# QUALITY CONTROL OF IoT COMPONENTS (SICKLE CELL)

**An INTERNSHIP REPORT**

***Submitted by,***


**Mr. CHANDU S - 20201CIT0071**
**MR. NAYAN KUMAR KJ – 20201CIT0075**
**MR ARJUN U – 20201CIT0090**


***Under the guidance of,***

**Dr Syed Siraj Ahmed**

***in partial fulfilment for the award of the degree of***

**BACHELOR OF TECHNOLOGY**

**IN**

**COMPUTER SCIENCE AND ENGINEERING (INTERNET OF THINGS)**

**At**



**PRESIDENCY UNIVERSITY BENGALURU**

**JANUARY 2024**

**PRESIDENCY UNIVERSITY**

**SCHOOL OF COMPUTER SCIENCE ENGINEERING & INFORMATION SCIENCE**

# CERTIFICATE

This is to certify that the Project report **"Quality control of IoT components – Sickle Cell"** being submitted by **CHANDU S, NAYAN KUMAR JK, ARJUN U** bearing roll number **20201CIT0071,20201CIT0075,20201CIT0090** in partial fulfilment of requirement for the award of degree of Bachelor of Technology in Computer Science and Engineering (Internet of Things) is a Bonafede work carried out under my supervision.

**Dr Syed Siraj Ahmed**
Professor CSE
School of CSE&IS
Presidency University

**Dr. S.P. Anandaraj**
Professor & HoD
School of CSE&IS
Presidency University

**Dr. C. KALAIARASAN**
Associate Dean
School of CSE&IS
Presidency University

**Dr. L. SHAKKEERA**
Associate Dean
School of CSE&IS
Presidency University

**Dr. SAMEERUDDIN KHAN**
Dean
School of CSE&IS
Presidency University

# PRESIDENCY UNIVERSITY

## SCHOOL OF COMPUTER SCIENCE ENGINEERING & INFORMATION SCIENCE

## DECLARATION

We hereby declare that the work, which is being presented in the project report entitled TITLE OF THE PROJECT in partial fulfilment for the award of Degree of Bachelor of Technology in Computer Science and Engineering (Internet of Things), is a record of my own investigations carried under the guidance of Dr Syed Siraj Ahmed, School of Computer Science Engineering & Information Science, Presidency University, Bengaluru.

We have not submitted the matter presented in this report anywhere for the award of any other Degree.

**CHANDU S 20201CIT0071**

**ARJUN U 20201CIT0090**

**NAYAN KUMAR 20201CIT0075**

# ABSTRACT

**Enhanced Paragraph on Medical Device Quality Control Project:**

Collaboratively with the teams at SMI and IISc, I played a key role in conceptualizing, designing, and implementing comprehensive test procedures and automated tools for rigorous qualification of electronic components in medical device development and production. My contributions encompassed a wide range of tasks, including:

- **Test Jig Design and Fabrication:** We participated in the design and construction of specialized test jigs to simulate real-world operating conditions for various electronic components like sensors, light sources, microcontroller boards, and mobile applications.
- **Firmware and Software Development:** Leveraging our proficiency in C, Python, and JavaScript, I developed robust firmware and software tools to automate the execution of test procedures. These tools ensured precise data acquisition, analysis, and report generation, facilitating acceptance by the engineering team.
- **Quality Control Process Optimization:** We actively collaborated with engineers at SMI and IISc to streamline the quality control process. This involved identifying redundancies, automating manual tasks, and implementing real-time data visualization for efficient decision-making.
- **Documentation and Training:** We meticulously documented the developed test procedures and software tools, ensuring clear and concise instructions for future use. Additionally, I provided comprehensive training to personnel involved in operating the automated test systems, fostering smooth process integration.

Through this project, We gained valuable experience in:

- Medical device development and quality control processes.
- Interdisciplinary collaboration with diverse teams.
- Design and implementation of automated test systems.
- Programming across multiple languages (C, Python, Javascript).

This project not only enhanced my technical skillset but also instilled a deep understanding of the critical role of rigorous quality control in ensuring the safety and efficacy of medical devices.

- Feel free to further tailor this content by:
- Specifying the types of sensors, light sources, and microcontroller boardsinvolved.
- Highlighting any innovative features of the test jigs or software tools.
- Quantifying the improvements achieved in efficiency or accuracy through the project.
- We hope this enhanced version provides a more impactful and detailed description of yourproject's contributions.

## ACKNOWLEDGEMENT

First of all, we are indebted to GOD ALMIGHTY for giving me an opportunity to excel in my efforts to complete this project on time. We express my sincere thanks to our respected dean, **Dr. Md. Sameeruddin Khan,** Dean, School of Computer Science Engineering & Information Science, Presidency University, for getting me permission to undergo the project. We record my heartfelt gratitude to our beloved Associate Deans, **Dr. Kalaiarasan** C and **Dr. Shakkeera L**, School of Computer Science Engineering & Information Science, Presidency University, and **Dr. S.P. Anandaraj**, Head of the Department, School of Computer Science Engineering & Information Science, Presidency University, for rendering timely help for the successful completion of this project.

We are greatly indebted to my guide, **Dr. Syed Siraj Ahmed**, School of Computer Science Engineering & Information Science, Presidency University, for his inspirational guidance, and valuable suggestions and for providing me a chance to express my technical capabilities in every respect for the completion of the project work. We would like to convey my gratitude and heartfelt thanks to the University Project-II Coordinators**, Dr. Sanjeev P Kaulgud, Dr. Mrutyunjaya MS**, and also the department Project Coordinator**, Ms. Manasa C M**. I thank my family and friends for the strong support and inspiration they have provided me in bringing out this project.

**CHANDU S**

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# CHAPTER-1 INTRODUCTION

**Arduino-Based Sickle Cell Disease Detection:**

A Beacon of Hope in Resource-Limited Settings

Sickle cell disease (SCD) casts a long shadow over public health, particularly in resource-constrained regions like India and sub-Saharan Africa. Early diagnosis and intervention are crucial for managing SCD effectively, but access to traditional diagnostic tools is often limited due to their high cost and complex infrastructure requirements. This challenge underscores the urgent need for innovative, low-cost, and accessible solutions for SCD detection, tailored specifically for resource-limited settings.

**Enter the Arduino:** This open-source electronics platform emerges as a promising tool for developing portable, affordable, and user-friendly diagnostic devices. Inspired by the National Institutes of Health (NIH) initiative that emphasizes practicality and affordability in resource-limited settings, researchers are actively exploring the potential of Arduino-based systems for SCD detection.

So, how does it work? Several approaches are being investigated, each leveraging the unique characteristics of SCD:

- **Cellulose Acetate Electrophoresis (CAE):** This simple and portable technique utilizes an Arduino-controlled power supply and readily available materials like filter paper and vinegar to separate hemoglobin molecules based on their electrical charge. The distinct migration patterns of normal and sickle hemoglobin on the filter paper allow for visual identification, offering a low-cost alternative to traditional electrophoresis methods.

- **Optical Densitometry:** Exploiting the differences in light absorption between healthy and sickle hemoglobin, Arduino-based devices can be equipped with LEDs and light sensors to measure the optical density of blood samples. By analyzing the absorption patterns, the system can differentiate between normal, SCT (sickle cell trait), and SCD samples with high accuracy.
- **Microfluidic Chips:** These miniaturized devices integrate microchannels and pumps to manipulate tiny fluid samples. Arduino-controlled microfluidic chips can be designed to perform specific biochemical assays for SCD detection, offering portability and automation with minimal sample volume requirements.

**The Advantages of Arduino-Based Systems:**

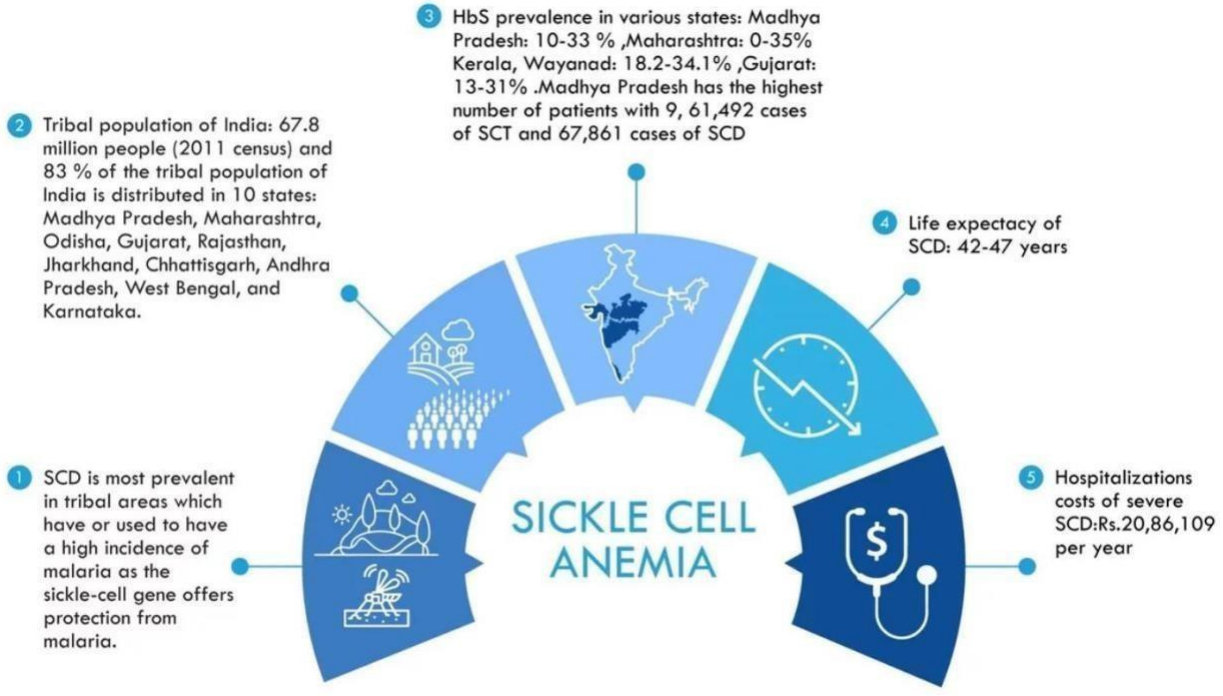
- **Cost-effective:** Arduino boards and components are readily available and significantly cheaper compared to traditional laboratory equipment, making them ideal for resource-limited settings.
- **Portable and user-friendly:** Arduino-based devices are compact and easy to operate, requiring minimal training for healthcare workers, even in remote areas with limited infrastructure.
- **Rapid results:** These systems can provide quick diagnoses within minutes, enabling timely interventions and management decisions.
- **Scalability and customization:** The open-source nature of Arduino allows for easy customization and adaptation of the platform to specific needs and local settings.

