C-VEIN : A LOW COST VEIN DETECTOR FOR INDIAN SCENARIOS

PRODUCT DESIGN PROJECT III

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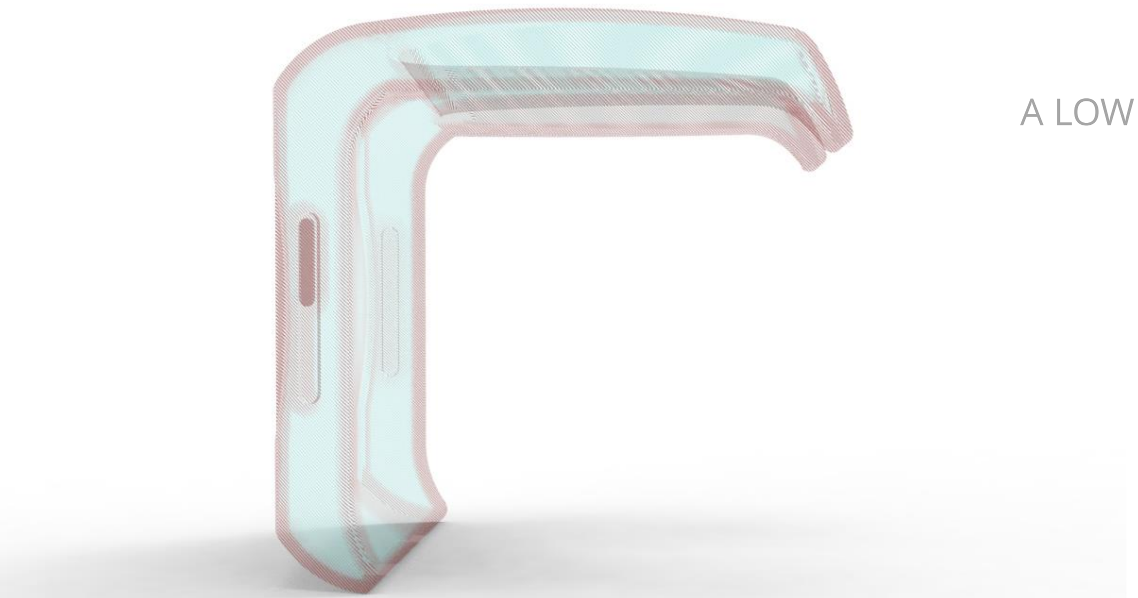

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APPROVAL SHEET

Industrial Design Project III

"A low cost vein detector for Indian scenarios"

By: Trivikram Annamalai

M.Des Industrial Design 2013-2015, Is approved as a partial fulfilment of requirements for a post graduate degree in Industrial Design at IDC, IIT-Bombay.

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ABSTRACT

Vein detection is a vital area of research which is concerned with spotting the patient's veins quickly and accurately, thereby avoiding multiple pricks. The project deals with making an effective low cost vein detection device based on the comprehensive study made about parallel products available in the market and analysis made on functional rigs.

The project focusses on design intervention in areas of product usability, aesthetics and manufacturability, apart from incorporating the technology into the product.

Although products which help find the veins do exist in the market, this project differentiates itself from other products by being affordable and better at usability aspects.

Table of Contents

“ He who has health has hope,
he who has hope has everything ”

- Thomas Carlyle

INTRODUCTION

Image 1 : Allergies and bruises due to wrong venipuncture methods

*Source : http://*www.thecambodiaherald.com

Vein detection is a novel and important area of research, the need to provide medical treatment without a time delay and in a less painful manner makes the research in this area significant. Difficulty in locating the veins leads to unnecessary needle penetrations causing blood clots, irritation, swelling, blackening of skin, etc. Vein detection is found to be useful in other potential applications like blood transfusion, blood donation, blood withdrawal and biometric security [1].

The existing methods used are:

(i) **Manual procedures**, which includes usage of belts around bicep muscles, feeling the veins and usage of chemicals.

(ii) **Ultrasound-guided procedures**, which uses ultrasound radiation on arms to find veins.

(iii) **Secondary light sources**, where multiple high intensity light sources are used for viewing veins.

(iv) **Red and near infra-red spectroscopy**, the visualization of the venous system by means of red and near infrared (NIR) spectroscopy [1].

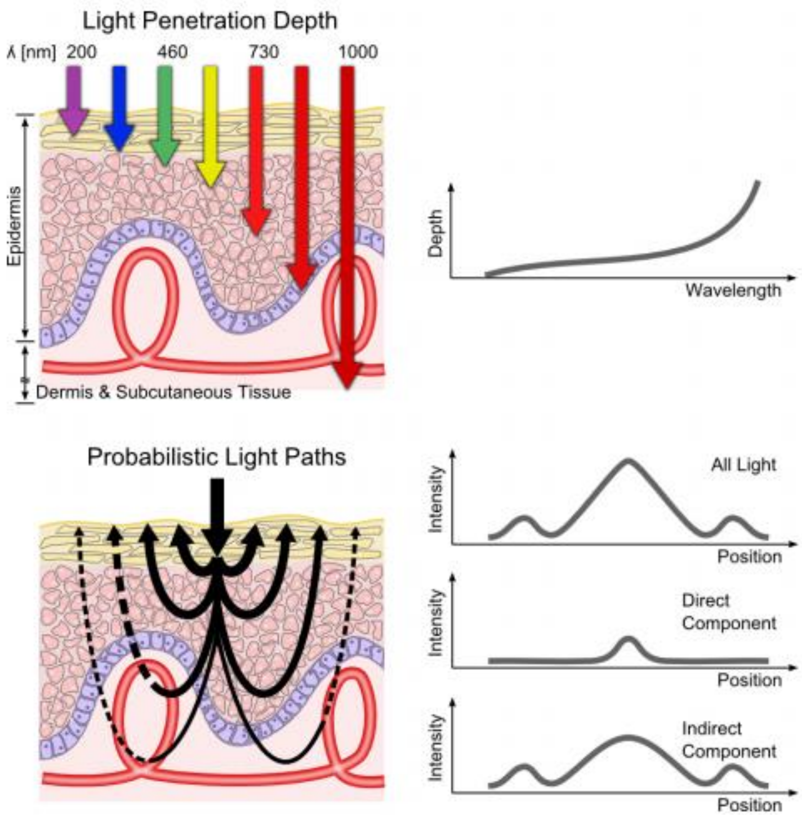


Image 2: Penetration of Wavelengths in skin

Source : http://web.media.mit.edu/~achoo/tr/msdg-tr.pdf

Manual procedures are the conventionally used methods, but they are not suitable for children and are not effective on people with dark skin tone. Ultrasound-guided procedures involve expensive machinery and need additional training to the staff. Secondary light sources require a darkened room and might cause burns on skin. Among the existing methods vein visualization by means of NIR spectroscopy is by far the most accurate and versatile method of vein detection.

The existing devices that are based on NIR spectroscopy, claim to solve difficulties in vein detection, but hardly few of them are being used in hospitals, primarily because of two reasons, the cost and portability issues. The need therefore arises to assess and quantify the pros and cons in existing devices and technologies used, and develop a low cost vein detection device which caters to the needs and constraints of Indian healthcare scenario.

The principle of vein detection using NIR spectroscopy is, when infra-red light is transmitted on palm it passes through tissue, which is absorbed by veins that have de-oxygenated blood. The veins appear darker than the surrounding tissue because of the absorbed radiations, which aids the medical fraternity to perform venipuncture in the first attempt.

Scope of the research is focused to affordability and improving the ease of product use. The learnings will be incorporated in developing a device which is robust in its core functionality of showing the veins that is otherwise not visible to the naked eye.

A comprehensive critical analysis is done on the products that exist in the market, later important parameters are evaluated for each of the product. The paper describes the design, development and initial evaluation of the product built.

PRELUDE

Image 3 : Photos taken during a visit to Blood Bank

Source :Author

The idea of making a vein detection device originated from a module 'Collaborative Innovation', taught during second semester in product design. The theme of the module was to design devices for 'fast and painless blood banks', during the field visits to the blood banks the design opportunity of making a vein detection device that would reduce the number of attempts needed for vein detection was thought about.

The Idea was continued in Project 3 after understanding the need and complexities involved in vein detection, Initial parallel product study and initial working rigs was made during 'Design Research Seminar'.

DESIGN METHODOLOGY

Image 4: Showing the design methodology followed for the project.
Source: Author

LITERATURE REVIEW

STUDY OF EXISTING PRODUCTS

Vein detection products have been in market for close to a decade now. These products can be broadly classified into two categories. Firstly, the products which have physical contact with the patient's arms and Secondly, non-contact type of products. The physical contact products are based on trans-illumination, which is a concept of using bright light on skin to illuminate the veins. These devices are of low cost and are widely implemented in hospitals. The drawback of these devices are, they have hygiene issues, as it involves a physical contact with the patient.

The non-contact detection devices use rather complex electronics and are extremely expensive. They are also usually bulky, making them less portable, for these reasons they are being implemented in fewer hospitals.

Apart from these categories of devices, there are others which subtly differ in their product features, five such devices have been chosen and reviewed, the conclusions of which have been used for making a design brief based on which the new device was developed.

Image 5. Venoscope

Source : http://cdnll.marketlab.com/images/xxl/ml6852.jpg

Product 1:

Venoscope, is a trans-illumination based product. It is a product in market since 2011 and is a low cost vein locating device available in the market that has had considerable commercial success. It is sold at a price close to $205 in U.S market, which makes it an affordable device in this product category of vein detection. The device can be effectively used on both adults and children which is supported by the FDA approvals.

The device is small and portable without any wires attached to it, making it extremely convenient for the nurses to use. The learning curve/cognitive load of the product usage is minimal on the user when compared to the other products in the market. The product claims to be used in emergency situations, neo-natal care, Sclerotherapy, IV infiltrations, etc.

However, the product efficiency is decreased in well-lit ambient lighting conditions and works well only in dim/dark lighting conditions. The user is advised to use the product by reducing the ambient light conditions, which may be a cumbersome process to do for every patient. The device does not assure versatility of usage on obese and dark skinned patients which questions the usage of the product under real life situations that would involve all kinds of patients with different skin tones.

Image 6. Accuvein

Source : http://evomed.com.au/wp-content/uploads/accuvain-main.jpg

The other big area where the product needs a makeover is the ergonomics, for instance, the handle of the product is box shaped with distinct edges and looks bulky.

This may not be the most suitable shape and size for different percentile users. The aesthetics of the product are mediocre, the product form does not strongly convey the idea of being a healthcare device which is dependable, hygienic and robust.

Product 2:

Accuvein, is by far the most advanced type of vein detector device that has been developed till date. It has lot of features neatly packaged into a small hand-held device, and it overcomes the shortcomings of all the predecessors of similar vein detecting devices.

Starting with the product aesthetics, the device has the visual requirements of being a typical healthcare product, which the previous product Venoscope severely lacked. The biggest advantage of the device is that the vein detection can be done in normal ambient light conditions, although the user manual recommends adjustment in room lighting if necessary.

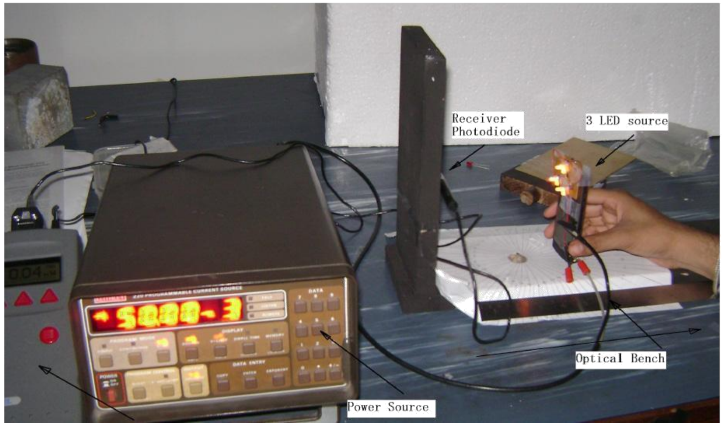


Image 7. Vein finding device setup by Yalavarthy.et.al

Source : Yalavarthy.et.al

The device has features, like LCD screen - which shows usage details with brightness control and multi-language display options, speaker to give voice alerts of low battery, USB slot to transfer data, rechargeable battery, stand, temperature alarm, etc. The device is small in size making it a feasible option to be used in mobile blood banks. The product also has stands as add-ons, for single person use.

The price of the product is the inhibiting factor, e-commerce websites quote the price to be as high as 2.5 Lakh rupees, which makes it a costly product to be used in small Indian hospitals. The statistics show that the device is being used only in 2000 hospitals worldwide, of which 1500 are in US alone, even though the product was launched nearly 5 years ago.

Product 3:

Phaneendra K. Yalavarthy, et. al.[3] have developed a device using a 4 LED setup that is incorporated on a clip on platform which can be attached to a mobile with camera for surface vein detection and imaging. The principle used in the product is, it utilizes the property of differential absorption of near infrared light by oxygenated and deoxygenated blood over normal tissue. The product has not yet been commercialized in the market, but the technique looks promising from the results shown in the paper, it claims to be an accurate and economical option that can suit Indian scenarios.

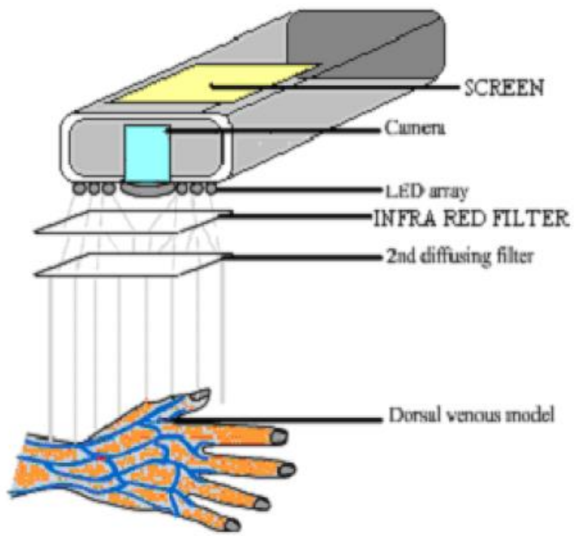


Image 8 : Working Principle of the model

Source : Koushik Kumar Nundy, Shourjya Sanyal, *'A Low Cost Vein Detection System using Integrable Mobile Camera Devices'*, 2010 Annual IEEE India Conference (INDICON

The project bypasses usage of complex image processing techniques which lead to high costs involved in their implementation. The proposed system also might reduce the possibility of 'light spots' which lead to leak of energy, hence reduce efficiency. The product cost aimed is $10 or lesser without the mobile phone, hence making the device affordable to medical practitioners.

The usage of product is straightforward and requires no prior specialized training or expertise, and can be implemented for various applications ranging from intravenous injection or blood drawing assistance, to mapping of surface veins.

From the results shown and discussed in the paper, we learnt that the detection of veins using this device is not exhaustive, but suggestive. The image quality depends on external variables like movement of patients hand, ambient illumination and skin tone. In the present form the device looks bulky with the external batteries, which might make the device difficult to hold and use.

Product 4:

Master's thesis by **Askwini Kolar, et.al,** group of students from College of Engineering, Pune are developing a vein detecting device, using a beagle board and an infra-red camera. The product is stationery i.e. needs to be fixed in a place, the patient's hand needs to be placed in the device for vein detection and veni-puncture, this feature could hamper the feasibility of using the device in mobile blood bank centers, where portability is a very important criteria.

The device has many individual components, which increases the complexity, time taken to develop the product and cost of the device. The efficiency of the product reduces when used on dark skinned, hairy or obese patients, which has been a problem with most devices that were reviewed, except in the case of Accuvein.

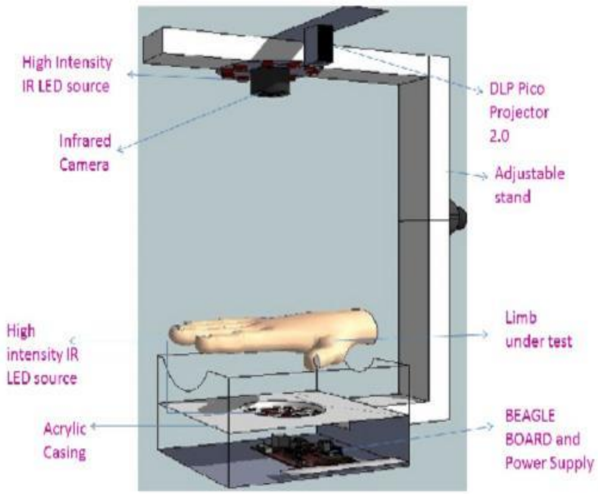


Image 9. Vein finding device setup by Kolar.et.al

Source : Ashwini Kolar.et.al

Product 5:

Vein EZ is a hand-held device that is meant for infants. It uses a simple method of detecting the veins where only a high intensity red light source is placed under the skin. The device does not use any complex processors or image processing algorithms, which makes the product relatively low priced. Vein EZ is a product made for infants, thereby it is extremely small in size and light in weight.

