Omnivisi

Continuous and Non-invasive Monitoring of Vital Signs

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Delft University of Technology
Industrial Design Engineering
Integrated Product Design

Delft, April 2019

Omnivisi

“Continuous and non-invasive monitoring of vital signs “

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Master thesis
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Dear reader,

In front of you lies my graduation thesis, "Continuous and non-invasive monitoring of vital signs ". It is written within the context of Industrial Design Engineering at Delft University of Technology, Master's programme Integrated Product Design.

This project started in October 2018, after my 4-months internship at Maasstad Ziekenhuis. My mentor, Armagan Albayrak, introduced me to Gona Aziz, who used to work as a coordinator at the science office within the hospital. Although I knew the complexity of this project from the very beginning, I still took the challenge and completed this project to the best of my ability.

It is difficult to express my happiness, struggles and emotions that I experienced throughout the project. I am certain that my friends and family members can tell you more about it. I learned a lot about myself, my own abilities, strengths and weaknesses through this rollercoaster-l ke process. I genuinely hope this project will contribute to healthcare and improve quality of life of patients in the near future.

Dear reader, thank you for your time and enjoy reading this thesis.

Peace be upon you.

Mucahit Aydin

Delft, April 2019

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With gratitude.

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ABCDEFG
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Executive Summary

Healthcare faces many challenges due to societal changes, such as aging population and increase of people with chronological diseases. Due to this, the costs of care have significantly increased over the years. In order to tackle some of these challenges, new methods should be used to increase work-efficiency, reduce costs of care and still maintain quality of life of patients. Research has shown that technological developments, such as mobile health (m-health) and electronic health (e-health), can be used to achieve this. The main focus of this project is to design and develop an e-health monitoring device.

This project is an initiative of the Department of Surgery in Maasstad Ziekenhuis. In the department, two types of patients undergo an abdominal surgery: 1) mobile obese patients 2) patients with cancer. These types of patients need personal contact and guidance, especially patients with cancer. However, nurses are overwhelmed with work and utilize a great amount of their time to measure the vital signs of patients three times a day. These vital signs are: heart rate, blood oxygen level, respiration rate, tympanic temperature and blood pressure. The current method of measuring the vital signs is highly inefficient and prone to error. Additionally, there is also a lack of an alarming system that can notify nurses when patients' health condition deteriorate. Currently, patients' health condition are assessed according to the MEWS, a scoring system used by medical staff.

There are existing wearable devices in the market that are not able to measure all aforementioned vital signs. So, these devices do not fulfill the needs and wishes of the user group. Therefore, the initial goal was to design a wearable device that is able to continuously and non-invasively measure vital signs of patients, taking into account the level of comfort for patients and level of user-friendliness for nurses.

In the analysis phase, different methods to measure the vital signs were researched and discussed with experts. Literature studies, interviews and observations provided new valuable insights for the wearable. A list of requirements and wishes were created for the final product. The most important requirements were: reliability, hygiene, and high level of comfort and user-friendliness.

In the conceptualization phase, several concepts were generated and discussed with patients, nurses and the client. These concepts were scored based on the requirements using the Harris Profile and Weighted Objectives method. Based on the scores and further research, the Earable V2 concept was chosen for further development.

In the embodiment phase, new insights and knowledge were generated to ensure perfect fit and comfort for patients. Due to lack of information on the curvature of the back side of the ear, hand models were created and 3D scanned to create an average model. The average model was 3D printed and tested with potential patients. Based on the results of the user-test, the design was improved on several aspects such as form, size and overall aesthetics. Another part of the embodiment phase was creating a proof of principle and demonstrating that the concept works. Different sensors were tested on various body areas and with the use of Arduino and Labview, the aforementioned vital signs were real-time visualized.

Omnivisi Earable is the final proposal of this project. It is a compact and wireless wearable that is able to continuously and non-invasively measure patient's vital signs. Due to lack of wires and extra modules, it can be easily attached on patients' body. The organic form of the Earable provides high comfort for patients. It is expected that the time saved to manually measure patients' vital signs will be used for personal contact and guidance, which is an important role in improving patients' health.

Definitions & Abbreviations

BP = blood pressure

BR = Breathing rate

Complete = The ability of the system to measure all vital signs, including heart rate, blood oxygen level, blood pressure, respiration rate and body temperature.

COW = Computer on Wheel

DHF = Dual heat flux

ECG = Electrocardiogram, shows the heart activity

EHR = Electronic Health Record, also known as HIX

EWS = Early Warning Score

HR = heart rate

HR = Heart Rate

IP = Impedance pneumography

LED = Light Emitting Diode

MEWS = Modified Early Warning Score

MZ = Maasstad Ziekenhuis

PD = photodiode

PPG = Photoplethysmography

PPG = Photoplethysmography, a sensor with LED, infrared and photodiode, used to measure heart rate and blood oxygen level

PTT = Pulse Transit Time, the time difference in milliseconds between the R-peak of ECG signal and peak of PPG signal

PWV = Pulse Wave Velocity expressed in meters per second, measured between two peaks of PPG signal

RIAV = Respiratory-induced Amplitude Variations

RIFV = Respiratory-induced Frequency Variations

RIIV = Respiratory-induced Intensity Variations

RR = Respiration rate

SpO2 = blood oxygen level

User-friendly = minimum actions performed by nurses

Vital signs = physiological signs that show the health condition of a person. These vital signs are heart rate, blood oxygen level, blood pressure, respiration rate and body temperature

ZHF = Zero heat flux

Reading Guide

Design process structure

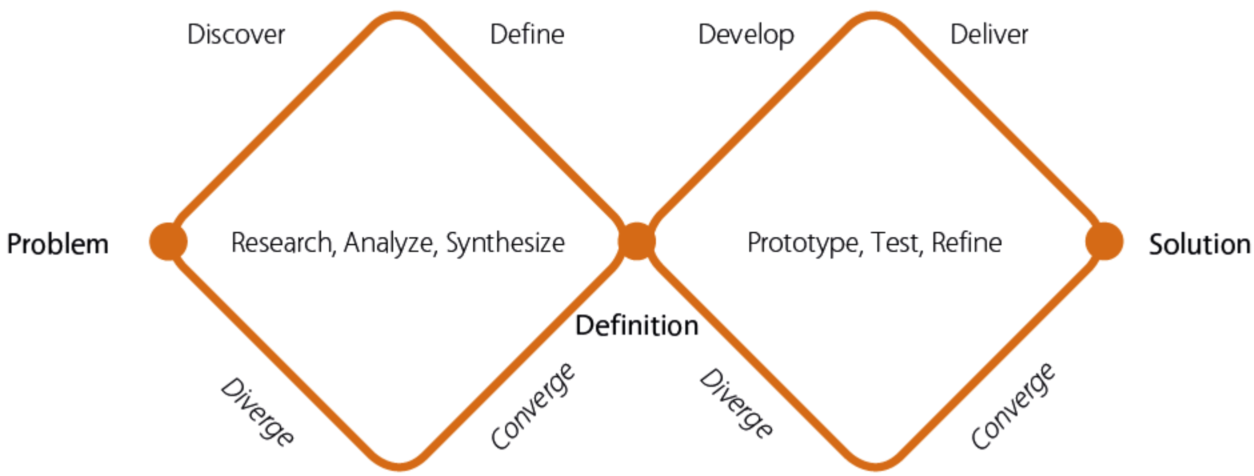
A complex design project requires a systemic approach to create solutions for the design problem. Therefore, the use of a design methodology, different methods and tools can be very helpful. Design thinking is a design methodology used to generate solutions for complex problems (see diagram below). It consists of different phases in which you diverge and converge multiple times to create possibilities and work towards the final solution. The process of this project is shown on the right.
During the design process, the Basic Design Cycle model (Roozenburg & Eekels, 1995) is used in combination with Participatory Design methodology (Dorst, 2006). Basic Design Cycle is a process of trial-and-error. The idea behind this process is to gain more knowledge about the problem and solution after each cycle and to create many iterations. The Participatory Design is an approach to actively consult users and stakeholders throughout the design project in order to create empathy and generate solutions to meet their needs.

Report Structure:

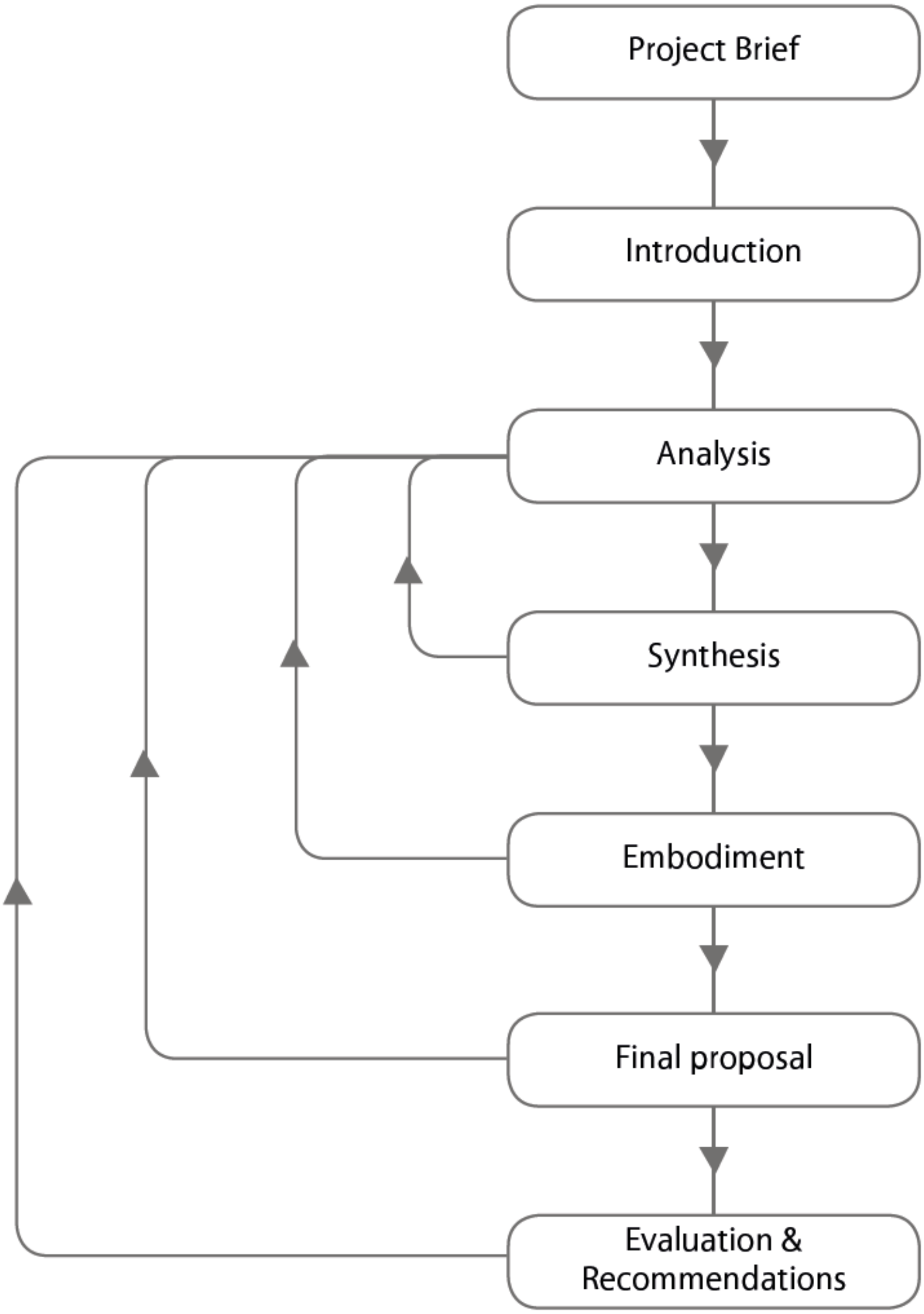
Each chapter starts with a brief introduction, describing the relevance of the chapter for the project. Each chapter ends with a conclusion and a design implication.

The conclusion briefly summaries the chapter and presents the relevant points regarding the design project.

Design implication is the translation of a relevant information to the final design. With other words, design implications directly affect the final design and its requirements.



Outline Thesis



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Orientation.

1 Introduction

This chapter is a brief introduction about the parties who are involved in this project, the mission, vision and core values of the company and the challenges of the current healthcare system. Lastly, the design goal for this project is presented.

01 Project Partners

This project is a collaboration between Delft Universtity of Technology, faculty of Industrial Design Engineering and Maasstad Ziekenhuis, Department of Surgery in Rotterdam.

Maastad Ziekenhuis

Maasstad Ziekenhuis is a teaching hospital which is based in Rotterdam. The project was inspired by both medical professionals, Rene Klaassen and Jaco Hoekman. After forming the project brief, the project was initiated.

TU Delft Industrial Design Engineering

This project is carried out within the faculty of Industrial Design Engineering in the master track Integrated Product Design. Both mentor and chair are responsible for the guidance of the graduate student by implementing an academic approach.

02 The Bigger Picture

The current healthcare system face many challenges due to societal changes. There is a need to increase work-efficiency and reduce costs of care. Technological developments can be a possible solution to tackle some of the challenges.

Aging population and increasing healthcare costs

Hospitals are dealing with various healthcare challenges, including aging population, chronic diseases and the cost of hospitalization (World Health Organization, 2011). In the Netherlands, there were 3.1 million elderly in 2016, which is about 18% of the total population. Within 10 years, this number will increase by 10% (Centraal Bureau voor de Statistiek, 2017). Moreover, life expectancy now far outweighs what it was 45 years ago, from 73 years to 81 years. This is due to the increase of quality of healthcare. The amount of 20-year-olds significantly decreased, from 35.8% to 23.6%. Due to this, the total expenditure on care has increased because elderly need more care (van der Horst, van Erp, & de Jong, 2011). Due to the growing elderly population, the demand for nursing has also doubled in 2017 (UWV, 2018).

Increase of people with chronic diseases

According to European Statistics of Income and Living, the amount of men and women with chronic diseases was 33.1% and 37.4% in the Netherlands, respectively. These numbers are slightly higher than the average of all European countries (Vo ksgezondheidenzorg, 2018). It is expected that the amount of people with chronic diseases will increase by 32% from 5 3 million in 2011 to 7 million in 2030 (Rijksinstituut voor Vo ksgezondheid en Milieu, 2014).

Technological developments

According to the research institute 'Centaal Plan Bureau', technological developments such as home telemonitoring or using robots will lead to a more efficient healthcare system and will help decrease the costs of healthcare (van der Horst et al., 2011). Another study shows that technology can support medical staff by making better diagnoses, treatment decisions and increase productivity of up to 30% by using mobile health applications. This is made possible when clinical information is easily accessed and analyzed (European Commission, 2014).

Summary

Due to societal developments, such as aging population and increase of people with chronic diseases, the current healthcare system will face many challenges in the near future. Research has shown that technology, such as m-health and e-health, can play an important role in increasing efficiency within the healthcare system and to reduce the costs of healthcare.

03 Maasstad Ziekenhuis

Maasstad Ziekenhuis' mission, vision and core values are very important because these define their standards, purpose and goals to succeed in achieving their aspirations. The policy plan of Maasstad Ziekenhuis presents their strategy to tackle the challenges in the healthcare system.

Maasstad Ziekenhuis (MZ) is based in Rotterdam South with 600 beds and more than 450.000 patients every year (Santeon, n.d.). The hospital is a part of 'STZ-ziekenhuis', which is an association of collaborating top clinical hospitals. Moreover, MZ is a part of 'Cooperatie Zorg op zuid' which is a group of four hospitals in the same district. These hospitals are: 'Het Van Weel-Bethesda Ziekenhuis', 'het kazia Ziekenhuis' and 'het Spijkenisse Medisch Centrum'. Recently, they switched over to the same Electronic Health Record called HiX, also known as EPD in Dutch, in order to collaborate more efficiently as a team and to share medical record with each other. Besides this, Maasstad is a part a hospital group called Santeon. The main objective of this hospital group is to improve the quality of care by sharing knowledge and experience with each other.

The Joint Commission International (JCI)

JCI is known as the world's largest healthcare accreditor and its goal is to improve patient safety and the quality of healthcare worldwide (Joint Commission International, n.d.). The high standards of JCI make it difficult to get accreditation the first time. In fact, less than 5% of the hospitals in the world get accredited the first time (Maasstad Ziekenhuis, 2015). Nevertheless, Maasstad Ziekenhuis received the JCI accreditation the first time on the 5th of June in 2018 and became the first top clinical hospital in the Netherlands. MZ's mission is to receive the JCI again in the near future.

The mission, the vision and core values

The main mission of MZ is to increase the quality of life of patients provided by highly skilled and expert staff. Since patients are limited when they enter the hospital, its highly important to take care of the patients as well as their relatives (Maasstad Ziekenhuis, n.d.).
In order to provide specialized referrals and specialized clinical care, MZ's vision is to optimize care by prioritizing education, quality and safety. During this process, it is important that the patients put their trust in MZ (Maasstad Ziekenhuis, n.d.).
The core values are the bridge between the vision and the mission. MZ has defined the following core values: guest-oriented, reliable, expertise, connecting and ambitious. Everyone in MZ knows these core values and works accordingly to achieve the mission (Maasstad Ziekenhuis, n.d.).

Maasstad policy plan

Maasstad ziekenhuis has written a policy plan for 2017-2021 called 'Strategisch Medisch Beleidsplan' (Maasstad Ziekenhuis, 2016). One of the main points discussed in the policy plan is innovation because it is essential to achieve MZ's ambitions. These ambitions include tackling the current problems in the healthcare system as well as to increase the quality of life of patients. The plan is to invest in eHealth, such as telemonitoring, self-management and interaction.

04 Department of Surgery

This project was initiated by the surgeon and supervisor of the Department of Surgery in Maasstad Ziekenhuis, Rene Klaasen and Jaco Hoekman. Their department's problems, current state, and solutions are explained.

Current situation

Department of Surgery is one of the departments at Maasstad Ziekenhuis. This department has in total 32 beds where two types of patients recover after they undergo abdominal surgeries. These patients are mobile obese patients and patients with cancer.

In order to assess healt condition of patients, their vital signs are manually measured three times a day. These vital signs are heart rate, blood oxygen level, respiration rate, blood pressure and tympanic temperature. With the use of a clinical scoring system called MEWS, Modified Early Warning Score, physiological changes can be documented and medical staff can act upon it if necessary. Although the MEWS shows relevant information about the health state of patients, it is possible that medical staff do not detect patient deterioration in time. This is especially the case at night when the majority of patients are not measured. This could explain why most unplanned Intensive Care Unit (ICU) admissions take place in the evening and at night.

Time-consuming process

Nurses utilize a great amount of time measuring vital signs of patients and documenting data into the Electronic Health Record (EHR). This significantly reduces the time for personal contact and guidance for patients, especially for patients who have cancer.

Early intervention with the use of a wearable

When manual measurement of vital signs is digitalized, patients can be continuously monitored. Due to this, small changes in patient's health condition can be detected and nurses can intervene immediately. Early intervention can prevent a patient's health from worsening and also prevent transfer to ICU, reanimation or even mortality.

Currently, there are wearable systems in the market that can continuously monitor patients' vital signs. Although these wearables claim to increase work-efficiency, ensure high quality of life of patients, reduce costs of care long term, these devices are not used in a large scale in clinical settings. See the next section for further information about the shortcomings of current wearable devices and why there is a need for the development of a new wearable that fulfills the needs of the user group.

05 Current Wearables

There are many wearables in the market but these are not yet utilized in a large scale within clinical settings. It is important to understand the shortcomings and disadvantages of these wearables and act upon it. Based on the findings from the research report, 'Wearables for medical applications' (Aydin, 2018), a design goal was stated and used as a starting point for the development of a new wearable.

Research report

The research report, 'Wearables for medical applications' (Aydin, 2018), compared 18 wearables that are placed on different body sites (Figure 1.1). It was concluded that current wearables for medical use are not comfortable nor user-friendly for patients and nurses, respectively (Figure 1.2). These devices were created to save time and increase work-efficiency. However, some wearable devices could significantly cost more time during installation or maintenance. A few examples are Radius-7 (Figure 1.3) and Visi Mobile System (Figure 1.4). These wearables consist of multiple modules that are interconnected with wires and must be attached on patients' body. This limits patients' mobility and it can cost more time to install it. The lost time is taking away from the personal guidance that a patient needs. Another disadvantage is the price of these types of wearable. For instance, Radius-7 values at €4365.20, including a monitoring device and a monitor. It would be a large investment when all patients need a monitoring

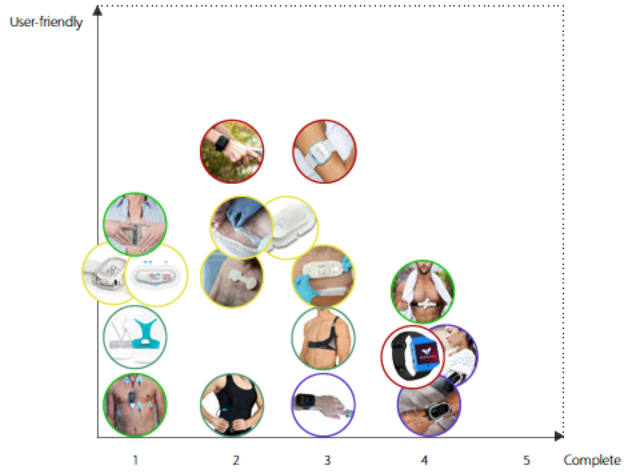


Figure 1.2: User-friendly-Completeness diagram (Aydin, 2018)

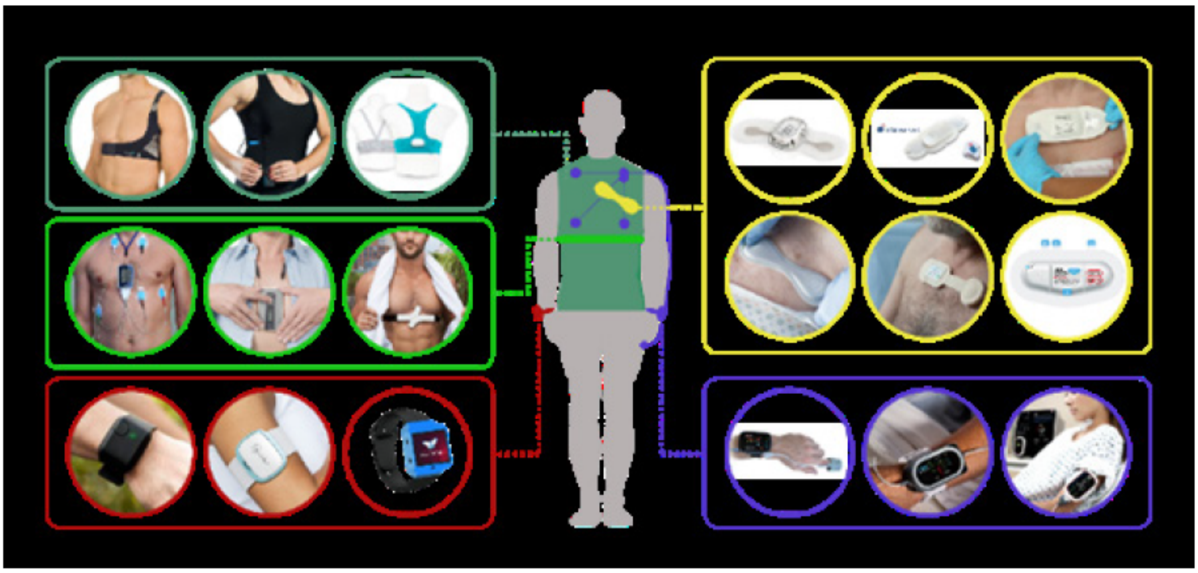


Figure 1.1: Wearables on different body areas (Aydin, 2018)

device. These wearables are also limited in measuring all vital signs for a complete MEWS. A comfortable and user-friendly wearable that is complete in its function can increase work-efficiency, reduce costs of care and ensure quality of life of patients.

Figure 1.3: Radius-7 by Masimo

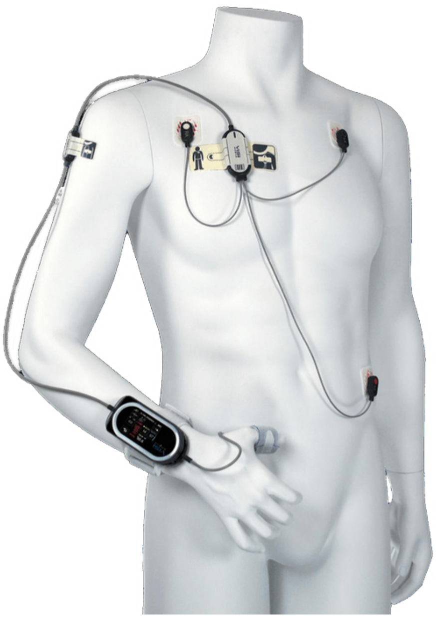


Figure 1.4: Visi Mobile System

Design goal

This project will focus on **exploring and generating** working principles in order to continuously measure patients' vital signs and alert nurses when the health condition of their patients deteriorates. It is very important that the proposed solution is **user-friendly** for nurses. This is to reduce their workload and increase **comfortability** for patients because they will have to wear the wearable for an extended period of time. After generating working principles, the aim is to present a **proof of principle**.

The following design goal was defined based on findings from the research report:

"Designing a wearable that is complete in its ability to measure all vital signs, user-friendly for nurses and comfortable for patients."

Expertise and Empathy.

2 Analysis

This chapter presents the context, problems encountered by patients and nurses and a more in-depth research relevant to the project. Additionally, a final conclusion is presented based on literature studies, interviews and expert meetings on how to measure all required vital signs.

01 Context

It is important to analyze the context and understand the user group regarding their wishes, goals and frustrations. Interviews with medical staff and patients were conducted and observations were performed in the Department of Surgery.

Structure Department of Surgery

In broad lines, every department in the hospital is similarly structured: there are 32 available beds, same amount of capacity for employees and budget to hire these employees. The 32 beds are divided in 20 hospital rooms, including 16 individual rooms and four wards with four beds in each ward. The beds in the Department of Surgery are often occupied. Below is the structure of the employees in the department:

a. 27 employees (fully qualified)
   i. HBO nurse
   ii. HBO oncology nurse
   iii. MBO nursing basic care
   iv. Supervising surgeons and student assistants
b. 15 student nurses
   i. HBO student nurse
   ii. MBO student nurse

Complexity of care at the Department of Surgery

The Department of Surgery has one of the most complex care, compared to other departments in the hospital. The complexity is in line with Medium Care and Intensive Care. Due to the complexity, nurses' workload increase because there is more need for personal guidance and personal contact. Both nurses and surgeons focus on high quality care and quick recovery of patients. A supervising doctors' main focus is to run the process as quickly and as smooth as possible. All disciplines, such as doctors, nurses and assistants combine their expertise to provide high quality care and improve the quality of life of patients.

Patients

In the Department of Surgery Gastroenterology (GE), patients are aged between 16 to 100 years old. The majority of patients are mobile, and they undergo abdominal surgeries, including stomach, gullet and bowel. According to the supervisor of the Department of Surgery (Figure 2.6), 50% of the surgeries are related to oncology and 50% are general stomach surgeries, such as appendices, gall and small bowel resection due to infection. Thus, there are two types of patients in the Department of Surgery: patients that have undergone general abdominal surgeries, including bariatric surgery (Figure 2 3) and oncology related patients (Figure 2.4) and. There is also a persona created for the supervisor of the department.

Mobile obese patients

Mobile obese patients undergo bariatric surgery to lose weight. They often have comorbidities. Due to their larger size, the human system keeps them intact longer. This is a high risk because nurses cannot anticipate early in the process when their health is deteriorating. Patients do not feel or notice anything wrong and nurses are unable to detect abnormalities. Nurses only detect the deterioration of patients in the very last moment when it is too late.

Hospitalization period

The average hospitalization time of patients is 4.7 days. After small surgeries, such as gastric bypass, patients are allowed to leave the next day if everything goes well. When patients undergo severe operations, such as whipple surgery, surgery for esophageal (food pipe) cancer and large bowel resection, they can stay at the hospital for a couple weeks to a couple of months. The risk for complications is also high for this type of operations. Patients may need more time to recover and sometimes they have to undergo a second surgery. In order to enhance the recovery process, the ERAS protocol was introduced, meaning that patients have to wa k as soon as possible after surgery. This prevents the loss of muscular power and stimulates the recovery process.

Nurses

Since MZ is a teaching hospital, there are nurses from different educational levels, aged 18 to 30 years old (Figure 2.5). The student nurses have the responsibility to provide basic care in the hospital such as washing the patients, refilling materials and escorting the patients to the operating room. Moreover, they are allowed to write reports and take care of the stoma under supervision. More experienced nurses act as a communicator between doctors, physiotherapists, dieticians and patients. In addition to this, they possess advanced clinical reasoning skills which ensure high quality care and safety of patients. So they act as the connecting link between all involved disciplines. See the next page for the archetypal representations of the user group (nurses and patients) describing their behaviour, values and needs.

Shift work of nurses

The working day of nurses is divided in three shifts and every shift lasts for 8.5 hours. In the morning there are eight working nurses in total. In the afternoon four working nurses and in the night just two working nurses. This is because student nurses are not allowed to work at night. As shown below, the nurse-patient ratio changes over time (Figure 2.1). Since the amount of nurses are the highest in the morning shift, the measurements of the vital signs are done at the start and at the end of the shift.

At night it would take a significant amount of time to measure all 32 patients with two nurses. This is why the last measurements taken are between 6pm and 8pm. A pitfall is that patient deterioration cannot be detected at night.

Surgeons

Surgeons stand in the center of the processes within the hospital: polyclinic, clinic and operating room (Figure 2.2). Their focus is more on polyclinic where they provide consultations to patients. The other point of focus is the operating room. The main objective of surgeons is to provide high quality care and quick recovery of patients. Both the surgical period and recovery time are known variables. Therefore, surgeons and assistants can estimate when a patient can be dismissed in the most ideal situation. A complication must be avoided otherwise this will result in a chain reaction, causing all kind of problems, such as increase of hospitalization period, additional research and costs. See Figure 2.7 for the persona created for this user group.

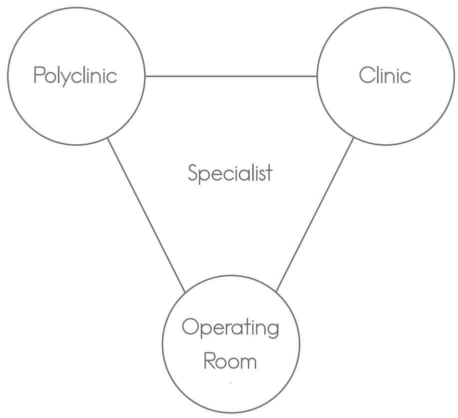


Figure 2.2: Three processes in the hospital with the specialist in the center

	Time	**Amount of employees**	**Ratio (nurse:patient)**	**Amount of measurements**
Morning	7:15 - 15:45	4 qualified nurses 4 student nurses	1:4	2 (start and end of the shift)
Afternoon	14:45 - 23:15	2 qualified nurses 2 student nurses	1:8	1
Night	23:00 - 7:30	2 qualified nurses 0 student nurses	1:16	0*

*patients whose health condition are not stable can be measured at night

Figure 2.1: Shift of nurses

Personas

Linda van Os

"I want to get back to my old shape and feel mentally and physically fit."

Age: 34

Profession: Secretary

Family: In relationship

Location: Sliedrecht, Zuid-Holland

Cautious | Social | Impulsive

BIO

Linda is working as a secretary for a software company. She gained a lot of weight due to her unhealthy lifestyle. Her job also requires her to sit for an extended period of time behind her desk. In order to get back in shape, she tried to exercise and eat healthier. However, she could not achieve her goals. The final solution was to undergo a gastric bypass surgery to lose weight. She hopes to get dismissed from the hospital in two days and start a new healthy life.

Personality

Introvert — Extrovert

Analytical — Creative

Conservative — Liberal

Passive — Active

Motivations

Comfort

Convenience

Social

Price

Efficiency

Goals

- To maintain contact with medical staff
- To exercise more and have a healthier lifestyle
- To get in shape as soon as possible

Frustrations

- Reduced mobility
- Unable to lose weight
- Low self-esteem

Technology

Social networks

Online & Social Media

Mobile Apps

Brands

Figure 2.3: Mobile obese patient

Amy Bakker

"I would want to have more personal contact and guidance from my nurses. This would bring me comfort from thoughts of being hospitalized with three children at home."

Age: 48

Profession: Sales manager

Family: Married, 3 kids

Location: Rotterdam, Zuid-Holland

Friendly | Social | Hard-working

BIO

Amy is a mom of three children and works as a sales manager for more than 20 years. After being diagnosed with cancer, her life turned upside down. She is more stressed and depressed than ever before. After she underwent surgery, she stayed in the hospital for more than 10 days. She hopes to recover as soon as possible and to regain control of her health.

Personality

Introvert — Extrovert

Analytical — Creative

Conservative — Liberal

Passive — Active

Motivations

Comfort

Convenience

Social

Price

Efficiency

Goals

- To maintain contact with medical staff
- To reduce her stress level
- To recover from the surgery as soon as possible

Frustrations

- To be woken up during night for the measurements of vital signs
- Reduced mobility due to pain
- Not knowing how long she will stay in the hospital

Technology

Social networks

Online & Social Media

Mobile Apps

Brands

Figure 2.4: Patient with cancer

Sophie van Dalen

"I would like to have more personal contact with my patients. Due to high workload, I do not have time to make small talk with them."

Age: 23-30

Profession: Nurse Department of Surgery

Family: Single

Location: Rotterdam, Zuid-Holland

Organized | Social | Compassionate

BIO

Sophie is a nurse who works full time in the Department of Surgery. Her shift usually starts at 7:15 until 15:45. Her daily duties are: washing patients, administering medications, monitoring vital signs, maintaining medical records and communicating with doctors and patients. Due to high workload, she is not able to spend much time with patients. She hopes that innovation and technology can help to increase her work-efficiency.

Personality

Introvert — Extrovert

Analytical — Creative

Conservative — Liberal

Passive — Active

Motivations

Comfort

Convenience

Social

Price

Efficiency

Goals

- To spend more time with her patients
- To reduce her workload and stress
- To ensure high quality care and safety of patients

Frustrations

- When the monitoring device is not working properly
- Due to high workload, there is less interaction and personal contact with patients
- Too many (false) alarms that leads to alarm fatigue

Technology

Social networks

Online & Social Media

Mobile Apps

Brands

SAMSUNG CITROËN Coca-Cola

Figure 2.5: Nurse at the Department of Surgery

Tim Klaver

"Nurses spend 3.5 hours to measure the vital signs of all patients in the department. This time can be used to provide personal guidance."

Age: 37

Profession: Supervisor Department of Surgery

Family: Married, 2 kids

Location: Rotterdam, Zuid-Holland

Disciplined | Responsible | Supportive

BIO

Tim is working as a supervisor in the Department of Surgery. He is responsible for the management of the medical staff and coordination of the activities to ensure high quality care.
According to Tim, healthcare will face many challenges due to an increase of chronological diseases and aging population. Therefore, he hopes to increase productivity through innovation and to reduce the hospitalization period of patients.

Personality

Introvert — Extrovert

Analytical — Creative

Conservative — Liberal

Passive — Active

Motivations

Comfort

Convenience

Social

Price

Efficiency

Goals

- To prevent complications and reduce hospitalization period of patients
- To increase work-efficiency
- To spend more time in personal contact and guidance of patients

Frustrations

- Stress due to high workload
- Conservative attitude of healthcare towards change
- Low budget to employ nurses

Technology

Social networks

Online & Social Media

Mobile Apps

Brands

Welch Allyn PHILIPS Healthcare GARMIN

Figure 2.6: Supervisor Department of Surgery

Kevin van Haperen

"I would like to be informed about my patients' health conditions, especially when their health start to deteriorate. This is important to give them the best possible care and prevent complications."

