Secuped

TU Delft

Design of the user experience for a diabetic foot scanner

To integrate preventive foot temperature monitoring into the daily life of diabetes patients and their healthcare professionals

Master thesis - Jannieke den Breejen - July 2025

Integrated Product Design

Master thesis
Delft, July 2025

Education

MSc. Integrated Product Design
Medisign specialization
Delft University of Technology
Faculty of Industrial Design Engineering

Supervisory team

Project chair
Prof. ir. D.J. van Eijk

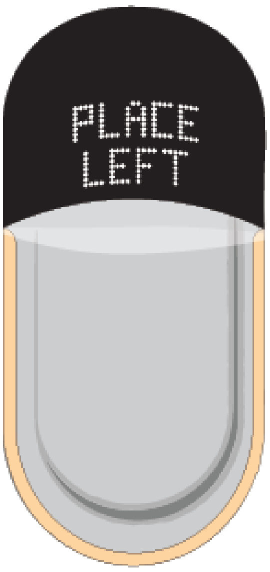
Project mentor
Ir. C.P.J.M. Kroon

Collaboration support

Secuped
Martijn van de Giessen

Author

Jannieke den Breejen



Design of the user experience for a diabetic foot scanner

To integrate preventive foot temperature monitoring into the daily life of diabetes patients and their healthcare professionals

Master thesis

Abstract

In this report, a user experience has been designed for the product developed by the company Secuped. It begins with an in-depth exploration of the literature and background of the target group- people living with diabetes who develop so-called ulcers on their feet. These wounds, if not detected in time, can lead to amputations. Ulcers typically form because patients often suffer from severe neuropathy and/or peripheral artery disease. The product aims to alert the patient early to prevent the progression of these wounds by using temperature monitoring. The relevance of the issue is illustrated in Figure 1.

What sets this product apart from its competitors like VistaFeet or Podimetrics is that it not only measures the plantar side (bottom of the foot) but also the sides, back and a portion of the top part of the foot.

The primary healthcare professionals involved with the patient are the podiatrist, pedicurist, and the POH diabetes. Several user journeys have been created to illustrate the roles and steps taken by the key stakeholders—Secuped, the patient, and the podiatrist. In addition, multiple user interviews were conducted to gain deeper insight into the patients' needs and desires. One example that emerged from these interviews is that patients prefer a light to shine on the entrance area, helping them to see how their foot is positioned. This increases their confidence that they are using the product correctly and not causing harm.

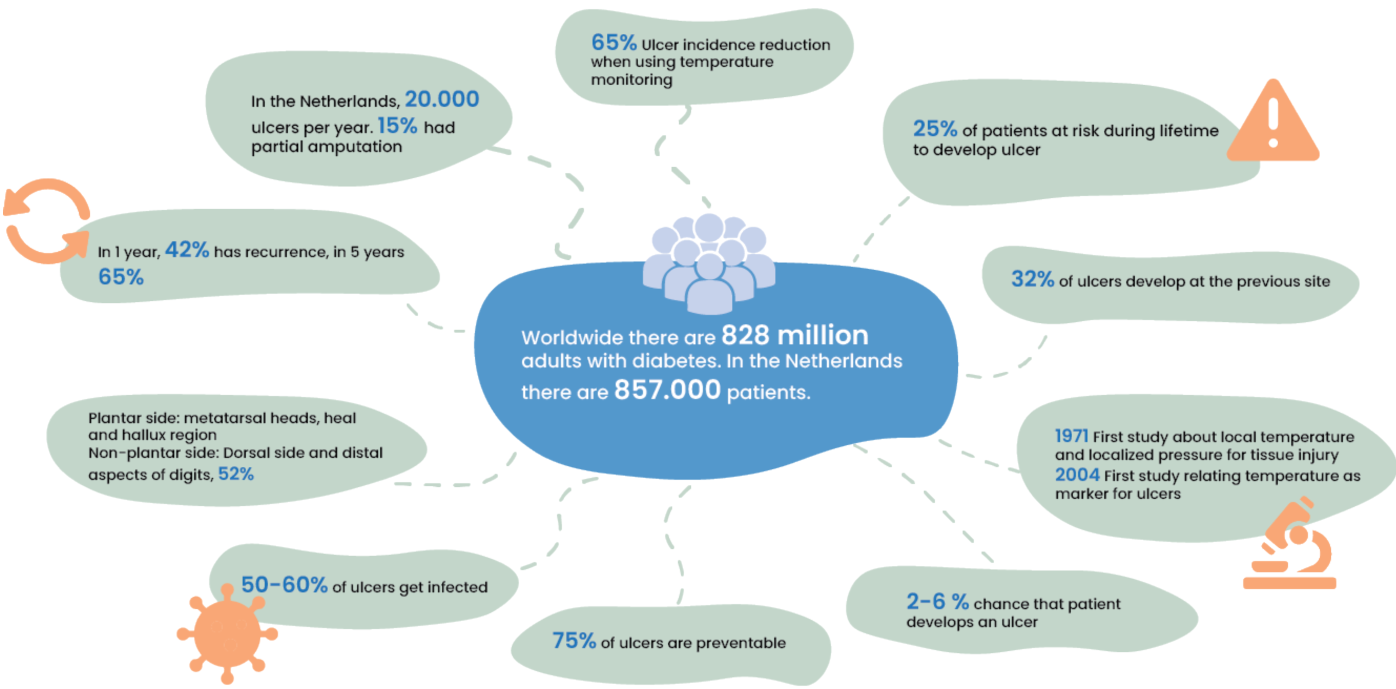


Figure 1. Overview relevance of issue

After the analysis phase, three main design directions were defined: the physical interface design of the product, the digital environment for the patient and the digital environment for the podiatrist. The physical interface features an LED grid of 50 x 16 pixels with a pitch of 2.5, along with an LED strip. A prototype was developed using various sensors and tested to evaluate whether users understood how to operate the product (Figure 2). The final result is based on several iterations, including individual testing of the display and the LED strip. In the end, two concepts were created - one using only icons and the other using only text. There appears to be a slight preference for the text-based concept.

The patient's digital environment is offered as an app, which can be used either on a smartphone or a tablet (Figure 3). It displays temperature data points and trends over time, helps monitor usage, and sends notifications to remind the patient to use the product. Lastly, it actively encourages the user to contact healthcare providers in case of a temperature elevation and shows the podiatrist's phone number.

Figure 2. Product in context and the final designs

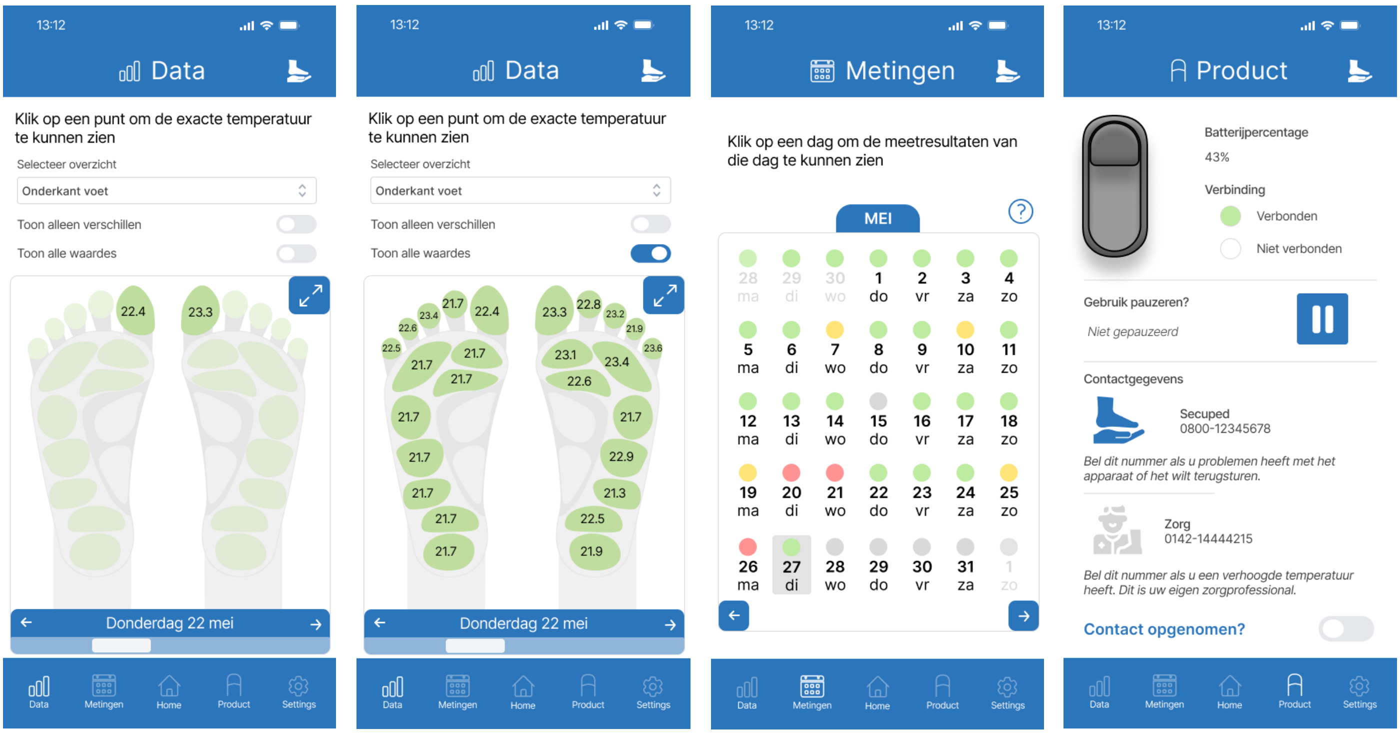


Figure 3. Digital environment patients

The podiatrist's environment includes a patient overview and to-do list that highlights warnings about patients who may be developing an ulcer and haven't contacted care yet (Figure 4). It also provides longitudinal measurement data to assist the podiatrist in making accurate diagnoses.

Figure 4. Digital environment podiatrist

Abbreviations

DFU = Diabetic Foot Ulcer
HCI = Human-Computer Interface
TPB = Theory of Planned Behaviour
PMT = Protection Motivation Theory
HCP = Healthcare Professional
RCT = Random Controlled Trial
EPD = Elektronisch Patiëntendossier (electronic patient record)

Contents

1. Introduction

This chapter provides a general introduction to the project, including its context, the company Secuped, and the assignment approach. It offers an initial overview before later chapters explore the details.

1.1 Context project

In 2022, it is estimated that worldwide, 828 million adults had diabetes, which is an increase of 630 million from 1990 (NCD-RisC & Ezzati, 2024). Diabetes can significantly impact life, including the common complication of diabetic foot ulcers (DFUs). There is an estimated 25% risk that people with diabetes develop a DFU during their lifetime (Singh et al., 2005). Other research suggested that 3.1-11.8% of persons with diabetes (or 12.9-49 million persons worldwide) have had foot ulceration in the past (Armstrong et al., 2017). These numbers show that foot ulceration is a major problem for a considerable group of diabetes patients. The causes of foot ulcers are peripheral neuropathy, foot deformity, increased plantar stress, peripheral vascular disease, and peripheral arterial disease (Armstrong et al., 2017). For instance, neuropathy causes stresses on the foot that are not solved, causing unnecessary stress, resulting in ulceration. As said by Armstrong et al. (2017), patients with neuropathy lost their 'gift of pain' and are no longer aware of warning signs. Around 50-60% of ulcers become infected, and 20% of moderate to severe infections are responsible for causing lower-limb amputations (Armstrong et al., 2023). Infection and progressive gangrene are the main reasons for these amputations. Every 20 s in the US, a lower limb is amputated as a result of diabetes complications; 85% of these amputations are preceded by foot ulcers (Edmonds et al., 2021).

Proper treatment and behaviour changes, such as resting, avoiding barefoot walking, and wearing therapeutic footwear, can prevent ulcer worsening. If this doesn't work, other options are surgical debridement or vascular reconstruction. Approximately 30-40% of DFUs heal within 12 weeks, but recurrence is common, occurring in about 42% within one year and 65% within five years (Armstrong et al., 2023). Furthermore, the mortality rate is a lot higher for patients with DFU, namely 231 deaths per 1000 person-years in comparison to 182 deaths per 1000 person-years for patients without DFUs (Armstrong et al., 2023).

Beyond healing, prevention offers significant benefits. Bus and Van Netten (2015) suggest that 75% of foot ulcers are preventable through measures like regularly inspecting the foot's surface. This enables timely intervention and helps prevent the ulcer from worsening. However, diabetes patients often face challenges like obesity, visual impairment, and limited hip and knee mobility, making self-inspection for ulcers difficult (Lavery et al., 2004). Despite their visual appearance, temperature monitoring effectively detects ulcers, as ulcer development increases local skin temperature due to inflammation and enzymatic autolysis (Lavery et al., 2004). Recently, the International Working Group on the Diabetic Foot (IWGDF), which provides guidelines for ulcer prevention, has included a recommendation for home temperature monitoring:

'Consider coaching a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference between corresponding regions of the left and right foot is above a temperature threshold of 2.2 °C (or 4.0 °F) on two consecutive days, coach the patient to reduce ambulatory activity and consult an adequately trained healthcare professional for further diagnosis and treatment' (Bus et al., 2023).

DFUs are a significant issue for some diabetes patients, but temperature monitoring can help prevent their development. This defines the project's context.

1.2 Assignment and Approach

This project was commissioned by Secuped, a start-up based in Leiden. The company currently has two owners and one product designer. The start-up is based on a product that helps patients with an increased risk of ulcer development to monitor their feet and prevent ulcers in this way. The development of the product started back in 2022, and in the meantime, a prototype was made, see Figure 5. The prototype can take temperature measurements and has a first initial display for interaction. This prototype was used to secure funding, which was successfully obtained. Recently, they secured funding for the Diamond project in partnership with LUMC, enabling real product development and contributing to the initiation of this graduation project.

The main goal of this project is to design the user experience of the product. Users will interact with the device and have certain expectations. This project will address several key questions: What is the best interface to communicate proper device usage to the user? What actions should be taken when a temperature difference is detected? How will the retrieved data be handled? What are the podiatrist's expectations regarding the patient? The focus of this project is primarily on the white section of the prototype, rather than the part where the feet are placed.

'Design a prototype that delivers an optimal user experience for diabetes patients using the device to measure their foot temperature for detecting the beginning of DFU at home, as well as for caregivers interpreting the provided data.'

Figure 5. Current prototype

2. Background and literature review

This chapter offers a detailed overview of foot ulcers, covering their development, common locations, and associated costs. It also discusses the benefits of temperature monitoring and the challenges faced by patients with foot ulcers. Following this, a persona and an overview of the target group size are provided.

2.1 Diabetes and foot ulcers

Chapter 1 introduced the importance of preventing Diabetic Foot Ulcers (DFUs). This chapter provides further details on their development, common locations, and associated costs, aiming to clarify the product's intended function and its potential cost-effectiveness.

Development of ulcers

Ulcers develop in various ways, with DFUs most commonly caused by repetitive stress (vertical or shear) on a specific area, particularly in patients with peripheral neuropathy (nerve damage that leads to sensory changes) (Armstrong et al., 2017). Also, peripheral artery disease (PAD) (narrowing or blockage of arteries leading to reduced blood flow) and autonomic neuropathy (autonomic nervous system damage, leading to dry skin and less protection against damage) contribute to the development of DFUs (Armstrong et al., 2023). Within peripheral neuropathy, a distinction is made between motor and sensory neuropathy. Motor neuropathy can lead to foot deformity and biomechanical abnormalities, while sensory neuropathy leads to loss of protective sensation (Armstrong et al., 2023). In the end, these changes lead to callus formation, under which haemorrhage can be caused by minor trauma or inflammation due to repetitive impact (Armstrong et al., 2023). Removing the callus reveals the ulcer, which is then already extending through the epidermis (outer layer of the skin), Dermis (middle layer of the skin), to the subcutaneous tissue (deepest layer of the skin) (Armstrong et al., 2023). This entire process is also shown in Figure 6, a Figure created by Armstrong et al. (2023).

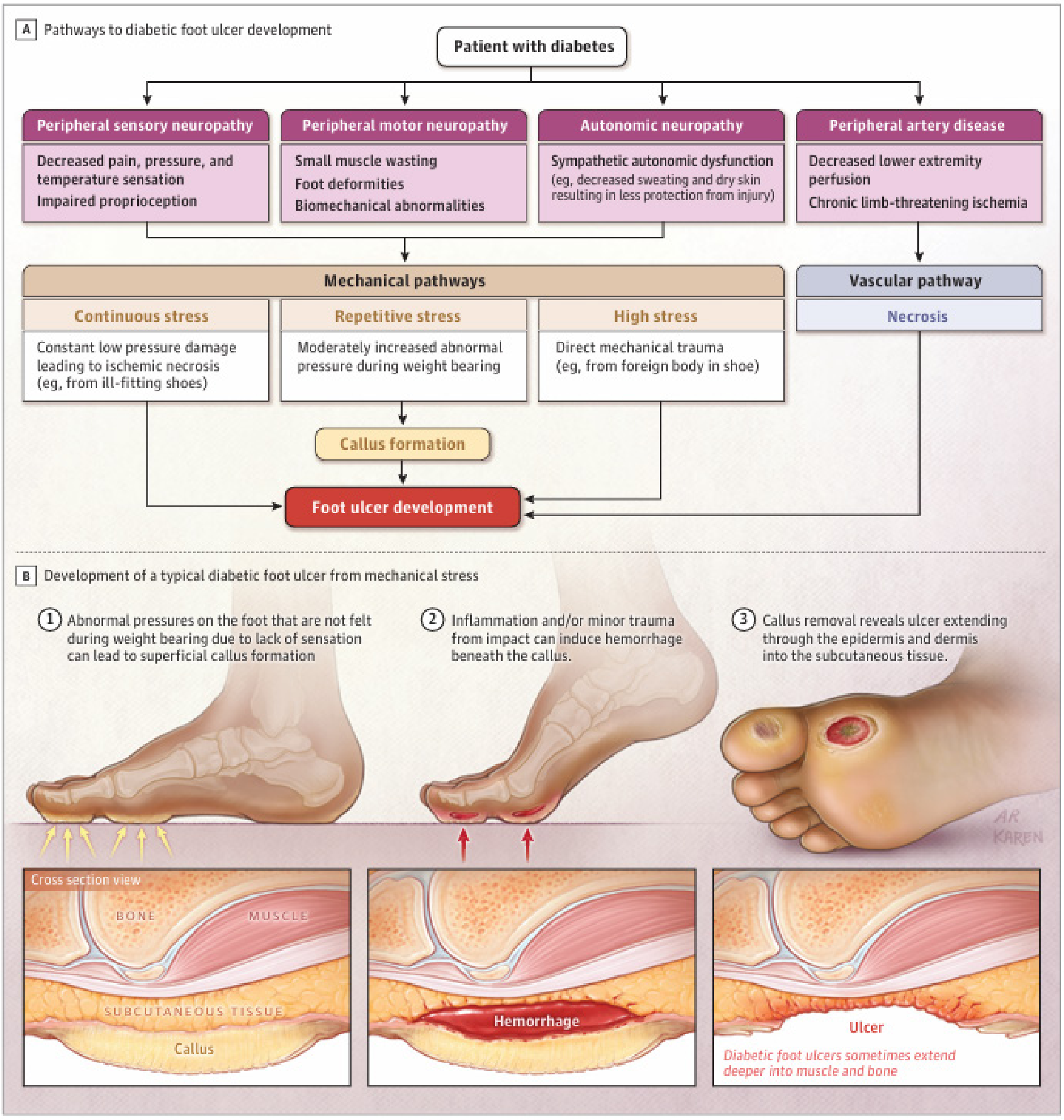


Figure 6. The development of an ulcer (created by Armstrong et al. (2023)).

Ulcer locations

Diverse studies have been conducted to identify the most common locations for these ulcers. Ulcers can be positioned at the plantar side (bottom of the foot) or the non-plantar side. Ulcers located on the plantar side are often located at the metatarsal heads, heal and hallux region (Veneman et al., 2021), while non-plantar ulcers are located at the dorsal side (top side foot) and on the distal aspect of digits (so the farthest point on a toe, like the nails) (Armstrong et al., 2017). Prompers et al. (2006) found that the dorsal side and interdigital area of the toes were the most frequent ulcer side (32% of the cases). They found that most ulcers were located on the non-plantar surface (52% of all ulcers found). In addition to these findings, Bus et al. (2021) summarise that only 32% or even less of the ulcers developed at the previous site and that 58% of ulcers developed at the measurement site (plantar side). As can be seen, the percentages of ulcers on plantar and non-plantar sides differ between studies. The main point is to give an estimate of the percentage. In Figure 7, the locations are visually shown.

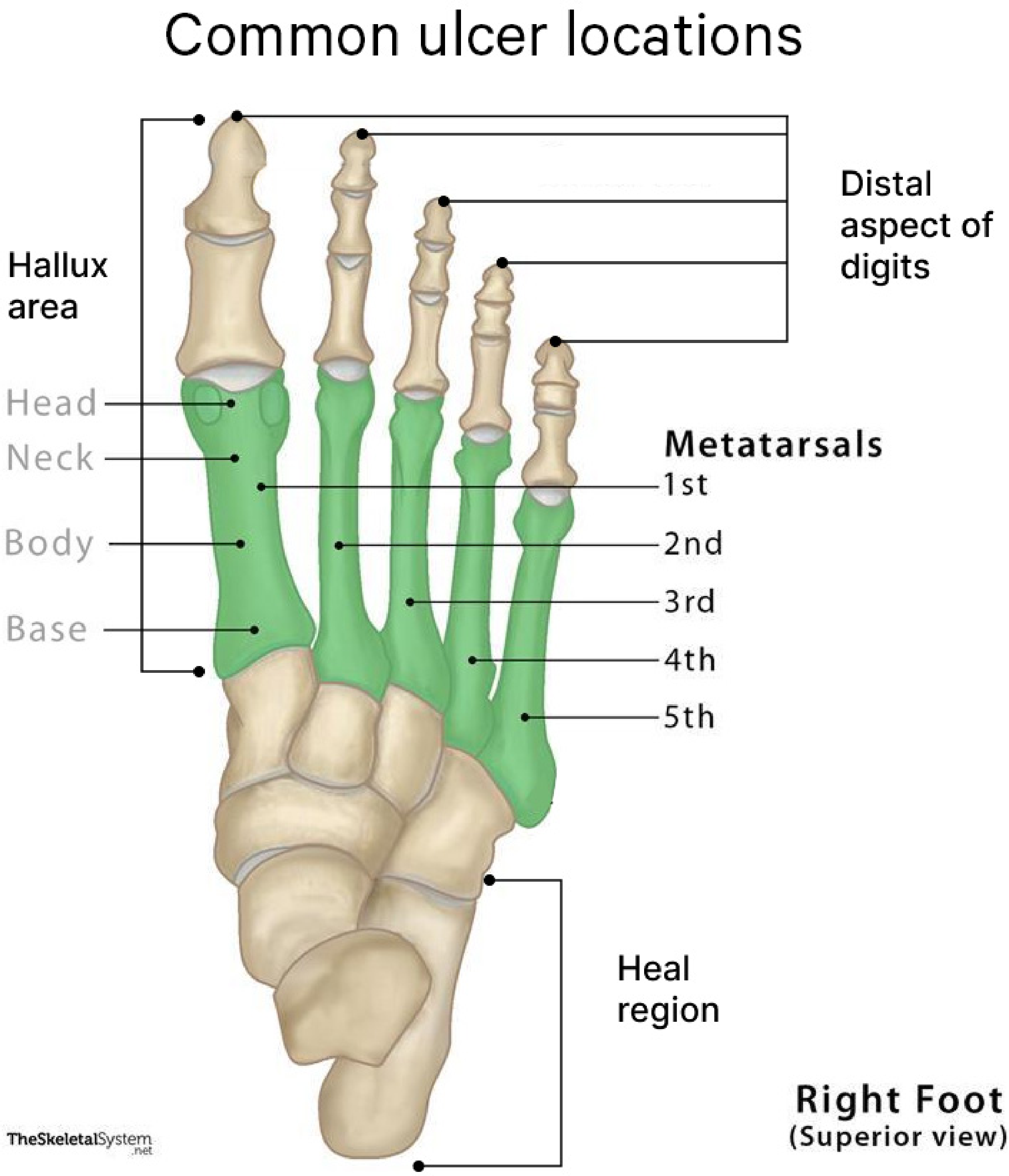


Figure 7. Common ulcer locations (adapted from TheSkeletalSystem, n.d.)

Costs

The costs around the DFUs are significant. Lower extremity complications such as DFUs and lower limb amputations make up one-third of the direct diabetes care costs (Abbott et al., 2019). In the US, the costs per patient with a DFU were about $33,000, which included 14 visits to outpatient healthcare providers and hospitalisation of around 1.5 times per year (Reyzelman et al., 2018). These DFU-related direct costs in the US exceeded $17 billion (Frykberg et al., 2017).

About half of the ulcer treatment costs are spent on hospitalisation and amputation. In the Netherlands, it was found that an ulcer episode costs around €10.000 (Van Netten et al., 2024). An interesting insight is that research spending on ulcer management (healing) is ten times higher than on prevention (Bus & Van Netten, 2015), highlighting an area with significant potential for improvement.

2.2 Temperature monitoring as a preventive measure

Over the past decade, multiple studies have been conducted to identify what can be done to prevent the development of DFUs. In 1971, increased local temperature and pressure were identified as potential markers for tissue injury (Armstrong et al., 2007). In 2004, in a random controlled trial (RCT) conducted by Lavery et al., it was already found that the group using a handheld thermometer to measure temperature in the morning and evening on 6-foot sites had significantly fewer ulcers.

Measuring the skin temperature of the foot has been identified as a marker for tissue inflammation and injury (Armstrong et al., 2007). In this study, half of the participants were instructed to measure the temperature, and if a difference of more than 2.2°C between the left and right foot at a specific site was detected, they were advised to reduce their activity. Of the measuring group, only 2% ulcerated, while 20% of the other group had an ulcer (Lavery et al., 2004). Figure 8 displays a graph illustrating the temperature difference observed when a participant developed an ulcer (please note that the values are in °F).

These findings are supported by another RCT, where the measuring group ulcerated 4.7% while the non-measuring group ulcerated 12.2% (Armstrong et al., 2007). Additionally, it was found that participants had a 4.8 times greater temperature difference at the site during the week prior to ulceration (Armstrong et al., 2007). However, it is emphasised that foot temperature does not significantly reduce the incidence of these DFUs unless participants reduce activity when hotspots are found (Bus et al., 2021). In their study, the measuring group had a 35% reduction in ulcer incidence. It does require a certain time commitment from users to perform these measurements daily and over the years (Golledge et al., 2022). Better adherence to monitoring and activity reduction has been linked to greater effectiveness in reducing the risk of DFUs.

On the other hand, a different study found that only 29% of participants who identified a hotspot reduced their activity by more than 50% (Golledge et al., 2022). In conclusion, a meta-analysis by Ena et al. (2020) of four studies showed that temperature monitoring reduced ulcer incidence by approximately 65%.

Although several RCTs have shown that temperature monitoring can be effective, there are some downsides to this preventive method. One key issue is that many diabetic patients suffer from neuropathy. This can affect lower extremity perfusion and temperature regulation, which makes it difficult to set one absolute skin temperature as a universal reference (Armstrong et al., 2007). This also brings along the challenge of measuring two feet, as both might have a different level of neuropathy. This already causes temperature differences, while there is no ulcer development. Secondly, the burden of long-term daily measurement and false-positive readings shouldn't be underestimated (Bus et al., 2021). Although the measurements might be successful, practical implementation in the day-to-day life of patients who already measure a lot for their disease can be cumbersome.

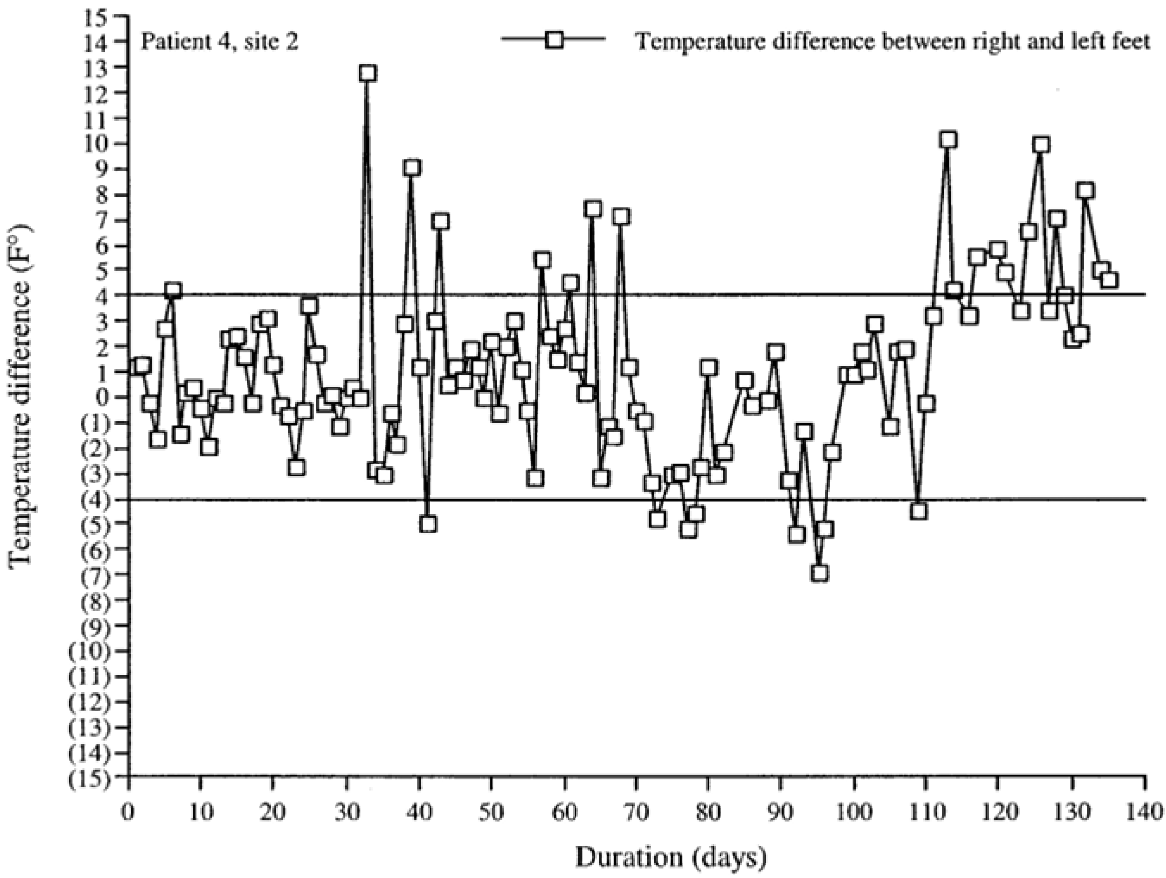


Figure 8. Temperature deviations when an ulcer develops (created by Lavery et al. (2004))

2.3 Current challenges in DFU care

The previous subchapters discussed various ways to prevent diabetic foot ulcers (DFUs). While it may seem obvious for a patient to visit a doctor upon noticing an ulcer, several factors can create barriers that prevent patients from taking action. In this subchapter, those will be briefly summarised to give a picture of what kind of challenges this target group faces. These challenges are taken from the study by Crocker et al. (2022) in which they researched the patient perspective on DFU care. Of course, these challenges might not apply to all patients and differ between countries, but they are mostly meant to give an overview.

1. Patients do not recognise or use the word ‘ulcer’; instead, words such as ‘injuries’ and ‘blisters’ are used.
2. Patients and non-diabetes medical specialists have some confusion about how to name and respond to pre-ulcerative lesions.
3. There is a lack of protocol for the treatment of DFUs. The patient simply doesn’t know where to seek care, and there are frustrating delays in processes such as specialist referrals. These delays result in a 0.6% increased risk of major amputation or death each day a referral to a medical centre is delayed (Armstrong et al., 2023). In addition, there are barriers to accessing medicines, bandages and regular doctors.
4. Patients are already focused on managing other aspects of their diabetes. Given the complex nature of diabetes and the presence of comorbidities, this can be particularly challenging.
5. Many patients are older and face additional life challenges, such as family deaths. Combined with the burden of their disease, this can lead to feelings of being overwhelmed.
6. Visual observation for foot ulcers is difficult due to the distance between feet and eyes, specifically when ulcers are located on the plantar side.
7. Patients are often unaware of the severity of the problem. Initially, they attempt to care for the wound themselves by cleaning and disinfecting it at home, which results in ulcers reaching advanced stages by the time hospital care is sought.

2.4 Target group

Persona

This sub-subchapter will highlight a few common characteristics to provide an overview of the target group for this product. The data presented here are based on the study of Van Netten et al. (2024), where 304 participants participated. Their baseline characteristics are described and were used to create the persona presented in Figure 9. The age group is around 60-70 years, and most patients have type 2 diabetes. Patients often have comorbidities such as retinopathy, neuropathy, and grade 1 peripheral artery disease. Most patients have semi or full custom-made footwear and visit foot care (medical pedicure or less regular podiatrist) every 1-8 weeks. They also often have moderate foot deformities, such as hammer toes or claw toes. In the study, most patients had an ulcer at the plantar forefoot or medial forefoot. Lastly, a big part of the target group is slightly overweight and struggles sometimes to use digital devices.

Mieke

69
Female
Widow, 2 children
Lives alone

Needs

- Something that helps me bring back the trust in my feet, that removes the anxiety of having another ulcer
- An easy to use solution that doesn't take a lot of time

Wants

- Something that is simple to take with me
- A device that isn't stigmatizing

Frustrations

- Sometimes she forgets what she was doing
- Worries about feet health
- Struggles to understand new products
- Difficult to check the underside of the feet due to issues with balance

Profile

Health situation:
Diabetes type 2 for more than 15 years
Cardiovascular problems & neuropathy
Foot ulcer 1 year ago (medial forefoot)
Retinopathy
Moderate foot deformity
Slightly overweight
Professional foot care every 5-8 weeks

Technology level:
She knows how to use the oven for cooking, but she doesn't own a smartphone. She did get a tablet, but except from reading she isn't using it a lot and often needs help from her children.

Story

Mieke is living alone in her appartement, where she drinks her morning coffee outside if she can. Two or three times per week someone comes by to help her shower.

Life continues slowly, she loves to read or watches tv. Also when there is some sunshine outside, she loves to work in the garden. She still does her grocery shopping by herself and tries to cook everyday. In this way she also knows best how to control her insulin levels.

In addition to daily activities she is also busy with healthcare appointments. Due to her recent ulcer, she visits the podiatrist more regulary and uses cream. Altough this seems to help, she is still afraid it will happen to her again. As the feeling in her foot is limited, she doesn't feel when a problem is developing. Furthermore, due to her slight overweight and older age, she struggles to bend and watch underneath her foot.

Current devices used for monitoring health

Glucosemeter | Moisturizing creams | Insulin pen | Full custom-made footwear

Characteristics

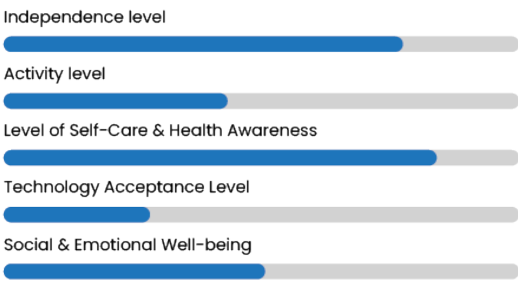


Figure 9. Persona to explain a person within the target group

Target group variety

Although in the previous alinea a persona is presented to give some picture of the target group, one should note that there are a lot of varieties, for instance, in the amount of care people receive. To get a full understanding, some explanation about SIMS classification and care packages should be provided. SIMS classification is a system used to classify how severe the risk is that a person will develop an ulcer. SIMS 1 and SIMS 2 both have a low ulcer risk, which means that, often, only once per year, a foot health professional is visited by the patient. SIMS 2 and 3 are the highest classes, which both have a moderate to high ulcer risk. In Figure 10, an overview is provided explaining all the different categories. These SIMS classifications are used to define the care package a patient will receive.

These care packages are very short summarised as follows:

- **Care package 1**: SIMS 1, Feet check is covered by basic insurance, but for a podiatrist, one needs supplementary insurance.
- **Care package 2**: SIMS 1 or SIMS 2, all care covered by basic insurance.
- **Care package 3**: SIMS 2, all care covered by basic insurance.
- **Care package 4**: SIMS 3, all care covered by basic insurance.

In conclusion, patients with SIMS classification 2 or 3 are most suitable for using the product described in this report.

SIMS 0

No neuropathy
No peripheral atherial vascular disease
Possible pressure spots present

Care profile
Ulcer risk: very low
Healthcare professional visit: once a year feetcheck by for instance GP

SIMS 1

Neuropathy
or
Peripheral atherial vascular disease
no pressure spots present

Care profile
Ulcer risk: low
Healthcare professional visit: once every 6-12 months by POH, diabetic podiatrist or pedicure.
Care profile: 1 or 2

SIMS 2

Neuropathy and peripheral atherial vascular disease
Neuropathy and pressure spots (foot deformity)
Peripheral atherial vascular disease and pressure spots (foot deformity)

Care profile
Ulcer risk: moderate
Healthcare professional visit: once every 3-6 months diabetic podiatrist
Care profile: 2 or 3

SIMS 3

Neuropathy and/or peripheral atherial vascular disease
and
Past ulcer or
past amputation or
end-stage renal disease

Care profile
Ulcer risk: high
Healthcare professional visit: once every 1-3 months diabetic podiatrist or foot team
Care profile: 4

Figure 10. Explanation SIMS class system

Potential number of users of the product

On the website of the International Diabetes Federation (n.d.), several numbers are published to estimate the population of patients living with diabetes. In the Netherlands, in 2021, there were 857.000 patients with diabetes; worldwide, this was 536.619.700. In 2015, 20.000 patients developed an ulcer, of which 15% had a partial amputation of (a part of) their leg (Federatie Medische Specialisten, 2017). To get an idea of the number of people that would benefit from monitoring, several papers were read to determine the number of patients that belong to the high-risk category. Percentages slightly differ per paper, and therefore two numbers as a minimum and maximum were chosen. In the study by Chappell et al. (2021), it was found that in the highest risk category (CPR score 4), there was a 2% probability of developing an ulcer. In the second highest risk category (CPR score 3), this was 4%. Therefore, it was determined that the percentage of patients developing an ulcer ranges from 2% to 6%.

It is assumed that 30% of these at-risk individuals will ultimately use this product. But not everyone will adhere to the product, and therefore, it is estimated that 80% will keep using the product. This means that 24% of the people at risk will use the device. In the Netherlands, this will be between 4414 - 12.341 products. On a global scale, the number of products needed is estimated to be between 2.6 and 7.7 million. While these figures are approximate, they provide an understanding of the target group's size both in the Netherlands and worldwide.

2.5 Conclusions/takeaways

In this chapter, the background of DFU development and related challenges are described, as well as an explanation of the target group and an estimation of the target group size. The main important lessons are:

- DFUs are most commonly caused by repetitive stress (vertical or shear) on a specific area, particularly in patients with peripheral neuropathy and peripheral artery disease.
- Several studies point out that ulcers often aren't located at the plantar (bottom) side but also on the non-plantar side, providing a need to measure on different sides of the foot.
- The costs for DFU treatment are high, in the Netherlands around €10.000 per ulcer episode.
- Temperature monitoring can be used as a preventive measure, where it is advised to take action when a difference of more than 2.2°C between the left and right foot is found.
- Challenges within DFU care are that care paths are sometimes hard to get through, or patients underestimate the severity of the wound and try treatment themselves or do not even recognise the word 'ulcer'.
- The patients in this target group often also have foot deformities, use custom-made footwear and already use a lot of devices to control their diabetes.
- There are multiple SIMS classes with accompanying care packages that help identify the profile of the patient and the associated care path.
- It is estimated that between 4400-12000 products in the Netherlands will be used, with 2.6-7.7 million worldwide.

3. Context analysis

To provide context for this project, several design methods were employed to create a clear picture. A stakeholder analysis was conducted, and a survey was used to gather information about the target group's current living situation. The existing prototype was also analysed, and a competitor overview was created to explore the market landscape. Finally, customer journeys were mapped to gain insight into the interactions between different stakeholders.

3.1 External stakeholders and their roles

To understand the context, a stakeholder map was created based on past interviews and research. The map is divided into three parts: general diabetes care, diabetes foot care, and external parties like insurance companies. The patient is placed at the centre, as the goal is to identify key stakeholders closest to the patient. Validation with patients will ensure accuracy. For diabetes foot care, symbols indicate preventive and curative roles. The map is shown in Figure 11.

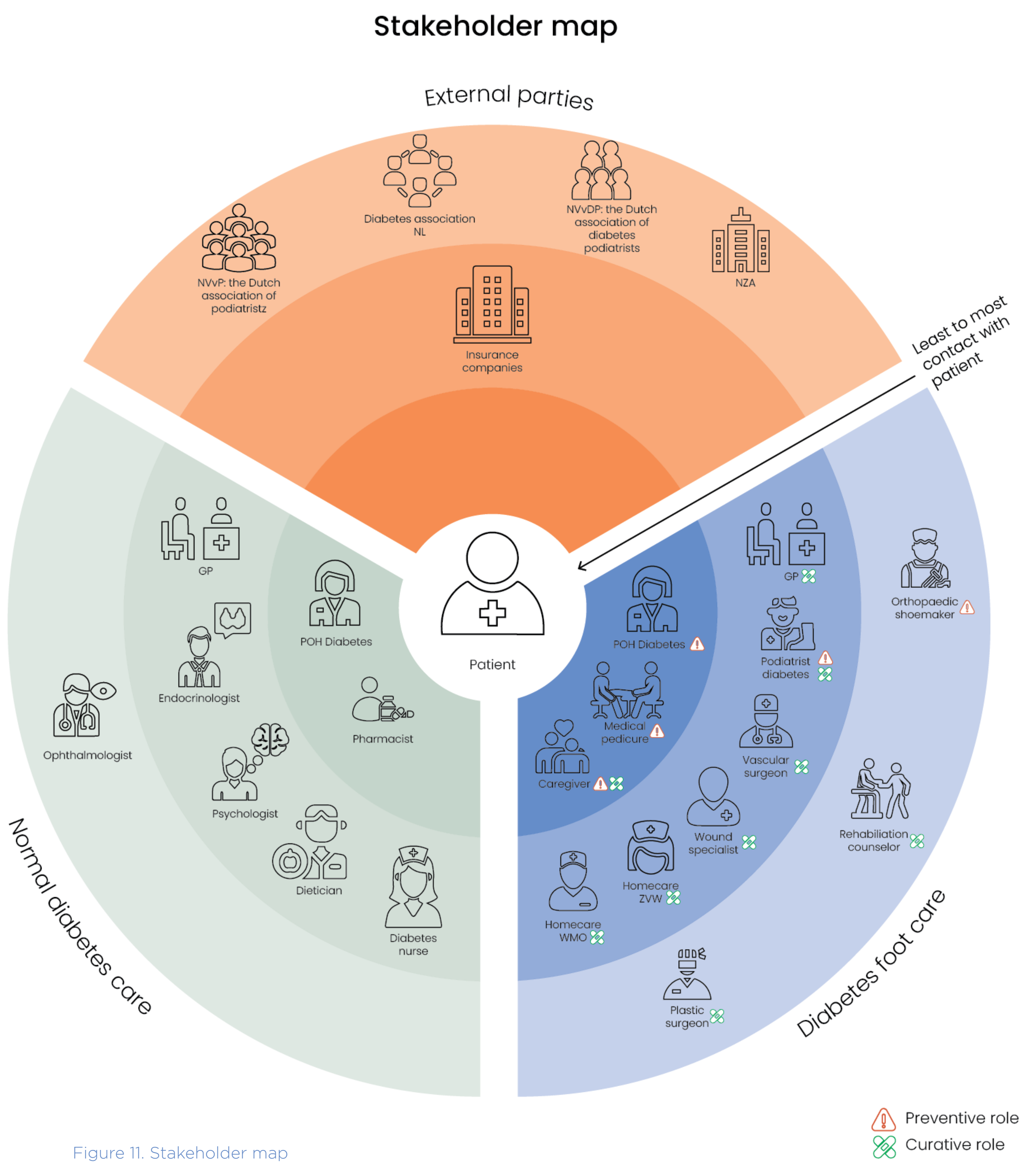


Figure 11. Stakeholder map

Key stakeholders and their roles are briefly discussed to clarify their connection to the patient and aid in understanding the customer journeys.

POH diabetes

This person examines the feet of diabetes patients annually (or more frequently) as a preventive measure. They check for signs of peripheral neuropathy, peripheral artery disease, and monitor the development of calluses and ulcers. With this person, all other diabetes-related matters, such as insulin use, can also be discussed.

Podiatrist diabetes

If the patient develops any issues, they are referred to "1.5-line care," which is provided by the podiatrist. The podiatrist removes excessive calluses, checks for ulcers, and ensures proper foot care. In the case of an ulcer, the podiatrist provides initial treatment (curative care). If necessary, they can refer the patient to an orthopaedic shoemaker for improved footwear (preventive care). It is important to note that podiatrists in the Netherlands have an HBO-level education, whereas in other countries, they often have a university degree. As a result, Dutch podiatrists (podotherapeuten) have fewer rights, such as limited referral capabilities, compared to their international counterparts.

Caregiver

The patient is often older and requires additional support for managing comorbidities. As a result, a caregiver (mantelzorger) is typically involved to assist with tasks such as checking the feet for ulcers or applying cream.

Medical pedicure

This person is responsible for foot hygiene and could help out with ingrown toenails, calluses, etc.

Vascular Surgeon

If the patient has peripheral artery disease and a foot ulcer that does not heal, a vascular reconstruction may be performed. This surgical procedure, conducted by the vascular surgeon, aims to restore blood flow. The surgeon also performs amputations in cases of severe ulcers.

Wound specialist

In case of an open ulcer wound that doesn't want to heal, this person can be contacted. With the right combination of cleaning and moisturising, healing can be achieved.

Orthopaedic shoemaker

A key aspect of foot ulcer prevention is wearing the right footwear. Footwear that doesn't exert continuous pressure on specific areas helps prevent ulcers. This person's role is to ensure the patient is fitted with the most optimal shoe.

Homecare WMO/ZCW (wet maatschappelijke ondersteuning & Zorgverzekeringswet)

This person's role is to assist with wound care and help the patient put on shoes. In the future, they may also assist with taking foot temperature measurements.

Communication between the foot stakeholders and the patient

The patient is influenced by the various stakeholders. However, each stakeholder plays a different role in the care path, which is visualised in Figure 12.

Care network around patient

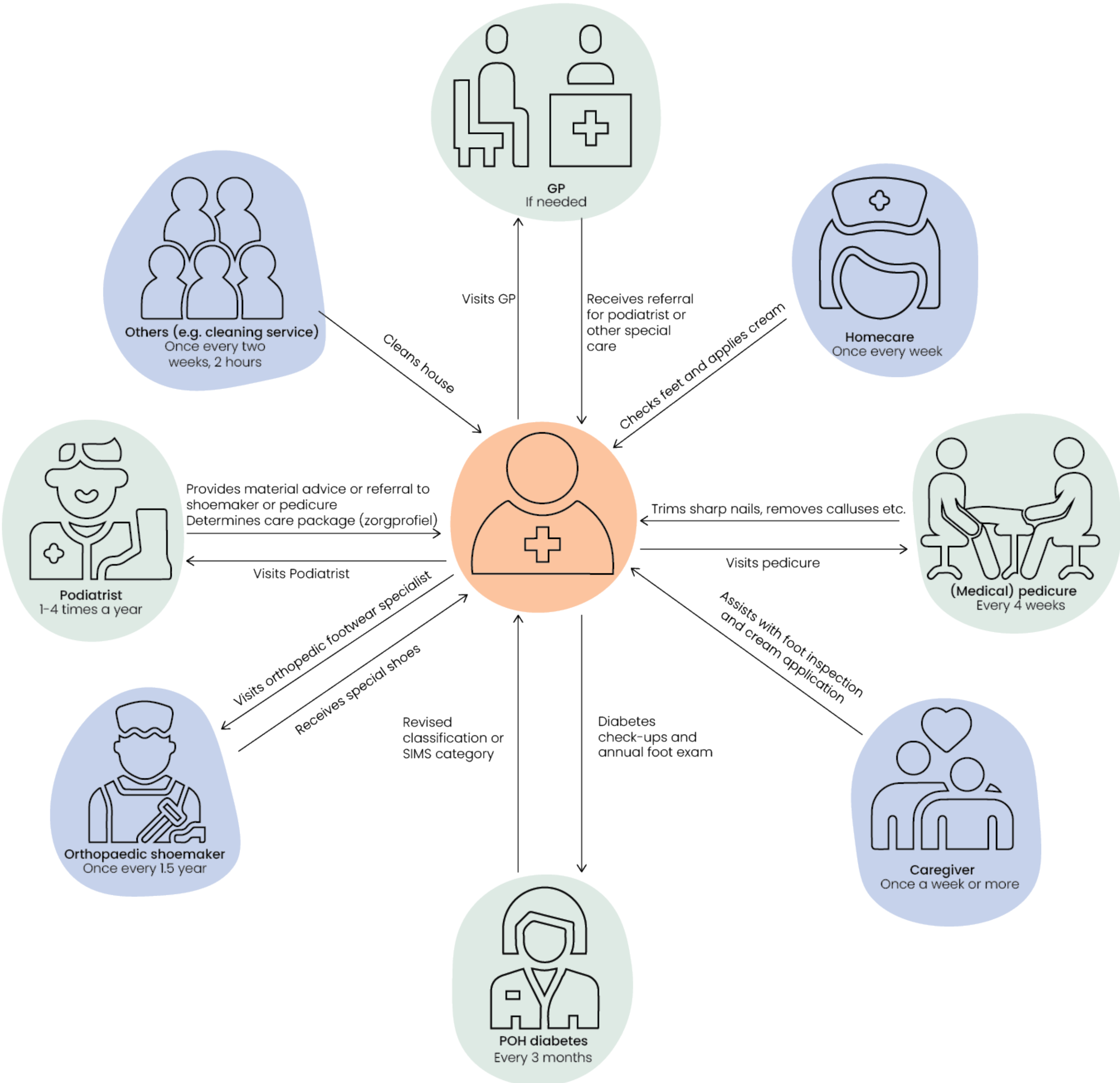


Figure 12. Interactions between foot care stakeholders and the patient

The data in this visual is based on patient interviews and presents possible interactions with stakeholders. Not all these interactions will apply to patients. Of course, the stakeholders also interact with one another; however, for the sake of clarity, these interactions have been left out of the visual. With a short story, this interaction between stakeholders will be visualised:

'A patient living with diabetes notices a problem with his/her foot and contacts the GP. The GP gives the patient a referral to visit the podiatrist. The podiatrist analyses the foot and determines the right care package for this patient. This care package can consist of multiple treatments at the pedicure. Sometimes the podiatrist also contacts the pedicure to give some advice on how the treatment could best be done for this specific patient. On the other side, the pedicure sometimes contacts the podiatrist to discuss a wound formation. While at the podiatrist, the patient is also advised to visit the orthopaedic shoemaker to get better footwear. This all seems to help the patient, but at some point, the patient still gets a wound, and it is quite severe; therefore, the podiatrist immediately contacts the GP (or the patient him/herself does this). The GP checks the wound and might give a referral to the second-line care, such as a wound specialist, vascular surgeon, etc. After the wound has healed, the patient still receives some care at home, where a person helps with applying cream.'

