Market Assessment and Commercial Opportunities for Equitable Pulse Oximetry

By

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Thesis

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Abstract of Market Assessment and Commercial Opportunities for Equitable Pulse Oximetry, by Oluwatosin Sogbesan, Sc.M., Brown University, May 2025.

Since its invention, pulse oximetry (SpO_2) has been fundamental in non-invasively estimating arterial blood oxygen levels (SaO_2) and is widely used as a diagnostic tool. Pulse oximeters function by calculating the ratio of oxygenated hemoglobin (oxyhemoglobin) to total hemoglobin. However, conventional pulse oximetry has limitations, often failing to detect hidden hypoxemia, a condition where low blood oxygen levels are not accurately reflected in SpO_2 readings. This disproportionately affects non-Hispanic Black patients, contributing to delayed treatment and poorer health outcomes. The COVID-19 pandemic further magnified these disparities, indicating the need for more accurate pulse oximetry technologies. To address this issue, the Probe Lab at Brown University is developing Equipulse, a polarization-based pulse oximeter designed to reduce skin-tone bias in SpO_2 measurements. As the first of its kind, a thorough market assessment and commercialization strategy are essential. This thesis integrates market research, device segmentation, and economic analysis to evaluate Equipulse's adoption potential and commercialization pathways. A systematic review of academic literature, industry reports, and market analyses provided insights into pulse oximetry trends. Segmentation by device type, end-use, and medical application identified opportunities in hospital, pediatric, adult, and sensor markets. Interviews with physicians and hospital administrators highlighted clinical limitations of current devices and market potential for Equipulse. Qualitative research suggested an increasing reliance on arterial blood gas (ABG) testing due to existing pulse oximetry inaccuracies. Economic analysis quantified the costs of hidden hypoxemia in chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and neonatal respiratory distress syndrome, demonstrating the value of equitable pulse oximetry in reducing ABG

dependence. Expert insights informed business model development, outlining key factors such as value proposition, market entry strategies, and target markets. Market entry opportunities include prioritizing the growing sensor segment through early-stage industry partnerships. Licensing options and regulatory considerations were also evaluated, emphasizing the need for compliance with administration requirements and the use of quantitative tools to assess skin-tone representation in clinical studies.

Chapter 1. Introduction

Since its invention, pulse oximetry has played a significant role in guiding clinical decisions and improving patients through its ability to noninvasively estimate blood oxygen concentration (SpO_2). Pulse oximeters work by measuring the percentage of oxygen in the blood measured as a ratio of oxygen-carrying hemoglobin (oxyhemoglobin) to the total amount of hemoglobin [1]. Pulse oximeters are composed of several key components, but their design varies by clinical application. These components include small light emitting diodes (LEDs), a photodetector which is typically a photodiode, microprocessors, sensors, a power source, and display [2]. Conventional pulse oximeters measure oxygen by using spectrophotometry. The LEDs within pulse oximetry devices emit two wavelengths through a translucent and vascularly dense region of the body [3]. This region is typically the fingertip or the earlobe though there are other forms. Both 660nm (red) and 940nm (infrared) wavelengths are used to highlight oxyhemoglobin and deoxygenated hemoglobin (deoxyhemoglobin). The use of two wavelengths allows for differentiation between oxyhemoglobin, which absorbs more infrared light and less red light, and deoxyhemoglobin, which absorbs more red light and less infrared light. The photodiode is a semiconductor device that operates by converting reflected light into an electrical current. It is positioned on the opposite arm of the probe and serves the purpose of detecting the intensity of light that passes though the tissue [4]. Once the light is detected, the photodiode measures its intensity. The microprocessor receives the electrical signals from the photodiode and calculates the ratio of red to infrared light. The ratio is displayed on the screen, providing critical information for monitoring patient health, and informing medical decisions. The absorption of the two wavelengths is calibrated against arterial oxygen concentration (SaO_2) measurements. SaO_2 measurements are obtained from arterial blood gas (ABG) tests. These tests

require an arterial puncture and are a more invasive pulse oximetry tool [5]. Low oxygen or hypoxemia is characterized by an oxygen saturation that is less than 90%. Note that various factors impact normal oxygen concentrations in a patient including health and elevation relative to sea level. Due to this variation, there is no single standard value that indicates hypoxemia for all individuals, as baseline oxygen saturation levels can differ based on physiological and environmental factors [6].

According to the US Food and Drug Administration (FDA), pulse oximeters are a Class II medical device and can be categorized as medical grade use pulse oximeters or over the counter (OTC) pulse oximeters [7]. Medical grade oximeters require clinical testing and validation to confirm accuracy before getting premarket authorization or a 510k clearance. In contrast, OTC products are not typically regulated by the FDA, however, that is at the discretion of the administration. OTC pulse oximetry devices are not intended for medical purposes [8]. Pulse oximeters are available in a variety of forms tailored to specific applications. These include fingertip, earlobe, forehead, and toe sensors, as well as more advanced configurations such as handheld, benchtop, phone-based, wearable, and multimodal devices. This array of options ensures adaptability to different clinical settings and patient needs. Pulse oximeter probes may be placed on the hallux if a patient has poor circulation in their fingers. Typically, this includes patients with Raynaud's disease or peripheral artery disease [9]. Similarly, forehead sensors provide SpO_2 measurements in patients who have reduced perfusion [3]. As previously mentioned, fingertip and earlobe sensors are most used to monitor patients. These sensors may come in the form of an adhesive that attaches to the measurement site. Both provide a fit that maintains proper contact, accuracy, and stable attachment reducing the risk of displacement. Modern advancements in medical technology have allowed for the integration of pulse oximetry

into larger monitoring systems. Multimodal pulse oximetry allows medical professionals to monitor additional vitals such as temperature and respiratory rate [10]. Similarly, phone-based, and wearable devices such as watches provide patients with the ability to independently track their health.

Pulse oximetry is frequently used in general practice and collected alongside other patient vitals. It serves as a beneficial tool to assess a patient's health. In addition to general practice, pulse oximetry is used to monitor patients in various disease states. Obtaining pulse oximetry data can provide insight on lung function in patients with chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), sleep apnea, and pneumonia [11]. Data on oxygen saturation also plays a crucial role in detecting hypoxemia, hyperoxia, and assessing the severity of these conditions. Additionally, oxygen measurements provide insight into patient health before, during, and after surgical procedures. In neonatal care, pulse oximeters are used to monitor neonates at risk for respiratory distress symptoms. Most recently, the emergence of the COVID-19 pandemic emphasized the importance of monitoring patients with mild symptoms. The data obtained from pulse oximetry allowed for the early detection of hypoxemia during a period when timely medical intervention was critical for minimizing mortality.

Though pulse oximetry has been considered a reliable tool for patient monitoring, there are many factors outside of poor circulation that can impact the accuracy of the device. According to the National Institutes of Health (NIH) factors such as fingernail polish, skin temperature, tobacco use, skin thickness, and intravenous dyes can affect pulse oximeter readings [12]. These factors can be mitigated through utilizing alternative pulse oximeter devices and ABG tests if necessary. Additionally, skin tone and melanin contribute to inaccuracy in currently available pulse oximetry devices. The onset of the COVID-19 pandemic led to an

unprecedented uptake in higher-than-normal SpO_2 readings acquired from pulse oximeters in specific demographics. Though other factors contribute to inaccurate blood-oxygen readings, skin pigmentation is one that poses significant risk to darker skinned patients. Researchers have found that non-Hispanic Black patients are 32% more likely to experience hidden hypoxemia than non-Hispanic White patients [13]. Hidden hypoxemia, also known as occult hypoxemia, occurs when blood oxygen levels are low but go undetected by pulse oximeter readings. This is characterized by an SaO_2 reading of 88% while the pulse oximeter device measures an SpO_2 reading of about 92%. Since the 1990s, these findings were largely ignored and even denied by manufacturers and regulators and are still not fully understood within the medical community. In another study conducted during the pandemic, Black patients had about 3 times the frequency of hidden hypoxemia than White patients [14]. These findings underscore the need to address racial biases in pulse oximetry, as no technology on the market currently corrects these biases.

Inaccurate readings may result in delayed clinical decision making for physicians and contribute to poorer patient outcomes in large patient populations. A 2023 observational cohort study assessed the rates of hidden hypoxemia across self-identified racial groups and their associations with clinical outcomes. Occult hypoxemia was more common in Black patients compared to White patients [15]. Additionally, Black, Asian, and American Indian patients were more likely to experience occult hypoxemia due to hospitalization. It was found that occult hypoxemia was associated with increased odds of mortality in both surgical and intensive care unit (ICU) patients. Additionally, occult hypoxemia was associated with lower hospital-free days in surgical patients. In another study, patients with hidden hypoxemia experienced higher organ dysfunction scores and higher in-hospital mortality [16].

Though the clinical impact of hidden hypoxemia has been evaluated, the economic impact of hidden hypoxemia in certain disease states remains widely unknown. The implementation of new technologies in medical facilities will come with additional costs for the replacement of current technologies. One study evaluated the cost to replace the pulse oximetry hardware throughout the U.S. healthcare system [17]. Using U.S. hospital data from the Centers for Disease Control and Prevention (CDC), it was estimated that the average cost to replace current pulse oximetry hardware would be about $6,800 per bed. When these costs were extrapolated to 5,564 US hospitals, the estimated cost of replacement would be $8.72 billion. Despite an understanding that the implementation of more equitable pulse oximetry will come with significant upfront costs, it is important to consider that there are costs associated with the shortcomings of current technology. The use of technology that addresses present biases could alleviate these costs. Additionally, this information can inform a commercial strategy for equitable technologies that are in development.

As pulse oximetry plays a significant role in guiding clinical decisions and triage classifications, the U.S. FDA has acknowledged the need for improved standardization requirements for pulse oximeters [18]. In a standardization committee meeting, the quality of premarket studies and evaluation methods for pulse oximeters was assessed. The FDA also noted the importance of considering a patient's skin pigmentation, race, and ethnicity in evaluating performance. Later in January of 2025, the administration released an updated draft of the guidance documents for medical grade pulse oximeters. These documents are used to inform performance evaluations and support premarket submissions. The administration noted that their recommendations are due to concerns that skin pigmentation, amongst other factors, can affect the accuracy of pulse oximeters [19]. Despite growing acknowledgment of these issues, medical

device companies have done little to address them. The limitations provided by current pulse oximetry technology must be addressed to improve health equity and patient outcomes.

The Probe Lab at Brown university has been developing a polarization-based pulse oximeter to reduce skin-tone bias in measuring SpO_2. This has included assessing how polarization and wavelength influence the quality and penetration depth of the signal from which SpO_2 values are derived, as a function of skin tone. Conventional pulse oximeters utilize two infrared wavelengths to measure light absorbed by oxyhemoglobin. Historically, these devices have been calibrated on lighter skin tones, not considering melanin's light absorbing properties. Equipulse utilizes polarized light to account for melanin's absorbance (Figure 1). This research evaluates Equipulse's potential economic and clinical impact through market research, device segmentation, cost-analysis, and physician interviews. Expert opinions also share the business model, highlighting key elements such as value proposition, market entry strategies, and key opportunities - all of which are key insights that will address the limitations of current devices and Equipulse's market potential. Additionally, a health impact calculator will serve as a tool to assess Equipulse's potential benefits in managing chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) and neonatal respiratory distress syndrome (RDS). Equitable pulse oximetry technology could lead to enhanced clinical decision-making and improved patient outcomes, particularly for populations affected by hidden hypoxemia. Closing the gap in equitable pulse oximetry requires a thorough market assessment to effectively introduce the technology and optimize commercial outreach, ensuring it reaches and benefits those most impacted by existing disparities.

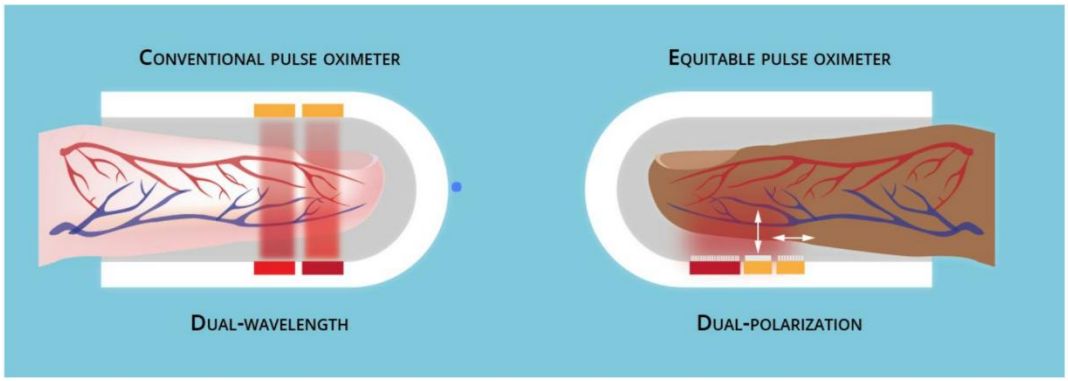

Figure 1. Equipulse (right), developed by Brown University's Probe Lab compared to conventional pulse oximeters (left).

Chapter 2. Pulse Oximetry Market Analysis

2.1 Market Size and Growth

In 2023, the global pulse oximetry market was valued at 3.3 billion USD [20]. With a compound annual growth rate (CAGR) of 6.6% from 2024 to 2030, there is a significant opportunity for Equitable pulse oximetry to thrive within the market. By 2030, the pulse oximetry market is estimated to be worth approximately 5.14 billion USD.

