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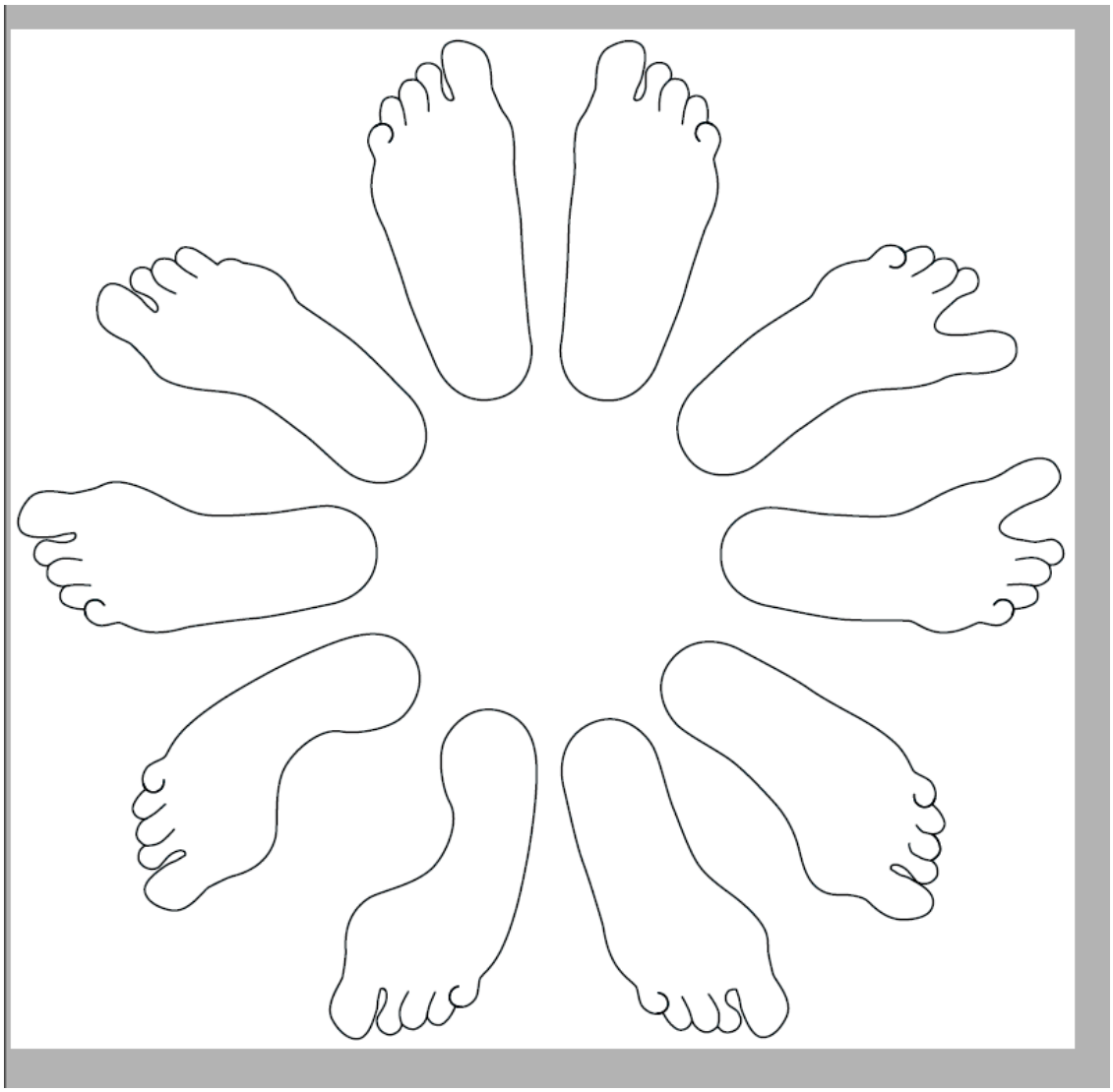

The design and usability of an eHealth demonstrator aimed to facilitate the prevention and care of persons with diabetes at risk to develop diabetic foot ulcers

Master's thesis in Biomedical Engineering

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DEPARTMENT OF ELECTRICAL ENGINEERING

CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2023
www.chalmers.se

Master's thesis 2023

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Cover: A visualization of human foot indicating the concept of the project work .

Typeset in LaTeX
Printed by Chalmers Reproservice
Gothenburg, Sweden 2023

The design and usability of an eHealth demonstrator aimed to facilitate the prevention and care of persons with diabetes at risk to develop diabetic foot ulcers
Foot assessment for persons with diabetes
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Abstract

INTRODUCTION: Diabetic Foot Ulcer (DFU), is one of the most serious complications of Diabetes mellitus, as it may result in major problems in the patient's life, for instance, amputation, organ damage, and death. One of the main reasons for this complication is the inability to diagnose the ulcer before it becomes worse. Hence, work is carried out in the Swedish healthcare region, Västra GötalandsRegionen, (VGR), in an attempt to, assess the risk (according to a risk scale) of the patient with diabetes to develop DFU. This assessment will be accomplished via an e-health tool, a mobile application to be used by district nurses when consulting a patient for a foot examination. Today the foot examination has no digital support, and there is a need for a smooth mobile tool that can help document the examination "foot-side", when and where the examination is carried out.
AIM: The aims were both to create and test a demonstrator of a digitalized process that will support healthcare professionals to make a structured foot examination in patients with diabetes.
METHODS AND MATERIALS: The demonstrator for the application was iteratively designed using a user-centered development approach and software, FIGMA. The demonstrator's efficiency and effectiveness were measured by performing an onsite usability test in VGR by nine healthcare professionals. In parallel with the usability test, a user satisfaction questionnaire, called System Usability Scale, (SUS), was used twice. First to measure the test participants' expectations before using the demonstrator, and later to measure their satisfaction with the usability of the demonstrator. Answers were gathered regarding the test participants' current experience of working with foot examinations, with or without digital support, as well as suggestions for improvements to the design.
RESULTS: Based on national clinical guidelines, regarding how to identify risk factors to develop DFU, an eHealth demonstrator was conceptually designed and validated. The demonstrator contained three modules: education, examination, and documentation. The demonstrator was designed in FIGMA, and formatively assessed on tablets by healthcare professionals, simulating an ordinary foot examination. Analyzing the individual results, 4 of 9 participants assessed, their satisfaction with the demonstrator was higher than their expectations. For both the expectancy score and the satisfaction score, mean (77;69) and median (77.5;70) values are within the "Acceptability ranges" (65-75; 75-100), when compared to SUS scores in general.
CONCLUSION: The study investigated the potential and benefit of applying digital support to be used by healthcare professionals when performing a structured foot examination. The study also investigated the benefits of promoting and disseminat-

ing such knowledge in a clinical context through the realization of a demonstrator, which was assessed by potential future users. In summary, 1) By testing a demonstrator via usability tests and questionnaires, we learned more about the digital support an app could provide in a real world setting and also, preferences required in future designs, as expressed by the test participants. 2) A novel, "dual use" of the SUS questionnaire was created. By comparing the users' expectations regarding the use of the demonstrator with their satisfaction of using the demonstrator, similarities or differences are revealed. Although there is a need for further methods' research of using SUS in a pre-test situation to gather expectations, this contribution to research is a novel take on one of the most well known and spread usability questionnaires.
The HCPs performing the tests also suggested improvements in the design of the demonstrator which will be considered for future development.

Keywords: DFU, usability test, user-centered design, System Usability Scale, expectation analysis, System Usability Scale Score

Acknowledgements

I may be the author of this thesis, but that does not mean I did it alone. I must firstly thank my supervisors throughout this project, Ulla Hellstrand Tang (Orthopedic technologist,Sahlgrenska University) and Isabella Scandurra (Assistant Professor, Health Informatics, School of Business, Örebro University). Without your guidance and pep-talks, this project would not have been possible. I sincerely appreciate your help with constructive ideas through weekly meetings for inspiring and valuable discussions. I would like to extend my gratitude to my examiner Stefan Candefjord (Assistant Professor, Health Informatics,Chalmers University of Technology) for guiding me through the process of this work.
I will also not miss the opportunity to thank all my new friends that I have met during my studies at Chalmers, for all their support throughout my studies.
And last but not least, I want to thank my family for supporting and believing in me throughout the years. I could never have done this without you.

Shivani Ravichandran, Gothenburg, February 2023

List of Acronyms

Below is the list of acronyms that have been used throughout this thesis listed in alphabetical order:

DFU	Diabetic Foot Ulcer
HCP	Healthcare Professional
app	Application
SUS	System Usability Scale
CPO	Certified Prosthetist and Orthotist
NDR	Swedish National Diabetes Register
DFE	Digital Foot Examination
VGR	Västra GötalandsRegionen
HIS	Health Information System
IT	Information Technology
UX	User Experience
UCD	User-Centered Design

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1
Introduction

Diabetic Foot Ulcer (DFU), a serious complication of diabetes can result in amputation [13]. The main reason for DFU is the delay in the diagnosis of the ulcer at the early stages. A consequence of delayed DFU diagnoses is that treatment also is delayed or even absent[42]. To facilitate the detection of early signs of DFU temperature monitoring has been tested[43]. In a study by Bus, an at-home-infrared thermometer was used to measure the temperature on the foot sole. Although the at-home foot temperature monitoring method was useful, the authors found a decrease in ambulatory activities, was needed to reduce the incidence of DFU as compared with a group not being advised to reduce activities when signs of DFU appeared. Daily inspections of the foot are recommended for persons with diabetes with the purpose of early detection if scars, pressure areas, or signs of DFU appear[44]. There is a lack of tools supporting patients and health care professionals (HCP) for early detection of risk factors to develop DFU. If signs are present, immediately contact health care professionals (HCP).
HCP should make an annual structured foot assessment of all patients with diabetes[13] and based on foot status rapidly initiate the recommended treatment e.g. podiatry, assessment to therapeutic footwear, and in the presence of DFU, to be referred to a multidisciplinary team.

1.1 Diabetes

Diabetes mellitus, generally termed diabetes, is a metabolic disease diagnosed in people who have elevated glucose levels in their blood[1]. The hormone insulin secreted by the pancreas converts the stored glucose to a certain form of energy, which is then used by the body. This insulin may be secreted in less quantity or the secreted insulin may not be used completely by the body for conversion, which leads to the glucose level in the blood getting heightened. Medical treatment, diet, and physical activity are components of the treatment of diabetes.

1.2 Etiology

The etiology of diabetic foot ulcers (DFU) depends on various factors. There are three important origins in developing DFU namely peripheral neuropathy, peripheral vascular disease, and foot deformities. Contributing causes for DFU are also the use of improper footwear and inability to self-care the feet, irritation due to friction or pressure, calluses, or dry skin.

People who have diabetes for the long term may eventually develop sensory neuropathy[16], a condition of reduced or complete loss of nervous sensation or extreme sensations in the feet. Other symptoms of neuropathy are dry skin due to autonomic neuropathy, and motor neuropathy leading to muscle imbalance and foot deformities[17]. Nerve damage can lead to sensory loss and no or limited ability to feel the pain in the feet. The development of DFU is associated with many risk factors with a great variety e.g. gender, age, duration of diabetes for longer than 10 years, high body mass index (BMI), and may also be accompanied by some other medical conditions like retinopathy, poor glycemic control, heart and kidney diseases[45].

1.3 Epidemiology

The annual incidence of DFU worldwide ranges between 9.1 to 26.1 million people[2]. If DFU is left untreated it is a risk that infection occurs and the condition might escalate to amputation and death. The prevalence of diabetes globally is 537 million[1]. In Sweden, 500 000 persons are diagnosed with diabetes[46]. Nearly 15% to 25% of people with diabetes are at risk to develop DFU[2]. DFUs affect a patient's life and decrease the quality of life[4, 5] and might lead to further complications such as amputation[8, 11].

1.4 Pathophysiology

Diabetic foot ulcers are developed in a step-by-step process. Prevention of ulcers is important for the patient in concern[13]. Initially, the skin is intact, but there will be spots in the foot with elevated pressure which is a high indication for the DFU to form. Often these spots are seen as calluses.
Already in 1989, the World Health Organisation set a goal to halve the prevalence of amputation among patients with diabetes[12]. The goal is yet not reached and efforts are needed to diagnose, prevent and treat the DFUs at the right time[13]. It is crucial to have a system to facilitate the prevention of developing DFU.

1.5 The need for eHealth as a tool in Diabetes care

The world is digitalized in many disciplines, like banking, education, industry, food supply, etc. Even in the field of healthcare, there are many digital applications(apps) that assist healthcare professionals (HCPs) as well as patients in their routines. When information technology (IT) is used in the healthcare domain, the terminology used is Health Information System (HIS) or more commonly eHealth[49]. It is defined as comprising all computer-based components which are used to enter, store, process, communicate, and present health-related or patient-related information, and which are used by healthcare professionals or the patients themselves in the context of inpatient or outpatient patient care. This definition includes e.g. documentation systems, decision support systems, archiving systems, healthcare

management systems, operational planning systems, report writing systems, general practitioner systems, and telemedical systems which are based on IT solutions[49]. eHealth systems may also help the patients e.g. in the self-management of disease. Some of the applications are accessed by both patients and healthcare providers, where the patients, e.g. take the tests (if the daily examination is necessary) and update their data in the app which is then cross-checked by the nurses or doctors. On their side, they may feed new instructions in the app. This limits the daily visit of patients to the hospital, although the healthcare providers are in continuous contact with the patient and their medical condition. If any readings give an abnormal result, the app alerts both the patient and the healthcare provider by which essential steps can be taken quickly[47]. These applications are available for conditions such as heart disease, obesity, Parkinson's, diabetes, and many more[47].
As more thoroughly described in the A FootSnap, DFUAPP, MyFootCare, The Risk Tool, and more, are some of the mobile apps under research across the world, whereas Glucose buddy, Dbees, mDiab, and NexJ Health Coach are some of the mobile applications which are practiced by patients to self-manage diabetes. Diabetic foot and shoe, Diabetic foot screening for patients, and SoPeD are some of the applications which are used for the self-management of DFU [18]-[31].
The focus of these applications is to help patients with DFU to treat the problem after they are diagnosed with DFU by instructing them to follow certain exercises, alarm notifications to have foot care, a healthy diet, and so on. But to date, there is, to our knowledge, no application available for healthcare professionals to diagnose the onset of DFU. Hence, in this work, we have created a demonstrator for an application that will be used by nurses, podiatrists, or physicians to make a structured foot assessment, a risk stratification of the foot, and give a result stating under which risk category the patient falls in developing DFU with the aim to start proper interventions earlier.

1.6 Aim

The aim of this thesis work was to create and evaluate an eHealth demonstrator that assists healthcare workers in performing a digital foot examination following national clinical guidelines and diagnosing the risk category under which the patient falls in order to treat them accordingly.

1.6.1 Research Questions

- How should a novel eHealth demonstrator be designed to capture and support the workflow in diabetes foot care?
- Is the demonstrator working the way it is expected to satisfy and potentially support its users in real work?
- In what way do the Usability testing, SUS pre-and post-test questionnaires help in improving the design of the demonstrator, and later, the application that will be built?

2

Theory and previous research

This chapter contains an overview of usability evaluations and the selected theoretical framework. The theory is linked with previous research on users' experiences and opinions of using digital tools in healthcare, as well as testing prototypes using a usability lab method and SUS questionnaires.

2.1 Human-Computer Interaction (HCI)

Human-Computer Interaction (HCI) is about designing computer-based systems that help mankind to execute an activity in a highly productive and safe manner[40]. It is a multidisciplinary field of study focusing on the design of computer technology and the interaction between humans (the users) and computers[37]. While initially, in the 1980s, concerned with computers[50], HCI has since expanded to cover almost all forms of information technology design. The definition of HCI is

Human-computer interaction is a discipline concerned with the design, evaluation, and implementation of interactive computing systems for human use and with the study of major phenomena surrounding them[50]

From its origin, HCI has expanded to incorporate multiple disciplines, such as computer science, cognitive science, and human-factors engineering[37]. With the rise of technologies such as the Internet and the smartphone, computer use would increasingly move away from the desktop to embrace the mobile world. Also, HCI has steadily encompassed more fields:

"... it no longer makes sense to regard HCI as a specialty of computer science; HCI has grown to be broader, larger, and much more diverse than computer science itself. HCI expanded from its initial focus on individual and generic user behavior to include social and organizational computing, accessibility for the elderly, the cognitively and physically impaired, all people, and for the widest possible spectrum of human experiences and activities. It expanded from desktop office applications to include games, learning and education, commerce, health and medical applications, emergency planning and response, and systems to support collaboration and community. It expanded from early graphical user interfaces to include myriad interaction techniques and devices, multi-modal interactions, tool support for model-based user interface specification, and a host of emerging ubiquitous, handheld, and context-aware interactions."

— John M. Carroll, author and a founder of the field of human-computer interaction.[37]

Today HCI plays a vital role in the development of any IT system and website[40],

also within the domain of healthcare.

2.1.1 Interaction design, user experience, and usability

HCI is the foundation of research fields like interaction design, user experience (UX) design, and usability, all concerning aspects of how a user interface or system is perceived by the users.
UX stands for **user experience** and is a field within interaction design. It is defined as the perceptions and reactions of users resulting from the use or expected use of a system, product, or service (ISO, 2018)[51]. Arvola (2020) writes that UX includes several areas such as feelings, beliefs, preferences, perceptions, physical and psychological reactions, behaviors, and performances that occur before, during, and after use[52]. UX is thus not only linked to human interaction with computers or an interface but goes beyond including several parameters that influence the user experience, such as aspects of branding, physical design, usability, and function. It's a story that begins before the device is even in the users' hands[37].

"No product is an island. A product is more than the product. It is a cohesive, integrated set of experiences. Think through all of the stages of a product or service – from initial intentions through final reflections, from the first usage to help, service, and maintenance. Make them all work together seamlessly."
— Don Norman, inventor of the term "User Experience."[37]

Usability is a commonly used word in development and design. Rubin[53](2008)has described usability and explains that a product or service is useful when "the user can do what he or she wants to do the way he or she expects to be able to do it, without hindrance, hesitation, or questions" (p.4)[53]. Georgsson & Staggers (2016)[54] explain how usability can be tested by using ISO 9241-11 [51], which describes how users should interact with a system to test usability. ISO (International Organisation for Standardization) defines usability as:

"the effectiveness, efficiency, and satisfaction with which specified users can achieve specified goals in a specified context of use" ISO 9241-11 (2018)[51]

A common way to test usability is to record users performing representative tasks by looking at the three aspects together:

1. *Effectiveness*: The extent to which a user can achieve a goal based on accuracy and completeness.
2. *Efficiency*: the level of effort and resources expended required for the user to achieve a goal relative to accuracy and completeness.
3. *Satisfaction*: The positive associations and the lack of negative experiences during the use of the system, e.g. comfort and acceptability of the system to its users.

If these aspects are met, the system can be seen as having an acceptable level of usability[54]. Don Norman coined the term **user experience** because he felt that the terms *interface and usability* were too narrow.UX encompasses all aspects of a person's experience with a system, it includes industrial design, graphics, interfaces, physical interaction and manuals[**52**], and it also includes the expectations that future users may have on a system, making this term relevant for this thesis.

2.1.2 User-centered design and evaluation

User-centered design is an iterative process where you take an understanding of the users and their context as a starting point for all design and development[48]and[59]. For the computer-based system to be widely accepted and used effectively, "User-centered" designing of the system is essential[55], where

Design is based upon an explicit understanding of users, tasks, and environments; is driven and refined by user-centered evaluation; and addresses the whole user experience. The process involves users throughout the design and development process and it is iterative.[37]

This system should be designed for the needs and capabilities of the people for whom they are intended and with an understanding that people with specific tasks in mind, will want to use them in a way that is seamless with respect to their work. Systems designers must be able to translate their understanding of future users' tasks into an operational system. This may be done using the User-centered design (UCD) process, and its four phases[56].

