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Towards an open-source hardware and appropriable emergency hospital

Analysis and first prototype of a medical aspirator

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"Open-source hardware is more than just a technical approach. It's a philosophy that recognizes that collaboration and sharing are essential to creating technologies that improve people's lives."

David A. Mellis, co-founder of the Arduino project.

Abstract

We all remember the COVID-19 crisis, during which a significant number of patients urgently needed ventilators. However, the demand exceeded the available supply, leading to a shortage. Some individuals lost their lives not just due to the virus but also due to the lack of medical devices. This crisis unveiled healthcare system vulnerabilities and triggered the need to rethink medical devices. Open-source hardware emerged as a viable solution to this problem. It offers the availability of critical medical devices during crises, as well as enhancing healthcare accessibility and affordability in underserved regions of the world. In line with this approach, the non-profit organization Open MedTech was established, focusing on developing open-source medical devices. This study contributes to Open MedTech's mission by presenting the conception of a first prototype for an open-source medical aspirator (also called medical suction pump). This device was chosen following a selection methodology to establish a list of the priority medical devices. The medical aspirator, a vital emergency device, aids in clearing airways and enhancing visibility during surgeries by the removal of excess bodily fluids. The prototype demonstrates promising performance comparable to commercially available devices and adheres to international technical standards. Further research and improvements are needed to realise a fully-fledged open-source medical device, available worldwide for free.

This work was made possible through donations collected during a fundraising campaign launched by the Louvain Foundation in the early months of the COVID-19 pandemic for the development and distribution of open-source medical devices.

All materials and resources essential for the prototype production and testing are available on Forge UCLouvain in the OpenMedTech group: `https://forge.uclouvain.be/openmedtech/medical-aspirator`

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This thesis would not have been possible without the Louvain Foundation and their generous contribution. The foundation raised funds during the early months of the COVID-19 pandemic with the aim of developing and distributing open-source medical devices. Their financial support played a pivotal role in realising the initial version of an open-source portable medical aspirator. Without their donation, the project's execution would not have been possible.

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- Mayssem Hadjili and Lucile Heinen

Contents

Introduction

The world often faced crises and emergencies due to various sources such as wars, natural disasters, etc. All these situations require an immediate large number of medical devices. For example, we all remember the COVID-19 crisis, during which masses of patients needed assisted breathing, leading to an immediate demand for ventilators. However, demand exceeded the number of devices available. People died not only because of the COVID-19 infection but also because of a lack of access to some critical medical devices. The healthcare system was overwhelmed by this crisis and did not have all the resources needed to overcome it [1]. This highlighted a flaw in the system. There exists a compelling necessity to reevaluate the healthcare system, aiming to develop medical devices that possess heightened accessibility, appropriateness, availability, and affordability [2]. This objective is directed towards the establishment of an appropriable emergency hospital, equipped and capable of effectively managing any future emergent crises.

To make up for this shortage, several people developed open-source ventilators [3]. One example is the *Breath4life* project, initiated at UCLouvain, where engineers, volunteers, doctors, industry players and investors joined forces during the COVID-19 crisis to develop a low-cost open-source medical ventilator [4]. To delve deeper, the Non-Profit Organisation Open MedTech was created with the aim of freely designing other precise yet low-cost technologies [5].

Open-source hardware, 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"* [6], holds substantial promise overall, and specifically within the domain of medical devices. This potential translates to enhanced resilience within the healthcare system, applicable during routine periods and critical emergencies crisis. It can pave the way for quicker responses to emergencies, increased accessibility, and widespread appropriation of life-saving technologies. An open-source version of the main devices used in hospitals would allow to overcome several problems, such as no longer encountering shortages or improving health care in several regions of the world that face difficulties in obtaining the necessary medical equipment.

Motivation

These events show that we need to consolidate our medical system on all fronts, including medical devices. This is what motivated the research topic of this thesis. The long-term objective is, therefore, to set up a database that will include an open-source version of each priority medical device. This initiative falls within the scope of Open Medtech's commitment towards the development of open-source medical equipment. Several open-source versions of various machines already exist. However, these are not always known by the public, not easily found and unreliable because no tests and results are published, etc. Hence, the establishment of a repository containing verified and validated open-source medical devices

that adhere to regulations and standards becomes imperative. Indeed, compliance with regulations and conformance with mandated technical standards are essential. Therefore, the necessary regulatory requirements and tests to approve them must be investigated and used.

Contribution and methods used

In this work[1], we delve into the challenges inherent in the existing healthcare system concerning medical devices, as well as the implications of open-source hardware and its potential contributions to the medical domain, particularly concerning appropriable medical devices. In addition, this thesis focuses on the analysis and production of a first prototype from a selected medical device. The medical aspirator (also called medical suction pump) has been chosen. This medical device is of paramount significance in crisis management, assuming a central role in mid-level surgical procedures and proving essential for pre-hospital care addressing airway blockages through the removal of bodily fluids.

Literature review and selection methodology

In other words, the first part of the research is to select the essential device on the basis of criteria such as its necessity in hospitals, its importance in healthcare during crises and other personal criteria like the size of the device, the physics involved in it and our specialisations. The selected device has been chosen in a database MeDevIS created by the World Health Organisation (WHO) gathering all the priority medical devices needed for the management of high-burden diseases and emergency surgery [7].

In addition, research on crises and emergencies is carried out, such as establishing a definition, the medical aids necessary to overcome them, and the NGOs involved. Indeed, these last years demonstrate several contexts of crises like the COVID-19 crisis, the Ukrainian-Russian war, and these involved high demands for emergency medical equipment. In such situations, NGOs intervene to provide both social and medical assistance, as well as to supply essential equipment.

By gathering all the research results conducted on hospital requirements and crisis scenarios, the medical aspirator or suction pump has been identified as a relevant medical device that aligns with all predetermined criteria.

Once the medical device is selected, an examination of its state of the art and its operating system, which centres around a vacuum pump, is conducted. Additionally, a compilation of all the prerequisites for utilising the device within a hospital setting and during crisis situations is performed.

Technical developments

Subsequently, the process of designing the prototype for the open-source version begins. It encompasses tasks such as conceptual design, component selection, dimensioning, as well as the manufacturing process of a first functional prototype. Four control modes have been implemented in the prototype to determine the most suitable option for this type of device. Finally, a comprehensive test protocol is set up to assess the prototype and evaluate its performance regarding three research axes:

[1] It is announced that ChatGPT was employed to assist in the writing process.

- Comparison of the different regulation modes implemented.
- Comparison of the prototype with the requirements set out in the specifications.
- Comparison with medical aspirators currently available on the market.

Structure

Chapter 1 studies the challenges associated with the medical sector and underscores the imperative to reconsider medical devices, with the objective of advancing towards a facility that is an appropriable emergency hospital. The chapter also presents the open-source hardware and its relevance to this concern, along with an exploration of the crises and emergency situations.

Chapter 2 addresses the methodology of the device selection process as well as our design and working approach and provides an overview of the medical aspirator, including its operational principles. This section additionally encompasses the compilation of essential requirements tailored to this medical device.

Chapter 3 details all our design and manufacturing processes to develop the prototype of the open-source medical aspirator.

Chapter 4 provides an overview of the risk analysis undertaken and its conclusion.

Chapter 5 presents all our experimentation. The conducted tests are aimed at establishing some parameters of operating modes, as well as a whole test protocol devised to assess the prototype's performance in alignment with the specifications. It concludes with a general discussion of the results.

Chapter 6 provides a list of the remaining tasks to be addressed concerning the prototype, encompassing potential enhancements, etc., in design and the conducted tests. The final goal for these future enhancements is to culminate in a finalised, tested, and publishable open-source version of a medical aspirator.

A conclusion closes this thesis by offering a summary of the conducted work, pivotal phases in prototype design and the main results and enhancements.

Chapter 1

Background and context

The objective of this opening chapter is to provide the context behind this thesis and elucidate the motivations driving the work in the field of open-source medical devices.

First, in Section 1.1, the significance of establishing an appropriable emergency hospital and the need of rethinking the medical devices is highlighted within the context of a crisis. Subsequently, Section 1.2 provides a definition of what open-source hardware entails. Whereas Section 1.3 dives into the concept of open-source medical devices from different perspectives to clearly understand its benefits in today's world. A challenge related to these open-source devices will also be explained, as well as a concrete example summarising this concept. Finally, Section 1.4 concludes this chapter by addressing the diverse crises and emergencies of recent years, to gain a better understanding of the role that medical devices occupy in such scenarios.

1.1 Need for an appropriable emergency hospital

Unveiling the vulnerabilities of the healthcare system

The emergence of the COVID-19 pandemic has shed light on significant shortcomings in the healthcare sector, particularly in crisis management. In one of its reports, the Organisation for Economic Co-operation and Development (OECD) highlight three major vulnerabilities health systems faced during the pandemic: they were underprepared, understaffed and suffered from underinvestment. They outline six recommendations aimed at strengthening the resilience of health systems and mitigating the effects of forthcoming shocks [8]:

1. **Promote population health:** *vulnerable populations make for vulnerable health systems.*
2. **Promote workforce retention and recruitment:** *people are the key to making systems resilient.*
3. **Promote data collection and use:** *without the right data, decision-makers are flying blind.*
4. **Promote international co-operation:** *responses are better together than alone.*
5. **Promote supply chain resilience**: *getting products and services when and where they are needed.*
6. **Promote governance and trust:** *without trust, whole-of-society responses are less effective.*

Let us direct our attention to Point 5. The pandemic's initial response was hindered by medical product shortages. Most OECD nations reported difficulties in acquiring crucial equipment like personal protective equipment (92%), testing materials (83%), and ventilators (68%). The medical device supply chain was highly impacted. The OECD stated [8]:

> *For those technologies that are useful in a crisis, ensuring that sufficient manufacturing capacity exists should be combined with supplier commitments to ensure access where the need is greatest. Investing in more resilient supply chains will not only improve outcomes during crises but also encourage predictability and reliability between times of disruption.*

Even more than a year after the onset of the pandemic, over 90% of countries have reported disruptions to vital healthcare services [9]. However, COVID-19 is not the only critical situation. In general, the healthcare system is often overwhelmed and faces shortages during mass casualty incidents. Mass casualties resulting from disasters and significant incidents frequently involve a high volume, severity, and range of injuries, which can quickly strain local medical capacities. Many deaths and long-term consequences for casualties caused by natural disasters can be prevented through prompt and suitable interventions. Medical intervention during a mass casualty incident occurs in two main settings: on-site, where the healthcare sector needs to be equipped with necessary medical devices to manage the injured, and within hospitals, experiencing an influx of patients requiring immediate critical care [10].

Hence, crises underscored the need for a comprehensive reevaluation of the medical field, prompting a closer examination of medical devices.

Rethinking medical devices

The World Health Organisation (WHO) said in the article *Medical Devices: Managing the Mismatch* [2] published in 2010:

> *Research is making rapid progress within the development of sophisticated medical technologies [. . .] Yet despite this progress, the majority of the world's population has little or no access to many of these innovations.*

Indeed, they have highlighted a significant mismatch regarding the availability of mains medical devices, especially in the developing world. To improve global access to appropriate medical devices and eliminate this mismatch, the WHO establishes the *4 A*:

- **Availability:** when a medical device can be found on the medical device market;
- **Accessibility:** refers to people's ability to obtain and appropriately use good quality health technologies when they are needed;
- **Appropriateness:** refers to medical methods, procedures, techniques, and equipment that are scientifically valid, adapted to local needs, acceptable to both patient and healthcare personnel, and that can be utilised and maintained with resources the community or country can afford;
- **Affordability:** the extent to which the intended clients of a health service or product can pay for it.

It is imperative to enhance the accessibility of medical devices, both during times of crisis (as exemplified here) and more broadly in low-resource regions where hospitals face constraints in accessing even seemingly commonplace medical equipment [11]. Rethinking medical devices is thus essential to move towards a well-equipped and prepared appropriable emergency hospital.

Our definition of an appropriable emergency hospital

When referring to appropriable emergency hospitals, we are describing medical facilities equipped with appropriable technologies ready to promptly address critical demands, effectively manage future challenges and crises (such as those stemming from mass casualty incidents) and facilitate the provision of necessary equipment in regions around the world where access to basic medical devices is often lacking. These appropriable devices should be:

- available promptly upon request and in the required quantities (*Availability*),
- tailored to the specific needs they will be utilised for, and their maintenance should be feasible without constraints, and without being totally dependent on a third party (*Appropriateness*),
- universally accessible and usable, as well as having good documentation (*Accessibility*),
- and affordable regardless of the region or available resources (*Affordability*).

There are various potential solutions to overcome these issues and move towards achieving an appropriable emergency hospital, with open-source medical devices emerging as a viable approach to address this challenge.

1.2 Open-Source Hardware

Open-source is a term becoming more and more popular. Although it mainly concerns computer science and the software world, it is also becoming more common regarding hardware, a term for tangible artefacts such as machines, devices, or other physical things. The Open-Source Hardware Association (OSHWA) set up a Definition and Statement of Principles (version 1.0) for open-source hardware, based on the general one for open-source software [6]:

> *Open source hardware is 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. The hardware's source, the design from which it is made, is available in the preferred format for making modifications to it. Ideally, open-source hardware uses readily-available components and materials, standard processes, open infrastructure, unrestricted content, and open-source design tools to maximize the ability of individuals to make and use hardware. Open-source hardware gives people the freedom to control their technology while sharing knowledge and encouraging commerce through the open exchange of designs.*

The definition comes with 12 criteria that have to be fulfilled to qualify open-source hardware (Table 1.1).

TABLE 1.1: Criteria for Open-Source Hardware, established by the OSHWA [6].

Criteria	Explication
1. Documentation	The hardware must be released with documentation including design files, and must allow modification and distribution of the design files. [...]
2. Scope	The documentation for the hardware must clearly specify what portion of the design, if not all, is being released under the license.

3. Necessary Software	If the licensed design requires software, embedded or otherwise, to operate properly and fulfil its essential functions, then the license may require that one of the following conditions are met: a) The interfaces are sufficiently documented such that it could reasonably be considered straightforward to write open-source software that allows the device to operate properly and fulfill its essential functions. For example, this may include the use of detailed signal timing diagrams or pseudocode to clearly illustrate the interface in operation. b) The necessary software is released under an OSI-approved open-source license.
4. Derived Works	The license shall allow modifications and derived works, and shall allow them to be distributed under the same terms as the license of the original work. The license shall allow for the manufacture, sale, distribution, and use of products created from the design files, the design files themselves, and derivatives thereof.
5. Free redistribution	The license shall not restrict any party from selling or giving away the project documentation. The license shall not require a royalty or other fee for such sale. The license shall not require any royalty or fee related to the sale of derived works.
6. Attribution	The license may require derived documents, and copyright notices associated with devices, to provide attribution to the licensors when distributing design files, manufactured products, and/or derivatives thereof. The license may require that this information be accessible to the end-user using the device normally, but shall not specify a specific format of display. The license may require derived works to carry a different name or version number from the original design.
7. No Discrimination Against Persons or Groups	The license must not discriminate against any person or group of persons.
8. No Discrimination Against Fields of Endeavor	The license must not restrict anyone from making use of the work (including manufactured hardware) in a specific field of endeavour. For example, it must not restrict the hardware from being used in a business, or from being used in nuclear research.
9. Distribution of License	The rights granted by the license must apply to all to whom the work is redistributed without the need for execution of an additional license by those parties.
10. License Must Not Be Specific to a Product	The rights granted by the license must not depend on the licensed work being part of a particular product. If a portion is extracted from a work and used or distributed within the terms of the license, all parties to whom that work is redistributed should have the same rights as those that are granted for the original work.
11. License Must Not Restrict Other Hardware or Software	The license must not place restrictions on other items that are aggregated with the licensed work but not derivative of it. For example, the license must not insist that all other hardware sold with the licensed item be open source, nor that only open source software be used external to the device.
12. License Must Be Technology-Neutral	No provision of the license may be predicated on any individual technology, specific part or component, material, or style of interface or use thereof.
Afterword	The signatories of this Open-Source Hardware definition recognize that the open-source movement represents only one way of sharing information. We encourage and support all forms of openness and collaboration, whether or not they fit this definition.

A well-known example of open-source hardware is the Arduino [12]. It is an open-source

electronic prototyping platform. The Arduino team released all the hardware documentation files under a Creative Commons license[1], and the software to program and run an Arduino is released under an open-source software license. In an interview given to Ars Technica [14], Massimo Banzi, co-creator of Arduino, was asked why is openness important in hardware. He replied *"Because open hardware platforms become the platform where people start to develop their own products. For us, it's important that people can prototype on the BeagleBone [a similar product] or the Arduino (Figure 1.1), and if they decide to make a product out of it, they can go and buy the processors and use our design as a starting point and make their own product out of it."* This is just one of the many benefits of open-source. Moreover, open-source hardware touches many fields, and specifically the medical one, where it has also many Advantages and plays an important role.

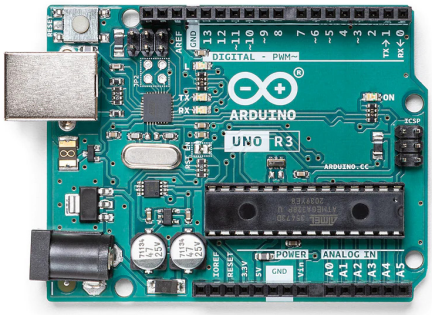


FIGURE 1.1: Arduino UNO, the most used and documented board of the whole Arduino catalogue [15].

1.3 Open-source applied to the medical world

When talking about open-source medical devices, many people think directly about the COVID-19 crisis and open-source ventilators. However, this is not recent. It has been used for years to provide medical equipment to health workers who do not have the resources, long before the pandemic brought these problems to light. For example, subsequent to the influenza pandemic, medical professors from Swansea University released open-source guidelines outlining the construction of an affordable emergency ventilator in 2010 [16], [17].

1.3.1 Benefits of Open-Source Medical Devices

Open-source medical hardware is a solution to the mismatch raised by the WHO and for moving toward an appropriable emergency hospital (see Section 1.1). Indeed, it allows medical devices to be low-cost (compared to commercial versions) and more affordable. This will lead to more available equipment in working order and they will be easier to repair, reducing also the environmental impact). Moreover, having a medical device available under an open-source license leads to a very rapid innovation compared to traditional methods by allowing anyone to improve the design of the medical device. It also allows more people to inspect and improve it, which increases the safety, security and robustness of the device [18].

In particular, open-source medical devices hold significant promise for low-income countries with limited access to essential medical devices. Consequently, some of these countries heavily depend on donations, constituting up to 80% of their medical device supply [19].

[1]Creative Commons is one of the available Open-source licenses [13].

However, as much as 40% of these devices prove nonfunctional, often due to a lack of spare parts or consumables [20]. But even if operational, certain devices remain unused because of the unavailability of manuals or inadequate user training [21]. As a result, open-source medical devices will enhance the availability and affordability of necessary medical equipment (manufactured at a low cost) and will come with comprehensive documentation to address usability and maintenance challenges effectively. Arguably, inadequately equipped healthcare systems in "developed" regions face analogous challenges, although on a distinct magnitude, implying that open-source medical devices could offer comparable advantages within these developed healthcare systems [18].

An example of a medical device to illustrate this mismatch is the well-known stethoscope, regarding its selling price compared to its important necessity. A Littmann Cardiology III, widely considered as the reference in the field, still sells for over $100, despite the fact that there has been minimal innovation in the manufacturing or design of this device for years. A Palestinian-Canadian doctor, Dr Tarek Loubani faced this problem while helping in Gaza during a mass casualty event in 2012. To tackle Gaza's medical shortages, he decided to create an affordable and clinically effective stethoscope which could also be fabricated during low-resource conditions. That is how the Glia project was born. The 1968 Littmann stethoscope design was used as inspiration. The Glia stethoscope research team published in 2018 a peer-reviewed article [22], validating that the 3D-printable stethoscope (Figure 1.2) performed at the same clinical standards of the Littmann Cardiology III. [23]

FIGURE 1.2: 3D printed stethoscope of The Glia Project [23]

1.3.2 Regulations

As already explained, open-source medical devices have the potential to significantly reduce the cost of medical equipment and increase accessibility to healthcare in low-resource settings. However, they are subject to certain limitations due to regulatory requirements, which may vary by country or region. Indeed, lives are at stake every day, therefore it is important that medical devices are highly regulated.

Regulatory Approval/Certification

The primary regulatory framework governing medical devices originates from certifying regulations, issued by regulatory agencies like the European Commission or the U.S Food

and Drug Administration (FDA). The nature of these regulations is dependent upon the classification of the device. In Europe[2], medical devices are classified into 4 categories (Table 1.2), depending on the potential risk to the patient, caregiver or any other person involved in the use of the device. Each category has specific rules. Defining the device's class is essential for identifying the constraints required to ensure the product's compliance with regulatory requirements [24]. The European regulations currently in force are listed in Table 1.3. They have been established in 2017 and took effect from 26 May 2021 for the Medical Devices (MDD) and Active Implantable Medical Devices (AIMDD) regulation, and 26 May 2022 for the In Vitro Diagnostic Medical Devices (IVDMD). The EU has revised the legal framework of the three previously existing directives to reflect the progress made over the past 20 years [25]. These regulations replace previous ones established in 1990 (AIMDD), 1993 (MDD) and 1998 (IVDMD) [26].

TABLE 1.2: The 4 European regulation classes and some examples [27].

Class #	**Example**
Class I (lowest risk class)	Corrective glasses, wheelchairs, stretchers, crutches, stethoscopes etc.
Class IIa (potential moderate/measured risk)	Syringes for infusion pumps, ultrasonic diagnostic equipment, thermometers, etc.
Class IIb (potential high/significant risk)	Ventilators, condoms, Surgical lasers, defibrillators etc.
Class III (highest risk class)	Breast implants, cardiovascular catheters, stents, hip replacements etc.

TABLE 1.3: New European regulations currently in force.

Regulation code	**Application area**
Regulation (EU) 2017/745 [28]	Medical Devices (MDD) & Active Implantable Medical Devices (AIMDD)
Regulation (EU) 2017/746 [29]	In Vitro Diagnostic Medical Devices (IVDMD)

International standards

In addition to the regulations, stated by regulatory agencies, there are also international standards, created by manufacturing Standards Developing organisations (SDOs) like the International Organisation for Standardization (ISO) [30] or International Electrotechnical Commission (IEC) [31] .

Government regulations, issued by authorities and regulatory agencies, establish overarching standards of safety, efficacy, and quality for the medical device sector. In contrast, international standards offer focused technical guidance, often tailored to specific device types or processes. While regulations are broad and mandatory, international standards can range from device-specific guidelines to broader quality management principles, fostering sector-wide compliance and best practices [32].

[2]European regulations are explained in this work and not FDA or other regulations because we are based in Europe and have decided to focus only on these regulations

Although compliance with these standards is technically voluntary in many cases, as ISO and IEC are considered the gold standard and state-of-the-art in this area, some international standards are used and made mandatory by medical regulatory bodies [33].

Most of these international safety standards are specific to each type of device, for example:

- *ISO 17510:2015* [34] for sleep apnea breathing therapy devices or
- *ISO 29821:2018* [35] for ultrasound scanners.

Other standards are more general, such as:

- *IEC 60601-1-11:2015* [36] for general requirements for basic safety and essential performance of medical electrical equipment,
- *ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes* [37] which ensures high-quality processes in the entire life-cycle of medical devices, guaranteeing regulatory compliance and patient safety or
- *ISO 14971:2019 Application of Risk Management to Medical Devices* [38] which attends to identify, estimate, evaluate and mitigate the associated risk through all the phases of a medical device life-cycle.

Open-source medical devices and regulations

These regulations are often an obstacle to the use of open-source medical devices because the costs and time to obtain certification are not insignificant. If an organisation creating an open-source medical device also decides to commercialise it in order to increase its accessibility for example, it must obtain the regulations in accordance with the class of the device. This is for example the case of the Glia stethoscope, a class I device manufactured both in Canada and in Gaza under a *Health Canada Medical Device Establishment License (License #6823)* [39].

To overcome these limitations, it is important to develop open-source medical devices in collaboration with regulatory agencies and stakeholders, such as healthcare professionals and patients. This ensures that devices are designed to meet regulatory standards and are safe and effective for use in medical settings. One approach is to establish a framework for evaluating and testing open-source medical devices, which can help to identify any potential risks or issues and ensure that the devices meet relevant regulatory standards. Additionally, establishing partnerships between open-source developers and established medical device manufacturers can help to address quality control and intellectual property concerns, while still maintaining the accessibility and affordability benefits of open-source technology [40].

1.3.3 Example: COVID-19 pandemic and development of open-source ventilators

Since December 2019, the coronavirus more precisely named SARS-CoV-2 virus is known to have spread rapidly worldwide and to lead to a declaration of a pandemic. This infectious respiratory illness has been the cause of a total of 755.703.002 confirmed cases and 6.836.825 deaths through February 13, 2023 [41].

As the number of cases continued to rise, the pandemic resulted in a significant increase in demand for personal protective equipment, medical products and devices, and treatment in intensive care units. Individuals severely impacted by COVID-19 might experience respiratory issues, necessitating the use of ventilators. As the epidemic led to the saturation of hospitals and in particular intensive care units, a shortage of ventilators was a major concern. Therefore, important and fast production of devices allowing the healing of patients was essential.

This is where the concept of open-source becomes compelling within the context of this pandemic. The availability of resources[3] that enable the production of low-cost and economically viable medical devices facilitates increased manufacturing, consequently ensuring widespread access to ventilators for all critically ill patients [3].

Concrete illustration: Breath4Life initiative

An example is the *Breath4Life Ventilator* (Figure 1.3) originated at UCLouvain and realised by a team of engineers, doctors, industry players and investors. It was created to be open-source and thus non-profit. Some words about the *Breath4Life* project can be interesting to describe the *4 A* demonstrated in Section 1.3.

Initially, this effort emerged from a request on a chat for MIT's Open-Source Ventilator project, aiming to develop cost-effective ventilators. Then, teams from different fields came together and began working on a ventilator project propelled by the beginning of the COVID-19 pandemic, which necessitated an accelerated timeline. The pressing scarcity of ventilators in Belgium intensified the urgency, inducing the rapid development of emergency ventilators to aid hospitals struggling with shortages.

An important aspect of this project was to respect the necessary technical specifications of the medical device. Therefore, the proposed ventilator has been submitted to strict test processes that are in line with the requirements of producing and using medical equipment, which are aspects referring to the **Accessibility** mentioned in the *4 A* rules. Due to the **Appropriateness** aspect of the open-source and the fact that the device has been created for an emergency and not for long-term marketing, the team of workers had to be in contact with federal regulation authorities to get rapidly the approval to use and produce the ventilator by avoiding the full certification process and financial issues. Also, the **Affordability** was emphasised. The open-source ventilator has been conceived at low-cost, more precisely a few hundred euros. The purpose of this project is to offer an entire conception without making money on it. The files of production are freely available on their website, allowing the medical device to be reproduced in any FabLab[4]around the world. This involves the **Availability** aspect [4], [43].

1.4 Crisis and emergencies

These last years of COVID-19 crisis point out the importance of technological research to improve medical devices and make them more easily accessible to hospitals. It is then

[3]For example small-scale manufacturing technologies (e.g. 3D printers, laser cutting, etc) or open-source microcontrollers.

[4]A FabLab (contraction of *fabrication laboratory*) is a place open to the public where all kinds of tools, including computer-controlled machine tools, can be used to design and build objects [42].

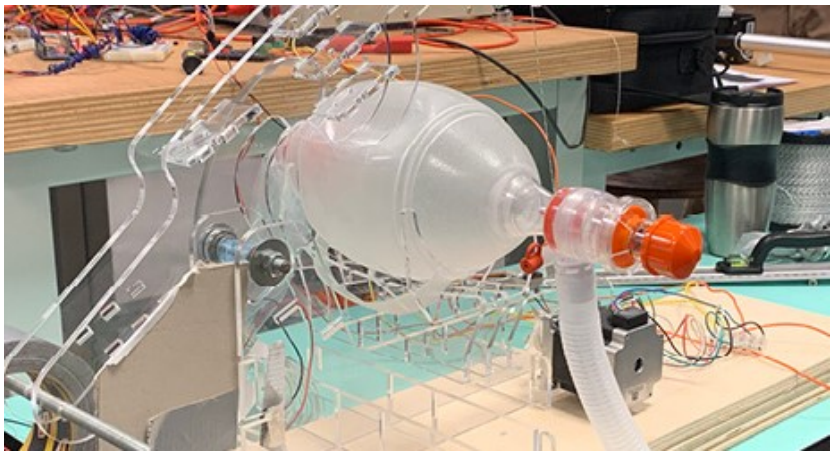


FIGURE 1.3: A prototype of the *Breath4Life* that has been designed in 10 days and successfully tested at the OpenHub of UCLouvain [4].

interesting to look at the notions of crisis and emergencies in order to extract the essential elements to anticipate and therefore better manage these complex situations.

1.4.1 Definitions of crisis and emergencies

Let's first take a closer look at the definition of these two notions. A definition of an emergency is *a serious, unexpected, and often dangerous situation requiring immediate action* [44]. A crisis is defined as *an event or a period that will (or could) lead to an unstable and dangerous situation affecting an individual, a group, or the entire society* [45]. Crises can impact various aspects of life, such as the economy, health, politics, the environment, etc. In response to these crises, swift decisions must be taken to manage potential impacts [45]. These two notions are closely linked since the crisis generates then a context of emergency. A list of situations gathering the two notions has been compiled in Table 1.4.

TABLE 1.4: Crisis and emergencies with some examples of existing situations.

Crisis and emergencies	**Examples**
1. Conflicts and civil/world wars	World War I (1914-1918) and World War II (1939-1945), Israeli-Palestinian conflict (1948-?), Algerian independence war (1962), Russian-Ukrainian war (2022-?), etc [46]
2. Natural catastrophes	Flooding, earthquake, tsunami, cyclone, tornados, storms, droughts, extreme temperatures (cold and hot), landslides, volcanic eruptions, fires, etc.
3. Epidemics / health crisis	Cholera, measles, Ebola, COVID-19, HIV, Black Death, Spanish Flu, etc [47]
4. Famines	Famine in the winter in Russia (1916-1917), Famine in the Netherlands (1944), Famine in Ethiopia (in the 1970s and 1980s), Famine in Yemen (2017), etc [48]
5. Exils and forced migrations	Refugees of Syrian inhabitants in neighbouring countries due to the war in the country: 3.000.000 exiles to Turquie, Jordanie, Liban and Egypte in 2014 and 3.000 arrivals in France; Hundreds of thousands of Rwandans who fled to Zaire after the 1994 massacres; etc [49]

Note that some of these situations are consequences of each other.

1.4.2 Figures on crisis and emergencies

It is important to determine the recurrence of each emergency situation and the extent of their impact on human health in order to sort out the medical devices necessary for such events. Obviously, this research could be entirely dedicated to a thesis. This is why here, the research that has been conducted is shallow to have a global view and understanding.

First, here are some figures on the recurrence and on the number of deaths and injuries from mass casualty incidents such as natural disasters, conflicts and (civil) wars, famines and epidemics.

Natural catastrophes

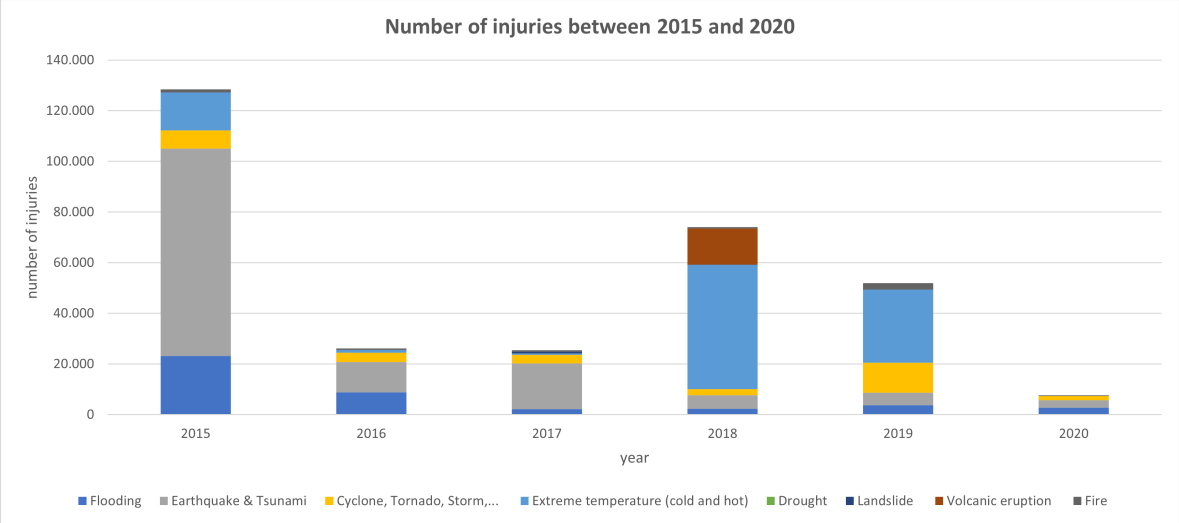


FIGURE 1.4: Number of injuries registered by *Our World in Data* [50].

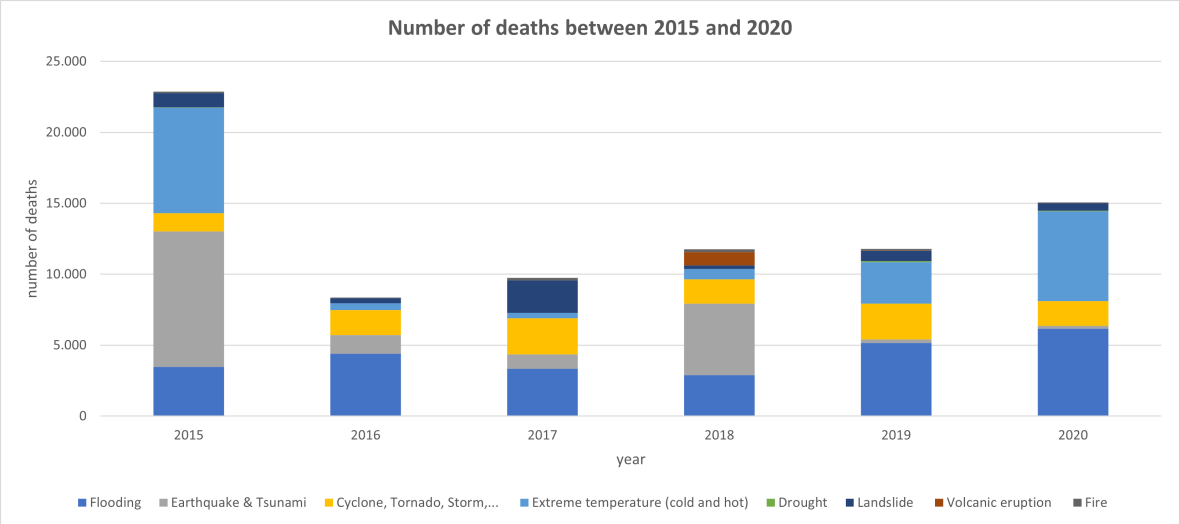


FIGURE 1.5: Number of deaths registered by *Our World in Data* [50].

Figures 1.4 and 1.5 [5] demonstrate floods, earthquakes and tsunamis, and extreme temperatures (cold and hot). These are the natural catastrophes causing the greatest number of injuries and deaths between the years 2015 and 2020. Indeed, the last decades have been particularly affected by major climate changes. A report written by the *World Meteorological Organisation* (WMO) [6] explains these changes and disasters associated [52]. It demonstrates 11.072 disasters were registered as being due to weather, climate and water hazards, involving 2.060.000 deaths between 1970 and 2019 whose specific disasters with their corresponding figures are shown in Figure 1.6.

These high numbers of casualties show the importance of a medical system adapted to the care of people affected by these disasters which have been shown to involve a large number of injuries and deaths.

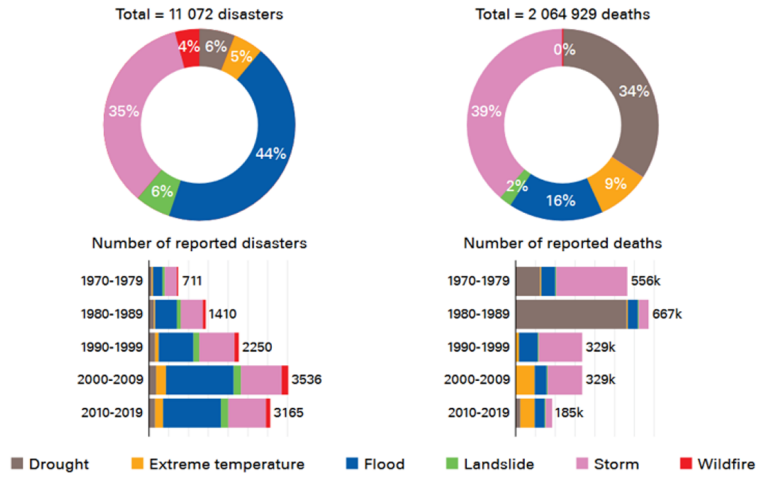


FIGURE 1.6: Number of disasters and deaths involved registered by the *WMO* [52].

Conflicts and wars

Even today, wars and conflicts in the world are a reality and have a strong impact on the health of populations as well as their mortality rate. The living conditions brought by these wars are not negligible due to a sudden high demand for emergency care.

The graphs below, taken from an article in *Our World in Data* (OWD) [53], provide an overview of the number of deaths involved in conflicts and wars and the number of conflicts in recent years. Figure 1.7 shows the global deaths in conflicts and one-sided violence between 2010 and 2020. The number of direct violent deaths counting civil and military is on average 98.300. This graph mentions three types of conflicts. One-sided violence is *"perpetrated by an organized armed group, either a state's military forces or an armed group, against civilians"* [54]. Non-state conflict is *"fought between two organized, armed actors, of which neither is the government of a state"* [54]. State-based armed conflict *"takes place between two states (inter-state conflict), or between one state and one or more rebel groups (civil conflict)"* [54].

[5] The both graphs represent data gathered from the scientific online publication *Our World in Data* [50].

[6] WMO is a specialized agency of the United Nations whose mandate covers weather, climate and water resources [51].

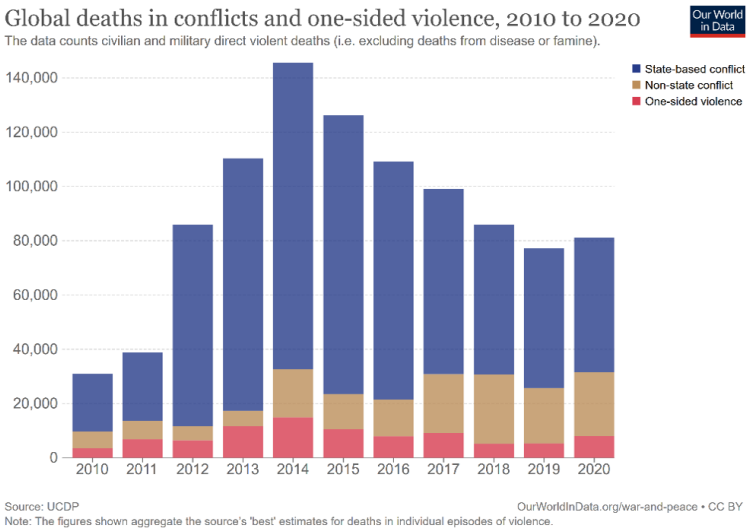


FIGURE 1.7: Number of global deaths in state-based conflicts, non-side conflict and one-side violence with data from *OWD* [53].

Figure 1.8 shows the number of civilian and military deaths in conflicts according to different regions in the world. The global number of combat deaths has declined in recent years but remains above 40.000.

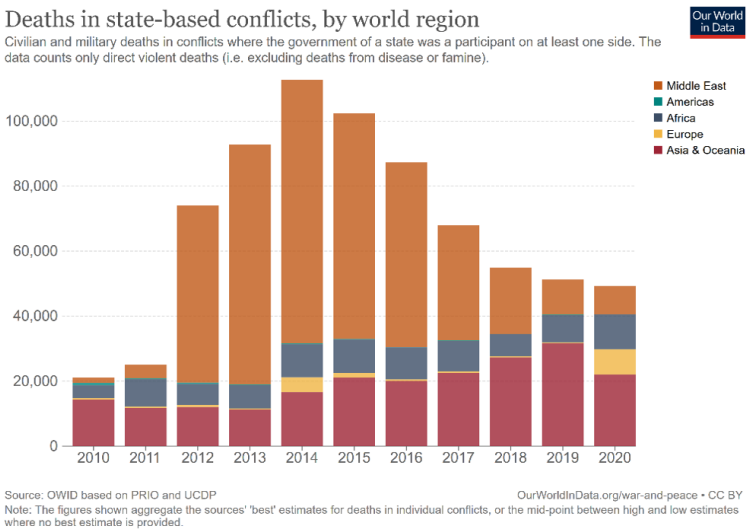


FIGURE 1.8: Deaths in state-based conflicts by world region between 2010 and 2020 with data from *OWD* [53].

Figure 1.9 represents the number of active state-based conflicts in the world between 2010 and 2020. This number is on average 44 in recent decades and it concerns in majority the case of civil conflicts.

Even though inter-state conflicts and wars have almost ceased to exist between 2010 and 2020, many civil conflicts are still present and as shown in the previous graphs, they lead to many deaths but even more injured people. Another current crisis in 2022 is the war

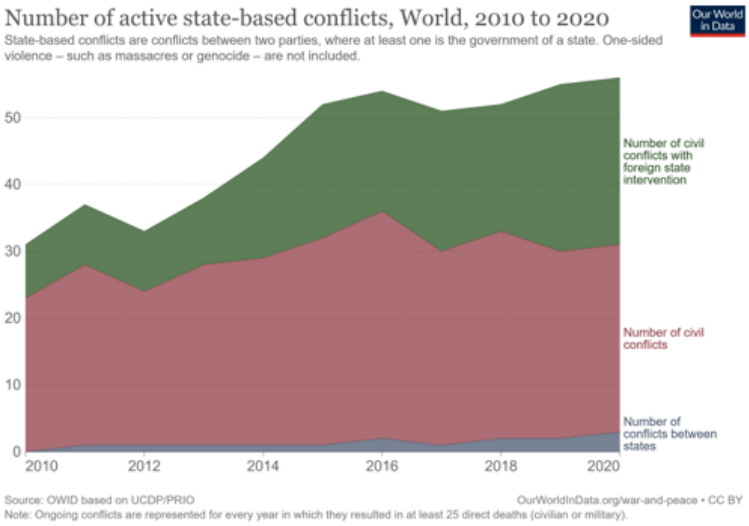


FIGURE 1.9: Number of active state-based conflicts in the world between 2010 and 2020 with data from *OWD* [53].

between Ukraine and Russia, which is therefore not included in the previous figures. An article on this subject states that the Office of the United Nations High Commissioner for Human Rights (also called UN Human Rights Office) has estimated the number of civilian casualties (7.031 deaths and 11.327 injured) in the country at 18.358 in February 2023 [55]. These numbers demonstrate a high demand for emergency and health care when crisis like wars and conflicts occur.

Epidemics

Epidemics have always existed and killed thousands of people or condemned them, depending on the disease contracted, to respiratory, muscular, cognitive difficulties, etc. An article [47] lists the largest known pandemics over several centuries. These epidemics have the particularity to be local and then spread worldwide. Figure 1.10 from this article shows that each pandemic results in millions of deaths worldwide.

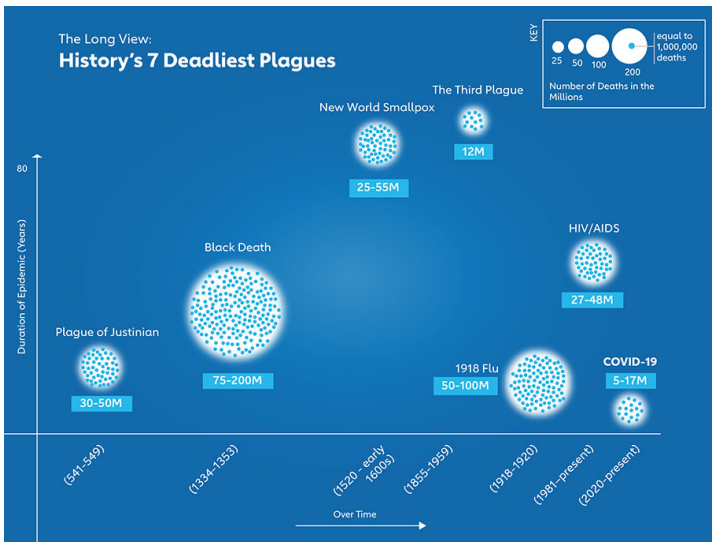


FIGURE 1.10: The seven deadliest pandemics in history listed by Gavi The Alliance Vaccines [47].

As explained in the previous section regarding the example of COVID-19, this pandemic has been the cause of 6.836.825 deaths (still currently updated) and other people who have been affected by this virus have sequels till now. COVID-19 is still a great concern today due to all the difficulties encountered in recent years. Indeed, it required a lot of work for medical professionals and also a large emergency production of medical care and devices in hospitals such as devices related to the administration of oxygen, ventilators, infusion pumps, suction pumps, etc [56].

1.4.3 Non-Governmental organisations.

NGOs are defined as *nonprofit entities independent of governmental influence*. They get involved in actions concerning environmental, social, advocacy and human rights and these are undertaken abroad or locally [57]. Therefore, some NGOs intervene also in the field of health and medicine during humanitarian emergencies. There are many organisations undertaking actions in the field of health such as :

- **Croix-Rouge** is widespread worldwide [58].
- **WHO** admits many countries of the world too [59].
- **MEMISA** is active in Benin, Burundi, Guinea, India, Mauritania, DR Congo and Belgium [60].
- **SIAMU** is a Belgium service and operates precisely in the Brussels-Capital Region [61].
- **Médecins du Monde** is involved independently in France and internationally i.e. Asia, Europe, America, Africa and Middle-East [62].

The emergencies, for which these organisations act, concern epidemics, natural disasters, humanitarian crises, famines, migrations, and still many other causes. These actions are carried out internationally and locally, and they consist of collecting donations, material and financial aid, construction of buildings, movement of voluntary (non-)medical teams and reception of refugees. These activities undertaken by organisations are always closely linked to the needs of the population. Looking into the actions of these organisations allows to get the essential materials to provide for medical needs during crises and emergencies. Therefore, some of these NGOs have been investigated.

Croix-Rouge

Initially, Croix-Rouge is involved in several relief operations. One of the operations is the Emergency Response Unit which consists of the deployment of teams of volunteers from the Belgian, Dutch and Luxembourg Croix-Rouge abroad. Their mission on site is to provide medical support, food aid, create or rehabilitate health posts, take care of the reception of the refugees and the management of the camps, rebuild and reintegrate the victims psychosocially and promote the rules of international law. Then, it engages in a stage of reconstruction by proposing rehabilitation programs. It also proposes a preparation of the populations for the risk of future disasters [63].

All these medical aids require not only a lot of medical professionals but also a large amount of medical supplies. An article of the Belgian Croix-Rouge [64] details one of their missions in Haïti to assist the population which was affected by an earthquake in 2010. The priority was to provide first aid, emergency health care, shelter, and access to food and clean

water. For this, Croix-Rouge brought tons of medical materials such as shelter tool kits, tarpaulins, buckets, jerry cans, kitchen sets, blankets, personal protective equipment, first aid supplies, and emergency health care.

MEMISA

MEMISA is an organisation specialising in strengthening the health system in Guinea. This assistance is provided through training in infection prevention and control and through the provision of medical materials such as [65]

- Infection prevention and control kits: disposable gowns, masks, gloves, hydro-alcoholic gel,...
- Delivery kits: medicines, placenta buckets, underpads for babies, forceps,...
- Donations for drilling and incineration to eliminate biomedical wastes

They explain that a reason for the degradation of health in the regions of Congo and Guinea is the effects of climate change. This results in floods, drought, heavy rain, bad harvest and therefore, malnutrition, infectious disease and degraded health posts [66].

