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DESIGN AND DEVELOPMENT OF A DEVICE TO VALIDATE THE PERFORMANCE OF A WEARABLE FOR VITAL SIGN MONITORING IN TELEMEDICINE APPLICATIONS

Tesis para obtener el título profesional de Ingeniero Electrónico

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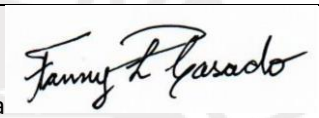
DNI: 40444557	Firma 
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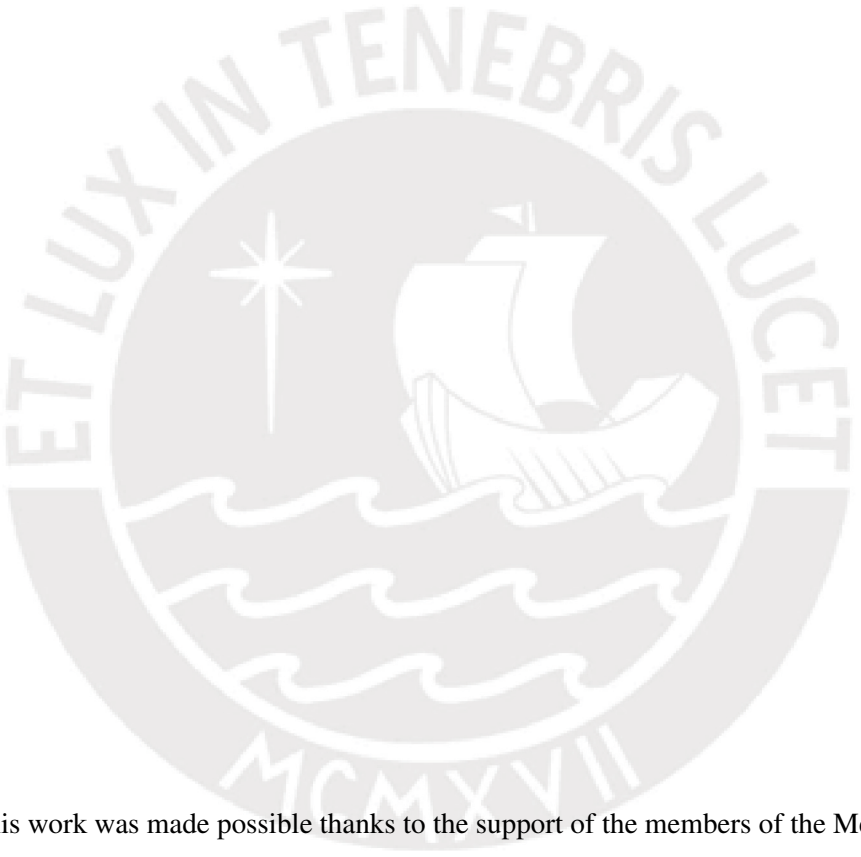

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Resumen

Este estudio tiene como objetivo proponer una solución para mitigar los riesgos de la aplicación de tecnología en servicios de telemedicina en una red de clínicas privadas en el Perú. Para este fin, se lleva a cabo un estudio de caso para evaluar riesgos, y se diseña una solución que se adapte al uso de cualquier dispositivo portátil para la medición de signos vitales. Mediante el uso del prototipo, se evalúa la precisión y confiabilidad del dispositivo portátil Corsano CardioWatch 2B para la medición de signos vitales comparándolo con las señales generadas por el simulador ProSim8, el cual sirve como estándar para las pruebas realizadas. La investigación se enfoca en dos tipos de análisis. El primero es un análisis de Bland-Altman para evaluar la correlación, y el segundo se centra en la calidad de la señal de ECG. Para el procesamiento de señales, se utiliza la transformada wavelet y el análisis del espectro de frecuencia de las señales procesadas para evaluar la correlación entre señales que contienen información del complejo QRS. Adicionalmente, para el análisis del estudio de caso, se sigue un procedimiento evaluado por el comité de ética de la PUCP para realizar consultas con colaboradores de una red de clínicas privadas en el Perú.

Se diseñó una placa electrónica con amplificadores de modo no inversor para una ganancia de 100, filtros Notch para interferencia de línea (60 Hz), filtros pasa-bajos (fc = 100 Hz), y filtros pasa-altos (fc = 0.005 Hz) para cada señal de cada electrodo utilizado para el ECG. Adicionalmente, se diseñó una estructura en modelado tridimensional para utilizar los transductores de los simuladores de signos vitales junto con el dispositivo portátil en un solo prototipo.

Durante la implementación, los resultados concluyeron con un coeficiente de determinación (R^2) de 0.802 para la medición de temperatura corporal, 0.734 para la frecuencia respiratoria, y 0.923 para la oxigenación sanguínea. Adicionalmente, se obtuvo una correlación de Pearson de 0.959 entre las señales de ECG y una correlación del espectro de frecuencia de 0.992. Los resultados demuestran que el Corsano CardioWatch 2B proporciona alta precisión y consistencia en las mediciones. La fuerte correlación y las métricas de bajo error subrayan el potencial del dispositivo para el monitoreo confiable en aplicaciones clínicas y de dispositivos portátiles. El estudio destaca el rendimiento del prototipo diseñado para mitigar los riesgos de errores de medición en dispositivos portátiles, enfatizando la necesidad de realizar tal análisis de estos dispositivos antes de su uso comercial en aplicaciones de telemedicina.

Palabras clave: ECG, complejo QRS, wavelet, MODWT, dispositivos portátiles, ProSim8, CardioWatch, reconstrucción de señales, análisis espectral, correlación de Pearson, Bland Altman, Telemedicina.

Abstract

This study aims to propose a solution to mitigate the risks of applying technology for telemedicine services in a network of private clinics in Peru. To this end, a case study is conducted to evaluate risks, and a solution is designed to adapt to the use of any wearable for measuring vital signs. Using the prototype, the accuracy and reliability of the Corsano CardioWatch 2B portable device for measuring vital signs are assessed by comparing it with the signals generated by the ProSim8 simulator, which serves as the standard for the tests performed. The research focuses on two types of analysis. The first is a Bland-Altman analysis to assess the correlation, and the second on the quality of the ECG signal. For signal processing, the wavelet transform and the frequency spectrum analysis of the processed signals are used to evaluate the correlation between signals containing QRS complex information. Additionally, for the case study analysis, a procedure evaluated by the ethics committee of PUCP is followed to conduct inquiries with collaborators from a network of private clinics in Peru.

An electronic board was designed with non-inverting mode amplifiers for a gain of 100, Notch filters for line interference (60 Hz), low-pass filters (fc = 100 Hz), and high-pass filters (fc = 0.005 Hz) for each signal from each electrode used for ECG. Additionally, a structure was designed in three-dimensional modeling to use the transducers from the vital signs simulators alongside the wearable in a single prototype. During the implementation, the results concluded with a coefficient of determination (R^2) of 0.802 for body temperature measurement, 0.734 for respiratory rate, and 0.923 for blood oxygenation. Additionally, there was a Pearson correlation of 0.959 between ECG signals and a frequency spectrum correlation of 0.992.

The results demonstrate that the Corsano CardioWatch 2B provides high accuracy and consistency in measurements. The strong correlation and low error metrics underscore the device's potential for reliable monitoring in clinical and wearable applications. The study highlights the performance of the designed prototype to mitigate the risks of measurement errors in wearables, emphasizing the necessity of such analysis of these devices before their commercial use in telemedicine applications.

Keywords: ECG, QRS complex, wavelet, MODWT, wearable devices, ProSim8, CardioWatch, signal reconstruction, spectral analysis, Pearson correlation, Bland Altman, Telemedicine.

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Introduction

Telemedicine can be defined as a method of delivering healthcare services remotely to patients. The use of telecommunication technologies allows healthcare professionals to evaluate, diagnose, and treat patients according to their needs and from their homes. Virtual appointments when compared to conventional methods of care provide the added value of convenience, time management, disease management, and constant monitoring [11]. However, there are limitations depending on the type of specialty under which the patient wishes to be seen. The aforementioned is due to the type of data needed by each specialty to diagnose including body weight, heart rate, oxygen saturation, etc. The COVID-19 pandemic has highlighted the need for telemedicine in Peru, with the potential to strengthen disease prevention programs, monitor patients with chronic diseases, and combat malnutrition in vulnerable populations. At the end of 2019, according to the Ministry of Health (Minsa), more than 6,000 tele-consultations were performed in the country, representing less than 5% of the 139.6 million outpatient care for that year. On the other hand, in the same year, the public administration began the implementation of a telemedicine system with the objective of strengthening the capacity to provide post-surgical follow-up and tele-orientation of older adults for disease control [12].

However, the implementation of telemedicine in Peru requires social innovation to overcome the significant barriers to access and the lack of existing telemedicine systems [13] [14]. This translates into a solution adapted to the specific local needs which may involve the design of platforms or technologies that can be accessible to the Peruvian community. For this research, it is necessary to identify the processes and roles that are part of the work performed by the network of private clinics for the provision of this type of services. To achieve this, we will empathize and collect relevant information for the case study.

This research evaluates the technological needs of a network of private clinics located in Lima, Peru to improve their current telemedicine approaches. The purpose is to propose technologies, by designing both hardware and software, that meet the needs of the different user profiles present in this network of clinics. First, the insufficient supply that can meet the demand of patients is

justified as a problem, followed by a presentation of the state of the art of existing solutions in the country together with the legal and technical limitations under which the proposed solution will be designed. Subsequently, the methodology used to collect and structure the information is presented. As a case study, the current application of telemedicine by the state and other health institutions in the country is described. Following this, a critical analysis is made to identify the technological needs of health institutions, according to the objectives of the network of clinics. Finally, the legal regulations in force for their operation, and international standards are explained in detail. The collection of primary information has been limited to studies and focus group surveys carried out by the network of clinics to its internal population of health personnel, and shadowing the different user profiles.

Chapter 1

Background

This chapter explains that in current telemedicine systems in Peru from the public and private sectors; the demand is not being satisfied, nor are patients receiving quality care that is adequate to the needs of each clinical specialty. Specifically, the following lines explain the technological need for a telemedicine approach for the specialties of cardiology and endocrinology. The design includes meeting the legal considerations set by the Peruvian government.

1.1 Problem statement

In Peru, according to publicly available national reports, the demand for telemedicine services has increased exponentially since the period of the health emergency caused by COVID-19. The need to maintain rigorous disease control, considering fast and safe healthcare for the patient and safe working conditions for the health personnel, led to the massive implementation of telehealth services in Peru. According to the Peruvian Ministry of Health (MINSA, an acronym in Spanish) records, the number of cases received by means of these services reached around 3.5 million care sessions, including tele-consultation, tele-interconsultation, tele-monitoring, and tele-guidance services, during the year 2020 [15]. According to the MINSA, telehealth services are defined as follows:

(1) Tele-consultation is the remote communication between the health user and a health professional to discuss health condition providing a diagnosis and treatment.

(2) Tele-interconsultation is the remote communication between health personnel and a health professional, who will provide recommendations for treatment.

(3) Tele-orientation is the communication between a healthcare system user and a health

professional, to receive health counseling to reduce the risk of a disease or improve the quality of life.

(4) Tele-monitoring is aimed at patients with chronic diseases that require constant data collection. [16].

In addition to the growing demand for remote health services, there is also a need for an adequate number of professionals in the health sector to serve the country's population. According to the World Health Organization (WHO), a minimum of 23 people are necessary on a team of doctors, nurses, and obstetricians per 10,000 inhabitants is recommended to guarantee adequate service provision. However, according to MINSA figures, during the year 2020, it is estimated that in Peru there were 13.6 physicians per 10,000 inhabitants. In Lima, it was estimated to be at around 20.5 physicians per 10,000 inhabitants, but this is still insufficient to cover the high demand for health services [17]. This MINSA's report also stated that the population assigned per health facilities in central Lima is around 3 million people [18].

The limitations of Peru's healthcare system are not limited to the lack of sufficient personnel to meet the existing demand in the metropolis. In addition, according to health facility management reports, the delivery of services becomes inefficient for both the patient and the professionals in the health sector. On the patient's side, their main problems are found in the lack of specialist doctors (34.97%), poor management of appointments (34.7%), and delayed care (28.14%). On the other hand, the deficient infrastructure (36.89%), bureaucracy and red tape (7.65%), and lack of coordination between institutions (5.46%) are also considered an important burden to the patients [19]. These problems are aggravated according to MINSA reports, in which in 2018 it was estimated that for about 10,000 patients there is only one bed available to be used, in addition, for every 3 administrative staff there is only one doctor in health institutions. In contrast, the WHO recommends the indicator of 2.7 beds per 1,000 inhabitants.[20].

Patients with chronic diseases usually are closely monitored by Cardiology and Endocrinology specialists for biometric data, dietary habits, and lifestyle. The management of diseases such as diabetes or cardiac conditions requires a demanding therapeutic follow, however, this is not accomplished in the Peruvian health system hindering the control of these diseases. That is to say, the programs for attention and prevention of chronic diseases have the potential to be further developed in Peru. Since chronic diseases are one of the main causes of death in Peru, the development of care and prevention programs will greatly contribute to the wellness of the population [21].

Due to the present problems, telemedicine is proposed as an ideal solution for the deficient management of the health system in the face of the high demand for care, lack of infrastructure,

and development of care programs for patients with chronic diseases. This is due to the fact that through the provision of remote services and under the management of an automated appointment system, the limitations of infrastructure and care are absolved since resources are optimized in the process of care and appointment generation [22]. Furthermore, the management of telemedicine resources involves a considerable volume of administrative personnel, a proportion similar to that found in MINSA reports. In addition, the adaptation within primary care centers allows patients with chronic diseases to continue with their treatment without the need to physically go to a facility. Moreover, it is a key tool for these patients to be monitored remotely in real-time, i.e., real information would be available on the patient's condition and lifestyle, factors that could not be accurately measured with traditional methods of care. It is worth mentioning that there is the possibility that these telemedicine systems could be used to develop content for educational and guidance purposes to promote prevention and active disease control [23]. The network of clinics that we will work with for this study is located in Lima, but for confidentiality reasons the name of this network will not be mentioned, and from this moment on it will be referred to as "NC".

1.1.1 State of art

1.1.2 Device TytoHome - TytoCare

Produced by the company Tytocare, it was released in 2018. Its design allows it to serve about 9 medical specialties among which is cardiology. This equipment has the ability to collect data in real-time to perform tele-monitoring and tele-consultation. It uses its own server which can be accessed by the health center staff. To use this device, an app of the same name as the brand is needed. After registration and entering the data of the insurance to which the user is associated, depending on the type of insurance, a health center that has the necessary connectivity to access its clinical records is assigned. Depending on the type of insurance and the clinical specialty, the physician who will receive the clinical examination data is assigned. There is a tutorial explaining the standardized protocols within the application [1]. Finally, the physician is in charge of reviewing the results and according to that, sends his interpretation of the results, and decides if it is necessary to schedule an in-person appointment to analyze the abnormal measurements as needed. Figure 1.1 shows the flow of the telemedicine care process, as described in its user manual.

Figure 1.1: TytoHome care process workflow [1].

This device has the ability to record audio and video, which are stored in real-time on a server of the brand, as a complement to the data obtained during the examinations. It should be noted that this equipment can only work with healthcare provider institutions (IPRESS, according to their Spanish acronym) associated with the brand, and that have the specialties that the equipment can cover [1]. In addition, the TytoHome product was approved by the FDA to enter the American market in 2019, and since its launch, it has been used by more than 220 healthcare organizations around the world [24].

1.1.3 Device HomeClinic - MedWand

This product of the MedWand company was launched on the market in 2022. Its design allows it to serve about 10 medical specialties, depending on the purchase of additional sensors of the brand, including cardiology, for needs involving a second level of medical care [25]. The second level of care is understood to be when surgical intervention is necessary according to MINSA[26]. It consists of a device with multiple sensors for biometric data collection, a console to visualize the results, and additional sensors according to the user's demand. This equipment, as in the previous case, has the capacity to collect data in real-time to perform tele-monitoring and tele-consultation activities. There are two modes when using this device, the first one is guided remotely by trained personnel who provide the indications to perform a medical examination, and the second one requires the patient to perform an examination that has been previously

standardized in the system.The figure 1.2 shows the direct patient care process for the business modality between the company (MedWand) and the user.

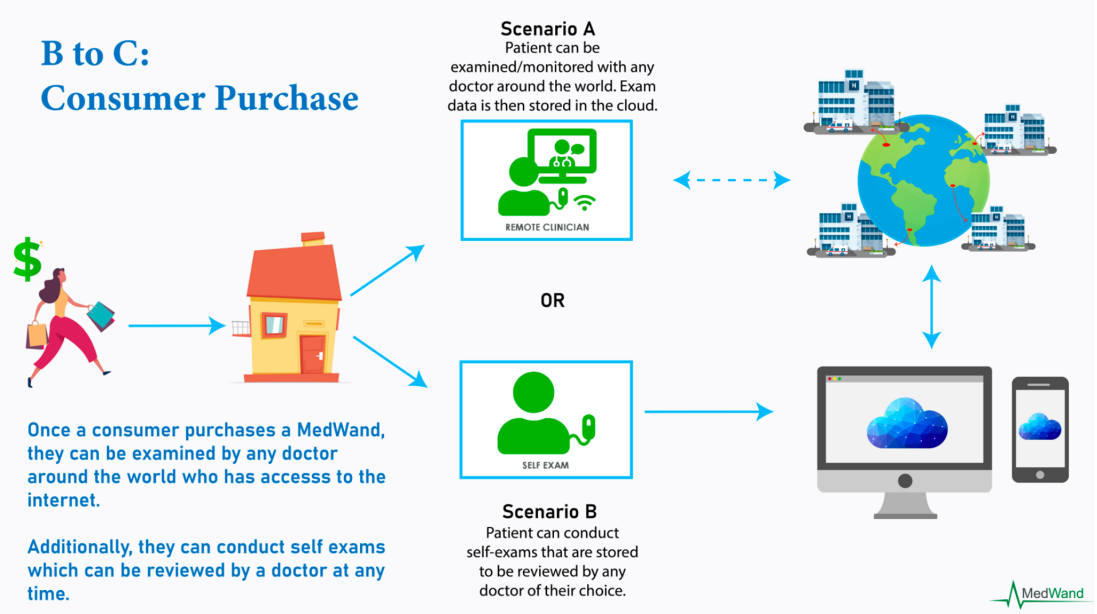


Figure 1.2: Flow of care process with HomeClinic by MedWand [2].