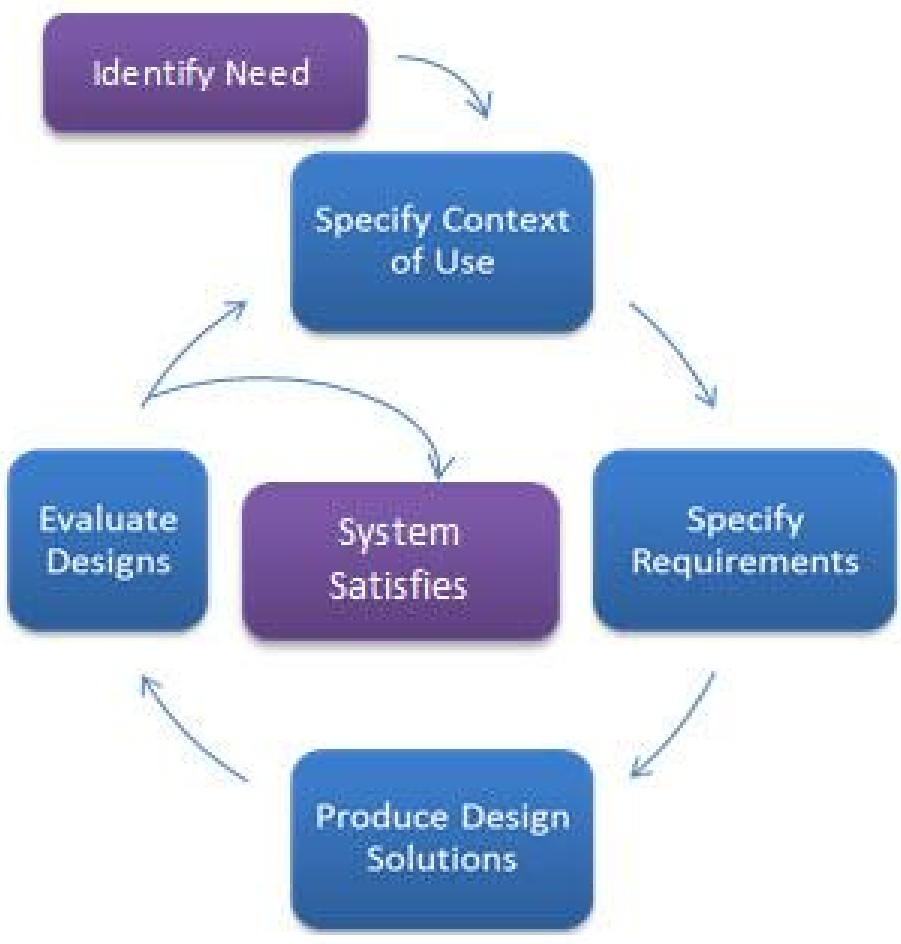


Figure 2.1: The User-centered design process (ISO 9241-210:2019)[56]

The following are the general phases of the UCD process, which were adhered during

the design of the demonstrator:

- Specify the context of use: Identify the people who will use the product, what they will use it for, and under what conditions they will use it.
- Specify requirements: Identify any business requirements or user goals that must be met for the product to be successful.
- Create design solutions: This part of the process may be done in stages, building from a rough concept to a complete design.
- Evaluate designs: Evaluation - ideally through usability testing with actual users - is as integral as quality testing is to good software development[55]

User-centered design has become an important concept in the design of interactive systems. It is primarily concerned with the design of sociotechnical systems that take into account not only their users but also the use of technologies in users' everyday activities, it can be thought of as the design of spaces for human communications and interaction[41, 57]

2.2 Usability Evaluation methods

There are several ways to evaluate and improve the usability of systems and interfaces. Usability evaluations are either designed as formative (constructive) or summative, with the designation depending on when the evaluation is employed during the development process[58]. Usability evaluations are used by companies and developers during and after the development of systems to improve the profitability and quality of systems, ultimately providing users with a better experience[53]. Here, the focus will be on the formative aspects of an evaluation, as the target for the usability evaluation in this thesis is located in the first iteration of the development process of a future tool that healthcare professionals will use. The term of usability testing is often used a bit carelessly to refer to several methods for evaluating or testing a product[53]. But the purpose should be clear:

The purpose of a usability evaluation is to find (potential) usability problems that users encounter in "real use" (i.e. in the actual work context) and that affect the efficiency, effectiveness, and satisfaction with which a user adopts a product, or in this case a health information system[59]

Two common types of methods of usability evaluation are **user testing (or usability testing)** and **expert evaluation**. Deciding on a type of evaluation depends on several factors such as cost, purpose, effectiveness, and accuracy[53].

Usability testing refers to evaluating a product or service by testing it with representative users. During a test, people act as users who are supposed to represent an imagined target group for the specific system. They perform tasks to be evaluated to see if the specific service or product meets selected usability requirements, while observers watch, listen, and take notes. The goal is to identify any usability problem, collect qualitative and quantitative data, and determine the participant's satisfaction with the product[55].

The second type of method is called **expert evaluations**, and it includes e.g. heuristic evaluation as a type of evaluation. It does not include ordinary people who act as users, but in this method, usability experts are used who proceeds from selected heuristics, or guidelines, when evaluating services and products[55]. The expert

evaluation will not be considered in this thesis, instead, we have run a usability test, in a constructive manner trying to get the following benefits:

- The design and development team may identify problems before they are coded. The earlier issues are identified and fixed, the less expensive the fixes will be in terms of both staff time and possible impact on the schedule[55]

During a usability test (at an early stage), you will:

- Learn if participants are able to complete specified tasks successfully
- Identify how long it takes to complete specified tasks
- Find out how satisfied participants are with the product or service
- Identify changes required to improve user performance and satisfaction
- Analyze the performance to see if it meets your usability objectives[55]

As long as there is a goal for conducting a usability test, there is no need for a formal usability lab to get valuable results. Also if the usability testing takes place in a setting with portable recording equipment or observers that take notes during the test, results may be beneficial for the development. However, following the procedure of a usability lab test, as close as possible has shown good results[59].

2.2.1 Usability lab test

A usability lab study is the most commonly used empirical usability evaluation method. A usability lab study can be used during all phases of an IT system's life cycle: during the analysis and design phase, in connection with a delivery test, and as a constructive assessment during implementation or for adjustments of the functionality of a system that already is deployed. The usability test is usually performed in three stages: preparation/planning, actual test, and follow-up[60]. The preparation usually consists of

- Recruitment of users where the selected participants should have the same characteristics as the intended user group.
- Choosing the tasks to be evaluated. The tasks should be representative and cover relevant parts of the system that are intended to be tested.
- A test plan: Data needs to be structured in advance, to analyze the participants' performance efficiently[60].

The test is then performed, often separated into three phases: the pre-test phase, the actual test, and the post-test phase. During the test, the participants follow the tasks assigned to the test. Often participants are encouraged to think aloud while performing the test to gather more substantial and qualitative data. After the test, the users are debriefed, preferably using both questionnaires and interviews. In the follow-up stage, the recordings are coded and collected data are analyzed. Specific problems found are analyzed in detail and results are reported[59].

In this work, we followed the conventional usability lab procedure as described by Dumas and Redish[61], adding the use of a System Usability Scale. Conventionally it was used to gather test participants' experiences when the usability test was accomplished, but here we also added a novel usage of the questionnaire; to gather user expectations of the demonstrator, prior to the usability test.

2.2.2 System Usability Scale

The use of the System Usability Scale(SUS) has been improving products since 1986 [62]. The post-test survey known as the System Usability Scale was introduced in 1986 by an engineer named John Brooke[63] and today one of the most widely used standardized questionnaire assessments of perceived usability and a recognizably reliable and robust method for measuring usability[64].
SUS is a tool for evaluating users' experiences with a product or service. It consists of a 10 item-questionnaire with five response options for respondents; from "Absolutely do not agree" to "Completely agree". Benefits of the SUS tool include that it is technologically agnostic (i.e. it can be used for many different types of IT systems), that it is quick and easy to use for both participants and researchers, that it provides a single score on a scale that is easy to understand, and that it is cost efficient due to its state of non-proprietary[65].
Using the System Usability Scale users give their opinion on how easy something is to use by agreeing or disagreeing with 10 statements. Users take the survey immediately after completing a usability test, and statements alternate between positive and negative statements, so respondents do not go on autopilot when checking off answers. Often the statements are slightly moderated to match the service or product that is tested, but here are the original SUS statements:

1. I think I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.
5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system[63].

While SUS was only intended to measure perceived ease-of-use (a single dimension), research by Lewis and Sauro[66] showed that it provides a global measure of system satisfaction and sub-scales of usability and learnability. Items 4 and 10 provide the learnability dimension and the other 8 items provide the usability dimension, making it possible to track and report on both subscales and the global SUS score[66]

2.2.2.1 Analyzing the SUS

Scoring SUS for the analysis is performed in the following steps:[67]

- For odd items: subtract one from the user response.
- For even-numbered items: subtract the user responses from 5
- This scales all values from 0 to 4 (with four being the most positive response).
- Add up the converted responses for each user and multiply that total by 2.5. This converts the range of possible values from 0 to 100 instead of from 0 to 40.

Jeff Sauro[67] has thoroughly reviewed the existing research on SUS and analyzed data from over 5000 users across 500 different evaluations. He concluded that the average SUS score from all 500 studies is 68. A SUS score above 68 would be considered above average and anything below 68 is below average. Following the pattern of 2.2, and the explanation of Dr.Sauro[67] a system needs to score above 80.3 to get an A-grade (the top 10% of scores). This is also the point where users are more likely to be recommending the product to a friend. Scoring at the mean score of 68 gets you a C-grade and anything below 51 is an F-grade (putting you in the bottom 15%).[67]

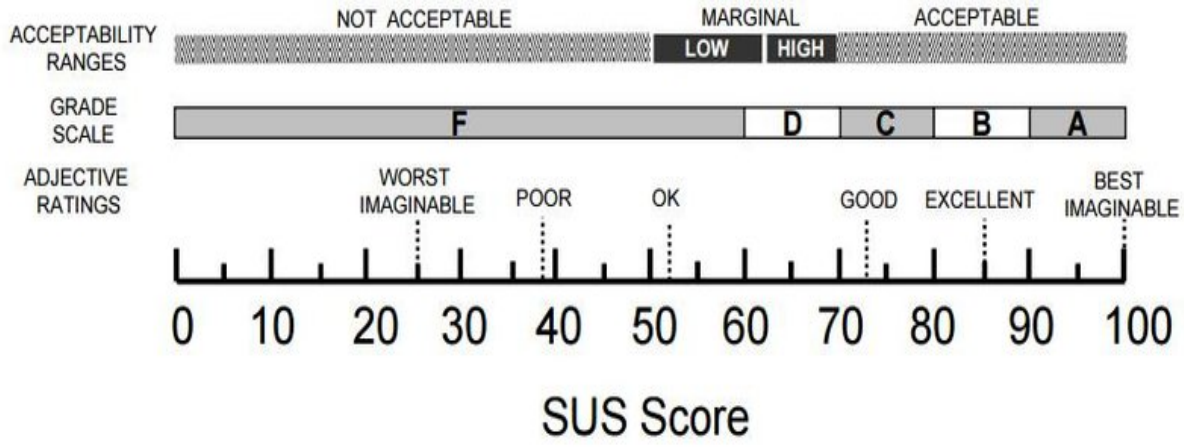


Figure 2.2: Grade rankings of SUS scores[64, 68]

Even though a SUS score can range from 0 to 100, it is not a percentage. While it is technically correct that a SUS score of 70 out of 100 represents 70% of the possible maximum score, it suggests the score is at the 70th percentile. A score at this level would mean the application tested is above average. In fact, a score of 70 is closer to the average SUS score of 68. It is actually more appropriate to call it 50% [67].

2.3 Previous research

There are a number of e-health tools available for DFU, namely Glucose buddy, Dbees, mDiab, NexJ Health Coach, M-DFEET, FootSnap, DFU APP,[18] - [31],[38]. Many of them are still under research projects and some are available on market for usage A. These applications assist the patients, nurses or healthcare providers, in managing the DFU, preventing further complications, and facilitating self-care. In Sweden, the Region of Västra Götaland (VGR), is in the national lead of innovating the process of foot examinations for patients with diabetes. A software, the D–Foot for prosthetists and orthotics has been developed and tested according to its construct validity and reliability[69]. The D-Foot has good reliability (>0,80) of intra-agreement between HCP for the examination assessing: amputation, DFU, hallux valgus, and the foot deformity of Charcot's foot. Another software, developed in the VGR and hence only available in Swedish, is My Foot Diabetes[70]. My Foot helps the patients to make a self-assessment of their feet and based on the individ-

ual findings the patient gets customized advice supporting self-care of the feet. The aim is to promote good foot health. In VGR, a collaboration between researchers, national councils, and registries have resulted in efforts to create a structured foot examination protocol to be used by HCP in primary care. A paper-based prototype has been tested and based on interviews with potential users of an eHealth system, improvements are suggested e.g. to define "callosities"[71]. The current study is a prolongation of this work, where steps are taken to transform the paper prototype into a digital tool (the demonstrator) supporting HCP to make a structured foot assessment for patients with diabetes. To our knowledge, there is not yet an eHealth application used to diagnose the risk to develop DFU that includes an automatically generated risk category aimed to be used by HCP.

3

Methods and Materials

This chapter explains the study setting, study ethics, the test participants(3.1), a literature search (3.2), and the design & creation of the demonstrator(3.3), as well as how the usability testing method(2.2) was adopted containing context-specific decisions(3.4) also the novel design of the pre-test questionnaire for the data collection. It also contains a description of the analysis of the data gathered(3.5) using the usability lab method and SUS questionnaires.

3.1 Study setting and participants

The study settings consisted of 9 healthcare professionals (HCPs) performing a Usability test on the demonstrator supported by Shivani Ravichandran as the test leader, Ulla Hellstrand Tang as the main observer, and Isabella Scandurra as the principal investigator. Observers were also Jan Johansson (the 1st and 4th of April 2022) and Lisbeth Hagström (4th of April 2022) taking additional notes as well as being responsible for video and sound recordings. The test was held at Skövde sjukhus 3.1 and 3.2 and Mölndals sjukhus, where conference rooms were booked to perform the study. It was considered easier to perform the test on-site, where the HCPs work, as they did not need to move to a usability lab situated elsewhere, which was another alternative. The rooms were modified to look like a primary care consulting room to give a sense of a "normal situation" for the HCPs, where they should perform the foot examination, supported by the demonstrator. A file containing all documentation on paper: pre-test questionnaires and consent forms; SUS as an expectancy questionnaire; Usability test tasks; Post-test questionnaires; and SUS measuring satisfaction of usage; was given to each participant. A presentation explaining all the SUS, Pre- and Post-tests, and the tasks, was given by Shivani and Ulla. It took approximately 30 minutes for each participant to perform the test.

Figure 3.1: During the usability tests the healthcare professionals performed tasks included in the test series

Figure 3.2: At the usability tests in Skövde, in April 2022, healthcare professionals led by the research team performed the usability tests

Note: To the right, Ulla Hellstrand Tang, research team, Carina Folkesson and Agneta Darius Wendt both podiatrists, and Shivani Ravichandran, research team.

3.1.1 Ethics

The study was approved by the Swedish Ethical Review Authority (Diary no. 2020–02715) and was conducted according to ethical principles described in the Helsinki Declaration[34]. All participants were informed, both verbally and in text, about the study before giving their written informed consent. The participants were ensured confidentiality and were free to withdraw at any time. The possible harm caused by the study was valued against the benefits. The participants were informed that any concerns could be clarified by contacting the research team. No such concerns were made. The participants also signed written consent allowing the research team to take photos and make recordings (video and audio).

3.1.2 Usability test participants

This usability test was carried out using mostly qualitative research techniques. We started with establishing a focus group and held a discussion on a given topic, i.e the demonstrator, also called the application/app, with a group consisting of 8-10 participants, for 1-2 hours, at two hospitals.

The focus group discussion helped us to obtain in-depth information on the motivation to use the future application, and functionality that was expected to be designed in the created demonstrator. It was also used as a basis for the recruitment of the test participants.
An on-site usability test was held at Skövde sjukhus and Mölndals sjukhus on 01st April 2022 and 04th April 2022 respectively. The test was performed by 9 HCPs including diabetes nurses, podiatrists, physiotherapists, and certified prosthetists and orthotics (CPOs) ranging between 37 to 68 years of age. These professionals have a minimum of one year to a maximum of 40 years of experience in the treatment of patients with diabetes. In their period of work, they have used digital tools to assess the health status of a diabetic patient like NDR and Picsara [4.10], but they have not used any tools to assess the foot status of patients with diabetes before.

3.2 Literature search

The literature search for this project work was carried out in the Google Scholar, PUB MED, Research Gate, and Science Direct search engines. The search was performed with the aim to find other solutions similar to the one that should be created for VGR. The terms Diabetic Foot Ulcers, E-health tools in diabetic foot ulcers, mobile applications for diabetic foot ulcers, and diabetic foot ulcer in e-health were used. Nearly 20 papers showed up out of which 14 relevant papers were studied as inspiration for the project work [18] - [31], **A**

3.3 Demonstrator

A *demonstrator* is a prototype used in early design phases, aimed to show features and functionality to future users of an IT- system or service[72], where there is no previous IT tool to look at or get inspiration from. In user-centered design projects, a demonstrator may be created in parallel with a requirement specification. A demonstrator can let usage data be fed back to the early design stage and be used to populate value models to reduce the uncertainty in engineering design decision-making [73]. It is used to validate that the requirements from the users are correctly understood by the designers or developers, as well as the contrary: to let future users in an early design phase understand what they can get from an IT tool [72].
That is, the demonstrator differs from an ordinary prototype which often is a result, of different levels of maturity, of a requirement specification. The demonstrator is seldom used to build further on but has many advantages anyway. Apart from validating requirements, and showing possible features and functions, it may also be used to let future users test their work procedures using a novel tool, which was the case in this project work.
The demonstrator was created as an eHealth app that assists healthcare workers in documenting a structured foot examination and diagnosing the risk category grade 3.3 under which the patient falls in order to treat them accordingly.
The demonstrator was developed using the prototyping software “Figma”[74]. Figma is a vector graphics editor and prototyping software. It is a user-friendly web-based

platform, which is supported in both Android and iOS systems. The apps mentioned earlier for diabetics and DFU are either Android-supported or iOS supported. But the demonstrator which we have designed using Figma is supported by both Android and iOS, and consequently, the testing could take part in either of the operative systems, on the test participant's choice.

Risk category	Symptoms	Chiropody/ foot care	Annual fotunder search	Orthopedist technical treatment
1	No signs of distal neuropathy, peripheral vascular disease or other foot problems	Training in self-care	YES	NO
2	There are signs of distal neuropathy or peripheral vascular disease	YES	YES	YES
3	Signs of distal neuropathy or vascular disease, foot ulcer / amputation, foot deformity, skin pathology (eg callus / fissure)	YES	YES	YES
4	There are ongoing foot ulcers, regardless of neuropathy or vascular disease, or severe osteopathy or pain syndrome	YES	YES	YES

Figure 3.3: Risk categories, as established in national guidelines[44]

3.3.1 Requirements of a Structured foot examination

In parallel with setting up the demonstrator, a workflow of a structured foot examination was created and decided, based on international[1] and national clinical guidelines[2] and discussion in an expert panel consisting of patient representatives, nurses from primary and municipality care, physicians in primary and specialist care, certified prosthetist and orthotics and podiatrists, see B, where a paper prototype of the structured foot examination is described in Swedish and translated into English[71]. The expert group also formulated the following requirements for designing the demonstrator:

1. The flow should be intuitive and easy to understand for the healthcare professional
2. The assessments being necessary to assess for each risk grade, see3.3 should be relevant and clinically applicable
3. The description of HOW to make the assessments should be easy to understand
   (a) Text, illustrations, and links should be included with the purpose to facilitate the examination
4. The risk grade should follow clinical guidelines

5. A report of the summary of the examinations should automatically be integrated
6. The summary and the risk grade are the basis for the care plan and for a dialog between the patients with diabetes and the caregiver regarding self-care.
7. The risk grade should be exported/integrated with national quality registries.

The demonstrator was designed to have three major sections, namely education, examination, and documentation. The output of using the demonstrator app comprises the summary of the examination, along with a documentation of the findings, and gives the risk category of the patient for the onset of DFU. Requirement number 7 was not accomplished in this version of the demonstrator, as the demonstrator is a stand-alone system. The design of the Demonstrator is described in Results, chapter 4.

3.4 Data collection procedure according to usability test methods

During the course of the usability test, the participants were asked to answer 2 pre-test questionnaires regarding their demographics and SUS for expectancy, as well as previous experiences of using digital tools in both diabetic care and healthcare (3.4.1 , 3.4.2, 3.4.6). They performed the test on the demonstrator, by following the pre-established usability tasks (3.4.3). The observers took notes. The complete test was recorded (video and audio) and pictures were also taken. After the usability test, they performed Post-test questionnaires and SUS for measuring their satisfaction (3.4.4, 3.4.5). The data collection procedure followed the general usability lab methods according to Dumas and Redish[61] (1999), although it was not performed in a lab.

3.4.1 Pre-test: Demographics

A set of pre-test questionnaires was given to the test performers. It was set to gather information about the performers' demographics. The pre-test questionnaire was created in English C. The pre-test questionnaire contained the following questions:

1. What is your name?
2. How old are you?
3. Gender
4. Where do you work?
5. What is your profession?
6. How many years have you worked in your profession?
7. Have you previously worked with digital tools to assess the foot status in patients with diabetes? If yes, which tools?
8. Have you previously worked with digital tools to assess the health status of patients with diabetes eg. patientenkäten from NDR (Nationella Diabetes Registret) or photo documentation? (exclude to mention the ordinary medical record system) If yes, which tools?

9. Have you ever taken a photo of the foot of a person with diabetes as a basis for the documentation?

3.4.2 Pre-test: System Usability Scale as an expectancy questionnaire

SUS as an expectancy questionnaire is a new initiative in our project work. It is one of the academic contributions of Shivani and the team. Its purpose was to quantify subjective responses that are seldom posed to a test participant, i.e. those of his/hers expectations, before performing the usability test. The survey is based on SUS[63], which was originally developed to measure usability and user satisfaction AFTER performing a usability test. We rephrased the 10 statements to contain questions about how you think it will be to work digitally, i.e., using laptop and web applications when you examine patients with diabetes and then do your documentation. The SUS expectancy measurement consists of 10 statements that are evaluated on a 5-point likert scale according to which extent the user disagrees or agrees with the statement. The questions include:

1. I think I will want to do a digital foot examination.
2. I think I will find digital foot examination unnecessarily complicated.
3. I think I will find it easy to do a digital foot examination.
4. I think I will need technical help to make a digital foot examination.
5. I think I will like the different features of making digital foot examination well-functioning.
6. I think I will find that the different parts of digital foot examination are illogically constructed.
7. I think most people will be able to quickly learn how to make a digital foot examination.
8. I think I will find it awkward to do a digital foot examination.
9. I think I will feel that it is safe to do a digital foot examination.
10. I think I will have to learn a lot of new things before I can do a digital foot examination.

Compared to the original SUS statements, these are posed in future tense and the original word “product” is changed to “a digital foot examination”, see D. The aim of letting the participants answer twice on a similar questionnaire during the same usability test was a way to elicit their unspoken thoughts about the demonstrator. It could be embarrassing to the participants to dislike the demonstrator, as the creator and the initiator were present. In this way, that bias was diminished. Another effect of using this Pre-test questionnaire was that you could compare the score of the expectancy with the usability score after using the demonstrator.