In 2020 during the health crisis in Congo, the evolution of COVID-19 was very fast as there was a great lack of health care. In order to reduce the increase in the number of infected patients, MEMISA has deployed medical resources such as hospital beds, washable mattresses, hygiene kits for patients and the manufacture of hydro-alcoholic products [67].

In a 2021 article about health in Congo [68], it is explained that the support of MEMISA, a partner with Action d'Espoir, has helped to improve health care and particularly maternity care. By collecting donations, they have provided the installation of separate maternity wards from the health centre with kits of delivery materials, medicine kits and delivery tables.

WHO

The World Health Organisation is an *United Nations specialized agency for global health. The purpose of this agency is to promote the highest attainable standard of health for every human being in the world, to safeguard global security and to serve vulnerable populations* [69].

A WHO mission was to help the Ukrainian population when the war in 2022 broke out in their country. The organisation sent emergency medical teams on-site to provide medical consultations to the population. They also brought a hundred tons of supplies and equipment to Ukraine, this includes some already existing kits suitable for treating up to 20.545 patients [70]. These delivered kits are :

- **Trauma and Emergency Surgery Kits (TESK) [71]:** contain oral and IV medicines including cold chain drugs and medical supplies including renewables and instruments. More precisely the first module of the TESK contains drugs and renewables for 50 patients hospitalised :
  - **Drugs :** basic, controlled, antidote rescue, cold chain, dangerous goods, infusions and disinfectants

  - **Renewable Commodities :** gloves, the basic material for anaesthesia, injection material, dressing material, plaster casting material, sterilisation, surgical drainage material, sutures, urine drainage material, surgical miscellaneous material and splints

  The second module of the TESK provides surgery instruments for a few domains:

  - **General surgery instruments :** basic surgery, craniotomy, laparotomy, debridement of surgical wounds, skin graft, thoracotomy
  - **Orthopedic surgery instruments :** amputation, basic bone surgery, bone wiring, plaster casts removal, traction
  - **Specialized surgery instruments :** dental instruments, ear-nose-throat instruments, gynaecology instruments (as dilatator curettage), ophthalmic trauma instruments, instruments for reproductive health kit, urethral sounds instruments and vascular instruments.

- **Interagency Emergency Health Kits (IEHK) in 2017 [72]:** it is a standardised kit that is used in case of a disruption of medical supplies in an emergency situation and it contains essential medicines, supplies and equipment.
- **Non-Communicable Disease (cancer, heart disease, chronic respiratory disease, diabetes) Kits (NCDK) [73]:** it provides the essential medicines and medical devices for diseases such as hypertension and cardiac conditions, diabetes and endocrine conditions, chronic respiratory diseases and mental health.

The WHO has also created a priority list of medical devices to specifically address the COVID-19 health crisis [74]. Due to the urgency to respond to the pandemic crisis, it was important to establish a reference list of basic and priority medical devices. This list ensures access, acquisition, availability and proper use of the mentioned devices in the health centres. It was established using a specific methodology whose steps are shown in Figure 1.11. It exists also another methodology allowing to determine the most suitable technical specifications of the priority devices of the list.

Here are some of the devices that emerged from the methodology [56] :

- Oxygen administration and measurement devices like oxygen concentrator, venturi mask, flow meter (Thorpe tube), exchanger and humidity filter, pulse oximeter, multiparametric patient monitor for non-invasive blood pressure and oxygen saturation, ...
- Invasive and non-invasive ventilators
- Infusion devices: infusion pump, syringe pump and drip chamber
- Additional medical equipment to support the clinical management of COVID-19: thermometer, portable electrocardiograph, laryngoscope, electric and manual suction pump (also called medical aspirator), and blood gas analyser
- Airway and critical care consumables and single-use medical devices
- Imaging equipment: portable ultrasound machine

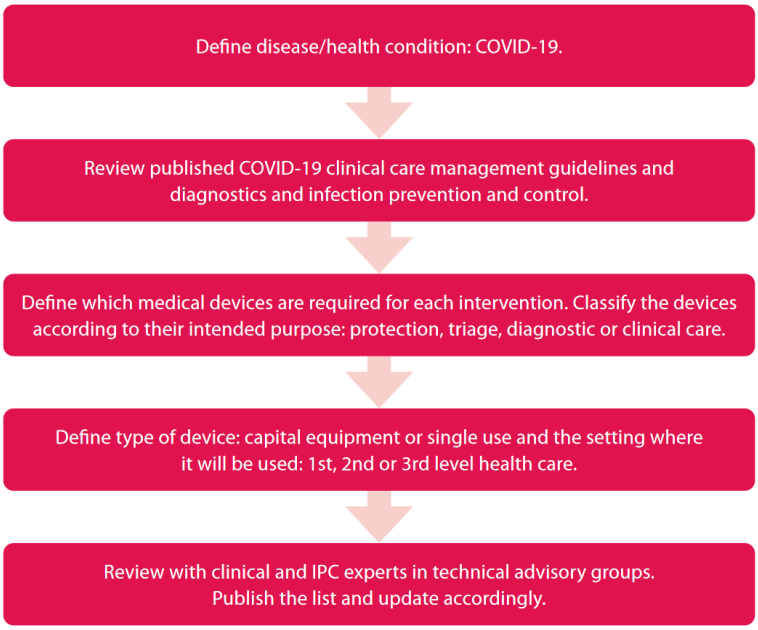


FIGURE 1.11: Steps of the WHO methodology to select a list of necessary devices for the COVID-19 pandemic [74].

Chapter 2

Device selection and state of the art

This chapter first addresses the methodology employed to select the medical device that will be the focus of the subsequent research and design efforts (Section 2.1). Subsequently, Section 2.2 introduces the design methodology adopted in this work. Section 2.3 presents the first step of this methodology. It consists of an overview of the selected device, encompassing its functionalities, usage, and currently available medical aspirators/suction pumps. The next step, depicted in Section 2.4, consists of the establishment of its specifications. Finally, a brief introduction to the theory of vacuum and its conventions are presented in Section 2.5 to aid the understanding in the subsequent stages of design and testing development.

2.1 Device selection methodology

In a hospital, a large number of medical devices are used. From the small surgical tool to the big MRI scanner, it has been estimated that there are 2 million different kinds of medical devices on the world market, categorised into more than 7000 generic device groups, according to the WHO [75]. Establishing a list of the most used device is crucial to choose which device is interesting to work on. A selection methodology must therefore be established.

MeDevIS database

During his master thesis, Louis Breels [76] discovered the MeDevIS database (Figure 2.1) [77]. MeDevIS (Priority Medical Devices Information System) is an open-access WHO electronic database of Medical Devices [78].

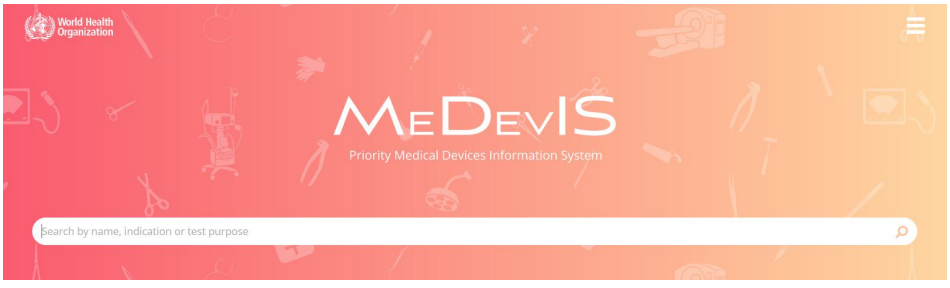


FIGURE 2.1: Home page of the MeDevIS database

The WHO was called by the resolution WHA60.29 (created during the 2007 World Health Assembly) to *"establish and update an evidence* ***web-based health technologies database*** *to serve as a clearinghouse which will provide guidance on appropriate medical devices according to the* ***levels of care***, ***setting*** *and* ***intended health intervention***, *which can be tailored to the specific needs of country or region"* [79].

The WHO created the Priority Medical Devices (PMD) project to establish the list. The selection methodology of the PMD has been explained in a WHO publication: *Medical devices: managing the mismatch: an outcome of the priority medical devices project* [2] and in the *Medical devices: managing the mismatch: an outcome of the priority medical devices project: methodology briefing paper* [80].

This approach involved the following points:

1 It starts by identifying the most important health problems by using the global burden of disease and/or disease risk factor estimates.

2 The second step was to identify the best way to manage the health problems by referring to the relevant clinical guidelines.

3 The final step was to link the results of the first two steps to produce a list of key medical devices needed to manage the high-burden diseases identified, at a given level of healthcare and in a given context.

This method enabled the PMD project to identify the main medical devices involved in the treatment and management of high-burden global diseases from relevant clinical guidelines.

As a result, three publications were developed to define the medical devices required for:

- Essential interventions for reproductive, maternal, newborn and child health [81]
- Management of cancer [82]
- Management of cardiovascular diseases and diabetes [83]

After the beginning of the COVID-19 pandemic in 2020, a technical publication on the priority devices needed for this virus was rapidly published [74]. More recently, other priority medical devices for the management of other diseases have been identified and selected based on relevant WHO materials and publications, such as the Package of eye care interventions [84] and medical devices that are part of the Trauma and Emergency Surgery Kit [85] (see Subsection 1.4.3).

The MeDevIS database gathers all the priority medical devices of these publications, and is continuously updated and includes newly selected priority medical devices based on recent WHO guidelines and recommendations. At the time of conducting the selection, 1723 medical devices were listed. Today (August 2023), this number has been updated to 2297 devices.

Setting up a list of selected devices from MeDevIS

Starting from the MeDevIS database containing 1723 devices, a series of criteria was applied directly in the database to sort the list and obtain a more restricted one. All the available criteria are shown in Figure 2.2.

- The first criteria concern the **Healthcare unit**. The *Emergency care*, *General surgery*, *Intensive care*, *Medical imaging* and *Accross all* were selected.

FIGURE 2.2: Selection criteria available in the MeDevIS database

- The second criteria was about **Various** or **Disease specific**. **Various** was selected because, for an open-source implementation, it is more beneficial to have a device that serves various diseases rather than being specific to one case.
- The next criteria was the **Regulatory classification**. Class 3 and implantable devices are eliminated because they are unattainable for the work of research presented in this master thesis. IVDs (in vitro medical devices) and all the related products (Annex II List A & B), as well as medicinal products, are also excluded, as shown in Figure 2.3.

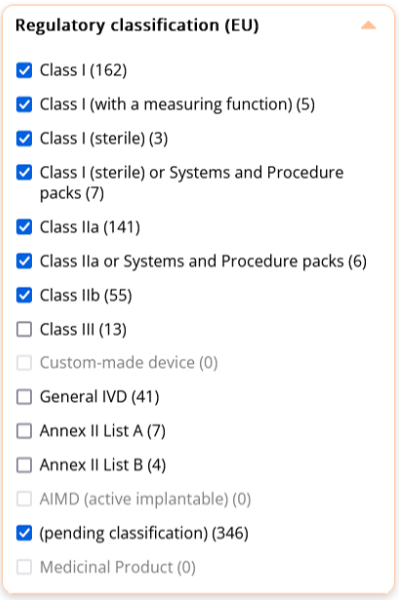


FIGURE 2.3: Selected items of the Regulatory classification criteria

- Devices requiring only a *basic* **Level of knowledge** are removed. Indeed, such devices are too basic and not interesting to work on, both for the purpose of a master thesis and the interest of making an open-source version.
- Another criteria was the **Type of devices**. Only the *capital* and *reusable* ones (not the *single use*) were kept.
- The last step was to **manually remove** "useless" devices such as scissors, pliers, cable, operating table, electrode, bowl ... By "useless" we mean all the devices for which is

not interesting to create an open-source version in the framework of the thesis and in general.

Once all these criteria were applied, a list was exported in an Excel file.

Sorting the obtained list

Subsequently, we applied subjective criteria to refine the list. Finally, the remaining devices will be analysed more in detail and evaluated using additional criteria.

These subjective criteria were the following:

- Center of interest
- Technical areas involved
- Size of the machine (scope of work)

Subjective criteria were applied, considering that it would be challenging to work on a device that does not align with our interests or falls beyond our technical competencies. Moreover, we excluded voluminous and complex devices, like an MRI scanner, as they do not fit within the scope of this thesis. Finally, 15 devices were selected.

Selection of the final device

To select the final device from the list established previously, additional criteria were applied. These criteria involve the crisis and emergency aspects. Specifically, the following elements were focused on:

- The principle of operation
- Sufficient or insufficient documentation
- Usefulness of this system (in normal context) :
    - o Average number of units per hospital in a normal context
    - o Average daily use of a unit in a normal context
- Usefulness in times of crisis:
    - o Context of use (what type of crisis)
    - o Frequency of occurrence of this type of crisis

But before applying these criteria, the main selection criterion was whether or not open-source versions of these machines existe. Indeed, two works can be done regarding this response:

- either a finished open-source version already exists, then the goal will be to make it, create a test protocol (according to the specifications of the device) and test it to validate the design. It is also envisaged to improve the device if improvements are possible ;
- or no version was found during the research, or no version exists, therefore the goal will be to develop an open-source version of this device and build a first functional prototype in accordance with the specifications. Additionally, writing a test protocol to test and validate the device.

We prefer to create an open-source version ourselves rather than testing an existing one. Once devices without an existing open-source version have been identified, the criteria mentioned above can be applied. This led to the selection of the electrically powered and portable medical aspirator/suction pump.

In its database, the WHO mentions two types of aspirators: manually powered and electrically powered. The distinction between these two devices, along with the overall framework for the use of medical aspirators, will be presented in Section 2.3.

However, some explanation behind this choice can already be provided. Firstly, this device aligns with the selection criteria mentioned earlier: it is compact, manageable within the scope of a master thesis workload, and our competencies are seemingly adequate for its development. In addition, the absence of an open-source version of this device[1] provides an opportunity to engage in research and create an initial prototype. Furthermore, this medical apparatus holds critical importance in crisis management, as it is part of the WHO's *Integrated Management on Emergency and Essential Surgical Care* tool kit [86]. It plays a pivotal role in mid-level surgery and is indispensable for pre-hospital care involving airway obstruction.

2.2 Design methodology

To design a device, whether medical or non-medical, we need to establish and follow a working methodology, to find an optimal solution to our problem from among all the possible ones.

We have decided to use the FDA methodology proposed in *Design Control Guidance For Medical Device Manufacturers* [87]: the waterfall model shown in Figure 2.4. It is a model discovered in our *Mechanical Design for Biomedical Engineering* course [88].

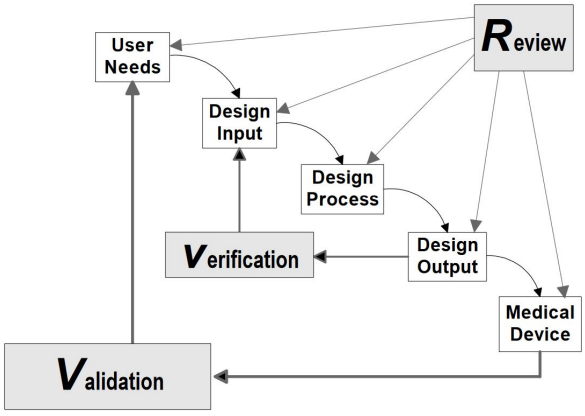


FIGURE 2.4: Waterfall model from [87].

User Needs

The initial step involves identifying all the objectives, functions, and user needs that the medical device must fulfil. To accomplish this task, an investigation was conducted into the state-of-the-art of medical aspirator/suction pump (Section 2.3). To go deeper, it would be

[1] This is asserted to the best of our knowledge based on the conducted research.

useful to inquire with healthcare professionals who use this type of equipment to respond to daily needs, on the desired functionalities, and expected performance of such a device. Due to the time constraints of this thesis, this step could not be undertaken. However, it is an interesting task to perform before a future prototype iteration.

Furthermore, given the open-source nature of the device, other open-source-related criteria should also be considered. These include factors such as the used manufacturing process, providing all manufacturing resources and plans that must be clear and easily accessible to all, striving for a low-cost device if possible, etc. For the first iteration of this prototype, it is already stated that the low-cost criterion has occasionally been set aside in favour of functionality and robustness. Our primary goal was to deliver a functional prototype that fulfils the requirements and achieves performance similar to commercially available devices. Once this objective has been achieved, a second possible iteration was envisioned (for future improvement). It would place emphasis on the low-cost aspect by exploring alternatives and more affordable components while still achieving comparable performance. It will be explained in more detail in Chapter 6.

Design Input

Unlike user needs, which can be challenging to quantify and measure, design inputs need to be objective, quantifiable, measurable, and independent of the solution. To carry out this task, the main functions and constraint functions were established. This subsequently helps determine the various requirements that the device must adhere to. Additionally, it is important to investigate applicable regulatory requirements and standards to determine the obligations placed on a medical device. This step is presented in Section 2.4.

Furthermore, conducting a risk analysis (as elaborated in Chapter 4) is crucial. All outcomes of this study must be incorporated into the design inputs.

Design Process and Design Output

As stated in the ISO13485 standard about medical devices quality management [89]: Design and development outputs shall:

a) meet the input requirements for design and development;

b) provide appropriate information for purchasing, production and service provision;

c) contain or reference product acceptance criteria;

d) specify the characteristics of the product that are essential for its safe and proper use.

Specifically, design outputs can take the form of drawings and calculations, part lists, process specifications, product and process software, manufacturing and inspection procedures, etc.

The design process involves the utilisation of tools such as Function Analysis to determine the main functions and device limitations or a morphological table to identify various potential solutions for each function and assess them based on different weighted criteria [88].

Verification and Validation

The Verification stage compares the proposed solution (a functional prototype) to the list of requirements. Whereas the Validation stage compares the *finished* medical device to real clinical needs.

Once the functional prototype is ready, it will be subjected to the requirements by developing a test protocol (Chapter 5).

2.3 Overview of the medical device

2.3.1 Uses of suction pump/medical aspirator

A medical suction pump, also called medical aspirator[2], is designed to remove excess bodily fluids (e.g. mucus, blood, vomit, and other bodily secretions) or even tissues (e.g. pieces of bone) that might obstruct the field of vision or need to be extracted from the body during various medical procedures [90]. To achieve this task, a medical aspirator is composed of a vacuum pump and a regulation system to create a desired vacuum level in a collection container. This creates a pressure difference between the collection container and atmospheric pressure (at the patient's body), enabling the bodily materials to be aspirated and collected in the container. Suction devices are available in several forms according to their intended use, in particular medical procedures in which they are employed.

The different medical procedures requiring the utilisation of a suction pump include [91]:

- **Evacuation of the airways :**
  - When a patient is unconscious, semiconscious, or disabled and unable to protect his airways. This can be manifested through the airways being blocked due to persistent vomiting or bleeding.
  - When a patient has an excess of secretions, mucus or other substances that make breathing difficult.
  - When a patient has compromised swallowing or coughing [92].

  Immediate suctioning is required for the patient when they manifest these respiratory complications [93] :

  - Respiratory insufficiency: occurs when the patient's respiratory system is not capable of satisfying the body's normal metabolic requirements.
  - Respiratory depression: is observed when the patient's breathing rate drops or the breathing rate fails to adequately ventilate or oxygenate the lungs.
  - Respiratory failure: when both factors above occur, they can lead to respiratory arrest.

  The two most critical respiratory complications [93] :

  - Aspiration: Pulmonary aspiration takes place when substances such as food, liquids, vomit, saliva or other materials, instead of being swallowed, are breathed into the airways and subsequently reach the lungs, infecting the lung tissues (leading to pneumonia aspiration [94]) and impeding normal breathing [95]. Pneumonia aspiration is a medical emergency when the patient shows continuous vomiting or bleeding from the airway [96].

[2]Throughout this thesis, we will mainly use the term medical aspirator.

  - Hypoxia: It exists in various forms, characterised by a range of psychological factors. The primary condition arises when the body or a specific body region experiences an insufficient supply of oxygen [93]. Hypoxia is also the most common complication associated with suctioning. At times, hypoxia emerges subsequent to suctioning due to the ineffectiveness of the procedure in clearing obstructions. Furthermore, during the suctioning process, the removal of obstructive secretions also results in the removal of oxygen. As such, extending the suctioning process could increase the likelihood of inducing a hypoxic state. An hyperoxygenation before suctioning or even oxygenating the patient after the suctioning can prevent from hypoxia [97].

  All these respiratory complications can be avoided through different effective suctioning [93], [98] :

  - Oral Suction: A technique involving the removal of oral secretions, vomit, etc., from the mouth using an aspiration catheter or tube.
  - Rhino-pharyngeal Suction: A technique used to clear the upper airways of obstructive secretions through the use of a single-use aspiration catheter.
  - Endotracheal Suction: A technique aimed at removing bronchial secretions through an intubation tube or tracheostomy cannula, utilising a single-use aspiration catheter.
  - Tracheo-bronchial Suction: Clearing of the tracheal and bronchial respiratory pathways using a single-use aspiration catheter in cases of tracheo-bronchial congestion.

- **Thoracic drainage:** also called chest/intercostal drains, it involves the removal of liquid and gas from the thoracic cavity by applying suction to the patient's thoracic cavity [99]. More precisely, chest tubes are utilised to evacuate blood, fluid, or air from the vicinity of the lungs, heart, or oesophagus. The tube positioned around the lung is inserted between the ribs and into the gap between the inner and outer linings of the chest cavity, known as the pleural space as shown in Figure 2.5. This procedure is carried out to facilitate the complete expansion of the lungs [100].

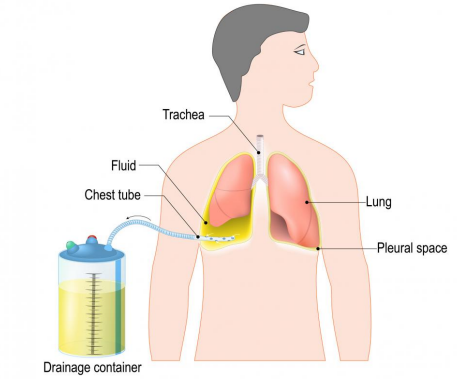


FIGURE 2.5: Thoracic drainage [101].

- **Surgery** : in surgical procedures, the medical aspirator can be used in conjunction with other medical technologies to clear the vision field of the surgeon and then, to facilitate the procedure and ensure patient safety. In or even after surgery, it is used [92], [96] :

  - to remove blood during surgery to clear the area of surgery;

  - to remove mucus, bones, gases and other tissues such as bones from the human body;
  - to remove materials from the surgical procedure: excess of surgical fluids from the intervention of irrigation, residual anaesthetic gases, etc.

- **Supporting other medical technologies:** Suction devices are used in both pre-hospital and in-hospital settings [102]. Indeed, for example, in any pre-hospital "ABC" resuscitation scenario (Airway, Breathing, and Circulation), the primary step for reviving the patient is to clear the obstruction [103]. In hospital settings, these devices can be utilised in conjunction with other medical technologies during various medical procedures [102]. For examples :
  - To remove blood that has built up within the skull after an intracranial or extradural haemorrhage.
  - It can be used to support ventilators when there are waveform, pressure or volume changes [96].
  - Aerosolisation of respiratory particles: during interventions such as dental procedures the suction can reduce the number of aerosolised particles in the air [96].
  - In dentistry to remove tooth fragments while the dentist works on the patient's teeth.
  - In endoscopic surgery, there are devices that incorporate both irrigation and suction functionalities.
  - etc.

2.3.2 Commercial versions of medical aspirator/suction pump

Medical suction pumps encompass a wide range of technologies and functions. An exploration of the spectrum of medical suction pumps available in the market is required to get an idea of all the possible designs for these devices. Each type of pump serves distinct purposes and is used for specific medical procedures. By examining their performances and functionalities, we can more effectively assess which design would be most suitable for emergency scenarios.

There are three types of medical aspirators: manually powered pumps, suction equipment powered from a vacuum or positive pressure gas source, and electrically powered suction equipment [93], [99]. Furthermore, there are two possible designs for the electric suction pump depending on the application: portable or in-hospital.

Manually powered devices

Usually, these pumps function through a bellows arrangement, which is manually actuated by hand. The extent of vacuum generation and displacement depends on the dimensions of the bellows and the force applied by the operator [91]. Manual suction devices represent a solution employed for rapid aspirating fluids from the oral and nasal regions. Notably utilised for emergency situations, these devices are characterised by their compact size, portability, and independence from external power sources [102]. Two examples of manual devices are shown in Figure 2.6. However, this solution has moved away from many hospitals and emergencies because the manual suction created is often unpredictable and inconsistent.

(A) HERSILL manual suction pump [104]. (B) V-VAC Manual Suction Unit [105].

FIGURE 2.6: Manual suction pumps currently available on the market.

Gas source powered devices

These devices are vacuum or positive-pressure gas source powered devices. These mechanisms employ the Bernoulli principle and Venturi effect, as shown in Figure 2.7. This illustrates that when a gas traverses a constriction in a tube, it leads to an augmentation in flow, subsequently resulting in a reduction of pressure. This phenomenon facilitates the entrance of suctioned materials into the tube due to the pressure difference. In general, the driving gas creating the vacuum effect can be in the form of compressed air, oxygen or steam [91]. Figure 2.8 shows commercially available suction devices by Venturi used in hospitals.

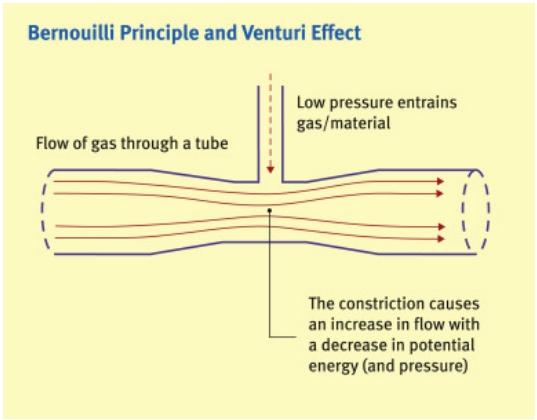


FIGURE 2.7: The Bernoulli principle and Venturi effect [91].

(A) High performance Venturi suction device [106].

(B) Pneumatic surgical suction pump with Venturi effect [107].

FIGURE 2.8: Gas source powered suction pumps currently available on the market.

Electrically powered device

This category of medical aspirator uses an electric motor-driven suction pump. It uses electrical energy to create negative pressure, using a vacuum pump, enabling it to draw in fluids, gases, or particles from the patient's body [90].

Electric and in-hospital devices Two main types of medical suction devices are commonly used in hospitals due to their weight and lack of portability.

- The first type is referred to as stationary, as it is designed to be mounted directly on the walls of hospitals, dental clinics, ambulances, and various other settings where patient mobility is not required [108]. It can also be integrated into medical facilities for surgical procedures and, therefore, becomes part of a monitoring system.
- Another mobile alternative is also viable within hospital settings. The medical suction unit can be placed on a trolley for use in emergency care scenarios, particularly during surgical interventions within the hospital. Figures 2.9 depict the setup of electric suction pump devices in a hospital context.

Electric and portable devices Portable medical aspirators are the most diversified and commonly used, as they can be employed in hospitals and emergency situations. They are compact and lightweight enough to facilitate easy transportation and are powered by AC power and equipped with a battery for field use [108].

2.3.3 Selection for an open-source implementation

As part of this open-source project, we aimed to create a versatile medical device capable of being used both in a hospital setting, (such as attaching it to a trolley), and in emergency situations (field use). During the development of the state-of-the-art for medical aspirators, we aimed to identify a model suitable for both emergency and in-hospital use, while accommodating various use cases. The electrically powered portable medical aspirators appear to be more suitable and promising for this objective. Consequently, the following sections

(A) Wall-mounted electric aspirator [109].

(B) Electric aspirator on a trolley [110].

FIGURE 2.9: In-hospital electrically powered suction pump.

(A) Vario 18 and 18c/i for small surgeries and airway suctioning [111].

(B) New Askir 30 cami portable suction pump [112].

FIGURE 2.10: Portable electric suction pump.

of this thesis will outline the design process steps and explore extensive research concerning portable electric medical aspirators, focusing on their use for emergency surgical procedures, for airway clearance requirements, and optimisation for in-hospital uses.

2.3.4 Performances and characteristics comparison

We will focus on electrical medical suction devices as they offer greater control, reliability, durability and versatility compared to manual and pneumatic suction devices. To ascertain the main features and performance of various models of electric medical suction devices, we will proceed to a comparison table between the models for in-hospital medical suction pumps (Table 2.1) and another for portable medical suction pumps (Tables 2.2). The tables show that the weight is the most distinguishing factor when comparing the two types of medical suction devices with an average of 17.3 kg for in-hospital devices and 3.5 kg for portable variant. Low weight and small size serve as a significant advantage for

portable medical suction devices, especially in emergency situations. Airflow rates, meanwhile, vary widely between models, although they are considerably higher for in-hospital suction pumps. Similarly, the achieved maximum vacuum levels remain more substantial for in-hospital suction pumps, with an average of 0.89 bar, compared to portable ones which have an average maximum vacuum level of 0.74 bar.

When it comes to establishing prices, acquiring cost information for medical devices is often challenging. Based on available data, the least expensive suction pump is a portable model priced at 219 €, while the priciest option is 4300€, a trolley-mounted pump designed for in-hospital use. By taking the average costs of eleven portable medical suction pumps (nine of which are shown in Table 2.2), we obtain an average price of 678.9€ (VAT excl.). For an in-hospital variant, the average of costs in Table 2.1 is 1732.8€. The table 2.2 indicate that among 9 portable medical aspirators for which the price is noted, a variety of five remains at a cost below 678.9€. Higher prices for hospital-grade medical aspirators generally reflect enhanced performance levels, additional features, and cart-mounted assembly for device portability. Overall, medical aspirator prices vary significantly based on machine features and brand. Notably, the cost of some portable pumps can even be comparable to certain hospital-grade models.

TABLE 2.1: Characteristics and performances comparison of in-hospital suction pumps.

In-hospital suction pumps						
Characteristics	**Medela Basic Aspirator [113], [114]**	**Medela Dominant Flex Aspirator [113], [115]**	**CA-MI HOSPIVAC 400 [116], [117]**	**HOSPI PLUS 2x4 [118], [119]**	**YX930D [120], [121]**	**S0002028 Unicef Pump suction [122]**
Weight [kg]	9.01	9.07	20	20	22.5	23.1
Dimensions [cm]	21.08x30.5x35.6	21.08x30.5x35.6	46x85x42	46x85x42	46.5x42.5x92	48x85x44
Air flow rate [l/min]	30	40 to 60	90	90	40	30
Vacuum pressure [bar]	0.9	0.95	0.9	0.9	0.9	0.8
Noise level [dB]	45	40	46.5	46.4	60	60.1
Use	In hospitals, clinics and medical practices	In hospitals, clinics and medical practices	Surgery	Surgery	Surgery	Surgery
Price [€]	2977 (VAT incl.)	4309	673 (VAT excl.)	1150 (VAT excl.)	390 (VAT excl.)	897,61 (indicative price)

TABLE 2.2: Characteristics and performances comparison of portable suction pumps.

Portable suction pumps					
Characteristics	**DeVilbiss 7305D [113], [123]**	**VacuMax [113], [124]**	**EuroLite [113]**	**Gomco OptiVac Model G180 [113], [125]**	**Laerdal LCSU 4 [126]**
Weight [kg]	1.72	2.27	4.5	5.2	1.5
Dimensions [cm]	22.9x17.8x20.3	31.5x24.9x20.6	30x14x33	42.7x19x23.9	28.2x25.2x25.8
Air flow rate [l/min]	27	25	12	>30	30
Vacuum pressure [bar]	0.1 to 0.73	0.2 to 0.7	0.8	0.03 to 0.73	0.73
Power Sources	DC battery and DC cord	DC battery and AC power	Battery	DC battery and AC power	DC battery and AC power
Battery autonomy	60min, rechargeable	50min, rechargeable	NA	3h, rechargeable	45min, rechargeable
Use	Clear airways	NA	NA	NA	Clear airways
Price [€]	291,64	219.5	NA	891,77	679 (excl. VAT) and 814.8 (incl VAT)

Portable suction pumps					
Characteristics	**S-SCORT Ten [113], [127]**	**Vario 18 Medela [128], [129]**	**Easy Vac Aspirator PM60 [130]**	**Schuco S130A [131]**	**Unicef S0002641 [132]**
Weight [kg]	4.5	3.5 to 4.2	NA	NA	5.5
Dimensions [cm]	24.1x17.8x35.6	38x17x28.5	NA	NA	28.2x25.2x25.8
Air flow rate [l/min]	>30	18	NA	40	$\geq$ 33
Vacuum pressure [bar]	0.16 to 0.7	0.75	0.85	NA	0.7
Power Sources	DC battery and AC power	DC battery and AC power	AC power	AC power	AC power & DC battery
Battery autonomy	30-45min, rechargeable	30min, rechargeable	-	-	60min, rechargeable
Use	NA	Surgical and airways	NA	NA	Clear airways
Price [€]	1236.96	1142.53 (VAT excl.)	315,19	453,75	378,23 (indicative price)

2.4 Design Inputs: Requirements and specifications

As explained in Section 1.3.2, medical devices are highly regulated. They must meet a number of requirements before they can be certified and thereby marketed. A medical aspirator is classified as Class IIa (under EU MDR 2017/745) [133]. It must therefore meet the European regulation for this class of medical devices. Moreover, it is also subject to international standards. In its MeDevIS database, the WHO provides for some medical devices a summary of the most important requirements it must meet, as well as the standards to which it is subject. For a medical aspirator/suction pump electrically powered, three international standards apply:

- IEC 60601-1 Ed. 3.1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Ed. 3.0:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- ISO 10079-1:1999 Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements.

The ISO standard tailored to this medical device is thereby the ISO-10079, which is split into four documents, as listed in Table 2.3. The first three documents contain requirements specific to the different types of aspirators according to their power source: manual, electricity and gas. The last document contains general requirements applicable to all kinds of medical suction pumps. However, Saketh R. Peri et al., in their article *Portable Medical Suction and Aspirator Devices: Are the Design and Performance Standards Relevant?* [103], criticised the lack of consideration given to the clinical needs and criteria of portable medical aspirators for pre-hospital use (size, weight, etc.) in the ISO10079 standard. They have reviewed the requirements and proposed improvements that take these additional needs into account.

TABLE 2.3: The four medical aspirator international standards proposed by the ISO [134]–[137].

Code	Name
ISO 10079-1:2022	Medical suction equipment — Part 1: Electrically powered suction equipment
ISO 10079-2:2022	Medical suction equipment — Part 2: Manually powered suction equipment
ISO 10079-3:2022	Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source
ISO 10079-4:2021	Medical suction equipment — Part 4: General requirements

Specifications

To create the first prototype of an open-source medical aspirator, we use the international standards (ISO10079-1 and ISO10079-4) to ensure regulatory alignment and the achievement

of necessary performance benchmarks, instead of regulatory certification because they are broader and not specific to the device performance[3]. We have grouped all the requirements that apply to electrically powered medical aspirators by looking at the ISO standard, as well as the summary provided by the WHO [138] and the improvements brought by Saketh R. Peri and his team. This set of requirements (called specifications) allows us to identify the performance that our prototype must achieve, as well as the functionality that it must implement. Moreover, in this section, we will only outline the most relevant requirements. The full specifications (with the source of each requirement) are available in Appendix A.

According to the ISO10079 norm, medical aspirators are labelled regarding their maximum vacuum and free airflow performance, as shown in Table 2.4. During our analysis of the devices available on the market, we noticed that most were high flow/high vacuum. Therefore, we decided to implement this level of performance in our prototype.

TABLE 2.4: Vacuum levels and free air flows for the category stated by ISO10079-4.

Category	**Vacuum level [kPa]**	**Free air flow [l/min]**	**Maximum time allowable to reach vacuum level and free air flow [s]**
High vacuum/High flow	≥ 60	≥ 20	10
High vacuum/Low flow	≥ 60	< 20	10
Medium vacuum	20 to 60	≥ 20	10
Low vacuum/Low flow	< 20	< 20	10
Low vacuum/High flow	< 20	≥ 20	10
Thoracic drainage for adults	< 10	> 15	5

We began by establishing the functions that a medical aspirator must perform (Table 2.5) and classifying the requirements according to them (Table 2.6).

TABLE 2.5: Main Function (M.F) and Constrain Function (C.F) a medical aspirator should perform.

Functions	
Type	**Description**
M.F. 1	Evacuation of gas, fluid, tissue, or foreign materials from the high airways
M.F. 2	Suction of blood, secretions, and other liquids for medium-level surgery interventions
C.F. 1	Fluid collected in a collection container via a suction tubing
C.F. 2	Electrically powered
C.F. 3	The least noisy possible
C.F. 4	The equipment must not pose a risk to the patient
C.F. 5	Easy to use by a health user
C.F. 6	Setting of the suction level
C.F. 7	Should be portable/transportable

[3]Future work must involve analysing the regulations thereby the prototype can become a fully-fledged medical device. This was not carried out in this thesis due to the available time constraints.

TABLE 2.6: Most relevant requirements of the specification (Appendix A).

Requirements	
Type	**Description**
Req M.F. 1/2.1	Sucking up a liquid
Req M.F. 1/2.2	Maximum vacuum not less than 450 mmHg (60kPa) (adjustable by control)
Req M.F. 1/2.3	Maximum suction capacity not less than 20 l/min (air)
Req M.F. 1/2.4	Maximum time allowable to reach vacuum level and free air flow shall be 10s
Req M.F. 1/2.5	Suction equipement intended for pharyngeal suction shall evacuate $\geq$ 200ml of simulated vomitus in not more than 10s
Req M.F. 1/2.7	The accuracy of the vacuum levels shall be within ±10% of the set or fixed vacuum level at zero flow (of liquid)
Req C.F. 1.1	Collection containers shall have a usable volume of at least 500mL
Req C.F. 1.5	Collection containers shall preferably have an automatic cut-off when full to prevent ingress of fluid to pump
Req C.F. 1.6	Overfill protection devices shall not activate until at least 90% of the indicated maximum capacity of the collection container has been reached
Req C.F. 1.8	Means shall be provided to prevent foam from passing the collection container into the vacuum source
Req C.F. 1.9	Collection containers should be disposable or autoclavable
Req C.F. 1.10	Leakage into the collection container assembly shall be <1kPa pressure drop
Req C.F. 1.11	Collection containers shall not implode, crack or permanently deform [...] after being subjected to a pressure of either 120% of the manufacturer's recommended maximum vacuum level or 95kPa below atmospheric, whichever is the stronger vacuum level, for 5min.
Req C.F. 1.13	Suction tubing shall have an inside diameter $\geq$ 8mm
Req C.F. 2.3	Powered preferably also by internal, rechargeable, replaceable battery
Req C.F. 3.1	Sound level not higher than 70 dBA
Req C.F. 4.2	Filter and overflow valve incorporated to the collection container to prevent cross-contamination (e.g. shatterproof material, overflow protection system)
Req C.F. 4.3	Negative pressure protection: If a means to limit the maximum vacuum level is fitted, the vacuum shall not exceed the maximum vacuum level by more than 10%
Req C.F. 5.1	Suction equipment shall be designed to be operated by one person, unaided
Req C.F. 6.1	Be provided with a means to easily set the device and see the choosing setting
Req C.F. 6.2	User settable valve shall allow adjustment of suction delivered to the patient
Req C.F. 6.3	Should display suction generated
Req C.F. 7.1	Max 2.25 Kg

2.5 Vacuum theory and convention

Vacuum definition

Vacuum is defined as a space in which the pressure is below atmospheric pressure. The standard atmosphere is the pressure for the normal state of a gas at a temperature of 0°C. By definition:

$$\begin{aligned} 1\ standard\ atmosphere &= 1.01325 \text{ x } 10^5 \quad [Pa] \\ &= 1013.25 \quad [mbar] \end{aligned}$$

Vacuum measurement

There are two ways to measure and express vacuum (illustrated in Figure 2.11), based on a reference pressure:

- **Absolute pressure** is measured in relation to absolute vacuum (also called perfect vacuum).
- **Relative pressure** is measured relative to ambient atmospheric pressure.

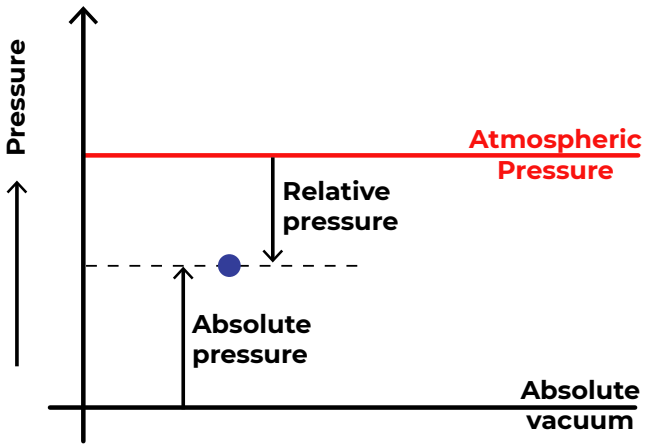


FIGURE 2.11: Schematic of the different pressure measurement types

In general, relative pressure is positive for pressure above atmospheric pressure, and negative below it (vacuum). However, in cases where a certain publication exclusively deals with vacuum-related topics (as in this thesis), it is occasionally observed that relative pressures are sometimes expressed without the minus sign.

Pressure units

The unit of pressure in the International System of Units (SI) is the pascal [Pa]. However, other units exist (Table 2.7) and are used depending on the specific field of study.

TABLE 2.7: Common units of pressure

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

The most widely used units in vacuum technology are pascal [Pa] and bar [bar].

Convention used in this thesis

Throughout this thesis, we will use the concept of relative pressure. All pressure values mentioned (unless otherwise stated) are therefore expressed with respect to atmospheric pressure, either with or without a minus sign.

The primary unit used will be bar. However, Pa is employed when referencing pressure levels from sources such as the ISO standards.

The following example (Figure 2.12) illustrates the convention and terminology used when expressing pressure, to avoid any misunderstanding:

Initially, the pressure was set to 600 mbar, and the vacuum level remains constant between t0 and t1. Between t1 and t2, the pressure decreases[4] *to reach -350 mbar, but then increases shortly afterward to stabilise around -700 mbar after t3. The final vacuum level (after t3) is thereby higher than the initial one (i.e. the final vacuum level is stronger than the initial level).*

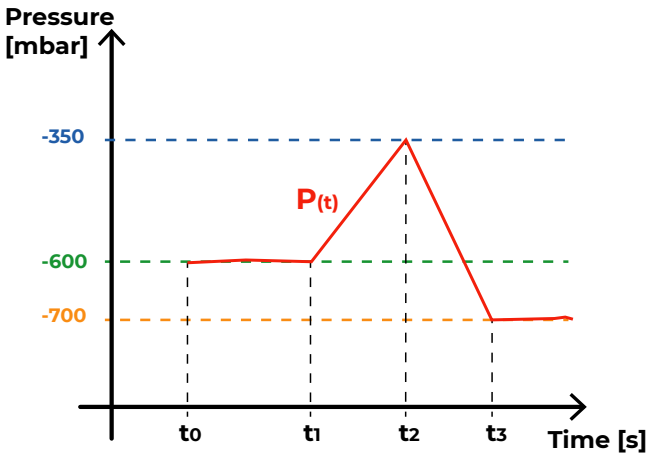


FIGURE 2.12: Example of a pressure variation over time.

[4]The use of *decrease* may appear counterintuitive, but for a clearer understanding, one can visualise the arrow representing the relative pressure in Figure 2.11 becoming smaller.

Chapter 3

Design and manufacture of the prototype

This chapter is dedicated to the design and prototyping of an open-source medical aspirator, from design, and choice of components to manufacturing. It is the Design Process and Outputs stages. The design is based on criteria and performance derived from the specifications (Table 2.6). But before delving into that, it is important to grasp the physics behind this medical device to better comprehend its design.

Firstly, Section 3.1 sets out the physics behind the medical device, to give a better understanding of its phenomena. This is followed by the design and conception of each part of the device:

- Section 3.2 deals with the vacuum pump selection.
- Section 3.3 discusses the regulation system. It begins by presenting various methods commonly used for vacuum regulation, explores the systems employed in commercially available medical aspirators, and concludes with the analysis and selection of the modes that will be implemented in the prototype.
- The development of the vacuum circuit, along with its constituent elements, will be outlined in Section 3.4.
- Section 3.6 introduces the electrical circuit implemented in the prototype, along with the key components used and their respective functions.
- Section 3.5 presents the overflow protection device implemented in the prototype, its characteristics, and the manufacturing process involved.
- In Section 3.7, the programming of the Arduino will be discussed. This will encompass its overall functionality, key variables, the implementation of regulation modes and their parameters, as well as the inclusion of additional features such as alarms and the level sensor.
- Section 3.8 depicts the structure created to assemble all components, facilitating the use of the prototype.

Then, Section 3.9 can be considered as a user manual. It showcases the user interface and provides step-by-step instructions for proper utilisation of the device. Finally, Section 3.10 concludes this chapter with an overview of the prototype, presenting all its components, as well as a glossary of terms helping to understand the rest of this thesis.

3.1 The physics behind a medical aspirator

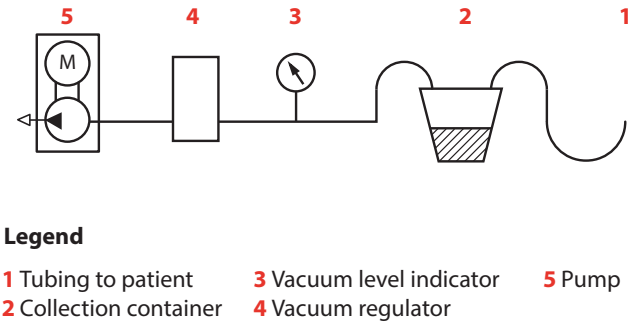


FIGURE 3.1: Explanatory diagram of the medical aspirator (open loop system, with no regulation)

A medical aspirator works by creating a vacuum in a collection container. This vacuum is created by a pump that sucks air from the container to the atmosphere and this involves, on the other side of the container, the suction of the human fluids/tissues. As a reminder, a vacuum is defined as a space in which the pressure is below atmospheric pressure (see Section 2.5 for further details).

The vacuum source (a vacuum pump) depicted at point 5 functions to aspirate air, creating a vacuum within the collection container at point 2. The level of vacuum is governed by the vacuum regulator system at point 4, thereby maintaining the pressure at a constant desired vacuum level within the container. An indicator denoting the vacuum level at point 3 is incorporated into the circuit. It provides continuous real-time information about the vacuum level system within the container. Point 1 represents the inlet of the suction tube, through which bodily fluids such as mucus, vomit, blood or even tissues are aspirated from the patient's body and collected into the container.

Define the flow of the fluids sucked out of the body

Like most of the fluids in our daily lives, the human body fluids are non-Newtonian, this means that they are characterised by a non-constant viscosity, called apparent viscosity, unlike Newtonian fluids (see Figure 3.2 for the example of the human blood viscosity [139]). Their viscosity is defined as resistance to the fluid flow and will vary according to shear rate and shear stress[1]. An everyday-life example illustrating a non-Newtonian fluid is ketchup. Indeed, when it is inside its bottle, it has a high viscosity as it is not subjected to any forces (shear). However, once it is subjected to shear forces, such as shaking the bottle or mixing it, its viscosity decreases, allowing it to easily flow out of the bottle and be poured [143].

[1]In continuum mechanics, shearing refers to the occurrence of a shear strain, which is a deformation of a material substance in which parallel internal surfaces slide past one another. shear rate is the rate at which a progressive shearing deformation is applied to some material. Shear stress is the component of stress coplanar with a material cross-section [140]–[142].

