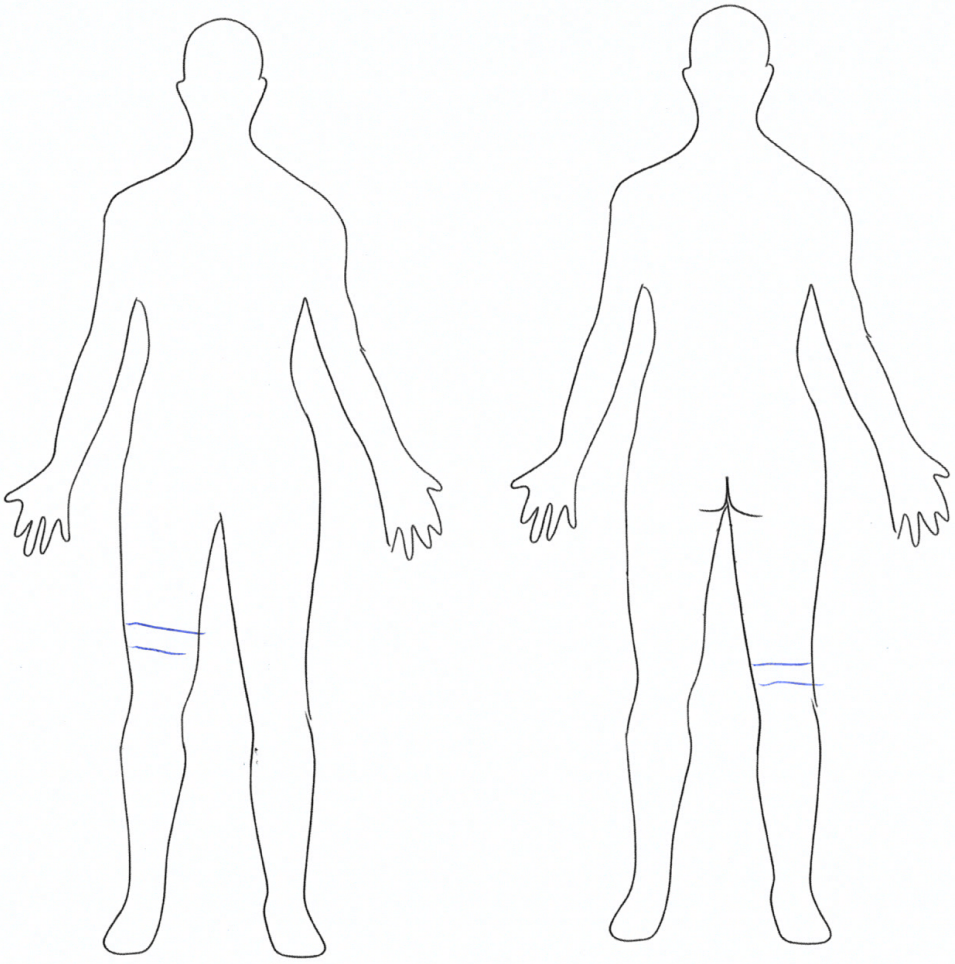


○ 'mentale discomfort' → "angst" voor afzakken / kapot maken

○ oppassen met hard onderdeel & kleding