3.4.3 Usability test tasks

Following Dumas and Redish[61], the Usability test tasks were designed as a Scenario, with a specific Goal, Start, and End-situation (see examples in E). Nine tasks were planned and executed. The tasks were to:

1. Enter the app (as Beata Belund, nurse)

2. Select your patient (Calle Citron)
3. Examine for pressure area
4. Examine for ingrown nails
5. Examine for Hallux Valgus
6. Ask Calle Citron if he has peripheral neuropathy
7. Examine Calle Citron if he has peripheral neuropathy
8. Look at the summary and confirm that the results are "OK"
9. Discuss the care plan with Calle Citron

For each of the tasks, observers were given certain duties to measure the effectiveness and efficiency of the demonstrator: to measure time and document the timings; to observe the test participants' performance; and note the comments given by them, as they were asked to think-aloud while performing the tasks.

3.4.4 Post test: User Improvement Suggestions questionnaire

A set of post-test questionnaires was given to the test performers. The User improvement suggestions questionnaire aimed to gather information about the performers' satisfaction about working with the demonstrator/app and at the same time gather improvement suggestions. The five questions were:

1. In the future, would you prefer to use a tablet or a mobile to make a digital foot examination?
2. Do you prefer to have an automatically generated risk scale in the app?
3. In the future, would you find it useful to always register the results for the left and right foot separately?
4. Do you think you would prefer a scroll down-function (going down to the screen) to the next question in the foot examination instead of what you have just tested?
5. How do you experience the structure of the app?

See F for the Post-test: User Improvement Suggestions questionnaire

3.4.5 Post-test: System Usability Scale for user satisfaction and usability aspects

The System Usability Scale[63], is a tool that makes it easy and affordable to assess and compare various systems' usability characteristics. The method involves a number of test participants solving the same well-defined tasks in the system and then answering the questions below, regarding their experiences of using/testing the tool/system/service. The SUS measurement consists of 10 statements that are evaluated on a 5-point scale according to which extent the user agrees or disagrees with the statement (see G). How was it to do a digital foot examination?

1. I think I will want to do a digital foot examination.
2. I think I will find digital foot examination unnecessarily complicated.
3. I think I will find it easy to do a digital foot examination.
4. I think I will need technical help to make a digital foot examination.

5. I think I will like the different features of making digital foot examination well-functioning.
6. I think I will find that the different parts of digital foot examination are illogically constructed.
7. I think most people will be able to quickly learn how to make a digital foot examination.
8. I think I will find it awkward to do a digital foot examination.
9. I think I will feel that it is safe to do a digital foot examination.
10. I think I will have to learn a lot of new things before I can do a digital foot examination.

3.4.6 Post-test: Previous experiences of foot examinations at work

Nine questions were posed regarding the test participants' previous experiences of foot examinations at work (see H).

What was it like when you last did a foot examination on a person with diabetes at work?

1. Did the patient receive advice on self-care of the feet?
2. Was the patient's illness/health condition discussed with the patient?
3. Did you provide information to the patient about where he or she should turn if he/she needed help or if further questions arose after the visit?
4. Did the patient receive information about any risks with the treatment?
5. Did the patient receive information about warning signals to pay attention to regarding their illness/their health condition or their aid?
6. Did you and the patient have enough privacy when the patient's condition or treatment was discussed?
7. Did you explain the results of a digital foot examination to the patient?
8. Did the patient receive oral information?
9. Did the patient receive written or digital information?

The response options contained four possibilities, ranging from 1. Not at all, 2, 3, 4. Yes, absolutely, and 5. Not current/Not applicable.

3.5 Data Analysis

After the tests, all the information and comments given by the performers via the Pre-tests: demographics; and SUS expectancy; and the Post tests: User improvements suggestion questionnaire; SUS for measuring satisfaction of usage; and Previous experiences at work; were analyzed as data for the project work. These data from the performers were sorted manually and converted into Excel tables and charts for further analysis. The raw data is saved according to the approval by the Swedish Ethical Review Authority (Diary no. 2020–02715) for further analyses within the project.

3.5.1 Calculating System Usability Scale Score

Before we go into the more complicated part of interpreting the System Usability Scale (SUS) score, we first needed to calculate the SUS score for each of the respondents. Below are the quickest and most simple steps to do so: Step 1: Convert the scale into number for each of the 10 questions

- Strongly Disagree: 1 point
- Disagree: 2 points
- Neutral: 3 points
- Agree: 4 points
- Strongly Agree: 5 points

Step 2: Calculate

- X = Sum of the points for all odd-numbered questions – 5
- Y = 25 – Sum of the points for all even-numbered questions
- SUS Score = (X + Y) x 2.5

The rationale behind the calculation is very intuitive. The total score is 100 and each of the questions has a weight of 10 points[13]. The score should not be mistaken for a percentage.
From the 2.2, the SUS scores can be interpreted that

100-75	Best imaginable/Excellent	Acceptable
75-65	Good	Acceptable
65-50	Ok	Marginal
50-0	Poor/worst imaginable	Not acceptable

Table 3.1: SUS score interpretation [64],[68]

4

Results and analysis

The aim of this thesis work is accomplished by creating an eHealth demonstrator that assists the healthcare workers in documenting a structured foot examination and diagnosing the risk category under which the patient falls in order to treat them accordingly (4.1). This demonstrator is then tested via Usability testing methods (4.2). The analyses are described in parallel in each section.

4.1 Demonstrator

The creation of the demonstrator was carried out in four stages: (i) describing the requirements by HCPs; (ii) creation of conceptual design using LucidChart[75] ; (iii) designing the demonstrator Figma; (iv) testing and improving the demonstrator iteratively. The last test with potential future users was conducted as a Usability test following the conventional method according to Dumas and Redish[61]. The co-creation of the demonstrator was achieved by one HCP researcher and a Usability expert, and a master thesis student. In addition, the work was iteratively evaluated and validated by an expert team consisting of HCPs and patient representatives.

4.1.1 Describing the requirements by HCPs

In stage (i), the patient-related questions and clinical examinations which are needed to evaluate the feet of the diabetic patient at risk to develop DFU were prepared based on national clinical guidelines and experiences from HCPs [32]. Approximately 20 questions/examinations [4.4 to 4.8] were formulated for the foot examination of the diabetes patient, see further K, the entire Conceptual Design.

4.1.2 Creation of conceptual design

The questions/examinations were then formulated into a conceptual design[4.1] in stage (ii), using the software LucidChart. The conceptual design holds the flow of the demonstrator, which includes all the 3 phases: education, examination, and documentation of the demonstrator. The overview of the conceptual design is found in 4.1, and the entire conceptual design is in K.

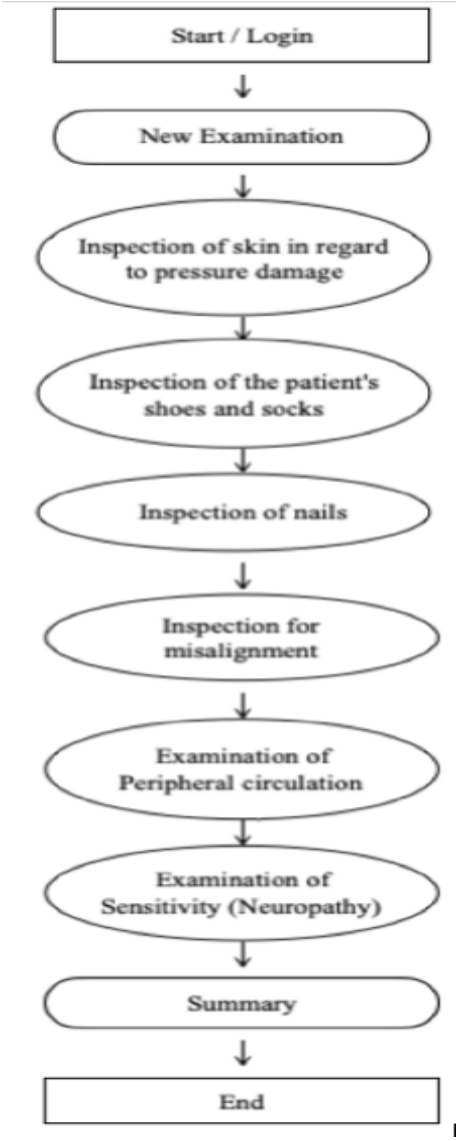


Figure 4.1: Conceptual design

4.1.3 Designing the prototype

The concepts from the conceptual design were implemented in the "FIGMA"[74] software and the demonstrator was created comprising all three phases namely, the education phase, examination phase, and documentation phase in stage (iii) [4.2]. The education phase explains more clearly what the questions/examinations exactly ask for. It consists of pictures and texts which demonstrate and explains how the examination should be carried out on the feet, and how or which area/spots of the feet should be examined. The examination phase holds the questions/examinations that the HCPs answer when evaluating the patient's feet. Finally, the documentation phase is where the answers to the questions in the examination phase are stored and are used in a final summary, in which the patient's risk category of developing DFU is discovered. The figures below (4.3-4.9) show the design of the demonstrator, as well as the workflow of the HCP.

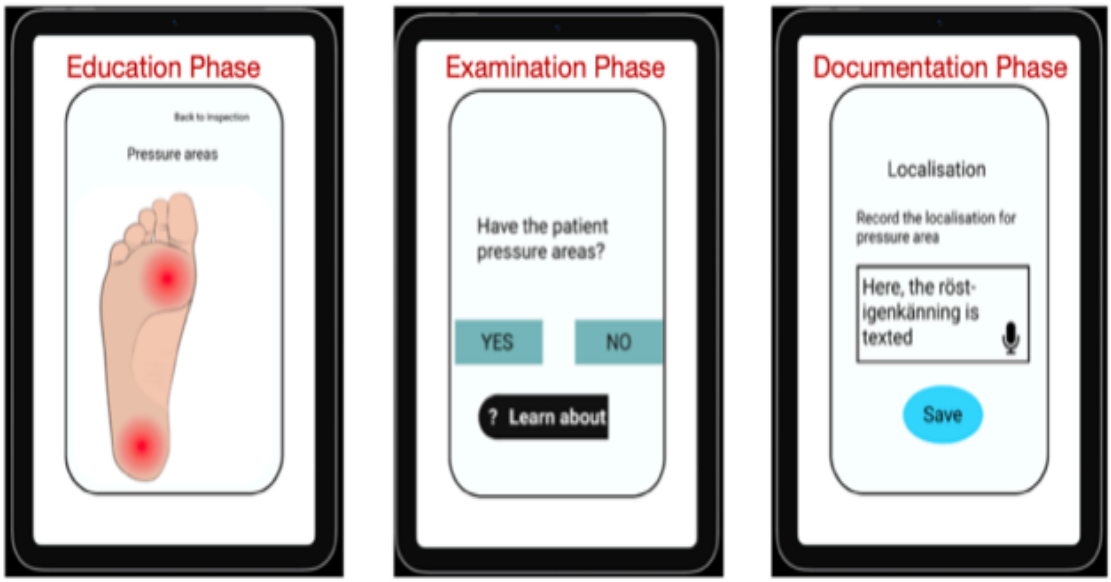


Figure 4.2: The three phases of the demonstrator

The 19 questions/examinations [4.4-4.8] in the examination phase are grouped into 6 modules:

- Inspection of the skin with a note of pressure damage, wounds, cracks, calluses, or lack of hair
- Inspection of the patient's shoes and socks
- Inspection of nails with regard to map nails, nail tightness, and/or suspicion of fungus
- Note misalignments such as hammer toe, ball toe, hallux valgus, and Charcot's foot
- Examine the skin, note for dry skin, skin temperature, and swelling. Ask about numbness in the feet, and changes in sensation in the feet compared to before
- Examination for peripheral circulation and neuropathy.

The answers/examination results which are documented in the documentation phase are finally summarized and the risk grade under which the patient falls is established [4.9]. The HCP may use this result to treat the patients according to the guidelines.
A brief view of the demonstrator

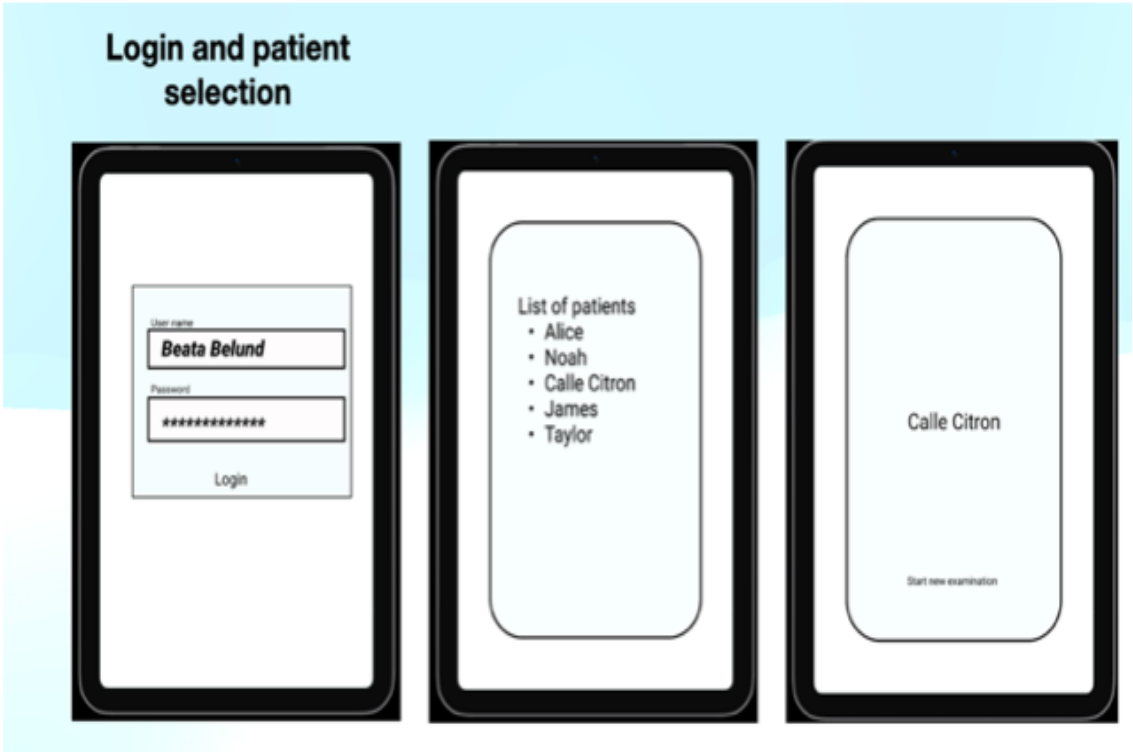


Figure 4.3: Login and Patient selection module

Note: Both the user and the patient in the Demonstrator are fake ones, as well as their data.