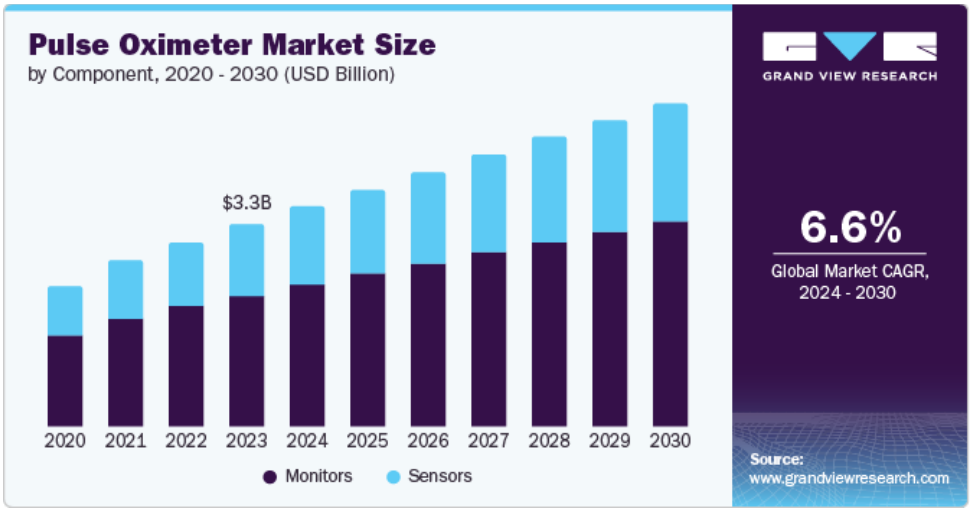

Figure 2. Global Pulse Oximetry Market has a CAGR of 6.6% and is forecasted to reach $5.14 billion by 2030. Note the market is separated by component with blue indicating sensors and dark purple indicating monitors.

2.2 The U.S. Pulse Oximetry Market

As Equipulse is currently in development, it is critical to understand the US market. Although future directions may include global expansion, it is important to establish a strong foundation on US based strategies. The US pulse oximeter market generated $973 million in 2023 and is projected to reach $1.47 billion by 2030 [21]. With a CAGR of 6.1%, there is a significant opportunity for Equipulse to contribute to this growth. Additionally, the US

contributed about 29.2% of revenue in the global market and is projected to continue to lead in 2030. By continent, North America has the largest market share, 39.4% [16].

2.3 Market Challenges and Drivers

Physicians rely on data from pulse oximeters to guide clinical decisions and adequately treat patients. Additionally, this data is used to monitor respiratory and cardiovascular diseases, as declines in oxygen levels could indicate worsening of disease and the need for life-saving oxygen delivery. One of the key drivers that contribute to the rising demand and growth within the pulse oximetry market is the increasing prevalence of cardiovascular and respiratory diseases. One study assessed the global burden of COPD through 2050. COPD prevalence is projected to reach 600 million cases by 2050 [22]. Additionally, prevalence is predicted to rise 23%, with low- and middle-income countries being impacted the most. Key contributors to increasing rates in low- and middle-income countries include the increased risk of respiratory tract infections due to housing conditions, environmental exposures, pollution, and limited access to treatment [23]. According to the American Lung Association, approximately 11.7 million adults in the US have COPD and it continues to be a leading cause of morbidity [24]. This translates to approximately 5.0% of women and 4.1% of men being impacted by the disease. Additionally, rates of congestive heart failure are on the rise. The prevalence and mortality rates for CHF are increasing amongst younger adults in certain racial/ethnic groups. The incidence of CHF is higher among Black individuals and the prevalence has increased amongst Black and Hispanic individuals over time [25]. About 6.7 million Americans over the age of 20 have heart failure [26]. It is estimated that 1 in 4 people will develop CHF in their lifetime. CHF is a chronic progressive disease with no cure however, options include treatments for symptom management to improve quality of life, surgery such as transplantation or bypass, and lifestyle

changes [27]. Most recently, the COVID-19 pandemic demonstrated the need for consistent monitoring as worsening of symptoms caused by the virus could lead to respiratory failure. The demand for pulse oximetry and other medical technology significantly increased during this time due to their effectiveness in measuring blood oxygen levels. Eventually, this demand led to a shortage resulting in delays and backorders at major retailers. Additionally, technological advancements and innovation within the pulse oximeter industry is a key factor in accelerating market growth. This is due to the increased development of wireless connectivity options, improved sensors, and the development of adaptable pulse oximeters that can be used in different regions of the body, leading to accelerated growth. Companies are also utilizing mergers and acquisitions to expand into other global markets. For example, Philips acquired Xhale Assurance Inc., a company that developed a disposable nose sensor that mitigates the limitations of fingertip pulse oximeters [28].

One of the notable challenges with the pulse oximeter market is growing regulatory oversight and concerns of inaccuracies in patients with darker skin tones. Regulatory bodies like the FDA have noted concerns with the limitations of current technologies. If more stringent regulations are put on medical grade pulse oximeters, companies who develop these technologies must find ways to correct these errors and consider potential new validation and verification requirements. An additional challenge is the development of alternative smart devices [29]. There has been a recent uptake in the smartwatch sector. Companies like Apple Inc. have developed devices that are able to monitor beyond pulse oximetry such as energy consumption and heart rate monitoring. This poses as a market challenge because it increases competition from multifunctional health technology devices, contributing to the extension of available health monitoring solutions. Consumers may favor smartwatches for their convenience. The growing

adoption of smartwatches may pressure traditional pulse oximeter manufacturers to lower prices or enhance their products to remain competitive. The presence of alternative oximetry-capable devices threatens the conventional pulse oximeter market by shifting consumer presence towards more integrated solutions. Although smart devices present competition in the pulse oximeter market, they do not undergo the same rigorous testing as medical grade-pulse oximeters. However, consumers may struggle to differentiate between FDA-approved medical devices and wellness gadgets, potentially relying on inaccurate data from unregulated devices to guide medical decisions.

2.4 Segmentation

When segmented by component, the monitor segment has the largest share or 65% of the revenue [20]. The sensor segment makes up just 35% of the pulse oximeter market. A monitor refers to the device that displays the SpO_2 measurement while the sensor is the component that is in contact with the body and utilizes light to measure blood oxygen levels. The sensor market is expected to growth the fastest between 2024 and 2030. They are the components critical for enhancing accuracy in measuring oxygen levels. The growth within this segment can be attributed to the market shifting to focus on patient outcomes.

By product type, the pulse oximeter market is segmented into fingertip, handheld, and tabletop devices. In 2024, the tabletop pulse oximeter segment had the largest market share [30]. Tabletop pulse oximeters are used in various healthcare facilities such as hospitals, emergency departments, and ICUs. They serve as a reliable means of measuring vital signs in an environment where efficiency is critical. Fingertip pulse oximeters are an affordable and compact option. They can be equipped with capabilities such as Bluetooth for ease of access to vital sign data. Handheld pulse oximeters are commonly used for athletes and have the benefit of

more accuracy in comparison to fingertip pulse oximeters. In one study, handheld devices had a lower failure rate (1-2%) when compared to fingertip devices (4-6%) [31].

When segmented by end use, the hospital segment makes up most of the market share at 42.8%, followed by home care, outpatient facilities, and then others (Figure 3). This is due to the significant role that pulse oximetry plays in clinical settings. Market leaders like Masimo are placing their focus in investing in technology that can be integrated into other patient monitoring systems.

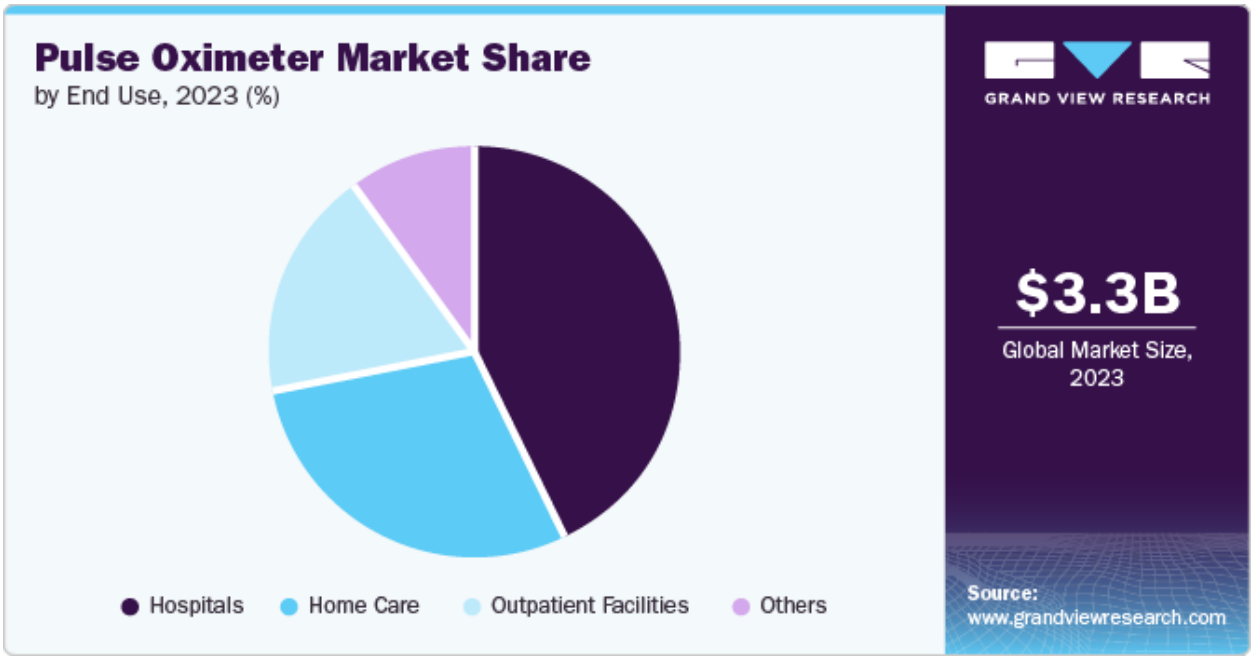

Figure 3. Pulse Oximeter Market Share by End Use in 2023 [20].

By age group, the market is segmented into adult and pediatric pulse oximeters. In 2023, the adult segment generated 62.6% of the market share. Despite generating less revenue, the pediatric segment is predicted to experience significant growth. One of the driving factors of this growth is the rising demand and opportunity to advance pulse oximetry technology used in neonatal monitoring. In November 2023, Owlet's Dream Sock received DeNovo clearance for monitoring oxygen saturation and heart rate in infants aged 1 to 18 months. The device notifies

caregivers if the infant's oxygen levels fall outside preset ranges [32]. Infant pulse oximetry monitoring is conducted by placing sensors on either the right hand or on the foot as neonates are too small for fingertip monitoring. It is important to note that this approval occurred prior to the administration's drafted guidance document. The FDA also noted that it plans to release and maintain a list of pulse oximeters that have adequately demonstrated not having disparities [18]. As the pediatric segment is estimated to experience significant growth in upcoming years, there is an opportunity to introduce novel technology that addresses the shortcomings of current technology.

2.5 Competitor Analysis

The pulse oximeter market consists of many market leaders, but it is critical to group these companies by their positioning within the pulse oximeter supply chain. In doing so, determining opportunities for growth and competitive differentiation becomes more strategic. Companies within the pulse oximeter market can be categorized into component manufacturers (i.e., software, sensors, or hardware), device manufacturers who either make advanced patient monitoring systems or standalone pulse oximeters and finally pulse oximeter device suppliers and distributors. Pulse oximeter suppliers are companies that directly market and sell pulse oximeters under their brand name to healthcare providers, retailers, and consumers. Understanding the supply chain positioning of key players also helps in assessing regulatory challenges, pricing strategies, and emerging trends that could shape the future of pulse oximetry technology.

Medtronic and Masimo are the most prominent within the market with Medtronic holding the largest share. Medtronic holds between 23-25% of the pulse oximeter market [33]. Outside of pulse oximeters, the company's portfolio spans a wide range including ventilators, advanced

surgical hardware, diagnostics, cardiovascular devices, neuromodulation systems, and diabetes management tools. The company is a global leader in developing innovative healthcare solutions across the medical technology landscape.

Masimo's product portfolio includes patient monitoring systems, handheld devices, and sensors. Most recently, the company is adding to their portfolio by making strategic partnerships in the wearable and telehealth solutions spaces. In September of 2024, the company announced its partnership with Qualcomm to develop a smartwatch reference platform for equipment manufacturers [34]. This platform will combine the company's leading biosensing capabilities to expand upon Google's Wear OS smartwatch operating system with whom they announced partnership earlier in the year. In 2024, Masimo invested $222.8 million into research and development compared to $175.2 million in 2023 [35]. Their core measurement technologies are their Measure-through Motion and Low perfusion pulse oximetry. They use the company's Signal Extraction Technology (SET) platform. Within the 10-k filing, the company cited that a significant portion of their revenue is generated from their SET platform and Rainbow SET. The company has claimed that Masimo SET has been shown to "perform accurately on patients of all skin tones" and additionally, they are strategically collaborating with regulatory agencies to improve access to accurate pulse oximetry, globally [36].

Nonin Medical is a privately held American company specializing in pulse and regional oximetry. While not required to publicly disclose financial information, it remains a leading manufacturer of fingertip and wrist-worn pulse oximeters. In addition to handheld devices, Nonin develops tabletop monitoring solutions that are designed for use in various healthcare settings, further solidifying its position in the market [20].

Contec Medical Systems is another leader within the medical device manufacturing segment. The company is known for its comprehensive portfolio of patient monitoring equipment including pulse oximeters and vital sign monitors [37]. The company has established a strong presence in both domestic and international markets focusing on cost-effectiveness for health care providers across different settings.

Sentec is a Swiss American medical device manufacturing company specializing in noninvasive monitoring technologies. The company is a leader in innovations for oximetry as they offer solutions designed to enhance patient care in both clinical and home healthcare environments. Additionally, the company's portfolio includes solutions for neonatal and pediatric intensive care settings [38].

Further assessment of the market revealed key leaders in the component manufacturing sector. Amongst software and algorithm manufacturers is Nihon Kohden, a Tokyo-based manufacturer, that is considered a pioneer in pulse oximetry. An engineer at the company invented the principle of pulse oximetry in the early 1970s [39]. Today, the company specializes in manufacturing SpO_2 sensors in addition to other measurement instruments. Analog Devices Inc. (ADI) is a chip manufacturing company that supplies their components to Masimo [34]. Their primary focus is the beginning of the supply chain as they develop analog and digital processing technologies critical for pulse oximetry. AmsOSRAM is an Austrian semiconductor manufacturer that develops and produces intelligent sensors and light emitter components (LEDs) that can be integrated into medical devices [40].

