

Department of Electronic and Telecommunication Engineering University of Moratuwa



BM 2210 - Biomedical Device Design Investigation Report

Team Meditrones

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1. Introduction

Meditrones is a startup that focuses on providing engineering solutions to the healthcare sector and other associated fields. When providing solutions our team has a set of criteria that will enhance the solution and addresses the problem in the best way possible. The general acceptance criteria is mainly based on our mission and other cornerstones such as strengths and weaknesses, opportunities, threats, our focus areas and our strategic approach in the domain.

2. Our Strategic Focus

2.1. Our Mission

Our mission is to provide innovative solutions for the biomedical engineering domain while making sure the consumer needs are met. Furthermore we make sure the provided solutions are feasible to the Sri Lankan community and make quality products that will drive attention of the world market to make wholesome profits from our innovations.

2.2. Our Strengths and Weaknesses

Team Meditrones are aware of its strengths and weaknesses, our weaknesses primarily lie on lack of knowledge about medical terminology and functions in human body to assess certain conditions and limited resources, whereas our strengths mainly rely on knowledge about electronics, sound exposure to the healthcare professionals, passion to learn new things and critical thinking.

2.3. Socio-economic Impact

By developing innovative medical technologies, team Meditrones can improve access to affordable and quality healthcare, particularly in rural and underserved areas. This will not only enhance patient outcomes but also reduce the financial burden on both individuals and the healthcare system. Additionally, the creation of high-skilled jobs and fostering local expertise in biomedical engineering will contribute to the economic development of the region, positioning Sri Lanka as a hub for medical innovation in South Asia.

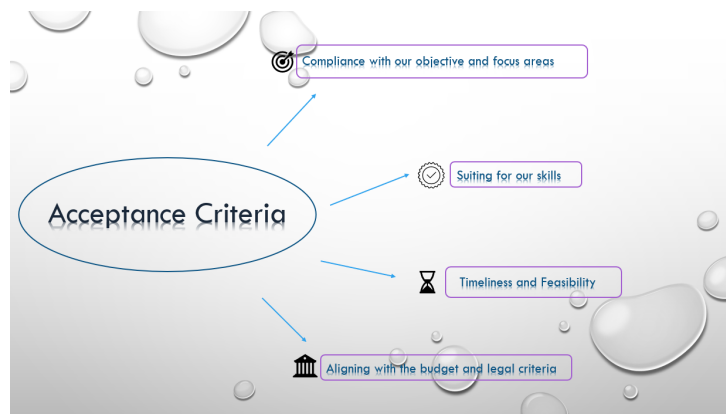
2.4. Resources and time constraints

We recognize that the limited timeframe of a single semester presents a significant challenge for our projects. Furthermore, the shortage of electronic devices in the local market, combined with rising costs driven by unstable exchange rates, adds to the difficulty. However, our team remains committed to overcoming these obstacles by leveraging resourcefulness and innovation, with the ultimate aim of delivering accessible healthcare solutions.

2.5. Acceptance Criteria

Our acceptance criteria is finalized after reasonable consideration of the above factors and aligned with our capabilities and constraints. Our acceptance criteria can be summarized as follows:

- Compliance with our strategic objectives and focus areas.
- Suiting for our skill set and expertise knowledge
- Timeliness of the solution and feasibility
- Aligning to the estimated project budget and legal constraints



3. Needs Finding

In our need-finding process, we began with a thorough exploration of existing needs, detailed in the attached methodology section. Through our research, we identified four key issues. For each of these problems, we crafted a precise need statement to clearly define the issue, target population, and desired outcomes.

3.1. A wearable to detect Carotid Artery Stenosis

Source: Physician, Sri Jayawardenapura General Hospital.

3.1.1. Introduction

The carotid arteries are the main blood vessels that carry blood and oxygen to the brain. When these arteries become narrowed, it's called carotid artery stenosis. It may also be called carotid artery stenosis. The narrowing is caused by atherosclerosis. This is the buildup of fatty substances, calcium, and other waste products inside the artery lining. Carotid artery stenosis is similar to coronary artery disease, in which buildup occurs in the arteries of the heart and can cause a heart attack.

