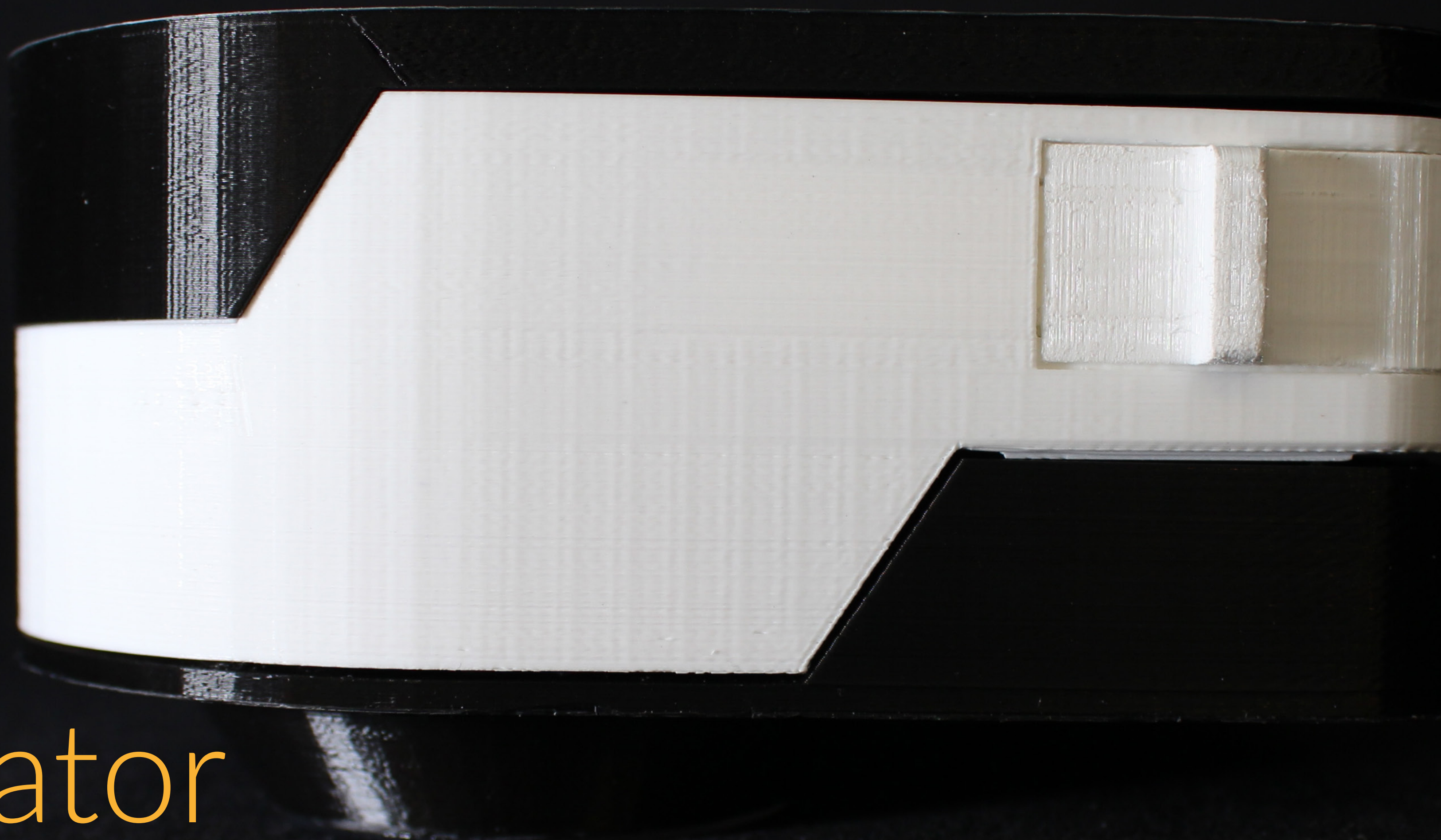

Veindicator

The development of a minimal viable product to facilitate the venipuncture procedure

Master thesis of Joy Hooft Graafland
Delft University of Technology
Industrial Design Engineering
Integrated Product Design

Delft, July 2019

TU Delft VIEWPOINT MEDICAL

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VIEWPOINT MEDICAL

The development of a minimal viable product to facilitate the venipuncture procedure

Acknowledgement

This report shows the development and process of my graduation thesis. I would not have been able to get the results I did without the help and support I recieved.

First, I would like to thank my supervisory team for guiding me throughout the whole process.

My mentor, Martien Bakker, thank you for always being available for the needed 'bakkie koffie'. Thank you for supporting me with the engineering and design but also for the mental support. I really enjoyed the sessions we had. At the beginning of every meeting I was not sure if I was able to finish the project, and after the meetings I felt like I could take over the world. Thank you.

My chair, JC Diehl, I would like to express my gratitude for helping me for this past year and a half (!) and introducing me to the field of design for emerging economies. The previous projects we did together were always great fun with great results. Therefore, I was super excited to have you as a chair for my thesis. I appreciate the opportunity for giving me this project and your always useful and effective feedback.

Secondly I would like thank my first company mentors, Ben Palmer and Georgia Lee, for trusting me with the responsibility to develop the first prototype for your start-up. Thank you for the faith you had in me and the freedom you gave me.

My second company mentor, Rahul Albuquerque, I am very grateful for your help during the development of the software for the prototype. By your help we were able to get to the level of development that we are now.

My technical support, Max Hoeboer, Thank you for being by my side for the past 5 months and helping me out whenever phython got the better hand. The tips given by you at the beginning of the project gave me a kickstart to successfully finalise the project.

With gratitude,

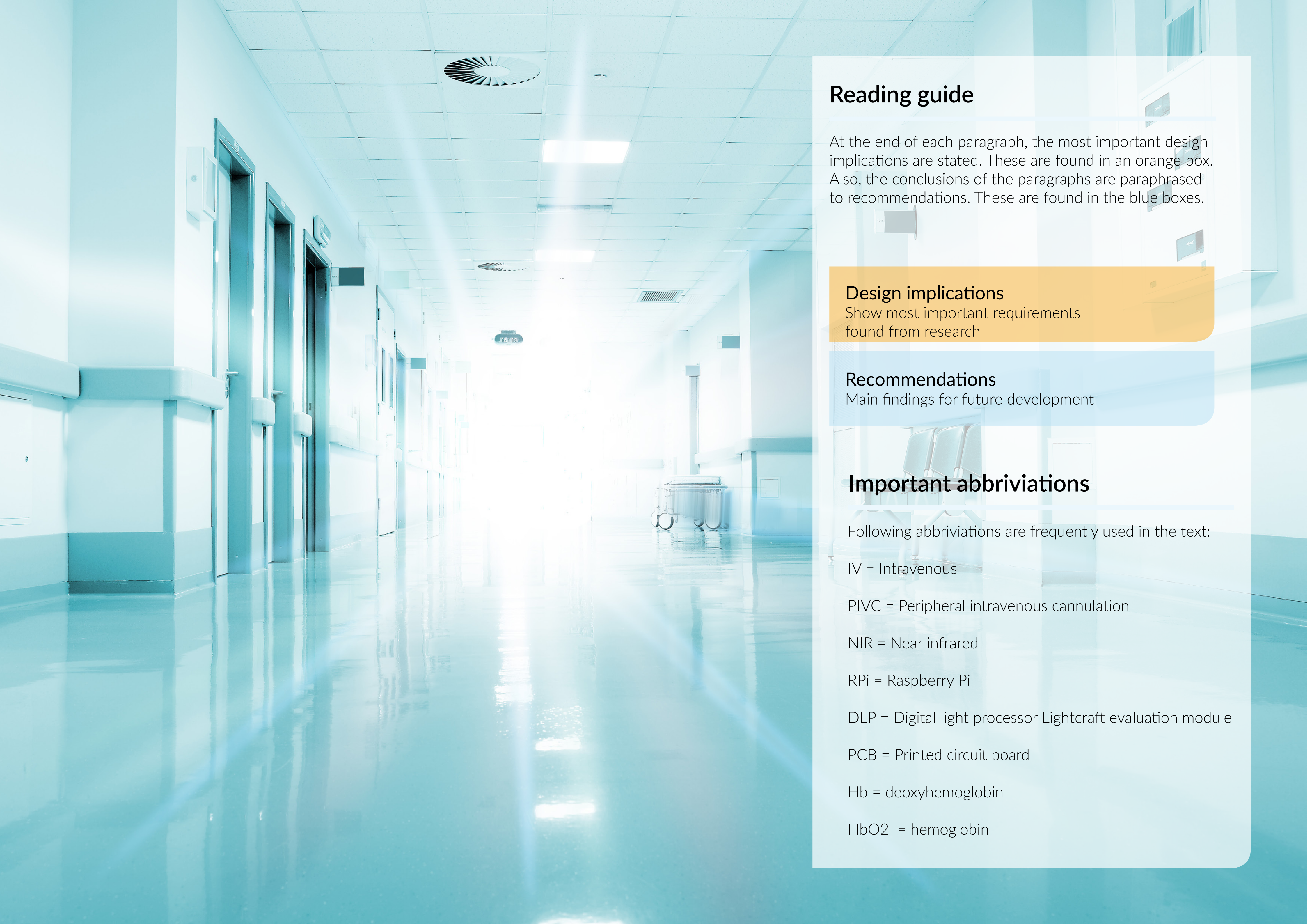
Joy Hooft Graafland

Executive summary

This report showcases the development of a product to aid the venipuncture procedure. Venipuncture is a procedure where intravenous access is obtained for several purposes. Finding a location and vein to insert the needle is the most important step of this procedure. Nearly 90% of hospitalised patients have to undergo the procedure. Despite venipuncture being the most performed procedure at hospitals, almost 50% of all cases fail at the first needle insertion attempt with adults and more than 60% with children. This failure leads to several complications such as bacterial infection, extravasation or phlebitis.

The product must be able to be used for all skin types and all healthcare contexts. For this, multiple end-users and use cases are within the scope of the project. To cover all use cases, a minimal viable product is developed. This is a product which has all minimal functionalities to make the product viable. The minimal viable product can be altered with minimal adjustments to make it fit to a specific context.

To increase first-attempt success rate, the Veindicator is developed. This product will have minimal viable functionalities to aid the venipuncture procedure. The Veindicator is a device which uses Near Infrared spectroscopy to visualise veins. Near infrared spectroscopy analyses the transmission and absorption of photons within the near infrared spectrum. Veins contain deoxygenated hemoglobin which, when exposed to near infrared radiation, almost completely absorb this radiation. By utilising the absorption characteristics of deoxyhemoglobin, veins can be distinguished from surrounding tissue. To further enhance the contrast of the vein pattern and the surrounding tissue, the exposure of NIR is increased. Looking at the optical absorption window, a light source is used with a wavelength between 700 - 900 nanometer within the electromagnetic spectrum. Here, the deviation between the attenuation coefficients of deoxyhemoglobin and human tissue are the highest. The image of the enhanced veins is captured and contrast is further increased by the use of digital image processing algorithms. Finally, the enhanced vein pattern is extracted from the image and via a projector, displayed back onto the skin. The projection increases the visibility of the veins and therefore aids the venipuncture procedure.



Reading guide

At the end of each paragraph, the most important design implications are stated. These are found in an orange box. Also, the conclusions of the paragraphs are paraphrased to recommendations. These are found in the blue boxes.

Design implications
Show most important requirements found from research

Recommendations
Main findings for future development

Important abbriviations

Following abbriviations are frequently used in the text:

IV = Intravenous

PIVC = Peripheral intravenous cannulation

NIR = Near infrared

RPi = Raspberry Pi

DLP = Digital light processor Lightcraft evaluation module

PCB = Printed circuit board

Hb = deoxyhemoglobin

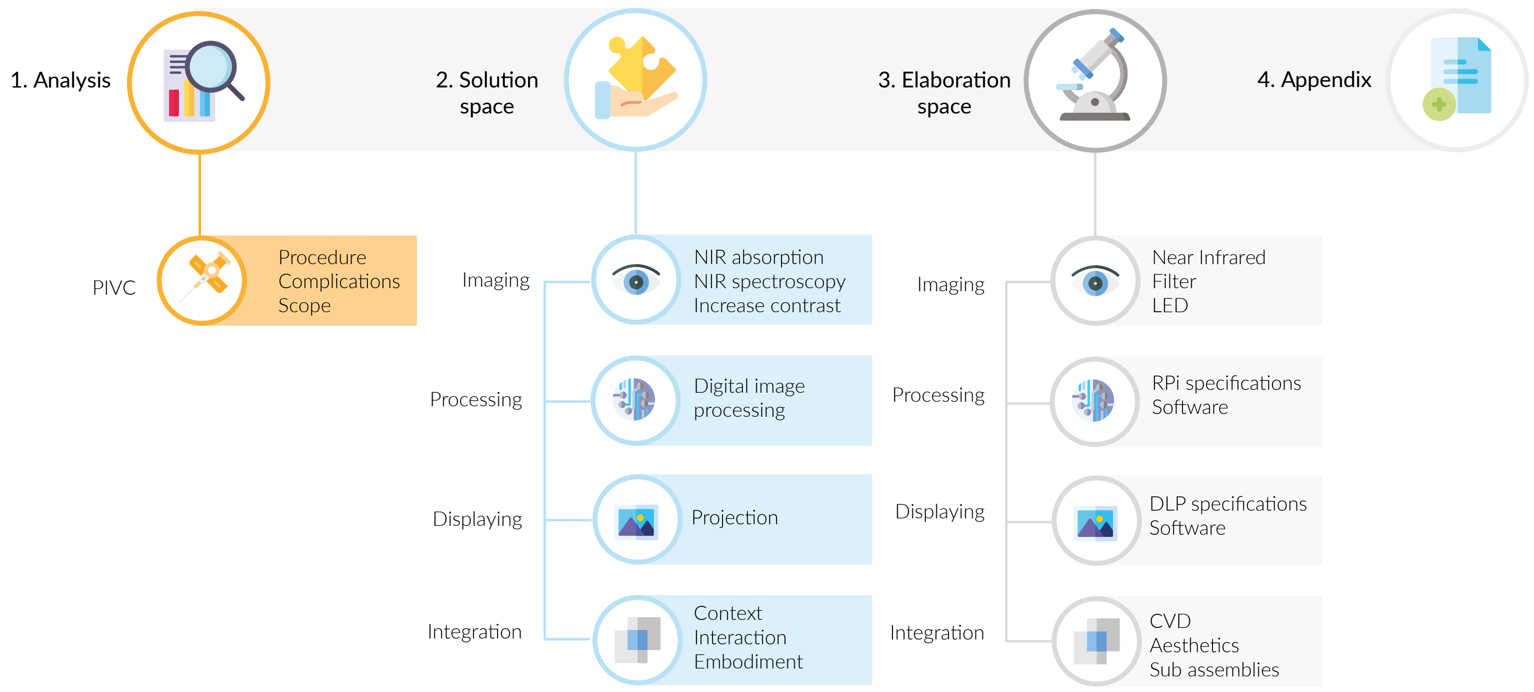
HbO2 = hemoglobin

Table of content

Introduction

This report showcases the research upon developing a minimal viable product to facilitate the venipuncture procedure. The goal of the project was to develop a product which can be used for testing in a healthcare environment. For this the device needs to be a fully working and functional prototype. Therefore, the focus of the project was to find the right electronical, optical and mechanical components and their configurations. And subsequently combine them to accomplish this goal.
The report is divided into four parts; the analysis, solution space and elaboration space and the fourth part is the appendix. In the first part, the current venipuncture procedure is explained, analysed and the challenges are specified. From this, the problem and scope of the project are defined.

In the second phase, the solution space, the development of the prototype is worked out. This part is subdivided into four paragraphs; Imaging, processing, displaying and integration. The first three paragraphs describe the technologies used to develop the minimal functionalities which the product needs to have to be viable. To increase the first attempt success rate, there has been looked into existing solutions and technologies used to identify veins. The fourth paragraph describes the aspects needed to ensure optimal integration.
In the third phase, elaboration on the solution space can be found. Here, the methods and techniques used to develop the prototype are explained in more detail. Finally, the researches conducted, which led to the solution space are found in the fourth phase, the appendix.



Analysis space

This chapter contains an analysis of the venipuncture procedure. The procedure is studied, worked out, and its complications are reported. Secondly, current products which are used to aid the venipuncture procedure are researched. Finally, from the analysis, the design opportunity and the scope are stated.

1. Venipuncture

Venipuncture is a procedure where intravenous access is obtained for blood sampling or intravenous therapy. The first purpose, blood sampling, is a medical procedure in which a needle is inserted into a vein to collect blood, see figure below. The blood collected is used to do laboratory testing. The second purpose of venipuncture is Intravenous (IV) therapy. This is a therapy where fluids are delivered directly into a vein. Which is the fastest and most effective way to deliver medication throughout the body since the supplements are directly administered into the bloodstream, bypassing the digestive system, making the supplements available for immediate use. It can be used to administer, nutrition, fluid substances, drugs, or to administer blood products via the intravenous route. It is estimated that 90% of all hospitalised patients have some form of intravenous therapy during their hospital stay. (Higa, 2017) Furthermore, a nursing survey showed that 25% of the nurse's hospital time is spent providing IV therapy services.

Peripheral intravenous cannulation (PIVC) is the most common procedure for intravenous therapy. During PIVC a cannula is placed into a peripheral vein. A cannula is an essential medical instrument which is used to administer these fluids and medications, see figure 1 for the explanation of the several parts of a cannula.

The placement of a PIVC is one of the most common minimally invasive medical procedures performed in hospitals today. Up to 90% of all patients admitted to hospitals worldwide will have a peripheral intravenous line inserted (Danski et al., 2016). For more extent research, see appendix A1 and A2

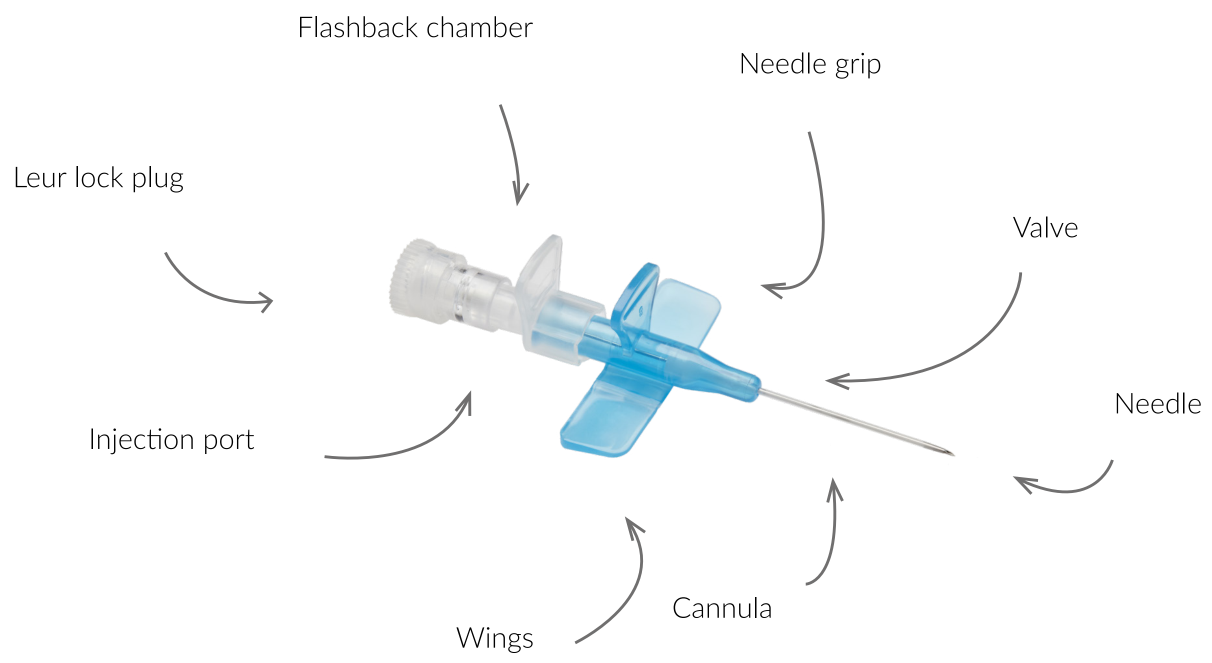


Figure 1, parts of a cannula

Procedure

To start the procedure , the following equipment is needed:

/ Alcohol cleanser
/ Gloves
/ An alcohol wipe
/ A disposable tourniquet
/ An IV cannula
/ A suitable plaster
/ A syringe

The first step in inserting an PIVC is placing a tourniquet, see figure 2. A tourniquet is a band which is strapped around the arm to create pressure in the arteries and veins. By creating pressure, the arteries and veins will increase in size, which will make them more visible. Increasing visibility of veins and arteries is important for the second step in the procedure identifying a suitable vein. Site selection is arguably the most important step in ensuring successful venipuncture or cannulation. To ensure successful intravenous access, health professionals are encouraged to locate a vein that is long, straight and accessible while ensuring it is not near a bony prominence. The most common veins used are the basilic, median cubital or cephalic veins of the forearm, see figure right as they allow for the placement of a variety of different sized cannulae (needles) and do not restrict the activity or movement of the patient. That is to say, the patient is able to carry out normal activities while the cannula is in situ .

The traditional method of locating veins involves visual inspection, using the sense of touch or a tourniquet to constrict the arm three to four inches above the puncture site.

After the site is selected, the doctor puts on gloves and disinfects the area. After the preparation is finished, the cannula is removed from its packaging. The skin is stretched by two fingers while the needle is held in the other fingers. The needle is then inserted in a 30 degree angle. The needle is advanced until a flashback of blood is seen in the chamber at the back of the cannula. After, the cannula is advanced two millimeters further into the vein while holding the needle in place. With one hand still applying pressure on the cannula, the tourniquet is released and the needle is removed with the other. The needle is disposed and a dressing is applied to the cannula.

1. Increase visibility of veins
2. Aid the localisation of veins

Equipment for intravenous cannulation

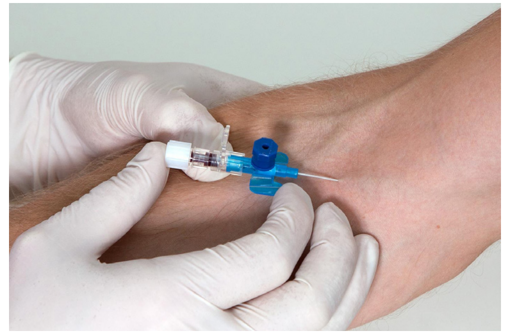
Apply tourniquet

Select site

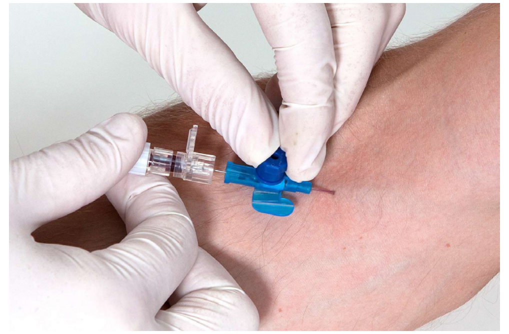
Clean the patients skin with the alcohol wipe

Remove the needle cover

Insert the needle, bevel upwards at about 30 degrees

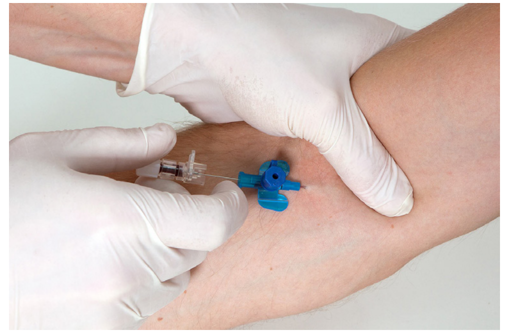


Flashback of blood is seen in the hub

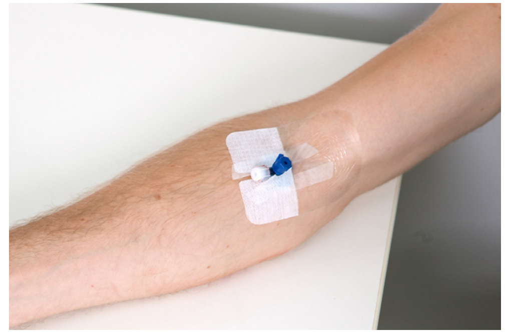


Advance the rest of the cannula into the vein

Release the tourniquet



Remove the needle



Apply the plaster to the cannula

Figure 2, steps PIVC procedure

Complications

PIVC is a high-risk procedure performed by physicians, nurses and paramedics. Since it is such a highly performed procedure, the potential for severe complications and safety risks to the patient are often forgotten. Research has shown that the first attempt of PIVC fails in 12-26 % of adults and 24-54 % of children (Malyon et al., 2014).

Venipuncture failure leads to several complications. The complications range from bruising to bacterial infection, extravasation, phlebitis, thrombosis, embolism and nerve damage. The most common complication during I.V. therapy is extravasation or infiltration. Extravasation is the leakage of infusing fluid from a vein into the surrounding tissues. This complication occurs when the cannula punctures out of the vein wall. If a steel cannula is used, the risk of extravasation is as much as 70% greater than when a plastic cannula is used. If a plastic cannula is used, extravasation is more likely to occur one or more days after insertion. With both the steel and plastic cannula, the risk increases whenever the cannula is inserted at a site near a joint. Rotation, flexion or extension can pull a cannula tip out of a vein. This occurs when a cannula is not inserted deeply enough into the vein, or when the vein is relatively deep, as in obese patients. Signs of extravasation include discomfort, burning or pain at the site.

Other common complications are phlebitis and thrombophlebitis, an inflammation of one or more layers of the vein. Although, a peripheral vein can be accessed in a single attempt, between two and ten attempts are usually needed to insert the needle successfully. Unsuccessful PIVC can lead to more invasive procedures resulting in infection and requiring higher operator skills. When repetitive peripheral IV access fails, intravenous medication doses and fluids are missed, healthcare providers consider placing more expensive devices such as peripherally inserted central catheters (PICC) or implantable ports. Excessive venipunctures, which cause distress, pain and anxiety in patients, are a significant problem and are time and resource consuming events (e.g., catheters, needles (Juric & Zalik, 2014) PIVC failure and its corresponding complications are expensive for the healthcare sector. The PIVC insertion costs averagely between $28 and $35 for a first-success insertion. This insertion cost is repeated with every failed attempt. (Webster et al., 2008)

The leading causes for multiple attempts are a lack of adequate skills, lack of adequate care and primarily because of difficult peripheral venous access caused by poorly visible veins.

The venipuncture procedure, which is considered indispensable to human health, can be especially tricky with infants and elderly, as well as in obese patients, dark-skinned people, intravenous drug abusers, hypotensive individuals, and those with multiple injuries that limit the number of available limbs and may require several attempts, causing distress. A difficult case is caused by the differences in patients' biological systems which make locating a vein more difficult. The differences are distinguished by the amount of subcutaneous fat present and its distribution, the condition of the vessels due to complications, excess oedema, the patients' skin type and colour. (Cantor-Peled & Halak, 2003)

3. Guide PIVC placement
4. Little training needed
5. Suitable for every patient, skin type and color
6. Improve first-stick success rate
7. Decrease resources needed

Existing non - technical solutions

The most common method to help locating the veins, is tapping the possible insertion site. Health professionals lightly tap the vein. Tapping the vein will stimulate blood flow and so, increase vein visibility. Tapping may be painful for the patient and can result in the formation of localised bleeding outside of veins, haematoma, in patients with fragile veins.

Other vein locating techniques are:
/ Tourniquet - This is a band which is strapped around the arm to create pressure. It is a prolonged application and repeated gripping and relaxing of the hand
/ Negative pressure - A rubber sleeve is put around the arm and vacuum is created mechanically. The sleeve is then used as a tourniquet, creating pressure in the arm.
/ Warming the area - The insert area is rubbed which increases local blood flow.
/ Application of alcohol - A pad with alcohol is wiped on the skin which changes the reflection of light on the skin. This is particularly helpful in dark skinned patients.

The above mentioned manual locating techniques are helpful in some cases, however in difficult cases they are proved to not be reliable. Use of pressure increasing methods are inadequate for patients with fragile veins, and inefficient for people with excess subcutaneous fat. (Cantor-Peled & Halak, 2003)

Figure 3, Applying alcohol

Figure 4 Ultrasound imaging

Figure 5, Doppler ultrasound

Existing technical solutions

Ultrasound imaging

To improve the venipuncture success rate, several technical approaches have been developed. Medical devices have been introduced, which use ultrasound technique to locate peripheral veins. Ultrasound imaging, which also called sonography, is a technique that visualises the inner body. The visualisation of veins is done by a vascular ultrasound, see figure 4. A vascular ultrasound uses ultrasonic sound waves to evaluate the body's circulatory system and it helps to identify blood clots and blockages in the arteries. The ultrasonic waves are transmitted and reflected back from the flowing blood in the vasculature. The different type of tissues have distinct characteristics. The varying tissue density and structure cause difference in the transmitted waves. The reflected light is captured and provides 3D information about tissue and the veins location. Ultrasound does not use ionising radiation, thus it has no harmful effects and provides images of soft tissues.
A second technique used is Doppler ultrasonography. The vascular locating technique is based on the Doppler effect, which is the change in wavelength in relation to the distance and movement relative to the source. The received frequency is higher during approached and lower during recession, compared to the emitted frequency.
The Doppler moves along the patient's arm and the probe emits an acoustical beam with a specific wavelength onto the skin. The frequency shift of the specific area is calculated and the position can be determined and visualised, see figure 5. This technique targets only a small area of the body, therefore it can take a long time to find a suitable insertion location. Where vascular ultrasound provides pictures of the body's veins and arteries, Doppler ultrasonography can also visualise the blood flow in abdomen, arms, legs, neck, brain and various body organs. A Doppler ultrasonography increases the performance of PIVC, however the ultrasound guided PIVC success rate is dependent on the level of skill of the technician and the costs of product using Doppler ultrasonography are very high. Furthermore, the techniques are limited by the expertise needed to operate the ultrasound device and the nurses' ability to perform the procedure at the same time.

