Improved vein Detection Device

From Development to Distribution

Content Outline

Introduction

In healthcare, precise vein visualization is crucial, especially for patients with high adiposity levels. To address this, we've chosen to explore enhancing vein visualization through a light source. This non-invasive approach aims to simplify the process, reduce costs, and offer a patient-friendly solution. Our focus is on developing a device that improves the accuracy of vein imaging, ensuring a more efficient and comfortable experience for medical procedures in challenging patient populations.

Market

$86.8M

In 2028

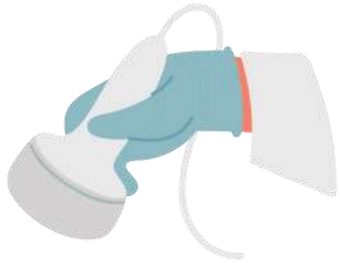
The rise in the elderly population suffering from chronic ailments, thus leading to an increase in the number of hospitalizations, will prompt the growth of the vein finders market over the forecast period. Hospitalized patients require IV insertions and blood samples for testing. Including our device, the vein finder provides better vein visualization with no pain and discomfort during the process.

Summary so far..

Stages of the Project

Needs Finding

Concept generation and screening



Biomedical Device design process

Needs Finding

During the needs exploration process we have observed several problems face by medical practitioners and patients.

After that we developed a proper need statement for each problem with problem, population and outcome.

Then we filtered these problems with our strategic focus and after that we have gathered information about disease state fundamentals, Excising solutions, Stakeholder analysis, Market analysis and stakeholder analysis.

Finally after careful investigation we finalized our prolem which we need to find a solution.

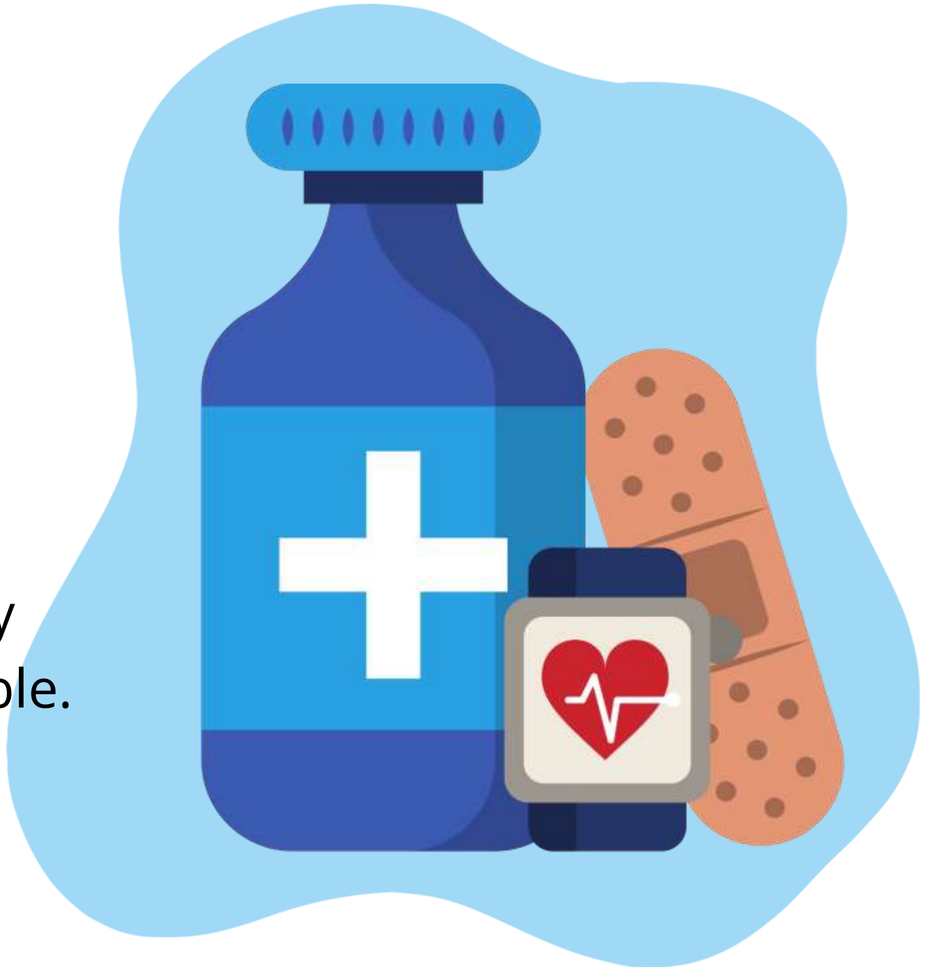
Need Statement :- **“A way to locate veins in all patients for efficient and more accurate needle placement.”**

Concept generation and screening

After finalizing the problem, we are going to address a solution. We brainstormed with our batchmates to get ideas to develop a feasible device.