In Sri Lanka, doctors generally use the method of listening to the carotid arteries. For this test, your doctor places a stethoscope over the carotid artery to listen for a sound called a bruit (pronounced brew-ee). This sound is made when blood passes through a narrowed artery. A bruit can be a sign of atherosclerosis. But, an artery may be diseased without producing this sound. Developing a wearable device for detecting carotid artery stenosis presents a transformative approach to cardiovascular health management. It combines early detection, convenience, and advanced technology to improve patient outcomes, reduce healthcare costs, and empower individuals in managing their health proactively.

3.1.2. Need Statement

- **Problem:** Listening to the carotid arteries with a stethoscope to detect a bruit, a sound caused by narrowed arteries, is limited because not all diseased arteries produce this sound. This can result in missed diagnoses, as an artery may be severely narrowed without any audible signs.

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- **Population:** Elderly People, patients with a history of hypertension, diabetes and other cardiovascular diseases.
 - **Outcome:** Early detection of carotid artery stenosis which can potentially save many lives without the risk of getting a stroke. It would allow for personalized healthcare, lower costs by preventing severe complications, and increase patient engagement in managing their health

“There is an urgent need for a reliable and non-invasive wearable device to detect carotid artery stenosis, enabling early diagnosis and prevention of strokes through timely medical intervention.”

3.1.3. Existing Solutions

In Sri Lanka, detecting carotid artery stenosis faces challenges similar to those in other regions, with current solutions such as Doppler ultrasound, magnetic resonance angiography (MRA), and computed tomography angiography (CTA) being utilized. Doppler ultrasound is effective but often limited by the availability of specialized equipment and trained personnel in rural or underserved areas. MRA and CTA provide detailed imaging but are costly and not always accessible in the public healthcare system, where resources can be constrained. The high cost and limited availability of these diagnostic tools make routine or continuous monitoring difficult, particularly in low-resource settings. Therefore, there is a pressing need for a more accessible, affordable, and user-friendly solution to improve early detection and management of carotid artery stenosis in Sri Lanka’s diverse healthcare landscape.

3.1.4. Stakeholder Analysis

- **Healthcare Providers:** Doctors and medical technicians are crucial for the effective use and integration of a wearable device for detecting carotid artery stenosis. Their input on device functionality and accuracy is essential for successful clinical adoption and patient outcomes.
- **Patients:** Individuals at risk of carotid artery stenosis, particularly the elderly and those with cardiovascular conditions, are the primary users of the device. Their acceptance and feedback on usability and comfort are vital for ensuring the device meets their needs.

3.1.5. Market Analysis

In Sri Lanka, there is a growing need for affordable, non-invasive health solutions due to increasing cardiovascular disease rates. Current diagnostic methods like Doppler ultrasound are limited by accessibility and cost. A wearable device for detecting carotid artery stenosis could address this gap, offering early detection and management to a broad and underserved population.

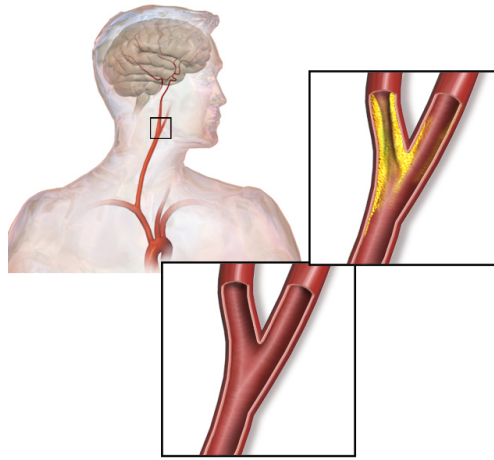


Figure 1: Carotid Artery Stenosis

3.2. Enhancing Holter Monitor Efficiency through an Application Software

Source: A physician, Sri Jayawardenapura General Hospital.

3.2.1. Introduction

A Holter monitor is a type of portable electrocardiogram (ECG). It records the electrical activity of the heart over 24 hours or longer while you are away from your healthcare provider's office. Unlike a standard ECG, which records for only a few seconds, a Holter monitor continuously records these signals for an extended period. This allows it to capture any irregularities, such as arrhythmias, that occur sporadically throughout the day or night. The electrodes are connected to an ECG machine by wires. The heart's electrical activity can be measured, recorded, and printed. No electricity is sent into the body.

