Veindicator

Appendices

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VIEWPOINT MEDICAL

Appendix A - Analysis

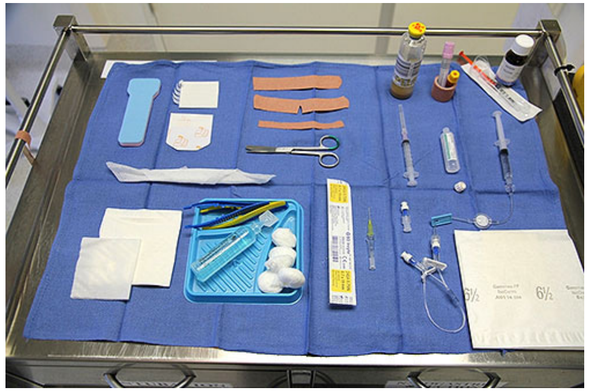
1. PIVC research

Peripheral intravenous catheter (PIVC)

Peripheral intravenous catheterization (PIVC) is one of the most common minimally invasive medical procedures performed in hospitals today. Up to 80% of all patients admitted to hospitals worldwide will have a peripheral intravenous line inserted in the forearm or hand to administer fluids, medications, and blood products. Today's hospitals rely on IV catheters as essential tools to deliver IV medications, blood products, and nutritional fluids to patients. Approximately, 90% of all patients entering the hospital environment for care have some form of intravenous therapy during their hospital stay. Site selection is arguably the most important step in ensuring successful venipuncture or cannulation. 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 (ref Figure 2) 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

PIVC necessities.

- Tourniquet
- Cleaning stick and wipes
- Gloves
- Needle
- Syringe and bottle of saline
- Bionector
- Cannula
- Blood tubes and adapters
- Cotton wool & tape



PIVC step-by-step

/ Check saline is in date and clean bottle with an alcohol wipe
/ Draw up your flush using your needle and syringe
/ Prep your bionector with a small amount of saline - this is to remove the air
/ Prepare any blood bottles by connecting them to the adapter
/ Apply the tourniquet 3 to 5 inches from where you want to insert
/ Select an appropriate vein from the hand till the elbow
/ The vein should be as large and straight as possible
/ Hold the cannula firmly with your index and middle fingers on the wings and thumb on the back of the cannula to control the needle
/ Clean the area of the skin
/ Apply traction to the skin to stabilise the vein
/ Insert the tip of the cannula at an acute angle
/ Keep skin tight to enter the vein
/ Gently advance the stilette of the cannula
/ Observe the flashback of the blood
/ Remove the needle from the cannula
/ Attach the bottle to take blood sample
/ Release the tourniquet
/ attach the bionector and flush
/ inject the flush
/ secure the cannula with the strips of tape
/ place rest of the dressing over the cannula
/ Clip the end of the bionector so it is neat and secured
/ Wash your hands and thank the patient

2. Skillz lab

Research objective:
How is the procedure executed in normal circumstances.
Blank areas to be researched:
Difference between normal and emergency situation
Experience the procedure
Empathise with executors of the procedure
What are the difficulties in the procedure
Which actions have to be performed
Location:
Erasmus MC
What:
Lesson for medicine students to practice the procedure
Findings:
1st case: Difficult to puncture student
If the vein is difficult to puncture, you can vary with a larger or smaller needle, insert the IV more slowly/quickly.

2nd case: Middle aged woman with chemo
If the patient is older, they will have a less firm skin. Because of the chemo, the patient will have stiff veins. These two will cause rolling veins. To help this, the nurse can tighten the skin with two fingers.
complications: the IV can be subcutaneou, and therefore cause a cavity with liquid which is very painful.
If the vein is too difficult to puncture, find another spot - distal to proximal (hands to shoulder). If that does not work, try the foot.

3rd case: an infection has occurred.
With infection, take the IV out. the veins will get firm really quickly.

4th case: the patient is in shock.
When in shock, the veins will get more narrow, this leads to that the patient is not pierceable anymore. Always try to put in an IV, is this does not work, puncture an artery.

Practical assignment insights:
/ In practice, feeling is more important than trying to locate the vein visually.

/ The first step is to put on the tourniquet, after tap the veins lightly, feel if you can locate a vein. Remember the spot and get your needle and puncture. Why you have to remember is because after feeling the first time, you have to make the spot sterile, where after you can not touch the location.
/ When do you know when you are in the vein? That is a matter of feeling. If you feel the needle sliding, you are in the vein.
/ When demonstrating to the students, the teacher missed on the first try
/ Even the fact that you can see the veins better, puncturing on the hand (IV) is more difficult. The veins are more narrow and fragile.
/ Putting in an IV is super painful, after missing a few times, the body can get into a shock because of the pain.
/ The student assistent has had a bad experience when practicing putting in IV's. With her, the first two tries did not succeed.
/ You can know the depth of the vein by feeling a bit of resistance. This occurs by going through the vein wall. If you are in the vein, there is less resistance.
/ While performing the procedure, you come one hand short. As seen in the picture, how the student holds the three way valve with two fingers, while tightening the skin with the other two.
/ The procedure is complicated since everything needs to be sterile and after opening, they need to stay sterile and can not come in contact with anything else.
/ There are a lot of parts needed for the procedure and there are a lot of steps to be taken
/ Focussing on the first part of the procedure, locating veins, it is now a guesstimate. The veins are localised by touch, sometimes veins and tendons are mixed up, after which the spot has to be remembered and the needle is inserted.
/ I was nervous trying it the first time, because after localising, I was uncertain whether if I had remembered it well. And I was insecure while inserting. It would have been helpful to have some sort of reference.
/ During the procedure, i noticed that you come one hand short to hold things for quick insertion. Maybe make the product also to help the nurse with other steps.

3. Market research

Existing products

VeinViewer

/ Allows you to switch colors within the image window. This unique feature assists clinicians in customizing the projected image based on factors such as skin tone, density of hair follicles and room brightness.
/ projection with over 3000 data points demonstrates our image accuracy.
/ VeinViewer's projected vein width for vessels most commonly accessed during peripheral IV placement (3-7 mm wide) displays with near perfect accuracy, a differential of +/- 0.06mm. That is 60 microns, or micrometers; 40% smaller than a human hair and only 20 microns away from the visibility threshold
/ HD imaging and exclusive Df2 technology (digital full field)
/ Ideal for minimizing surface structures such as hair and wrinkles.
/ Enhances finer structures, ideal for identifying small veins in pediatric patients.
/ With our AVIN™(Active Vascular Imaging Navigation), you can assess all possible options for peripheral vein access
/ VeinViewer's Eyes On Patient (EOP) hands-free technique allows you to easily integrate this technology into your normal procedure;
/ Determine the location of valves and bifurcations and avoid these problematic structures.
/ Increase first stick success by up to 100%
/ Find the optimal access point and vessel target that is sufficient for the length of the catheter.
/ Navigate curves in the vessel.
/ Visualize a rolling vein.

IV-eye

/ This is the method used by the IV-eye. By transmitting NIR light from both sides of the target area, the device transmits light deeper into the patient's tissue than the reflective method, therefore displaying deeper veins more clearly.
/ NIR Light is transmitted straight into the skin from above. This method is more suitable for viewing superficial veins close to the surface of the skin, and is the method utilised by almost all of the other near infrared vein imaging devices currently available on the market.
/ The IV-eye is placed flat on a patient's peripheral limb (lower arm or back of hand) and uses near-infrared light to illuminate the skin and the subcutaneous tissue. The near infrared (NIR) light is transmitted by means of light emitting diodes (LEDs) in the flexible wings. The near infrared light penetrates the patient's skin, is absorbed by the haemoglobin in the blood, and passes through the fat and other tissue surrounding a vein. The camera on the underside of the IV-eye captures an image of the blocked light and a digital processor creates an image of the underlying vascular structure. This is then shown on an LCD display situated on the top of the device.

Easy Eye

The light is absorbed by different biological tissues in different manners. In particular, the deoxygenated hemoglobin (Hb) absorbs the Near InfraRed radiations, i.e. wavelengths right outside the visible band, in a more effective manner with respect to other biological tissues.
Therefore, through the illumination of the region of interest with this radiation (NIR light) and the acquisition of the image capturing the backscattered radiation allows to create an image with luminosity variations where the superficial venous vessel are located. By aborating these images in real-time it is possible to reveal and show the reconstructed venous map allowing the identification of the best insertion point.

Table 1. Advantages, disadvantages and costs for each technology.

Method	Color Vision[a]	Pressure Sensor	LED	Infrared	Ultrasound[b]	Multi-spectral[c]
Pros	Simple No battery No electricity Suitable for outdoor light Portable Wearable	Simple Fast detection For use in every environment	Simple Portable Various wavelengths Veins depth and diameter can be evaluated Keep the vein from rolling	Various wavelengths Vein map shows on the skin Up to 15 mm depth No patient contact Works in light or dark	Large screen Can see the needle inside the body Needle guide device Vein depth and diameter can be estimated Very deep peneterating	Multispectral camera Ultrasound Real-time sharing Portabale No patient contact Wearable
Cons	Will not work in the dark Not for the colorblind	No image No visability improvment	Need a dark environment Many kinds of products Requires patient contact	Vein depth and diameter can be estimated Requires practical training	Not portable Expensive Complicated Requires practical training	Heavy (300 gr without battery) Requires practical training
Price [USD]	~ 300 (for glasses or bulb)	120	200-630	~ 27,000 not portable/4,500 portable	~ 27,600	~ 10,000
% of Improved PDVA		~ 91%	80%	93%	93%	

[a] The success rates for the color vision glasses are not presented because the glasses were originally made for the colorblind
[b] The price is for a specific designated ultrasound machine. The price of an ordinary ultrasound machine starts from 20,000 USD
[c] The success rates for the multispectral glasses are not presented because they only recently came on the market