Pulse oximetry using polarization rather than traditional light-based methods, such as photoplethysmography, is still being explored. To date, however, the FDA has not approved any devices using this technology. Though many market leaders claim to account for skin tone in

their devices, the FDA only recently released a draft guidance to improve pulse oximetry testing processes across diverse populations. A fully standardized and enforceable process to ensure equitable performance across all skin tones has yet to be finalized.

2.6 Key Challenges and Unique Opportunities

Despite the advancement in medical technology, there is still no cure for CHF. As rates are expected to rise within the next 10 years, more patients will require accurate means to assess blood oxygen levels as they are an indication of treatment effectiveness and disease severity. Pulse oximetry also plays a role in detecting any subtle change in oxygen levels. These changes are indicative of worsening disease and the need for medical intervention. As the prevalence and incidence of CHF is highest in Black and Hispanic individuals, the introduction of more equitable pulse oximetry could improve outcomes for those with darker skin tones, especially for organ transplantation [25]. Researchers at the University of Michigan's School of Medicine found that biases could limit the opportunities for Black patients with CHF to receive heart pumps and transplants [41]. Health care providers use the data from pulse oximetry to determine patient eligibility for these interventions. Due to current biases and inequities in the US healthcare system, racial and ethnic minorities are already less likely to receive these interventions than their White counterparts, but pulse oximetry inaccuracies worsen these disparities. One physician noted that "For our Black patients with heart failure, we need to either measure oxygen saturation directly from the blood or use other methods to measure hemodynamics if we are using them to guide treatment of these patients" [41]. As previously mentioned, the way to measure oxygen saturation (SaO_2) is by ABG test. Despite being more accurate than current pulse oximeters, they are more costly and invasive. There is an opportunity

for equitable pulse oximetry solutions to penetrate the market as there is a demonstrated clinical need.

As market leaders are shifting their investment focus to technology that can be integrated into larger monitoring systems, there is an opportunity to penetrate the growing sensor component segment. At the core of pulse oximetry, sensors are responsible for detecting blood oxygen levels, as Equipulse's key differentiation is the use of polarization, there an opportunity to transform this segment. The monitor segment is heavily saturated and as previously mentioned, the sensor segment is expected to grow the fastest in upcoming years. Additionally, the pediatric segment is also set to experience the highest growth in upcoming years so including neonates in addition to the adult segment market would serve as a strategic choice. A potential challenge in addressing this segment is the additional regulatory requirements associated with neonatal indications, however, there is vast opportunity to innovate within this space. Additionally, conditions like RDS in neonates born with underdeveloped lungs is a disease state which requires continuous monitoring of SpO_2 levels. Continuous monitoring is performed to ensure patients are staying within target ranges and to detect worsening of their condition.

Despite market leaders claiming to have equitable technology, there are many ways to account for skin tone. Companies like Masimo have recommended using a standardized pigment categorization tool such as the Monk Skin Tone (MST) scale however, like other qualitative tools, it is subjective as shown in Figure 4 [35].

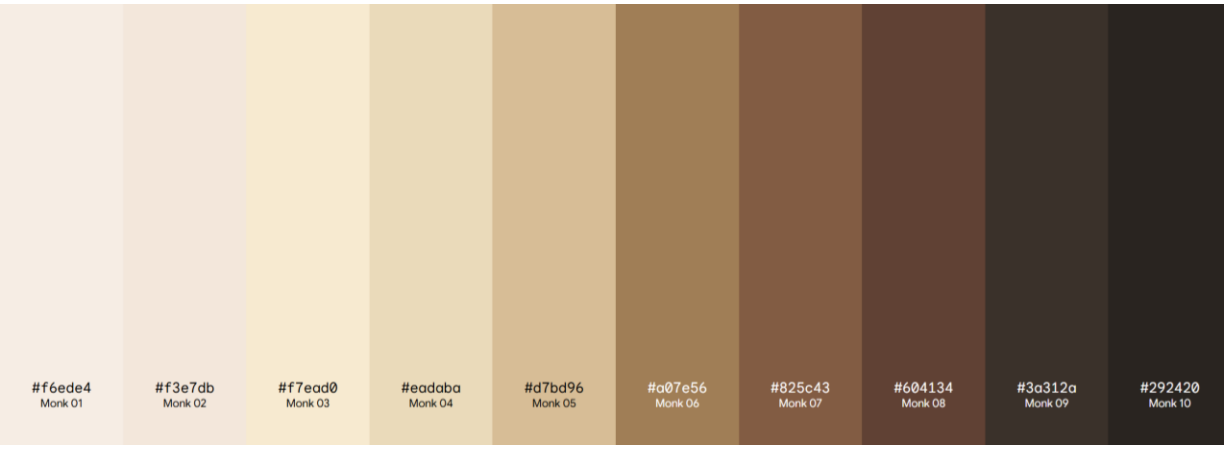

Figure 4. The Monk Skin Tone (MST) Scale comprised of 10 single-colored rectangles with each swatch providing the most representative color within its MST group [42].

Other tools to quantify skin tone are the Fitzpatrick skin type scale that categorizes skin tone on a scale of I to VI with VI being the darkest [18] (Figure 5).

Figure 5. The Fitzpatrick skin phototype scale [43].

The interpretation of skin tone can vary between individuals, making the use of quantitative tools to measure skin tone during pulse oximetry testing more reliable. Another limitation is the lack of comprehensiveness amongst existing methods. Qualitative tools, for example, fail to account for individuals who fall between the predefined categories of skin tone.

As previously mentioned, only after the FDA establishes a clear framework for ensuring equitable performance can the reliability of current devices be meaningfully compared. By incorporating quantitative and qualitative assessments of skin tone, Equipulse can demonstrate its reliability to stakeholders and investors. Colorimetry, for example, is a quantitative tool that can be used to measure skin tone. One common method is the Individual Typology Angle (ITA) which is calculated from colorimeter measurements. This technique uses device-independent color space to quantify skin color based on all colors visible to the human eye [44]. A consideration of the use of quantitative tools is that it carries some additional costs. However, the use of methods that account for the limitations of qualitative measurements will strengthen the evidence that Equipulse can provide. While differentiation is key in a highly saturated medical technology market, recognizing and addressing the shortcomings of existing solutions is just as critical.

Chapter 3. Stakeholder Primary Market Research

3.1 Interview Methodology

Physicians play a key role in clinical decision-making, and pulse oximetry is a key component of that process. Since the hospital segment was identified as a market opportunity, it was essential to gather insights from stakeholders who rely on the device in their daily workflows. Additionally, there was uncertainty surrounding awareness of the limitations in current pulse oximetry technology, and whether these issues influence decision-making processes. To address this, interviews were conducted with physicians and other key stakeholders to assess perceptions, concerns, willingness to integrate equitable technologies, and remaining uncertainties. Interviews explored the perceived need, potential barriers, and broader market considerations. These insights informed the market positioning, strategic adoption approach, and commercialization pathways for Equipulse.

Participants were selected based on predefined criteria to ensure relevant insights into the operational aspects of pulse oximetry use in hospital settings. Participants were eligible if they had direct patient contact or if they contributed to a hospital's technology adoption processes. Additionally, participants working at large tertiary care hospitals were targeted due to the higher probability of serving minority populations as these groups are more likely to have hidden hypoxemia.

A total of 9 stakeholders were interviewed. For the purposes of the research, personally identifiable information (PII) such as the names of participants will not be included. This maintains participant privacy and follows ethical research practices outlined by institutional review boards. This includes 1 Director of Engineering, 1 Chief Medical Officer, 1 Transplant Surgeon, 1 Attending Anesthesiologist, 2 ICU Medical Directors, and 3 Pulmonologists. All

stakeholders were U.S. based. The inclusion of these professions allowed for well-rounded insights from a hospital setting. 8 out of 9 participants practiced in Rhode Island. 1 participant practiced in California. 2 participants, the Director of Medical Engineering and Chief Medical Officer were involved in the purchasing and technology adoption processes for their hospitals. 1 participant worked at a Veteran's Affairs Medical Center.

Participants were contacted via emails primarily found using university and hospital directories. Insights were obtained using 30-minute qualitative interviews via semi-structured video platforms or phone calls. Participants were asked to answer a series of questions pertaining to pulse oximetry. The specifications of Equipulse were not discussed to prevent biases in participants' responses. This ensured that their feedback remained focused on general perceptions, concerns, and barriers related to pulse oximetry technology rather than being influenced by specific features of a product. Interviews were transcribed (see Appendix A).

Note that some questions were not asked depending on the role of the participant. For example, individuals involved in the technology adoption process were not asked about their daily use of pulse oximetry. Additional probes were asked during points where participants provided incomplete responses or when further clarification was needed to explore their experiences. Probes could include asking about stories as it related to their experiences with patients. These probes helped ensure a deeper understanding of the participant's views. Interview questions are listed below:

a. In which clinical scenarios is pulse oximetry crucial in your daily operations?
b. What challenges or pain points do you experience with current pulse oximetry devices in use at your hospital?
c. What would you like to see in future pulse oximetry technology?
d. What are the potential effects of inaccurate pulse oximetry readings in your clinical practice?
e. What constitutes inaccurate, quantitatively?

f. How does the presence of melanin in a patient's skin impact the accuracy of pulse oximetry readings? What are the effects of that?
g. What are the key features and specifications that hospital staff prioritize when selecting pulse oximeters for patient monitoring?
h. What is the preferred form factor for pulse oximeters in your hospital, such as handheld, fingertip, or wrist-worn devices?
i. What are the current methods and technologies used for monitoring patients before, during, and after organ transplant surgery?
j. Can you share some of the most common respiratory conditions or diseases you encounter in your practice? Any specific patient populations?
k. How do you use pulse oximetry data and other information to make treatment decisions for patients with respiratory conditions? Any specific patient populations?
l. Who are the key stakeholders involved in the purchasing decisions, and what are their primary considerations when selecting pulse oximetry equipment?
m. What factors do you consider when/if switching from one pulse oximeter manufacturer to another, or to upgrade existing devices?
n. What are the primary considerations when selecting new pulse oximetry technology?
o. What drives the decision to adopt pulse oximetry technology?
p. How do you typically assess the need for new pulse oximetry devices in your hospital?
q. Have you encountered any recent challenges or issues with your current pulse oximetry devices that you are looking to address with new equipment?
r. How do you typically gather information about new medical devices, including pulse oximeters? Do you rely on industry publications, vendor presentations, or peer recommendations?

After transcription, insights were assessed to confirm the potential use of equitable pulse oximetry within the hospital segment and the specifications of its application in the clinical decision-making process. Additionally, these questions informed how hospitals adopt new technologies, and the key considerations administrators focus on when selecting technology. A thematic analysis was conducted using interview transcriptions to determine key areas of attention from stakeholders. Thematic analysis is a qualitative research method used to identify and report themes within a data set to obtain meaningful insights [45].

3.2 Primary Market Research Results

A variety of insights were obtained from conducting the interviews. Participants noted a variety of ways in which pulse oximetry is used in their daily operations. Pulse oximetry data is obtained for vital signs, patient monitoring in ICUs, and during various surgical procedures. Additionally, patients may be discharged with supplemental oxygen if the pulse oximeter indicates that this is needed. One physician noted that pulse oximetry is an essential tool for monitoring patients before, during, and after surgery. During surgery, there is risk of oxygen dropping and if a patient's SpO_2 levels drop below the healthy range, physicians will be alerted to respond accordingly. Another application that was not previously considered is the use in organ procurement. After a patient passes, there is a limited time frame for physicians to procure their organs for transplantation. Pulse oximetry data provides an accurate measure of when to procure their organs, as low oxygen can indicate inadequate organ perfusion. Outside of surgery, the most common respiratory conditions were flu, severe asthma, pneumonia, COPD, sleep apnea, and COVID-10. When asked about current pain points experienced with pulse oximeters in use at their place of work, one physician noted that many patients purchased "poor pulse oximeters from the internet or large retailers." This is an indication of increased demand for over-the-counter pulse oximeters which are often not regulated by the FDA. The lack of quality control for OTC devices was an area of concern amongst physicians. About half of the participants noted inaccuracies in patients with darker skin tones as a challenge with current pulse oximetry devices in use at their hospitals. If the patient's pulse oximeter reading is normal, despite worsening symptoms, there could be delays in treatment ultimately leading to poorer outcomes. The need for better algorithms that accommodate skin tones and present false negatives was emphasized. Additional factors impacting the accuracy of pulse oximeters were impaired vascular perfusion, electrical and optical interference, and carbon monoxide poisoning.

Nail polish and connective tissue disorders were also mentioned as factors that impact accuracy. When asked about what percentages constitutes as an inaccurate reading, physicians noted a 5-10 percentage point difference from actual.

Participants involved in the technology adoption processes noted that the input from the nursing and respiratory therapy team was critical in making purchasing decisions for medical devices. Technology brand, cost, ease of use, functionality, and algorithm quality were all factors that were considered when a hospital changes from one pulse oximeter manufacturer to another or upgrading existing devices. Another key consideration was the new technology's ability to be integrated into larger monitoring systems and other already existing technology for a centralized process. Specifically, there was an emphasis on integrating with CO_2 monitoring technology as it is critical for enhancing the accuracy of respiratory assessments. It was mentioned that hospitals do not have the budget to buy new technology frequently. Smaller monitoring systems typically cost between $1,000 and $2,000, while larger monitors can range from $10,000 to $20,000 or more. Hospitals generally replace entire monitoring systems every 7 to 10 years, as their circuitry remains reliable over extended periods. One participant noted Masimo and Nellcor, which is now owned by Medtronic, as companies that have sold and licensed their technology for use in larger hospital systems. Additionally, some companies sell circuit boards as components to be installed into larger monitoring devices.

Results from the stakeholder market research demonstrate awareness of the role that skin tone plays in the accuracy of pulse oximeter data. Overall, participants emphasized the wide range of applications that pulse oximetry has within the hospital segment. Outside of skin tone, there is an emphasized need for improvements in current technology that Equipulse could correct. As the monitor segment is heavily saturated, insights from the interviews indicate an

opportunity for Equipulse to be involved early in the supply chain. As hospitals prioritize seamless integration with existing monitoring systems and rarely replace entire systems due to high costs, entering the sensor component segment would be a strategic approach to gaining market entry and adoption.