Age: 45

Profession: Surgeon, with the focus on bariatrics

Family: Married, 3 kids

Location: Utrecht, Zuid-Holland

Disciplined | Responsible | Supportive

BIO

Kevin has been working as a surgeon for more than 10 years now. His expertise is abdominal surgeries, with the focus on bariatrics. Besides doing surgeries, he is doing consultations with patients, and educates medical students and surgeons. Due to his extremely busy schedule, he must manage his time efficiently. Unfortunately, he spends a lot of time on meetings and paperwork which is taken away from personal contact with patients. He hopes that innovation can give him more insights into patients health condition and eventually will prevent complications.

Personality

Introvert — Extrovert

Analytical — Creative

Conservative — Liberal

Passive — Active

Motivations

Comfort

Convenience

Social

Price

Efficiency

Goals

- To prevent complications and reduce hospitalization period of patients
- To increase work-efficiency
- To keep close contact with patients and spend more time with them

Frustrations

- Stress due to high workload
- Increasing paperwork
- Overwhelming number of meetings

Technology

Social networks

Online & Social Media

Mobile Apps

Brands

PHILIPS Healthcare

Mercedes-Benz

Figure 2.7: Surgeon Department of Surgery

02 Admission & Dismissal

The process of patient admission to dismissal is explained and the importance why patients must be discharged from the hospital as soon as possible.

Process

The process of patient admission and discharge is as follows (Figure 2.8):

1. The patient would firstly go to the polyclinic for diagnosis and counselling. The anesthetist will carry out a check-up for the surgery and will also plan a date for the surgery.
2. Before the surgery, the patient will visit the clinic for a patient admission interview. The nurses will check the personal information of the patient and will explain the procedure. Additionally, the patient will be prepared for the surgery and will be escorted to the operating room.
3. Depending on the type of surgery, the patient will stay at the operating room for a certain period of time.
4. After the surgery the patient will be moved to the recovery department next to the operating room where the patient's vital signs will be continuously monitored.
5. After a few hours the patient will be moved to the clinic again for full recovery.
6. Depending on the patient's health condition, the patient will be dismissed from the hospital.

Quick patient dismissal

Studies show that a longer length of stay (LOS) increases the possibility of a hospital-acquired condition (HAC), such as falls and trauma, blood incompatibility and surgical site infection (Centers for Medicare & Medicaid Services, 2015). This will harm patients and increase their stay in the hospital as well as costs. A lower LOS can increase the capacity in the hospital system. As a result, more patients can be served in the hospital. The costs of a hospital stay per day in the Maasstad Ziekenhuis is €900. This amount does not include the costs for surgeries and other expenses. When a complication starts, the hospitalization period will significantly increase, resulting in more complaints and slower recovery. The hospital will spend more money on research, materials and services. Additionally, the health insurance will pay for the extra services and costs. Problems or complications will adversely affect the time devoted to other patients. Therefore, the patient should be dismissed as quickly as possible after being recovered from surgery.

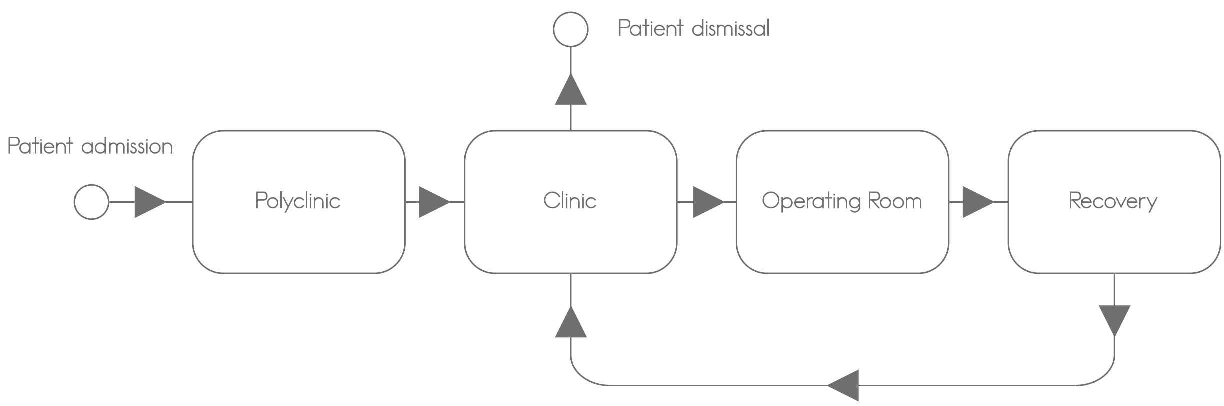


Figure 2.8: Patient admission and dismissal

03 Current Workflow

The current workflow of nurses regarding measuring vital signs was observed to understand the problems and frustrations encountered by both nurses and patients. Nurses were shadowed during the measuring process and most relevant points were written down (Appendix F).

Monitoring devices

Nurses use a vital sign monitor, the Welch Allyn Series 300 (Figure 2.9), to measure the blood pressure, the heart rate and the blood oxygen level. The blood pressure is measured with a cuff that is attached around the arm of the patient and inflates to detect the systolic and diastolic blood pressure (Figure 2.10). The heart rate and blood oxygen level are measured with a finger probe that is mostly put on patient's index finger (Figure 2.11). When the heart rate or blood oxygen level is not accurate, the probe will placed on the auricle (external ear) for more accurate results. The temperature is measured with Braun pro 4000, a wireless portable ear thermometer (Figure 2.12).

The respiration rate is measured by observing the patient for 20 seconds. The amount of breaths is multiplied by 3 to get the total breaths per minute. Some nurses do not measure the respiration rate but rather observe if the patient is breathing normally. When the patient's breaths have been identified as normal, the nurses will enter a value between 12 and 16 in the Electronic Health Record.

Figure 2.9: Vital sign monitor

Figure 2.10: cuff for blood pressure measurement

Figure 2.11: finger probe

Figure 2.12: Ear thermometer

Limited COWs

Since there are limited Computer on Wheels (COWs, Figure 2.13) at the Department of Surgery, the measurements cannot be put directly in the EHR. The measurements have to be written on a piece of paper first. After all patients are measured, the data can be entered in the EHR by using the COW or the nursing computer in the department.

When measuring the patients, nurses have to wa k either with a COW and vital sign monitor (Figure 2.13) or only with a vital sign monitor (Figure 2.14). A nurse walking with both a COW and vital sign monitor is not user-friendly, especially when nurses must walk from one patient room to another with both devices.

Figure 2.13: Nurse with a COW and vital sign monitor

Figure 2.14: Nurse with vital sign monitor

Process measuring vital signs

The process of measuring the vital signs consists of several steps and can be described as follows:

1. Nurse is searching for an available COW and vital sign monitor. If there is no COW available the nurse writes down the values on a piece of paper and enters the values afterwards after measuring all patients.

2. Nurse goes to patient room and introduces her or himself

3. Nurse puts finger probe on the patient's finger and waits for a stable saturation level and heart rate. Nurse documents the values.

4. Nurse measures the systolic and diastolic blood pressure by using the non-invasive cuff. Nurse documents the values.

5. Nurse measures the tympanic temperature by using the in-ear thermometer. Nurse documents the values.

6. Nurse measures the respiration rate by observing the patient for 20 seconds and multiplies this number with three to calculate the breaths per minute. Nurse documents the values.

7. Nurse cleans the vital sign monitor and stores it

8. When a COW is not used, all measurements are put into the EHR with the use of a personal computer or a COW.

This process repeats for at least three times a day.

Average time

According to the measurements (Appendix F), it takes on average of 5 to 6 minutes, which includes, wa king to patient's room, measuring and documenting all measurements. This means that nurses spend up to **3 hours and 12 minutes daily** to measure 32 patients in the department. This time can significantly increase in the following situations:

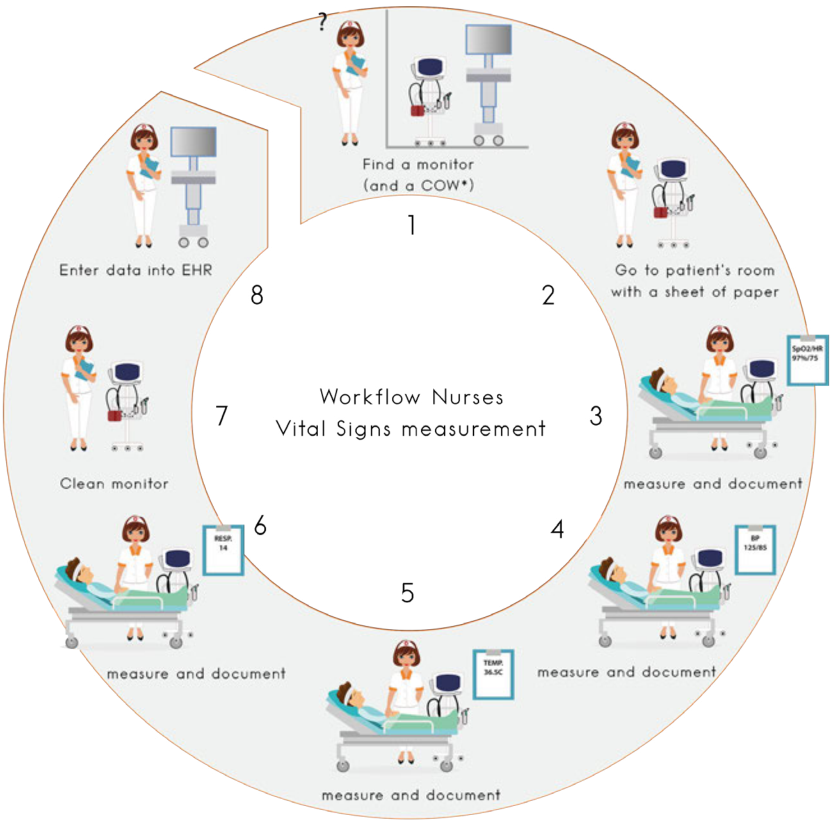
1. In the case of an emergency

2. Nurses will have to re-measure the vital sign(s) if the vital sign monitor is not properly functioning

3. When the measurements deviate too much from the baseline values, nurses will have to re-measure the vital sign(s)

4. When the measurements differ too much from the previous measurements, nurses will have to re-measure the vital sign(s)

The process of measuring the vitals signs can be visualized as follows:



Workflow nurses

**If a COW is available, the measurements will be directly entered into the EHR after each measurement.*

(M)EWS

EWS, also known as Early Warning Score, is a scoring system that gives assistance to caregivers to detect changes in physiological parameters and clinical deterioration in patients. This scoring system was changed into Modified Early Warning Score/System, known as the MEWS. The only difference between EWS and MEWS is that exceeding parameters in the MEWS get a certain score (Figure 2.15).

Patients are measured three times a day (morning, afternoon, evening) and the total MEWS is automatically calculated when the values are entered in the EHR. When the total MEWS is greater than 3, the doctor must be informed about the patient's clinical condition. The doctor will react accordingly before the condition worsens. Besides the MEWS, the experience of nurses and their gut feeling plays an important role in the decision-making process. When the department cannot provide the required treatment, the Spoed Interventie Team (SIT) will be contacted for assistance, also known as the Medical Emergency Team (MET).

MEWS (Modified Early Warning System): Alarm signals for critical patient							
Score	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Heart rate (HR, pulse/minute)	≤ 40	41-50	51-60	61-90	91-110	111-130	≥ 131
Respiration Rate (RR, times/minute)	≤ 8		8-11	12-20	21-24	25-30	≥ 31
(Systolic) Blood Pressure (SBP, mmHg)	≤ 80	81-90	91-100	101-200		≥ 201	
Saturation level (SpO_2, %)	≤ 91	92-93	94-95	≥ 96			
Temperature (T, °C)	≤ 35.0		35.1-36.0	36.1-38.5		≥ 38.6	
Consciousness			Delirium	A	V	P	U
Diuresis per 4 hour (mL)	≤ 40		≤ 120	≥ 120			
If 'something does not feel right' add 1 point extra							
A = Alert	**V= responsive to Verbal**			**P = responsive to Pain**			**U = Unresponsive**

Figure 2.15: MEWS scoring system

04 Identified Problems

Based on literature studies, interviews and observations, many problems were identified. A few of these problems are explained in more detail below.

Incorrect data

Nurses often have difficulties measuring all vital signs, such as the respiration rate. Some nurses would often guess the breaths per minute and enter this value into the system. This results in incorrect or incomplete data. The measured parameters can also be inaccurate when patients are in the presence of nurses. This is known as the white coat effect (Blood Pressure UK, n.d.).

High workload

The Department of Surgery has one of the most complex care, compared to other departments in the hospital. The complexity is in line with Medium Care and Intensive Care. Sometimes patients from the IC are placed in the Department of Surgery because patients' health state is stable. Due to the complexity of care, nurses' workload increases too, which can result in medical mistakes.

Prone to error

After measuring the vital signs, the values are written on paper first and/or manually put in the EHR, which leaves room for error. The values can be swapped or entered wrong. Since Maasstad Ziekenhuis is a teaching hospital, the interpretations of the values by student nurses can be wrong. Another factor is that nurses can be distracted by other patients while measuring the vital signs or when an emergency occurs. This leaves room for error.

Lack of an alarming system

Another disadvantage is the lack of an alarming system that notifies nurses in case the values exceed its boundaries or when a patient's clinical condition slowly deteriorates over time. Nurses must be completely informed about their patients, even about patients who are dismissed the next day after a small surgery.

"Personally, I find it really difficult to measure the respiration rate because you have to take the time and the breaths at the same time. This measurement can also take a significant amount of time. Many nurses also guess the respiration rate." - Student nurse Department of Surgery

"You always observe the patient first. If someone breathes normally then I will not monitor the respiration rate of every patient." - Nurse Department of Surgery

"We have a long To-Do list. We are continuously crossing tasks off the list and reporting what we have done." - Nurse Department of Surgery

"Every day, 3.5 hours are spent to measure the vital signs of all patients, we can spend this time better, for instance, for patient care" - Supervisor Department of Surgery

"Due to the complexity of care in this department, there should be more personal contact, especially for patients with cancer." - Nurse Department of Surgery

"I would like to spend more time with patients, however, this is not possible due to high workload." - Nurse Department of Surgery

Detection of patient deterioration

Research has shown that deterioration can be observed 8 to 12 hours before the decline in patients' health (Hillman et al., 2001, 2002). The delay of early diagnosis can lead to unplanned hospitalization in the ICU, increase of length of stay in the hospital, reanimation or even mortality (Hillman et al., 2001; McQuillan et al., 1998). However, it is difficult to identify a trend when patients are only measured three times a day and the majority of patients are not measured at night.

Figure 2 16: Summary identified problems and possible consequences

Conclusion

Based on interviews, literature studies and observations, it can be concluded that the whole process of measuring the vital signs is highly inefficient and ineffective to detect patient deterioration in time. Daily, nurses spend hours to monitor vital signs of patients, however, this time can be utilized for personal guidance and contact. A summary of all identified problems and possible consequences are placed in a diagram (Figure 2.16).

05 Technology Of Measuring Vital Signs

Each vital sign is thoroughly researched to select the most promising method of measurement for the project. The method must provide continuous and accurate measurements in the most non-invasive way possible.

Five vital signs

There are five vital signs that are routinely measured during the day: heart rate, blood oxygen level, blood pressure, respiration rate and tympanic temperature. It is necessary to include all vital signs in order to have a complete MEWS and to assess patients' health state. The method of measurements of every aforementioned vital signs were thoroughly researched and analyzed.

1. Heart rate

Heart rate is the number of heartbeats per minute and it is based on the number of contractions of the ventricles, also known as the lower chambers of the heart (MedicineNet, Reviewed on 2018, June 3). According to the MEWS, a normal heart rate varies between 61 and 90.

There are three techniques to measure heart rate: pulse palpation, electrocardiography (ECG) and with electronic pulse meters (Palatini, 2009). Pulse palpation is a traditional method whereby the pulse rate is measured from any point of the body where the artery is close to the surface. The amount of pulse rate is measured, for instance, 15 seconds and multiplied by four in order to get total beats per minute. A disadvantage is that this method is prone to error because it is done manually by nurses. This may increase the chances of missing measured values, especially when patients suffer from arterial fibrillation.

ECG is measured with three to twelve leads. The ECG leads are placed on specific points on the upper body. When three leads are used, the specialist places the leads according to the Einthoven triangle.

Another method is to use electronic pulse meters, such as a photoplethysmography (PPG) sensor. This sensor can be placed on different areas of the body. In clinical settings, the finger, earlobe, auricle or toe is used. By detecting the peaks and the interval between the peaks, the heart rate per minute can be determined.

2. Blood oxygen level

Blood oxygen level (SpO2) or oxygen saturation is the percentage of oxygenated hemoglobin (HbO2), which is responsible for transporting oxygen in arterial blood to the organs (Shao et al., 2016). According to the MEWS, a normal blood oxygen level is 96% and above.

The most widely used device to measure blood oxygen level is the pulse oximeter that is placed on the finger, earlobe or toe. Pulse oximeter uses a PPG sensor which is a continuous and non-invasive method. This method uses two different light sources, red LED (wavelength of 660nm) and infrared LED (wavelength of 940nm) and a photodiode as the light detector. Light can be absorbed by different substances, such as biological tissue, bone and blood vessels, but most light is absorbed by the photodiode. This sensor can measure the light intensity either through reflection or transmission (Tamura, Maeda, Sekine, & Yoshida, 2014). For the transmission method, the LEDs and photodiode are placed on the opposite sides of the tissue. For the reflection method, the LEDs and photodiode are place on the same side of the tissue (Figure 2.17).

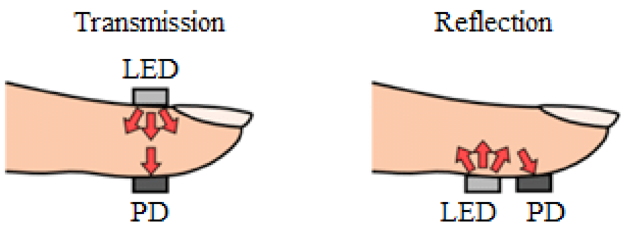


Figure 2.17: Transmission and reflection method (Tamura et al., 2014)

Limitations finger pulse oximeter

Finger pulse oximeter is effective yet it has several disadvantages. For instance, it can cause discomfort because it requires tight fitting, especially over extended monitoring periods. Patients tend not to use the hand with the sensor attached. This can interrupt daily activities, such as eating or washing hands. Physical activity and pressure exerted on the sensor can affect PPG signals, resulting in inaccurate measurements. In case of vasoconstriction the finger cannot be used to obtain reliable measurements. It is also non-hygienic because the sensor limits patients from washing their hands properly.

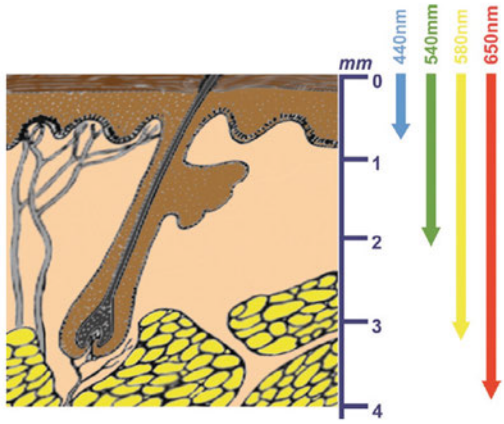


Figure 2.18: Depth of light penetration into human tissue at different wavelengths (Fodor, Ullmann, & Elman, 2011)

LED light penetration

LED light penetration in human tissue depends on wavelengths. The higher the wavelength, the deeper the light can penetrate the tissue (Figure 2.18). For wearable devices either green or red light are used. Although red light reaches a greater depth, the reflected light may not be good enough due to scattering (Figure 2.19).

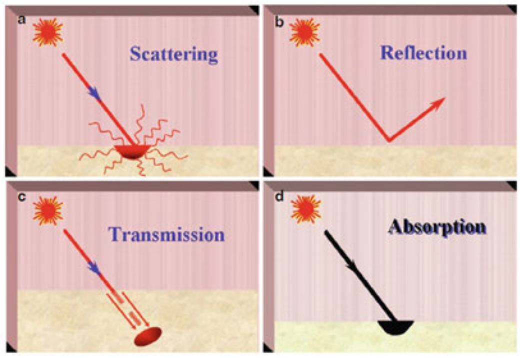


Figure 2.19: Behavior of Light (Fodor et al., 2011)

Conclusion

In clinical settings, heart rate and blood oxygen level can both measured with the finger pulse oximeter. This sensor uses red light, infrared sensor and a photodiode. Although strong signal can be obtained from the finger, it has its limitations that can affect the measurements. The finger also limits the user to perform daily activities, such as eating or washing hands. The color of the LED light also plays an important role in obtaining sufficient signals.

Design implication

It is a great advantage that both heart rate and blood oxygen level can be measured with a PPG sensor, which reduces the amount of sensors used. The placement of this sensor is important to obtain accurate and reliable measurements without being obtrusive for patients. More information about the position of PPG sensor will be given in section 2.7 of this chapter.

3. Blood pressure

Blood pressure is the pressure of blood against the sides of the blood vessels. It consists of two numbers, which shows the upper and lower values in units of millimeters of mercury (mmHg). The upper value is the systolic blood pressure. This happens when the heart is contracting and pumping blood into the blood vessels. The lower value is the diastolic blood pressure and this happens when the heart is relaxing between beats.

Existing devices

There are two devices used in clinical settings to non-invasively measure the blood pressure: the traditional sphygmomanometer (Figure 2.20) and a digital blood pressure device (Figure 2.21). Both devices are cuff-based and use air pressure in the cuff to detect the first and second pounding sound in the brachial artery (IQWiG, 2010, updated 2016, September 25). Cuff-based oscillometric method has some limitations, the patient must stay still during the measurements and the cuff inflation can cause discomfort and pain to patient. Additionally, improper size and placement of the cuff may affect the measurements (Manning, Robinson, & Panerai, 2015). Another method is placing an arterial catheter into the blood vessel. In contrast to the aforementioned devices, this method is able to continuously monitor the blood pressure. However, it is an invasive method which increases the risk of complications and this method is only used for critically ill patients.

Figure 2.20: sphygmomanometer

Figure 2.21: Digital Blood pressure device

Continuous blood pressure measurement

There are a few devices in the market that can continuously and non-invasively measure the blood pressure: Portapres by Finapres (Figure 2.22) and NIBP100D by BIOAPAC (Figure 2.23). These devices apply continuous pressure on the finger by using a finger cuff. The sensor in the finger cuff detect the blood pressure changes in the artery and immediately reacts on this by putting a counter pressure. The actual blood pressure is obtained when the pressure in the finger is equal to the counter pressure (Demcon, 2015). According to the developers of the aformentioned devices, it is recommended to wear the finger cuff for a maximum of three hours before placing it on another finger, this is to prevent irritation. These devices are an improvement of interval blood pressure measurement, such as cuff-based blood pressure monitors. However, there are still some limitations. The use of multiple wires and modules will limit patient mobility and it will cause irritation when it is used for a long period of time.

According to the MEWS, a normal person has a systolic blood pressure of 120 and a diastolic blood pressure of 80. However, these values vary for each individual, depending on the compliance, length and diameter of blood vessel, blood volume, viscosity of blood and cardiac output (OpenStax, 2013).

Figure 2.22: Portapres by Finapres (Demcon, 2015)

Figure 2.23: NIBP100D with the CNAP monitor (Biopac, n.d.)

PTT and PWV

Since 1974, many studies and experiments are done on continuous and non-invasive monitoring of blood pressure by using the Pulse Transit Time (PTT) or Pulse Wave Velocity (PWV) (Peter, Noury, & Cerny, 2014). PTT is the time difference in milliseconds between two R-peaks of ECG and PPG (Figure 2.24). In order to measure ECG, at least three ECG leads are placed on the chest by using the triangle of Einthoven. The arrival of pulse wave is measured with a PPG sensor on the finger. The first R-peak occurs when the blood is ejected from the heart to the aorta, which further flows to the periphery. Pulse Wave Velocity (PWV) is calculated from the predefined distance divided by the time difference between the two succesive pulses (Figure 2.25). Thus, a significant difference between PTT and PWV is that PTT is the average measurement over a long distance while PWV is for shorter distances and it gives the local measurement of pulse wave pressure (van Velzen, Loeve, M k, & Niehof, 2017).

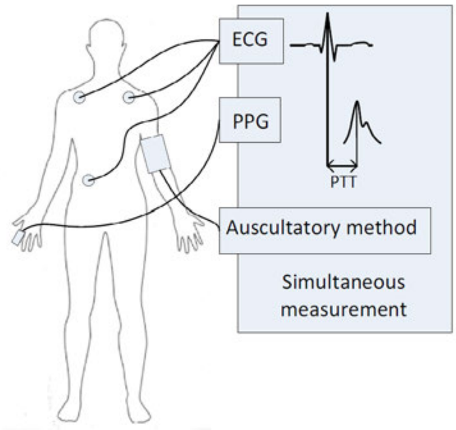


Figure 2.24: Determining PTT with ECG and PPG (Peter et al., 2014)

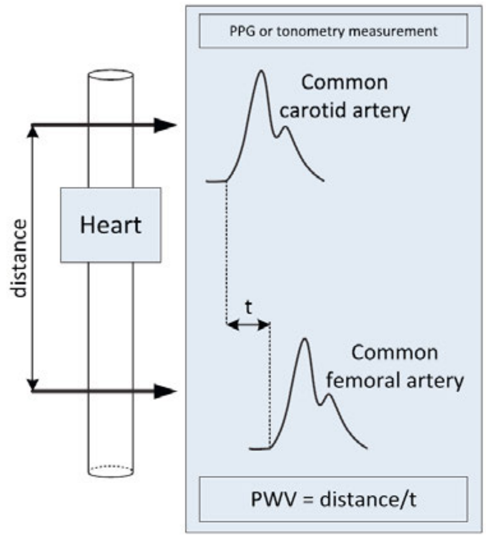


Figure 2.25: Determining PWV by using two PPG sensors (Peter et al., 2014)

The advantage of using PTT or PWV is the indirect measurement of the pressure cycle without the need of medical supervision. Moreover, patients can be measured continuously and non-invasively over long period without using a cuff. Hence, patients will be more comfortable during daily activities and medical staff are able to analyze the data over a longer period of time. Although there are a few limitations, for instance, the blood pressure can be affected by the state of the cardiovascular system and the presence of diseases. Many authors make claims on the high correlation between PTT and blood pressure, but testing is mostly done with healthy volunteers and not with the intended user group, such as patients with comorbidities. ViSi Mobile system is the first FDA cleared wearable system which uses PTT to estimate continuous blood pressure. However, it is not applicable for people with cardiovascular diseases and mobile patients (Sotera Wireless, 2014). Therefore, more research is needed to clinically validate PTT and PWV as a parameter for blood pressure for mobile patients. These patients may have multiple diseases which can affect the reliability of this method.

Blood loss and (de)compensated shock

Blood loss, or haemorrhage, is very difficult to detect in the initial phase. When there is an internal bleeding, the body is able to keep the blood pressure stable due to compensated shock (EMS1, 2016). The body reacts on the blood loss by increasing the heart rate and constricting the blood vessels. When the body loses 30% of the total blood volume, it will end up in a decompensated shock. In this state, the body is unable to maintain the blood pressure anymore. Also, vital organs would not be provided with oxygenated blood. This can cause irreversible damage to the organs and patients who stay in this stage will die eventually (Edgerly, 2008). In a conversation with surgeon R. Klaassen (personal communication, November 11, 2018), it was explained that a young and fit person can compensate a blood loss for a very long time before the blood pressure drops. Therefore, it is a life-threatening situation when a young person with low blood pressure is brought to the emergency department. Therefore, it is vital to detect blood loss in the early stage. On the other hand, the blood pressure of elderly drops gradually. Therefore, continuous monitoring of patients' vital signs is very important to detect small changes in their health condition.

PTT and blood loss

Research has shown that PTT may reflect change in pre-ejection period (PEP) and central blood volume during progressive blood loss (Chan, Middleton, Celler, Wang, & Lovell, 2007). It is shown that PTT is high during the blood loss process, meaning that the pulse pressure takes more time to get from one point to another point in the artery. When PTT is monitored over a longer period of time, it can be a useful indication in early stages of blood loss (Chan et al., 2007; Wang, Lu, Lin, Abbod, & Shieh, 2012). Since PTT is inversely related to PWV (Byeong Cheol et al., 2004), PWV may be used to detect blood loss as well. Both methods have not been clinically validated yet. There is also more research required to tackle the limitations regarding placement of sensors, optimal duration for the detection of blood loss, patient groups who have limited response to change in preload (Chan et al., 2007).

PWV vs PTT

PWV is the speed of the pulse pressure between two predefined locations on the body (van Velzen et al., 2017). This must not be confused with the speed of blood. Generally, the measurement of PWV is known for its accuracy, simplicity and highly reproducibility (van Velzen, Sto ker, Loeve, Niehof, & Mik, 2018). It is widely used for the measurement of arterial stiffness (Nurnberger, Dammer, Opazo Saez, Philipp, & Schafers, 2003). Since this value increases with age, it can be used to assess the condition of the total vascular system (Munakata, 2016). Currently, carotid-femoral PWV (cfPWV) is used as the gold standard. Another method is brachial-ankle PWV (baPWV) which was developed in the year 2000.

PWV can be measured with non-invasive methods, such as: Doppler ultrasound (Lehmann, Gosling, Fatemi-Langroudi, & Taylor, 1992), tonometric, oscillometric and piezoelectric (Jatoi, Mahmud, Bennett, & Feely, 2009). These aforementioned methods do not provide comfort for patients or convenience for operators. Therefore, a multiphotodiode array (MPA) was designed to non-invasively measure the PWV (2017). This sensor consists of multiple PPG sensors that are placed on the finger. There are several advantages of using PWV, by using 2 PPG sensors between two short predefined locations, instead of PTT based on ECG-PPG:

1) it does not require trained personal
2) elimination of ECG
3) decrease of costs
4) reacts quicker than PTT
5) no difference between gender
6) less sensitive for motion artifacts

Moreover, PWV is a more universal measure for indirect blood pressure (2017; S.Niehof, personal communication, November 21, 2018). However, there is a non-linear relationship between PWV and blood pressure (Chen, Wen, Tang, & Teng, 2008). This makes it more difficult to estimate the absolute values of blood pressure by only measuring PWV or PTT, especially for elderly. More variables may be needed to accurately estimate this, such as age and patients' cardiovascular health. Moreover, there is more research required to investigate whether the PWV of the local area correlates with the rest of the vascular system. Therefore, it was suggested by clinical physicist, Sjoerd Niehof, to use the change of PWV values instead of trying to convert the PWV values into absolute blood pressure values (personal communication, August 8, 2018).

Conclusion
PWV is an indirect measurement of blood pressure. It can be calculated by placing two PPG sensors on the body between two predefined locations. PWV measurement has many advantages over PTT measurement. Such advantages include, elimination of wires, no requirement of trained personal and reduction of costs. There is still more research required to clinically validate this parameter.

Research has shown that PTT can be used as an indication to detect blood loss in early stages. Since PTT is inversly related to PWV, PWV may have the same potential to detect blood loss. There is still more research needed to clinically validate this.

Design implication
The placement of the sensor can be anywhere on the body where the arteries are close to the skin. These areas are known as pulse points on the body, however, other areas such as the auricle, earlobe and finger are also possible. More information will follow about the position of the PPG sensor in section 2.7 of this chapter. The distance between the sensors can be quite small. However, this requires a higher sample rate, which adversly affects the operating time of the battery.

4. Respiration rate

Respiration or respiratory rate (RR) or breathing rate (BR) is the amount of breaths per minute. According to the MEWS, a normal person breathes between 12 and 20 times per minute. The respiration can be measured with various methods.

Respiration derived from PPG

The respiratory rate can be detected in three different ways by using a PPG sensor, namely RIAV, RIIV and RIFV (Figure 2.26) (Karlen et al., 2013):

1. Respiratory-induced Amplitude Variations (RIAV) is the change of the peripheral pulse strength. This is caused by the decrease of cardiac output.

2. Respiratory-induced Intensity Variations (RIIV) is caused by the exchange of blood between the heart-lung circulation (pulmonary circulation) and heart-body circulation (systemic circulation). This results in the change of perfusion baseline.

3. Respiratory-induced Frequency Variations (RIFV) is caused by the variation of heart rate that matches with the respiratory cycle, also called respiratory sinus arrhythmia (RSA). The heart rate increases during inhalation and decrease during exhalation.

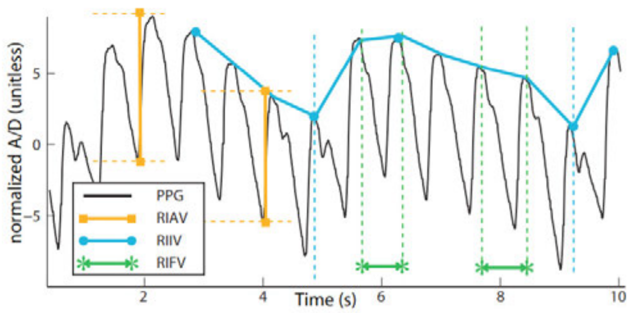


Figure 2.26: FPPG waveform, RIAV, RIIV and RIFV (Karlen et al., 2013)

According to Karen et al., it is vital to combine all aforementioned respiratory-induced variations for a stable estimation of the respiration rate. The PPG sensor can be placed on any part on the body where the artery is close to the surface. See section 2.7 of this chapter for further information about the position of the PPG sensor.

Impedance pneumography (IP)

This method is used to continuously measure the respiration rate in hospitals by using two or four electrodes placed on patients' chest (Charlton et al., 2016) (Figure 2.27). Four electrodes are used for more precise measurements, however, extra leads are required (Gupta, 2011). Therefore, two electrodes are mostly used for IP. The electrodes send a high-frequency AC current through the tissue. During inspiration, the resistance, known as electrical impedance, increases due to: 1) increase of gas volume in the chest and 2) increasing length of conductance because of expansion (2011). The change of electrical impedance results in the change of voltage. The varying voltage can be used to measure the respiration rate.

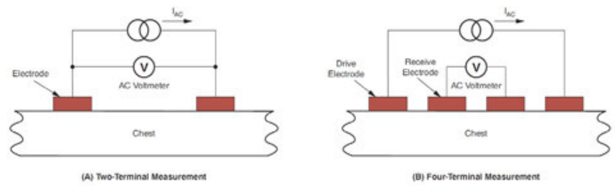


Figure 2 27:Two leads (left) and four leads (right) placed on the chest (Gupta, 2011)

Respiratory Inductive plethysmography

This method requires two belts that must be worn around the thorax and abdominal (Figure 2.28). The electrodes or the bands create signals that are corresponding to the movements of both thorax and abdominal (Barbosa, Carvalho, & Moriya, 2012). The disadvantages of this method are the use of two belts and calibration is needed before use (2012).

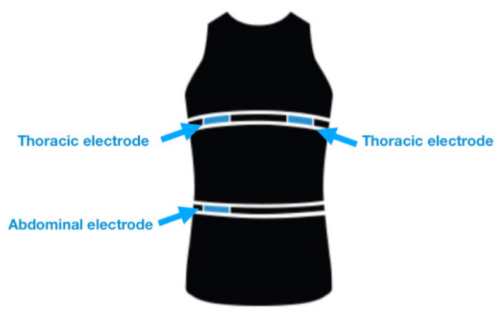


Figure 2.28: Hexoskin skirt using thoracic and abdominal electrodes (Trinh, 2018)

Nasal temperature change

This method uses a temperature sensor that is placed inside the nose to measure the change in temperature during breathing. According to research, respiration rate based on nasal temperature change accurately shows the respiration rate by using a nasal thermocouple (Marks, South, & Carter, 1995). However, it is possible that the patient is breathing through his or her mouth. This reduces the reliability of this method.

