Report 1: Pulmo-Vest

Biomedical Systems Design

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Abstract- This document presents the development of a project focused on the design of biomedical systems. It analyzes and discusses real needs that could be solved, identifies related projects, and compares them with the proposed solution. The study details the technical specifications of the project, as well as its intended functions and expected performance. Specifically, the project aims to address respiratory diseases through the design of a percussive vest that facilitates therapy. Additionally, an interface will be developed to enable patients to perform the therapy from home, enhancing accessibility and treatment.

I. DESIGN PHASES

The engineering design phases are essential for structuring and developing projects efficiently, effectively, and safely. To begin with, it is important to understand the concept of design. Design is a structured process intended to meet a need while adhering to specific constraints. This process can be viewed as a closed-loop system that strives to achieve Six Sigma, which can be defined as a quality improvement methodology focused on identifying and eliminating defects in a process (Hanna & McLaughlin, 2024). The methodology consists of five key stages: Define, Measure, Analyze, Improve and Control.

The design process is typically divided into six main phases:

1. **Recognition of the Need:** Design is naturally a creative process, but it only qualifies as true design when it addresses a specific need, which forms the core of any design activity. Needs can vary in their level of innovation, but the ultimate goal is always to meet client expectations. Defining the need requires identifying the problem and posing questions to establish the limitations of the design process.
2. **Problem Definition:** At this stage, a detailed specification of the desired product is created. This involves gathering information through focus groups, user experiences, and literature reviews to determine whether proposed solutions meet the initial requirements.
3. **Conceptual Design:** Known as the formative and creative stage, this phase involves calculations and selecting software or hardware components based on the project's needs. These components must collectively address the primary requirement.
4. **Embodiment Design:** In this phase, the prototype of the system is developed.
5. **Evaluation:** Once the prototype is complete, it undergoes evaluation to ensure it meets all initial specifications and requirements.
6. **Market Introduction:** When the design is finalized and meets all criteria, the product is launched and made available to customers.

Although these stages define the typical design process, the sequence may vary depending on challenges encountered. Revision is often necessary to ensure the final product meets expectations and avoids potential issues for clients or economic losses.

Various design models provide frameworks for structuring this process, such as Pugh’s and Pahl and Beitz’s models. These models place particular emphasis on the early stages, especially defining the need, as thorough initial planning can save significant time and resources as the project progresses. Proper documentation of each stage is also important to maintain organization and clarity throughout the process.

In the context of medical device design, the process remains largely the same but with additional regulatory requirements. International standards and institutional regulations mandate strict design controls to ensure that devices meet safety and functional criteria.

Following a structured design methodology is important

for medical device designers. As Ogrodnik (2013) notes, using the Six Sigma approach helps maintain high-quality outcomes: "If your first three designs are rubbish, then your next 999,997 have to be spot on." Effective process control not only saves time but also reduces costs and accelerates time to market, offering significant competitive advantages.

II. CASES

Environmental and health challenges require innovative solutions on a global scale. In Mexico, issues such as air pollution, non-communicable diseases, and limited access to healthcare are major obstacles affecting public health. The following cases emphasize the need for technological advancements and engineering solutions to address these critical health problems and improve the well-being of the population.

Case 1: Air pollution

The United Nations (UN) has developed several projects for the prevention of global dangers, including the creation of the United Nations Development Program (UNDP), which supports different infrastructures in member countries. One of the fundamental aspects of this program is the protection of health in the participating nations.

In the case of Mexico, air pollution represents one of the main environmental and public health crises. It is estimated that approximately seven million deaths worldwide are related to exposure to air pollutants, which increases the risk of respiratory and cardiovascular diseases. In response to this problem, the country has committed to substantially reducing, by 2030, the number of deaths and illnesses caused by hazardous chemicals, as well as air, water and soil pollution.

