Department of Electronic & Telecommunication Engineering

University of Moratuwa

BM2210 - Biomedical Device Design

Feasibility proposal

Submitted by,

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Content

1 Introduction

This report describes the procedure for addressing the previously identified problem. We follow the steps of ideation and concept screening outlined in the book.

2 Need statement

“A way to locate veins in all patients for efficient and more accurate needle placement.”

The need statement emphasizes the urgent need for an innovative solution to address the difficulty of locating veins in patients, particularly those with high adipose tissue levels. In such situations, the conventional method of manually locating veins for intravenous (IV) procedures and vaccinations is challenging and ineffective. This frequently leads to multiple painful attempts and inaccurate needle placements, which can have negative effects on patient health and healthcare efficiency. Therefore, there is a critical need for a reliable and effective technology or technique that can accurately and rapidly identify veins in all patients, making medical procedures more efficient and comfortable for patients.

3 Ideation

In an effort to find solutions, a brainstorming session was held on 13.09.2023 to generate ideas for addressing the issue; the ideas generated are summarized below.

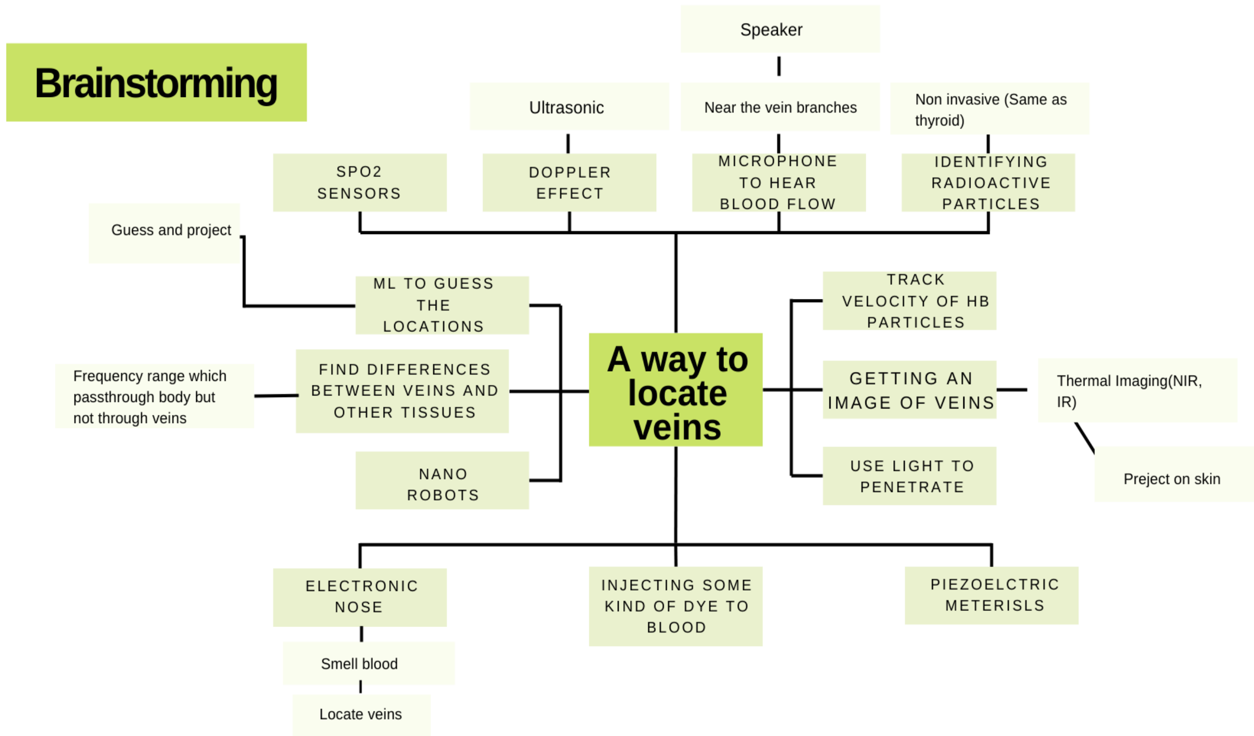


Figure 1: Ideation

4 Initial Concept Selection

In the process of refining our strategy for efficiently and precisely locating veins, we conducted a comprehensive evaluation of various proposed ideas. The objective of this evaluation was to identify concepts that were both technically feasible and in line with our primary objective. As a result, several concepts were identified as not feasible for different reasons. First, the concept of using radioactive particles to identify veins was dropped due to safety concerns and regulatory complexities. Second, the concept of using nano robots for this purpose was deemed too advanced and intrusive, posing potential risks to patient safety.

