Open Access Library Journal
2024, Volume 11, e11580
ISSN Online: 2333-9721
ISSN Print: 2333-9705

Smartphone Oximeter SPO_2 Integrated Measurement

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How to cite this paper: Sri, Y.V.R. (2024) Smartphone Oximeter SPO_2 Integrated Measurement. *Open Access Library Journal*, **11**: e11580.
https://doi.org/10.4236/oalib.1111580

Received: April 16, 2024
Accepted: July 20, 2024
Published: July 23, 2024

Abstract

Smartphone-based Oximetry device as early healthcare detection is a technological frontier. Smartphone oximetry devices offer a convenient method for remote SpO_2 monitoring and early detection of critical health issues, especially during pandemics when vital indicators are necessary. Rising healthcare demands, and the COVID-19 pandemic are recent causes necessitating the prevalence for accessible early detection tools. This research investigates smartphone oximetry device as a convenient SpO_2 monitoring, crucial for identifying hypoxia, a silent risk factor in medical conditions. The selection criteria for Samsung Note 10 smartphone following the research aims to perform 1) Literature Review to analyse articles showcasing smartphone oximetry functions and importance of Photoplethysmography Sensors for accurate SpO_2 measurement. 2) The smartphone (Samsung Note 10) was selected for compatibility with FDA/ISO medical device standards. 3) To develop a User Requirements Document (URD) for the chosen smartphone, outlining user needs and functionalities for optimal performance. Smartphone-derived SpO_2 measurements met full FDA/ISO accuracy requirements following RMSD 2.6% vs <3.5% threshold reflected in Table 1. This aligns with the critical role of pulse oximeters in managing COVID-19 patients and detecting silent hypoxia.

Subject Areas

Bioengineering, Bioinformatics, Biotechnology, Clinical Medicine, Diagnostics

Keywords

Biosensors, Smartphone, Hypoxia, Pulse Oximeter, Photoplethysmography

1. Background

In 2021, the Singapore Department of Statistics reported that the number of

households in Singapore was 1.39 million, and on July 5, 2021, one Pulse Oximeter was issued to each household Ministry of Trade & Industry [1]. According to digital news agency Mothership SG [2], The Pulse Oximeter issued by Temasek [3] Foundation is now valued between 19.90 and 30 Singapore dollars (SGD) per unit in the open market. A tangible market value of Pulse Oximeters in circulation is 2.78 million dollars' given one unit is valued at 20 SGD dollars within the Singapore market. According to Forbes [4] Health, the Pulse Oximeter ranges from 20 US dollars to 50 US dollars. In the Global market with a compound annual growth rate of 6.4% from 2023 to 2030, the devices would reach USD 3.9 billion by 2030 Grand View Research [5]. A technology disruptor to Pulse Oximeter market trend is Pulse Oximetry alternatives emerging with advances in smartphone interfaces and mobile applications, providing access to essential health monitoring and the measurement of blood oxygen saturation SpO_2 with the convenience of the latest smartphone devices. In previous decades Smartphones were not known to possess the functionality to perform SpO_2 measurement, however with improvements in technology, Smartphone devices are a ready alternative to a standard pulse oximeter on the patient's finger to measure hypoxia which is a warning sign for Pneumonia according to Tarassenko and Greenhalgh [6] and COVID-19 can cause silent hypoxemia which is also monitored with the pulse oximeter and especially usefully in remote consultations according to Greenhalgh *et al.* [7].

Table 1. Highlights.

Focus	*Key Findings*	*Impact*
Smartphone Oximetry	Analysis from 3 articles, to determine accurate SpO_2 through Photoplethysmography Sensors.	Potential for broader SpO_2 access and early healthcare detection.
Device Selection	Identified Samsung Note 10, exceeding FDA/ISO medical device standards.	Reliable smartphone platform for SpO_2 measurement.
User Requirements Document	To develop a technical document URD for Note 10, outlining user needs and functions for optimal performance.	Efficient and user-friendly SpO_2 monitoring.
Results and Significance	Full FDA/ISO accuracy using Smartphone SpO_2 met RMSD 2.6% vs. <3.5% threshold.	Applicable for COVID-19 patient management needs and detecting silent hypoxia.
Conclusion	Smartphone oximetry device from Samsung Note 10 holds promise as an accessible and accurate tool for early healthcare detection and self-management, in isolations potentially improving health outcomes for vulnerable populations.	To addresses accessibility challenges and offers remote health monitoring for at risk groups.

2. Introduction

In response to the growing demand for healthcare resources and the heightened vulnerability of the elderly population to infections, early detection measures are imperative Nazario [8]. In 2021, the Singapore Department of Statistics distributed a Pulse Oximeter to each of the 1.39 million households in the country,

underscoring the significance of this device Ministry of Trade & Industry [1]. This research project explores the potential of smartphone devices equipped with Oximetry functions, aligned with GMP & ISO 13485 requirements. It also assesses User Needs and Requirements for Intended Use, in accordance with Health Sciences Authority [9] guidelines. The project aims to address the design and development of smartphone devices with Oximetry capabilities within the context of medical and diagnostic devices, with a primary goal of enabling early hypoxia detection. To gain approval from the US Food and Drug Administration (FDA) and the International Organisation for Standardisation (ISO), developers must meet two essential requirements firstly appropriate hardware integration, including sensors, and second to develop proprietary software applications (apps) that effectively collect, analyse, and interpret biological data. The emerging landscape of diagnostic tools is disrupted by pulse oximetry alternatives facilitated by smartphone interfaces and mobile applications, offering convenient access to vital health monitoring, particularly blood oxygen saturation SpO_2 measurements, which are critical in detecting conditions such as hypoxia, a warning sign for pneumonia Tarassenko and Greenhalgh [6]. Silent hypoxemia, another concerning condition associated with COVID-19, can also be monitored effectively with pulse oximeters. This research thus explores the transformative potential of smartphone devices in revolutionising hypoxia detection.

3. Methods

The methods section outlines the selection criteria for the Samsung Note 10 smartphone following the research aims:

1) To perform a literature review on smartphone devices with Oximetry functions.