After all the ideas given by our batchmates, we carefully selected a procedure that we can develop and be feasible.

The concepts were grouped and screened according to different aspects like technical feasibility and appeal to stakeholders.



Strategy Development

We are focusing on 4 strategies.

- IP strategy
- R&D strategy
- Clinical strategy
- Quality management

IP Strategy

- Status of the IP landscape: - **Medium,** **other** patents in the field, but claims are broad enough to potentially be invalidated.

- Required action: - Comprehensive claims analysis detailing the limitations of every relevant claim. Development of careful risk mitigation strategies

IP stretegy

- Finding Innovations and Getting Patents Filed Early
- Analysis of Competitors and Freedom to Operate
- Worldwide Patent Application Methodology and Prospective Licencing.
- Employee agreements and regulatory alignment
- Strategy modifications and routine IP audits

R & D stretegy

Proof of Concept

- Objective: Establish the scientific and technical feasibility of the vein detection concept.
- Key Activities:
  - Conduct a literature review and theoretical research on the vein detection methods we adopt.
  - Develop and conduct simulations to assess feasibility.

Bench model prototype

- Objective: Create the first working prototype demonstrating effective performance in a controlled bench model setting.
- Key Activities:
  - Engineering design and development of the prototype with 12 RGB LEDs and basic SpO2 sensing.
  - Testing and optimization of the method in a simulated environment.

R & D stretegy

Tissue testing prototype

- Objective: Refine the prototype to perform effectively in tissue testing, mimicking physiological conditions.
- Key Activities:
  - Integration of additional sensors in order to enhance the accuracy.
  - Conduct testing on tissue phantoms to simulate varying skin properties.

Since the product is not risky we can directly do the human testing part

Human testing prototype

- Objective: Develop prototypes for initial testing in humans.
- Key Activities:
  - Clinical trial planning and protocol development.
  - Initial trials on a group of volunteers to assess safety and efficacy.
  - Conduct comprehensive clinical trials with diverse participant groups.

R & D stretegy

Pre-production device

- Objective: Develop a device that demonstrates manufacturing feasibility.
- Key Activities:
  - Optimize the manufacturing process for scalability.
  - Develop quality control measures and ensure regulatory compliance.

Production device

- Objective: Create a production-ready device supporting scalable manufacturing.
- Key Activities:
  - Establish manufacturing protocols and scale up production.
  - Ensure consistency, quality, and regulatory compliance in mass production.

R & D stretegy

Regulatory approvals

- Objective: Obtain necessary regulatory approvals for market entry.
- Key Activities:
  - Prepare and submit regulatory documentation. (Under regulatory requirement and FDA approval)
  - Collaborate with regulatory bodies for approvals.

Market entry and adoption

- Objective: Introduce the vein detection device to the market and ensure widespread adoption.
- Key Activities:
  - Develop marketing strategies and educational materials for healthcare professionals.
  - Establish distribution channels and partnerships.

Quality management

QUALITY ASSUARENCE

Create a proactive quality assurance system to ensure regulatory compliance. Establish a thorough quality assurance procedure for early interaction with regulatory bodies.- To find potential hazards and opportunities, do routine quality assurance assessments.

QUALITY CONTROL

Put in place QC processes to keep an eye on changes and guarantee dependability. To keep an eye on the efficiency of quality systems during transitions, conduct QC inspections. To guarantee dependability during the product transition phase, use QC checks.