Initiatives implemented in Mexico:

To mitigate the effects of environmental pollution, Mexico has promoted various strategies, among which the following stand out:

1. **Vehicle Verification Program**: Implemented to reduce polluting emissions from vehicles, this program has contributed to a 20% reduction in emissions from mobile sources.
2. **“Hoy No Circula”:** Program that restricts the circulation of vehicles on specific days with the aim of reducing air pollution.
3. **Regulation of Industrial Emissions:** Implementation of measures to control emissions of volatile organic compounds in household products, cosmetics and paints.

These initiatives have contributed to the reduction of air pollution, especially in large cities such as Mexico City, Puebla, Guadalajara and Monterrey, where population density and the use of private transport are high.

From the perspective of biomedical engineering, it is essential to develop strategies that allow the early detection of respiratory and cardiovascular diseases caused by pollution. Some of the technological solutions that can be implemented include:

Design and supply of medical devices for continuous monitoring of lung and cardiovascular function in people exposed to pollutants.

Development of pulmonary and cardiovascular therapies for patients with conditions derived from environmental pollution.

The development of these solutions will not only reduce the negative impact of pollution on health but also improve the quality of life of the affected population.

Case 2: Non-communicable diseases

In recent years, international organizations such as the World Health Organization have overseen monitoring and looking for factors of change in the face of global problems in the health sector. To date, it is reported that every two seconds people between the ages of 30 and 70 die prematurely due to non-communicable diseases, such as cardiovascular diseases, diabetes, cancer, and chronic respiratory diseases. The World Health Organization seeks to reduce this premature mortality rate by a third by 2030 through prevention and treatment protocols, in turn promoting mental health and general well-being related to these diseases. To address these problems, good health is essential for sustainable development. With this, the UN 2030 agenda relate these two concepts considering economic and social inequalities, as well as environmental factors and emerging challenges with non-communicable diseases.

Different problems in the health sector have been pointed out, where the field of engineering seeks to contribute in different ways to mitigate these and move towards sustainable development for global health. With new advances in science and technology, there is great potential to be able to develop new protocols to address global health issues.

Among the problems pointed out in "Emerging trends and technologies: a horizon scan for global public health" of the UN, we find 2, which could be related to chronic respiratory diseases as mentioned above, although they do not speak directly of respiratory diseases, they are problems that can encompass the need that we seek to satisfy with the use of engineering

technologies.

1. **Pandemic preparedness and prevention:** This point establishes that there is an area of significant improvement in pandemic preparedness and response through trials of therapeutic interventions and preparation of post-pandemic protocols. From this last point the following analysis is derived. After having lived through the COVID 19 pandemic, many patients who were infected by this virus were able to recover, however, many came to present considerable sequelae to recover their original lifestyle. The main sequelae that have been recorded can be shown on Table 1:

Afectación clínica secular y consecuencias del coronavirus más frecuentes.

Tejido o sistema	Síntomas seculares asociados a la COVID-19
Vía aerea respiratoria superior	Grado residual de anosmia y/o ageusia Tos
Vía aerea respiratoria inferior	Disnea de esfuerzo Tos Secreción mucosa Dificultad para inspiración profunda Dolor torácico
Muscular	Debilidad generalizada Dolores erráticos
Neurocognitivo	Falta de atención Pérdida de memoria Mala calidad del sueño Insomnio
Psicológico	Ansiedad Depresión
Digestivo	Atragantamiento Cambio en el ritmo deposicional Sensación de plenitud
Otros	Pérdida de peso

Table 1. Clinical affectation, sequelae and stronger consequences of the coronavirus (Molina-Molina, 2020).

2. **Digital diagnosis and surveillance:** On this point, it establishes itself as "Digital Health", which encompasses the use of information, electronics, and telecommunications for medicine. There is talk of portable devices, databases, and information technologies for medicine. Mainly the devices that we have for this point are monitoring devices.

Then again, as biomedical engineers, it is essential to provide a therapy that helps the patient recover their respiratory capacity through high-frequency vibrations and the recording of respiratory volumes, which are stored and opens the possibility that the therapy can be performed remotely, without the need for the patient to go to a health center while the therapy is being performed.

