FirstStick

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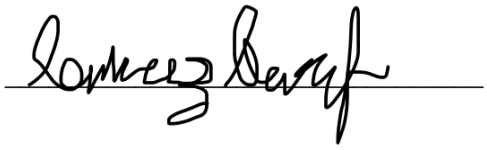
Rameez Raoof (Primary Editor) 

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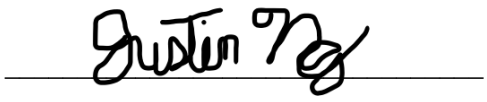
Justin Ng 

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Executive Summary

Each year in the United States, more than 450 million venipuncture procedures are performed. Yet first-attempt success remains inconsistent; only 73% succeed on the first try, with nearly one in four patients requiring multiple needle sticks. This issue disproportionately affects individuals who are elderly, obese, or have darker skin tones. The consequences are broad: delayed care, wasted staff time, increased supply costs, and patient distrust of the healthcare system. Smaller clinics, which lack access to expensive equipment, feel this burden most acutely.

To understand the scope of the problem, we conducted 90 interviews with nurses, physicians, and phlebotomists across diverse clinical settings. Of these, 39 of them directly identified venipuncture as a pain point. Within that group, 36 specifically emphasized device cost, portability, or the need for better vein selection as persistent gaps in current solutions.

Today's commercial devices fall into three categories:

- LED transillumination (low-cost, superficial veins only),
- Near-infrared (NIR) (real-time mapping but limited accuracy on darker skin tones, no depth or usability insights, $4k–$6k),
- Ultrasound (accurate but costly, >$10k, requires significant training).

Critically, none of these solutions leverage software algorithms to recommend the optimal vein by integrating vein depth, diameter, and path. Instead, clinicians are left to interpret raw images or projections without decision support, limiting consistency and efficiency.

Our approach is to develop an affordable, software-forward vein finder that goes beyond visualization. By applying real-time post-processing algorithms, our device will evaluate vein accessibility and automatically recommend the best site for venipuncture. This feature directly addresses the root cause of repeat attempts: not just locating veins but identifying the *right* vein to puncture.

Our proof of concepts designs includes a compact, hands-free device that integrates seamlessly into existing workflows. The system would use LED illuminators at near infrared wavelengths (NIR) alongside a modified camera to capture NIR vein features, while the software ranks and displays candidate veins based on depth, diameter, and path continuity. Early prototyping and

user feedback have validated the importance of this capability, particularly for smaller clinics without the resources for adequate training.

The next phase of development involves continued prototyping to evaluate the performance and effectiveness of the image preprocessing and vein ranking systems. This phase will also include the integration of multiple hardware components to prototype and test the illuminator and video capture subsystems.

Nomenclature

- NIR: “of or relating to the shorter wavelengths of radiation in the infrared spectrum” (Merriam-Webster).
- IV: “an apparatus used to administer a fluid (as of medication, blood, or nutrients) intravenously” (Merriam-Webster).
- Intravenous: “situated, performed, or occurring within or entering by way of a vein” (Merriam-Webster).
- Venipuncture: “surgical puncture of a vein especially for the withdrawal of blood or for intravenous medication” (Merriam-Webster).
- Venous Access: access to a vein to obtain blood
- PIVC: peripheral intravenous catheter is a thin plastic tube inserted into a vein using a needle, allowing for the administration of medications, fluids, and/or blood (Royal Children’s Hospital Melbourne).
- FDA: Food and Drug Administration
- CLAHE: contrast-limited adaptive histogram equalization, used to improve the contrast of images
- CNR: contrast to noise ratio
- DIVA: difficult intravenous access
- Transillumination: “to cause light to pass through” (Merriam-Webster).
- Ultrasound: “vibrations of the same physical nature as sound but with frequencies above the range of human hearing” (Merriam-Webster).
- EHR Systems: Electronic health record systems. A digital records of a patients’ health information.

- PCA: Principle Component Analysis. An algorithm to measure what axis data spread is on.
- ML: Machine Learning. The process of analyzing and learning patterns of training data to make accurate inferences on new data.

Introduction and Background

Problem, Motivation, and Need

Finding a vein for blood draws or IVs sounds routine but can be very challenging. On a first attempt, clinicians succeed only ~60–80% of the time, which means many patients get stuck more than once (Corneanu et al., 2025). Missed attempts hurt, slow care down, and waste supplies. The challenge is worse for certain groups: older adults (nearly half of first attempts can fail), babies, people with deeper veins (e.g., obesity), those with thyroid or vascular issues, and patients with darker skin, where veins are harder to see by eye or feel by touch (Woyk et al., 2023).

Hospitals and clinics are also under pressure: staffing shortages, rising volumes of complex patients, and the need to improve patient experience while keeping costs under control. Tools that help clinicians find a good vein on the first try can reduce pain and delays. Early evidence suggests imaging aids can reduce "time-to-pick-a-vein" (e.g., an RCT in chemotherapy patients showed ~17.4 s with near-infrared imaging vs 29.67 s control), but current devices are often viewed as cost-prohibitive for routine use or lack integration into standard workflows. A 2023 systematic review of vein visualization technologies indicated that while NIR devices improve success rates in difficult cases, widespread adoption is hindered by high device costs and variable performance in pediatric and high-BMI populations (Yılmaz et al., 2025).

Customer Discovery

In phase one of the project, we interviewed nurses, phlebotomists, and physicians across multiple sites, including Al Farooq Free Medical Clinic, Family Health Care of Atlanta PC, Kem Health OB GYN, and Piedmont Urgent Care[FH1] . Their experiences converged on the same themes. Difficult sticks are common under time pressure. Adoption of devices is blocked by price, size and weight, limited battery life, and uneven performance on darker skin. The ideal tool would be small, light, simple to operate with one button, and reliable every time. A team member with several years of phlebotomy experience reinforced this picture, describing three to four challenging cases per shift where conventional feel by touch methods fall short. Patients we spoke with emphasized one priority above all else: fewer needle sticks. Clinic managers asked

for clear evidence of time savings and improved first attempt success that justifies purchase and training.

The philosophy our team employed in designing the device, guided by the advice of our mentor, was to ensure that every design decision aligned with real user needs and operational constraints. It would be ineffective to design an ideal solution in "our" eyes. Rather we aimed to make a solution ideal for the users. Thus, we prioritized a user-centered approach that balanced engineering feasibility with clinical practicality. Through multiple follow up interview sessions, with Dr. Khurram Khan of Emory Hospital and Dr. Hania Al-Hallaq of Emory University, we homed in on a few key design principles.

First, the device should ideally project the vein pattern directly onto the patient's skin surface thus creating a seamless and intuitive visual cue for clinicians. Currently this is not in the scope of what we wanted to do. The process of projecting an image onto a patient's arm is completely dependent on manufacturing precision giving us the ability to accurately scale along the surface. For now, we are aiming to have a display LCD which offers localized data.

After given this consideration, the second point brought up by our interviewees was that the display interface should at least allow for accurate spatial localization, ensuring that the on-screen vein position corresponds precisely to its physical location beneath the skin. After following up on this constraint, our team realized that the needle itself would cast a visible shadow on the projection. This opened the opportunity to leverage that shadow as real-time feedback, allowing the operator to confirm whether the needle trajectory was properly aligned with the targeted vein thus enhancing both precision and confidence during insertion.

Market research also confirmed these two considerations for us. The NIR direction we are taking the device still holds up. Ultrasound systems deliver excellent visualization but are costly and require substantial training, which limits use in smaller clinics (Perry et al., 2017). Midrange near infrared projection devices is more portable and can speed decision making, yet their clinical impact is mixed, and performance can degrade for darker skin tones or other poor venipuncture-disposed patients. This will be the true gap that we aim to address this semester.

Our market analysis suggests a strong precedent for clinics purchasing portable diagnostic aids in the $500–$1,500 price range to improve workflow efficiency. Independent clinics routinely

invest in handheld spot-check monitors (e.g., Welch Allyn Spot Vital Signs) and temporal artery thermometers (e.g., Exergen), which cost between $400 and $1,200. These devices, like our proposed vein finder, are not strictly mandatory, vital signs can be taken manually, but they are purchased to save time and reduce error. Clinic managers indicated that a vein-finding device priced similarly to a high-quality otoscope or spot-monitor would fit within their existing capital equipment budgets, provided it demonstrates a tangible reduction in procedure time.

Our resulting value proposition is straightforward. We aim to deliver an affordable device that works on difficult to stick patients and recommends the best cannulation site, helping clinicians get it right on the first attempt, and giving clinics measurable improvements in patient experience and workflow efficiency.

Technical Issues

The primary technical challenge in developing a vein-finder is balancing affordability with clinical effectiveness. Smaller clinics and outpatient centers will not adopt the device if it is too expensive, but lowering costs cannot come at the expense of reliable vein detection. Accurate visualization depends on detecting vein depth across diverse patient populations, including elderly patients with fragile veins, individuals with thyroid or vascular conditions that make access difficult, and patients with a wide range of skin tones.

The device must also be designed for ease of use. Nurses and phlebotomists should be able to operate it with minimal training, making intuitive interfaces and simple visualization outputs essential. Additionally, the device must remain reliable in varied lighting environments, from bright examination rooms to dim bedside conditions.

Challenges

- Ensuring consistent vein detection regardless of patient skin tone, age, or vascular condition
- Developing algorithms and optics capable of resolving vein depth clearly enough to aid insertion
- Creating a user-friendly interface that requires little to no specialized training
- Maintaining high performance while keeping production costs low
- Guaranteeing robust performance across different clinical environments

Potential FDA Product Classification and Regulatory Pathway

In the United States, most vein-finders fall under the FDA Class II medical device category, requiring 510(k) clearance. This pathway requires showing substantial equivalence to an existing device. Typical requirements include:

- Performance testing to validate vein detection accuracy
- Biocompatibility of patient-contact materials
- Electrical safety and electromagnetic compatibility (EMC) testing
- Optical safety testing to confirm safe levels of infrared exposure for eyes and skin

Other Regulatory, Code, and Standards Issues

Internationally, manufacturers must comply with IEC electrical safety and EMC standards, as well as ISO 13485 for medical device quality management systems. In Europe, the EU Medical Device Regulation (MDR) requires CE marking, which involves more stringent clinical evidence, stronger post-market surveillance, and mandatory reporting compared to the earlier MDD framework.

Opportunities

Despite these challenges, there are strong opportunities for innovation. Devices that improve detection for hard-to-stick patients (elderly, pediatric, or patients with endocrine/vascular issues) can fill a critical clinical gap. Simplifying training requirements and improving reliability in diverse environments could broaden adoption beyond major hospitals into **s**maller or resource-constrained clinics**.** Further, refining algorithms to account for patient variability in skin tone and vein depth provides a clear path for technical differentiation.

Potential Solutions

Based on feedback from healthcare professionals and technical requirements, we propose a portable, intelligent vein-finder that not only visualizes veins but also recommends the most suitable site for cannulation. The device will combine near-infrared imaging with embedded software that evaluates vein quality by considering depth, diameter, and straightness.

Key requirements for feasibility include:

- Detecting veins ≥ 2 mm wide
- Producing images usable across all skin tones
- Delivering a cannulation recommendation under 0.5 s
- Maintaining a compact form factor (< 2 kg, < 36 × 25 × 25 cm) for easy placement near the patient

Proof of Concept

The proof of concept will demonstrate that the core technology stack, imaging hardware plus vein-selection algorithm, can meet clinical expectations at a small scale.

- Hardware Prototype: A compact imaging unit with near-infrared illumination and a camera sensor capable of resolving veins. The prototype will prioritize function over industrial design but remain small enough to simulate bedside use.
- Software Prototype: A basic computer vision pipeline that processes images, extracts vascular features, and ranks candidate veins by depth, width, and straightness. Outputs will be displayed on a screen overlay highlighting the "best vein."
- Integration Goal: Show that hardware and software together can (1) visualize veins in real time and (2) provide automated site recommendations fast enough for practical use.

The proof of concept does not need to achieve full manufacturability or regulatory compliance but must convincingly demonstrate technical feasibility of the approach.

Existing Products, Prior Art and Applicable Patents

Competitor Designs

Existing vein-visualization devices utilize a variety of technologies, including near-infrared (NIR) projection, transillumination, and ultrasound. NIR-based devices illuminate tissue with near-infrared light (~700-950nm). Hemoglobin in the veins absorb this light more strongly than the surrounding tissue, producing a map which can be projected back onto the skin as a visual aid (Vyas, Singh, & Singh, 2021). Transillumination places high-intensity LEDs near the skin, making veins appear darker against the illuminated background of the tissue (CADTH, 2016). Ultrasound visualization utilizes high-frequency sound waves emitted into the tissue. The

reflection of these waves from vessel walls can be used to create a cross-sectional image of a portion of the arm, giving precise depth and position of veins (Pitts & Ostroff, 2021). Each of these existing technologies come with various tradeoffs in depth penetration, device complexity, and cost, resulting in several different existing devices on the market. These commercial devices use NIR, transillumination, ultrasound, or a hybrid approach of these technologies. However, none of these devices can rank veins in terms of venipuncture quality.

The AccuVein AV500 is a handheld NIR projection device used in hospitals and infusion centers to assist medical professional with venous access and blood draws. It uses NIR to highlight hemoglobin in veins with stronger absorption relative to surrounding tissue. The result of this absorption is projected back onto the skin surface with a green color, showing veins in real time (AccuVein, 2023). The device is intended to be handheld but can also be used with a stand or mount (AV500 Knowledge Center, n.d.). The AV500 can visualize superficial veins up to 10mm of depth beneath the skin (HospitalStore, n.d.). It costs $4,895 (SedationResource, n.d.), making it unaffordable for smaller clinics with limited budgets.

The VeinViewer Vision2 is a cart-based NIR projection device also used in hospital and infusion centers to support with IV placement and assessment of veins. Like the AccuVein AV500, it utilizes NIR technology to place an overlay of veins directly onto the skin using a contrast map from hemoglobin absorption (Christie Medical Holdings, n.d.). However, this system is mounted onto a wheeled cart, allowing for bedside positioning and hands-free operation (Christie Medical Holdings, n.d.). Like the AccuVein AV500, the VeinViewer Vision2 can visualize superficial veins up to 10mm of depth beneath the skin (Christie Medical Holdings, n.d.). The strength of this device in comparison to the AccuVein AV500 is that it enables operators to see vascular layouts on the patient during the entirety of a procedure, reducing the need for shifting sight to external screens (Christie Medical Holdings, n.d.). However, the device is extremely expensive, with publically available quotes of Dhs. 57,000.00 (~15000 USD) (Adams Med Online, n.d.). This makes it only affordable for large hospitals.