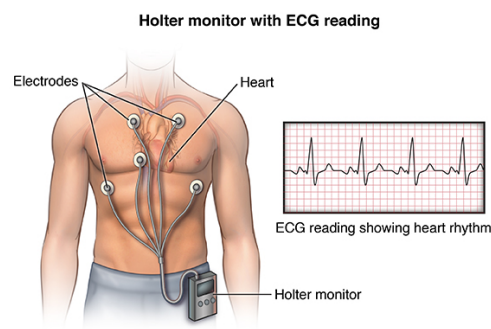


Figure 2: Holter Monitor

3.2.2. Need Statement

- **Problem:** In a country like Sri Lanka, the number of Holter monitors available in government hospitals is very limited, and many patients end up on long waiting lists to access them. Medical consultants have highlighted this issue, mentioning that the process of printing ECG reports through the hospital's printing division adds to the inefficiency and cost and it take more time.
- **Population:** Patients with prolong cardiovascular disorders, doctors, elderly people and patients with the risk of having heart implications.

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- **Outcome:** To address this problem, we proposed developing an app that allows ECG waves to be viewed digitally, eliminating the need for printing. This solution would significantly reduce costs related to paper and printing services, making the process more efficient and accessible for both patients and healthcare providers.

“In a country like Sri Lanka, the number of Holter monitors available in government hospitals is very limited, and many patients end up on long waiting lists to access them. To address this problem, we proposed developing an app that allows ECG waves to be viewed digitally, eliminating the need for printing. This solution would significantly reduce costs related to paper and printing services ”

3.2.3. Existing Solutions

Patches are emerging as a modern alternative to traditional Holter monitor probes for ECG monitoring. As an example, Philips company extended Holter – ePatch provides 3–14-day monitoring. However, this is not a cost-effective solution for low-resource settings like Sri Lanka due to their higher initial costs, limited reusability, and lack of infrastructure. From our perspective an app-based approach that enhances the utility of existing Holter monitors offers a more practical, scalable, and affordable solution

3.2.4. Stakeholder Analysis

- **Doctors:** Doctors can access ECG data anytime and anywhere through their smartphones, tablets, or computers, allowing for more flexible and timely consultations and diagnoses. Remote access capabilities enable doctors to review patient data even when they are not physically present in the hospital, facilitating telemedicine and remote patient management.
- **Patients:** Eliminating the dependency on printed reports speeds up the diagnostic process, especially in emergency or urgent care scenarios. The app ensures that ECG data is always available and can be referred to during follow-up visits or consultations without the risk of losing or misplacing paper records.
- **Hospital Administration:** Digital access to ECG data reduces administrative tasks, such as managing print, handling physical records,

and manually entering data into electronic systems. Further, the app eliminates the need for paper, ink, and printing equipment, significantly reducing costs associated with producing and managing hard copies of ECG reports.

3.2.5. Market Analysis

A low-cost Holter monitor would make continuous cardiac monitoring more accessible to a broader population, especially in regions with limited health-care infrastructure. The affordability factor would appeal to healthcare providers aiming to offer economical solutions to patients.



Figure 3: Existing solutions by Philips Holter patch

3.3. Upholding Hygiene Standards in Sri Lankan Hospital Wards

Source: V.C. Boralugoda, 5th year medical student, Faculty of Medicine, University of Ragama.

3.3.1. Introduction

Maintaining high hygiene standards in hospital wards is critical to preventing hospital-acquired infections (HAIs), which are a significant issue in Sri Lanka's healthcare system. In both government and private hospitals, overcrowded wards, limited resources, and infrastructural challenges often compromise the ability to maintain the necessary hygiene levels. This issue is particularly pronounced in public hospitals, where high patient volumes and financial constraints lead to overstretched facilities and staff, making it difficult to ensure proper sanitation and cleanliness. Hygiene lapses in hospital wards can lead to the spread of infections among patients, especially those who are already vulnerable due to underlying health conditions. The impact is severe, resulting in longer hospital stays, increased healthcare costs, and higher mortality rates.