This point is complemented by the provisions of the Global Health Strategy 2025-2028, in the section "Health information systems strengthened, and digital transformation implemented".

Case 3: Limited access to healthcare services in Mexico

The Mexican Constitution mandates the creation of a National Development Plan (NDP), which guides federal programs. The NDP 2019-2024 served as the principal planning tool for that administration, defining key national priorities. Although the administration recently changed and the new NDP is unavailable, the previous plan remains a reference point. One of its essential health objectives is to "Guarantee public health services to the entire population without social security, including free medical care, exams, and medications listed in the National Compendium of Health Supplies." (“DOF - Diario Oficial de La Federación,” 2020).

This objective responds to persistent challenges in the Mexican healthcare system. Bautista (2023) highlighted that in 2022, 4.6% of the population reported a healthcare need in the previous three months, but only 44% received care from public health services. Factors contributing to this gap include limited accessibility, poor service quality, personnel shortages, and insufficient medication availability.

To mitigate these issues, biomedical engineers can play a crucial role by developing integrated technological solutions. Proposed measures include real-time medication supply monitoring systems, preventive maintenance strategies for health units, and training programs for community health promoters in marginalized regions. These initiatives aim to improve access to public health services and ensure more equitable healthcare delivery across the country.

III. IDENTIFIED NEEDS

Table 2 below provides a summary of the previously discussed cases along with their corresponding needs.

Case 1: Air Pollution	
Need	Developing strategies for the early detection of respiratory and cardiovascular diseases caused by pollution, including the creation of medical devices for continuous monitoring and therapies for affected patients.
Case 2: Non-communicable diseases	

Need	A therapy that helps the patient recover their respiratory capacity to address problems derived from chronic respiratory diseases using digital systems for diagnosis and monitoring, thus promoting the use of technologies and information systems for remote monitoring and the so-called "digital health".
Case 3: Limited access to healthcare services in Mexico	
Need	Creation of integrated technological systems for real-time monitoring of medication supply, preventive maintenance of health units, and training of community health promoters in marginalized regions to ensure universal access to medical services.

Table 2. Identified needs.

Our focus will be on addressing the needs related to Case 2: Non-communicable diseases. Our project aims to develop a system that targets respiratory issues, specifically in the upper and lower airways.

The primary objective is to develop a therapy system that supports patients in recovering their respiratory capacity through high-frequency vibrations. Additionally, the system will record and store respiratory volumes, making it possible for the therapy to be performed remotely, without the need for patients to visit healthcare facilities.

In addition to addressing health concerns, our project will promote the integration of digital tools, health records, and information systems. These systems will help eliminate inequalities and structural barriers, such as gender and disability, and guide the digital transformation of health systems. By ensuring a people-centered approach, we aim to improve the effectiveness of health programs, enhance real-time monitoring, and improve the management of healthcare resources. This digital transformation will modernize data systems, leading to improved healthcare access and performance.

IV. RESEARCH PROJECTS THAT ADRESS THE SELECTED NEED

PEP (Positive Expiratory Pressure):

Small and portable instruments are commonly used for airway clearance therapy. Indicated for patients with respiratory diseases that produce excessive amounts of mucus in the lungs. This device works by generating mechanical oscillations, which in turn generate vibration inside the airway. Together with these vibrations, positive pressure is generated, which pushes the mucus, favoring its clearance. **Acapella** vibratory positive expiratory pressure devices are designed for individual and reusable use, providing PEP (positive expiratory pressure) therapy to patients with pulmonary conditions such as cystic fibrosis, COPD, asthma, atelectasis, and other diseases that affect secretion clearance. (*AcapellaTM Respiratory Therapy Systems*, n.d.). Image 1 shows an example of PEPD:

Image 1. Acapella PEPD.

