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Facultad de Ingeniería y Ciencias

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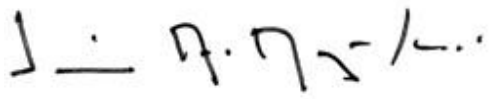
Director: Jaime Alberto Aguilar Zambrano

Como indica el artículo 2.27 de las Directrices de Trabajo de Grado, he verificado que los estudiantes indicados arriba han implementado todas las correcciones que los Jurados del Proyecto de Grado definieron que se efectuaran, como consta en el Acta de Calificación correspondiente.



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Pontificia Universidad Javeriana Cali
Faculty of Engineering and Sciences
Department of Electronics and Computer Sciences
Electronic Engineering
Bachelor's Dissertation

Design and implementation of an electronic system to monitor lung re-expansion physiotherapy processes

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February 3, 2023

Pontificia Universidad
JAVERIANA
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Santiago de Cali, Diciembre 4 de 2022.

Señores
Pontificia Universidad Javeriana Cali.
Dr. Luis Eduardo Tobón Llano
Director Carrera de Ingeniería Electrónica.
Santiago de Cali.

Cordial Saludo,

Por medio de la presente me permito informarle que los estudiantes del programa de Ingeniería Electrónica Julián Andrés Hernández Potes (cod:8935552) y Diana Carolina Sánchez Rengifo (cod:8935387) trabajaron bajo nuestra dirección en el trabajo de grado titulado "Design and implementation of an electronic system to monitor lung re-expansion physiotherapy processes".

Atentamente,

Ph.D. Jaime Alberto Aguilar-Zambrano

M.Sc. Manuel Vicente Valencia Díaz

Santiago de Cali, Diciembre 4 de 2022.

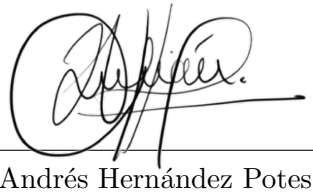
Señores
Pontificia Universidad Javeriana Cali.
Dr. Luis Eduardo Tobón Llano
Director Carrera de Ingeniería Electrónica.
Santiago de Cali.

Cordial Saludo,

Nos permitimos presentarles el trabajo de grado titulado "Design and implementation of an electronic system to monitor lung re-expansion physiotherapy processes" con el fin de optar al título de Ingeniero/a Electrónico/a. Esperamos que este trabajo no solo cumpla con todos los requisitos académicos, sino que también sirva de apoyo para el desarrollo de futuros trabajos.

Al firmar aquí, atestiguamos que entendemos y conocemos las directrices para trabajos de grado de pregrado de la Facultad de Ingeniería y Ciencias, aprobadas el 26 de Noviembre de 2009, en donde se establecen los plazos y normas para la presentación del trabajo de grado.

Atentamente,



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- Julián Andrés Hernández Potes.

A distinctive thanks to my mother Diana Rengifo, my father Harold Sanchez and my sisters Nathalia and Isabella for all their support and unconditional love throughout the development of this Bachelor's Dissertation. This is another achievement of a life project that we have built together.
- Diana Carolina Sánchez Rengifo.

Abstract

For the 2020-2021 biennium, cardiopulmonary diseases ranked third in the group of the first five causes of mortality in Colombia, a figure that is even more overwhelming when it comes to COVID-19 infection solely [1]. Bearing this in mind, it can be stated that the number of people suffering from these diseases and/or the sequelae they leave is considerable, often requiring respiratory physiotherapy processes to cope with their recovery. In this regard, physiotherapy plays an important and decisive role in the life of each patient who suffers the aftermath of diseases, making it imperative to develop alternatives to accompany these processes.

Currently in Colombia, the support devices for the accompaniment of physiotherapies do not provide sufficient information regarding the physiological variables involved in the recovery process of the patient. With all this said, this Bachelor's Dissertation will address the design and implementation of an electronic system capable of monitoring and accompanying the recovery process of patients in pulmonary re-expansion physiotherapy, one of the most important physiotherapy classes for the functional recovery of the respiratory system. Consequently, the inventive methodologies TRIZ and Design Thinking will be used, which will provide a guiding path towards the systemic and integral analysis of the project, as well as a gradual approach towards innovative solutions focused on the needs of patients and physiotherapists. The convergence of the implementations carried out throughout the course of the project will be supported by the application of the Axiomatic Design and the determination of value criteria suggested by the AHP decision-making technique.

Meanwhile, the implementation and results were mostly developed in three fundamental phases: the first one deals with the approach of a respiratory flow monitoring system through the NI LabVIEW graphical interface which, although not focused on the precise measurement of the physiological variable, provided a receptive environment with which the first impressions of the project were obtained; the second one corresponds to the implementation of the final prototype of the project through a microcontrolled system, with which it is possible to acquire and process the respiratory flow, and determine the volume and respiratory frequency; the third one covers the acquisition modeling of the respiratory flow through the differential pressure principle in Orifice Plate sensors, which is based essentially on the ISO 5167 standard and subsequent adaptations to make it viable in medical spirometry applications.

This local project is part of the research project *Respiratory incentive system for lung re-expansion in patients with sequelae of COVID-19*, and is mainly focused on the development of the electronic system.

Resumen

Para el bienio 2020-2021, las enfermedades cardiopulmonares ocuparon el tercer lugar en el grupo de las primeras cinco causas de mortalidad en Colombia [1], cifra que es aún más contundente cuando se trata solamente de la infección por COVID-19. Con esto en consideración, es posible aseverar que el número de personas que atraviesan por estas enfermedades y/o por las secuelas que dejan es considerable, necesitando a menudo de procesos de fisioterapia respiratoria para hacer frente a su recuperación. En este sentido, la fisioterapia entra a jugar un papel importante y decisivo en la vida de cada paciente que sufre las consecuencias posteriores a las enfermedades, haciendo imperante el desarrollo de alternativas que permitan acompañar estos procesos.

Actualmente en Colombia, los dispositivos de apoyo para el acompañamiento de las fisioterapias no proporcionan suficiente información al respecto de las variables fisiológicas envueltas en el proceso de recuperación del paciente. Con lo anterior en mente, en esta Disertación de Pregrado se abordará el diseño y la implementación de un sistema electrónico capaz de monitorear y acompañar el proceso de recuperación de los pacientes en fisioterapia de re-expansión pulmonar, una de las clases de fisioterapia más importantes para la recuperación funcional del sistema respiratorio. Consecuentemente, se hará uso de las metodologías inventivas TRIZ y Design Thinking, que brindarán un camino de guía hacia el análisis sistémico e integral del proyecto, así como un acercamiento paulatino hacia soluciones innovadoras centradas en las necesidades de los pacientes y fisioterapeutas. La convergencia de las implementaciones llevadas a cabo a lo largo del desarrollo del proyecto, serán soportadas en la aplicación del Diseño Axiomático y la determinación de criterios de valor sugeridos por la técnica de toma de decisiones AHP.

La implementación y la obtención de resultados se desarrolló mayoritariamente en tres fases fundamentales: la primera aborda la aproximación de un sistema de monitoreo del flujo respiratorio a través de la interfaz gráfica de NI LabVIEW que, aunque no estaba enfocada en la medición precisa de la variable fisiológica, brindó un ambiente receptivo con el que se obtuvieron las primeras impresiones del proyecto; la segunda, corresponde a la puesta en marcha de el prototipo final del proyecto a través de un sistema microcontrolado, con el que es posible adquirir y procesar el flujo respiratorio, y determinar el volúmen y frecuencia respiratoria; la tercera, abarca el modelado de la adquisición del flujo respiratorio a través del principio de presión diferencial en sensores de Placa de Orificio, el cual está basado fundamentalmente en la normativa ISO 5167 y posteriores adaptaciones para hacerlo viable en aplicaciones médicas de espirometría.

Este proyecto local hace parte del proyecto de investigación *Sistema incentivo respiratorio para re-expansión pulmonar en pacientes con secuelas de COVID-19*, y se centra funamentalmente en el desarrollo de el sistema electrónico.

Contents

List of Figures

List of Tables

List of Abbreviations

AFNOR Association Française de Normalisation

AHP Analytic Hierarchy Process

ASIC Application Specific Integrated Circuit

ASME American Society of Mechanical Engineers

COPD Chronic Obstructive Pulmonary Disease

CR Consistency Ratio

DAQ Data Acquisition

ERV Expiratory Reserve Volume

FEF Forced Expiratory Flow

FRC Functional Residual Capacity

FVC Forced Vital Capacity

IC Inspiratory Capacity

IRV Inspiratory Reserve Volume

ISO International Organization for Standardization

MBC Maximal Breathing Capacity

PEF Peak Expiratory Flow

RMSE Root Mean Square Error

RV Residual Volume

SVC Slow Vital Capacity

TLC Total Lung Capacity

TRIZ Theory of Inventive Problem Solving

TS Technical System

TV Tidal Volume

VC Vital Capacity

Chapter 1

Introduction

Reduced respiratory capacity is common after surgical procedures or diseases of the respiratory system that weaken or atrophy the muscles and organs responsible for carrying out the breathing process. To cope with the serious consequences caused by these conditions, it is necessary for the affected persons to start a proper rehabilitation process, so that later complications can be avoided and daily activities can be resumed. Nowadays, one of those rehabilitation processes consists of pulmonary re-expansion physiotherapies, in which the patient must go through a set of special exercises prescribed by the physiotherapist to recover his pulmonary functions. In Colombia, this type of physiotherapies are accompanied by the use of pneumatic equipment to monitor the pulmonary function of the patients. Nevertheless, there are several circumstances that compromise the real effectiveness of the equipment currently used in physiotherapy processes, which has increased the importance of innovation in the support of these processes, in order to make up for the deficiencies in information, handling and performance obtained with the current devices.

Along these lines, the timely recovery of the health of patients has posed enormous challenges to health systems, not only in Colombia, but throughout the world, among which stands out the promotion of an effective, well-monitored and adequately instructed treatment of the tasks to be performed in physiotherapies, resulting in a strong adherence by patients. Thereby, facing the recovery processes demands nowadays, among many aspects, an optimization of the monitoring and follow-up of the evolution of the patients in physiotherapy, which allows both, them and the physiotherapists, to have access to a greater detail in the variables and particular elements involved in each process and that cannot be reached with the current devices.

Accordingly, by inquiring into better technologies for monitoring patient progress, it is possible to have alternative platforms and/or equipment that will ensure favorable outcomes in the lives of patients with sequelae of lung disease. Thus, advances in portable monitoring and control technologies have a very high potential to address current problems in patient treatment.

Due to the prevailing situation presented, it became necessary to design, implement and validate a new instrumentation system to monitor patients with pulmonary sequelae in their physiotherapies, bearing in mind that the system will be involved in a gamification incentive environment (as part of the comprehensive research project and not the local project), as opposed to traditional devices, which will favor the functional recovery of patients, promoting patient adherence to physiotherapy exercises, which is also expected to reduce recovery times, facilitating early integration of the patient to their daily activities. Thus, this document will address the entire monitoring system design and implementation process.

1.1 Problem Statement

Along with the advent of respiratory diseases commonly come unavoidable sequelae in patients, even after overcoming the disease, which requires the effective application of physiotherapy processes for a timely recovery. Thereby, as a prominent example, in December 2019, an epidemic of pneumonia associated with the coronavirus (SARS-CoV-2) began in Wuhan (China), which was declared a pandemic by the WHO[1] on March 11, 2020. The high mortality of the viral infection is associated with the triggering of Severe Acute Respiratory Syndrome which is defined by an acute onset of non-cardiogenic pulmonary edema, hypoxemia, and the need for mechanical ventilation [2]. Approximately 30% of people who overcome COVID-19 are left with insufficient lung capacity requiring lung re-expansion physiotherapy [3]. Similarly, there are more examples for which it is imperative deepen the recovery of patients suffering from the sequelae of diseases affecting their respiratory system.

Current physiotherapy processes for lung re-expansion require the assistance of a physiotherapist in assessing the progress of the patient qualitatively and quantitatively, based on the performance of local physiotherapy. Nevertheless, the support equipment currently used in Colombia to assist these processes does not provide sufficient or accurate information to patients and physiotherapists, leading to the abandonment and poor performance of the exercises by patients and, consequently, to a deficient recovery.

In accordance with the foregoing and, considering that through a good handling of these physiotherapy processes it is possible to solvent many of the consequences caused by pulmonary diseases [4], the question of how to improve the performance of lung re-expansion physiotherapies from the perspective of support and measurement devices has been addressed. Hence, this open-ended question will be a basis for the orientation and development of the project.

1.2 Justification

Patients suffering from diseases that affect their respiratory system not only experience respiratory impairments, but also a deterioration of their physical capacity, leading to a loss of strength and, consequently, the inability to adequately exercise their muscles, which eventually implies a decrease in their quality of life [5]. Therefore, respiratory physiotherapy processes play an important role in the timely and effective recovery of patients, by deploying a compendium of special techniques that help the progressive wellness of patients undergoing sequelae of pulmonary diseases [4]. In turn, for the development of the physiotherapy techniques, special equipment is commonly needed to support the monitoring of patients under the supervision of a professional caregiver and to ensure their proper recovery. Nevertheless, the current challenging circumstances regarding the actual effectiveness of equipment for physiotherapy processes have increased the importance of looking for ways to substantially improve and support these processes, alleviating the burden of the disease for both patients and healthcare personnel.

The pandemic due to the new coronavirus disease, has brought negative consequences worldwide, causing millions of deaths and affecting the physical and mental health of the people [6].

[1] Acronym for World Health Organization.

In this regard, the coronavirus pandemic is a very recent case among many others where pulmonary diseases make it necessary to modify methods to counteract the sequelae in patients. As a matter of fact, the growth of respiratory diseases has increased the importance of new technologies capable of reliably monitoring recovery from lung failure.

Facing pulmonary diseases right now require an optimization of health systems that allow the provision of alternative platforms that ensure the monitoring and recovery of patients with sequelae, all this without the need to physically involve patients with health personnel or caregivers, allowing isolated interventions without high risk of contagion or with a chance of preventing worsening of the disease. Thus, advances in portable health monitoring and detection technologies have very high potential to address problems in the treatment of the variety of pulmonary disease after-effects.

With all this said, it is imperative to emphasize that most of the pulmonary sequelae need a timely and well-managed treatment, avoiding poor monitoring (which may be null) and inadequate instruction of the physiotherapy tasks/exercises to be performed. Thereby, increasing the use of better monitoring technologies, that may include telehealth features, will improve the evolution of the patients over time. Due to this prevailing situation, it becomes necessary to design, implement and afterwards validate an instrumentation system to monitor patients with pulmonary sequelae in their rehabilitation process, bearing in mind that the system shall be involved in a gamified/incentive environment as part of the associated research project *Respiratory incentive system for lung re-expansion in patients with sequelae of COVID-19*. Accordingly, unlike the devices traditionally used in Colombia, the system to be developed will seek to promote the functional recovery of patients with sequelae in their respiratory system due to pulmonary diseases, encouraging patient adherence to physiotherapy exercises and providing reliable information about the performance of the process to its users.

Chapter 2

Objectives

2.1 General Objective

Design, implement and validate an electronic instrumentation differential-pressure-based system to reliably monitor physiological variables in pulmonary re-expansion physiotherapies for patients with sequelae of pulmonary diseases, as part of the research project "Respiratory incentive system for lung expansion in patients with sequelae of COVID-19"[1].

2.2 Specific Objectives

- To pre-process the acquired signals involved in respiratory physiotherapy such as inspiratory-expiratory flow and volume, and respiratory rate.
- To model the inspired-expired flow and volume measurement system.
- To communicate the processed data wirelessly to a mobile device.
- To implement and evaluate physical and functional prototypes of the system.
- To validate the operation of the designed system.

[1] Inter-institutional and transdisciplinary research project financed by the Pontificia Universidad Javeriana Cali, as main executor, and Universidad del Valle as co-executor.

Chapter 3

State of Art

Respiratory incentive systems have contributed to the accompaniment of physiotherapies to address different limitations in the respiratory system for several decades. The classic spirometry incentive of the 1970s is the most representative example: a simple device whose operation consists of inspiring through a mouthpiece, with the objective of lifting a mobile sphere housed inside an internal wall (see fig. 3.1), with which the patient can perform respiratory physiotherapy exercises in a control system, receiving feedback by a visual stimulus [7].

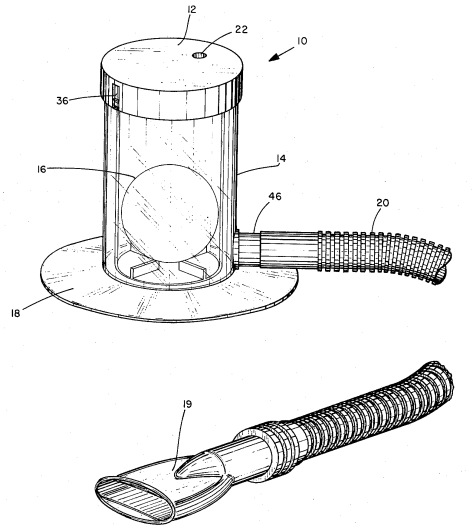


Figure 3.1: Patented therapeutic incentive spirometer.
[7]

Along with technological development, respiratory incentive systems that are currently being designed seek to involve a greater number of features that motivate patients to correctly perform the physiotherapies prescribed by health professionals. By including electronic and software systems, the concept of physiotherapy evolves, and several outstanding examples can be found on this matter, such as a device that uses gaming software to motivate children with cystic fibrosis in their lungs and engage them in physiotherapy treatment [8], offering them access to a gamified environment with different levels of intensity that they can control through a mouthpiece.

Likewise, it is possible to find a bunch of patented devices with electronic and software systems that seek to support pulmonary rehabilitation by physiotherapy. A brief compendium of these devices is listed as follows: Respiratory therapy instrument offering game-based incentives,

training, and telemetry collection [9], Electronic pocket spirometer [10], Telecentive spirometer [11], Systems and methods for portable monitoring of incentive spirometry [12], Incentive spirometer [13], Respiratory therapy device and system with integrated gaming capabilities and method of using the same [14], Incentive spirometer and musical instrument [15], Diagnostic and incentive spirometer using smartphone application [16], Patient reminder system and method for incentive spirometer utilization [17], Personal spirometer [18], Systems and methods for respiration-controlled virtual experiences [19].

Furthermore, among the most commonly used commercial devices for pulmonary rehabilitation processes by physiotherapy, there are those of a purely pneumatic type, i.e., without any use of electronic instrumentation, such as the *Breathacise spirometer* [20], which encourages lung exercise for physiotherapies involving deep inspiration, through an integrated basketball game; and those of an electronic type, such as the *Silverfit-flow* device [21], which incorporates electronic instrumentation and allows the patient to perform various breathing exercises through different gaming interfaces integrated into a computer interface, in which is also stored the data of the exercises and scores, so that the progress of the patient is supervised. With the *Silverfit-flow* device, the prescribed physiotherapy that the physiotherapist integrates into the treatment must be achieved independently by the patient inhaling and exhaling through a spirometer. Another of the currently used devices in the market are the series of respiratory incentives *Spirobank Smart* I & II [22], with which it is possible to reach precise measurements of inspiration and send them to a cell phone or a mobile device through Bluetooth technology. In addition, it allows monitoring of respiratory diseases such as asthma, Chronic Obstructive Pulmonary Disease (COPD), care in lung transplants and cystic fibrosis. *Spirobank Smart* is thus a portable, autonomous, tablet-based, and PC-based device, with the option of oximetry, which has incentive animations that support patient compliance during their pulmonary physiotherapy processes, but the monetary costs of the device are considerably high (approximately 300 to 1200 USD[1]) and not easily affordable for individuals without medical affiliations.

As a consequence of the high monetary costs of the devices mentioned in the previous paragraph (also see fig. 3.2), especially the last two, their acquisition is relatively limited as not all people can opt to purchase one of them, giving rise to other nuances of low-cost commercial devices that also seek the same purpose. Meanwhile, the low-cost commercial devices (non-electronic functionalities and features) that are currently used in the Colombia are *Triflo* [23] and *Voldyne* [24], which are common incentive spirometer devices that do not have digital gamification interfaces or integrated software (see fig. 3.3), but which are currently and widely used in processes for lung re-expansion physiotherapies.

Finding devices with electronic implementations that support pulmonary rehabilitation processes for physiotherapies is often costly, in addition to being a concept that, particularly in Colombia, is not very widespread.

[1] Prices extracted from the market.

(a) Breathacise [20]

(b) Silverfit-flow [21]

(c) Spirobank Smart I [22]

(d) Spirobank Smart II [22]

Figure 3.2: Promotional view of commercially available respiratory incentive devices.

(a) Triflo [23]

(b) Voldyne [24]

Figure 3.3: Commercial non-electronic devices commonly used in Colombia for lung re-expansion physiotherapies.

3.1 Electronic Monitoring Systems for Lung Re-expansion Physiotherapies within the COVID-19 Framework.

Regarding the background of previous work on the incentive treatment of COVID-19 sequelae, a variety of portable (wearable) sensing and telehealth technology with high potentials in disease monitoring and recovery is being used. Among the applications of telemedicine in monitoring the treatment of COVID-19, several studies have shown that the implementation of programs via internet connection, through video platforms, are able to identify new or recurrent problems in the treatment and establish care plans through a virtual examination. There is evidence that patients report improvements, not only in their lung capacity but also in other aspects such as transportation to hospitals and a reduction in the risk of infection or worsening of the disease [25].

From another perspective, a bunch of devices that sense different physiological variables are now used in the treatment of the disease. Such is the case of wearable chests-based devices, armband devices for measuring vital signs or clinical systems designed for monitoring vital signs that can be placed in different parts of the body [6]. All these devices make it possible to positively affect the health of the patient and improve their recovery, being aware of the state of variables such as oxygen saturation in the body, inspired lung volumes and respiration rate, among others, accompanying the entire process with constant monitoring through graphical user interfaces and mobile devices. In turn, mobile health and telemedicine technologies are marking a turning point in a handful of aspects of the diagnosis and treatment of COVID-19 and, although not new, they have emerged as fundamental tools in the fight against the disease, hand in hand with devices for contact tracing, remote physiological monitoring, tele-imaging, tele-robotics, among others [26].

Chapter 4

Theoretical Background

4.1 Theory of Inventive Problem Solving

From 1946 onwards, the Soviet engineer and writer Genrich Altshuller, along with a few associates, began to develop the methodology proposed by the Theory of Inventive Problem Solving (TRIZ)[1], although the first publication mentioning it was not known until 1956 in the journal *Issues of Psychology* under the title *On the psychology of inventive creation* [27]. This classical methodology allows approaching design problems and processes in an inventive way, supported by a set of systematic techniques and axioms that help to determine the key characteristics and aspects of the problem at hand, while stimulating the invention process.

In *Engineering of Creativity*, Savransky describes TRIZ as a human-oriented knowledge-based systematic methodology of inventive problem solving [28], and although the application of the theory does not provide a direct solution to the problem by itself, it does provide a structured form that favors the generation of ideas on which to base a solution linked to the needs of the people involved, namely, the end users.

For the application of the methodology TRIZ specific problems are converted into general problems in a process of abstraction, resulting in a set of general solution proposals that encompass ideality, with which the designer can derive specific solution proposals to the original problem [29].

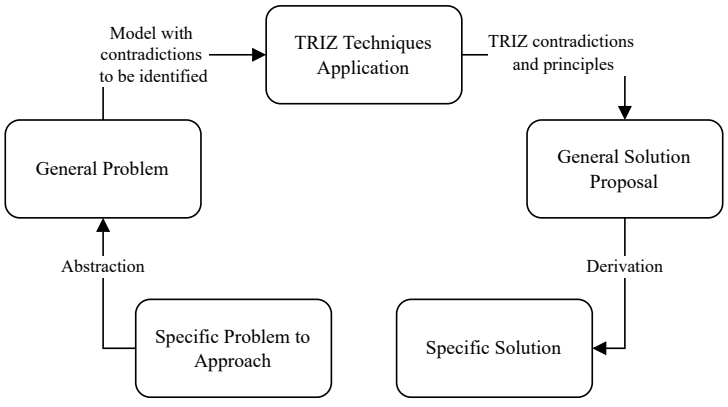


Figure 4.1: Illustrative path for problem solving with TRIZ.

Figure 4.1 shows an overview of the process involved in the TRIZ methodology. The basis of the problem analysis proposed by TRIZ is framed in the identification of the problem to

[1] Russian acronym transliterated as Tieoriya Riesheniy a Izobrietatielskij Zadach.

be solved subordinated to a representative view of its Technical System (TS), recognizing the evolution of the system through a user-centered analysis. In this regard, the TS can be defined as a set of elements that takes energy from the outside and converts it to perform a Main Function on an object [29].

Technical system **4.1-1**

As stated by Savransky [28], the TS is modeled by five conforming elements:

1. **Engine:** Generates the required energy to enable the working tool. The energy may have transformations.
2. **Transmission:** Carries the energy from the engine to the working tool and may vary in the process.
3. **Working tool:** Included in all TS, it directly interacts with a raw target object in order to perform the primary function.
4. **Control:** Collects information, handles regulation and management to generate a control action within the system and thus ensure the performance of the Main Function.
5. **Casing:** Provides protection layer and a physical organization for the TS.

Once the TS has been established as the basis for the specific problem abstraction, considering its parts as shown in box 4.1-1, it is necessary to confront its characteristics by means of TRIZ tools, in order to subsequently generate inventive ideas to solve the initial problem. One of the tools used by the TRIZ methodology is the systemic analysis of the problem by means of a space-time decomposition called *nine-window analysis*.

The main purpose of the nine-window analysis is to reveal the complexity of the problem and to break down its characteristics and parts in a structured way, leading to the recognition of the evolution of the TS from the past to the future and allowing first impressions towards the ideal attributes that the solution could have in the future, without knowing exactly what that solution is.

4.1.1 Nine-window Analysis

To understand the operational foundation of nine-window analysis, it is important to clarify the concept of system, subsystem and supersystem. Figure 4.2 helps to understand this concept, presenting the system as an element that hosts different subsystems that in turn link various types of components and act as one more element in the environment, also called supersystem. Thus, for example, if the system is a pencil, the subsystem would be the elements that make up that pencil, that is, the wood, the graphite, the eraser, each one linking different elements in itself; in turn, the pencil is part of a desk with a person ready to use it on a piece of paper.

The nine-window analysis plays with these spatial subsystem concepts and combines them with temporal characteristics. Figure 4.3 shows how its components can be approached. In this analysis, the past and present denote evolution and the future proposes the conception of ideality in the design process.