Capnography

The gold standard of monitoring respiration rate is capnography (Brookes, Whittaker, Moulton, & Dodds, 2003). This method detects the partial pressure of exhaled carbon dioxide (CO2) by using a nasal cannula (Figure 2.29). Although capnography is designed for operating rooms, it is also utilized in other areas in the hospital, such as emergency rooms, ICU, x-ray rooms and trauma fields (Kodali & Kodali, 2017).

Figure 2.29: Nasal Cannula (Lovego Service, 2017)

Chest circumference change

The change in lung volume is directly related to chest circumference change (Padasdao, Shahhaidar, & Boric-Lubecke, 2013). Based on this, various methods have been developed to monitor the respiration rate. Utilizing pneumatic belts, ultrasound emitter and receptor, magneto-resistive sensor are just a few examples (2013).

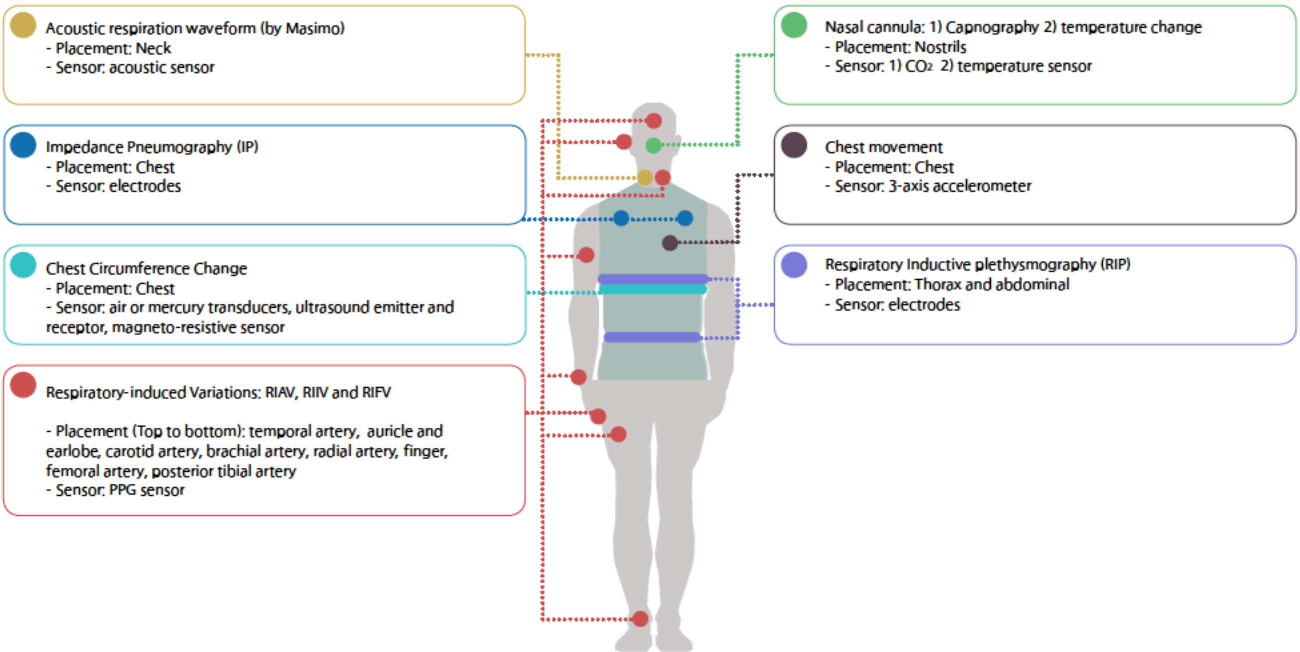
Movement of chest

The change in lung volume is also directly related to chest wall displacement (Padasdao et al., 2013), meaning that respiration can be derived by using a 3-axis accelerometer that is placed on patient's chest. During inspiration and expiration, the chest is moving in a certain direction. This can be detected by the sensor, even though the movements are small and hard to catch with the naked eye. It is required to combine the sensor output with algorithms and filters to reduce noise and to obtain reliable measurements.

Acoustic respiration waveform (by Masimo)

Respiration rate can be measured by using an Acoustic sensor. This sensor detects the airflow sounds produced in patients' upper airway. The sensor, that is placed on the neck of patients, converts the detected signals into respiration rate (Masimo Corporation, 2014) (Figure 2 30).

Figure 2.30: Acoustic respiration detection



Summary respiration rate measurement

Conclusion

The respiration rate can be measured with various methods. Each method has its own sensors which must be placed on specific areas of patients' body. The level of accuracy and type of sensor differ for every method.

Design implication

It is very important that the chosen method provides reliable measurements and is not obtrusive for patients. Therefore, the following methods were found interesting for the wearable: impedance pneumography, respiratory induced variations and chest movement. These methods use small sensors that will not limit patients in performing their daily activities. Accurate measurements can be obtained with additional signal noise filtering methods and smart algorithms.

5. Core temperature

The core temperature is found within the blood stream of vital organs, abdominal and thoracic cavities (McCallum & Higgins, 2012). The core temperature can be affected by both internal and external factors, however, less by external factors. The peripheral temperature, which refers to the skin, is more affected by external factors such as weather conditions. As shown in Figure 2 31, the core temperature is 37 degrees Celsius. According to the MEWS, a healthy person has a tympanic temperature ranged between 36.1-38.5C.

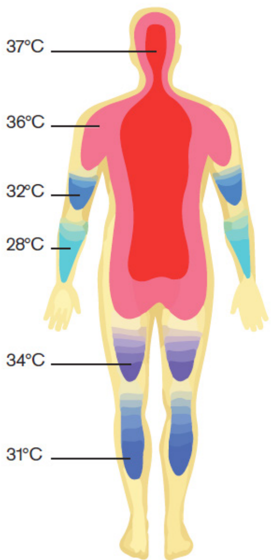


Figure 2.31: Peripheral and core temperature distribution (Drager Medical GmbH, 2015)

(Less) invasive techniques

Nowadays, there are many methods to measure the core and body temperature. In clinical settings, the gold standard of measuring the core temperature is with invasive techniques, such as inserting a catheter in the pulmonary artery or measuring the cerebrum. These methods have a high risk of complications and infections. Less invasive techniques, such as oral (mouth), or rectal (anus) temperature are easier but do not always provide reliable measurements. Additionally, it causes discomfort for patients and it is impractical, especially for ambulatory patients.

Axillary temperature

The axillary temperature can be used for continuous measurement such as the Sensium Patch by placing a sensor under the armpit (Sensium, 2016). According to research, the placement of the thermometer for axillary measurement is important (Davie & Amoore, 2010). The sensor must be placed as high as possible in the armpit without moving the sensor. It is essential that there is good contact between the sensor and the skin.

Tympanic temperature

Tympanic temperature can be continuously measured with an in-ear infrared (IR) sensor. The IR sensor must be pointed towards the eardrum to obtain reliable tympanic temperature. The ear canal must also be free of ear wax, otherwise, the measurements will be affected.

Zero-heat-flux

The zero-heat-flux (ZHF) method has great potential to continuously and accurately monitor the core temperature. It is non-invasive, easy to use and safe for patients. The sensor consists of a thermal insulator, two thermistors and a heater. This widely used method is able to measure 1 to 2 cm below the skin surface (Eshraghi et al., 2014). A disadvantage of this method is the significant amount of electricity used by the heater that keeps the temperature equal between the two thermistors.

Dual-heat-flux

Kitamura et al. (2010) developed a new method called dual-heat-flux (DHF) and it does not use a heater. This results in highly energy-efficient and continuous measurements using battery instead of AC power. However, both ZHF and DHF methods have relatively high response time compared to other core temperature measurement methods. It takes 15 to 20 minutes for the zero-heat-flux method to reach first equilibrium, 30 to 40 min for the dual-heat-flux method. Nevertheless, both methods react well on change in body temperature after equilibrium (Kitamura, Zhu, Chen, & Nemoto, 2010). Another disadvantage is the limited depth of measurement of the DHF probe. According to research, the measured depth remained static at 7.6 mm (Huang, Chen, Kitamura, Nemoto, & Tamura, 2013). Therefore, the sensor is only applicable on limited areas, such as the forehead. More research is required to estimate the core temperature of deeper sites.

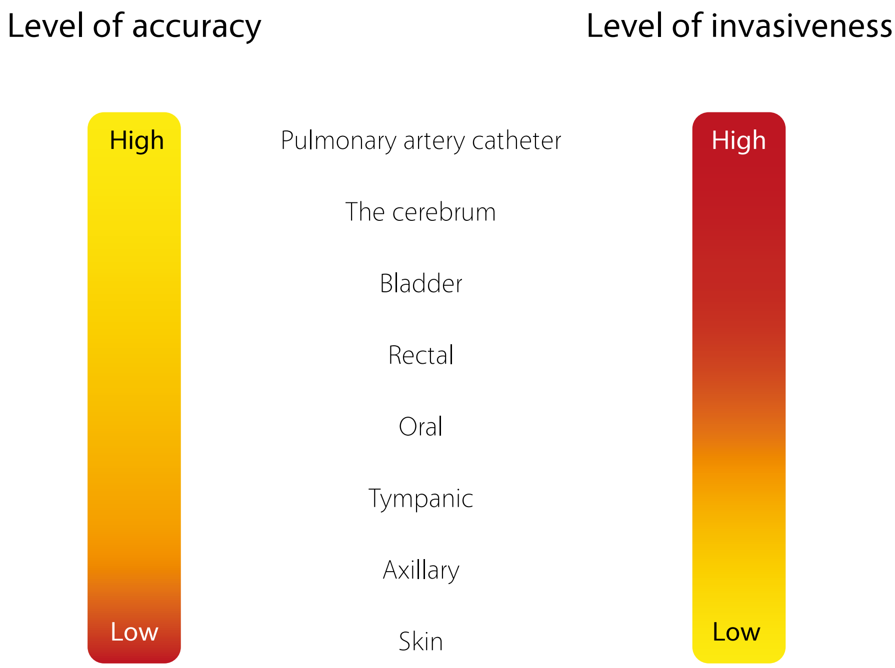


Figure 2.32: summary level of accuracy-invasiveness to measure body temperature

Conclusion

The core temperature can be measured with several methods, however, the level of accuracy increase with the level of invasiveness (Figure 2.32). Therefore, it was decided together with the client to use either tympanic or axillary temperature for continuous measurements of the body temperature.

Design implication

The measurement of the body temperature was limited to two methods: tympanic temperature and axillary temperature. In order to measure the tympanic temperature, the infrared sensor must be placed in the ear. The axillary temperature can be measured by placing a thermistor or thermocouple under the armpit. Both methods can be considered as (minimal) non-invasive, convenient and reliable.

06 Position PPG Sensor

Different body areas and pulse points were evaluated based on the following predefined criteria: reliability, comfort and hygiene. Based on this information, the best scored areas are highlighted and taken into account in the next chapter when generating concepts.

Predefined criteria

In clinical settings, the pulse oximeter is placed on the index finger. If the finger does not provide reliable measurements and one of the reasons may be caused by vasoconstriction, other areas of the body are used. The earlobe, auricle (external ear) or toe are other alternatives. For continuous measurements, it is important to have reliable and accurate measurements without obstructing patients in their daily activities. Moreover, a high level of hygiene must be maintained. Using PPG sensor for continuous monitoring has a few challenges, especially when patients move throughout the day. Motion artifacts, environmental light, contact force between sensor and body are just a few examples. Therefore, it is important to place the PPG sensor on body areas where one can overcome the aforementioned challenges and yet assures **reliability, comfort** and **hygiene.**

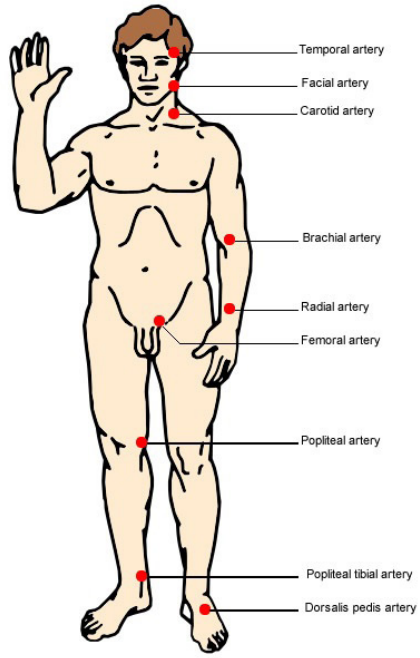


Figure 2.33: Pulse points

Pulse points

The body has several points on the body called 'pulse points', where the blood vessel is close to the surface of the skin (Figure 2.33). When sensors are properly placed on these pulse points, strong PPG signals can be obtained.

Potential areas

For the wearable, the following pulse points and areas were found interesting: temporal artery, earlobe, auricle, ear canal, brachial artery, radial artery, finger and ankle. Table 1 gives an overview of different body areas with the advantages, disadvantages and the score for the following criteria: reliability, comfort and hygiene. The user group (cancer and obese patients) were taken into account when scoring the body areas.

Table 1: Potential areas

Body area	Advantages	Disadvantages	Reliability (--, -, +, ++)	Comfort (--, -, +, ++)	Hygiene (--, -, +, ++)
Forehead (Temporal artery)	- Strong signals due to thin skin and high density of blood vessels - Minimal motion artifacts	- It can cause discomfort for continuous measurements - Low patient acceptance - Moderate hygienic level due to production of sweat	++	--	+-
Earlobe	- Strong signal due to lack of cartilage and large blood supplies - Not sensitive to poor peripheral perfusion - Minimal motion artifacts - Applicable for obese patients too due to lack of excessive body fat	- It can cause irritation over time when measured with an ear clip	++	-	+
Auricle	- Strong signal because blood vessels are close to surface - Minimal motion artifacts - Not sensitive to poor peripheral perfusion - Comfortable place - Applicable for obese patients too due to lack of excessive body fat	- The sensor must placed on specific areas on the auricle to obtain good signal	+	++	+
Ear canal	- Good signal (according to wearable Cosinuss one) - Minimal motion artifacts - Not sensitive to poor peripheral perfusion - Applicable for obese patients too due to lack of excessive body fat	- The sensor must be placed correctly in the ear canal - Moderate hygienic level	+	+	+-
Upper arm (brachial artery)	- Comfortable place for continuous measurement - No hygienic concerns	- The blood vessel lays relatively deep within the skin - Signal strength is moderate, especially for overweight people - Sensitive to motion artifacts	+-	++	+
Wrist (Radial & ulnar artery)	- Comfortable place for continuous measurement	- High senstive to motion artifact - Signal strength is moderate - Moderate hygienic level	+-	++	+-

Finger	- Strong signal strength in normal conditions - Applicable for obese patients due to lack of excessive fat	- Poor signal strength in case of vasoconstriction, especially for women - Not hygienic - Obstructs patient to perform daily activities, such as eating - High sensitivity to motion artifacts	+	+-	--
Ankle (posterior tibial artery)	- Easy to wear - Comfortable place	- Area is far from the heart. Due to this, the measurements may not be reliable - It may not applicable for obese patients due to excessive fat in this region - High sensitivity to motion artifacts, especially when walking	--	+	+

Discussion

As can be seen in table 1, the auricle scores the best with the given criteria to obtain PPG signals. Although the upper arm is also a comfortable area to place the sensors, the signal strength may not be strong enough, especially when measuring overweight people. The wrist can also be used to continuously measure the PPG signal, however, this area is more sensitive to motion and the signal strength is moderate.

Other areas such as the finger and earlobe are known areas to place PPG sensors in clinical settings. Unfortunately, they do not meet all given criteria regarding reliability, comfort and hygiene.

Design implication

Due to the small size of a PPG sensor, there are many options to place on the body. According to the evaluation, a PPG sensor can be placed on the auricle, the wrist and the upper arm. However, it can be challenging to obtain a stable and strong signal from both wrist and upper arm.

Final conclusion

PPG sensors are able to measure: heart rate, blood oxygen level and respiration rate. The respiration rate can be derived from the PPG signal in three different ways: 1) amplitude variations 2) frequency variations and 3) intensity variations. In order to increase reliability, all three methods should be combined.

When two PPG sensors are used, PWV can be measured continuously and non-invasively. This value gives the pulse pressure in the artery and provides an indirect estimation of the blood pressure. The absolute values of PWV are not relevant but the change of PWV does. This relates to the change of blood pressure. The PWV must be validated as a clinical value for blood pressure measurements.

When PPG sensors are combined with tympanic or axillary temperature sensor, all five vital signs can be measured continuously and non-invasively. Possible areas to place the sensor are: the auricle, wrist and upper arm. These body placements will be used to create concepts in the next chapter. It should be taken into account that obtaining reliable measurements from the wrist and upper arm is a challenge, especially from obese patients.

In clinical settings, the earlobe or finger are used to measure the heart rate and blood oxygen level. However, these areas do not fullfil all criteria for being considered as reliable, comfortable and hygienic.

Exploration.

3 Synthesis

This chapter presents concepts that are generated based on predefined criteria. These criteria are obtained from interviews as well the information from the analysis phase. Lastly, a list of requirements is presented with all important characteristics that the wearable must meet.

01 Conceptualization

Several concepts were generated that are in line with the the design vision. Each concept is explained, with its advantages and disadvantages. One final concept for further development is selected .

Design vision

The design vision was created after combining the insights and information from the analysis phase. This vision presents the desired final result:

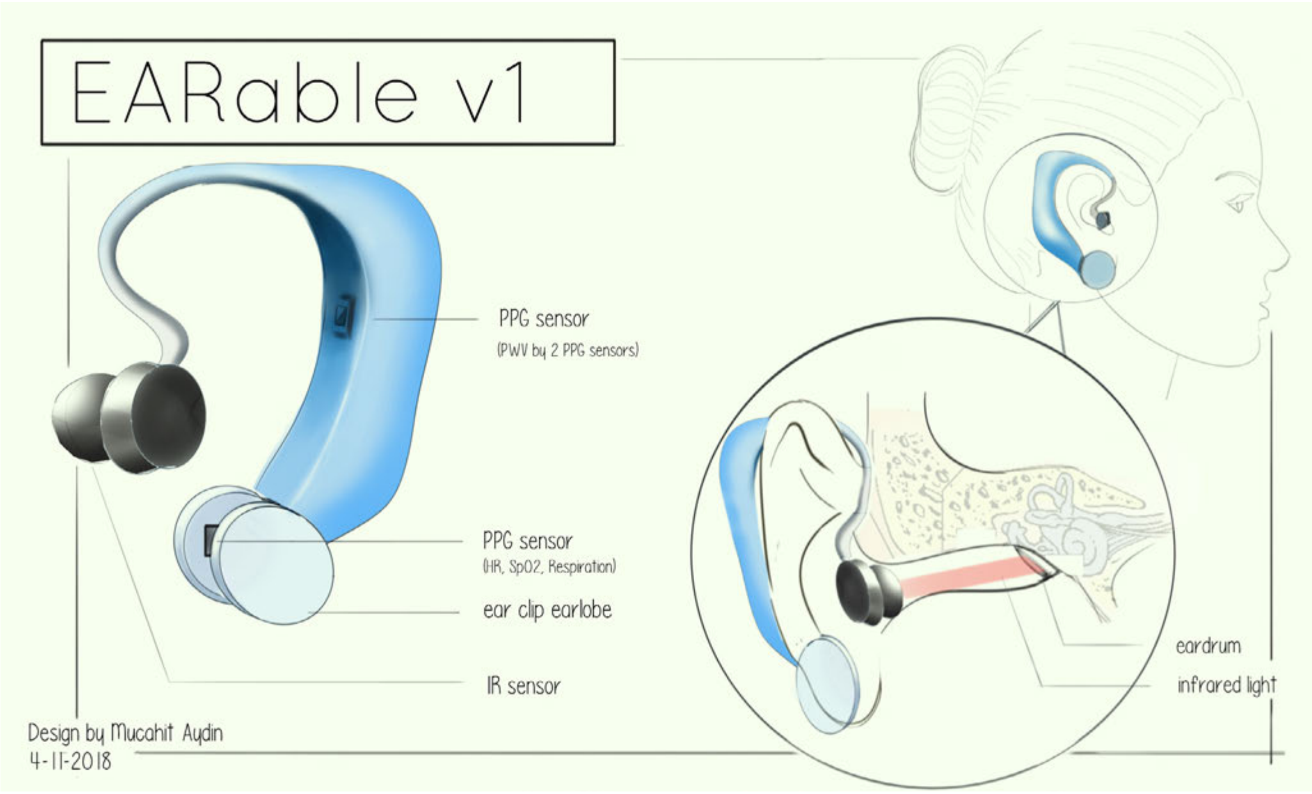
"Designing a reliable wearable for continuous and non-invasive measurement of the vital signs, aiming to ***increase work-efficiency****, to* ***ensure high quality of life of patients****, and to* ***reduce overall costs****. This wearable provides* ***comfort for patients*** *without interrupting their daily activities and it is* ***user-friendly for nurses****, meaning that the amount of performed actions is minimal."*

Concept generation

Based on the analysis phase, the auricle scored the best for the given criteria for continuous measurement. Other body areas, such as the wrist, earlobe, finger and upper arm, were taken into consideration during concept generation. This is done to explore new possibilities for the final concept. Various combinations were tried out in order to come up with best solution and eventually scored according to the following criteria:

1) All vital signs are measured
2) Reliable data
3) Comfortable for patients
4) Hygienic
5) User-friendly (minimal performed actions by nurses)
6) Easy to install and to remove
7) Robustness
8) Compact

Concept 1



Earable V1

Earable V1 is a wearable that is placed behind the ear, similar to a hearing aid. The IR sensor is placed in the ear canal to measure the tympanic temperature. One PPG sensor is positioned behind the auricle and one PPG is integrated in the ear clip to obtain PPG signals from the earlobe.

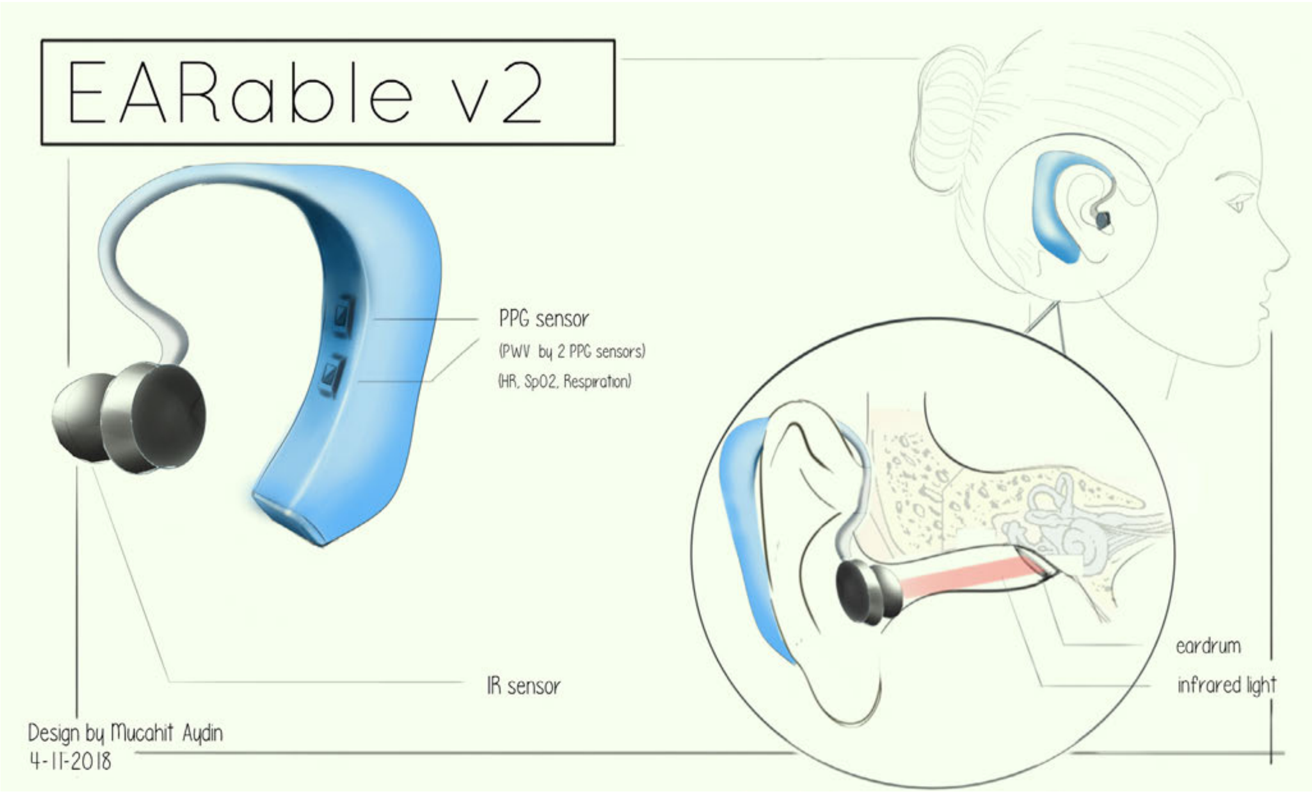
Advantages:

- Highly compact size
- Wireless
- Reliable measurements and less motion artifacts
- Not obtrusive for patients in performing their daily activities
- Auricle is a good area to measure for both obese and non-obese patients

Disadvantages:

- Patients with two hearing aids have to remove one hearing aid to place the wearable
- The ear bud reduces the ability to hear properly
- IR sensor must be pointed towards the eardrum and ear must be free from earwax
- The ear clip can cause discomfort due to the sensitivity of the earlobe
- Level of robustness can be moderate
- PWV is not yet clinically validated to indirectly measure the blood pressure

Concept 2



Earable V2

Earable V2 concept is a variation of the previous concept. The only difference is the placement of the second PPG sensor. Both sensors are relatively close to each other. This eliminates the need for an ear clip. However, a higher sample rate is required to measure the pulse wave velocity in the artery.

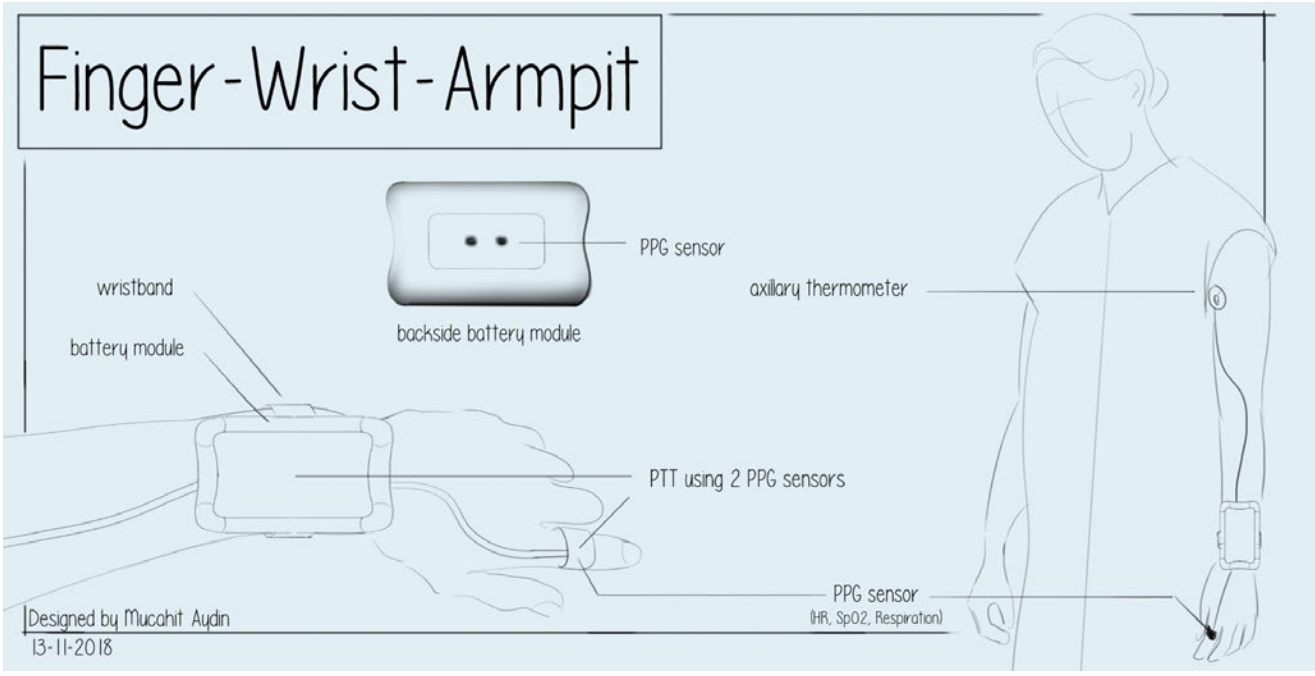
Advantages:

- Highly compact size
- Wireless
- Reliable measurements and less motion artifacts
- Not obtrusive for patients in performing their daily activities
- Auricle is a good area to measure for both obese and non-obese patients
- It is more comfortable compared to concept 1 due to the elimination of the ear clip

Disadvantages:

- Patients with two hearing aids have to remove one hearing aid to place the wearable
- The ear bud reduces the ability to hear properly
- IR sensor must be pointed towards the eardrum and ear must be free from earwax
- Level of robustness can be moderate
- PWV is not yet clinically validated to indirectly measure the blood pressure

Concept 3



Finger-Wrist-Armpit

Finger-Wrist-Armpit concept consists of three parts: finger wrap with an integrated PPG sensor, wrist module with battery module and two PPG sensors, and an axillary thermometer. The wrist module has two PPG sensors to increase the reliability of the signal. The disadvantage of this concept is the need for multiple parts that are placed on the body. Moreover, patients tend to not use the hand with the sensor attached.

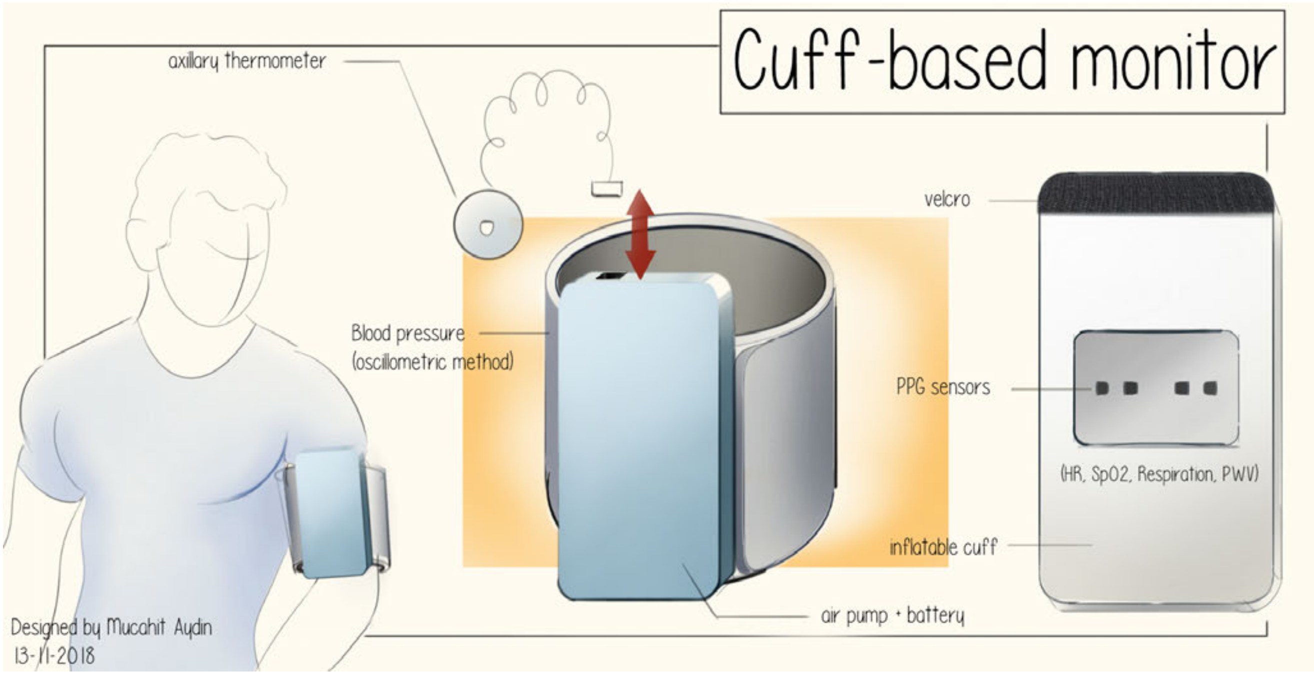
Advantages:

- The wrist is a comfortable area to place a wearable
- The measurements from the finger are reliable if no pressure is applied on the sensor or when the hand is not moved excessively
- Disposable parts, such as finger cuff, wristband and axillary thermometer all prevent cross-contamination

Disadvantages:

- This concept is less compact than the Earable concept
- The measurements from the wrist are moderate
- The sensor on the finger limits patients to perform daily activities, such as eating. Patients also tend to not use the hand with the sensor attached.
- It is not hygienic, especially when patients want to wash their hands after going to the washroom
- There is a long cable from the wrist going to the armpit. This cable must be attached on the arm with tape

Concept 4



Cuff-based monitor

The concept Cuff-based monitor is a wearable with the following parts: disposable cuff, battery module with multiple PPG sensors and axillary thermometer. Multiple PPG sensors are integrated in the arm module to increase reliability of the signal. The disadvantage of this concept is the need for an inflating cuff that measures the blood pressure. It is not possible to continuously measure the blood pressure and this method will cause discomfort for patients.

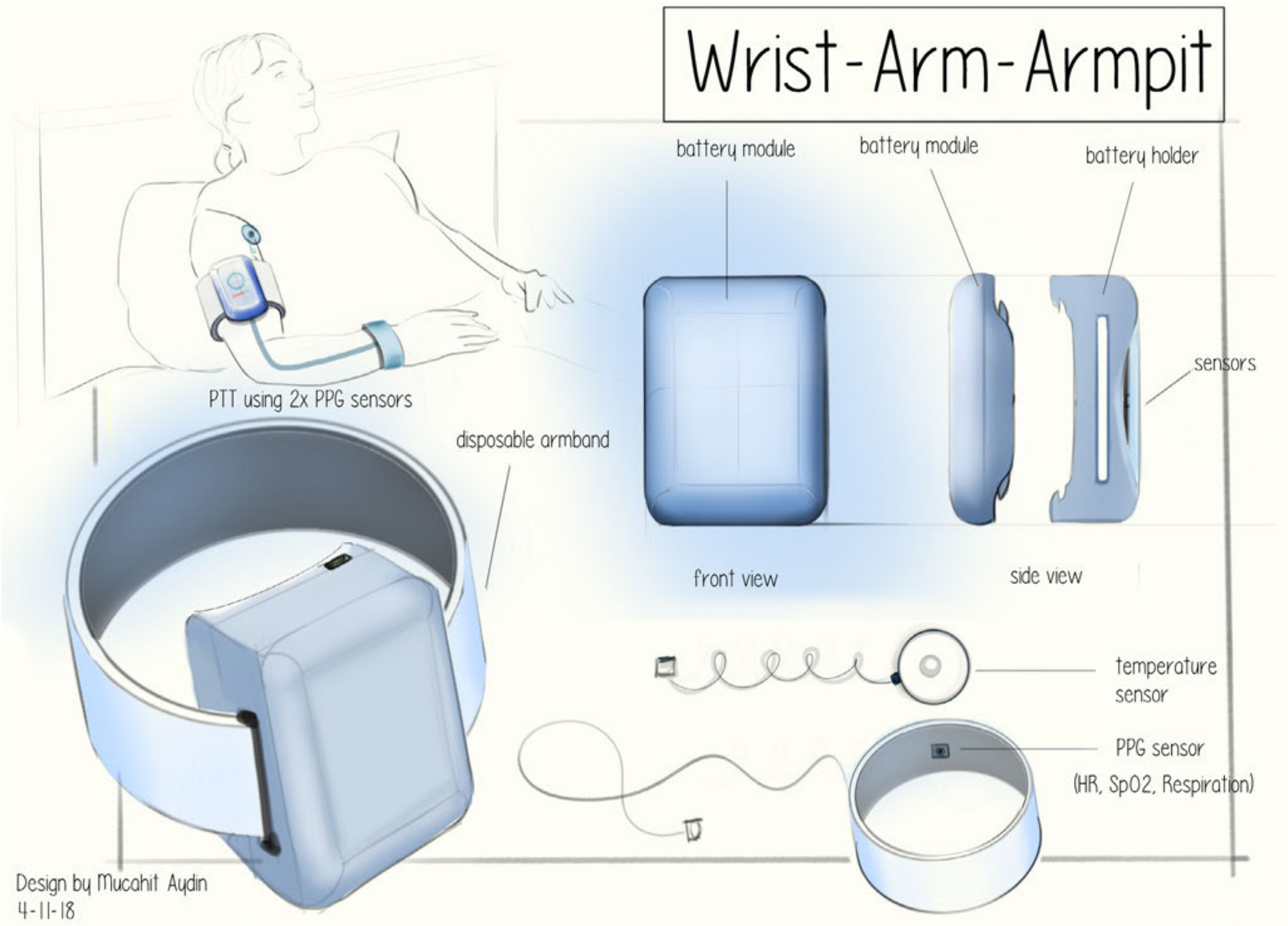
Advantages:

- Compact design
- If cuff is placed properly, the measurement of the blood pressure is clinically validated and expressed in absolute values
- Disposable cuff and axillary thermometer prevent cross-contamination

Disadvantages:

- The measurement of blood pressure causes discomfort and disturbs sleep at night.
- Continuous measurement of blood pressure is not possible with an inflating cuff.
- Patients must lay still during blood pressure measurement otherwise it can affect the results
- The cuff must be wrapped tightly around the arm. This can cause discomfort and even pain over time

Concept 5



Wrist-Arm-Armpit

Wrist-Arm-Armpit concept consists of the following parts: wristband with an integrated PPG sensor, armband, battery module, battery holder with integrated PPG sensors and axillary thermometer. The parts are placed on relatively comfortable places on the body. However, nurses have to install multiple parts and this may not be user-friendly for nurses.

