

École polytechnique de Louvain

Design and prototyping of alternative negative pressure wound therapy devices to reduce the risk of amputation in low-income countries

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ABSTRACT

In many low- and middle-income countries (LMICs), access to advanced medical devices is limited, creating significant challenges in managing chronic wounds. Negative Pressure Wound Therapy (NPWT) is a proven method for promoting wound healing and reducing infection rates. However, the high costs and infrastructure requirements of commercial NPWT devices often render them inaccessible in resource-constrained settings. In regions like Cameroon, this inaccessibility exacerbates the risk of preventable amputations, leading to profound social and economic impacts.

This thesis addresses the need for a cost-effective and context-sensitive alternative by designing an open-source NPWT device tailored to the unique challenges of LMICs. Cameroon is used as a case study to identify specific design requirements, including affordability, simplicity, and robustness. While the device is tailored to Cameroon's unique context, it is designed to be adaptable for use in other LMICs with similar challenges. To guide design decisions and support future implementation, multiple prototypes were developed and evaluated comparatively.

The study presents the development and testing of three functional NPWT prototypes: a PVC-based pump, a syringe-based system, and an electromechanical device. The syringe-based prototype showed the most potential, demonstrating a good balance of cost, effectiveness, and usability, despite its challenges in maintaining suction during wound simulation. The electromechanical version, while more complex and expensive, offers better control and is suited for outpatient care. Although the PVC-based design did not meet performance expectations during testing, it showed potential for future refinement due to its modular design, which has been shown to be functional in previous studies.

Overall, this work highlights the potential of open-source hardware to reduce healthcare inequalities by enabling locally adaptable, affordable medical solutions. The approach combines engineering design with community-driven innovation, laying the groundwork for improved wound care, reduced amputation rates, and increased healthcare self-reliance in LMICs.

Keywords: Negative Pressure Wound Therapy, NPWT, Vacuum Assisted Closure, VAC, Low and middle-income countries, LMICs, Wound, Amputations.

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Acronyms

AIMDD Active Implantable Medical Devices Directive 32

CAMFDA Cameroon Food and Drugs Authority 34

EC European Commission 31, 34

EU European Union 31

FDA Food and Drug Administration 31, 33, 34

IEC International Electrotechnical Commission 33

ISO International Organization for Standardization 33, 34

LEA lower extremity amputations 7

LMICs low and middle-income countries 1, 5, 9, 19

MDD Medical Devices Directive 32

MDR Medical Device Regulation 31, 32

NPWT Negative Pressure Wound Therapy 1, 5, 11, 12, 14, 15, 18–21, 26, 28, 31, 34, 36, 42, 50, 51, 57, 60

NPWTi-d NPWT With Instillation and Dwell Time 18

sNPWT Single-use NPWT 18

VAC Vacuum-assisted closure 1, 11

Introduction

In a world striving for equitable access to healthcare solutions, access to medical devices remains a significant barrier in low-resource settings [1]. Negative Pressure Wound Therapy (NPWT), also known as Vacuum-assisted closure (VAC), is a highly effective technique for managing chronic and complex wounds and clearly illustrates this disparity. Despite its proven effectiveness in accelerating healing and reducing infection rates [2, 3], the high cost and dependence on advanced infrastructure render it largely inaccessible in low and middle-income countries (LMICs) [4].

This lack of access has severe consequences, particularly for patients with chronic wounds. In LMICs like Cameroon, untreated or poorly managed wounds frequently result in preventable amputations. These amputations extend beyond physical disability, imposing profound emotional, social, and economic burdens on patients and their families. Loss of mobility often leads to unemployment, reduced household income, and increased dependency, perpetuating cycles of poverty and diminished quality of life [5]. At a broader level, these outcomes strain already overstretched healthcare systems, further limiting the ability to provide adequate care [6].

Given these challenges, there is an urgent need for innovative solutions that are both cost-effective and adaptable to resource-constrained environments. Open-source hardware presents a transformative opportunity in this context. By making medical device designs publicly available for adaptation and local manufacturing, open-source approaches empower communities to create affordable and sustainable technologies.

This thesis seeks to bridge that gap by conceptualizing an open-source, affordable, and context-appropriate NPWT device tailored to the unique challenges of Cameroon. Through this effort, it aims not only to improve wound care outcomes and reduce the prevalence of amputations but also to foster local innovation and self-reliance, contributing to a more equitable and accessible global healthcare landscape.

Open-Source and Healthcare Innovation

Open-source hardware represents a paradigm shift in technology development, prioritizing transparency, adaptability, and collaboration. Defined as “hardware whose design is made publicly available so that anyone can study, modify, distribute, make, and sell the design or hardware based on that design,” open-source technology offers unique advantages in addressing global challenges [7].

In healthcare, where access to medical devices can mean the difference between life and death, open-source innovation provides a pathway to scalable, sustainable solutions [1]. By embracing open-source principles, communities can collaborate to create innovative medical devices that address local needs. Unlike proprietary solutions, open-source devices encourage transparency, adaptability, and affordability, empowering regions with limited resources to develop and maintain their medical technologies sustainably [7]. These principles are particularly relevant to LMICs, where healthcare systems often face shortages of essential equipment. Applying open-source methodologies to NPWT device development not only addresses immediate needs but also fosters local innovation ecosystems capable of addressing future challenges.

Motivation

In Cameroon, as in many other LMICs, chronic wounds pose a significant healthcare burden. Conditions such as diabetic foot ulcers, untreated infections, and surgical complications frequently lead to amputations, significantly impacting patients’ quality of life and imposing financial and emotional stress on families [8, 9, 5]. These outcomes are often preventable with timely and effective wound care [10, 11]. However, the high costs and complexity of existing NPWT systems render them inaccessible in much of the country.

The motivation for this thesis arises from the intersection of this healthcare challenge and the untapped potential of open-source solutions. By developing an affordable NPWT device specifically designed for Cameroon’s context, this work seeks to:

- Reduce the prevalence of preventable amputations.
- Improve wound care outcomes in underserved regions.
- Strengthen the capacity of local healthcare systems to address similar challenges independently.

Moreover, this project is driven by a broader vision of fostering innovation in LMICs through open-source principles, enabling these regions to transition from passive consumers to active creators of medical technology.

Objectives

The overarching goal of this thesis is to design and prototype an open-source NPWT device that addresses the specific needs of healthcare providers and patients in Cameroon. This goal can be broken down into the following specific objectives:

- **Cost Reduction:** Develop a device that is affordable to produce, operate, and maintain using readily available materials.
- **Adaptability:** Ensure the design is flexible enough to be adapted to different clinical and infrastructural contexts within LMICs.
- **Sustainability:** Incorporate features that make the device durable and easy to repair, even in remote or resource-limited settings.
- **Performance and Effectiveness:** Ensure the device delivers reliable negative pressure, enhances wound healing outcomes, and meets clinical standards.

To support effective implementation, multiple prototypes were developed and comparatively evaluated to inform design trade-offs and guide decision-making for future adopters.

Contributions and Methodology

This thesis contributes to the field of medical device engineering by leveraging open-source principles to address healthcare disparities in resource-limited settings. It follows a structured methodology comprising the following stages:

Background and Context

The project begins with a detailed case study of Cameroon, examining its healthcare infrastructure, socio-economic conditions, and cultural dynamics. Comparative insights from other LMICs help contextualize Cameroon’s healthcare challenges and guide the design process. Emphasis is placed on affordability, usability, and robustness—key factors for NPWT devices in low-resource environments.

State of the Art

An extensive review of NPWT technologies is conducted, focusing on clinical benefits, operational principles, and limitations in LMIC settings. Other open-source medical devices are also reviewed to identify effective strategies and common pitfalls.

Requirements Definition

Requirements were defined based on insights from the contextual study and literature review. Input from key stakeholders, including the supervisors and Dr. Joseph

Djoko, was incorporated through consultations to ensure clinical and contextual relevance. Additionally, a targeted review of applicable standards and regulatory frameworks for NPWT devices informed the specification of safety, performance, and usability criteria. These requirements served as the foundation for guiding design decisions.

Design and Prototyping

Three distinct NPWT prototypes were developed—two manually operated mechanical systems and one electromechanical device. The designs were guided by the defined requirements and emphasized cost-effectiveness, simplicity, and local manufacturability.

Testing and Validation

The performance of all three prototypes was characterized through targeted tests assessing their ability to generate and maintain negative pressure. Key parameters such as pressure generation, flow rate, and stability were assessed to determine suitability for low-resource clinical settings. Testing also simulated wound conditions using airtight enclosures and tubing to replicate real NPWT operation.

Structure of the Thesis

This document is organized into six chapters, each addressing a critical aspect of the research:

- **Chapter 1: Background and Context** provides an overview of healthcare challenges in LMICs, focusing on Cameroon and the role of NPWT in addressing these issues.
- **Chapter 2: State of the Art** reviews existing NPWT devices, including commercial systems and previous open-source adaptations.
- **Chapter 3: Design Requirements** explains the working principles of the NPWT system in details and outlines design requirements, including client needs and technical specifications from regulations and standards.
- **Chapter 4: Prototype Development** covers the design, testing, and comparison of several mechanical and electromechanical NPWT prototypes.
- **Chapter 5: Testing and Validation** details the experimental evaluation of the prototypes, with a comparative analysis against existing systems.
- **Chapter 6: Future Work** explores potential improvements to the various prototypes developed in this thesis, aiming toward the refinement and finalization of a fully tested, open-source NPWT system ready for broader dissemination and implementation.

Chapter 1

Background and Context

In LMICs, healthcare providers encounter major difficulties in managing complex and chronic wounds [12]. These regions often lack advanced medical technologies, have limited healthcare resources, and possess inadequate infrastructure. In addition, money is limited, and it is often hard to get maintenance, spare parts, and supplies for medical equipment. These challenges make effective treatment more difficult, resulting in higher infection rates, delayed healing, and an increased risk of amputation [13, 14].

NPWT has been found to be effective in promoting wound healing by applying controlled negative pressure to the wound area [11, 2]. However, these devices are costly and require complex infrastructure to use. This limits their availability and creates a significant barrier to improving wound care in LMICs, where such treatments are urgently needed [15].

Developing a cost-effective NPWT device tailored to the specific needs of LMICs could significantly improve wound care outcomes and reduce the burden on healthcare systems in these regions. To identify these needs, a case study of Cameroon has been conducted. Section 1.1 explores Cameroon’s economy, healthcare system, culture, education level, infrastructure, industry, and governance, highlighting the factors that play a crucial role in the successful implementation and use of medical technologies in such settings. Section 1.2 positions Cameroon within the broader context of LMICs, comparing its challenges and opportunities to ensure the potential for wider adoption of solutions. Section 1.3 examines the implications of these findings for NPWT device design, focusing on how the insights can inform a device tailored to low-resource environments.

1.1 Case Study - Cameroon

1.1.1 Economy

Cameroon’s economy is classified as lower-middle-income, with a population of approximately 28 million and a Gross National Income (GNI) of approximately 1,500 EUR per capita in 2023. The country’s Gross Domestic Product (GDP) was projected to be around 43.6 billion EUR in the same year, with economic growth estimated at 4.0% [16]. This growth is primarily driven by the forestry, logging,

and services sectors, alongside a wealth of natural resources, including oil, gas, mineral ores, timber, and agricultural products such as coffee, cotton, cocoa, maize, and cassava [17]. In contrast, Belgium, classified as a high-income country, has a significantly higher GNI per capita, estimated at approximately 49,100 EUR in 2023, with a GDP projected to be around 567 billion EUR [18, 19].

Despite the availability of natural resources, poverty reduction has stagnated, with about 40% of Cameroonians living below the national poverty line. Approximately 23% live below the extreme international poverty line of 1.95 EUR per person per day. Corruption and bureaucratic inefficiencies significantly hinder economic progress, reflected in Cameroon's ranking of 144 out of 180 countries on the Corruption Perceptions Index [20].

1.1.2 Political and Social Landscape

Cameroon is located along the Atlantic Ocean and shares borders with the Central African Republic, Chad, Equatorial Guinea, Gabon, and Nigeria (Figure 1.1). The country is divided linguistically into Anglophone and Francophone regions, with the former primarily in the northwest and southwest. The Cameroon People's Democratic Movement (CPDM) has dominated the political landscape, winning nine out of ten regions in the first regional elections held in December 2020. These elections marked the start of the decentralization process as outlined in the 1996 Constitution.



Figure 1.1: Location of Cameroon in Africa [21]

Despite having several decades of stability, Cameroon has faced significant instability in recent years. These include attacks by Boko Haram in the Far North and a secessionist insurgency in the Anglophone regions since 2017. These conflicts have displaced over one million people internally and led to an influx of refugees, primarily from the Central African Republic and Nigeria. As of July 2024, Cameroon hosts over 472,000 refugees [16].

1.1.3 Healthcare

As of 2016, Cameroon had about 5,166 public and private healthcare facilities spread across 10 regions, 189 health districts, and 1,800 health areas. The healthcare infrastructure includes general hospitals, central hospitals, regional hospitals, district hospitals, district medical centers, integrated health centers, and ambulatory health centers. However, access to healthcare services was limited, with just 2.19 facilities available for every 10,000 people [6, 22].

1.1.3.1 The Burden of Amputation in Cameroon

Amputation is a life-altering event often resulting from disease or trauma, with lower extremity amputations (LEA) being the most common type [23, 8, 9]. In Western Sub-Saharan Africa, where Cameroon is located, over 1.4 million people were estimated to live with traumatic amputations in 2017 [9]. Although official records on amputations in Cameroon are lacking, it is estimated that around 800 cases of LEA occurred in 2019 [24]. The leading causes of LEA in the region include trauma, complications from diabetes mellitus, untreated infections, and chronic wounds [8, 9]. Locally, amputees in Cameroon are referred to as "*moto ma iyende*", "*epassa moto*", or "*ebwoa*", meaning "half person", reflecting the profound physical and social impact of amputation [24].

Amputation is associated with significant physical, psychological, and socio-economic challenges. The loss of mobility and independence often leads to disability, joblessness, and a reduced quality of life. Psychological effects include a loss of body image, increased vulnerability, and poor mental health outcomes [5]. Families and healthcare systems face increased burdens, and individuals with amputations may experience higher mortality rates [5]. However, advanced wound care techniques, such as NPWT, have shown promise in reducing the risk of amputation, emphasizing the importance of improving access to effective treatment to mitigate these devastating outcomes [10, 11].

1.1.4 Infrastructure

Cameroon's infrastructure is a critical component of its economic framework, encompassing several key sectors: transport, power, and water supply. Each of these sectors has its unique characteristics, achievements, and challenges that significantly impact the country's overall development [25].

In the transport sector, Cameroon plays a crucial role as a transit hub for landlocked Central African countries, with the Port of Douala (Figure 1.2a) serving as the primary maritime gateway. While the port has seen some reforms and private sector participation that have improved its performance, it still faces significant challenges,

such as long dwelling times and inefficiencies in cargo handling. Similarly, the CAMRAIL railway network (Figure 1.2b), which stretches approximately 1,100 kilometers and connects Douala to Chad, suffers from outdated infrastructure and rolling stock. Although Cameroon’s road network is extensive, it is hindered by poor quality and maintenance issues (Figure 1.2c), leading to high transport costs and delays.[25].



(a) Port of Douala [26].



(b) CAMRAIL Railway Network outdated infrastructure [27].



(c) Cameroon Road Network poor quality and maintenance issues [28].

Figure 1.2: Infrastructure challenges in Cameroon’s transport sector.

The power sector in Cameroon has seen improvements in access, with national electricity access rising from 37% in 1996 to 48% in 2007. However, the supply remains both expensive and unreliable, with frequent outages impacting businesses and households. While the privatization of the national utility, AES Sonel, has resulted in increased connections and investments in generation capacity, the sector still struggles with high distribution losses and issues related to underpricing [25].

Cameroon has made some progress in improving water supply and sanitation, particularly in urban areas; however, significant disparities remain between urban and rural populations, with rural communities facing much lower access to clean water. The institutional framework for water and sanitation services is fragmented, and the sanitation sector lacks a coherent strategy. Despite government-led reforms aimed at improving utility performance, issues such as underpricing and inefficiency continue to hinder access and result in economic losses[25].

1.2 Comparison of Cameroon with Other LMICs

To make a meaningful impact on wound care in Cameroon and similar contexts, it is essential to consider the country's position in relation to other LMICs. Cameroon, like many other African countries, faces significant healthcare challenges due to its lower-middle-income economy, high poverty rates, and limited infrastructure. When compared to other West African countries, Cameroon's healthcare system has a lower density of healthcare workers, with only 0.34 nurses per 1,000 people projected for 2024, and limited social health coverage, reaching just 6.46% of the population.

In contrast, Nigeria and Ghana have developed more extensive healthcare infrastructures. Nigeria, with about 80% of the region's healthcare facilities, has invested in public-private partnerships and established the National Health Insurance Authority to improve access, though rural areas still experience a shortfall in service distribution. Ghana's National Health Insurance Scheme, covering nearly 69% of its population, reflects a more comprehensive approach to accessible healthcare [29].

Cameroon also faces barriers in adopting advanced healthcare solutions. While countries like Nigeria and Ghana have implemented telemedicine and mobile health initiatives to bridge access gaps, Cameroon struggles with insufficient infrastructure, a shortage of trained professionals, and limited financial resources to support similar advancements. Additionally, regional instability in Cameroon has led to further declines in operational facilities, with 18% of health centers in the North-West and South-West regions shutting down since April 2023. These factors highlight the need for an NPWT device in Cameroon that is affordable and simple to use.

In contrast, other LMICs have developed more extensive healthcare infrastructure, like for example Nigeria and Ghana. These nations benefit from stronger healthcare facilities, public health programs, and more extensive support systems, allowing them to afford higher-priced technologies that require more infrastructure and specialized knowledge [29].

Given Cameroon's significant challenges in medical resources and infrastructure, adapting the NPWT device to its context offers a valuable opportunity to create a replicable model for other low- and middle-income countries. Success in Cameroon could demonstrate the feasibility of implementing such devices in similar conditions, extending to countries like Nigeria, which has a slightly more developed healthcare system. This adaptability highlights the potential for scalable solutions to improve wound care across various low-resource settings, providing benefits for regions with shared healthcare challenges.

1.3 Implications on NPWT Design

For the purpose of this study, we will focus on Cameroon, where the NPWT device needs to be designed with the following considerations:

- **Affordability:** The device must be low-cost to ensure it is accessible to a broad portion of the healthcare facilities. This includes minimizing expenses for initial purchase, maintenance, and consumables, and using locally available materials to facilitate repairs and replacements in areas with limited access to spare parts and technical support.
- **Robustness:** The device must function reliably in environments with frequent power fluctuations. This requires incorporating a backup power source, such as batteries or solar power, to ensure continuous operation in low-resource settings.
- **Ease of Use:** The design should prioritize simplicity, with clear instructions and minimal training requirements to accommodate healthcare providers with varying levels of education, particularly in rural and underserved areas.

By addressing these considerations, the NPWT device can be effectively tailored to Cameroon's healthcare challenges, ensuring better wound care outcomes. Furthermore, this context-driven approach enhances the scalability of the design, allowing it to benefit other low-resource regions facing similar healthcare constraints.

Chapter 2

State of the Art

This chapter presents the essential information for understanding the design and application of NPWT, also known as VAC. It reviews the development, mechanisms of action, and new technologies in NPWT, covering both high-tech healthcare settings and low-resource environments. This background is critical for addressing the challenges and opportunities discussed in the following chapters.

Section 2.1 covers the historical development of NPWT and its role in modern wound care, including the mechanisms that promote healing. Section 2.2 explains the working principles of NPWT devices, covering the physics of vacuum generation. Section 2.3 provides an overview of various NPWT devices, examining their key components, such as vacuum pumps, dressings, and drainage systems, as well as their operation methods. Section 2.4 discusses the advantages and limitations of NPWT, particularly in resource-limited settings, focusing on issues such as cost and accessibility. Finally, Section 2.5 explores innovative adaptations of NPWT for low-resource environments, stressing the importance of sustainable solutions for wound care. Finally, section 2.6 presents the problem statement, outlining the key challenges and gaps in existing NPWT systems that this work aims to address.

Through these sections, this chapter sets the foundation for the more detailed analysis and system design explored in later chapters, highlighting both the potential benefits and practical challenges of implementing NPWT in different healthcare contexts.

2.1 Overview of Negative Pressure Wound Therapy (NPWT)

NPWT is a medical technique used to promote wound healing by applying controlled negative pressure to the wound (see [Figure 2.1](#)). The concept of using negative pressure for wound treatment is not new. Christine Miller traces its origins to ancient times, when Roman doctors used mouth suction to remove poison or infected fluid from the wounds of soldiers [30]. The modern use of NPWT began in the 1990s, when Dr. Louis Argenta and Dr. Michael Morykwas at Wake Forest University developed the first commercial NPWT systems. These systems were

designed to treat chronic wounds, such as those caused by diabetes, and to promote healing by secondary intention in patients with impaired healing capacity [11].

Before the advent of NPWT, wound care involved frequent manual dressing changes, which often caused pain, bleeding, infection, and hindered healing progress [31]. This challenge led to the development of closed-system vacuum dressings. The first published studies on NPWT appeared in 1997, sponsored by Kinetic Concepts, Inc. (now 3M, Acelity L.P. Inc) [11]. These studies showed significant improvements in wound healing, including better removal of wound exudate, reduced interstitial edema, decreased bacterial load, increased granulation tissue, and improved wound perfusion [2]. These effects contributed to faster healing, shorter hospital stays, and cost savings [3].

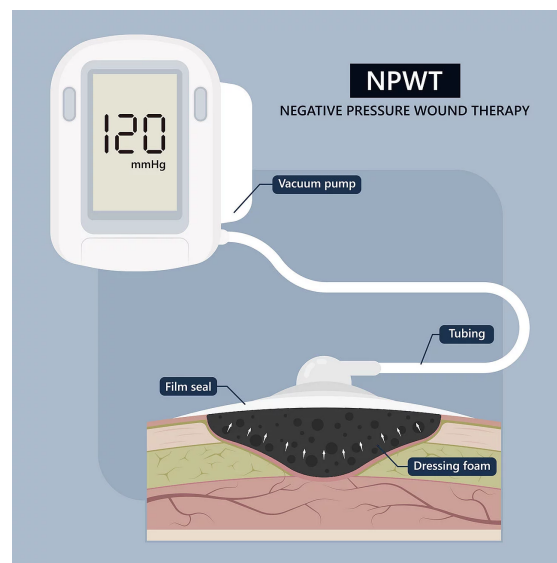


Figure 2.1: Illustration of NPWT healing a wound [32].

2.1.1 Effect of NPWT on Healing

The benefits of NPWT in promoting wound healing are attributed to four primary mechanisms (Figure 2.2) and their accompanying secondary effects [33]:

1. **Macrodeformation (coarse wound contraction):** Negative pressure creates deformational forces at the wound edges, promoting contraction and reducing wound size through edema reduction, granulation tissue formation, and scarring [34, 35] .
2. **Microdeformation of the wound surface:** Mechanical loading of the tissue causes minute deformation at the foam-wound boundary, stimulating cell

proliferation, cell migration, angiogenesis, and granulation tissue formation [35]. This microdeformation is considered the most important mechanism [10].

3. **Fluid removal:** NPWT drains wound exudate from the wound surface, reducing tissue edema and microvascular compression, which in turn increases blood flow to the wound [34, 36]. This process also removes inflammatory cytokines and proteolytic enzymes that inhibit wound healing [37].
4. **Stabilization of the wound environment:** NPWT dressings, made with semipermeable polyurethane film and foam materials, provide an airtight and moisture-retentive environment that is beneficial for wound healing and acts as a barrier to bacteria and external contaminants [34, 36].

These primary mechanisms interact to produce cellular responses and secondary effects that lead to wound healing [10].

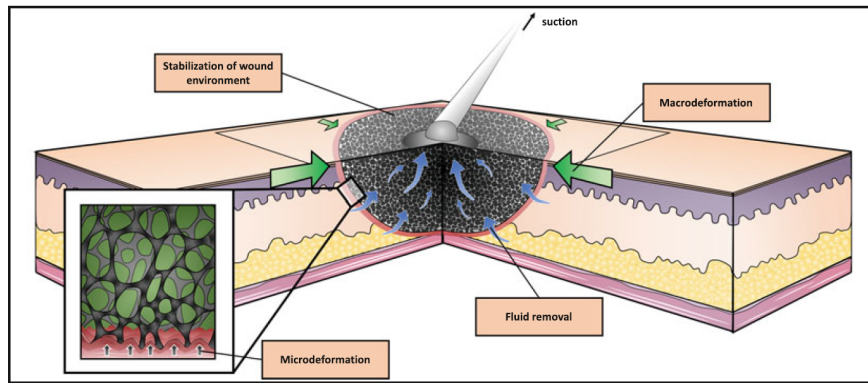


Figure 2.2: Schematic illustration of NPWT with its four primary mechanisms of action [33].

The secondary effects of NPWT include:

1. **Angiogenesis and Blood Flow:** NPWT stimulates angiogenesis by causing microvascular destabilization and regression in early treatment stages and promoting microvascular stabilization later on, increasing microvascular density and blood flow at the wound site [38].
2. **Granulation Tissue Formation:** NPWT enhances granulation tissue growth, upregulating collagen production and promoting wound healing [11, 2].
3. **Bacterial Load Reduction:** NPWT devices significantly decrease tissue bacterial counts, improving wound bioburden and contributing to overall wound healing [11, 39].

2.1.2 Drawbacks and Limitations of NPWT

While NPWT offers numerous benefits, it also has several drawbacks and limitations.

1. **Complications:** Complications range from minor to serious, often due to human factors like poor patient selection or procedural problems.
 - Direct application of NPWT to exposed organs or blood vessels can cause severe damage, such as intestinal fistulas or major bleeding [10].
 - Infection is another potential complication, as the foam dressing can harbor bacterial growth if bleeding occurs [40].
 - Pain during treatment, particularly with intermittent NPWT, is another concern, though starting treatment at low pressure and gradually increasing it can mitigate this issue [41].
2. **Contraindications:** NPWT is contraindicated for wounds with malignant tumors or exposed vital organs due to concerns about tumor growth and fatal complications [42].