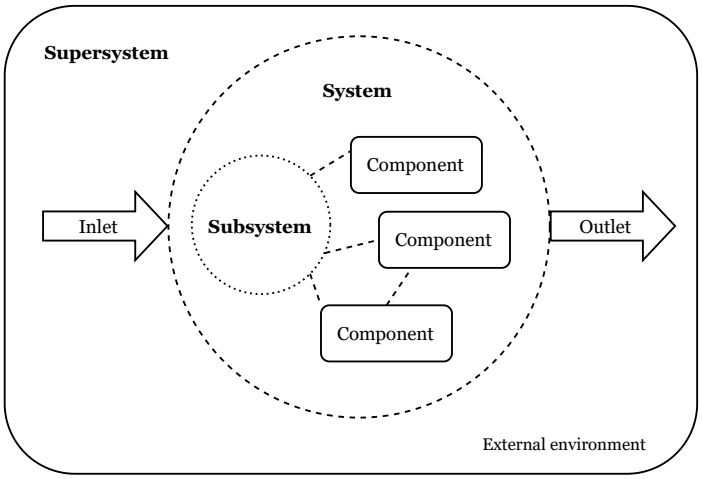


Figure 4.2: Basic representation of the notion of a system.

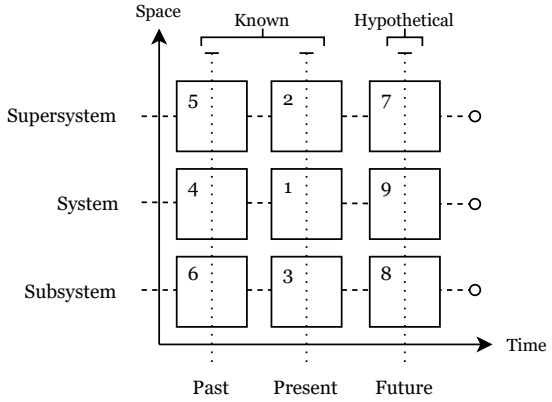


Figure 4.3: Components of the nine-window analysis. [29]

Once this has been defined, it is important to note the second immediate purpose of the application of the systemic analysis, namely, that thanks to the definition of the ideal attributes and the expanded view of the problem provided by the nine-window analysis, the contradictions obtained from this analysis can be determined. Contradictions can be found by analyzing in detail the transition between the present and future windows. In the TRIZ methodology, contradictions are key elements, situations that clash with the ideality of the attributes and requirements obtained in the analysis process because they are unachievable from the base TS, but which provide the necessary elements to guide the solution in an inventive way [29]. In this regard, a second TRIZ tool is employed: *the contradiction matrix* [28].

4.1.2 Contradiction Matrix

The contradiction matrix provides a set of parameters (see table 4.2) that support the problem synthesis process, describing in a technical and general way the contradictions between the characteristics to be improved and the characteristics that may be affected by such improve-

ments [28]. Once these contradictions have been identified within the matrix, a list of inventive principles (see table 4.3) can be extracted that stimulate ideas to propose a satisfactory solution to the initial problem. Savransky compiles detailed information on what each parameter and principle means in the TRIZ methodology [28], which should be considered when analyzing contradictions. In table 4.1 it is possible to see a portion of the contradiction matrix, whose individual cells contain the indices of the inventive solution principles proposed by TRIZ.

Characteristics			Characteristic getting worse				
			1	2	3	4	5
Characteristic to improve	1	Weight of a mobile object		-	15,8, 29,34	-	29,17, 38,34
	2	Weight of a stationary object	-		-	10,1, 29,35	-
	3	Length of a mobile object	8,15, 29,34	-		-	15,17, 4
	4	Length of a stationary object	-	35,28, 40,29	-		-
	5	Area of a mobile object	2,17, 29,4	-	14,15, 18,4	-	

Table 4.1: Initial section of Altshuller's contradiction matrix. [30]

TRIZ parameters	
1. Weight of a mobile object	21. Power
2. Weight of a stationary object	22. Waste of energy
3. Length of a mobile object	23. Waste of substance
4. Length of a stationary object	24. Loss of information
5. Area of a mobile object	25. Waste of time
6. Area of a stationary object	26. Amount of substance
7. Volume of a mobile object	27. Reliability
8. Volume of a stationary object	28. Accuracy of measurement
9. Speed	29. Accuracy of manufacturing
10. Force, intensity	30. Harmful factors acting on object
11. Tension, pressure	31. Harmful side effects
12. Shape	32. Manufacturability
13. Stability of an object	33. Convenience of use
14. Strength	34. Repairability
15. Durability of a mobile object	35. Adaptability
16. Durability of a stationary object	36. Complexity of device
17. Temperature	37. Complexity of control
18. Brightness	38. Level of automation
19. Energy spent by a mobile object	39. Productivity
20. Energy spent by a stationary object	

Table 4.2: Parameters proposed by TRIZ. [30]

Once the inventive principle proposed by TRIZ has been identified, it is possible to present an overview of propositional solutions that can be derived to give rise to the specific solution of the problem, corresponding to the last step of the path shown in fig. 4.1. In this regard, it is

possible to integrate some of the tools offered by other methodologies. Axiomatic Design is one of them [29] (see section 4.3), whose final integration is based on the formal identification of the *requirements* and *design ranges* and, from there, of the alternatives with which each requirement can be fulfilled, *design alternatives* that will consider the inventive principles proposed by TRIZ in order to avoid contradictions. Meanwhile, the Analytic Hierarchy Process exposed in section 4.4 shall provide convergence in the decision process of the alternatives and thus derive the specific solution to the problem.

TRIZ principles	
1. Segmentation	21. Rushing
2. Extraction	22. Convert harm into benefit
3. Local quality	23. Feedback
4. Asymmetry	24. Mediator
5. Combining	25. Self-service
6. Universality	26. Use copies
7. Nesting	27. Inexpensive, short-lived objects
8. Counterweight	28. Replacement of a mechanical system
9. Prior counter-action	29. Pneumatic or hydraulic construction
10. Prior action	30. Flexible membranes or thin film
11. Cushion in advance	31. Use of porous material
12. Equipotentiality	32. Changing the color
13. Inversion	33. Homogeneity
14. Curvature increase	34. Rejecting and regenerating parts
15. Dynamicity	35. Transformation of an object states
16. Partial or overdone action	36. Phase transformation
17. Moving to a new dimension	37. Thermal expansion
18. Mechanical vibration	38. Use strong oxidizers
19. Periodic action	39. Inert environment
20. Continuous action	40. Composite materials

Table 4.3: Inventive principles proposed by TRIZ. [30]

4.2 Design Thinking

Design Thinking is a human-centered approach to innovation that, together with a set of tools, allows identifying the real needs of the people involved in a design problem [31]. Its application is fundamentally based on five stages: Immersion, Analysis and Synthesis, Ideation, Prototyping and Testing. Through these stages, the designer will be able to recognize the state of the problem, identifying the key factors, conducting a complete field analysis and being able to apply an iterative prototyping methodology to improve the design until the problem is completely and optimally solved [32]. Although its stages do not provide a step-by-step guide on how to solve the problem, they do provide useful tools for structuring a good solution.

4.2.1 Immersion

The immersion stage seeks to contextualize the team from the user's point of view [32]. It is divided into two phases, Preliminary and In-Depth immersion, where the first phase rethinks the problem and understands it from a superficial perspective, while the second one identifies the needs and opportunities that arise directly in the context of the problem.

Particularly, during the preliminary immersion, a documentation and field research is carried out, where the contextual factors involved in the problem are identified, as well as the potential users. Moreover, during the In-depth immersion it is possible to go deeper into the approach to the problem, using anthropological techniques that are directly related to the people involved, such as interviews, field visits, surveys, among others [32]. These techniques are particularly important because it is not only a matter of understanding the problem from a different perspective, but also of delving into the interactions of the users, their concerns and their needs.

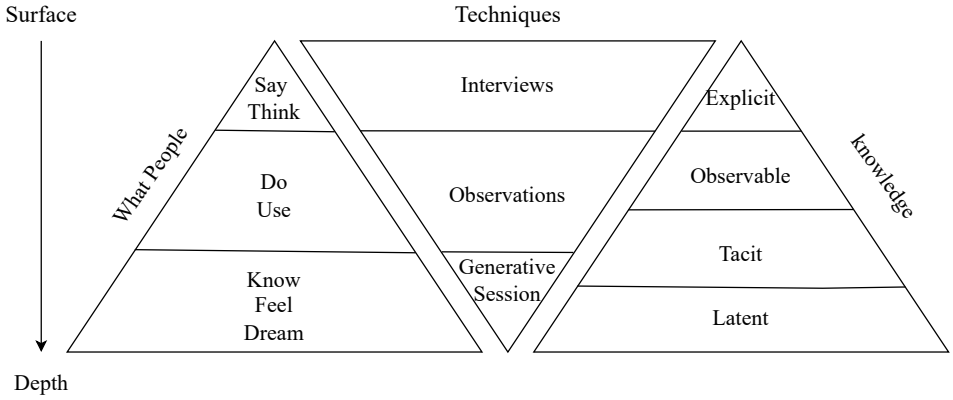


Figure 4.4: Visual summary of the understanding of the problem through the immersion stage.
[32]

The fig. 4.4 summarizes the immersion process, understanding as a *surface* the previous knowledge that progressively, through anthropological techniques, deepens in the context of the problem, facilitating the identification of both evident and implicit needs.

4.2.2 Analysis and Synthesis

This stage summarizes and classifies all the information collected in the previous stage, in order to identify the *Insights* (discoveries and possible opportunities). In the framework of Design Thinking, information organization techniques are facilitators that clarify the research and the results of interviews, field visits or cultural surveys.

To carry out these organizational techniques, it is necessary to begin with the production of compact summaries, facilitating the handle of large volumes of information. This may result in the creation of summary cards better known as insight cards, which contain specific information, in addition to including source, date and distinctive factors [31]. The next step consists in a strategical categorization of the cards, considering similarities and dependencies, to consequently

build a conceptual map that can structure the information in a simple and graphic way at different levels of abstraction.

Finally, with enough categorized information on the characterization of the users and actors, it is necessary to construct *Archetypes*, fictitious characters, who acquire characteristics of the different types of users in the context of the problem. These archetypes can represent desires, motivations, expectations, and most importantly, needs.

4.2.3 Ideation

In this stage, innovative ideas are generated considering the meeting of the identified needs, regardless of the complexity of their implementation. People's participation involved in different areas of knowledge is pertinent, the multidisciplinary teams are a great advantage at this stage [32]. One of the most common resources for generation of solutions is the brainstorming, which is the gathering of spontaneous ideas that are subsequently selected and validated through decision matrices or directly with users if necessary.

4.2.4 Prototyping and Testing

The Prototyping and Testing stages are related to each other because they validate the generated ideas. In Prototyping, the ideas become tangible going from abstraction to a real representation, which can be simple but functional. Meanwhile, testing step is closely related to the previous one because the resulting prototypes must be constantly validated in different types of contexts. There are three basic types into which the resolution level of the developed prototypes can be classified [32]:

Fidelity levels in prototypes **4.2-1**

1. **Low fidelity:** Being a conceptual sketch of the idea, without the construction of a model or physical representation.
2. **Middle fidelity:** Containing several aspects of the idea, without necessarily being a faithful representation of what is intended in the solution idea.
3. **High fidelity:** Containing specific references as close to the idea as possible. The idea can be represented by a mock-up with a high level of closeness to the final solution, so that it is useful for testing it with users.

In addition to the levels of fidelity in the prototypes exposed in box 4.2-1, there are different contexts in which the prototypes can be tested, that can be classified as follows: restricted, general, partial and total [32]. The restricted level, represents a totally controlled environment without the participation of users, whereas the general level still has a partially controlled environment and no user interacts directly. The partial level, directly tests the prototype in the real environment or with a user, while the total level strictly tests both scenarios.

At the same time, it is important to emphasize the documentation and organization of the prototypes to take full advantage of the iterative stages of the process. Figure 4.5 shows a general idea of the components that make up the prototyping process, from which it is possible to get closer to the solution of the initial problem with each new prototype.

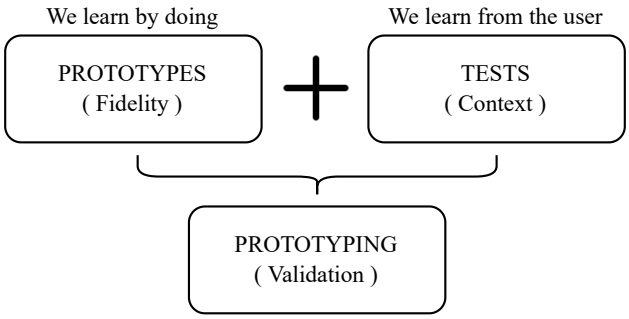


Figure 4.5: Components that make up the prototyping process.
[32]

4.3 Axiomatic Design

An adequate design process must have the capability of being easily understandable and transferable for all the people that make up a work team. Therefore, in many cases, a structure is needed to distinguish what is required when approaching the design process, which is achieved through the use of methodologies such as Axiomatic Design. In this methodology, the word *axiom* plays an important role in the approach to a design based on its structure, since two important axioms must be considered:

- **Functional independence:** to avoid couplings and redundancies of specific functions in the design product by controlling the entire process.
- **Minimum information content:** to determine the quality of the design product, where quality refers to the fulfillment and satisfaction of the proposed requirements.

As mentioned above, Axiomatic Design can be used in conjunction with TRIZ methodology, where its integration can be summarized in the definition of design *requirements* and how these are materialized in the form of *design parameters* or *design alternatives*. Thus, the definition of these Axiomatic Design elements work hand in hand with the inventive ideas proposed by TRIZ, so that the design process can continue its course in a structured fashion and can be guaranteed to be controlled, so that the proposed solutions can satisfy each of the *requirements* without affecting other functions of the product.

Thereupon, the Axiomatic Design contributes to the concreteness of the design, since it is based on a logical and rational thinking process, through a clear formulation of design objectives. Additionally, it provides clear criteria for decision-making that reduce subjectivity and contribute to the reduction of time for the generation of new products [33].

4.4 Analytic Hierarchy Process

The Analytic Hierarchy Process (AHP) is a structured technique for making decisions involving multiple criteria. The technique was developed by Thomas L. Saaty between 1971 and 1975 at the University of Pennsylvania and is based on a nonlinear framework that allows several factors (called criteria) to be considered simultaneously when making a decision, accompanying

the process with numerical operations that allow synthesis or value conclusions to be reached and that, in turn, encompass the development of inductive and deductive thinking [34]. Although this technique is now more than 40 years old, it has continued to be studied and refined since its development.

In simple terms, the AHP technique provides support for directing a choice problem towards a viable alternative that stands out among the others, and it does so through the quantification of the importance and subsequent pair-wise comparison of criteria among the different alternatives considered.

Saaty describes in his theory that three fundamental principles govern decision making with the AHP methodology: decomposition, comparative judgements and synthesis of priorities [34]. The first principle is based on the hierarchical structuring of the problem, starting from the focus at the top level, passing through the selection criteria at the second level and the sub-criteria at the third level (if any) and all lying on the alternatives. A graphical representation in this respect is shown in the image of fig. 4.6. The second principle described by Saaty, on the other hand, is applied to the construction of pairwise comparisons of the elements in the hierarchy (the criteria by themselves and the alternatives by each criterion), resulting in the quantification of the importance level of each element. The third principle mediates the synthesis of the scores of each alternative with respect to the criteria, giving rise to the global priority of the elements and, therefore, an important clue at the time of making the decision.

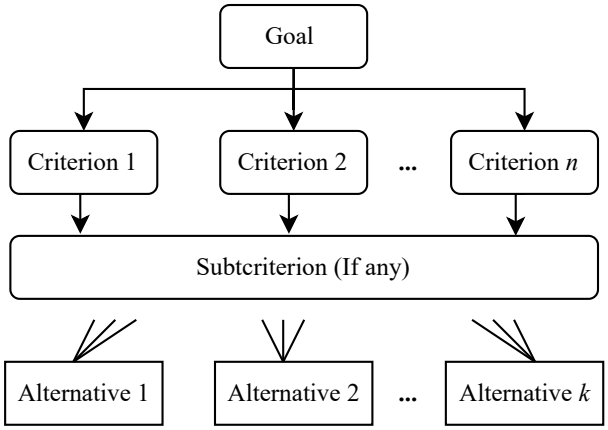


Figure 4.6: Graphical representation according to the decomposition for AHP.

4.4.1 Axioms of the AHP

With all this said, it is imperative to get into the formal execution of the process. For this, it is necessary to describe in the first instance two of the four axioms that govern the method, which are the baseline for the use of pairwise comparisons (the axioms not included are related to the construction of a hierarchy and the representation of ideas). A brief definition of the axioms is included here, for more details please consult the source [34].

Let $\mathbb{U}$ be a finite set of n-elements called alternatives, and $\mathbb{P}$ a set of elements called criteria,

with respect to which the elements in $\mathbb{U}$ are compared. Particularly, the comparisons are performed on the elements in $\mathbb{U}$ in contrast to each element in $\mathbb{P}$ (one by one) and the weights of the criteria are mediated by paired scoring of the elements in $\mathbb{P}$. All comparisons are represented in matrix form. To skip the theoretical notation about the comparisons, the table 4.4 represents the fundamental scores in which the paired elements are rated.

Intensity of importance on an absolute scale	**Definition**	**Explanation**
1	Equal importance	Two elements contribute equally to the objective
3	Moderate importance of one over another	Experience and judgement strongly favor one element than another
5	Essential or strong importance	Experience and judgement strongly favor one element than another
7	Very strong importance	An element is strongly favored and its dominance demonstrated in practice
9	Extreme importance	The evidence favoring one element over another is of the highest possible order of affirmation
2, 4, 6, 8	Intermediate values between the two adjacent judgments	When compromise is needed
Reciprocals	If element i has one of the above numbers assigned to it when compared with element j, then j has the reciprocal value when compared with i	

Table 4.4: Fundamental scale values.
[34]

Prior to the axioms, the following theoretical basis should be considered:

$A \in \mathbb{R}^{n\times n}$ is a *pairwise comparison matrix* [35], if it satisfies three properties:

$$(1)\ a_{i,j} > 0$$
$$(2)\ a_{i,i} = 1$$
$$(3)\ a_{i,j} = 1/a_{j,i}$$

defined for all $i, j = 1, 2, \ldots, n$. These properties lead us to define A as a positive matrix having the following form:

$$A = \begin{pmatrix} 1 & a_{1,2} & \cdots & a_{1,n} \\ 1/a_{1,2} & 1 & \cdots & a_{2,n} \\ \vdots & \vdots & \ddots & \vdots \\ 1/a_{1,n} & 1/a_{2,n} & \cdots & 1 \end{pmatrix}$$

It is also important to point out that if A satisfies that $a_{i,k} \times a_{k,j} = a_{i,j}$ for all $i, k, j = 1, 2, \ldots, n$, then A is called *consistent*, otherwise will be *inconsistent*.

Axiom 1 (reciprocity)

As stated above, this axiom determines that for all elements $A_i, A_j \in \mathbb{U}$ and all elements $C \in \mathbb{P}$:

$$P_c(A_i, A_j) = 1/P_c(A_i, A_j)$$

where $P_c \equiv a_{i,j} \in \mathbb{R}$ represents the intensity or strength of preference for one element in the pairwise comparison matrix A (in this case related to alternatives) over another. Thus, this axiom basically establish that the set of comparisons must be reciprocal constructions in which if an element A_i is 2 times more preferred than another element A_j, then A_j is 1/2 times preferred than A_i, i.e. less preferred.

Another important aspect associated with this axiom is the concept of consistency. To provide a simple example in this regard, let us go back to our previous example: if an element A_i is 2 times more preferred than another element A_j, and an element A_j is 3 times more preferred than an element A_k, then the preference of the element A_i over the element A_k should be six times stronger. Nevertheless, maintaining this consistency is not always a simple task, and it should be noted that using the AHP method does not require having a consistent matrix, although if it does, the results could be more accurate [34]. When the pairwise comparison matrix is inconsistent, then it is possible to measure that inconsistency through a Consistency Ratio (CR).

Axiom 2 (homogeneity)

This axiom is intended to establish meaningful comparisons, in the sense that unrelated items cannot be compared. In the case of a large disparity, the elements should be placed in separate groups of reasonable relation.

4.4.2 Extraction of Weights from Pairwise Comparison Matrices

Now, with the main concepts on paper, the definition of the calculation of weights and priorities for the AHP method follows. Once the hierarchy that embraces the decision problem has been determined, according to the homogeneity axiom described in section section 4.4.1, the pairwise comparisons between the defined criteria must be established, seeking to determine their relative importance [34]. Consequently, the alternatives must be compared with respect to each of the criteria considered to subsequently synthesize the results. Figure 4.7 shows a follow-up model of the AHP whole method.

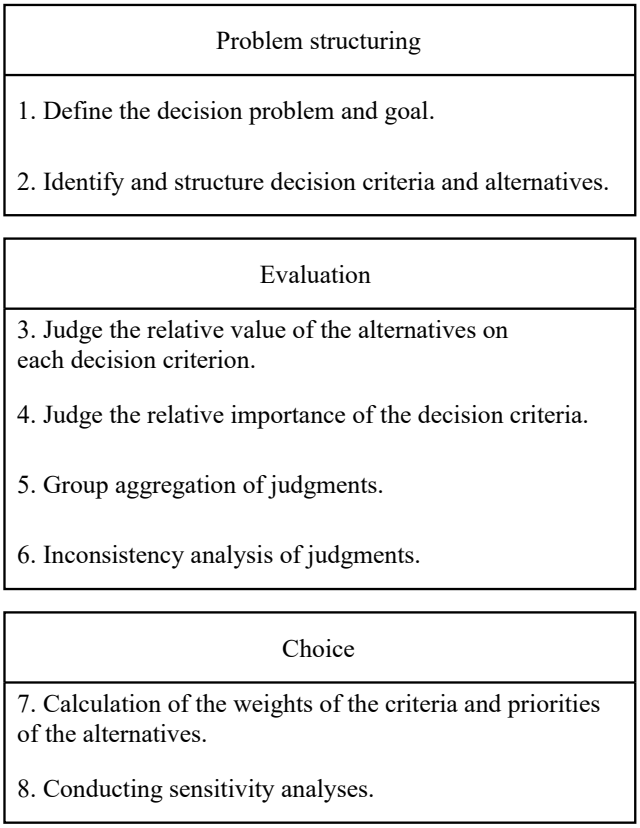


Figure 4.7: Summarized AHP steps.
[36]

Several methods exist to determine the weights of the pairwise comparison matrix, such as the arithmetic means method [37], the least squares method [38] and the original method described by Saaty, the *principal eigenvalue* method [34], among others. Golany and Kress [35] have compared many of the available methods for obtaining the weight of pairwise comparison matrices and have concluded that each method has advantages and weaknesses, so there is no establishment of which method is the best. Therefore, a fundamental description of the original method and one of its alternatives, the arithmetic means method, will be addressed here.

Principal Eigenvalue

The weights in this method are derived from by solving the principal eigenvector of the pairwise comparison matrix and subsequent normalization of the result [34]. The Perron-Frobenius theorem justifies the development of AHP by means of eigenvectors since it states that:

> If all entries of a $n \times n$ matrix A are positive, then it has a unique maximal eigenvalue. Its eigenvector has positive entries [39].

The statements of the Perron-Frobenius theorem make it possible to define the principal eigenvectors used by Saaty's method for the calculation of the weights.

Meanwhile, the theory also describes the use of the CR when the comparison matrix is inconsistent. This consistency ratio is based on the definition of a Consistency Index (CI) having the form $(\lambda_{max} - n)/n - 1$ and the subsequent comparison with Random Consistency Indices (RI) stated by Saaty [34], with which it is possible to judge how coherent the results obtained are when the matrix of comparisons is inconsistent. The eigenvectors method allows the weights obtained to contain all the dominant information given by the matrix, when it is inconsistent. The theory establishes a tolerance of 10% of inconsistency, i.e., when the CR is greater than 10, the results obtained by AHP must be reviewed and carefully judged.

Finally, to synthesize the overall priority weights, it is necessary to **multiply each priority value of the alternatives by the relative weight of the respective criterion.** The result comprises an important clue to cope with the decision-making problem.

Arithmetic Mean

This method allows us to avoid the process of computing the eigenvectors and eigenvalues for the pairwise comparison matrices when the matrix is not very large. To find the weights, it is necessary to normalize the matrix by columns, and then take the arithmetic mean across the rows, thus approximating the eigenvectors with a simpler method. With this method it is also possible to approximate the CR without having to find the eigenvalues of the matrix, for this purpose it necessary to multiply each column of the original matrix (without normalizing) by their respective weights and then add the results obtained by rows. Subsequently, each result is divided respectively with the initially calculated weight to then extract the arithmetic mean of the outcomes, whose value will correspond to an approximate of the principal eigenvalue of the matrix. From there, it is possible to apply the same steps to find the CR described in the previous section, as well as the overall priority weights for each alternative.

4.5 Respiratory System

The human respiratory system is a set of organs and structures responsible for carrying out gas exchange between the body and the environment. The vital functions associated with this system are to provide oxygen to the body, eliminate carbon dioxide (waste product) and help to maintain acid-base balance in the organism. Non-vital functions include odor detection, speech production, straining for cough or childbirth [40].

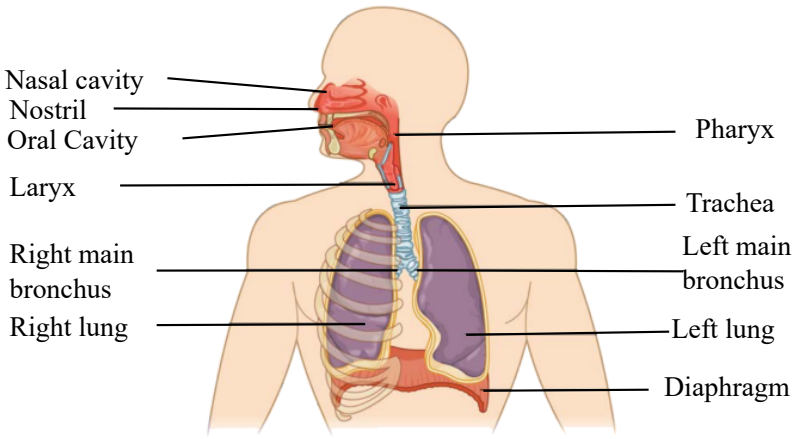


Figure 4.8: The major respiratory structures span the nasal cavity to the diaphragm.
[40]

The respiratory system, whose main structures can be distinguished in fig. 4.8, can be functionally divided into the conducting zone and the respiratory zone. The former is formed by the organs and structures that are not directly involved in gas exchange, since this process takes place rather in the respiratory zone.