Device Overview

The Device

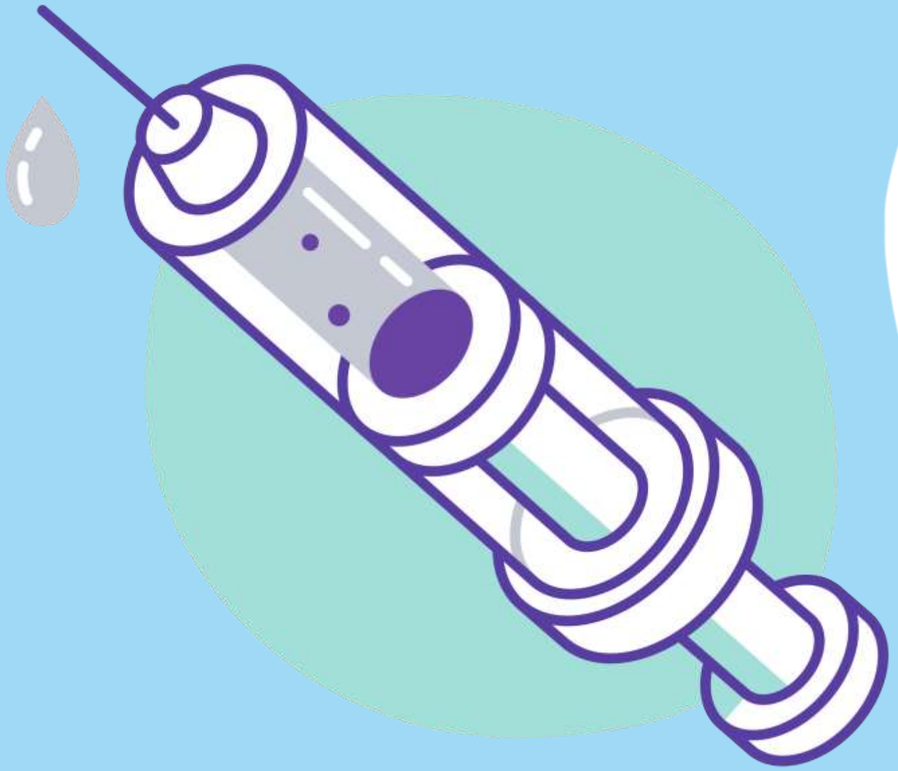
- An innovative device that employs 12 RGB LEDs strategically designed to optimize hemoglobin absorption frequencies for enhanced vein visualization.

- The device integrates a SpO2 sensor, offering real-time measurements of blood oxygen levels and heart rate.

- By combining these features into a single, compact tool, our device aims to streamline medical procedures, reduce patient discomfort, and elevate the overall standard of patient care.

Proposed Device Overview

- It contains a circular array of LED lights with variable intensity and wavelength.
- LEDs are arranged in a manner to facilitate the placement of a needle in the middle.
- It is a simple electronic design that contains rechargeable batteries, a few buttons, and a display.
- The device includes a display to configure the intensity/wavelength variation
- Enclosure of the device will be best designed to be handheld.



DESCRIPTION OF THE PROPOSED VEIN FINDER:

- Technology
- Functionality
- Compact design
- Non - Invasive approach
- Customizable Settings
- Battery powered
- User friendly interface

TARGET USERS

- Healthcare Professionals
- Clinical Settings
- Pediatric Care

DESIGN FEATURES AND PRINCIPLES:

- Optimized LED Configuration
- Integration of SpO2 Sensor
- Ergonomic Form Factor
- Durability and Reliability
- Versatility
- Safety Features

Gaps against the guidance documents in US FDA

Gap Analysis

While specific FDA guidelines on LED lights are absent, we closely aligned our device development with related guidelines. This ensures compliance and adherence to safety standards in our pursuit of a non-invasive vein imaging solution.

- Effective Visual Control of Laser Projections (Laser Notice 47)
- User Instruction for Medical Products (Laser Notice 44)
- Ethical Considerations for Clinical Investigations of Medical Products Involving Children: Draft Guidance for Industry, Sponsors, and IRBs

VISUAL CONTROL REQUIREMENTS:

The guideline emphasizes the necessity for the operator to have effective visual control of all beam paths, especially in outdoor settings. This requirement is specific to the hazards associated with laser emissions and may not directly apply to LED-based vein visualization.

MANUFACTURING AND QUALITY CONTROL:

Limited details on the manufacturing process and quality control measures.