8. High accuracy
9. Quick process
10. Suitable for different body parts
11. Hands free operable

Near infrared imaging

To gain additional optical information from human tissue and fluids, several medical devices utilise Near Infrared (NIR) radiation with wavelengths outside of the visible spectrum. NIR electromagnetic radiation has a longer wavelength than visible light and therefore appears to be invisible to the human eyes. The spectral window of visible light lies within range of frequencies of approximately 400 until 700 nanometers (nm). Near infrared is a type of electromagnetic radiation within the spectral window of 700-2500 nanometers (nm), see figure 6. Near Infrared spectroscopic imaging is based on the absorption of incident NIR light.

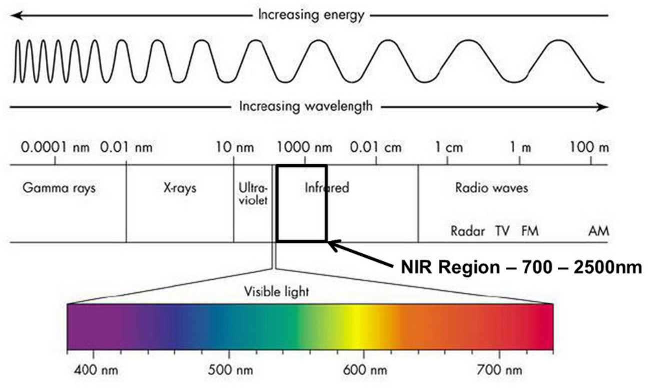


Figure 6, Electromagnetic radiation

Each molecule has its distinct absorption spectrum. The absorption characteristics and spectrum of a material is therefore defined by the composition of the molecules (Davies, 2005).
Due to the NIR absorbing characteristics of human tissue structures, the spectroscopy can also be used to analyse, characterise and distinguish different human tissue and fluids (Jackson & Mantsch, 1999)
Arteries carry oxygenated blood from the heart to the rest of the body, where veins carry blood back to the heart without any oxygen. Veins contain deoxygenated hemoglobin which, has a different absorption then hemoglobin, see the figure below. By utilising the absorption characteristics of oxy- and deoxyhemoglobin, veins and arteries can be distinguished. Also, by comparing to the absorption spectrum of veins and the surrounding tissue, the veins can be identified. For PIVC, veins have do be targeted.

In the optical window of 700 - 900 nm, deoxyhemoglobin has a higher absorption of light than its surrounding tissue. The figure shows the molar attenuation coefficient of several human tissue, which is a measurement of how much light is reduced due to absorption or scattering of photons. In figure 7 it is seen that the level of absorption of light is higher than subcutaneous fat and skin between 700 and 900 nm. It can also be seen that at 950 nm water will absorb nearly 90% of the radiation emitted. Since a human consists of approximately 70% water, the light absorbed by water will interfere with the spectroscopic image and the various tissues can not be distinguished. Hence, the optical window used for imaging will lie between 700-900 nm.

NIR spectroscopy uses a NIR light source and a NIR sensitive camera. The light emitted will be within the chosen optical window. The incident light is then absorbed by deoxyhemoglobin and reflected back by the surrounding tis-

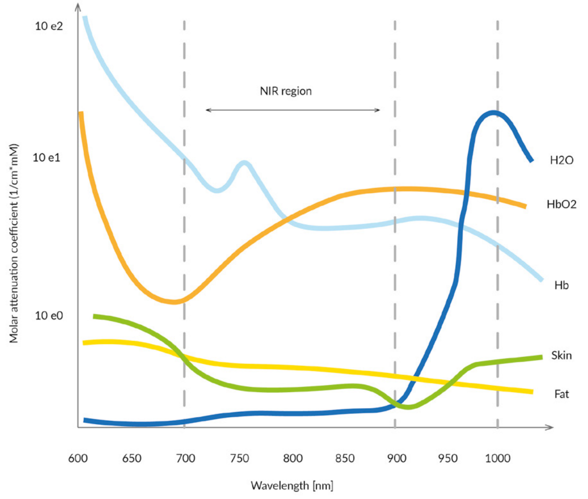
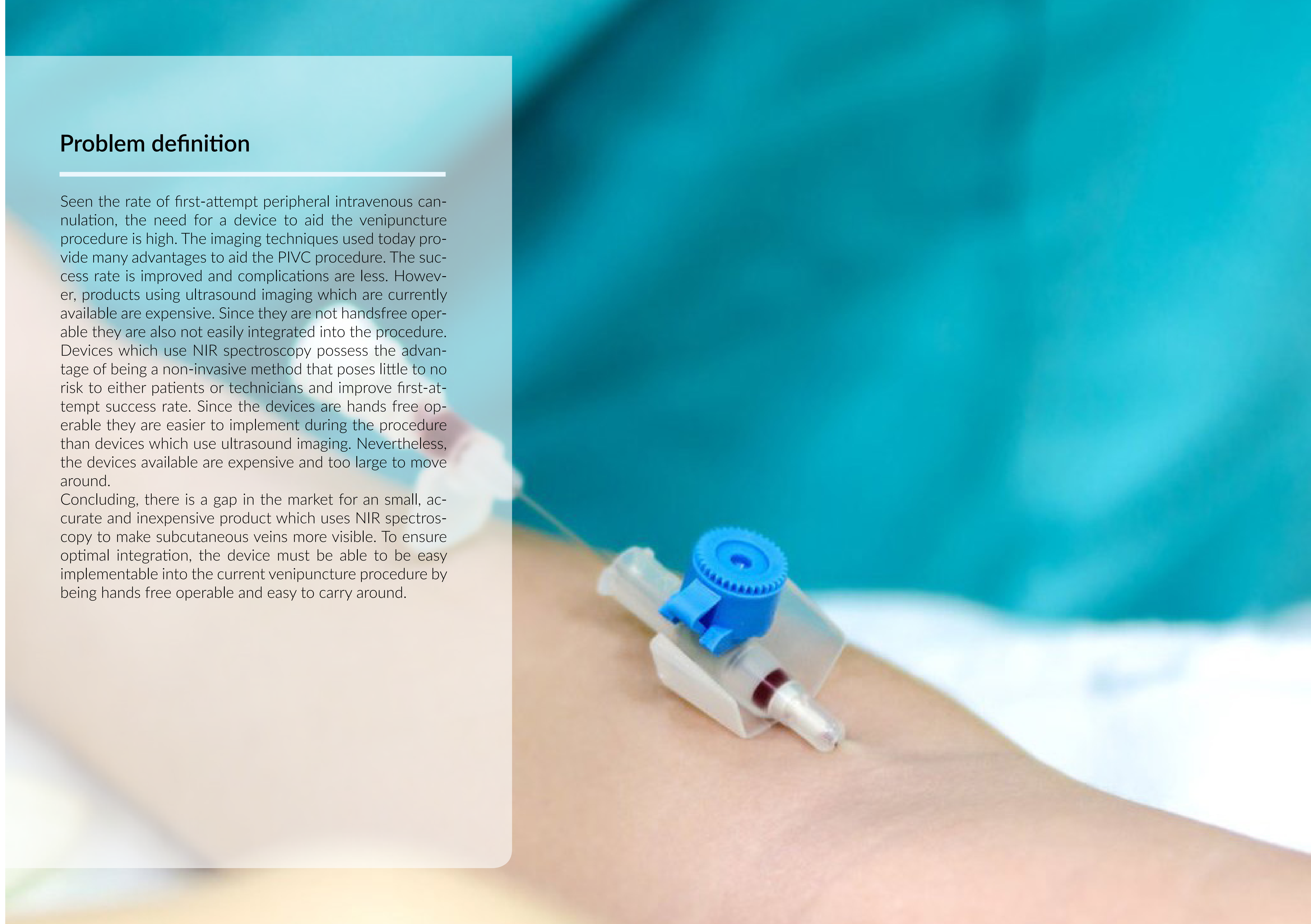


Figure 7, attenuation coefficient of human tissue

sue due to the differing optical characteristics. This reflected light is then captured by a camera. The image captured by the camera shows black where the light is absorbed and white where the light is reflected. The veins can therefore be easily distinguished from the surrounding tissue. [8]

The available commercial devices which use NIR spectroscopy provide a valuable clinical function, however there are still some major issues. The accessibility of the devices is limited by the costs. A single device is priced between 2000 and 26000 euros. The integration of the existing devices is low due to the operating conditions. The devices do not allow hands free operation and some often have to be operated with little surrounding light as possible, which in a hospital setting is not optimal. The products which are handsfree operable have a large stand and are not easy to move around, resulting in non-use. See appendix A.3 for an extensive competitive market analysis.

12. Distinguish veins from surrounding tissue by means of NIR in the optical window 700-900 nm
13. Less expensive than existing products
14. Operable in varying environmental light
15. Easy to move around
16. Easy to implement



Problem definition

Seen the rate of first-attempt peripheral intravenous cannulation, the need for a device to aid the venipuncture procedure is high. The imaging techniques used today provide many advantages to aid the PIVC procedure. The success rate is improved and complications are less. However, products using ultrasound imaging which are currently available are expensive. Since they are not handsfree operable they are also not easily integrated into the procedure. Devices which use NIR spectroscopy possess the advantage of being a non-invasive method that poses little to no risk to either patients or technicians and improve first-attempt success rate. Since the devices are hands free operable they are easier to implement during the procedure than devices which use ultrasound imaging. Nevertheless, the devices available are expensive and too large to move around.
Concluding, there is a gap in the market for an small, accurate and inexpensive product which uses NIR spectroscopy to make subcutaneous veins more visible. To ensure optimal integration, the device must be able to be easy implementable into the current venipuncture procedure by being hands free operable and easy to carry around.

Scope

The product must be able to be used for all skin types and all healthcare contexts. For this, multiple end-users and use cases are within the scope of the project.
The scope covers three opposing use cases. Covering all three use cases, will make sure that the product can be used in every possible case due to the extreme and diverse requirements these three cases give.
The first possible end-users are for instance within the western healthcare context. Here, the product must be able to be used in hospitals, blood donation centers and ambulances. These are use cases where venipuncture is already often performed. Within this context it is important that the product is very accurate, compact and reliable. The second possible end-users are healthcare workers within the african healthcare context. Here it can be placed in healthcare centers and in field hospitals. Within this context the product must be able to detect veins on darker skin since veins are even harder to find on skin with a dark colour. Furthermore, the product has to be inexpensive an not-dependent on electricity. The third use case within the scope is field missions. These entail NGO's and military field hospitals. Field hospitals and NGO's take care of casualties close to battlefield or disaster areas. Within this context, the product has to be robust, easy to carry and with a long battery life.
Concluding, the different use cases have differing requirements for the product. To comply to these opposing use cases a Minimal Viable Product, MVP, will be developed. The the requirements of the MVP are the minimal functionalities which the product needs to have to be viable. This MVP will be a starting point for further development and will be easily adjustable to fulfill the differing needs. The end product of this project should enable first testing of functionalities.

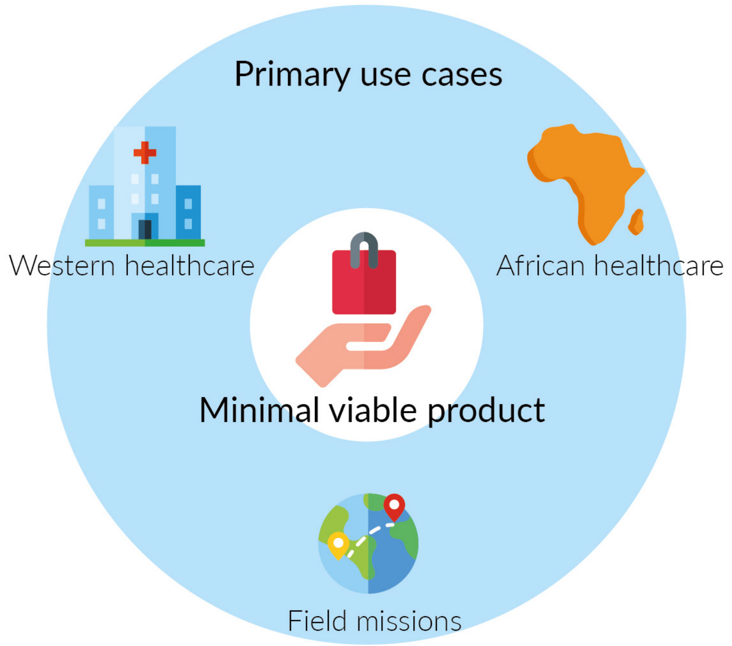
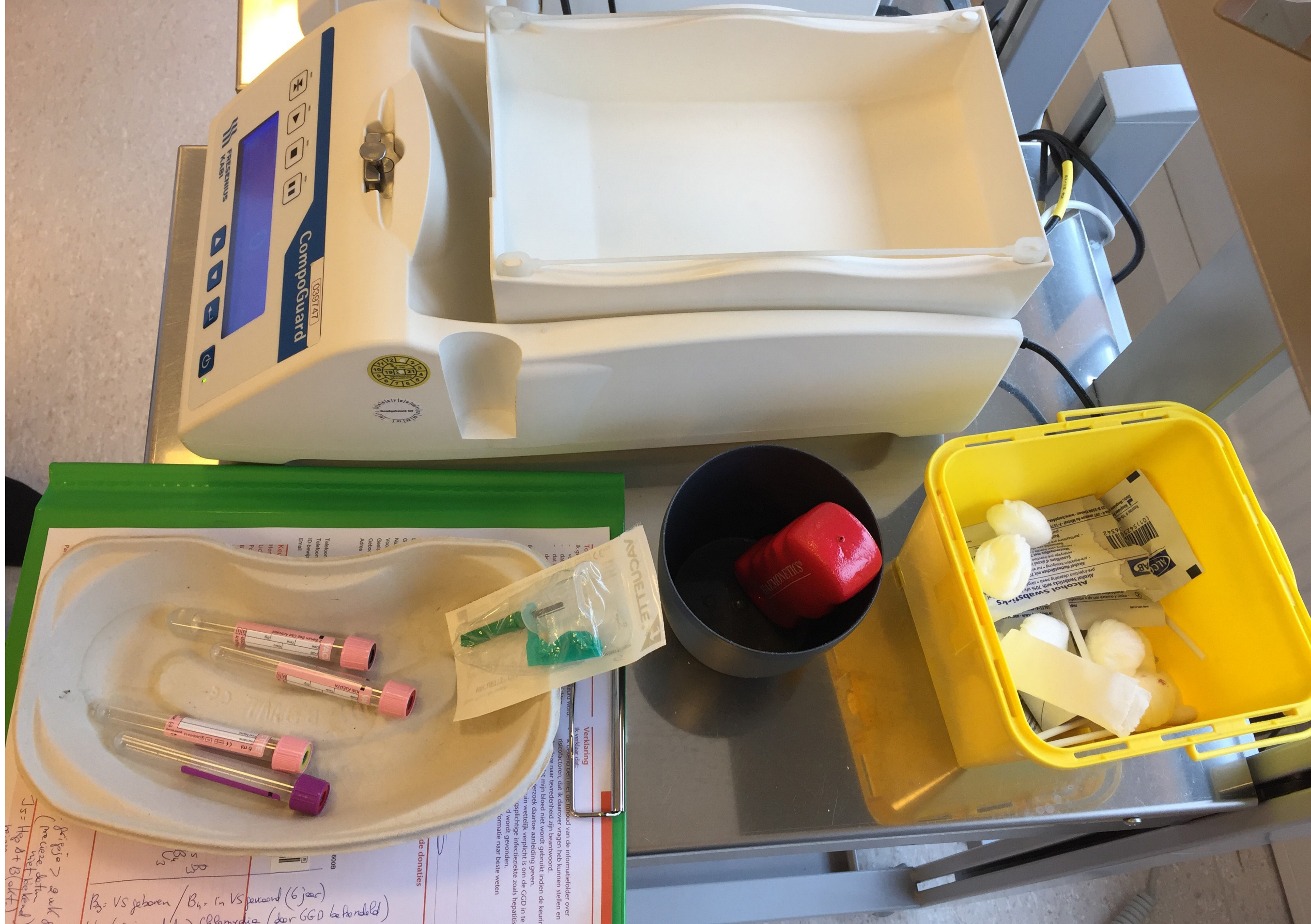


Figure 8, Three opposing use cases to find minimal viable product

17. Used in all healthcare contexts
18. Reliable
19. Non dependent on the mains
20. Robust
21. Long battery life
22. Adjustable to differing needs



Programme of requirements

In this chapter the minimal requirements which need to be met to develop a minimal viable product are stated. The requirements are ordered following the life-cycle of the prototype. The cycle starts with development. Here design, production and verification are of importance. The second step is how the product will be distributed and used. Paragraph C, use is divided into the minimal functionalities of the product. Finally, in paragraph D, the requirements for end-of-life are listed.
At the end of every paragraph, the most important requirements found from the specific research are summarized. An extended Programme of requirements is found in appendix B.

A. Development

a. Design
1. Prototype shows enhanced image of veins through infrared
2. can be used for pilot trial in september
3. is a minimum viable product
4. is suitable for healthcare context
5. can be succesfull integrated into healtcare context
6. is suitable for every age, skin and body type

b. Production
1. Prototype is made out of PLA
2. Model is suitable for 3D printing
3. Material is suitable for medical context
4. Prototype has low manufacturing costs

c. Verification
1. Prototype is tested with end-user
2 Safe to use
3. Prototype quickens venipuncture procedure

d. Components
1. are firmly in place
2. are low cost
3. are off-the-shelf components

e. Assembly
1. Product can be assembled within an hour
2. Product can be disassembled within an hour
3. All steps of assembly are clear

f. Sub assemblies
1. All subassemblies form a single unit
2. All subassemblies are tested by supplier

g. Price
1. Prototype is less expensive than existing products
2. Prototype will be tested during a pilot trial

B. Distribution
1. After pilot trial, the product is distributed via network channels
2. Prototype is distributed in a suitable box
3. Prototype is distributed with charger

C. Use

a. Charging
1. the prototype can be used for a day
2. Charging ports are reachable from the outside
3. Prototype does not depend on the mains (230 V)

b. Carrying
1. Prototype has dimensions of 145*95*50 mm
2. Prototype is lighter than 0,5 kilograms

c. Use flow

1. Positioning
   1. Prototype uses a stand to attach to furniture
   2. Stand can be attached to different furniture in a hospital setting
   3. Stand has a minimum distance of 20 cm from the subject
   4. Stand is adjustable in height to allow for differences in arm size (thickness)
   5. Stand is light weight
   6. Stand is not in front of projection
   7. Stand does not interfere with the procedure
   8. Stand can hold a weight of 0,5 kg without deforming
   9. Prototype is stable when attached to stand

2. Prodecure
   1. It is clear how the device should be turned on
   2. The button does not have sharp edges
   3. The button is operable with gloves
   4. If button is pressed, the script is activated
   5. Prototype has intuitive usage
   6. No training is needed to operate prototype
   7. Interface is easy to understand
   8. Prototype increases first attempt venipuncture
   9. Automatic shut down after 2 minutes of non-use

3. Imaging
   1. Veins are distinguished from surrounding tissue
   2. Near infrared radiation is used for imaging veins
   3. Imaging can be done on differen types of skin
   4. Imaging is done in real time
   5. Camera can image in low light and full light conditions
   6. Camera provides high contrast image
   7. Image is suitable for image processing

4. Processing

   Hardware:
   1. Processor is used which can run digital image processing software
   2. Processor can be programmed and controlled

   Software:
   1. A script is written to enhance the vein pattern from the surrounding tissue
   2. Computational power needed is low to minimise resourc es needed
   3. Software uses algorithms to extract vein pattern
   4. Software can be adjusted for different needs

5. Displaying
   1. Inhanced vein image created is displayed back to end-user
   2. Image displayed has same optical allignment as image cap tured
   3. Image is displayed in real time
   4. Image is projected directly on top of the actual veins

d. Unintentional use
1. Prototype still works after dropping it from 1 meter height
2. Components stay in place when held in every direction

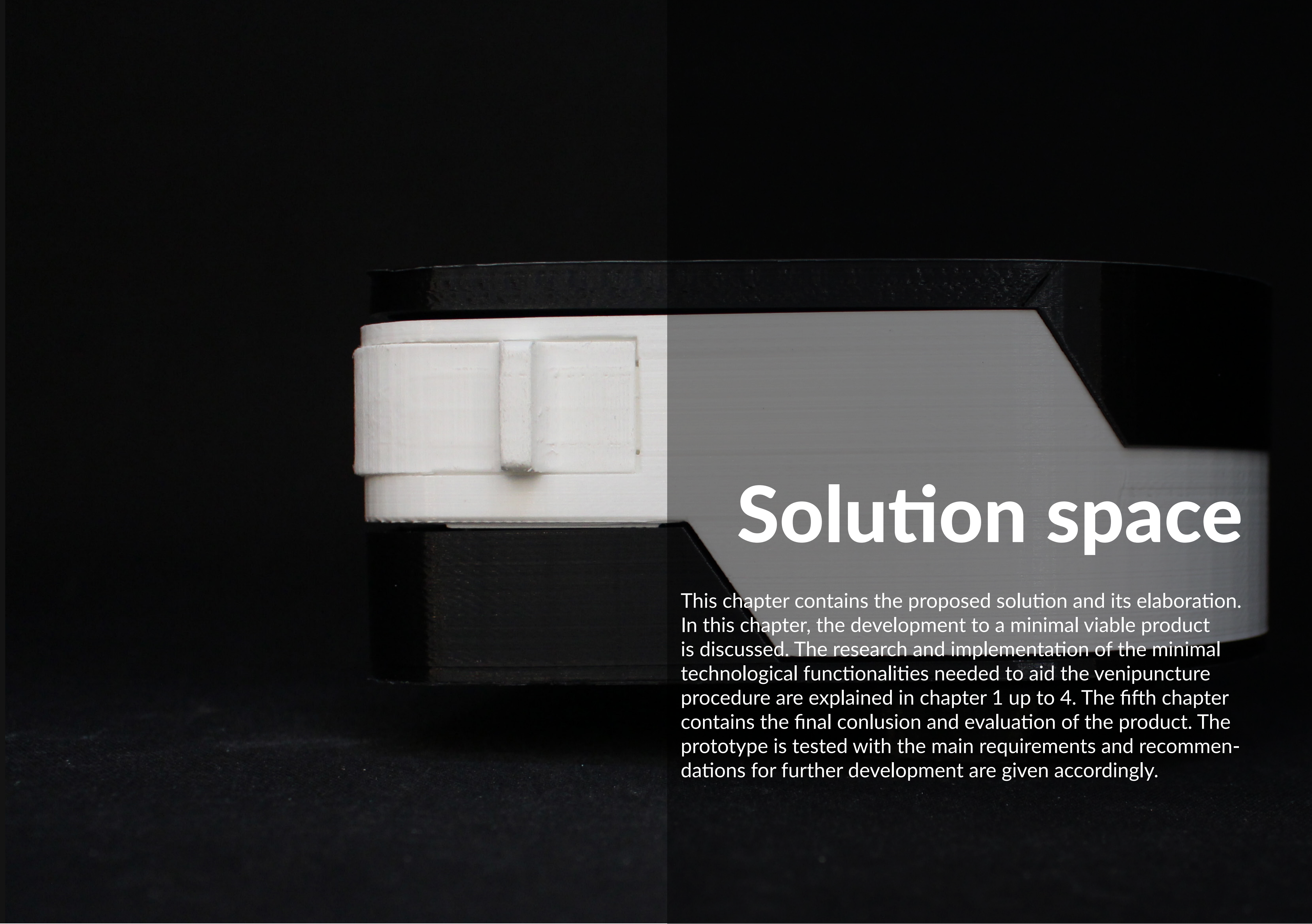
e. Repair
1. Product can be openend to be repaired
2. Components can be taken out and repaired individually
3. Technical manual contains set-by-step repair plan

f. Maintenance
1. Prototype can be opened to reach and replace components
2. Raspberry Pi can be re-programmed to suit differing needs

g. Integration
1. Prototype contains minimal functionalities for it to be viable
2. The minimal viable product can be adjusted to fit into different healtcare contexts.
3. The intuitive use increases integration

D. End of life

a. Recycle
1. All electronic components can be seperated for recycling
2. Plastic casing can be seperated for recycling
3. Nuts and bolts can be seperated for recycling



Solution space

This chapter contains the proposed solution and its elaboration. In this chapter, the development to a minimal viable product is discussed. The research and implementation of the minimal technological functionalities needed to aid the venipuncture procedure are explained in chapter 1 up to 4. The fifth chapter contains the final conlusion and evaluation of the product. The prototype is tested with the main requirements and recommendations for further development are given accordingly.

Proposed solution

To respond to the design challenge of the need for a product to aid the venipuncture procedure, the Veindicator is developed. The Veindicator has the ability to hands free and accurately, detect and visualise peripheral subcutaneous veins in real time. This product uses near infrared spectroscopy imaging technique to enhance the visibility of superficial veins so that it can be easily distinguished from surrounding tissue. Using near infrared light, provides the ability to image beyond the visible range of light and therefore to acquire more information as veins show up in near infrared light.
To create the highest quality image the contrast between the veins and surrounding tissue needs to be as high as possible. For this purpose, illumination with the same wavelength as the absorption of deoxyhemoglobin is used. Looking at the optical absorption window, a light source will be used with a wavelength between 700 - 900 nanometer (nm) within the electromagnetic spectrum. Light in this optical window is absorbed by veins and the surrounding tissue will reflect the light back, which increases contrast. This image is then captured by a near infrared camera, resulting in a digital image with a negative picture of the vein pattern.
To eliminate the effect of daylight, a longpass filter is placed in front of the camera. The longpass filter blocks all (visible) light up until a wavelength of 650 nm, assuring the near infrared light, reflected back from the hand into the camera, to pass.
The near infrared light, which has passed the filter into the camera, creates an image. This image is processed by a small, affordable single board computer, a Raspberry Pi (RPi). To achieve low scanning errors, the captured image must be noiseless. Therefore the RPi contains an image processing programme with various algorithms, which digitally enhance the vein pattern. This digitally processed image is then projected back onto the subjects' skin by a DLP Lightcrafter Display, a low-cost digital light processing display evaluation module. Due to the projected enhanced vein image, the nurse can easily gain venous access.
To differentiate from existing products and to ensure optimal integration into the context, off-the-shelf components are used, making the development of this product manageable. Due to its hands free operation, the device is also better implementable into the venipuncture procedure. The straightforward operation and intuitive use increase integration into the healthcare context and will assist medical staff without extensive training needed.