In turn, the main functions of the conducting zone include providing a path for incoming and outgoing air, removing and filtering pathogens or debris from the incoming air, as well as heating and humidifying it. The structures that comprise this area are: nose and its adjacent sectors, paranasal cavities, mouth, pharynx, larynx, trachea and bonchi [41].

Meanwhile, the respiratory zone has to do with allowing the diffusion of oxygen within the lung capillaries in the exchange of carbon dioxide [41]. This zone is composed of the tiny alveoli (200µm diameter), which are particularly responsible for gas exchange and helping to maintain air pressure [40]; and the lungs, the essential organs for breathing and blood oxygenation.

4.5.1 Breathing Process

The process of exchanging oxygen (O_2) and carbon dioxide (CO_2) between the body and the atmosphere is called external respiration [40]. The process of gas exchange between the blood in the capillaries and the cells of the tissues is internal respiration. These two concepts are involved in the breathing process.

External respiration, specifically, is divided into four main stages: pulmonary ventilation or exchange of gases between the atmosphere and the alveoli through inspiration or expiration; diffusion of gases or passage of oxygen and carbon dioxide from the alveoli to the blood and vice versa; the transport of gases through the blood and body fluids to reach the cells; and the regulation of the respiratory process [41].

Particularly, *pulmonary ventilation* as the first stage of the breathing process consists of the movement of air (flow) in and out of the lungs, called *inspiration* and *expiration* [41],

which will be key words in the development of this project. During inspiration, contraction of the diaphragm and inspiratory muscles increases the capacity of the thoracic cavity, causing intrapulmonary pressure to drop slightly below atmospheric pressure, making the air flows in the airways. During expiration, the respiratory muscles relax and return to their resting positions, so the capacity of the thoracic cavity decreases and the intrapulmonary pressure rises above atmospheric pressure causing air to leave the lungs [41]. Figure 4.9 shows this process graphically.

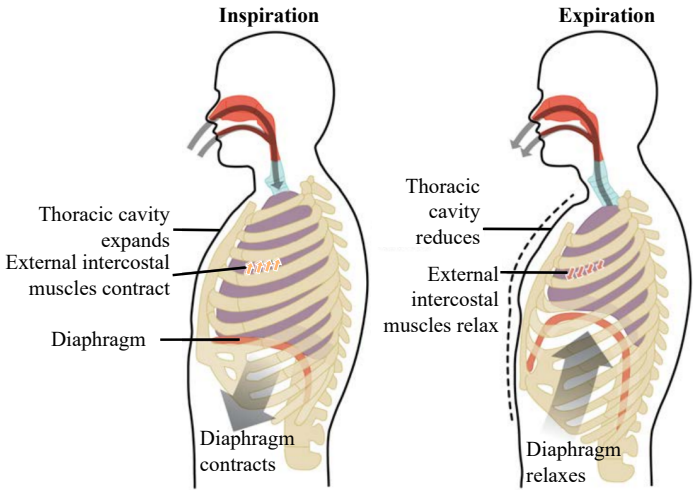


Figure 4.9: Illustration of the breathing process for pulmonary ventilation. [40]

Since the lungs are unable to expand and contract on their own, they have to move in association with the chest and muscles of thoracic cavity. The combination of the outward stretching force of the thoracic cavity and the inward elastic force of the lungs creates a negative intrapleural pressure, i.e., lower than atmospheric pressure [41], making possible the movements of expansion and contraction that give rise to inspiration and expiration.

4.5.2 Respiratory Volumes and Capacities

Respiratory volume is a term that describes different types of quantification of air interacting with the respiratory system. There are four types of respiratory volumes: tidal, residual, inspiratory reserve, and expiratory reserve. The Tidal Volume (TV) is the amount of air normally circulating in the lungs during eupnea[2], which is approximately 500 milliliters [40]. On the one hand, the Expiratory Reserve Volume (ERV) is the volume of air that someone can forcefully exhale beyond a normal tidal expiration, it is up to 1200 milliliters for men and, on the other hand, the Inspiratory Reserve Volume (IRV) is the one produced by a deep inhalation, beyond a normal inspiration. The Residual Volume (RV), is the amount of air that remains in the lungs when exhaling as much air as possible, which facilitates breathing by preventing the collapse of the alveoli [40]. Section (a) of fig. 4.10 shows a graphical representation of these respiratory volumes.

[2]Natural breathing (inspiration and expiration) that occurs without effort and in a relaxed state.

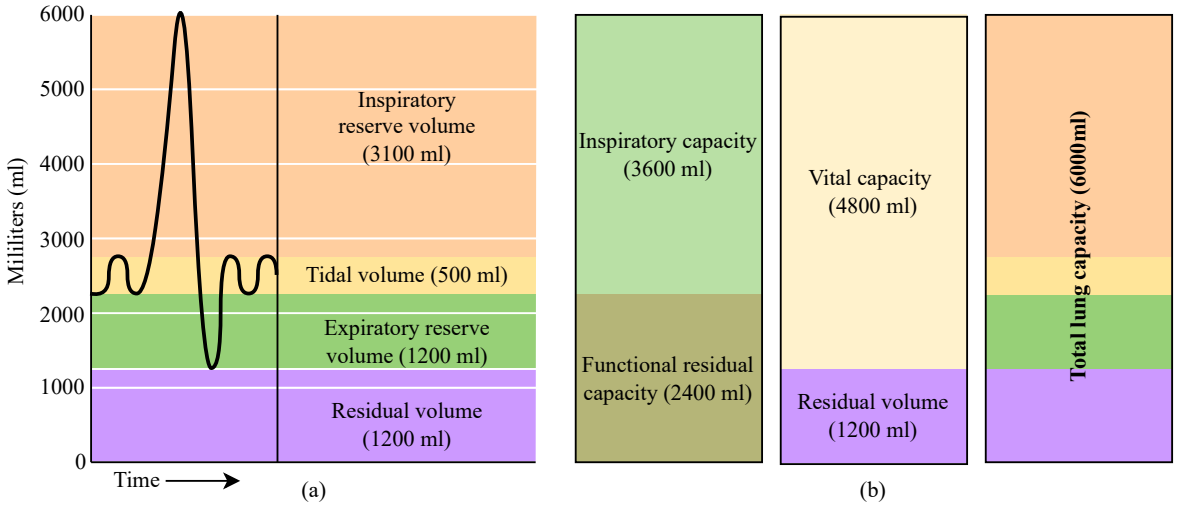


Figure 4.10: (a) Respiratory volumes. (b) Respiratory capacities. [40]

Respiratory capacity is the combination of two or more selected types of respiratory volume, which also describes the amount of air in the lungs during a certain period of time [40]. For instance, Total Lung Capacity (TLC) is the sum of all respiratory volumes mentioned above (TV, ERV, IRV, and RV), which represents all the air a person can retain in the lungs after a forced inspiration. The TLC is about 6000 milliliters of air for men and about 4200 milliliters for women. Likewise, the Vital Capacity (VC) is the amount of air a person can move into or out of their lungs and is the sum of all volumes except the residual volume (TV, ERV, and IRV), which is between 4000 and 5000 milliliters. As for the Inspiratory Capacity (IC), it is the maximum air that can be inhaled beyond a normal tidal inspiration, being the sum of TV and IRV. Moreover, the Functional Residual Capacity (FRC) is the volume of air that remains in the lung after a normal tidal expiration, namely the sum of ERV and RV [40]. A representation of all these respiratory capacities can be found in section (b) of fig. 4.10.

It is important to mention that respiratory volumes and capacities depends on a variety of factors, and measuring them can provide important clues about a person's respiratory health. Their measurement is usually carried out with specialized medical equipment and in the company of health professionals. Table 4.5 shows the necessary equipment to carry out the studies and measurements of respiratory volumes, capacities and flows, as well as an extension of them.

4.5.3 Respiratory Rate

The respiratory rate is defined as the number of complete breathing cycles[3] a person does per minute. The rate is usually measured when a person is at rest and basically involves counting the number of breaths for one minute, standarized as *bpm*. Respiration rates may increase with fever, illness, and other medical conditions. In turn, when analyzing breathing, it is important to observe if the person has any difficulty breathing [42].

[3]One cycle is composed by a complete inspiration and expiration process.

Pulmonary Function Test	Instrument	Measures	Function
Spirometry	Spirometer	Forced Vital Capacity (FVC)	Volume of air exhaled after maximum inhalation.
		Forced Expiratory Volume (FEV)	Volume of air exhaled in one breath.
		Forced Expiratory Flow (FEF)	Air flow in the middle of exhalation.
		Peak Expiratory Flow (PEF)	Rate of exhalation.
		Maximum Voluntary Ventilation (MVV)	Volume of air that can be inspired and expired in one minute.
		Slow Vital Capacity (SVC)	Volume of air that can be slowly exhaled after inhaling after the tidal volume.
		TLC	Volume of air in the lungs after maximal inhalation.
		FRC	Volume of air left in the lungs after normal expiration.
		RV	Volume of air in the lungs after maximum exhalation.
		ERV	Volume of air that can be exhaled beyond normal exhalation.
Gas diffusion	Blood gas analyzer	Arterial blood gases	Concentration of oxygen and carbon dioxide in the blood.

Table 4.5: Measurements and instruments for the determination of volumes and respiratory capacity.
[40]

4.5.4 Respiratory Patterns

Respiratory patterns can be defined in different types [43]:

Eupnea: refers to the normal respiratory rate, where gas exchange occurs naturally and involuntarily.
Hyperventilation: describes very rapid and deep breathing, commonly caused by voluntary exertion, prior to exercise, or by psychological factors such as hysteria.
Hypoventilation: describes a slow, shallow breathing pattern.
Dyspnea: refers to labored or difficult breathing also associated with hypoventilation.
Apnea: occurs when breathing stops completely for a short period of time, regardless of the cause.
Respiratory arrest: refers to the non-resumption of breathing after a period of apnea.

4.5.5 Diseases of the Respiratory System

The diseases and conditions affecting the respiratory system have different causes, whether they are pathologies of bacterial or viral origins, pulmonary contusions, obstructions, pulmonary impairment or hereditary illnesses, among others. All of them can affect the respiratory capacity of people and their lives in general, requiring respiratory physiotherapy to promote a prompt recovery on their vital functions. In the following paragraphs some pathologies of the respiratory system are briefly outlined, which have special importance in this project due to their connection with the respiratory physiotherapies for lung re-expansion (see section 4.6) in the recovery process.

Chronic Obstructive Pulmonary Disease

It is defined as a slow and progressive airflow obstruction, which is only partially reversible. The effects of COPD in patients are measured by caregivers depending on the degree of lung function abnormality, since this disease reduces the maximum respiratory flow [44]. Patients suffering from this disease, mostly smokers, are prescribed respiratory physiotherapy, as this improves not only the future course of the disease but also its quality and life expectancy.

Asthma

Asthma is characterized by chronic inflammation of the airways, presence of bronchial hyperreactivity and generalized pulmonary obstruction [45]. Asthma is associated with difficulty breathing and narrowing of the airways, accompanied by excess mucus secretions that give rise to the asthmatic crisis. There are two types of asthma, extrinsic and intrinsic. Whereas the former is mostly hereditary and the most common (about 80% of patients have it), the latter is related to the adverse reaction to acetylsalicylic acid (commonly known as aspirin). [46]. Asthma symptoms can be reduced by respiratory physiotherapy, where breathing exercises seek to re-educate breathing to achieve an improvement in the perception and control of asthmatic crises [47].

Pulmonary Cystic Fibrosis

Cystic fibrosis is a congenital disease characterized by a dysfunction of the exocrine glands, causing abnormally thick secretions. When this disease occurs in the pulmonary area, the secretions obstruct the airways and increase chronic bacterial infections, causing an excessive inflammatory response [48]. Although this disease is incurable, the treatments currently available are aimed at reducing its effects. Through respiratory physiotherapy and appropriate medication, patients can improve their quality of life [49].

Neuromuscular Diseases

Neuromuscular diseases are a group of diseases that affect the skeletal muscle, causing progressive loss of muscle mass and therefore muscle weakness. When this weakening occurs in the pulmonary area, it can compromise three main groups of muscles: inspiratory, expiratory, and those that innervate the upper airways [50]. Respiratory physiotherapy in a patient with neuromuscular conditions should be initiated as soon as the disease is detected.

4.6 Physiotherapies for Lung Re-expansion Processes.

Supportive physiotherapies for lung re-expansion processes are intended to promote the rehabilitation of lung capacity and the reopening of the airways of patients undergoing sequelae, collapse or atrophy due to respiratory diseases. Thereby, the common follow-up model for respiratory physiotherapies usually starts from the ventilatory deficiencies of each patient and allows them to improve their functional capacity and quality of life [51].

The establishment of rehabilitation physiotherapies begins with a first stage in which the patient is evaluated through different methods such as auscultation, X-rays, analysis of symptoms or chest inspection, among others. Subsequently, the physiotherapist in charge must issue a medical prescription that will contain the objectives that the patient must achieve for their recovery. Thereafter, the physiotherapist should continuously monitor the progress of the patient with physiotherapy. The components of each physiotherapy process are briefly outlined in box 4.6-1.

Components of the physiotherapy process **4.6-1**

1. **Physiotherapy:** Macro set of the whole rehabilitation process of the patient, including evaluation, examination, diagnosis, treatment and re-evaluation.
2. **Prescription:** Selection of intensity and appropriate physiotherapy techniques/exercises to be carried out by the patient.
3. **Sessions:** Amount of time in months, weeks, days or hours in which what is prescribed by the physiotherapist must be carried out.
4. **Series:** Number of times a given physiotherapy exercise is repeated per session.

At the same time, the pulmonary re-expansion physiotherapies are usually accompanied by spirometry processes, either common or incentive, which allows testing the pulmonary function during the course of the physiotherapy and evaluating the performance of the patient, leading to the effective monitoring of the evolution of the respiratory diseases that are sought to be treated. Thus, the usefulness of spirometry is essential when implementing each of the physiotherapy techniques for lung re-expansion processes [52].

From there, a compendium of physiotherapies emerges and the choice of the most appropriate one will depend on, as mentioned above, each deficiency of the patient, in addition to the variables of height, age, weight and sex. In the prescription, aspects such as the intensity, frequency (in terms of series and repetitions) and duration of each lung re-expansion physiotherapy scheme are also considered, as well as the position in which the patient should be during the exercises.

The compendium of physiotherapies considered under the comprehensive main research project is shown in table 4.6. These physiotherapy techniques are established by the physiotherapists associated with the development of the project, who have provided us with a detailed description of the process and the steps in which each technique is carried out in Colombia.

Technique	Description/steps
Deep inspiration	1. Slow nasal inspiration until reaching the Maximal Breathing Capacity (MBC). 2. Apnea for 3 to 10 seconds. 3. Slow expiration through the mouth with pursed lips (in whistle form).
Diaphragmatic ventilation	1. Slow nasal inspiration. 2. Slow expiration through the mouth with pursed lips (in whistle form) until reaching FRC.
Fractional inspiration	1. Slow and short nasal inspiration. 2. Subsequent inspiration after an apnea of at least 2 seconds (the physiotherapist determines how many fractions will be handled, since it can be a fractional inspiration in 2, 3 or 4 times). 3. Slow expiration through the mouth with pursed lips (in whistle form).
Short expiration	1. Slow and short nasal inspiration, expiring a small amount of air through the mouth with pursed lips (in whistle form). 2. Repeat until determined by the physiotherapist.
Inspiratory sighs	1. Short, forceful inhalation (nasal/mouth) until reaching the MBC without apnea. 2. Slow expiration through the mouth with pursed lips (in whistle form).
Active cycle	1. Diaphragmatic ventilation technique. 2. Any of the techniques mentioned above. 3. Cough. 4. Diaphragmatic ventilation technique.

Table 4.6: Description of techniques/exercises for lung re-expansion processes.

4.7 Bernoulli's Equation

Bernoulli's equation essentially states a conservative relationship between velocity, pressure and elevation of a flowing fluid.

$$P + \frac{\rho V^2}{2} + \rho g h = \text{constant, along a streamline}^4 \tag{4.1}$$

Equation (4.1) is the standard form of Bernoulli's equation [53], where ρ is the density of the fluid, V is its velocity, P is the static pressure and h is its elevation with respect to a reference

[4]Streamline is an imaginary curve in the field of a stationary flow that traces the path of a single particle within the flow, where the velocity vector at any point on the curve is always tangential to the curve [53].

point.

The terms of the equation assert that the sum of the static pressure P, the dynamic pressure $\frac{\rho V^2}{2}$ and the hydrostatic pressure $\rho g h$ are constant for a fluid flowing along a streamline (with special emphasis on the flowing characteristic since, when motionless, the fluid velocity is zero and the equation reduces to $\Delta P = \rho g \Delta h$, i.e., the hydrostatic equation [54]). Therefore, by examining this assertion, it is also possible to state that Bernoulli's equation is nothing more than a statement of the principle of conservation of energy [53], since its terms refer fundamentally to a gain in kinetic energy to increase the fluid velocity, and a gain in potential energy exerted by the fluid due to gravity, that come at the expense of the work done by the static pressure. The fig. 4.11 shows a standard representation of the relationship exposed by Bernoulli's equation:

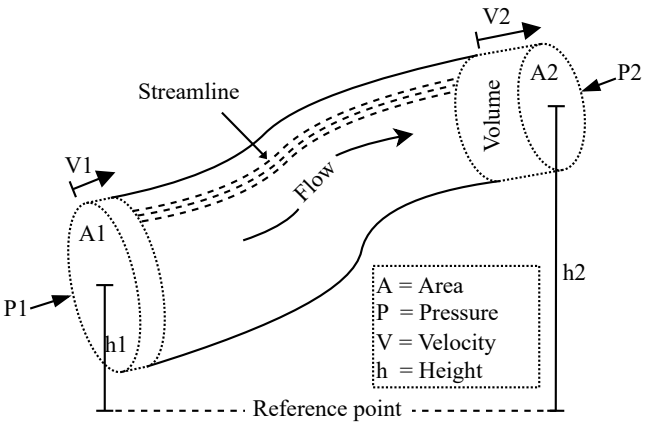


Figure 4.11: Representation of Bernoulli's equation in a pipe through which a flow passes.

At the same time, it is important to mention that this particular mathematical expression of Bernoulli is derived from the principle that bears the same name, which states the following:

> When an incompressible, smoothly flowing fluid gains speed, internal pressure in the fluid decreases and vice versa [54].

Since Bernoulli's principle can be applied to different types of fluids and in different environments, Bernoulli's equation can have complex and varied forms [53], and it should be noted that the standard form presented in eq. (4.1) involves certain limitations and considerations. Whether its standard expression is obtained by deriving the principle of conservation of energy, or from Newton's second law [54], the constraints that must be considered for the standard Bernoulli's equation to be valid are set out in the box 4.7-1.

Constraints and assumptions **4.7-1**

1. **Steady flow:** It must be assumed that the fluid does not vary with time, although this does not imply that the same conditions must be present throughout the entire flow field, but rather that the flow pattern is the same throughout the field, in other words, a laminar flow [53].
2. **Inviscid flow:** Throughout, it is assumed that the flow will have a viscosity coefficient equal to zero and, although this implies less accuracy, it is still possible to obtain sufficiently reasonable results when the problem at hand does not involve the interaction of the flow with certain regions of objects or circumstances where viscosity is an important aspect to consider [53]. Thus, when the fluid is air, for example, the assumption of non-viscosity is ideal since it behaves as such, nevertheless, when it interacts with some regions near the edges of a solid, the effects of its low viscosity can be appreciated [55].
3. **Incompressible:** It is assumed that the density of the fluid is always the same, so it does not consider its compression. When it comes to air, once again, it is a fact that it can be compressed, nevertheless, air compression occurs at considerably high velocities, so as long as it can be assured that the air flow will have sufficiently low velocity (close to half the speed of sound) then variations in air density will be negligible [53].
4. **No heat addition:** When heat is added to a fluid, its density characteristics may change, so it is assumed that the fluid density behaves over a constant temperature [56].

Thereby, keeping in mind the third assumption stated in box 4.7-1, eq. (4.1) can be expressed in an even simpler form by removing the small changes that exist with respect to the fluid density in every point of the streamline (see eq. (4.2)).

$$P + \frac{\rho V^2}{2} = \text{constant} \tag{4.2}$$

Now, when stating the constant equality of eq. (4.2), it is possible to rewrite it in another way, bearing in mind the graphical representation shown in fig. 4.11, since being constant implicitly relates an equality at all points of the streamline. Taking two points as reference, eq. (4.3) establishes the constant relation between two points with respect to incompressible fluids passing through a pipe.

$$\begin{aligned} P_1 + \frac{\rho V_1^2}{2} &= P_2 + \frac{\rho V_2^2}{2} \\ \frac{P_1 - P_2}{\rho} &= \frac{V_2^2 - V_1^2}{2} \end{aligned} \tag{4.3}$$

4.7.1 Bernoulli's Equation for Compressible Fluids

Although the assumption and limitation about certain phenomena in fluids simplifies calculations and can provide reliable results, modeling flow problems will not always allow such assertions to be made. It is important to remark that there are also other versions of Bernoulli's equation that can be applied to compressible and unsteady fluids.

When it comes to compressible fluids, the eq. (4.4) should be considered [53]. It is noticeable that, if the constraint of an incompressible fluid is applied, then the $\int_{P_1}^{P} dP/\rho = P/\rho$ and the equation turns into the standard form exposed above.

$$\int_{P_1}^{P} \frac{dP}{\rho} + \frac{V^2}{2} = \text{constant, along a streamline} \tag{4.4}$$

4.8 Flow Measurement

It is possible to perform both mass and volumetric[5] flow measurements, both concepts incorporating the same techniques for measuring flow with slight modifications, as well as their own compendium of techniques for obtaining the physical variable (more information in [57]).Accordingly, the development of this project will cover the joint use of the concepts associated with mass and volumetric flow measurement.

Among the most notorious techniques for volumetric flow measurement, it is possible to find principles such as differential pressure, variable area, velocity (as found in conventional anemometers) and force, among others [57].

With special emphasis on the differential pressure principle for volumetric flow measurement as being particularly sensitive and accurate [58], the *Orifice Plate* and *Venturi Tube* sensors are highlighted, which will be particularly considered in the development of this project.

Thereby, differential pressure sensors are based on Bernoulli's principle and its mathematical representation can be derived from Bernoulli's equation. The eq. (4.3) approached in section 4.7, is one of the fundamental equations to link the flow with the differential pressure principle since, considering that a volumetric flow Q_v through two points of the streamline is described as $Q_v = A_1V_1 = A_2V_2$ and therefore $V_1 = A_2V_2/A_1$, eq. (4.3) can be expressed as follows (considering $\Delta P = P_1 - P_2$ for simplification):

$$\frac{2\Delta P}{\rho} = V_2^2 \left(1 - \frac{A_2^2}{A_1^2}\right) \tag{4.5}$$

Considering that the cross-sectional area of the pipe/sensor is circular (as shown in fig. 4.11), A_1 and A_2 will be replaced by the area of the circle with diameter D and d respectively, yielding the following:

[5] While the mass measurement is based on the number of molecules in the fluid, the volumetric measurement is based on the space these molecules occupy. Both measurements are comparable when pressure and temperature compensations are included in the volumetric flow.

$$\frac{2\Delta P}{\rho} = V_2^2 \left(1 - \frac{d^4}{D^4}\right) \tag{4.6}$$

From here, it is possible to derive the fundamental equations for the description of the relationship between the flow and the differential pressure.

Taking the speed V_2 as main term:

$$V_2 = \sqrt{\frac{2\Delta P/\rho}{1 - d^4/D^4}} \tag{4.7}$$

Now solving the flow by $Q_v = A_2 V_2$, the following expression is drawn:

$$Q_v = A_2 \sqrt{\frac{2\Delta P/\rho}{1 - d^4/D^4}} = \frac{\pi d^2}{4} \sqrt{\frac{2\Delta P/\rho}{1 - \beta^4}} \tag{4.8}$$

Where $\beta = d/D$ is a ratio used as a parameter in sensor design. It is important to keep in mind that eq. (4.8) can be solved also for V_1 as main term.

Additionally, it should be noted that by not considering the compressibility of the fluid and the losses associated with friction, temperature, some experimentally determined correction factors must be added to eq. (4.8). Among the organizations responsible for the standardization of these factors are American Society of Mechanical Engineers (ASME), Association Française de Normalisation (AFNOR) and International Organization for Standardization (ISO) [57].

Laying a general foundation on the standardization provided by ISO, the ISO-5167 standard on *Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full*, establishes a guide for approaching flowmeters and is comprised of four parts:

Part 1: General principles and requirements.
Part 2: Orifice plates.
Part 3: Nozzles and Venturi nozzles.
Part 4: Venturi tubes.

In its first part, ISO 5167-1 describes the generalities that have already been addressed in the current section, in addition to considering two important factors that are added to eq. (4.8), which seek to compensate for losses due to fluid compressibility, the geometry of the sensor and the turbulence turbulence in relation to the Reynolds Number[6] in the pipe. These coefficients are: the discharge coefficient C and the expansion coefficient ϵ [59]. Consequently, the mass and

[6]Dimensionless number used in fluid mechanics, reactor design, and transport phenomena to characterize the motion of a fluid. Its value indicates whether the flow follows a laminar or turbulent pattern.

volumetric flow can be redefined as shown in eq. (4.10), considering $Q_v = Q_m/\rho$ as the ISO standard specifies the coefficients regarding the mass flow.

$$Q_m = \frac{C\epsilon}{\sqrt{1-\beta^4}} \frac{\pi d^2}{4} \sqrt{2\Delta P \rho} \tag{4.9}$$

$$Q_v = \frac{C\epsilon}{\sqrt{1-\beta^4}} \frac{\pi d^2}{4} \sqrt{\frac{2\Delta P}{\rho}} \tag{4.10}$$

It should be noted that the value of C and ϵ are values modeled on the basis of experimental tests and depend on the type of sensor to be implemented.

4.8.1 Venturi Tube Sensor

A Venturi sensor is basically a tube whose cross-sectional area has a decrease in area that is the smallest with respect to the dimensions of the other sections (see fig. 4.12). Flow is then obtained by measuring the pressure drop across the converging pipe section.

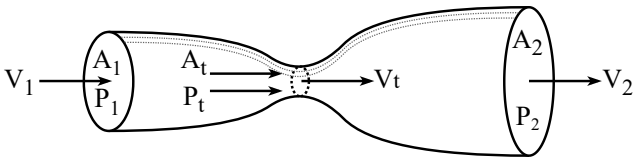


Figure 4.12: Venturi tube illustration without pressure taps.