3.3.2. Need Statement

- **Problem:** Maintaining adequate hygiene standards in hospital wards is challenging due to overcrowding, limited resources, and inconsistent cleaning practices, leading to a higher risk of hospital-acquired infections.
- **Population:** Patients, healthcare workers, and hospital administrators, particularly in government and rural hospitals with limited resources.
- **Outcome:** Reduce infection rates, improve patient outcomes, create a safer work environment for healthcare staff, and enhance the overall efficiency and reputation of hospitals.

“There is an urgent need for effective and sustainable solutions to uphold hygiene standards in hospital wards across Sri Lanka. These solutions must be adaptable to the specific challenges faced by Sri Lankan hospitals, including overcrowding, resource constraints, and infrastructural limitations, to ensure a safe and clean environment for patients and healthcare workers.”

3.3.3. Existing Solutions

Various measures have been implemented to enhance hygiene in hospital wards, including regular cleaning protocols, waste management systems, disinfection practices, and training programs. However, adherence to cleaning schedules is often inconsistent, especially during peak times, and waste management systems struggle to handle the large volumes in high-traffic hospitals, leading to improper disposal and contamination risks. Disinfection of surfaces and equipment is standard but can be irregular due to limited availability of disinfectants, particularly in smaller hospitals. Additionally, while the Ministry of Health conducts regular training on hygiene practices, these programs may not reach all staff, especially in rural or understaffed facilities, and their impact can diminish over time without continuous reinforcement.

3.3.4. Stakeholder Analysis

- **Hospital Administrators:** They play a crucial role in implementing and monitoring hygiene practices within wards. Their ability to allocate resources effectively is essential for maintaining high hygiene standards.
- **Healthcare Workers:** Nurses, doctors, and support staff are on the front lines of maintaining ward hygiene.
- **Patients and Families:** Patients are directly affected by the level of hygiene in hospital wards, and their safety depends on the cleanliness and sanitation of their environment.

3.3.5. Market Analysis

The market for hygiene products and services in Sri Lanka is influenced by economic factors, with government hospitals often facing budgetary constraints. However, there is a growing awareness of the importance of hospital hygiene, particularly after the COVID-19 pandemic. There is significant demand for affordable, scalable solutions that can improve hygiene standards in both urban and rural hospitals. Innovations that can be implemented within the existing resource limitations of Sri Lankan hospitals have strong potential in this market. International health organizations and NGOs may play a critical role in funding and supporting the introduction of new hygiene solutions in hospitals, especially in public healthcare facilities

3.4. Device for Monitoring Respiratory Rate in Infants

Source: Medical Officer, PCU, Lady Ridgeway Hospital for Children.

3.4.1. Introduction

Monitoring the respiratory rate in infants is crucial for early detection of respiratory distress and other life-threatening conditions such as pneumonia, sepsis, and sudden infant death syndrome (SIDS). Infants are particularly vulnerable to respiratory issues due to their underdeveloped lungs and immune systems, making continuous monitoring essential, especially in neonatal intensive care units (NICUs) and during postnatal care in both hospitals and home settings. Traditional methods of monitoring, such as manual counting or periodic checks by healthcare staff, are prone to errors and may not provide timely alerts in case of a sudden change in an infant's respiratory status.

In low-resource settings, including many parts of Sri Lanka, there is often a lack of sophisticated monitoring equipment, leading to delayed interventions and increased infant mortality. A reliable, non-invasive device that continuously monitors the respiratory rate of infants could significantly improve the early detection of respiratory problems, leading to quicker responses and better health outcomes.