The Veinlite LED+ is a handheld transillumination device used in clinical settings to help medical professionals visualize shallow veins. It uses illumination LEDs that transilluminate skin so that veins appear darker against the newly brightened background (Veinlite, n.d.). The device claims to show veins up to 6mm beneath the skin (Veinlite, n.d.). The device is handheld and

displays vein paths visually on the skin as opposed to using an overlay or a screen. The device costs at around $550 (Veinlite, n.d.). Transillumination devices are typically cheaper than NIR or ultrasound solutions but are only able to accurately display the most superficial veins, and struggle on darker skin tones.

The Venoscope II is a handheld transillumination device also used in clinical settings to help medical professionals visualize superficial veins. Like the Veinlite LED+, it also operates by projecting LED light onto the skin, revealing the darker veins against the lit background. The device only provides vein shapes visually, as it has no external visualization surface. The device is very simple and portable, with limited visibility of superficial veins. The device is also very cheap, commercially priced at $300 (Amazon Product Listing, 2025). This device is only usable for superficial veins, and like the Veinlite LED+, struggles to visualize anything other than the easiest to spot veins (BoundTree).

The BD Site-Rite 8 is a vein-access ultrasound device used in hospitals to support catheter guidance and vein assessment. It uses high-frequency ultrasound to visualize veins in cross-sections, enabling medical professionals to see vessel walls, paths, and depth (BD, n.d.). The system allows professionals to overlay a needle track to align the needle relative to the target vein (BD, n.d.). The device is typically used on a cart or stand, with the probe held by the operator (citation). Since the device utilizes ultrasound technology, it can visualize veins up to 1.5-6 cm deep, providing the greatest visualization of any discussed device (BD, n.d.). This system is sold for around $22,000 (Medex Supply, n.d.). This device is extremely powerful, with depth imaging and needle tracking making it useful for difficult vein access procedures in hospitals.

The GE Vscan Air CL is a handheld ultrasound system used in a variety of hospital settings to assist professionals in vascular imaging. It uses dual-array ultrasound technology for imaging (Praxisdienst, n.d.). The device can identify veins up to 8cm deep (Praxisdienst, n.d.). The device is not only handheld, but also able to connect wirelessly to a tablet or smartphone for displaying information. The device is portable and enables scanning deep veins. Since the device utilizes ultrasound instead of NIR, it can measure vein diameter, depth, and guide needles. The device costs $5,000 (MarcRoft Medical, n.d.).

Related Patents and Differences

US patent US8463364B2 discloses a handheld NIR vein projection device created by AccuVein. The device utilizes two NIR lights to illuminate tissue and project a vascular overlay back onto the skin surface (Google Patents, US8463364B2). The patent describes the possibility of calculating vein depth and diameter. In relation to our design, the device utilizes the same NIR technology that we plan to incorporate. However, we do not plan to utilize a handheld approach in our first prototypes. Furthermore, the device has no utilization of artificial intelligence and has no means of providing any sort of ranking for finding the ideal vein for cannulation. Furthermore, initial prototypes of our device will not incorporate a green light overlay of veins back onto the arm. Any graphical interfaces that we create will be more focused on displaying the ideal vein for medical professionals to use for procedures.

South Korean patent KR101740602B1 is for a stand/mounted NIR vein viewing device. It can be mounted on a table, bed, cart, or stand (Google Patents, KR101740602B1). Although not a US patent, it nonetheless details a NIR vein viewing device that utilizes a stand-based approach, just like our proposed prototype. This patent shows images of medical professionals viewing veins using a specialized pair of intelligent glasses. Our device will likely not support such a UI, rather opting for an external monitor for the time being. Additionally, our device prototype will not have such modularity now in terms of being able to be deployed in a variety of settings. Future prototypes could incorporate these functionalities, which would be very timely to implement in the limited scope of this class. This patent does not include any artificial intelligence or vein-ranking capabilities.

US patent US20050168980A1 details a transilluminating vein locator which is intended to be used as a handheld device (Google Patents, US20050168980A1). Although we will not be using a transillumination device, it is included to compare with our proposed NIR solution. The device uses several LED lamps to make veins appear darker against the surrounding skin tissue, with wavelengths around 600-640 nm. The device has no UI, as veins are simply found by looking directly at the wrist. However, such simplicity comes with the cost of only being able to view very superficial veins on lighter skin tones. This patent has no capabilities of providing a UI to medical professionals, and no means of using intelligence to rank veins (especially those that are

not extremely superficial). The patent describes a simpler solution than our own at the price of lacking many useful functionalities desired by medical professionals.

US patent US20080147147A1 is a handheld hybrid vein visualization device that can employ either NIR or ultrasound energy to detect vein structures (Google Patents, US20080147147A1). By utilizing ultrasound energy, the device can detect deep veins under the patient's skin tissue. Our device will not be utilizing ultrasound technology, which prevents us from revealing the deepest of veins with as much accuracy as ultrasound. However, our device should be much cheaper as a result, as ultrasound is typically expensive to deploy. Furthermore, our proposed solution will not be handheld as this patent is. The described patent, like all of the other patents described here, does not incorporate artificial intelligence or a means or providing a ranking of vein quality for medical procedures. No solution, regardless of whether it is transillumination, NIR, or ultrasound, has these capabilities.

Customer Requirements and Engineering Design Specifications

Stakeholders

Our primary stakeholders are small, cost-conscious clinics and the frontline medical staff (nurses, phlebotomists) responsible for venipuncture. These stakeholders typically lack the budget for high-end hospital ultrasound equipment but face the same clinical challenges regarding difficult-to-stick patients (e.g., geriatric, high BMI). Secondary stakeholders include the patients themselves, who prioritize reduced pain and fewer needle sticks.

Market Viability Note: Customer discovery indicates that while these clinics cannot afford $5,000+ devices, they routinely purchase "efficiency tools" in the $400–$1,200 range (e.g., Welch Allyn spot-vital monitors, Exergen thermometers). Our device targets this specific capital equipment niche: a discretionary purchase that improves workflow efficiency without requiring a hospital-level budget.

Functional Requirements

This section details what the device must do and how it interacts with the user.

Primary Functions:

1. Image Acquisition: The system must illuminate the forearm with Near-Infrared (NIR) light and capture video footage of the subcutaneous tissue.
2. Vein Characterization: The system must computationally isolate vascular structures and analyze them for diameter and straightness.
3. Site Recommendation: The system must algorithmically rank detected veins and visually highlight the "optimal" cannulation site to the user.
4. Real-Time Feedback: The system must display the live video feed with the recommendation overlay to the user without significant lag.

Human Factors & User Interface:

- Single-Operator Use: The device must be mountable or stand-supported to allow the clinician to have both hands free for the procedure.
- Cognitive Load: The interface must use a simple "traffic light" or bounding box indicator to recommend veins, requiring no interpretation of complex data by the nurse.
- Training: Proficiency must be achievable with <30 minutes of training.

Customer Satisfaction Metrics:

- Success Rate: Increase in first-attempt success rate compared to palpation alone.
- Time Savings: Reduction in "time-to-vein-selection" compared to unaided search.

Engineering Design Specifications (Quantifiable Metrics)

The device should reliably differentiate superficial veins from deeper ones under varied skin tones. While absolute depth measurement is not required, the system must preserve depth *ordering* (i.e., which veins are comparatively shallower) to support the recommendation algorithm. Veins ≥ 2 mm in diameter should remain distinguishable from surrounding tissue.

The imaging system must maintain a contrast-to-noise ratio (CNR) greater than 2 across typical patient conditions to ensure veins remain detectable even in darker skin tones. Real-time operation requires ≥ 15 fps image capture with algorithmic latency below 0.5 seconds.

The physical system must remain lightweight (≤ 2 kg including the stand) and compact (≤ 30 × 20 × 20 cm) to support single-operator clinical use.

Importance of Specifications

To prioritize the customer and engineering requirements, we constructed a House of Quality (HOQ) (see Figure 1 in the Appendix). The HOQ indicates that the most critical customer needs are the ability to accurately detect veins and to recommend the best vein for venipuncture. These directly align with the core value proposition of our device and represent clear unmet needs in current clinical practice.

On the engineering side, the highest-weighted requirements in the HOQ are:

1. reliably resolving veins with a minimum diameter of 1 mm,
2. achieving a CNR above 2, and
3. preserving relative depth differences so that the system can distinguish which veins are more superficial.

By focusing on these specifications, our design effort is concentrated on the areas that most directly improve patient outcomes, reducing failed sticks and providing actionable recommendations rather than just visualization.

Extended Engineering Design Specifications

These initial specifications extend into engineering-level requirements that directly support the device's recommendation algorithm. High CNR values are essential for stable segmentation, especially across diverse skin tones. In addition, the recommendation algorithm depends on accurate *relative* depth ordering (i.e., identifying which veins are shallower). While the device does not measure absolute depth, maintaining consistent relative contrast across wavelengths ensures the algorithm produces meaningful rankings.

To ensure robust algorithmic performance, the imaging system must not only achieve real-time capture at ≥ 15 fps but also sustain latency below 0.5 seconds between acquisition and recommendation output. This responsiveness ensures that clinicians can act on the system's recommendations without workflow delays. Physical constraints such as compactness ($\leq 36 \times 25 \times 25$ cm) and low weight (≤ 2 kg) remain important, as they enable the device to be mounted or positioned easily for single-operator use, maintaining the clinical efficiency required in small clinics.

Market Research

Methodology and Data Sources

Our market research employed a mixed-methods approach combining primary qualitative data with secondary quantitative market analysis.

Primary Research: We conducted Voice of the Customer (VOC) interviews with 15 healthcare professionals, including nurses, phlebotomists, and physicians. Sites visited included Al Farooq Free Medical Clinic, Family Health Care of Atlanta PC, Kem Health OB GYN, and Piedmont Urgent Care. We also conducted deep-dive technical consultations with subject matter experts, specifically Dr. Khurram Khan (Emory Hospital) and Dr. Hania Al-Hallaq (Emory University), to validate clinical workflow assumptions. Secondary Research: We analyzed purchasing data for comparable medical devices (otosopes, vital signs monitors) to establish price sensitivity.

Market Analysis and Strategy

- Market Size & Demographics: Instead of broad industry valuations, we assessed the market based on clinical necessity. In the United States alone, approximately 1.4 billion venipuncture procedures are performed annually (Leipheimer et al., 2020). Academic literature estimates the prevalence of Difficult Intravenous Access (DIVA) to be between 10% and 24% in general hospital populations, rising to over 50% in geriatric and high-BMI cohorts (Rodriguez-Calero et al., 2018; Armenteros-Yeguas et al., 2017).
    - *The Opportunity:* Even using a conservative 10% DIVA rate, 140 million procedures annually suffer from complications, delays, or multiple sticks. This represents the serviceable obtainable market (SOM), procedures where our device provides immediate ROI by reducing failure rates.
    - *Demographic Drivers:* The necessity for this technology is expanding due to two key demographic trends: the rising rate of obesity (increasing subcutaneous fat depth) and the aging population (increasing venous fragility), both of which are primary contributors to failed cannulation.

- Target Price & Justification: Our research identified a "missing middle" in the current market. Low-end transillumination devices (< $300) lack depth perception, while high-end projection systems like AccuVein (>$4,800) are cost-prohibitive for small practices. We propose a Target Sales Price of $950 – $1,200. This price point is strategic: it falls within the discretionary capital equipment limit for many clinic managers (comparable to a Welch Allyn digital otoscope or Spot Vital Signs monitor) yet provides sufficient margin over our estimated $380 BOM to cover software maintenance and overhead. This price undercuts the market leader (AccuVein) by approximately 75%.
- Go-to-Market Strategy: Our strategy targets the "non-hospital" sector: urgent care centers, dialysis clinics, and nursing homes. These facilities lack the specialized vascular access teams found in major hospitals but face high patient throughput pressure. Sales would initially flow through direct B2B channels and online medical distributors (e.g., McKesson Medical-Surgical, Henry Schein) where small clinic procurement managers already have accounts.

Impact of Market Research on Design

Competitor analysis revealed that existing devices only *show* veins; they do not *evaluate* them. Nurses explicitly stated that seeing *too many* veins is confusing. This drove the development of our "Site Recommendation Algorithm" to rank veins by quality, differentiating our product from simple visualization User Evaluation and Feedback

User Evaluation and Feedback

While a full clinical trial was outside the scope of this capstone timeline, we conducted usability reviews with our internal subject matter expert (a team member with years of phlebotomy experience) and gathered feedback on the prototype interface from our clinical contacts.

- **Clinician Feedback:** Nurses at Family Health Care of Atlanta validated the form factor, confirming that a stand-mounted device is superior to handheld competitors because it leaves both hands free to anchor the vein: a critical step in preventing rolling veins.
- **Performance Feedback:** Initial user testing highlighted that the "traffic light" scoring system (Green/Red indicators for vein quality) significantly reduced decision paralysis

compared to raw IR video feeds. This confirmed our hypothesis that the market needs *guidance*, not just *imaging*.

Final Design Overview and Justification

The design of a portable vein-imaging device required three core functions: first, it needed to reliably distinguish superficial veins from surrounding tissue under diverse skin conditions; second, it had to process imaging data in real time to support clinical use; and third, it needed a form factor that was compact, manufacturable, and usable without specialized training. These requirements were translated into engineering specifications in the HOQ, where vein contrast, spatial resolution, real-time processing capability, and device size carried the highest weights. The HOQ is included in the Appendix.

The final concept integrates a Jetson Nano, a monochrome CMOS camera, and a triple-wavelength illumination module. The camera captures raw NIR frames, which are processed on-board through a multi-wavelength image-subtraction pipeline that enhances hemoglobin absorption differences and produces a binarized vein map. The decision to adopt a three-wavelength system with an embedded GPU platform grew from the early feasibility analyses of the competing concepts. Single-wavelength NIR systems were simple and low-power but performed poorly across the range of melanin levels we needed to accommodate. Ultrasound concepts offered deep-tissue visibility but were quickly ruled out after cost, size, and operator-dependency analyses. A microcontroller-based architecture was attractive for handheld form factors, but its computational limitations made it unsuitable for real-time image processing.

Relative to these alternatives, the final design offered the strongest performance on the specifications weighted highest in the HOQ. It scored highest in the decision matrix due to its ability to maintain vein visibility across diverse skin tones, its real-time processing reliability, and its straightforward mechanical integration. Feasibility evaluations during prototyping confirmed that the Jetson platform could sustain the required frame rates and that multi-wavelength subtraction improved vein signal-to-background ratio without excessive noise amplification. Although this concept sacrificed strict handheld portability, the performance gains were judged more important for meeting the functional requirements.