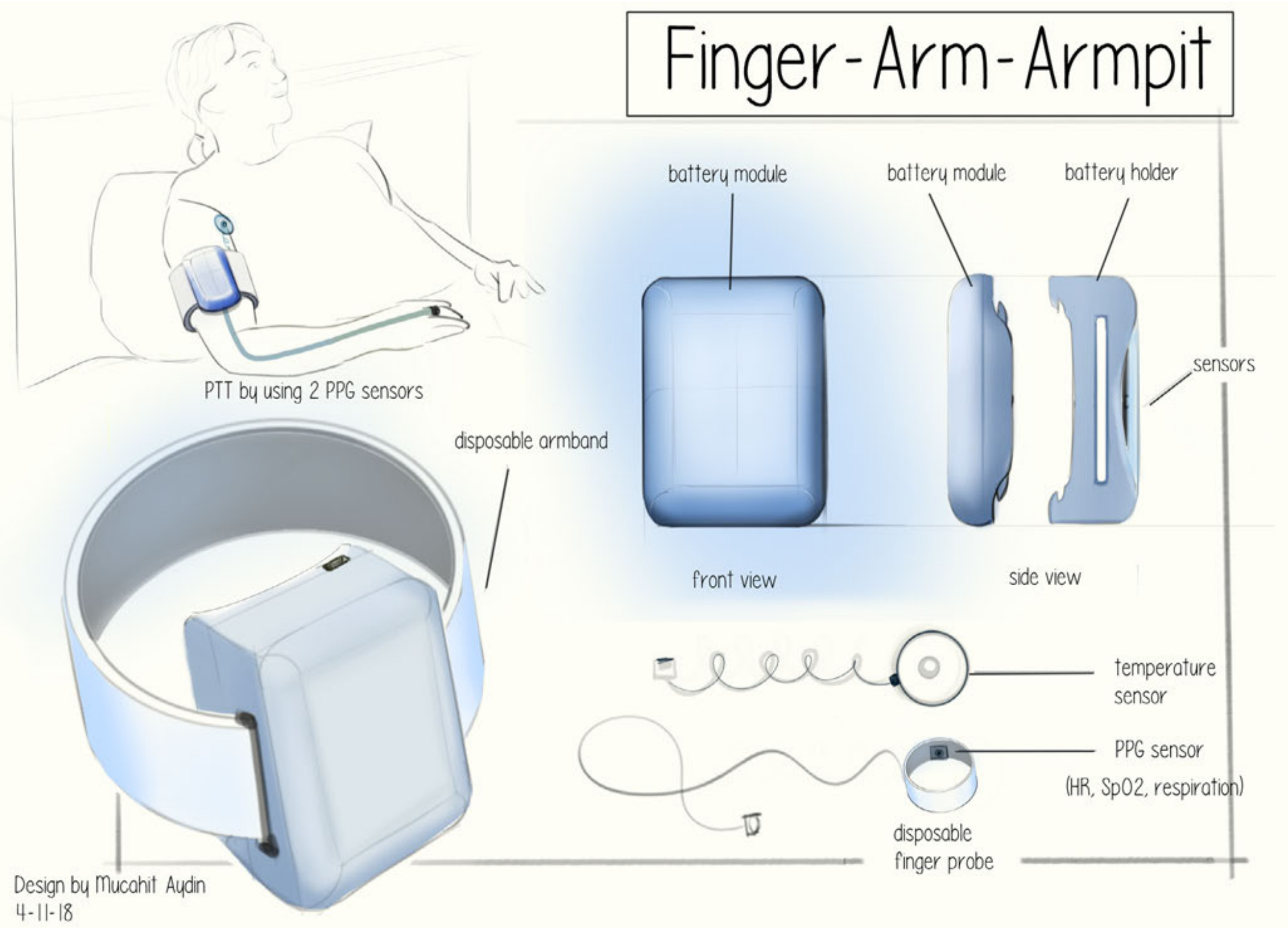
Advantages:

- The wrist and arm are comfortable areas on the body
- The wristband provides more control over his or her own situation compared to the finger sensor
- The wristband is more hygienic than the finger sensor
- The armband is close to the armpit. This makes it easy to apply the axillary thermometer.

Disadvantages:

- This concept is not compact because multiple modules must be placed on the arm
- Measurements from the arm may not be as reliable as the finger or auricle
- The cable between the arm and wrist module be fixated with tape

Concept 6



Finger-Arm-Armpit

Finger-Arm-Armpit concept is a variation of concept 5 (Wrist-Arm-Armpit). The only difference is that the wristband is replaced by a finger wrap. The disadvantage of this concept is that patients are tend not to use the hand with the sensor attached. Moreover, it is not hygienic when patients want to wash their hands.

Advantages:

- Finger measurements are more reliable than wrist
- Comfortable places on the arm
- Disposable parts, such as finger sensor, armband and axillary thermometer all prevent cross-contamination

Disadvantages:

- It is unhygienic to place a sensor on the finger
- Patients tend to not use the hand with the sensor attached. This limits patients from performing their daily activities
- The cable between the arm and finger sensor must be fixated with tape.

02 Concept Selection

All concepts were discussed with both nurses and patients. In order to make the selection easier, all concepts were evaluated with the Harris Profile and Weighted Objectives. In the end, one concept was chosen for further development based on well-founded arguments.

Nurses and Patients

Before selecting one final concept, all concepts were evaluated with nurses and patients. For each concept the advantages and disadvantages were discussed. At the end of the meeting all concepts were ranked (Table X). Earable V2 was chosen by patients as the best concept due to its compact size. According to patients, the product is compact and would not limit them in performing their daily activities. Concept 5, 'Wrist-Arm-Armpit', was chosen as the best concept by nurses. According to nurses, the product would be more understandable for patients and more comfortable to wear.

Harris Profile

Harris Profile shows the strengths and weaknesses of each concept based on the predefined requirements (Daalhuizen et al., 2014). All concepts were evaluated and compared with each other. See the following tables for scores given to each concept.

Requirements	-- (bad)	- (moderate)	+ (good)	++ (excellent)
All vital signs are measured				
Reliable data				
Comfortable for patient				
Hygienic				
User-friendly (minimal performed actions by nurses)				
Easy to apply and to remove				
Robustness				
Compact				

Earable V1

Requirements	-- (bad)	- (moderate)	+ (good)	++ (excellent)
All vital signs are measured				
Reliable data				
Comfortable for patient				
Hygienic				
User-friendly (minimal performed actions by nurses)				
Easy to apply and to remove				
Robustness				
Compact				

Earable V2

Requirements	-- (bad)	- (moderate)	+ (good)	++ (excellent)
All vital signs are measured				
Reliable data				
Comfortable for patient				
Hygienic				
User-friendly (minimal performed actions by nurses)				
Easy to apply and to remove				
Robustness				
Compact				

Finger-Wrist-Armpit

Requirements	-- (bad)	- (moderate)	+ (good)	++ (excellent)
All vital signs are measured				
Reliable data				
Comfortable for patient				
Hygienic				
User-friendly (minimal performed actions by nurses)				
Easy to apply and to remove				
Robustness				
Compact				

Cuff-based Monitor

Requirements	-- (bad)	- (moderate)	+ (good)	++ (excellent)
All vital signs are measured				
Reliable data				
Comfortable for patient				
Hygienic				
User-friendly (minimal performed actions by nurses)				
Easy to apply and to remove				
Robustness				
Compact				

Wrist-Arm-Armpit

Requirements	-- (bad)	- (moderate)	+ (good)	++ (excellent)
All vital signs are measured				
Reliable data				
Comfortable for patient				
Hygienic				
User-friendly (minimal performed actions by nurses)				
Easy to apply and to remove				
Robustness				
Compact				

Finger-Arm-Armpit

Weighted Objectives

Based on the Harris profile, Earable V2 concept scores the best. Earable V1 scores the second best. The Wrist-Arm-Armpit concepts scores the third best. In order to make the decision making process easier, 'Weighted Objectives' method was used. This method is ideal to compare multiple concepts based on the total value of each concept (Daalhuizen et al., 2014). As can be seen in Table 2 below 'Earable V2' and 'Wrist-Arm-Armpit' score the best for the given criteria.

Discussion

Throughout the process, several discussion sessions were performed with all involved parties, including patients, nurses, medical experts, client and supervisors, regarding preferred areas on the body to place the wearable and eventually select the desired concept. When the parties were asked to rank the concepts, there were different views and opinions. For instance, nurses and client preferred concept 5 over concept 2, even though this concept consists of multiple modules and may have a lower level of user-friendliness. When patients were asked, some patients did not want a wearable around the head and preferred concept 5, while other patients did not mind to place a wearable around the ear and selected concept 2.

This part of the process is where technology and human merged together, taking into account the feasibility of the concept, and desires of the user group (Figure 3.1). Therefore, it is very important to see **the bigger picture** as a designer and make choices based on the collected insights.

Before a concept choice was made, an additional meeting was planned with clinical physician, Sjoerd Niehof (personal communication, November 21, 2018). In the conversation, the reliability and accuracy of the PPG sensors were discussed. It was explained that there is no difference in accuracy between the transmission and reflection method (see Chapter 2, 2.6). However, with the transmission method, one can measure up to 2cm through tissue, however, the muscle and bone are can reduce the range of the sensor. In addition to this, the reflection method can measure up to 1cm. It can be an issue when PPG sensors are placed on the arm of obese patients when the reflection method is used. Fat is known for significantly reducing signal strength. Therefore, concept 2 was selected for further development.

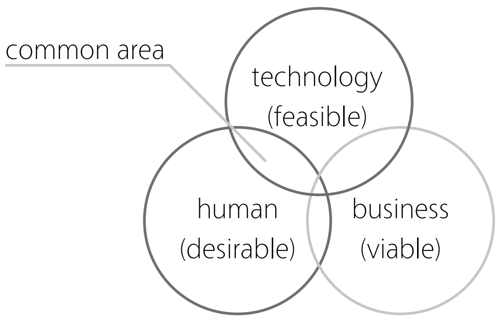


Figure 3.1: Common area of human and technology

Table 2: Weighted objectives

	Weight	Concept 1 Earable V1		Concept 2 Earable V2		Concept 3 Finger-Wrist-Armpit		Concept 4 Cuff-based monitor		Concept 5 Wrist-Arm-Armpit		Concept 6 Finger-Arm-Armpit	
Requirements		**score**	**total**	**score**	**total**	**score**	**total**	**score**	**total**	**score**	**total**	**score**	**total**
Reliable data	5	8	40	8	40	9	45	10	50	9	45	9	45
All vital signs are measured	5	9	45	9	45	8	40	3	15	4	20	7	35
Comfortable	5	2	10	6	30	6	30	1	5	8	40	6	30
Hygienic	5	5	25	7	35	3	15	8	40	8	40	3	15
User-friendly	4	8	32	8	32	5	20	7	28	5	20	5	20
Easy to install	4	9	36	9	36	6	24	8	32	6	24	6	24
Robustness	4	3	12	3	12	7	28	8	32	7	28	7	28
Compactness	3	8	24	9	27	4	12	6	18	4	12	4	12
Total score	**35**		**224**		**257**		**214**		**220**		**229**		**209**

Conclusion

After discussing both concepts with experts and client, Earable V2 concept was chosen. The following arguments were given:

- Reliable data can be obtained from all patients, including obese patients, when Earable V2 is used. In a conversation with clinical physician (S. Niehof, personal communication, November 21, 2018), it was concluded that PPG sensors are limited to measure areas with excessive fat, including arms. Due to this, 'Wrist-Arm-Armpit' will not provide reliable measurements.

- Due to the compact size of Earable V2, minimum actions are required by nurses compared to Wrist-Arm-Armpit concept. Wrist-Arm-Armpit consists of multiple modules which requires nurses to spend more time to install it on patients' body. Therefore, Earable V2 is more user-friendly for nurses.

03 Program Of Requirements

A list of requirements was created based on the insights from the conducted interviews with patients, nurses, client and experts.

1. General

1.1 The complete system must be able to get a full MEWS
1.2 The complete system should reduce stress level and workload of nurses
1 3 The complete system should minimize the hospitalization period of patients with one day
1.4 The complete system should reduce costs of care
1.5 The complete system should increase work-efficiency of nurses
1.6 The complete system should maintain connection between patients and nurses
1.7. The complete system should be implementable in the current hospital communication infrastructure
1.8 The complete system should enable early interventions and prevent complications

2. Performance

2.1 The wearable must continuously monitor the following vital signs: heart rate, blood oxygen level, blood pressure, core temperature and respiration rate
2.2 The system must alarm nurses when parameters exceed the limits
2 3 The wearable must send data and alarm when an increase and decrease is detected in the vital signs
2.4 The wearable must function in peak times, when the vital signs are above and below the normal values
2.5 The wearable must have accurate and reliable integrated sensors
2.6 The wearable must be very energy-efficient
2.7 The wearable must store the data on an integrated flash memory when connection is lost and must send the data when reconnected with the Bridge
2.8 The wearable must be robust
2.9 The wearable must be re-usable
2.10 The wearable must be rechargeable
2.11 The wearable must be sweat and water resistant
2.12 The wearable must be able to function 8 hours with a full battery
2.13 The wearable should count the activity e.g. steps of patients

3. Life in service

3.1 The wearable must be able to be used 24/7

4. Design: Aesthetic, Appearance and Finish

4.1 The wearable must be intended for people aged from 16 to 100
4.2 The design must be unisex
4 3 The wearable must have a minimalistic, clean and modern design
4.4 The wearable must not have unnecessary holes and cavities in which dirt and dust can accumulate
4.6 The wearable must not have sharp edges or corners that can harm patients and nurses

5. Maintenance

5.1 The wearable must be easy to clean
5.2 The wearable must have a disposable ear-in and ear hook part to prevent cross-contamination

6. Weight

6.1 The wearable must weigh less than 18 grams

7. Standards, rules and regulations

7.1 The materials must comply with ISO 10993 'Biological evaluation of medical devices'
7.2 The wearable must comply with the Medical Device Directive 93/42/EEC Class IIb (rule 10) intended for long term use (longer than 30 days) (Council of the European communities, 1993, p-14).
7 3 The material used for the wearable must be biocompatible

8. Ergonomics

8.1 The wearable must be very comfortable and must not interrupt the daily activities of the patient
8.2 The wearable must be user-friendly for nurses. Thus, the tasks performed by the nurses are simple, fast and with minimal effort.
8 3 The wearable must be easily attachable to patient's body and also detachable from patient's body

9. Reliability

9.1 The chance of failure and errors of the system, including wearable, the Bridge and the server, must be minimal.
9.2 There must be an extra server that backs up all patient information

10. Connection wearable

10.1 The wearable must wirelessly connect to the Bridge via Bluetooth
10 2 The Bridge must transmit the data to the server via WLAN
10 3 The server must wirelessly send the data to the application on the mobile device and via WLAN to the application on the computer
10.4 The transmission time of data must be adjustable for each patient, e.g. nurse can configure on the application to receive data from patient A every 10 minutes and for patient B every 5 minutes.

11. Application

11.1 The application must show the following information: patient photo (if available), patient name, room number, bed number, gender, vital signs, battery status and signal strength
11.2 The application includes a page showing a trend graph with the day and time
11 3 The interface of the application must be intuitive and simple for nurses
11.4 Authorized medical staff must be able to change the limits of the vital signs for each patient

12. Data access

12.1 The data must only be accessible for patient and assigned medical staff

13. Server

13.1 The server must be able to process the data
13.2 The server must alert the nurses when the MEWS is 4 and above
13 3 The server must alert the nurses when an increasing or decreasing trend is detected
13.4 The server must be able to store big amount of data
13.5 The server must comply with international standards for transferring clinical data to avoid intervention from outside
13.6 The server must notify the nurses when wearable is outside the department to prevent theft and to inform nurses about the location of patients
13.7 The server must alarm when data is not sent due to technical problems
13.8 There must be a back-up server that stores all patient information in case the first server failes

4 Embodiment

The chosen concept is further detailed in this chapter. The first part describes the ergonomic shape study that has been done to study the comfort and fit. The second part presents a proof of principle, demonstrating that the idea work.

01 Ergonomic Prototyping

Proper contact between sensors and auricle is an essential requirement in order to obtain strong and reliable signals. In order to achieve this, the curve behind the ear must be known. However, there were no sufficient data available. Therefore, it was required to research this and accomplish a high level of comfort and fit. New insights and valuable knowledge were gained after creating and testing the models.

Lack of data

For this project, specific data were needed regarding the back side of the auricle. Unfortunately, there is lack of available data on the body area that connects the auricle to the head. Therefore, 10 ear models were made with Polymorph (Figure 4.1). Polymorph is a polymer than can be formed and reformed multiple times by using hot water. The aim was to create an average model with the right curvature which can provide comfort and fit.

Sport earphones

The curvature of the back side of the auricle is essential for two reasons: 1) to create comfort and fit 2) to obtain strong signal. There are existing devices in the market, such as sport earphones with earhooks and bluetooth headsets. However, these products do not require proper contact on specific points (figure 4.2), while this is a requirement for the Earable.

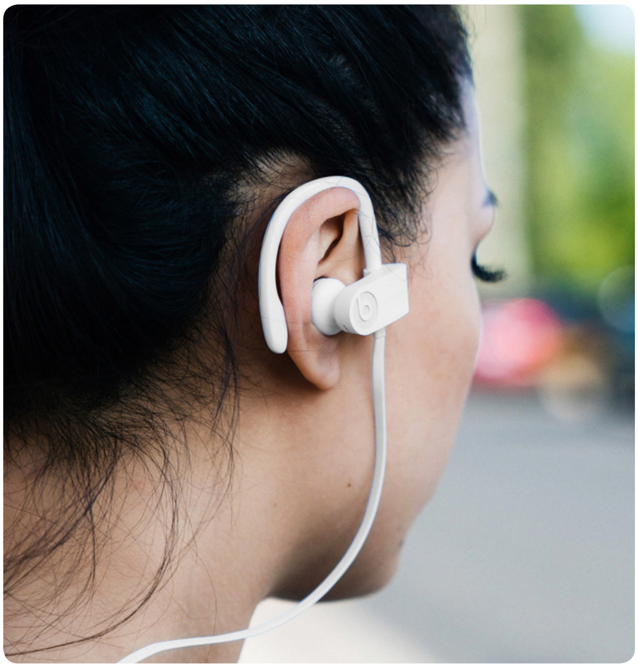


Figure 4.2: No proper contact between the ear and ear hook

Figure 4.1: Handmade Polymorph models

The process

Each model was made using the following steps (Figure 4 3):

1-3. For each model, the same amount of Polymorph was used.

4. Polymorph must be put in hot water with the desired pigment color.

5. This plastic granules becomes translucent and soft.

6. After kneading the Polymorph granules together, it becomes one shape.

7. When the color is dispersed equally, it can be shaped into the desired form.

8. The hair of the participant must be covered to prevent harm for the participant. The Polymorph can stick to the hair and this is difficult and painful to remove.

9. The form is pressed behind the ear to obtain the correct curve and stretched out to the concha (hollow next to the ear canal).

10. After shaping the desired form, it must be worn for a few minutes to cool it down a bit and to prevent any change in shape.

11. The model must be cooled down in ice cold water for a few minutes to fixate the form. After a few minutes, the color of the model will be lighter and the material will become solid.

12. The model is done and ready to be worn by the participant for the final check. In order to finetune the model, it must be placed in hot water again and reshaped until the desired form has been achieved.

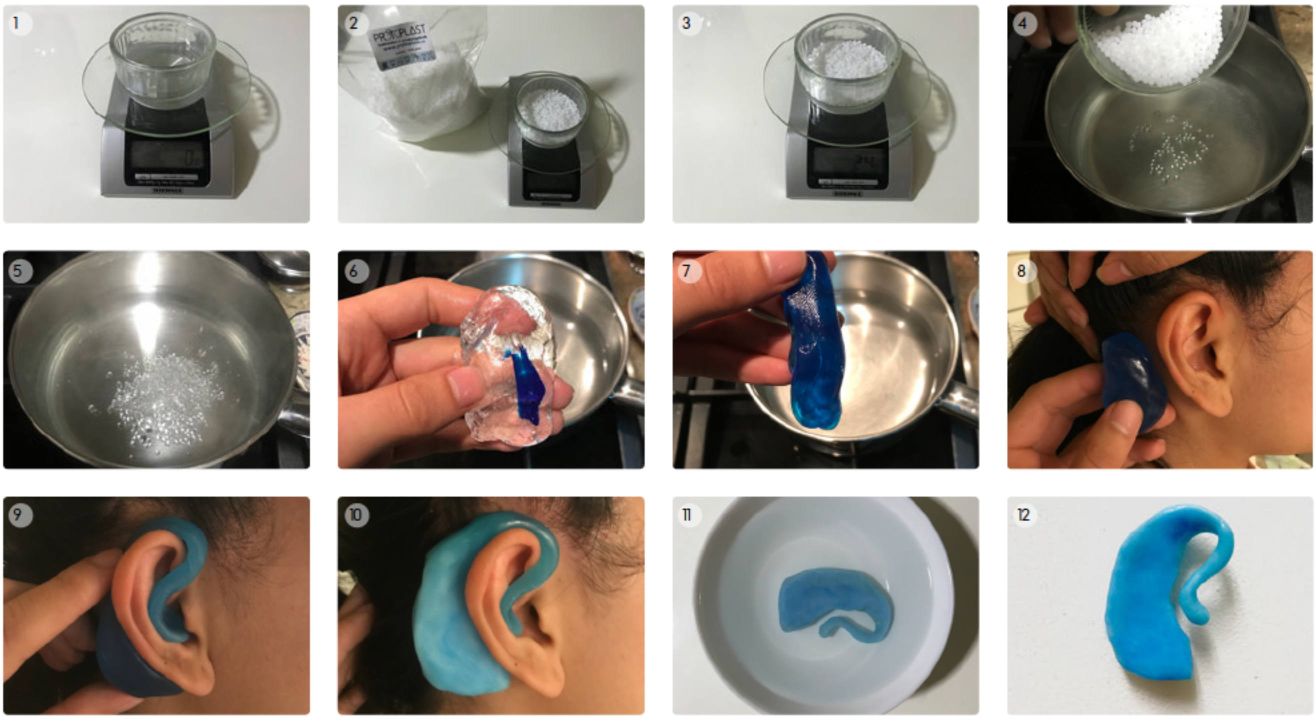


Figure 4.3: making of the handmade models

Average model

In order to find out whether one size would be sufficient, one average model was created and tested with potential patients. This was done by scanning all 10 models with an accurate industrial 3D scanner, Artec Space Spider (Figure 4.4). After scanning, all data were processed with Wrap which is a software for 3D scans (Figure 4.5).

For each model, three reference points were selected and merged together to create the average model (Figure 4.6). The model was printed in PLA with the Ultimaker 2+ (Figure 4.7) and tested with 10 participants. See the next section for the results of the user-testing.

Figure 4.4: Scanning the polymorph models

Figure 4.5: 3D scans of all Polymorph models

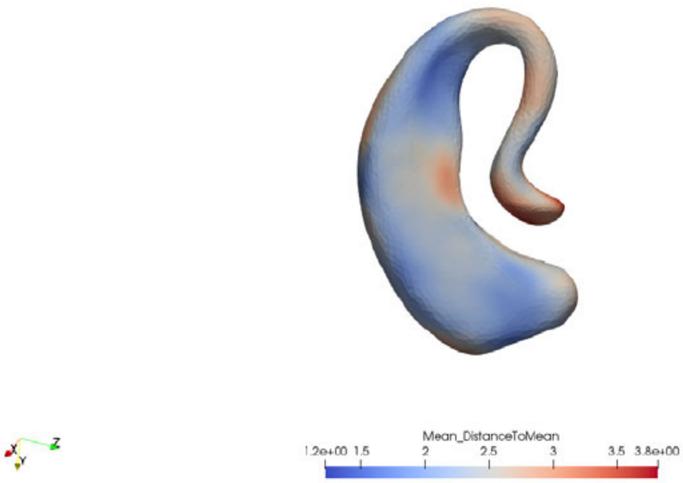


Figure 4.6: The average form of all 3D scans

Figure 4.7: 3D printed average model

02 Ergonomic User Test

Research question

The research question was formulated as follows: "*How comfortable is the average model when it is worn for an extended period of time?*"

Method

In order to test the comfort level of the average model, ten participants were asked to wear the 3D model as long as possible while they are laying, sitting and wa king. After the test, participants were asked to fill in a questionnaire with a few open questions (Appendix E).

Participants

In total 10 participants were used for the test. 3 participants were not asked prior to the creation of the Polymorph models and were added later on for the user test. The other 7 participants were asked prior creating the Polymorph models. The age varied from 24 to 54 years old.

Result

On average the model was worn for about five hours. The minimum time was three hours, the maximum time was 10 hours. Two participants also slept with the wearable on. This did not cause any discomfort or pain. On average, the model scored a 3 (1=not comfortable, 5=comfortable). Only three participants felt discomfort after a couple of hours. Their experience was that the model became 'heavier' over time. seven participants did not feel any discomfort while sitting and did not focus on the wearable. When participants started wa king, the 3D model was moving. This resulted in annoyance and discomfort. The area that felt most uncomfortable or annoying was the part between the mid part and upper part (Figure 4.8). Two participants felt the 3D model touch their head whenever they turned their head. Some participants also stated that it is difficult to wear glasses in combination with the 3D model.

Side view

view

Post-user test discussion

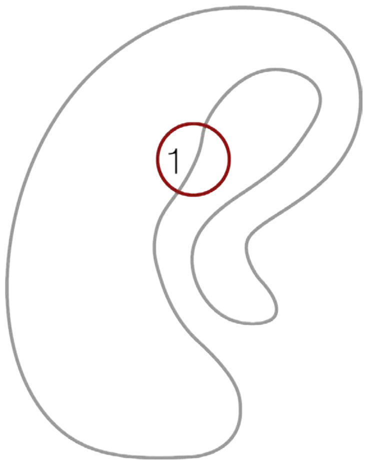


Figure 4.8: Area 1 was felt most discomfortable

Design implication

The 3D model has certain contact points with the auricle and concha (Figure 4.9). In order to get used to the 3D model, it must have good and tight contact with the ear. If the contact is too loose or too tight, it will create discomfort or pain. Therefore, the level of tightness must be sufficient. Another factor that may affect the level of comfort is the amount of contact points with the ear. It was decided to reduce the amount of contact points during the iteration process. Both criteria are important to ensure comfort for users and to get a strong signal from the ear. See the next section for the improvements that were made.

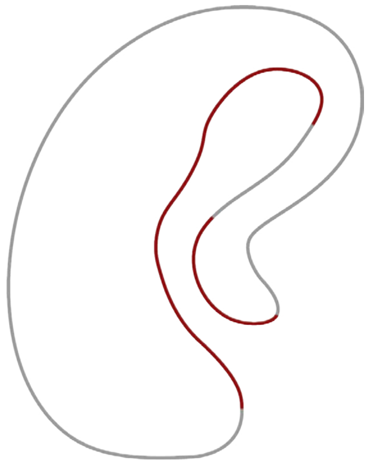


Figure 4.9: contact points with the ear in red

Discussion

The aim of the user test was to research the comfort level of the 3D model when it is worn for an extended period of time. The result shows that the 3D model scored an average score. It did not feel fully comfortable neither did it feel fully uncomfortable.

Participants' ear size differed from one another as well as the distance between the auricle and the head. Since the 3D model was the average form of 10 scans, it might not be fully comfortable for every participant. Participants who had smaller ears, gave lower scores than participants with bigger ears. Therefore, it is recommended to have multiple sizes in order to ensure high comfort for all users. Another factor is the distance between the head and the auricle. The smaller the distance, the more discomfort the model became. They might be other factors that could have played a role for the discomfort feeling, such as the type of material and its flexibility.

Conclusion

It can be concluded that the model has potential to be used for an extended period of time. However, more iterations and testing must be done in order to ensure high comfort for users. This is very important because patients have to wear the wearable for at least 24 hours, even during their sleep. It is also recommended to create multiple sizes, for instance, one small size and one average size. The following variables should be taken into account when creating the final model: form, material, flexibility and size.

03 Iteration Improvements

Several iterations and design decisions were made during the process. This process of trial-and-error resulted in one final iteration that is used for the prototype as well as for the final design.

Average model

The organic shape of the average model enables proper contact between the ear and the integrated PPG sensors. After user-testing, many points were improved to achieve comfort and fit. The following iterations were created with SolidWorks by using the average model as a reference.

Dimensions

The model has the following dimensions:

Width: 50mm
Height: 70mm
Thickness:
- top: 8.5mm
- middle: 13mm
- bottom: 15mm

1st iteration

Due to the big size of the average model, the minimum size of final product was determined after doing research on the electronic components together with an electrical engineer. The bottom part of the model is made straight to reduce the amount of contact points with the ear. In this design the PPG sensors are still fully integrated in the model.

Dimensions

The model has the following dimensions:

Width: 48mm
Height: 56mm
Thickness:
- top: 5.5mm
- middle: 9mm
- bottom: 10mm

2a iteration

This form is based on collages and some ideation sketches. This design is slightly bigger and has a more organic shape compared to 1st iteration. This is done to distinguish the design from hearing aids and achieve a more coherent design. Another difference is that the PPG sensors stick out a little from the design in order to reduce the amount of contact points between the model and the ear. The exact position of the sensors were also explored in this iteration.

Dimensions

The model has the following dimensions:

Width: 46mm
Height: 67mm
Thickness:

- top: 4.5mm
- middle: 8mm
- bottom: 8mm

2b iteration

This design was simultaneously made with iteration 2a. A major difference is that the model does not touch the concha but it goes directly into the ear. The main reason is to reduce the amount of contact points. The right angle of the ear bud was also explored in this iteration.

Dimensions

The model has the following dimensions:

Width: 46mm
Height: 59mm
Thickness:

- top: 10mm
- middle: 10mm
- bottom: 10mm

3rd iteration

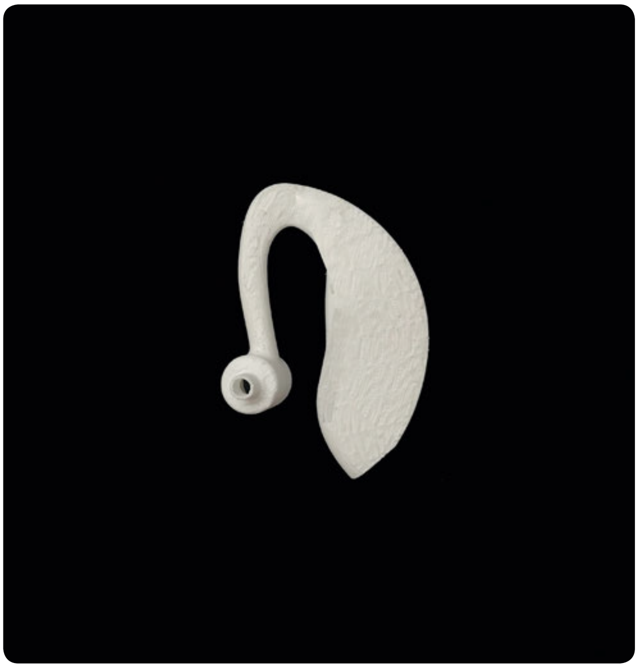
This iteration is a combination of iteration 2a and 2b. The the top part was reduced to allow users to wear glasses together with the Earable. The in-ear part has holes to plug in the IR sensor with the disposable ear bud. After use, the IR sensor together with the plug can be thrown away.

Dimensions

The model has the following dimensions:

Width: 45mm
Height: 62mm
Thickness:

- top: 5mm
- middle: 8mm
- bottom: 8mm



Final iteration

This design is more sustainable compared to the previous design because the IR sensor is integrated in the model. The disposable ear bud can be put on the extruded part that can be seen in the photo above. After use, the disposable ear bud can be thrown away.

Dimensions

The model has the following dimensions:

Width: 45mm
Height: 73mm
Thickness:

- top: 5mm
- middle: 9mm
- bottom: 8mm

Design decisions

After many iterations and tests, one final design was created with the following improvements:

1) PPG sensors not fully integrated
2) smaller top part
3) less contact points with the ear
4) ensure comfort and fit
5) easy docking
6) extra space to integrate the infrared sensor
7) thinner and more realistic form.
8) reduced width

Here is a summary for each design decision that was made until the final iteration was completed:

1) The PPG sensors were fully integrated in the average model, however, it was decided to the sensors out a little to reduce the contact points with the ear.

2) The top part of the design was made smaller in order to make it more comfortable for people wearing glasses.

3) Compared to the average model, the bottom half of the model that touches the ear is not curved. This is done to reduce the contact points with the ear and to prevent irritation.

4) The last three iterations do not touch the concha. It can be difficult to create optimal comfort and fit when there are too many different curves and shapes of the concha. It was decided to make a design that goes directly in the ear and use other methods to keep the wearable firm on the ear. A possible solution are ear hooks that are used for sport earphones.

5) The bottom part of the model was made straight in order to make it easy to put it in the docking station.

6) In the final iteration, extra space was created to integrate the IR sensor. Compared to the 3rd iteration, this solution is more sustainable because the IR does not have to be thrown away after use, only the disposable ear bud.

7) The final design was made thinner compared to the average model. This is very important to ensure comfort for patients, especially for patients whose auricle is close to their head. Additionally, the final design has more realistic dimensions. These dimensions were based on the electronics, such as battery, sensors and other electronic components.

8) Compared to the average model, the width of the final model was decreased too, in order to prevent the wearable from touching the head when patients turn their head.

04 Electronic Prototyping

After a thorough analysis, it was required to create a a proof of principle for the concept and demonstrate that the idea can work.

PulseSensor

PulseSensor is an optical heart rate sensor with an integrated green LED (Figure 4.10). It is able to measure the heart rate, heart rate variability and pulse transit time when two PulseSensors are used. The sensor comes with a velcro strip that has to be attached to the finger and an earlobe clip. It is important that the sensor makes good contact with the skin. Additionally, the body must be at rest when measuring, otherwise the measurements will be affected. This sensor is used during the exploration phase and not used in the final prototype.