In addition, with this equipment, there is the possibility of connecting with doctors from any country around the world who are associated with HomeClinic. There are sensors that can be acquired in addition to the equipment necessary to perform electrocardiograms, measure weight or glucose, and upload them to the same database of the patient [25]. This product was approved by the FDA in 2022, and released to the market [27].

1.1.4 Smartwatch Fitbit Sense - Fitbit

This product is a device with potential applications in the health sector. Besides being an object of easy portability, it is an ergonomic and user-friendly product. It allows the measurement of everything from calories burned to oxygen saturation. This specific model allows us to measure the temperature and offer personalized exercise routines. To collect biometric data the user does not have to follow any kind of tutorial or similar since the data collection begins at the moment the watch is worn on the wrist [28]. In addition, this watch has the ability to generate files in .pdf extension, where the data is displayed visually for users. It is recognized as a medical device for its cardiogram application, and as shown in figure 1.3, it is a smartwatch that has an interface designed to have additional applications to the capacity of taking biometric data, in order to be more accepted by the user [29].

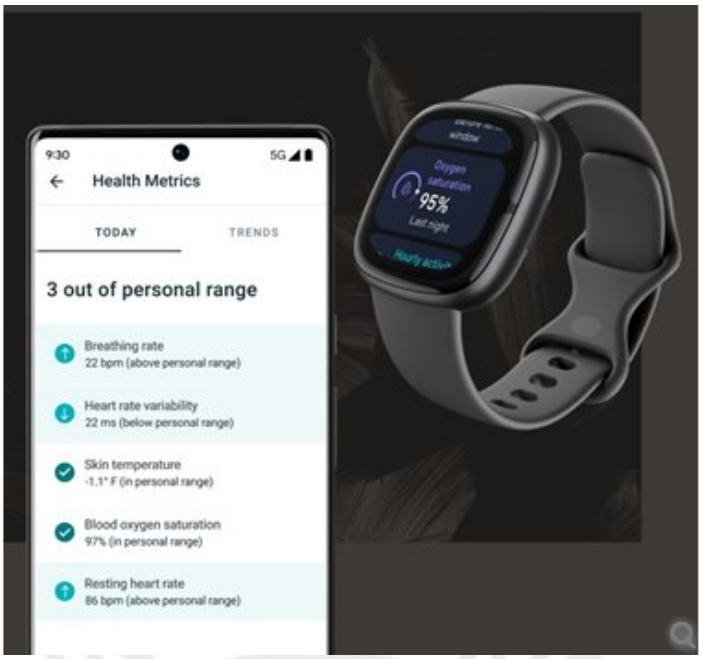


Figure 1.3: Fitbit Sense device [3].

It should be noted that this product was approved by the FDA for its ECG application, however, according to recent tests this device does not have the ability to calculate an accurate energy expenditure. Therefore, its use as a medical device is limited. Also, it is not officially used for formal patient care, but for academic study purposes, in addition to its commercial and sports use [30].

1.2 Legal context

In Peru, telemedicine is regulated by several laws, decrees, and technical standards that establish the general guidelines for its development and strengthening. Peruvian Law No. 30421, passed in 2016, known as the ”telehealth Law” establishes the general guidelines for the development of telehealth in the country. It defines telemedicine, establishes its principles and objectives, and establishes the competencies of MINSA in telemedicine. It also details the services related to telemedicine that use telecommunication technologies to provide health services [16]. Legislative Decree No. 1490 complements the law and extends the scope of telehealth. In particular, it allows the provision of telemedicine services in primary care, specialized care, medical education, and research [31]. In addition, Supreme Decree No. 003-2013-JUS approves the Regulation of the Law on Digital Signature and Certificates, which is relevant for information security in the context of telemedicine [32].

Similarly, during the health emergency in Peru, directives were established that allowed the

development of an emergency action plan through the use of technology to provide telemedicine services, such as Ministerial Resolution 117-2020-MINSA, which approved the directive for the implementation and development of servers. The guidelines for the implementation of synchronous and asynchronous, which allow real-time care and deferred consultation of information, respectively [33].

The Ministerial Resolution 116-2020-MINSA approves Administrative Directive No. 284-MINSA-2020-DIGTEL, which establishes the ”Telemanagement Directive” for the implementation and development of telemedicine. It establishes the guidelines for telemedicine management, including the organization of services, assignment of responsibilities, and coordination between the different actors involved. It also promotes the integration of telemedicine into existing health information systems, guaranteeing interoperability and information security [34].

Also, there are technical standards and administrative directives that complement the regulation of telemedicine in Peru. The Technical Health Standard on Telehealth, approved in 2008, establishes the guidelines for the operation of health facilities and health services in the telehealth sector [35]. In relation to the protection of information, the Personal Data Protection Law No. 29733 is also relevant, as it establishes the rules for the protection of personal data in the country [36].

The MINSA is the competent entity to regulate telemedicine in Peru. The governing principles of telemedicine in Peru are established by Law No. 30421. These principles are:
(1) Equity, telemedicine must be accessible to the entire population, regardless of their geographic location or socioeconomic status.
(2) Efficiency, telemedicine must be efficient in terms of costs and resources.
(3) Quality, telemedicine services must comply with the quality standards established by the MINSA.
(4) Safety, telemedicine services must guarantee the safety of patients and medical information and the scope of telemedicine, being able to provide services related to remote medical diagnosis and consultation [16].

1.3 Objectives

1.3.1 General

Design and implement a device to verify a wearable for monitoring vital signs before its use in telemedicine services within a private clinical network in Peru.

1.3.2 Specific

- Assess technological needs in telemedicine services identified from in-depth interviews with healthcare professionals.
- Design and implement an electronic device to mitigate risks associated with the use of wearables in telemedicine, with an emphasis on cardiology and endocrinology applications.
- Establish a protocol to use the implemented device to perform experimental testing, statistical validation, and ECG signal processing of a commercial wearable device to evaluate its fitness for use in telemonitoring.

Chapter 2

Methodology

The following is a description of the methodology and tools to be used to assess the needs in the application of telemedicine services in the NC. The research will be carried out under the perspective of Involving end users in the ideation and design of telemedicine systems is crucial for several reasons. User-Centered Design (UCD) principles dictate that engaging end users in the design process ensures that the telemedicine system is tailored to their needs, preferences, and workflows. This approach leads to a user-centered design that is not only more likely to be accepted but also used more effectively [37].

Moreover, the participation of end users fosters trust and acceptance of telemedicine services. Studies have indicated that involving end users in the development of telehealth solutions can significantly enhance patient involvement in treatment and care, leading to successful self-management practices[37].

A key benefit of actively involving end users lies in the improved usability and satisfaction of the telemedicine system. By considering the input from these stakeholders, the system can be designed to be more intuitive, user-friendly, and better aligned with the specific requirements of healthcare providers and patients. This alignment ultimately results in higher satisfaction and better usability[38].

In the initial section, our objective lies in delineating the internal procedural frameworks enacted within the NC pertaining to the realm of telemedicine. This entails not only discerning the delineated processes but also the identification of the roles integral to these processes, along with an exploration of their requisites. Additionally, we aim to juxtapose these requisites with the internationally recognized benchmarks within the domains of cardiology and endocrinology.

Subsequently, the ensuing section will focus on ascertaining the instrumental tools instrumental in facilitating the aggregation and amalgamation of the accumulated data.

Concurrently, efforts will be directed towards establishing a mechanism for validation, intended to assess the degree of concurrence and acceptance of the proposed model by the pivotal roles involved in the operational facets of the NC. To accomplish this objective, a comprehensive morphological analysis will be undertaken, complemented by the utilization of visual resources strategically aimed at streamlining and optimizing the intricacies of the design process.

2.1 Analysis

2.1.1 Design Thinking

Design thinking is a problem-solving methodology that emphasizes understanding users, challenging assumptions, redefining problems, and creating innovative solutions through an iterative process. It is useful because it helps organizations be more innovative, differentiate their brands, and bring products and services to market faster.Design thinking is particularly effective in social innovation as it focuses on creating products and services that are human-centered and addresses the needs of the people who will consume them [39].

It offers a structured process that helps innovators break free of counterproductive tendencies that thwart innovation, making it a valuable social technology [40].

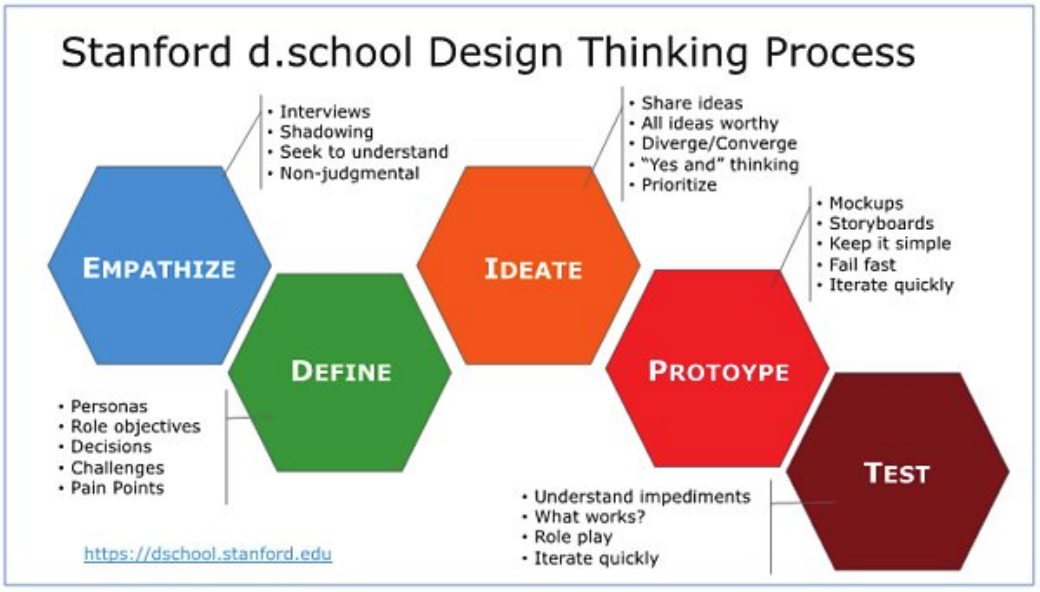


Figure 2.1: Design thinking flow [4].

Figure 2.1 shows how each step of this process is referenced, in which the key roles in the research case are identified and empathized with.

2.1.2 Collection of information on roles, processes and objectives related to telemedicine in the network of private clinics.

As part of the proposed methodology (Design thinking), the participants of the telemedicine process are analyzed in order to understand their needs and thus, design an adequate solution proposal that allows sufficient reliability to be accepted. Therefore, the information about the processes carried out in the NC will be obtained from primary sources, specifically, from administrative and medical personnel of the NC. This will be done through surveys, and for validation of acceptance of a proposal, through questionnaires.

There is formal authorization from the director of the telemedicine area of the NC to conduct this research. Initially, the interview (Annex 1.4) will be applied. The purpose of the interview is to collect information about the processes that are carried out in the NC for the provision of telemedicine services in order to understand in depth the functioning, objectives and limitations of the NC in the application of telemedicine services.

The questions have been posed as open-ended as possible to allow the maximum number of themes to emerge from the participants.The order in which the questions are asked may vary, following the form of a conversation, with no structured patterns. New questions may also arise according to the interviewee's answers. The results of this survey will allow to identify the roles and processes that are carried out in the NC for this type of services, which will serve as a starting point for the design proposal.

2.1.2.1 Selection criteria

1. Inclusion criteria: Individuals who currently work in the NC, in the telemedicine area or who have influence in any part of the telemedicine service provision process. In addition, people who are recurrent patients of telemedicine services provided by the same NC.

2. Exclusion criteria: Not applicable.

2.1.2.2 Sample size

The objective is to survey and interview at least 5 people who currently work in the telemedicine area of the network of private clinics with which the research is being conducted. Also, at least 3 people who are recurrent clients in the use of these telemedicine services in the same NC.

2.1.2.3 Procedures

The first step will be to contact the NC officials. These contacts will be made through telephone calls or e-mails. In case the contacted person shows interest, the date and time of the interview will be coordinated, either by phone call or via video call software, to which they will first be shown the interview informed consent form (Annex 1.2), which must be reviewed and filled out in order to start the interview. During the beginning of the virtual meeting, the participant will be asked for his or her approval to record the interview, and an informed consent procedure will be followed to conduct the interview. The recording will serve as evidence of this consent. For the interview there is a guide of questions (Annex 1.4), formulated in an open-ended manner to encourage the emergence of various topics by the participants. The order of the questions may vary, following the natural flow of a conversation, without a structured pattern. In addition, new questions may arise based on the interviewee's answers.

At the conclusion of the interview, the participant will be asked if he/she is willing to be contacted to complete a survey once the proposed telemedicine system has been designed.

2.1.2.4 Confidentiality

The identity of all participants in the research process will be treated confidentially and will be presented anonymously in the results. Their role in the telemedicine service provision process will be shown, but not their identities. In addition, all files generated by the research will be downloaded and stored in encrypted folders.

2.1.3 Identification of needs for the provision of telemedicine services in the NC

An analysis will be conducted based on the information gathered in previous steps to identify the technological needs of the NC. Initially, a comparison will be made between the current needs and improvement opportunities with internationally recognized standards recommendations. Additionally, a literature review will be conducted to identify proposed services or processes that could meet the institution's objectives. This will result in a compilation of specific needs.

2.1.4 Iterative cycle for the evolution of standards

One critical aspect in designing a telemedicine system for a network of private clinics lies in bridging evidence gaps related to patient access to broadband connectivity. These gaps, referred to as "bridge evidence gaps," denote existing limitations in high-speed, reliable connectivity that

patients require to access telemedicine services. Understanding and addressing these limitations are crucial to ensuring an effective design of the telemedicine system [41].

Within the scope of research aiming to develop a telemedicine system for a network of private clinics, closing these evidence gaps is paramount. A detailed understanding of patient connectivity conditions using the system and the technological environment of the private clinics is necessary. This will facilitate the development of adaptive and effective solutions to ensure a reliable, high-quality connection during remote medical consultations [41].

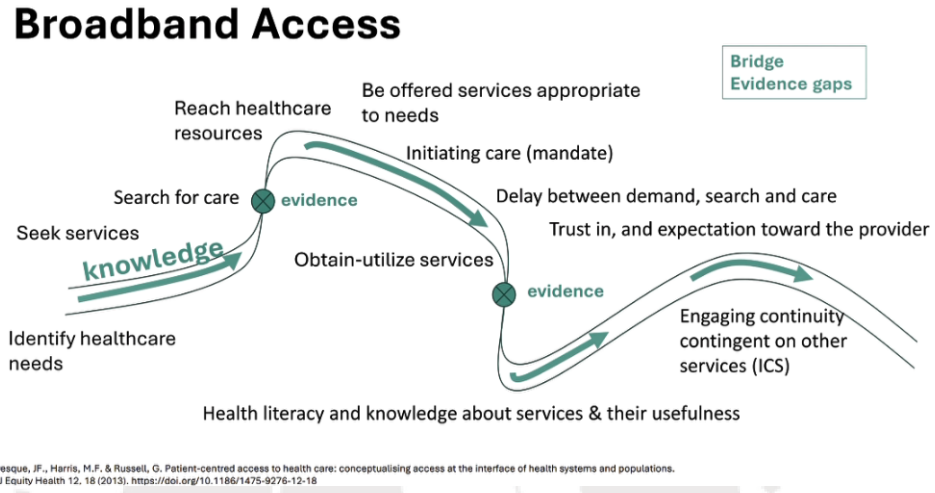


Figure 2.2: Patient broadband access [5].

Figure 2.2 shows the most common gaps during the care process from the patient's perspective.

2.1.5 Journey Map

A customer journey map serves as a graphical illustration delineating the various sequences and phases a patient traverses during their engagement with a healthcare provider, notably within the realm of telemedicine. This comprehensive depiction encapsulates the entirety of a patient's encounter, commencing from their initial awareness of telemedicine services and extending through to the subsequent post-consultation phase. The development of this map entails thorough market research and integration of patient input, thereby empowering healthcare providers to glean valuable insights into patient requirements, areas of concern, and inclinations [42].

By customizing this instrument for application within the scope of this study, two objectives can be attained that hold significance concerning the acceptance of the ultimate product by users:

1. Comprehend Patient Requirements: By delineating the patient's journey, healthcare providers can attain a more profound comprehension of patient requirements, inclinations,

and areas of concern. This understanding empowers them to customize telemedicine services, aligning them more effectively with patient expectations[43].