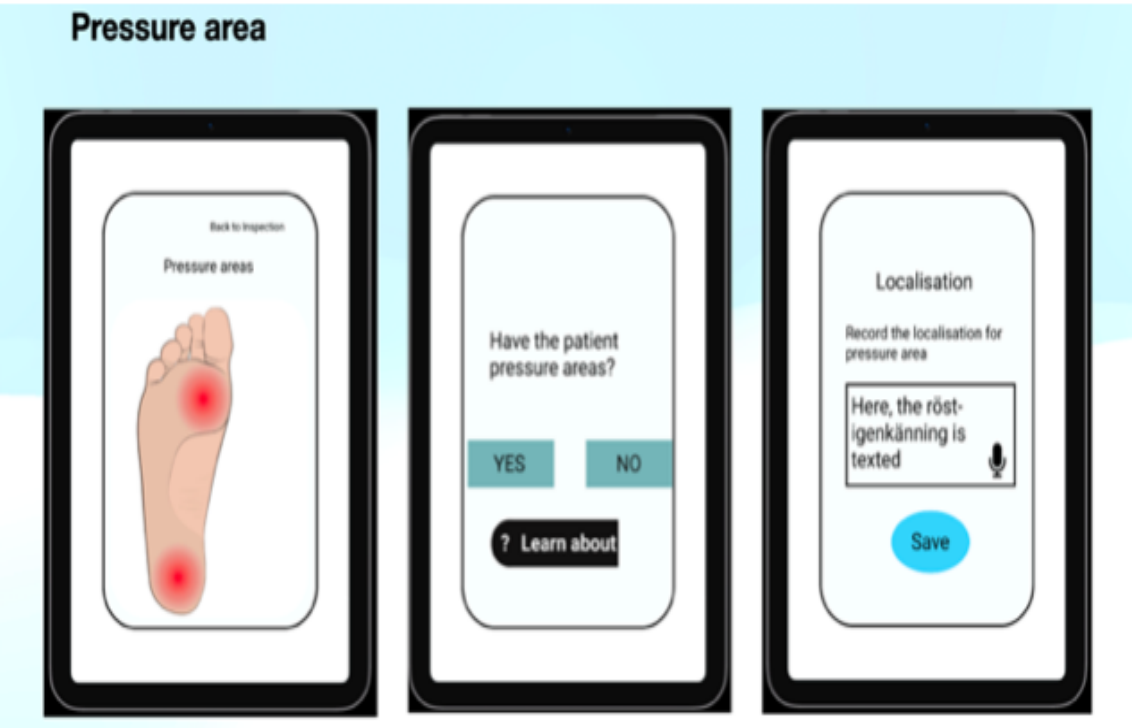


Figure 4.4: Pressure area module#

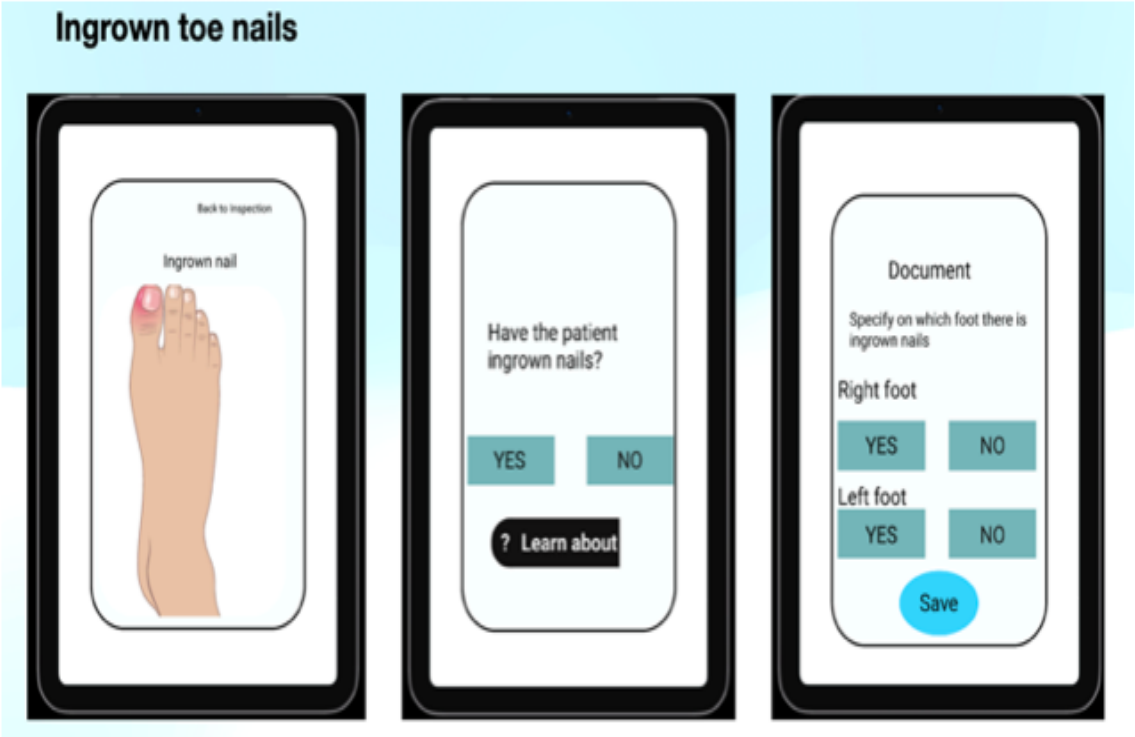


Figure 4.5: Ingrown toenail module#

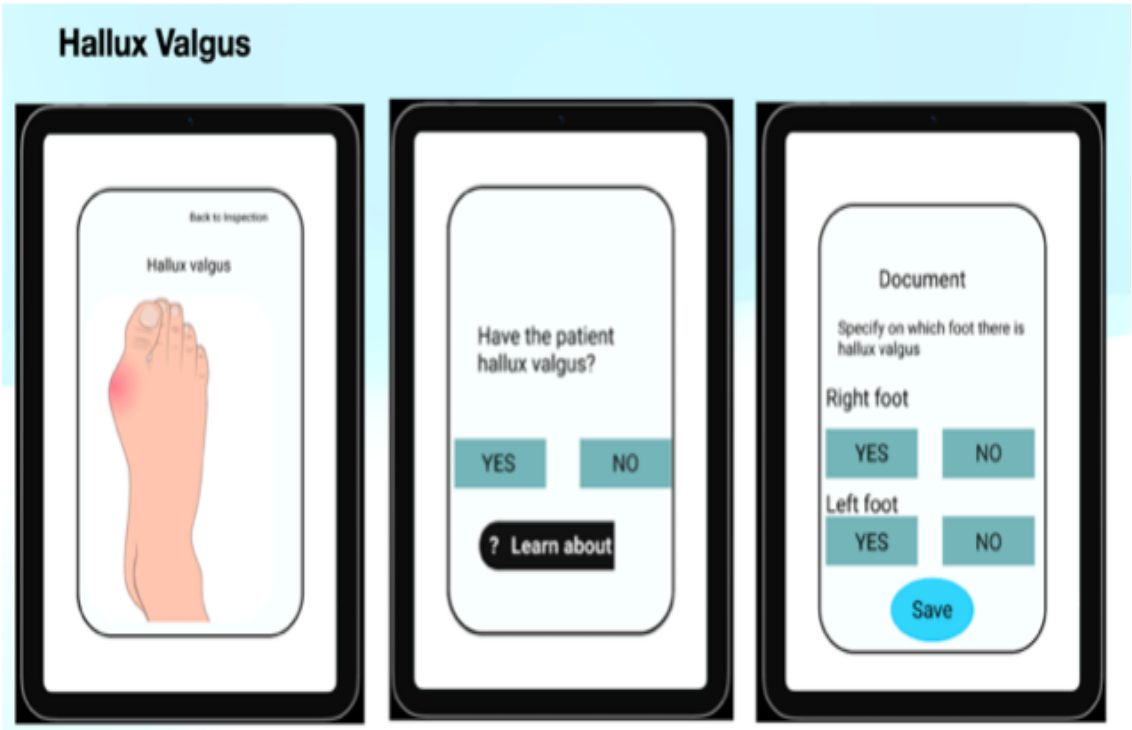


Figure 4.6: Hallux Valgus module#

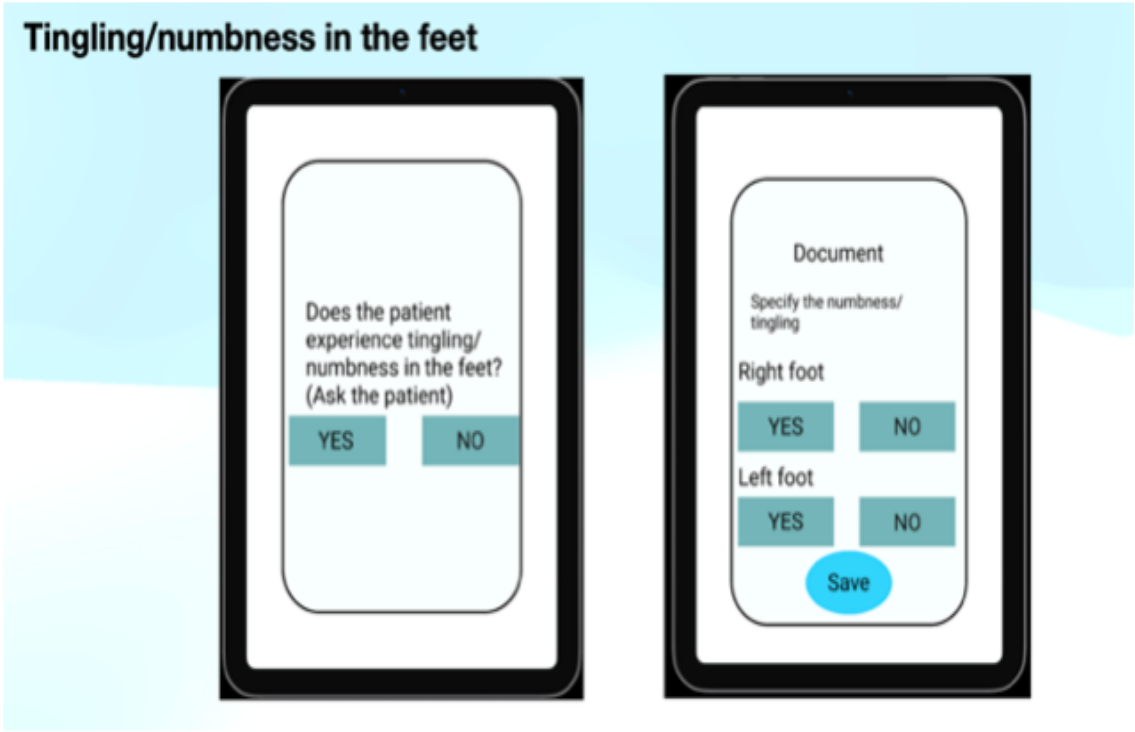


Figure 4.7: Tingling/Numbness module

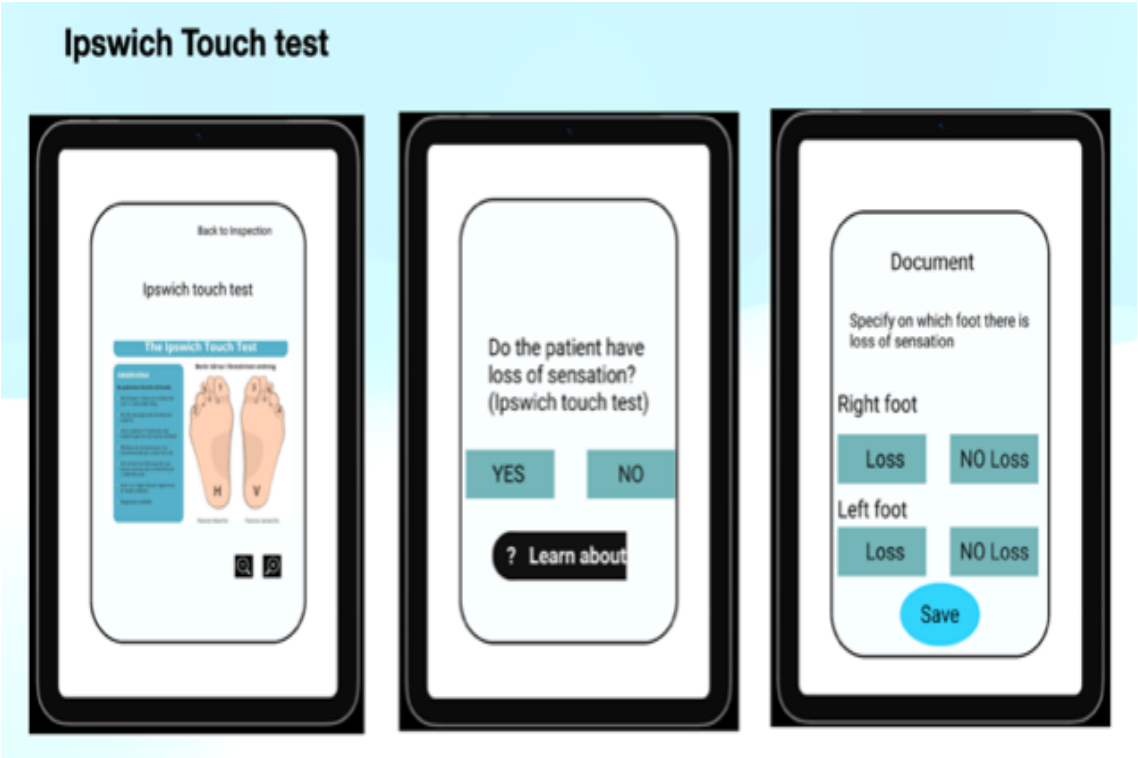


Figure 4.8: Ipswich touch test module#

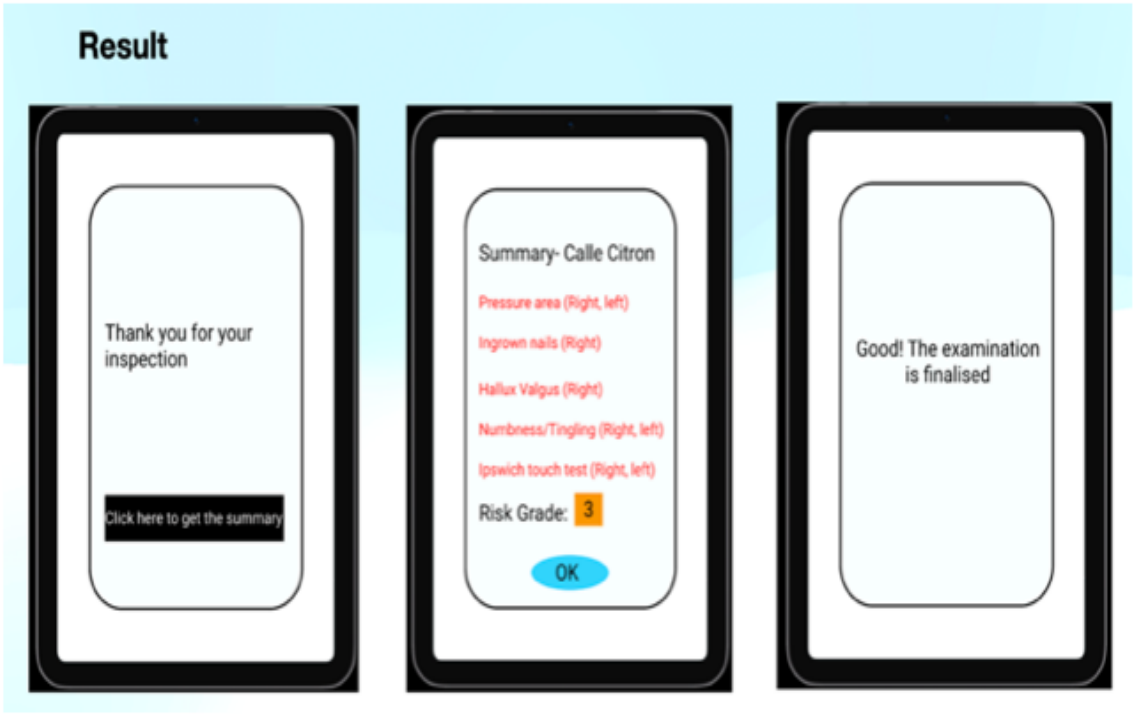


Figure 4.9: Result module

Graphic foot illustrations are designed by Pontus Andersson for an innovation project at VGR

4.1.4 Iterative evaluation of the demonstrator

In user-centered design, iterative evaluation is highly recommended. Therefore, the demonstrator has undergone several steps of evaluation. In each evaluation or walk-through, the demonstrator has step-by-step fulfilled the requirements of the test panel, consisting of team members of the project with expertise like patient experiences of diabetes, CPOs, registered nurses, usability, and software development.
A usability test was the final evaluation of the Demonstrator. All details about the Usability test are found in section 4.2. Pre-test demographics, User improvement suggestions (Post-tests), SUS as an expectancy questionnaire, and SUS for user satisfaction and usability aspects were the questionnaires used to evaluate the demonstrator, adding to the actual test procedure.

4.2 Usability test results

The answers given by the nine test performers through the pre-test, SUS as an expectancy questionnaire, and through the post-test, SUS for measuring satisfaction of usage questionnaires, were collected and analyzed using SUS scores 4.2.7. Other information was collected from Pre-test: demographics, and Post-test, containing User improvement suggestions, which were sorted in tables [4.10 and 4.14]. SUS

as an expectancy (pre-test) questionnaire [4.11] and SUS for user satisfaction and usability aspects (post-test questionnaire) [4.15] data are displayed in charts, as well as the questions of Previous experiences of foot examinations at work [4.16] for a more clear understanding.

4.2.1 Pre-test: demographics

The Pre-test questionnaire comprised some basic information about the participants and their experiences of using digital tools for foot examination [4.10]. The participants of the test were HCPs between 37 years to 69 years of age and had a professional experience in diabetes care between 1 year and 40 years. In the study, seven women and two men participated. In 4.10 the descriptives are presented including the participants' experiences of using digital tools for healthcare and foot care for diabetes.

Pre-test

Pre-test	1101	1102	1103	1104	1105	1106	1107	1108	1109
Profession	Diabetic Nurse	Nurse	Nurse	Podiatrist	Podiatrist	Podiatrist	Podiatrist	Physiotherapist	CPO
Experience in profession (years)	1	4	15	32	24	40	10	20	25
digital tool to assess foot of diab patient	No	No	No	No	No	No	No	No	No
If yes name it									
Digital tool to assess health of diab patient	Yes	Yes	Yes	No	No	No	No	No	No
If yes name it	NDR Documents	NDR	Foto i picsara, NDR	Picsara	Picsara				
Photo of foot	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Preference of tablet	Android	Ipad	Android	iPad	Dont know	Ipad	Android	Ipad	Ipad

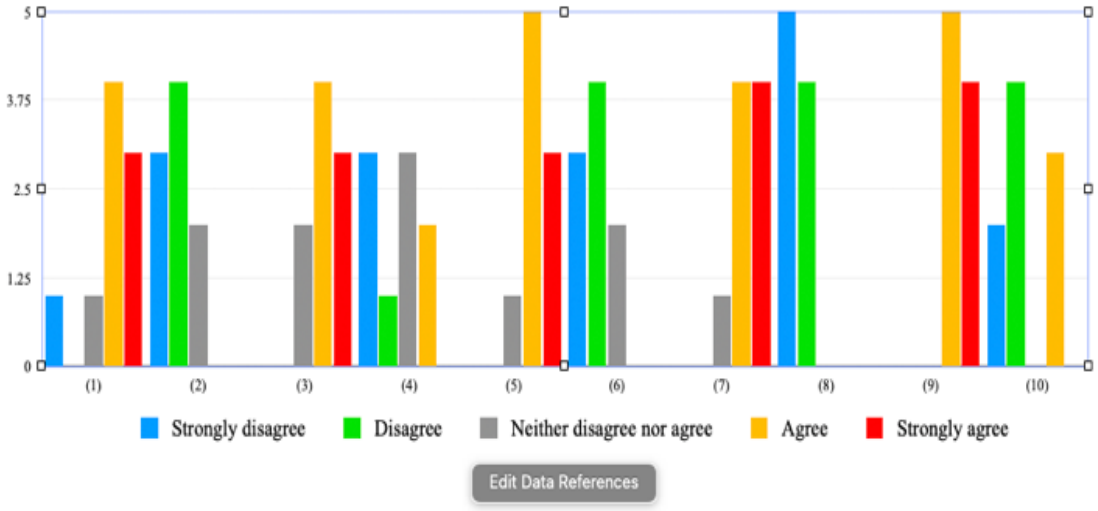
Figure 4.10: Pre-test: Demographics

Note: diab = diabetes ; CPO = Certified Prosthetist & Orthotist; NDR = Swedish National Diabetes Registry; Picsara = software for photos used in Region Västra Götaland

None of the 9 HCPs had ever used any digital tools to assess the foot of a diabetic patient. Few (3 of 9) HCPs had used a digital tool to assess the health of a diabetic patient, which was for three respondents the NDR *(Swedish National Diabetes Registry)*online, and three respondents had used Picsara *(software for photos used in Region Västra Götaland)*. One respondent had used Foto i. A majority (5 of 9) of the interviewed HCPs preferred iPads for future use of the app and three opted for the Android version.

4.2.2 Pre-test: System Usability Scale as an expectancy questionnaire

The results from the SUS as an **expectancy questionnaire** are presented in 4.11. All the questions were answered by all nine respondents. The questionnaire stated every odd-numbered question as a "Positive expectation" and every even-numbered question as a "Negative expectation". The first step analysis of data is shown in the chart and table of 4.11.



SUS as expectancy

	I think I will want to do DFE (1)	I think I will find DFE unnecessary complicated (2)	I think I will find it easy to do DFE (3)	I think I will need technical help to make DFE (4)	I think I will like the different features of making DFE is well-functioning (5)	I think I will find that the different parts of DFE are illogically constructed (6)	I think most people will be able to quickly learn how to make DFE (7)	I think I will find it awkward to do foot examination (8)	I think I will feel that it is safe to do a DFE (9)	I think I will have to learn a lot of new things before I can do DFE (10)
Strongly disagree	1	3	0	3	0	3	0	5	0	2
Disagree	0	4	0	1	0	4	0	4	0	4
Neither disagree nor agree	1	2	2	3	1	2	1	0	0	0
Agree	4	0	4	2	5	0	4	0	5	3
Strongly agree	3	0	3	0	3	0	4	0	4	0

Figure 4.11: Pre-test data: How the users responded to the SUS as an expectancy questionnaire

Note: DFE = Digital Foot Examination Analyzing the data, we see that the respondents paid attention when reading the statements of the questionnaire, answering mainly positively to the odd-numbered questions, and negatively to the even-numbered questions. The odd questions in 4.11 have mainly scored 4 and 5 points and the even questions mainly scored 1 to 3 points. After converting the row numbers to a SUS score of 0-100, the SUS score of the expectancy questionnaire reached 77. Based on an average of "all 500 SUS-evaluations studied" by Jeff Sauro[67] a SUS score above 68 would be considered above average. The score of 77 indicates that the respondents believe in the demonstrator that they are going to

test. Without having tried out a similar system or app before, they seem to think the demonstrator will be worth using in their work context. The calculation of the SUS score is shown in J.

4.2.3 Usability test results and analysis

The usability test results of the tasks carried out during the course of the test are given in I. We had 2 warm-up tasks before entering into the actual test tasks, and it took a minimum of 00:06 seconds to a maximum of 00:45 seconds for the nurses to complete the warm-up tasks. Almost all the nurses have completed every task in the test, and the goals measured were achieved with high efficiency and effectiveness (see 4.12below).

Task	Efficiency		Effectiveness	
	Minimum time (Minute:seconds)	Maximum time (Minute:seconds)	Goals reached	Goals not reached
Tasks 1 & 2 : Warm up (not part of the test)	00:06	00:45	9	0
Task 3: Examine for Pressure areas	00:45	02:33	9	0
Task 4: Examine for ingrown nails	01:00	04:31	9	0
Task 5: Examine for Hallux Valgus	00:17	01:42	9	0
Task 6: Ask Calle Citron if he has peripheral neuropathy	00:20	02:45	8	1
Task 7: Examine Calle Citron if he has peripheral neuropathy	01:47	09:20	9	0
Task 8: Look at the summary and confirm that the results are "OK"	00:07	03:15	9	0
Task 9: Discuss the care plan with the Calle Citron	00:07	04:40	9	0

Figure 4.12: Analysis of Usability test results with tasks

From the 4.12, it can be seen that almost all the goals of the task were achieved except for one. The reason for this could be that, either the tester faced a problem in using the tablet, that he/she could touch the button twice instead of once, or the nurse would not have followed the task details properly. From this analysis, we can arrive at the conclusion that the application so far created is **adequate**. In terms of efficiency, certain tasks have consumed lesser time while others took more which completely depends on the testers. "Task 7: Examine Calle Citron if he has peripheral neuropathy", consumed more time comparatively, this could be because of the procedure to be carried out for the examination, or it might be difficult to understand what exactly needs to be done in the task, whereas the "Task 9: Discuss the care plan with the Calle Citron" took less to more time comparing to others,

which depends on how deep the nurse provides the discussion with the patient(Calle Citron).

Testers	Efficiency		Effectiveness	
	Minimum time	Maximum time	Goals reached	Goals not reached
T1	00:45	Not applicable	9	Nil
T2	00:19	02:10	9	Nil
T3	00:11	01:47	9	Nil
T4	00:07	02:30	9	Nil
T5	00:10	03:51	9	Nil
T6	00:36	03:15	8	1 (Skipped)
T7	00:07	09:20	9	Nil
T8	00:16	05:29	9	Nil
T9	00:06	04:13	9	Nil

Figure 4.13: Analysis of Usability test results with testers

The 4.13, gives a brief view of the effectiveness and efficiency of the individual testers. From this, we can assess the complete effectiveness and efficacy of the application with a variety of users/testers. Some testers like T1, T2, T3, and T4 consumed lesser time for each task comparatively, which can be because of the understanding of the tasks, or experience in the field of diabetic care also could be the experience of using digital healthcare/digital tools. Testers like T5, T6, T8, and T9 consumed moderate timing to complete the tasks, whereas only T6 skipped a task throughout the course of the test. T7 is the only tester who took much time to complete the task, which could be due to doubts or clarifications for the tasks, also, T7 used a Samsung S21 device, and all the testers who used Samsung S21 felt it hard or difficult to touch/click the required button. This difficulty may be due to the presence of the screen protector which was on the screen of the mobile phone. And T7 could have found it more difficult.
A drawback of the test was that the observers were beginners, and had no prior experience of observing a test session where the participants sometimes fulfilled a task very quickly. Therefore they missed out on documenting all the activities of the testers, such as registering the time taken, goals achieved, and comments by the nurses. The observers failed to take notes promptly, therefore, some comments or time measurements or the goal achieved are mentioned as “Not applicable” in the table. Out of 9 testers 8 reached the goal and only one tester skipped certain tasks but reached the overall goal in the end. The comments given by the nurses

were considered as a suggestion for future improvement of the demonstrator and are described in **Discussion**, whereas the respondents' thoughts that were captured in a questionnaire, are described below, in 4.2.4 Post-test: User improvement suggestions questionnaire.

4.2.4 Post-test: User Improvement Suggestions questionnaire

The Post-test questionnaires [4.14] includes questions regarding the performers' preferences for using a digital tool in the future, improvements to be considered when bringing the demonstrator to further development, creating features and functionality that the HCP would use in their work situations in the future.

The questions elicited the test performers' thoughts about the structure and flow of the demonstrator, as well as on which platform such a tool could be used.

The majority (7 of 9) of the test performers preferred tablets rather than mobile phones. All the testers preferred to have a function that automatically generated risk grades in the app because they found it easy to manage, more secure, and clear to assess, inform and take necessary actions about the result. One participant also considered an automatically generated risk grade as a support to the "clinical gaze", but with the possibility to adjust the automatically proposed grade, if the competence of the HCP judged the results differently.

Eight of nine testers also preferred separate examinations and results for the right and left foot, as opposed to the routine of today.

A design question posed did not result in any sharp decision, nor any help for future designers, the one of "Do you think you would prefer a scroll down-function (going down on the screen) to next question in the foot examination, instead of what you have just tested (click on a button to come to next question)?" Half and half considered one of the two design proposals to be the best, and to find out, there is a need for a distinct user test, testing out that specific functionality with a larger number of users.

General experiences of the app were positive, however, the app was built in English and some testers (who used to work in Swedish) found it difficult to use. Three testers pointed out that the structure could need a "back button" so users could easily move between the different examinations, in case they do not follow the suggested order by the national clinical guidelines.