Conclusions of stakeholder analysis

From this analysis, it can be concluded that the podiatrist plays a significant role in the care path of the patient. This person is responsible for determining the care package (at least here in the Netherlands) and could probably play a significant role in our product system, or at least be the person responsible for prescribing the product. The role of the medical pedicure should also not be underestimated, as the patient visits this person almost every month. Also, the POH diabetes is a person who has regular contact with the patient and might be a key stakeholder in motivating the patient. This person is also responsible for prescribing the SIMS category, which helps the podiatrist to come up with the correct care package. So far, there are no conflicting relationships between any of the stakeholders, as each has their own distinct responsibilities.

3.2 Survey results

From February 26 to March 12, a survey was posted online (on diabetes.nl and within Facebook groups) to gather initial insights into the context of the target group. The survey, created in Qualtrics, consisted of several sections. Depending on the answers provided, participants were directed to different parts of the survey, while other responses led to the survey's conclusion. These sections focused on foot ulcers and temperature monitoring, and were only shown to those who had experienced a foot ulcer or used temperature monitoring. Most participants were recruited via the Type 2 Diabetes Facebook group. The characteristics of the participants and the survey questions can be found in Appendix B.

General information

The survey was primarily completed by women aged 55–64. Nearly half of the participants (45%) have been living with diabetes for over 10 years. The most commonly used products among respondents include blood glucose meters (selected 17 times), insulin pens or syringes (13 times), and continuous glucose monitors (12 times).

The most frequently mentioned foot-related health products were moisturising foot creams (9 mentions), compression stockings (5 mentions), specialised diabetic footwear (2 mentions), and offloading devices, such as special insoles or braces (1 mention). Additionally, two participants mentioned other products: the Freestyle Libre 2 (a diabetic monitoring system) and Metformin (a medicine).

Contact with a podiatrist & a hypothetical situation of ulcer development

The majority of participants (62%) have never visited a podiatrist. Among those who do, most engage through in-person visits (83%) or phone calls (17%), typically seeing their podiatrist once a year or less. Only one participant reported visiting their podiatrist monthly, while three others go every few months. At the same time, one person pointed out receiving emails in which an explanation was given to prevent the worsening of the foot problem. When there was contact with the podiatrist, most participants were able to get an appointment directly, two participants mentioned that they had to send pictures, and one participant mentioned that the podiatrist asked a lot of questions.

Only 5 out of the 26 survey respondents had experienced a foot ulcer in the past. The others were asked how they would respond if they developed an ulcer (hypothetical situation), and the majority (53%) said they would contact their podiatrist or doctor. Others indicated they would wait a few days (16%), while three participants admitted they wouldn't know what to do. One participant mentioned (s)he would reach out to a diabetes nurse instead of a podiatrist or doctor.

Foot ulcer

Among the five participants who had experienced a foot ulcer, four had it once, while one had it more than three times. This individual also reported visiting their podiatrist monthly, sending pictures for assessment, and receiving emails with guidance on preventing further complications.

When noticing an ulcer, two participants immediately contacted their doctor or podiatrist, while one waited a few days, another sought advice from family or friends, and one could not remember his/her response. Two participants reached out to their podiatrist on the same day, whereas two others waited more than a week.

Regarding preventive measures, three participants did not follow any specific precautions. The remaining two engaged in visual foot inspections, moisturizing, and general foot care to keep their feet dry—spending an average of 5–10 minutes per day on these routines.

Lastly, none of the five participants used temperature monitoring as a method to detect ulcers.

Summary of survey findings

The main conclusions from this survey will shortly be summarised below:

- The most commonly used diabetes management tools are blood glucose meters, insulin pens or syringes, and continuous glucose monitors.
- In terms of foot care, moisturising creams and compression stockings are the most frequently mentioned products.
- Contact with podiatrists primarily occurs through in-person visits, with occasional phone calls. Most patients see their podiatrist infrequently, typically once a year or less.
- When reaching out to a podiatrist, most participants were able to get an appointment immediately, though some were asked to send a photo for evaluation.
- Most participants indicated that if they discovered an ulcer, they would contact their podiatrist or doctor immediately, rather than wait.
- Among those who had previously developed an ulcer, responses were evenly split between seeking immediate medical advice and waiting a week before taking action.
- Most participants who had experienced an ulcer did not follow any preventive measures. Those who did focus on visual foot inspection, moisturising, and general foot care spent an average of 5–10 minutes per day.
- None of the participants used temperature monitoring to detect ulcers.

These findings provide insight into how individuals with diabetes manage their condition daily, their interactions with podiatrists, and the preventive measures they take - if any - to reduce the risk of ulcers.

3.3 Assessment of the current prototype

At the start of this project, a proof-of-concept prototype was already available. It is a basic setup containing all necessary components, built using Arduino. The prototype includes six temperature sensors and a pressure sensor for each foot. Several LEDs indicate the user's progress during the measurement process. It currently measures the metatarsals, midfoot, heel, and big toe. The device operates on battery power but also has a power input. Data is transmitted via a personal Wi-Fi setup to a web portal for visualisation. Additionally, the foot placement is slightly angled to accommodate users with obesity, who tend to position their feet apart. In Figure 13 & Figure 14 an explanation of the error and normal usage of the product can be found.

Figure 13. Error flow of the prototype

Current prototype flow

Left foot is placed on the device

The pressure sensor notices the foot and the device wakes up. At the left side the LEDs start blinking.

Right foot is placed on the device

The pressure sensor notices the right foot. LEDs at the right side start blinking.

Both feet are correctly placed on the device

The system continues to the next step, which is the start of the temperature measurement. The second LED above 'sit still' starts blinking. This indicates the test is running.

Test is finished. The feet can be removed

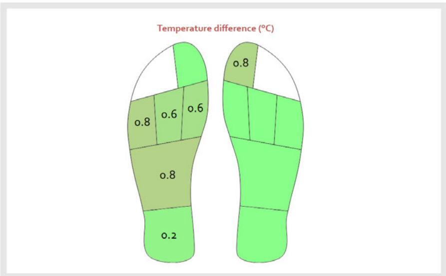
The test is finished! The LEDs above 'get up' start blinking and the 4 LEDs on the left & right side start blinking as well. This is the moment the data is send to the cloud.

Both feet are removed

The LED for 'ready' start blinking, both pressure sensors notices the absent of pressure.

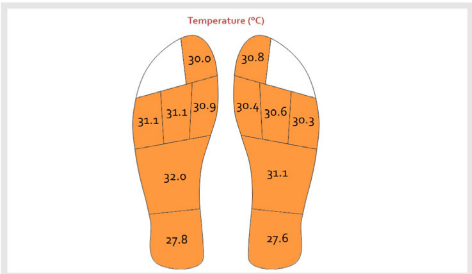
The product isn't used anymore

The product goes back into sleep mode, all LEDS are off. This happens after a few seconds



The user visits the portal

Data is sent by WiFi to the webportal.



Scrolls down on webpage and sees real temperature

Data is sent by WiFi to the webportal.

Figure 14. Normal usage flow of the prototype

User tests have already been conducted with this prototype, and key findings are summarised in Figure 15. This brief study involved testing the prototype with a small group of elderly participants (non-diabetic) and one individual living with diabetes. The primary aim was to gather initial reactions to the prototype. As such, these findings should be viewed as preliminary impressions rather than definitive conclusions. They represent the participants' first responses and will be further explored in the broader scope of this graduation project, where additional testing with a larger group will take place.

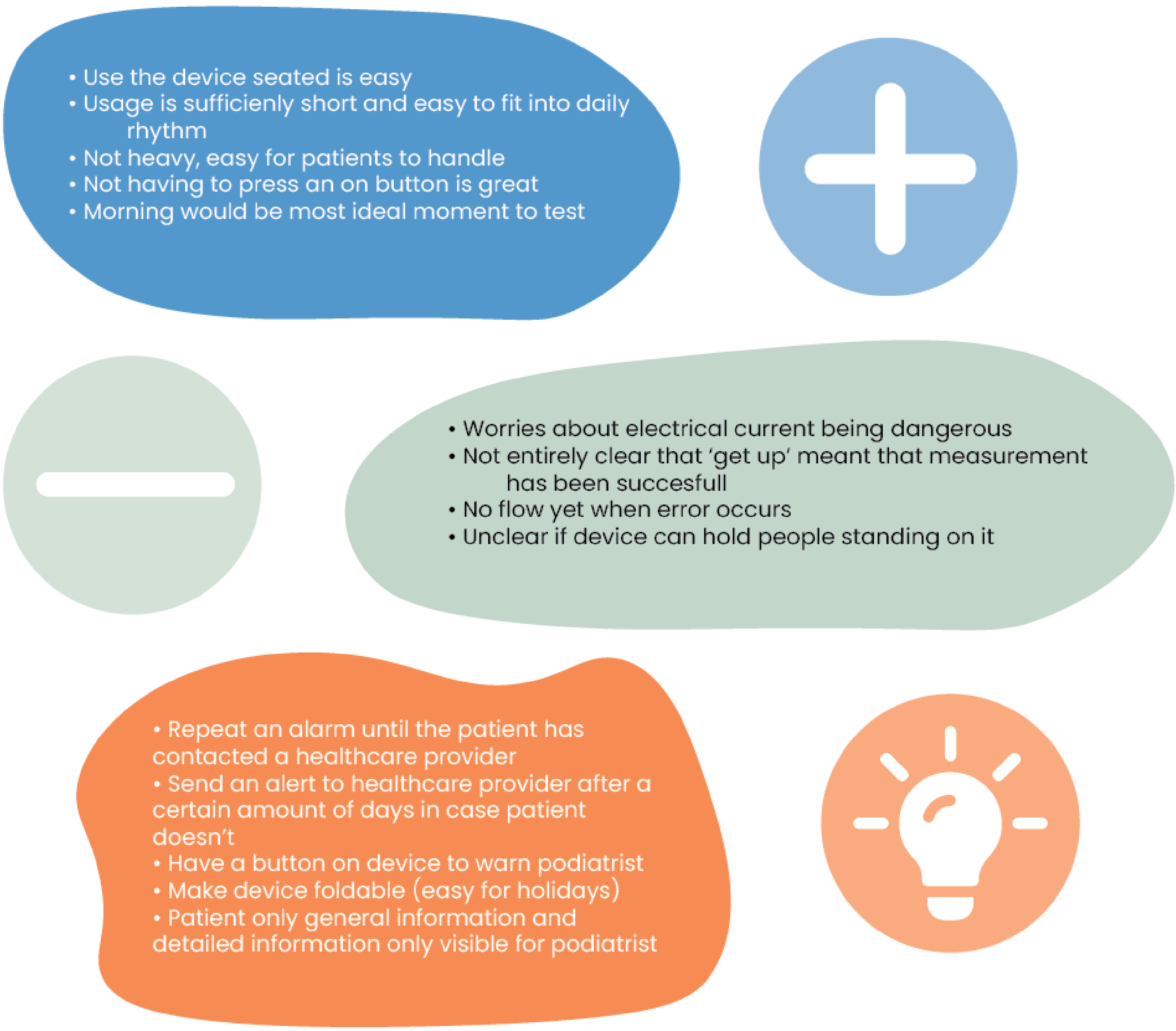


Figure 15. Findings of earlier user tests

3.4 Analysis of existing solutions

Several companies are actively addressing the need for diabetic foot monitoring through temperature measurement. This subchapter highlights five existing solutions: Siren Socks, Podimetrics, VistaFeet, Orpyx, and Bluedrop Medical (see Figure 16). Each product will first be briefly described, followed by a discussion of its strengths and limitations. These insights will form the basis for recommendations related to the product development presented in this report.

- Siren socks are socks that can be worn all day and measure the temperature at 6 locations. By means of a hub, data is shared and also shown in the app.
- Podimetrics is a device that can be used once a day to measure the temperature. It has a simple display which instructs the user how to use the device.
- VistaFeet measures the bottom feet' temperature and communicates its measurement results in the app.
- Orpyx's product is specialised insoles. It was initially developed to monitor pressure and later incorporated temperature monitoring. It comes with an app in which live feedback is given.
- Bluedrop Medical is a device that integrates temperature monitoring with visual data capture (taking pictures). In this way, feedback can be given on the lifestyle as well, and wounds can be directly seen.

It is important to note that all these devices are limited to measuring plantar foot temperature and do not account for the non-plantar (e.g., dorsal or lateral) aspects of the foot.

Siren socks

Podimetrics

VistaFeet

Orpyx

Bluedrop medical

Figure 16. Overview of the different competitors

A user journey analysis has been conducted for each of these devices, which can be found in Appendix C. This section will highlight key takeaways and important insights that can inform the development of the current product. To start, several competitors use a type of activation before the product can be used, either by calling a number, by connecting to the WiFi or setting up a Bluetooth connection with the app. This process can be burdensome for the target demographic, which primarily consists of older adults who may have limited experience with technology and might not have access to a WiFi router at home. Among the reviewed products, only Podimetrics addresses this challenge by including a built-in cellular connection, allowing it to function without relying on the user's home network. For Secuped, the goal is that the product functions without a WiFi connection and complicated activation steps, allowing it to work straight 'out of the box'.

Additionally, several competitors offer an app that provides more specific measurement data. Orpyx, Siren socks and VistaFeet have this option, see Figure 17. Again, the question arises as to what extent it can be expected that the target group can handle these 'complex' digital interactions. Therefore, a user study among Secuped's target group is needed to determine whether this approach is feasible.

VistaFeet Siren socks Orpyx

Figure 17. App designs of several competitors

Of course, these competitors also demonstrate several positive features, for example, the educational resources provided by Siren Socks and their consideration of the user's medical history. It could be interesting for Secuped to research if there is an added benefit to knowing the patient's past ulcer history when connecting the patient to the device. In addition, Bluedrop Medical, as well as Siren Socks and Podimetrics, do not have an on/off button, which removes the need for the user to click or press something on the device that's located on the ground before being able to use the device. This is a desire that Secuped also wants to put into practice. Another valuable insight is that Bluedrop Medical uses a backlight to illuminate the foot placement area, helping users correctly position their feet (see Figure 18). This raises an important design question: "how can the product effectively communicate correct foot placement to the user, and what guidance can be provided to ensure proper use?"

All competitors rely on some form of data transmission, though the methods vary, from Bluetooth connectivity and smartphone integration to the use of built-in cellular networks. In addition, Orpyx invested in making clear data overviews for HCPs and enabling them to export overviews easily. Although Podimetrics and VistaFeet also enable data sharing with HCPs.

Podimetrics and Bluedrop Medical do not provide users with real-time data; instead, they contact the user only when an issue is detected. The other three competitors do share detailed information with the users. Orpyx shows live feedback but comes with two modes: 'interactive' and 'do not disturb', which still helps to tailor this option to the users' specific needs. The user study that will be conducted by Secuped will further explore the needs of Dutch users, specifically if detailed information should be provided and, if so, in what format or manner it should be delivered. Regarding charging, there are some differences, where Bluedrop medical and Siren socks don't require charging at all, Orpyx needs almost daily charging and Podimetrics once per month. For VistaFeet, no information about charging could be found.

Figure 18. Backlight of Bluedrop Medical (picture taken from website Bluedrop, 2024)

The closest competitor regarding interaction seems to be Podimetrics, and therefore, a few good things they did will be highlighted (see also Figure 19). When the test is conducted, messages are shown on a small display. While the display may be considered small and potentially difficult to read for users with visual impairments such as retinopathy, Podimetrics does accommodate users by offering multiple language options. This broadens the user group and makes it more user-friendly. Additionally, users can adjust the volume of the sounds, giving them greater control over the product. Clear communication is provided during the test, including a loading wheel and a message confirming that the test has been saved. In addition, it shows the days the user has been monitoring, and there is a reminder light integrated to prompt the user. Furthermore, the option to test connectivity is available, which is a useful feature, considering that cellular coverage may not be consistent in all areas.

All these functionalities should be considered and possibly integrated into Secupeds' design as well. But there is more to the story, as there are also some downsides (and therefore design opportunities for Secuped) worth mentioning. The feet icon, used to indicate incorrect foot placement, is quite small, similar to the display, raising concerns about whether users (with, for instance, retinopathy) would be able to clearly see and read the information. The same issue applies to the empty battery icon. However, it is a valuable idea to inform the user when the test cannot be completed successfully, and Secuped should consider incorporating this feature into their design as well.

Lastly, the test result isn't communicated to the user. So, unless something is wrong, the user will not receive a call and has to trust the system that everything is alright. A study conducted by Podimetrics highlighted the need for users to view the results of the scan (Rothenberg et al., 2025).

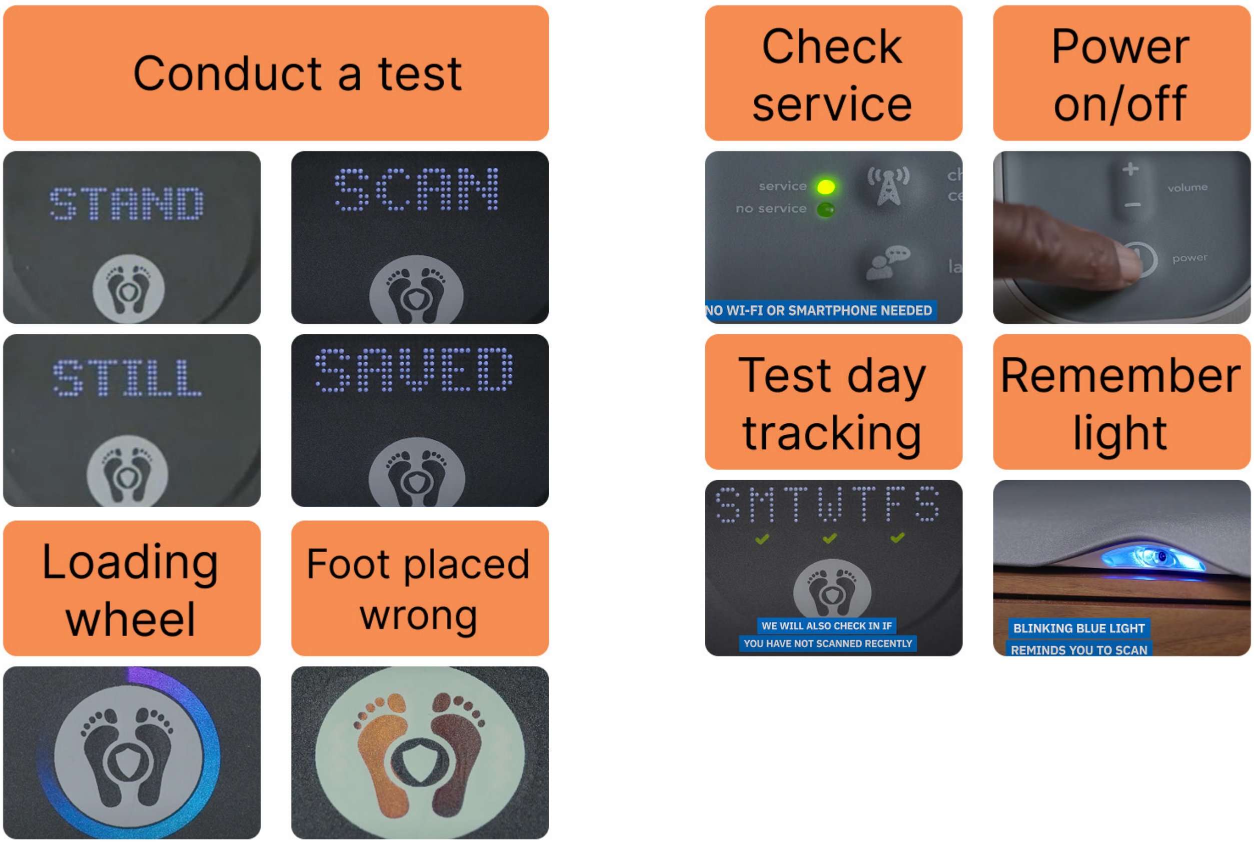


Figure 19. Some main interaction features Podimetrics (pictures taken from website Podimetrics)

To conclude, it is important to note that the biggest competitor in the Netherlands for now seems to be VistaFeet. They have tested their new device in the Netherlands with a group of patients. They are already selling devices in Sweden and Denmark and received CE marking back in 2023. The main drawbacks of this product appear to be its lack of accommodation for different foot sizes and a very minimal device interface, which may be difficult for users to understand. In addition, the patients got frustrated by the interaction with the device as they struggled to do a correct measurement. This stresses the importance of clear communication to the user and telling them what is going wrong.

Conclusion/takeaways competitors

Many things can be learnt from the different competitors. In Table 1, a last overview of the differences between the competitors is shown. What can be learnt from this analysis is that Secuped should be able to answer the following questions and incorporate other aspects:

- How is an error communicated to the user?
- How is data transferred, and in what way will it be communicated that the connection got lost?
- Should the history of the patient be considered?
- How is it ensured that patients with retinopathy can still use the device?
- Are users looking for detailed information about the scan results? In what way?
- How can the test result be communicated to the user?
- The device should be designed for maximum ease of use: eliminating the need for an on/off button, minimising charging requirements, offering sound and/or language options, and ensuring clear communication.
- A backlight to guide users could be useful in ensuring correct foot placement.

Table 1: Overview of important characteristics of different competitors

	Onboarding	Charging	Connection to the outside world	App	Cost price
Siren socks	Connect the sock to the app by scanning the QR code	n.a.	Connection hub	Yes	$19.95 a month (which amounts to $239 per year)
Podimetrics	Call number for activation	Every month, it takes 4 hours	Cellular service	No	Approximately $3,500.
VistaFeet	Connect the board and the app	Unknown	Unknown	Yes	Monthly description 36€, purchase: 850€ for product, 1365€ for product and sharing data option
Orpyx	Call number for activation	Every 2 weeks, it takes 6-8 hours	Digital device connected with Bluetooth	Yes	$500 per year for custom insoles
Bluedrop Medical	n.a.	n.a.	WiFi or cellular router	No	Unknown

3.5 Customer journeys: patient, podiatrist and Secuped

The Secuped team has a preferred product interaction in mind, but it has not yet been visually documented. Therefore, three different types of user journeys were created for the most important stakeholders, namely the podiatrist, patient and Secuped themselves. The main goal of these journeys is to identify where uncertainties lie and where clarification with the use of interviews is needed. It is tried to use similar colours for the same stages in all three journeys to make it easier to see the connections between the journeys. All three will be discussed shortly. The journeys outline user activity steps, interactions with Secuped/patients, and pain points - mainly areas requiring further clarification through interviews. Additionally, initial needs, opportunities, and potential solutions have been identified. It's important to note that these journeys are based on insights collected by the two founders over the past two to three years, which were shared during two in-depth group sessions. While most aspects have been reviewed by experts - either podiatrists or end-users - some elements remain assumptions at this stage.

Customer Journey patient

Figure 20 illustrates the key parts the patient experiences when interacting with the device. An effort was made to identify all possible interactions the user could have with the product. A few important lessons learned from creating this journey are:

- The product should work 'out-of-the-box', meaning it should work without requiring activation or initial charging.
- It is unclear what data should be sent to the user and who will have access to the monitoring data.
- It's uncertain what happens if a temperature stays high even after visiting the Podiatrist. This could mean the user keeps receiving warnings, which is not desired.
- It is uncertain whether users prefer full access to their measurement data or just a simple good/not good indication.
- The product should remind users to use it, but the best method for this remains uncertain.
- The device should have a special cable due to medical regulations.
- An empty battery alert should be given a long time in advance to ensure it will be charged in time.
- The method for providing user support, such as where to find a contact number for assistance, remains unclear.

These are the most important insights.
The entire user journey can be found in Appendix D.

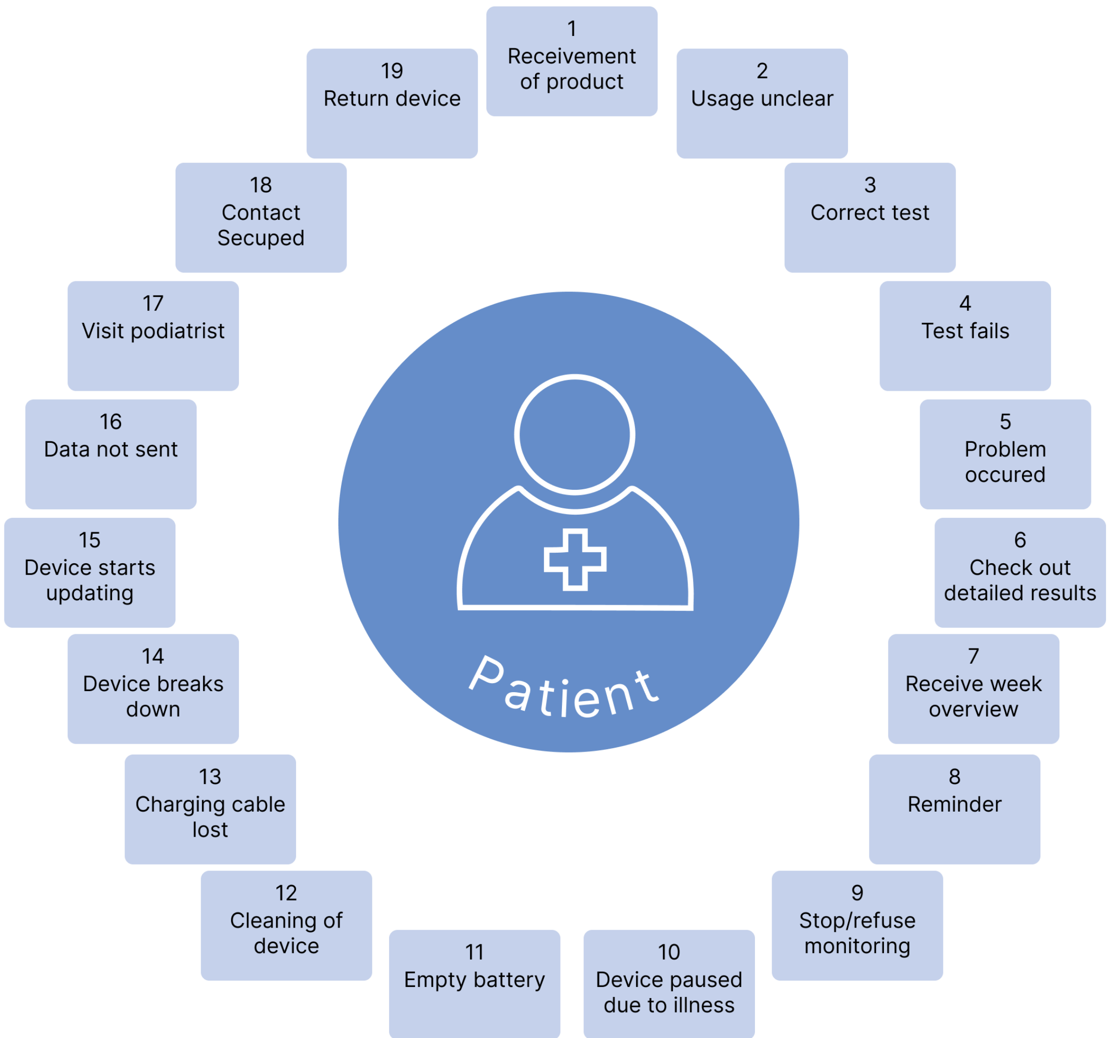


Figure 20. Actions/situations patient based on customer journey

Customer Journey podiatrist

The podiatrist is a key stakeholder in the device's interaction, as they will be responsible for explaining the device to the patient and making a diagnosis based on the temperature readings. There are multiple situations the podiatrist encounters, for instance, good monitoring by the patient or receiving a high-temperature warning (Figure 21).

The entire journey can be found in Appendix D. The main insights from this journey are:

- The podiatrist could be the person responsible for explaining the device to the patient.
- The process for requesting the device should be simple and straightforward.
- This product should be integrated into the existing systems of the podiatrist; however, it is unclear what those systems are.
- The podiatrist should receive a high-temperature warning after a certain period, but the responsibility should remain with the patient.
- There is some uncertainty about what happens if a warning is sent to a podiatrist who is currently out of office (for instance, on vacation).
- The return policy is unclear, specifically whether the podiatrist should initiate the return or if the patient can also request it.
- The data provided to the podiatrist should support their work and help them to give the right diagnosis. It is still a bit unclear what type of data (s)he needs.

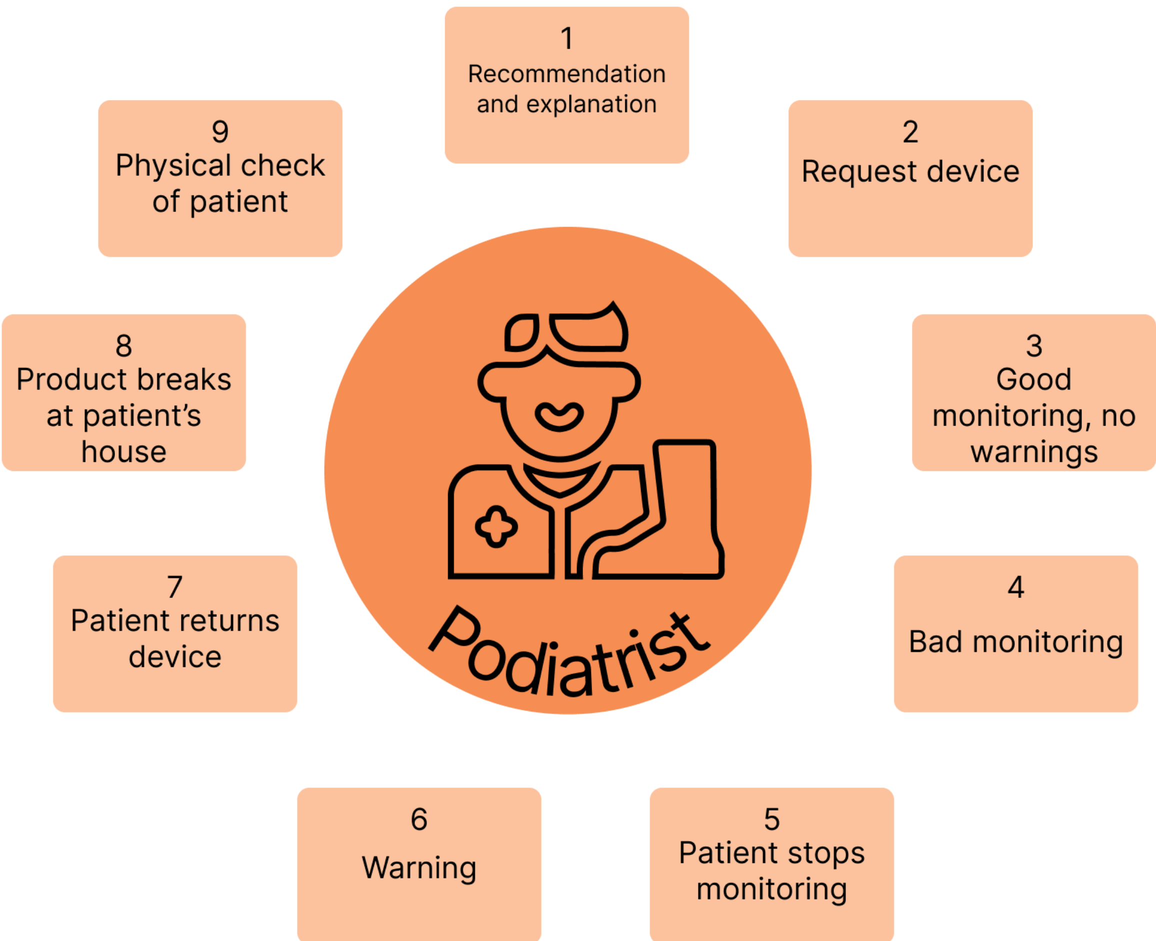


Figure 21. Actions/situations podiatrist based on customer journey

Customer Journey Secuped

Secuped also has multiple touchpoints with the patients and the podiatrists. There is still some uncertainty about whether all actions presented in their customer journey will be conducted by them. For example, during the interview with Diederik Zeven on March 20th, it was discussed that as the numbers increase, it might be more beneficial to have someone else take over the call centre operations. For now, it is assumed that all actions are conducted by Secuped (Figure 22), and this resulted in the customer journey as presented in Appendix D. Some important takeaways are:

- Secuped should handle the connection of the patient to the device, ensuring out-of-the-box functionality and eliminating the need for patient activation.
- The device might get broken, which could mean a new device is sent to the patient. Therefore, it should be possible to connect two devices to a patient for a short period in case of failure.
- The device might need updates from Secuped and should therefore allow remote updating.
- Secuped should include a penalty clause for cases where the device is not returned, especially when usage costs are covered by insurance companies.

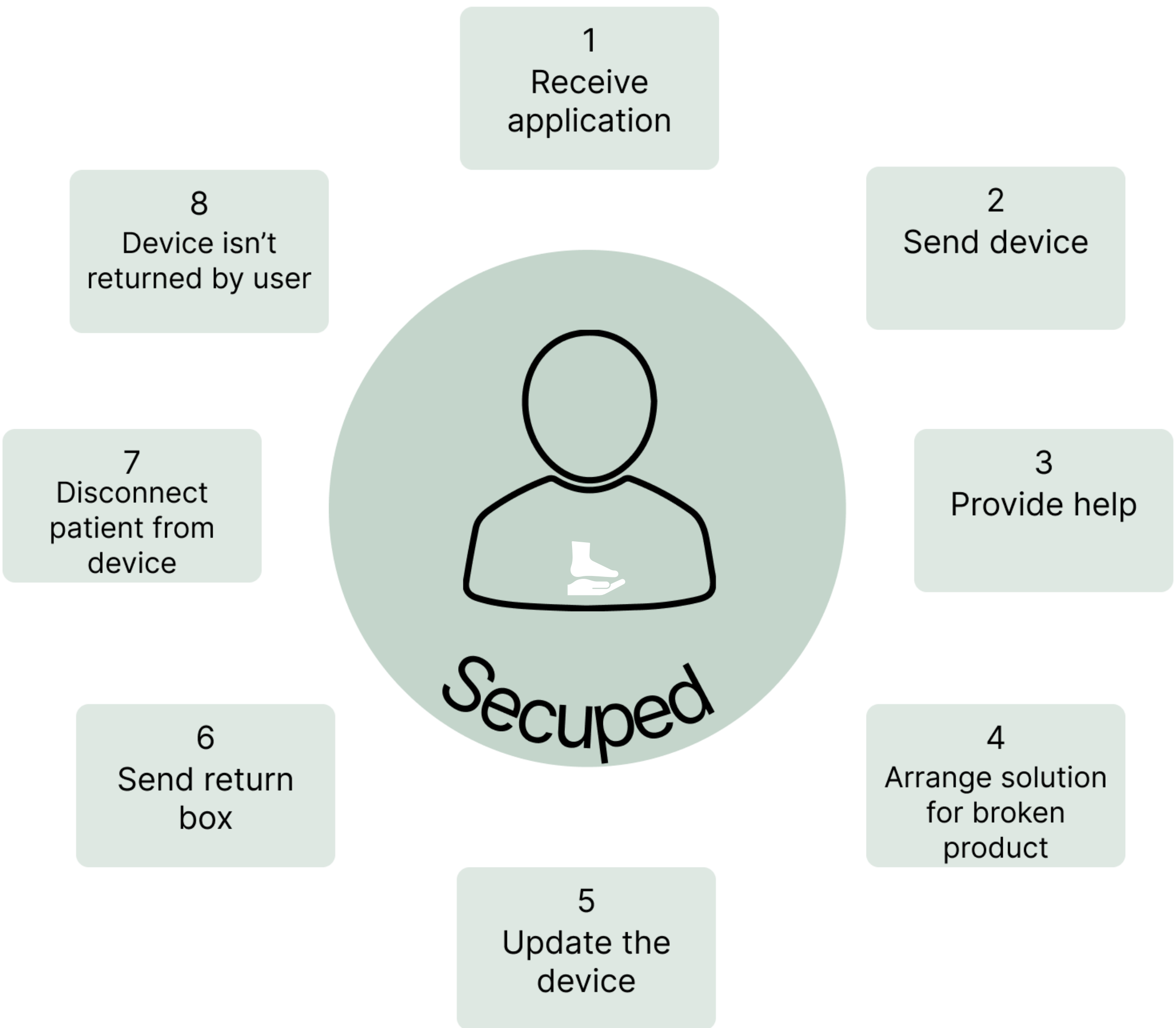


Figure 22. Actions/situations Secuped based on customer journey

3.6 Insights important stakeholders

In the initial analysis phase, several interviews were conducted to gain insights into the context, identify problems faced by stakeholders, and clarify how the revised design assignment should be structured. In collaboration with the diabetes association in the Netherlands, a group of seven people was gathered. In addition, two podiatrists from two different locations were interviewed. First the insights from the podiatrists will be discussed, then the insights from the first round of interviews with patients.

Podiatrist insights

For these interviews, a variety of material was prepared. Mostly questions were asked to get a better insight into the current system. In addition, several situations were explained about the futuristic usage of the product. The podiatrists were asked to react to those situations. In total two podiatrists have been interviewed, one from a small podiatry practice and one from a bigger practice.

The main goals of this study are:

- To get insight into whether temperature monitoring is already advised for patients.
- To figure out if the podiatrist is willing to explain the usage of the product to the patient.
- To get insight into currently used systems by podiatrists and the most optimal way to notify podiatrists in case of a temperature rise.
- To get insight into what kind of data podiatrists would like to see and what happens in case of a temperature rise.
- To understand the procedures and actions taken when the responsible podiatrist is unavailable and the patient encounters an issue.

Based on the answers, several themes were identified; therefore, the results will be presented according to these themes.

Target group

One of the podiatrists sketched an image of the type of patients she regularly meets in her practice. She described that the target group consists of a group with low technology acceptance and below-average literacy. She notices that it is very hard to explain to this group that they have a serious problem. They continue to believe, "If something were wrong, I'd feel it," even though they've lost all sensation in their feet. In addition, she mentioned that the device could help in changing behaviour: 'it is harder to accept that the shoes they have been wearing for multiple years now form the core of the problem, than a device that detects a rising temperature'. She would divide her patients into orange and red categories, as shown in Figure 23. In her opinion, 75% of the red group would be open to using the product. Lastly, she notes that the target group is very honest, when they say no, they truly mean it, and they prefer saying no over giving a false yes.

Currently used systems

At the big practice, they have developed their own EPD (Electronic Patient Dossier) system. In this system, patients also have their own log-in portal in which the podiatrist, for instance, can share some additional material for the patient. The system also uses notifications to warn podiatrists about certain actions to take. At the small practice, James is used for patient management, DM voetzorg for communication with (medical) pedicure and Doctolib Siilo for communication between HCPs (some kind of WhatsApp for HCPs). If a notification system is needed for this smaller practice, she would prefer to receive notifications via Doctolib Siilo.

Potential usage of the device

Podiatrists suggest using the device in the morning when waking up or in the evening, as '80% of the wounds are caused by shear and pressure forces, and that doesn't happen in bed'. Both podiatrists are willing to explain the usage of the device to the patient and to

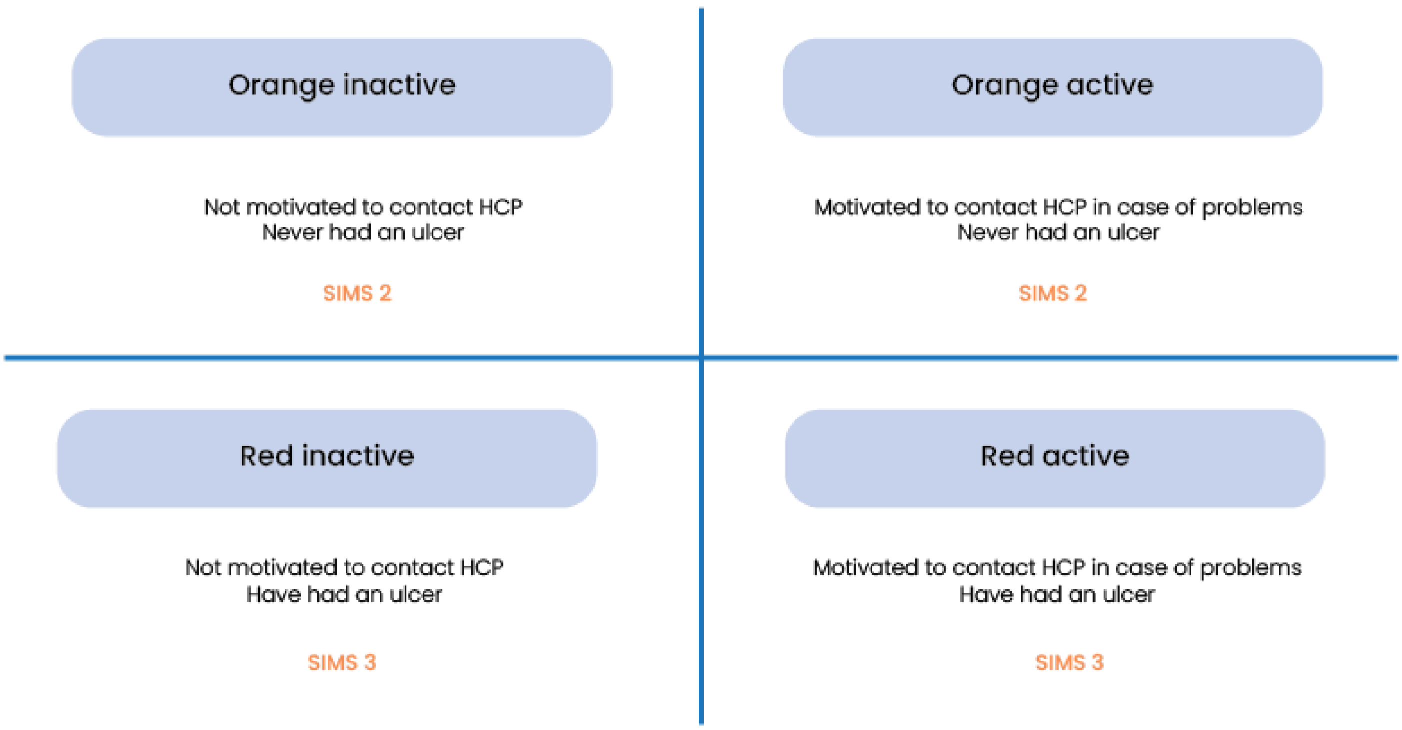


Figure 23. Orange and red categorization

practice the usage together. Both would like to have an additional explanation folder, with many visuals and not too long, again due to lower literacy. Another reason is that one of the podiatrists mentioned that some of them do not even have an email address, so a folder would prevent a lot of hassle. In addition, this folder should exaggerate the added benefit of using this product. Both the podiatrist and the patient should receive a notification, according to both podiatrists. However, it's important to ensure that it doesn't create unnecessary fear. One podiatrist also mentioned she wants to know if a patient isn't measuring anymore, and she would contact the patient to ask why. With one podiatrist, we went a bit deeper and asked what she expects to happen in case of elevated temperatures. She preferred that the patient come by instead of having a phone call, as she wanted to see and feel the foot to be able to make a diagnosis.

Data overviews

For these interviews, no data overviews were shown, but it was asked what they would expect to see and why. One podiatrist mentioned that she wanted data about when the temperature started rising and wanted to see the exact values. This enabled her to ask the patient what (s)he did that day to figure out if certain behaviours could have led to the rise. Data about the usage of the device is also preferred. The other podiatrist mentioned that she saw a potential research opportunity: 'Can I see something in the past time, for this warm spot? So I can figure out if we could have done something earlier or if we could narrow the parameters?'

Current workflows within podiatry

It was discovered that the medical pedicure has much more frequent contact with the patient compared to the podiatrist, who typically sees the patient only once every 6 to 12 months, while the medical pedicure checks the feet every 6 weeks. The podiatrist and the medical pedicure have a close collaboration. The amount of contact per patient differs heavily and is dependent on the self-care level patients exhibit. One podiatrist mentioned that when she noticed a patient wasn't therapy compliant, she would rather keep the patient herself 'as the patient would then first think of her in case of problems'. Also, treatment differs per patient, from providing educational information to removing calluses. Extra data is very much appreciated, for instance, a picture of a possible wound. The podiatrist is allowed to treat wounds for two weeks unless the patient has peripheral artery disease or infections. In that case, the person is directed to the hospital. If someone enters the appointment with red or swollen, or black feet, she immediately calls the GP of the patient to ensure care is delivered as fast as possible. Temperature monitoring as treatment advice is provided by the podiatrists, but is occasionally recommended due to the hassle involved. Both podiatrists explained that if they are absent, there is still someone else who can take over. Most podiatry clinics have a telephonist, and all podiatrists in the clinic can access the data of all patients, including those who are not their own.

Cost coverage

The podiatrist receives around 460€ per year per patient to cover the care. However, there is significant variation in how much of this budget is allocated per patient. At the end of the year, this balances out. One podiatrist mentioned that she would research whether Secupeds' product could fit within this budget, as it could be seen as a replacement for physical consultation. The question arises whether that would be possible.

Other podiatry practices

In the Netherlands, there are multiple smaller podiatry practices. There are also three larger practices, namely Wender, Hermanns and Rondom. The education for podiatrists is located in Enschede and Eindhoven.

Other information

One more thing was mentioned during the interview with one of the podiatrists, which was about the risk of a Charcot foot. When this happens, the bow construction in the foot collapses and becomes the lowest point of the foot, making this an ideal location for wounds. The temperature rises and stays high for 8 months. Only 1 or 2% of patients living with diabetes get a Charcot foot.

Patient insights

In the time span of two weeks, several interviews were conducted to get a better understanding of the needs and wishes of the user. In total, seven users with diabetic feet were interviewed. In Figure 25, the flow of the study is shown. In Appendix E, the questions asked and the materials used are presented. To be able to get the most out of the study, several materials were prepared to visualise the concepts for the user, such as a minor Arduino interface with a pressure sensor to start the test, A3 papers with all choice options and a user story. In Figure 24, some materials are presented. Most ideas were created in Figma and presented on the corresponding tablet or phone.

The main goals of the study are:

- To get insight in the most optimal and comfortable way of positioning the feet for patients
- Get insight into how patients would like to receive information about how to start using the device
- Get insight into whether the device should measure one or two feet at the same time
- Get insight into the most optimal way of seeking help
- Get insight into what type of data is interesting for the patient, how this should be communicated and accessed and with whom it should be shared
- Get a first direction on how the device could help the user remember to use the product
- Get more insight into therapy adherence by this group and whether they are supported by a caretaker.

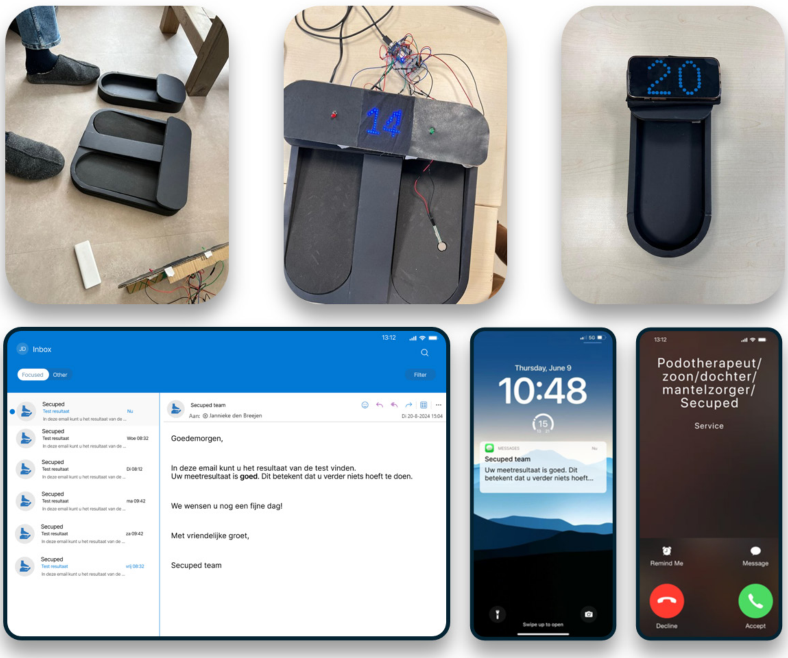


Figure 24. Some materials prepared for patient research

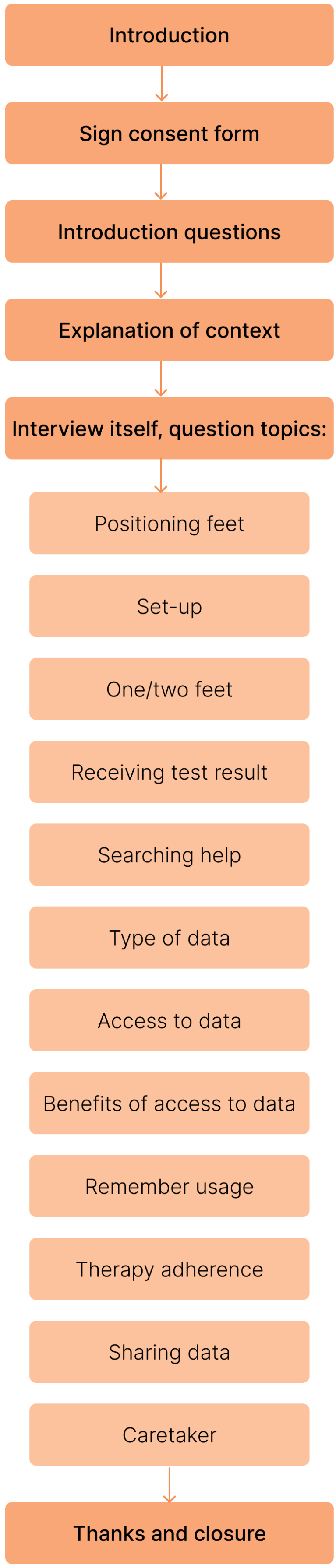


Figure 25. Patient research set-up

Before the results of the interviews are presented, a few things should be mentioned about the interviewed group, as a certain bias was present. The patients were found through the newsletter of the DNV (Diabetes Vereniging Nederland) where they had to fill in a form to be able to participate. This recruitment method targets a specific group: individuals with digital skills who take the initiative to participate in a user test. Earlier in this report, an overview of patient groups was presented, and in Figure 26, the people interviewed are mapped in this diagram.