Image 10. Vein EZ

Source : http://zd-med.en.alibaba.com/product/60078661456-0/mini_type_Vein_viewer.html

The device has shortcomings, firstly, the target users are children – based on the product usage instructions, it seems like the child is expected to hold the device tightly in the wrist while being injected. This method of veni-puncture might not be feasible. The pictures shown in the website looks like device does not work well under normal ambient lighting conditions. The product usage is limited to viewing of veins in the wrist, but most of the veni - puncture happen in the forearm.

EVALUATION OF THE PRODUCTS

Products were evaluated on a scale of 0-10 points, the parameters considered are as follows:

Cost: The evaluation based on cost was done for each product based on which price range the product falls into and we evaluated how affordable the product is for the Indian scenarios.

Price Range	<10,000	<1,00,000	>1,00,000
Points	10	5	0

Hygiene factor: The products are broadly chosen as the one which touches the body, to show up the veins and the other is the non-contact device, which shows the veins by projecting an image back on the hand or on a portable screen.

Considering the hygiene issues, it is preferred to have a non-contact device, and the devices which have human contact need sterilization after every use.

The evaluation criteria for hygiene factors are as given alongside

Criteria	Non-contact device	Contact device
Points	10	5

Effectiveness in ambient light conditions: One of the biggest challenges in detection of veins using infra-red based technologies is overcoming the loss of vein visualization quality.

This might happen mainly due to interference from ambient light sources like sunlight and electric bulbs. The external light sources make the veins appear as dull brown lines making vein visualization difficult. Based on the results of the product usage evaluation criteria has been set.

Criteria	Works in light	Suggestive veins	Does not work
Points	10	5	0

Portability of the device: Portability plays an important role in ease of use of the product. The conditions under which the product could be used is diverse, for instance hospitals, blood banks, mobile blood camps, etc. In the evaluation criteria the devices which are wireless are given 10 points, whereas the devices which are stationery are given 5.

Criteria		Wireless device		Stationery device	
Points			10		5

Criteria	Works in light	Suggestive veins	Does not work
Points	10	5	0

Performance on challenging patients: Research proves vein detection is difficult to perform on the following kinds of patients:

- Obese patients
- Dark skinned patients
- Children
- Deep veined patients

Hence depending on how effectively the device works on these patients, an evaluation criteria has been set

Evaluation table of the products:

	Venoscope	Accuvein	Yalavarthy	Kolar	VeinEZ
Cost	10	0	5	5	10
Hygiene	5	10	10	10	5
Light	5	5	0	5	No data
Challenging Patients	5	5	0	5	0
Portability	10	10	10	5	10
Total	35	30	25	30	25/30

Inferences from product evaluation:

Based on the parameters chosen and their corresponding points, all the products were evaluated. Product 1, Venoscope emerges as a winner, which is a trans-illumination based contact device. It is a low cost product which will be researched further with a scope of making a more effective product.

TECHNICAL INSIGHTS FROM LITERATURE REVIEW

Human eyes can detect visible light that is in the wavelength of 400 - 700nm of the entire electromagnetic spectrum.

The special attributes of near-infrared wavelength which makes it suitable for vein detection are:

1. NIR can penetrate into biological tissue up to 3mm of depth.
2. The veins appear to be darker than the surrounding tissues as the reduced haemoglobin in venous blood absorbs more of the infrared radiation than the surrounding tissues.

In order to achieve penetration through the tissue and be able to clearly visualize the veins, the infra-red lighting should be performed under a tight optical window, which is 740 nm to 960 nm.

Naoya Tobisawa, et. al [1] proposes a system consisting of a high-intensity and low-leak light source, near-infrared CMOS camera and a small –one-eye head mounted display. Using the set up, they could obtain the trans-illumination images in all parts of the adult forearm, they could also obtain a clear image of deep-seated blood vessels [1], [2] the optical window needed for vein visualization is a window spanning 740 to 760nm.

The experimental setup consists of 18 near infrared LEDs which have a radiation emission peak at 740nm and 5mm casing, which are placed in three concentric circles in the same focal plane.

The distribution of the LEDs are as follows:

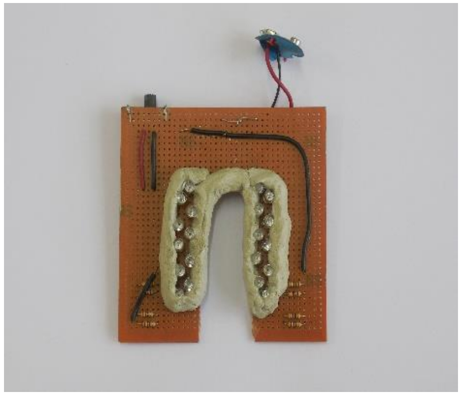
- First circle uses 5 LEDs
- Second circle uses 6 LEDs
- Outermost circle uses 7 LEDs

A low cost web camera which has a CCD sensor array is used to acquire the vein images. The CCD alone is perfectly capable of detecting near infrared radiations up to a wavelength of 1mm but all modern cameras have an inbuilt infrared cutoff filter. The filter is placed in front of the sensor, thereby the web camera can see maximum amount of visible radiations. The procedure to visualize the veins in the infra-red region the filter needs to be removed and replaced with a custom made filter that is capable of blocking all the radiations which are below 720nm and allow only the NIR radiations to pass through.

The modified web camera is placed in the middle of the concentric distribution of LEDs, the radiations produced by this system is a constant source of light. In order to reduce the glare, and obtain even illumination, a diffusion filter is placed in front of the illumination system. Another problem that needs to be addressed is the specular reflexion observed at the skin surface. This problem can be solved by placing a polarizing filter, which would provide good contrast images with uniform lighting [2].

The device has a clip-on platform which is externally attached to the mobile camera and the mobile phone display allows the user to view the veins. The clip on has an infra-red illumination system and a pass filter that blocks the visible light and allows the infra-red light to pass through. Through the inbuilt camera we can see the reflected infrared light at a required wavelength. The output image is seen as minor undulations on the surface of the skin which clarify the presence of the veins [3].

Photography involves usage of infra-red filters, this is possible because of the CCD sensors which are sensitive to infra-red wavelength and this is the reason why all CCD cameras have an in-built IR filter. In order to make a camera into an infra-red detecting camera, the in-built IR filter needs to be carefully removed. The camera also needs to have sufficiently high spatial resolution to be able to detect the vein details clearly [4].



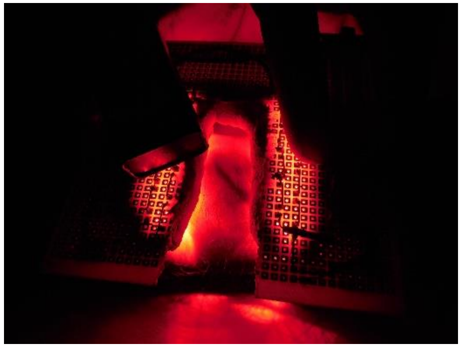


Image 11 : Photos of circuit rig 1 and vein visualization on a subject

Source :Author

BUILDING WORKING RIGS

Based on the technical insights obtained by various researchers, many prototypes were built as a working rig and to test their feasibility in various lighting conditions and users, following are the iterations involved in the prototype building process:

ITERATION 1

In the first rig 20 Red LEDs were used of wavelength 650nm, the prototype was of a tuning fork design with space for viewing veins.

The rig highlights the already visible superficial veins, but it's not effective in cases of challenging users like deep veined, obese, dark skinned and children.

But, the rig is slightly more efficient when the tests are done in darkness, where the veins appear to be darker.

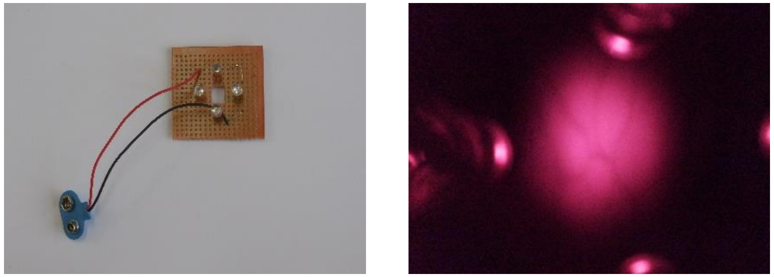


Image 12: Photos of circuit rig 2 and vein visualization on a subject

Source :Author

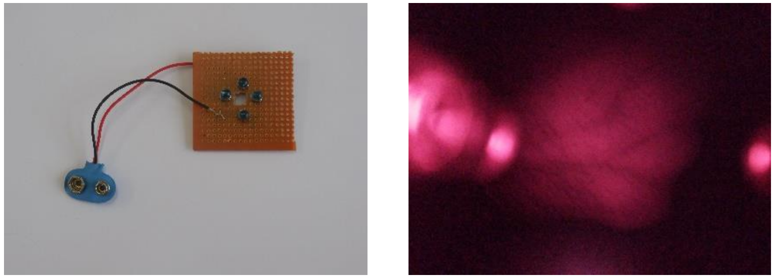


Image 13: Photos of circuit rig 3 and vein visualization on a subject

Source :Author

ITERATION 2

Based on the results obtained from rig 1, it was decided to use a different type of LED and thereby reduce the number of LEDs being used and make a more compact device. In this prototype a non-contact device was made and tested, where 4 LEDs were attached to the mobile phone based on the details mentioned in a research paper [3], [2]. The device faced similar difficulties like Iteration 1, where the device is ineffective in producing good clarity vein images under bright ambient conditions, a possible reason could have been the wrong usage of IR wavelength.

ITERATION 3

For the third iteration, LEDs with specific wavelength of 750nm were procured and tested in a setup very similar to Iteration 2, the results here were a notch better, analysis of the output images proved that the camera that was in the mobile phone had a partial Infra-red block filter which was interfering with the quality of veins viewed that were viewed.

Inferences: Non-contact prototypes tested in iterations 2 and 3 do not give good quality images with a mobile phone camera in bright ambient light conditions, unless image processing is done on the output images. Secondly, the mobile phone camera being used needs to have its infra-red filter removed and replaced with a pure infra-red filter which completely blocks visible light and allows only the infra-red wavelength to pass through. Hence the approach of having a non-contact device has the winning property of being hygiene, but falls back on factors like increase in system complexity and cost – which contradicts the goal of having an efficient and low cost vein viewing device.

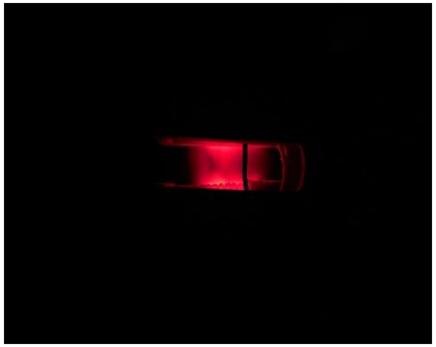


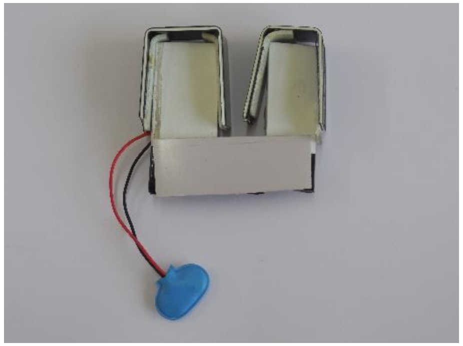
Image 14: Photos of circuit rig 4 and vein visualization on a subject

Source :Author

ITERATION 4

Based on the inferences obtained in previous iterations, it was decided to further explore the contact devices with different LEDs and configurations. Red Colored LEDs with higher intensity were used in the rig along with an enclosure which avoided the leakage of ambient light in the vein viewing area. The results were satisfactory as the veins viewed were more distinct and darker than the previous rigs[5]

Inferences: The increase in the LED output intensity and having an enclosure to avoid the leakage of ambient light improved the output results, but the rigid enclosure made the vein viewing difficult in places where there were bends/uneven skin surfaces like the elbows.



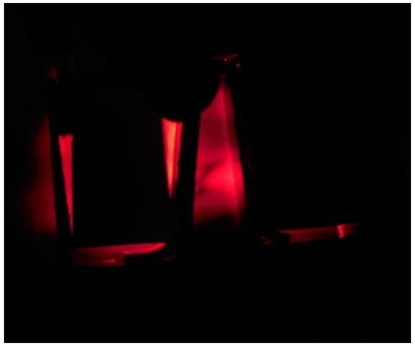


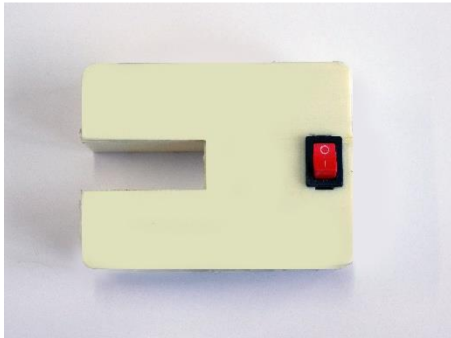
Image 15: Photos of circuit rig 5 and vein visualization on a subject

Source :Author

ITERATION 5

In the iteration 5, a flexible device enclosure was made to facilitate vein viewing in places with bends and uneven surfaces, also the number of LEDs used were increased to 3 to improve upon the intensity.

Inferences: The flexible enclosure and increase in intensity helped in improved vein viewing, but the leakage of light reduces the effectiveness of dark veins being visible in ambient light conditions.



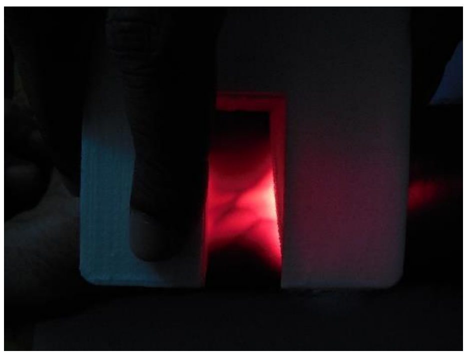


Image 16: Photos of circuit rig 6 and vein visualization on a subject

Source :Author

ITERATION 6

A 3d printed enclosure with 6 closely placed LEDs was used in the iteration, the objective was to make a device with high intensity and least leakage of light, the results obtained with the device was by far the most effective, and worked well in bright ambient light conditions and across various kinds of challenging users. Hence this prototype was considered as the final rig for initial evaluation with doctors, nurses and patients.

EVALUATION OF THE RIG

The objective of the survey was to find the need for a product that would help the medical fraternity locate the veins, the awareness levels the doctors and nurses have about using an electronic device for vein viewing, the

price a hospital could afford for a vein detecting device and suggestion for improvement from the doctors and nurses about the prototype.

Details of the survey:

People interviewed	12, Doctors = 5, Nurses = 7
Hospital Type	Government hospital : 1 Private Hospital : 2 Blood Banks : 1
Average age of Users	32.75 Years
Average experience of the Users	7.8 Years

Mode of survey : Questionnaire – Interview

Type of interview : Semi-structured

Questions asked –

Q1. Do you have difficulties spotting veins in patients? if yes, how often?

a.Everyday	b.Once in 3 days	c.Once a week	d.More than once a week	e.Never

Q2. What are the existing methods you follow to spot the correct vein?

a.Feel the veins	b.Using Traction	c.Trial and error	d.Electronic devices	e.Others

Q3. Would you use an electronic device, if it can help you find the veins? - Yes/No/Maybe Dont Know ? Why?

Yes	No	Maybe	Don't know

Q4. How much would you pay for such a device? Why ?

a.<500	b.500-1000	c.1000-10,000	d.>10,000

Q5. Are you aware of the vein detection technology and similar products? - Yes/No

Questions asked after using the prototype

Q1. How well do you think the product works under following conditions :

Conditions	Works well, veins are visible	Veins are not very clear	I can't see the vein

Q2. Did you find the device easy to use? yes/no , Why?

Q3. Do you find the usage of device has increased the efficiency of vein detection? yes/no , Why?

Q4. What do you think is the price of the device? Why?