2.2 The Working Principle of NPWT Systems

Understanding the working principle of NPWT systems requires first grasping the fundamental concepts of vacuum and pressure, as these are central to how negative pressure therapy functions.

2.2.1 The Concept of Vacuum and Pressure

Vacuum refers to a space where the pressure is lower than the atmospheric pressure. Atmospheric pressure is the force exerted by the Earth's atmosphere on objects within it, and it is considered the reference pressure for normal conditions. The pressure is always related to the absolute zero (absolute vacuum). This can be measured in two distinct ways, depending on the reference used:

- **Absolute Pressure:** This is the pressure measured relative to absolute zero (also referred to as absolute vacuum or perfect vacuum). All physical equations about pressure work normally with absolute pressure data.
- **Relative Pressure:** This is the pressure measured relative to the ambient atmospheric pressure. Relative pressure is positive when the pressure exceeds atmospheric pressure, and negative when it is below atmospheric pressure (creating a vacuum).

In specific scientific contexts, including this thesis, relative pressures are sometimes expressed without the negative sign for simplicity when dealing explicitly with vacuum pressures.

2.2.1.1 Units of Pressure

The International System of Units (SI) defines the pascal [Pa] as the standard unit of pressure. However, several other units are commonly used depending on the application. These are summarized in [2.1](#).

Table 2.1: Common Units of Pressure and Their Conversion to Pascal

Units	Conversion to Pascal
Bar [bar]	1 bar = 10^5 Pa
Torr or mmHg [mmHg]	1 Torr = 1 mmHg = 133.32 Pa
Pound per square inch [Psi]	1 psi = 6895 Pa
Standard atmosphere [atm]	1 atm = 1.013×10^5 Pa

In the context of NPWT, the most commonly used units for pressure are millimeters of mercury (mmHg), despite the widespread use of pascal (Pa) and bar in other fields of vacuum technology. For clarity, this thesis primarily uses the SI unit pascal (Pa) and (mmHg), which is typical in the medical context.

2.2.1.2 Pressure Convention in This Thesis

This thesis will adopt the concept of relative pressure, where all pressure values (unless stated otherwise) are referenced to atmospheric pressure. The relative pressure may be presented with or without a minus sign depending on the context. For simplicity, mmHg will be the primary unit used throughout the thesis, although pascal (Pa) is referenced when discussing standard units from other sources.

2.2.2 The Physics Behind a NPWT System

NPWT systems works by creating a vacuum in a wound dressing to promote healing. This vacuum is generated by a pump that removes air and exudates from the wound site through a drainage system. As a reminder, a vacuum is defined as a space in which the pressure is below atmospheric pressure (see [Section 2.2](#) for further details).

Figure 2.3 illustrates the working principle of a NPWT system in three distinct phases. The system operates by using a vacuum pump to generate negative pressure within the wound dressing, facilitating the removal of exudates and promoting wound healing. A vacuum regulation mechanism is used to maintain a stable pressure within the dressing. The inlet of the suction tube allows bodily fluids such as exudates and blood to be drained and collected. A collection tank stores the drained fluids, preventing backflow and ensuring proper containment within the NPWT system.

The detailed fluid dynamics underlying exudate suction, including flow modeling and assumptions, are provided in [Appendix A](#).

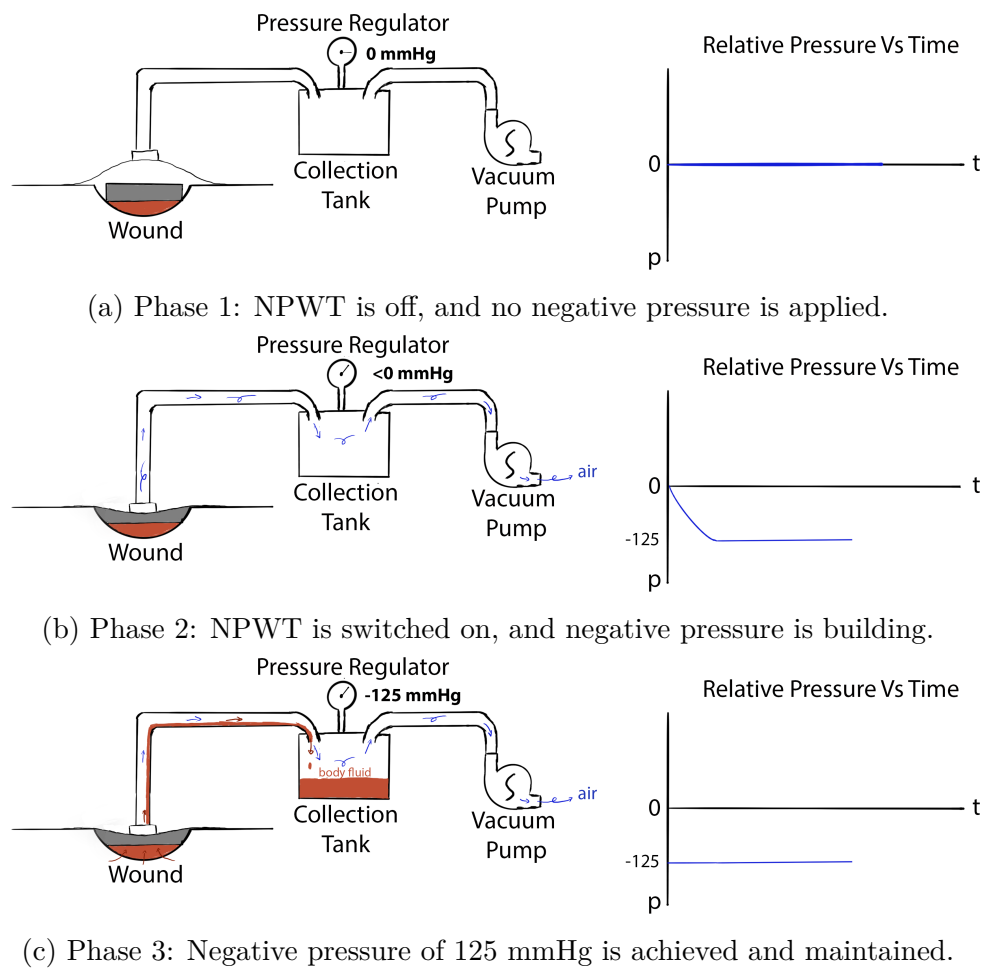


Figure 2.3: Schematic representation of the working principle of an NPWT system, illustrating the three operational phases.

2.3 Modern NPWT Devices

NPWT devices (Illustrated in [Figure 2.4](#)) are composed of the following essential components:

- **Vacuum Pump:** The vacuum pump is the core component of a NPWT system. It creates the negative pressure necessary to remove exudate from the wound site with **125 mmHg (16.6 kPa)** frequently utilized. The pump can be programmed to deliver continuous or intermittent pressure, depending on the clinical requirements and the specific device used [\[43, 44, 45\]](#).
- **Dressing:** The dressing, which can be either foam or gauze, is applied directly to the wound bed. These dressings are often impregnated with antimicrobial agents to reduce the risk of infection. The dressing serves to distribute the negative pressure evenly across the wound surface [\[44, 46\]](#).
- **Drainage Tube:** The drainage tube connects the dressing to the vacuum pump. This tube provides a pathway for the removal of fluids and exudate from the wound. Typically made from flexible materials such as silicone or polyurethane, the drainage tube ensures a consistent and unobstructed flow of exudate [\[47\]](#).
- **Canister:** The canister collects the exudate that is removed from the wound. It is designed to prevent contamination and is often disposable. The size of the canister varies depending on the expected volume of exudate[\[43\]](#).

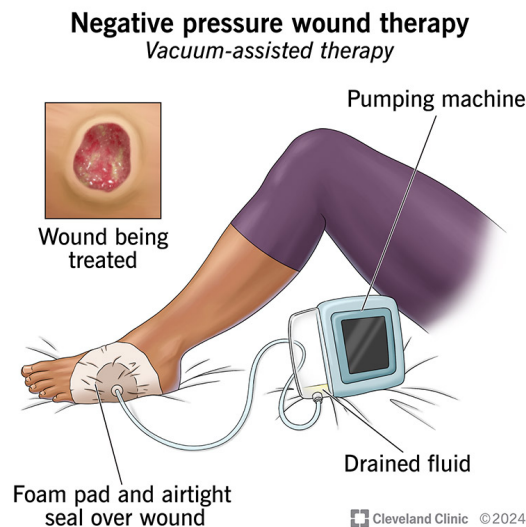


Figure 2.4: Illustration of a modern example of NPWT Device [\[43\]](#).

NPWT devices have evolved significantly, particularly during the 2010s, with various modifications to improve treatment effectiveness. One key advancement is the development of Single-use NPWT (sNPWT) systems, as shown in [Figure 2.5b](#). These systems typically operate without canisters, using evaporation to remove fluid. They are designed primarily for outpatient settings, and they incorporate specialty dressings with a non-adherent interface layer and a sponge that absorbs wound fluids [\[48\]](#). Some studies suggest that sNPWT may be more effective than traditional NPWT in certain cases [\[48\]](#).

Another development is the NPWT With Instillation and Dwell Time (NPWTi-d) ([Figure 2.5a](#)), which includes instillation systems designed to enhance wound cleansing. These systems irrigate the wound with solutions like saline or sodium hypochlorite, which promotes faster healing and reduce hospital stays compared to standard NPWT systems [\[49, 50\]](#).



(a) A NPWT device adapted with instillation [\[44\]](#)



(b) A Single Use NPWT device [\[47\]](#).

Figure 2.5: The 2 most common types of modern NPWT devices.

2.3.1 Mode of Operation

The operation of an NPWT device involves several steps, which are critical for ensuring effective wound healing. The process is as follows:

1. **Preparation:** The wound should be cleaned thoroughly before applying the NPWT device to reduce infection risk. Any dead tissue should be removed if necessary.
2. **Dressing Application:** A dressing, such as foam or gauze, is cut to fit the wound size and placed directly on the wound. This ensures full coverage and proper treatment.
3. **Dressing Sealing:** A clear adhesive drape is placed over the dressing to form an airtight seal. This is important to maintain the negative pressure environment around the wound [\[44\]](#).

4. **Tube Installation:** One end of the drainage tube is attached to the dressing, and the other end is connected to the vacuum pump. This setup helps remove wound fluids efficiently.
5. **Activation:** The vacuum pump is set to the prescribed level of negative pressure, which can be continuous or intermittent, depending on the wound's needs and clinical guidelines [47].
6. **Monitoring:** The system should be checked regularly to ensure it is working correctly. The exudate levels in the canister should be monitored, and the dressings should typically be changed every 48-72 hours, or more frequently if needed. Monitoring helps identify any issues early and allows for adjustments to the therapy if necessary. Changes to the negative pressure level or dressing type may be made based on how the wound is healing [43].

2.4 NPWT Gold Standard

Commercial NPWT devices have been available since 1995, and there are currently 35 different products on the market. For a decade, the NPWT market was largely dominated by a single entity, Kinetic Concepts, Inc. (KCI), an American company that was part of Acelity Inc., which was later acquired by 3M. KCI sponsored the first research in 1997, patented the technology, and became the exclusive manufacturer of NPWT devices [11]. Their traditional V.A.C.® System remained the sole NPWT option for ten years. However, with after the expiration of KCI's patent, competition entered the market, resulting in increased product diversity over the last decade.

Currently, the NPWT market is dominated by several major companies, primarily located in the USA and Europe. The top five companies in this field are:

1. **KCI-3M (US):** Known for products like VeraFlo, ActiVAC, Nanova, and Snap.
2. **Smith & Nephew (UK):** Offers devices such as Pico and Renysus.
3. **Mölnlycke Healthcare AB (Sweden):** Provides the Avance Solo device.
4. **ConvaTec Group Plc (UK):** Known for the Avelle product.
5. **Cardinal Health (US):** Features products like Catalyst and All.

This market expansion shows the growing competition and diversity in NPWT products, positioning these companies as key players in the development of wound care technology. However, the NPWT market remains heavily focused on Western countries, limiting the availability of these products in LMICs.

A report by MarketsandMarkets shows that North America leads the NPWT device market, followed by Europe [51]. In contrast, Asia, the Middle East, and Africa hold a much smaller share (see Figure 2.6), underscoring the urgent need to expand NPWT access in these underserved regions.

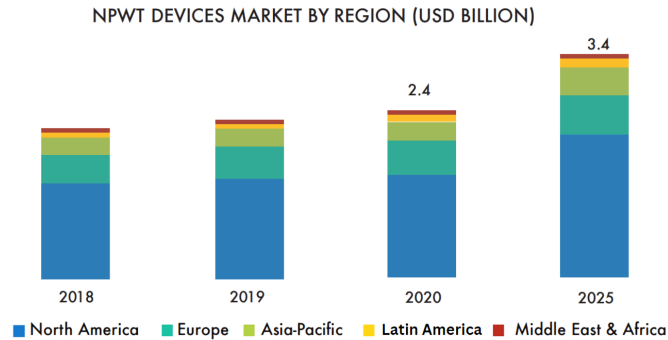


Figure 2.6: A graphical representation of the global Market Share of NPWT devices (Adapted from [51]).

2.4.1 NPWT Cost Estimation

The cost of NPWT devices is typically high, ranging from 7,500 to 12,000 EUR. Dressing kits, pre-sized for single use, generally cost between 50 and 300 EUR, depending on whether a canister is included. These kits are essential for proper NPWT application and must be supplied continuously to avoid treatment interruptions. Healthcare facilities must therefore maintain sufficient stock. However, actual prices vary, as many vendors do not publicly disclose their pricing structures. Devices are also often leased monthly, with the lease typically covering maintenance and repair services.

In standard hospital settings, NPWT treatment costs are estimated at 100 to 150 EUR per patient per day—approximately 5% higher than standard treatments [4]. While NPWT may offer long-term cost savings [3], the high initial investment remains a significant barrier for many institutions.

2.4.2 Limitations of Current NPWT Devices for LMICs

Current NPWT systems are generally unsuitable for low-resource settings like Cameroon due to several key limitations. Many are prohibitively expensive (often over 10,000 EUR) or designed for single use, making them unaffordable for facilities with limited budgets. They also rely on specialized dressings that may not be locally available, further limiting their effectiveness in such contexts.

Beyond cost and availability, NPWT systems require ongoing maintenance and technical support, increasing their operational complexity. Most of these devices are imported from the US or Europe, leading to delays and making them harder to access where they are needed most, as seen in Cameroon’s infrastructure problems. Moreover, their advanced technology demands proper user training, which is difficult to provide in rural or under-resourced areas.

2.5 NPWT in Low-Resource Settings

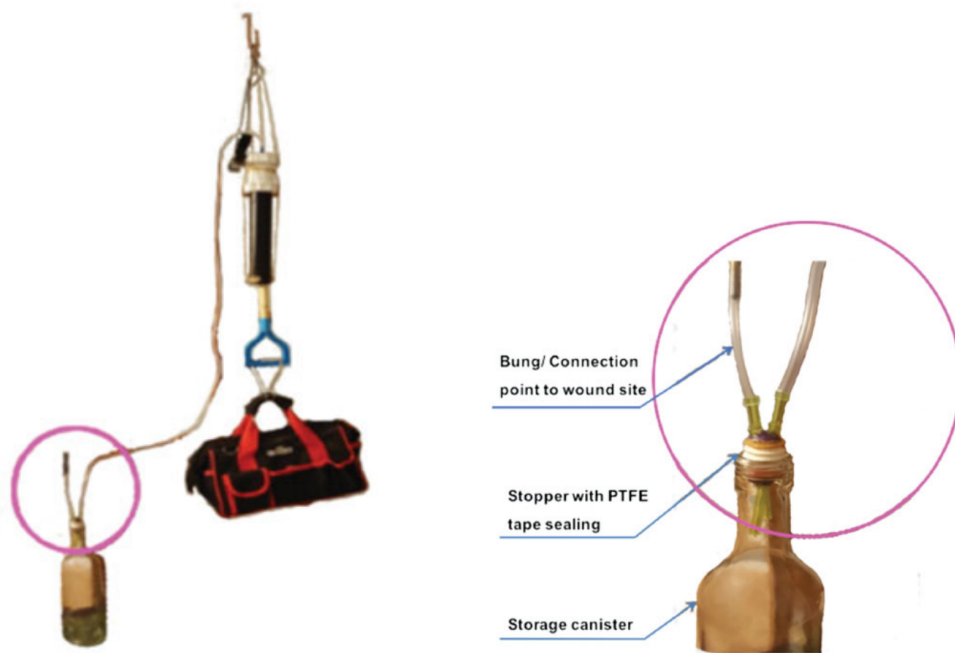
Traditional NPWT systems, which depend on complex equipment and specialized dressings, are often unaffordable and inaccessible in resource-limited hospitals. To address this gap, various adaptations have been developed using locally available materials. Local doctors and engineers have played a key role in creating low-cost, improvised NPWT systems, making wound care more accessible in underserved regions.

A notable example is the manually operated Wound-Pump NPWT system developed in Rwanda (Figure 2.7). [52]. This mechanical system uses a hand-powered bellow pump and a collection canister, combined with locally sourced dressings. Hospital trials confirmed its practicality in power-constrained settings, and the total cost of the system is estimated at around 40 EUR, including the reusable pump and dressing materials.



Figure 2.7: Illustration of the hand-powered NPWT system developed in Rwanda [52].

Similarly, in the United Kingdom at the University of Plymouth, a Gravity NPWT System (Figure 4.11) has been constructed using simple materials such as a PVC pipe, a compression waste straight coupler, and a plastic bottle lid [53]. This more stable mechanical version operates by applying a constant pressure of 125 mmHg (16.6 kPa), achieved through the use of hanging mass to create suction. Calibration was done to find the corresponding mass required to achieve pressures ranging from 40 mmHg to 125 mmHg (5.3 to 16.6 kPa), as literature suggests the optimum pressure for healing wounds is within this range. The total cost of parts for this system was approximately 6.80 EUR in 2016. Tests showed it could maintain the required suction for up to five hours, and clinical trials in Kenya received positive feedback.



(a) Overview of the Gravity system. (b) Detailed view of the Gravity system.

Figure 2.8: Illustration of the Gravity NPWT system [53].

In the Philippines, the AquaVac NPWT system (shown in Figure 2.9) was designed to offer a low-cost alternative to commercial systems [54]. It employs a modified aquarium aerator pump as the vacuum source, with dressings assembled from locally available materials such as kitchen wrap, sterile gauzes, and repurposed intravenous bottles. The modified pump costs approximately 60 EUR and can be reused up to 20 times. Dressing changes cost around 3.40 EUR per use, bringing the total cost per use to approximately 63.40 EUR.

Despite its simplicity, studies show that the AquaVac system performs comparably to the commercial VAC ATS device in terms of wound healing effectiveness [54]. The VAC ATS, developed by KCI (now 3M), is a leading commercial solution in wound care. AquaVac’s comparable performance, coupled with its low cost, makes it a financially viable option for low-resource settings, where minor issues like pressure fluctuations can be manually managed.



Figure 2.9: Illustration of the AquaVac NPWT system with its components

Although these device adaptations have significant potential, they still do not offer the same level of precision and reliability as commercial NPWT systems. Additionally, these variations in quality can also result in variations in the outcome of treatment. Nonetheless, these low-cost NPWT systems demonstrate a strong case for more work to be done on developing and integrating any such techniques into practice for management of chronic wounds in low-resource environments.

Several open-source systems have been developed to provide advanced and reliable options with better functionality. An Open-Source NPWT System was developed in Barcelona (Illustrated in Figure 2.10), utilizing off-the-shelf materials, including an electric pump, a pressure transducer, an Arduino Nano microcontroller, and various electronic components [55]. The total retail cost for the components is around 70 EUR, with 58 EUR allocated for the main components and 9 EUR for 3D printing materials for the enclosure. This device allows users to set therapeutic ranges of intermittent negative pressure (25–175 mmHg or 3.3–23.3 kPa) and can operate continuously or intermittently, featuring two independent safety mechanisms to prevent excessive pressure. Bench tests showed that the device was able to maintain the required pressure and effectively remove exudate [55].

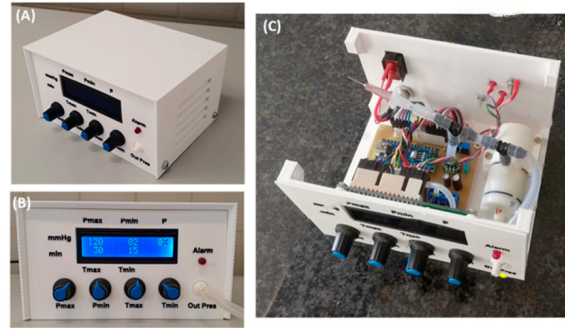


Figure 2.10: Illustration of the low-cost negative pressure device: (A) General view of the device; (B) Front panel showing adjustable pressure settings; (C) Interior components including the pump, Arduino and pressure transducer. (Adapted from [55])

Similarly, the WOCA Wound Pump (Figure 2.11), designed at Delft University of Technology, presents a simple, affordable, and robust NPWT solution [56]. This battery-powered device, was made entirely from locally sourced components with a portable design and a battery life of up to 15 hours. Some of its notable features include automatic pressure control, compatibility with self-made dressings and standard canisters, and a simple interface for ease of operation. The cost of the individual components is approximately 82 EUR, while the total cost, including assembly and logistics, is under 250 EUR. It is worth noting that the WOCA pump has not yet been employed in practice. However, during the evaluation, it underwent a bench test and passed most of the critical criteria for successful wound care and management.



Figure 2.11: Illustration of the WOCA Wound Pump System demonstrating portability and use [56]

Analysis of existing NPWT adaptations reveals a significant gap in reliable data regarding wound care practices in low-resource settings. During the course of this study, it became clear that there is limited information on how NPWT is actually used and maintained in these environments. This lack of data restricts our ability to evaluate effectiveness and guide improvements in treatment protocols.

In response to the high cost of conventional NPWT systems, many studies focus on low-cost alternatives. These are usually developed by local healthcare workers and engineers using readily available materials. While these solutions show creativity and adaptability, they often lack reliability, standardization, and thorough testing.

This highlights the need for more than just cost-effective improvisation. There is a clear opportunity to develop a more advanced NPWT solution that balances affordability with reliability and adaptability across different clinical scenarios. Future research should not only support the refinement of these systems but also work to build a stronger evidence base around NPWT use in low-resource settings, guiding both design and policy toward better wound care outcomes.

2.6 Problem Statement

In low-resource settings like Cameroon, the lack of access to advanced medical technologies significantly hampers the effective management of chronic wounds, leading to preventable amputations and adverse socio-economic consequences. Existing Negative Pressure Wound Therapy (NPWT) devices are often prohibitively expensive and require complex infrastructure, making them inaccessible in resource-constrained settings. These devices typically rely on electrical power, advanced maintenance, and consumables that are difficult to procure in rural or underserved areas. The high cost and complex design of current NPWT systems create a significant barrier to their widespread adoption.

This thesis aims to address these challenges by developing open-source, cost-effective, and easily manufacturable NPWT designs that can serve as viable alternatives for healthcare providers in low-resource environments like Cameroon. The research focuses on designing and prototyping mechanical and electromechanical alternatives that leverage readily available materials to ensure affordability and ease of fabrication. By providing detailed design methodologies and preliminary prototype evaluations, this work seeks to empower potential manufacturers, local innovators, and healthcare institutions with scalable and accessible solutions for NPWT implementation. Ultimately, the proposed designs aim to enhance wound care accessibility, promote faster healing, and reduce the incidence of preventable amputations in underserved regions.

Chapter 3

Design Requirements

This chapter lays the foundation for developing NPWT devices by outlining the essential design requirements and regulatory considerations. It begins by estimating preliminary performance needs for the vacuum pump, ensuring the device can reliably maintain the required negative pressure in clinical use. The chapter then defines detailed design specifications based on stakeholder consultations, balancing medical effectiveness with practical constraints in low-resource settings. Finally, it reviews the regulatory landscape, including international standards and certification challenges—particularly important for open-source medical devices.

Section 3.1 presents the preliminary estimation of the vacuum pump’s capacity and performance parameters. Section 3.2 details the functional and constraint-based design requirements that guide device development. Section 3.3 provides an overview of relevant regulations, compliance standards, and the challenges encountered when certifying innovative medical devices for clinical use.

This chapter provides a solid foundation for prototyping the NPWT system by integrating scientific principles, engineering constraints, and regulatory considerations, ensuring that the design is well-suited for low-resource environments.

3.1 Preliminary Estimation of Pump Performance Requirements

A preliminary estimation of the vacuum pump’s performance is essential to support early-stage design decisions for the NPWT system. The pump must maintain a consistent negative pressure within the wound dressing by compensating for both air leakage at the dressing interface and the inflow of wound exudate.

To estimate the required power and airflow, Bernoulli’s equation is applied to the airflow through the pump under the following assumptions:

- The fluid is air, treated as a perfect gas.
- The flow is incompressible and steady..
- Pressure losses and viscous effects inside the pump are neglected.

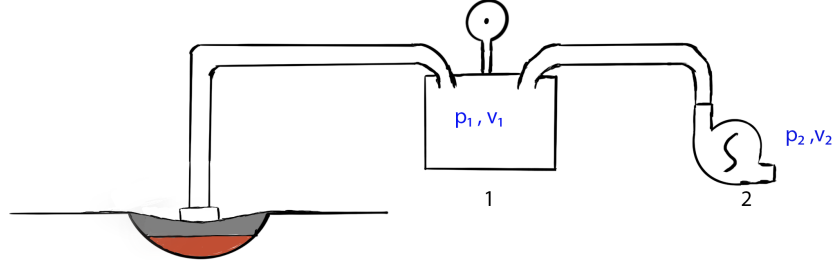


Figure 3.1: Illustration of vacuum pressure states modeled for the NPWT pump design.