Post-test

Post-test	1101	1102	1103	1104	1105	1106	1107	1108	1109
In the future, would you prefer to use a tablet or a mobile ta make a digital foot examination?	Doesn't matter	Tablet to get bigger otherwise maybe no difference	Tablet	Tablet	Yes	Tablet	Tablet	Tablet	Tablet
Do you prefer to have an automatically generated risk scale in the app? Please, tell us about your thought about your answer.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
If yes,Comment	becomes clear and allows you to assess and inform about the result	fair judge. be able to adjust if the "Clinical gaze" says otherwise	No comments	Easy, Smooth	No comments	No comments	Easy management	No comments	Make it more secure
In the future, would you find it useful to always register the results for the left and right foot separately? Please, tell us about your answer	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Comment	No comments	No comments	No comments	Since you often put different loads on your feet, it is important to examine both the feet and find the right foot	No comments	crystal clear separate	No comments	they are not the same	No comments
Do you think you would prefer a scroll down- function (going down on screen) to next question in the foot examination instead of what you just have tested?	No	No	No	Yes	Yes	Yes	Yes	Yes	No
Comment	No comments	easy to see one page at a time but must be easy to go back	No comments	No comments	important to be able to move from behind	No comments	No comments	No comments	No comments
How do experience the structure of the app	Ok	light, no frills distracting, the layout was good. The questioners (what order) should come is probably difficult for all things different. You learn quickly	Good	deformity, circulation, neuropathy nails, etc.	feeling first then skin color temp hair nails	Somewhat hard-working especially the language	Good	No comments	I'ts logical. Want to have "Back" button
Other comments	No comments	No comments	No comments	No comments	No comments	No comments	No comments	No comments	Seems to be useful, but need some small improvements

Figure 4.14: Post test: User Improvement Suggestions questionnaire

Note : app = application

Improvement suggestions mentioned by the testers were to pay attention to the workflow order, and the order you should perform the examinations. Now the design followed the national clinical guidelines. One found it logical, while others found that some changes were needed. Analyzing the results, one could ask the question if the order of the examinations would turn out differently compared to the current workflow in the national clinical guidelines when it is supported digitally.

4.2.5 Post-test: System Usability Scale for user satisfaction and usability aspects

The SUS questionnaire for measuring satisfaction with usage revealed answers about how it was to perform the digital foot examination using the demonstrator. All questions were answered by all nine respondents. The first step analysis of data is shown in the chart and table of 4.15.

The questionnaire consisted of 10 questions, and in 4.15 the bars in the diagram sum up the options that the participants chose from the Likert scale. The questionnaire is constructed in a way that odd-numbered questions are "Positive experiences" and even-numbered questions are "Negative experiences".

After converting the row numbers to a SUS score of 0-100, the SUS score for measuring satisfaction of usage was 69 [4.17], just above the average SUS score of 68 [67].

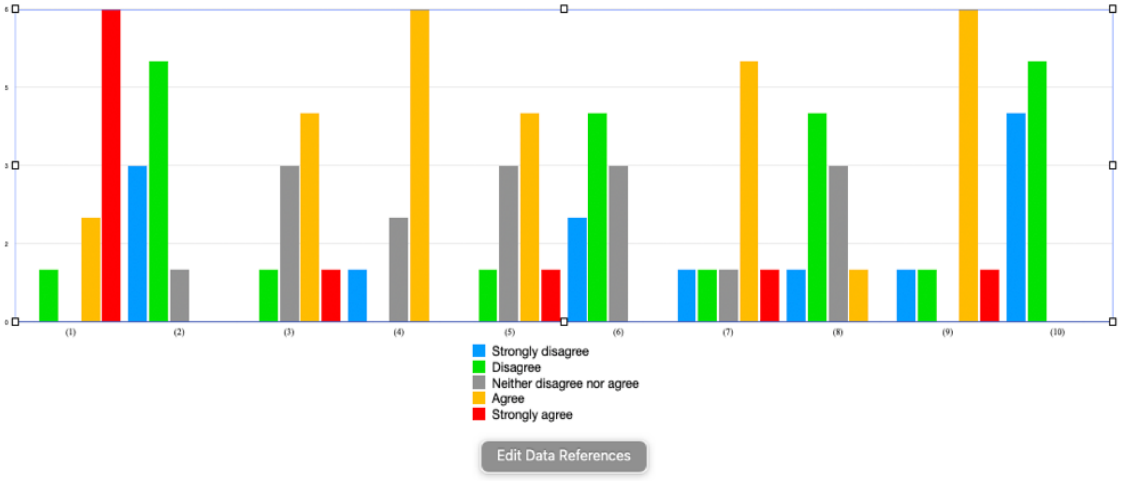


Table 1

	(1) Want to do DFE	(2) DFE is unnecessarily complicated.	(3) easy to use DFE	(4) needed technical help	(5) various features works well	(6) Some parts are illogically structured	(7) people will quickly learn to perform DFE	(8) DFE difficult to use.	(9) DFE felt safe to use.	(10) need to learn many new things
Strongly disagree	0	3	0	1	0	2	1	1	1	4
Disagree	1	5	1	0	1	4	1	4	1	5
Neither disagree nor agree	0	1	3	2	3	3	1	3	0	0
Agree	2	0	4	6	4	0	5	1	6	0
Strongly agree	6	0	1	0	1	0	1	0	1	0

Figure 4.15: Post-test: System Usability Scale measuring user satisfaction and usability aspects

Note: DFE = Digital Foot Examination Analyzing the odd questions, with positively tending responses, we see that 8 of the respondents wanted to do a DFE, while one did not agree. Five of nine agreed the DFE was easy to perform using the demonstrator, although six also stated they needed technical support (item 4). Five (of 9) stated that the various features worked well, and seven stated DFE felt safe to use. Six also said that people will quickly learn how to perform a DFE using the demonstrator.

Analyzing the even questions where the respondent should negate in order to "reply in a positive way", we see that the participants show overall satisfaction. Eight testers think that the DFE is not too complicated, and 9/9 state that they did not need to learn many new things. Six of 9 did not agree that some parts were illogically structured, whereas 3 did neither agree nor disagree. Whether the 3+1 testers that stated that DFE was difficult to use (5 stated it was not) were referring to the fact that the demonstrator was designed in English and not Swedish we cannot tell, as the SUS questionnaire does not provide any free text answers.

In sum, the respondents were answering mainly positively to the odd-numbered questions, and negatively to the even-numbered questions, showing overall satisfaction. The odd questions in 4.13 have mainly scored 4 and 5 points and the even questions mainly scored 1 to 2 points, apart from item 4, where the majority stated they needed technical help. A reply that was understandable. Technical assistance was needed for the devices which were used to carry out the usability test, an iPad,

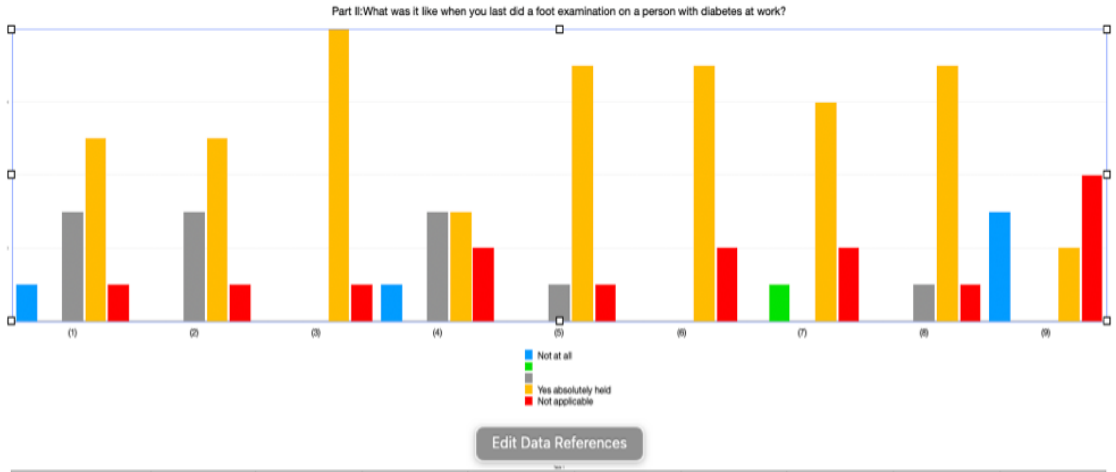
and a Samsung mobile phone. While using iPad, certain slides of the test were skipped, which was a technical issue but unable to fix on that very day. The tester who used a Samsung mobile phone found it hard to touch/click the buttons. This might be due to the presence of a physical screen protector on the mobile phone. In hindsight, the technical problems that occurred during the test session could have been foreseen with a more thorough pre-test on both of the devices, made by the observers and the test team.

The fact that they all (9/9) stated that *they did not need to learn many new things may refer* to the "unwritten code of work competence"; by acknowledging that you know of the examinations that were to be tested, you also acknowledge that you are skilled in your work.

After converting the individual row numbers to a SUS score of 0-100, the post-test SUS score reached 69. The calculation of the SUS score is shown in [4.17]. Comparing this score (69) to the previous score of the expectancy questionnaire (77), the conclusion is that the expectations were higher than what the demonstrator succeeded in delivering. The option "neither agree nor disagree" was used 12 times in the Pre-test Expectancy questionnaire, whereas 16 times in the post-test usability questionnaire, showing that the respondents were somewhat more insecure after testing the demonstrator, compared to their high expectations before testing. Comparing the SUS score of 69 with the literature review results made by *Sauro [67]* on 5000 users and 500 SUS evaluations, this evaluation scored just above the average of 68 and is thereby considered "acceptable" in the ranges based on the analyses by Sauro [67] (see 2.2 and 3.1).

4.2.6 Post-test: Previous experiences of foot examinations at work

Previous experiences of foot examinations at work were collected in the 9 questions relating to *What was it like when you last did a foot examination on a person with diabetes at work?*, presented in 4.16. The scale was from [1: Not at all], to [4: Yes, absolutely]. The results are shown in 4.16 reveal previous experiences of foot examinations at work. The respondents were asked to think about the last foot examination done and answered based on whether the patient received information including e.g.advice for foot self-care, risks with treatment, and if healthcare providers and patients had enough privacy when the patient's condition or treatment was discussed. The respondents mostly agreed to reply [4] "Yes, absolutely" on the questions posed, but two questions stood out; 4) *"Did the patient receive information about any risks with the treatment"* where 6 of 9 answered that this was not the case. Question 9) *"Whether the patient received written or digital information"* also collected negative answers [1: not at all] and [Not applicable] by 7 of 9 respondents.



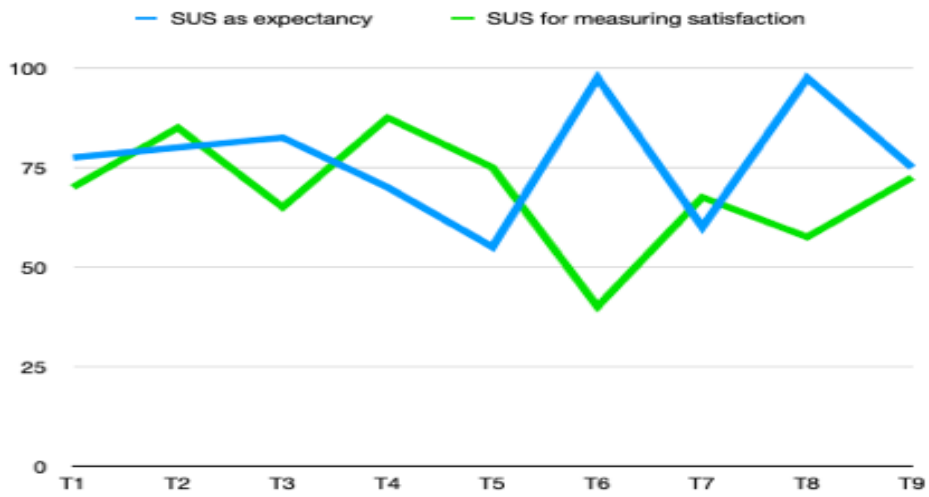
	(1) Do patient receive advice on feet self-care	(2) Is illness / health condition discussed with the patient	(3) Is relevant informations are provided to the patient if needed help?	(4) Do patient receive information about risks with the treatment	(5) Do patient receive information about warning signals regarding their health status	(6) Do healthcare providers and patient had enough privacy when the patient's condition or treatment was discussed	(7) Do healthcare providers explain the results of digital foot examination to the patient?	(8) Do the patient receive oral information	(9)Do the patient receive written or digital information
Not at all	1	0	0	1	0	0	0	0	3
	0	0	0	0	0	0	1	0	0
	3	3	0	3	1	0	0	1	0
Yes absolutely held	5	5	8	3	7	7	6	7	2
Not applicable	1	1	1	2	1	2	2	1	4

Figure 4.16: Post-test: Previous experiences of foot examinations at work

Regarding the remaining seven questions, answers were mainly positive, replying (4) or (3). Eight of nine respondents stated that their last patient (8) received oral information, including (1) advice on self-care of the feet, (2) health condition was discussed with the patient, (3) information was provided where to turn after the meeting, in case of need, as well as (5) information about warning signals to pay attention to. Seven healthcare professionals considered them to have (6) enough privacy when the patient's condition was discussed. The answers regarding question number 7:*Did you explain the results of the digital foot examination?* may indicate a misunderstanding. Six respondents stated 'Yes absolutely', but to our knowledge (based on answers from the Pre-test, 4.10) only three of them have used a digital tool to assess the feet.

4.2.7 Analyzing System Usability Scale Scores

The SUS results from the expectancy and satisfaction measurements were used to calculate the SUS scores. We had 9 HCP participants for the test, hence we had 9 responses for each of the statements of the questionnaires (see chart and table in 4.15). The SUS score was calculated for each tester individually using the formula discussed in section 3.5.1. The detailed calculation and the SUS measures are shown in J. Mean and median values were also calculated: for expectancy mean was 77, and for usability mean was 69. For the expectancy median was 77.5, and the usability median was 70.
It can be seen that the participants had high expectations towards the demonstrator, and had experienced a somewhat lower satisfaction with the demonstrator.



Tester	SUS as expectancy	SUS for measuring satisfaction
T1	77.5	70.0
T2	80.0	85.0
T3	82.5	65.0
T4	70.0	87.5
T5	55.0	75.0
T6	97.5	40.0
T7	60.0	67.5
T8	97.5	57.5
T9	75.0	72.5

Table 2

	SUS as expectancy	SUS for measuring satisfaction
Mean	77.0	69.0
Median	77.5	70.0

Figure 4.17: Analysis of SUS Score

Analyzing the individual results, 4 of 9 participants assessed their satisfaction with the demonstrator as higher than their expectations. Two participants lowered their results by 7.5 points or less, whereas three participants were more disappointed, showing a decrease of 17.5 points; 40 points; and 57.5.
For both the expectancy score and the satisfaction score, mean and median values still are within the “Acceptability ranges”, (65-75; 75–100) when compared to SUS scores, in general, [67] (2.2 and 3.1).

5

Discussion

In such a big study as this, several topics may be discussed, both widely and on a detailed level. Here the results are reflected, in relation to the research questions and the methods used.

5.1 Research questions and results

In the current study several interesting findings were registered and presented, a novel eHealth demonstrator was designed using a user-centered development approach and software, FIGMA. Below are the most important findings presented answering the research questions. Question one addresses: How an eHealth demonstrator could be designed to capture and support the workflow in diabetes foot care? The developing team found that the software's Lucid-chart and Figma complemented each other and that the conceptual design enabled the team to work interactively and iteratively. As the link was shared in Lucid-chart among the team, design decisions regarding the workflow made it clear how the future demonstrator should be programmed. Questions, such as "Shall a Learn about-icon be inserted here?"... "Shall a going-back-icon be placed at the bottom of the screen?" . . . " How shall the zooming function be designed?" could be validated immediately by potential future users of the system. The conceptual workflow enabled the team to make decisions about the workflow that in the next phase was programmed in Figma. In a similar way the demonstrator, the co-design, was developed by all in the team and had access to the Figma link. By pilot-testing the demonstrator, prior to the real usability test, the order of the examinations was checked by the developing team.
Research question two was answered by a package of usability test answering, if the demonstrator worked in the way it was expected to satisfy and potentially support its users in real work? By testing the demonstrator among a variety of HCP, not homogenous, consisting of a group of different professions and gender, several aspects were gathered from potential users. Some had more experience using tablets, others not. Doing the usability tasks took a long time for some test participants and was made quicker by others.
Research question three, "In what way did the Usability testing, SUS pre-and post-test questionnaires help in improving the design of the demonstrator, and later, the application that will be built?" By looking at the results expectancy Score pre-test versus post-test, 77 and 69 respectively, the developing team has started to improve the next version following the suggestions made by the testers. Overall, the lower post-test results of the System Usability Scale measuring satisfaction and that some

test participants yield scores of 40 to 57.5 indicate that either the foot examination flow; the functioning of the device; the test settings, or the demonstrator had major problems. However, the other six test participants had a score ranging from 67.5 to 87.5, around the number 68 that is suggested to be above average, according to the study by Sauro [67].

1. The novel eHealth demonstrator's workflow was designed using a Lucid chart which is then designed as an application.
    - To create a novel eHealth demonstrator accurate planning of the demonstrator is crucial. This is achieved in this thesis work by creating a conceptual design [4.1] containing the workflow of the application.
2. The demonstrator worked the way it should, and it has satisfied and potentially shown support for the users in real work.
    - The demonstrator was tested by HCPs. The testers were satisfied with the application. They found the application to be useful.
3. With the help of Usability tests like Pre-test demographics, User satisfaction questionnaire (Post-test), SUS as an expectancy questionnaire, and SUS measuring satisfaction of usage questionnaires, we received many suggestions and feedback which help in the improvement of the application. The most important suggestions for improvements were,
    - Create a "Back" button in all the slides and a voice recording option for documenting the documentation.
    - "More-information" box to add some important messages added to the documentation box.
    - Have an illustration of the feet and mark the spots of calluses/pressure areas rather than writing it. And to include left/right separate foot options to document the examination results.
    - To enable the Pinch-to-zoom option, operate "Zoom in" and "Zoom out" by using your fingers.
    - To have the "Scroll-down" option rather than swiping it to the right or left. And to have a clickable button, which shows the button that has been clicked.

5.2 Discussion about methods

The Usability test was carried out at Skövde sjukhus and Mölndals sjukhus. Usability testing plays a vital role in the iterative development of digital tools. The results or outcomes of the Usability testing are aimed to help us to enhance the prototype, and the demonstrator is expected to lead in the right way to deliver a useful yet creative product for the HCP. System Usability Scale as an expectancy questionnaire is a new initiative in our project work. It is one of the academic contributions of Shivani and the team. The usage of bilingual questionnaires and the creation of demonstrators in English gives opportunities to reuse in international studies, but the language barriers also hindered the Swedish HCP from fully answering the way they wanted, they complained. Also, the test procedure suffered from testing a demonstrator that was not designed in the language of the testers. Probably some of the test participants had scored the demonstrator differently if it was written in

Swedish. In the current study, the recordings (audio and video) have not yet been analyzed. Noticed, a limitation was that 3-4 test participants in the current study were gathered in the same room and only one voice recorder and one video camera were used. That led to the observations being limited recorded. It was impossible to record all test participants and it was not possible to record both from the front view and back view of the test participant. In future studies, consider using questionnaires, written in the language spoken by the test participants. In addition, the test procedure can be improved if one observer/test participant can make the observations in a separate room, fully equipped with timers, a voice recorder, and several video cameras. By the use of several video cameras, both the front and back views of the test participant can be recorded and used in post-evaluation work. Observations made from separate rooms would allow the tester to be more focused on the tasks and allow the observer to be focused on the test participant's action moreover, the recordings would be of good quality, and useful in post-evaluation. Finally, the test team is recommended to make a general rehearsal of the procedure before, in order to be familiar with the test rooms that will be used in the study.

5.2.1 Lessons learned

The demonstrator was tested via Usability testing, where conference halls were booked to perform the test. The rooms used for the tests were too small. We had time constraints when performing the test, hence having general rehearsals with staff was inappropriate. We recorded the whole test, and we just had a single camera and microphone for all the participants. Therefore, we were unable to record the audio and video of participants individually. The test was executed on both Android and iOS platforms in both locations. The demonstrator worked well in both systems, however, it showed some minor malfunctioning in iOS like skipping certain slides. All the devices were connected to wifi connections in both places. The whole project was carried out in a bilingual way, both in Swedish and English. Some questionnaires used in testing were in Swedish which was then translated into English. The demonstrator is developed in English which can be translated into Swedish later. The usability tests, Pre-test demographics, and User satisfaction questionnaire (Post-test) were not validated, rather the tests SUS as an expectancy and SUS measuring satisfaction of usage were validated as SUS scores [section 4.2.6].

5.3 Future Studies

Validate questionnaires (Pre-test demographics, User satisfaction questionnaire(Post-test)) that are not validated. Calculate the Standard deviation for SUS as an expectancy and SUS measuring satisfaction of usage. Validate the results [4.9] that are generated in the application. To improve the application with respect to the suggestions and feedback received from usability tests.

6
Conclusion

There is a lack of diagnostic tools for diabetic foot ulcers. In co-creation with users, and in an iterative development process, an eHealth demonstrator was designed, aiming to support the workflow when examining the feet of patients with diabetes. The demonstrator (app) was the first initiative to digitally enrich the prevention of diabetic foot ulcers regarding the possibility on site, close to the feet, and let healthcare personnel document a foot examination using an electronic tool. Based on the documentation, the risk category for the onset of ulceration was assessed. The nine test participants found the demonstrator to satisfy their needs to various degrees. The majority experienced, according to the satisfaction questionnaire System Usability Scale, that the demonstrator was useful (score 69), and the usability test showed that the effectiveness and efficiency of the demonstrator were achieved at this stage of development. A novel way of using the System Usability Scale as an expectancy questionnaire was created and used. It was one of the major academic contributions of the research team. It was considered good to have the automated risk grade establishment, which potentially makes the job of the healthcare professionals easier, both to document the foot examination as well as to treat the patients accordingly. Several suggestions for improvements were documented and will be used in the next phase of creating an eHealth tool supporting the foot examination.

