Towards a clinical trial of the WOCA

Verification, validation and optimisation of a vacuum-assisted closure device for low- and middle-income countries

Lisa van de Weerd

Delft University of Technology

TU Delft

Towards a clinical trial of the WOCA

Verification, validation and optimisation of a vacuum-assisted closure device for low- and middle-income countries

by

Lisa van de Weerd

to obtain the degree of Master of Science
at the Delft University of Technology,
to be defended publicly on Tuesday November 5, 2024 at 10:45 AM.

Student number: 5556066
Project duration: February 1, 2024 – November 5, 2024
Thesis committee:

Prof. dr. J. Dankelman	Chair
Dr. ir. A. Knulst	Daily Supervisor
Prof. dr. ir. J. C. Diehl	Graduation Committee

An electronic version of this thesis is available at http://repository.tudelft.nl/.

TU Delft

Executive summary

This report details the preparation of the WOCA device for a clinical trial at Green Pastures Hospital (GPH).

The prevalence of chronic and complex wounds is high in low- and middle-income countries (LMICs). Due to the lack of adequate treatment wound conditions are likely to worsen. Improving access to wound care in LMICs is crucial for enhancing the quality of life for the people living there. Vacuum-assisted closure (VAC) therapy is an effective treatment for chronic and complex wounds. By applying a negative pressure to the wound the healing process is promoted. However, due to the high cost of VAC devices, their availability in LMICs is limited. A. Knulst works as a biomedical engineer at GPH and recognized this problem. In GPH the AquaVAC, a converted aquarium pump, is used to be able provide VAC therapy to patients. The use of the AquaVAC is not meeting the users' requirements.
Recognizing this problem, A. Knulst initiated the WOCA project to develop a VAC device tailored for LMICs. Over the past three years, the project has progressed to creating three simple yet functional prototypes using locally available materials in GPH. Based on the findings of A. Knulst a suitable next step for the WOCA is determined to conduct a clinical trial to evaluate the WOCA's effectiveness in wound healing.
Designing the goal of this graduation project; preparation of the WOCA for the performance of a clinical trial conducted in GPH. Based on analysation of this goal preparation of the WOCA consists of verification, and validation of the design requirements, verification of the applicable ISO-criteria, and the performance of a risk assessment. By making a redesign the current WOCA at GPH will also be made compatible with these stated requirements.
By making a redesign during this graduation project the canister is implemented and the noise is reduced for the WOCA. This new version of the WOCA is verified for its design requirements as well as validated, also the applicable ISO-norms are verified and a risk assessment is performed.

Based on this performed effort it is shown that the WOCA is exceeding the allowed noise level determined to be reached before the WOCA can start the clinical trial. Furhtermore, recommendations have been given for additional validation and verification of the WOCA before conducting the clinical trial.

Steps have been taken during this graduation project to improve the access to wound care in LMICs by a contribution to the open-source-publication of the WOCA device, and the development of a study protocol for the performance of a clinical trial.

Contents

List of Figures

List of Tables

1

Introduction

This chapter introduces the topic of this graduation project. Starting with the problem definition, the aim of this project is defined. As this graduation project is a continuation of an already existing project, the current situation of this project is described and the context is explained.

1.1. Problem Definition

1.1.1. Wounds in LMICs

The prevalence of chronic and complex wounds in low- and middle-income countries (LMICs) is high [7]. One of the underlying causes of this phenomenon is the lack of traffic regulation. A significant number of road traffic accidents result in traumatic injuries. Moreover, habits common in LMICs, such as walking barefoot or cooking on open fires, contribute to increased wounds and wound infections [15].

In addition to the causes of wounds, the lack of appropriate treatment in LMICs contributes to the worsening condition of wounds; the distances people have to travel to reach a hospital are long. Also, there is a lack of well-organized insurance as most people have to pay for a hospital visit out of pocket. This, combined with co-morbidities such as stress, diabetes, smoking and poor nutrition, means that acute traumatic wounds often become chronic wounds [6].

As chronic wounds require longer hospital stays, the social and economic impact of hospitalization increases [2]. Most people living in poverty tend to delay seeking medical care until it is absolutely necessary. However, if a chronic wound is not treated in time, it can lead to adverse outcomes such as depression, stress, anxiety, and social isolation. These outcomes can lead to reduced quality of life and increased poverty. Together, this results in the vicious cycle of poverty and disability [8]. To break through this vicious cycle for people suffering from wounds, it is necessary to improve the accessibility to wound care and the wound care itself in LMICs.