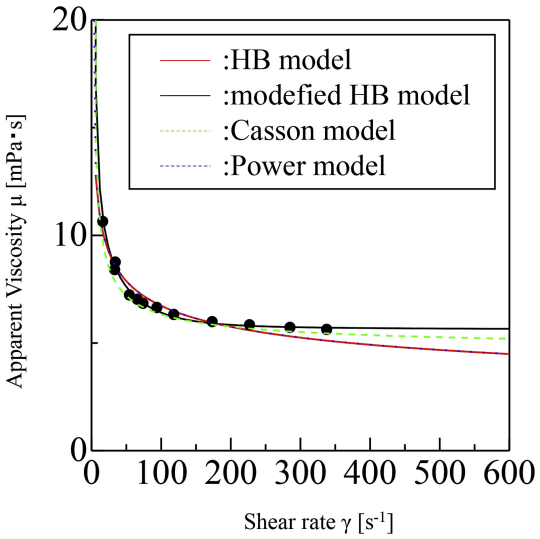


FIGURE 3.2: Changes in the apparent viscosity of blood as a function of applied shear stress for a volume flow modelled by different physical models [139].

The equations leading to the general fluid flow equation in a cylindrical pipe (see Figure 3.3) with a pressure difference across the tube can be found in Appendix B.

$$Q_V = \frac{\pi n}{3n+1}\left(\frac{-1}{2K}\frac{\partial P}{\partial z}\right)^{1/n} R^{\frac{3n+1}{n}} \tag{3.1}$$

where

- Q_V : is the volumetric flow rate of fluid $[m^3.s^{-1}]$.
- $\frac{\partial P}{\partial z}$: is the partial derivative of pressure with respect to the z-axis $[Pa.m^{-1}]$.
- R : is the radius of the cylindrical pipe [m].
- K : is the dynamic viscosity when shear rate equals to one $[Pa.s^n]$.
- n : is the power-law index defining the steepness of the shear stress-shear rate graph as represented in Figure 3.4. According to its value, the fluid will be defined in different ways [144] :
  - n < 1: are the non-Newtonian pseudoplastics, for which the apparent viscosity decreases with increasing stress. For the highest n values, they are plastic bingham fluids with constant n values, but the shear rate occurs from a certain shear forces.
  - n = 1: define a linear graph for a Newtonian fluid, where K is the fluid constant dynamic viscosity (denoted as μ).
  - n > 1: are the non-Newtonian dilatants, for which the apparent viscosity increases with increasing stress.

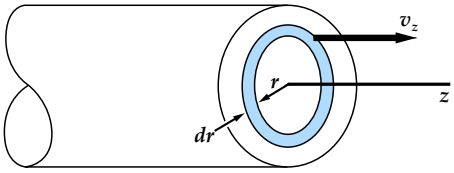


FIGURE 3.3: Cylindrical coordinates in a horizontal cylindrical pipe : v_z is the fluid velocity along z-axis, z-axis is the rotational axis and $r - axis$ is along the pipe radius [145].

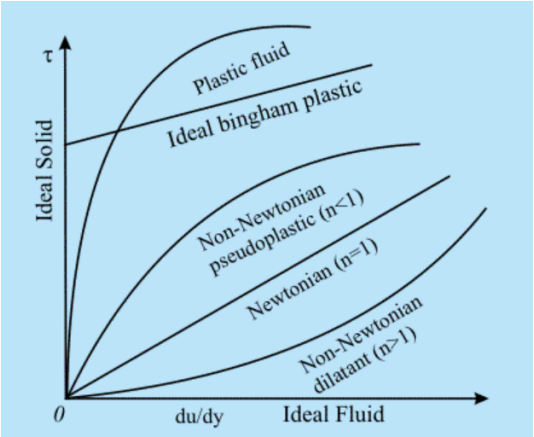


FIGURE 3.4: Shear stress and deformation rate relationship of different fluids (different n values) [144].

Considering the complexity of solving this equation 3.1 due to its non-linearity, we will shift our focus to linear equations, specifically those applicable to Newtonian fluids where n equals 1. This simplifies calculations in order to enhance the understanding of the phenomenon involved in a medical suction pump. By substituting n with 1 in the flow equation 3.1, we obtain the linear expression for Poiseuille's law applicable to the laminar flow of Newtonian fluids :

$$Q_V = \frac{\pi}{4}\left(\frac{-1}{2K}\frac{\partial P}{\partial z}\right)R^4 \tag{3.2}$$

An article studying the *Determination of the effective Viscosity of non-Newtonian fluids through porous media* [146] establishes a connection between Poiseuille's law (n=1, eq 3.2) and the flow expression for non-Newtonian fluids (n≠1, eq 3.1). This article attempts to find an equation for the effective viscosity of non-Newtonian fluids, i.e. to find the analogous average velocity of the fluid. It explains that the most common model to estimate the effective viscosity μ_{eff} of a non-Newtonian fluid has as a first step to define $\mu_{power-law}$ by equalising the flow rate of a Poiseuille's law with the flow of non-Newtonian fluid such as:

$$\frac{\pi}{8\mu}\frac{\delta P}{L}R^4 = \frac{\pi n}{3n+1}\left(\frac{-1}{2K}\frac{\partial P}{\partial z}\right)^{1/n} R^{\frac{3n+1}{n}} \tag{3.3}$$

$$\mu_{power-law} = K\frac{3n+1}{4n}\left(\frac{\delta P}{2KL}\right)^{\frac{n-1}{n}} R^{\frac{n-1}{n}} \tag{3.4}$$

As the power-law viscosity can also be determined such as $\mu_{power-law} = K\left(\frac{\partial u}{\partial y}\right)^{n-1}$, the effective shear rate $\frac{\partial u}{\partial y} = \dot{\gamma}_{eff}$ can be determined by equating both equations of $\mu_{power-law}$. With a few more laborious calculations, we finally obtain the effective viscosity μ_{eff}. This viscosity formulation allows to compensate the change in shear rate of viscosity. Therefore, the effective viscosity value is a single representative viscosity value for fluid flow under a given set of conditions that depends on the model fluid chosen (for further details see reference [147]).

Therefore, to simplify the physics in a medical aspirator we will utilise Poiseuille's law, which links volume flow and pressure drop. As part of our simplification, we will assume a constant viscosity for bodily fluids such as an effective viscosity, allowing to better understand the phenomenon involved in a medical suction pump.

Nonetheless, our intention with these calculations is not to construct an exact physical model of the flow through the suction tube. Instead, we aim to present an approximation of the fluid's behaviour, highlighting the evolution of parameters (pressure and flow rate) throughout the suction process.

Poiseuille law

We assume that the physical principle emanating from the suction of human fluids in a tube is the Poiseuille's law. This law describes the laminar flow of viscous fluids in a cylindrical pipe. It states the theoretical relation between the flow rate of a fluid Q and the pressure difference ΔP at the ends of the pipe with length L as described at equation 3.2, which we rewrite in the following form :

$$Q = \frac{\Delta P \pi R^4}{8L\mu}. \tag{3.5}$$

This equation is assumed for permanent regime (such as $\frac{\partial}{\partial t} = 0$) and incompressible fluid. It is also important to confirm the laminar flow of fluids in order to apply the Poiseuille's law. To achieve this, the Reynolds number calculation will be employed, which is the ratio of inertial to viscous forces. Laminar flow is observed when Reynolds values are below 2000. The Reynolds number is calculated as follows :

$$Re = \frac{\rho c d}{\mu} \tag{3.6}$$

where

- ρ is the fluid density $[kg.m^{-3}]$,
- μ is the fluid dynamic viscosity $[Pa.s]$,
- d is the diameter of tubing $[m]$, and
- c is the velocity of the fluid $[m.s^{-1}]$.

Table 3.1 provides the viscosity μ and Reynolds number values for the various fluids extracted from the human body. The viscosity values found are not explicitly defined as an effective viscosity. They are only used to give an approximation and therefore to give an idea of the properties of the fluid. The viscosity of the blood is estimated such as the relation between shear rate and shear stress for higher shear rate assumes the Newtonian ideal and their slope is the viscosity equalised to $3.2 * 10^{-3}$ Pa.s [148]. These determinations consider an 8mm tubing diameter [2] and a velocity of 0.4m/s, which corresponds to the required minimal flow rate of 200ml (of vomit) in 10 seconds for the pharyngeal suction (see Table 2.6 in Section 2.4):

$$c = \frac{2 \times 10^{-5}[m^3/s]}{A_{SuctionTubing}} = \frac{2 \times 10^{-5}}{\pi R^2_{SuctionTubing}}, \text{ with } R_{SuctionTubing} = 0.004m.$$

TABLE 3.1: Dynamic viscosity and Reynolds number of different viscous fluids.

Types of fluids	**Ranges of dynamic viscosity** μ $[Pa.s]$	**Density** $[kg.m^{-3}]$	**Reynolds**
Blood	3.2×10^{-3} [148]	1055	1055
Vomit	20×10^{-3} to 25×10^{-3} [103]	1020	130.56 to 163.2
Mucus	0.148 to 15 [149]	1010	0.024 to 21.84

To sum up, when the device is in a steady state, i.e. $\frac{\partial}{\partial t} = 0$, Poiseuille's law (equation (3.5)) can be applied to describe the volume flow rate of bodily fluids drawn into the suction pipe, given a finite pressure drop across the pipe ends.

After the container: Pump level

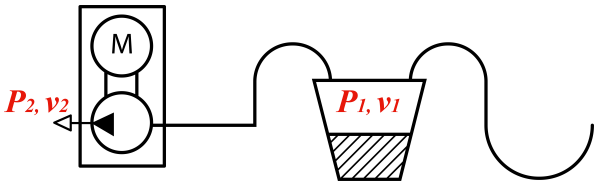


FIGURE 3.5: Diagram of the pressure regulation part of the pneumatic circuit.

To maintain a constant pressure inside the container, the volume inflow must be equal to the volume outflow such that: $Q_{fluid} = Q_{air}$ where Q_{fluid} is the fluid flow on the patient side (the inflow) and Q_{air} is the airflow on the pump side (the outflow). Consequently, to uphold a constant pressure, the pump must intake an airflow volume equivalent to the inflowing fluid volume.

The following Bernoulli [150] equation (3.7) (with states 1 and 2 determined as shown in Figure 3.5) has these hypotheses:

- The fluid is air, perfect gaze.

[2] This specified diameter is employed in accordance with the requirement outlined in the article of Saketh R. Peri et al. [103].

- Incompressible and stationary flow.
- Neglect pressure loss and viscous effect inside the pump.

$$\frac{1}{2}\rho_{air}v_1^2 + p_1 + \rho_{air}gz_1 + \frac{P_{pump}}{Q_V} = \frac{1}{2}\rho_{air}v_2^2 + p_2 + \rho_{air}gz_2 \tag{3.7}$$

where

- $\rho_{air} = 1000[kg.m^{-3}]$, air density,
- $p_1 = p_{container}$ is the pressure [Pa] before the pump (state 1 in Figure 3.5), i.e. pressure in the container,
- $p_2 = p_{atm}$ is the pressure [Pa] after the pump (state 2 in Figure 3.5), i.e. the atmospheric pressure,
- $v_1 = v_2$, the air velocity $[m^2.s^{-1}]$ before and after the pump are equal.
- $z_1 = z_2$, the height [m] of the fluid before and after the pump remains the same.
- $P_{pump} > 0$ is the pump power [W] and,
- $Q_V = Q_{air}$ is the air volume flow $[m^3.s^{-1}]$ through the pump.

From the Bernoulli equation (3.7) adapted for flow passing through a pump, we can determine the pump power. With the different parameter definitions, the pump power required to suck up the needed volume of air is directly related to the following equation:

$$P_{pump} = Q_{air}(p_2 - p_1) = Q_{fluid}(p_{atm} - p_{container}) \tag{3.8}$$

3.2 Vacuum pump

The vacuum pump is a critical component of a medical aspirator, whose main performance comes directly from this element. Without a robust and reliable pump, it would be difficult to effectively remove unwanted substances from the patient's body, potentially compromising the safety and accuracy of medical procedures.

Various vacuum pump types and technologies exist, tailored to the specific vacuum levels they aim to generate. Exploring these technologies is valuable for comprehending the functioning of a vacuum pump. However, as this advanced knowledge is not essential to understand the remainder of the thesis or to choose the aforementioned component, it has been placed in Appendix C. Nonetheless, we strongly encourage its reading, as it confers a more profound insight into vacuum generation.

To select the pump suitable for this device, we have gathered two essential sources of information, namely the requirements for the machine, as well as the level of performance proposed by the commercial medical aspirators. The medical aspirators must meet the following requirements according to the ISO10079 standard and based on its usage as a portable open-source device :

- Maximal air flow rate ≥ 20 l/min

- Maximal vacuum relative pressure $\geq$ 60 kPa (= 0.6 bar)
- Sound level $\leq$ 70dB
- Weight as low as possible by knowing that the device must not be heavier than 2.5kg
- DC motor is required for powering it with a battery (as a future improvement)
- Acceptable price range (for the pump only) for a low-cost open-source philosophy (according to us): [100 ; 300]€
- Origin of the pump was also important in order to limit delivery times (in case of an immediate need)

As presented in the state of the art in Table 2.2, portable medical aspirators commercially available exhibit the following average performances:

- Maximal vacuum pressure [bar]: 0.74bar
- Airflow rate [l/min] : This characteristic varies widely from 12 to >30l/min from one portable medical vacuum to another.
- Weight [kg]: 3.5kg. The lightest medical suction pump found is 1.72kg and the heaviest is 5.2kg.
- They are powered by an external battery with an average autonomy of 46.25 minutes, except for one device with an operational battery of 3h.
- Price [€]: It varies from 220€ to 1200€ depending on the performance and the design of the device.

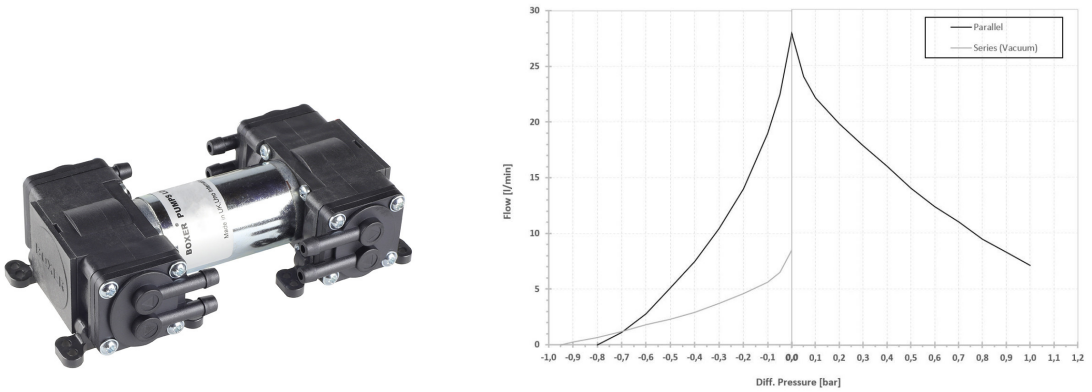
We have to use a safety margin with regard to the pump's performance, i.e. taking a pump with higher performance than that required, as there is a risk of a leak in the vacuum circuit, and it is important that the pump is capable of compensating for failures in the vacuum circuit.

After a long study of the vacuum pumps available on the market and which meet all the performance requirements, we have selected some of them, listed in Table 3.2.

We decided to emphasise the pump's origin by favouring European companies, which also improve short travel distances and delivery times. Among the pumps meeting the various specified criteria, those from specialised pump brands also appeared to be a better choice in order to ensure the pump's quality, robustness and reliability of its announced performance. Given the budget granted by the Foundation that supported our project, we preferred to select a good quality pump that would enable us to be delivered quickly and carry out reliable tests with it. Therefore, we chose the fourth pump presented in Table 3.2: the 3KQ Boxer vacuum pump [151] (Figure 3.6a), which meets all the requirements and is from a reliable German brand. This pump is used in parallel connection to achieve a higher maximum airflow and its performance can be seen in the pressure-airflow curve of Figure 3.6b.

TABLE 3.2: Comparative table of pumps on the market meeting most of the requirements. (NA = Not Available).

Vacuum pumps on the market	Supplier	Pump type	Max. airflow rate [l/min]	Max. vacuum relative pressure [kPa]	Sound level [dB]	Weight [g]	Motor type	Price (VAT incl.) [€]	Origine
Mini electric air pump [152]	**Amazon**	NA	20, 25 or 48	-60, -75 or -85	< 65	600	DC 45W 12V	135,93	China
BD-08VB-S [153], [154]	**Bodenflo**	Piston	20-45	-85	65-75	690	DC 24V	181.59	China
KV8 D-030E [155]	**DürrTechnik**	Piston	30	-100	53	4400	DC 0.1kW 12V	NA	Germany
3KQ [156]	**Boxer**	Diaphragm	28	-80	53	575	DC 18-43kW 12V	260	Germany
Micro air pump [157]	**Alibaba**	Diaphragm	7-22	(-150)/(-350)	NA	NA	DC 12V	31.78	China
N838 KNDC [158]	**KNF**	Diaphragm	32	-90	NA	2200	DC 12V	NA	Europe and USA



(A) 3KQ vacuum pump from Boxer (B) Pressure - airflow curve of the 3KQ Boxer vacuum pump

FIGURE 3.6: The selected pump for our application is the 3KQ Boxer vacuum pump [151].

3.3 Vacuum regulation and measurement

Vacuum measurement and regulation are important features of a medical aspirator. The ability to measure the level of vacuum being applied to the patient's body allows healthcare professionals to ensure that the procedure is being carried out safely and efficiently. Furthermore, the ability to regulate the vacuum level can help to reduce the risk of complications such as tissue damage or bleeding.

In ISO10079, the accuracy of the vacuum regulation is constrained by the following requirement: *The accuracy of the vacuum levels shall be within ±10% of the set or fixed vacuum level at zero flow (of liquid)*. This requirement is illustrated in Figure 3.7.

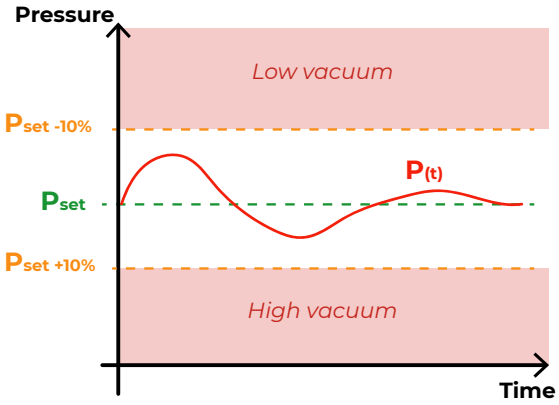


FIGURE 3.7: Illustration of the vacuum regulation requirement. *Pset* represents the set vacuum level at zero flow of liquid (i.e. the setpoint pressure). The two orange dashed lines are the 10% limits.

3.3.1 Common practices

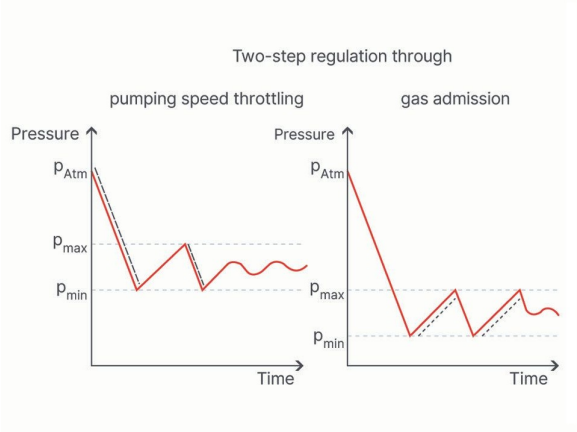
There are two ways to adjust the pressure in a vacuum system: firstly, by changing the pumping speed (by changing the speed of the pump or throttling it by closing a valve); secondly, by admitting gas (by opening a valve). Moreover, two main types of control modes are possible: discontinuous pressure regulation and continuous pressure regulation [159].

Discontinuous regulation

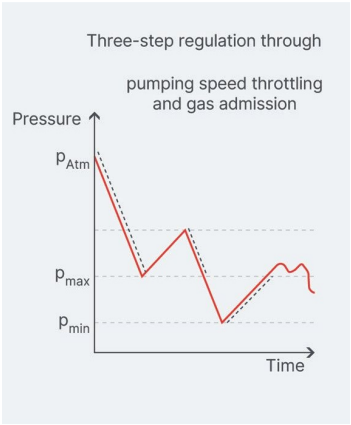
Discontinuous regulation (e.g. two-step or three-step control) specifies a pressure window, within which the pressure can vary, either by using throttling, by gas admission, or by using both for the three-step control, as shown in Figure 3.8. Pressure-dependent switching contacts are required to define the window limits. It does not matter here whether the switch contacts are installed in a gauge with display or whether it is a pressure switch without display.

Continuous regulation

Continuous regulation uses a specified set-point pressure, which must be maintained as accurately as possible. In practice, this regulation can be achieved in two ways: either by using an electric controller, or a mechanical diaphragm controller. However, it is also possible to regulate the vacuum by controlling the speed of the pump with an appropriate controller (e.g. PID controllers), and therefore the airflow removal rate. With this regulation technique,



(A) Two-step regulation schematic diagram.



(B) Three-step regulation schematic diagram.

FIGURE 3.8: Two and three-step regulation schematic diagram. **(A)** In the left diagram, the dashed lines correspond to when the pump is switched on. In the right diagram, they correspond to the valve opening to admit ambient gas into the system. **(B)** The dashed lines correspond either to the pump switched on or to the valve opening [159].

the speed of the pump is continuously changed to match the airflow requirements of the system [160].

Electrical controllers are the combinations of a controller (e.g. PID controllers) and a proportional valve as the actuator. This valve can be a piezoelectric gas inlet valve, an inlet valve with motor drive, a butterfly control valve, a throttle valve, etc [159]. An example of an electrical regulator can be seen in Figure 3.9a.

Mechanical diaphragm regulators (also called mechanical vacuum regulators) work on a force balance principle. An example of a mechanical diaphragm regulator can be seen in Figure 3.9b. There are two types of mechanical regulators: vacuum regulators and vacuum breakers [161].

(A) Electrical controller

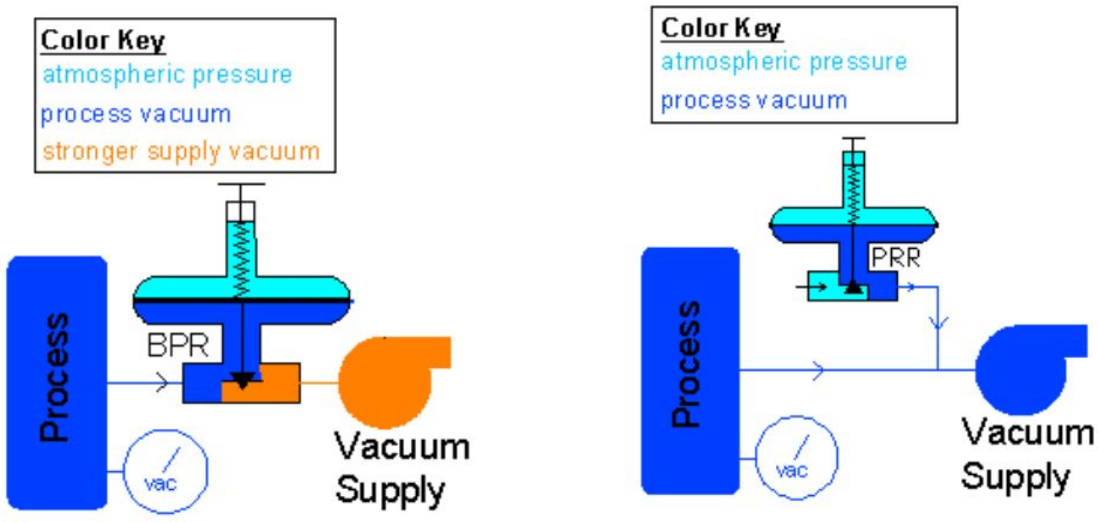
(B) Mechanical diaphragm regulator

FIGURE 3.9: Electrical and mechanical diaphragm vacuum regulators from SMC [162].

Vacuum regulators work by throttling the flow between the vacuum pump and the process, thereby managing the process vacuum. Despite being commonly known as *vacuum*

regulators, this particular type is technically a Back Pressure Regulator since it controls the pressure at the inlet port. The regulator closes to decrease the vacuum level. Figure 3.10a shows the working principle of such a regulator. A spring-loaded diaphragm controls the vacuum pressure. On the lower side of the diaphragm lies the process vacuum (dark blue), and on the top there is the atmospheric pressure (light blue). The spring is pulling up or down to provide the negative setpoint bias. Two cases can arise:

- When the absolute process pressure (or operating pressure) becomes too low (vacuum level too intense), the diaphragm lowers, which results in a restriction of the gas flow between the process and the vacuum pump (orange) that will therefore reduce the vacuum level.
- When the absolute process pressure increases above the setpoint (vacuum level too low), the plunger rises and the airflow between the process and the vacuum pump increases, which thereby increases the vacuum level.



(A) Vacuum regulator controls process pressure by throttling flow to the vacuum pump

(B) Vacuum breaker controls process pressure by allowing bleed air into the entire pump system

FIGURE 3.10: Operating diagram of the two mechanical diaphragm vacuum regulators [161].

Vacuum breakers (also called *vacuum relief* regulators) introduce ambient air into the system to regulate the vacuum level. They are actually a type of Pressure Reducing Regulator because the pressure controlled is at the outlet port, as shown in Figure 3.10b. They also use a spring-loaded diaphragm to regulate the vacuum level. The atmospheric pressure is on the upper side (light blue) and the process vacuum pressure is on the lower side (dark blue). The spring pulls up and down the diaphragm to set the negative setpoint pressure. Two cases can arise:

- When the absolute process pressure becomes too low (vacuum level too intense), the plunger forces the valve to open, resulting in more ambient air into the process.
- When the absolute pressure increases above the setpoint (vacuum level too low), the plunger rises which decreases the in-flow of air.

Vacuum measurement and display

The vacuum can be measured and displayed in several ways. The sensor type depends on the vacuum level to be measured, but also on the regulation system being used, for example choosing between a purely mechanical gauge pressure or a sensor with an electrical output. A pressure gauge is composed of an elastic body, for example, a Bourdon tube, a diaphragm, a capsule or even a bellow, and a transducer to express this vacuum level either mechanically (with amplification) or through an electrical signal. The electrical signal can be performed thanks to several components like variable capacity, variable resistance, piezoelectric, etc [163].

3.3.2 Systems used in commercial machines

We have analysed several commercially available medical aspirators to find out which regulation mode they have and how they measure and display the vacuum level. However, only few brands explicitly present their regulatory system.

Medela [164], one of the leaders in vacuum generation, clearly explains that they use mechanical diaphragm regulators. Nevertheless, they do not specify which type they use (vacuum regulator or vacuum breaker). In general, looking at what medical aspirators are made of and how they work makes it easy to understand that they all use mechanical regulators. Only a few suction pumps are ambiguous about the regulating system used. Indeed, most of them have a large knob without precise graduation and a manometer for displaying the current pressure, as shown in Figure 3.11a and 3.11b. The mechanical vacuum regulator seems to be the gold standard for medical aspirators. Regarding the pressure measurement and display, most use a manometer and few use a pressure transducer with a digital display (light gauge in Figure 3.11c).

In addition, when analysing the technical files of several machines, some (equipped with a battery) mention an intermittent mode (time-cycles of ON and OFF). This has the advantage of saving battery power. For instance, a portable medical electric vacuum characterised by a low flow rate features a programmable intermittence button that enables users to select between continuous suction and three different programmed time intervals as follows: 10 seconds ON - 5 seconds OFF, 20 seconds ON - 10 seconds OFF, or 40 seconds ON - 20 seconds OFF [165].

(A) Interface of the Medela Dominant flex [164]

(B) Interface with regulator knob and manometer for vacuum display [166].

(C) Interface with regulator knob and digital vacuum display (light gauge) [167].

FIGURE 3.11: Interface of selected commercial medical suction pumps to analyse their regulation system and vacuum measurement and display

3.3.3 Analysis and choice of regulation system

Based on the state-of-the-art of the systems used in commercial aspirators, it would appear that the mechanical regulator has become the gold standard. It seems thereby interesting to implement this control mode. However, one practice is widespread does not mean it is always the best. There is often limited research to improve a device when it already conforms to the standards. The example of the Glia stethoscope proves it (Section 1.3). Therefore, we decided to brainstorm and imagine several possible modes of regulation (continuous, discontinuous, intermittent), to compare them on the basis of defined criteria and choose the most suitable one.

We began by putting together our ideas for possible regulation modes that could be implemented in the machine by creating a morphological table (Table 3.3). We imagined continuous, discontinuous and intermittent modes. By intermittent, we mean intermittent powering of the pump (on/off), with the main aim of saving energy (for use with a battery). The classification according to their type (i.e. mechanical, electrical or hybrid) is available in Table 3.4. A few explanations are needed to fully understand them:

- **Continuous with the mechanical regulator:** This system uses a mechanical vacuum regulator (either a vacuum regulator or a vacuum breaker) to perform the continuous regulation.
- **Continuous with PID on the pump (speed variation):** This regulation system uses a PID controller to control the pump speed to continuously match the airflow requirements to maintain a constant vacuum level.
- **Continuous with PID with solenoid valve:** This system aims to use a solenoid valve controlled with a PID controller. The valve, placed between the vacuum pump and the collection container, will quickly open and close to maintain a continuous vacuum level.
- **Continuous with an electrical regulator:** This system uses an electrical vacuum regulator, like the one presented in Figure 3.9a.
- **Intermittent time-cycle:** In this mode, a mechanical regulator is used and set to a given pressure. The pump is subject to an on/off time cycle.
- **Intermittent hybrid time-pressure:** In this mode, the mechanical regulator is set to a given pressure. The ON period of the pump is fixed in time. The OFF is fixed by the pressure level, the pump is switched off and only switched on once the pressure has fallen below a certain threshold.
- **Discontinuous Two-step regulation with solenoid valve:** This regulation system aims to perform a two-step regulation with throttling (as illustrated in Figure 3.8a). The solenoid valve will cut off the vacuum supply without switching off the pump.
- **Discontinuous Two-step regulation with motor pump On/Off:** This regulation system performs a two-step regulation with pump speed throttling (as illustrated in Figure 3.8a). Unlike the two-step system using a solenoid valve, in this mode, the pump is switched ON and OFF to stay in the pressure window.

We evaluated these ideas on the basis of the following criteria:

- Accuracy of the operating pressure

- Resolution of the selection of the operating pressure
- Ease of selection of the operating pressure
- Ease of implementation and modification of the system
- Ease of maintenance
- Power consumption
- Robustness
- Cost

Firstly, we looked for the ideal mechanical regulator for our application, listing (in Table 3.5) the advantages and disadvantages of the two types of mechanical regulator as used in industry. This enabled us to choose the vacuum breaker[3] because it is cheaper, smaller and easily available from websites such as RS or Misumi.

[3]From now on, we will use the term *mechanical vacuum regulator* to refer to the vacuum breaker.

TABLE 3.3: Morphological table of the vacuum measurement and regulations mode solutions.

		Alternatives			
		1	**2**	**3**	**4**
Vacuum Measurement		Manometer	Pressure transducer		
Regulation mode	**Continuous**	Mechanical vacuum regulator	Electrical regulator	PID on solenoid-valve (quick opening/closing of the valve to maintain a continuous vacuum level)	PID on pump (speed variation)
	Discontinuous	Two-step regulation with solenoid valve opening/closing	Two-step regulation with motor pump on/off	Intermittent time-cycle with mechanical regulator for limiting the vacuum level	Intermittent hybrid time-pressure with mechanical regulator

TABLE 3.4: Classification of control modes according to their type, i.e. mechanical (= use of the diaphragm controller), electrical/digital or hybrid.

	Mechanical regulation	**Hybrid**		**Electrical regulation**		
Continuous	Continuous regulation with mechanical vacuum regulator	-		PID on solenoid valve (quick opening/ closing of the valve to maintain a continuous vacuum level)	PID on pump (speed variation)	Electrical regulator
Discontinuous	-	Intermittent time cycle with mechanical regulator	Intermittent hybrid time-pressure with mechanical regulator	Two-step regulation (with solenoid valve opening/closing)	Two-step regulation with motor pump on/off	

TABLE 3.5: Pros and cons of each type of mechanical vacuum regulator according to Equilibar, a mechanical vacuum regulators manufacturer [161].

	Vacuum Regulator	**Vacuum Breaker**
Pros:	• Minimize the gas flow through system, which can be very advantageous where multiple processes share a common vacuum utility. • Minimized gas flow is very desirable for pumps such as oil flooded or oil sealed pumps. • Minimized gas flow may, depending on the pump specifics, reduce electrical energy consumption. Depending on design and sizing, can provide very precise control.	• Are sometimes smaller than Vacuum Regulators because it typically takes less mass flow to reduce the system vacuum. • Useful in protecting certain types of vacuum pumps from exceeding their design vacuum level (i.e. some dry and liquid ring pumps). • Generally less expensive than vacuum regulators.
Cons:	• Must be sized large enough to pass the entire vacuum flow. • For pumps which require a minimum gas throughput (such as liquid ring or dry vane), vacuum regulators may need to be used in conjunction with a vacuum breaker supplied by the pump manufacturer. • Generally more expensive than vacuum breaker.	• For some types of vacuum pumps, the excessive gas flow caused by the vacuum breaker is not desirable or a waste of energy. • For multiple vacuum process sharing a common header, using a vacuum breaker can degrade the performance of the other processes. In some situations, the pressure variations between one vacuum process and another can lead to very poor process control. • In most situations, vacuum breakers do not provide precise control across a wide flow rate window

Secondly, we analysed these control modes in a general way, grouping them into two categories (Table 3.6). Electrical/digital regulation corresponds to the 3rd column of Table 3.4. Mechanical regulation corresponds to the regulation modes using the mechanical regulator. We then analysed each control mode independently and assigned weights to enable the best system(s) to be chosen.

On the basis of this analysis, we have put aside the electric vacuum regulator because it is far too expensive for this type of appliance (around 500€). It is not interesting compared with the costs of other systems, which are much lower. A mechanical vacuum breaker costs around €100-€150 and other electric/digital systems only need a microcontroller and a pressure sensor. We have also put aside the continuous mode which uses a solenoid valve because the switching frequency could be too high and it would generate a lot of noise with this type of valve. The two discontinuous two-step modes are similar in every way (if we put aside the cost of the solenoid valve, which is not the most costly thing). The only difference is that in one case the pump runs continuously and in the other, it does not. This would allow energy savings that could be interesting. This mode will be referred to as *Intermittent two-step* from now.

TABLE 3.6: Comparison of digital/electrical and mechanical regulation modes

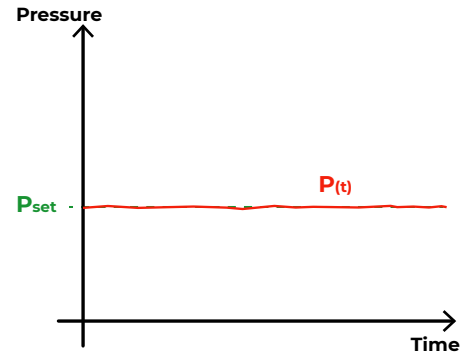
Criterion	Digital/electrical regulation	Mechanical regulation
Accuracy of the operating pressure:	Can be more accurate as it uses real-time pressure measurements to adjust the vacuum pump and maintain a constant pressure	• Vacuum regulators may not be as accurate as digital regulators and may have more difficulty maintaining a constant pressure under changing conditions • May be slower to respond to pressure changes, which may make them less suitable for applications requiring rapid pressure regulation
Resolution of the selection of the operating pressure	Can be programmed to maintain specific pressure levels depending on the application	Cannot be programmed to maintain specific pressure levels depending on the application, which may limit their use in applications requiring high accuracy
Ease of selection of the operating pressure	Easy and quick selection of the desired pressure (pressure can be precisely entered into the controller)	Not as accurate as digital regulation, the knob of the regulator must be turned and the pressure read in real time until it reaches the desired pressure
Ease of implementation of the system	The system is more complex to set up as it requires more hardware, programming of the micro-controller, etc	Easier to set up, but it is possible that such a mechanical regulator would be more complicated to find, compared with a simple pressure sensor + micro-controller.
Robustness	• May be more sensitive to power supply fluctuations and may require additional adjustments to compensate for these fluctuations. • More sensitive to environmental changes (humidity, heat,...)	• Can be more robust and resistant to power supply fluctuations • More robust to environmental changes (humidity, heat,...)
Cost	• Built-in electrical regulator cost around 500€ • Arduino + pressure transducer < 50€	• Vacuum breakers cost around 100€-150€

Given that it was difficult to distinguish theoretically between the remaining modes, we decided to implement four modes in our device so that we could test them and evaluate their performance experimentally. The modes implemented are the following (and will be named like that in this thesis):

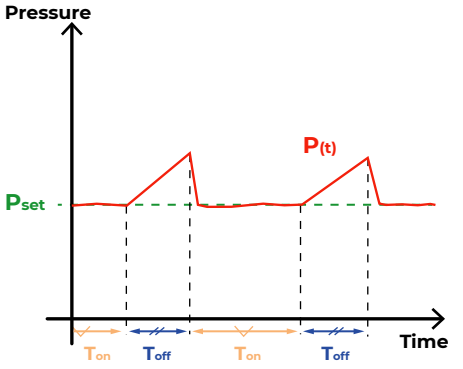
- Continuous (with mechanical vacuum regulator) (Figure 3.12a)
- Intermittent time-cycle (Figure 3.12b)
- Intermittent hybrid time-pressure (Figure 3.12c)
- Intermittent two-step regulation (Figure 3.12d)

The continuous mode with PID on the pump (for a speed variation) will not be implemented, but we aim to test if such a regulation mode is feasible for our kind of vacuum pump

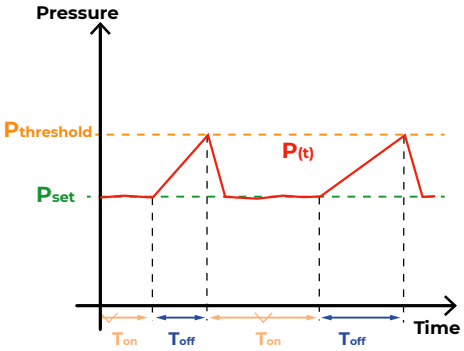
(i.e if there is a significant variation of the airflow rate from the pump based on the supply voltage). Furthermore, we will assess the feasibility of covering the required vacuum range and achieving precise vacuum levels by adjusting the pump's power supply, with the aim of a potential viable regulation mode. These tests will be carried out in Section 5.2.2.



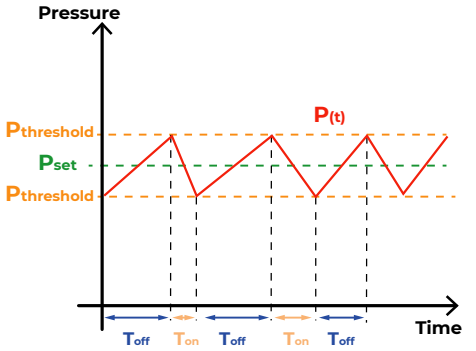
(A) Continuous mode



(B) Intermittent time-cycle with fixed T_{ON} and T_{OFF}



(C) Intermittent hybrid time-pressure with fixed T_{ON} and variable T_{OFF} depending on the vacuum level



(D) Intermittent two-step regulation with variable T_{ON} and T_{OFF} depending on the vacuum level

FIGURE 3.12: Theoretical pressure variation and regulation behaviour for the four implemented regulation modes. T_{ON} and T_{OFF} are respectively the time range when the pump is switched on and off (for the intermittent modes). *P_set* is the set vacuum level (i.e. the setpoint pressure), *P(t)* is the real pressure being measured and *P_threshold* is the vacuum threshold.

Components selection

Some research is now needed to find the components for the regulation systems and to measure and display the pressure by looking at the websites that are easily available to us, such as RS, Digikey, Farnel or Misumi. We need the following components to implement the four regulation modes mentioned above:

- A mechanical vacuum regulator (a vacuum breaker) is needed. As explained above in the comparison (Table 3.6), vacuum breakers are cheaper and smaller. Moreover, only vacuum breakers are available in Misumi and RS. Therefore, we opted for the IRV10 (Figure 3.9b) from SMC [162], which can regulate vacuum over a range from -100 to -1.3 kPa, as well as handling air flows of up to 140 L/min.

- For the intermittent two-step regulation, as well as the intermittent hybrid time-pressure, we need to read the pressure, process the information, and switch the pump on or off accordingly. To do this, we opted for an Arduino Nano and a pressure transducer. Following a market survey of available sensors, we chose the Panasonic ADP5111, which is suitable for the vacuum range being measured [168]. This pressure sensor read relative pressure up to -100 kPa.
- A Manometer is also needed for the continuous mode (as well as for the intermittent time-cycle). Although this isn't really necessary as the device will already have a pressure sensor, we still want to test the use of this component too. The prototype will therefore have two pressure displays.
- Since we will use an Arduino to read and process the data from the pressure sensor, it will also be used to perform the intermittent function of switching the pump on and off.

3.4 Vacuum circuit

As explained earlier in the physics Section 3.1, a medical aspirator works on the principle of creating a vacuum in a bottle that collects the fluids of the human body. To do this, a vacuum source and a regulation system that can generate chosen negative pressure in the container and a whole circuit to guide air and fluid flows are needed. As the suction capacity of the device will depend on the vacuum circuit, it is important to have an efficient vacuum source and good-quality vacuum components to connect the circuit elements.

In the literature, the different components identified for the operation of suction machines are as follows [91], [169], [102]:

- Vacuum pump
- Vacuum regulator
- Patient tubing / Suction tubing
- Connection tubing / Intermediate tubing
- Disposable canister / Collection container
- On/off switch
- Vacuum gauge
- Suction catheter / Surgical suction accessory: the design varies based on the procedure

On the other hand, the following components are added to secure the device:

- Filter and float: These protective mechanisms prevent the contamination of the pump and the passage of fluids from the container into the vacuum regulation side (including pump, regulator, and tubing).
- Cut-off valve: This valve prevents pump contamination in case of malfunction of the float or filter.

TABLE 3.7: Vacuum circuit components in different commercial medical aspirators.

Mucosity portable suction pump AS-12V BR [170]	**Vario 18 suction pump portable Medela** [129]	**Mucosity portable suction pump CA-MI AS-200** [171]	**Surgical portable suction pump ATMOS C 451** [172]	**Portable suction pump ATMOS C 341 battery** [173]
• vacuum pump, • vacuum regulator, • suction tubing in silicone, • biconical connector, • intermediate tubing in silicone, • one suction jar 1l, • overflow protection (stop valve), • anti-bacterial filter.	• vacuum pump, • vacuum regulator, • sterile suction tubing PVC with fingertip, • sterile intermediate tubing PVC, • silicone tubing, • tube connectors, • suction jar 1.5l with bag protection or not, • overflow protection (float and stop valve), • bacteria filter.	• vacuum pump, • vacuum regulator, • silicone tubing, • tube connectors, • suction jar 1l autoclavable, • overflow protection (safety valve), • bacteria and hydrophobic filter single-use.	• vacuum pump, • vacuum regulator, • tube kit DDS, • suction jar DDS, • overflow protection (safety valve), • bacteria filter.	• vacuum pump, • vacuum regulator, • reusable suction tubing in silicone, • single-use suction tubing, • intermediate tubing, • tube connectors, • vacuum stoppers, • suction catheter, • suction jar 1l, • overflow protection (floating ball), • bacteria filter.

In practice, Table 3.7 presents the different vacuum systems found in medical aspirators on the market. These vacuum circuits are similar to the presented theoretical design, with the exception that not all of them incorporate additional safety elements. The final vacuum circuit that we propose, based on the bibliography and the existing devices, is depicted in Figure 3.13.

Model of the vacuum circuit Figure 3.13 shows the vacuum circuit as initially designed with all its components. This model was based on the regulation systems chosen in Section 3.3 and of course, on the exploration of existing vacuum circuits. Each of these components and their use in the circuit are described below.

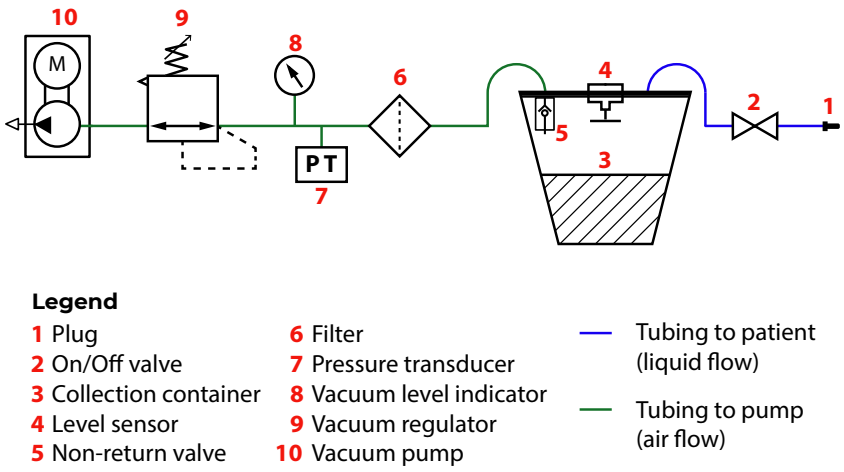
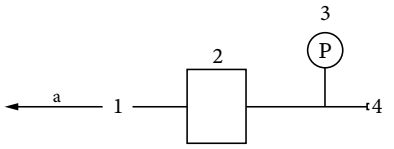


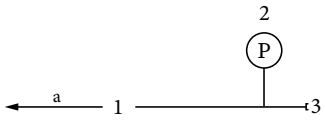
FIGURE 3.13: Designed vacuum circuit based on research carried out on commercial medical aspirators.

Vacuum source and mechanical vacuum regulator The vacuum source consists of a vacuum pump selected in Section 3.2 above and for three out of four regulation modes the selected vacuum level is maintained by a vacuum regulator: continuous regulation, intermittent time-cycle regulation, and intermittent hybrid time-pressure regulation. These components are connected by tubes and vacuum connectors, which can be seen in Figure 3.14a. In the setup of the fourth mode (intermittent two-step regulation), the vacuum regulator is removed from the circuit. As the regulation is carried out through an Arduino controller for this fourth mode, there is a direct tubing connection between the pump and the container (see Figure 3.14b).



Key
1 *vacuum source*
2 *vacuum regulator*
3 internal *vacuum level indicator* (P)
4 tubing to the *collection container assembly*
a direction of flow

(A) vacuum system for continuous, intermittent time-cycle and intermittent hybrid regulations.



Key
1 *vacuum source*
3 internal *vacuum level indicator* (P)
4 tubing to the *collection container assembly*
a direction of flow

(B) Vacuum system for the intermittent two-step regulation.

FIGURE 3.14: Vacuum system according to the regulation modes.

The tube connections linking the pump to the air circuit are connected in parallel (see Figure 3.15a), as this configuration allows the pump to achieve a higher maximum airflow but a lower maximum vacuum of 0.15bar than in a series connection according to the pump datasheet as shown in Figure 3.6b. The tubes fit directly around the pump inlets, so a disadvantage is that there is no way of ensuring a perfect seal between the tubes and the inlets. The vacuum regulator has vacuum connectors for tubes with an external diameter of 8mm. We can set different vacuum levels, first by lifting the grey knob above the regulator, then by turning it to stabilise the vacuum displayed on the manometer at a desired level, and finally by pressing the knob to record the pressure (see Figure 3.15b).

(A) Vacuum pump and its parallel tubing connections.

(B) Vacumm regulator, its knob above and its integrated gauge.

FIGURE 3.15: View of the pressure regulation components.

Tubes and connectors The tubes (Figure 3.16) used for the prototype are made of PVC and vary in diameter (internal diameter of 9mm, 7mm, 5mm and 3mm) and length, as all the circuit components do not have the same connection dimensions.