The Venturi Tube is ideal for measuring flows that carry suspended solids (although they must not be abrasive). For this type of sensor, the pressure taps should be located in the convergent section of the tube and on the shorter side with respect to this section [57]. As exposed above, the ISO 5167-4 standardizes the design of Venturi Tube sensors based on the eq. (4.9) [60].

Thus, the standard defines the discharge coefficient C as constant, depending on the type of Venturi Tube design. This coefficient can be 0.984, 0.985 or 0.995 depending on the conditions and construction parameters of the pipe [60]. Moreover, eq. (4.11) describes the behavior of ϵ established by the standard.

$$\epsilon = \sqrt{\left(\frac{\kappa \tau^{2/\kappa}}{\kappa - 1}\right)\left(\frac{1-\beta^4}{1-\beta^4\tau^{2/\kappa}}\right)\left(\frac{1-\tau^{(\kappa-1)/\kappa}}{1-\tau}\right)} \tag{4.11}$$

It is important to mention that eq. (4.11) is valid only for fluids with an isentropic exponent κ determined, as is the case of air, steam or natural gas. The equation is also limited for values of P2/P1 greater than or equal to 0.75 and under specific conditions that can be checked in the standard ISO 5167-4 [60].

4.8.2 Orifice Plate Sensor

It is a sensor widely used for flow measurement of liquids and gases, characterized by being simple and robust, low cost, having an acceptable accuracy and not requiring calibration as long as the calculations and tolerances have been properly designed [57]. This type of flowmeter consists of a flow obstruction by installing a thin perforated plate inside a pipe (see fig. 4.13).

As the perforation in the plate can be located at different positions, as exposed in fig. 4.13, the selection of one of them depends essentially on the application and the composition of the fluid. On the one hand, the *Eccentric* and *Segmental* positions of the perforation in the Orifice Place are commonly used for applications whose fluids contain materials in suspension or steam condensate. On the other hand, *Concentric* types of Orifice Plates are recommended for clean and low-viscosity liquids, as well as for most gases and low velocity steam [57].

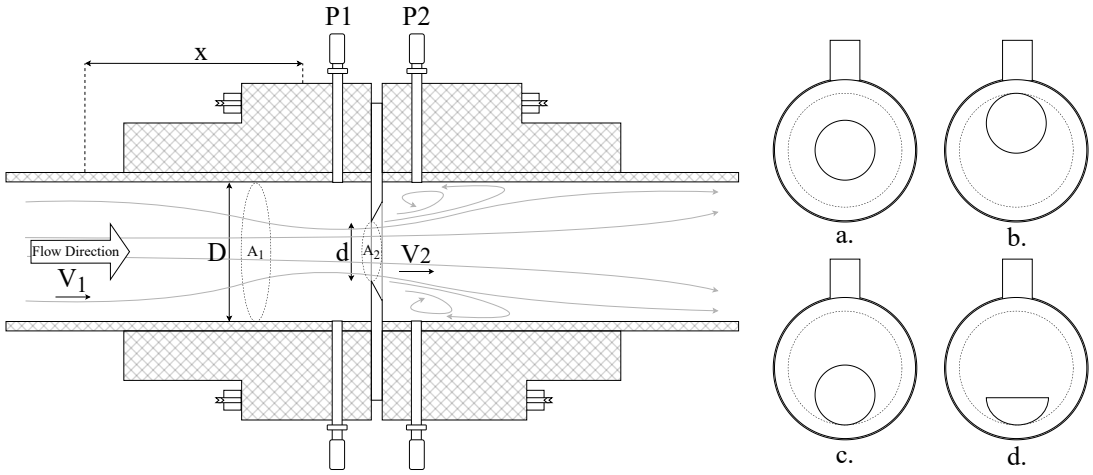


Figure 4.13: Orifice Plate structure. Perforation locations: (a.) concentric, (b.) and (c.) eccentric, (d.) segmental.

As mentioned above, the ISO 5167-2 supports the design of Orifice Plate sensors based on the eq. (4.9). The two coefficients addressed by the equation, C and ϵ, are modeled in the standard depending on the characteristics of the fluid and the structure of the Orifice Plate itself [61]. Thus, for the design of these sensors, the following is considered: the physical dimensions of the Orifice Plate, namely the diameters d and D, and the distances from the plate to the pressure taps P1 and P2, i.e., l_1 and l_2 respectively, as well as the viscosity μ of the fluid flowing through the tube. Bearing this in mind, eq. (4.12) comes to describe the behavior of the discharge coefficient C.

$$\begin{aligned} C = 0.5961 + 0.0261\beta^2 - 0.216\beta^8 + 0.000521\left(\frac{10^6\beta}{Re_D}\right)^2 + (0.0188 + 0.0063A)\beta^{3.5} \\ \left(\frac{10^6}{Re_D}\right)^{0.3} + (0,043 + 0,080e^{-10L_1} - 0,123e^{-7L_1})(1 - 0,11A)\frac{\beta^4}{1-\beta^4} \\ -0.031(M_2 - 0.8M_2^{1.1})\beta^{1.3} \end{aligned} \tag{4.12}$$

Where L_1, L_2, A, M_2 and Re_D bear the following expressions:

$$L_1 = \frac{l_1}{D}, \quad L_2 = \frac{l_2}{D}, \quad A = \left(\frac{19000\beta}{Re_D}\right)^{0.8}, \quad M_2 = \frac{2L_2}{1-\beta}, \quad Re_D = \frac{4Q_m}{\pi\mu D}$$

Finally, ϵ is determined by the eq. (4.13), which was determined experimentally in the standard, and is valid only for fluids for which the *isentropic* exponent κ has been determined, as is the case of air, steam or natural gas. It is important to mention that ϵ is limited to modeling values of P_2/P_1 greater than or equal to 0.75.

$$\epsilon = 1 - (0.351 + 0.256\beta^4 + 0.93\beta^8)\left(1 - \left(\frac{P2}{P1}\right)^{1/\kappa}\right) \tag{4.13}$$

4.8.3 Root Mean Square Error

The Root Mean Square Error (RMSE) measures the average difference between two data sets. It is usually applied for the comparison of a set of known or certain data and a set of measured data. In turn, it us used as a standard statistical metric to measure model performance in many fields of study [62].

The RMSE is defined mathematically as follows:

$$RMSE = \sqrt{\frac{\sum_{i=1}^{N} |x_i - y_i|^2}{N}} \tag{4.14}$$

Where x and y are the two vectors to be compared with a length N.

Chapter 5

Methods and Materials

The development process of the electronic system for monitoring the physical variables involved in the physiotherapy processes will be covered. For the sake of conducting a structured and deductive implementation, whose results can be effectively integrated into the comprehensive external project, a conscious use of the methodology proposed by TRIZ will be made, with certain essential nuances of Design Thinking, in order to achieve a systematic approach to the problem that leads to inventive and innovative implementations. At the same time, the Axiomatic Design and the decision methodology proposed by the AHP will be of crucial support in the selection of the devices suggested by the outcomes of the systemic analysis, so that sensible decisions can be addressed based on weighty criteria for contextual implementations. Meanwhile, Bernoulli's aerodynamic theory along with standardizations also support the development of the models for capturing the physical variables involved in the breathing process.

Last but not least, it is worth highlighting that some of the local developments will be closely related to materials, results and approaches obtained in different units of the comprehensive external project framework throughout its work, leading to the integration of transdisciplinarity and inter-institutionality. Although the results to be obtained with the development of this local project are closely related to the progress of the external project, it is important to differentiate them carefully, since they are not the same, and the local work will correspond only to the developments in the monitoring system. It is important to point out that each section covered here will implicitly address the specific objectives stated in chapter 2 on page 4.

5.1 TRIZ Method

Approaching the breakdown of the problem from the TRIZ methodology framework will require a judicious initial formulation of the problem, which will lead to a well-founded systemic analysis. Thus, it is possible to point out that the basis of the problem lies in the need to support the recovery process of patients with sequelae of pulmonary diseases, who undergo treatment with lung re-expansion physiotherapies, through an electronic monitoring system that is able to offer better characteristics than those obtained with the currently used devices. It is worth mentioning that the subsequent integration, within the framework of the external project, of the electronic solution obtained with this development, will mainly seek to solve the problems of adherence to the physiotherapies and provide information on the patient's performance throughout the recovery process.

Having defined the problem to be addressed, the abstraction process shown in the fig. 4.1 on page 9 follows, which proposes the identification of the representative view of the TS. Before proceeding, it should not be forgotten to establish the definition of the Main Function performed

by such system, which will be essentially to monitor the variables of inspiratory and expiratory flows and volumes involved in the physiotherapy processes of lung re-expansion, providing feedback and adherence to the patient. As a reference TS that responds to the Main Function, we will take one of the most common commercial systems for hospital use in Colombia, the *Triflo* incentive spirometer (see fig. 3.3 on page 7), although the volume monitoring feature can be referred in the same way to the *Voldyne* exerciser.

As regards the definition of the components of the TS, based on box 4.1-1 on page 10, the following has been established:

> **Engine:** Respiratory system (refer to section 4.5).
> **Transmission:** Spirometer structure, i.e., air duct.
> **Working tool:** Internal spheres that vary in height with respect to a reference point.
> **Control:** Central nervous system (visual system).
> **Casing:** Inner walls of the device.

With the TS delimited (also shown in fig. 5.1), the systemic analysis through *nine-window analysis* is carried out as a fundamental means to determine the complexity of the problem and its most substantial attributes, as well as the evolution of the TS itself in completeness.

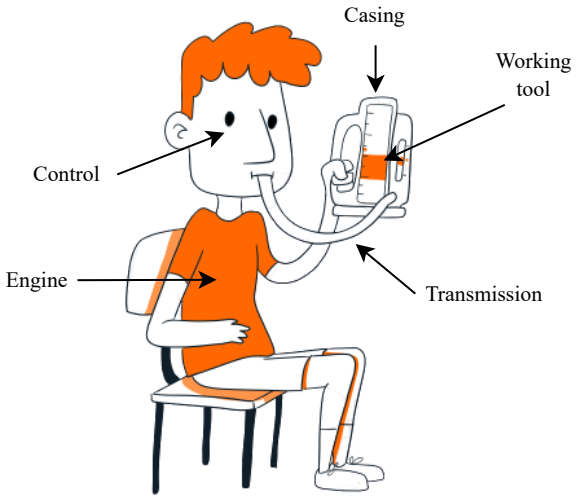


Figure 5.1: Graphical representation of the technical system.

5.1.1 Systemic Analysis

Starting from the reference TS and the Main Function linked to its operation, we first postulate the definition of the temporal windows of present and past in all their spatial stays (following the numerical proposition of fig. 4.3 on page 11), i.e. the known field of the components of the problem, to then get into detail on the hypothetical windows of the future.

Analysis of the Present

(W1). **System:** Within the framework of the reference TS, there are currently conventional pneumatic systems used in hospitals. The aforementioned *Triflo* and *Voldyne* spirometers are a clear reference. These incentive support equipment have, among their most notorious characteristics, low acquisition costs and wide availability in the market, making them easily accessible for both patients and physiotherapists. Their designs are not excessively complex, since they have generic mouthpieces that can generate discomfort at the time of use. Although they include simple visual feedback for the patient, their purpose is to serve as flow or volume meters, rather than as incentives or informative elements about the performance of the physiotherapies. Nevertheless, they are comfortable and easy-to-use devices that do not require external power sources or calibration systems.

Moreover, despite the high costs already mentioned, there are also devices that offer more advanced features for the common purpose of supporting respiratory physiotherapies. *Breathacise*, *Silverfit-Flow* and Spirobank Smart spirometry devices (see chapter 3 State of Art for more information about them) are well suited to this purpose, despite their low presence in Colombian health centers.

(W2). **Supersystem:** Regarding the supersystem associated with the present time, special mention should be made of incentive spirometry as a totalizing component. Incentive spirometry is a non-invasive approach to respiratory physiotherapy to prevent and recover pulmonary complications by promoting controlled inspiration with patient-friendly methods. Meanwhile, with respect to incentive spirometry, it is known that its effectiveness has a strong dependence on adequate and carefully patient instruction and supervision by health personnel or other caregivers [4], in such a way that it is possible to improve many of the consequences caused by pulmonary diseases and have prompt recovery. Nevertheless, when incentive spirometry is performed with insufficient instructions or by self-administration without the necessary knowledge, it can result in pulmonary complications, so it is not recommended to practice it without professional supervision.

Being part of the present supersystem, the spirometry incentive also encompasses the necessary equipment and resources for its execution, i.e. spirometers, the export and import of support equipment for physiotherapies and the production lines for this equipment. Nevertheless, the current challenging circumstances regarding the actual effectiveness of equipment and resources for physiotherapy processes with spirometry have increased the importance of looking for ways to substantially improve and support these processes, alleviating the burden of the disease for both patients and healthcare personnel.

It is also possible to harbor some nuances of respiratory diseases in this supersystem, as the existence and constant evolution of these diseases make the use of physiotherapy support equipment imperative. To provide a brief example, the pandemic due to the recent coronavirus (SARS-CoV-2) declared by the World Health Organization on March 11, 2020, has brought millions of deaths and negative consequences worldwide, resulting in high mortality associated with viral infections due to Severe Acute Respiratory Syndrome (SARS). In this sense, the coronavirus pandemic is a very recent case in which

pulmonary diseases force to modify the methods to counteract the sequelae in patients. At the same time, the growth of respiratory diseases has increased the importance of new technologies capable of managing recovery from pulmonary failure. Consequently, the timely recovery of the health of patients has posed enormous challenges to global healthcare systems, including promoting the adherence of patients to prescribed treatments through incentive procedures [63].

Additionally, it is also worth mentioning that one element of the present supersystem is the Sustainable Development Goals (SDG) of the United Nations Development Program, of which the one related to *Good Health and Well-being* stands out in this regard. This goal in particular mentions that good health is fundamental for sustainable development, in addition to the fact that health coverage must be comprehensive and without inequality [64].

(W3). **Subsystem:** As part of the present subsystem, it is possible to determine the components of the current system, namely the plastic materials that make up the walls, spheres and ducts of the device. At the same time, the markers made for the measurement of flow or volume variables, and the brief user's manuals are part of these components. As mentioned previously, their design and structure are not essentially complex, since the elements that make up their subsystem can be easily differentiated without disassembling the equipment.

The move towards the digital and electrical domain in other versions of the current system has brought with it the integration of various sensor and microcontrolled systems, becoming part of the current subsystem as well. Frequent use of differential pressure and hot-wire sensors can also be observed nowadays in respiratory flow monitoring systems. Turning a blind eye to the high monetary costs and just to provide an example, hot-wire sensors are modern solutions that deliver digital and fully calibrated output signals, avoiding the use of signal conditioners or analog-to-digital converters (ADC). At the same time, hot-wire sensors allow flow readings in both directions without major complications in their implementation [65]. It is also worth mentioning that, currently, many of the respiratory flow measurements are hampered by constant changes in humidity or temperature, as well as by contamination of the tubing or expiratory sensors with sputum, pathogens and blood.

In turn, the various techniques that exist for the measurement of respiratory flow are part of the subsystem. Although the development of the project will only cover the direct flow method by differential pressure, it is important to know some of the other techniques to obtain this variable in spirometry. Figure 5.2 summarizes these techniques, which range from those based on direct air flow, through sound measurement, air temperature, humidity, chemical components of the air, chest movements, and even those obtained by modulation of cardiac activity [58]. Each of them is associated with a certain sensor or measuring device with which the direct or indirect measurement of respiratory flows and volumes can be carried out.

The subsystem also includes physiotherapies, i.e., the actual procedures carried out in order to recover the pulmonary functionality of patients (refer to section 4.6). These

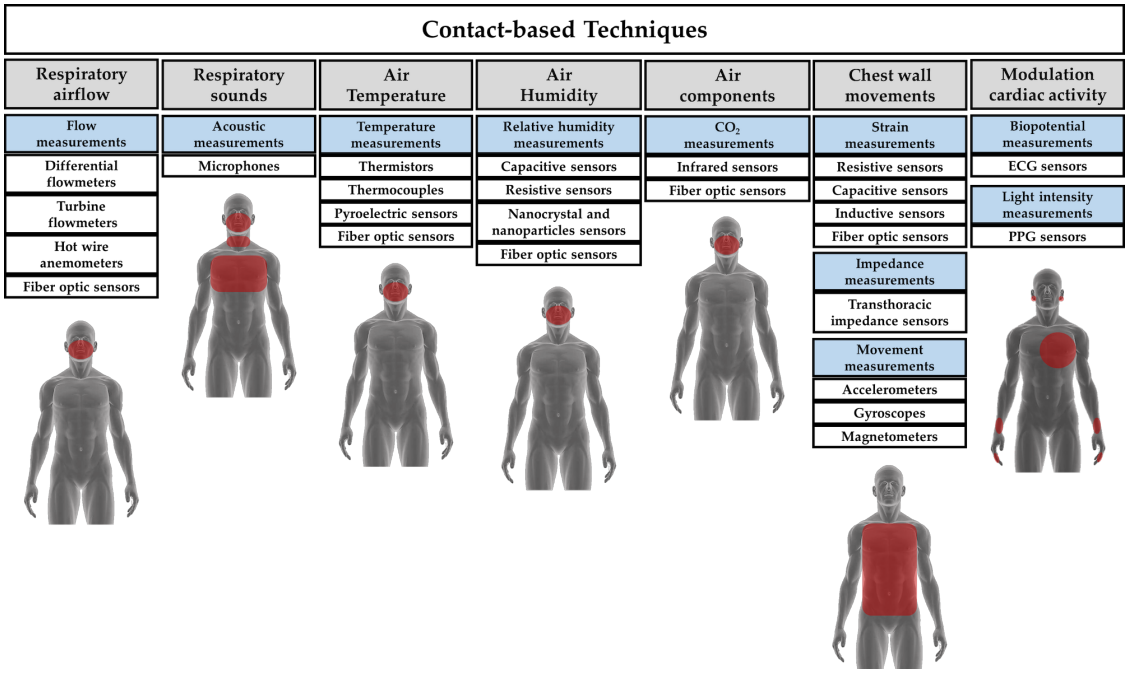


Figure 5.2: Most popular techniques for measuring respiratory flow. Figure taken directly from article in reference.
[58]

physiotherapy processes fundamentally require the assistance of a physiotherapist and the evaluation of the patient's progress based on the performance and evolution of the treatment. Currently, physiotherapy processes for pulmonary rehabilitation are done through individualized treatment in patients after making detailed evaluations. Most physiotherapies are based on physical training, in addition to having psychological and nutritional support. This approach aims to improve physical and mental conditions and early family reintegration after recovery from the aftermath of pulmonary diseases [3]. Hence, respiratory physiotherapy processes play an important role in the timely and effective recovery of patients, by deploying a compendium of special techniques that help the progressive improvement of patients [4].

Analysis of the Past

(W4). **System:** Besides the classic *Therapeutic Incentive Spirometer* mentioned in chapter 3 State of Art (which is hardly different from the current *Triflo* spirometer), in the past it was common to use *Peak-flow* meters, a device that measures flow in patients by means of a pneumatic indicator that is driven by expiring through a mouthpiece.

Although peak-flow meters provide reliable information on lung function, the quantitative measurement of flows and volumes involved in the physiotherapy process is still approximate and prone to errors when using this device, which is not a calibrated equipment, so that the use of different devices of the same class under the same conditions may lead to different measurements [66]. Nevertheless, the peak-flow meter has the advantage

of being easily used anywhere and at any time, since it is an easy to find and disposable device. It is also important to note that this device does not provide the patient with useful information on his or her evolution, and therefore does not offer any kind of user adherence to physiotherapies.

(W5). **Supersystem:** On the one hand, high levels of pollution associated with lung diseases occupy a notorious position within the supersystem of the past. Highly polluting factories that depreciate air quality are elements that, although strongly pronounced in the past, continue to do so even today with enormous repercussions on health.

On the other hand, the limited coverage of health systems for respiratory physiotherapy rehabilitation services in Colombia, including the low popularity of these services in the private sector, could be framed within this supersystem.

(W6). **Subsystem:** The peak-flow meter is made of plastic materials, is simple and portable. Despite its disadvantages, this equipment can still be used nowadays to test the success of physiotherapy treatments against acute diseases [66]. It usually has green, yellow and red markers (although the colors may vary) to indicate flow intensity levels so that the physiotherapist in charge can make pertinent decisions.

There are also records that in the past rotameters were used as components to measure volumetric flows of gases administered in anesthetic ventilators. These devices consisted of a cylindrical float, generally denser than the fluid with which it was planned to work, placed inside a vertical conical tube. As the flow passed from bottom to top, the cylindrical float was lifted, providing a flow measurement proportional to the variation of its height [57].

Meanwhile, in the 1990s electromechanical flow sensors for spirometry could also be found. A great example of this is the 1996 patent *Electronic Pocket Spirometer* [10], which makes use of an encoder as a sensor for flow and volume measurements (see fig. 5.3). Back then, there were devices that operated on mechanical and pneumatic principles, coupled to certain electronic attachments, such as displays for data visualization.

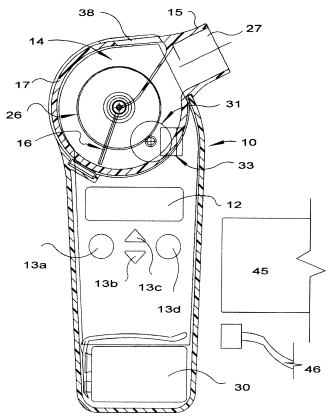


Figure 5.3: Front view of the patented Electronic Pocket Spirometer. [10]

As for physiotherapies for pulmonary re-expansion, they are maintained in the same conditions as those exposed in the present subsystem, being conformed by health systems and rehabilitation centers.

Analysis of the Future

The systemic analysis of the future must begin with an overview of the supersystem and conclude with the ideality of the system in the future in order to abstract the hypothetical problem domain and define its attributes, naturally, in a merely imaginary context.

(W7). **Supersystem:** Within the subsystem of the future, it is possible to propose an inclusion of the Industry 4.0 concept within incentive spirometry, corresponding to a significant impact on the development of physiotherapy support systems for pulmonary rehabilitation. The added value that Industry 4.0 brings to the production of devices to support physiotherapies could improve the adoption and adherence of patients and physiotherapists to their treatments, as well as the quality and quantity of features of the devices.

Likewise, it is possible to think that actions against air pollution will be better considered by the world community, leading to substantial improvements in air quality and therefore a decrease in respiratory diseases.

Although it can currently be seen in some health centers, the adoption of personalized care for patients undergoing physiotherapy by health systems could be a key element in the effectiveness rates of treatments.

(W8). **Subsystem:** Reusable and easily sterilizable materials, as elements of the subsystem for supporting equipment, can play an important role in both cost reduction and environmental impact.

In addition, an interesting component could come with the inclusion of wireless communication and/or cloud-based storage of the patient's progress in physiotherapy treatment, so that healthcare professionals can keep track of the progress of their patients without them having to come to the medical center.

Regarding sensor and measurement systems, one could think of easily calibrated elements that meet the objectives of monitoring accurately, resulting in reliable results. In turn, it would also be possible to think in terms of reducing the energy consumption of electronic systems as an ideal feature of the support devices.

(W9). **System:** Regarding the system in the future, ideally we would postulate the updating of the support equipment for lung re-expansion physiotherapies towards more technological systems, which would allow the adequate monitoring of the evolution of the patient in the treatment and provide useful information to both the patient and the physiotherapist about the performance. Proposals such as this could be achieved through the integration of microcontroller units, reliable sensor stages (such as those approached by differential pressure sensors and transducers), data storage/transmission for later analysis, the possibility of remote care and easy accessibility for people without the need for invasive or costly procedures, mobile phones and graphic interfaces to the systems, among others.

Having gone through each of the spatio-temporal windows proposed by the TRIZ methodology, which can be summarized as shown in fig. 5.4, it is now possible to determine the key attributes between the present system and its ideal counterpart.

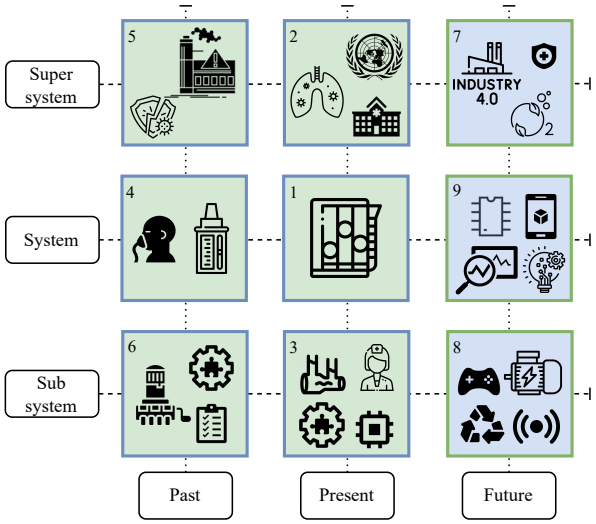


Figure 5.4: Graphical representation of the conducted systemic analysis.

5.1.2 System Attributes

With the thorough analysis of the nine windows, it is possible to determine the characteristics or attributes of both the current TS taken as a reference and the ideal system as the basis for the design to be achieved.

Present System Attributes

Triflo and/or *Voldyne* reference systems currently have the following most prominent attributes:

- Low cost and easy access.
- Does not require electrical power sources.
- Not clear or sufficiently accurate in its measurements.
- Low level of feedback.
- Does not require calibration.
- Does not allow the physical therapist to follow up without being present.
- Uncomfortable.
- Disposable.
- For inspiration only (exclusive).

Future System Attributes

After going into detail among the different space-time windows, several attributes were defined for the ideal system, from which the following were derived:

- Accurate and reliable measurements.
- Flow, volume and respiratory rate measurement in the same device.
- Technological attachments for data transmission.
- Bidirectional flow measurement, i.e., inspiration and expiration.

Hint: attributes such as providing better patient engagement and effective patient feedback, comfortable and ergonomic handling, patient orientation and data storage, among others, are not within the scope of the local project but in the external one, as the development of this project (particularly in the area of the electronic device) will implicitly help to reach them in future work.

At this point, the contradictions that arise when evaluating the transition between the attributes of the present system and the hypothetical system shall be analyzed.

5.1.3 Identification of Contradictions

Regarding the contradictions, it is necessary to analyze the way in which the ideality of the attributes of the future system is affected when they are desired to be fulfilled from the perspective of the reference TS, considering that this analysis will serve as a basis to solve those affectations and provide design alternatives from an inventive perspective.