This indicates that, apart from one exception, only people with an ulcer were interviewed, most of whom are highly proactive in managing their health. Additionally, the majority had a high level of education.

To present the materials clearly, themes are identified. The main conclusions are presented, and a visual shows some relevant quotes and a picture (drawn by Tom Hinkens) providing the context of the theme.

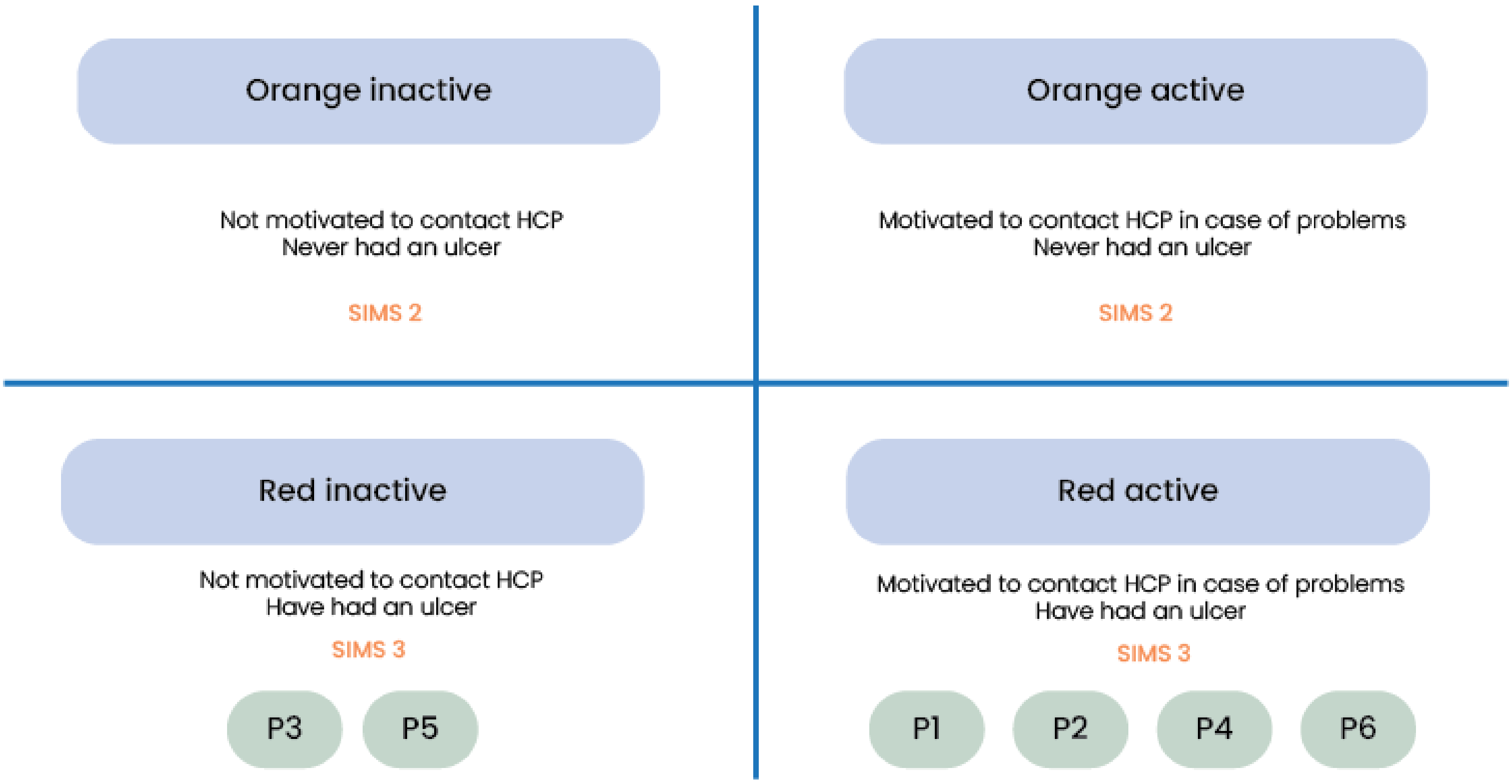


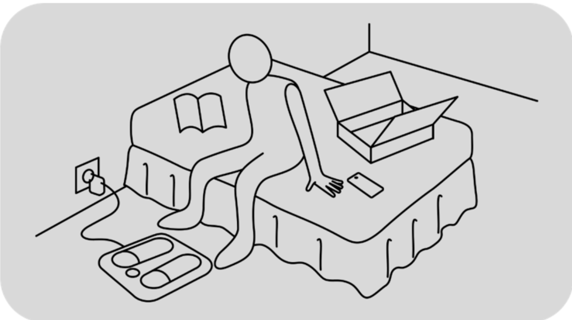
Figure 26. Participants' categorisation based on active/inactive and red/orange

Set-up of the product

There is a need for a careful explanation of the product by the HCP to explain the added benefit, daily usage, the meaning of the results and steps to take in case of a temperature elevation. Users prefer to have a leaflet and a video so they can look at their own pace another time (Figure 27). The users stress that the product must be very easy to use, requiring only a single explanation. Two participants mentioned the training they must undergo when receiving a new insulin pump. This could also be an option for starting up the product.

Requirements:

- The product should come with clear instruction material for the HCP.
- The product should come with clear instruction material for the user in the shape of a leaflet and a video.



If the podiatrist only explains it then you know it, but cannot find it again.

If I can't figure it out I'll just visit the GP.

Give people a leaflet, but also let them attend a short training course.

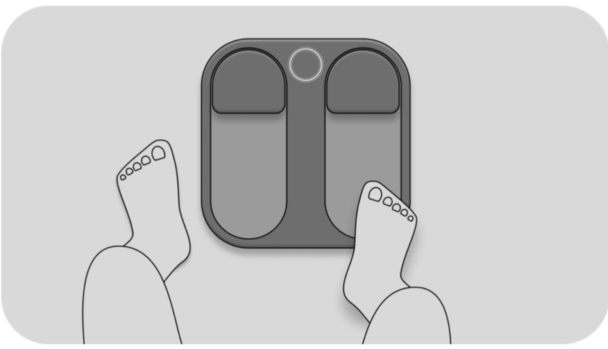
Figure 27. Set-up of the product

Positioning of the foot

There is a need for clear feedback about the correct placement of the foot or feet (Figure 28). This feedback can be restrictive (physically limiting) and/or in the form of positive feedback from the device. Due to the severe neuropathy these users experience, they often lose sensation below the knee. This makes the movements of their feet hard. Therefore, they do not know exactly when their feet are placed correctly. One participant was therefore afraid that he would damage his foot if he had to slide it underneath something, as he doesn't feel it when he scratches his skin.

Requirements:

- The product should provide feedback about the correct placement of the foot.
- The design of the product guides the user into the correct placement.
- The toe coverage should be of very soft material, so it doesn't damage the toes when sliding in.



I would like to know if my foot is positioned right.

During piano playing, I don't even notice if my foot slips off the pedal.

I want something that forces my feet into the right position. If I don't look, my foot goes out like this.

Figure 28. Positioning of the feet

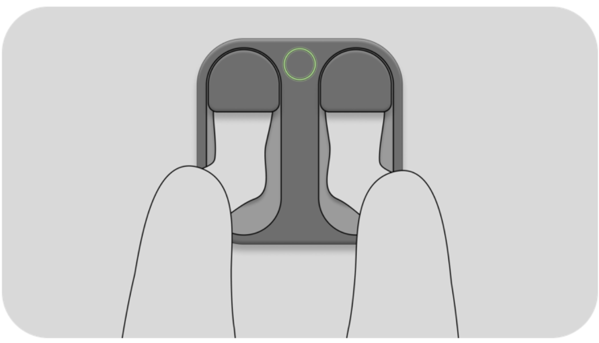
Presenting results

There is a clear need for immediate visual and auditory feedback from the device after measuring (Figure 29), even when nothing is wrong. By providing positive feedback, users start their day on a positive note. This could be done by simply using lights, as everyone understands this, according to the participants. One participant with retinopathy and limited vision (only 25% sight) suggested that an illuminated display with high contrast would be very helpful. In addition, the text should be very big. A combination of text and icons is preferred. Additionally, it was mentioned that the screen's illumination would be helpful, especially if it's still dark outside. Finally, the countdown before displaying the results was appreciated, as it gave people a sense of how long to wait, making the wait more tolerable.

When something is wrong, a distribution can be made between a one-day temperature elevation and a risk (a two-day in a row elevation). The question raised is whether people prefer to know temperature elevation directly or only when it is a real risk. Five participants wanted to know the direct elevation, while two others preferred to only get warned when there is a serious risk. The reason for knowing the direct elevation is that it could motivate the user to keep measuring to make sure nothing is wrong. The reason given for not knowing was that it lingers in your mind all day, even though it might not be a serious risk. Optionally, the device could point out which foot is the problem. More detailed measurement results should be presented in a digital environment.

Requirements:

- The product should communicate the test result using auditory and visual feedback.
- The product should point out which foot is causing the problems.
- The product should make a difference between a one-day elevation and a serious risk in presenting the result.
- The product, if using a display, should be illuminated and have a big contrast and size.



The most critical thing is to know which foot is the problem.

Due to retinopathy, I have poor vision, a large display with contrast and illuminating screen would help me.

These figures are easy to read, good contrast, you have done that well.

If an increase is seen more often, I would also start measuring more.

I only want to know if action is needed, otherwise I will start worrying about nothing at all.

A good result takes a lot of worries away from me.

Figure 29. Presenting results

Digital Environment

Five of the seven participants expressed a need for a digital environment where more in-depth information can be accessed (Figure 30). Users would like to see an overview of measurements, temperature differences and the real temperature values. The motivation for this is to have the possibility to recognise trends in the data. To learn that something could have been prevented or to learn that everything goes well. This digital environment is primarily consulted when the device gives an alarm or at the start of product usage. Over time, users expect that the frequency of checking out the data will decrease if everything is alright.

The access to the data is mostly preferred through an app (4x), a portal (1x) or email (1x). It should be noted again that the interviewed group was quite eager to do self-management with their diabetes and would therefore be more open to these overviews.

Requirements/wishes:

- The product should come with a digital environment in which an overview of measurements, temperature differences and real temperature values are presented.
- The digital environment is potentially accessed through an app (wish).

The podiatrist has probably something else to do. Self-management is kind of ingrained in me.

Measuring is knowing. I don't just like a red or green light.

That it has been going well for a month, well done.

Prefer an app then you are logged in all the time instead of having to go to a website.

In the beginning I will watch, but if it goes well for a while then I won't watch it anymore.

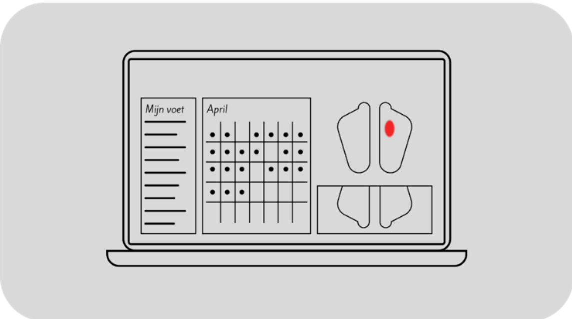


Figure 30. Digital environment

Therapy adherence

There seems to be a slight preference for creating a remembering mechanism using a light (3x) (Figure 31). However, users are concerned that the reminders might occur at undesirable times, such as during a visit or at night. Users are also open to receiving a notification from their podiatrist if they forget for an extended period. At the same time, this raises the need to have some type of pause button in case of sickness or holiday.

Requirements/wishes:

- The product should have a pause option in case of sickness, ulcer development or something else.
- The product could provide a remembering option by means of a light (wish).

This is easier than using insulin, which I already do very faithfully.

There must be a pause option for when I am sick in bed for a week.

Rather no reminder at all. Because of all my devices, I am fairly alarm tired.

I know darn well I use that device every day.

The device will be under my bed, so I really won't see that light.

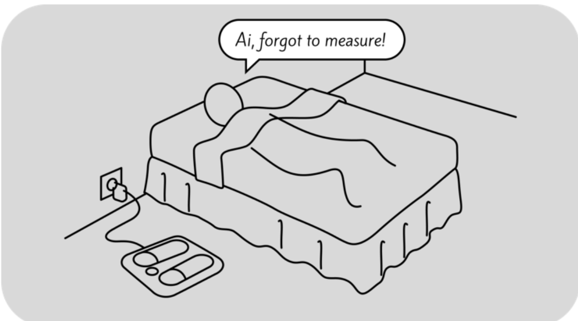
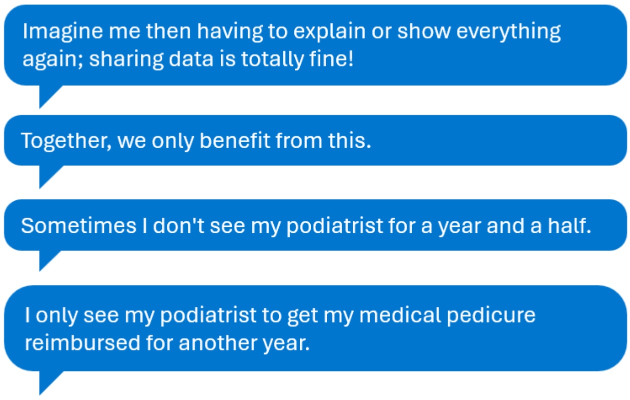


Figure 31. Therapy adherence

Communication with HCP

Users know how to contact their healthcare provider, but the care system and the interactions surrounding the user vary significantly (Figure 32). Some users see their podiatrist only once per year (2x) and only to get the medical pedicure covered, while others see their podiatrist every three months. Contact with the pedicure is more frequent, ranging between every three to six weeks. The conclusion of this theme is that more research is needed to understand the roles different healthcare providers play in a patient's life. No conclusions can be drawn about this topic from this interview round yet.

Figure 32. Communication with HCP



One foot versus two feet model

It seems that participants prefer the one-foot model over the two-foot model, but real conclusions cannot yet be drawn based on these interview results. The one-foot model is preferred because of its dimensions, weight and stability. The size was often mentioned in the context of taking the device with you on a trip. Regarding stability, it was mentioned that keeping one foot on the ground while moving the other helps to remain stable, especially if the product is used while the user is seated on the bed (Figure 33).

Participants chose the two-foot model because it takes less time, and the device doesn't need to be moved during use. One participant tried this movement with the one-foot model and struggled a bit with moving the device from the left to the right side. Participants mentioned they would like to move the device underneath their bed to prevent it from being in the way. Participants prefer not to bend forward to do this, primarily because they are unable to. The medical appearance and the size were mentioned as downsides of the two-foot model. No conclusions can be drawn regarding the position of the feet being close together, as none of the participants were severely overweight. One participant did suggest adjusting the width between the feet, but overall, participants felt the current setup was fine.

An important point regarding this theme is that testing the duration of the measurement for the one- and two-foot models may not have been optimal. The participants were using the device for the first time. The environment wasn't completely silent during testing, which may have prevented them from fully perceiving the duration of the measurement. This situation differs from daily use, when the device is used after waking up, when it is probably completely silent. It's unclear whether the participants fully felt the time it took and whether they could make an accurate judgment. This needs more research in the next phase, but for now, five of the seven participants chose the one-foot model. Questions remain regarding whether the device can detect the difference between the left and right foot, if consecutive measurements affect its reliability, and whether moving the device between measurements poses a problem.

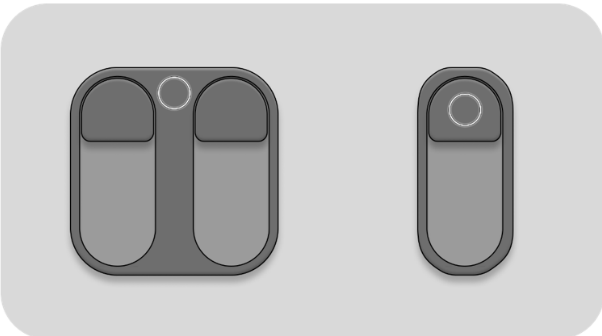


Figure 33. One-foot vs. two-foot model

Requirements:

- The product should be small and lightweight to take with you on a trip.
- The product should remain stationary during measurement.
- The product should be easy to move over the ground, so it can be placed underneath a bed.

It looks much friendlier and less 'apparatus-like' ~ about the one-foot model

I'm definitely not taking that big one on holiday.

20s - 40s, I'm retired anyway.

I (and women in general) have somewhat wider thighs. I would like it slightly wider.

This (distance between feet) is fine.

I won't bend down to move it. I'd hop it out from under my bed with my toe.

Design of the device

Along with the interview, two cardboard prototypes were presented to show the user some initial design concepts (Figure 34). One participant strongly highlighted his fear of damaging his feet by using the device. Right now, the cardboard prototypes have sharp edges, which made this participant uncomfortable using the device. Multiple participants preferred a more spacious entrance for the feet. One participant suggested having an open device, like a weighing scale, with something folding down over the toes. Another suggested integrating a light or using a transparent top so users could see how their toes slide into the device. This way, the risk of damaging the feet is reduced. Additionally, it was mentioned that the device should be easy to clean, especially in cases of foot fungus.

Requirements:

- The product should have a spacious entrance and no sharp edges to prevent foot damage.
- The product should have easily accessible surfaces for cleaning.

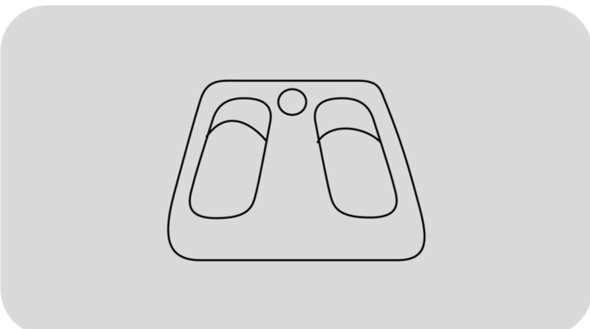


Figure 34. Design of the device

A generous opening would be nice, I am afraid of damaging my feet.

Shape colour and light also play a role.

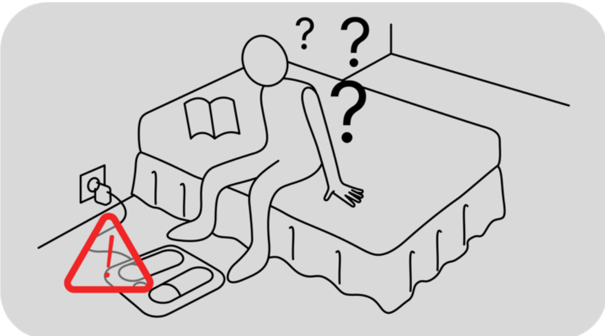
Because of neuropathy, my fingers also bother me, which is inconvenient when cleaning.

Problem with the device

Lastly, it was researched how people would respond in case of product failure, whether they expect us to contact them or if they contact us (Figure 35). Most participants preferred to call themselves, simply by having the phone number on the device itself or in the instruction manual. Another option offered was a chat conversation in the app, but multiple people were afraid that this would be a chatbot, and that was something they didn't like at all. People would, in that case, prefer a real person to talk to.

Requirements:

- The product should have a phone number which can be contacted in case of product failure.
- The instruction manual, website and possible app should also have the phone number easily accessible.



Is it another one of those computers behind it? Those usually don't understand me.

Simply a sticker with the phone number at the bottom of the device would be enough for me.

Rather call myself because then I can just do that when it suits me.

Figure 35. Problem with the device

3.7 Conclusion/takeaways

This chapter aimed to provide a clearer understanding of the product's context, outlining key stakeholders, competitors, and user scenarios. Feedback was gathered through evaluations with two podiatrists and seven patients. The key insights are:

- **Stakeholders:** Primary stakeholders in diabetic foot care are the POH diabetes, medical pedicure, and podiatrist. In severe cases, the GP, vascular surgeon, or wound specialist may also be involved.
- **Patient Survey:** Most patients contact their podiatrist via in-person visits. Photos are commonly used to quickly assess potential ulcers.
- **Prototype Feedback:** The prototype meets the basic need for plantar temperature monitoring, but the interaction flow (e.g. knowing when the test is complete) still needs refinement.
- **Competitor Landscape:** Key competitors include Siren Socks, Podimetrics, VistaFeet, Orpyx, and Bluedrop Medical. VistaFeet is already conducting trials in the Netherlands. Podimetrics' interaction design could serve as inspiration.
- **Customer Journeys:** Separate journeys were mapped for the patient (testing and receiving notifications), Secuped (managing device connections and returns), and the podiatrist (monitoring data and responding to alerts).
- **Podiatrist Interviews:** Various digital systems are used, such as EPD, James, Doctolib, and Siilo. Podiatrists were open to explaining the device to patients and appreciated clear data summaries for diagnosis support.
- **Patient Interviews:** Patients showed a preference for a one-foot model, valued app-based data access, and wanted to be informed of even minor daily temperature elevations, even if not critical.

4. Design for elderly users

A lot of products nowadays have a certain interface with which users interact. Most often, these interfaces are digital and use a touchscreen. This project involves designing an interface specifically for elderly users. The needs of this target group are unique and often limited by their digital skills. Therefore, this chapter will elaborate more on how to design for the elderly and what things to consider. This section discusses the needs and challenges of the target group, theories on why the elderly would adopt the product (motivation), and the impact of the product's appearance on its use. Additionally, external factors influencing usage and design guidelines found through research will be explored.
The papers referenced in this analysis focus specifically on Human-Computer Interaction (HCI) for the elderly.

4.1 Needs and challenges

The elderly have different kinds of needs. From a broad perspective, the needs are health, safety/security, peace of mind, independence, mobility, and social contact (Sharma et al., 2016). Especially, independence is often named as important as people want to be able to keep doing things themselves. However, there are multiple challenges these people face. First, there is physical decline, for instance, cardiovascular decline, but also a decline in moving ability, osteoporosis and an increased risk of stumbling (Yang et al., 2016).

In addition, these people also face cognitive challenges, such as auditory or visual fade, and deficiency in learning. When it comes to the interaction with interfaces, elderly people often misrecognise functional buttons (Yang et al., 2016). Then there is also the mental change which makes them feel lonely and nervous, not open to strange environments and learning new things. This affects the interaction with interfaces as they might be less open to trying new products (Yang et al., 2016).

4.2 Theories about elderly adoption of a product

On the 7th of February, the Secuped team visited Izi House in the Hague. Here, various types of innovations for elderly care are presented, which can be borrowed for a trial period. There was one important thing that was learnt during this visit. Although many products look awesome and indeed could help the elderly with a certain need, only a few were really adopted. To explain the adoption of a product by the elderly different theories/ models in the literature can be found. For instance, the Health Belief Model is tailored to explain and predict health-related behaviours based on analysing individuals' perceptions of benefits, barriers and other parts of the behaviour. However, this project is directed at the use of a product and about predicting the health IT acceptance of users. For this, the Theory of Planned Behavior (TPB) model and Protection Motivation Theory (PMT) can be used as was found in literature papers. Both have a slightly different approach, but in Figure 36 the integrated version of these two theories is shown.

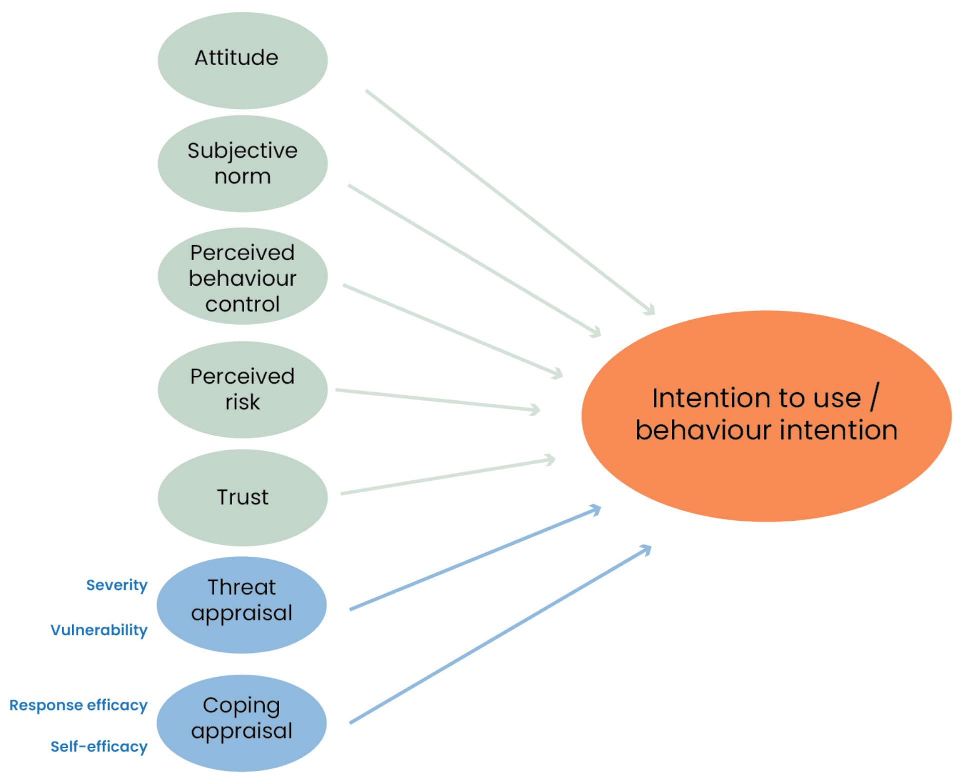


Figure 36. PMT and TPB models combined, based on the studies by Ku and Hsieh (2016) & Coventry & Briggs (2016)

In the PMT, two appraisals influence the intention: threat and coping. The threat appraisal is about the perceived severity and vulnerability. To what extent do the elderly perceive themselves as vulnerable to this problem, and how severe do they perceive it to be? The coping appraisal is to what extent people are able to deal with the threat. Do they feel empowered by the system and does using the system reduce the threat (response efficacy)? Additionally, do they believe they are capable of using the system effectively (self-efficacy) (Coventry & Briggs, 2016)?

In the study by Ku and Hsieh (2016), the TPB model is applied to explain whether people want to use certain cloud services in healthcare. They extended the model with two determinants compared to the traditional TPB model: trust and perceived risk. The other key determinants influencing the elderly's usage intention are attitude, subjective norm and perceived behaviour control.

The terms are explained according to Ku and Hsieh (2016) as follows:

- Attitude refers to how the individual evaluates performing a specific behaviour, either positively or negatively, which is also shaped by beliefs and values.
- Subjective norm is the individual's perception of what other people think about performing a certain behaviour (Ku & Hsieh, 2016).
- Perceived behavioural control is to what extent the user feels (s)he is in control while engaging successfully in a behaviour.
- Perceived risk refers to the uncertainty experienced when using the product or service, along with any potential negative consequences.
- Trust is behaving in a social, ethical way.

In their study, it was found that trust and perceived risk are predictors of usage intention. Perceived behavioral control, attitude, and subjective norm are direct determinants of usage intention, with subjective norm having the strongest effect (Ku & Hsieh, 2016).

4.3 Theory about the impact of product appearance on usage

The behaviour intention and its influences have already been discussed, but to bring it closer to this project, a theory was found explaining aspects of an interface influencing the user experience. Cai & Chen (2020) even state that 'appearance characteristics of products have the greatest influence on operation time and intuitive use'. In their study, the affordance theory is used, which is divided into three subparts: Functional affordance, Conventional affordance and Physical affordance.

- **Functional affordance** (FA): enables the user to achieve their goals and intentions by interacting with the product, based on behavioural intentions and product features.
- **Conventional affordance** (CA): previous experience and knowledge of users help them understand product features, such as icons, symbols, or text.
- **Physical affordance** (PA): It refers to the size, shape, and material of the product, which can assist the user in using it effectively.

These affordances come in a certain order, as explained in Figure 37.

In addition to this theoretical framework, Cai & Chen (2020) also had some practical findings. For instance, operating tasks are often experienced by the elderly as too complicated, and there are too many functions which are not needed (FA aspect). Furthermore, it is stated that 75% of usability problems are connected to CA. The steps to be taken do not correspond with the previous experience of the elderly, making CA a very important aspect to consider when designing an interface (Cai & Chen, 2020). This finding is repeated in another study by Chen, where it is stated that 'Elderly users' intuitive use of product interfaces is related to their use experience' (Zhao & Chen, 2020).

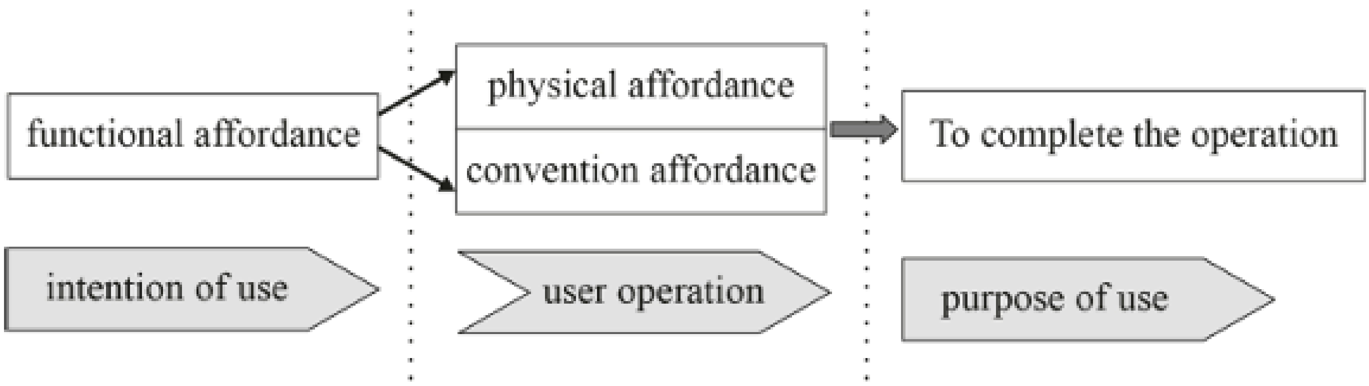


Figure 37. Order of affordance in user operation (Figure taken from the study conducted by Cai & Chen (2020))

4.4 The role of external factors in product adoption and use

The theories discussed in this chapter cover a broad spectrum of factors that influence behaviour when it comes to the adoption and use of a product. However, the role of external influences is not yet highlighted enough. In the Theory of Planned Behaviour, it was already concluded that the Subjective norm has the greatest influence. The elderly are very receptive to what other people think they should use and would be more open to using new technology if told so (Ku & Hsieh, 2016). This could be the extrinsic motivator. Other types of extrinsic motivation are training, technical support, promotion, peer support, support from healthcare professionals (HCPs) and device feedback (Moore et al., 2021). Peer support plays a crucial role, alongside technical support, which is particularly important during the initial stages and throughout the product's use. Additionally, HCPs are key for both adoption and continued use (Moore et al., 2021).

4.5 Design guidelines for interface design for the elderly

In the literature, some suggestions are given on how to design an interface for the elderly. Of course, this is dependent on the type of interface (for instance, a remote control or a rice cooker), but some general guidelines (ranging from positioning to appearance) are given and summarised below:

- Have a focus on the centre and block out distractions or other stimuli as the elderly have a reduced width of the visual field (Sharma et al., 2016).
- 'Use bigger text on a screen, more spacing between keys, more colour contrast, loud ringtones, prolonged backlight and strong feedback (low frequency in case of audio)' (Sharma et al., 2016).
- A medical look of a product can lead to rejection by the elderly as they do not want to be viewed as 'patients' (Moore et al., 2021). Yang et al. (2016) therefore propose to use warm colour design and the use of approachable material design like acrylic, polycarbonate and rubber paint spray. This could increase their connection with the product and therefore reduce their resistance towards technology products.
- The size of a button influences operation time and error rate. If the size decreases, operation time and error rate increase (Zhao & Chen, 2020).

Salera et al. (2016) provide numerous guidelines on how to enhance engagement for older adults. The relevant ones for this project are summarised below:

- Avoid moving text and unnecessary info; this leads to a better understanding.
- Group similar information together to improve understandability.
- Create simple displays to minimise mental workload.
- Audio follows linguistic structure and pauses, which minimises mental workload and leads to higher engagement.
- Information should be focused on the centre for better readability.
- Use of customer-focused language for higher engagement.
- Have the shortest steps possible to complete actions to minimise mental workload.
- Ensure that there is plenty of time to read information to minimise mental workload and improve readability.
- Have simple instructions that are context-based to minimise mental workload.
- Have a focus on recognition rather than recall during development to minimise mental workload.
- Use high contrast between foreground and background to minimise mental workload and better readability.

4.6 Conclusion/takeaways

In this chapter, several aspects of designing for the elderly are highlighted. This information should be applied in the rest of this project, and therefore, some important conclusions will be highlighted:

- The target group is challenging as people often have comorbidities and struggle with physical and cognitive limitations.
- Predictors of usage intention are trust and perceived risk of the product. Therefore, it should be ensured that there is no risk in using the product and that it always works and gives the correct information to ensure a trust relationship is built.
- Subjective norm is a key determinant of usage intention. During the design process, attention should also be given to identifying who influences the patient and who can play a constructive and encouraging role in enhancing usage intention.
- Functional affordance influences the intention to use the product. The system design should allow for exploration of how to effectively communicate to users that the product can support them in achieving the goal of healthier feet.
- As 75% of usability issues are linked to conventional affordances, it is essential during the design process to carefully consider users' past experiences with similar devices, as well as the types of icons and symbols that are familiar to this target group. Gaining deeper insight into the previous experiences of elderly users can help ensure the product is accessible and usable for them.
- Extrinsic motivation should be a central focus, potentially delivered through healthcare professionals (HCPs) or technical support. Further research is needed to determine how, and to what extent, HCPs can contribute to enhancing extrinsic motivation.
- Design guidelines to consider are that it should be as simple as possible, it should use a big font and have great contrast with customer-focused language. All this should be done to minimise mental workload.

5. Synthesis

This chapter summarises the analysis and presents a system map that informs various design directions for the project. Finally, an initial list of requirements is outlined.

5.1 Summary analysis

In this first part, an analysis was conducted about the context of patients living with diabetes who experience ulcers. Some numbers and explanations were given to help the reader understand the need for this problem. In Figure 38, these numbers are summarised into one visual. The most common locations for ulcers are the Hallux area, metatarsals, heel region and the distal aspects of the digits. Temperature monitoring can help to prevent those ulcers, but the difference should be more than 2.2 °C between the left and right foot. Temperature monitoring is not widely practised currently due to the difficulty of measuring under the foot. In addition, these patients are already very busy managing their diabetes or have visual problems, which makes it even harder to check their feet. Peripheral artery disease and neuropathy are common comorbidities among these individuals. Some of them also have foot deformities. The most important stakeholders around the patient are the medical pedicure, podiatrist and POH diabetes and in some cases, a caregiver.

The current prototype fulfils the first need of measuring plantar temperature. A few suggestions were provided on how the prototype could be improved, for example, a button to alert the podiatrist or an automatic alarm notification sent directly to them. Other competitors, such as Siren Socks, Podimetrics, Vistafeet, Orpyx, and Bluedrop Medical, have already integrated some of these features. The approach to meeting the need for temperature monitoring, however, is met differently by these companies, ranging from pressure measurements or capturing images of the feet.

With the help of customer journeys, many pain points were identified. For example, determining who is responsible for seeking help in case of temperature elevation (podiatrist or patient) and deciding what type of data should be shared and how it should be presented to both the podiatrist and the patient. Interviews were conducted to gather insights and find answers to these questions.

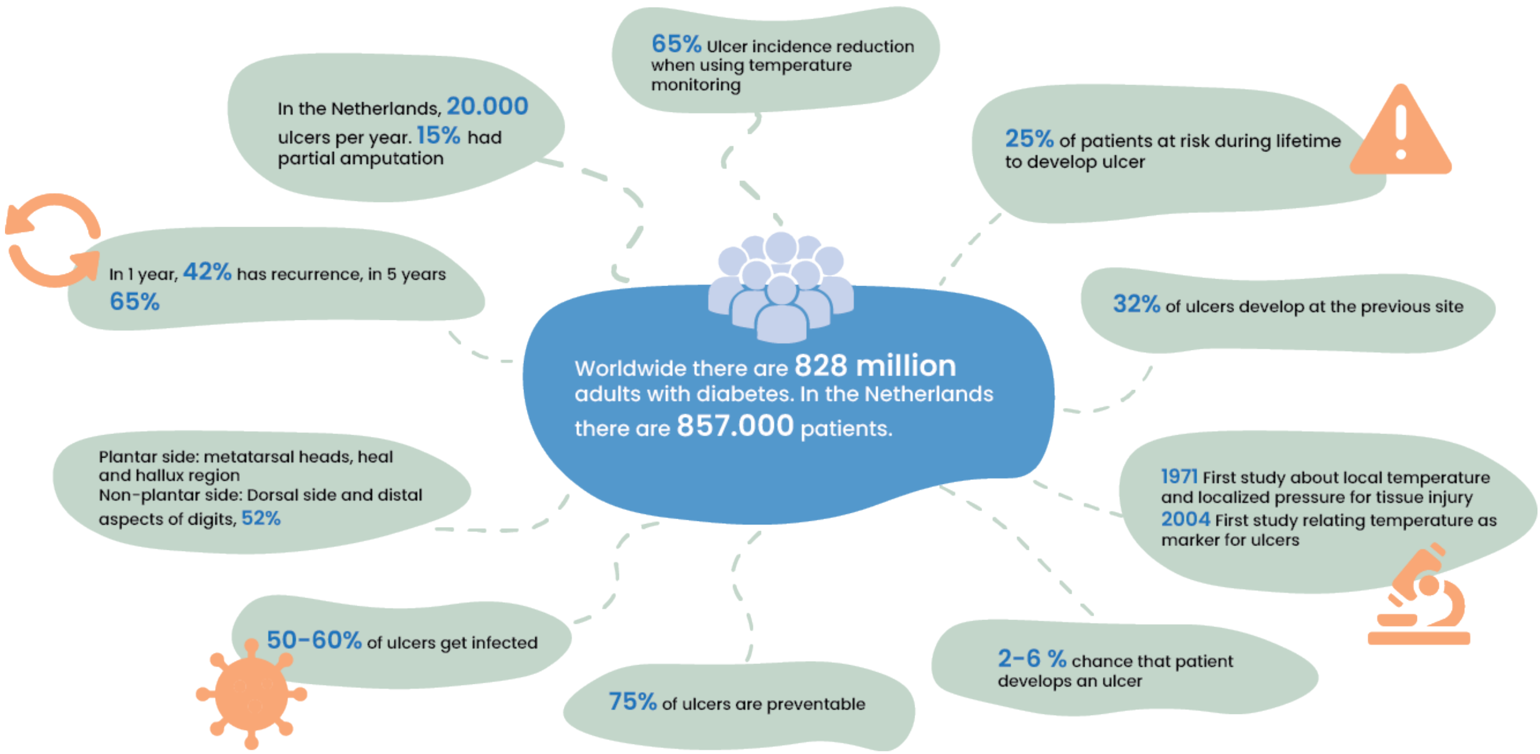


Figure 38. Data overview

The most interesting insight was learning about the various systems podiatrists use, such as Doctolib Siilo, DM voetzorg and James. In addition, regarding the patients, it was interesting to learn that most people preferred the one-foot version rather than the two-foot version. And patients want to have control over the device themselves, meaning that they would like to be the ones calling the podiatrist or have access to the exact measuring data.

Lastly, a literature review is presented with a specific focus on design for the elderly. They face different challenges, such as wanting to be independent but also dealing with a decline in cognitive and physical health. Two theoretical models helped to explain what influenced the behaviour intention of the elderly to start using the product, namely attitude, subjective norm, perceived behaviour control, perceived risk, trust, threat appraisal and coping appraisal. Also, the impact of the product's appearance on usage is described, discussing terms such as functional, conventional and physical affordance. In the end, some guidelines for interface design for the elderly are summarised, which can be used to create the final design.

5.2 System blueprint and design directions

System blueprint

Figure 39 illustrates the interactions between various stakeholders, offering a visual overview of their connections. This diagram helped identify key design aspects of the project. One important element is the ‘Secuped system’, a cloud-based platform designed to facilitate data communication between Secuped, the patient, and the podiatrist.

The diagram also attempts to map out each stakeholder’s role in relation to the patient. However, some aspects remain unclear. For example, it is not yet certain who is responsible for returning the device. Could the podiatrist initiate the return, or should the patient do it themselves? The involvement of other care providers is also ambiguous. They may help encourage the patient or possibly access the data as well. These points require further investigation.

Additionally, the subjective norm identified in Chapter 4 is reflected in the influence others have on the patient. Secuped might also contribute to this by communicating the benefits of the system to the patient’s family.

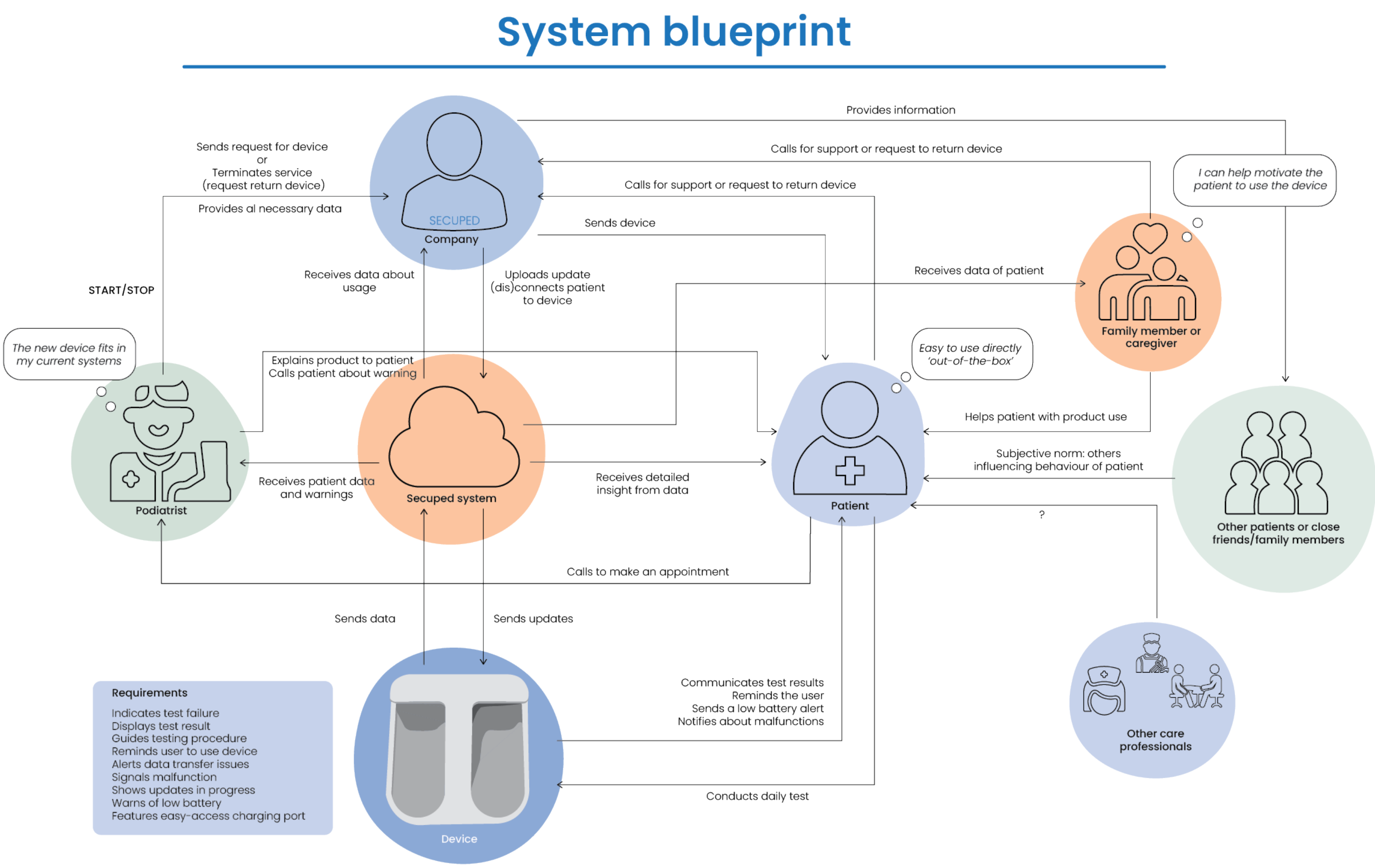


Figure 39. Blueprint of the system

Design domains within the project

Four design domains are formulated based on the system blueprint. These directions will be considered in the following part of this report, and all of them will be briefly discussed.

Design domain 1: Interface design: interaction device and patient

This is probably the most extensive direction as it is about the creation of the interface and its electronics. A physical prototype will be necessary, and a study on the most effective way to integrate electronics into the device must be conducted (Figure 40). Questions related to this design direction are:

- How is it communicated that the test is running or has failed?
- How are test results displayed to the user?
- How is a low battery alert communicated?
- How is an ongoing device update indicated?
- How is a malfunction communicated?
- How is a network connection failure communicated?
- What is the best way to remind the user to use the product?
- Should the test measure one foot at a time or both simultaneously?
- How could the communication of data look like (eSIM or IoT network)?
- Which technologies (IoT/5G) are suitable for use across different countries?

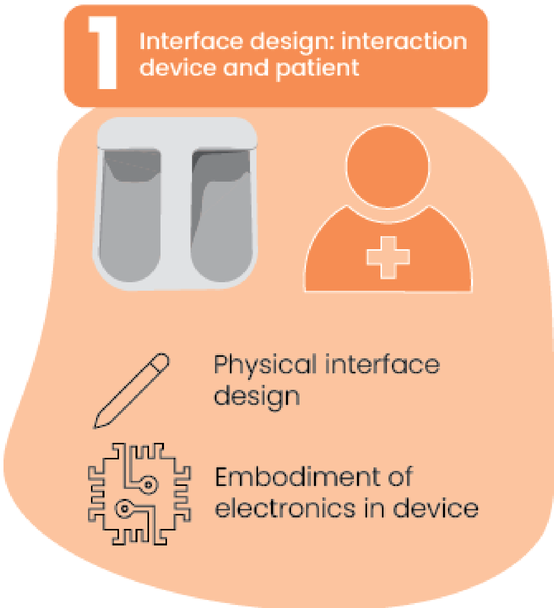


Figure 40. Design domain 1

Design domain 2: Communication of data with the podiatrist

Ultimately, some data from the device will be shared with the podiatrist. Ideally, this data would be seamlessly integrated into the podiatrist's existing systems. However, the exact process and the systems used by podiatrists remain unclear. In addition, a design will be required for the data presentation (Figure 41). This raises the following questions:

- How can patient data be integrated into existing podiatry systems?
- What should the design of data overviews look like?
- How should the warning and notification system be structured?

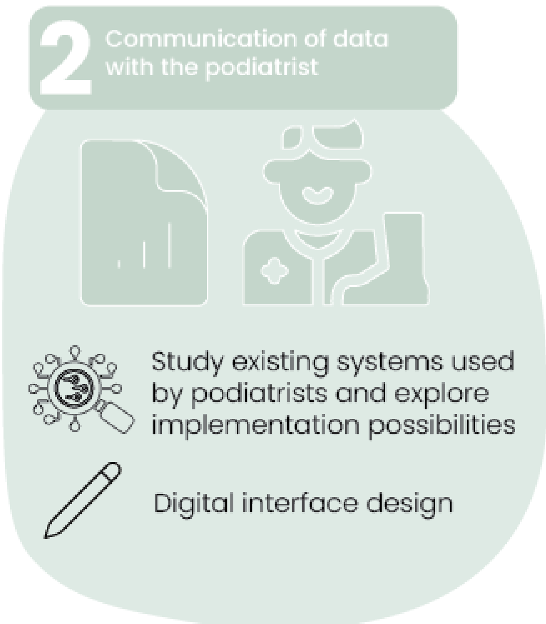


Figure 41. Design domain 2

Design domain 3: Communication of data with the patient

Similar to design direction 3, this direction is about the communication of the data with the patient. What type of information would they like to receive, and in what way should this be visualised (Figure 42)? There is the possibility that patients do not want any additional information besides what is provided on the device, which would eliminate this design direction. If not, the questions to be asked are:

- What type of information should be shared with the patient?
- How should the data be visually presented?
- What is the best way for the patient to access their data?