IV-EYE® COMPETITIVE ANALYSIS

USD $ 1.45
Euro € 1.3

CORRECT FEB 2016	IV-EYE®	LEADING COMPETITIVE DEVICES		
Company	Novaris Ltd	AccuVein Inc	Christie Medical Holdings	
Website	http://novaris.com/	http://www.accuvein.com/	https://www.christiemed.com	
Product	IV-EYE®	AccuVein AV400	VeinViewer Flex	VeinViewer Vision
Picture				
PRICING				
List Price €	SEE LATEST PRICE LIST	€ 3,950	€ 5,000	€ 9,500
List Price $		$ 5,728	$ 7,250	$ 13,775
List Price €		€ 5,135	€ 6,500	€ 12,350
INFORMATION				
Launched	2014	2014	2010	2008
Manufactured	UK	USA	USA	USA
Warranty	2 years	1 year	5 years	5 years
Extended warranty option	Yes			
Adult / Paediatric / Neonatel	Adult / Paed	Adult / Paed/Neonate	Adult / Paed/Neonate	Adult / Paed/Neonate
PERFORMANCE				
Vein Depth mm	Up to 10mm	Up to 10mm	Up to 10mm	Up to 10mm
REGULATORY				
FDA 510K	Pending	No	No	No
FDA Class (I, II, III)	I	I	I	I
CE Mark	Yes	Yes	Yes	Yes
CE Mark ISO Class (I, II, IIa, III)	IIa	IIa	IIa	IIa
OPERATIONAL				
Requires Stand	No	Yes	Yes	Yes
Pre-hospital use	Yes	Difficult	Difficult	Difficult
Viewable sun light and darkness	Yes			
Technology	NIR LED 850nm	NIR 795nm	NIR LED 850nm	NIR LED 850nm
Technique	Transilluminiation	Reflective light	Reflective light	Reflective light
Disposables required	Recommended	No	No	No
Patient Contact	Yes	No	No	No
Battery or AC Power	Battery	Battery	Battery	AC
Product description (from websites)	Simplicity The IV-eye is easy to operate, requires no calibration and can be used with minimal training. Portability The IV-eye is a portable, lightweight, handheld device that is about the size of a smartphone. Performance The IV-eye uses trans-illumination and advanced digital processing to display a real-time image of the tissue and veins underneath the surface to depths of up to 10mm.*	The AccuVein AV400 digitally displays a map of the vasculature on the surface of the skin in real time, allowing clinicians to verify vein patency and avoid valves or bifurcations. It is handheld, weighing 9.7 ounces (275g), but requires a stand to be hands-free. (Stand costs £450)	This small VeinViewer model is a handheld vein illuminator that provides benefits for all patients during the entire Pre-, During- and Post-vascular access procedure. It is targeted to alternate care facilities, such as surgery and blood/plasma centers, as well as home healthcare and Emergency Medical Services (EMS). VeinViewer Flex is designed for durability and maximum portability. Flex is also suited for hospital departments such as the Emergency Department and NICU where space requirements and speed of assessment demand an ultra-portable and reliable vein finder.	With HD imaging and exclusive DP technology, this VeinViewer model offers to-the-bedside mobility, quick set up and an optimal hands-free solution. VeinViewer Vision, the third generation HD VeinViewer, with our exclusive DP2 technology allows clinicians to see deeper vasculature with more accuracy. The Vision model offers fast set up time and runs on Battery or AC power. Vision's durable cart allows for Eyes On Patient™ hands-free technique.
Novaris notes		Market leader but viewed as very expensive and provides limited value to user. Many dissatisfied ex-distributors and tales of user problems with stand, blurred vision.	The original technology. Much improved and shrunken in size but still very expensive and requiring stand.	

IV-EYE® COMPETITIVE ANALYSIS

USD $ 1.45
Euro € 1.3

CORRECT FEB 2016	HEAD MOUNTED DEVICES		CHINESE COPIES	
Company	VueTek Inc	Evena Med	Vivo Light	ZD Medical
Website	www.vuetekscientific.com	www.evenamed.com	http://www.vivo-light.com/	http://www.zd-med.com/en/home.php
Product	VeinSite	Evena – Eyes-On	Vivo-light	SureView
Picture				
PRICING				
List Price £	£ 2,900	£ 20,000	£ 1,379	£ 1,379
List Price $	$ 4,600	$ 30,000	$ 2,000	$ 2,000
List Price €	€ 3,770	€ 26,000	€ 1,538	€ 1,538
INFORMATION				
Launched	2012	2013	2013	2013
Manufactured	USA	USA	China	China
Warranty	1 year	Unknown		
Extended warranty option				
Adult / Paediatric / Neonatel	Adult / Paed	Adult / Paed	Adult / Paed	Adult/Paed
PERFORMANCE				
Vein Depth mm	Up to 7mm	Not Available		
REGULATORY				
FDA 510K	Yes	No	No	No
FDA Class (I, II, III)	I	I	N/A	N/A
CE Mark	Yes		No	No
CE Mark ISO Class (I, II, IIa, III)	IIa	IIa	N/A	N/A
OPERATIONAL				
Requires Stand	No		Yes	Yes
Pre-hospital use	Difficult	Yes	No	No
Viewable sun light and darkness				
Technology	NIR LED 850nm	NIR	NIR	NIR
Technique	Reflective light	Reflective light	Reflective light	Reflective light
Disposables required	No	No	No	No
Patient Contact	No	No	No	No
Battery or AC Power	Battery	Battery	Battery	
Product description (from websites)	"Portable", Hands-Free, Vascular Imaging using a head set mounted device. Veinsite allows clinicians to detect difficult to see veins, valves, bifurcations, and possible infiltrations on patient types ranging from neonates to elderly, darker skin, obese, as well as those with compromised vasculature. Compared to projection based vein finders, the Veinsite claims to display the high quality images and a large viewing area. The Veinsite uses near infrared light that can aid clinicians in reducing multiple IV sticks, unnecessary central lines/PICCs, hospital costs, and concurrently improve nurse efficiency and patient satisfaction scores	The Evena Glasses system is appropriate for pre-hospital, physician offices, clinics or hospitals. The Glasses unit is battery powered and offers portability and ease of use. Unique Eyes-on Glass features include •Multi-Spectral Imaging - for the deep penetration and detailed and sharp images, effective for almost all physiologies. •Real-time anatomically accurate images •EMR/PACS interface enables automated documentation of appropriate care. •Hands-free, cart-free, wearable technology. •allows the user to have full situational awareness plus a clear view of the patient's area of interest, enabling quick and easy location and access to the best vein		
Novaris notes	Interesting device but depth limited and quite cumbersome - not particulary practical	attracted a lot of interest but very, very expensive. Images do not show the batterypack/portable computer that is attached to the glasses. A lot of image capturing and image transfer technology built in. Limited use.	These products are copies of Accuvein & Flex. Brochure shows CE mark but no notified body number. Not possible for class 2a device.	Not seen in Europe

IV-EYE®
COMPETITIVE
ANALYSIS

USD $ 1.45
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CORRECT FEB 2016	VARIOUS NEAR INFRARED DEVICES WITH SCREENS			
Company	InSano	Infrared Imaging Systems Inc	Vasculuminator	Near Infrared Imaging Inc.
Website	www.insano.it	www.irimagesys.com	http://www.dimp.nl/en/products/vasculuminator	www.nearinfraredimaging.com
Product	EasyVein	IRIS VascularViewer	Vasculuminator	Vein Eye
Picture				
PRICING				
List Price £	£ 2,990	£ 4,138	£ 1,724	£ 1,534
List Price $	$ 4,336	$ 6,000	$ 2,500	$ 2,225
List Price €	€ 3,887	€ 5,379	€ 2,241	€ 1,995
INFORMATION				
Launched	2013	2006	2013	2014
Manufactured	Italy	USA	NL	USA
Warranty				
Extended warranty option				
Adult / Paediatric / Neonatel	Adult / Paed	Adult	Adult / Paed	Adult/Paed
PERFORMANCE				
Vein Depth mm	N/A	Through limb		
REGULATORY				
FDA 510K	No	Yes	No	No
FDA Class (I, II, III)	I	I	N/A	N/A
CE Mark			Yes	
CE Mark ISO Class (I, II, IIa, III)				
OPERATIONAL				
Requires Stand	Yes	Yes	Yes	Yes
Pre-hospital use	No	No	No	No
Viewable sun light and darkness		N/A		
Technology	NIR	NIR 850nm	NIR	White Light
Technique	Reflective light	Reflective light	Reflective light	Transilluminaton
Disposables required	No	Yes	No	Yes
Patient Contact	No	Yes	Yes	No
Battery or AC Power	AC	AC	AC	AC
Product description (from websites)	EasyVein is an electronic device that permits to detect and visualize the superficial venous structure of the body in real-time. EasyVein is particularly useful when the venous vessels are very hard to be revealed by conventional analysis. EasyVein allows to the operator to perform the best sampling or infusion procedure since it shows clearly and precisely where the vessels are located. EasyVein shows some many details that cannot observed by conventional analysis and thus it guarantiies easyer and more secure operative sessions on the patient	The VascularViewer generates accurate, real time images of veins and more deeply located arteries. .Important features include •Digital (solid state) device on a stand with nIR camera, computer and touchscreen controlled displays •Safe non invasive, plus nIR has no known harmful effects •U.S. FDA 510(k) clearance and IEC-60601-1 Safety Certification •Manufactured in compliance with FDA GMP and ISO13485 requirements •Separate arms for camera and the display provide flexibility in positioning the device	The Vasculuminator makes the circulatory system visible on a TFT-screen by using infrared technology. Puncturing the vessels is done in a patient friendly and efficient manner. Searching for veins and mispunctures are a thing of the past. The Vasculuminator was developed in cooperation with medical processionals and scientists from several leading Dutch academic hospitals.	
Novarix notes	Italian university product not seen at trade shows or in market	Specialist device primarily designed for arterial sticks	Dutch University product for Paediatric use only.	Screen based American university product, retailing at very low price - not sure of commercial basis of business.

IV-EYE®
COMPETITIVE
ANALYSIS

USD $ 1.45
Euro € 1.3

CORRECT FEB 2016	WHITE LIGHT (POWERFUL TORCH) TRANSILLUMINATORS		
Company	Venoscope	Philips	Veinlite
Website	http://www.venoscope.com/	http://www.usa.philips.com/healthcare-products/HC989805603761/wee-sight-neonatal-transilluminator	www.veinlite.com/
Product	Venoscope II	Wee-Sight Transilluminator	Veinlite LED
Picture			
PRICING			
List Price £	£ 138	£ 69	£ 419
List Price $	$ 200	$ 100	$ 608
List Price €	€ 179	€ 90	€ 565
INFORMATION			
Launched	1994		
Manufactured	USA	NL / USA	USA
Warranty	2 years	2 years	5 years
Extended warranty option			
Adult / Paediatric / Neonatel	Adult / Paed	Paed	Adult
PERFORMANCE			
Vein Depth mm	minimal	transillumination	
REGULATORY			
FDA 510K	Yes	No	Yes
FDA Class (I, II, III)	I	I	I
CE Mark			Yes
CE Mark ISO Class (I, II, IIa, III)			
OPERATIONAL			
Requires Stand	No	No	No
Pre-hospital use		No	No
Viewable sun light and darkness	Prefer darkened room	Prefer darkened room	Prefer darkened room
Technology	White Light	White Light	Orange/red LED
Technique	Transilluminaton	Transilluminaton	Transilluminaton
Disposables required	Yes	Possibly	Yes
Patient Contact	Yes	Yes	Yes
Battery or AC Power	Battery	Battery	AC & Battery
Product description (from websites)	The Venoscope® II transilluminator, The Vein Finder™, allows a clinician to easily locate hard to find veins, making it faster and more efficient for health care providers and clinicians to deliver a higher level of quality care.	Wee-Sight TransilluminatorWee Sight Transilluminator uses a strong LED light to help accurately locate the tiny veins in a neonate's small limbs for improved insertion of an IV, without emitting heat.	The rechargeable Veinlite LED® features 24 LEDs. The 12 high-contrast orange and 12 deep red LEDs can be operated together or separately. With no need to keep spare batteries on hand, this is the most popular model in hospitals. Veinlite® IV access accuracy (85%) vs Standard of care Accuracy (74%) •Fewer IV access failures, needle sticks, Less pain in for the patient and Fewer wasted supplies. Finds veins in children, adults, dark skinned and overweight patients. The C-shaped design stretches the skin for easy needle insertion and stops vein from rolling during access
Novarix notes	Very old powerful torch like product. Sits on skin. Best used in dark but limited success.	Light that sits in babies hand , transilluminating the skin.	Powerful "torch" using orange & red LED's (not infra-red). Good market penetration. Used on varicose veins but not good vascular imager.