2) To select a suitable smartphone device with Oximetry functions in the context of medical and diagnostic devices.

3) To develop a user-requirements document (URD) on the smartphone device with Oximetry functions.

4. Literature Review

Three distinct literature articles have emerged, each presenting relevant smartphone devices integrated with software applications (apps) and oximetry designs within the user interface for their intended purposes. Notably, all three articles highlight the incorporation of sensors in conjunction with software applications. Photoplethysmography Sensors are a prevalent component found with advanced smartphones. These sensors deploy infrared light to measure the volumetric variations of blood circulation that contribute to the device's oximetry capabilities. The first article, according to Press Release Distribution [10], The Pulse Oximeter app measures, and monitors SpO_2 readings for data storage and exports data to files with CSV format. However, the Pulse Oximeter app does not intend to meet FDA requirements with 510(K) substantial equivalence or

ISO13485 CE European conformity and is not intended for medical and diagnostic purposes. Another study promising literature article provides technical components of the smartphone device with the intended use as a Pulse Oximeter for medical and diagnostic purposes. According to a recent study by Browne, Bernstein and Bickler [11] a "Breathe down" testing in the laboratory showed that the total root-mean-square deviation of oxygen saturation (Spo_2) measurement was 2.2%, which meets FDA/ISO standards. Smartphone sensor with app tested met laboratory FDA/ISO standards and could be used to obtain highly accurate and repeatable measurements across a varied population. Full FDA/ISO approval would require additional laboratory testing to incorporate at least 200 data points referenced to blood sample analysis by Browne, Bernstein and Bickler [11]. This research article did not provide laboratory testing. The third literature article is a preprint on February 18, 2021, from "medrxiv.org," the med-archive in medical and health sciences with Yale University, The BMJ, Cold Spring Harbor Laboratory published a preprint report titled Accuracy of Samsung Smartphone Integrated Pulse Oximetry Meets Full FDA Clearance Standards for Clinical Use according to Browne *et al.* [12]. The preprints are co-authored by two Medical Doctors, a specialist, one in Infectious Diseases, and another a Professor and Chief of Neuroanesthesia and an engineer with extensive experience in pulse oximeter device development and validation. According to the research, the Pulse oximeter produced by Samsung is compliant and has full FDA/ISO requirements for clinical pulse oximetry using Lab testing which is the requirement for fast-tracking FDA/ISO under the 'Emergency Use Authorisations' for 'Remote or Wearable Patient Monitoring Devices associated with the Covid-19 pandemic. Data and Methods for Usability of the Smartphone Pulse Oximeter in this study, a Samsung S9+ smartphone equipped with Maxim Integrated biosensors (part number MAX86916) and the proprietary Samsung Health App is evaluated for its accuracy in measuring blood oxygen saturation (SpO_2). The study calculated the bias, which represents the difference between the smartphone pulse oximeter's readings and the reference values obtained from arterial blood samples (ABGs) Browne *et al.* [12]. Amongst the 12 participants measured in the report, 3 individuals have darkly pigmented skin. The bias was reported as root mean square deviation (RMSD) and RMSD value at 2.6%. This value is critical because it quantifies the overall accuracy of the smartphone pulse oximeter in comparison to the reference ABG values refer to **Table 2**. Visualisation of Smartphone-Based Pulse Oximeter Accuracy.

5. Results from the Selected Article

A modified Bland-Altman Plot was generated and is a visualisation technique used to assess the agreement and potential bias between two measurement methods, the smartphone-based device and the reference ABGs. The plot indicated the upper and lower limits of agreement. This plot demonstrated that the smartphone pulse oximeter's measurements were within the acceptable limits

specified by the Bland-Altman analysis, as outlined in the FDA [13] guidance. The study compared the RMSD of 2.6% with the accuracy requirements prescribed by the FDA/ISO for clinical pulse oximetry. These standards typically specify a maximum allowable RMSD value which is considered acceptable for clinical use. In this report, the RMSD of 2.6% fell below the FDA/ISO requirement of <3.5% RMSD for SpO_2 values to demonstrate that the smartphone derived pulse oximetry measurements met full FDA/ISO accuracy certification requirements. Particularly in the context of the COVID-19 pandemic, the data from smartphone pulse oximeter's accuracy has surpassed that of many standalone oximeters available on the market. This suggests that smartphones, which are widely accessible, are an option for accurate clinical-grade pulse oximetry readings. In this regard, the third article addresses the suitability for smartphone devices with Oximetry functions in the context of medical and diagnostic devices, refer to Table 2. Visualisation of Smartphone-Based Pulse Oximeter Accuracy.

Table 2. Visualisation of smartphone-based pulse oximeter accuracy.

Metric	Smartphone vs. ABGs	Acceptable Limits	Result	Significance
Bland-Altman Plot	Agreement and potential bias	Upper & Lower Limits of Agreement	Measurements within limits	Acceptable for clinical use
RMSD	Measured vs. reference values	<3.5% RMSD for SpO_2	2.6% RMSD	Meets FDA/ISO accuracy requirements
Comparison to Standalone Oximeters	Accuracy	Market average	More accurate	Potential for clinical use
COVID-19 Context	Increased demand for oximetry	Smartphone accessibility	Wider access to accurate measurements	
Article 3 Relevance	Suitability for medical/diagnostic devices	Smartphone compatibility with oximetry functions	Supports smartphone-based oximetry use	

Summary:

- Metric: Bland-Altman Plot, RMSD, Comparison to Standalone Oximeters, COVID-19 Context, Article 3 Relevance
- Smartphone vs. ABGs: Agreement and potential bias, Measured vs. reference values, Accuracy, Increased demand for oximetry, Suitability for medical/diagnostic devices
- Acceptable Limits: Upper & Lower Limits of Agreement, <3.5% RMSD for SpO_2, Market average, Smartphone accessibility, Smartphone compatibility with oximetry functions
- Result: Measurements within limits, 2.6% RMSD, More accurate, Wider access to accurate measurements, Supports smartphone-based oximetry use
- Significance: Acceptable for clinical use, Meets FDA/ISO accuracy requirements, Potential for clinical use

6. Discussion

Uses of Oximeter for pandemics is essential and the limited diagnostic tools during the first wave of COVID-19 caused global panic with lockdowns and stay-at-home notices for travelers as asymptomatic spread continued globally. According to the World Health Organisation [14], above 75% of hospitalised patients require supplemental oxygen, "Pulse oximeters are a critical tool for managing patients with COVID-19". A substantial number of patients with

COVID-19 reach a significant level of clinical hypoxemia without shortness of breath or other warning signs. The occurrence known as "silent hypoxia" poses a potential risk as it may lead to a delay in medical intervention until the patient has progressed to more advanced stages of lung injury, this delay increases the chances of complications and mortality associated with the condition according to World Health Organisation [14]. Blood oxygen saturation is critical to classify

Table 3. World Health Organisation (2020).