1.1.2. VAC/NWPT

Chronic and complex wounds require vacuum- assisted closure (VAC) therapy, also referred to as Negative Wound Pressure Therapy (NWPT). VAC therapy is used for wounds that fail to heal properly over time such as ulcers, pressure sores, skin grafts, and both traumatic and chronic wounds. During VAC therapy, the application of negative pressure facilitates the healing process by removing pressure from the wound site, thereby increasing local blood flow. A wound dressing is secured in place by applying an adhesive film directly to the wound, covering and sealing the foam or gauze dressing. A drainage tube is connected to the adhesive film and the vacuum pump, which is responsible for removing the air. The application of suction removes waste from the wounds, which is collected in a separate canister [2]. The use of VAC facilitates wound healing and makes treatment more comfortable for the patient. Compared to wound healing without VAC, fewer re-operations and dressing changes are required. Additionally, VAC reduces wound swelling and facilitates cleansing [16]. The working mechanism of VAC

therapy is described in figure 1.1. Due to the high prevalence of chronic and complex wounds in LMICs, these countries would benefit from VAC therapy. However, this type of therapy is not readily accessible in LMICs due to the high cost of the medical equipment and consumables required for the therapy [15].

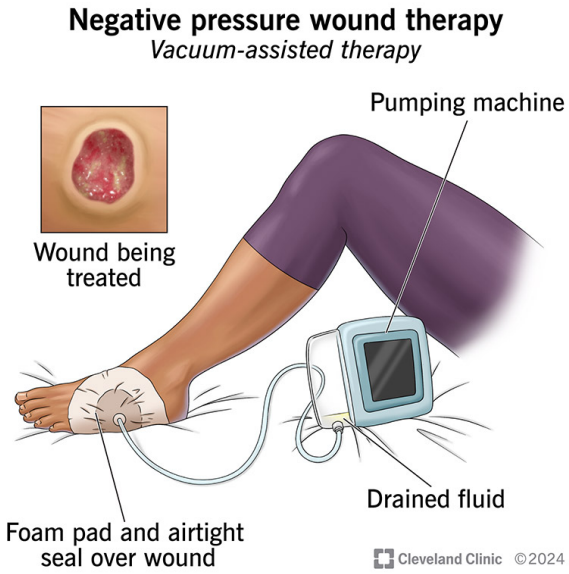


Figure 1.1: "Explanation of working mechanism for VAC therapy [14]"

1.1.3. GPH

One of the hospitals that can't afford this expensive VAC equipment is Green Pastures Hospital (GPH). As a non-profit organization owned by the International Nepal Fellowship (INF), GPH serves the poorest and most marginalised part of Nepal's population [17]. With more than 20% of the population living below the poverty line, as reported by the Worldbank in 2022, it can be said that Nepal is struggling with poverty [13]. GPH treats patients with disabilities or complex wounds. As the hospital relies on donations, its financial resources are limited, posing an additional challenge to the provision of care [17].

1.1.4. AquaVAC/TurtleVAC

At the time of writing, GPH is using the AquaVAC, also referred to as the TurtleVAC device, to deliver VAC therapy to patients. The AquaVAC is a modified aquarium pump that shows to be effective in improving wound healing [3]. A picture of the AquaVAC is shown in figure 1.2. However, feedback from local staff at GPH indicated three potential limitations of the device. Firstly, the device is not portable, which can cause discomfort for the patients. In addition, the device employs a variety of power converters, which, when combined with the lengthy cables, may compromise the overall safety of the device. Finally, the device is provided as a donation which precludes the possibility of repair in the event of damage.

1.1.5. Start of WOCA project

In response to feedback from the GPH staff, a project to develop a VAC device specifically designed for LMICs is initiated by A. Knulst who works as a biomedical engineer at GPH. This new device address the limitations of the existing AquaVAC by improving its safety, portability and user-friendliness. While the project focus on GPH, the device is designed with wider implementation in LMICs in mind.

This project, called the WOCA, represents a significant advancement in the provision of wound care in resource-limited settings.

Figure 1.2: AquaVAC

1.2. Current Situation

1.2.1. 1st version of the WOCA

At the beginning of the project, E. Raaijmakers made a significant contribution by establishing design specifications for the VAC device suitable for LMICs, outlined in table 1.1.

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

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

Table 1.1: Design Requirements at the start of the WOCA project by E. Raaijmakers [15]

In response to these specifications, E. Raaijmakers designed the WOCA, shown in figure 1.3.