2. Refine Patient Engagement: It facilitates the refinement of each interaction point throughout the patient's journey, ensuring a coherent and favorable experience across the entire telemedicine continuum, encompassing initial awareness through to post-consultation follow-up[43].

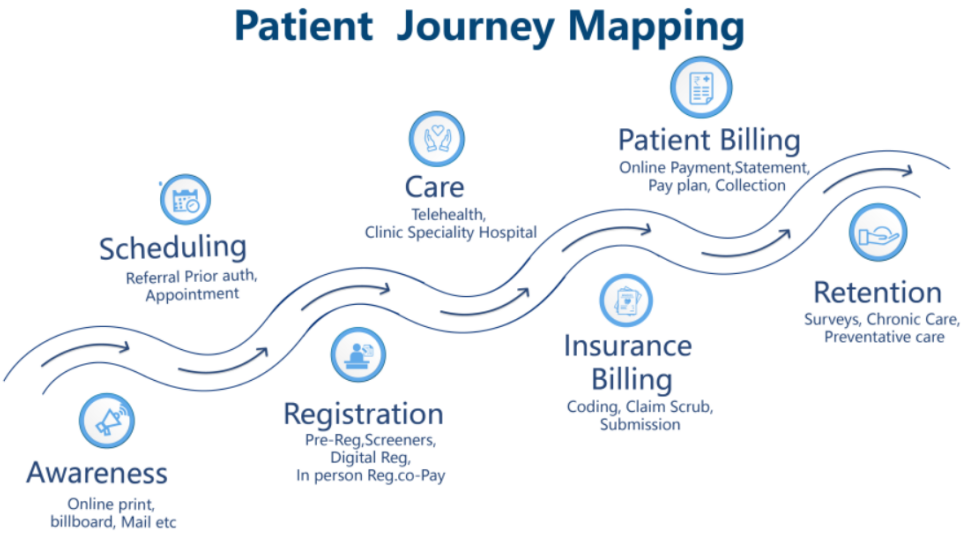


Figure 2.3: Patient journey mapping [6].

Figure 2.3 delineates a use case scenario about the patient role. It encapsulates the entire sequence of events experienced by the patient throughout the teleconsultation service, commencing from the scheduling of the medical appointment and extending to the post-consultation care phase. The utilization of the customer journey map facilitates an exhaustive analysis of the patient's perspective within each scenario, thereby facilitating a comprehensive understanding of their needs and objectives at various stages. This methodology can be replicated across all identified roles within the NC telemedicine process, ensuring a comprehensive case study.

2.2 Design

2.2.1 TSQ (Telemedicine Satisfaction Questionnaire)

The TSQ (Telemedicine Satisfaction Questionnaire) is a questionnaire used to assess the quality of telemedicine services. This questionnaire consists of 21 items that measure patient satisfaction

with the care received through telemedicine, and are grouped into four dimensions: accessibility, quality of care, patient satisfaction and confidentiality [44]. The TSQ is a useful tool for improving patient care and can be used in different healthcare settings.

In the verification of telemedicine proposals, the TSQ is used to assess the quality of proposed telemedicine services. The questionnaire makes it possible to identify the strengths and weaknesses of services and improve patient care. In addition, the TSQ is easy to administer and can be used in different healthcare settings [45]. The TSQ can be applied in the following ways [45] :

- Administering the TSQ questionnaire to patients who have received care through the telemedicine service.
- Administer the TSQ questionnaire to health care personnel who have provided care through the telemedicine service.
- Analyze the results of the TSQ questionnaire to identify the strengths and weaknesses of the telemedicine service.

The questionnaire can be found in Annex 1, this will be conducted in Spanish, the native language of all interviewees.

2.2.2 Data Collection on Proposed Model Satisfaction

For the evaluation of the final design proposal, a survey will be conducted among interested participants to obtain information on their opinion about the proposed new model.

There is a survey plan (Annex 1.3), which is the TSQ (Telemedicine Satisfaction Questionnaire). The TSQ consists of items without categories and covers a variety of satisfaction factors, such as quality of care, quality of virtual visits, interpersonal interactions, and has fewer items. The TSQ has been used quite frequently in research studies evaluating telemedicine services.

2.2.2.1 Procedures

The first step will be to contact NC officials and recurrent patients who are interested in participating. These contacts will be made through telephone calls or e-mails. If the participant agrees, upon testing the proposed telemedicine model, the sending of the survey link (Annex 1.3) will be coordinated through telephone or e-mail communication, after explanation of the informed consent protocol for surveys (Annex 1.1), in addition to his/her signature and having

duly filled in his/her data, the survey can begin. The entire process of collecting information and contacting the participants for this survey will be carried out virtually.

2.2.2.2 Confidentiality

The identity of all participants in the survey process will be presented anonymously in the results. Their role in the telemedicine service delivery process will be shown, but not their identity. This is in order to show the level of satisfaction of each of the roles within the telemedicine application process in the NC.

2.2.3 Technical requirements

2.2.3.1 Functional structure

The initial phase of a PCB design involves a comprehensive delineation of all functions required by the PCB. This foundational step sets the stage for the design and evaluation stages that follow:

- **Function Identification:** This involves pinpointing and defining each essential function that the PCB is expected to perform, covering both the primary operational functions and the supporting auxiliary functions [46].
- **Analysis of Structure:** Post identification, the interrelationships among these functions are analyzed. This step is crucial for designing a PCB that operates as a cohesive and efficient unit [46].

This analysis allows for the identification of the necessary inputs and outputs required to conduct the experiments for the research. Additionally, it helps organize the structure that the electronic design will need in order to efficiently fulfill the desired functions.

2.2.3.2 Morphological matrix

A morphological matrix is an analysis and problem-solving tool that helps to generate ideas and explore solutions by combining different elements. It consists of a matrix that combines different options for each variable and allows exploring all possible combinations. The morphological matrix is a key concept within morphological analysis [47]. By combining different elements of each category, new ideas can be generated. The morphological matrix is a useful tool for product or service innovation and design, as well as for complex problem solving . To construct a morphological matrix, the following steps should be followed [48]:

- Identify the problem or situation to be solved.
- Define the variables relevant to the problem.
- By decomposing a problem into different components, each part of the problem is approached from different perspectives.

2.2.3.3 Features of the wearable with which the tests will be conducted

As part of the context in which the consultations are applied, a wearable device was selected that has the capability to perform measurements of the most common vital signs relied upon by health professionals for diagnosis in the fields of endocrinology and cardiology. Consequently, it was determined that this device should possess FDA certification to ensure that it has the appropriate characteristics for collecting patient information and can gather the necessary data for the validations that will be conducted.

Due to these requirements, a Corsano brand wearable, model 287-2B, was chosen due to its information collection capabilities, FDA certification, and other functionalities.

Figure 2.4: Corsano cardiowatch 287-2B [7]

The usage flow of this wearable will be presented below, which will provide an understanding of how this device is used and the order in which measurements or data recording are conducted.

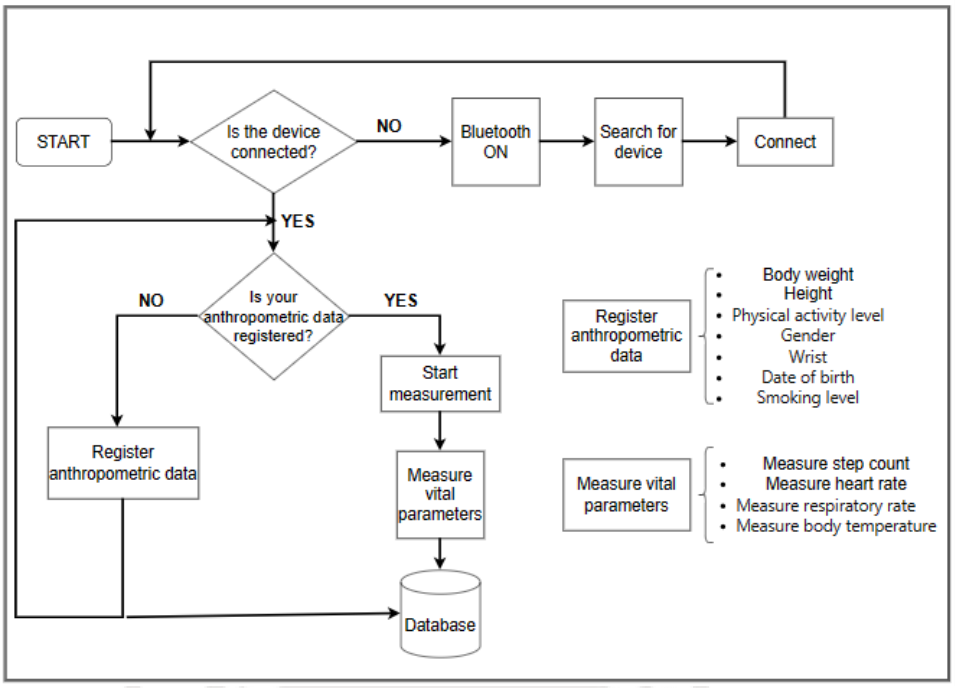


Figure 2.5: Corsano cardiowatch flowchart

It is important to note that for conducting an ECG (crucial for diagnosis in cardiology), this type of wearable performs a Lead I ECG, one of the fundamental leads used to measure the heart's electrical activity, specifically recording the difference in voltage between the right and left arm electrodes. This lead is pivotal as it captures the heart's horizontal electrical signals, offering insights into heart rhythm and potential abnormalities [8].

This lead is popular in wearable devices due to its practicality and effectiveness. Two electrodes are located on the case back of the Bracelet, contacting the wrist skin through dry contacts. They are the positive ECG electrode and the right-leg electrode. The right-leg electrode enables to increase the rejection of noise and common-mode signals. The third electrode is the metal frame on the top of the Bracelet. This is the negative ECG electrode.

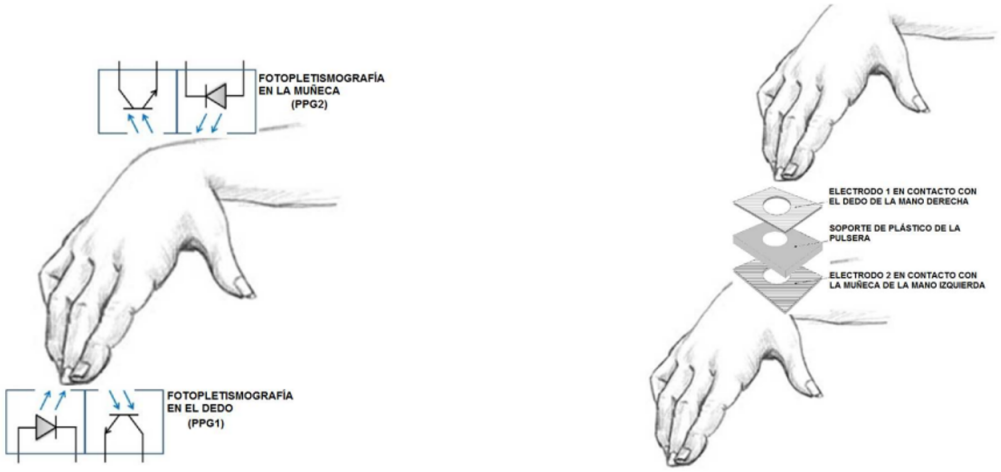


Figure 2.6: Lead 1 ECG in a wearable [8]

Figure 2.6 shows how it works. The patient must wear the Bracelet on one wrist and touch the top frame with the other hand to enable the ECG system to measure the electrical heart signal flowing from one arm to the other. Despite its simplicity, Lead I effectively monitors heart rate and identifies significant rhythm anomalies like atrial fibrillation [8].

Additionally, for the measurement of vital signs such as temperature, blood oxygenation, heart rate, etc., the type and characteristics of the sensors available in the wearable must be considered.

Clinical Function	Definition	Unit	Range	Acquisition time	Update time	Accuracy *
Pulse Rate	Number of beats of the heart per minute	beats/minute (bpm)	25-250	5-10 s	1 s	1.95 bpm Arms
RR Interval	Elapsed time between two consecutive heart beats	msec	300-2000 ms	5-10 s	1 s	RR Interval ±50 ms MAD, ±5% MARD (at rest)
Heart Rate Variability	Beat to beat (RR interval) variations	msec	0-200 ms	5-10 s	1 s	HRV ±10 ms MAD, ±5% MARD (at rest)
Respiration Rate	Number of breaths (inhalation - exhalation cycles) per minute	breaths/minute (brpm)	4-60 brpm	20-30 s	1 s	0.91 bprm Arms
Sleep Stages	Detection of specific sleep stages & sleep HR	awake, light sleep, deep sleep, REM	sleep stage	At the end of sleep session	1 min	Sleep Stage ±10 % MAD
Sleep Score	Sleep performance and sleep consistency with equal weight	%	0-100%	10 s	1 s	Sleep Score ±5 % MAD
SpO2	Functional oxygen saturation	% saturation	70-100%	1 min	1 s	1.39% Arms
Body Temperature	Temperature of the body at the measurement site	Degree Celsius	34-42°C	30 min	1 min	+/- 0.3°C

Figure 2.7: Clinical performance - Corsano cardiowatch [7]

Figure 2.7 displays the clinical performance of the device. This includes the measurement intervals, which will be considered for the validations to be conducted in the research alongside

reference equipment.

To capture the ECG readings from the Corsano device, the open-source code provided by the brand, named ”Corsano SDK Sample,” was adapted. This adaptation allowed the app to save the ECG values generated and exceed the brand’s default portal limit of 20 seconds. The purpose of this modification is to retain more data, which will be beneficial for analyzing the ECG’s accuracy. The project was developed in Android Studio and utilized Gradle as the build automation system. Moreover, it was developed in Kotlin due to its concise syntax compared to Java, and for the robust error resolution support provided by Android. With this development kit, approximately four minutes of ECG data were successfully stored from the wearable device directly onto the connected smartphone.

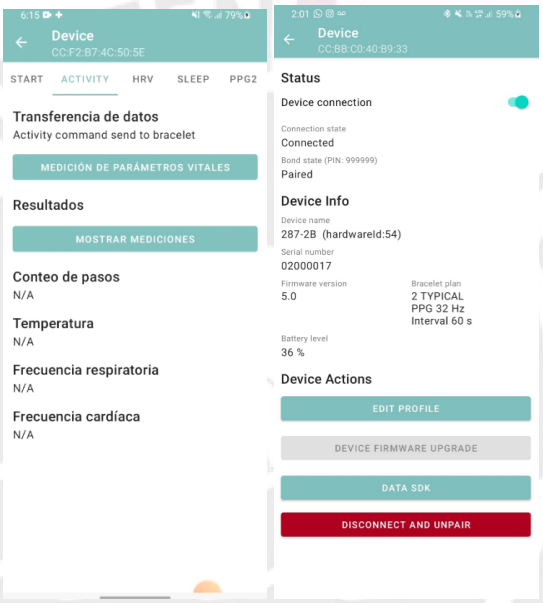


Figure 2.8: Images when launching the Application - Taking measurements screen

In Figure 2.8, the interface through which access is gained to the measurement information collected by the Corsano is displayed. With this interface, measurements are stored locally on the phone and exported for subsequent analysis in Matlab.

2.3 Validation of intended use

A validation will be conducted regarding the capability of the selected wearable within the research, given the selected risk and its importance in medical practice, since it is a fundamental aspect on which health professionals rely to make a diagnosis and define the next steps to take with the patient. For this purpose, objective tests of the aspects to be analyzed for each type of vital sign, whether studied qualitatively or through waveform image analysis, are conducted. Two

validations will be carried out: Wavelet analysis of the ECG waveforms and Concordance analysis of the biometric sensors for Temperature, SpO_2, and other signals.

2.3.1 Reference equipment used for the testing pattern

In this study, the ProSim 8 vital signs simulator from Fluke Medical will be employed as the reference standard equipment to evaluate the accuracy of the mentioned wearable device. The ProSim 8 is capable of generating precise and consistent physiological signals that mimic a variety of human conditions, such as heart rates, breathing patterns, blood pressure, and electrocardiographic signals [49]. The selection of this simulator as a reference is due to its high precision and reliability, which ensures consistency in testing and eliminates the variations inherent in using human subjects. Furthermore, the use of this device facilitates a controlled and standardized testing environment, essential for the validation of the functionality and accuracy of medical wearables, simulating the necessary regulatory and quality requirements for clinical and everyday use.

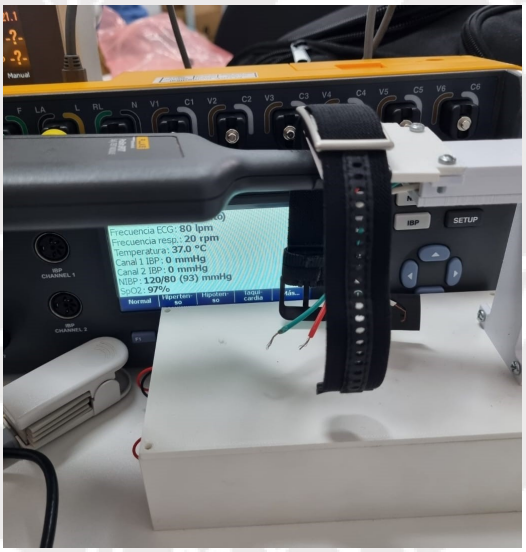


Figure 2.9: Setup for storing biometric signals generated by the ProSim 8 to the Corsano

Figure 2.9 illustrates the use of the vital signs simulator for receiving vital signals generated on the Corsano, data that will subsequently be used for precision analysis of the wearable. The transducer used in the figure is designed to simulate the blood oxygenation (SpO_2) of a patient.