Appendix B

Extended programme of requirements

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. Prototype is at TRL 3
5. is suitable for healthcare context
6. can be succesfull integrated into healtcare context
7. has necessary functionalities to facilitate venipuncture procedure
8. is suitable for every age, skin and body type
9. has low invasiveness

b. Production

1. Prototype is made out of PLA
2. Model is suitable for 3D printing
3. Production method is 3D printing
4. Material is suitable for medical context
5. Next prototype is made out of SLS
6. Prototype has low manufacturing costs
7. Future prototype is suitable for mass production

c. Verification

1. Prototype is tested with end-user
2. Prototype is facilitates procedure
3 Safe to use
4. Prototype quickens venipuncture procedure
5. Prototype follows medical guidelines
6. Prototype complies to medical ISO standards

d. Components

1. can be delivered within 2 weeks
2. can be replaced if needed
3. are firmly in place
4. are low cost
5. 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
4. Before use, product is tested
5. Embodiment houses all components
6. Prototype is designed for disassembly
7. Only one size and type of nuts and bolts is used

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. handleiding van 1 A5 without text
3. doos
4. charger

C. Use

a. Charging

1. With a 7.000 mAh battery, the prototype can be used for a day
2. Charging ports are reachable from the outside
3. Battery can power all electronic circuits
4. Prototype does not depend on the mains (230 V)
5. Charger takes all mains voltages

b. Carrying

1. Prototype is pocketable
2. Prototype has dimensions of 145*95*70 mm
3. 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 is adjustable to differences in height of furniture
4. Stand can be detached from furniture by one person
5 Stand is made out of medical approved material
6. Stand has a minimum distance of 20 cm from the subject
7. Stand is adjustable in height to allow for differences in arm size (thickness)
8. Stand is light weight
9. Stand is detachable from prototype
10. Stand is moveable in y and z direction (height and position along the arm)
11. Stand can be positioned precisely above subject
12. Prototype can be positioned and adjusted perpendicular to subjects arm
13. Hand and arm placement should be clear
14. Stand is not in front of projection
15. Stand does not interfere with the procedure
16. Stand can hold a weight of 0,5 kg without deforming
17. Prototype is stable when attached to stand
18. Stand has an offset of 1 cm both sides when holding prototype
19. Stand will not break when dropping
20. When bumped into, stand will not break
21. Prototype should not obstruct the view and operating space of the end user during the procedure
22. Stand does not have sharp edges
23. Stand is ergonomically moved

2. Prodecure

1. It is clear how the device should be turned on
2. The button used to turn on, is easily sterilised
3. The button is waterproof
4. The button does not have sharp edges
5. The button is operable with gloves
6. The button does not allow dirt to get in
7. Button shows indication of status of product
8. If button is pressed, the script is activated
9. Use is easily understood by end-user
10. Prototype has intuitive usage
11. No training is needed to operate prototype
12. Interface is easy to understand
13. Prototype can be operated by one end-user
14. Prototype can be used while the procedure is carried out
15. Prototype increases first attempt venipuncture
16. Prototype has high accuracy and has a success rate greater than 85%
17. Prototype decreases amount of consumables needed
18. Needle is visible in projection
19. Use of prototype reduces venipuncture complications
20. No disposables are needed to operate device
21. Prototype shuts down when button is pressed
22. Automatic shut down after 2 minutes of non-use

3. Imaging

1. Superficial veins are targeted for imaging
2. Veins are distinguished from surrounding tissue
3. Electromagnetic radiation is used for imaging
4. Infrared light within the optical absorption window of de oxyhemoglobin is used
5. Lighting has a tight optical window of 840-860 nm, for which a LED array of 850 nm is used
6. Imaging can be done on differen types of skin
7. The LED array provides a hight contrast between the vein and surrounding tissue
8.
9. The LED array is concentric alligned around the camera
10. The LEDs are powered by the prototype
11. The LEDs use a voltage of 12 V for optimal intensity
12.
13. The LEDs provide uniform lighting
14. The LEDs provide constant illumination
15.
16. The current drawn by the LEDs should be as low as possible

17. A camera with high sensitivity to the sub-spectrum of infrared radiation is used
18. The camera has a resolution of 8 MP
19. Camera iimages in real time
20. Camera provides high quality images
21. Camera is commenly available
22. Camera focus is preset to 19 cm distance to arm
23.
24. Camera feed is sent to a processing computer
25. Camera is inexpensive
26.
27. Camera is easy implementable
28. Camera can image in low light and full light conditions

30. Camera provides high contrast image
31. Image is suitable for image processing
32. Prototype is operable in daylight
33. The illumination system works in different surrounding lighting systems
34. The camera set up only captures infrared light
35.

4. Processing

Hardware:

1. Processor is commonly available
2.Processor can run software
3. The processor is compact
4. The porcessor is used for prototyping
5.The processor is a single board processor
6.The processor fits in the prototype
7. Processor is inexpensive
8. Processor is easy to source
9. Processor can be programmed and controlled
10. Processor can be linked to subcomponents
11. Processor can power subcomponents
12. Processor has a CSI (camera serial interface) connector
13. Processor has linux operating system
14. Processor has at least 1 GB operating memory
15. Processor has onboard wifi connector and ethernet connection
16. Processor is supplied with 5v
17. Processor is supplied with less than 1 A
18. Processor board can supply DLP with 5 V, 750 mA

Software:

18. When button is pressed, software is activated
19. Computational power needed is low to minimise resources needed
20. Software must be able to process the image
21. Image processing increases contrast
22. Software reduces the image noise
23.
24. Software subtracts background
25. Software uses algorithms to extract vein pattern
26. Software reduces image noise by blocking hair
32. Software can be adjusted for different needs

5. Displaying

1. Image created is displayed back to end-user
2. DLP lightcrafter moducle projects image to user
3. DLP is compact
4. DLP is widly available
5. DLP is programmable
6. DLP can be used with embedded host processors
7.DLP is ultra mobile
8. DLP is powered by RPi
9.
10. DLP is firmly placed in embodiment
11. DLP is optically alligned with the camera
12.
13. Visible light projected must be blocked by the IR filter
14. Projected light should not interfere with the camera
15.
16. Filter is placed in a angle of 45 degrees
17. Filter has a >95% reflection of visible light
18. Filter has a >95 % transmission of IR light
19. Camera is placed in a 90 degree angle with DLP
20. Filter is positioned in a 45 degree angle between camera and DLP
21. Access to focus is subject of test
22. Image displayed is 50*70 mm
23. Image displayed has same optical allignment as image captured
24.
25. Image displayed has the exact field of view as the image captured
26. Image is displayed in real time
27. Image is projected directly on top of the actual veins
28. Image projected is blocked from reaching the camera
29. Vein location information is returned to end-user
30. Returned information is 100% reliable and consistend with reality
31. Eliminated surrounding light interference
32. Projected light is absorbed by inner surrounding of emodiment to reduce optical noise and reflection back to camera
33. All projected light is reflected by filter

d. Unintentional use

1. Prototype still works after dropping it from 1 meter height
2. Prototype is spash proof
3. Button can be pressed repeatedly
4. Components stay in place with shaking of device
5. Prototype can hold a weight up to 10 kg without breaking
6. Components stay in place when held in every direction
7. Product can withstand a heat up to 50 degrees
8. Electronic wiring are fixed into place
9. Electronics can heat up during use until 50 degrees without creating a short circuit
10. The product does not contain any cavities or sharp edges

e. Repair

1. Product can be openend to be repaired
2. Components can be seperately replaced for repair
3. New parts of casing can be printed an replaced
4. Components can be taken out and repaired individually
5. Technical manual contains set-by-step repair plan
6 Components can be easily disassembled from baseplate
7. Placeholders indicate position of components

f. Maintenance

1. Prototype can be opened to reach and replace components
2. Casing can be unscrewed to reach the inside
3. New versions of software can be updated by uploading it to the Raspberry Pi
4. Raspberry Pi can be re-programmed to suit differing needs

g. Integration

1. Prototype is minimal viable product
2. Prototype contains minimal functionalities for it to be viable
3. Prototype can be easily adjusted to suit differing needs
4. The minimal viable product can be adjusted to fit into different healtcare contexts.
5. Additions can be made to optimise prototype for differing contexts
6. Additional software can be added to increase accuracy of the analysis
7. User test have to be conducted to optimise prototype
8. Minimal functionalities improve understanding of the product
9. The intuitive use increases integration
10. To further optimise integration, research specific context

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

Appendix C

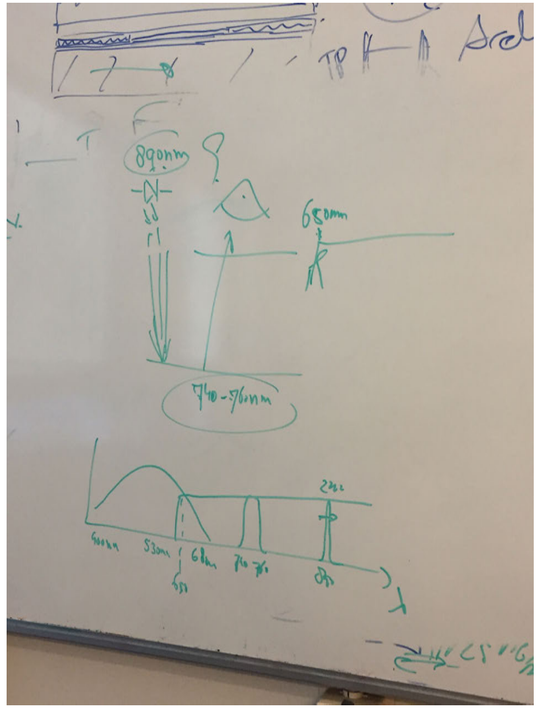
Imaging

Interview Roland Horsten 26/03/2019
Associate professor Applied Physics
Department Imaging Physics (ImPhys)

Visible is until 660 nanometer
When researching filters, look to the relative response of the filters .

Optical setup proposal

Explanation
Take a LED with the exact same wavelength as the absorption of deoxyhemoglobin.This will result in the most absorption and the most contrasted image.
When looking for LEDs, look at the spectral bandwidth. Normally, this is a few nm. So, if you have a LED which emits 890 nm, the spectral bandwidth will be 888-892.
No diffuser is needed, because the light is uniformly distributed on the hand. For you application, test with light intensity and find something similar.



Appendix D

Processing

Interview software expert - Interview Mick Vleeshouwer 29/03
Software developer Microsoft
Goal: Assistance by developing software for image processing

Use OpenCV - That is an open source software where different image processing building blocks can be found. It are ready made models which can be used. These can then be tested and put after each other. The commands for every step are stated with the blocks and can be used.
Steps:
Try the different image processing possibilities with one images
try the different commandos
find a suitable combination
put the different models subsequently from each other
Run the script
look on OpenCV for existing projects
You can ask questions on stack overflow

Optimisation
Quick test setup
use different backgrounds to test how you can lower the computing power
leave machine learning for now, you can put if you want in recommendations
test with CLAHE
try to vary the setup and background - hospital blue - white of the bedsheets

Advice
for the next steps, look at the effect of a curved surface
big data and storage is not necessary for this application
try getting it in real time, and if not, it is already good to achieve it with one image

Software requirements

Working process
If - on/off button is pressed -> start up system
When system is activated -> display product name, after few seconds run script (see image processing for detailed specifications)
When the script is activated -> show enhanced image of veins (see software for detailed specifications)
If on/off button is pressed again -> script will stop running -> display product name after few second product will shut down
If the button is not pressed -> the script will automatically stop running after a couple of minutes (exact time still to be determined)

While there are few papers in the field describing algorithms for the recognition of vein patterns, most of all use simple processing techniques in order to keep the computational needs to a minimum [6,7].