The Bernoulli equation for states 1 and 2 illustrated in [Figure 3.1](#)

$$\frac{1}{2}\rho_{air}v_1^2 + p_1 + \rho_{air}gz_1 + \frac{P_{pump}}{Q_V} = \frac{1}{2}\rho_{air}v_2^2 + p_2 + \rho_{air}gz_2, \quad (3.1)$$

where:

- ρ_{air} : Air density ($\approx 1.225 \text{ kg/m}^3$),
- p_1 : Pressure before the pump (pressure in the container, $p_{container}$),
- p_2 : Pressure after the pump (atmospheric pressure, p_{atm}),
- $v_1 = v_2$: Air velocity before and after the pump are equal,
- $z_1 = z_2$: Height of the fluid before and after the pump remains the same,
- P_{pump} : Pump power (> 0),
- $Q_V = Q_{air}$: Air volume flow rate through the pump.

Under the given assumptions ($v_1 = v_2$, $z_1 = z_2$, and neglecting viscous effects), Bernoulli's equation simplifies to:

$$p_1 + \frac{P_{pump}}{Q_V} = p_2. \quad (3.2)$$

Rearranging the equation, ($Q_V = Q_{air}$, $p_2 = p_{atm}$, $p_1 = p_{container}$), the pump power is given by:

$$P_{pump} = Q_{air}(p_{atm} - p_{container}). \quad (3.3)$$

To ensure stable negative pressure, the vacuum pump's airflow rate (Q_{air}) must exceed the combined inflow from air leakage and wound exudate, guaranteeing the system's continuous and effective operation:

$$Q_{\text{air}} \gg Q_{\text{air_leak}} + Q_{\text{wound}}. \quad (3.4)$$

From the literature, the air leakage in a wound dressing is reported to be at most 100 mL/h [56], while the wound exudate flow is significantly lower, with a maximum of 0.3 mL/h [57]. Since the exudate flow is negligible, the total inflow can be approximated as 100 mL/h. To maintain stable negative pressure, the pump must exceed this threshold, ensuring continuous vacuum operation and preventing pressure fluctuations that could compromise NPWT effectiveness and wound healing.

3.2 Design Requirements

The development of a viable NPWT solution for low-resource settings requires the establishment of a comprehensive set of design requirements. These requirements are critical to ensuring the device's functionality, cost-effectiveness, and adaptability to the unique challenges of the region. The design must not only address technical and operational needs but also take into account the socio-economic and healthcare infrastructure conditions that prevail in such settings.

To define these requirements, consultations were held with key stakeholders, including Prof. Benoît Herman, Prof. Benoît Lengelé, and Dr. Joseph Djoko, whose insights helped shape the technical direction of the project. Their input, along with the support of teaching assistant Mayysem Hadjili, led to the identification of essential requirements for the prototype. These were grouped into two main categories: Main Functions (F) and Constraint Functions (C).

Main Functions refer to the core actions or tasks that the device must perform to achieve its intended purpose. These functions are essential for the device to meet its primary objectives and must be clearly defined to guide the design process. On the other hand, Constraint Functions represent the strict limits or conditions that the design must adhere to for the device to be deemed acceptable. These are non-negotiable requirements that set the boundaries within which the device must operate, ensuring its suitability for deployment in low-resource environments.

Each function, whether main or constraint, is associated with specific Requirement (FR and CR) which quantify the performance of the system. These requirements serve as measurable benchmarks, allowing for objective evaluation of the prototype's capabilities. By establishing these requirements, we ensure that the device is not only functional but also meets the minimum thresholds for performance, safety, and reliability in its target context.

The detailed functions and requirements were compiled into [Table 3.1](#) and [Table 3.2](#) for the main functions and constraint functions respectively.

Table 3.1: Main Functions and Their Requirements

Functions	
Type	Description
F1	The device must generate and sustain negative pressure at the sealed wound site for the entire treatment cycle.
F2	The device must efficiently drain wound fluids (exudate) from the wound area.
F3	The device must incorporate a collection canister for storing the drained wound fluids.
Functional Requirements	
FR1.1	The device must generate negative pressure ranging from 50 to 200 mmHg (6.6 to 26.6 kPa).
FR1.2	The device must allow pressure adjustments within the specified range both before and during treatment.
FR3.1	The canister must be detachable.
FR3.2	The canister must be leak-proof.

Table 3.2: Constraint Functions and Their Requirements

Constraints	
Type	Description
C1	The device must ensure patient safety.
C2	The device must comply with medical regulatory standards.
C3	The device should be resilient and maintainable.
C4	The device must be affordable for the target market.
C5	The device must be easy to manufacture.
C6	The device must be user-friendly.
Constraint Requirements	
CR1.1	The device should not generate negative pressure exceeding 200 mmHg (26.6 kPa).
CR1.2	The device must provide a means to indicate when the canister is full.
CR1.3	The canister and potential tubing systems must provide visual feedback when fluid color changes, indicating potential infection or bleeding.
CR1.4	The device must avoid backflow of fluid to prevent infection from returning to the wound.
CR1.5	The reusable part of the fluid circuit of the device must be sterilizable.
CR3.1	The device must be easily repairable.
CR4.1	The device's material cost for prototyping must be under 300€.
CR4.2	The device must be compatible with locally available dressings.
CR6.1	The device must be manufacturable using materials accessible in the target market.
CR6.2	The device should be designed to be simple to assemble and disassemble.
CR6.3	The device should be designed for easy reproduction.
CR7.1	The device must be simple and intuitive to use.
CR7.2	The device must come with well-described and clear instructions for use.

3.3 Regulations for NPWT

Medical devices, including NPWT systems, are subject to stringent regulations that ensure their safety, efficacy, and quality. Regulatory oversight is essential, as the failure of medical devices can have serious consequences for patient health and safety. Regulatory standards vary across different regions and countries, with agencies such as the European Commission (EC) and the U.S. Food and Drug Administration (FDA) enforcing these standards [58, 59]. This section provides an in-depth analysis of the regulations governing NPWT devices, including the classification system, the role of international standards, and the challenges posed by regulatory compliance, especially for open-source medical devices.

3.3.1 Regulatory Approval and Certification

Regulatory approval for medical devices, including NPWT systems, follows a rigorous process governed by national and international regulations. The regulatory process varies depending on the classification of the medical device, which is determined based on the level of risk it poses to patients, healthcare workers, and other users. In the European Union (EU), the regulation of medical devices is based on the Medical Device Regulation (MDR) and is overseen by national competent authorities and notified bodies [58].

The EU classifies medical devices into four categories based on their risk level, with stricter requirements applied to devices in higher-risk categories [60]. These categories are as follows:

Table 3.3: The 4 European Regulation Classes and Examples

Class	Example
Class I (low risk)	Corrective glasses, wheelchairs, stethoscopes
Class IIa (moderate risk)	Syringes, infusion pumps, thermometers
Class IIb (high risk)	Ventilators, surgical lasers, defibrillators
Class III (highest risk)	Breast implants, cardiovascular stents, hip replacements

NPWT devices generally fall into **Class IIa** or **Class IIb** categories, depending on the specific design, intended use, and potential risks associated with their use. Devices classified as **Class IIa** or **Class IIb** are subject to more stringent regulatory requirements, including comprehensive clinical evaluations, quality control measures, and documentation [60]. These devices must be tested for safety and effectiveness before they are marketed, and they must undergo rigorous scrutiny by authorized bodies known as notified bodies.

3.3.2 Current European Regulations for Medical Devices

The European Union’s MDR and Active Implantable Medical Devices Directive (AIMDD) govern the approval and certification of medical devices in the region. The MDR, established in May 2017, replaced the previous Medical Devices Directive (MDD) and aims to improve the safety and performance of medical devices across the EU. The MDR became fully enforceable on May 26, 2021, and it includes more stringent requirements for device testing, clinical evaluations, and post-market surveillance [58].

The regulations applicable to NPWT devices are outlined in the following European documents:

Table 3.4: Current European Regulations for Medical Devices

Regulation Code	Application Area
Regulation (EU) 2017/745 [61]	Medical Devices (MDD) and Active Implantable Medical Devices (AIMDD)
Regulation (EU) 2017/746 [62]	In Vitro Diagnostic Medical Devices (IVDMD)

In addition to these regulations, the European Commission’s standards also stipulate that NPWT systems must comply with specific technical and performance standards to ensure their safe operation in medical environments.

3.3.3 International Standards for NPWT Systems

While regulatory frameworks ensure the overall safety and performance of medical devices, international standards provide detailed guidance on how devices should be designed, tested, and maintained. These standards are set by recognized organizations such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). These standards help manufacturers meet regulatory requirements and maintain consistent device quality across different markets.

Some key international standards applicable to NPWT systems include:

- **ISO 13485:2016** [63] - This standard specifies requirements for a quality management system tailored to the medical device industry, covering all stages from design to post-market activities. It plays a critical role in ensuring consistent product quality, regulatory compliance, and is often required for certification across many global markets.
- **ISO 14971:2019** [64]- This standard outlines the application of risk management processes to medical devices. It guides manufacturers in identifying, assessing, and mitigating risks throughout the lifecycle of the device, which is crucial for NPWT systems that involve patient safety.
- **IEC 60601-1:2012** [65] - This standard covers the general requirements for the safety and essential performance of medical electrical equipment. It ensures that NPWT systems, which often involve electrical components, meet stringent electrical safety criteria.
- **ISO 10079-1:2022** [66] — This standard covers electrically powered medical suction equipment, defining safety and performance requirements critical for NPWT systems that rely on controlled suction for wound healing.
- **ISO 10079-2:2022** [67] — This standard specifies safety and performance requirements for manually powered medical suction equipment, ensuring reliability and safety in non-electrical NPWT devices.

Beyond international standards, the U.S. FDA has issued specific guidance for non-powered NPWT devices. The FDA's *"Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)"* document [68] provides recommendations on device performance, biocompatibility, sterility, and labeling to ensure safety and effectiveness. This guidance is particularly relevant for manufacturers seeking market entry in the United States.

Adherence to these standards and regulatory guidelines ensures that NPWT devices are safe, effective, and meet the necessary performance criteria for clinical use.

3.3.4 Regulatory Landscape in Cameroon

In Cameroon, the regulation of medical devices, including NPWT systems, is overseen by the Medical Devices Department of the Cameroon Food and Drugs Authority (CAMFDA) [69]. While Cameroon maintains its own certification process, it recognizes approvals from established regulatory bodies such as the EC and the FDA as part of its evaluation. Manufacturers seeking market approval must submit technical documentation, including proof of compliance with international standards (e.g., ISO 13485), and may undergo additional administrative review or local testing. Specific guidelines are typically obtained via direct communication with CAMFDA, often through formal email inquiries [70].

The certification process involves:

- Submission of device specifications, intended use, and risk classification.
- Evidence of prior approvals (e.g., EC or FDA clearance), if applicable.
- Payment of administrative fees and possible in-country audits.

This hybrid approach aims to balance local oversight with global harmonization, though delays in approval timelines may occur due to resource constraints [69].

3.3.5 Challenges for Open-Source Medical Devices

Open-source medical devices offer a promising way to reduce costs and improve access to healthcare in low-resource settings. However, bringing such devices to market presents significant challenges, particularly in meeting regulatory requirements [71, 72]. Medical devices must comply with strict safety and performance standards, and the certification process can be costly and time-consuming, often discouraging smaller teams or individuals from pursuing approval [73].

Some key challenges include:

- **Regulatory Compliance:** Open-source devices must meet the same safety and performance standards as commercial ones, requiring rigorous testing, documentation, and agency approval. In countries like Cameroon, where regulatory systems are still developing, open-source developers may encounter additional difficulties, such as unclear certification procedures or delays in communication with authorities. Early engagement with CAMFDA is crucial to clarify expectations [70].
- **High Certification Costs:** Certification involves expenses for clinical testing, quality assurance, and regulatory fees, which can be unaffordable for small open-source teams [73].

- **Intellectual Property Issues:** Developers must navigate existing patents and legal barriers. Some device components may be protected, limiting modification or distribution. Open-source licenses can also introduce conflicts with regulatory obligations [71, 72].

To help overcome these challenges, open-source NPWT developers should work closely with regulators, medical experts, and other stakeholders. This collaboration ensures that the devices are designed with regulatory compliance in mind while still benefiting from the affordability and accessibility that open-source models provide. Some possible solutions include:

- **Regulatory Support for Open-Source Devices:** Governments and regulatory agencies could create specific approval processes that recognize the unique nature of open-source projects, making it easier for them to meet safety and quality standards [74, 71]. In low-resource settings like Cameroon, partnerships with local healthcare institutions or NGOs could facilitate compliance with national regulations (e.g., CAMFDA) by providing clinical validation data or logistical support for certification [70].
- **Partnerships with Medical Device Companies:** Working with established manufacturers can help open-source projects meet certification requirements, improve quality control, and navigate legal issues [73, 71].

By creating better support systems for open-source medical devices, these innovations can be made safer, more affordable, and more widely available to those who need them most.

Chapter 4

Prototypes Development

This chapter presents the design and development of multiple cost-effective mechanical NPWT prototypes and an electromechanical system adapted from a modified medical aspirator. The goal of this work is to explore alternative solutions that optimize performance while reducing costs, making NPWT more accessible in low-resource settings.

Section 4.1 details the different mechanical prototypes, each utilizing distinct passive mechanisms to generate and maintain negative pressure without requiring electronic components. Section 4.2 introduces the electromechanical prototype, which is based on a modified medical aspirator to provide a controlled and reliable negative pressure source. Section 4.3 provides a comparative overview of all developed prototypes, highlighting their respective advantages, limitations, and suitability for different resource contexts. Section 4.4 concludes the chapter with a risk analysis that evaluates the safety and reliability of the designs.

This chapter focuses on the design and fabrication of these prototypes, providing insight into the materials, construction methods, and operational principles of each system. The manufacturing was carried out in the MakingPro lab at UCLouvain, which is equipped with rapid prototyping tools. By exploring mechanical and electromechanical approaches, this chapter presents cost-effective NPWT designs for low-resource settings, empowering local implementers to adapt and deploy practical solutions efficiently.

4.1 Mechanical Prototypes

The mechanical NPWT prototypes presented in this section consist of two main components: a vacuum pump and a connection to an exudate collection tank, which is further linked to the wound area. The vacuum pump generates negative pressure, while the exudate collection tank ensures efficient suction and containment of wound fluids, preventing contamination and maintaining a sterile environment. A schematic representation of the system layout is shown in [Figure 4.1](#).

The design of these vacuum pumps was guided by the availability of materials in low-resource regions, particularly in hospitals in Cameroon. Accessibility, affordability, and ease of fabrication were key considerations to ensure practical implementation in low resource settings.

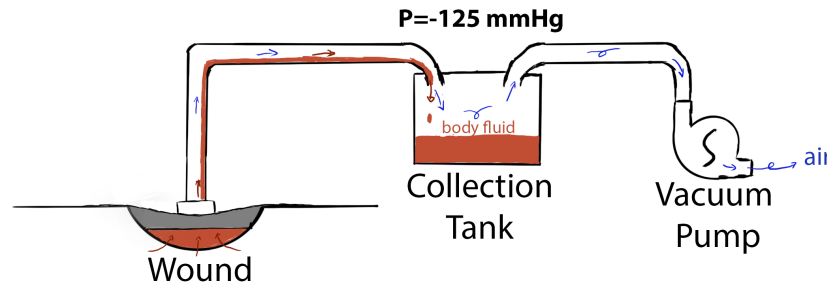


Figure 4.1: Schematic representation of the mechanical NPWT system, illustrating the vacuum pump, the exudate collection tank, and their connection to the wound area.

Two vacuum pump designs were explored, each utilizing different approaches to generate negative pressure. These include:

- A suction pump constructed from PVC pipes.
- A vacuum system created by connecting multiple syringes in parallel.

4.1.1 Common Operating Principle of the Mechanical Pumps

Both mechanical vacuum pump prototypes—the PVC suction pump and the syringe-based system—operate on the same fundamental principle: generating negative pressure by controlling volume displacement. According to Boyle’s Law, when the volume of a closed system increases while temperature remains constant, the internal pressure decreases [75]. This reduction in pressure creates a vacuum effect, which draws air from the wound system through a connected exudate collection chamber, facilitating negative pressure wound therapy.

The vacuum cycle consists of two phases: expansion and compression. During the expansion phase, the piston or plunger is retracted, increasing the internal volume of the chamber. This increase in volume causes a reduction in pressure, which draws air from the wound system into the chamber through an inlet valve. Once the piston reaches its maximum extension, it must be returned to its initial position to begin the next phase. This marks the start of the compression phase, during which forward movement of the piston decreases the chamber’s volume and expels the captured air through an outlet valve.

To prevent air from re-entering the system during the reset motion, a one-way valve ensures that no backflow occurs as the system returns to its starting position, ready for the next cycle.

4.1.2 PVC Suction Pump Design

The first design explored is the PVC suction pump. This system is based on a gravity-driven NPWT device originally developed in the United Kingdom at the University of Plymouth ([Figure 4.11](#)) [53]. The design was modified with inspiration from a publicly available instructional video [76]. The core of this prototype is a custom-built PVC hand pump designed to create a controlled vacuum, prioritizing simplicity, low cost, and ease of fabrication using readily available PVC pipes and fittings.

4.1.2.1 Components

The PVC suction pump is constructed using various PVC/Alpex pipes, fittings, and sealing components. All components were carefully selected for compatibility and ease of assembly and can be easily sourced from hardware stores. The key components are as follows:

- **3/4 inch (25mm) PVC pipe:** Serves as the plunger and piston, responsible for generating the negative pressure.
- **1 inch (32mm) Alpex pipe:** Forms the main body of the pump, providing an airtight chamber for pressure changes.
- **Rubber O-rings:** Two 3mm thick O-rings were used to create a seal between the piston and the main body, ensuring efficient air displacement.
- **Two one-way check valves:** Regulate the direction of airflow to enable proper suction and exhaust.
- **Tee fitting:** Acts as the handle and structural support for operating the pump.
- **1-inch straight threaded adapter:** Provides a secure connection between the main body and external tubing.
- **Reducer fittings:** A series of reducers were used to transition from the 1-inch adapter to a 6mm outlet for tubing connection:
 - 1-inch to 1/2-inch reducer
 - 1/2-inch to 1/4-inch reducer
 - 1/4-inch to 6mm Hose-Tail Barb connector

A detailed Bill of Materials is provided in [Appendix B](#).

4.1.2.2 Assembly of the PVC suction Pump

The assembly process of the PVC suction pump was carried out in multiple stages to ensure structural integrity, airtight seals, and proper functionality. Each step was executed with careful measurements, lubrication, and sealing to minimize air leaks and optimize suction performance.

1. **Piston Construction:** The piston was constructed using a 3/4-inch (25mm) Alpex pipe. To ensure an airtight seal between the piston and the inner walls of the pump's main body, grooves were cut into the outer surface of the pipe to accommodate rubber O-rings.

The grooves were machined to a depth of 1.5mm using a rotary tool with a cutting disc attachment. This allowed the O-rings, which had a thickness of 3mm, to fit snugly while protruding slightly, ensuring sufficient contact with the walls of the main body. The O-rings were then installed into the grooves, making sure they were evenly distributed and properly seated to avoid air leakage, as illustrated in [Figure 4.2](#).

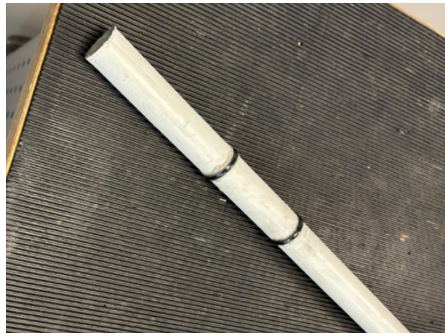


Figure 4.2: Grooved Piston with installed O-rings to ensure an airtight seal inside the pump body.

2. **Main Body Assembly:** The main body of the pump was formed using a 1-inch (32mm) PVC pipe, which serves as the vacuum chamber. The length of the 1-inch PVC pipe was cut slightly shorter than the 3/4-inch piston to allow for adequate movement during operation.

To ensure smooth piston motion while maintaining an airtight seal, a lubricant was applied to the inner surface of the 1-inch pipe. Vaseline was used as the lubricant as it is easily accessible and able to create a thin sealing layer.

The handle end was sealed by a 1-inch threaded adapter. A hole was cut through the adapter to allow the 3/4-inch piston to pass through freely, ensuring a more secure and airtight connection. The assembled main body is shown in [Figure 4.3](#).



(a) Piston tube assembly showing the piston inserted into the vacuum chamber.



(b) Main body assembly with 1-inch adapter sealed at the handle end.



(c) Installed one-way valves for airflow regulation at both ends.

Figure 4.3: PVC suction pump assembly components: piston tube, main body, and one-way valve installation.

3. **Valve Installation:** To regulate airflow, two one-way check valves were installed on the pump: one at the handle end to expel air during the reset motion, and the other at the suction end to draw air in when the piston was pulled (shown in [Figure 4.4](#)).

To install the first valve, the $3/4$ -inch PVC pipe was threaded for a $1/2$ -inch thread using a pipe threading tool (shown in [Figure 4.3a](#)). The thicker-walled Alpex pipe, used for hot water applications, was suitable for threading. The threaded check valves were then securely screwed into the pipe ends, with Teflon tape applied to the threads to improve the seal and prevent air leaks. The installed valves are shown in [Figure 4.3c](#).

4. **Fitting Connections:** To enable connection to external tubing for fluid collection, a series of fittings were installed at the suction end of the pump. A 1-inch threaded adapter was first glued to the main body using PVC adhesive to ensure an airtight seal. This adapter was then connected to a sequence of reducer fittings and a one-way valve, gradually transitioning from 1 inch to 6 mm to accommodate standard medical or laboratory tubing. The following components were used:

- 1-inch to $1/2$ -inch reducer (female-to-female threads)
- $1/2$ -inch to $1/4$ -inch reducer (male-to-female threads)

- 1/2-inch one-way valve (male-to-male threads)
- 1/2-inch to 6 mm hose-tail barb connector

Each connection was sealed with Teflon tape to enhance the system's airtightness, as illustrated in [Figure 4.4](#).



Figure 4.4: Stepwise reduction from the main body to the 6mm tubing connection using reducer fittings and a one way check valve.

5. **Handle Attachment:** A handle was constructed using a T-fitting, securely attached to the piston rod to allow manual operation of the pump. This setup provided a firm grip for smooth pushing and pulling of the piston. A 3/4-inch to 1-inch coupler was used to connect the handle assembly to the pump body, ensuring a secure transition between pipe sizes. Segments of 1-inch PVC pipe were inserted into the T-fitting to complete the handle structure.

The final assembled pump, including all components, is shown in [Figure 4.5](#).



Figure 4.5: Fully assembled PVC suction pump.

A key advantage of this design is its modularity, allowing the suction capacity to be customized. Using longer PVC tubing increases the internal volume, enabling the system to maintain negative pressure for longer periods before requiring a reset. This makes the design adaptable to various clinical needs.

4.1.2.3 Negative Pressure Dimensioning for the PVC Suction Pump

The PVC suction pump was designed to maintain a negative pressure of 125 mmHg, a standard therapeutic level for NPWT applications. Converting this to Pascals (Pa) using the standard conversion:

$$P = 125 \text{ mmHg} \times \left(\frac{101325}{760} \right) = 16665 \text{ Pa} \quad (4.1)$$

To generate this vacuum pressure, the required force F_v at the piston must be determined using the relation between pressure and cross-sectional area:

$$F_v = P \times A \quad (4.2)$$

Assuming a perfectly sealed system with no leakage, the vacuum pressure corresponds directly to the force applied to the piston. Given a tube diameter of 32 mm, the cross-sectional area A is:

$$A = \pi \left(\frac{0.032}{2} \right)^2 = 8.042 \times 10^{-4} \text{ m}^2 \quad (4.3)$$

Substituting into the force equation:

$$F_v = 16665 \times 8.042 \times 10^{-4} = 13.402 \text{ N} \quad (4.4)$$

In this design, gravity is used to generate the force by applying weights to the handle. The equivalent mass m needed to apply this force is:

$$m = \frac{F_v}{g} = \frac{13.402}{9.81} \approx 1.366 \text{ kg} \quad (4.5)$$

Rounding up to account for minor leakage, a mass of approximately 1.5 kg is required to maintain the desired vacuum pressure.

However, analytical estimation of the friction force from the piston O-ring proved unreliable due to surface imperfections and irregular extrusion within the PVC tube—typical of low-cost or locally sourced materials. To better estimate the total resistance, a dynamometer was used to measure the actual force during piston motion, yielding a frictional force of approximately 5 N. This corresponds to an additional mass of about 0.5 kg. Similar friction measurements should be performed when adapting this design, especially when using different materials or fabrication methods.

Therefore, the total required mass to both generate the target pressure and overcome friction is approximately 2 kg.

In resource-limited settings, this mass can be improvised using common household items such as a 2-liter water bottle or 2 kg bags of rice or sugar. For testing however, standard laboratory weights were used to ensure precision and validate the system's performance under controlled conditions.

For future adaptations, especially where different vacuum levels may be required, the following equation provides a simplified method to estimate the necessary weight in kilograms based on a target pressure in mmHg:

$$m = \frac{P \times A}{g} \times \left(\frac{760}{101325} \right) + 0.5 \quad \text{kg} \quad (4.6)$$

where:

- P is the desired negative pressure in mmHg
- A is the cross-sectional area of the piston in m^2
- g is the acceleration due to gravity (9.81 m/s^2)
- 0.5 kg accounts for frictional resistance

4.1.3 Syringe-Based Vacuum Pump

The second pump design explored in this study is a syringe-based vacuum pump. This alternative mechanical design utilizes medical syringes arranged in parallel to generate negative pressure. The system was designed with accessibility in mind, leveraging commonly available medical syringes, which are inexpensive and widely used in healthcare settings, particularly in low-resource environments such as hospitals in Cameroon.