For ECG waveform analysis, the study is conducted using the signal generated by the reference equipment, whereby the simulator acts as the test standard. Considering the aforementioned, an EDAN iM70 vital signs monitor will be utilized due to its capability to receive ECG signals produced by the ProSim 8 and store them for subsequent use, given that the

visual information from the generated signal displayed on the vital signs simulator is insufficient for waveform analysis. Therefore, the previously mentioned monitor is used, which also allows for visual validation of the waveform being received to ensure it is as desired, before storing it on an external storage unit.

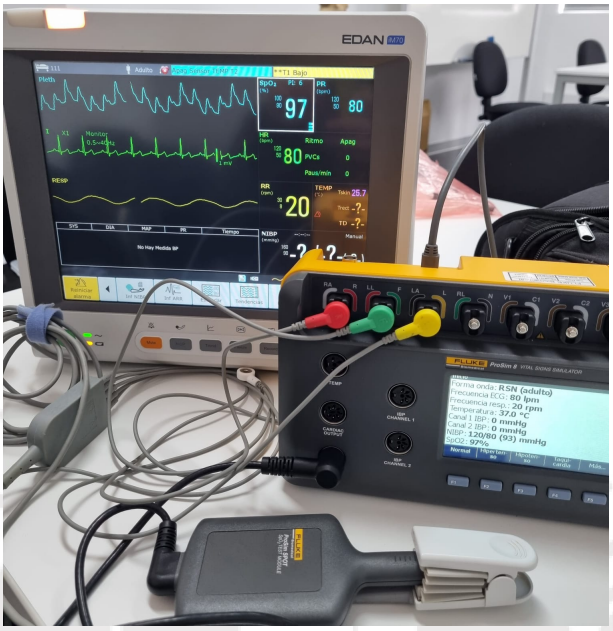


Figure 2.10: Setup for storing ECG generated by the ProSim 8 to the Monitor EDAN iM70

As shown in Figure 2.10, the monitor displays all the vital signs of the patient according to the transducers that are connected to it. The image illustrates the ECG waveform being generated by the ProSim 8 through the electrodes connected for Lead I, and for illustrative purposes, it also shows the use of the transducer to measure blood oxygenation, which is also reflected on the monitor's screen.

2.3.2 Electrocardiogram waveform analysis

Conducting an ECG waveform analysis is essential to mitigate measurement errors in ECG monitoring devices used with patients, thereby assuring the dependability and precision of diagnostic outputs. This scrutiny examines the waveform features to identify any inconsistencies or irregularities, which may signal issues with the device's performance or its calibration. The focus of this analysis is the electrical activity of the heart, particularly examining elements like the QRS complex. The QRS complex, indicative of the swift depolarization of the heart's ventricles, is crucial for assessing cardiac rhythm, timing, and detecting various cardiac disorders. Effective analysis ensures that the ECG device delivers accurate data, which is fundamental for making precise clinical assessments and enhancing patient treatment[50].

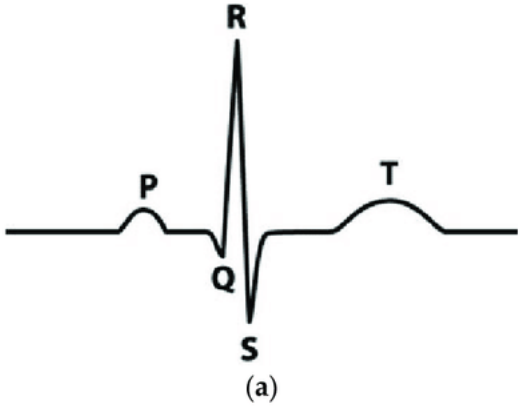


Figure 2.11: ECG waveform - QRS complex[9]

The wavelet transform is highly effective for ECG analysis owing to its ability to perform multi-resolution analysis. Wavelet analysis has the capability in reducing noise is significant while preserving the integrity of the signal. Furthermore, the wavelet transform is adept at identifying specific features in non-stationary signals like ECGs, which exhibit varying statistical properties. This accuracy is crucial for precisely detecting abnormalities within the ECG, which is vital for the diagnosis of various cardiac conditions[51].

In processing this type of signals using the Wavelet Transform, the following processing steps will be undertaken[52]:

1. Wavelet admissibility condition:

   A wavelet ψ must satisfy the admissibility condition, ensuring that it is suitable for both continuous and discrete wavelet transforms:

   $$\int \frac{|\hat{\psi}(\omega)|^2}{|\omega|} d\omega < \infty$$

   where $\hat{\psi}(\omega)$ represents the Fourier transform of $\psi(t)$. This condition ensures that the wavelet can accurately capture transient features in the signal without being influenced by its average value.

2. Discrete Wavelet Transform (DWT):

   The DWT is defined as:

   $$DWT(a,b) = \frac{1}{\sqrt{|a|}} \int f(t)\psi\left(t - ba\right) dt$$

   Here, a and b denote the scale and translation parameters, respectively, allowing for the precise analysis of the signal at various resolutions

The selection of a wavelet depends on its waveform resemblance to the one it will identify, which entails strong correlation and the signal component of interest for effective detection. Moreover, it must be finite to ensure accurate localization in time and frequency. [10]

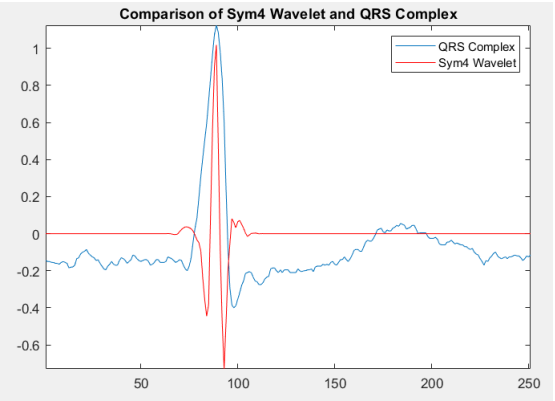


Figure 2.12: Wavelet Sym4 [10]

The ”sym4” wavelet resembles the QRS complex, making it a suitable choice for QRS detection. To illustrate, a QRS complex and a dilated, translated ’sym4’ wavelet are extracted for comparison.

3. Application in QRS Complex Detection:
   - Wavelet Selection and Decomposition:
     The Haar wavelet is used for its effectiveness in detecting discontinuities. The ECG signal is decomposed into various levels to analyze high-frequency components.
   - Soft Thresholding:
     To minimize noise, the soft thresholding technique is applied for adjustment of wavelet coefficients
4. Signal Reconstruction:
   The ECG signal is reconstructed from wavelet coefficients:

$$f(t) = \sum_{j,k} c_{j,k} \psi_{j,k}(t)$$

where $\psi_{j,k}(t)$ are wavelets at different scales and $c_{j,k}$ are the transform coefficients.

2.3.3 Consistency of biometric sensors

To determine the status of wearable sensors, concordance tests are conducted in comparison with calibrated equipment used as a reference. This is because the tests are carried out under the same

conditions, allowing concordance comparisons to be made to ascertain how consistent their data readings (vital signs) are in comparison to a reference device used for calibrating these types of sensors in laboratories.

The Bland-Altman method is particularly important for concordance tests with standard equipment because it provides a detailed analysis of agreement between two quantitative measurement methods, which is critical in fields like healthcare where precise measurements are essential[53]. For analysis, the following expressions and modes of result interpretation are considered:

- **Differences between Measurements:**

$$D_i = Y_i - X_i$$

  where X_i and Y_i are the measurements from Methods A and B, respectively, for subject i.

- **Average of Measurements:**

$$M_i = \frac{X_i + Y_i}{2}$$

- **Average of Differences (Systematic Error):**

$$\overline{D} = \frac{1}{n} \sum_{i=1}^{n} D_i$$

  where n is the total number of subjects. Represents a consistent bias between two measurement methods, indicated by the mean difference between the methods. A mean difference near zero suggests little to no bias [53].

- **Standard Deviation of Differences (Random Error):**

$$S_D = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (D_i - \overline{D})^2}$$

  Reflects the variability or scatter in the differences that isn't due to systematic bias. It's quantified by the standard deviation of these differences, contributing to the calculation of limits of agreement which indicate the precision of the measurements [53].

- **Limits of Agreement:**

$$\text{Limits of Agreement} = \overline{D} \pm 1.96 \times S_D$$

These limits are designed to encompass approximately 95% of the differences between the measurements of the two methods, assuming that these differences follow a normal distribution [53].

Graphical Interpretation:

The Bland-Altman plot displays the differences D_i against the averages M_i, facilitating visualization of the agreement between the two measurement methods.

Chapter 3

Electronic Design

As part of the proposed solution for this research, an electronic design has been developed to enable comparisons and analysis of both signals and sensors related to the wearable. The objective of this design is to have the capability to capture signals from the reference equipment, so that they can be received by the wearable, including both ECG and biometric sensor readings. Therefore, in addition to a schematic, a 3D, Three Dimensional, modeling has been carried out to ensure the usability of this PCB, printed circuit board, within the patient area in the NC.

Given that a future application within the same user area of the NC is envisioned, the design will aim to require the minimum number of additional connected devices, aside from the reference equipment and the wearable. This leverages the transmission capabilities of the readings from both the wearable and the reference equipment used.

3.1 Functional Structure

For this design, a functional structure is employed initially, as it organizes and clarifies the purposes of each part of the design. This approach allows for a modular design, where components are developed and tested before being integrated. Additionally, a well-defined structure simplifies both diagnosis and maintenance, enabling the identification of faults and the implementation of updates without affecting the entire system. It also facilitates the scalability of the design, allowing for the incorporation of new functions or the expansion of capabilities without the need to redesign the system from scratch.

To achieve this, the black box design is presented before developing the functional structure. The black box focuses on the inputs and outputs of the system without initially considering the internal details, allowing for a clear definition of the design requirements and objectives. This approach helps identify essential functions and key interactions between components. Once these

foundations are established, a detailed functional structure can be developed.

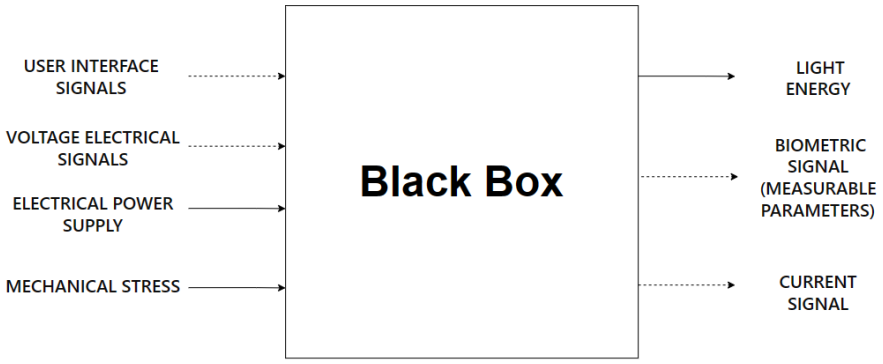


Figure 3.1: Black box approach used to design the device

This black box considers the following inputs: User Interface Signals, which are the signals generated by the user when energizing the device; Voltage Electrical Signals, which are the signals captured by the bio metric sensors of the wearable; Electrical Power Supply, which is the power source for the device; and finally, Mechanical Stress from holding the wearable.

The outputs are light energy, provided by the LED or indicator that the device is on; bio metric signals with measurable parameters captured by the wearable; and current signals in the case of the ECG. When analyzing the inputs/outputs of the black box, the necessary functions have been defined to achieve the expected results that will fulfill the objectives of the research. The following function structure has been established to continue with the subsequent steps in the electronic design:

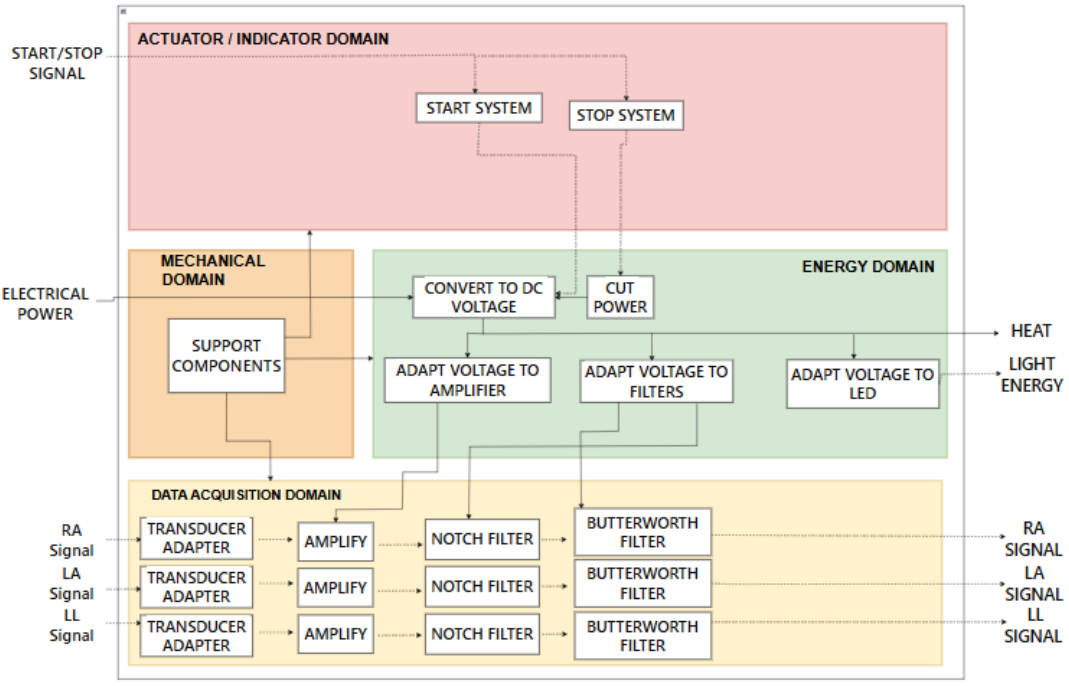


Figure 3.2: Functional structure of the device

In the structure, the following domains are defined: Actuators/Indicators, where the user indicates whether to turn the device on or off; the Mechanical domain to support all the components within the device's domains; the Energy domain, to adapt the power supply to the needs of each stage of filtering or signal amplification; and the Data Acquisition domain, to obtain a noise-free signal that retains the necessary information for conducting the expected analysis.

3.2 Morphological matrix

This matrix is based on the structure of functions previously mentioned, where for each function of each domain, components are selected based on possible solutions. It is considered essential that these components meet the design requirements, that there are sufficient supplies available from the supplier, and that the cost of the components is affordable for the research.

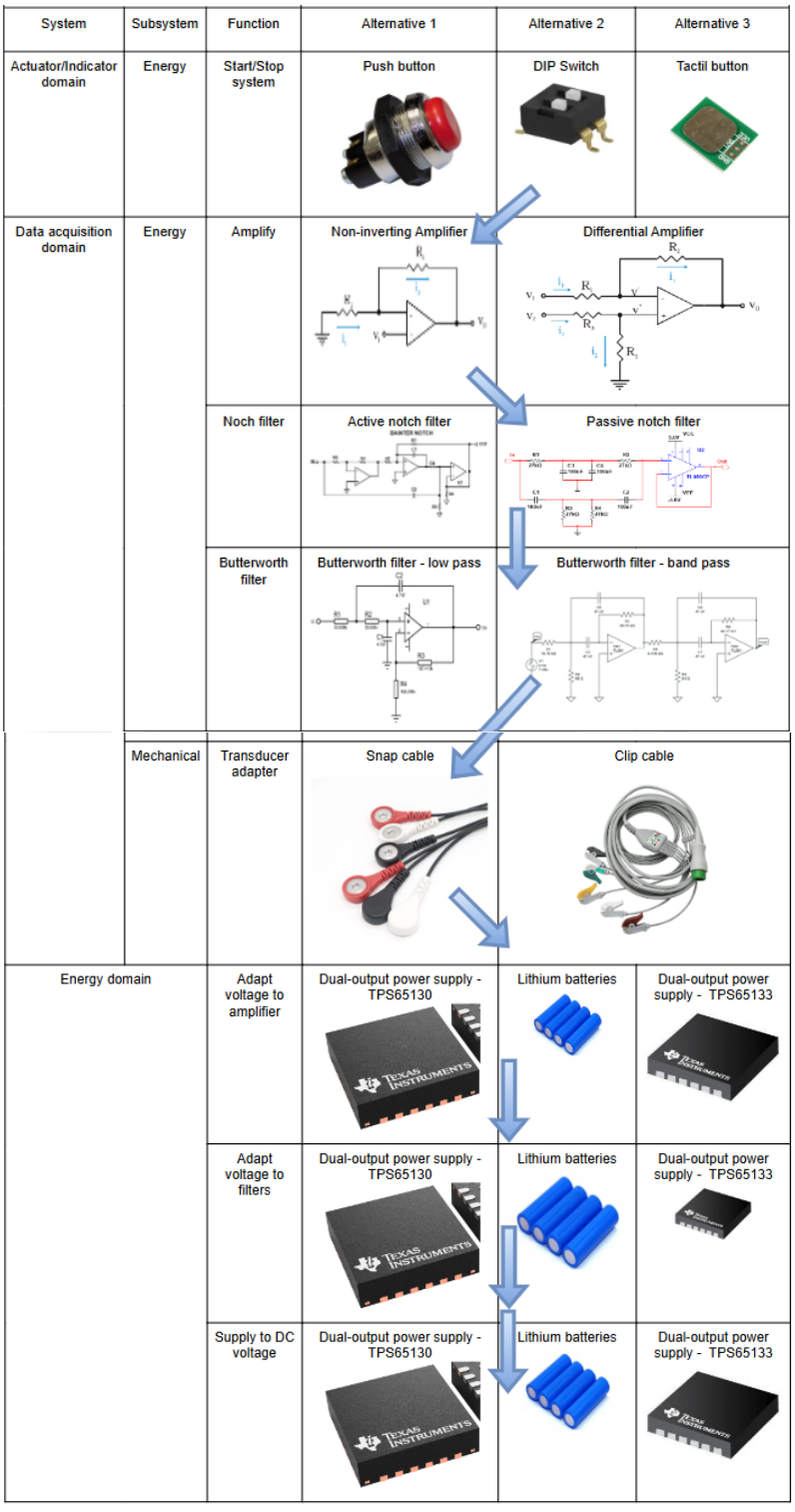


Figure 3.3: Morphological matrix

Figure 3.3 displays the solution choices made for this design. Additionally, it serves to organize the information that will facilitate and be reflected within the PCB modules.