/ Show only a rectangular surface
/ Automatic alignment -Ensure that the vein image is projected directly on top of the actual veins themselves. For now: test pattern to determine the parameters needed for the magnification, rotation and translation of the vein image in order to achieve correct alignment with the veins. (

Program: project the four-dot test pattern on the screen, capture a camera image of the test pattern, measure the location of the dots, calculate the average difference between the x and y positions of the points in the projected image and captured image as well as rotation. (do this continually and you will have the same projected image)

Method for projection / vein alignment (software)
Software is also used to ensure that the vein image is projected directly on top of the actual veins themselves. The projector light, which is colored green with a green filter to simulate the green LED A test pattern, consisting of four 25 pixel radius dots located at the corners of a rectangle centered in the image, is projected on the screen and the location of the dots on the camera is measured in order to determine the parameters needed for the magnification (different in the horizontal and vertical directions), rotation, and translation (different in the horizontal and vertical directions) of the vein image in order to achieve correct alignment with the subject's veins. (paper: The clinical evaluation of vein contrast enhancement)

A software program was written that projected the four-dot test pattern onto the screen, captured a camera image of the test pattern, measured the location of the dots, and calculated the average difference between the x and y positions of the points in the projected and captured images, as well as the rotation of the captured image with respect to the projected image. The program displayed the measured and calculated information on a computer monitor and repeated the measurements every 7 s to allow the effects of translating or rotating the optical axes to be observed continually. If the projector image and the camera image overlay exactly at the focal distance, the average difference between the x and y positions of the points in the projected and captured images would be zero, and there would be no detectable rotation angle between the two images.

Appendix E

Integration

1. User test

Interview Sonja Paus-Buzink
Department: applied ergonomics and design
How to user test

Goal: find a way to test the interaction with the prototype while is does not work.

/ See where and the time of process
/ test expectations
/ Use paper prototyping
/ Make a cardboard model and ask which button they would press for a specific functionality
/ Create a scenario, give the user a story
/ Give them tasks similar to the envisioned working principle for instance: How would you use the product to make a scan. What would you do after you have made the scan?
/ Tell the user to think out loud
/ Ask them questions such as why they did what they did, and what made them do it. What made you expect it and why
/ For a medical product, check medical usability / safety test : IEC62366
/ Look into medical device legislation : michael Wiklund - book
/ Ask for prefered aesthetics
/ Make different concepts

2. Context variation by design

Research: Make product fit to multiple contexts
Interview Wouter Kersten

Context Variation by Design (CVD) is an approach and mind-set that acknowledges and in fact cherishes complexity, i.e., reality, in order to address contemporary (large scale) issues. More specifically, it uses as a starting point that such large scale issues occur in multiple contexts, e.g. regions, countries, user groups; in other words: use cases. By intentionally sourcing views and insights from these multiple contexts from the start a rich issue analysis and corresponding design space is created. This design space acts as a basis for rich, (more) creative solutions with contextual variations that have benefited from bringing together collective intelligence early on. This as opposed to approaches aiming at an optimal solution for one given context followed by scaling to new contexts, which either results in full or partial redesign, again and again, or creates a severe path dependency based on the initial solution. The latter in practice often means that this 'upgrade' for new contexts only constitutes small variations of the initial solution, which do not really meet the needs. All in all, by taking into account different use cases from the start, a more adaptable and adaptive integrated product and business architectures can be developed.

The CVD approach and mindset explicitly aims for larger scale impact and inclusiveness, because more target groups are involved and reached than just in the initial context. Furthermore, it is reasonable to expect that this intentional approach to acknowledge contextual variations and likelihood of scale at the same time will lead to lower end-to-end costs and shorter overall timelines for adoption on a substantial scale.

Guidelines:
/ Focus on multiple use context
/ Problems and needs of different user groups are still more similar.
/ Address the globalising and connected society
/ Complicated situations so not have to be fixed by simplification.
/ Allow for and learn to manage emergence as opposed to wanting to predict and control everything
/ Complex picture emerging where requirements, context and stakeholders seem to get tangled up
/ Intentionally innovating for multiple contexts, by varying the most important context variables while at the same time connecting the intelligence from these contexts
/ Global design and innovation thinking requires attention
/ intentionally & consciously incorporate insight from various contexts & create shares solution space
/ Make use of diverse eco-systems that require allowing and managing emergence
/ embrace complexity. Manage emergence instead of just using controlled focussed management methods will reduce tension between complexity and manageability
/ If a situation or challenge seems to complex, address the complexity by focussing on characteristics of the problem, i.s.o. sub-systems - framing problem
/ Seeking the complexity of the issue at hand by intentionally allowing multiple interpretations and by also reflecting on possible interrelations between these interpretations and their underlying facts and insights
/ Find shared solution space which will allow for faster adaptation
/ Successful adaptation is increased by increasing technological capabilities, usability, fit context and functionality
/ Develop an adaptive product architecture and make it scale well to new contexts.
/ Combine insights from different contexts in an early stage to develop an architecture which can be adapted to needs in multiple contexts - the chance of a broader total level of adoption also strongly increases
/ Lay similarities/differences in use next to each other

Define need to have and nice to have. Have one central product architecture and make variations for this. Work different types of use cases in the process and after, systematically vary upon this. Find the overlap between the use cases. Lay different dimensions over each other and compare these situations. Find the essential characteristics of the use cases and determine whether, for example costs are more important or expertise. With all these findings, create a use case typology. This will include the context, expertise etc characteristics. Have the essential requirements as a baseline and after, look at how to fulfill the 'nice to have'. You can also add this optionally. Play with the different situations and define the scope and look for the main dimensions and characteristics

Context variation by design steps:
/ Detail every use case
/ Plot against each other
/ Find overlay and differences
/ Find core characteristics
/ Find which attributes are distinguishable from others
/ Choose scope
/ Keep reachability of stakeholders in mind, you don't have to satisfy every use case for 100%
/ Don't satisfy but go for satisficing

3. Student user test

User test - students
Thank you for participating in this test. It will be a short test of 5/10 minutes. If I could ask you to speak everything what comes to your mind out loud, since this information is really useful. Do you mind if I record and take pictures? The pictures will only be used for scientific purposes. *Make sure to record and mention to speak out loud*

1. If you look at the product, and I tell you it will be used in a medical setting, what do you think the product will do.

2. How would you operate the device?

3. The device will be used to make veins more visible to support the procedure of inserting an IV or to draw blood by projecting an enhanced image of the veins on the arm. What do you now think of the product?

4. You have 4 buttons - where would you place them and what will you use them for? What would your prefered way of operating the device be? What do you think would be the right way to operate the device?

5. Roleplay: A patient comes with badly visible veins and needs an IV. How would you expect to use the product and create an image of the veins to support this procedure? - you need to tape a toothpick in the place of the veins.

6. For now there are 3 buttons, on/off, s and c. You have to make an image of a person with a dark skin tone, green light is more visible on a dark skin tone. Could you change the color of the light for me?

7. What do you think of the user operation?

8. What kind of information would you want from the device?

9. What do think you should change to improve the interaction?

10 Do you think the product is an enrichment to the procedure?

11. What do you think of the inverted image & which one do you prefer?

12. Extra comments:

1. Patrick MSc student EWI

1. I think it it a product to scan a certain body part

2. I would put my arm in the scan and I would press a button, the scan would bo on and I would be able to see the veins

3. I think it will be a useful product

4. I would turn the product on, the veins will be shown, I would have an on off button, and a button to change the intensity, because I can imagine that not everyone's the same and that different types of skin will need different intensity. And I will have a third button to reduce intensity. So you can tune the device

5. Oh I would not use it myself, the device will turn on. The device will give an indication of where the best site is to place an iv. If not the doctor will mark an indication of where to insert the IV and then turn it off again. and then place the iv when the hand is underneath it, or the hand can be taken from underneath and then the iv will be placed
6. The home screen is seen, and it is not changing, so I think I have to change the intensity to when it is focussed and it will automatically turn on. Oh it is not turned on, maybe I need to press a button. When I press the button I see that the image is changed. If I press the button again, the scan goes off so I press the last button

7. Straightforward

8. Location

9. -

10. -

11. I prefer the one only showing the veins, it is more clear

12. -

2. Dan - MSc student IDE

1.Scan

2. I don't know where and how to put my arm, maybe have some directional or placement indicator.

3.If it is a scan, I am concerned of the difference in thickness of arms. Adjustment would be nice to have to have the focus at the same point for every arm. Furthermore, I have also a tipping concern. The product goes far out and looks like if I will touch it it will tip over. Maybe if it is attached to a bed or cart.

4.Do you also have knobs? Do you turn on the light? Knob to turn up the projection intensity. For light skin people super easy to see, for dark skin people not easy to see. Knob to move the scanning area. I would not want to have a lot of functionality, because it will be used to decrease my insertion time. I would automate it as much as possible. If it detects an arm underneath it should go on. And just an up and down arrow to adjust height. Or it can tell me which way to go for best vein location. Keep information projected also as little as possible

5. I would put your hand underneath, press scan. I have an issue here, I can not see anything. There is no access and there is no free visibility. Top access would be nice. maybe instead of putting the projector below it, put it here, so it would project sideways. Is the corner would be cut off instead of square.

6. It would be nice if it would auto change colour for me. You have a scanner and also an image. So you know the brightness of the surface and also the image. So if the brightness will be in this category, the projected light should be green, and if it is in the light skin category, it should be blue (for instance).

7. Check if the position of the patient in relation to the position of the doctor; laying in bed or sitting in a chair. The doctor will be higher or lower, see if the product will give enough of visibility possibilities.

8. Not sure, i'm not a nurse

9.-

10. -

11. I would prefer the non-inverted but i'm not sure which one is better for the actual procedure.

12.-

3. Rahul - MSc EWI

1.-

2. I would put my hand underneath and press something on the side to activate the system.

3. -

4. I would have a zoom in and out knob to determine focus. Also i would have a tune knob to change between the visible range of light.

5. I would have the product when you turn it on to automatically start. First the product name would be seen and then the scanning will automatically start

6. For scanning, if the nurse would be in a hurry, it would be very useful.

7.The changing color is useful, but I don't see the added value of an extra scan button.

8. -

9.-

10.-

11. I would prefer the non-inverted image. to me it is more clear

12. -

4. Meike- MSc - IPD

1.Lamp, its on a desk. A gel nail lamp

2. Move the stand to my hand to harden my gel nails.

3.I think I would be at the doctor and I think the stand can be adjusted to focus on my hand

4.I would put everything on the top, so that you will have some sort of remote control. On off button will mean that the lamp will turn on and that you will be able to see the veins. I will have a minus and plus button to change light intensity. And I would have a scan button so you can do the final scan and the image could be captured and maybe used for data. as if you would press 'copy'. Maybe I would also have a contrast and brightness button, just like photoshop to adjust the image. I think I would prefer buttons instead of knobs so I would know how much steps I would be taking. so buttons: contrast, brightness take picture, on/off.