This is an adapted table from the World Health Organisation that provides recommendations for in-patient care or hospital admissions and outpatient pulse oximeter measurements and Principles for the use of oximeters in the initial remote triage and remote monitoring of patients with confirmed or suspected COVID-19 diagnoses.

In-patient: (Primaryand Community Care Settings)
Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings. The measurement is also beneficial for Telemedicine in patient remote care settings. Other influences besides Oxygen Saturation includes, Respiratory rate, Heart rate and NEWS 2 (National Early Warning Score).

Oxygen Saturation	Mild 95% or greater	**Actions**	Consider remote monitoring
	Moderate Saturation 93% - 94%		Consider hospital admission/face-to-face evaluation
	Severe 92% or less		May recommend Hospital admission

Outpatient:
Recommendations Interpretation of oxygen saturation results with pulse oximetry in outpatients with confirmed or suspected cases of COVID-19.

SpO_2 >96% (RR < 20 and no emergency signs) (28)	- Normal value. (3, 27, 31, 34) - Isolate patients with suspected COVID-19 in their home or assigned facilities to receive care. (28) - Administer acetaminophen (500 mg every 6 to 8 hours, maximum 4 g per day) in case of fever or pain. (28) - Provide appropriate recommendations on hydration and nutrition; and identify emergency signs. (28) - Do not administer antibiotics. (28)
SpO_2 94% - 96% (RR < 20 and no emergency signs) (28)	- Consider whether the patient requires closer evaluation or referral to a health center. (31, 33, 34) - The patient may be asked to do brief exercise (climb the stairs, walk on site for a minute) to assess whether desaturation occurs with exercise. It is important to note that the clinical importance of desaturation during exercise, when the O_2 levels dip due stress on lungs and body is an impact on patient management that is still under discussion. (31, 33, 34)
SpO_2 90% - 94%*	- Isolate in health care provider facilities and consider moving to the second level of care. - Monitor vital and emergency signs. - Consider oxygen intake and fluid administration. - Laboratory tests and imaging for analysis.
SpO_2 <90%	- Refer to the second level of care and consider supplemental oxygen treatment. (28) - COVID-19 patient management guidelines from the Pan American Health Organization (27) and the World Health Organization3 recommend administering supplemental oxygen therapy to any patient with or without emergency signs with SpO_2 < 90%. (2, 26)
Drop in SpO_2 ≥3%	- Referral to a respiratory specialist in case of possible progressive clinical deterioration. (20, 21)

*Oximeters should be used for mild case monitoring and early detection of silent hypoxemia, although it is noted that remote care and oximeter use is at the discretion of the physician. **If the patient has COPD, a saturation value of 88%33 should be considered. ***Systematic laboratory tests (depending on availability): Respiratory specimens for viral assessment of COVID-19, liver function, blood count, other laboratory tests based on local epidemiology (such as influenza, other respiratory infections, dengue, malaria), uroanalysis.

the stage of severity of patients and consequently informs the physician about the choice of treatment. Home-use pulse oximeters are a useful tool in remote monitoring patients, the use of pulse oximetry in patients with confirmed or suspected cases of COVID-19 and Hypoxemia that may occur with conditions affecting the lungs, such as pneumonia, bronchiolitis, asthma, and respiratory failure, among others, including systemic diseases such as sepsis and trauma according to World Health Organisation [14] also refer to **Table 3**. World Health Organisation (2020).

To select a suitable smartphone Pulse Oximetry device two important features are Hardware Capabilities and Software Applications. Many modern smartphones are equipped with Hardware Capabilities such as built-in sensors, such as photoplethysmography (PPG) sensors which are part of the optoelectronic system. Reflected in **Figure 1** Photodetector and **Figure 2**, the PPG sensor is vital in this study which includes two essential components firstly, the Light Source from Light-emitting Diode (LED) that emits light in two different wavelengths, red light also depicted as (λr) and Infrared light as (λIR). Second is the Photodetector to detect light passing through from epidermis and dermis tissue of the forefinger to reflect the pulsatile waveform of blood flow. There are two types of Photodetectors, namely Photodiode (PD) which converts light into an electrical current proportional to the intensity of the received light and Phototransistor which received light to modulate the flow of current through the device, this is similar to a Photodiode. PPG devices may include Signal Processing Unit (SPU) which performs initial amplification and filtering of the raw signal from the photodetector and a Housing and Lens which lenses focus the light source and housing encased to protect internal components to optimise light collection. The formula for the total absorption of light $(\lambda) = dc(\lambda) + ac(\lambda)$ with their respective components of absorption where ac represents the pulsating components of the light, this pulsation is a clause by the rhythmic pumping of the blood through the arteries per heartbeat and dc represents the non-pulsating components of the light, this includes light absorbed by the tissues other than blood, such as bones, muscles and skin, and both ac and dc light forms are absorbed by the fingertip. This sensor can measure blood oxygen levels by detecting changes in light absorption and reflection, which are indicative of oxygen saturation levels in the blood. Smartphone applications (apps) can utilise the hardware capabilities mentioned above to perform oximetry measurements using the Software applications. These apps use algorithms to process the data captured by the sensors and calculate oxygen saturation levels, typically displayed as SpO_2 (peripheral capillary oxygen saturation) readings. The article by Browne, Bernstein and Bickler [11] mentions about PPG light-emitting diodes (LEDs) and a photodetector in the Samsung device are used for SpO_2 readings, further illustration is found at **Figure 1** Photodetector and **Figure 2** Signal-to-Noise Ratio (SNR) Samsung Newsroom [15]. Reflected in the chart at the Y-axis is decibels and X-axis is seconds along with the signal power in the waveform. In this case, it corresponds to the variations in the PPG waveform caused

Figure 1. Photodetector.