3.3 Printed circuit board

According to the function matrix, the modules that will be part of the electronic design of the PCB were defined. Similarly, the morphological matrix was useful in determining the best solution for selecting which components to use, taking into account the accessibility available in Peru and the economic availability of the selected components.

To begin, the following figure illustrates the power supply module, which will provide 12V (negative and positive) to the modules in the data collection section. Two battery sockets will be used to supply these different voltages. Additionally, on the other side, the input for the ECG signals can be seen; in this case, the input is a 3.5mm audio jack. This was selected because the signals are being handled in an analog manner, and due to its compatibility with accessories and connectors, this input was determined to be ideal for the prototype. The component labeled S1 is the pin switch of the board, which allows turning it on or off as needed.

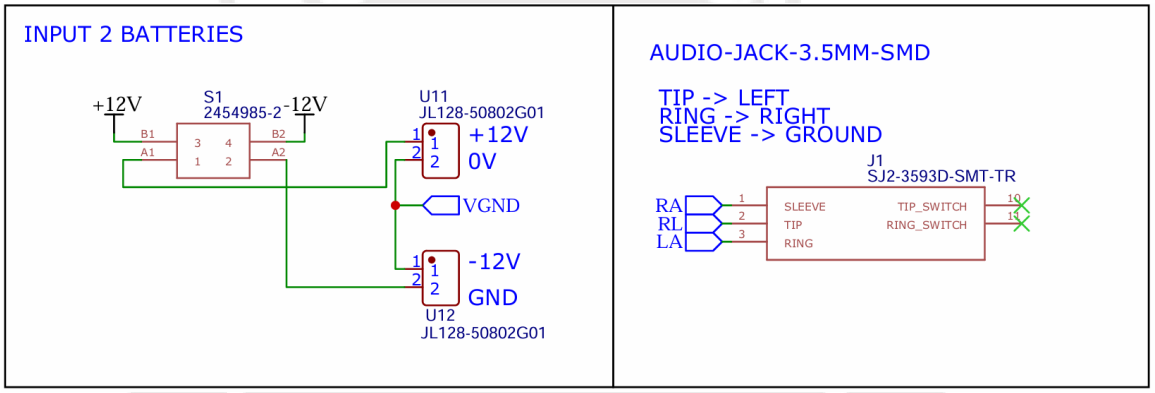


Figure 3.4: Schematics of the Printed Circuit Board - Inputs

In the following image, the amplification module is presented. As mentioned in the methodology section for ECG Lead I, the signal from the right leg functions as the ground reference for the differential between the signals from the left and right arms, which is why this signal is grounded. The signals from the arms are amplified with a gain of 100 (G = 100) using an OPA188 operational amplifier in non-inverting mode. This component was selected due to its characteristics of current range, noise resistance, and operating frequency according to the supplier's data.

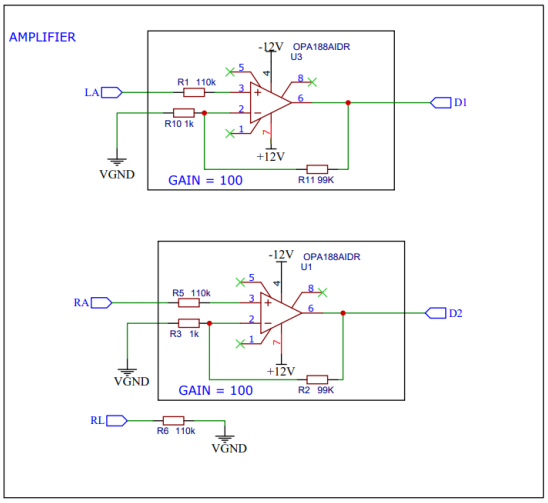


Figure 3.5: Schematics of the Printed Circuit Board - Amplifier

The filtering module is repeated for both the left and right arm signals. This module starts with a second-order high-pass filter with a cutoff frequency of 0.005 Hz, aimed at eliminating peaks induced by noise. This is followed by a 60 Hz Notch filter module, designed to eliminate line interference caused by the board's power supply or other electromagnetic interference from the board itself. Finally, the signal goes through a low-pass filter to remove any residual noise that the study signal may carry, with a cutoff frequency of 100 Hz.

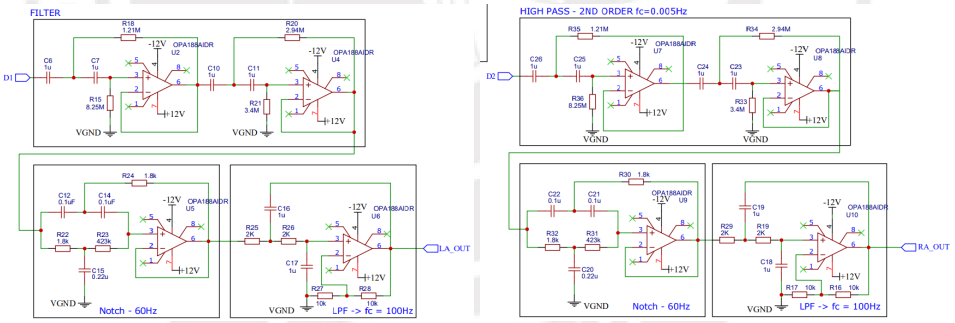


Figure 3.6: Schematics of the Printed Circuit Board - Filters

In the output modules section of the board, there is a LED that serves as an indicator to show whether the board is powered on or off. Additionally, posts have been provided to allow for the connection of clip-type cables or for soldering if necessary.

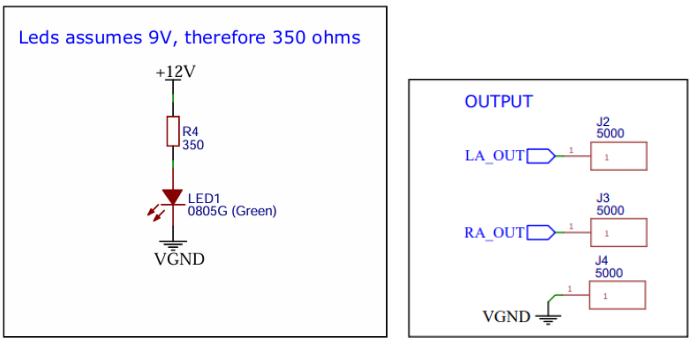


Figure 3.7: Schematics of the Printed Circuit Board - Outputs

This PCB meets the requirements of the experiment and facilitates the capture of necessary data for conducting comparisons and studying signals for the purpose of this research. A two-layer routing has been executed, with the necessary considerations for the analog handling of signals for this study. The complete schematic and routing can be found in Appendix 2 of the document.

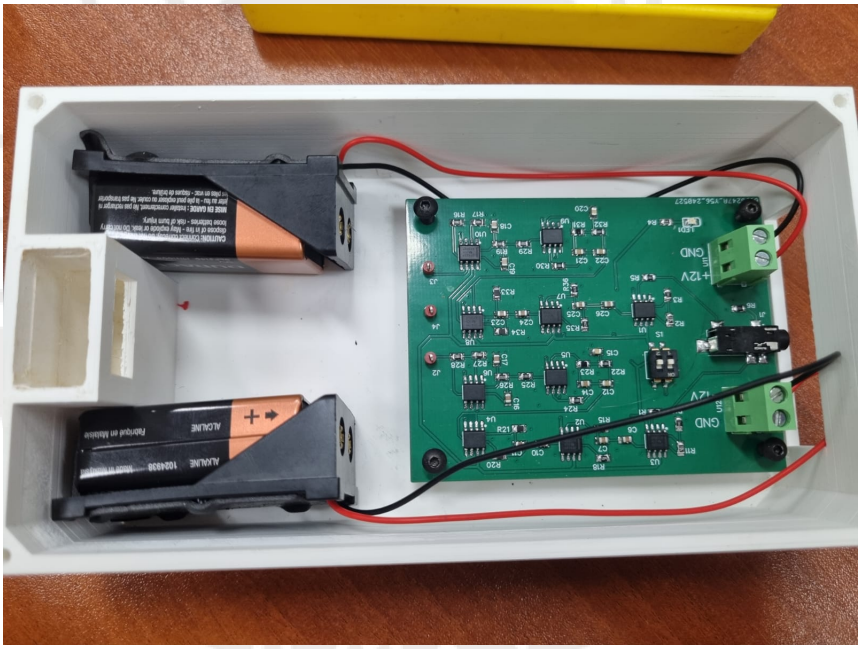
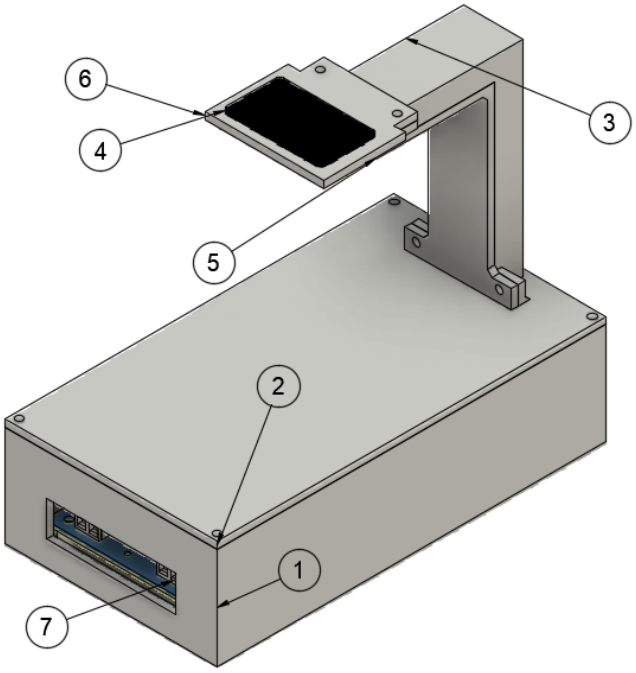


Figure 3.8: Soldered board

In Figure 3.8, the outcome of the electronic design is displayed. The design was implemented, and the selected electronic components were soldered. Additionally, connections to the battery sockets were soldered to ensure the desired power supply. When the PCB is powered on, the LED within the design lights up, indicating its operation. Screws with a diameter of 3 mm were chosen due to their local availability to secure the board to the prototype case's print, as shown in the figure.

3.4 Three Dimensional Design

In order for the device to be used in the user area, a Three Dimensional Design (3D) modeling has been carried out to meet the connectivity needs of the reference calibration equipment utilized, as well as the chosen type of wearable, given the type of connector/electrode each possesses. In this instance, a Fluke Medical vital signs simulator is employed, which features Stay-connected ECG posts, and the wearable that includes contact electrodes. In this regard, the following modeling has been conducted:



Parts list		
Element	Quantity	Part
1	1	Body base
2	1	Body cover
3	1	Arm stand
4	1	Wearable socket
5	1	Arm base
6	1	Wearable base
7	1	PCB
8	2	Batthery socket

Figure 3.9: 3D modeling of the device

The material used was PLA, specifically chosen in white given the clinical service oriented context in which it will be used in the future. Additionally, it features a space on the lid for connection with the reference equipment to be used in the experiment. The arm it possesses is designed to hold the connectors that will come into contact with the diodes of the wearable, allowing it to capture data for subsequent processing. The measurements and detail of each component of the design can be found attached in the Appendix 3.

The dimensions of the entire prototype assembly are 165 mm in length, 90 mm in width, and a height of 137 mm, measured from the base to the support where the wearable will be placed. The printed circuit board measures 87.25 x 66 x 12 mm.

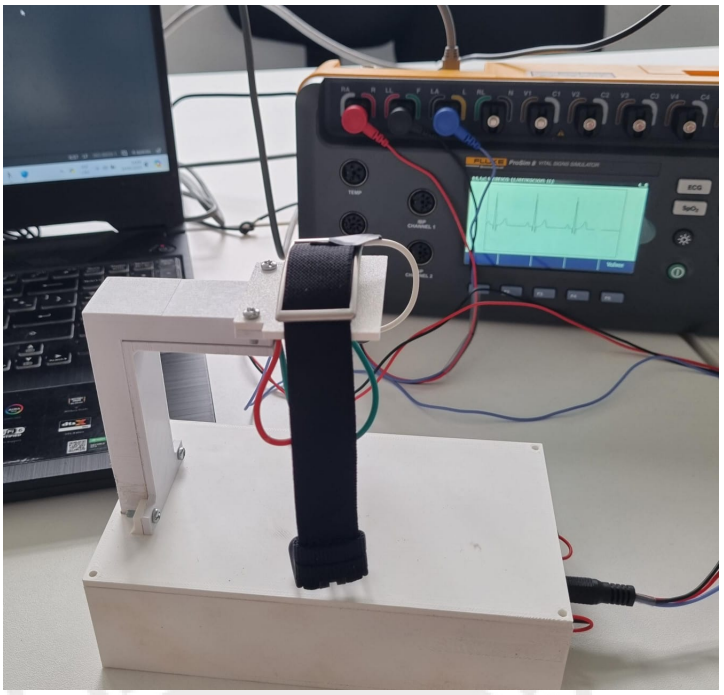


Figure 3.10: Picture of the implemented 3D design

Figure 3.10 highlights the final result with the implementation of the 3D design. It shows the assembled design, through which the electrodes were connected to capture the ECG wave in the wearable. The design ensures that the cable lengths between the board and the device are not visible and allows the device to be connected without the need for additional assistance.

Chapter 4

Results

In this chapter, the results of the trials will be presented, and the procedure used to process the obtained information will be shared. This includes how the graphs and tables that will be presented in the chapter were generated.

4.1 Identified risks based on perception from clinical collaborators

To gather information from the NC, interviews were conducted that adhered to an ethical protocol to safeguard the ethical principles of the research and the nature of the questions posed. All interview protocols, a summary of the research, and its objectives were sent to the university's ethics committee for approval. The committee's ethics approval is attached in Appendix 3.

Based on the information collected by the clinic's collaborators, the vital signs were identified as the most important biomarker of interest for the customer profile of the NC's telemedicine service, specifically in the fields of cardiology and endocrinology. These are mentioned in the following figure:

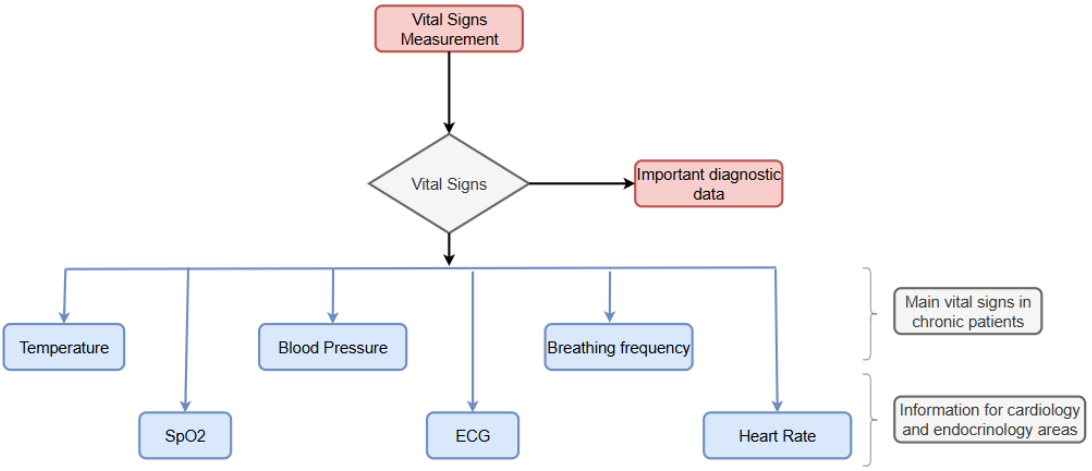


Figure 4.1: Biomarkers comprising vital signs informationfor NC

Regarding the information obtained during the interviews, a total of four health professionals in each specialty under study (cardiology and endocrinology) were interviewed. The interview protocol for NC collaborators was followed, and through this, four main risks were identified that have hindered ensuring the quality of care in the NC's telemedicine service for patients. These are presented in the following figure, which details each identified risk and those present in most of the interviews conducted.

