# WOCA

Design of a low-cost device for Negative Pressure Wound Therapy in low and middle income countries

**Master Graduation Thesis**
Msc. Integrated Product Design
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# PREFACE

With this thesis I finalize my master Intergrated Product Design and conclude my studies at TU Delft.
First, I would like to express gratitude to my graduation team, my chair Jan Carel Diehl and my mentor Armagan Albayrak for the for the guidance and, above all, endless patience throughout this graduation project. I was incredibly pleased to be part of the Global Initiative community, where everyone is always motivated to make a positive impact and passionate about their projects.
J.C, I would like to thank you for always staying positive and giving me energy at the times I was short of it. Moreover, thank you for connecting me with other peers and experts from the field, I am grateful for the time that I was invited to join your diverse and international network of people.
Armagan, throughout this project I always felt heard and supported by you. Thank you for guiding me, also on a personal level, and giving me space and extra time when I needed it.

Secondly, I would like to thank Arjan Knulst for giving me the opportunity to work on this project. Thank you for making time to talk with me, via Zoom and in real life and checking in with me every now and then.  I enjoyed our collaboration and I still wish that I will be able to join you in Nepal some day. Which brings me to Suraj Maharjan, who I would like to thank as well for his collaboration and for providing me with great footage of his work in the hospital.

In addition, there is a long list of incredible friends and family members that I want to express my endless gratitude to, as I can genuinely say, this time, I could not have done it without you.. I'd like to say specially thanks to the hero's of my 'Green dream team' that dragged me to the finish line during the final phase: Ludo, Anniek, Marieke, Sharon, Rosa, Wallie, Leo and Esther. Your help, emotionial support, healthy meals, dogwalks, peptalks and more, is hugely appreciated!

Furthermore, I'd like to thank my companions Frank, Mariska, Luna, Jelle and Martine for the great times we had at our Kantoor, we made an awesome graduation team. The same accounts for Kina and Jard, thank you for your advises, I enjoyed working together.

Moreover, I am incredibly thankful for my room mates, Eva and Linda. Thank you two for taking care of me, distracting me and cheering me up when I needed the most.

Last but not least, I'd like to say thanks to my mam, dad and brother for supporting me in every way possible. I feel lucky to have such caring people in my life.

With gratitude,

Eileen

# WOCA

A battery powered wound pump
designed for low-resource settings


- Includes **automatic** pressure control
- **Compatible** with self-made dressings & standard canisters
- **Portable** design, battery lasts for 15 hours
- **Simple** interface, enables smooth operation & monitoring
- Easy to repair with **widely available**, replaceable components

# EXECUTIVE SUMMARY

This report contains the full documentation of the design process and research associated with the design of the 'WOCA Wound Pump'. This project was commissioned by A. Knulst in collaboration with the Green Pastures Hospital, located in Pokhara (Nepal).

Many people living in low-middle-income countries (LMICs) are affected by injuries that develop into chronic wounds and, without adequate treatment, may lead to disabilities or even cause death. Negative Pressure Wound Therapy (NPWT) is currently a highly suitable manner to treat complex and chronic wounds. NPWT uses controlled negative pressure to stimulate wound healing and requires a vacuum device that is connected to a sealed vacuum dressing by a tube system. However, due to lack of resources in money and medical equipment, this treatment is still inaccessible to marginalised patients in LMICs, The context of this research is the Green Pastures Hospital (GPH) in Nepal. This test location is typical for LMICs. In GPH a converted aquarium pump (AquaVAC) is currently used as a NPWT device. There are a multitude of complications in relation to this equipment. Therefore, the following design goal is formulated: 'Treat chronic and complex wounds in LMICs with a device that is affordable, safe and reliable and made out of widely available, replaceable components.'

In order to design such a device, extensive context analysis, literature and expert review has been done in Phase I. It was found that international guidelines for treatment, as well as design standards and safety regulations, assume a western context or high-resources setting, and do not comply with the needs of end-users at GPH. This led to a new set of requirements and design guidance for the WOCA Wound Pump in Phase II.
Analysis of the market shows that NPWT systems are unnecessarily costly, due to the complexity of the devices and reliance on specific wound dressings. Low-cost solutions, such as the AquaVAC, show good results, however, these devices lack reliability, safety and ease of use.

The design proposal of the WOCA contributes to solving these issues in several ways. Hence, the design proposal that was developed in Phase III, is based on availability, compatibility and simplicity. The WOCA Wound Pump is a simple, cheap and robust NPWT device. The battery powered vacuum pump is portable and can be made completely from locally sourced components. The product can be disassembled with standard tools and all individual components are replaceable, which ensure a long lifespan. Special features of this design are 1) automatic pressure control, 2) compatibility with self-made dressings and standard canisters, 3) portable design with a battery that lasts for 15 hours, 4) simple interface for smooth operation and monitoring, 5) easy to repair and made from widely available components. Even so, the WOCA is affordable, the main components are purchased and produced for less than 100 USD.

To conclude, the WOCA Wound Pump has much potential in LMICs. After the evaluation of the final design, it turned out that in therapy most requirements set for a NPWT used in LMICs, were met. However, future steps have to be taken in order to fulfil its potential and make an actual contribution to the healing of chronic and complex wounds in LMICs. Firstly, the prototype needs to be finished. Design iterations should be made in order to fulfil the current dissatisfiers from the requirement list still, such as noise production, shockproof design and cleaning possibilities. Subsequently, the prototype should be validated with end-users and collaborations should be set up for funding, distribution and education. This process would probably take years, but it has the potential to profoundly improve the healthcare for chronic and complex wounds in low-resource settings.

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CHAPTER 1

# INTRODUCTION

This chapter introduces the subject of this graduation thesis. First, it explains the relevance of the project and outlines the background of the assignment. Next, it provides insight on the initial requirements and the approximate scope at the start of the project. Finally, the project outline is presented, including an overview of the design phases.

# 1.1. Current situation

### 1.1.1. The burden of chronic wounds

Developing countries or Low-middle Income Countries (LMICs) tend to have characteristics in common, such as poor access to healthcare, drinking water and sanitation. Likewise, the prevalence of complex and chronic wounds appears to be alarmingly high in these regions. Various studies point out that actual data on this topic barely exists and the problem has been widely underestimated [1], [2].
This assumption is based on the following observations. First, acute wounds and burns are more prevalent in the developing world, which is most likely related to the dangerous conditions in which people live and work. For instance, due to poor road conditions and traffic law adherence, traffic accidents are a frequent occurrence and account for a high rate of traumatic injuries. Other habits that are common in low-resource settings, such as walking barefoot and cooking on an open fire, also contribute to the occurrence of wounds and wound infections ([2]. Secondly, acute wounds tend to develop into chronic wounds, due to a lack of access to adequate wound care in combination with underlying conditions that affect wound healing, variating from diabetes and malnutrition to stress and obesity [3].

Given these points, it is important to acknowledge that chronic wounds, such as diabetic foot ulcers and pressure sores, are an everyday occurrence for many people living in LMICs.

### 1.1.2. Poverty and disability: A vicious circle…

Once a wound has become chronic, it requires long and intensive treatment to heal. Because healthcare services are poorly available in these areas, a large group of patients is forced to travel great distances. Furthermore, due to lack of proper (governmental) health insurances, the medical expenses must be paid out-of-pocket. Hence, hospitalisation comes with a large financial and social burden. As a result, people living in poverty tend to avoid treatment or wait until the last moment to seek medical help. Without treatment, chronic wounds can get badly infected and lead to severe disability and morbidity. Disability severely affects the quality of life and the ability to work, which creates more poverty [4]. A. Knulst (2019) has conducted research in Nepal and refers to this situation as the 'The vicious cycle of poverty and disability', which is shown in figure 1.

To summarise, due to circumstances chronic wounds are common in LMICs and lead to severe disabilities without treatment. Current treatment is expensive and poorly accessible for the population with a low income. Disability creates more poverty and to break this cycle, therfore....

**"There is an urgent need for faster and cheaper wound healing techniques in low-resource settings"** (Yadav et al., 2017)

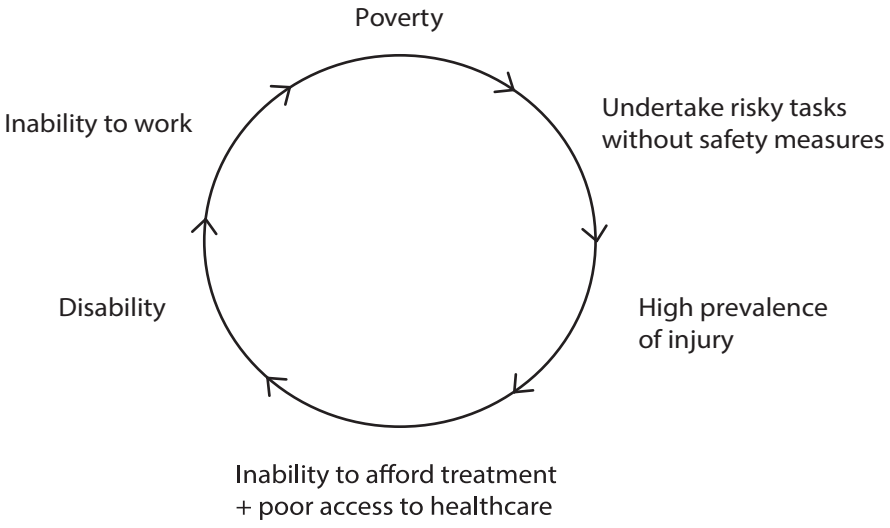



*Figure 1: The vicious cycle of wounds and disability, based on research in Nepal (Knulst et al., 2019).*

*Figure 2: Living conditions increase the risk of developing chronic wounds and wound infections in LMIC.*

*Figure 3: Rural communities rely on non-profit organisations, such as the Red Cross, for basic healthcare, medical facilities do not exist here.*

# 1.2. Assignment

This graduation project was initiated by Arjan Knulst, who is working as a biomedical engineer at Green Pastures Hospital, located in Pokhara, Nepal. The idea to develop a low-cost device for wound treatment arose when Arjan observed the local staff treating patients with a converted aquarium pump, instead of regular medical equipment.

### 1.2.1. Green Pastures Hospital

Green Pastures Hospital (GPH) is a resource-poor hospital, owned by a Nepalese non-profit organization called International Fellowship Nepal (INF) that provides specialized medical care to the poor. GPH was founded as a missionary hospital for leprosy and dermatology and has over 60 years of experience in wound care. Many of their patients need specialized wound care because they suffer from disabilities or complex injuries. Providing this care is challenging, due to the limited availability of financial resources at GPH. Most of the hospital income is generated through donations and therefore treatment budgets are highly restricted.

### 1.2.2. NPWT (or VAC therapy)

Negative Pressure Wound Therapy (NPWT), also known as Vacuum Assisted Closure (VAC), is a method for wound treatment that is widely used in the developed world to treat burns, ulcers, and other complex injuries. The wound is sealed with a special vacuum dressing, while suction is applied to remove the excrement and collect the wound fluids in a separate container. Wounds treated with NPWT tend to heal faster and require fewer dressing changes and less revision surgeries. Unfortunately, NPWT requires medical equipment and consumables that are currently highly expensive and not available in LMICs.

### 1.2.3. The AquaVAC

Due to the lack of proper equipment, some doctors working in LMICs came up with alternative solutions themselves to be able to provide NPWT to their patients. The medical staff of GPH currently uses a converted aquarium pump to treat patients with vacuum wound therapy (see figure 4). Treatment with this device: '*The AquaVAC*', has shown to be very effective in terms of wound healing, but still has quite a few limitations according to the local staff. Problems include the fact that the system is not portable and not convenient to use outside. Moreover, the pump was donated and purchased abroad, which means it cannot be repaired or replaced once it breaks down. Lastly, patients find treatment with this device uncomfortable, because it contains long tubes that limit their mobility and independence.

### 1.2.4. Assignment proposal

Based on the observations by A. Knulst, the initial assignment for this graduation project was formulated as follows: *"Develop a low-cost, portable VAC system that uses standard and widely available components and consumables"*. This became the starting point of the project, as will be further explained in the next section, *1.3 Project approach*

### 1.2.5. Parties involved

For this graduation project, the assignment has been adopted by TU Delft Global Initiative (Surgery for All) and executed in collaboration with local clinicians from GPH. It is the first time a design student works on this subject, hence, no other research teams or partners are involved yet. This thesis can be considered as a first exploration and impulse to a project that will hopefully be continued to grow into a larger collaboration that includes more stakeholders. See Appendix B: *Stakeholder analysis* for an analysis of the current and future stakeholders for this project.

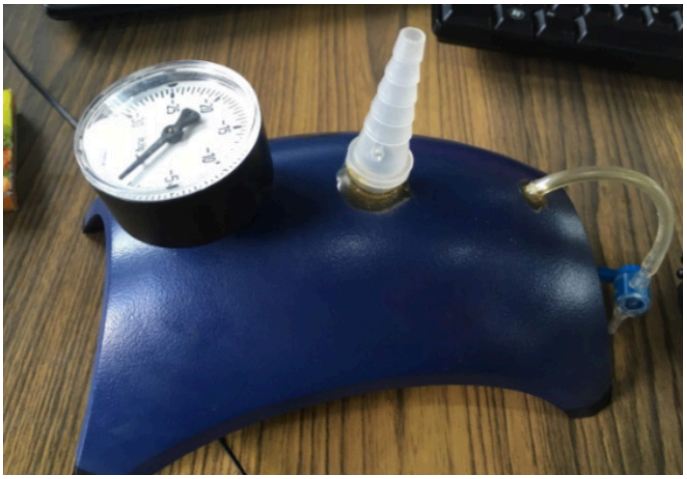


*Figure 4: The AquaVAC is an aquarium pump converted into a suction device, also known as TurtleVAC due to the characteristic shape.*

*Figure 5: Equipment that is used for VAC therapy, including: a) AquaVac b) canister c) extension cord d) converter e) dressing materials f) tubes and g) clamp.*


*Figure 6:* The International Fellowship Nepal (INF) has multiple work locations in Nepal, including the Green Pastures Hospital in Pokhara.

# 1.3. Project approach

A specific project approach is used for this project, which is based on the methods used in the past for projects with a similar context. It considers the factors that play a role when developing a product to use in a low resource setting. The approach is inspired by "Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide" [5]

### 1.3.1. Scope

Before diving into the specific approach, a few clarifications must be made reading the scope of this project.

**1) Design context:** Green Pastures Hospital in Nepal.

The context of low-middle-income countries (LMICs) is too large and too variable to see as a workable design context. Therefore, the case at Green Pastures Hospital (GPH) in Nepal is considered as a pilot study of a resource-poor hospital in a low-middle-income country. GPH is a prime example of a healthcare facility that operates with limited resources under challenging conditions, where affordable NPWT can have a large impact on the lives of patients/quality of care. The local staff of GPH is already treating patients with NPWT using a self-made device, and therefore chances are high that the new product will be successfully implemented. The final goal is to develop a design (concept) that is applicable in comparable settings in other LMICs.

**2) Target group:** Hospitalised patients with chronic wounds receiving regular NPWT.

Another clarification must be made regarding the application of NPWT and associated patient groups. NPWT has a wide range of indications, meaning it can be used to treat a variety of injuries. Apart from traditional NPWT, more advanced modifications of NPWT exist that require devices with special features. Furthermore, NPWT is used in different settings, including inpatient care and homecare. Not all treatment applications are relevant, considering the context of a LMIC and therefore a focus needs to be chosen. For this project, the focus lies on the use of standard NPWT to treat hospitalised patients (inpatient care) with chronic wounds.

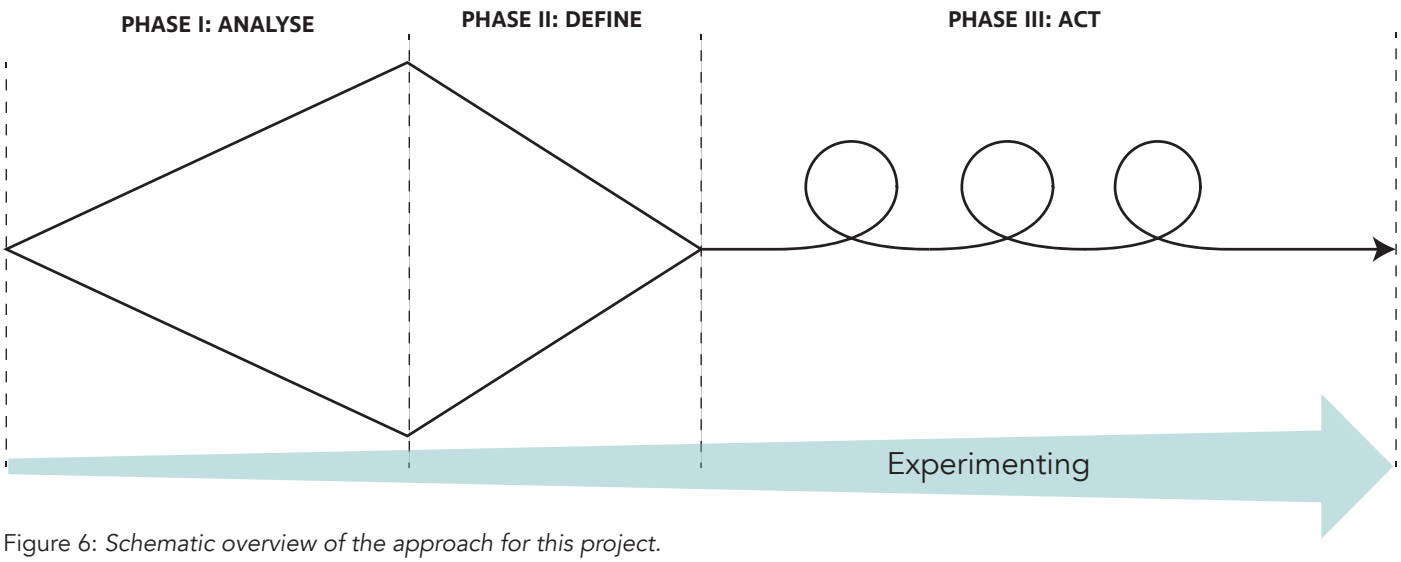



Figure 6: *Schematic overview of the approach for this project.*

### 1.3.2. Three phase approach

The specific approach consists of three different phases to reach in a systematic way a new product design, which is shown in the figure above.
**Phase I: Analyse** - *Ensure proper understanding of the context*

To make sure the context around the product is fully understood, the approach starts with an analysis phase. This approach mainly consists of research study. The main findings resulting from the analysis phase are the input for the next phase.

**Phase II: Define** - *Determine implementation strategy and design requirements*

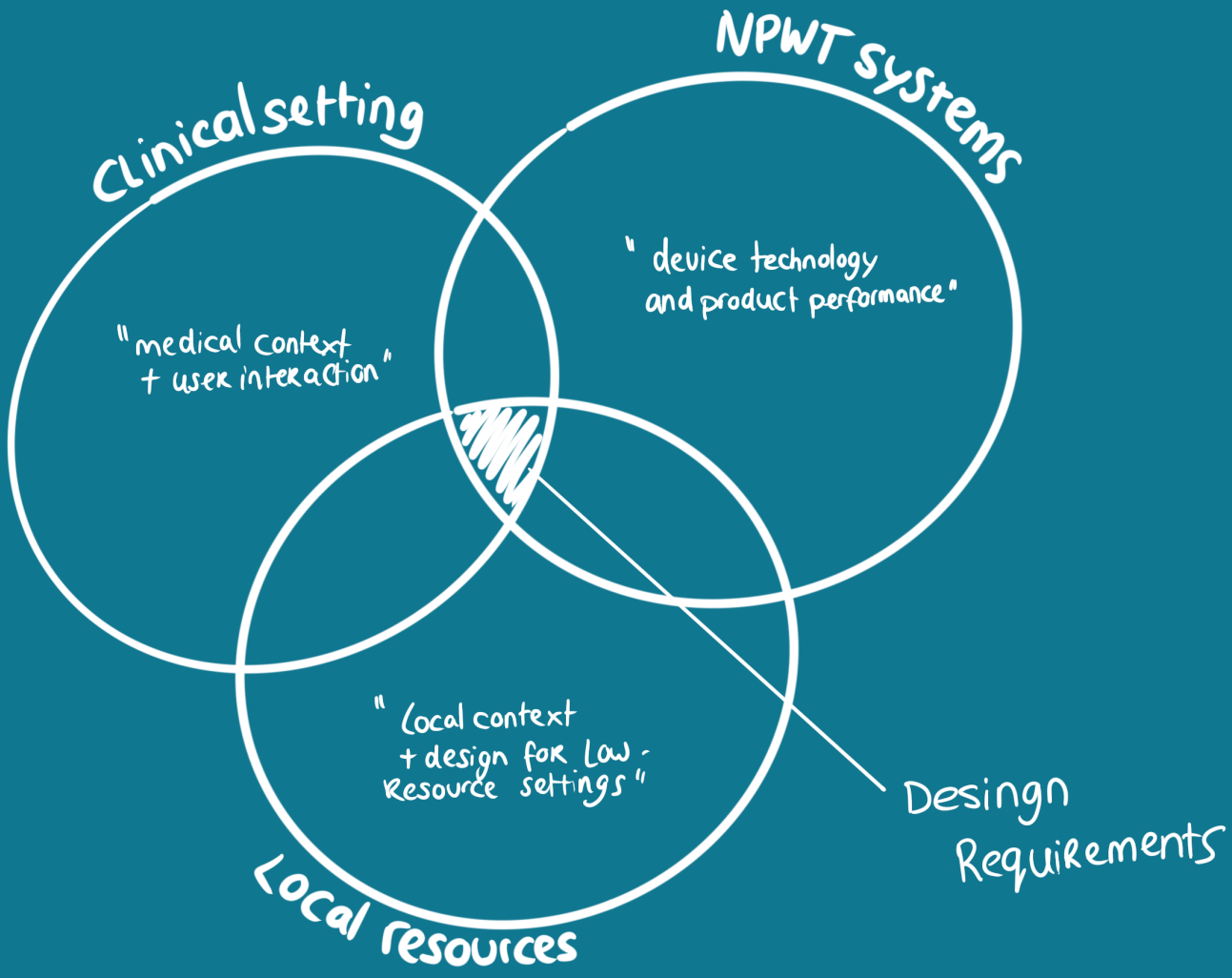
*During the definition phase of the approach the problem is defined in more detail. Furthermore, a scenario is envisioned resulting in requirements and the key focus points for the design.*

**Phase III: Act** - *Design and prototype in collaboration with local end-users*

The act phase begins with the selection and validation of the internal components with the aim to set a 'proof of principle'. Afterwards, a conceptual design based on the selected requirements follows. The evaluation of the concept product will lead to an improved final design, which is the final design that is detailed out and validated.

### 1.3.3. Research through design

A special approach was taken within this project, where prototyping and testing has been integrated from the start. Design activities were an essential part of research, resulting in an iterative and experimental design process. This method is referred to as 'Research through design' and in literature it is stated that in this practice, design researchers focus on how design actions produce new and valuable knowledge [6].


Clinical setting
NPWT systems
"medical context + user interaction"
"device technology and product performance"
"Local context + design for Low-Resource settings"
Local resources
Desingn Requirements

# PHASE I: ANALYSE

"Ensure a proper understanding of the design context"

The first phase of the  project is dedicated to research and analysis. The goal of Phase I is to ensure a proper understanding of the topic and design context, prior to setting design requirements and developing a strategy for implementation of the final product.

Phase I is divided into two sections: (1) Research and analysis of the **medical, technical and market perspective** of the topic and (2) analysis of the **design context**, including research on user experience and product interaction.

Research activities included an elaborate study of literature on the topics "*Wound care*" and "*Negative Pressure Wound Therapy*" as well as conducting interviews with healthcare professionals in Nepal, India and the Netherlands. A visit to the Erasmus Medical Centre was made to take a closer look at the equipment and observe how NPWT is applied in a high-end hospital. Additionally, the gathered information was thoroughly analysed and relevant findings were extracted.

The findings and considerations based on the two steps of the analysis phase were explored and summarized into a framed design context that are used as input for the next phase.

*Warning: This chapter includes images of injuries and wounds that may be disturbing to some readers.*

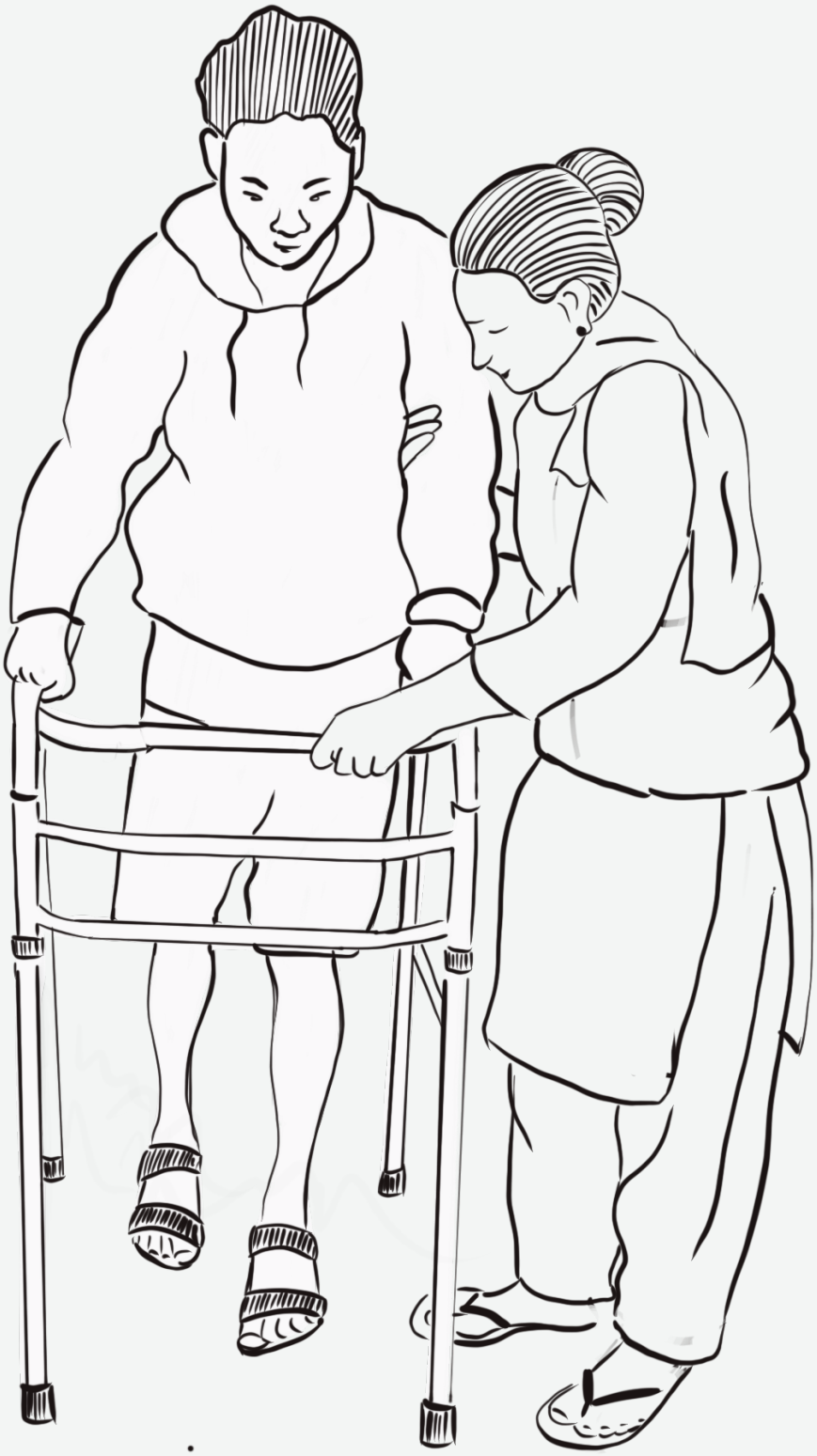
CHAPTER 2

# RESEARCH

This project seeks to design a low-cost product for providing Negative Pressure Wound Therapy (NPWT) to patients with chronic wounds. To understand the domain of this treatment, the requirements for a device in this domain and the medical procedures and guidelines, it was necessary to conduct primary research in the domain.

First, literature research on the topic of 'Negative Pressure Wound Therapy' as well as interviews with healthcare professionals resulted in a general understanding of the treatment procedure and associated medical guidelines. Next, the technical aspects of a NPWT system are analysed as well as the current market and existing products. Furthermore, a literature review of previous projects published on low-cost NPWT in similar countries prepared for what challenges to expect when designing a device for this specific context. The chapter ends with an overview of the main findings retrieved from this research, which include design considerations and implications that form the basis for the synthesis in Phase II.

In this chapter



# 2.1. Negative Pressure Wound Therapy

This section provides answers to the questions: *"What is Negative Pressure Wound Therapy (NPWT) and why, when, where and how is it used?*

## 2.1.1. Definition and principle

**Negative Pressure Wound Therapy** or Vacuum-assisted Closure therapy is a type of treatment that uses controlled negative pressure to stimulate wound healing. In literature, a variation of names is used to indicate the same treatment, including VAC and TNP (Topical Negative Pressure) [7], while doctors and nurses commonly say 'VAC-therapy' or 'Wound VAC'. In this report the scientific name of the treatment is used, which is abbreviated as NPWT.

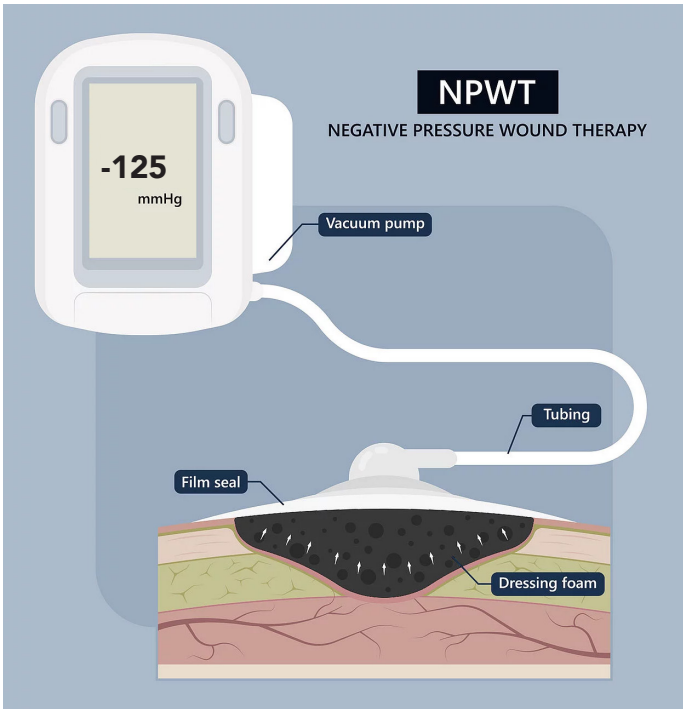



*Figure 7: Illustration of a wound treated with Negative Pressure Wound Therapy.*

**The principle of NPWT** includes the following steps: Seal the wound area from the environment (1), apply controlled negative pressure (2) and extract fluids and infectious materials from the wound (3). Wound fluids are either absorbed in a wound dressing or collected in a separate container [8]. After 3-5 days of suction, the wound dressing is changed. This cycle can be repeated until full wound closure is achieved or until the wound is ready for a follow-up treatment. The total treatment may last from a few weeks to a few months.

NPWT was first proposed by Argenta and Morykwas in 1997 [9] and quickly became a popular treatment that is nowadays used in almost all surgical areas. NPWT has several benefits that have been clinically proven [7], [10], [11] First of all, wounds treated with NPWT tend to heal faster, require fewer dressing changes and surgical interventions [7]. As a result, time spent in the hospital by the patient and the workload of the medical staff is reduced. Moreover, NPWT improves patient comfort, because it increases the mobility of patients and provides hygienic wound closure [7]. Finally, it has been suggested that NPWT can be more economical in the long term, compared to conventional wound treatment [12]. Disadvantages of NPWT include experienced pain or discomfort, the need for special knowledge and equipment, air leakage, system errors and costs [13].

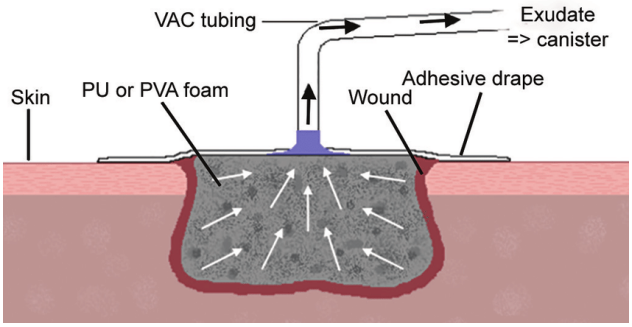



*Figure 8: A closer view of the vacuum dressing in which a spongy wound filler is placed inside the wound and adhesive drape is placed on top to seal the entire area.*

### 2.1.2. Indication for use

NPWT has a wide range of indications and is used for treatment of acute, chronic, and post-surgical wounds [7]. The treatment is used in a wide variety of clinical scenarios, ranging from skin-gram repairs to abdominal surgery [14]. Note that NPWT cannot be applied when contraindications are present [7], this includes for instance malignant wounds, which means cancer patients should not immediately be treated with vacuum therapy [8]. For this reason, it is important to evaluate the patient and identify underlying factors or comorbidities prior to the start of the treatment. As mentioned before, it has been decided to focus this project on the treatment of patients with chronic wounds in LMICs.

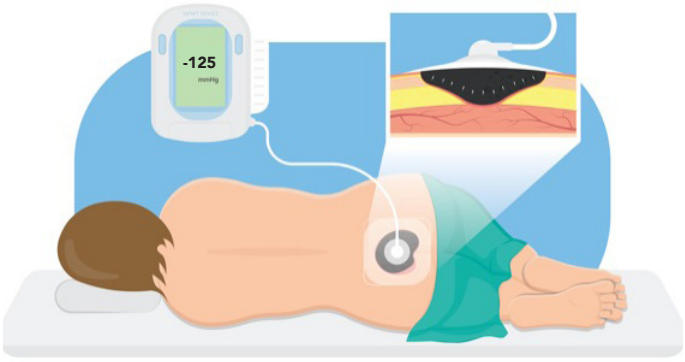



*Figure 9: Illustration of a patient being attached to the NPWT system and receiving treatment while laying down.*

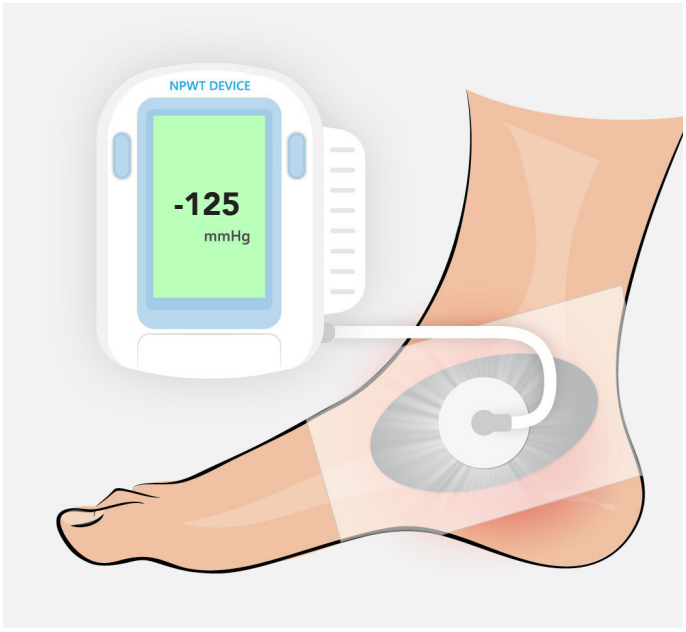



*Figure 10: Illustration of the vacuum wound dressing that is placed on the wound and connected to the NPWT device.*

Chronic wounds or non-healing wounds, are wounds that do not heal within 4 to 6 weekends, due to a postponed, incomplete or uncoordinated healing process [3], [15], [16] This condition, also known as impaired wound healing, can be caused by local factors, such as hypoxia or poor vascularisation of the wound location and systemic factors, such as older age, metabolic diseases (diabetes mellitus) and malnutrition [3]. Chronic wounds are in a permanent state of inflammation and therefore associated with pain, excretion of wound fluids (wet wounds) and abnormal proliferation of tissue, (ugly wounds). The wound area often shows signs of inflammation, including redness, swelling and warm skin. Because chronic wounds stay moist and do not close, patients remain prone to infection. The treatment of chronic wounds, also referred to as wound management, is expensive and time consuming, resulting in high medical costs[17], [18].

As mentioned before, a great deal of the poor population in LMICs suffers from chronic wounds. Wound types that are particularly common include pressure ulcers (due to inadequate prosthesis and wheelchair), Diabetic Foot Ulcers (DFU), leg ulcers and burns [19].

### 2.1.3. Effect on healing

Success rates in clinical trials have proven that NPWT has a stimulating effect on wound healing, resulting in faster healing and better wound closure [7]–[9], [20]. It was found that the **combination of suction and pressure** triggers a series of effects, which altogether promote wound healing [21]

These positive effects include:
- Stabilisation of wound environment
- Reduction of wound oedema
- Reduction of bacterial load
- Improved tissue perfusion and angiogenesis.

NPWT creates an environment that is free of bacteria and well provided with oxygen, and therefore favourable for the formation of new cells. As a result, the formation of premature tissue (**granulation tissue**) on the surface of the wound increases and closes the wound. The speed at which granulation tissue is formed can be measured and is frequently used in clinical trials as an indicator for successful healing [18].