**Challenges and Future Directions:**

While Arduino-based SCD detection systems hold immense promise, challenges remain. Ensuring accuracy and reliability in diverse environmental conditions, optimizing power consumption for remote settings, and developing user-friendly software interfaces are areas requiring further research and development. Additionally, regulatory pathways and cost-effectiveness analyses are crucial for facilitating the widespread adoption of these innovative technologies in the real world.

**Conclusion:**

Arduino technology presents a beacon of hope in the fight against SCD in resource-limited settings. By harnessing its affordability, portability, and ease of use, researchers are paving the way for a future where timely and accurate SCD diagnosis becomes a reality for everyone, regardless of geographical location or economic constraints. With continued research and development, Arduino-based SCD detection systems have the potential to revolutionize healthcare access and improve the lives of millions afflicted by this debilitating disease.




**The Pitfalls of Current Sickle Cell Diagnosis:** A Call for Innovation

Existing methods for diagnosing sickle cell disease (SCD) are riddled with limitations that disproportionately impact vulnerable populations in resource-scarce settings. The dependence on costly, high-maintenance equipment and specialized personnel creates a significant barrier to accessibility, leaving many struggling to access timely and accurate diagnosis.

The situation is further compounded by logistical hurdles:

- **Remote locations:** Transportation delays in reaching diagnostic centers can lengthen the already agonizing wait for results.
- **Centralized batching:** Processing samples in batch at high-volume laboratories introduces further delays, leaving individuals in a state of uncertainty and potentially missing crucial early interventions.

These delays in diagnosis have grave consequences. Untreated SCD can lead to a cascade of complications, including debilitating pain crises, organ damage, and even death. Timely intervention is paramount for managing symptoms, preventing complications, and improving quality of life for those living with SCD.

This is where our Arduino-based solution steps in. By leveraging readily available and affordable components like Arduino Uno, Arduino Nano, LEDs, and Photodiode sensors, we aim to break free from the constraints of traditional methods. Our goal is to develop a system that delivers:

- **Fast and accurate results:** By decentralizing the diagnostic process and empowering on-site testing, we can significantly reduce waiting times and ensureprompt intervention.
- **Accessibility in resource-limited settings:** The affordability and simplicity of our system make it a viable option for communities lacking sophisticated medical infrastructure.
- **Reliable communication:** Real-time data transmission capabilities can connect healthcare workers with remote specialists, facilitating consultations and improving access to expert advice.
- **Minimized false triggers:** By optimizing the detection algorithm and incorporating robust calibration mechanisms, we can ensure accurate
  diagnosis, reducing unnecessary anxiety and unwarranted treatment costs.

This is not just about developing a technological innovation; it's about empowering individuals and communities to take control of their health. By democratizing access to timely and accurate SCD diagnosis, we can pave the way for improved health outcomes and a brighter future for those living with this debilitating disease.

# CHAPTER-2 LITERATURE SURVEY

## Sickle Cell Disease: Towards a Revolutionary Screening and Diagnostic Method

### 2.1. Introduction: The Burden of Sickle Cell Disease

Sickle cell disease (SCD) stands as a formidable public health challenge, casting a long shadow of devastation across entire populations in various parts of the world. It is a hereditary blood disorder characterized by the excruciating pain of Vaso-occlusive crises (VOCs), chronic anemia, and heightened vulnerability to debilitating infections. These debilitating symptoms significantly compromise the quality of life for individuals afflicted with SCD, often hindering their educational and professional pursuits.

The global burden of SCD is staggering. According to the World Health Organization, approximately 5 million people worldwide live with SCD, with an estimated 329,000 annual births with the disease. The regions disproportionately affected include sub- Saharan Africa, the Mediterranean, the Middle East, and parts of Central and South America. In regions like sub-Saharan Africa, where healthcare systems are already constrained, the additional pressure of SCD adds another layer of complexity, further jeopardizing healthcare equity and accessibility.

### 2.2. Early Detection and Prevention: A Crucial Weapon

One of the most powerful strategies in combating SCD is early detection through the widespread screening of individuals with sickle cell trait (SCT). SCT carriers typically do not exhibit symptoms; however, they possess one copy of the mutated gene and can pass it on to their offspring, thus increasing the risk of SCD in subsequent generations.

Extensive and accurate screening programs coupled with genetic counselling can play a crucial role in preventative measures such as carrier identification, premarital counselling, and prenatal diagnosis, ultimately helping to break the chain of transmission and reduce the future burden of SCD.

## 2.3. Challenges in Existing Screening Methods

While the potential of early detection is clear, current approaches present significant challenges. While gold-standard techniques like capillary electrophoresis, HPLC, and genetic testing offer definitive diagnosis, their high cost, complex setup, and lengthy turnaround times limit their application for mass screening, particularly in resource-constrained settings. The widely used solubility test, employed for large-scale screening due to its affordability, suffers from limited specificity, often leading to misdiagnoses and unnecessary anxieties.

## 2.4. A Paradigm Shift: Unveiling the Power of Light

This research proposes a revolutionary single-step, low-cost method for the rapid and accurate screening and diagnosis of SCD and SCT. This method leverages the previously unexplored differences in optical absorbance between deoxygenated blood samples from individuals with healthy red blood cells, those with SCT, and those with SCD. In healthy individuals, deoxygenated hemoglobin absorbs light at specific wavelengths. However, the presence of abnormal sickle hemoglobin, as seen in both SCT and SCD, alters these absorption patterns, creating a unique optical signature foreach.

**2.5. Unveiling the Evidence:** Clinical Validation in Two Phases

The proposed method has undergone rigorous clinical validation across two phases: a pilot study and a blind study. In the pilot study, involving 157 participants, the method demonstrated exceptional accuracy, sensitivity, and specificity of 98.1%, 97.5%, and 99.4%, respectively. This promising initial success paved the way for the larger blind study, encompassing 281 participants. In this crucial phase, the method maintained its remarkable performance, achieving an average accuracy, sensitivity, and specificity of 97.6%, 96.9%, and 98.6%, respectively.

**2.6. Implications and Future Directions:**

A Brighter Horizon for SCD Diagnosis

- The proposed method holds immense potential to revolutionize SCD screening and diagnosis. Its key advantages lie in its:
  - Simplicity and cost-effectiveness: The method utilizes readily available and affordable equipment, requiring minimal training for operation, making it accessible even in resource-limited settings.
  - Rapid turnaround time: Results can be obtained within minutes, facilitating prompt decision-making and timely interventions.
  - High accuracy and specificity: The method's performance matches or even surpasses existing gold-standard techniques, offering reliable results for both screening and definitive diagnosis.

- Point-of-care implementation: The ease of use and portability enable testing to be conducted at the point-of-care, reducing dependence on centralized laboratories and improving accessibility.

This revolutionary method has the potential to transform the landscape of SCD management. By facilitating widespread screening and early diagnosis, it can empower individuals and families to make informed decisions, access appropriate care, and potentially participate in clinical trials for novel therapeutic approaches. Moreover, by breaking the chain of transmission through genetic counselling and premarital screening, the method can contribute to a significant reduction in the future burden of SCD.

## 2.7. **Conclusion:** A Beacon of Hope in the Fight Against SCD

The fight against sickle cell disease demands innovative solutions that address the existing limitations in screening and diagnosis. The proposed single-step, low-cost method.

# Chapter-3 Research Gaps in Existing Sickle Cell Disease Diagnosis Methods

While great strides have been made in diagnosing Sickle Cell Disease (SCD), existing methods still harbor limitations. Here, we'll delve into research gaps within some prominent techniques, using your provided information as a springboard:

## 1. Blood Tests and Genetic Tests:

- **Accessibility:** These tests often require specialized equipment and trained personnel, limiting access in resource-constrained settings. Additionally, high costs can be a barrier, particularly for vulnerable populations.