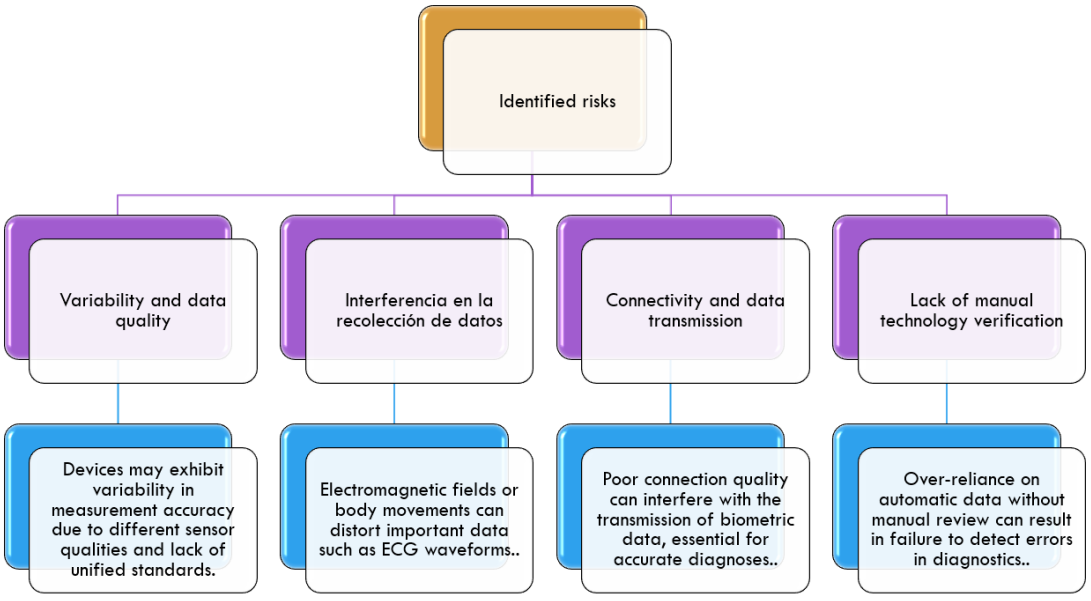


Figure 4.2: Identified risks of the NC

During the interviews, four risks associated with telemedicine services were identified, based on information obtained through interviews with health professionals specializing in cardiology

and endocrinology. These risks significantly converge at a critical point: the risk of measurement errors in wearables, a factor that can seriously compromise the effectiveness and safety of the telemedicine service provided.

1. The variability and quality of data are highlighted as a fundamental risk, given that the accuracy of wearables is essential for reliable diagnostics and clinical monitoring. Without consistency in the collected data, any attempt at treatment based on these data may be harmful. Variable data can lead to erroneous interpretations of the patient's condition.

2. The risk of interference in data collection also has a direct impact on the measurement accuracy of wearables. Distortions in ECG waveforms and other biometric data can result in incorrect diagnoses or inadequate monitoring of chronic conditions.

3. Connectivity and data transmission: Data loss or corruption during transmission can result in a lack of essential information for making timely and accurate clinical decisions. This risk is exacerbated by variabilities in the technological infrastructure, which is a constant challenge in the implementation of large-scale telemedicine solutions.

4. Lack of manual technology verification: This underscores the importance of the human factor in technology supervision. Sole reliance on technology, without proper human intervention or oversight, can lead to undetected errors that could have been identified and corrected in time.

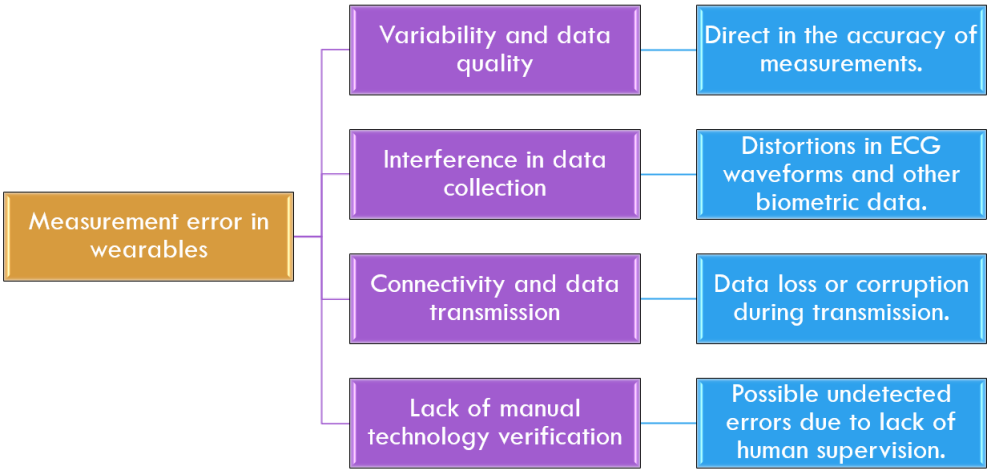


Figure 4.3: Synthesis of the identified risks

Mitigating the risk of measurement errors in wearables has a fundamental impact on the other identified risks, to ensure medical-grade wearables not only as an efficient activity monitoring

tool but also as a safe and reliable provision of telemedicine services. Additionally, accurate measurement of vital signs ensures appropriate diagnostic quality for the patient and allows for the definition of supervision protocols for this type of device. For this reason, it is imperative to find a solution to this risk.

4.2 Experiment between wearable and calibration standard equipment

For the subsequent experiments, the technological proposal of this research was designed. The electronic design emphasized allowing the wearable to capture the same ECG waveform as the standard equipment for subsequent analysis. Additionally, the 3D design was carried out with the aim of enabling connectivity with the standard equipment's transducers, which simulate vital signs to capture data readings and conduct further Bland-Altman analysis.

4.2.1 Bland Altman comparison

For each test, 40 measurements were conducted for each vital sign on each device, with the Corsano Cardiowatch as the test equipment and the Prosim8 from Fluke Medical as the reference equipment. In each subsection by vital sign, the scenario under which the measurements were taken for the Bland-Altman analysis is specified.

4.2.1.1 Body temperature

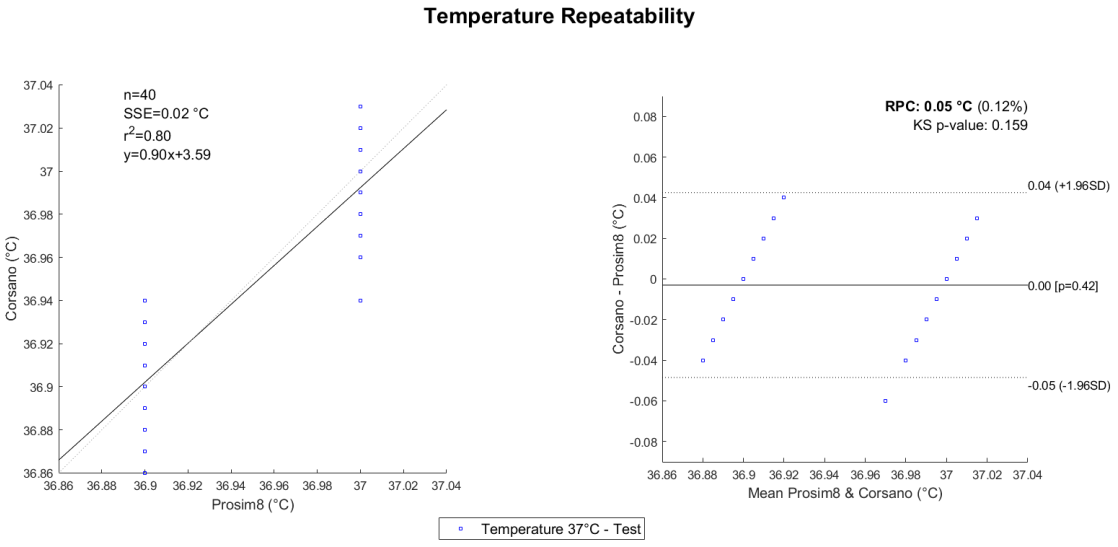


Figure 4.4: Regression and Bland-Altman Analysis Graphs for Body Temperature Measurement

The results of the Bland-Altman analysis and linear regression indicate excellent agreement and consistency among the temperature measurement devices used in the study. The Pearson correlation coefficient is 0.895, and the coefficient of determination is 0.802, demonstrating a strong correlation and that approximately 80.2% of the variability in the measurements of one device is explained by the other. The differences between the devices are minimal with a standard deviation of 0.023 and a mean difference of -0.003, which are not statistically significant as suggested by the p-values of 0.419 and 0.558.

Furthermore, the Repeatability Coefficient (RPC) of 0.046 and a coefficient of variation (CV) of 0.063 reinforce the low variability and high repeatability of the measurements. The distribution of the differences is almost symmetric and concentrated around the mean, with a kurtosis of 2.70 and a skewness of -0.028. These results suggest that both devices can be interchangeably used for the measurement of body temperature, with adequate fit and consistent precision.

4.2.1.2 Respiration rate

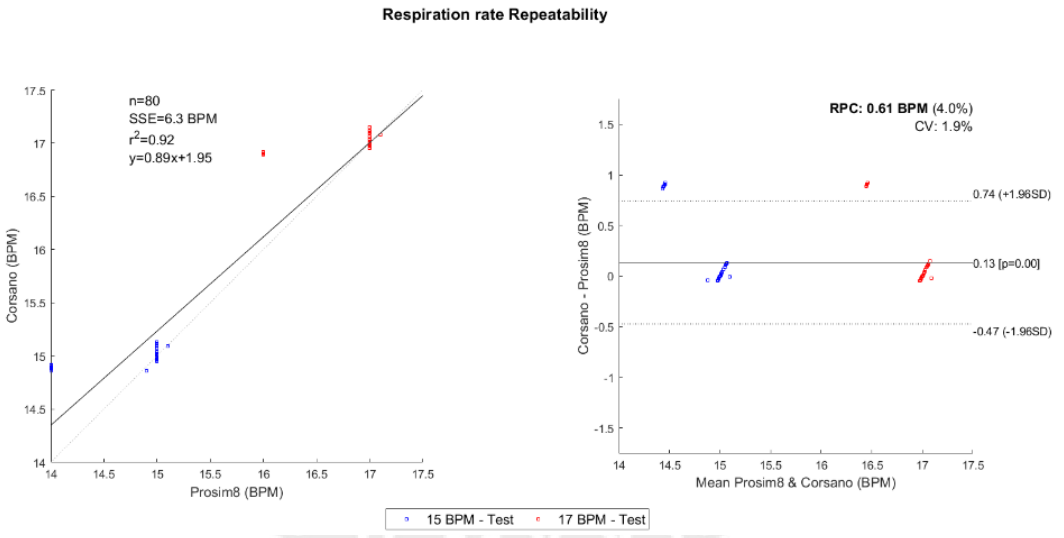


Figure 4.5: Regression and Bland-Altman Analysis Graphs for Respiration Rate Measurement

In the previous results, the statistical analysis of respiration rate measurements in breaths per minute (bpm) shows a very strong correlation between the devices tested, with a Pearson correlation coefficient of 0.960 and a coefficient of determination (R^2) of 0.922. This indicates that about 92.25% of the variability in the measurements of one device is explained by the other, suggesting excellent predictability and reliability.

The polynomial regression model with a slope of 0.8857 and an intercept of 1.947 fits the data well, with a Root Mean Square Error (RMSE) of 0.284, indicating a tight fit. Bland-Altman

analysis shows a standard deviation of differences at 0.3093, with a mean difference of 0.134, which is statistically significant $p = 2.16 \times 10^{-4}$. The Repeatability Coefficient (RPC) is 0.606, indicating that the maximum expected difference between repeated measurements under identical conditions is reasonable for clinical settings. Overall, these results suggest that the devices are generally consistent and reliable for measuring respiration rates

4.2.1.3 Oxygen levels in the blood - SpO_2

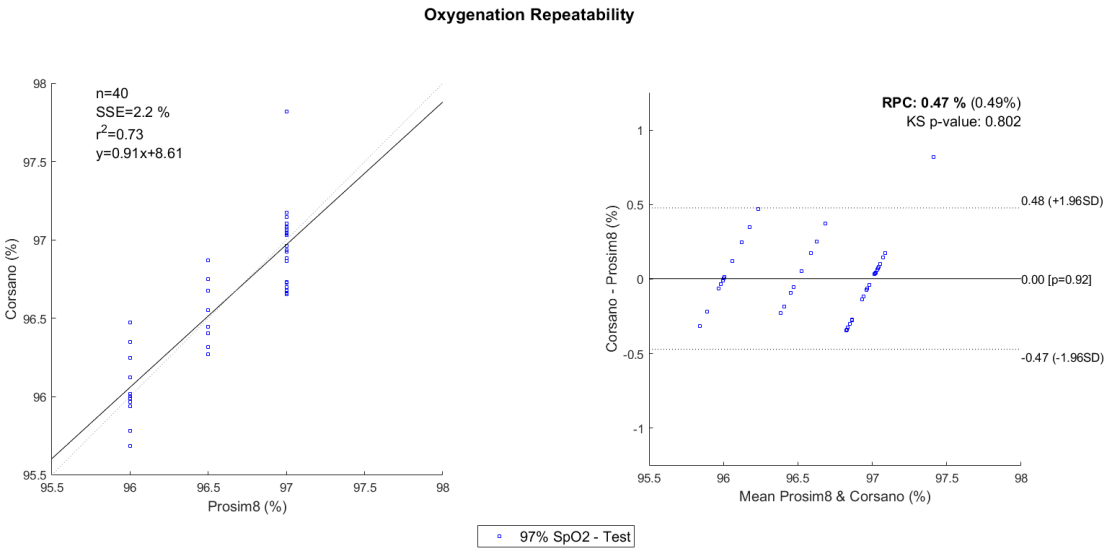


Figure 4.6: Regression and Bland-Altman Analysis Graphs for SpO_2 Measurement

The statistical analysis of the blood oxygenation (SpO_2) measurements reveals a robust agreement and consistency among the devices used in the study. The Pearson correlation coefficient is 0.856, and the coefficient of determination is 0.7337, indicating a strong correlation whereby approximately 73.37% of the variability in the measurements of one device is explained by the other. The polynomial regression model with coefficients of 0.910 for the slope and 8.6131 for the intercept shows a good fit to the data. The differences between the devices are minimal with a standard deviation of 0.2418 for the differences, a mean difference of 3×10^{-3}, and a median difference of -25×10^{-4}, with p-values of 0.924 and 0.814, respectively, indicating that these small differences are not statistically significant.

Moreover, the Repeatability Coefficient (RPC) of 0.473 and a coefficient of variation (CV) of 0.250 underscore the low variability and acceptable repeatability of the measurements. The distribution of the differences is not perfectly symmetric but shows a right skewness (0.960) and a higher peak than a normal distribution (kurtosis of 4.698). These statistical findings suggest that the different devices used for measuring SpO_2 are comparable and can be used interchangeably

with adequate accuracy and consistency.

Table 4.1: Summary of the Bland-Altman experiments conducted

Vital Sign	Pearson r	Determination (R^2)	Mean Difference	Median Difference
Body temperature	0.895	0.802	-0.003	0.00
Respiration rate	0.857	0.734	0.004	-0.003
SpO2	0.961	0.923	0.134	0.010

Source: Author's Own

This table consolidates the key Bland-Altman statistics across the previous tests, providing a clear view of the correlation, differences, and variability metrics that are central to assessing the comparability of measurement devices in these studies.The code used can be found in Appendix 3.1.

4.2.2 Wavelet Transform Analysis of ECG Waveforms

As demonstrated in Chapters 2 and 3, a PCB is designed to ensure the same ECG waveform is maintained. Additionally, the experimental setup was presented in Chapter 2. This setup ensures that the Corsano wearable receives the same ECG waveform that the reference device is generating, which facilitates the comparative analysis between the two. Both waveforms must be saved for analysis in the Matlab tool, and the generated file must be converted to a .csv or .mat format for further analysis. To this end, it should also be considered that the Corsano has a sampling frequency of 256 Hz, which assists in processing the data from the number of measurements and converting it into a time vector.