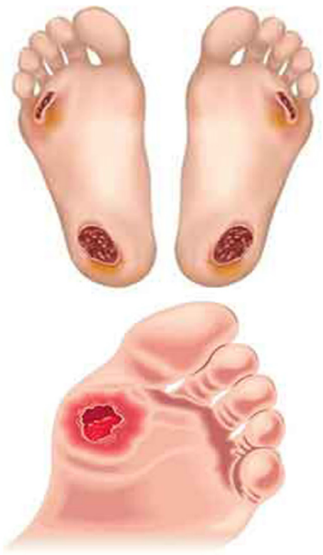


*Figure 11: Illustration chronic, non healing wounds, also known as ulcers.*

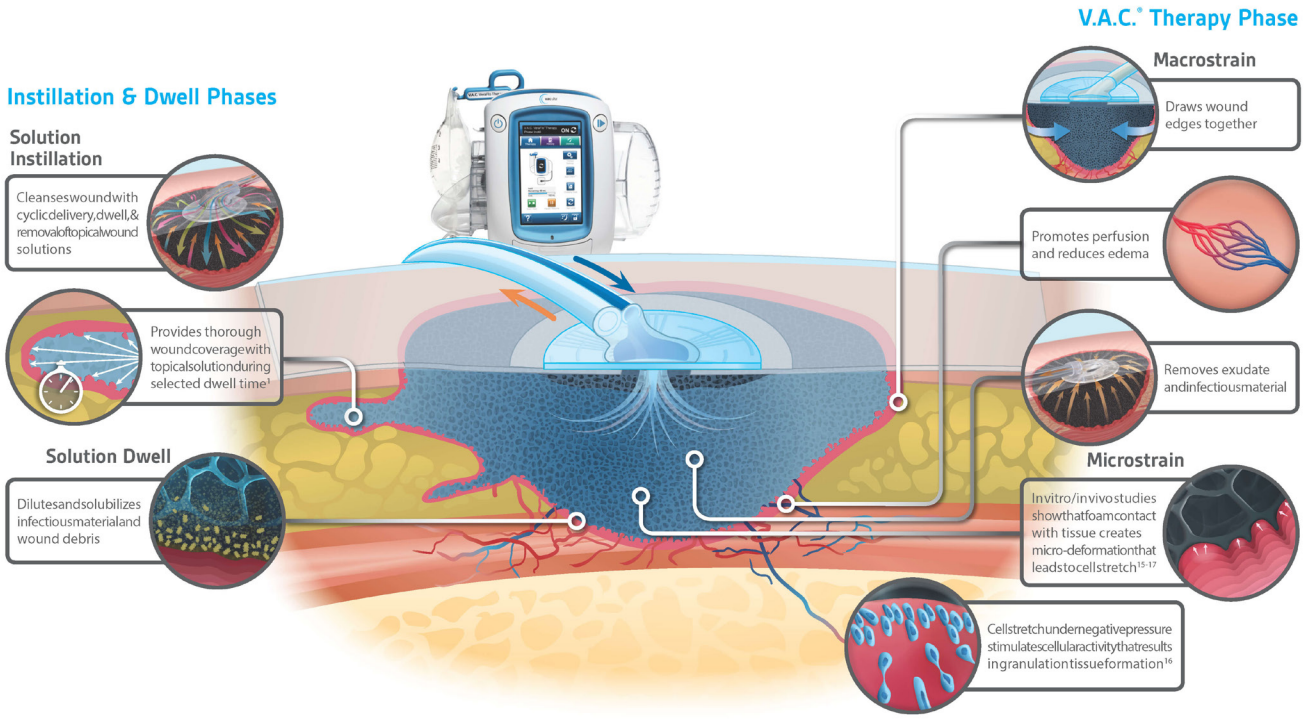



*Figure 12: Wound healing is a complex and dynamic process. On the right side of this image: Effects that trigger wound healing during NPWT are caused by macro strain (on tissue level) and micro strain (on cellular level).*

### 2.1.4. Equipment

For vacuum wound therapy,  a **NPWT system** is needed, which consists of a vacuum device and vacuum dressing that are connected to each other by a tube system (see figure 13).

A wound filler made of porous 'spongy' material, usually polyurethane (PU) or polyvinyl alcohol (PVA) [7], [22] is placed inside the wound, before applying the dressing on top, to provide an equal distribution of the pressure.
The sealed canister is used to collect the wound fluids that pass through the filler and is made detachable to empty from time to time. Canister less systems exist as well, these systems use highly absorbent dressings to collect the exudate.

The NPWT-system can be divided into the device and the dressing, separable from each other by disconnecting the tubes.

- **The NPWT device** (or therapy unit) creates and controls the vacuum, so it matches the intended level of negative pressure. It has adjustable settings, depending on the brand and type, and includes indicators and alarms for safety purposes. The device can be disconnected from the dressing and is either disposed of or reused after cleaning.

- **The NPWT dressing** comes in a sterile package and is meant for single use. This package includes wound filler, adhesive film, and a piece of tube that is altogether removed and discarded after one treatment cycle (3-5 days). The dressing should provide a good seal and remain in place day and night. Without a properly sealed dressing, the NPWT-system cannot build pressure. Multiple wounds can be treated with one device when connecting two dressings with a piece of filler (bridging technique) [7]

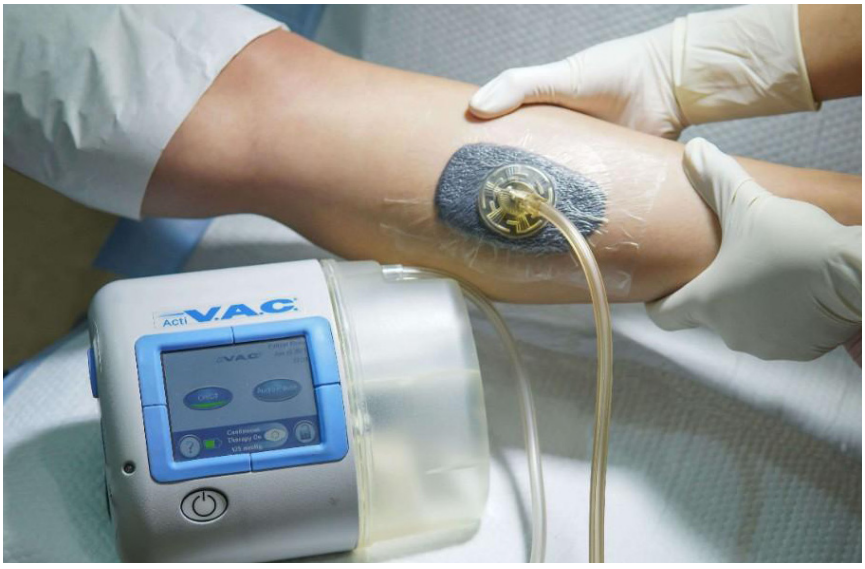



*Figure 13: Patient with a leg ulcer receives Negative Pressure Wound Therapy (using the ActiVAC device by KCI). The suction device is connected to the special sealed wound dressing by a disposable tube system*

### 2.1.5. Treatment procedure

Patients that receive NPWT in the hospital or home care setting are treated according to evidence-based guidelines [7], [23]. Treatment protocols are established by hospitals and product specific instructions are provided by the manufacturer [24]. Patients that receive NPWT at home learn how to use the device and change the dressing, which indicates this operation is not extremely complicated. Instruction videos on how to use an NPWT system are widely available online (VAC Folie Bijplakken Bij Luchtlekkage - YouTube, n.d.).

The therapy is applied in repeatable cycles that last 3-5 days. After each **treatment cycle** the dressing is changed and the wound is evaluated, to decide if another cycle is needed based on the healing progression.

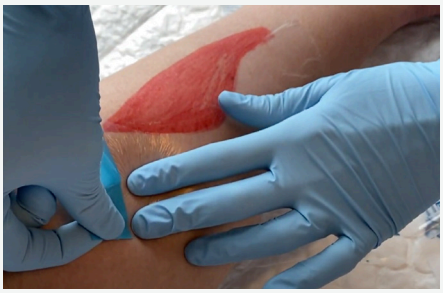
A general **treatment procedure** for NPWT includes five steps: Wound preparation (1), dressing application (2), system activation (3), system monitoring (4) and dressing removal (5).

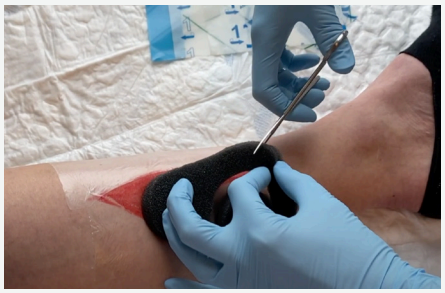
**STEP 1: Wound preparation**
Before applying the dressing, a trained professional should check the wound(s) and determine if a patient is eligible for NPWT. This step is called *'wound assessment'* and includes the evaluation of the patient and wound area. The next step is *cleaning and debridement* of the wound, which means to remove all infectious and unwanted tissue before placing the dressing. Each patient case is different and therefore careful evaluation is required, whereafter the doctor decides on an individual *treatment plan* that fits the needs of this patient.

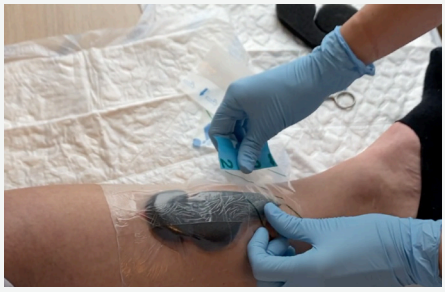
**STEP 2: Dressing application**
Now the wound is prepared for the treatment, the dressing is placed. Most standard dressings for NPWT are pre-sized and must fit the size of the wound. Wound fillers are cut to the right size and placed inside the wound. The dressing pad should be placed carefully so the wound is completely sealed, but not deprived from oxygen supply.

## 2) DRESSING APPLICATION


*2a) Cut strokes from the sheets of drape*


*2b) Put film around the wound edges*


*2c) Place wound filler inside the wound*


*2d) Apply drape, smooth out the wrinkles and make sure the area is sealed without leaks*


*2e) Cut a hole (the size of a coin) and place the tube-end from the dressing kit on*


*2f) Attach the canister and tube, secure the connectors between tube ends*

*Figure 14: Shows two steps of the general treatment procedure for NPWT. The images are obtained from instruction videos, provided online by the wound center of the Erasmus MC*

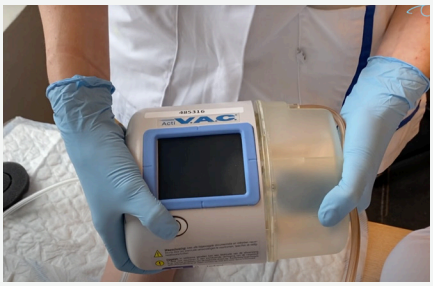
**STEP 3: System installation & activation**
When the wound is sealed and the device settings are correct, the system is activated. The dressing should shrink a little when the pressure is built. Now, the system and dressing must be checked to identify possible air leaks ('seal check') and verify the pressure level. When the dressing is in place, the treatment cycle has started.

**STEP 4: System monitoring**
To ensure effective treatment it is important that the therapy is not interrupted and therefore the patient is attached to the system day and night. It is possible to disconnect the dressing during treatment for a short time, for example for a toilet visit, if the pressure is restored within two hours. If the pressure is lost for more than two hours, the dressing is saturated and should be changed (Nolan et al., 2018). During treatment, the patient is monitored. Most NPWT systems have integrated safety alarms to detect problems, such as a loss of pressure, a full canister, or a blockage of the tube.

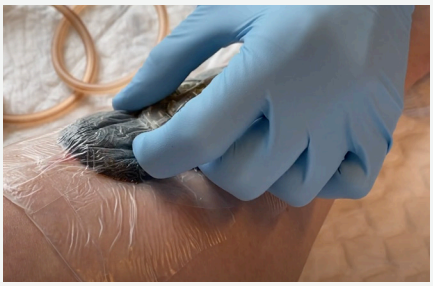
**STEP 5: Dressing removal**
At the end of the treatment cycle, the wound dressing is removed and carefully discarded to avoid any cross-contamination. The doctor is now able to evaluate the wound and update the patient wound chart. In case the treatment is continued, the steps are repeated. In case the treatment is ended, the dressing is removed to start follow-up treatment. The NPW device is cleaned and sterilized after treatment.

To conclude, the general treatment procedure consists of five steps that are repeated for each new treatment cycle of 3-5 days. Step 3 and 4 of the procedure include the use of a NPWT device, which is installed after the dressing is applied.

## 3) VAC INSTALLATION AND ACTIVATION



*3a) Turn on VAC device, adjust settings and press START*


*3b) check if pressure is building (seal check)*

### 2.1.6. Treatment variables

Treatment variables are parameters that influence the effectiveness of NPWT. Some of these variables may be chosen according to the patient needs, disease, wound type, and shape [11]. To set requirements for the performance of the low-cost device, it is important to understand what settings or product adjustments can alter the effect of the treatment.

It was stated in the previous section that the application of pressure and suction creates the healing effect during NPWT. Therefore, relevant treatment variables related to the device are: (1) pressure level, (2) pressure mode, (3) suction or fluid flow rate. Variables related to the dressing include: the wound filler material, the presence of contact layers and the use of installation fluids, which are outside of the scope of this project. The conclusions found about the desired level of pressure and suction, and the application methods to ensure effective treatment are described in the following section.

- **Guidelines for pressure level**

The most widely used pressure level for NPWT is -125 mmHg, which is considered the optimum pressure for most wounds [7], [8], [10]. Research indicates that the effective range for this treatment lies between -75 and -125 mmHg [7]. In specific situations, reduced pressure is preferred, for example when treating sensitive wounds or when the patient experiences pain during treatment [7]. A pressure level of -80 mmHg is known to be used in clinical practice, mostly when treating smaller or sensitive wounds. It was found that when applying -80 mmHg granulation is still formed, while below -75 mmHg the effect significantly decreases [7], [9]. The maximum recommended pressure is -200 mmHg, because stronger pressures do no longer stimulate healing and can result in tissue damage [7].

The considered optimum pressure is -125 mmHg (= 16.665 Pa), the effective range is -75 to -125 mmHg and the maximum pressure is -200 mmHg.

- **Guidelines for pressure mode**

NPWT is commonly used in continuous mode, which means the same pressure is applied throughout the therapy. Another option is to apply intermittent pressure in cycles of 5 minutes on and 2 minutes off. Research indicates that due to the 'massaging effect' this could increase the healing effect [7]. Nevertheless, intermittent pressure is less used in hospitals as it can be experienced as uncomfortable or painful.

*Continuous mode is preferred; Intermittent mode is not required.*

- **Guidelines for suction**

For effective treatment, wound fluids should be continuously removed from the wound area. If suction is insufficient, wound fluids accumulate inside the dressing. As a result, the healing effect decreases, and the risk of infections increases. Large wounds that excrete high levels of exudate need more suction, i.e a higher fluid flow rate [L/min], compared to small wounds with lower excretion rates.

The suction capacity or fluid flow rate [L/min] should match the excretion rate of the wound.

To summarize, the three relevant parameters to consider are pressure level (1), pressure mode (2) and fluid flow rate (3).

### 2.1.7..Risk and complications

NPWT is associated with a certain level of risk. During treatment, complications might occur that can harm the patient, which should be always avoided. Clinical studies and FDA documents are analysed to identify risks and complications that occur during NPWT [7], [11]. Not all complications are influenced by the design of the NPWT system, therefore the most relevant issues for this project are selected and listed below.

Three complications to consider when designing a NPWT system include:

- **Bleeding:** This complication occurs in case the pressurized system is accidentally in touch with an exposed blood vessel. Due to the suction, the patient can lose a significant amount of blood in a short time. Excessive bleeding is not common but can have severe consequences and is therefore considered the most serious complication. To avoid large blood loss, most NPWT-devices use smaller canisters (300-500 ml) with overflow protection and safety alarms to alert the user in case of a full canister or rapid increase of fluid flow.

The device should have a small canister (300-500 ml) with overflow protection and safety alarms to indicate bleeding.

- **Infection:** This complication occurs when a wound gets contaminated, resulting in bacterial growth underneath the sealed dressing. This is the most common complication and is usually solved with medication. However, if an infection remains undetected it may spread into a deeper (systemic infection) that can be deadly. Therefore, patients are closely monitored and frequently checked on specific signs, including fever (i.e., high body temperature), local swelling, increased pain or a change in the appearance or smell of the exudate. In addition, the risk of cross-contamination is minimized by making sure devices and dressings are clean and sterilized, the wound is well debrided and bacterial filters are in place. Canisters and tubes are made transparent, so a change of color of the wound fluids can be easily detected.

The tube system and canister should be transparent and include a bacterial filter.

- **Tissue damage;** First, ischemia (i.e. death of tissue) occurs when the local pressure is too strong, and the tissue is deprived of oxygen. Secondly, pressure could also damage organs close to the wound location, although this is a rare occurrence [7]. Thirdly, ingrowth of wound filler occurs at times, for instance when using a bad quality wound filler, and causes pain and tissue damage when the dressing is removed. To avoid unsafe situations, most NPWT devices have a maximum pressure of -200 mmHg. Moreover, to avoid tissue damage, careful wound assessment and dressing application is important as well.

The device should have a safety stop at -200 mmHg

### 2.1.8. Treatment costs

The average treatment costs for NPWT in a regular hospital are estimated around **100-150 EUR** per patient per day, which is approximately 5% higher compared to standard treatment [26].

Treatment costs include investment costs as well as recurrent costs. Although it has been suggested that NPWT can save costs in the long-term, it might be unappealing at first to invest in NPWT, because the equipment is expensive [26].

NPWT-device prices range from **7500 to 12000 EUR** and dressing price range from **30-50 EUR.** These dressing kits are pre-sized and meant for single use, therefore a continuous supply and sufficient stock of dressings is required. NPWT devices are often leased through monthly payment which includes services for maintenance and repair. Note that prices are estimated, and the actual prices cannot be retrieved as vendors do not share information on their arrangements with customers.


*Figure 15: The K.C.I (now 3M) Veraflo is a traditional NPWT device that is used at the Erasmus MC and was demonstrated during a visit to the wound centre*

### 2.1.9. Visit Erasmus MC

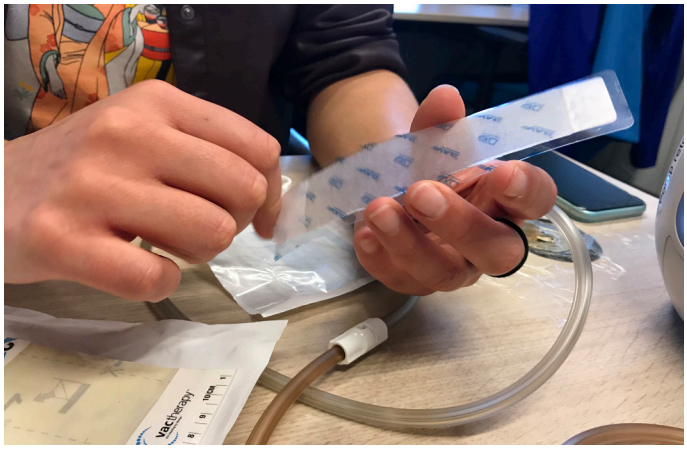
In addition to the literature research, a visit to the Erasmus Medical Centre was made to take a closer look at the equipment and observe how NPWT is applied in a high-end hospital.
The equipment that is used for NPWT is purchased from GD Medical, which is the largest distributor of vacuum therapy devices in the Netherlands [27]. At Erasmus MC the most used NPWT systems are the VeraFlow, a traditional device that is used in the hospital and the ActiVAC, a portable device that is used for home care. During the visit, a wound expert demonstrated these devices. During the demonstration, user cases based on the experience of the wound consultants were discussed to get insight in the practical use of the systems. Appendix X further elaborates on this interview.

Key observations:

- Both NPWT devices that were demonstrated are complex, including a large variety of (unused) functionalities and a touch screen.
- Both devices are expensive and require special, single-use dressing kits that are costly too.
- The current NPWT systems are leased by the hospital and lots of service is included, such as advice on use and replacement in case the device has a problem.
- NPWT has more use when the wound is deeper, it is not that useful when a wound is already at skin level
- The wound dressing is made to measure by hand, which requires a good eye.
- At difficult wound locations, such as the buttocks region, which is curved and often moist, it is harder to apply a dressing and the risk of leakage is higher. The pressure level is always set to -125 mmHg, only in case of of pain or sensitive tissue (skin-graft) the suction strength is decreased
- A pressure exceeding -125mmHg is never used and intermittent pressure is never used
- Patients do complain about the noise of the ActiVAC, especially at night

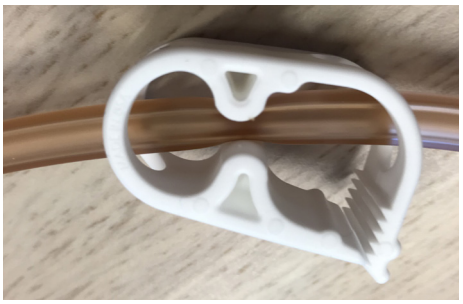
In conclusion, the visit and demonstration provided valuable insights on how NPWT systems are used in high-end hospitals and most assumptions that were made based on literature, were confirmed.


a) ActiVAC for therapy at home



b) Adhesive film that is place on the wound area.

c) Two types of wound fillers and gauze



d) Close tube when disconnect dressing

e) sterile packed dressing kit

*Figure 16 a-e: Images of NPWT equipment that was demonstrated during the demonstration at the Erasmus MC.*

## KEY INSIGHTS 2.1

Research on the topic of 'Negative Pressure Wound Therapy' resulted in a general understanding of the treatment procedure and associated medical guidelines which apply in hospitals in high-income countries. Here is a recap of the key insights taken from this paragraph.

In hospitals in HICs:

- NPWT is widely used for the management of acute, chronic, post-surgical wounds
- The main benefits of NPWT are faster healing with fewer dressing changes and fewer surgical interventions, but it also improves patient safety and patient comfort.
- A NPWT-system consists of a vacuum device, a special wound dressing and a tube system.
- Treatment is applied in cycles of 3-5 days, in between cycles the wound is evaluated and the dressing is changed
- Relevant treatment variables to consider are Pressure level, pressure mode and suction capacity
- The most widely used pressure for NPWT is -125 mmHg (= 16.665 Pa)
- Important complications of NPWT to consider are bleeding, infection, and tissue damage
- The costs of standard NPWT are estimated approximately between 100-150 USD per patient per day.
- Equipment for NPWT is expensive, the price of a traditional NPWT-device is estimated around 7.500-20.000 USD per device and 30-60 USD per dressing kit.

## DESIGN CONSIDERATIONS

- To provide effective NPWT according to the general guidelines, there is a need for:
- A device that applies continuous pressure and removes wound exudate
- A device that applies -125 mmHg by default, since that is the most optimal pressure, but it should be A device that has a detachable container to store the wound fluids
- A sterile dressing that seals airtight.

# 2.2 NPWT systems

This paragraph answers the questions "What technology is behind a NPWT device? What products exist currently on the market? What are the rules and regulations for this product category?

## 2.2.1. General

A NPWT system (or VAC system) consists of a vacuum device (1) and a vacuum dressing (2) that are connected to each other with a drainage tube (3). Altogether, this is considered as a piece of pneumatic equipment that consists of components to affect the movement and control of air, such as pumps, tubes, valves, seals, fittings, etc. In these types of products, one important aspect to consider is air leakage, because it directly affects the functionality and efficiency of a pressurized system. Air leakage is also a recurring theme in this report. Dealing with air leakage is challenging because it is often hard to detect as the source of leakage is not directly visible.

The aim for this project is to design a minimal viable product, with basic functionalities. Therefore, going back to the core of the product, first defining the main function, main components, and minimal criteria for these components.

## 2.2.2. Technical analysis

A technical analysis was conducted, including rough calculations on the system parameters, these are explained in Appendix C: *Analysis of a NPWT system*. In this section, the working principle is only briefly explained to have a basic understanding of how a NPWT systems and what parameters are involved.

**Main function**
First, the main function of a NPWT system is defined as: "*Create and maintain a negative pressure of -125 mmHg at the sealed wound location for at least one treatment cycle (3-5 days).*"

A distinction can be made in functionality between the *device* and the *dressing*. The main function of the dressing is to provide a proper sealing that remains in place, while the device should contain a vacuum pump that creates vacuum and a system that controls the pressure within the system at the desired level.

**Negative pressure [p]**
The term negative pressure must be explained, because it is frequently used in this report. Negative pressure, in this context also referred to as *vacuum* or *vacuum pressure*, indicates a pressure level below the atmospheric pressure (101,325 Pa), which is why negative values are used. At times, this might be confusing when using the words 'lower' or 'higher' to describe a change in the (negative) pressure level. Therefore keep in mind that the term indicates a *relative pressure*.
Another thing that might be confusing is the fact that pressure is indicated in different units. In this report the following units are primarily used: The SI-unit Pascal (Pa), which is mostly used by technicians, and millimeter of mercury (mmHg), which is used in a medical context.

**Flow [Q]**
The term *fluid flow* or *flow rate* also reoccurs in this report. In general it indicates the movement of a fluid (liquid or gas) as a result of a force, expressed in volume per time unit. A negative pressure causes the fluid to move from the location, as a result of this force. The movement is always in the direction from higher pressure to towards lower pressure. A flow rate of the liquid is primarily indicated in cubic meters per second (m3/s) or litre per minute (L/m).

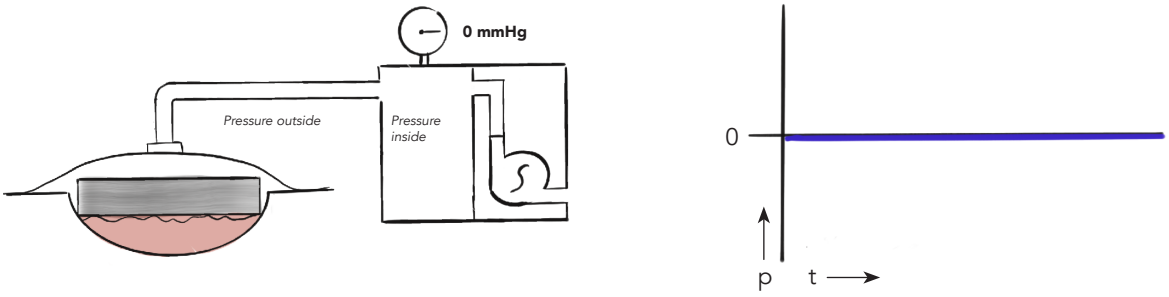
**The working principle of a NPWT system**
The working principle of a vacuum system is explained in figure 17.

**Conclusion**
From the technical analysis (Appendix C) it is concluded that to fulfill the main function, the pressure inside the NPWT system (P_system) should be controlled at -125 mmHg (-16.7 kPa).

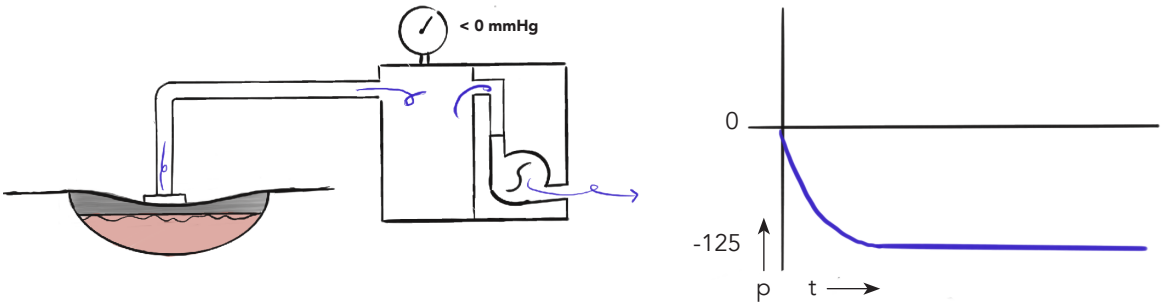
The system pressure is mainly influenced by the **pump characteristics** (Q_pump, P_pump), pump speed (v_pump) and the **quality of the dressing sealing** (Q_airleak).

*Figure 17: The working principal of a vacuum wound system is schematically explained in this simplified sketch.*

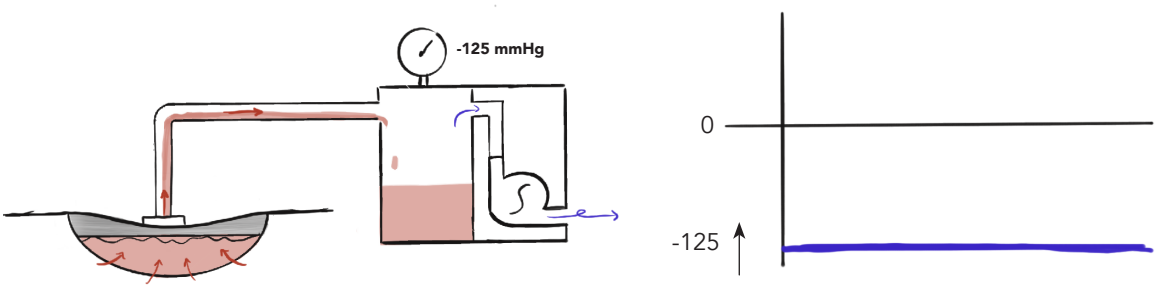
I: No pressure difference (device OFF)




II: Pressure is building (device ON)




II: Negative pressure of -125 mmHg is achieved and maintained




*Phase I:* The pump is not activated, pressure levels are equal, as a result the flow Q = 0

*Phase II:* The pump is activated, removing air from the system, resulting in a pressure difference. This creates a flow (Q_pump), causing a movement of wound fluids (Q_wound) from the wound to towards the canister (lower pressure).

Phase II: Because the dressing does not seal 100%, an air flow is created into the system (Q_airleak), which limits the increase of the relative pressure. To maintain a pressure difference of -125 mmHg, Q_pump >> Q_airleak + Q_wound.

In case the pressur is too strong, the air flow can be increased with a relief valve: Q_pump = Q_airleak + Q_wound (- Q_valve)

In case the pressure is too weak, the air leak must be reduced, or the pump speed (Q_pump) must be increased.

### 2.2.3.Market analysis

Analysis of the NPWT devices market provided several insights. First, it revealed that the global market is currently dominated by western companies. One thing that is particularly interesting, is that the NPWT device market has been dominated for ten years by one single company. The american company KCI (part of Aceility Inc.), which was recently acquired by 3M (3M Completes Acquisition of Acelity, Inc., n.d.) sponsored the first studies on vacuum wound therapy in 1997.

KCI immediately patented this technology and became the sole manufacturer of NPWT devices. For ten years, their traditional V.A.C.® System was the only NPWT system on the market. Only recently, the patent was lifted, and other companies were able to finally enter the market. This change is visualised in figure 18 and 19.

As a result, in the past decade, the market has become more diverse and nowadays includes a larger variety of products. The top 10 companies of NPWT devices are listed below. Note that all these companies are based in the USA and Europe.

**Traditional NPWT:** Traditional NPWT systems include a canister for fluid collection from the wound. The pressure applied is adjustable, with continuous and intermittent modes of operation possible. Often powered by a main electricity source, traditional NPWT devices are mostly used for inpatients but can also be adjusted for the use in outpatient care. Moreover, traditional NPWT can be adapted and used with a wound cleanser (NPWT installation). *Example:* **KCI VeraFlo**

**Single use NPWT: (sNPWT)**; or pocket, cannister-free, mechanically powered, disposable, portable): Some sNPWT devices are canister-free and handle fluid mainly through evaporation from the outer layer of the dressing. Mainly suitable for low to moderate exudate levels. The pressure is applied continuously and is not usually adjustable. sNPWT devices are often battery powered, and tend to be used in outpatient care, although more research is required. *Example:* **PICO (Smith & Nephew)**

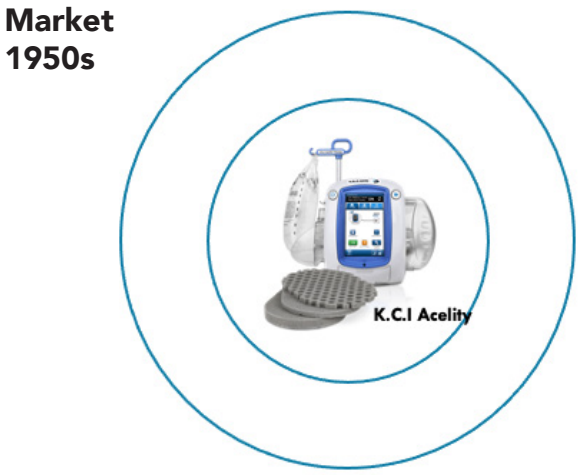



*Figure 18: The market offer in the 1950s, when K.C.I was the sole manufacturer of NPWT devices.*


*Figure 19: The current market offer (2020) contains a wider product variation.*

### Key market players

- KCI-3M (**US)** - *VeraFlo, ActiVAC, Nanova, Snap*
- Smith & Nephew **(UK)** - *Pico, Renysus*
- Mölnlycke Healthcare AB **(Sweden**) - *Avance Solo*
- ConvaTec Group Plc **(UK)** - *Avelle*
- Cardinal Health **(US)** - *Catalyst, Ally*
- Paul Hartmann AG **(Germany)** - *Vivano*
- DeRoyal **(US)** - *Prospera pro*
- Lohmann & Rauscher International GmbH & Co KG. **(Germany)** - *Suprasorb*
- Medela LLC **(Switzerland)** - *Invia liberty*
- Genadyne Biotechnologies, Inc. **(US)** - *XLR8*

**Trends**
Secondly, several market trends were discovered.

Four trends that will influence the NPWT device market and associated innovations in the nearby future and therefore worth mentioning, are:

1. The demand for NPWT is increasing worldwide and the market is expected to grow significantly (6.1%) in the next five years.
2. Companies from emerging economies (India, Japan and China) are expected to enter the market in the nearby future.
3. The global interest is shifting from traditional NPWT devices towards portable NPWT systems that are suitable for home care.
4. The demand for disposable NPWT systems (dNPWT/sNPWT) is increasing.

**Global market**
Finally, the NPWT devices market is completely western-oriented, and the current products are hardly available in LMIC. As shown in figure 20, North America accounts for the largest share of the NPWT devices market, while the market share of Asia, Middle East and Africa is significantly smaller. (Negative Pressure Wound Therapy Market - Global Forecast to 2025 | MarketsandMarkets, n.d.). To illustrate this, it turns out that the products of KCI-3M and Smith & Nephew) cannot be purchased in Nepal.

**Existing products**
NPWT systems can be divided into traditional and single NPWT systems (also referred to as sNPWT or dNPWT), which is explained on the previous page. To find more prominent examples of NPWT devices that are currently on the market, see Appendix D: *Benchmark.*

**Why are current products not suitable for use in LMICs?**

It was concluded that the NPWT systems that are currently on the market are not suitable for low-resource settings, because these products:

- Are either expensive (>10.000 USD) or meant for single use
- Rely on specific dressings
- Require additional service
- Are poorly available in some parts of the world, because they are shipped from the US or Europe
- Use advanced technology and therefore require technical support
- Are complex to use and therefore require a certain level of intelligence and/or training
- Unreliable or unsupported (in case of replicas from alibaba.com)

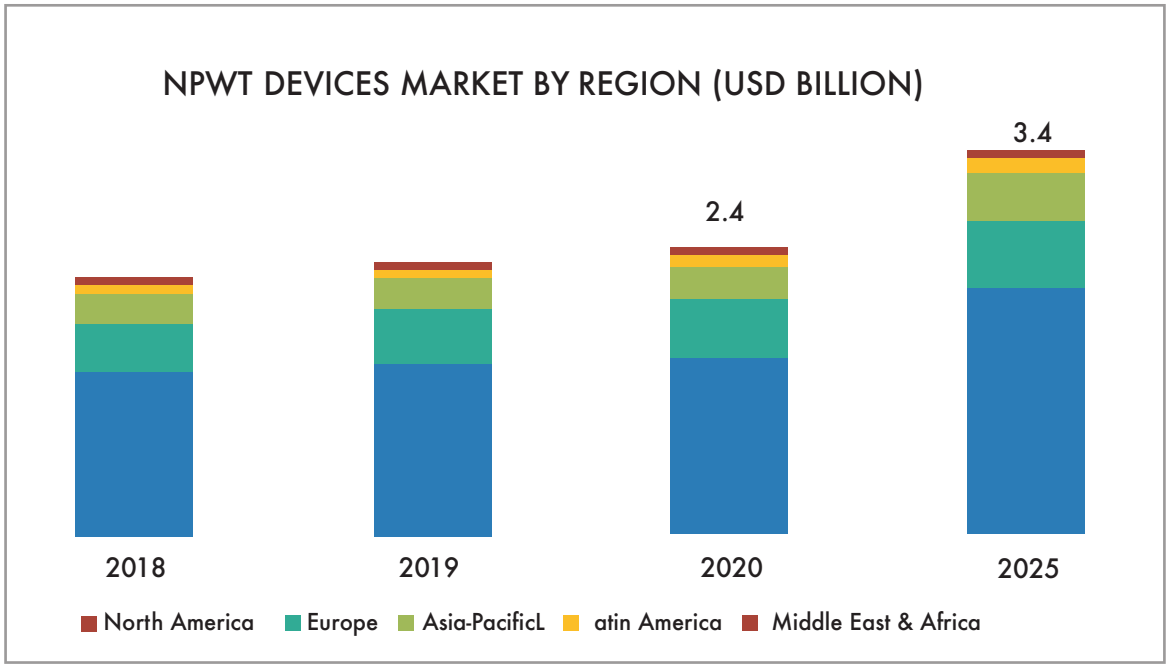



*Figure 20: A graphical presentation of the value of the global market of NPWT devices from 2018 and with respect to predictions for 2025, divided per geographical region.*

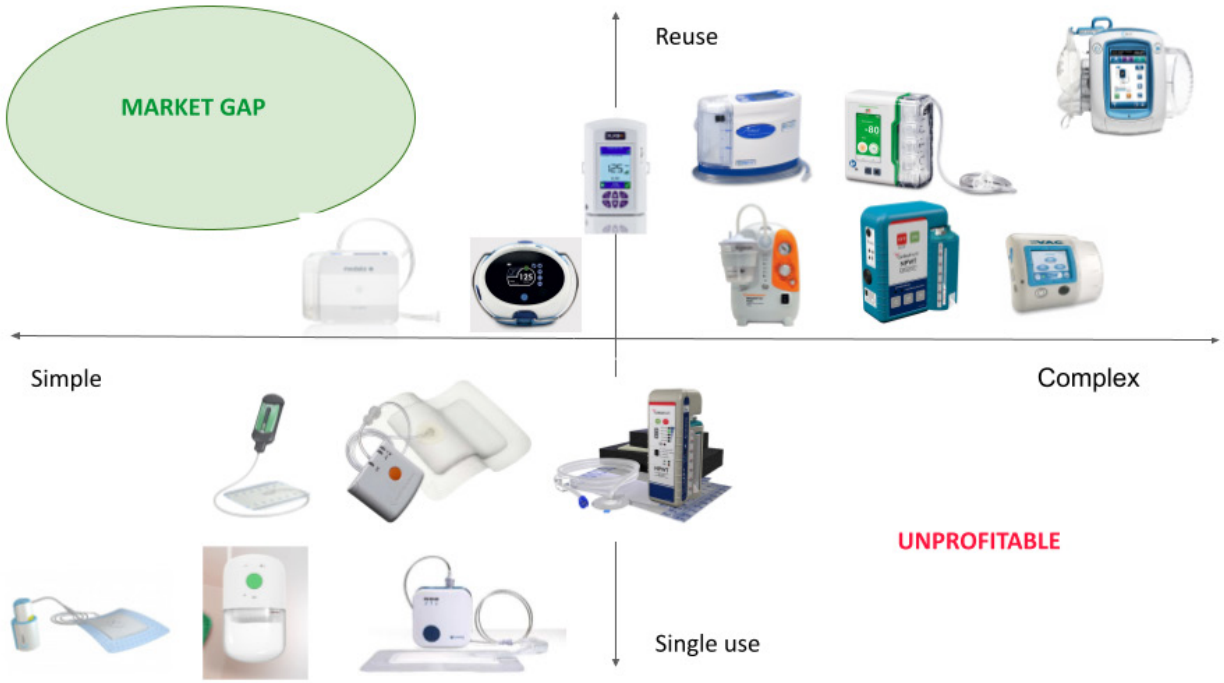



*Figure 21: Result of the Benchmark analysis (Appendix D) clearly indicates a gap in the current market offer.*

**Market gap**
A small benchmark analysis was conducted to identify the competitors on the NPWT market and to explore the market opportunities for the envisioned product (see Appendix X). Figure X shows the ranking of the analysed NPWT systems. The figure shows that simple products that are easy to use are meant for single use only, while products that are reused tend to be complex, in terms of technology and user settings. In addition, all presented products are meant to be used with wound dressings from the same brand that are usually quite expensive (30-50 USD per dressing kit). It suggests that dressing sales generate a revenue that is part of the business model of these companies.