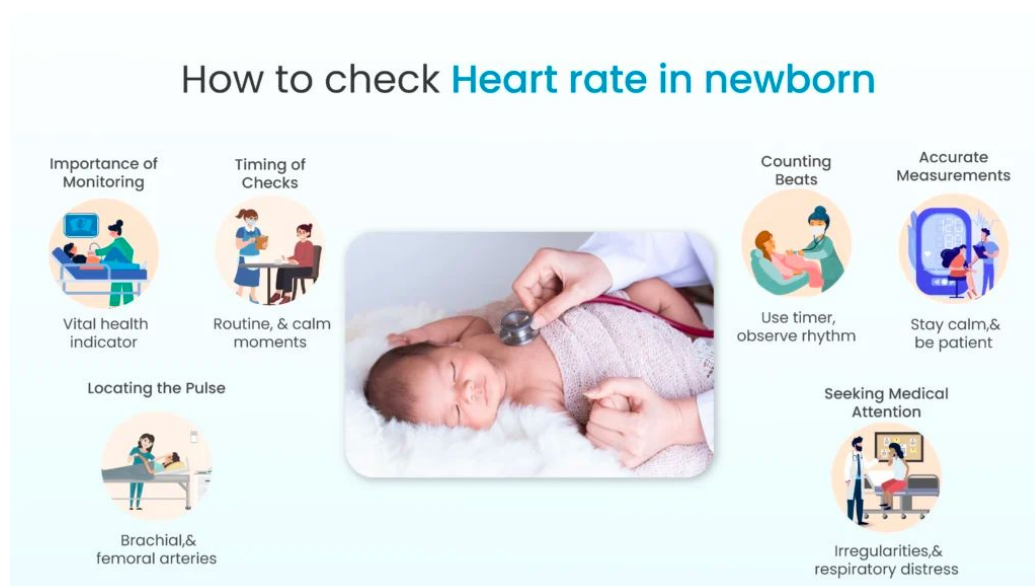


Figure 4: Need for monitoring respiratory rate in infants

3.4.2. Need Statement

- **Problem:** Infants are at high risk for respiratory issues, and the absence of continuous, accurate monitoring can delay the detection of potentially life-threatening conditions.
- **Population:** Newborns, premature infants, and those with health conditions, as well as healthcare providers and caregivers who monitor their well-being.
- **Outcome:** A reliable, non-invasive respiratory rate monitor would enable early detection of issues, leading to timely interventions and improved infant health outcomes.

“There is an urgent need for a reliable and non-invasive, respiratory rate monitoring device for infants to enable early detection of respiratory issues and ensure timely medical intervention.”

3.4.3. Existing Solutions

Existing solutions include manual counting by healthcare providers, pulse oximeters, capnography, and apnea monitors. Manual counting is prone to errors and is not continuous, while pulse oximeters and capnography, though more advanced, can be expensive and may not provide accurate readings in certain conditions, such as low perfusion or infant movement. Apnea monitors are designed to detect breathing pauses but may not effectively track the respiratory rate continuously. These methods often fall short in providing reliable monitoring, especially in low-resource settings.

3.4.4. Stakeholder Analysis

- **Neonatal and Pediatric Healthcare Providers:** Doctors, nurses, and support staff in NICUs and pediatric wards are the primary users of respiratory monitoring devices. Their ability to quickly and accurately assess an infant’s respiratory status is critical to patient outcomes.
- **Parents and Caregivers:** In home settings, parents and caregivers rely on monitoring devices to ensure their infants are breathing normally, especially during sleep.

3.4.5. Market Analysis

The market for infant respiratory monitoring devices is growing, driven by the increasing awareness of infant health risks and the need for early detection of respiratory issues. In Sri Lanka and other low-resource settings, there is a strong demand for affordable, easy-to-use devices that can be deployed in both hospital and home environments. The device would need to be cost-effective, reliable, and capable of functioning in environments with limited access to advanced medical technology. Partnerships with NGOs, international health organizations, and government bodies could facilitate the distribution and implementation of these devices in underserved areas.

4. Needs Screening

Based on our screening process we have allocated marks for the above needs on the basis of different criteria and ranked them in the order of preference.

Need	Estimated Market (out of 5)	Patient Impact (out of 5)	Providers Impact (out of 5)	Feasibility Index (out of 5)	Co-Owner's Preference (out of 15) 5 per owner	Total (out of 35)	Rank
<i>A wearable to detect Carotid Artery Stenosis</i>	4	4	3	3	11	25	3
<i>A low cost Holter monitor for Hospitals in Sri Lanka</i>	4	5	4	4	12	27	1
<i>Upholding Hygiene Standards in Sri Lankan Hospital Wards</i>	3	2	1	2	10	21	4
<i>Device for Monitoring Respiratory Rate in Infants</i>	4	5	4	3	10	26	2

5. Conclusion

After analysing all the problems and the acceptance criteria we have concluded that the **2nd opportunity** of making low cost holter monitor with enhanced efficiency for hospitals would be a timely problem that can be addressed within the given time constraint and resources. Thus we will be focusing on it to provide a reliable solution using our strengths and capabilities.

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