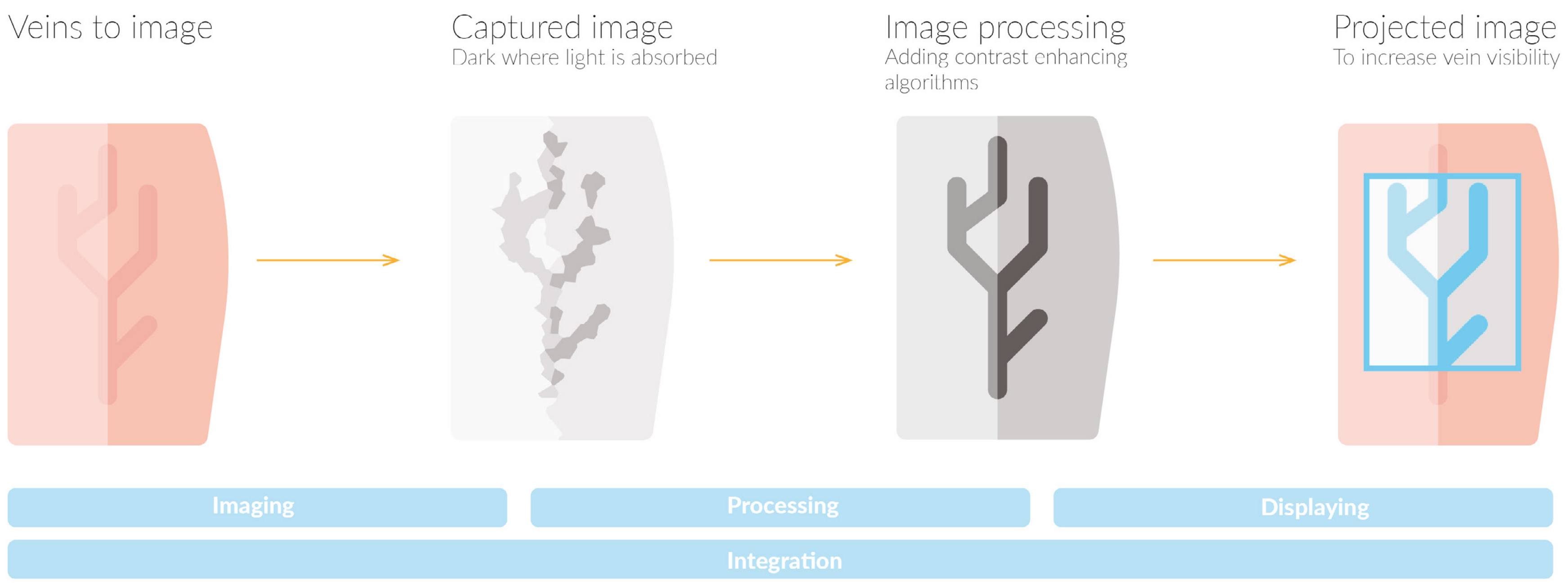
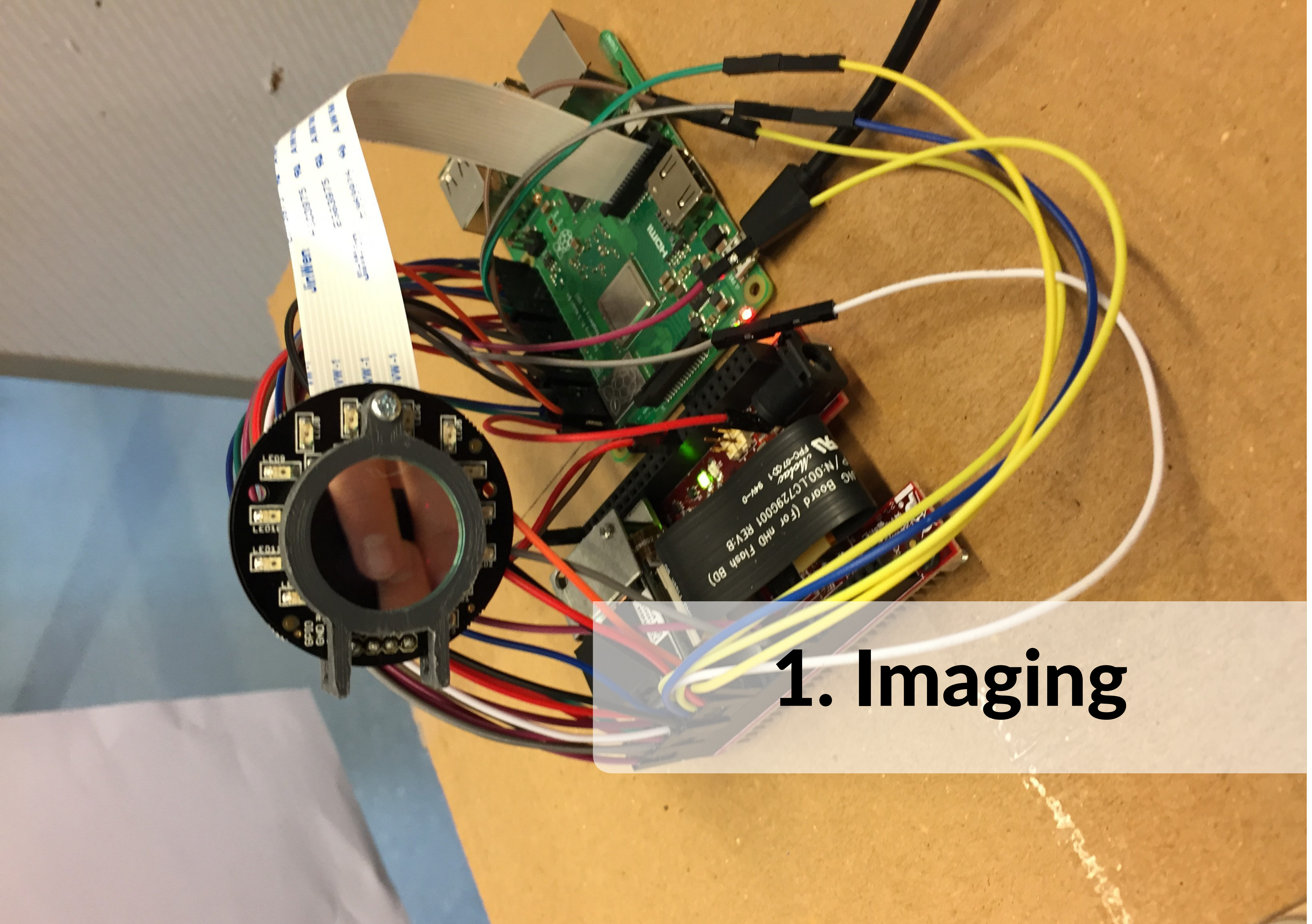


Figure 9, Development process

The main principle of the solution is to create and display an enhanced image of the patient's subcutaneous vein pattern. An enhanced image is a high contrast image in which the veins are easily distinguished from its surroundings, giving the end-user an optimal indication for the location of the veins. The process of giving the user an optimal indication of the vein location is subdivided into four themes; imaging, processing, displaying and integration. This chapter elucidates on these four themes.
The first key steps in the process of generating this high contrast image, are acquiring and capturing the image. Paragraph 1, imaging, discusses the principles used to capture an image of the area. For this, suitable hardware and optimal illumination are of great importance. By optimising these two, less image processing is needed, resulting in a reduction of computational power. This leads to the second phase of the process, processing.
Within this theme, it is discussed how the captured image is further modified to enhance contrast by using algorithms and a single board processor.
Paragraph 3 discusses how this further modified image is then displayed back to the user. For the proposed solution, the image is returned via a micro projector onto the subject.
And finally, paragraph 4, integration, elucidates on how interaction, context and embodiment are optimised to ensure optimal integration.



1. Imaging

To distinguish veins from surrounding tissue several methods were used. Veins contain deoxyhemoglobin(Hb), which absorb a significant part of light at a wavelength between 700 - 900 nanometer (nm) in the Near Infrared (NIR) spectrum. NIR spectroscopy extends the visualisation beyond the visible spectral range. It allows the study of spectral phenomena, which is not observed by the human eye. NIR spectroscopy is explained in paragraph 1.1 of this chapter. To be able extract the effect of NIR from the image, a filter is added to the setup to block the visible spectral range. The method to reduce environmental light influences are clarified in paragraph 1.2, Near-Infrared spectroscopy. To further enhance the contrast of the vein pattern and the surrounding tissue acquired in paragraph 1.1 and 1.2, the exposure of NIR is increased. This method is described in paragraph 1.3, Increase contrast. By applying the previously mentioned steps, the veins are distinguished from the surrounding tissue in a high contrast image. The image is captured and thereafter used for further processing, explained in chapter 2, Processing.

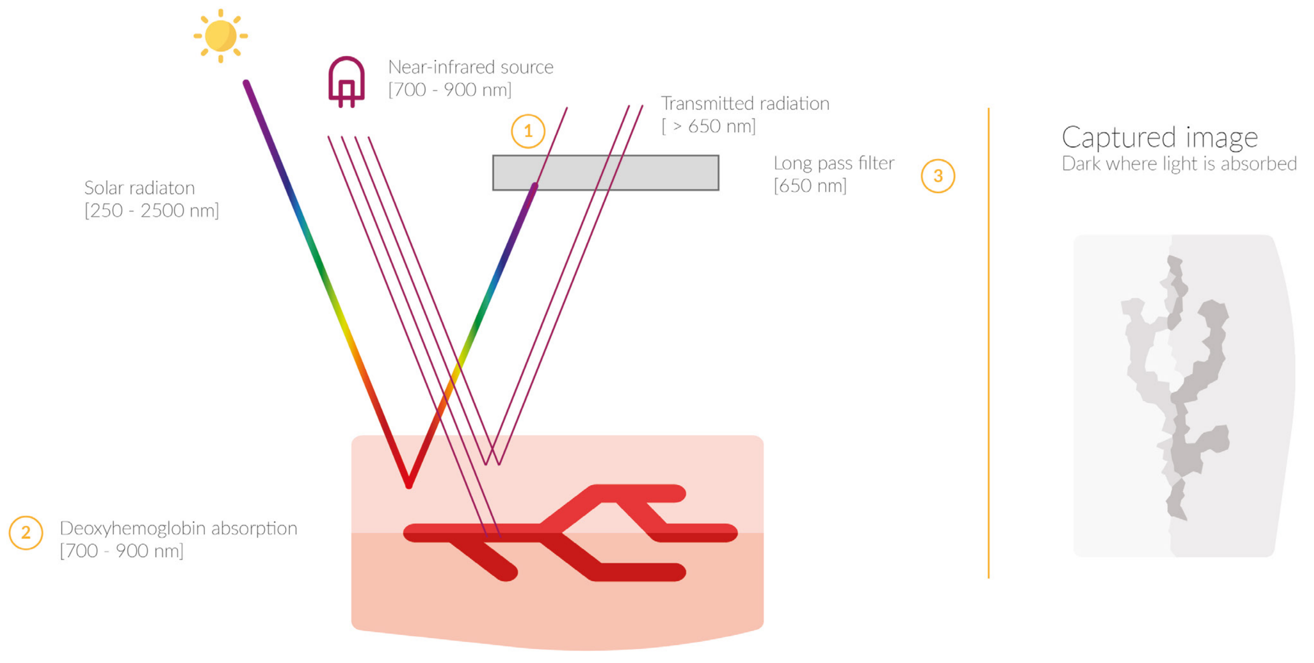


Figure 10, Imaging process

1.1 NIR absorption by deoxyhemoglobin

1.1.1 Analysis

Radiation can be used for major medical benefit, with minimal costs and risks. Radiation applications used are MRI, CT, X-ray, and ultrasound. When dosed correctly, with minimal invasion, much internal medical information is gained. The most common medical procedure for radiation application is the use of X-rays, a type of radiation which passes through the skin. The radiation does not have enough energy to pass through structures denser than skin, such as bones, thus will cast shadows. These shadows are then detected on a photographic film. Most X-rays have a wavelength between 0,01 and 10 nm, see figure 12 for examples of medical appliances within the electromagnetic spectrum.

Another application of radiation imaging is Near Infrared (NIR) Imaging. The use of NIR for imaging is a non-invasive solution. Similar to the X-ray, the NIR penetrates the skin and subcutaneous fat. NIR can penetrate up to several centimeters into human tissue due to a combination of reduced scattering and absorption compared to light in the visible spectrum. The depth of NIR penetration depends on the photonic energy of the light and the absorption characteristics of the specific tissue, (Miyake et al., 2006) see figure 13. In elaboration 3.1.1, more background information about NIR is found.

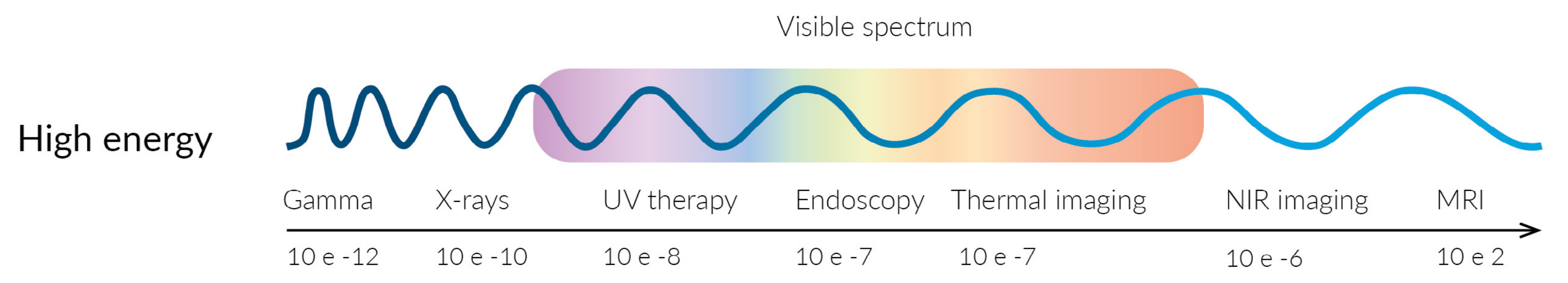


Figure 12, Radiation energy

1.1.2 Synthesis

The absorption characteristics of several human tissues have been researched in the optical window of NIR [700-900nm] (Crisan & Tebrean, 2017), see figure 14. The figure shows the molar attenuation coefficient of several human tissue, which is a measurement of how much light is reduced due to absorption or scattering of photons. Arteries contain oxyhemoglobin (HbO2) and veins contain deoxyhemoglobin (Hb). In the figure is seen that the attenuation coefficient of veins is higher than surrounding tissue at a wavelength between 700 - 900 nm. This has as effect that NIR is reflected by the skin and subcutaneous fat and scattered in all directions, while absorbed by deoxyhemoglobin.(Miyake et al., 2006)
The scattered light is reflected back from the subject into a camera with a NIR detection range. The NIR is absorbed by deoxyhemoglobin and so reproduce as dark. Hence, the image is reflected back from the subject is a negative image of the vein pattern.
It can also be seen that at 950 nm water will absorb nearly 90% of the radiation emitted. Since a human consists of approximately 70% water, the light absorbed by water will interfere with the spectroscopic image and the various tissues can not be distinguished. Hence, the optical window used for imaging will lie between 700-900 nm.

1.1.3. Evaluation

In the optical window of 700 - 900 nm, deoxyhemoglobin has a higher absorption of light than its surrounding tissue. To distinguish veins from surrounding tissue, the NIR absorption characteristics by deoxyhemoglobin will be addressed. Scattering of surrounding tissue and the high absorption by veins will allow for an enhanced vein pattern to so, aid the peripheral intravenous cannulation and reduce complications.

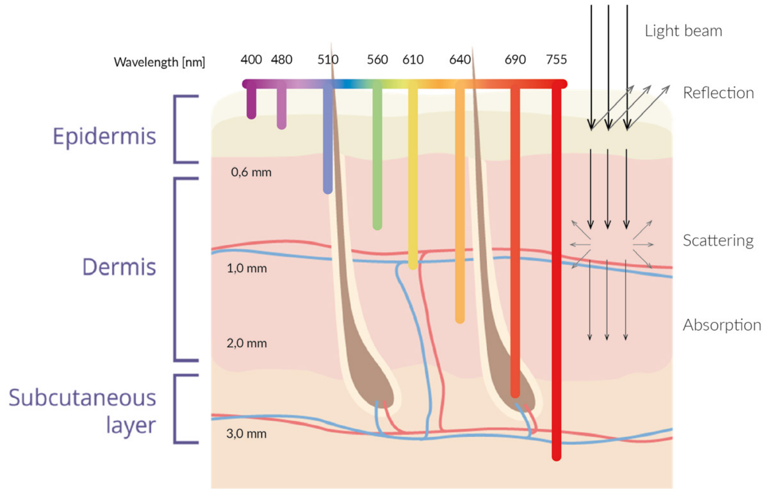


Figure 13, Absorption and scattering characteristics of human skin

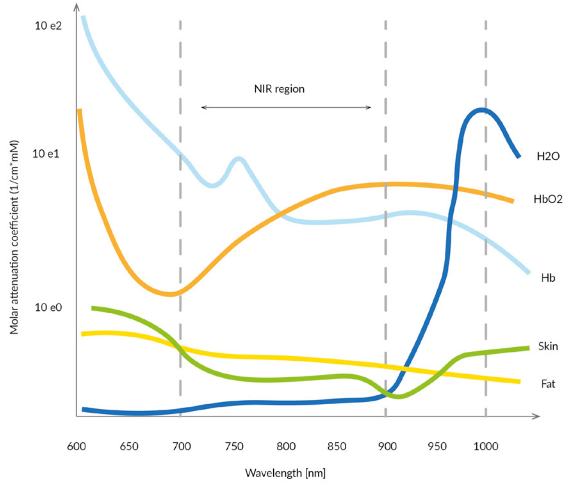


Figure 14, Attenuation coefficient human tissue

1.2 Near Infrared spectroscopy

1.2.1 Analysis
Near Infrared (NIR) spectroscopy extends the visibility beyond the visible spectral range. It allows to visualise spectral phenomena which are not observed by the human eye by showing the image created by the NIR spectrum, (Mangold et al., 2013), see figure 15.

1.2.2 Synthesis
In modern photography, the near infrared spectrum of incident radiation is blocked by an infrared cut-off filter on cameras to match the appearance of the photographs to the human visual experience. If removing the filter, near infrared light is also in the incident radiation spectrum, and will therefore be captured by the camera and change the appearance of the resulting image.
Near-infrared spectroscopy uses light within the region of the electromagnetic spectrum of infrared light, from 700 to 1000 nm. A sample is exposed to radiation and absorbs a part of the photonic energy from the emitted radiation. The absorption of light is then measured. After which, the transmission and absorption of photons within the infrared spectrum is analysed. The intensity and the spectrum of the frequency which is absorbed is analysed and from this information a particular substance which is present can be determined. The NIR spectroscopy is a non-invasive method used to perform medical and physiological diagnostics.
To be able to only see the effect of near infrared spectroscopy, a filter is added t block the visible spectral range. The images underneath show the difference between normal and infrared imaging.


Figure 15, Images with and without the effect of near infrared

1.2.3 Simulation
To be able to only see the effect of near infrared spectroscopy, optical filters have been researched matching the spectral signature of the radiation source to reduce environmental influences. Optical filters have the technical property of controlling the spectral content of a light beam. By applying such filter in front of the camera, only infrared light will pass through. For this application, a longpass filter with a cut-off length of 650 nm is used. 1.1.2. Synthesis

A film of an image sensor which is sensitive to visible as well as infrared light is used. For this specific application, the Raspberry Pi NoIR camera module is used. This camera does not have a infrared filter built in, which means it can acquire images in the spectrum from 350 - 1100 nm with a resolution of 8 megapixels. Besides capturing the whole spectral range, the module also converts the analogue information gained to digital data, which can be used for image processing, see chapter 2: Processing.

Different optical filters were researched to block visible light, see elaboration 3.1.2. The main requirement of the optical filter is that it has to block light below the spectral wavelengths of near infrared, allowing it to pass. A long-pass filter with a cut-off length of 650 nm is used for this application. This filter is used to exclude low wavelengths that are not required. This filter removes all unwanted wavelengths from the desired cut-off point and it transmits the higher wavelengths. See figure 16 for specifications.

1.2.4 Evaluation
The first image in figure 17 shows an image created without a filter placed in the previous mentioned set up. The second image shows an image with the filter placed in front of the NoIR camera. Comparing the two images, the monochrome image has a higher contrast. However, in terms of better vein imaging it will be more beneficial if the veins would have gained even higher contrast with surrounding tissue. The low contrast in the image can be explained by the quality of the filter. Optical filters are expensive because of the time, knowledge and expertise that is needed for manufacturing. The filter used is an inexpensive filter. Inexpensive filters have transmission and reflection rates which are not 100% precise and do not have a perfect cut-off. To improve the contrast a more expensive filter. can be implemented. More expensive filters have a more accurate cut-off and a higher transmission and reflection rate.
A second explanation for little contrast is the amount of NIR which is subjected to the hand. Solar radiation contains NIR light, the effect of this NIR is seen in figure 17. To further increase contrast, the amount of NIR which is transmitted to the skin can be increased. This is further researched in paragraph 1.3.

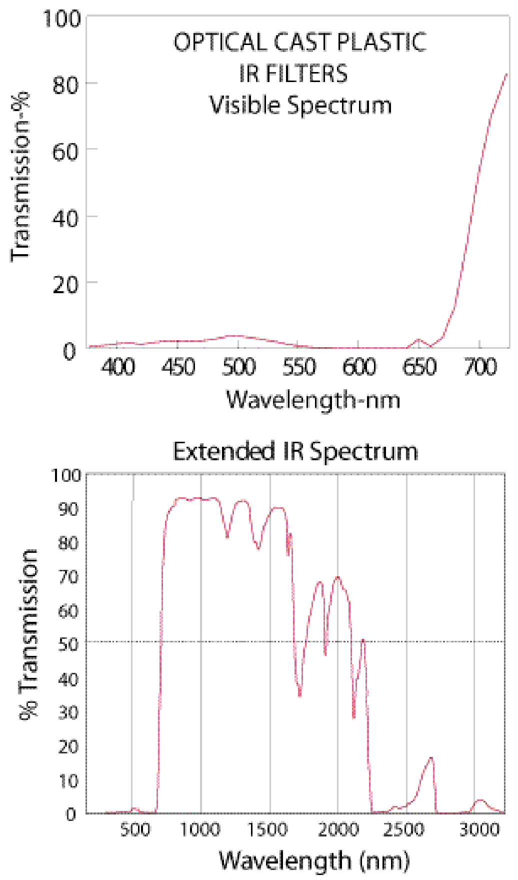


Figure 16, Optical characteristics NIR filter


Figure 17, Images with and without effect of NIR

23. Image suitable for digital image processing
24. High contrast between veins and surrounding tissue

1. Research other cameras
2. Research higher quality filters

1.3 Increase contrast

1.3.1. Analysis

To aid the venipuncture procedure, the veins have to be clearly distinguished from its surrounding tissue. As stated before, to achieve this the NIR absorption characteristics of human tissue are researched. By targeting only NIR which is transmitted from solar radiation, the image in figure 17 is created. To further increase contrast in the image, the absorption of deoxyhemoglobin should be increased.

1.2.2 Synthesis

To increase absorption, the veins must be exposed to more NIR to amplify the absorption characteristics of veins. To achieve this, illumination within the optical window of 700-900 nm is needed, see appendix C. Within this window, the attenuation coefficient of deoxyhemoglobin is higher than its surrounding tissue, increasing contrast leaving a darker reproduction where the veins are located, (Crisan et al., 2017). For this application, NIR LEDs within the optical window of 700 - 900 nm will provide this needed illumination. Three sets of LEDs will be tested to determine the most effective wavelength. Thereafter, the power of the LEDs will be adjusted. By differing the power supply, the light intensity also changes and therefore the absorption characteristics. After the optimal intensity of the LED array was determined, an electrical circuit was developed to recreate the parameters, see elaboration 3.1.3.

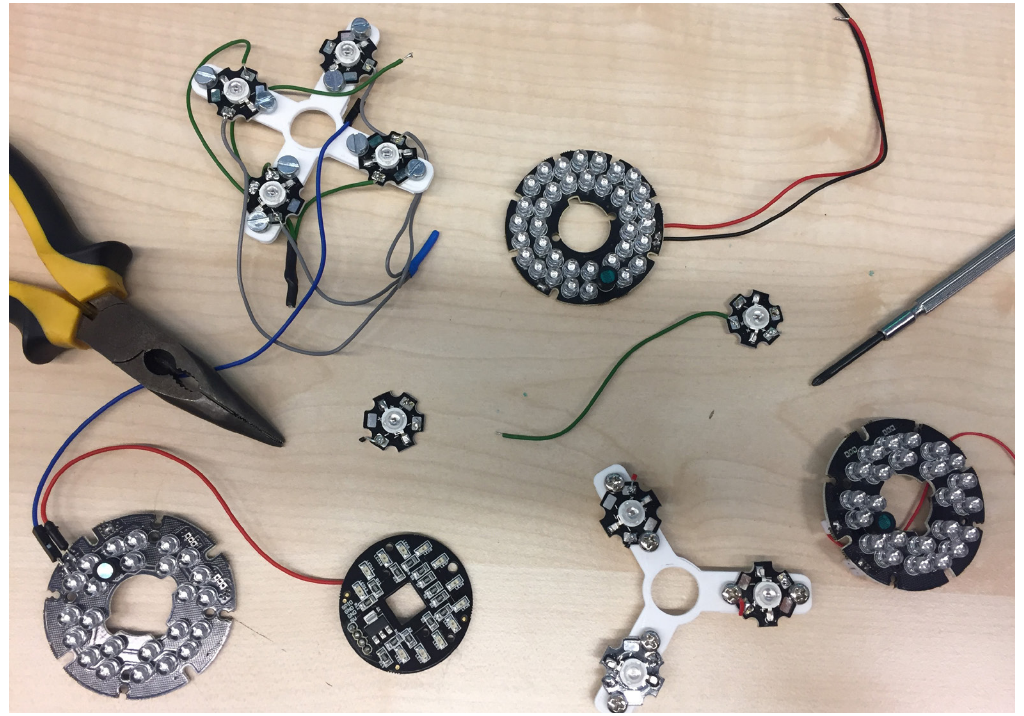


Figure 18, Different types of LEDs

1.2.3 Simulation

Three different LED arrays with wavelengths in the optical absorption window of deoxyhemoglobin have been looked into, varying from 750, 850 and 950 nm.
These light were then subjected to a differing power supply from 0, 50, 100% of their input voltage. The images in figure 19 were all taken by the same environmental lightning conditions and with the same test subject.

1.2.3 Evaluation

Looking at the three different set-ups, veins are clearly more visible than when no LEDs are used. It can be seen for all three set-ups, that by increasing intensity, the contrast in the image also increases. From the three options, the 850 nm LED array creates the highest contrast image, which are used for further development.

3. Enquire exact LED transmission characteristics
4. Further optimise LED setup; amount, distance, arrangement of LEDs

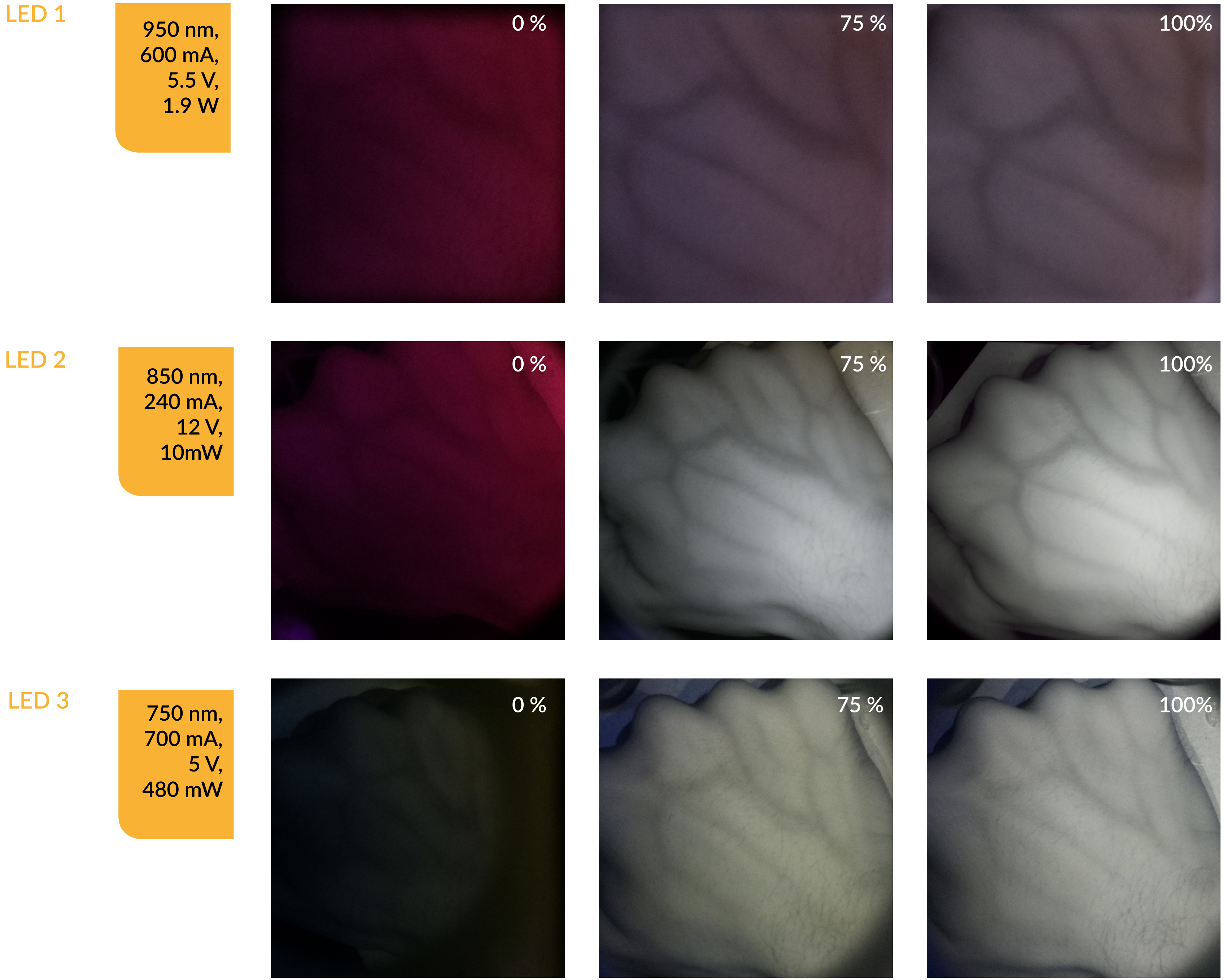
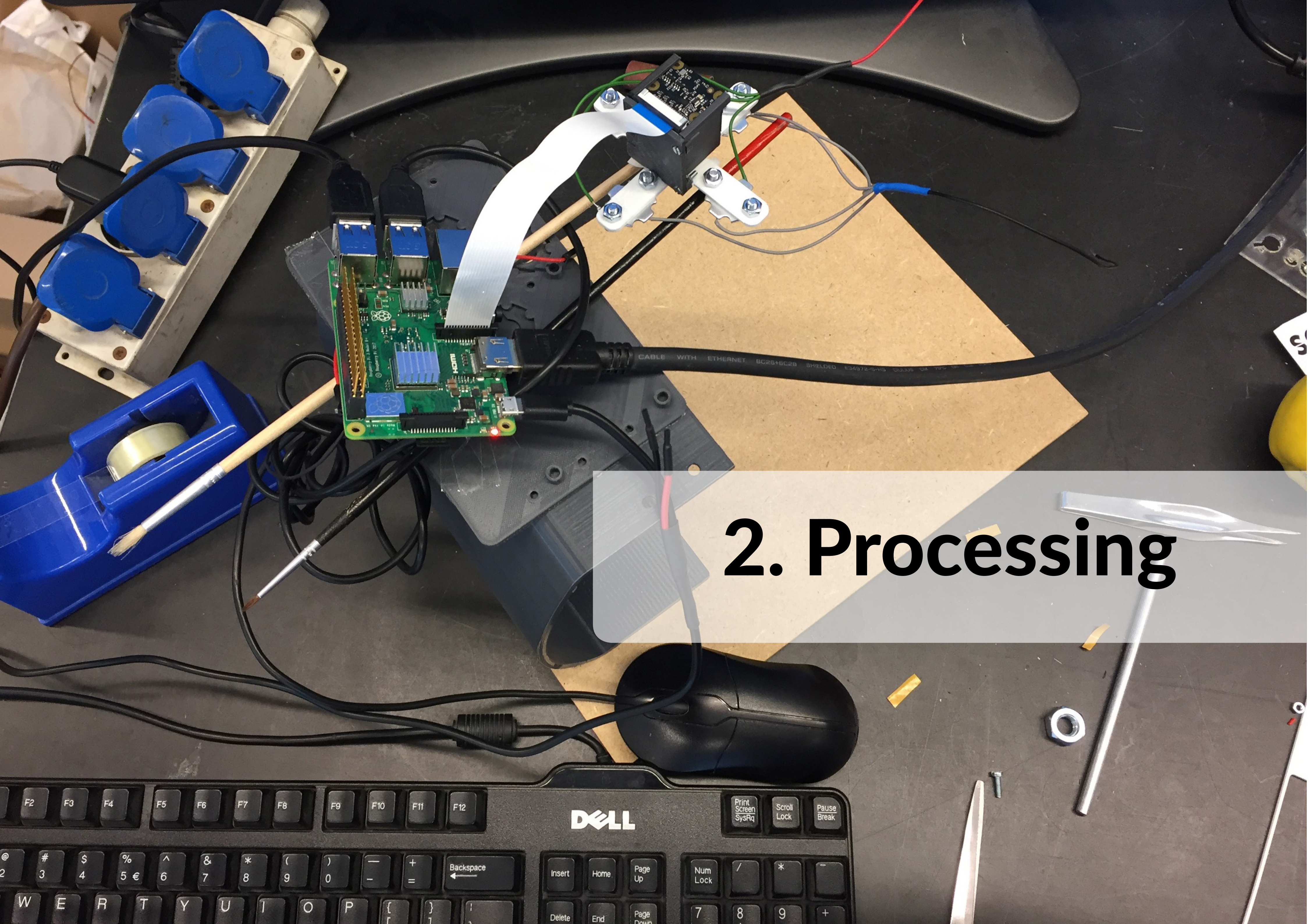


Figure 19, LED test results



2. Processing

2.1 Digital image processing

To aid the venipuncture procedure, an image with high contrast between the veins and the surrounding tissue is needed. In the previous chapter it is described how to use the absorption characteristics of deoxyhemoglobin to accommodate high contrast.
This chapter explains how the captured image in chapter 1 is further modified to enhance contrast by using algorithms and a single board processor. Digital image processing algorithms are implemented to extract the vein pattern. Extracting the vein pattern from the subject allows the next step of the process, displaying, which is discussed in chapter 3. The algorithms written use simple yet accurate processing techniques to keep computational needs to a minimum.