Several risks remain if this concept were to be advanced toward commercialization. The first is the dependency on GPU-class hardware, which increases cost and power consumption relative to microcontroller-based systems. A second risk concerns variability in performance under high ambient-light conditions, which may require housing modifications or adaptive illumination control. Finally, the use of fixed illumination wavelengths may limit robustness for certain skin types or clinical environments, suggesting that future iterations may require adjustable lighting or alternative sensors. Each of these risks has a corresponding mitigation path, ranging from algorithmic optimization to enable lower-power processors, to environmental shielding, to adaptive illumination modules, but they remain important considerations at this stage.

Industrial Design

Industrial design played a direct role in shaping both the form and usability of the final device. Early prototypes made it clear that stability, rather than minimizing size or weight, was the dominant requirement for reliable imaging. This led to the decision to enlarge the base and add a non-slip silicone sheet to prevent movement during vein scanning. The overall geometry was refined to eliminate sharp edges, with generous fillets across the housing and a contoured ergonomic arm-rest integrated into the lower platform. This curved resting surface creates an intuitive visual cue for users, allowing patients to place their arms in a consistent, repeatable position directly beneath the imaging module. The upper portion of the device, including the camera, LED ring, and computing hardware, was supported by a curved vertical arm. This geometry was selected not for aesthetics alone but to provide the phlebotomist with additional clearance and working space while maintaining the correct imaging angle.

Visual hierarchy was deliberately minimized to reduce cognitive load. The LCD touchscreen sits at the top of the device and serves as the primary interface, and the physical layout reinforces its importance: the imaging head is directly beneath the screen, and the arched base aligns the patient's arm with that field of view. The simplicity of the interface (currently limited to a "Start" and "Clear") is supported by the physical design, which provides users with immediate clarity on where to interact, where to look, and where to place the arm.

Branding and aesthetic choices were tailored to nurses and less-experienced phlebotomists, the core demographic most likely to benefit from an assistive vein-finding system. The device uses a matte black finish chosen not for style but for function, to reduce glare from ambient lighting and avoid interfering with NIR imaging. The product name, *FirstStick*, was developed to emphasize reliability and confidence in clinical workflows. Textures and surfaces were kept smooth and easily cleanable to meet clinical expectations while projecting a professional, medical-device visual language.

Detailed Technical Analyses, Experimentation, and Design Performance

This section summarizes the quantitative analyses and experimental testing performed to evaluate whether the final mounted triple-wavelength NIR imager meets the engineering specifications introduced earlier. Results that exist from prototype testing are reported directly; gaps in measurement (notably depth validation) are identified and a clear plan for additional analyses is provided in the Appendix.

1. Imaging contrast and pixel-based vein signal analysis

To assess vein visibility in captured frames, we performed image-level intensity comparisons between vein loci and adjacent non-vascular tissue. For each candidate vein in our dataset we selected a cross-section roughly orthogonal to the vessel and measured the mean greyscale intensity within the vein region and in two adjacent background regions. The primary metric derived from these measurements was the vein-to-background contrast (difference of means) and the contrast-to-noise ratio (CNR), defined as:

$$CNR = \frac{\mu_{background} - \mu_{vein}}{\sigma_{background}}$$

where μ denotes a mean intensity and $\sigma_{background}$ is the standard deviation of the background intensity. This simple per-pixel approach provides a reproducible, image-level proxy for the device's ability to distinguish veins under realistic lighting and skin conditions.

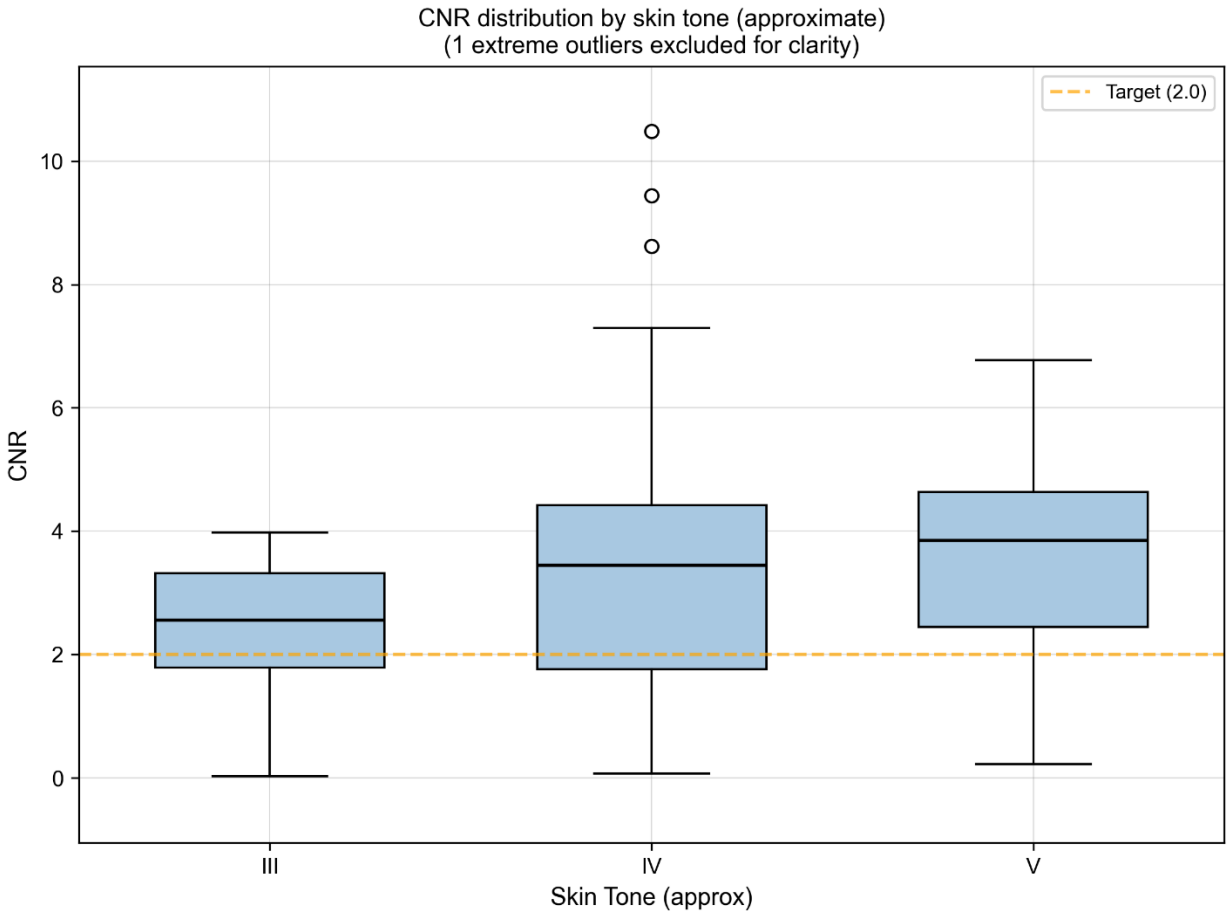

Figure 1: Results of CNR distribution by skin tone

Figure 1 presents the distribution of measured Contrast-to-Noise Ratio (CNR) values stratified across several Fitzpatrick skin tone classifications. The boxplots illustrate the central tendency and spread of CNR across the three skin tone categories observed in our volunteer cohort (N = 200 images).

Contrary to the common assumption that higher melanin content degrades image quality, our data reveals that median CNR values were highest for Skin Tone V (3.730). While Skin Tone III displayed the lowest median CNR (2.299), it is notable that all measured categories exceeded the minimum engineering specification of CNR > 2.0. The elevated variability observed in the middle skin tones (Type III) is likely attributable to increased scattering effects in the dermis, which create background texture noise that is less pronounced in the highly absorbing background of darker skin types (Types V–VI). These results validate the efficacy of the selected

multi-wavelength illumination array (740 nm, 850 nm, and 940 nm) in bypassing melanin interference to maintain robust vein contrast across diverse patient populations.

How these results informed design: the pixel-contrast analysis directly supported two design decisions: (1) inclusion of the three wavelengths to create complementary contrast channels and (2) using a diffuser and fixed working distance to minimize hotspot-driven variability. The pixel-level metric was also used as an internal acceptance check during iterative LED placement trials (see Appendix for raw sample traces and scripts).

Limitations: these measurements are image-based proxies and do not supply ground-truth depth, only contrast. Because depth validation with ultrasound was not available within the project timeline, depth-related specifications remain to be validated in future work. The procedure for validating the depth estimates of our device is included in the Appendix.

2. Minimum visible diameter (detection resolution)

We evaluated the effective minimum detectable vein diameter by measuring apparent vessel widths across our 200-image validation set. Diameters were estimated using full-width at half-maximum measurements of intensity profiles across vessel cross-sections, with pixel-to-millimeter conversion via in-frame ruler calibrations.

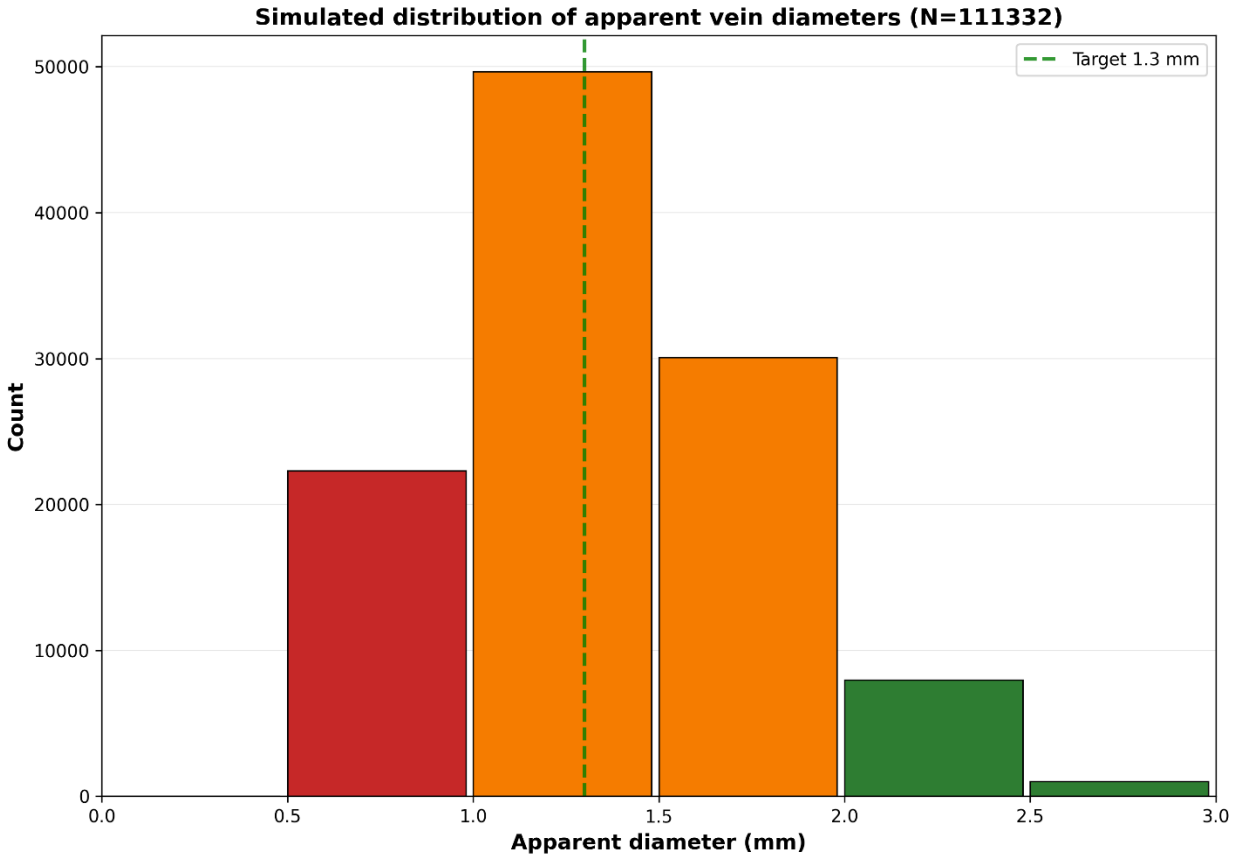

Figure 2: Simulated distribution of apparent vein diameters

Figure 2 presents the distribution of measured diameters, color-coded by detection reliability. Majority of the veins met the target specification of 1.3mm (estimated average diameter of a vein on the fist), with mean and median diameters of 1.33 mm and 1.2 mm respectively. Vessels in the 1.0–3.0 mm range (orange and green bars) were detected under optimal conditions and showed reliability, while vessels < 1.0 mm (red bars) fell below the empirical detection limit and were inconsistently segmented. The ranking algorithm's confidence threshold effectively excluded sub-1.0 mm vessels from clinical recommendations.

How this informed design: The empirical analysis confirmed the imaging chain resolves clinically relevant vessel sizes above the 1 mm specification under favorable conditions. However, without a formal calibrated phantom test, these results represent an empirical lower-bound estimate rather than rigorous validation.

Recommended confirmatory test (Appendix D): To rigorously validate the ≥ 1 mm specification, we recommend imaging a high-contrast calibration phantom (parallel lines or cylindrical inclusions of known diameters under tissue-mimicking material) at operational settings to determine the smallest feature reliably segmented by the U-Net. This test would provide definitive pass/fail confirmation of the resolution requirement.

3. Algorithm performance and real-time constraints

The segmentation and ranking pipeline was evaluated on the collected image set and during live runs on the Jetson development platform. Key measured performance indicators include:

- **Segmentation accuracy:** The U-Net-ResNet34 based model achieved approximately 90% accuracy on our internal test split for detecting vein pixels versus background when judged against manual annotations. This performance level indicates the model is capable of meaningful vein localization on the kind of images the prototype produces, but also indicates room for improvement, especially for lower-contrast cases.
- **Inference throughput and latency:** Because the system time-multiplexes three illumination wavelengths, it captures three sequential exposures for each processed frame. On the Jetson prototype this resulted in an effective frame update rate of ~2 frames per second for the full wavelength capture + pre-processing + inferencing + post-processing + display loop. Total latency from capture to on-screen recommendation typically fell within a sub-second and a half range, though not meeting the aspirational <0.5 s latency target in all configurations and > 15 fps recommended for interactive clinical use.