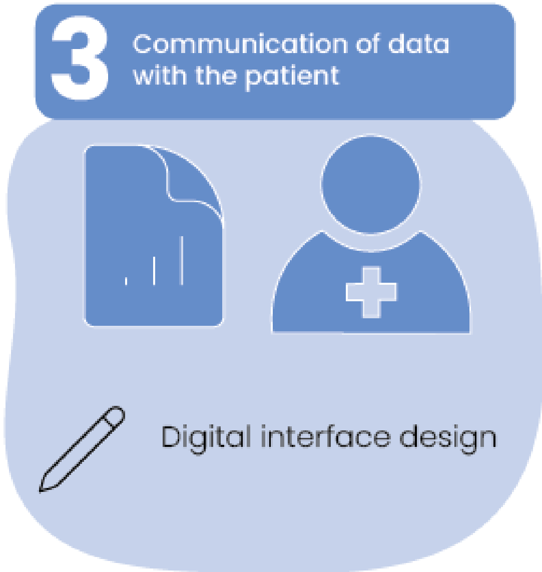


Figure 42. Design domain 3

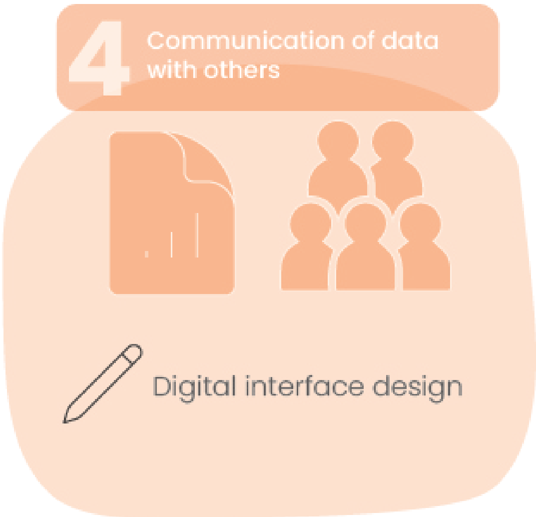


Figure 43. Design domain 4

Design domain 4: Communication of data with others (if required)

This design is still uncertain and will depend on user needs and preferences. For now, it is assumed that patients may prefer others to check or help them access their data (Figure 43). Caretakers, for example, could encourage patients to use the product more regularly. If this design direction is necessary, the following questions will need to be addressed:

- Should others have access to the patient's data?
- What role should a potential caretaker play in accessing or managing the data?
- What specific data should be shared with others, if applicable?

5.3 List of requirements

Below is a list of requirements is given which have been used for product development. For each requirement, the source is provided.

1. Performance

1.1. The product should measure temperature differences between two feet (project assignment).

1.2. The product should notify the patient and the podiatrist in case there is a foot skin temperature elevation for 2 days or more in a row (Secuped, Personal communication, 20 February 2025).

1.2.1. In case of the absence of a podiatrist, another podiatrist should receive the notification (Secuped, Personal communication, 20 February 2025).

1.3. The product should only need charging every 3 months and communicate 2 weeks in advance that the battery is running empty (Secuped, Personal communication, 20 February 20252025).

1.3.1. The product should have a special charging cable, specific to this product (Medical regulations).

1.3.2. The charging port should be easily accessible (Secuped, Personal communication, 20 February 2025).

1.4. The product should save some data locally but also send the measurements directly over the cloud to the Secuped secured environment (Secuped, Personal communication, 20 February 2025).

1.5. The product should function on its own and shouldn't require an infrastructure of the user, such as a Wi-Fi connection (competitor analysis).

1.6. The product should always be ready to use, so there is no on/off button that needs to be clicked before usage (competitor analysis).

1.7. The product should have a pause option in case of sickness, ulcer development or else (Interview round, April 2025).

1.8. The product should remain stationary during measurement (Interview round, April 2025).

1.9. The product should be easy to move over the ground, so it can be placed underneath a bed (Interview round, April 2025).

1.10. The product should have some memory to save test results for at least 3 days in case there is no service available (Ideation, May 2025).

1.11. The product should be able to conduct the test without being connected to the Secuped cloud (Ideation, May 2025).

2. Interaction

2.1. The product should communicate the test result to the user, which is the patient living with diabetes (Podiatrist, Personal communication, 20 March 2025).

2.1.1. The product should communicate the test result using (auditive and) visual feedback (Interview round, April 2025).

2.1.2. The product should make a difference between a one-day elevation and a serious risk (2 days+ elevation) in presenting the result (Interview round, April 2025).

2.1.3. The product should communicate to the user which foot is causing the problems (Interview round, April 2025).

2.2. The product should provide feedback about the correct placement of the foot (Interview round, April 2025).

2.2.1. The design of the product guides the user into the correct placement (Interview round, April 2025).

2.3. The product should have a reminder function to help the user remember to use it (Secuped, Personal communication, 20 February 2025).

2.4. The product should communicate to the user that it is updating (Secuped, Personal communication, 20 February 2025).

2.5. The product should communicate to the user in case it is malfunctioning (Secuped, Personal communication, 20 February 2025).

2.6. The product should communicate to the user if the measurement has failed (Secuped, Personal communication, 20 February 2025).

2.7. The product should communicate when the battery is running low (Secuped, Personal communication, 20 February 2025).

2.8. The product should communicate if it cannot connect to the network, so it cannot transfer the data (Secuped, Personal communication, 20 February 2025).

2.9. The interaction of the device with the user should also be possible when the user has limited visual capabilities (Yang et al., 2016).

2.10. The most important components of the interface should be located in the centre as the elderly have reduced widths of the visual field (Sharma et al., 2016).

2.11. Similar information should be grouped together to improve understandability (Salera et al., 2016).

2.12. There should be a high contrast between foreground and background to minimise mental workload and better readability (Salera et al., 2016).

2.13. There is an on/off button which functions to reset the system or turn off the device during travel (Ideation, May 2025).

2.14. There is a pause button which allows the user to pause its usage due to sickness or something else which prevents usage of the product (Ideation, May 2025).

3. Safety, environment and size

3.1. The product should be lightweight to ensure it can be carried by the elderly to the charging point (Interview round, April 2025).

3.2. The product should be small, so it is possible to take it with you on a trip (Interview round, April 2025).

4. Materials

4.1. The surface should be sufficiently watertight to allow cleaning with a damp cloth (Secuped, Personal communication, 20 February 2025).

4.2. The entire surface of the product should be easily accessible for cleaning (Interview round, April 2025).

4.3. The toe coverage should be of very soft material, so it doesn't damage the toes when sliding in (Interview round, April 2025).

4.4. If the product is using a display, it should be illuminated and have a big contrast and size (Interview round, April 2025).

4.4.1. The display should have at least 50 pixels to ensure all words can be presented (Ideation, May 2025)

4.5. The product should have a spacious entrance and no sharp edges to prevent foot damage (Interview round, April 2025).

5. Aesthetics

5.1. The product should not be stigmatising (Secuped, Personal communication, 20 February 2025).

5.2. The product should not have a medical look (Moore et al., 2021).

6. Installations and usage

6.1. The product should come with Instructions for Use (IfU) in the shape of a leaflet and a video (Interview round, April 2025).

6.2. The product should come with clear instruction material for HCP (Interview round, April 2025).

6.3. The product package should contain information about how to call Secuped and how to return the device (for instance, in case of death) (Secuped, Personal communication, 20 February 2025).

6.4. The product should work 'out of the box', so it can be on the thuiszorgmiddelenlijst (Secuped, Personal communication, 20 February 2025).

6.5. The service around the product should acquire data about the patient for the set-up, such as the name of the patient, name of the podiatrist, phone numbers, if there is a caretaker, etc. (Secuped, Personal communication, 20 February 2025).

6.6. The product should be easily connected to the correct patient and should also enable disconnection when returned (Secuped, Personal communication, 20 February 2025).

6.7. The product should allow a patient to be connected to two devices in case of product failure, which means a new device is sent (Secuped, Personal communication, 20 February 2025).

6.8. The product (and possible app, manual and website) should have a phone number which can be contacted in case of product failure (Interview round, April 2025).

6.9. The products can be set to the correct language in case words are used (Ideation, May 2025).

7. Digital Environment

7.1. The product should come with a digital environment in which an overview of measurements, temperature differences and real temperature values are presented (Interview round, April 2025).

7.2. The digital environment should send reminders in case the user hasn't used the product for a longer period (Interview round, April 2025).

7.3. The digital environment gives the option to give feedback that the user has taken action on elevated temperature (Interview round, April 2025).

7.4. The digital environment also gives an alarm in case of multiple days of elevation (Interview round, April 2025).

7.5. In the digital environment, the usage of the product can be paused in case of sickness, vacation or an active ulcer (Interview round, April 2025).

7.6. The digital environment shows connection details of the device and also general information such as serial number, battery level (Interview round, April 2025).

8. Sustainability

8.1. The product should last at least 4 years (Secuped, Personal communication, May 2025).

9. Product costs

9.1. The costs of the product should not exceed 100 euros (Secuped, Personal communication, May 2025).

9.2. The product costs should be covered by insurance companies and provided through a lease system (Secuped, Personal communication, 4 February 2025).

10. Regulations

10.1. The icons used on the product should be according to the regulations around medical devices (medical regulations).

11. Communication between systems

11.1. The podiatrist should receive a notification in case of elevated temperatures in a system they already use (for instance, Doctolib Siilo) (Podiatrist, Personal communication, 20 March 2025).

11.2. The podiatrist should receive data on measured temperatures, temperature variations, the date of elevation, and overall device usage (Podiatrist, Personal communication, 20 March 2025).

12. IT systems

12.1. The product should use an ESIM or some type of IOT network for communicating the data to the systems of Secuped (D. Zeven, Personal communication, 20 March 2025).

12.2. The IT systems should support the ability to push updates to all devices in users' homes (Secuped, Personal communication, 20 February 2025).

Wishes

- The podiatrist would like the system to fit into existing systems, so there is no need to add another system (Podiatrist, Personal communication, 20 March 2025).
- The digital environment is potentially accessed through an app (Interview round, April 2025).
- The product could provide a remembering option using light (Interview round, April 2025).

6. Ideation

After finding four clear design directions, this chapter will describe the various ideations conducted. The primary focus has been on the physical interface of the device, which will therefore be the central topic of this chapter.

It will begin by describing the required interactions for the interface, which were identified in previous chapters. After that, three initial concept drawings will be presented. Then, the research conducted on choosing the right display is described, followed by an explanation of the Arduino-based prototyping process. Then, two main concepts are described which came from the ideation with the LED strip and display. These concepts were further refined through user feedback, and the iterations are briefly summarised. Finally, the chapter concludes with the most important key takeaways.

6.1 Interactions with the device

Before describing the interactions, an important decision was made. *The focus at this stage will be on the one-foot model* (Figure 44). This approach introduces additional challenges, such as indicating to the user which foot to place and requiring the test to be performed twice. If the decision is later made to switch to a two-foot model, the interaction will be simplified, and no extra interaction design will be needed. The interactions with the device are shortly described to give a clear understanding of what is expected from the device. The primary interactions will be described first, followed by the secondary interactions.

Figure 44. Renders of the one-foot model created by Tom Hinskens

Main interactions

In Figure 45, an overview is presented. There is no on/off button, so the device should give some type of feedback that it is turning on. For now, *it is assumed that the device cannot detect which foot is placed;* therefore, it will indicate to the user which foot should be positioned. This will always be the same direction, starting with the left foot, as this is also how people read from left to right. There should be clear feedback when the foot is correctly positioned, so the user knows not to move it further. The other interactions, such as 'measuring' and 'failure measurement', are quite straightforward. Showing *the result of the test is limited to telling which foot is the problem*. The digital environment is created to give a more detailed result of the test. Finally, it should be clearly communicated whether the data will be shared with the Secuped system, and, by extension, with the podiatrist.

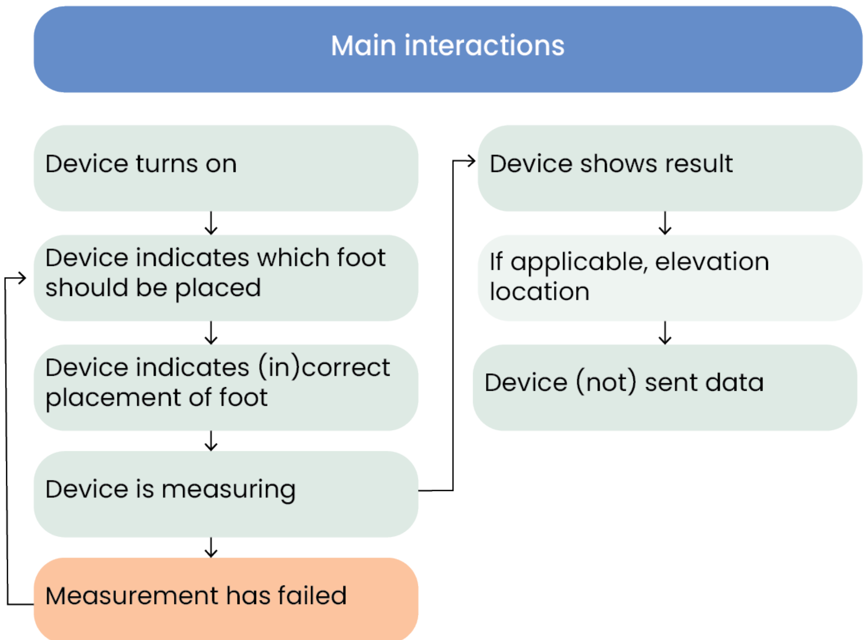


Figure 45. Main interactions physical interface

Secondary interactions

From the user interviews and the analysis of competitors, a certain number of secondary or supplementary interactions were identified (Figure 46). Most of them are straightforward; for instance, when plugging in the battery charger, it is expected that some type of feedback is given that it is charging. Regarding 'updating', this interaction is still uncertain if it will be present. It is possible that Secuped pushes updates to all devices over its system. This will disable usage of the product for some time, and it would be good to communicate this to the user. In addition, the device should indicate whether it is connected or not. The last interesting interaction is the 'pause usage' option. User interviews revealed that individuals would like the option to pause their usage, such as during illness or holidays, to avoid the risk of the podiatrist contacting them about a lack of device activity. There should be a clear indication to the user that the device usage has been successfully paused.

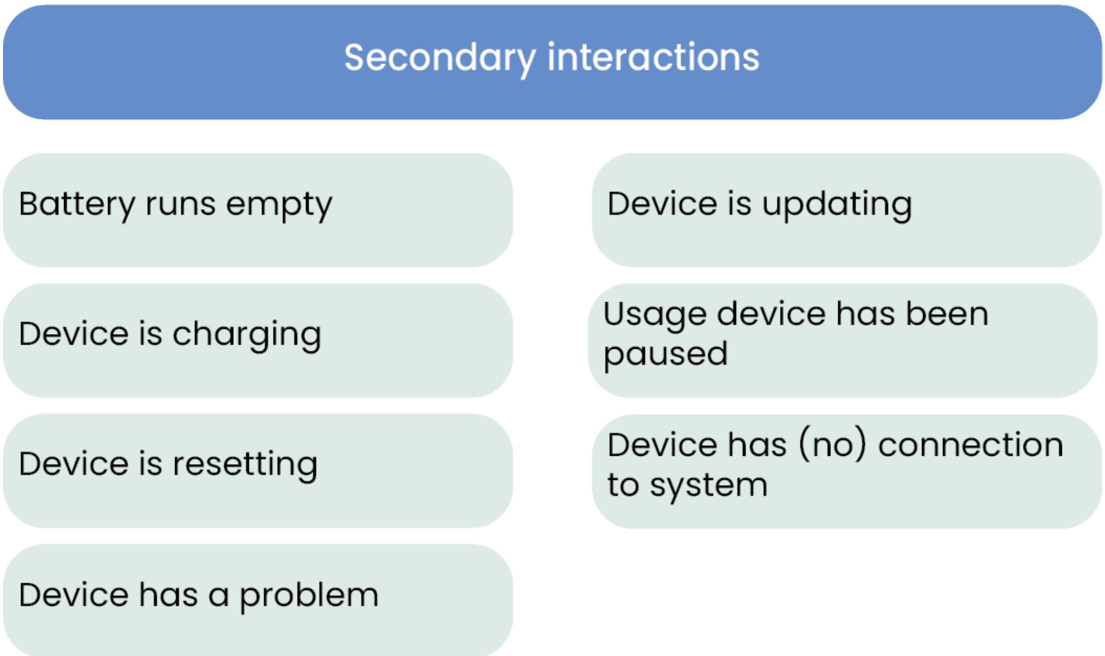


Figure 46. Secondary interactions physical interface

6.2 Three initial design directions for the physical interface

The ideation process began by exploring each interaction individually. For example, several approaches were designed to communicate to the user that the device is measuring. From this very broad ideation, three design directions emerged, which are presented in Figure 47. A few advantages and disadvantages of each direction will be given.

Direction 1

- (+) Language can convey messages very clearly and is less likely to be misinterpreted compared to icons.
- (+) The absence of colour makes this direction accessible for colourblind people.
- (-) Using language requires multiple language versions of the product, as it will be sold internationally.
- (-) People who have low literacy may have difficulty understanding the messages.
- (-) A wider display is needed to show full-text messages.

Direction 2

- (+) Icons, when understood correctly, are very clear and don't require any reading, making them more accessible for people with low literacy.
- (+) The use of colour provides additional support in conveying the message.
- (-) Colour-blind users might not see the colours, which could reduce message clarity.
- (-) It is uncertain whether the icons will be clearly visible on an LED grid.

Direction 3

- (+) Eliminates the need for an LED grid, likely making this approach more cost-effective.
- (+) Very straightforward, less hard to understand once explained to the user.
- (-) Heavily reliant on colour, which may make it inaccessible for colour-blind users.
- (-) Involves the use of language, meaning the shell with engravings or stickers would need to be adapted for each country.

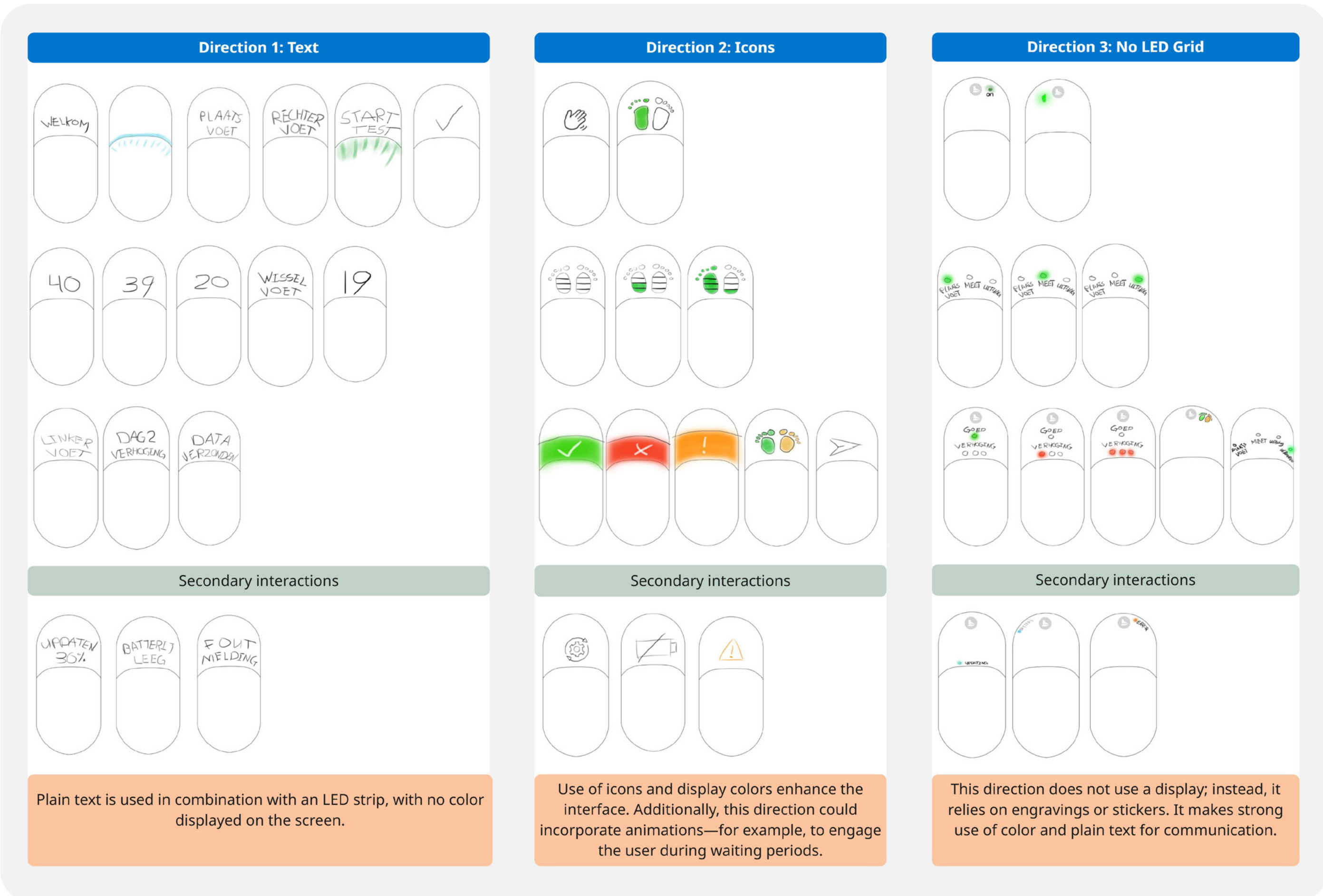


Figure 47. Sketches of the three directions

These directions served as a foundation for developing more concrete concepts. For example, the initial ideation revealed that incorporating an LED strip could be highly beneficial. This feature directly addressed a need expressed during user interviews: one participant mentioned wanting more light when placing their foot into the device, as they were afraid of injuring it. The additional lighting would help them see what's happening and increase their trust in the device. All directions were briefly tested with some paper models and a display, as shown in Figure 48. This allowed for a preliminary validation to assess whether the concepts were feasible to realise in practice.

Figure 48. Low-fi prototyping of the three directions

6.3 Display selection & integration

Before continuing with the ideation, an in-between step was conducted to figure out what type of display would be suitable for this design. At the same time, some requirements were found for the use of an LED grid. This chapter will briefly summarise these findings as they form the base for the design that will be presented at the end of this report.

OLED vs. LED Grid

Both options would be suitable for this design. The OLED was briefly tested with some paper models to try out the size of 3.5 inches, see Figure 49. An advantage is the higher visual quality that it offers. Regarding the LED grid, it was determined that a size of 50 by 16 pixels was necessary (further details are provided below). The readability of the text in the case of an LED grid depends on the type of diffuser used and the distance between the different pixels (pitch size). With a small test (Figure 50), it was concluded that most people (4 out of 6), including an elderly user aged 87, preferred the 2.5 mm pitch due to its improved legibility. Things to consider in this decision are the production costs and the visual quality. More arguments can be found in Appendix F.

In conclusion, it was decided to proceed with the LED grid. There are no specific requirements for high visual quality or vibrant colours which apply to an OLED screen. Additionally, the OLED screen has higher manufacturing costs and lower peak brightness, which can be a drawback if the device is used in well-lit environments, such as rooms with direct sunlight. OLEDs also have a shorter lifespan, meaning they would need to be replaced more frequently compared to LED grids. While LED grids have poorer colour representation and are thicker, these limitations are not critical for this product.

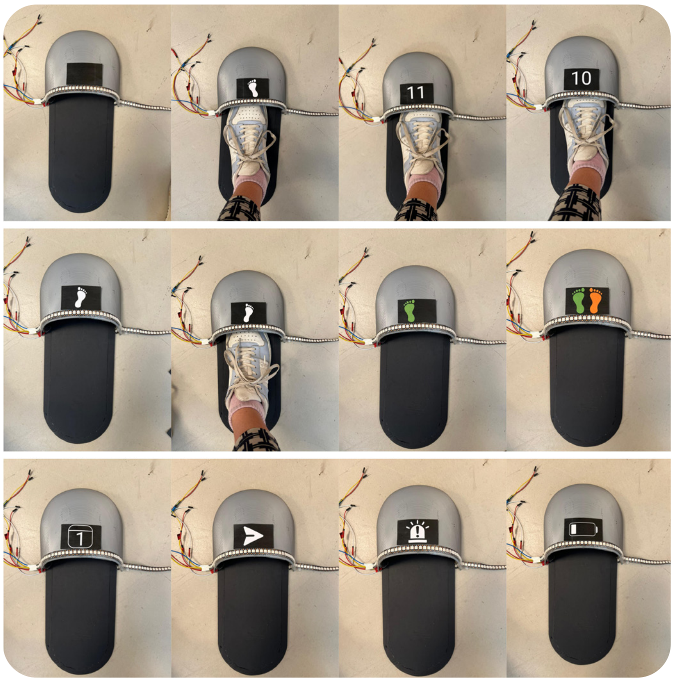


Figure 49. Possible OLED screen layout

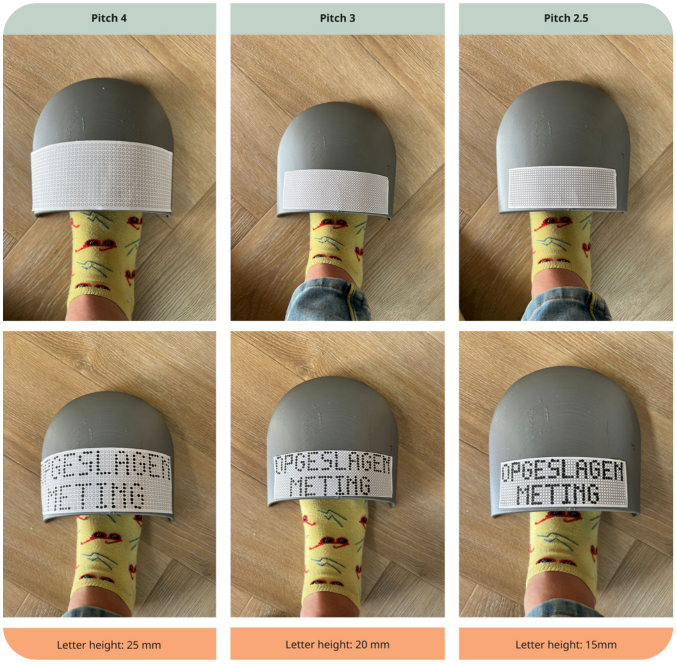


Figure 50. Pitch variations

Font design & LED grid size selection

To determine the appropriate size of the LED grid, an overview was created listing all potential messages required for interaction with the product. These were translated into several languages such as Dutch, English, German, Danish and Spanish (see Figure 52).

A typical LED grid letter height is 7 pixels, which, when including two blank rows for spacing, results in a total height of 16 pixels. This configuration is common and was therefore assumed as a given. Regarding the width, several options are possible as described in Appendix G. It was decided to create a custom font with the help of this website: [LED font creator](). This font uses 4 pixels for most capital letters, except for K, M, T, V, W, Y, and Z, which require 5 pixels due to their complexity. The letter I is only 3 pixels wide. In Figure 51, an overview of the design of every letter is shown. As the website provided a bit array, this has been translated to a hex notation, which was required to create the GFX font. More information about the GFX font creation can also be found in Appendix G.

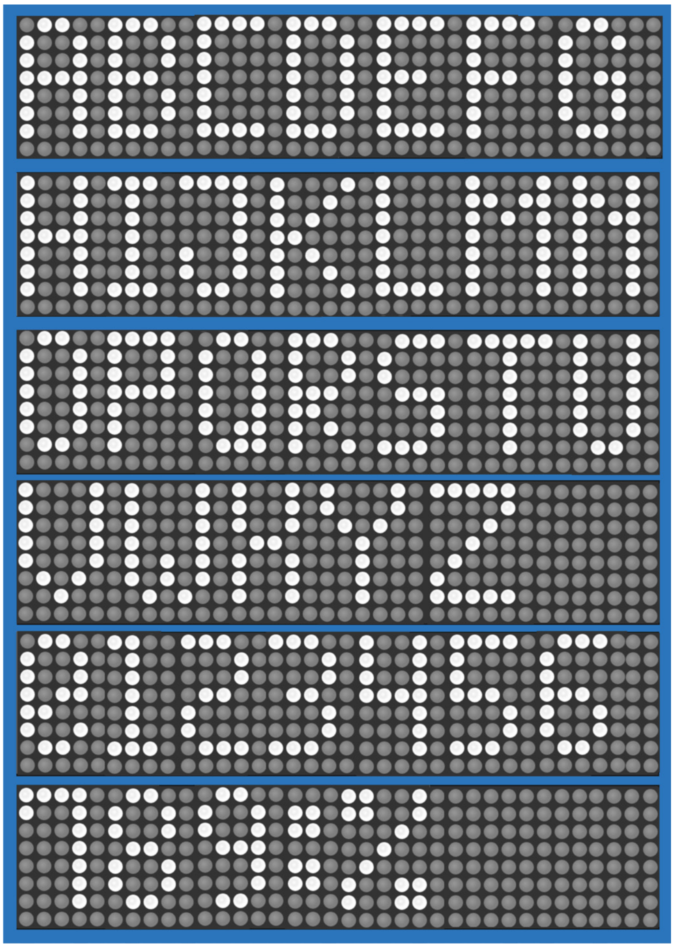


Figure 51. Generated font

Dutch translation:

- Schakelt in
- Gaat aan
- Welkom -->Guten Tag
- Goede morgen
- Linker voet
- Rechter voet
- Plaats opnieuw
- Start test
- Wissel voet
- Probeer opnieuw
- Mislukt
- scan gelukt
- Resultaat meting
- Goed
- Fout
- Verhoging
- Verzenden mislukt
- Data verzonden
- Opgeslagen
- Verzonden
- Updaten
- Even geduld
- Verbinden
- Batterij leeg
- Laad op
- Contact Secuped

English translation:

- Powering on
- Turning on
- Welcome
- Good morning
- Left foot
- Right foot
- Reposition
- Start test
- Switch foot
- Try again
- Failed
- Scan successful
- Measurement result
- Good
- Error
- Increase
- Sending failed
- Data sent
- Saved
- Sent
- Updating 30%
- Please wait
- Connecting
- Battery empty
- Charge now
- Contact Secuped

German translation:

- Einschalten
- Wird eingeschaltet
- Willkommen
- Guten Morgen
- Linker Fuß
- Rechter Fuß
- Neu platzieren
- Test starten
- Fuß wechseln
- Erneut versuchen
- Fehlgeschlagen
- Scan erfolgreich
- Messergebnis
- Gut
- Fehler
- Erhöhung
- Senden fehlgeschlagen
- Daten gesendet
- Gespeichert
- Gesendet
- Aktualisiere 30 % of Update
- Bitte warten
- Verbinden
- Batterie leer
- Aufladen
- Kontakt Secuped

Danish translation:

- Tænder
- Tændt
- Velkommen
- Godmorgen
- Venstre fod
- Højre fod
- Placer igen
- Start test
- Skift fod
- Prøv igen
- Mislykkedes
- Scanning lykkedes
- Måleresultat
- God
- Fejl
- Forhøjelse
- Afsendelse mislykkedes
- Data sendt
- Gemt
- Sendt
- Opdaterer
- Vent venligst
- Forbinder
- Batteri tomt
- Oplad
- Kontakt Secuped

Spanish translation:

- Encendiendo
- Encendido
- Bienvenido
- Pie izquierdo
- Pie derecho
- Recolocar
- Iniciar prueba
- Cambiar pie
- Intentar de nuevo
- Fallido
- Escaneo exitoso
- Resultado de la medición
- Bueno
- Error
- Aumento
- Envío fallido
- Datos enviados
- Guardado
- Enviado
- Actualizando
- Un momento por favor
- Conectando
- Batería baja
- Cargar
- Contactar Secuped

Figure 52. Diverse translations of the interaction texts

6.4 Arduino prototyping

To test the intended interaction, Arduino was used as a prototyping platform. This subchapter provides an overview of the code structure, covering topics such as hardware components, LED matrix libraries, the way of coding and the creation of one's own icons. The goal is to offer background information on how the code was developed, rather than to present the final version.

Hardware usage

The following items were used during this prototyping phase:

- NODEMCU ESP8266
- ESP32 Dev Module
- LED strip
- Breadboards
- Diverse LED grids: Waveshare RGB 64x32 pixels 4 mm pitch & Waveshare flexible RGB Pitch 2.5 96x48 pixels, both have a HUB75.
- FSR sensors
- TSL2561 light sensor
- Multiple resistors
- Button
- Power adapter for LED grid: 5V, 3A

Initially, the designs were developed using the ESP8266 board. However, due to its limited number of digital pins and the need to incorporate additional sensors, the decision was made to switch to the ESP32. This board has a higher uploading speed and a greater number of digital pins, making it better suited for this prototype. The wiring can be found in Figure 53.

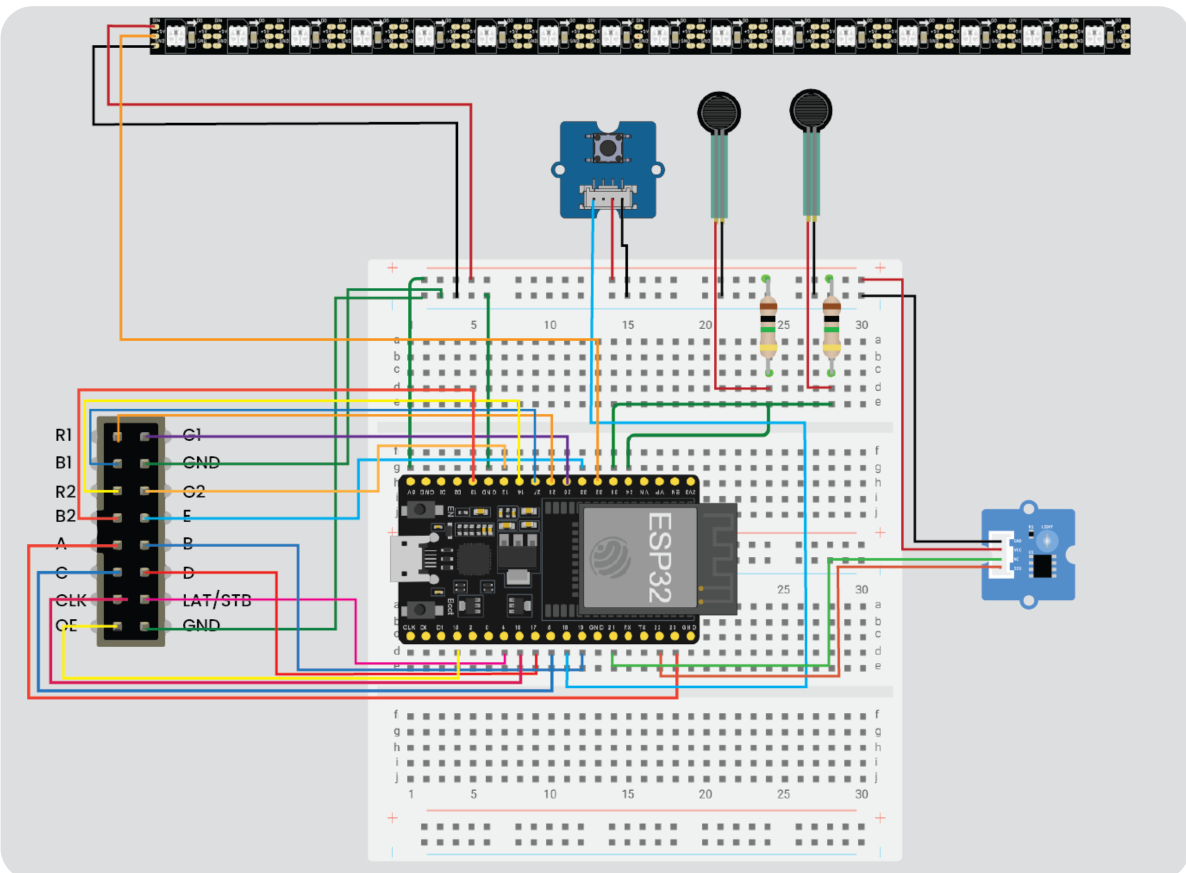


Figure 53. Connection components

LED matrix libraries

Initially, the ESP8266 board was used, and the PxMatrix was implemented to control the LED grid. This library supports the usage of GFX fonts, which allowed for the creation of the first designs. However, upon switching to the ESP32 board, this library was no longer supported. PxMatrix relies on bit-banging, a method less suited to the ESP32's architecture.

Instead, an I2S-DMA library has been used. DMA is Direct Memory Access, and the I2S of the ESP32 is used to stream data directly to the LED grid. In comparison with the PxMatrix, CPU usage is a lot less. This new library also works more efficiently and is more stable. However, it is also more complex to start with.

There are several I2S-DMA libraries available online, but since a GFX font had already been created, a library that supported GFX fonts was needed to maintain control over text size and appearance. This library was found on this website: DMA Library. The functionality of this library is also dependent on the specific LED matrix hardware used. The alignment of the system can be a bit off when using the library, meaning that the first letter is not shown correctly. This was the case for the Waveshare LED grids used for this prototype. It is then important to add an extra rule in the code, namely 'mxconfig.clkphase = false;' before the 'matrix.begin(mxconfig);' to resolve this problem.

Additionally, when using the flexible Waveshare LED grid with a 2.5 mm pitch, another issue occurred where text was cut off halfway across the display. To resolve this, one should add the rule 'matrix.setTextWrap(false);'. These are just a few important lessons and technical considerations when working with LED matrices in prototyping.

Coding set-up

This section briefly summarises the code structure to help the reader understand the flow of the prototype. Since both an LED strip and a light sensor were used, the relevant libraries, FastLED.h, Digital_Light_TSL2561.h, and Wire.h, were included at the beginning. Additionally, math.h library (for the spinning wheel) and the ESP32-HUB75-MatrixPanel-I2S-DMA.h were included.

To keep the code organised, several tabs were created: one for the GFX font (OwnFont.h), one for the icons and one for the interactions. On the interactions tab, the functions were defined. These interaction functions are called from the main tab. For example:

```
void TXTmeasurementfailed() {
matrix.fillScreenRGB888(0, 0, 0);
matrix.setFont(&OwnFont);
matrix.setTextWrap(false);
matrix.setCursor(30, 33);
matrix.setTextSize(1);
matrix.setTextColor(myWHITE);
matrix.print("MISLUKT"); }
```

In the main tab, the function 'TXTmeasurementfailed();' was simply called in one of the loops. To control the interaction flow, a button was implemented to manage states, allowing users to skip certain steps or retry a test. This also prevents the prototype from running immediately when powered on.

- State 0: The device is off
- State 1: Left foot measurement
- State 2: Right foot measurement
- State 3: The device is broken
- State 4: The battery is running empty
- State 5: The device is updating

After State 1 and State 2, the system resets to State 0, allowing the user to restart the process. This approach ensures correct interaction flow and prevents unintended use. Other information which might be interesting to know about the build-up of the code can be found in Figure 54.

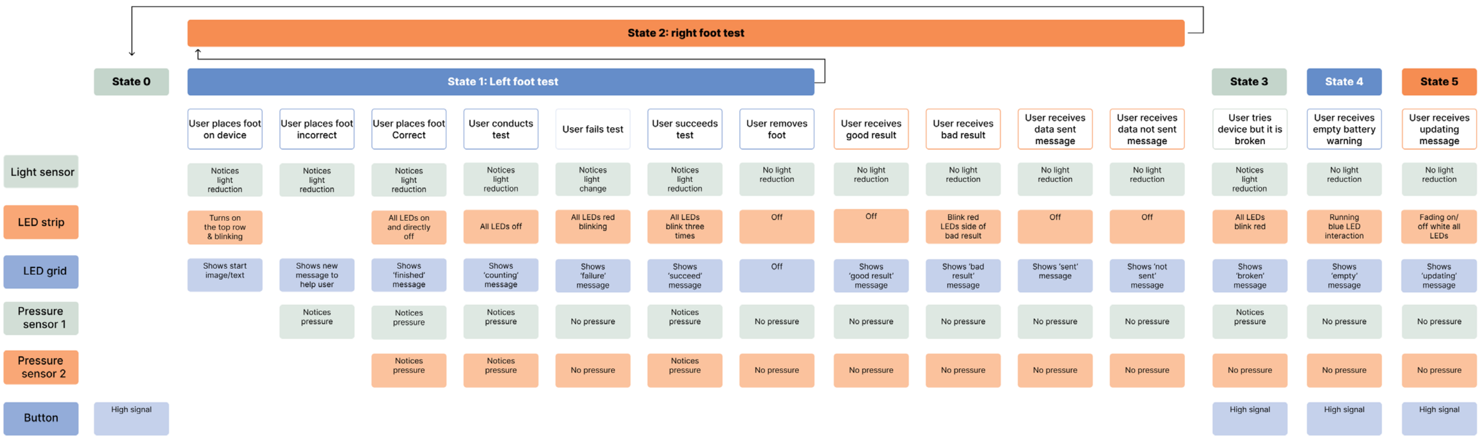


Figure 54. Explanation of the interaction with the sensors

Icon usage on the LED grid

One of the design directions explored the usage of icons. In Figure 55, some tests are shown- experimenting with filled and unfilled icons as well as icons with overlay (e.g. cross), as initially it was expected that the LED grid wouldn't offer sufficient visual quality. The creation of these icons was done in a pixel-accurate file in InDesign, allowing white icons to be positioned precisely. These were converted into bitmap image arrays using an online tool. Images could be translated to a UTFT library, which is a Universal TFT that can be used to send data to TFT screens. This process helped speed up icon creation by eliminating the need to manually draw each pixel.

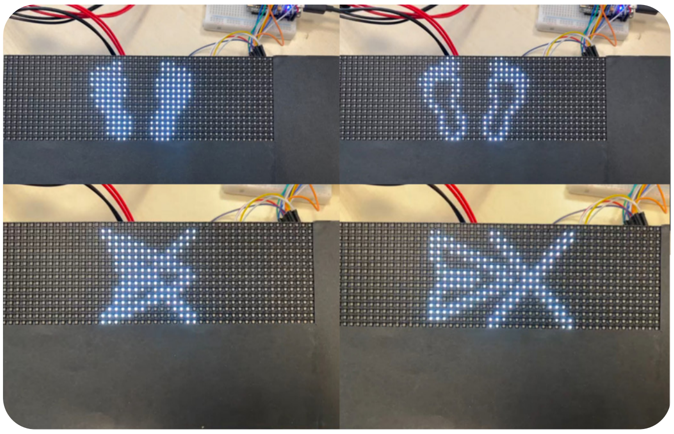


Figure 55. Icon try-outs

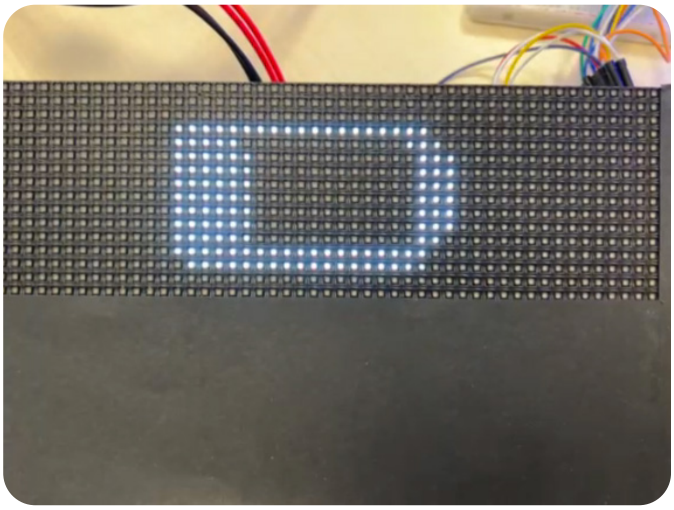


Figure 56. Battery icon missing pixels

However, the website had some limitations, as can be seen in Figure 56. The battery icon misses some pixels. Finetuning was therefore done by this online tool, which positions the PNG on the correct pixel map but allows individual pixels to be changed. In this way, icons could be shaped a bit better before they are translated into a bitmap. Additionally, by incorporating light grey pixels, a subtle dim or glow effect could be added to enhance the icon's appearance.

6.5 Iterations and evaluations of two concepts

This chapter presents several iterations, and the goal is to describe how, in the end, two concepts were developed. First, some initial design concepts will be discussed, where variations with the LED grid and the display are described. After that two main concepts are presented: one with text and one with icons. For these, the display has the main role, and the LED strip supports. The development of these concepts has been very iterative, as it has been tested by over ten people. These evaluations form the closure of this subchapter.

Iterations with the LED strip and display

To develop initial design concepts, several iterations were carried out to explore the possibilities of using an LED strip and a display. First, both options were considered separately and later combined in different configurations. In total, four design directions were created: only the LED strip, only the display, the LED strip as the main element and the display as secondary and the display as the main element and the LED strip as secondary. For each design, the following core interactions were developed: main flow, error message, updating and battery running empty. The differences between all concepts and the accompanying videos showing the flow can be found in Appendix H.

The main variations involved using colour on both the LED strip and the display, employing the LED strip for a countdown effect, or showing countdown numbers directly on the display. These design directions have been tried and shown to several people to get some initial feedback. Most participants preferred the integration with the LED strip and felt it should play a supporting role. There was no clear preference yet between the use of icons or text. Additionally, the impact of colour on the design shouldn't be underestimated. Also, when considering colour-blind users. Therefore, the next iterations will use fewer colours to find a more basic design to which colours can be added later if needed. Lastly, the communication of the result was preferred by using the display, as this LED strip interaction was found to be hard to see (Figure 57).

Two ways of communicating the measurement result

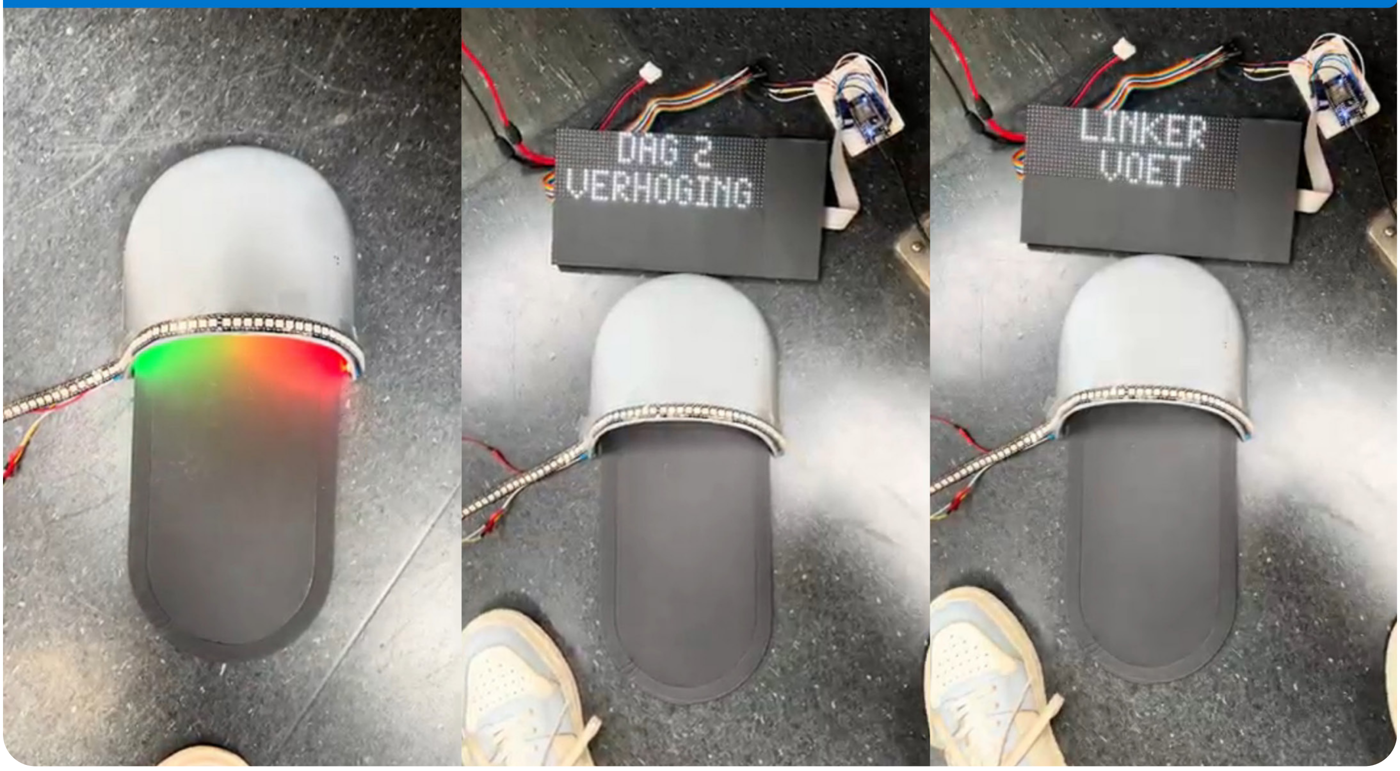


Figure 57. Example of two different concepts, one using an LED strip to communicate the result and the other using text (day 2 elevation, left foot).

Initial concepts

The first concepts created are shown in Figure 58 and Figure 59. Explaining an interaction through pictures can be challenging; therefore, videos are also available for Concept 1 and Concept 2.