It was necessary to add several vacuum connectors, shown in Figure 3.16, between the tubes in order to connect other components to the circuit.

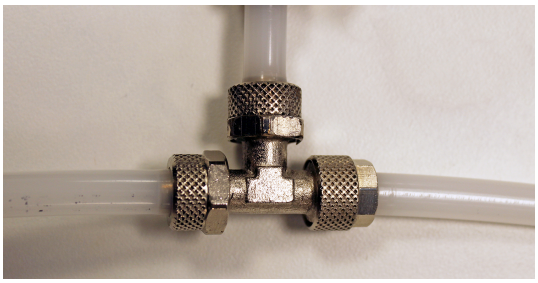


FIGURE 3.16: Tubes and vacuum connectors used in the vacuum circuit.

The whole vacuum circuit dimensions are described in Figure 3.17. It illustrates all the tubing size diameters needed to interlock with the various circuit components and this, using mostly vacuum connectors. All these connections are actually weaknesses of our model from an airtightness point of view, in particular the pneumatic connector, which is not intended for vacuum applications. These leaks generated by the different connections will be evaluated experimentally in Section 5.3.3. In Figure 3.17, the setup for the three modes is also illustrated: continuous regulation, intermittent time-cycle regulation, and intermittent hybrid time-pressure regulation. To obtain the setup of the fourth, we simply remove the vacuum regulator and the connections remain identical.

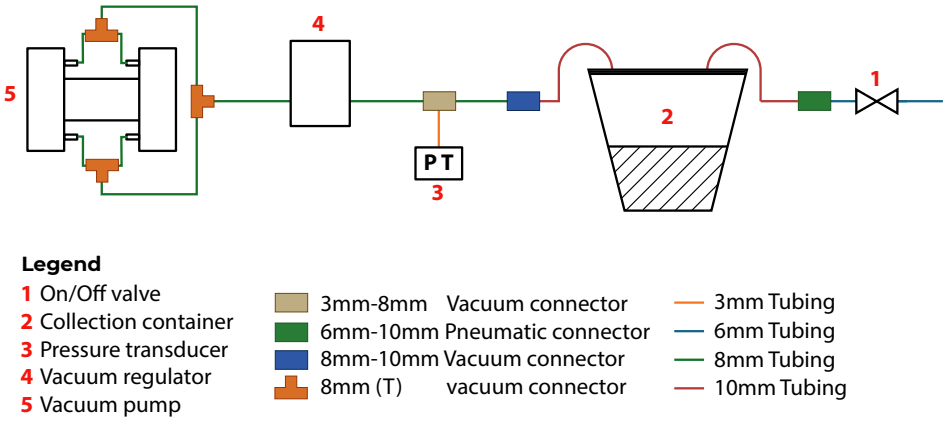


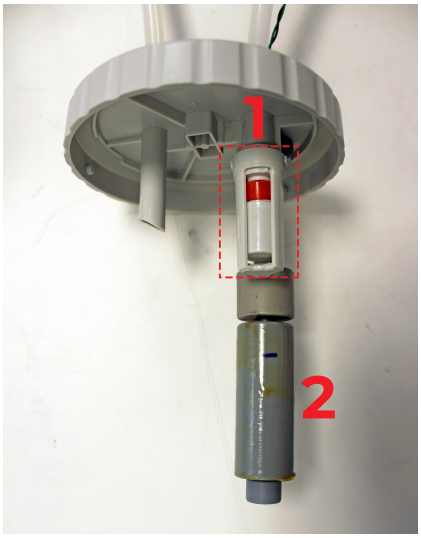
FIGURE 3.17: Tube connections in the vacuum circuit and their dimensions (external diameter for tubes and internal diameter for connectors).

Vacuum level indicators The vacuum system contains a pressure transducer connected in series with the circuit but also a pressure gauge directly integrated into the vacuum regulator to see the pressure changes when the regulator knob is moved. The additional pressure transducer for the tests was connected in series too as shown in Figure 3.18.

FIGURE 3.18: Series connection in the vacuum circuit. The example is illustrated with the pressure transducer.

Collection container There is also a collection container in which the extracted secretions are drained. The container (Figure 3.19a) is designed specifically for medical suction pumps. To carry out tests and obtain relevant results, it was important to use a container capable of withstanding vacuum of minimum -0.6 bar and not collapse in reaction to the vacuum applied. Therefore, we opted for quality and choose the CA-MI flacon collect of 1l [174]. As it is used for commercial medical aspirators, it meets the requirements such as a clear display of graduations, vacuum-proof, autoclavable and it has a non-return valve (Figure 3.19b) on its lid outlet to protect the vacuum source if the fluid volume rises too much.

(A) Collection container with the volume graduations and the non-return valve.



(B) Non-return valve integrated into the container lid (1) and the level sensor (2).

FIGURE 3.19: Overviews of the collection container and its overflow protection system.

On/off valve An on/off valve (Figure 3.20) is integrated into the circuit on the fluid supply side of the container in order to close the rest of the circuit to the atmosphere and thus generate a vacuum in this container.

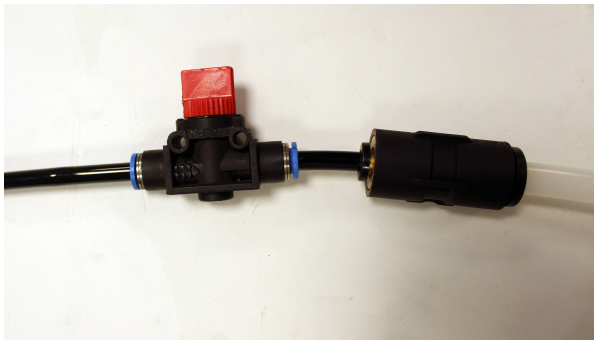
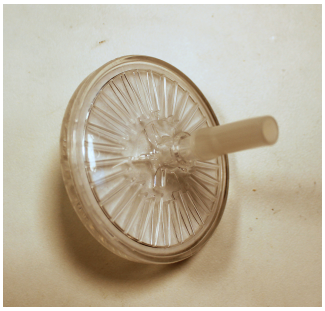


FIGURE 3.20: On/off valve used to close the inlet port to the atmosphere (left) and 6mm-10mm pneumatic connector (right).

Level sensor As seen in Table 3.7, most of the commercial suction pumps are equipped with an overflow protection system such as a float, a floating ball or a non-return valve. In general, this system is more common in non-portable aspirators. The designed vacuum circuit is composed of a non-return valve that is integrated into the jar lid but also, with the intention of having a complete design, an added float switch level sensor (see Section 3.5) to warn the fluid level limits. These two systems are shown in Figure 3.19b.

Filter and plug/catheter The filter is present in commercial medical suction pumps (see Figure 3.21a). Its advantage is to avoid contamination, dust and noxious gases entering the vacuum source. This component has not been integrated into the prototype in order to avoid another leak source, because the connectors of the purchased filter were not adapted to the diameter tubes. Also, the plug (suction catheter + a finger-hole) shown in Figure 3.21b is not implemented in this first prototype, for the same reason, but is strongly recommended in the final version of the device. It provides more precise suction, particularly for procedures that require it, thanks to a smaller inlet port. It is also used as a preventive means. This is a safety feature because to be able to suck in fluid you have to plug the top hole of the plug and put its inlet into the fluid. When the flow rate is too high, you simply lift your finger from the plug to let air in and reduce the vacuum.



(A) Anti-bacterial filter

(B) Plug

FIGURE 3.21: Pictures of the filter and plug purchased but not used

Overview of the designed vacuum circuit Figure 3.22 is the vacuum circuit with all essential components to be integrated into the prototype in order to ensure proper functionality. In comparison, Figure 3.23 shows how the components presented previously are assembled to form the vacuum circuit. All components purchased to assemble this vacuum circuit and their characteristics are described in Appendix E.

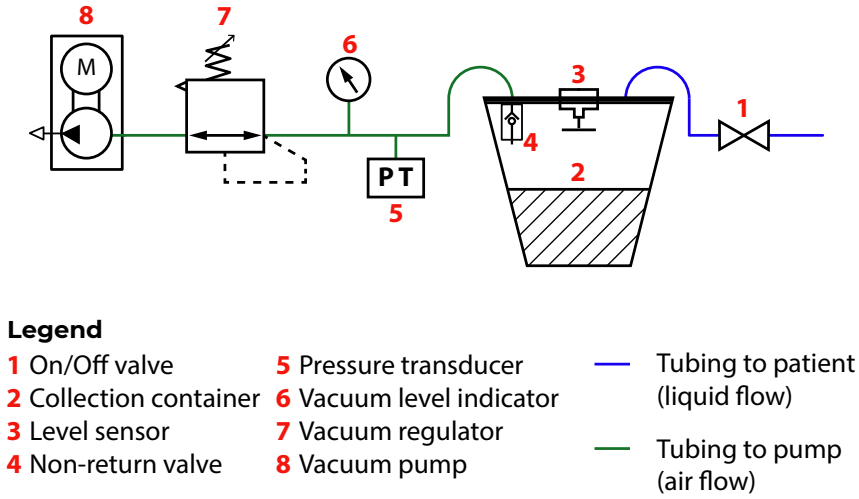


FIGURE 3.22: The vacuum circuit model designed for the prototype.

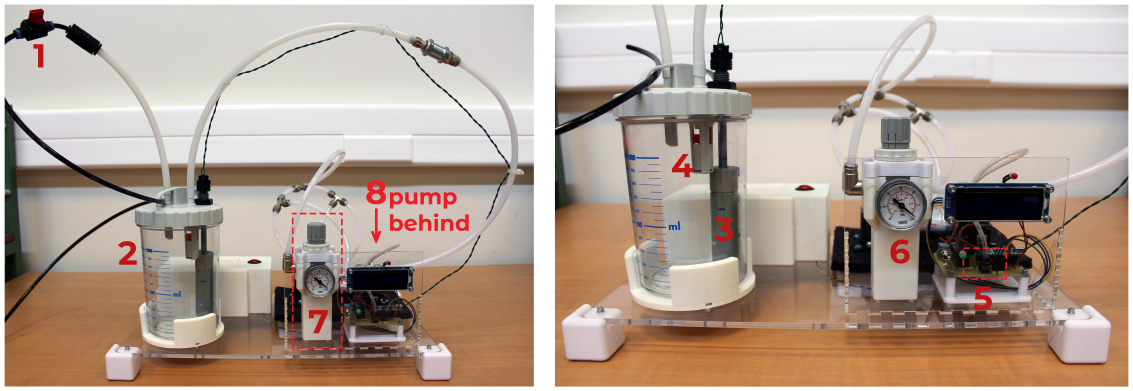


FIGURE 3.23: Overview of the vacuum circuit, with the elements labelled as the legend in Figure 3.22.

3.5 Overflow protection system

Requirements

In the case of application to a medical suction pump, the overflow protection system is a device to prevent liquid or solid particles from entering the intermediate tubing (tube between the container and vacuum regulator) but this system is not compulsory for medical aspirators. However, if this system is integrated into the appliance then it is constrained on several points by requirements described in the ISO10079 standard and based on the device uses:

- Should not be activated until at least 90% of the maximum capacity of the collection container.
- Prevent foam from passing the collection container into the vacuum source. This prevention means could be added to the level sensor design but it could just as easily be made by another part of a component.
- Should preferably be autoclavable and reusable.

- Made of materials resistant to high vacuum levels (max. 0.1 bar: pressure relative to atmospheric pressure).
- Should be adapted to all existing human body fluids such as vomit, mucus, gastric fluid, blood, ...

State of the art of existing level sensors in commercial medical aspirators

Most commercially portable medical aspirators do not have an overflow protection system as it is not a mandatory requirement in the medical suction pump ISO standard, but we decided to design one in order to complete and perfect the prototype. As an overfill protection will be designed, it must then meet the above requirements. Research into these protections in medical aspirators shows that most operate purely mechanically with a float and/or non-return valve / a floating ball, protecting the container oulet to the vacuum source and are directly integrated into the container lid. Figures in Table 3.8 show the two types of protection found for suction jars: the left figures show an overflow protection system composed of a float and a non-return valve, which are activated at 90% of the usable volume; and the right figures show a non-return or a floating ball, which has the same principle as the non-return valve.

TABLE 3.8: Overflow protection system inserted in the lid of medical aspirator container.

Float and stop valve [175], [176]	**Stop valve [177], [178]**
	
	

Types of level sensors

As an improvement of the overflow protection already integrated into the collection container, an additional prevention tool has been implemented. It is a design with an electronic part such as a switch in order to stop the pump when the maximum fluid level is reached in the bottle. Therefore, we will add a level sensor for our application to send an electrical signal to the Arduino when the substance is detected at a certain level. To find the type of level sensor that is best suited to our application, research was carried out to provide an overview of all the existing types. There are several types of level sensors, some of which give the fluid level continuously as it flows through a container, while others are activated

once a specific volume of fluid has been reached. Of all the sensor models found, four types have been studied :

- Capacitive [179] :
  - Capacitive level sensor [180]: The capacitance measurement is suitable for continuous measurement and fill-level detectors. The principle is that the arrival of fluid around the two electrodes making up the sensor will modify their electrical capacitance and increase the current flow, resulting in a signal. The measured capacitance will be higher when there is a fluid than when there is a vacuum between the two electrodes.
  - Capacitive proximity sensor [181]: This sensor must be placed facing a wall of a container with a fluid, granule, etc. rising along the opposite side. Its working principle is based on a capacitor that is two parallel plates separated by a dielectric material, air, which is a poor conductor of electricity. Once a voltage is applied to the capacitor, one plate becomes negatively charged and the parallel plate is positively charged creating an oriented electric field with an attractive force between them. This force holds the charge of the capacitor. When a target material which has a dielectric constant higher than air comes near the sensor, the capacitance between the plates will be higher too, which triggers a signal to warn of the material level.
- Optical [182], [183]:
  This sensor contains an infrared light-emitting diode (LED) and a phototransistor. When the optical head of the sensor is in the air, the light from the LED is transmitted directly to the phototransistor. However, if the sensor tip is submerged in fluid, then the emitted light beam will be refracted and will not be transmitted to the phototransistor anymore, which triggers a signal. The refracted light intensity is thus transformed into a measurable quantity such as an electric signal.
- Resistance/Conductivity [182]:
  It uses a probe to read conductivity. It contains a pair of electrodes and applies current (allowing the measure of conductivity) to them. Once a fluid covers the probe, a change of resistance between the 2 electrodes will be detected.
- Mechanical:
  There are several mechanical level sensors. Three of them have been analysed, and they are used as level detectors. Here are a few brief explanations of how they work:
  - Vibrating (tuning fork) level sensor [182]: use of a fork-shaped sensing element with two prongs. The two forks vibrate at their natural resonance frequency. When the level changes and reaches the sensor, the frequency of the fork changes, which is detected by an electrical circuit that sends a signal back.
  - Float switch level sensor [184]: a float switch sensor can be designed in several ways but the principle remains the same. This type of sensor uses a float that will raise when a product (fluid or solid) is applied. It will close a circuit as the level raises moving the float, which will send a signal due to the level detector. The circuit closure is caused by an electrical switch closure, which is operated differently according to the sensor design.
  - Rotary paddle level switch [185]: Paddle rotates at the end of the sensor. When the paddle rotation is impeded by a material that rises into the container, it triggers a signal.

Based on a number of criteria, we drew up a comparison table (Table 3.9) to determine which model of level sensors explained would be the most suitable or could be designed easily for our application.

Of all these solutions, we chose the float switch because it initially activates once a precise level has been reached, and according to the advantages and disadvantages comparison, it is also the most robust, easy to manufacture and insensitive to the nature of the fluid. Another advantage is its shape, which can be modifiable during its fabrication. In order to avoid the addition of a non-return valve, the shape taken by the float could prevent fluid from entering the inlet of the lid towards the pressure regulation system. For instance, the float could block this inlet once the liquid level is reached.

TABLE 3.9: Comparison table of the level sensor types : capacitive, capacitive proximity, optical, resistance and mechanical.

Criteria	Capacitive	Capacitive proximity	Optical	Resistance
Use cases	Liquid storage tanks, chemical, food, water treatment, and battery industries [179],[182], [186]	Detection of liquids, metal, plastics, wood, paper, glass and cloth, and detect material inside a container which can be non-metallic thanks to an adjustable sensing range [187]	Detection of the heat, colours, gazes or chemical components[188]. Domains: photography, spatial imaging, pattern recognition [189]	Used for boiler water, highly corrosive liquids and reagent monitoring
Advantages	Small, cheap compared to other sensors, high accuracy, no moving part, easy to use [182], [186]	non-invasive, small, cheap, no moving part, easy to use	no moving part, unaffected by high pressure and temperature, small, independent of fluid nature, invasive, easily manufacturing [182]	No moving part cheap, easy to use [182]
Disadvantages	Invasive, detection depends on the dielectric coeff of the fluid [182], [186]	detection depends on the dielectric coeff of the target material	Dirt and lens coatings can affect measurements **srouce_1**, [182]	Invasive, depend on conductivity coeff of fluid, probe erosion [182], [186]

Criteria	Float switch	Rotary paddle	Vibrating
Use cases	medical aspirator, tank level detection, pump alarm, refrigerants, industrial washers [190]	Used for solid materials such as powders and granules and is mainly used on industrial sites [191]	use in industries of mining, food, beverage and chemical industries. Detection of solids and liquids (such as foamy and sticky materials) [182]
Advantages	mechanical functioning, independent of fluid nature, cheap, easy to use, easily manufacturing and can take any shape [182]	Cheap, easy to use, high temperatures and pressures resistance [182]	low-cost, compact, easy to install, maintenance-free, robustness, suitable for several domains [185]
Disadvantages	Invasive, moving part [182]	Not suitable with low fluid density, invasive [185]	Invasive, no shock and temperature resistance, interfering vibrations compromising accuracy [182]

Level sensor implemented

The implemented solution meets a number of requirements and advantages such as :

- Activation to at least 90% of the usable volume:
  Ensuring the activation at a specific level requires an accurate sizing of the float. The float, partially submerged, rides on the process liquid surface and then, moves the same distance the liquid level moves, thus precisely tracking liquid surface motion [192]. This operating mode is based on Archimedes' principle whose buoyancy criterion is $\rho_{fluid} g V_{fluid} = m_{Float} g$, with ρ_{fluid} is the density $[kg/m^3]$ of the suctioned fluid, g is the gravity coefficient $[m/s^2]$, V_{fluid} is the fluid volume $[m^3]$ and m_{float} is the float mass $[kg]$. This sizing will be discussed in greater detail later in this section.

- Ease of implementation:
  For a first prototype, the float can easily be designed using 3D printing. Of course, for a final design, 3D printing will not be suitable as it should be autoclavable and reusable. Further research into a material better suited to the requirements will have to be carried out. The 3D printing allows the shape to be adapted as required. The level sensor activation mode is based on a particular float level sensor design [193]. This design comprises a float into which a magnet is inserted. This float rises around a rod. At a certain level of this rod, there is a normally open magnetic switch which, when a magnet approaches it, forms a contact and allows a current to flow [194]. This current flow can be connected to an Arduino that will detect it and trigger an alarm.

- Stop pump:
  When the float containing a rising magnet reaches a precise volume level, it closes the reed switch along the rod (along which the float rises) and allows then an electric current to flow. This signal activates an alarm to stop the pump.

- Protection of the vacuum pump:
  Our prototype has a non-return valve integrated directly into the suction jar lid. This plugs the outlet of the container into the vacuum source. If the collection container does not contain this valve it is still possible to reshape the float and control its trajectory as required so that it blocks the lid outlet to the vacuum source once the maximum volume level has been reached.

For time-efficiency reasons, we have reused a float switch level sensor found in the laboratory to design the prototype sensor (Figure 3.24). The mass of the float still had to be modified to meet the specification that it must be activated at 90% of the usable volume. To find the additional mass required, the following calculations were carried out when the fluid drawn in is water (fluid used for tests on the prototype):

1. As explained above, we started from the buoyancy criterion so that the weight of the float equals the Archimedes' thrust :

$$\rho_{fluid} g V_{fluid} = m_{float} g \tag{3.9}$$

   where V_{fluid} is the unknown, $\rho_{water} = 1000 kg/m^3$ and $g = 9.81 m/s^2$.

2. A total float mass of 24g ($m_{ExistingFloat} + m_{AddedMass} = m_{float} = 0.024 kg$) has been arbitrary fixed based on an existing float mass of 9g, which gives a submerged volume of $24 cm^3$ from the equation 3.9.

3. By knowing the dimensions of the section area (Figure 3.24) and the submerged volume, the float height can be calculated such as :

$$h = \frac{V_{submerged}}{A_{FloatSection}} \tag{3.10}$$

$$h = \frac{24}{\pi\left(\left(\frac{2.65}{2}\right)^2 - \left(\frac{1}{2}\right)^2\right)} \tag{3.11}$$

$$\implies h = 5.07cm \tag{3.12}$$

4. By a measurement on the float level sensor, there must have a float height of 4cm (top of float) above the liquid level out of the fluid to active the sensor at 900ml of fluid in the container (see Figure 3.25) $\implies$ $4 + 5.07 = 9.07$ is the total moving parts height needed. As the float of the sensor used already has a height of 2.25cm, the height of the hollow cylinder added to the float must have a height of $9.07 - 2.25 = 6.82cm$.

5. Given that the existing float already weighs 9g and that we had fixed a total weight of 24g, the added part must therefore have a weight of $24 - 9 = 15g$ and a height of 6.82cm.

6. The added piece has been designed in the slicer[4] allowing to get a mass of 15g by varying the infill density.

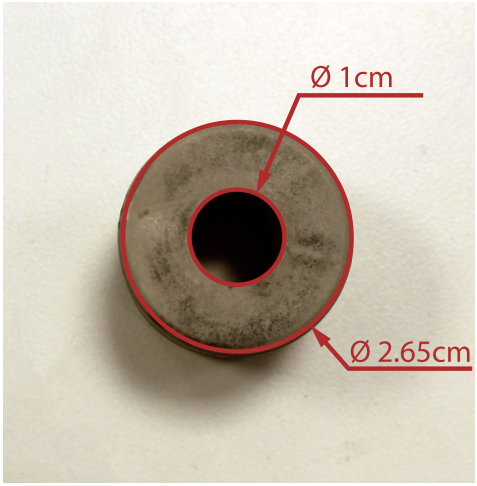


FIGURE 3.24: Float dimensions.

All the sizing explained above is carried out on the basis of water suction. However, the advantage of this level sensor system is that it can be adapted to any fluid by adding or removing a new or old weight, or even adapting the rod length along which the float glides. The weight can be sized using the above calculations, but this time considering a density equivalent to that of the new fluid sucked in. Indeed, if the fluid density, which is the case for the human body fluids (see densities in Table 3.1), is greater than that of water ($1000kg/m^3$), the level sensor will trip before reaching a fluid volume of 900ml.

[4]A slicer is a toolpath generation software, used to convert a 3D object into a file readable by the 3d printer (printer commands). For example, the conversion of a *STL* file into a *g-code* file. *g-code* is the format used for Fused Deposition Modeling (FDM), the technique used in 3D printers using plastic filament [195].

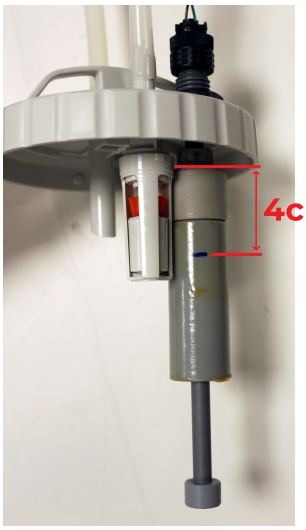


FIGURE 3.25: The figure illustrates the 4cm from the water level (dark blue line) to the magnetic switch (at the lid level).

The added mass for the prototype was printed in PLA (a porous plastic material) and, to ensure watertightness, it was coated with a protective layer of lacquer used to waterproof boats. Further research will have to be carried out to find a material that is suitable for medical use, i.e. so that the sensor is completely autoclavable and reusable for medical purposes.

3.6 Electric circuit

The purpose of the machine's electrical circuit is to supply the pump and the various components with energy and to ensure the control of the various components by the Arduino microcontroller board. Figure 3.26 shows an overall diagram of the prototype's electrical architecture. It contains all the electrical components and the main connections.

Controller As already mentioned in the section about vacuum regulation system (Section 3.3), an Arduino will be used. We have chosen an Arduino Nano [196] because it is small and suitable for our application. It will be the brain of the machine that will process the information from the sensors, the human-machine interface, etc. More information about the Arduino and its programming is available in Section 3.7.

Power Supply The prototype's electrical circuit consists of a power supply unit that converts AC voltage into 12V DC. This voltage is then lowered to 5V using a linear regulator (LM7805 [197]) to power the Arduino and other components. The pump is supplied with 12V via a relay controlled by the Arduino. The main switch cuts off the AC 220V supply directly for safety reasons.

Pinout The pinout diagram with all the used electrical components is available in Figure 3.27. Some explanations and justifications for certain connections and use of components:

- The LCD display is connected via I2C.
- A NPN transistor Q1 is used between the Arduino and the relay to limit the current that the Arduino will have to supply to the relay coil.
- R1 is used to limit the current flowing to the transistor.

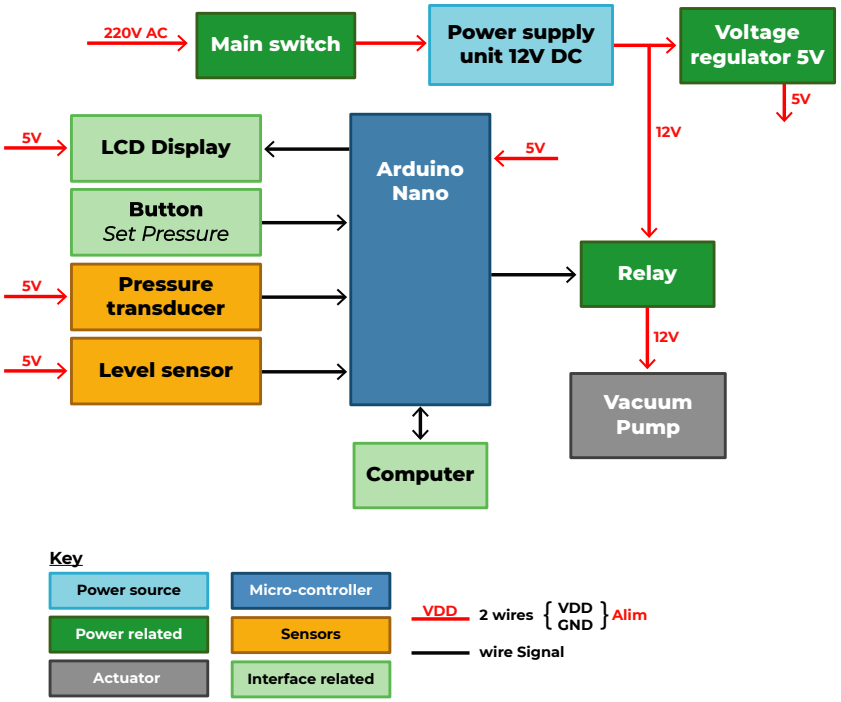


FIGURE 3.26: Global schematic of the electrical architecture of the prototype

- R2 and R5 are pool-down resistances.
- Decoupling capacitors C1 and C2 are used at the voltage regulator level. Their values are determined from the LM7805 data sheet [197].
- A diode D1 is used to protect the circuit from potential inductive kickbacks that can occur when the relay coil is switched off.
- D2 and D3 are LEDs used respectively for the set pressure procedure and the implemented alarms.
- D3 is a LED connected in parallel with the pump. It switches on and off at the same time as the pump. Its role is simply to act as a warning light, useful when testing the circuit.
- SW_1 is the level sensor explained in Section 3.5.
- SW_2 is the button used for the set pressure procedure.

The circuit was first assembled and tested on a breadboard. Once the circuit is functional, it is soldered onto a prototyping board. The results can be seen in Figure 3.28.

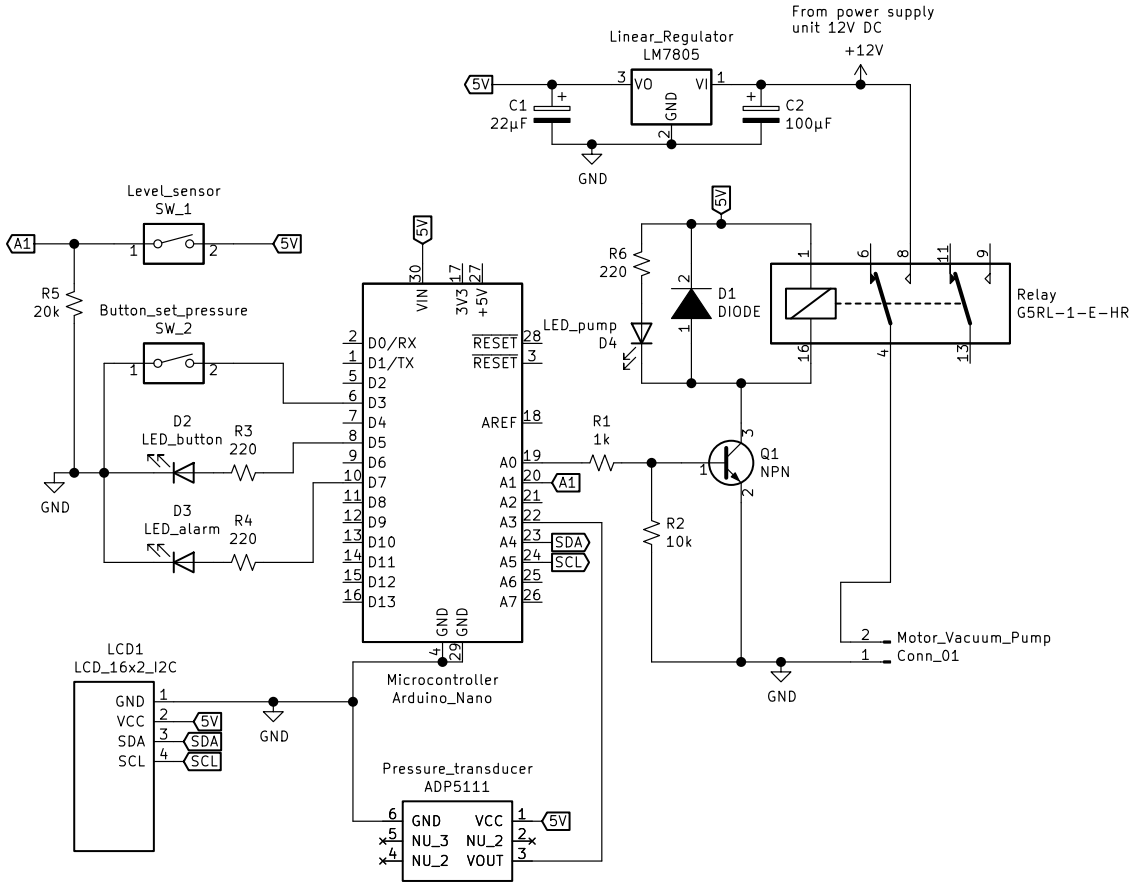


FIGURE 3.27: Electrical pinout schematic of the prototype.

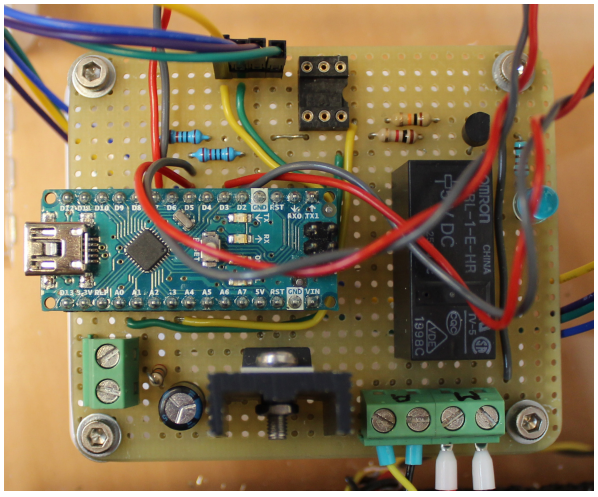


FIGURE 3.28: Electrical circuit soldered onto a prototyping board

3.7 Programming the Arduino

The controller of the prototype is an Arduino Nano. The entire code is available in Appendix D. The global code block diagram can be seen in Figure 3.29.

Note: The pressures displayed and used in the Arduino code are relative pressures expressed in absolute values (mathematical point of view), i.e. without a negative sign.

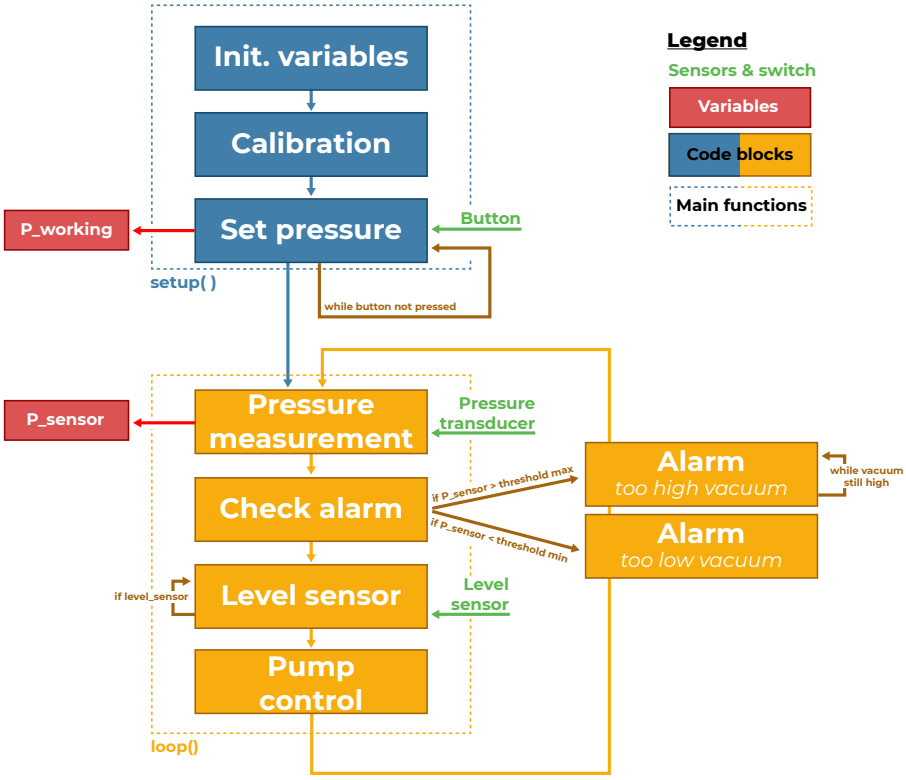


FIGURE 3.29: Arduino code block diagram

The implemented code works as follows:

1. The program begins by initialising all the variables that will be used.
2. Next comes the calibration of the pressure sensor. In this step, the Arduino performs 90 measurements of atmospheric pressure (for 4.5s) and calculates the average of these measurements to obtain the zero deviation, which will be subtracted from each measurement taken with the sensor.
3. Once the calibration is finished, the pump starts up and we enter the set pressure block. In this block, the desired work pressure (i.e. setpoint pressure) will be saved. Depending on the operating mode selected, two cases will occur:
   - **Inter. Two-step regulation:** the pressure written directly in the Arduino code(`SETPOINT_PRESSURE` is recorded in the `P_working` variable.
   - **The 3 other modes:** we enter a while loop until the user clicks on the *set pressure* button. Once this has been done, we read the pressure measured by the pressure sensor and record it in the variable `P_working`.

These 3 steps complete the sub-functions of the `setup()` main function. We now enter the `loop()` function, which will be repeated as long as the machine is running.

4. The first step in this main function is to read the pressure measured by the sensor and record it in the variable `P_sensor`. The pressure sensor measures and transmits pressure relative to atmospheric pressure.
5. The code then checks the implemented alarms. If an alarm is triggered, the machine will behave differently depending on the nature of the alarm, as explained in Section 3.9.
6. The level sensor is then used to check that the bottle is full. If this is the case, the pump is switched off immediately.
7. The last sub-function manages the pump power supply. This block will be different depending on the control mode chosen.

Regulation modes and their code implementation

Extract of the Arduino code space for defining operating modes variables

```
/*
*   The available operating modes are the following:
*     0 = "continuous"
*     1 = "inter_time_cycle"
*     2 = "inter_hybrid_time_pressure"
*     3 = "inter_two_step"
*   Choose one value for the OPERATING_MODE variable
*/
#define OPERATING_MODE  0

#define T_ON            7000  // [ms]
#define T_OFF           2000  // [ms]

#define MIN_PRESSURE_COEF 0.08
#define MAX_PRESSURE_COEF 0.08

#define SETPOINT_PRESSURE 0.5 // [bar] (for inter_two_step only)
```

0 **Continuous mode:** For continuous mode, the *pump control* block is empty. The pump is supplied continuously.

1 **Intermittent time-cycle:** This control mode involves time-fixed pump supply cycles. The `T_ON` variable is the on time for the pump during this mode and `T_OFF` is the off time, i.e. when the pump is cut off. The value of these two variables will be set experimentally (see Section 5.2) and the results are : `T_ON` = 7s and `T_OFF` = 2s.

2 **Intermittent hybrid time-pressure:** This mode is governed by two variables. The first, `T_ON`, defines the cycle during which the pump is switched on for a certain number of seconds (as for the time-cycle mode). Once `T_ON` seconds have passed, the pump switches off. Then, `MIN_PRESSURE_COEF` defines the vacuum level threshold below which the pump is switched back on. This threshold is defined as a percentage of the working pressure `P_working` (i.e. the set vacuum level). The parameter `T_ON` will be still set experimentally to 7s (see Test 5.2). The second parameter `MIN_PRESSURE_COEF` is set according to a requirement suggesting that the accuracy vacuum level shall be within $\pm$10% of the set vacuum level. With a safety margin of 2%, the `MIN_PRESSURE_COEF` is then equal to 8%.

3 **Intermittent two-step regulation:** This mode is governed by two pressure thresholds, defined by `MIN_PRESSURE_COEF` and `MAX_PRESSURE_COEF`. These two coefficients are expressed as percentages of the working pressure (`P_working`). The setpoint pressure is initially defined by the user in `SETPOINT_PRESSURE`. As explained for the `MIN_PRESSURE_COEF` in the above regulation mode, the parameters' values are: `MIN_PRESSURE_COEF` = 8% and `MAX_PRESSURE_COEF` = 8%.

A summary of the different regulation modes and their associated variables is available in Table 3.10.

TABLE 3.10: Summary of the different operating modes and their related parameters in the Arduino code.

Mode	OPERATING_MODE	ON cycle defined by	OFF cycle defined by
Continuous	0	-	-
Inter. time-cycle	1	`T_ON`	`T_OFF`
Inter. hybrid time-pressure	2	`T_ON`	`MIN_PRESSURE_COEF`
Inter. two-step regulation	3	`MAX_PRESSURE_COEF`	`MIN_PRESSURE_COEF`

Alarms

We decided to implement three alarms: one to warn when the vacuum level is too high, another for when the vacuum level is too low, and one last for managing the level sensor. For the two alarms regarding the vacuum level, their activation range is shown in Figure 3.30. *Threshold min* is calculated as

`P_working` * (1 - `SECURITY_PRESSURE_COEF`)

and *Threshold max* as

`P_working` * (1 + `SECURITY_PRESSURE_COEF`)

where `SECURITY_PRESSURE_COEF` is a variable expressed in % of the working pressure above/under which to raise an alarm. This coefficient is set to 0.1 (10%).

- ***Too high vacuum* alarm:** When the vacuum level is too high, the alarm LED lights up, an alarm message is displayed on the screen and the pump is immediately switched off. The code runs in a loop until two conditions are met: the vacuum level decreases and returns to normal & the user must press the button to restart the pump. Once these two conditions have been met, the pump starts up again and the prototype operates normally.
- ***Too low vacuum* alarm:** When the vacuum level is too low, the alarm LED lights up and an alarm message is displayed on the screen specifying that the vacuum level is too low. The prototype continues to operate normally. Once the vacuum level returns to normal, the LED goes out and the message disappears.
- **Level sensor:** When the bottle is full, the level sensor is triggered. The pump will immediately switch off and the code runs in an infinite loop. The user has to restart the prototype.

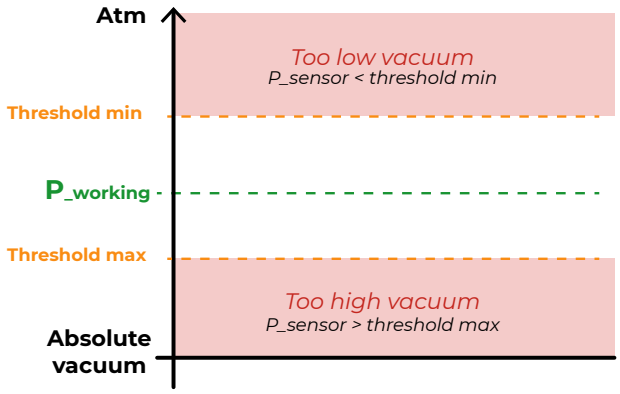


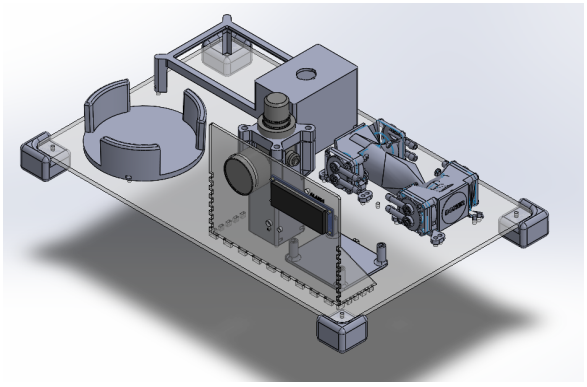
FIGURE 3.30: Activation range of the *too low* and *too high vacuum* alarms. *Atm* is the atmospheric pressure, *P_working* is the working pressure(i.e. the set-point pressure), *Threshold min* and *Threshold max* are calculated as ±10% of *P_working*. *P_sensor* is the relative pressure measured by the pressure sensor.

3.8 Design of the prototype structure

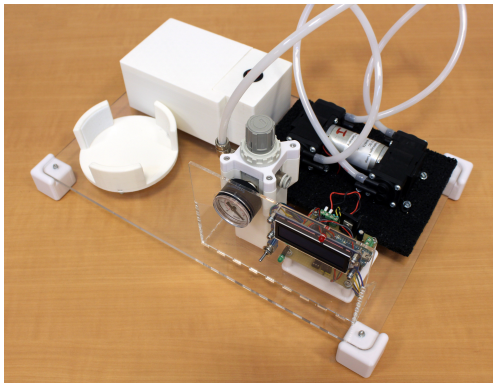
Once the vacuum and electrical circuits have been finalised, we can start designing a structure to group the different components together and make the prototype easier to use. We wanted this structure to be as open as possible and the various components to be accessible in case modifications had to be made.

Figure 3.31a shows the structure modelled using Solidworks [198] (a CAD software). Two manufacturing methods are used:

- The different elements in grey are the component supports. 3D printing is chosen to manufacture these parts because it is an additive manufacturing technique suitable for rapid prototyping. It produces strong and lightweight parts within hours. Moreover, as part of an open-source project, this technique is very well suited to this type of application thanks to the ease of access to a 3D printer.
- The base of the structure and the interface panel are made of laser-cut plexiglass, a method adapted to this type of part.



(A) 3D modelling of the prototype structure



(B) Picture of the prototype structure

FIGURE 3.31: Pictures of the 3D modelling and real-life prototype structure

3.9 Interface and operating mode

Setting up the prototype

The interface of the machine, or in other words the interaction with the user is an important element. The machine must be easy to use, a health user must be able to understand quickly and correctly how the appliance works and to use it even if he wears gloves during surgery for example. For the prototype[5], the chosen design and interface are presented in Table 3.11.

TABLE 3.11: Interface design

Functions	Components
Pressure display	via 16x2 LCD screen & manometer in [mbar] unit
Choice of working pressure	Push button or via computer (depends on the mode used)
Operating mode selection	Via computer directly

The following steps describe how to prepare and use the prototype :

- The selection of the operating mode must be done on the computer before uploading the code to the Arduino. Then, depending on the selected modes, the next steps are different:

  For intermittent two-step regulation mode :

  1. Either remove the vacuum regulator from the circuit or make the regulator inactive by turning it as far as it will go in the positive direction indicated on the knob. The regulator setpoint is then set at a vacuum level much higher than the maximum vacuum level that can be reached by the pump and the regulation will therefore be carried out by the Arduino control.
  2. Directly set the desired vacuum level in [bar] in the Arduino code, (in the `SETPOINT_PRESSURE` parameter)(more information about the programming of the Arduino in Section 3.7).
  3. Then, upload the file to Arduino.
  4. Start the device by pushing on the power button (see Figure 3.33b).
  5. A calibration starts. If you receive a calibration error message on the screen, check that the vacuum circuit has been stabilised at atmospheric pressure. The device will restart itself.
  6. Once the calibration is complete, the pump is activated.
  7. Sealing the end of the patient tubing by closing the on/off valve.
  8. The pump will run until it reaches the vacuum level specified in the Arduino. As soon as it switches off, the desired pressure is reached. The device will now continue to operate as shown in Figure 3.32
  9. The first pump stop is the signal for the health user to start sucking up liquid.

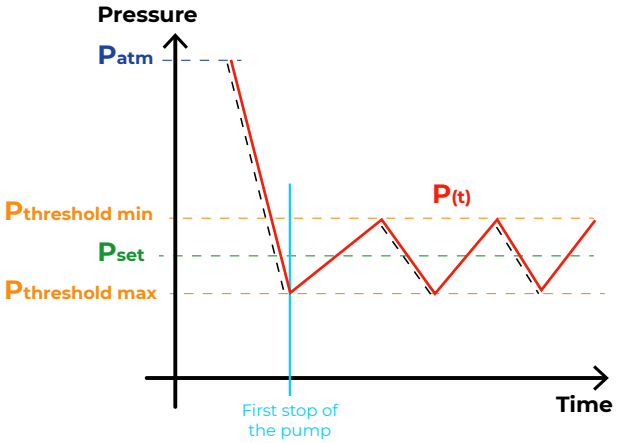


FIGURE 3.32: Vacuum level in the collection container in two-step regulation mode. The dashed black lines represent the times when the pump is switched on. The light blue line represents the first stop of the pump once the desired vacuum has been reached. It is the signal for the user to start sucking in liquid.

For continuous, intermittent time-cycle, and intermittent hybrid time-pressure regulation modes : no vacuum circuit handling or additional Aduino code change is required. The steps in machine operation for those modes are as follows:

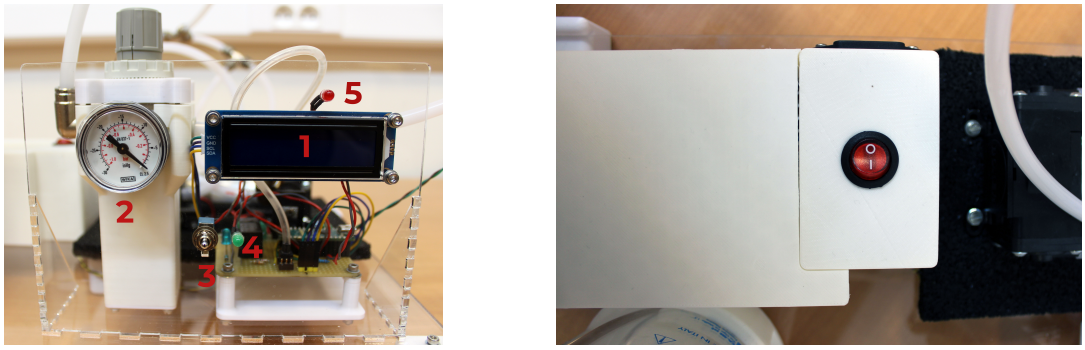
1. Start the device by pushing on the power button (see Figure 3.33b).
2. The calibration starts. If you receive a calibration error message on the screen, check that the vacuum circuit has been stabilised at atmospheric pressure. The device will restart itself.
3. Once the calibration is complete, the pump is activated and start the pressure setting step.
4. Seal the end of the patient tubing by closing the on/off valve.
5. Turn the regulator knob and wait until the pressure stabilises at the desired level. There are simultaneous displays of the pressure on the manometer and on the screen (redundancy for more security). The user has 2 minutes to set the chosen pressure before the controller displays a message on the screen saying the pressure setting has been forgotten.
6. Once the desired pressure is reached and stabilised, click on the *set pressure* button (see element 3 in Figure 3.33a) to save the desired working pressure in the Arduino (more information about the programming of the Arduino in the section 3.7).
7. The LCD screen now displays the current measured vacuum level.