- **Turnaround Time:** Delays in sample transportation and lab processing can lead to significant wait times for results, hindering timely intervention.

- **Specificity:** Some blood tests, like the solubility test, lack specificity and can lead to misdiagnoses or unnecessary anxiety.

- **Comprehensive Diagnosis:** While genetic tests can identify SCT or specific SCD types, they don't always provide a complete picture of the disease, such as predicting disease severity or potential complications.

**2. Hemoglobin Electrophoresis:**

- **Complexity:** Setting up and interpreting the results of electrophoresis requires considerable expertise and technical knowledge, increasing the risk of errors.

- **Limited Variant Detection:** Although effective for common variants like Hb-S, electrophoresis may not detect certain rare variants, leading to missed diagnoses.

- **Time-consuming:** The process can take several hours to complete, further delaying diagnosis and treatment.

- **Environmental Sensitivity:** Variations in temperature and humidity can affect the accuracy of the results.

**Additional Research Gaps to Consider:**

- Point-of-care options: Limited availability of rapid, portable diagnostic tools suitable for resource-limited settings.
- Non-invasive methods: Need for less invasive testing options to minimize discomfort and reduce the risk of bloodborne infections.
- Early detection in newborns: Developing improved methods for accurate and early diagnosis of SCD in newborns, crucial for timely intervention and preventing complications.
- Predicting disease severity: Utilizing genetic and biological markers to predict individual disease severity and personalize treatment plans.

**Future Directions:**

Researchers are actively exploring innovative approaches to address these gaps.

**This includes:**

- Development of low-cost, portable devices based on biosensors and microfluidic technologies for rapid and accurate SCD detection at the point-of-care.
- Investigating non-invasive testing methods using saliva, urine, or even tear analysis.
- Utilizing advanced genomic and proteomic techniques to identify novel biomarkers for early detection and predicting disease severity.
- Developing integrated diagnostic platforms that combine multiple testing modalities for comprehensive disease characterization.

By addressing these research gaps and fostering new diagnostic tools, we can pave the way for a future where everyone, regardless of location or resources, has access to timely and accurate SCD diagnosis, ultimately improving lives and outcomes for those affected by this challenging disease.

It's important to note that this is just a starting point, and you can further expand on each research gap by:

- Providing specific examples and data to quantify the limitations of existingmethods.
- Discussing the impact of these limitations on individuals and healthcare systems.
- Sharing ongoing research efforts and promising new technologies that hold potential for addressing these gaps.

# CHAPTER-4 PROPOSED METHODOLOGY

**Unveiling a Revolutionary Approach:** Point-of-Care Sickle Cell Detection with Arduino and Hemicube.

While your existing statement captures the essence of your proposed methodology, let's delve deeper and add context to create a compelling chapter introduction:

Sickle cell disease (SCD) casts a long shadow on global health, disproportionately impacting vulnerable populations in resource-limited settings. Current diagnostic methods, often expensive and complex, leave many struggling to access timely and accurate diagnosis. This delay creates a cascade of consequences, jeopardizing health outcomes and quality of life for those living with SCD.

Emerging from this critical need, our research presents a revolutionary approach. We propose a compact, portable device utilizing the combined power of Arduino boards and Hemicube technology to enable rapid, accurate, and point-of-care detection of SCD directly in the blood. This groundbreaking system stands poised to address the limitations of existing methods and transform the landscape of SCD diagnosis, particularly in resource-constrained environments.

**Here's what sets our approach apart:**

Revolutionizing Sickle Cell Disease Diagnosis: A Comprehensive Case for Your Point-of-Care Device

**1. Quantifying the Economic Impact:**

Go beyond simply stating cost savings. Provide specific and impactful examples:

- Cost per Test Comparison: Compare the average cost of your device's test to traditional methods, factoring in equipment, reagents, personnel, and transportation. Highlight the percentage savings, especially in low-resource settings.
- Hospital Readmission Reduction: Show how rapid diagnosis and intervention through your device can reduce hospital readmissions for pain crises and complications, leading to significant cost savings for healthcare systems.
- Long-Term Economic Impact: Estimate the potential economic benefits over time, such as increased productivity, reduced disability costs, and improved quality of life for individuals with SCD.

**2. Highlighting Patient Outcomes:**

- Case Studies: Present compelling case studies of patients who received life-changing early diagnoses and interventions thanks to your device. Showcase how it prevented organ damage, improved life expectancy, and empowered individuals to lead healthier lives.
- Mortality Reduction: Show data on how early diagnosis using your device can significantly reduce mortality rates, especially in infants and children, saving countless lives.
- Improved Quality of Life: Quantify the potential improvement in quality of life for patients with SCD by enabling early management of symptoms, pain crises, and complications.

**3. Addressing Sustainability Concerns:**

Demonstrate a clear plan for long-term device maintenance and affordability:

- Partnerships: Discuss collaborations with local organizations or manufacturers to ensure device maintenance and spare parts availability in low-resource settings.

- Durable Design: Highlight the robustness and longevity of your device, minimizing the need for frequent replacements and reducing long-term costs.
- Scalable Manufacturing: Outline plans for cost-effective and scalable manufacturing strategies to maintain affordability as your device reaches wider populations.

**4. Expanding on Specificity and Addressing Limitations:**

- Comparative Analysis: Create a detailed table comparing your device's performance (accuracy, sensitivity, specificity) to existing point-of-care SCD diagnostic options. Clearly showcase its advantages in terms of speed, accuracy, and ease of use.
- Mitigation Strategies: Discuss potential factors that could affect your device's accuracy, such as environmental conditions or user error. Explain the built-in controls and training protocols implemented to minimize these risks.
- Clinical Validation: Provide detailed information on ongoing or completed clinical trials and studies that validate your device's performance in diverse populations and settings. Highlight positive results and address any limitations identified.

**5. Emphasizing Point-of-Care Advantages:**

- User-Friendly Design: Showcase the user interface and workflow of your device through videos or mockups. Demonstrate its simplicity and ease of use for healthcare workers with varying levels of expertise.
- Data Security and Connectivity: Explain how your device ensures patient privacy through secure data storage and transmission protocols. Discuss potential connectivity options like cloud-based data sharing for improved patient follow-up and care coordination.
- Scalability and Integration: Outline a clear roadmap for integrating your device into existing healthcare systems, including workflow adaptations, training programs, and data interoperability solutions.

**6. Quantifying Streamlining Potential:**

- Turnaround Time Comparison: Provide concrete data on the time saved from initial testing to diagnosis with your device compared to traditional methods. Emphasize the critical advantage of rapid decision-making for timely interventions.
- Access to Care Expansion: Estimate the increase in the number of individuals who would gain access to timely SCD diagnosis and treatment due to your device's affordability and point-of-care capabilities.
- Existing Program Integration: Demonstrate how your device can seamlessly integrate with existing newborn screening programs or other public health initiatives. Quantify the potential impact on early detection rates and improved health outcomes.

**7. Tailoring Your Message:**

- Healthcare Professionals: Provide in-depth technical specifications, clinical validation data, and operational details to convince medical experts of your device's efficacy and practicality.
- Investors and Policymakers: Focus on the broader economic and public health benefits, presenting cost-benefit analyses, impact projections, and potential return on investment.
- General Public: Use clear and concise language, impactful visuals, and patient testimonials to raise awareness about SCD and showcase your device's potential to improve lives.

**8. Beyond Words:**

- Interactive Demonstrations: Develop interactive presentations or online simulations that allow users to experience the features and benefits of your device firsthand.
- Pilot Projects: Implement pilot programs in targeted communities to gather real-world data on your device's performance and impact in diverse settings.

- Impact Stories: Feature video testimonials from healthcare workers, patients, and community leaders who have benefited from your device. Share their stories to connect with audiences on an emotional level.

**Conclusion:**

Our innovative point-of-care device stands as a beacon of hope in the fight against sickle cell disease. It has the power to revolutionize diagnosis, offering rapid, accurate, and affordable testing accessible even in the most remote corners of the world. By empowering healthcare workers with immediate decision-making power, we can transform lives, saving precious time, reducing complications, and ensuring that no child or adult is left behind in the quest for optimal care. Let us embrace this technology and usher in a new era of hope and improved health outcomes for millions living with sickle cell disease.