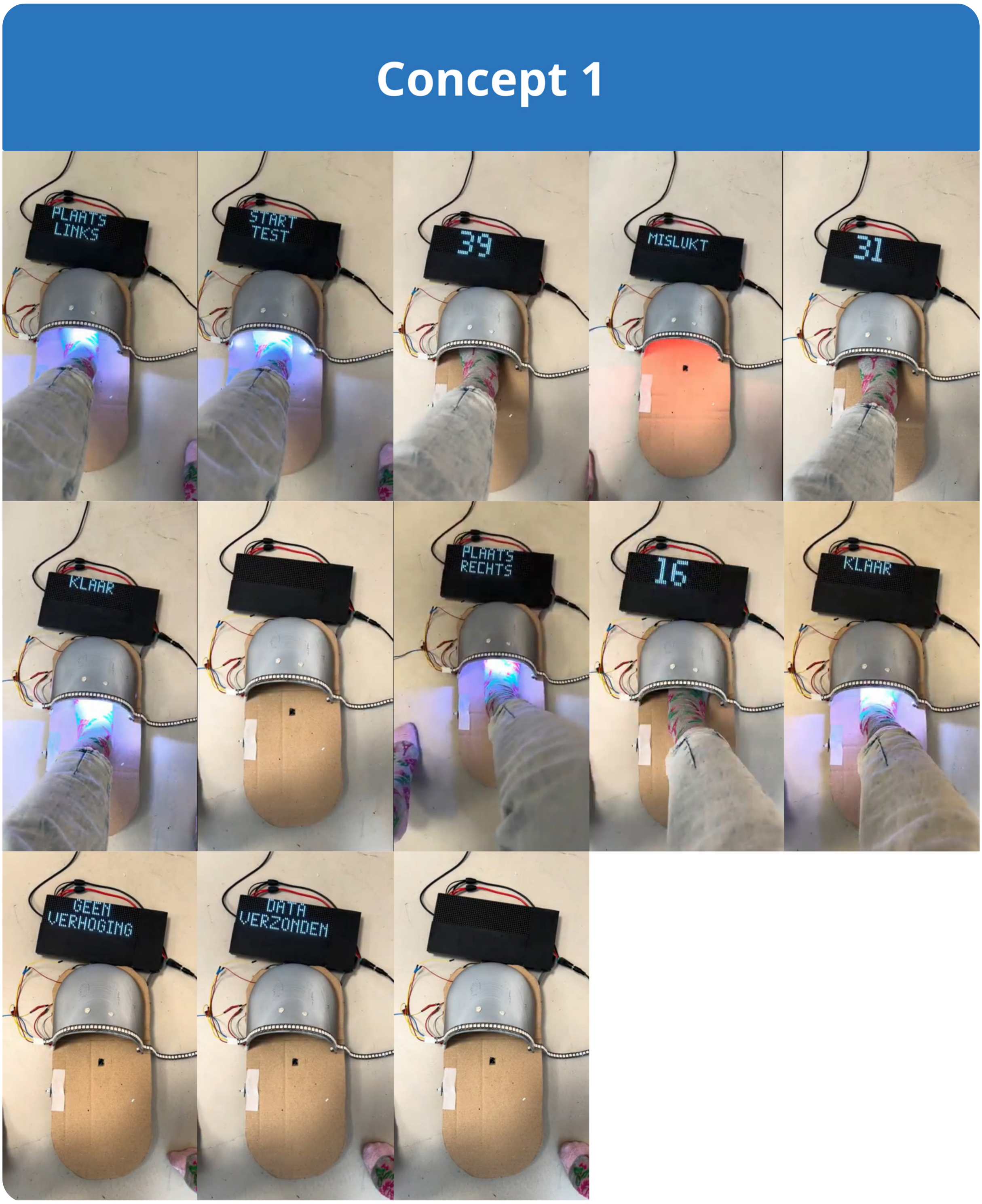


Figure 58. Concept 1 with text interactions

Concept 2

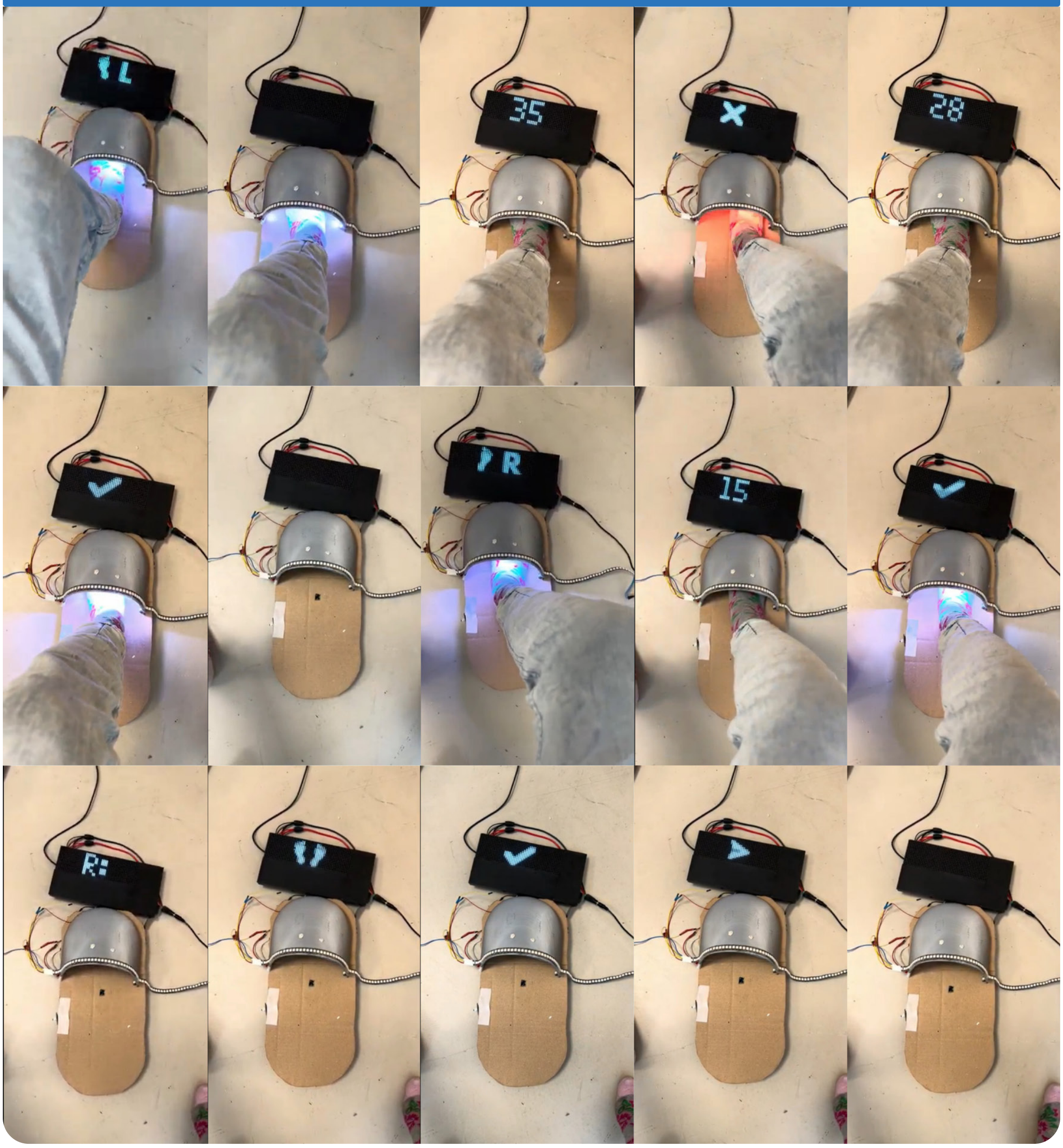


Figure 59. Concept 2 with icon interactions

In-between feedback

The concepts have been tested with over ten participants, resulting in very diverse feedback. A total of four iterations were conducted before the user test concepts were developed. This sub-subchapter briefly highlights some key changes made during these iterations.

Positioning of sensors

In the first iteration round, many participants struggled to start the test. The test was triggered by a pressure sensor detecting force, but even when participants placed their feet correctly, the sensor often failed to respond. This problem was resolved by using a higher resistor (1MΩ), which increased the sensor sensitivity. Additionally, the sensor was replaced diagonally, which significantly improved its performance.

The light sensor location has also been changed. The display is programmed to activate when the light sensor detects a change in light, but in the initial setup, it was placed too close to the dorsal shell (the grey part in the photos). Initially, the reason for placing the sensor this close to the dorsal shell was to enable very accurate failure detection (if the foot is removed during the test). As a result of this close position, the device only activated once the foot was already inside, eliminating the opportunity for the LED strip to illuminate the entrance beforehand. The light sensor has been moved slightly backwards but still ensures it remains covered by a typical adult foot during testing (Figure 60). Lastly, a failure detection mode was created, which was different for both concepts. For Concept 1, this feature is based on the light sensor value, while for Concept 2, it is based on the value of the pressure sensor.

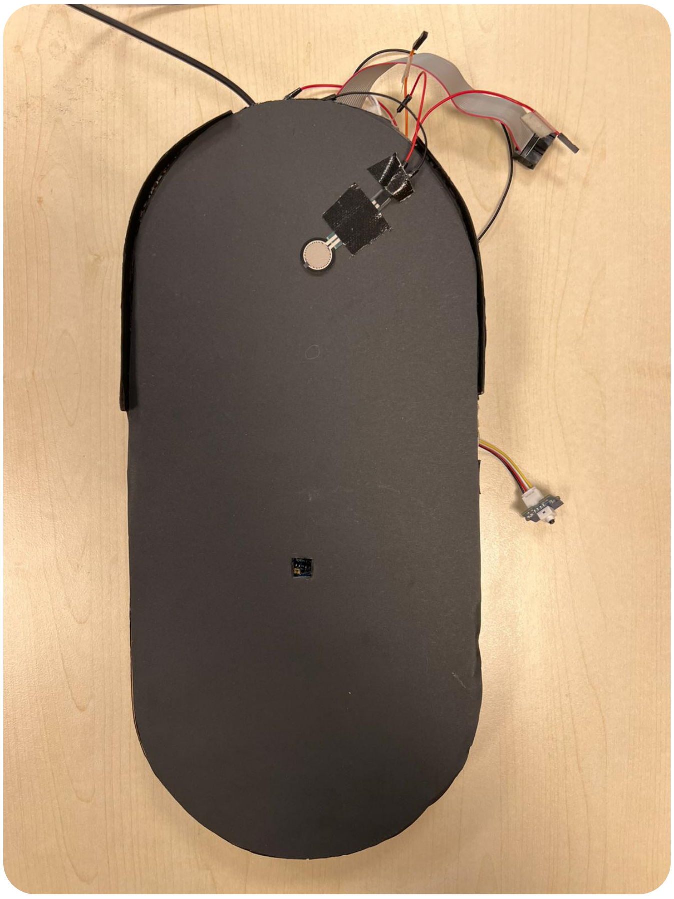


Figure 60. New locations pressure and light sensors

Black screens and waiting

The first concepts had some black screens during the interaction. This often occurred during moments when the interaction was communicated through the LED strip. For instance, between placing the foot and the start of the test, a black screen was shown, while the LED strip communicated that the foot was correctly positioned and the measurement was about to begin. The same applied at the end of the measurement when the user removed the foot of the device. A delay was built in as the device might need some time to get to the result. But during this waiting time, a black screen was shown. Often, participants commented that they worried something was wrong with the device, as it suddenly went all black. To solve these problems, feedback is provided on the display when the user has positioned their foot correctly (see Figure 61). At the end of the interaction, a loading wheel is shown to indicate that the device is processing (see Figure 62). In this way, the user is no longer left in the dark.

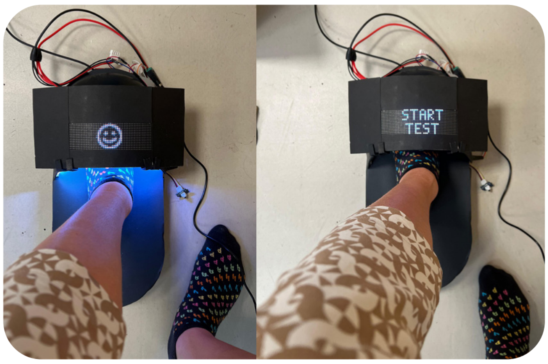


Figure 61. Screen correct placement

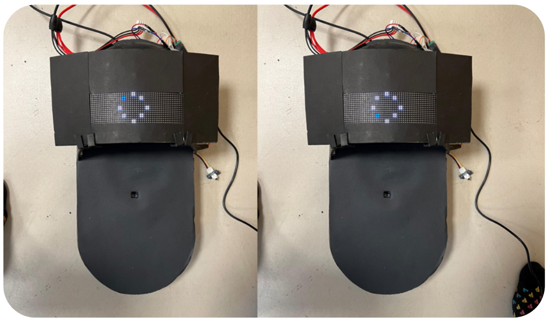


Figure 62. Loading wheel

Result presentation

The presentation of the results for both concepts was perceived as very unclear. For the text concept, it was unclear what 'R:' meant. It also showed the message 'Left foot', which meant there was a problem with the left foot. However, people started placing their left foot again. The same happened with the icon design, where the left foot was shown in case of a problem, but here, participants also thought they had to retest their left foot. Especially showing the foot first and then a cross in the next screen interaction was perceived as confusing. Participants preferred to see the result in one go instead of in two separate screens (see Figure 63). The same applies to the text design (see Figure 64).

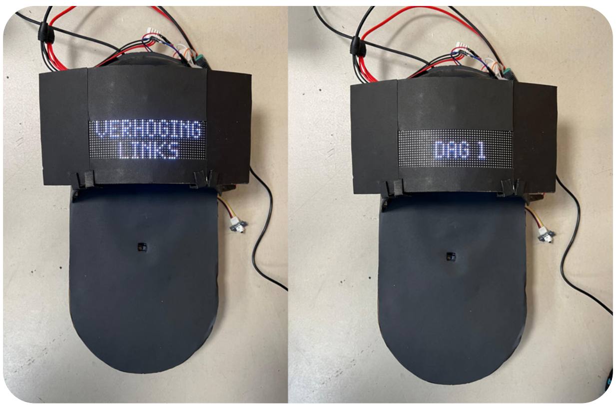


Figure 64. Text result

Additionally, it was added that the result is shown twice. Participants mentioned that they were afraid to miss the result in case they got distracted by something. Lastly, a call to action was added to the text design in case of temperature elevation. For day 1, the text 'measure again tomorrow' has been added and for day 2, the text 'contact care'.

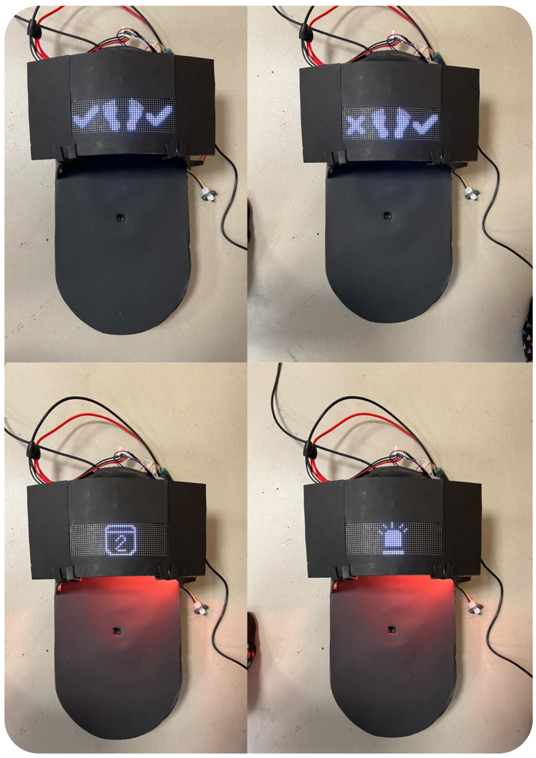


Figure 63. Icon result

Start interaction

As described earlier, the pressure sensors still occasionally malfunction, which caused frustration among participants as they were unable to initiate the measurement. To address this issue, an additional pressure sensor has been added. If either of the two sensors is activated, a message will appear to guide the user. For the text design, this is 'move forward', and for the icon design, this is an arrow pointing upwards (Figure 65). Additionally, the LED strip interaction was enhanced to more effectively indicate that the foot is not yet positioned correctly. The top row of LEDs is still white at the start; however, 10 LEDs on the left and right sides will start blinking. The blinking stops when the foot is positioned correctly. This interaction also occurs on some irons and was therefore familiar to the participants.

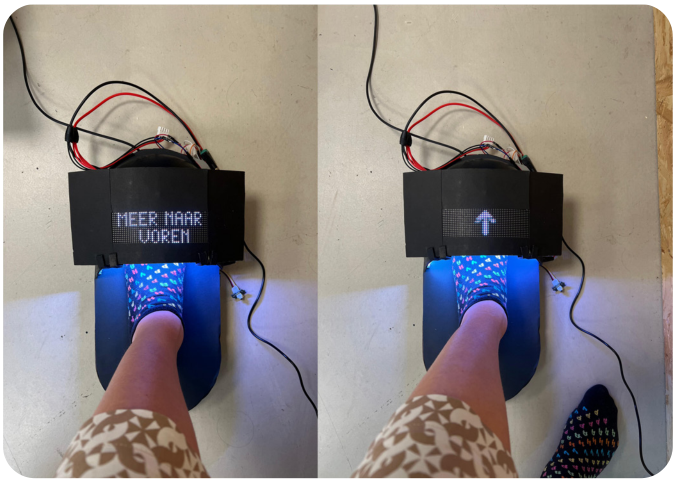


Figure 65. Improved start interaction

Other minor changes

There were also some changes on the detailed level, which will be briefly summarised below:

- The 'send' icon was unclear and therefore changed to a moving icon, which makes it clearer that it 'leaves' the device. If the data cannot be sent, the moving icon stops midway, and a cross appears next to it on the screen (Figure 66).
- Counting will be from 20 to 0, instead of 40 to 20 and 20-0. Participants perceived 40 as a high number, whereas two times 20 and counting down to 0 felt more motivating.
- The message 'contact Secuped' in case of an error was unclear, as the question arose about what Secuped is. Participants forgot the company name. Therefore, this is changed to 'contact supplier'.
- At the end of the interaction, a 'turn off' screen is shown. Participants were a bit confused that after the 'data sent' interaction, the device just showed black. They wanted to be sure it was off; therefore, this was added (Figure 67).

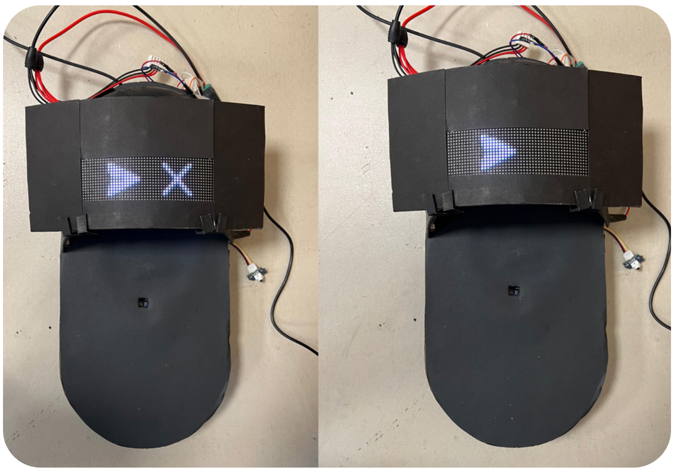


Figure 66. Improved data sent interaction

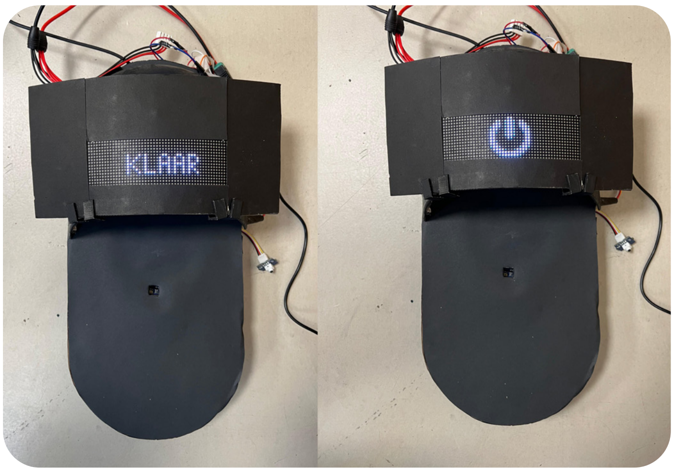


Figure 67. Device turns off

6.6 Conclusions/takeaways

This chapter has elaborately described the ideation process that led to the final designs. Below, a few important key insights are summarised that led to important design decisions and conclusions:

- The main interactions of the device are: device turning on, indicating which foot should be placed, indicating (in)correct placement, measuring in progress, measurement failed, showing result, data successfully or unsuccessfully sent.
- The side interactions of the device are: battery empty, battery charging, device resetting, device malfunctioning, device updating, usage paused, and no connection to the system.
- The use of colour has been limited to prevent problems for colour-blind users.
- It is decided to use an LED grid instead of an OLED screen, as it is cheaper, more energy efficient, and more durable in the long term.
- A custom font is created, which has a standard width of 4 pixels except for the letters K, M, T, V, W, Y, and Z, which require 5 pixels. The letter I is only 3 pixels.
- For the prototype, an ESP32 board has been used in combination with a light sensor, two pressure sensors and a button.
- For the final concepts, it is decided to use the display as the main component and the LED strip as a supporting component.
- Several iterations have been done to prevent black screens, have a better start interaction and a clear result presentation.

7. Final design

This chapter will present the final design. It begins with the final design of the physical interface, including sensor recommendations for the real product. Then the design of the back of the bottom part is shown. Next, the digital environment for the patient is discussed, followed by initial sketches of the podiatrist' digital environment. Finally, the system interactions between the different stakeholders are highlighted, and a storyboard about usage is presented.

7.1 Design physical interface

In the end, two concepts were developed: one using text and one using icons. These concepts were presented on one prototype (Figure 68). These concepts are largely similar. The text-based design has the advantage of being able to communicate specific actions, such as the advice to contact care on day 2 of an elevation, which is more difficult to express through icons. Aside from this minor difference, the concepts were very similar. Since interactions are easier to understand through video, links to Concept 1 (text) and Concept 2 (icon) are provided. Concept 1 is shown in Figure 69, and Concept 2 in Figure 70.

Figure 68. Prototype in context

Figure 69. Concept 1 Interaction design

Figure 70. Concept 2 Interaction design

7.2 Design of the back of the bottom part

The user study, the customer journey and the competitor analysis lead to some additional functionalities which cannot be shown on the display. Most of them require an action for the user to start. Possible extra functionalities/text are:

- A volume button to regulate sound levels.
- A 'test service' button to test if the device is connected to the Secuped system.
- Feedback if the device is connected to the Secuped system.
- A language button in case text is used to change the language to the preferred language.
- A 'connect patient' button to enable Secuped to connect the patient to the device.
- A 'pause usage' button to enable the user to pause usage in case of sickness. Using the device again will automatically unpause the system.
- A reset button
- Secuped' phone number, which can be called in case of product failure.
- Serial number to identify each product.

Initially, these requirements led to the design as presented in Figure 71. This design has been thoroughly discussed with several people, which has led to some changes. For example, there is no need for a 'connect patient' button, as this will be handled by Secuped and likely occurs by plugging in the device or via the cloud by linking the serial number to a patient. The same applies to the language button, as the patient's preferred language will be asked for and set by Secuped. The volume button is also left out for now, as several participants during testing expressed a negative opinion about the use of sound for the device.

The 'test service' button is also removed and integrated into the regular flow of the measurement. At the end of the measurement, a message is shown whether the data could be sent or not. If the user frequently notices that the data isn't sent, it is recommended to contact Secuped. The reset button is also removed and replaced by an on/off button.

Figure 71. Initial design back of bottom part

Officially, the device will remain on at all times, but during travel, users might prefer to turn it off to prevent battery drain. This button also enables the user to reset the device if it malfunctions - turning it off and on again might solve the problem as it restarts the software.

Lastly, the design of the electronics is mostly located at the top, and it would be easier to locate the buttons on the PCB. Therefore, the remaining buttons are located at the top. In Figure 72, the final design is presented.

Of course, one could note that locating buttons at the bottom of the product might lead to accidental presses during use. The idea is to position the buttons slightly recessed into the back and cover them with a soft material. This approach has also been implemented by Podimetrics in their design, so no issues are expected.

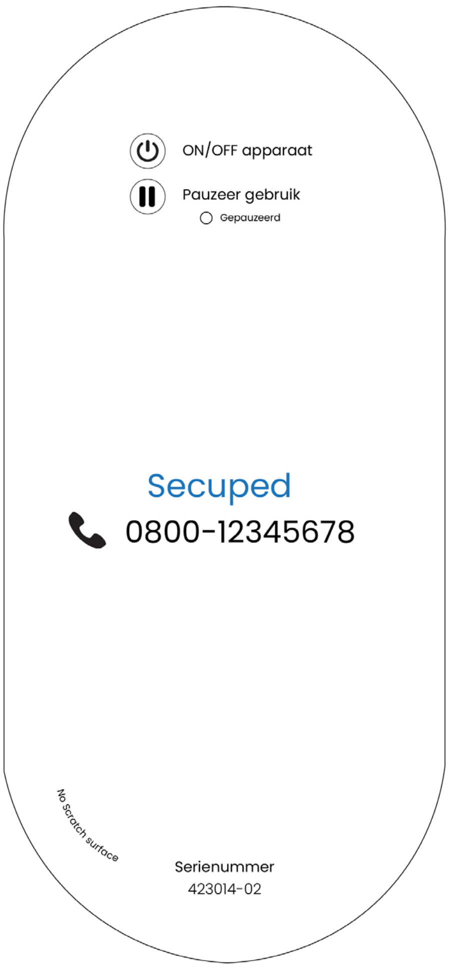


Figure 72. Final design back of bottom part

7.3 Patients' digital environment

The goal of the device is that it will be able to work on its own. Therefore, it is suggested to do the measurement analysis on the device itself without needing a connection with the Secuped cloud. However, several functionalities cannot be implemented on the device. For instance, showing the overview of when the user measured or more detailed results about the exact location of the elevation. That's why a design for a possible app is drawn in which these details are covered. From the user tests, it was found that users had a slight preference for an app. In the end, these overviews will probably be integrated into an existing app from, for instance, a podiatry practice. The design has been created in Dutch as the test participants are Dutch. As pictures do not show the interaction, this link shows a video showing the navigation.

Data overview types

The device will measure at many locations, namely: the bottom of the foot, top of the foot, side of the big toe, side of the little toe, and back of the foot. Since the system analyses the difference between both feet, the data for each foot is always displayed together with the other foot. In Figure 73, all data overviews are shown.

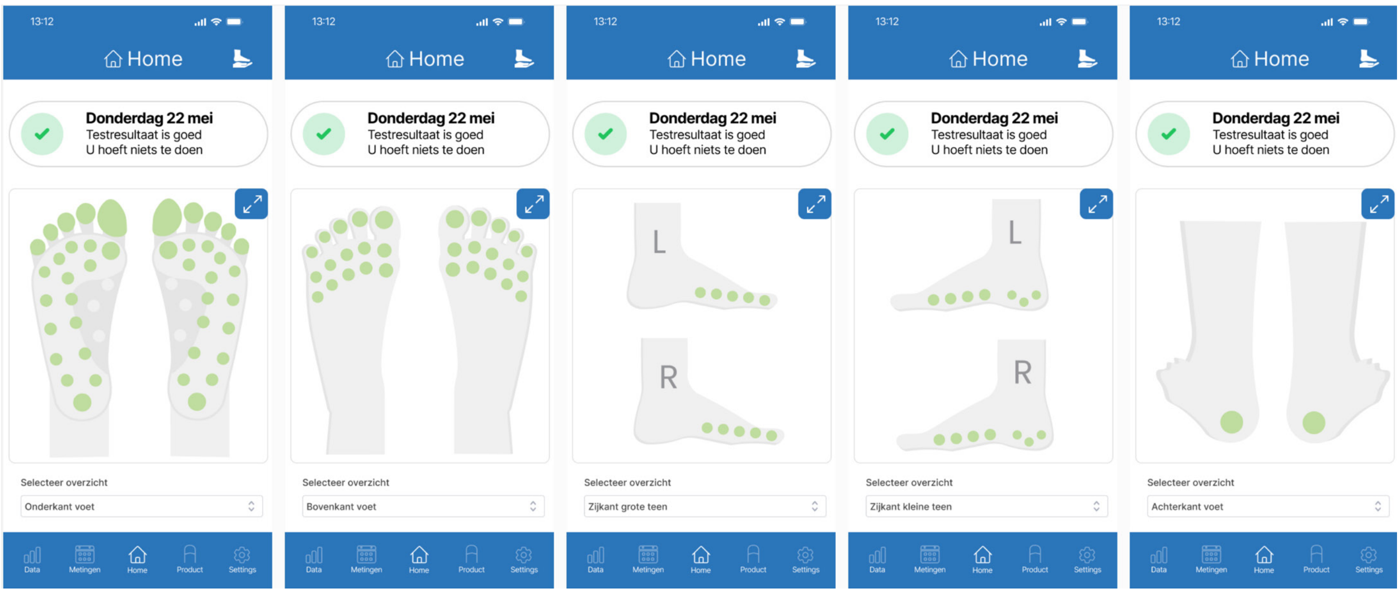


Figure 73. Measured foot sides

Detailed data

The detailed data shown in the app includes actual temperatures and their differences. Users can also tap on a specific area to view the temperature of that exact spot. Additionally, they can scroll back to previous days to track the temperature of a particular location over time (see Figure 74).

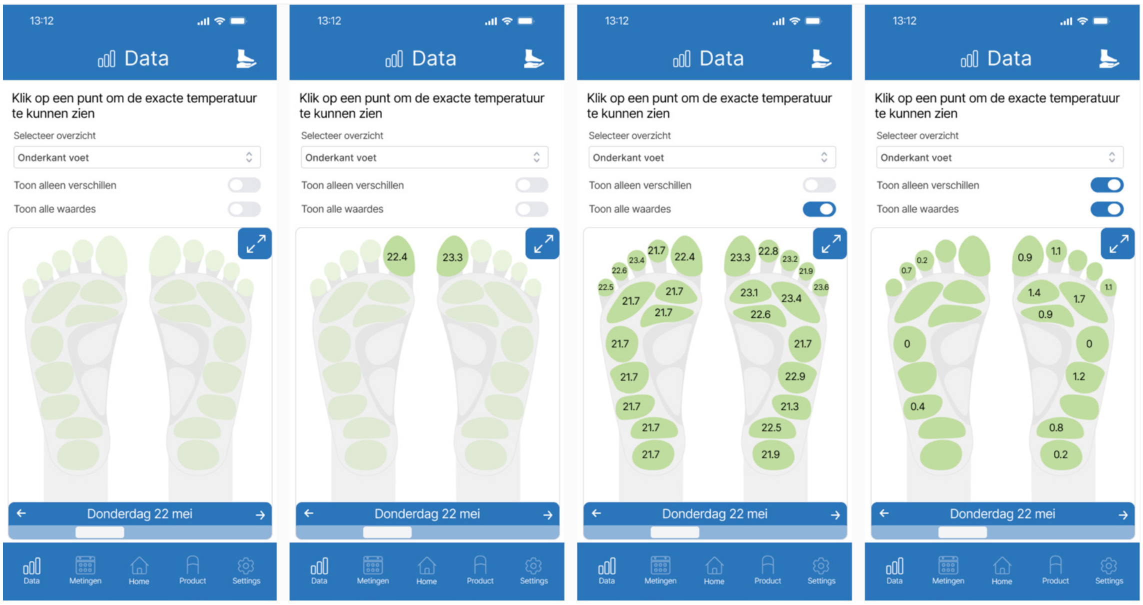


Figure 74. Foot temperature data

Measurement overview

In these measurement overviews, users can see one-day elevations (orange), days when the device wasn't used (grey), serious risk alerts (red), and good results (green) (Figure 75). Clicking on one of these days will open detailed data overviews of that day.

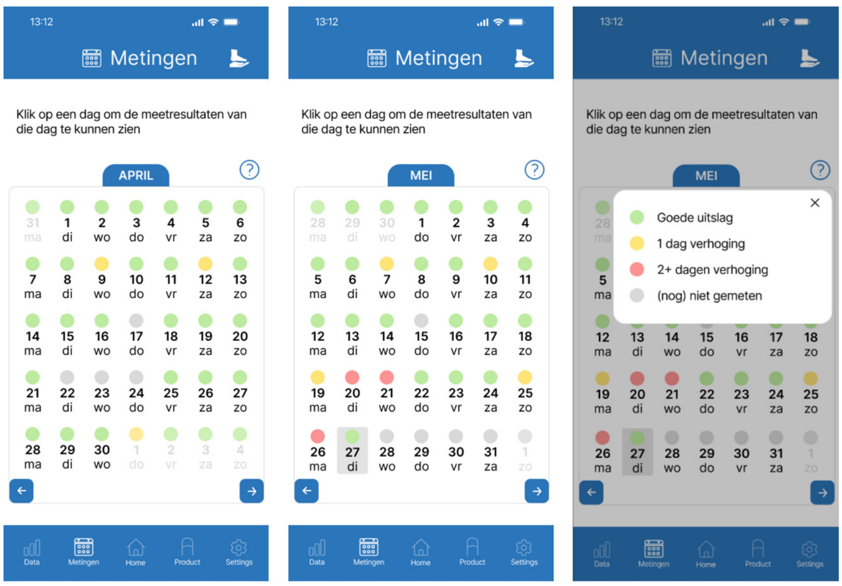


Figure 75. Measurement overviews

Product information, contact details and settings

Here, information about the product and its settings is presented, such as battery percentage and whether it has a connection with the Secuped system (Figure 76). A very important functionality on these screens is the Boolean, which the user can toggle in case an HCP has been contacted. If an elevation has been detected for more than one day, the user is instructed to contact an HCP. However, if the user delays this for several days, the HCP will reach out to them. It is therefore preferred that the user can inform the system once they have contacted an HCP, to prevent unnecessary notifications in the system of the podiatrist. Here, the phone number of the HCP can also be found.

In the settings, the user can decide what types of notifications to receive, such as 'measurement value ready', 'remember to measure' or weekly overviews with the number of days the user has measured.

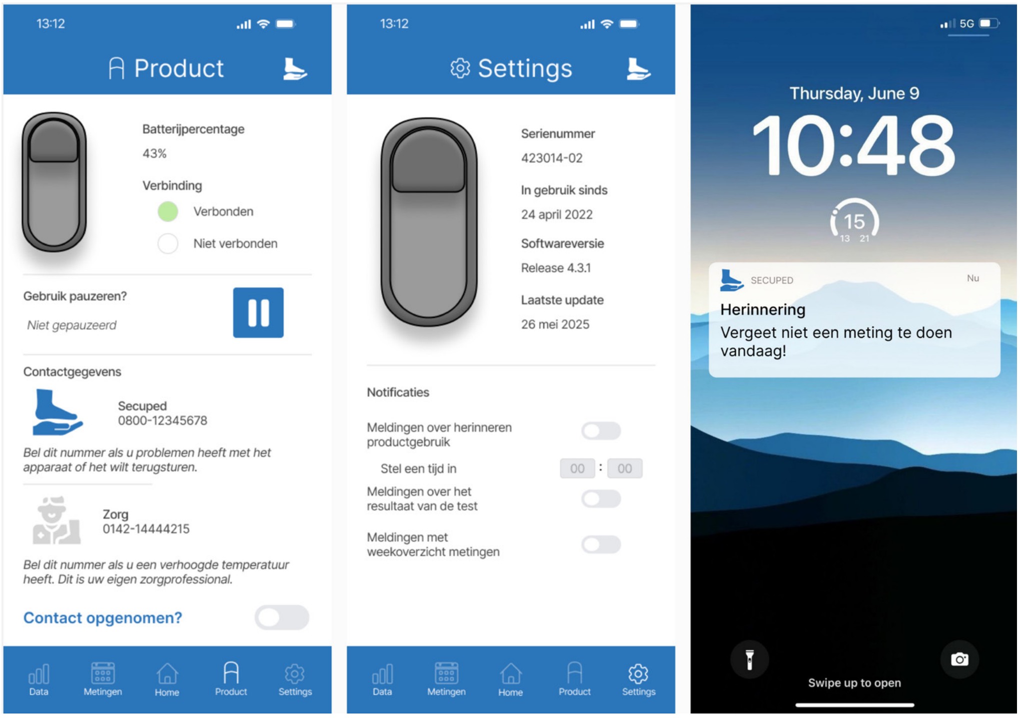


Figure 76. Product details, settings and notification example

Warnings and notifications

In case of an elevation, the result will be shown in orange in the app along with the message to measure again tomorrow. If there are two consecutive days of elevation, the screen will display a message asking whether the user has contacted an HCP. If there is an issue with the device, the app will notify the user and tell them to contact the supplier (Secuped). All warnings are presented in Figure 77.

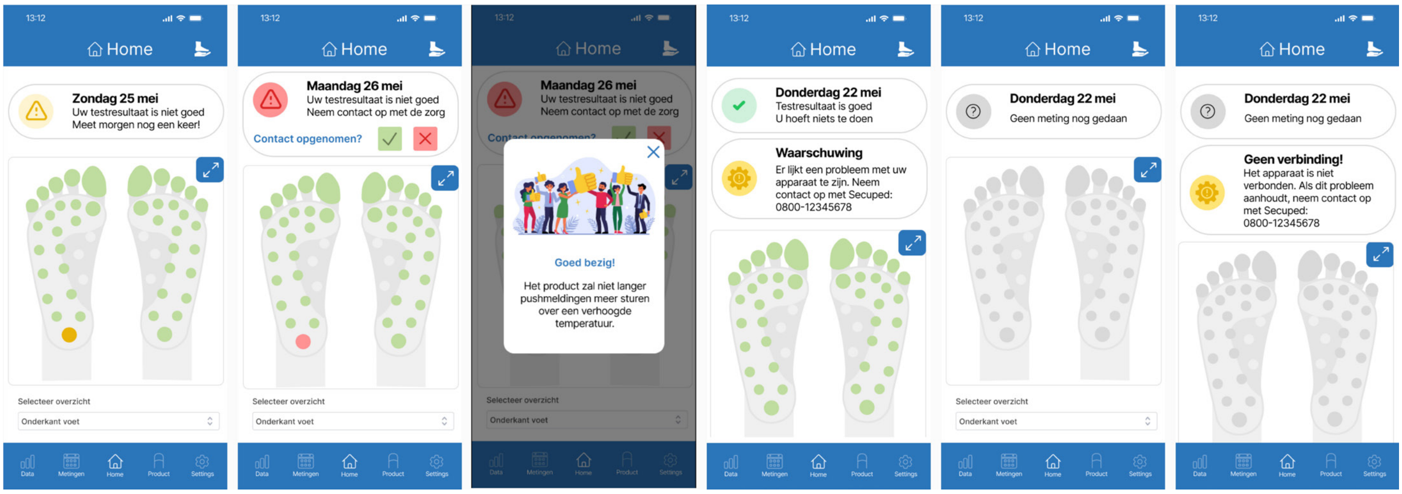


Figure 77. Warnings in the app

Tablet design

During the user test, participants often mentioned they preferred using a tablet over a smartphone due to the larger letter size. Therefore, the design has been translated to a tablet version for those who prefer this (Figure 78) (Link to video showing navigation).

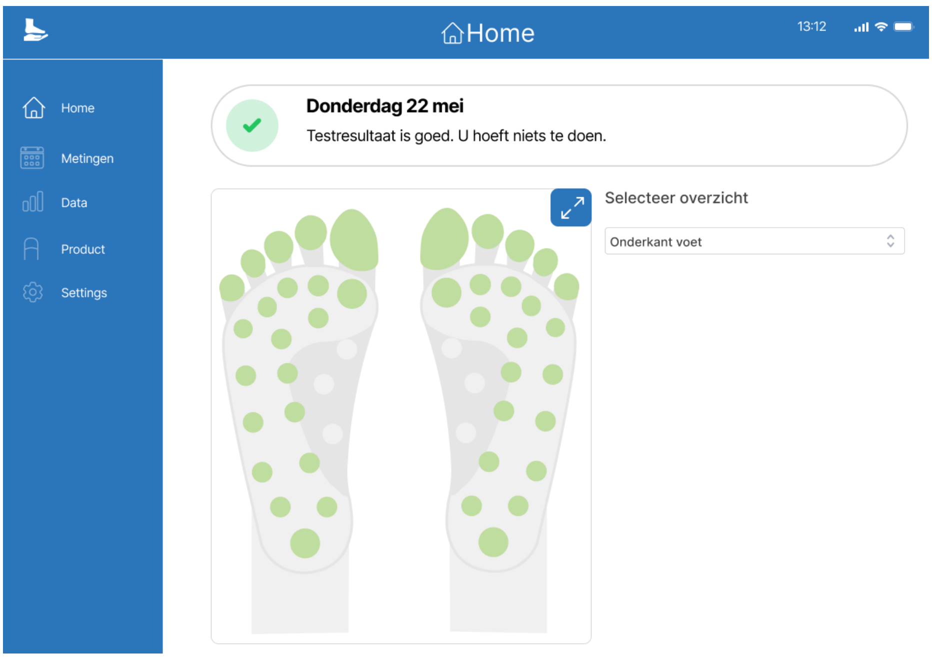


Figure 78. Tablet version of the app

7.4 Podiatrist's Digital Environment

For now, it is assumed that the podiatrist will play a main role in supporting the patient in using the device. In addition, during the user studies, it was found that patients do not mind sharing their data, which allows for extra data insights for the podiatrist. This chapter presents a possible design of this environment (this link directs to a video showing the navigation).

It should be noted that, eventually, this will likely be integrated into existing systems of a podiatry practice. Therefore, it should be seen as a direction to initiate the conversation about the requirements of such an environment.

Entrance portal

The podiatrist is expected to log into the portal before accessing the data. After logging in, the welcome screen is shown (see Figure 79). Here, notifications from patients are displayed alongside a list of all patients. If a specific patient has a warning, it will be indicated here as well.

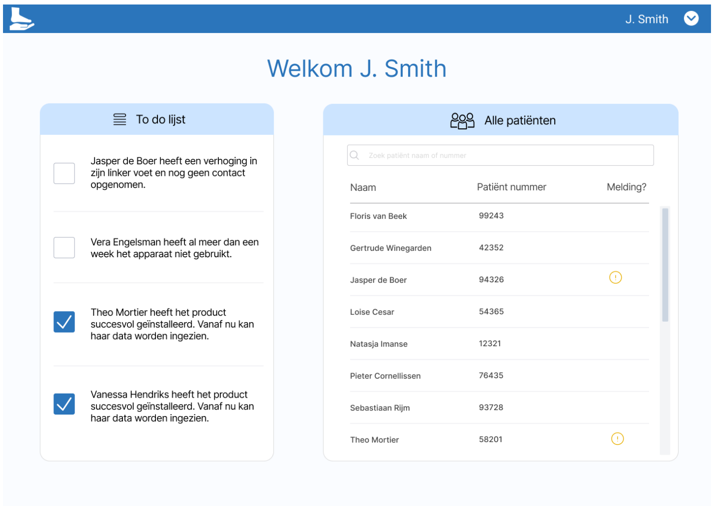


Figure 79. Entrace of portal podiatrist

Figure 80. Patient overview

Patient data overviews

By clicking on a patient name from the patient overview, the data of that specific patient is opened (see Figure 80). It opens on the data of the current day but also allows scrolling back in time to view data of other days. This page shows the mean measurement value and the date of the last temperature elevation.

Additionally, it provides access to detailed information, a measurement overview, options to edit patient data (e.g. phone number), download a report (e.g. to send to a pedicure), view notifications, and pause usage. While the user can pause usage themselves, the podiatrist should also be able to do this in case the user does not have a digital environment.

Lastly, there is the option to provide feedback to the system confirming contact with the patient in case of a temperature elevation.

Clicking on one of these overviews opens the detailed data page. Here, data overviews can be generated either by clicking on a spot in the image or by toggling the Booleans to show all data of that overview (Figure 81).

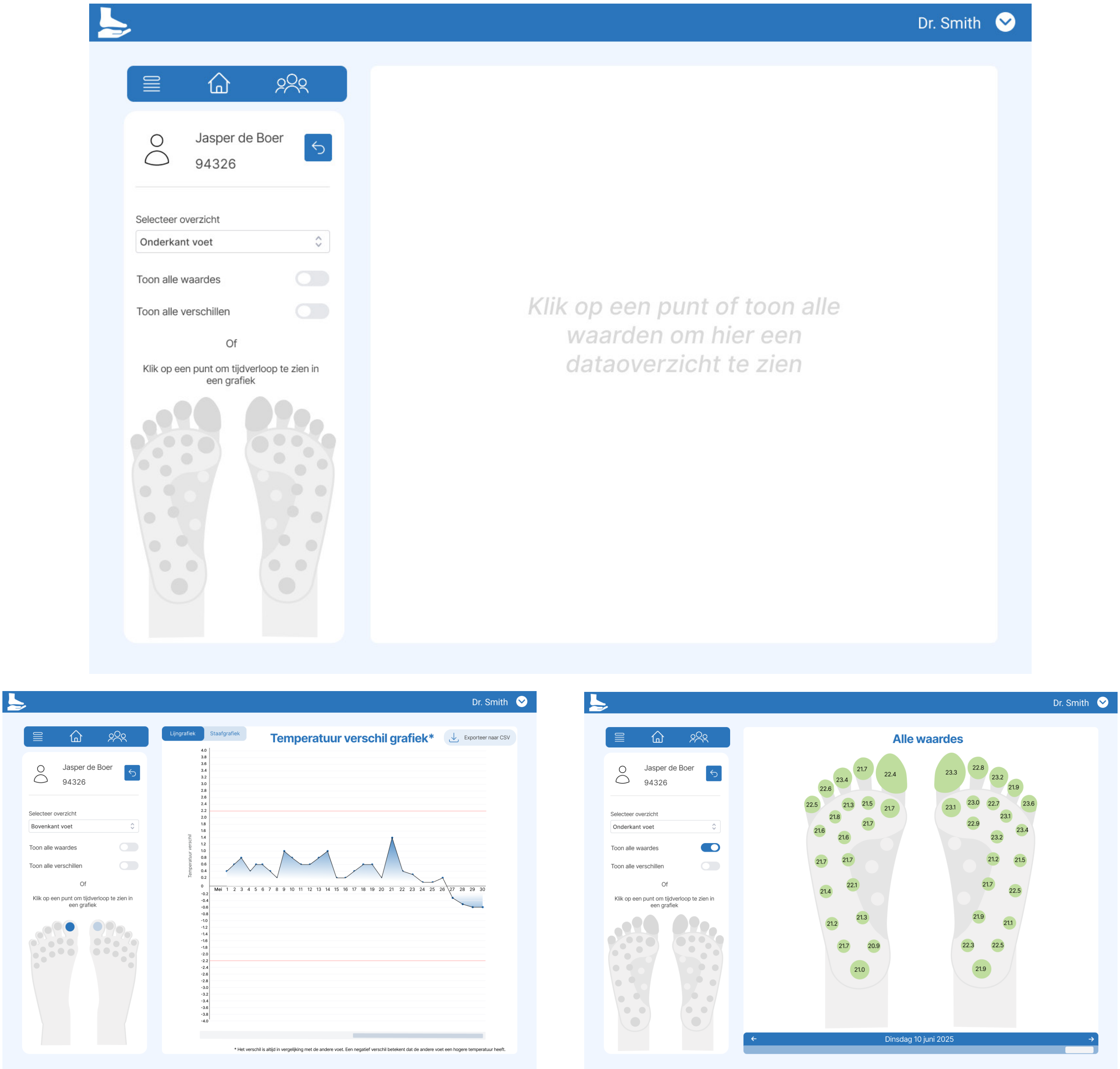


Figure 81. Data overviews

It should be noted that if the right foot shows a temperature elevation, the left foot will display a negative difference. Lastly, the option is provided to present the data using bars instead of a line (Figure 82).

Figure 82. Different types of data presentation

Measurement overview and to-do list

For a specific patient, the measurement overview can be accessed. Here, it can be directly seen when the user had an elevation. By clicking on a specific date with an elevation, the detailed data overview for that day is shown, highlighting the affected spot. Additionally, there is a to-do list in which notifications related to the patients are shown. There are the following types:

- The patient has had an elevation for more than 4 days
- The patient has not used the device for more than 7 days
- The patient has paused usage of the device for more than 20 days
- The patient's device is not connecting, so data is unavailable
- The patient has successfully started using the product

All these overviews are presented in Figure 83, where an example is also shown about how such a warning might appear on the patient overview page.

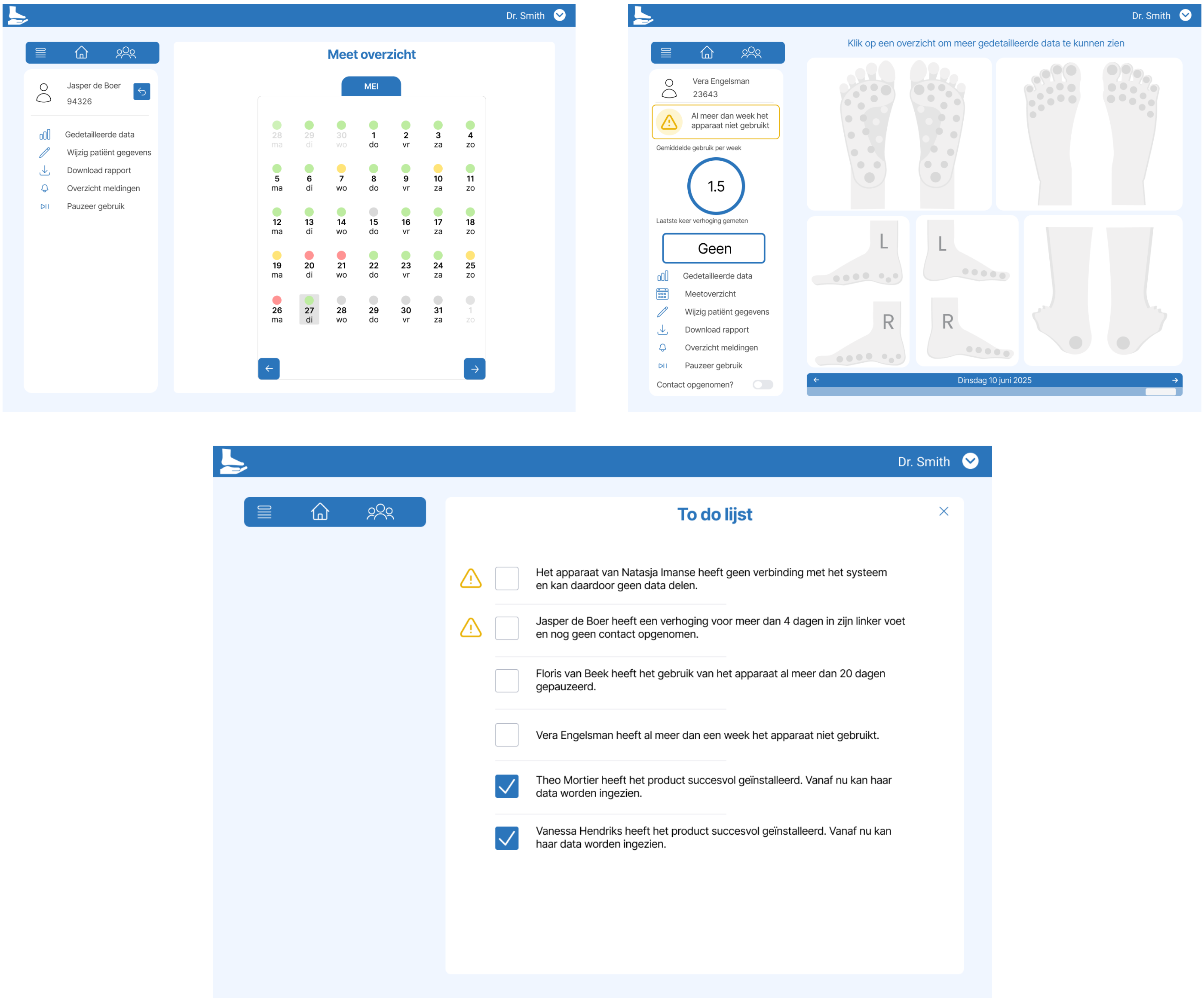


Figure 83. Measurement overview and notifications list

Patients overview

An overview page lists all registered patients. From here, a request form can be accessed to add a new patient. This form requires details such as the patient's contact information and address for device delivery. It also includes fields for language preference, the podiatrist's phone number (to be displayed in the app), and whether the patient wants the podiatrist to be notified if something is wrong.