Figure 4.10: Pulse sensor

MAX30105 pulse oximeter

MAX30105 is a breakout board with integrated LEDs (IR, green and red) and photodetectors (Figure 4.11). The photodetector measures the reflected light for SpO2 measurement. The BPM is calculated by using the Penpheral Beat Amplitude algorithm which can detect the beats. This sensor must correctly be placed on the body. It is prone to error when you move during the measurements. It is recommended to use a rubber band when placing the sensor on the finger.

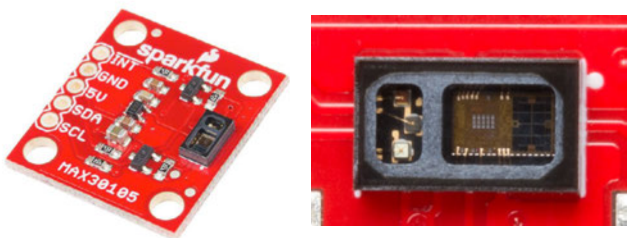


Figure 4.11: MAX30105

NTC thermistor

NTC thermistor is a resistor with a Negative Temperature Coefficient (Figure 4.12). The resistance of this component decreases when the temperature increases. This component is small, low-cost and highly sensitive. The operating temperature range varies between -40 and +125 C. The quick response time of 1.2 seconds makes this component ideal for continuous measurements. It is important that the thermistor makes good contact with the body. This sensor was not used for the final prototype..

Figure 4.12: NTC thermistor

MLX90614 Infrared sensor

The MLX90614 is a contactless infrared sensor which detects the temperature by absorbing the emitted IR waves (Figure 4.13). It is able to accurately measure between -70 to 380 C. The 90-degree Field Of View (FOV) makes it easy to calculate the average temperature. This sensor is more expensive and larger in size compared with the 10k thermistor. The MLX90614 sensor has different types with smaller FOV , such as the MLX90614

Figure 4.13: MLX90614

Multiplexer

When two identical sensors are used with fixed I2C address, a multiplexer must used to command each sensor separately. TCA9548A is a multiplexer with eight sets of multiplexed pins (Figure 4.14). In other words, eight I2C devices can be connected with the use of this component.

Figure 4.14: Multiplexer TCA9548A

Microcontroller

Arduino Mega 2560 Rev3 is a microcontroller with 54 digital I/O pins and 16 analog inputs (Figure 4.15). It has more flash and RAM memory compared to Arduino Uno. Therefore, it is more suitable for more complex projects.

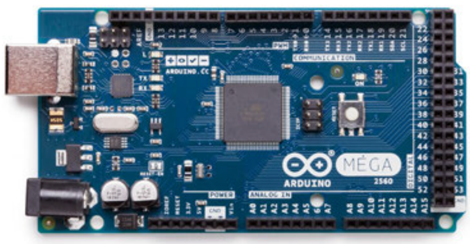


Figure 4.15: Arduino Mega

05 Position Sensors

This section is to research the best possible positions to place the sensors on the auricle based on ear anatomy.

Vascular supply

In general, one's auricle (external ear) does not significantly differ from one another in terms of thickness, regardless of background, age, sex and most importantly, body mass index. It consists of an elastic cartilage surface, except the lobe, that is covered with a thin layer of skin. The auricle is supplied through branches of the superficial temporal artery anteriorly and posterior auricular artery posteriorly (Shiffman, 2013). The superficial temporal artery has three main branches that goes toward the auricle: inferior, medial and anterosuperior auricular artery. The posterior auricular artery supplies the posterior part of the auricle. This artery is a branch of the external carotid artery. The main branches are: inferior, medial and posterosuperior auricular artery (Figure 4.16). The location of these arteries in the ear determines the placement of the sensors.

Position pulse oximeter sensors

The position of the sensor is very important to have a high signal-to-noise Ratio (SNR). This means that the level of the desired signal is strong compared to the noise, for instance, motion artifacts. Therefore, the sensors must be placed correctly on the posterior part of the auricle. It was decided to place the sensor on the middle and upper part of the auricle, assuming that the sensor will measure medial and posterosuperior auricular artery respectively. It was tested with the pulse oximeter sensor MAX30105 from Sparkfun and data were visualized with Labview. Since the sensor is really sensitive to movement and pressure, it was attached on a piece of foam first (Figure 4.17).

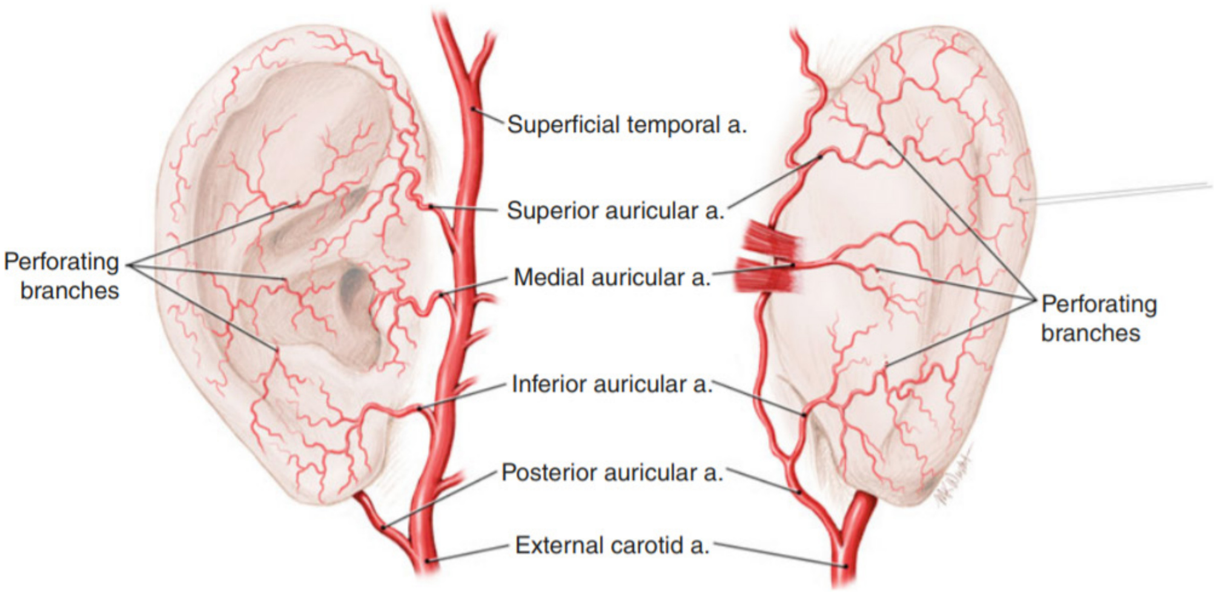


Figure 4.16: Vascular supply of the ear

Signal strength

As can be seen in Figure 4.19, the heart beats are clearly visible when the sensor is placed on the middle part of the auricular (Figure 4.18). The time difference between two peaks shows the interbeat interval (IBI) in milliseconds. This value can be used to calculate the beats per minute (BPM) by multiplying it by 60.

When the sensor is placed on the upper part of the auricular (Figure 4 20), the peaks are still visible, however, the amplitude of the signal is lower (Figure 4.21). There could be a few reasons for this difference, such as, the pressure on the sensor and the position of the sensor on the ear.

Another difference in both graphs is the amount of beats. It can be concluded that the heart rate was higher in figure X in comparison to figure X.

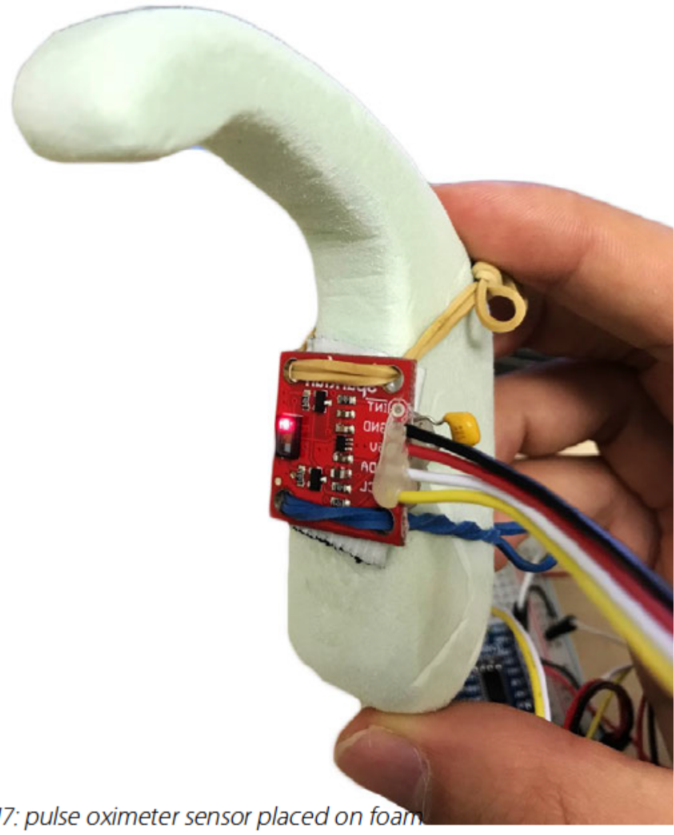


Figure 4.17: pulse oximeter sensor placed on foam

Figure 4.18: Sensor placed on the middle part of the posterior auricle

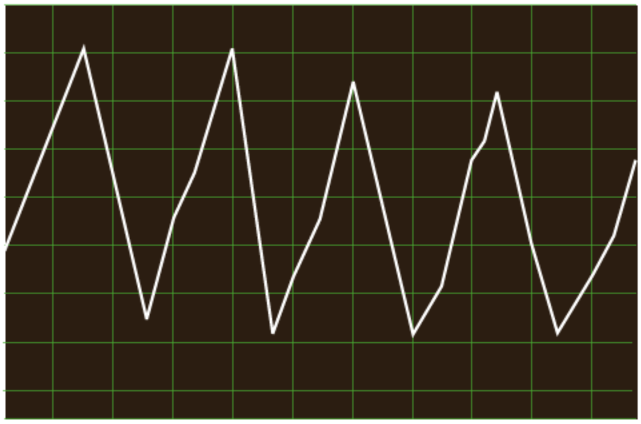


Figure 4.19: Signal strength of the middle part

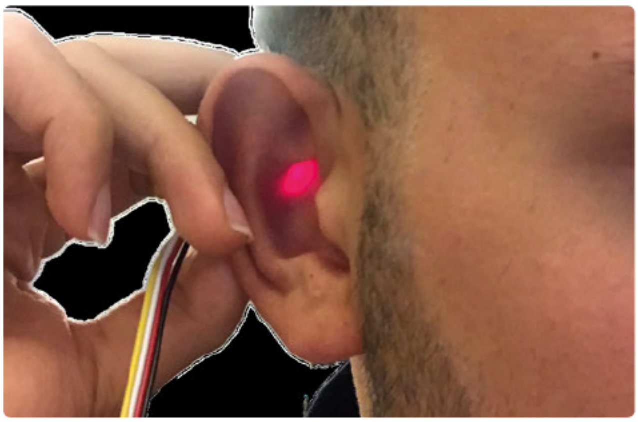


Figure 4.20: Sensor placed on the upper part of the posterior auricle

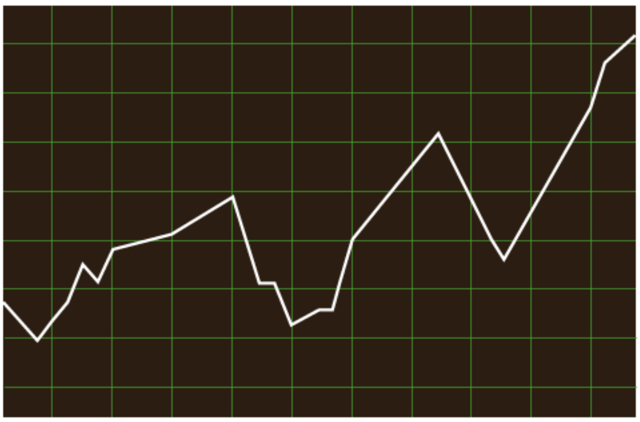


Figure 4 21: Signal strength of the upper part

Two pulse oximeter sensors

Two pulse oximeter sensors were tested at the same time (Figure 4.22). Although, the size of the breakout board limited the placement of the sensors on the foam, it was possible to get signals from the auricle. The numbers on the photo corresponds with the signals (Figure 4.23 and Figure 4.24). It can be seen that signal 2 has more noise compared to signal 1. This may be due to the placement of the sensors. In this phase, no particular filter was used to filter out the noise from the signals.

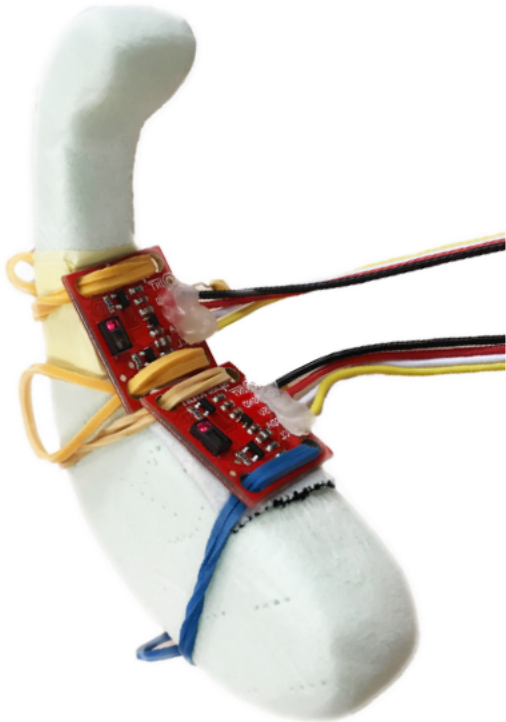


Figure 4.22: Both sensors attached on the foam

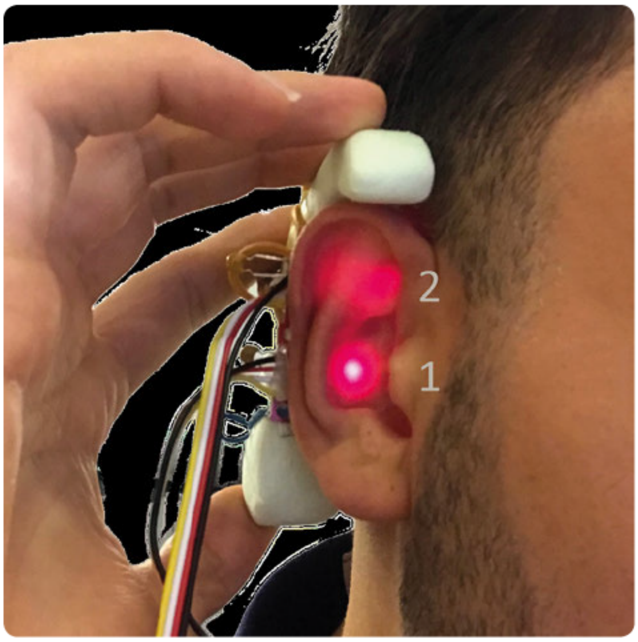


Figure 4.23: foam model held on the auricle

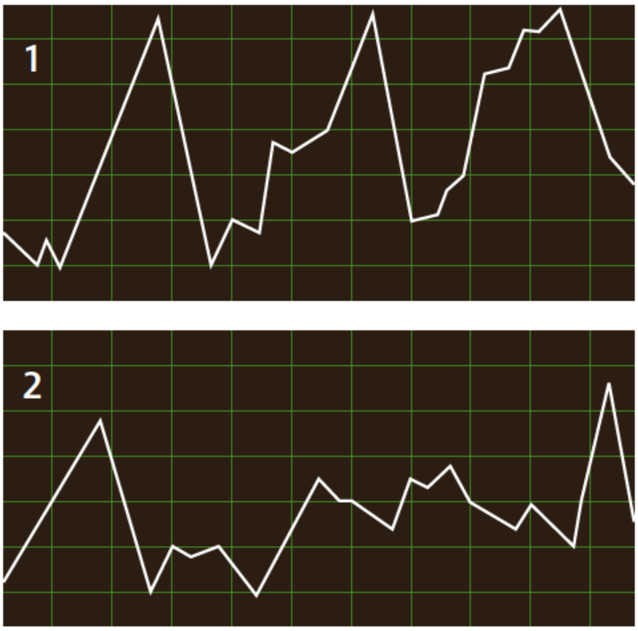
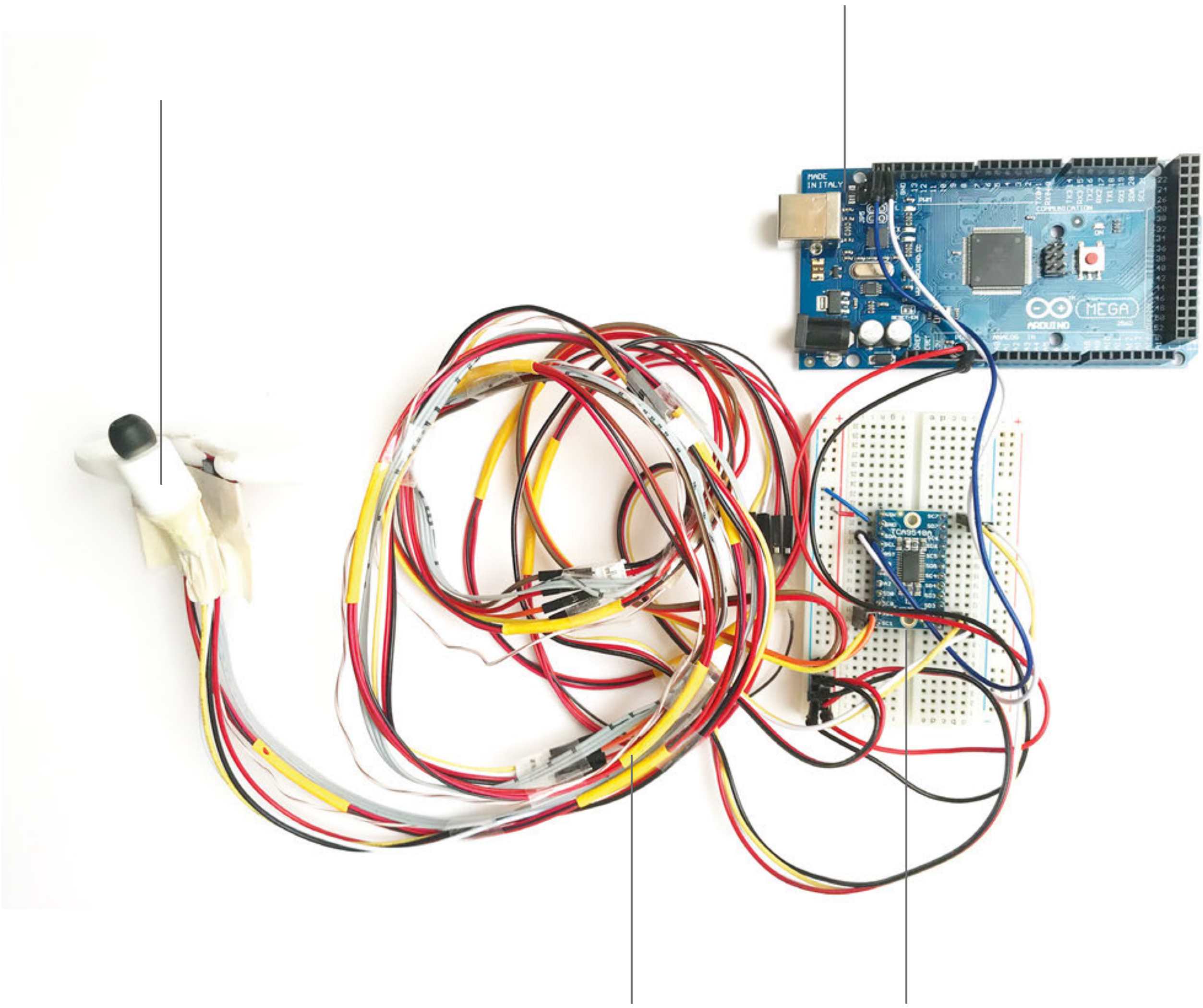
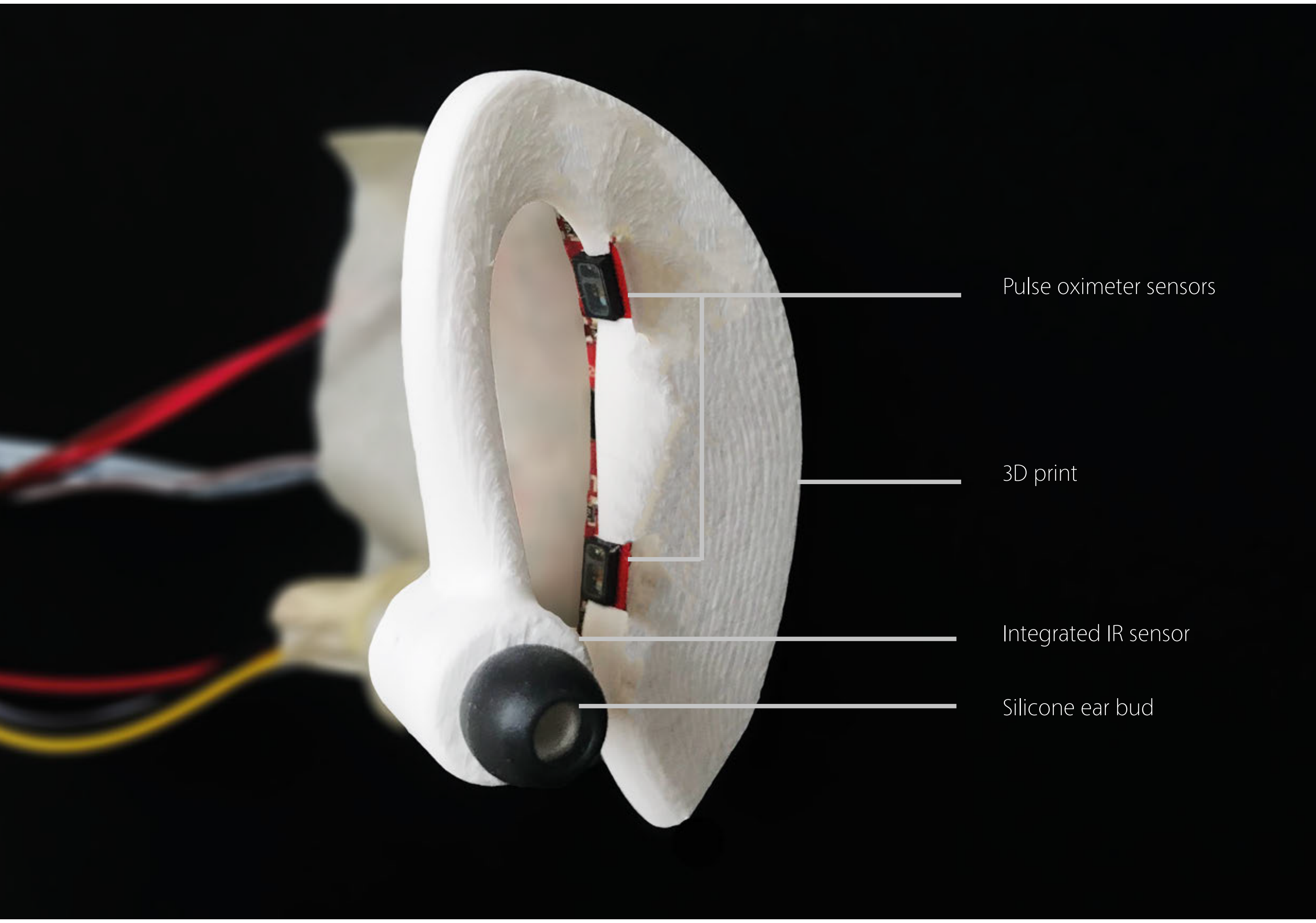


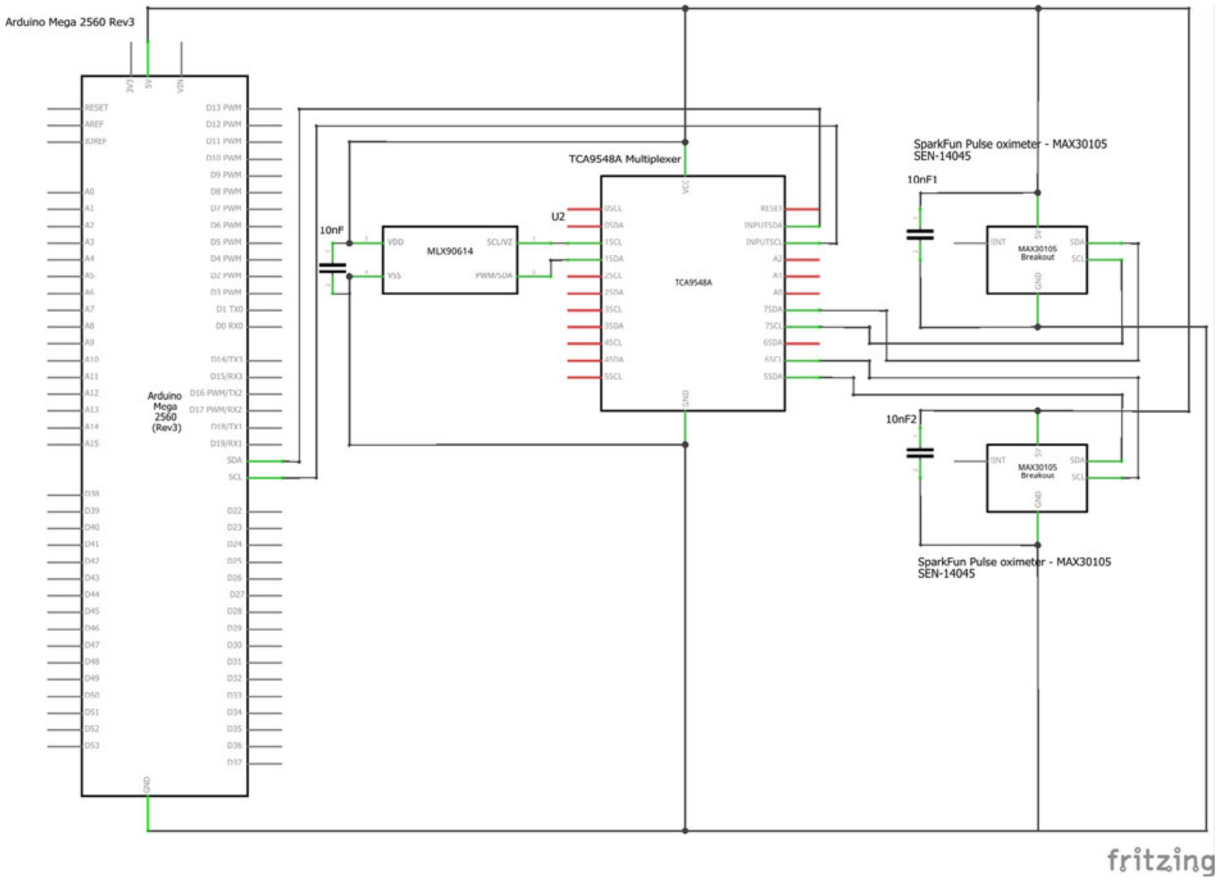
Figure 4.24: Both signals visualized with Labview

06 Final Prototype




Pulse oximeter sensors
3D print
Integrated IR sensor
Silicone ear bud

07 Electric Circuit



08 Data Visualization

All relevant data were visualized in real-time with the use of both softwares: Arduino and Labview (Appendic C and D).

Arduino and Labview

After programming with the open-source prototyping platformm, Arduino, it was possible to obtain relevant data from the sensors (Figure 4.25). Another software platform, Labview, was used in order to, 1) process signals to receive all vital signs in real-time with graphs as well as absolute values, 2) use functions to obtain more reliable measurements and, 3) use filters, if necessary, to eliminate false measurements. Eventually, the following data were visualized: heart rate, blood oxygen level, tympanic temperature, IR signals from both sensors, respiration rate, pulse wave velocity, and the MEWS based on HR.

Heart rate

The pulse oximeter sensor MAX30105 has a wide range of available algorithms to measure different values, such as heart rate (BPM), blood oxygen level and values from all integrated sensors. However, the algorithm to measure the heart rate was not reliable. Therefore, the IR signal was used to calculate the heart rate based on the peak detection function in Labview. This method gives a more reliable and stable measurement. As shown in Figure 4.26, the heart rate was expressed in absolute values. These values were also used to create a graph.

Blood oxygen level

As described in Chapter 2, blood oxygen level can be measured by combining red LED, IR sensor and a photodiode. As shown in Figure 4.27, the blood oxygen level was expressed in absolute values and used to create a graph. The algorithm used in the Arduino code was not sufficient to create fully reliable measurements. For instance, a blood oxygen level of 85% is not realistic for a healthy and fit person. This problem can be solved by using advanced algorithms and filters to eliminate these false postiives.

Tympanic temperature

The tympanic temperature was expressed in absolute values. These values were also used to create a graph (Figure 4.28). It can take some time before the sensor is in thermal equilibrium. This is important for reliable and accurate measurements. MLX90614 with 90 degrees Field of View (FOV) was used for the prototype. Due to the wide FOV, the temperature is rather low. There are other types with smaller FOV, such as MLX90614DCI and MLX90614CDH. These infrared sensors have medical grade accuracy and a FOV of 5 and 12 degrees, respectively.

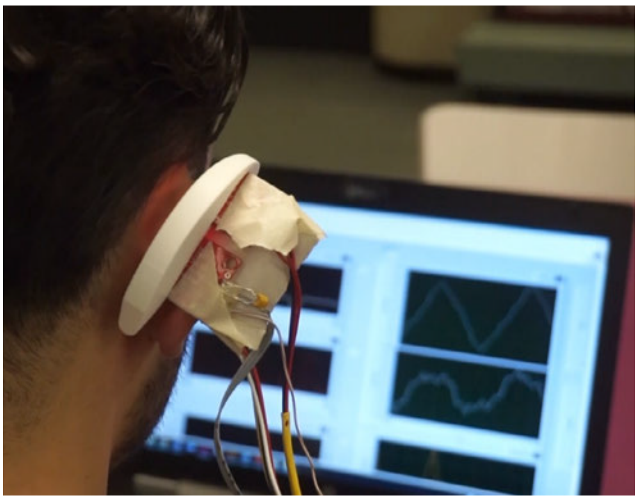


Figure 4.25: Visualizing data from the sensors, using Labview

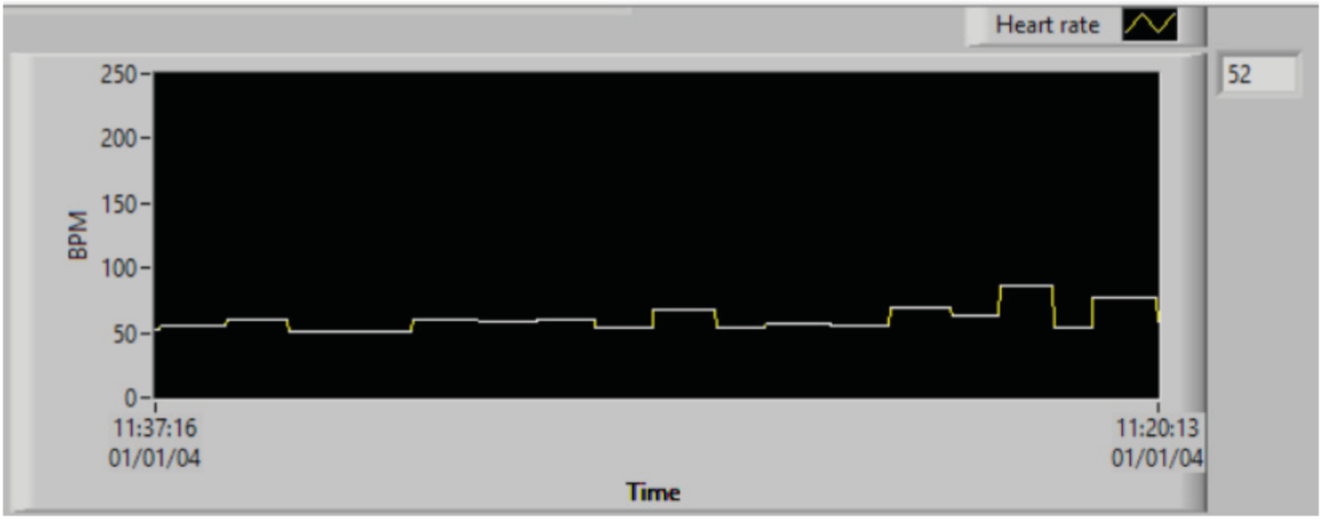


Figure 4 26: Heart rate graph with absolute values based on IR signal peaks

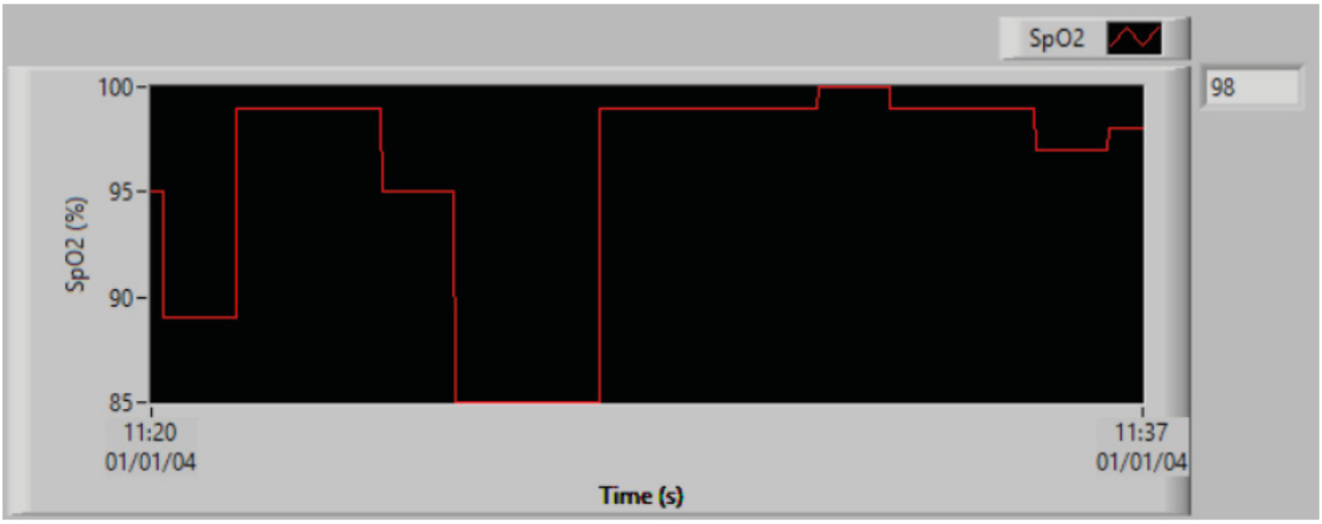


Figure 4 27: Blood oxygen level graph with absolute values

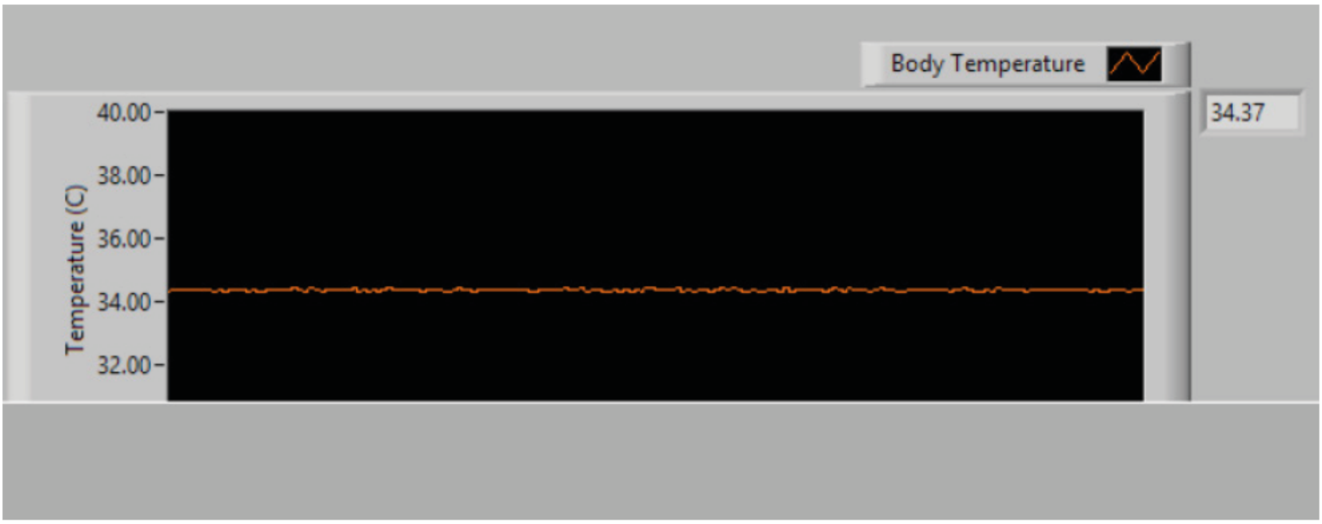


Figure 4.28: Body temperature graph with absolute values

Respiration rate

The respiration rate measurement was based on Respiratory-induced Frequency Variations (RIFV) method (see Chapter 2). As shown in Figure 4.29, the decreasing trend shows the inhalation and the increasing trend show the exhalation. When peak detection function is applied, breaths per minute can be calculated and used to assess patients' health condition. The measurement of the respiration rate can be more robuust when this method is combined with both RIIV and RIAV (see Chapter 2).

