Department of Electronic and Telecommunication Engineering

University of Moratuwa

BM 2210 - Biomedical Device Design
Feasibility Report

Team Meditrones

Boralugoda.M.S - 220074B
Liyanage.D.L.B.B - 220362G
Madusanka.S.P.S - 220374U

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1. Introduction

This report details the concept generation and screening process undertaken to develop an innovative and cost-effective solution for the previously identified problem.

2. Need Statement

"There is a need for an affordable and reliable Holter monitor with a mobile app interface in Sri Lankan hospitals to improve access to continuous heart monitoring, enhance cardiac care, and address the limitations of current costly devices."

Cardiovascular diseases (CVDs) are a leading cause of mortality in Sri Lanka, yet access to consistent and affordable cardiac monitoring remains a challenge in many healthcare facilities. Continuous heart monitoring devices, such as Holter monitors, play a critical role in diagnosing irregular heart rhythms and other cardiac conditions. However, the high cost of traditional Holter monitors limits their availability, especially in resource-constrained settings like Sri Lankan government hospitals.

Recognizing this need, our start-up is developing a low-cost Holter monitor with an integrated mobile app interface. This solution aims to provide hospitals with an affordable option for continuous cardiac monitoring, while also enhancing usability through real-time data transmission to healthcare providers. By addressing both affordability and usability, our proposed device has the potential to improve cardiac care and outcomes across Sri Lanka and other resource limited settings.

3. Ideation

During the brainstorming session, various ideas were generated to address the requirements of the low-cost Holter monitor project. The session focused on identifying key needs and exploring potential solutions. The following requirements were discovered.

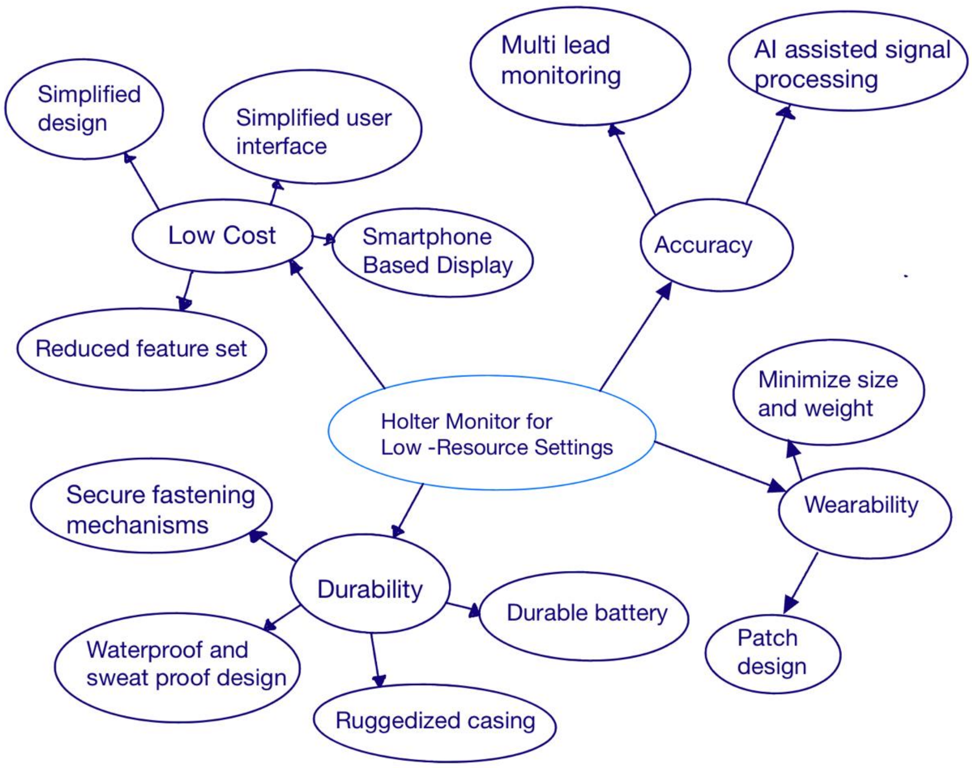

Figure 1: concept map

4. Initial Concept Selection

The success of a low-cost Holter monitor relies on minimizing cost while ensuring accuracy and durability for daily use. It must be easy to use for patients and providers, with power efficiency to minimize recharging. Enhancing wearability for comfort, ensuring scalability for mass production are also key factors for widespread adoption.
Based on the brainstorming phase, we selected a few potential concepts for the Holter monitor:

- **3-Lead, Smartphone-Dependent Monitor**: A basic single-lead ECG Holter monitor that transmits data to a smartphone app for analysis and display.

- **3-Lead Standalone Monitor**: A compact monitor with a built-in display and processing capabilities, featuring 3 ECG leads for more monitoring.

- **Patch-Type Monitor with Disposable Electrodes**: A wearable patch-style monitor that uses disposable electrodes, focusing on comfort and simplicity.
- **Multi-Lead Advanced Monitor with AI Integration**: A higher-end, multi-lead monitor that uses AI algorithms for real-time analysis and diagnosis on the device.

5. Concept Screening

5.1. Intellectual Property (IP)

Intellectual Property (IP) is a crucial factor in determining the potential competitive advantage of each concept.

5.1.1. Patentability of Technological Innovations

The **3-Lead Standalone Monitor** has moderate potential for patenting its design and methods, but it faces significant competition in the market. In contrast, the **3-Lead, Smartphone-Dependent Monitor** presents high potential for IP protection, particularly in the area of app integration and user interface design. Since the app deals with sensitive health data, it's essential to clearly outline data ownership and control. Developing a unique approach to securely handle patient data, including encryption methods or data access protocols is an IP opportunity. The **Patch-Type Monitor** with Disposable Electrodes offers moderate IP opportunities, focusing on its comfort and design; however, it must contend with existing competition. The **Multi-Lead Advanced Monitor** with AI Integration has high potential for patenting, especially concerning its AI algorithms and advanced features, which could set it apart from competitors.

Existing Patents

One example is a patent for a disposable sensor patch designed for non-invasive, long-term cardiac monitoring. These developments indicate the trend toward simple, wearable devices. It is designed to be thin, flexible, and comfortable for continuous wear on the chest, allowing for automatic ECG analysis and recording around 4 to 14 days.

Existing Patent Link

Trademarks
As we develop a distinct brand identity for our cost-effective Holter monitor, securing a trademark will protect the name and logo, ensuring it stands out in the medical technology space.

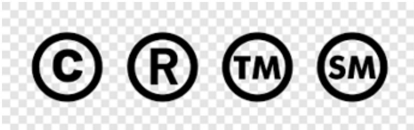

Figure 2: Trademarks

5.2. Regulation

Since our innovation deals with medical data and patient health, we must ensure that our intellectual property is in compliance with regulations. This includes the FDA (in the US) or CE marking (in Europe) for medical devices and software. Our product would likely be classified as a medium-risk medical device by the FDA. The **3-Lead Standalone Monitor** requires standard medical device certification, presenting moderate regulatory complexity. On the other hand, the **3-Lead, Smartphone-Dependent Monitor** involves more complex regulatory requirements due to its software component and the need for validation. The **Patch-Type Monitor with Disposable Electrodes** has lower regulatory hurdles because of its simpler design, making it easier to navigate the certification process. Conversely, the **Multi-Lead Advanced Monitor with AI Integration** faces high regulatory complexity due to the necessity for extensive clinical trials and validation, potentially slowing its market entry.