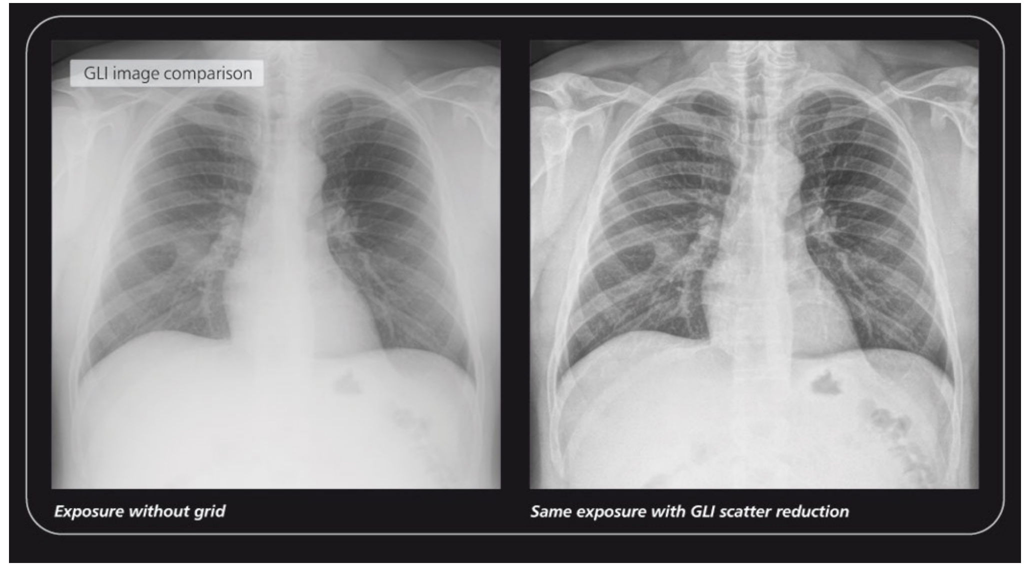


Figure 20, Results of noise reduction and contrast optimisation

2.1.1 Analysis

Figure 19 in 1.1.3 shows the imaged vein pattern after exposing the subject to NIR. To enhance the image further, software is implemented. By adding software, several digital image processing algorithms can be applied to the digital image to create an enhanced image useful to extract better vein location information. Digital image processing uses computer algorithms to adjust the image conforming to the needs, (Tailor, 2011). Examples are noise reduction and contrast optimisation, see figure 20.

Digital image processing has many advantages. Implementing software can decrease hardware needed for similar functions. A wide range of algorithms can be applied that can decrease noise and signal distortion. Digital filters can be used to blur and sharpen the captured image without the need of adding more hardware. Also the software can be easily adjusted to the different needs of the end-users. Thus, to further enhance contrast of the capture image digital image processing is implemented.

2.1.2 Synthesis

To realise image processing, suitable hardware is needed. The software programmed is supported by a central processing unit, and the processor executes the instructions provided by the code. The latest Raspberry Pi (RPi), model 3b+, is chosen for this purpose. An RPI is a low-cost and high-performance computer on which self-written software can be implemented. The small single board computer contains a central processing unit (CPU) an on-chip graphics processing unit (GPU) and a 1,2 GHz 64-bit quad core processor. See elaboration 3.2.1, for more detailed documentation on the hardware used. On this single board computer, the digital image processing software is performed. This software contains algorithms and can be run to enhance contrast further digitally.

The algorithms applied will process the image using localised dark regions to identify the locations of veins. First, the background will be subtracted from the image, which will create a region of interest. Subsequently, contrast increasing methods are applied, which enhance dark areas where the veins are positioned. To create a more realistic structure, a thresholding method will be used as well. After these thresholded dark regions, will be transformed into green to give a clear indication of the location of the veins as will be described in chapter three: Displaying, see Appendix D for the software background research.

2.1.3 Simulation

The steps followed in the software are:

/ HSV. An object with a certain color can be detected by adding an algorithm to change the image's hue, saturation and value (HSV). The HSV values are varied until the arm which needs to be detected is in one colour.

/ Masking. The HSV image acquired in the previous step is the region of interest for the software. In the image this region should be isolated from the background. By masking the image, all pixels which are not pink are set to a background value. The pin pixels are set to non-zero. Therefore, the arm shape is identified.

/ Foreground detection / background subtraction. After masking, the foreground is detected and the background is removed to create the region of interest. The white pixels are identified as foreground and everything else will be seen as background.

/ Canny - Edge detection. After the background is subtracted, the edges of the arm are defined. This is accomplished by applying edge detection. The algorithm identifies points at which the image brightness clearly changes. These points are organised into a set of curved line segments, and then combined into a contour pattern. Edge detection is fundamental in image processing for feature detection and extraction. (Das, 2016)

/ Dilation. The arm shape created in the previous step is probed and expanded in this step. Dilation uses structuring elements for this. The effect on the image is that the boundaries of the region of interest is clarified to so have more tolerance.

/ Discrete sine transformation. This is a method which smoothes the object boundaries. The dilated image has got very sharp edges. By applying a discrete sine transformation, the objects boundaries are smoothed.

/ Gray level transformation. This method will convert the colored image to a grayscale image. A grayscale image will have a two dimensional function which allows for image enhancement.

/ CLAHE (contrast limited adaptive histogram equalization). CLAHE is an image processing technique used to increase contrast in images. This adaptive method redistributes the lightness values, each corresponding to a distinguishable section of the image. The two dimensional image created in the previous step is improved in contrast by locally increasing definitions.

/ Red Green Blue Alpha (RGBA). This is a method to supplement the colors with a fourth channel, alpha. Alpha indicates the opaqueness of each pixel. By including RGBA, the image can be combined with other images.

/ Convert black to green. The alpha compositing allows for an extra image to be combined to the captured image. With this method, the obtained black color can be changed to green. By changing the black to green, a clear indication of the vein location is given.

/ Thresholding. Thresholding is a method of image segmentation where a specific intensity is selected, after which each pixel with the same or greater intensity can be replaced. This allows for selecting an area to be converted into another colour.

By applying all these steps, a vein pattern can be found which is showed by the color green. See elaboration 3.2.2 for a more detailed software script.

2.1.4 Evaluation

Figure 21 shows the steps taken for vein pattern extraction. The final image shows the combination of all the algorithms and distinction between the veins and the surrounding tissue.

In the last image it is seen that the boundaries of the arm also show up as green. For future use, the screen which is captured should have a fixed size. When the area is limited to the middle of the arm, the boundaries of the arm are not seen anymore.

By having a fixed screen size, there will be less background noise and the algorithm values can be optimised and the image created will be more accurate.

Currently, the illuminating intensity and the distance between the arm and the camera have to be altered to get an optimal image. Ideally the product will be able to automatically focus at every distance and automatically change light intensity for every type of environmental light. This will ease operation and will always create an optimal image.

Finally, for optimal integration, the software has to be tested with users with different body hair and skin types. Presently, the software is optimised for light skin with little body hair.

25. Digital processing for further enhancement

5. Further calibrate software
6. Fixed screen size
7. Automatic focus and illumination adjustments
8. Test with different skin and body types
9. Implement hair removal software

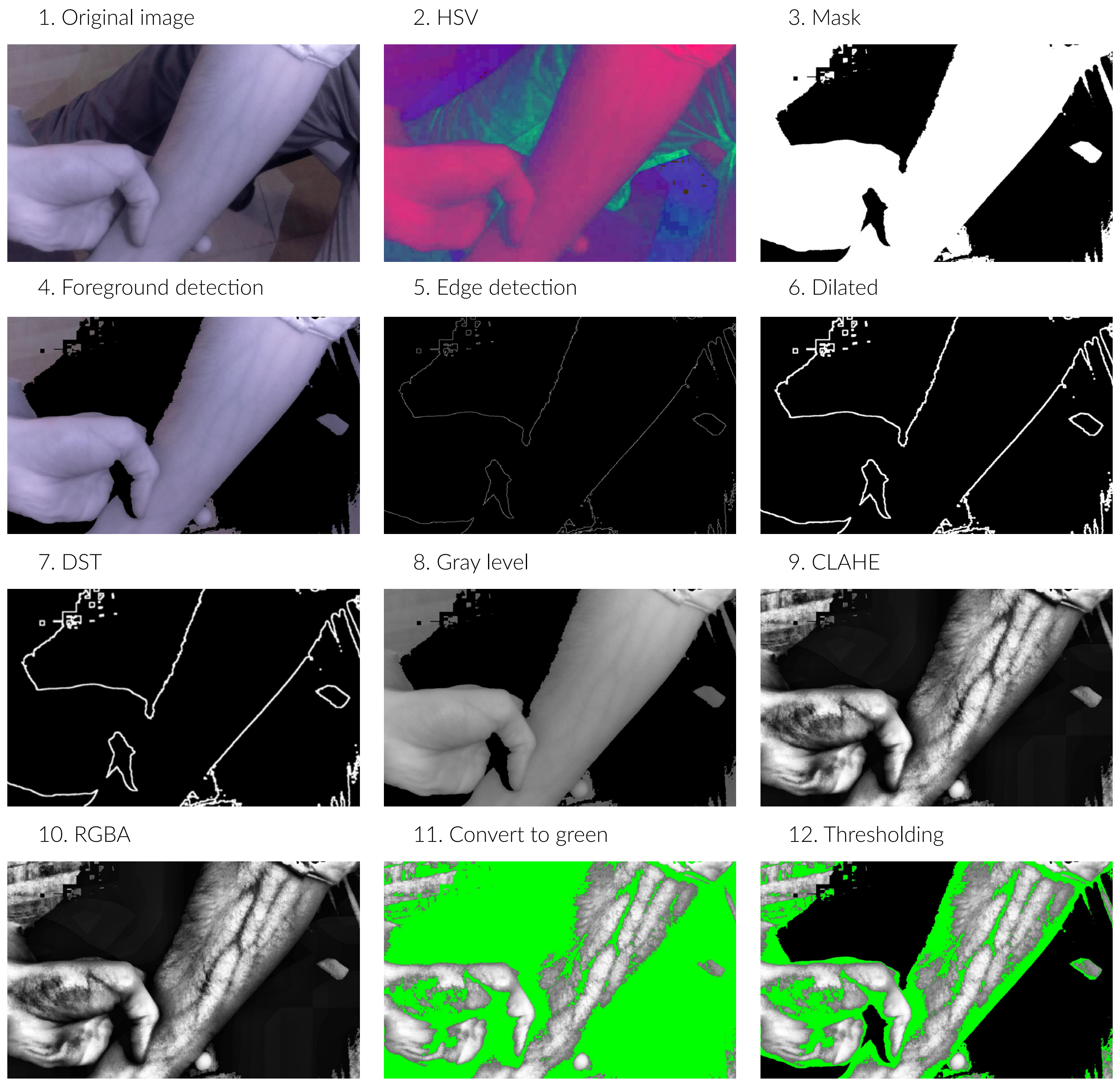
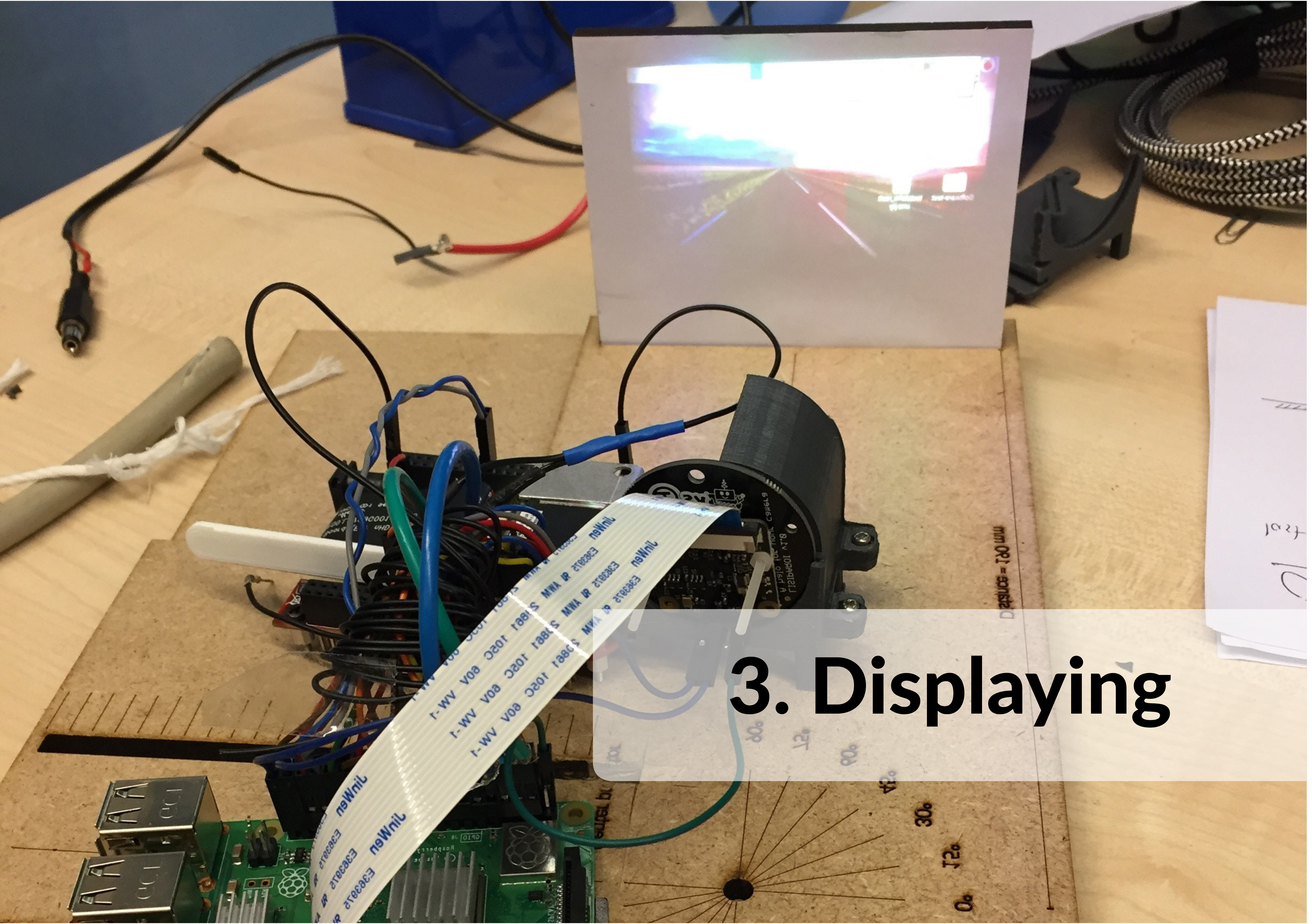


Figure 21, Software process steps



3. Displaying

3.1 Projection

The previous chapters described how to extract a contrasted image of the vein pattern. To make the product useful for the end-user during the venipuncture procedure, the extracted vein pattern must be displayed back on the subject. This chapter describes the research and steps taken to project the vein pattern back to the end-user.

3.1.1 Analysis

After gaining an extracted vein pattern image with optimal contrast, the image in chapter 2.1.3 has to be returned to the end-user. By displaying the image back on the skin, the product will show the user an enhanced vein pattern which will help by locating a suitable vein for the venipuncture procedure. This will aid the nurse and increase first-insertion success.

3.1.2 Synthesis

The image created by the methods explained in the chapters: 1. Imaging and 2. Processing is displayed back on to the skin. This is achieved using a Digital Light Processing-lightcrafter evaluation module. This is a micro projector which is a low-cost platform, enabling the use of digital light processing technology with an embedded host processor. The benefits of using this module are that it is ultra mobile because of its size, it is programmable and it enables processing through the Raspberry Pi. For more technical specifications, see elaboration 3.2.1.

The most important requirement of the projected image is that it is displayed directly on the same position as the actual veins. For this, it needs to have the exact same magnification, rotation and translation as the actual veins. Therefore, what the camera captures and the projector displays need to be in perfect optical alignment (Zeman et al., 2008). For perfect alignment, the elements should be placed according to the theoretical, optical and mechanical design requirements.

3.1.3 Simulation

In order to achieve perfect optical allignment, a research set-up has been made. In this setup, all of the components used for displaying are put together. Afterwards, they are configured to find perfect alignment. See elaboration 3.3.2 for more details on the research set up.

If the camera and DLP are placed next to each other, the field of view will not fully overlap, and keystone distortion will occur. Keystone distortion is the effect of deformation of an image which is caused by projecting it onto an angled surface, creating a trapezoid shape projection, see figure 22.

Thus, to acquire optical alignment, the hardware needs to be placed differently. For the same field of view, the projector and camera have to be in a 90 degree angle. To reflect the light beams of the projector onto the same surface, a mirror is placed in between see figure 23. This allows for identical field of views with the same optical alignment.

To suit the requirements in 1.1, and also the requirement of the projector and camera being in a 90 degree angle, a beam splitter is used. A beam splitter is used to block light below a certain wavelength and instead of absorbing, the beam splitter reflects the light above that wavelength, see elaboration 3.1.2 for more details. Thus, the projected light (which is in the visible spectrum) will be reflected from the mirror onto the skin and the NIR light which reflects back from the skin passes through to the camera, see figure 23.

The beam splitter used is a cold mirror. Cold mirrors feature a multi-layer dielectric coating optimized for more than 95% reflection of visible light and more than 90% transmission of IR wavelengths, Reflecting the entire visible light spectrum and efficiently transmitting infrared wavelengths, see figure 24. Cold mirrors are designed for an incidence angle ranging from 0 - 45 degrees. For the application of the Veindicator, a cold mirror with an incidence angle of 45 is used, allowing a 90 degree angled setup between camera and DLP.

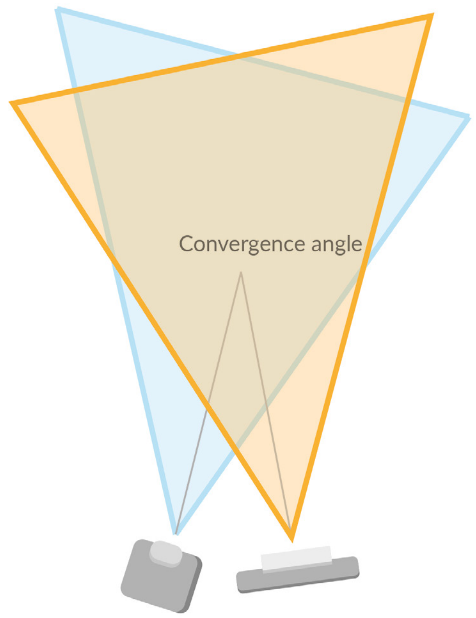


Figure 22, Keystone distortion

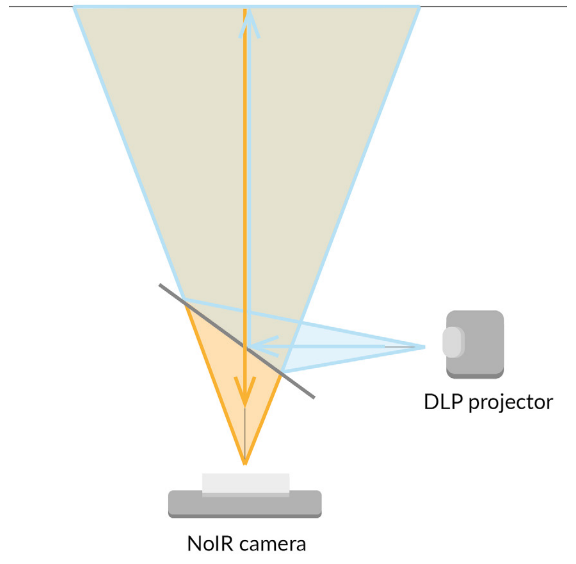


Figure 23, Optical allignment

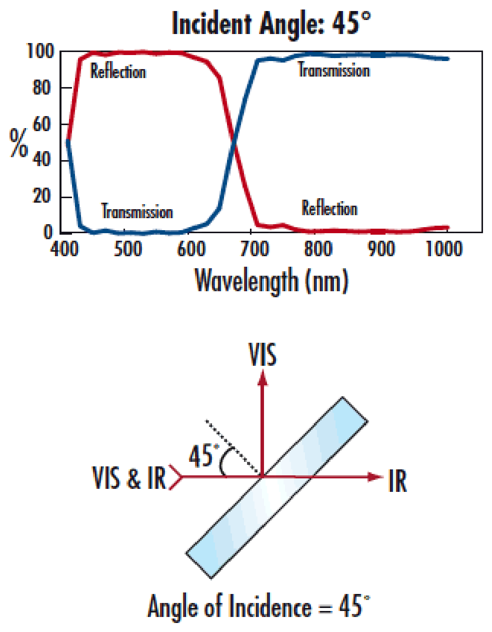


Figure 24, Cold mirror specifications

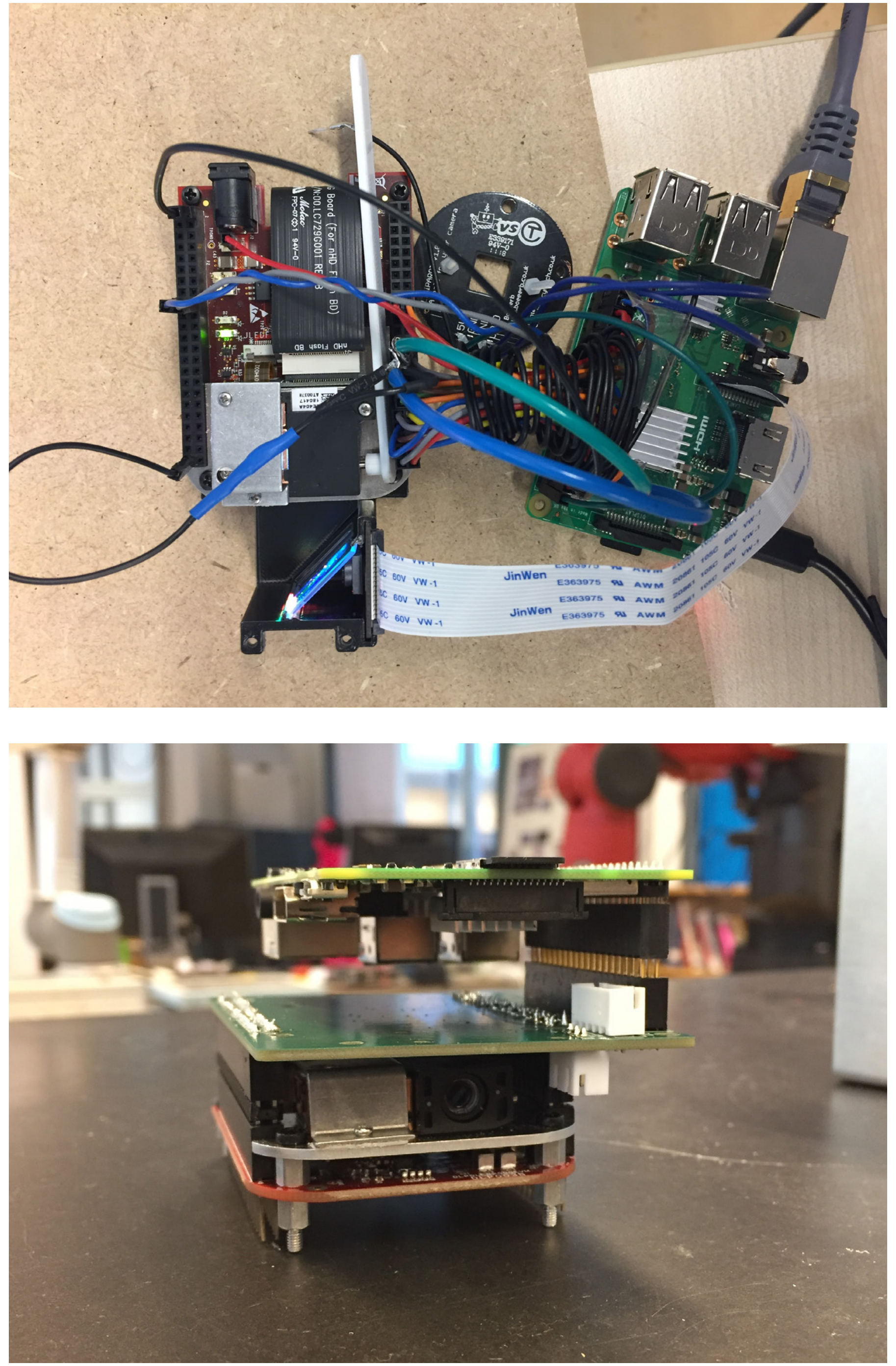


Figure 25, Integration of PCB

3.1.4 Evaluation

After setting the DLP with the RPi, it showed that the image projected contained a lot of optical noise due to connectivity issues. To solve the connectivity issues, a printed circuit board (PCB) design has been made. A PCB electrically and mechanically supports electronic or electrical components using conductive paths, tracks and other features etched from multiple layers of copper. These tracks are laminated between or onto sheet layers of a non-conductive substrate. A PCB ensures a clearer projection onto the surface by decreasing the connectivity errors. The implementation with previous wiring and the PCB integrated setup can be seen in the pictures below. The electric wire setup and explanation can be found in elaboration 3.2.2. Besides connectivity issues being solved with the implementation of a PCB, also the space is optimised. The wiring is replaced by a thin board and the components can be stacked on top of each other, see figure 24.

During realtime projection, the camera captures the projected image, leading to optical resonance. Resonance occurs when the frequency which is periodically applied is equal to the natural frequency of the system. This causes oscillation with ever increasing amplitudes. This optical resonance creates too high intensity for the camera to capture, leading to a electrical shutdown of the system. (Liu, 2017)

A possible cause can be that the cold mirror used in the system has a 95% reflectance within the 400 - 650 nm range and 90% transmission within the 750 - 1200 nm range. The light which is now projected is within the whole visible spectrum, i.e. the light which is projected is not optimally filtered out and interferes with the camera. A way to avoid this resonance is by programming the DLP so it projects in light which is 100% blocked by the cold mirror. For this a wavelength around 500 nm which corresponds to green, can be used. This still needs to be solved.