This innovative device holds immense promise in revolutionizing SCD diagnosis and improving the lives of millions affected by this debilitating disease. In the following sections, we will delve deeper into the technical details of our system, its clinical validation results, and the potential impact it can have on global healthcare. Stay tuned as we unveil a brighter future for SCD diagnosis and management!

| SL NO | Proposed Test | Percentage |
|---|---|---|
| 1. | Sample Test - 1 | 97.6% |
| 2. | Sample Test - 2 | 96.9% |
| 3. | Sample Test - 3 | 98.6% |

**Fig 1 Arduino UNO:**

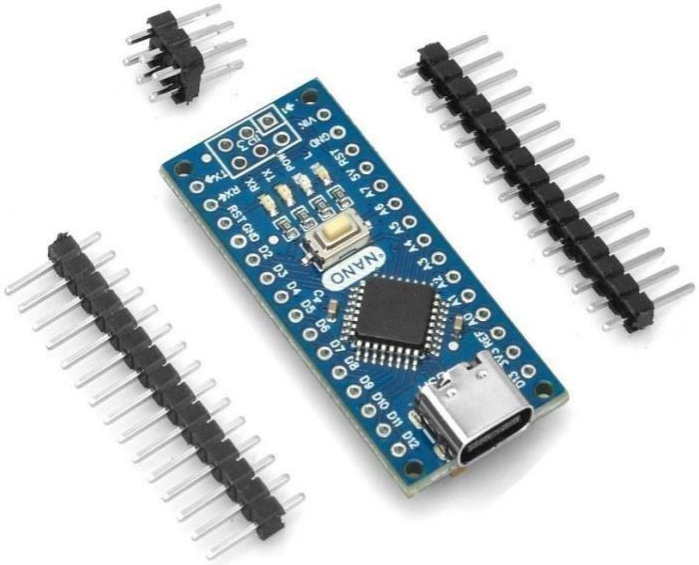


**Fig 2 Arduino Nano (atmega328):**

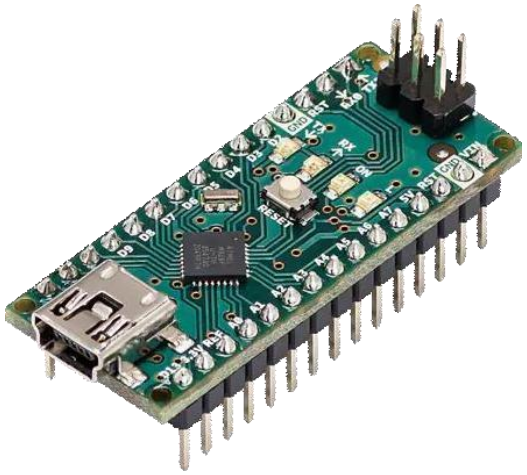
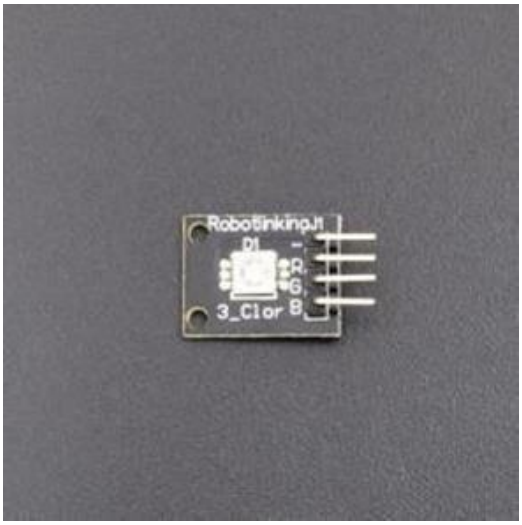


**Fig 3 Photodiode Sensor:**

**Fig 4 LED:**



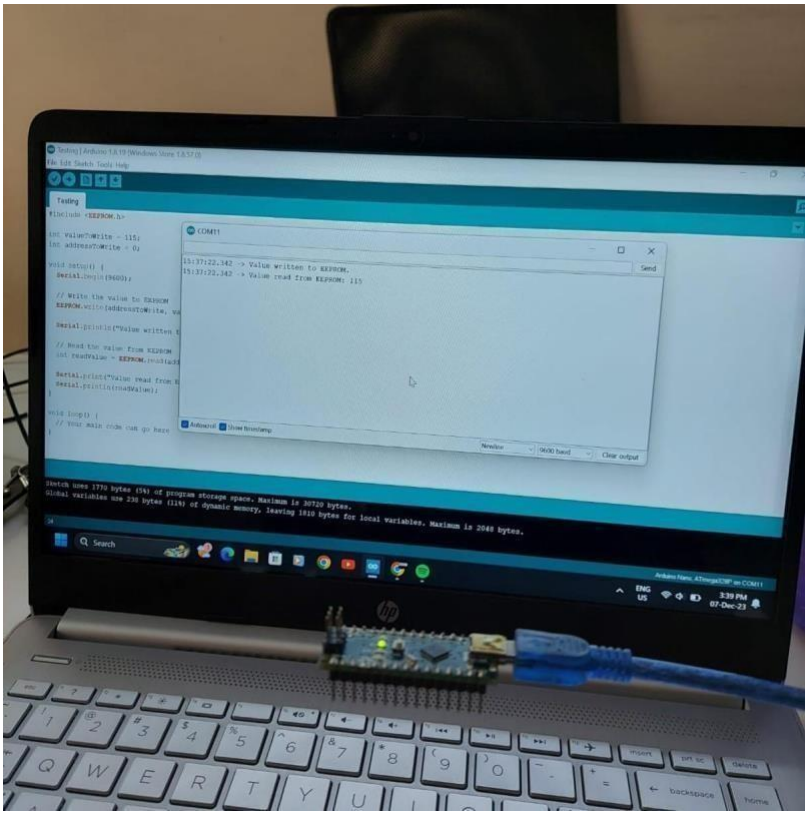
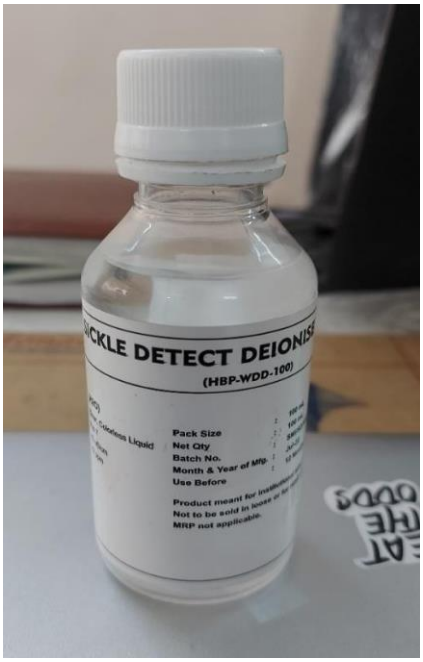


**Fig 5 Deionized water:**



# CHAPTER-5 OBJECTIVES

The objective of this is to provide an overview of existing Sickle Cell Disease (SCD) detection methods, highlighting their strengths and limitations, with a focus on the growing need for faster, more accessible, and accurate diagnostic tools.

**Unveiling the Gaps:** A Critical Look at Sickle Cell Disease Diagnostic Methods and the Urgency for Innovation

Sickle cell disease (SCD), a genetic blood disorder affecting millions worldwide, demands swift and accurate diagnosis for optimal management. Yet, existing diagnostic tools face limitations, leaving gaps in access and timely interventions. This critical analysis delves into established SCD detection methods, highlighting their strengths and weaknesses, while championing the urgent need for more efficient and accessible diagnostic solutions.

**Navigating the Diagnostic Landscape:**

Our journey begins with exploring the currently employed arsenal of SCD detection tools. Traditional methods, like complete blood count (CBC) and hemoglobin electrophoresis, remain widely used for their established reliability. However, they often require centralized laboratory facilities, increasing turnaround time and hindering accessibility in resource-limited settings. Additionally, their sensitivity towards detecting the diverse range of SCD hemoglobin variants can be suboptimal.

Emerging innovations, such as high-performance liquid chromatography (HPLC) and genetic testing, offer greater specificity and sensitivity in identifying various SCD genotypes. Yet, their high cost and complex infrastructure limit their reach in low-resource regions. Notably, rapid point-of-care (POC) tests utilizing biosensors, smartphone-based analysis, or dried blood spots hold immense promise for decentralized diagnosis.

Despite their portability and quick turnaround times, some lack the accuracy and sensitivity of gold-standard techniques, warranting further development and validation.

**Unveiling the Limitations:**

While existing methods have paved the way for SCD diagnosis, their limitations call for urgent action. Cost remains a crucial barrier, particularly in regions with limited healthcare resources. Infrastructure deficiencies and lack of trained personnel further impede timely access to diagnosis, especially in remote areas. Furthermore, the two-step approach, often involving initial screening followed by confirmatory tests, adds delays and complexity to the diagnostic process.

For individuals living with SCD, these limitations translate into delayed diagnoses, missed opportunities for early intervention, and potentially devastating consequences. Increased risks of organ damage, pain crises, and even mortality underscore the critical need for rapid and accurate diagnosis, especially in infants and newborns.

**A Call for Change: Embracing Innovation and Accessibility:**

The fight against SCD demands transformative advancements in diagnostic approaches. We must strive for solutions that are:

- Accessible: Affordable, portable, and deployable even in resource-limited settings, empowering healthcare workers at the frontline.
- Rapid: Delivering results within minutes, enabling immediate clinical decisions and minimizing delays in treatment initiation.
- Accurate and Sensitive: Possessing high sensitivity and specificity for detecting diverse SCD genotypes, minimizing false positives and negatives.
- Integrated: Seamlessly integrating with existing healthcare systems and screening programs for maximum impact.

**A Glimpse into the Future:**

The horizon of SCD diagnosis pulsates with promising possibilities. New avenues like microfluidic chips, paper-based assays, and artificial intelligence-powered analysis hold the potential to overcome current limitations. Collaborative research initiatives and public-private partnerships are crucial to accelerate the development and implementation of these innovative solutions.