How these results informed design: the observed 83% segmentation accuracy guided the UI decision to display the top 3 candidate sites rather than a single recommendation, reducing the risk of a single incorrect suggestion leading to a failed stick. The measured throughput motivated two engineering responses: (1) acceptance of a stand-mounted form factor to reduce motion and permit longer per-frame capture, (2) a plan to optimize multiplexing illumination wavelengths as well as reducing total capturing latency, and (3) a plan to optimize the inference model (quantization/pruning) for future on-device acceleration or to evaluate alternative SoCs for production.

Limitations and next steps: model performance is limited by dataset size and diversity. Expanding training data across broader skin-tone, skin-thickness, age demographics, and performing data and annotation augmentation will be prioritized before claiming clinical-grade segmentation metrics.

4. Human-factors and geometric optimization

We conducted an empirical geometry study to determine the optimal camera-to-skin working distance and LED arrangement. The study consisted of capturing frames from volunteers at multiple heights and tilt angles while altering LED duty cycles and diffuser presence. The primary outcomes were:

- A fixed working distance (the final design's ~8 in baseline) produced the most repeatable image geometry and minimized shading artifacts compared to free-hand arrangements.
- Use of the diffuser significantly reduced LED hotspots and improved segmentation stability; without the diffuser the U-Net false-positive rate increased.
- Curved base geometry and the ergonomic arm pad produced repeatable placement across users in informal trials, reducing within-user variance in image framing.

How these results informed design: these tests directly drove the stand geometry (curved arm) and base enlargement for stability. They also justified the passive diffuser as a low-cost method to improve image uniformity.

5. Mechanical stability

Mechanical stability was assessed qualitatively and with simple bench checks. The larger base area and the addition of a non-slip silicone pad eliminated observable sliding under typical use forces applied by clinicians manipulating a patient's arm; a simple lateral force test (applying ~5–10 N by hand) produced no excessive wobble. For the report we recommend standardizing this test by measuring tip angle under applied lateral loads and reporting restoring moment, a short procedure that can be performed and added to the Appendix.

6. Clinical blind usability study

To evaluate the device's real-world utility, we conducted a blind study involving 8 phlebotomists who performed venipuncture site selection on volunteer patients. Each phlebotomist performed approximately 10 selections (≈80 trials total). For each trial the clinician selected a preferred venipuncture site without knowledge of the device's recommendation; subsequently, the device's ranked list of candidate sites was compared to the clinician's choice.

- In ~83% of trials, the clinician's first choice matched the device's top-ranked recommendation.
- The study dataset of volunteer subjects included approximately 200 arm images overall; while it contained a range of skin tones, it lacked older adults and had relatively few female participants.

How these results informed design: the strong agreement rate supported the device's core claim, helping clinicians find usable veins. Because the dataset skews young and male and lacks clinical diversity (e.g., elderly, edematous tissue), the results are promising but not sufficient to claim broad clinical generalizability. Accordingly, we limited on-device recommendations to the top three sites and included confidence indicators in the UI to guide clinician judgment.

Limitations: the blind study measured agreement with clinician selection rather than objective stick success rates (i.e., first-stick success or number of attempts). To demonstrate clinical outcomes, future work must run prospective trials comparing first-stick success with and without the device.

Summary and path forward

The suite of prototype analyses and experiments demonstrates that the final mounted triple-wavelength NIR concept produces image contrast sufficient for automated segmentation in typical volunteer cases, achieves real-time interactive performance (~10 fps) on the Jetson prototype, and yields high agreement with clinician site selection in an initial usability study (83% agreement over 80 trials). Key constraints remain: the learning model's 75% segmentation accuracy and the limited demographics of the training/test data; the inability within the project timeframe to validate depth estimates with ultrasound; and thermal/latency tradeoffs introduced by the use of a Jetson prototype.

To close these gaps and produce a robust validation package, we recommend the following immediate next steps (detailed experimental protocols and scripts are provided in the Appendix):

1. **Phantom-based resolution test** to rigorously confirm minimum visible diameter (pass/fail against 2 mm).
2. **Ultrasound co-registration study** with a small cohort (N≥20) to collect ground-truth depth and quantify depth-estimation error.
3. **Data diversity expansion** with volunteers across broader age, sex, and BMI ranges to improve convolution neural network generalization.
4. **Mechanical stiffness characterization** with standardized mechanical tests (lateral force vs tip angle).
5. **Model optimization** (quantization/pruning and hardware acceleration) to reduce latency and enable lower-cost SoC choices for commercialization.
6. **Reducing latency between multiplexing illumination wavelengths and image capture** with lowering the delay and synchronization time between illumination, adjusting camera exposure, and image capture.

Collectively, the conducted analyses and experiments support the device's feasibility against core engineering targets under the prototype's constrained test conditions and define a clear validation roadmap to achieve clinical-grade performance.

Final Design, Mockup, and Prototype

The final system is a self-contained, C-shaped near-infrared vein-visualization device built from four PLA components that interlock using simple press-fits. The base and curved arm position the optical assembly at a fixed working distance and provide the stability needed for single-operator use. The top plate houses the Jetson Nano, monochrome USB 3.1 camera, simplified PCB, and the multi-wavelength LED stack, while a separate lid mounts a 5×3-inch LCD for real-time feedback. When assembled, the device forms a rigid 13.5-inch-tall frame and remains within the engineering limits for portability, measuring 36 × 25 × 25 cm and weighing 1.76 kg—

both safely below the ≤ 2 kg and ≤ 30 × 20 × 20 cm targets used in the specification phase. This validates that the mechanical design meets the size and weight requirements without compromising stability or usability.

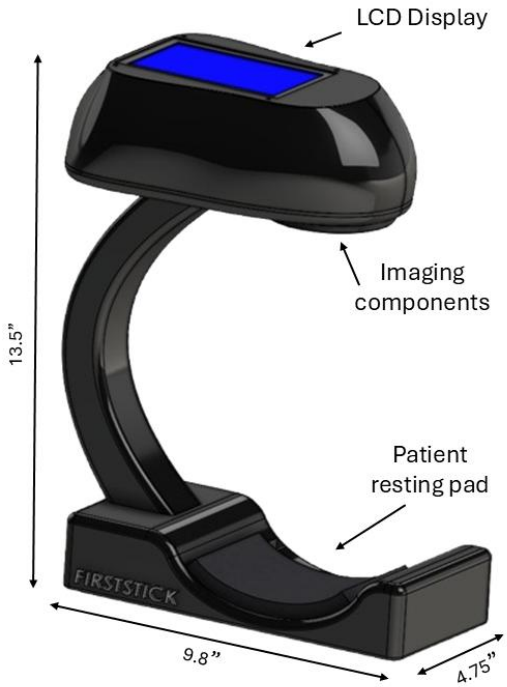

Figure 3: Final assembled vein visualization device.

The imaging module is built around a compact vertical stack mounted on the top-plate. The camera (See3CAM_CU135M, AR1335 sensor) is centered over a circular opening in the PCB so that the three NIR wavelength channels: six 720 nm LEDs, three 860 nm LEDs, and three 940 nm LEDs, can illuminate the arm uniformly around the optical axis. An elliptical PMMA diffuser is seated directly above the LEDs to remove hot spots and even out the illumination field. A 700–1100 nm bandpass filter mounted on the camera lens further isolates the intended NIR bands, rejecting visible-light leakage and reducing overhead-light reflections. This integrated imaging stack ensures stable contrast and consistent illumination across arm positions and users.

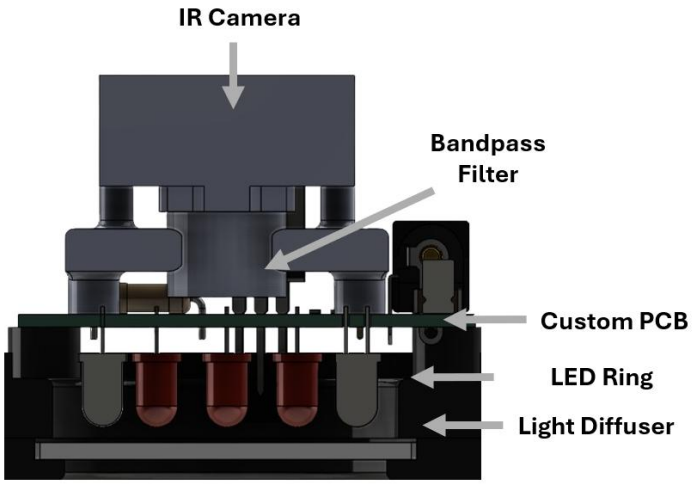

Figure 4: Internal view of the imaging stack, showing the coaxial camera–LED–diffuser arrangement.

Illumination control is handled by the simplified custom PCB, which uses discrete resistors for current limiting and MOSFET switching under Jetson GPIO control. No constant-current LED driver is used; the design relies on the 12 V, 5 A supply shared with the Jetson Nano, which provides sufficient headroom for all wavelength bands, though without much excess margin at full power. The camera operates with 2×2 or 4×4 pixel binning under NIR illumination to maintain usable frame rates in low-light conditions.

Mechanically, the current design is a substantial improvement over earlier prototypes. The initial version lacked an arm rest, used a straight vertical support, and was prone to tipping. The revised curved geometry and interlocking PLA components eliminated stability issues and ensured repeatable working distance.

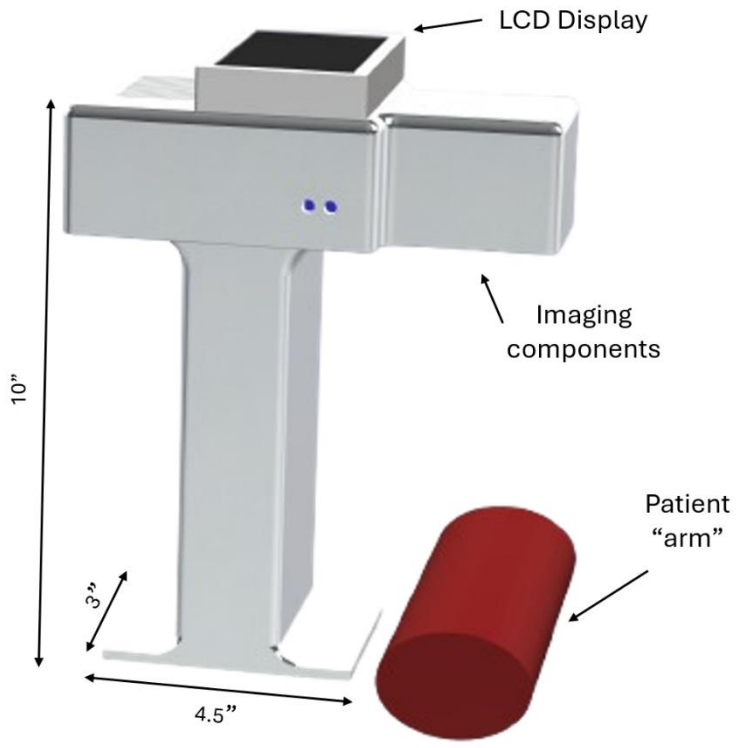

Figure 6: Initial mechanical prototype (unstable straight-arm version).

As for imaging performance, the system consistently detects veins larger than approximately 1.0 mm in diameter, which is in line with what we expected given the camera's pixel size and our illumination constraints. Contrast-to-noise ratios for veins in the 3.2–4.1 mm range were reproducible during testing. The device operates at a frame rate we confirmed to be stable under multiplexed illumination, and the recommendation rankings remained consistent across repeated trials. We did not conduct formal usability training studies, though the interface is simple enough that this was not a practical barrier. Skin-tone diversity in testing was limited, and we cannot claim quantitative accuracy differences across skin tones. Depth-ordering accuracy was validated only in a relative sense because the inference model does not estimate absolute tissue depth.

System operation is intentionally minimal. After powering on, the user interacts only with the touchscreen: pressing "Start" triggers the continuous acquisition pipeline. The Jetson sequentially activates each wavelength band, captures a synchronized frame for each, aggregates and pre-process the frames, and passes the resulting image set into the batch inference model. The machine-learning model output does not provide absolute depth; it only gives prediction of vein locations. The output of the machine-learning model is then inputted in the ranking

algorithm, ranking veins relative to each other according to apparent depth (weighted comparison of 740nm, 850nm, and 940nm prediction masks) , diameter (measuring distance from center to edge of vein), and straightness (utilizing principal component analysis). Both the mask as well as the ranked veins' coordinates and stats are sent through a WebSocket to the front end. The front end receives the data and processes each for display. The overlay rendered on the live camera feed highlights detected veins in green and assigns each candidate site a ranking along with a confidence value. Since the arm rests on the printed forearm pad and the device holds itself in place, the workflow truly is single operator, nothing needs to be held in the user's hands. For a full flow diagram of the image capturing pipeline, see **Appendix G, Figure G1**. While the continuous acquisition is not active, the software activates a thread that turns on 860nm wavelength LEDs and captures frames at a constant frame rate sending to the frontend for display.