Additionally, there is the option to request access to the digital environment and to provide the phone number of a caretaker who can be contacted in case of issues. The patient overview page also contains the request return form, which notifies Secuped of a device return. See Figure 84 for an overview of these screens.

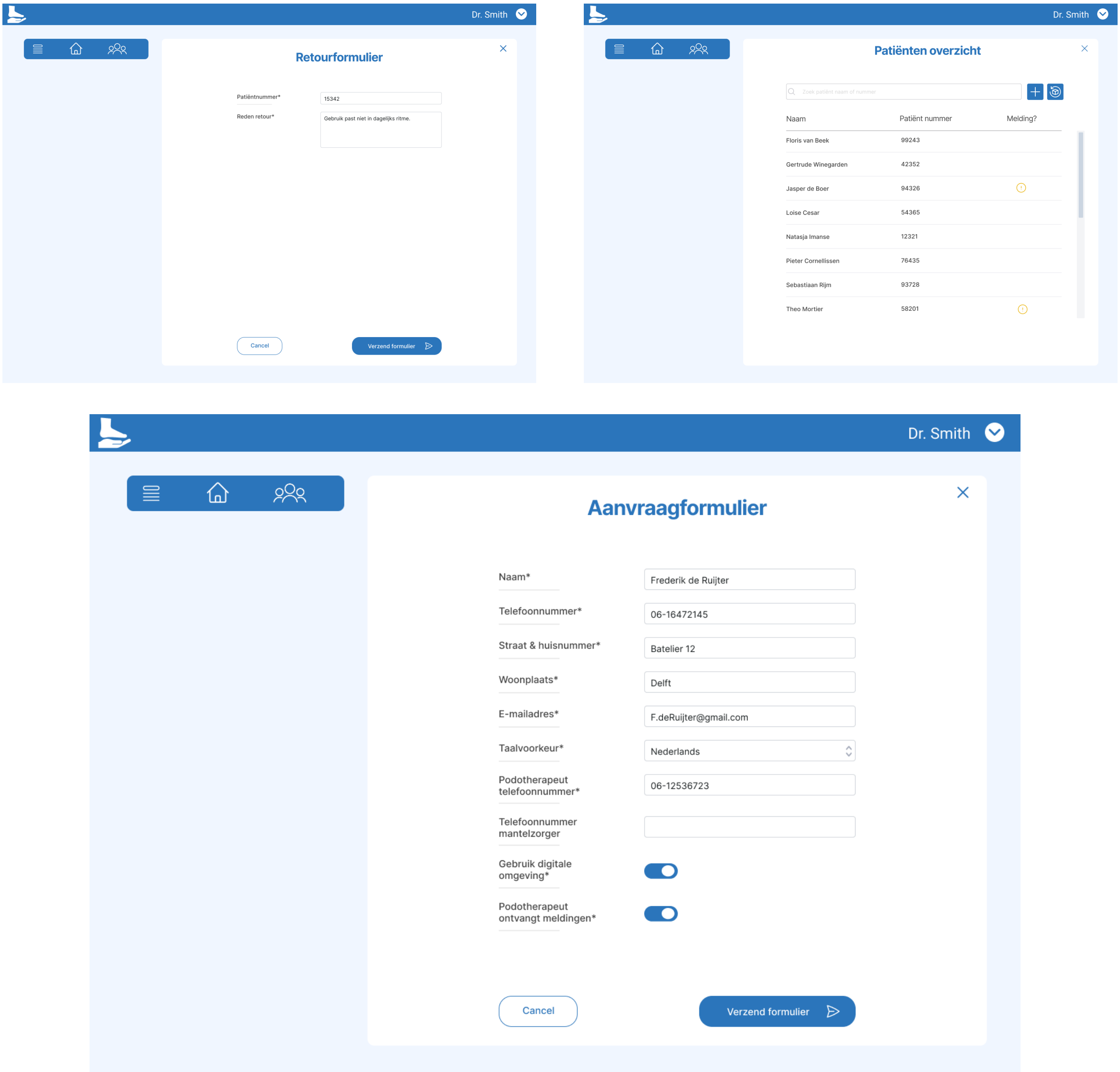


Figure 84. Request and return forms on patient overview page

7.5 System integration

The diverse components have now been presented separately, but in the end, all of these will work together to facilitate the entire system. In Chapter 5.2, this has already been highlighted by means of a system blueprint. This will be briefly repeated here again but highlighting different aspects. In addition, a notifications overview will be shown.

System blueprint

The key players in the system remain the podiatrist, patient and Secuped (Figure 85). The podiatrist will take the lead in explaining the product to the user and having insight into the available data. The device itself will run tests and save these measurements. However, a connection with the Secuped system is required to ensure the data can be accessed by the podiatrist. The patient receives information about the measurements from the system by means of the digital environment. Data is sent from the device to the system and in this way shared with the patient and podiatrist. In future scenarios, it could be possible that a family member has access to the data as well to help the patient with keeping track of the data.

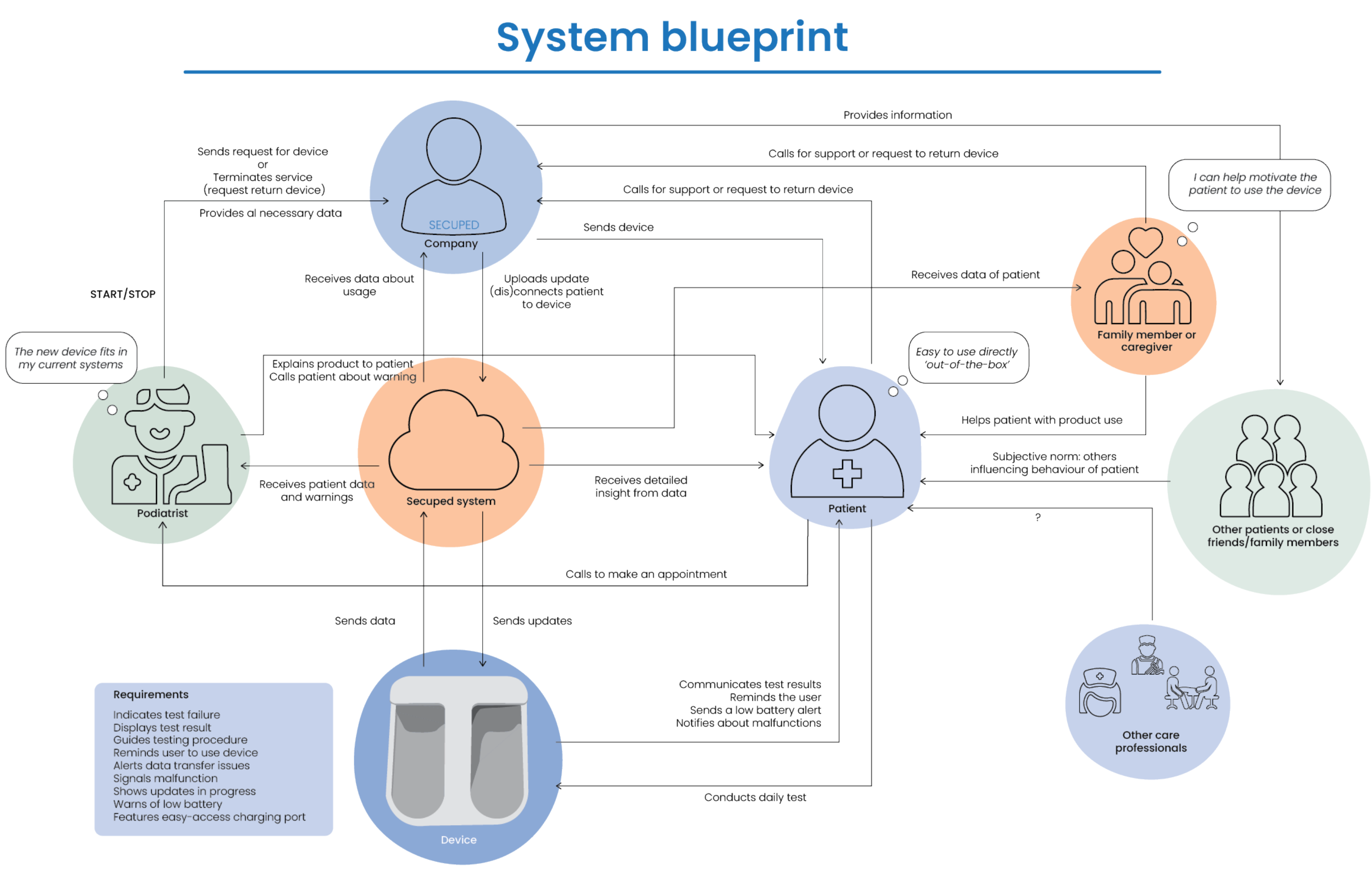


Figure 85. System blueprint showing interactions between diverse stakeholders

Notifications overview

There are a lot of different notifications sent by the device for a variety of periods. Therefore, an overview was created to communicate when a message is sent and to whom (see Figure 86). It also shows the accompanying action in blue. These actions for the user are often displayed on the device itself, and sometimes are also shown in the app. All these notifications and timespans can also be found back in the user journey (Appendix D).

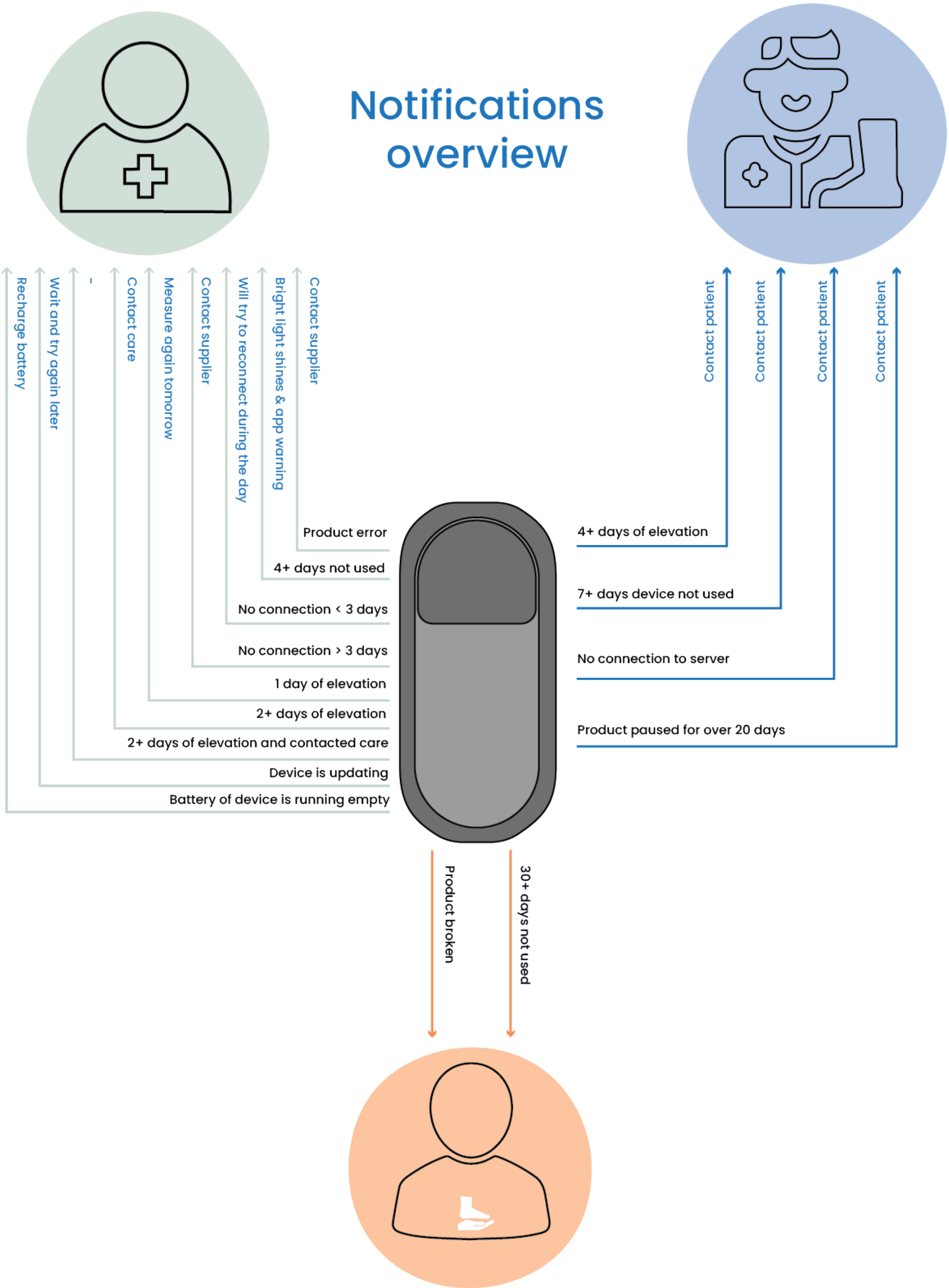


Figure 86. Notifications sent by the device

Storyboard

To provide insight into the user interaction, Figure 87 shows a storyboard outlining a potential daily flow of how a patient might use the product. This is also explained in Appendix M, which shows the manual.

Figure 87. Storyboard presenting possible use

8. Evaluation

The final design has been evaluated by several people throughout the process. In the end, it was tested with elderly users to assess whether the interaction was sufficiently clear (see ethical approval in Appendix I). Additionally, one patient was interviewed to gain insight from a real end-user's perspective. This chapter will show the results of these evaluations. Additionally, it evaluates the entire system and product, which leads to the identification of challenges. Lastly, recommendations are provided for the next step in the product's development.

8.1 user tests

The tests have been conducted with several people, namely two ambassadors of the IZI house, one person directly from the target group, one patient living with diabetes but without a diabetic foot and four persons who match the age of the target group but do not have diabetes (see Figure 88). In the last case, the situation of usage was clearly explained, with the help of a user story explaining the living situation of the patient. As before, the results will be presented based on themes, and quotes will be used to enrich the story. The results and reactions will be provided below and will be connected to the literature provided in Chapter 4. The questions and interview set-up can be found in Appendix J, K & L. The only materials used for these interviews are the prototype with two concepts on it, namely the interaction with the icon and with the text, and the digital environment, either the smartphone or tablet layout, depending on what the participant is used to.

Figure 88. Diverse user tests

User experience with the device

It was noted that the learning curve is quite steep but short, meaning that when participants tried the second concept, the positioning of the feet was quicker. In general, participants very quickly understood the product and the interaction. There was a need to explain that the left foot needed to be placed first, but after explaining this once, all participants did it correctly the next time. There was still some uncertainty if they were allowed to remove their foot when the text 'measurement done' was presented. However, after being told once that they could remove their foot, it happened automatically the next time. The waiting time wasn't experienced as long. One participant even noted that having a waiting time increased his trust in the device; otherwise, he might not trust it, as it would seem too quick to take a proper measurement.

All participants agreed that the screen is very easy to read, even a participant aged 87. The only unclear message was what needed to happen when the data could not be sent. After this message, no further action is described, as the device will continue trying to send the data at a later moment. However, participants got a bit concerned about what the 'data not sent' message meant. In the future, it should also display 'contact supplier' to help the user out.

Regarding the pause button, some explanation was needed to ensure participants understood its function. After explaining, the added benefit was recognised. There was simply no previous experience with this type of interaction, and therefore, this feature was not understood (Conventional affordance, Chapter 4).

Lastly, participants were asked whether they would like to have some kind of sound, for instance, when the device is waking up. No one was particularly in favour of this idea, as one participant also noted that the light already indicates the device is waking up. The only reason one participant could imagine adding sound was for someone who cannot read; he suggested that, in that case, the device could read the screen aloud. All quotes related to these topics are shown in Figure 89.

> It's simple, you hardly have to do anything, just put your feet in.

> You can see this perfectly well without glasses.

> If I had to do this every day, it's nice and quick — I'm not spending hours on it.

> If it goes too fast, you don't trust it either.

> From me it's not necessary, the light goes on anyway.
> ~ About adding sound to the device

Figure 89. Quotes about user experience

Sensors and physical placement

The foot placement was sometimes experienced as a struggle. Some participants didn't fully cover the light sensor, or the pressure sensor failed to detect any signal. Three participants reacted positively to the 'move forward' text, which indeed helped them to initiate the test. One participant had repeated difficulty continuing the test without failure. Each time the countdown began, it would suddenly stop. It is strongly recommended to provide clear feedback when this occurs, as she got very frustrated by the number of errors. Feedback such as 'keep feet still' or 'Too much movement' could be considered.

The importance of a smooth start interaction shouldn't be underestimated. Every effort should be made to ensure that the participant can easily start the measurement and, by remaining relatively still, successfully complete it on the first attempt. If the start interaction is not effective, the user may become frustrated and may not wish to continue using the product. Therefore, the Functional Affordance (FA) of this prototype wasn't sufficient; some participants were unable to achieve the goal of performing a successful measurement.

Interface understandability: text vs. icons

The text variant was experienced as the clearest, although the icons were also received positively (see Figure 90). One elderly participant even mentioned that he felt happy when a smiley appeared after he correctly placed his foot on the device. Some icons were not understood, particularly the ‘sent’ icon, which, despite being animated, was still unclear. After an explanation, participants understood its meaning, but initially it was not obvious.

The same applied to the alarm bell icon. The first-time participants saw this icon, its meaning wasn’t understood. One participant even questioned whether it would be clear what action should be taken and expressed concern that users might call 112 instead of contacting their podiatrist. The action to take when seeing this icon is unclear unless it is clearly explained to the user. Furthermore, the icon design still uses some text, namely L and R. In the end, this might need to be replaced by an arrow.

For the text concept, the word ‘updaten’ may not be familiar to older users and might need to be replaced with a more accessible term. This is related to the conventional affordance (CA) as described in Chapter 4, where previous knowledge of the user is required to understand certain product features.

An additional advantage of using text, as highlighted by participants, is the ability to clearly inform the user what is wrong with the device. Clear instructions or actions can be communicated more effectively through text, whereas this is significantly harder to achieve with icons. Two participants would choose the icon design, as they found it more visually appealing. The participants who chose the text variant mentioned that it required less thinking and was immediately clear in its meaning.

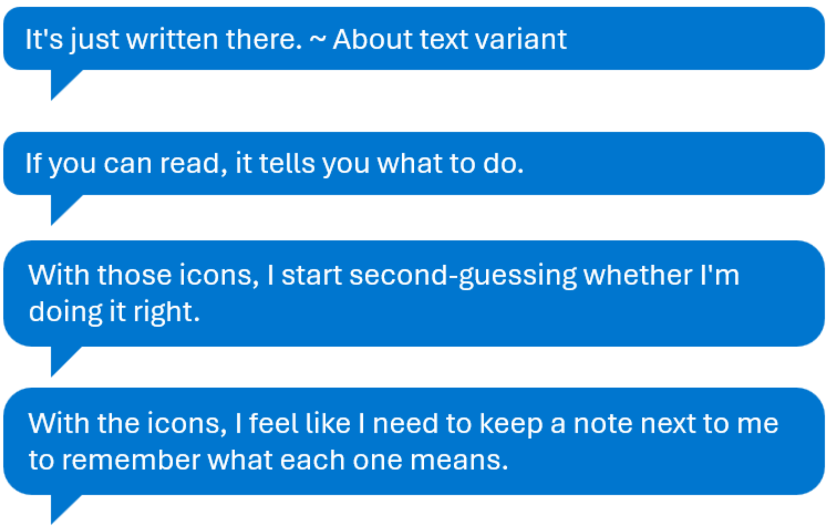


Figure 90. Quotes about icons vs. text variant

Digital environment

Depending on the type of digital device the participant uses in daily life, either the tablet or smartphone version of the app was shown. Here again, the Conventional Affordance (CA) of the user was relied upon in presenting certain features. In general, the text size was experienced as problematic on the smartphone, particularly the measurement values on the feet drawing. It was suggested to perhaps write out in text where and what the elevation was, e.g. 'you had a temperature elevation of 2.4 degrees Celsius at the bottom of your left toe'. However, describing a random location at the top of the foot in a clear way can be quite challenging. Another suggestion was to enable a zoom-in function, allowing the image to be enlarged and the values to be more easily readable.

In addition, the measurement overview lacked an explanation of the colours, which confused participants. Interaction with the Figma prototype was occasionally cumbersome, as it did not always respond as expected. Some participants struggled with touching the screen and interacting with the app. Several participants were also against the use of an app altogether and preferred not to use one.

The tablet version was perceived very positively and did not require larger text. The sending of notifications was also seen as a positive feature, but there should be a focus on how these can be delivered in a motivating manner. One participant suggested including the option to set a specific time for the notification or even having an alarm function, to ensure she wouldn't forget to use the device. Lastly, it was suggested to add an overview showing all recorded elevations along with the time intervals between them. This participant wanted to track whether the time between elevations was increasing. Relevant quotes about this subpart are presented in Figure 91.

> It's great if you're able to do all this and see it like that.

> If people understand it, they can take part — and actually benefit from it themselves.

> This is much better for older people. ~ about the tablet app

> These days, you have to download an app or log in for everything.

Figure 91. Quotes about the digital environment

Design itself

This part describes the Physical Affordance (PA) but also the Functional Affordance (FA) of the interaction. Participants were asked to respond to the overall appearance and interaction of the device (Figure 92). In particular, they were asked what they thought of testing one foot and then the other foot (FA). Most participants acknowledged the reasoning around balance and feeling more stable with one foot on the ground. Additionally, one participant noted that he already occasionally experienced test failures with just one foot and was concerned this would occur more frequently if both feet were tested at the same time.

Another participant suggested providing the product with a special bag for transport to prevent damage. This was supported by someone else, who would prefer a box, like a shoebox. He also expressed a preference for a completely different colour to make the product appear more cheerful, as opposed to the current serious-looking black. Some comments were also made regarding the size of the design. Several participants questioned whether the product really needed to be this large, as they had smaller feet. They expressed a preference for multiple sizes and the ability to order a size S version.

Finally, participants were asked whether they would take the design with them on holiday. Opinions varied: one person said that if everything was fine, he wouldn't take it, as he still considered it quite bulky. However, another said he would bring it if needed, provided it came with a suitable protective bag (PA). And a third participant preferred to take it with him in a box. In conclusion, participants would likely bring the product with them, but expressed significant concern about potentially damaging it.

> I've got little desire to end up in a wheelchair, so I'd definitely use it if I had to.

> Measuring two feet at once: then if one moves, the measurement fails right away.

> I think it's a fantastic device — especially if people can just use it at home.

> A bag to store it neatly in, so the product doesn't get damaged.

> Does it really need to be this big?

> I quite like the idea of putting my feet into a lit-up tunnel.

Figure 92. Quotes about the design of the product

Interaction with a podiatrist

The interaction with the podiatrist and the product has also been addressed. Some participants expressed concern that the podiatrist might be overwhelmed with messages about them. It is indeed crucial to take this into account and to determine which notifications are important for the podiatrist, as well as how frequently they should be sent.

Furthermore, in relation to the explanation provided at the podiatry practice, it was suggested that the digital environment should also be introduced at this stage. Many participants found the digital environment to be quite advanced and needed an explanation before they could manage the app independently.

Other

- Some other important points mentioned include a concern raised by one participant about whether the light from the LED strip might influence the measurement. It is unclear whether this could occur, but it should be investigated.
- The appearance of the design was often referred to as a giant slipper.
- The LED strip is difficult to see in well-lit rooms, raising questions about its usefulness and whether users should have the option to turn it off.
- One participant particularly appreciated the interaction with the LED strip. He mentioned that he might not always look at the display, but if the colour suddenly changed, it would alert him to pay attention.

8.2 Identified challenges

Although the complete system has been outlined, several aspects still require further consideration. These have been identified as challenges, which are things that are still unfinished or simply not yet ready to be developed. To support the next phase of this user experience design, a summary list has been created to capture all these open points in one place.

- It remains unclear who should be responsible for the return. For now, it is assumed that a patient will tell the podiatrist (s)he no longer wants to use the device. But this responsibility might be moved to the patients themselves. In that case, the podiatrist should receive a notification about the return.
- The interactions currently do not account for the scenario in which a user starts measuring while wearing socks instead of being barefoot. It remains unclear what should happen in this case, but the user should receive feedback indicating that the test cannot proceed. Explaining the reason for this may be challenging, as the test could also fail due to other causes, such as incorrect foot placement.
- In case the user has a temperature elevation that persists over a longer period, it is unclear how notifications should be handled. Currently, once care (e.g. podiatrist) has been contacted, the alarms are turned off for that specific location. The question remains whether the device should continue to send warnings during prolonged elevation or if a different protocol should be implemented.
- There is still the chance that someone measures their feet, has an elevation and then doesn't measure the following day. It is unclear what happens in such a case. Likely, the next time a measurement is taken and another elevation is detected, it will be counted as day 2. However, further study is needed to determine whether this is the appropriate approach to handle this situation.
- It is unclear how the device knows for sure someone isn't measuring the same foot twice. The program should require a signal change from the 'start' sensors before starting another test. The challenge is whether the device can be made in such a way that it recognises which foot is placed, eliminating this challenge.
- It is unclear what happens when someone else places their feet on the device, for instance, a grandchild running around and discovering the device.
- It is unclear what happens if someone measures twice in one day, first with no elevation, and later with an elevation. The question arises as to which measurement is considered valid and how this will be presented in the digital environment for both the patient and the podiatrist.
- Measurement accuracy is another challenge. It is important to prevent frequent false alarms.
- A balance must be found regarding the number of notifications a podiatrist wishes to receive. This may vary per individual, but it is essential to avoid overwhelming them with alerts. The challenge is to find the right balance.
- The greatest challenge may be integrating the measurement routine into a patient's daily life over several years, while maintaining consistency in daily measurements.

8.3 Recommendations

Based on the evaluations and the overall design process, several areas for improvement have been identified. These are outlined below as concrete recommendations. A separate section is included for recommendations related to sensor performance.

- **Improve start interaction:**
  The start interaction should be as stable and intuitive as possible, with clear feedback on incorrect foot placement. Although an additional pressure sensor was introduced to detect whether the foot is placed deep enough, this alone is insufficient. Users sometimes place their foot too far forward, or too much to the left or right, which still prevents the test from starting. This initial interaction must be highly reliable to prevent frustration.
- **Introduce baselining at initial use:**
  A calibration or baselining step at the start of product use could be helpful. Since it is common for one foot to be naturally warmer than the other, capturing this baseline may reduce false alerts and improve measurement accuracy.
- **Add landing pages:**
  The interaction around turning the device on or off has not been addressed in this report. It is recommended to develop landing screens that briefly show relevant information, such as battery level or the last result, when the device is powered on.
- **Consider a caretaker digital environment:**
  Not all users will have the digital literacy or motivation to interact with the app independently. It may be beneficial to explore the development of a digital environment for a caretaker. This would require user research to assess whether this need exists, and if so, how such an interface should be designed to support them in assisting the user.
- **Icon clarification:**
  If the icon-based interface is chosen, it is recommended to provide a legend explaining the more complex icons. This could be placed on the back of the bottom part of the device. While not an ideal location for quick reference, it offers sufficient space for stickers and could help users understand icon meanings.
- **Re-display functionality:**
  The device should remain in a low-power "always-on" mode, allowing it to be activated by a simple movement. If the device is reactivated within one hour after a measurement, it could briefly display the last test result again, in case the user missed the result.
- **Reconsider button placement:**
  The current placement of the on/off and pause buttons at the back of the bottom part is not optimal. Relocating them to the side of the device may enhance usability. However, care must be taken to avoid accidental presses in this new position.
- **Evaluate the use of sound feedback:**
  The potential benefit of adding auditory feedback should be studied. Users with visual impairments, such as those with diabetic retinopathy, might benefit from sound cues to navigate the interaction more easily.
- **Evaluate and improve display visibility:**
  The visibility of the display in well-lit environments is limited. This should be addressed when designing the flexible LED grid to ensure consistent readability under different lighting conditions.
- **Clarify roles of other HCPs:**
  The roles of the pedicure and the POH are currently not well-defined in the system. Future research could explore how these professionals can be effectively integrated into the workflow.
- **Explore alternatives to flexible LED Grid:**
  Although the flexible LED grid allows design freedom, it significantly increases production costs. Investigating the feasibility of a rigid display may provide a more cost-effective alternative while still maintaining sufficient functionality.
- **Assess compliance with medical and sustainability regulations:**
  To maintain design flexibility, regulatory and sustainability considerations were not included in this phase. It is now recommended to evaluate whether the proposed designs comply with medical safety standards and sustainability requirements.

- **Include broader user demographics in testing:**
  Future user testing should involve participants with lower education levels and those less inclined to adopt new technologies. This will ensure the design accommodates a wider range of potential users and supports inclusiveness.
- **Utilise medical history in risk assessment:**
  Investigate the potential benefit of integrating patient medical history, such as previous ulcer locations. Literature suggests ulcers do sometimes recur at the same site, and a temperature rise in these areas may warrant stronger warnings.
- **Improve waiting time experience:**
  While a countdown clock has been implemented, no iterations have been made on the waiting experience. Exploring playful elements, such as animations, could enhance user engagement during this period.
- **Implement motivational messaging:**
  The digital environment and display offer opportunities to include motivational prompts. Consider testing the impact of weekly progress summaries or encouraging notifications to promote consistent usage.
- **Provide a protective carrying bag or box:**
  Users expressed concern about damaging the device. Supplying a dedicated protective bag could alleviate these worries and support safer transport, for instance, for holidays.
- **Enhance text readability in the app:**
  The current font size in the mobile app is too small, especially for smartphone users. The design should be updated with larger text and potentially include zoom functionality.
- **Clarify the role of the podiatrist:**
  There should be more research about the role of the podiatrist. In the Netherlands, podiatrists are educated at HBO level and therefore may lack the authority to prescribe certain treatments. It is questionable whether the podiatrist is the person who should prescribe the product or if this should be the GP.
- **Explore extrinsic motivation strategies:**
  While literature emphasises the importance of extrinsic motivation, this aspect has not been deeply addressed in this report. Future studies should examine how caregivers or family members can help encourage daily device usage.
- **Enhance interaction design with visual elements:**
  The current interface uses simple text and white icons. Evaluate whether the use of colours, animations, or other visual enhancements can make the interaction more enjoyable and intuitive.
- **Assess the need for multiple device sizes:**
  Many participants indicated the device was too large for their feet. Consider developing the product in multiple sizes (e.g., S, M, L) to better fit users and reduce unnecessary bulk in the home environment.

Recommendations about the sensors

The sensors used in the prototype are intended to simulate how real-world interactions could work. Currently, two pressure sensors and one light sensor have been implemented. The light sensor serves multiple functions: it starts the program, wakes up the device, and checks whether the foot remains in place during measurement. The pressure sensors are used to provide feedback to both the user and the program, indicating whether the foot has been positioned correctly and the measurement can begin.

It is difficult to define exactly what these sensors will look like in the final design. Their implementation depends on several factors, such as the available space within the device and the need to avoid interference with temperature measurements. Another consideration is whether the thermoresistors could also take on the role of the pressure sensors by detecting foot placement and removal, though it is uncertain whether the resistors can do this in a short period of time.

In general, the sensors must fulfil the following tasks:

- Wake up the device
- Detect foot placement
- Detect significant foot movement or removal

It is also critical that the sensors consume minimal energy, as higher energy use would require a larger battery, increasing both size and cost. Potential sensor options include: light sensors, movement sensors, pressure sensors, Time-of-Flight sensors, IR-distance sensors, accelerometers, piezo elements, and touch sensors.

The choice of wake-up method influences which type of sensor is most suitable. A piezo element is a logical choice, as it generates a small current when moved. These elements are inexpensive and energy-efficient. For example, the device could be activated by tapping on its back. Another option is to have the device wake up upon movement, likely to occur as the user prepares for testing. In this case, a shock sensor like the KY-002 could be used.

For tap-based interaction, the KY-031 knock sensor is a suitable alternative. However, a drawback of the shock sensor is that it triggers wake-up upon any movement, not necessarily when the user intends to start testing. Therefore, if a suitable mounting location can be found, the tap sensor is likely the better choice.

For detecting foot placement, Force Sensitive Resistors (FSRs) are still recommended despite not functioning properly in the current prototype. Their advantages include small size, low energy consumption, and ease of integration into the design. It is suggested to use a total of four to five FSRs to provide clear feedback to the user (see Figure 93).

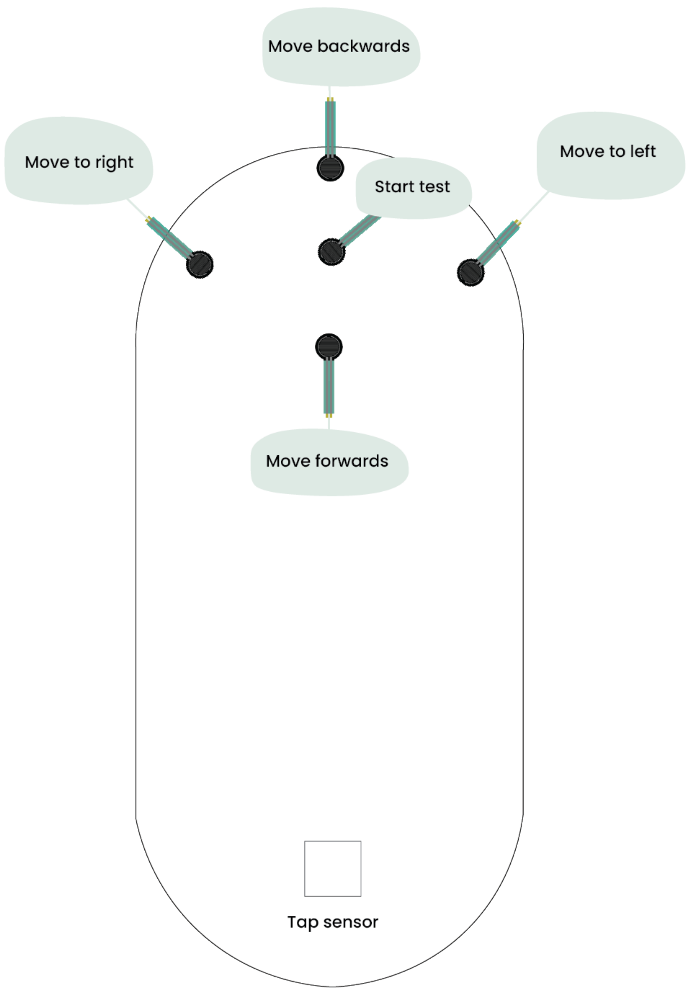


Figure 93. Possible sensor locations of the future product

9. Closing

This final chapter reflects on the extent to which the initial assignment has been fulfilled. It will include a conclusion about the project. Additionally, the chapter includes a discussion of the results and a reflection on the overall process, highlighting also the limitations of this study.

9.1 Conclusion

This report presents the development of a user experience design for a foot temperature monitoring device aimed at preventing the development of foot ulcers for diabetic patients. It outlines a complete system involving the podiatrist, patient and Secuped as the primary stakeholders. Two physical interfaces were developed through an extensive iterative process- one based on text and one based on icons. There seems to be a preference for the text-based concept. However, it still needs some work to ensure the start interaction is clear and fluent to the user. Certain issues, such as how the system responds when the user begins a measurement with the wrong foot, also remain unresolved.

Furthermore, digital environments have been designed to clarify the essential components that such systems require. These designs can be shown to patients and podiatrists to assess whether the environments meet their needs or if further elements are required. Finally, the created customer journeys can be used to get a clear understanding of the system and outline the steps each user will take when engaging with the product-service combination.

9.2 Discussion and Reflection

This subsection will discuss and reflect on the design and the process of this graduation thesis. It will also highlight some limitations of this study.

Reflection on the design (assignment)

The assignment as formulated was:

'Design a prototype that delivers an optimal user experience for diabetes patients using the device to measure their foot temperature for detecting the beginning of DFU at home, as well as for caregivers interpreting the provided data.'

This report presents a user experience design for Secuped's product, developed through a physical interface, digital environments, user journeys and a system blueprint. There are many possible approaches to physical interface design, and early in the process, it was decided to work with an LED grid and an LED strip. The underlying goal was to create a minimal, energy-efficient interface. Although the LED grid consumes more power, it became clear that an LED strip alone was insufficient for communicating all necessary information. The LED grid provides the flexibility to display a wide range of messages and will be integrated into a bent surface. While this surface shape was not flagged as problematic by any participant, it does increase production costs and may not be strictly necessary. Nevertheless, I do believe that using an LED grid is the most effective for supporting intuitive interaction. The LED strip's role seems less essential. The main reason it has been integrated is to illuminate the area where the foot needs to be placed. Maybe this should be the only interaction the LED strip should have. Although the colour feedback for indicating, for instance, an error has been positively perceived.

In general, the response to the product and its intended purpose has been very positive. People clearly recognise the value of the product. Despite being only a small part of the full service, the physical interface proved engaging, users enjoyed testing it and were curious about how it worked and what results they would get.

The digital environments are designed in a straightforward manner and primarily serve as a basis for discussion. It was clear from the beginning that these environments would eventually need to be integrated into existing apps or portals. Nonetheless, they were created as stand-alone prototypes in order to visualise the user experience and key functions. They have not yet been thoroughly tested, and future work could include usability testing with the same participants from the earlier user studies. Since portal designs from competing products were used as a reference, no major usability issues are expected, but further evaluation is necessary. I think there are still many things that can be added to these environments, such as allowing podiatrists to quickly view all instances of elevated temperature or generate reports compatible with the patient's electronic care records. The current version outlines the most important functionalities but leaves space for future expansion.

To conclude, this report presents a solid user experience for diabetes patients who will use the product. From Chapter 5.3, the three design domains are addressed within this report. Design domain four is left as a recommendation, as the need for this direction remains uncertain. From design domain one, the communication system, such as IoT or 5G, has also been excluded, as the focus has been on creating the most optimal interaction. Ultimately, the product can be used independently (without the app), but for those who wish to gain deeper insights, the digital environment offers valuable additional information.

Reflection on the design process

Over the past 20 weeks, a wide range of activities have been undertaken to arrive at the final designs. These included two visits to the IZI house, conducting a survey, interviewing eight patients and two podiatrists, and learning about service design from Diederik Zeven. In addition, a thorough literature review was conducted to gain a solid understanding of the system, the disease and the target group. Competitor research provided valuable insight into existing solutions. To map the context, several tools were used, such as a system map, customer journeys, and stakeholder maps. All these steps were essential to gain a comprehensive understanding of the context and to be able to come to the final designs.

Looking back on the process, I believe that most of the goals I set out to achieve have been met. However, I do wish there had been more time to conduct a full evaluation of both final concepts. It proved challenging to recruit participants from the target group on short notice, especially with the uncertainty around when the prototype would be ready. Working with Arduino, especially when combining multiple components, brought unpredictable technical issues that complicated the timeline.

The user tests were especially insightful and taught me far more than reviewing academic literature alone. In future projects, I would aim to schedule these tests earlier in the process to gain user feedback sooner. Another significant challenge was the research ethics application, which consumed a substantial amount of time. Nevertheless, it was a valuable learning experience to understand the requirements and responsibilities involved in conducting user testing involving human participants.

Limitations

A key limitation of this study was the recruitment of participants for the user tests. The designs were primarily tested by patients who were open to trying new technologies and often had a higher level of education. This might give a distorted view of the needs and wishes of the end users. Additionally, the significant travel time required to visit participants individually at home took a lot of time. The ethics application process was another time-intensive element, taking several days and many emails before approval was granted. Technical limitations also played a role: the use of Arduino components, such as an unreliable pressure sensor, negatively impacted the interaction quality and the creation of an optimal user experience. Finally, the overall time constraint of 20 weeks limited the depth of research, iteration, and testing. To ensure a robust and inclusive design, further time and testing with a more diverse group of users will be necessary.

9.3 Acknowledgement

I would like to thank everyone who supported me throughout my graduation process.
Thank you to my supervisors, Daan van Eijk and Caroline Kroon, for guiding me through this journey, providing valuable feedback when I needed it most.

I am also very grateful to Secuped for giving me the opportunity to work on this project. Thank you to Martijn and Arjen for attending the meetings and helping me find participants for the interviews. I also truly appreciate all your efforts in making me feel welcome as part of the team!

A special thanks to Tom, I really appreciated doing the interviews together, receiving so much helpful feedback, and being able to borrow your tablet each time again.

Many thanks as well to my friends and family for listening to my stories, offering feedback, and repeatedly testing the interface. I'm also very thankful to everyone who participated in the interviews; your time and insights helped me gain a much deeper understanding of the context and greatly contributed to testing both concepts. I've learned a great deal from you all!

Lastly, I want to thank my boyfriend for his support throughout the entire process. He helped keep my stress levels down, made sure I didn't overwork, and stayed right by my side the whole way through.

Reference list

Abbott, C. A., Chatwin, K. E., Foden, P., Hasan, A. N., Sange, C., Rajbhandari, S. M., Reddy, P. N., Vileikyte, L., Bowling, F. L., Boulton, A. J. M., & Reeves, N. D. (2019). Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study. The Lancet Digital Health, 1(6), e308–e318. https://doi.org/10.1016/s2589-7500(19)30128-1

Armstrong, D. G., Boulton, A. J., & Bus, S. A. (2017). Diabetic foot ulcers and their recurrence. New England Journal of Medicine, 376(24), 2367–2375. https://doi.org/10.1056/nejmra1615439

Armstrong, D. G., Holtz-Neiderer, K., Wendel, C., Mohler, M. J., Kimbriel, H. R., & Lavery, L. A. (2007). Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. The American Journal of Medicine, 120(12), 1042–1046. https://doi.org/10.1016/j.amjmed.2007.06.028

Armstrong, D. G., Tan, T., Boulton, A. J. M., & Bus, S. A. (2023). Diabetic foot ulcers. JAMA, 330(1), 62. https://doi.org/10.1001/jama.2023.10578

Bluedrop Medical. (2024, March 1). Bluedrop Medical • reducing the burden of diabetic foot disease. https://bluedropmedical.com/

Bus, S. A., De Stegge, W. B. A., Van Baal, J. G., Busch-Westbroek, T. E., Nollet, F., & Van Netten, J. J. (2021). Effectiveness of at-home skin temperature monitoring in reducing the incidence of foot ulcer recurrence in people with diabetes: a multicenter randomized controlled trial (DIATEMP). BMJ Open Diabetes Research & Care, 9(1), e002392. https://doi.org/10.1136/bmjdrc-2021-002392

Bus, S. A., Sacco, I. C. N., Monteiro-Soares, M., Raspovic, A., Paton, J., Rasmussen, A., Lavery, L. A., & Van Netten, J. J. (2023). Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update). Diabetes/Metabolism Research and Reviews, 40(3). https://doi.org/10.1002/dmrr.3651

Bus, S. A., & Van Netten, J. J. (2015). A shift in priority in diabetic foot care and research: 75% of foot ulcers are preventable. Diabetes/Metabolism Research and Reviews, 32(S1), 195–200. https://doi.org/10.1002/dmrr.2738

Cai, H., & Chen, L. (2020). Affordance requirements in product interface design for elderly user. In Communications in computer and information science (pp. 21–28). https://doi.org/10.1007/978-3-030-50732-9_3

Carle, J. (2025, April 3). OLED vs. LED: A Detailed Guide to Modern Display Technologies — infinityPV. infinityPV. https://www.infinitypv.com/roll-to-roll-academy/oled-vs-led-a-detailed-guide-to-modern-display-technologies?utm_source=chatgpt.com

Chappell, F. M., Crawford, F., Horne, M., Leese, G. P., Martin, A., Weller, D., Boulton, A. J. M., Abbott, C., Monteiro-Soares, M., Veves, A., & Riley, R. D. (2021). Development and validation of a clinical prediction rule for development of diabetic foot ulceration: an analysis of data from five cohort studies. BMJ Open Diabetes Research & Care, 9(1), e002150. https://doi.org/10.1136/bmjdrc-2021-002150

Coventry, L., & Briggs, P. (2016). Mobile technology for older adults: protector, motivator or threat? In Lecture notes in computer science (pp. 424–434). https://doi.org/10.1007/978-3-319-39943-0_41

Crocker, R. M., Tan, T., Palmer, K. N. B., & Marrero, D. G. (2022). The patient's perspective of diabetic foot ulceration: A phenomenological exploration of causes, detection and care seeking. Journal of Advanced Nursing, 78(8), 2482–2494. https://doi.org/10.1111/jan.15192

Edmonds, M., Manu, C., & Vas, P. (2021). The current burden of diabetic foot disease. Journal of Clinical Orthopaedics and Trauma, 17, 88–93. https://doi.org/10.1016/j.jcot.2021.01.017

Ena, J., Carretero-Gomez, J., Arevalo-Lorido, J. C., Sanchez-Ardila, C., Zapatero-Gaviria, A., & Gómez-Huelgas, R. (2020). The association between elevated foot skin temperature and the incidence of diabetic foot ulcers: A Meta-Analysis. The International Journal of Lower Extremity Wounds, 20(2), 111–118. https://doi.org/10.1177/1534734619897501

Federatie Medische Specialisten. (2017, April 3). Diabetische voet. Richtlijnendatabase. Retrieved March 3, 2025, from https://richtlijnendatabase.nl/richtlijn/diabetische_voet/startpagina_diabetische_voet.html

Frykberg, R. G., Gordon, I. L., Reyzelman, A. M., Cazzell, S. M., Fitzgerald, R. H., Rothenberg, G. M., Bloom, J. D., Petersen, B. J., Linders, D. R., Nouvong, A., & Najafi, B. (2017). Feasibility and efficacy of a smart mat technology to predict development of diabetic plantar ulcers. Diabetes Care, 40(7), 973–980. https://doi.org/10.2337/dc16-2294

Golledge, J., Fernando, M. E., Alahakoon, C., Lazzarini, P. A., De Stegge, W. B. A., Van Netten, J. J., & Bus, S. A. (2022). Efficacy of at home monitoring of foot temperature for risk reduction of diabetes-related foot ulcer: A meta-analysis. Diabetes/Metabolism Research and Reviews, 38(6). https://doi.org/10.1002/dmrr.3549

INC. (2021, May 6). Smart socks? How this tech startup is targeting a common medical problem. Retrieved March 5, 2025, from https://www.inc.com/amrita-khalid/siren-socks-remote-patient-monitoring-best-industries-2021.html

International Diabetes Federation. (n.d.). Diabetes estimates (20-79 y): People with diabetes, in 1,000s. https://diabetesatlas.org/data/en/indicators/1/

Ku, W., & Hsieh, P. (2016). Acceptance of Cloud-Based healthcare services by elderly Taiwanese people. In Lecture notes in computer science (pp. 186–195). https://doi.org/10.1007/978-3-319-39943-0_18

Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Armstrong, D. G., Athanasiou, K. A., & Agrawal, C. M. (2004). Home Monitoring of foot skin temperatures to prevent ulceration. Diabetes Care, 27(11), 2642–2647. https://doi.org/10.2337/diacare.27.11.2642

Moore, K., O'Shea, E., Kenny, L., Barton, J., Tedesco, S., Sica, M., Crowe, C., Alamäki, A., Condell, J., Nordström, A., & Timmons, S. (2021). Older Adults' experiences with using wearable Devices: Qualitative systematic review and meta-synthesis. JMIR Mhealth and Uhealth, 9(6), e23832. https://doi.org/10.2196/23832

NCD-RisC, & Ezzati, M. (2024). Worldwide trends in diabetes prevalence and treatment from 1990 to 2022: a pooled analysis of 1108 population-representative studies with 141 million participants. In The Lancet (Vol. 404, pp. 2077–2093). https://doi.org/10.1016/S0140-6736(24)02317-1

Orpyx. (2024, February 1). Orpyx | Extending healthspan for people living with diabetes. https://www.orpyx.com/

Podimetrics. (2025, February 5). Podimetrics - Revolutionize diabetic foot care for your patients. Retrieved March 5, 2025, from https://podimetrics.com/

Prompers, L., Huijberts, M., Apelqvist, J., Jude, E., Piaggesi, A., Bakker, K., Edmonds, M., Holstein, P., Jirkovska, A., Mauricio, D., Tennvall, G. R., Reike, H., Spraul, M., Uccioli, L., Urbancic, V., Van Acker, K., Van Baal, J., Van Merode, F., & Schaper, N. (2006). High prevalence of ischaemia, infection and serious comorbidity in patients with diabetic foot disease in Europe. Baseline results from the Eurodiale study. Diabetologia, 50(1), 18–25. https://doi.org/10.1007/s00125-006-0491-1

Reyzelman, A. M., Koelewyn, K., Murphy, M., Shen, X., Yu, E., Pillai, R., Fu, J., Scholten, H. J., & Ma, R. (2018). Continuous Temperature-Monitoring Socks for home use in patients with Diabetes: Observational study. Journal of Medical Internet Research, 20(12), e12460. https://doi.org/10.2196/12460

Rothenberg, G. M., Munson, J., Josephson, E., & Bloom, J. (2025). Moving beyond the device: Key lessons in creating a positive patient experience for a remote foot health program. Journal of Patient Experience, 12. https://doi.org/10.1177/23743735251314646

Salera, K. H., Salehi, P., Desai, N., Tsotsos, L. E., & Warren-Norton, K. (2016). Improving user experience and engagement for older adults: a case study. In Lecture notes in computer science (pp. 248–255). https://doi.org/10.1007/978-3-319-39949-2_24

Sharma, R., Nah, F. F., Sharma, K., Katta, T. S. S. S., Pang, N., & Yong, A. (2016). Smart Living for Elderly: Design and Human-Computer Interaction Considerations. In Lecture notes in computer science (pp. 112–122). https://doi.org/10.1007/978-3-319-39949-2_11

Singh, N., Armstrong, D., & Lipsky, B. (2005). Preventing foot ulcers in patients with diabetes. JAMA, 293(2), 217. https://doi.org/10.1001/jama.293.2.217

Siren. (n.d.). Preventative Foot Care For Patients | Siren. Retrieved February 20, 2025, from https://www.siren.care/for-patients

VA news. (2019, December 6). New technology identifies potential diabetic foot ulcers - VA News. VA News. https://news.va.gov/69096/new-technology-identifies-potential-diabetic-foot-ulcers/

Van Netten, J. J., De Stegge, W. B. A., Dijkgraaf, M. G. W., & Bus, S. A. (2024). Cost-effectiveness of temperature monitoring to help prevent foot ulcer recurrence in people with diabetes: A multicenter randomized controlled trial. Diabetes/Metabolism Research and Reviews, 40(4). https://doi.org/10.1002/dmrr.3805

Veneman, T., Schaper, N. C., & Bus, S. A. (2021). The Concurrent Validity, Test–Retest Reliability and Usability of a New Foot Temperature Monitoring System for Persons with Diabetes at High Risk of Foot Ulceration. Sensors, 21(11), 3645. https://doi.org/10.3390/s21113645

Vistafeet. (n.d.). VistaFeet. CapraBalance AB. Retrieved April 15, 2025, from https://vistafeet.com/

Yang, M., Huang, H., Yuan, H., & Sun, Q. (2016). Interaction design of products for the elderly in smart home under the mode of medical care and pension. In Lecture notes in computer science (pp. 145–156). https://doi.org/10.1007/978-3-319-39949-2_14

Zhao, R., & Chen, L. (2020). Research on interface design for the elderly. In Communications in computer and information science (pp. 128–135). https://doi.org/10.1007/978-3-030-50732-9_18

Image reference

Metatarsal bones. (n.d.). Theskeletalsystem. https://www.theskeletalsystem.net/metatarsal-bones

Appendices

Appendix A: Project brief

DESIGN FOR our future

TU Delft

Personal Project Brief – IDE Master Graduation Project

Name student Jannieke den Breejen **Student number** 5,062,594

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT
Complete all fields, keep information clear, specific and concise

Project title Integrating preventive foot monitoring into daily life of diabetes patients and their healthcare professionals.