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A
Appendix 1

CARES4WOUNDs (C4W) system	**INTENDED USE:** Captures the image of the wound, which is then processed for the management of DFU				
	FEATURES: Artificial intelligence-enabled wound imaging mobile application				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Nurses	Research Project	Singapore	iOS	[27]

M-DFEET	**INTENDED USE:** Facilitate early detection to prevent complication				
	FEATURES: The app has some features which are a login menu, main menu containing patient identity, diabetes screening form regarding patient beliefs, foot assessment items (visual, touch, sensation), conclusions from early foot assessment results, recommendation, health education about foot care, and notification				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Patients	Research Project	Indonesia	Andrid	[28]

Smart Assistant Diabetes	**INTENDED USE:** Facilitate self-care				
	FEATURES: It has Exercise info, BMI calculator, Blood Sugar Graph, Food Database and Calories Display, Reminder for Mealtime, Take Medication, and do Exercises.				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Patients	Research Project	Indonesia	Android	[29]

FootSnap	**INTENDED USE:** To standardize foot photographs with intended future use in diabetic foot lesions				
	FEATURES: The objective of the app is to standardise the captured diabetic foot for longitudinal/follow-up investigations of plantar surface of the foot				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Operator/ experimenter	Research Project	United Kingdom	iOS	[30]

DFUAPP	**INTENDED USE:** This application supports nurses in the decision-making process with regard to topical treatment of DFU.				
	FEATURES: The app includes some basic information about DFU, Evaluation of DFU, Treatments, and Clinical recommendations.				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Nurses	Research Project	Brazil	Android	[31]

M-DAKBAS	**INTENDED USE:** Facilitate self-care				
	FEATURES: Register glucose values and foot observations				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Patients with diabetes	Research Project	Turkey	Not Clarified	[18]

The Risk Tool	**INTENDED USE:** To predict risk of foot ulceration				
	FEATURES: A risk stratification is assessed based on a foot examination				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Health care professionals	Implemented in care	United Kingdom/ Scotland	Not Clarified	[19-21]

MyFootCare	**INTENDED USE:** To engage patients with diabetes in the healing process of the foot ulcers by setting goals, reminders om self-care and monitoring the healing progress				
	FEATURES: Take foot of the foot ulcer and facilitate engagement by by setting goals, reminders om self-care and monitoring the healing progress				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Patients	Research Project	Australia	Android	[22]

Telemedicine	**INTENDED USE:** DFU assessment				
	FEATURES: To assess DFU by telemedicine web platform were photos taken with mobile + ulcer record from primary health care to specialist health care for assessment of the wound				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Primary care nurses	Research Project	Norway	Not Clarified	[23-25]

Diabetic foot examination (CDFE)	**INTENDED USE:** To improve the completeness and frequency of diabetic foot exams.				
	FEATURES: a standardized documentation form +, an electronic reminder				
	USER	**TYPE**	**COUNTRY**	**PLATFORM**	**REFERENCE**
	Healthcare professionals	Research Project	United States Of America	Not Clarified	[26]

B

Appendix 2

Appendix 1. The structured foot examination in paper format
In English:

Foot examination in diabetes

Risk category	Instructions	Risk level if "Yes" to questions	Risk category 1-4 1=healthy foot	
Inspect and examine			R	L
Skin pathology	Are there any ulcers?	4		
	Pressure sores, cracks, callosities, corns, nail problems that could result in a risk of ulcer formation?	2		
Reduced blood circulation/nerve function	Is there any dry skin, pale skin, skin temperature, swelling or reduced hair growth?	2		
Foot deformity	Is there any amputation on the toe-foot-bone or hallux valgus, hammer toes?	3		
Palpate and examine				
Reduced blood circulation pulses	Is it not possible to palpate a. dorsalis pedis and/or a. tibialis posterior (continue with a doppler exam)	2		
Reduced nerve function superficial	Does the patient have reduced nerve function according to the Ipswich Touch Test/monofilament?	2		
Reduced nerve function deep	Does the patient have reduced nerve function tested with a tuning fork C128 Hz ?	2		
Patient's symptoms and previous ulcers				
Reduced nerve function	Does the patient experience tingling or numbness/walking on pillows in their feet or a change of sensation in their feet compared with before?	2		
Previous ulcers	Has the patient previously had a foot ulcer that had difficulty healing?	3		

From the above examination and patient history, categorise the risk and define it as follows.

Put the highest risk level in the box ☐ Give the risk level (1-4)
The highest risk level is automatically transferred to the NDR

Have you spoken to the patient with advice on self-care, both verbally and in writing?
☐ Yes

Document the action in the medical record

C

Appendix 3

ID 1101	Date .....

Pre-tests

Information: when you fill in the paper your are welcome to speak-out-load if you have any comments or questions.

1. What is your name:

2. How old are you?

3. Gender?

☐ Women
☐ Man
☐ Other

4. Where do you work?

5. What is your profession?

6. How many years have you worked in your profession?

7. Have your previously worked with digital tools to assess the foot status in patient with diabetes?

☐ Yes
☐ No

8. If yes, which tools?

9. Have you previously worked with digital tools when you assess the health status in patients with diabetes e.g. patientenkäten from NDR or photo documentation) (and exclude to mention the ordinary medical record system)?

☐ Yes
☐ No

10. If yes, which tools?

11. Have you ever taken a photo of the foot in person with diabetes as a base for the documentation?

12.

D

Appendix 4

Questionnaire for healthcare professionals participating in the study "Optimized care of people with diabetes and foot complications in primary care"

The questionnaire contains questions about foot examinations that you performed on patients with diabetes and foot complication. Answer the questions by selecting the answer option that suits you best. If you are unsure, still check the box that feels most correct. Put a cross in the box like this☒

Part I:How was it to do digital foot examination?

1) **I think I will want to do digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

2) **I thought digital foot examination was unnecessarily complicated.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

3) **I found it easy to use digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

4) **I needed technical help to perform digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

5) **I thought the various features of digital foot examination were well-functioning.**

System Usability Scale and questions about care meeting Date: 2022-..-..

Id: 110

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

6) **I thought that the different parts of digital foot examination were illogically structured.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

7) **I think most people will quickly be able to learn to perform digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

8) **I found digital foot examination difficult to use.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

9) **It felt safe to use digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

10) **I needed to learn many new things in advance to conduct digital foot**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

E

Appendix 5

Usability test of a digital foot examination for persons with diabetes

Task for the test of the usability of diabetic foot examination

You will sit by a table and have a tablet in front of you. First, we use some tasks just to warm-up. Then you have specific tasks written on the paper. A goal is set for each task and you will get an instruction of how to reach the goals. When the task is over you tell the observer you have finished the task by saying "jag är klar".

When going through the tasks, please "speak-out-load" what you think. This is of great help for the observers. And remember, it is the app that is being tested, not you. You are our valuable tester in this usability test.

1. Task: to enter the app

Scenario: *You are the nurse Beata Belund. You are going to make a structured foot examination by using the app.*

Goal: To enter the app and to log in.

Start:

1. Start the app on the tablet and
2. log in.

End: Tell the observer when you are ready.

Observer

a. Warm-up task:

Measure the time for task 1 (min-sec) = not part of the test

Usability test of a digital foot examination for persons with diabetes

2. Task. Select your patient (Calle Citron)

Scenario: *You are at the clinic and have Calle Citron in front of you. Calle Citron is booked in the system. You will now start the structured foot examination.*

Goal: To select Calle Citron to be ready to start the examination.

Start:

1. Find Calle Citron on the list.
2. Click on his name.
   Note: Calle Citron appears among other fake patients. However no personal number appears because the patient is faked.
3. Click on "Start new examination"

End: Tell the observer when you are ready.

Observer

a. Warm-up task:

Measure the time for task 2 (min-sec)

---

3. Task. Examine for pressure area

NOTE: in this app there is a fake possibility to make a voice recording, that you will use in this task.

Scenario: *Calle Citron´s feet are photographed. Look at the photo beside you and examine the feet for presence of pressure area.*

Goal: To assess and document the localisation of the pressure area.

Start:

1. Start the examination by reading "Have the patient pressure areas".
2. Examine the feet by looking at the photo.
3. Save the results.
4. Record the localisation of the pressure damages by talking out loud to the app.
5. Click save.

End: Tell the observer when you are ready.

Observer

In between Have the patient pressure areas YES

a. Measure the time for task 3 (min-sec) – and how much time did the tester use outside the app [examining the feet]

.....

b. Did the tester save Yes (pressure) for left and right foot?

- ☐ Ja
- ☐ Nej

Comments:

.....

☐ Ja

4

Usability test of a digital foot examination for persons with diabetes

☐ Nej

Comments:

.....

.....

FOR next version of the app: Design a clickable button, that shows that the button has been clicked on.

Usability test of a digital foot examination for persons with diabetes

c. Did the tester record for both feet?

- ☐ Ja
- ☐ Nej

Comments:

.....

4. Task. Examine for ingrown nails

NOTE: HELP tester to Move forward in the app, by clicking "NO" through the examinations that you will NOT do: (foot ulcer, cracks on the foot, calluses, loss of hair on toes, inappropriate shoes)

Make sure the tester starts at the right point:

Scenario: *You look at the toes of Calle Citron. You are unsure of what ingrown nails looks like. Calle Citron has ingrown nails on the hallux on the right side.*

Goal: To assess and document the localisation of ingrown nails.

Start:

1. Start the examination by reading "Have the patient ingrown nails".
2. Click on "learn about" to see how ingrown nails look like.
3. Click on "Back to inspection"
4. Specify the localisation of the ingrown toe nails [YES on Right foot, NO on left foot]
5. Click save

End: Tell the observer when you are ready.

Observer

a. Measure the time for task 4 (min-sec)

.....

b. Did the testers save Yes (ingrown nails) for right foot?

☐ Ja

5. Task. Examine for Hallux Valgus

NOTE: *You are doing well.* Move forward in the app, by clicking "NO" through the examinations that you will NOT do: (thickened nails, signs of fungus on nails, hammer toe)

Scenario: Now you should examine for hallux valgus. You are not sure what it could look like, when you are examining the photo of Calle Citron. To be sure, you want to find out how a hallux valgus could look like.

Goal: To assess and document the localisation of hallux valgus

Start:

1. Start the examination by reading"Have the patient hallux valgus?"
2. Click on "learn about" to see how hallux valgus look like.
3. Click on "Back to inspection"

➔ Look at the photo of the feet of Calle Citron

4. Specify the localisation of the hallux valgus.
5. Save the result.

End: Tell the observer when you are ready.

Observer

a. Measure the time for task 5 (min-sec)

.....

b. Did the tester look at the "Learn about"

- ☐ Ja
- ☐ Nej

c. Did the testers save Yes (hallux valgus) for right foot?

- ☐ Ja
- ☐ Nej

6

Usability test of a digital foot examination for persons with diabetes

Comments:

.....

As a difference from last task, we give less information here on #4: Where they should click YES on right foot, and NO on left foot. = Measure Increase of know how,,!

.....

6. Task. Ask Calle Citron if he has peripheral neuropathy

NOTE: Move forward in the app, by clicking "NO" through the examination that you will NOT do: (skin dry etc)

6. Task. Ask Calle Citron if he has peripheral neuropathy

NOTE: Move forward in the app, by clicking "NO" through the examination that you will NOT do: (skin dry etc)

Scenario: *When talking with Calle Citron he says that he has strange sensations in his feet. Sometimes he feels a tingling sensation, sometimes a sudden pain exists and all toes feel numb.*

Goal: *To assess and document the presence of numbness/tingling sensation in the patient's feet.*

Start:

1. Start the examination by reading "Does the patient experience tingling/numbness in the feet?". (Ask the patient)
2. Specify the localisation of the tingling/numbness
3. Save the result

End: Tell the observer when you are ready.

Observer

a. Measure the time for task 6 (min-sec)

.....

b. Did testers save "Loss" for left and right foot?

- ☐ Ja

Usability test of a digital foot examination for persons with diabetes

- ☐ Nej

Comments:

.....

.....

.....

.....

.....

.....

The right way is to Answer YES and YES on right/left foot.

7. Task. Examine Calle Citron if he has peripheral neuropathy

NOTE: Move forward in the app, by clicking "NO" through the examinations that you will NOT do: (Ask the patient if the sensation in the foot...? Ask if the patient, previously, have had a hard to heal foot ulcer? Have the patient loss of palpable pulses in arteria dorsalis pedis? Have the patient loss of palpable pulses in tibialis posterior?)

Scenario: *You want to examine if Calle Citron have peripheral neuropathy by using the Ipswich Touch Test. In this scenario Calle has loss of sensation in all toes on the left foot.*

Goal: *To assess and document peripheral neuropathy by using the Ipswich Touch Test*

Start:

1. Start the examination by reading "Do the patient have loss of sensation (Ipswich Touch Test)"
2. Click on "learn about".
3. You find the text too small, so you click on "zoom in"
4. You read the description on how to do, and you look at the picture of the feet describing in which order you should perform the test.

➔ Pretend that you make the Ipswich Touch test on the toes that you find in the photo of the feet of Calle Citron

5. Then you go "Back to inspection"
6. You want to save the result for each foot
7. Click save

End: Tell the observer when you are ready.

Observer

a. Measure the time for task 7 (min-sec)

.....

b. Did the testers click on "Learn about"?

- ☐ Ja
- ☐ Nej

Usability test of a digital foot examination for persons with diabetes

Comments:

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The right way is to Answer LOSS and LOSS on right/left foot.

Usability test of a digital foot examination for persons with diabetes

c. Did the testers save "Loss" for left and right foot?

- ☐ Ja
- ☐ Nej

Comments:

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8. Task. Look at the summary and confirm that the results are "Ok".

NOTE: Move forward in the app, by clicking "NO" through the examinations that you will NOT do:
(Monofilament? Peripheral neuropathy (Tested with tuning fork))

Scenario: *You have made all the examinations that are included in the app. You would now like to look at the summary and confirm that the results are "Ok"*

***Goal**: Confirm that the results are "Ok".*

Start:

1. Start the examination by reading"Thank you for your inspection".
2. Read the summary
3. Confirm that what is recorded/saved is ok.

End: Tell the observer when you are ready.

Observer

a. Measure the time for task 8 (min-sec)

.....

b. Did the tester scroll down to the Ipswich Touch Test?

- ☐ Ja
- ☐ Nej

Comments:

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They look at the SUMMARY, and see the listed RISK FACTORS in red, in the text.

The questions that do not bring forward any problems are NOT SHOWN.

9. Task. Discuss the care plan with Calle Citron

Scenario: *You show the results and the risk grade for Calle Citron. When Calle sees that podiatry is recommended for persons with risk grade 3 he says "But I have never been referred to a podiatrist, nor have I been referred to the department of Prosthetics & Orthotics.*

***Goal**: To close the examination of the feet of Calle Citron*

Start:

1. Show the risk grade and the summary for Calle [or an observer]
2. Show Calle also the (printed) recommendations related to his Risk grade 3.
3. Tell Calle that he will be referred to podiatry, and to the department of Prosthetics and Orthotics for proper shoes. He will be called back to the primary care in 6 months.

End: Tell the observer when you are ready.

Observer

a. Measure the time for task 9 (min-sec)

.....

b. Did the tester show the results for Calle Citron?

- ☐ Ja
- ☐ Nej

c. What discussion had Beata Belund with Calle Citron regarding the care plan?

Comments:

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.....

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Appendix 6

Post-tests

ID 11....	Date .....

Information: when you fill in the paper your are welcome to speak-out-load if you have any comments or questions.

1. In the future, would you prefer to use a tablet or a mobile ta make a digital foot examination?

2. Do you prefer to have an automatically generated risk scale in the app? Please, tell us about your thought about your answer.

☐ Yes
☐ No

3. In the future, would you find it useful to always register the results for the left and right foot separately? Please, tell us about your though about your answer

☐ Yes
☐ No

Post-tests

4. Do you think you would prefer a scroll down- function (going down on screen) to next question in the foot examination instead of what you just have tested?

☐ Yes
☐ No

5. How do you experience the structure of the app?

6. In the future, would you find it useful to always register the results for the left and right foot separately?

7. Other comments

G

Appendix 7

Questionnaire for healthcare professionals participating in the study "Optimized care of people with diabetes and foot complications in primary care"

The questionnaire contains questions about foot examinations that you performed on patients with diabetes and foot complication. Answer the questions by selecting the answer option that suits you best. If you are unsure, still check the box that feels most correct. Put a cross in the box like this☒

Part I:How was it to do digital foot examination?

1) **I think I will want to do digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

2) **I thought digital foot examination was unnecessarily complicated.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

3) **I found it easy to use digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

4) **I needed technical help to perform digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

5) **I thought the various features of digital foot examination were well-functioning.**

System Usability Scale and questions about care meeting Date: 2022-..-..

Id: 110

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

6) **I thought that the different parts of digital foot examination were illogically structured.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

7) **I think most people will quickly be able to learn to perform digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

8) **I found digital foot examination difficult to use.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

9) **It felt safe to use digital foot examination.**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

10) **I needed to learn many new things in advance to conduct digital foot**

1. Strongly disagree	2. Disagree	3. Neutral	4. Agree	5. Strongly agree
☐	☐	☐	☐	☐

H

Appendix 8

Part II:What was it like when you last did a foot examination on a person with diabetes at work?

Answer the questions by selecting the answer option that best fits in the scale from 1 (very bad or not at all) to 4 (very good or Yes, completely).
If you are unsure, still check the box that feels most correct. Put a cross in the box like this ☒

11) **Did the patient receive advice on self-care of the feet?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

12) **Was the patient's illness / health condition discussed with the patient?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

13) **Did you provide information to the patient about where he or she should turn if he or she needed help or further questions arose after the visit?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

14) **Did the patient receive information about any risks with the treatment?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

15) **Did the patient receive information about warning signals to pay attention to regarding their illness / your health condition or their aid?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

Did you and the patient have enough privacy when the patient's condition or

3

System Usability Scale and questions about care meeting Date: 2022-...-...

Id: 110

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

17) **Did you explain the results of digital foot examination to the patient?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

18) **Did the patient receive oral information?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

19) **Did the patient receive written or digital information?**

1. Not at all	2.	3.	4. Yes, absolutely	5. Not current
☐	☐	☐	☐	☐

19. If yes to question 26, you can develop your answer here. Please text clearly.

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Appendix 9

Tasks	**Patients**					
	Tester 1			Tester 2		
Device used for the test (Platform)	Ipad (iOS)			Samsung S21 (Android)		
	Measured time (minutes:seconds)	Goal (Yes/No)	Comments	Measured time (minutes:seconds)	Goal (Yes/No)	Comments
Warm up tasks 1 and 2 :Measure the time for task1 and 2 **(not part of the test)**	0:45			0:25		
Task 1: To enter the app						
Goal: to enter the app and to log in						
Task 2: Select your patient (Calle Citron)						
Goal: to select Calle Citron to be ready to start the examination.						
Whether the task is been completed		Yes			Yes	
Tasks (measured)						
Task 3: Examine for Pressure areas						
Goal: To assess and document the localisation of pressure area						
○ Measure the time for task 3	Not applicable			1:02		
○ Did the tester save Yes(pressure) for left and right foot		Yes	Not applicable		Yes	Not applicable
○ Did the tester record for both feet?		Not applicable	Not applicable		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 4: Examine for ingrown nails						

Tasks	Patients					
Goal: To assess and document the localisation of ingrown nails						
○ Measure the time for task 4	Not applicable			1:43		
○ Did the tester save Yes(ingrown nails) for right foot		Not applicable	Not applicable		Yes	After 7 clicks the command "Back to inspection" was executed. The tester would like the button Yes/ No to be highlighted when clicked on. This would validate and indicate for the user that the result is registered.
Whether the task is been completed		Yes			Yes	
Task 5: Examine for Hallux Valgus						
Goal: To assess and document the localisation of Hallux Valgus						
○ Measure the time for task 5	Not applicable			0:40		
○ Did the tester look at the "Learn about"		Not applicable	Not applicable		Yes	Not applicable
○ Did the tester save Yes(Hallux Valgus) for right foot		Not applicable	Not applicable		Yes	The tester would like the button Yes/No to be highlighted when clicked on. This would validate and indicate for the user that the result is registered.
Whether the task is been completed		Yes			Yes	
Task 6: Ask Calle Citron if he has peripheral neuropathy						

Tasks	Patients					
Goal: To assess and document the presence of numbness/tingling sensation in the patient's feet						
○ Measure the time for task 6	Not applicable			0:20		
○ Did the testers save "Loss" for left and right foot		Not applicable	To have an icon "back" in the system		Yes	The tester would like the button Yes/No to be highlighted when clicked on. This would validate and indicate for the user that the result is registered.
Whether the task is been completed		Yes			Yes	
Task 7: Examine Calle Citron if he has peripheral neuropathy						
Goal: To assess and document peripheral neuropathy by using the Ipswich Touch Test						
○ Measure the time for task 7	Not applicable			2:05		
○ Did the tester click on "Learn about"		Not applicable	A larger description in "Learn about". When zooming in, it is not clear that there are two illustration/ explanations.		Yes	A zoom function is desired, not just a button for zoom in /zoom out
○ Did the testers save "Loss" for left and right foot		Not applicable	Not applicable		Yes	Not applicable