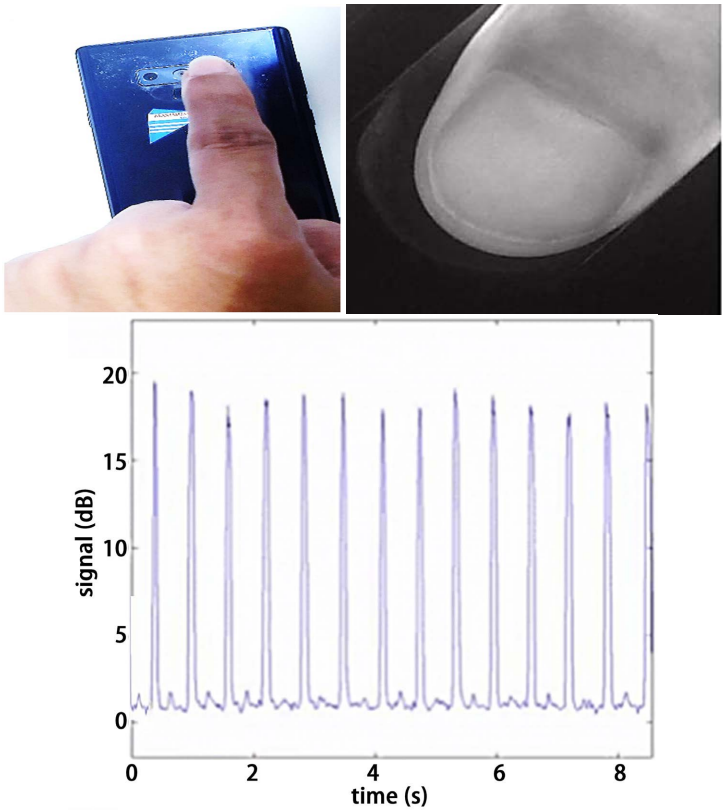

Figure 2. Signal-to-Noise Ratio (SNR) (Samsung Newsroom, 2022).

by changes in blood oxygenation levels. The higher the amplitude of these variations, the stronger the signal power noise Maxim Integrated [16]. The noise power refers to any unwanted disturbances or interference that may affect the PPG signal from various sources, such as motion artifacts, ambient light, electrical noise, or physiological noise, and noise power in large should ideally be minimised to improve the SNR Maxim Integrated, with a clearer signal-to-noise ratio, the pulse oximeter can more accurately differentiate between the effects of light absorption by hemoglobin and random noise. [16], refer to **Figure 3** PPG light-emitting diodes (LEDs) and a photodetector. According to the University of Iowa Hospitals & Clinics [17], optoelectronic sensors used in pulse oximetry

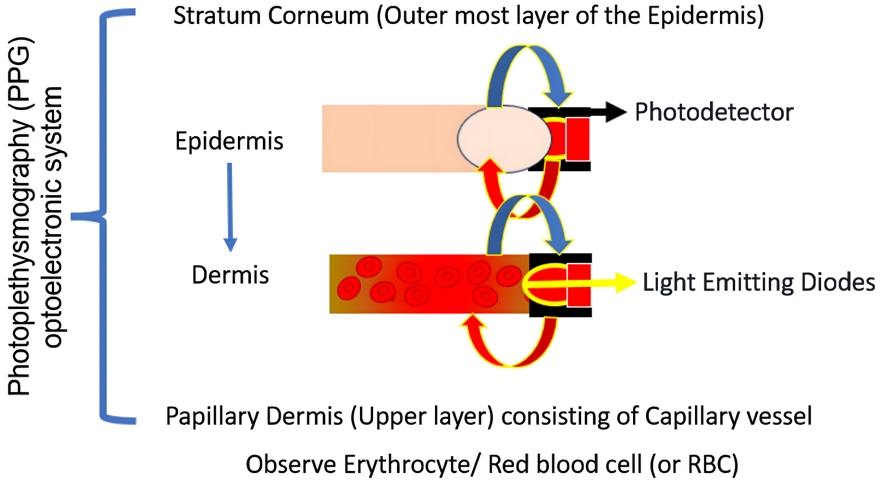

Figure 3. PPG light-emitting diodes (LEDs) and a photodetector.

may include multiple LEDs emitting light at different wavelengths, typically around 660 nm (red) and 940 nm (infrared). The Beer-Lambert law, $A(\lambda) = \log10(Io/I) = \mu CL$ reflects the logarithm (log) transforms the exponential relationship between light intensity and concentration into a linear one, "$A(\lambda)$" is the total absorption of light at a specific wavelength "(λ)", and "Io" is the initial light intensity, "I" is transmitted light intensity, "μ" is the absorption coefficient, "C" is the concentration of the absorbing substance, and "L" is the path length. Assuming a healthy individual with a SpO_2 of 100%, the blood contains a high concentration of oxygenated hemoglobin (HbO_2 or OO_2Hb), which absorbs more red light (λ_red) than infrared light (λ_infrared). $A(\lambda) = AOO_2Hb(\lambda) + AHb(\lambda)$. Healthy individuals with SpO_2 of 100% shall demonstrate almost all haemoglobin carrying oxygen and Light Source, Pulse oximeter emitting red light (λr) at 660 nm and infrared light (λIR) at 940 nm with the material fingertip tissue containing a high concentration of HbO_2 and minimal Hb. The Beer-Lambert Law which governs light absorption through a substance, which states that the intensity of light transmitted through a medium decrease exponentially with the thickness of the medium and the concentration of absorbing substances within it [17]. These specific wavelengths to the absorption peaks of oxygenated and deoxygenated hemoglobin, the transmitted red light serves as a measure of the oxygen saturation level in the blood and demonstrates the relationship between transmitted light intensity and oxygen saturation level in pulse oximetry device [17]. The peripheral oxygen saturation, also known as SpO_2, is measured through a non-invasive method using the oximeter and arterial oxygen saturation also known as SaO_2 is measured through a CO-oximetry device which is an invasive method. Rapid changes in oxygenation, SpO_2 readings may not reflect rapid changes in oxygen saturation as quickly as SaO_2. Conditions like anemia, abnormal blood flow, or severe vasoconstriction (narrowing of blood vessels) can affect the accuracy of pulse oximetry SpO_2 method, leading to a larger difference between SpO_2 and SaO_2. Skin pigmentation, very dark or light skin pigmentation can also slightly influence SpO_2 readings also mentioned by