4.1.3.1 Components

The syringe-based vacuum pump is constructed using medical syringes, tubing, and simple mechanical components. These parts were selected for their accessibility and ease of assembly in low-resource settings, and can be readily sourced from medical supply stores. The key components are as follows:

- **Syringes (10 mL, 6 units):** Used to create suction by pulling air.
- **Tubing (6 mm diameter):** Ensures simultaneous air intake from all syringes.

- **Three-way infusion stopcock (1 unit):** Act as one-way valves to control the flow of air and ensure proper suction operation, and prevents backflow when the pump is reset.
- **Vacuum T-connectors (5 units):** Distribute airflow efficiently within the tubing circuit.
- **Wooden support plates (2 units, 5mm thick):** Secure the syringes in place. These were cut using a laser cutter in the lab, which is equipped with rapid prototyping tools. In low-resource settings, these can be fabricated using manual drilling. Detailed drawings are provided in [Appendix E](#).
- **Wooden outlet plate (1 unit, 5mm thick):** Guides the tubing system towards the collection chamber. This part was also manufactured using laser cutting, but it can also be made through manual methods in low-resource settings. Drawings are available in [Appendix E](#).
- **Wooden plunger plate (1 unit, 3mm thick):** Connects the plungers of the syringes, allowing them to be pulled simultaneously. It also holds the weights that generate the vacuum. The plate was laser-cut to include holes for bolts, nuts, and a screw hook. In low-resource settings, these holes can be manually drilled. Drawings are provided in [Appendix E](#).
- **Threaded screw hook (1 unit):** Attached to the wooden plunger plate to hold the weights needed for vacuum generation.
- **M10 threaded rods (4 units):** Provide stability to the system. In low-resource settings, simple wooden stands can be used instead.
- **Nuts and bolts:** Secure the plates together, distributing force evenly, and attach the syringe plungers to the wooden plates. Bolts are also used to fasten the structure to the threaded rods.
- **Wooden base plate (1 unit):** Provides structural integrity to the setup by securing the threaded rods and preventing the system from toppling over. This ensures stability during operation.

A detailed Bill of Materials is provided in [Appendix C](#).

4.1.3.2 Assembly of the Syringe-Based Pump

The syringe-based pump was assembled methodically to ensure proper alignment, airtight connections, and smooth operation. Each stage of the assembly process was carefully executed to guarantee both functionality and efficiency. The detailed steps involved in the assembly are outlined below:

1. **Mounting the Syringes:** The six syringes were securely positioned within two laser-cut wooden support plates to allow free movement of the plungers.

The plates were fastened together using bolts and nuts to maintain alignment and structural integrity, ensuring stability and proper positioning of the system, as illustrated in [Figure 4.6](#).

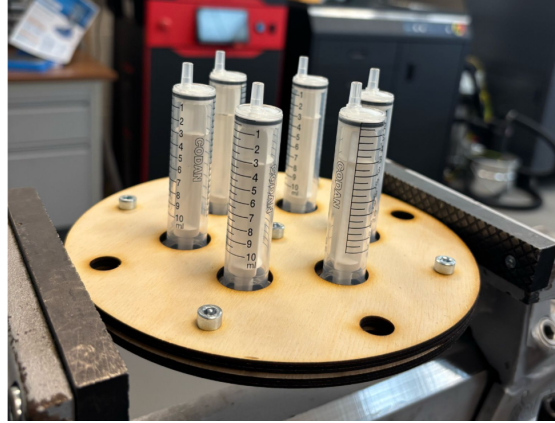


Figure 4.6: Syringes mounted in laser-cut wooden support plates.

2. **Attaching the Plunger Plate:** A wooden plunger plate was used to connect the plungers of all six syringes. This plate was carefully aligned to ensure that all plungers moved simultaneously when force was applied. Threaded holes were machined into the wood to accommodate bolts and nuts, which firmly secured the plungers in place. This setup allowed for even distribution of the applied force and minimized the risk of misalignment during operation, as depicted in [Figure 4.7](#).

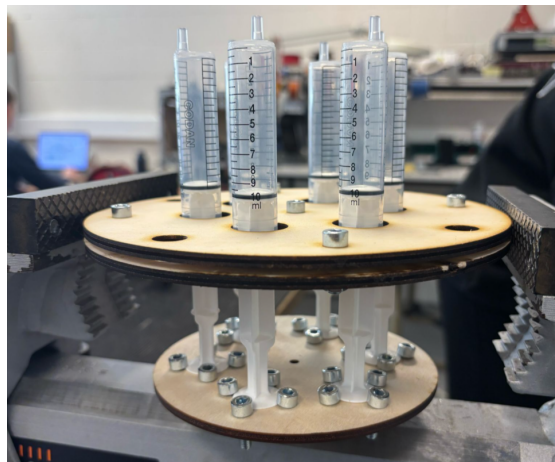


Figure 4.7: Wooden plunger plate securing syringe plungers for synchronized movement.

3. **Connecting the Tubing:** Flexible 6 mm diameter tubing was cut to precise lengths and connected to the outlets of each syringe using vacuum T-connectors. This ensured that all six syringes functioned in parallel, allowing simultaneous air intake. The tubing circuit was arranged neatly to prevent kinks or blockages, as shown in [Figure 4.8](#).
4. **Securing the Prototype Structure:** The syringe-based prototype was first mounted onto M10 threaded rods to establish a stable framework for the assembly. These threaded rods were then secured into the wooden base plate to provide structural integrity. Once secured, a wooden outlet plate was added to organize the tubing and direct airflow toward the collection chamber. The tubing was routed through pre-machined holes in the plate, ensuring a structured and secure layout. Nuts and bolts were used to fasten all components together, preventing movement and maintaining structural integrity, as illustrated in [Figure 4.9](#).

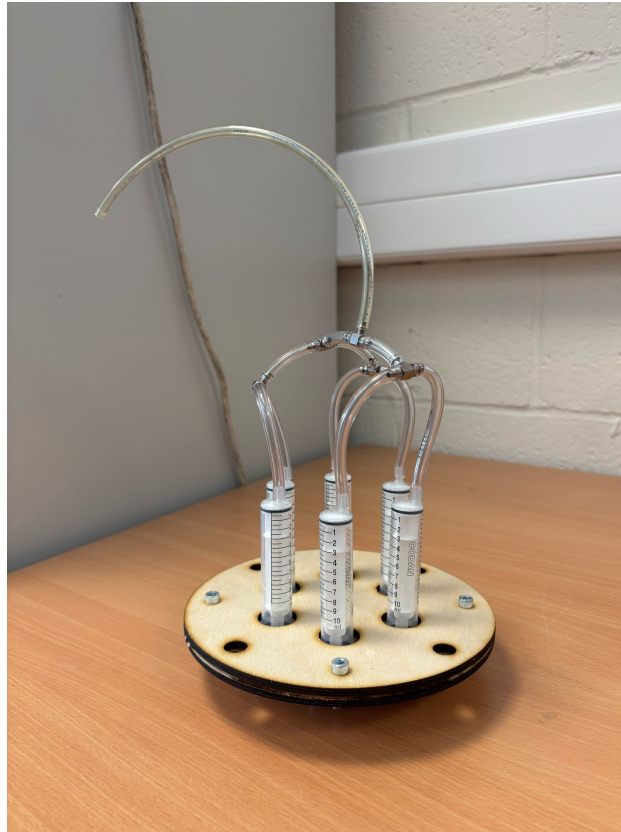


Figure 4.8: Parallel connection of syringes using flexible tubing and vacuum T-connectors.

5. **Adding the Screw Hook for Weights:** A screw hook was installed at the center of the wooden plunger plate. This component allowed external weights to be attached, generating the necessary pulling force to create a vacuum. The positioning of the hook ensured even distribution of force, minimizing strain on individual components. A complete assembly is shown in [Figure 4.9](#).



Figure 4.9: Fully assembled syringe-based vacuum pump.

In this prototype, six syringes were used to achieve a compact design while maintaining effective suction. To increase suction capacity and prolong the duration of sustained vacuum pressure before requiring a reset, the system can be adapted in two ways: by integrating additional syringes or by using larger syringes. Both approaches increase the total displaced air volume per cycle and require corresponding adjustments to the applied weight. This modular design allows the system to be adapted based on specific clinical needs, balancing efficiency, size, and ease of operation.

4.1.3.3 Negative Pressure Dimensioning for the Syringe-Based Pump

The pressure generated by the syringe-based pump depends on the volume of the syringes and the force applied to withdraw the plungers. The target pressure of 125 mmHg (16665 Pa) was calculated based on the effective surface area of the plungers and the required force.

The negative pressure dimensioning for the syringe system follows a similar procedure to that used in the PVC-based design in subsection 4.1.2.3, as the general calculations are the same. The system was designed to maintain the same negative pressure of 125 mmHg, which corresponds to 16665 Pa as calculated in Equation 4.1.

The primary difference lies in the cross-sectional area, which is derived from the diameter of the syringe and scaled by a factor of six to account for the six syringes used in the system.

The vacuum pressure force F_v was calculated using the relation between pressure and area, as shown in Equation 4.2. However, the cross-sectional area A was adjusted to account for the syringe diameter of 14 mm and the six syringes used:

$$A = 6 \times \pi \left(\frac{0.014}{2} \right)^2 = 6 \times 1.539 \times 10^{-4} = 9.234 \times 10^{-4} \text{ m}^2 \quad (4.7)$$

Substituting this area into Equation 4.2, the vacuum pressure force F_v was calculated as:

$$F_v = 16665 \times 9.234 \times 10^{-4} = 15.39 \text{ N} \quad (4.8)$$

Finally, the equivalent mass m required to produce the vacuum force was determined by rearranging the equation for weight $F = m \times g$:

$$m = \frac{F_v}{g} = \frac{15.39}{9.81} \approx 1.6 \text{ kg} \quad (4.9)$$

Thus, a mass of approximately 1.6 kg is required to maintain the target negative pressure.

A dynamometer was used to directly measure the resistance force in the syringe during plunger motion, with friction measured at approximately 7 N—equivalent to an added mass of about 0.7 kg. As a result, a total mass of around 2.5 kg is needed to maintain the desired negative pressure and overcome friction. Similar friction measurements are recommended when modifying the design for different syringe models, materials, or configurations to ensure accurate sizing and reliable performance.

In practical, low-resource settings, this weight could be improvised using commonly available items such as bags of rice or water bottles filled with 2.5 litres of water. For our study, calibrated standard weights were used to ensure precision.

As demonstrated in subsection 4.1.2.3, the required mass for varying treatment pressures can be calculated similarly using Equation 4.10:

$$m = \frac{P \times N \times A}{g} \times \left(\frac{760}{101325} \right) + 0.5 \quad (4.10)$$

where:

- P is pressure in mmHg
- N is the number of syringes
- A is the cross-sectional area of a single syringe in m^2
- g is the gravitational acceleration (9.81 m/s^2)
- 0.5 kg represents the mass required to overcome friction

4.1.4 Exudate Collection Tank

The exudate collection tank serves as a sealed reservoir for fluids drawn from the wound site, protecting the vacuum pump from contamination and ensuring controlled suction. For all mechanical the prototypes, a 1-liter *CAMI Flacon Collect* container (Figure 4.10) was used due to its availability in the lab and suitability for testing [77]. It had previously been employed in a medical aspirator project by Mayssem Hadjili and Lucile Heinen [78]. The container features 9 mm inlet and outlet ports, which were connected to the 6 mm outlets of the PVC and syringe-based pumps using a 9 mm to 6 mm tubing adapter.



Figure 4.10: Exudate collection tank (CAMI Flacon Collect).

While the CAMI container was used across all mechanical prototypes due to its availability in the lab and suitability for testing, a low-cost alternative can be implemented in resource-limited settings. A simple collection tank can be fabricated from a sealed jar with a secure lid. Two holes can be drilled into the lid: one for the inlet tube connecting to the wound site and another for the outlet tube leading to the vacuum pump. Ideally, the canister should be transparent to allow users to monitor fluid levels and detect when it is full.

To maintain proper suction, all connections must be airtight. Any leaks could reduce efficiency and impact the negative pressure level. The tubing should be securely fixed to both the lid and the container, which can be achieved using adhesive glue or silicone sealant. A similar approach has been demonstrated in the United Kingdom at the University of Plymouth, where a Gravity NPWT system was constructed using simple and accessible materials, as shown in [Figure 4.11](#) [53].

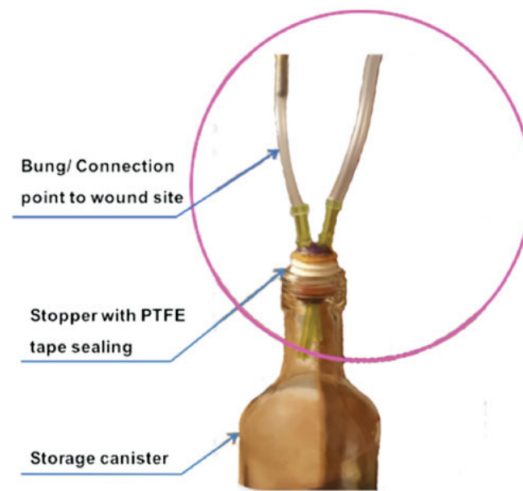
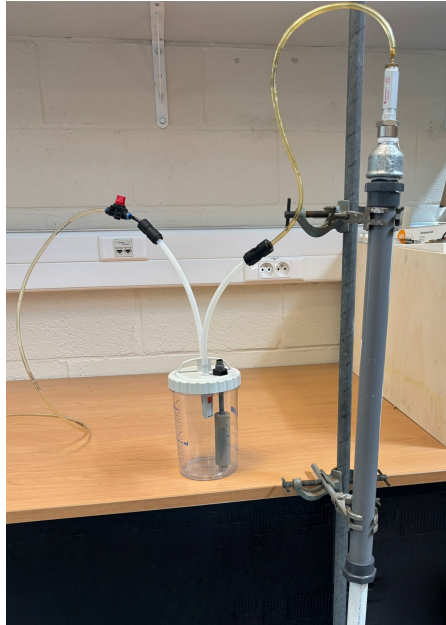


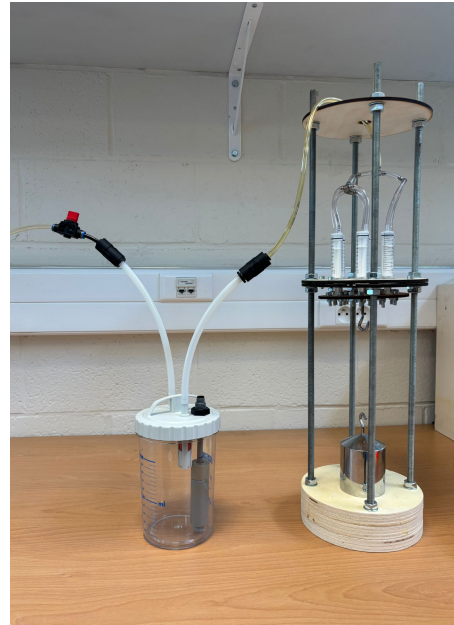
Figure 4.11: Example of a low-cost NPWT collection canister and vacuum setup [53].

4.1.5 Mechanical NPWT System Assembly and Operation

The mechanical prototypes for NPWT were assembled by connecting the suction pump—either the PVC suction pump or the syringe-based pump—to the exudate collection tank using flexible tubing. Since both pumps have a 6 mm outlet tube, and the collection tank features 9 mm ports, an adapter was required to ensure a secure and airtight connection. The second port of the collection tank was connected to another tube leading to the wound site. The assembled setups of both pumps with the collection chamber are shown in [Figure 4.12](#).



(a) PVC pump assembly with collection chamber



(b) Syringe-based pump assembly with collection chamber

Figure 4.12: Assembled Mechanical NPWT prototypes showing integration of the pumps with the exudate collection tank.

During operation, weights applied to the pump generate a pulling force that creates negative pressure within the collection tank. In the syringe-based system, the weight is suspended from a screw hook attached to the plunger, while in the PVC pump, the weight is applied directly to the handle. This pressure differential draws air from the wound site through the tubing, enabling exudate removal and supporting wound healing. Maintaining an airtight system is essential to ensure consistent suction and effective negative pressure therapy.

For hygiene and patient safety, the tubing connected to the wound site must be single-use per patient to prevent cross-contamination. Additionally, a single-use filter should ideally be placed between the collection canister and the vacuum pump to further protect the system and ensure that no contamination reaches the pump. The collection tank should also be sterilized after each treatment session to uphold clinical hygiene standards. This setup ensures that the NPWT system remains both effective and safe for use in various healthcare environments, including resource-limited settings.

4.2 Electromechanical Prototype

The electromechanical prototype was developed based on the master thesis work of Mayssem Hadjili and Lucile Heinen [78], which presented an open-source design for a medical aspirator. This prototype served as the foundation for subsequent modifications to meet the specific requirements of our application.

4.2.1 Design and Components of the Medical Aspirator

The medical aspirator is an open-source device intended for emergency and health-care applications. It comprises several interconnected systems responsible for fluid aspiration, vacuum regulation, overflow protection, and user control.

The device's vacuum circuit, responsible for fluid aspiration and pressure regulation, includes the following components (Figure 4.13):

- **Vacuum Pump:** The system is equipped with the 3KQ Boxer vacuum pump, a two-chamber device capable of generating a maximum vacuum pressure of -0.8 bar and a flow rate of up to 28 L/min (Figure 4.13a).
- **Vacuum Regulator:** A mechanical vacuum regulator provides precise control of the negative pressure through a manually adjustable knob (Figure 4.13b).
- **Pressure Transducer:** The Panasonic ADP5111 vacuum pressure transducer monitors real-time vacuum levels within the system, with an operating range from 0 to -100 kPa and an output voltage of 0 to 4.5V (Figure 4.13d).
- **Tubing and Connectors:** PVC tubing of varying diameters (8mm, 6mm, and 4mm) connects system components, ensuring secure and efficient fluid transfer (Figure 4.13d).
- **Collection Container:** The CAMI flacon collect, with a 1L capacity, serves as the primary reservoir for collected fluids and includes an integrated non-return valve (Figure 4.13c).
- **On/Off Valve:** A manually actuated 3/2 bistable shut-off valve isolates the vacuum circuit when necessary.



(a) Vacuum pump.



(b) Vacuum regulator.



(c) Collection container with the non-return valve.



(d) Tubing and connectors with a pressure transducer (in black).

Figure 4.13: Vacuum circuit components: (a) Vacuum pump, (b) Vacuum regulator, (c) Collection container, and (d) Pressure transducer [78].

The device includes an overflow protection system (Figure 4.14) to prevent liquid ingress into the pump, ensuring longevity and safety. It includes:

- **Float Level Sensor:** An RS PRO Vertical PP Float switch is employed to detect liquid levels and alarm in case of overfilling.
- **Non-Return Valve:** Integrated into the collection container lid, this valve prevents backflow and potential contamination.



Figure 4.14: Overflow protection system with level sensor (in grey) and non-return valve (in red) [78].

The electrical system provides power and control functionalities, ensuring the proper operation of all components. The circuit, containing all electrical components, is soldered onto a PCB as shown in [Figure 4.15](#).

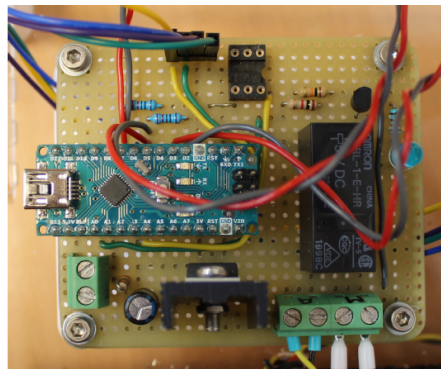


Figure 4.15: Electrical circuit OF the medical aspirator soldered onto a prototyping board [78].

The electrical system includes:

- **Microcontroller:** The Arduino Nano serves as the primary control unit, operating at 5V with an input voltage range of 7-12V. It powers and controls all system components such as the pump, display, and sensors.

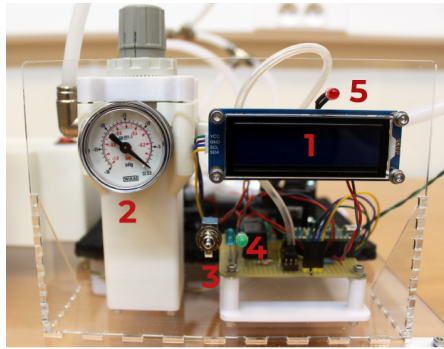
- **Power Supply Unit:** The LCS75US12 AC/DC converter delivers 12V at 6A, providing a total power output of 72W, which powers the pump, Arduino, and other components.
- **Voltage Regulator:** A Texas Instruments LM7805 linear voltage regulator steps down 12V to 5V, ensuring stable operation of the Arduino and sensors. The pump operates at 12V, while the Arduino and other components require 5V for operation. Therefore, the regulator ensures that the proper voltage is supplied to the Arduino and other low-voltage components, while maintaining the pump's 12V requirement.
- **Relay Circuit:** An Omron G5RL-1E-HR DC5 relay is implemented for controlled operation of the vacuum pump.

The prototype features a robust structural design that securely houses all components while maintaining ease of maintenance. It consists of:

- **3D Printed Supports:** Used for component holders, offering a lightweight yet durable solution.
- **Laser-Cut Plexiglass Base:** Forms the primary chassis and interface panel, providing structural stability.

The user interface integrates multiple control elements to ensure intuitive operation (Figure 4.16). It includes:

- **LCD Display:** A Waveshare LCD1602 I2C module, featuring a 16x2 character display, provides real-time vacuum level readings and system status. It is powered by the Arduino and shows messages and alarms for overfilling or inconsistent pressure, indicating when the pressure is either too high or too low..
- **Power Switch:** A SWITCH ROCK ON-OFF H8500XBAAA button is employed for system activation and deactivation.
- **Set Pressure Button:** After the user manually regulates the pressure using the pressure regulator, the set pressure button encodes this pressure level into the Arduino's control algorithm, ensuring that the pump maintains the desired pressure continuously throughout the operation.
- **LED Indicators:** Kingbright2 LEDs (5V, 0.19€/piece) provide visual alerts regarding vacuum levels and system status. These LEDs light up when the user is setting the pressure using the manual regulator and turn off once the pressure has been set. They also illuminate during alarm conditions, such as overfilling or inconsistent pressure levels, alerting the user to system issues.



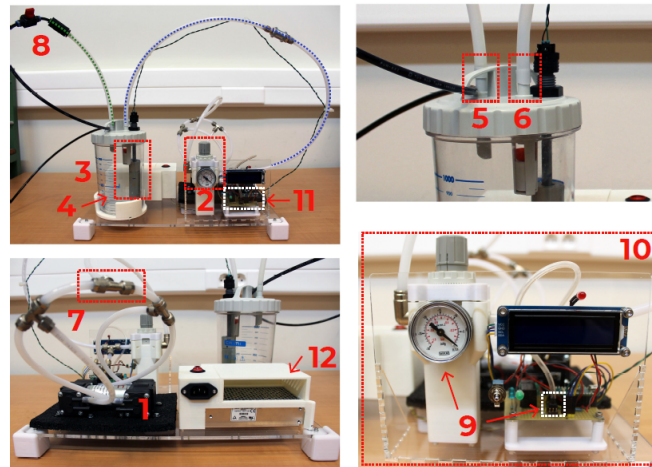
(a) Interface panel and its components. (1) LCD screen; (2) Manometer; (3) Set pressure button; (4) LED button; (5) LED alarm.



(b) Power switch on the power supply.

Figure 4.16: User interface components: (a) Interface panel and (b) Power switch [78].

The final assembled prototype, integrating all components into a functional system, is shown in Figure 4.17.



Legend

- | | | |
|------------------------|---------------------------|--------------------------------------|
| 1 Vacuum pump | 7 Vacuum connector | Suction tubing (liquid flow) |
| 2 Vacuum regulator | 8 On/Off valve | Intermediate tubing (air flow) |
| 3 Collection container | 9 Vacuum level indicators | |
| 4 Overflow protection | 10 Interface panel | |
| 5 Inlet port | 11 Electrical circuit | |
| 6 Outlet port | 12 Power supply unit | |

Figure 4.17: Overview of the medical aspirator with highlighted main parts [78].

4.2.2 Modifications for NPWT Application

To adapt the medical aspirator prototype for NPWT applications, modifications focused on optimizing functionality, reducing cost, and simplifying complexity.

For experimental validation, only the Arduino control algorithm was modified. While the original device supported multiple operating modes, only the continuous suction mode was retained for NPWT, simplifying control without changing hardware. The updated Arduino script is in [Appendix F](#).

Further optimizations aimed at reducing cost and noise were identified. The 3KQ Boxer vacuum pump was found to be oversized for NPWT, as it generates up to 80 kPa of vacuum, while NPWT requires just 16.7 kPa (125 mmHg). It is also relatively noisy. A more suitable, quieter, and cost-effective alternative is the DEWIN 5V DC vacuum pump, which provides sufficient negative pressure for NPWT and costs around 13 EUR on Amazon [79]. This pump was successfully used in a similar open-source NPWT system by the University of Barcelona [55].

The mechanical vacuum regulator originally selected for the prototype was chosen for its high quality and reliability, particularly because it was designed for high-pressure applications. However, since NPWT systems operate at low pressure, a more affordable alternative—such as models available on Amazon—can be used without compromising performance. Similarly, the vacuum transducer used in the prototype was relatively expensive due to overseas shipping costs. This component can also be replaced with a significantly cheaper sensor that still provides sufficient accuracy for monitoring low-pressure environments.

These changes would reduce the cost of the adapted medical aspirator from an estimated 500 EUR to about 230 EUR. The updated Bill of Materials for the NPWT-adapted aspirator is in [Appendix D](#).