- The user can now start using the device and sucking up liquid by putting the inlet port of suction tubing in the fluid and then opening the on/off valve.

Managing alarms

Several alarms have been set up to protect both the patient and the user when using the device. Here are the steps to take if an alarm is activated :

[5]This is the interface and operating mode designed for our prototype, in which 4 different regulation modes have been implemented for testing. For a final version of this medical device, the interface and operating mode will obviously be different. For example, for a machine implementing the two-step regulation mode, the choice of the working pressure will be made directly on the prototype, by means of additional knobs.



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

(B) Power button on the power supply unit.

FIGURE 3.33: Pictures of the interface panel and power supply unit of the prototype.

- **Too high vacuum level:**
  1. The controller displays a message on the screen saying the pressure is too high.
  2. The alarm red LED goes on (element 5 in Figure 3.33a) and the pump is automatically switched off.
  3. The user should stop suctioning and close the on/off valve (because a too high vacuum level can be dangerous).
  4. The vacuum level will decrease. Once the vacuum level decreases and returns to normal (as previously shown in Figure 3.30), the green LED goes on meaning that the user must click on the *set pressure* button to restart the pump.
  5. The user can suck up fluid again.
- **Too low vacuum level:**
  1. The controller displays a message on the screen saying the pressure is too low.
  2. The alarm red LED goes on.
  3. The user should stop suctioning and close the on/off valve to let the system restores the set vacuum level.
  4. Once the vacuum level is restored, the red LED goes off and the user can suck up fluid again.
- **Level sensor tripped:**
  1. This alarm is triggered once the fluid volume level has reached approximately 900ml.
  2. The alarm red LED goes on and the pump is stopped.
  3. Immediately close the on/off valve to prevent more fluid from entering the container and switch off the machine.
  4. Empty the bottle and replace it.
  5. The machine can now be restarted.

3.10 Overview of the prototype

The Bill Of Materials (BOM) is available in Appendix E. The prototype costs approximately 507.3€, including the material prices and manufacturing expenses.

Figure 3.34 shows the finished prototype and highlights some of the different components and vocabulary words listed and defined below.

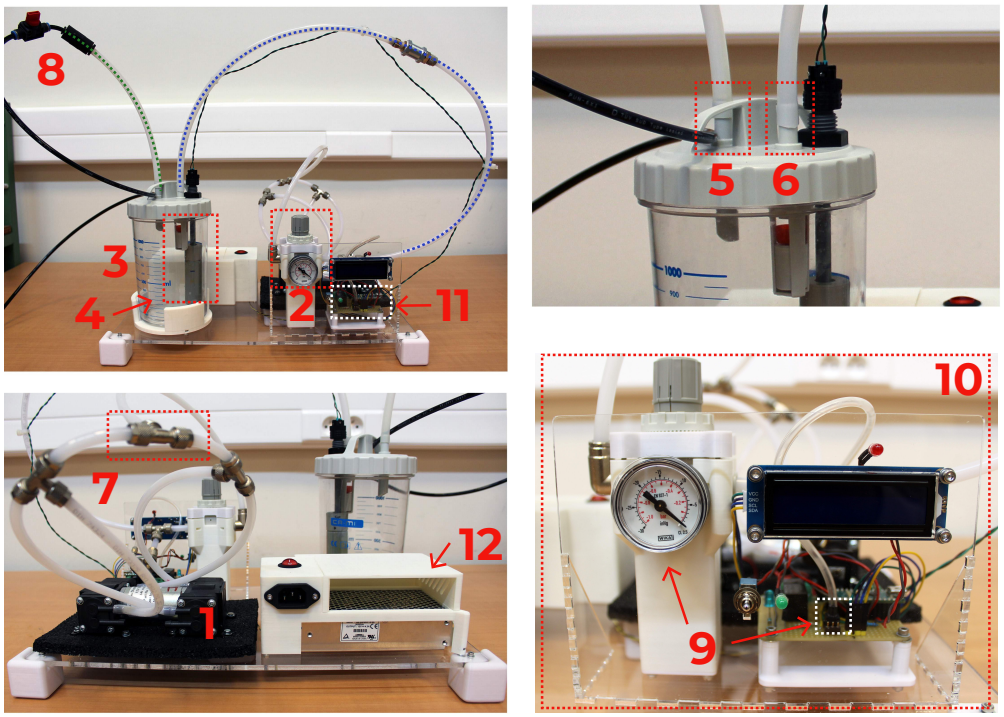


FIGURE 3.34: Overview of the prototype with highlighted main parts.

- **Vacuum circuit:** a circuit in which the various fluids (body fluids and air) circulate and in which the components used to create and regulate the vacuum are located.
- **Vacuum regulator:** device for controlling the applied vacuum level.
- **Vacuum source:** Component or device for generating a vacuum as a vacuum pump for example.
- **Collection container:** container in which liquids and solid particles are collected.
- **Inlet port:** the orifice in the collection container lid that allows the liquids, solid particles or gas to enter into the collection container. Sometimes inlet is also used for the

suction tube inlet. In very rare cases, it is used to refer to the opening in the container lid leading to the pump.

- **Exhaust/Outlet port:** the orifice in the collection container through which the gas sucked in by the pump escapes to create the vacuum in the container.
- **Overflow protection devices:** it prevents liquid or solid particles from entering the intermediate tubing. Therefore, it protects the pump in case of an overflow in the collection container.
- **Free airflow:** rate of unrestricted flow of air through a designated inlet. This is the flow rate when there is only suction of air and thus, the maximum flow rate at atmospheric pressure.
- **Suction tubing :** tubing for the conduction of liquid, solid particles or gas between the end-piece and the collection container.
- **Intermediate tubing :** tubing between the collection container and the vacuum source.
- **Connectors:** assemble the various tubes and components of the vacuum circuit.
- **On/off valve:** allows closing the inlet port to the atmosphere.
- **Vacuum level indicator:** device for displaying the vacuum level. Gauge displays the vacuum mechanically and the pressure transducer displays it in the Arduino as a signal.
- **Electric circuit and Arduino:** control and manage all components.
- **Interface:** is made up of LEDs (alarm and setting), the screen and the set pressure button.
- **Power supply unit:** supplies the electrical circuit and therefore also the vacuum pump. It contains the power button.
- **Prototype, device ,machine:** these terms are used to describe the prototype as a whole, regardless of the operational regulation mode.
- **Regulation modes, operating modes:** these terms are used to designate the implemented and utilised regulation modes in the prototype.
- **working pressure, set vacuum level, desired vacuum level:** these terms are used to designate the setpoint vacuum level chosen by the user.

Chapter 4

Risk analysis

Conducting a risk analysis on medical devices is paramount to ensure patient and health user safety and regulatory compliance. By identifying potential hazards, assessing their impact, and implementing means of mitigation, the analysis helps preemptively address risks, enhance device reliability, and maintain the highest standards of healthcare quality.

Section 4.1 introduces the resources employed and outlines the approach taken to assess risk. Section 4.2 presents the outcomes of this risk analysis. Finally, Section 4.3 concludes this risk analysis with a discussion.

4.1 Risk management process

The risk analysis was conducted in accordance with the ISO14971 standard [38], an international standard that outlines the principles and process for managing risks associated with medical devices. This standard provides an approach to identifying, analyzing, evaluating, and mitigating risks throughout the entire life cycle of a medical device. Appendix C within this standard was the main interest in conducting this risk analysis, it addresses a series of questions aimed at discerning the characteristics of a medical device that may impact its safety.

Additionally, a safety framework was employed to formulate a risk assessment for the advancement of a prototype or experimental apparatus, or for overseeing non-CE [1] designated equipment at UCLouvain [200]. This document offers a framework for adhering to relevant safety standards during the design and development of a prototype. The objective is to mitigate potential risks associated with the machine from its design stage. Addressing these risks at the prototype stage is crucial as it can significantly minimise them during the subsequent industrialisation phase. In practice, it is not feasible to fully meet all standards at the initial prototype creation stage.

To assess the severity of risks, we will employ a method that enables the calculation of a provision criticality index. As suggested in ISO14971 [38], the combination of two factors: the probability of harm and the severity of that harm, defines a level of risk in the medical domain. By multiplying a third factor, the occurrence probability, we obtain the risk criticality index associated with a specific hazard. This index aids in prioritizing risk mitigation efforts and allocating resources efficiently to ensure the highest levels of safety in device development and deployment. This method is also employed by Matrix Requirements, a

[1] By applying the CE marking to its products, the manufacturer asserts its adherence to all the stipulated requirements associated with the marking, thus assuming responsibility for the distribution of these products within the European Economic Area [199].

leading platform for software in Medical Devices manufacturing [201]. This platform includes a risk analysis, involving the assessment of risks based on these three specific factors, each assigned a value within a certain range. The factors in question are scaled as follows :

- 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).

Subsequently, the criticality index is calculated through the combination of these three factors (C = P x H x S). This risk criticality is scaled in this way :

- $C > 35$: very high risk (consign equipment).
- $20 < C \leq 35$: real and substantial risk, correction is required to reduce risk.
- $C \leq 20$: risk may be acceptable.

The upcoming risk analysis will focus on describing the potential hazards inherent in the utilisation of a medical aspirator. The mentioned risks stem directly from the considerations outlined in Appendix C of ISO 14971, as well as the potential risks listed in the prototyping document, which are also related to safety. Each individual risk shall be initially stated, followed by the computation of its criticality index through the utilisation of the methodology used in Matrix Requirements. Subsequently, we will describe any solutions that have been developed for the prototype to reduce the risks. Conversely, in cases where no solution has yet been established, remedial measures will be proposed. Finally, each of the risks will be reassessed, taking into consideration the mitigation solutions implemented in the design, as well as those that were not able to be implemented but could serve as potential enhancements for future iterations of the prototype.

4.2 Risk analysis output

We have identified eleven risks and categorised them into five groups:

- Risk related to unintended vacuum levels
- Risk of misuse
- Risk associated with invasiveness
- Risk of component damage
- Risk of suctioning complications

4.2.1 Risk related to unintended vacuum levels

4.2.1.1 Risk of excessive vacuum level

Hazard and harm : There is a potential risk of excessive vacuum pressure being reached. If the suction inlet port comes into close proximity to tissues or organs (such as lungs, heart, etc.), it could result in their damage, potentially causing harm or injury to the patient.

TABLE 4.1: Criticality index of risk 4.2.1.1: Before mitigation.

Factors	Factor value
Occurrence	2 (not often)
Harm probability	2 (probable)
Gravity	5 (fatal)
Criticality index	20

Mitigation solution : When the vacuum level rises above 10% of the set vacuum level, an alarm is initiated, causing a red LED to illuminate and a message displayed on the screen as a warning signal to the user. Simultaneously, the pump is halted automatically, and it remains inactive until the vacuum levels are restored to an acceptable range.

TABLE 4.2: Criticality index of risk 4.2.1.1: After mitigation (proposed solutions and solutions implemented on the prototype)

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	10

4.2.1.2 Risk of too low vacuum level

Hazard and harm : When the vacuum level becomes excessively low, the medical aspirator loses its ability to effectively draw body fluid at a sufficiently high rate or might cease fluid aspiration. This situation can pose a significant harm, especially when dealing with patients experiencing obstructed airways or when the medical aspirator is employed to enhance the visibility of the operator performing a procedure.

TABLE 4.3: Criticality index of risk 4.2.1.2: Before mitigation.

Factors	Factor value
Occurrence	3 (occasional)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	30

Mitigation solution : When the vacuum level decreases by 10% compared to the set vacuum level, an alarm is triggered, illuminating a red LED and displaying a message. The user is required to halt the use of the medical aspirator and close the on/off valve to restore as soon as possible the suction vacuum level.

TABLE 4.4: Criticality index of risk4.2.1.2: After mitigation (proposed solutions and solutions implemented on the prototype)

Factors	Factor value
Occurrence	3 (occasional)
Harm probability	1 (not likely)
Consequences	5 (fatal)
Criticality index	15

4.2.1.3 Clogged suction tubing

Hazard and harm : In instances where solid material from the body is aspirated, it is possible that the material's size could exceed the diameter of the suction tube, consequently leading to a complete obstruction of the aspiration process.

TABLE 4.5: Criticality index of risk 4.2.1.3: Before mitigation.

Factors	Factor value
Occurrence	2 (not often)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	30

Mitigation solution : No solution has been implemented for this scenario. The adjustment of the suction tube diameter is carried out during the design of the medical aspirator. During this design phase, it is important to assess the size and nature of the materials being suctioned in order to adapt the diameter of the suction tube so that they do not obstruct it. Also, the selection of vacuum circuit components must then be appropriate for the dimensions of this tube. In the article [103], the authors suggest a minimum internal diameter of 8mm, as bone fragments or even teeth can be aspirated, and a tooth can have a diameter of up to 8mm.

4.2.2 Risk of misuse

4.2.2.1 Risk of an unintentional aspiration of patient tissues or organs

Hazard and harm : During the operation of the medical aspirator, its nozzle may come into too close proximity to a patient's tissue or organ, potentially resulting in harm or injury.

TABLE 4.6: Criticality index of risk 4.2.2.1: Before mitigation.

Factors	Factor value
Occurrence	2 (not often)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	30

Mitigation solution : First, it has to be specified (in technical files) that the medical aspirator must be operated by a qualified medical professional familiar with proper usage protocols when applying it to a patient, in order to mitigate the risk of unintended aspiration of undesired components. In case such a risk arises, the implementation of a vacuum interruption mechanism (plug) (see Figure 4.1) can be beneficial for medical procedures that need it. Creating a vacuum involves placing a thumb over the upper hole, and upon its removal, air ingress occurs, subsequently reducing the vacuum and aspiration effect.

TABLE 4.7: Criticality index of risk 4.2.2.1: After mitigation (proposed solutions and solutions implemented on the prototype).

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	10

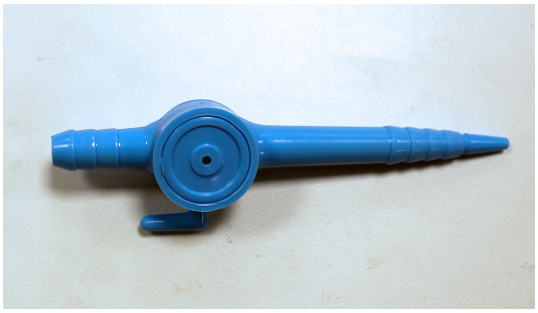


FIGURE 4.1: Vacuum arrest mechanism featuring an upper perforation to prevent air ingress.

4.2.2.2 Risk of unsuitable setting

Hazard and harm : This risk occurs when the user employs an unsuitable pressure setting for the fluid being aspirated. For instance, the aspiration of vomit necessitates higher pressure than blood aspiration due to different viscosities (see Section 3.1). This could present a hazard since, in the case of an individual with obstructed airways, an unsuitable pressure setting could impede fluid flow entirely, thereby compromising the individual's safety.

TABLE 4.8: Criticality index of risk 4.2.2.2: Before mitigation.

Factors	Factor value
Occurrence	2 (almost never)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	20

Mitigation solution : Once again, it has to be specified (in technical files) that the medical device should be operated by a qualified medical professional who is acquainted with the necessary parameters for a successful intervention. However, the current prototype does not offer a means to mitigate this risk, as the machine needs to be turned off and on again to adjust the pressure. Indeed, the working vacuum level cannot be changed once the pressure setting stage is completed. A potential solution to mitigate the risk would involve incorporating the capability to adjust the vacuum level even during operation.

TABLE 4.9: Criticality index of risk 4.2.2.2: After mitigation (proposed solutions and solutions implemented on the prototype).

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	10

4.2.3 Risk associated with invasiveness

4.2.3.1 Risk of patient contamination

Hazard and harm : Considering the medical aspirator's intended reusability, there exists a potential risk of patient contamination from one use of the device to another.

TABLE 4.10: Criticality index of risk 4.2.3.1: Before mitigation.

Factors	Factor value
Occurrence	5 (always)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	75

Mitigation solution : To prevent any contamination, the component of the aspirator in contact with bodily fluids should be constructed from autoclavable materials and be sterilised

before each use. However, the current prototype does not exclusively consist of autoclavable materials; the level sensor is composed of non-autoclavable materials. Additionally, the vacuum regulation part, housing the pump and vacuum regulator, can be protected against bacteria from bodily fluids using an antibacterial filter. The vacuum regulation section is also protected from contamination by a non-return valve, which prevents fluid ingress into the vacuum regulation inlet.

TABLE 4.11: Criticality index of risk 4.2.3.1: After mitigation (proposed solutions and solutions implemented on the prototype).

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	15

4.2.4 Risk of component damage.

4.2.4.1 Risk of vacuum regulation damage

Hazard and harm : There is a risk that if the fluid level in the bottle rises too high, the fluid might pass through the bottle outlet and enter the vacuum regulation section. This could potentially cause damage to the regulator and pump, as these components are designed for air, not fluids.

TABLE 4.12: Criticality index of risk 4.2.4.1: Before mitigation.

Factors	Factor value
Occurrence	3 (occasional)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	45

Mitigation solution : To prevent fluid from damaging the vacuum regulation part, we have implemented a float switch level sensor that triggers an alarm to stop the pump when the fluid level reaches a critical volume in the container. Additionally, there is a non-return valve integrated into the container lid's outlet, leading to the pump, which prevents fluid from passing through.

TABLE 4.13: Criticality index of risk 4.2.4.1: After mitigation (proposed solutions and solutions implemented on the prototype)

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	15

4.2.4.2 Risk arising from environmental conditions

Hazard and harm : Considering the medical aspirator's portability for emergency scenarios, it is susceptible to damage from environmental conditions such as rain, which could particularly harm the electrical circuit.

TABLE 4.14: Criticality index of risk 4.2.4.2: Before mitigation.

Factors	Factor value
Occurrence	4 (often)
Harm	3 (very likely)
Consequences	5 (fatal)
Criticality index	60

Mitigation solution : To prevent any issues related to water infiltration into the electrical circuit, it is essential to incorporate an enclosure that protects the circuit from external conditions. However, as a first prototype, no protective enclosure has been designed or implemented yet, except for housing the components.

TABLE 4.15: Criticality index of risk 4.2.4.2: After mitigation (proposed solutions and solutions implemented on the prototype)

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	3 (very likely)
Consequences	5 (fatal)
Criticality index	15

4.2.4.3 Misfunctioning of the alarms

Hazard and harm : A risk can arise if the activation of an alarm triggered by a certain state of the machine causes the machine to stop, and then it restarts automatically when the machine returns to a normal state. For instance, this could become dangerous during a

surgical operation if the machine activates unintentionally (after an alarm for example) while the healthcare worker has not initiated the action, especially if the suction tube is positioned near an organ.

TABLE 4.16: Criticality index of risk 4.2.4.3: Before mitigation.

Factors	Factor value
Occurrence	4 (often)
Harm	2 (very likely)
Consequences	5 (fatal)
Criticality index	40

Mitigation solution : To remedy this risk, we have implemented a function in the code that detects a vacuum level that is too high. This alarm will stop the pump, and once the vacuum level drops again, the user must click on the set pressure button for the pump to restart.

TABLE 4.17: Criticality index of risk 4.2.4.3: After mitigation (proposed solutions and solutions implemented on the prototype)

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	2 (very likely)
Consequences	5 (fatal)
Criticality index	10

4.2.5 Risk of suctioning complications

4.2.5.1 Iatrogenic complication

Hazard and harm : This is a risk of suction-related mistakes. An iatrogenic airway injury is common when the user lacks a complete understanding of the suction device they are using [108]. This injury has no connection with the primary reason for the intervention. It refers to tissues or even organs that have been damaged during the procedure due to persistent suction by the user on a sensitive tissue area of the patient [202]. If the damaged tissues are those of the lungs, for example, it can be very dangerous.

TABLE 4.18: Criticality index of risk 4.2.5.1: Before mitigation.)

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	10

Mitigate solution : Once again, this risk highlights the critical importance of the user being a trained medical professional proficient in operating any type of medical suction device, as only their skills can prevent such a risk from occurring.

4.2.5.2 Hypoxia complication

Hazard and harm : Hypoxia arises when the body or a specific body region experiences an insufficient supply of oxygen. Hypoxia is one of the most common complications as it can arise following suction due to the procedure's inefficiency in removing obstructions and its effectiveness in removing oxygen from tissues [93]. The longer the suction process is prolonged, the higher the likelihood of inducing hypoxia becomes.

TABLE 4.19: Criticality index of risk 4.2.5.2: Before mitigation.)

Factors	Factor value
Occurrence	3 (occasional)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	30

Mitigate solution : An article [203] suggests performing hyperoxygenation before proceeding with suction in order to maximize the oxygen supply to the patient's body tissues prior to suction. If the procedure is prolonged, reoxygenating can reduce the risks of hypoxia.

TABLE 4.20: Criticality index of risk 4.2.5.2: After mitigation (proposed solutions and solutions implemented on the prototype)

Factors	Factor value
Occurrence	1 (almost never)
Harm probability	2 (probable)
Consequences	5 (fatal)
Criticality index	10

4.3 Final risk assessment

In conclusion, the risk analysis conducted on the medical aspirator has provided valuable insights into potential hazards associated with its use. By identifying these risks, assessing their impact, and proposing mitigation strategies, we aim to enhance patient safety, regulatory compliance, and overall device reliability.

Some solutions are yet to be enhanced, and further exploration is required for certain risks, but the vast majority of risks have been adequately mitigated through various solutions implemented on the prototype or suggested as future improvements. However, the risk involving potential blockage of the suction tube lacks a proposed solution, except for a better initial design of the medical aspirator based on the procedure for which it will be used. Also, other risks highly depend on the medical users' ability to operate the device.

The risk analysis could be further enhanced, as there are still unidentified risks that necessitate ongoing investigation and exploration.

Chapter 5

Experimentation and discussion

The Verification stage consists in evaluating the proposed solution according to a list of application-specific requirements. A test protocol has been established. It is intended to be as comprehensive as possible to make it easily reusable by other researchers in the field willing to test and validate their own open-source medical aspirator. It includes the tests required to verify that the device complies with the main requirements (Table 2.6), but also tests more specific to this work, such as the comparison of different regulation modes on the basis of defined criteria. While the ISO 10079 standard offers tests for some requirements, it does not encompass all of them. Consequently, the established test protocol includes direct and adapted tests from ISO 10079, as well as newly developed tests.

Naturally, the created test protocol remains incomplete for a medical aspirator to be certified. Nevertheless, it already contains a significant number of tests and we believe that these are the most relevant in order to assess the main requirements. Furthermore, due to the restricted timeframe of this thesis, we have decided to focus on a specific set of tests enabling us to address the three main research axes of our thesis linked to the analysis and evaluation of the prototype's performance:

- the comparison of the different regulation modes implemented,
- the comparison of our prototype with the requirements set out in the specifications,
- as well as a performance comparison with the medical aspirators currently available on the market.

The tests not performed are presented in Appendix F. Moreover, two preliminary tests have been carried out in order to :

1. to determine the parameters of the intermittent time-cycle and intermittent hybrid time-pressure regulation modes,

2.1 to explore the feasibility of the PID controller mode with pump speed variation

2.2 and to verify whether precise vacuum levels could be achieved by adjusting the voltage supplied to the pump (as explained in Section 3.3.3)

These parameters are presented and explained before proceeding with the test protocol.

Therefore, this chapter begins by presenting all the experiments and analyses performed on the prototype and the test protocol established. The general materials and methods, common to all experiments, will be described first. Then, for the sake of readability, the apparatus setup and procedure, as well as the results and discussion, are provided concurrently for each experiment rather than in different sections. The chapter concludes with a general discussion of the three research dimensions stated earlier.

Specifically, Section 5.1 outlines the setups employed to conduct the various tests. Then Section 5.2 presents the tests for the identification of regulation mode parameters. Section 5.3 introduces four tests to assess prototype-specific performances, which are applicable across all four regulation modes. Subsequently, the tests specific to certain components are discussed. Section 5.4 deals with the mechanical vacuum regulator. The internal vacuum level indicators (manometer and pressure transducer) are tested in Section 5.5. Then, the collection container, as well as the overflow protection system (level sensor), are evaluated in Section 5.6. Section 5.7 pertains to the means put in place to prevent a too high vacuum level (alarm). The last set of tests (Section 5.8) presents the evaluation of the four regulation modes against defined criteria.

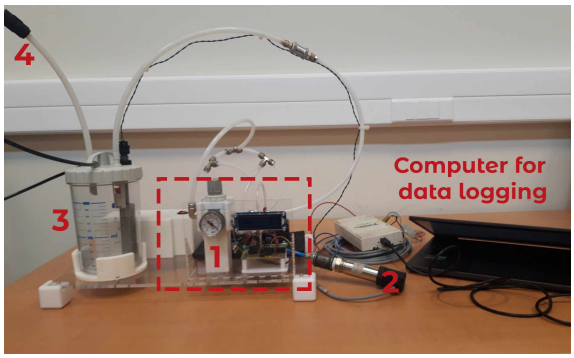
Finally, Section 5.9 sums up this chapter by providing a general discussion of the experimentation structured according to the three axes mentioned above.

5.1 Materials and test conditions

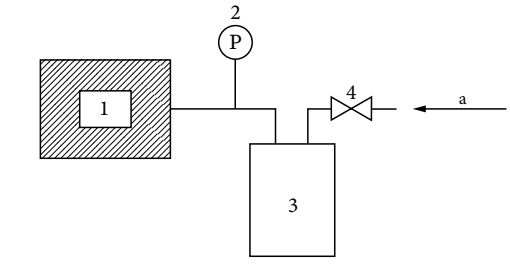
The test conditions:

- Temperature: room temperature
- Atmospheric pressure around the device
- Liquid: water
- Container simulating the patient and containing the liquid: a bucket

Two primary setups are employed for most tests. Figure 5.1 depicts the arrangement used to measure vacuum level variation, and Figure 5.2 portrays the setup for assessing free airflow. Additionally, distinct and specific setups, with particular equipment shown in Figure 5.3, tailored to certain tests have been utilised, which will be directly illustrated during the respective tests. All the equipment used is sourced from the materials available at the Credem platform lab[1].



(A) Picture of the setup.

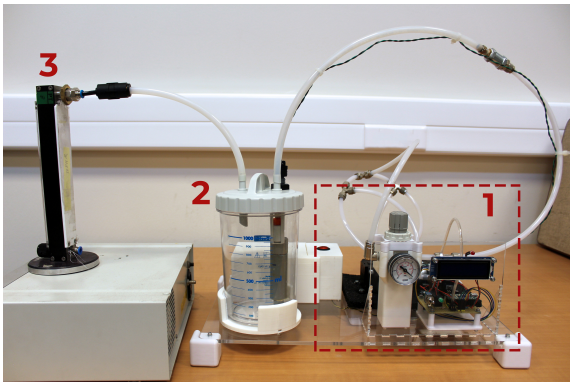


Key
1 *suction device* under test
2 *vacuum level indicator* (P)
3 *collection container assembly*
4 *on/off valve*
a direction of flow

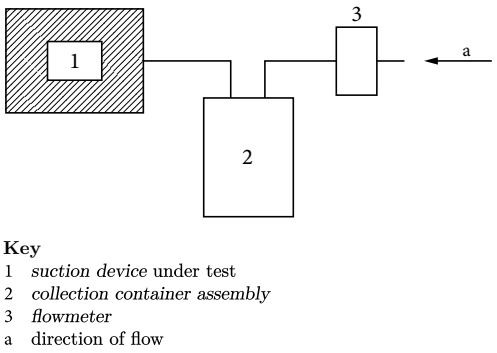
(B) Schematic of the test apparatus setup.

FIGURE 5.1: Picture and schematic of the test apparatus setup for pressure measurement using a calibrated external pressure transducer with data logging capabilities, measuring vacuum levels up to -1 bar.

[1]The CREDEM is a technological platform (based in UCLouvain) that ensures the design, the manufacturing, the control, and the in-use testing of electromechanical devices [204].



(A) Picture of the setup.



(B) Schematic of the test apparatus setup.

FIGURE 5.2: Picture and schematic of the test apparatus setup for free airflow measurement using an airflow meter set to measure airflow rates ranging from 0 to 30 l/min.

(A) Oscilloscope.

(B) Variable power supply.

FIGURE 5.3: Picture of the materials used for the power consumption test (A) and the characterisation of the pump voltage-pressure/airflow relationship tests (B).

5.2 Identification of regulation mode parameters

5.2.1 Identification of T_ON and T_OFF of the pump for the cycling mode

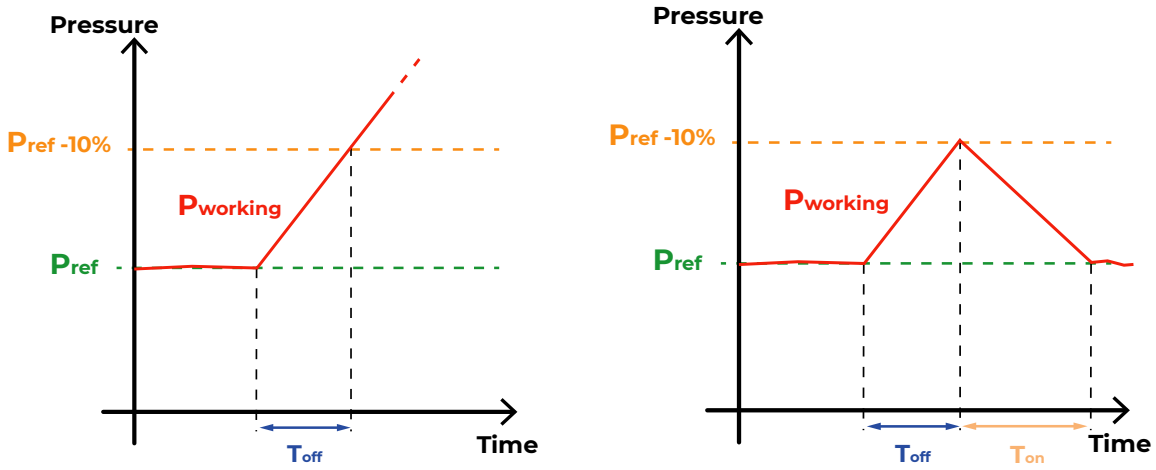
As seen previously in Subsection 3.3.3, the intermittent time-cycle mode is characterised by two time ranges called `T_ON` during which the pump is powered and `T_OFF` when the pump is not powered.

a) Principle and objective

The specifications require that the vacuum levels shall be within ±10% of the set vacuum level. `T_OFF` and `T_ON` have therefore been calculated to ensure they do not surpass a 10% threshold. Both values of `T_OFF` and `T_ON` have been computed during an experiment in which water is sucked in.

The value of `T_OFF` is computed experimentally once the pump is stopped, how long it takes for the vacuum to drop, due to the water suction and leaks in the circuit, below a level of 10% of the pressure initially reached before stopping the pump, as shown in Figure 5.4a.

The value of `T_ON` is determined based on the pre-calculated value of `T_OFF`. While water is being aspirated, the pump is restarted after being stopped for `T_OFF` seconds, and the time taken to return to the initially set pressure is recorded under the parameter `T_ON`. The principle diagram is shown in Figure 5.4b.



(A) Diagram of the procedure for measuring T_OFF (B) Diagram of the procedure for measuring T_ON

FIGURE 5.4: Diagrams of the procedures for Measuring T_OFF and T_ON, once T_OFF has been calculated

b) Apparatus setup

For this test, the setup of Figure 5.1 is used.

c) Procedure

First, `T_OFF` must be defined.

1. In the Arduino code, set the operating mode to `continious`.
2. Switch on the device and close the inlet port to the atmosphere.
3. Wait until the vacuum is stabilised at -0.2 bar which will be the set vacuum level.
4. Start sucking up water with the device.
5. Immediately switch off the device (which will automatically switch off the pump) and in parallel, start recording the time and the pressure levels until the vacuum drops up to 10% of the set vacuum level.
6. Stop sucking up water.
7. Save the time taken for a 10% vacuum drop.
8. Repeat these steps for the following set vacuum level: -0.4 and -0.6 bar.
9. Finally, calculate the average time needed to reduce the vacuum by 10%: `T_OFF`.

Then, `T_ON` is calculated once `T_OFF` is defined in the code.

1. In the Arduino code :

- Save the value of T_OFF previously calculated under the variable T_OFF.
- Save a value of T_ON higher than 15 seconds to ensure that the set vacuum level has enough time to be re-established.
- Set the operating mode to intermittent time-cycle.

2. Switch on the device and wait until the vacuum is stabilised at -0.2 bar which will be the set vacuum level.
3. Start sucking up water.
4. Let the pump switched off for T_OFF seconds due to the controller.
5. Once the pump is restarted, start recording the time and the pressure levels until the set vacuum level is recovered.
6. Stop sucking up water.
7. Save the time taken to reach the set vacuum level.
8. Repeat these steps for the following set vacuum level: -0.4 and -0.6 bar.
9. Finally, calculate the average of the different values gathered.

d) Results and discussion

Results of times taken to achieve an 10% vacuum drop (T_OFF) depending on the set vacuum levels are summarised in Table 5.1. The table demonstrates that the initially set pressure has minimal influence on the time taken for a 10% vacuum decrease, as the recorded times vary within the range of centisecond. T_OFF is then calculated by computing the mean of the times saved for each set vacuum level (second column of Table 5.1). This time is rounded to T_OFF = 2s, and corresponds to the time during which the pump will be switched off for the intermittent time-cycle regulation mode.

Since the initially set pressure seems to have a negligible contribution on the durations of T_OFF, the time required to return to the initially set pressure when the pump is restarted (T_ON) is recorded only once for an initial vacuum level of -0.521 bar. This time measurement is illustrated in Figure 5.5, bounded by the dashed green lines. This range of time corresponds to approximately 7s.

Some additional tests could be needed to refine the method for determining T_OFF because we are well aware that a 2-second T_OFF is very short in comparison to the intermittent cycles suggested by a portable medical aspirator, as described in Subsection 3.3.2. In these intermittent cycles, the minimal T_OFF was 5 seconds and the maximum was 20 seconds. However, this short T_OFF is still not negligible as the 10% granted are the limits.

Finally, Table 5.2 resumes all the parameter values related to each mode.

TABLE 5.1: Results of the different T_OFF [s] obtained for various set vacuum levels [bar].

Set vacuum levels [bar]	**Times [s] taken to achieve a 10% vacuum drop**
-0.204	1.97
-0.403	1.96
-0.590	1.98

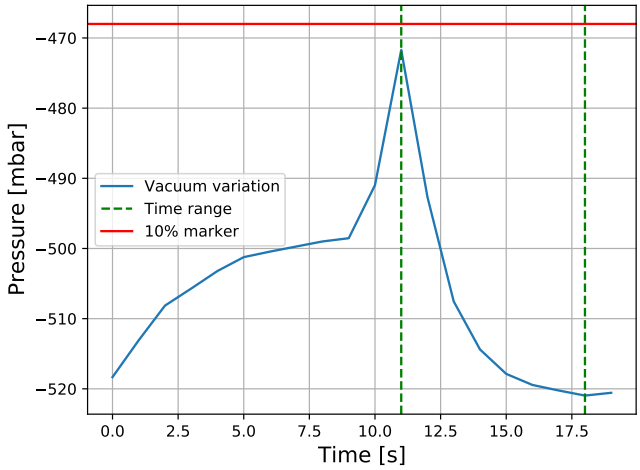


FIGURE 5.5: Graph of pressure evolution when water is sucked in from time 0 s and in intermittent time-cycle mode with a T_OFF = 2 s. The two dashed green lines show the time range of 7s from the highest vacuum drop point, corresponding to the restart of the pump, to a stabilised pressure level around the initial set pressure. The red line represents the 10% mark under the set vacuum level.

TABLE 5.2: Table of the different regulation modes and their related parameters in the Arduino code.

Regulation Mode	**Number**	***T_OFF* [s]**	***T_ON* [s]**
Continuous	0	-	-
Intermittent time-cycle	1	2	7
Intermittent hybrid time-pressure	2	-	7
Intermittent two-step regulation	3	-	-

5.2.2 Characterisation of the pump voltage-pressure/free airflow relationship

a) Principle and objective

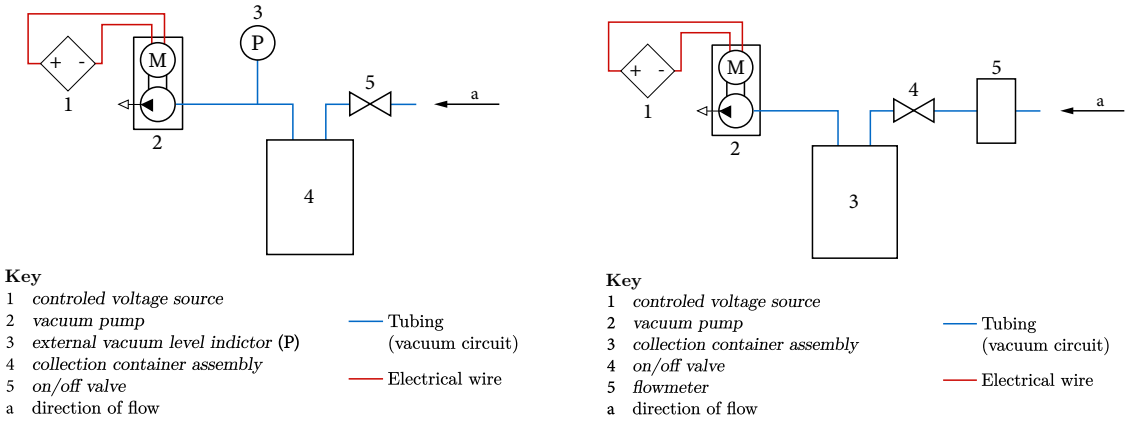
The following tests aim to assess two aspects:

1. During the examination of feasible regulation modes, the question arose whether precise vacuum levels could be achieved by varying the voltage supplied to the pump. The aim of this test is to verify this hypothesis.

2. In addition, a second test is also carried out to measure the variation in airflow as a function of the driving voltage to assess the feasibility of the PID controller mode with pump speed variation.

b) Apparatus setup

The test apparatus setups for the pressure and airflow tests are shown in Figure 5.6a and 5.6b respectively. An adjustable voltage source is required for this test.



(A) Schematic of the apparatus setup for the voltage-pressure relationship characterisation.

(B) Schematic of the apparatus setup for the voltage-free airflow relationship characterisation.

FIGURE 5.6: Schematic of the apparatus setup for the voltage-pressure/free airflow relationship characterisation.

c) Procedure

Voltage - pressure test:

1. Use the apparatus setup of the Figure 5.6a.
2. Power the pump at 6V (to get started).
3. Close the inlet port to the atmosphere.
4. Vacuum the collection container until the pressure stabilises.
5. Once the pressure is reached: Record the reached pressure level.
6. Repeat steps 1 to 4 while increasing the voltage by 1V each time (up to 12V).

Voltage - free airflow test:

1. Use the apparatus setup of the Figure 5.6b.
2. Power the pump at 6V (to get started).
3. Record the reached free airflow level.
4. Repeat steps 1 to 4 while increasing the voltage by 1V each time (up to 12V).

d) Results and discussion

1. As shown by the results in Table 5.3, the pressures reached do not cover the required vacuum range (i.e. from approximately 0.1 bar to 0.75, the maximal vacuum level achievable by the pump). The covered range spans from 621 mbar to 722 mbar, encompassing only 100 mbar, with no vacuum level achievable below 621 mbar. It represents an average increase of 20 mbar/V. On the basis of the results, we can establish that this type of regulation is not feasible because not all pressure ranges can be reached.
2. The free airflow changes significantly with voltage. From 10.61 l/min at lowest voltage to 18.02 l/min at nominal voltage, which represents an average increase of 1.482 (l/min)/V. Therefore, implementing a pump PID controller appears feasible.

TABLE 5.3: Voltage - pressure - free airflow relationship of the vacuum pump

Input voltage [V]	Pressure (relative) [mbar]	Free airflow [l/min]
6	Pump not working	-
7	621	10.61
8	660	12.39
9	689	14.08
10	702	15.58
11	710	16.08
12	722	18.02

5.3 Tests for the device characterisation and performance assessment

The device characterisation and performance assessment will be performed through four criteria:

1. Maximum vacuum level not less than 0.6 bar
2. Free airflow not less than 20 l/min
3. Quantification of air leaks of the vacuum system with mechanical vacuum regulator.
4. Quantification of air leaks of the vacuum system without mechanical vacuum regulator.

5.3.1 Test the maximum vacuum level:

a) Principle and objectives

This test characterises the maximum vacuum level that can be achieved by the prototype. As the suction equipment is considered to be a high vacuum device, the maximum vacuum level must not be less than 0.6 bar according to the specifications, and must be maintained for at least 10s.

b) Apparatus setup

This test needs an external vacuum level indicator and the apparatus setup is shown in Figure 5.1.

c) Procedure

1. Set up the entire suction equipment with its collection container and the external vacuum level indicator connected to the vacuum circuit as shown in Figure 5.1.
2. In the Arduino code: set the operating mode to `continuous`
3. Make sure the inlet port is closed to the atmosphere thanks to the on/off valve.
4. Beginning from no vacuum, activate the suction equipment and operate for no less than 10 s at the maximum vacuum level setting.
5. Verify that the recorded vacuum level is not lower than 0.6 bar and maintained during at least 10s.

d) Results and discussion

The highest vacuum level recorded is -757 mbar which is higher than required (i.e. $>$ 600 mbar). Hence, the requirement is validated.

5.3.2 Test the maximum free airflow :

a) Principle and objectives

This test characterises the free airflow of the prototype. As specified in the specifications for the high vacuum/high flow device, the free airflow must not be less than 20 l/min and shall be reached in less than 10s.

b) Apparatus setup

This test needs an external airflow meter and the apparatus setup is shown in Figure 5.2.

c) Procedure

1. Switch on the device and set the pressure at its maximum vacuum level while the inlet port of the collection container is closed to the atmosphere and then, switch off the device. Hence, the appliance is ready to operate at this set vacuum level.
2. Connect the flowmeter to the inlet port of the suction tubing and make sure the connection is airtight to avoid air leaks.
3. Switch the device back on.
4. Record the flow rate over time, it shall be reached in less than 10s.
5. Repeat the procedure several times and take the mean to obtain a more accurate value of maximum free airflow.

d) Results and discussion

Theoretically, the free airflow recorded should be 28 l/min which is the free airflow of the pump as mentioned in its datasheet. However, in practice, there are air leaks in the system, which is why the measured free airflow rate does not exceed 18.01 l/min. This means an airflow loss of 9.99 l/min in the circuit. A more in-depth analysis of pressure losses and their main sources is provided in the test 5.3.3. As a result of this test, the required minimal free airflow of 20 l/min is not reached by the prototype. As a result, it cannot be labelled as High flow, but rather as Low flow.

5.3.3 Test for air leakage into the vacuum system

a) Principle and objective

The vacuum circuit may be subject to leaks. These can come from various components such as the collection container, the connectors, or the mechanical vacuum regulators (when used). It is important to test how much room air leaks into the system will affect the vacuum level of the suction equipment. The evaluation can be conducted by measuring pressure changes over a specific duration after evacuating and sealing the collection container, and subsequently turning off the pump. This test characterises the complete vacuum circuit, i.e. when it is composed of the mechanical regulator.

The only requirement concerning air leakage in the ISO 10079 standard concerns the collection container. No requirement is provided for the rest of the machine. Therefore, we decided to use this requirement to evaluate the leakage of the whole prototype, which states that the relative pressure does not decrease by more than 1 kPa (= 10 mbar) within 10 s (see *Req C.F. 1.10* in Table 2.6).

b) Apparatus setup

To perform this test, an on/off valve and a calibrated vacuum level indicator are needed. The apparatus setup is shown in Figure 5.1

c) Procedure

1. Use the apparatus setup in Figure 5.1 to evacuate the collection container assembly to a vacuum level of 0.4 bar below atmospheric pressure. Make sure the inlet port is closed to the atmosphere thanks to the On/Off Valve.
2. Once the pressure is reached: switch off the vacuum source.
3. Calculate the average pressure leakage rate (to be used for the next test)
4. Finally, verify that the relative pressure does not decrease by more than 1 kPa (10 mbar) within 10 s.

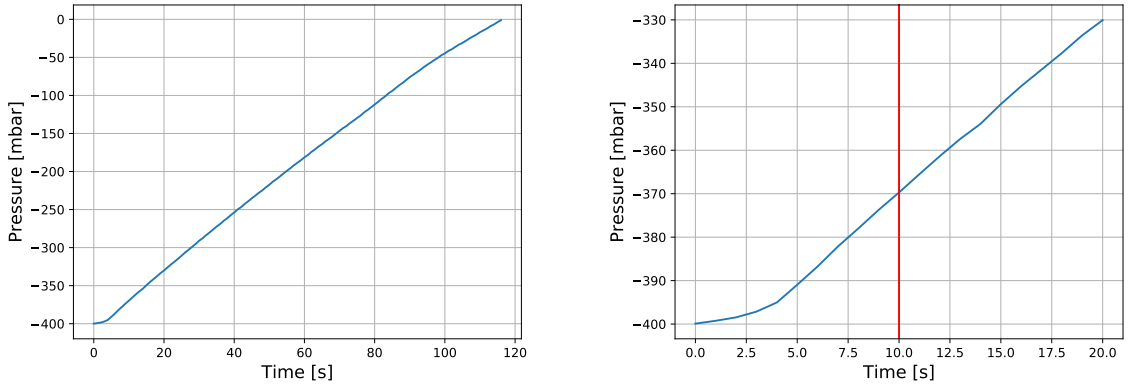
d) Results and discussion

Figures 5.7 illustrate the pressure variation. These graphs show that the relative pressure decrease of 30.2 mbar in 10 s. The system has a leakage rate of about 207.7 mbar/min, as calculated from Figure 5.7a.

The circuit is subject to a change greater than 1kPa (0.1 bar) in 10s. Accordingly, we have quite significant leaks in the vacuum circuit. Further tests have therefore to be carried out to identify the source of these leaks to mitigate them. We have identified 5 potential leak locations:

- The various vacuum connectors
- The vacuum regulator, and in particular the connectors integrated into it
- The collection container
- The connections between tubing and pump connectors
- The pneumatic On/Off valve that is not intended for vacuum applications

The most likely sources of major leaks are the vacuum regulator (test carried out), the collection container (test not carried out), and the pneumatic On/Off valve that is not intended for vacuum applications. The other two sources appear less likely to contain leaks. The vacuum connectors are designed for vacuum use and are of good quality. The connections at the pump level seem well sealed. They were secured using heat.



(A) Vacuum drop until reaching the atmospheric pressure caused by leaks.

(B) Zoom of vacuum drop over the first 20 seconds with the red line highlighting the 10s limit.

FIGURE 5.7: Vacuum drop once the vacuum pump is cut off after reaching the approximate relative pressure of 0.4 bar, to quantify the air leakage of the whole system.