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Digital spirometer:

NDD Medical Technologies designs advanced and user-friendly devices for pulmonary function testing, making the diagnosis and treatment of respiratory diseases highly precisely. As can be seen in Image 2, **EasyOne** product line, specializing in spirometry and comprehensive lung function tests, stands out for its reliability and ease of use, making it one of the best options available in the healthcare sector. (ndd Medical Technologies, n.d.)

Image 2. EasyONE spirometer devices.

High frequency chest compression:

A pulmonary therapy vest is a medical device designed to help people with lung conditions such as cystic fibrosis or bronchiectasis. It works by applying controlled vibrations through air chambers in the vest that surround the patient's torso. These vibrations help to mobilize pulmonary secretions adhered to the walls of the lungs, thus facilitating their expulsion through coughing or expectoration, improving lung function, and

reducing the risk of respiratory infections. From Image 3 the inCourage device is an effective tool for long-term lung health management. (inCourage [respire tech], 2018)

Image 3. inCourage therapy vest.

IV. COMPARATIVE ANALYSIS AND IMPACT

To position our percussive vest in the market, a comparative analysis was conducted between existing solutions, such as the Hill-Rom Vest Airway Clearance System [24] and the AffloVest [25]. To evaluate the impact that a new percussive vest could have on the market, we took into account its possible global, cultural, economic, social and environmental impact, taking into consideration the existing options currently available.

- **Global impact**

The Hill-Rom Vest is a widely recognized airway clearance system, predominantly used in developed countries such as the United States and Europe. Similarly, the AffloVest has gained attention due to its portability and battery-powered operation. However, both devices remain largely unavailable or unaffordable in many low-income countries due to their high costs and reliance on advanced medical infrastructure. Our proposed vest seeks to bridge this accessibility gap by offering a low-cost alternative that can function efficiently in diverse settings, including regions with limited healthcare resources.

- **Cultural impact**

In various parts of the world, respiratory therapies are not widely understood or accepted due to cultural perceptions of treatment methods. Many communities rely on traditional remedies or manual percussion therapy administered by caregivers. The current vests require patient education and adaptation, which can be a barrier to their widespread adoption. Our design seeks to integrate user-friendly instructions and interface, as well as localized training tutorials to ensure that patients and caregivers can easily understand and utilize the device efficiently, promoting better acceptance in different cultural contexts.

- **Economic impact**

Both the Hill-Rom Vest and AffloVest are priced at several thousand dollars, making them inaccessible to a large portion of the global population. The high cost is primarily due to specialized manufacturing processes, patented technologies, and limited competition in the market. Our approach focuses on developing a cost-effective alternative using locally sourced materials, open-source design principles, and simplified manufacturing methods. By significantly reducing production costs, we aim to create an affordable solution that can be adopted by hospitals, clinics, and even home users in low- and middle-income countries.

- **Social impact**

The financial burden of chronic respiratory conditions affects patients and their families, leading to long-term healthcare costs and reduced quality of life. Current percussive vests, while effective, are often prescribed only to patients who can afford them or have access to extensive health insurance coverage. Our proposed vest would provide an opportunity to lowe-income patients to receive the same benefits, helping to reduce hospitalization rates and caregiver fees (since our interface focuses on being user-friendly and easily accessible for both patients and family members), improving overall health outcomes. By making airway clearance therapy more widely available, we can enhance social equity in healthcare access.

- **Environmental impact**

Existing percussive vests rely on electronic components and materials that contribute to waste when they reach the end of their life cycle. Additionally, some models require significant power consumption, increasing their carbon footprint. Our vest aims to incorporate sustainable design principles, such as recyclable materials, modular construction for easy repairs, and energy-efficient operation. By prioritizing environmental responsibility, we aim to create a product that not only benefits human health but also minimizes ecological harm.

V. DEFINE THE PRODUCT DESIGN SPECIFICATIONS.

The product design specifications are presented in Tables 3 to 6. The specification comments were selected based on various references.