First Contradiction

If more accurate and reliable measurements are desired, the TS could adopt alternative forms of measurement, but in doing so it becomes more difficult to control and put into operation.

Therefore, the parameters proposed by the TRIZ methodology (refer to table 4.2 on page 12) that are related in this contradiction are: *Accuracy of Measurement* (28) as an improving element and *Complexity of Control* (37) as a worsening element.

By using the *contradiction matrix*, the conflicting parameters give rise to the following inventive principles:

- **Use copies (26):** Use unexpensive and simple copies.
- **Mediator (24):** Use an intermediary carrier article or process; merge one object temporarily with another.
- **Changing the Color (32):** Change the color of an object or its external environment.
- **Replacement of Mechanical System (28):** Replace a mechanical means with a sensory means; use electric, magnetic or electromagnetic interactions; change unstructured to structured fields.

Upon reviewing the description of each principle provided by the *contradiction matrix* (here and in the forthcoming contradictions, brief fragments of the principles extracted from Savransky [28] are shown), the principle that allows addressing the contradiction is number 28, since it suggests changing the measurement mechanics of the physical variables of the current system for ones that make use of electrical transducers whose implementation is not excessively complex.

Second Contradiction

If it is desired to determine flow, volume and respiratory rate in the same measuring device, the input of the TS might be connected to an instrument that allows the capture of the three variables at the same time, but in doing so, the system would become more complex as it involves more elements to handle.

Now, the parameters proposed by the TRIZ methodology that are related to this contradiction are: *Level of Automation* (38) as an improving element and *Complexity of Device* (36) as a worsening element.

By using the *contradiction matrix*, the conflicting parameters give rise to the following inventive principles:

- **Dynamics (15):** Allow or design the characteristics of an object, environment or process to change to be optimal or to find an optimal operating condition; divide an object into parts capable of movement relative to each other.
- **Mediator (24):** As described above.
- **Prior Action (10):** Perform, before necessary, a required change of an object; pre-arrange objects so that they can act without losing time.

In reviewing the description of each principle yielded by the *contradiction matrix*, the principle that allows addressing the contradiction is number 24, since a microcontrolled system can be used as a mediator between the acquisition and internal processing of the data, so that the respiration variables involved in the physiotherapy processes can all be carried out by a microcontroller and without additional human/device intervention.

Third Contradiction

If technological attachments for the transmission of the measured data are desired, the system could include an integrated wireless transmission system, but in doing so the system would need more parts and more steps to link the transmission to a receiving device.

In turn, the parameters proposed by the TRIZ methodology that are related to this contradiction are: *Productivity* (39) as an improving element and *Manufacturability* (32) as a worsening element.

By using the *contradiction matrix*, the conflicting parameters give rise to the following inventive principles:

- **Transformation of an Object States (35):** Change an object's physical state, concentration, consistency or degree of flexibility.

- **Mediator (24):** As described above.
- **Extraction (2):** Separate an interfering part or property from an object, or single out the only necessary part.
- **Replacement of Mechanical System (28):** As described above.

Checking the description of each principle given by the *contradiction matrix*, inventive principle number 24 may help to resolve the contradiction, since it is possible to use an intermediary element such as a mobile phone to receive the data wirelessly from the transmitting measuring device, avoiding the inclusion of an additional receiving device.

Fourth Contradiction

If bidirectional operation is desired, the system would have to contemplate a differential pressure flow sensing technique (fixed due to the scope of the project), but doing so would increase the design complexity of the device as differential pressure sensors are built with specific parameters and considerations.

For this last contradiction, the related parameters proposed by the TRIZ methodology are: *Adaptability* (35) as an improving element and *Complexity of Device* (36) as a worsening element.

Using once again the *contradiction matrix*, the conflicting parameters give rise to the following inventive principles:

- **Dynamics (15):** As described above.
- **Pneumatics or Hydraulic Construction (29):** Use gas and liquid parts of an object instead of solid parts; use Archimedes forces to reduce the weight of an object; use negative or atmosphere pressure.
- **Thermal Expansion (37):** Use thermal expansion or contraction of materials.
- **Replacement of Mechanical System (28):** As described above.

This time, when reviewing the description of each principle yielded by the *contradiction matrix*, principle number 15 allows addressing the contradiction from the perspective that, the characteristics of the flow sensor are designed in advance so that it has an optimal performance and can be easily implemented.

5.2 Requirements and Design Alternatives Through Axiomatic Design

As a nod to *Axiomatic Design*, the requirements and design alternatives are established in a general way, which will consider each of the inventive principles extracted from the TRIZ methodology for the consistent proposal of each alternative.

Requirement N°1: To measure the inspiratory and expiratory flow variable.
Requirement N°2: To transduce measurement data.
Requirement N°3: To process measurement data.
Requirement N°4: To transmit measurement data wirelessly.

Along with the definition of the fundamental requirements for the ideation of the device, certain considerations are to be considered during the whole design process, since they are either a fundamental part of the scope established for the local project or directly inferred from the working field and/or by the main parties involved (see section 5.4 for archetypes). Accordingly, in fig. 5.2 it has been seen that there are currently many more techniques for the acquisition of this physical variable, but differential pressure has been considered as the only option within the initial scope of the local project since, by means of this principle, it is possible to avoid some inconveniences obtained with other techniques such as those using turbines or temperatures, whose data acquisition is linked to *excursions* of the variable due to physical effects of inertia; or even those using chest movements or modulation of cardiac activity, whose use, in addition to being significantly more invasive, requires larger budgets for their implementation compared to obtaining the flow variable by pressure difference. Meanwhile, design ranges also come into play, which will be of weight in the choice of alternatives.

5.2.1 Design Ranges

Three fundamental design ranges have been established, covering flow measurement, transduction and data transmission:

1. Regarding the design ranges of the respiratory flow measurement (for the volume variable it is not necessary to establish a range), it is possible to establish them in at least two ways:

   - The first is to take as the maximum flow measurement range the reference TS range, which currently guarantees a flow measurement of 1200 cc/s, i.e. about **1,2 L/s.**
   - The second is to go directly to the regulations and recommendations for spirometry devices: the SEPAR regulation for spirometry (taken as reference) state the following [52]:

Parameter	Range	Accuracy	Flow Range
SVC	0,5-8 L	± 3% of the measurement or 0,05 L.	0-14 L/s
FVC	0,5-8 L	± 3% of the measurement or 0,05 L.	0-14 L/s
FEV	0,5-8 L		0-14 L/s
PEF		± 10% of the measurement or 0,30 L.	0-14 L/s

Table 5.1: Minimum specifications to be met by a spirometer. [52]

Table 5.1 which contains a portion of the minimum specifications that a spirometer must meet according to SEPAR regulation, shows that for expiratory flow (which

is normally greater than inspiratory flow and is therefore taken as the prevailing variable) the range is between **0 to 14 L/s**, something that can be easily evidenced in pneumatic devices such as the *Peak Flow Meter*. The application of SEPAR regulation regarding the flow range to be addressed can also be seen in the maximum average biological ranges, where the normal PEF is 7,5 to 11,6 L/s for men and 5 to 8,3 L/s for women [67].

There is therefore a disparity between the range offered by the TS device and the ranges established for spirometry devices by SEPAR regulation, nevertheless, it is important to bear in mind that the reference device is intended for use with people with reduced lung capacities, making it a difficult task for patients requiring physiotherapy to achieve even a flow rate of 1.2 L/s, since diseases reduce PEF values.

Although it is not necessary, since the volume can be extracted by integrating the flow without the need for additional equipment [52], the SEPAR regulation also establish a range for volume measurement, where it is suggested that volumes close to 8 L should be guaranteed, something that can also be seen in fig. 4.10 on page 24, but which in practice is difficult to achieve, since 5 L are almost never exceeded.

2. Regarding the design range for the differential pressure transducer to be chosen, it could be tailored in the first instance to the maximum inspiratory and expiratory pressures for measuring devices, the source of which could come directly from the *ATS/ERS Statement on Respiratory Muscle Testing* [68] and the *ARTP Statement on Pulmonary Function Testing* [69].

   In particular, the 2001 ATS/ERS Statement establishes that piezoelectric pressure transducers (see box 5.2-1 to get information about this class of devices) for inspiratory and expiratory pressure measurements should have a range of **±19,6 kPa** and an accuracy of 0,049 kPa, although it specifically states that the required range and *sensitivity of the transducers depends fundamentally on the respiratory test.* Delving a little deeper into the ATS/ERS Statement, it can be found that these values are actually for specific tests of the muscles involved in breathing that are measured directly at the mouth (also addressed in ARTP Statement), where the peak expiratory and inspiratory pressure values for men range from 23,4 ±45 kPa to 12,7 ±3,1 kPa respectively and for women from 16,1 ±2,9 kPa to 9,6 ±2,4 kPa respectively. Therefore, since these values are for devices that test pressures directly in the mouth, it is `not appropriate` to take them as ranges for this project.

Piezoelectric transducers **5.2-1**

These are devices that use the *piezoelectric effect* to capture changes in physical variables such as pressure, acceleration, strain or temperature and transduce them into electrical signals. The *piezoelectric effect* or *piezoelectricity* refers to the appearance of positive and negative charges in different parts of crystalline materials when external forces and deformations are applied [70].

Nevertheless, the same ATS/ERS Statement says that patients with pulmonary deficien-

cies and weaknesses cannot exceed **±1,5 kPa** in spirometry tests, so this range could be included within the possibilities. In turn, the ARTP Statement of 2020, a little more recent, mentions that measurements of expiratory and inspiratory pressures should not exceed **±1 kPa** for measurements of the variable not in the mouth directly but through mouthpieces.

At the same time, to address the low cost constraint, a transducer voltage range up to 5 volts is established.

3. Regarding data transmission, the ARTP Statement establishes that in order to provide an accurate representation of the data it is necessary that the sampling frequency of the system is at least **100 Hz**, i.e. 100 samples per second.

5.2.2 Design Alternatives

Having established the above through a structured and well-founded analysis, the alternatives considered to meet the requirements and design ranges are listed below, as well as the selection criteria used, which will be of vital importance at the time of decision making through the AHP.

For the measurement of the **inspiratory and expiratory flow variable**, according to differential pressure principles, the following implementation alternatives have been proposed:

- *Venturi Tube sensor* (refer to section 4.8.1 on page 33).
- *Orifice Plate sensor* (refer to section 4.8.2 on page 34).

Now, with regard to the **transduction of physical signals**, considering the established design ranges, as well as the whole ideation process, the alternatives that have been derived for the implementation are the following:

- *Differential pressure transducer MPXV7025DP* [71]: It is a state-of-the-art piezoresistive differential pressure transducer designed for a wide range of applications involving microprocessors with A/D inputs. It is particularly designed to measure positive and negative pressures with an offset of 2,5 V ideally, instead of 0,0 V as with other transducer series such as the *MPX5010DP*. The measurement range of this transducer is ±25,0 kPa with a maximum error of 5,0% under normal temperature conditions. Aditionally, its response time is 1,0 ms. The selling price from its official distributor (NXP Semiconductors) is 24,62 USD per unit for Colombia. Shipping time depends on the region of destination, but it takes around 52 weeks from manufacture to home if there is no stock, although if there is, the time is reduced because the shipment is immediate. Figure 5.5 shows a general outline of this transducer series.
- *Differential pressure transducer MPXV7002DP* [72]: The features and details of this differential pressure transducer are similar to the *MPXV7025DP*, although this time designed to measure ±2,0 kPa, i.e. a smaller range that better fits the considerations made on the design ranges. Its accuracy is also 5,0% under normal temperature conditions and its response time is also 1,0 ms. From its official distributor it costs around 25,20 USD per

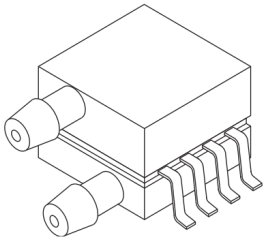


Figure 5.5: Outline package of the differential pressure transducer. [71]

unit, but its availability is usually limited and shipments for Colombia are from 25 units and up.

- *Differential pressure transducer XGZP6897D* [73]: It is a silicon pressure transducer that provides a digital IIC interface for differential pressure readout. In addition to incorporating a piezoresistive sensor, it provides an Application Specific Integrated Circuit (ASIC) for signal conditioning. This transducer is fully calibrated and robust, satisfying temperature compensations, sensitivity and non-linearities. Its special features make it ideal for applications in medical equipment such as ventilators, breathing machines, *spirometers* and air monitors, among others. The available pressure span includes several ranges, not a specific pressure range, which is stated in its datasheet as -100,0 kPa $\cdots$ -0,5 $\sim$ 0 $\sim$ 0,5 $\cdots$ +200,0 kPa, with a 5,0 V voltage source. Its accuracy is $\pm$2,5% and the resolution of the integrated ADC converter is 24 bits. Moreover, its response time is 2,5 ms. From its official distributor, the price could not be known as it needs a quotation, but from external suppliers it can be found at an approximate price of 15,41 USD to Colombia, although shipping takes between two and three months.

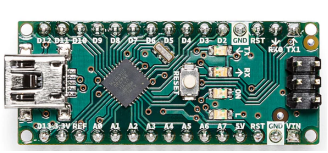
Now, as for the **processing system**, the following options have been chosen, considering the speed and ease of acquisition and initial prototyping, as well as their integration into the formal device when passing the prototyping process (promotional views can be seen in fig. 5.6):

- *Arduino Uno*: It is a microcontroller board operating at 5,0 V, with 14 digital input/output pins, 6 analog inputs and a working frequency of 16 MHz. The resolution of the ADC is 10 bits, so it will be able to detect changes in the analog inputs of about 4,9 mV. Its current consumption is about 45 mA in standby mode. Nevertheless, its size is much larger than the other options listed below, as its board dimensions are 53,4 x 68,6 mm.

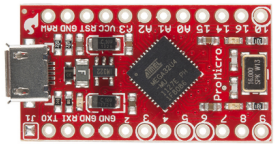
- *Arduino Nano*: It is a small microcontroller board that also operates at 5,0 V, with 22 digital input/output pins, 8 analog inputs and a clock frequency of 16 MHz. It also has a 10-bit resolution, detecting 4,9 V analog changes. It consumes around 15 mA in standby mode. In terms of size, its board is smaller than the Uno version, with 18 x 45 mm.

- *SparkFun Pro Micro*: This board is similar to Arduino microcontroller boards and can also become compatible with their coding, its costs are slightly lower than its counterparts while its dimensions are 17,7 x 33,0 mm. It has 12 digital input/output pins and 10 analog inputs, and its operating specifications are 5,0 V at 16 MHz. Like its Arduino counterparts, the SparkFun Pro Micro features 10-bit resolution for its ADC.

- *National Instruments DAQ*: This Data Acquisition (DAQ) board is useful when fast prototyping in combination with NI LabVIEW software, as it allows adding certain features to the acquired electrical signals and integrating the processing results with graphical interfaces.



(a) Arduino Nano [74]



(b) Sparkfun Pro Micro [75]

(c) NI DAQ [76]

Figure 5.6: Commercial views of processing devices.

Regarding **data transmission** and considering that almost all devices can currently comply with the established design range, the proposed design alternatives are presented. It is necessary to consider one of the inventive principles of solution that resulted from the TRIZ analysis, where it is suggested that the data reception is done through a mobile device cell phone, so the proposals for data transmission must be able to be paired with these devices.

- *Bluetooth Module HC-05*: A practical module that allows the connection between two devices by means of a serial communication that operates between 2,402 and 2,480 GHz, following the Bluetooth modulation format, where the data is fragmented and then sent in packets. The use of these devices allows low power consumption, although it depends on the communication rate configured.
- *ESP8266 Wi-Fi module*: It is a low-cost microchip that enables connection to Wi-Fi wireless networks via TCP/IP networking software. Although it is a microchip with a 32-bit RISC architecture that allows power saving, its power consumption for small applications remains high when active, often requiring reactive circuits to guarantee the power needed for communications.

Upon the **reception of the data**, an investigation of which mobile devices could be proposed as alternatives for implementation has been carried out. Evaluating in the first instance the statistics of the DANE technical bulletin on quality of life, by 2018 more than 88% of people in Colombia had a cell phone as a mobile device, whose pattern does not show significant changes over the years [77].

With this in mind, it is necessary to determine which type of mobile device is the most

common in Colombia in order to subsequently search for suitable alternatives. *Hootsuite* and *We Are Social* companies provide a yearly statistical report on the digital area in several countries, including Colombia. For the year 2021, it was reported that in Colombia more than 97% of the population between 16 and 64 years old has a smartphone compared to 13% who have normal cell phones [78].

Now then, regarding the question of which smartphone to choose for the first implementation and prototyping tests, it has been found that in Colombia there is a preference for mid-range devices of 68%, above the high and low range [79], so these types of devices will be ideal for prototyping.

5.3 Decision-making for Implementation

The methodology proposed by AHP will serve as a support to make decisions concerning the choice of equipment and elements in the implementation of the system, since all of the proposed design alternatives meet the design ranges of the requirements and, as each of them is a suitable option, it is necessary to involve value criteria to make a decision. Nevertheless, it is important to clarify that the AHP results are not a binding constraint for the initial prototyping processes that are planned to be carried out within the Design Thinking framework, since they may not be momentarily accessible, even if they are better options. At the same time, it is possible to make *quick choices* without the need to use AHP, since the criteria might be exclusive and self-evident.

5.3.1 Sensor for Measuring the Inspiratory and Expiratory Flow Variable

In order to choose one of the alternatives proposed above for the flow sensor, the following parameters or criteria have been considered.

- Bidirectional air intake to facilitate inspiration and expiration in the same device.
- Accuracy.
- Ease of use/implementation.
- Production costs.

Although the characteristic of a bidirectional implementation is more easily achieved with the Orifice Plate, it is also possible to obtain bidirectional measurements with the Venturi Tube and, although involving a higher degree of difficulty and implementation, the Venturi Tube also offers a higher level of accuracy than that obtained with the Orifice Plate. Therefore, both alternatives have their own advantages and disadvantages, so the integration of AHP in this respect will be useful when deciding.

According to the process indicated in section 4.4 on Analytic Hierarchy Process and having the criteria and alternatives as a result of the decomposition of the problem exposed in fig. 5.7, the evaluation of weights is carried out by means of the pairwise comparison matrix (see fig. 4.7 on page 20).

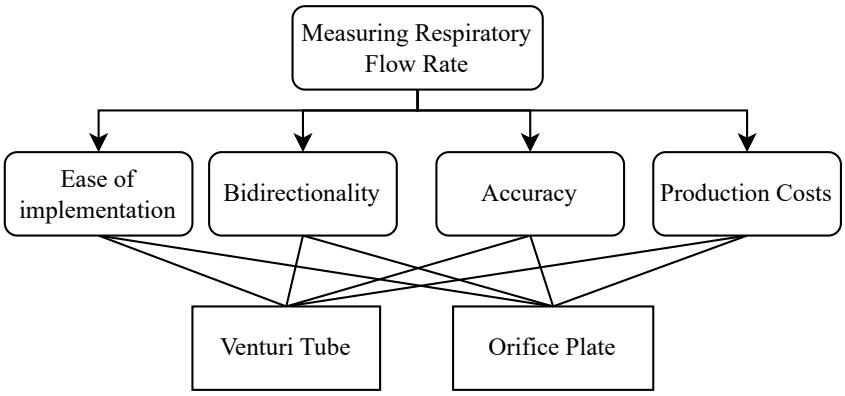


Figure 5.7: AHP decomposition for measuring respiratory flow rate.

CRITERIA	Bidirectionality	Accuracy	Ease of Use	Prod. Cost
Bidirectionality	1	7	1/2	3
Accuracy	1/7	1	1/3	1/3
Ease of Use	2	3	1	3
Prod. Cost	1/3	3	1/3	1

Table 5.2: Pairwise comparison of the relative importance for each criterion.

The weights defined in table 5.2 have been evaluated according to the fundamental scales of table 4.4 on page 18, and in turn have been defined following the axioms of reciprocity and homogeneity proposed in AHP theory. Thus, for example, the bidirectionality criterion has a very strong importance that prevails over the importance of accuracy, and likewise for the other criteria. Now, the relative weights of each of the criteria are extracted using the *Principal Eigenvalue* method, although very similar results are obtained through the *Arithmetic Mean*. For this purpose, a MATLAB application has been created and is available in the GitHub repository [80] with both approaches.

After evaluation, the weights of the criteria have been found to be consistent enough, i.e. $CR = 0.09$, so the weights for the criteria are as follows:

$$\text{Criteria weitghts} = \begin{pmatrix} \text{Bidirectionality} & \text{Accuracy} & \text{Ease of Use} & \text{Prod. Cost} \\ 0.3468 & 0.0810 & 0.4182 & 0.1541 \end{pmatrix}$$

Bidirectionality and ease of use have high importance, about 34,6% and 41,8% respectively. The next step is to judge the relative importance of each alternative with respect to the criteria:

BIDIRECTIONALITY	Venturi Tube	Orifice Place
Venturi Tube	1	1/7
Orifice Place	7	1

ACCURACY	Venturi Tube	Orifice Place
Venturi Tube	1	4
Orifice Place	1/4	1

EASE OF USE	**Venturi Tube**	**Orifice Place**
Venturi Tube	1	1/5
Orifice Place	5	1

PRODUCTION COST	**Venturi Tube**	**Orifice Place**
Venturi Tube	1	3
Orifice Place	1/3	1

By executing the weight calculation method, the results of the pairwise comparisons of each alternative with respect to the criteria are as follows:

Alternative Weights	**Venturi Tube**	**Orifice Plate**
Bidirectionality	0.1250	0.8750
Accuracy	0.8000	0.2000
Ease of Use	0.1667	0.8333
Prod. Cost	0.7500	0.2500

Table 5.3: Isolated priority of each alternative in contrast with the criteria.

Once the necessary elements are in place, the priority of each of the alternatives with respect to the importance of each criterion is calculated, thereby obtaining an important clue at the moment of decision-making. The priority is extracted by performing a matrix multiplication of the results in table 5.3 as follows:

$$\begin{pmatrix} 0.1250 & 0.8000 & 0.1667 & 0.7500 \\ 0.8750 & 0.2000 & 0.8333 & 0.2500 \end{pmatrix} \begin{pmatrix} 0.3468 \\ 0.0810 \\ 0.4182 \\ 0.1541 \end{pmatrix} = \begin{pmatrix} 0.2934 \\ 0.7066 \end{pmatrix}$$

Thus, the priority for the Venturi Tube is 29,3% while the priority for the Orifice Plate is 70,7%. Consequently, with the support of the AHP methodology, it has been decided to choose the implementation of an *Orifice Plate* for this project. More details about its design can be found in section 5.5.

5.3.2 Transducer

In this regard, the following selection criteria have been proposed:

- Narrow pressure range.
- Response time.
- Availability (related to delivery times).
- Acquisition costs.

Considering that a MPXV7025DP sensor obtained as a sample from the distributor is available, we propose the implementation in preliminary prototypes with this transducer; nevertheless, in the case of the alternatives presented for transduction, it is possible to choose one

without the need of the AHP technique, since all the alternatives have similar characteristics in terms of response time, voltages, linearity and operating ranges, differing mainly in availability, acquisition costs and certain particular characteristics that the XGZP6897D transducer has regarding medical applications. Bearing this in mind and the details mentioned in the corresponding section of the transducers proposal, it is decided that the *XGZP6897D* differential pressure transducer is the most suitable for the project for future implementations, in spite of the considerable time involved in its acquisition. In the meantime, tests will be performed with the available *MPXV7025DP* sample transducer.

5.3.3 Processing Device

Similarly, for the choice of the processing device among the proposed alternatives, the following criteria have been considered:

- Board/device size.
- Energy consumption.
- Scalability.

Other more particular criteria such as operating frequency have been discarded since the processing requirement is not very high. The choice of the processing device has been supported with the use of the AHP methodology, although in order not to bore the reader, the summarized process will be shown. The tree of criteria and alternatives is presented in fig. 5.8. Thus, the criteria have been evaluated as follows:

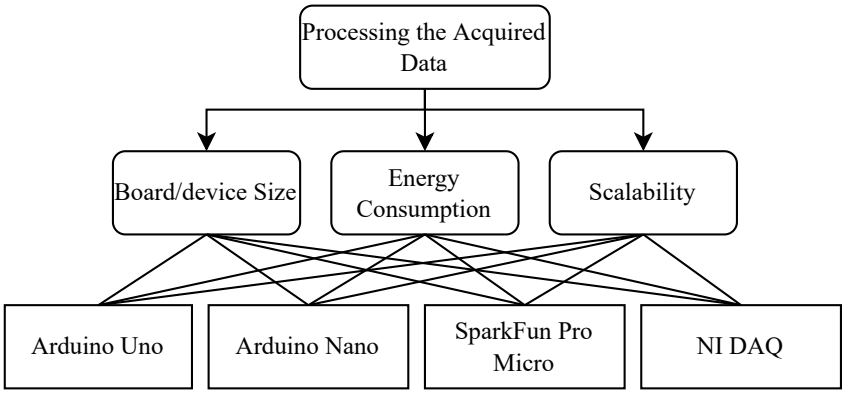


Figure 5.8: AHP decomposition for processing device.

CRITERIA	Size	Consumption	Scalability
Size	1	3	1/2
Consumption	1/3	1	1/2
Scalability	2	2	1

Table 5.4: Pairwise comparison on criteria for processing device.

The evaluation of table 5.4 have a $CR = 0.05$ and the criterion weights are as follows: 0.3338,

0.1416 and 0.5247 for size, consumption and scalability respectively. Now, the evaluation of each alternative with respect to the criteria has been done as follows:

SIZE	**Arduino Uno**	**Arduino Nano**	**SparkFun Pro Micro**	**DAQ**
Arduino Uno	1	1/5	1/6	2
Arduino Nano	5	1	1/2	7
Sparkfun Pro Micro	6	2	1	8
DAQ	1/2	1/7	1/8	1

CONSUMPTION	**Arduino Uno**	**Arduino Nano**	**SparkFun Pro Micro**	**DAQ**
Arduino Uno	1	1/3	1/4	1/2
Arduino Nano	3	1	1/2	3
Sparkfun Pro Micro	4	2	1	4
DAQ	2	1/3	1/4	1

SCALABILITY	**Arduino Uno**	**Arduino Nano**	**SparkFun Pro Micro**	**DAQ**
Arduino Uno	1	3	4	7
Arduino Nano	1/3	1	1	4
Sparkfun Pro Micro	1/4	1	1	5
DAQ	1/7	1/4	1/5	1

The comparisons between the alternatives and each criterion are sufficiently consistent, with CRs of 0.02, 0.03 and 0.04 in the order shown above. Evaluating the individual weights obtained with those of the criteria for the calculation of priorities, the following is addressed:

$$\begin{pmatrix} 0.0860 & 0.0937 & 0.5519 \\ 0.3418 & 0.2939 & 0.1950 \\ 0.5202 & 0.4790 & 0.1977 \\ 0.0520 & 0.1334 & 0.0554 \end{pmatrix} \begin{pmatrix} 0.3338 \\ 0.1416 \\ 0.5247 \end{pmatrix} = \begin{pmatrix} 0.3315 \\ 0.2580 \\ 0.3452 \\ 0.0653 \end{pmatrix}$$

So the *Sparkfun Pro Micro* microcontroller, with a 34.5% priority, would be the most suitable for the implementation because of the features it offers, being small and scalable for upgrades.