Finally, there still has to be looked into projection and vein alignment. Software can be added to ensure that the image is projected on top of the actual vein location. A possible method is to add four dots, each in a corner to the projection. By capturing an image of these dots, the average distance between them can be measured, and from that the magnification and rotation with respect to the projected image can be determined. If the camera image and the projected image overlay exactly, the average distance between the dots would be zero and thus there will not be a rotation angle between the images (Zeman, 2005), see appendix D.

26. Project image back to user
27. Vein pattern projection on exact actual location

10. Improve PCB design to the amount of current running
11. Reduce optical resonance by testing different wavelengths of projected light.
12. Research how to project on the same location

4. Interaction

This chapter will elaborate on all aspects which need to be optimised in order to create optimal integration. The extent of integration determines the competitive success of the product. For this specific case, the product is integrated within three main areas; interaction, context & technology.
In the first paragraph, it is found how the prototype is developed to fit into the healthcare context. The value of a product is determined by customers. Customers have different values which respond to differences in their contexts. How they value a product depends on the personal contexts where they use the product. The degree of context integration will increase the value of a product in its context (Nemoto et al., 2015).
The second paragraph contains the methods and techniques applied to create an effortless meaningful interaction between the user and the prototype. An effortless way of operating the device will increase customer satisfaction and facilitate easy integration.
The technological integration is worked out in the last paragraph. Technological integration is the well-integrated use of the technological resources such as the working principle, product architecture and its technological requirements into the daily practices to achieve better product performance. Translating technological research and design into products is important to satisfy the market's needs, ensuring competitive strength of the product.
These three aspects of integration will enable the user to operate the product naturally, maximising customer satisfaction (Person, 2007).

4.1 Context

4.1.1 Analysis

A minimal viable product complies to all minimal functionalities for a product to be viable. The minimal technological functionalities are described in chapter 1,2,3 of the solution space. Besides technological functionalities, the product also has to comply to contextual functionalities. In this case, the product has to answer to medical requirements of contexts in which the product will be used. These second, more subjective set of requirements are the ones set by the different use cases. By collecting insights from the different contexts and its user, the overlaying minimal context functionalities can be found.

4.1.2 Synthesis

To find the minimal contextual functionalities, the method of context variation by design will be applied. This method is useful when addressing large scale of end-users. It states that by early research into the requirements of the different use cases, a shared solution space can be created (Engelen et al., 2019). This shared solution space will contain the collective requirements which will be met by the prototype. After, the specific requirements of the specific use cases can be met by small alterations of the device. By taking the different use cases into account from the start, a more adaptable and adaptive integrated product architecture can be developed. For this analysis, different cases in western healthcare and healthcare in developing countries healthcare are taken into account.

4.1.3 Simulation

In chapter 'scope, all the primary use cases and their secondary use cases are clustered. To find the minimal contexual functionalities, these primary use cases were researched uand after the essential characteristics were listed and ranged to importance. Subsequently, limiting characteristics were combined into a shared solution space and from that, one central product architecture is designed. In figure 24 the main technological and contextual requirements are listed.
In elaboration 3.4.1 the context variation by design research is found.

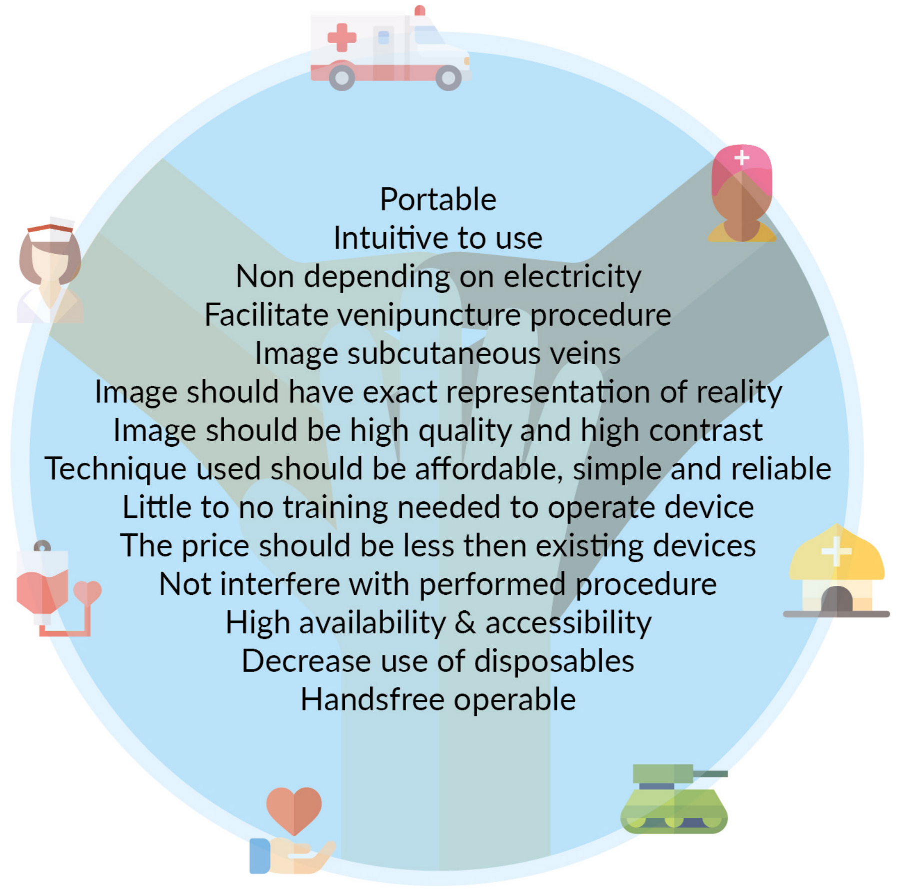


Figure 24, Solution space requirements

4.1.4 Evaluation

The first common requirement which was found, is the efficacy of vein pattern extraction. When designing a medical device, the product has to be 100% accurate and the users will need to trust the product. For this, the technical working principle of the prototype is optimised on software and hardware to the highest extent which was possible in the given limitations.
The second requirement is the importance of the portability of the device. If the product is to be used on a field mission or by paramedics, there is not much extra space for medical devices. Also, in the western context, the device is meant as a pocketable device which healthcare workers, whom have to perform the venipuncture procedure, always carry on them. To comply to this requirement, the device has been optimised in space and weight. Only components required for the minimal functionality were used and the components are tightly put together to reduce space, see chapter 4.3 for more details.
Thirdly, to ensure maximal context integration, the product has to be understood in each use case. For this, intuitive interaction is of high importance. This will contribute to high product accessibility. The way of interacting is context dependent. The consumers background, education level and knowledge of technology depends on their individual context. Since intuitive interaction is of such high importance, to facilitate high understandability in these different contexts, interaction tests have been conducted, and functionalities have been reduced to only the necessary, see chapter 4.2.
For the development of the device, the technology and components used should be affordable and reliable. For the western context, this requirement is not of high importance. However, for the african context this is one of the most important requirements because the lack of resources. So to comply to the different stakeholders, the product abides by this requirement. Later, functionalities can be added when the product is altered for a specific context.
To comply to all the different use cases, the most important requirements have been listed and one shared solution product architecture for the device has been created. To merge these requirements into one single product does not exclude any final context design. Small iterations can make the MVP suitable for every specific user case. For further development, this however still needs to be done.

28. Intuitive to use - effortless interaction
29. Adaptable integrated product architecture
30. High understandibility

13. Further optimise for space and weight
14. Research how to adapt MVP to specific user cases

4.2 Interaction

4.2.1 Analysis

The first step of optimising integration is to create an effortless meaningful interaction between the user and the design. If product is understood directly by the context specific user the competitiveness of a product is improved. An effortless interaction will increase customer satisfaction which is a means to increase new product success. (Gruner & Homburg, 2000)

4.2.2 Synthesis

To optimise interaction, a test has been conducted to acquire the most intuitive and prefered interaction of the end-users with the product. A hypothetical interaction has been made to test the responses of users. The test was conducted among 10 students from different disciplines, ranging from the faculty of Industrial Design Engineering to the faculty of Electrical Engineering, Mathematical and Computer science. In this test the students were given various assignments to test the interaction and usability. The objective of this test is to find factors to optimise the hypothetical interaction for intuitive use. The factors which will improve the user operation, can then be combined into an preferred interface, see appendix C.5. Subsequently, the students' preferred interface and operation was tested by the actual end-user. The aim of this test was to add the factors and functionalities needed by the end-user and make an extra iteration to create an optimised interaction.

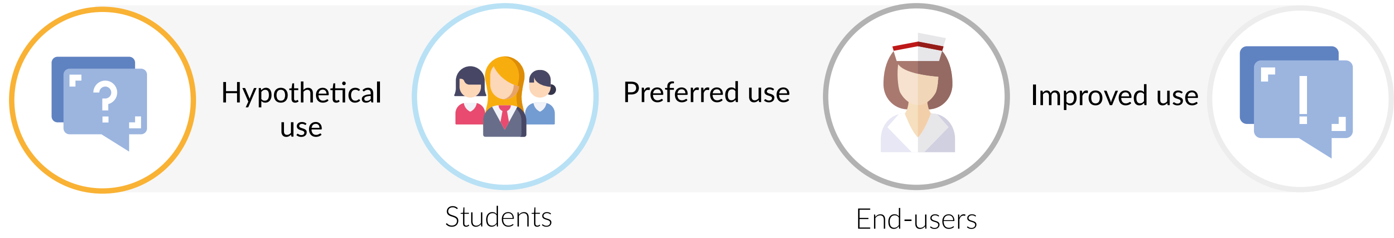
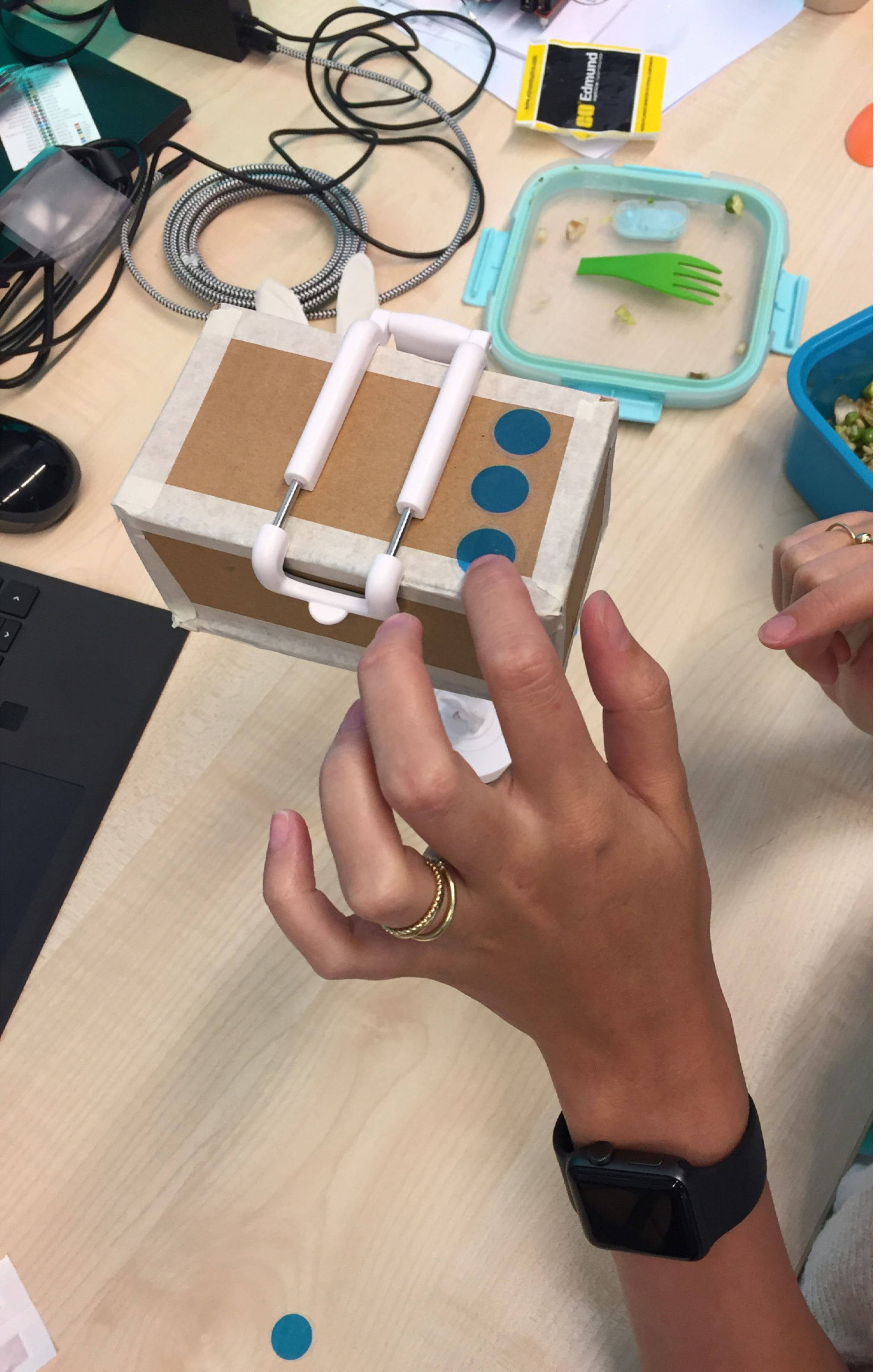


Figure 25, User test set up



4.2.3 Simulation

To find the intuitiveness of use, the Veindicator was given to test subjects. Without giving any explanation, the student subjects were asked what their expected function and use of the prototype would be and how to operate the device, see appendix C.3 for the research setup. After explaining the main function of the device, the test subjects were given a task to give functionalities which they thought were needed to operate the device. Subsequently, they had to assign several knobs to these functionalities and place them anywhere on the product where they preferred.
For the second test, the students were given a hypothetical use with three buttons. The students had to come up with a critical function for the buttons to operate the device. The function and way of operating of the buttons were not given in advance. While proceeding, images were shown, replicating the working and technological interaction of the prototype. These findings, led to a preferred interaction.
The students preferred interaction was then tested with the actual end-users. This research also started with the expected functionality and use of the prototype by the end-user. Secondly, after explaining the functionality, the same task as the students of operating the device, was conducted, leading to the preferred interaction of the medical experts.

4.2.4 Evaluation

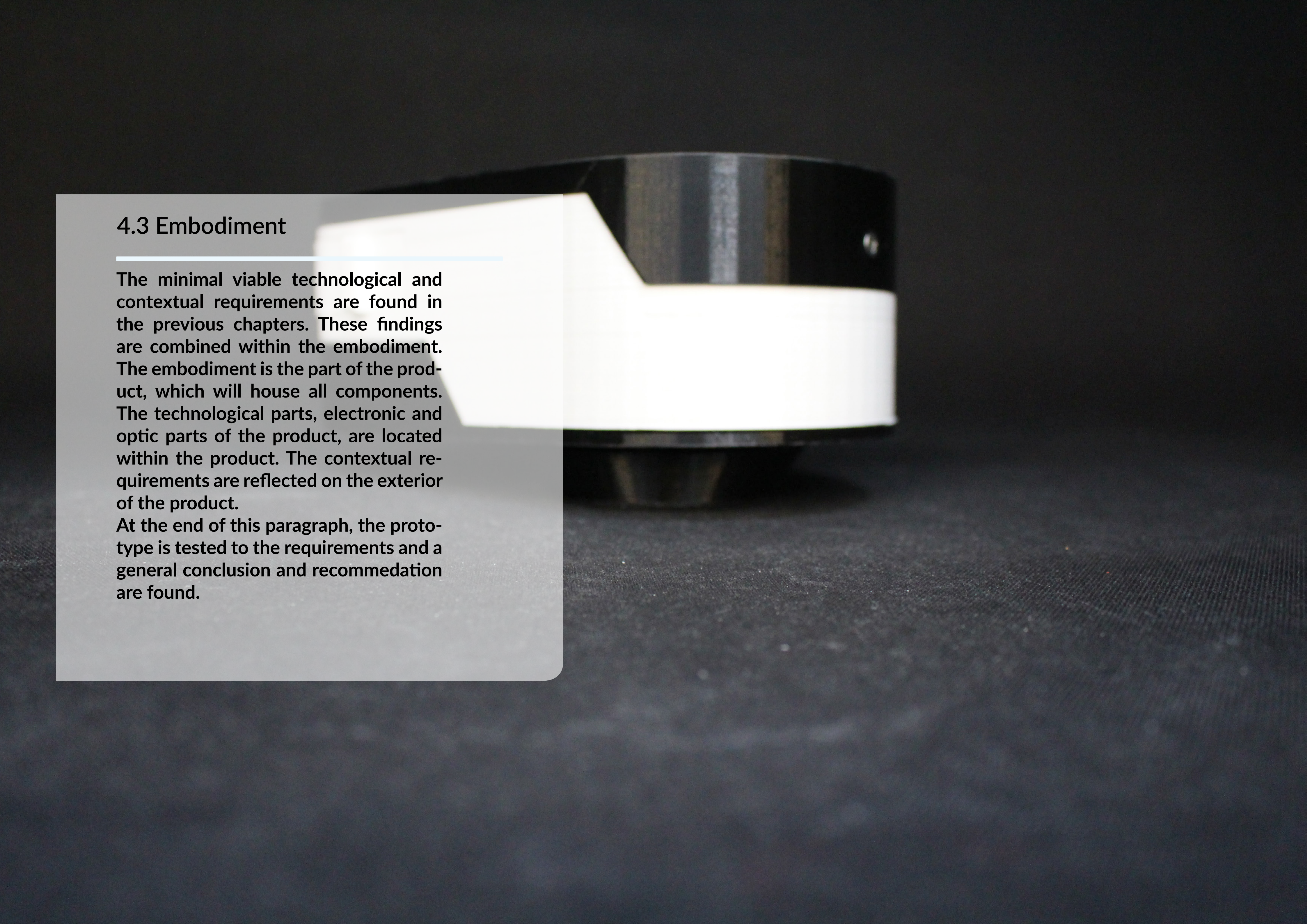
The student research showed that the hypothetical functionalities of the product were not clear and from only seeing the device, it was not clear how to operate it. Secondly, the research showed that the students preferred a straight-forward interaction. The essence of the device is to increase first-stick success to so lower time and resources needed. Thus, the functionalities should be reduced to only the necessary. Therefore the functionality in the final prototype is limited to one button which, when activated, directly starts scanning.

From the end-user research was found that extra information given by the device should be as little as possible. While using the device, the nurses only want to receive information about the location of the veins. For this, it is decided to not project additional information and only to project the vein pattern back onto the skin.
Secondly, it should be ensured that the device will in no case obstruct the end-users view or space needed for the venipuncture procedure. Furthermore, for maximal integration, handling the device must be optimised. The buttons should be operable with gloves and placed on top, so they are reachable from all sides. Therefore, in the final prototype, the button is positioned on top of the device.
The tests were only conducted with western healthcare workers. To further optimise the interaction, the tests have to be conducted with users from different contexts. An overview of the key insights are shown in the elaboration 3.4.1. In appendix C.4 all the results of the test are found.

Finally, there were several findings which are outside of the scope for the minimal viable product, but can be used for more complex functionalities. To extend functionalities, automatic activation and focus, for differing arm thicknesses, are valuable to incorporate. Automatic focus will have the benefits of being more precise than manually changing focus and it will also reduce interference and interaction needed.
Additionally, the end user research showed the importance of product positioning. Positioning the device, should be an easy process. For every patient, the use case is different, and the prototype has to adapt to it. Meaning, for use in the hospital the prototype will need to be positioned and attached to types of furniture. While positioning, another concern which came forward was that the stand used should be sturdy. The procedure is very precise, and any movement will distort the image. To differ the MVP to a context, product positioning should be carefully researched. For the positioning of the device in a intensive care unit in the western context a research set up has been made, see appendix C.5.

31. Do not obstruct the end-users view
32. Allow for product positioning

15 Further improve interaction
16 Test final interaction with end-users
17. Test in different contexts



4.3 Embodiment

The minimal viable technological and contextual requirements are found in the previous chapters. These findings are combined within the embodiment. The embodiment is the part of the product, which will house all components. The technological parts, electronic and optic parts of the product, are located within the product. The contextual requirements are reflected on the exterior of the product.
At the end of this paragraph, the prototype is tested to the requirements and a general conclusion and recommendation are found.

4.3.1 Analysis

All findings from the previous mentioned research, are combined into an embodiment. This embodiment will be the casing for the product. The embodiment is a selection of the most desirable contextual, interactive and technical product details. These product details have been established in the previous chapters.

4.3.2 Synthesis

From the technological research in chapter 1, 2 & 3, the components which need to be used and their position in relation to each other for the desired functionality were determined. To find the minimal dimensions for a compact casing (req-size) the size of this aggregation was measured. These minimal dimensions acted as the design boundaries. Within these boundaries the casing was designed.
From the interaction and contextual research the functionalities which need to be added to the product were found, developed and subsequently implemented into the design. The functionalities are divided into 6 parts:

1. PCB stucture
2. Optics
3. Electronics
4. Fixtures
5. Casing

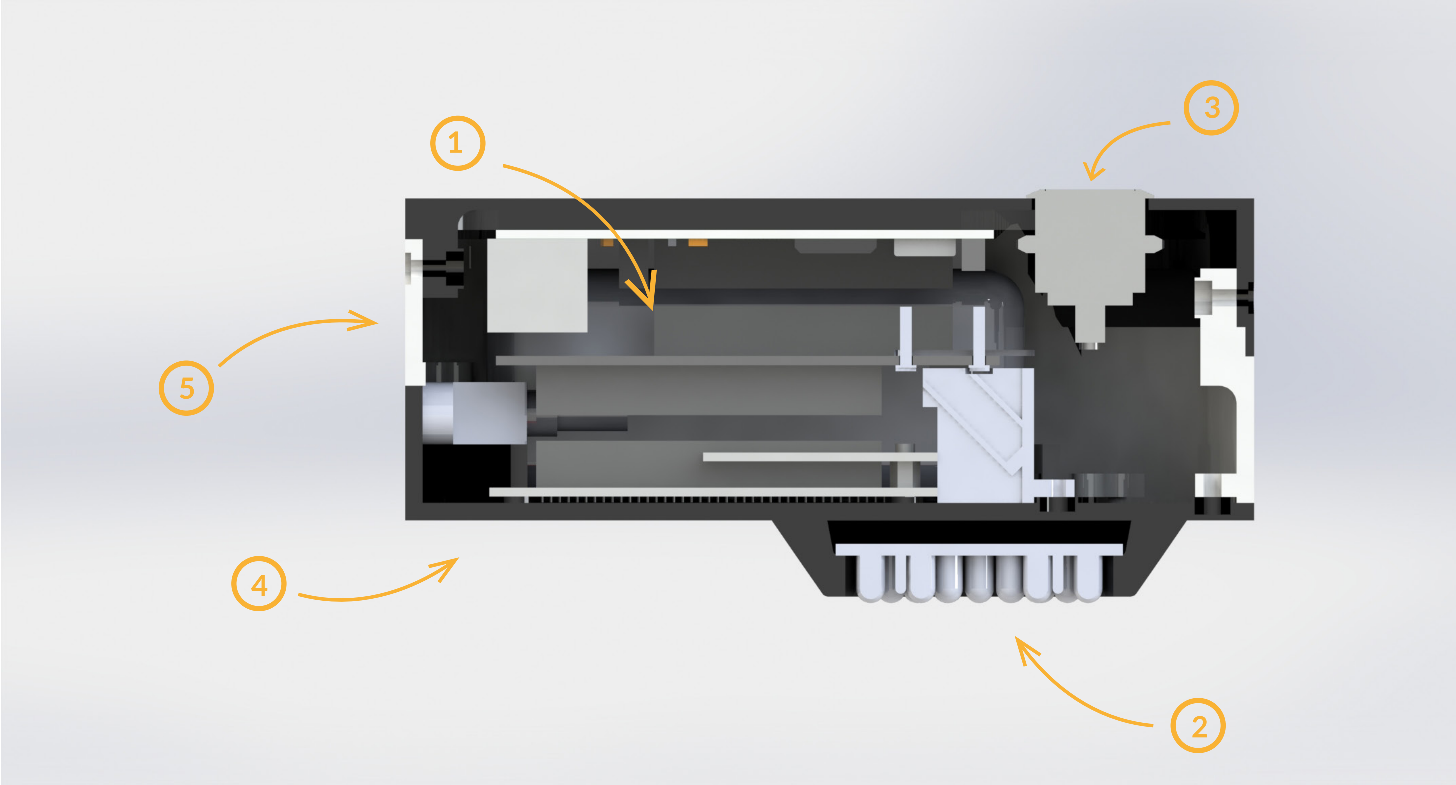
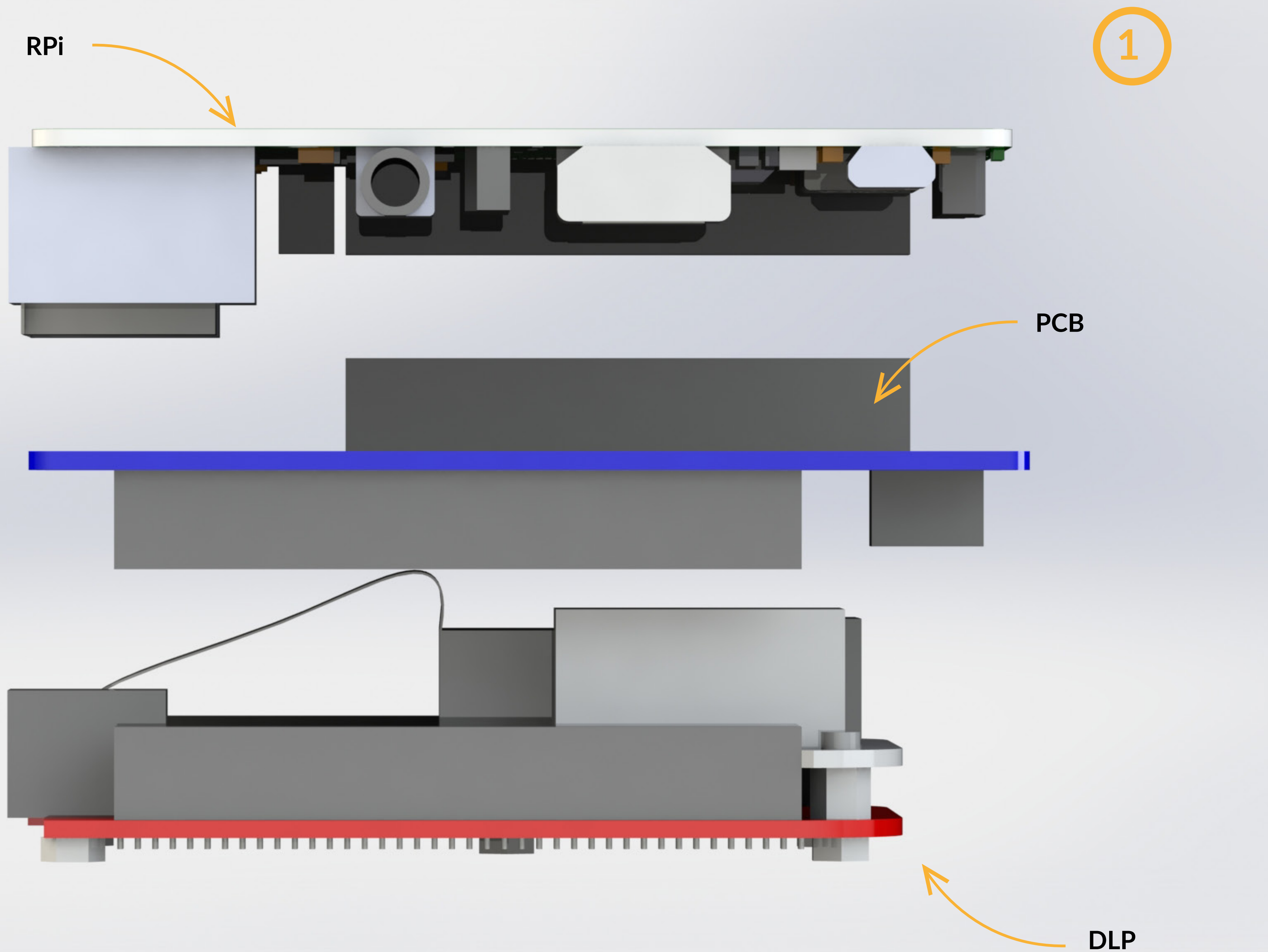


Figure 26, The 6 main functionalities

4.3.3 Simulation

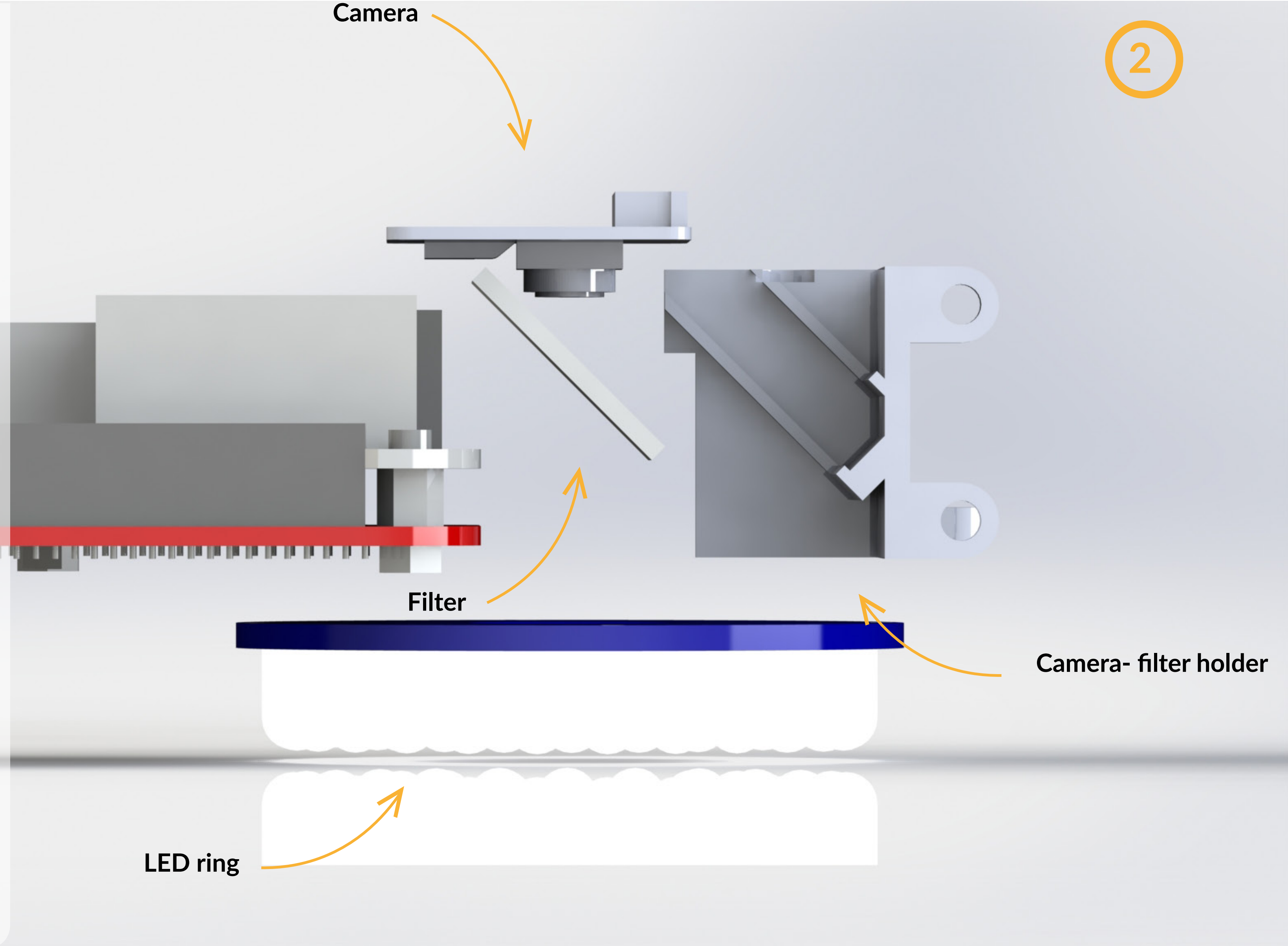
4.3.3.1 PCB structure

The first components which are needed to fill functionality are the RPI and the DLP. The pins at the bottom of the DLP have been removed, to optimise for space (req-size). Also, the nuts on the bottom now can be used for fitment. (req-robust)
Furthermore, it was decided to place the components on top of each other to so optimise for space. (req-size) These components have to be electrically connected for them to be able to communicate without any distortion(req-clear image). For this, a PCB is designed, see chapter 3. The PCB is situated between the two components and has electronic headers on both sides. The headers make sure that the pins of the two components are able to slot in and so, attach to one another. The PCB holds two extra slots for electronic wires to attach to the other electronic components needed. For extra fitment, the components are also connected together with steel rod spacers, nuts and bolts. These nuts and bolts are also able to be attached to the base plate, see paragraph 4.3.3.3.