5.First I would make sure the light settings are good. I would turn the light on with the on /off button. If I press the second button, the color changes, I think this is used to change contrast. If I press the button, I can see information on my computer. however during the procedure, I would be in the light beam with my hands.

6. I press the on/off button. if I press C, it changes color, if I press it again, it will change again. I think the color button is just skipping through the colors and if you do it more often, you will know which color comes when.

7. For me it is still a little bit vague what the added value is of the scan button. maybe if you want to capture the image for data on your computer. If it is not linked to the computer, then i would like to have a screen on the product. because during the procedure, your hands interfere with the light, and with the screen, you would still be able to see what you are doing.

8. Best insertion location.
9.adding a screen so i will still be able to see what i am doing if my hands will interfere with the projection.
10.yes
11.I would go for outline, because I would trust the computer that it will be more precise than my own eyes. So I think it would be nice if the computer would give a cadre of where i can insert the needle.
12. If I don't have a screen, then I would not be able to see the projection at all times.

5. Ludo - MSc - IPD

1.Some kind of imaging process, I think that something will be captured underneath the box.

2. I would put my arm underneath and set the right height with the stand. I now only have the idea that the only interaction is setting the height.

3.-

4. I would place the on/off button on the stand, because you don't want to turn it off accidentally when you set up the device. Furthermore, I would have to buttons to change light intensity. I can imagine that it would be nice if you put your arm underneath, you can change the intensity to check if you can see the veins even better. But the product will have to be more stable that when you change the intensity that it won't wobble. Maybe you can also have a knob for the brightness on the stand, so you won't interfere with the projected image.

5. With these 3 buttons, i would first turn it on. By turning it on you will only see the logo. but that is not enough, because we want to see your veins. So I would press another button to scan. Yes the next button is indeed scanning. Okay so the next step then would to know in which vein to insert so I would press the last button, with color, and I see the color changes to green, but I think that that would mean that this all will be good to insert. After insertion, i would press the on/off button again to turn the device off.

6. So you assume there is difference in skin stype? so you could change color, brightness or intensity with that button but you still have to research which functions need to change. Yeah that sounds logical. I would start testing with the difference for the skin types. If it comes forward, for instance, that one color is the best for every skin type, and the highest intensity makes it best visible, I would skip the button and reduce the amount of buttons.

7. The first thing what comes to my mind, is that when you turn it on, the logo shows, and that you then have to press another button to scan. I don't really see the added value of the extra button or that the home screen is shown separately and that it won't start scanning automatically. Furthermore I am concerned of the stability of the device while making a scan. Because if you press a button, the device wobbles.

8. blood pressure maybe? That would be nice for in future, and it can also be projected as well.

9. I wouldn't put the buttons on the device but on the stand or a different controller next to the device, for stability, but also because I think if the doctor has to operate the device from the top and i would be sitting here, i think it will be awkward and an invasion of my personal space.

10. -

11. I think only the veins, i think it would be more clear.

12. I would like to have the vein image tattooed on the hand. haha no but would be nice to be able to still see the veins and insertion location after the hand is pulled away from underneath. because if you want to insert, you will have your hand in the way of the projection.

6. Roosmarijn - MSc Biomechanical design

1.Looking at the shape I think it is some kind of lamp. but in medical settings, i think because of the box, that it will gather data and from the box it will go to a system.

2. I think I would need to press a button on the device or on a thing next to it and the system will go on and run.

3. I think you need to put your arm underneath, keep it in place for a while so it can scan and then if it is ready, I think it will automatically so the next step and show the lines of the veins. I don't think that the user has to activate the system, I think the device will give a sound to let the user know it is ready.

4.I would not put anything on the top, because it will wobble too much. So i would place them at the bottom of the stand and on the spine of the stand. one button will be on/off. The next button will be a button to start the scan and these two will be settings. And I think you would need to tell the product what kind of patient is going to be scanned; child, weight etc. And what kind of skin type he/she has. To make this easier you could have a display with a menu. And I would place this on the top so it would be easy to look at. And then maybe have 3 buttons underneath the screen for previous, next and oke - no touchscreen because you don't want to wobble the device.
If the product can be used without stand, I would place the buttons on the top and would have an on/off, start (to start the process). And I would have a touchscreen which will guide you through the steps, so you won't forget a step.

5. After I give you instructions where to place your hand, I would press on/off button. Oh I see that the scan start automatically. Then I would press the second button, i think it is freeze. It changes color but i don't really know what the function is. Oh i think you can use it when the image is not really clear, or maybe when you have a different skin color as the previous patient

6.I would press the second button

7. Well, it is not easy reachable. But I still managed. But maybe for the next version, it will be nice to have more space. If i would be a doctor i would be bent over the product and it will be in your sight, it maybe will cause shade, and you can't really move freely. I think you can solve this by first marking an insertion location

8. I think the information I would want is what the right type of light is for each skin type. maybe you can install it on the device that it would give the best option automatically. And maybe the device can also give a sound notification when the vein situation changes, so the doctor knows he/she has to be alert.

9. it was self explanatory and it actually showed me procedure issues, that i didn't think of myself, that you need different kinds of light for different types of patients. furthermore it was very intuitive.

10.-

11.I think i would prefer to have shown where i should insert the iv, instead of where not to insert. And maybe it would be nice to have a line to indicate the middle of the vein, so you would have the most chance of success.

12. If you capture from the top, when inserting an iv, not only the product is in the way, but also your hands. And maybe you can do something with sound use-cues or feedback

7. Lieve - MSc Management of the Built Environment

1. A scan for some part of your body

2. I think it is a static product and that you can not move it, because it is fragile. and I think that I have to go to the product instead of that the product comes to me

3.It is used for drawing blood and that i would be seated in a chair and that then the product will come my way to scan my hand or arm.

4.The first thing I could think of, is that you will need buttons to change brightness for people with a dark skin. Because I think people with a dark skin will need a different light intensity or color. Furthermore, maybe a lock function that when the product is in position to lock the position. I think I would position the on/off on a stable location, so on the stand. if it is on the product, it may wobble. The brightness I would place on the stand as well. If the product is also used without stand, I would place them on top. Or maybe on the side, because then you can look at the buttons from the side.

5. Then I would first place your hand underneath and then press the on/off button which also directly show veins. And after the veins are visible, I would adjust the image. Now it is super blue, and green, which is making the veins less visible, so I would press the button again, and orange is making it worse, so i'll press again. So the button is to change the color to see veins in different depths.

6. Yes, i would press the button.

7. I think it was a good interaction, it was easy understandable

8. I think the basics? Like temperature, blood pressure?

9.If you want to have a high and easy usability, I would leave it like this. but if you want to further develop it, I think you would need a display with temperature and extra information so everyone can use it to insert a needle.

10.-

11. I would use the non-inverted image because it would have a higher resemblance to the actual situation

12. -

8. Leoni - MSc SPD

1. I think you need to put something underneath and then it will scan the object and with these images you can do something.

2. I would put someone's hand underneath and then I would click somewhere to turn it on, I think on the top. and then you can operate the device and maybe also change the height with a handle or to put it more close. And then an option for focussing

3.-

4. This would be on, this would be focussing. I think zooming in and out would be a knob. Maybe you can have a manual and automatic focus option. The on/off would be at the side and the others on the top

5. I would turn the device on with the on/off button. Now I see the logo and then automatically the veins. There is another button, which I press. and the color changes, I think that is so the light adapts to different skin types.

6.-

7. I can imagine that there would be something around it so you can better see the projection. Maybe i would like to adjust the height so I can see the buttons on top better and have more overview of the hand, or I could be seated higher.

8. I would want to save the patient's data. I can imagine that that information could be quite useful for if someone gets ill or maybe there is something else you can derive from the vein image. And maybe I would like to see the data on a display op top. And i would prefer to have it on a display instead of it being projected as well, since I think people will trust a display more.

9.A placement indication, now I don't really know where to place my hand. Or if you are in bed, maybe a stand where you can put your hand. But these are more additions to the product and not for the interaction. for interaction I think i would add zoom in and out and make it a digital function instead of a mechanical function. If it is mechanical, it is less precise.

10.-

11. I would go for inverted, because with projecting on the veins, you actually cover the veins, and by projecting around the vein, you will still be able to see the vein.

12. -

Conclusion

1.A scanning device, lamp, data collecting device

2. / I would put my arm underneath and with a button on the device to activate the system.
/ I would press a button next to the device to activate the system.
/ Maybe have some placement indicator.
/ Move the stand closer to my hand
/ Set the right height
/ I don't think you can move the system, it looks fragile

3. / Useful
/ I'm concerned about the different thicknesses of arms for focus
/ Product looks unstable

4. Knobs:
/ On / off button - 100%
/ Just the device
/ start scanning right away
/ Change intensity 100%
/ Plus and minus
/ Scan
/ Brightness 75%
/ Plus and minus
/ Knob
/ Focus - height adjustment - zoom in and out
/ Up and down arrow
/ Focus - digitally
/ Zoom in and out knob
/ Automatic
/ Change between visible range of light
/ option to change light for different types of patients and skin types
/ Display 50%
/ Touchscreen - to guide through the steps
/ No touchscreen - to not interfere with the projection
/ Setting option

Comments:
/ I would prefer to reduce functionality because the product is used to decrease procedure time
/ Automatic device activation through arm detection
/ Automate it as much as possible

/ Show optimal insertion location
/ Keep information projected as little as possible to reduce confusion
/ Place the buttons so that you don't interfere with the projection
/ Place on/off somewhere else than the tune functions

Location:
/ See images

5. / Difficult to choose a position when the product is in the way
/ No free visibility - top access would be nice
/ Automatically start scanning would be a good option
/ Interference by hand with projection
/ The green color seems as if all the veins are good to inject
/ Change color to see veins in different depths

6.-

7. / It is very straight forward
/ Confusing to first have a start screen - don't see the added value
/ Color changing is useful
/ Concerned about stability of the product
/ Not easy reachable
/ Easy understandable
/ Intuitive (2 buttons)

8. / Insertion location
/ Blood pressure?
/ Right type of light for each skin type
/ Sound notifications when the situation changes
/ The basics?
/ Display / store patients data
/ Reduce amount of buttons, stick to necessities

9. / Give insertion location (check this with nurses)
/ Placement indication
/ Auto change color for each skin type - you know the brightness of the surface and also the image
/ Add screen so you will still be able to see what you are doing if hand interfere with projection
/ Put buttons on the stand or different controller for stability
/ Leave it like this, but for a fancy product have all extra information on a display so everyone can insert a needle
/ Automatic zoom in and out - more precise than mechanical

10. Yes - 100%

11. / Veins 60%
/ Inverted 40%
(Check which one is better for the actual procedure)
/ Have a line to indicate the middle of the vein so you have the most chance of success

12. / Concerned for the hand and product blocking the projection
/ If I don't have a screen, then I would not be able to see the projection at all times.
/ Have the veins still visible when I take my hand underneath
/ do something with sound use-cues and feedback

4. User test - nurse

Gebruikerstest - Medici / Verpleegkundigen
1. Als je naar dit prototype kijkt, en ik je vertel dat het in een medische setting gebruikt gaat worden, wat denk je wat de functie ervan is?