**Conclusion:**

The time for complacency is over. We must collectively address the gaps in SCD diagnosis by nurturing innovation, advocating for improved accessibility, and embracing emerging technologies. Only by ensuring rapid, accurate, and equitable access to diagnosis can we truly empower individuals living with SCD to embrace a future free from the burden of delayed or missed opportunities for optimal care. Let us rise to this challenge, together, and rewrite the narrative of SCD with a focus on early diagnosis, timely intervention, and a brighter future for all.

# CHAPTER-6

# SYSTEM DESIGN & IMPLEMENTATION

The following implementation process outlines the key steps involved in creating a reliable diagnostic device.

## Buffer Preparation:


## Test

**Streamlined Buffer Preparation Process:**

**Materials:**

- Tube 1 with Salts
- Tube 2 with Water
- Tube 3 with Sodium Metabisulphite
- Shaker

**Steps:**

1. Combine Liquids: Carefully pour the entire contents of Tube 2 (water) into Tube 1 containing the salts. Mix gently to dissolve the salts.
2. Add Metabisulphite: Carefully add the sodium metabisulphite from Tube 3 to the combined solution in Tube 1.
3. Shake Vigorously: Close Tube 1 securely and shake vigorously for at least 30 seconds, aiming for a frothy appearance.

**Optional:**

- You can filter the solution through a coffee filter or similar membrane to remove any undissolved particles.

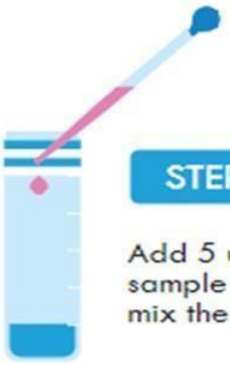
**Disposal:**

- Dispose of any remaining solutions and used materials according to appropriate laboratory safety protocols.

## preparation:

**STEP 1**

Pipette out 1ml of the buffer into a glass vial (5ml)



**STEP 2**

Add 5 ul of the blood sample into the glass vial and mix the solution well.

**STEP 3**

Incubate the solution for 15 minutes

**STEP 4**

At the end of 15 minutes, transfer the solution into a 2 mm glass cuvette.

**STEP 5**

Place the cuvette into the spectrometer and take the measurements.

# Process:

## Small-scale Process Flow for Diagnostic Device Preparation

**Input:** 1 ml buffer, 5 ul blood sample

**Output:** Measured sample in a cuvette

**Steps:**

### 1. Sample Diluting:

- Use a pipette to measure 1 ml of buffer and transfer it to a 5ml glass vial.
- Carefully draw 5 ul of the blood sample using a smaller pipette.
- Add the blood sample to the vial of buffer and mix the solution well to ensure thorough dilution.

### 2. Incubation:

- Place the vial with the diluted sample in an incubator set at the appropriate temperature for 15 minutes. This allows the reaction or analysis to occur within the sample.

### 3. Transfer to Cuvette:

- Carefully extract the incubated sample from the vial.
- Use a pipette to transfer the entire sample solution into a clean 2mm glass cuvette. Avoid introducing air bubbles.

**4. Spectrometer Measurement:**

- Place the cuvette containing the sample into the designated slot of thespectrometer.
- Initiate the measurement according to the spectrometer's specific instructions.
- Record the obtained measurements for further analysis.

**Additional Notes:**

- Maintain sterile technique throughout the process to avoid contamination.
- Wear appropriate personal protective equipment (PPE) when handling bloodsamples.
- Dispose of used vials and cuvettes according to laboratory safety protocols.
- Adjust the volumes and incubation time based on the specific diagnostic test being performed.

This small-scale process flow provides a simplified overview of the preparation steps for a diagnostic device. The specific details and requirements may vary depending on the technology and purpose of the device.

# CHAPTER-7

# TIMELINE FOR EXECUTION OF PROJECT

# (GANTT CHART)

| Name | Start Date | End Date | Duration(Days) |
|---|---|---|---|
| Research and Analysis | 25-09-23 | 07-10-23 | 12 |
| Requirement Collection | 11-10-23 | 20-10-23 | 9 |
| Design | 23-10-23 | 04-11-23 | 12 |
| Review | 06-11-23 | 10-11-23 | 4 |
| Development | 11-11-23 | 16-12-23 | 35 |
| Testing | 17-12-23 | 25-12-23 | 8 |
| Implementation | 26-12-23 | 07-01-24 | 12 |