Section 1: Regulatory and statutory		
Number	Comment	Source
1	NOM-241-SSA1-2021 Good manufacturing practices for medical devices.	[21]
2	NOM-036-1-STP-2018 Ergonomic risk factors in the workplace - Identification, analysis, prevention, and control.	[22]
3	NOM-240-SSA1-2012 Installation and the operation of techno vigilance.	[23]

Table 3. Regulatory and statutory.

Section 2: Technical specifications		
Number	Comment	Source
1	Adjustable vest.	[15]
2	DC Motors: • Oscillations from 2 to 25 Hz. • Connectivity: Arduino UNO.	[18]
3	Lung capacities measurement: • Flow rate: ±10 L/s • Dead Space: 93 mL	[16]
4	PC Software: • Lab View.	[17]
5	Environmental conditions • Relative humidity between 15% and 93%, without condensation.	[28]
6	Working Temperature • Between 18 and 28 ºC ambient temperature.	[21]
7	Electrical requirements for the entire system: • External power source.	[18]
9	Cleaning requirements: • Hands must be washed before and after the start of the therapy. • Disinfection of the vest and the spirometer after therapy with sanitizer. • The spirometer tube must be disposable.	[29]
10	Calibration requirements: • There will be no calibration because the therapy will be already established.	[13]

Table 4. Technical Specifications.

Section 3: Performance		
Number	Comment	Source
1	The vest will generate vibrations in the anterior and posterior thoracic cage from 2 to 25 Hz with motors.	[11]
2	Measurement of lung capacities with a Spirometer and an acquisition card NI USB 6009: • Flow rate: ±10 L/s • Dead Space: 93 mL • Nominal Output: 128 mV/[L/s] • Detachable Flow Head	[12,16]
3	Save your data daily and weekly on the PC storage (max. twice a	[13]

	day).	
4	The therapy will last 30 minutes, divided into 12 steps of 2.5 minutes. The therapy will be configured with the default parameters as follows: • It increases from 6 Hz to 15 Hz over a 2.5-minute period, then it drops from 15 Hz to 6 Hz during the next 2.5 minutes and repeats for a total of 30 minutes. User configurable parameters: • Start button. • Emergency stop button (pause).	[13]
5	The vest will be adjustable for each patient.	[13]
6	There will be a PC LabView interface: • Indicates when and how the patients need to breathe to start taking measurements. (Following a reference) • Indicates when to start the therapy.	[14]

Table 5. Performance.

Section 4: Environmental		
Number	Comment	Source
1	Recycled materials: • For external and internal packaging. • All the components will be classified at the end of the product lifetime. • Promote the recovery of electronic components, plastics, metals, or other parts of the device.	[27]
2	Disposal:	[21]
3	Energy efficiency: • The system will consume the lowest possible energy during its usage.	[27]
4	Product lifetime: • The life expectancy of the motors is approximately 6 years, considering two daily therapies.	[26]

Table 6. Environmental.

VII. DEVELOP A FEASIBILITY ANALYSIS (TECHNICAL AND ECONOMICAL) OF THE PROJECT

- Assessing Technical Requirements

For our respiratory therapy vest, we need a design that can adjust to different body sizes to ensure both comfort and the proper alignment of therapeutic components with the anterior and posterior thoracic areas. This adjustable design is important because it helps deliver the required vibratory therapy effectively while also ensuring that respiratory measurements taken before and after the therapy are accurate. However, integrating electronic components into a fabric structure presents challenges in terms of ensuring that the vest maintains its mechanical integrity and that the components remain securely attached without compromising comfort or function. Additional considerations are the proper distribution of forces and taking into consideration people of bigger / smaller body sizes.

The vest will incorporate DC motors to produce oscillations in the thoracic regions, with operating frequencies mentioned in Table 4 and 5. These motors must be connected through an Arduino UNO to allow for controlled, programmable movements. The integration of the Arduino UNO will enable us to manage the motor functions effectively; however, careful attention must be paid to signal management and synchronization across the entire frequency range. One potential challenge is

ensuring that the motors perform consistently without interference from nearby components, especially since they need to maintain performance across a specific range of frequencies.