5.3. Business Model

The evaluation of Business Models indicates varying revenue potentials for each concept. The **3-Lead Standalone Monitor** could follow a direct sales model aimed at hospitals, offering moderate revenue potential with limited recurring income. In contrast, the **3-Lead, Smartphone-Dependent Monitor** allows for a subscription-based model for app services and potential partnerships with hospitals, maximizing its revenue potential. The **Patch-Type Monitor** with Disposable Electrodes can generate recurring revenue through the sale of disposable components, although it may command a lower price point. The **Multi-Lead Advanced Monitor with AI Integration** presents opportunities for high-value contracts and premium pricing but will require significant investment in partnerships and development.

6. Screening Matrices

6.1. Risk Scoring Matrix

Concepts	Intellectual Property (IP)	Regulation	Business Models
3-Lead Standalone Monitor			
3-Lead, Smartphone-Dependent Monitor			
Patch-Type Monitor			
Multi-Lead Advanced Monitor with AI Integration			

Figure 3: Risk scoring matrix

	Low Risk
	Moderate Risk
	High Risk

6.2. Selection Matrix

Concepts	Cost	Accuracy	Durability	Ease of Use	Power Efficiency	Wearability	Scalability	Integration with App	Total Score	Rank
3-Lead, Smartphone-Dependent Monitor	4	4	3	5	4	5	5	5	**38**	1
Patch-Type Monitor with Disposable Electrodes	5	3	3	5	4	5	5	4	**34**	2
3-Lead Standalone Monitor	3	5	4	4	3	3	3	3	**28**	3
Multi-Lead Advanced Monitor with AI Integration	2	5	3	2	2	2	2	4	**22**	4

Figure 4: concept selection

The 3-Lead, Smartphone-Dependent Monitor emerges as the most viable concept for development, followed closely by the Patch-Type Monitor with Disposable Electrodes.

7. Final Concept Selection

7.1. Prototyping

Considering the screening process 3-Lead holter monitor device with the mobile application for the user interface and the patch type monitor with disposable electrodes as two viable solutions but due the the easy access to components and due to time limitations and other constraints we decided to propose the app base low cost holter monitor as our solution.

As the initial step we plan to do the signal acquisition using a digital IC such as AD 8232 ECG Monitoring chip and use 3 electrodes alongside with it to obtain the signals from the host and the received signal is provided to MCU for further processing and analysis where we plan to use a MCU with wireless communication capabilities(ESP-32) so that the received data can be transferred to the application for the use of medical officers and this recorded data will be stored locally as well in a solid state memory such as micro-SD card.

Also we plan to implement any alterations for the prototype while testing in order to maintain standards that we proposed and to mitigate certain trade offs of the device while understanding the primary objective of our solution.

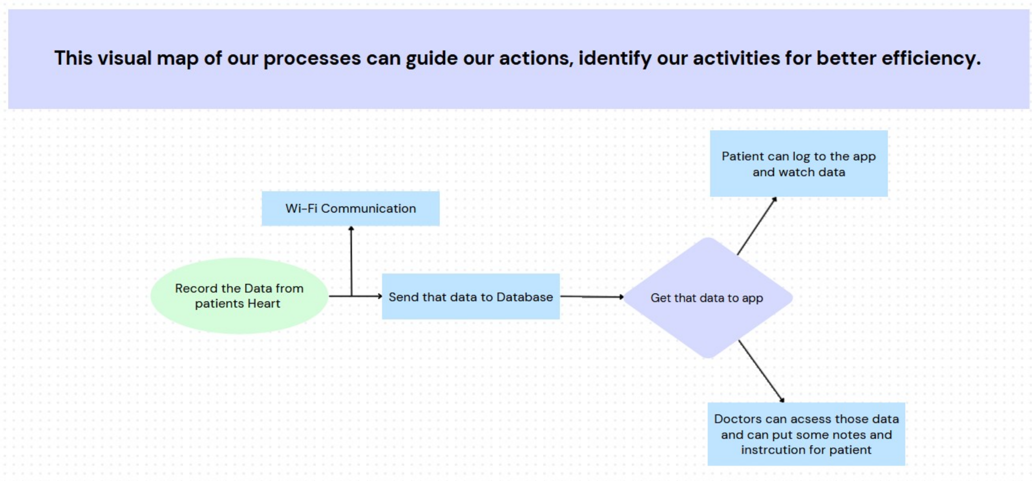

Figure 5: Methodology

The abstract model of the proposed solution is as follows:

- **Low-cost hardware integration:** Validate that the 3-lead monitor functions effectively with our app, focusing on basic recording and alert systems.
- **User Interface (UI) Prototype:** Design a, simple interface that fits the needs of both patients and doctors.
- **Database Prototype:** Ensure that all captured ECG data, including abnormal patterns, is correctly stored in a database for future reference.

Estimated Initial Budget:

- AD8232 ECG module: 1600LKR
- ESP-32 Dev module:1200LKR
- Power Source : 400LKR
- Micro-SD module: 380LKR
- Buck booster: 500LKR
- Other:1000LKR
  Initial Total cost is 5080LKR so far but we expect to increase with testing and design alterations to be made in the future in order to meet the requirements.

7.2. Technical Feasibility

The hardware components of our device fall within the capabilities achievable by second-year undergraduates, making this aspect quite feasible.Furthermore the fundamental understanding of web and application development is another strength in our team so we can develop the user interface required for the device.Therefore we are confident that this solution is technically feasible as per our capabilities.

7.3. Testing

To ensure that our device is up to the expected standards we are planning to carryout some rigorous tests and make sure the accuracy is within the expected levels and make the device simple in operation by carrying out test runs for the public so that the prior knowledge required to operate the device is minimum making it highly user friendly.

Initially we have identified the following set of testings are required for our prototype and we hope to alter them in the future depending on the status of the device and requirements.

- ECG Data Display: Ensure that 3-lead ECG data is correctly displayed and easy to review.
- Pattern Detection: Test the app's ability to detect common arrhythmia or heart abnormalities.
- Offline Functionality: Verify that the app works without an internet connection, syncing data once online.
- Data Encryption: Ensure all sensitive ECG and patient data is encrypted during storage and transmission.

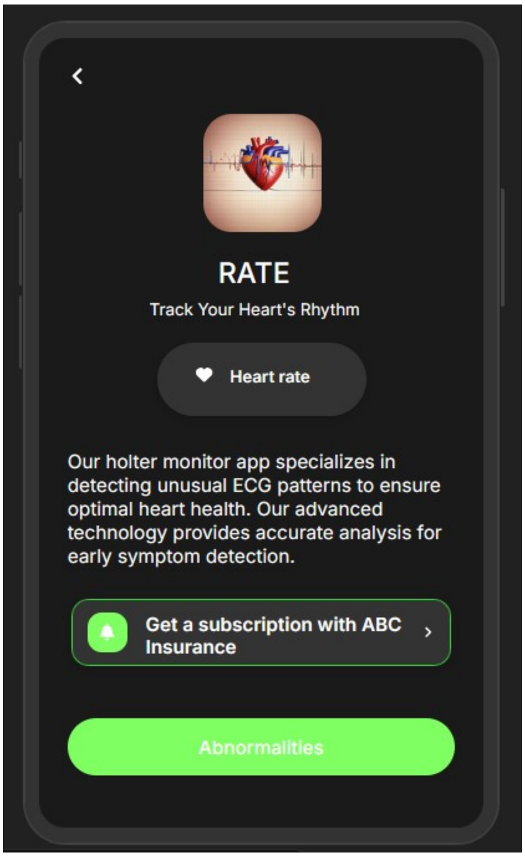

Figure 6: Proposed User Interface

8. Conclusion

In order to address the cost effectiveness and make it accessible for the patients easily we came to a conclusion that the 3 lead holter monitor with mobile app for user interface will be a potential solution and it can be seen that it is feasible in various aspects thus making this product a good opportunity for us to grow as a company as well. We are committed to meet the standards and requirements of the device in order to make this device highly recognized and useful.

9. References

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