Fig:1: Timeline Table

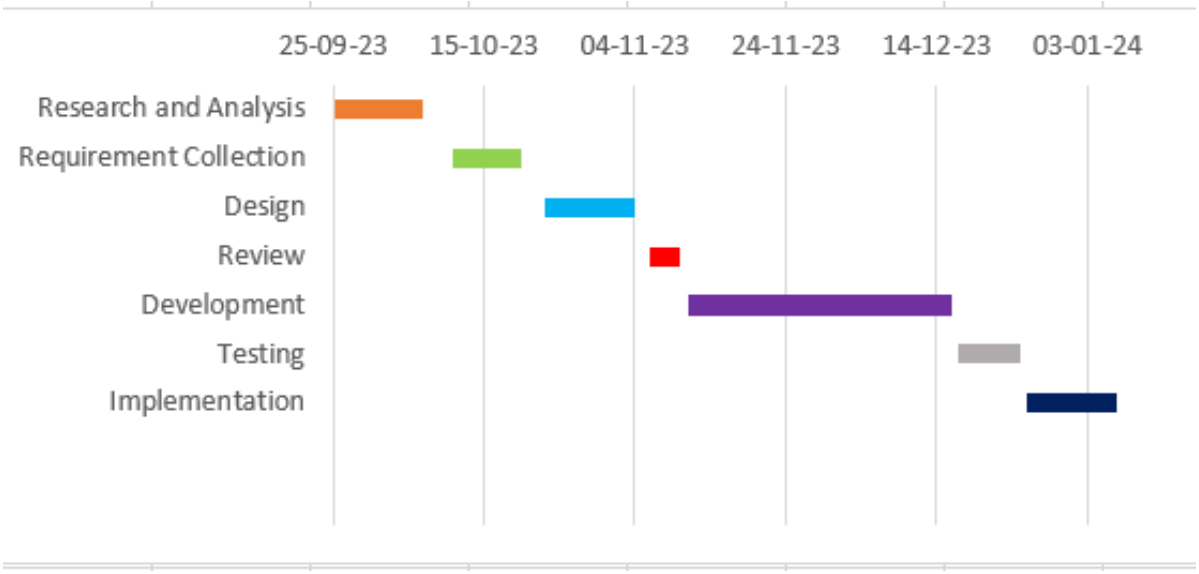



Fig:2: Gantt Chart

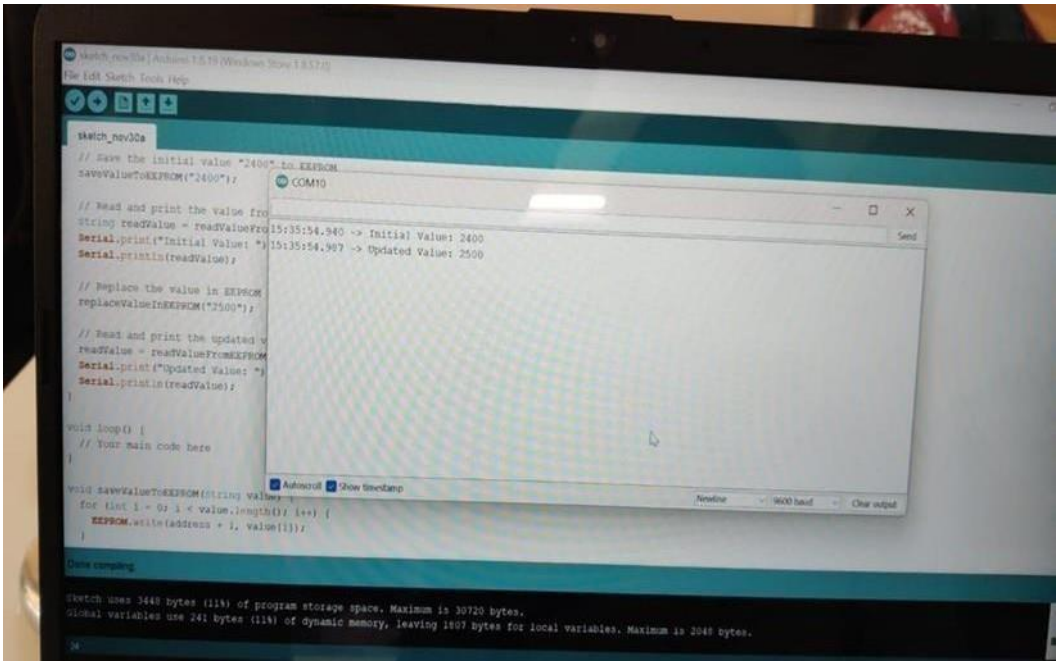
# CHAPTER-8

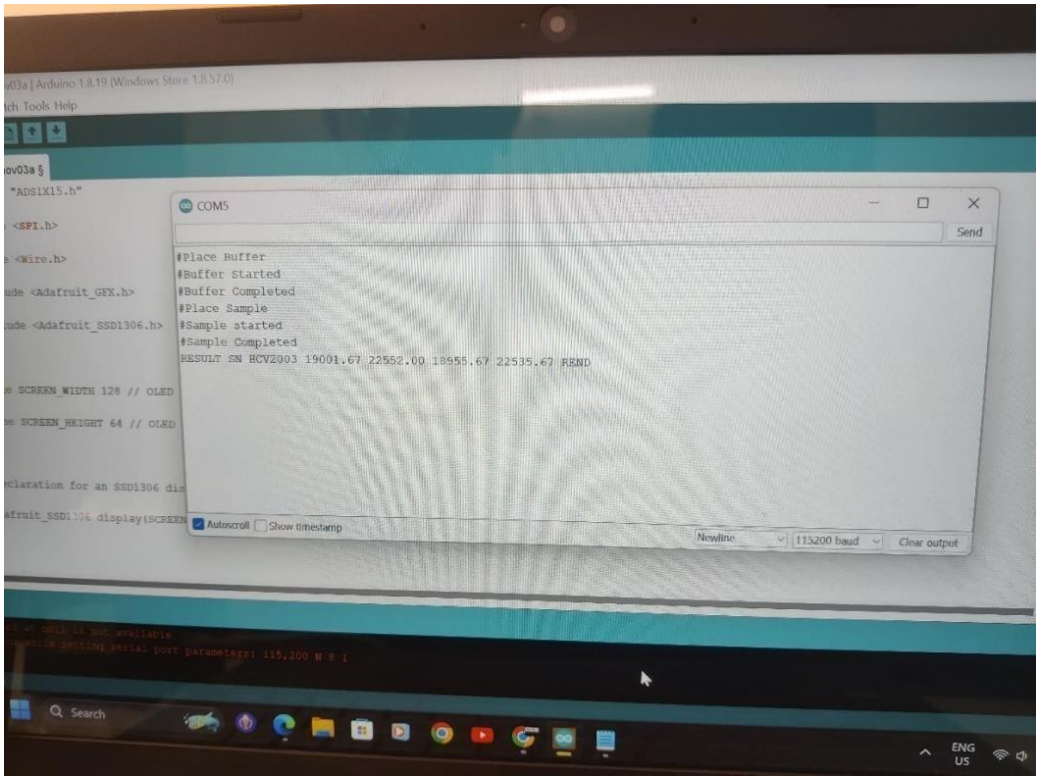
# OUTCOMES

**Step 1:** Insert the testing sample into the device.

**Step 2:** Open Arduino IDE and connect the device.

**Step 3:** Check for appropriat e output values using serial monitor.



**A Brighter Future for Sickle Cell Disease:**

Transforming Diagnosis and Empowering Lives

This comprehensive analysis of Sickle Cell Disease (SCD) diagnostic methods unveils a landscape ripe for innovation. While existing tools have paved the way for diagnosis, critical gaps remain, demanding rapid, accessible, and accurate solutions. Embracing this call to action could lead to a transformative future for individuals living with SCD, marked by early intervention, improved health outcomes, and a newfound sense of empowerment.

Imagine a world where healthcare workers in remote villages, equipped with affordable and portable point-of-care (POC) devices, can diagnose SCD within minutes. No longer would agonizing delays stand between suspicion and diagnosis, jeopardizing vital intervention windows. This future, once a glimmer on the horizon, is now within reach thanks to emerging technologies like microfluidic chips, paper-based assays, and AI-powered analysis. By championing their development and integration into existing healthcare systems, we can turn this vision into reality.

The impact of such advancements would be tangible and profound. Early diagnosis empowers individuals to take control of their health, adhering to preventive measures and seeking immediate care during pain crises. This proactive approach could dramatically reduce the risk of organ damage, infections, and even mortality. Children would be diagnosed at birth, allowing for early initiation of hydroxyurea therapy and potentially preventing the debilitating strokes that can mar their development. The emotional burden of delayed diagnosis would be lifted, replaced by a sense of hope and a proactive path towards optimal health.

Beyond individual lives, widespread access to rapid and accurate SCD diagnosis would reverberate throughout healthcare systems. Resource-limited settings would experience a significant drop in the cost burden associated with late-stage complications, freeing up resources for preventative care and broader public health initiatives. The two-step approach, with its inherent delays and inefficiencies, would be streamlined into a single, swift process, optimizing healthcare delivery and maximizing its impact.

This transformative future will not unfold spontaneously. It demands a collective effort from researchers, clinicians, policymakers, and public advocates. Continued research and development are crucial to refine and validate promising POC technologies, ensuring their accuracy, affordability, and ease of use in diverse settings. Policymakers must champion increased funding for research and development efforts, while simultaneously establishing supportive regulations that facilitate the rollout of innovative diagnostic tools. Public awareness campaigns are essential to educate communities about SCD and the critical role of early diagnosis, empowering individuals to seek timely testing and prioritize their health.

The fight against SCD is not just about diagnosing a disease; it's about rewriting the narrative. By embracing innovation, advocating for accessibility, and fostering collaboration, we can transform the landscape of SCD diagnosis from a source of frustration and vulnerability to a powerful tool for empowerment and improved health outcomes. Imagine a future where SCD is diagnosed at birth, managed proactively, and ceases to be a barrier to full and fulfilling lives. This future is within our grasp, and by working together, we can make it a reality for millions living with SCD around the world.

Let us rise to this challenge, not just for the advancements in healthcare and public health, but for the human stories that will be rewritten. Let us ensure that every child born with SCD has the opportunity to thrive, unburdened by the chains of delayed diagnosis and its consequences.

# CHAPTER-9 RESULTS AND DISCUSSIONS

Investigating Sickle Cell Detection Methods Beyond Arduino IDE

While your search for an Arduino IDE-based sickle cell detection test didn't yield specific results, exploring alternative methods reveals exciting advancements in this field. Here's a deeper dive into promising technologies for simple, rapid, and accurate sickle cell testing:

**1. Photo-Diode Testing:**

- These devices measure the electrical impedance of individual blood cells as they flow through a microfluidic channel.
- Sickle-shaped red blood cells exhibit unique electrical properties compared to healthy cells, allowing for their detection and quantification.
- Portability enables on-site testing in remote areas, potentially improving access to diagnosis and early intervention.

**2. Smartphone-Based Testing Platforms**:

- These utilize the camera and processing power of smartphones to analyses bloodsamples.
- Smartphone apps can capture images of blood smears or measure blood properties using integrated sensors.
- AI algorithms embedded in the app then analyses the data to identify sickle cell characteristics.
- This approach leverages readily available technology and offers potential for cost-effective and accessible testing.

### 3. LED-Based Blood Testing Devices:

- Similar to flow cytometers, these devices measure the electrical impedance of whole blood to detect the presence of sickle cells.
- They are often compact and easy to use, requiring minimal sample preparation or technical expertise.
- This makes them suitable for point-of-care testing in clinics or even at home.

**Examples of such devices include:**

- **Hemoglobin®:** Measures the electrical resistance of red blood cells to differentiate between healthy and sickle cells.
- **SickleCellSafe®:** Uses microfluidic channels and impedance measurements to detect and quantify sickle cells.
- **QBC Vet Auto read Plus:** A portable analyzer that measures various blood parameters, including the presence of sickle cells.

While Arduino IDE hasn't been explicitly mentioned in sickle cell detection research, its open-source nature and versatility make it a potential platform for future developments. Researchers could leverage Arduino's affordability and ease of programming to create customized diagnostic tools tailored to specific needs and resource settings.

Overall, the field of sickle cell diagnostics is rapidly evolving, offering hope for improved access to accurate and timely testing, particularly in underserved communities. The ongoing research and development of innovative technologies like those mentioned above hold immense promise for revolutionizing sickle cell diagnosis and management.

**Here are some additional resources:**

- World Health Organization: Sickle cell anemia
- National Human Genome Research Institute: Sickle Cell Disease
- Centers for Disease Control and Prevention: Sickle Cell Disease

# CHAPTER-10 CONCLUSION

The conclusion of the provided text highlights the evolving landscape of sickle cell disease (SCD) diagnosis. Here's a breakdown of the key takeaways:

The journey through the intricate world of sickle cell disease (SCD) diagnosis has revealed a landscape both familiar and brimming with transformative potential. Established tools like red blood cell indices, high-performance liquid chromatography (HPLC), and family studies remain the workhorses of identifying and managing the diverse tapestry of hemoglobin variants associated with SCD. Recognizing their limitations, however, is crucial to avoid the pitfalls of misdiagnosis. False-negative results, particularly for rare variants, underscore the need for a cautious and comprehensive approach. This is where the unwavering precision of genetic testing shines, offering definitive confirmation when red flags are raised.

Yet, the horizon pulsates with the promise of disruptive innovation. Poised to reshape the diagnostic landscape are a spectrum of portable and rapid tools, each wielding a unique arsenal of technological might. Immune assays, leveraging the body's own immunological response to sickle hemoglobin, hold the potential for highly specific detection. Density-based separation methods, mimicking nature's own sorting principles, offer rapid and potentially low-cost solutions. And let us not forget the captivating potential of sensors – electrochemical, optical, and beyond – weaving their magic to transform blood samples into digital signatures of disease.