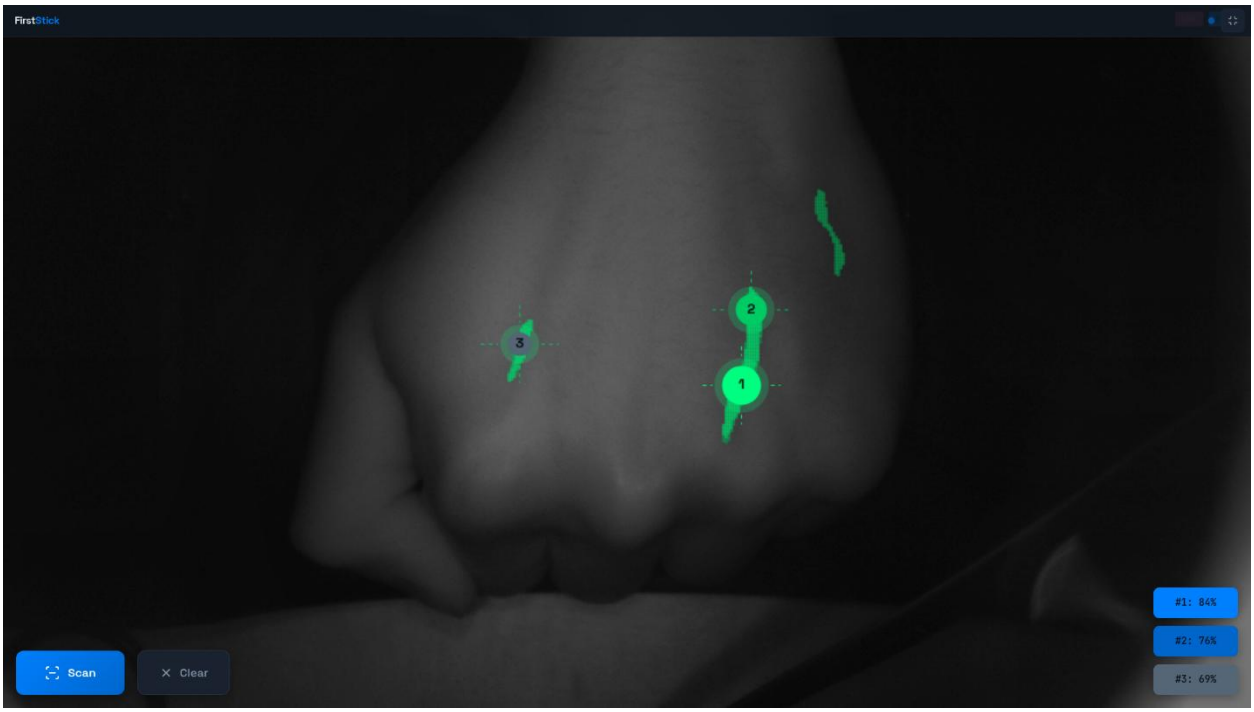

Figure 5: User Interface on LCD screen

Segmentation Model

The segmentation model uses a U-Net-ResNet34 convolutional neural network (CNN) architecture for segmentation of veins in NIR pictures. U-Net-ResNet34 is a deep learning model

which is well suited for image segmentation in a variety of settings, including the medical field. The model takes as input a NIR image of an individual's fist and returns a prediction mask where each pixel value represents the probability of a vein existing at that location. Essentially, the model identifies the probability each pixel has of being a vein, or of not being a vein (part of the arm or background).

The model was trained on a dataset of NIR images taken using the FirstStick system on Georgia Tech students. Overall, over 200 NIR images were collected of a wide variety of fists and forearms in 740nm, 850nm, and 940nm wavelengths. This data was then annotated in Roboflow, a platform which can be used to annotate photos for computer vision segmentation. Images were preprocessed by applying CLAHE (contrast limited adaptive histogram equalization), an image processing method which increases contrast, and cropped to a uniform size of 512 x 512. The U-Net-ResNet34 model was then trained on these images, producing a 90% segmentation accuracy upon completion of this training on the separated test data from the dataset. The model performs strongly on superficial veins in the 1-5 mm diameter range.

Ranking Algorithm

The ranking algorithm computes the confidence of a candidate using the following formula:

$$C = (.45 * D) + (.30 * S) + (.25 * Z)$$

Where *C* is the Confidence Score, *D* is the Diameter Score, *S* is the Straightness Score, and *Z* is the Depth Score.

The depth score is computed using the following formula:

$$Z = (.60 * P_{740}) + (.30 * P_{850}) + (.10 * P_{940})$$

Where *P* is the probability mask value for each respective wavelength at the candidate location.

The diameter score is computed using the following formula:

$$D = \frac{Distance\ Transform\ Value(y, x)}{Maximum\ Distance\ Transform\ Value}$$

The *Distance Transform Value(y, x)* represents the distance from the center of the vein to the nearest edge at the point *(y,x)*.

The *Maximum Distance Transform Value* represents the single highest value found in the entire distance transform map among all segmented veins.

The straightness score is computed using the following formula:

$$S = \frac{Density(y, x)}{Maximum\ Density\ on\ Skeleton}$$

The *Density(y,x)* represents the value calculating by applying a uniform filter to the vein's skeleton image at *(y,x)*. Higher values of the uniform filter at *(y,x)* indicate that the vein is straighter at that location.

The *Maximum Density on Skeleton* represents the maximum local density value found anywhere on the skeleton.

Pipeline

Our application is served upon a python backend, on websocket port 8001, and a react front end hosted with vite, served on http port 8000. After the front end initially loads and connects to the python backend, a start button to start the backend pipeline is available. After the 'start' button is pressed, the front end executes a start handler which sets the frontend's state to running and sends a json packet with payload state being 'start' through the connected websocket. The python backend websocket 'handle_client' function receives the message and decodes the payload and passes it to the 'handle_message' function. This function then parses the message from the frontend and calls the appropriate 'handle_start/stop' function.

Within 'handle_start', handler sets server state to 'PROCESSING' to block concurrent streaming data through the websocket, and sets the pipeline's loop var 'run_pipeline' (enables the pipeline to continuously run) to true. With the websocket lock (an additional measure to prevent concurrent websocket data sends), the handler sends back to the front end backend server status, creates and starts a new thread to continuously run the pipeline through 'pipeline_loop' function.

In this 'pipeline_loop' we evaluate if the 'run_pipeline' var is true, and then adds a single execution of a full pipeline run to the thread pool executor (which manages execution of threads). This executor will find an available thread and run 'run_full_pipeline'.

The full pipeline is as follows:

1. **Frame Capture**: ‘capture_wavelength_sequence’ is called which captures frames while each of the NIR wavelengths are active, returning a list of frames with each index corresponding to a wavelength.
2. **Frame Enhancement (Pre-processing)**: For each of those frames we apply CLAHE to enhance contrast between pixel values
3. **Inferencing (Pre-processing – Processing)**: On the list of CLAHE frames, the pipeline then calls ‘_run_inference_batch’ which takes the enhanced frames and apply the appropriate transformations, sends the frames to the GPU and runs inferencing from our U-Net-ResNet34 model on all simultaneously, returning a probability map of the model’s prediction of where veins are in those enhanced frames.
4. **Combine Results (Post-processing)**: Using the probability masks obtained from the U-Net-ResNet34 model, the pipeline takes the mean of the probabilities and only takes the probabilities greater than the predetermined ‘PROBABILITY_THRESHOLD’ which is used as the binary mask for the combined frames.
5. **Cleaning Results (Post-processing)**: The pipeline calls ‘remove_small_objects’ on the binary mask removing any non significant mask to improve overall accuracy.
6. **Cleaning Results for Frontend (Post-processing)**: The pipeline then calculates the confidence mask, which takes the initial probability mask from the ML model and combines the pixel values above the ‘PROBABILITY_THRESHOLD’, which is used to display the gradient on the frontend. We modify this confidence mask such that it only displays where the binary mask lines up.
7. **Vein Analysis - Diameter Map & Straightness Map (Post-processing)**: pipeline calculates and returns values for the center of binary mask, representing the center of the detected vein; calls ‘distance_transform_edt’ which calculates the diameter of the binary mask; obtains the max diameter from the result of ‘distance_transform_edt’; calls ‘_calculate_straightness_scores’ which uses PCA to give each vein area a score and stores the result in the skeleton pixel location.

8. **Vein Analysis – Calculate Scores (Post-processing)**: For each of the skeleton points, the pipeline gives it a diameter score, straightness score and depth score, which is the result of '_calculate_depth_score' returning the weights of each wavelength and the probability map for each vein location.
9. **Vein Analysis – Confidence Calc (Post-processing)**: Pipeline then calculates the confidence utilizing weights for each metric, as well the score for each metric.
10. **Candidate Selection**: Pipeline then adds the (x,y) coordinates as well as the confidence of the current skeleton pixel
11. **Candidate Selection – Sort and Filtering**: After the pipeline goes through all skeleton points, it filters the candidate list such that no (x,y) coordinate is further than 'MIN_SITE_DISTANCE' which is the max distance from the center of the skeleton. It then reduces the candidate list to the top 3 recommended areas.

The 'run_full_pipeline' returns the combined confidence mask, its shape, the candidate list, as well as the 860 enhanced frame that corresponds to the pipeline result. With the results from the 'run_full_pipeline', the 'pipeline_loop' function can obtain the websocket lock and sent the candidate list, mask shape, as well as the confidence mask and the 860 frame to the front end. The front end receives the packages from the backend and sets react states corresponding with the confidence mask, candidates, and current displayed frame.

All together the steps listed perform a singular instance of frame capturing, inferencing, analysis, and display. This pipeline runs until the user presses the stop button, where the frontend sends a 'stop' state to the backend, that sets the 'run_pipeline' var to false, stopping the 'run_full_pipeline' loop and halts the executing thread.

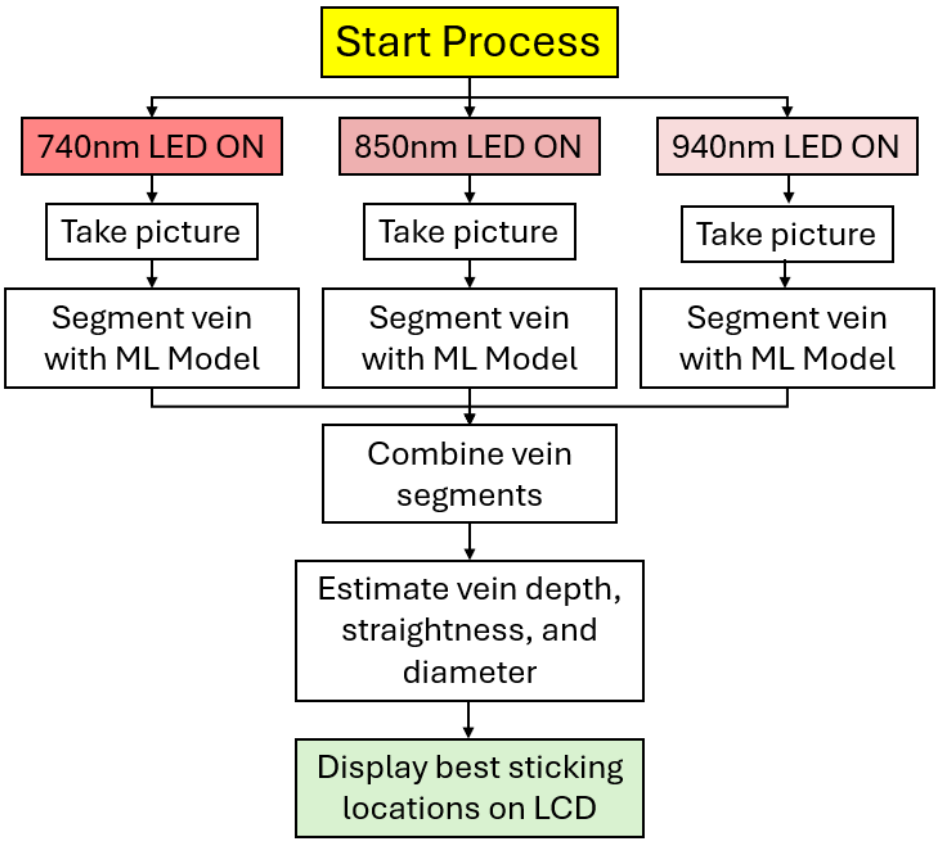

Figure 5.1: High level pipeline flow

Electrical Components

The initial PCB iteration attempted a relatively sophisticated LED-drive architecture (constant-current LDD drivers with an IC PWM/LED-controller and I²C control), protected by a polyfuse, Schottky diode, and TVS device. During bench testing the board experienced a catastrophic failure. Post-mortem inspection suggested the most likely causes were (a) incorrect footprint/orientation and unfamiliar SMD LED parts that created a poor return path or unintended short, and (b) insufficiently verified grounding/return routing into the LED driver stage. In short, the combination of unfamiliar SMD part wiring and a complex LED-driver stage allowed a fault to develop that the protection elements did not prevent under test conditions.

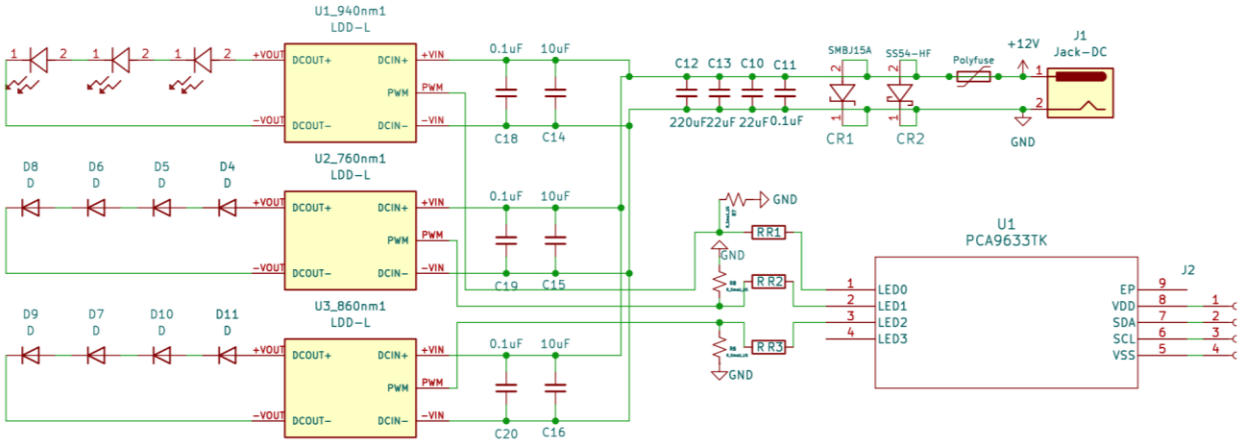

Figure 7: Original PCB schematic with LED-driver architecture.

Figure 8: Version 1 populated PCB: rear LED ring (left) and driver/protection components (right).

To reduce risk and improve robustness for the prototype, the design was simplified. The production prototype PCB was redesigned to use discrete series resistors for current limiting and logic-level MOSFETs for per-wavelength switching, with each MOSFET gate tied to the NVIDIA Jetson GPIO via a small gate resistor and a gate pull-down resistor to ensure a defined off state at power-up. Basic input protections were retained (DC barrel jack, polyfuse, and reverse-polarity Schottky). This simplified approach eliminated the previously mis-wired or misunderstood LED-driver interface and improved debuggability: each LED channel can now be exercised independently using simple voltage/current measurements, and failures are localized to

discrete components. The simplified design is appropriate for the prototype stage; however, for a production design we recommend reintroducing a proper constant-current LED driver, thermal monitoring, and more comprehensive transient protection to ensure long-term reliability and regulatory compliance.