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

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

The project is part of the development of a home-monitoring solution for the prevention of diabetic foot ulcers (wounds). It will be conducted in collaboration with the development team of Secuped, and diabetic patients at risk of these wounds. The focus of this project is on the interaction they have with the product, which helps them monitor foot ulcers. As such, the project primarily addresses diabetic foot management and preventive care. The product will be designed for use in a home setting by the patients themselves, making them a key stakeholder in the process. Consequently, the product must be user-friendly, reliable, and have a subtle appearance.

Additionally, healthcare professionals such as podiatrists, wound care specialists, and homecare or GPs will be involved. They need accurate data and actionable insights to provide appropriate advice without increasing their workload.

In summary, the project presents opportunities to improve the patient experience with the device leading to an increased or more consistent use of the device, which leads to better prevention of foot ulcers.

However, potential limitations include challenges with patient adoption and consistent use, obtaining insurer approval, and integrating the product effectively into daily routines.

→ *space available for images / figures on next page*

introduction (continued): space for images

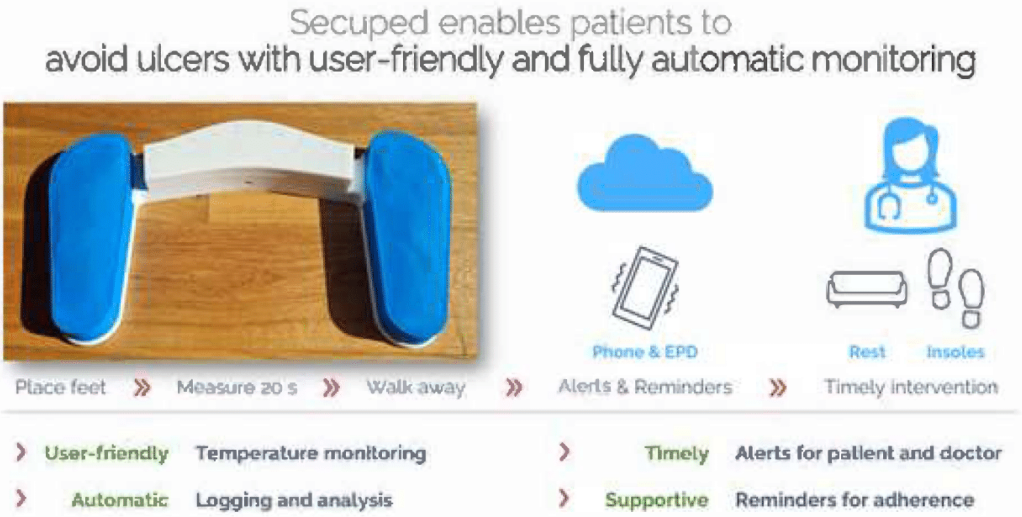


image / figure 1 Current version of the prototype

image / figure 2

Personal Project Brief – IDE Master Graduation Project

Problem Definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.
(max 200 words)

The main issue to address is that while the current product prototype has received positive feedback from users, it is still incomplete. Further research is needed to better integrate the device into the daily lives of patients and to determine what information and signals patients and healthcare professionals (HCPs) need to receive, and how, to effectively support their tasks without overwhelming them. My focus will be on identifying the specific needs of patients and HCPs and incorporating these insights into the product's design to ensure it better meets their requirements.
The project will concentrate on the user's interactions with the device. How do you inform them that their feet are correctly positioned, that the measurement has been successfully taken, or guide them when a measurement is incorrect? What steps should be communicated when users forget to use the device? Additionally, how can this information be effectively conveyed to the HCP and patient?
By enhancing the user experience, the product will encourage greater adoption by patients and provide Secuped with more opportunities for user testing, which is crucial for demonstrating the product's effectiveness. Additionally, making these improvements will support the goal of securing investments and therapy adherence, as the enhanced usability will increase the likelihood of adoption by patients, caregivers and other stakeholders.

Assignment

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

Design a prototype that delivers an optimal user experience for diabetes patients using the device at home, as well as for caregivers interpreting the provided data.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

To achieve this goal, user research methods such as interviews, surveys, focus groups (if feasible), and a literature review will be conducted. The insights gained from this research will be used to develop personas and journey maps. Building on these findings, various ideation and concept development methods, such as mind mapping, morphological charts, and brainstorming, will be employed. This will lead into the prototyping phase, where both low- and high-fidelity prototypes will be created to test initial ideas. These will probably be some type of hardware prototype. Finally, real user testing with the prototype will be conducted to evaluate whether the design aligns with user needs.

Project planning and key moments

To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a ***kick-off meeting, mid-term evaluation meeting, green light meeting*** *and* ***graduation ceremony****. 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 course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	5 Feb 2025
Mid-term evaluation	3 Apr 2025
Green light meeting	10 Jun 2025
Graduation ceremony	3 Jul 2025

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	
For how many project weeks	
Number of project days per week	

Comments:

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).

Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.
(200 words max)

I want to pursue a graduation project related to healthcare to make a meaningful impact on patients' lives. In the future, my goal is to design healthcare products and collaborate directly with patients. During my internship at a design company, I gained deeper insight into real-world product development, and I want to further explore if this career path is something I aim for.

For this project, I can apply the user research skills I developed during the ACD course (working with COPD patients), but I am also eager to enhance my prototyping abilities. Additionally, I would like to enhance my Arduino skills. While it is not the primary focus of this project, there may still be some opportunities to do so.

A personal learning ambition for me is to discover whether I can independently manage a project for 20 consecutive weeks, maintaining the necessary motivation and creativity to see it through successfully.

Appendix B: Survey & Participant Details

Characteristics	Count	Percentage
Number of participants	34 (26 completed)	100%
Age		
35-44	4	12%
45-54	9	27%
55-64	11	33%
65-74	7	21%
75-84	2	6%
Gender		
Men	11	33%
Women	21	64%
Non-binary/ third gender	1	2%
Years diagnosed with diabetes		
Less than 1 year	8	24%
1-5 years	6	18%
6-10 years	4	12%
More than 10 years	15	45%
Visit podiatrist?		
Yes regularly	6	23%
Yes, but only when I have a problem	3	12%
No, I do not see a podiatrist	17	65%
How often do you visit the podiatrist??		
Once a month	1	4%
Every few months	3	12%
Once a year or less	6	23%
Never	16	62%
How do you usually communicate with your podiatrist? (multiple choice)		
In-person visits	10	38%
Phone calls	2	8%
Online consultation (telemedicine)	0	0%
I don't have a podiatrist	16	62%

What happens when you call your podiatrist with concerns about your foot? (multiple choice)		
The podiatrist asks a series of questions	1	4%
The podiatrist asks me to send a photo	2	8%
I can get an appointment immediately	6	24%
I am advised to rest right away	0	
Other (not applicable or 'via email text explanation what to do to prevent worse')	19	76%
Have had a foot ulcer?		
Yes	5	19%
No	21	81%

Questions

Wat is uw leeftijd?

Wat is uw geslacht?
- Man
- Vrouw
- Non-binair / derde gender
- Verkies ik niet te zeggen

Hoe lang heeft u diabetes?
- Ik heb geen diabetes
- Minder dan 1 jaar
- 1-5 jaar
- 6-10 jaar
- Meer dan 10 jaar

Welke van de volgende producten gebruikt u om uw diabetes te beheren? (Selecteer alle toepasselijke opties)
- Bloedglucosemeter
- Continue glucosemonitor (CGM)
- Insulinepomp
- Compressiekousen
- Insulinepennen of -spuiten
- Gespecialiseerd diabetisch schoeisel
- Hydraterende crèmes voor de voeten
- Drukverlagende hulpmiddelen (bijv. speciale inlegzolen of braces)
- Anders: ________

Gaat u momenteel naar een podotherapeut voor voetverzorging?
- Ja, regelmatig
- Ja, maar alleen als ik een probleem heb
- Nee, ik ga niet naar een podotherapeut

Hoe vaak bezoekt u de podotherapeut?
- Meer dan eens per maand
- Eén keer per maand
- Om de paar maanden
- Eén keer per jaar of minder
- Nooit

Hoe communiceert u meestal met uw podotherapeut?
- Fysieke afspraken
- Telefonisch contact
- Online consulten (telemedicine)
- Ik heb geen podotherapeut

Wanneer u uw podotherapeut belt met zorgen over uw voet, wat gebeurt er meestal?
- De podotherapeut stelt een reeks vragen
- De podotherapeut vraagt mij een foto te sturen
- Ik kan direct een afspraak krijgen
- Mij wordt geadviseerd om direct rust te nemen
- Anders: ________

Heeft u ooit een voetulcus gehad?
Uitleg: Een voetulcus begint als een blaarachtige wond, maar kan leiden tot ernstige complicaties, zoals slecht genezende wonden of zelfs amputatie als het niet wordt behandeld.
- Nee
- Ja

Als u een voetulcus zou ontwikkelen, wat zou uw eerste stap zijn?
- Thuis behandelen met vrij verkrijgbare producten
- Onmiddellijk contact opnemen met mijn arts of podotherapeut
- Een paar dagen afwachten en het in de gaten houden voordat ik hulp zoek
- Eerst advies vragen aan familie, vrienden of online bronnen voordat ik actie onderneem
- Ik weet niet zeker wat ik zou doen
- Anders: ________

Subpart foot ulcer
Hoe vaak heeft u een voetulcus gehad?
- Eén keer
- 2-3 keer
- Meer dan 3 keer

Wat was uw eerste stap nadat u een voetulcus ontdekte?
- Thuis behandeld met vrij verkrijgbare producten
- Onmiddellijk contact opgenomen met mijn arts of podotherapeut
- Een paar dagen gewacht en gemonitord voordat ik besloot hulp te zoeken
- Eerst advies gevraagd aan familie, vrienden of online bronnen voordat ik actie ondernam
- Geen actie ondernomen en gewacht tot het erger werd
- Anders: ________

Hoe lang heeft u gewacht voordat u een arts raadpleegde na het ontdekken van de voetulcus?
- Dezelfde dag
- Binnen een paar dagen
- Binnen een week
- Meer dan een week
- Meer dan een maand
- Meer dan 2 maanden

Welke preventieve maatregelen heeft uw podotherapeut u aangeraden? (Selecteer alle toepasselijke opties)
- Visuele voetinspectie
- Temperatuurmonitoring
- Hydrateren
- Regelmatig de voeten wassen
- Geen
- Anders (specificeer): ________

Hoeveel minuten per dag besteedt u aan deze preventieve maatregelen?

Monitort u de temperatuur van uw voeten om mogelijke voetulcera te detecteren?
- Ja, regelmatig (dagelijks of bijna dagelijks)
- Ja, af en toe (een paar keer per week of maand)
- Nee, maar ik ben op de hoogte van temperatuurmonitoring voor het voorkomen van voetulcera
- Nee, ik monitor mijn voettemperatuur niet en ben hier niet mee bekend

Subpart foot temperature monitoring
Welke methode gebruikt u?
- Infraroodthermometer, zoals: ________
- Slimme sokken of temperatuurmonitorende inlegzolen, zoals: ________
- Temperatuurmeetmat, zoals: ________
- Anders: ________

Hoeveel moeite kost uw temperatuurmonitoringmethode?
(Schaal: 1 = zeer weinig moeite, 7 = zeer veel moeite)

Wat zou het makkelijker voor u maken?

Hoe consequent volgt u deze monitoringmethode?
(Schaal: 1 = af en toe, 7 = elke dag)

Hoe houdt u uw temperatuurmetingen bij?
- Pen en papier
- Mobiele app
- De gegevens worden automatisch doorgestuurd naar mijn zorgverlener
- Ik houd de metingen niet bij
- Anders: ________

Deelt u de resultaten met uw podotherapeut, of interpreteert u ze zelf?

- Ik deel ze met mijn podotherapeut
- Ik interpreteer ze zelf
- Beide

Op welk moment van de dag meet u meestal uw voettemperatuur?

- Ochtend
- Middag
- Avond
- Wisselend

Hoe zeker voelt u zich over uw voetgezondheid na een normale temperatuurmeting?
(Schaal: 1 = Ik maak me nog steeds zorgen, 7 = Ik voel me de hele dag volledig gerustgesteld)

Heeft u zorgen over het delen van deze gegevens met uw zorgverlener?

Hoe reageert uw podotherapeut meestal op een verhoogde temperatuurmeting?

Hoe bereid bent u om rust te nemen na het detecteren van een verhoogde temperatuur in een van uw voeten?
(Schaal: 1 = Ik bepaal zelf of ik rust neem, 7 = Ik volg altijd het advies van de podotherapeut op)

Appendix C: Competitor overviews

Bluedrop medical

Price unknown

Picture from Bluedrop Medical (2024)

Prescribe

Prescribe

Healthcare provider

Healthcare provide has to prescribe the device. Within one week after prescription the user will receive the device at home.
'USA Federal law restricts this device to sale by or on the order of a physician'

Onboarding

Setup

Device

1. Unpack the device
2. Connect the device to wifi either your own wifi or from the cellular Router provided with this product as well.
3. For the connection with own wifi a mobile phone is needed. Here you connect to Bluedrop Wifi network and then enter the wifi credentials. Once connected there is no need to use this phone anymore.
4. Place the device on a hard surface and make sure it is always plugged in.

Picture from Bluedrop Medical (2024)

Connectivity

Cellular router

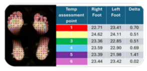
LCD displays if connected to WiFi. Always keep plugged in to ensure data can be sent. When traveling ensure to reconnect to WiFi. After the scan it takes 35 min before scan in processed and send.

Picture from Bluedrop Medical (2024)

Measuring locations

Locations

The system measures over 100 points on each foot with every scan.



Temp assessment point	Right Foot	Left Foot	Delta
1	22.71	23.41	0.70
2	24.62	24.11	0.51
3	23.36	22.85	0.51
4	23.59	22.90	0.69
5	23.39	21.98	1.41
6	23.44	23.42	0.02

Picture from Bluedrop Medical (2024)

Measure

Start test

Procedure

Simply stand on the scanner for 30 seconds. The scanner works in the same way as a normal weight scales. You can step on the scanner when the screen is blank. The scanner will automatically detect your weight and start a scan.

LED screen provides messages such as 'Ready/step on device', 'Stay still', 'Scan complete', 'Scan failed', 'Scan canceled', 'Processing'.

Picture from Bluedrop Medical (2024)

Scan failed

On device

LCD display notification SCAN FAILED

In manual

Correct and incorrect foot positioning image.
You need to ensure that each foot is placed in the sensing area (highlighted in green below). If your foot is not in this region, the scanner will not be able to take a scan of your feet.

Picture from Bluedrop Medical (2024)

Scan ready

Done

If scan is finished it shows the message 'Scan complete' on the display.
Processing of the scan might not take place directly after finishing. The device will communicate when processing by showing the message 'processing/try later' on the LCD and by dimming the screen backlight. Once it is finished with processing, the scanner enters sleep mode.

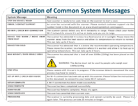
Picture from Bluedrop Medical (2024)

User Feedback

Warning / notification

On device

LCD display warning notifications such as 'Error/ contact support', 'Device too warm / move away from heat', 'No wifi/ check wifi connection', 'Device too cold', 'Max weight/ over 330lb/ 150 kg', 'set up wifi / check user guide'

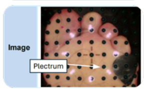


Picture from Bluedrop Medical (2024)

Education

Lifestyle

In case something visual, like dirty feet, is detected, the call center might contact to discuss lifestyle changes, such as walking barefoot.



Picture from Bluedrop Medical (2024)

Tracking adherence

Scan adherence

If a scan hasn't been made for 3 days in a row, a reminder will be send by SMS or phone.

Need to tell engagement specialist that you go on a holiday to prevent they try to reach out when you are away.

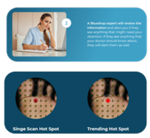
HCP reviewing data

Contact with HCP

Check in periodically to ensure everything is alright.

In case of an identification of an issue, patient is contacted. In 62% of the cases the HCPs were able to remotely intervene (25%) or continue to monitor (37%). Only 10% of flagged reports resulted into bringing the patient in for an emergency appointment. The prescriber is alerted if a trend persists beyond 3 days in a row.

Sometimes a patient is contacted to talk about type of activities. For instance when dirty feet are detected, meaning the patient is walking barefoot in an environment which might damage their feet.



Picture from Bluedrop Medical (2024)

Charging

No charging

As the device is always plugged in there is no need to charge the device.

Podimetrics

The cost of the mat is approximately $3,500.
(VA news, 2019)


Picture from Podimetrics (2025)

Prescribe

Prescribe

Podiatrist

The Podimetrics RTM System is intended to be used by a patient in conjunction with a healthcare professional or caretaker for periodic evaluation of the temperature over the soles of the feet for signs of inflammation.


Picture from Podimetrics (2025)

Onboarding

Setup

Device

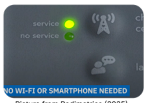
1. Unpack device and rotate to access buttons on the back
2. Turn on the device
3. Set volume level
4. Choose language
5. Test connectivity with cellular network
6. Call to activate device

Picture from Podimetrics (2025)

Connectivity

Cellular device

Activated with button on the back



Picture from Podimetrics (2025)

Measuring locations

Measure

Start test

On device

Led matrix animation instruction to STAND STILL
Colored spinner

Picture from Podimetrics (2025)

Scan failed

On device

Yellow feet blinking + 'error' sound


Picture from Podimetrics (2025)

Scan ready

On device

Led matrix animation

Picture from Podimetrics (2025)

User Feedback

Warning / notification

Call center

We Reach Out to You We reach out to you and your doctor so preventive action can be taken.

Education

Booklet

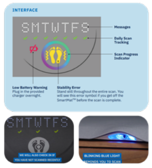
Tips about moitoring foot health.

Picture from Podimetrics (2025)

Tracking adherence

On device

On the device there is a daily scan tracking showing the user how often (s)he has measured during the day. On the device there is also a blue light that turns on after 09.00 am to remind you to scan.



Picture from Podimetrics (2025)

HCP reviewing data

Podiatrist with help of dashboard

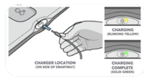
Podimetrics will reach out to you and your doctor if needed


Picture from Podimetrics (2025)

Charging

Charging

It takes 4 hours to recharge battery. Battery can be used for 1 month when device is daily used.



Picture from Podimetrics (2025)

VistaFeet

PedesHome direct payment:
9375 kr = 852,91 €
PedesHome leasing:
399 per month = 36,30 €
VistaFeet PRO- starting pack
14996 kr plus VAT = 1364,29 €


Picture from Vistafeet (n.d.)

Prescribe

Prescribe

No prescription

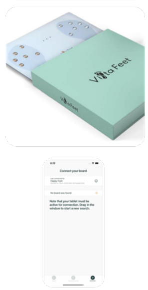
It seems that the current system works without prescription. Patients are able to order the product on the website.

Onboarding

Setup

Device

1. Download the app and create a new profile
2. Turn device on
3. Step on device when green light flashes
4. Connect the board and the app


Picture from Vistafeet (n.d.)

Connectivity

App

After the measurement you should synchronize the pad with the app. It uses Bluetooth for sending data.

Measuring locations

Locations

It measures 8 locations on the foot, mostly focused on the forefoot (see picture below).


Pictures from Vistafeet (n.d.)

Measure

Start test

Procedure

Place your feet for 30 seconds on the pad. Lights on the pad will indicate when the measurement is finished.


Picture from Vistafeet (n.d.)

Scan failed

Unclear

It's unclear if the device gives feedback if the measurement failed.

Scan ready

Done

If the scan is finished the lights will indicate it's done. After that the pad needs to be synchronized with the app to get detailed results or write comments.

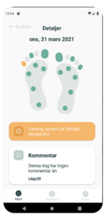

Picture from Vistafeet (n.d.)

User Feedback

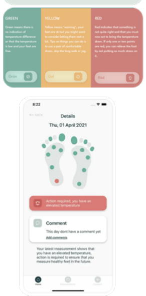
Warning / notification

In app

In case there is an elevation in temperature this will be displayed in the app. A green, yellow and red system is used. Green means there is no or a small temperature difference. Yellow means there is a warning and red means there is something not right and the user should act now.



Picture from Vistafeet (n.d.)

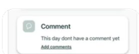


Pictures from Vistafeet (n.d.)

Education

Information in the app

In the app there is more information about Vista Feet and their vision. In addition, the user can add comments to a day measurement to learn how their behaviour might influences the measurements. 'Enter comments when you have done something special, such as changing from summer shoes to autumn shoes, been to your podiatrist or ran a marathon. In this way, you will learn how exactly your feet react, and can act accordingly (Vistafeet, n.d.).

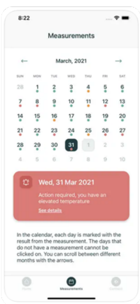


Picture from Vistafeet (n.d.)

Tracking adherence

Scan adherence

As far is known there is no remembering functionality integrated in the system. There is the option to have a monthly overview to check which days one has used the device.



Picture from Vistafeet (n.d.)

HCP reviewing data

Contact with HCP

It is possible to share the data with a HCP. VistaFeet Pro is the communication platform between patients and care givers


Picture from Vistafeet (n.d.)

Charging

Charging

It is unclear how often the device needs charging, but it has a power input on the side.

Siren socks

Siren Socks are covered by many insurances, including Medicare.

One year of Siren patient monitoring will cost typically $19.95 a month (which amounts to $239 per year)

(INC, 2021)

Picture from Siren (n.d.)

Prescribe

Prescribe

Podiatrist

Get an Rx (doctor's written order) for Siren Socks
A Certified Siren Provider determines if you qualify for Siren Socks and writes you a prescription.

Picture from Siren (n.d.)

Onboarding

Setup

App & device

1. Download the app
2. Create an account
3. Report current foot health situation (by telling previous foot ulcer locations)
4. Connect sock to app, by scanning QR code on inside box
5. Plug in the Hub

Pictures from Siren (n.d.)

Connectivity

Connection hub

The hub is connected to the internet when there is a little light visible. It turns green when start wearing the socks.

Picture from Siren (n.d.)

Measuring locations

In the picture below several measuring locations are shown. In the encircled area there is a bluetooth chip, MCU and battery.

Picture from Reyzelman et al. (2018)

Measure

Start test

By simply wearing the socks the user is recording its foot temperature.

In app

Colored dots for corresponding points
Graph with live temperature

Picture from Siren (n.d.)

Scan failed

Scan ready

User Feedback

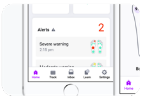
Warning / notification

Call center / text message

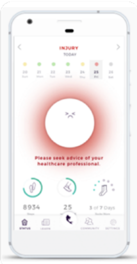
Nurses Monitor Foot Health Licensed nurses review the data for signs of inflammation and call patients regularly to check on their health.

In app

Colored dots



Pictures from Siren (n.d.)

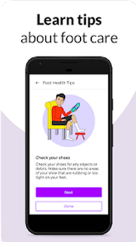


Pictures from Siren (n.d.)

Education

In app

Tips about monitoring foot health.



Tracking adherence

In app

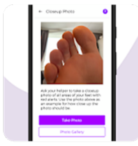
Overview how long the socks have been worn and also some motivational messages.

Picture from Siren (n.d.)

HCP reviewing data

Podiatrist

Providers Manage Patient Care Providers are alerted to potential injuries and determine if a clinic visit is necessary.



Picture from Siren (n.d.)

Charging

Not needed

The socks come with a fully charged battery and do not need to be recharged for the 6 months they can be worn. They automatically turn off when not worn.

Orpyx

Most supplemental policies pay up to C$500 per year for custom insoles with a physician's prescription

Picture from Orpyx (2024)

Prescribe

Prescribe

Healthcare provider

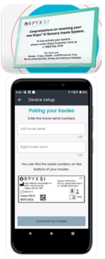
Healthcare provider is the one that can help you manage peripheral neuropathy and apply for Orpyx SI Sensory Insole.

Onboarding

Setup

Device

1. Unpack soles and digital display (mobile phone)
2. Soles and display are already connected
3. Call number to activate system
4. In case of replacement of old soles, you need to connect the soles again
5. Go to settings in app
6. Remove the old soles
7. Restart digital display
8. Connect new soles by entering correct serial numbers (found in manual, box and on sole itself)

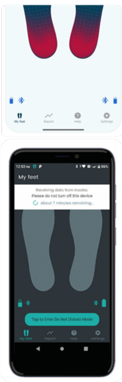


Picture from Orpyx (2024)

Connectivity

Bluetooth insoles connected to phone app

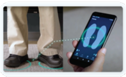
Bluetooth pairing on the phone. When within 6 feet of the digital device the data is transferred to the healthcare institute.



Picture from Orpyx (2024)

Measuring locations

Pressure is measured on the entire plantar side of the foot.



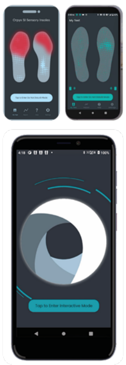
Picture from Orpyx (2024)

Measure

Start test

Automatically measuring

The device is automatically measuring the pressure during the day. Dependent on the mode (interactive or do not disturb) alerts are sent.



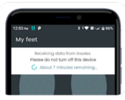
Picture from Orpyx (2024)

Scan failed

Scan ready

On device

When close to the phone it will send the data.



Picture from Orpyx (2024)

User Feedback

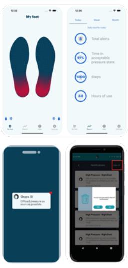
Warning / notification

Call center

Remote nurses can contact you to talk about making adjustments to prevent complications.

In app notifications

Live colored pattern
Receive alerts for sustained high pressure levels when in iteractive mode. There is an overview where all notifications can be viewed.

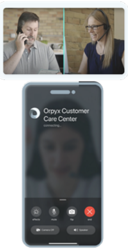


Picture from Orpyx (2024)

Education

Call center

At least once per month (although dependent on package chosen) the nurses contact the patient to talk about last month and required adjustments.



Picture from Orpyx (2024)

Tracking adherence

Healthcare provider and patient

Both can see the amount of time the soles were used.

Picture from Orpyx (2024)

HCP reviewing data

Podiatrist with help of web based dashboard

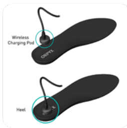
- Cloud-based, HIPAA-compliant dashboard for on-demand data access by credentialed remote patient monitors
- Data is refreshed daily enabling ability to monitor protocol adherence and product utilization
- Data is easily exported
- Ease of data collection for CRO, study teams, and participants

Picture from Orpyx (2024)

Charging

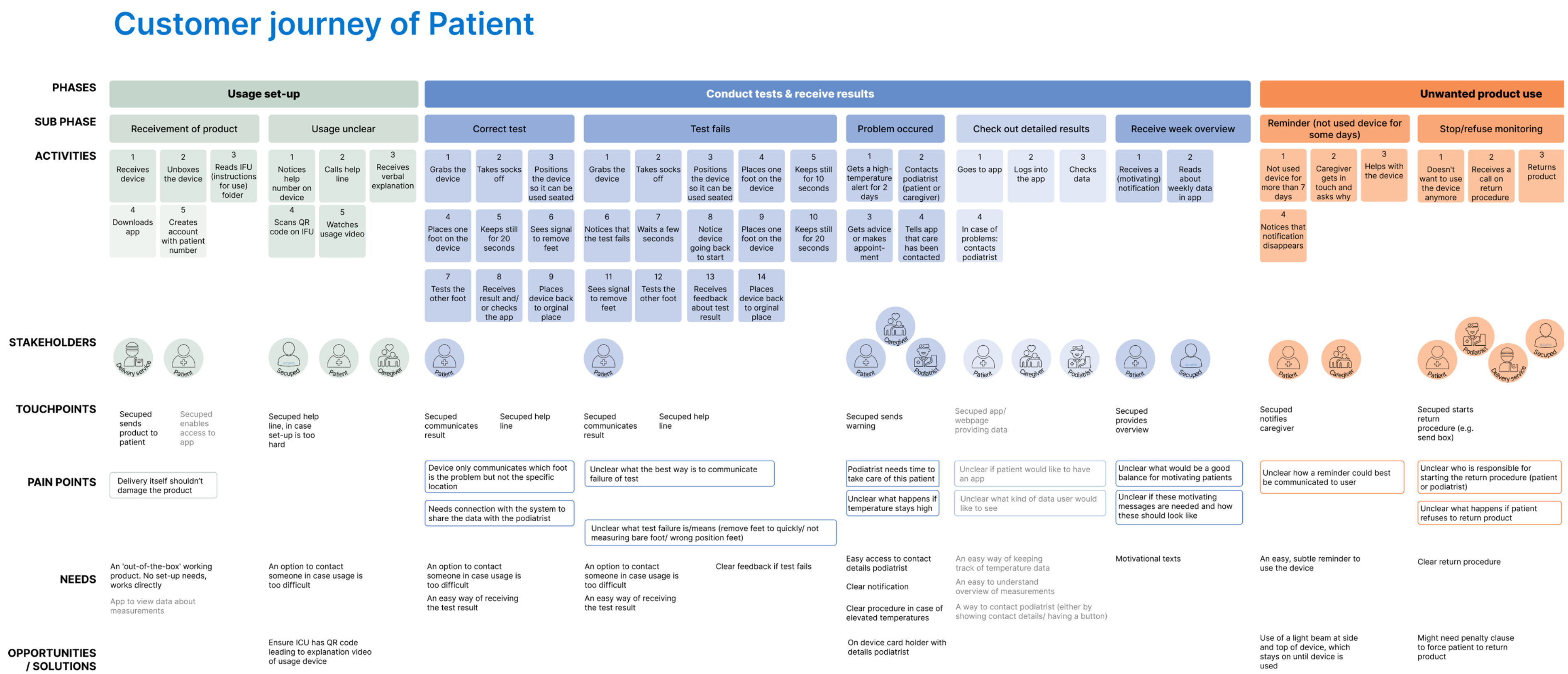
In app help Manual

- Wireless charging coils and magnets in the heels of the insoles.
- It takes 6 to 8 hours to charge when fully drained
- Every 2 weeks charging required. When more in interactive mode this can change to daily charging



Picture from Orpyx (2024)

Appendix D: Customer journeys



Maintenance (problems occur)

Device paused due to illness/ holidays
1. Rotates device
2. Clicks pause button
3. Receives pause message

1. Opens app
2. Goes to settings
3. Pauses device usage

Patient · Podiatrist · Secuped

Secuped receives paused message of user

When should Secuped undertake action after what amount of time

Clear 'pause' procedure

Empty battery
1. Gets low-battery alert (2 weeks ahead)
2. Moves device to outlet
3. Plugs in power supply
4. Gets full-battery alert
5. Unplugs power supply
6. Returns device to original spot

Patient · Caregiver

Secuped sends empty battery signal to caregiver?

Special (not standard USB-c) charging cable required to meet medical regulations

Unclear how long charging time is

A clear on time indication battery is running empty

Clear feedback when battery is charged

Cleaning of device
1. Takes the device to the kitchen
2. Wipes surface with a damp cloth

Patient · Caregiver

Unclear if unclean surface matters for test accuracy

Unclear when you need to clean

Requires splashproof device

Requires easy to reach surfaces

Charging cable lost
1. Reports lost cable to Secuped via service call
2. Pays a fee and receives a new cable

Patient · Delivery service · Caregiver · Secuped

Secuped provides new cable

Unclear what procedure would be, who pays for lost cable

A cable that is difficult to lose

A clear procedure in case a cable is lost

Use the same principle as a vacuum cleaner, so cable is attached to device itself

Device breaks down
1. Gets alert of potential device malfunction
2. Rotates device and presses reset button
3. Not working? calls Secuped
4. Explains problems
5. Gets return box for broken device
6. Mails return box

Patient · Secuped

Secuped service line

Unclear if the app, ICU, and device together are sufficient locations to communicate the service number

Unclear what is meant with a defect

A clear protocol in case of device failure

Device communicates to Secuped that there might be a problem and Secuped contacts patient to arrange a solution

Device starts updating
1. Wants to use the device
2. Receives updating notification

Patient · Secuped

Secuped pushes update to the device

Unclear whether updating from a distance is permitted within Secuped's system

A system that allows updating from a distance

Data not sent
1. User receives test result
2. Receives 'not sent' message
3. After 3 days receives 'contact supplier'

Patient · Secuped

Connection to Secuped's system failed/ rejected

Unclear what 'not sent' message means

Interaction with care

Visit podiatrist
1. Enters podiatrist office
2. Receives physical examination
3. Receives advice what to do next
4. Stops usage product?

Patient · Podiatrist

Unclear if user can continue usage product and how is dealt with alerts

Clear procedure about product usage after elevated temperatures

Return device

Contact Secuped
1. Calls Secuped for return device
2. Gets return request confirmat ion

Patient · Secuped

Secuped arranges return

Unclear how return confirmation is given

Clear procedure for return

Return device
1. Gathers all components
2. Puts all components into the return box
3. Brings to post service

Patient · Delivery service

Clear procedure for return

Customer journey of Secuped

PHASES	Device delivery		Support and maintenance (problems occur)			Arrange return		
SUB PHASE	Receive application	Send device	Provide help (e.g. set-up, problem monitoring, cable lost)	Arrange solution in case of product breakdown	Update the device	Send return box	Disconnect patient from device	Device isn't returned by user
ACTIVITIES	1 Gets completed application form 2 Registers patient in system 3 Connects specific device to patient 4 Sets product language	1 Packs device into box 2 Prints label and attaches it to box 3 Hands over to delivery service	1 Receives call from patient 2 Provides necessary support	1 Receives call from patient 2 Concludes product is broken 3 Connects new device to patient 4 Sends new device as well as a return box	1 Sends out updates to all devices	1 Retrieves patient details 2 Prints label 3 Brings return box to delivery point	1 Receives device 2 Enters device number in system 3 Disconnects patient from device 4 Stores patient data	1 Gets alert: Patient didn't return for 2 weeks 2 Calls patient to explain penalty clause 3 Starts penalty procedure
STAKEHOLDERS	Podiatrist, Secuped	Delivery service, Secuped	Patient, Secuped	Patient, Secuped	Patient, Secuped, Podiatrist	Patient, Secuped, Delivery service	Patient, Secuped	Patient, Secuped
TOUCHPOINTS	Podiatrist provides required information		Patient receives needed help	Patient receives new product	Patient receives updates	Patient should have provided all neccessary data	Patient receives confirmation product has been received	Patient received a call to remember to return the product
PAIN POINTS	Unclear how device is exactly connected to the patient		Unclear how the help is provided (on the phone, someone visiting etc.)	For a short time two devices will be connected to the user	Unclear how update is transferred to all devices		Unclear how it is communicated to patient that the device has been received	Unclear how penalty clause could look like and how payment details patients are retrieved
NEEDS	A form providing all the neccessary information	A box that can easily be used for delivery	A clear help procedure	A clear failure procedure Possibility to connect another device to a patient	Possibility to push software updates to all devices at a certain time	Easy retrieval of patient data from system	Procedure to disconnect a patient and its data from the device	Penalty procedure
OPPORTUNITIES / SOLUTIONS								

Customer journey of Podiatrist

	Recommendation and explanation	Request device	Good monitoring, no warnings	Bad monitoring	Patient stops monitoring	Warning	Patient returns device	Product breaks at patient's house	Physical check of patient
PHASES	Prescription	Prescription	Monitoring by patient	Monitoring by patient	Monitoring by patient	Problems occur	Problems occur	Problems occur	Interaction with patient
SUB PHASE	Recommendation and explanation	Request device	Good monitoring, no warnings Note: podiatrist doesn't have to do anything unless (s)he wants to.	Bad monitoring	Patient stops monitoring	Warning	Patient returns device	Product breaks at patient's house	Physical check of patient
ACTIVITIES	1 Suggests temperature monitoring 2 Grabs demo model 3 Asks patient to remove both socks 4 Positions patient's foot on device 5 Explains to sit still for 20 seconds 6 Allows patient to test both feet 7 Shows and explains app to patient 8 Requests consent to share patient data 9 Provides IFU folder to patient	1 Opens application form on website 2 Enters required details 3 Sends application form	1 Searches for patient dossier 2 Looks at data sent by Secuped	1 Gets alert patient hasn't used device for 7 days 2 Contacts patient to ask about it	1 Gets alert patient stopped measuring 2 Arranges return of device	1 Gets high-temperature warning after 4 days 2 Contacts patient 3 Opens data report of patient 4 Requests more details, like photos 5 Gives advice what to do 6 Notify system about care contact	1 Gets alert: Patient has returned device	1 Learns from patient that product is broken 2 Calls Secuped and request new device	1 Opens patient data 2 Conducts physical examination 3 Gives advice to patient what to do 4 Notify system about podiatrist visit
STAKEHOLDERS	Patient, Podiatrist	Podiatrist, Secuped	Podiatrist	Patient, Podiatrist, Secuped	Patient, Podiatrist	Patient, Podiatrist, Secuped	Podiatrist	Patient, Podiatrist, Secuped	Patient, Podiatrist, Secuped
TOUCHPOINTS		Application form positioned on Secuped website Service to call for more consultation or questions about application	Secuped makes sure latest data is pushed into dossier	Secuped sends notification of bad monitoring	Secuped provides necessary forms to apply for return	Secuped sends alert for elevated temperature monitoring Secuped provides report with relevant data	Secuped sends notification to inform podiatrist	Contact with service line Secuped	Secuped provides report with relevant data
PAIN POINTS	Need to ask permission from patient to share data with Secuped Unclear how interaction with the app can be explained to patient Not guaranteed that podiatrist takes time to explain usage product	Unclear what kind of information is needed from podiatrist to set-up system	Unclear how Secuped can push data into patient dossier	Unclear when notification should be send to podiatrist Unclear how podiatrist should act upon this notification	Unclear who arranges return	In case podiatrist is absent, another podiatrist should take over Podiatrist needs to have time to do these prevent check-ups inbetween	Unclear if this can happen without podiatrist knowing	Unclear if Secuped will immediately send a new product or if service will be provided at home	Unclear what kind of data the podiatrist would like to see at this moment
NEEDS	Some kind of training for podiatrist Explanation folder for user, ideally with QR code to get access to usage video	Simple request procedure of the device	Simple access to data of patient at any time	A notification that user isn't monitoring	Clear return procedure	A notification that user has elevated temperatures	A notification to tell podiatrist patient has returned product	A number that can be called in case of problems	A clear summary of relevant data for accurate diagnosis
OPPORTUNITIES / SOLUTIONS	Provide podiatrists with a demo model				Return form on Secuped website			Provide a 'common problems' manual	

Appendix E: Patient interview materials

Questions

Vooraf aan interview

Introductie
Wie zijn wij: Secuped, 5 klinische studies, temperatuur monitoring, handtemperatuur meten.
Wat is het doel: Inzicht krijgen waar deze doelgroep behoefte aan heeft wat betreft de interactie met het product.
Tekenen van toestemmingsformulier

Inleidende vragen:
V 0.1: Wat is uw leeftijd?
V 0.2: Welk type diabetes heeft u en hoelang al?
V 0.3: Heeft u al eens een ulcus gehad? Indien ja, kunt u hier iets over vertellen? Over uw ervaringen en wat dit met u deed?
Wat kan u dan wel en niet?
Hoe is u dag anders dan normaal?
Krijgt u ondersteuning en zo ja welke (partner, familie, gemeente)?
Hoeveel uur is dit in de week (schatting)?
Blijft u ondersteuning gebruiken ook toen de ulcus weg was? zo ja welke en hoeveel?
V 0.4: Heeft u een podotherapeut? Hoe vaak ziet u deze persoon?
V 0.5: Weet u hoe u contact met deze persoon kan opnemen als er iets met uw voeten is? Hoe?
V 0.6: Heeft u momenteel een smartphone of tablet?
V 0.7: Gebruikt u weleens email?
V 0.8: Ziet u het zitten eventueel uw schoenen uit te doen?

Uitleg context:
Stelt u zich voor dat u een verhoogd risico heeft op ulcus. Uw podotherapeut heeft u aangeraden om voortaan uw temperatuur te gaan meten van uw voet. Als u dit namelijk zou doen kunt u voordat er iets zichtbaar is op de huid al zien dat er mogelijk een ulcus aankomt. Omdat het vrij lastig kan zijn de temperatuur onder uw voet te meten, zijn wij bezig met de ontwikkeling van een apparaat dat hierbij kan helpen. Het meet op bepaalde plekken van uw voet de temperatuur en vertelt u wanneer het niet goed gaat met uw voet.

Dit is ongeveer hoe het gebruik eruit kan zien (user journey laten zien). Uw podotherapeut adviseert dit product te gaan gebruiken. Later krijgt u het product thuis opgestuurd en gaat u het gebruiken. Ik hoop er nu met u stap voor stap door heen te gaan hoe dit eruit zou kunnen zien. We hopen met dit interview dat het duidelijker wordt hoe u dit apparaat zou willen gebruiken. Daarom willen we u vragen vooral hardop na te denken en te zeggen wat u denkt, want dat helpt ons met de ontwikkeling van dit product.

V 0.9: Wat is uw eerste indruk van dit product?

Start test:
Zoals uitgelegd zijn we bezig met de ontwikkeling van een mat die de temperatuur meet. Er is al een eerste prototype. Dit lijkt een beetje op een weegschaal waarop u uw voeten plaatst.
Ik ga nu een papier neerleggen. Hierop staat hoe u de voeten zou positioneren als u de mat zou gebruiken. Ik wil u vragen uw voeten in de vakken neer te zetten.
V1: De vraag is of u dit een comfortabele positie vindt? Ook als u in uw achterhoofd houdt dat dit de productgrootte beïnvloedt?
Leg een A3+ vel neer met hoe huidige prototype is.

V2: Als u iets zou mogen veranderen aan de positie wat zou dat zijn?
Hiervan foto's maken eventueel

We gaan nu verder met het gebruik van het product.

V3: U weet uiteraard momenteel nog niet hoe het product werkt. De vraag is hoe zou u dit willen leren. U kunt kiezen uit:
A. Een folder die gebruik uitlegt (Klein geprint foldertje)
B. Een kort filmpje die gebruik laat zien (Filmpje Tom)
C. Uw podotherapeut die het aan u uitlegt, ook al krijgt u wel later het product pas thuis
D. Of een familielid die het aan u uitlegt
E. Anders?
Zou u willen dat hierbij een familielid betrokken is?

Nu duidelijk is hoe u het product kan gebruiken, gaan we het product gebruiken. Er zijn twee opties hoe het product eruit kan zien. De eerste optie is dat het product beide voeten tegelijk meet, de tweede optie is dat eerst de ene voet en dan de andere voet gemeten wordt. We gaan beide nu even proberen.

Ik wil u vragen uw voet temperatuur te 'meten' door uw voeten op dit prototype te zetten. Dan mag u nu even 20 seconden wachten terwijl te test wordt uitgevoerd (geef aan wanneer 20 seconden voorbij zijn). Dan mag u nu uw voeten er weer afhalen.

We gaan hetzelfde nu doen met het één voet prototype. U mag u linker voet erop zetten en wederom 20 seconden wachten (aangeven wanneer 20 seconde voorbij zijn) en nu mag u uw rechtervoet erop zetten. Na 20 seconden mag u deze er weer afhalen.

V4: Welke van de twee opties heeft uw voorkeur? Zou u liever allebei tegelijk meten of één voet per keer? Waarom?

V5: Stel u heeft dit apparaat thuis staan en gebruikt het elke dag. Nu gaat u op vakantie, zou u het apparaat meenemen? Heeft deze situatie nog invloed op uw antwoord van de vorige vraag of welke van de twee opties uw voorkeur heeft?

Zoals uitgelegd, geeft het apparaat uw testresultaat weer.
V6: Stel u ontvangt een slecht resultaat, met wie zou u dan contact opnemen?
Voor de rest van de vragen gaan we het model met de twee voeten gebruiken. Ik wil u wederom vragen een test uit te gaan voeren. We willen namelijk u meerdere manieren laten zien hoe u uw test resultaat kan ontvangen en u vragen welke u voorkeur heeft.

U mag nog een keer uw voeten op het apparaat plaatsen en dan zal ik eerst verschillende manieren laten zien van een positieve uitslag ontvangen. Daarna zal ik hetzelfde doen voor een negatieve uitslag.

V7A: Welke manier van positief testresultaat ontvangen heeft uw voorkeur? Dit mag ook een combinatie zijn.
A. Resultaat op apparaat zelf (Papiertje met lampjes op apparaat leggen)
B. Geluidje laten horen (Positief geluid +stem vanaf telefoon afspelen)
C. SMSje sturen (Figma op telefoon maken waarop smsje binnen lijkt te komen)
D. App notificatie (Figma op telefoon maken waarop app notificatie binnenkomt)
E. Email ontvangen (Figma op tablet maken waarop mail binnen lijkt te komen)
F. U hoort niets als het goed is
G. Anders?

V7B: Welke manier van negatief testresultaat ontvangen heeft uw voorkeur? Dit mag ook een combinatie zijn.
A. Resultaat op apparaat zelf (Papiertje met lampjes op apparaat leggen)
B. Geluidje laten horen (Negatief geluid +stem vanaf telefoon afspelen)
C. SMSje sturen (Figma op telefoon maken waarop smsje binnen lijkt te komen)
D. App notificatie (Figma op telefoon maken waarop app notificatie binnenkomt)
E. Uw podotherapeut neemt contact met u op (Figma op telefoon waarop call binnenkomt)
F. Email ontvangen (Figma op tablet maken waarop mail binnen lijkt te komen)
G. Anders?
Ik heb dit nog niet uitgelegd, maar u moet meerdere dagen op rij een verhoogde temperatuur hebben voordat het als een risico gezien wordt. Soms kan het dat u eenmalig een hogere temperatuur heeft, maar dan hoeft dit nog niets te betekenen.

V8: Zou u al willen weten dat u een verhoogde temperatuur heeft ondanks dat dit de eerste dag is? Of zou u dit pas willen weten als er echt een risico is?

Stel u heeft een probleem met het apparaat. Het product geeft namelijk een foutmelding en u weet niet wat u nu moet doen. Dus u gaat hulp zoeken.
V9: Welke van de onderstaande manieren zou u het meeste aanspreken om hulp te zoeken?
A. Zelf contact opnemen (telefoonnummer Secuped op product plakken)
B. Hulp knop op apparaat en Secuped belt u (knopje uitprinten en erop plakken)
C. In de app contact opnemen (Geef een telefoon en laat Figma frames zien)
D. Via website contact opnemen (Geef een tablet en laat Figma frames zien)
E. Anders?

V10: Zou u zelf contact opnemen of iemand voor u laten bellen?

Inmiddels gebruikt u het product al een tijdje. Maar u bent wel benieuwd wat voor data er allemaal uit komt.

V11: De vraag is wat wilt u allemaal weten als u dit apparaat gebruikt?
Eerst open vraag stellen en daarna keuzeopties geven.

Gebruik van Figma ontwerp op tablet waarin knoppen naar verschillende type data leiden.
A. Alleen of mijn meetresultaat goed of fout is
B. De werkelijke temperatuur van mijn meting vanmorgen in mijn voet
C. De temperatuurverschillen in mijn voet
D. Alleen probleemgebied in voet zonder getallen
E. Overzicht hoeveel metingen u heeft gedaan afgelopen maand & dag
F. Anders?
V12: Hoe denkt u toegang te verkrijgen tot deze data?
A. Online via een portaal (Figma op tablet)
B. Via email (Figma op tablet)
C. In app (Figma op telefoon)
D. In tekstbericht (Figma op telefoon)
E. Anders?

V13: Wanneer zou u toegang tot deze data willen en hoe vaak zou u het bekijken?

V14: Hoe gaat deze informatie u helpen in uw dagelijkse leven?
Eventuele opties:
A. Deze informatie geeft mij meer vertrouwen, vermindert angst en onzekerheid
B. Deze informatie geeft mij duidelijke feedback of ik goed bezig ben
C. Deze informatie helpt mij om een goed gesprek met de podotherapeut te kunnen voeren
D. Deze informatie helpt mij om meer gemotiveerd te worden om goed voor mijn voeten te zorgen

Inmiddels zijn we bijna aan het eind van de gebruik test gekomen. Hierna zullen nog een aantal afrondende vragen volgen.
Wat nog een belangrijke onderdeel van het gebruik is, is wat er gebeurt als u vergeet een meting te verrichten. Er zijn een aantal opties uitgewerkt:

V15: Welke manier van helpen herinneren zou u het beste helpen?
A. Een herinnering op het apparaat zelf d.m.v. licht (Zaklampje aan zijkant vastmaken en laten schijnen)
B. Een herinnering op het apparaat zelf d.m.v. geluid (Geluidje afspelen)
C. Melding ontvangen op digitaal device (Telefoon of tablet met Figma-->melding)
D. Gebeld worden door zorgverlener (Figma frame met call, naam zoon/ podotherapeut, mantelzorger)
E. Anders?