In addition, the idea of introducing a dye into the patient's bloodstream to improve vein visibility was discarded because it was beyond our engineering capabilities. After careful consideration and elimination of these unfeasible alternatives, we have narrowed our focus to three ideas. These ideas will be subjected to additional analysis and evaluation to determine their viability and suitability for addressing the problem of efficient and precise vein location.

4.1 Doppler ultrasound for vein imaging

Doppler ultrasound, a powerful imaging technique used to assess blood flow within the body's blood vessels, offers a possible solution for vein imaging in our attempt to improve the efficiency and precision of needle placement, particularly in patients with high levels of adipose tissue. This non-invasive method is based on the Doppler effect, a phenomenon in which the frequency or wavelength of sound waves interacts with moving blood cells. Doppler ultrasound allows medical professionals to precisely visualize the location and flow of blood within veins during vein imaging.

The Doppler ultrasound device can produce real-time images of veins and their blood flow patterns by directing the ultrasound probe over the area of interest. This provides vital information on the size, depth, and accessibility of veins, making it significantly easier for healthcare providers to pinpoint suitable locations for needle insertion during procedures such as IV insertions and vaccinations. Moreover, Doppler ultrasound can be particularly advantageous in cases where manual vein identification is difficult due to high levels of adipose, as it provides a non-invasive and effective alternative that minimizes discomfort and the need for multiple attempts. Doppler ultrasound technology is a valuable tool for vein imaging, providing precise and real-time information that can significantly improve the precision and efficacy of medical procedures involving vein access.