**Conclusion:** A market gap exists for simple, reusable devices that are compatible with affordable wound dressings.

## 2.2.4. Rules and regulations

When determining the design requirement, it is important to consider the safety requirements, since the risks related to the design of the product can affect the patient's safety. Although safety standards may differ in low-resource settings, the low-cost NPWT device must comply with the same safety requirements as other NPWT-devices to get certified and be sold on the market. Therefore, this section includes information on classification and certification of a NPWT-device.

**Classification**
Before launching a medical device to the market, it must first qualify as a medical device. Medical devices are placed in four risk categories [28] . The product that is developed in this project is expected to classify as a class IIb medical device.

**Certification**
A medical device should comply with the rules that are followed in the country where it is used. In Europe, the device should have a CE-certificate, and to enter the global market (especially in the USA) it should also comply with the rules of the FDA. In most LMICs a CE-certification should be sufficient and therefore the focus is on the CE-mark in this project. To obtain a CE-certificate, the product must comply with the rules of the MDR (Medical Device Regulation). This includes a set of basic rules for medical devices and a set of product specific rules. In case of a NPWT device the rules are included in the ISO-10079 for electrically powered medical suction equipment [29]. These rules include the need for a risk analysis, risk evaluation and risk control of the final product as well as rules for cleaning and sterilisation [30]

**Clinical validation**
As part of the CE-certification process all NPWT devices must be validated through clinical trials with patients. During this trial the therapy must be applied according to the evidence-based guidelines and the instructions provided by the manufacturer. Therapy with the chosen NPWT devices is usually compared with treatment with conventional dressings or another NPWT device. To measure the healing effect of NPWT in clinical trials, these primary end points are commonly used [7]

- Time to complete healing
- Time to prepare for surgery
- Graft take/graft quality
- Number of infections
- Number of mortality / complications / adverse events (AE)

The most common method to monitor the healing progress is to frequently measure the size of the wound (area and depth) and determine the percentage of granulation tissue. The most convenient way to do this is taking pictures of the wound and analyse the number of pixels, using an editing program, such as Photoshop.

**Conclusion:** The NPWT should meet the requirements to be classified as class IIb medical device and have a CE-certificate.

**Every country has its own set of regulations (ISO = Europa, FDA = USA), the device has to comply to the rules of the country where it is used (not produced)**

ISO-10079

## KEY INSIGHTS 2.2

The technical aspects of a NPWT system are analysed as well as the current market and existing products. This resulted in the following insights.

**Technical aspects**

- The main function of a NPWT system is to create and regulate the system pressure of -125 mmHg and 100 mL/min (flow).
- The pressure level is influenced by the pump characteristics, resulting in certain boundaries and the amount of air leakage.
- The air leakage rate depends on the quality of the sealing of the dressing, which is highly variable and expected to range between 10-100 mL.
- Decreasing the air leakage (especially in the dressing) is beneficial because it improves the efficiency of the system and reduces the power consumption.

**Market aspects**

- A market gap exists for simple, reusable devices that are compatible with affordable wound dressings.

**Rules and regulations**

- NPWT systems are FDA class II devices
- To obtain the CE-mark this device should meet the ISO-10079 standards
- Clinical validation of the device is required to obtain the CE-mark

## DESIGN CONSIDERATIONS

To develop a functional NPWT system (i.e the minimal viable product), there is a need for:

- A device with a vacuum pump that matches the desired range of operation
- A device that can compensate for air leakage < 100 ml/hr
- A device that controls the system pressure, either passively or actively
- A dressing that provides adequate sealing (air leakage < 100 ml/hr)
- A device that can be cleaned and sterilised, according to the ISO-10079 standards

# 2.3 NPWT in low-resource settings

This section answer the following questions "Is NPWT also applied in low-resource settings? What are the differences in relation to clinical practice in high-resource settings (e.g. Erasmus MC)? What are the foreseen challenges and opportunities of providing NPWT in low-resource settings?"

### 2.3.1 Literature review

Review of literature on NPWT in low-resource settings led to several insights. In the first place, there is a significant lack of reliable data on wound care in developing countries and therefore little is known about the current situation and to what extent NPWT is used in these regions [31]. Secondly, it can be stated that regular NPWT systems are not affordable to resource-poor hospitals and in general poorly available in low-resource settings [2]. Hence, most publications on NPWT in LRS are initiated by local doctors or engineers who came up with alternative solutions and use locally available materials to build a NPWT system. Finally, because little information can be found in literature, interviews with people from the field provide valuable information on the use of NPWT in low-resource settings. Moreover, talking to local doctors revealed several differences between their clinical practice and, for instance, the observations performed in the Erasmus Medical Centre.

### 2.3.2 Low-cost NPWT vs. standard NPWT

The first notable difference between NPWT in low-resource settings and hospitals in high-income countries is the **equipment** that is used. Due to the absence of NPWT and wound dressings in LMICs, in some hospitals doctors use alternative, self-made systems to treat patients. These low-cost NPWT-systems usually consist of an improvised device in combination with a self-made dressing. To give an idea of what these solutions look like, these are explained below.

- **Self-made NPWT device**

NPWT devices require a vacuum pump to create a differential pressure, which can be either an electronic device or a mechanical (hand) pump. If the hospital has a centralised vacuum system, it is possible to use a wall-suction device. In this case, connecting a canister and some tubes to the suction outlet is all that is needed to build a NPWT system. Another option is to use an existing product, such as an aquarium pump, and convert it into a NPWT device. Finally, human-powered pumps, such as bicycle pumps or syringes can be used to build a NPWT device.

- **Self-made dressing**

Vacuum wound dressings were made from materials collected around the hospital, such as sponges, feeding tubes and adhesive film.

Secondly, it can be stated that in LRS treatment protocols are less strictly followed and more freedom is allowed in the **treatment approach.** The guidelines for NPWT that were mentioned before are less valued because improvisation is often required due to a lack of resources, such as reliable equipment, or overcrowding.

Finally, the **patients** that come to resource-poor hospitals are different compared to patients seen in high-end hospitals. Patients seen in hospitals in LMICs are often in worse shape when they arrive, because reaching medical care usually takes longer. For instance, wounds may be large and badly infected by the time the patient is brought in. Furthermore, the time that patients are able to spend in the hospital is often limited, due to the high financial burden of hospital admission. As a result, patients are leaving the hospital before the end of their treatment, with wounds that are not completely healed.

### 2.3.3. Evaluation of previous projects

In this research, a total of 10 case reports on low-cost NPWT were evaluated to investigate what has been tried before and what can be taken from it [22], [32]–[40].

Each study includes the use of a low-cost alternative to treat patients with vacuum wound therapy. Publications originate from various LMICs, including India, Nepal, Malaysia, and Rwanda. The review is included in Appendix E: *A review of studies on low-cost NPWT*, the main findings are presented here.

Most relevant learnings:

- Wall-suction (or other suction apparatus) is the easiest, most reliable, and affordable vacuum source for low-cost NPWT. Most resource-poor hospitals do not have wall-suction; therefore this option does not apply.
- Self-made dressings are less absorbent compared to standard NPWT dressings, moreover, providing an air-tight sealing that remains in place is challenging
- Non-powered systems that use a manual pump are significantly cheaper, but often report problems with air leakage. Powered systems do not seem to have this problem and are used for diverse wound types, including large and highly exuding wounds.
- Systems that operate on lower negative pressure also report positive patient outcomes, suggesting that maintaining the standard pressure of -125 mmHg is not crucial in this context and variations in pressure level are acceptable, if pressure level stays between -80 and -125 mmHg
- The most important complications to consider are excessive bleeding and wound infection, if safety features (e.g. built in sensors and alarms) are not in place, the patient needs constant monitoring.

With the low-cost solutions NPWT is made available and affordable. However, these self-made devices are not safe, nor reliable nor easy to use. Moreover, the low-cost devices lack standardization and therefore these solutions are not scalable. This confirms the need for a design of a low-cost device for NPWT in low-resource settings, which has the functionalities as described below.

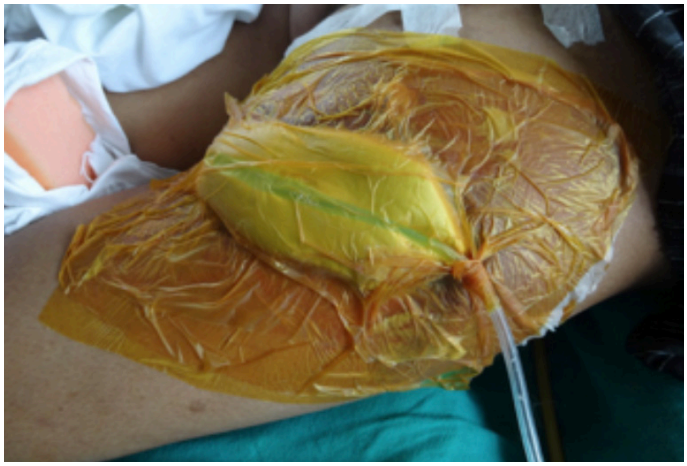


*Figure 22: Example of a self-made dressing from locally available materials (Green Pastures Hospital, Nepal)*

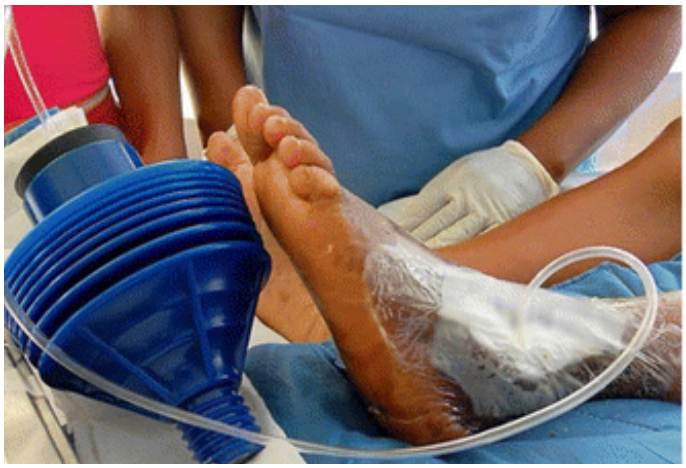


*Figure 23: WiCare Wound pump, a low-cost solution for vacuum wound therapy by Zurovcik et al.*

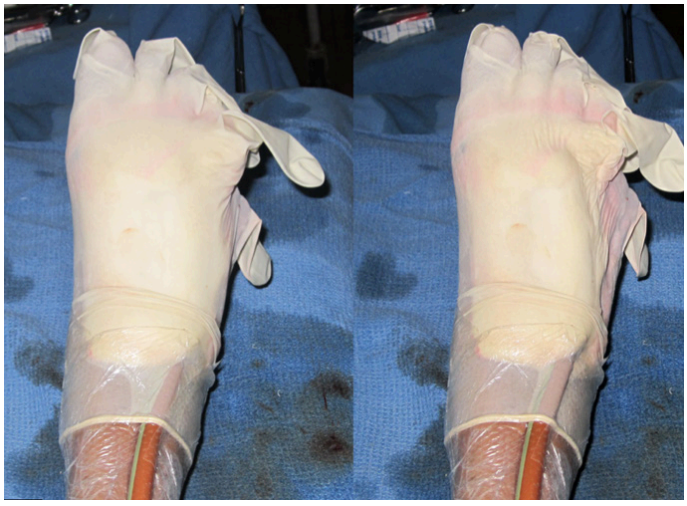


*Figure 24: Example of a cheap alternative for vacuum wound dressings, using sterile gloves by Sreelesh & L. Bhandari*

### 2.3.4. Challenges and opportunities

The greatest benefit of applying NPWT in LMICs is the fact that this therapy can effectively heal the wounds of severely injured patients. All reviewed publications reported positive patient outcomes which indicates a great opportunity to create impact at a far lower price. If low-cost NPWT can prevent amputations of limbs, this is a great opportunity to break the cycle of poverty and disability that was mentioned in the first chapter. Finally, NPWT is a proven technique that does not require complex technology and therefore considered a feasible solution for LRS.

Unfortunately, some factors are limiting the implementation of NPWT in LMICs; (1) poor availability and the high costs of NPWT devices and associated wound dressings, (2) lack of pre-made dressings because of unsteady supply of medical goods, (3) affordability of these dressings by the patients themselves, and (4) lack of maintenance service or skilled personnel [2].

In conclusion, there is a clear need for new low-cost solutions for NPWT that are affordable, safe and reliable. Furthermore, additional research is needed to quantify the global burden of chronic wounds and this research must include the low and middle-income countries as well.

## KEY INSIGHTS 2.3

A literature review of previous projects published on low-cost NPWT in similar countries prepared for what challenges to expect when designing a device for this specific context. Here is a recap of the key findings of this section.

In low-resource settings:

- The main barrier for providing NPWT in low-resource settings is the lack of (affordable) equipment
- Self-made NPWT-devices and dressings, made from local materials, are used to treat patients in regions where this equipment is not available.
- The studied examples of low-cost NPWT include electronic (powered) and mechanical (non-powered) solutions to create vacuum.
- Low-cost solutions lack reliability, safety, and ease of use.

## DESIGN CONSIDERATIONS

For the implementation of NPWT in low-resource settings, there is a need for:

- A simple and reliable device
- A device that is cheap and locally available
- A devices that is reusable
- A device that is compatible with a self-made dressing
- A device that operates independently and does not require additional services

# 2.4. Main findings // RESEARCH

The main findings of the research within Phase I of this project are described in the sections below.

### 2.1 Negative Pressure Wound Therapy

Negative Pressure Wound Therapy or Vacuum-assisted Closure therapy is a type of treatment that uses controlled negative pressure to stimulate wound healing. The most important characteristics are summarised:

#### Effect on healing
The primary function of this NPWT system is to stimulate wound healing resulting in faster and better wound closure, compared to the outcomes of regular wound treatment. For now, it is assumed that a positive effect on healing is achieved when the device meets the functional requirements. Finally, it will be necessary to validate these clinical outcomes through a clinical trial in order to get the device certified and launched to the market.

#### Applicability
To help as many patients as possible, it is desirable to maximise the range of applications for the envisioned NPWT device. Wounds currently treated with VAC include chronic wounds, such as pressure ulcers and leg ulcers, and also larger traumatic injuries. Therefore, the device must be compatible with self-made dressings that can be adjusted to all wound sized and wound locations. In addition, the pump capacity should be sufficient for large and highly exuding wounds.

#### Safety
The AquaVAC and other self-made devices lack safety and reliability, leading to unsafe situations and complications that may seriously harm the patient. Three complications that are known to frequently occur, include

- Bleeding / haemorrhage; If suction is applied on bleeding tissue or vessels, this may cause excessive blood loss and lead to exsanguination.
- Infection; If microorganisms are growing under the vacuum dressing, which is left without changing for several days, the wound can get infected. If the infection is unnoticed, it can spread into a deeper infection and even to a sepsis (life threatening, systemic infection).
- Loss of negative pressure; If an air leak occurs, the vacuum gets lost. The exudate is no longer removed and the dressing gets too moist, which inhibits the wound healing process and increases the risk of infection. If the pressure is not restored soon (<120 min) the dressing is wasted.

The aim is to integrate adequate safety features and warning systems to minimise these risks and guarantee safe use of the device. Additionally, the NPWT device has to meet the safety ISO-10079 criteria to obtain a CE mark.

### 2.2 NPWT systems

The parameters to take into account when designing a NPWT system are described in the next paragraphs.

#### Pressure
The optimum and most used pressure for NPWT is -125 mmHg, fluctuations within the effective range (-75 and -125 mmHg) are acceptable because treatment will still be effective. Reduced pressure (-80 mmHg) is used at times for painful or sensitive wounds. Pressure should not exceed -200 mmHg, because this may cause tissue damage.

#### Air flow
To create a vacuum, the wound dressing should be sealed air tight. In reality ,a perfect sealing of the wound dressing is not possible, due to irregularities of the skin. Air leakage must be minimised to increase efficiency and reduce energy consumption, however, a certain amount of leakage (10-100 mL/min) should be taken into account when designing the pump system..

#### Fluid flow
To effectively stimulate wound healing, the NPWT system should continuously remove exudate from the wound bed. The fluid flow rate caused by the differential pressure should be sufficient to remove the fluids of low to high exuding wounds, with a maximum of 0.2 ml/min (300 ml/day).

#### Fluid collection
Wound fluids that are removed from the wound need to be either absorbed into the dressing or collected in a sealed container. Large or highly exuding wounds need a canister of at least 300 mL. Because fluids contain infectious materials, the canister should be non-leaking and detachable. A (sudden) change in colour or fluid flow rate are indicators for a complication. Safety considerations

include the use of a smaller canister (<500 mL) to prevent large blood loss and overflow protection.

### 2.3 NPWT in low-resource settings

The most important findings based on the analysis of the NPWT in low-resource settings are summarised below.

#### Availability

All established firms for NPWT systems are based in the USA or Europe, and their products are hardly sold in Nepal and other LMICs. The unavailability of equipment is one of the barriers to provide adequate wound care in the developing world. The solution is to design a product that is made of standard components and materials that are widely available, while maintaining quality. Moreover, due to a poor infrastructure, it should be possible to manufacture and assemble the product in the country of use.

#### Costs

In most LMICs decisions are based on costs and long-term investments are difficult due to a lack of financial resources. The investment costs for NPWT are high, due to the expensive equipment. Premade wound dressings are not suitable for this context, due to high price, poor infrastructure and lack of reimbursement system (consumables are paid out-of-pocket by patients). Instead, the new device should be compatible with the cheap, self-made dressings from local materials (<1 USD/ dressing). It is estimated that healthcare facilities in LRS are likely to consider buying a NPWT device, only if the selling price is <300 USD. In case the price is higher, it might not be affordable for these customers.

#### Maintenance and repair

Maintenance and repair is essential to ensure a long product lifespan, but may not have the highest priority in low-resource settings. The device should therefore be made out of sturdy components that do not require a high level of maintenance. The aim is to enable repair of the device in-house, at the technical department of healthcare facility, using basic skills and tools. Components should be widely available online or within a radius of 100km.

#### Lifespan

If the lifespan of the product is long, a higher price is paid for the product. Easy maintenance and repair will contribute to longer lifespan. If the product costs 300 USD, a lifespan of 3-5 years is acceptable and 500 USD if it survives 5-10 years.

CHAPTER 3

# CONTEXT

In this chapter the context is analyzed on three contextual levels: country, hospital and ward. All the findings described in this chapter are based on expert interviews, video observations and literature research. On a country level, a general view on the country is given and considerations for the design of a medical device in such a country are explained.

In paragraph 3.2 elaborates on the current situation and the origin of the Green Pastures Hospital. The description of the ward at the Green Pastures Hospital provides context on the environment in which the envisioned product will be used. In paragraph 3.4 the most important stakeholders are introduced and paragraph 3.5 gives insight into the patient journey when using the NPWT system used in the Green Pastures Hospital: AquaVAC. The patient journey is used to identify pains and opportunities related to the interaction with the equipment. This helps formulate design requirements. The chapter concludes with main findings which are taken from the context analysis into the design of WOCA.

In this chapter

# 3.1 Nepal

The context in low-and-middle income countries in which medical equipment is used, differs from high income countries, especially in terms of financial resources and access to maintenance, spare parts, and consumables [5]. The research focuses on the low-middle income country of Nepal. In the following paragraphs certain aspects of the country are described in relation to the requirements of a NPWT device. The aspects that are discussed are: the economy, healthcare, culture, education level, infrastructure, industry, and government.

### 3.1.1 Economy

Nepal is a low-middle income country with a GNI of 4060 USD and a low ranking of 142/189 in the Human Development index. Currently, 17.5% of the population lives in poverty [41].

Nepal is also a popular destination for tourism that concentrates around the national parks and the cities Kathmandu and Pokhara. Although tourism contributes to the economy, most Nepali live from agriculture. Around 80% of the population lives in rural areas, where poverty rates are especially high, and resources are limited.

Nepal made huge improvements in the past decades, significantly reducing the poverty rate. However, the economy remains unstable, and part of this economical vulnerability is the fact that Nepal is one of the most disaster-prone countries in the world. Earthquakes, landslides, fires and floods, etc. are occurring threats that result in the loss of lives and properties, damage to the infrastructure and disruption of economic development.  In 2020, Nepal was affected by the pandemic of COVID-19. As a result, economic activity was disrupted, especially tourism.

### 3.1.2 Healthcare

Analysis of the healthcare system in Nepal revealed various shortages; First, the system is highly underdeveloped and public hospitals only exist since the 1950s. Still, the current number of healthcare facilities does not fit the size of the population. Moreover, the quality of public care is poor and fails to meet international standards, illustrated by the fact that wealthier citizens tend to go to private clinics. Secondly, there is no reimbursement system in place, which means expenses for public care are paid out-of-pocket by patients. Public care is not affordable for the poor and marginalised, hence, this population relies primarily on the support of NGOs and missionary hospitals. A third problem is the poor accessibility of care. Because the current healthcare facilities are concentrated in the larger cities, people in rural areas have no access to care or must travel long distances to find treatment [42]

- In Nepal, the medical staff is not used to medical technology and therefore medical products need to be simple, intuitive and easy to use
- Advanced treatment (such as NPWT) is not part of common medical practice, expect a lack of knowledge and experience in this area
- No reimbursement, so consumables must be cheap
- Underdevelopment healthcare system that lacks infrastructure and organization

### 3.1.3 Culture

Nepal is a multicultural and multi ethnic society and due to their traditional beliefs, some Nepali perceive illness and disabilities as a punishment for bad behavior in the current or previous life, (bad karma). Stigmatization and shame are important barriers for organizations to provide adequate care to people in Nepal. The study by Knulst et al. (2019) showed that Nepali often fear or do not trust medical practice, which can be attributed to a combination of stigma and a lack of education [4]. It is known that a great deal of the population still prefers to go to a traditional healer.

- Due to traditional beliefs and a lack of education, there is distrust among patients towards medical practice
- People are not familiar with (medical) technology
- It is important to build trust before introducing a new type of treatment and/or piece of equipment
- Stigmatizing of people with disease and disability

### 3.1.4 Education

Most citizens of Nepal have a basic level of education, as 97% of the population went to primary school and the adult literacy is around 67.9%. [43]. A language barrier exists, because Nepalese is only spoken by 40% of the population and very few people know English (<0.01%). Especially in the rural areas, people speak in local dialects [43]

- English should not be the guiding language for instructions and manuals, instead, use images for clarification
- Instructions to patients must be simple and direct, using universal signs to communicate a message.

### 3.1.5 Infrastructure

Transporting goods in Nepal is considered slow and expensive. Due to the mountainous terrain and poor road conditions, it takes relatively long to cover small distances on the map. Besides, traveling by car is considered dangerous in some areas, due to the high rate of traffic accidents. Aviation is a safer alternative, but more expensive. As a result, delivery prices in Nepal are high and delivery times are unreliable. As a result, there is a lack of steady supply of medical goods, especially in the rural areas. Electricity is widely available, except for some of rural communities that lack a reliable power supply. Only 37,7% of the population has access to the Internet (World Bank Open Data | Data, n.d.).

- Transportation of goods is slow and expensive
- Packaging should protect the product during transport
- Ordering goods (materials, spare parts) should be planned well ahead
- Electricity might not always be available in rural communities
- Digital communication is not common, less than 40% has access to internet

### 3.1.6 Industry

The industry of Nepal can be defined as 'low-tech' and mainly consists of the processing of agricultural goods. Most products are imported from neighbors India and China, as both countries have a large industrial capacity. The few factories that exist in Nepal are concentrated in the urban areas, mostly in Kathmandu. Here, basic manufacturing is available, such as metal and wood working (Industry - Nepal - Growth, Sector, n.d.) Outside of the cities people rely on local workshops for the production and repair of products.

- Consider only basic manufacturing techniques for production
- Order components online (from China and India) and keep spare parts in reserve
- Lack of industrialization

### 3.1.7 Government

Nepal is a parliamentary republic with a multi-party system. For years, there has been political instability, which does contribute to the lack of business investment. The national government is known for its bureaucracy and slow, inefficient procedures. Applying for permits or visas can be a time-consuming process. Corruption is another issue and leads to unfair distribution of resources in the country perpetuating the issue of poverty in Nepal [44] . Lastly, Nepal relies on external aid as many services are provided by foreign institutions (NGO's).

- As a (starting) company, be aware of the existing problems of bureaucracy and corruption
- Consider extra time for procedures that involve collaboration with these authorities.
- Project financing is usually obtained through international organizations

**Key factors: What contextual factors are typical for Nepal, in comparison with other LMICs?**

- Underdevelopment healthcare system that lacks infrastructure and organisation
- Stigmatising of people with disease and disability
- Problem of difficult road transport
- Lack of industrialization
- Lack of business investment due to political instability, bureaucracy and corruption.

# 3.2 Green Pastures Hospital

The first batch of the low-cost NPWT devices will be used in Green Pastures Hospital, located in Pokhara (Nepal) and in two smaller clinics, located in Banke and Surkhet [45].

**Green Pastures Hospital (GPH)** was founded by the non-profit governmental organisation **INF** (International Nepal Fellowship) in 1957. It was originally founded as a missionary hospital for leprosy to serve the poor and marginalised who had no access to care at the time. GPH is a medium-sized hospital with approximately 100 beds that serves around 11.000 patients per year. The clinics in Banke and Surket have around 25 beds each [46]

**Type of care**
The type of care that is provided at GPH is diverse. Originally, the hospital specialised in dermatology and skin diseases, therefore their experience with wound care is quite extensive. Over time, specialties have been added including physiotherapy, general disability, occupational therapy, orthopaedics, cerebral palsy, spinal cord injury and palliative care. GPH became a qualified centre for rehabilitation and disability. The facility includes a workshop, where adaptive prostheses and wheelchairs are made (see figure 29). Recently another building for palliative and chronic care was added. Furthermore, GPH organised the Ear clinics in local communities as part of their medical outreach program.

**Facility and staff**
The facility is built on a spacious compound, surrounded by a garden where patients can go around and do their rehabilitation exercises (figure 28). The staff of GPH consists of medical, nursing, paramedical, administrative, and technical staff members. The saff is a mixture of volunteers and paid employees, from Nepal and abroad. This enables a rich transfer of knowledge and skills, but also causes inconsistency due to a high employee turnover.

**Organisation**
GPH and the two smaller clinics in Surkhet and Banke are owned by INF, a christian, non-government organisation that has an international board and more offices around the world. The hospital superintendent is the executive director of GPH, i.e. the one in charge and responsible for the management of the hospital. This person works in collaboration with the central office in Pokhara, under the supervision of the INF board. Within the hospital, each department has a chief who is in charge.

**Finances**
The hospital income is generated mostly by funding and partly through local income from farm sales, pharmacy sales and patient fees. A great deal of the hospital budget relies on overseas sponsors and donations. Patients that are able to afford it, pay a small fee that is used to cover the expenses for consumables. Large projects, such as the construction of the rehabilitation center (figure 27), require a special request for investment by sponsors.

**Equipment**
The medical equipment of the hospital is managed by the technical department. This equipment is purchased by the hospital management, often on request of the medical staff. Some of the devices are donated, brought along by expat doctors. Sometimes the western products are not compatible with other machines, which requires creative solutions. Finally, part of the equipment is home-made by the technical staff, using what is locally available. As a result, the consistency and quality of the equipment varies. If a piece of equipment breaks down, it is sent to the technical department for repair. It can be stated that incidental repairs are their main activity, while preventive maintenance of medical equipment is not too common.

**!! Trigger warning !!**
The following pages include images of wounds that might be disturbing, go to 3.4: *Stakeholders* to skip this part.

*Figure 24: Entrance of Green Pastures Hospital, Pokhara*

*Figure 25: The compound of GPH*

*Figure 26: Portrait of a patient resting in the ward of GPH*

*Figure 28: Child with a prosthetic leg in exercising in the garden of GPH*

*Figure 27: Patients of the rehabilitation center at GPH*

*Figure 28: Patient hanging out at the compound of GPH*

*Figure 29: Local workshop at GPH where customized wheelchairs and prostheses are made.*

# 3.3 NPWT at Green Pastures Hospital

This paragraph provides information on the environment in which the envisioned product will be used. The primary source for this information are interviews and footage provided by one of the local doctors (Suraj Maharjan) who is a plastic surgeon at GPH.

### 3.3.1 Wound treatment

At GPH, vacuum wound therapy is currently used to treat patients with acute, chronic and post-surgical wounds. Patients that receive this treatment are located in the leprosy ward, the spinal cord ward, the general ward, the skin clinic and orthopedic department.
Wounds that require vacuum therapy include pressure ulcers, diabetic foot ulcers, traumatic injuries, open fractures and burns. Patients that had an amputation or suffer from a spinal cord injury are likely to develop non-healing wounds, due to the use of prostheses or wheelchairs in combination with a loss of sensation or paralysis. At GPH, vacuum therapy is frequently used for deeper wounds and followed by a skin graft placement.

To provide vacuum therapy, the local surgeon uses various devices, depending on what is available and suitable for the specific type of wound. Figure x shows the NanovaTM in use. The Nanova and PICO are single-use, canisterless NPWT systems that the hospital occasionally receives through donation. At GPH these devices are reused and used for smaller wounds, such as leg ulcers (see figure x). To seal the wound, Suraj uses pre-made dressing pads and if these are not available, he makes a dressing out of local materials (figure 32). The tube end is made from a piece of perforated feeding tube. Wound filler is made from a sponge that is soaked in saline and dried to sterilize before placing it inside the wound (figure 33).

### 3.3.1. AquaVAC

This device was introduced before as the starting point of this project. It consists of an aquarium pump that is converted into a suction device. The pump was brought in from the USA and remade into a NPWT device in the local workshop. A manometer and relief valve are added to check and regulate the pressure and a suction inlet is attached to connect the tube system to the pump. The AquaVAC works on grid power and cannot be moved from the patient's bedside, without using an extension cord. A separate canister to collect wound fluids is placed next to the device and connected with tubes. The AquaVAC is primarily used for larger wounds with high levels of exudate and patients are treated successfully. Figure 36 shows a paralyzed patient that is treated with the AquaVAC, which is placed on the ground.

Problems that have been experienced by the staff include:

- If the pump itself breaks down, it cannot be replaced (not available in Nepal) nor repaired
- The system is not portable, patients are bound to their beds
- It makes noise that disturbs the patients in the ward
- The pump works on 110 V and needs a converter

### 3.3.2. Patient ward

Patients treated at GPH stay on average for 35-40 days. Spinal cord patients may even stay for 3-6 months, because their recovery usually takes time. In this time, patients receive the wound treatment together with other therapies and exercise to support their rehabilitation.

Patients stay the night in the ward that has space for 6 beds. This room is spacious and has a shared sanitary room. There is running water and electricity and without heating or AC, temperatures vary between 15-25 degrees (see figure 36). Nurses make their rounds to check on the patients twice a day. The patient is always accompanied by a caregiver (a relative) that provides food and assists in their basic needs. Suraj is currently the only doctor at GPH who has the knowledge and experience to treat patients with vacuum therapy. He is teaching nurses how to change the dressing independently. It can be concluded that apart from appropriate equipment, there is also a need for training on the topic of NPWT for the medical staff at Green Pastures Hospital.

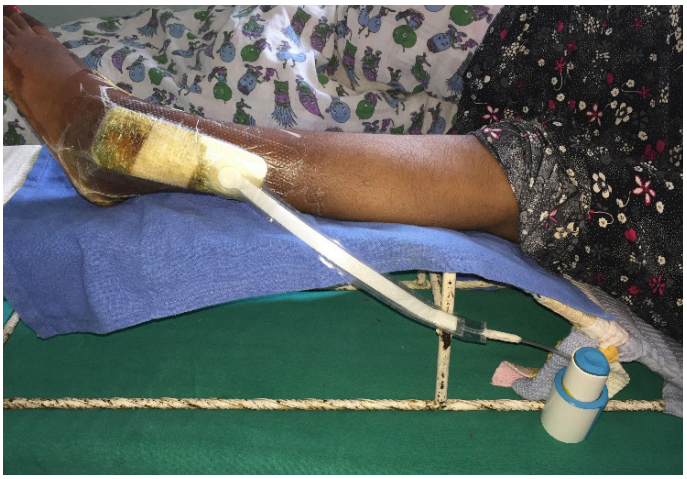


*Figure 30: The Nanova is a non-powered NPWT device that is meant for single use, but reused at GPH to treat patients.*

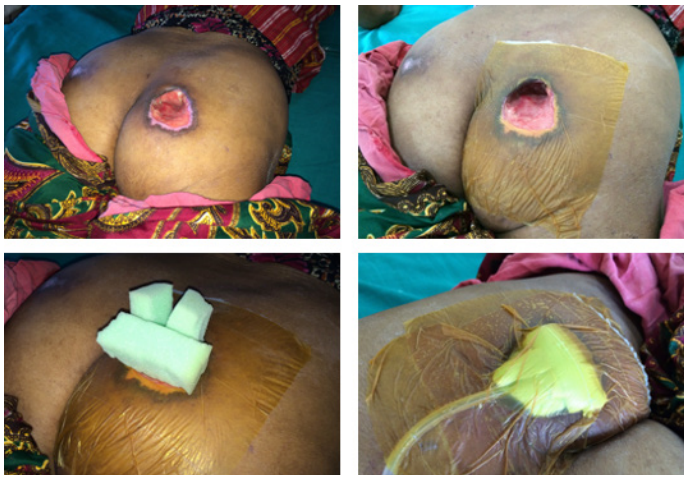


*Figure 31: Example of a patient that was treated with the AquaVAC and the progress is clearly visible*

*Figure 32: Self-made dressing applied the foot, which is a difficult location for VAC therapy*


*Figure 33: Materials used to make a vacuum dressing at GPH*

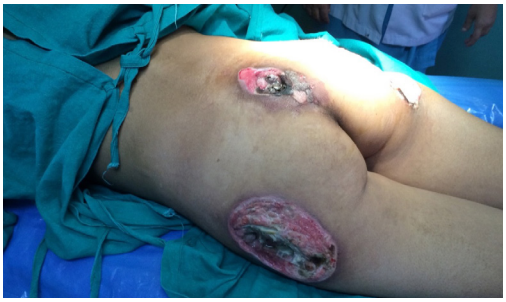


*Figure 34: To show how bad wounds can get in this context*

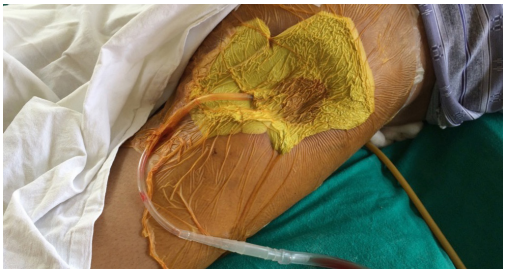


*Figure 35: This self-made dressing provides sufficient sealing to build pressure in the NPWT system*

*Figure 36: Patient room at GPH. The patient is treated with the AquaVAC (on the ground) and also connected to a catheter, due to his paralysis. Apart from the nurse and assistant nurse, a personal caregiver is also present. This is a common thing in hospitals in Nepal.*

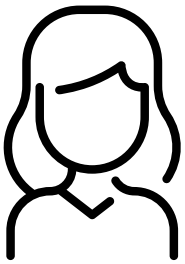
# 3.4 Stakeholders

A stakeholder analysis is performed for the Green Pastures Hospital case and can be found in appendix B: *Stakeholder analysis*. The results of the analysis are included in the context description. The most important stakeholders that should be focused on during the product design are the users, elaborated on in the next section.

### 3.4.1. Users

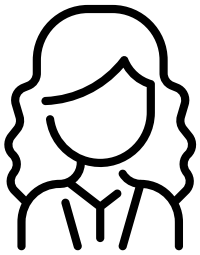
A description of the users is required to obtain a complete picture of the context. The users of the NPWT system can be divided into direct users and indirect users. This paragraph includes the general responsibilities, motivations, worries and needs of each user group.

**Patient**
Most patients at GPH are Nepalese, have a low economic status and live far away in towns or rural communities. Patients are suffering from non-healing wounds and often have mobility problems using prostheses, wheelchairs, crutches to move around. They may be sick and in a lot of pain. Some patients speak Nepalese, others only speak in local dialect. Most patients are not familiar with technology nor used to receiving medical care when they arrive. Patients tend to stay for a fews weeks or months and the hospital becomes their home for a while. Many patients are breadwinners for their families, and without a social support system, their hospital admission also financially affects the people at home.



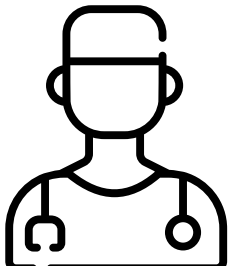
NEED: Affordable care
NEED: Fast recovery, go home, resume work
WISH: Sleep without disturbance
WISH: Move around freely

**Caregiver**
In Nepal it is required that someone accompanies the patient during the entire stay inside the hospital. This person is usually a close relative from their hometown. The caregiver is responsible to take care of the patient, to provide food and assist in tasks, such as monitoring the patient during vacuum treatment.