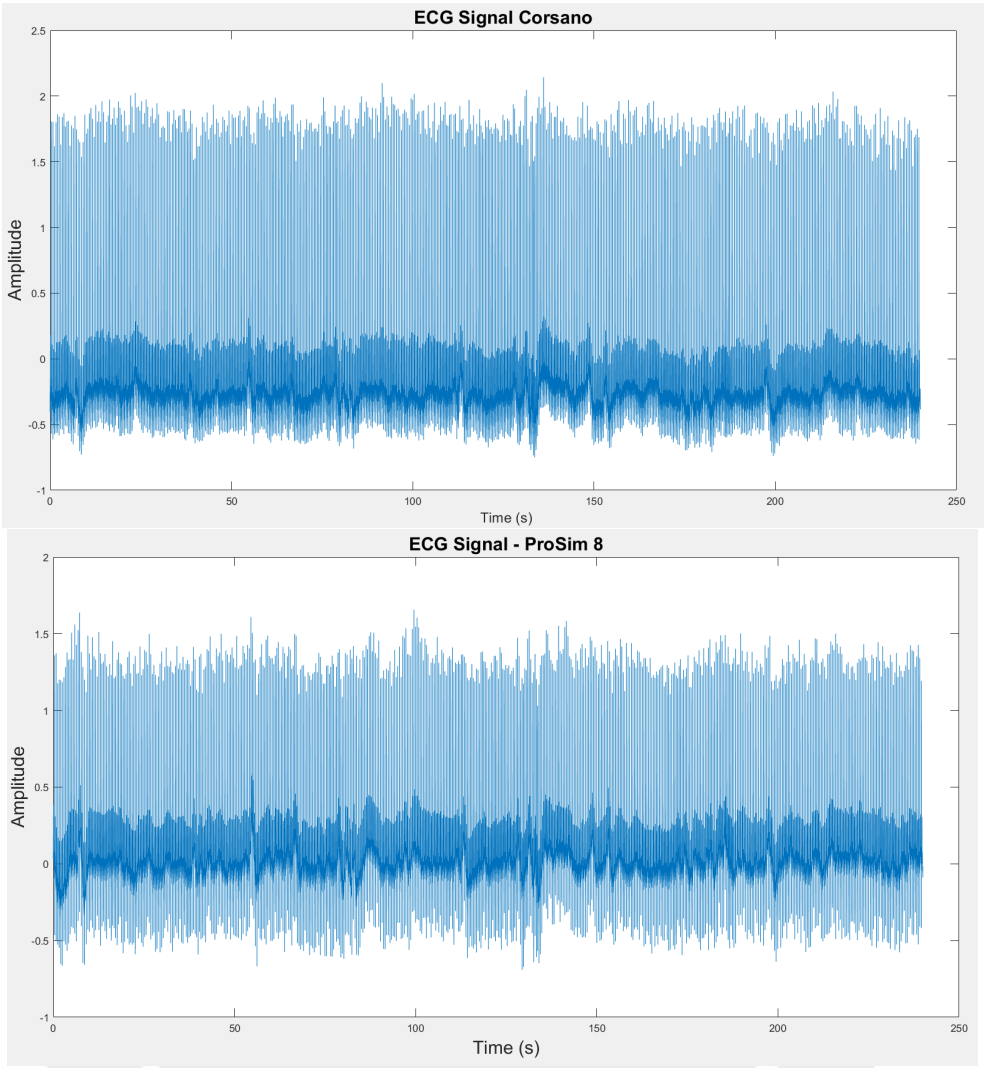


Figure 4.7: ECG signals acquired - Raw data

Figure 4.7 illustrates the acquired ECG waveforms, the data has been collected up to the 4th minute, given the software limitations that allow the Corsano to store ECG readings. Therefore, the data collected up to the 240th second has been saved for analysis. Additionally, the signal amplitude is shown in the figure. To perform a correlative comparison between the results from the Corsano test equipment and the ProSim8 reference device, a preprocessing procedure and QRS complex detection are carried out, which are the main focus when analyzing an ECG. For this purpose, the signal is decomposed at level 5 by the Maximal Overlap Discrete Wavelet Transform (MODWT). This is done in order to capture events that occur approximately in the frequency range of [5.625 to 11.25] Hz.

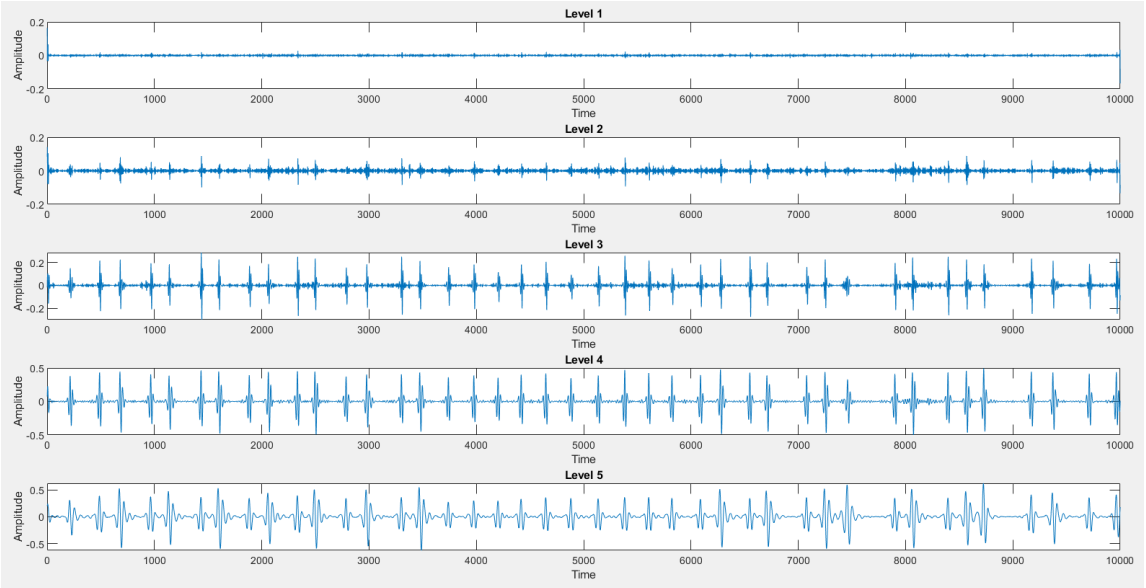


Figure 4.8: Wavelet descomposition - ProSim8 ECG Signal

Figure 4.8 shows the decomposition of the ECG waveform from the ProSim8, allowing us to appreciate the information provided at each level by the frequency range it covers. This is done to capture the study information, reduce noise, and analyze signal patterns. After the wavelet decomposition, the signal is reconstructed at levels 4 and 5, as it provides a relevant version of physiological signal information in the frequency range [11.25, 22.5] Hz

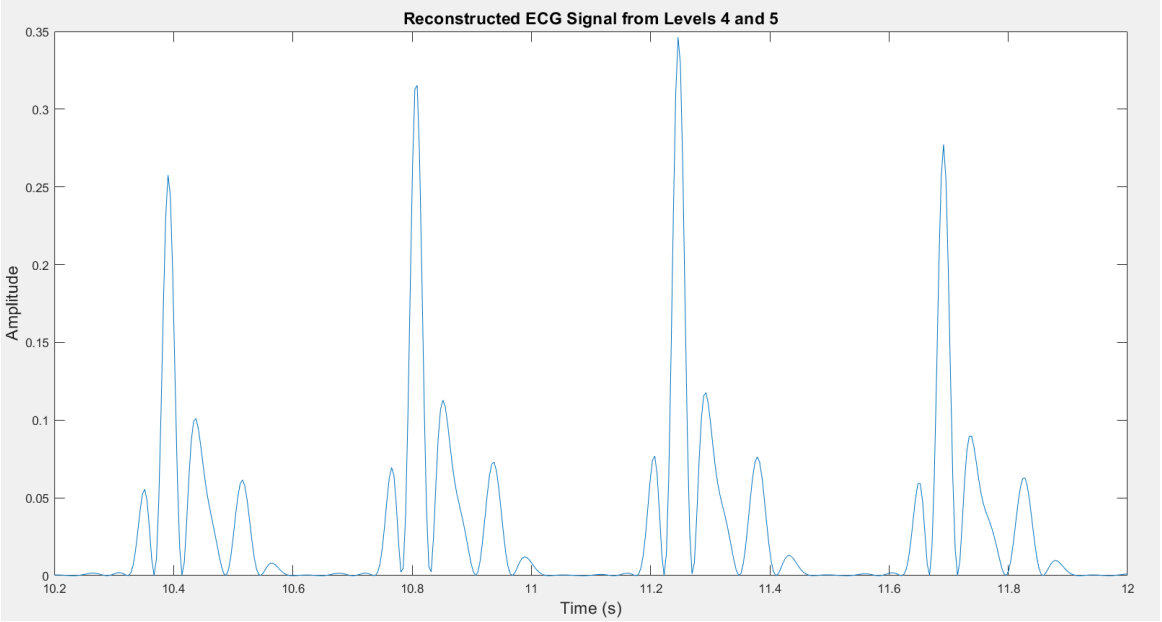


Figure 4.9: Wavelet reconstruction - ProSim8 ECG Signal

Figure 4.9 plots the reconstruction of the ECG waveform at a localized frequency. This is done in order to capture the detail of the QRS complexes, meaning the band that maximizes the energy

of the complex is selected. This was done using the inverse MODWT and the ”sym4” wavelet. MODWT is used for its protection against aliasing and edge effects, to retain the most important information.

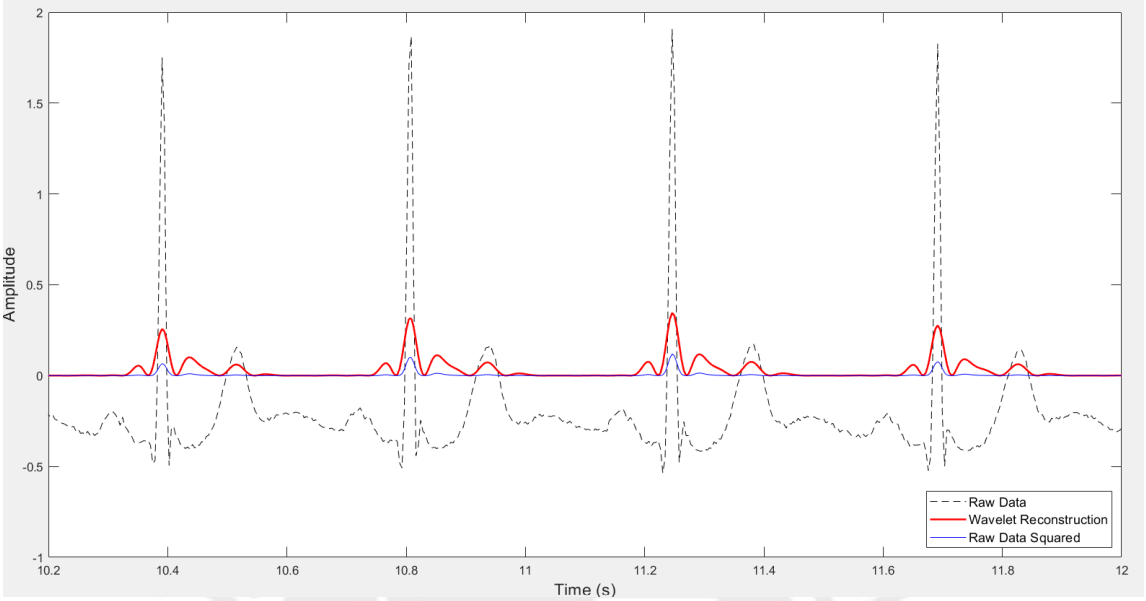


Figure 4.10: ECG Comparison - ProSim8 ECG Signal

The comparison of the reconstruction of the original signal is presented in Figure 4.10, to show that the reconstruction has successfully isolated the QRS complex for analysis. The result is due to the selected frequency band range for the reconstruction. This procedure is applied to both signals (ProSim8 signal and Corsano signal).

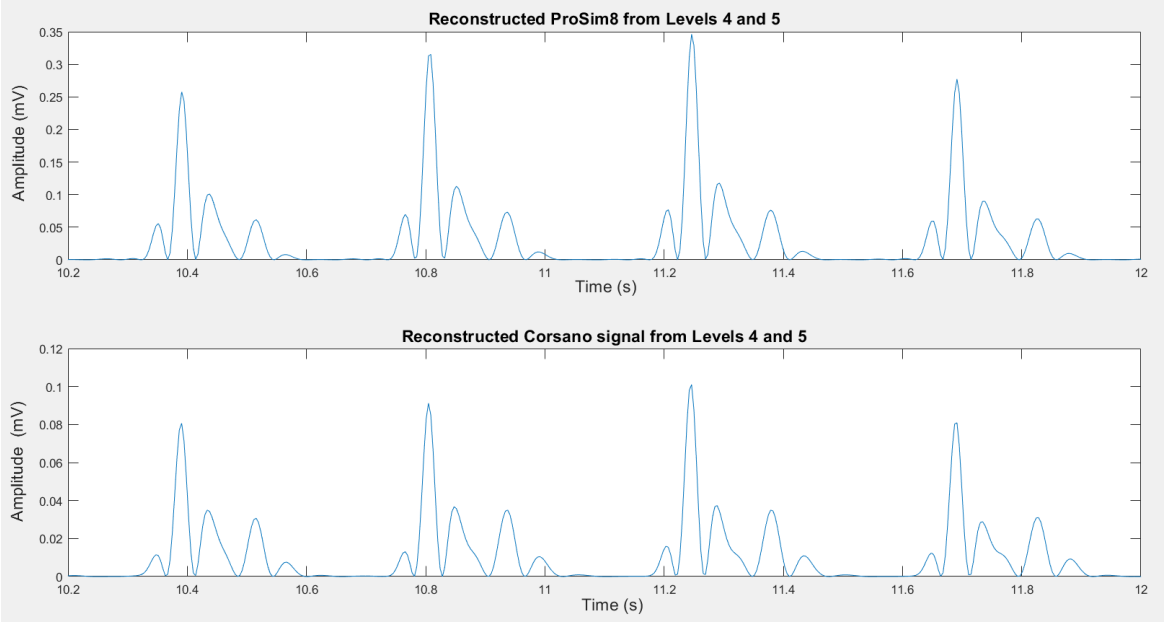


Figure 4.11: Comparison of Waves Reconstructed by Inverse MODWT

After the reconstruction of both waves, as part of the visual analysis, Figure 4.11 is plotted to demonstrate the similarity between the two waves after isolating the information of interest in both ECG waves. To obtain objective results, a correlation analysis will be performed between the signals, similar to what is done in the Bland-Altman analysis, to evaluate the consistency of the results over time. However, when analyzing ECG waves, which are non-stationary waves, it is necessary to perform a similarity analysis in the frequency domain.

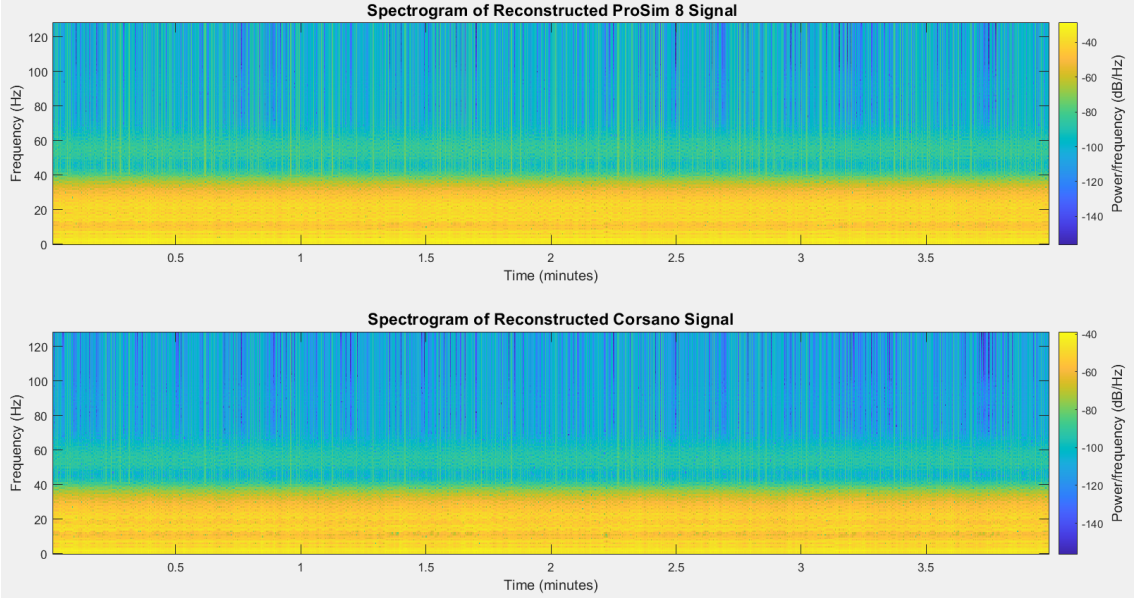


Figure 4.12: Comparison of Spectrum Between Signals

A similar energy distribution can be observed in both spectrograms in Figure 4.11. For more quantitative results, the frequency spectrum correlation between both signals will be calculated. These results will be presented along with the signal correlation results in the same table.

Table 4.2: Correlation Results Between Reconstructed ECG Waves (ProSim 8 vs Corsano)

Signals Correlation	MSE	MAD	Standard Deviation	Frequency Spectra Correlation
0.959	2.324×10^{-3}	0.022	0.042	0.992

Source: Author's Own

The results of the comparison between two reconstructed ECG waves indicate a high degree of similarity and accuracy between the signals. The Mean Absolute Difference (MAD) of 0.0226 suggests that, on average, the absolute differences between the amplitudes of the two signals are small, indicating good point-by-point agreement. The Mean Squared Error (MSE) of 2.324×10^{-3} quantifies the average squared difference between the signals, showing that the discrepancies are very small, which is indicative of high precision in the reconstruction. The Pearson Correlation Coefficient of 0.959 reflects a strong linear relationship between the two

signals, meaning that the waveforms are very similar in terms of their joint variation. Finally, the Frequency Spectrum Correlation of 0.992 reveals that the two signals have extremely similar frequency distributions, ensuring that important spectral characteristics of the ECG are well preserved in both reconstructions. Taken together, these results demonstrate that the reconstructed signals capture the relevant physiological information very accurately and consistently. The main difference is that the energy of the ECG signal reconstruction from the ProSim8 is 270.649 mV^2, whereas from the Corsano signal it is 22.108 mV^2. However, the statistical values, mainly the correlation, indicate that the information in the reconstructed signal is maintained. The code used can be found in Appendix 3.2.