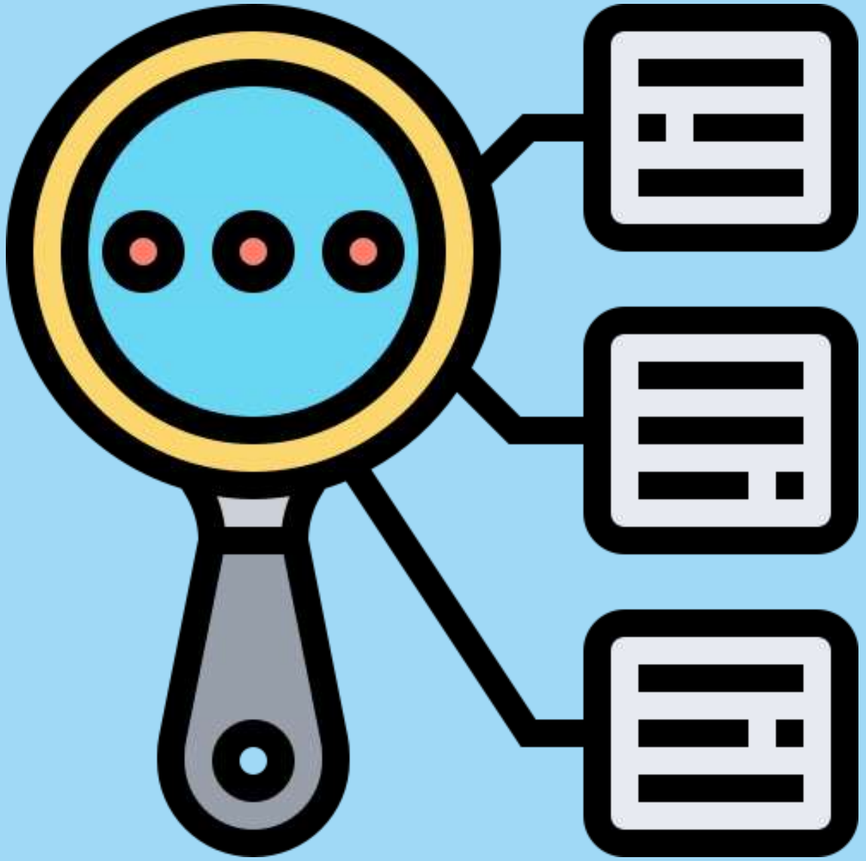
Regulatory Requirements for FDA Approval

Key Regulatory Requirements for FDA Approval

- Device Classification
- 21 CFR Part 820 - Quality System Regulation (QSR)
- 510(k) Premarket Notification
- Regulation of Labeling
- Clinical Evaluation

DEVICE CLASSIFICATION

- Classification: **Class II**
- Risk Level: **Moderate**
- Regulatory Controls: **Specific controls for safety and effectiveness**
- Pathway: **510(k) Premarket Notification**



510(k) Premarket Notification

A main step in the process of 510(k) Premarket Notification is,

Identifying a Predicate Device

AccuVein AV500:

- The AccuVein AV500 is an FDA-cleared vein visualization device designed to assist healthcare professionals in locating veins for various medical procedures.
- Similarities to Our Device:
  - Non-invasive vein visualization.
  - Handheld design for ease of use.
  - Battery-operated for portability.
  - Intended for aiding in vein location during medical procedures.
  - Use of contrasting visual cues for vein identification

Regulation of Labelling

- **Device Description:**
  - Clearly outlines the vein identifier's design, emphasizing the non-invasive use of adjustable LED lights for vein illumination.
- **Intended Use:**
  - Defines the device's purpose, focusing on assisting healthcare practitioners in locating veins for medical procedures using adjustable LED light color and intensity.
- **Directions for Safe Use:**
  - Provides comprehensive usage instructions, including step-by-step guidance on operating the device and adjusting LED light color and intensity.
- **Adjustable Features:**
  - Specifies adjustable features as LED light color and intensity, offering clear instructions on modifying these settings for optimal vein visualization.

Improved Device

Overview of Implimented Improvements

The ability to vary the intensity and wavelength of the red light allowing to visualize veins adjusting to all kinds of skin complexions, haemoglobin concentrations and other vascular conditions. This flexibility also allows to locate veins in patients with different body fat levels.