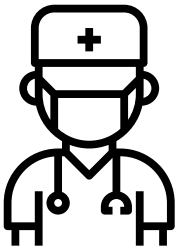
NEED: Fast recovery for the patient
WISH: Easy tasks and clear instructions on how to assist during treatment

**Doctor**
The doctor is a specialist, either Nepelse or expat, with a medical degree. The doctor treats patients daily and has a few years of working experience, and he/she might understand English. This doctor has experience with NPWT and has the responsibility to guide and supervise the nurses in his department. The doctor's goal and responsibility are to help patients and provide the best treatment possible, while avoiding any complications that may harm the patient.



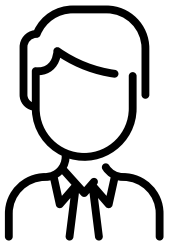
NEED: Safe treatment to avoid complications
NEED: Adequate equipment that works
NEED: Adequate supply of consumables
WISH: Equipment that saves time or reduces the workload

**Nurse**
The nurse is either Nepalese or expat and is either paid or works as a volunteer. The nurse works closely together with the doctor and usually assists during treatment interventions. He or she is educated but has little experience with NPWT. Responsibilities include monitoring the patient, which means checking in on every patient at least twice a day.



WISH: Easy monitoring of (a group of) patients
WISH: Reduced workload and more time for each patient

**BMET (Engineer)**
The technical department is managed by a technician that is defined here as the biomedical engineer technician (BMET). He or she has a degree in engineering and a drive to implement new innovations. Usually the BMET speaks English and has knowledge about medical devices. Responsibilities include the repair and maintenance of hospital equipment and the management of the inventory of the medical machines. He or she guides and supervises the technical assistant.



NEED: Equipment that can be repaired with available tools and components
WISH: Equipment with a low level of maintenance

**Technical assistant**
The technical assistant is usually a Nepalese handyman, someone that has basic skills but little experience with medical equipment and may not speak English. Responsibilities mainly include the execution of maintenance tasks and small repairs around the hospital, according to instructions.

NEED: Equipment that requires only basic knowledge and skills to repair
WISH: Equipment that is easy to disassemble

**Conclusion:** It is the priority of the medical staff to provide safe and good quality treatment. Patients need to receive treatment that is effective and affordable. The technical staff needs to repair the device with the tools and skills that are available at the hospital.

# 3.5 Patient journey

As part of the context analysis, research on the user interaction was performed. The method that was used is described as Patient Journey analysis (Delft Design guide). Information is collected through interviews and videos provided by the local staff of Green Pastures Hospital. The goal of this analysis is to get an insight into the workflow of the medical staff and identify pains and opportunities related to the use of the current VAC system to design a product that meets the needs of the direct users.

The compressed version of the patient journey is represented on the next two pages. This visual describes a typical journey of a patient with non-healing wound(s) that is treated at GPH with NPWT using the AquaVAC system. Appendix F: *Patient Journey Analysis* contains the full journey and includes more details.

### 3.5.1. Hospitalization

Considering the entire healing process, the patient journey initiates at incidence of the first injury and ends when the wound is fully healed. With regard to the location of treatment, the healing process can be divided in three phases; (1) before arrival, (2) hospitalization and (3) after discharge. The hospitalization phase is the relevant phase for this project because the envisioned device will be used for inpatient care.

Figure x represents the period of hospitalization in which the patient undergoes treatment with the AquaVAC. The treatment is divided into steps, according to the treatment procedure, which is quite similar to what was explained before, in Chapter 2: *Research.*

The treatment steps shown in this figure are repeated for each cycle of 3-5 days. At the end of each cycle the wound is assessed again and if NPWT is continued, a new dressing is applied.

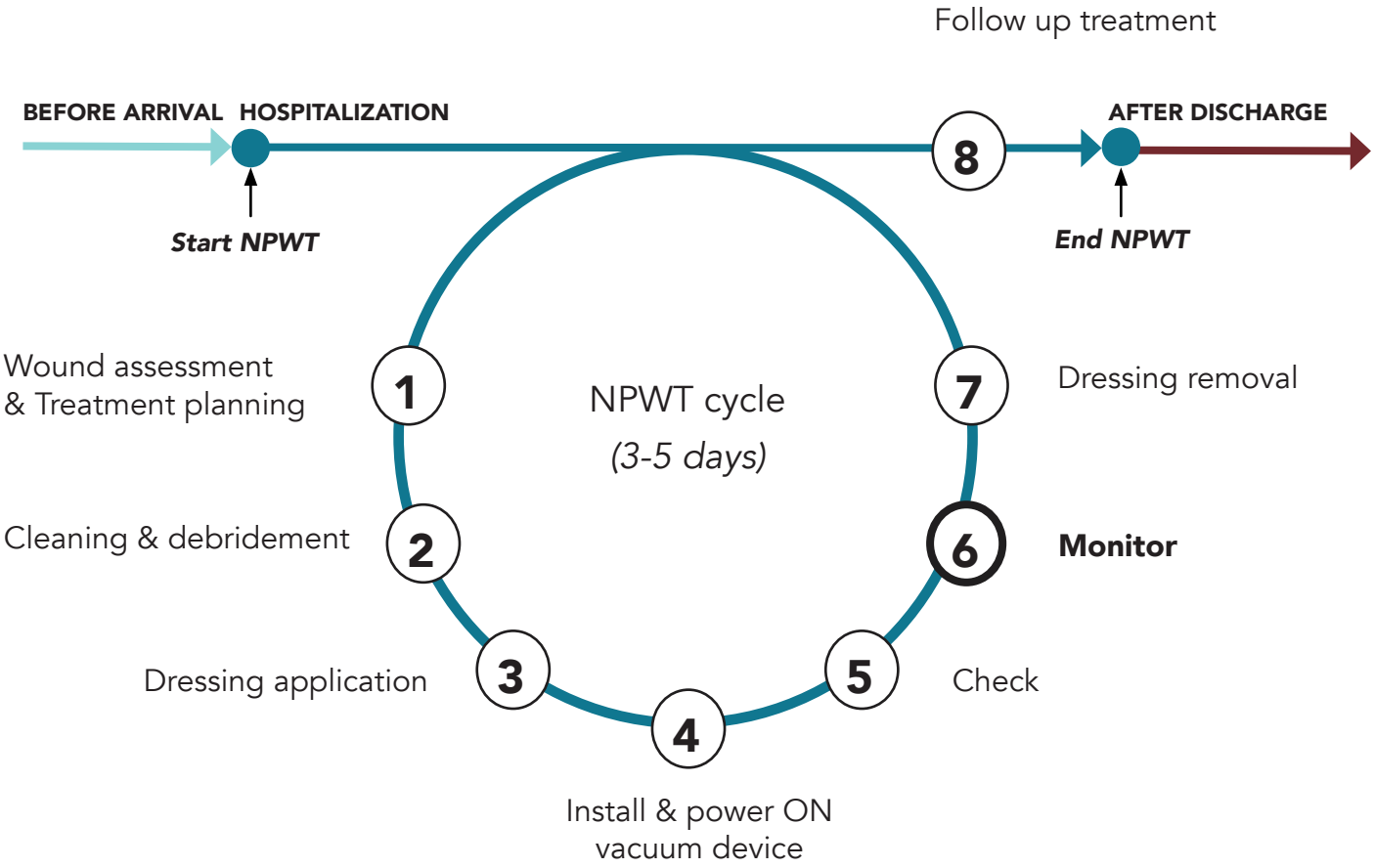
### 3.5.2. Monitoring

The period in between dressing the dressings changes, is defined as Monitor (6). During this 3–5-day period the patient remains attached to the AquaVAC system that is plugged in and placed beside the bed. In this time, several events may occur that require the assistance or immediate attention of the medical staff. These can be divided into two categories:

**1. Regular activities**
The NPWT cycle is at least 3-5 days and with repeated cycles probably much longer. During the time in the hospital, the patient needs to go to the toilet and other short activities but also should be able to do longer activities, such as a walk or going outside with a visitor. Activities are recurrent situations that require adjustments to the NPWT system to enable the patient to leave the ward.

- In case of a short activity (<30 min), the AquaVAC is disconnected and both tube ends are clamped. The patient may leave the room while the dressing remains in place. When the patient returns, the AquaVAC and canister are reconnected, the clamps are released, and the system pressure is restored.
- In case of a long activity (>30 min), the system pressure must be maintained and therefore the AquaVAC is moved together with the patient. Because the device depends on grid power, an extension cord is used to continue the treatment outside the ward.

**2. Unwanted events**
Complications are unwanted situations that affect the treatment and therefore require action. The urgency depends on the situation and the level of risk that is associated. A bleeding requires immediate action, while a loss of pressure is not that urgent. Other unwanted events include device errors and system failures.



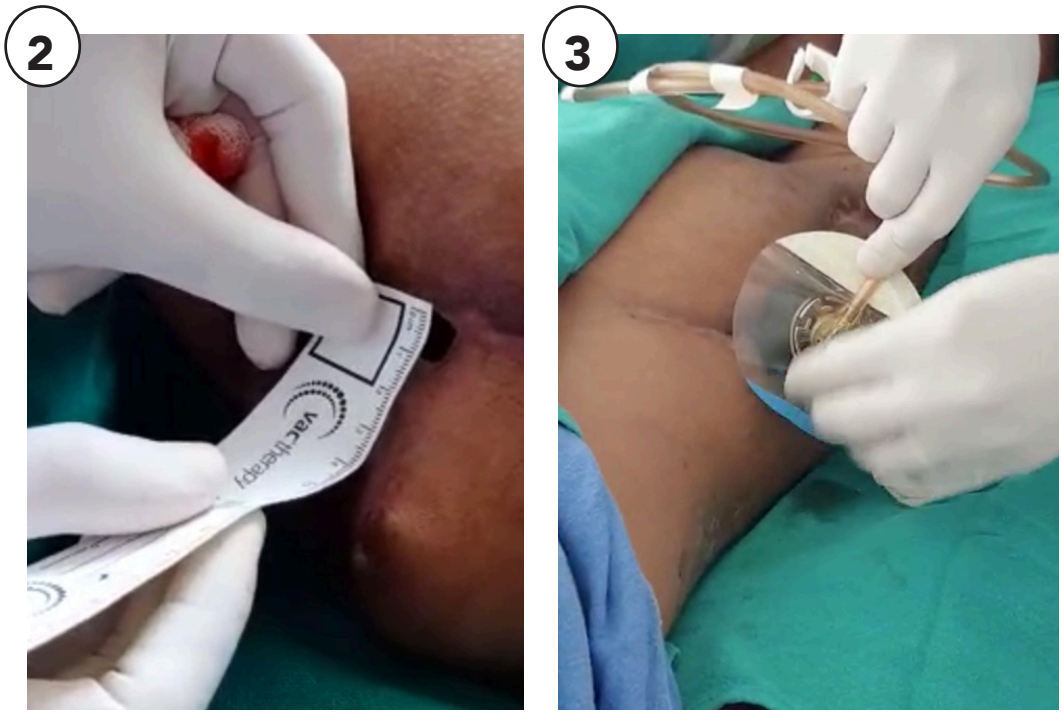
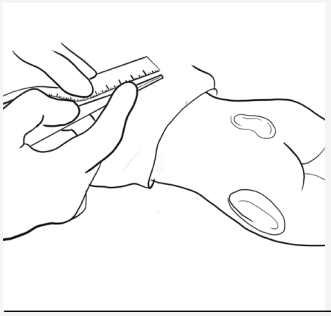




*Figure 37: Schematic overview of the treatment procedure during hospitalization at GPH*

**NEGATIVE PRESSURE WOUND THERAPY AT GREEN PASTURES HOSPITAL: A PATIENT JOURNEY**

HOSPITALIZATION

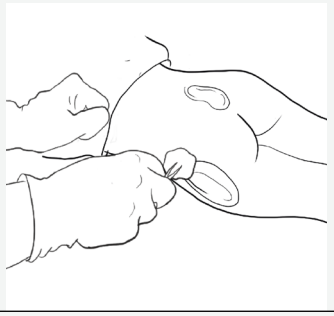


**1. WOUND ASSESSMENT & PLANNING**

**Doctor** examines the patient and wounded area(s) according to the guidelines for wound assessment [ref].
**Doctor** decides that NPWT is necessary and makes a treatment plan

**Patient** is informed and gives consent

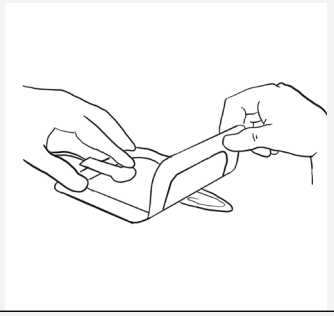
**D P**



**2. CLEANING & DEBRIDEMENT**

**Doctor** surgically removes unwanted tissue (in the OK or at patient's bedside) and cleans the wound

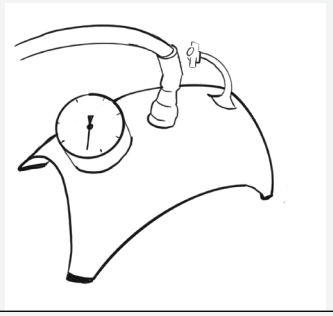
**D**



**3. DRESSING APPLICATION**

The **doctor** and **nurse** prepare the dressing together
1. Prepare the skin
2. Cut, sterilise and place the wound filler
3. Prepare the dressing - remove from package or compose from local materials.
4. Place dressing carefully
5. Cut adhesive foil and place on top to seal airtight

**D N**



**4. CONNECT AND INSTALL DEVICE**

The **doctor** instals the NPWT system
1. Connect canister to both tube ends
2. Secure connectors
3. Connect the AquaVAC to power

**D**

*Figure 38: The journey of a patient with non-healing wound(s) that is treated at GPH with NPWT using the AquaVAC system.*

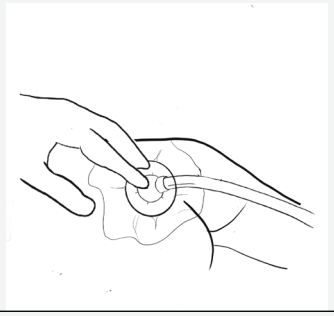
### 3.5.2 Issues and opportunities during treatment

Analysis of the Patient Journey resulted in the following selection of issues and opportunities related to the use of the current AquaVAC system.

**Dressing availability**
Pre-made wound dressings are mainly donated and therefore occasionally available at Green Pastures Hospital. Moreover, the variation in size is limited. As a result, dressings are often either too big or too small for the patient's wound. Extra dressings cannot be purchased by the hospital because consumables are paid out-of-pocket and there is no budget to buy these expensive pre-made dressings. As a result, self-made dressings are used which have a higher leaking rate and cannot be used with the smaller pumps.

Requirements:
- A device that is compatible with cheap, locally made dressings that are always available at GPH
- If the new device is compatible with cheap, locally made dressings, these can be used for all patients.

**Dressing application**
The preparation and application of a self-made dressing is time consuming and normally requires more than one person. First, the dressing material needs to be cut in the right size by one person, while held by a second person to keep it sterile. Subsequently, the adhesive foil must be applied smoothly and without wrinkles on the patient's skin. This process takes time (15-20 min) and cannot be done by one nurse only. When the medical staff is busy, finding the time for long procedures is difficult



**5. SYSTEM CHECK**

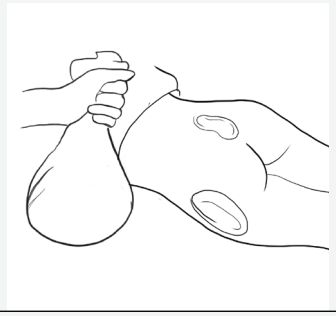
**Doctor** / **nurse** verifies if the systems works, by checking
- The pressure meter
- Dressing site
- Tube system

**N**

**6. MONITOR**

The **patient** remains connected to the system during the therapy. The **nurse** checks the wound and patient's vitals twice a day. The **caregiver** and **patient** receive instructions to monitor the system in the meantime, and warn a **nurse** when something happens.
The **nurse** repsonds first and calls the **doctor** in case there is serious complication.

**N P C**



**7. DRESSING REMOVAL & EVALUATION**

The **doctor** / **nurse** disconnects the system and removes the dressing material, which is discarded immediately. The **doctor** evaluates the wound to check the healing progress and decides to continue/adjust the treatment plan.The **nurse** fills in the patient's (wound) charge.

The **patient** and **caregiver** are informed about the next step

**D N**

**8. FOLLOW-UP**

The **doctor** decides to finish the NPWT treatment and the patient is ready for follow-up treatment. In case needed another treatment procedure is started or the patient is prepared for discharge to further recover at home

**D N P C**

Requirements:
- A dressing that is cut and sterilised beforehand saves time during the application process
- A dressing that is easy to apply by one person enables nurses to change NPWT dressings without assistance

**Difficult to monitor**
Nurses check on the patients on average twice a day. In between these checks, the patient and caregiver are asked to monitor the NPWT system. Since neither has a medical background or experience with technology, and the patient is usually quite sick, the caregiver has a difficult job. Moreover, at night when most people are asleep, the system is probably not monitored at all. This can result in dangerous situations, as some situations, such as a sudden bleeding, can lead to severe complications when undetected.

Requirements:
- Integrate a simple interface with clear indicators that is understandable for the patient / caregiver
- Include automatic error detection and audio-visual warnings, so active monitoring by the patient and caregiver is no longer needed, as they can respond to the alarms.

**Complex troubleshooting during air leak**
Air leaks are common incidents during NPWT, because the dressing does not always stay in place, e.g in case the patient moves. When this happens, the differential pressure drops. To restore the pressure, a nurse or doctor must locate the air leak and close it with extra drape. Air leaks are not visible and therefore difficult to locate. If the pressure is not restored within 2 hours, the dressing becomes saturated and must be changed. Air leaks and other device errors may disrupt the workflow and increase the workload of the medical staff, especially when troubleshooting is complex and time consuming.

Requirements:
- Ensure that the internal technology of the device is simple and reliable
- Ensure that troubleshooting is quick and easy
- Facilitate assistance in locating air leaks
- Prevent misuse where possible

**Limited mobility**
The AquaVAC system is not easy to carry or suitable for outdoor use, because it relies on grid power and is connected to a large canister (>1L). Moreover, the patient feels trapped inside the tubes and they prefer to have more freedom of movement.

Requirements:
- A portable system that is easy to carry
- A battery powered system that can be used outdoors

**Safety improvements**
During NPWT there is a risk of complications, such as bleeding or infection. If these issues are not solved adequately, it can lead to situations that seriously harm the patient. Therefore, it is important to integrate features into the design to warn the medical staff in case of such an event.

Requirements:
- Include safety features, so complications are not overlooked
- Prevent cross contamination, because the patient remains connected to the system and clamping tubes is no longer needed.

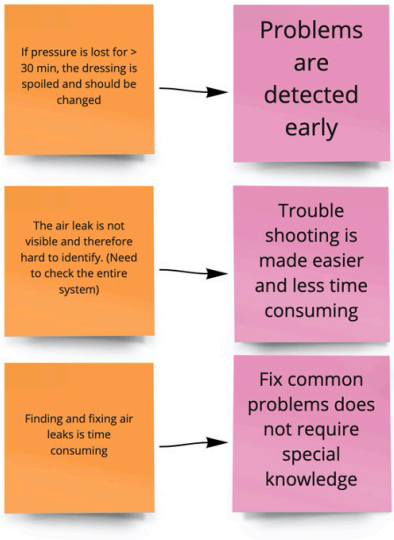



*Figure 39: Shows how the analysis of the patient journey resulted in identification of pains that were translated into opportunities.*

# 3.6 Main findings // CONTEXT

The resulting main findings of the context analysis are summarized in the following paragraphs.

### Usability
This NPWT system is primarily used by trained doctors and nurses and often monitored by the patients and the personal caregiver, who are neither familiar with healthcare nor technology. Intuitive and ease of use is highly important, as well as clear instructions. Because NPWT is not a well-known concept in Nepal, the medical staff has little experience with these devices and therefore guidance and training is required.

### Portability
One of the problems of the converted pumps and wall suction NPWT systems, is the limited mobility of the patients. Patient immobility causes discomfort, and it takes time to disconnect the system every time the patient needs to move, for example for a toilet visit. A portable NPWT system (small size, low weight) is desired to overcome these issues.

### Power
Green Pasture Hospital has a stable power supply. The sockets are located next to the patient's bed and therefore the device can be charged at night. Therefore, a battery that lasts for about 8 hours is suitable for a NPWT device in this context. Note that the situation might be different in other clinics, especially in remote areas.

### Noise
The patient is connected to the NPWT system 24/7. If the system makes noise, it can disturb the sleep of this patient and all other patients staying in the shared ward. Sound levels above 30 Db can disturb sleep. If the system cannot be made silent, or isolated from the patient, the noise should be < 30 Db.

### Cleaning
The NPWT system consists of disposable and reusable parts. The reusable parts should be cleaned and sterilised at the end of each treatment. At GPH medical equipment is cleaned with disinfectant solution (saline). The materials of the device should be suitable for this procedure. The device should be easy to clean by a nurse or cleaning staff and the risks of cross-contamination should be minimised.

### Transportability
Nepal has a difficult infrastructure, therefore transport of goods is slow and expensive. Local manufacturing is desired to reduce the need for long distance transportation. This situation requires adequate stockage of spare parts and materials, new orders need to be planned. Finally, durable packaging is required that can withstand impact during transport.

### Manufacturing
Nepal has a low-tech industry. Possibilities for manufacturing are limited, therefore consider only basic techniques. Components (especially electronic parts) are imported from neighbouring countries India and China. Online delivery from international webshops is quite reliable, delivery time usually around 1 week. Finally, the workshop at GPH has basic tools available to do assemblies and small repairs.

# PHASE II: DEFINE

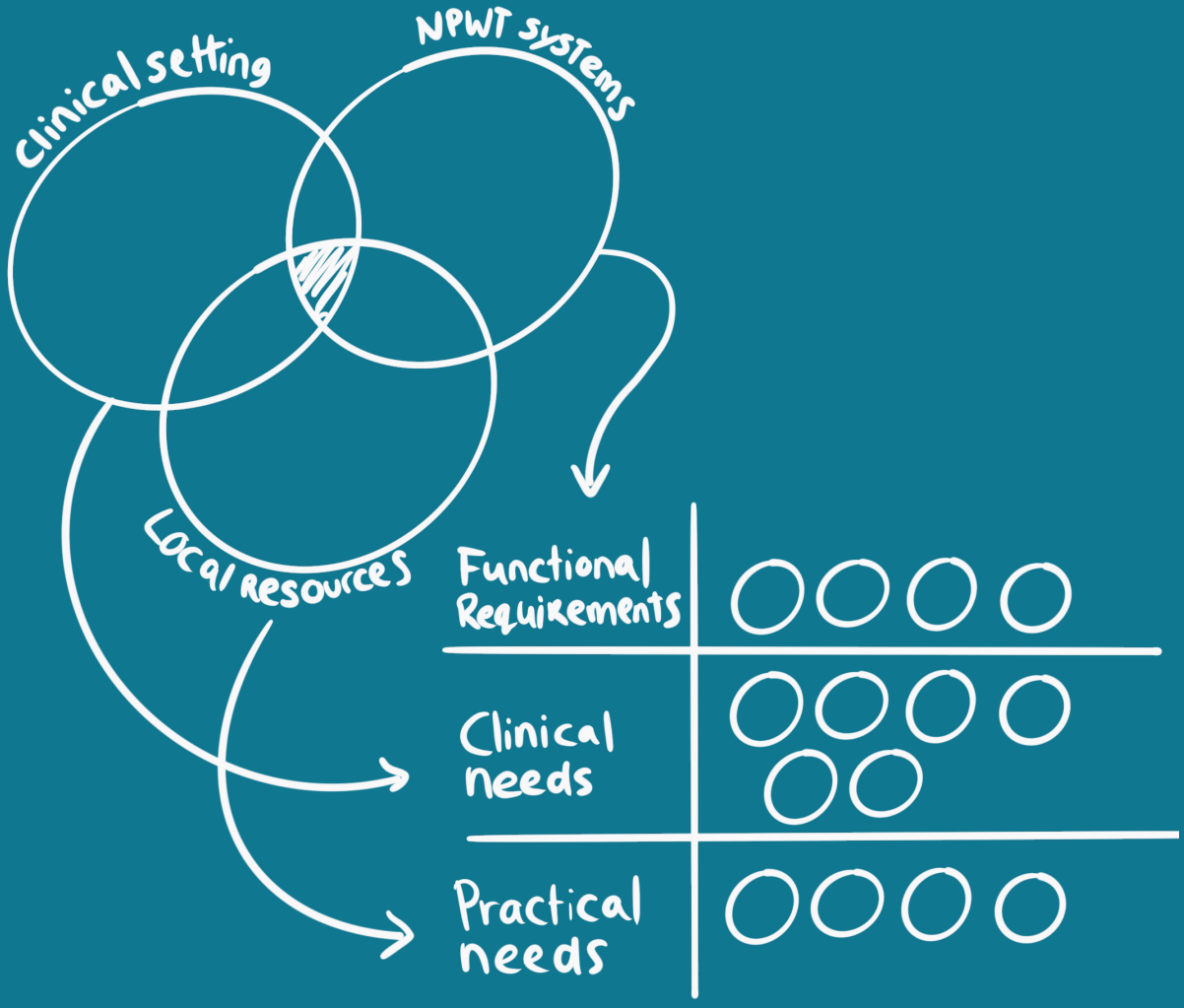
"Determine implementation strategy and design requirements"

Phase I has delivered rich insights and takeaways regarding the domain of NPWT, NPWT device technology and the context of Nepal. However, this huge amount of information alone is not enough to extract the core user needs, challenges to overcome, and to provide guiding directions for further design activities.

The goal of Phase II is to translate insights from research and the identified user needs, into a workable format that will guide the design process towards a final design proposal. This workable format consists of a list of design requirements, design drivers and design challenges that are all inspired by a general vision on how the final product can create the most impact.

Chapter 4: *Synthesis* starts with a definition of the problem, based on the insights of phase I, followed by the envisioned scenario, i.e  a view on the solution direction and the future role of the envisioned product in the context. It concludes with the list of requirements, i.e a set of quantifiable criteria to assess the final design proposal.

Chapter 5: *Focus* starts with a general design vision, followed by several design challenges, which divides the project goal into smaller design goals to solve with the final design proposal. The last section elaborates on several fundamental decisions that were made and form the starting point of the design process, as described in phase III.


Clinical setting
NPWT systems
Local resources
Functional Requirements
Clinical needs
Practical needs

CHAPTER 4

# SYNTHESIS

In this chapter the constructed design criteria are presented. These are derived from the research insights.

In this chapter :

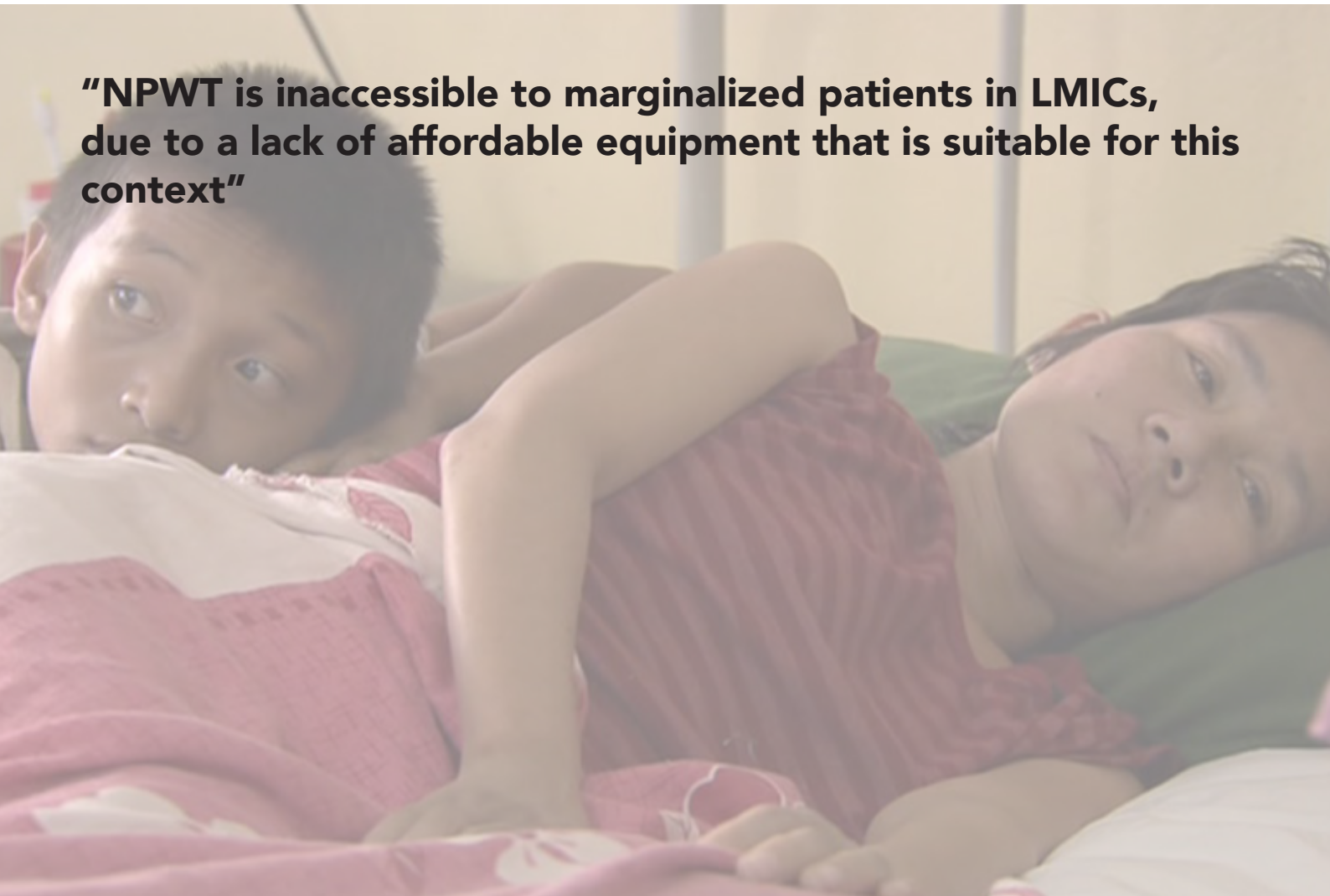
# 4.1 Problem definition

As mentioned in the introduction of this report, many people living in low-middle-income countries are affected by injuries that develop into chronic wounds and, without adequate treatment, may lead to disabilities or even cause death. Negative Pressure Wound Therapy is currently the most suitable manner to treat complex and chronic wounds. NPWT stimulates wound healing and reduces treatment time. The medical staff of GPH wishes to treat wounded patients with NPWT.'

However, it turns out that specific equipment is needed to provide this therapy and most resource-poor hospitals are not equipped with these NPWT devices and special wound dressings. This is due to the lack of resources, in money and in medical equipment.

In the Green Pastures Hospital there is a donated AquaVAC. This device has complications, especially for LMICs. The device is not compatible with self-made dressings which are oftentimes used because there are no pre-made wound dressings available or not in the right size. Air leaks are common incidents of the treatment, only troubleshooting with the AquaVAC is difficult. Another disadvantage of the AquaVAC is that the patient is bedridden because it relies on grid power. Moreover, the AquaVAC has no safety features which makes the treatment dependent on constant visual monitoring which is not possible at GPH. The most profound problem with the AquaVAC is that there are no spare parts available LMICs and that once the AquaVAC breaks down it cannot be repaired. This makes the life changing and life saving NPWT treatment fully dependent on donations from abroad.

All in all, the following general problem statement is formed: "NPWT is inaccessible to marginalised patients in LMICs, due to a lack of affordable equipment that is suitable for this context"



# 4.2 Envisioned scenario

Figure 40 shows a schematic overview of the envisioned scenario. It explains how and why the design of a new NPWT system could contribute to solving the general problem statement.

First, medical equipment that is currently donated can not be locally repaired. In the future scenario the product is locally assembled at a low price and therefore will be locally repaired in case it breaks down.
Secondly, instead of using sponsored money to buy expensive device that are not suitable for this context, a long-term budget is made available to produce low-cost device in house, in collaboration with local partners.

Thirdly, the plan is to introduce regular maintenance for the future device. Because it will be a low maintenance product, it will only include small tasks that do not require any expertise.

*Figure 41: Workshop at GPH.*

Lastly, instead of buying devices that are produched overseas and shipped, the envisioned product can be locally assembled from the locally sourced components. The workshop (figure 41) at GPH has already tooling and skilled employees, therefore it seems a suitable location for the assembly of the envisioned product.

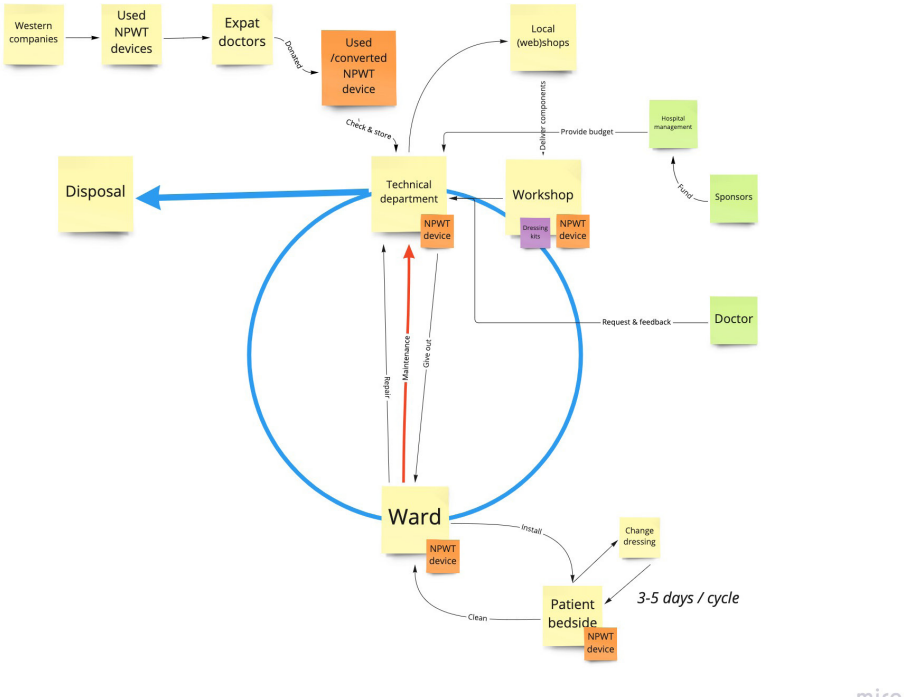



*Figure 40: Schematic presentation of the envisioned scenario*

# 4.3 Requirements

To develop a final product that fits the context and meets the needs of the end-users, an extended list of requirements is constructed. These are based on the findings of phase I, the problem statement and the envisioned scenario.

### 4.3.1. Functional requirements

The functional requirements are described below. These are the minimal requirements for a viable product. The functional requirements are used as input for the design criteria in order to test on the performance of the intended design.

**Pressure**
☐ One default pressure level (-125 mmHg)
☐ One adjustable pressure level (-80 mmHg)
☐ Maintain pressure for one treatment cycle (3-5 days)
☐ (Self)regulate pressure level (+/- 10%)

**Air flow**
☐ Minimal air leakage
☐ Sufficient pump capacity to compensate for leak rate of dressing (until 100 mL/min)

**Fluid flow**
☐ Smooth drainage of wound fluids
☐ Prevent tube blockage

**Fluid collection**
☐ Canister is reusable (suitable for cleaning)
☐ Canister size 300-400 mL
☐ No leaking
☐ Prevent large blood loss
☐ Include overflow protection and bacterial filters
☐ Canister content is clearly visible

### 4.3.2. Clinical needs

The most important clinical needs are described below. These are related to needs for this specific context of the intended patients and hospitals in which WOCA will be used. These are integrated in the list of requirements and wishes for the intended design

**Effect on healing**
☐ Meet functional requirements
☐ Validate clinical outcomes

**Applicability**
☐ Compatibility with various dressings (including self-made)
☐ Suitable for large wounds (high level of exudate)

**Usability**
☐ Simple and intuitive to use
☐ Easy to monitor
☐ Clear instructions
☐ Guidance and training included

**Portability**
☐ Portable power source
☐ Small size, low weight
☐ Noise
☐ Silent device (< 35 Db)

**Cleaning**
☐ Easy to clean with disinfectant (external parts)
☐ Suitable for autoclave (critical parts)

**Safety**
Indication that pressure is within effective range (-75 to -125 mmHg)
☐ Alarm when pressure is too weak (> -75 mmHg)
☐ Mechanical pressure limit (max. -200 mmHg)
☐ Overflow protection and bacterial filters
☐ Transparent canister and tubes
☐ Protection from excessive blood loss (>1000 ml)

### 4.3.4. Practical needs

The most important practical needs are described below. These are related to the specific needs of LMICs. This is a low-resource setting in which resources such as money, equipment and medical expertise and staff is scarce.

**Costs**
☐ Affordable device price <300 USD
☐ Very low dressing price (1-2 USD)

**Availability**
☐ First batch of 10 reusable devices
☐ Use of standard and widely available components
☐ Local manufacturing
☐ Consider available materials, tools and skill

**Maintenance and repair**
☐ Low level of maintenance
☐ Sturdy components
☐ Protective housing
☐ Spare components available online or <100 km
☐ Easy to disassemble

**Lifespan**
☐ Long lifespan
☐ Repair is easy
☐ 300 USD for a lifespan of 3-5 years
☐ 500 USD for a lifespan of 5-10 years

CHAPTER 5

# FOCUS

In this chapter the focus of the design is described. The design vision and design goal are formulated, followed by the design challenges with corresponding requirements and wishes. The chapter is concluded with profound design decisions in which the scope of the product and the design focus is set. The output of this chapter provides the direction for the next phase, starting the design process

In this chapter: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OUT PATIENT DEPARTMENT

# 5.1 Design drivers

Before starting the design process, a focus has been defined for this project. First, a set of design drivers were selected, presented on the right, to give priority to the design requirements, as well as a general direction for the design solution.