Tasks	Patients					
Whether the task is been completed		Yes			Yes	
Task 8: Look at the summary and confirm that the results are "OK"						
Goal: Confirm that the results are "OK"						
○ Measure the time for task 8	Not applicable			0:19		
Whether the task is been completed		Yes			Yes	Good to have a summary and not just the risk grade. A Function that allows the tester to see the full result for example the result of Ipswich touch test when clicking on "Ipswich Touch Test" is wanted. Would like to have the possibility to look at All results when needed. Would like to choose to see either All results or only the Risk Factors.
Task 9: Discuss the care plan with the Calle Citron						
Goal : To close the examination of the feet of Calle Citron						
○ Measure the time for task 9	Not applicable			2:10		
○ Did the tester show he results for Calle Citron?		Not applicable	Not applicable		Yes	Not applicable
○ What discussion had Beata Belund with Calle Citron regarding the care plan?			Not applicable			Calle wanted to see the results. Digital referrals wanted : The podiatrist/the department of Prosthetics and Orthotics are with a "pling" or "flag" noticed about the new referral or a new need. Free text section: if the patients are getting a referral (in hand) and don't want to go to the podiatrist. The nurse (Beata Belund) wants to

Tasks	Patients					
○ What discussion had Beata Belund with Calle Citron regarding the care plan?			Not applicable			Calle wanted to see the results. Digital referrals wanted : The podiatrist/the department of Prosthetics and Orthotics are with a "pling" or "flag" noticed about the new referral or a new need. Free text section: if the patients are getting a referral (in hand) and don't want to go to the podiatrist. The nurse (Beata Belund) wants to make a note about the care that are offered.
Whether the task is been completed		Yes			Yes	

Tasks						
	Tester 3			Tester 4		
Device used for the test (Platform)	Ipad (iOS)			Ipad (iOS)		
	Measured time (minutes:seconds)	Goal (Yes/No)	Comments	Measured time (minutes:seconds)	Goal (Yes/No)	Comments
Warm up tasks 1 and 2 :Measure the time for task1 and 2 **(not part of the test)**	0:11			0:14		
Task 1: To enter the app						
Goal: to enter the app and to log in						
Task 2: Select your patient (Calle Citron)						
Goal: to select Calle Citron to be ready to start the examination.						
Whether the task is been completed		yes			Yes	
Tasks (measured)						
Task 3: Examine for Pressure areas						
Goal: To assess and document the localisation of pressure area						
○ Measure the time for task 3	1:08			2:33		
○ Did the tester save Yes(pressure) for left and right foot		yes	Not applicable		Yes	More on Left foot
○ Did the tester record for both feet?		yes	Not applicable		Yes	Not applicable
Whether the task is been completed		yes			Yes	
Task 4: Examine for ingrown nails						

Tasks						
Goal: To assess and document the localisation of ingrown nails						
○ Measure the time for task 4	1:00			Not applicable		
○ Did the tester save Yes(ingrown nails) for right foot		Yes	The image of the foot was in rear view, therefore the tester was not able to locate the ingrown nails		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 5: Examine for Hallux Valgus						
Goal: To assess and document the localisation of Hallux Valgus						
○ Measure the time for task 5	0:17			Not applicable		
○ Did the tester look at the "Learn about"		Yes	Not applicable		Yes	Not applicable
○ Did the tester save Yes(Hallux Valgus) for right foot		No	The tested commented that the patient has Hallux Valgus on Left foot.		No	Tester says that the patient has Hallux Valgus on Left foot
Whether the task is been completed		Yes			Yes	
Task 6: Ask Calle Citron if he has peripheral neuropathy						
Goal: To assess and document the						

Tasks						
Goal: To assess and document the presence of numbness/tingling sensation in the patient's feet						
○ Measure the time for task 6	1:02			Not applicable		
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 7: Examine Calle Citron if he has peripheral neuropathy						
Goal: To assess and document peripheral neuropathy by using the Ipswich Touch Test						
○ Measure the time for task 7	1:47			2:30		
○ Did the tester click on "Learn about"		Yes	Not applicable		Yes	Not applicable
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		Yes	Not applicable

Tasks						
Whether the task is been completed		Yes			Yes	
Task 8: Look at the summary and confirm that the results are "OK"						
Goal: Confirm that the results are "OK"						
○ Measure the time for task 8	0:27 (Time taken for task 8 and 9)			0:07		
Whether the task is been completed		Yes			Yes	
Task 9: Discuss the care plan with the Calle Citron						
Goal : To close the examination of the feet of Calle Citron						
○ Measure the time for task 9	0:27 (Time taken for task 8 and 9)			Not applicable		
○ Did the tester show he results for Calle Citron?		Yes	Not applicable		Not applicable	Not applicable
○ What discussion had Beata Belund with Calle Citron regarding the care plan?			Nice to have the application.		Not applicable	Not applicable

○ What discussion had Beata Belund with Calle Citron regarding the care plan?			Nice to have the application.		Not applicable	Not applicable
Whether the task is been completed		Yes			Yes	

Tasks						
	Tester 5			Tester 6		
Device used for the test (Platform)	Samsung S21 (Android)			Ipad (iOS)		
	Measured time (minutes:seconds)	Goal (Yes/No)	Comments	Measured time (minutes:seconds)	Goal (Yes/No)	Comments
Warm up tasks 1 and 2 :Measure the time for task1 and 2 **(not part of the test)**	0:10			0:36		
Task 1: To enter the app						
Goal: to enter the app and to log in						
Task 2: Select your patient (Calle Citron)						
Goal: to select Calle Citron to be ready to start the examination.						
Whether the task is been completed		Yes			Yes	
Tasks (measured)						
Task 3: Examine for Pressure areas						
Goal: To assess and document the localisation of pressure area						
○ Measure the time for task 3	0:45			2:07		
○ Did the tester save Yes(pressure) for left and right foot		Yes	Not applicable		Not applicable	Spoken out loud
○ Did the tester record for both feet?		Yes	Not applicable		Not applicable	Not applicable
Whether the task is been completed		Yes			Yes	
Task 4: Examine for ingrown nails						

Tasks						
Goal: To assess and document the localisation of ingrown nails						
○ Measure the time for task 4	2:48			3:00		
○ Did the tester save Yes(ingrown nails) for right foot		Yes	The tester had to press real HARD on the screen to get forward. When trying to press less the screen responded. The tester tried to have the mobile in her hand to get the screen to respond. Missed to click "Learn about". The tester was confused if we meant that the illustration of the ingrown nails was from a real patient or just a demo of an ingrown nail.		Not applicable	Spoken out loud
Whether the task is been completed		Yes			Yes	
Task 5: Examine for Hallux Valgus						
Goal: To assess and document the localisation of Hallux Valgus						
○ Measure the time for task 5	0:43			1:38		
○ Did the tester look at the "Learn about"		Yes	Not applicable		No	The tester used the function "Learn about" for nail-thickened examination.
○ Did the tester save Yes(Hallux Valgus) for right foot		Yes	The tester would like the button Yes/No to be highlighted when clicked on. This would validate and indicate for the user that the result is registered.		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 6: Ask Calle Citron if he has peripheral neuropathy						

Tasks						
Goal: To assess and document the presence of numbness/tingling sensation in the patient's feet						
○ Measure the time for task 6	1:24			0:37		
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		No	Not applicable
Whether the task is been completed		Yes			Skipped it	
Task 7: Examine Calle Citron if he has peripheral neuropathy						
Goal: To assess and document peripheral neuropathy by using the Ipswich Touch Test						
○ Measure the time for task 7	3:51			2:07		
○ Did the tester click on "Learn about"		No	The tester did not find the "Back to inspection" button. The tester wants a "Back" button for every task that should be design in an intuitive manner. The tester used the back-function in the Samsung phone. The tester was confused "Shall I press the toes on the illustration in Learn About?…and if Yes…does the app register it as a YES when I press a toe that "in reality with the patient in front of me" have identified as a toe with sensory loss?. The nurse was unclear whether she should register yes/feet or Yes/toe?		Yes	Not applicable
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		Yes	Not applicable

Tasks						
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 8: Look at the summary and confirm that the results are "OK"						
Goal: Confirm that the results are "OK"						
○ Measure the time for task 8	0:10			3:15 (Time taken for both task 8 and 9)		
Whether the task is been completed		Yes			Yes	The tester had some doubts and got clarified
Task 9: Discuss the care plan with the Calle Citron						
Goal : To close the examination of the feet of Calle Citron						
○ Measure the time for task 9	2:46			3:15 (Time taken for both task 8 and 9)		
○ Did the tester show he results for Calle Citron?		Yes	Not applicable		Not applicable	Not applicable
○ What discussion had Beata Belund with Calle Citron regarding the care plan?			Good to print the results including the risk grade. Good to have the risk grade schema at work, visible to refer to in discussion. Mobile should be useful for healthcare professionals. Tablet(with greater text) good for patients. A button "back to start" is missing.			The nurse says that Calle Citron has got risk grade 4 and the nurse doesn't want to click "OK" in the "Summary-Calle Citron" frame.
Whether the task is been completed		Yes			Yes	

Tasks						
	Tester 7			Tester 8		
Device used for the test (Platform)	Samsung S21 (Android)			Samsung S21 (Android)		
	Measured time (minutes:seconds)	Goal (Yes/No)	Comments	Measured time (minutes:seconds)	Goal (Yes/No)	Comments
Warm up tasks 1 and 2 :Measure the time for task1 and 2 **(not part of the test)**	0:34			0:16		
Task 1: To enter the app						
Goal: to enter the app and to log in						
Task 2: Select your patient (Calle Citron)						
Goal: to select Calle Citron to be ready to start the examination.						
Whether the task is been completed		Yes			Yes	
Tasks (measured)						
Task 3: Examine for Pressure areas						
Goal: To assess and document the localisation of pressure area						
○ Measure the time for task 3	1:04			1:47		
○ Did the tester save Yes(pressure) for left and right foot		Yes	Not applicable		Yes	Wants to have a picture of the foot in "Top View". The "Have the patient…side" disappeared. 3-4 clicks was needed to click YES
○ Did the tester record for both feet?		Yes	Not applicable		Yes	15 clicks was needed to assess the pages
Whether the task is been completed		Yes			Yes	
Task 4: Examine for ingrown nails						

Tasks						
Goal: To assess and document the localisation of ingrown nails						
○ Measure the time for task 4	4:31			1:40		
○ Did the tester save Yes(ingrown nails) for right foot		Yes	When register Yes and No how do I know that it means Yes, right and Yes, Left. The nurse pressed "Learn about" and was looking for information if the nurse could register for each foot respectively? Better to only have the choice to register Yes/right and Yes/ left or No/right and No/Left. Exclude the Yes/No alternative that not says what foot it is. Highlights wanted to show that the tester had clicked for instance "Yes"		Yes	Highlights wanted to show that the tester had clicked, for instance "Yes"
Whether the task is been completed		Yes			Yes	
Task 5: Examine for Hallux Valgus						
Goal: To assess and document the localisation of Hallux Valgus						
○ Measure the time for task 5	1:42			0:35		
○ Did the tester look at the "Learn about"		Yes	Not applicable		Yes	2 clicks was needed to assess "Learn about"
○ Did the tester save Yes(Hallux Valgus) for right foot		Yes	A back-button is needed		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 6: Ask Calle Citron if he has peripheral neuropathy						

Tasks						
Goal: To assess and document the presence of numbness/tingling sensation in the patient's feet						
○ Measure the time for task 6	0:26			0:40		
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		Yes	Not applicable
Whether the task is been completed		Yes			Yes	
Task 7: Examine Calle Citron if he has peripheral neuropathy						
Goal: To assess and document peripheral neuropathy by using the Ipswich Touch Test						
○ Measure the time for task 7	9:20			5:29		
○ Did the tester click on "Learn about"		Yes	The tester wants a "Back" button for every task that should be design in an intuitive manner. The tester used the back-function on the Samsung mobile. The tester wanted the illustration to be interactive so that the app register it as a YES when I press a toe in the illustration that "in reality with the patient in front of me" have identified as a toe with sensory loss?. Discussion about voice recording or texting the results or the above solution (an inter-active illustration). To dictate the results might be stressful for patient and nurse/podiatrist and take away the focus from the feet and the communication with the patient.		Yes	The tester wants a "Back"button for every cast that should be design in an intuitive manner. Wants a zoom function to be used with 2 fingers. Confusing with the zoom in/zoom out function to what illustration belongs it? Does something happen when I click on the toes on the illustration(inter-active function?) Wants a "Back to the test" button from the Learn about. Difficult to quit the Learn about.
○ Did the testers save "Loss" for left and right foot		Yes	Not applicable		Yes	Not applicable

Tasks						
Whether the task is been completed		Yes			Yes	
Task 8: Look at the summary and confirm that the results are "OK"						
Goal: Confirm that the results are "OK"						
○ Measure the time for task 8	0:27			0:30		
Whether the task is been completed		Yes			Yes	
Task 9: Discuss the care plan with the Calle Citron						
Goal : To close the examination of the feet of Calle Citron						
○ Measure the time for task 9	0:07			4:40		
○ Did the tester show he results for Calle Citron?		Yes			Yes	Not applicable

○ What discussion had Beata Belund with Calle Citron regarding the care plan?			The app should appear in the medical record system that is used in the unit. Photo documentation of ulcer healing over time is wanted. Photo documentation of changes of foot deformities, Neuropathy, Angiopathy is wanted. With the photo of the patients foot, the personal can mark for calluses, cracks, etc, with special symbols.			Digital referrals to podiatry and department of prosthetics and orthotics based on the summary is wanted. Option to print a referral and give to Calle or to send a link to his mobile. Thereafter Calle walks, calls, mails to the podiatrist and dept. of prosthetics and orthotics to get help. Able to take photos of the feet, dorsal, plantar view. The photos should be available for the patients and for personal. Calle shoes need to be adjusted.
Whether the task is been completed		Yes			Yes	

Tasks				
		Tester 9		
Device used for the test (Platform)		Ipad (iOS)		
		Measured time (minutes:seconds)	Goal (Yes/No)	Comments
Warm up tasks 1 and 2 :Measure the time for task1 and 2 **(not part of the test)**		0:06		
Task 1: To enter the app				
Goal: to enter the app and to log in				
Task 2: Select your patient (Calle Citron)				
Goal: to select Calle Citron to be ready to start the examination.				
Whether the task is been completed			Yes	
Tasks (measured)				
Task 3: Examine for Pressure areas				
Goal: To assess and document the localisation of pressure area				
○ Measure the time for task 3		2:00		
○ Did the tester save Yes(pressure) for left and right foot	e the 3-4 ES		Not applicable	Spoke out loud
○ Did the tester record for both feet?	ss		Yes	Not applicable
Whether the task is been completed			Yes	
Task 4: Examine for ingrown nails				

Tasks				
Goal: To assess and document the localisation of ingrown nails				
○ Measure the time for task 4		1:17		
○ Did the tester save Yes(ingrown nails) for right foot	at		Yes	Not applicable
Whether the task is been completed			Yes	
Task 5: Examine for Hallux Valgus				
Goal: To assess and document the localisation of Hallux Valgus				
○ Measure the time for task 5		1:06		
○ Did the tester look at the "Learn about"	s		No	Not applicable
○ Did the tester save Yes(Hallux Valgus) for right foot			Yes	Not applicable
Whether the task is been completed			Yes	
Task 6: Ask Calle Citron if he has peripheral neuropathy				

Tasks				
Goal: To assess and document the presence of numbness/tingling sensation in the patient's feet				
○ Measure the time for task 6		2:45		
○ Did the testers save "Loss" for left and right foot			No	No loss on both legs
Whether the task is been completed			Yes	
Task 7: Examine Calle Citron if he has peripheral neuropathy				
Goal: To assess and document peripheral neuropathy by using the Ipswich Touch Test				
○ Measure the time for task 7		4:13		
○ Did the tester click on "Learn about"	ton used the oes ck on er- ack earn arn		Yes	Not applicable
○ Did the testers save "Loss" for left and right foot			Yes	Loss for right and no loss for left

Tasks				
Whether the task is been completed			Yes	
Task 8: Look at the summary and confirm that the results are "OK"				
Goal: Confirm that the results are "OK"				
○ Measure the time for task 8		0:15		
Whether the task is been completed			Yes	
Task 9: Discuss the care plan with the Calle Citron				
Goal : To close the examination of the feet of Calle Citron				
○ Measure the time for task 9		Not applicable		
○ Did the tester show he results for Calle Citron?			Yes	Not applicable
○ What discussion had Beata Belund with Calle Citron regarding the care plan?	ıd d ıary mails ıet he			Need training. Search option in list of patients. "Recommended" to have Zoom in options for all images. "Back"button is needed in all questions. Needed to answer all question and it shouldn't change unless the doctor or healthcare professional wishes to change it. Options to show what they have early selected, under each question.

○ What discussion had Beata Belund with Calle Citron regarding the care plan?	ıd d ıary mails ıet he r the lle			Need training. Search option in list of patients. "Recommended" to have Zoom in options for all images. "Back"button is needed in all questions. Needed to answer all question and it shouldn't change unless the doctor or healthcare professional wishes to change it. Options to show what they have early selected, under each question.
Whether the task is been completed			Yes	

J

Appendix 10

System Usability Scale

Pre-test: System Usability Scale for expectancy

Reference: http://www.measuringusability.com/sus.php

	1		2		3		4		5		6		7		8		9		10		
User:	I think that I would like to use this application frequently	SUS#	I found this application to be unnecessarily complex	SUS#	I thought this application was easy to use	SUS#	I think that I would need the help of a support person to use this application	SUS#	I found the various functions in this app were well integrated	SUS#	I thought there was too much inconsistency	SUS#	I would imagine that most people would learn to use this application very quickly	SUS#	I found this application very cumbersome to use	SUS#	I felt very confident using this application	SUS#	I needed to learn a lot of things before I could get going with this application	SUS#	SUS Score
T1	4	3	2	3	4	3	1	4	4	3	2	3	3	2	2	3	4	3	1	4	**77.5**
T2	5	4	2	3	4	3	3	2	4	3	2	3	5	4	1	4	4	3	2	3	**80.0**
T3	5	4	2	3	5	4	3	2	3	2	2	3	5	4	1	4	5	4	2	3	**82.5**
T4	1	0	1	4	4	3	4	1	5	4	1	4	4	3	1	4	5	4	4	1	**70.0**
T5	3	2	3	2	3	2	4	1	4	1	3	2	4	3	2	3	4	3	4	1	**55.0**
T6	5	4	1	4	5	4	1	4	5	4	1	4	5	4	1	4	5	4	2	3	**97.5**
T7	4	3	3	2	3	2	3	2	4	3	3	2	4	3	2	3	4	3	4	1	**60.0**
T8	4	3	1	4	5	4	1	4	5	4	1	4	5	4	1	4	5	4	1	4	**97.5**
T9	4	3	2	3	4	3	2	3	4	3	2	3	4	3	2	3	4	3	2	3	**75.0**
Mean Value																					**77.0**
Median																					**77.5**

		Key
	1	strongly disagree
	2	disagree
	3	neutral
	4	agree
	5	strongly agree

System Usability Scale

Post-test: System Usability Scale for measuring satisfaction of usage

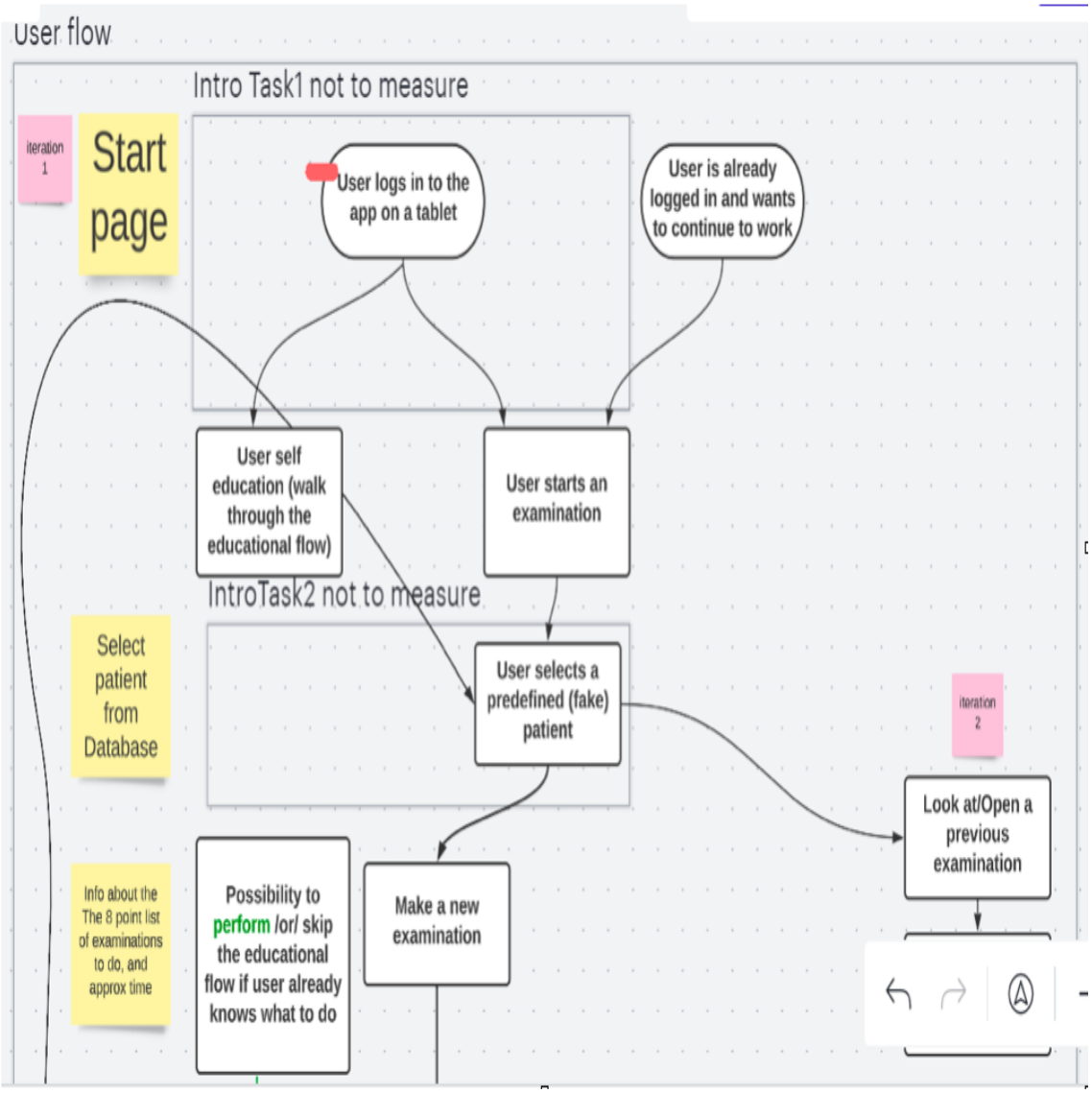
Reference: http://www.measuringusability.com/sus.php