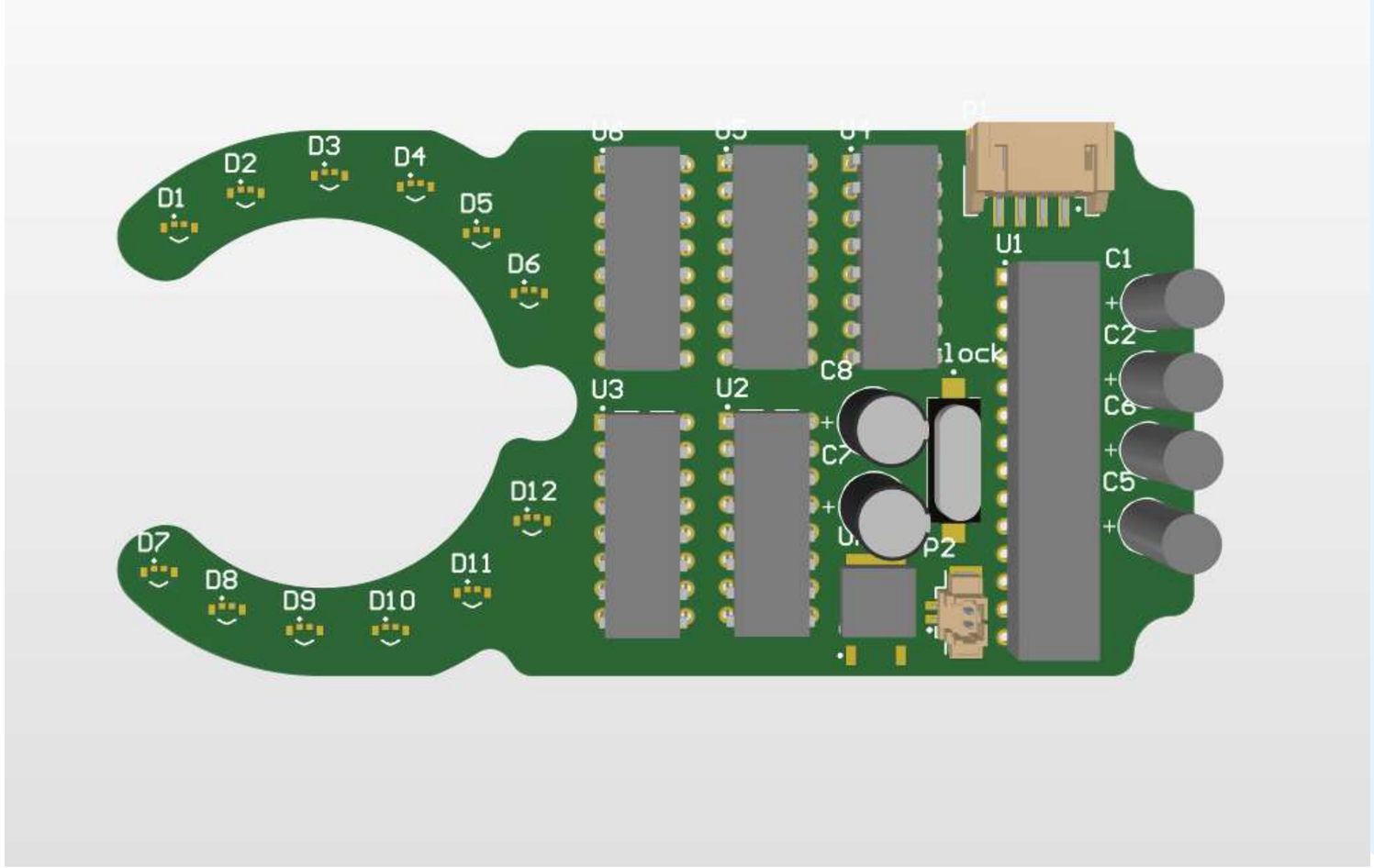
The additional implementation of a SpO2 measurement functionality provides convenience for clinical personnel to take blood oxygen level measurement.

The presence of a on-device rechargeable battery allows seamless continuous operation with each charge cycle. Additionally the recharging module allows the device to operate on cable power while being connected to the charger.

The OLED display ensures simplified user-experience for functionalities such as increasing the intensity of light, changing the color/wavelength of light, viewing charge level and charging status.