It was stated that the foremost criteria for successful implementation is that is availability and affordability of components to ensure the device can be produced and repaired at the location of use. Furthermore, patient safety is highly valued, because the main goal is to speed up the healing process and shorten the hospital stay of patients. Complications will delay the recovery and therefore must be avoided. The last driver, portability, was added because it was valued by the end users, as it will increase the quality of life of patients that receive long-term wound treatment.

A general vision was derived based on these drivers 'Heal chronic and complex wounds in LMICs with a device that is affordable, safe and reliable and made out of widely available, replaceable components.'

**AVAILABILITY**

**SAFETY**

**MAINTENANCE & REPAIR**

**PORTABILITY**

# 5.2 Design challenges

Following the project goal and design vision, seven design challenges are indicated to guide the design process. Design challenges can be treated as (sub)design goals and solutions must meet the requirements. The challenges are listed in order of their priority and the suggested method for validation is already indicated.

1. **Performance** *(Lab test)*

Firstly, the functional requirements as described in 4.3 :*Requirements*, must be met in order to create a functional, minimal viable product. According to insights from the context analysis, the minimal required performance to fulfill the main function is to create and maintain the demanded pressure level, while generate sufficient suction to extract the wound fluids. Selecting the components to achieve this, will be the first goal to achieve.

2. **Pressure regulation** *(Lab test)*

As soon as the minimal performance criteria are satisfied, the next challenge is to control the pressure to ensure it is maintained within the adequate range. Insights from research revealed that the effectiveness of NPWT is lost when the pressure is not within the effective range and air leakage is a common issue in vacuum therapy. Therefore, it must be further explored how to regulate the pressure.

3. **Canister integration** *(User test)*

Analysis of the context and currently used AquaVAC showed that the separation of the canister and the device is disadvantageous during treatment. The tubes are in the way of the patient and the medical staff and there is a risk of knocking it over. The aim is to combine these two elements in a way that is convenient and portable.

4. **Safety features** *(User test + expert review)*

The first priority, after having a functional device with integrated canister, is to guarantee improve patient safety. From the context analysis is appeared that there is a need for safety alarms during patient monitoring at GPH, which are not included in the AquaVAC. Additionally, it was found that none of the low-cost solutions for NPWT meet the safety standards required to obtain a CE-mark. Hence, the next priority is to solve this issue with the envisioned product.

5. **Portability** *(User test)*

From the start, it has been a clear demand from the client and end users to make the VAC device portable. A portable device is expected to increase patient comfort by increasing their mobility and independence. One of the limiting factors is the power supply, which is therefore one of the issues that must be solved.

6. **Operation and monitoring** *(User test)*

Research insights showed that current NPWT devices are unnecessarily complex and for this context, the device must be as simple as possible. This will be the challenge regarding the interface of the envisioned product.

7. Manufacturing and repair *(Expert review)*

Even though it is on the bottom of the list, this aspect is highly valued. For successful implementation on the long-term, it is essential that the product can be locally made and repaired. Therefore, this is one of the design challenges.

# 5.3 Decisions and direction

Based on the research, requirements and challenges, fundamental design decisions were made. These are the starting points for the concept development.

First, a powered system will be developed instead of a mechanical pump. This choice is made because a powered system better meets the practical needs of the context. See Appendix G: *Powered vs. mechanical NPWT* a comparison between these options.

Secondly, the device must be reusable in this context, due to issues related to transportability and limited financial resources.

Thirdly, it was decided that the project focuses on the design of the vacuum device. Designing wound dressings is considered outside the scope of this project, instead the device must be compatible with self-made dressings.

Lastly, it is not the aim of the project to also develop a canister, instead the device will be compatible with existing canisters.

**Battery powered**
- Portable
- Provides opportunity for automatic pressure control
- Handle air leakage

**Reusable**
- Single use products are not suitable for LRS
- Poor infrastructure
- Different standards for cleaning in LRS

**Compatible with self-made dressings**
- Able to use what is available
- Not rely on specific consumables
- Consumables are paid by the patients > have to be cheap

**Fit standard canister(s)**
- Bacteria filter + connections + overfill protection
- Widely available
- Cheap
- No need to produce > saves money, time and energy
- Make use of existing supply chain
- Downside > only large sizes, size/shape is unknown > more difficult to design canister holder

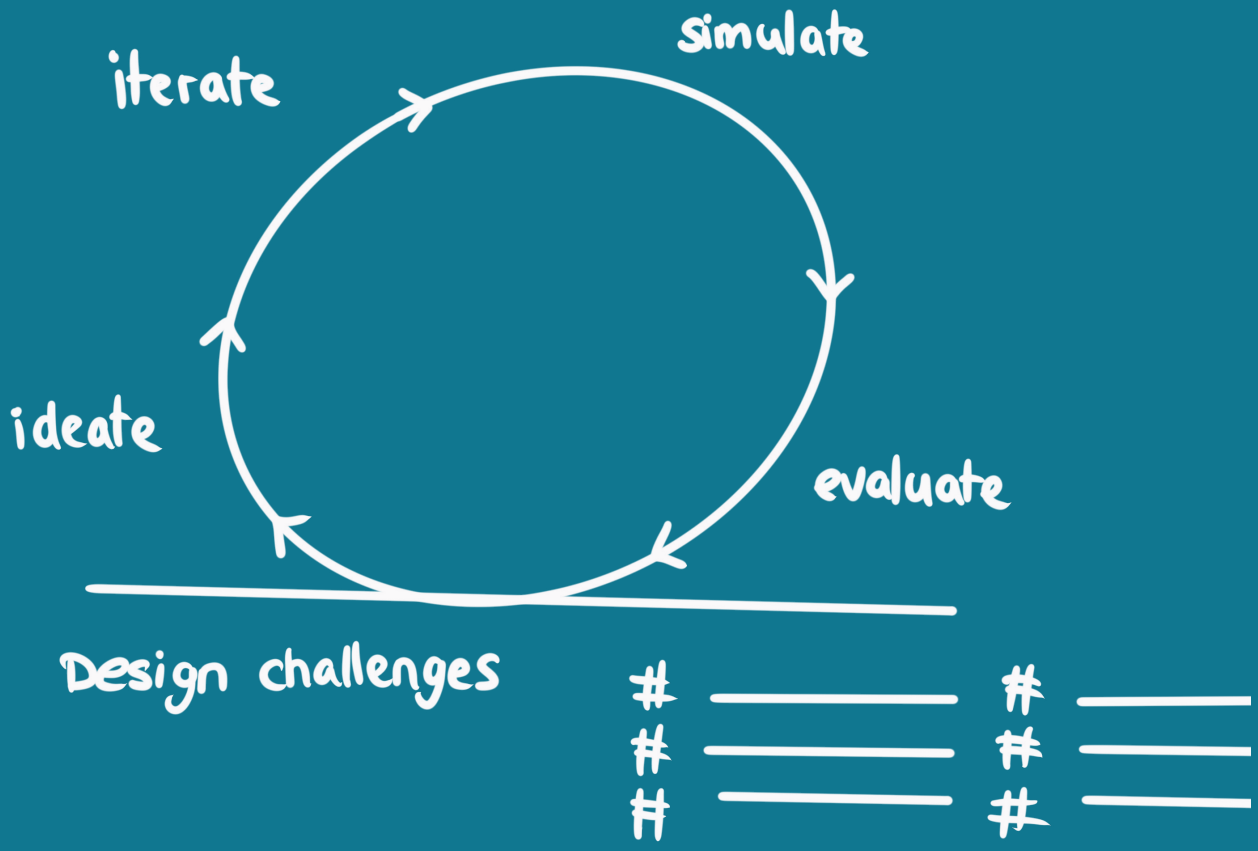

MACHINE ROOM

# PHASE III: ACT

"Design, built and test prototypes in close interaction with local end users"

The goal of the third phase is to develop a conceptual design proposal for a low-cost wound pump that fits the context described in the previous sections. This section will work towards a minimal viable product (MVP) with the help of feedback of local end users.

From the design goal and criteria defined in phase II, the full design cycle will be covered: by repetitive ideation, selection, simulation and evaluation, a final design proposal is given.


simulate
iterate
ideate
evaluate
Design challenges

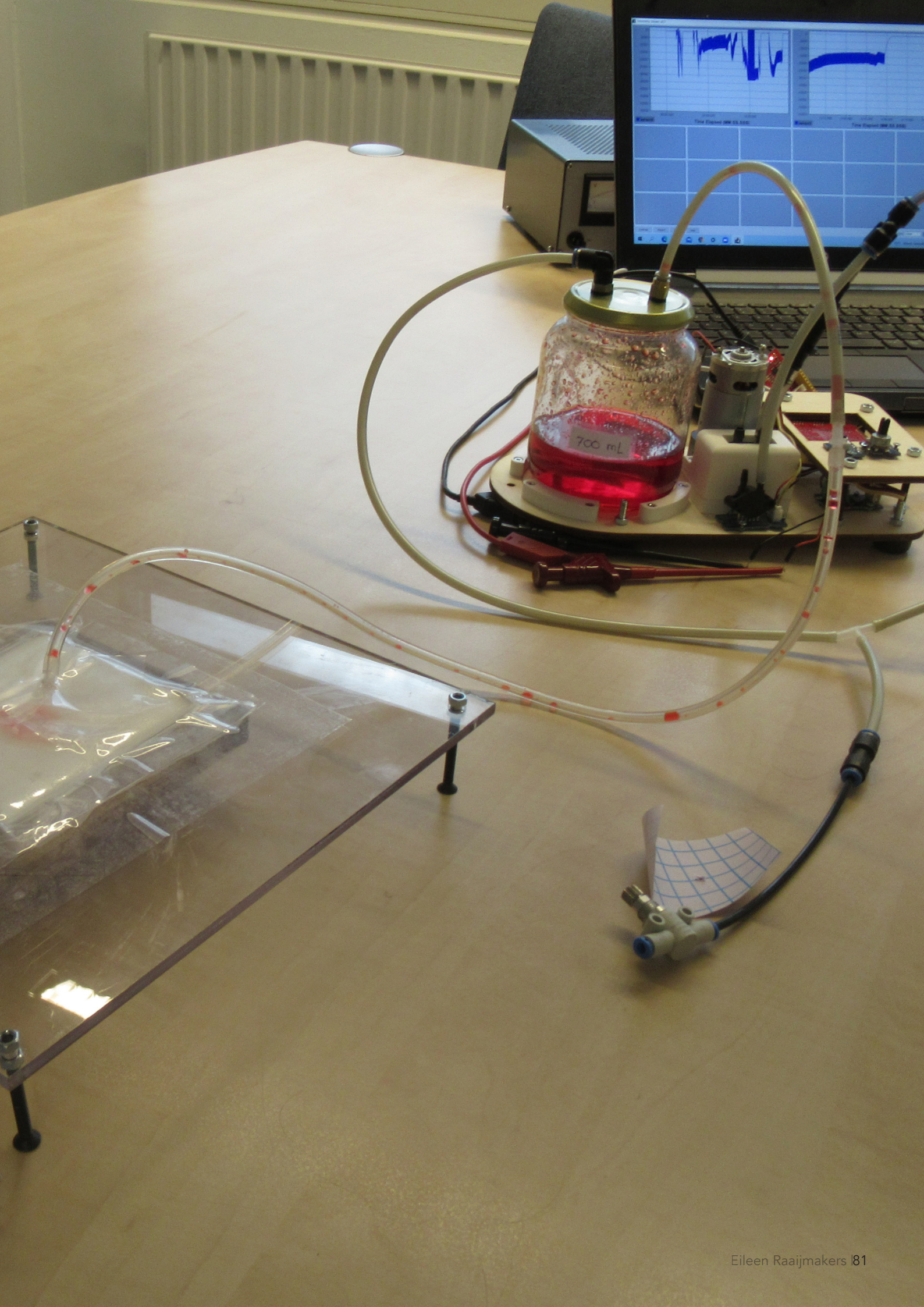
CHAPTER 6

# PROOF OF PRINCIPLE

This chapter describes the first step of the design process, which includes the selection and validation of the internal parts of the NPWT device. This activity concerns the first design challenge 'Performance' and the goal is to find out if this combination of parts can meet the functional requirements as presented in Phase II.

The internal components are combined into a prototype, which is presented first. This section is followed by a brief explanation of the test setup that was created to take measurements of the prototype. Subsequently, several test results are discussed and finally the chapter ends with the main findings that are taken to the next design phase.

In this chapter:


700 mL

# 6.1. Prototype

A first prototype was made, primarily to test how the individual components act together.
Two publications of projects on low-cost NPWT were found that make use of Arduino, these were used as inspiration [47], [48].
The prototype (figure x) consists of one baseplate in combination with mounting parts, hence, it was possible to try multiple combinations and switch components around. Due to this flexibility, the design method 'Research through design' (see Chapter 1: *Introduction*) could be easily applied.

### 6.1.1. Components

The list of components for this prototype is provided and briefly explained below. These are considered the main components to build a functional NPWT device.

The vacuum pump (1) that is used in this prototype is a standard diaphragm vacuum pump (12V DC) that is widely available online at a price of 10-15 USD. According to the specifications, the pump has a free flow rate of 12-15 L/min and a maximum pressure of -406 mmHg.

A Seeduino board (3) in combination with Arduino software is used to control the pump speed, in combination with a potentiometer (rotary angle sensor) and push button. Only a small piece of coding was required, which is included in Appendix X. Note that a MOSFET driver is required to enable control of the higher voltage pump (12V) with the low voltage (5V) of the Seeduino.
A small LED light is included for visual feedback to see if the pump is turned ON or OFF.

To measure the system pressure, an electronic pressure sensor (2) is added, connecting the inlet of the sensor to the tube in between the pump and the canister. The sensor is connected with the Seeeduino and data can be read by connecting the Seeeduino to a computer with software for data visualisation.

### 6.1.2. Integration

The components are attached to the wooden, laser-cutted base plate (9) and held in place with 3D printed mountings (11,12), fixed with standard nuts and bolts.

Several types of canisters were used for this test, including a medical suction canister (7) with a size of 850 mL, as shown in figure x. Push-in connectors (Festo) are used in combination with pieces of standard tubing (Festo) to ensure the setup is air tight.

The prototype is connected to an external voltage source (8) of 12v to simulate a battery powered system.

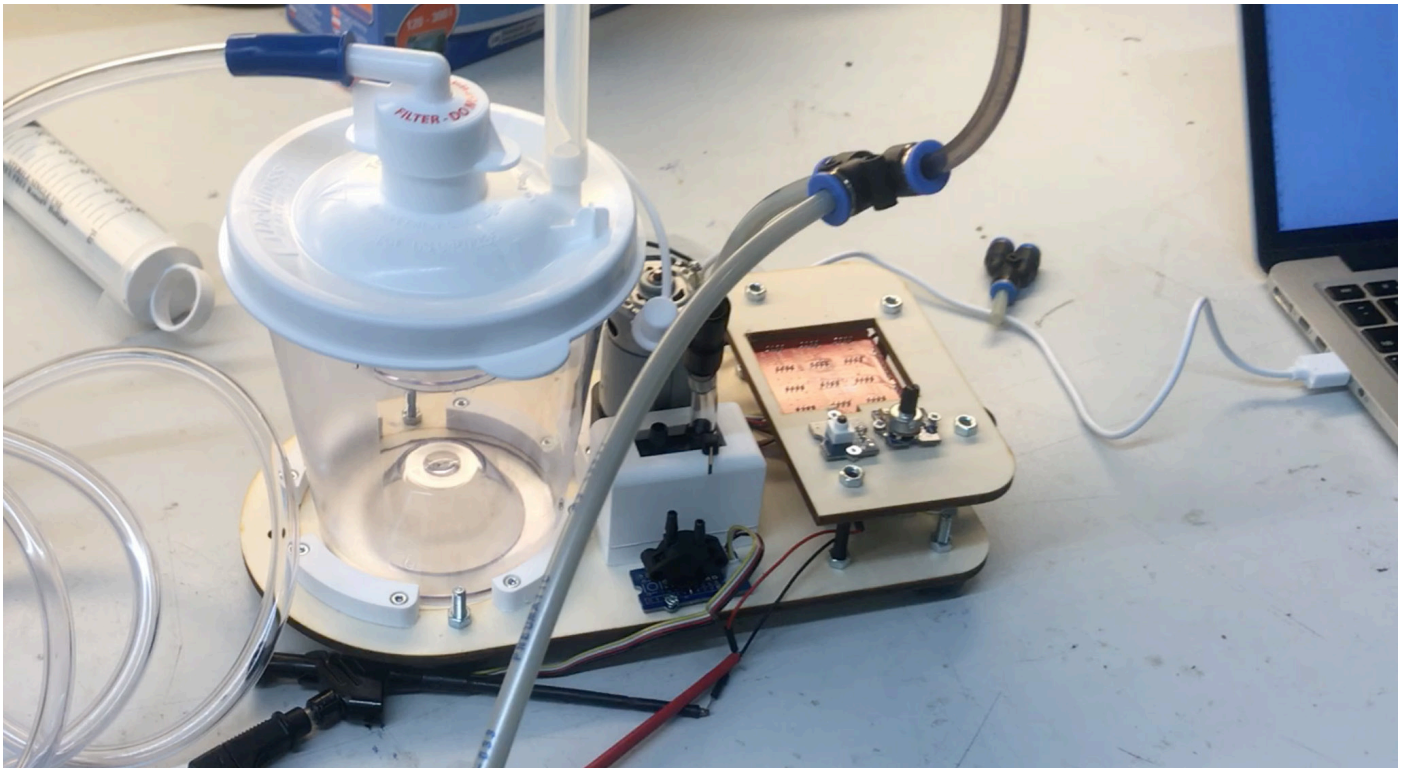
### 6.1.3. Issues

When making this prototype, the following problems were encountered that had to be solved:

- **Add tube connection;** The diameter of the tube (6/4 mm) did not match the diameter of the pump inlet. To solve this, a connecting piece was required to ensure an airtight connection between the two product parts.

- **Change canister;** The initial idea, to use plastic food containers for the canister, did not suffice as none of the containers that were tested provided an air tight sealing. Additionally, glass jars were tried and this worked, because these could be sealed air tight due to the screwing cap. Glass jars are easily recycled and widely available, therefore it seems a great solution. However, tube connections still have to be integrated and sealed airtight. Another downside is the added weight to the product. In the end, a medical suction canister was purchased and used for the final test, satisfying all requirements as mentioned above.

*Figure 41: The prototype that was used for the 'Proof of principle'.*



Prototype components

1. Vacuum pump
2. Pressure sensor
3. Seeeduino board
4. MOSFET driver
5. Potentiometer
6. Push button
7. Canister
8. External voltage source
9. Base plate
10. Top plate
11. Pump mounting
12. Canister mounting
13. Rubber foot
14. Nut
15. Bolt

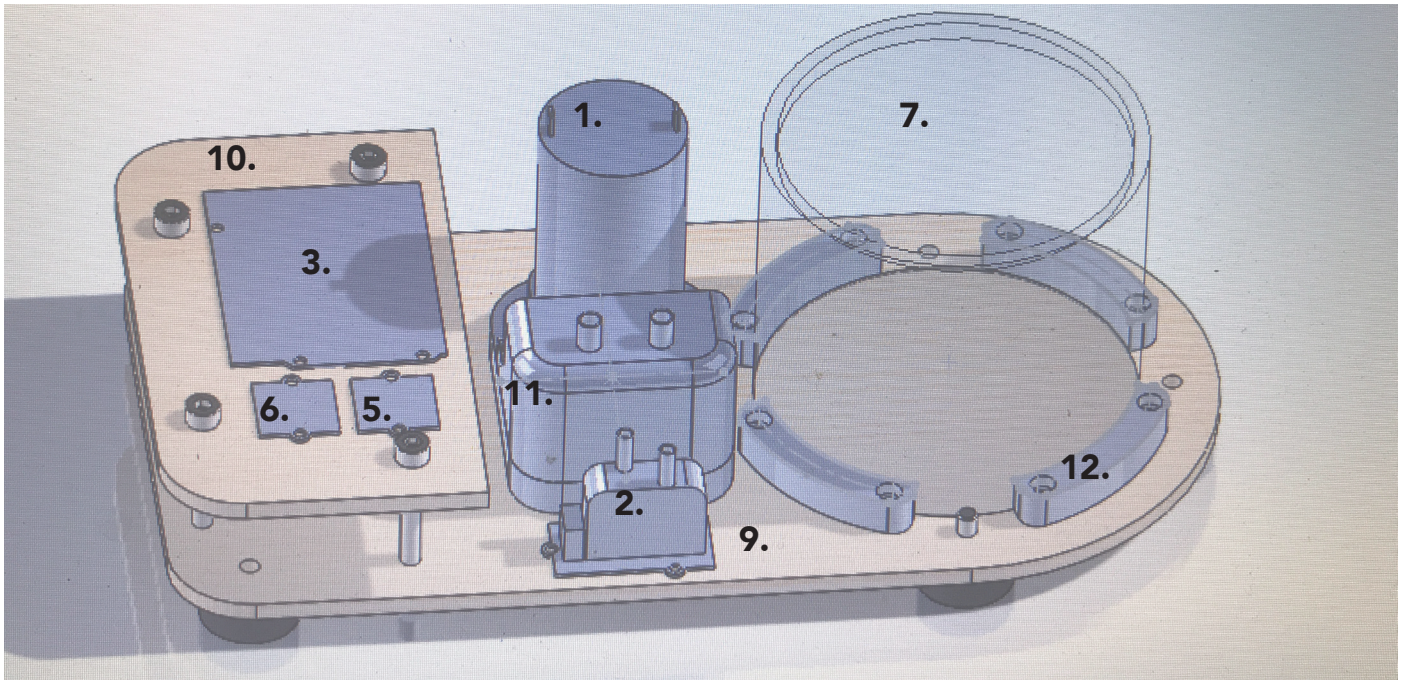



*Figure 42: 3D model of the prototype*

# 6.2. Test

### 6.2.1 Approach

•
The goal of the 'Proof of principle' is to determine a final selection of internal components that meets the performance criteria for a functional NPWT device.

The following requirements were selected from the list of requirements (Appendix H: *List of requirements)* that resulted from Phase II:

*1.1 The device can create and maintain a pressure level of -125 mmHg during one treatment cycle (3-5 days).*
*2.1 The device can overcome an air leak ratio of 0-100 ml/hr*
*3.1 The device can extract fluids from a wound with a flow rate ranging from 1-300 mL/day. Wound fluids are collected into a sealed canister without spillage*
*4.1 Wound fluids are collected into a sealed canister without spillage*

### 6.2.2. Test setup

To simulate the environment in which the NPWT is used in a lab setting, a test setup was created (figure 46). This setup is adjustable and provides freedom to try different experiments. It consists of the following components

**Vacuum dressing**
To imitate a self-made vacuum dressing (figure 42), materials were chosen that resemble the dressing materials that are used at Green Pastures Hospital, including sponges and adhesive film. This method of application was also imitated, based on observations of the footage of VAC dressing application by the medical staff at GPH. In addition to this self-made dressing, a regular pre-made dressing pad of Smith&Newphew was tested as well to compare the results.

**Wound model**
To simulate the wound, including the excrement of wound fluids, a wound model (figure 43) was made from transparent perspex with an extrusion of 20x12x2 cm to resemble a medium sized wound. The bottom part was perforated to connect the syringe (100mL) with a tube. To run 'wet' tests, the syringe was filled with water to resemble wound fluids that are excreted at a certain flow rate. Red pigment was used to make the fluids visible during the test.

**Pressure sensors**
Two Seeduino boards and two digital pressure sensors were used to control the pump and measure the pressure in the tube system as well as the dressing area. The sensors are calibrated first, using a digital differential pressure gauge. The data is visualized with software called Telemetry viewer 8.0.

### 6.2.3. Issues

Due to encountered issues, the following adjustments were made to the test setup:

- **Wound model;** The first wound model was not air tight and because air could leak in on the side of the model, it was not suitable for testing. This was solved by making a second model from perspex that was sealed with glue.
- **Self-made dressing;** Applying a self-made wound dressing without leakage turned out to be difficult, especially where the tube enters the dressing. It took a few attempts to find a method to apply a dressing without wrinkles and create an airtight connection with the tubes. Applying a bit of pressure on the dressing when the pump was part of the solution.
- **Flow measurement;** The initial test setup included a flow meter to measure the air flow within the system. However, the only flow meter at hand suitable for this range of air flow, did not provide accurate data and therefore it was left out in the final setup.

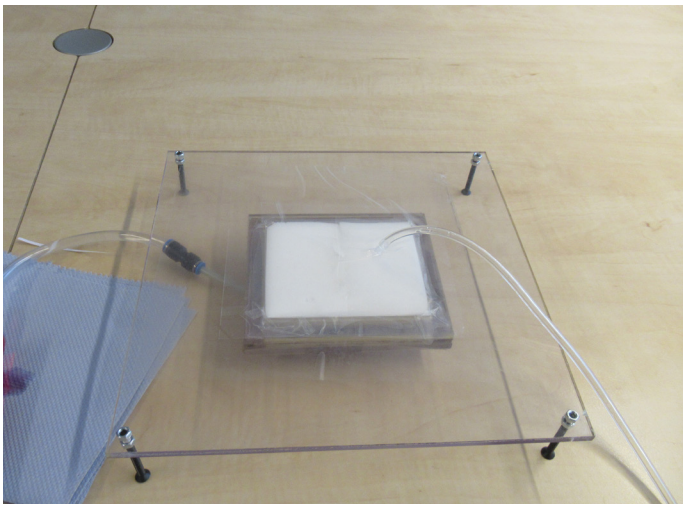


*Figure 42: Dressing made from sponges and adhesive film.*

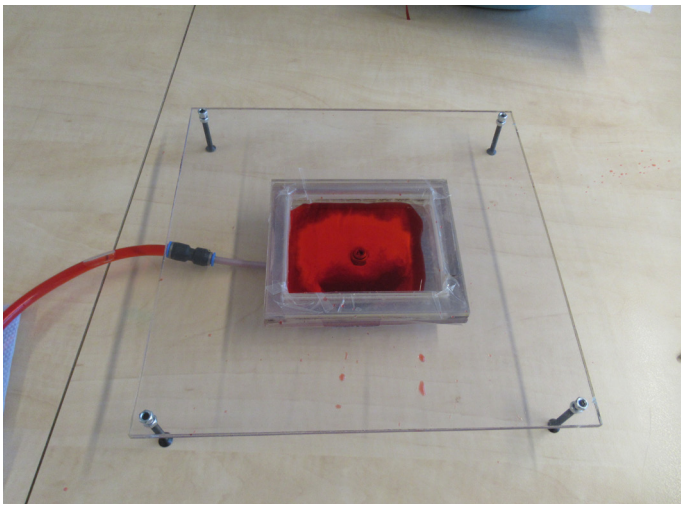


*Figure 43: Wound model filled with colored water.*

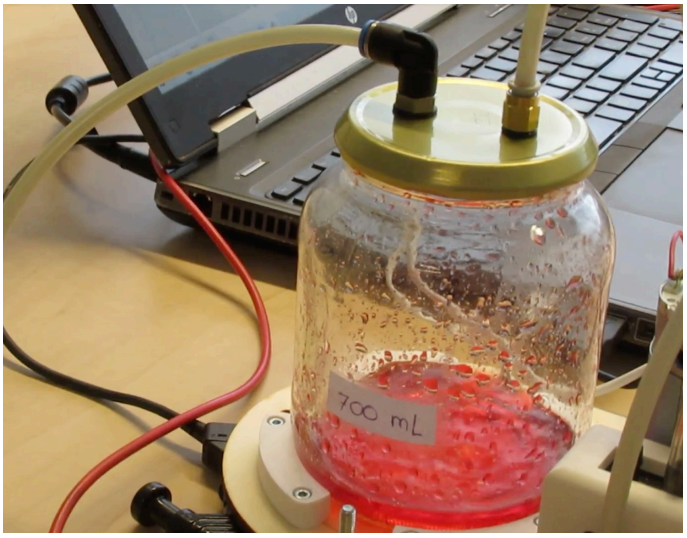



*Figure 44: The canister is filled with fluids.*

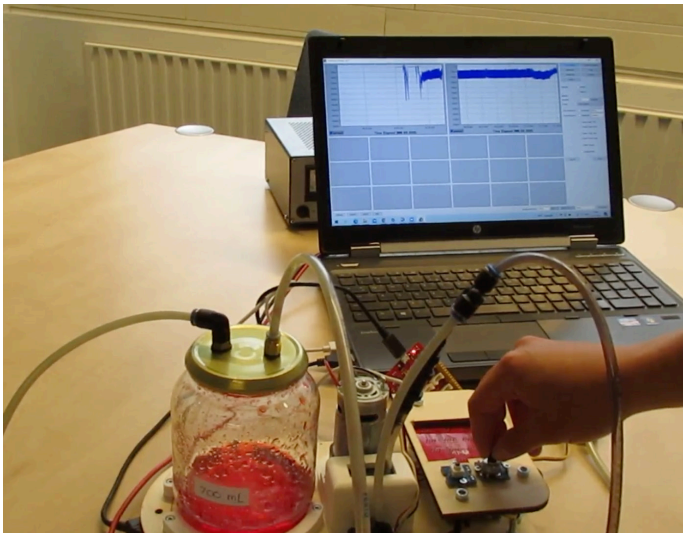


*Figure 45: The pump speed is manually adjusted, while the pressure is being measured.*

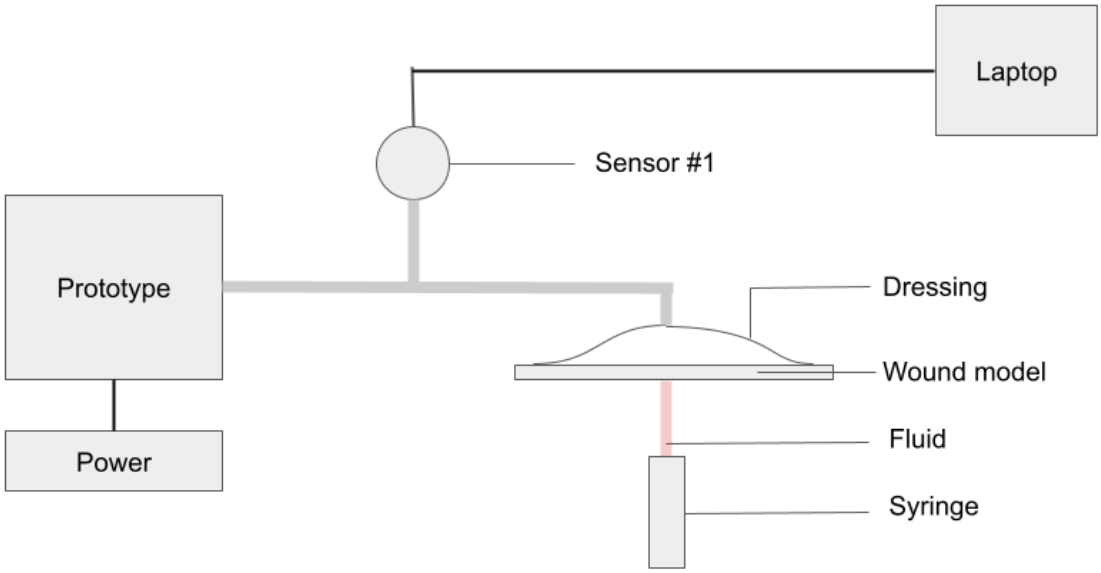



*Figure 46: Final test setup that was used for the 'Proof of principle'. During the sensor comparison test, the sensor was attached at the location of the syring, to measure the pressure at the dressing site.*

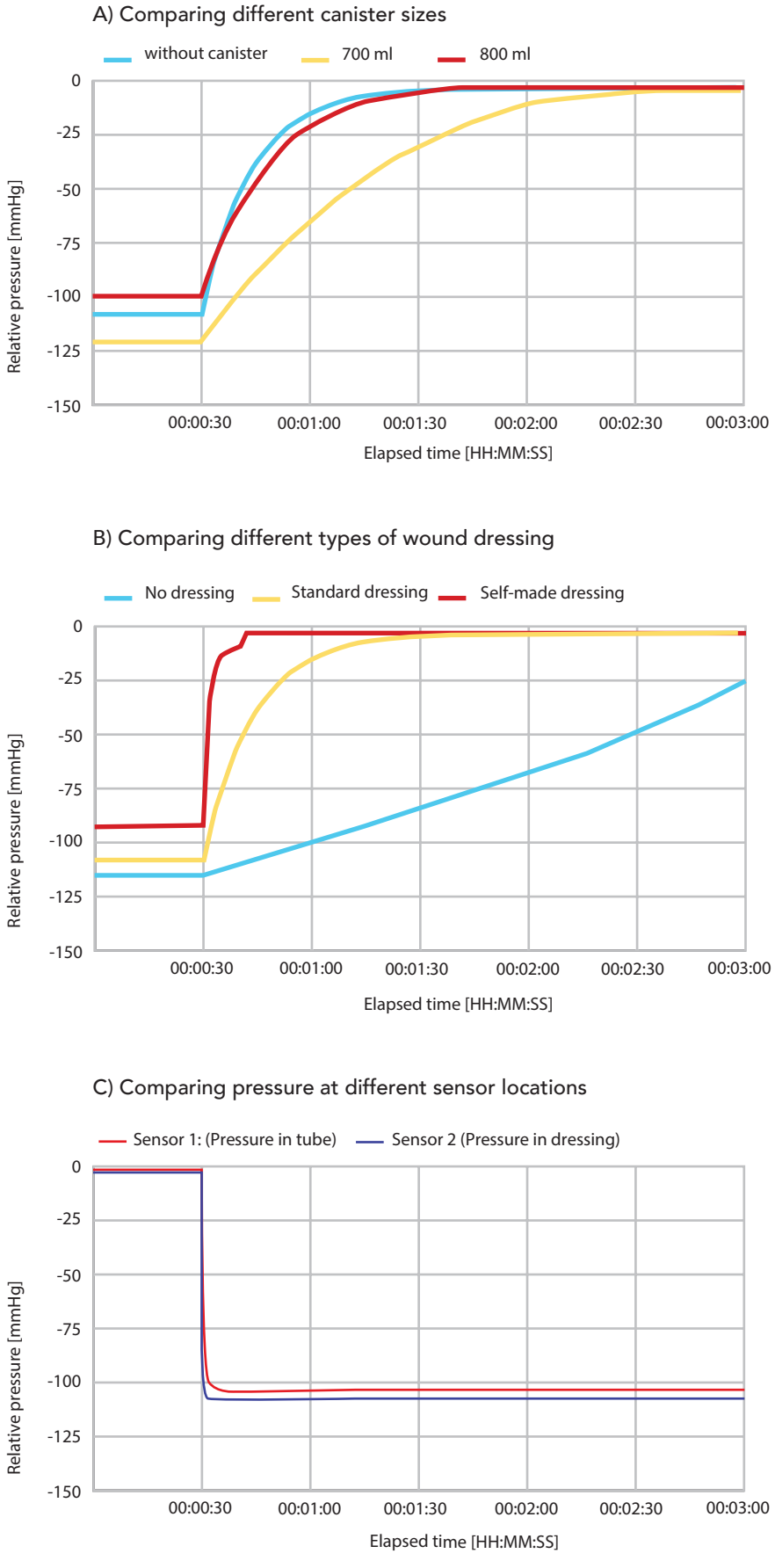



*Figure 47: Graphs of measurements taken during the 'Proof of principle' experiments.*

### 6.2.3. Test results

Various experiments were conducted to test the prototype on the criteria that were mentioned, the main findings are discussed below.

By means of a 700 mL canister and a self-made dressing, a final simulation of the NPWT could be obtained to carry out the testing of the concept. The key requirements that were tested were the pressure level, air leakage, fluid flow and fluid collection that could be obtained with the pump in a simulated setting. With the chosen combination of components, it could be concluded that 3 out of 4 criteria were met, namely pressure level, fluid flow and fluid connection. The one criterion that could not fully be validated is air leakage.

**Pressure level**
The regulation of the pressure level turned out to be challenging, which has a possible consequence of tissue damage. Adjusting the pump speed did not result in a lower pressure, because as soon as the pump was activated, the pressure reached its maximum allowable value. Therefore, the final design needs to include a pressure regulator to act as a fallback when the pressure reaches the maximum allowed value.

**Air leakage**
The one criterion that could not be fully validated is requirement 2.1 related to air leakage, which will be elaborated on later onwards. The main challenge of this test setup remains in the air leaking, which turned out to be higher than hoped-for. The main difficulty is in making an adequate estimation of the air leak ratio of the dressing, taking into account a variety of dressing types.

**Fluid flow and collection**
In the testing scenarios, the fluid flow could be simulated successfully, which means without leakage and with a sufficient suction strength. In regards to the fluid collection, the canister size has proven to be a crucial part of the final design success. The tests show that if one works with a well regulated pump, different canister sizes can be used to deal with a wide variety of circumstances. Since the canister can counter fluctuations, bigger diameters can deal with stronger fluctuations in pressure level. Therefore, with the use of a well regulated pump, one can work with a smaller canister. In circumstances with higher pressure levels, a bigger diameter is required.

### 6.2.4. Conclusion

From this test, it can be concluded that 3 out of 4 criteria are met with the chosen combination of internal parts. The one criteria that could not be fully validated is the requirement 2.1 related to air leakage, because it was not possible to make an adequate estimation of the air leak ratio of the dressing.

Other insights include:
- The max pressure of the chosen pump was too strong, which means a safety valve should be integated
- Regarding the canister size: The canister can counter fluctuations, larger canisters can deal with stronger fluctuation in pressure level. Hence, if the pump is well-controlled, a smaller canister can be used, if not a larger canister is preferred.
- The amount of air leakage was higher than expected and is it is assumed that due to this leakage, a mechanical solution (hand pump) would not be feasible.
- The pump made a lot of noise and the sound level exceeded the acceptable range, which was perceived highly annoying. This should be improved in the next iteration.

# 6.3. Internal parts

Figure 48 shows the main components required for a functional NPWT device. Per component the desired functionalities of these components are described based on the finding in the tests results.