5.3.4 Test for air leakage into the vacuum system without the mechanical vacuum regulator

a) Principle and objective

In this test, leakage from the vacuum system, when the vacuum regulator is removed, are quantified to assess two aspects:

- Initially, we quantify the leaks found within the vacuum system used with the intermittent two-step regulation mode (i.e. vacuum circuit without mechanical vacuum regulator),
- which will subsequently enable us to quantify the leakage rate at the mechanical vacuum regulator level as follow:

$$Q_{regulator} = Q_{system-with} - Q_{system-without} \quad [\text{mbar/min}] \tag{5.1}$$

with $Q_{regulator}$ the leakage rate from the mechanical vacuum regulator, $Q_{system-with}$ the leakage rate of the complete system with regulator, $Q_{system-without}$ the leakage of the system without regulator.

b) Apparatus setup

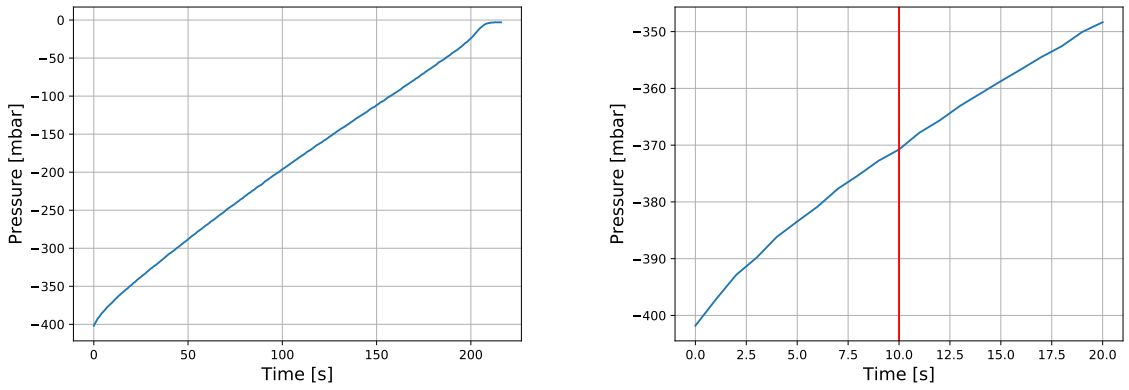
To perform this test, the same apparatus setup as the previous test is used (Figure 5.1) except the mechanical vacuum regulator is removed from the vacuum circuit.

c) Procedure

1. In the Arduino code, set the operating mode to `inter_cycling_pressure`
2. Use the apparatus setup in Figure 5.1 to evacuate the collection container assembly to a vacuum level of 0.4 bar below atmospheric pressure. Make sure the inlet port is closed to the atmosphere thanks to the On/Off Valve.
3. Once the pressure is reached: switch off the vacuum source.
4. Verify that the relative pressure does not decrease by more than 1 kPa within 10 s.
5. Compute the vacuum leakage of the tested system and compute the mechanical regulator leakage rate according to equation (5.1).

d) Results and discussion

Figure 5.8 illustrates the pressure variation over time. These graphs show that the relative pressure decreased by 30.1 mbar in 10 s. The system without mechanical vacuum regulator has an average leakage rate of about 112.3 mbar/min. Therefore, according to equation 5.1, the vacuum regulator yields a leakage of 207.7 - 112.3 = 95.4 mbar/min.



(A) Vacuum level drop before reaching atmospheric pressure

(B) Zoom of vacuum level drop over the first 20 seconds with the red line highlighting the 10s limit

FIGURE 5.8: Vacuum level drop once the vacuum pump is cut off after reaching the approximate relative pressure of 0.4 bar, to quantify the air leakage of the closed system without vacuum regulator

Upon comparing pressure losses in the entire vacuum system with those when the mechanical regulator is excluded from the setup, a noticeable difference emerges. Specifically, removing the regulator leads to a reduction in the average leak rate (from 207.7 mbar/min to 112.3 mbar/min). However, despite this variation, the vacuum level drop during the initial 10 seconds remains remarkably similar in both configurations.

When comparing pressure losses within the complete vacuum system to those when the mechanical regulator is removed from the circuit, it is observed that while the average leak rate decreases when the regulator is removed (from 207.7 mbar/min to 112.3 mbar/min), the vacuum level drop during the initial 10s remains nearly identical between the two systems. Only the subsequent evolution of pressure is different, as can be clearly seen in Figures 5.7b and 5.8b.

It is quite surprising to observe that leaks are also present at the regulator level, particularly concerning its connectors, despite being designed for vacuum regulation.

5.4 Tests of the mechanical vacuum regulator

The following tests are designed to evaluate the performance of the mechanical vacuum regulator in terms of the accuracy of maintaining the set vacuum level.

5.4.1 Setpoint retention

a) Principle and objective

Setpoint retention refers to the ability of the vacuum regulator to maintain the initial setpoint, and preserve it after turning off and restarting the prototype. This test aims to measure how accurately the regulator can keep the initial setpoint.

We assessed the setpoint retention of the mechanical vacuum regulator by adjusting the vacuum level to a specific pressure of 0.5 bar. Then, we observe the stability of the pressure when the prototype was turned off and subsequently restarted.

b) Apparatus setup

The test apparatus setups is shown in Figure 5.1.

c) Procedure

1. In the Arduino code, set the operating mode to `continuous`
2. Close the inlet port to the atmosphere.
3. Switch on the suction pump and set the vacuum level around -0.5 bar by turning the regulator knob.
4. Once the required vacuum is reached: switch off the device.
5. Wait for the pressure inside the collection container to return to atmospheric pressure.
6. Switch on the device again and close again the inlet port to the atmosphere. Do not touch the regulator knob and start recording the pressure over time with the external vacuum level indicator until the pressure stabilises.
7. Compare this achieved vacuum level with the initially set target.

d) Results and discussion

The initial setpoint was adjusted to 535 mbar. Graph 5.9 reveals that, after powering off and restarting the device, it takes 7.5s for the vacuum regulator to return to the set pressure (dashed green line), and then it stabilises at a vacuum level of 556 mbar (indicated by the dashed red line). This value deviates from the initial set vacuum level by 3.92%.

This measure provides a single estimate of the time taken to return to the preset pressure and the accuracy with which this pressure is regained. Repeating the experiment 3 times would increase the robustness of the results.

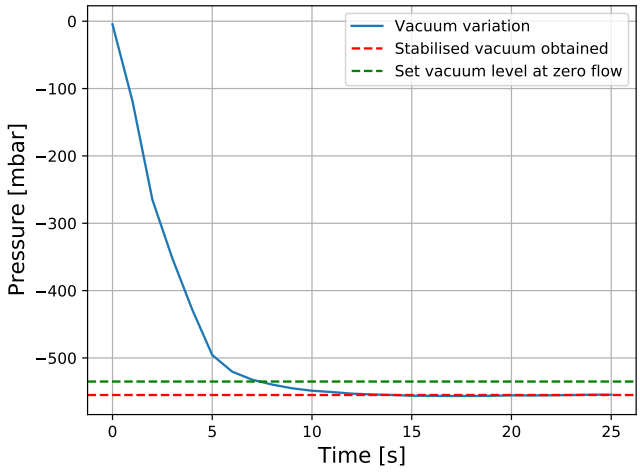


FIGURE 5.9: Pressure variation during the setpoint retention experiment. The dashed green line indicates the initial setpoint and the dashed red line represents the reached vacuum level once the device has been restarted.

5.4.2 Difference between the vacuum level at zero flow and the vacuum level while suctioning water

a) Principle and objective

When operating the prototype with the mechanical vacuum regulator (with the continuous mode, intermittent time-cycle, and intermittent hybrid time pressure), we noticed that there is always a pressure difference between the pressure set in the regulator at zero flow and the stabilised pressure once water is drawn in. This test consists in observing the evolution of the pressure inside the collection container when the prototype sucks in water. It aims to quantify this vacuum loss and assess whether or not the 10% accuracy around the set vacuum level is respected.

This test is conducted for various initial vacuum levels to assess whether the pressure drop caused by water aspiration varies with the working vacuum level. A total of three relative pressure levels are tested: 0.2, 0.4, and 0.6 bar.

b) Apparatus setup

To perform this test, the test apparatus setup is shown in Figure 5.1.

c) Procedure

1. In the Arduino code, set the operating mode to `continuous`
2. Use the apparatus setup of Figure 5.1 to set the mechanical regulator and evacuate the collection container assembly to a relative vacuum level of 0.2 bar.
3. Once the pressure is reached: start sucking up water.

4. Record pressure variation until the collection container is full.
5. Repeat steps 1 to 4 with the other vacuum levels (0.4 and 0.6 bar).
6. Finally, compare the set vacuum level at zero flow with the vacuum level while suctioning water and verify that the pressure attained while aspirating water remains within a precision range of 10% around the initial set pressure.

d) Results and discussion

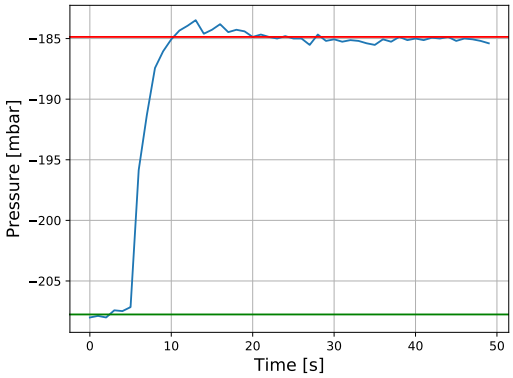
The pressure evolution in the collection container at different operating vacuum levels is described in Figures 5.10. Green lines represent the set vacuum level at zero flow, and the red lines represent the stabilised pressure during water suction. A pressure difference of 22.8, 30, and 35.8 mbar are observed for a working pressure of respectively 200, 400, and 600 mbar. On average, the vacuum level drop is 29.6 mbar.

We observe that the stabilised vacuum level is never identical to the set vacuum level and this difference (calculated as a percentage relative to the pressure at zero water flow $\frac{\Delta P}{P_{setup}} \times 100$) tends to increase as the set pressure decreases, as shown by the numerical results calculated and summarized in Table 5.4. Based on this observation, it can be deduced that the regulator demonstrates optimal performance at higher relative operating vacuum levels. As the vacuum decreases, the regulator's efficiency reduces, and it becomes progressively more difficult to maintain the desired pressure. This becomes evident to the extent that, for an initial low vacuum level of 0.2 bar, the vacuum while suctioning water drops below the 10% accuracy threshold.

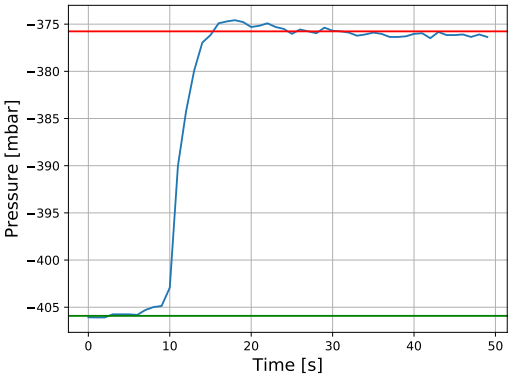
Now that we are aware of this vacuum level deviation once water is aspirated, it must be considered for the subsequent tests and thus will be integrated into the Arduino code. In the code, the pressure thresholds of 8% required by the intermittent modes will be implemented around the stabilised pressure during water aspiration instead of the set vacuum level, as shown in Figure 5.11. In other words, the `P_working` variable (defining the setpoint pressure, see Subsection 3.7 for more information) will be initially decreased by 30 mbar in the Arduino code. This will also affect the alarm functions (see Section 3.7), ensuring that the current pressure remains within a 10% range around the stabilisation pressure, rather than the set pressure.

TABLE 5.4: Numerical results computed from the difference between the vacuum level at zero water flow (P_{setup}) and the vacuum level while suctioning water ($P_{stabilised}$) test.

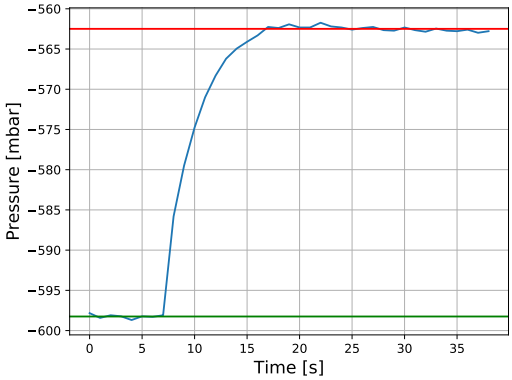
Vacuum levels tested [mbar]	P_{setup} **[mbar]**	$P_{stabilised}$ **[mbar]**	$\Delta P = P_{setup} - P_{stabilised}$ **[mbar]**	**Difference relative to set pressure [%]**
200	207.76	184.86	22.89	11.01
400	405.91	375.76	30.15	7.42
600	598.25	562.46	35.79	5.98



(A) Vacuum drop for a set pressure of 0.2 bar



(B) Vacuum drop for a set pressure of 0.4 bar



(C) Vacuum drop for a set pressure of 0.6 bar

FIGURE 5.10: Pressure evolution over time for water suction into the collection container, for different set vacuum levels. The green line is the set pressure at zero water flow. The red line is the stabilised pressure.

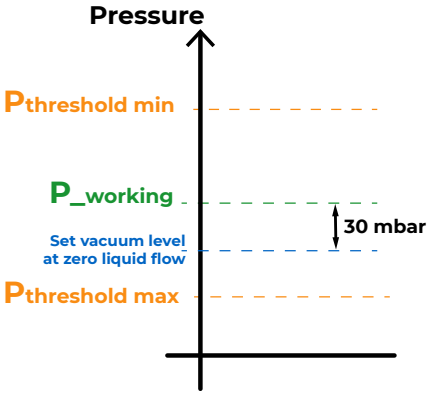


FIGURE 5.11: Schematic representation of modifications following the test concerning the difference between vacuum level at zero flow and during water suction. P_working is now defined as the set vacuum level at zero liquid flow minus 30 mbar, in order to calculate regulation mode thresholds and alarm triggers based on the stabilised pressure once water is aspirated.

5.5 Tests of the internal vacuum level indicator accuracy

a) Principle and objective

The vacuum level indicators shall be accurate to within ±5% of the full-scale value, i.e. within $\pm$0.05bar for a manometer indicating the pressure from 0bar to -1bar. Therefore, this test aims to check if the vacuum level indicators of the prototype are well-calibrated and accurate by testing them at several vacuum levels to encompass the widest range of the full scale.

b) Apparatus setup

This test requires an external well-calibrated vacuum level indicator (used as an indicator reference). The test apparatus setup is shown in Figure 5.1.

c) Procedure

1. Connect the external vacuum level indicator as shown in Figure 5.1. Make sure the connections are watertight to prevent pressure leaks.
2. Set the vacuum level to 0.2 bar.
3. Once the pressure is stabilised on the external indicator and the vacuum level indicator under test, record both data.
4. Analyse these data and compute the percentage difference between the two values expressed regarding the full scale of -1bar - 0bar.
    - If the difference is less than ±5% of the full-scale, the vacuum level indicator under test meets the accuracy requirements.
    - If the difference is greater than ±5% of the full scale, it does not meet the accuracy requirements.
5. Repeat these previous steps, adjusting the reference source to different vacuum levels: 0.4 , 0.5 , 0.6 and 0.7 bar to check the accuracy of the vacuum level indicator over its entire measuring range.

d) Results and discussion

Table 5.5 compares vacuum measurements from the tested indicators (manometer and pressure transducer) with those from the reference indicator. The pressure sensor demonstrates a high accuracy, closely matching the reference indicator, with an average error of 1.6 mbar, well within the $\pm$5% required precision range. In contrast, the internal manometer exhibits a significantly higher average error of 38.4 mbar. Nonetheless, it still meets the required vacuum level for each tested vacuum level.

TABLE 5.5: Result and comparison for the internal vacuum level indicators accuracy (pressure transducer and manometer) based on an external pressure transducer.

External vacuum level indicator [mbar]	Internal pressure transducer [mbar]	Internal manometer [mbar]
258	256-255	210
412	411-410	370
511	509	475
601	600-599	560
726	726-725	700

5.6 Tests of the collection container and overfill protection device

5.6.1 Test of the legibility through the collection container and usable volume:

a) Principle and objective

The collection container is subject to two visual requirements:

- *The collection containers shall clearly show the level of contents.*
- *The usable volume of the collection containers, expressed in millilitres and graduations at 50ml to 250ml intervals shall be marked.*

Furthermore, the bottle's capacity should be greater than 500ml, except in cases of field or transport applications, where capacities greater than 300ml are acceptable if the device includes overfill protection, and capacities greater than 200ml are permissible if such protection is not incorporated. Therefore, this test serves as a qualitative assessment to ensure that the collection container effectively displays and marks the content level, while also confirming that the usable volume aligns with the specified requirements.

b) Results and discussion

Illustrated in Figure 5.12, the transparency of the bottle allows for clear visibility of the liquid contents. The collection container has a usable volume of 1l. Moreover, the level of graduation is thick and clearly visible. The graduations are expressed in ml and spaced at 100ml intervals. Hence, the collection container meets all the criteria.

FIGURE 5.12: Collection container level indicators.

5.6.2 Test of the overfill protection device:

a) Principle and objective

The specifications state that:

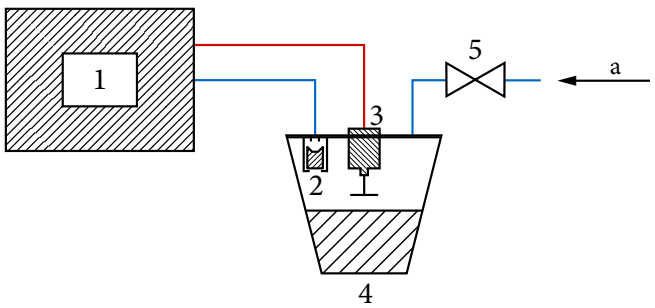
- *Collection container shall preferably have an automatic cut-off when full to prevent ingress of fluid to the pump.*
- *Overfill protection device shall not activate until at least 90% of the indicated maximum capacity of the collection container has been reached.*
- *Means must be provided to prevent foam from passing from the collection container into the vacuum source.*

The overfill protection device implemented for the prototype is a float sensor level linked to the container, which should therefore not activate before the liquid reaches 90% of the usable container volume. Moreover, the means implemented to prevent foam from passing is a valve (see 2 in Figure 5.13) built directly into the lid of the container. The test consists simply of sucking up water with the device and waiting for the overflow alarm to go off.

The level sensor alarm is initiated when the float attains the position of the reed within the rising stem. Upon this attainment, the Arduino-implemented alarm function (see Section 3.7) is activated. To determine the precise water level at which the sensor triggers, the procedure will be repeated three times and the average of the attained levels will be calculated.

b) Apparatus setup

An on/off valve is required along with a water container of greater capacity than the maximum volume of the collection container being tested. The apparatus setup is available in Figure 5.13.



Key

1 *suction device*
2 mean to prevent foam passing from the *collection container* into the *vacuum source*
3 *level sensor*
4 *collection container assembly*
5 *on/off valve*
a direction of flow

Tubing (vacuum circuit)
Electrical wire

FIGURE 5.13: Apparatus setup of the level sensor test.

c) Procedure

1. Connect the overfill protection device as shown in Figure 5.13.
2. Close the inlet port to the atmosphere and set the vacuum level to 0.5 bar.
3. Once the vacuum level is reached, start sucking up water into the collection container until the shut-off mechanism of the overfill protection device is activated.
4. Once the mechanism is activated, stop sucking up water by closing the on/off valve.
5. Note the water level reached.
6. Repeat steps 1 to 6 a total of three times.
7. Take the mean of the obtained volume levels. For more accurate results, it could be interesting to calculate the standard deviation in order to ensure relevant data.
8. Verify that the sensor does not activate before 90% of the full capacity level.

d) Results and discussion

The volumes obtained from the level sensor experiment are 907, 905, and 905ml. The average volume at which the alarm is triggered is 905.67ml, which corresponds to 90.5% of container volume and its standard deviation is 0.94, which means that the average is relevant. This requirement is therefore respected.

5.7 Tests of the prevention system for risk reduction

5.7.1 Negative pressure protection:

a) Principle and objective

The ISO10079-4 states that *if a mean to limit the maximum vacuum level is fitted, the vacuum shall not exceed the maximum vacuum level by more than 10%.*

The means implemented is an alarm that is triggered as soon as the pressure exceeds the set pressure at zero water flow by 10%. Hence, it naturally works for maximum pressure. More information about the alarm is available in Subsection 3.7.

b) Apparatus setup

To test it, the same apparatus setup as a previous test is used (Figure 5.1).

c) Procedure

1. Close the on/off valve to the atmosphere and set the mechanical regulator to evacuate the collection container assembly to the relative pressure of 0.6 bar.
2. Once the set pressure procedure is complete (see Subsection 3.9) and the machine operational: adjust the vacuum regulator knob to increase the setpoint, enabling a higher vacuum level within the collection container.
3. Check that the alarm is triggered once the vacuum level has increased by 10%.
4. Verify that the alarm function properly by launching a message, lighting up a red LED, and switching off the vacuum pump.

d) Results and discussion

As expected, the alarm is triggered once the vacuum level exceeds 10%, and it switches the pump off. The machine will only restart once the vacuum level has returned to normal condition, and the user has clicked the button. No automatic start is performed for safety.

5.8 Tests for the regulation modes comparison

To be able to compare the four regulation modes and determine the most effective, five criteria have been established:

- Accuracy of the regulation
- Response to a disturbance
- Power consumption
- Suction water flow rate
- Ease of use and accuracy of the set pressure selection

The different setting parameters of each regulation mode are referenced in Section 3.7.

The aim of each test is to compare them according to one criterion. The last criterion is evaluated throughout the different tests carried out and its conclusion will be addressed in Section 5.9 *General discussion and test conclusion*.

5.8.1 Test of the accuracy of the different regulation modes while suctioning water:

a) Principle and objective

The aim of this test is to quantify the accuracy of the vacuum level once stabilised during water suction for the 4 different regulation modes. It is therefore an opportunity to check the vacuum regulator's performance when there is fluid suction for a constant set vacuum level. The accuracy shall be within $\pm 10\%$ of the set vacuum level as stated in the specifications.

However, as the regulator generates an offset of 30 mbar that seems constant regardless of the working pressure, this specification is not quantified with respect to the setpoint pressure, but with respect to the stabilisation pressure when water is sucked in, as explained in the previous test (see results of Test 5.4.2).

b) Apparatus setup

The test apparatus setups is shown in Figure 5.1.

c) Procedure

1. In the Arduino code, set the operating mode to `continuous`.
2. Close the inlet port to the atmosphere.
3. Switch on the device and set the vacuum level around -0.5 bar.

4. Once the vacuum level is reached and stabilised, start sucking up water and recording the pressure over time until the vacuum level stabilises.
5. Check that the stabilised vacuum level while suctioning water is within $\pm$10% of the initially stabilised vacuum level.
6. Repeat steps 1-5 for each operating mode.

d) Results and discussion

Figures 5.14 represent the evolution of the vacuum level when the prototype starts to draw in water for each operating mode.

In Figure 5.14a, 5.14b and 5.14c (figures of the three modes using the mechanical regulator), we observe the phenomenon described during the previous test. As water begins to be drawn in, the vacuum level drops from the set pressure to around -510 mbar, at which point the vacuum level stabilises (indicated by the dashed green line).

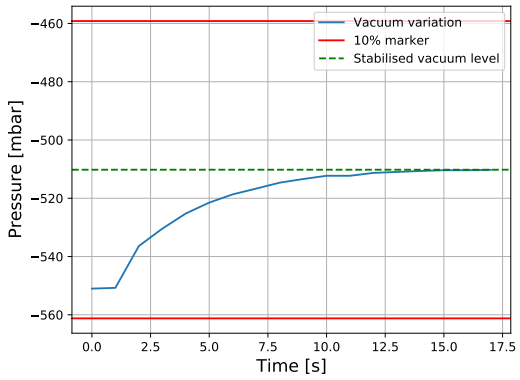
Figure 5.14a describes the pressure evolution over time for the continuous mode in which water starts to be sucked in from 2.1s. The vacuum level remains stable around -510 mbar without oscillation, eliminating the risk of exceeding the 10% range marked by the two red lines.

Figure 5.14b has been captured under intermittent time-cycle mode, depicting the pressure variation over time as the prototype begins drawing in water at 0 second. The three cycles of time, indicated by the three peaks, are distinctly noticeable (yet the third cycle is only partially visible). Within each cycle, as the vacuum level increases (indicating pump activation), the pressure consistently settles at 12 mbar above the initial stabilised pressure of -510 mbar. This 12 mbar overage represents a deviation of 2.35% from the initially stabilised pressure. Another key observation in Figure 5.14b is that, while the pressure curve remains well within the $\pm$10% range of the stabilised vacuum level, the peaks represent a 5.3% variation. This indicates a significant margin before reaching the 10% limit and suggests the possibility of a longer `T_OFF`. More comprehensive testing is needed to optimize these parameters further.

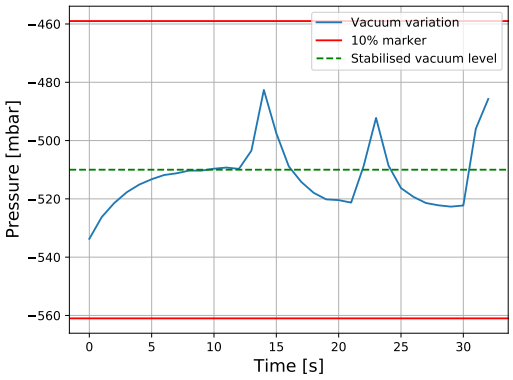
Figure 5.14c depicts intermittent hybrid time-pressure regulation. In this graph, the observations closely resemble those of the intermittent time-cycle mode, except for a more significant 8% decline in the vacuum level during pump deactivation, dropping by 8%, compared to the 5.3% drop associated with a predefined time threshold. However, this method of regulation still ensures the necessary 10% accuracy is upheld around the stabilised pressure during water suction. In each cycle, as the vacuum level rises (indicating pump activation), the pressure consistently stabilises at 25 mbar above the initial stabilised pressure of -507 mbar. This 25 mbar excess corresponds to a deviation of 4.93% from the initially stabilised pressure.

In Figure 5.14d, pressure oscillates within the range defined by dashed blue lines set at the 8% thresholds. This behaviour reflects the intermittent two-step regulation method, where the vacuum pump activates and deactivates upon reaching these pressure thresholds. The dashed green line denotes the set vacuum level within the Arduino, around which pressure oscillates. The red lines indicate the required $\pm$10% accuracy range. Notably, the vacuum exceeds the threshold dictated by the regulation mode and even surpasses the red line consistently during pump operation

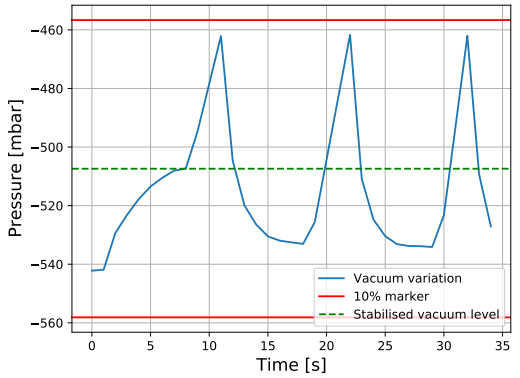
To sum up, in both intermittent time-cycle and intermittent hybrid time-pressure modes, during the phase when the pump is activated, the vacuum level tends to exceed the initially stabilised vacuum level (dashed green line). Regarding the last regulation mode, depicted in Figure 5.12d, the vacuum level consistently goes beyond the 8% threshold. This phenomenon could potentially arise from the pump's inertia, leading to a delayed halt in the vacuum rise upon pump deactivation. Conducting further experimentation to determine optimal thresholds for this regulation mode would contribute valuable insights.



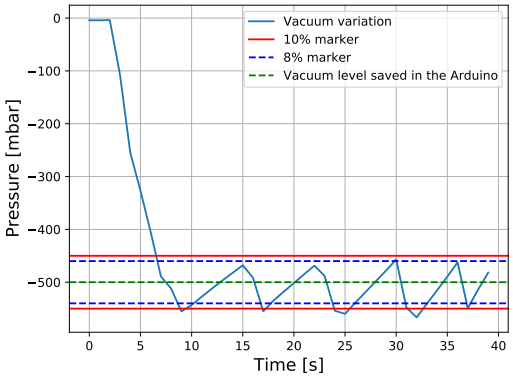
(A) Pressure variation over time during water suction in **continuous** mode. The stabilised vacuum level during water suction is -510 mbar.



(B) Pressure variation over time during water suction in **intermittent time-cycle** mode. The stabilised vacuum level during water suction is -510 mbar.



(C) Pressure variation over time during water suction in **intermittent hybrid time-pressure regulation** mode. The stabilised vacuum level during water suction is -507 mbar.



(D) Pressure variation over time during water suction in **intermittent two-step regulation** mode. The set pressure is -500 mbar. The dashed blue lines are the 8% thresholds defining the pressure window.

FIGURE 5.14: Pressure evolution over time during water suction obtained by testing the pressure regulation accuracy of the different modes while suctioning water. The dashed green line is the stabilised vacuum level during water suction for (A), (B) and (C), and the set pressure saved in the Arduino code for (D). The horizontal red lines delineate the permissible range of ±10% deviation from the stabilised vacuum level.

5.8.2 Testing the response of the different vacuum regulation systems to a disturbance

a) Principle and objective

Exploring the prototype's reaction to a disturbance, such as air suction, could provide insights into the regulatory system's ability to restore the operational pressure within a 10% accuracy range in under 10 seconds following the disturbance's cessation. This test is conducted across the four regulation modes to analyse the response to a disturbance within each mode.

While submerging the tube in water and initiating water aspiration, a disruption is introduced by briefly lifting the tube out of the water for approximately 2 seconds. This action draws in air, thereby generating the disturbance. The tube is promptly re-submerged in water thereafter.

b) Apparatus setup

The test apparatus setups is shown in Figure 5.1.

c) Procedure

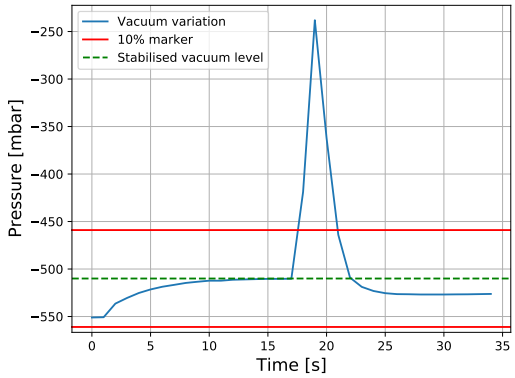
1. In the Arduino code, set the operating mode to `continuous`.
2. Close the inlet port to the atmosphere.
3. Switch on the device and set the vacuum level around -0.5 bar.
4. Once the vacuum level is reached, suck up water and record the pressure over time.
5. Make a disturbance by suctioning air for 2 seconds and plunge back the inlet port in water until the required vacuum is recovered.
6. Analyse the time required to return to a stabilised vacuum level (should take less than 10s) and with what accuracy (shall be within $\pm$10%).
7. Repeat steps 1-6 for each of the 3 remaining modes.

d) Results and discussion

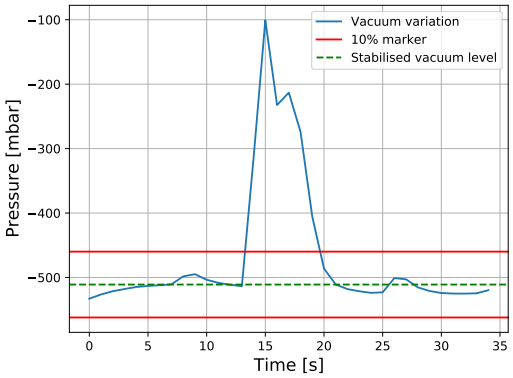
Figures 5.15 depict pressure changes induced by a disturbance, involving the aspiration of air instead of water for a brief duration.

In Figure 5.15a, illustrating continuous operation, the vacuum level stabilises around -510 mbar as water suction begins. At 18 seconds, a 2s disturbance leads to a drop to -245 mbar. Subsequently, the curve rises during water suction, with the vacuum level surpassing the initial stabilisation at -522 mbar, resulting in a 2.3% overshoot. The vacuum level stabilises near the initial level within 3s of disturbance cessation, which is significantly below the required 10s threshold.

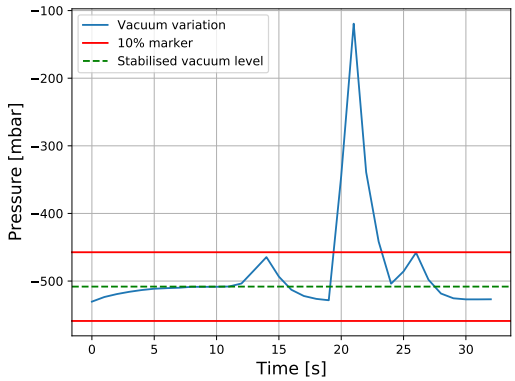
Figure 5.15b illustrates a 2s disturbance within the intermittent time-cycle mode. The disturbance is visible between 13s and 15s, causing the vacuum level to drop to -0.1 bar. During the disturbance recovery, the off-cycle is initiated, leading to a local vacuum level drop around 16s. Once the off-cycle concludes (after 2 seconds), the pump restarts, and the vacuum level stabilises. The control system restores the stabilised pressure within 6.5s after the disturbance. Similar to the continuous mode, there is a slight overshoot of 1.96% as the vacuum briefly drops to -520 mbar instead of -510 mbar. However, the vacuum level remains within the required 10% accuracy threshold after the disturbance.



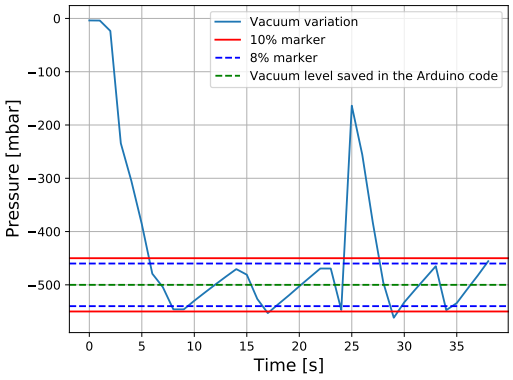
(A) Pressure evolution over time with disturbances during water suction in **continuous** mode. The stabilised vacuum level during water suction is -510 mbar.



(B) Pressure evolution over time with disturbances during water suction in **intermittent time-cycle** mode. The stabilised vacuum level during water suction is -508 mbar.



(C) Pressure evolution over time with disturbances during water suction in **intermittent hybrid time-pressure** mode. The stabilised vacuum level during water suction is -505 mbar.



(D) Pressure evolution over time with disturbances during water suction in **intermittent two-step regulation** mode. The setpoint pressure is -500 mbar. The dashed blue lines are the 8% thresholds defining the intermittent two-step regulation.

FIGURE 5.15: Pressure evolution over time with disturbances during water suction for the four regulation mode. The dashed green line is the stabilised vacuum level during water suction for (A), (B) and (C), and the set pressure saved in the Arduino code for (D). The horizontal red lines delineate the permissible range of $\pm$10% deviation from the stabilised vacuum level.

Figure 5.15c shows the pressure variation with a disturbance in the intermittent hybrid time-pressure regulation mode. Beginning at 19.5s, a 2s disturbance occurs, resulting in a vacuum decrease to -115 mbar. The set vacuum level is promptly restored within 3s. Following this recovery, the pump shuts down without causing the vacuum to drop by more than 10% of the stabilised value, i.e. beyond the upper red line. Hence, this pressure regulation system maintains stability within 10% of the stabilised pressure during water intake, even in the presence of disturbances.

Figure 5.15d displays the intermittent two-step regulation response to a disturbance during water suction. This mode is characterised by pressure oscillation between the 8% thresholds above and below the set value of -500 mbar. Initiated at 23s, the disturbance causes a vacuum drop to -170 mbar. Subsequently, the vacuum level swiftly returns to its set value

within 3s, even overshooting the set threshold. The pressure curve exceeds the $+10\%$ accuracy bound (i.e. the geometrically lower bound), indicating that the requirement is not satisfied for this mode.

In conclusion, all modes effectively manage disturbances, maintaining the vacuum level within a range of $\pm 10\%$ of the initially stabilised pressure. Moreover, disturbance recovery occurs within less than 10s. This process takes approximately 3s for continuous, intermittent hybrid time-pressure, and intermittent two-step regulation modes. However, the time-cycle mode takes longer, around 6.5s, due to an off-cycle occurring during disturbance recovery.

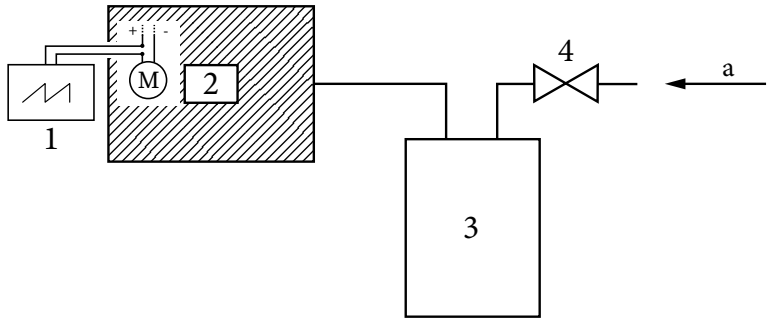
5.8.3 Test to measure power consumption:

a) Principle and objective

The prototype's power consumption is quantified, in order to compare the different regulation modes and determine whether or not an intermittent mode is worth implementing in terms of energy savings compared to a continuous power supply.

b) Apparatus setup

To perform this test, a data-recording oscilloscope is used to measure the current consumed by the prototype. These data are then used to determine the device's average power consumption over a given period of time. The test apparatus setup is shown in Figure 5.16. Current measurement is performed while the device is sucking in water up to the full capacity of the collection container (1l).



Key
1 *oscilloscop* for current measurement
2 *suction device* under test, with *pump motor* (M) highlighted
3 *collection container assembly*
4 *on/off valve*
a direction of flow

FIGURE 5.16: Schematic of the test apparatus setup of power consumption.

c) Procedure

1. Use the apparatus setup in Figure 5.16 to evacuate the collection container assembly to a vacuum level of 0.5 bar below atmospheric pressure. Make sure the inlet port is closed to the atmosphere using the On/Off Valve.

2. Once the pressure is reached: start sucking in water and launch the current data recording.
3. Stop the device and the recording once the collection container is full.
4. Process the data and calculate the prototype's average consumption over a given period of time. 35s is chosen because it is the average time needed to fill the collection container.
    - Power consumption is calculated by digitally integrating the pump's current consumption over the experiment duration and multiplying this value by the nominal voltage (12v)
    - Then, divide this power consumption by the recording time and multiply the result by 35s. Hence, all the consumptions are calculated on an equivalent time basis.
5. Repeat steps 1-4 for the other regulation modes.

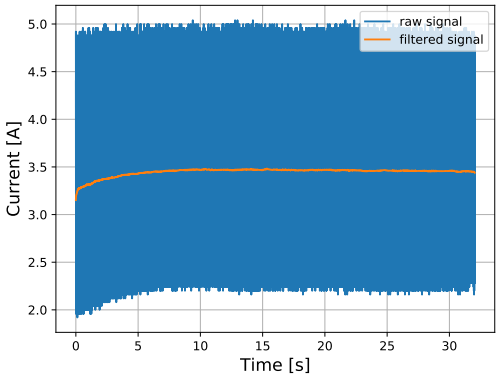
d) Results and discussion

The current consumption of the different regulation modes can be seen in Figure 5.17. The signals have been filtered for greater clarity. The average power consumption is calculated as explained in the Apparatus setup section. Results are summarised in Table 5.6.

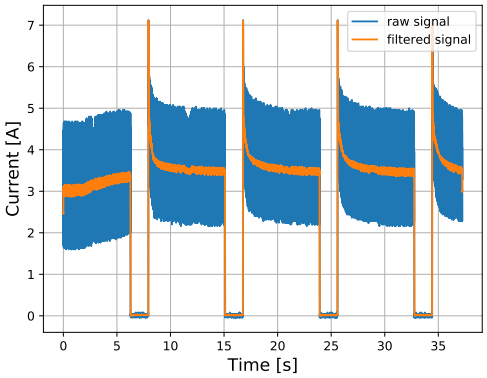
By looking at the results, it is evident that intermittent modes have lower energy consumption than continuous mode. In comparison to the continuous mode, the intermittent time-cycle mode consumes 15.9% less energy, the intermittent hybrid time-pressure consumes 17.35% less, and the intermittent two-step regulation, being the most energy-efficient, consumes 71.7% less. Based on these results, we can see that the last regulation mode (Figure 5.17d) stands out as the most energy-efficient option, as it significantly reduces energy consumption. The other intermittent modes, despite their lower energy consumption compared to a continuous supply, are not as optimal as expected in terms of energy efficiency. They deserve further research and experimentation to identify the optimal parameters that would enhance their energy efficiency while maintaining the required level of accuracy.

However, every time the pump is switched on, there is a current peak (inrush current[2]) of about 7A. The electrical circuit should be redesigned to reduce these peaks as a future improvement. Moreover, the intermittent two-step regulation mode requires a higher average current level (around 4.75 A) than the other modes, which have an average current level of around 3.6 A.

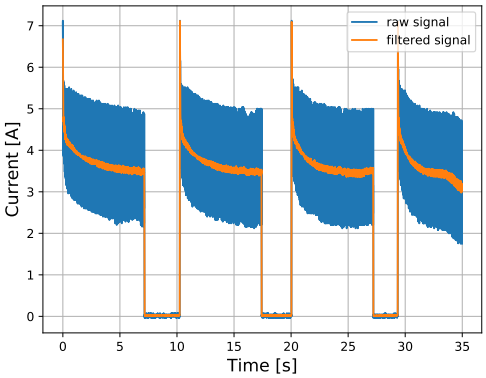
[2]As the name suggests, "inrush current" refers to a sudden rush of a large amount of current into the circuit when a device is switched on. In definition, is the maximal instantaneous input current drawn by an electrical device when first turned on [205].



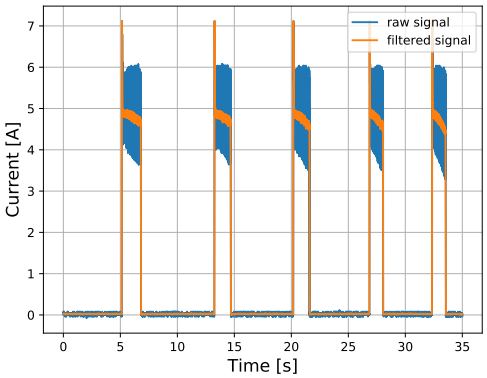
(A) Continuous regulation mode



(B) Intermittent time-cycle regulation mode



(C) Intermittent hybrid time-pressure regulation mode



(D) Intermittent two-step regulation mode

FIGURE 5.17: Current consumption of the pump for the four regulation modes at a 12V nominal supply. The blue curve represents the raw signal, and the orange curve represents the averaged and filtered signal for better readability

TABLE 5.6: Result of the power consumption test for the four regulation modes comparison

Regulation mode	**Current consumed over experiment duration [A]**	**Experiment duration [s]**	**Power consumption over 35s [kW]**
Continuous	110.45	32.04	1.447
Intermittent time-cycle	108.01	37.27	1.217
Intermittent hybrid time-pressure	99.54	34.95	1.196
Intermittent two-step regulation	34.13	34.99	0.409

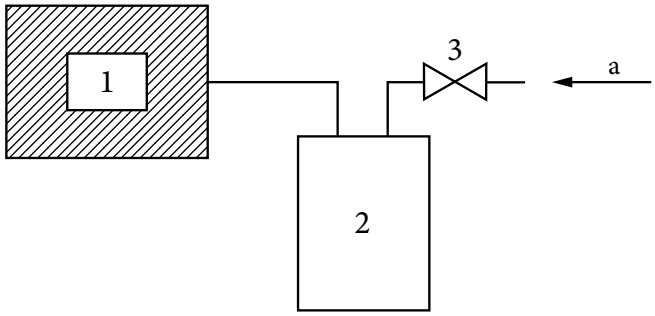
5.8.4 Test to measure suction water flow rate :

a) Principle and objective

The suction water flow rate is measured to quantify the suction power in terms of liquid drawn, a useful measurement for characterising the prototype's performance. Additionally, this test is also designed to allow a comparison of the achieved water flow rates between the regulation modes.

b) Apparatus setup

To perform this test, the test apparatus setup is shown in Figure 5.18. A stopwatch is also required.



Key
1 *suction device* under test
2 *collection container assembly*
3 *on/off valve*
a direction of flow

FIGURE 5.18: Schematic of the test apparatus setup of the suction water flow rate measurement.

c) Procedure

1. In the Arduino code, set the operating mode to `continuous` and set up the vacuum circuit in accordance with the mode used
2. Disable the level sensor to not disturb the test
3. Use the apparatus setup of Figure 5.18 to evacuate the collection container assembly to the relative pressure of 0.5 bar.
4. Once the pressure is reached: start sucking up water and launch the stopwatch
5. Stop the stopwatch when the water level reaches 1 l.
6. Repeat the test three times with the same regulation mode.
7. Compute the mean and standard deviation of the obtained results.
8. Repeat steps 1 to 7 for the other regulation modes.
9. Finally, compare the results of the different modes.

d) Results and discussion

Results are shown in Figure 5.19. We can observe that the first 3 modes have a statistically similar result (confirmed with T-tests[3]). They all suck up water with a similar flow rate (range of [1.67 ; 1.73] l/min), and this does not change whether in continuous or intermittent mode. However, the water flow obtained with the intermittent two-step regulation mode (number 3) is significantly different and slightly higher than the other by approximately 0.043 l/min. We can explain this difference in two ways:

- A first explanation would be that this was the first regulation mode tested involving the removal of the vacuum regulator. Disconnecting the vacuum connectors can be somewhat challenging once they are in place. It's likely that our approach and precision during this initial test were not as refined as those employed in subsequent tests.
- The second potential explanation is that, in accordance with the threshold parameter of 8% (refer to Section 3.7), the regulation system in this mode tends to reach slightly over 8% above the preset vacuum level. This contrasts with the other mode, wherein the vacuum level does not surpass the set vacuum level by more than 5%, as elucidated in the preceding test 5.8.1. This higher vacuum level enables a greater flow rate.

Furthermore, we can observe that the device achieves an average flow rate of 1.697 l/min at a relative pressure of 0.5 bar, so the 1-litre collection container is filled with water in an average of 35.2 seconds.

In conclusion, all the regulation modes offer similar suction water flow rates, only the last regulation mode offers a slightly higher flow of 0.043 l/min.

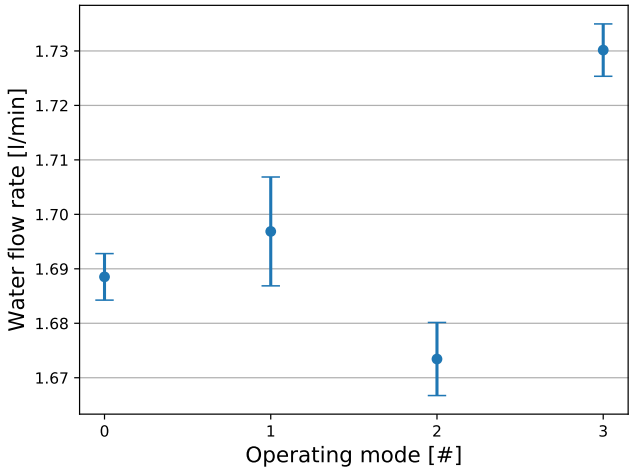


FIGURE 5.19: Mean and standard deviation of the suction water flow rate measurements for the different operating modes, at the relative pressure of 0.5 bar. 0 = continuous mode; 1 = intermittent time-cycle; 2 = intermittent hybrid time-pressure; 3 =intermittent two-step regulation

[3]A t-test is a statistical test employed for comparing the means of two groups. It is commonly used in hypothesis testing to ascertain whether a process or treatment has an effect on the population of interest or if there are differences between the two groups [206].