Another tool to assess oxygen levels is ABG testing which requires blood sampling via a catheter and sample processing. ABG tests are typically performed in emergency situations such as treating cases of severe infection, respiratory distress, metabolic imbalances, and critical conditions like sepsis or organ failure. These situations require precise measurements of oxygenation, carbon dioxide levels, and acid-base status. All of which are essential for clinical decision-making. Additionally, they are used to assess whether a patient requires oxygen therapy or mechanical ventilation. These tests are deemed to be the gold standard for pulse oximetry assessments however, it is more costly and time consuming to conduct. One physician noted that initially, they were not trained to have to do ABG testing for patients outside of emergency scenarios because it was assumed that pulse oximetry was accurate however, there are growing concerns regarding its reliability. They noted that more ABGs are done now despite previously relying on pulse oximeters.

There is no reported evidence on the increased use of ABGs in hospitals in recent years, however qualitative reports from physicians suggest a growing reliance on the more invasive and costly test. Additionally, SpO_2 is inherently an imperfect predictor of arterial oxygen saturation, particularly when SpO_2 levels fall below 90%. Arterial blood draws are ordered when hypoxia due to alveolar hypoventilation is suspected, even when pulse oximeter levels appear normal [46]. Physicians may order an ABG when symptoms such as shortness of breath, cyanosis, lightheadedness, chest pain, dizziness, and numbness are present [47].

Despite the inherent limitations of pulse oximetry compared to ABG analysis, advancements can mitigate certain factors affecting accuracy. Skin tone related discrepancies can be addressed through improved design and enabling more equitable and precise measurements across diverse patient populations. While ABG testing remains the gold standard and will not be replaced, technological improvements may reduce its frequency of use. These insights into the economic impact of this use informed the next chapter of this research.

Chapter 4. Economic Evaluation of Conventional vs. Equitable Pulse Oximetry

4.1 Objective of the Health Impact Calculator

While the clinical consequences of hidden hypoxemia (HH) have been documented, the economic impact remains uncertain and largely unexplored. While there is no reported evidence of increased ABG use in hospitals in recent years, qualitative reports from physicians suggest the growing reliance on ABG testing. Despite the limitation of pulse oximetry compared to ABG analysis, advancements in technology can improve accuracy. ABG testing will remain the gold standard however technological improvements could reduce its frequency of use. Understanding the economic impact of these limitations is essential for assessing the financial burden of hidden hypoxemia and the potential cost savings associated with the use of more accurate pulse oximetry technology. This analysis estimates the cost of HH by evaluating how the limitations of standard pulse oximetry contribute to HH prevalence across different racial populations, and the potential cost savings from reducing HH with more accurate, equitable pulse oximetry technology. Since HH can only be determined through sequential ABG testing, this model assumes that for each at-risk individual an ABG test is performed as part of routine assessment to confirm hypoxemia that may have been missed by using pulse oximetry alone (i.e., a patient presents symptoms of hypoxemia, but the pulse oximeter reads as normal). As pulse oximetry is essential for monitoring and managing conditions such as COPD, CHF, and RDS in neonates, it is important to evaluate its pitfalls and their impact on the use of medical resources. The costs of conventional pulse oximetry were compared to those of an alternative device, with the terms “conventional” and “standard” pulse oximetry used interchangeably throughout this evaluation. The economic evaluation was conducted in accordance with the 2022 Consolidated Health Economic Evaluation Reporting Standards (CHEERS) to ensure a structured approach [48].

4.2 Methods

The prevalence of HH by race or ethnicity was obtained by calculating the mean reported rates of from six reference studies evaluating its impact across racial groups (Table 1). These rates represented the probability of HH when using conventional pulse oximeters.

Race/Ethnicity	**2004 (%)**	**2022 (%)**	**2022 (%)**	**2022 (%)**	**2022 (%)**	**2024 (%)**	**Average (%)**
Black	33.0	6.8	19.6	21.5	28.5	9.5	**19.82**
White	20.0	4.9	15.6	10.2	17.2	6.4	**12.38**
Hispanic/ Latino	19.0	6.0	16.2	8.6	29.8	8.6	**14.70**
Asian	24.0	4.8	—	9.2	30.2	7.2	**15.09**

Table 1. Rates of hidden hypoxemia by race/ethnicity across studies in order of publication year (left to right: 2004-2024). Sources: Data compiled from multiple references [49-54].

Data on the prevalence of HH among Black and White neonates was obtained from studies specific to neonatal populations (Table 2). Due to limited available data on other racial groups among neonates, only Black and White neonates were included in the neonatal model.

Race/Ethnicity	Reference Year	Probability of Hidden Hypoxemia (%)
Black	2022	9.2
	2023	12.0
	2023	12.0
Black (Avg.)	—	**11.1**
White	2022	7.7
	2023	4.0
	2023	4.0
White (Avg.)	—	**5.2**

Table 2. Rates of hidden hypoxemia in neonates by race/ethnicity and reference year (2022-2023) Sources: Data compiled from multiple references [55-57].

To model the racial distribution of Black, White, Hispanic/Latino, and Asian individuals in the COPD, CHF, and neonatal RDS sample populations, data from the U.S. Census was used [56]. Disease probabilities for each disease state were derived from published epidemiological studies (Table 3 and Table 4).

Race	US Census Population (%)	Probability of COPD	Probability of CHF
Black	12.1%	.062	.046
White	57.8%	.064	.033
Hispanic/Latino	19.1%	.041	.028
Asian	5.6%	.023	.018

Table 3. The US Census population distribution, COPD probability, and CHF probability by race/ethnicity. Sources: Data derived from multiple references [59-60].

Incidence of RDS by Gestational Age (p)			
Race	**34 weeks**	**28 weeks**	**24 weeks**
Black	0.361	0.860	0.980
White	0.361	0.860	0.980

Table 4. Incidence of neonatal respiratory distress syndrome by race/ethnicity and gestational age (weeks). Sources: Data compiled from published study [61].

A decision tree model was constructed to compare the financial outcomes for conventional versus equitable pulse oximetry across different racial groups and disease states. Each node represented a clinical decision or potential outcome, aligning with the current standard of care. A sample population of N_{Adults}=100 million was used in the COPD and CHF model scenarios to ensure robust estimations of financial impact. The U.S. birth rate is about 11 per 1,000 people [62]. Additionally, in the U.S., premature infants born before 37 weeks account

for 1 in 10 births. Therefore, a sample population of $N_{Neonates}$= 330,000 was used to be representative of real-world scenarios, based on a total U.S. population of 300 million [63].

Decision tree modeling is a structured approach used to visually represent complex decision-making processes in which multiple choices are shown with each branch representing a potential outcome and its associated probability [64]. In this evaluation, the model quantified the costs associated with using conventional versus equitable pulse oximetry in patient care. To simulate real world clinical scenarios, the model incorporated the probabilities of disease exacerbation, high risk exacerbation, high risk hospitalization, ICU admission, hidden hypoxemia, and probability of having a disease.

Model Structure

Decision trees were constructed for COPD, CHF, and neonatal RDS to compare the economic outcomes using conventional and equitable pulse oximetry. Each tree for COPD and CHF consisted of nodes (variables) representing clinical decisions. Probabilities of these variables were used from previously published studies. For COPD, the nodes and corresponding probabilities used for cost outcomes were as follows: exacerbation (p = 0.87), high-risk exacerbation (p = 0.26), high-risk hospitalization (p = 0.96), and ICU admission (p = 0.90) [65-67]. Annual exacerbation rates, ranging from a low of 0.5 to a high of 3.5, were obtained from the literature [65]. Probabilities for each risk category were assigned as 0.13 for low risk and 0.87 for high risk to ensure the probabilities in the decision tree summed to 1. The risk distribution was assumed to be 70% for low risk and 30% for high risk. These values were used to calculate the overall probabilities, resulting in low risk (p = 0.61) and high risk (p = 0.26). A similar methodology was applied to determine the probabilities of hospitalization and ICU admission. The cited low and high rates of hospitalization were 0.09 and 2.4, respectively,

translating to low-risk probability (p = 0.04) and high-risk probability (p = 0.96) [66]. The cited low and high rates of ICU admission were 0.02 and 0.19, respectively, translating to low-risk probability (p = 0.10) and high-risk probability (p = 0.90) [67].

For CHF, the nodes and corresponding probabilities used for cost outcomes were as follows: exacerbation (p = 0.67), high-risk exacerbation (p = 0.20), ICU admission (p = 0.80), and high-risk hospitalization (p = 0.51) [68-70]. Annual exacerbation rates, ranging from a low of 2 to a high of 4, were obtained from the literature[68]. Probabilities for each risk category were assigned as 0.33 for low risk and 0.67 for high risk to ensure the probabilities in the decision tree summed to 1. The risk distribution was assumed to be 70% for low risk and 30% for high risk. These values were used to calculate the overall probabilities, resulting in low risk (p = 0.47) and high risk (p = 0.20). A similar methodology was applied to determine the probabilities of ICU admission and hospitalization. The cited low and high rates of ICU admission were 0.5 and 2, respectively, translating to low-risk probability (p = 0.20) and high-risk probability (p = 0.80) [69]. The cited low and high rates of hospitalization were 0.84 and 0.89, respectively, translating to low-risk probability (p = 0.49) and high-risk probability (p = 0.51) [70].

For each disease state, the model accounted for the probability of HH, and subsequent clinical pathways (Figure 6). The analysis assumes that due to the limitations of pulse oximetry, physicians are increasingly relying on ABG tests to diagnose and treat hypoxemia in at-risk individuals. It is also assumed that each patient with potential HH (SpO_2 < 88%) undergoes an ABG test as part of routine assessment, recognizing that HH can only be identified through ABG measurements. Additionally, the probabilities of exacerbation, exacerbation risk, hospitalization risk, and ICU admission were consistent between racial and ethnic categories but varied by

disease state based on published data. The costs of an ABG test, $200, were based on public data though it is acknowledges that these costs may vary by institution and location [71]. All cost outcomes were calculated in US dollars (USD) using the product of the probabilities (p) of each clinical outcome as represented in the equation below:

$$Cost\ (USD) = \$200 \times N_{Adults} \times p_{Race} \times p_D \times p_{EX} \times p_{EXH} \times p_{HHR} \times p_{ICU} \times p_{HH}$$

Where p_D represents the probability of disease, p_{race} probability of belonging to a specific racial/ethnic demographic (White, Black, Hispanic/Latino, or Asian), p_{EX} denotes the probability of exacerbation, and p_{EXH} corresponds to the probability of high-risk exacerbations. Additionally, p_{HHR} is the probability of high-risk hospitalization, p_{ICU} is the probability of ICU admission, and p_{HH} refers to the probability of hidden hypoxemia. For each disease and racial group, two cost outcomes were calculated: one for conventional pulse oximetry and one for equitable pulse oximetry.

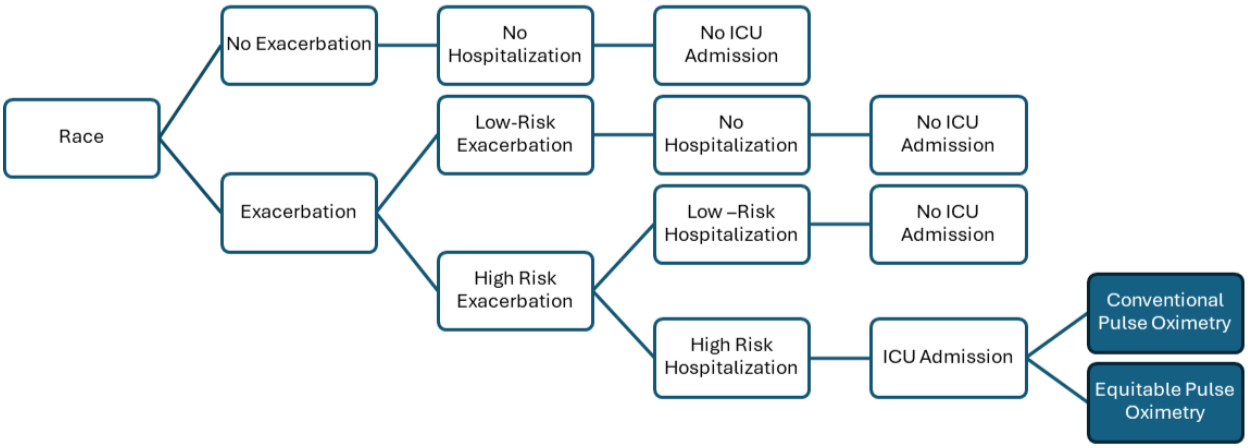

Figure 6. Decision tree for chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF), with branches representing probabilities of disease and diagnostic outcomes.

The models for RDS in neonates did not include the following probabilities: exacerbation risk, hospitalization, and ICU admission (Figure 7). Under the current standard of care, neonates with RDS are typically already hospitalized, as the condition primarily affects preterm infants [72]. RDS occurs due to underdeveloped lungs and prevalence varies by gestational age. For this evaluation, the gestational ages used within the neonatal model were 38, 28, 24 weeks with corresponding prevalences of 0.361, 0.860, 0.980, respectively [61]. The prevalence of RDS by gestational age was obtained from published epidemiological data. The cost outcomes for neonatal RDS were calculated in USD using the product of the probabilities of each clinical outcome as represented in the equation below:

$$Cost\ (USD) = \$200 \times N_{Neonates} \times p_{race} \times p_{RDS} \times p_{HH}$$

Where p_{race} is the probability of belonging to a specific racial demographic (Black or White), p_{RDS} is the probability of RDS and p_{HH} is the probability of hidden hypoxemia. For each gestational age and racial group, two cost outcomes were calculated: one for conventional pulse oximetry and one for equitable pulse oximetry.