2. Bij deze functie, hoe zou je het product gebruiken?

3. Het product zal gebruikt worden om de intraveneuze toegang te verbeteren door aderen beter zichtbaar te maken. Voor bijvoorbeeld venapunctie en het aanleggen van een infuus. Het zal een versterkte afbeelding van de aderen op dezelfde plek terug projecteren. Wat is je eerste reactie van het product als je dit hoort?

4. Je krijgt 5 knoppen. Elke (draai)knop mag je een eigen functie en ook locatie geven op het product. Wat zou jouw voorkeur hebben van het bedienen van het product? Hoe zou jij het bedienen?

5. Rollenspel: Het product heeft nu 2 knoppen, waarvan de functies nog onbekend zijn. Zou jij met het product te gebruiken een infuus aanleggen bij mij? Hoe zou je verwachten dat je het zou gebruiken om een ader projectie te krijgen? Wat heeft je voorkeur voor het gebruiken? Normaal een spuit - nu een prikker

6. Wat denk je dat de functie van de knoppen waren?

7. Wat vond je van het gebruik?

8. Wat zou je veranderen om het gebruik te verbeteren?

9. Wat voor een informatie zou je van het product willen?

10. Waar zou je het gebruiken?

11. Wat zou je er van vinden als het product een injecteer locatie zou aangeven?

12. Waar in de handeling zou je het gebruik van het product toevoegen?

13. Wat vind je van de omgekeerde afbeelding, en welke heeft je voorkeur?

14. Extra opmerkingen

1 & 2 Interview with nurse & trauma nurse

1.Something with radiology or echo. So you will put something underneath

2. You would put an arm under. But if you do this, you will need something to see it. Or it can be an advanced desk lamp
I have used one at my internship. But they don't have them everywhere because they are very expensive. I thought it was very convenient. It was at a liver (nier) department. And those people often have bad veins, so it is difficult to see the veins then. And such a device is nice to see them, however you still don't know the depth of the veins. But you are helped. Sometimes they use an echo to visualise veins.

3. Buttons; I think brightness of the image. And I think it will be nice to have them on the top and not at the stand, because maybe you will touch it with the arm. And I think it will be nice to have them all together for the clarity. If you can move the device maybe a button to keep it in place. I don't think you need to capture the image. I don't think that will be necessary. That will not have any added value. If the veins shift, you would want to see that shift as well.
I think if the buttons are clear enough a display will not be needed. If there is a display, make sure it is interactable with gloves as well. But you can also combine all the buttons into the display.

4. -

5. Q: Rollenspel voor infuus: Put the device on. Do we use tourniquet to bring veins up? This makes it way easier because the veins come up. First have a look on both arms which is best, then put tourniquet on and then put the sateprikker in.
Q: Why didnot you use the second button?
Because we saw it directly. Not needed to switch between colours.

6.-

7. I now work with children, and sometimes it is scary to put your arm into something. So it should be easy to access for kids or make it look more child friendly (example of a monkey face)
Q: What is easy accessible?
If it is high enough then there will be enough space to insert needle. Maybe there will be shade due to the device due to lamps in the room.
You fully look at the arm when inserting the needle. You also have to look at the needle. In an image you will see the needle, so even possible to check on a screen if you are working correctly.
With this distance a display is not needed because you have to learn again how to insert needle with a display.

Q: What to use/how to use?
Something which can be attached to bed properly but is easy to handle

8. Should be easy to use. Should take the same time as it now costs, so no extra time/handling due to the device.
For the hals it is even more important to insert the needle correctly. Especially used in Intensive Care.

Q: Can this device be used in a sterile process?
Yes, if first attached to bed, then after sterile gloves on etc.

9.-

10-

11. If it is a good suggestion, that is always usefull.
There is a difference between the best technical position and the best user friendly position to insert the needle.
Advice is useful, the doctor can choose to use this advice.

Maybe this advice will be used by heroin adicts. We dont want to learn them what the best spot is.

12.-

13. Inverted is usefull for coloured skin. So white veins for dark skin and dark veins for light skin.
The possibility to switch would be useful so you can determine per patient what is the best choise.

14.
Would be nice to switch between vein and slagader. Especially in Intensive Care, because there the blood pressure is lower.
To insert in a central line this device would be really usefull.

3. Interview ICU nurse

1. I don't see a relation between blood afname and this device.

2. Practical challenge to bring this device to the bed of an ill patient. How to place it on a bed? Mattress is too unstable to place it on. With a clamp it might work because it can be placed at the head side of the bed. It can also be possible to attach to the OKlamp. I don't want it to be in the workspace. Also it should be adjusted properly so it won't fall on top of the patient

3. Button to adjust intensity of light, depends on the effect of a change of intensity. A rotary knob would be best for this. Preferably a smooth knob because that way it can easily be cleaned.
Intensity and power button are enough.
The buttons would be best on the front side because if it is on the top you cannot reach it if it is hanging over a patient in bed. All buttons on the front side would be logical. Maybe power button on the side for it to be clear. Rotary button for intensity in the middle on the front side

4. -

5. I put on a tourniquet I get the device. I connect the device to the bed or somewhere. I power on, now I clearly see the veins. If not I would adjust the intensity. Now I insert the vein with a needle.

6. Q: What was the function of both buttons?
A: Power on/off and intensity.
Q: Do you think different colouring for different skin colour would work?
A: Yes I think this is a nice functionality. But it needs good testing to find best colours for different skin types. Besides sight you also need a lot of sensing with the hands to find a vein. Feeling the vein for me is more important. Also some experience is needed to properly find the vein.

7.-

8.Most important to me is how to place it in a bed of a patient. That should be easy and that it shines from the top on the patient. Also that it is not in contact with the patient. Lastly, it should be easy to clean

13. I would like to see the veins projected because those are the main subject.

4. Interview with ICU nurse

1. It looks like a suprisebox. A pump which can be attached. I would use the clamp.

2. I would not put the device in bed. So I would place it over the bed

3.-

4. Power on/off. A start scan button to scan. Maybe a button adjust the depth of the scan, possibly with slider. And then a stop scan button. I would place the buttons next to each other so you can work with it with one hand. See picture.

5. I would explain the use of the machine shortly as introduction for the patient. Start with disinfecting. I would need an extra hand to hold the device. The hand must be placed below the machine. Now I start scanning and will choose a vein for inserting the needle.

6. The function of both buttons is: on/off and scan button. I like that it is only two buttons because it is easy and you will not be confused with the amount of buttons. Even better would be one button for all. Power on is scanning on. Maybe an extra button to adjust depth. Simplicity is key.

7. I think the size now is a bit too big. It might be hard to perfectly align the device with the patient. Also it can be stand in the way of the doctor. A proper setup should be researched. Maybe position the clamp on the other side of the bed than the doctor will sit. How to install is an important issue. Possibly as a camping light fixated on the doctors head. Flexible positioning is needed as every patient in bed is lying differently.

13. I would like to insert the needle where indicated. So not the negative image. Probably it would not matter but I feel for me this would work best.

Conclusion

1. / Something with radiology or making an echo. It is clear that something needs to be put underneath.
/ Looks like a suprisebox

2. / I would put an arm underneath, however then i am missing the display of information
/ I have used one at my internship. But they don't have them everywhere because they are very expensive. I thought it was very convenient
/ If it is for the patient, i will not know how to place it on the bed. A clamp might work because it can be placed at the head of the bed.
/ Should be placed so it would not fall on top of the patient
/ I would not put it on the bed, but over

3. / Brightness
/ Set position
/ Light intensity - smooth knob, so it can easily be cleaned
/ Start scan button
/ Adjust depth

/ on top, otherwise it might touch the arm
/ all together for clarity
/ capturing image will not be necessary - if the vein situation changes, you would want to see that as well
/ no display needed
/ if there is a display, make sure it is interactable with gloves as well
/ intensity and power button are enough
/ put the buttons on the top, so they are reachable from all sides
/ buttons next to each other so it is operable with one hand

4. -

5. / Only one button was used, since it already gave the right image
/ I would first connect the device somewhere, power on and if I would not see the veins, I would adjust the intensity
/ Explain the device to patient, disinfect the insertion location, place hand below the machine and start scanning

6. / Power on/ off & intensity
/ Changing color to adjust for different skin types is useful, however this should be carefully researched.
/ On/off & scan
/ I like that it is only two buttons because it is easy and you will not be confused with

the amount of buttons. Even better would be one button for all. Power on is scanning on. Maybe an extra button to adjust depth. Simplicity is key.

7./ Make it more child-friendly, since children have very difficult veins
/ Make it more operable, so it is not interfering with the procedure. You have to be able to see the full arm. With a large enough distance a display will not be needed, since you already see what you are doing.
/ It should be attached to the bed properly but still be easy to handle
/ Size too big, might be hard to perfectly align the device with the patient and it can also be in the way of the doctor. A proper setup should be researched.
/ Flexible positioning is needed as every patient in bed is lying differently

8./ It should be easy to use
/ time needed for procedure while using product should be same or less
/ See possibilities for inserting in the neck for the carotid arteries, this is useful in the intensive care
/ Most important to me is how to place it in a bed of a patient. That should be easy and that it shines from the top on the patient.
/ should not make contact with the patient.
/ It should be easy to clean

11. / If it is a good suggestion, that is always useful.
/ There is a difference between the best technical position and the best user friendly position to insert the needle.
/ Advice is useful, the doctor can choose to use this advice.

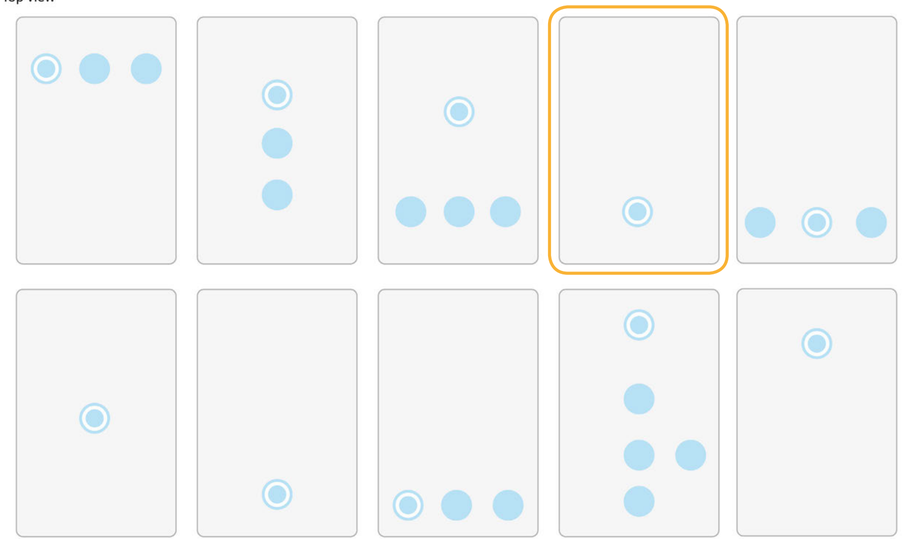
12. -

13. / Inverted is useful for coloured skin. So white veins for dark skin and dark veins for light skin.
/ The possibility to switch would be useful so you can determine per patient what is the best choice.
/ I would like to insert the needle where indicated. So not the negative image.
/ I would like to see the veins projected because those are the main subject.

14. / Research possibility to be able to switch between seeing an artery and a vein, this will be useful in the intensive care because of low blood pressure
/ To insert in a central line this device would be really useful.