5.9 General discussion and test conclusion

5.9.1 Comparison of the different regulation modes

5.9.1.1 Mechanical vacuum regulation: strengths and weaknesses

The three out of four vacuum regulation modes utilise a mechanical vacuum regulator integrated directly into the vacuum system. Based on the tests carried out in Section 5.4, we are now able to identify the different strengths and weaknesses with the utilisation of this mechanical regulator.

Setpoint retention

As explained in Test 5.4.1, setpoint retention refers to the ability of the vacuum regulator to preserve or maintain the initial setpoint even after turning off and restarting the machine. This is properly carried out by the vacuum regulator as it demonstrated its ability to return to the initially set pressure level once the device was turned off and subsequently restarted. This has been achieved in 7.5 seconds and within a precision of 3.96%.

Difficulty in maintaining the vacuum level as soon as the water is sucked up

Moreover, we were also able to test the performance of the mechanical vacuum regulator when the appliance operates, such as sucking up water. Figures 5.10 (continuous regulation mode) reveal that when the pump is active at the system's onset, the water suction causes an automatic vacuum level drop by an average of 29.6 mbar. This difference is calculated between the initially set vacuum level and the stabilised vacuum during water suction.

This observation is valid for various initial vacuum settings. It is also applicable to all the other intermittent regulations using the vacuum regulator during the first few seconds before the pump deactivates. This highlights some of the difficulties faced by the vacuum regulator in maintaining the initial set vacuum level (at zero water flow) once water is drawn. This difficulty results in a vacuum level drop relatively constant regardless of the tested vacuum levels.

However, this offset remains for most setting pressures within the required accuracy range of $\pm 10\%$ around the set vacuum level at zero flow, except for low setting vacuum levels, such as 0.2 bar. Consequently, due to this consistent vacuum decrease during water suctioning, it is advisable to set the vacuum level initially 30 mbar above the vacuum needed.

Choosing a precise set vacuum level

Another disadvantage of using a mechanical vacuum regulator is that it is difficult to handle. It can be time-consuming and difficult to set the system pressure to millibar accuracy. The regulator is very sensitive when its knob is turned, which makes it difficult to control the pressure. If the knob is turned too quickly or too sharply, the adjusted vacuum level can be greatly disturbed. In contrast, the intermittent two-step regulation mode which requires no mechanical vacuum regulator sets the vacuum level digitally and directly in the Arduino. It is easier and quicker to choose the working pressure with this mode. However, this method is not yet finalized, as it still requires a reprogramming of the Arduino before each use of the prototype to select the setpoint pressure.

5.9.1.2 Regulation modes comparison

Pressure accuracy during water suction

We also examined the accuracy level of stabilised pressures when water is drawn by the device across various regulation modes. As elucidated earlier, water aspiration leads to an average vacuum decrease of 30 mbar. Following this observation, the stipulated 10% accuracy requirement is assessed around the stabilisation pressure during water aspiration, rather than around the initially set vacuum level.

Moreover, since this offset remains relatively constant, it has been directly incorporated into the Arduino code, allowing both the alarm and the intermittent hybrid time-pressure regulation to accommodate this deviation. To achieve this, the set vacuum level stored within the Arduino code (in the `P_working` variable) is downwardly adjusted by 30mbar, ensuring that the pump restarts as soon as the vacuum level has decreased by 8% relative to the stabilisation pressure during water aspiration, rather than relative to the initial set vacuum level.

The continuous regulation mode always remains at stable pressure once the device sucks in water. It is only affected at the beginning when there is a drop of vacuum at the start of water suction.

In the case of the intermittent time-cycle regulation, the highest vacuum level exceeds the stabilised pressure by around 3% and for the intermittent hybrid time-pressure regulation, this is around 5%. Despite this overshoot, the pressure remains within the 10% precision level required relative to the stabilised pressure.

The lowest vacuum levels reached by these two intermittent modes consistently fall within the 10% precision range around the stabilised pressure (at non-zero water flow). The lowest level achieved by the intermittent hybrid time-pressure regulation precisely drops by 8% relative to the stabilised vacuum level, as encoded in the Arduino. In contrast, the other intermittent mode has a low vacuum level of only 5% below the stabilised vacuum level instead of approaching the 10% threshold, indicating sub-optimal regulation.

The intermittent time-cycle regulation mode exhibits a poor pressure range, as its parameters `T_ON` and `T_OFF` do not allow a pressure variation close enough to the 10% range around the stabilised pressure when water is aspirated. In fact, these parameters enable to decrease the vacuum level by only 5.3% relative to the stabilised vacuum level. This could be due to a flawed testing process for defining these parameter values, thereby leading to an erroneous assessment of these parameters. One explanation for this misjudgment is that, initially, we were unaware of the average 30mbar vacuum level drop during water suction. As a result, we assessed first these parameters in relation to the set pressure rather than the stabilisation pressure during water aspiration. Therefore, to assess these parameters properly, the test should be rectified so that the time taken to reduce the vacuum level by 10% is recorded from the moment the pressure stabilises when water is sucked in and the pump can then be switched off in order to let the vacuum level dropped. More in-depth tests are needed to optimize these `T_ON` and `T_OFF` parameters

The intermittent two-step regulation tends to fall outside the range of precision required by the specifications. When the pump is running, it constantly moves towards a higher vacuum than that defined by the +8% around the set vacuum level. The vacuum level goes

even beyond the 10% mark. Whereas its lowest vacuum level always drops at precisely 8% of the set pressure in the Arduino code and never dropped lower.

The four control modes were able to manage the air suction disturbances because they were all able to return to stable pressure in less than 10s and within the required accuracy range, even if we observed a slight offset of an average +2.8% compared with the initial stabilisation pressure when water was sucked in.

Power consumption comparison between the four regulation modes

The continuous mode has clearly demonstrated to consume more energy compared to the intermittent modes. It is even more striking to note that the intermittent two-step regulation mode stands out as the most energy-efficient. As discussed above, all the parameter values for the other intermittent modes have not been optimised properly, so it would be interesting to redo this energy consumption test by trying to optimise all the parameters too. Especially the intermittent time-cycle for which the `T_OFF` time step could be longer, it would allow it to be more energy-efficient. Another observation is that the switching on of the pump causes an inrush current of 7A. Although this current level does not seem problematic for the power supply unit (its circuit can handle higher inrush currents), it is possible to incorporate inrush current protection circuits [205].

Fluid flow rate comparison between the four regulation modes

Another important parameter for comparison is the water flow rate generated by each regulation mode. The conducted tests reveal that the flow rates exhibit minimal variation across the different modes, falling in the range of [1.673 ; 1.73] l/min. The intermittent two-step regulation still has a higher water flow than the other modes. An explanation is its vacuum level remains on average quite higher than the other, as it allows the vacuum level to increase by 8% compared to the stabilised pressure. Given the marginal flow rate differences between the modes, the flow rate is not the most important parameter to take into account when determining the most efficient mode.

Robustness and safety criteria

In terms of regulation robustness, the mechanical regulator exhibits a considerable level of resilience and, so far it has never run away, despite a few minor deviations. Even in the event of a digital malfunction within the Arduino, or any hardware problem, causing the pump to remain active, the mechanical vacuum regulator acts as a fail-safe by always constraining the maximum vacuum level. This stands in contrast to digital control, such as the intermittent two-step regulation, where a digital failure while using the device can be challenging. In this scenario, if the pump continues to operate due to a malfunction, there is no means to restrict the vacuum, potentially leading to damage the prototype or being dangerous for the patient.

5.9.1.3 The most efficient mode

In order to determine the most performing regulation mode between the four modes implemented, we establish a weighted table (Table 5.7) with different weights from 0 to 5, where 0 means *not performed* and 5 means *perfectly performed*, assigned to each regulation mode to assess their performances based on the criteria. The weights of the regulation modes based on the criteria are directly linked to the results of various tests comparing these four modes. There is an additional weighting system for grading the importance of the criteria, as follows:

- *The robustness and safety [x5]*: The device must be capable of maintaining pressure regulation despite disturbances/failures and ensure safety for both the patient and the user. Given that the work revolves around a medical prototype, the criteria of robustness and safety are of utmost importance with the highest weight of 5. This is because the prototype might be employed in emergency situations, such as saving a person with obstructed airways. If the operating mode does not ensure a robust pressure regulation, the prototype could potentially prove ineffective in aiding the patient.
- *The power consumption [x3]*: Criterion determines which mode requires the least amount of energy for pressure regulation. The prototype, intended to be portable for emergency situations outside of hospitals, aims to be battery-powered in a future iteration. A low-energy-demanding regulation mode is crucial, as it has an impact on the potential duration of an intervention using the prototype.
- *The accuracy vacuum level [x4]*: It leads to the comparison of the precision with which the regulation modes are capable of maintaining a suction pressure. This criterion appeared to be the second most important criterion, as it is a crucial parameter for the operation as the vacuum level determines the fluid aspiration rate. Different parts of the body come into contact with the inlet port during various medical procedures, and therefore, based on their sensitivity, precise different vacuum levels are recommended.
- *The fluid flow rate [x1]*: It aims to determine the regulation mode that allows the highest fluid flow rate. This parameter emerged as the least significant in the case of our prototype. Indeed, the regulation modes showed minimal variations, remaining within very similar flow rates.
- *The way of regulating [x2]*: This final criterion aims to compare the means provided to the user for pressure regulation. This parameter appeared to be less important compared to the others because it has less impact on the performances required for the prototype. However, it still remains a significant factor as in cases of emergency, quick access to a specific level of vacuum is essential to avoid time delays.

Of course, the weights assigned to the various criteria remain subjective in relation to our application and the performance aspects we aimed to optimise throughout our work.

The analysis in the table 5.7 shows that, with this weighting of criteria, the intermittent hybrid time-pressure regulation mode is the most efficient and suitable for the designed medical aspirators. It can be observed that the final scores of the regulation modes are still very close. A different approach to the weighting of the criteria would have yielded different scores and potentially highlighted other regulation modes.

5.9.2 Prototype performance and requirements satisfied

Thanks to the tests carried out, we were able to evaluate and validate the performance of the prototype by comparing it with the requirements stated in the specification for this type of medical device and a large number of tests validated those requirements. However, there is still a need for further testing before achieving a medical device that meets the criteria for actual medical interventions.

Vacuum generation and fluid evacuation

With regard to the machine's performance in terms of vacuum regulation and generation, our prototype contains air leaks in its vacuum circuit. As explained in the corresponding test,

TABLE 5.7: Comparison of the efficiency of the 4 regulation modes on the basis of defined criteria.

Regulation mode	**Way of regulating vacuum [x2]**	**Accuracy vacuum level [x4]**	**Power consumption [x3]**	**Flow rate [x1]**	**Robustness and safety [x5]**	**Scores total**
Continuous	2.5	5	1	3	4	51
Intermittent time-cycle	2.5	3	2	3	4	46
Intermittent hybrid time-pressure	2.5	4	3	3	4	53
Intermittent two-step regulation	4	3.5	5	3.5	2	50.1

we assume that these leaks come mainly from the collection container and the pneumatic valve. Although there is no requirement linked to the leaks in the circuit (it only exists for the collection container), these losses have an impact on the accuracy of the regulation, as well as the free airflow, which is constrained by requirements. The initial objective was to create a High vacuum/ High flow device. However, with a maximal flow rate of 18.01 l/min, the prototype is currently characterised as High vacuum/ Low flow. The accuracy of the regulation has been validated and discussed in the previous section when comparing the different regulation modes implemented.

Ease of use and machine's user interface

A drawback concerning the regulation modes utilising the mechanical regulator is that once the pressure has been set before starting aspiration, it cannot be altered during the prototype's operation. Consequently, the implemented device must be turned off and the setting process restarted at the desired new pressure to change the operating pressure. This is, of course, impractical for medical procedures involving the aspiration of different fluids, requiring varying pressure levels. A future enhancement would involve enabling pressure adjustment during device operation.

The drawback of being unable to modify the pressure during the prototype's operation also applies to the two-step regulation mode, as currently, the working pressure must be directly encoded into the Arduino code via the computer. The same enhancement for this functionality should also be applied to this operating mode.

Alarm and level sensor

The level sensor fulfils its function by activating at 90% of collection container volume and it stops the pump as required, but does not provide means to stop the liquid flow. However, the level sensor is an optional feature (as stated in the ISO10079) and it is not present in all commercial medical aspirators.

The alarm correctly prevents too high vacuum level as it allows to switch off the pump when the vacuum increases by 10% of the stabilised vacuum level.

5.9.3 Comparison with commercial medical aspirators

Following the tests carried out, we can establish certain characteristics of our prototype in order to be able to compare it with some commercial medical aspirators. We have selected 4 commercial devices for comparison. The characteristics of our prototype and commercial devices are listed in Table 5.8.

We selected one surgical device for hospital use (MEDELA basic suction pump), and three portable devices, one for airways aspiration (LAERDAL Suction Unit), and the two others (MEDELA Vario 18 and SEBA SA01PB) intended for both airways and small surgical interventions. They are all medium-sized, and medium-price. The first three analysed are High Vacuum/ High Flow devices. Only the last device (Medela Vario 18) is categorized as a High Vacuum/ Low Flow. Only MEDELA medical aspirators provide clear information about the used regulation system. They both use a mechanical membrane vacuum regulator. They all have an overfill protection device, either reusable or disposable. Only one device gives no information on this subject. We, therefore, assume that it does not have one.

By comparing the performance of these devices with the prototype, we observe that the designed prototype aligns with the performance of commercial devices. Indeed, the prototype maximum vacuum level is similar to two of the four selected devices. Concerning the flow rate, as explained in the tests performed, we do not achieve the minimum required flow to be a High Flow device due to air leaks. Our prototype is labelled as Low flow for the moment until the air leaks will be identified and mitigated.

Regarding the price, although the manufacturing cost of our prototype is lower, it remains fairly close to the price of certain commercially available medical aspirators. However, considering the law of supply and demand and the severe shortage, it is well-known that during periods of health crises, the prices of emergency devices tend to increase [207]. Also, as the manufacturing cost depends mainly on the pump, it could be drastically reduced if, for example, less reputable and reliable commercial brands with similar performance characteristics were used. But we opted for a reliable brand-name pump manufactured in Europe (Germany) to guarantee the specified performances and robustness.

TABLE 5.8: Main characteristics of the prototype and some selected commercial medical aspirators

Criteria	**Our prototype**	**Basic suction pump** [208]	**Laerdal Suction Unit** [209]	**SA01PB**	**Vario 18** [111], [129]
Constructor	-	MEDELA	LAERDAL	SEBA	MEDELA
Type of device	High vacuum/ High flow	High vacuum/ High flow	High vacuum/ High flow	High vacuum/ High flow	High vacuum/ Low flow
Type of use	Intended for hospitals & field use	Hospital use	Field use	Hospital & field use	Hospital use
Portability		Trolley	Portable	Portable	Portable
Usage	Surgical & airways	Surgical pump	Airway pump	Surgical pump	Surgical & airways
Max. vacuum level [kPa]	75	90	73.3	86.6	75
Free airflow [l/min]	18.02	30	25	20	18
Dimensions [mm]	NA	305x285x375	330 x 315 x 160	380x135x290	380x170x285
Weight [kg]	NA	9.5	4	4	3.5/4.2(with battery)
Pump technology	Diaphragm pump	Piston/cylinder technology	NA	Oilless Piston Pump	piston/cylinder
Power supply AC and battery	only AC for the moment	AC	AC and battery	Battery	AC
Pressure display unit	bar	mmHg	mmHg	mmHg	mmHg et kPa
Noise level [dB(A)]	NA	36.3	56	< 50	51.2
Type of regulation	Various (under test)	Membrane vacuum regulator	NA	NA	Membrane vacuum regulator
Additional intermittent mode	Yes	No	Yes	No	Yes
Collection container capacity [l]	1		1	1.2	
Overfill protection device	Mechanical and electrical float sensor	Mechanical overflow protection	Available but no info.	NA	Disposable overflow protection
Price [€]	507.3 (VAT excl.)	2 977	1050 (VAT excl.)	1024	1142 (VAT excl.)

Chapter 6

Future work

As this thesis approaches its conclusion, it remains evident that the task is not yet complete. There is still a considerable journey ahead before achieving an open-source medical aspirator that can be published and made available to the global community. Further efforts are required to finalise the development and ensure its accessibility on a global scale.

This chapter aims to summarise our perspective on the remaining tasks at hand. Section 6.1 summarises the remaining tasks for the prototype, including potential ideas and solutions that have come up during our work. Section 6.2 covers the tests, research and analyses that remain to be conducted.

6.1 Future improvements of the prototype

PVC tubing The tubes used in our prototype are reclaimed laboratory offcuts. These have high rigidity, leading to a relatively bulky vacuum circuit. To address this, a potential solution involves looking for more flexible tubing, capable of withstanding the vacuum conditions without collapsing, or alternatively, keeping the rigid tubes while integrating multiple elbow connectors.

Battery addition As outlined in the state of the art, portable medical aspirators use batteries for operation outside of hospitals. The electrical circuit needs to be modified to enable the prototype to function with both batteries and 220V power supply.

User interface and Arduino code Once the final control mode has been chosen, the machine's user interface will need to be adapted and updated, and the Arduino code updated accordingly.

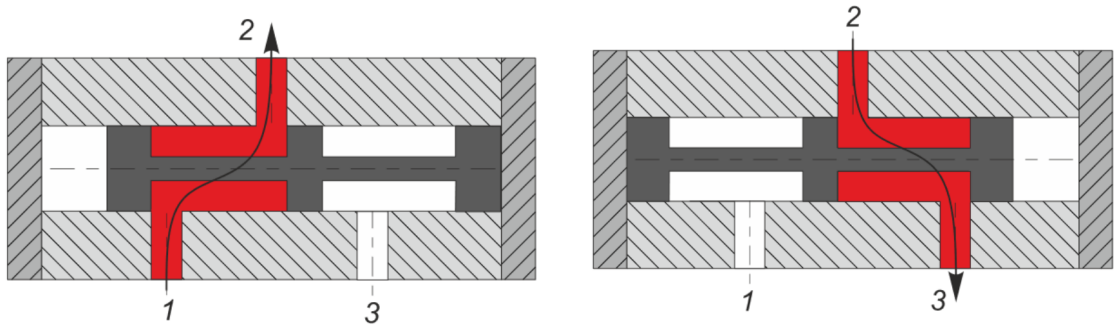
Machine structure In order for the prototype to become a fully-fledged medical device, it must be incorporated into a suitable structure that is, for example, watertight, easily transportable and contains a space for the collection container.

Trolley for in-hospital use When designing the structure of the medical suction pump, it is noteworthy that it can be attached to a trolley (an open-source version of a trolley can be fabricated) to enable efficient hospital use.

Improved ON/OFF valve and plug During the design and use of the prototype, we used an on-off valve to cut off the inlet to the atmosphere (instead of using your thumb as all commercially available suction pumps suggest in their user manuals). In addition, a plug is commonly used (see Section 3.4 for explanation). It would be interesting to implement a

valve fulfilling the function of these two devices. One idea that came up during meetings with our developers was to implement a kind of 3/2 valve, as shown in Figure 6.1. This valve would have 3 connections and 2 positions.

Figures 6.1 represent the operating diagrams of a 3/2 directional pneumatic valve. Based on these diagrams, we propose to create a 3/2 valve such as when it is idle (Figure 6.1a), the link is established between ports 1 and 2. Port 3 (collection container inlet) is close to the atmosphere. When the user engages the valve by pushing on it (Figure 6.1b), the connection is established between 2 and 3. Outlet 1 is closed and liquid can be sucked in. The significant advantage of such a system is that when the user does not aspirate anything, the vacuum level is maintained in the bottle, and the patient-level connection remains at atmospheric pressure, which avoids certain risks that could occur.



(A) Valve in idle position: link between 1 and 2 [210]. (B) Valve pushed down: link between 2 and 3 [210].

FIGURE 6.1: Inspiration of these diagrams to create a 3/2 valve that gathers the function of the ON/OFF valve used and the plug.

6.2 Further device testing and analysis

Intermittent modes parameters optimisation As explained in the discussion section of Chapter 5, it is necessary to reiterate the testing process to identify the most suitable parameters for the three intermittent modes. Once these parameters are optimized, the comparative tests should be repeated to obtain more consistent results to determine the optimal regulation mode.

Implementation of the *PID controller with pump speed variation* system The PID mode (with speed pump control) has not been implemented due to lack of time, as explained in Section 3.3. It would therefore be interesting to implement it in order to compare it with other modes already applied.

Vacuum system leakage As indicated by the leakage test results (Section 5.3.3), our device exhibits a significant amount of leaks. Additional testing is required, particularly concerning the collector container, to identify these leaks and take measures to mitigate them.

Test not performed A number of tests still need to be carried out to confirm that the open-source medical device complies with the requirements. Furthermore, all tests conducted so far have employed water as the testing medium. Performing the artificial vomit test will provide valuable insights into the prototype's performance within a more realistic context.

Toward a medical device certification The journey to obtain a certified device is still quite long. It involves carefully studying European regulations and thoroughly enhancing the risk analysis (that has been initiated) based on the device's life-cycle. These steps are crucial for applying this approach throughout the device's development, to make sure that the device meets all the requirements for certification.

Theoretical model of the medical aspirator It would be interesting to go further into the physical analysis of the device (Section 3.1). For example, it would be useful to model mathematically the evolution of the vacuum level in the collection container when the pump is switched off and liquid is sucked in.

Health worker consultation insights In addition to conducting research in the literature, it is highly valuable to consult healthcare workers who regularly use a medical suction pump. Gathering insights from these professionals regarding their experiences, requirements, functionalities, and concerns related to the medical device can help address real-world issues and needs effectively.

Next Iteration: Emphasizing low-cost as an objective As explained in Section 2.2, during the design of this initial prototype, the emphasis was placed on functionality and meeting the requirements. In our view, a potential next iteration could prioritize cost-effectiveness. Exploring more affordable alternatives for the components could be considered. For instance, the primary cost driver of the prototype is the pump, which constitutes 45% of the total manufacturing cost. Opting for a less expensive pump while maintaining similar performance levels could be explored. The second most costly component is the regulator, which amounted to 95€ (VAT excl.). It is possible to find similar regulators on Amazon for around 30€. How do they compare in terms of quality, reliability, and performance? Answering these questions would be valuable. Ultimately, this could lead to two Bills of Materials (BOMs): one with locally manufactured and sourced elements within Europe (which would mitigate dependence on non-European countries during crises, avoiding component shortages), albeit at a higher cost, and another with more affordable components, but with the potential risk of longer delivery times or unavailability during emergency periods.

Conclusion

The recent health crisis caused by COVID-19 has notably affected the healthcare sector. Failures have emerged due to inadequate preparedness for this pandemic, as well as a shortage of resources concerning emergency medical supplies. This has highlighted a pressing need to rethink medical devices and move towards an appropriable emergency hospital. However, COVID-19 is just one crisis among others. Through research into these crises and emergency situations, medical devices have emerged as vital instruments for safeguarding public health, thereby showcasing potential interest in their development as open-source solutions. The purpose of this thesis was thereby to investigate this issue, establish a selection methodology to choose a device for which an appropriable open-source version would be developed, as well as conduct a risk analysis and establish a testing protocol. The device chosen as a result of this research is a medical aspirator, which is essential in hospitals as well as in emergency situations.

Initially, the concept of open-source hardware was explored to gain a comprehensive understanding of this concept and its implications. It finds application across various domains and entails publicly sharing design and resources for hardware creation, modification, and distribution. In the wake of recent crises, the development of open-source medical devices has become increasingly prevalent. Open-source medical devices offer numerous advantages, particularly in two key scenarios. Firstly, they enhance medical device availability during crises, mitigating shortages. Secondly, they improve affordability, offering significant assistance to resource-constrained hospitals that cannot afford intensive purchase of essential emergency equipment. Additionally, open-source enhances accessibility and appropriateness by providing detailed manufacturing, usage, and maintenance processes. Despite of the open-source nature, medical equipment remains subject to diverse regulatory requirements and technical standards. These regulations encompass safety, efficacy, and quality standards for the medical devices sector. They were particularly applied in this work to define the specifications and risk analysis of the designed medical aspirator.

The upcoming phases outline the first prototype development of an open-source portable medical aspirator tailored for hospitals and outdoor emergency scenarios. Operating based on the principle of vacuum generation within a container, it collects fluids and tissues from the patient's body. The purpose of this prototype is to be used for procedures involving the clearance of patients' respiratory pathways as well as for mid-level surgical procedures. A risk analysis was conducted, identifying certain risks associated with the use of this machine. Some of these risks were directly addressed during the prototype design.

To ascertain the most suitable regulation mode for this open-source device, the designed prototype has four regulation modes implemented using a mechanical vacuum regulator and an Arduino microcontroller:

- Continuous regulation: where pressure is regulated by the vacuum regulator and the pump operates continuously.

- Intermittent time-cycle regulation: where pressure is regulated by the vacuum regulator and the pump follows an on/off time cycle (on: 7s - off: 2s).
- Intermittent hybrid time-pressure regulation: where pressure is regulated by the vacuum regulator and the pump operates for 7s before turning off. It only starts up again once a vacuum threshold has been reached.
- Intermittent two-step regulation: where pressure is directly regulated by the controller, with the pump switching on and off between two pressure thresholds.

The Arduino also facilitates alarm control, triggering alerts when pressure limits are exceeded and when the container becomes filled with fluid.

The last two sections address the prototype's performance and outline potential future enhancements aimed at optimising the functionality of the designed medical aspirator. These various performance levels achieved by the four modes were evaluated through a testing protocol. Based on these results, a comparison of the four modes was conducted to ascertain the most effective one. The development and implementation of this test protocol and the analysis of the results required a lot of time. This gave us a small glimpse of the work, the long road, and the large number of tests to which a medical device must be subjected before being put on the market.

Results show that the regulation modes utilising the mechanical regulator benefited from several advantages, such as robustness and safety due to their mechanical operation, as well as efficient setpoint retention. However, the regulator exhibited certain weaknesses, generating an average offset of approximately 30mbar from the set pressure when aspirating water. Another drawback of the regulator lies in the sensitivity of its control knob during pressure adjustments, making it challenging to achieve precisely desired pressure levels. In contrast, the two-step regulation mode enables digital selection of the setpoint pressure, which offers greater resolution. However, this mode is less safe than the others, as a software or hardware bug could potentially disrupt the entire regulation system. An important factor that led to the exploration of both continuous pump operation mode and intermittent modes was energy consumption. This analysis revealed a significant advantage for the intermittent modes in terms of energy efficiency. Lastly, the accuracy of vacuum level control was examined. This accuracy proved to be more robust in the continuous and hybrid time-pressure regulation modes.

All these observations have demonstrated that the hybrid time-pressure regulation mode seems the most robust solution implemented in the prototype. However, more in-depth testing remains essential, along with the inclusion of additional comparison criteria and components more suited for vacuum conditions, to establish a final operational mode. The achieved performance levels in this first prototype are a vacuum level of -0.75 bar and a free airflow of 18 l/min, this categorises our prototype as a High Pressure/Low Flow rate device. The final cost for developing the prototype is 507.3 €. This remains lower than 678.9 €, an average calculated from an analysis of eleven commercial portable electric medical aspirators. However, it is still relatively high compared to 219.5 €, the lowest price found on the market. It is advisable to explore testing with other pumps that may be more cost-effective while still achieving similar performance levels.

In conclusion, this work has led to the design of an initial prototype for an open-source medical aspirator, which adheres to most of the imposed requirements and demonstrates

performance comparable to commercially available devices. Further iterations and research are essential to achieve a fully-fledged version ready for practical use, contributing to the open-source appropriable hospital of the future.

Appendix A

Specifications

This appendix presents the specifications for the design of our open-source medical aspirator prototype. This document is also made freely available on the Forge repository of the Open MedTech Group `https://forge.uclouvain.be/openmedtech/medical-aspirator`

Date of creation: 25/02/23	**Specifications**
Date of last edit: 08/03/23	Electrically Powered Medical Aspirator/Suction Pump with High Vacuum/High Flow
Version: 1.1	**Note:** These requirements are for electrically powered suction device only. For pressure/venturi or manually powered, one should respectively take a look at the **ISO 10079-3:** *Suction equipment powered from a vacuum or positive pressure gas source* and **ISO 10079-2:** *Manually powered suction equipment*

Functions

Date	Origin	Type	Description
25-02-23	WHO req. sheet	M.F. 1	Evacuation of gas, fluid, tissue, or foreign materials from the high airways
25-02-23	WHO req. sheet	M.F. 2	Suction of blood, secretions, and other liquids for medium-level surgery interventions
25-02-23	WHO req. sheet	C.F. 1	Fluid collected in a collection container via a suction tubing
25-02-23	WHO req. sheet	C.F. 2	Electrically powered
25-02-23	WHO req. sheet	C.F. 3	The least noisy possible
25-02-23	WHO req. sheet	C.F. 4	The equipment must not pose a risk to the patient
25-02-23	WHO req. sheet	C.F. 5	Easy to use by a health user
25-02-23	WHO req. sheet	C.F. 6	Setting of the suction level
25-02-23	WHO req. sheet	C.F. 7	Should be portable/transportable

Requirements

Date	Origin	Type	Description
25-02-23	WHO req. Sheet	Req M.F. 1/2.1	Sucking up a liquid and other materials (gas, tissue or foreign materials)
25-02-23	WHO req. Sheet	Req M.F. 1/2.2	Maximum vacuum not less than **450 mmHg** (**60kPa**) (adjustable by control)
07-03-23	ISO 10079-4:2021	Req M.F. 1/2.3	Maximum suction capacity not less than **20 L/min** (air)
08-03-23	ISO 10079-4:2021	Req M.F. 1/2.4	Maximum time allowable to reach *vacuum level* and *free air flow* shall be **10s**
08-03-23	ISO 10079-4:2021	Req M.F. 1/2.5	Suction equipement intended for pharyngeal suction shall evacuate **≥ 200ml** of simulated vomitus in not more than **10s**
08-03-23	ISO 10079-4:2021	Req M.F. 1/2.6	The accuracy of the cycling frequency of *intermittent* vacuum equipment shall be within **±10%** of the specified fixed frequency or the mid-range setting, if adjustable
08-03-23	ISO 10079-4:2021	Req M.F. 1/2.7	The accuracy of the vacuum levels shall be within **±10%** of the set or fixed vacuum level at zero flow (of liquid)
07-03-23	ISO 10079-4:2021	Req C.F. 1.1	Collection containers shall have a usable volume of at least **500mL**
08-03-23	ISO 10079-4:2021	Req C.F. 1.2	Collection containers for field use or transport use shall: a) have a usable volume **≥ 300ml** if provided with an overfill protection device that stops the flow or b) have a usable volume **≥ 200ml** if designed to continue operating when collection container is full
07-03-23	ISO 10079-4:2021	Req C.F. 1.3	Collection containers shall clearly show the level of contents
08-03-23	ISO 10079-4:2021	Req C.F. 1.4	The usable volume of the collection containers, expressed in millilitre and graduations at 50ml to 250ml intervals shall be marked
25-02-23	WHO req. sheet	Req C.F. 1.5	Collection containers shall preferably have an automatic cut off when full to prevent ingress of fluid to pump
08-03-23	ISO 10079-4:2021	Req C.F. 1.6	Overfill protection devices shall not activate until at least **90%** of the indicated maximum capacity of the collection container has been reached
08-03-23	ISO 10079-4:2021	Req C.F. 1.7	When an overfill protection device is activated, suction shall cease and prevent > 5ml of fluid from passing downstream of the overfill protection device within 2min
08-03-23	ISO 10079-4:2021	Req C.F. 1.8	Means shall be provided to prevent foam passing from the collection container into the vacuum source
25-02-23	WHO req. sheet	Req C.F. 1.9	Collection containers should be disposable or autoclavable
08-03-23	ISO 10079-4:2021	Req C.F. 1.10	Leakage into the collection container assembly shall be **< 1kPa** pressure drop
08-03-23	ISO 10079-4:2021	Req C.F. 1.11	Collection containers shall not implode, crack or permanently deform [...] after being subjected to a pressure of either 120% of the manufacturer's recommended maximum vacuum level or 95kPa below atmospheric, whichever is the stronger vacuum level, for 5min.
08-03-23	ISO 10079-4:2021	Req C.F. 1.12	It shall not be possible to connect suction tubing or intermediate tubing to collection container exhaust ports
08-03-23	Article$_1$	Req C.F. 1.13	Suction tubing shall have an inside diameter ≥ **8 mm**
08-03-23	ISO 10079-4:2021	Req C.F. 1.14	Suction tubing shall have a degree of collapse ≤ 0.5 throughout its entire length
08-03-23	ISO 10079-4:2021	Req C.F. 1.15	Tubing to patient to be minimum **1.3 m** long, non-collapsible type (can be shorter for field or transport use)
25-02-23	WHO req. sheet	Req C.F. 2.1	Powered by mono-phase electrical source, AC line 110–220 V, 60–50 Hz, ± 10% with line connection plug compatible with local standards
25-02-23	WHO req. sheet	Req C.F. 2.2	Protections against over-voltage and over-current line conditions
25-02-23	WHO req. sheet	Req C.F. 2.3	Powered preferably also by internal, rechargeable, replaceable battery
07-03-23	ISO 10079-1:2015	Req C.F. 2.4	When battery fully charged should operate continuously for at least **20min** while maintaining a *free air flowrate* of not less than **2 l/min** and a *vacuum level* not less than **40kPa**

07-03-23	ISO 10079-1:2022	Req C.F. 2.5	Be provided with a means to indicate the charges status of the battery
07-03-23	ISO 10079-1:2022	Req C.F. 2.6	Interruption and restoration of the power supply to the suction equipment shall not cause the *vacuum level* and *free air flow* shall not vary by more than **±10%** from the set value
25-02-23	WHO req. sheet	Req C.F. 3.1	Sound level not higher than **60 dBA**
25-02-23	WHO req. sheet	Req C.F. 4.1	Air line to pump to incorporate bacterial filter
25-02-23	WHO req. sheet	Req C.F. 4.2	Filter and overflow valve incorporated to the collection container to prevent cross-contamination (e.g. shatterproof material, over flow protection system)
08-03-23	ISO 10079-4:2021	Req C.F. 4.3	Negative pressure protection: If a means to limit the maximum vacuum level is fitted, the vacuum shall not exceed the maximum vacuum level by more than **10%**
08-03-23	ISO 10079-4:2021	Req C.F. 4.4	Means shall be provided which prevents fluid flowing back to the patient due to the pressure differential between the equipment and the patient
08-03-23	ISO 10079-4:2021	Req C.F. 5.1	Suction equipement shall be designed to be operated by one person, unaided
08-03-23	ISO 10079-4:2021	Req C.F. 5.2	Suction equipment intended to be dismantled by the user (e.g. for cleaning) shall be designed to facilitate correct assembly or market to indicate correct reassembly
25-02-23	WHO req. sheet	Req C.F. 5.3	System integrated holder for suction cannulas/tubing easy and safe positioning
25-02-23	WHO req. sheet	Req C.F. 5.4	Any necessary greasing/oiling to be simple, accessible and possible by health users
07-03-23	Personal	Req C.F. 6.1	Be provided with a means to easily set the device and see the choosing setting
25-02-23	WHO req. sheet	Req C.F. 6.2	User settable valve shall allow adjustment of suction delivered to patient
25-02-23	WHO req. sheet	Req C.F. 6.3	Should display suction generated
08-03-23	ISO 10079-4:2021	Req C.F. 6.4	Suction equipement with an operator-adjustable vacuum regulator shall indicate the vacuum level at the inlet side of the vacuum regulator (see figure C.1)
08-03-23	ISO 10079-4:2021	Req C.F. 6.5	Analog displays shall have graduation ≥ 2mm apart with each graduation representing ≤ 5% of the full-scale value
08-03-23	ISO 10079-4:2021	Req C.F. 6.6	Digital displays shall indicate the *vacuum level* at intervals ≤ 5% of the full-scale value
08-03-23	ISO 10079-4:2021	Req C.F. 6.7	Movement of rotary analogue vacuum level indicators should be anti-clockwise for an increase in vacuum level
08-03-23	ISO 10079-4:2021	Req C.F. 6.8	Vacuum level indicators shall be accurate to within ±5% of the full-scale value
25-02-23	Article[1]	Req C.F. 7.1	Max 2,25 Kg
07-03-23	Article[1]	Req C.F. 7.2	30x10x10cm (for portable equipment)
07-03-23	ISO 10079-1:2015	Req C.F. 7.3	60x30 cm (with no mention of height)
25-02-23	WHO req. sheet	Req C.F. 7.4	There must be no sharp edges on the unit surface is to be hard and corrosion resistant
25-02-23	Personal	Req C.F. 7.5	The collection container musts fit into the machine and form a whole
25-02-23	Personal	Req C.F. 7.6	Frame with handle
08-03-23	ISO 10079-4:2021	Req C.F. 7.7	*Foot-operated* suction equipement intended for *field use* or *transport use* shall meet the requirement given in Clause 7 as appropriate when placed on a surface 20° +-2° frome the horizontal
08-03-23	ISO 10079-4:2021	Req C.F. 7.8	Unless otherwise indicated in the instruction for use, the suction equipment, suction tubing and intermediate tubing shall operate within its specification while being subjected to the following environmental conditions: a) a temperature range of (0 to +40)°C; b) a relative humidity of (15 to 90)%, non condensing, but not requiring a water vapour partial pressure >50 hPa and c) an atmospheric pressure range of 620 hPa to 1060 hPa
08-03-23	ISO 10079-4:2021	Req C.F. 7.9	Unless otherwise indicated in the instruction for use, suction equipement, *suction tubing* and *intermediate tubing* shall withstand in their protective transport packaging, the following environmental conditions: a) Temperatures from -40°C to +70°C; b) Relative humidity from 15% to 90% non-condensing and c) Atmospheric pressures from 620 hPa to 1060 hPa

Source:

[1] **Article:** Peri S.R, Akhter F., De Lorenzo R.A and Hood R.L, Sensors: *Portable Medical Suction and Aspirator Devices: Are The Design and Performance Standards Relevant?* ,Sensor 2022,22,2515. [Online at] https://fr.scribd.com/document/583185640/sensors-22-02515-v2#

ISO10079-1:2022 - *Medical suction equipment — Part 1: Electrically powered suction equipment.*

ISO10079-4:2021 - *Medical suction equipment — Part 4: General requirement*

WHO requ. sheet, *Suction pump, electric* . [Online at] https://medevis.who-healthtechnologies.org/files/attachments/YkoSGN1Ia6PRg0zNpa8ZIvMB5UnNR70Z41hrcsak.xlsx

Appendix B

Supplement to the physics behind the device

B.1 The physical law of a non-Newtonian fluid

If we consider the non-Newtonian fluid flow of Power-law type [145] in a horizontal cylindrical pipe, the equation linking the shear stress and shear rate is defined as follows:

$$\tau = K(\frac{\partial u}{\partial y})^n \tag{B.1}$$

where the different parameters are:

- shear stress : τ [Pa],
- shear rate : $\frac{\partial u}{\partial y}$ [s^{-1}], also noted $\frac{\partial v_z}{\partial z}$ in cylindrical coordinates where the axis are represented in Figure B.1. This is the velocity gradient perpendicular to the cylindrical pipe section, so that it is along rotational axis (z-axis).
- K : is the dynamic viscosity when shear rate equals to one [$Pa.s^n$].
- n : is the power-law index defining the steepness of the shear stress-shear rate graph as represented in Figure B.2. According to its value, the fluid will be defined in different ways [144] :
  - n < 1: are the non-Newtonian pseudoplastics, for which the apparent viscosity decreases with increasing stress. For the highest n values, they are plastic bingham fluids with constant n values, but the shear rate occurs from a certain shear forces.
  - n = 1: define a linear graph for a Newtonian fluid, where K is the fluid constant dynamic viscosity (denoted as μ).
  - n > 1: are the non-Newtonian dilatants, for which the apparent viscosity increases with increasing stress.

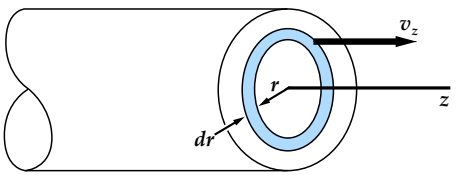


FIGURE B.1: Cylindrical coordinates in a horizontal cylindrical pipe : v_z is the fluid velocity along z-axis, z-axis is the rotational axis and $r - axis$ is along the pipe radius [145].

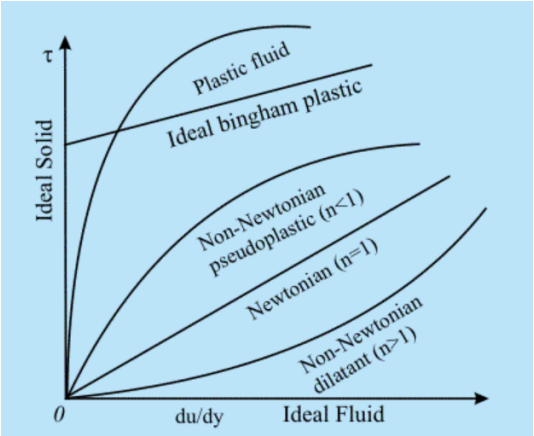


FIGURE B.2: Shear stress and deformation rate relationship of different fluids (different n values) [144].

From the continuous equation and the equations of motion expressed in cylindrical coordinates, we can find an expression of the volume flow of the fluid as a function of the pressure difference between both sides of the cylindrical pipe. To simplify these equations, several assumptions [145] are made:

- Permanent regime such as $\frac{\partial}{\partial t} = 0$,
- Flow along the axis of revolution, axis-z (see Figure B.1) $\implies v_r = v_\theta = 0$ and $v_z \neq 0$,
- Axisymmetric flow $\implies \frac{\partial}{\partial \theta} = 0$,
- Horizontal cylindrical pipe and low diameter $\implies \rho g = 0$,
- And incompressible fluid.

Upon simplification, the continuity equation validates that the fluid's axial velocity within the pipe remains constant along the axis of rotation: $\frac{\partial v_z}{\partial z} = 0$. This logical deduction arises from the fact that, in an infinite pipe, the fluid cannot attain an infinite velocity, and any deceleration would eventually lead to zero speed at the end. Since inflow must equal outflow, this scenario is not feasible.

The motion equations are simplified into the following two equations:

$$\begin{cases} \dfrac{\partial P}{\partial r} = 0 \\ \dfrac{\partial P}{\partial z} = \dfrac{1}{r}\dfrac{\partial}{\partial r}\left(\dfrac{\partial r \tau_{rz}}{\partial r}\right) \end{cases} \tag{B.2}$$

where

- $\frac{\partial P}{\partial z}$: is the partial derivative of the pressure P with respect to the z-axis.
- $\frac{\partial P}{\partial r}$: is the partial derivative of the pressure P with respect to the radial axis.
- τ_{rz} : is the shear stress defined at equation B.1 by the Power-law.

By substituting the power-law B.1 into the equation of motion B.2 and imposing boundary conditions (shown in Figure B.3) on our system [211] such as :

- $r = 0$, on the z-axis : v_z is finite
- and $r = R$, at the pipe wall : $v_z(R) = 0$ because of friction against wall.

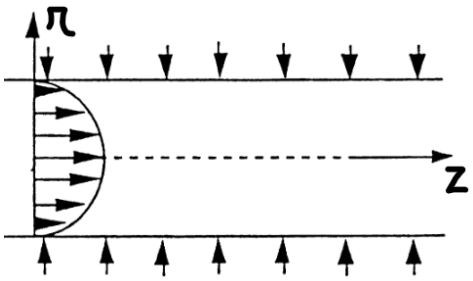


FIGURE B.3: Illustration of the boundary conditions [212].

We obtain the equation for the velocity of the fluid dependent on the pressure drop in the pipe as follows [211]:

$$v_z(r) = \frac{-n}{n+1}\left(\frac{-1}{2K}\frac{\partial P}{\partial z}\right)^{1/n}\left(r^{\frac{n+1}{n}} - R^{\frac{n+1}{n}}\right) \tag{B.3}$$

From the equation B.3 describing the velocity perpendicular to the cross-section of the pipe, we can calculate the fluid flow rate Q_V by integrating the relation $dQ_V = v_z(r)dS$ with respect to radius r, where $dS = 2\pi r dr$. The volume flow equation [211] is expressed as :

$$Q_V = \frac{\pi n}{3n+1}\left(\frac{-1}{2K}\frac{\partial P}{\partial z}\right)^{1/n} R^{\frac{3n+1}{n}} \tag{B.4}$$

Appendix C

Vacuum pump technologies

The main part of the machine is the pump, whose role is to generate a vacuum by pushing gas or air molecules out of a sealed chamber. In this device, the goal is to create a vacuum in a bottle in order to create a pressure difference to draw in liquid.

There are different degrees of vacuums that can be achieved. In general, the different pressure ranges in vacuum technology are defined as shown in Table C.1 [213].

TABLE C.1: Common scheme of the vacuum range

Type of vacuum	**Range (absolute)**
Low or Rough vacuum	Atmosphere to 1 mbar
Medium or Fine vacuum	1 to 10^{-3} mbar
High vacuum	10^{-3} to 10^{-7} mbar
Ultra-high vacuum	10^{-7} to 10^{-12} mbar
Extreme high vacuum	less than 10^{-12} mbar

According to the specification (Section 2.4), the maximum negative pressure generated should be not less than 450 mmHg, which equals 600 mbar. This pressure corresponds to a rough vacuum. Many pump technologies correspond to this vacuum level, as shown in Figure C.1.

The most common pumps for a rough vacuum are therefore the followings:

- Diaphragm pump
- Piston/ Rotary piston pump
- Plunger pump
- Rotary vane pump
- Screw pump (not investigated)
- Roots (or Lobs) pump (not investigated)
- Scroll pump (not investigated)

Diaphragm pump These pumps use a diaphragm (deformable metallic or elastomer membrane) attached to a rod which is moved forwards and backwards, as shown in Figure C.2. The movement of the diaphragm will change the volume of the chamber and thus the pressure. When the diaphragm moves in, the gas moves in through an inlet valve. When the diaphragm moves back, the inlet valve closes and the gas is pressurised before it escapes through the exhaust valve.

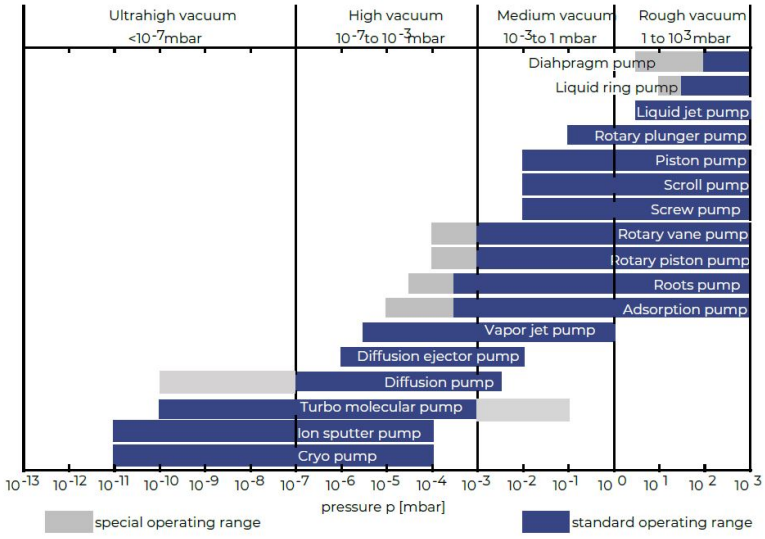


FIGURE C.1: Working range of different pump technologies according to the vacuum level [213]

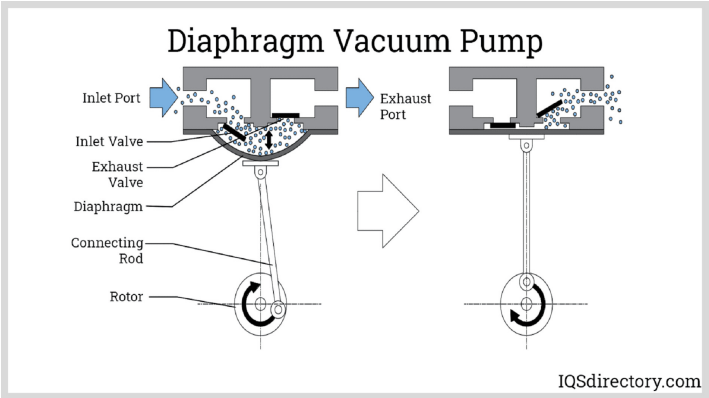


FIGURE C.2: Diaphragm vacuum pump working principle [214]

Piston Pump In this type of pump, the movement of a piston (commonly made of cast iron, bronze, or steel, and sealed against a cylinder) will generate vacuum and compression. The piston is connected to the crankshaft via a connecting rod and is pushed back and forth within the cylinder by the rotation of this crankshaft, as shown in Figure C.3. During the movement, the suction valve and the discharge valve will in turn be opened or closed according to the movement of the piston, allowing the gas to move in and be expelled.