5.3.4 Data Communication

There are two alternatives to choose from for data transmission: Bluetooth or Wi-Fi communication. Thus, the following selection criteria have been considered:

- Energy consumption.
- Ease of use.

Since very long distances are not required, criteria such as communication range have not been considered. For these communication devices it is not necessary to apply the AHP technique upon making the decision, since, when looking at the criteria considered, the *Bluetooth HC-05* module has a better performance, since the energy consumption (in standby and over runtime) is lower (see box 5.3-1), and it is easier to use and implement with respect to its counterpart, the ESP8266 Wi-Fi module.

Bluetooth HC- modules consumption **5.3-1**

According to the instruction manual of the HC- modules regarding their consumption, the current is fluctuating between the range 30-40 mA during pairing (with a mean of 25 mA) and, after pairing, regardless of whether communication is being processed or not, the current is 8 mA [81].

5.4 Undertaking Design Thinking

The inclusion of the Design Thinking methodology presented in section 4.2 on page 13, addresses the partial application of its stages, since the stages of Immersion, Analysis and Ideation are addressed in conjunction with the TRIZ methodology and the short excerpts of Axiomatic Design. At the same time, the **Prototyping stage** is the most prevalent in the application of this methodology, since, as will be seen in chapter 6, the implementation will involve several stages of rapid prototyping, testing and updates that follow the guidelines of Design Thinking.

It is also important to make a brief digression to determine something that has not been sufficiently clarified at this point: the parties involved in the project. For this purpose, the archetypes suggested by Design Thinking are defined to allow an approach towards the people who surround the course of the project.

- **Patient archetype**: The patient is the person with deficiencies in the respiratory system that must be treated with pulmonary re-expansion physiotherapies. The average patient is uncomfortable with the current equipment for performing the exercises in the physiotherapies and would like equipment with which he/she could do them better, as corroborated in interviews with patients conducted by the physiotherapist team.

- **Physiotherapist archetype**: The physiotherapist is the person who is mainly involved in the recovery process of the patient, from the evaluation to the continuous monitoring of the patient's evolution in order to achieve an improvement in their pulmonary functions. The physiotherapist finds that current equipment for accompanying physiotherapies could be replaced with improved devices that can help monitor patients in physiotherapy and provide physiotherapists with better data for decision making and optimal performance during the process.

The **entire team** behind the process, including engineers in different branches, developers, stakeholders, physiotherapists, biologists and research assistants are also part of the people involved in the project, but are not defined within the user archetypes.

5.5 Design Methodology for an Orifice Plate Sensor Based on ISO-5167-1/2

The design of an Orifice Plate sensor based on ISO 5167-2 consider a long list of suggestions for guaranteeing the uncertainty raised in the standard. First of all, the standard sensor structure presented in fig. 4.13 on page 34 is the main basis for the implementation of an Orifice Plate and, considering that this project seeks to acquire flow in both directions (inspiratory and expiratory), certain restrictions should be considered in the design process. Meanwhile, the standard establishes some initial requirements for the construction of the sensor, which are presented in box 5.5-1.

Physical requirements of an Orifice Plate sensor ISO 5167-2 based **5.5-1**

1. **Shape:** the plate inside the pipe shall be circular and concentric with the pipe centreline. The faces of the plate shall always be flat and parallel [61].
2. **Upstream and downstream faces:** They shall be flat when the plate is installed in the pipe with zero differential pressure across it. Both of them should meet a roughness criterion $R_a < 10^{-4}d$, due to the bidirectionally [61].
3. **Thickness of the plate:** The thickness e of the orifice shall be between *0,005D* and *0,02D* [61].
4. **Diameter *d*:** The diameter d shall be greater than or equal to 12.5 mm and No diameter shall differ by more than 0.05 % from the value of the mean diameter. The diameter ratio β, must be greater than or equal to 0.10 and less than or equal to 0.75 [61].
5. **Diameter *D*:** The internal diameter of the pipe should be equal to or greater than 50 mm.
6. **Material and manufacture:** The plate may be manufactured from any material that can meet all the previous requirements [61].
7. **Distances l_1 and l_2:** The pressure taps P1 and P2 must be taken at a distance l_1 and l_2 equal to 25.4 mm due to the *bidirectional condition*, their radius must be less than $0{,}013D$ and less than 13mm, and their longs more than 5 times of that radius.
8. **Reynolds number:** $Re_D > 5000$ and $Re_D > 170\beta^2 D$.

The design process is mainly based on compliance of the previous requirements, also considering the design ranges such as the maximum respiratory flow and the maximum differential pressure to be measured. Thus, the design methodology presented in ISO 5167-2 refers to the calculation of the diameter of the hole in the plate d, where the designer must choose a suitable diameter D for the application and the calculation of d then is made with one eye on reaching the requirements presented.

Therefore, as already discussed in the sections of chapter 4, eq. (4.9) on page 33 is the fundamental relationship for calculating the flow through the differential pressure principle and, in turn, is the basis for undertaking the calculation of the diameter d. Nevertheless, when analyzing this relationship in detail, it can be noted that the flow through the Orifice Plate sensor is substantially dependent on the discharge and expansion coefficients C and ϵ respectively,

already exposed in eq. (4.12) on page 34. At the same time, the flow calculation is also dependent on the characterization of the flow Q_m with the Reynolds number. Consequently, to calculate the flow and solve the diameter d, it is necessary to solve a nonlinear system of equations that can meet all the requirements stated in box 5.5-1. For this purpose, ISO 5167-1 presents an approximation through numerical methods hand in hand with a linear approximation that solves the computation problem. For convenience, it is possible to rewrite eq. (4.9) as follows:

$$Q_m = C\epsilon\frac{\pi}{4}d^2(1-\beta^4)^{-0.5}(2\Delta P\rho)^{-0.5} \tag{5.1}$$

The methodology is based on the grouping of all the known and unknown terms in eq. (5.1). The expression resulting by grouping the known terms is called *invariant* and with the equation obtained from the unknown terms, it should be proposed an iterative equation X which has two equivalent forms: one depending on the target variable (i.e. d, Q_m, D and ΔP); and the other defined with respect to the invariant term (i.e. C and/or ϵ depending on the case). Bearing this in mind, the iterative process must start with the provision of a first guess of the unknown values C and/or ϵ, namely for the equation X that is defined for the invariant term. This first guess allows to calculate the target variable, which is necessary to recalculate the values that were initially guessed. When the new guessed values are obtained, it is necessary to perform the process again (that is why it is iterative) until a new value for the target variable is reached. The iterative process should stop when the difference between the two equivalent forms of equation X is close to 0 or as small as the designer decides [59].

Chapter 6

Implementation and Results

This chapter presents the details about the development of the breathing monitoring system for the support of lung re-expansion physiotherapies. Thereby, the series of rapid prototypes that were performed to obtain the results and approaches of the monitoring system are presented, as well as the execution of the sensor design for the capture of the flow variable. It is important to bear in mind that the decisions made for the construction of the device, in the previous chapter, will be incorporated gradually with the update of the prototypes.

6.1 Prototyping, Tests and Simulations

The implementation of the electronic device has been involved in several fast prototypes with different resolutions and objectives, naturally, these approaches correspond to one of the most important elements proposed by the Design Thinking methodology (see section 4.2 on page 13).

6.1.1 Prototype N°1: NI LabVIEW and SparkFun Pro Micro

This is a preliminary implementation that acquires data from the MPXV7025DP sample transducer by means of a SparkFun Pro Micro board (as one of the design and decision-making methodology outcomes) and transmits the data to the NI LabVIEW simulation environment through the serial port of the computer. To perform the tests, a low-resolution prototype of the Orifice Plate sensor was built, although without carrying out a conscious design, since it was desired to analyze if the differential pressure could really be captured through it. Figure 6.1 shows the physical dimensions with which the preliminary Orifice Plate was built, which, again, does not follow the guidelines established in the design methodology since it is a low-resolution prototype.

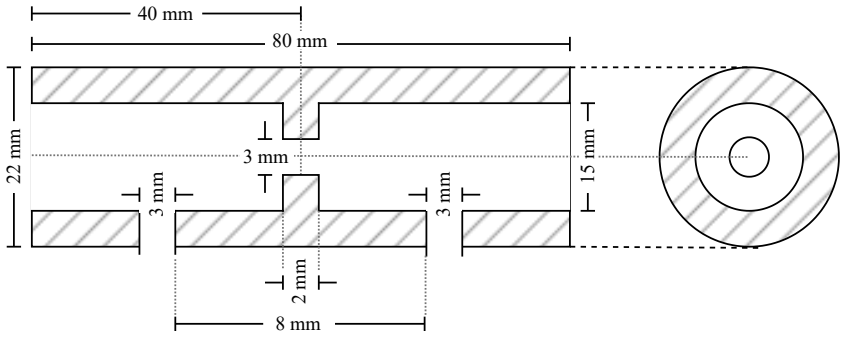


Figure 6.1: First prototype of the Orifice Plate.

An initial simulation of the flow flowing inside the prototype Orifice Plate has been generated and can be seen in fig. 6.2. In the simulation it is possible to see the expected change of pressures before and after the Orifice Plate.

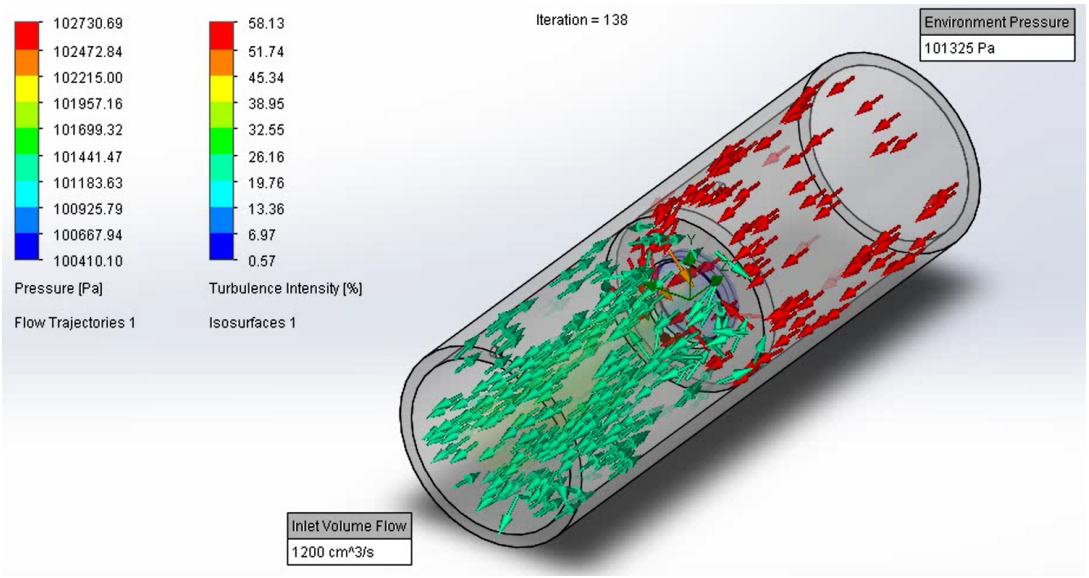


Figure 6.2: Simulation of flow through the Orifice Plate without pressure taps.

At the same time, the air intake also constitutes a low-resolution prototype coupled with the Orifice Plate and the electronic implementation, since a conventional oxygen mask was used to which the air outlet was adapted directly to the Orifice Plate sensor. Figure 6.3 shows a real view of the air intake prototype.

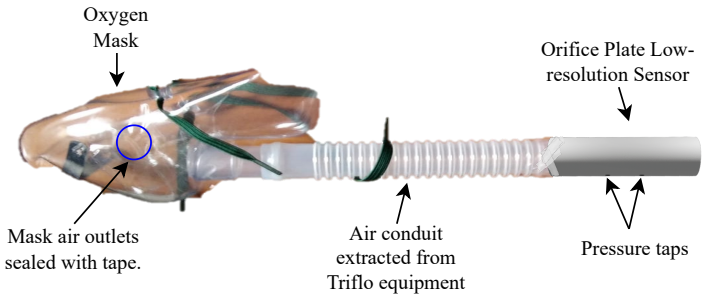


Figure 6.3: Low-resolution prototype used as air intake.

After acquiring the flow variable, the results are to be processed in NI LabVIEW environment and the signal was conditioned directly by means of the tools offered by the software. Figure 6.4 exposes a simple flowchart of the process.

The programming environment of the SparkFun microcontroller consists solely of the declaration of variables and elements necessary for reading the analog port connected to the transducer, as well as the initiation of data communication through the serial port. Regarding the back-end of the NI LabVIEW environment, a description is presented in the following figures.

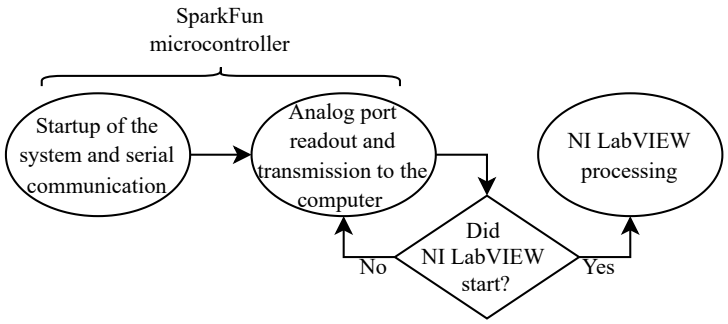


Figure 6.4: Simple flowchart of the prototype operation.

Figure 6.5 shows the back-end on the serial port readout in NI LabVIEW. A communication rate of 9600 baud is set which is sufficient for this application, since the maximum data obtained at this communication rate is enough. At the same time, the number of bits output by the SparkFun ADC is obtained.

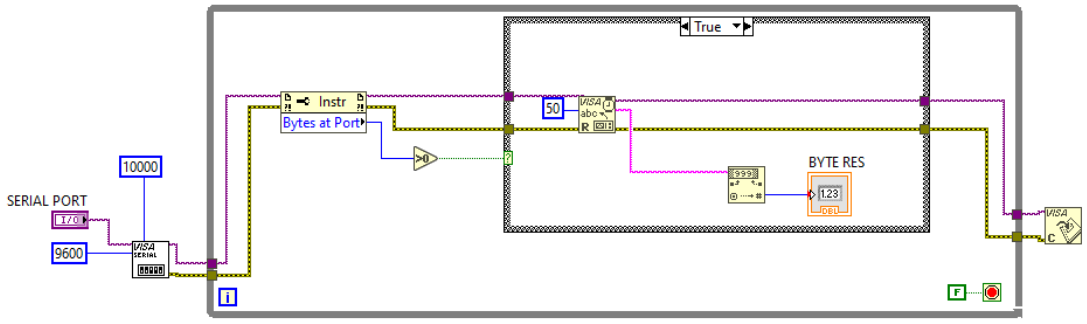


Figure 6.5: Serial port reading.

Subsequently, the voltage value is derived and the differential pressure is calculated using the transfer equation from the datasheet (fig. 6.6 and fig. 6.7).

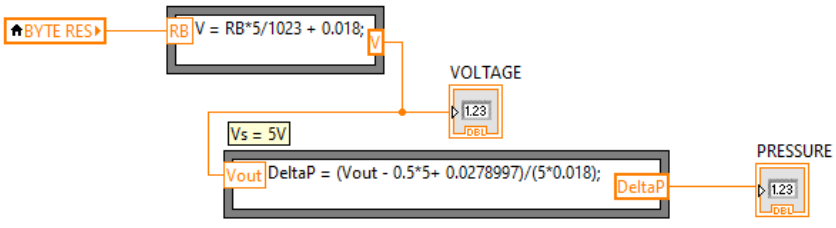


Figure 6.6: Pressure computation through the sensor transfer function.

In another block (see fig. 6.8), there is a method for stabilizing the system during the first seconds of startup by means of arithmetic mean data correction. When the `SYSTEM OK` flag is activated after the system stabilizes, the calculation of the velocity of the fluid passing through the Orifice Plate proceeds. Nevertheless, since this prototype does not contemplate a formal

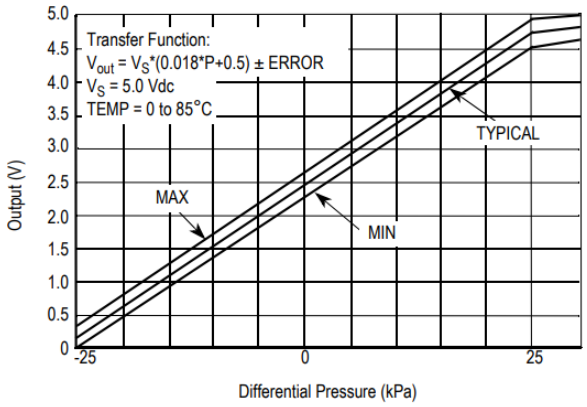


Figure 6.7: Transfer function of the differential pressure transducer. [71]

sensor design, the velocity has been modeled in its simple and general form, that is, without considering the compressibility of the fluid, its losses and any factors associated with the design, as shown in the eq. (4.7) on page 32. This is the main part of the back-end and it can be seen in fig. 6.10.

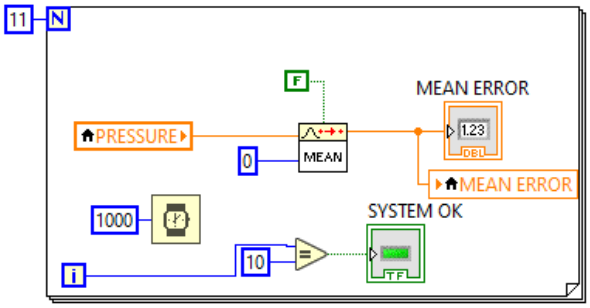
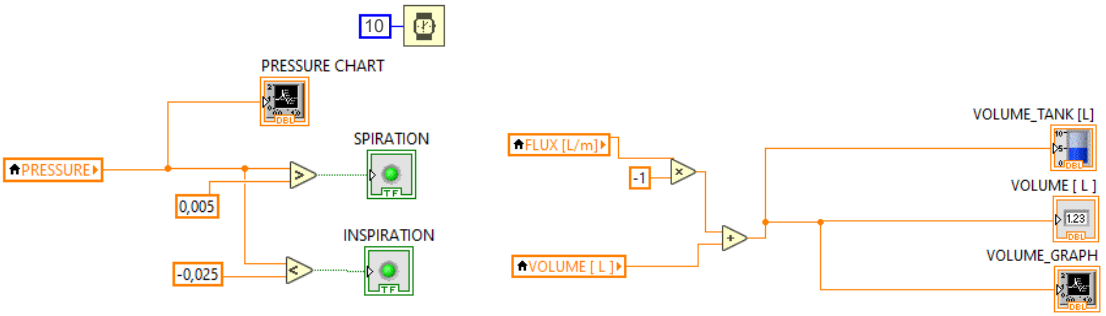


Figure 6.8: Section for system stabilization.



(a) Inspiration and expiration.

(b) Volume extraction from flow rate.

Figure 6.9: Volume and moments of inspiration and expiration.

The recognition of inspiratory and expiratory moments has also been contemplated by means

of the behavior of the differential pressure. At the same time, the determination of the volume through the summation of the flow in a unit time differential has also been included. Both implementations can be seen in fig. 6.9.

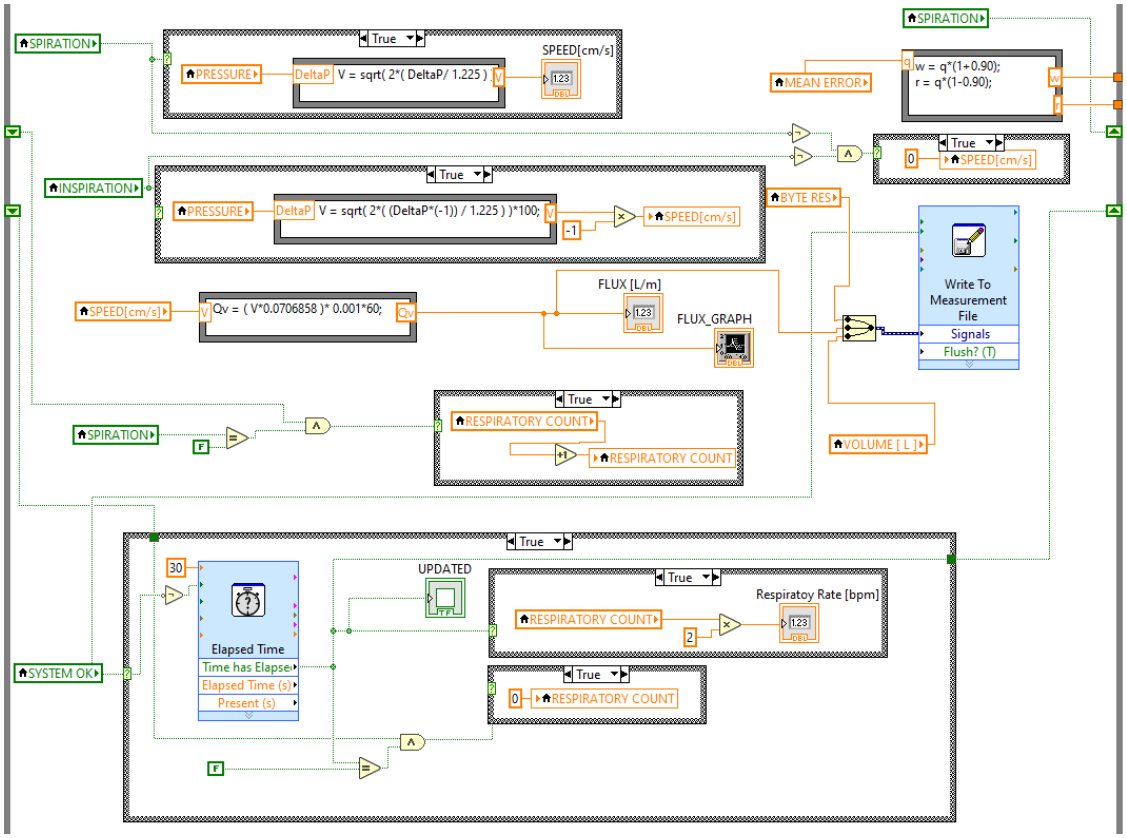


Figure 6.10: Computation of fluid velocity, flow rate, respiration rate and system update status.

The whole system operates at a frequency of 100 Hz, as proposed in the design ranges for data presentation. It is important to point out that for this preliminary prototype, wireless communication was not addressed, so there is no mention of the Bluetooth protocol implementation. Figure 6.11 summarizes the operation process of the back-end in NI LabVIEW by means of a flowchart.

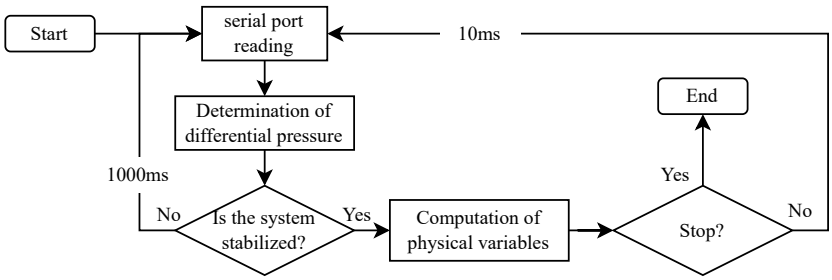


Figure 6.11: Flowchart for NI LabVIEW processing prototype.

When the system was executed, it was determined as a prototype of low functional resolution,

with which a first approach to the processing of the variables involved in the breathing process was obtained. Figure 6.12 shows the NI LabVIEW simulation front-end environment where the change of the variables can be seen. Nevertheless, the **results of this first low-resolution prototype are not reliable and have errors**, since its parameters were not properly designed and the volume is not correctly calculated. In the forthcoming prototype, a proper determination of the volume will be addressed.

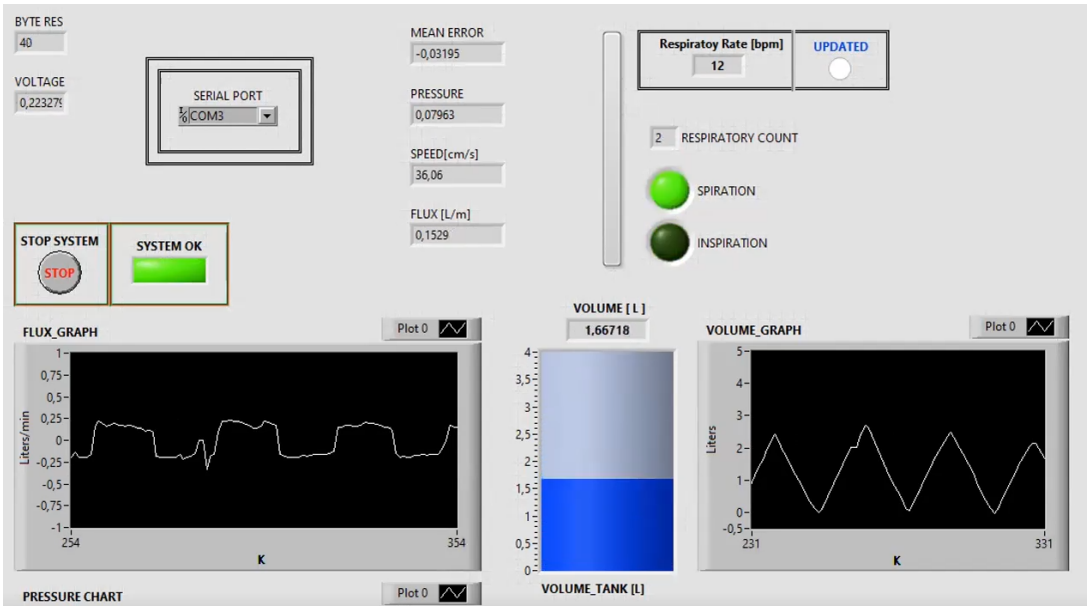


Figure 6.12: System simulation in NI LabVIEW.