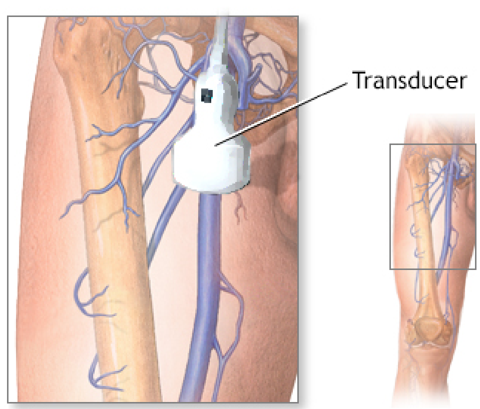


Figure 2: Doppler ultrasonography

4.2 Using Near-Infrared Technique for Vein Imaging

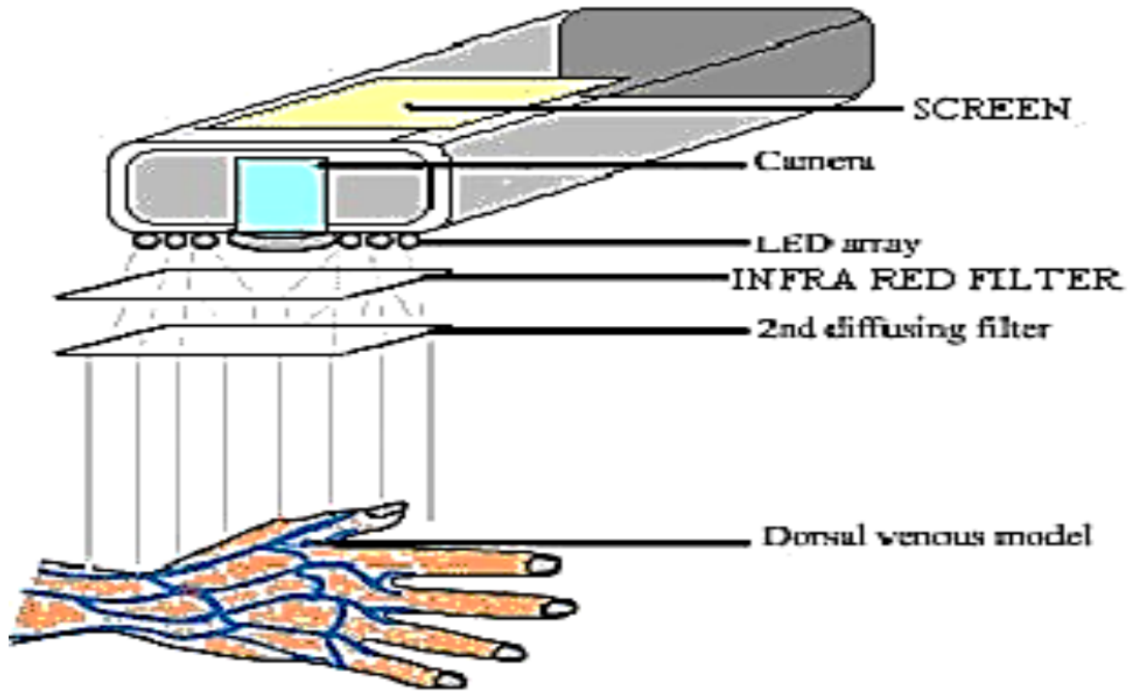


Figure 3: Working principle of NIR vein finder

Near-Infrared (NIR) vein finder technology provides a non-invasive and highly effective method for locating veins during medical procedures. This technology illuminates the skin with near-infrared light, specifically in the 700-900 nm wavelength range. This light can penetrate the skin and subcutaneous tissues approximately 3 millimeters deep. Importantly, it is absorbed differently by the underlying tissues, with increased absorption of deoxygenated hemoglobin in veins. This difference in absorption is detected by the device's camera, and the resulting image is projected onto the patient's skin in real time.

Overall, the technology not only reduces the number of cannulation attempts, but also improves the efficacy and accuracy of medical procedures, thereby substantially enhancing patient outcomes.