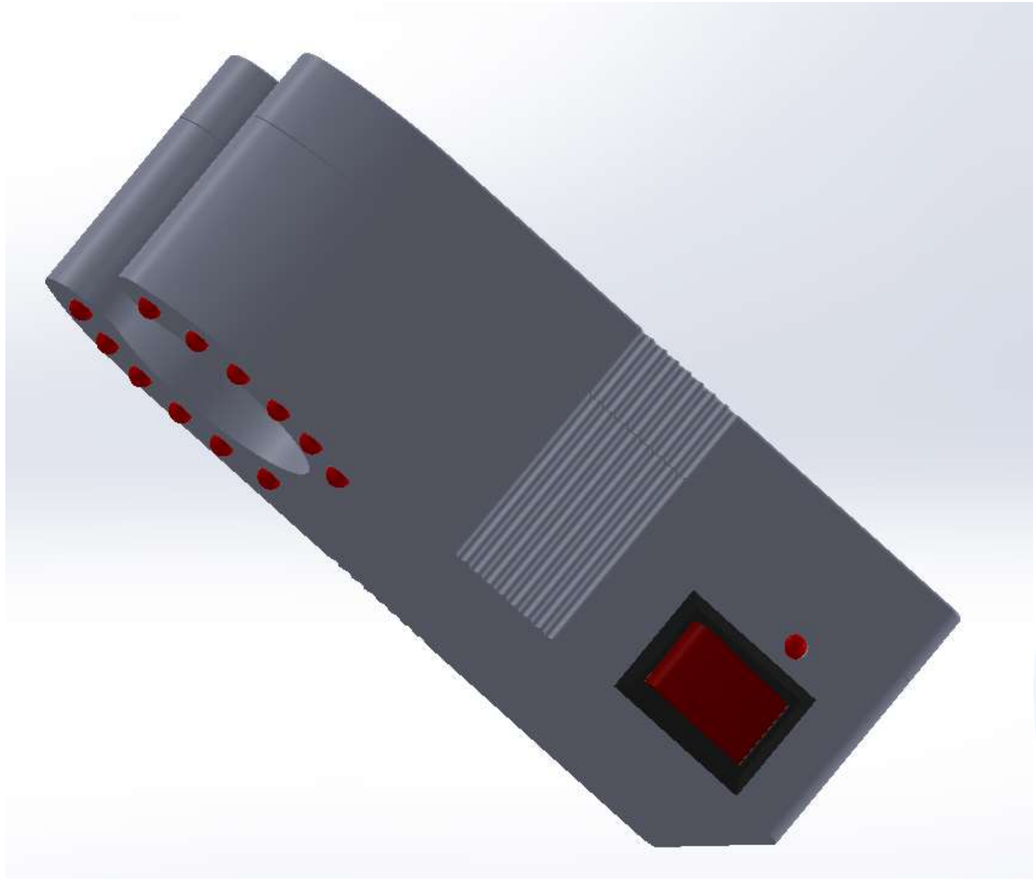
The PCB

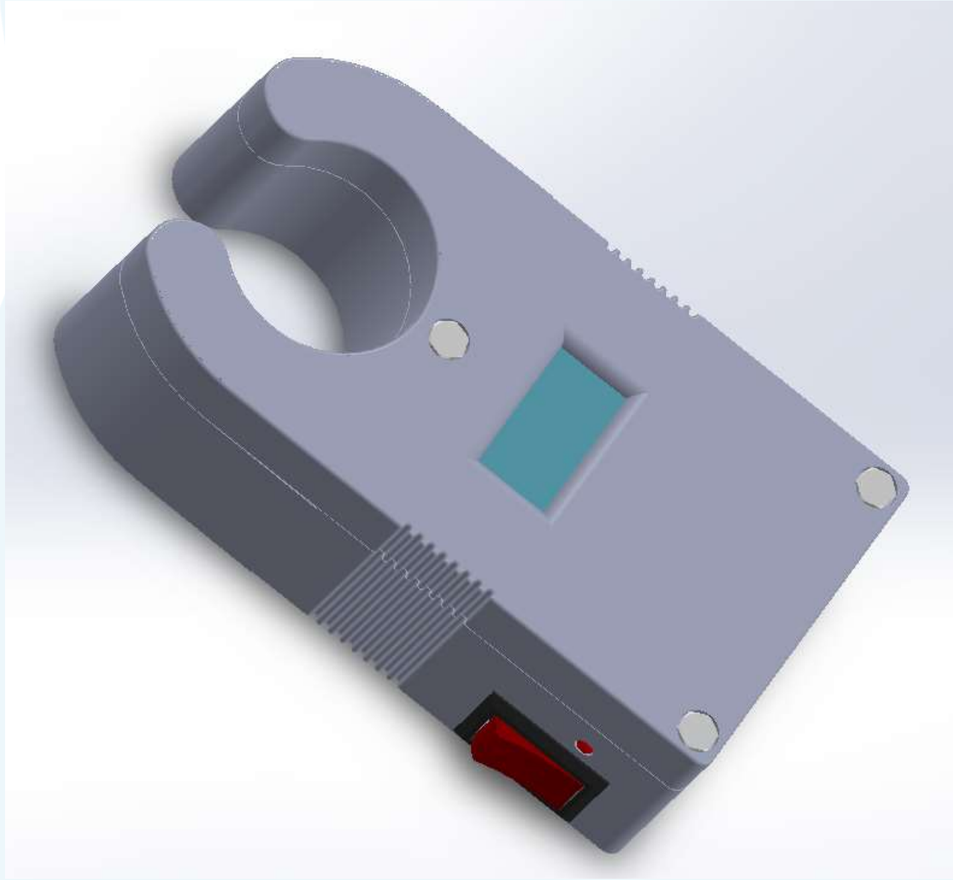
PCB design was done using Altium Designer.



The Enclosure