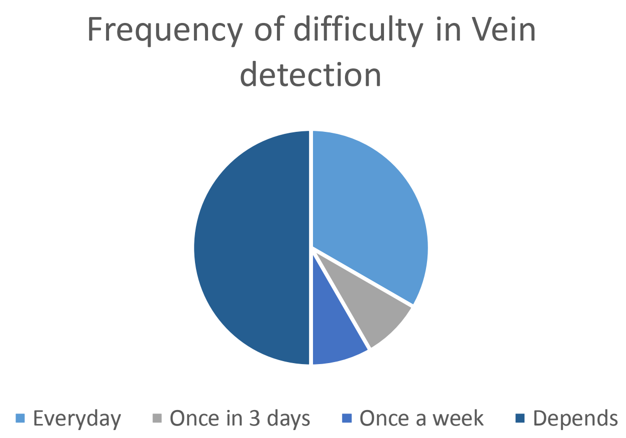
a.<500	b.500-1000	c.>1000	d. don't know

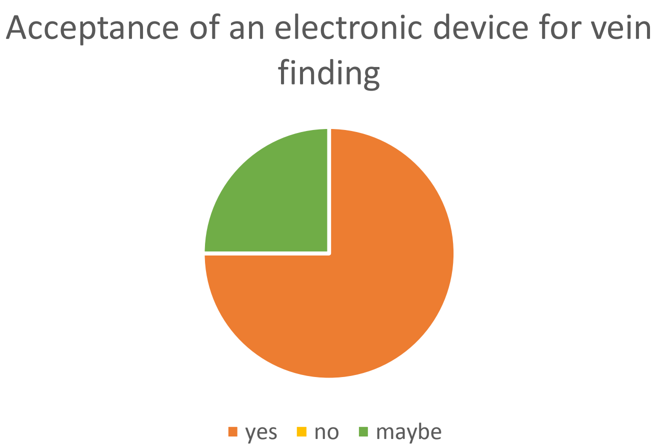
Q5. Device touches the skin of the patient - Do you think it would cause hygiene issues? how do you suggest to sterilize the device?

Q6. Would you prefer a non-contact device, even if the price is higher? yes/no ,why?

Q7. Can you suggest any improvements to the device?

After asking the above mentioned questions the replies were recorded on questionnaire sheets, this data was later used for analysis of various parameters involved and thus come up with a design brief.





INFERENCES FROM THE SURVEY

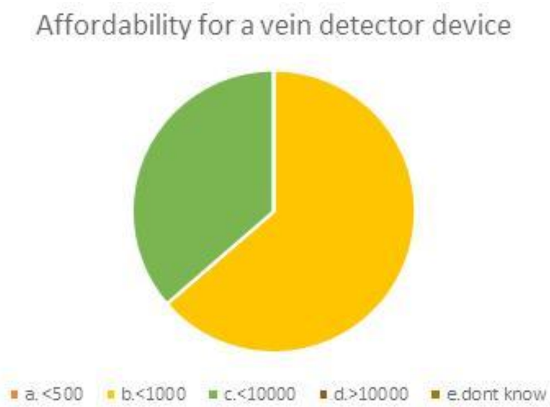
Of the 12 people surveyed, all agreed that there were instances when it was difficult to spot the veins especially amongst the challenging patients. There were no clear data on how often they faced difficulties in spotting the veins, due to lack of statistics.

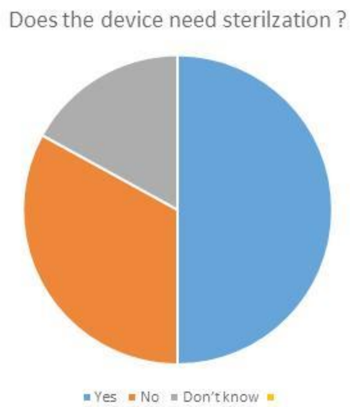
The various preferred methods used to spot the correct vein are :

1. Feel the veins with fingers
2. Using Traction belts
3. Usage of electronic gadgets
4. Trial and error

From the survey we learnt that every venipuncture process involves usage of a traction belt and pressing/feeling of veins. For cases when difficulty in spotting veins persists even after usage of traction belt, trial and error process is followed, where multiple veni-punctures are administered leading to pain and trauma to the patients. An interesting insight that was got in the blood banks -– on occasions where there was difficulty in spotting veins,

usually the blood donors are rejected to avoid causing pain to the donor, this leads to reduction in the amount of blood collected in donation camps.





The acceptance level of using an electronic device to spot veins was encouraging. Most of the people interviewed were eager to use technology which could reduce the human errors involved in venipuncture.

Many of the government hospitals and blood banks prefer to have a low cost vein detection device, which is in the price range of less than 5000 rupees. This makes the trans-illumination method of vein viewing the most suitable choice, as non-contact devices are more expensive.

The awareness about vein viewing technology was minimal amongst the medical fraternity. Usually nurses in blood banks were aware of the technology and some of them had used vein viewing devices.

The next part of the survey involved a demonstration on how to use the product. The prototype was then tested by the doctors and nurses to validate its effectiveness, the inferences obtained about the product were:

The prototype showed veins on the forearms of the people on whom it was tested, under ambient light conditions. More detailed study needs to be done on a larger user base for concrete statistics about the versatility of the prototype.

The learning curve involved in the product usage had to be kept minimal. The process of using the device and performing venipuncture must not be an additional tedious process for the user when compared to the conventional procedure.

Trans-illumination devices touch the patient's hand during vein visualization, this lead to hygiene issues. When asked about the consequences of having a device which would touch a patient -- doctors and nurses had remarks and suggestions. Few doctors suggested sterilizing the patients hand instead of sterilizing the device.

DESIGN BRIEF

The results of the survey gave a very good understanding about the awareness people have about vein detection devices, the parameters that are to be considered from healthcare standards point of view, the cost that would be considered affordable for such a product. Based on those results a design brief was evolved that covered aspects of design like aesthetics, usability issues and cognitive load.

To Design a low cost, infrared vein detection device for Indian scenarios, that has the following features :

- Product should be **affordable** *(Price range between Rs1000-2000)*
- Works effectively on **diverse users** *(Diverse users = Dark skinned,obese,children,deep veined,etc)*
- Considers **Hygiene issues** *(like physical contact of device on patient's skin)*
- Works efficiently in **practical usage scenarios** - i.e ambient light, daily use, etc *(in blood banks and hospitals)*
- Product is easy to use after **minimal training**
- Portable*(needs to be wireless, small, light in weight)*
- Needs less maintenance
- Aids venipuncture process
- Aesthetic

TARGET USERS

Image 17 : Images showing various users

Source: untiedmag.com

The **primary users** are the medical fraternity who would be directly performing the venipuncture process, such as the nurses and doctors.

The **secondary users** would be the following 4 categories, on whom the device will be used upon:

- Obese patients
- Geriatrics
- Children
- Normal people with deep veins

After the final prototype is built, it will be comprehensively tested on the above mentioned secondary users. The effectiveness of the product may vary according to the target user category which will be quantified after a thorough user testing.

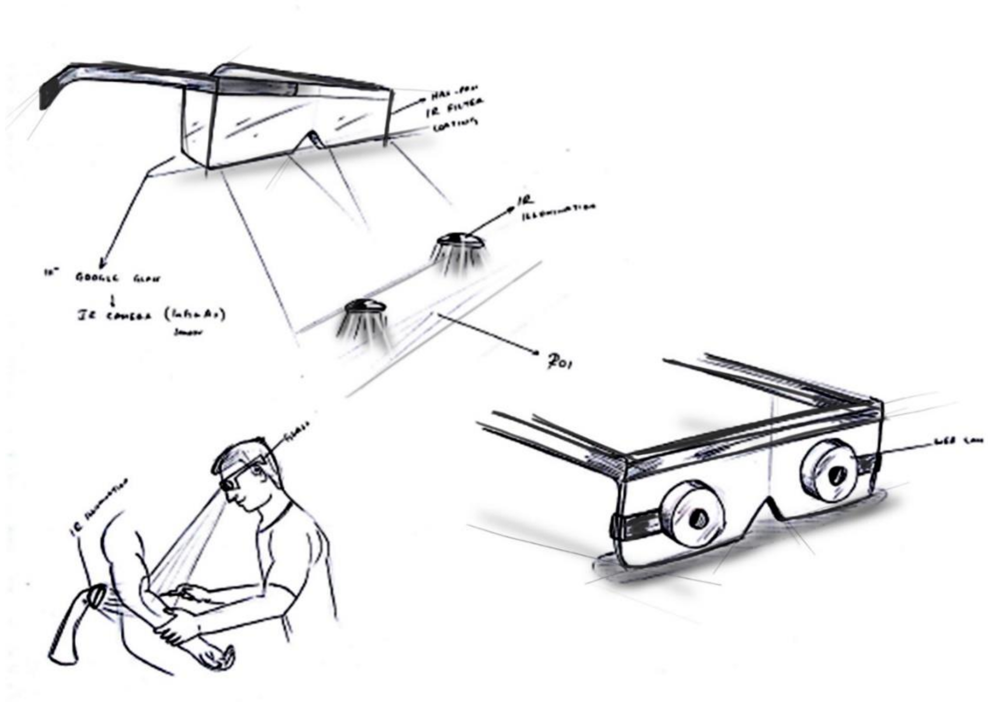


Image 18 : Idea of vein detecting spectacles

Source: Author

After exploring various options of L.E.D configurations, the finalized configuration was taken ahead and various ideas were thought off around the constraints set by the electronics.

The approach taken was initially going wild with the ideas without any constraints in the mind, this was primarily done using the brainstorming techniques such as ideating using analogies, card sorting, etc.

Few of the chosen ideas are -

Idea 1:

Using a vein detecting spectacles, which would have the ability to filter out visible light and allow only infra red radiations reach the eyes through an infra red pass filter. When the forearm is illuminated with infra red LEDs, the user would be able to view the veins as dark grey lines.

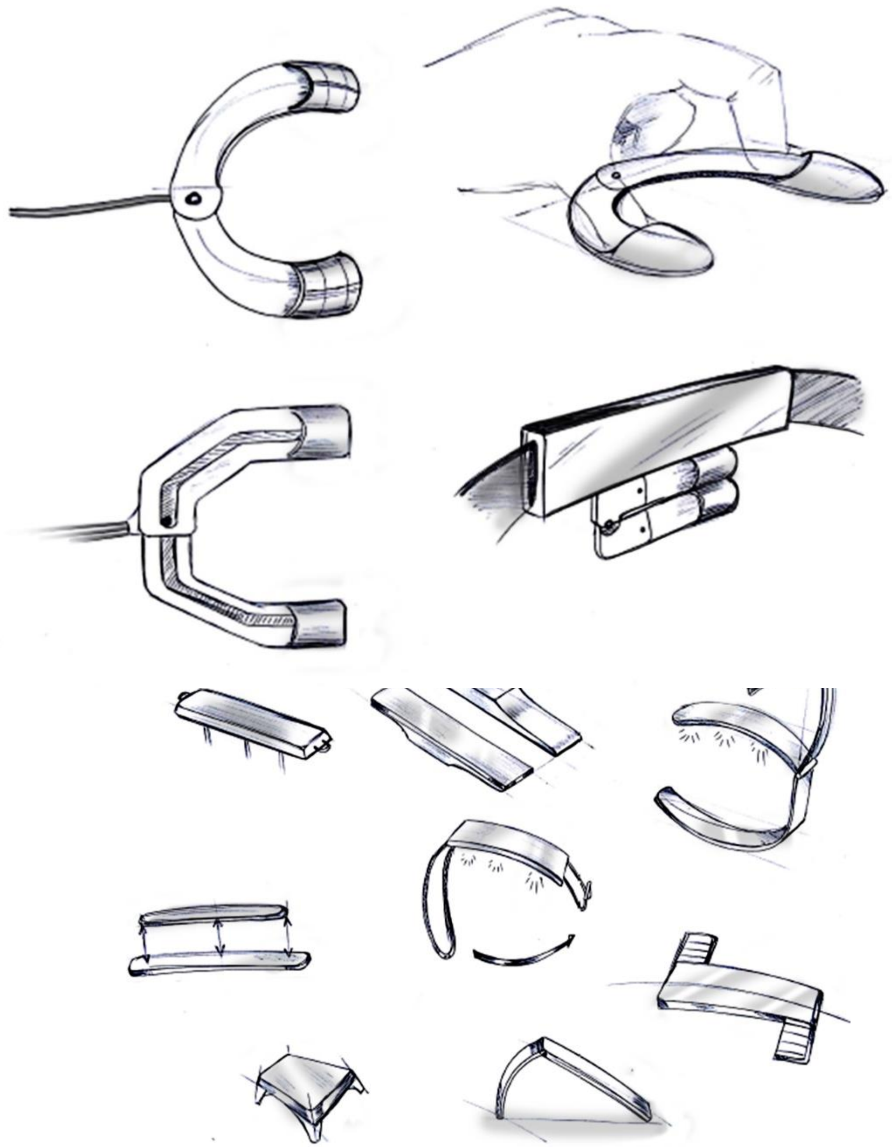


Image 19 : Ideas of clamp mechanisms

Source: Author

Idea 2:

Various possible explorations were made in regards with the possible ways of holding the LED clips using fingers.

The strap adjustability and clamp mechanisms were also thought about to get enough clarity on various possibilities available before refining the ideas further.

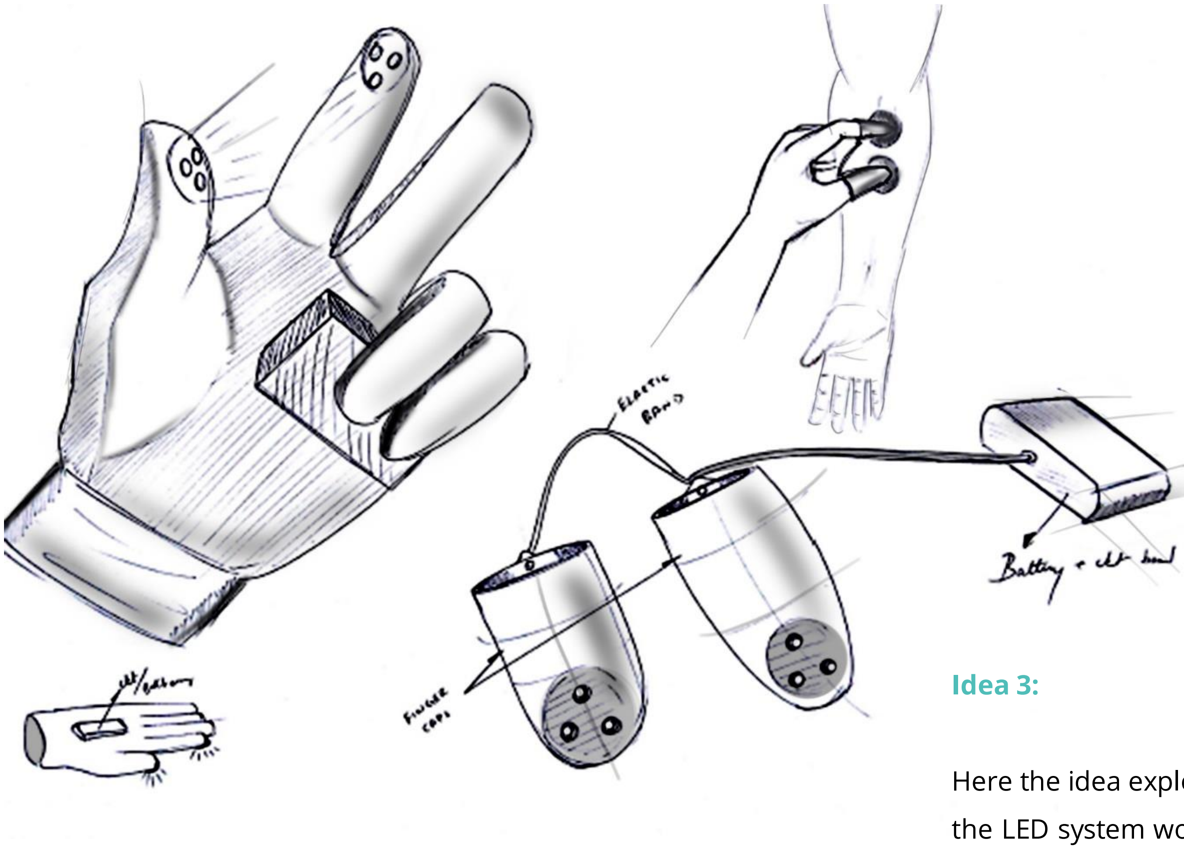


Image 20: Finger clip ons and glove concept
Source: Author

Idea 3:

Here the idea explored is of a vein viewing glove, were the LED system would be embedded in the finger tips region of the glove and rest of the circuit would be placed away from the finger tips.