4.3 Enhancing vein visualization through light source

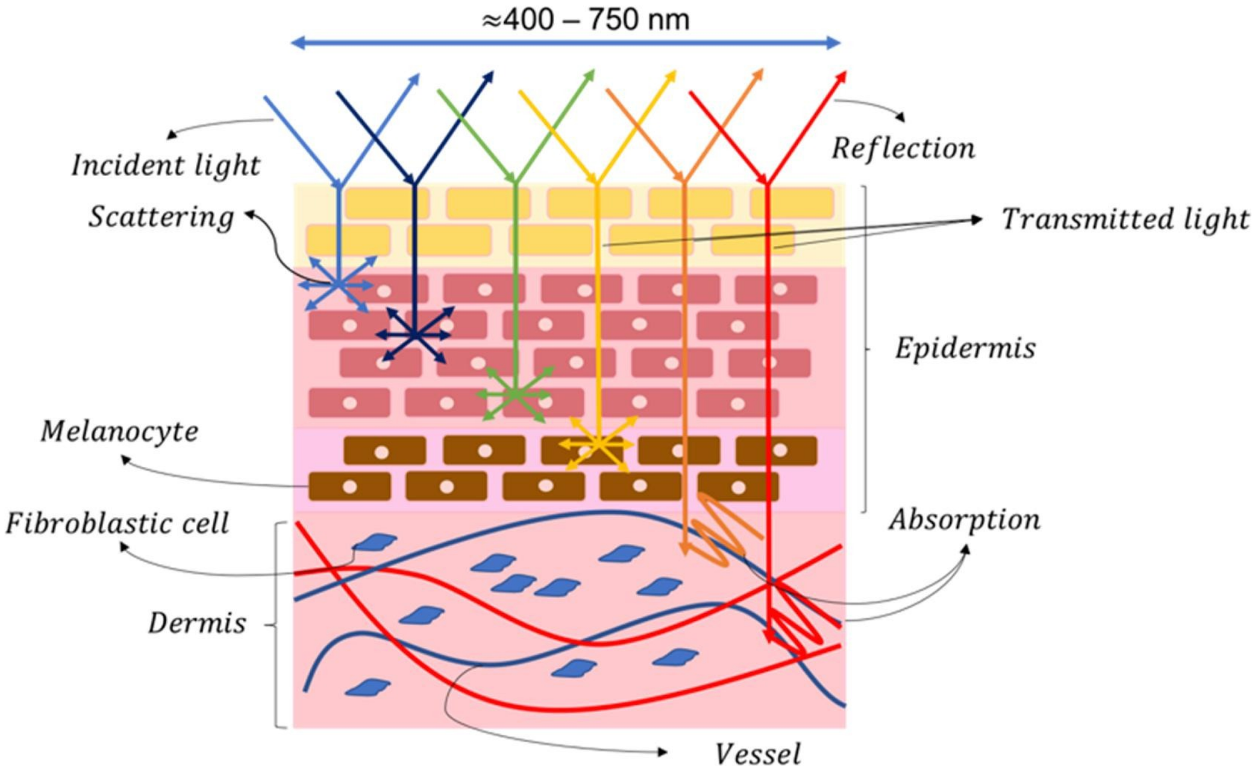


Figure 4: Light propagation in the skin schema

This method involves fine-tuning the device's light source, which typically operates in the biphotonic range, in order to improve vein visualization. Using two different wavelengths of light to illuminate the skin and veins is the basis of this technique. By carefully optimizing these wavelengths and their intensities, can increase the contrast between veins and surrounding tissues, thereby enhancing the accuracy and efficiency of vein identification.

Through successive layers of different compositions and properties, the skin is intricately designed to reduce light penetration. These differences in optical, physical, and biological properties help to explain why blood vessels become visible when the skin is exposed to specific wavelengths of visible light. Reflection, scattering, and absorption are among the key optical phenomena at play. At the initial interface between light and skin, reflection limits light propagation, whereas absorption limits light penetration into the skin. Concurrently, scattering modifies the path of light within the skin. It is noteworthy that 4% to 7% of light is reflected due to differences in refractive index between air and skin. Thus, by carefully selecting and optimizing the wavelengths and their intensities, healthcare professionals can increase the contrast between veins and surrounding tissues, allowing for more precise and effective vein identification. This process involves selecting wavelengths that align with the optimal absorption properties of hemoglobin, further accentuating the visibility of veins against the background tissue, particularly in the context of improving medical procedures like intravenous access.

5 Concept Screening

5.1 Intellectual Property (IP)

5.1.1. Vein location device using infrared source

This device use red light in wavelength between 600nm and 640nm to identify blood veins. Blood hemoglobin will absorb light in this wavelength and viewer can observe blood vessals in shaded black color. User can identify vein elements by placing device with angle of 30 degrees to 15 degrees

Reference :- US20050168980A1 - Vein locator - Google Patents

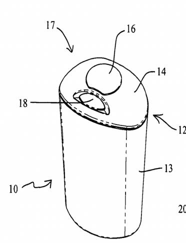


Fig. 1

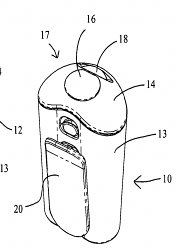


Fig. 2

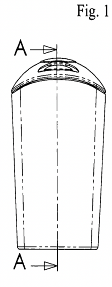


Fig. 3

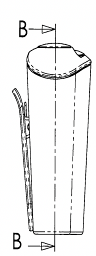


Fig. 4

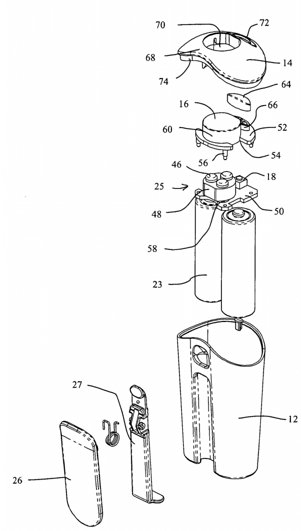
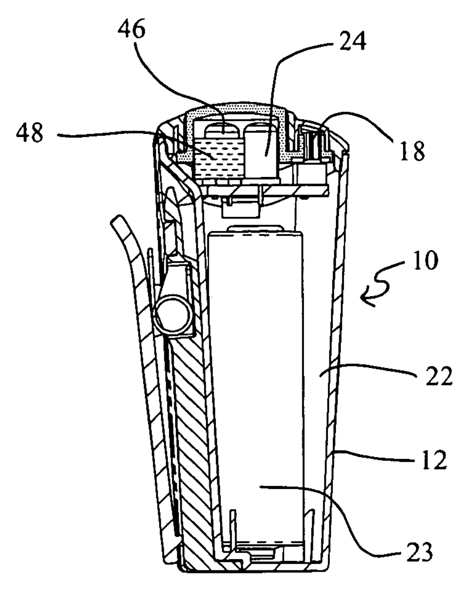