This modification allows the original open-source medical aspirator to also function as an NPWT device. This flexibility is particularly beneficial for low-resource settings, where hospitals can maximize equipment utility, enhancing patient care with fewer specialized devices.

4.2.3 Operation of the Electromechanical Prototype

The electromechanical prototype generates and regulates vacuum pressure for fluid aspiration. The vacuum pump creates negative pressure by drawing air from the collection container, which is transmitted through medical-grade tubing to the wound site for exudate removal. A pressure transducer continuously monitors the vacuum level, providing real-time feedback to the Arduino microcontroller. The microcontroller processes the pressure data and displays it on an LCD screen.

The operation in continuous mode follows these steps:

1. Power on the device to initiate automatic calibration. If an error appears, ensure the circuit is at atmospheric pressure and the device will restart.
2. Once calibration completes, the pump starts and enters the pressure setting phase.
3. Seal the patient tubing by closing the on/off valve.
4. Adjust the regulator knob and wait for the pressure to stabilize. The target pressure is displayed on both the manometer and screen.
5. Press the set pressure button to store the value in the Arduino.
6. The LCD now shows the real-time vacuum level. Monitor for pressure stability.
7. For fluid aspiration, place the suction tubing in the fluid and open the on/off valve.

4.3 Overview of Prototypes

This chapter presented three NPWT prototypes—two mechanical and one electromechanical—developed with a focus on affordability, simplicity, and adaptability to resource-limited settings. The mechanical prototypes offer low-cost, manual solutions using readily available materials, while the electromechanical design provides enhanced functionality through automated pressure control. The choice between these approaches depends on the specific needs and constraints of healthcare facilities. [Table 4.1](#) summarizes the key differences in cost, materials, operation, and pressure control to support informed decision-making across various contexts.

Table 4.1: Comparison of NPWT Prototypes

Prototype	Estimated Cost (EUR)	Materials	Pressure Control Method
PVC Suction Pump	84.97€	PVC pipes & fittings	Manual-Weight based
Syringe-Based Pump	59.50€	Medical syringes & wood	Manual-Weight based
Electromechanical Pump	228.95€	Electronic components & plastic casing	Automated - Electric regulation

4.4 Risk Analysis

Conducting a risk analysis of the NPWT prototypes was essential to ensure user safety, improve design robustness, and meet regulatory standards, especially in low-resource healthcare settings. The goal was to identify potential hazards, assess their impact, and implement mitigation strategies during the design and testing phases.

The analysis followed the guidelines of **ISO 14971** [64], the international standard for medical device risk management. A structured risk assessment was carried out using a criticality index approach—similar to the method used in **Matrix Requirements** [80]—which considers both the probability and severity of each hazard. Eight major risks were identified and grouped into five categories:

1. **Pressure-related risks:** Excessive negative pressure, insufficient negative pressure, incorrect pressure settings
2. **Misuse risks:** Incorrect pressure setting
3. **Contamination risks:** Patient cross-contamination
4. **Component damage risks:** Pump failure, tubing blockage
5. **Environmental risks:** Power supply instability

Each risk was analyzed in terms of its potential consequences and likelihood of occurrence. Most were categorized as acceptable, with a few substantial risks requiring corrective actions. These included design changes, integration of pressure monitoring systems, single-use consumables, and improved user guidelines. For example, pressure issues were mitigated through built-in control mechanisms and clearer interfaces, while tubing blockage was addressed by increasing the tubing diameter and adding mesh filters—though further refinement is possible.

User-related risks, such as improper dressing application or incorrect pressure configuration, are more difficult to eliminate. These are best mitigated through user-friendly design, clear instructions, and training. In low-resource contexts, usability and proper guidance are especially important.

No critical or unacceptable risks were identified in the current prototypes. While most risks have been reduced to acceptable levels, some require continued monitoring as the device undergoes real-world testing. A detailed breakdown of the risk evaluations and mitigation strategies is provided in [Appendix G](#).

In summary, the risk analysis informed key design improvements and supports the safety and reliability of the developed prototypes. Ongoing evaluation, including user testing and field deployment, will be essential for validating these results and guiding further development.

Chapter 5

Testing and Validation

This chapter describes the experimental procedures and validation methods used to assess the performance of the NPWT devices. It outlines the methodology for evaluating key aspects of the system, ensuring its effectiveness for clinical application.

Section 5.1 focuses on characterizing the mechanical NPWT prototypes by evaluating their ability to generate and maintain vacuum pressure. Section 5.2 assesses pressure retention during simulated clinical use, where fluid is introduced to test how well suction is maintained. Finally, Section 5.3 discusses the implications of these findings in NPWT applications, including their potential to reduce amputation risk, their cost-effectiveness, and areas for further improvement.

Each test is introduced with a detailed description of the test protocol and the design of the experimental setup. The results offer valuable insights into the strengths and limitations of each design, serving as a foundation for further development and optimization.

5.1 Device Characterization and Performance Assessment Tests

To evaluate the performance of the mechanical prototypes—PVC suction pump and the syringe-based vacuum pump—two key performance indicators were selected:

1. Pressure generation.
2. Volume flow rate

These criteria were chosen to assess the reliability, consistency, and sealing integrity of each system, particularly under the conditions required for NPWT applications.

All tests were performed under standard room conditions:

- Temperature: room temperature (approximately 20–23 °C)
- Atmospheric pressure: ambient pressure around the device

This ensured that results reflect typical usage environments.

5.1.1 Pressure Generation Test

5.1.1.1 Principle and Objectives

This test aimed to assess the mechanical prototypes' ability to generate and maintain a stable vacuum pressure over time. A target pressure of 125 mmHg (approximately 16.7 kPa) was selected for evaluation, as this value is commonly used in clinical NPWT applications. The objective was to verify whether each system could reach and sustain this pressure level under static conditions

5.1.1.2 Apparatus Setup

The following equipment was used to ensure accurate data collection and repeatability:

- **Digital pressure transducer:** Cerabar T PMC131 (Range: -1.6 to 1.6 bar, Accuracy: $\pm 0.5\%$ FS)
- **Data acquisition system (DAQ):** USB-connected, sampling rate of 1 kHz
- **Power supply:** 24V DC, 30W for the transducer
- **Laptop with LabVIEW software:** Used to visualize and record pressure data in real time

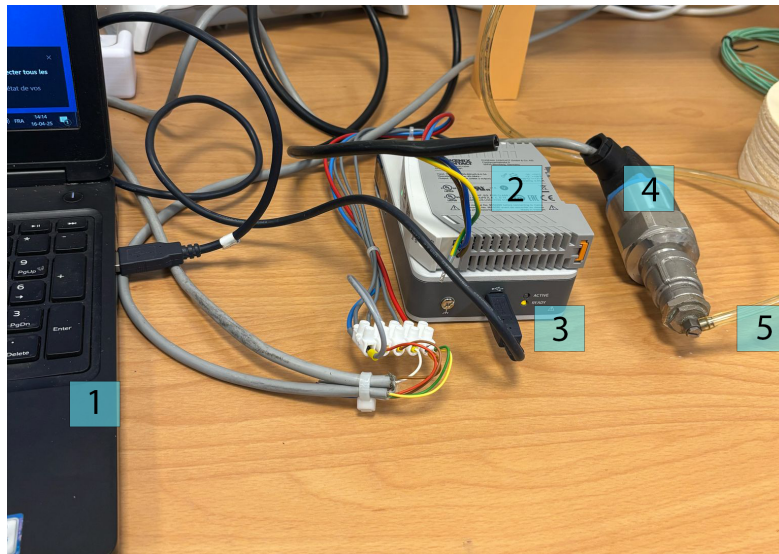


Figure 5.1: Test setup for pressure generation assessment: (1) Laptop, (2) Power Supply, (3) Data acquisition system, (4) Pressure transducer, and (5) Connection tube from prototype.

5.1.1.3 Testing Procedure

PVC Suction Pump

1. Connect the 6 mm outlet tube from the pump to the pressure transducer using a suitable adapter.
2. Power the DAQ and start the LabVIEW data acquisition software on the laptop.
3. Load the pump handle with a calibrated 2 kg weight (corresponding to 125 mmHg vacuum generation).
4. Record and post-process the pressure data.

Syringe-Based Vacuum Pump

1. Connect the outlet tubing to the pressure transducer as in the previous setup using a suitable adapter.
2. Initiate the DAQ system and begin real-time recording in LabVIEW.
3. Hang a 2.5 kg weight from the screw hook to actuate the syringe plungers and generate vacuum.
4. Record and analyze the collected pressure data.

5.1.1.4 Results

PVC Suction Pump

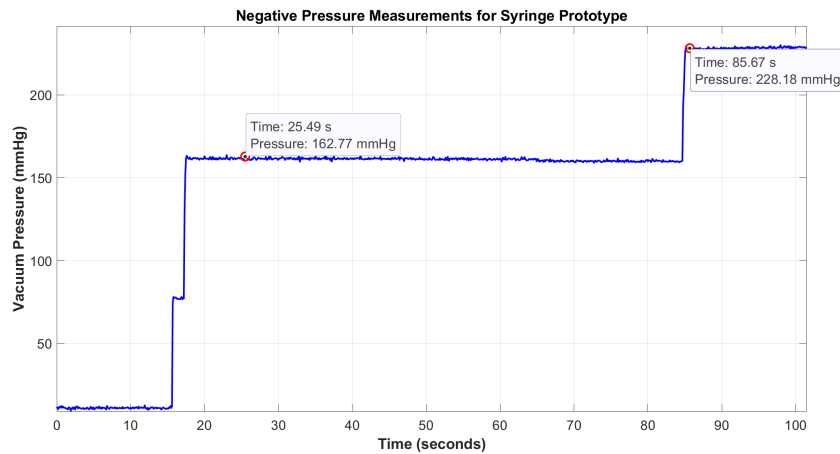


Figure 5.2: Pressure generation test results for the PVC suction pump showing unstable vacuum generation with two distinct peaks (1: 162.77 mmHg initial rise, 2: 228 mmHg secondary peak) over a 5-minute test period.

The pressure profile recorded for the PVC suction pump is presented in Figure 5.2. Upon application of the 2 kg weight, the vacuum pressure initially rose rapidly to 162.77 mmHg. Following a brief stabilization phase, the pressure exhibited a secondary abrupt increase, peaking at 228 mmHg. This value significantly exceeds the target pressure of 125 mmHg defined for NPWT applications. Pressures above 200 mmHg are considered potentially harmful in clinical settings [81], indicating that the measured behavior is unsuitable for medical use.

Syringe-Based Vacuum Pump

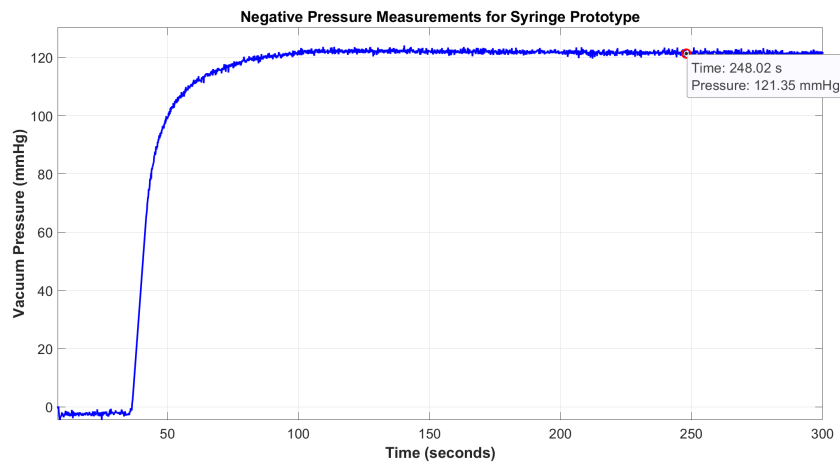


Figure 5.3: Pressure generation test results for the syringe-based vacuum pump demonstrating stable vacuum generation, reaching the target pressure (121 mmHg, within ± 2 mmHg variation) within 2 minutes and maintaining it consistently for 5 minutes.

The pressure profile recorded the syringe-based vacuum pump is presented in Figure 5.3. Following the application of a 2.5 kg weight, the vacuum pressure gradually increased and stabilized at approximately 121 mmHg within two minutes. The system was monitored for a total duration of five minutes, during which the pressure remained within a narrow fluctuation range, indicating a stable and sustained vacuum.

5.1.1.5 Discussion

PVC Suction Pump

The pressure instability observed in the PVC prototype is attributed to mechanical inconsistencies. Specifically, the combination of hard rubber O-rings and the irregular internal surface of the PVC pipe results in poor sealing and uneven piston motion. As the piston moves along the cylinder, localized gaps may allow pressure

leakage and sudden acceleration, while tighter sections impede movement, leading to unpredictable behavior. This lack of consistency compromises both performance and safety, rendering the current design unsuitable for clinical application.

Despite the current prototype's limitations, its modularity remains a notable advantage. For instance, extending the length of the PVC vacuum chamber could allow prolonged negative pressure before requiring manual reset. However, in its current form, the design was deemed unsuitable for further evaluation due to its inability to deliver safe and consistent performance under controlled conditions.

Syringe-Based Vacuum Pump

The more favorable pressure generation and maintenance observed with the syringe-based pump can be attributed to the higher manufacturing precision of medical-grade syringes. Designed for clinical use, these components feature uniform internal surfaces and precise plunger geometries, enabling effective sealing and smooth axial motion. Unlike the PVC-based prototype, the syringes did not show signs of irregular sealing or abrupt pressure variations.

The observed pressure generation also suggests a minimal rate of air leakage within the system. This is critical for negative pressure wound therapy applications, where a reliable vacuum must be maintained for extended periods to ensure therapeutic effectiveness.

5.1.2 Volume Flow Rate Test

5.1.2.1 Principle and Objectives

This test aimed to evaluate the airflow capacity of the mechanical prototypes under a negative pressure of 125 mmHg. Flow rate is a critical performance metric as it reflects the pump's ability to both remove wound exudate and compensate for system air leakage, particularly through the dressing interface.

As explained in the preliminary pump dimensioning section of the design requirements chapter ([section 3.1](#)), the minimum flow rate needed for NPWT to work properly is around 100 mL/h. This value mainly comes from the need to compensate for air leaks through the dressings at the wound site. Pumps that do not reach this level may have limited effectiveness and might not perform well enough for clinical use.

5.1.2.2 Testing Method

The test was performed by hanging a weight that generated approximately 125 mmHg of vacuum. A stopwatch was used to record the time taken to complete one full stroke—the motion that pulls air into the pump. From this time and the known volume moved per stroke, the flow rate in mL/h was calculated.

5.1.2.3 Results and Discussion

PVC Suction Pump

The PVC pump could not provide consistent results. The piston movement varied unpredictably due to gaps between the O-rings and the inner wall of the pipe, which had an uneven surface. In some sections, the piston moved too quickly, while in others it stalled. This irregular stroke behavior made it impossible to measure a reliable flow rate. Because of this, the PVC pump was excluded from the final flow rate and power analysis.

Syringe-Based Pump

The syringe pump, on the other hand, showed smooth and consistent performance. Six medical-grade syringes, each with a volume of 11 mL, were connected and actuated at once using a hanging weight. All plungers completed their strokes in 23.61 seconds. Since the total air volume moved was 66 mL, this results in a flow rate of approximately 2.796 mL per second. When converted to an hourly rate, this corresponds to around 10,064 mL/h. This far exceeds the 100 mL/h minimum requirement and confirms the capability of the syringe-based pump to handle both exudate and air leakage under the test conditions.

5.1.2.4 Estimated Pumping Power

Based on the flow rate and the average vacuum pressure recorded, the pumping power was calculated using the method described in the Preliminary Estimation of Pump Performance Requirements section ([section 3.1](#)) using [Equation 3.3](#). The results are summarized in [Table 5.1](#).

Table 5.1: Flow Rate and Estimated Pumping Power of Mechanical Prototypes

Prototype	Average Flow Rate (mL/h)	Pumping Power (mW)
PVC Suction Pump	N/A	N/A
Syringe-Based Pump	10,064	46.6

5.2 Negative Pressure Retention Test

5.2.1 Principle and Objectives

The negative pressure retention test was conducted under simulated clinical conditions to evaluate how well the system could maintain vacuum pressure after wound dressing application. Stable negative pressure is essential for effective wound healing, as it facilitates fluid removal, supports tissue regeneration, and reduces infection risk. Rather than measuring fluid removal, the test focused on pressure stability over time—particularly in the presence of fluid—to assess the system’s ability to sustain suction without significant leaks or pressure loss.

5.2.2 Aparatus Setup

A custom test bench was designed to simulate a realistic wound environment for evaluating NPWT performance under controlled conditions. It included a 3D-printed wound model, an exudate infusion mechanism, and a sealed reservoir. The system allowed for fluid introduction to mimic exudate production and assess the ability of each prototype to maintain negative pressure within a simulated wound scenario. A detailed description of the test bench design is provided in [Appendix H](#).

Vacuum pressure was measured using the same Cerabar T PMC131 digital pressure transducer and DAQ system described in subsection [5.1.1.2](#) for the pressure generation test. A T-connector was placed in the tubing between the wound dressing and the collection canister to monitor pressure without disrupting airflow. The setup is illustrated in [Figure 5.4](#).

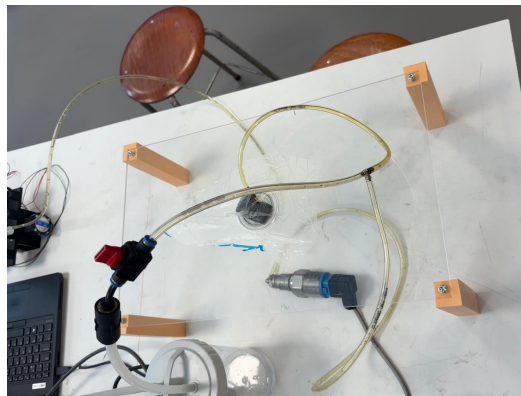


Figure 5.4: Experimental setup for pressure retention testing using the wound test bench. The configuration includes a T-connection with an integrated digital pressure transducer placed between the dressing and collection canister.

5.2.3 Testing Procedure

Each prototype was evaluated using the following steps:

1. Assemble and seal the wound model and reservoir using an O-ring.
2. Mount the assembled wound model and reservoir onto the test bench structure.
3. Apply the dressing onto the wound model, ensuring proper coverage and seal.
4. Insert a T-connector into the tubing and attach the pressure transducer.
5. Connect the selected prototype pump to the canister outlet.
6. Connect the fluid injection line from the perfusion pump to the wound.
7. Initiate fluid injection at 1–3 mL/h using the syringe actuator.
8. Record pressure data continuously throughout testing, and repeat the procedure for each prototype under identical conditions.

5.2.4 Results

PVC Suction Pump

The PVC-based suction pump was excluded from this test due to inadequate performance in prior evaluations. It failed to generate or sustain negative pressure reliably, and therefore could not be assessed under wound-simulated conditions.

Syringe-Based Pump

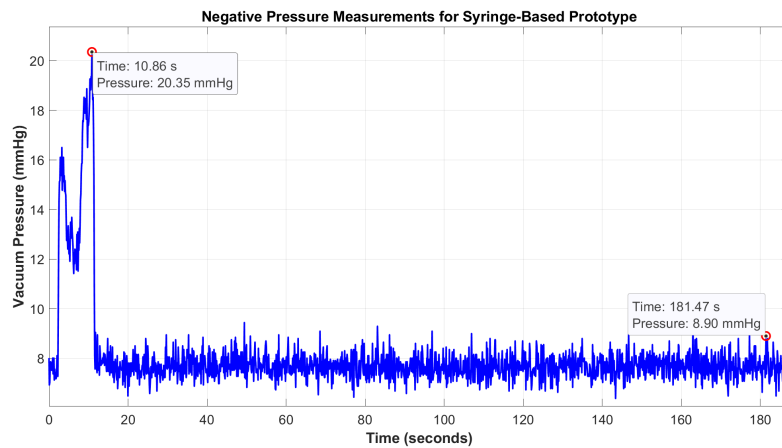


Figure 5.5: Pressure retention test results for the syringe-based pump showing an initial vacuum peak of 20.35 mmHg followed by a sustained pressure of approximately 8.9 mmHg with high fluctuations, indicating unstable suction performance.

The pressure profile obtained during the wound simulation test using the syringe-based pump is shown in Figure 5.5. Upon activation, the pump generated an initial negative pressure that peaked at 20.35 mmHg. However, this pressure was not sustained. Shortly after the initial rise, the vacuum level dropped and stabilized at an average of 8.9 mmHg. This lower pressure plateau was marked by frequent fluctuations, suggesting that the system was struggling to maintain consistent suction.

Electromechanical Prototype

The pressure profile recorded during testing of the electromechanical prototype is presented in Figure 5.6. Upon activation, the device generated a rapid increase in vacuum pressure, reaching an initial peak of 156.15 mmHg. Following this transient peak, the system stabilized and maintained a vacuum pressure of approximately 128.56 mmHg for the remainder of the test duration, with only minor fluctuations observed. The initial vacuum spike remained well below the harmful threshold of 200 mmHg [81] and is therefore considered acceptable.

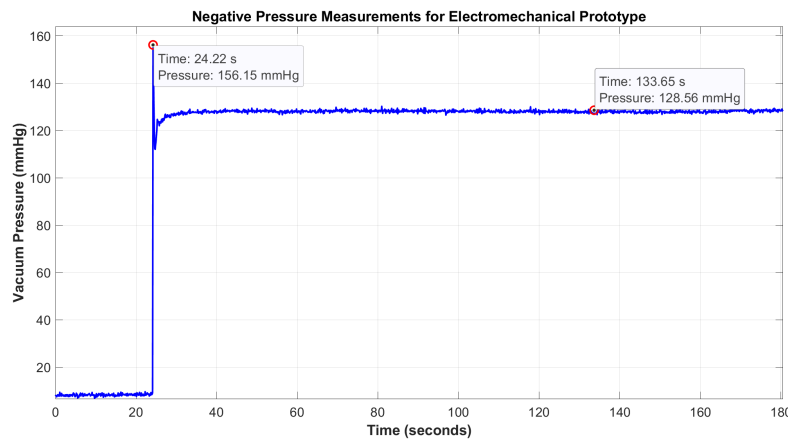


Figure 5.6: Pressure retention test results for the electromechanical device showing an initial peak of 156.15 mmHg followed by stable maintenance of approximately 128.56 mmHg, with minimal fluctuations during wound simulation.

5.2.5 Discussion

Syringe-Based Pump

The inability of the syringe-based pump to maintain stable vacuum pressure is primarily attributed to its limited power output and inherent mechanical constraints. Despite the syringe's precise geometry and smooth internal surface, which help reduce leakage, the estimated power of 46.6 mW (Table 5.1) was insufficient to compensate air leaks-particularly from the test bench.

Additionally, the plunger reached its maximum stroke before achieving the desired vacuum level, prematurely ending the pumping cycle. These limitations prevented sustained pressure regulation and highlighted the system's dependence on minimal leakage to function effectively. However, the system successfully generated negative pressure under static conditions and achieved an acceptable flow rate in earlier tests. In a clinical setting—where leaks are confined to the dressing rather than the entire system—and with enhanced sealing of the wound interface, the syringe-based pump could still function effectively.

Electromechanical Prototype

The electromechanical device demonstrated consistent and reliable vacuum pressure retention under simulated wound conditions. The initial spike reaching 156mmHg at the start of the simulation resulted from the system's preloading sequence. As described in subsection 4.2.3, the vacuum is first built up in the collection canister while the valve to the wound remains closed. When the valve opens to begin fluid aspiration, the preloaded vacuum rapidly transfers to the wound system, causing a brief pressure overshoot. However, this spike stayed well below the harmful threshold of 200 mmHg [81] and is considered acceptable. After this initial adjustment, the system maintained stable pressure throughout the simulation. This prototype's superior performance highlights the importance of adequate power and controlled operation in NPWT devices, enabling them to overcome leaks and maintain target pressure for safe and effective therapy.

5.3 Interpretation of Results

This section interprets the findings from all experimental tests, including pressure generation, flow rate measurements, and pressure retention. These results help assess the clinical relevance and reliability of each prototype in delivering effective Negative Pressure Wound Therapy.

5.3.1 Prototype Performance Analysis

The syringe-based prototype was able to generate vacuum in static conditions but struggled during the wound simulation. The failure to keep suction is mainly due to its limited mechanical power and significant air leaks from the test bench. These results suggest the idea is promising. However, the prototype could be improved by better sealing and increased suction power. This could be done by adding more syringes or using larger ones. With these changes, it could work better in real wound conditions.

The PVC-based pump showed poor results overall. It generated unstable vacuum pressure that made it difficult to perform wound simulation testing. This instability renders the design unsuitable for clinical NPWT use without significant design improvements.

The electromechanical prototype showed the most effective and reliable performance. It maintained the target vacuum pressure even after fluid introduction and effectively compensated for air leaks. Additional features, such as adjustable pressure settings and integrated safety alarms, enhance its clinical usability. Despite its higher production cost, its automation and consistent performance make it well-suited for extended care scenarios, including outpatient treatment and use in district hospitals.

5.3.2 Clinical Impact and Scalability

NPWT promotes wound healing by removing excess fluid, reducing edema, and stimulating tissue regeneration [11, 2]. A device capable of consistently generating and maintaining therapeutic vacuum pressure—despite the presence of wound exudate and minor air leaks—is essential for minimizing complications and reducing the risk of amputation.

Given its mechanical simplicity and affordability, the syringe-based pump design is well-suited for low-resource settings. It uses widely available, inexpensive components, operates without electricity, and requires minimal maintenance. This makes it a practical option for field clinics, mobile care units, or home use in rural areas. With proper training, community health workers or family caregivers can easily use it. With further refinement, the syringe-based system could become an effective low-tech NPWT solution for communities where commercial devices are inaccessible.

In contrast, the electromechanical prototype, while more complex, remains significantly less costly than commercial NPWT solutions. Its digital pressure control, integrated alarms, and reliable fluid handling improve safety and usability. This makes it ideal for healthcare centers that provide long-term or high-volume wound care with limited staff.