This would give an added flexibility for the nurses to perform the veni-puncture process, as the additional range of finger movement would help the nurse adjust the optimum area of vein viewing area with ease.

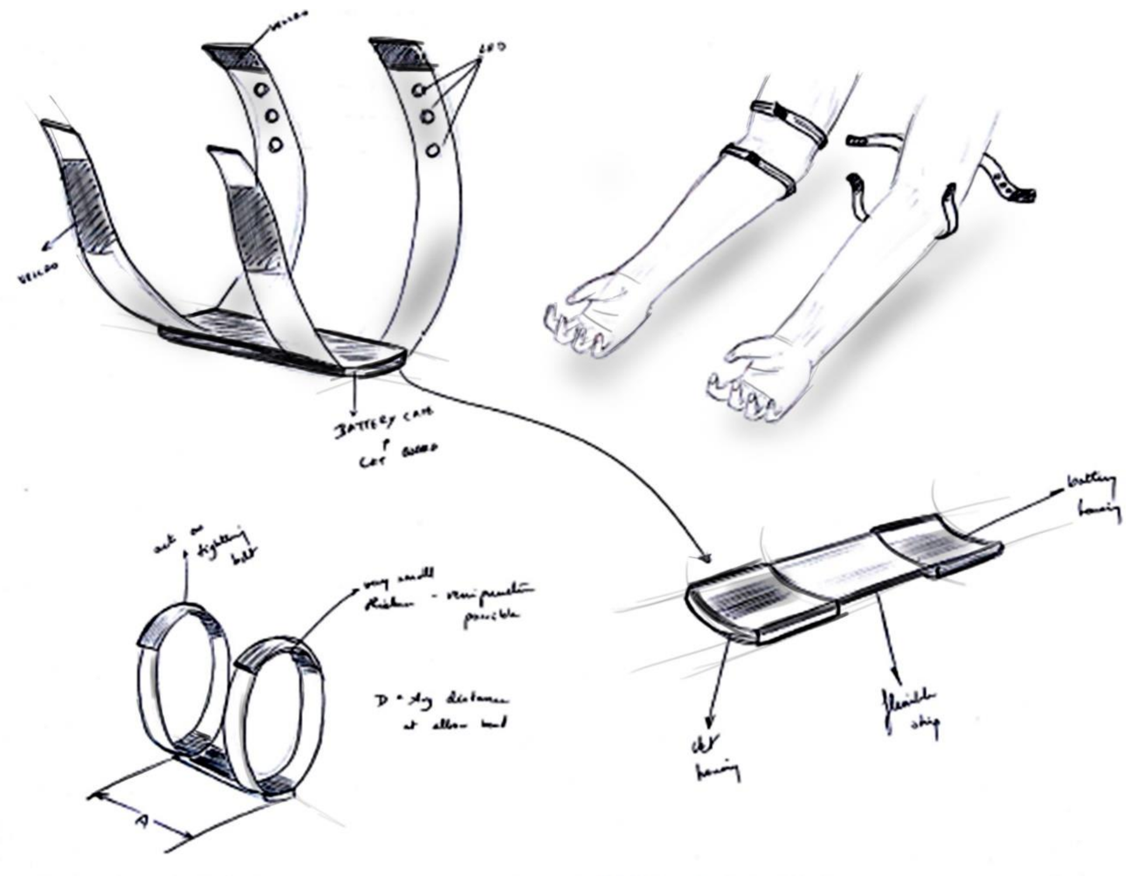


Image 21 : Ideas of strap mechanisms

Source: Author

Idea 4:

This idea is about a velcro strap mechanism that could be strapped around the elbow region. Here the L.E.Ds would be in the bottom side of the strap which touches the skin surface. Rest of the electronics would be concealed inside a box and placed under the elbows. The concept has the advantage of increased adjustability which could be worn by patients of varied hand diameters.

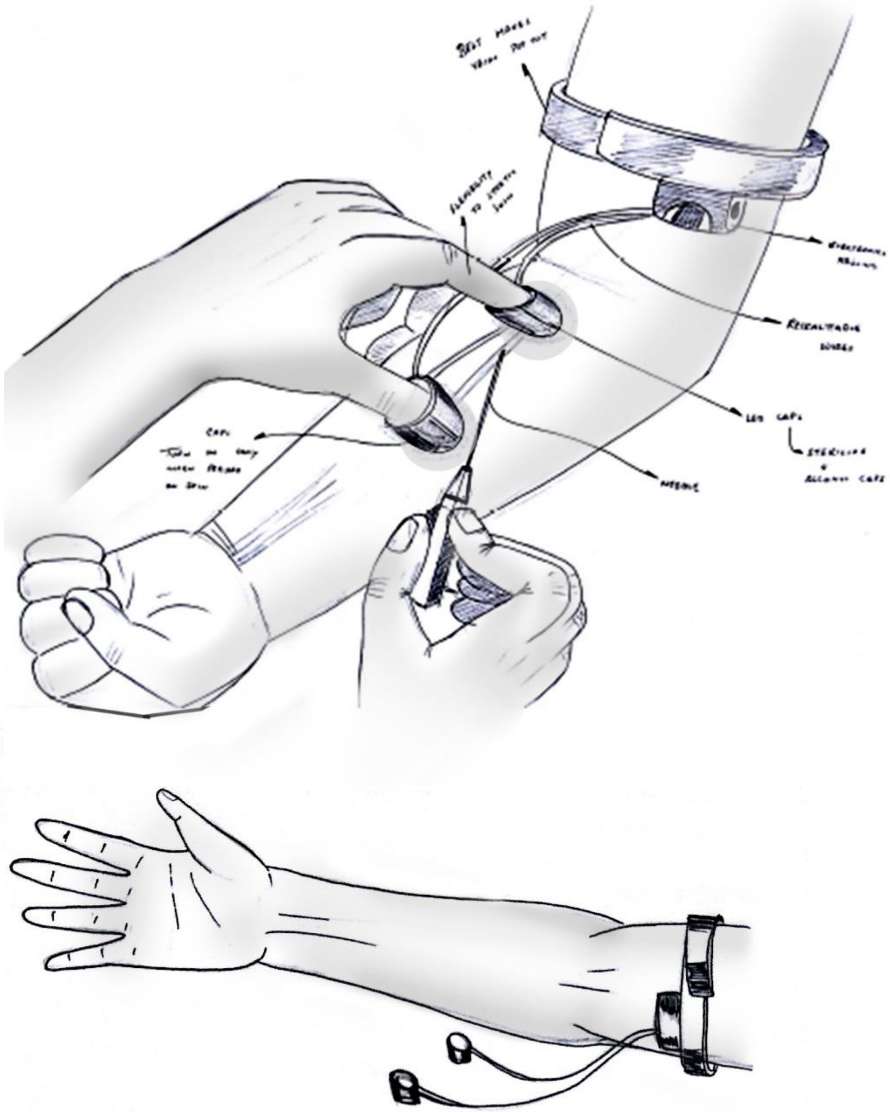


Image 22 : vein finder attached to tourniquet

Source: Author

Idea 5:

The idea of piggy banking on the existing devices used in the hospitals for veni puncture process was thought about in this idea. Usage of a tourniquet belt around the biceps region is a common practice followed in order to constrict the veins and allow them to pop out naturally.

A new tourniquet has LEDs system integrated in them, such that the LED clip ons can be worn on the fingers and used to view the veins, and after the vein visualization the clip ons would retract back into a console.

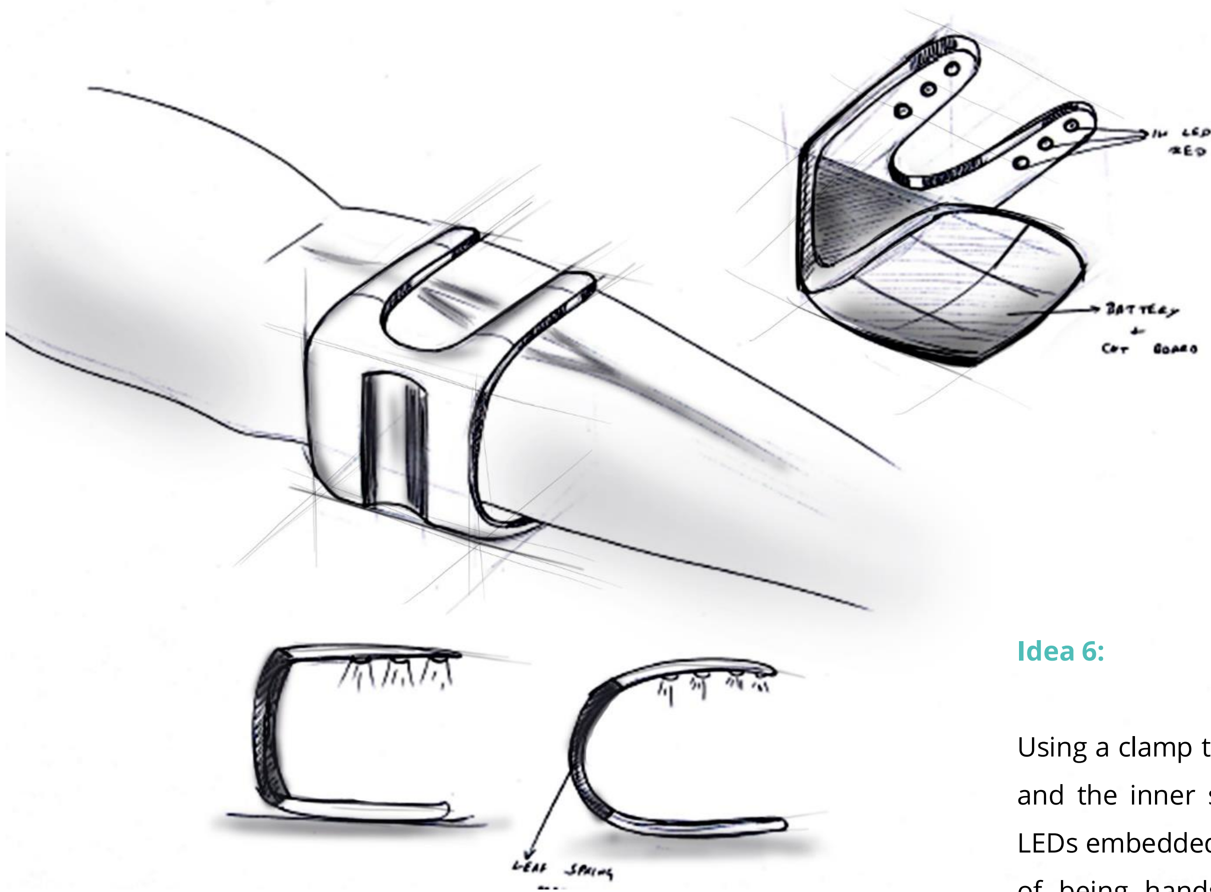


Image 23 : Ideas of clamp mechanisms

Source: Author

Idea 6:

Using a clamp that would cling on to the elbow region and the inner surface of the device would have the LEDs embedded on them. This idea has the advantage of being hands free giving more freedom for the nurses to perform the venipuncture procedure.

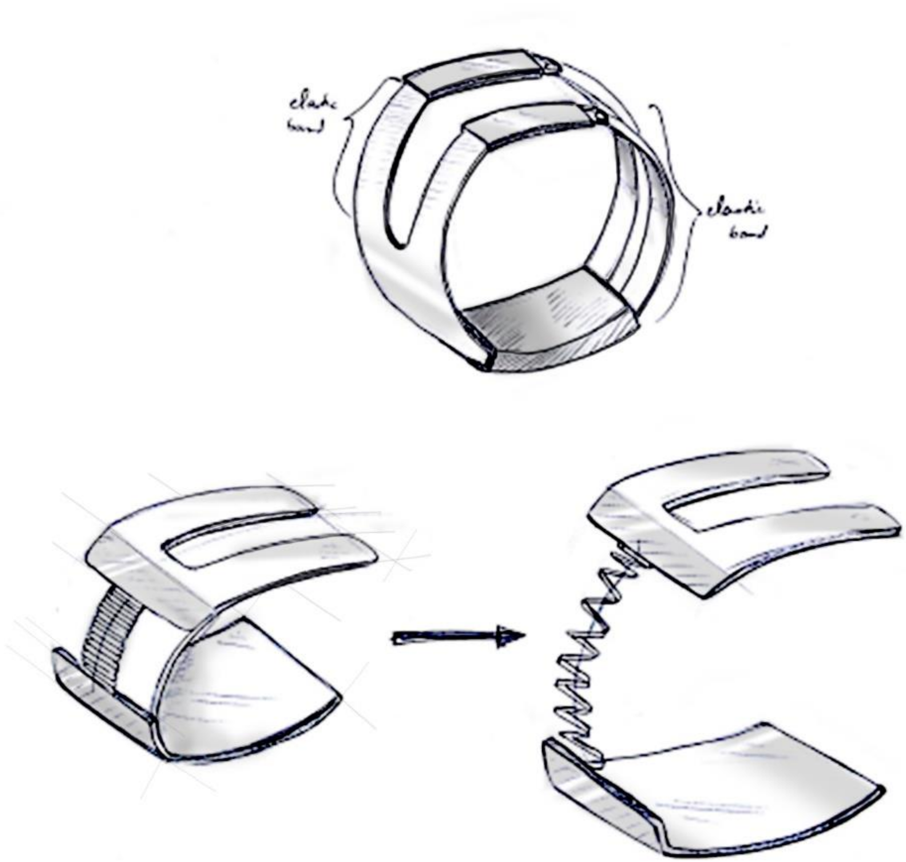


Image 24 : Ideas of clamp mechanisms

Source: Author

Idea 7:

This Idea is a more evolved form of the strap mechanism previously mentioned. Here more ideas of incorporating the electronics along with the getting an adjustability option was made.

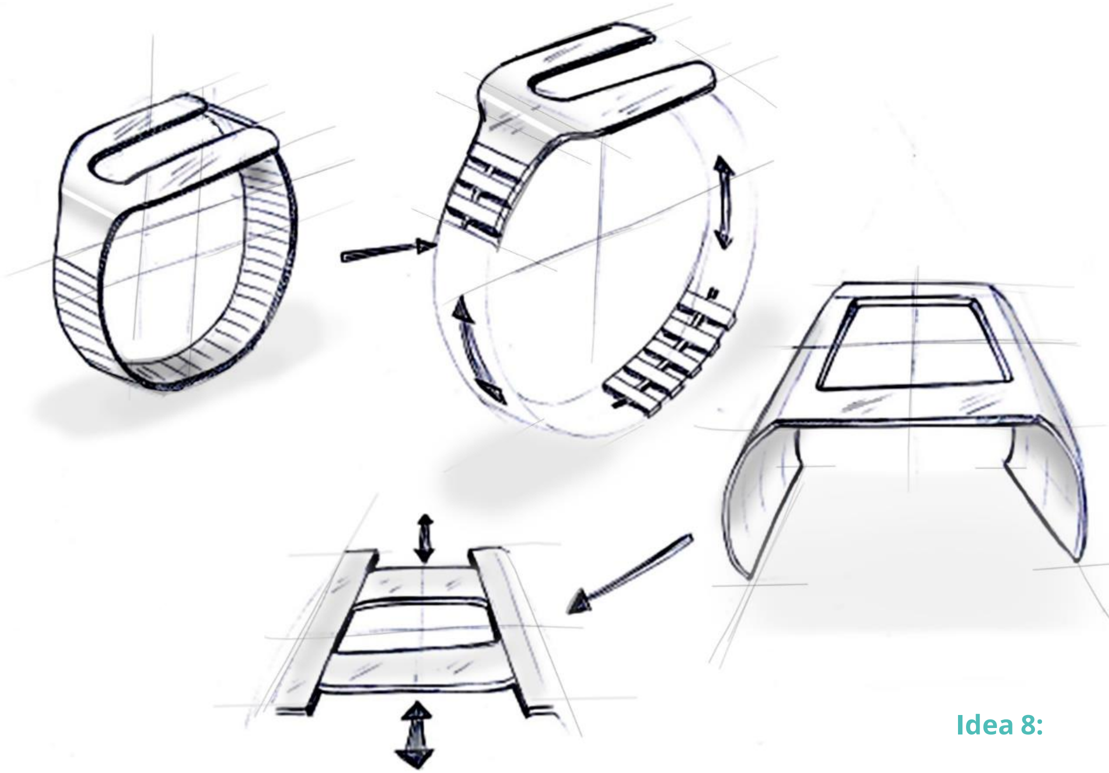


Image 25 : Ideas of clamp mechanisms

Source: Author

Idea 8:

This Idea is of an adjustable watch mechanism, which would be worn by the patient like a bangle. A further refined idea was to have a adjustable frame like structure that would aid the veni-puncture process.