Enclosure was designed with Solidworks





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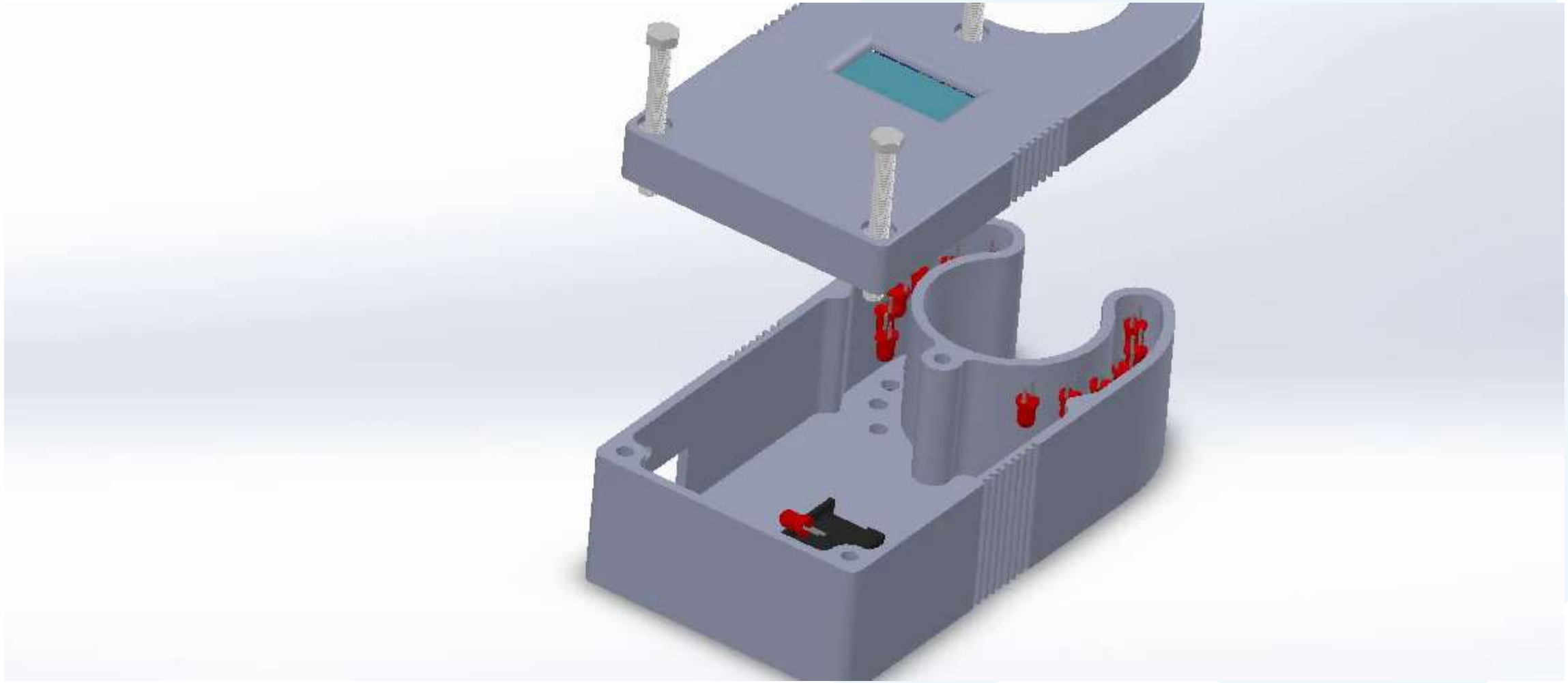