4.3.3.3 Optics

The projector and the camera should be perpendicular aligned for exact vein projection location(req-alignment), see chapter 3. In between the two components, the cold mirror is placed. The cold mirror is in a 45 degree angle and as close to the projector and the camera as possible, see chapter 1 for the research. The cold mirror is enclosed by two layers of foam, making the set up more robust (req-robust). The parts are kept in place by a 3D printed holder. This part holds the mirror in a 45 degree angle and positions the camera in place in a 90 degree angle with the protector. To close the holder, a latch is fixed to the side.
The LED ring is placed at the bottom of the set up, concentric to the camera.



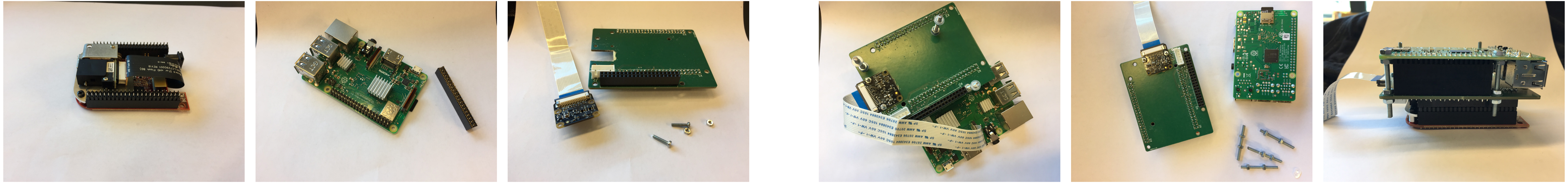


Figure 27, Assembly of PCB structure

4.3.3.3 Electronic components

To ensure portability, a power bank has been added to the prototype. (req-nondependent) This power bank supplies the electronic components and makes the device cordless and handheld operable. (req-handheld) This powerbank powers the RPI, DLP, the buttons and the LED ring. See figure 26 for the electronic wiring. The LED ring requires 8V for optimal illumination, see chapter 1. The powerbank supplies 5V which thus needs to be converted to 8 V. For this purpose a DC/DC converter is used.
The powerbank is placed at the side of the product to minimise space. It was found that when placing the powerbank on top, more space was needed to aslo incorporate the button. If placed on the side, the product would be more compact. (req-size)
The button to start the scanning procedure is placed on top of the device for easy reachability, see chapter 4, interaction. (req - intuitive use)This single button indicates an use - cue. Found in the interaction research, seen in chapter 4.1, simplicity is of importance. This single button will ensure full operation of the device. After pressing, the LED which is integrated into the button will light up, indicating that the system is powered and subsequently the script is activated. Two minutes after the button is pressed, the button LED will switch off, and the system will automatically shut down to save energy. To maximise illumination, the IR LEDs were placed on the outside of the product concentric to the camera. (req)
At the back of the prototype, there is an input which can be reached from outside to charge the power bank via a micro SD adapter. The button next to the input is to turn the device on and off. On the side there is a power indicator. This will give the status of the power left. The prototype should be charged when only one light is blinking.

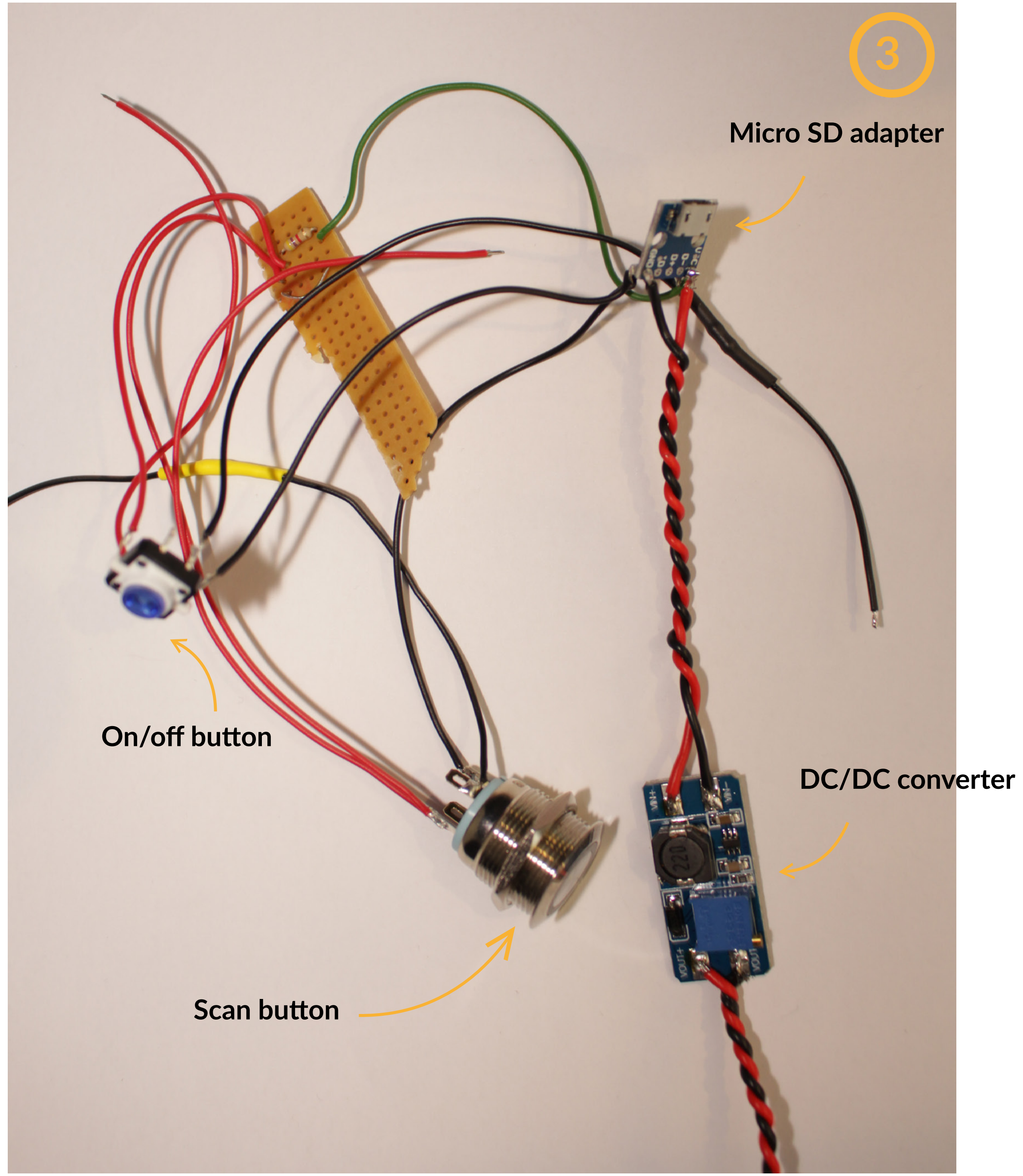


Figure 28, assembly of electronic components

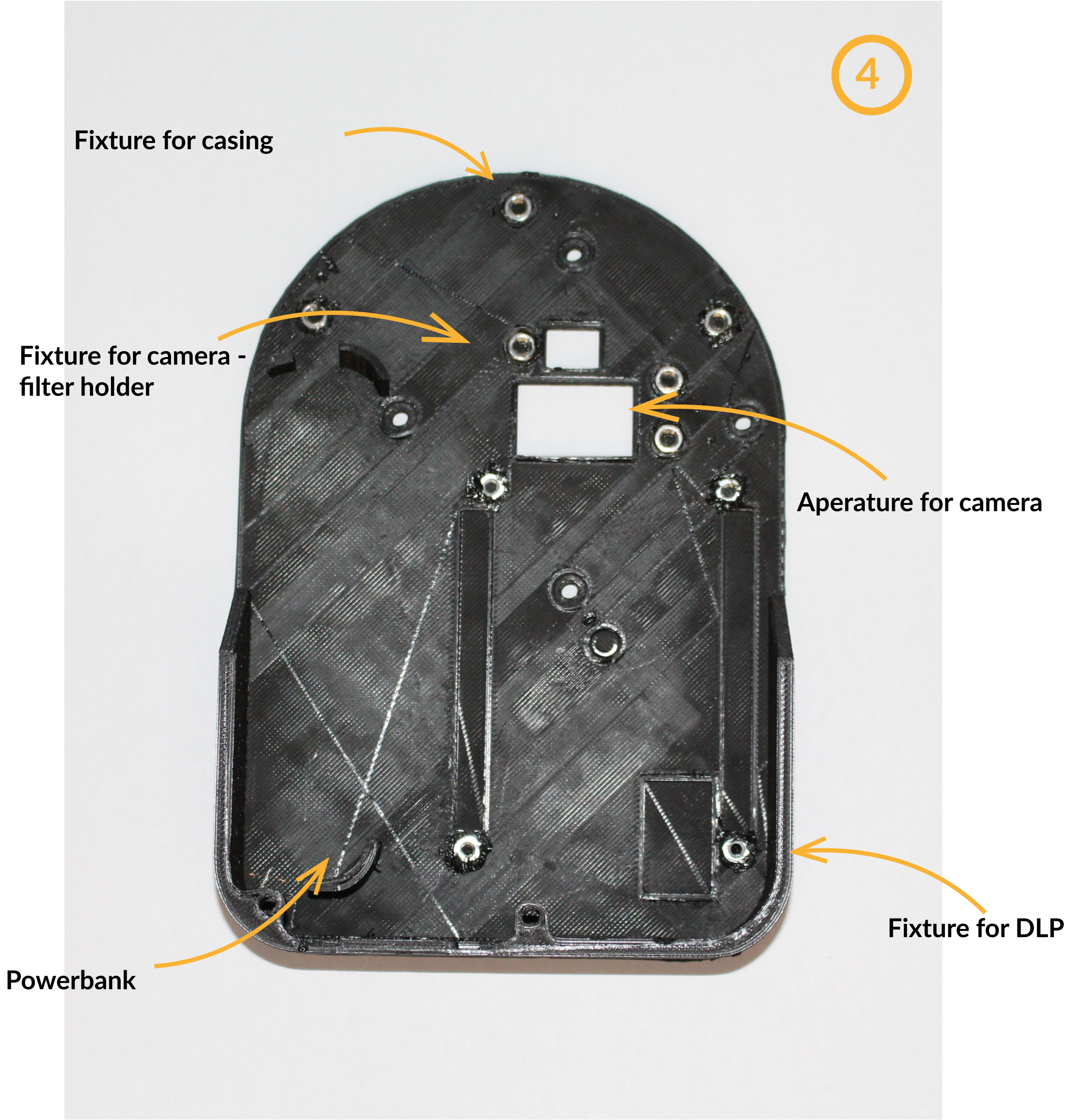


Figure 29, Assembly of baseplate

4.3.3.3 Fixtures

The base plate consists of several placement holders for the subassemblies. To keep all components in position, there are heat inserts and ledges. The heat inserts are placed to attach the bolts of the electronic component fixation, the filter-camera holder and the LED ring. These are situated at the exact locations of for the optimal component positioning. (req) Because all electronic components are connected together via the PCB, holding the base of the DLP in place, will ensure stability and positioning of this subassembly.
There are also several bolts which are attached to fixate the outer casing to the baseplate, see figure 29. Few ledges have been added to keep the powerbank in place. (req) The assembly steps which need to be taken are shown in appendix 7.

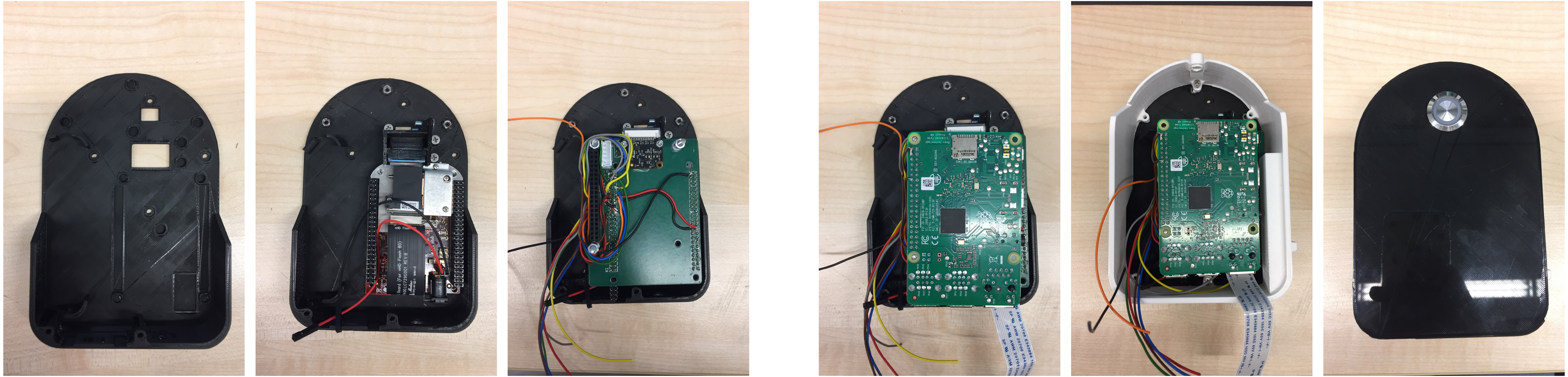
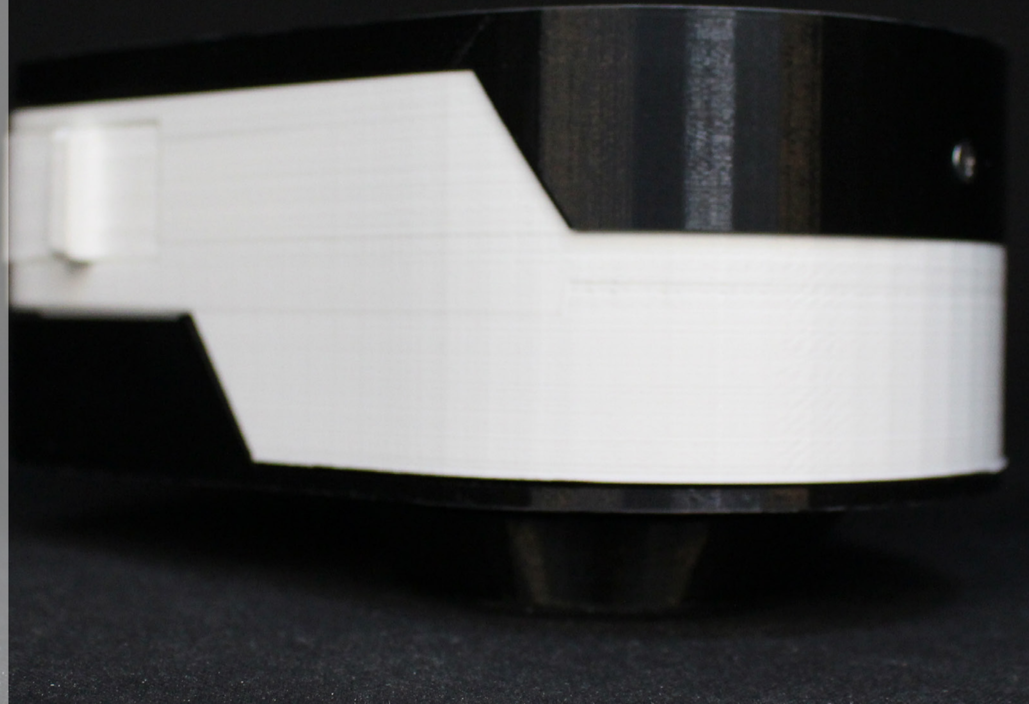


Figure 30, Assembly of fitments

5

4.3.3.2 Casing

By combining all components, the minimal dimensions have been determined. To house all the components, the embodiment has a size of 145 x 95 x 50 mm.
To comply to the requirements of the shared solution space, the method ‘form follows function’ has been followed. This implies that the casing is designed around the minimal restrictions. The PCB composition and powerbank were the limiting factors of the width and height of the product. The LED ring ensured the rounded shape on the front of the product. The design of side of the casing follows the shape of the LED holder.
By having minimalistic aesthetics, the prototype can easily be adjusted to context.(req) See elaboration 3.4.3, for the aesthetic research.
The device has a white casing, to fit into the medical context. To add contrast and indication for use, the top plate is black with a button placed in the middle(req). On the side of the product, a sliding mechanism has been added. The cover can be slid off, and then the device can be slid onto a stand. This option is added for future use if the device needs to be handsfree operated.



4.3.4 Evaluation

The prototype which is developed fulfils all the minimal functionalities needed for a viable product. It complies to all the set requirements and is easy adjustable to different stakeholders needs. The product is portable because of its size and weight. The understandability of the device is high because of its straightforward interaction, which followed from end user testing. Securing all components in place makes the product robust and suitable to perform user tests. Adding a powerbank to the embodiment makes the product useable without the need to be connected to the mains. Adding the costs of the separate components, see appendix 8, gives a total price of xx for the device. Being less expensive than existing solutions, makes the veindicator better accessible and better integratable (req).
Having an option to connect a stand will result in hands free operation and no interference during the procedure. (req)
For validation, the product still needs to be tested with the end-users. To test if the product fits into context, interviews with the end-users still need be conducted. Here the improvements by the context requirements of the prototype can be found. The second test, which still needs to be conducted for validation, is its adaptability of the MVP to differing context. To execute this research, the MVP will need to be further developed for several specific contexts. From results from this research the minimal viability can be confirmed.
To validate the product for technical requirements, (req) the functionality of the prototype also has to be compared to the current way of operating. This can be done by having a pilot trial in which the prototype will be used by nurses while performing PIVC procedures.
In appendix C.6, the technical documentation is found.
In chapter 5, the general evaluation and recommendations for the prototype are elaborated on.

18. Validate prototype
19. Validate increase of first-stick attempts
20. Test in different contexts
21. Conduct pilot trial

5.1 Conclusion

figure 32 presents the main requirements. The prototype is tested on these and evaluated accordingly. The blue dots mean that the product meets the requirement and the orange still needs to tested and verified.

Looking at the proposed solution and it can be concluded that the working principle of the imaging and processing are proven. The prototype increases the visibility of the veins and therefore it aids the PIVC process. The contrasted image gained via use of NIR with a wavelength of 850 nm, is able to be processed by the written algorithms. Figure 32 shows the final result. The image shows green where the vein pattern is. The technology developed can now, with these results be used for testing. The prototype shows an enhanced image of the vein pattern. Comparing it to a normal hand, the accomplished result is definately an improvement.

By adding an powerbank with a high mAh, the product is not dependable on the mains. Additionally, the size and the weight of the product are optimised and reduced which allow for portability. Having a single functionality and single indication for use, the interaction with the product is highly understandable and intuitive. Adding a positioning option to the casing increases adaptability and ensures hands-free operating. Since a hand can be just placed underneath the product, the use is very quick and reliable.

By developing the minimal functionalities required for the working principle and by following the form-follows-function method for the design of the casing, the product is easily adjustable for differing requirements and contexts.

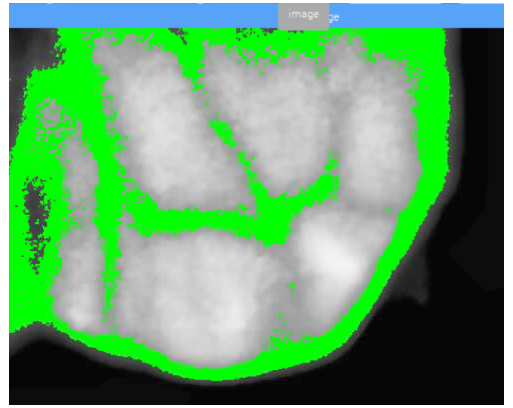


Figure 32, Final result

Main requirements

- 1. Increase visibility of veins
- 2. Aid the localisation of veins
- 3. Guide PIVC placement
- 4. Little training needed
- 5. Suitable for every patient, skin type and color
- 6. Improve first-stick success rate
- 7. Decrease resources needed
- 8. High accuracy
- 9. Quick process
- 10. Suitable for different body parts
- 11. Hands free operable
- 12.Distinguish veins from surrounding tissue by means of NIR in the optical window 700-900 nm
- 13. Less expensive than existing products
- 14. Operable in varying environmental light
- 15. Easy to move around
- 16. Easy to implement
- 17. Used in all healthcare contexts
- 18. Reliable
- 19. Non dependent on the mains
- 20. Robust
- 21. Long battery life
- 22. Adjustable to differing needs
- 23. Image suitable for digital image processing
- 24. High contrast between veins and surrounding tissue
- 25. Digital processing for further enhancement
- 26. Project image back to user
- 27. Vein pattern projection on exact actual location
- 28. Intuitive to use - effortless interaction
- 29. Adaptable product architecture
- 30. High understandibility
- 31. Do not obstruct the end-users view
- 32. Allow for product positioning

Figure 33, Main requirements for evaluation

5.1 Recommendations

Technological

For further development, as can be seen in figure 33, not all veins are completely found. To achieve that all veins are distinguished from its surrounding tissue, there can be looked into implementing different, more expensive hardware. This will increase the price of the product but nevertheless, also improve the quality of the image. This is a consideration still to be made. To improve the image without adding extra costs, the calibration of the software can be improved. By making the software more accurate, it will be able to more precisely pick up veins. Secondly, the effect of light intensity and values in the software on different skin types and colours have to be tested. The current code and set up is optimised for light skin with little body hair. To ensure adaptability in different contexts, the prototype has to work on all skin types and colours. Subsequently, to further optimise the prototype there can be looked into automatically changing these values for different skin type and colour.

Furthermore, in the image created, the edges of the hand are clearly visible. This may be confusing for the end user to distinguish veins. To solve this, a fixed area of capturing has to be implemented, see figure 33. This will ensure that only veins are displayed ans not the edges of the hand, increasing understandibility.

With the current set up, an enhanced image of veins is found. However to be useful for the end-user this image needs to be projected back onto the skin. For future development this still needs to be implemented. Research showed that the projection of the DLP interfered with the image captured by the camera. To minimise optical interference, research has to be done into the possibilities of changing the projected image. Secondly, the exact location of the projection relative to the location of the veins needs to be adressed. Possible methods for doing so are found in appendix D. To implement the projector, the PCB design has to be improved. The current tracks are too narrow to let all current run properly, resulting in no possible connection and communication between the RPi and the DLP.

Contextual

The focus of this report was create a minimal viable product. Within this focus there was looked into creating a working principle. However, to implement the device into a healthcare context, the device needs to comply to medical-ISO standards. These need to be researched and applied to the device.

Furthermore, for implementation, the device needs to be verified by the end-user. For this, usability tests have to be conducted. These will show the areas of improvement in terms of ubsability and contextual aspects. These findings can then be implemented into the design.

Finally, a comparison has to be made between first-stick success rate of the current procedure and the procedure aided by the Veindicator.