● achter je rug aantrekken

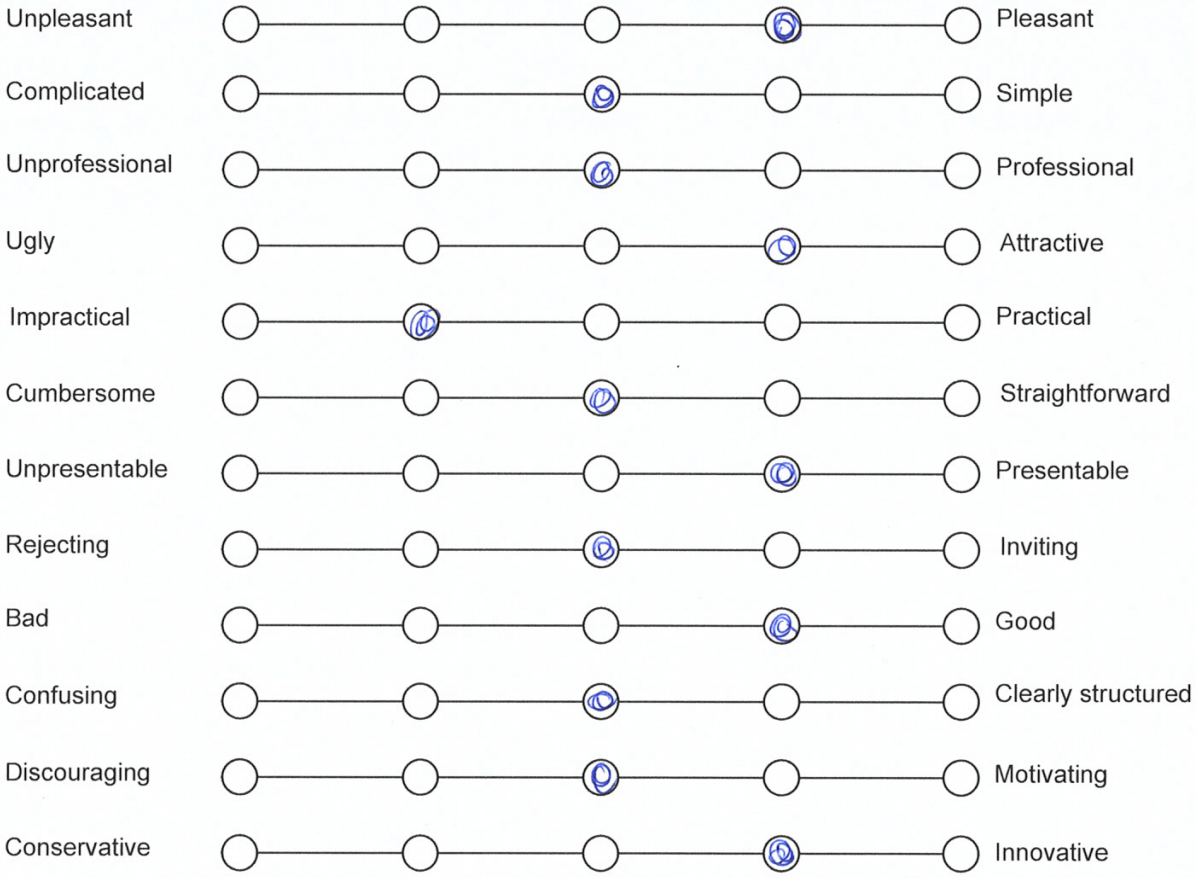
Ру



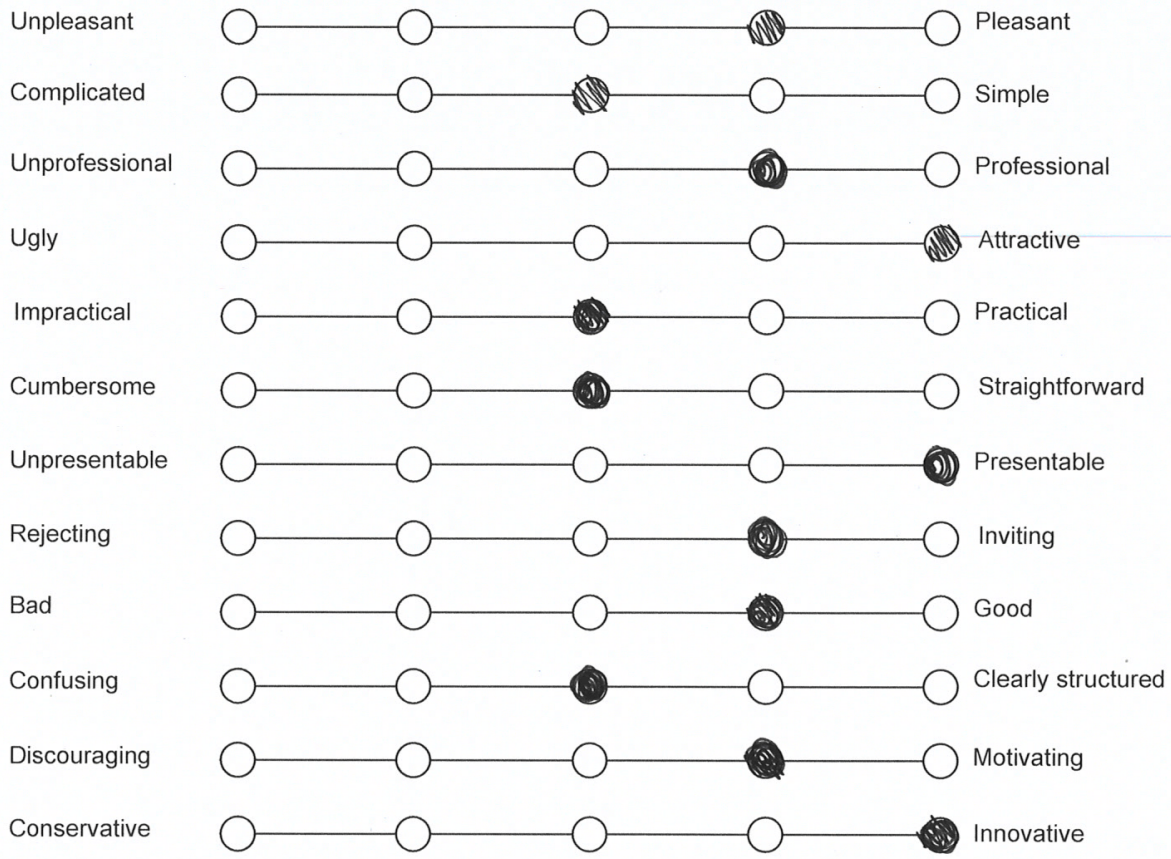
APPENDIX L Final experience questionnaire