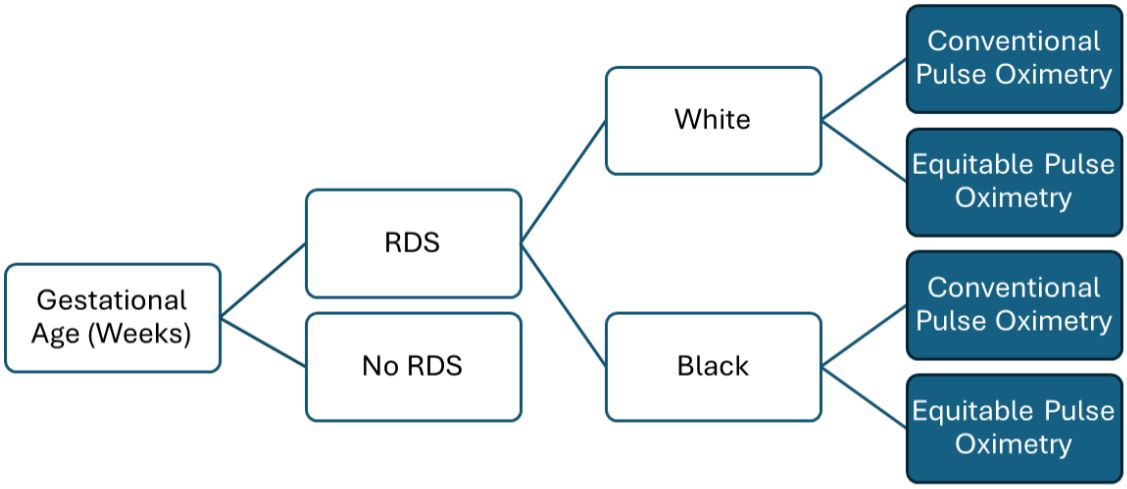

Figure 7. Decision tree for neonatal respiratory distress syndrome (RDS). Decision trees were constructed for each gestational age (34, 28, and 24 weeks), with branches representing probabilities of disease and diagnostic outcomes.

Sensitivity Analysis

A sensitivity analysis was conducted to evaluate the potential impact of equitable pulse oximetry in reducing HH across racial groups. Reductions of 25%, 33%, and 50% were applied to the probability of HH using equitable pulse oximetry where a 0% reduction represents the baseline or rates of HH using standard equipment. For example, if the probability of HH for a given racial group was 12% (p=0.12), a 25% reduction would yield a probability of 9% (p=.09). Full probability adjustments for each disease state are represented in Table 5 and Table 6.

Race/Ethnicity	Standard Device (Baseline, p)	50% Reduction (p)	33% Reduction (p)	25% Reduction (p)
Black	0.20	0.10	0.13	0.15
White	0.12	0.06	0.08	0.09
Hispanic/Latino	0.15	0.07	0.10	0.11
Asian	0.15	0.08	0.10	0.11

Table 5. Sensitivity analysis probabilities of hidden hypoxemia for adult diseases, COPD and CHF (from left to right: standard (0% reduction), 50% reduction, 33% reduction, 25% reduction).

Race/Ethnicity	Standard Device (Baseline, p)	50% Reduction (p)	33% Reduction (p)	25% Reduction (p)
Black	0.11	0.06	0.07	0.08
White	0.05	0.03	0.04	0.04

Table 6. Sensitivity analysis probabilities of hidden hypoxemia for neonatal RDS (from left to right: standard (0% reduction), 50% reduction, 33% reduction, 25% reduction).

Cost Burden

Despite Non-Hispanic White individuals making up much of the U.S. population, or 57.8%, they experience lower rates of hidden hypoxemia in comparison to Black, Hispanic/Latino, and Asian individuals. To account for this, cost burden per 1,000 people was calculated, which balances the overall impact of hidden hypoxemia by considering both the prevalence within racial/ethnic groups and the total number of individuals affected. These calculations help to better understand the relative economic burden each group faces. The cost per 1,000 people was calculated using the equation below:

$$Cost\ Burden\ per\ 1{,}000\ people = \frac{Total\ HH\ Cost\ (Standard)}{Population\ Share} \times 1{,}000$$

4.3 Results

Total costs associated with HH in COPD patients across racial groups was $28.7 million using conventional pulse oximetry (Figure 8). The costs associated with a 25% reduction in HH using equitable technology were: $13 million, $4.4million, $3.4 million, $600 thousand amongst White, Black, Hispanic/Latino, and Asian patients, respectively. Costs associated with a 33% reduction were $11.6 million, $3.8 million, $3.1 million, and $400 thousand, respectively. Costs associated with a 50% reduction were $8.7 million, $2.9 million, $2.4 million, and $400 thousand, respectively. When considering both the prevalence within racial/ethnic groups and the total number of individuals affected, the burden of hidden hypoxemia per 1,000 individuals was highest in Black individuals $484.6. Asian individuals had the lowest cost burden on $134.9 per 1,000. Cost burden was $240.4 per 1,000 in Hispanic/Latino patients and $300.2 per 1,000 in White Patients (Table 7).

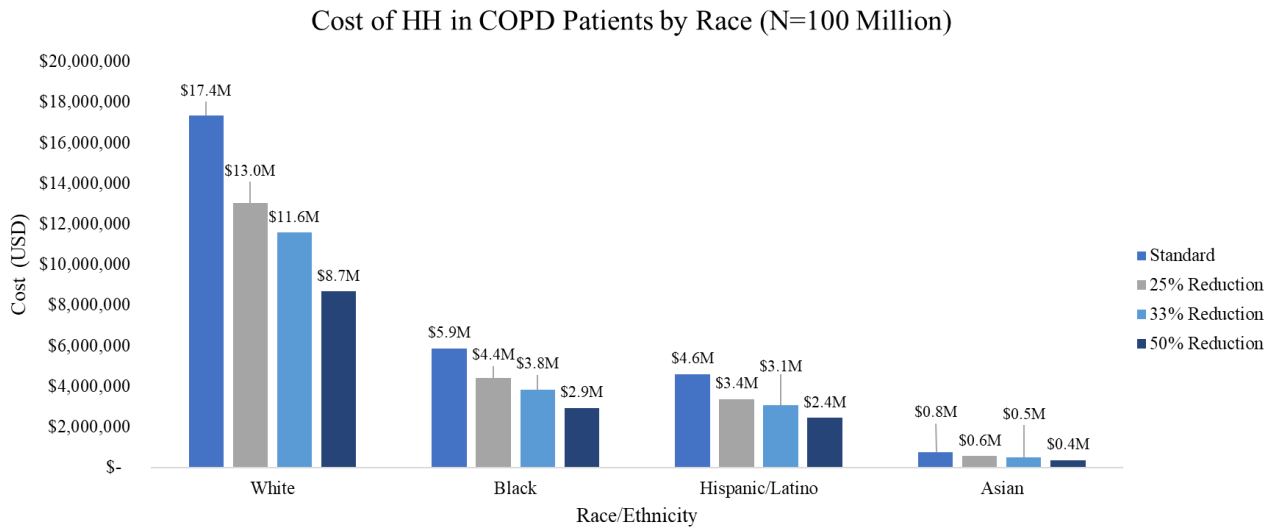

Figure 8. Cost of hidden hypoxemia (HH) in chronic obstructive pulmonary disease (COPD) by race/ethnicity. From left to right: Standard (0% reduction), 25% reduction, 33% reduction, and 50% reduction.

Race/Ethnicity	Total HH Cost (Standard)	Sample Population Share (millions)	Cost Burden per 1,000 People
White	$17,351,035.45	57.8 people	$300.19
Black	$5,864,667.49	12.1 people	$484.68
Hispanic/Latino	$4,591,396.74	19.1 people	$240.39
Asian	$755,167.80	5.6 people	$134.85

Table 7. Cost burden of hidden hypoxemia in chronic obstructive pulmonary disease (COPD) per 1,000 people by race/ethnicity. Sample population share is based on US census data [56].

In a sample population of N=100 million individuals, total costs associated with HH in CHF patients across all racial groups (Black, White, Hispanic/Latino, and Asian) was $6.5 million using conventional pulse oximetry (Figure 9). The costs associated with a 25% reduction

in HH using equitable pulse oximetry were: $1.7 million, $1.0 million, $700 thousand, $200 thousand amongst White, Black, Hispanic/Latino, and Asian patients, respectively. Costs associated with a 33% reduction were: $1.5 million, $900 thousand, $600 thousand, and $100 thousand, respectively. Costs associated with a 50% reduction were: $1.1 million, $700 thousand, $500 thousand, $100 thousand, respectively. When considering both the prevalence within racial/ethnic groups and the total number of individuals affected, the burden of hidden hypoxemia per 1,000 individuals was highest in Black individuals, $109 per 1,000 people. Hispanic/Latino patients had the second highest burden of $49.20 per 1,000 people. The cost burden for Asian and White individuals was $37.7 and $39.4 per 1,000, respectively (Table 8).

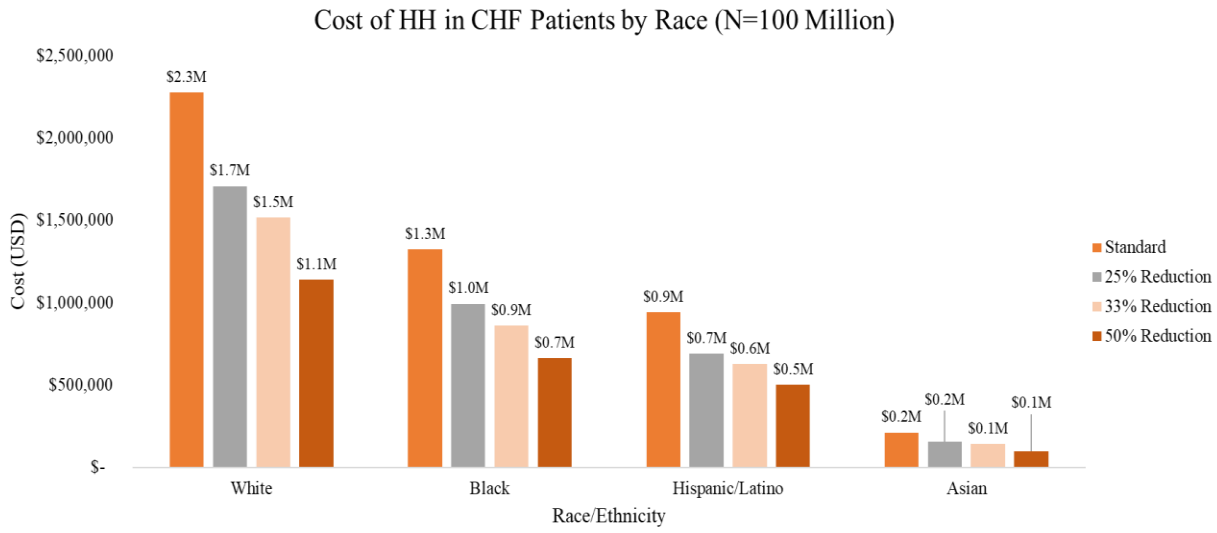

Figure 9. Cost of hidden hypoxemia (HH) in congestive heart failure (CHF) by race/ethnicity. From left to right: Standard (0% reduction), 25% reduction, 33% reduction, and 50% reduction.

Race/Ethnicity	Total HH Cost (Standard)	Sample Population Share (millions)	Cost Burden per 1,000 People
White	$2,275,229.95	57.8 people	$39.36
Black	$1,323,062.40	12.1 people	$109.34
Hispanic/Latino	$939,811.68	19.1 people	$49.20
Asian	$211,252.61	5.6 people	$37.72

Table 8. Cost burden of hidden hypoxemia in congestive heart failure (CHF) per 1,000 people by race/ethnicity. Sample population share is based on US census data [56].

In a sample population of N=330,000 individuals, total costs associated with HH in neonatal RDS across Black and White neonates was $6.3 million. A 25% reduction in HH resulted in a total cost of $4.8 million (Figure 10). A 33% reduction resulted in costs of $4.2 million total (Figure 11). A 50% reduction in HH resulted in costs of $3.1 million (Figure 12). The cost burden for Black neonates was higher, totaling $48,700 per 1,000, compared to $23,000 per 1,000 for White neonates (Table 9).

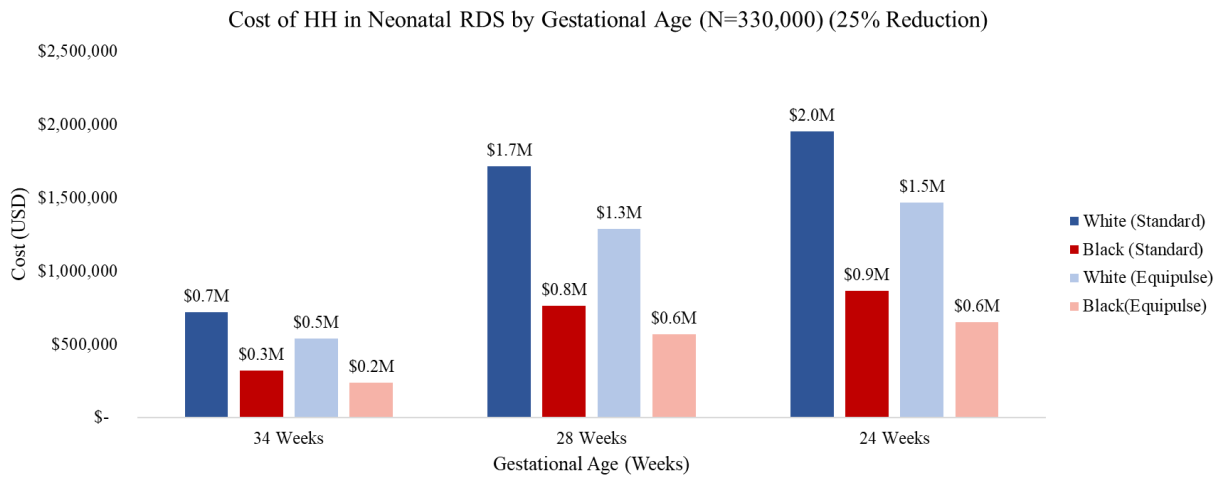

Figure 10. Cost of hidden hypoxemia (HH) in neonatal respiratory distress syndrome (RDS) by race and gestational age (weeks). From left to right: White (Standard, 0% reduction), Black (Standard, 0% reduction), White (25% reduction), Black (25% reduction).