6.1.2 Prototype N°2: SparkFun Pro Micro and Bluetooth Transmission

For the second prototype, the use of the NI LabVIEW simulation environment was completely discarded and all processing was carried out using the SparkFun Pro Micro microcontroller. At the same time, a preliminary approach to data communication via Bluetooth to a smartphone was added to this prototype. The smartphone purchased for the development of the external project was a mid-range device as suggested. At this point, the mask and Orifice Plate from the previous prototype are retained and, since the same MPXV7025DP transducer is still used while the XGZP6897D transducer is purchased and delivered, it has been decided to implement an amplification stage as ±25 kPa is a very large range for out-of-mouth pressure measurements, something that has already been explained in the Design Ranges in section 5.2 on page 46.

The flowchart in fig. 6.13 explains the general operation of this prototype. In the calibration stage, a data correction by arithmetic mean is performed, to then start with the reading of the analog port and the calculation of the flow and velocity signals of the fluid through the Orifice Plate. When the data is ready, it is sent via Bluetooth to the smartphone. In this way, by means of the Bluetooth HC-05 module in slave configuration, it is possible to send/receive data to/from the mobile device. The reception of the data to the smartphone was performed using an application available in the Playstore (Android OS), called *Serial Bluetooth Terminal*,

in which a continuous reading of the serial data arriving in the mobile buffer is executed. In turn, a communication rate of 9600 baud was chosen as it is sufficient for the presentation of the data in this prototype, as well as allowing the module to operate at low power. At the same time, the update and data sending rate is 10 ms. This prototype does not have a stop condition but simply shutdown.

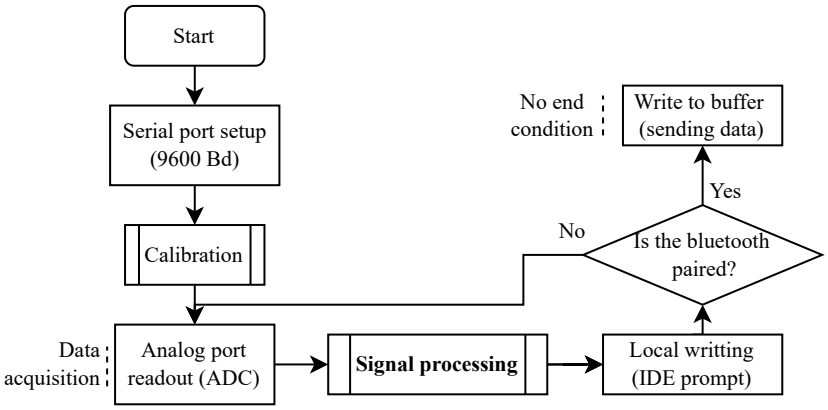


Figure 6.13: General flowchart for second prototype.

In this prototype there is no specific data encapsulation since only one type of data is sent in a sequence: speed, flow and volume. These data sent in packets using the Bluetooth protocol (firmware 2.0-20100601) are protected by error detecting and correcting codes, so that with the protocol it is possible to reject and resend information.

By looking in detail at the signal processing block in fig. 6.13, it is possible to find the whole process for the calculation of velocity and flow through the simple velocity model for the undesigned Orifice Plate, basically the same approach as in the first prototype (something that is going to change in the next update).

On the operational amplifier side, a general purpose reference was chosen to perform the conditioning of the voltage signal output by the transducer: LM358P, which has 2 amplifiers in a single case.

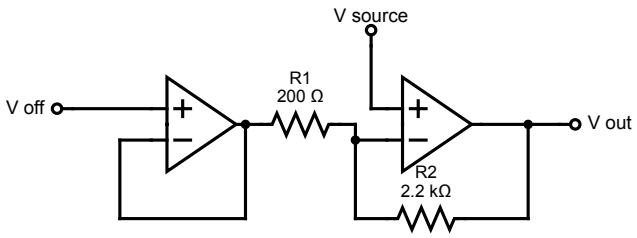


Figure 6.14: Non-inverting operational amplifier with offset.

Figure 6.14 shows the configuration used for the operational amplifier. Considering that the transducer variation voltages were approximately 2.3 to 2.7 V, it was designed for a gain that

would supply amplification over the entire 0 to 5 V span without losing the original offset of the sensor (i.e. approximately 2.5 V). The theoretical gain G was 11.5, and the resistors $R1$ and $R2$ had values of 0.2 and 2.2 kΩ, respectively. Equation (6.1) shows the transfer function for the circuit shown in fig. 6.14.

$$V_{out} = V_{source}\,(1+G) - V_{off}G, \text{ for } G = \frac{R2}{R1} \tag{6.1}$$

Update N°1: Experimental Model and Interaction

As the results that were being obtained did not provide sensible values (mainly due to not having a formal Orifice Plate design that could be properly addressed), it was decided to try a fast approach towards more accurate results. For this purpose, it was considered to perform a practical characterization of the voltage signal obtained with the transducer by means of a regulated flow source. As a flow source, an oxygen tank with regulating valve up to 15 L/min was chosen (fulfilling the proposed Design Ranges), whose air output was connected directly to the air inlets of the Orifice Plate sensor while the voltage values were measured internally from the microcontroller and externally with a multimeter.

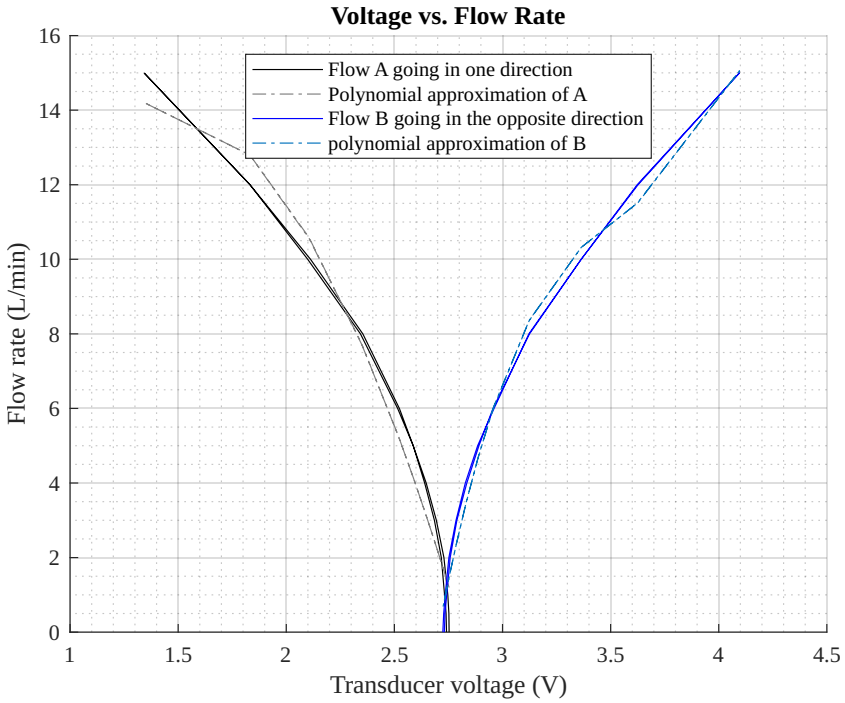


Figure 6.15: Experimental flow curves and polynomial approximations for both directions.

Figure 6.15 shows a plot of the results of the approach by experimentally characterizing the flow through the Orifice Plate versus the transducer voltage. The measurements were made starting from a flow rate of 0 L/min up to 15 L/min and vice versa, for both directions of the sensor. By doing this, it could be noted that the hysteresis of the transducer is not significant, something that can be better seen in fig. 6.16.

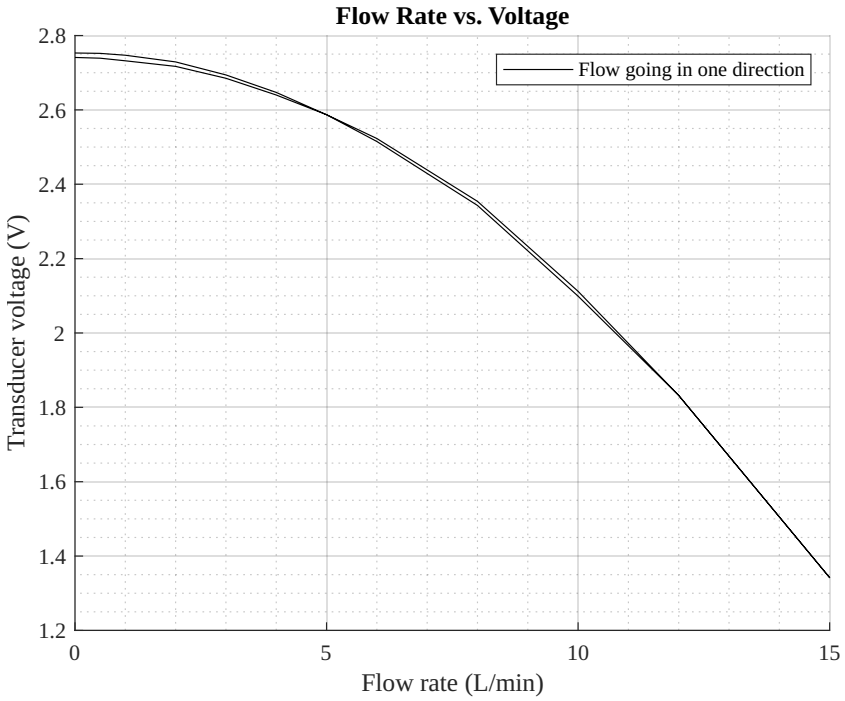


Figure 6.16: Transducer experimental hysteresis for flow in one direction.

From here, two polynomial models were extracted that could be fitted to the behavior of the data taken in the experimental approach. A comparison of the polynomials obtained with respect to the experiment can be seen in fig. 6.15.

Now, the flow variable is to be obtained from the polynomials produced by the approximation (only for this prototype). After that, a process is performed for the estimation of the **respiratory frequency** and also for the calculation of **respiratory volume** through the discretization of the signal, something that is explained in greater detail in sections section 6.3 and section 6.3.2 of this chapter. In particular, the expression for the volume calculation has the following form, where `f` stands for flow rate and `v_old` for the previous sample volume:

```
volume = (sample_time * (f + f_old) + 2 * v_old) / 2;
```

As mentioned, in this prototype update the possibility of interacting with the smartphone by means of short messages in the communication buffer was added. By sending two words from the smartphone, *OK* or *NO*, it is possible to start or stop sending data. At the same time, an inactivity function was added where the device stops sending data when a certain time, defined by the user, has been exceeded without performing inspiration or expiration. It is possible to resume operations using the start command from the smartphone. A more detailed flowchart of this version of the prototype can be seen in fig. 6.17.

At this point of the prototype it was decided to perform a Printed Circuit Board (PCB) implementation to show the first results to the external project. The netlist was then made and the `gerber` files for printing were generated, which are also available in the GitHub repository with all the codes used for prototyping [80]. Figure 6.18 shows the PCB made for this prototype.

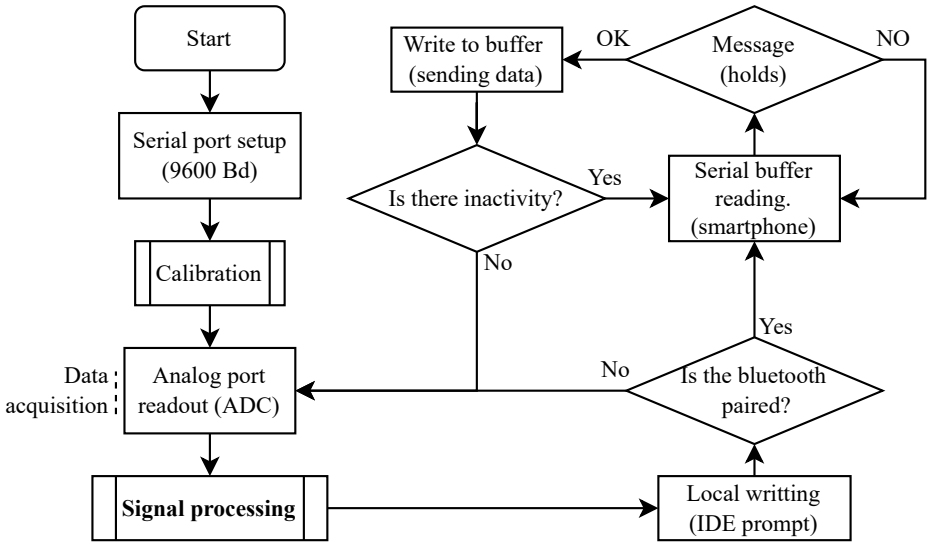
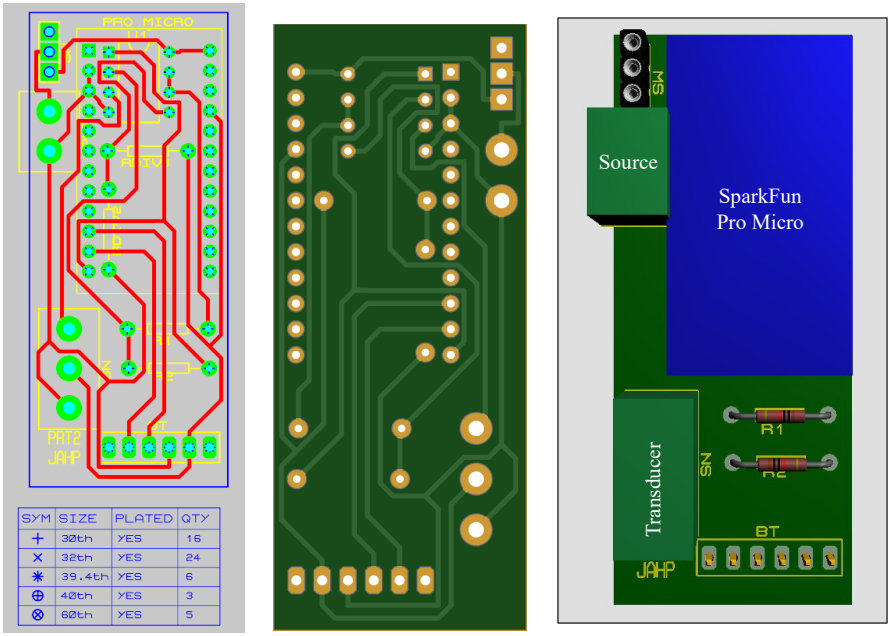


Figure 6.17: Flowchart of the prototype. Sampling rate is 100 Hz.

It is important to mention that the power supply in this case was not completely designed, so a 9 V battery was chosen since the implementation with the operational amplifier requires a voltage higher than 6.5 V to work properly, otherwise, the amplification results are wrong.



(a) Top Layer. (b) Bottom layer. (c) 3D model.

Figure 6.18: Printed Circuit Board for the prototype.

By simulating and testing this prototype, **more convincing results** were obtained for flow, volume and respiratory rate than those obtained with the preliminary prototype in NI LabVIEW. Thus, the simulation results for flow and volume are shown in fig. 6.19 and fig. 6.20,

which are obtained from the *Serial Plotter* of the microcontroller IDE. Since it is not possible to modify the axes to make them more informative, fig. 6.19 shows the flow in L/min over time, which in this case are samples since it is discrete time; while fig. 6.20 shows the volume in L in contrast to the simulation samples.

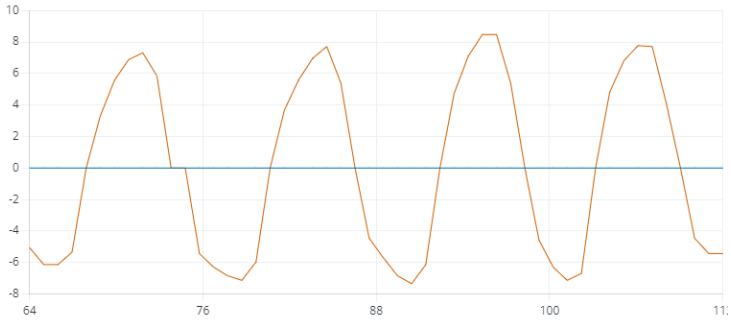


Figure 6.19: Flow test results. Span from -15 to 15 L/min.

Figure 6.20: Volumen test results.

At the same time, a portion of the results sent towards the smartphone (from the microcontroller IDE) is shown in fig. 6.21.

```
05:04:28.096 -> 0 Flow: 4.66/ Volume: 2.90/ Resp_Rate: 12
05:04:28.174 -> 0 Flow: 4.66/ Volume: 2.97/ Resp_Rate: 12
05:04:28.281 -> 0 Flow: 3.26/ Volume: 3.04/ Resp_Rate: 12
05:04:28.391 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:28.507 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:28.575 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:28.687 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:28.798 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:28.912 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:29.015 -> 0 Flow: 0.00/ Volume: 3.07/ Resp_Rate: 12
05:04:29.092 -> 0 Flow: 2.91/ Volume: 3.09/ Resp_Rate: 12
05:04:29.202 -> 0 Flow: 3.02/ Volume: 3.14/ Resp_Rate: 12
05:04:29.313 -> 0 Flow: 0.00/ Volume: 3.17/ Resp_Rate: 12
05:04:29.392 -> 0 Flow: 0.00/ Volume: 3.17/ Resp_Rate: 12
05:04:29.502 -> 0 Flow: 0.00/ Volume: 3.17/ Resp_Rate: 12
05:04:29.612 -> 0 Flow: 0.00/ Volume: 3.17/ Resp_Rate: 12
05:04:29.722 -> 0 Flow: 0.00/ Volume: 3.17/ Resp_Rate: 12
```

Figure 6.21: Data sent from the microcontroller to the smartphone.

It is important to mention that in the smartphone the stream of data sent is merely numerical

since from the external project it is planned to take the raw data and process it in a gamified application.

The Orifice Plate sensor **must now be properly designed** in order to dispense with the experimental model and obtain reliable results based on a conscious design. The following section addresses this problem.

6.2 Orifice Plate Sensor for Respiratory Flow Measurement

6.2.1 Design of an Orifice Plate Sensor Adapted for a Medical Application

The design of a flowmeter based on an Orifice Plate sensor is developed considering the methodology presented in the section section 5.5 on page 58, where the main objective will be to calculate the diameter d by means of the iterative process explained there. The diameter d is the fundamental variable in this design, since its calculation involves the constraints proposed in the box 5.5-1 on page 58 and the Design Ranges for flow and differential pressure proposed in section 5.2 on page 46.

The design proposed by ISO 5167 standard is intended to guide the process of design and implementation of flowmeters in **industrial environments**, this means that the definitions of the discharge and expansion coefficients in eq. (4.12) and eq. (4.13) on page 35 suggested by the standard are limited to certain conditions, as in the case of diameter D, where only a dimension greater than 50 mm is allowed. Nevertheless, since this project is meant to be developed in a medical environment, the flow to be measured has small magnitudes (between 0 and 14 L/s) and, therefore, it is important to prioritize good ergonomics for the user, in this case the patient, by providing a device with adequate dimensions. For these reasons an **adaptation** in C and ϵ has been made. A study carried out by the *University of Texas* along with the *Technological Institute of Celaya*, has developed an alternative formulation for the C and ϵ coefficients, making it possible to calculate the flow through an Orifice Plate sensor with diameter D less than 50 mm. The study found good approximations to the real behavior of the discharge and expansion coefficients characterizing them for the air and some other gases [82]. The new approaches are presented below:

$$C = a_1 + a_2\beta^{3.75} + a_3\beta^4 + a_4\left(\frac{\Delta P}{P1}\right)^{1.25} + a_5\left(\frac{\Delta P}{P1}\right)^{2.25} \tag{6.2}$$

$$\epsilon = b_0 + b_1\frac{\Delta P}{P1} + b_2\left(\frac{\Delta P}{P1}\right)^2 + b_3\left(\frac{\Delta P}{P1}\right)^3 \tag{6.3}$$

Where $a1 = 0.59865$, $a2 = 0.81891$, $a3 = -0.86143$, $a4 = 0.25169$, $a5 = -2.2216$, $b0 = 1$, $b1 = -0.5046$, $b2 = -0.1615$ and $b3 = -0.0582$. As can be seen, eq. (6.2) now describes the discharge coefficient C, which no longer depends on the Reynolds number, making the calculation of the flow does not require the application of the iterative methodology in section 5.5 on page 58, since it can be calculated by direct replacement of the air density ρ, the differential pressure ΔP, the manometric pressure P_1 and the dimensions of the sensor [82]. Nevertheless,

for the design of d, it is necessary to apply the iterative methodology, since C still depends on β, which is an unknown value at designing.

Consequently, in order to carry out the design of d in the Orifice Plate sensor following the iterative methodology of ISO, the known therms are μ, ρ, D, Q_m, ΔP, P_1 and unknown terms are d and β. The known values, as it was explained in its respective section, are taken directly from the design ranges and D, l_1 and l_2 will be strategically chosen by the designer considering needs of the application. Particularly, the manometric pressure value P_1 has been considered as the maximum expiratory pressure, which is determined by the Black and Hyatt equations [83]. Thereby, for the current design the following values will be considered.

Air density $\rho =$ 1.225 kg/m^3
Dynamic viscosity of air $\mu = 1.849\ 10^{-}5Pas$
Diameter $D = 0.03$ m
Distance $l_1 = 0.015$ m
Distance $l_2 = 0.015$ m
Maximum expiratory pressure $P_1 = 26281\ Pa$
Maximum volumetric flow $Q_v = 0.014\ m^3/s$
Maximum mass flow $Q_m = 0.0172\ kg/s$
Maximum differential pressure $\Delta P = 1000\ Pa$

Continuing with the methodology, the first step to follow is to group the known and unknown terms in eq. (5.1) on page 59, in order to find the definition for the invariant form, which in this case will be called A; and the two forms of the iterative equation X as follows:

$$\frac{\mu Re_D}{D\sqrt{2\Delta P\rho}} = C\epsilon\left(\frac{\beta^2}{\sqrt{1-\beta^4}}\right) \tag{6.4}$$

$$A = \frac{\mu Re_D}{D\sqrt{2\Delta P\rho}} = 0.4902, \quad X = \frac{\beta^2}{\sqrt{1-\beta^4}} = \frac{A}{C\epsilon} \tag{6.5}$$

Now, to start with the iterative process properly, ISO 5167-1 advises taking the values of $C = 0.606$ and $\epsilon = 1$ as a first guess [59], then it is possible to calculate the value of X trough the invariant side definition in eq. (6.5), resulting in $X = 0.5053$. Continuing with the process, the value of our target variable d is calculated easily by clearing the value of d from the expression of β on eq. (6.5), i.e., $\beta = d/D$:

$$d = D\left(\frac{X^2}{\sqrt{1+X^2}}\right), \quad \beta = \frac{d}{D}$$

Carrying out this process results in a value $d = 0.0201$, making it possible the calculation of β with which in turn will be recalculated the values of C and ϵ that are defined by eq. (6.2) and eq. (6.3) respectively. Therefore, the value of X will be recalculated with these new results, allowing the calculation of a value of d closer to the solution than the previous one. In turn, the error between the two definitions of X is defined as $|(A - XC\epsilon)/(A)|$ and this process

must be repeated until the error is less than a set tolerance that, in this case, is less than 10^{-6}. Ultimately, an approximate value of $\boldsymbol{d = 0.0239\ m}$ is obtained. The implementation of the iterative method carried out in MATLAB, whose code can be found on the GitHub repository [80].

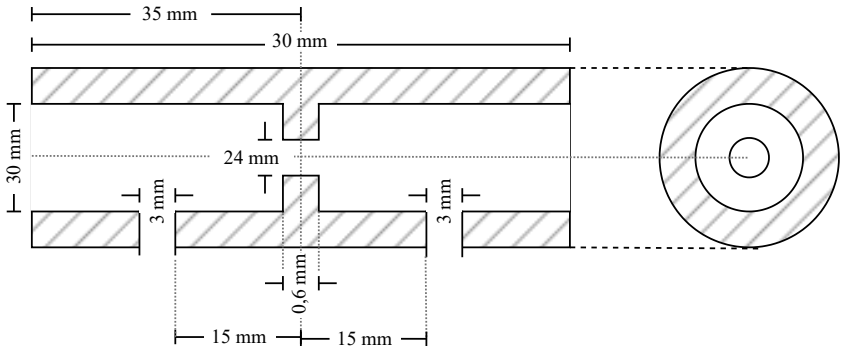


Figure 6.22: Resulting Orifice Plate design.

Figure 6.22 shows the **final design** of the Orifice Plate sensor, considering its application in a medical environment for the measurement of respiratory flow rate. The dimensions or the pressure taps P1 and P2, were chosen smaller than those presented in ISO 5167-2, due to the changes in the dimensionality.

6.2.2 Model of a Respiratory Flowmeter Based on an Orifice Plate Sensor

The model that has been finally developed in this Bachelor's Dissertation is fundamentally based on the study of the behavior of air flow through a pipe, applying the concepts of Bernoulli's theory, conservation of energy and conservation of mass contained in a defined volume. At the same time, the inference of the model was complemented with the approach of the ISO 5167 standard, which considers the compressibility and dynamic viscosity of the air through parameters such as the coefficient of expansion ϵ and the coefficient of discharge C. In turn, the standard was finally adapted to address an implementation that went beyond the restrictions imposed by the ISO, for the sake of developing an adequate medical flowmeter. Thus, eq. (6.6) presents the model that approximates the flow behavior through an Orifice Plate sensor in m^3/s, considering the new formulations for C and ϵ in eq. (6.2) and eq. (6.3) on page 71.

$$Q_v = \frac{KC\epsilon}{\sqrt{1-\beta^4}} \frac{\pi d^2}{4} \sqrt{\frac{2\Delta P}{\rho}} \tag{6.6}$$

The multiplicative factor K is considered in multiple developments of respiratory flowmeters based on differential pressure principle [84], this is a dimensionless **correction factor** that helps to calibrate the equation depending on the experimental results between real flow measurements and model outcomes for a given differential pressure, which in this case takes the value of 80. A summary of the variables present in the model of eq. (6.6) is given in the box below.