5. Button placement

Top view



6. Product placement

Similar existing products & their placement

Intracranial Pressure Monitor (ICP monitor)
This is a small pressure sensor that is placed surgically beneath the skull. It attaches to the ICP monitor at the top of the bed. It allows staff to continuously watch the ICP.

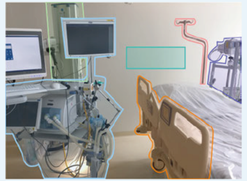
Intravenous Pumps (IV)
Along-side the bed there will be several poles with small machines attached. It is common to see several machines and bags of fluid at the bedside. The IV pumps deliver fluids and medications to your loved one.

Monitors
The monitor is a machine at the side or head of the bed. It helps to watch the heart rate and rhythm. It also gives readings of blood pressure, respirations, and heart and lung pressures when needed.

- Heart rate and heart electrical tracing (ECG)
- Oxygen levels in the blood I Blood pressure
- Pressure in the veins (CVP) I Urine output
- Temperature
- All the fluids, food and drugs.
- ventriculostomy

Ventilator - breathing machine
This machine is used to help your loved one breathe and keep enough oxygen in the blood. A tube is inserted through the mouth or nose into the trachea (wind pipe) and is attached to the ventilator. The patient will not be able to talk until this tubes removed.

Kidney machines
Some patients' kidneys stop working due to their illness. The kidneys work to filter the blood and remove waste products (and in doing so produce urine) so if they fail, it is important that the machines take over this job. To do this a special large tube is put into one of the big veins in the leg or neck.



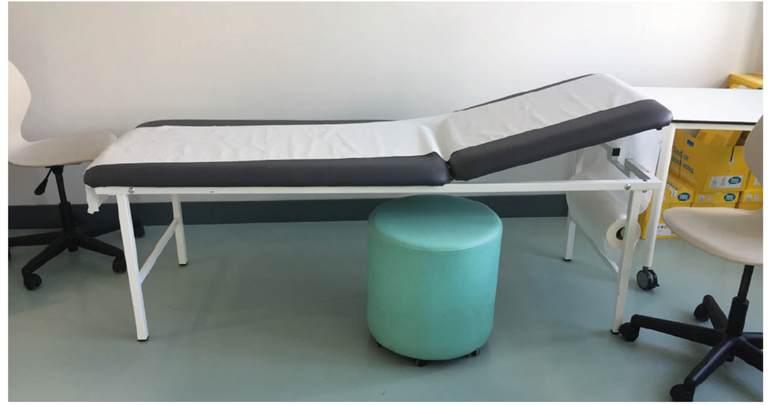
Other possible placements
Besides the possibility to clamp the prototype to an ICU device, it can also be positioned onto other objects in the ICU.

Room frame
- Monitors / medical arm / pole mounted
- Bedrail
- Wall mounted
- IV stand
- Regulator

After considerations, the best location to place the product on an object which will always be present for every patient, which is the bed. Positions for placing the device on the bed, are the bed rails on either side or at the head board. After discussing with a nurse, she suggested to not place the product where it might fall onto the patient. It would be safest to not let the product hang above the patient. Thus, the bed rails would be the best option.
At sanquin, the blood donation department, there also has been looked into the best placement for the product. Here, the chair also has several clamp possibilities on either side of the arm rests.

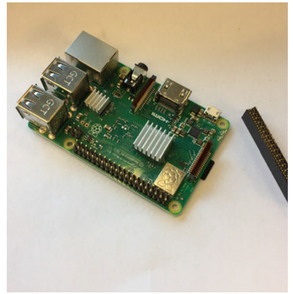
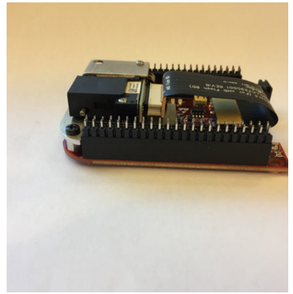
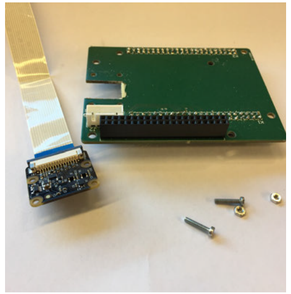
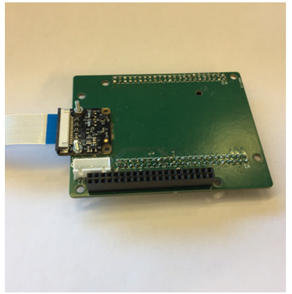
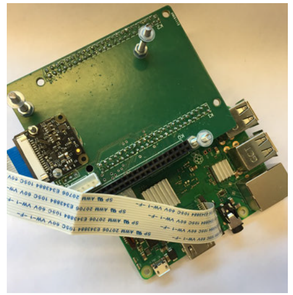
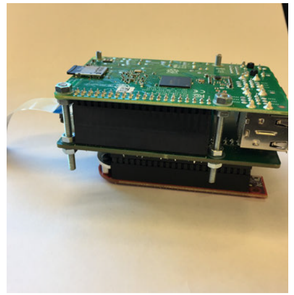
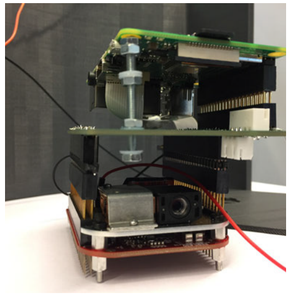
Finally, there has been looked at possibilities at the general practitioners. Here also, the object the patient will be located on has clamping possibilities.

Production
After a visit to Reinier de Graaff, a researcher suggested looking at a ICU technical product specialist, provita, instead of designing an own stand. Looking at their offer, these following products can be combined to get the desired stand. See figure below