P1

P2


Unpleasant
Pleasant
Complicated
Simple
Unprofessional
Professional
Ugly
Attractive
Impractical
Practical
Cumbersome
Straightforward
Unpresentable
Presentable
Rejecting
Inviting
Bad
Good
Confusing
Clearly structured
Discouraging
Motivating
Conservative
Innovative

P3


Unpleasant
Pleasant
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Unpresentable
Presentable
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Confusing
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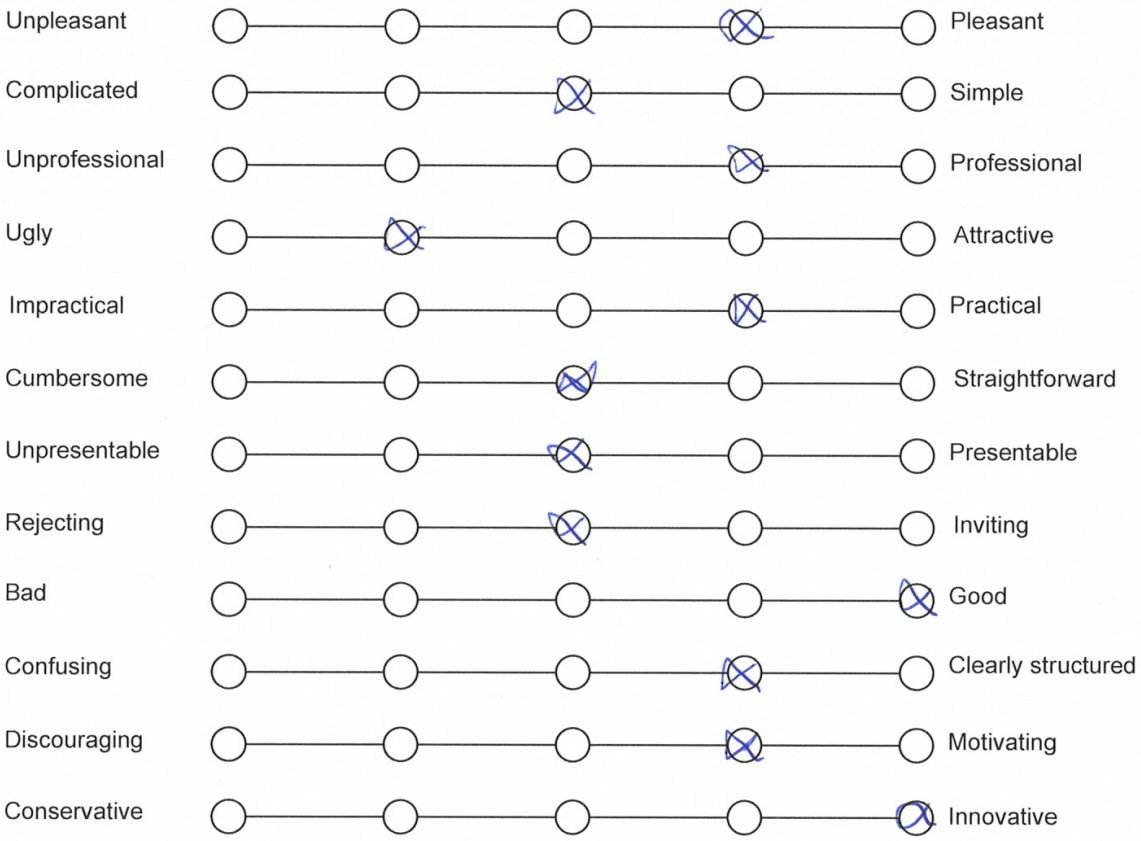
Motivating
Conservative
Innovative