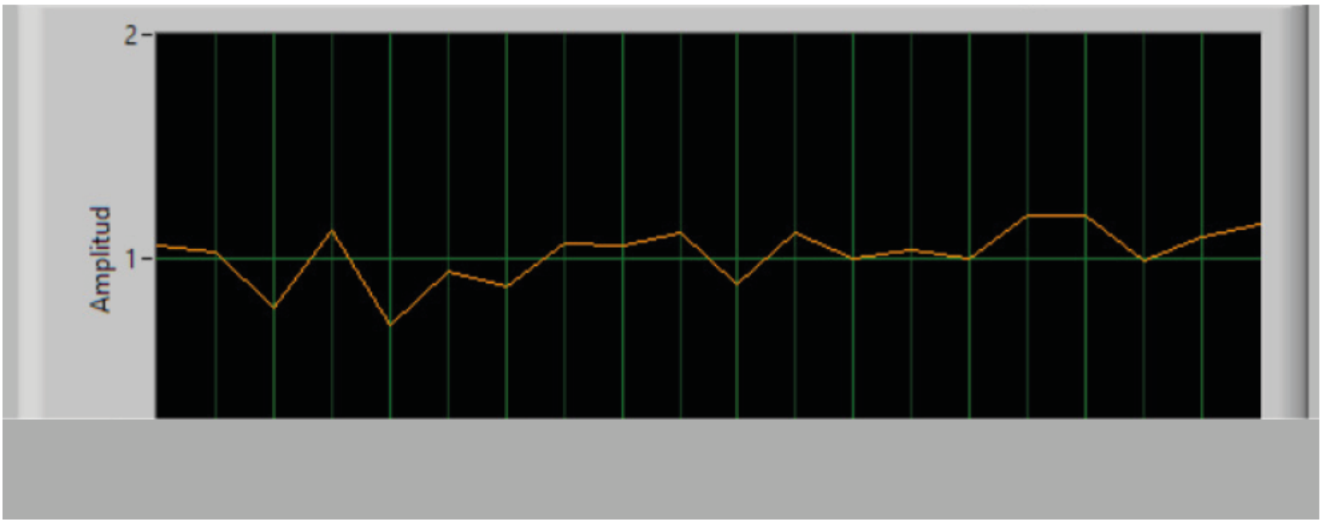


Figure 4.29: Respiration graph

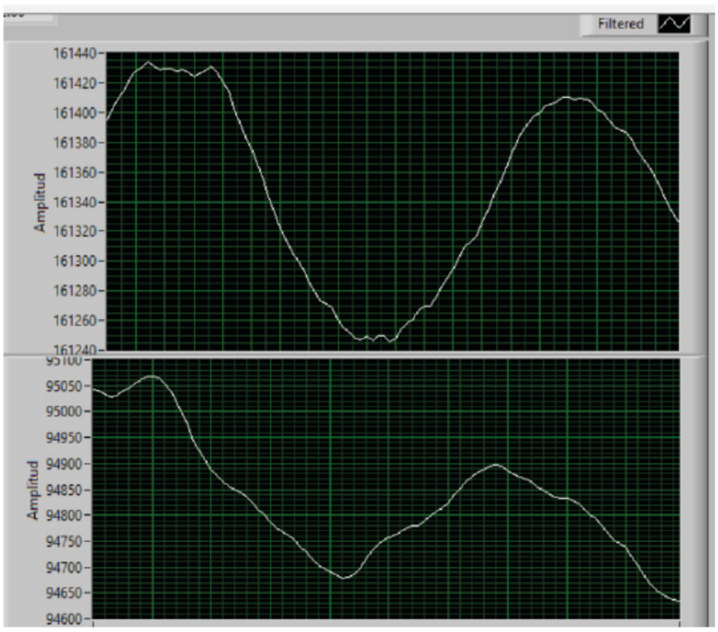


Figure 4.30: IR signals of both sensors

PWV

PWV was determined by using the distance between both pulse oximeter sensors and time difference between two succesive IR peaks. It is convenient to use the peaks of these IR signals as a reference (Figure 4 30). Eventually, the PWV values were used to create a graph (Figure 4 31).

MEWS

MEWS was expressed in absolute values. These values were used to create a trend. If vital signs are measured over a longer period of time, medical staff can asses patients' health condition based on changes in trend. In this case, MEWS graph is only based on heart rate due to its stability (Figure 4 32).

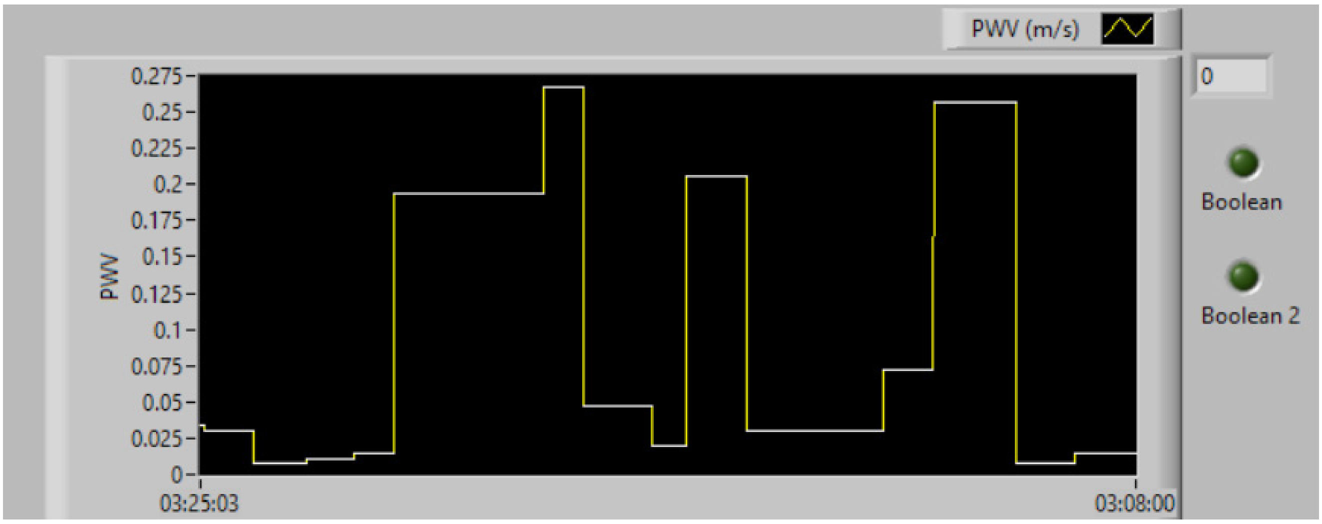


Figure 4.31: Pulse Wave Velocity graph

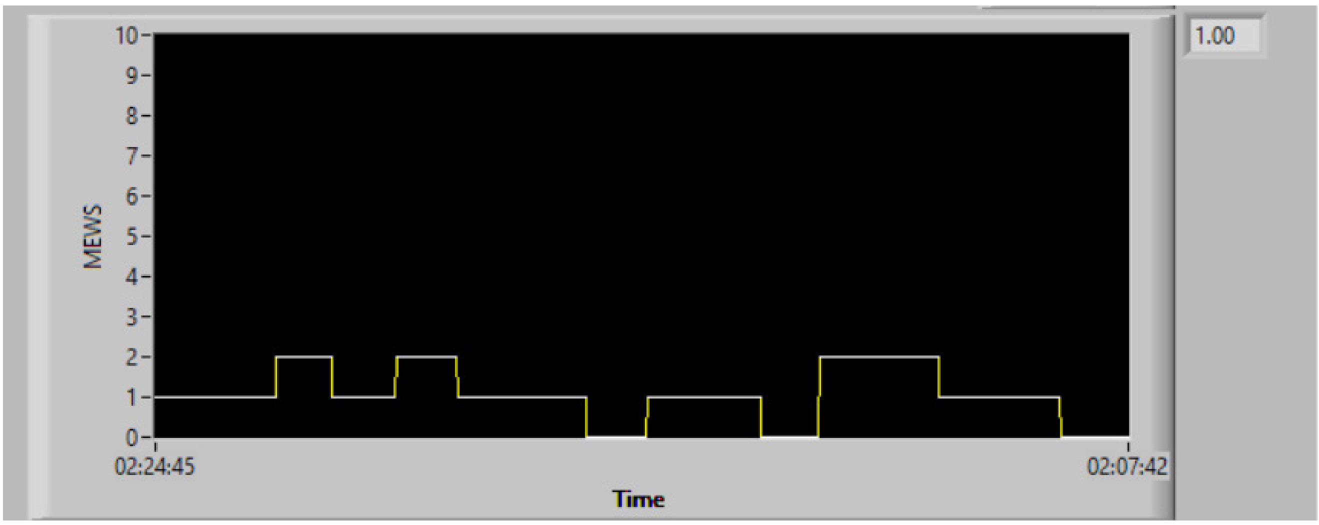


Figure 4.32: MEWS graph based on heart rate

Execution.

5 Final Proposal

This chapter presents the final proposal together with the moodboards, final design, product detailing, dimensions and cost estimation.

01 Moodboards

Moodboards were used as an inspiration source for the final design. In order to design a wearable that expresses certain qualities, such as safety, reliability and simplicity, certain colors, shapes and materials were taken into account while designing the wearable.

Collage existing wearables devices

Moodboard color and shape

Moodboard color and shape

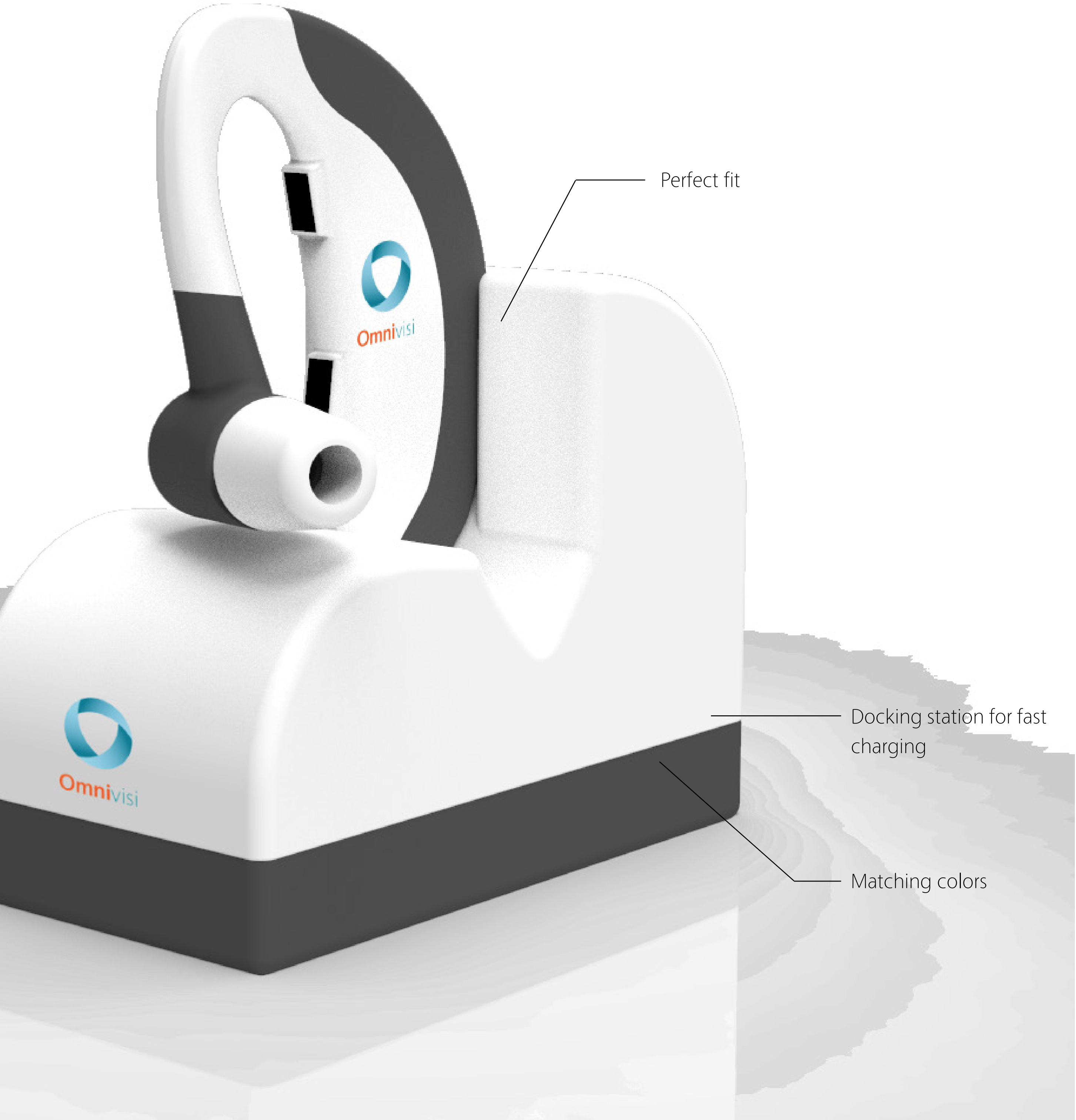
02 Omnivisi Earable

After doing extensive research and iterative processes, a final design is created: Omnivisi Earable. A unique wearable device that can measure all vital signs.

Final design

The compact and wireless design enables patients to perform their daily activities without being limited. Since patients can freely move within the hospital, it will also speed up their recovery process and decrease the hospitalization period. Additionally, the product is designed to be user-friendly for nurses, meaning their actions are simple, fast and minimal when they install the product. There is no need for wires or multiple modules that have to be placed on patients' body.

Omnivisi


Omnivisi
Omnivisi
Perfect fit
Docking station for fast charging
Matching colors


Omnivisi
8

Omnivisi
Charging points


Omnivisi

03 Aesthetics And Material

Form and color

The form of the final design is a combination of organic and non-organic shapes. The fine edges of the design give the design a modern look. It is also important to create consistency in the final design in order to express the desired qualities, such as simplicity and reliability. In order to make the design more robust and prevent accumulation of dirt, the Omnivisi Earable does not have unnecessary gaps or holes. This will make the sterilizing process also easier for nurses. It is also important to have as little parting lines as possible to prevent accumulation of bacteria, increase robustness and maintain smooth surfaces.

The chosen colors give the final design a clean and reliable look. The white and dark grey color are neutral colors and suitable for both men and women. This color combination is usually used for medical products as well.

Material selection

The housing of Omnivisi Earable consists of two different materials: 1) Medical grade silicone rubber (white middle part) 2) ABS (dark grey parts). Silicone is known for its great properties, including high biocompatibility, temperature and chemical resistance, mechanical and electrical properties (Medical Device & Diagnostic Industry, 1999). Silicone is far superior compared to other polymers. It often complies with standards, such as ISO and FDA. Due to possible long term use of the Omnivisi Earable, it must be highly compatible with human tissue. Silicone meets this very important criteria. Another important material property is that silicone does not support bacterial growth. Since the wearable device will be used within the hospital, bacterial growth or cross-contamination must be prevented.

Silicones can withstand a wide range of temperature and resist liquids, including water, acids, ammonia, oxidizing chemicals and isopropyl alcohol. This is important when the product is being sterilized after use by nurses.

Silicone also has high tear, tensile strength and flexibility. The white part must be strong and flexible to provide convenience when users put and remove the wearable device. Lastly, it has insulating properties, meaning that it is non-conductive (Medical Device & Diagnostic Industry, 1999). This is very important because electronic components are integrated into the product.

The grey parts are made of ABS. This material provides a great balance of several properties, including impact resistance, biocompatibility, excellent surface quality, temperature and chemical resistance and durability (Elix Polymers, n.d.). The main reason to choose ABS for the grey parts is to increase the level of robustness of the product and give it an excellent finishing touch.

04 Main Components

Sensors

The final design has four integrated sensors. The two PPG sensors (Figure 5.1) are able to monitor: heart rate, blood oxygen level, respiration rate and PWV. The infrared sensor is able to monitor the tympanic temperature (Figure 5.2). Lastly, the 3-axis accelerometer is able to count the steps of patients (Figure 5 3). By doing so, nurses have a better insight into their recovery process and can encourage them to wa k more often.

Figure 5.1: PPG sensors

Figure 5.2: IR sensor

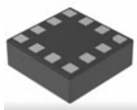


Figure 5.3: 3-axis accelerometer

Microcontroller

The final product has a microcontroller, Blue Gecko BGM13S, with an integrated memory, antenna and Bluetooth 5.1 (Figure 5.4). The latest Bluetooth communicaton protocol enables to track the Earable and reduce the amount of Bridges. It has an integrated memory to save the data for hours when connection is lost.

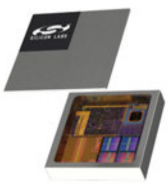


Figure 5.4: Microcontroller

Battery

LiPo batteries are rechargeable, flexible, cheap, lightweight and customizable (Figure 5 5). In order to charge the battery the charging points, it must be placed on the pins that are integrated in the docking

Figure 5.5: Customized LiPo battery

station.

Disposable ear buds and ear hooks

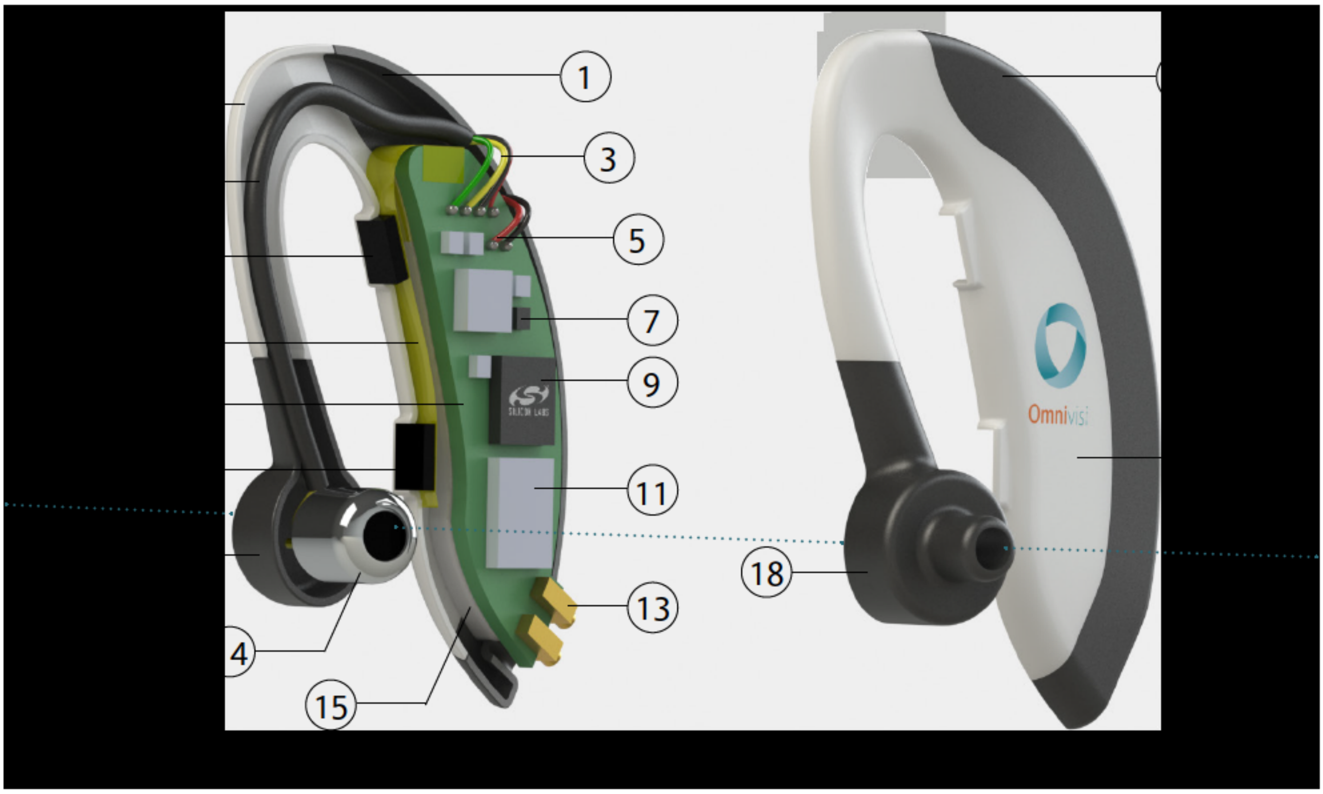
Disposable silicone ear buds and ear hooks were chosen (Figure 5.6 and Figure 5.7). Both parts are cheap, lightweight and available in different sizes. The main reasons for using these parts are to increase the level of comfort and fit and to prevent cross-contamination. Medical grade silicone is also known for its biocompatibility.

Figure 5.6: Silicone ear buds

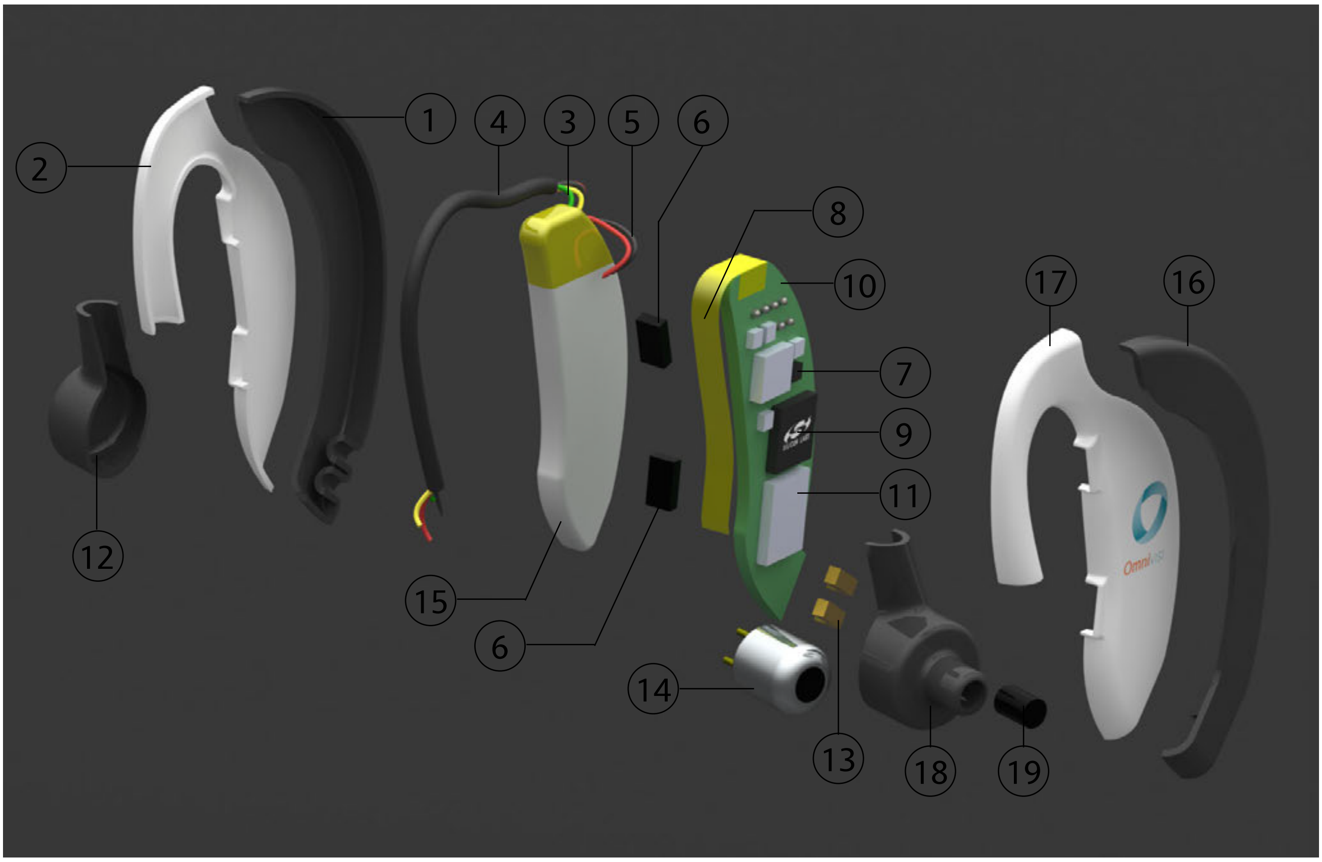
Figure 5.7: Silicone ear hooks

05 Product Detailing

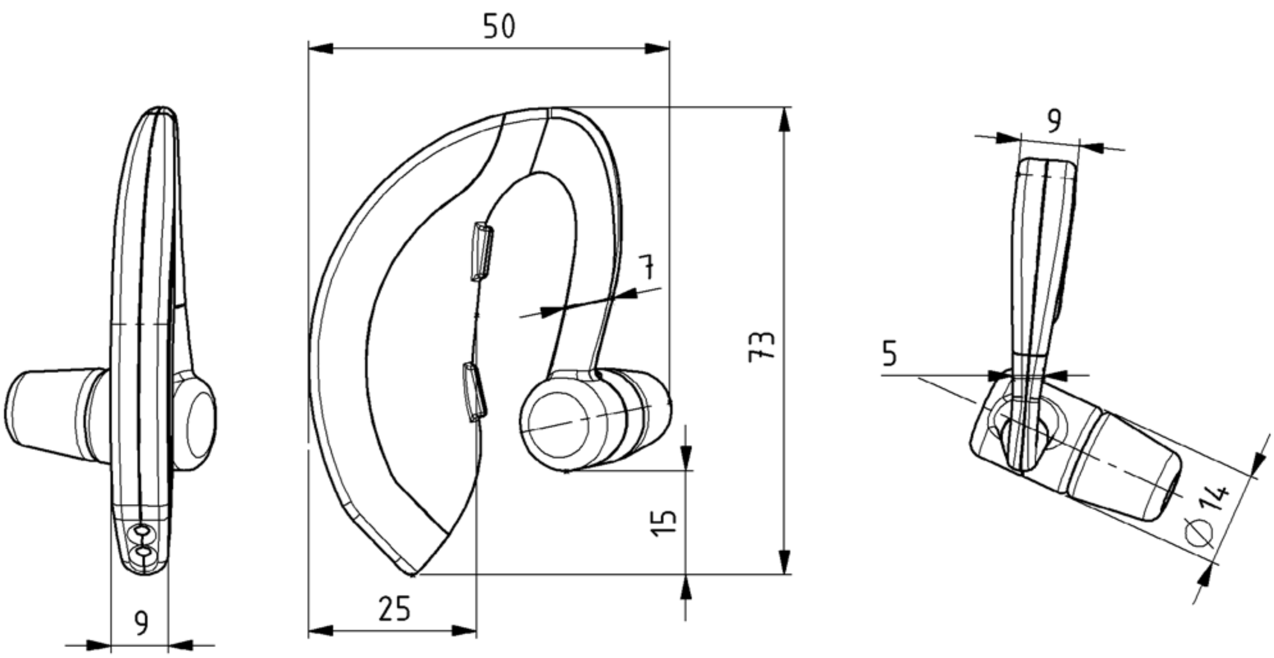
This section presents an exploded view of the product including the parts and the dimensions of the average model.



1. Casing back side ABS (left)
2. Casing silicone (left)
3. Wires for IR sensor
4. Extra isolation for wires
5. Wires of battery
6. MAX30105 PPG sensor
7. 3-axis accelerometer
8. Flexible PCB
9. BGM13S microcontroller, Bluetooth 5.1
10. PCB
11. LiPo protection and charging circuit
12. Casing IR sensor ABS (left)
13. Charging points
14. MLX90614 IR sensor
15. LiPo battery
16. Casing back side ABS (right)
17. Casing silicone (right)
18. Casing IR sensor ABS (right)
19. Glass protection IR sensor



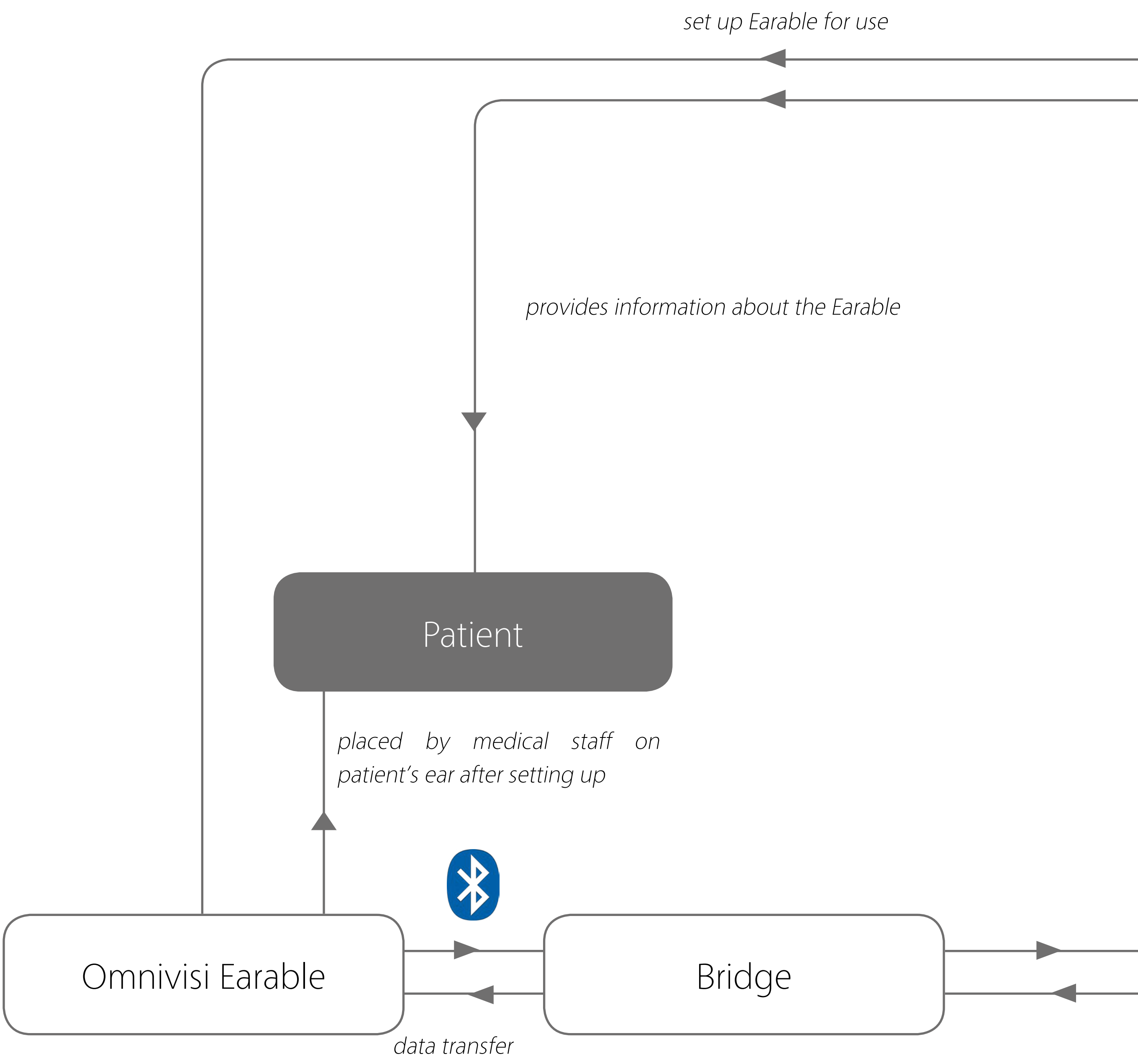
Dimensions

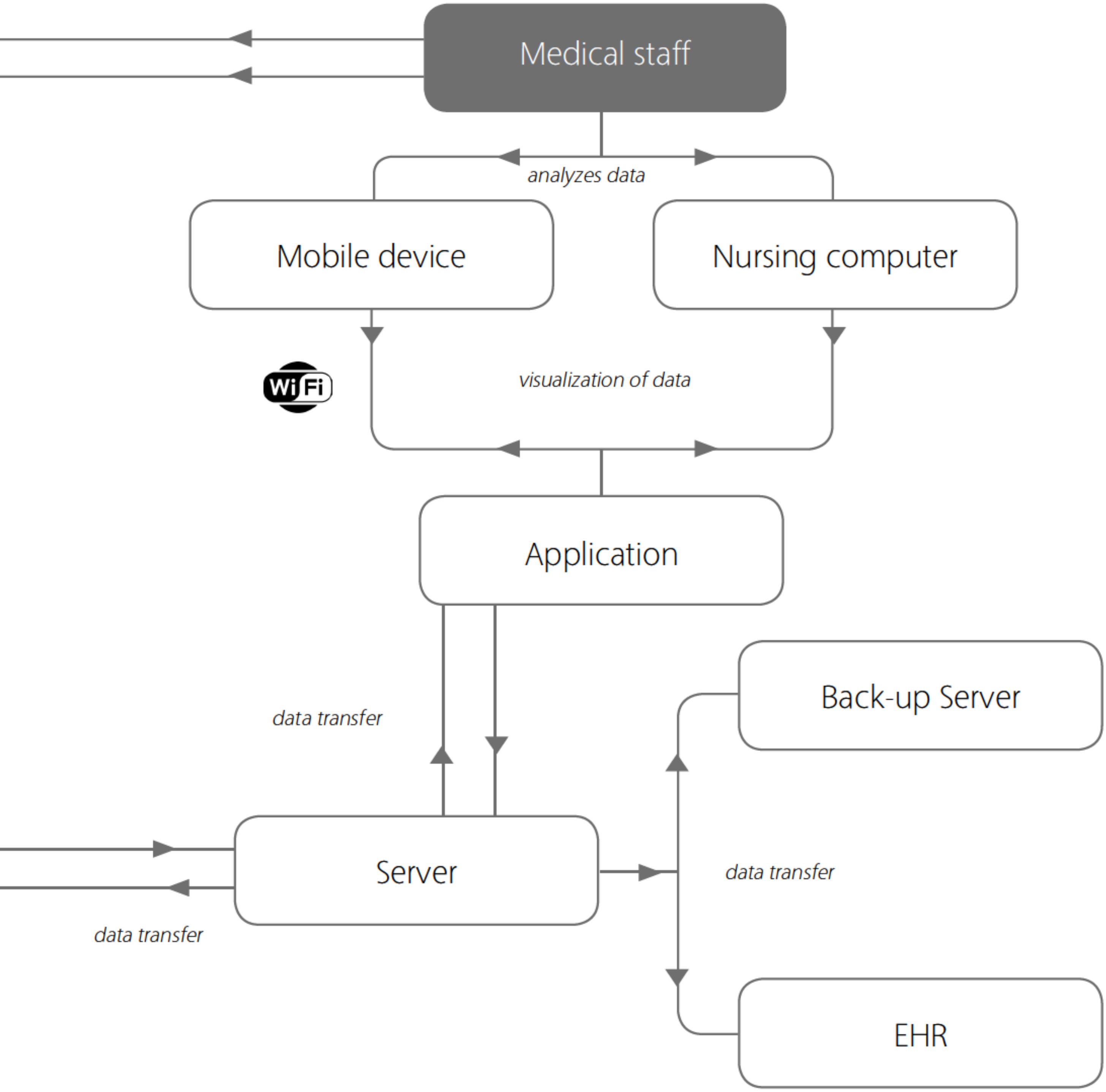


Back view *Right view* *Top view*

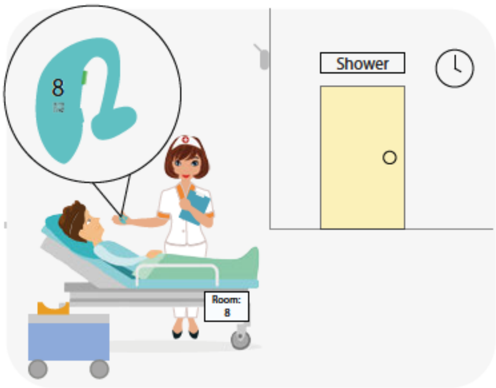
06 Product-User Ecology

Omnivisi Earable is a part of a bigger system. This system consists of multiple devices and services that will ensure safe data transmission. The closed loop will prevent unauthorized people from intruding or changing personal data of patients. Patients and medical staff are both users of this system.