Another key requirement is the ability to measure lung capacities both before and after vibratory therapy. The device must capture flow rate measurements with a range of ±10 L/s and account for a dead space of 93 mL. These measurements will help evaluate the effectiveness of the therapy by comparing respiratory data before and after treatment. A significant challenge in this area is to capture reliable data under different conditions while maintaining the repeatability of the results. This will require careful sensor integration and possible data processing techniques to reduce measurement errors.

For data visualization and analysis, the project will use a LabVIEW-based PC software interface. Initially, there was an idea to work with computer systems students to develop a custom application, but due to time and logistical constraints, LabVIEW has been chosen as the primary platform. LabVIEW is well regarded for its capabilities in data acquisition and visualization, and it will help monitor therapy sessions and analyze respiratory data in real time. Although using LabVIEW simplifies some aspects of software development, it is important to ensure that the interface is user-friendly and can manage real-time data streams effectively without delay.

The vest must also operate reliably within specified environmental conditions. It should perform well in the temperature ambient relative humidity levels specified in Table 4. These parameters are important for both the comfort of the patient and the correct functioning of the device’s electronic components. Designing the system to handle these environmental factors might require additional protective measures for sensitive parts, particularly in conditions that approach the specified limits.

Regarding electrical requirements, the entire system will rely on an external power source. This means that the design must incorporate a stable power supply that provides consistent energy to all components, including the DC motors and the data acquisition system. Managing the power supply effectively is important to avoid issues such as voltage fluctuations or interruptions during therapy sessions.

Finally, calibration procedures are not part of the operational workflow, as the therapy parameters will be predetermined and set by default (as specified in Table 5 of the project documentation). While this approach reduces the need for ongoing calibration by the end user, it places a strong emphasis on the initial configuration. The default settings must be carefully validated during the design and testing phases to ensure that they deliver the intended therapeutic benefits.

- Estimating Financial Viability

In assessing the overall financial feasibility of our respiratory therapy vest project, we need to look at both the direct costs we will incur and the resources that are already available to us. Our approach here is a broad estimate of the expenses involved, keeping in mind that some of the equipment and materials are provided by our university's facilities.

The first cost to consider is purchasing the adjustable vest. Our project requires a vest that offers comfort, flexibility, and durability, especially since it must house both the electronic and mechanical components needed for therapy. Based on our preliminary research, we expect that a vest will cost approximately $30 to $80 per unit. This price range accounts for a vest that can be adapted to fit various body sizes and provide a secure platform for the integration of other components.

Another significant expense comes from integrating DC motors into the vest. In addition to purchasing the DC motors, we will also need to buy the necessary materials for their integration, such as wiring, mounting hardware, and any protective casings or insulation. Early estimates suggest that each motor and its integration materials could cost between $20 and $40, depending on the specifications and the quantity needed. For our prototype, we might use several motors, and the total expense will be the sum of these individual costs.

One of the benefits of this project is that several critical items are already available through our university’s electronics laboratory. For instance, we have access to the LabVIEW software, which will serve as our data acquisition and visualization tool. This eliminates the need for additional expenses in software licensing. Moreover, the external power source and other related electrical components required for the system are also available in the lab. Leveraging these existing resources helps keep the overall cost lower and makes the project more feasible from a financial perspective.

Taking all these factors into account, the primary costs for our project are associated with purchasing the vest and the DC motors along with their integration materials. For a prototype, our total estimated investment ranges from about $50 to $120. This estimate reflects the costs for a small-scale, proof-of-concept model rather than a full-scale production run. It is also important to recognize that if the project were to advance beyond the prototype stage,

additional expenses such as labor, further design iterations, and extensive testing would need to be included in the budget.

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