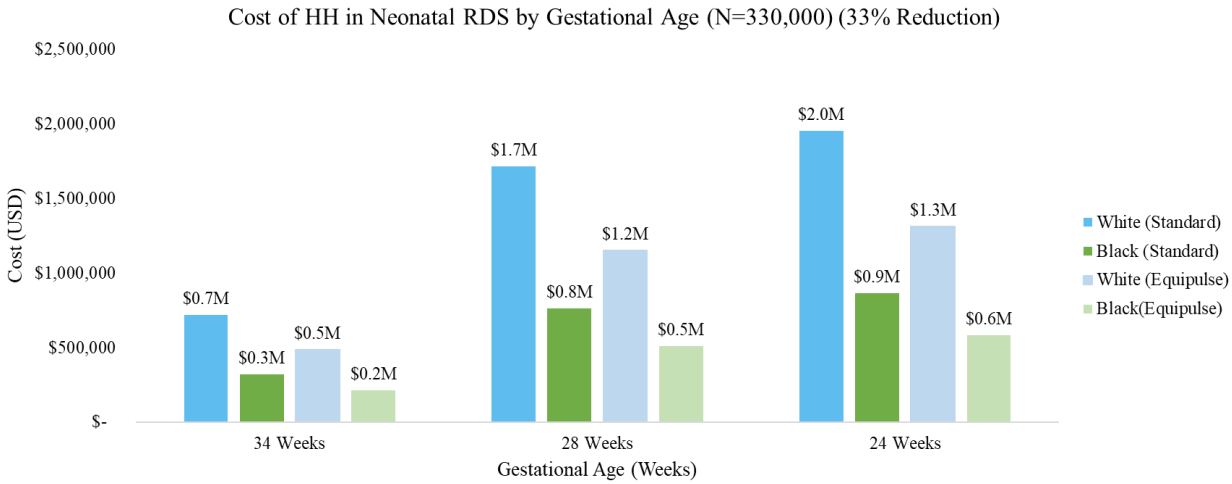

Figure 11. Cost of hidden hypoxemia (HH) in neonatal respiratory distress syndrome (RDS) by race and gestational age (weeks). From left to right: White (Standard, 0% reduction), Black (Standard, 0% reduction), White (33% reduction), Black (33% reduction).

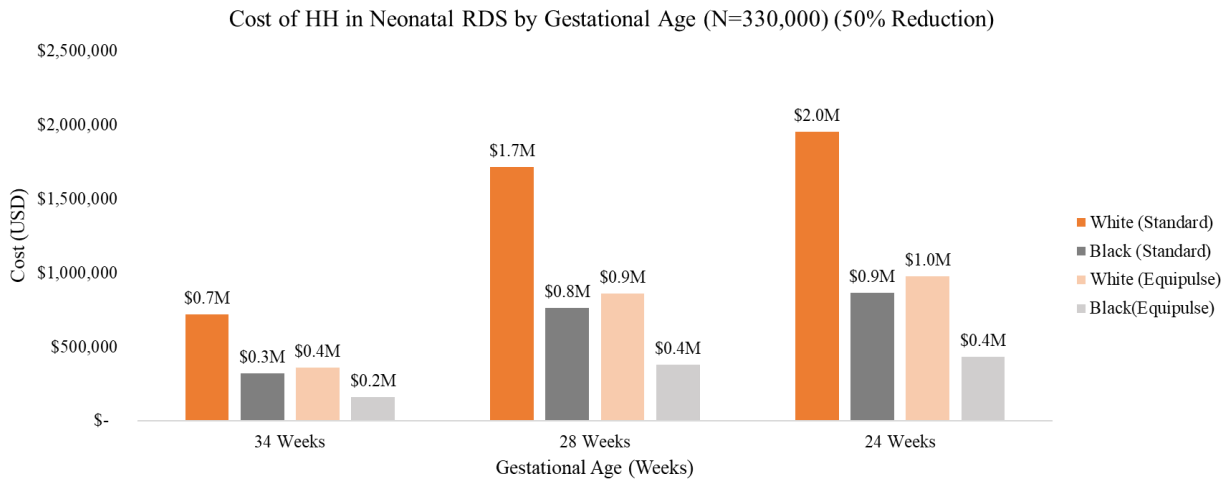

Figure 12. Cost of hidden hypoxemia (HH) in neonatal respiratory distress syndrome (RDS) by race and gestational age (weeks). From left to right: White (Standard, 0% reduction), Black (Standard, 0% reduction), White (50% reduction), Black (50% reduction).

Race/Ethnicity	Total HH Cost (Standard)	Sample Population Share	Cost Burden per 1,000 People
White	$4,394,103	190,740 neonates	$23,037
Black	$1,945,209	39,930 neonates	$48,715

Table 9. Cost burden of hidden hypoxemia in neonatal respiratory distress syndrome (RDS) per 1,000 people by race. Sample population share is based on US census data [56].

Chapter 5. Industry Partner Interviews

5.1 Interview Methodology

Stakeholder market research revealed the high costs associated with replacing entire monitoring systems in clinical settings. Additionally, the importance of integrability was emphasized by hospital administration. In Chapter 2, the monitoring segment made up the largest share of the market. Despite only making up 35% of the market, the sensor segment is expected to grow the fastest in upcoming years. Sensors are an integral part of pulse oximetry and there is an opportunity for replacement of these components rather than producing larger monitoring systems. Industry partnerships are a critical component for academic institutions. They serve as a non-dilutive tool to commercialize products and expand market outreach. Often, industry partners are equipped with the capital and credibility to validate early-stage technologies. Nonin Medical and AmsOSRAM were two companies that were identified as potential industry partners. Nonin Medical is one of the leading manufacturers of tabletop minoring solutions for use in various healthcare settings while AmsOSRAM is a semiconductor manufacturer that develops and produces sensors and LED components that can be integrated into medical devices. Being involved in the early stages of the pulse oximeter supply chain is critical for securing competitive advantage and optimizing production costs. Industry partner interviews were conducted to determine how companies differentiate themselves within the market as well as how they navigate changing regulatory requirements. Additionally, these interviews provided insights that could guide partnerships and technology development. Understanding industry perspectives on technology partnerships informed the best approach for Equipulse's market entry and long-term success.

2 potential partners were interviewed. For the purposes of the research, PII will not be included to maintain confidentiality. A product manager overseeing Asia, the Americas, and Europe was interviewed from AmsOSRM, while a Senior Director of Global Marketing and Communications was interviewed from Nonin Medical. Participants were contacted via emails found using LinkedIn and university resources. Insights were obtained using 30-minute qualitative interviews via semi-structured video platforms. Participants were asked to answer a series of questions pertaining to pulse oximetry technology. Questions that did not pertain to the company's segment were not asked. Interviews were transcribed (see Appendix B). Interview questions are listed below:

a. What sets your chip (semiconductor) manufacturing approach for pulse oximeter devices apart from others in terms of technology or innovation?
b. What is the extent to which you are tracking the regulatory discussions about pulse oximeter accuracy?
c. Do you have anything planned to address any anticipated upcoming changes to the regulatory landscape?
d. How does your company address regulatory requirements for medical device components, to adhere to compliance with industry standards?
e. How closely do you monitor FDA discussions regarding pulse oximeter accuracy, and do you have plans to address regulatory changes? How concerned are you about that? How do they hear about it and how do they think about that?
f. How does your company approach innovation in chip manufacturing for pulse oximeter devices, and are there any emerging trends you find noteworthy?
g. What factors guide your company's decisions in forming partnerships or developing new technology for client companies?
h. What are the key considerations when making a licensing deal?
i. How does your company perceive current market trends for pulse oximeter devices, and how do your products align with these trends?
j. How do you conduct clinical trials/testing for your products? (i.e., criteria, study design)
k. Can you share insights into your company's approach to adopting new pulse oximetry technologies?
l. What does your internal R&D focus on, and how do you acquire new technologies?

m. What criteria are crucial when considering integrating new technologies into your products?
n. How does your company expand its market presence and stay competitive?
o. What factors do you consider when forming partnerships with other companies/institutions?
p. What attributes do you consider indicative of a successful partnership, and conversely, what are red flags that may signal a problematic collaboration?

Thematic analysis was used to highlight key themes and informed commercial pathways.

5.2 Key Findings and Implications for Commercial Strategy

Industry partners noted that they are consistently monitoring regulatory discussions on standardization requirements by the FDA and the European Medicines Agency (EMA). It is critical to determine best practices to ensure their products meet these requirements. Nonin Medical noted that they primarily focus on the FDA's guidelines for manufacturing as monitoring these changes gives the company insights inro how to keep their innovations up to date. Additionally, they consider other products already on the market as well as open forums to determine the best strategies for their products. Nonin noted that their primary focus when integrating products into their existing technology is whether it complies with their mission and vision. More specifically, if the technology performs to their standards. In the past, the company noted that there was not much emphasis on ensuring that testing was done on diverse patient populations. Additionally, the company uses the Monk and Fitzpatrick scales to identify individuals in diverse populations. Though these qualitative tools have been used in the past, the company agrees that the next step in refining data quality and performance would be the use of quantitative tools, like colorimetry. When asked about current pulse oximetry trends, the company emphasized the importance of high-quality products. While their technology comes at a high cost, they consider quality a critical priority. A notable challenge was the heavy focus on

fingertip monitoring within the form factor segment. The company noted that there is room for improvement within this segment and currently, they are working to bring new form factors to the market. This ensures a wide range of individuals get just as accurate measurements as they would from their fingertips. When asked about industry partnerships, the company emphasized that they did not want low cost and low performing technology. Quality was again emphasized as one of the most principal factors. Additionally, the entity that they are working with must have already produced enough clinical information that demonstrates that their device or algorithm aligns with Nonin's standards. Another factor is whether the entity is addressing issues that currently exist within the market such as diversity in patient populations.

AmsOSRAM only tests specific components and follows the study requirements of the most stringent entities such as the FDA and Asian regulatory bodies. This minimizes the number of studies conducted while maintaining high standards that can be applicable in less stringent markets. They also noted that most of the burden of testing and adherence is placed on medical device manufacturers. The company indicated that they are always looking to drive innovation and do so by keeping in close contact with their customers, following market trends, and evaluating the needs within the market. Like Nonin, AmsOSRAM notes the importance of taking skin tone into consideration. Within chip manufacturing, they are currently looking for ways to quantitatively assess skin tone. While these tools are under investigation, they can strengthen the quality of pulse oximeter sensors. The company was unwilling to share specifics regarding plans for addressing upcoming changes in the regulatory landscape but noted that they were evaluating these areas. When asked about industry partnerships, the company noted the need for each entity to bring value to one another. It is critical to assess the strengths and weaknesses to determine how they can benefit each other. Indicators of a beneficial partnership include the use of novel

ideas for information technology and algorithms. The assets must also fit within the company's mission. Indicators of poor partnerships include issues with investment and misalignment. Additionally, if there is no longer value for the product, it is critical to reassess the strategy. If the technology is no longer of value and re-strategizing is not an option, it is best to discontinue the partnership. Some of the key considerations when making a licensing deal are intellectual property (IP) agreements. The company noted that patent infringement is a risk and could slow development therefore, both parties shall be aligned on the use of technology. Additionally, the company prefers testing to be done in their own labs. This strategy allows them to generate their own data and limits the amount of information that is shared, decreasing the risk of IP infringement.

Chapter 6. Results and Strategic Recommendations for Equipulse

6.1 Value Proposition

A critical component of a business model is the value proposition. It is a statement that summarizes why an innovation is attractive to its customers and investors. Although Equipulse is currently in development, it is important to assess ways to attract entities that could be involved in any stage of the commercialization process. In this case, it is important to be quantitative, relevant, testable, and specific. Inaccurate pulse oximetry could result in poorer outcomes and delayed care, Interviews from physicians revealed growing concerns with the technology currently in use at their hospitals. Physicians order ABG tests if a patient presents with symptoms aligning with hypoxia even when the pulse oximeter reads as normal. Symptoms include shortness of breath, cyanosis, lightheadedness, chest pain, dizziness, and numbness. Though there is no published evidence of increased use of ABG testing however, stakeholder interviews suggest that there may be a growing reliance. If that is the case, there may be additional costs associated with this reliance. In addition to evidence generated from clinical testing, an economic evaluation of patient outcomes using standard pulse oximetry in comparison to a more accurate technology would strengthen stakeholder interest. Market analysis also revealed increasing prevalence of respiratory diseases as a driving factor for growth. Additionally, the pediatric market revealed opportunity for entry specifically for neonatal monitoring. With these opportunities being taken into consideration, disease states of interest for the economic analysis were COPD, CHF, and Neonatal RDS. The economic evaluation in Chapter 4, revealed additional costs associated with the use of standard pulse oximetry and how an alternative device would decrease these costs by decreasing the rates of hidden hypoxemia. In a sample population of 100 million individuals, standard pulse oximetry

costs approximately $35.2 million combined across racial groups. Additionally, in a sample of 330,000 individuals, this cost is $6.3 million amongst Black and White neonates. ABG testing takes roughly 20 minutes per test and although costs may vary by institution, reducing the use of ABG testing by decreasing rates of hidden hypoxemia could generate millions of dollars in savings [73]. It is acknowledged that ABG testing will not be completely replaced by equitable pulse oximetry however, there is opportunity to reduce the impact that skin tone has on hidden hypoxemia.

6.2 Target Market and Opportunities for Entry

Market analysis identified key opportunities for Equipulse's market entry. When segmented by end use, hospitals generate most of the market share. Despite medical grade pulse oximeters requiring FDA approval, having approval would increase the integrity of Equipulse's technology thus increasing physician interest. When segmented by component, monitors have the largest share of the market. As this segment is heavily saturated, there are limited opportunities to capture a large market share. Companies like Masimo and Medtronic are two of the key market leaders within this segment. Additionally, these entities have demonstrated trust amongst large hospital chains so there is minimal opportunity to create a larger monitoring device that could penetrate the market. The sensor segment is estimated to experience high growth in the next 6 years, despite currently holding less than 50% of the market share. Through stakeholder interviews, hospital administration revealed the high costs associated with changing entire monitoring systems and the low replacement frequency. Technology must be able to be integrated to be considered for use in hospital settings. As mentioned in Chapter 2, the sensor is the component that is in contact with the body and utilizes light to measure blood oxygen levels. The sensor market is expected to growth the fastest between 2024 and 2030. They are the

components critical for enhancing accuracy in measuring oxygen levels. With this taken into consideration, it is advisable to enter the sensor segment while targeting the hospital segment for use in adult and pediatric patients.