Fig. 8



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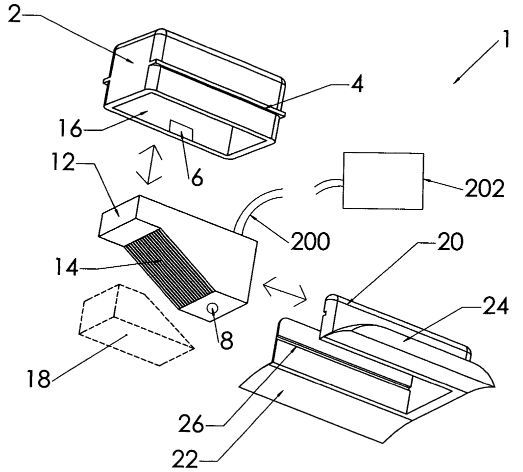
5.1.2 Use of doppler effect on finding veins



This device use transducer and ultrasound system to generate and transmit ultrasound beams which will return back to detector. This method can be used to identify blood vessals by analyzing received echo and the effect to the frequency. Furthermore, device will search for maximum signal amplitude by changing direction of the sound waves. Can measure real time data which is displayed by the device.

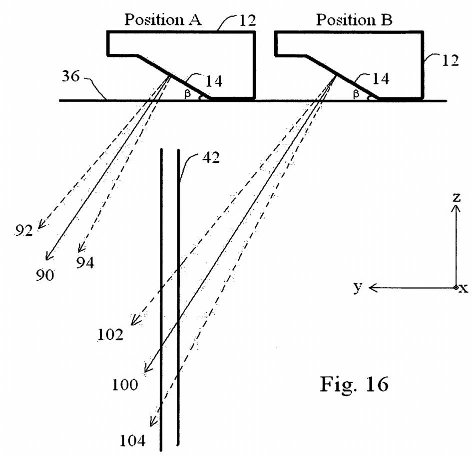


Fig. 16

Reference :- [US20050168980A1 - Vein locator - Google Patents]

5.2 Regulatory requirement

Regulatory approval is essential to the development and deployment of all three vein finder concepts. These devices fall under Class II FDA approval requirements, and the 510(k) pathway can be pursued. This pathway requires demonstrating the safety and efficacy of the devices, which is crucial for ensuring patient safety during medical procedures. To obtain approval for these innovative technologies, it is necessary to adhere to the relevant regulatory standards. Compliance with industry standards and guidelines is essential to ensure the safe and effective use of vein finders in the medical field, despite the fact that specific regulatory requirements may vary based on the exact characteristics of each vein finder.

5.3 Reimbursement

Because of the current situation in the country Sri Lankan citizens tend to use more cheaper options than expensive methods. Out of these methods, enhancing vein visualization is the cheapest solution and it will generate more income than other methods because of the lower price and effectiveness and will be more attractive to patients and medical practitioners.

5.4 Business model

The success of implementing the chosen vein finder solutions in Sri Lanka is depending on the development of a cost-effective and sustainable business model. These technologies should be priced within a range that is affordable for healthcare providers and facilities in order to be widely available. Additionally, the business model should consider maintenance, training, and support. In addition, it should be consistent with the nation's current healthcare infrastructure and economic conditions. The project aims to reduce complications and enhance patient outcomes by providing cost-effective solutions that simplify and improve vein location for healthcare professionals. This strategy ensures that the proposed innovations not only meet regulatory requirements, but also seamlessly integrate into the local healthcare system, ultimately benefiting patients and healthcare providers.

5.4.1 Doppler ultrasound for vein imaging

The Doppler ultrasound vein finder is a promising solution for accessible and cost-effective vein location. Doppler ultrasound devices are regarded as advanced because they offer advanced features for vein identification, but they also present certain difficulties. Compared to conventional methods, the initial cost of acquiring and implementing Doppler ultrasound devices may be relatively high. In addition, operating and interpreting Doppler ultrasound readings frequently require specialized training. However, the benefits are notable. Doppler ultrasound provides accurate vein location in real-time. The complexity of Doppler ultrasound technology may necessitate careful budgeting and training, but the long-term cost savings and improved patient care make it a worthwhile investment.