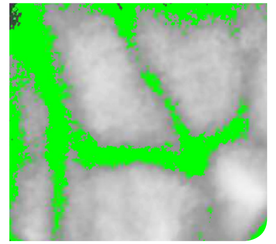


Figure 34, Recommended result

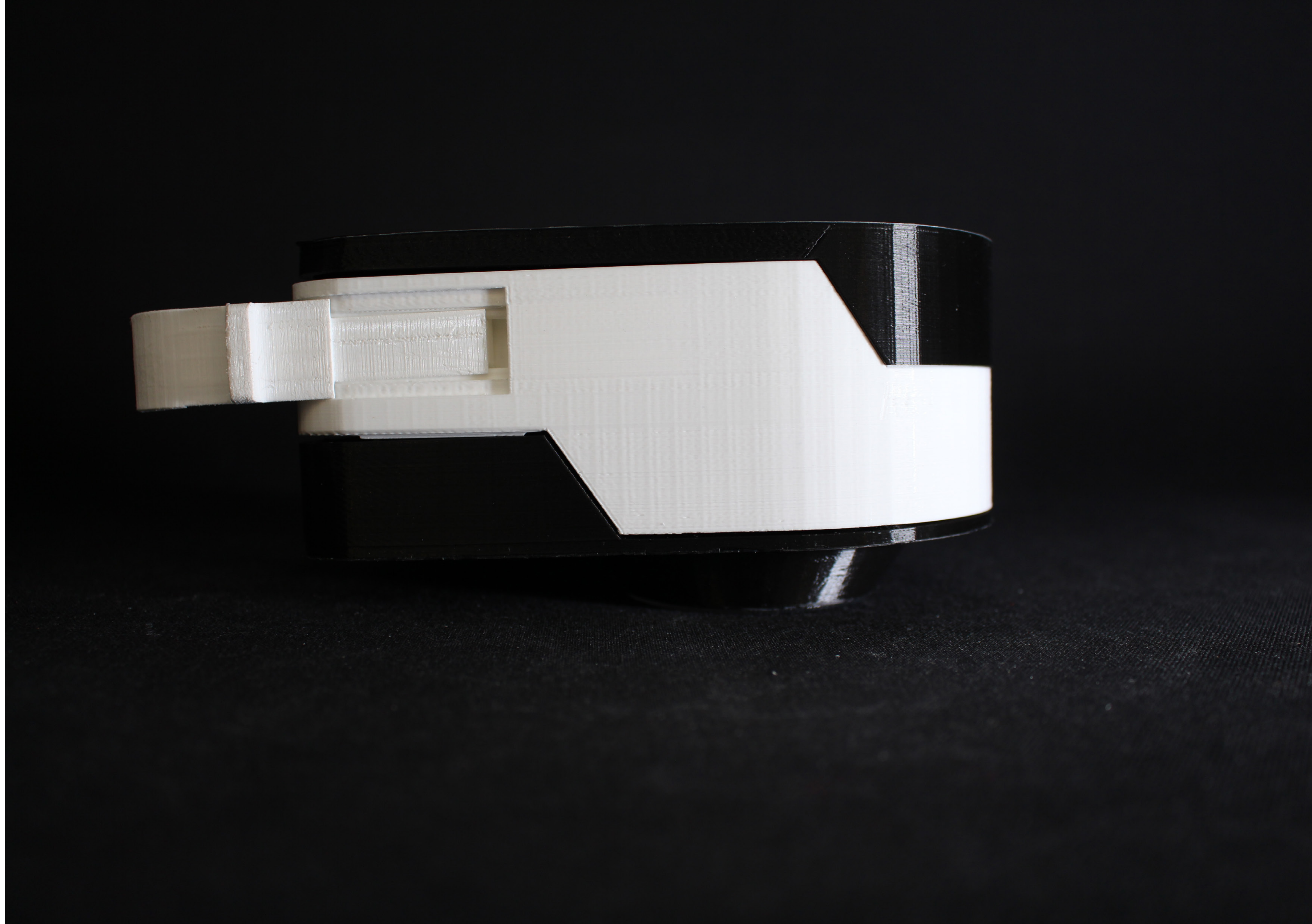
Recommendations

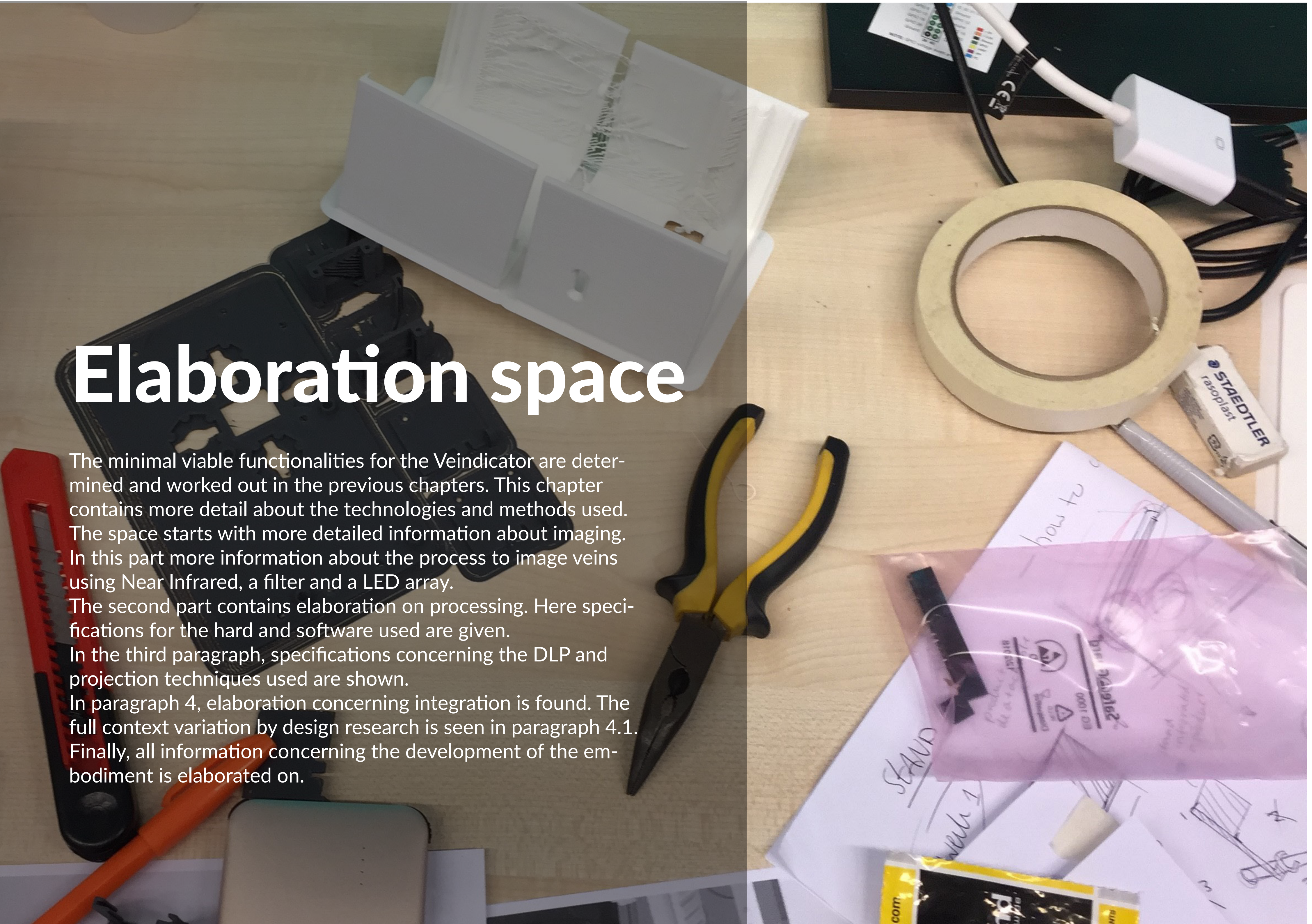
1. Research other cameras
2. Research higher quality filters
3. Enquire exact LED transmission characteristics
4. Further optimise LED setup; amount, distance, arrangement of LEDs
5. Further calibrate software
6. Fixed screen size
7. Automatic focus and illumination adjustments
8. Test with different skin and body types
9. Implement hair removal software
10. Improve PCB design to the amount of current running
11. Reduce optical resonance by testing different wavelengths of projected light.
12. Research how to project on the same location
13. Further optimise for space and weight
14. Research how to adapt MVP to specific user cases

15 Further improve interaction

16 Test final interaction with end-users

17. Test in different contexts
18. Validate prototype
19. Validate increase of first-stick attempts
20. Test in different contexts
21. Conduct pilot trial





Elaboration space

The minimal viable functionalities for the Veindicator are determined and worked out in the previous chapters. This chapter contains more detail about the technologies and methods used.
The space starts with more detailed information about imaging. In this part more information about the process to image veins using Near Infrared, a filter and a LED array.
The second part contains elaboration on processing. Here specifications for the hard and software used are given.
In the third paragraph, specifications concerning the DLP and projection techniques used are shown.
In paragraph 4, elaboration concerning integration is found. The full context variation by design research is seen in paragraph 4.1.
Finally, all information concerning the development of the embodiment is elaborated on.

3.1 Imaging

3.1.1 Near Infrared

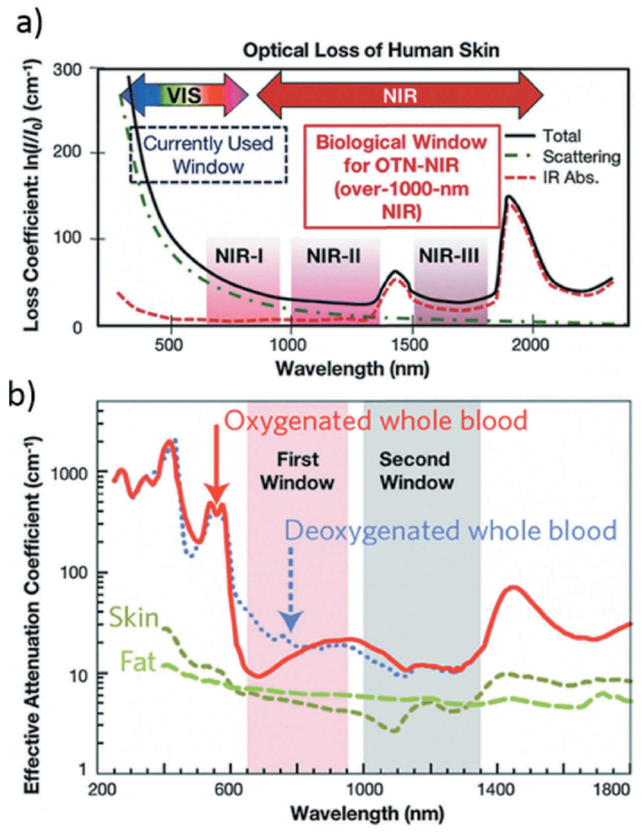
Infrared, or infrared radiation is not a perceivable electromagnetic radiation by the human eye. It has wavelengths of approximately 780 nanometers (nm) and 1 millimeter(10e6 nm), so between the visible, red light and the microwaves. Often, the wavelength area from 780 nm until 10 micrometer is indicated as near-infrared, from 10 until 30 micrometer the middle-infrared, from 30 micrometer until 300 micrometer far-infrared and from 300 micrometer until 1 millimeter the sub-millimeter area. Infrared means, under the red, because the frequency of infrared is a little lower than the frequency of red light (Lucas, 2019).

Optical absorption hemoglobin
Molar extinction coefficient (e) is how strongly a substance absorbs light at a given wavelength, per molar concentration (Crisan, 2016).

absorbance (a) =

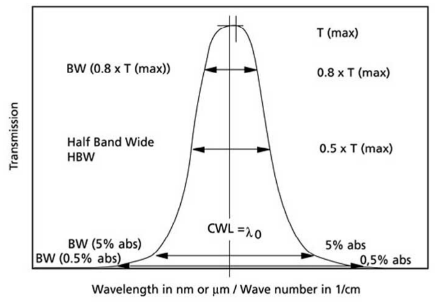
$$(e[(1/cm)/(mol/liter)] \cdot x\,[g/L] * 1[c]]) \div (molecular\ weight\ [g/mol])$$

Veins carry deoxygenated blood which contains deoxy hemoglobin. The complex (hemoglobin, iron, oxygen absorbs higher energy (which has a shorter wavelengths) blue & green, leaving red wavelengths for our eyes to detect. It appears blue because blue light does not penetrate the skin as well as red light. If a vessel is near the surface of the skin, almost all blue light is absorbed by the vessel. if the vessel is deeper (< 0,5 mm deep) not as much blue or red light will be absorbed. Once it is deep enough, it won't be seen at all, as light of all wavelengths will be reflected before it can interact with the blood (Bokobza, 1998).
IR penetrates the skin well, 830 nm goes to a depth of 2-3 mm.

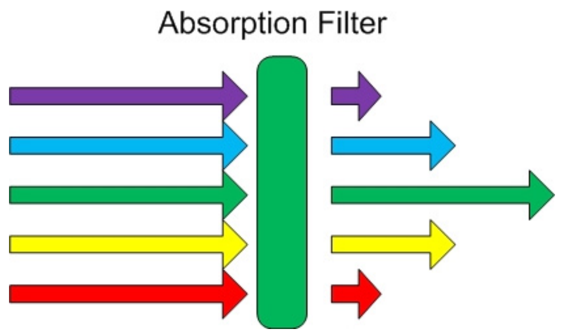


3.1.2 Filter

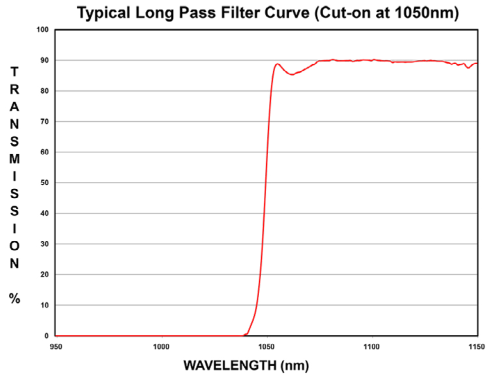
An optical filter is a see-through medium which is meant to change the spectral composition or intensity of transmitted light.
There are several optical filters for visible, ultraviolet and infrared light. The filters work by selective absorption of reflection (interference filters) of the projected light. The two principles here used are absorption and reflection. The most color filters contain color dependent light absorbing material.



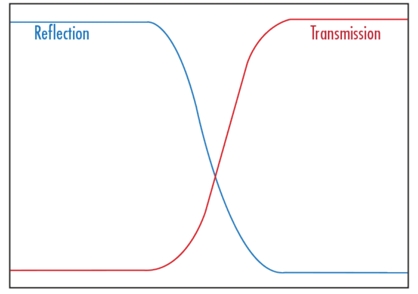
The first filter which can be used for the veindicator applicator is a bandpass filter. This is a filter which has a cut-on and cut-off length. A bandpass filter can be precisely tuned and the wavelengths can be precisely chosen. An optical bandpass filter can be used to very selectively transmit a section of the spectrum and block the rest. They are mainly used for fluorescence spectroscopy, microscopy, clinical chemistry or imaging.



The second filter which can be used is an absorption filter This is a filter which absorbs light at a certain wavelength, and only allows radiation of a particular wavelength to pass through. So if a red filter is used, the filter will only let red light pass, and block all the other colored lights.
For the veindicator, there can be looked into stacking absorption filters for every colored light to block the visible light.



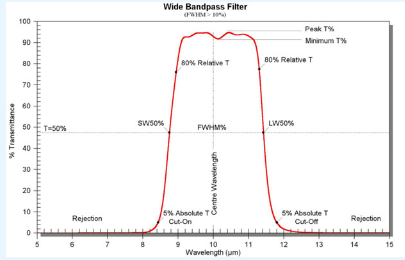
The third possible filter which can be used is a longpass filter. This filter characterises itself by having a specific cut-off length. This filter blocks light below this cut-off value and transmits the values higher than this value. Longpass filters can have a relatively sharp cut-off length ranging from 50-95 % of peak transmission.



(Wavelength)

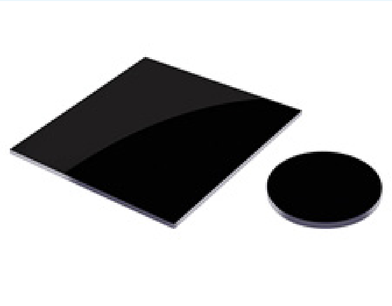
The fourth is a dichroic filter. This filter is a reflective filter. mostly is is a coating which is made of a glass substrate and optical coatings. These filters reflect the portion of light which is not wanted and will transmit the rest. The filters work by interferens. The coatings have reflective cavities which will resonate the wanted values. the others will be destroyed by these cavities or reflected back. The wanted color range can be exactly set by the amount of layers and the order of the coatings. This is why they can be perfectly used for very precise work. This however, also makes them very expensive and delicate.

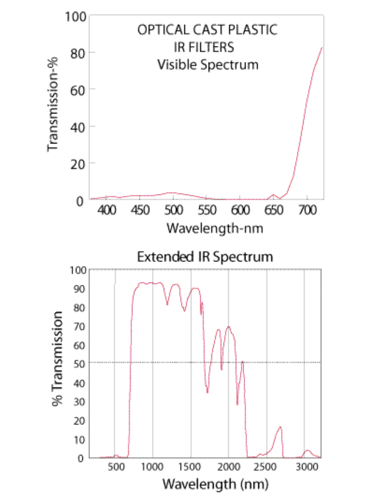
IR bandpass



Center wavelength: 2.7 - 10.6 nm
Transmission: 80%
Price: 425 $

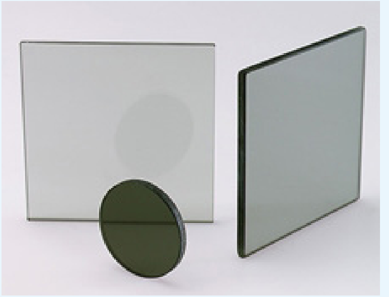
IR longpass

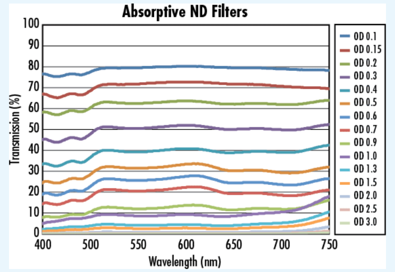




Block: 680 nm
Transmission: >90%
Price: 11.5 $

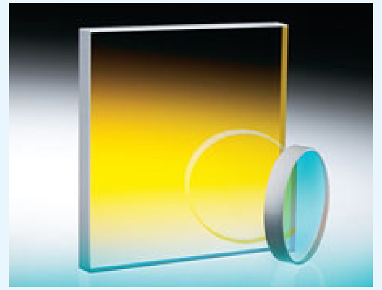
Absorption

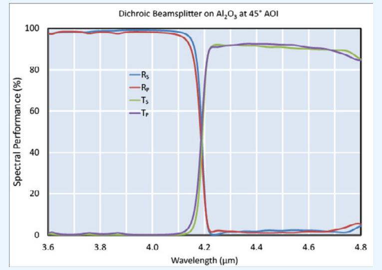




Block: 400-700 nm
Transmission: 79%
Price: 37.5 $

Dichroic filter





Cut on: 615 nm
Reflection: 640-750 nm
Transmission: >90%
Price: 75$

3.1.3 LED research electrical circuit & electronic circuit (Power intensity)

To get a better understanding of electricity, there has been looked into the very basics.
Voltage is an electrical potential difference. In an electrical circuit, the voltage will push the electrons through. If a electrical appliance has '5V' on it. It means that this is the maximum amount of voltage(force) it is designed to be able to withstand.
The second property to an electrical circuit is amperage. Amperage stands for how much electrons are flowing past. By dividing the voltage with the current, the electrical resistance can be found. Electrical resistance is its opposition to the flow of electric current. If the resistance is low, the ease of which an electrical current passes will increase.

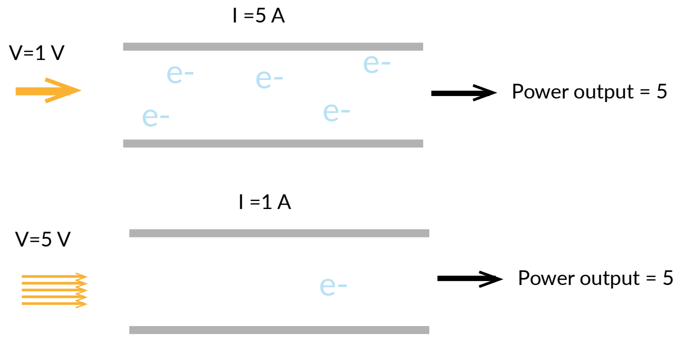
$$R[\Omega] = V[v] \,/\, I[A]$$

The power of a circuit is determined by the amount of current and voltage flowing through:

$$P[w] = I[A] * V[v]$$

And the power stand for how much electrical energy is transferred by the electrical circuit.
To determine the optimal brightness, there can be looked into these three values. The brightness of a device stands for luminous flux, which is the amount of light coming from a source. By differing the electrical energy (power) which goes through the electrical circuit, the brightness will also differ.
The power can be varied by varying the current. If the current is constant, you can vary the brightness by controlling both resistance & supply voltage
So if the current is constant the following equation can be used:

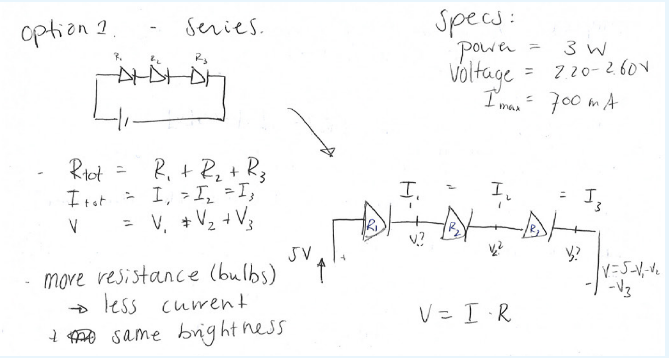
$$P = V^2 / R$$



Requirements for the LEDs are to be powered by the voltage provided by either the RPi or the power bank, and draw as little current as possible.
A battery bank has a certain amount of milliampere hours. This value stands for the amount of milliamperes can be drawn for a certain amount of time. For this instance, the power bank has 10.000 milliampère hours. Which means it can draw a value of for instance,1 milli ampere for 10.000 hours, 250 milli amperes for 40 hours. So to have as little current as possible is drawn, it means that the battery will last long.

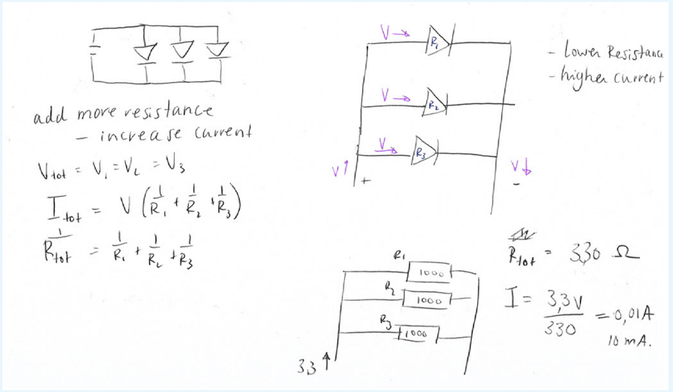
The specifications of the LEDs are:
Wavelength: 850 nm
Current: 240 mA
Voltage: DC 12 V
Power: 10 mW

Series



There are two ways of connecting the components in an electric circuit; parallel and in series.
The first option is connecting the LEDs in series. This means that the cathode of one LED is connected to the anode of the other. A serial connection is a configuration of components in which the current is equal and the current is divided over all components.
The well known series connection are christmas lights. If one light is broken, all lights stay off. This is because the current will not flow through anymore.
Within a serial connection, the total resistance over the circuit adds up, which will result in less current, but the same brightness.

Parallel

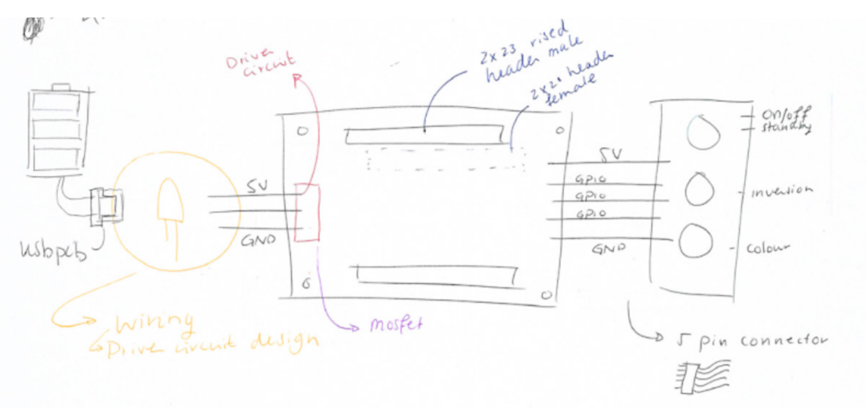


The second option is connecting the LEDs parallel. Within this circuit, all anodes and all cathodes of the LEDs are connected together. The current will be divided among the LEDs and the voltage will stay equal. A benefit of this connection is that if one LED is broken, the other will still be on because the current is divided among the components. For the specific application, the downside is that the resistance over a parallel circuit is determined via;
1/Rtot=1/R1+1/R2...+1/ Rn

Which means the total resistance will be lower, which will increase current.

Final circuit

The final circuit contains a 6.700 mAh powerbank. This powerbank supplies 5V, 2A which will supply the system for at least 8 hours. The LEDs require 8V, so to convert the 5V to 8V a DC/DC converter is added. The LEDs are connected to the driver circuit of the RPi. Furthermore, two buttons are added to the circuit and are connected to the RPi via GPIO pins. Via the GPIO pins, the buttons can send a signal to activate the script.



3.2 Processing

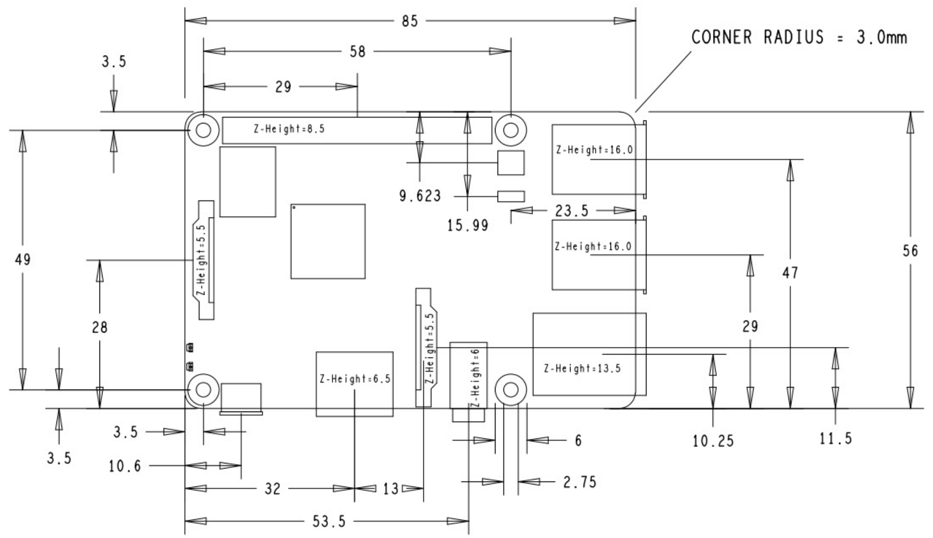
3.2.1 RPi specifications

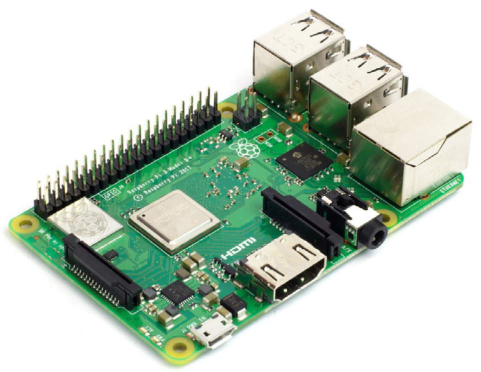
The Raspberry Pi is the name of diverse singleboardcomputers based on a ARM-processor which is sold for a low price. It was developed by the university of cambridge and was meant for educational purposes.
The hardware characterises by an open structure which is similar to the first IBM personal computers. The present General Purpose Input/Output (GPIO)-bus makes it possible to connect a addon-board to the Raspberry Pi. The present Universal Serial Bus (USB)-ports, Display Serial Interface(DSI)- and a Camera Serial Interface (CSI)- connector make it possible to connect multiple USB-devices, a display and a camera to the board. The addon-boards can easily be changed just like the microSD-card with the live-system and the software. This live-system and software is programmable.