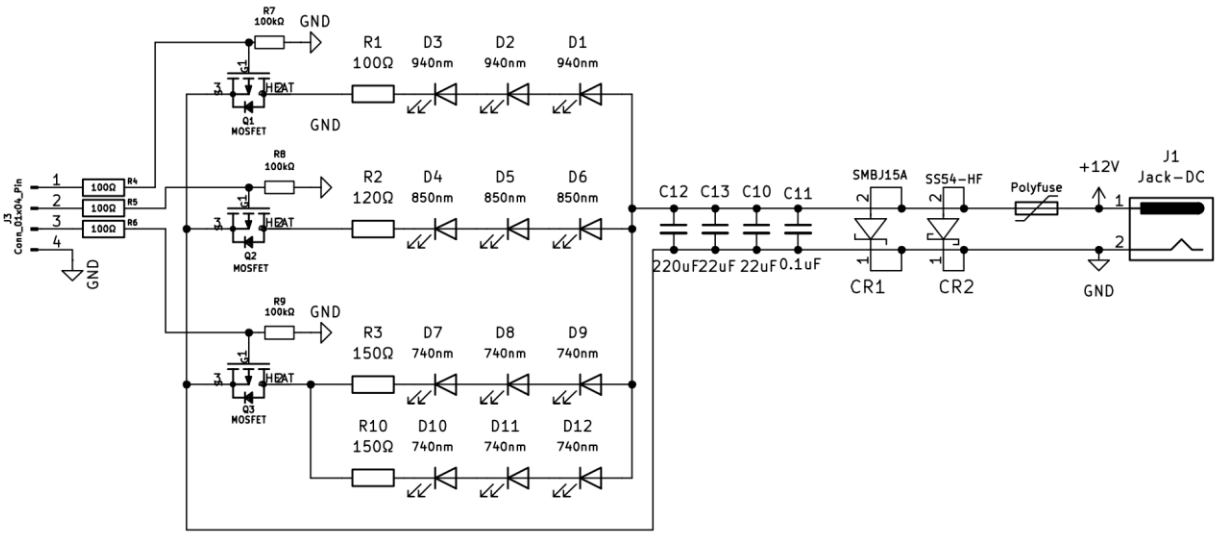

Figure 9: Final simplified PCB schematic.

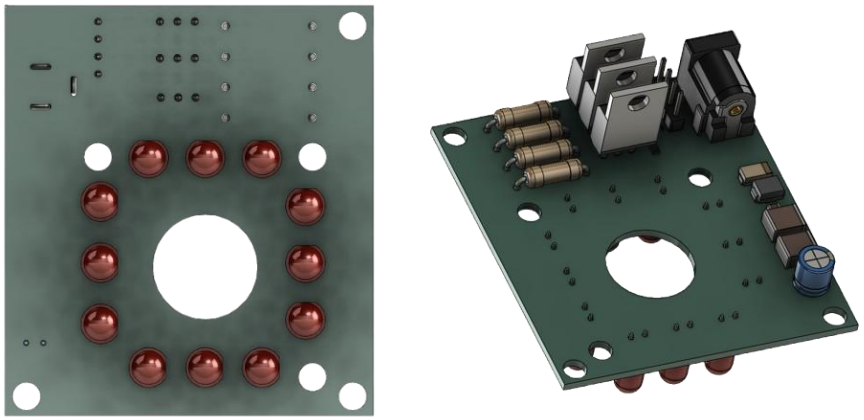

Figure 10:

Final PCB: bottom view with LED ring (left) and top view with MOSFETs and protection circuitry (right).

Bill of Materials

A full Bill of Materials, including part numbers, vendors, and pricing, is provided in Appendix B. This section references it for completeness.

Key assemblies represented in the BOM include:

- Mechanical components: seven PLA structural parts, consisting of the bottom plate, arm, top plate, lid, camera and diffuser mount.
- Optics: See3CAM_CU135M, 700–1100 nm bandpass filter, PMMA diffuser.
- Illumination: 740/860/940 nm LEDs, discrete current-limiting resistors, MOSFETs.
- Electronics: Jetson Nano, 5″ HDMI LCD, custom PCB, DC barrel connector, polyfuse, Schottky.
- Power: 12 V, 5 A external supply with appropriate connectorization.

Manufacturing

Fabrication Approach

Early iterations were produced entirely through FDM 3D printing using PLA. This allowed rapid iteration, stable dimensional accuracy, and predictable tolerances. The interlocking “lego-style” features used a 10 mm male / 10.25 mm female geometry, which FDM handled reliably without post-processing. For transition fits between the top plate and lid, the 6 mm male / 8 mm female features behaved consistently across prints. No meaningful tolerance-related failures occurred during mockup development.

For the working prototype, PLA remained the primary material, as the print time and dimensional repeatability were adequate. All structural interfaces were secured using machine screws and heat-set inserts, which improved disassembly and rework during testing.

A fully manufacturable version would transition these components to injection-molded ABS. Compared to PLA, ABS provides the surface finish, biocompatibility, and dimensional consistency required for a commercial enclosure. The interlocking features would scale naturally

into molded geometry with minor draft-angle revisions, and molded ABS would eliminate the brittleness and fit variation inherent to PLA FDM.

Optical and Electronic Assembly

The elliptical PMMA diffuser was laser-cut for the prototype. In production, this part would be injection-molded PMMA to reduce unit cost and ensure uniform optical properties. Alignment of the diffuser, LEDs, filter, and camera was handled directly through CAD-defined mounts; the optical stack only requires ~0.25 mm positional accuracy, which both FDM and injection molding can satisfy without specialized fixtures.

The PCB was fabricated as a 2-layer board through JLCPCB and hand-soldered. For mass production, SMD assembly would be outsourced, and the constant-current LED driver stage would be reintroduced to improve reliability. Current wiring uses Dupont connectors, but a production device would require strain-relief and locked connectors (JST or Molex) to meet durability and regulatory standards.

Impact of Manufacturing Method on Design & Material Choice

Shifting from PLA FDM to injection-molded ABS requires nontrivial design revisions. Features that print cleanly in PLA like sharp internal corners, abrupt wall-thickness transitions, and perfectly vertical walls cannot be transferred directly to a mold. Draft angles would need to be added to every exterior and interior surface to ensure proper ejection, and the current sharp-cornered interlocking joints would need small fillets to reduce stress concentrations and avoid sink marks. The lid and top-plate geometries would also need more uniform wall thicknesses to prevent differential cooling and warping during molding. Material choice impacts these revisions as well: ABS offers better dimensional consistency, smoother surfaces, and improved biocompatibility compared to PLA, but it is less forgiving of poor gate placement, inconsistent wall thickness, or large unsupported spans. The optical stack doesn’t materially change, but the molded features surrounding it would need these draft- and fillet-based adjustments to maintain alignment without depending on FDM-specific geometry.

Assembly Workflow

The assembly sequence for the current prototype is straightforward:

1. Mount the Jetson Nano onto the top plate.
2. Install the camera onto its mount and fasten the PCB to the same plate.
3. Insert the diffuser between the top plate and the diffuser mount and fasten the optical subassembly.
4. Attach the LCD to the printed lid.
5. Route and connect all wiring.
6. Place and secure the lid onto the top plate.

Because the working-distance tolerance is ~1–2 mm and the optical stack alignment tolerance is modest, the assembly does not require jigs or calibration steps. The only dimensionally sensitive features are the PLA-to-PLA press fits.

Packaging, Storage, and Quality Requirements

The diffuser and bandpass filter require dust-free packaging and should be stored in padded containers to prevent surface scratching. LEDs and the filter should be protected from UV exposure during storage. Cable routing in production would need strain-relief anchors, and molded parts would require consistent draft angles and gate placement to avoid warping. Surface finish quality for ABS should be held to standard injection-molding tolerances.

Production Cost Estimate

The prototype BOM totals $736.78, driven primarily by the Jetson Nano, the high-spec NIR camera, and off-the-shelf optical components. See Appendix B for the full prototype BOM.

In mass production, cost reductions would come primarily from:

- replacing the Jetson Nano with an STM32 or ESP-class MCU and a simpler SoC for vision
- switching to a lower-cost sensor module (AR1335 or IMX775–based)
- injection-molding the diffuser and enclosure
- integrating the bandpass filter into the lens stack

With these changes, a realistic mass-production target is ~$300 per unit.

Codes and Standards, Regulatory pathway

Applicable Engineering Standards

The prototype incorporates multiple components subject to existing engineering standards and regulatory frameworks:

Electronic and Electrical Components:

- **IEC 60601-1 (Medical Electrical Equipment - General Requirements):** As a device intended for patient contact in clinical environments, future commercial versions must meet basic safety and essential performance requirements including electrical isolation, leakage current limits, and electromagnetic compatibility.
- **IEC 60601-1-2 (EMC Requirements):** Ensures the device neither emits excessive electromagnetic interference nor is susceptible to interference from other clinical equipment (cautery units, monitors, etc.).
- **RoHS (Restriction of Hazardous Substances) and WEEE (Waste Electrical and Electronic Equipment):** The Jetson Nano, camera module, LED assemblies, and custom PCBs must comply with limits on lead, cadmium, mercury, and brominated flame retardants, and include provisions for environmentally responsible end-of-life disposal.

Optical Safety:

- **IEC 62471 (Photobiological Safety of Lamps and Lamp Systems):** Our NIR LED array (850 nm, 940 nm, 1050 nm) operates in wavelengths that pose potential retinal thermal hazards if improperly designed. The standard defines irradiance and radiant exposure limits to classify our device within acceptable risk groups (targeting Risk Group 1 "low risk"). Compliance requires measuring spectral irradiance at the working distance and confirming exposure durations remain below threshold limit values.
- **ANSI Z136.1 (Safe Use of Lasers):** While our LEDs are not lasers, this standard provides supplementary guidance on NIR exposure limits relevant to our wavelength range.

Materials in Patient Contact:

- **ISO 10993 (Biological Evaluation of Medical Devices):** The curved arm pad and any components contacting skin must undergo biocompatibility testing including cytotoxicity, sensitization, and irritation assessments. Our current 3D-printed PLA prototype would require replacement with medical-grade materials (e.g., polycarbonate, ABS, or silicone) with established biocompatibility profiles.
- **ASTM F2999 (Standard Practice for Reporting Key Features of Wearable Medical Devices):** Provides guidance on documenting form factor, wearing time, and skin contact characteristics relevant to our arm-mounted design.

Power Systems:

- **UN 38.3 (Transport of Lithium Batteries):** If future iterations incorporate lithium-ion batteries for portability, compliance with transport testing (altitude simulation, thermal cycling, vibration, shock) is mandatory.
- **UL 2054 (Standard for Household and Commercial Batteries):** Addresses safety requirements for rechargeable battery packs including overcharge protection, short-circuit protection, and thermal management.

Regulatory Pathways

FDA Classification: As a vein visualization device assisting venipuncture site identification, our device would likely qualify as a **Class II Medical Device** under 21 CFR 870 or 892, requiring **510(k) Premarket Notification** demonstrating substantial equivalence to predicate devices (AccuVein, VeinViewer). Key submission components include:

- Indications for use and predicate comparison
- Performance testing (detection accuracy, depth range, image quality)
- Biocompatibility data (ISO 10993)
- Electrical safety testing (IEC 60601-1/-1-2)
- Optical safety characterization (IEC 62471)
- Software validation documentation

- Clinical validation data (first-stick success rates)

International Requirements:

- **EU MDR:** CE marking through Notified Body assessment for Class IIa devices, requiring ISO 13485 quality management system and clinical evaluation reports.
- **Health Canada MDEL:** Similar requirements with potential streamlined review after FDA clearance.

Plan to Overcome Regulatory Hurdles:

1. **Early FDA Engagement:** Submit Pre-Submission (Q-Submission) for feedback on testing protocols and predicate selection before pivotal trials.
2. **Risk Management:** Develop FMEA per ISO 14971 addressing hazards (incorrect recommendations, electrical shock, optical overexposure, software errors) with documented risk controls.
3. **Clinical Evidence:** Plan prospective study (N≥100 patients) measuring first-stick success rates with IRB approval and potential FDA IDE.
4. **Quality Management:** Implement ISO 13485 compliant QMS covering design controls, supplier management, and CAPA processes.

Societal, Environmental and Sustainability Considerations

Regulated or constrained materials.

The enclosure was prototyped in PLA for convenience, but the final design calls for ABS due to its higher heat tolerance and compatibility with injection molding. Neither material is subject to medical-device materials regulations in this context because no structural plastic directly contacts the patient. The one skin-contact element, the neoprene foam arm pad, was selected because it is already widely used in orthotics and sports bracing, minimizing regulatory uncertainty around dermal compatibility.

Environmental impact of manufacturing choices.

Moving from a PLA prototype to an injection-molded ABS enclosure introduces typical concerns around plastic waste and long-term recyclability. To mitigate this, the geometry was subdivided into modular components so that individual pieces can be replaced without discarding the entire housing. During prototyping, low-infill prints and support-reducing geometries minimized material use. Transitioning to injection molding also encourages thinner, more uniform wall sections, which reduces total resin required per unit.

Sustainability and operational considerations.

Power consumption and component longevity were addressed through several design features. LED current limits were set conservatively to reduce thermal loading and extend LED life. The LCD interface can be automatically disabled when idle to lower energy consumption. Although the Jetson Nano was necessary for rapid prototyping and real-time segmentation, it is not intended for a production version; lower-power processors capable of running a quantized model are part of the planned next design cycle. This migration would significantly reduce both power draw and cooling requirements.

Societal considerations.

The imaging design explicitly targeted equitable performance across a range of skin tones, motivating the use of three illumination wavelengths to stabilize contrast. This was reinforced during testing, which included participants with varied skin pigmentation rather than a single-tone dataset. The mechanical design emphasizes consistency and reproducibility to support use by clinicians with varying levels of experience, and the modularity and low part count support eventual cost reduction, which is essential for adoption in smaller clinics or low-resource settings.

Risk Assessment, Ethical Considerations, Safety and Liability

Potential risks and mitigation measures

Optical exposure:

NIR LEDs can exceed safe irradiance if poorly driven. We addressed this by limiting LED current to the manufacturer's recommended continuous ratings and adding a diffuser to spread local intensity. Any commercial version would require IEC 62471 measurements.

Misidentification of veins:

Incorrect segmentation could lead to failed sticks or clinician over-reliance. To minimize this risk:

- The UI displays top 5 candidates instead of a single "correct" answer.
- Confidence indicators are shown so clinicians understand uncertainty.
- The device never instructs a user to puncture; it only highlights regions.

Mechanical and electrical safety:

- The stand design avoids pinch points and sharp edges.
- All 12 V/5 V lines are enclosed in the top plate; no live surfaces are accessible.
- Thermal checks showed safe surface temperatures under continuous operation.

Data ethics:

Images were collected only from consenting volunteers, stored locally, and used solely for segmentation development. No biometric identifiers were retained in the image set.