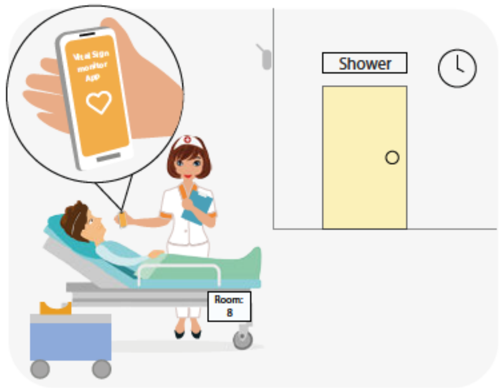



Medical staff
analyzes data
Mobile device
Nursing computer
visualization of data
Application
data transfer
Back-up Server
Server
data transfer
data transfer
EHR

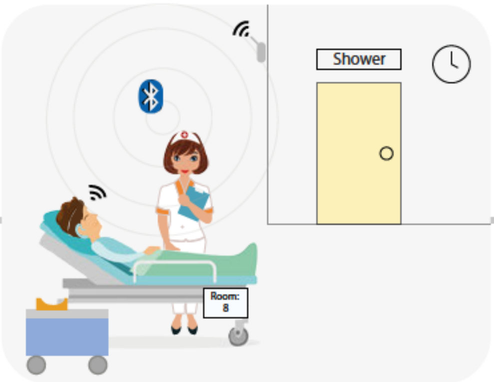
07 Storyboard



1) The nurse picks the Earable with the corresponding room number from the docking station. Earable automatically turns on.

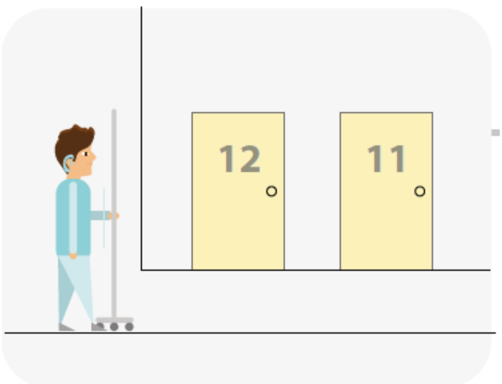


2) The nurse activates the application on the mobile device.

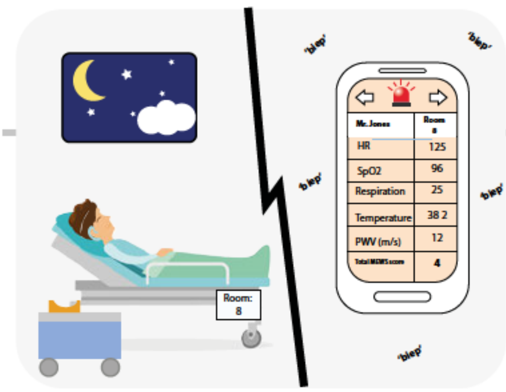


5) The Earable is energy-efficient due to the Bluetooth connection with the Bridge.

6) The Bridge is able to transfer the data from the Earable to the mobile device by using both Bluetooth and WiFi.

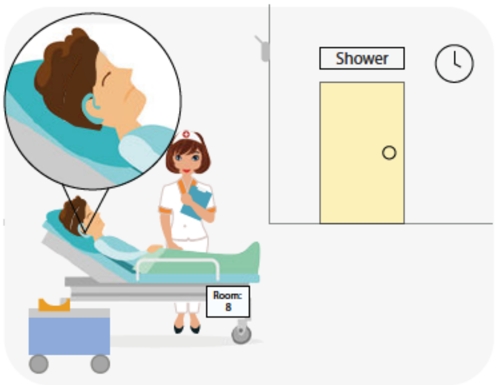


9) Earable supports mobility for quick recovery due to its compact form and lack of wires. The data is saved on the integrated memory of the Earable.

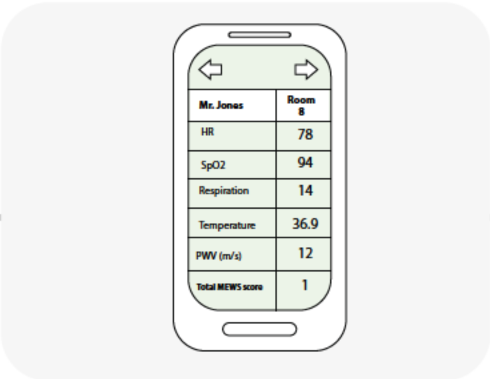


10) When the total MEWS score is more than 3 and when there is an abnormal increasing and decreasing trend, the mobile device alarms the nurse.

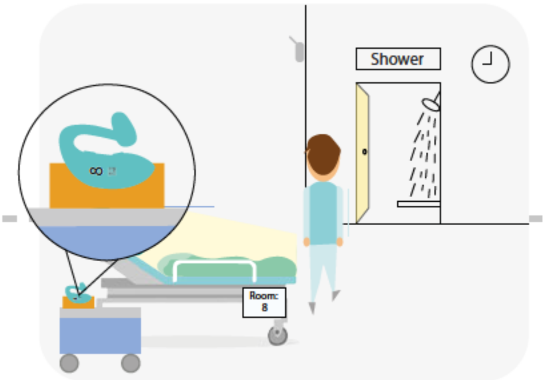
3) The QR code on the Earable should be scanned to link the patient to the Earable.



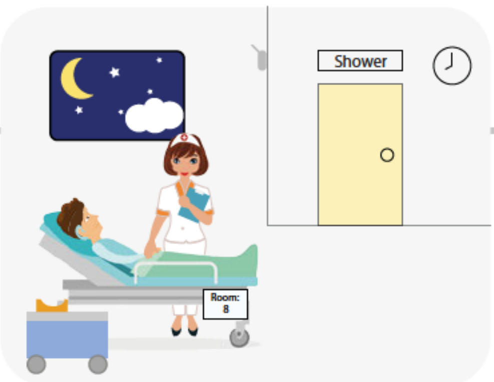
4) After installing the Earable, the vital signs are continuously measured.



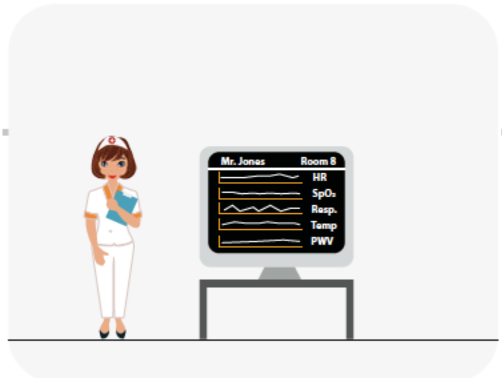
7) The nurse is able to see the vital signs on the mobile device with the total MEWS score.



8) The patient can easily take the Earable off before showering without help.



11) The nurse can intervene before the patient's health state worsens.



12) The patient's vital signs can be analyzed in more detail with the use of a computer.

08 Cost Estimation

This section presents a matrix with wearables with similar functions intended to be used within the hospital or for fitness tracking. The aim is not to exceed the price of the competitors. In order to roughly estimate the cost-price of the final design, a diagram was made presenting the main components.

Competitors

The wearable must have a reasonable and competitive price when it is introduced in the healthcare market. Currently, there are ear devices in the market or still in development that are able to measure vital signs of athletes and patients. Most of these devices use optical sensors, temperature sensors and accelerometer to measure: heart rate, heart rate variability, blood oxygen level, respiration rate and activity. The wearables are connected to the smartphone through Bluetooth. A few examples of these devices are: Philips biosensor, FastFocus, Freewavz, Cosinuss and Ear-clip type PC (Figure 5.8). The aforementioned examples are competitors of the Omnivisi Earable. Therefore, these are placed into a diagram to compare the functions and prices (Diagram 5.9). Unfortunately, not all information could be found regarding their function, price and weight. Based on the available information, the price of the wearable varies between €129 and €219. One must take into account that none of these wearable are medically certified yet.

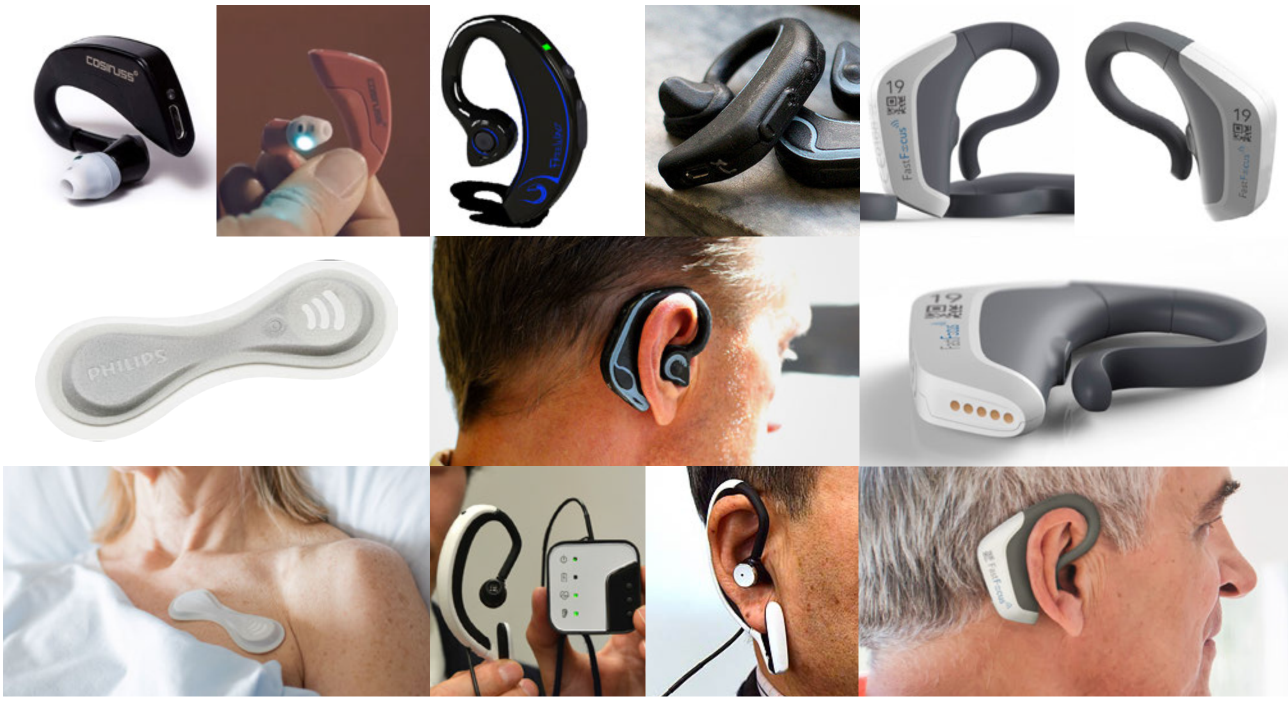


Figure 5.8: Current wearables devices

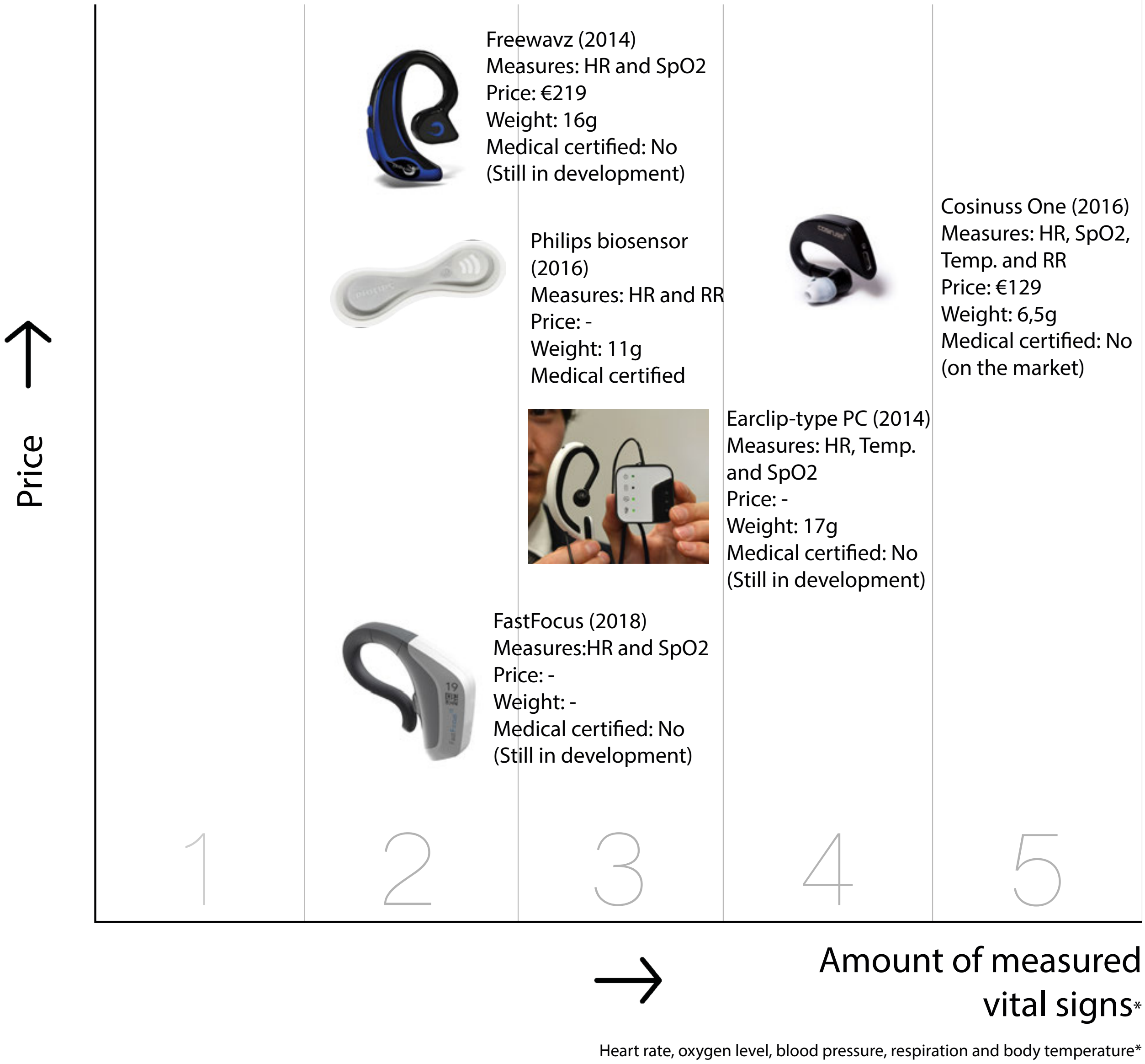


Diagram 5.9: Price vs amount of measured vital signs diagram

Rough cost estimation

The main components were put into a diagram to roughly estimate the price (Diagram 5.10). Depending on the type of battery used and casing, the final product can have a total weight between 16 and 18 grams (Appendix B). The total price of the main components will be €38.87. This value can change depending on the type of sensor and battery. Type MLX90614 has IR sensors with small field of view (FOV) features. The smaller the FOW the more expensive the sensor. IR sensors with FOV could be more reliable when measuring the tympanic temperature but these sensors are more expensive.

A solution for this is to use a lens to converge the IR beam. This can significantly reduce the total price. This lens system must provide reliability and must be cheaper compared to IR sensors with small FOW.

Other expenses, such as material, manufacturing, certification, packaging and distribution were not included. It is known that molds for injection molding can be really expensive, however, if the product is mass produced, the costs per unit is relatively low.

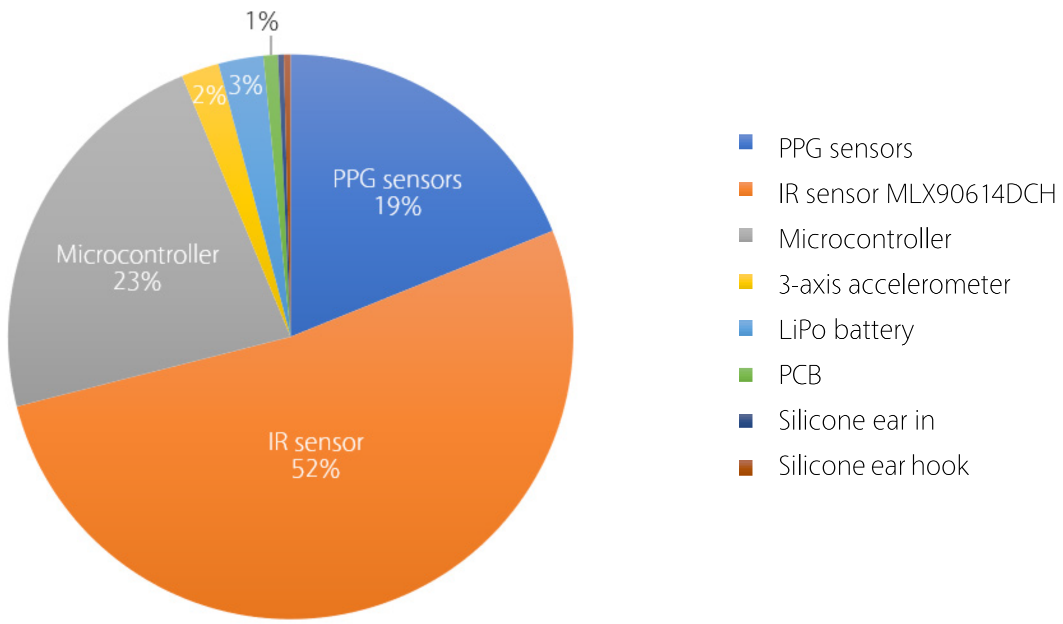


Diagram 5.10: Diagram cost-estimation

6 Evaluation & Recommendation

In this chapter, an overall evaluation, future recommendations and a personal reflection are presented.

01 Evaluation

This section shows an overall evaluation of the design assignment that was described in Chapter 1.

Unique selling points

Omnivisi Earable provides **continuous** and **non-invasive** measurement without limiting patients from performing their daily activities.

Omnivisi Earable is unique in its functionality compared to existing wearable devices. It is able to measure **all vital signs**.

Omnivisi Earable is **user-friendly** due to its **compact** and **wireless** design. Nurses can **easily and quickly** attach the Earable on patients' body without performing too many actions.

Omnivisi Earable is **comfortable** due to its organic form and lightweight.

Omnivisi Earable is **durable** due to its strong material and high impact resistance.

Omnivisi Earable can provide **reliable** and **accurate** measurements from the ear, also from mobile obese patients. This area has sufficient vascular supply for continuous and accurate measurements.

Omnivisi Earable **prevents cross-contamination** by easing the cleaning process for nurses and also by using disposable parts.

Omnivisi Earable **prevents complications** due to its **alarminging function** when it detects patient deterioration. Due to this, high quality of life of patients can be maintained and costs associated with additional research and admission to ICU can be prevented.

Omnivisi Earable provides nurses more insight into the **activity level** of their patients. They can encourage their patients to wa k more often. This will **speed up the recovery process** after surgery.

Design assignment

The design assignment was to explore and generate working principles for a non-invasive wearable that can continuously measure patients' vital signs and alert nurses when the health condition of their patients deteriorates. It was expected to present a proof of principle measuring all five vital signs, ensuring high comfort for patients and user-friendliness for nurses.
As can be seen in Chapter 4 Embodiment, all vital signs were real-time visualized by using multiple sensors. After some improvements, it is expected that the lightweight and compact wearable will provide high comfort for patients and is user-friendly for nurses. This still needs to be tested and validated with real users.

Design vision

*"Designing a reliable wearable for continuous and non-invasive measurement of the vital signs, aiming to **increase work-efficiency**, to **ensure high quality of life of patients**, and to **reduce overall costs**. This wearable provides **comfort for patients** without interrupting their daily activities and it is **user-friendly for nurses**, meaning that the amount of performed actions is minimal."*

In this project, the focus was put on creating a comfortable and user-friendly wearable. Due to limited time and resources, not every design outcome as defined above could be tested. More research is required to find out whether the wearable will increase work-efficiency, reduce overall costs of care and ensure high quality of life of patients. It is expected that nurses will save three hours on a daily basis. This time can be used for personal guidance, contributing to better care. In the following section, several recommendations were given to improve the wearable and its system.

02 Future Recommendations

There are many different aspects of the final design that require more exploration and research. A list was made with recommendations, including sensors, size, algorithms and whole system around it.

Shape and fit
In this project, an average model was created based on 10 scans. More scans of ear models can improve the comfort and fit of the final product to tailor for a larger demographic. The scans must be made from people of different ages and gender. According to Dr. Huysmans, assistant professor Applied Ergonomics and Design, usually 50 scans are needed for this type of applications. After doing this, more user tests must be done to verify the level of comfort and fit.

Left ear
For this project, a wearable was designed for the right ear. It could be interesting if a model is created for the left ear. By doing so, patients who wear a hearing aid for the right ear, do not have to take it off.

Different sizes
In order to provide comfort for users, it is recommended to create at least two sizes of the Earable: an average size and a small size. The average size is intended for people with average and large ear size. The small size is intended for people with small ear size. If the average size is not comfortable for people with large ears, a wearable with large size must be created.

Several PPG sensors
Two PPG sensors were used for the final prototype and final proposal. The level of robustness can increase if more PPG sensors are used (van Velzen et al., 2017). However, the downside is that it requires more power and it increases the cost of the product.

Wireless charging
Wireless charging can be a very convenient method to charge the wearables. However, this method requires additional electronic parts. The wireless charging board can have a low efficiency level compared to traditional charging methods. Due to this, it may take longer time to charge the device.

Alarming
The alarming system is based on MEWS scoring system and detection of increasing and decreasing trend. There is a need for smart algorithm that is able to detect the change in the MEWS and change in trend. In both cases, data must be send to the application to notify or alarm the nurses, depending on the emergency level. Moreover, nurses must be notified when: 1) patients have removed the Earable, 2) sensors are not measuring anymore, 3) Earable is out of range and when patients are outside the surgery department and, 4) low battery. The alarming system must not cause alarm fatigue or false positives and false negatives.

Different LED colors
During the project, red LED light was used to obtain signal from different body sites. However, different wearables devices, such as Fitbit and Apple Watch, use green LED. Therefore, it is recommended to explore with different LED colors, such as yellow, blue, green and infrared, to obtain the most accurate and stable signal from the auricle.

Placement PPG sensors

There are available products, such as Cosinuss One, that place the PPG sensor in the ear to measure the heart and blood oxygen level. Due to a limited number of available sensors in this project, it was not possible to explore this. It could be interesting to place one of the sensors inside the ear and test whether this is a comfortable and reliable place to obtain signals. Furthermore, there are other areas on the ear and around the ear where strong signals can be obtained, such as the tragus or on the exernal ear. More research must be done to find this out.

Infrared sensor

Depending on the type of infrared sensor, a lens that converges infrared radiation to one point may be neccessary. The MLX90615 has a wide range field of view compared to MLX90614. Therefore, an extra lens may be needed for the MLX 90615. The infrared sensor MLX90614 does not need an extra lens due to its small field of view feature. Extra research is also needed to correctly point the sensor towards the ear drum and also notify sensors when this is not the case.

Signal processing

During the project, a great amount of time was spent on signal processing to filter out the needed information from the signals. There are still many factors to improve the reliability and accuracy of the signals, such as amplifying signals from sensors, applying filters to eliminate noise and ambient light, and to reduce both false positives and false negatives. There are experts in the field of signal processing who can improve this.

Power efficiency with algorithms

The product will continuously measure patients' vital signs. Therefore, power efficiency is very important. Although Bluetooth is known for its energy-efficient communication protocol, smart algorithms can improve efficiency even more. The most battery power is lost with data transmission, therefore, it is recommended to reduce the amount of data transmissions per hour. The wearable can also calculate the average measurements per minute after 10 seconds of measuring and turn to standby instead of continuously measuring.

Secure data transmission

There must be a secure data transmission between the wearable and the Bridge as well as between the Bridge and server. There are different communication protocols for patient data transmission. Health Level 7 is a known international standard and can be sufficient for hospital-use.

PWV validation

There must be a coordinated clinical study to validate PWV as a parameter to indirectly measure the blood pressure. It would be even more interesting if PWV values can be converted into absolute SBP and DBP blood pressure values. There are still many studies going on to validate this.

PWV and blood loss

Research has shown that PTT can be a useful indication for the detection of blood loss. However, there are no papers found that shows the relationship between PWV and blood loss. It is known that PWV and PTT are inversely related to each other. Therefore, there should be another study to verify the relationship between PWV and blood loss and validate this for clinical use.

Application

The application used by nurses must be user-friendly and easy to use, meaning that nurses are not overloaded with information and the system is not too complex. Nurses must not perform many actions to get the information they want. Additionally, only the most relevant information must be displayed. More research is needed to design an intuitive and user-friendly application for nurses.

Mobile device

A mobile device is required to get notifications and alarms from the Earable. Ascom Myco 2 has the needed specifications and has the potential to be used within the hospital by nurses. More research must be done on its compatibility and ease of use within the context.

The Bridge

It must be researched how many Bridges it is required for all patients in the department. There is a high possibility to decrease the amount of Bridges due to longer range of Bluetooth 5.1 compared to previous versions of Bluetooth. It must be researched whether it is possible to link multiple patients to one Bridge.

3D model optimization

The CAD model must be optimized to create a more organic form similar to the average model in Chapter 4 "Iterations". Additionally, the model must be enhanced for mass production. A possible production method is injection molding.

Docking station

There must be a docking station that can quickly and safely charge the wearables. This docking station must be made from a tough and impact resistant material to protect the integrated electronic circuit. The color and form of the docking station should be in line with the design of the wearable. Lastly, it must comply with the hospital standards and regulations.

Customized PCB and electronics

In order to create a compact wearable, the PCB and electronic components must be customized and assembled. This highly complex process requires expertise from different fields, including electrical engineers, sensor developers and researchers.

Data Flow

It is important to create a data flow diagram between user and components of the system. By doing so, there will be a clear overview of the processes within the system and a logical flow of data between different parts. In this case there will be a data flow between the wearable device, the Bridge, the Server, mobile device, and EPD.

Instruction manual

An instruction manual with illustrations would make it easier to understand for nurses and patients. Therefore, it is highly recommended to create one before a pilot study is conducted.

Pilot study

After developing this product further, it can be tested with real patients and nurses by executing a pilot study. Furthermore, it must be researched whether the wearable increases work-efficiency, reduces cost of care, enables early intervention and prevents complications. One must take into account that before the product can be introduced into the market, it must be researched and clinically validated on several aspects, including sensors, material, safety and possible adverse effects.

Potential for home-use

The Earable may have potential for home-use, therefore, more research is required regarding the use of this type of wearable by elderly and other patients. Continuous monitoring of elderly outside the hospital has many benefits, such as: reducing cost of care, enabling early intervention and encouraging elderly independence.

03 Personal Reflection

Before I started with this project, I had defined some goals for myself, such as improving my prototyping and programming skills, enhancing my visualization skills and acquiring an in-depth knowledge in the field of medical design. Throughout the process, I used different tools and methods to achieve these goals, such as programming with Arduino and Labview, making sketches with Sketchbook, and analyzing many medical related articles. After conducting interviews with patients, nurses, surgeons and technical experts, new valuable insights were gained that helped me to steer the project to the right direction.

I had also defined a couple of ambitions. My first ambition was to present a working prototype that is promising for further development. This was the most challenging part of this project because it required a thorough understanding of the human body, sensors and programming skills. Through the trial and error process, the chosen concept was made tangible and real-time data was visualized. This was probably the most satisfying moment throughout the project.

My second ambition was to successfully manage a design project within a team. Personally, I believe that I pro-actively managed this project to the best of my ability and involved all parties often throughout the project. I have also learned to take more initiatives and not be afraid to make mistakes. A journey without challenges and ups and down is not a journey at all. This project made me aware of my own skills, knowledge and limitations. Now, I am equipped with a luggage full of new knowledge and skills that will help me in the real world.

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8 Appendix

Appendix A

2908

DESIGN FOR our future

TUDelft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

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

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

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

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

family name
initials
student number
street & no.
zipcode & city
country
phone
email

[redacted]

Your master programme (only select the options that apply to you):

IDE master(s): IPD (selected) | Dfl | SPD

2nd non-IDE master:

individual programme: - - (give date of approval)

honours programme: Honours Programme Master

specialisation / annotation: Medisign | Tech. in Sustainable Design | Entrepeneurship

SUPERVISORY TEAM **

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

** chair: Kaspar Jansen — dept. / section: design engineering

** mentor: A. Albayrak — dept. / section: applied erg.& design

2nd mentor: R. Klaassen

organisation: Maasstad Ziekenhuis

city: Rotterdam — country: The Netherlands

comments (optional)

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

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

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

Procedural Checks - IDE Master Graduation

TU Delft

APPROVAL PROJECT BRIEF

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

chair Kaspar Jansen date 22-10-18 signature KJ

CHECK STUDY PROGRESS

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

Master electives no. of EC accumulated in total: 30 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 30 EC

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

YES all 1st year master courses passed

NO missing 1st year master courses are:

name date 9-11-18 signature CB

FORMAL APPROVAL GRADUATION PROJECT

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

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

Content: V APPROVED NOT APPROVED

Procedure: V APPROVED NOT APPROVED

comments

name A Huwae date 27-11-2018 signature

Non-invasive and continuous wearable device to monitor vital signs — project title

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

start date 18 - 10 - 2018 — 21 - 03 - 2019 end date

INTRODUCTION **

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

Patients are currently measured three times a day by nurses in order to assess their health condition and identify potential deterioration. Nurses monitor the vital signs by measuring the heart rate, blood pressure, respiration rate, blood oxygen level and temperature with different monitoring devices. With the use of a clinical scoring system called MEWS, Modified Early Warning Score, physiological changes can be detected and healthcare professionals can act upon it. A high MEWS score is highly correlated with admission to the intensive care unit (ICU), cardiac arrest and mortality (Subbe, Kruger, Rutherford, & Gemmel, 2001). Although MEWS shows relevant information about the health state of patients, it is possible that the measurements do not detect patient deterioration in time. This is especially the case at night when patients are not measured. This could explain why most of unplanned ICU admissions take place in the evening and at night.

Nurses utilize a great amount of their time measuring the vital signs of patients and entering the data into the Electronic Health Record (EHR). This significantly reduces the time nurses have to provide personal attention to their patients. Personal attention is needed at the short stay surgery department because 50% of the surgeries are cancer related.
Non-invasive and continuous monitoring systems can detect the early stages of deterioration. Early intervention can prevent a patient's health from worsening. Currently, there are many wearable systems that can continuously monitor vital signs. These systems will dramatically improve patients' mobility, provide comfortability as well as reduce the workload of nurses. Although these systems can be beneficial for both patients and nurses, it is still not utilized in the healthcare sector due to high costs, technical limitations and the adverse psychological side effects for the patients.

This project will focus on exploring and developing a non-invasive wearable that can continuously measure the vital signs of patients and alert nurses when the health condition of their patients deteriorates. It is very important that the system is user-friendly for nurses to reduce their workload and comfortable for patients because they will have to wear the wearable for an extended period of time. The project is a collaboration with Maasstad Ziekenhuis, a hospital based in Rotterdam for the department of short stay surgery.

1. Subbe, C. P., Kruger, M., Rutherford, P., & Gemmel, L. (2001). Validation of a modified Early Warning Score in medical admissions. QJM, 94(10), 521-526.

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introduction (continued): space for images

image / figure 1: Philips wearable biosensor is applied on patient's upper chest

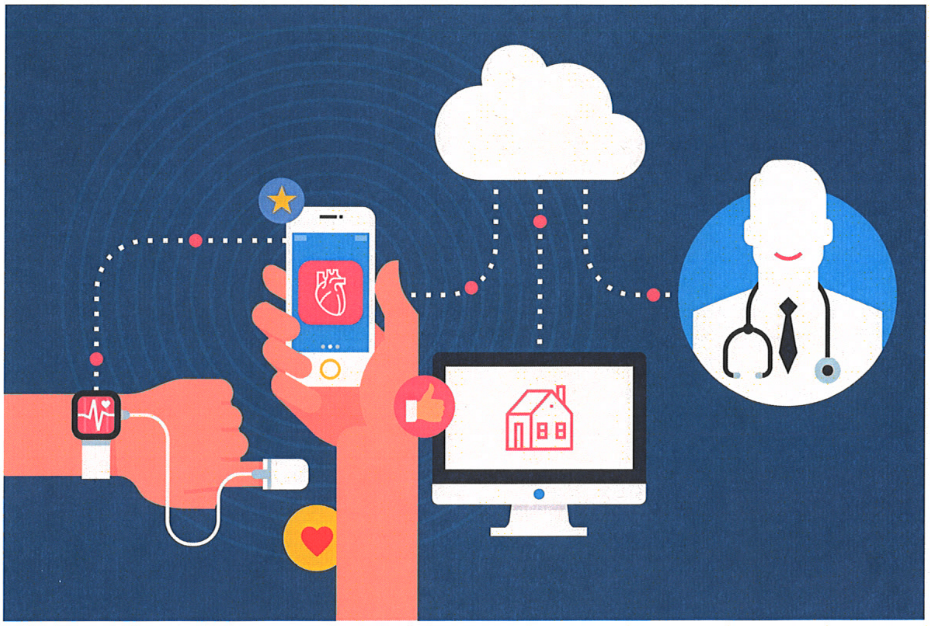


image / figure 2: Remote patient monitoring

PROBLEM DEFINITION **

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

Nurses spend 3.5 hours measuring the vital signs of all patients at the short stay surgery department on a daily basis. Since nurses are overwhelmed with work and are busy with other patients, the risk of medical errors is also increased. Another disadvantage is the lack of an alarming system that can notify the nurses in case the values exceed the boundaries or when patient's clinical condition slowly deteriorates. The delay of early diagnosis can lead to unplanned hospitalization at the Intensive Care (IC), increase of length of stay at the hospital, reanimation or even mortality (Hillman et al., 2001; McQuillan et al., 1998). Lastly, the overall hospital costs also increases when patients have a longer hospitalization periods. Therefore, the current system of obtaining measurements manually is highly inefficient, prone to error and may also lead to higher financial costs.