Incorporating the electronic components like battery would be a hurdle to overcome in this concept.

Image 26: Sticky notes clusters used for concept finalization

Source: Author

At the end of the ideations process many clusters of promising ideas were generated, in order to choose the winning concept, a detailed list of features were jotted down in sticky notes. These features were primarily the pros and cons of each idea.

The sticky notes were then arranged under four primary headings called:

- Clamp type
- Handheld type
- Complementary type
- Others

The cluster formation under these 4 broad categories acted as an important tool to segregate the pros and cons, thereby identify what should be the features incorporated in the final design direction.

ETHICS COMMITTEE MEET

Image 27. Ethics committee meet, IIT Bombay, March 11th 2015

Source: Author

As the project was in the area of healthcare, the device that was developed needed to be tested on users. Any healthcare device if it had to be tested on humans, had to have the approval from the institute ethics committee meet, which is a body in IIT Bombay RnD Centre.

A proposal to study perform 'a feasibility study of the vein detector device' was approved by the committee after their review.

Highlights of the meet:

- Total number of patients on whom the device will be tested would be 30 and this will be a proof of concept study.
- The inclusion criteria should be participants whose veins are not visible to the naked eye. And the exclusion criteria would be whose veins are visible to the naked eye.
- It was recommended to have at least 3 observers to opine on the visibility of the vein in presence of the vein detecting device.
- The ease of vein visibility could be given a score by the observers on a scale of 0-5.

MOCK UPS

Image 28. Mock ups made for initial analysis

Source: Author

The ideas that demanded a tangible form, for better imagination and analysis were made as mock ups.

All the mock ups were made to scale for more realistic visualization. The materials used were styrene and ABS.

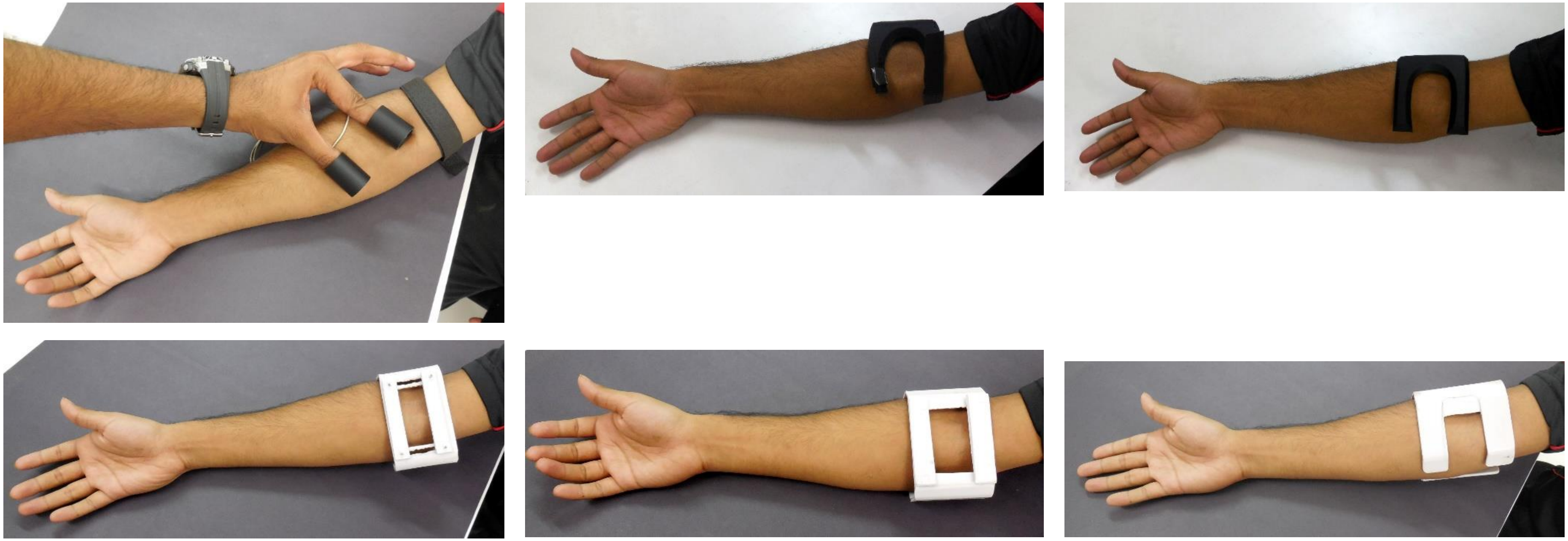


Image 29. Mock ups tested on users

Source: Author

The mock ups were then tested on users and they were evaluated on the basis of :

- Comfort to the user
- Ease of veni-puncture
- Optimum dimensions for ease of use and incorporating the electronics
- Default form factor that evolved with functionality

The results were analyzed and the results were used in further refinement of the concepts.

ACTIVITY ANALYSIS

Image 30. Activity analysis done using the mock ups

Source: Author

The mock ups were used for performing the activity analysis of a veni-puncture process. The analysis tried to simulate the conventional veni-puncture process along with the vein detector device.

The steps simulated are as follows:

1. Wear the gloves, clean the patient's puncture site with alcohol swab.
2. Ready the needle and injection.
3. Feel the veins that needs to be punctured.
4. If the veins cannot be easily found, use the vein detector device to locate the veins, by temporarily placing it over the puncture site.
5. If the vein detector needs to be continuously placed on the puncture site for difficult veins, strap the device onto the venipuncture site.

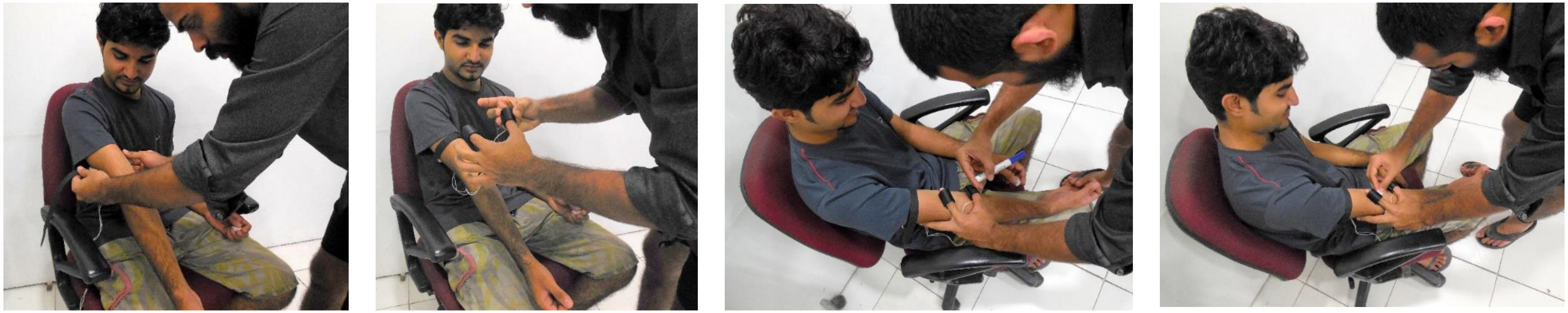


Image 31. Activity analysis done using the mock ups

Source: Author

6. Perform the veni-puncture, remove the vein detector device.
7. Clean the puncture site using cotton swabs.
8. Clean the veni-detector device using alcohol swabs.

Learnings from the activity analysis:

- The need to have more open area for performing veni-puncture
- Quantify the optimum vein viewing area
- The need to incorporate veni-puncture angle
- Address the hygiene issues
- Device strapping onto elbow
- Need to have a compact console which houses all the electronics

Hand dimensions	Min.	Max.	Mean	SD	CV	Skew ness	Percentile		
							5th	50th	95th
Fist circumference	252.00	305.00	277.65	10.57	3.81	-0.093	259.00	280.00	305.00
Hand circumference	225.00	265.00	243.82	8.52	3.49	-0.100	228.00	245.00	262.00
Max. hand circumference	310.00	379.00	344.50	12.87	3.74	-0.251	319.00	346.00	373.00
Index finger circumference	60.00	77.00	67.28	3.76	5.59	-0.075	61.00	68.00	74.00
Wrist circumference	149.00	185.00	164.54	6.92	4.21	0.153	152.00	165.00	180.00
Arm length	692.00	847.00	771.16	27.36	3.55	-0.025	727.00	776.00	821.00
Elbow length	423.00	501.00	459.91	15.70	3.41	0.260	434.00	462.00	493.00
Elbow flexed	223.00	320.00	263.72	18.11	6.87	0.113	234.00	266.00	295.00
Max. internal grip diameter	35.00	52.00	42.68	4.05	9.49	0.163	35.00	44.00	50.00
Middle finger palm grip diameter	12.00	22.50	16.33	2.47	15.12	0.188	12.50	17.50	21.00

All dimensions are in mm

Table 1. Anthropometric table of hand dimensions

Source: ispub.com

In order to suitably fit the device unto the hand on the patient, one had to take into the anthropometric considerations, as the target users range from an obese adult to a child.

In order to fit onto most patient’s hand the dimensions of hand circumference were taken into account.

The 95^{th} percentile dimensions of hand circumference is 262mm, the radius is 4.1cm. The device’s inner circumference has been based on this dimension.

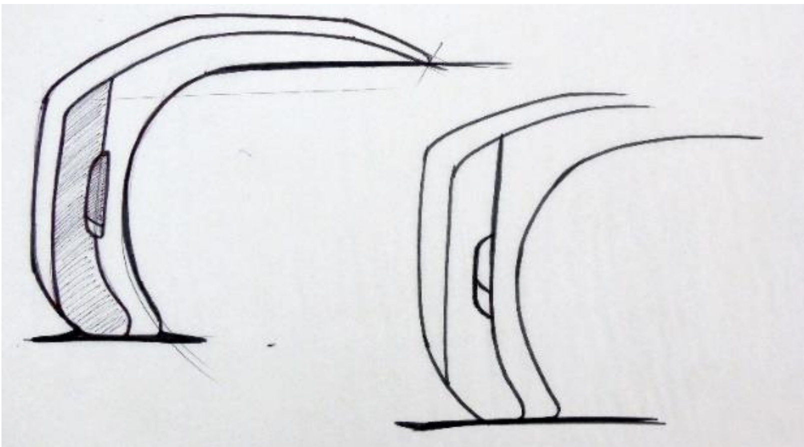


Image 32 : Sketch showing the side profile and switch positions

Source: Author

The ergonomic factors considered during the design of the device were:

- The optimum width of the device
- The thickness of the LED surface
- The position of the switch and intensity knob
- The optimum vein viewing area

Each of the above said parameters does not have any known pre defined standards, hence the optimum values were defined based one the analysis of the 1:1 mock ups that were built.

People interviewed	13, Doctors = 6, Nurses = 7
Hospital Type	Government hospital : 1 Private Hospital : 2 Blood Banks : 1

In order to have a better idea about the medical terms
And human biological aspects, there was a dire need to
Seek expertise from doctors.

Among the many interactions that was had with the medical fraternity, many of the following queries were answered:

1. Existing **methods** of venipuncture
2. The most commonly used **types of needles**
3. Typical **sites** of performing venipuncture
4. Possible **ways of cleaning** the device

The most commonly used needle in hospitals for veni-puncture is a 22G 1", for most adults it serves well for routine blood sample collection i.e 5-20ml. 21-23 G needles are used for adults,23 – 25G 1/2 inch for used Paediatric needs. Higher gauge needles are used for vaccination, insulin delivery etc. The finest ones being in range of 30-31G. 16G are used in Blood transfusions and rapid IV fluid delivery in case of emergencies.

It was also said that finer bore needles have higher propensity for haemolysis of sample, so selection of the needle varies from one patient to the other.

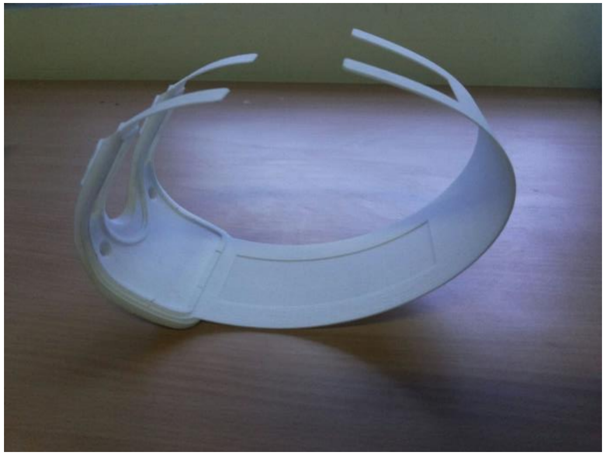


Image 32: 3D printed parts of the upper and lower parts of the prototype

Source: Author

Peripheral Veins have a 3-layered wall composed of an internal intima layer surrounded by a thin muscular layer, which in turn is surrounded by a layer of connective tissue, called adventitia.

Identification of the optimal site for venous access is often subjective, it involves both visual and tactile evaluation and more importantly how frequent samples need to be drawn. Application of a tourniquet proximal to the site of puncture is usually just above the elbow (cubital fossa) which is ideally 4-5 fingers above the site of prick.

On palpation, the vein should be soft and bouncy, it should refill after being depressed, and, ideally, it should be well supported by the surrounding tissue, which makes needle entry into the vein more precise.

The veins in order of preference is Median cubital vein then Cephalic vein and Basilic vein, these sites are preferred when the access required in temporary patients. Median cubital vein because of its large size and superficial location. The median cubital vein usually shunts some of the blood collected by the cephalic vein to the Basilic vein. Its most visible vein in most cases, and easiest to access.

The cephalic vein is relatively large in size and is well positioned for puncture and IV administration. It drains the radial side of the forearm and arm. It readily accommodates a large cannula, and the forearm provides a natural splint for the cannula.

CIRCUIT DESIGN

The circuit design forms the core integral part of the product, the effectiveness of the product depends on the efficiency of the circuit. After figuring the best circuit configuration that helps in vein viewing the approach was to make it as compact and low cost as possible.

The configuration of the circuit used is as follows:

L.E.D type : HI 1watt red L.E.D

Wavelength : 635nm

Number of L.E.Ds : 6

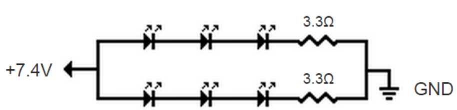
Voltage rating : 7.4V

Forward current : 300mA

Battery mAh : 1100mAh

1W Red L.E.D

Li-ion battery



L.E.D circuit

Image 33. Images showing the L.E.D , Battery and circuit used in the prototype

Source: Author

Safety factors of the circuit

The circuit built uses LEDs that falls under the range of Red-Near infra red wavelength category.

The exact wavelength of the LEDs are 635nm, this wavelength falls under the Risk group : Exempt/ RG1, under the category RG1, the LED safety standards prescribe that there will be no photo biological harm to skin and eye under normal behavioural limitations

CHALLENGES

As the project evolved over different stages, few challenges were particularly identified and needed to be addressed.