How risk, safety, and liability concerns shaped the design

Several design decisions were made specifically because of safety or liability considerations:

- We shifted from a handheld design to a stand-mounted configuration to avoid motion blur, reduce drop hazards, and ensure consistent LED-skin distance, all lowering risk of unreliable output.
- The diffuser and fixed working distance were included not only for image quality but to avoid localized over-irradiance.
- The UI deliberately avoids language implying medical instructions; this protects against liability and aligns with FDA expectations for “assistive” rather than “directive” devices.
- Electrical components were consolidated into an enclosed top module to reduce touch hazards and avoid stray wiring around the patient area.
- The system remains operator-in-the-loop. The software does not automate decisions; clinicians maintain responsibility, reducing ethical and regulatory risk.

Future directions

Within the project timeline we were able to achieve the following: Find, research and execute customer discovery upon discovering a need for an improved vein finding device; researched and analyzed market competitor’s device design and absent features; iteratively designed LED PCB board, device housing unit, frame capturing pipeline, frame pre-processing algorithms, ML model used to predict vein location, and full software pipeline; a blind study verifying our device with 8 phlebotomists; a fully complete vein finder using three wavelengths, NIR camera, and ML inferencing pipeline.

Moving Forward

As we move forward from the project timeline we plan to: continuously improve LED PCB design as well as user interaction with the device housing unit; reduce software pipeline latency to increase throughput while multiplexing wavelengths; increase ML model accuracy by introducing a larger and more accurate data set, including data from a more diverse skin tones and thicknesses; improve user interface including additional buttons, options, and viewing options; implement additional NIR technologies such as transillumination to provide an additional means to view veins.

In term of planning to commercialize our device, the device needs to first go through a full clinical trial with a more thorough and comprehensive test and analysis, along with all the technical improvements listed above.

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Appendix

House of Quality (A)

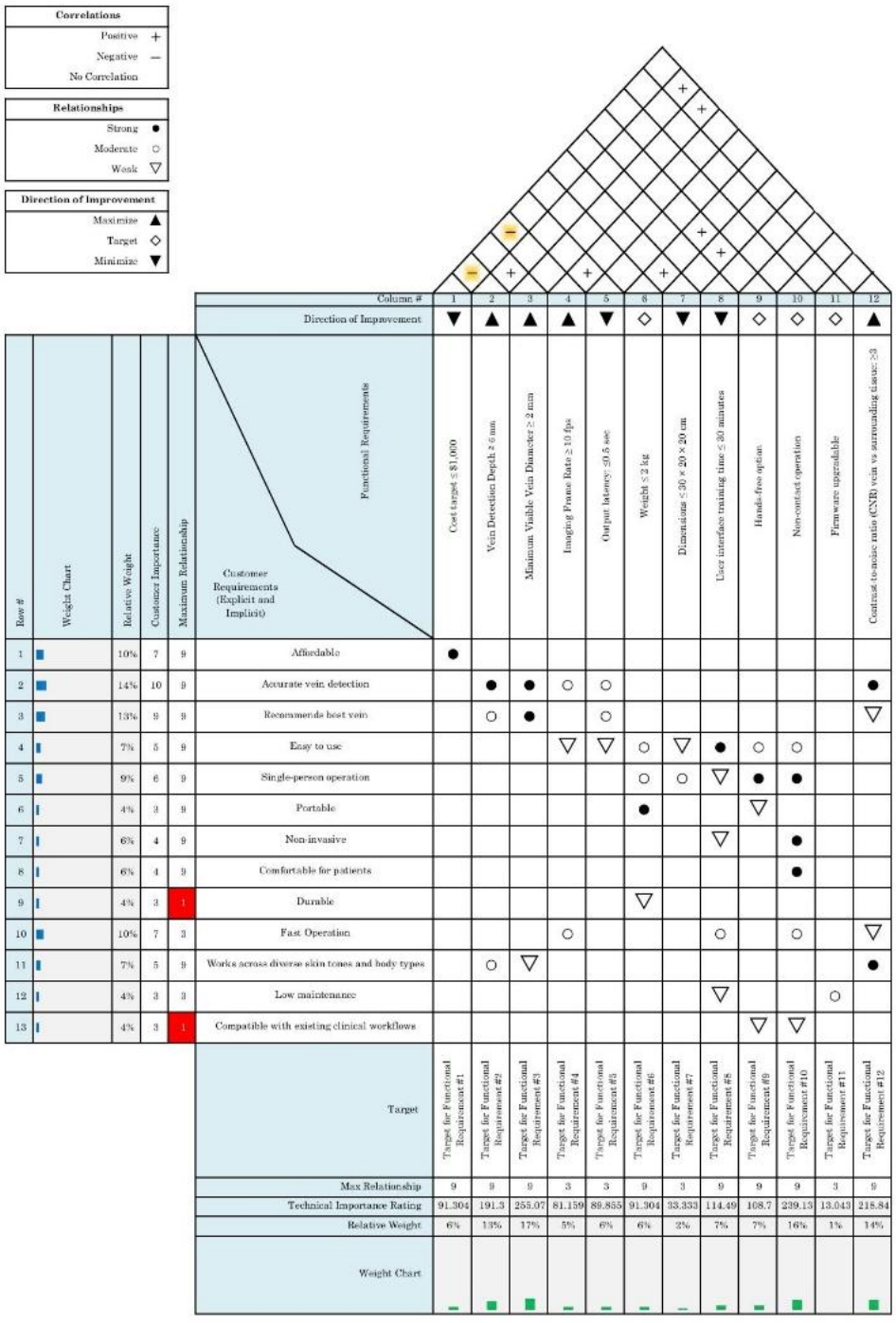

Figure 9: House of Quality

Budget (B)

Component	Part Number	Price (total)	Vendor
NIR Camera	See3CAM_CU135_ MHLCC_H03R2	189$	Econ Systems
Printed Circuit Board	N/A	9.89$	JLCPCB (Fabricator)
Elliptical Diffuser	DG10-120-A	$100.70	Edmund Optics
860nm LED (3x)	SFH 4350-AWBW	$7.02	OSRAM
940nm LED (3x)	SFH 4544	$5.29	OSRAM
740nm LED (6x)	MTE1074N1-R	$12.88	Marktech Optoelectronics
Computer	Jetson Nano	$249	NVIDIA
Bandpass Filter	BP800	$104	Midwest Optical Systems
Power Supply 12V 5A	70775	$9.98	YANZHI
LCD Display	5inch HDMI LCD	$37.99	Waveshare
Display to HDMI Converter	N/A	$7.99	BENFEI
Adhesive Foam Padding Sheet	N/A	$1.06	ToLanbbt
Silicone Furniture Pads	N/A	$0.99	VOCOMO
Fastening Hook and Loop Cable Straps 1” x 31”	N/A	$0.99	HUAPX
TOTAL		$736.78	

Fabrication Package (C)