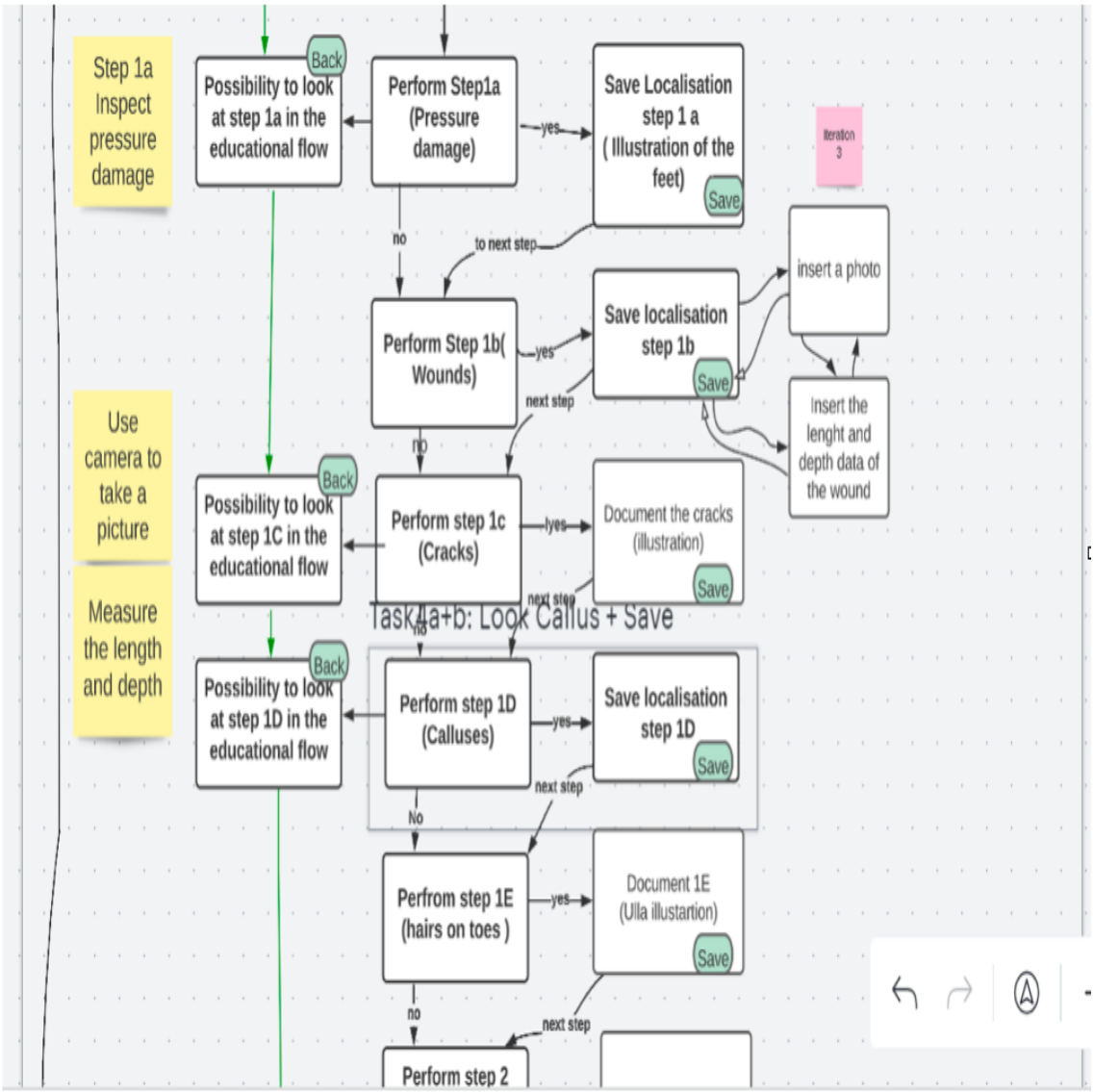
	1		2		3		4		5		6		7		8		9		10		
User:	I think that I would like to use this application frequently	SUS#	I found this application to be unnecessarily complex	SUS#	I thought this application was easy to use	SUS#	I think that I would need the help of a support person to use this application	SUS#	I found the various functions in this app were well integrated	SUS#	I thought there was too much inconsistency	SUS#	I would imagine that most people would learn to use this application very quickly	SUS#	I found this application very cumbersome to use	SUS#	I felt very confident using this application	SUS#	I needed to learn a lot of things before I could get going with this application	SUS#	SUS Score
T1	5	4	1	3	4	3	4	3	4	3	2	3	1	2	2	3	4	3	1	4	**70.0**
T2	5	4	2	3	5	4	1	4	4	3	3	2	5	4	2	3	4	3	1	4	**85.0**
T3	5	4	2	3	3	2	4	1	3	2	2	3	4	3	3	2	4	3	2	3	**65.0**
T4	5	4	2	3	4	3	4	1	5	4	1	4	5	4	1	4	5	4	1	4	**87.5**
T5	5	4	1	4	4	3	4	1	4	3	2	3	4	3	2	3	4	3	2	3	**75.0**
T6	2	1	3	2	2	1	4	1	3	2	3	2	3	2	3	2	1	0	2	3	**40.0**
T7	4	3	2	3	3	2	3	2	3	2	1	4	4	3	3	2	4	3	2	3	**67.5**
T8	5	4	1	4	5	4	4	1	2	1	3	2	2	1	4	1	2	1	1	4	**57.5**
T9	4	3	2	3	4	3	3	2	4	3	2	3	4	3	2	3	4	3	2	3	**72.5**
Mean value																					**69.0**
Median																					**70.0**

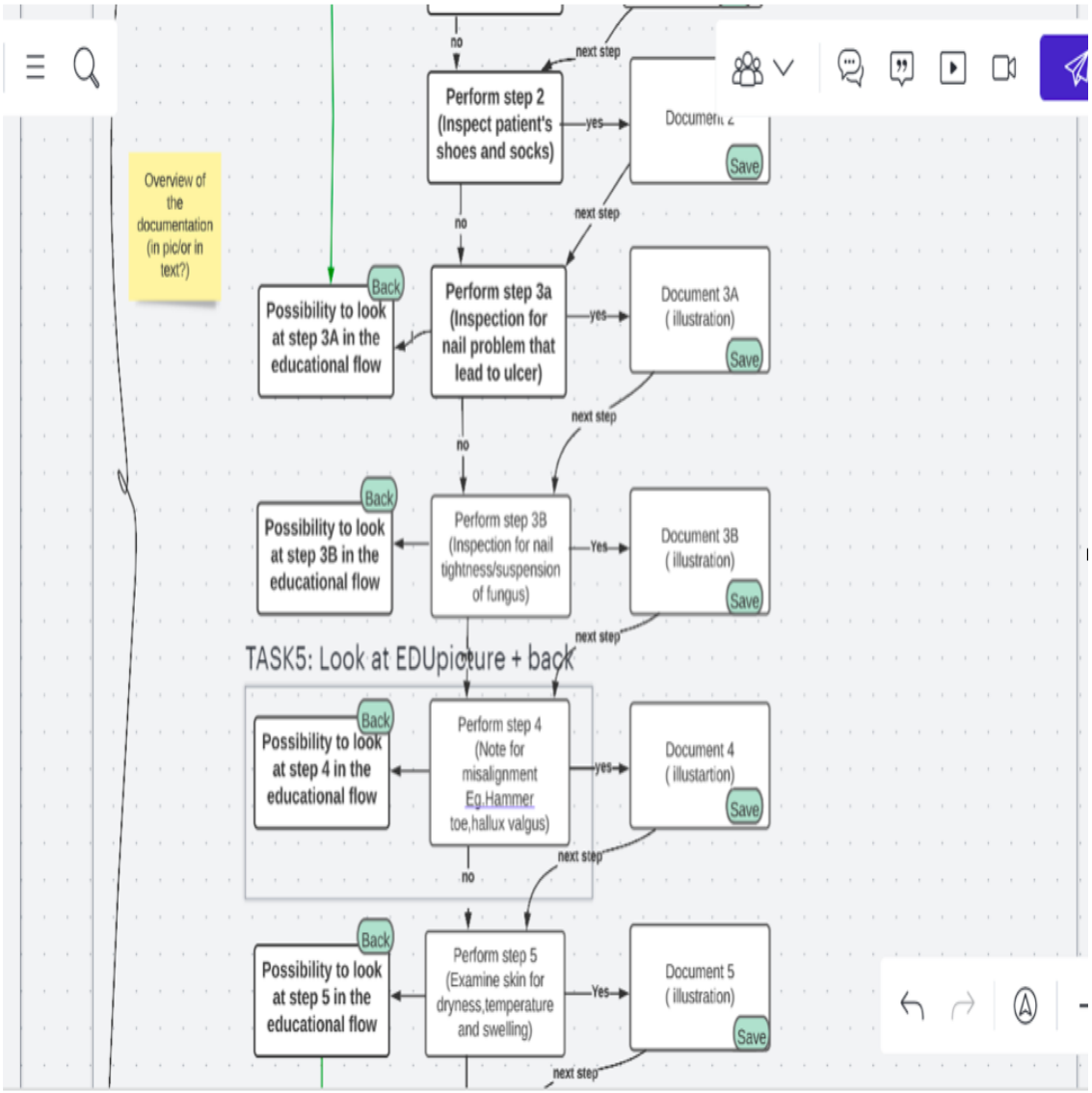
		Key
	1	strongly disagree
	2	disagree
	3	neutral
	4	agree
	5	strongly agree

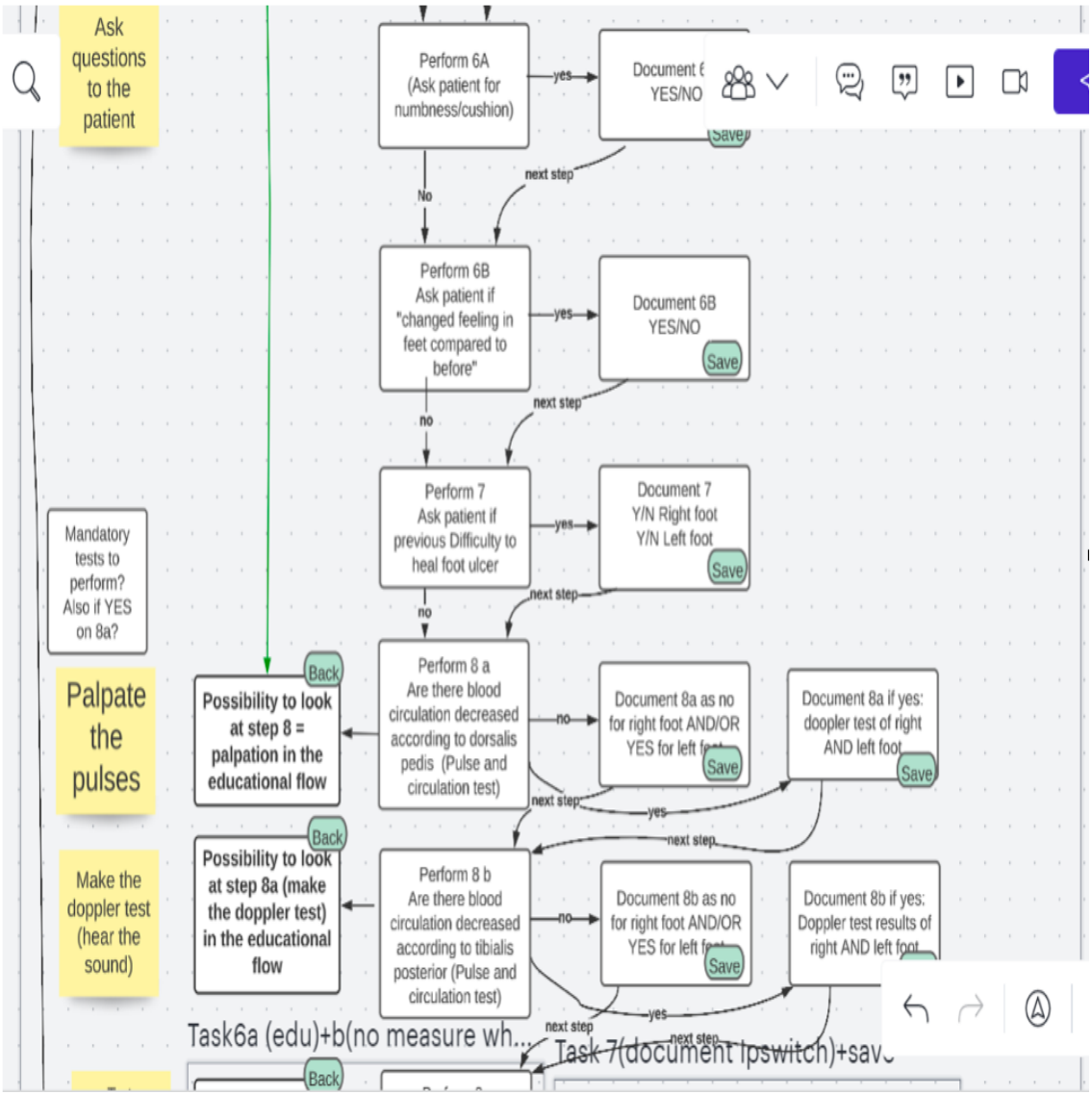
K

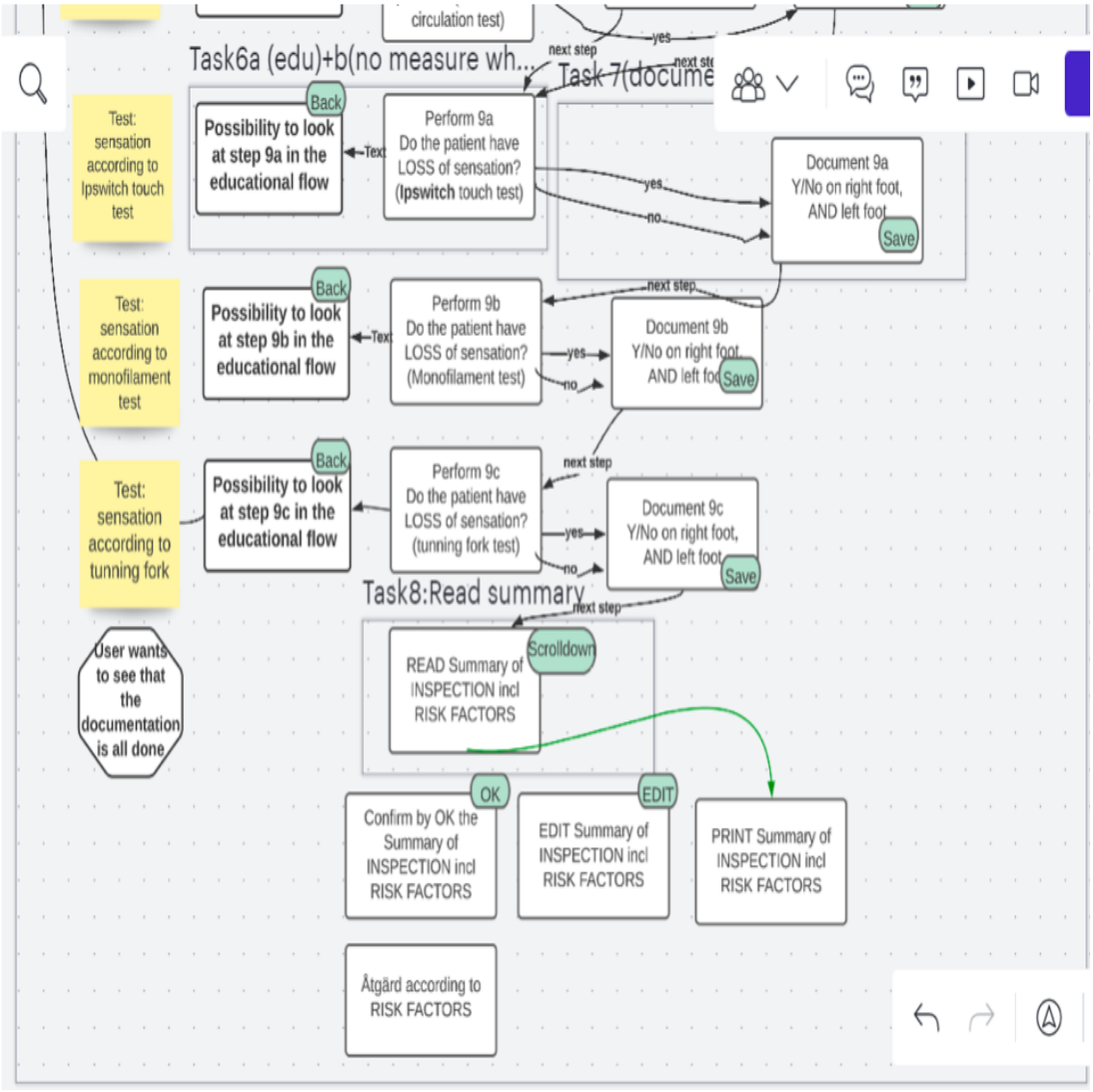
Appendix 11




Step 1a Inspect pressure damage
Use camera to take a picture
Measure the length and depth
Back
Possibility to look at step 1a in the educational flow
Perform Step1a (Pressure damage)
yes
Save Localisation step 1 a (Illustration of the feet)
Save
Iteration 3
no
to next step
Perform Step 1b(Wounds)
yes
Save localisation step 1b
Save
insert a photo
Insert the lenght and depth data of the wound
next step
no
Back
Possibility to look at step 1C in the educational flow
Perform step 1c (Cracks)
yes
Document the cracks (illustration)
Save
next step
no
Task 4a+b: Look Callus + Save
Back
Possibility to look at step 1D in the educational flow
Perform step 1D (Calluses)
yes
Save localisation step 1D
Save
next step
No
Perfrom step 1E (hairs on toes)
yes
Document 1E (Ulla illustartion)
Save
no
next step
Perform step 2


Overview of the documentation (in pic/or in text?)
Perform step 2 (Inspect patient's shoes and socks)
yes
Save
no
next step
Back
Possibility to look at step 3A in the educational flow
Perform step 3a (Inspection for nail problem that lead to ulcer)
Document 3A (illustration)
Possibility to look at step 3B in the educational flow
Perform step 3B (Inspection for nail tightness/suspension of fungus)
Yes
Document 3B (illustration)
TASK5: Look at EDUpicture + back
Possibility to look at step 4 in the educational flow
Perform step 4 (Note for misalignment Eg.Hammer toe,hallux valgus)
Document 4 (illustartion)
Possibility to look at step 5 in the educational flow
Perform step 5 (Examine skin for dryness,temperature and swelling)
Document 5 (illustration)


Ask questions to the patient
Perform 6A (Ask patient for numbness/cushion)
yes
Document 6 YES/NO
Save
next step
No
Perform 6B Ask patient if "changed feeling in feet compared to before"
yes
Document 6B YES/NO
Save
next step
no
Perform 7 Ask patient if previous Difficulty to heal foot ulcer
yes
Document 7 Y/N Right foot Y/N Left foot
Save
next step
no
Mandatory tests to perform? Also if YES on 8a?
Palpate the pulses
Back
Possibility to look at step 8 = palpation in the educational flow
Perform 8 a Are there blood circulation decreased according to dorsalis pedis (Pulse and circulation test)
no
Document 8a as no for right foot AND/OR YES for left
Save
Document 8a if yes: doopler test of right AND left foot
Save
next step
yes
next step
Back
Possibility to look at step 8a (make the doppler test) in the educational flow
Make the doppler test (hear the sound)
Perform 8 b Are there blood circulation decreased according to tibialis posterior (Pulse and circulation test)
no
Document 8b as no for right foot AND/OR YES for left
Save
Document 8b if yes: Doppler test results of right AND left foot
yes
next step
next step
Task6a (edu)+b(no measure wh...
Task 7(document Ipswitch)+save
Back


circulation test)
yes
Task6a (edu)+b(no measure wh...
next step
Task 7(docume
Test: sensation according to Ipswitch touch test
Back
Possibility to look at step 9a in the educational flow
Perform 9a
Do the patient have LOSS of sensation? (Ipswitch touch test)
yes
no
Document 9a
Y/No on right foot, AND left foot
Save
Test: sensation according to monofilament test
Back
Possibility to look at step 9b in the educational flow
Perform 9b
Do the patient have LOSS of sensation? (Monofilament test)
next step
yes
no
Document 9b
Y/No on right foot, AND left foot
Save
Test: sensation according to tunning fork
Back
Possibility to look at step 9c in the educational flow
Perform 9c
Do the patient have LOSS of sensation? (tunning fork test)
next step
yes
no
Document 9c
Y/No on right foot, AND left foot
Save
Task8:Read summary
next step
User wants to see that the documentation is all done
READ Summary of INSPECTION incl RISK FACTORS
Scrolldown
OK
Confirm by OK the Summary of INSPECTION incl RISK FACTORS
EDIT
EDIT Summary of INSPECTION incl RISK FACTORS
PRINT Summary of INSPECTION incl RISK FACTORS
Åtgärd according to RISK FACTORS

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