- The optimum vein viewing area and shape
- The clamping of the device onto the patient's hand during veni-puncture
- Incorporating the 30 degree angle of needle insertion
- Ways of keeping the device clean and hygienic

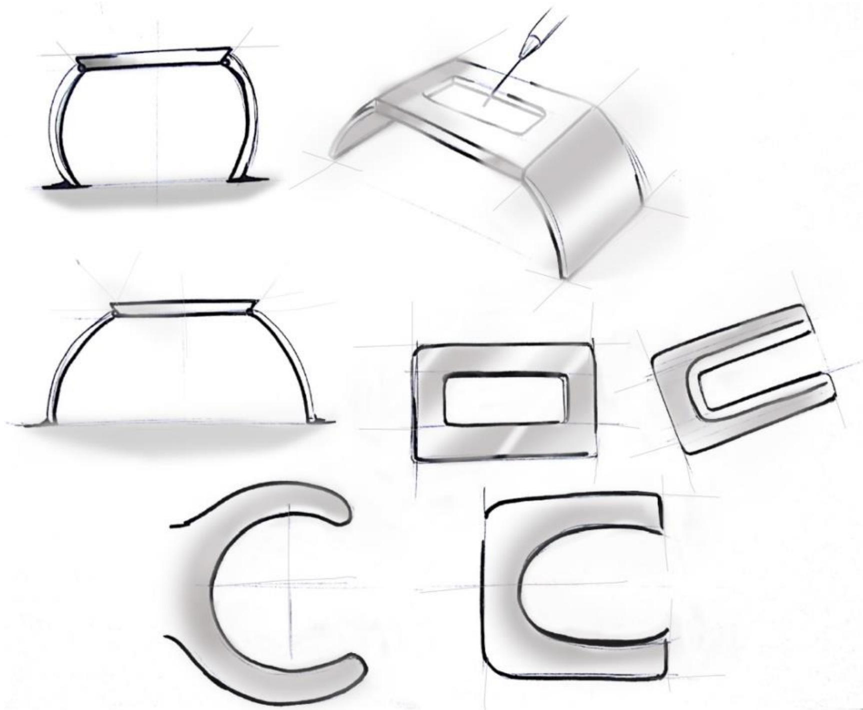


Image 17 : Sketches showing explorations of vein viewing shapes

Source: Author

Image 34: 3d printed L.E.D housing to check the optimum vein viewing area

Source: Author

The optimum vein viewing area and shape

The vein viewing area is by far the most critical aspect of the product as it determines how well the veins are visible to the user for performing the veni-puncture. To find out this parameter 3d printed bases embedded with L.E.Ds were used, these bases were moved apart and closer on many users in order to find out at which distance the veins were best visible.

A frame structure of vein viewing area was one of the ideations proposed, but when a mock up was made and tested, it was quickly found out that the closed vein view area would give a very good contrast of the veins but would become impossible for the nurse to remove the needle unless or until the vein detector device, which could turn out to be extremely dangerous in cases of emergency.

It is for this reason that the designs of the vein viewing area turned out to be 'U shaped' in all the consecutive ideations.

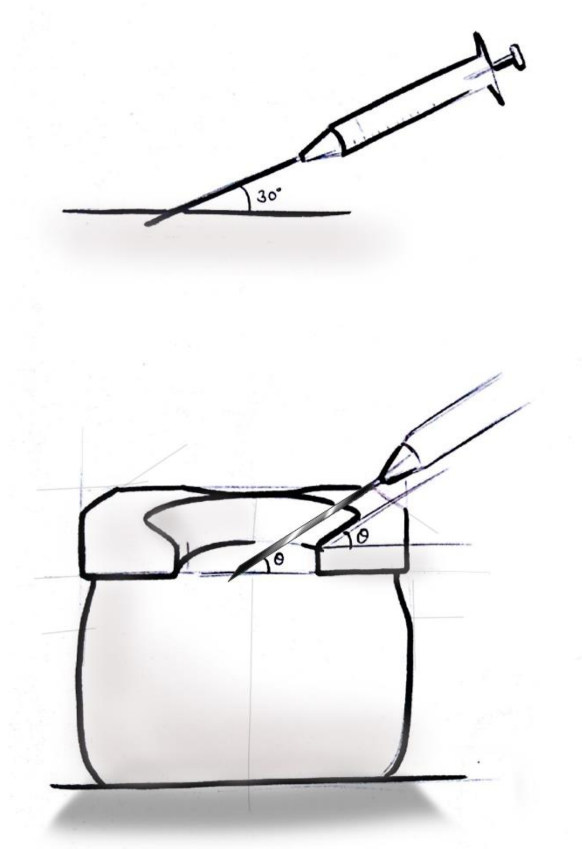


Image 35 : Sketches showing 30 degree angle of needle insertion

Source: Author

Incorporating the 30 degree angle of needle insertion

The prescribed safe practice for veni-puncture is to insert the needle into a patient's vein at an angle of 30 to 45 degrees, any insertion that happens outside this range would lead to incorrect veni puncture and lead to pain and undesired effects on the user.

In order to assist the nurse in successfully performing the veni puncture in the prescribed angle, the sides of the vein viewing area of the device are chamfered at an angle of 35 degree, this would act as a guide for the nurse while performing the veni puncture as the nurse would be encouraged and trained to do the needle insertion in a manner that is parallel to the side walls of the device and thereby stay close to the required 30 degree angle.

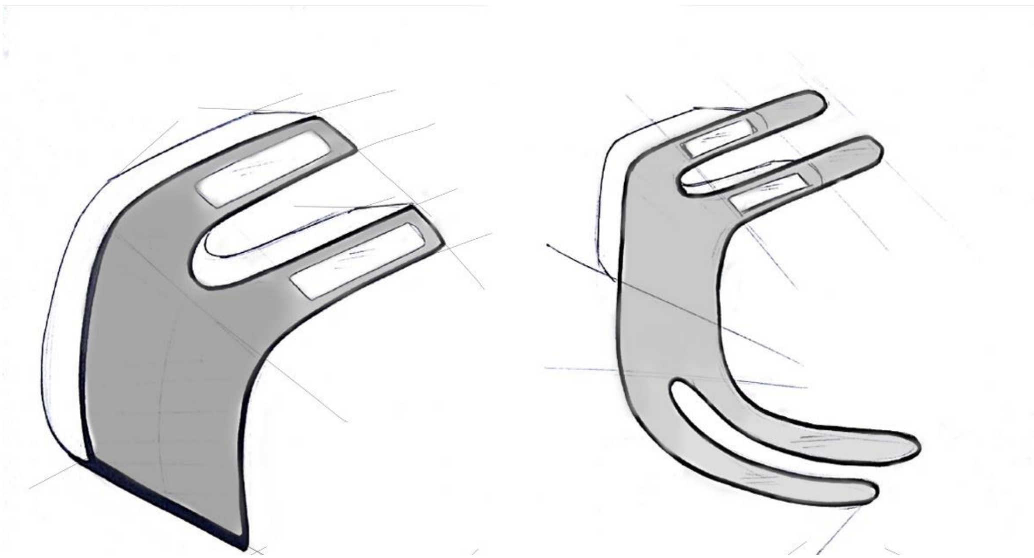


Image 36: Inside surfaces clad with a single material

Source: Author

Ways of keeping the device clean and hygienic

Healthcare products need to be invariably clean, to avoid hygiene related issues. Considering the fact that the device will be used on multiple patient’s involving skin contact, the device needs to be as sterile as possible.

In order the achieve this the design interventions done are, to use a single continuous surface on the inner side of the device without any protrusions or parting lines was made. This would avoid the accumulation of dirt over prolonged usage.

To avoid dirt accumulation on the joining details of the product like the connection of the Velcro strap, care was taken to make the inner rubber core a one single continuous loop that extends all the way unto the other end of the strap.

Another consideration made was to use bio-compatible materials that would not cause any un desired health effects to the patients.

Image 37: Clamping mechanism and its range of expansion
Source: Author

The clamping of the device onto the patient's hand during veni-puncture

A common feedback got during the user testing of the prototype was to incorporate some kind of movable clamp that would cling onto the patient's hand. In that regard when the explorations were made it was found that making a clamp mechanism would make the device more rigid leading to difficulty in attaching the device onto different percentile users, especially the obese patients.

Also, it was decided to have minimal movable parts on the device to increase the product life and avoid wear and tear of the components.

FORM EXPLORATIONS

The product designed is a medical device, hence it invariably has to have the healthcare device aesthetics and the approach towards the explorations were driven by the constraints set by the electronics that's present in the device.

In other words, the engine was built and tested before hand, and the body of the vehicle was built around the engine in such a way that it further enhances the overall efficiency and performance of the device.

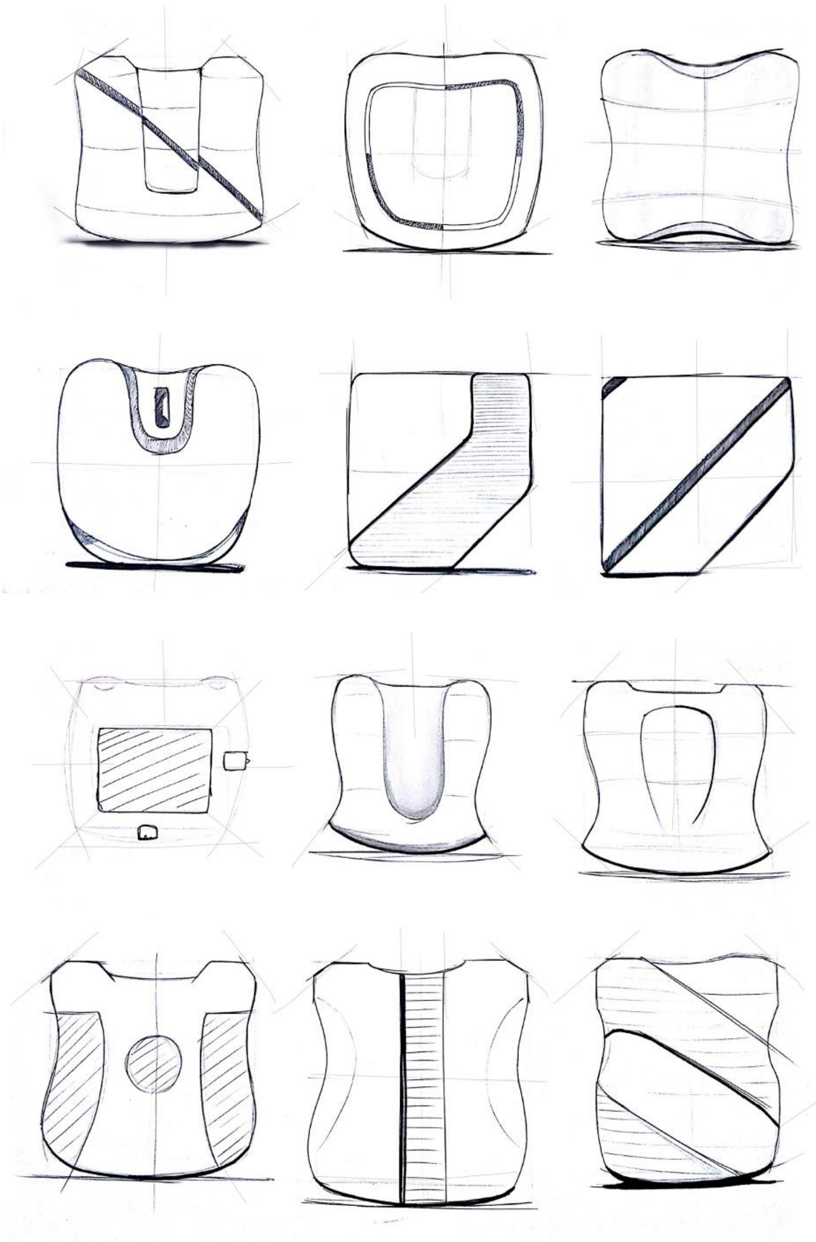
The form had to take into the considerations of dimensions of the electronic components, along with ergonomic factors for comfortable grip and effective vein viewing.

The details considered while doing the form explorations are:

- The Color shades on the body
- The Radii of curvature of the edges
- Details on avoiding dirt accumulation
- Self explanatory usage of product through the form
- Incorporation of the logo

Image 38. Mood board and keywords chosen for form exploration

Source: Various sources, Refer citations



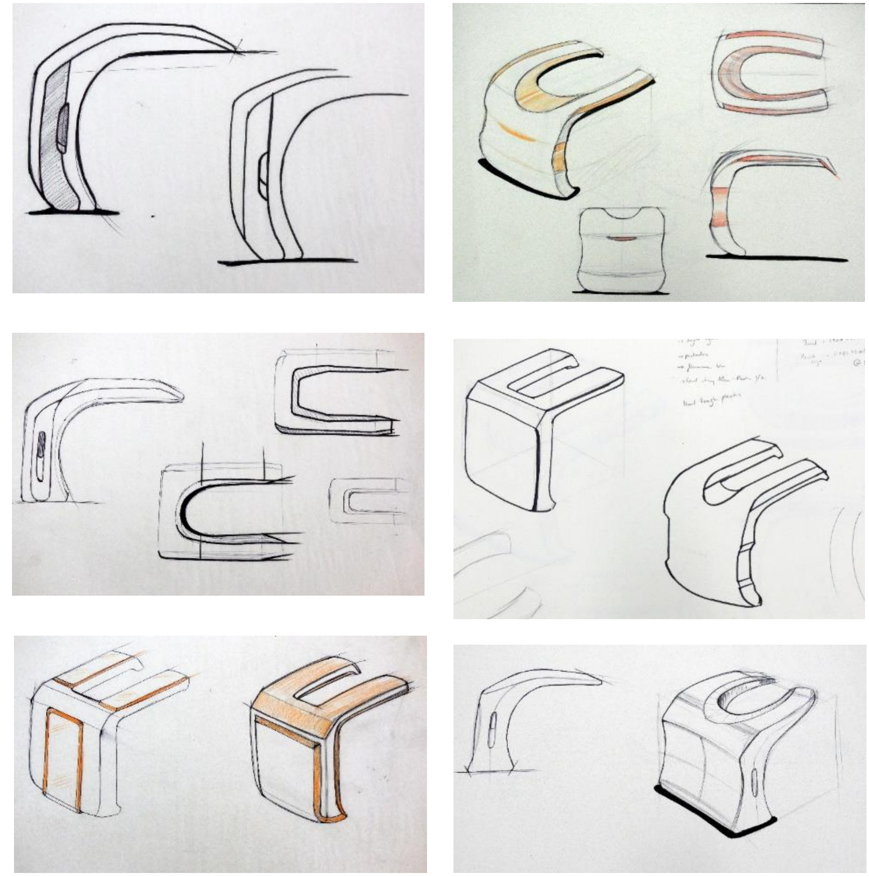
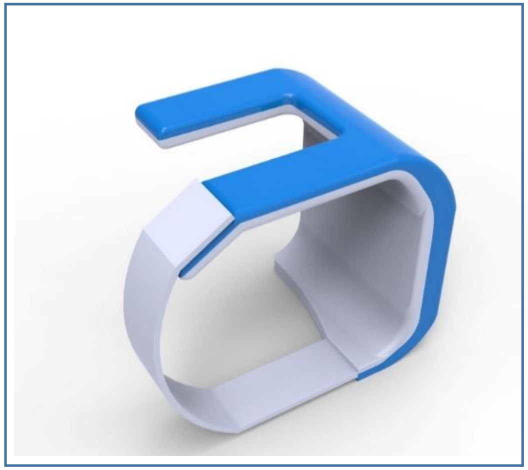
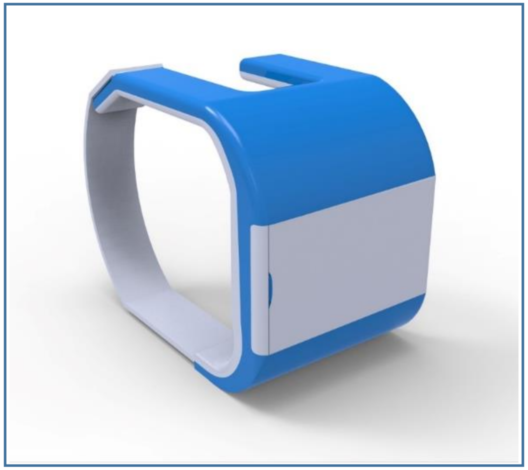


Image 39: initial form exploration sketches
Source: Author

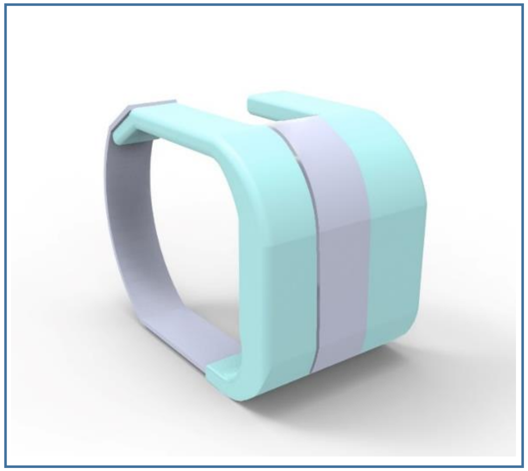
EXPLORATION 1

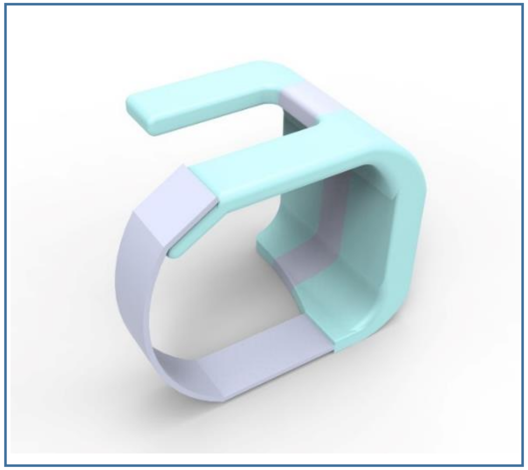




Initial form explorations involved forms which utmost importance to functionality of the product, hence very subtle and minimalistic elements were incorporated.