Browne *et al.* [12]. The intended use for the Samsung Health (app) paired with PPG system is to perform clinical pulse oximetry and can be downloaded to other mobile devices including Apple iPhones. For compatibility, the PPG sensors need to be integrated with the other smartphone devices to function as a clinical pulse oximetry device.

7. A User-Requirements Document (URD)

Overview of the smartphone device with oximetry functions. The purpose of the URD is to outline the user requirements for smartphone devices with oximetry functions. The European Union (EU) is determined by the Medical Devices Regulation (MDR) 2017/745. The MDR establishes different risk-based classes for medical devices, including oximeters, based on their intended use and potential risks to patients and users. According to EU risk classification of medical device Pulse Oximeters are classified as IIB medical-grade oximeters. According to Mccormick and Sanders [18] Good Manufacturing Practices (GMP) in the context of smartphone devices with oximetry functions refers to the set of guidelines and standards that ensure the manufacturing processes of these devices adhere to high-quality and safety standards. Published by World Health Organisation [14] with the Regulatory Aspects and the Technical Specifications for Finger Pulse Oximeter shall include, general requirements, operational characteristics, display parameters, alarm, and electrical characteristics. To ensure GMP in are in medical devices aligned with ISO 13485 International Organisation for Standardisation [19] refer to **Figure 4** GMP and **Table 4**. URD (Samsung Galaxy Note Series 10). GMP ensures that the devices are consistently produced and controlled according to established quality standards throughout their entire life cycle. Since the Pulse Oximeter is an existing device, the FDA reports using a 510(K) for substantial equivalence with predicate devices to determine desirable compatibility. When applying 510(K) for Premarket Notification Submissions for substantial equivalence a comparative table places the predicate device side by side with the new device to determine the features including, intended patient population, intended application site, Safety Specifications along with other Features in a form of a checklist, refer to **Table 5**. 510(K) for Premarket Notification Submissions. FDA 510(K) suggests the smartphone device is substantially equivalent to the predicate device of the Pulse Oximeter with a checklist affirming suitability based on the descriptors. The principal investigator selected the device Samsung Note 10, having fulfilled the basic requirements that the Samsung Health (app) paired with PPG system and ready access to the device owned by principal investigator for the purpose of this project provides convenience sampling. The Samsung Note 10 device is selected to perform a user needs and requirements for Intended Use and design and development Health Sciences Authority [9], for the selected smartphone device with Oximetry function in the context of medical and diagnostic device, follows the user-requirements document (URD) refer to **Figure 5** URD. The format of the URD takes precedence from Food and Drug Administration, FDA [13].

Table 4. URD (Samsung Galaxy Note Series 10).

User Requirements Document (Samsung Galaxy Note Series 10)	
Description: This is a tabled formatted User Requirements Document (URD) to reflect the research in this article from Technical and Compliance documents. The URD covers: 1) Introduction 2) User Profile 3) Intended Use 4) Functional Requirements 5) User Interface 6) Performance Requirements 7) Environmental (Conditions affecting device performance) 8) Safety and Regulatory Compliance 9) Usability and Ergonomics 10) Maintenance and Support 11) Documentation and Training 12) Constraints and Limitations	
1	Introduction This User Requirements Document outlines the specifications and functionalities expected from the Samsung Galaxy Note Series 10 smartphone device, particularly focusing on its oximetry functions. The device is designed to cater to a diverse user base, including outpatient healthcare professionals and individuals monitoring their health at home. This document takes into account various user profiles, intended use cases, functional requirements, user interface considerations, performance criteria, safety and regulatory compliance, usability and ergonomics, maintenance and support, as well as constraints and limitations.
2	User Profile 1) Target users for the smartphone device includes outpatient healthcare professionals and individuals monitoring their health at home. 2) In Singapore the Level of technical expertise and familiarity with pulse oximeter is high due to the investment and dissemination of pulse oximeters to every household. 3) Clear instructions should be provided to patients before starting home monitoring. 4) Ensure that warning signs (including saturation thresholds) are properly known and how to proceed in each case. 5) These instructions should be translated into the appropriate languages. 6) People should be encouraged to seek care if the overall trend in oxygen saturation over a set time period is descending, even if measured values remain above the established threshold. 7) Thresholds for seeking care may need to be lowered when monitoring in communities located at higher altitudes. 8) Additional considerations are Remote care and oximeter use is at the discretion of the physician.
3	Intended Use Intended Use of the Smartphone Device with Oximetry Functions: The intended use of the smartphone device with oximetry functions encompasses several critical aspects: 1) Medical Use: This device is intended for medical applications, including but not limited to the following scenarios: ● Monitoring patients with acute respiratory infections. ● Managing patients with Chronic Obstructive Pulmonary Disease (COPD). ● Assisting in the care of individuals with severe asthma. 2) Pulse Oximetry: The device is equipped with a pulse oximetry function, primarily designed to measure two vital parameters: ● Blood oxygen saturation levels (SpO_2). ● Pulse rate (heart rate). 3) Clinical Decision Support: Pulse oximetry is recognised as an invaluable tool for healthcare professionals in making informed clinical decisions. It aids in the assessment and management of various medical conditions.

Continued

4) Additional Considerations: It's essential to note that the use of the device for remote care and oximetry measurements should be at the discretion of a qualified physician. Medical professionals should determine when and how the device is employed for patient monitoring.