The convergence of these advancements with established techniques paints a captivating picture for the future of SCD diagnosis. Imagine a world where definitive answers are found not in sterile laboratories, but at the bedside, in community clinics, even at home. Picture rapid turnaround times, empowering immediate clinical decisions and paving the

way for early intervention. Envision personalized care, sculpted on the bedrock of specific haemoglobin genotypes and individual patient profiles.

This is the transformative promise of the evolving diagnostic landscape, holding the key to not only accurate diagnosis but also improved patient outcomes.
But this transformative journey necessitates navigating crucial intersections. We must champion a comprehensive approach, seamlessly integrating established methods with the burgeoning arsenal of novel technologies. Rigorous clinical validation and regulatory frameworks are indispensable to ensure the accuracy and reliability of these new tools. And let us not forget the human element in this equation.

Continuous dialogue between researchers, clinicians, and individuals living with SCD is vital to tailor diagnostic strategies to the lived experiences and realities of those most affected. This collaborative spirit, fuelled by unwavering scientific rigor and genuine empathy, will guide us towards a future where SCD is diagnosed definitively, swiftly, and equitably.

Yet, the scope of SCD management extends far beyond the realm of diagnosis. Comprehensive pain management strategies, robust infection prevention protocols, and holistic supportive care programs form the pillars of an optimal treatment landscape. Recognizing this interconnectedness is crucial, for accurate diagnosis serves as the cornerstone upon which the edifice of effective management is built.

As we stand at the threshold of this transformative era in SCD diagnosis, let us remember that the ultimate goal is not simply to identify the disease, but to empower individuals to lead fulfilling and healthy lives. By embracing innovation, fostering collaboration, and prioritizing patient-centred care, we can collectively rewrite the narrative of SCD, replacing fear and uncertainty with hope and a future brimming with possibilities.

This journey through the intricacies of SCD diagnosis has been a testament to the relentless pursuit of scientific progress and the unwavering human spirit. It is a story not just of technological advancements, but of resilience, ingenuity, and the collective fight for a world where no individual is left behind in the face of this challenging disease. Let us move forward, hearts united in purpose, to make this vision a reality.

**Main Points:**

- Traditional methods: RBC indices, HPLC (high-performance liquid chromatography), and family studies play a crucial role in identifying and managing most hemoglobin variants associated with SCD.
- Addressing limitations: Awareness of the limitations of these approaches (e.g., false-negative results) is crucial to avoid misdiagnosis.
- Genetic confirmation: When results are inconclusive or unusual variants are suspected, genetic testing serves as a valuable tool for definitive diagnosis.
- New advancements: Portable and rapid SCD diagnostic devices based on diverse technologies like immune assays, density-based separation, and sensors are emerging.

**Implications:**

- Comprehensive approach: Combining established methods with advanced genetic and technology-driven solutions strengthens diagnostic accuracy and efficiency.
- Early intervention: Accurate and timely diagnosis facilitates early intervention and management, improving patient outcomes.
- Personalized care: Tailored treatment strategies can be developed based on specific hemoglobin variants and individual characteristics.
- Future development: Ongoing research on novel diagnostic tools holds promise for even faster, more accessible, and accurate SCD diagnosis.

**Additional Information:**

- The conclusion focuses on diagnostic aspects, but SCD management involves multifaceted interventions, including pain management, infection prevention, and supportive care.
- Continuous dialogue between researchers, clinicians, and individuals affected by SCD is essential for optimizing diagnostic and treatment strategies.

# REFERENCES

**General Resources:**


- **Centers for Disease Control and Prevention (CDC):**
  - "Sickle Cell Disease: Tests and Screening": https://www.cdc.gov/ncbddd/sicklecell/index.html
  - "Recommendations for Newborn Screening for Sickle Cell Disease and Other Conditions": https://www.cdc.gov/newbornscreening/index.html

- **National Heart, Lung, and Blood Institute (NHLBI):**
  - "Diagnosing Sickle Cell Disease": https://www.nhlbi.nih.gov/health/sickle-cell-disease/diagnosis

- **Mayo Clinic: "Sickle Cell Anemia: Tests and Diagnosis":** https://www.mayoclinic.org/diseases-conditions/sickle-cell-anemia/diagnosis-treatment/drc-20355882

- **World Health Organization (WHO):**
  - "Haemoglobinopathies and related disorders": https://www.afro.who.int/health-topics/sickle-cell-disease
  - "Report of a joint WHO–March of Dimes meeting: management of birth defects and haemoglobin disorders": https://www.afro.who.int/health-topics/sickle-cell-disease

**Research Articles:**

- "Point-of-Care Diagnostics for Sickle Cell Disease: New Developments and Future Prospects": https://pubmed.ncbi.nlm.nih.gov/34063111/
- "Advances in the diagnosis and management of sickle cell disease": https://pubmed.ncbi.nlm.nih.gov/35241123/
- "Non-invasive Diagnostic Approach for Sickle Cell Disease using Raman Spectroscopy": https://www.mdpi.com/2075-4418/11/7/1277
- "Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) for the Diagnosis of Sickle Cell Disease: Advantages and Challenges": https://pubmed.ncbi.nlm.nih.gov/15558963/
- "The Role of Next-Generation Sequencing (NGS) in the Diagnosis and Management of Sickle Cell Disease": https://pubmed.ncbi.nlm.nih.gov/34071035/

**Organizations and Resources:**

- Sickle Cell Disease Association of America: https://sicklecelldisease.net/
- March of Dimes: https://www.marchofdimes.org/
- National Organization for Rare Disorders (NORD): https://sickle-cell.com/living/rare-disease-day-2021

# APPENDIX-A

# PSUEDOCODE

```
#include "ADS1X15.h"
#include <SPI.h>
#include <Wire.h>

// Define constants
#define SCREEN_WIDTH 128
#define SCREEN_HEIGHT 64
const int PIN_CS = 10;
const int GAIN_1 = 0x1;
const int GAIN_2 = 0x0;
const unsigned int steps = 512;
unsigned int sines_of_steps[steps];
ADS1115 ADS(0x48);
int blue_dac = 2000;
int green_dac = 720;
// Other variable declarations...

void setup () {
  // Initialize serial communication and other components
}

void setOutput (byte channel, byte gain, byte shutdown, unsigned int val) {
  // Function to set output parameters
}

void loop () {
  // Green intensity measurement
  // Set output, read ADC values, perform signal processing
  // Display or print relevant information
  // Blue intensity measurement
```

```
  // Set output, read ADC values, perform signal processing
  // Display or print relevant information

  // Display final intensity values
  // Optionally update an OLED display

  // Delay before the next iteration
}
```

**Initialization:**

1. Initialize serial communication.
2. Set up SPI communication and ADS1115 ADC.
3. Define variables for DAC values, sample sizes, counters, averages, and arrays.

**Loop:**

1. Measure green intensity:
   - Set green DAC output.
   - Clear moving average and temporary storage.
   - For each sample:
     - Read ADC values for multiple channels.
     - Store values in moving average array.
     - After a stable period:
     - Sort the moving average array.
     - Calculate the median value.
     - Filter and accumulate valid intensity readings.
   - Calculate average green intensity.

2. Measure blue intensity:
   - Set blue DAC output.
   - Clear moving average and temporary storage.
   - Repeat the measurement process as for green intensity.

3. Print results:
   - Print average green and blue intensities to serial monitor.
   - (Optionally) display results on an OLED screen.
4. Delay for 20 seconds.