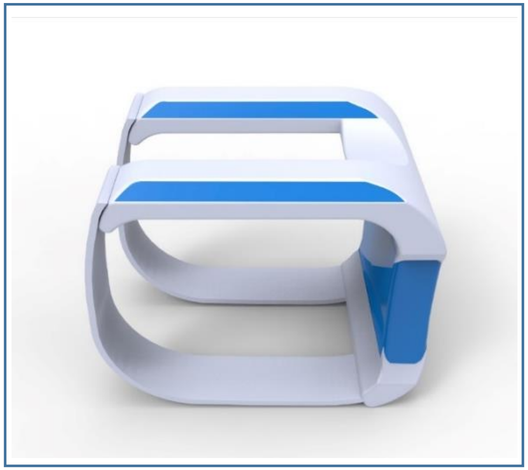
EXPLORATION 2

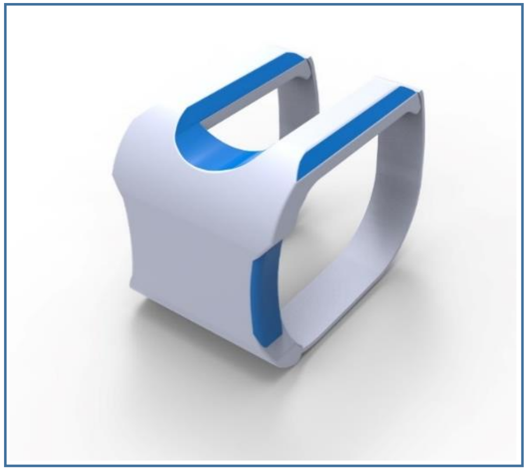




Color plays a very significant role in giving an identity to healthcare products, in that regard many pastel shades of blue and green were considered.

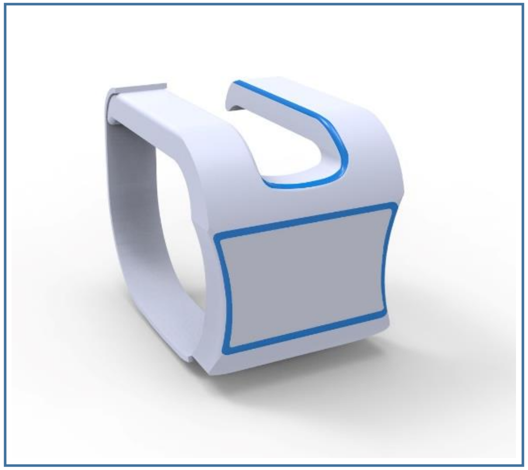
EXPLORATION 3

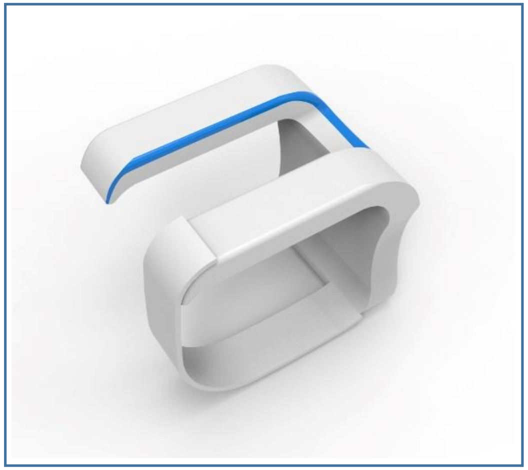




This exploration had more bold cuts and facets to bring in the strength and essence of contemporary forms. This form had double straps system.

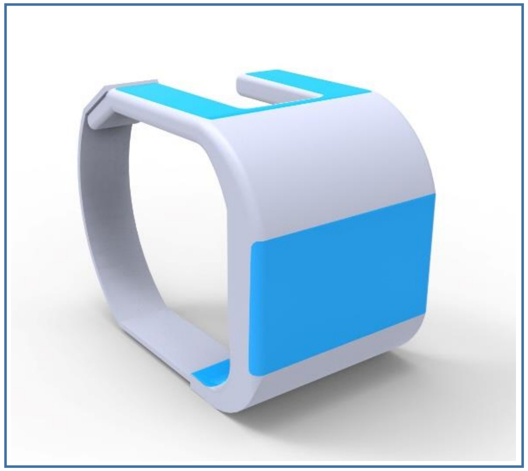
EXPLORATION 4

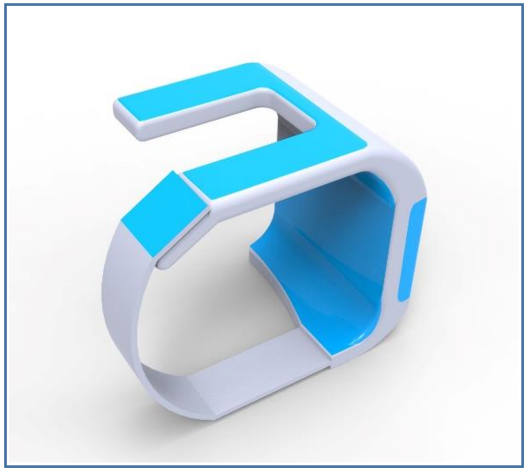




Flow of outlines along the LEDs and battery pack.

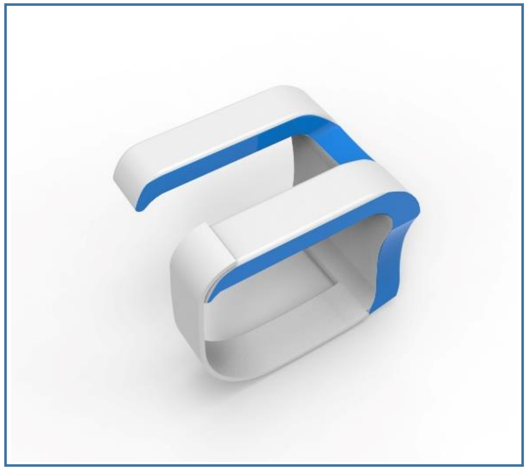
EXPLORATION 5





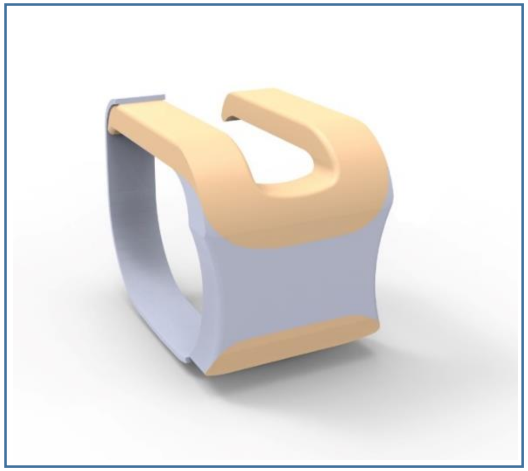
Using a distinct color patch on the underside of the device, to underplay the hygiene issues.

EXPLORATION 6

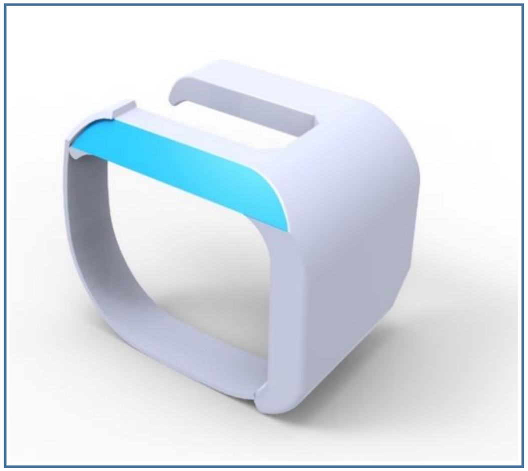


The outlines along the product side cuts have been emphasized.

EXPLORATION 7

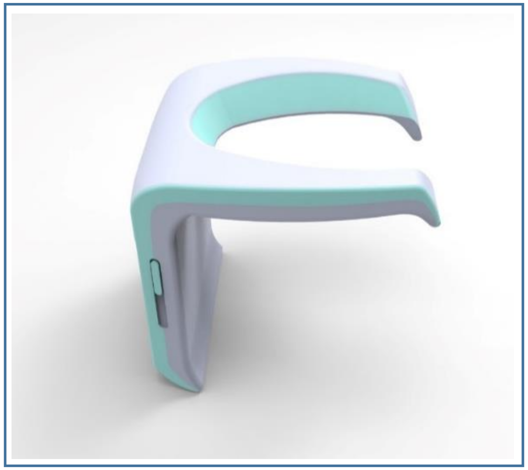


EXPLORATION 8



A more off-beat colour has been tried, along with un-conventional cuts.

EXPLORATION 9



A more refined form which takes into considerations of features like the switch, parting lines and vein viewing shape.

EXPLORATION 10

In this form, importance was given to the profile of the device that would aid comfortable placement of the device on to the elbow.

Image 40. Render of the prototype as worn on a patient's arm

Source: Author

With every exploration, a more evolved form was evident. The renders were circulated among people who were both designers and non-designers. Based on the feedback obtained refinements were done to the final form.

The parameters considered for choosing the final form are:

- The shape of the vein viewing area
- Profile of the elbow
- Color considerations
- Stringent considerations were also made with regards to the component dimensions
- Positioning of the switch and the recharging port

Finalized Form

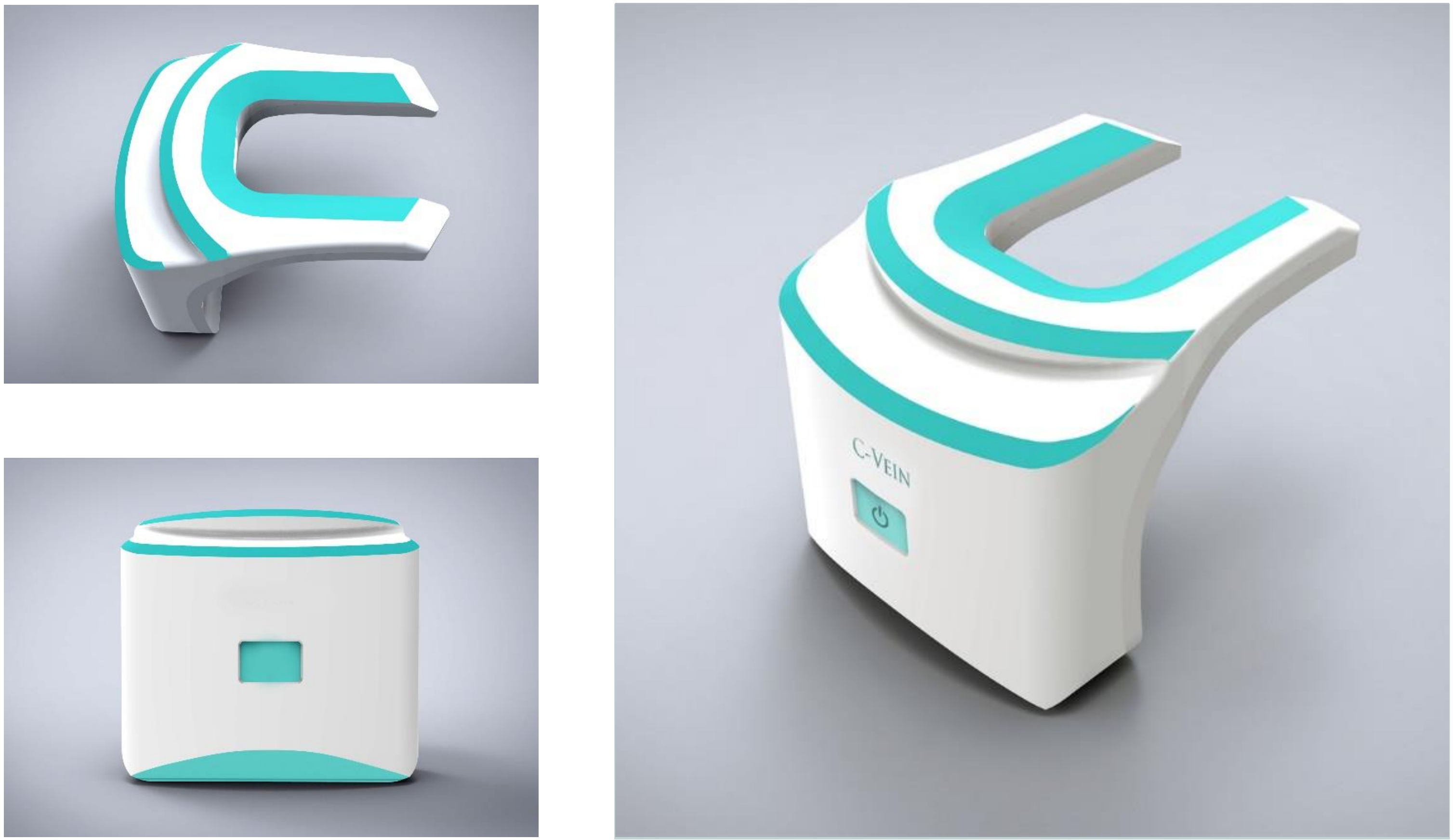
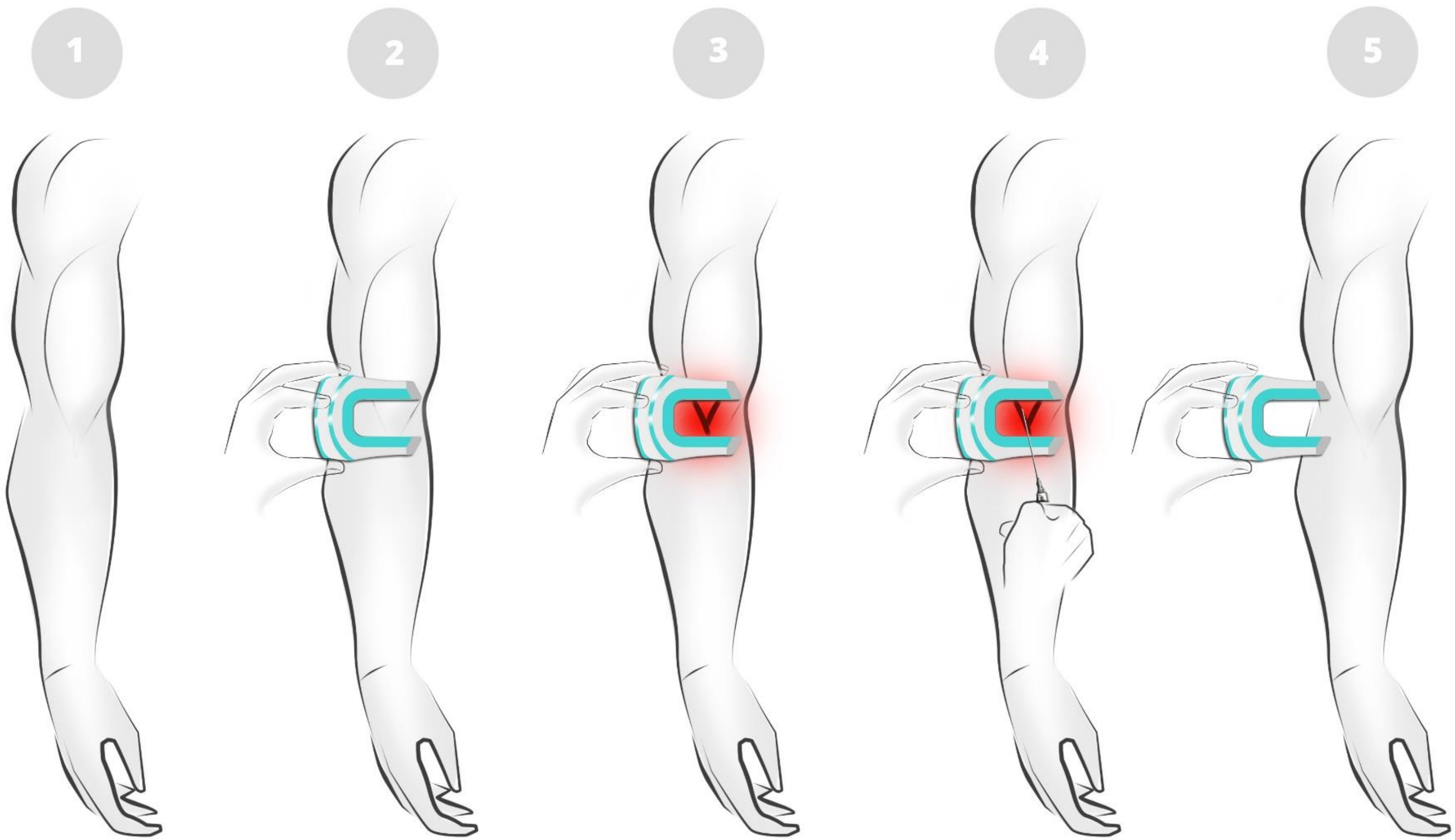