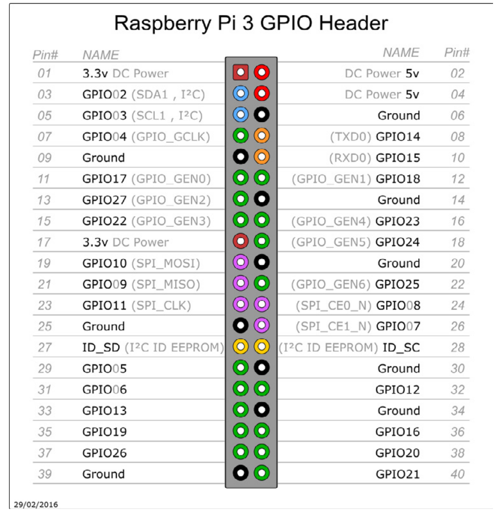
Technical specifications:

Processor: Broadcom BCM2837B0, Cortex-A53 64-bit SoC @ 1,4 GHz
Memory: 1 GB LPDDR2 SDRAM
Connectivity: / 2,4 GHz and 5 GHz IEEE 802.11.b/g/n/ac wireless LAN, Bluetooth 4.2, BLE
/ Gigabit Ethernet over USB 2.0 (maximum throughput 300 Mbps)
/ 4 x USB 2.0 ports
Access: Extended 40-pin GPIO header
Video & sound: / 1x full size HDMI
/ MIPI DSI display port
/ MIPI CSI camera port
/ 4 pole stereo output and composite video port
SD card support:Micro SD format for loading operating system and data storage
Input power: / 5V / 2.5 A DC via micro USB connector
/ 5V DC via GPIO header
/ Power over Ethernet (PoE)-enabled (requires separate PoE HAT)
Environment: operating temperature 0 - 50 degrees
Production lifetime will remain in production until january 2023

Mechanical specifications







Raspberry Pi 3 GPIO Header

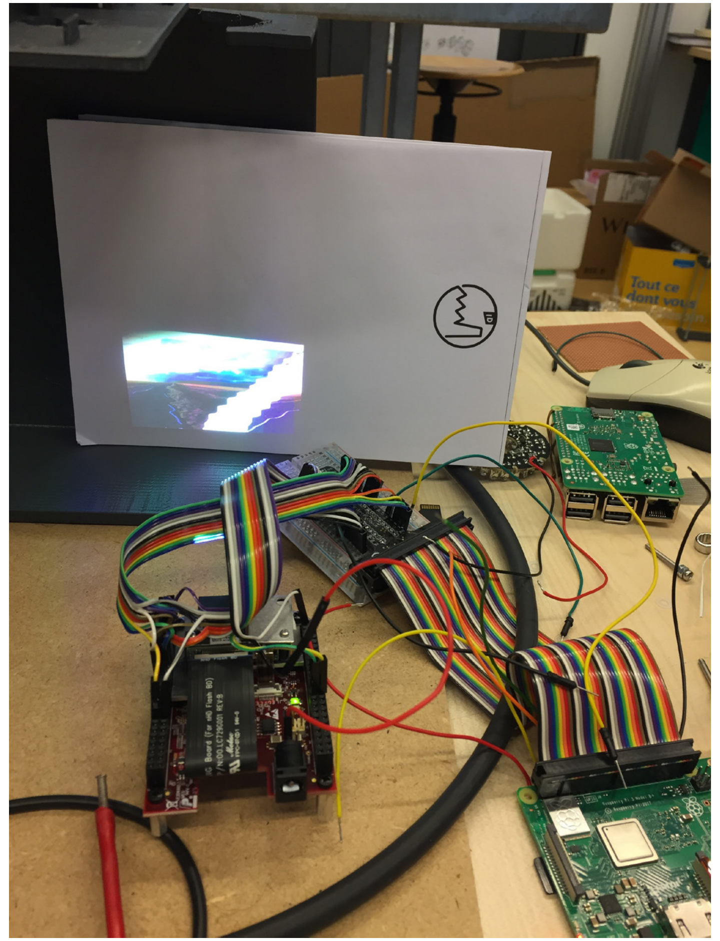
Pin#	NAME	NAME	Pin#
01	3.3v DC Power	DC Power 5v	02
03	GPIO02 (SDA1 , I²C)	DC Power 5v	04
05	GPIO03 (SCL1 , I²C)	Ground	06
07	GPIO04 (GPIO_GCLK)	(TXD0) GPIO14	08
09	Ground	(RXD0) GPIO15	10
11	GPIO17 (GPIO_GEN0)	(GPIO_GEN1) GPIO18	12
13	GPIO27 (GPIO_GEN2)	Ground	14
15	GPIO22 (GPIO_GEN3)	(GPIO_GEN4) GPIO23	16
17	3.3v DC Power	(GPIO_GEN5) GPIO24	18
19	GPIO10 (SPI_MOSI)	Ground	20
21	GPIO09 (SPI_MISO)	(GPIO_GEN6) GPIO25	22
23	GPIO11 (SPI_CLK)	(SPI_CE0_N) GPIO08	24
25	Ground	(SPI_CE1_N) GPIO07	26
27	ID_SD (I²C ID EEPROM)	(I²C ID EEPROM) ID_SC	28
29	GPIO05	Ground	30
31	GPIO06	GPIO12	32
33	GPIO13	Ground	34
35	GPIO19	GPIO16	36
37	GPIO26	GPIO20	38
39	Ground	GPIO21	40

29/02/2016

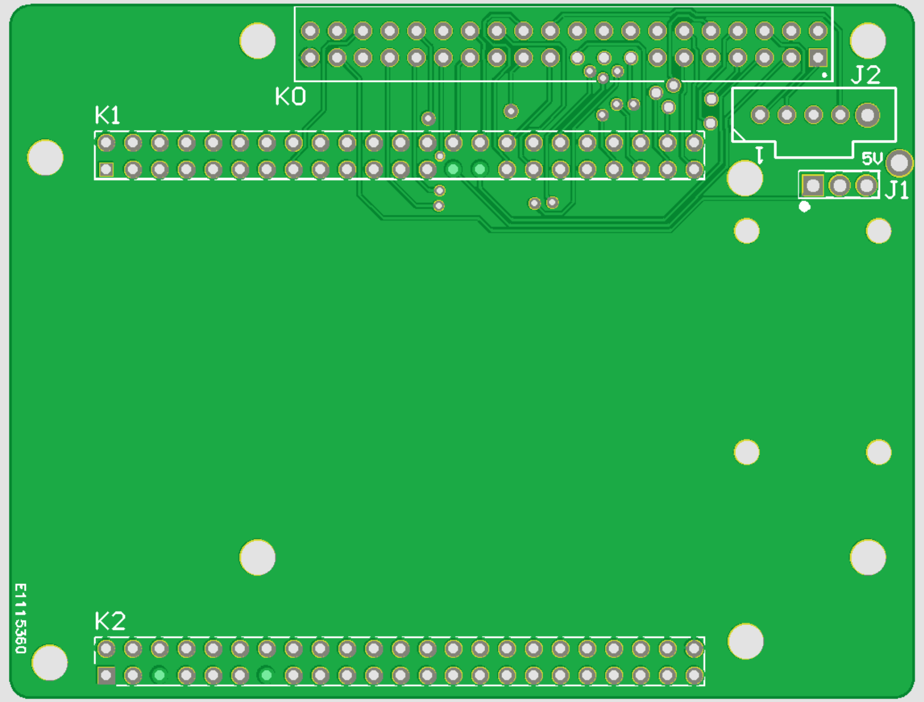
3.2.2 PCB specifications

The DLP and RPi are connected via the PCB. the undermentioned wiring diagram

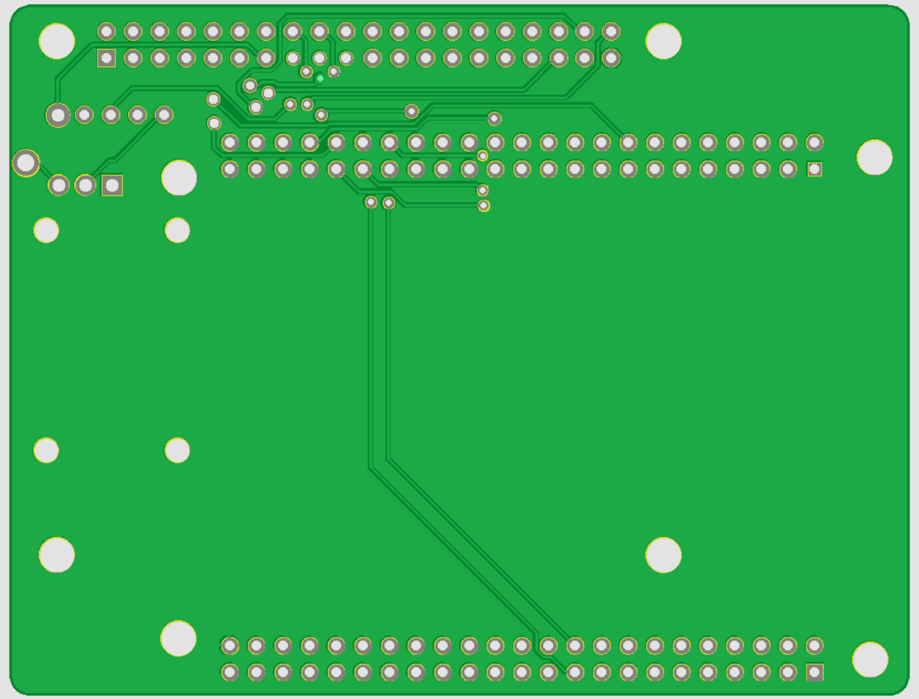
	1	3.3 v power	5v power	2	LED - 5V
PROJ - VSYNC	3	GPIO 2(SDA)	5v power	4	PROJ - J3
PROJ - HSYNC	5	GPIO 3(SCL)	GND	6	PROJ - GND
PROJ - 17	7	GPIO 4(GPCL)	GPIO 14(TDX)	8	PROJ - 9
	9	GND	GPIO 15(RXT)	10	PROJ - 10
PROJ - 0	11	GPIO17	GPIO 18	12	PROJ - 1
Button 3	13	GPIO 27	GND	14	
Button 1	15	GPIO22	GPIO 23	16	PROJ - EXT_SDA
	17	3.3 V power	GPIO 24	18	PROJ - EXT_SCL
PROJ - 5	19	GPIO 10(MOSI)	GND	20	
PROJ - 15	21	GPIO 9(MISO)	GPIO 25	22	Button 2
PROJ - 6	23	GPIO 11(SCLK)	GPIO 8(CE0)	24	PROJ - 14
	25	GND	GPIO 7(CE1)	26	PROJ - 13
PROJ - PCLK	27	ID_SD(EEPROM)	ID_SC(EEPROM)	28	PROJ - DATAEN
PROJ - 11	29	GPIO 5	GND	30	
PROJ - 12	31	GPIO 6	GPIO 12	32	PROJ - 7
PROJ - 8	33	GPIO 13	GND	34	
PROJ - 2	35	GPIO 19	GPIO 16	36	PROJ - 16
LED - GPIO	37	GPIO 26	GPIO 20	38	PROJ - 3
LED - GND	39	GND	GPIO 21	40	PROJ - 4



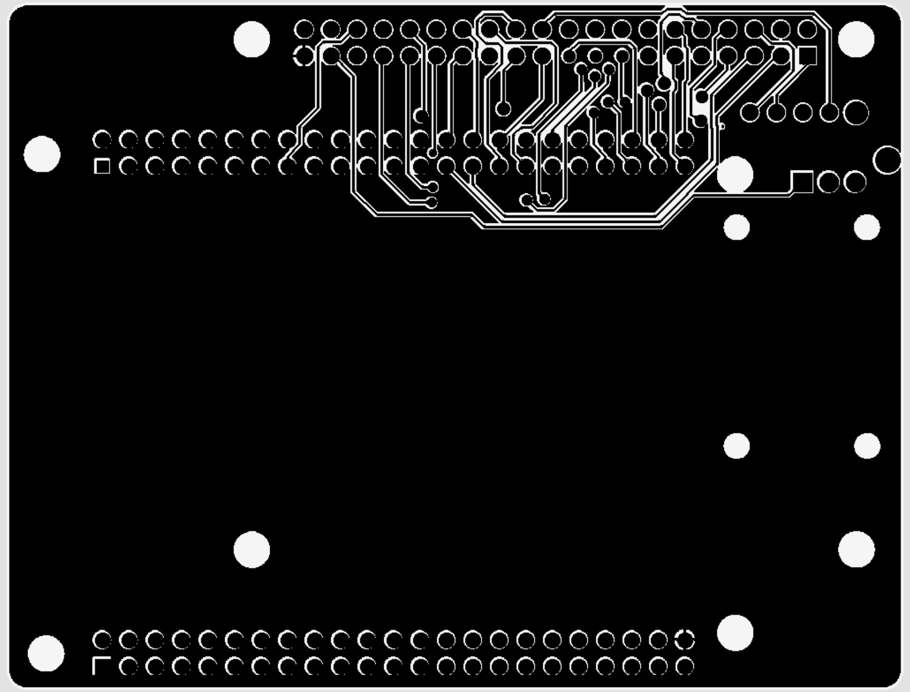
E1115360 PCB view TOP (topview)



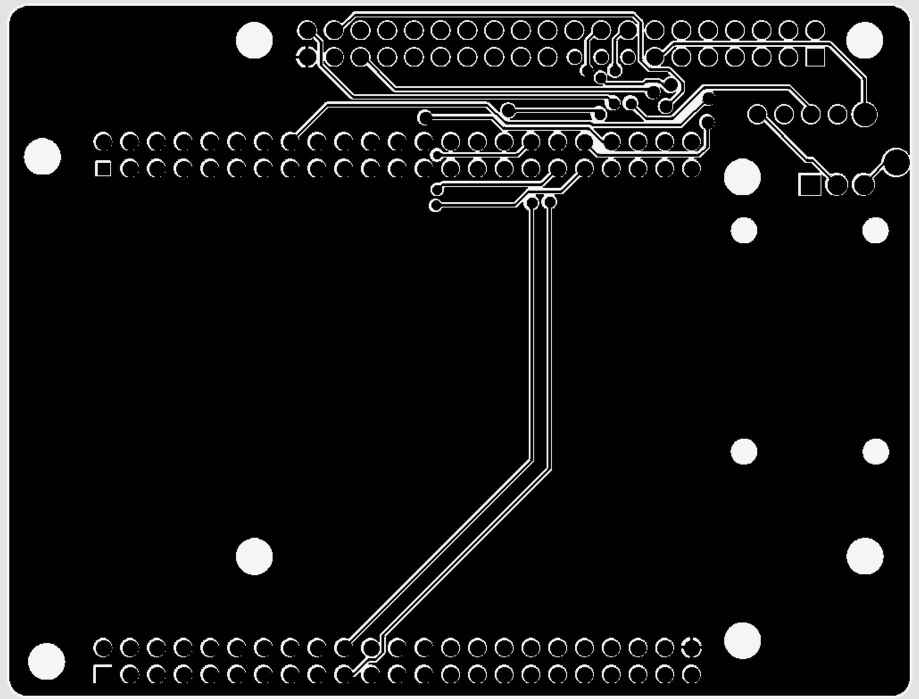
E1115360 PCB view BOTTOM (bottomview)



E1115360 TOP layer Image (topview)



E1115360 BOTTOM layer Image (topview)



3.2.2 Software

This part will contain the software code and explanation of the features used. This will be added after the software is finalised and tests are executed. The final code is written in the blue frame and the explanation for the steps is besides it.

```
import numpy as np
import cv2
from matplotlib import pyplot as plt
import RPi.GPIO as GPIO
from picamera import PiCamera
from picamera.array import PiRGBArray
import time
import argparse
from PIL import Image

GPIO.setwarnings(False)
GPIO.setmode(GPIO.BOARD)
GPIO.setup(13, GPIO.OUT)
#GPIO.setup(37, GPIO.OUT)
GPIO.setup(22, GPIO.IN, pull_up_down=GPIO.PUD_UP)

w = 640
h = 480
fps = 60

class FrameRecorder:
   def __init__(self, filename, w=3840, h=2748):
      fourcc = cv2.VideoWriter_fourcc(*'MJPG')
      self.out = cv2.VideoWriter(filename, fourcc, 3.0,
(int(w), int(h)), 0)

   def save(self, frame):
      self.out.write(frame)

   def saveasimage(self, filename, frame):       cv2.im-
```

For saving files to a video/image

```
write(filename, frame)

   def release(self):
      print("FRAMERECORDER RELEASED")
      self.out.release()

def multi_clahe(img, num):
   for i in range(num):
      img = cv2.createCLAHE(clipLimit=2.0, tileGrid-
Size=(4+i*2,4+i*2)).apply(img)
   return img

GPIO.output(13, GPIO.LOW)
number = input("Video recording number: ")
camera = PiCamera()
camera.resolution = (w, h)
camera.framerate = fps
rawCapture = PiRGBArray(camera, size=(w, h))

time.sleep (0.1)
recorder = FrameRecorder('recording_{}.mp4'.format(-
number), w, h)

while GPIO.input(22):
         time.sleep(0.1)
         time.sleep(1)
GPIO.output(13, GPIO.HIGH)
         time.sleep(1)


i = 0
for frame in camera.capture_continuous(rawCapture,
format = "bgr", use_video_port=True):
   img = frame.array
   ##pts=np.array([[10,50], [400,60], [30,89], [90,68]],
np.int32)
```

Release after saving a video/image

Filtering to enhance the veins for detection

Name the video recording

Initialise the camera

Change these for the width and height of camera measurement

The frame per second for the camera

Store the video in an array for future use

Store it in .mp4 format but .avi and others also can work

Sleep while button not pushed

Implementation of video Image Process

#bgr

#lets define four points


```
   # gray = cv2.cvtColor(img, cv2.COLOR_BGR2GRAY)
   hsv = cv2.cvtColor(img, cv2.COLOR_BGR2HSV)

   low_skin = np.array([0,20,103])
   high_skin = np.array([180,255,255])

   mask = cv2.inRange(hsv, low_skin, high_skin)



   res = cv2.bitwise_and(img, img,mask=mask)


   # cv2.imwrite('image.jpg',res)
   edges = cv2.Canny(mask,100,150)

   kernel = np.ones((5,5),np.uint8)
   kernel2 = np.ones((5,5),np.float32)/25
   dilate = cv2.dilate(edges,kernel,iterations = 1)
   dst = cv2.filter2D(dilate,-1,kernel2)


   gray = cv2.cvtColor(res, cv2.COLOR_BGR2GRAY)

   final = multi_clahe(gray, 4)


   im = cv2.cvtColor(final, cv2.COLOR_GRAY2RGBA)

     data = np.array(im)
numpy array
   red, green, blue, alpha = data.T



   minB = 2
   maxB = 70
```

Convert BGR to HSV

Define the range of the skin pigment (setup for light pigmented skin)

Threshold the HSV image to get only the skin without the veins

Bitwise-AND mask and original image

Canny with ideal parameters sent to it

Dilation and filtering of skin edges with the appropriate parameters (kernel)

Convert the BGR coloured image to gray

Perform filtering to enhance the display of the veins

Convert the gray image to RGBA format

Place the RGBA image into an array for manipulation

“data” is a height x width x 4

Temporarily unpack the bands for readability

The parameters for filtering based on shades of Red, Green and Blue but not Alpha (intensity of light)

```
   min = 0.5
   max = 100


   black_areas = ((red >= minB)&(red <= maxB)) & ((blue
>= minB)&(blue <= maxB)) & ((green >= minB)&(green
<= maxB))

   data[..., :-1][black_areas.T] = (0,0,0)



   white_areas = ((red >= min)&(red <= max)) & ((blue >=
min)&(blue <= max)) & ((green >= min)&(green <= max))


   data[..., :-1][white_areas.T] = (0, 255, 0)



   turngreen = cv2.cvtColor(data, cv2.COLOR_RGBA2B-
GR)


   inv_mask = cv2.bitwise_not(dst)




   green = cv2.bitwise_and(turngreen, turngreen,
mask=mask)



   recorder.save(green)
   blur = cv2.bilateralFilter(green,9,75,75)
   cv2.imshow('image', blur)

     key = cv2.waitKey(1) & 0xFF
   rawCapture.truncate(0)

   i += 1
```

The parameters for identifying the veins and colouring them specifically

Convert black pixels to white. (Leaves alpha values alone.)

Transpose the surroundings of the camera housing from black to white

Convert the identified veins to green, within certain gray shading parameters

Transpose the camera image from different shades of gray to green (approx. 560 nm)

First convert the image from RGBA to RGB to capture the green colour

Not used but inverts the boundary between skin and surroundings to use as a mask in next step

Filters out the turngreen vectors with the scalar mask

Save the final video recording and filter these for good quality before displaying it

Check for the quit key “q”, capture and close the video stream

```
    if key == ord("q") or not GPIO.input(22):   # Check for the quit key
        break                                   # and break the loop. Check
                                                # that the script can be
                                                # started

recorder.release()                              # Release the recording
cv2.destroyAllWindows()                         # and close all windows
```


3.3 Displaying

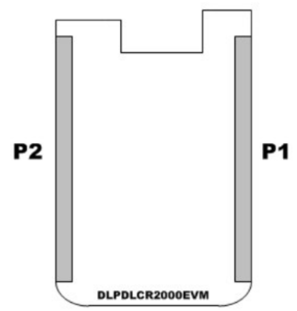
3.3.1 DLP specifications

The DLP lightcrafter 2000 display is an easy to use, plug and play evaluation platform. It can be used for ultra portable and mobile display applications. It consists of a light engine and a driver board subsystem which supports 8/16/24- bit parallel video interface.

The DLP LightCrafter Display 2000 EVM consists of two subsystems:
• Light engine: Includes the optics, red, green, and blue LEDs, and the 640 × 360 (nHD) DLP2000 DMD. Features a factory-default LED current drive of 320 mA (approximately 20 lumens) out of the box.
• Driver board: Includes the DLP chipset comprising of DLPC2607 display controller and DLPA1000 PMIC/LED driver.

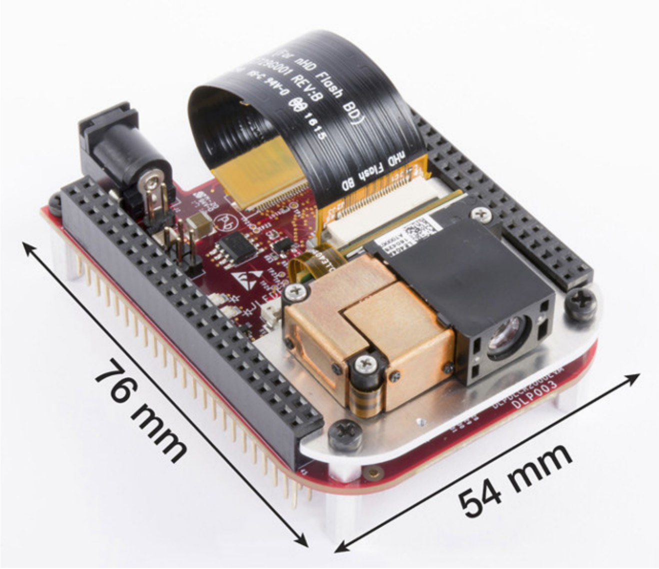
This EVM communicates with the outside world using a pair of GPIO connectors designated P1 and P2. These connectors can be interfaced with the following sources:
• Parallel video driver (using adapter board)
• Host processor (via direct GPIO)

P2	
1: GND	2: GND
3: VINTF	4: N/A
5: N/A	6: N/A
7: N/A	8: N/A
9: N/A	10: N/A
11: N/A	12: N/A
13: N/A	14: N/A
15: PROJ_ON_EXT	16: N/A
17: N/A	18: N/A
19: EXT_SCL	20: EXT_SDA
21: N/A	22: N/A
23: N/A	24: N/A
25: N/A	26: N/A
27: N/A	28: N/A
29: N/A	30: N/A
31: N/A	32: N/A
33: N/A	34: N/A
35: N/A	36: N/A
37: N/A	38: N/A
39: N/A	40: N/A
41: N/A	42: N/A
43: HOST_PRESENTZ	44: GND
45: GND	46: GND



Legend:
Not Used
Parallel I/F Video Data
Parallel I/F Video Control
I2C Bus
System Supply Lines
System Control Lines

P1	
1: N/A	2: N/A
3: N/A	4: N/A
5: N/A	6: N/A
7: N/A	8: N/A
9: N/A	10: N/A
11: Data18	12: Data19
13: Data22	14: Data21
15: Data16	16: Data17
17: Data20	18: GPIO5
19: Data23	20: N/A
21: N/A	22: N/A
23: N/A	24: N/A
25: N/A	26: GPIO_INIT_DONE
27: VSYNC	28: PCLK
29: HSYNC	30: DATAEN
31: Data14	32: Data15
33: Data13	34: Data11
35: Data12	36: Data10
37: Data8	38: Data9
39: Data6	40: Data7
41: Data4	42: Data5
43: Data2	44: Data3
45: Data0	46: Data1



3.4 Integration

3.4.1 Context variation by design/ use case typology

3.4.1.1. Western hospitals

Use case 1: Western hospital
1.1 Non-emergency - blood donation
The patients come by to the hospital in their spare time to donate blood. The procedure takes approximately an hour. The patient comes in, has to wait until there appointment start and will get seated. A nurse will come by to perform the cannula and then the patient has to wait until the procedure is finished. After the procedure, they advise the patient to keep the rest of the day of, concluding, the stress level is low and the time available for the procedure is high. There are multiple patients and a couple of doctors and nurses performing the procedure. Besides that having a cannula is not a nice procedure, the stress levels of the patient is very low. The expertise level of the nurse is high, and they are experts in the procedure since they perform is multiple times per day. The resources needed are widely available and fully developed.
1.1.2 Need to have
Stable
Accurate
Identify best vein to inject
Show size / diameter of vein
High efficacy
Show needle entering

1.1.3 Nice to have
Compact
Useable in daylight conditions
Contactless to decrease sterilisation procedures
Show vein depth
Intuitive to use

1.2 Emergency situation
A patient comes in from a severe accident. The patient's situation is life threatening. The patient is very vulnerable - stress level is high by both doctor and patient. The patient comes either from the ambulance or the IC and needs to be transported to the ER in the shortest time possible, time is limited. They are on the go and in a rush - stability is low due to moving situation. There are multiple doctors and one patient. The doctors available are competent and know how to deal in every situation. It is of importance that every action happens as quick as possible. All the resources needed are available and fully developed.

1.2.1 Need to have
Stable
Free hands to operate
Portable
Intuitive to use
Usable in daylight conditions
Identify best vein to inject
High efficacy

1.2.2 Nice to have
Good battery
Contactless to decrease sterilisation procedures
Show vein size
Show needle entering

3.4.1.2. Paramedics

The second use case analysed is western point-of-care, paramedics. These are medical specialist who provide medical help outside the hospital.

2.1 Non emergency situation
The location of paramedics differ, so everything they have to use, they have to bring. And they have to be resistant to different types of weather and environmental factors. In a non stress situation, for instance, the paramedics are stand by at an event. There are always two paramedics for one patient. During the event, nothing life threatening happens and only some people come by to do minor checks. So the stress level is quite low and the time available for the procedure is high. The paramedics are experts in their field and know how to handle the situation.

2.1.2 Need to have
Accuracy
Good battery
Identify best vein to inject
Compact
Non dependent on electricity
Portable
High efficacy
Show needle entering

2.1.3 Nice to have
Easy to use
Useable in daylight conditions
Contactless
Free hands to operate
Contactless to decrease sterilisation procedures

2.2 Emergency situation
2.2.1 Situation sketch
The paramedics are called with an emergency situation. There are always two paramedics for one patient. However if it is very severe, multiple ambulances will be on site. They have to get to the emergency scene as quick as possible. When they arrive, the situation of the patient is critical and they have to act fast. They take their response bag to the site and help the patient. The stress level is very high and the time available for the procedure is low. The patient stress level can vary, it can be between being in shock to unconscious. The patient will be stabilised and helped to the extent they can do on site, afterwards he will be transported to the nearest hospital. Resources on site are limited but they are fully developed. The paramedics are experts in their field and know how to handle the situation.

2.2.2 Need to have
Easy to use
Free hands to operate
Usable in daylight conditions
Compact
Good battery
Identify best vein to inject
Intuitive to use
Portable
High efficacy
Non dependent on electricity

2.2.3 Nice to have
Contactless to decrease sterilisation procedures
Show size / diameter of vein
Show needle entering

3.4.1.3 Emerging economies

The third use case the product is planned to be used in are emerging countries. Here, there are lots of areas which are not easily accessible and remote. The people in the remote areas are often unaware and sceptic about new methods of healthcare since the level of development is low.

3.1 On field

3.1.1 Situation sketch

Most people in emerging economies do not have the means to visit a doctor. The doctor occasionally makes field visits. The doctors most of the time go by motorbike and have to bring everything they need by themselves since in the remote areas, resources are very low. When they arrive a town crier is held to announce that the doctor has arrived and people from the village can come and get help. This happens in a underdeveloped environment, often outside at a simple table. Only small and simple procedures can be made due to lack of equipment and sometimes expertise. The doctors who go to the field are often not well trained and there are only few. The workload of these doctors is high due to lack of healthcare workers and many patients. Sometimes, NGO's are present to perform procedures.

3.1.2 Need to have

Inexpensive
No training needed
Intuitive to use
Contactless, to decrease sterilisation procedures
Compact
Good battery
Identify best vein to inject
Non dependent on electricity

3.1.3 Nice to have

Hands free
Show vein size

3.2 Healthcare center

3.2.1 Situation sketch

In emerging economies, there are different levels of healthcare. Varying from a hospital to a primary level healthcare center (PHC). In a hospital, more advanced equipment is available. In a PHC, there is a nurse with basic equipment. There are more PHC than hospitals and the centers are located more locally, so the PHC is the first point of care for the vast majority. Patients go to the healthcare center for instance with symptoms of fever or malaria. In the healthcare center, there are a lot of patients waiting to get help and little nurses available to help. There is no electricity available and because a lack of (developed) equipment, there is only that much a nurse can do. The most common procedures are simple stitches, sex-education and prescription of drugs. The main prescriptions are antibiotics and antimalarial drugs. Sometimes, there are so many patients that there is a que from 4 am in the morning to get help. So the stress of the healthcare workers is high, of the patients low.

3.2.2 Need to have

Inexpensive
No training needed
Intuitive to use
Contactless, to decrease sterilisation procedures
Good battery
Identify best vein to inject
No training needed
Non dependent on electricity

3.2.3 Nice to have

Operable in daylight conditions
Hands free
Compact

3.4.1.4 Field hospitals (military)

The fourth and last use case which will be researched is a military field hospital. A field hospital is a small mobile medical unit, or mini hospital, that temporarily takes care of casualties on-site before they can be safely transported to more permanent facilities. This term is used overwhelmingly with reference to military situations, but may also be used in times of disaster. A field hospital is a medical staff with a mobile medical kit and, often, a wide tent-like shelter so that it can be readily set up near the source of casualties. There are 3 different levels of field hospitals. the first level is the first point of care the patients from the field go to. Here, basic wound care, fracture immobilisation and simple surgery can be performed. After basic care, the patient is brought to the second level. This is a more advanced field hospital. It has specialist diagnostic resources, surgical and medical capabilities. Here the patients can get preventive medicine, odontology, ophthalmology, gynecology and other specialities. In the second level, attention to stress in combat, reanimation, surgery and emergency dental treatment can be given. There are also a basic laboratory and radiology modules present .

4.1 Non emergency situation

4.1.1. Situation sketch

For this case there will be focussed on the third level of field hospitals. In this hospital there are several recovering soldiers and soldiers who need minor surgery. The stress levels are lower and there is more time and capacity to perform a procedure. There are 30-40 man staff and there is a capacity of 1000. The level of expertise of the staff is high, and there are sufficient developed resources.

4.1.2 Need to have

Hands free
Contactless, to decrease sterilisation procedures
Compact
Good battery
Identify best vein to inject

4.1.3 Nice to have

Intuitive to use
Operable in daylight

4.2 Emergency situation

For this case there will be focussed on the second level of field hospitals. A soldier from the field comes in with heavy injury and needs to be helped right away. It is chaos and 4 nurses and doctors rush to the wounded soldier. The stress of both the patient and nurse are high and the soldier goes into shock. The soldier needs to have blood transfusion as quickly as possible. In the field hospital they have somewhat advanced equipment but they do not have a fully equipped hospital. The expertise of the healthcare workers is high and the patient can be helped.

4.2.2 Need to have

Intuitive to use
Hands free operable
Useable in daylight conditions
Compact
Good battery
Identify best vein to inject
Portable
Non dependent on electricity

4.2.3 Nice to have

Contactless, to decrease sterilisation procedures

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