Together, these prototypes offer scalable NPWT solutions adaptable to different levels of healthcare infrastructure. By lowering cost and technical barriers, they increase access to effective wound care and help reduce preventable limb loss. Future work should include clinical validation and long-term monitoring to better assess their impact on patient recovery and amputation rates. Nonetheless, the current results show strong promise for their use in preventive wound care strategies.

Chapter 6

Future Work

This project has shown the feasibility of developing low-cost mechanical and electromechanical NPWT devices for use in low-resource settings. However, several technical and usability challenges remain. Section 6.1 presents directions for improving the PVC-based suction pump, which was not functional in its current form. Section 6.2 outlines potential upgrades to the syringe-based prototype. Section 6.3 discusses cost-reduction and miniaturization strategies for the electromechanical prototype. Finally, Section 6.4 highlights regulatory and risk-related work necessary to ensure safety and prepare for clinical implementation.

6.1 PVC Suction Pump

The PVC-based pump was not considered functional in this study due to inconsistent piston movement and vacuum instability. The main issue was linked to the hard O-rings used for sealing, which did not adapt well to the uneven surface of the PVC pipe. Future work should explore alternative sealing materials, such as foam discs or softer O-rings. These materials can conform better to surface irregularities, potentially improving piston motion and enabling more stable vacuum generation. For example, a foam disc seal was successfully used in a gravity-driven NPWT system developed at the University of Plymouth, which maintained stable pressure for up to five hours [53].

Despite its limitations, the PVC design offers a modular structure that could be optimized. For instance, increasing the length of the vacuum chamber could help sustain pressure for longer periods without requiring frequent resets.

Another promising approach involves integrating low-cost commercial manual vacuum pumps. These pumps are inexpensive—typically priced below 10 euros—and readily available in various markets. They come equipped with built-in piston and valve systems that generate suction effectively. However, the relatively small vacuum chambers in these pumps may limit the volume of fluid they can handle at once.

Combining manual vacuum pumps with an extended vacuum chamber could help address this limitation. By increasing the chamber size, the pump could maintain the necessary vacuum for NPWT without complex modifications or costly components. This approach offers a cost-effective and practical solution,

especially in low-resource settings where affordability and simplicity are essential for effective wound care. Additionally, it provides a significantly simpler alternative to manufacturing a complete vacuum pump from scratch, reducing production complexity while ensuring reliable performance.

6.2 Syringe-Based Vacuum Pump

The syringe-based prototype showed promising results in pressure generation and flow rate tests, confirming its potential as a low-cost vacuum source. However, during the pressure retention test, its performance revealed a key limitation: the system relied on minor leaks to maintain vacuum due to its low power. This vacuum loss is likely caused by minor leaks in the dressing and significant leaks in the test bench, combined with the syringe mechanism's limited pumping capacity.

In addition to these technical challenges, a significant usability limitation is the need to manually reset the plungers after each stroke. This manual step requires human input, making the system unsuitable for continuous or unattended operation.

Future work should focus on two key areas to improve the syringe-based prototype's performance and usability. First, increasing pumping power—through larger syringes or multiple units in parallel—and enhancing sealing at connection points could significantly improve vacuum stability and efficiency. Second, developing a simple mechanism to automate or assist the plunger reset process would enable semi-continuous operation. Possible solutions include integrating a manual crank to reset the plungers between cycles or using low-cost electric motors with limit switches to detect stroke completion and trigger automatic retraction.

The choice between manual and automated reset methods should balance design constraints and cost. Implementing such improvements would enhance usability while maintaining affordability and mechanical simplicity, making the prototype more suitable for low-resource healthcare settings.

6.3 Electromechanical Prototype

The electromechanical prototype, adapted from a medical aspirator, proved functional but relied on off-the-shelf components, making it relatively costly for low-resource settings. The original components were designed for high-pressure applications, introducing unnecessary complexity and expense for NPWT, which operates at significantly lower pressures. Future work should prioritize the design of a purpose-built electromechanical system using low-cost components and simplified circuitry tailored specifically to NPWT requirements.

Incorporating a rechargeable battery would enable use during power outages or in mobile settings, enhancing usability in remote or off-grid areas. Additional improvements, such as noise reduction, could also increase user comfort and acceptance. To ensure accessibility in low-income healthcare environments, the total system cost should aim to remain below 150 EUR while maintaining clinical effectiveness.

6.4 Regulatory and Risk Considerations

In addition to technical improvements, future efforts should focus on regulatory aspects of the device. A comprehensive risk analysis and failure mode assessment should be conducted for both the mechanical and electromechanical prototypes. This would include identifying critical points of failure, evaluating patient safety risks, and proposing mitigation strategies. A preliminary risk analysis was conducted during this study and is included in [Appendix G](#). However, more comprehensive evaluations will be needed before any clinical use or regulatory submission.

Furthermore, the certification pathway for each device category should be studied to ensure that any future version can meet local or international medical device regulations. This will be essential for clinical deployment and large-scale adoption.

Conclusion

Access to proper wound care should not depend on where a person lives or their financial means. Yet, in many low- and middle-income countries, advanced treatments like Negative Pressure Wound Therapy (NPWT) remain inaccessible. This thesis aimed to address that gap by designing and testing low-cost, open-source NPWT devices tailored to the realities of resource-limited settings, using Cameroon as a case study. Rather than replicating commercial systems, the objective was to rethink NPWT design by balancing performance, simplicity, and affordability.

Three functional prototypes were developed: a PVC-based suction pump, a manual syringe-driven system, and an electromechanical version with automated pressure control. Each addressed different technical and user challenges. The syringe-based model, despite struggling to maintain suction during wound simulation, showed promise due to its simplicity and use of widely available materials. The electromechanical version offered more reliable performance and better control, making it suitable for outpatient or clinical settings. The PVC-based pump did not perform as expected in this study but holds potential given prior demonstrations of its modular design.

The potential impact of these designs is significant. By offering affordable alternatives to commercial NPWT systems, they could help reduce preventable amputations from untreated chronic wounds. Importantly, they empower local providers and technicians to build and maintain their own equipment, encouraging self-reliance and local innovation. The use of simple construction and local materials supports deployment in rural and remote areas.

Beyond the technical outcomes, this thesis contributes to a growing movement in medical engineering focused on open design, affordability, and user-centered thinking. It demonstrates how applying engineering principles within a healthcare context can lead to solutions that are both meaningful and sustainable. The documented development process offers a useful resource for future researchers and practitioners.

Ultimately, this work is about more than engineering. It challenges the notion that quality healthcare must be expensive and shows that with creativity and empathy, we can design medical technologies that truly serve everyone. Further clinical testing and refinement are needed, but the foundation is strong. This project is a step toward closing the global health gap—and a reminder that impactful innovation often begins with asking: how can we do more, with less?

Appendix A

Fluid Flow Modeling in NPWT Systems

This appendix provides a detailed discussion of the fluid dynamics involved in NPWT systems. It focuses on the flow behavior of wound exudates through the suction tubing and the applicability of Poiseuille’s law under laminar conditions. Assumptions regarding fluid properties and analytical simplifications are also described to support the design and evaluation of the system.

A.1 Fluid Flow of Wound Exudates

Wound exudates are non-Newtonian, meaning they exhibit a variable viscosity known as apparent viscosity, unlike Newtonian fluids [82]. Their viscosity depends on shear rate and shear stress¹. Under low shear conditions, they maintain a semi-solid or gel-like structure due to the presence of fibrin, cellular debris, and high molecular weight proteins [86]. However, when shear forces increase, their viscosity decreases, allowing them to flow more easily. Biological fluids often behave similarly to gels, where their viscosity is shear-dependent [82]. A familiar example is ketchup, which remains thick when at rest but flows easily when shaken or squeezed. When a glass bottle of ketchup is turned upside down, the ketchup may not flow due to its high viscosity. However, tapping or shaking the bottle applies force that lowers the viscosity, enabling smooth flow. This behavior, known as shear thinning, is similar to how wound exudates behave under different shear conditions—thick and gelatinous at low shear but becoming more fluid when suction is applied in an NPWT system.

To model the flow inside an NPWT tube, we will consider fluid flow through a cylindrical pipe. The general equation for fluid flow in a cylindrical pipe with a pressure difference is given by [87]:

¹In continuum mechanics, shearing describes the deformation of a material where parallel internal layers slide past each other, resulting in shear strain[83]. The shear rate quantifies the speed at which this strain develops within the material, indicating how velocity varies with distance [84]. Shear stress represents the force per unit area acting tangentially to a material’s cross-section. [85]

$$Q_V = \frac{\pi n}{3n+1} \left(-\frac{1}{2K} \frac{\partial P}{\partial z} \right)^{1/n} R^{\frac{3n+1}{n}} \quad (\text{A.1})$$

Where:

- Q_V : Volumetric flow rate of the fluid (m^3/s).
- $\frac{\partial P}{\partial z}$: Partial derivative of pressure with respect to the z -axis (Pa/m).
- R : Radius of the cylindrical pipe (m).
- K : Dynamic viscosity when shear rate equals one ($Pa.s^n$).
- n : Power-law index determining the fluid type:
 - $n < 1$: Pseudoplastics (apparent viscosity decreases with stress increase).
 - $n = 1$: Newtonian fluids (constant viscosity μ).
 - $n > 1$: Dilatants (apparent viscosity increases with stress).

The equation above is quite complex due to its non-linear nature. To simplify the analysis and make it more manageable, we assume $n = 1$, which corresponds to the behavior of a Newtonian fluid. This assumption significantly reduces the complexity of the equation and makes it easier to model the flow of the fluid in the NPWT system. By substituting $n = 1$ into the original equation [87, 88], we arrive at the linear expression for Poiseuille's law, which describes laminar flow in Newtonian fluids:

$$Q_V = \frac{\pi}{4} \left(-\frac{1}{2K} \frac{\partial P}{\partial z} \right) R^4. \quad (\text{A.2})$$

This simplification assumes that the fluid maintains constant viscosity and follows laminar flow conditions, which are typical for Newtonian fluids.

A.2 Poiseuille's Law

In the context of NPWT systems, we assume that the fluid behavior follows Poiseuille's law, which applies to the suction of bodily fluids through a tube. This law describes the laminar flow of viscous fluids in a cylindrical pipe [89]. It establishes a theoretical relationship between the flow rate Q and the pressure difference ΔP across the pipe, which is expressed by the equation:

$$Q = \frac{\Delta P \pi R^4}{8L\mu}. \quad (\text{A.3})$$

where:

- Q : Volumetric flow rate of the fluid (m^3/s),
- ΔP : Pressure difference between the two ends of the pipe (Pa),
- R : Radius of the cylindrical pipe (m),
- L : Length of the pipe (m),
- μ : Dynamic viscosity of the fluid ($Pa.s$).

This equation assumes a steady-state (permanent regime) flow where $\partial/\partial t = 0$, and the fluid is incompressible.

For Poiseuille's law to be applicable, it is essential to ensure that the flow remains laminar, as the law is valid only under these conditions [89]. Laminar flow occurs when the fluid moves in smooth layers, and the inertial forces are much smaller than the viscous forces. To confirm that the flow is indeed laminar, the Reynolds number Re is calculated, which represents the ratio of inertial forces to viscous forces. Laminar flow is expected when Re is below 2000.

The Reynolds number is given by the following equation:

$$Re = \frac{\rho c d}{\mu}. \quad (A.4)$$

Where:

- ρ : Fluid density (kg/m^3),
- μ : Fluid dynamic viscosity ($Pa.s$),
- d : Diameter of the tubing (m),
- c : Fluid velocity (m/s).

If the calculated Reynolds number is below 2000, the flow remains laminar, and the assumptions made by Poiseuille's law are valid, ensuring the relationship between flow rate and pressure difference can be applied effectively in NPWT systems.

From the literature, there are estimates of the Reynolds number (Re) and dynamic viscosity (μ) for various bodily fluids, which are essential for determining whether the flow remains laminar and Poiseuille's law is applicable. [Table A.1](#) summarizes the dynamic viscosity, density, and Reynolds number for different fluids under the given assumptions. These values can help us calculate the Reynolds number to ensure that the flow behaves according to the assumptions made by Poiseuille's law.

To begin, we first need to calculate the velocity c of the fluid in the suction tubing. The required minimal flow rate of 200 mL (or $2 \times 10^{-5} m^3$) in 10 seconds, along

with the tubing diameter of $D_{\text{SuctionTubing}} = 0.004$ m, leads us to the following equation for the fluid velocity:

To begin, we first need to calculate the velocity c of the fluid in the suction tubing. The wound exudate flow rate from the literature is estimated to range from a minimum 0.3 mL/h (8.33×10^{-11} m³/s) for low exudate wounds to 3 mL/h (8.33×10^{-10} m³/s) for high exudate wounds [57]. With a tubing diameter of $D_{\text{SuctionTubing}} = 0.004$ m, the fluid velocity is given by:

$$c = \frac{\dot{V}}{\pi R_{\text{SuctionTubing}}^2}. \quad (\text{A.5})$$

Substituting the radius $R_{\text{SuctionTubing}} = 0.002$ m and the given flow rates:

For low exudate wounds:

$$c_{\text{low}} = \frac{8.33 \times 10^{-11}}{\pi(0.002)^2} \approx 6.63 \times 10^{-6} \text{ m/s}. \quad (\text{A.6})$$

For high exudate wounds:

$$c_{\text{high}} = \frac{8.33 \times 10^{-10}}{\pi(0.002)^2} \approx 6.63 \times 10^{-5} \text{ m/s}. \quad (\text{A.7})$$

Now we can calculate the maximum Reynolds number Re for each fluid by using the maximum velocity $c = 6.63 \times 10^{-5}$ m/s and substituting the values of ρ , c , d , and μ from Table A.1.

Table A.1: Dynamic Viscosity and Reynolds Number of Different Viscous Fluids

Types of Fluids	Dynamic Viscosity μ [Pa.s]	Density ρ [kg/m ³]	Reynolds Number Re
Blood	3.5×10^{-3} [90]	1060 [91]	1.1×10^{-6}
Exudate	0.7 [82]	1016 [92]	4.8×10^{-9}

From Table A.1, we can see that the Reynolds number for all the fluids is still well below 2000, validating that the flow remains laminar and confirming that Poiseuille's law is applicable for modeling the fluid behavior in NPWT systems.

Appendix B

Bill of Materials for PVC Suction Pump

This Bill of Materials (BOM) provides a detailed breakdown of the components required for the fabrication of the PVC suction pump prototype. The components are categorized into three main sections: PVC vacuum pump components, collection chamber components, and manufacturing costs. Each component includes details such as description, dimensions, additional notes, purchase links, and total price.

B.1 PVC Vacuum Pump Components

B.1.1 PVC Components

1 inch PVC Pipe

Name	PVC drukbuis 32 mm x 2,4 mm PN16 lengte 1 meter
Description	Regular PVC pipe used for plumbing.
Dimensions	32mm diameter, 1m length
Purchase Link	https://haxo.be/pvc-drukbus-32-mm-x-2-4-mm-pn...
Total Price	3.19€ (VAT incl.)

3/4 inch Alpex Pipe

Name	TECEflex Alupex buis 25 mm per meter
Description	A multilayer composite pipe with an aluminum core and PEX plastic layers, primarily used for heating systems.
Dimensions	25mm diameter, 1m length
Purchase Link	https://haxo.be/teceflex-alupex-buis-25-mm-per...
Total Price	7.14€ (VAT incl.)

1-inch Straight Threaded Adapter

Name	Georg Fischer Plastic Pipe Fitting, Straight Threaded Adapter, 32mm, R 1in to Cement 32mm
Description	PVC threaded adapter for connecting pipes
Dimensions	32mm inner diameter with standard threads
Quantity	2
Purchase Link	https://befr.rs-online.com/web/p/plastic-pipe-fittings/4328009?gb=a
Unit Price	9.38€ (VAT incl.)
Total Price	18.76€ (VAT incl.)

1-inch to 3/4-inch Coupler

Name	SmartProduct 32mm x 25mm MDPE PP Pipe Compression Reducer
Description	PVC coupler for reducing pipe size from 1-inch to 3/4-inch
Dimensions	32mm to 25mm reduction in diameter
Purchase Link	https://www.amazon.com.be/SmartProduct-Connecteur-pour-tuyaux-MDPE/dp/BOBMW9W4WC
Total Price	10.95€ (VAT incl.)

1-inch Tee Fitting

Name	PVC T-stuk 90°
Description	PVC tee fitting for creating branch connections
Dimensions	1-inch three-way 90deg connection
Purchase Link	https://www.toolstation.be/pvc-t-stuk-900/p12854
Total Price	1.28€ (VAT.incl)

B.1.2 Fittings and Sealing Components

Rubber O-rings

Name	O-ring Zwart 25 x 3 mm
Description	Three 3mm thick O-rings used to create a seal between the piston and main body.
Dimensions	3mm thick, appropriate diameter
Quantity	2
Purchase Link	https://www.paracord.nl/o-ring-zwart-25mm?srsltid=AfmB0oqmcQev0taRS3RTg6K_kQhMzOXbK1kfj4qbarJTvmu2W04f0wIG7ms&gQT=1
Total Price	0.9€

Two One-Way Check Valves

Name	Stainless Steel Check Valve, 1/2" Male to Male
Description	Stainless steel threaded one way valve with standard G 1/2" male to male threads.
Quantity	2
Purchase Link	https://www.amazon.com.be/dp/B0D1Q4943Z/ref=twister_B0D1QZ525Q?_encoding=UTF8&th=1
Unit Price	8.41€ (VAT incl.)
Total Price	16.82€ (VAT incl.)

APPENDIX B. BILL OF MATERIALS FOR PVC SUCTION PUMP

1-inch to 1/2-inch Reducer

Name	1 x 1/2 - Verloopsok A4
Description	PVC reducer fitting for connecting different pipe sizes 2ith female to female threads
Dimensions	1-inch to 1/2-inch reduction
Purchase Link	https://www.rvspaleis.nl/fittingen/verloop-sok/335-4-1x1[_]2_1
Total Price	5.19€ (VAT incl.)

1/2-inch to 1/4-inch Reducer

Name	YOUZMY brass reducer 1/2 to 1/4 inch adapter
Description	Threaded reducer with male to female connections
Dimensions	male thread with diameter 20mm x female threaded with diameter 12mm
Purchase Link	https://www.amazon.com.be/YOUZMY-reducer-adapter-threaded-connection/dp/BODDJQ8K8F
Total Price	6.99€ (VAT incl.)

1/2-inch to 6mm Hose-Tail Barb Connector

Name	Hose-Tail Barb Connectors
Description	Connector for transitioning from pipe to 6mm tubing
Dimensions	1/2-inch threaded end to 6mm barbed connection
Purchase Link	https://www.easycomposites.eu/hose-tail-barb-fitting
Total Price	1.75 (VAT excl.)

APPENDIX B. BILL OF MATERIALS FOR PVC SUCTION PUMP

Tubing

Name	SenTECH Silicone Tube
Description	Transparent tubing for gases and fluids.
Dimensions	6 mm (internal), 8 mm (external), 2 m length
Material	Silicone
Weight	60 g
Purchase Link	https://www.amazon.com.be/Silicone-Flexible-%C3%A9paisseur-Tuyau-m%C3%A8tre/dp/B07MZ6QN89?th=1
Total Price	12€ (VAT incl.)

Total Material Cost of the PVC Suction pump: 84.97€

Appendix C

Bill of Materials for Syringe-Based Pump

This Bill of Materials (BOM) provides a detailed breakdown of the components required for the fabrication of the syringe pump prototype. The components are categorized into three main sections: syringe pump components, collection chamber components, and manufacturing costs. Each component includes details such as description, dimensions, additional notes, purchase links, and total price.

C.1 Syringe Pump Components

Syringes

Name	GSSFASHION Needle-Free Syringes
Description	Medical-grade syringes for industrial/lab use
Capacity	10 ml volume
Purchase Link	https://www.amazon.com.be/-/en/GSSFASHION-Needle-Free-Syringes-10-ml-volume/dp/B08F7H7H7H
Total Price	5.24€ (VAT incl.)

Vacuum T Connectors

Name	Hsthe Barbed T-Shaped Fittings
Description	Brass T-connectors for tubing systems
Dimensions	6mm barbed connections
Quantity	5 units
Unit Price	1.20€
Purchase Link	https://www.amazon.com.be/-/en/Hsthe-Barbed-Fittings-6mm-Barbed-Connections/dp/B08F7H7H7H
Total Price	5.99€ (VAT incl.)

APPENDIX C. BILL OF MATERIALS FOR SYRINGE-BASED PUMP

Tubing

Name	SenTECH Silicone Tube
Description	Transparent tubing for gases and fluids.
Dimensions	6 mm (internal), 8 mm (external), 2 m length
Material	Silicone
Weight	60 g
Purchase Link	https://www.amazon.com.be/Silicone-Flexible-%C3%A9paisseur-Tuyau-m%C3%A8tre/dp/B07MZ6QN89?th=1
Total Price	12€ (VAT incl.)

Three-Way Infusion Stopcock

Name	Discofix 3-Way Stopcock (Blue)
Description	Medical-grade three-way stopcock for infusion systems
Purchase Link	https://www.medipost.shop/fr/soins-pansements/robinet-a-3-voies-discofix-bleu.html
Total Price	1.06€ (VAT incl.)

Threaded Rods

Name	LumenTEC M10-1000 Threaded Rods
Description	Steel threaded rods (class 8.8 strength)
Quantity	5 units
Unit Price	3.00€
Purchase Link	https://www.amazon.com.be/-/en/Threaded-M10-1000-strength-class/dp/B0C621LBT7
Total Price	14.99€ (VAT incl.)

Threaded Screw Hook

Name	PRIOstahl M5 Threaded Hooks
Description	Stainless steel screw eyelets that can function as a hook to attach weights
Dimensions	M5 thread X 20mm length
Purchase Link	https://www.amazon.com.be/-/en/PRIOstahl-Screws...
Total Price	0.75€ (VAT incl.)

Nuts and Bolts

Name	Barcelona M5 Screw Set
Description	Galvanized nuts and bolts kit
Dimensions	M5 thread X 20mm length
Purchase Link	https://www.amazon.com.be/-/en/Barcelona-Screws-Galvanised-Service-Machine/dp/BOB613Y2YB
Total Price	9.47€ (VAT incl.)

Total Material Cost of the Syringe-based pump: 48.44€

C.2 Manufacturing Costs

Laser Cutting (Wooden Plates)

Material	Wooden 4mm thick plate
Description	Laser-cutting for structural components
Location	Makilab
Time Required	1 hour
Total Price	10.00€ (VAT incl.)

Total Prototyping Cost for the Syringe-based Pump: 58.44€

Appendix D

Bill of Materials for Electromechanical Prototype

This Bill of Materials (BOM) provides a detailed breakdown of the components required for the fabrication of the open-source medical aspirator prototype. The components are categorized into three main sections: vacuum circuit components, electrical circuit components, and manufacturing costs. Each component includes details such as description, dimensions, performance specifications, purchase links, and total price.

D.1 Vacuum Circuit Components

Mechanical Vacuum Regulator

Name	Vvikizy Pneumatic Vacuum Regulator
Description	Precision pressure regulating valve for vacuum applications.
Pressure Range	-100 to 1.3 kPa
Dimensions	19 × 14 × 5 cm
Connection Type	Standard pneumatic fittings
Application	Industrial and laboratory vacuum systems
Purchase Link	https://www.amazon.com.be/-/en/Pneumatic-Vacuum-Regulator-Pressure-Re..
Total Price	31.99€ (VAT incl.)

APPENDIX D. BILL OF MATERIALS FOR ELECTROMECHANICAL PROTOTYPE

Vacuum Pump

Name	DEWIN Mini Pompe
Description	Micro Electric vacuum pump is made of high quality aluminum and plastic.
Performance	Max Flow Rate: 3.6 l/min, Max Vacuum: -420mmHg
Dimensions	13.8 x 8 x 2 cm.
Weight	40 g
Power Consumption	16 to 30 W
Voltage	12V DC
Purchase Link	https://www.amazon.fr/dp/B07DVBQJCR?ref=cm_sw_r_cso_cp_apin_dp_J7851HKF26GWE9Z3E2XX&ref_=cm_sw_r_cso_cp_apin_dp_J7851HKF26GWE9Z3E2XX&social_share=cm_sw_r_cso_cp_apin_dp_J7851HKF26GWE9Z3E2XX
Total Price	8.09€ (VAT incl.)

Tubing

Name	SenTECH Silicone Tube
Description	Transparent tubing for gases and fluids.
Dimensions	6 mm (internal), 8 mm (external), 2 m length
Material	Silicone
Weight	60 g
Purchase Link	https://www.amazon.com.be/Silicone-Flexible-%C3%A9paisseur-Tuyau-m%C3%A8tre/dp/B07MZ6QN89?th=1
Total Price	12€ (VAT incl.)

APPENDIX D. BILL OF MATERIALS FOR ELECTROMECHANICAL PROTOTYPE

Collection Container

Name	Flacon Collect pour AS-100 et AS-36BR
Description	1L volume capacity with 100 mL graduation and stop-valve.
Inlet Port Diameter	9 mm
Purchase Link	https://nmmedical.be/products/flacon-collect-1l-pour-as-100-et-as-36br?variant=42473603760239
Total Price	35.50€ (VAT incl.)

Vacuum Connectors

Name	FCK 6 MSV T-connector
Description	Nickel-plated brass connector for vacuum circuits.
Dimensions	8x6 mm (left/right/median)
Operating Pressure	-0.99 to 10 bar
Unit Price	4.66€ (VAT incl)
Quantity	4
Purchase Link	https://www.landefeld.com/artikel/fr/raccord-a-vis-en-t-8x6-8x6mm-laiton-nickele/FCK%206%20MSV
Total Price	18.64€ (VAT incl.)