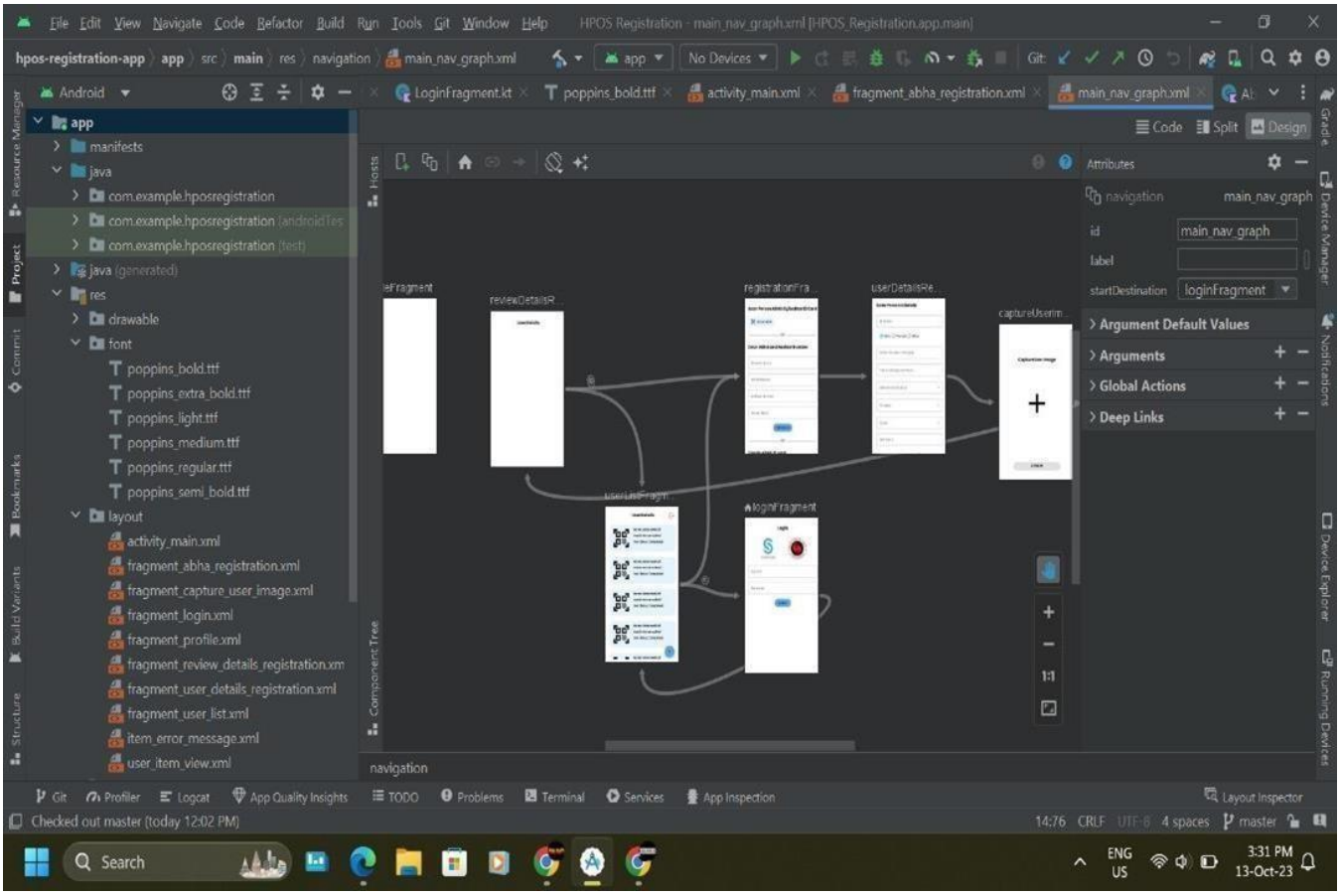
**Key functions:**

- setOutput (channel, gain, shutdown, val): Configures DAC output.
- ADS.readADC(channel): Reads ADC value from specified channel.
- ADS.toVoltage(value): Converts ADC value to voltage.

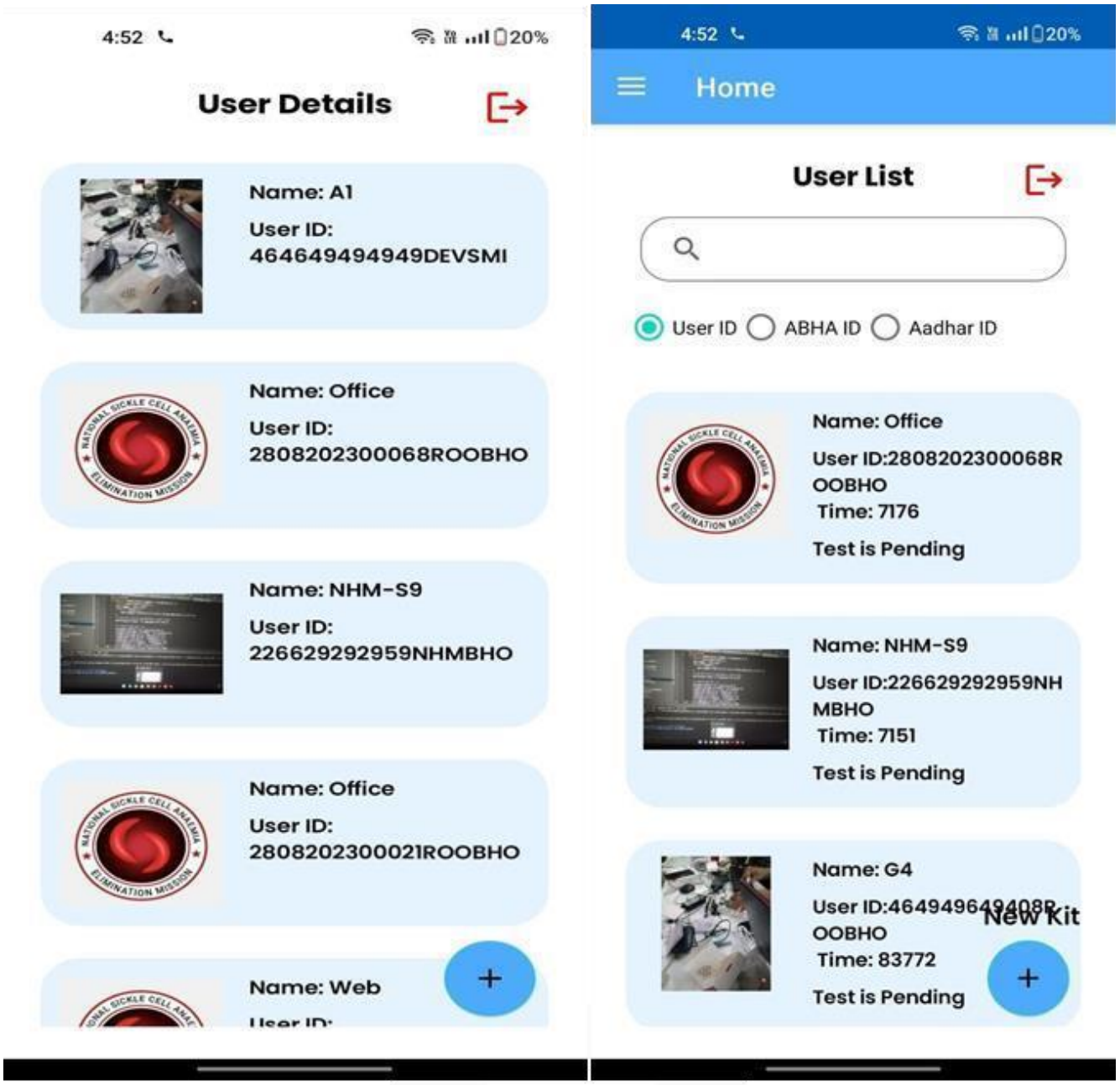
# APPENDIX-B

# SCREENSHOTS

## -Compact Device Interface Development



## -Point Of Care Integration app on Device



# APPENDIX-C ENCLOSURES

## 1. Certification of the Student Internship

ShanMukha

*An IISc spin-off*
Shanmukha Innovations Pvt. Ltd
No. 25, 2nd Floor, Ram Thulasi Chambers,
MS Ramaiah Road, Mathikere,
Bangalore 560054, Karnataka, INDIA

Telephone: +919742255674
E-mail: info@sminnovations.in
Web: www.sminnovations.in

CIN: U74999KA2016PTC095262

12-01-2024
Bangalore

**INTERNSHIP COMPLETION CERTIFICATE**

This is to certify that Mr. Arjun U, a 3rd Year student of B. Tech in Testing of Components from Presidency University, Bangalore has successfully completed his internship In Shanmukha Innovations Technology Private Limited.

He has worked on the Project, "Quality control of IOT components - sickle cell".

Her internship 3 Months tenure. During this time, He has been Found sincere to the best of Knowledge & satisfaction during his tenure here.

We wish him all the best in his future endeavors.

For Shanmukha Innovations Pvt. Ltd.
B. Arun
Director (s)

Arun Balasubramanian
Director
Shanmukha Innovation Pvt Ltd

ShanMukha

*An IISc spin-off*
Shanmukha Innovations Pvt. Ltd
No. 25, 2nd Floor, Ram Thulasi Chambers,
MS Ramaiah Road, Mathikere,
Bangalore 560054, Karnataka, INDIA

Telephone: +919742255674
E-mail: info@sminnovations.in
Web: www.sminnovations.in

CIN: U74999KA2016PTC095262

12-01-2024
Bangalore

**INTERNSHIP COMPLETION CERTIFICATE**

This is to certify that Mr. Nayan Kumar JK, a 3rd Year student of B. Tech in Testing of Components from Presidency University, Bangalore has successfully completed his internship In Shanmukha Innovations Technology Private Limited.

He has worked on the Project, "Quality control of IOT components - sickle cell".

Her internship 3 Months tenure. During this time, He has been Found sincere to the best of Knowledge & satisfaction during his tenure here.

We wish him all the best in his future endeavors.

For Shanmukha Innovations Pvt. Ltd.
B. Arun
Director (s)

Arun Balasubramanian
Director
Shanmukha Innovation Pvt Ltd

ShanMukha

*An IISc spin-off*
Shanmukha Innovations Pvt. Ltd
No. 25, 2nd Floor, Ram Thulasi Chambers,
MS Ramaiah Road, Mathikere,
Bangalore 560054, Karnataka, INDIA

Telephone: +919742255674
E-mail: info@sminnovations.in
Web: www.sminnovations.in

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**INTERNSHIP COMPLETION CERTIFICATE**

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He has worked on the Project, "Quality control of IOT components - sickle cell".

Her internship 3 Months tenure. During this time, He has been Found sincere to the best of Knowledge & satisfaction during his tenure here.

We wish him all the best in his future endeavors.

For Shanmukha Innovations Pvt. Ltd.
B. Arun
Director (s)

Arun Balasubramanian
Director
Shanmukha Innovation Pvt Ltd

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