Plunger pump This pump works in a similar way to the piston pump, but uses a plunger made generally of hard-coated ceramic. The long profile of the plunger allows the high-pressure seal to be stationary relative to the cylinder, in contrast with piston pumps where the seal is attached to the piston. This deference enables the use of more complex sealing systems and it is better for more demanding conditions.

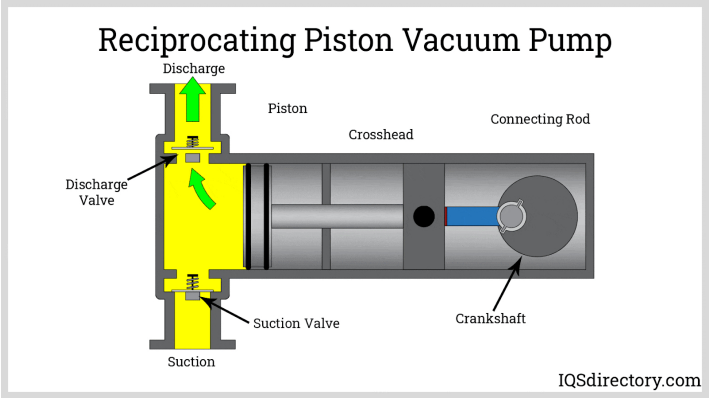


FIGURE C.3: Piston vacuum pump working principle [214]

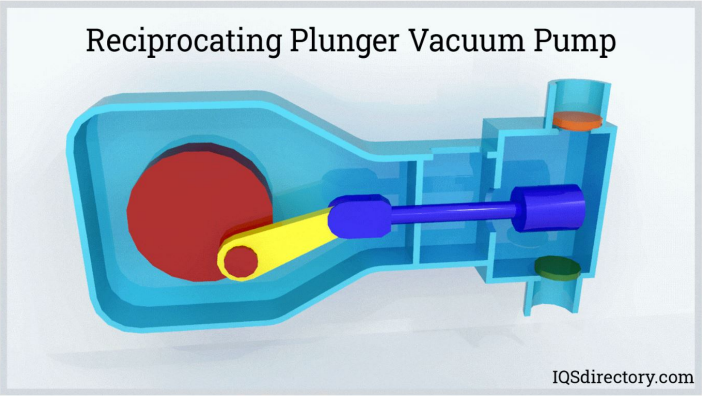


FIGURE C.4: Plunger vacuum pump working principle [214]

Appendix D

Arduino code

In addition to this appendix, the Arduino code file of the prototype is available on Forge UCLouvain in the Open MedTech group:
`https://forge.uclouvain.be/openmedtech/medical-aspirator`

```
/*=====================================================================
*  Arduino code of the open-source medical aspirator
*  (Open MedTech project)

*  Created by Mayssem HADJILI and Lucile HEINEN
*  June 2023
*
*  Note: The calibration function is taken from the open-source
*  negative wound plate code [https://doi.org/10.3390/jcm11185417]
* ====================================================================*/


#include <Wire.h>
#include <Waveshare_LCD1602_RGB.h>

Waveshare_LCD1602_RGB lcd(16,2);  //16 characters and 2 lines of show
int r,g,b,t=0;

#define PRESSURE_SENSOR A3  // Pressure transducer in analog pin A3
#define LED_ALARM       7   // LED alarm in digital pin 7
#define LED_BUTTON      5   // LED button in digital pin 5
#define RELAY           A0  // Relay in analog pin A0
#define SET_PRESSURE    3   // set pressure button in digital pin 3
#define LEVEL           A1  // Level sensor in analog pin A1

#define SAMPLING_TIME   10  // Sampling time (in ms)

/*
*   The available operating mode are the following:
*     0 = "continuous"
*     1 = "inter_time_cycle"
*     2 = "inter_hybrid"
*     3 = "inter_two_step"
*   Choose one value for the OPERATING_MODE variable
*/
#define OPERATING_MODE  0  // Available mode: see above

#define T_ON            7000 // ON time for  inter. hybrid time-pressure and
    for inter. time cycle (in ms)
#define T_OFF           2000 // OFF time for  inter. hybrid time-pressure and
    for inter. time cycle (in ms)

```

```
41 #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
42 #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
43
44 #define SECURITY_PRESSURE_COEF 0.1 // % of the setpoint pressure (P_working)
       under/above which to raise an alarm
45
46 #define DISPLAY_UNIT 0  // 0 = bar ; 1 = mmHg
47
48 #define SETPOINT_PRESSURE 0.5  // [bar] Setpoint pressure  for the inter.
       two-step regulation mode only
49
50
51
52 // ===== Global variables =====
53
54 // Pressure transducer related
55 unsigned long t0,t1,t2;
56 int sample_pressure[25]; // to perform the calibration
57 double totalpress = 0, corrected_pressure, zero, samplezero, totalzero=0;
58 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
59
60 float corrected_pressure_init; // pressure befor setpoint selection with the
       regulator [mmHg]
61 float corrected_pressure_init_bar;  // pressure befor setpoint selection with
       the regulator [bar]
62
63 float P_sensor;      // Measured pressure from sensor in mmHg
64 float P_sensor_bar;  // Measured pressure from sensor in bar
65 float P_working;     // Setpoint pressure chosen by the user in mmHg
66 float P_working_bar; // Setpoint pressure chosen by the user in bar
67
68
69 // Operating mode
70 bool motor_on = false;
71
72 // Alarm
73 bool alarm_stop = false; // variable to true once the Too High Vacuum alarm
       is triggered
74 bool alarm_led = false;  // variable to true once the Too Low Vacuum alarm is
       triggered
75
76 //Level sensor
77 bool bottle_full = false; // variable to true once the collector container is
       full
78
79
80
81 // ===== Functions =====
82
83
84 void setup() {
85
86
87   pinMode(LED_ALARM,OUTPUT);              // LED alarm as output
88   pinMode(LED_BUTTON,OUTPUT);             // LED button as output
89   pinMode(RELAY,OUTPUT);                  // RELAY as output
90   pinMode(SET_PRESSURE,INPUT_PULLUP);     // SET_PRESSURE button as input
91   pinMode(LEVEL,INPUT);                   // LEVEL as input
```

```
92
93    analogWrite(RELAY,0);                    // switch off the vacuum pump to
        guarantee zero pressure
94    digitalWrite(LED_ALARM,LOW);             // Turn off the LED alarm
95    digitalWrite(LED_BUTTON,LOW);            // Turn off the LED button
96
97    lcd.init();
98    r = 160;  // Change color if needed
99    g = 150;
100   b = 205;
101   lcd.setRGB(r,g,b);
102
103   lcd.setCursor(0,0);
104   lcd.send_string("Welcome to the");
105   lcd.setCursor(0,1);
106   lcd.send_string("OS Aspirator");
107   delay(5000);                 // 5s delay to guarantee zero pressure
108   lcd.clear();
109
110   calibration();               // Launch of the calibration process
111   lcd.setCursor(0,0);
112
113   // Pressure selection procedure:
114   lcd.send_string("Pressure Select.");
115   delay(3000);
116
117   lcd.clear();
118
119
120   if (OPERATING_MODE == 3){ // If inter. two-step regulation mode
121
122     P_working_bar = SETPOINT_PRESSURE ;
123     P_working = SETPOINT_PRESSURE/0.00133322 ; // mmHg conversion
124
125   } else{
126     // Switch ON the vacuum pump:
127     analogWrite(RELAY,255);          // Pump ON : PIN = RELAY
128     motor_on = true;
129     long t_test = millis();
130
131     // Wait till the user set the working pressure
132     bool not_pressed = true;
133     digitalWrite(LED_BUTTON,1); // Switch ON the LED button to start the
        pressure set up
134     while(not_pressed){
135
136       corrected_pressure_init = analogRead(PRESSURE_SENSOR)- zero;
137        //conversion of pressure from mmHg to bar:
138       corrected_pressure_init_bar =
      mmHg_to_bar(abs(voltage_to_pressure(corrected_pressure_init)));
139
140       if (DISPLAY_UNIT == 0){
141         dtostrf(corrected_pressure_init_bar,2,3, pressure_init_string); //
      convert to string for display [bar]
142         lcd.setCursor(0,1);
143         lcd.send_string("Press:       bar");
144         lcd.setCursor(7,1);
145         lcd.send_string(pressure_init_string);
146       } else{
147         dtostrf(corrected_pressure_init,3,1, pressure_init_string); //
      convert to string for display [mmHg]
148         lcd.setCursor(0,1);
149         lcd.send_string("Press:      mmHg");
```

```
150         lcd.setCursor(7,1);
151         lcd.send_string(pressure_init_string);
152       }
153
154
155       if(millis() - t_test > 120000){ // > 2 minute
156         lcd.setCursor(0,0);
157         lcd.send_string("You forgot to");
158         lcd.setCursor(0,1);
159         lcd.send_string("set the pressure");
160       }
161       if(digitalRead(SET_PRESSURE)== LOW){ // if button pressed
162         not_pressed = false;
163       }
164     }
165     digitalWrite(LED_BUTTON,0); // Switch off the LED button
166     lcd.clear();
167
168     // once pressure has been set: store it in the variable P_working
169     corrected_pressure = analogRead(PRESSURE_SENSOR)- zero;      // zero
      deviations correction
170
171     P_working = abs(voltage_to_pressure(corrected_pressure));    //conversion
      of pressure to mmHg
172     P_working_bar = mmHg_to_bar(P_working); //conversion of pressure to BAR
173
174     // Correction of 0.03 bar (--> stabilised vacuum level)
175     P_working_bar = P_working_bar - 0.03;
176     P_working = P_working - 22,5; // 0.03bar = 22.5 mmHg
177   }
178
179   lcd.setCursor(0,0);
180   lcd.send_string("Press. selected:");
181   lcd.setCursor(0,1);
182
183   if (DISPLAY_UNIT == 0){
184     dtostrf(P_working_bar,2,3, P_working_string); // convert to string for
      display
185     lcd.setCursor(0,0);
186     lcd.send_string("        bar");
187     lcd.setCursor(2,1);
188     lcd.send_string(P_working_string); // in bar
189   } else{
190     dtostrf(P_working,3,1, P_working_string); // convert to string for display
191     lcd.setCursor(0,0);
192     lcd.send_string("         mmHg");
193     lcd.setCursor(2,1);
194     lcd.send_string(P_working_string); // in mmHg
195   }
196   delay(3000);
197
198   lcd.clear();
199
200   t0 = millis();  // time for the timestep
201   t1 = millis();  // time for the ON time for inter_hybrid and
      inter_cyle_time mode
202   t2 = millis();  // time for the OFF time for inter_time_cycle mode
203 }
204
205
206 void loop() {
207
208   // measure current pressure:
```

```
209   corrected_pressure = analogRead(PRESSURE_SENSOR)- zero;       // zero
        deviations correction
210   P_sensor = abs(voltage_to_pressure(corrected_pressure));      // voltage to
        pressure conversion [mmHg]
211   P_sensor_bar = mmHg_to_bar(P_sensor);                        // pressure
        conversion to bar
212
213   if (DISPLAY_UNIT == 0){
214     dtostrf(P_sensor_bar,2,3, P_sensor_string);
215     lcd.setCursor(0,1);
216     lcd.send_string("Press:       bar");
217     lcd.setCursor(7,1);
218     lcd.send_string(P_sensor_string);
219   } else{
220     dtostrf(P_sensor,3,1, P_sensor_string);
221     lcd.setCursor(0,1);
222     lcd.send_string("Press:      mmHg");
223     lcd.setCursor(7,1);
224     lcd.send_string(P_sensor_string);
225   }
226
227   // test if raise alarm or not:
228   alarm();
229
230   // test if the bottle is not full:
231   level_sensor();
232
233   // Pump control:
234   switch (OPERATING_MODE) {
235     case 0:    // "continuous":
236       // do nothing
237       break;
238     case 1:    // "inter_time_cycle":
239       inter_time_cycle();
240       break;
241     case 2:    // "inter_hybrid":
242       inter_hybrid();
243       break;
244     case 3:    // "inter_two_step":
245       inter_two_step();
246       break;
247
248
249   }
250 }
251
252 /*=====================================================================
253  *    CALIBRATION
254  *====================================================================*/
255
256 /* Calibration of the pressure transducer to compute 'zero' pressure (at atm
      pressure).
257  * Store it in the 'zero' variable */
258 void calibration(){
259
260   int i;
261   for(i=0; i< 24; i++) {sample_pressure[i] = 0;} //array initialization
262   lcd.clear();
263   lcd.setCursor(0,0);
264   lcd.send_string("Calibrating zero");
265   lcd.setCursor(0,1);
266
```

```
267   for(i=0; i< 91; i++){          //record every 50ms pressure value for a
        total time of 4.5s and accumulates the sum in totalzero variable
268
269     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){
        //writes * every 300ms in the LCD
270       lcd.setCursor(i/6,1);
271       lcd.send_string(".");
272     }
273
274     samplezero = analogRead(PRESSURE_SENSOR); //readings of pressure sensor
275     totalzero = totalzero + samplezero;   //recordings accumulated
276     delay(50);
277   }
278
279   zero=totalzero /i; //recording averaging to have real zero calculated
280   if (DISPLAY_UNIT == 0){
281     lcd.setCursor(0,1);
282     lcd.send_string("Press.:      bar");
283   } else{
284     lcd.setCursor(0,1);
285     lcd.send_string("Press.:     mmHg");
286   }
287
288
289   // ------------------------------------------------------------
290   // Verification that zero pressure correction is OK (<5mmhg)
291   // If not, gives an error and restarts
292   // ------------------------------------------------------------
293
294   for(i=0; i< 50; i++) {
295
296     corrected_pressure = analogRead(PRESSURE_SENSOR)-zero;     // zero
        deviations correction
297     P_sensor = abs(voltage_to_pressure(corrected_pressure));   // conversion
        of pressure to mmHg
298     P_sensor_bar = mmHg_to_bar(P_sensor);                     // conversion
        of pressure to bar
299
300     if (DISPLAY_UNIT == 0){
301       dtostrf(P_sensor_bar,2,3, P_sensor_string);
302     } else{
303       dtostrf(P_sensor,3,1, P_sensor_string);
304     }
305     lcd.setCursor(7,1);
306     lcd.send_string(P_sensor_string);
307
308
309     delay(30);
310
311
312     if (P_sensor >5 ){        // calibration error (>5mmHg)
313
314       lcd.setCursor(0,0);
315       lcd.send_string("Calibration err.");
316       lcd.setCursor(0,1);
317       lcd.send_string("                ");
318       lcd.setCursor(4,1);
319       lcd.send_string(P_sensor_string);
320       delay(2000);
321       lcd.setCursor(0,1);
322       lcd.send_string("Restart software");
323       delay(2000);   // 2s
```

```
324       totalzero = 0;
325       lcd.clear();
326       setup();              // RESTART
327     }
328   }
329
330   // if calibration ok
331   lcd.setCursor(0,0);
332   lcd.send_string(" Calibration OK ");
333
334   delay(2000);  //2s
335   lcd.clear();
336 }
337
338 /*=====================================================================
339  *    PRESSURE TRANSDUCER RELATED FUNCTION
340  *====================================================================*/
341
342 float voltage_to_pressure(float pressure_measured){
343   float sensitivity = -188.5; //sensitivity of the pressure sensor (mmHg/V)
344   float voltage = pressure_measured * 5 / 1024;
345   return (voltage * sensitivity);
346 }
347
348
349 /*=====================================================================
350  *    PRESSURE CONVERSION FROM mmHg TO bar
351  *====================================================================*/
352
353 float mmHg_to_bar(float pressure_mmHg){
354   return pressure_mmHg * 0.00133322 ; // pressure in [bar]
355 }
356
357
358 /*=====================================================================
359  *    REGULATION MODE FUNCTIONS
360  *====================================================================*/
361
362
363 void inter_time_cycle(){
364   if(motor_on){ // motor on
365     if(millis() - t1 > T_ON){
366       analogWrite(RELAY,0);          // switch OFF the vacuum pump
367       motor_on = false;
368       t2 = millis();
369     }
370   } else{ // motor off
371     if(millis() - t2 > T_OFF){
372       analogWrite(RELAY,255);          // switch ON the vacuum pump
373        motor_on = true;
374        t1 = millis();
375     }
376   }
377 }
378
379
380 void inter_hybrid(){
381    if(motor_on){
382     // if cycle time exceeded and pressure must be above min threshold:
383     if((millis() - t1 > T_ON) && (P_sensor > P_working*(1-MIN_PRESSURE_COEF))
     ){
384       analogWrite(RELAY,0);          // switch OFF the vacuum pump
385       motor_on = false;
```

```
386     }
387   } else{ // motor off
388     if(P_sensor < P_working*(1-MIN_PRESSURE_COEF)){
389       analogWrite(RELAY,255);          // switch ON the vacuum pump
390        motor_on = true;
391        t1 = millis();
392     }
393   }
394 }
395
396
397 void inter_two_step(){
398   if(motor_on){ // motor ON
399     if(P_sensor > P_working*(1+MAX_PRESSURE_COEF)){
400       analogWrite(RELAY,0);          // switch OFF the vacuum pump
401       motor_on = false;
402     }
403   } else{ // motor off
404     if(P_sensor < P_working*(1-MIN_PRESSURE_COEF)){
405       analogWrite(RELAY,255);          // switch ON the vacuum pump
406        motor_on = true;
407     }
408   }
409 }
410
411
412 /*=====================================================================
413  *     ALARM
414  *=====================================================================*/
415
416 /* if pressur < x% (SECURITY_PRESSURE_COEF) of the working one, or other
       trouble: light up a red LED !*/
417 void alarm(){
418
419   // TROUBLE 1: Too Low Vacuum:
420   if (P_sensor < P_working*(1-SECURITY_PRESSURE_COEF)){ // (NB: Relative
      pressure)
421     digitalWrite(LED_ALARM,HIGH);
422     alarm_led = true;
423     lcd.setCursor(0,0);
424     lcd.send_string("Press. to low!" );
425   }
426
427   // if too low vacuum triggered
428   if(alarm_led){
429     if(P_sensor > P_working*(1-SECURITY_PRESSURE_COEF)){
430       // system returned to normal condition
431       alarm_led = false;
432       digitalWrite(LED_ALARM,0);
433       lcd.clear();
434     }
435   }
436  //=====================================================
437
438   // TROUBLE 2: Too High Vacuum:
439   if (P_sensor > P_working*(1+SECURITY_PRESSURE_COEF)){
440
441     analogWrite(RELAY,0); // switch of the motor
442     motor_on = false;
443     alarm_stop = true;
444     digitalWrite(LED_ALARM,HIGH);
445     lcd.setCursor(0,0);
446     lcd.send_string("Press. to high!" );
```

```
447     lcd.setCursor(0,1);
448     lcd.send_string("Pump stop" );
449     delay(1000);
450 
451     // Loop and block the system until the vacuum level lowers AND the user
    push the button:
452     while(! ((digitalRead(SET_PRESSURE)== LOW) && (P_sensor <
    P_working*(1+SECURITY_PRESSURE_COEF)))){
453 
454       corrected_pressure = analogRead(PRESSURE_SENSOR)-zero;     // zero
    deviations correction
455       P_sensor = abs(voltage_to_pressure(corrected_pressure));   //
    conversion of pressure to mmHg
456       P_sensor_bar = mmHg_to_bar(P_sensor);                      //
    conversion of pressure to bar
457 
458       if (DISPLAY_UNIT == 0){
459         dtostrf(P_sensor_bar,2,3, P_sensor_string);
460         lcd.setCursor(0,1);
461         lcd.send_string("Press.:      bar");
462         lcd.setCursor(7,1);
463         lcd.send_string(P_sensor_string);
464       } else{
465         dtostrf(P_sensor,3,1, P_sensor_string);
466         lcd.setCursor(0,1);
467         lcd.send_string("Press:      mmHg");
468         lcd.setCursor(7,1);
469         lcd.send_string(P_sensor_string);
470       }
471 
472 
473 
474       // if the pressur lowers and become under the max security threashold:
475       if(P_sensor < P_working*(1+SECURITY_PRESSURE_COEF)){
476         digitalWrite(LED_BUTTON,HIGH);
477         lcd.setCursor(0,0);
478         lcd.send_string("Press. corrected");
479 
480       }
481     }
482 
483     // Switch ON the pump and "restart" the system (back to loop() function):
484     alarm_stop = false;
485     digitalWrite(RELAY,255);
486     motor_on = true;
487     digitalWrite(LED_ALARM,LOW);
488     digitalWrite(LED_BUTTON,LOW);
489     lcd.clear();
490     loop();
491   }
492 
493 }
494 
495 
496 /*====================================================================
497  *    Level Sensor Function
498  *====================================================================*/
499 
500 
501 /*Level sensor*/
502 void level_sensor(){
503   int level_sensor = analogRead(LEVEL);
504 
```

```
505   if(level_sensor > 450){
506     analogWrite(RELAY,0); // switch off the motor
507     motor_on = false;
508     alarm_stop = true;
509     digitalWrite(LED_ALARM,HIGH);
510     lcd.setCursor(0,0);
511     lcd.send_string("Bottle Full" );
512     lcd.setCursor(0,1);
513     lcd.send_string("Pump stop" );
514     delay(1000);
515
516   }
517 }
```

Appendices/OS_Medical_Aspirator_FINI.c

Appendix E

Bill Of Materials

This appendix presents the BOM of the prototype.

Date of last edit: 16/08/2023	**Bill Of Materials** Open-source medical aspirator prototype

The components required for the prototype's fabrication are listed, along with some of their key characteristics and prices. This list is divided into three parts: vacuum circuit components, electrical circuit components, and manufacturing process.

Vacuum circuit components:

Vacuum pump

Name	*3KQ Diaphragm Pump*
Performance in parallel connection: • **Free flow** • **Max Pressure** • **Max vacuum**	 • 28l/min • 1bar • -800mbar
Performance in series connection (vacuum only): • **Free flow** • **Max vacuum**	 • 8.5l/min • -950mbar
Weight	575g
Dimensions	147.1x86.4x44.4mm
Power consumption	16 to 30 W
Voltage	12V DC / EPDM
Other	Gas diaphragm pump Other wetted parts: PPS Max ambient operating temperature: 50°C Max media temperature: 100°C Origin: Deutschland
Purchase link	https://box-it.boxerpumps.com/3kq-diaphragm-pump/3114.129
Price (VAT excl.)	227.62€

Mechanical vacuum regulator

Name	*IRV10/20, Vacuum regulator (IRV10-C08BGN)*
Control method	Linear
Pressure range	-100 to -1.3 kPa
Operating flow	140 l/min

Dimensions • **Connectors** • **Height** • **Width**	• For tube with an external diameter of 8mm • 83mm • 50mm
Other	• Clip attachment type that makes is easy to attach/detach the pressure gauge or digital pressure switch. • Manual operating.
Purchase link	https://fr.misumi-ec.com/vona2/detail/221006501197/?HissuCode=IRV10-C08BGN#
Price (VAT excl.)	95.24€

Tubing

This tube was selected to obtain an idea of the average prices for the tubing used in our prototype. Instead of looking at the price of each different size, we took a general approach. The total length of tubing used when connected end-to-end is estimated to be 2 meters.

Name	*Tube SenTECH*
Dimensions • **Internal diameter** • **External diameter** • **Length**	• 6mm • 8mm • 2m
Material	Silicone
Weight	60g
Other	• Transparent • For gases and fluids
Purchase link	https://www.amazon.com.be/Silicone-Flexible-%C3%A9paisseur-Tuyau-m%C3%A8tre/dp/B07MZ6QN89?th=1
Price (VAT incl.)	12€

Filter

Name	*CAMI anti-bacterial filter*
Purchase link	https://www.nmmedical.be/cami-filtre-anti-bacterien.html
Price (VAT excl.)	5.62€

Collection container

Name	*CAMI flacon collect*
Volume information: • **Volume capacity graduated** • **Volume graduation**	• 1l • 100ml
Inlet port external diameter	9mm
Accessories	• Lid

	• Stop-valve at the pump inlet
Purchase link	https://www.nmmedical.be/cami-flacon-collect-1l-as-100-200-12br-3.html
Price (VAT excl.)	27.69€

Vacuum connectors

Name	*FCK 6 MSV Raccord à vis en T 8x6/8x6mm*
Connector dimensions: • **Diameter left/right external x internal** • **Diameter median external x internal**	 • 8x6mm • 8x6mm
Material	Nickel-plated brass
Weight	35g
Operating pressure	-0.99 to 10bar
Purchase link	https://www.landefeld.com/artikel/fr/raccord-a-vis-en-t-8x6-8x6mm-laiton-nickele/FCK%206%20MSV
Unit price incl. VAT	4.36€
Unit price excl. VAT (estimate at 21%)	3.44€
Total price excl. VAT	4x3.44 = 13.76€

Manometer

Name	*WIKA Dial Pressure Gauge 7203726*
Pressure range displayed	• 0 to -1 bar • 0 to -30 inHg
Pressure graduation	• 0.05 bar • 1 inHg
Gauge dimensions • **Diameter** • **Thickness** • **Connector**	 • 62mm • 80mm • G1/4B, overflat of 14
Weight	110g
Purchase link	https://befr.rs-online.com/web/p/pressure-gauges/4055616
Price (VAT excl.)	15.18€

On/off valve

Name	Festo HE-3-QS-6 Pneumatic Manual Control Valve
System	Shut-off valve manually actuated : 3/2 bistable
Dimensions • **Connector** • **Length**	 • 2 pneumatic ports : QS-6 • 53.2mm
Weight	27g
Note • **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
Price (VAT excl.)	17.84€

Float switch level sensor

Name	*RS PRO Vertical PP Float switch*
Dimensions • **Length** • **External diameter**	 • 53mm • 24mm
Electrical characteristics • **Switching current max.** • **Switching voltage max.** • **Switch output** • **Cable length**	 • 1A • 200VDC or 140VAC • **Direct Load** • 300mm
Material	Polypropylene (PP)
Note : use in	Water, dilute acids, …
Purchase link	https://benl.rs-online.com/web/p/float-switches/0519236?gb=b
Price (VAT excl.)	6.50€

Pressure transducer

Name	*ADP5111 vacuum pressure transducer Panasonic electronic components*
Pressure range	0 to -100 kPa
Dimensions • **Connector** • **Length**	 • Vacuum male – 3mm • 7.2 x 7.2 mm
Electrical characteristics • **Voltage** • **Output type**	 • 0 to 4.5V • Analog voltage
Comment	Upon purchasing our sensor (May 2023), it was priced at 13.11€ on RS. However, the price has now (August 2023) increased to 37.97€.
Purchase link	https://www.digikey.be/en/products/detail/panasonic-electronic-components/ADP5111/4754302
Price (VAT excl.)	13.11€

Total price excl. VAT of pneumatic part: 434.56€

Electric circuit components:

Microcontroller

Name	*Arduino Nano*
Weight	7g
Dimensions	5x5mm
Electrical characteristics • **Operating Voltage** • **Input Voltage**	 • 5V • 7-12V
Purchase link	https://store.arduino.cc/products/arduino-nano
Price (VAT excl.)	21.6€

Power supply unit

Name	*LCS75US12 AC/DC CONVERTER 12V 72W*
Weight	220g
Dimensions	99 x 97 x 30 mm
Output voltage	12V
Output current	6A
Power	72W
Comment	It is not the same model as the one used (retrieved, not purchased), but the performances are similar.
Purchase link	https://www.digikey.be/en/products/detail/xp-power/LCS75US12/13618417
Price (VAT excl.)	16.22€

LCD Screen

Name	*Module Waveshare LCD1602 I2C, Blanc sur Bleu, LCD 16x2 Caractères, 3.3V/5V*
Screen dimensions	64,5 x 16 mm
Input voltage	3-5V
Communication interface	I2C
Input voltage	7.5 – 35V
Purchase link	https://eu.robotshop.com/fr/products/waveshare-lcd1602-i2c-module-white-on-blue-16x2-characters-lcd-33v-5v
Price (VAT excl.)	7.27€

Linear Voltage Regulator

Name	*Texas Instruments LM7805CT/NOPB, 1 Linear Voltage Regulator 1A, 5 V 3-Pin, TO-220*
Dimensions	10.16 x 4.7 x 8.89mm
Output voltage	5V
Output current	1A

Input voltage	7.5 – 35V
Purchase link	https://befr.rs-online.com/web/p/voltage-regulators/7968060?gb=s
Price (VAT excl.)	1.8€

Relay

Name	*Omron G5RL-1E-HR DC5*
Dimensions	10.16 x 4.7 x 8.89mm
Coil voltage	5V DC
Rated load	12A at 24V DC
Purchase link	https://be.farnell.com/en-BE/omron/g5rl-1e-hr-5dc/relay-spdt-277vac-24vdc-16a/dp/1333637
Price (VAT excl.)	5.57€

Main switch

Name	*SWITCH ROCK ON-OFF H8500XBAAA*
Dimensions	10.16 x 4.7 x 8.89mm
Coil voltage	5V DC
Rated load	12A at 24V DC
Comment	It is not the same model as the one used (retrieved, not purchased), but it is similar.
Purchase link	https://www.digikey.be/fr/products/detail/bulgin/H8500XBAAA/9598439
Price (VAT excl.)	1.47€

Set pressure switch

Name	*Push button PFS6B205MM1CAS05L01*
Comment	It is not the same model as the one used (retrieved, not purchased), but it is similar.
Purchase link	https://fr.rs-online.com/web/p/boutons-poussoirs/1759425?gb=b
Price (VAT excl.)	2.03€

LEDs

Name	*Texas Instruments LM7805CT/NOPB, 1 Linear Voltage Regulator 1A, 5 V 3-Pin, TO-220*
Dimensions	10.16 x 4.7 x 8.89mm
Output voltage	5V
Output current	1A
Input voltage	7.5 – 35V
Purchase link	https://befr.rs-online.com/web/p/leds/2286004?gb=b
Number of pieces	3

Unit price (VAT excl.)	0.19€/pce
Total Price (VAT excl.)	0.19€ x 3 = 0.57€

Transistor NPN

Name	*BC549BTA*
Comment	/
Purchase link	https://www.digikey.be/fr/products/detail/onsemi/BC549BTA/975557
Price (VAT excl.)	0.34€

Diode

Name & reference	*Diode 1N4148TR*
Comment	/
Purchase link	https://www.digikey.be/fr/products/detail/onsemi/1N4148TR/458811
Price (VAT excl.)	0.09€

Resistors

Needed values	• 220Ω (x3) • 1k (1x) • 10k (x1) • 20k (x1)
Purchase link	https://www.digikey.be/fr/products/detail/stackpole-electronics-inc/CF18JT220R/1741639
Price (VAT excl.)	0.09€/piece
Total Price (VAT excl.)	0.09€ x 6 = 0.54€

Total price VAT excl. of electronic part: 58.07€

Total price VAT excl. of all components: 492.63€

Manufacturing process:

3D Printing

Weight of PLA	~330g
Price per Kg	26€/kg
Purchase link	Amazon link of a standard spool here
Where	With any 3D printer
Total Price • **(VAT incl.)**	• 8.58€

• **(VAT excl.)**	• 6.77€

Laser cutting

Material	*(x1) Plexiglas plate*
Times needed	<30min
Where	Performed in the Makilab
Price (VAT incl.)	5€ + 5€/30min
Total Price • **(VAT incl.)** • **(VAT excl.)**	 • 10€ • 7.9€

Total price VAT excl. of the whole prototype (material + manufacturing costs): 507.3 €

Appendix F

Test protocol: tests not performed

This appendix aims to present a series of additional tests required to evaluate the requirements of a medical aspirator that could not be tested during our work.

F.1 Testing the pump's performances

F.1.1 Check the pump's performances curve (pressure-air flow) given in the pump's technical data sheet :

a) Principle and objective

The pump is the core element of the machine, and its proper operation, as specified by its pressure-air flow curve, is vital for the performance, efficiency, and effectiveness of the medical device.

b) Apparatus

To assess this, it is important to set up an appropriate test bench, consisting of a high-precision pressure gauge and flowmeter with data logging capability, to reproduce the characteristic curve.

c) Procedure

1. Set up the test bench as explained in the apparatus section.
2. Switch on the vacuum pump and allow it to operate until it reaches its maximum stable vacuum. During this phase, continuously record the flow and pressure values.
3. Once the pump has reached its maximum vacuum and the data has been recorded, stop the pump and conclude the data recording.
4. Plot the pressure-air flow characteristic curve with the recorded data. You can use data processing software to smooth the curve and refine the data points.
5. Compare the obtained curve with the one provided by the manufacturer.

F.2 Testing the collection container

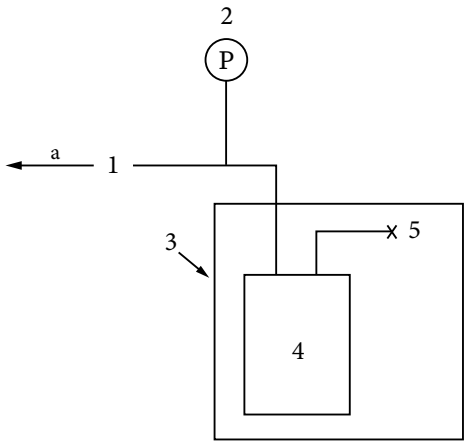
F.2.1 Strength of the collection container :

a) Principle and objective

The collection container will be subjected to different levels of pressure during use. It is important to check that it can withstand the maximum vacuum at which the device can operate. Hence, this test prevents implosion, cracking, or deformation of the collection container when subjected to the maximum vacuum level of the appliance. In the case of reusable container, they should be tested after being disinfected or sterilized as this can affect the material and the overall strength. This test must be carried out in a protective chamber to safeguard the person carrying out the test from possible flying debris.

b) Apparatus

The diagram of the test apparatus setup is represented in Figure F.1. The test bench uses a vacuum source, a vacuum level indicator, and a protective enclosure which is loose fitting and not sealed. The vacuum source includes a vacuum pump capable of generating a vacuum higher than the machine, and a vacuum regulator to precisely select the desired vacuum level.



Key

1	*vacuum source*	4	*collection container assembly* under test
2	*vacuum level indicator* (P)	5	*inlet port* closed to atmospher
3	protective enclosure	a	direction of flow

FIGURE F.1: Schematic of the apparatus for the collection container strength test

c) Procedure

1. Place the collection container assembly in a protective enclosure at 20°C to 25°C.
2. If a filter is used, it should be attached to the vacuum circuit between the collection container and the vacuum regulator and placed in the protective enclosure.
3. Switch on the vacuum source and evacuate the collection container assembly to 120% of the maximum vacuum level of the device
4. Hold the vacuum level for at least 5 minutes and then release by opening the inlet port.
5. Repeat the procedure
6. Verify that the filter and the collection container have not imploded and there is no permanent cracking or deformation in them.

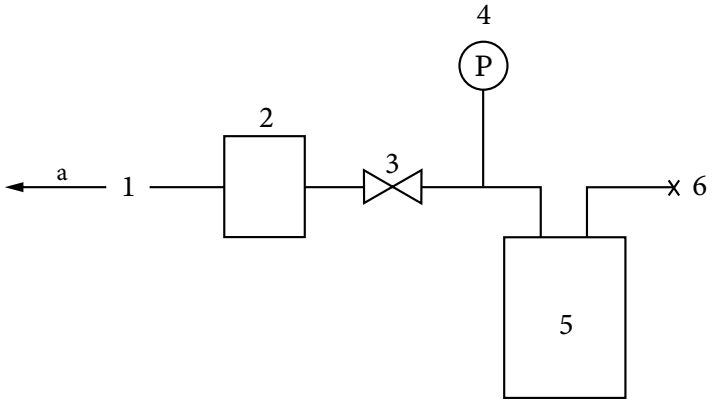
F.2.2 Test for air leakage into the collection container assembly :

a) Principle and objective

The collection container assembly consists of the collection container and its closure with connectors for suction. It is important to test how much an entry of room air leaks into the collection container will affect the vacuum level of the suction equipment. It can be evaluated by measuring the changes in pressure, over a period of time, after the collection container has been evacuated and sealed off. The requirements state that the relative pressure does not decrease by more than 10 mbar

b) Apparatus

See Figure F.2 for schematic of test apparatus setup.



Key
1 *vacuum source*
2 *vacuum regulator*
3 *on/off valve*
4 *vacuum level indicator* (P)
5 *collection container assembly* under test
6 *inlet port* closed to atmospher
a direction of flow

FIGURE F.2: Schematic of the apparatus for the collection container air leakage test

c) Procedure

1. Evacuate the collection container assembly to a vacuum level of 400 mbar. The inlet port musts be closed to the atmosphere.
2. Once the pressure is reached: close the on/off valve (number 3 in Figure F.2).
3. Verify that the pressure does not decrease by more than 10 mbar within 10 s.

F.3 Testing the tubing

F.3.1 Degree of collapse of suction and intermediate tubing :

a) Principle and objective

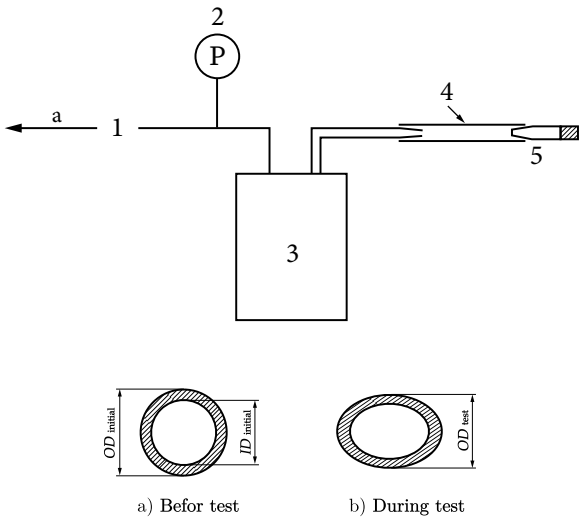
This test suggests that the tubing should be subjected to the device's maximum vacuum level for 5 minutes in order to ensure that the tubing is not collapsing. To assess this, the degree of collapse is calculated in the following way :

$$A = \frac{OD_{init} - OD_{test}}{ID_{init}}$$

where OD and ID are the outer and inner diameters of the tubing as represented in Figure F.3. The diameter of the suction tubing and intermediate tubing is measured before and after it is subjected to the maximum vacuum level. A second test consists of coiling the suction tubing and the intermediate tubing around a 100mm diameter cylinder to test if the suction tubing or intermediate tubing kinks.

b) Apparatus

See Figure F.3 for a schematic of the test apparatus setup. A caliper is also needed to measure the diameter.



Key

1	*vacuum source*	4	*suction or intermediate tubing*
2	*vacuum level indicator* (P)	5	plug
3	*collection container*	a	direction of flow

FIGURE F.3: Schematic of the apparatus for the degree of collapse of suction and intermediate tubing

c) Procedure

1. At 20°C to 25°C, uncoil the suction tubing or intermediate tubing to its full length and plug one end to prevent any airflow through it, this will allow it to reach the maximum vacuum level.

2. Attach a vacuum source to the other end of the suction or intermediate tubing and adjust the vacuum level to its maximum.

3. Hold the vacuum level for more than 5 min.

4. Calculate the degree of collapse by measuring the outside diameter of the suction tubing or intermediate tubing along its length with calipers as illustrated in Figure F.3.
5. Repeat the test while the tube is loosely coiled around a $\pm$100 mm diameter cylinder.
6. Calculate again the degree of collapse and verify that it is lower than 0.5 as required in the specifications.

F.4 Test for the device's performances

F.4.1 The evacuation of at least 200ml of simulated vomit in not more than 10s:

a) Principle and objective

The aim is to test the prototype under extreme conditions, namely the suction of the most viscous fluid, vomit. The ISO10079-4 standard proposes a recipe for simulating vomit with the highest viscosity value. The recipe is the following :

Comprising 10g of food grade xanthan gum in 1l of distilled water and 100+/-1g of 1mm diameter glass beads having a specific gravity of approximately 2,55. Benzoic acid 0,1% (mass fraction) can be added as a preservative.

b) Apparatus

To test this function, you need a graduated cylinder with a capacity of at least 300ml and graduations no more than 50ml apart, and a timer.

c) Procedure

1. Agitate the simulated vomit to disperse the beads.
2. Pour 250ml at ambient temperature into the graduated cylinder.
3. Chose the operating mode of the pump and operate the entire suction equipment with the level of the simulated vomit at the same horizontal level as the top of the collection container.
4. Once the suction tubing is placed into the simulated vomit contained in the cylinder container, record the time taken to evacuate 200ml.
5. Verify that the time measured is less than 10s.

F.5 Test for the electrical supply

F.5.1 Test for the battery :

There are tests for the battery-powered transportable equipment to determine whether the battery has good capacities and performance.

Battery performances

a) Principle and objective

The type of equipment intended for use in the field and/or during transport must, when fully charged, operate continuously for at least 20min, during which time it must produce a free airflow of at least 2 l/min and a vacuum level of at least 0.4 bar, according to ISO10079-1

b) Apparatus

This test needs a fully charged battery and a calibrated airflow meter.

c) Procedure

1. Power the equipment with a fully charged battery.
2. Place the airflow meter at the suction inlet port.
3. Set the vacuum level to a pressure of at least -0.4 bar at a free airflow of 2 l/min and record the free air flow for at least 20 minutes.
4. Check that the battery has not been switched off before 20 minutes have elapsed and that the airflow rate remains stable around at least 2 l/min over these 20 minutes.

Battery charge display

a) Principle and objective

The charge level of the battery provided on the device display should be tested in order to know its accuracy.

b) Apparatus

This test needs a fully charged battery, a battery voltage meter and the discharge curve of the battery.

c) Procedure

1. Connect the battery voltage meter to the battery of the device.
2. Power the appliance with this battery.
3. While the device is operating, record the voltages obtained.
4. Then convert these recorded voltages back into charge level using the battery discharge curve.
5. Then compare the charge level obtained with that displayed by the device.

Effect of an interruption of power supply

a) Principle and objective

Interruption and restoration of the power supply to the suction equipment shall not cause the vacuum level and free airflow to vary by more than $\pm 10\%$ from the set value.

b) Apparatus

This test requires an air flow meter and an external vacuum level indicator.

c) Procedure

1. Set the air flow meter to the suction inlet port and the external pressure indicator in the vacuum circuit.
2. Connect the device to a power supply and switch it on.
3. Set the vacuum level to 0.5 bar and note the set pressure and flow rate reached.
4. Switch off the device by stopping power it and wait 5min before switching it back on.
5. After 30s: Verify that the vacuum level and free air flow do not vary by more than $\pm$10% from the set value.

F.6 Noise test

a) Principle and objective

The noise level of the device is tested whilst being operated across its range of settings and with the suction inlet port closed but also when it is opened to the atmosphere. The sound level should not be higher than 70 dBA.

b) Apparatus

This test needs the use of a sound-level meter.

c) Procedure The following procedure is proposed by the ISO10079-4 Annex B.6 :

1. Place the microphone of the sound-level meter at the position of maximum sound pressure level in the horizontal plane passing through the geometric center of the suction equipment at a distance of 1m from the reference box.
2. Operate the suction equipment over its range of vacuum levels and flows with the inlet port open to the atmosphere.
3. Take the measurements using the frequency-weighting characteristics A and the time-weighting characteristic S on the sound-level meter in a free field over a reflecting plane.
4. Verify that the measured sound pressure level does not exceed 70dB.
5. Take the measurements using the frequency-weighting characteristic A and the time-weighting characteristic S on the sound-level meter in a free field over a reflecting plane.
6. Verify that the measured sound pressure level does not exceed 70dB and that the A-weighted background level of extraneous noise is at least 10dB below that measured during the test.

F.7 Test for the means put in place to reduce the risk to the patient

F.7.1 Preventing fluid flowing back to the patient

a) Principle and objective

A requirement states: *Means shall be provided which prevents fluid flowing back to the patient due to the pressure differential between the equipment and the patient*. The medical aspirator must contain a means of preventing liquids from flowing back towards the patient, if a pressure problem occurs, for example. This could be a non-return valve or any other device that performs the same function.

Check the conformance of the device by inspection of its technical file.

F.8 Test for the ease of use by a health user

F.8.1 Ease of use and operation

a) Principle and objective

An ISO10079 requirement states that: *Suction equipment shall be designed to be operated by one person, unaided*. By *operated* we understand *being able to switch on and set up the machine, sucking up liquid and stop the machine, all without external help*. Therefore, this test verifies this qualitatively by asking a health user to use the machine to suck up liquid.

b) Apparatus

No specific apparatus is used.

c) Procedure

Ask the health user to :

- Switch on the machine.
- Set the machine to the desired pressure.
- Suck in water until the collection container is full.
- Once the collection container is full: remove it and place another empty one (if the health user has not finished his work).
- Switch off the machine once the work is finished.
- Finally, ask the health user to assess the ease of use of the device.

F.8.2 Ease of dismantling, maintaining and cleaning

a) Principle and objective

Several requirements refer to the ease of dismantling, maintaining and cleaning:

- Suction equipment intended to be dismantled by the user (e.g. for cleaning) shall be designed to facilitate correct assembly or market to indicate correct reassembly.
- Any necessary greasing/oiling to be simple, accessible and possible by health users.

Therefore, this test verifies this qualitatively by asking a health user to dismantle and clean the machine.

b) Apparatus

No specific apparatus is used.

c) Procedure

Ask the health user to :

- Dismantle the machine to gain access to the pump and the various internal machine components.
- Oil/grease components that need it (if any).
- Clean the parts that need it (if any).
- Reassemble the device.
- Finally, ask the health user to assess the ease of dismantling, maintaining and cleaning.

F.9 Test for the ease of portability

To make the device more accessible for emergency use, it is important that it meets portability criteria such as weight and size, as well as being able to withstand extreme environmental conditions, given that it will be used outside hospitals.

F.9.1 Weight and size

a) Principle and objective

It is important that it does not exceed a certain weight to make it easily portable. That is why an article [103] discusses the important points that a portable medical aspirator must meet in a military emergency, including the fact that the device must weigh no more than 2.25 kg and recommend to not exceed a size of 30x10x10cm. However, as ISO10079-4 states, medical aspirators are always used in conjunction with other resuscitation equipment, so the device should be as small and light as possible.

The procedure is quite simple as it only requires weighing the device before any fluid has been drawn in and measuring the height and width when the collection container is placed on the appliance.

F.9.2 Strength to environmental conditions

a) Principle and objective

The environmental conditions to which the device may be exposed are extreme temperatures, humidity, and different atmospheric pressures. Annex B.15 of ISO 10079-4 suggests that all the previous tests in the test protocol should be tested under all extreme conditions.

b) All extreme conditions that should be covered :

- Test machine operation at temperatures range of [-40 to +70]°C,
- Test machine operation in a relative humidity range of [15 to 90]%, non-condensing, but not requiring a water vapour partial pressure > 50hPa,
- Test machine operation in an atmospheric pressure range of 620hPa to 1060hPa.

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