5.4.2 Using Near-Infrared Technique for Vein Imaging

The implementation of Near-Infrared (NIR) technology for vein finders has the potential to significantly transform vein location in Sri Lanka's healthcare system. Although NIR technology is considered innovative and may incur initial expenses, the benefits it brings to vein identification are substantial. By optimizing these devices with NIR wavelength calibration, we improve vein visualization, thereby easing the burden on medical professionals. However, it is important to recognize that the initial investment in NIR vein finder devices may be perceived as relatively expensive in certain Sri Lankan healthcare settings. Additionally, healthcare professionals may require specialized training to effectively utilize these devices. Nonetheless, these considerations should be weighed against the potential long-term benefits, including improved accuracy and efficiency in vein location procedures, which can ultimately lead to cost savings and enhanced patient care.

5.4.3 Enhancing vein visualization through light source

The introduction of vein finder devices optimized by light source calibration is a practical and cost-effective method for vein identification in Sri Lanka. These devices can be designed to improve vein visibility, thereby decreasing the need for costly and invasive procedures. This concept has lower initial development costs, and the long-term savings and improved healthcare outcomes justify the initial investment. Importantly, light source optimization in biphotonic devices aligns with Sri Lanka's healthcare priorities, providing a safer and more effective alternative for vein location. The government can allocate resources effectively, thereby enhancing patient care while reducing invasiveness and the cost of healthcare. Patients and the healthcare system as a whole will benefit from these vein finder solutions, which are tailored to the country's economic and healthcare climate.

5.5 Screening matrix

With the analysis presented above, the viability of the products is determined.

5.5.1 Risk scoring matrix

	Intellectual Property	Regulatory Requiremen ts	Reimbursem -ent	Business Model
1. Doppler ultrasound for vein imaging				
2. Using Near-Infrared Technique for Vein Imaging				
3. Enhancing vein visualization through light source				

Table 1.1: Risk Analysis

5.5.2 Selection matrix with requirements

User and design requirements that we identified are,

1. **Accuracy in Vein Identification (Weight: 5):** The most important requirement for a vein finder is to locate veins with a high degree of precision.
2. **Vein Finder Must Be Non-Invasive (Weight: 4):** The device must be non-invasive and locate veins without requiring surgical incisions.
3. **Compatibility with Various Clinical Environments (Weight: 4):** The vein finder device should be adaptable for use in hospitals, clinics, and ambulatory care settings, among others.
4. **Appropriate size (Weight: 3):** The vein finder device should have an appropriate size, taking patient comfort and usability into account.

5. **Efficiency in Vein Identification (Weight: 3):** The device should efficiently locate veins, allowing medical procedures to be performed with minimal delays.

Requirements	Weight	Manual vein palpation (Baseline)	Doppler ultrasound for vein imaging	Using Near-Infrared Technique for Vein Imaging	Enhancing vein visualization through light source
Accuracy in Vein Identification	5	0	0	+1	+1
Vein Finder Must Be Non-Invasive	4	0	+1	+1	+1
Compatibility with Various Clinical Environments	4	0	-1	-1	+1
Appropriate size	3	0	-1	+1	+1
Efficiency in Vein Identification	3	0	+1	+1	0
Rank score			0	11	16

Table 1.2: Requirements ranking

6 Final Concept Selection

With the aid of the screening analysis above, we have identified “Enhancing vein visualization through light source” to be the optimally feasible out of the above three methods.

6.1 Concept exploration and testing

6.1.1 Prototyping

The proposed device contains an array of red LED lights to emit the fine-tuned red light. This array of LEDs is placed in a curved or forked arrangement to facilitate the placement of a needle in the middle, where a clear visual of the vascular elements will be obtained. The high intensity light emitted using the above panel of LEDs will penetrate the skin. Due to different absorption properties the vascular elements will be visible in darker shades of red, while the background will be illuminated in lighter red color. This contrasting visual will help to locate the veins. The surrounded arrangement of the light panel with a cut in the front will enable the insertion and placement of a needle.