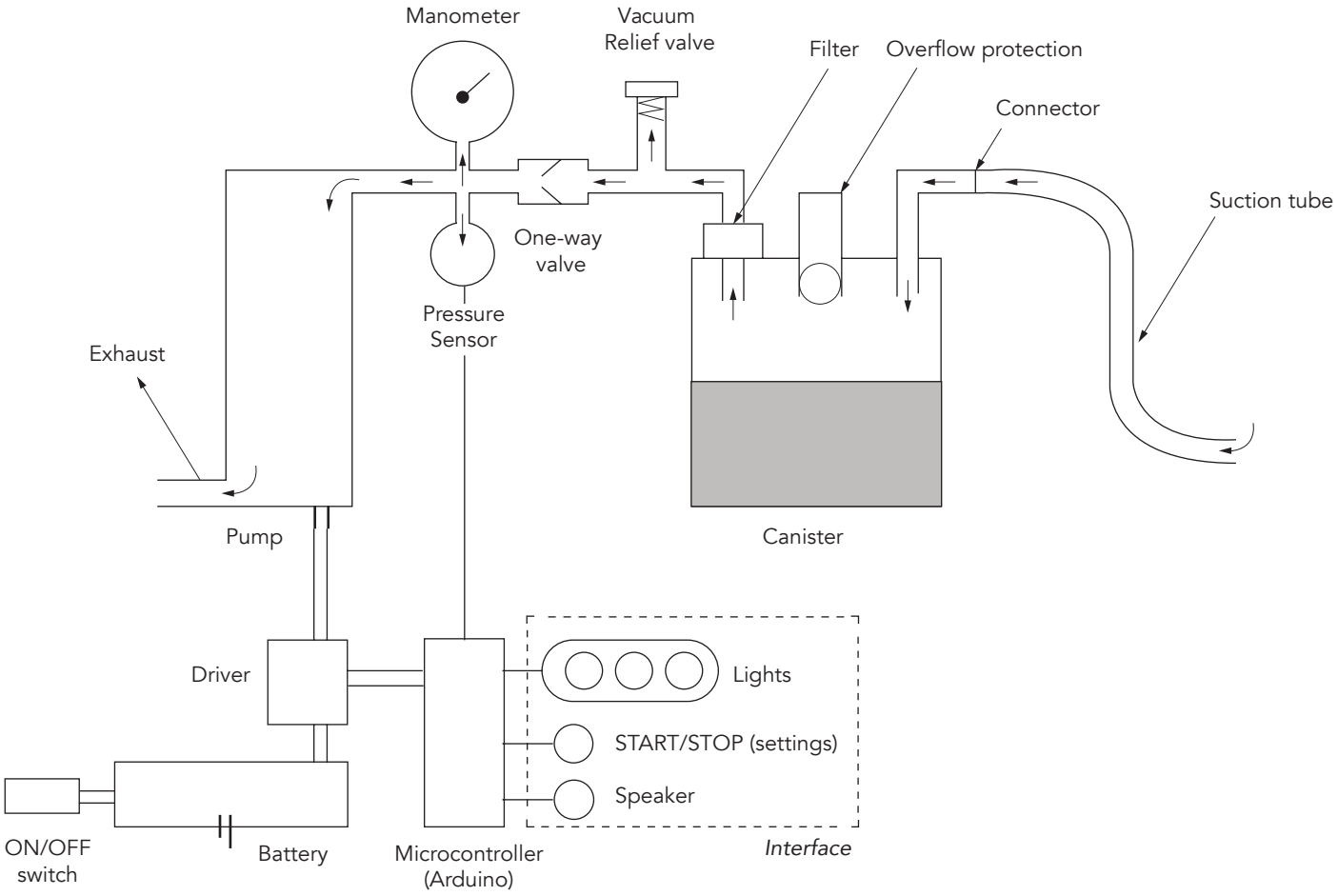



*Figure 48: Overview of internal components*

**Vacuum pump**
- Air pump (Diaphragm)
- Low pressure (-125mmhg = -16.665 Pa = -166.7 mbar = 16.4%) and high flow (estimated around 3L/min)
- 12V
- 2x Inlet
- Preferably silent, <35 dB

**Pressure sensor**
- Electronic pressure sensor
- Pressure range between 0-30 kPa (= 0-225mmHg)
- Sensitivity: > 2 mV/kPa

**Battery**
- Rechargeable
- Portable <500 g
- 12V

**Safety valve**
Adjustable to -125mmHg

**Manometer**
- Vacuum pressure
- Minimal required range 0-200 mmHg

**Canister**
- Off-the-shelf component

**Internal tubes**
- Should not collapse
- PU tubes are suitable material
- Standard diameter of 6/4 mm
- Bending radius <25mm

**Protective housing**
- Sturdy housing

CHAPTER 7

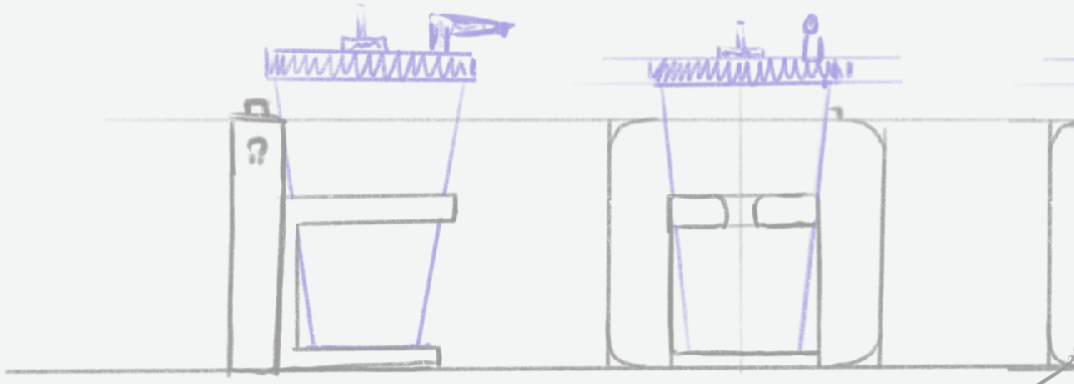
# CONCEPT GENERATION

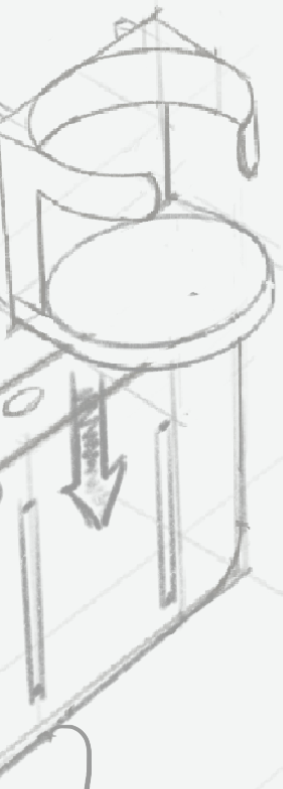
This chapter describes the development of the conceptual idea for the WOCA wound pump. This creative process included several activities.
During the ideation phase, several solution directions are explored using different methods to generate ideas. Through this process, four concepts are developed and presented. The next paragraph gives an overview how the several concepts score on the weighted criteria.
Moreover, adjustments are suggested to further improve the design. The last paragraph of this chapter concludes the findings and gives direction to the concept of the final design.

In this chapter:

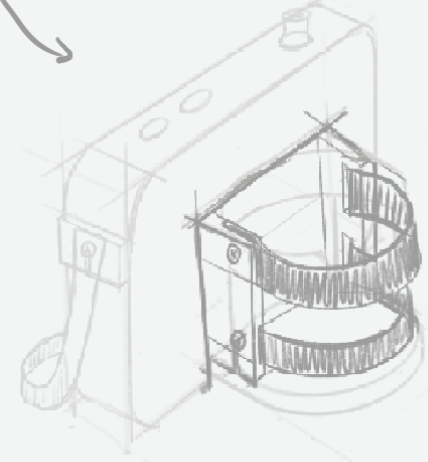
SIDE

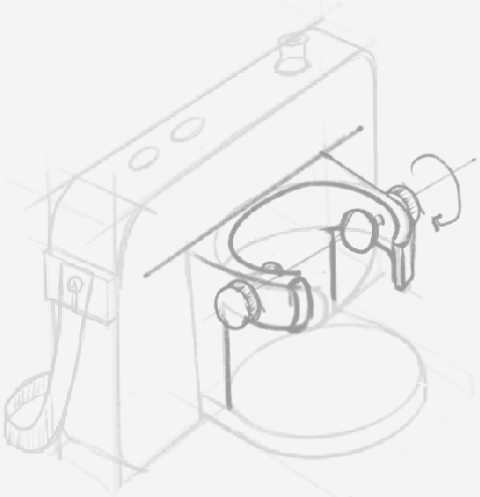
FRONT





variations

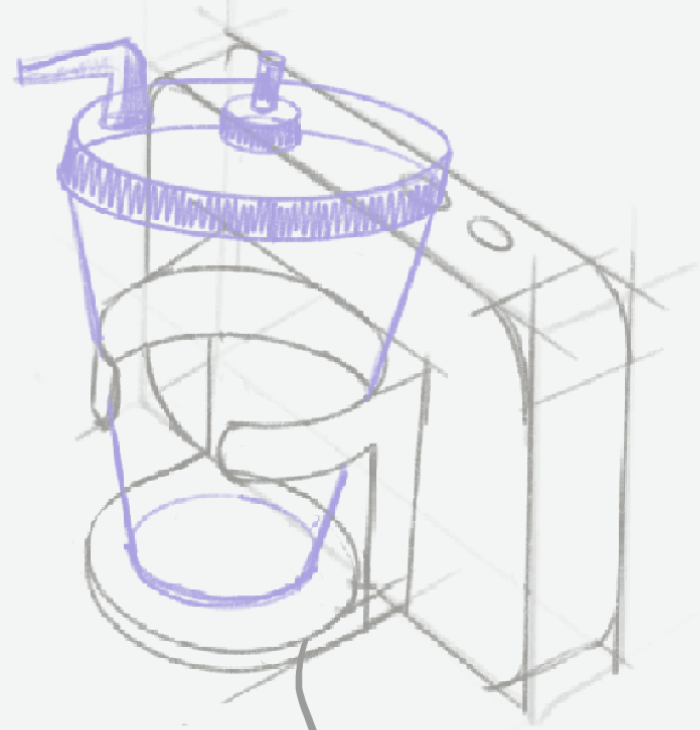


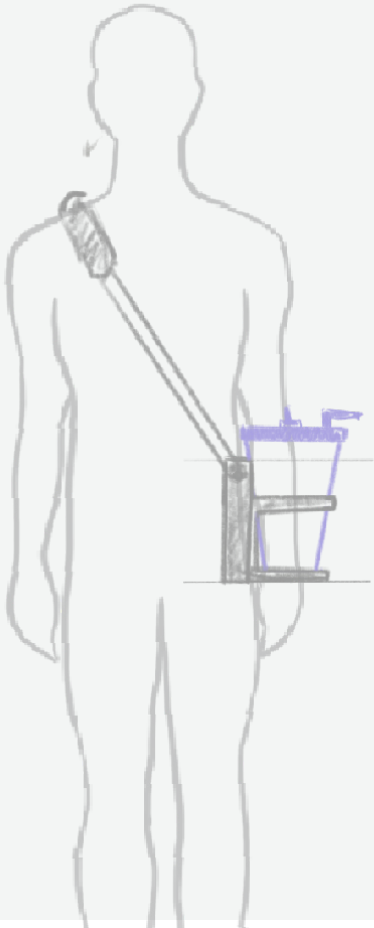


modular design

Velcro

screw clamp





fits different sizes of canisters

modular

# 7.1. Ideation

The aim of the project is to fulfill the current need to make NPWT easily accessible for marginalized patients in LMICs. To fulfill the goal, a NPWT device should be designed that meets the functional requirements, clinical and practical needs. In short, a design that scores good on the design requirements. To create such a product, a design process as described in this section is followed.

### 7.1.1 Creative sessions

Four creative sessions have been organized. In the course 'creative facilitation' four separate teams brainstormed about the subject and possible designs. First the problem statement was introduced. Following the participants focused on two relevant themes: modularity and patient safety. Figure 49 shows one of the Miro boards that was in the creative sessions. Those ideas were used to stimulate the design process and enriched the morphological map with extra design solutions. From all the different ideas generated through the ideation phase, the most feasible and promising ideas were selected, combined, and elaborated further into four different concepts.

### 7.1.2 Brainstorm activities

By using brainstorm techniques a lot of ideas were created. Free drawing was used to investigate certain design challenges. Three 'how to' questions were explored with the free drawing method.

1. How to use available components?
2. How to make the design modular?
3. How to create and regulate pressure?

This leads to different design solutions which were used in the generation of the concepts.

*Figure 50: Making an explanatory video for the CF participants, explaining de project case*

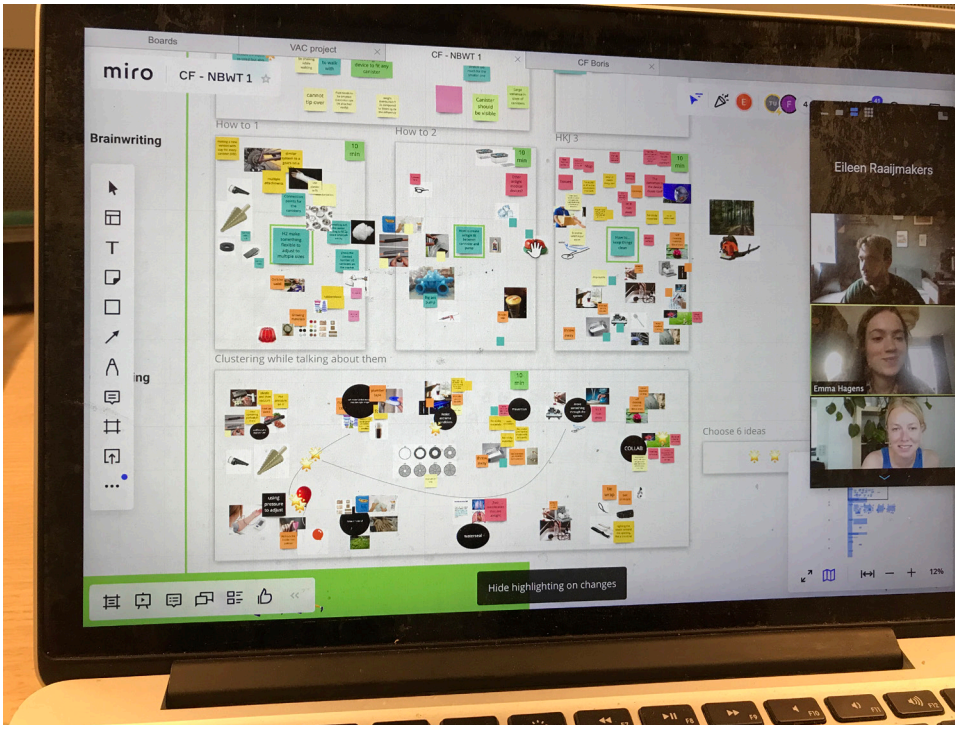



*Figure 49: 'Zoom' session of one of the creative sessions facilitated by course participants using the digital brainstorming tool called Miro.*

### 7.1.3 Card board models

Research through design is a way of materializing knowledge and insights based on hands-on design work. This special approach uses and gains insights from physical concepts. In this case cardboard models were made of the four concepts. By making the concepts tangible, the performance became more clear. New insights were obtained by this approach. For instance the weight distribution and its implications for the use of the device was optimized. Research through design is an essential part of creative research, resulting in an iterative and experimental design process.

*Figure 51: One of the concept ideas modeled in cardboard*

*Figure 52: Applying research through design methodology*

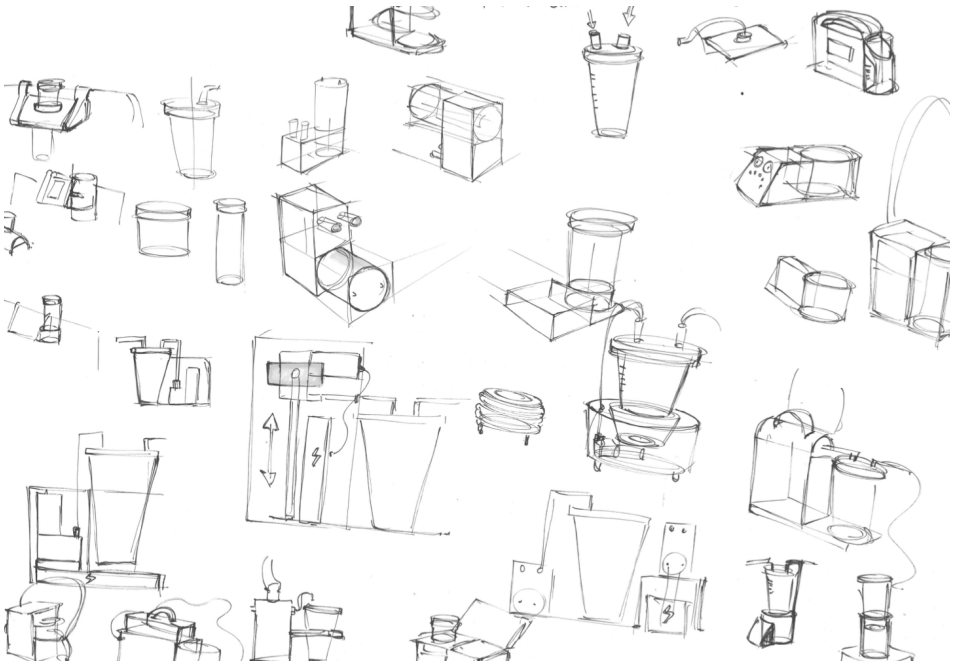
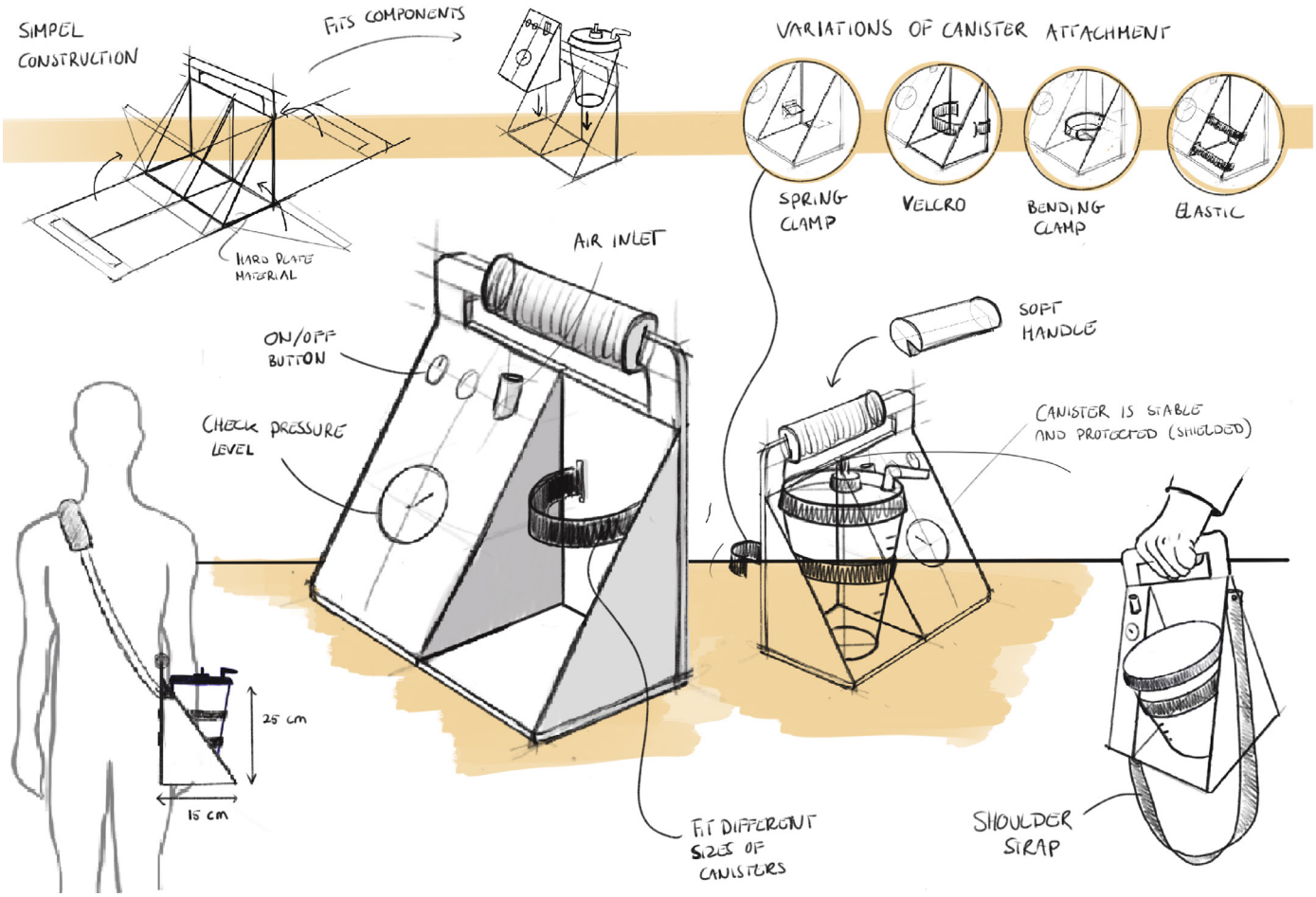


*Figure 53: Result of free drawing brainstorm activity on how to combine the existing components*

# 7.2. Concepts

At the end of the ideation, four ideas were selected and further explored. As a result, a total of four concepts is created and presented in this section.



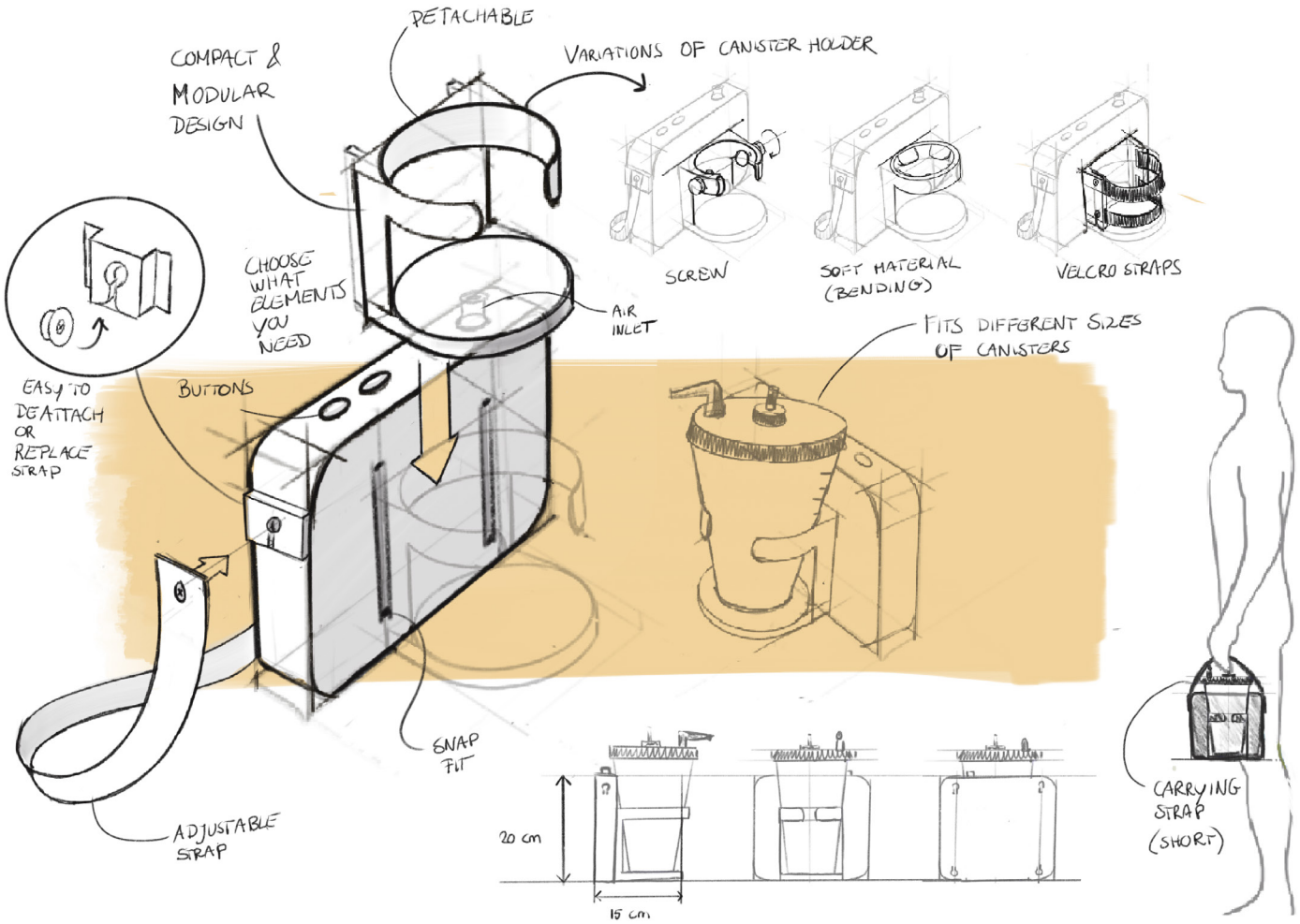

### 7.2.1. VacuRamp

This NPWT device is **simple** and **sturdy.** The design was inspired by coffee carriers, that are usually made of cardboard. The housing offers space for the canister, which is hold in place by a single adjustable Velcro strap. The canister is well protected and cannot be knocked over easily. The interface was placed on an angle, which makes it easy to monitor for the patient and caregiver, when placed on the ground or on the nightstand.

This device can be carried in various ways. The handle on top has a soft grip to quickly lift and move the device. For longer periods, it can be carried with an adjustable shoulder strap.

+ Simple design, easy to manufacture
+ Affordable materials
+ Easy to (dis)assemble
+ Canister is well protected and clearly visible
+ Easy to monitor, due to large interface

- Non-equal distribution of weight, canister tends to lean to one side
- Canister attachment is not secure, canister tends to fall out
- Velcro straps not suitable for conical shaped canister, due to small contact surface

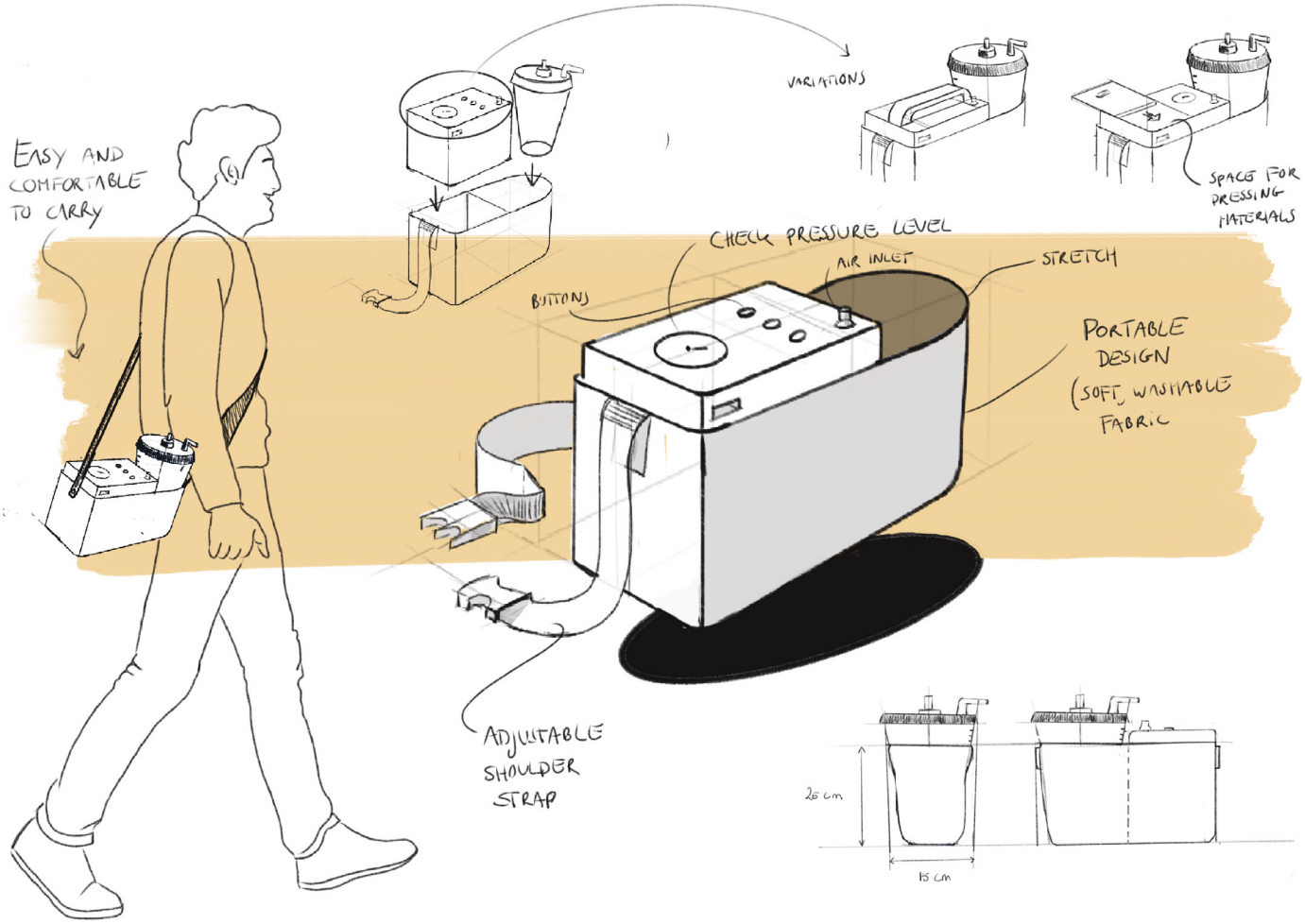



### 7.2.2. ModiVac

This NPWT device is **compact** and **modular**. The design was inspired by adjustable cup holders in vehicles. The housing only contains the pump, sensor and battery pack. The interface is minimal, sound and single lights will be used to communicate to the user.
Elements, such as the canister holder, can be added or easily removed. Removing the canister holder can be useful for cleaning or in case a canister is not needed during therapy. The adjustable straps can be attached to the device in multiple ways, which makes it possible to carry the device in any way that is preferred, for example in the hand, on the back, on the hip or even on the belly. Straps can be easily removed and washed. Elements can be easily removed and replaced, in case something breaks, which will increase the lifespan of this device.

+ Small and light
+ Modular, can be used in multiple situations
+ Elements can be removed and replaced
+ Adjustable to individual patient

- Unequal distribution of weight
- Canister is exposed and not securely attached
- Uncomfortable shape to carry
- Canister holder is fragile compared to the rest of the product




### 7.2.3. WoundBag

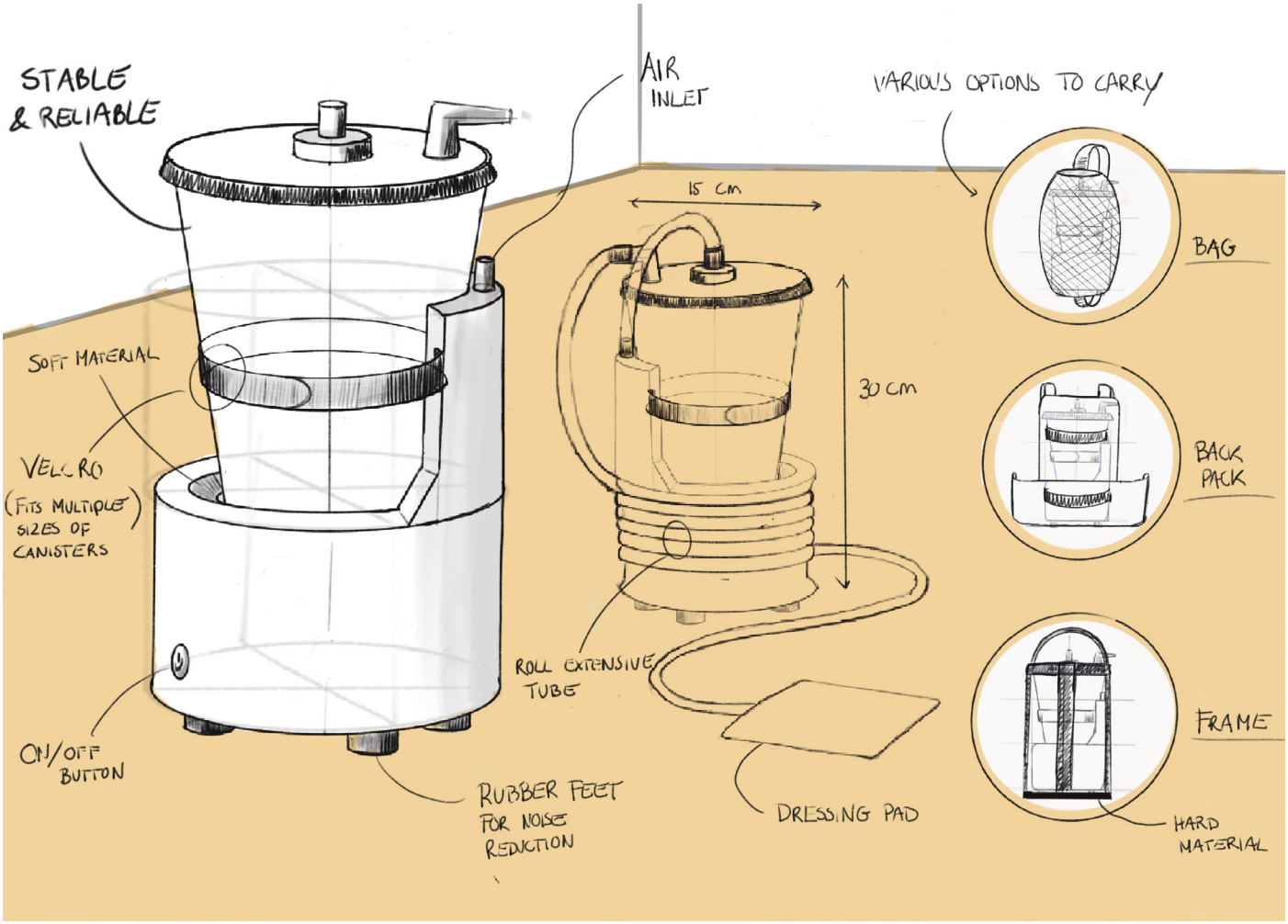
This NPWT device is focused on **portability** to improve **patient mobility**.

The idea is based on the design of a camera bag that has multiple compartments and suitable for prolonged carrying of delicate components. The therapy unit and canister are integrated in a soft bag, which can be carried just like a normal shoulder bag. The large interface is placed on top and is always visible.

Because the compartment for the pump and battery pack is quite large, it has space for additional features, such as the storage of dressing materials. A handle can be placed on top to move or lift the device quickly. The soft bag is made of washable fabric and has a basic shape, therefore easy to manufacture in a local sewing workshop.

+ Feels comfortable for the patient
+ Canister is enclosed and securely attached
  Easy to carry

- Large and bulky
- Poor visibility of the canister, smaller canisters are not visible at all
- A little shaky during walking
- Fabric can get dirty when placed in the ground or close to the patient




### 7.2.4. SuctionPillar

This device provides **stability** to the canister, during NPWT therapy. It was inspired by the shape of coffee machines. Ideally, the device is placed on the ground, next to the patient bed, or on a nightstand. The rubber feet are damping the movement of the pump and reducing the amount of noise. The canister is placed on top of the cylinder, which contains the internal components, including the battery and vacuum pump. Soft and stretching material surrounds the canister and a velcro strap was added to keep the canister in place. Due to the symmetric shape, the weight is equally distributed, and the canister will not fall over. The suction tube can be rolled around the bottom. The canister and the tubes look organised and are always clearly visible.
It is possible to take the device with you by placing it inside a bag or carrying frame.

+ Stable design, keeps canister in place
+ Equal distribution of weight
+ Symmetrical design is more appealing

- Difficult to carry
- Canister not well protected against impact
- Less robuust, due to fragile components

### 7.2.5. Evaluation

Four concepts are thoroughly reviewed (figure x, overview of concepts, appendix x scoring weighted criteria). All the concepts comply with the functional requirements. Taking the weighted criteria and the expert reviews into account, VacuRamp (concept 1) and the WoundBag (concept 3) score the best. WoundBag has the highest score on the weighted criteria. The specifications such as the comfortable portability, large interface and durability of the design are highly valued.

However, the WoundBag becomes dirty easily and has poor visibility of smaller canisters. Evaluating VacuRamp (concept 1), the most important advantages of the VacuRamp were related to the shape of the housing in which all canisters are fully visible. The housing is found durable, affordable and easy to manufacture. Hence, the advantages of the WoundBag will be combined by the advantages of the VacuRamp resulting in the final design. The design choices made in this iterative design process have led to a device concept that scores good on all the selection criteria.

# 7.3. Conclusion

The chosen concept is a fusion between VacuRamp (concept 1) and WoundBag (concept 3) with the desired modifications. The design will have a handle in the middle resulting in an even weight distribution and the canister will be placed in the middle of the device, above the internal parts.

Important takeaways from chapter 7, concept development:

- Modular design is not necessary and comes with difficulties, in terms of cleanability and durability. The design should be modular, but more in terms of possibilities to disassemble easily and add new features. This leaves room for changes in the design;
- Portability is important only to some extent. It should be possible to lift and move the device easily and the canister should be firmly attached, so the patient can move around freely and safely. However, comfort during carriage is not given the highest priority because carrying is probably uncomfortable for most patients anyway, due to their disabilities and mobility problems;
- In general, it is important that the device allows patient mobility in a sense that no grid power is needed, the device can be carried short distance and can be placed somewhere, during basic activities (going to the toilet and outside);
- Weight distribution of the product is important, as well as making sure that internal components are securely fastened and well protected.