Additional Uses of Pulse Oximeter during Pandemics like COVID-19:

In addition to its general medical use, especially during pandemics like COVID-19, the pulse oximeter serves as a critical medical device for monitoring and assessing the blood oxygen saturation levels (SpO_2) of individuals. Its significance in healthcare management includes:

- COVID-19 Monitoring: Pulse oximeters are indispensable tools for monitoring patients who have contracted COVID-19. They facilitate healthcare professionals in continuously tracking the oxygen levels of these patients.
- Assessment of Severity: Blood oxygen saturation levels are pivotal in classifying the severity of a patient's condition, particularly for COVID-19 patients and those with other respiratory illnesses. Knowledge of SpO_2 levels informs healthcare providers about the appropriate level of treatment required.
- Remote Monitoring: Pulse oximeters are invaluable for remotely monitoring patients, especially those with confirmed or suspected cases of COVID-19. They enable individuals to monitor their SpO_2 levels at home, providing healthcare professionals with real-time data without the need for frequent in-person visits.
- Complementary Role: It's important to emphasise that while the pulse oximeter is a vital tool, it does not replace comprehensive clinical evaluation. It is most effective when used in conjunction with other clinical assessments and as part of a holistic approach to patient care.

4 Functional Requirements

List the essential functions that the smartphone device with oximetry functions should perform.

Proposed algorithm:

- SpO_2 >96%: normal values
- SpO_2 93 - 96%: consider brief exercise and check for desaturation
- SpO_2 ≤92%: hypoxia and indication of supplemental oxygen treatment.

- The expected accuracy, reliability, and precision of the oximetry measurements.

Evaluation of test instrument oximeter performance was done using controlled steady-state hypoxia at the UCSF Hypoxia Research Laboratory on the Samsung device. The work was sanctioned by the UCSF Committee on Human Research, protocol 10-00437.

- Additional features and capabilities include data storage, potential trend analysis, and connectivity with external devices.

5 User Interface

User interface requirements for the smartphone device.

Interaction Methods:

- The preferred interaction methods are touch screen, buttons and potential voice commands to open the app.
- In addition to touchscreen interaction, the device should incorporate physical buttons for essential functions, ensuring that users have multiple ways to interact with the device. These buttons should be tactile and well-placed for ease of use.
- Voice Commands: The device should support voice commands to open the oximetry app. Voice recognition technology should be accurate and responsive, enhancing accessibility for users who may have physical limitations or prefer voice interaction.
- The App contains Clear and intuitive instructions, visual cues, and feedback during device operation.

6 Performance Requirements

Performance criteria that the smartphone device should meet basic specifications or compatible to a Samsung Galaxy Note Series 10.

Critical Device Sensors for operability:

- Accelerometer, Barometer, Fingerprint Sensor, Gyro Sensor, Geomagnetic Sensor, Hall Sensor, RGB Light Sensor, Proximity Sensor
- Physical specification
- Dimension (H × W × D, mm) 151.0 × 71.8 × 7.9
- Weight (g) 168
- Battery

Continued

	• Internet Usage Time(LTE) (Hours) Up to 15 • Internet Usage Time(Wi-Fi) (Hours) Up to 15 • Battery Capacity (mAh, Typical) 3500
7	Environmental (Conditions affecting device performance) • Nail polish, dirt, or artificial nails may cause lower values or may not allow reading. • Poor perfusion (due to hypotension, hypovolemic shock, or cold environment), movements including trembling, arrhythmias, or heart failure can make it difficult to identify the pulse signal properly and may not allow proper reading. • Very bright artificial light or sunlight can cause erroneous low values. For SpO_2 values
8	Safety and Regulatory Compliance Mechanical Safety: The Samsung Galaxy Note Series 10 adheres to stringent mechanical safety standards to ensure the physical well-being of its users. The following international standards have been followed: • EN 50360: 2017 • EN 50566: 2017 • EN 50663: 2017 • EN 62311: 2008 • EN 623681: 2014 + A11:2017 These standards cover aspects such as electromagnetic radiation, electrical and mechanical safety, and environmental impact, ensuring that the device is safe for use and environmentally responsible. Electrical and Environmental Safety: In line with environmental regulations and energy efficiency, the Samsung Galaxy Note Series 10 adheres to the following electrical and environmental safety requirements: • Eco-design for Energy-Related Products Regulations 2010: These regulations are implemented as per Regulation (EC) No 1275/2008. They focus on standby and off-mode power consumption and have been amended to align with the Eco-design for Energy-Related Products and Energy. The device is designed to be energy-efficient, with measures in place to minimise standby and off-mode power consumption, contributing to environmental sustainability. Certification for Oximetry Function: The Samsung Galaxy Note Series 10 includes an oximetry function and must meet specific medical device standards. The following certification is a requirement and 510(K) for Premarket Notification and According to Browne *et al.* (2021b) Accuracy of Samsung Smartphone Integrated Pulse Oximetry Meets Full FDA Clearance Standards for Clinical Use. ISO 13485: ISO 13485 is a quality management system standard specifically tailored for medical devices, including software applications used in a medical context (Software as a Medical Device - SaMD). Quality Management System (QMS): To ensure compliance with ISO 13485, a robust Quality Management System (QMS) has been established. This QMS encompasses processes and procedures that align with the ISO 13485 requirements. • A third-party certification body accredited for ISO 13485 certification has been engaged to evaluate and assess the QMS for compliance. • The assessment on the QMS aims to determine its alignment with ISO 13485 standards. If the QMS successfully meets the requirements of ISO 13485, certification will be issued. Risk Assessment and Mitigation (ISO 14971): The safety and regulatory compliance strategy includes a comprehensive risk assessment process, adhering to ISO 14971 standards. This process identifies potential risks and hazards associated with the device's operation and usage. • A Hazard Traceability Matrix has been developed, mapping identified risks to applicable risk controls and mitigation measures. • The Risk Assessment Tool facilitates a systematic evaluation of identified risks, their severity, and the effectiveness of the proposed risk controls. By adhering to ISO 14971, the Samsung Galaxy Note Series 10 ensures that potential risks and hazards are thoroughly analysed and mitigated, contributing to user safety and regulatory compliance. This comprehensive approach to safety and regulatory compliance demonstrates Samsung's commitment to producing a device that not only meets international standards but also prioritises user safety and environmental responsibility.