$K =$ correction constant, dimensionless
$C =$ discharge coefficient, dimensionless
$\epsilon =$ expansion coefficient, dimensionless
$\rho =$ Air density in kg/m^3
$\beta =$ Diameters d/D relation, dimensionless
$d =$ Diameter of the plate perforation in m
$\Delta P =$ differential pressure in Pa

6.2.3 Volumetric Flow Measurement with Specialized Setup (Model Validation)

The process that has been carried out for the validation of the model for the Orifice Plate sensor developed in this Bachelor's Dissertation, has been implemented through the articulation with the comprehensive external project, because the realization of the specialized setup for the data acquisition of the volumetric flow, based on the differential pressure principle in an Orifice Plate system, was carried out by the main project team. Hence, the results achieved by the setup will serve as a reference in the evaluation of the model.

The setup itself can be seen in fig. 6.23, where a *CITREX H3* flowmeter was used, which is a specialized device for the measurement of bi-directional gas flow with an acceptable level of accuracy, as well as providing additional data such as pressure and temperature [85]. The flow source was provided by a Calibration Syringe for spirometry of the Medical International Research (MIR), with which the air flow was injected into the system.

Figure 6.23: Setup for flow measurement.

The Orifice Plate sensor with which the measurements were made is shown in fig. 6.24. Although this sensor does not consider the dimensions designed in section 6.2.1 (since it was implemented before the model was ready), it is possible to perform the measurements, since the objective is to validate the accuracy and reliability of the developed model. At the same time, the measurement of the differential pressure was carried out with an air pressure manometer *AR1890* from *PerfectPrime*, a specialized device for high-precision differential pressure measurement [86].

After performing several measurements and tests with the setup, it was possible to obtain the measurements of the volumetric air flow in contrast to the differential pressure, which are presented in the graph shown in fig. 6.25.

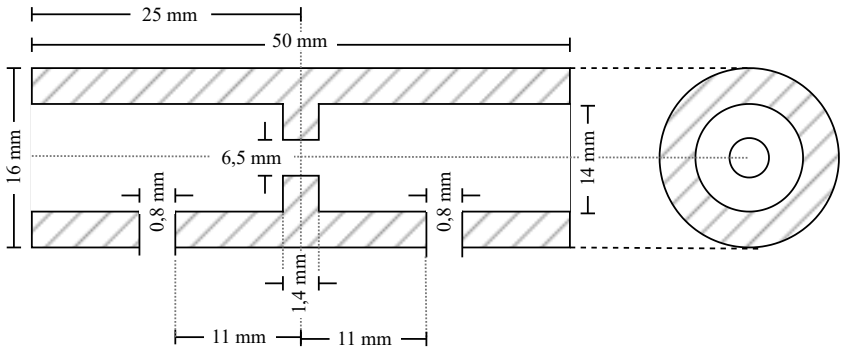


Figure 6.24: Orifice Plate sensor implemented in the validation setup.

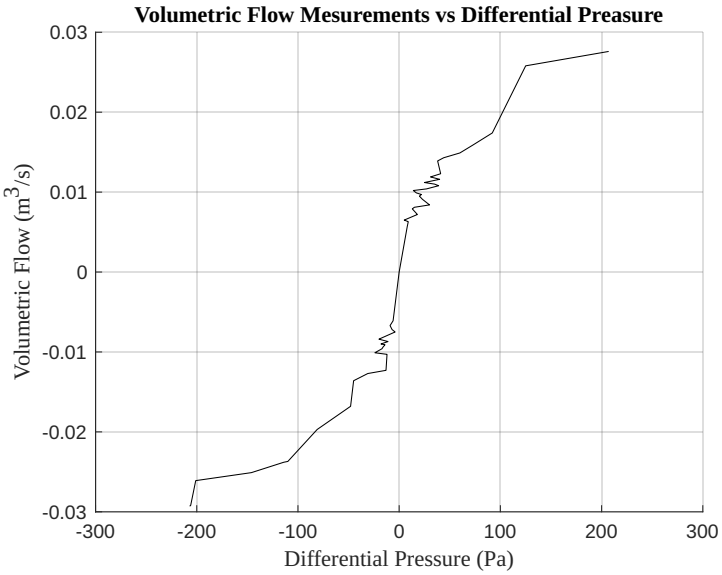


Figure 6.25: Measurements of the volumetric flow vs. the differential pressure on the Orifice Plate sensor.

6.2.4 Resulting Response of the Model Developed for the Sensor

The verification of the model response, with a differential pressure input obtained by means of the setup explained in section 6.2.3, was carried out by evaluating the differential pressure point-to-point for obtaining the estimate volumetric flow shown in fig. 6.26. It should be noted that the value of the manometric pressure P_1 is a variable that must be measured in the implementation process, nevertheless, since there is no measurement for this value in the setup, it was considered a constant value of $26281Pa$, which refers to the maximum value of expiratory pressure.

As shown in fig. 6.26, the response to the model inputs was close to the measured volumetric flow reference. Hence, in order to objectively compare the approximation between both graphs, the RMSE between model response and reference was calculated by applying the theory explained in section 4.8.3 on page 35, obtaining a value of **0.0017**. It is worth mentioning that the implementation of the model evaluation was carried out in MATLAB, whose code can be

found on the GitHub repository [80].

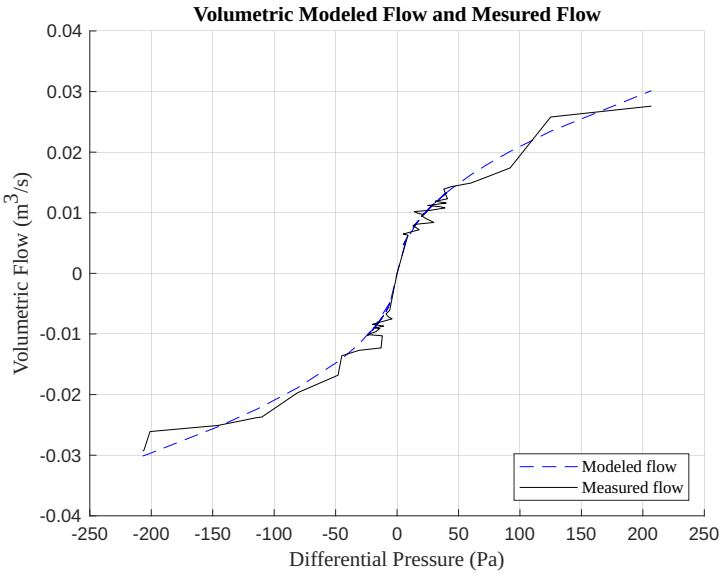


Figure 6.26: Model response of a flowmeter with an input differential pressure.

6.3 Calculation Process Proposal for Volume and Respiratory Rate Derived from Respiratory Flow

The calculation of physiological variables such as respiratory rate and volume can be estimated from a manipulation of the respiratory flow measurements. In this section, two processes that were implemented for the estimation of these variables are explained, bearing in mind that they have to be implemented in a programming environment, as is the case of the prototype developed in section 6.1.2.

6.3.1 Respiratory Volume Measure Based on Respiratory Flow

Respiratory volume can be easily extracted by measuring respiratory flow due to the basic definition of volumetric flow Q_v: the amount of volume Vol flowing in a pipe for a given period of time. Thereby, the flow can be mathematically expressed as the derivative of volume with respect to time, as below:

$$Q_v(t) = \frac{dVol}{dt} = Vol'(t) \tag{6.7}$$

As can be seen, a first order linear differential equation is proposed in continuous time domain, nevertheless, as it is expected that the volume implementation will be carried out in a discrete time, this differential equation has to be solved by difference equations[1], which can be

[1]Mathematical expression that relates different discrete mathematical sequences where one of the sequences is unknown.

easily implemented in a digital environment. In order to obtain a solution based on difference equations, there should be a change in the temporal domain from continuous to discrete time. This process can be developed in a simple way, as long as the differential equation to be solved is linear and of finite order, as shown in eq. (6.7). To carry out the domain change, a formulation in the Z domain should be considered, since this gives the starting point for obtaining the solution in discrete time. Nevertheless, the problem is initially posed in the temporal domain. In turn, an easy way to formulate the equations in the discrete domain is carrying out a transform to the *Laplace* domain at first, considering that the volume at $time = 0$ is has a value of 0 as follows:

$$\mathcal{L}\{Q_v(t)\} = \mathcal{L}\{Vol'(t)\}, \quad Q_v(s) = sVol(s), \quad \frac{Q_v(s)}{Vol(s)} = s \tag{6.8}$$

With this result the domain transformation between *Laplace* and Z can be calculated using a discrete equivalent. In this case, the trapezoid rule[2] $s = (2/\tau)((z-1)/(z+1))$ has been used, where τ is the sampling time, as below:

$$\mathcal{Z}\left\{\frac{Q_v(s)}{Vol(s)}\right\} = \mathcal{Z}\{s\}, \quad \frac{Q_v(z)}{Vol(z)} = \left(\frac{2}{\tau}\right)\left(\frac{z-1}{z+1}\right) \tag{6.9}$$

$$\tau Q_v(z) + \frac{\tau Q_v(z)}{z} = 2Vol(z) - \frac{2Vol(z)}{z} \tag{6.10}$$

Equation (6.10) is the representation in the Z domain of eq. (6.7), which was strategically written to carry out its reformulation to a difference equation, resulting in eq. (6.11).

$$\tau Q_v(n) + \tau Q_v(n-1) = 2Vol(n) - 2Vol(n-1) \tag{6.11}$$

From where, finally, the volume variable can be cleared as shown below:

$$Vol(n) = \frac{\tau}{2}(Q_v(n) + Q_v(n-1)) + Vol(n-1) \tag{6.12}$$

The eq. (6.12) is then the solution with which the digital implementation of **volume calculation in the discrete time domain is possible**. It should be clarified that τ must be expressed in the same time units with which the volumetric flow has been established, besides considering that the initial values (i.e. at time zero) of flow and volume are zero, which means that for this application the lungs of the patients must be emptied initially, i.e., it should be started after a complete inspiration or expiration. In the flowchart presented in fig. 6.27, it is shown the implementation of the solution from a graphic perspective.

[2]Convergent geometric approximation, widely used in computational methods in computer science, for its great help in the approximation of integrals, and its application to Laplace transforms [87].

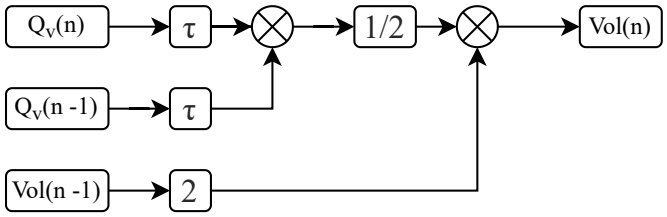


Figure 6.27: Flowchart of the respiratory volume calculation.

6.3.2 Methodology for Determining Respiratory Rate

The implementation for the estimation of the respiratory rate was carried out by analyzing the falling edge of the respiratory flow rate, this due to the change in sign that occurs when the flow changes from inspiration to expiration or vice versa. As described in section 4.5.3 on page 24 about respiratory rate, it is a fundamental vital sign that by convention is measured in breaths per minute (bpm), which means that this variable has a very low frequency response, typically 12 to 16 bpm, so in order to make a correct estimation without waiting a minute to obtain the result, this variable must be monitored for a considerable period of time to be able to extrapolate it afterwards, something that commercial respiratory rate meters also perform. It should be also noted that a breathing cycle should be counted when the person has made a complete inspiration and expiration.

Accordingly, the detection of a falling edge in respiratory flow can be implemented by comparisons of its sign between the current and the immediately preceding sample. Thus, the detected falling edges must be counted for a certain amount of time and then extrapolated to bpm. The digital implementation for respiratory rate estimation ultimately follows the diagram shown in fig. 6.28.

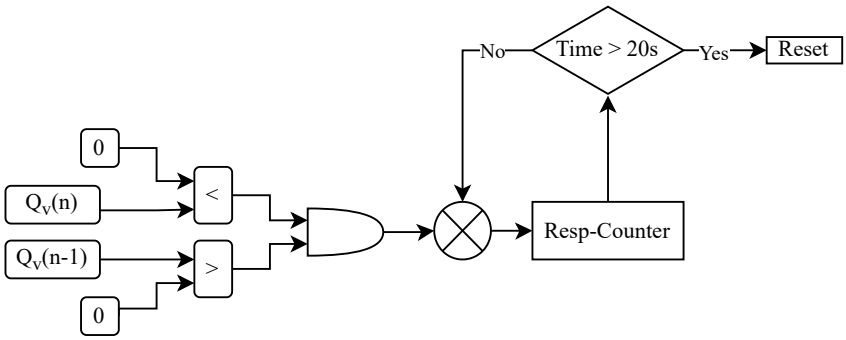


Figure 6.28: Flowchart respiratory rate estimation.

Chapter 7

Discussion

7.1 Model for the Estimation of Respiratory Flow Based on an Orifice Plate Sensor

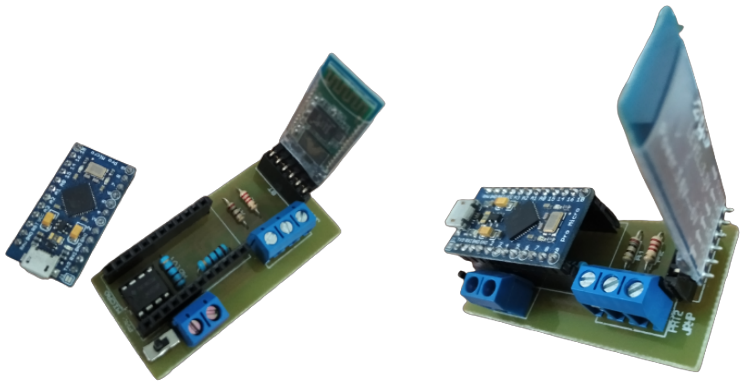
The result obtained by evaluating the model for the estimation of the respiratory flow in section 6.2.4 on page 75, accounts for an approximate response between the data obtained and the reference measured flow data. Additionally, a quantified estimate of the approximation was calculated by evaluating the RMSE, with which a measure of the mean dispersion of the respiratory flow values around those estimated by the model was calculated, obtaining a value of 0.0017. The small number obtained in the RMSE evaluation means that the measured air flow values fluctuate within 0.0017 m^3/s with respect to those estimated by the model. It is in turn possible to state that the model response, considering a differential pressure input and the dimensions of the Orifice Plate sensor, adequately approximates the real respiratory flow.

7.2 Electronic Device to Monitor Respiratory Flow Variable

Further electronic implementations in the development of the device were not carried out beyond the second prototype, since the necessary means were not available to continue the prototyping and prototyping stage of the device. Nevertheless, as a remarkable outcome, a physical implementation of the second updated prototype was achieved (see fig. 7.1), capable of capturing the respiratory flow variable and deducing the respiratory frequency and volume values adequately, as well as transmitting these data to a smartphone.

It is necessary to note that this implemented prototype was only tested by means of a low-resolution Orifice Plate sensor that was not properly designed since it was a preliminary prototype that could not be updated during the course of the local project. In turn, the wait for the proposed differential pressure transducer XGZP6897D exceeded the time in which it was possible to make physical prototypes, so it was not possible to implement a third prototype with this transducer.

As part of the comprehensive external project, the image in fig. 7.2 has been extracted, which shows a game application that receives the respiratory flow data sent by the system designed in this local project, and converts them into visual stimuli for patients in lung re-expansion physiotherapies. As a brief overview, the idea of the game was not to collide with the obstacles presented in the environment (the patient is the otter and the obstacles are algae), by means of inspiration and expiration, so that the patient can better engage in the physiotherapy processes of lung re-expansion.



(a) Main view of the acquisition and transmission circuit.

(b) Rear view of the acquisition and transmission circuit.

Figure 7.1: Acquisition electronic device.

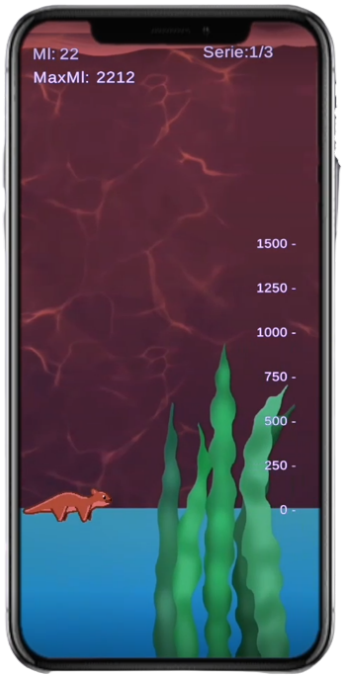
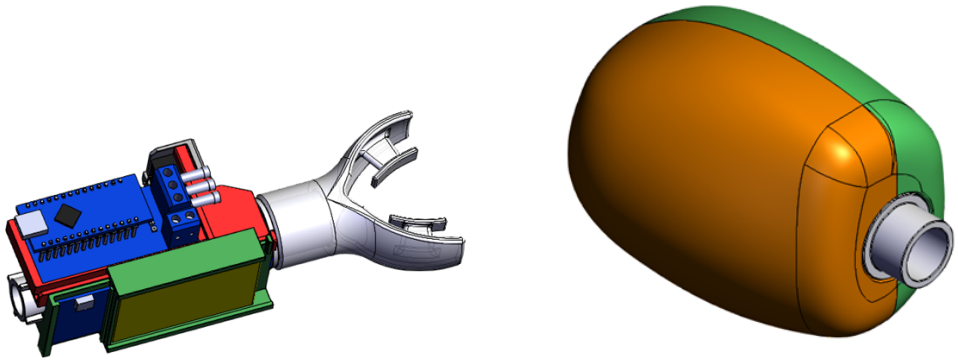


Figure 7.2: Game application developed within the framework of the comprehensive external project.

At the same time, a preliminary cover was designed for this prototype, to house the electronic measuring equipment. This approach can be seen in fig. 7.3.

As will be seen in the appendices, the constant updates of this base prototype, carried out by the external project team, led to the creation of the *UBICU* breathing incentive (refer to Comprehensive Project Outcomes).



(a) Inner structure. (b) Outer structure.

Figure 7.3: Preliminary cover proposal.

7.3 Technology Readiness Level (TRL)

Having a frame of reference in the scale for estimating the maturity of technologies, what has been developed in this local project lies between a **TRL 4 and 5**, as expected with the initial proposal of the project scope, since the prototyping and laboratory simulation processes have been achieved, which are characteristics of these levels [88].

Chapter 8

Conclusions

Throughout the development of this project, it was possible to design and implement a functional respiratory flow monitoring system for patients undergoing respiratory physiotherapy, that allows to achieve the objectives initially proposed within the scope of the local project. Thus, the physical system is capable of acquiring and processing the variables to determine inspiratory and expiratory flow, deriving the values of volume and respiratory rate, and communicating the acquired data to a mobile device via Bluetooth.

The conscious application of TRIZ methodology and Design Thinking concepts allowed the recognition and structured approach to the problem from a systemic perspective and with special emphasis on the needs of the user, and towards the device to support physiotherapies. Thus, the analytical breakdown of the problem gave rise to inventive solution propositions that, along with the requirements proposed by the Axiomatic Design method, paved the way for the design and implementation of the monitoring device, using the AHP decision-making method and the progressive improvement in the development of the system by means of iterative prototyping proposed by Design Thinking. In particular, it was possible to reach a convergence of the implementation alternatives proposed within the framework of the Axiomatic Design, by means of the conscious evaluation of criteria using the AHP method.

The adoption of the differential pressure principle was crucial for the acquisition of respiratory flow, whose advantages stand out over other acquisition methods such as those approached by turbines and hot wire transducers, among others, since it avoids problems associated with kinetic inertia, high costs or complex implementations. Upon application of the principle, the systemic analysis guided the implementation of an Orifice Plate sensor whose characteristics stand out from the Venturi Tube sensor, since it is possible to capture inspiratory and expiratory flow in the same device. Moreover, for the Orifice Plate sensor, a reliable model was developed that allows its use in medical (slow-flow and small dimensions) rather than industrial environments, through an adaptation of the ISO 5167 standard, by adopting a reformulation for the discharge and expansion coefficients. At the same time, it was possible to validate the model for the acquisition of flow rate in the measurement system through an Orifice Plate, which fits well with the actual reference flow data obtained in a controlled environment and, although the designed Orifice Plate sensor was not included in the reference setup for volumetric flow measurement, the one used meets the minimum design constraints, yielding reliable results.

Regarding the electronic acquisition and processing system, it was possible to implement the proposed methodologies for the determination of the volume and respiratory rate variables. On the one hand, for the determination of the volume variable, a solution using difference equations was proposed, which allows implementation in the discrete time domain. On the other hand, for the respiratory rate, the proposed solution is based on the detection of falling edges in the

acquired flow signal.

As a noteworthy remark, the designed system could be used for applications beyond lung re-expansion physiotherapies, as a device for general use in spirometry processes involving the joint estimation of respiratory volumes and capacities, for the sake of patient health monitoring.

It is worth highlighting that the results achieved in the development of this project were achieved through continuous collaboration with the main interdisciplinary project team, which resulted in a comprehensive design. Furthermore, the achieved results will serve as a basis for the continuation of the course of the main project and the *INSPIRAR* project, since it would be possible to implement an inspiratory and expiratory flow acquisition system.

Chapter 9

Future work

During the development process in the course of the project, a new approach to flow measurement was found that should be studied in future applications. This approach is based on the implementation of an Orifice Plate sensor to measure respiratory flow, which also considers the influence of air temperature in the flow estimation process, reducing the measurement error. This gives rise to a new model that relates flow rate to pressure drop using a power law exponent obtained by fitting experimental data [84].

$$Q_v = N_{vp} \frac{C\epsilon d^2}{\sqrt{1-\beta^4}} \frac{\sqrt{\rho_{f1}}}{\rho_b} \sqrt{\Delta P} \tag{9.1}$$

The way in which the authors in [84] relate this new approach is carried out by means of an analysis very similar to the one developed in this project, nevertheless, it takes another approach by considering that density depends on temperature. Equation (9.1) is the result of the analysis performed in the study, where there are now three new terms: ρ_{f1}, the upstream gas density at flowing conditions; ρ_b, the gas density at base conditions (T=288.15 K, P=101325 Pa); and N_{vp}, a factor for flowing volume with density determination [84]. In turn, eq. (9.2) describes the density as a function of temperature T, which was extracted from an experimental extrapolation.

$$\rho_{air} = -0.004T + 1.286 \tag{9.2}$$

Consequently, the model proposed in the study to relate the volumetric flow rate to the differential pressure and air temperature is shown in eq. (9.3).

$$\Delta P = \frac{\alpha^2}{-0.004T + 1.286} Q^2, \quad \alpha = \rho_b \frac{\sqrt{1-\beta^4}}{N_{vp}} C d^2 \epsilon \tag{9.3}$$

Moreover, it might be important to consider the implementation of a modification to the Orifice Plate structure shown in fig. 9.1 [84], particularly on the inner plate. This plate modification considers the addition of two diagonal cuts of α angle with respect to a vertical plane in the middle of the plate. These angular cuts have been made symmetrically respect to the middle of the plate so they guarantee symmetry and, therefore, bidirectionality. Thus, this modification gives rise to improvements in accuracy and reduction of uncertainty in volumetric flow measurement.

By adding two diagonal cuts at the edges of the plate, the flow can move more smoothly through the orifice. Typically the angle for which these improvements have been considered

is an angle of 45° [84], which is measured with respect to a horizontal drawn by another ring concentric to the orifice of the plate.

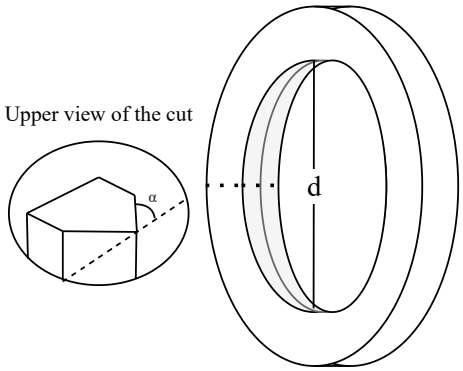


Figure 9.1: Consideration in the structure of the plate.

Furthermore, as a proposal for future work, it is possible to suggest the implementation of the electronic system making use of the differential pressure transducer XGZP6897D (product of the analysis and selection) that integrates a ready-to-use digital system with IIC interface, in addition to its own signal conditioning system. It is also possible to replace the general-purpose amplifiers used in the designed system with instrumentation amplifiers. At the same time, the implementation of the Orifice Plate sensor designed for future developments is proposed, since it will have a conscious construction for a medical environment that responds to the developed model and allows the acquisition of inspiratory and expiratory flow.

Appendices

Appendix A

Comprehensive Project Outcomes

A.1 Contests, Articles and Conferences

Throughout the development of the project, we have participated in contests, conferences and article publications. These events are briefly listed below:

- Minciencias: *Convocatoria 895-2021 Reactivos, Insumos y Metodologías de Prevención de Enfermedades Desatendidas y Transmisibles, del Programa Nacional de Ciencia, Tecnología e Innovación en Salud. Línea Temática: Equipos y Dispositivos Médicos.* Project name: *Sistema Incentivo Respiratorio para Fisioterapia Remota de Pacientes con Secuela COVID-19.* **Approved**.
- Participation in *Congreso de Investigación Javeriana 2021.*
- Lecturer at *Tercer Encuentro Javeriano de Semilleros de Investigación.*
- Conference and poster at *Encuentro Internacional de Educación en Ingeniería de la Asociación Colombiana de Facultades de Ingeniería (ACOFI)*, under the event *Mujeres en Ingeniería.* Conference name: *DISEÑO INTERDISCIPLINAR DE UN SISTEMA INCENTIVO RESPIRATORIO* [89].
- Participation in *II Coloquio de Tecnología Aplicada a la Salud México 2021.* Participation pending for 2022.
- Presentation for *Agencia de Desarrollo Tecnológico Reddi.* Project name: *Sistema Incentivo Respiratorio.*
- Participation and article for *Red Nacional de Semilleros de Investigación (RREDSI).* Code: V8021-1717. Conference Name: *Diseño Interdisciplinar de un Sistema Incentivo Respiratorio.*
- **Winning project** in *Premios a la Innovación Universitaria 2022 CIDESCO.* Category: *Innovaciones Superiores.* Project name: *UBICU.*
- Scientific article currently under construction for one of the Minciencias approved journals.

A.2 Respiratory Incentive System UBICU

Along with the external/main project team it was possible to evolve the device to a higher degree of application (out of scope of the local project), although the feature of acquiring the respiratory flow in both directions was discarded since it was implemented with a Venturi Tube

as a sensor. The device resulting from this development was named *UBICU*. A promotional and informative video about this device can be seen in the reference [90].

Figure A.1: Respiratory incentive system UBICU.

Figure A.1 shows the electronic device and gaming application developed under the external project. It should be noted that it is now a clinically tested device, in the patenting process and on the way to commercial implementation.

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