Image 41: Render of the final form

Source: Author



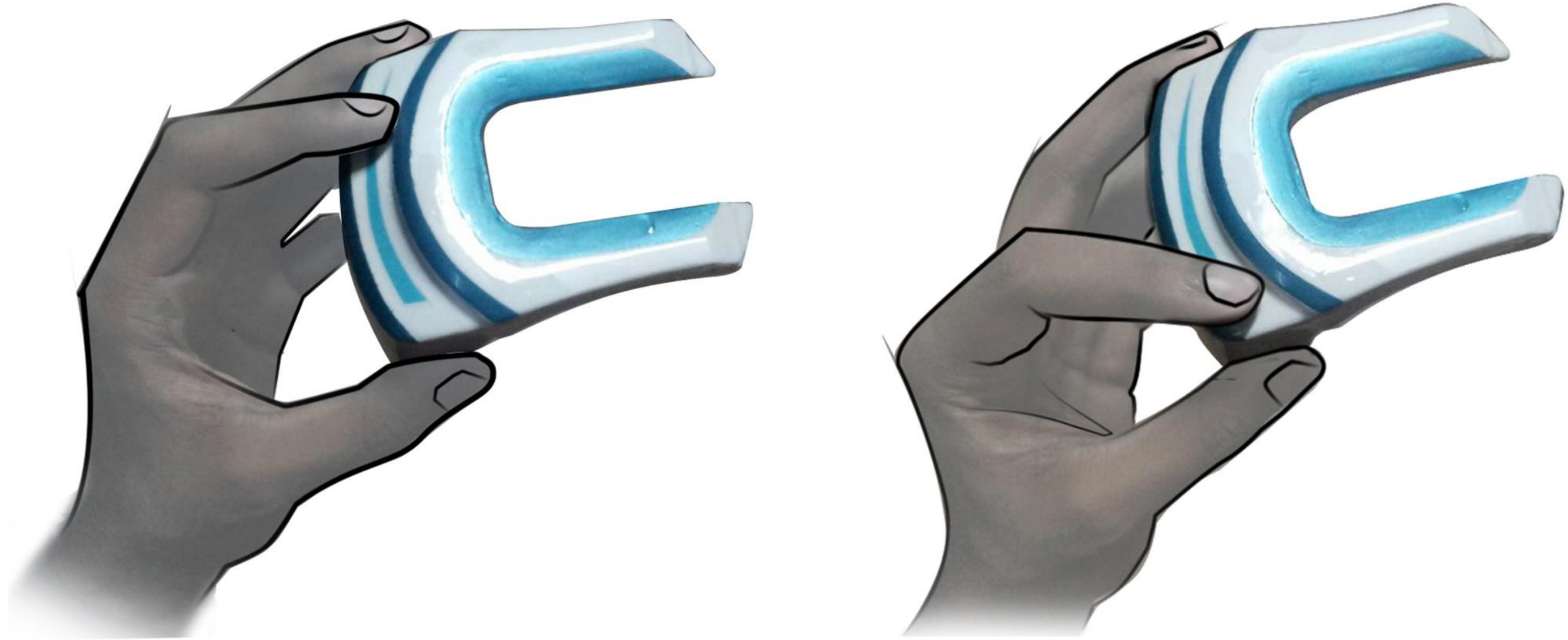
Sterilize the veni-puncture site

Place the device over the site

Turn on the device and vary the brightness to view the veins

Perform the veni-puncture process

Turn off the device and remove it



All the controls like switch and brightness knob are embedded inside the device body. This is achieved by having capacitance touch sensors embedded in the body. By moving one's finger over the body, we can adjust the brightness, as shown in the picture above.
By not having external switches and brightness adjustability, chances of dirt accumulation is reduced, hence improving the hygiene factors of the device.

Image 42: Snapshots of the final prototype

Source: Author

DETAILING

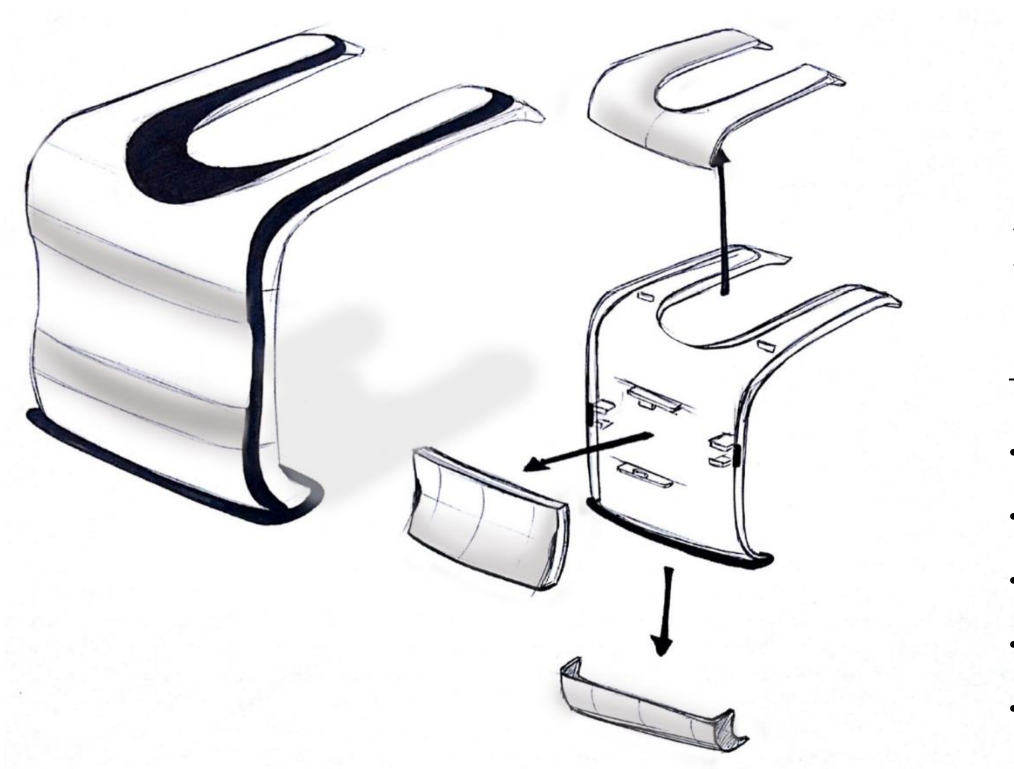


Image 43: Initial sketches of body detailing
Source: Author

After finalising the form and internal components, the challenging task of integrating circuit within the given window of dimension range was done.

The various factors considered during detailing of the product are:

- Material consideration
- Attaching mechanisms
- Manufacturability
- Slots for internal components
- Colour combinations
- Branding
- Strap mechanisms

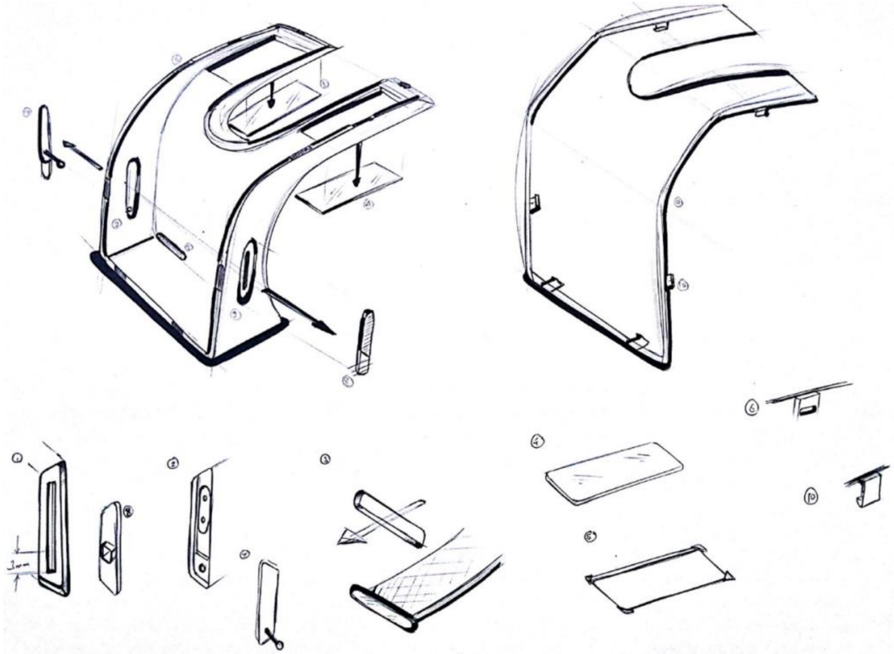


Image 23: Sketches of various individual components in the device
Source: Author

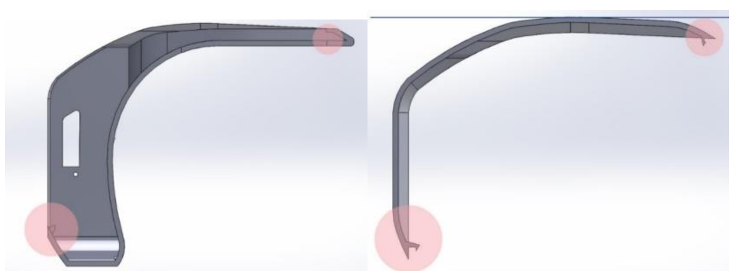


Image 44: Renders of snap ons
Source: Author

Material considerations:

The material considered needs to be bio-compatible as the device would be in direct contact with the patient’s skin. The materials considered for the final prototype are ABS (Acrylonitrile butadiene styrene) and silicone.

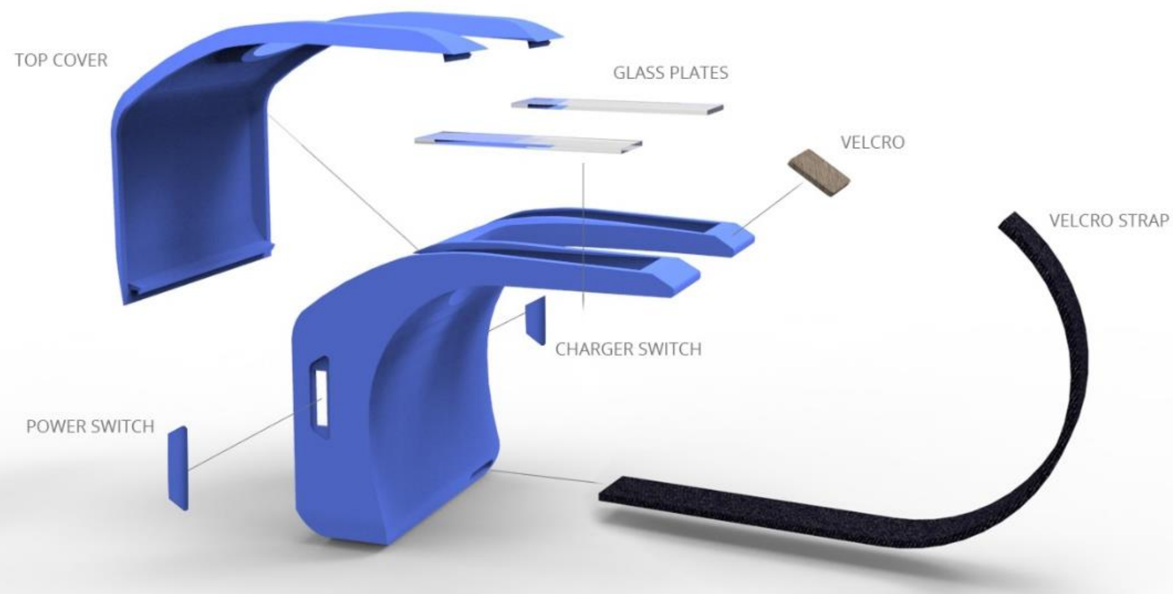
Manufacturability

The detailing of the parts is being done with considerations to the mould such that there will be less number of movable moulds involved, in order to save mould cost.

Colour combinations

The colours chosen would be white and pastel shades of green, this combination was decided after studying the colour palette of hospital interiors and medical products.

EXPLODED VIEW OF THE PROTOTYPE



Components

- Top cover
- Power switch
- Charger switch
- Velcro
- Velcro strap
- Glass plates

USER TESTING

Image 45: User testing of the prototype

Source: Author

The project is under initial user testing phase, where in the prototype is being tested on users. The users are being chosen on the basis of vein being visible to the naked eye, points are given out of 5 depending on the quality of the vein visualisation. This procedure is done in order to find out the efficiency of the prototype.

Two prototypes have been built so far, which will be given to nurses and doctors and asked to simulate the veni-puncture process. This will be done in order to understand the usability issues.

Based on the analysis and feedback obtained with respect to the prototypes, refinements will done and a final prototype will be built.

Until now, one common feedback obtained in the initial phase of user testing is that the brightness of the LEDs are too high. In order to overcome this issue steps are being taken to vary the intensity of the LEDs brightness according to the individuals needs.

FUTURE SCOPE

A working prototype was developed and tested on preliminary set of users. The project has immense scope for further development, refinements in the following areas would enable deployment of the product in pilot testing.

1.Recharging of battery :

With a single charge of battery, the device works for 2 hours of usage. In the current model, the battery needs to be removed from the device and charged separately, which could be a tedious process in actual product usage scenarios. New circuitry needs to be developed which has an integrated charging unit.

2.Thickness of 'U' strip :

During user testing it was found that the needle insertion using the product becomes difficult as the thickness of the body is very high to facilitate smooth needle insertions, further miniaturization needs to be made in the electronics to make device like a thin strip. Else the device can be used only for the purpose of vein viewing but not to perform veni-puncture along with the usage of the device.

3.Hygiene factor :

In the latest prototype the hygiene factor was handled by removing grooves from the surface of the device and by having a silicon film on the underside of the product. This silicon film can be a disposable that can be used for every patient. But a more efficient method of keeping the product hygienic needs to be still developed.

4.Clamp on to hand :

How the device holds onto the patients hand has been a challenging aspect throughout the project, many refinements have made in that regard, like using a velcro strap. A more efficient method of clamping needs to be developed which is easy to use.

5.Approval of healthcare standards :

Medical devices have lot of standards to adhere to, although the product is non-invasive there are parameters that the device has to qualify, for instance CE accreditations. These factors still needs to be thoroughly researched before commercializing the product.

BRANDING

Giving an identity to the product in terms of logo or brand name is a very important aspect in making an end to end product.

In that regard efforts were taken to choose a suitable product name that would reflect the core essence of the product.

Brainstorming techniques were done in order to choose the right name:

Few of the names that were thought about were:

Vein-one = as we find the vein and do veni puncture in one attempt.

Veintrix

Vein fix

Veincare = reduced pain and trauma to patients

VeinX = vein expose (as it shows hidden veins)

Veinpact

Veinsoft

Vein it = Win it (because it helps nurses to win the problem of having to find difficult vein)

C-VEIN

Font : Trajan Pro

Veiner	**Vein-al**
Veinfind	Inveint
Veinpact	Veinaid= helps find veins

Veinsure = sure to find a vein using the product

Veinjoy	Veinspot

Cvein =, you get to SEE the vein

Vein pro

Amongst the various names chosen **C-Vein** was the most crisp name as it directly addresses the core functionality of helping one see the difficult veins.

CONCLUSION

The project was done using a formal design methodology. The end goal of the project is to bring the product to a substantial level of feasibility that it can be implemented in the field such that it would prove to be beneficial to the patients.

The efficiency of the product can be evaluated only after comprehensive user testing and refinements, the product may not be able to find affirmative veins in every test subject, but it would give a suggestive idea of the vein's position.

An end to end product design approach was successfully implemented in this project, which involved circuit building, product design, prototype building, user testing and branding.

Although many products do exist in the market, according to the study done with parallel products it can be safely concluded that C-Vein is be the most affordable and usable vein detector.

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