Continued

9	Usability and Ergonomics This real-world feedback has driven continuous improvements to ensure that the Samsung Galaxy Note Series 10 meets the needs of all users. The Devic specifications including device size, weight, and ergonomics are comfortable to use. It features well-balanced weight distribution, making it comfortable to hold and operate for extended periods without causing user fatigue. The placement of buttons and controls is ergonomic, allowing users to access essential functions with ease and minimal strain. The device has an intuitive user interface and has a user manual which is easy to operate and understand. Samsung Galaxy Note Series 10 offers built-in user training and tutorials. Users, especially those who may not be familiar with advanced smartphone features, can access these resources to learn how to make the most of the device's capabilities and Accessibility considerations has support for users with physical limitations and disabilities.
10	Maintenance and Support Outline any maintenance requirements, including battery replacement, software updates, or calibration procedures. The expected lifespan of the device, Samsung phones have an average lifespan of 3 - 6 years. Warranty Period12 Months for Scope of Warranty, Labour & parts. The technical support or service centers with daily operating hours. Based on Samsung merchant in Singapore: 1) Plaza Singapura 2) Westgate 3) Vivocity 4) Causeway Point 5) Bedok Mall
11	Documentation and Training The documentation and training requirements for users include downloadable user manual found in the annex and video instructional guides. User manuals, quick-start guides, or online resources are available. Samsung Galaxy Note Series 10 offers built-in user training and tutorials. The mobile application is intuitive, and users can simply place their finger with guided instructions before with the provision of video training materials and educational resources before application download to ensure users can effectively utilise the oximetry functions.
12	Constraints and Limitations There are no specific constraints or limitations to the design or functionality of the smartphone device. There are factors such as medical and diagnostics regulatory compliance with ISO 13485 and FDA with recent research to recommend substantial equivalence with device use and data outputs.

Table 5. 510(K) for premarket notification submissions.

Description	Your Device	Predicate Device	Equivalence
Intended patient population, such as neonate, infant, pediatric, adult	Adults	Adults	☑
Intended application site, such as finger, ear, foot, hand, forehead, back, nose	Finger	Finger	☑
Performance Specifications (including use under motion and low perfusion conditions, if applicable, and any indices or signals provided to the user)	Suitable for detection in low perfusion conditions Visual and audible High/low SpO_2	Suitable for detection in low perfusion conditions Visual and audible High/low SpO_2 High/low pulse rate	☑
Safety Specifications (e.g., electrical, mechanical, environmental)	Electrical, mechanical, environmental safety available reference Safety and Regulatory Compliance in User Requirements Document.	Safety testing for Type BF or CF applied part as referenced in ISO 80601-2-61: 2011.	☑

Continued

Features (e.g., alarms, display and indicators, modes)	Touch Display Monitor Sensor error or disconnected. Low battery	LCD Display monitor Sensor error or disconnected. Low battery	☑

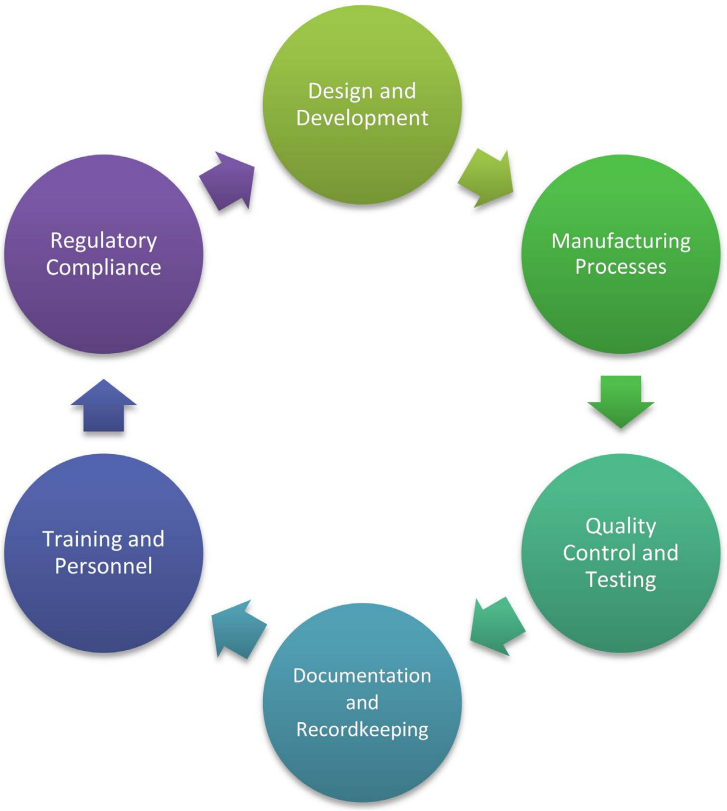

Figure 4. GMP.

Figure 5. URD.

8. Challenges and Solutions

A lack of resources and access to diagnostic tools globally, especially during the COVID-19 pandemic is a challenge with the solution being smartphone devices with oximetry functions to provide an alternative to standard pulse oximeters, allowing individuals to monitor their blood oxygen levels remotely. To ensure the safe and effective use of the smartphone device with oximetry functions FDA reports using a 510(K) Premarket Notification for substantial equivalence with predicate devices to demonstrate that the device is ready to be marketed safely and effectively. Clinical smartphone pulse oximetry devices are set by regulatory bodies like the US Food and Drug Administration (FDA) and International Organisation for Standardisation (ISO). In this project, Browne *et al.* [12] have full FDA/ISO requirements for the smartphone clinical pulse oximetry device using lab testing. Rigorous laboratory testing should be conducted to validate the accuracy and reliability of the smartphone device's oximetry function. Additional testing can be done using a large sample size and referencing blood sample analysis for comparison. Based on post-laboratory test data, Browne *et al.* [12] support Full FDA/ISO approval and an opportunity for emergency use for global pandemic response.