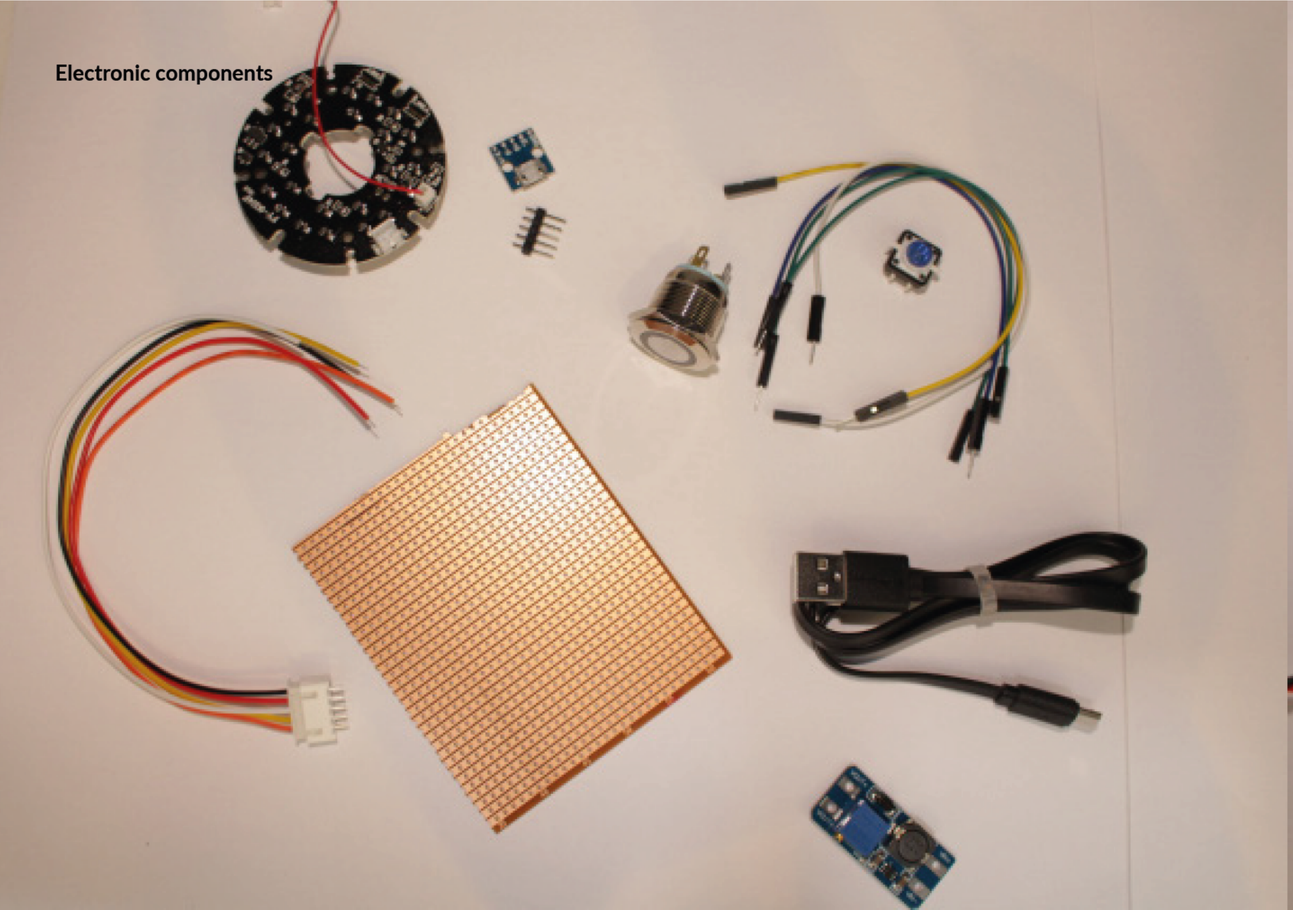


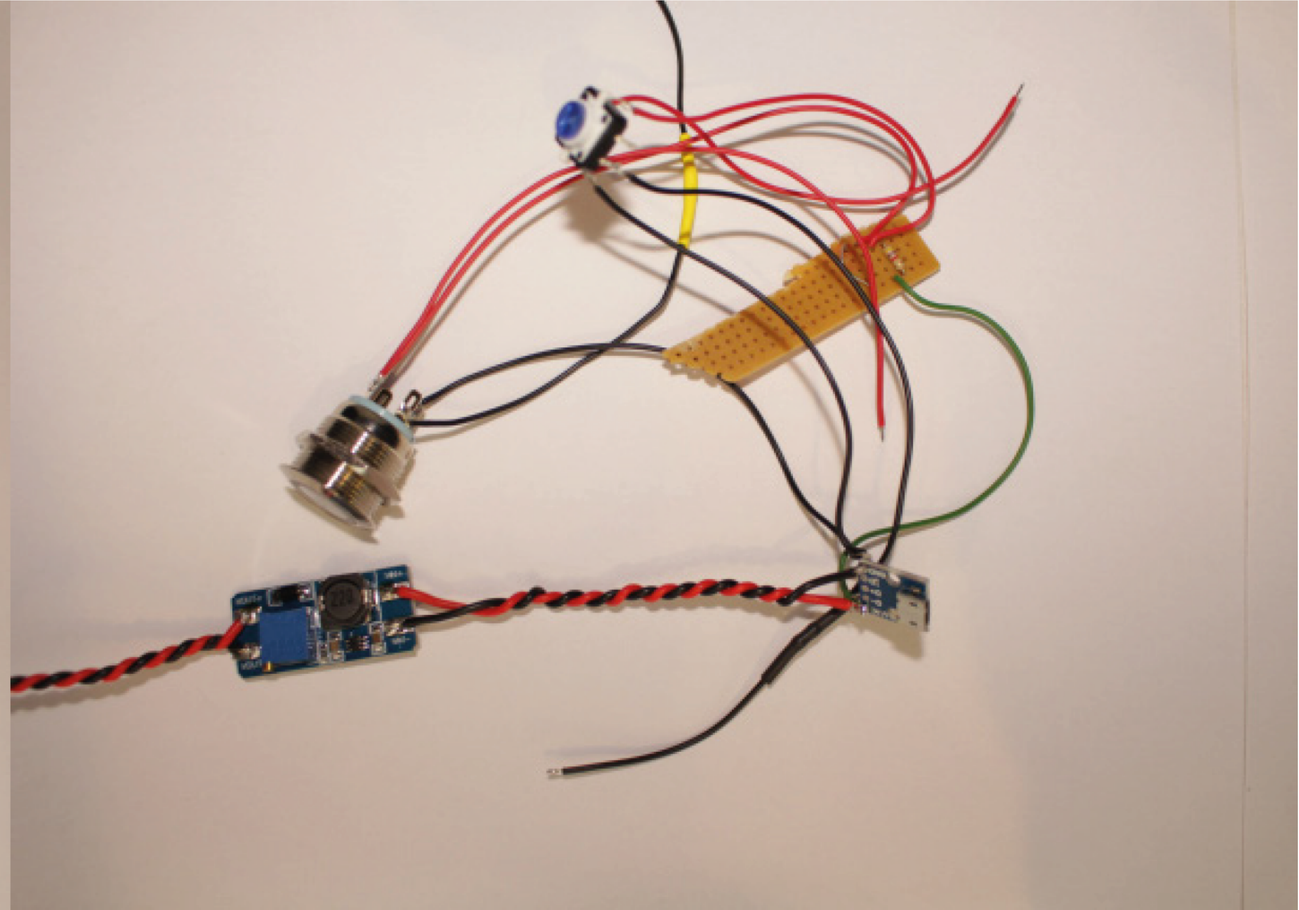
7. Full assembly

PCB connection

Electronic components





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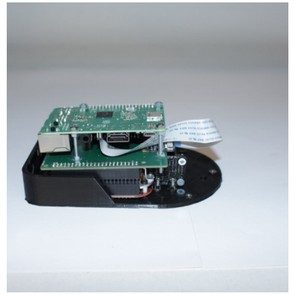
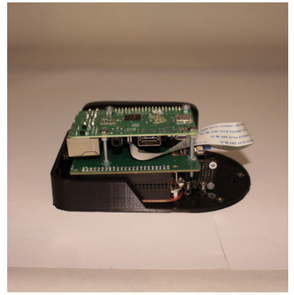
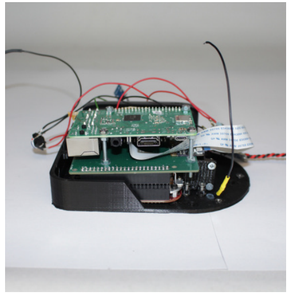
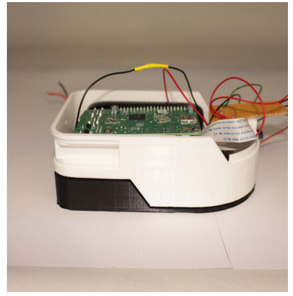
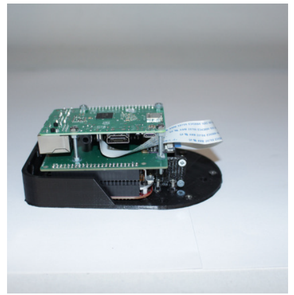
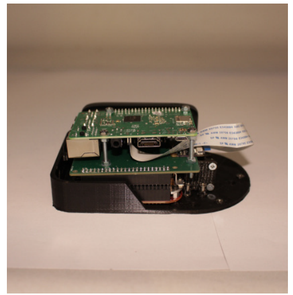
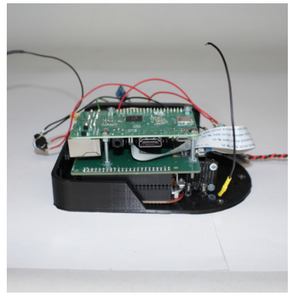
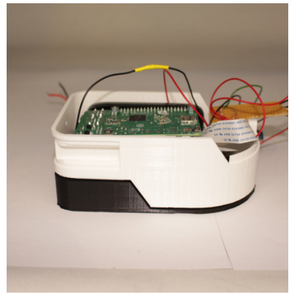
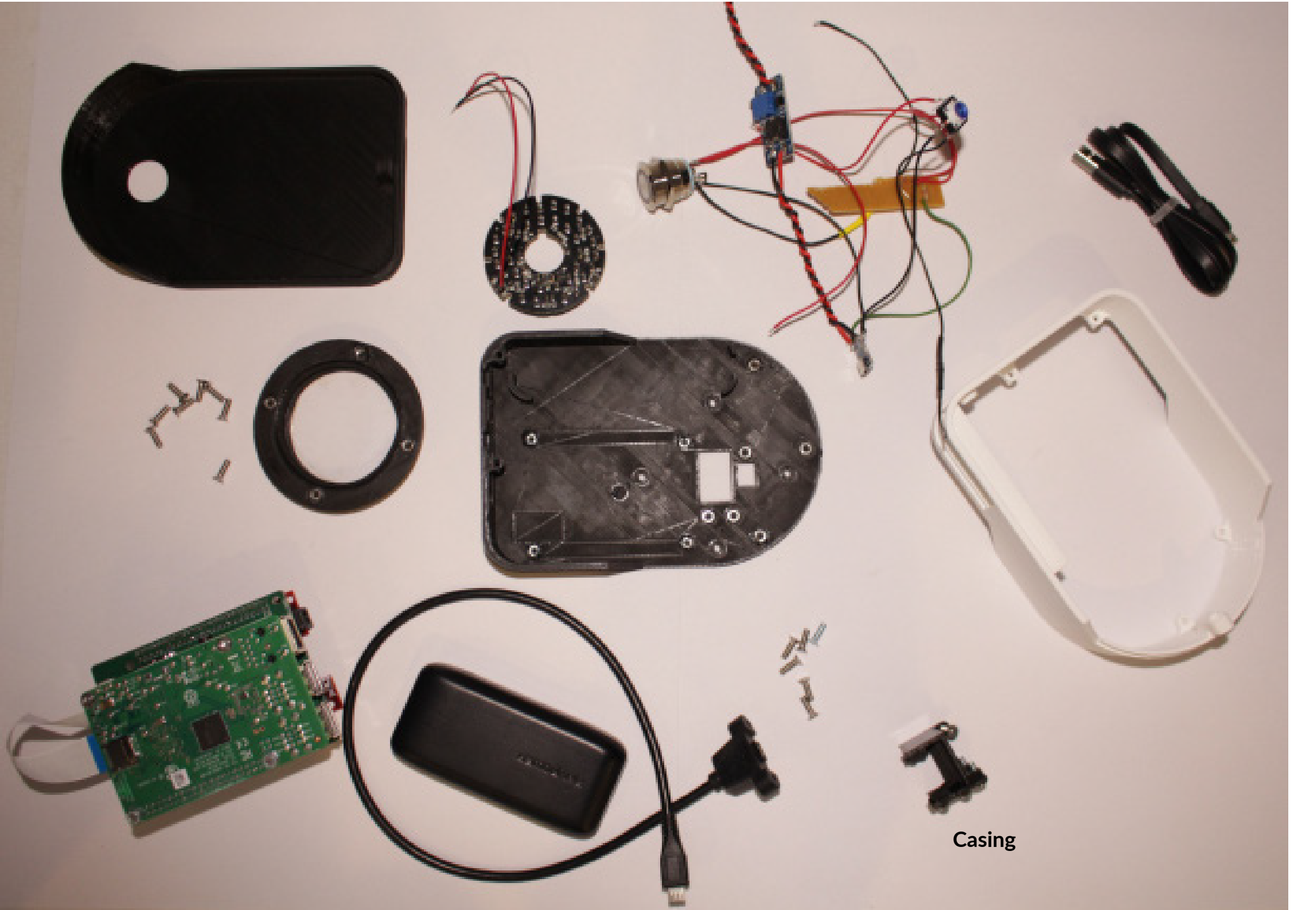





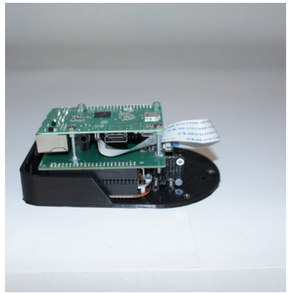
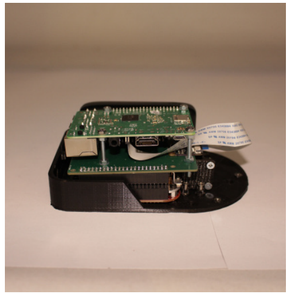
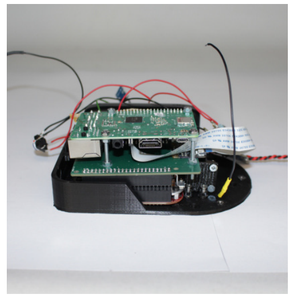
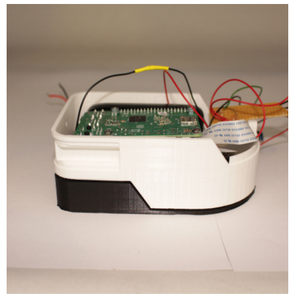


Casing




8. Bill of materials

Part	What	Model	Amount	Cost	Website link	Lead time [work
	RPi	Raspberry Pi 3 M	1	€ 38,95	https://www.kiwi-	1
	Projector	TI DLP® LightCr	1	€ 89,00	http://www.ti.com	5
	Powerbank 68.000 mAh	RAVPower RP-I	1	€ 19,95	https://www.ama	3
	RPi NoIR camera	V2 - 8 MP	1	€ 29,95	https://www.kiwi-	1
	Micro USB charger	5V - 230 A	1	€ 3,00		
Optics	IR filter	45 deg cold filter	1	€ 33,70	https://www.edm	3
	LED	fy-5036	1	€ 1,00		20
Embodiment	Casing (PLA)	Custom	1	-		
	Top plate (acrylic)	Custom	1			
	Stand	custom / provita	1			
	Charger	micro usb	1	€ 6,00		
PCB	PCB	custom	1	€ 20,00		3
	JST-XH 5-pins - connector	JST-XHCABLE5I	1	€ 1,00	https://www.tinyt	1
	JST-XH 3-pins connector	JST-XHCABLE3I	1	€ 0,60	https://www.tinyt	1
	PCB - RPi headers	2x20PFEMALE	1	€ 0,40	https://www.tinyt	1
	USB dip adapter	MINIUSBDIP5	1	€ 0,50	https://www.tinyt	1
	2x 20 female connector	SSQ-120-03-G-D	1	€ 1,00	https://www.samt	1
		SSQ-123-03-G-D	2	€ 1,00	https://www.samt	1
	on/off button	AB6Y-A-6.3V-BL	1	€ 3,00	https://www.tinyt	1
Connectors	M3 threaded rod	45 mm	4			
	M3 threaded rod	35 mm	4			
	M3 nuts		72			
	M3 bolts	10 mm	8			
	M2 bolts	10 mm	2			
	M2 nuts		4	€ 6,00		

Appendix F