6.3 Industry Partnerships and Considerations

Making strategic partnerships with companies that develop technology that can be integrated into monitoring systems would generate high returns for Equipulse. As Equipulse is being developed within an academic institution, there is an opportunity to license the technology to other entities. In a licensing agreement, the licensor is the party who owns the IP and grants the licensee permission to use the IP. Though there are multiple types of license agreements that vary by exclusivity of rights, exclusive licenses and non-exclusive licenses are two to consider for Equipulse. Exclusive licenses grant the licensee or industry partner the right to commercialize the patented product. In this option, no other entities between the two can commercialize the product. The benefits of this license type are that there are higher royalties being generated and a higher commitment from the industry partner. Additionally, having only one entity involved in the commercialization process mitigates the risk of delays due to error. This is due to closer monitoring of product development and manufacturing processes. It is also important to consider the downsides of this type of agreement as the licensee may have a single focused market approach. This limits the potential of the product prior to patent expiration. Additionally, with just one entity being involved, there are higher risks of commercialization failure if misalignment arises. Non-exclusive licenses allow the licensee to commercialize the product in addition to other licensees and the owner of the IP. Benefits to this and partially exclusive licenses include having multiple paths to market, the ability to address multiple markets simultaneously, and increased chances of commercialization. Some of the drawbacks of this type of license include

the fact that having multiple entities involved may increase the possibility of disagreements later in the development process. Managing multiple licensees requires clear alignment on responsibilities to mitigate this risk or it could result in financial losses for all parties involved. To maximize commercial success, it is essential to consider options that best align with the goals of Equipulse's licensor.

6.4 Regulatory Considerations

The FDA has acknowledged the need to consider skin tone during clinical studies for pulse oximetry however, there are important considerations to make when commercializing Equipulse. In recent years, the FDA has discussed factors that can impact the accuracy of pulse oximeter readings, including skin tone. Although the administration has released a draft guidance document issued by the Center for Devices and Radiological Health (CDRH), the contents of the document are merely nonbinding recommendations. These recommendations focus on the importance of considering race, ethnicity, and skin tone when selecting study population. The document also notes the use of tools to assess skin tone using objective measures. While many companies will look to adhere to these updated requirements in future innovations, current technologies who may not be accurate in darker skin tones are still in use across the country. The administration is looking to release a list of devices that adhere to these recommendations. This will allow for a better perception and understanding of competitor products. In the meantime, it is important that Equipulse to adheres to these recommendations and endpoints to ensure credible and validated results. Additionally, if Equipulse is to enter international markets, it is important to adhere to the regulatory requirements of other nations. Some regions will have varying clinical evidence standards where additional clinical endpoints may need to be met.

6.5 Market Adoption

While there is evidence of inequities in pulse oximetry technology, it is important to engage with key opinion leaders (KOLs) to drive awareness and advocate for clinical integration. KOLs do not only include pulmonologists but other clinicians who use pulse oximetry to guide clinical decisions. It is evident that not all stakeholders are aware of the shortcomings of current technology therefore educating them is a critical factor for market adoption. During these discussions it is also important to quantify the market need. Utilizing economic outcomes alongside clinical data and evidence will further strengthen Equipulse's adoption strategy and investor interest. Additionally, having been developed in an academic institution, early adoption through healthcare systems and research institutions can be facilitated through using existing relationships, clinical trial collaborations, and grant funding opportunities. Partnering with research centers and hospitals can help generate evidence and enhance clinical confidence in Equipulse's technology.

6.6 Long-Term Growth Strategies

There is growing interest in personal health technologies, particularly in at-home pulse oximetry integrated into smartwatches and other wearable devices. While many consumer-grade pulse oximeters are not FDA-regulated as medical devices, they have gained significant traction in the personal health market. This presents an opportunity for Equipulse to establish an early presence in the consumer space while maintaining a pathway toward regulatory approval. Once FDA clearance is obtained for clinical use, Equipulse could expand into broader applications including remote patient monitoring, telehealth, and integration into digital health ecosystems. It is important to first demonstrate, through clinical studies, that Equipulse reduces the rate of hidden hypoxemia across skin tones. Additionally, skin tone should be assessed using

both qualitative and quantitative measures to ensure more reliable data. As the global demand for accessible and reliable health monitoring solutions rises, there is the opportunity to expand into international markets in the future. Countries with growing investments in digital health infrastructure and regulatory frameworks for medical devices offer strategic opportunities for commercialization beyond the US market.

Chapter 7. Discussion

7.1 Discussion

Despite technological advancements, the prevalence of hidden hypoxemia remains high in patients with darker skin tones. More specifically, non-Hispanic Black patients are more likely to experience hidden hypoxemia than their White counterparts, highlighting the need for more innovative and equitable solutions. With current standards, conventional pulse oximeters put the medical provider's ability to provide efficient care at risk. These risks include delayed treatment and poorer outcomes in minority communities. The development of Equipulse, a technology that uses polarization, is a promising opportunity to transform the pulse oximeter market. The commercialization of equitable technology requires thorough market assessment, economic evaluation, and commercial strategy to evaluate its potential impact on current clinical practices. A systematic review of academic journals, industry reports, and market analyses was conducted to understand trends in pulse oximetry. Segmentation by device type, end-use, and medical application further informed the market landscape. The US pulse oximeter market is expected to grow significantly in upcoming years and many market leaders pride themselves on having technology that accounts for skin tone. To date, Equipulse is the first of its kind, using polarized light to accurately measure SpO_2 levels. It was important to assess not only the opportunities for success but also key considerations. Market analysis revealed opportunities within the pediatric and adult segments, primarily focusing on hospitals as the end-user. Physician market research not only confirmed the need for more accurate pulse oximetry technology within their hospitals but also noted possible increases ABG testing as COVID-19 pandemic emphasized inequities in pulse oximetry. Though there is no published evidence on the increase used of ABG testing, interviews and physician opinions informed the next stages of the market assessment. This

presumption was used to inform an economic analysis. With the key drivers of market growth being the uptake in respiratory illness and heightened growth in the pediatric market, an economic analysis emphasized the costs associated with pulse oximetry in model populations of COPD, CHF, and neonatal RDS. Using decision tree modeling, the financial outcomes for conventional/standard pulse oximetry were compared to an equitable alternative. The evaluation also showed a higher cost burden per 1,000 people among minority groups, further highlighting the value of a technology like Equipulse in reducing hidden hypoxemia. The total costs associated with inaccurate care in these model scenarios were approximately $42 million. Equitable solutions could help reduce excessive spending within the healthcare system by lowering the probability of hidden hypoxemia. Given that pulse oximetry is valued for its timely and non-invasive results, developing technology that addresses these issues is highly recommended. While ABG testing will likely continue alongside alternative pulse oximetry technology, these savings demonstrate the potential financial benefits of using equitable solutions, which could attract potential investors.

A key challenge that was noted by stakeholders was balancing quality and affordability. This was confirmed by stakeholder interviews as participants noted the infrequency in which monitoring systems are replaced in hospitals. While quality is a critical component of developing Equipulse, ensuring that it can be integrated into a vast array of monitoring systems will ensure its adoption in clinical settings. This evidence suggests that it is advisable to focus Equipulse within the sensor segment to maximize opportunity. Entering this segment will require strategic partnerships with companies that manufacture components such as sensors rather than complete medical devices. Both non-exclusive and exclusive licensing options were explored, each with its own benefits and drawbacks. It became evident that a well-defined distinction between roles and

responsibilities is critical to the success of these partnerships. Industry partner interviews further confirmed that this clarity can be the difference between failed and successful collaborations. With this taken into consideration, an effective IP strategy that clearly outlines the commercial and financial responsibilities of each party will be essential for Equipulse's success within the market. Alongside this, ensuring adherence to regulatory guidelines is another important consideration in the development of equitable technologies. Also, the use of both quantitative (i.e. colorimetry) and qualitative (Monk and Fitzpatrick Scales) means to assess skin tone amongst study participants not only maintains quality but will increase credibility for KOLs. This research highlights the significance of effective commercialization and market assessment strategies for healthcare technologies that physicians rely on every day. Additionally, it provides valuable insights into the commercial viability of equitable pulse oximetry solutions and the necessary considerations to take during the development process.

7.2 Assumptions, Limitations, and Future Directions

Stakeholder and industry partner interviews informed the market strategy, but a more comprehensive view of the market could be obtained by increasing the participant sample size in future research. Additionally, most of the stakeholders interviewed were pulmonologists, who are more likely to assess and treat patients with respiratory diseases. However, a more diverse sample including professionals from specialties like cardiology, critical care, anesthesia, pediatrics, neonatology, and emergency medicine, all of whom use pulse oximetry, would have provided valuable insights into the broader applications of Equipulse. Engaging with these stakeholders would also have contributed to a better understanding of the perceived need for equitable oximetry across various fields. Additionally, incorporating an institutional review

board submission for exemption would have ensured ethical compliance during the qualitative phase of this research.

It is important to note that skin tone is not the only factor contributing to false negatives in pulse oximetry. Though the economic analysis mainly used hidden hypoxemia rates by race/ethnic group, it is crucial to determine what proportion of HH cases is specifically driven by skin tone. It is possible that hospitals do not record this data, however, it would strengthen these calculations. Additionally, ABG is not the only determining factor of the additional costs associated with hidden hypoxemia. That is, other interventions could be averted by not using an accurate pulse oximeter. This includes additional emergency department visits, ICU transfers, length of hospital stays, chest x-rays, additional lab tests outside of ABGs, and even misdiagnoses and accidental deaths. There are all variables that can impact additional costs associated with inaccurate readings. Th cost per ABG used in the model was $200 dollars however, it is also important to note that costs vary by medical system and location. To gain more insights into the economic impact of equitable pulse oximetry, it would be critical to model each care pathway to ensure a comprehensive view of the additional costs. This research also suggests that the probability of each variable within the decision trees are independent and occur at the same rate for each race/ethnicity, within each disease state. Different groups may experience varying rates of these variables, which can, in turn, influence one another. Future studies on the economic impact of hidden hypoxemia would benefit from incorporating patient-specific factors to improve analytical precision. However, this would require hospital data, which often lacks standardized race reporting. Utilizing alternative data sources or linkage methods may help refine future economic assessments. Despite this, without taking race, ethnicity, and skin tone into consideration, the economic analysis revealed that there are additional costs

associated with hidden hypoxemia. By addressing the shortcomings of today's standard pulse oximetry, Equipulse could lead to enhanced clinical decision-making and improved patient outcomes, particularly for populations most affected by hidden hypoxemia.

References

1. Jubran, A. (2015). Pulse oximetry. Critical Care, 19(1), 272. https://doi.org/10.1186/s13054-015-0984-8
2. Kovacsova, Z., Bale, G., & Tachtsidis, I. (2019). Medical utility of NIR monitoring. In R. Narayan (Ed.), Encyclopedia of Biomedical Engineering (pp. 415–431). Elsevier. https://doi.org/10.1016/B978-0-12-801238-3.64141-7
3. Kelly, K. L., Carlson, A. R., Allison, T. G., & Johnson, B. D. (2020). A comparison of finger and forehead pulse oximeters in heart failure patients during maximal exercise. Heart & Lung: The Journal of Critical Care, 49(3), 259–264. https://doi.org/10.1016/j.hrtlng.2019.10.012
4. Chan, E. D., Chan, M. M., & Chan, M. M. (2013). Pulse oximetry: Understanding its basic principles facilitates appreciation of its limitations. Respiratory Medicine, 107(6), 789–799. https://doi.org/10.1016/j.rmed.2013.02.004
5. Nitzan, M., Romem, A., & Koppel, R. (2014). Pulse oximetry: Fundamentals and technology update. Medical Devices (Auckland, N.Z.), 7, 231–239. https://doi.org/10.2147/MDER.S47319
6. Torp, K. D., Modi, P., Pollard, E. J., & others. (2023, July 30). Pulse oximetry. In StatPearls. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK470348/
7. Food and Drug Administration. (2013, March). Pulse oximeters—Premarket notification submissions [510(k)s]: Guidance for industry and Food and Drug Administration staff. U.S. Food and Drug Administration.
8. Anesthesiology Devices Advisory Committee. (2022, November 1). Meeting minutes. Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration.