In this project, a non-invasive and continuous multi-sensor wearable will be developed to solve the aforementioned problems. The wearable will monitor the majority of patient's vital signs and alarm the nurses when the vital signs exceed the limits. There is a possibility that the wearable will be further developed, optimized and implemented in the hospital in the future.

1. Hillman, K. M., Bristow, P. J., Chey, T., Daffurn, K., Jacques, T., Norman, S. L., . . . Simmons, G. (2001). Antecedents to hospital deaths. Intern Med J, 31(6), 343-348.

2. McQuillan, P., Pilkington, S., Allan, A., Taylor, B., Short, A., Morgan, G., . . . Smith, G. (1998). Confidential inquiry into quality of care before admission to intensive care. BMJ, 316(7148), 1853-1858. doi:10.1136/bmj.316.7148.1853
Thx

ASSIGNMENT **

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

First, I will research the best possible solution to continuously monitor the vital signs of patients. Additionally, I will generate working principles and aim to integrate them in a wearable prototype.

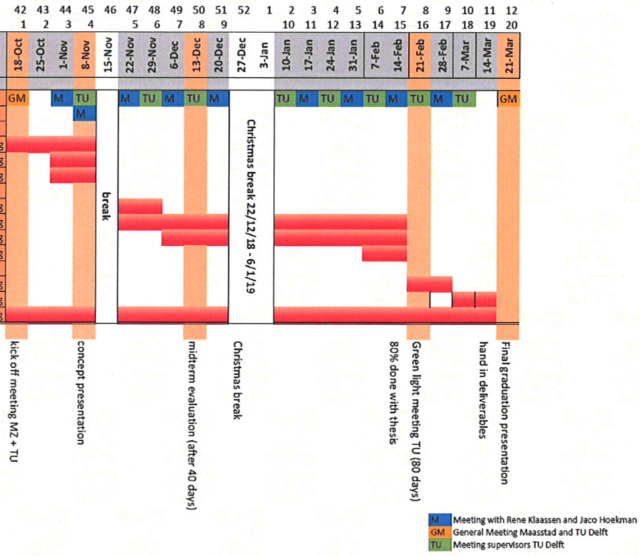
PLANNING AND APPROACH **

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

start date 18 - 10 - 2018 | 21 - 3 - 2019 end date

Calendar week
Project week

Activity	Start Date	End Date	Status
Meetings			
Ideation			
Conceptualization (sketching)	23-Aug	8-Nov	Pending
User scenarios	1-Nov	8-Nov	Pending
Personas	1-Nov	8-Nov	Pending
Embodiment			
Research electronics	22-Nov	29-Nov	Pending
Prototyping (iterations)	22-Nov	14-Feb	Pending
User-testing	6-Dec	14-Feb	Pending
Evaluate	7-Feb	14-Feb	Pending
Finalizing			
Recommendations	21-Feb	28-Feb	Pending
Prepare final presentation	7-Mar	14-Mar	Pending
Final graduation thesis	6-Sep	14-Mar	Pending



Ideation: Based on literature study, interviews and observations, several ideas and concepts will be generated to monitor the vital signs. Moreover, user scenarios and personas will be created to understand the context even better.

Embodiment: In this phase, sensors for the prototype will be chosen and tested. As can be seen, large amount of the planning is dedicated to prototyping and testing with (potential) users. Eventually a working prototype will be created based on tests and evaluations.

Finalizing: This phase of the project will be dedicated to writing recommendations to optimize the product for further development. Moreover, the master thesis and the final presentation will be prepared.

MOTIVATION AND PERSONAL AMBITIONS

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

From Advanced Embodiment Design project I have learned skills that I can use in this project, such as creating mock-ups, user-testing, designing the interaction between the product and user. In addition, I want to utilize my visualization skills that I have developed during my MSc programme.

My personal learning ambition are to improve my prototyping skills and programming skills with Arduino. Moreover, I would like to acquire in-depth knowledge in the field of medical design, regarding wearable devices in a healthcare setting, the user-group in the short stay surgery department, and medical device regulations. My ambition is to end up with a functional prototype that is promising for further development. Another personal learning ambition is to successfully manage a design project within a team.

Since the beginning of my study, I have always been interested in healthcare design in order to improve people's quality of life. I feel honored to complete my study with a challenging healthcare related project and that I am able to work with experts from TU Delft and Maasstad Ziekenhuis who will support me during this journey.

FINAL COMMENTS

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

Initials & Name M Aydin Student number 4633636

Title of Project Non-invasive and continuous wearable device to monitor vital signs

Appendix B

Function	Part	Quantity	Size (in mm)	Price per unit (€)	Weight (g)
Vital signs	MAX30105 	2x	5.6mmx3.3 mmx1.55mm	3.67€ (50+) (2x 7.34€)	2g
Body Temperature	(X°=Field of View measurement) -MLX90614 standard (90°) (+ extra lens system to converge the IR beam is needed)  Or -MLX90614DCI (5°)  Or - MLX90614DCH (12°)  Or MLX90615 (100° - 80°) → MLXSSG-DAG-000-TU (+ extra lens system to converge the IR beam is needed) 	1x	**MLX9614 DAA**: 8.20mm diameter Height 4.10 mm **MLX90614 DCI**: 9mm diameter Height 20.20 mm **MLX90614 DCH**: 8.30mm diameter Height 9.15 mm **MLX90615**: 7.20mm diameter Height 2.70mm	**MLX90614: DAA** 10.91€ (100+) **MLX90614: DCI** 36.19€ (100+) **MLX90614: DCH:** 20.27€ (100+) **MLX90615:** 12.84€ (100+)	1g
Microcontroller: **-Connection** **-Multiplexer** **-Memory** **-Distance of the product and angle**	Blue Gecko BGM13S Bluetooth® Module 	1x	6.5mm x 6.5mm x 1.4 mm 51mm² package size	8.82€	1g
Activity	3-axis accelerometer → LIS2DH12 	1x	2x2x1mm	0.84€ (100+)	0.14

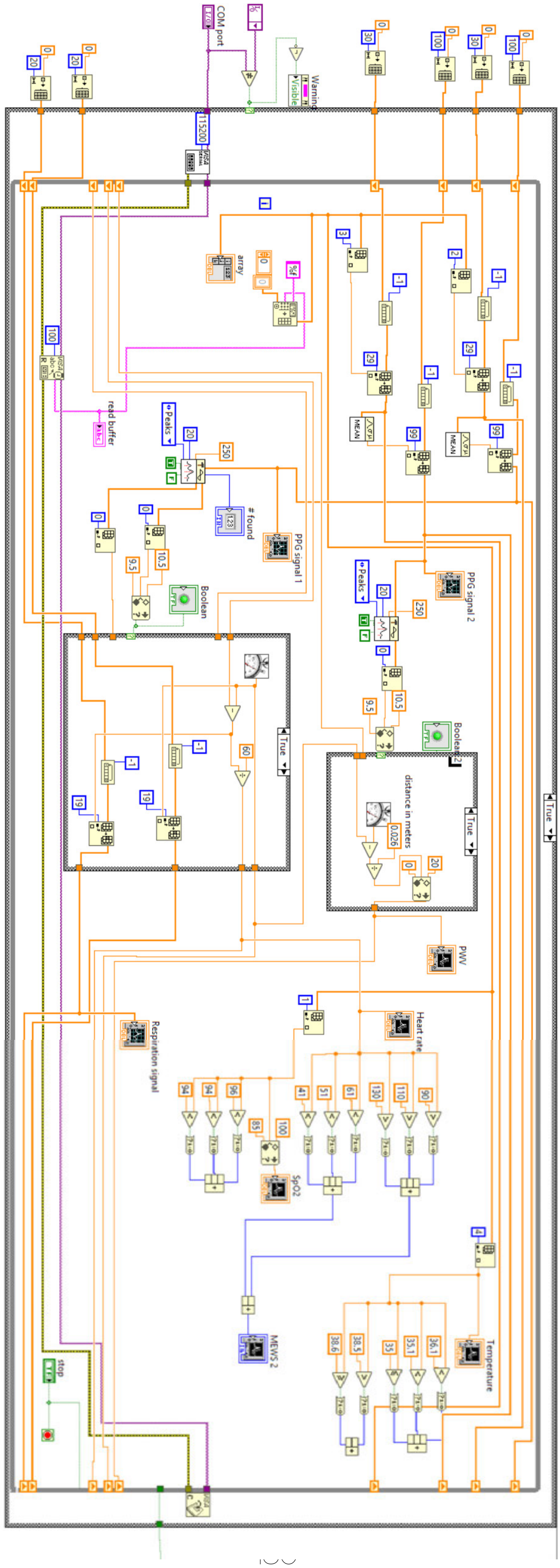
Power	Varta Coinpower CP 1654 A3: 3,7V, 120mAh  Or Li-Po battery: 3,7V, 120mAh 	1x	**CP:** 16.1mm diameter 5.4mm height **LiPo:** Width:10mm Length: 42mm Thickness:3.7 mm	**CP:** 6€ (100+) **LiPo:** 1€ (200+)	**CP:** 3g **LiPo:** 2-3g
Connecting	PCB	1x	35x8x1.54	0.32€ (100+)	1g
Protection	Casing	1x	45x73x9mm	-	5g
Connecting	Other small electronic components	1x	8x12x1.6mm	-	1g
Ear-in plug	Silicone ear in 	1x	S=10mm M=12mm L=14mm	0.13€	0.5g
Ear-in hook	Silicone ear hook 	1x	Small Medium Large	0.15€	1g
Total			**38.87€ - (MLX90614DCH IR sensor + LiPo battery)**		**±16g**

Appendix C

```
/*
  Optical SP02 Detection (SPK Algorithm) using the MAX30105
Breakout
 By: Nathan Seidle @ SparkFun Electronics
 Date: October 19th, 2016
 https://github.com/sparkfun/MAX30105_Breakout

 This demo shows heart rate and SPO2 levels.

 It is best to attach the sensor to your finger using a rubber band or
other tightening
 device. Humans are generally bad at applying constant pressure to
a thing. When you
 press your finger against the sensor it varies enough to cause the
blood in your
 finger to flow differently which causes the sensor readings to go
wonky.

 This example is based on MAXREFDES117 and RD117_LILYPAD.ino
from Maxim. Their example
 was modified to work with the SparkFun MAX30105 library and to
compile under Arduino 1.6.11
 Please see license file for more info.

 Hardware Connections (Breakoutboard to Arduino):
 -5V = 5V (3.3V is allowed)
 -GND = GND
 -SDA = A4 (or SDA)
 -SCL = A5 (or SCL)
 -INT = Not connected

  The MAX30105 Breakout can handle 5V or 3.3V I2C logic. We
recommend powering the board with 5V
 but it will also run at 3.3V.
*/

#include <Wire.h>
#include “MAX30105.h”
#include “spo2_algorithm.h”
#include <Adafruit_MLX90614.h>
#define TCAADDR 0x70


void tcaselect(uint8_t i) {
 if (i > 7) return;

 Wire.beginTransmission(TCAADDR);
 Wire.write(1 << i);
 Wire.endTransmission();
}

Adafruit_MLX90614 mlx = Adafruit_MLX90614();

MAX30105 particleSensor;

#define MAX_BRIGHTNESS 255

uint32_t irBuffer1[100]; //infrared LED sensor data
uint32_t redBuffer[100];  //red LED sensor data
uint32_t irBuffer2[100]; //infrared LED sensor data

int32_t bufferLength; //data length
int32_t spo2; //SPO2 value
int8_t validSPO2; //indicator to show if the SPO2 calculation is valid
int32_t heartRate; //heart rate value
int8_t validHeartRate; //indicator to show if the heart rate calculation
is valid

byte pulseLED = 11; //Must be on PWM pin
byte readLED = 13; //Blinks with each data read

void setup()
{
 Wire.begin();
 Wire.setClock(400000);
 tcaselect(1);

  if (!particleSensor.begin(Wire, I2C_SPEED_FAST)) //Use default I2C
port, 400kHz speed
 {
   Serial.println(F(“MAX30105 was not found. Please check wiring/
power.”));
   while (1);
 }

  Serial.begin(115200); // initialize serial communication at 115200
bits per second:
 Serial.println(F(“MAX30105 found.”));
 pinMode(pulseLED, OUTPUT);
 pinMode(readLED, OUTPUT);

 byte ledBrightness = 55; //Options: 0=Off to 255=50mA
 byte sampleAverage = 4; //Options: 1, 2, 4, 8, 16, 32
 byte ledMode = 2; //Options: 1 = Red only, 2 = Red + IR, 3 = Red
+ IR + Green
 int sampleRate = 1000; //Options: 50, 100, 200, 400, 800, 1000,
1600, 3200
 int pulseWidth =118; //Options: 69, 118, 215, 411
 int adcRange = 4096; //Options: 2048, 4096, 8192, 16384
    particleSensor.setup(ledBrightness, sampleAverage, ledMode,
sampleRate, pulseWidth, adcRange); //Configure sensor with these
settings
 tcaselect(2);
 mlx.begin();
 tcaselect(7);
    particleSensor.setup(ledBrightness, sampleAverage, ledMode,
sampleRate, pulseWidth, adcRange);
}

void loop()
{

  bufferLength = 100; //buffer length of 100 stores 4 seconds of
samples running at 25sps

 //read the first 100 samples, and determine the signal range
 for (byte i = 0 ; i < bufferLength ; i++)
 {
   tcaselect(1);
   while (particleSensor.available() == false) //do we have new data?
     particleSensor.check(); //Check the sensor for new data

   redBuffer[i] = particleSensor.getRed();
   irBuffer1[i] = particleSensor.getIR();
```

```
    particleSensor.nextSample(); //We're finished with this sample so move to next sample

    tcaselect(7);
    while (particleSensor.available() == false) //do we have new data?
      particleSensor.check(); //Check the sensor for new data

    irBuffer2[i] = particleSensor.getIR();
    particleSensor.nextSample(); //We're finished with this sample so move to next sample

    Serial.print(F("red="));
    Serial.print(redBuffer[i], DEC);
    Serial.print(F(", ir="));
    Serial.println(irBuffer1[i], DEC);
  }

  //calculate heart rate and SpO2 after first 100 samples (first 4 seconds of samples)
  maxim_heart_rate_and_oxygen_saturation(irBuffer1, bufferLength, redBuffer, &spo2, &validSPO2, &heartRate, &validHeartRate);

  //Continuously taking samples from MAX30102.  Heart rate and SpO2 are calculated every 1 second
  while (1)
  {
    //dumping the first 25 sets of samples in the memory and shift the last 75 sets of samples to the top
    for (byte i = 25; i < 100; i++)
    {
      redBuffer[i - 25] = redBuffer[i];
      irBuffer1[i - 25] = irBuffer1[i];

      irBuffer2[i - 25] = irBuffer2[i];

    }

    //take 25 sets of samples before calculating the heart rate.
    for (byte i = 25; i < 100; i++)
    {
      tcaselect(1);
      while (particleSensor.available() == false) //do we have new data?
        particleSensor.check(); //Check the sensor for new data

      digitalWrite(readLED, !digitalRead(readLED)); //Blink onboard LED with every data read

      redBuffer[i] = particleSensor.getRed();
      irBuffer1[i] = particleSensor.getIR();

      particleSensor.nextSample(); //We're finished with this sample so move to next sample

      tcaselect(7);
      while (particleSensor.available() == false) //do we have new data?
        particleSensor.check(); //Check the sensor for new data

      digitalWrite(readLED, !digitalRead(readLED)); //Blink onboard LED with every data read

      irBuffer2[i] = particleSensor.getIR();

      particleSensor.nextSample(); //We're finished with this sample so move to next sample

      //send samples and calculation result to terminal program through UART
      Serial.print(heartRate, DEC);

      // Serial.print(F(","));
      // Serial.print(validHeartRate, DEC);

      Serial.print(F("\t"));
      Serial.print(spo2, DEC);

      // Serial.print(F("\t"));
      // Serial.print(validSPO2, DEC);

      Serial.print(F("\t"));
      Serial.print(irBuffer1[i], DEC);

      Serial.print(F("\t"));
      Serial.print(irBuffer2[i], DEC);

      Serial.print(F("\t"));
      tcaselect(2);
      Serial.println(mlx.readObjectTempC());

    }

    //After gathering 25 new samples recalculate HR and SP02
    maxim_heart_rate_and_oxygen_saturation(irBuffer1, bufferLength, redBuffer, &spo2, &validSPO2, &heartRate, &validHeartRate);
  }
}
```

Appendix D



COM port
Warning
Visible
115200
array
read buffer
Peaks
found
PPG signal 1
Boolean
PPG signal 2
True
distance in meters
PWV
Respiration signal
Heart rate
SpO2
MEWS 2
Temperature
stop

Appendix E

TU Delft & Maasstad Ziekenhuis

Research

Interview patients and medical staff

Mucahit Aydin
30-10-2018

Content

Medical staff

Name:
Age:

1. What is your function?
2. How long have you been working in this deparment?
3. What are your main duties?
4. Can you tell me more about this department, the type of patients and surgeries and the hospitalization period?
5. Can you tell me more about your workload in this department?
6. Do you spend sufficient time on personal contact of patients?
7. When and how long do patients stay out of their room?
8. What is the process of patient admission to dismissal within this department?
9. Is the MEWS a good scoring system?
10. How many times are patients measured?
11. How long does it take to measure the vital signs of all patients per day?
12. How do you know the health condition of your patients?
13. When do you have to inform the doctor about patients' health condition?
14. Is there a domino effect when patients' health condition deteriorate?
15. What is the function of the beeper?

Patient

Name:

Age:

1. What type of surgery did you undergo?
2. What is your daily program here in the hospital, i.e. what do you do in the morning, afternoon and evening?
3. Do you have any limitations while sleeping, laying, standing, sitting and walking?
4. How many times do you get out of your bed?
5. How many times do you walk around in the department?
6. How many times do you walk outside the department?
7. For how long do you leave the department?
8. What was your stress level before, during and after your first visit in the polyclinic?
9. What was your stress level before and after the surgery and after one day in the hospital?
10. Are you open for new innovations and products?
11. How do you perceive yourself: more conservative or innovative?
12. Do you have experience with wearables and if yes can you tell your experience?

Questions for both patients and medical staff

Interviewees will be briefly interviewed in order to create a clear understanding about the context, their stress level, and their perception about wearables. This interview will also be used to define the requirements and wishes regarding the wearable.

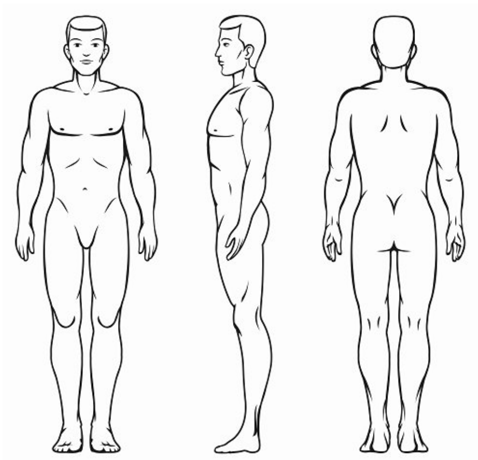
There will be a brief explanation about these wearables, including their function and purpose, to give the interviewee an idea what wearables for medical applications are.

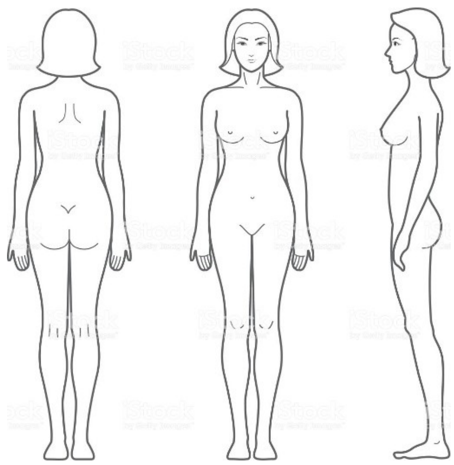




Position wearable:

1. Where on your body would you prefer to place the wearable and where on your body would you not prefer?





2. What would be the advantages and disadvantages of these products according to you?

How important are the following factors for you?

Comfortable

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Safe use

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Waterproof

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Amount of modules placed on your body

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

All vital signs are measured

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Alarming function when your vital signs deteriorate

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Protection of your personal data

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Minimal performed actions by nurses

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Easy attachable on the body

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Robustness

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Size

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Weight

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Hygiene

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Re-usable

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Disposable

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Affordable

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Position on the body

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Visibility of the wearable

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Moving without being limited

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

How other people perceive me

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Color

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Aesthetics

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Material

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

Texture

□ Very important □ Important □ Moderately important □ Slightly important □ Not important

What are your requirements and wishes regarding this wearable?

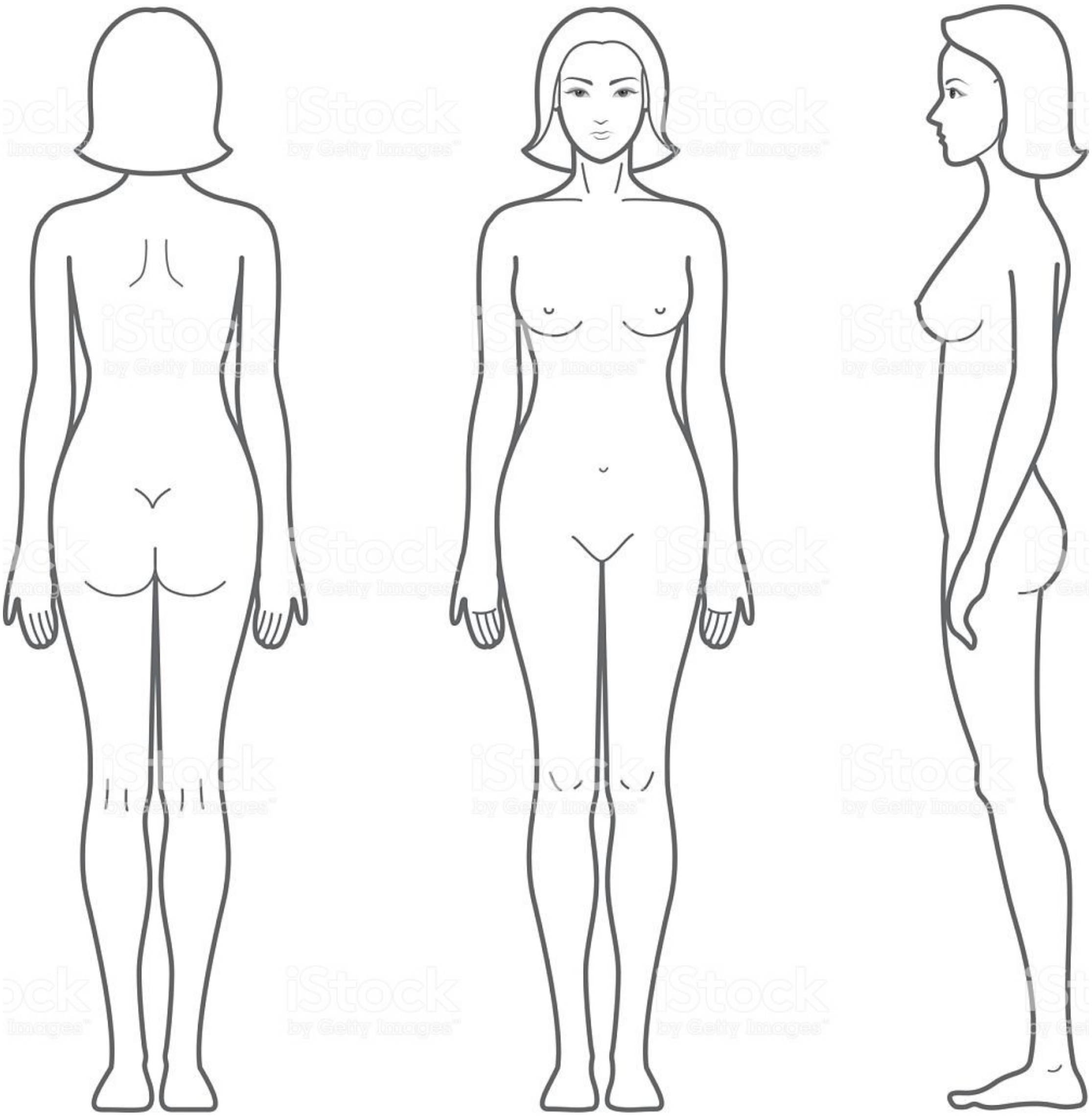
………

………

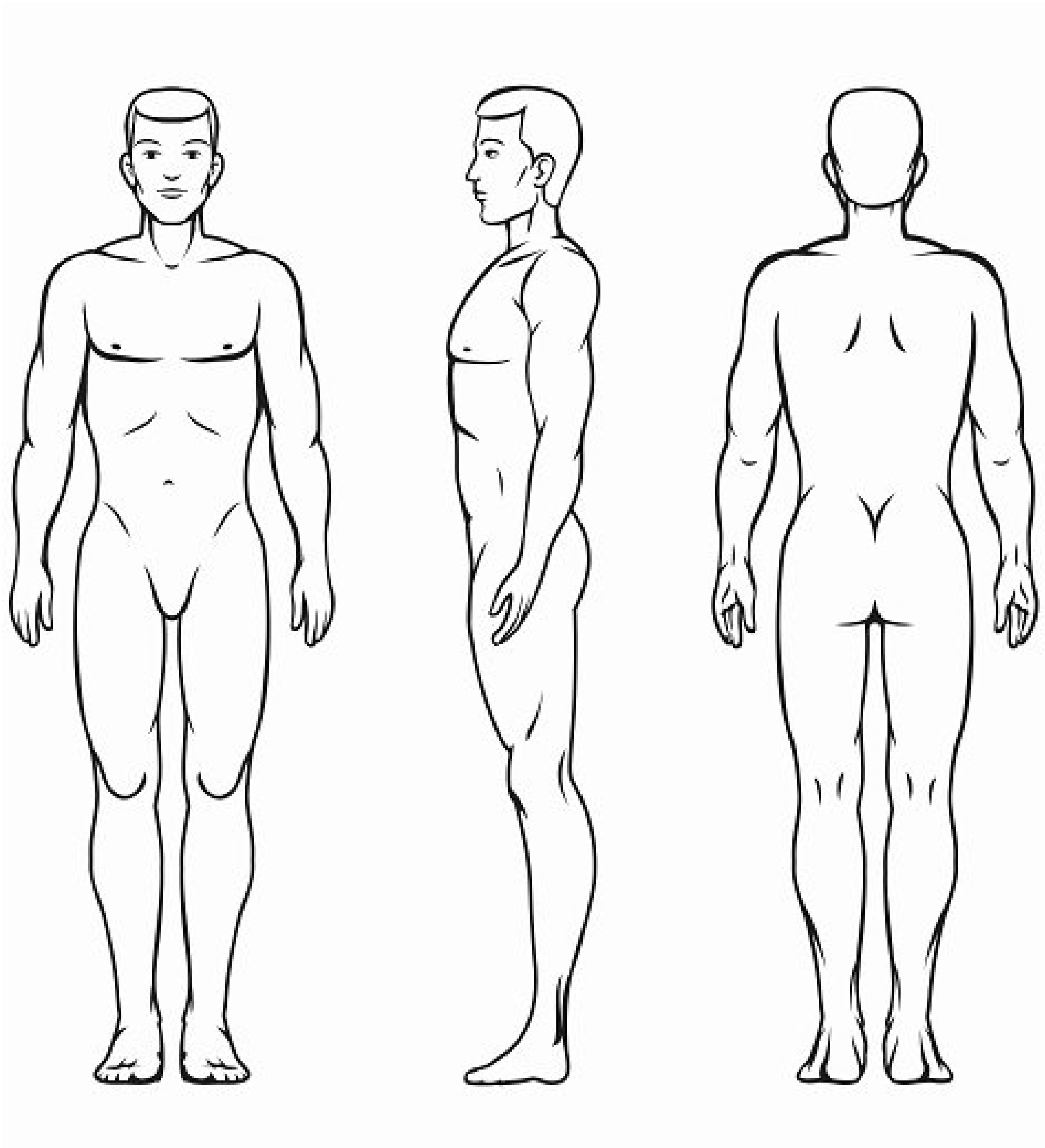
………

………

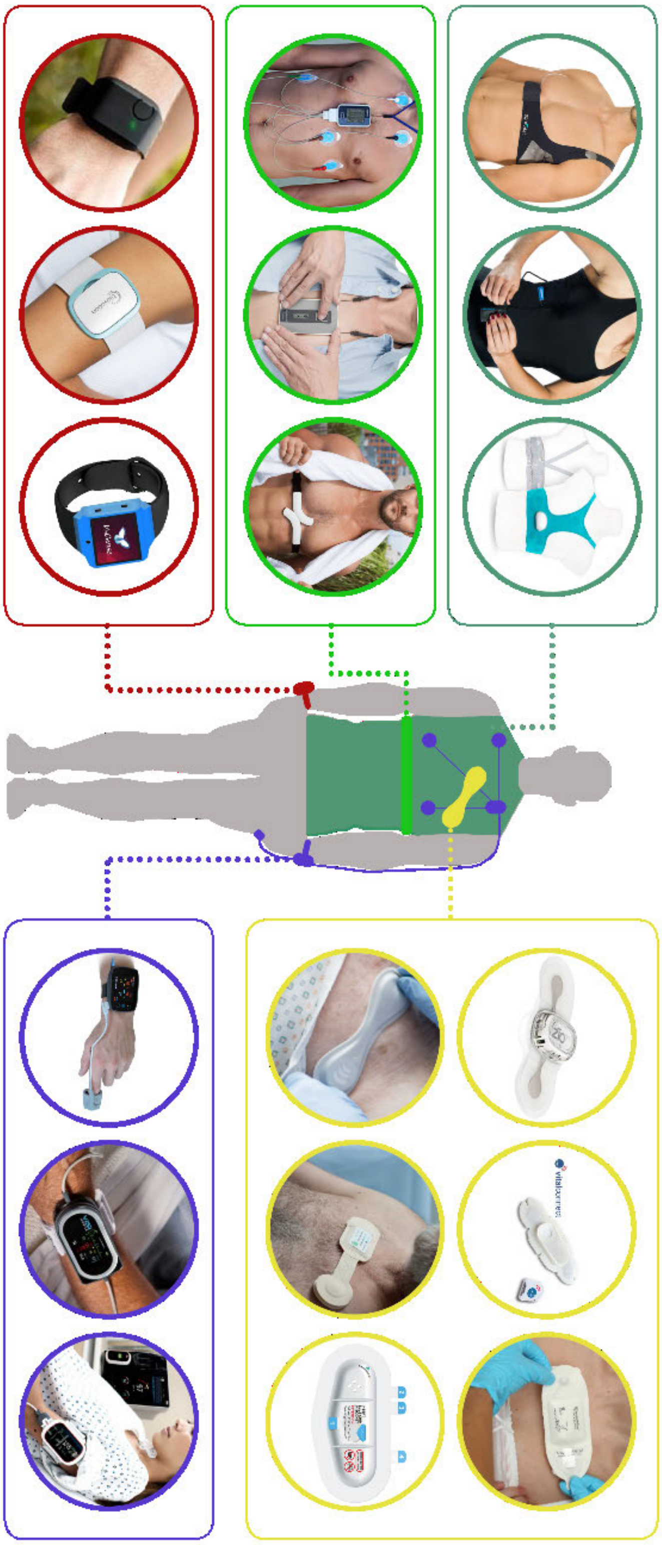
Position wearable woman



Position wearable man



Current wearables



Appendix F

11-7-2018 observations day

Short stay surgery department

Nurse uses a vital sign monitor. the Welch Allyn Series 300, to measure the blood pressure, the heart rate and the saturation level. The temperature is measured with Braun pro 4000, a wireless portable ear thermometer. The respiration is not always measured but the method to measure the respiration is by observing the patient for 20 seconds. The amount of respirations is multiplied by 3 to get the total breaths per minute.

Since there are limited Computer on Wheels (in total 5 COWs) at the department, the first measurements are not directly put in the EHR but first written on a piece of paper. After all measurements are done, the values are entered in the EHR by using the COW or central computer. The second measurements are directly put in the EHR with the help of the COW.

Single bed units		
Patient nr.	**Time to measure**	**Notes**
	+1 min to walk to patient	
1	5 min to measure and ask patient how he feels	**Procedure:** - Nurse introduced herself to patient - Patient asked questions and wants to renew band aid - Nurse starts with measuring the tympanic temperature. 1st one ear is measured, because the measurement deviate too much, other ear is measured too, after measuring nurse walks to toilet to throw away the disposable probe cover that she puts on the thermometer. - 2nd blood pressure is measured, it is sensitive to movement → patient should not move - 3rd saturation and HR, nurse had to wait for a stable saturation level since this value was increasing, nurse writes down the maximum measured value
	+1 min to walk to other room	
2	3:55 min	- Device is not measuring the blood pressure, other arm is measured - Nurse asks patient to give a grade for the pain and asks about defecation
	+1 min to walk to patient	

3	5:46 min to measure and ask patient how she feels	- Patient has to put off her vest to measure blood pressure - Cuff is not user friendly - Temperature values too low → measured twice - Blood pressure + saturation level + heart rate + temperature are measured simultaneously
	+1 min to walk to patient	
4	3 min	- Patient has just been operated - Nurse measures both ears, because first measurement is not accurate - Nurse asks patient to give a grade for the pain - Patient has pain at the operation site
	+1 min to walk to patient	
5	3:43 min	- Since patient is infected, a different blood pressure device is used. According to nurse this device not as accurate as the Welch Allyn Series 300 - Reading and interpretation of the measurements is prone to error because the nurse can switch the values or can think that the patient is not in danger
	+1 min to walk to patient	
6	Measurements 1:04 (measuring the blood pressure failed) + 2:04 min total time	- Nurse is looking for another Welch Allyn Series 300 after the visit because BP measurement is giving error - When some values are too low or too high, new measurements are done for double-checking or after intervention to check the effect of it
	+1 min to walk to patient	

Measuring the vital signs and putting them directly in the EHR with the use of the COW. Place: 4-beds unit		
7	3:40 min measuring and entering the values in the EHR	- Measurements are done and are put directly in the EHR with the help of the COW - If patient is asleep, the measurements are done later in the day - Patient is questioned and is measured at the same time - Blood pressure, saturation and HR are done at the same time - The measured values are put immediately in the system - Measuring the blood pressure failed 2 times - The respiration is measured by observing the patient for 20 seconds. This number is multiplied by 3 to get the total respiration per minute.
8	2:34 min measuring and entering the values in the EHR	- Saturation is not accurate, ear shell is used to measure saturation and HR
9	2:33 min	- Patient needs assistance to clean the bleeding - Since patients are in the same room, nurse can easily be distracted by other patients

The total time is sum of: measuring the vital signs, entering the parameters in the EHR and arriving at the next patient (in the other room*[1]). During the measurements the nurse is also asking the patient how the patient is feeling.

The time was measured with a smartphone. The timer started when the nurse turned the monitoring device on. The timer stopped when nurse arrived in the next room.

Patient nr. (In single bed room)	**Total time (in seconds)** *[1]
1	480
2	355
3	466
4	300
5	343
6	244
average	364 seconds
Patient nr. (In 4-beds room)	**Total time with COW *[2]**
1	220
2	154
3	153
4	270
Walking	150
average	236 seconds

***[2]** The total time is less at 4-beds room than at the single bed unit, because the patients at the 4-beds room have had minor operations, such as gastric bypass. So they need less help compared the patients in the single bed units.

According to table above, it takes on average 5 to 6 minutes to measure one patient. This includes walking to patients' room, measuring the vital signs, helping patients if needed and answering questions. This means that one nurse would spend around 2 hours and 40 minutes to 3 hours and 12 minutes to measure all 32 patients. Since patients are measured three time a day by four nurses, it can take up to **2 hours and 24 minutes per day** to measure all patients in the department. The time can significantly increase in case of an emergency, when the measuring device is not properly working or when patients must be measured again.