Conclusion

As a result of the research, it has been possible to comprehensively identify the technological risks faced by the network of clinics (NC) when attempting to meet the telemedicine needs of their patients. This investigative process has been crucial for the technological proposal aimed at mitigating these risks to ensure the quality and efficiency of the processes that patients undergo when receiving care using telemedicine. After assessing the technological risks through analysis of in site interviews to medical specialists, the vital signs where identified as their main concern when following up patients remotely.

The assessment suggested that monitoring to minimize measurement errors in wearable devices will mitigate the risks and concerns during implementation of telemedicine services. This information provided with the requirements to design and implement a flexible solution that can adapt to be uses with any wearable device and facilitate connectivity with calibrated equipment to evaluate accuracy. This work includes the design of an electronic board to adapt ECG signals and enable their analysis, with a notch filter for current interference (60 Hz), a high-pass filter to eliminate low-frequency components (0.005 Hz) that distort the baseline, and finally, a low-pass filter to eliminate high-frequency components (100 Hz) to isolate the relevant information from the signal.

When validating the viability of the proposed solution using as a case study the Corsano brand CardioWatch 2B commercial wearable device, it can be asserted that it maintains adequate accuracy for measuring the evaluated vital signs, achieving a high correlation (Pearson $r > 0.89$ for temperature) and a high coefficient of determination ($r > 0.80$ for temperature, $r > 0.92$for respiration, and $r > 0.73$ for oxygenation), indicating that the device under test is very much in alignment with the standard equipment in terms of measurement. When measuring ECG signals, a very high correlation of 0.959 indicates that it retains the information of interest for analyzing QRS complexes of the heart. Since the data are consistent and the evaluations are predictable, the tests performed . Therefore, the implemented solution successfully addresses the technological risks perceived by the medical specialists in the context of telemedicine services of a NC.

Recommendations

The information collected within the NC has provided a valuable contribution to the evaluation of telemedicine services in Peru, considering that there is still no control over the measurement equipment used by patients themselves in these types of services. It is hoped that the knowledge generated and the prototype designed will raise awareness about the importance of evaluating risks prior to implementing new devices for remote vital signs measurement.

The work carried out is expected to influence decision-making for the commercial launch of such services. Moreover, the risks identified can be seen as opportunities for innovation to generate improved prototypes to mitigate the risks of using wearables in telemedicine, and with the participation of end-users and patients as stakeholders to test these technologies that are already being implemented worldwide in the health sector.

Furthermore, the entire process of information collection, processing to identify risks, and the design of a solution prototype aimed at mitigating them has been consequential for the results obtained, and encourage future research in the health sector from the perspective of promoting the use of new technologies.

Despite the technical efforts made, there were economic limitations during the design process regarding the type of power supply to use, since depending on this, it may or may not induce line interference. Furthermore, it is recommended to use medical-grade ECG cables due to the noise protection they offer when making connections.

For a rigorous design, a noise analysis of the circuit should be conducted, taking into account white noise. Additionally, if a function structure similar to the one implemented is used, the phase shift caused by line delay when amplifying signals from each electrode separately must be analyzed.

Bibliography

[1] TytoCare, *TytoHome General Operation User Guide for Consumer v3.2*. mTelehealth™, 2018, [Online]. Available: https://mtelehealth.com/wp-content/uploads/2019/06/Document-760-00066-B01-TytoHome-General-Operation-User-Guide-for-Consumer-v3.2-2018-12-01.pdf.[Accessed: 20-May-2025].

[2] MedWand, "Consumer electronics show conference exhibitor success story: MedWand," Consumer Electronics Show, 2023, conference presentation.

[3] Fitbit, "Fitbit sense 2, product description," 2021, [Online]. Available: https://www.fitbit.com/global/es/products/smartwatches/sense2. [Accessed: 20-May-2025].

[4] A. Benedek and K. Nyíri, *Visual Learning: A Year After Visual Learning Lab Papers*, 08 2019, iSSN 2498-7441.

[5] D. Kalogeropoulos, "Adapted figure based on levesque, jf. harris, m.f. russell health care research," 2023, research paper.

[6] P. Teo, "How to create patient journey mapping for superior healthcare experiences," 2022, [Online]. Available:https://www.keyreply.com/blog/patient-journey-mapping. [Accessed: 20-May-2025].

[7] Corsano Health B.V., *Corsano CardioWatch 287-2 Bracelet & Corsano App Instruction Manual*, Corsano Health B.V., 2023.

[8] A. B. Cañizares, M. G. González, and V. F. Mileo, "Design, development, and test of a wristband prototype to record the electrocardiogram and pulse wave," 2016, universidad Politécnica de Cataluña. Technical Report.

[9] S. Savalia and V. Emamian, "Cardiac arrhythmia classification by multi-layer perceptron and convolutional neural network," *Journal of Medical Imaging and Health Informatics*, vol. 9, no. 8, pp. 1649–1655, 2019, doi: 10.1166/jmihi.2019.2790.

[10] MathWorks, “R-wave detection in the ecg,” [Online]. Available: https://la.mathworks.com/help/wavelet/ug/r-wave-detection-in-the-ecg.html. [Accessed: 20-May-2025].

[11] B. W. Hasselfeld, “Benefits of telemedicine,” Johns Hopkins Medicine, 2021, [Online]. Available: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/benefits-of-telemedicine. [Accessed: 20-May-2025].

[12] Ministerio de Salud, “Personal de salud atendió más de seis mil teleconsultas a nivel nacional durante 2019,” 2020, [Online]. Available: https://www.gob.pe/institucion/minsa/noticias/78096-personal-de-salud-atendio-mas-de-seis-mil-teleconsultas-a-nivel-nacional-durante-2019. [Accessed: 20-May-2025].

[13] Pan American Health Organization, *eHealth Conversations: Using Information Management, Dialogue and Knowledge Exchange to Move Towards Universal Health Coverage*. PAHO, 2016, [Online]. Available: https://iris.paho.org/handle/10665.2/28510. [Accessed: 20-May-2025].

[14] W. H. Curioso, P. J. García *et al.*, “Reforzando las capacidades en investigación en informática para la salud global en la región andina a través de la colaboración internacional,” *Revista Peruana de Medicina Experimental y Salud Pública*, vol. 27, no. 3, p. 449–457, doi: 10.1590/s1726-46342010000300020, 2010.

[15] A. Calderón, “Perú digital. el camino hacia la transformación,” 2021, [Online]. Available: https://faculty.up.edu.pe/en/publications/per%C3%BA-digital-el-camino-hacia-la-transformaci%C3%B3n. [Accessed: 20-May-2025].

[16] Congreso de la República del Perú, “Ley N° 30421, Ley Marco De Telesalud - MINSA,” 2016, [Online]. Available: https://cdn.www.gob.pe/uploads/document/file/3389780/Reglamento%20de%20la%20Ley%20N%C2%B0%2030421%2C%20Ley%20marco%20de%20Telesalud.pdf. [Accessed: 20-May-2025].

[17] ComexPerú, “Rumbo al bicentenario: Recursos humanos de salud,” 2023, [Online]. Available: https://www.comexperu.org.pe/articulo/rumbo-al-bicentenario-recursos-humanos-de-salud. [Accessed: 20-May-2025].

[18] MINSA, “Reporte: Población asignada por establecimientos de salud minsa,” Ministerio de Salud del Perú (MINSA), informe técnico, 2023.

[19] E. Espinoza-Portilla, W. Gil-Quevedo, and E. Agurto-Távora, "Principales problemas en la gestión de establecimientos de salud en el perú," *Revista Cubana de Salud Pública*, vol. 46, p. e2146, 2021.

[20] M. Sausa. (2018) Situación de la salud en perú: Ineficiencias del sector afectando a millones de peruanos. Perú21. [Online]. Available: https://peru21.pe/peru/situacion-salud-peru-ineficiencias-sector-afectando-millones-peruanos-396225-noticia/. [Accessed: 20-May-2025].

[21] C. Zeballos-Palacios, O. Morey-Vargas, J. Brito, and V. Montori, "Toma de decisiones compartidas y medicina mínimamente impertinente en el manejo de las enfermedades crónicas," *Revista Peruana de Medicina Experimental y Salud Pública*, vol. 31, no. 1, pp. 111–117, Jan. 2014, [Online]. Available: http://www.scielo.org.pe/scielo.php?script=sci_arttext&pid=S1726-46342014000100016&nrm=iso. [Accessed: 20-May-2025].

[22] J. A. Oliva, "Adaptación de los centros de atención primaria a la virtualidad," *Atención Primaria Práctica*, vol. 3, 2021, doi: 10.1016/j.aprimpr.2021.100119.

[23] M. Martínez-García, M. Bal-Alvarado, and M. Guerra, "Telemedicina con telemonitorización en el seguimiento de pacientes con covid-19," *Revista Clínica Española*, vol. 220, no. 8, pp. 472–479, 2020, doi: 10.1016/j.rce.2020.05.005.

[24] U.S. Food and Drug Administration, "Document number: K221614," 2019, [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221614. [Accessed: 20-May-2025].

[25] MedWand, "Medwand user manual," 2022, [Online]. Available: https://support.medwand.com/portal/en/kb/articles/medwand-device-user-manuals.[Accessed: 20-May-2025].

[26] U.S. Food and Drug Administration, "Document number: K212975," 2011, [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212975. [Accessed: 20-May-2025].

[27] Congreso de la República del Perú, "Resolución Ministerial N.° 546-2011-MINSA," 2022, [Online]. Available: https://www.gob.pe/institucion/minsa/normas-legales/243402-546-2011-minsa. [Accessed: 20-May-2025].

[28] Fitbit, *Fitbit Sense User Manual v2*. MedWand Solutions, 2021, [Online]. Available: https://www.manua.ls/fitbit/sense-2/manual.[Accessed: 20-May-2025].

[29] L. M. Feehan, J. Geldman, E. C. Sayre *et al.*, "Accuracy of fitbit devices: systematic review and narrative syntheses of quantitative data," *JMIR mHealth and uHealth*, vol. 6, no. 8, p. e10527, 2018, doi: 10.2196/10527.

[30] D. Cho, V. Kadiyala, and A. Huang, "At the crossroads! time to start taking smartwatches seriously," *The American Journal of Cardiology*, vol. 179, pp. 96–101, 2022, [Online]. Available: https://www.sciencedirect.com/science/article/pii/S0002914922006543. [Accessed: 20-May-2025].

[31] Congreso de la República del Perú, "Decreto Legislativo N° 1490," [Online], 2020, [Online]. Available: https://www.gob.pe/institucion/presidencia/normas-legales/575965-149. [Accessed: 20-May-2025].

[32] ——, "Decreto Supremo N° 003-2013-JUS," 2020, [Online]. Available: https://www.gob.pe/institucion/minjus/normas-legales/1941246-003-2013-jus. [Accessed: 20-May-2025].

[33] ——, "Resolucion ministerial 117-2020," 2020, [Online]. Available: https://www.gob.pe/institucion/minsa/normas-legales/462720-117-2020-minsa. [Accessed: 20-May-2025].

[34] ——, "Resolucion ministerial 116-2020," 2020, [Online]. Available: https://busquedas.elperuano.pe/dispositivo/NL/1869114-1. [Accessed: 20-May-2025].

[35] ——, "Norma Técnica de Salud en Telesalud," 2009, [Online]. Available: https://www.gob.pe/institucion/minsa/informes-publicaciones/321987-norma-tecnica-de-salud-en-telesalud-nts-n-067-minsa-dgsp-v-01. [Accessed: 20-May-2025].

[36] ——, "Ley de proteccion de datos personales N° 29733," 2011, [Online]. Available: http://sistemas3.minjus.gob.pe/transparencia2/directiva-de-seguridad.pdf. [Accessed: 20-May-2025].

[37] J. A. M. Canelo, M. A. Sardá, and H. I. de Sena, "Metodología de investigación en salud laboral," *Medicina y Seguridad del Trabajo*, vol. 56, pp. 347–365, Dec. 2010, [Online]. Available:http://scielo.isciii.es/scielo.php?script=sci_arttext&pid=S0465-546X2010000400009&nrm=iso. [Accessed: 20-May-2025].

[38] A. Kester and Y. Kurata, "Factors influencing the acceptance of telemedicine in the Philippines," *Technology in Society*, vol. 70, p. 102040, 2022, doi: 10.1016/j.techsoc.2022.102040.

[39] T. Brown and J. Wyatt, “Design thinking for social innovation,” *Stanford Social Innovation Review*, vol. 8, no. 1, pp. 31–35, 2009, doi: 10.48558/58Z7-3J85.

[40] E. Han, *What is Design Thinking & Why is it Important?* Boston, MA: Harvard Business School Online, 2022, [Online]. Available: https://online.stanford.edu/what-design-thinking-and-why-should-i-care [Accessed: 20-May-2025].

[41] J.-F. Levesque, M. F. Harris *et al.*, “Patient-centred access to health care: conceptualising access at the interface of health systems and populations,” *International Journal for Equity in Health*, vol. 12, no. 1, p. 18, 2013, [Online]. Available: http://dx.doi.org/10.1186/1475-9276-12-18. [Accessed: 20-May-2025].

[42] M. R. Feras Mahdi, “Customer journey mapping: a great place to start your digital transformation,” 2021, [Online]. Available:https://www.iqvia.com/locations/asia-pacific/blogs/2021/10/customer-journey-mapping-a-great-place-to-start-your-digital-transformation. [Accessed: 20-May-2025].

[43] M. Arias, E. Rojas, S. Aguirre, A. Muñoz-Gama, M. Sepúlveda, and D. Capurro, “Mapping the patient’s journey in healthcare through process mining,” *International Journal of Environmental Research and Public Health*, vol. 17, no. 18, p. 6586, 2020, doi: 10.3390/ijerph17186586.

[44] S. Hajesmaeel-Gohari and K. Bahaadinbeigy, “The most used questionnaires for evaluating telemedicine services,” *BMC Medical Informatics and Decision Making*, vol. 21, p. 36, 2021, doi: 10.1186/s12911-021-01407-1.

[45] M. P. Yip, A. M. Chang, J. Chan, and A. E. MacKenzie, “Development of the telemedicine satisfaction questionnaire to evaluate patient satisfaction with telemedicine: a preliminary study,” *Journal of Telemedicine and Telecare*, vol. 9, no. 1, pp. 46–50, 2003, doi: 10.1258/135763303321159693.

[46] M. S. Hundal, “A systematic method for developing function structures, solutions and concept variants,” *Mechanism and Machine Theory*, vol. 25, pp. 243–256, 1990.

[47] D. Rakov, “Advantages and disadvantages of morphological methods in engineering,” *MATEC Web of Conferences*, vol. 329, p. 03028, 2020, doi: 10.1051/matecconf/202032903028.

[48] Y. Geum and Y. Park, "How to generate creative ideas for innovation: a hybrid approach of wordnet and morphological analysis," *Technological Forecasting and Social Change*, vol. 111, pp. 176–187, 2016, doi: 10.1016/j.techfore.2016.06.026.

[49] Fluke Medical, "Prosim 8 vital signs simulator – manual de funcionamiento básico," 2016, pN 3984515.

[50] A. E. Curtin, K. V. Burns, A. J. Bank, and T. I. Netoff, "Qrs complex detection and measurement algorithms for multichannel ecgs in cardiac resynchronization therapy patients," *IEEE Journal of Translational Engineering in Health and Medicine*, 2018.

[51] C. Rodríguez-Díaz, M. A. Gurrola-Navarro, and R. Romo-Vázquez, "Detección de ondas qrs del ecg usando la transformada wavelet analógica," *Pistas Educativas*, 2014.

[52] N. García, "Uso de la transformada wavelet para detección de complejo qrs en electrocardiogramas," *Universidad Nacional del Sur.*, 2014, tesis de bachiller.

[53] J. L. Carrasco and L. Jover, "Métodos estadísticos para evaluar la concordancia," *Medicina Clínica*, vol. 122, pp. 28–34, 2004.

Appendix

Appendix 1: Github repository link

The link to the repository of documentation for this research: https://github.com/Alvarin201/Proyecto-de-Tesis/tree/main

Appendix 1.1: Informed consent protocol for surveys

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/main/Protocolo-de-consentimiento-informado-para-encuestas.pdf

Appendix 1.2: Informed consent protocol for interviews

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/main/Protocolo-de-consentimiento-informado-para-entrevistas.pdf

Appendix 1.3: TSQ - Telemedicine Satisfaction Questionnaire

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/main/TSQ%20-%20Telemedicine%20Satisfaction%20Questionnaire%20%20.pdf

Appendix 1.4: Role of questions

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/main/Rol%20de%20preguntas%20-%20Tesis.pdf

Appendix 2: Prototype documentation

The link to the repository of documentation for this research: https://github.com/Alvarin201/Proyecto-de-Tesis/tree/main

Appendix 2.1: Assembly drawings

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/6ed175a0141c774ee0af753593f6df2d22d2d088/Ensamble%20Dibujo%20v1.pdf

Appendix 2.2: Electronic board schematic design

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/main/Dise%C3%B1o%20esquematico.pdf

Appendix 3: Matlab Code

The link to the repository of documentation for this research: https://github.com/Alvarin201/Proyecto-de-Tesis/tree/main

Appendix 3.1: Bland Altman analysis

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/3c186ffad1a56840854814b2efec3203ebe99f5d/Bland%20Altman%20code.zip

Appendix 3.2: ECG processing

https://github.com/Alvarin201/Proyecto-de-Tesis/blob/6037794e31d7533704761b3e277df9284c3cb77e/ECG%20Code.zip

Appendix 4: Corsano App - Android project

The link to the repository of documentation for this research: https://github.com/Alvarin201/Corsano-Code/tree/main