V16: Wat zou u er van vinden als wij, als Secuped, u hierover bellen?

V17: Dit apparaat zou u elke dag gaan gebruiken. Op ten duur gaat u dit misschien vergeten, wat zou u dan helpen? Heeft u voorbeelden hiervan?

Afrondende vragen:

V18: Zou u bereid zijn uw meetgegevens te delen met uw podotherapeut, waarom wel/niet?

V19: Heeft u een mantelzorger, wie is dit?
Indien ja: Ziet u voor u dat uw mantelzorger u zou helpen met het gebruik van dit product? Zou u deze persoon ook informeren over uw meetresultaten? dus vindt u het belangrijk dat uw mantelzorger weet als er iets mis is of u het product niet meer gebruikt?

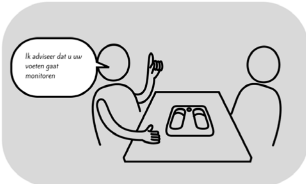
V20: Zou u er voor open staan om een telefoon/tablet/email aan te schaffen om dit product te kunnen gebruiken?

V21: Heeft u nog op en aanmerkingen? Dingen die u nog kwijt wilt?

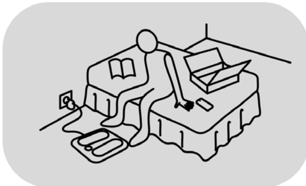
Additional materials

Komt van de huisarts

De podotherapeut adviseert

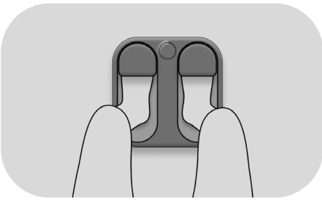


Eerste keer gebruik van apparaat

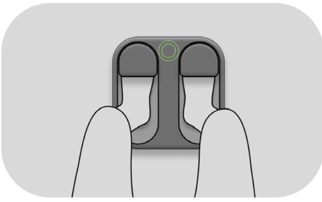


Start gebruik

Meten

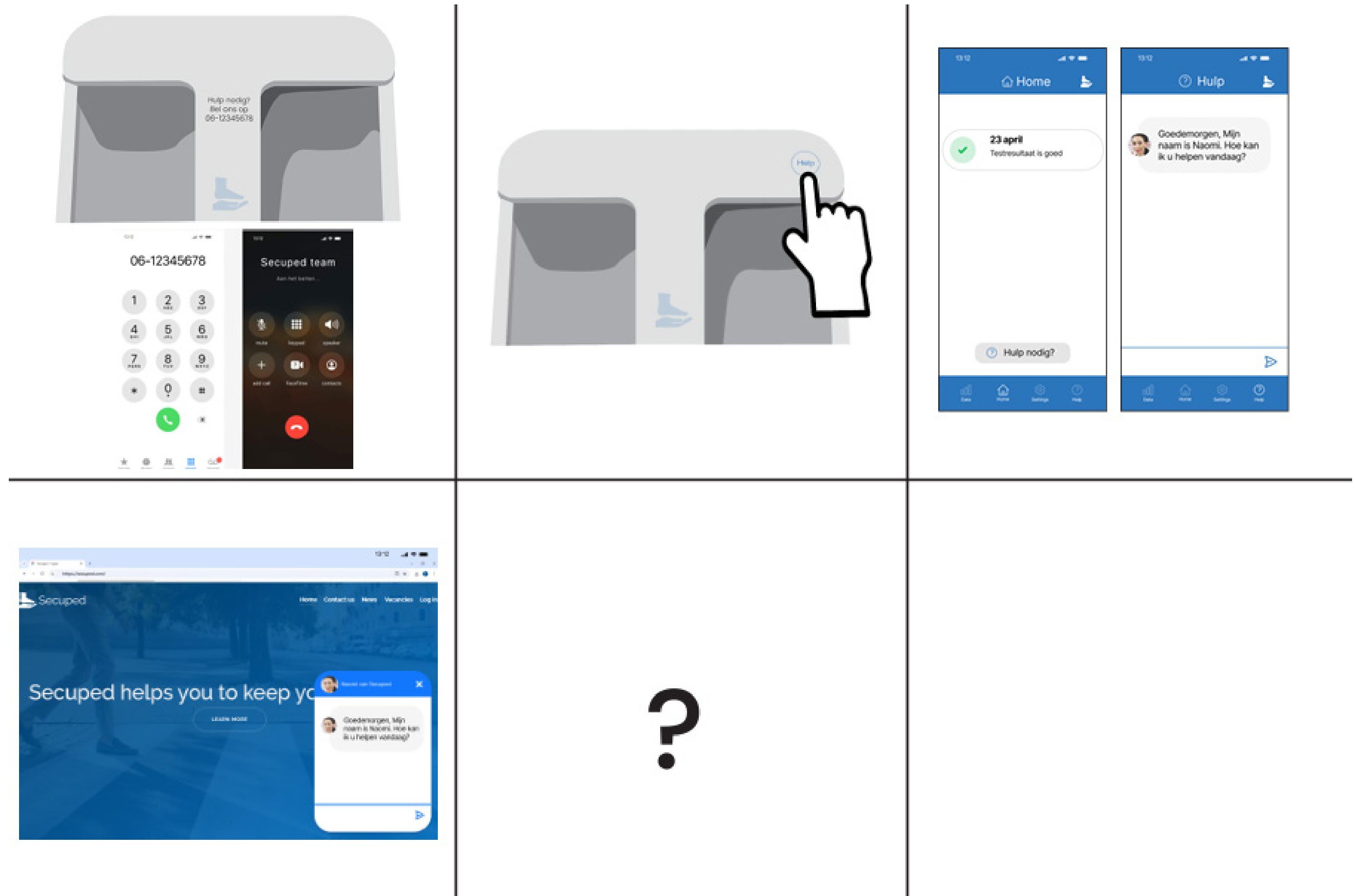


Klaar met meten



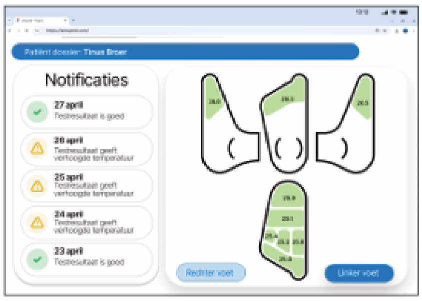
De 521e keer

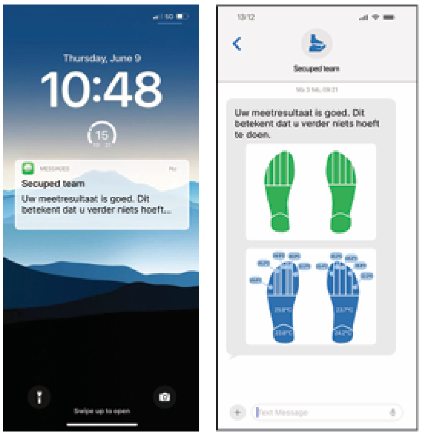
User journey was created by Tom Hinskens



Vraag 7

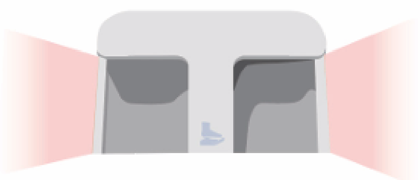
Vraag 8

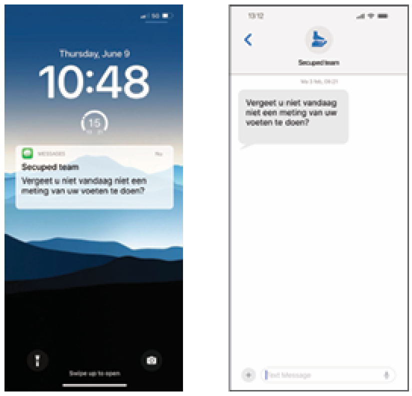




?

Vraag 9





?

Vraag 13

Appendix F: OLED vs. LED grid

In this appendix, more elaborate arguments are given for the decision between an OLED and an LED grid. When deciding between these options, cost is a key consideration. Higher production costs result in a higher product price, which may reduce the likelihood of the device being covered by health insurance. The primary argument for choosing an OLED screen is its ability to display icons more clearly. As a result, text orientation was not factored into the decision regarding OLED screen size.

To make an informed decision on pricing, it is advisable to contact various manufacturers for quotes. Nevertheless, a broader comparison of the general pros and cons of both options can also support the decision-making process. Carle (2025) created an overview of this, which is briefly summarized:

LED matrix grid

- (+) Durability and longevity, longer lifespan than OLED panels as they are less vulnerable to burn-in
- (+) Lower production costs as it uses simple technology and cheaper materials.
- (+) Higher brightness makes them better visible in environments with for instance sunlight.
- (+) A bit more energy efficient than an OLED, especially in well-lit environments as it doesn't require a lot more power. This isn't the case with OLED.
- (-) Poorer colour representation
- (-) Thicker designs in comparison with OLED

OLED

- (+) Vibrant colours and higher visual quality
- (+) Faster response time allowing the creation of animations
- (+) Ultrathin design possible
- (-) Burn-in when pictures are displayed for a considerable amount of time, some pixels degrade faster than others.
- (-) Higher manufacturing cost caused by using organic materials and the needed precision during the production process.
- (-) Lower peak brightness, making it harder to see outdoors or in well-lit rooms.

Appendix G: Font size decision and GFX font creation

Three options for the font were identified, based on what is already common for LED grids:

1. All capital letters, each 5 pixels wide.
2. Capitalised first letter only, with capitals at 5 pixels wide and lowercase letters at 4 pixels.
3. Custom font, using a standard width of 4 pixels for most capital letters, except for K, M, T, V, W, Y, and Z, which require 5 pixels due to their complexity. The letter I is only 3 pixels wide.

With the help of ChatGPT, these three options were analysed for each language (see figure below for an example table). The analysis showed that options 2 and 3 allowed for the effective display of all words within a 50-pixel width. As option 3 has more height than option 2 (using lowercase letters instead of capital letters), it was decided to go for option 3.

Creation GFX font

The GFX font uses certain numbers ranging from 32- 90. These are the ASCII classes and standards defined. This means that, for instance, always ASCII 48 is number 0, ASCII 49 is number 1 etc. Initially, only ASCII 48-90 was defined as these are the numbers 0-9 and all the capital letters A to Z. However, later on, there was the desire to add 'space' and 'percentage' signs, which formed ASCII class 32-47. Therefore, these classes have also been added, but only 'space' and 'percentage' were created. The other hex notations are placeholders in the code and should therefore not be used.

Word	Option 1	✅/❌	Option 2	✅/❌	Option 3	✅/❌
Schakelt	39	❌	36	❌	41	❌
in	11	✅	9	✅	8	✅
Gaat	23	✅	20	✅	20	✅
aan	17	✅	14	✅	14	✅
Welkom	35	❌	32	✅	32	✅
Goede	29	✅	26	✅	24	✅
morgen	38	❌	34	❌	30	✅
Linker	35	❌	31	✅	29	✅
voet	28	✅	24	✅	21	✅
Rechter	39	❌	35	❌	35	❌
Plaats	35	❌	32	✅	34	❌
opnieuw	39	❌	36	❌	34	❌
Start	29	✅	25	✅	25	✅
test	28	✅	24	✅	21	✅
Wissel	35	❌	31	✅	29	✅
Probeer	39	❌	35	❌	34	❌
Mislukt	39	❌	36	❌	36	❌
scan	28	✅	24	✅	20	✅
gelukt	35	❌	31	✅	31	✅
Resultaat	44	❌	40	❌	41	❌
meting	35	❌	31	✅	30	✅
Goed	23	✅	20	✅	19	✅
Fout	23	✅	20	✅	19	✅
Verhoging	44	❌	40	❌	41	❌
Verzenden	44	❌	40	❌	46	❌
mislukt	39	❌	35	❌	36	❌
Data	23	✅	20	✅	19	✅
verzonden	44	❌	40	❌	46	❌
Opgeslagen	49	❌	45	❌	49	❌
Updaten	39	❌	35	❌	34	❌
Even	23	✅	20	✅	19	✅
geduld	35	❌	31	✅	29	✅
Verbinden	44	❌	40	❌	45	❌
Batterij	44	❌	40	❌	39	❌
leeg	28	✅	24	✅	19	✅
Laad	23	✅	20	✅	19	✅
op	17	✅	14	✅	9	✅

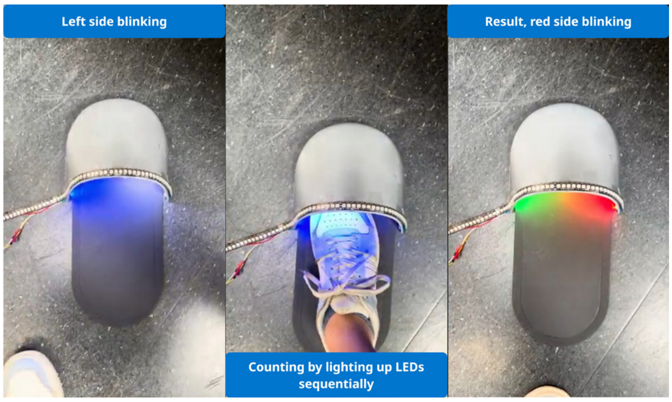
Appendix H: LED strip and display designs

The developed iterations are difficult to fully capture in this report or through images. The interactions are best demonstrated via video; therefore, below is a list of links to short videos showcasing the interactions.

LED strip only

In this design direction, the LED strip was used to indicate which foot the user should place, using blue blinking as a signal. As the LED strip consisted of 40 LEDs, each LED lit up sequentially to visualize progress. Problems with this design direction were that it heavily depended on colour usage, making it hard to use for colour-blind users. Especially communicating the result with red and green was challenging. To address this, the red indicator was made to blink, allowing even colour-blind users to distinguish the outcome through movement rather than colour alone (see Figure).

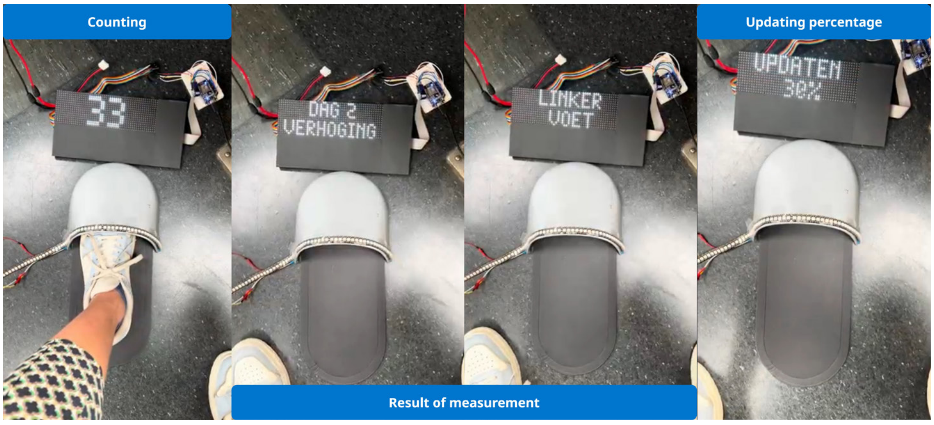
- Entire flow
- Battery empty
- Updating
- Product failure
- Not sent



Display only

This design direction focused on text and the custom-made font. The unique aspect of this design is the clear communication of results, such as 'Elevation day 2' and 'Left Foot'. A countdown timer was used to show measurement progress. In addition, this design direction also communicated the update status by means of a percentage (see Figure).

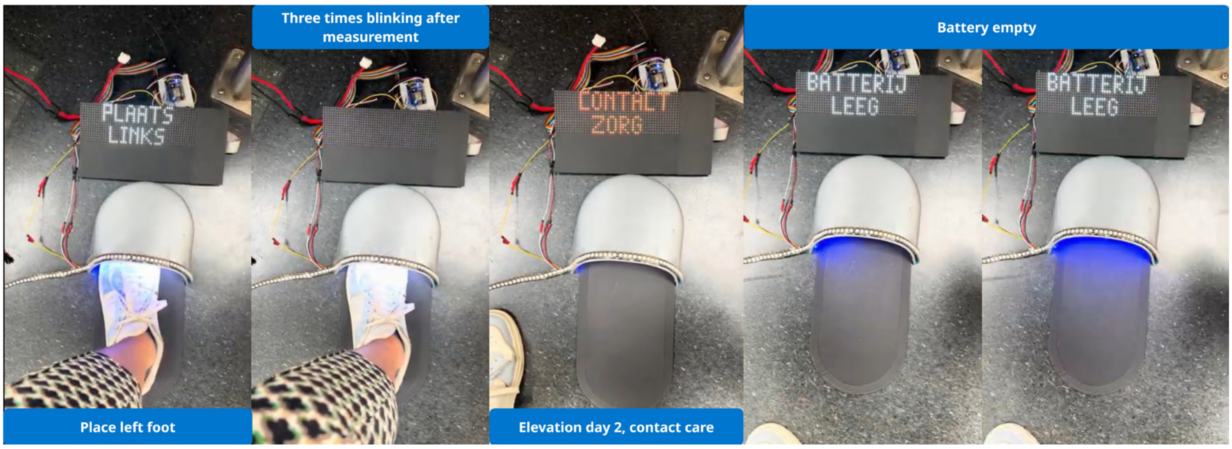
- Entire flow
- Battery empty
- Updating
- Product failure
- Not sent



Display (main) and LED strip

The LED strip is integrated to support the messages shown on the display. For example, it blinks three times to indicate that the user should remove their foot after the countdown finishes. This design also includes a red text prompting the user to contact care. Overall, it is a straightforward combination of the text-based design with the LED strip. For instance, during the empty battery interaction, the LED strip shows a pulsing light while the display reads “Battery empty” and “Recharge” (see Figure).

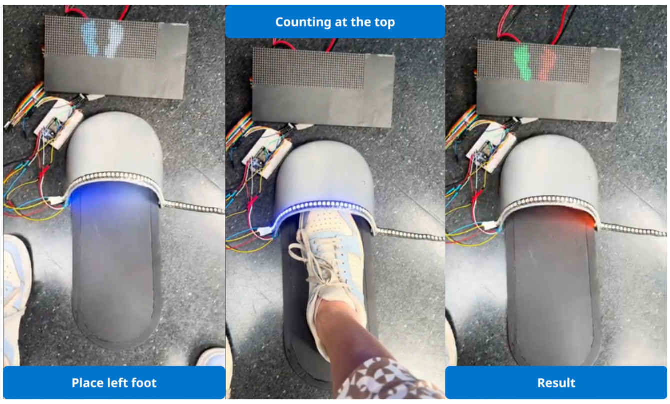
- Entire flow
- Battery empty
- Updating
- Product failure
- Not sent



LED strip (main) and display

For this design, the display primarily shows icons to support the LED strip interactions. An additional LED strip was added to the front to make the counting process more visible. During the result presentation, the display used the same colour as the LED strip for consistency (see Figure).

- Entire flow
- Battery empty
- Updating
- Product failure
- Not sent



Appendix I: Ethical Approval user tests

Date 02-Jun-2025
Correspondence hrec@tudelft.nl

TU Delft Delft University of Technology

Human Research Ethics
Committee TU Delft
(http://hrec.tudelft.nl)

Visiting address
Jaffalaan 5 (building 31)
2628 BX Delft

Postal address
P.O. Box 5015 2600 GA Delft
The Netherlands

Ethics Approval Application: Integrating preventive foot monitoring into daily life of diabetes patients and their healthcare professionals
Applicant: Breejen, Jannieke den

Dear Jannieke den Breejen,

It is a pleasure to inform you that your application mentioned above has been approved.

Thanks very much for your submission to the HREC which has been approved.

In addition to any specific conditions or notes, the HREC provides the following standard advice to all applicants:
• In light of recent tax changes, we advise that you confirm any proposed remuneration of research subjects with your faculty contract manager before going ahead.
• Please make sure when you carry out your research that you confirm contemporary covid protocols with your faculty HSE advisor, and that ongoing covid risks and precautions are flagged in the informed consent - with particular attention to this where there are physically vulnerable (eg: elderly or with underlying conditions) participants involved.
• Our default advice is not to publish transcripts or transcript summaries, but to retain these privately for specific purposes/checking; and if they are to be made public then only if fully anonymised and the transcript/summary itself approved by participants for specific purpose.
• Where there are collaborating (including funding) partners, appropriate formal agreements including clarity on responsibilities, including data ownership, responsibilities and access, should be in place and that relevant aspects of such agreements (such as access to raw or other data) are clear in the Informed Consent.

Good luck with your research!

Sincerely,

Dr. C. Shelley-Egan
Chair HREC
Faculty of Technology, Policy and Management

Appendix J: Consent form

Onderzoek naar integratie van preventieve voetzorg

U wordt uitgenodigd om deel te nemen aan een onderzoek genaamd Integratie van preventieve voetzorg in het dagelijkse leven van patiënten die met diabetes leven en hun Zorgnetwerk. Dit onderzoek wordt uitgevoerd door Jannieke den Breejen van de TU Delft samen met werknemers van de start-up Secuped.

Het doel van dit onderzoek is om een beter beeld te krijgen van hoe het nieuw te ontwikkelen product in het dagelijkse leven kan inpassen en zal ongeveer 30-60 minuten in beslag nemen. De data zal gebruikt worden voor de ontwikkeling van het product en zal gepubliceerd kunnen worden in de master scriptie die over dit onderwerp geschreven wordt.
U wordt gevraagd om diverse prototypes te proberen, waarna u gevraagd zal worden hoe u deze interacties heeft ervaren. Ook zullen er vragen gesteld worden over hoe u het gebruik van dit product in uw dagelijkse leven terug zou willen zien.

Zoals bij elke online activiteit is het risico van een databreuk aanwezig. Wij doen ons best om uw antwoorden vertrouwelijk te houden. We minimaliseren de risico's door alle gegevens anoniem te verzamelen. Alle data wordt wel opgeslagen tot het einde van de onderzoeksperiode of na publicatie van de master scriptie. Daarna zullen alle gegevens verwijderd worden. Als er eventueel foto's gemaakt worden zal u altijd anoniem in beeld worden gebracht of wordt u anoniem gemaakt. Uiteraard alleen als u hier toestemming voor heeft.

Uw deelname aan dit onderzoek is volledig vrijwillig, en u kunt zich elk moment terugtrekken zonder reden op te geven. U bent vrij om vragen niet te beantwoorden.

Mocht u later nog contact willen opnemen, kunt u dat doen met mij:

Jannieke den Breejen

j.m.denbreejen@student.tudelft.nl

Kruis de juiste vakjes aan	Ja	Nee
A: ALGEMENE OVEREENSTEMMING - ONDERZOEKSDOELEN, TAKEN VAN DEELNEMERS EN VRIJWILLIGE DEELNAME		
1. Ik heb de informatie over het onderzoek gedateerd [/ /] gelezen en begrepen, of deze is aan mij voorgelezen. Ik heb de mogelijkheid gehad om vragen te stellen over het onderzoek en mijn vragen zijn naar tevredenheid beantwoord.	☐	☐
2. Ik doe vrijwillig mee aan dit onderzoek, en ik begrijp dat ik kan weigeren vragen te beantwoorden en mij op elk moment kan terugtrekken uit de studie, zonder een reden op te hoeven geven.	☐	☐
3. Ik begrijp dat mijn deelname aan het onderzoek de volgende punten betekent • Dat indien nodig het gesprek wordt opgenomen (alleen audio) • Dat aantekeningen zullen worden gemaakt over de bevindingen • Dat audio recordings verwijderd zullen worden na publicatie van de scriptie of aan het einde van de onderzoeksperiode (afhankelijk van wat eerst komt) • Dat ik verschillende prototypes zal testen en daarover feedback zal geven • Dat ik meerdere vragen zal krijgen over hoe ik het gewenste gebruik van dit nieuwe product voor mij zie.	☐	☐
4. Ik begrijp dat mijn deelname aan het onderzoek als volgt wordt gecompenseerd, namelijk dat ik reiskostenvergoeding ontvang en een cadeaukaart als compensatie voor mijn tijd	☐	☐
5. Ik begrijp dat de studie na 30-60 min eindigt.		
B: MOGELIJKE RISICO'S VAN DEELNAME (INCLUSIEF GEGEVENSBESCHERMING)		
6. Ik begrijp dat mijn deelname de volgende risico's met zich meebrengt, namelijk dat de prototypes kunnen stoppen met werken of fysieke schade kunnen toebrengen door bijv. oververhitting van de elektronica. Ik begrijp dat deze risico's worden geminimaliseerd doordat ik altijd kan aangeven te willen stoppen met dit onderzoek en doordat het prototype een ingebouwde beveiliging tegen oververhitting heeft en geen scherpe randen bevat.	☐	☐
7. Ik begrijp dat mijn deelname betekent dat er persoonlijke identificeerbare informatie en onderzoeksdata worden verzameld, met het risico dat ik hieruit geïdentificeerd kan worden, maar dat de onderzoeker ten alle tijden de data anoniem zal maken om dit te voorkomen.	☐	☐
8. Ik begrijp dat binnen de Algemene verordering gegevensbescherming (AVG) een deel van deze persoonlijk identificeerbare onderzoeksdata als gevoelig wordt beschouwd, namelijk vragen die gaan over uw medische achtergrond wat betreft huidige voetzorg of cognitieve vaardigheden om huidige prototypes te kunnen gebruiken en begrijpen.	☐	☐

Kruis de juiste vakjes aan	Ja	Nee
9. Ik begrijp dat de volgende stappen worden ondernomen om het risico van een databreuk te minimaliseren, en dat mijn identiteit op de volgende manieren wordt beschermd in het geval van een databreuk: - Alle data wordt anoniem verzameld - In het geval van foto's of videos worden deze geblurred. - Audio opnames krijgen alleen dag/datum label en bevatten geen persoonlijke identificeerbare gegevens.	☐	☐
10. Ik begrijp dat het onderzoek wordt uitgevoerd door TU Delft in samenwerking met medewerkers van de start-up Secuped. Medewerkers van Secuped en TU Delft die direct betrokken zijn bij het onderzoek krijgen toegang tot geanonimiseerde onderzoeksdata voor de ontwikkeling van het product. Zij krijgen geen toegang tot persoonlijke identificeerbare informatie zoals naam, contactgegevens of medische gegevens.	☐	☐
11. Ik begrijp dat de persoonlijke data die over mij verzameld wordt, vernietigd wordt op aan het einde van dit onderzoekstraject of na publicatie van master scriptie.	☐	☐
C: PUBLICATIE, VERSPREIDING EN TOEPASSING VAN ONDERZOEK		
12. Ik begrijp dat na het onderzoek de geanonimiseerde informatie gebruikt zal worden voor de ontwikkelingen van het te ontwerpen product en uiteindelijk terecht kunnen komen in een master scriptie of masterpresentatie. Ook kan de informatie gebruikt worden voor het maken van een nieuwe iteratie van het product of voor het aantrekken van nieuwe investeerders. Hiervoor zullen nooit foto's gebruikt worden waarin deelnemers te identificeren zijn.	☐	☐
13. Ik geef toestemming om mijn antwoorden, ideeën of andere bijdrages anoniem te quoten in resulterende producten.	☐	☐
D: (LANGDURIGE) OPSLAG, TOEGANG EN HERGEBRUIK VAN GEGEVENS		
14. Ik geef toestemming om de geanonimiseerde data, zoals uitspraken die ik heb gedaan, die over mij verzameld worden gearchiveerd worden in drive en deze gebruikt kunnen worden voor toekomstig onderzoek, maar zullen worden verwijderd zodra de onderzoeksperiode is afgelopen.	☐	☐

Signatures

__________________________ _______________________ ____________

Naam deelnemer Handtekening Datum

Ik, **de wettelijke vertegenwoordiger**, verklaar dat de informatie en het instemmingsformulier aan de potentiële deelnemer correct zijn voorgelezen, en dat hij/zij de kans heeft gekregen om vragen te stellen. Ik verklaar dat de potentiële deelnemer zijn/haar instemming vrijwillig heeft gegeven.

______________________________	__________________________	__________
Naam wettelijke vertegenwoordiger	Handtekening	Datum

Ik, **de onderzoeker**, verklaar dat ik de informatie en het instemmingsformulier correct aan de potentiële deelnemer heb voorgelezen en, naar het beste van mijn vermogen, heb verzekerd dat de deelnemer begrijpt waar hij/zij vrijwillig mee instemt.

___________________________	____________________	_________
Naam onderzoeker	Handtekening	Datum

Contactgegevens van de onderzoeker voor verdere informatie: [Naam, telefoonnummer, emailadres]

Appendix K: Izi house interview set-up

Vooraf aan interview

Introductie
Wie zijn wij
Wat is het doel: achterhalen welke van de twee concepten het beste werkt en waar de voorkeur naar uit gaat. Daarbij ook onderzoeken of de digitale omgeving duidelijk genoeg is of dat daarin nog dingen ontbreken.
Tekenen van toestemmingsformulier

Inleidende vragen:
V 0.1: Wat is uw leeftijd?
V 0.2: Heeft u momenteel een telefoon of tablet?
V 0.3: Hoe vaak gebruikt u deze?
V 0.4: Ziet u het zitten uw schoenen uit te doen?

Uitleg context:
Stelt u zich voor dat u diabetes heeft. Hierdoor verliest u het gevoel in uw voeten, waardoor u niet meer goed kan voelen wanneer er bijvoorbeeld een steentje in uw schoenen zit. U loopt hier vervolgens de hele dag op waardoor er een voetzweer (ulcer) ontstaat. Door uw diabetes is de bloedtoevoer in uw benen beperkter geworden en dit wordt dus niet eenvoudig meer opgelost. Bovendien voelt u helemaal niets in uw voeten, dus u heeft geen enkel idee dat dit aan het ontstaan is. De ontwikkeling waar wij mee bezig zijn is om dit probleem te voorkomen. Het apparaat meet de temperatuur onder de voet en de zijkanten waardoor het kan zien dat er mogelijk een voetzweer aankomt. Dit komt doordat de temperatuur op die locatie 2.2 graden of meer hoger wordt in vergelijking met uw andere voet.

De ontwikkeling van dit product loopt nog, maar we proberen het ook zo gebruiksvriendelijk te maken. Daarom wil ik u vragen twee concepten met een interactie te testen. Dit prototype meet niet echt de temperatuur onder uw voet maar is vooral bedoeld om te kijken of u begrijpt hoe het product werkt. Verder kunt u de resultaten ook nog bekijken in een digitale omgeving die u later ook nog getoond zal worden.

Start test:
Dit is het huidige prototype. U moet u voorstellen dat u dit product eens per dag zal moeten gebruiken zodat het ook effect zal hebben. Verder zou u in het echt het apparaat met blote voeten moeten gebruiken, dit hoeft voor nu niet.
V1: Waar hier in de IZI woning zal u dit product neerzetten?

Ik ga u nu twee interacties laten zien. Aan het einde ga ik u vragen welke uw voorkeur heeft. De ene zal gebruik maken van tekst en de ander van icoontjes. Houd u in uw achterhoofd dat u dit product dag in dag uit zal gaan gebruiken voor misschien wel meerdere jaren.

Concept 1 (tekst):
Dit is de variant met tekst. Ik wil u vragen de stappen te volgen die op het scherm staat. Als u het niet zeker weet stel vooral vragen en denk hardop wat u gek vindt of niet begrijpt.
Laat hele interactie zien.

V2: Vond u dit duidelijk? Wat was er nog onduidelijk?
V3: Begreep u het resultaat?
V4: Kan u het goed lezen?
V5: Vond u dat er dingen inzaten die niet nodig zijn? Dus overbodig zijn?
Nu gaan we nog een keer een stukje doen. U mag wederom uw linkervoet erop zetten, maar als hij aftelt wil ik u vragen uw voet weg te trekken. Daarna mag u het nog eens proberen.
V6: Vond u dit duidelijk? Begreep u wat u moest doen? Was er een moment dat u twijfelde of u het wel goed deed?

Dit was de belangrijkste interactie. Ik zal u nu nog een aantal kleine interacties laten zien. Daarbij is vooral de vraag of u dit duidelijk genoeg vindt. De eerste situatie is dat u het product wil gaan gebruiken maar er is een probleem mee:
Laat State 3 zien
Of de batterij is bijna leeg. Als u dan klaar bent met meten komt dit nog kort op het scherm:
Laat State 4 zien
Als laatste kan het dat u het product wil gaan gebruiken maar deze is aan het updaten. U komt dan aan en het volgende wordt getoond:
Laat State 5 zien

V7: Waren er nog dingen onduidelijk voor deze kleine interacties?

Concept 2 (Icon):
Dit is de variant met icoontjes. Ik wil u vragen de stappen op het scherm te volgen. Als u dingen niet begrijpt laat het vooral weten. Probeer hardop na te denken.
Laat hele interactie zien

V8: Vond u dit duidelijk? Wat was er nog onduidelijk?
V9: Begreep u het resultaat?
V10: Kan u het goed lezen?
V11: Vond u dat er dingen inzaten die niet nodig zijn? Dus overbodig zijn?

Nu gaan we nog een keer een stukje doen. U mag wederom uw linkervoet erop zetten, maar als hij aftelt wil ik u vragen uw voet weg te trekken. Daarna mag u het nog eens proberen.
V12: Vond u dit duidelijk? Begreep u wat u moest doen? Was er een moment dat u twijfelde of u het wel goed deed?

Dit was de belangrijkste interactie. Ik zal u nu nog een aantal kleine interacties laten zien. Daarbij is vooral de vraag of u dit duidelijk genoeg vindt. De eerste situatie is dat u het product wil gaan gebruiken maar er is een probleem mee:
Laat State 3 zien
Of de batterij is bijna leeg. Als u dan klaar bent met meten komt dit nog kort op het scherm:
Laat State 4 zien
Als laatste kan het dat u het product wil gaan gebruiken maar deze is aan het updaten. U komt dan aan en het volgende wordt getoond:
Laat State 5 zien

V13: Waren er nog dingen onduidelijk voor deze kleine interacties?
Vragen over beide concepten:
Dit waren de beide concepten. De verschillen zijn dus erg klein alleen de manier van presentatie is anders.
V14: Naar welk concept zal uw voorkeur uitgaan? De variant met tekst of met icoontjes? waarom?
V15: Zou u nog iets aan het ontwerp veranderen?
V15: Wat vindt u er van dat eerst de ene voet getest wordt en dan de andere?
V16: Hoe makkelijk of moeilijk vindt u dit apparaat om te gebruiken?

Digitale omgeving:
Er is ook nog een digitale omgeving gemaakt waarin testresultaten worden getoond. Hierin kunt u nog meer details vinden. Het is in de vorm van een app waarin de data getoond wordt. Ik zal u een paar kleine opdrachtjes geven om u kennis te laten maken met de app. Daarna zal ik nog wat afsluitende vragen stellen. Laat het vooral weten als u iets niet duidelijk vindt, te klein, te groot etc.

O1: Bekijk het overzicht van de zijkant grote teen op groot scherm.
O2: Bekijk de metingen data. Hierin kunt u zien wanneer u gemeten hebt en het resultaat goed of fout was.
O3: Ga een maand terug in de tijd en klik op 9 april
O4: Klik weer op de homepagina
O5: Ga nu naar data tab. Gisteren had u een verhoging bekijk deze.
O6: Als u nu teruggaat naar ‘vandaag’ bent u wel benieuwd wat de temperatuur in uw grote teen was.
O7: Bekijk alle waardes
O8: Bekijk alleen de verschillen
O9: Bekijk de tab product
O10: Bekijk de tab settings

Nu kan er ook de situatie zijn dat u zojuist voor de tweede dag op rij een verhoging gemeten heeft. U moet dan contact opnemen met een zorgverlener om dit te laten checken. Als u na deze meting de app erbij pakt ziet deze er als volgt uit.
O11: Geef aan dat u nog niet gebeld heeft.
O12: Geef aan dat u al wel gebeld heeft.

Dat was het. Nog wat afrondende vragen.
V17: Wat vond u van deze omgeving? Zijn er dingen onduidelijk? mist u nog dingen?
V18: Vond u het groot genoeg, kon u het goed lezen?
V19: Vond u dit een toevoeging op het apparaat of zou voor u het apparaat alleen ook genoeg zijn?
V20: Ziet u zichzelf dit product in het dagelijks leven gebruiken? Waarom wel of niet?

Eventueel nog:
V21: Wat zou voor u de grootste reden zijn om dit niet te gebruiken?
V22: Wat zou voor u de grootste reden zijn om dit wel te gebruiken?

Appendix L: Patients interview set-up

Vooraf aan interview

Introductie
Wie zijn wij
Wat is het doel: achterhalen welke van de twee concepten het beste werkt en waar de voorkeur naar uit gaat. Daarbij ook onderzoeken of de digitale omgeving duidelijk genoeg is of dat daarin nog dingen ontbreken.
Tekenen van toestemmingsformulier

Inleidende vragen:
V 0.1: Welk type diabetes heeft u en voor hoe lang al?
V 0.1b: Heeft u ulcers gehad in het verleden?
V 0.2: Heeft u momenteel een telefoon of een tablet?
V 0.3: Hoe vaak gebruikt u deze?
V 0.4: Ziet u het zitten uw schoenen uit te doen?

Uitleg context:
Stelt u zich voor dat u diabetes heeft. Hierdoor verliest u het gevoel in uw voeten, waardoor u niet meer goed kan voelen wanneer er bijvoorbeeld een steentje in uw schoenen zit. U loopt hier vervolgens de hele dag op waardoor er een voetzweer (ulcer) ontstaat. Door uw diabetes is de bloedtoevoer in uw benen beperkter geworden en dit wordt dus niet eenvoudig meer opgelost. Bovendien voelt u helemaal niets in uw voeten, dus u heeft geen enkel idee dat dit aan het ontstaan is. De ontwikkeling waar wij mee bezig zijn is om dit probleem te voorkomen. Het apparaat meet de temperatuur onder de voet en de zijkanten waardoor het kan zien dat er mogelijk een voetzweer aankomt. Dit komt doordat de temperatuur op die locatie 2.2 graden of meer hoger wordt in vergelijking met uw andere voet.

De ontwikkeling van dit product loopt nog, maar we proberen het ook zo gebruiksvriendelijk te maken. Daarom wil ik u vragen twee concepten met een interactie te testen. Dit prototype meet niet echt de temperatuur onder uw voet maar is vooral bedoeld om te kijken of u begrijpt hoe het product werkt. Verder kunt u de resultaten ook nog bekijken in een digitale omgeving die u later ook nog getoond zal worden.

Start test:
Dit is het huidige prototype. U moet u voorstellen dat u dit product eens per dag zal moeten gebruiken zodat het ook effect zal hebben. Verder zou u in het echt het apparaat met blote voeten moeten gebruiken, dit hoeft voor nu niet.
Ik ga u nu twee interacties laten zien. Aan het einde ga ik u vragen welke uw voorkeur heeft. De ene zal gebruik maken van tekst en de ander van icoontjes. Houd u in uw achterhoofd dat u dit product dag in dag uit zal gaan gebruiken voor misschien wel meerdere jaren.
Als eerste zou ik even willen testen of het lukt met het correct plaatsen van uw voet. De ervaring leert dat dat soms lastig is met dit prototype dus dit wil ik eerst los even oefenen.

Concept 1 (tekst):
Dit is de variant met tekst. Ik wil u vragen de stappen te volgen die op het scherm staat. Als u het niet zeker weet stel vooral vragen en denk hardop wat u gek vindt of niet begrijpt.
Laat hele interactie zien.

V1: Vond u dit duidelijk? Wat was er nog onduidelijk?
V2: Begreep u het resultaat?
V3: Wat vind u er van dat uw uitslag getoond wordt? Verhoging vs risico?
V4: Kan u het goed lezen?
V5: Vond u dat er dingen inzaten die niet nodig zijn? Dus overbodig zijn?

Nu gaan we nog een keer een stukje doen. U mag wederom uw linkervoet erop zetten, maar als hij aftelt wil ik u vragen uw voet weg te trekken. Daarna mag u het nog eens proberen.
V6: Vond u dit duidelijk? Begreep u wat u moest doen? Was er een moment dat u twijfelde of u het wel goed deed?
Dit was de belangrijkste interactie. Ik zal u nu nog een aantal kleine interacties laten zien. Daarbij is vooral de vraag of u dit duidelijk genoeg vindt. De eerste situatie is dat u het product wil gaan gebruiken maar er is een probleem mee:
Laat State 3 zien
Of de batterij is bijna leeg. Als u dan klaar bent met meten komt dit nog kort op het scherm:
Laat State 4 zien

Als laatste kan het dat u het product wil gaan gebruiken maar deze is aan het updaten. U komt dan aan en het volgende wordt getoond:
Laat State 5 zien

V7: Waren er nog dingen onduidelijk over deze kleine interacties?

Concept 2 (Icon):
Dit is de variant met icoontjes. Ik wil u vragen de stappen op het scherm te volgen. Als u dingen niet begrijpt laat het vooral weten. Probeer hardop na te denken.
Laat hele interactie zien

V8: Vond u dit duidelijk? Wat was er nog onduidelijk?
V9: Begreep u het resultaat?
V10: Kan u het goed lezen?
V11: Vond u dat er dingen inzaten die niet nodig zijn? Dus overbodig zijn?

Nu gaan we nog een keer een stukje doen. U mag wederom uw linkervoet erop zetten, maar als hij aftelt wil ik u vragen uw voet weg te trekken. Daarna mag u het nog eens proberen.
V12: Vond u dit duidelijk? Begreep u wat u moest doen? Was er een moment dat u twijfelde of u het wel goed deed?

Dit was de belangrijkste interactie. Ik zal u nu nog een aantal kleine interacties laten zien. Daarbij is vooral de vraag of u dit duidelijk genoeg vindt. De eerste situatie is dat u het product wil gaan gebruiken maar er is een probleem mee:
Laat State 3 zien
Of de batterij is bijna leeg. Als u dan klaar bent met meten komt dit nog kort op het scherm:
Laat State 4 zien
Als laatste kan het dat u het product wil gaan gebruiken maar deze is aan het updaten. U komt dan aan en het volgende wordt getoond:
Laat State 5 zien

V13: Waren er nog dingen onduidelijk over deze kleine interacties?

Vragen over beide concepten:
Dit waren de beide concepten. De verschillen zijn dus erg klein alleen de manier van presentatie is anders.
V14: Naar welk concept zal uw voorkeur uitgaan? De variant met tekst of met icoontjes? waarom?
V15: Zou u nog iets aan het ontwerp veranderen?
V15: Wat vindt u er van dat eerst de ene voet getest wordt en dan de andere?
V16: Hoe makkelijk of moeilijk vindt u dit apparaat om te gebruiken?
V17: Zou u zelf actie ondernemen als het apparaat aangeeft contact met de zorg op te nemen? En met wie zou dit dan zijn?
V18: Wat vind u van het gebruik van licht? Ziet u dit als toegevoegde waarde?
V19: Zou u aan dit ontwerp nog geluid toevoegen? Waarom wel/waarom niet?
V20: Ziet u zichzelf dit apparaat elke dag gebruiken? Waarom wel/niet?
V21: Zou u dit apparaat meenemen op vakantie?

Digitale omgeving:
Er is ook nog een digitale omgeving gemaakt waarin testresultaten worden getoond. Hierin kunt u nog meer details vinden. Het is in de vorm van een app waarin de data getoond wordt. Ik zal u een paar kleine opdrachtjes geven om u kennis te laten maken met de app. Daarna zal ik nog wat afsluitende vragen stellen. Laat het vooral weten als u iets niet duidelijk vindt, te klein, te groot etc.

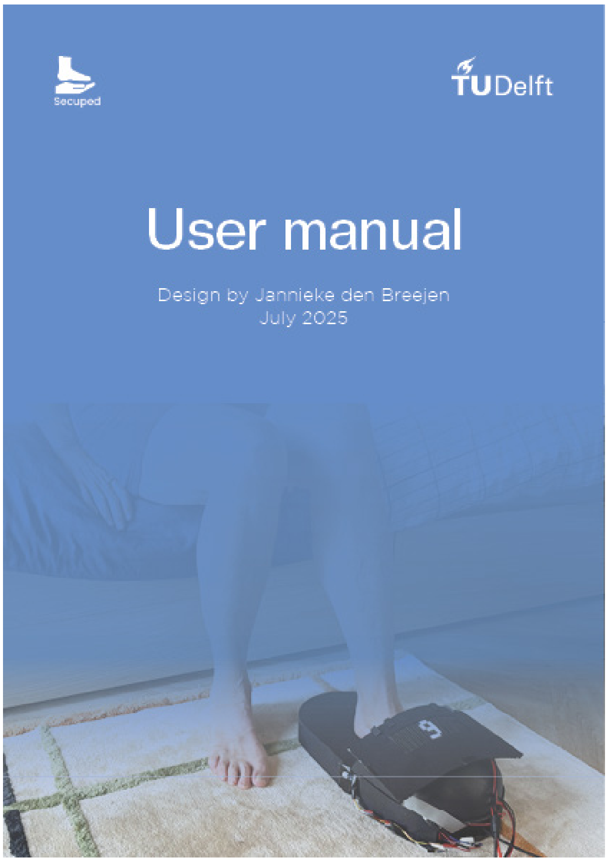
O1: Bekijk het overzicht van de zijkant grote teen op groot scherm.
O2: Bekijk de metingen data. Hierin kunt u zien wanneer u gemeten hebt en het resultaat goed of fout was.
O3: Ga een maand terug in de tijd en klik op 9 april
O4: Klik weer op de homepagina
O5: Ga nu naar data tab. Gisteren had u een verhoging bekijk deze.
O6: Als u nu teruggaat naar ‘vandaag’ bent u wel benieuwd wat de temperatuur in uw grote teen was.
O7: Bekijk alle waardes
O8: Bekijk alleen de verschillen
O9: Bekijk de tab product
O10: Bekijk de tab settings

Nu kan er ook de situatie zijn dat u zojuist voor de tweede dag op rij een verhoging gemeten heeft. U moet dan contact opnemen met een zorgverlener om dit te laten checken. Als u na deze meting de app erbij pakt ziet deze er als volgt uit.
O11: Geef aan dat u nog niet gebeld heeft.
O12: Geef aan dat u al wel gebeld heeft.

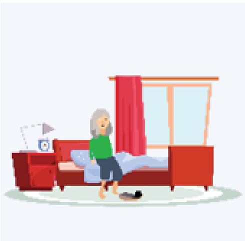
Dat was het. Nog wat afrondende vragen.
V22: Wat vond u van deze omgeving? Zijn er dingen onduidelijk? mist u nog dingen?
V23: Vond u het groot genoeg, kon u het goed lezen?
V24: Vond u dit een toevoeging op het apparaat of zou voor u het apparaat alleen ook genoeg zijn?
V25: Ziet u zichzelf deze digitale omgeving in het dagelijks leven gebruiken? Waarom wel of niet?
V26: Zou u meldingen willen ontvangen van deze omgeving? bijv. om te herinneren van gebruik naast de implementatie van het lampje. Waarom wel waarom niet?

Eventueel nog:
V27: Wat zou voor u de grootste reden zijn om dit niet te gebruiken?
V28: Wat zou voor u de grootste reden zijn om dit wel te gebruiken?

Appendix M: Possible design manual



Normal use



1. Start your day

After waking up, pick up the device straight away. Moving it will automatically wake it up and get it ready to use.

2. Place your left foot

Place your left foot on the device.

3. Adjust your position

If it's not positioned correctly, you'll receive feedback.

4. Test begins

Once your foot is correctly placed, the test will begin automatically.

5. Stay still

Wait while the countdown runs. Keep your foot still throughout the test.

6. Test fails when foot is moved

If you move your foot, a warning will appear. In that case, remove your foot and try again with the same foot.

7. Test is done

Once the first test is complete, remove your left foot.

8. Place your right foot

Now, place your right foot on the device.

9. Test begins

If it's correctly placed, the countdown will start.

10. Wait for the countdown

Again, keep still to avoid triggering a warning. If that happens, remove your foot and try again.

11. Test is done

Once the second test is finished, remove your foot and wait a few seconds.

12. Wait for the result

Your results will appear automatically on the screen.

Understanding your results

No elevation

No elevation

Everything looks good, there's no elevation detected in your feet.

One-day elevation

One-day elevation

An elevation was measured. The device tells you which foot.

One-day elevation

It is the first day.

Measure again tomorrow

Please measure again tomorrow.

Measure again tomorrow

It could be that nothing is wrong, this sometimes happens.

Two-day elevation

Two-Day Elevation

Again an elevation was measured.

Two-Day Elevation

This has been for two days in a row.

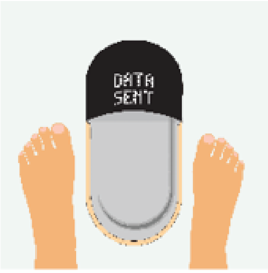
Contact care

Please contact your podiatrist, GP, or whoever you normally talk to about your feet.
Don't delay.

Contact care

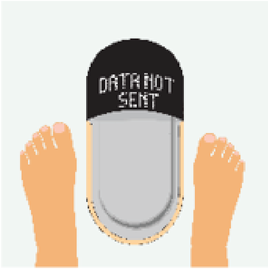
Try to do this the same day!

Data messages



13. Data sent

Your data has been successfully shared with your healthcare provider. You can now view it in the app.



13. Data not sent

The device isn't connected to the system right now. Don't worry, it will keep trying to send your data. The data might not appear in the app yet.

Contact supplier

If the data hasn't been sent after 2 days, the device will notify you. In that case, please contact the supplier: 06-12345678.

14. Test finished

When everything is done, the device will automatically turn off.

Other messages and issues

Product failure

Something went wrong

If the device displays an error and doesn't start, something may be wrong.

Contact supplier

Please contact the supplier for support: 06-12345678.

Battery low

Battery running low

If the battery is running low, you'll see a message after your test.

Recharge

Please recharge the device as soon as possible.

Updating

Device is updating

Occasionally, the device may update itself , usually overnight. If you try to use it during an update, it will let you know. Just wait a little while and try again later.