Future Improvements

Advanced Imaging Technologies:

Explore integration with advanced imaging technologies like infrared imaging or multispectral imaging for enhanced vein visualization.

User-Friendly Interfaces:

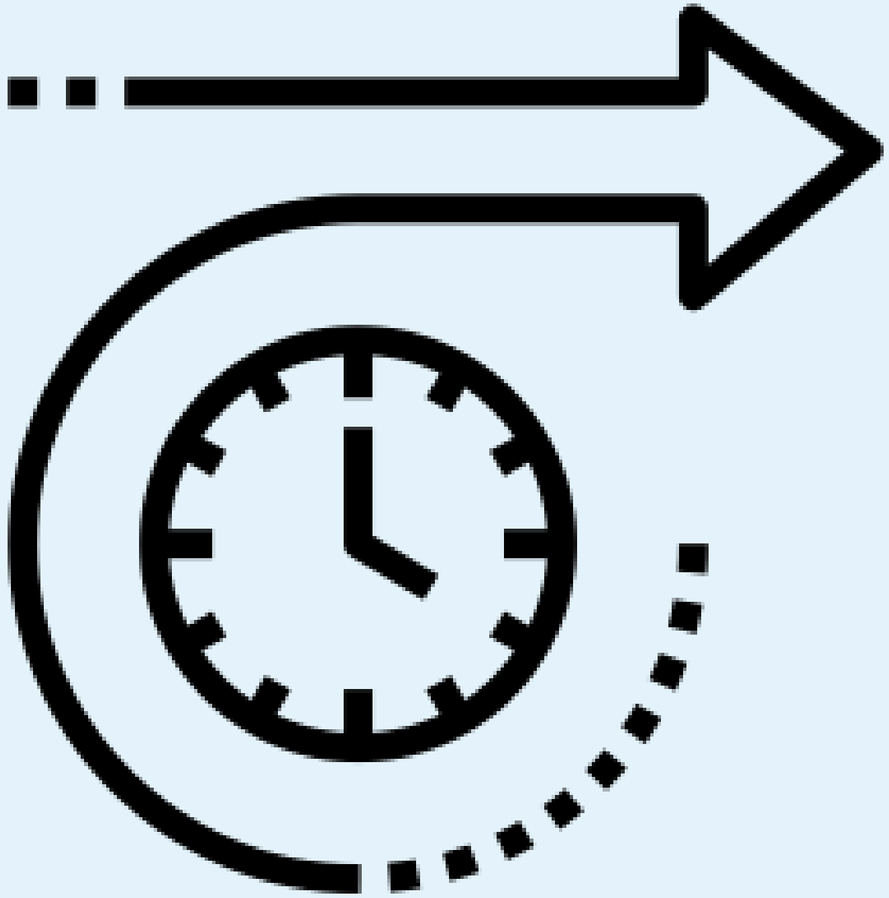
Invest in user-friendly interfaces with touchscreens or gesture controls, enhancing the overall user experience for healthcare practitioners.

Compact and Portable Design:

Focus on developing more compact and portable designs for increased mobility and flexibility in various healthcare settings.

Simplified hardware

A design to implement the same or extended functionality without using hardware such as shift registers. This is a challenge with the limited amounts of MCU pins



Thank you!

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