APPENDIX D. BILL OF MATERIALS FOR ELECTROMECHANICAL PROTOTYPE

Manometer

Name	WIKA Dial Pressure Gauge
Description	Displays vacuum pressure in bar and inHg.
Pressure Range	0 to -1 bar (0 to -30 inHg)
Dimensions	62 mm diameter, 80 mm thickness
Purchase Link	https://befr.rs-online.com/web/p/pressure-gauges/4055616
Total Price	18.55€ (VAT incl.)

On/Off Valve

Name	Festo HE-3-QS-6 Pneumatic Valve
Description	Manual shut-off valve with 3/2 bistable actuation.
Nominal Flow Rate	390 l/min
Operating Pressure	-0.95 to 10 bar
Purchase Link	https://befr.rs-online.com/web/p/pneumatic-function-fittings/1366516
Total Price	21.51€ (VAT incl.)

Pressure Transducer

Name	XGZP6847A100KPGN Pressure Sensor
Description	Analog output pressure sensor for vacuum applications.
Pressure Range	-100kPa to 0kPa (-14.5PSI to 0PSI)
Connection	3mm tube male connector
Output	0.5V to 4.5V analog
Purchase Link	https://www.digikey.be/en/products/detail/cfsensor/XGZP6847A100KPGN/22530765
Total Price	7.66€ (VAT incl.)

D.2 Electrical Circuit Components

Microcontroller

Name	Arduino Nano
Description	5V microcontroller for system control.
Dimensions	5 x 5 mm
Input Voltage	7-12V
Purchase Link	https://store.arduino.cc/en-be/products/arduino-nano
Total Price	26.62€ (VAT incl.)

Relay

Name	Omron G5RL-1E-HR DC5
Description	SPDT relay for switching high-current loads
Dimensions	10.16 × 4.7 × 8.89 mm
Coil Voltage	5V DC
Rated Load	12A at 24V DC
Purchase Link	https://be.farnell.com/en-BE/omron/g5rl-1e-hr-5dc..
Total Price	5.57€ (VAT excl.)

Power Supply Unit

Name	LC575US12 AC/DC Converter
Description	12V, 6A power supply for the system.
Dimensions	99 x 97 x 30 mm
Power	72W
Purchase Link	https://www.digikey.be/en/products/detail/xp-power/LC575US12/13618417
Total Price	11.19€ (VAT incl.)

APPENDIX D. BILL OF MATERIALS FOR ELECTROMECHANICAL PROTOTYPE

LCD Screen

Name	Waveshare LCD1602 I2C Module
Description	16x2 character display with I2C interface.
Screen Dimensions	64.5 x 16 mm
Input Voltage	3-5V
Purchase Link	https://eu.robotshop.com/fr/products/mod...
Total Price	9.21€ (VAT incl.)

Main Switch

Name	SWITCH ROCKER SPST 15A 250V H8800VAAAB
Description	Rocker Switch for power supply with Panel Mount and Snap-In Design.
Dimensions	10.16 x 4.7 x 8.89 mm
Rated Load	12 A at 24V DC
Purchase Link	https://www.digikey.be/fr/products/detail/bulgin/H8800VAAAB/9598452
Total Price	2.05€ (VAT incl.)

LEDs (Assorted)

Name	Kingbright2 L-53GD LED
Description	Standard LEDs for status indication with a 5mm Through Hole mounting.
Unit Price	0.24€ (VAT incl.)
Quantity	3
Purchase Link	https://befr.rs-online.com/web/p/leds/2286004?gb=b
Total Price	0.72€ (VAT incl.)

APPENDIX D. BILL OF MATERIALS FOR ELECTROMECHANICAL PROTOTYPE

Set Pressure Switch

Name	RS Pro PB Switch Off-Mom SPDT Snap Solder
Description	Push button for pressure control input with snap panel mounting.
Purchase Link	https://fr.rs-online.com/web/p/boutons-poussoirs/1444357
Total Price	1.79€ (VAT incl.)

Transistor NPN

Name	BC549BTA NPN Transistor
Description	General-purpose NPN transistor.
Purchase Link	https://www.digikey.be/fr/products/detail/onsemi/BC549BTA/975557
Total Price	0.33€ (VAT incl.)

Diode

Name	Diode 1N4148TR
Description	Fast switching diode.
Purchase Link	https://www.digikey.be/fr/products/detail/onsemi/1N4148TR/458811
Total Price	0.11€ (VAT excl.)

Resistors (Assorted Values)

Name	Resistors CF18JT220R
Needed Values	220 Ω (x3), 1k Ω (x1), 10k Ω (x1), 20k Ω (x1).
Purchase Link	https://www.digikey.be/fr/products/detail/stackpole-electronics-inc/CF18JT220R/1741639
Total Price	0.65€ (VAT incl.)

D.3 Manufacturing Costs

3D Printing (PLA Material)

Name	PLA Filament
Description	330g of PLA for 3D-printed parts.
Price per Kg	26€/kg
Total Price	6.77€ (VAT excl.)

Laser Cutting (Plexiglas Plate)

Material	Plexiglas Plate
Description	Laser-cutting for structural components
Location	Makilab
Time Required	<30 minutes
Total Price	10.00€ (VAT incl.)

Total Prototype Cost (VAT incl.) = 228.95€

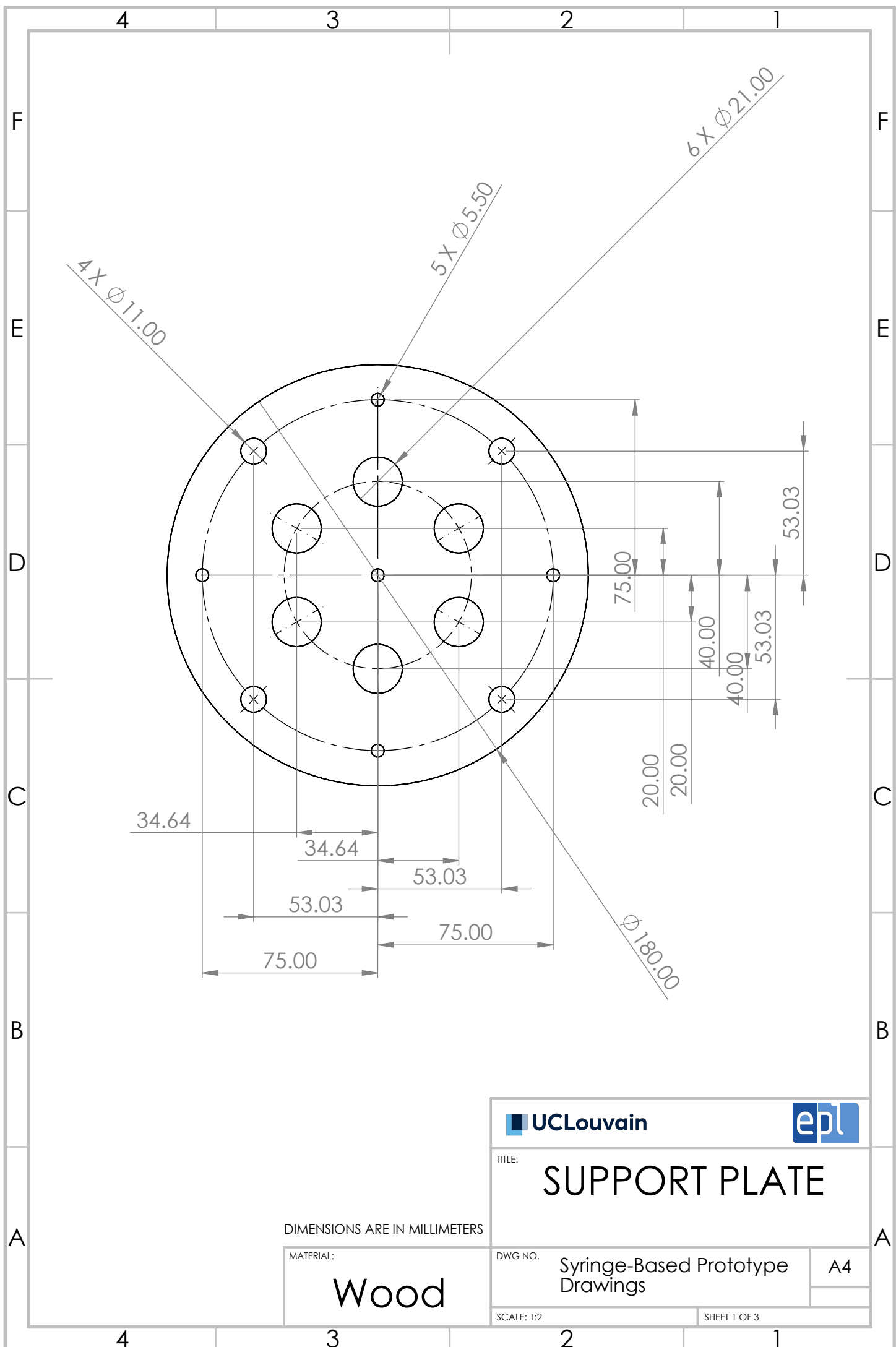
Appendix E

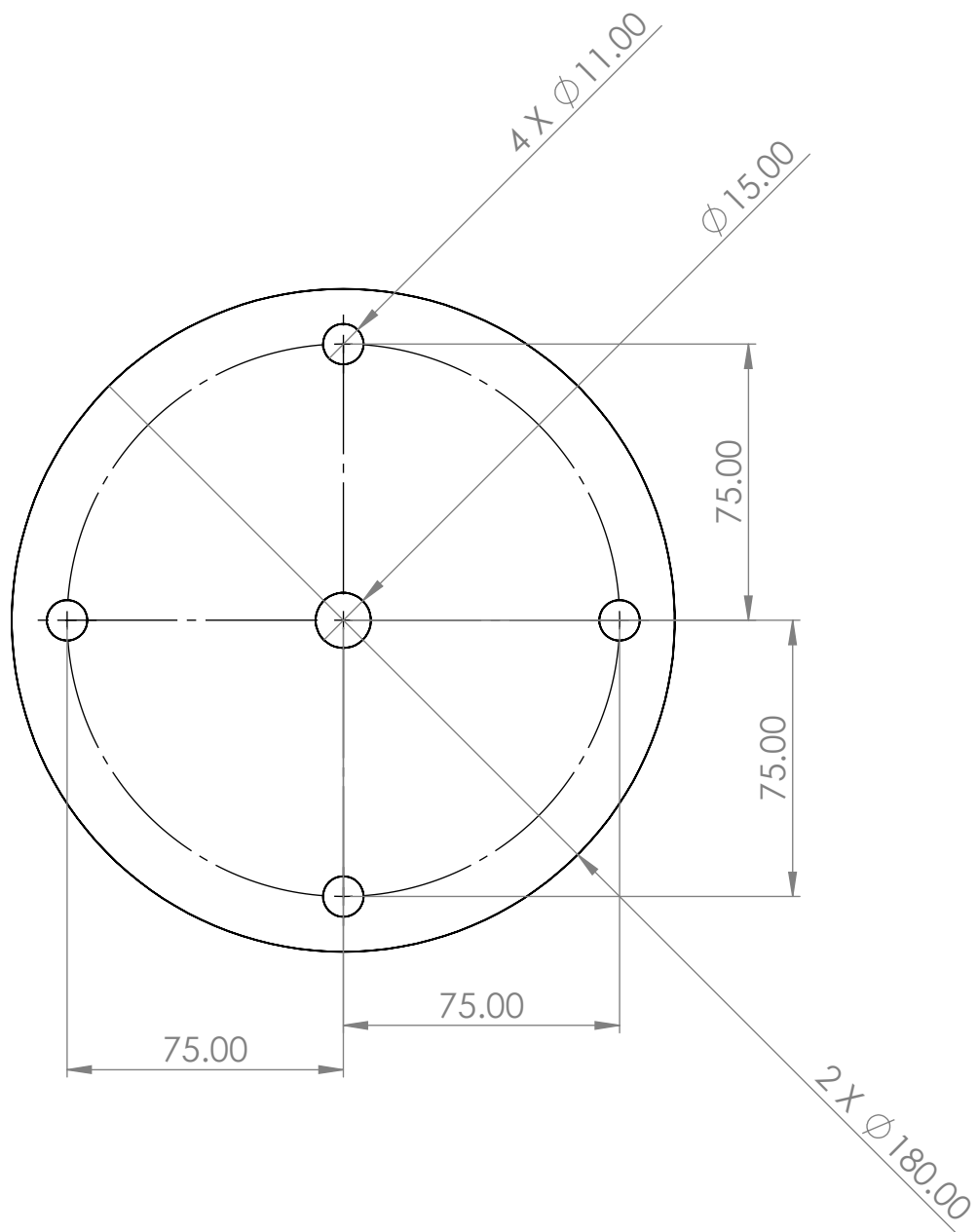
Technical Drawings of the Syringe-Based Vacuum Pump

This appendix presents the technical drawings (top view) used for the fabrication of the syringe-based vacuum pump prototype. These drawings were primarily created for laser cutting but are also suitable for manual fabrication in low-resource settings. All components were manufactured from wood.

The following components are included:

1. Support plate (2 units)
2. Outlet plate
3. Plunger plate





DIMENSIONS ARE IN MILLIMETERS

MATERIAL:

Wood

UCLouvain

epl

TITLE:

OUTLET PLATE

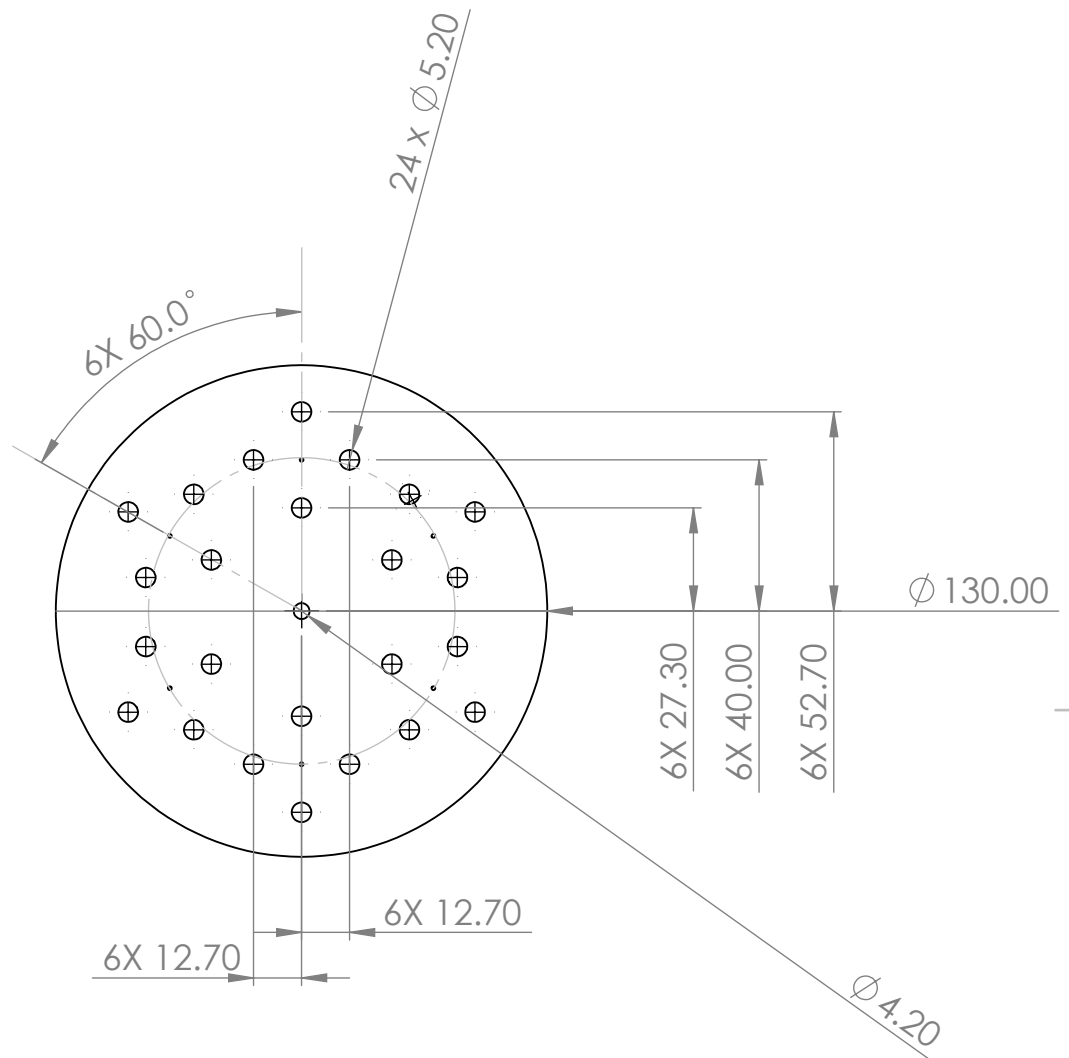
DWG NO.

Syringe-Based Prototype
Drawings

A4

SCALE: 1:2

SHEET 2 OF 3



DIMENSIONS ARE IN MILLIMETERS

MATERIAL:

Wood

UCLouvain

epl

TITLE:

PLUNGER PLATE

DWG NO.

Syringe-Based Prototype
Drawings

A4

SCALE: 1:2

SHEET 3 OF 3

Appendix F

Arduino Code for the Electromechanical Prototype

```
1
2
3 /*=====
4  *   Arduino code of the open-source Negative Pressure Wound Therapy
      (NPWT) Device
5
6  *   Created by SHIMWA MUHIRE Beni
7  *   April 2025
8  *
9  *   Note: This code was adapted from the Master thesis work of
      Mayssem HADJILI
10  *   and Lucile HEINEN [https://hdl.handle.net/2078.1/thesis:43342]
11  *   The calibration function is taken from the open-source
12  *   negative wound plate code [https://doi.org/10.3390/jcm11185417]
13  *   =====*/
14
15 #include <Wire.h>
16 #include <Waveshare_LCD1602_RGB.h>
17
18 Waveshare_LCD1602_RGB lcd(16, 2); // 16 characters and 2 lines of
      show
19 int r, g, b, t = 0;
20
21 #define PRESSURE_SENSOR A3 // Pressure transducer in analog pin A3
22 #define LED_ALARM 7        // LED alarm in digital pin 7
23 #define LED_BUTTON 5       // LED button in digital pin 5
24 #define RELAY A0           // Relay in analog pin A0
25 #define SET_PRESSURE 3     // set pressure button in digital pin 3
26 #define LEVEL A1          // Level sensor in analog pin A1
27
28 #define SAMPLING_TIME 10 // Sampling time (in ms)
29
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
30 #define T_ON 7000 // ON time for inter. hybrid time-pressure and
    for inter. time cycle (in ms)
31 #define T_OFF 2000 // OFF time for inter. hybrid time-pressure
    and for inter. time cycle (in ms)
32
33 #define MIN_PRESSURE_COEF 0.08 // % of the setpoint pressure (
    P_working) under which to restart the pump in the 'inter_hybrid
    ' & 'inter_two_step' mode
34 #define MAX_PRESSURE_COEF 0.08 // % of the setpoint pressure (
    P_working) above which to cut off the pump in the '
    inter_two_step' mode
35
36 #define SECURITY_PRESSURE_COEF 0.5 // % of the setpoint pressure (
    P_working) under/above which to raise an alarm
37
38 #define DISPLAY_UNIT 1 // 0 = bar ; 1 = mmHg
39
40 // ===== Global variables =====
41
42 // Pressure transducer related
43 unsigned long t0, t1, t2;
44 int sample_pressure[25]; // to perform the calibration
45 double totalpress = 0, corrected_pressure, zero, samplezero,
    totalzero = 0;
46 char pressure_init_string[5], P_sensor_string[5], P_working_string
    [5], pmaxstring[4], pminstring[4], T1mstring[3], T2mstring[3];
    // for printing to the lcd screen
47
48 float corrected_pressure_init; // pressure befor setpoint
    selection with the regulator [mmHg]
49 float corrected_pressure_init_bar; // pressure befor setpoint
    selection with the regulator [bar]
50
51 float P_sensor; // Measured pressure from sensor in mmHg
52 float P_sensor_bar; // Measured pressure from sensor in bar
53 float P_working; // Setpoint pressure chosen by the user in
    mmHg
54 float P_working_bar; // Setpoint pressure chosen by the user in
    bar
55
56 // Operating mode
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
57 bool motor_on = false;
58
59 // Alarm
60 bool alarm_stop = false; // variable to true once the Too High
    Vacuum alarm is triggered
61 bool alarm_led = false; // variable to true once the Too Low
    Vacuum alarm is triggered
62
63 // Level sensor
64 bool bottle_full = false; // variable to true once the collector
    container is full
65
66 // ===== Functions =====
67
68 void setup()
69 {
70
71     pinMode(LED_ALARM, OUTPUT);           // LED alarm as output
72     pinMode(LED_BUTTON, OUTPUT);          // LED button as output
73     pinMode(RELAY, OUTPUT);                // RELAY as output
74     pinMode(SET_PRESSURE, INPUT_PULLUP);  // SET_PRESSURE button as
        input
75     pinMode(LEVEL, INPUT);                // LEVEL as input
76
77     analogWrite(RELAY, 0);                // switch off the vacuum pump
    to guarantee zero pressure
78     digitalWrite(LED_ALARM, LOW);         // Turn off the LED alarm
79     digitalWrite(LED_BUTTON, LOW);        // Turn off the LED button
80
81     lcd.init();
82     r = 160; // Change color if needed
83     g = 150;
84     b = 205;
85     lcd.setRGB(r, g, b);
86
87     lcd.setCursor(0, 0);
88     lcd.send_string("Welcome to the");
89     lcd.setCursor(0, 1);
90     lcd.send_string("OS NPWT");
91     delay(5000); // 5s delay to guarantee zero pressure
92     lcd.clear();
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
93
94     calibration(); // Launch of the calibration process
95     lcd.setCursor(0, 0);
96
97     // Pressure selection procedure:
98     lcd.send_string("Pressure Select.");
99     delay(3000);
100
101     lcd.clear();
102
103     // Switch ON the vacuum pump:
104     analogWrite(RELAY, 255); // Pump ON : PIN = RELAY
105     motor_on = true;
106     long t_test = millis();
107
108     // Wait till the user set the working pressure
109     bool not_pressed = true;
110     digitalWrite(LED_BUTTON, 1); // Switch ON the LED button to
111     start the pressure set up
112     while (not_pressed)
113     {
114         corrected_pressure_init = abs(voltage_to_pressure(
115         analogRead(PRESSURE_SENSOR) - zero));
116         // conversion of pressure from mmHg to bar:
117         corrected_pressure_init_bar = mmHg_to_bar(
118         corrected_pressure_init);
119
120         if (DISPLAY_UNIT == 0)
121         {
122             dtostrf(corrected_pressure_init_bar, 2, 3,
123             pressure_init_string); // convert to string for display [bar]
124             lcd.setCursor(0, 1);
125             lcd.send_string("P:      bar");
126             lcd.setCursor(3, 1);
127             lcd.send_string(pressure_init_string);
128         }
129         else
130         {
131             dtostrf(corrected_pressure_init, 3, 1,
132             pressure_init_string); // convert to string for display [mmHg]
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
129         lcd.setCursor(0, 1);
130         lcd.send_string("P:          mmHg");
131         lcd.setCursor(3, 1);
132         lcd.send_string(pressure_init_string);
133     }
134
135     if (millis() - t_test > 120000)
136     { // > 2 minute
137         lcd.setCursor(0, 0);
138         lcd.send_string("You forgot to");
139         lcd.setCursor(0, 1);
140         lcd.send_string("set the pressure");
141     }
142     if (digitalRead(SET_PRESSURE) == LOW)
143     { // if button pressed
144         not_pressed = false;
145     }
146 }
147 digitalWrite(LED_BUTTON, 0); // Switch off the LED button
148 lcd.clear();
149
150 // once pressure has been set: store it in the variable
151 P_working
152 corrected_pressure = analogRead(PRESSURE_SENSOR) - zero; //
153 zero deviations correction
154
155 P_working = abs(voltage_to_pressure(corrected_pressure)); //
156 conversion of pressure to mmHg
157 P_working_bar = mmHg_to_bar(P_working); //
158 conversion of pressure to BAR
159
160 lcd.setCursor(0, 0);
161 lcd.send_string("Press. selected:");
162 lcd.setCursor(0, 1);
163
164 if (DISPLAY_UNIT == 0)
165 {
166     dtostrf(P_working_bar, 2, 3, P_working_string); // convert
167     to string for display
168     lcd.setCursor(0, 1);
169     lcd.send_string("          bar");
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
165     lcd.setCursor(0, 1);
166     lcd.send_string(P_working_string); // in bar
167 }
168 else
169 {
170     dtostrf(P_working, 3, 1, P_working_string); // convert to
string for display
171     lcd.setCursor(0, 1);
172     lcd.send_string("          mmHg");
173     lcd.setCursor(0, 1);
174     lcd.send_string(P_working_string); // in mmHg
175 }
176
177 // Correction of 0.03 bar (--> stabilised vacuum level)
178 P_working_bar = P_working_bar - 0.03;
179 P_working = P_working - 22.5; // 0.03bar = 22.5 mmHg
180
181 delay(3000);
182
183 lcd.clear();
184
185 t0 = millis(); // time for the timestep
186 }
187
188 void loop()
189 {
190
191     // measure current pressure:
192     corrected_pressure = analogRead(PRESSURE_SENSOR) - zero; //
zero deviations correction
193     P_sensor = abs(voltage_to_pressure(corrected_pressure)); //
voltage to pressure conversion [mmHg]
194     P_sensor_bar = mmHg_to_bar(P_sensor); //
pressure conversion to bar
195
196     if (DISPLAY_UNIT == 0)
197     {
198         dtostrf(P_sensor_bar, 2, 3, P_sensor_string);
199         lcd.setCursor(0, 1);
200         lcd.send_string("P:          bar");
201         lcd.setCursor(3, 1);
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
202     lcd.send_string(P_sensor_string);
203 }
204 else
205 {
206     dtostrf(P_sensor, 3, 1, P_sensor_string);
207     lcd.setCursor(0, 1);
208     lcd.send_string("P:          mmHg");
209     lcd.setCursor(3, 1);
210     lcd.send_string(P_sensor_string);
211 }
212
213 // test if raise alarm or not:
214 // alarm();
215
216 // test if the bottle is not full:
217 // level_sensor();
218 }
219
220 /*=====
221 *    CALIBRATION
222 *=====*/
223
224 /* Calibration of the pressure transducer to compute 'zero'
225    pressure (at atm pressure).
226 * Store it in the 'zero' variable */
227 void calibration()
228 {
229
230     int i;
231     for (i = 0; i < 24; i++)
232     {
233         sample_pressure[i] = 0;
234     } // array initialization
235     lcd.clear();
236     lcd.setCursor(0, 0);
237     lcd.send_string("Calibrating zero");
238     lcd.setCursor(0, 1);
239
240     for (i = 0; i < 91; i++)
241     { // record every 50ms pressure value for a total time of 4.5s
242         and accumulates the sum in totalzero variable
```


APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
241
242     if (i == 0 || i == 6 || i == 12 || i == 18 || i == 24 || i
    == 30 || i == 36 || i == 42 || i == 48 || i == 54 || i == 60
    || i == 66 || i == 72 || i == 78 || i == 84 || i == 90)
243     { // writes * every 300ms in the LCD
244         lcd.setCursor(i / 6, 1);
245         lcd.send_string(".");
246     }
247
248     samplezero = analogRead(PRESSURE_SENSOR); // readings of
    pressure sensor
249     totalzero = totalzero + samplezero;        // recordings
    accumulated
250     delay(50);
251 }
252
253 zero = totalzero / i; // recording averaging to have real zero
    calculated
254 if (DISPLAY_UNIT == 0)
255 {
256     lcd.setCursor(0, 1);
257     lcd.send_string("P:      bar");
258 }
259 else
260 {
261     lcd.setCursor(0, 1);
262     lcd.send_string("P:      mmHg");
263 }
264
265 // -----
266 // Verification that zero pressure correction is OK (<5mmhg)
267 // If not, gives an error and restarts
268 // -----
269
270 for (i = 0; i < 50; i++)
271 {
272
273     corrected_pressure = analogRead(PRESSURE_SENSOR) - zero;
    // zero deviations correction
274     P_sensor = abs(voltage_to_pressure(corrected_pressure));
    // conversion of pressure to mmHg
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
275     P_sensor_bar = mmHg_to_bar(P_sensor);
276     // conversion of pressure to bar
277
278     if (DISPLAY_UNIT == 0)
279     {
280         dtostrf(P_sensor_bar, 2, 3, P_sensor_string);
281     }
282     else
283     {
284         dtostrf(P_sensor, 3, 1, P_sensor_string);
285     }
286     lcd.setCursor(3, 1);
287     lcd.send_string(P_sensor_string);
288
289     delay(30);
290
291     if (P_sensor > 5)
292     { // calibration error (>5mmHg)
293
294         lcd.setCursor(0, 0);
295         lcd.send_string("Calibration err.");
296         lcd.setCursor(0, 1);
297         lcd.send_string(" ");
298         lcd.setCursor(4, 1);
299         lcd.send_string(P_sensor_string);
300         delay(2000);
301         lcd.setCursor(0, 1);
302         lcd.send_string("Restart software");
303         delay(2000); // 2s
304         totalzero = 0;
305         lcd.clear();
306         setup(); // RESTART
307     }
308
309     // if calibration ok
310     lcd.setCursor(0, 0);
311     lcd.send_string(" Calibration OK ");
312
313     delay(2000); // 2s
314     lcd.clear();
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
315 }
316
317 /*=====
318 *    PRESSURE TRANSDUCER RELATED FUNCTION
319 *=====*/
320
321 float voltage_to_pressure(float pressure_measured)
322 {
323     float sensitivity = -188.5; // sensitivity of the pressure
324     sensor (mmHg/V)
325     float voltage = pressure_measured * 5 / 1024;
326     return (voltage * sensitivity);
327 }
328
329 /*=====
330 *    PRESSURE CONVERSION FROM mmHg TO bar
331 *=====*/
332
333 float mmHg_to_bar(float pressure_mmHg)
334 {
335     return pressure_mmHg * 0.00133322; // pressure in [bar]
336 }
337
338 /*=====
339 *    Level Sensor Function
340 *=====*/
341
342 void level_sensor()
343 {
344     int level_sensor = analogRead(LEVEL);
345
346     if (level_sensor > 450)
347     {
348         analogWrite(RELAY, 0); // switch off the motor
349         motor_on = false;
350         alarm_stop = true;
351         digitalWrite(LED_ALARM, HIGH);
352         lcd.setCursor(0, 0);
353         lcd.send_string("Bottle Full");
354         lcd.setCursor(0, 1);
355         lcd.send_string("Pump stop");
356     }
357 }
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
355         delay(1000);
356     }
357 }
358
359 /*=====
360 *    ALARM
361 *=====*/
362
363 /* if pressur < x% (SECURITY_PRESSURE_COEF) of the working one, or
   other trouble: light up a red LED !*/
364 void alarm()
365 {
366     // TROUBLE 1: Too Low Vacuum:
367     if (P_sensor < P_working * (1 - SECURITY_PRESSURE_COEF))
368     { // (NB: Relative pressure)
369         digitalWrite(LED_ALARM, HIGH);
370         alarm_led = true;
371         lcd.setCursor(0, 0);
372         lcd.send_string("Press. to low!");
373     }
374
375     // if too low vacuum triggered
376     if (alarm_led)
377     {
378         if (P_sensor > P_working * (1 - SECURITY_PRESSURE_COEF))
379         {
380             // system returned to normal condition
381             alarm_led = false;
382             digitalWrite(LED_ALARM, 0);
383             lcd.clear();
384         }
385     }
386     //=====
387
388     // TROUBLE 2: Too High Vacuum:
389     if (P_sensor > P_working * (1 + SECURITY_PRESSURE_COEF))
390     {
391         analogWrite(RELAY, 0); // switch of the motor
392         motor_on = false;
393         alarm_stop = true;
394         digitalWrite(LED_ALARM, HIGH);
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
395     lcd.setCursor(0, 0);
396     lcd.send_string("Press. to high!");
397     lcd.setCursor(0, 1);
398     lcd.send_string("Pump stop");
399     delay(1000);
400
401     // Loop and block the system until the vacuum level lowers
402     AND the user push the button:
403     while (!((digitalRead(SET_PRESSURE) == LOW) && (P_sensor <
404     P_working * (1 + SECURITY_PRESSURE_COEF))))
405     {
406         corrected_pressure = analogRead(PRESSURE_SENSOR) -
407         zero; // zero deviations correction
408         P_sensor = abs(voltage_to_pressure(corrected_pressure)
409         ); // conversion of pressure to mmHg
410         P_sensor_bar = mmHg_to_bar(P_sensor);
411         // conversion of pressure to bar
412
413         if (DISPLAY_UNIT == 0)
414         {
415             dtostrf(P_sensor_bar, 2, 3, P_sensor_string);
416             lcd.setCursor(0, 1);
417             lcd.send_string("Press.:      bar");
418             lcd.setCursor(7, 1);
419             lcd.send_string(P_sensor_string);
420         }
421         else
422         {
423             dtostrf(P_sensor, 3, 1, P_sensor_string);
424             lcd.setCursor(0, 1);
425             lcd.send_string("Press:      mmHg");
426             lcd.setCursor(7, 1);
427             lcd.send_string(P_sensor_string);
428         }
429
430         // if the pressur lowers and become under the max
431         security threshold:
432         if (P_sensor < P_working * (1 + SECURITY_PRESSURE_COEF
433         ))
434         {
435             digitalWrite(LED_BUTTON, HIGH);
```

APPENDIX F. ARDUINO CODE FOR THE ELECTROMECHANICAL PROTOTYPE

```
429         lcd.setCursor(0, 0);
430         lcd.send_string("Press. corrected");
431     }
432 }
433
434     // Switch ON the pump and "restart" the system (back to
loop() function):
435     alarm_stop = false;
436     digitalWrite(RELAY, 255);
437     motor_on = true;
438     digitalWrite(LED_ALARM, LOW);
439     digitalWrite(LED_BUTTON, LOW);
440     lcd.clear();
441     loop();
442 }
443 }
```

Listing F.1: Arduino for the Electromechanical NPWT Prototype

Appendix G

Risk Analysis

Conducting a risk analysis on NPWT devices is crucial to ensure patient safety and regulatory compliance, particularly in low-resource settings. By identifying potential hazards, assessing their impact, and implementing mitigation strategies, this analysis helps preemptively address risks, enhance device reliability, and maintain healthcare quality standards.

Section G.1 introduces the methodology and standards employed in the risk assessment. Section G.2 presents the outcomes of the risk analysis for both mechanical and electromechanical prototypes.

G.1 Risk Management Process

The risk analysis was conducted in accordance with ISO 14971 [64], the international standard for medical device risk management. This standard provides a framework for identifying, analyzing, evaluating, and mitigating risks throughout the entire life cycle of a medical device.

To assess risk severity, we employed a criticality index method similar to that used in Matrix Requirements [80], a leading platform for medical device software. This method combines three factors:

- Occurrence probability (P): scales from 1 (almost never) to 5 (always)
- Harm probability (H): scales from 1 (not likely) to 3 (very likely)
- Severity of harm (S): scales from 1 (negligible) to 5 (fatal)

The criticality index is calculated as:

$$C = P \times H \times S \tag{G.1}$$

Risk levels are categorized as follows:

- $C > 35$: very high risk (consign equipment)
- $20 < C \leq 35$: substantial risk requiring correction
- $C \leq 20$: potentially acceptable risk

The following analysis focuses on potential hazards inherent in NPWT device usage, considering both mechanical and electromechanical prototypes. Each risk is stated, followed by its criticality index calculation. Mitigation solutions are then described, including those implemented in the prototypes and proposed future improvements.

G.2 Risk Analysis Output

Eight potential risks associated with the NPWT device operation were systematically identified and analyzed. These risks were organized into five main groups:

1. Pressure-related risks
2. Misuse risks
3. Contamination risks
4. Component damage risks
5. Environmental risks

G.2.1 Pressure-Related Risks

Pressure-related risks are associated with the negative pressure maintained during wound therapy, which is critical for the device's effectiveness in promoting healing. If not properly managed, these risks can compromise patient safety and hinder the healing process.

G.2.1.1 Excessive Negative Pressure

Hazard and Harm: Applying too much negative pressure can damage healthy tissue, cause pain, and restrict blood flow around the wound. This risk arises if the vacuum level exceeds safe therapeutic limits (typically above 125–200 mmHg), potentially leading to serious complications [81].

Criticality Index: Excessive Negative Pressure

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	3 (occasional)	2 (not often)	1 (almost never)
Harm probability	2 (probable)	2 (probable)	2 (probable)
Severity	4 (serious injury)	4 (serious injury)	4 (serious injury)
Criticality index	24	16	8

Mitigation Solution: The electromechanical prototype is equipped with a pressure sensor that continuously monitors vacuum levels. If the pressure rises more than 10% above the safe threshold of 125 mmHg, the system triggers an alarm and automatically shuts off the pump. In mechanical designs, the use of calibrated weights helps ensure that pressure remains within the therapeutic range, preventing accidental over-suction. Additionally, a manometer can be integrated to provide a visual indication of the applied pressure.

G.2.1.2 Insufficient Negative Pressure

Hazard and Harm: Insufficient negative pressure can compromise therapy by failing to remove wound exudate effectively, leading to delayed healing and increased risk of infection. This typically occurs when the pressure drops below the therapeutic threshold, reducing the mechanical contraction needed to support tissue regeneration and drainage [81].

Criticality Index: Insufficient Negative Pressure

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	3 (occasional)	3 (occasional)	2 (not often)
Harm probability	1 (not likely)	1 (not likely)	1 (not likely)
Severity	3 (moderate injury)	3 (moderate injury)	3 (moderate injury)
Criticality index	9	9	6

Mitigation Solution: In the electromechanical prototype, visual and auditory indicators notify users when pressure falls below safe limits. Additionally, the system is designed to automatically adjust or halt operation in response to sustained low pressure. For mechanical systems, pressure must be checked regularly by caregivers to ensure it remains within the therapeutic range, with adjustments made as needed to restore adequate suction.

G.2.1.3 Pressure Fluctuations

Hazard and Harm: Pressure fluctuations, caused by issues such as leaks, inconsistent pump performance, or power interruptions, can disrupt the effectiveness of the NPWT therapy. These fluctuations may lead to reduced therapeutic benefits, potentially causing discomfort for the patient or ineffective wound treatment [81].

Criticality Index: Pressure Fluctuations

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	3 (occasional)	3 (occasional)	2 (not often)
Harm probability	1 (not likely)	1 (not likely)	1 (not likely)
Severity	2 (minor injury)	2 (minor injury)	2 (minor injury)
Criticality index	6	6	4

Mitigation Solution: To minimize pressure fluctuations, it is recommended to use improved sealing methods, such as double-layer adhesive drapes, and to regularly inspect the wound interface for potential air leaks. For the electromechanical prototype, incorporating a rechargeable battery can help maintain consistent pressure during brief power outages, ensuring continuous therapy.

G.2.2 Misuse Risks

Misuse risks arise from improper handling or operation of the device, potentially leading to ineffective therapy or causing harm to the patient. Proper user training and adherence to guidelines are essential to mitigate these risks.

G.2.2.1 Incorrect Pressure Settings

Hazard and Harm: Incorrect pressure settings, whether too low or too high, can impair wound healing or cause tissue damage [81]. This risk is especially pronounced when users are not familiar with the specific requirements of the wound.

Criticality Index: Incorrect Pressure Settings

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	3 (occasional)	3 (occasional)	1 (almost never)
Harm probability	2 (probable)	2 (probable)	2 (probable)
Severity	3 (moderate injury)	3 (moderate injury)	3 (moderate injury)
Criticality index	18	18	6

Mitigation Solution: To mitigate this risk, predefined pressure settings tailored to various wound types should be implemented. For mechanical prototypes, weight-based presets could be introduced to ensure the application of safe pressure ranges for different therapeutic needs. Furthermore, a manometer can be integrated to provide a visual indication of the applied pressure.

G.2.3 Contamination Risks

Contamination risks are critical for infection control during NPWT therapy, as improper handling or inadequate sterilization of components can lead to cross-contamination between patients. Ensuring proper sterilization procedures and using single-use components are essential measures to prevent infection and safeguard patient health during treatment.

G.2.3.1 Patient Cross-Contamination

Hazard and Harm: If patient-contact components such as dressings, tubing, or canisters are reused without proper sterilization, there is a high risk of microbial transmission [93]. Pathogens from one patient can easily be transferred to another through residual fluids or via the pump system if protective barriers are not in place. This could lead to serious infections and compromise patient safety.

Criticality Index: Patient Cross-Contamination

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	2 (not often)	2 (not often)	1 (almost never)
Harm probability	3 (very likely)	3 (very likely)	3 (very likely)
Severity	5 (fatal)	5 (fatal)	5 (fatal)
Criticality index	30	30	15

Mitigation Solution: All components in contact with wound exudate are designed for single use. Reusable parts, such as the collection canister, are compatible with hospital sterilization procedures. After each use, the canister must be thoroughly sterilized, and wound tubing must be discarded. Additionally, a single-use microbial filter should be integrated between the canister and the pump tubing to prevent cross-contamination when reusing the pump.

G.2.4 Component Damage Risks

Component damage risks can compromise the functionality and durability of the NPWT device, potentially causing interruptions in therapy or reduced device effectiveness. Damage to key components such as the pump, tubing, or seals may result in system malfunctions, which could hinder the wound healing process and cause delays in patient care.

G.2.4.1 Pump Failure

Hazard and Harm: Pump failure can result in a complete loss of negative pressure, interrupting therapy. This interruption may delay wound healing and increase the risk of infection or wound deterioration, particularly in high-exudate or chronic wound cases [94].

Criticality Index: Pump Failure

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	3 (occasional)	3 (occasional)	2 (not often)
Harm probability	2 (probable)	2 (probable)	2 (probable)
Severity	2 (minor injury)	2 (minor injury)	2 (minor injury)
Criticality index	12	12	8

Mitigation Solution: The electromechanical prototype is equipped with an alarm system to notify users in case of pump malfunction. Additionally, the pump unit is low-cost (around 4 euros), making replacement easy and affordable. For mechanical designs, failure is minimized through the use of durable materials such as high-grade PVC and reinforced assemblies with wood, bolts, and nuts to enhance structural reliability and reduce breakdown risk. Furthermore, a manometer can be integrated to provide a visual indication of the applied pressure.

G.2.4.2 Tubing Blockage

Hazard and Harm: Blockages in the suction tubing, caused by coagulated exudate or tissue fragments, can impede fluid drainage, potentially leading to back pressure and bacterial growth [95].

Criticality Index: Tubing Blockage

Factors	PVC Pump	Syringe Pump	Electromechanical Pump
Occurrence	3 (occasional)	3 (occasional)	2 (not often)
Harm probability	2 (probable)	2 (probable)	2 (probable)
Severity	2 (minor injury)	2 (minor injury)	2 (minor injury)
Criticality index	12	12	8

Mitigation Solution: Larger tubing diameters and inline mesh filters will reduce the likelihood of blockages. The transparent design also allows for visual flow

monitoring, and disposable tubing sets should be regularly provided to replace the ones on the prototypes.

G.2.5 Environmental Risks

Environmental risks can significantly impact the performance and reliability of the NPWT device, particularly in regions with unstable or inconsistent power supplies. Power interruptions, extreme temperatures, or high humidity levels can disrupt therapy and compromise the device’s functionality, leading to potential delays in wound healing and patient safety concerns.

G.2.5.1 Power Supply Instability

Hazard and Harm: Inconsistent power supply may disrupt therapy, particularly in areas with frequent power cuts, leading to loss of therapy effectiveness and confusion among users [94].

Criticality Index: Power Supply Instability

Factors	Electromechanical Pump
Occurrence	4 (often)
Harm probability	2 (probable)
Severity	2 (minor injury)
Criticality index	16

Mitigation Solution: A rechargeable battery could be integrated into the electromechanical design to ensure continuous therapy in case of power failure or short-term power outages.

Appendix H

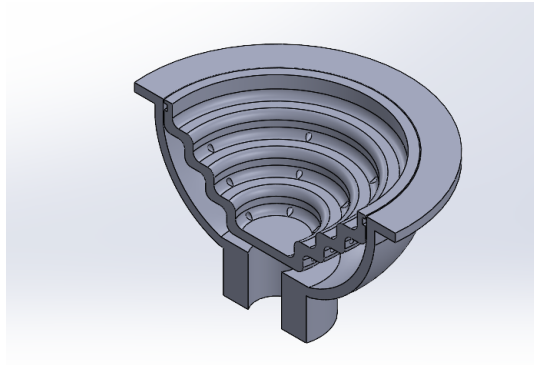
Wound Model Test Bench Design for NPWT Evaluation

To accurately assess the performance of the NPWT prototypes, a dedicated test bench was designed to simulate a realistic wound environment. This setup enabled controlled fluid introduction and pressure retention measurements, reflecting conditions encountered during actual wound therapy. The test bench incorporates a wound phantom, exudate infusion system, and a sealed collection reservoir, supporting reproducible and comparative testing across prototypes.

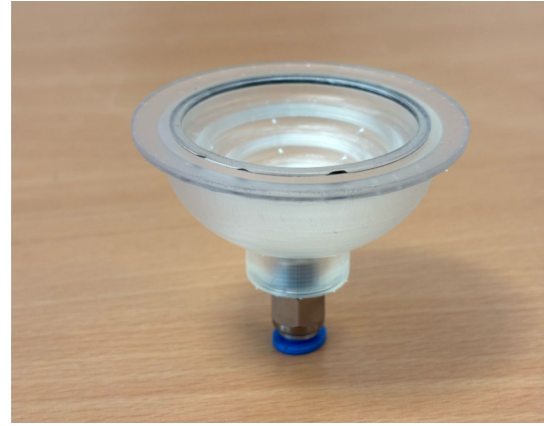
H.1 Design of the Wound Model

The test bench was designed to simulate a realistic wound environment, allowing for the controlled evaluation of NPWT performance. The design was modeled based on a wound phantom that was developed following a previously established methodology [96]. The wound model consisted of a truncated cone-shaped cavity with a diameter of 5 cm and a depth of 2 cm. To enhance realism, the wound model incorporated ribs to mimic the heterogeneous texture of wound surfaces. The wound was centered on a flat platform representing healthy skin, and the entire structure was 3D-printed using biocompatible resin to ensure durability and consistency in testing conditions (Figure H.1b).

A crucial element of this test is to simulate the presence of wound fluid in order to observe how the system maintains negative pressure under realistic conditions. To achieve this, the wound model was designed with small perforations that allow controlled injection of fluid into the dressing. Although previous studies used viscous synthetic exudate to better mimic wound conditions [57], water was used in this test setup for simplicity and consistency. While less representative of natural exudate viscosity, this approach still allowed evaluation of how well the system retains vacuum when fluid is introduced into the wound model.



(a) CAD section view of the wound model with the integrated exudate collection chamber.



(b) 3D-printed wound model prototype illustrating structural details.

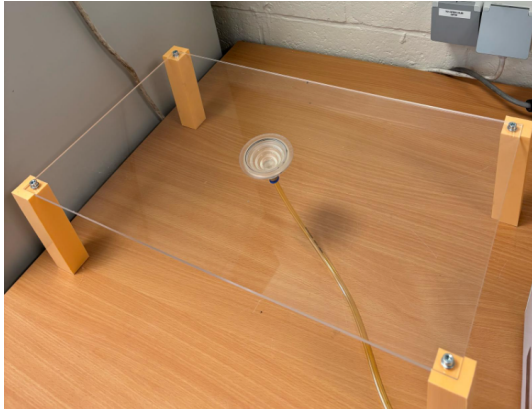
Figure H.1: Wound model design and realization

H.2 Reservoir and Exudate Infusion System

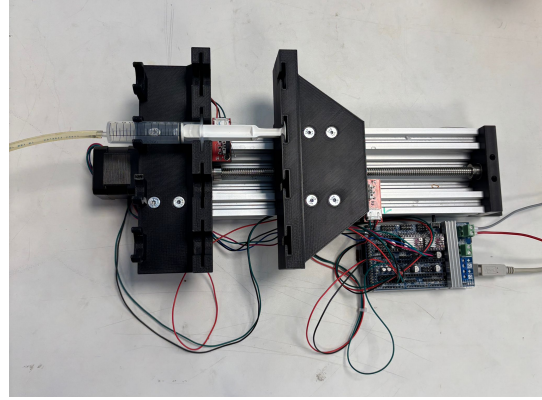
The wound model was enclosed within a semi-spherical reservoir that served as a collection chamber for the exudate ([Figure H.1a](#)). An O-ring was incorporated between the model and the reservoir to ensure a secure and airtight seal. The reservoir was equipped with an inlet hole through which fluid could be injected to simulate continuous exudate production during testing.

The entire wound model and reservoir assembly were mounted onto a support plaque with structural legs to provide stability and maintain proper alignment. To simulate exudate production, a modified perfusion system was developed using a syringe mounted on a motorized linear actuator. The actuator was driven by a stepper motor controlled via an Arduino circuit, allowing precise control of flow rate. The syringe infused water into the wound model at up to 3 mL/h, representing high exudate wounds [57]. The complete setup, including the wound assembly and the fluid delivery mechanism, is illustrated in [Figure H.2](#).

APPENDIX H. WOUND MODEL TEST BENCH DESIGN FOR NPWT EVALUATION



(a) Complete exudate test bench assembly showing integration of the wound model.



(b) Modified perfusion system with syringe actuator and Arduino-controlled motor.

Figure H.2: Negative pressure retention test bench and fluid infusion mechanism.

Glossary

angiogenesis Angiogenesis is the process by which new blood vessels form, allowing the delivery of oxygen and nutrients to the body's tissues. It is a vital function, required for growth and development as well as the healing of wounds. 13

cell migration In adult organisms, cell migration occurs during vital cellular processes such as tissue renewal and repair, wherein old or damaged cells are replaced by the migration of newly formed cells from the underlying tissue layers. 13

cell proliferation An increase in the number of cells as a result of cell growth and cell division. 12

Complications A complication in medicine, refers to a medical problem that occurs during a disease, or after a procedure or treatment. The complication may be caused by the disease, procedure, or treatment or may be unrelated to them. 14

Contraindications A contraindication is a specific situation in which a medicine, procedure, or surgery should not be used because it may be harmful to the person. 14

edema Edema is the medical term for swelling caused by fluid trapped in your body's tissues. 12

fibrin Fibrin is an insoluble protein that is produced in response to bleeding and is the major component of the blood clot [97]. 75

granulation tissue Granulation tissue, also known as granulation, is a type of tissue that forms during the healing process of a wound. It is characterized by the growth of small blood vessels and collagen fibers, which produce a pink, fleshy appearance. 12, 13

open-source Open-source software/system is a software/system that is released under a license in which the copyright holder grants users the rights to use, study, change, and distribute the software/system and its source code to anyone and for any purpose. 23, 26, 31

shear rate In physics, mechanics and other areas of science, shear rate is the rate at which a progressive shear strain is applied to some material, causing shearing to the material [\[84\]](#). 75

shear stress Shear stress (often denoted by τ) is the component of stress coplanar with a material cross section. It arises from the shear force, the component of force vector parallel to the material cross section [\[85\]](#). 75

wound bioburden Wound bioburden refers to all of the dimensions of wound microbiology believed to be important in the development of wound infection. These dimensions include microbial load, microbial diversity, and the presence of pathogenic organisms. 13

wound exudate Wound exudate is The fluid that is secreted from a wound during the healing process 12, 13, 26, 78

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