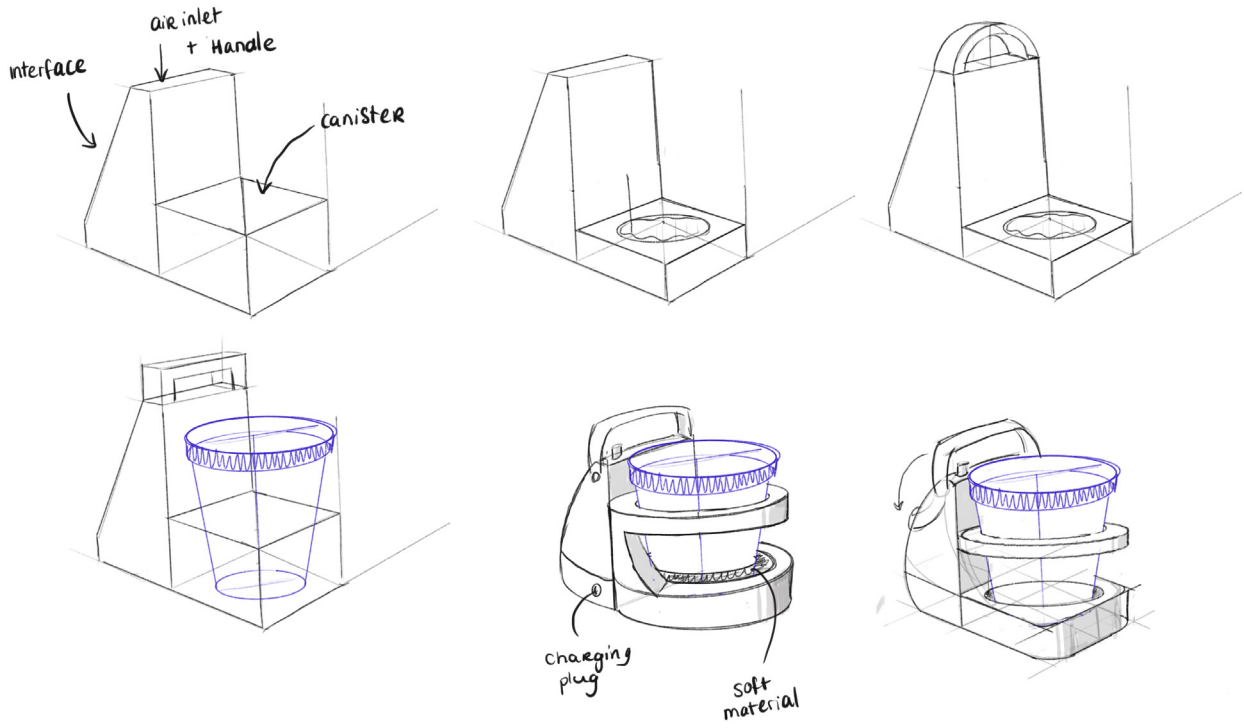



*Figure 54: Further development of the conceptual idea for the wound pump.*

CHAPTER 8

# FINAL DESIGN

This chapter presents the final design proposal for the WOCA wound pump. It contains an overview of the design, specifications, and its special features. Furthermore, it explains the use, followed by a detailed list of components, specifications and an estimation of the costs. The chapter ends with a proposed strategy for the implementation of the WOCA wound pump in resource-poor hospitals in LMICs.

In this chapter:


WOCA

# 8.1. Overview

The WOCA Wound Pump is a simple, cheap and robust NPWT device. The battery powered, reusable vacuum pump is portable and can be made completely from locally sourced components. This affordable wound pump is fully compatible with standard canisters and self-made wound dressings. All components are replaceable which ensure a long lifespan. WOCA effectively and safely heals chronic and complex wounds, especially for the people who need it most.

*Figure 55: Back-side render of the WOCA Wound Pump*

*Figure 56: Front view of the WOCA Wound Pump*

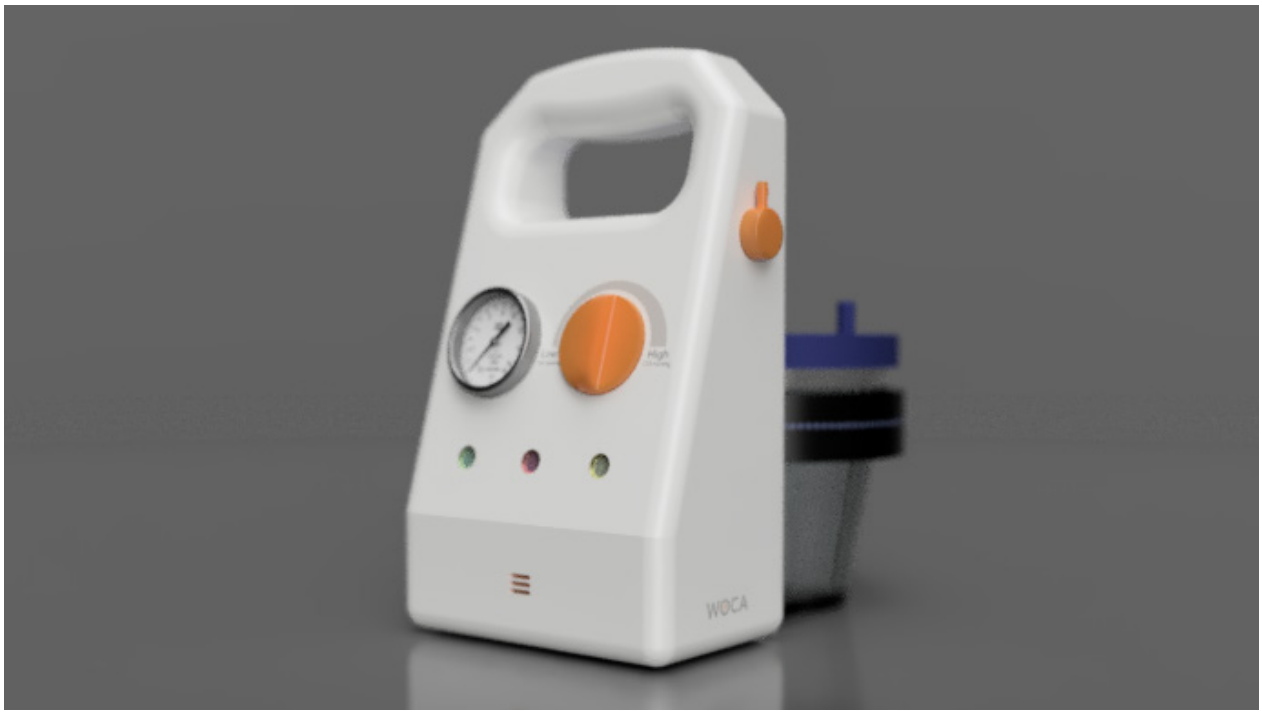



*Figure 57: Front-side render of the WOCA Wound Pump, including the canister (800 mL)*

# WOCA

A battery powered wound pump
designed for low-resource settings


- Includes **automatic** pressure control
- **Compatible** with self-made dressings & standard canisters
- **Portable** design, battery lasts for 15 hours
- **Simple** interface, enables smooth operation & monitoring
- Easy to repair with **widely available**, replaceable components

# 8.2 Features

The WOCA wound pump has been designed for use in low-resource settings by medical staff members and patients of resource-poor hospitals. As a result, the design includes several special features that are presented in this section. Each of these aspects is also discussed in more detail in the next chapter, Chapter 9: *Design detailing.*

### 8.2.1 Pressure control system

WOCA automatically controls the pressure that is applied on the wound area. A pressure sensor and microelectronic are integrated to regulate the system pressure by adjusting the pump speed, using the sensor data as a feedback. This is not only energy efficient, but also ensures effective treatment, according to medical guidelines. The pressure can be set in a range of -80 mmHg to -125 mmHg, turning the big knob clockwise.
A mechanical safety valve is integrated and releases when the system pressure exceeds the limit =125 mmHg. Hence, the pressure is always managed within a safe range. Another feature called 'seal check' is included to communicate if the pressure level is OK (green light) or the pressure is outside of the acceptable range (red light). Additionally, the manometer on the left provides extra feedback and can be used as a reference of the actual system pressure.

**Air leakage**
This device is designed to be compatible with self-made dressings and therefore includes a vacuum pump with a higher flow capacity, compared to other NPWT devices. Hence, it can deal with a higher leakage ratio
Secondly, the device has air leak detection, starting with a red light indication, as was explained before, followed by a sound alarm if the pressure is lost.

- *Automatic pressure regulation within 10% of set pressure*
- *Options for low (-80 mmHg) and high (-125 mmHg) negative pressure (also adjustable in between)*
- *Seal check with light indications*
- *Flow capacity of 4.5 L/min*
- *Air leak detection with audiovisual feedback*

### 8.2.2 Portable design

The WOCA is a portable device that is easy to relocate. Due to its limited dimensions and weight it can be easily lifted and relocated by staff members or patients. Meanwhile, the device is designed to treat larger wounds and provides stability and protection of the canister. Therefore, the device can be safely placed on the ground or bedside table. Patients with mobility problems can take the device to the restroom or outside, which increases their mobility and gives a feeling of freedom.

- *Dimensions: 24cm x 24cm x 15cm*
- *Weight: 1.2 kg*
- *Ergonomic handle*
- *Fits in regular camera bag*

### 8.2.3 Rechargeable battery

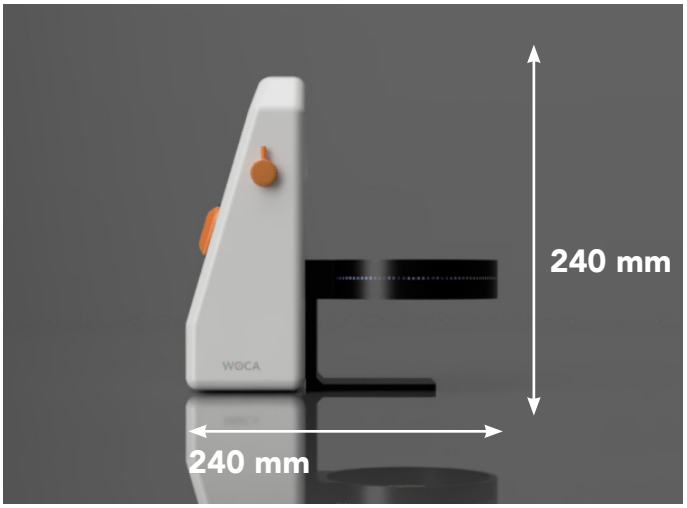
The WOCA includes a rechargeable battery that lasts for 15 hours when the pump runs continuously at full speed. Hence, it can be used outside during the day and recharged during the night. Moreover, it will operate during (small) power cuts. Recharging the battery can be done simply by plugging the external charger into a power socket, e.g. at the patient's bedside, while the device is still on and treatment continues.

- *Power consumption: ~ 6W*
- *Rechargeable battery (12V, 9900mAh)+ adapter*
- *Lasts for 15 hours without charging*
- *Includes battery indicator*

### 8.2.4 Canister holder

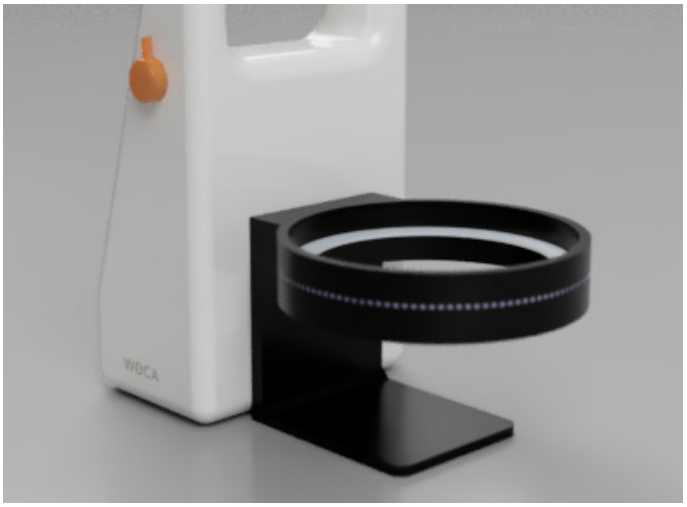
Due to the canister holder design, the WOCA can hold different canister models. This was made possible through addition of a soft part (rubber ring) inside the canister holder. This rubber ring provides support, but also flexibility and the canister can be easily removed and emptied.

- *Canister holder fits canisters (800 - 1000 mL)*
- *Soft ring is interchangeable*




*a) Dimensions of the WOCA*


*b) Dimensions of the WOCA*



*c) Canister holder*

*d) Battery indicator and jack plug for charging*

*Figure 58 a-f: Rendered features of the WOCA Wound Pump*

### 8.2.5 Interface

The WOCA is designed for simple operation and provides relatively fast application. The enlarged, angled interface is clearly visible, also from a top view when the device is placed on the ground. The turning knob enables one-button operation for adjustments to the pressure settings and includes 2 predetermined options for low (-80 mmHg) and high (-125 mmHg) vacuum to avoid misuse. Secondly, the WOCA is intended to be monitored by patients and therefore includes a yellow light that indicates unwanted events during treatment and can be easily recognized by the patient. The patient can call a medical staff member for help

- *Enlarged, angled interface*
- *One-button operation to set pressure*
- *Yellow light to communicate problems*

### 8.2.6 Safety alarms

The WOCA  includes several features to increase the safety of the treatment that is provided. This includes early detection of a number of common or high-risk complications and the integration of intuitive and convenient alarms to notify the end users. WOCA is equipped for the following 5 scenarios: Pressure loss (1), infection (2), tube blockage (3), loose connector (4), bleeding (5). These are further discussed in Chapter 9: *Design detailing.* Three lights (red, green, yellow) are integrated to indicate problems that require intervention of a medical staff member. In case of an urgent event, a sound alarm is added.

- *3 lights (green, red, yellow) to communicate issues*
- *Includes speaker (Hz)*

### 8.2.7. Internal parts and housing

The WOCA is designed to be locally repaired with standard tools and minimal skills. The internal parts (pump, battery, interface, fixations) are standard components that are either purchased online, locally sourced or locally manufactured.
The orientation of internal parts as well as the design of the housing, enable complete disassembly of the product. Hence, broken parts can be replaced with spare components increasing the product life span. The housing parts, as well as the canister holder, can be reprinted and replaced. Repairs can be done without involving a specialist, as it does not require special skills tools. This ensures that the WOCA can be repaired in a low-resource setting.

- *Housing*
- *Standard and widely available components*
- *Customized parts are 3D printed*

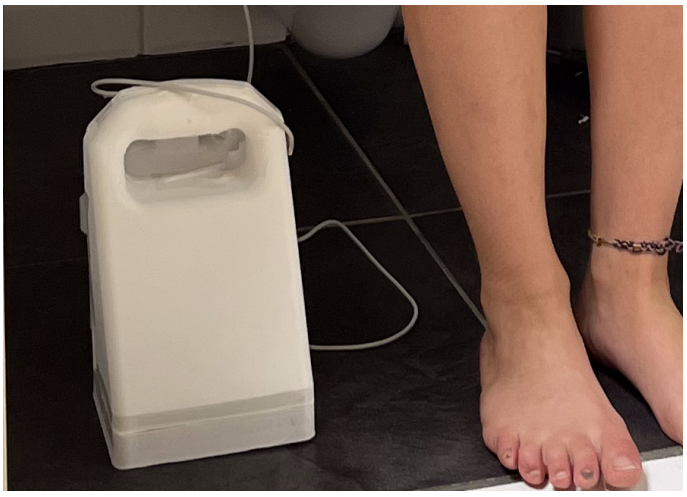
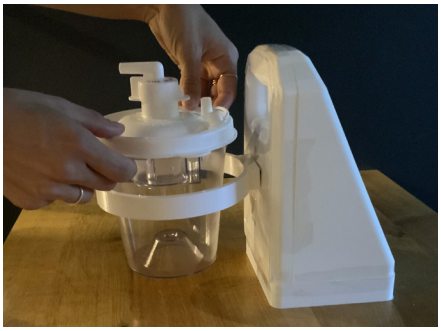


*Figure 59: Toilet visit with WOCA*

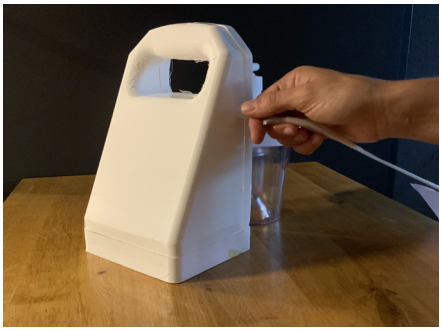
*Figure 60: Demonstrating portability of the design*

## 8.3 Use

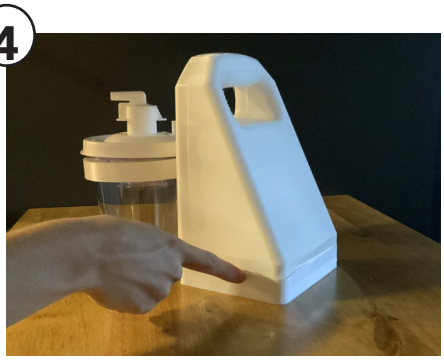
The user scenario of the WOCA is intended to fit the treatment procedure and workflow of the medical staff at Green Pastures Hospital, as described in 3.4 *Patient journey.*



1. Place canister



2. Connect dressing tube




3. Turn device ON


4. Adjust pressure


5. Check sealing & start treatment

6. Lift to relocate device

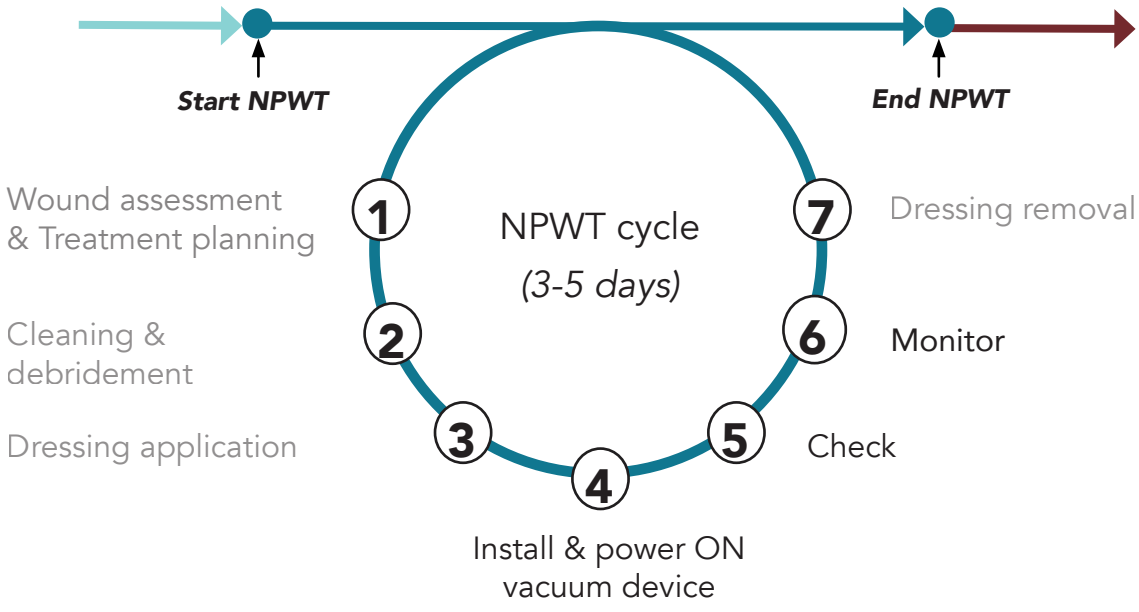



*Figure 61: Presents the user scenario for the envisioned device that is intended to match the current workflow of the medical staff at GPH.*

# 8.4 Specifications and costs

In this section, the technical specifications and costs estimation for the WOCA wound pump design are discussed. Note that this design is a first proposal that can be used as a starting point for further development. The embodiment design does not yet include all the details, as more design iterations will follow, including the realization of a prototype. Recommendations on further development

### 8.4.1. Specifications

The WOCA wound pump can be described according to the following specifications:

- Size: 24cm x 24cm x 15cm
- Weight: 1.2 kg
- Pressure range: -80 to -125 mmHg
- Operating mode: Continuous
- Flow capacity: 4.4 L/min
- Canister included: No
- Power consumption: ~ 6W
- Battery runtime: 15 hours
- Voltage: 12V, charged on 220V grid power

### 8.4.2. Bill of Materials (BoM)

Figure x shows a cross-section of the 3D model that shows the internal components of the WOCA. An overview of the main product components is added. The complete Bill of Materials (BoM) for the final design is included in Appendix X.

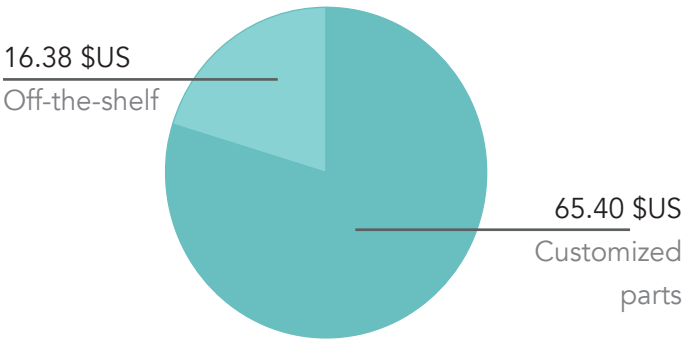



*Figure 62: Pie chart of the costs of the components*

### 8.4.4. Estimation of costs

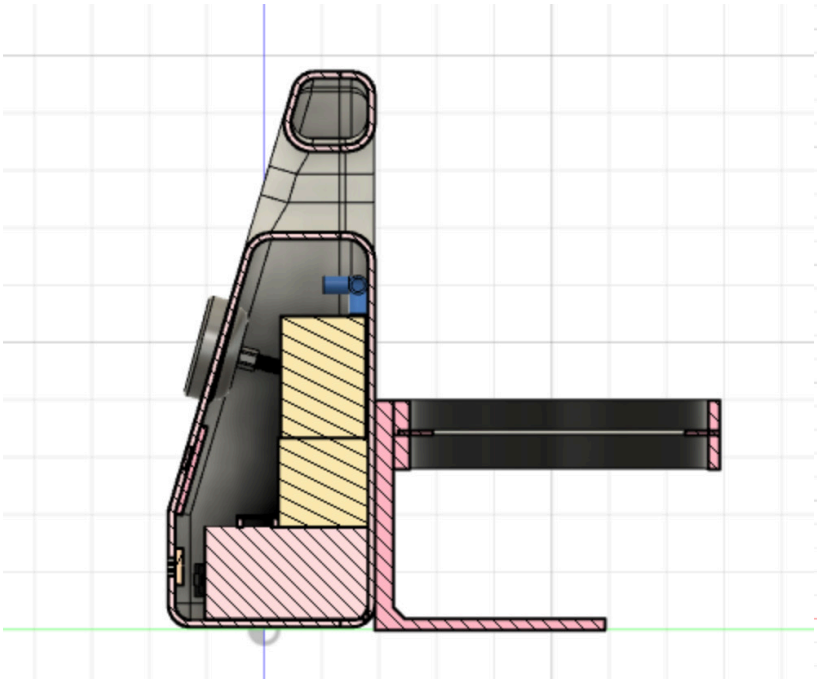
The goal of this section is to provide a general idea of the costs that can be expected when this design is produced in a batch size of 10 products.

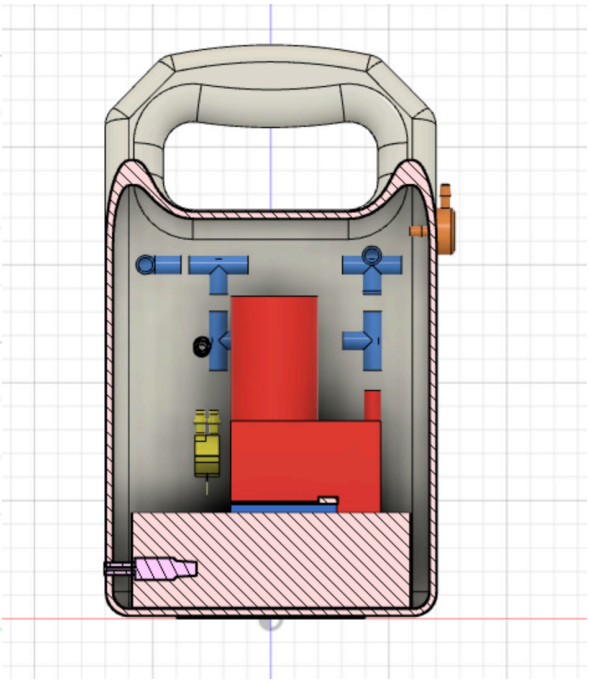
This final design proposal for the WOCA consists of standard **off-the-shelf parts** and a number of **customized parts.** Off-the-shelf parts can be either locally sourced or ordered online (ordering list is included in the BoM in Appendix x). Prices are based on info provided by suppliers on Aliexpress and Alibaba.

Customized parts can be 3D printed, either produced in house, if a 3D printer is available, or outsourced to a local manufacturer. These production costs are calculated based on prices for PETG filament and energy consumption (see Appendix X). The total costs for both categories of components are shown in table x and x and presented in figure x.

The total price for all product components will be around **82 USD.**

Additional costs that are excluded in this analysis are: Shipping costs, costs for the canister, dressing material and suction tube, laboring costs. These costs are estimated to be > 100 USD. Hence, this design can be realized for less than 250 USD.





| # | Part name | Estimated price ($US) |
|---|---|---|
| 1 | Vacuum pump | 40 |
| 2 | Pressure sensor | 4.5 |
| 3 | MOSFET driver | 0.35 |
| 4 | Arduino Nano | 2.24 |
| 5 | Potentiometer | 0.05 |
| 6 | Battery pack (incl. charger) | 8.87 |
| 7 | Switch | 0.182 |
| 8 | LED | 0.02 |
| 9 | Speaker | 0.6 |
| 10 | Manometer | 3.3 |
| 11 | Vacuum relief valve | 1.02 |
| 12 | Internal tube | 0.31 |
| 13 | Connector L | 0.7 |
| 14 | Connector T | 1.26 |
| 15 | PCB | 2 |
| | **TOTAL** | **65.402** |

Table 1. Cost estimation of off-the-shelf components

| # | Part name | Estimated price ($US) |
|---|---|---|
| 16 | Housing front | 6.7836 |
| 17 | Housing back | 3.7538 |
| 18 | Turning knob | 0.2005 |
| 19 | Tube connector | 0.08561 |
| 20 | Canister top | 1.2142 |
| 21 | Canister L | 3.1316 |
| 22 | Canister bottom | 1.2142 |
| | **TOTAL** | **16.38353** |

Table 2. Cost estimation of customised parts

### 8.4.3. Road map for manufacturing

At the start of this project, a small batch size of 10 devices was defined. These products are intended for use at the Green Pastures Hospital and two smaller clinics in Banke and Surkhet. Nevertheless, this project has the potential to make a larger impact when it can be extended to other hospitals in LMICs. Therefore, a roadmap for manufacturing is described.

**STEP 1: Batch size < 10**
At this stage of the project, the suggested method to produce the customised parts required for this design is 3D printing (PETG). This method is recommended due to the small batch size and early stage of development, as it provides freedom to make changes and quickly reprint components. PETG is chosen, based on its characteristics [ref] and the fact that it was successfully used for other products designed for low-resource settings [ref].

**STEP 2: Batch size 10 - 100**
When upscaling the production to a larger batch size (>100), a more suitable method for manufacturing is rotational moulding. Investment costs are relatively low due to low tooling and machining costs [[49]. A suitable material for this would be polyethylene (PE), because it is economical, suitable for rotational moulding and has a good impact resistance[50].

**STEP 2: Batch size > 100**
When further upscaling the production to a batch size > 100, for example to extend production to other countries, it is suggested to switch to injection molding, as the investment costs will level out and production will be cheaper. A suitable material for injection molding would be **Acrylonitrile Butadiene Styrene (ABS)**, which is widely used to make housings for electronic devices [50].

More information on manufacturing is included in Chapter 9: *Design detailing*

## 8.5 Implementation strategy

The implementation strategy is an important part of the success of WOCA. Without a solid implementation strategy, a successful introduction of the device is not possible. Therefore, a thorough implementation plan including the key stakeholders has to be set up before full introduction of WOCA. This paragraph gives guidance on the important aspects of a successful implementation strategy of WOCA.

Woca should be available to all interested hospitals. WOCA is open source. The complete design is freely available on the internet. Therefore, hospitals in LMICs can download all the design CAD-files with the manual online. All parts can be ordered online in Nepal or can be 3D printed with the free available 3D printing files. Training and instruction videos will be also provided online. Personal assistance can be bought for a small fee.

Start a collaboration with non-profit and medical organisations working in LMICs countries. The potential of WOCA should be known to the key organisations. For instance the red cross has a large network in Nepalese hospitals. This can be used to introduce WOCA in those hospitals.

Monitor and improve. The effect of WOCA should be monitored. Assistance for the implementation should be available for multiple years, preferably decades. In this way the effect can be measured but also the device itself can adapt to changing context and wishes of the users.

CHAPTER 9

# DESIGN DETAILING

This chapter elaborates on the previous chapter and provides the background information to substantiate key design decisions. Furthermore, in this section one can find the iterations that were required to arrive at certain solutions.

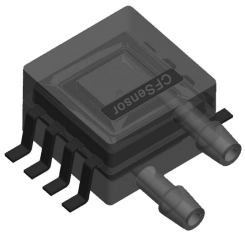
In this chapter:

# 9.1. Pressure regulation

The second design challenge includes the control the pressure level to ensure it is maintained within the adequate range.

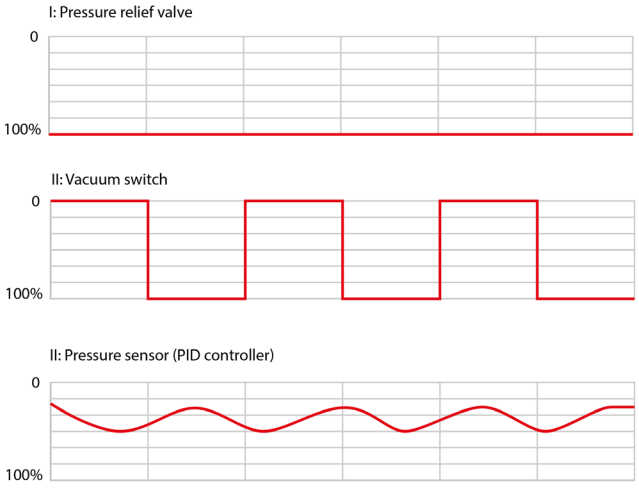
### 9.9.1 Starting point

The AquaVAC pump had a fixed speed, no adjustments could be made. The pressure was regulated with one valve.



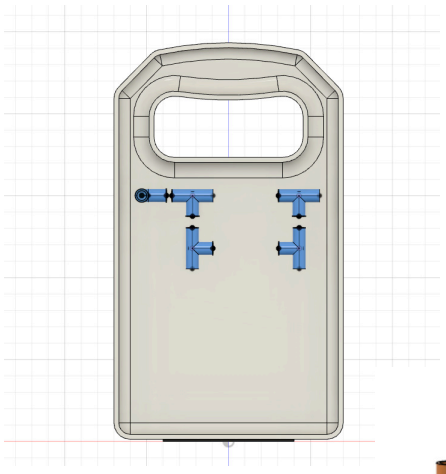

### 9.9.2 Active pressure control

Already in Phase I, various different air pumps were tested to find out if the pump characteristics matched the range of operation required for this situation and if the level of -125 mmHg could be reached. Because none of the evaluated pumps was found to meet the desired criteria, a 12V DC air pump was selected for the 'proof of principle' (see chapter 6: Proof of principle). Insights from these tests revealed that the pump easily reached a maximum pressure of -467 mmHg, which is too strong and therefore this pressure must be regulated.

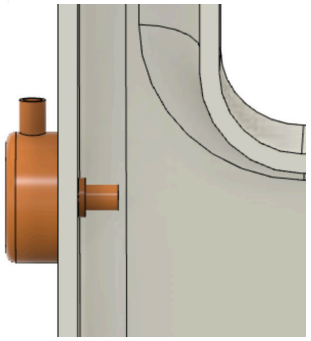



In the first prototype (6.2: *Prototype*) the pump speed was manually adjusted with a potentiometer. Three options were defined to automate pressure regulation: (1) vacuum relief valve (see figure x), (2) vacuum control switch and (3) pressure sensor with controller. The difference is shown in figure x.

The decision was made to go for the third option, because even though a high level of accuracy is not required, active pressure control is more energy efficient and pressure is easier to manage in case of leakage. Additionally, the first option, a vacuum relief valve is integrated as well but purely as a safety stop

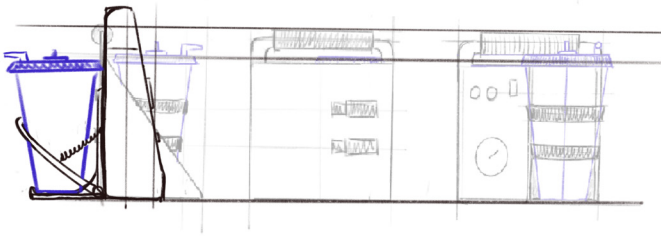


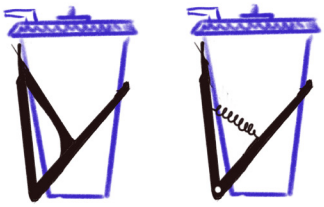
**Final result:** A conceptual idea for a PID pressure controller, shown in figure x.



# 9.2. Canister integration

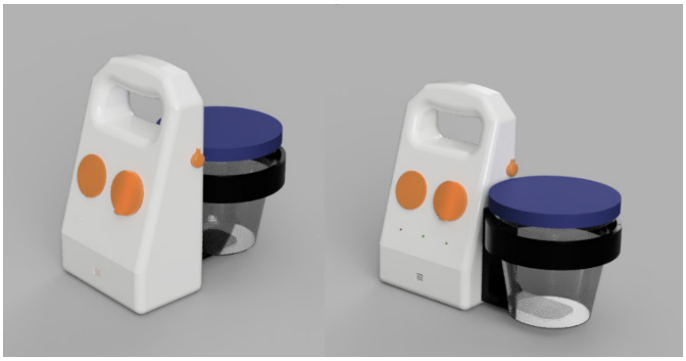
Designing the canister holder was one of the bigger challenges to be overcome. The corresponding design decisions come in two parts. Firstly, where the canister needs to be stable and tight during usage, but on the other hand it should also be easily be removed when the canister needs to be emptied. Secondly, one important requirement was to use locally available canisters, but there are great varieties in shape and size. This makes it hardly possible to assemble something on the canister.





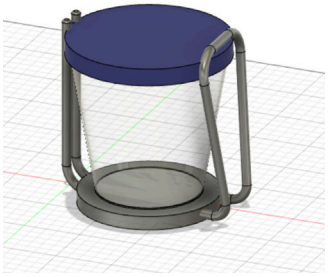
### 9.2.1. Starting point

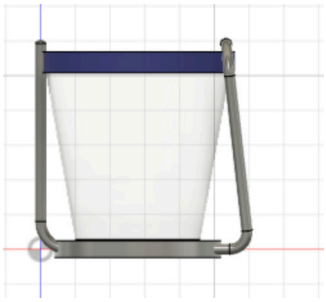
Currently, the staff at GPH uses a glass jar (2000 mL) to collect wound fluids with the AquaVAC.
The problem was that the canister was not integrated and a lot of tubes were involved.



### 9.2.2. Determine canister size range

After the 'proof of principle' it was decided to use an off-the-shelf canister. Therefore, the design had to fit standard canister models. A parametric design method was used to determine what would be an acceptable range of diameters to fit the canister holder. Figure x shows how this range was chosen.



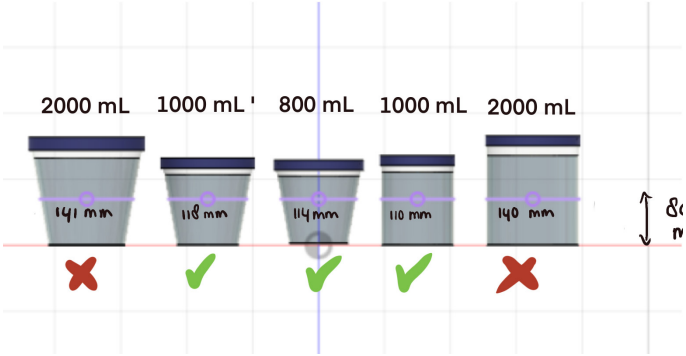


### 9.2.3. Develop canister holder

Several brainstorm sessions were done on how to fit different canister into one holder. Different methods were considered and tried in card board models,  using both elastic and velcro. Eventually, the decision was made to use a relatively simple, circular base with a connection made from rubber. This allows for both the conical as the straight canisters to fit, and for different diameters and ranges.

**Final result:**
The WOCA has a canister holder to attach the canister to the device, so the entire thing can be moved as one product. The canister holder fits canisters between 800-1000 mL, with a diameter range of 100-120 mm

The above mentioned solution allows for further optimization when one is aware of the canisters that are at present in the local hospitals.



# 9.4. Safety features

The first priority, after having a functional device with integrated canister, is to guarantee improve patient safety. Hence, the next priority is to solve this issue with the envisioned product.

### 9.4.1 Starting point

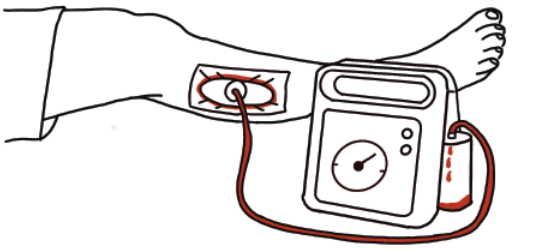
The AquaVAC had no safety features included, except for a valve for pressure limitation.

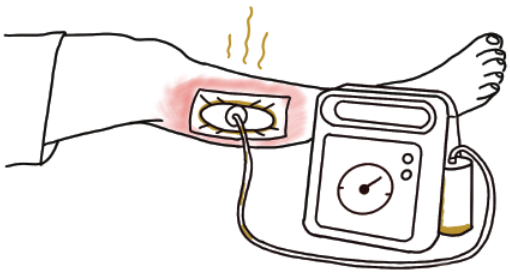
First, five scenarios are chosen in which the device should signal, based on FDA reports on errors and complications. If there are too many signals, the doctor or caregiver would not be as alert in case of an event. Moreover, it makes it easier to monitor. Even without a medical background, unwanted events are easily recognised.  There are three lights on the device which all signal different events. In case of an urgent event, the device will sound an alarm.

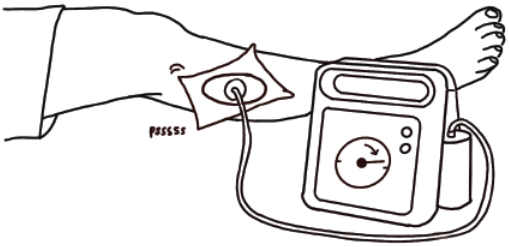
- WOCA constantly monitors pressure to ensure effective treatment
- WOCA has transparent canister and tubes to monitor fluids (signs of infection)
- WOCA can detect tube blockage + alarms user
- WOCA can detect a loose connector + alarms user, to prevent spillage of fluids (contamination)
- WOCA is used in combination with a canister that has overflow protection that prevents excessive blood loss, the safety alarm (due to pressure change) warns the user to check on the patient.