P4


Unpleasant
Pleasant
Complicated
Simple
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Practical
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Presentable
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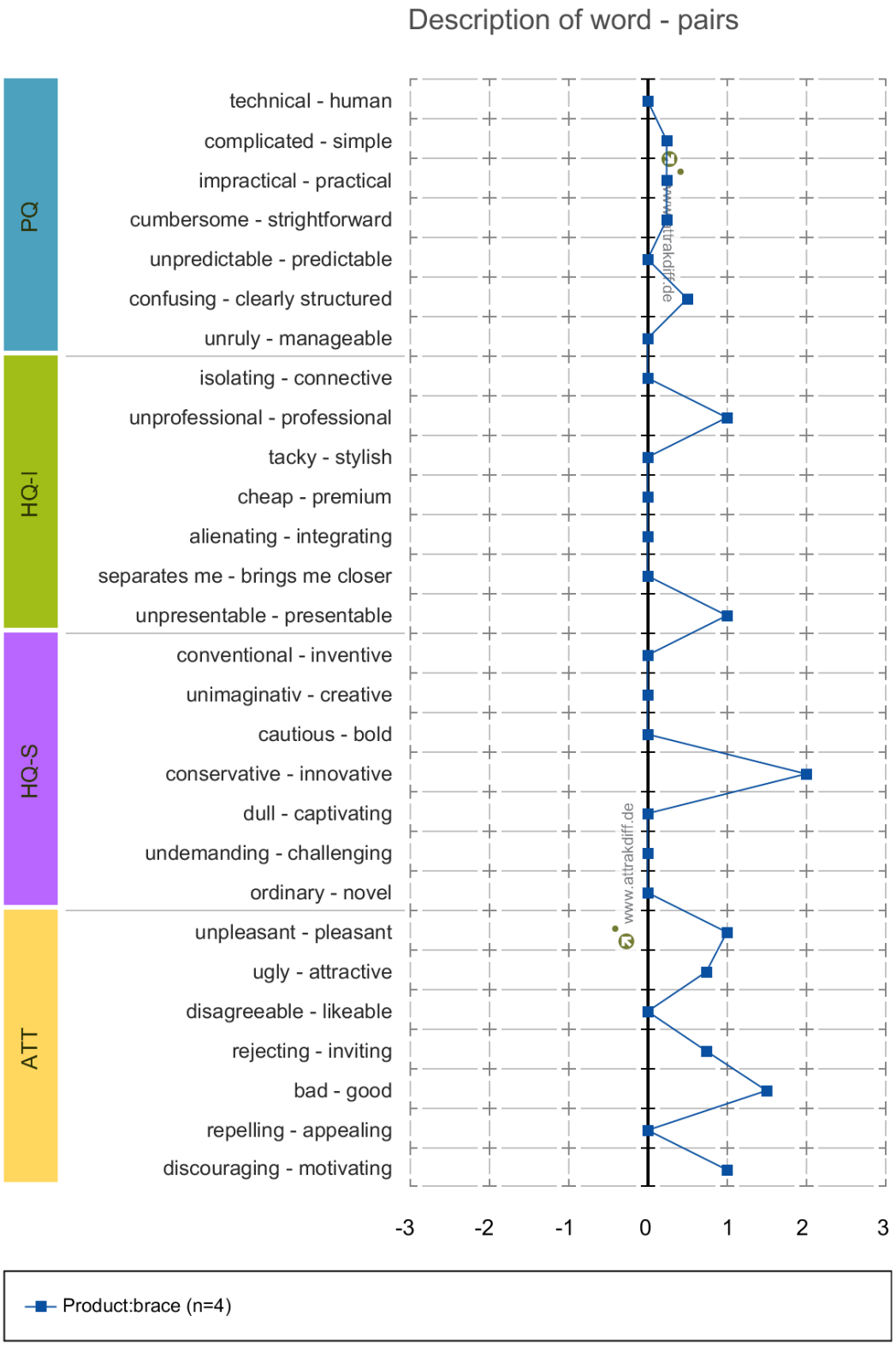
Description of word - pairs
PQ
technical - human
complicated - simple
impractical - practical
cumbersome - strightforward
unpredictable - predictable
confusing - clearly structured
unruly - manageable
HQ-I
isolating - connective
unprofessional - professional
tacky - stylish
cheap - premium
alienating - integrating
separates me - brings me closer
unpresentable - presentable
HQ-S
conventional - inventive
unimaginativ - creative
cautious - bold
conservative - innovative
dull - captivating
undemanding - challenging
ordinary - novel
ATT
unpleasant - pleasant
ugly - attractive
disagreeable - likeable
rejecting - inviting
bad - good
repelling - appealing
discouraging - motivating
-3
-2
-1
0
1
2
3
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Product:brace (n=4)