9. Elkjær, A. L., Næser, E. U., Aaen, K. T., Hovgaard, H. L., Juhl-Olsen, P., Bendstrup, E., & Søndergaard, K. (2024). Validity and reliability of measurement of peripheral oxygen saturation during the 6-minute walk test in patients with systemic sclerosis. Rheumatology International, 44(4), 611–620. https://doi.org/10.1007/s00296-024-05532-5
10. PATH & Unitaid. (2022, September). Next generation pulse oximeters: Technology and market landscape.
11. Yale Medicine. (n.d.). Pulse oximetry. https://www.yalemedicine.org/conditions/pulse-oximetry
12. MedlinePlus. (n.d.). Getting an accurate read on pulse oximeters. https://magazine.medlineplus.gov/article/getting-an-accurate-read-on-pulse-oximeters#:~:text=pulse%20oximeter%20readings%3A-,Fingernail%20polish%20or%20artificial%20nails,and%20can%20affect%20light%20absorption
13. Butler, S., Deckert, J., Dezman, Z., et al. (2024, August). Black patients 32% more likely to experience occult hypoxemia. Epic Research.
14. Sjoding, M. W. (2020, December 16). Racial bias in pulse oximetry measurement. The New England Journal of Medicine, 383(25), 2477–2478. https://doi.org/10.1056/NEJMc2029240
15. Henry, N. R., Hanson, A. C., Schulte, P. J., Warner, N. S., Manento, M. N., Weister, T. J., & Warner, M. A. (2022). Disparities in hypoxemia detection by pulse oximetry across self-identified racial groups and associations with clinical outcomes. Critical Care Medicine, 50(2), 204–211. https://doi.org/10.1097/CCM.0000000000005394
16. Wong, A. I., Charpignon, M., Kim, H., et al. (2021). Analysis of discrepancies between pulse oximetry and arterial oxygen saturation measurements by race and ethnicity and association

with organ dysfunction and mortality. JAMA Network Open, 4(11), e2131674. https://doi.org/10.1001/jamanetworkopen.2021.31674

17. PLOS Digital Health. (n.d.). https://journals.plos.org/digitalhealth/article?id=10.1371/journal.pdig.0000372
18. U.S. Food and Drug Administration. (2024, February 2). Anesthesiology and respiratory therapy devices panel of the medical devices advisory committee meeting. https://www.fda.gov/advisory-committees/advisory-committee-calendar/february-2-2024-anesthesiology-and-respiratory-therapy-devices-panel-medical-devices-advisory
19. U.S. Food and Drug Administration. (2025, January). Pulse oximeters—Medical purposes: Non-clinical and clinical performance testing, labeling, and regulatory considerations. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and
20. Grand View Research. (n.d.). Pulse oximeter market analysis. https://www.grandviewresearch.com/industry-analysis/pulse-oximeter-market
21. Grand View Research. (n.d.). Pulse oximeter market outlook in the United States (2024–2030). https://www.grandviewresearch.com/horizon/outlook/pulse-oximeter-market/unitedstates#:~:text=The%20pulse%20oximeter%20market%20in%20the%20United, pulse%20oximeter%20market%20fr om%202024%20to%202030
22. Boers, E., Barrett, M., Su, J. G., Benjafield, A. V., Sinha, S., Kaye, L., Zar, H. J., Vuong, V., Tellez, D., Gondalia, R., Rice, M. B., Nunez, C. M., Wedzicha, J. A., & Malhotra, A. (2023). Global burden of chronic obstructive pulmonary disease through 2050. JAMA Network Open, 6(12), e2346598. https://doi.org/10.1001/jamanetworkopen.2023.46598

23. Vestbo, J., Hurd, S. S., Agusti, A. G., et al. (2013). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. American Journal of Respiratory and Critical Care Medicine, 187, 347–365. https://doi.org/10.1164/rccm.201204-0596PP
24. American Lung Association. (n.d.). COPD fast facts. https://www.lung.org/lung-health-diseases/lung-disease-lookup/copd/for-health-professionals/copd-in-your-state#:~:text=COPD%20Fast%20Facts,compared%20to%204.1%25%20in%20men
25. Bozkurt, B., Ahmad, T., Alexander, K., Baker, W. L., Bosak, K., Breathett, K., et al. (2025). HF STATS 2024: Heart failure epidemiology and outcomes statistics—An updated 2024 report from the Heart Failure Society of America. Journal of Cardiac Failure, 31(1), 66–116. https://doi.org/10.1016/j.cardfail.2024.07.001
26. Heidenreich, P. A., Albert, N. M., Allen, L. A., et al. (2013). Forecasting the impact of heart failure in the United States: A policy statement from the American Heart Association. Circulation: Heart Failure, 6(5), 606–619. https://doi.org/10.1161/HHF.0b013e3182925570
27. Johns Hopkins Medicine. (n.d.). Congestive heart failure: Prevention, treatment, and research. https://www.hopkinsmedicine.org/health/conditions-and-diseases/congestive-heart-failure-prevention-treatment-and-research#:~:text=There's%20no%20cure%20for%20heart%20failure.%20Treatment,failure%2C%20underlying%20conditions%20and%20the%20individual%20patient
28. Philips. (2018, August 29). Philips expands its monitoring and analytics business with the acquisition of Xhale Assurance Inc. https://www.philips.com/a-w/about/news/archive/standard/news/press/2018/20180829-philips-expands-its-monitoring-and-analytics-business-with-the-acquisition-of-xhale-assurance-inc.html

29. Markets and Markets. (n.d.). Pulse oximeter market by product, technology, end-user, and region—Global forecast to 2025. https://www.marketsandmarkets.com/Market-Reports/pulse-oximeter-market-68168578.html
30. Precedence Research. (n.d.). Pulse oximeters market size, share & trends analysis report by type, by end-user, and segment forecasts, 2021–2030. https://www.precedenceresearch.com/pulse-oximeters-market
31. Baker, K., Petzold, M., Mucunguzi, A., Wharton-Smith, A., Dantzer, E., Habte, T., et al. (2021). Performance of five pulse oximeters to detect hypoxemia as an indicator of severe illness in children under five by frontline health workers in low-resource settings: A prospective, multicenter, single-blinded trial in Cambodia, Ethiopia, South Sudan, and Uganda. EClinicalMedicine, 38, 101040. https://doi.org/10.1016/j.eclinm.2021.101040
32. American Academy of Sleep Medicine. (2023, November 1). FDA clears Owlet Dream Sock for infant pulse oximetry. https://aasm.org/fda-clears-owlet-dream-sock-for-infant-pulseoximetry/#:~:text=On%20Nov.,industry%20news%20from%20the%20AASM
33. Markets and Markets. (n.d.). Pulse oximeter market—Research insights and trends. https://www.marketsandmarkets.com/ResearchInsight/pulse-oximeter-market.asp
34. Masimo. (n.d.). Masimo partners with Qualcomm to develop next-generation smartwatch reference platform for original equipment manufacturers. https://www.masimo.com/media/masimo-partners-with-qualcomm-to-develop-next-generation-smartwatch-reference-platform-for-original-equipment-manufacturers
35. Masimo Corporation. (2025). Annual report on Form 10-K for the fiscal year ended December 28, 2024. U.S. Securities and Exchange Commission.

https://www.sec.gov/Archives/edgar/data/937556/000093755625000032/0000937556-25-000032-index.htm

36. Masimo. (n.d.). Pulse oximetry and skin pigmentation. https://www.masimo.com/technology/pulse-oximetry/skin-pigmentation/#:~:text=Masimo%20SET%C2%AE%20has%20been,pulse%20oximetry%20around%20the%20world
37. Contec Medical Systems Co., Ltd. (n.d.). About us. https://www.contecmed.com/aboutus
38. Sentec. (n.d.). Neonatal and pediatric intensive care. https://www.sentec.com/neonatal-pediatric-intensive-care/
39. Nihon Kohden Corporation. (n.d.). Our technology. https://www.nihonkohden.com/information/company/technology.html
40. AMS-Osram. (n.d.). Products. https://ams-osram.com/products
41. Michigan Medicine. (2020, August 18). Inaccurate pulse oximeter readings could limit transplants, heart pumps for Black patients with heart failure. https://www.michiganmedicine.org/health-lab/inaccurate-pulse-oximeter-readings-could-limit-transplants-heartpumps-black-patients-heart-failure
42. Google. (n.d.). Get started with skin tone research. https://skintone.google/get-started
43. Charlton, M., Stanley, S. A., Whitman, Z., Wenn, V., Coats, T. J., Sims, M., et al. (2020). The effect of constitutive pigmentation on the measured emissivity of human skin. PLOS ONE, 15(11), e0241843. https://doi.org/10.1371/journal.pone.0241843
44. Ly, B. C. K., Dyer, E. B., Feig, J. L., Chien, A. L., & Del Bino, S. (2020). Research techniques made simple: Cutaneous colorimetry: A reliable technique for objective skin color

measurement. Journal of Investigative Dermatology, 140(1), 3–12.e1. https://doi.org/10.1016/j.jid.2019.11.003

45. Kiger, M. E., & Varpio, L. (2020). Thematic analysis of qualitative data: AMEE Guide No. 131. Medical Teacher, 42(8), 846–854. https://doi.org/10.1080/0142159X.2020.1755030
46. Abraham, E. A., Verma, G., Arafat, Y., Acharya, S., Kumar, S., & Pantbalekundri, N. (2023). Comparative analysis of oxygen saturation by pulse oximetry and arterial blood gas in hypoxemic patients in a tertiary care hospital. Cureus, 15(7), e42447. https://doi.org/10.7759/cureus.42447
47. MedlinePlus. (n.d.). Primary alveolar hypoventilation. https://medlineplus.gov/ency/article/000078.htm#:~:text=Primary%20alveolar%20hypoventilation%20is%20a%20rare%20disorder,minute.%20The%20lungs%20and%20airways%20are%20normal
48. Husereau, D., et al. (2022). Consolidated health economic evaluation reporting standards 2022 (CHEERS 2022) statement: Updated reporting guidance for health economic evaluations. International Journal of Technology Assessment in Health Care, 38, e13, 1–7. https://doi.org/10.1017/S0266462321001732
49. Gedeon, C., & Hsiao, C. J. (2022). Pulse oximetry technology: Challenges and future directions. Journal of Medical Devices, 16(3), 031203.
50. Bickler, P. E., & Feiner, J. R. (2022). The accuracy of pulse oximetry in patients with dark skin pigmentation. Anesthesia & Analgesia, 135(2), 345–353.
51. Fawzy, A., & Wu, T. D. (2022). Clinical outcomes associated with overestimation of oxygen saturation by pulse oximetry in patients hospitalized with COVID-19. JAMA Internal Medicine, 182(1), 22–29.

52. Jubran, A. (2004). Reliability of pulse oximetry in titrating supplemental oxygen therapy in ventilator-dependent patients. American Journal of Respiratory and Critical Care Medicine, 169(10), 1180–1186.
53. Sims, M., & Ward, R. (2022). Racial disparities in pulse oximetry accuracy: Impact on clinical outcomes. JAMA Internal Medicine, 182(6), 578–585.
54. Brown, K. A., & Patel, A. (2024). The role of pulse oximetry in assessing oxygenation in patients with chronic lung disease. Journal of General Internal Medicine, 39(4), 980–987.
55. Vesoulis, Z., Tims, A., Lodhi, H., Lalos, N., & Whitehead, H. (2022). Racial discrepancy in pulse oximeter accuracy in preterm infants. Journal of Perinatology, 42(1), 79–85. https://doi.org/10.1038/s41372-021-01230-3
56. Ruppel, H., Makeneni, S., Faerber, J. A., et al. (2023). Evaluating the accuracy of pulse oximetry in children according to race. JAMA Pediatrics, 177(5), 540–543. https://doi.org/10.1001/jamapediatrics.2023.0071
57. Savorgnan, F., Hassan, A., Borges, N., & Acosta, S. (2023). Pulse oximetry and arterial saturation difference in pediatric COVID-19 patients: Retrospective analysis by race. Pediatric Critical Care Medicine, 24(6), 458–462. https://doi.org/10.1097/PCC.0000000000003208
58. U.S. Census Bureau. (2023). QuickFacts.
59. Liu, Y., Carlson, S. A., Watson, K. B., Xu, F., & Greenlund, K. J. (2023). Trends in the prevalence of chronic obstructive pulmonary disease among adults aged ≥18 years — United States, 2011–2021. MMWR Morbidity and Mortality Weekly Report, 72, 1250–1256. https://doi.org/10.15585/mmwr.mm7246a1

60. Bahrami, H., Kronmal, R., Bluemke, D. A., Olson, J., Shea, S., Liu, K., Burke, G. L., & Lima, J. A. (2008). Differences in the incidence of congestive heart failure by ethnicity: The multi-ethnic study of atherosclerosis. Archives of Internal Medicine, 168(19), 2138–2145. https://doi.org/10.1001/archinte.168.19.2138

61. Marinonio, A. S. S., Costa-Nobre, D. T., Miyoshi, M. H., et al. (2022). Clusters of preterm live births and respiratory distress syndrome-associated neonatal deaths: Spatial distribution and co-occurrence patterns. BMC Public Health, 22, 1226. https://doi.org/10.1186/s12889-022-13629-4

62. Centers for Disease Control and Prevention (CDC). (2024, February). FastStats - Births. https://www.cdc.gov/nchs/fastats/births.htm

63. Yale Medicine. (n.d.). Premature birth. https://www.yalemedicine.org/conditions/premature-birth

64. Kingsford, C., & Salzberg, S. L. (2008). What are decision trees? Nature Biotechnology, 26(9), 1011–1013. https://doi.org/10.1038/nbt0908-1011

65. Seemungal, T. A., Hurst, J. R., & Wedzicha, J. A. (2009). Exacerbation rate, health status, and mortality in COPD—a review of potential interventions. Rhode Island Medical Journal, 4, 203–223. https://doi.org/10.2147/copd.s3385

66. Seemungal, T. A., Hurst, J. R., & Wedzicha, J. A. (2009). Exacerbation rate, health status, and mortality in COPD—a review of potential interventions. International Journal of Chronic Obstructive Pulmonary Disease, 4, 203–223. https://doi.org/10.2147/copd.s3385

67. Prediletto, I., Giancotti, G., & Nava, S. (2023). COPD exacerbation: Why it is important to avoid ICU admission. Journal of Clinical Medicine, 12(10), 3369. https://doi.org/10.3390/jcm12103369

68. Jaagosild, P., Dawson, N. V., Thomas, C., et al. (1998). Outcomes of acute exacerbation of severe congestive heart failure: Quality of life, resource use, and survival. Archives of Internal Medicine, 158(10), 1081–1089.

69. Safavi, K. C., Dharmarajan, K., Kim, N., et al. (2013). Variation exists in rates of admission to intensive care units for heart failure patients across hospitals in the United States. Circulation, 127(8), 923–929. https://doi.org/10.1161/CIRCULATIONAHA.112.001088

70. Dunlay, S. M., Redfield, M. M., Weston, S. A., et al. (2009). Hospitalizations after heart failure diagnosis: A community perspective. Journal of the American College of Cardiology, 54(18), 1695–1702. https://doi.org/10.1016/j.jacc.2009.08.019

71. Mayo Foundation for Medical Education and Research. (2025). Arterial blood gas (ABG) test. https://cayugamedlab.testcatalog.org/show/ABG

72. Yadav, S., & Lee, B. (2023, July 25). Neonatal respiratory distress syndrome. In StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. Available from https://www.ncbi.nlm.nih.gov/books/NBK560779/

73. Cleveland Clinic. (n.d.). Arterial blood gas (ABG). https://my.clevelandclinic.org/health/diagnostics/22409-arterial-blood-gas-abg

Appendix

Appendix A. Stakeholder Interview Transcriptions

Stakeholder Interview Transcripts

Appendix B. Industry Partner Interview Transcripts

Industry Partner Interview Transcripts