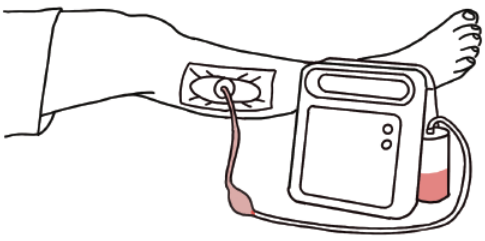
**Final result:** Safety alarms to detect errors and/or complications.

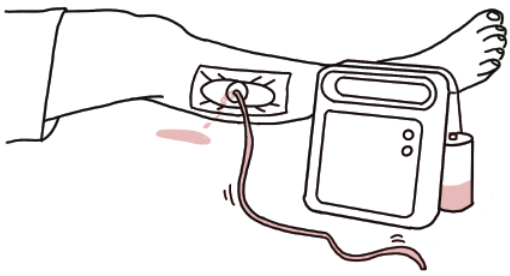
Situation











# 9.3. Power and portability

A portable device is expected to increase patient comfort by increasing their mobility and independence. One of the limiting factors is the power supply, which is therefore one of the issues that must be solved.

### 9.3.1 Starting point

The AquaVAC was not portable, because it has to be attached to the grid power. Moreover, it was only suitable for 110V and therefore a converter was always required.

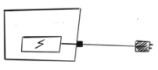
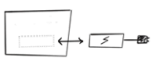
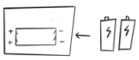
Different factors contribute to the portability of the product are described below.

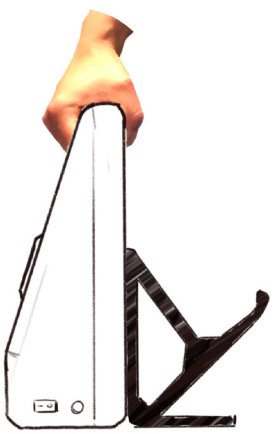
- **Dimensions and weight** of the pump have been kept to the minimum required values, to avoid any undesired additional usage of materials and keep the product as concise as possible. In order to come to the final design of the vacuum pump, a deliberate decision on the composition of the separate elements was made. The first key requirement was the distribution of weight of the inlet and outlet with respect to the tubes.

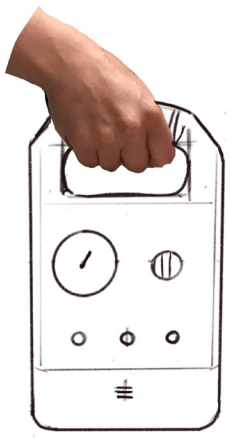
- **Battery powered systems** make it possible to move around without being connected to the grid. A battery powered system means that the device can be used without the absolute necessity of local power supply. Based on the chosen design for the pump, and a thorough calculation of the energy usage, the choice was made for the most efficient battery. The battery lasts for over 15 hours. This is calculated by a rough estimation of the energy consumption of the device and coupling that to the most cost-quality efficient battery which is locally available and suitable for the device. As soon as the electronic circuit is further developed, more precise tests can be done.

- The design includes two different features to allow for easy **transportation i**n different circumstances. A handgrip can be used when the product is carried over short distances, but a shoulder strap offers a comfortable way to carry the product over relatively longer distances, for example with sanitary visits. Both the hand grip as the shoulder strap should be attached in a strategic place with respect to the centre of weight of the product, which can vary when the canister is either full or empty.

**Final result**: WOCA includes a rechargeable battery pack and therefore it can be taken anywhere

| Type | Pros | Cons |
|---|---|---|
| Fixed battery  | • Battery cannot get lost<br>• Easy to charge (Plug-in)<br>• Durable, because no moving parts or wear of battery or casing<br>• Cheap | • Battery cannot be charged outside the device, it has to return to a wall socket to charge<br>• Device cannot be used in case the battery is empty and there is no power source (no back-up)<br>• Repair takes more effort; device must be taken apart |
| Changeable battery (2x)  | • Battery can be charged outside of the device, while the device is used in another location<br>• Changing and charging a battery is a common thing to do<br>• A back-up battery is available in case of unexpected empty battery<br>• Batteries last longer due to less intensive use | • Risk of battery getting lost<br>• Risk of forgetting to charge the back-up battery<br>• Broken battery can be easily replaced<br>• Battery should have protective casing<br>• More expensive compared to fixed battery, due to the casing |
| Single-use batteries (standard)  | • Available in local shops everywhere in the world<br>• Used for other domestic electronic devices, these batteries can be used in case of emergency<br>• Not dependent of grid power | • Not sustainable, causing harmful waste<br>• More expensive on the long-term<br>• If no batteries are in stock, the device cannot be used (dependent on battery stock) |





# 9.5. Operation and monitoring

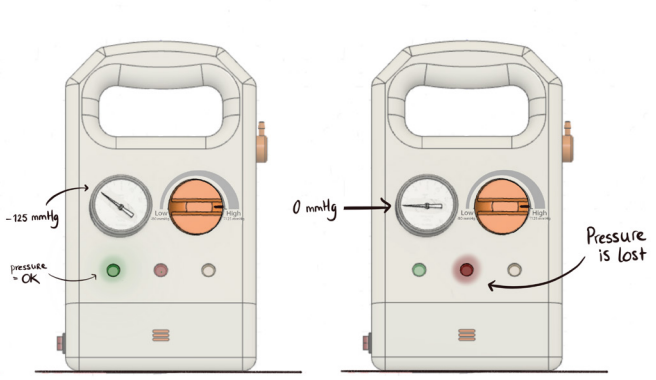
The envisioned device must be as simple as possible. This will be the challenge regarding the interface of the envisioned product.

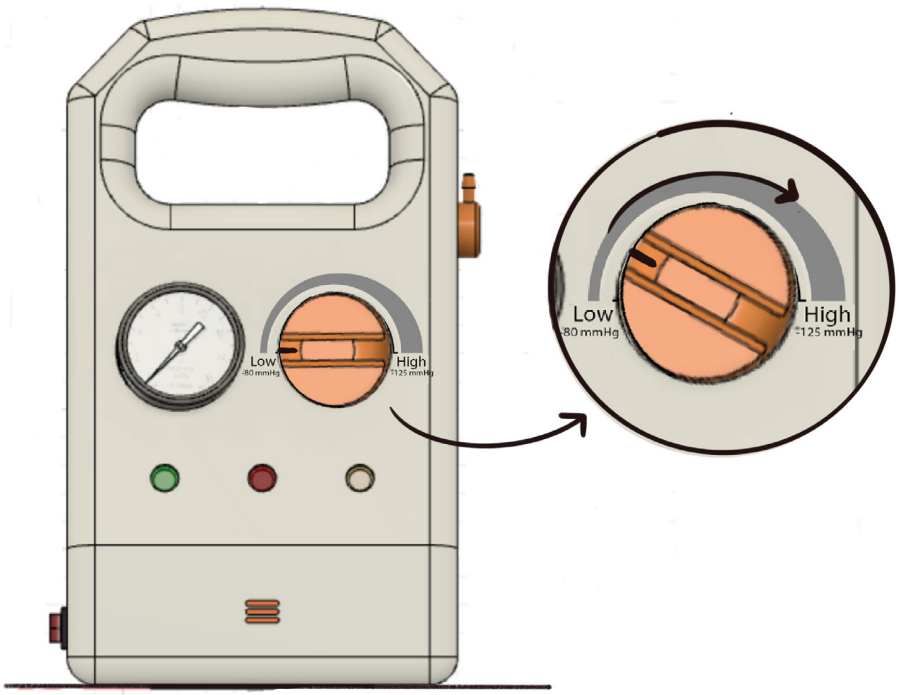
### 9.5.1 Starting point

The AquaVAC had a limited user interface, the only reference that was used included a manometer to check the pressure.

The interface is chosen to facilitate an easier way of monitoring for both the patient and the caregivers. The choice for adding a manometer can be explained as an extra check for the medical staff, since it shows the current qualitative state of the product and gives insight into the need for maintenance. The rotary knob is the preferred choice when there are a few standard settings, in this situation the staff can easily switch between the two standard settings in place. Three lights in universal colors (red, green and yellow) provide an intuitive way of communication. The lights are supported by an auditory signal, which is only enabled in case of emergencies, when immediate action is needed from the medical staff.

**Final result: T**he WOCA has an enlarged interface and one-button operation that enables easy monitoring for the patient and caregiver, as well as intuitive operation for the medical staff.



# 9.6. Manufacturing and repairability

For successful implementation on the long-term, it is essential that the product can be locally made and repaired. Therefore, this is one of the design challenges.

### 9.6.1. Starting point

The AquaVAC was donated an purchased in the US. In the past, there were two machines, however, one of these broke down and could not be repaired. Only one device is used ever-since.

- **Make use of standard components**

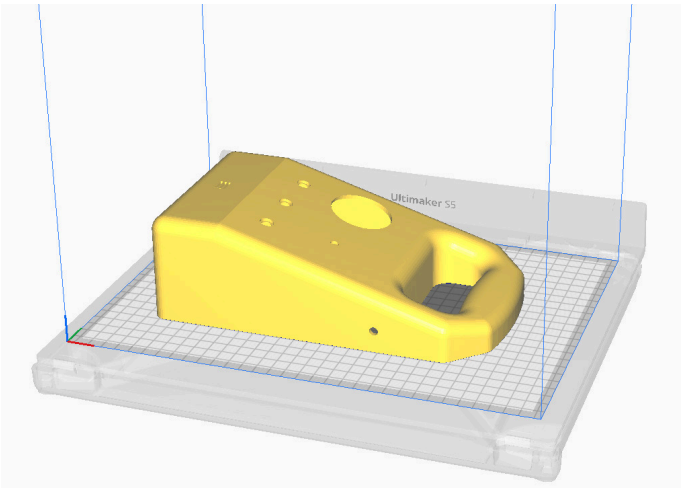
Moreover, the small number of different components makes it a low maintenance product. The fact that the device will often be carried  to different locations, makes it important that the different parts are assembled solidly and that the body of the product is shockproof.

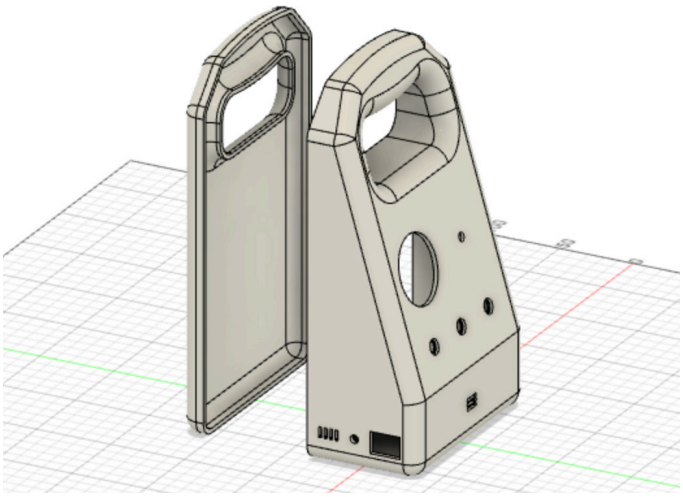
- **Design for disassembly**

Next to this, one needs to make sure that the product can be disassembled and again assembled without any consequences. The body is designed in such a way that the front part can be easily disassembled, so that all other subparts can easily be reached. Everything is attached with the use of screws rather than glue, which means that subparts can be replaced, lengthening the lifecycle of the product as a whole.

- **Local manufacturing**

Lastly, the 3D print-bed of the vacuum pump needs to comply with the allowable design dimensions.



CHAPTER 10

# CONCLUSION

This chapter concludes the reports. It describes the most important insights and findings. The paragraph evaluation provides information of the validation and evaluation of the final design based on expert review and a check on the defined requirements. The conclusion pinpoints the most important insights taken from this research, the crucial design solutions and a view on how to proceed with the project. At last, the process of the design research is reflected upon.

In this chapter:

# 10.1 Evaluation

## 10.1.1 Expert review

The design is validated by expert review. Suraj Maharjan, a plastic surgeon already working at GPH with vacuum wound therapy, provided feedback on the current design. His feedback is important because he has knowledge and experience with the treatment in this particular context. The interview was focused on the medical perspective. This was done if WOCA meets the clinical needs that were determined at the end of Phase II (effect on healing, applicability, usability, portability, noise, cleaning, safety). Furthermore, his general opinion on the design proposal and associated features, as well as the proposed strategy for implementation and his vision on how to continue this project. The pressure regulation was marked as the most important feedback in relation to the design. In general, WOCA was indicated as a good design that would work in the context of GPH. In the next paragraph the most important feedback is summarised and certain design iterations based on this feedback are explained.

**Pressure regulation**
Based on theory, the pressure settings are minimised to two prefixed options: low (-80 mmHg) to high (-125 mmHg). Former research shows that two options of pressure are enough to provide safe treatment and more variation in pressure will not have a positive effect on the treatment. However, the doctor at GPH prefers to have the possibility to change the pressure. In his opinion this was an important feature and only two pressure options were insufficient. During current treatment processes, the pressure is frequently altered based on the wishes and needs of the patient. Because, the willingness of the doctor to use WOCA is important to its success. The option to have variation between the two prefixed settings has been made possible. Even so, this necessity should be validated by a multitude of medical staff in the same context.

Another design iteration that was based on the expert review is the height of the safety threshold. The level of the mechanic safety valve was -200 mmHg. In practice is -125 mmHg already sufficient. With higher pressure rates, complications can occur in the treatment.

**Air leakage**
The WOCA can detect when the pressure level is changing and therefore can warn the user in case the pressure is lost and there might be an air leak. The red light will be the first indication that the pressure is not OK. When the pressure is $< -30$ mmHg the sound alarm will go off. This was marked as a good feature. The alarm is especially useful because WOCA is not always monitored visually.

**Canister integration**
Another important feature of WOCA is related to the canister integration. The device is compatible with widely available, standard models of 800 mL or more. The ideal canister size is 300 mL, but due to the low availability of these canisters online the design is suitable for larger canisters. Suraj endorsed this and stressed the wish to have a smaller canister because this will improve the treatment. Currently, 2000mL canisters are used, so 800 mL would already be an improvement. If in the future smaller canisters would be widely available, WOCA could be easily transformed into a model that is compatible with smaller canisters. Moreover, Suraj endorsed the stability and the canister configuration as suitable.

**Portable design**
A battery powered and portable device is a profound improvement in relation to the current AquaVAC. The patient comfort has improved greatly. Moreover, the device is now secure for power cuts. In GPH they had recently a power cut of half a day. In the case of using WOCA, this will not influence the treatment. In the expert opinion the design was very suitable to carry and has a long enough battery to only charge at night which was intended.

**Safety features**
The Nepalese doctor was especially happy with the safety alarm for bleeding. Bleeding could seriously harm the patient and therefore should be detected as quickly as possible. The alarm sound next to visual alarm signals, has added value. The other safety features are seen as positive but not as important as the bleeding

**Operation and monitoring**
Suraj commented that the device most probably will be placed under the bed. In this way, the device will not be knocked over by accident. Other places (like a nightstand) could also be possible, but is currently not intended. This makes the audio alarm feature extra important.

### 10.1.2. Evaluation of criteria

The final design is evaluated based on the defined requirements. The list of requirements was combined through design, literature research, context analysis and expert review. The final design is made in such a way that in theory almost all requirements are fulfilled. The next step is to test on those requirements in a real-life context (end-user testing at GPH).

The table presented on the next page, gives a clear overview on which requirements WOCA were satisfied and which improvements still need to be made

| Groep | # | Req / Wish | Description | Score |
|---|---|---|---|---|
| Pressure | 1.1 | Req | The device can create and maintain a pressure level of -125 mmHg during one treatment cycle (3-5 days) | T |
| | 1.2 | Wish | The device has one default pressure level of -125 mmHg and one adjustable pressure level of 80 mmHg | T |
| | 1.3 | Wish | The device can self-regulate the pressure within 10% of the indicated pressure range | T |
| | 1.4 | Req | The device has a (mechanical) safety stop to ensure the pressure level will never exceed -125 mmHg | T |
| Air flow | 2.1 | Req | The device is able to overcome an air leak ratio of 0-100 ml/hr | V |
| | 2.2 | Wish | The device is able to overcome an air leak ratio of 100-3000 ml/hr | T |
| Fluid flow | 3.1 | Req | The device is able to extract fluids from a wound with a flow rate ranging from 1-300 mL/day | V |
| Fluid collection | 4.1 | Req | Wound fluids are collected into a sealed canister without spillage | V |
| | 4.2 | Req | The canister is non-leaking, airtight, detachable and can store at least 300 mL of fluids. | V |
| | 4.3 | Req | The canister cannot overflow (overflow protection is in place) | V |
| Applicability | 5.1 | Req | The device is compatible with self-made wound dressings | V |
| Usability | 6.1 | Req | The device is easy to operate by medical traff with minimal training | T |
| | 6.2 | Req | The device is easy to monitor by patients and caregivers with basic instructions | T |
| Portability | 7.1 | Req | Dimensions of the device (including carrying case or frame) should be within 600 x 300 mm and the weight should be < 6 kg | V |
| | 7.2 | Req | The canister is firmly attached to the device, while it can be easily removed for emptying | T |
| | 7.3 | Req | The device has a portable and rechargeable power source (battery) | V |
| | 7.4 | Req | The device operates for at least 8 hours on a full battery | T |
| | 7.5 | Wish | The device is suitable for outdoor use and therefore re-sistant to UV, splash water, shocks, and scratches. | X |
| | 7.6 | Wish | The device can be carried by patients with mobility problems | T |
| Noise | 8.1 | Req | The operating sound level does not exceed 35 dB. | X |

| Groep | # | Req / Wish | Description | Score |
|---|---|---|---|---|
| Safety | 9.1 | Req | The device should remain stable on the ground without the risk of tipping over | T |
| | 9.2 | Req | The device (or canister) prevents a loss of > 300 mL of blood in case of a bleeding | X |
| | 9.3 | Req | The content of the canister and fluid tube should be clearly visible during use (to be able to detect any signs of infection) | V |
| | 9.4 | Req | The device alerts the user in case the pressure level > -30 mmHg (indicating an air leak) | T |
| Cleaning | 10.1 | Req | All external parts of the device are suitable for cleaning with disinfectant. | T |
| | 10.2 | Wish | The canister and connectors are suitable for sterilisation (autoclaving) | X |
| Costs | 11.1 | Req | The selling price of the device is < 500 USD | V |
| Reliability | 12.1 | Wish | The number of components is reduced as much as possible | V |
| Availability | 13.1 | Wish | The device consists as much as possible out of standard, off-the-shelf components that are widely available | V |
| | 13.2 | Req | ff-the-shelf components are available (online or within 100km radius) and custom-made parts can be manufactured locally in Nepal and other LMICs. | V |
| Repairability | 14.1 | Req | The device can be (dis)assembled with local skills and tools | T |
| | 14.2 | Req | Individual parts can be removed and replaced | T |
| Maintenance | 15.1 | Wish | The device is low-maintenance | T |
| Lifespan | 16.1 | Req | The device (in package) can withstand transportation on difficult roads | T |
| | 16.2 | Req | The device can withstand rough handling (shocks and small impact) | T |
| | 16.3 | Req | The total lifespan of the device (including small repairs) is at least 3-5 years. | V |
| | | | | |

Table 3. Overview evaluation of criteria according WOCA scores

V Requirement was satisfied
X Requirement was not satisfied
T Requirement was not yet tested in practise

# 10.2 Conclusion

It can, above all, be stated that designing a NPWT device for a low-resource context is challenging and requires broad knowledge on both medical and technical aspects, as well as a wide set of skills to design a product that meets all the requirements. The proposed design has the potential to meet most of these requirements and is estimated to be manufacturable for <100 USD. However, assumptions must be validated first, and the embodiment design needs to be further developed to confirm these statements. In this section the design goal and project results are reflected upon, followed by the discussion of the project limitations.

**Initial project goal**
The initial assignment was formulated as "Develop a low-cost, portable VAC system that uses standard and widely available components and consumables" that was later refined to: "Develop a design proposal for a NPWT device that is affordable, safe and reliable while made of widely available, replaceable components" and divided into 7 sub design goals, formulated as design challenges.

**Results**
It can be concluded that in this project, extensive analysis of the subject and context has resulted into a broad list of valuable insights and an extensive set of design criteria, which take into account the medical, technical and market aspects as well as specific contextual factors. Subsequently, the 'proof of principle' testing phase resulted in a test setup that was able to collect the required data on pressure measurements, and a careful selection of internal parts for the NPWT device. Although more testing is still required, the first step towards a functional 'minimal viable product' was made. Eventually, the design phase resulted in a conceptual proposal for the WOCA Wound Pump and provides a visual representation of a design solution that meets the criteria for use in LRS.

**Validation of results**
As already extensively mentioned in the recommendations, the proposed design leaves much room for improvement and many aspects have not been validated yet. Plans were made for lab testing in user testing, however, because the design proposal was still in an early stage and the prototype is not yet finished, these plans were not executed during this project. The expert validation provided several insights, however, involvement of more end-users is needed to know how the design for the WOCA Wound Pump will be received. It can be concluded that a first step was made for validation, and the desirability, feasibility and viability of the WOCA still need to be validated.

**Limitations**
This project had several limitations. First, unfortunately, field research could not take place due to circumstances, including the outbreak of COVID-19. As for all similar projects that take place in LMICs executed by designers living in HICs, it is important to gain a good understanding of the design context and the best way to do this is to experience it. Instead, in this project the context analysis had to be done remotely and although digital technology made it possible to video call and quickly send videos and photos through WhatsApp, it was difficult to retrieve all the information that was required. Secondly, because the project was conducted remotely, interaction with local end-users was extremely difficult. During this project, user feedback and input from experts was missing. The third limitation that is worth mentioning is the fact that this project was conducted by a single designer, while it requires more input from other disciplines.

# 10.3 Recommendations

This section includes recommendations for further improvement of the design and implementation of the envisioned product.

### 10.3.1. General recommendations

1. Visit context

In general, it can be stated that extensive research on NPWT and the local context has led to many valuable insights. Consequently, the assumptions that were made to set the design requirements are well supported with facts. However, no field research was conducted in this project to validate these assumptions. To add to this, the design context has not been explored before by others, because no one has worked on this assignment before. Hence, it is very likely that important information is lacking. Therefore, the number one recommendation is to visit the context and to validate the assumption on which the design for the WOCA was built. To do this, the first step is to finish the prototype, as will be explained in the next section, 10.4 Continuation.

2. Involve end users

One of the activities that should be part of this validation, is the execution of interviews with nurses and patients, to clarify their needs and wishes. They are considered direct users; accordingly, their demands are highly important for further development of the design. If possible, performing small user tests with this target group would be even better to quickly validate usability features. Furthermore, it is recommended to involve more doctors and technical staff members in the design process, to add to the information that was provided by the surgeon, the head of nurse and BMET that participated up to now.

3. Involve experts

In addition, it is recommended to involve more experts and specialists in the next phase of the design process. It has been found that developing a NPWT device requires a great deal of knowledge in multiple areas of expertise, including the medical and technical field.
It is highly recommended to use the input of experts, e.g biomedical engineers, healthcare professionals and other designers that have experience with pneumatic devices. During this project, connections have been made with the wound centre of the Erasmus MC in Rotterdam and provides opportunities to involve wound experts as well.

4. Team up!

In addition to this, for continuation of this project, it is recommended to have a team, preferably a multidisciplinary team, working on further development of the WOCA wound pump.

### 10.3.2. Recommendations for further testing and validation

At the end of Phase II a selection of the most critical requirements was made and these requirements were reviewed in 10.1 Evaluation. This evaluation showed that a great deal of requirements could not be evaluated, because more testing and validation is required.

1. Lab test

The first recommendation on this topic is to conduct a lab test, as soon as the prototype is finished. The functional requirements, including the knees related to air leakage and pressure regulation, can be validated in a lab-setting, using the test setup that was created for the 'proof of principle' study.

2. User test

Secondly, it is recommended to do a user test with a (simulated) interface to validate clinical needs, i.e requirements related to usability and safety. For example, the safety alarms can be simulated and tested with test subjects. This type of testing is preferably done with end-users, but could also be executed with participants found in the Netherlands. Another aspect that requires validation is to see if the product can fit the workflow of the medical staff and investigate if there are any problems related to the use of the WOCA inside the hospital, which must be tested in the design context.

3. Expert review

Thirdly, it is recommended to perform expert reviews to validate the practical needs, i.e. requirements related to manufacturing, repair, lifespan, costs, repairability, etc. These reviews can be done by interviewing people with experience on these specific topics.

### 10.3.2. Design recommendations

The evaluation of design criteria, showed that not all design criteria are met by the final design proposal. These insights were complemented by feedback from the expert review (10.1 Evolution). Hence, for the next design iteration, the following recommendations are listed.

1. Add pressure control

First of all, the controller for the pressure regulation needs to be further developed. At this point, the design proposal includes an idea of how the pressure should be regulated, using the sensor feedback to control the pump speed. The next step is to develop and prototype the controller, using the selected components. In addition, it might be useful to conduct flow measurements of the air leakage, if appropriate equipment is available, to validate if the selected vacuum pump is the most suitable choice for this device. Currently, the design includes an Arduino Nano (the prototype uses a Seeeduino board), it may be possible to use a different type of microcontroller

2. Design embodiment

Secondly, the embodiment for this design needs further improvement. The following parts need to be designed

- Electrical circuit (PCB) + coding
- Mountings for the internal parts
- Internal tubing system, Preferably the number of connectors is reduced.
- Fixings for the housing and canister holder

3. Reduce noise

The third recommendation addresses the noise of the vacuum pump (>50 dB). Noise is a problem because patients cannot sleep at night with this sound level. This issue has been noticed and discussed with sound engineers, which resulted in the advice to try two options: (1) use a different mounting for the pump that

resonates less and (2) find another vacuum pump that is more silent.

4. Solve canister problem

The holder is designed to support canisters that range from 800mL-1000mL, which is too large in relation to the amount of fluids that need to be collected and allows a blood loss of 800 mL before the device is shut off due to the overflow protection. It is safer and more convenient to use a canister of 300mL, however, it remains unclear if these would be available at the location of use. Standard canisters of 800 mL are widely available online and therefore this was the safest option to design for. In the next iteration, it is important to find out what canisters are exactly available. Moreover, it should be reconsidered if off-the-shelf canisters are the best options, as it might be worth it despite the additional costs, to include a custom made canister in the design, if it turns out smaller canisters are not available.

5. Conduct analysis on 3D printing parameters

3D printing (PETG) was chosen as the method of manufacturing at this stage of the project. However, it is known that 3D printing is challenging and comes with some difficulties, such as variation in print quality and the risk of print failures when the settings are not correct. Therefore, it is recommended to include research and analysis of the printing parameters in the process of embodiment design. It should also be researched if cleaning and sterilisation is possible.

6. Design for cleaning

The device is meant for reuse and therefore must be suitable for cleaning. First, more research is needed to define more specific requirements on this topic, whereafter design adjustments can be made to the reusable parts of the design.

7. Test and improve durability

According to the requirements, the product should be durable and suitable for outdoor use. The design is intended to be sturdy, however, this is not yet validated. It is recommended to first perform a FEM analysis to evaluate the product structure and identify weak elements. To improve product durability, the housing can be improved by changing the thickness or selecting a different material, if required. It should be explored if the device could be upgraded to a version that is suitable for outdoor use and therefore resistant to UV, splash water, shocks, and scratches.

8. Reduce power consumption

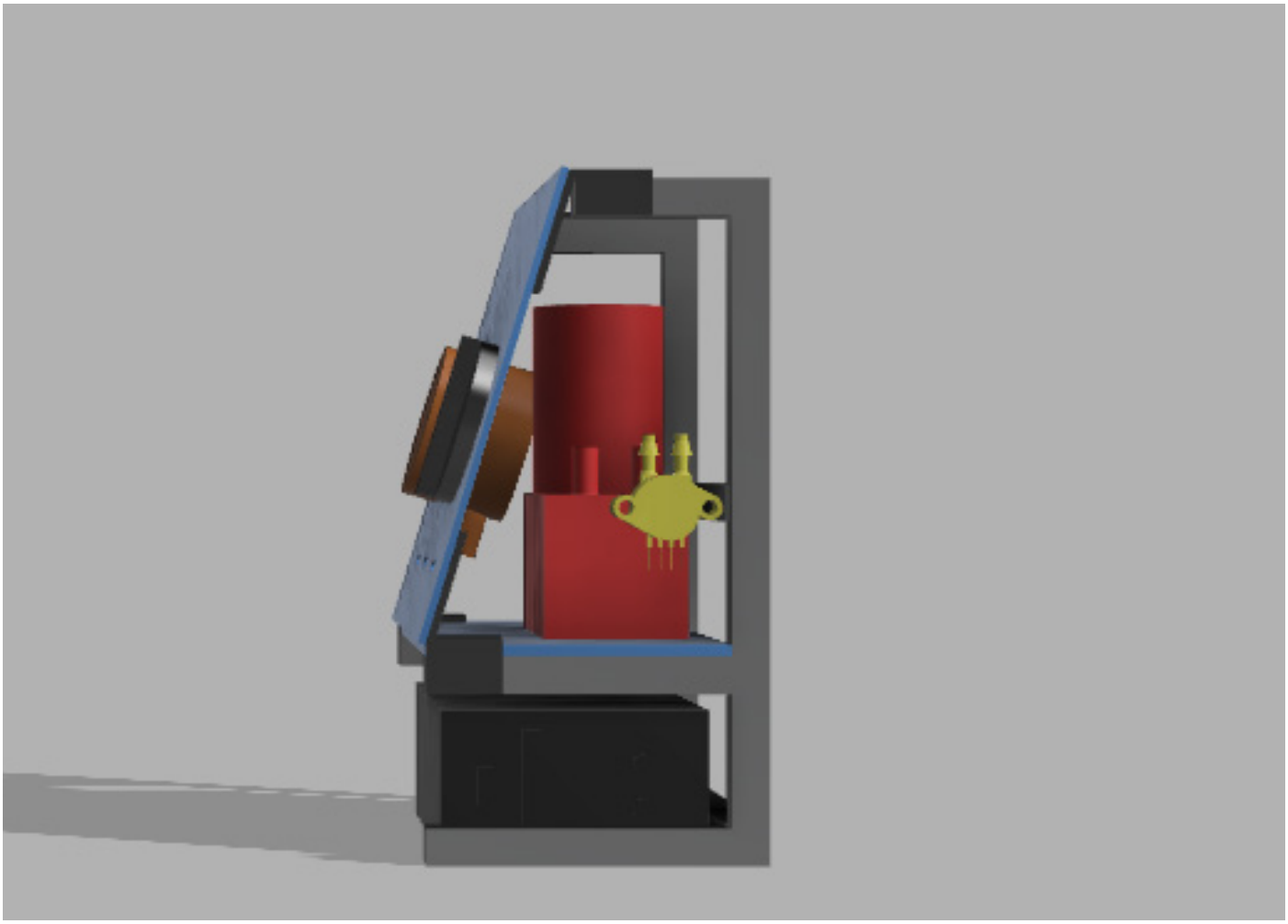
The estimated power consumption for the design proposal is approximately 6W, which is relatively high. When the power circuit is further developed, it is recommended to perform measurements on power usage with the intention to reduce the power consumption. Moreover, the integration of a pressure controller and minimizing air leakage of the dressing, also contribute to a device that is more energy efficient.

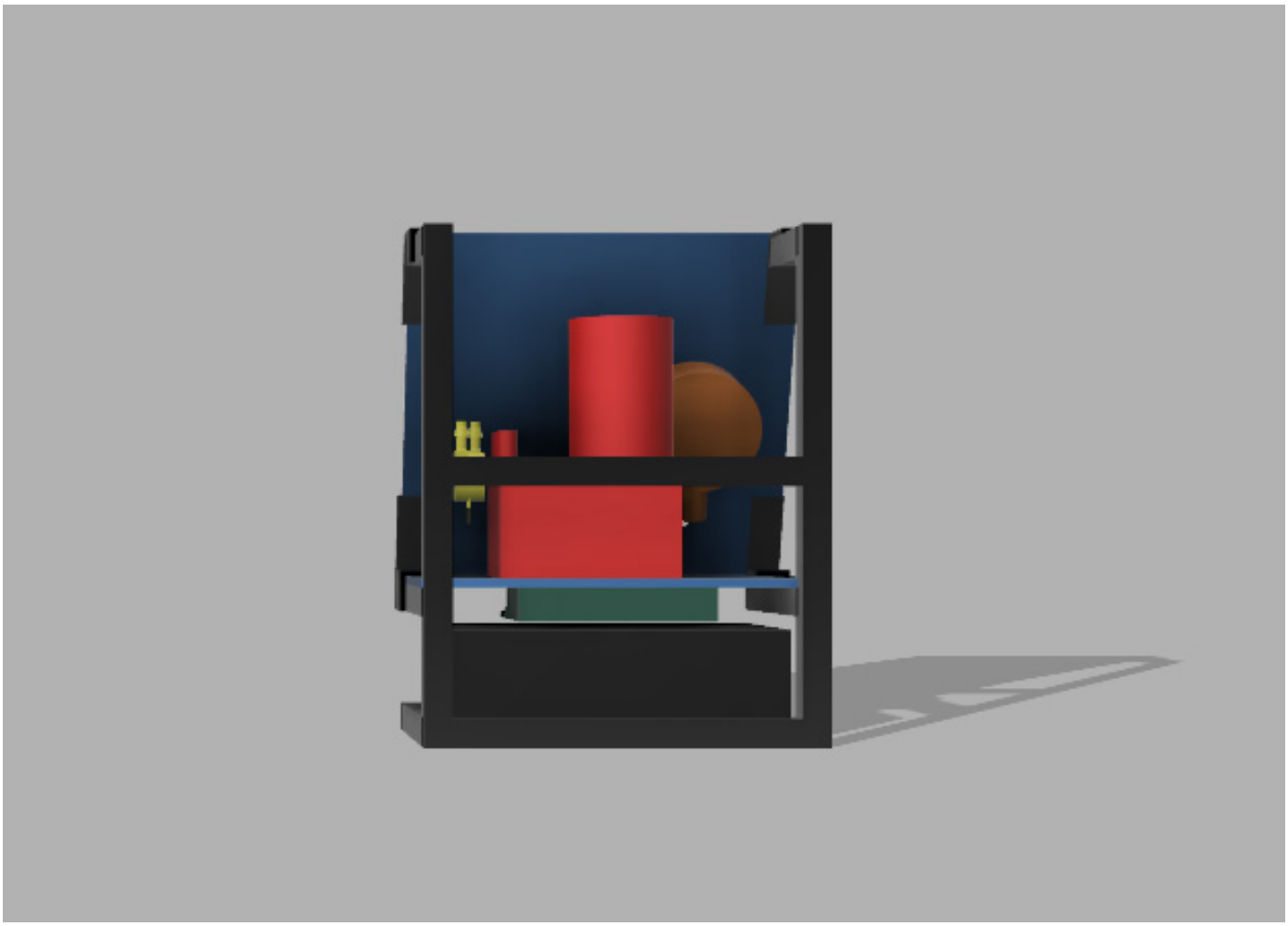
# 10.4 Continuation

To continue this project the following steps should be taken to investigate if the final design could be successful in LMICs:

- Inhouse testing of the final design with a prototype to validate the product by taking into account the wishes and requirements that are not tested yet (see section Recommendations).
- Embodiment and manufacturing of the product in collaboration with a design team.
- Technical development by an engineer to make sure the pressure controller, which is part of the final design, is suitable for usage.
- Develop a business case based on gathered data to convince investors and the hospital board of GPH to fund the steps required to perform the pilot project.
- A usability study in LMICs, ideally in Nepal, to investigate  The pilot project at GPH can be considered a starting point, as opportunities exist to extend the project and meet the same need in many other healthcare clinics in LMICs all over the world.
- Gather additional funding based on the proposed final design to invest in further steps to take.
- Find local partners to collaborate with to manufacture the devices and bring the product into the market.
- Upscaling of the product manufacturing.

If those steps are taken, the full potential of the WOCA Wound Pump could be reached. This process would probably take years, but it has the potential to profoundly improve the healthcare for chronic and complex wounds in low-resource settings.





# 10.5 Reflection

When I started this graduation project at the end of 2020, I did not expect the process to evolve the way it did. Unexpected circumstances played a role, as most of this project was executed during the COVID-19 outbreak. During this challenging experience, much was learned about wounds, the context and myself. It has been a long and difficult road, but in the end I am proud of what I have achieved and how much I've grown as a person.

There are certain aspects of the process that I would like to reflect upon, starting with my personal learning ambitions. My personal learning goals for this project included: Working remotely and individually as well as further developing my skills in terms of prototyping, testing, 3D modelling, manufacturing and rendering, and lastly, project planning and time management.

Firstly, working alone proved to be challenging for me. It requires a different approach compared to working in a team.This became already visible when defining the scope, setting boundaries on research and design activities. Especially, when those decisions had to be made only by me. This resulted in much time spent on researching the context than anticipated. Hence, this experience made me realise I am much happier when working in a team, pursuing the same goals and celebrating success together.

In regards to the development design skills, it can be concluded that all skills I was eager to improve, have been applied during this project, although I believe I could have learned more, if I had involved the expertise of others. I wish I had shown results earlier to supervisors, experts and peers and asked for more feedback. I have learned this is a process of letting go of criticism and perfectionism, patterns that are deep inside me.

Perfectionism is also related to the next point. In regards to the planning, I structurally underestimated tasks and set timewise unrealistic goals. My ambitions with this project were sky-high, because I was passionate and saw a huge potential in this project. I came to realise that putting that much pressure on it, leaves no room for mistakes and blocks all the creativity. In research through design, the ability to try and fail is absolutely essential. Learning how to deal with perfectionism will take more time and training, a journey that I wish to continue in my professional life.

Apart from these aspects, there are a few things I would approach differently. In hindsight, I would have included more user tests and reviewing when making design choices rather than using secondary sources (internet, literature). This would save me time I spend on research and overthinking assumptions. Looking back, I wish I had spent less time on researching the context and more time on design and prototyping.

Last but not least, it would have been amazing to visit Nepal and do field research, hopefully there will be an opportunity in the future to visit this beautiful country!

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