9. Conclusion

Smartphone-based oximeter provides a convenient and accessible way to monitor their blood oxygen levels remotely. These devices are useful during pandemics and airborne viruses such as COVID-19, along with early detection of hypoxia as a crucial health measurement. The Samsung Note 10 fulfills the basic requirements for oximetry functions to qualify for medical device regulatory endorsement. In the user requirements document, necessary specifications are outlined. This includes performance criteria and safety considerations for smartphone devices with oximetry functions.

10. Future Plans

The potential to acquire medical device regulatory endorsement, requires further documentary support such as the FDA 510K to ensure it meets the regulatory requirements of organisations, US FDA and ISO certifications are used as global harmonised standards for substantial equivalence. This research provides information on laboratory testing, incorporating feedback from medical professionals. The potential to optimise the hardware and software components for greater accessibility in other smartphone models for greater compatibility. The software (app) has compatibility options with other smartphone models, such as Apple iPhones with PPG sensors along with brand smartphones with PPG, to broaden the accessibility and reach of smartphone devices with oximetry functions. Education and Support for user guidance, developing clear and intuitive instructions, translated into appropriate languages, to educate users on the proper use of smartphone devices for oximetry measurements. Customer support, docu-

mentation, and training materials will guide users in effective device utility. Continuous Improvement, continuously monitor advancements in smartphone technology and healthcare regulations.

Ethics Approval and Consent to Participate

As this study does not involve primary data collection or human subjects, ethics approval and consent to participate are not applicable.

Consent for Publication

Since this study is based on existing literature and secondary data analysis, consent for participation and publication was not required.

Availability of Data and Material

The study is based on existing literature and publicly available data sources. All references are provided in the reference section.

Competing Interests

The authors declare no competing interests.

Funding

This study did not receive any specific funding.

Acknowledgements

The following organisations are acknowledged for their contributions to this article. Maximum Wellness, a research institute and education service provider affiliated with Skillsfuture Singapore, for providing devices used in this research. I would also like to thank my colleagues and family for their support and encouragement throughout this project.

Permission

I have obtained permission from Maximum Wellness mentioned in this Acknowledgements section.

Covid-19 Dedicated-Research

Intellectual content developed in 2023 April for COVID-19 emergent utility.

Conflicts of Interest

The author declares no conflicts of interest.

References

[1] Singapore Department of Statistics (2023) Population Trends 2021. https://www.singstat.gov.sg/-/media/files/publications/population/population2021.

pdf

[2] Mothership (2021) Temasek Foundation's Free Oximeters Sold on Carousell. Mothership.SG—News from Singapore, Asia and around the World.

[3] TEMASEK (2021) One Free Oximeter for Every Singapore Household. Temasek Corporate Website English. https://www.temasek.com.sg/en/news-and-resources/news-room/news/2021/one-free-oximeter-for-every-singapore-household

[4] Forbes (2023) Best Pulse Oximeters for Seniors of 2023. Forbes Health. https://www.forbes.com/health/healthy-aging/best-pulse-oximeters/

[5] Grand View Research, Inc. (2023) Pulse Oximeter Market Size, Share & Trends Analysis Report by Product Type (Fingertip pulse Oximeters, Handheld Pulse Oximeters), by Type, by Age Group, by Technology, by End-Use, by Region, and Segment Forecasts, 2023-2030. https://www.giiresearch.com/report/grvi1268899-pulse-oximeter-market-size-share-trends-analysis.html

[6] Tarassenko, L. and Greenhalgh, T. (2020) Can We Use Smartphones to Measure Oxygen Saturation? https://www.cebm.net/covid-19/question-should-smartphone-apps-be-used-as-oximeters-answer-no/

[7] Greenhalgh, T., Koh, G.C.H. and Car, J. (2020) Covid-19: A Remote Assessment in Primary Care. *BMJ*, **368**, m1182. https://doi.org/10.1136/bmj.m1182

[8] Nazario, B. (2022) Pneumonia and Coronavirus: Does Everyone with COVID-19 Get Pneumonia? https://www.webmd.com/lung/covid-and-pneumonia

[9] Health Sciences Authority (2023) Regulatory Guidelines for Software Medical Devices—A Life-Cycle Approach.

[10] PRLog (2016) Free iPhone App—Heart Rate Plus—Heart Rate Monitor for Free. https://www.prlog.org/12522628-free-iphone-app-heart-rate-plus-heart-rate-monitor-for-free.html

[11] Browne, S.H., Bernstein, M. and Bickler, P.E. (2021) Accuracy of Samsung Smartphone Integrated Pulse Oximetry Meets Full FDA Clearance Standards for Clinical Use. https://europepmc.org/article/MED/33619504

[12] Browne, S.H., Bernstein, M., Pan, S.C., Gonzalez Garcia, J., Easson, C.A., Huang, C., *et al.* (2021) Smartphone Biosensor with App Meets FDA/ISO Standards for Clinical Pulse Oximetry and Can Be Reliably Used by a Wide Range of Patients. *Chest*, **159**, 724-732. https://doi.org/10.1016/j.chest.2020.08.2104

[13] U.S. Food and Drug Administration (FDA) (2023) Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification

[14] World Health Organization (2023) Technical and Regulatory Aspects of the Use of Pulse Oximeters in Monitoring COVID-19 Patients. https://iris.paho.org/bitstream/handle/10665.2/52589/PAHOHSSMTCOVID-19200029_eng.pdf

[15] Samsung Display (2023) Monitoring Heart Rate with LED? Photoplethysmography (PPG). https://global.samsungdisplay.com/29237/

[16] Maxim Integrated (2023) Signal-to-Noise Ratio as a Quantitative Measure for Optical Biosensors. AN6410. https://cdn.sparkfun.com/assets/8/6/0/9/c/AN6410.pdf

[17] University of Iowa Hospitals & Clinics (2023) Pulse Oximetry: Basic Principles and Interpretation. https://medicine.uiowa.edu/iowaprotocols/pulse-oximetry-basic-principles-and-interpretation

[18] McCormick, K.L. and Sanders, J.H. (2022) Good Manufacturing Practice—An Overview. In: Gruenwald, S.M., Ed., *Science Direct Topics*, Academic Press, 9-18.

[19] International Organization for Standardization (ISO) (2023) ISO 13485: 2016—Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes. https://www.iso.org/standard/59752.html