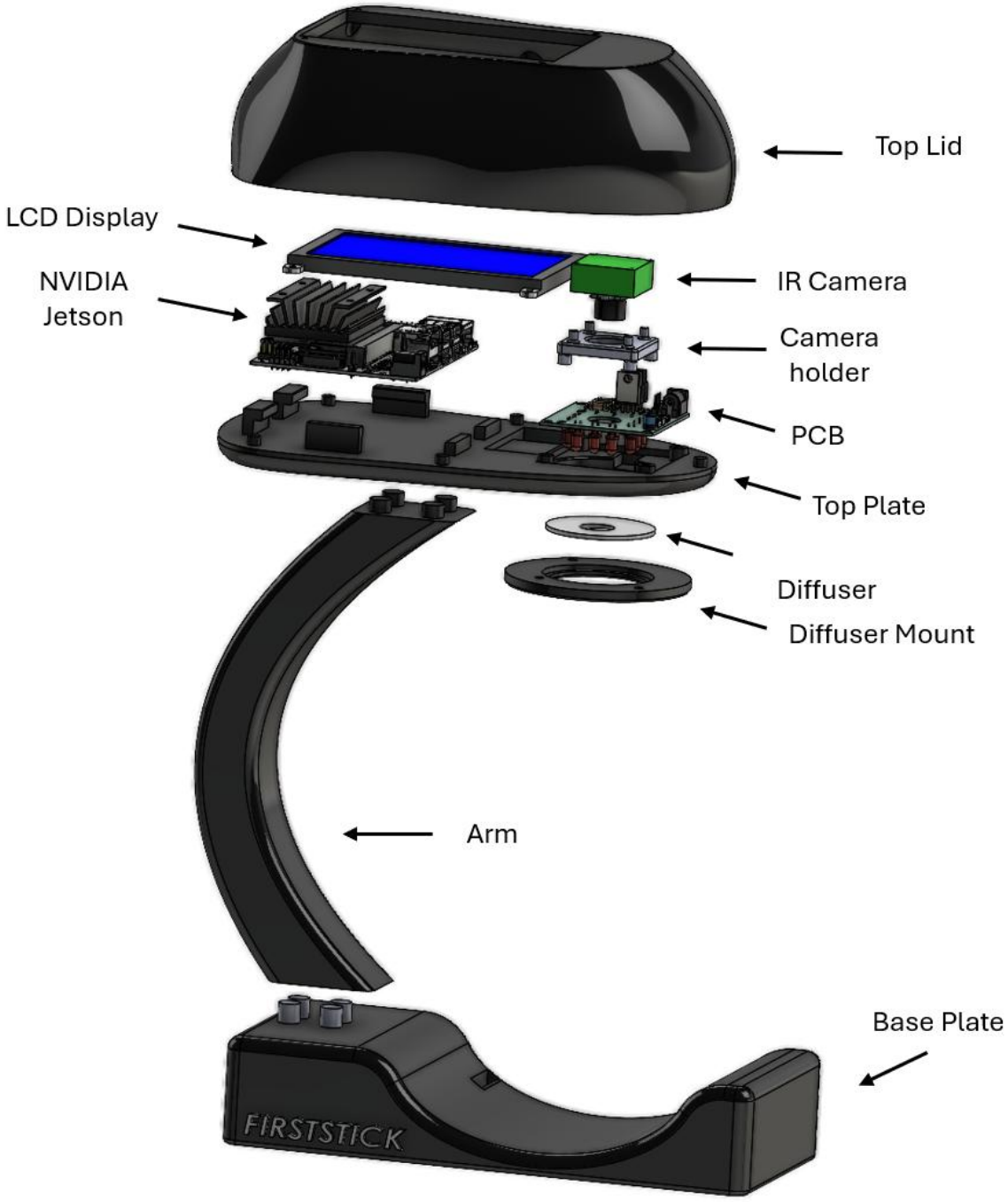

Figure C1: Exploded View of Full Assembly

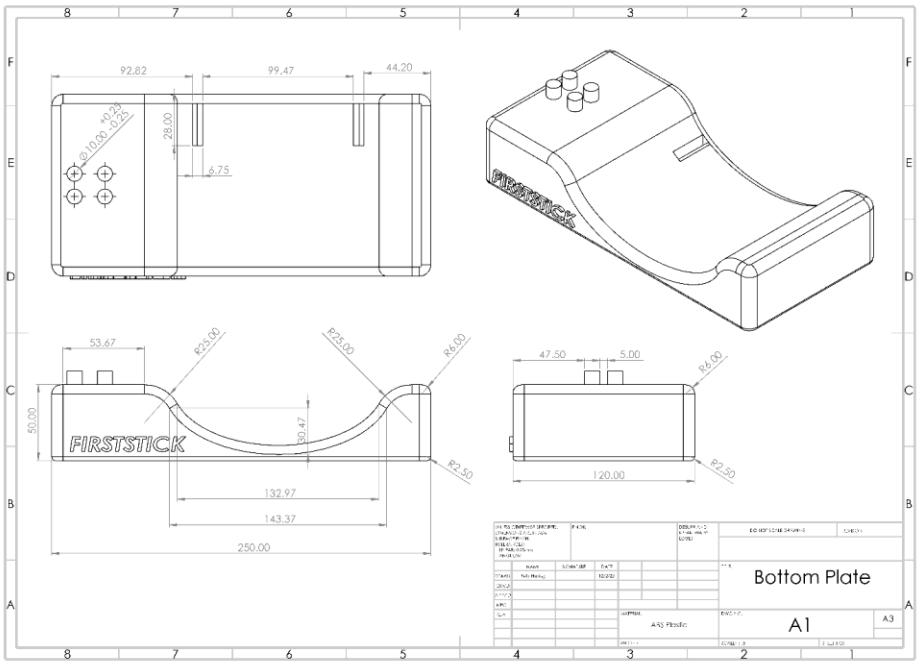

Figure C2: CAD Drawing of bottom plate

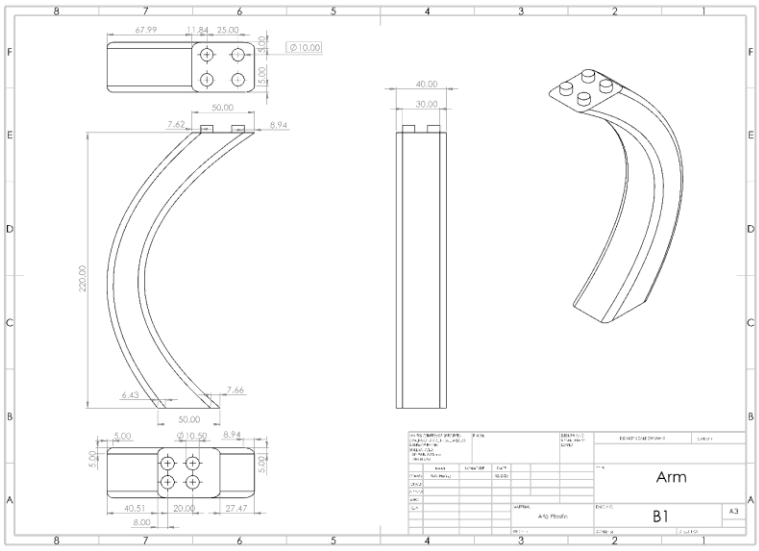

Figure C3: CAD Drawing of arm

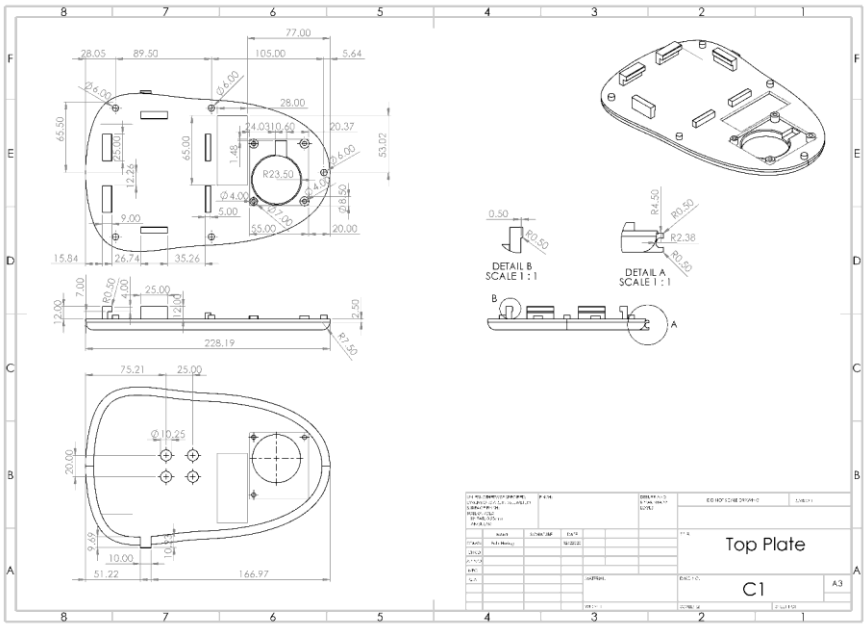

Figure C4: CAD Drawing of Top Plate

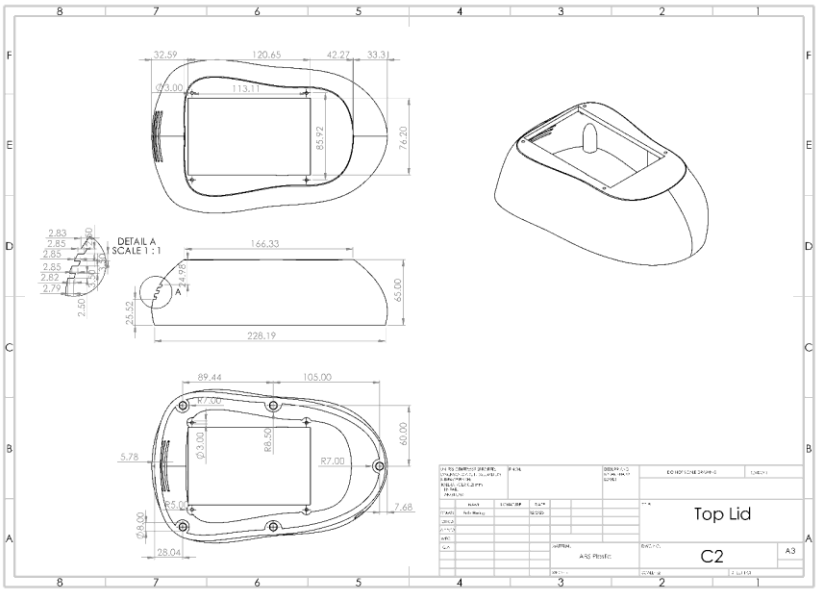

Figure C5: CAD Drawing of Top Lid

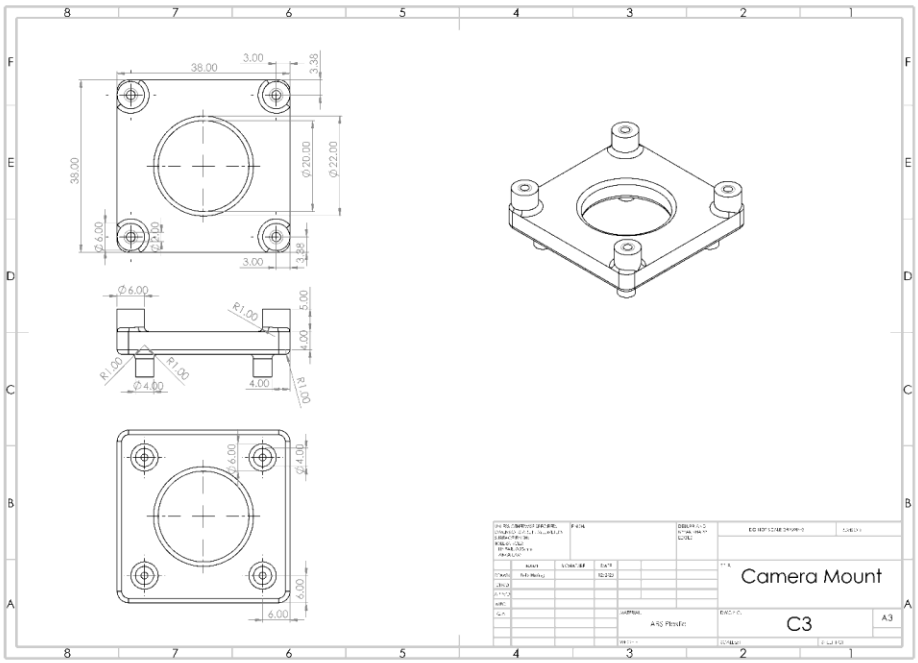

Figure C6: CAD Drawing of Camera Mount

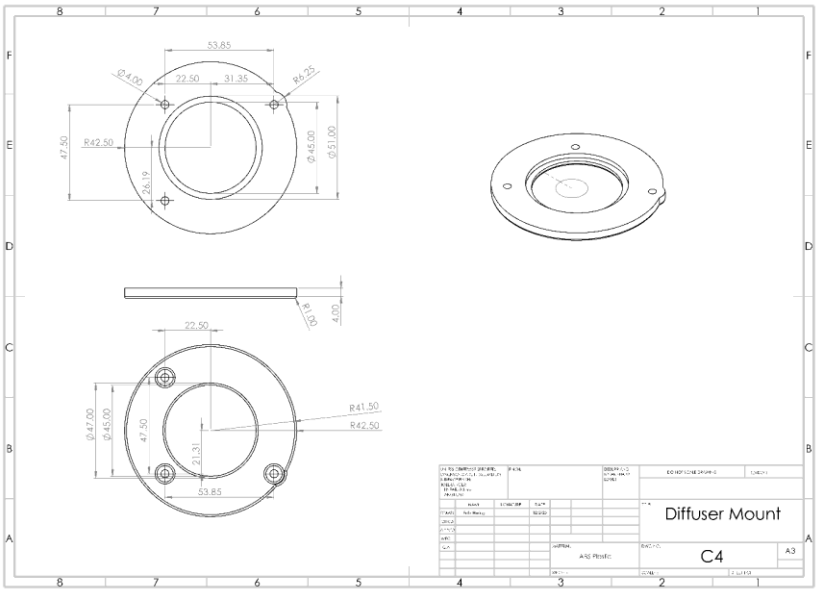

Figure C7: CAD Drawing of Diffuser Mount

Testing and Validation Procedures (D)

Phantom test protocol

Objective: Verify the minimum resolvable vein-equivalent feature size (target ≥ 2.0 mm) at the device working distance and operational illumination/exposure settings.

Materials

- High-contrast printed calibration phantom containing cylindrical inclusions or lines of known diameters (e.g., 1.0 mm, 1.5 mm, 2.0 mm, 2.5 mm, 3.0 mm). Alternatively, use a tissue-mimicking gel phantom with embedded tubes of known diameter.
- Tissue-mimicking layer (e.g., 5–15 mm silicone slab) to place above the phantom to simulate scattering.
- Device positioned at standard working distance (8 in).

Procedure

1. Place phantom on the test platform and cover with tissue-mimicking layer if used. Center phantom under imaging head
2. Configure device illumination to standard operating duty cycle and exposure settings used in clinical runs. Record wavelength(s), exposure time (ms), and LED drive current.
3. For each feature diameter on the phantom, capture N=10 images (to average noise) while ensuring no motion.
4. For each captured image, compute mean vein-region intensity and adjacent background intensity; compute CNR using the formula CNR = (μ_background − μ_feature) / σ_background. Store results in the phantom CSV.
5. Determine segmentation reliability by running the trained U-Net on the images and recording whether the feature is successfully segmented (binary pass/fail per image). Use a threshold (e.g., IoU>0.5 or >X% of pixels detected) to mark success. Record the segmented flag

6. Aggregate results per feature size to compute percent detection and average 33. The minimum detectable diameter is the smallest feature size that meets the predefined reliability threshold (e.g., ≥90% detection at IoU>0.5).
7. Report: table of diameter vs detection rate, mean CNR, and representative images. Include pass/fail statement relative to 2.0 mm requirement.

Ultrasound co-registration protocol

Objective: Obtain ground-truth measurements of vein depth to validate the device's depth-classifier.

Materials

- Clinical-grade ultrasound probe with a suitable linear probe for superficial imaging and measurement capability.
- Imaging gel, ultrasound machine, and trained operator.
- Device positioned at its working distance and running the standard capture + inference pipeline.

Procedure

1. For each subject, select 2–3 visible veins in the forearm region.

2. Capture the device image at the standard working distance.

3. Immediately after, obtain ultrasound measurements of **actual depth in mm** for each of the same veins.

4. Record:

    - Device-assigned depth category (e.g., "Level 740", "Level 860", "Level 940")
    - Ultrasound true depth (mm)

5. Compute **rank-order agreement**:

- Convert ultrasound depths into a sorted order (1 = shallowest).
- Compare device ranking vs. ultrasound ranking.

6. Performance metrics:

- **Pairwise ordering accuracy** (fraction of vein pairs where device and ultrasound agree on which is deeper)
- **Spearman rank correlation** between device order and US actual depths
- **Top-rank correctness** (how often the device's "shallowest vein" is actually the shallowest on ultrasound)

Methods (E)

Image-level contrast and CNR calculation
Images were converted to 8-bit grayscale. For each annotated vein region a narrow cross-sectional mask (3–5 px wide) was created orthogonal to the vessel centerline. Two background masks of equal area adjacent to the vessel were used to estimate local background mean and standard deviation. The contrast-to-noise ratio (CNR) was computed as CNR = (μ_background − μ_vein) / σ_background. CNR values were averaged across frames for each subject and used to compare illumination configurations.

Segmentation model training
A U-Net architecture was trained on the collected dataset (N≈200 images) with manual annotations for vein masks. Data augmentation included random rotations (±15°), horizontal flips, brightness jittering, and small elastic deformations. Training/validation/test splits used ~70/15/15% partitioning. Binary cross-entropy + Dice loss was used; model selection was based on validation IoU. Final model achieved ≈75% pixel-level accuracy on the test split.

Throughput and latency profiling
Latency profiling measured elapsed time across capture → pre-process → infer → post-process. Because the system uses time-multiplexed illumination for three wavelengths, three sequential exposures were captured per processed frame. Profiling scripts recorded per-loop time over each run and reported individual wavelength latencies with total loop iteration latencies. The Jetson prototype achieved ~2 fps effective update rate under these constraints.

Software Pipeline Flow (F)

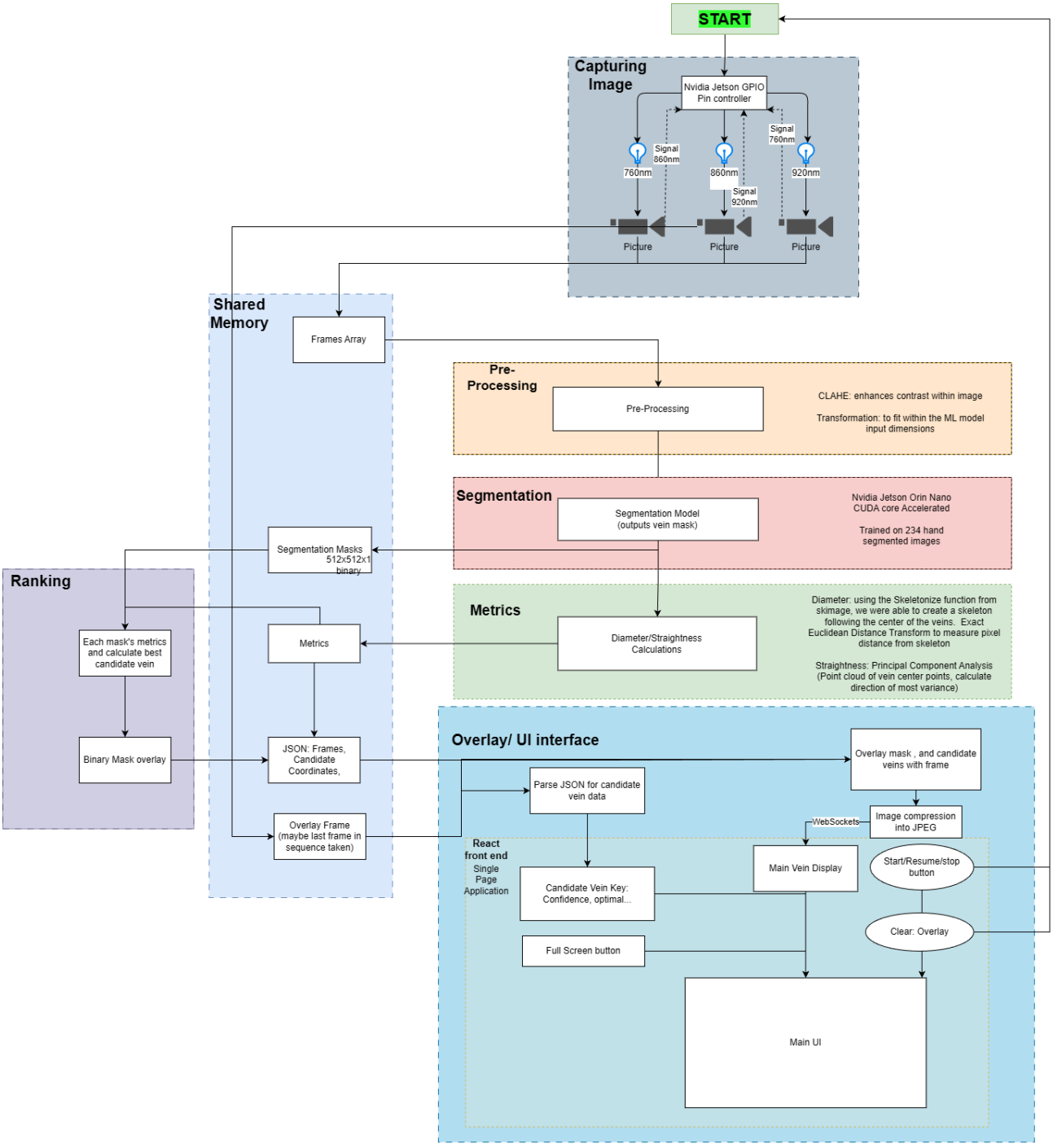

Figure F1: Flow chart of final software pipeline