The electronic design of the device operation would be simple. The internal circuit of the device would only consist of parallel connections to the LEDs along with a suitable impedance for protection. Furthermore, this circuit should be switched on and off using a simple on/off switch. All of this could be easily fabricated on a printed circuit board.

The enclosure of the device will be best designed to be handheld. This way the clinical practitioner could hold the instrument in one-hand to visualize veins and use the other hand to place the needle. It would be ideal for the device to be battery operated or rechargeable rather than being connected to the power through a power cable.

6.2 Technical Feasibility

The electronic components and circuitry as mentioned above are readily available in the market and setting up the circuit as well as mounting on a printed circuit board is a feasible task. The enclosure design and fabrication is also made effortless through available CAD software.

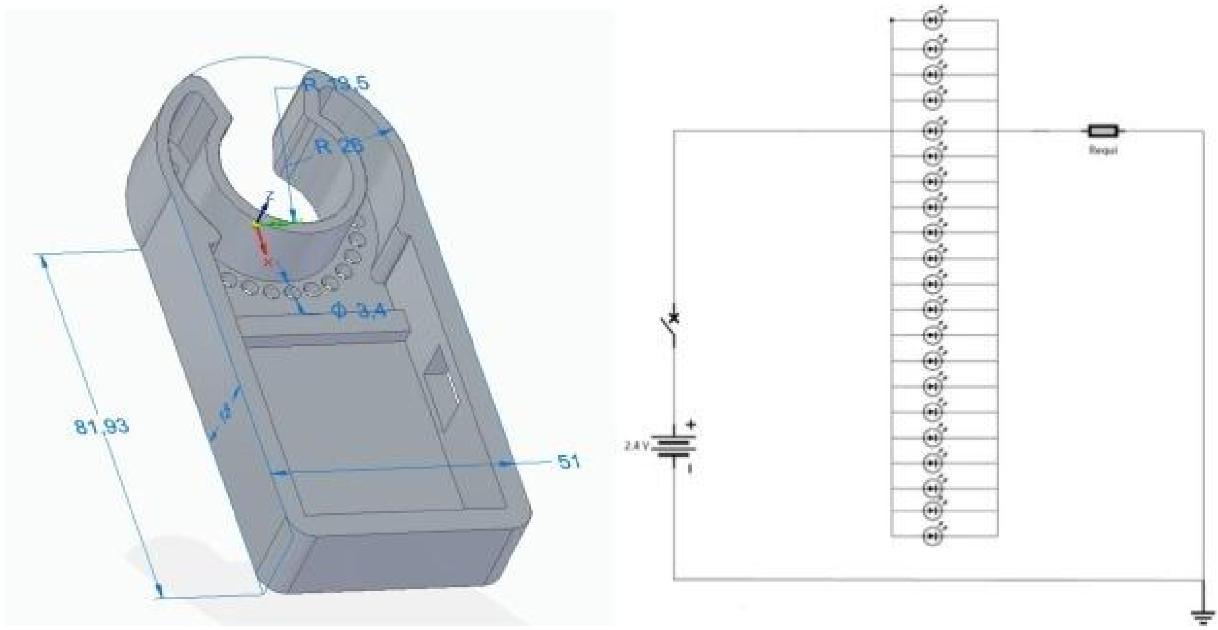


Figure 6: Design process of the device

6.3 Testing

The assembled device prototype could be tested on a subject to measure and fine-tune the accuracy and efficiency of the device.

7 Conclusion

In conclusion high intensity red light can be used to visualize vein and vascular structures in patients for more accurate and efficient needle placement. We can leverage this methodology to craft a compact portable handheld device which can be used in clinical environments to enhance the vein visualization process. A device prototype could be effortlessly fabricated by utilizing common electronic components and 3D printing workflows.

References

[1]https://www.mountsinai.org/health-library/tests/doppler-ultrasound-exam-of-an-arm-or-leg#:~:text=This%20test%20uses%20ultrasound%20to,that%20echo%20off%20the%20body).

[2]https://www.medicaleducation-bulletin.ir/article_141801_95be83ffcbfc7c3d51749d7fb0c3fd0a.pdf

[3] https://www.sciencedirect.com/science/article/pii/S2211379718318874

Appendix: Brainstorm canvas

The original image taken from the brainstorming session is shown below