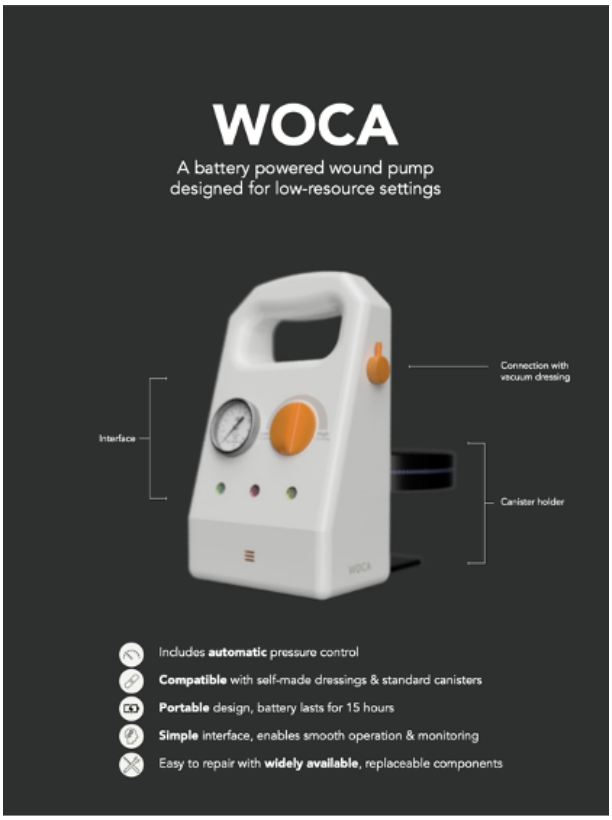
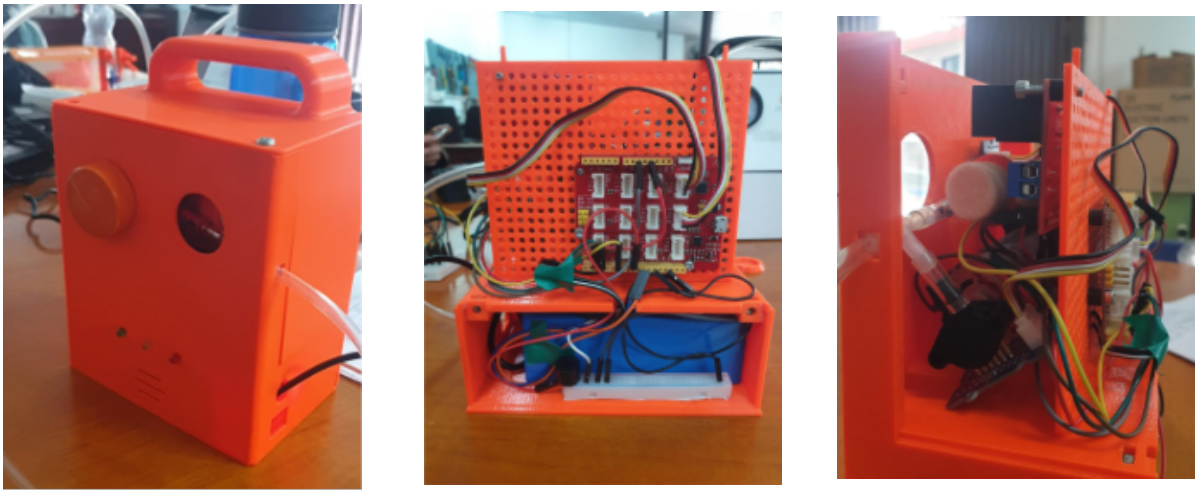


Figure 1.3: Initial design of the WOCA by E. Raaijmakers [15]

1.2.2. 2nd version of the WOCA

This design formed the basis for the creation for a simplified yet functional prototype by N. Nicolai. The prototype included a housing for the device, an electrical circuit, a feedback loop to regulate and maintain pressure and safety features to ensure that the device maintains a consistent pressure, enhancing both usability and patient safety.

A photograph of the prototype is included in figure 1.4 [12].



(a) WOCA frontside

(b) WOCA backside

(c) WOCA inside

Figure 1.4: Prototype developed by N. Nicolai [12]

Figure 1.5: Final Design for 3rd version of the WOCA

1.2.3. 3rd version of the WOCA

After building the initial prototype, J. van den Boom proceeded to fabricate three devices. These models incorporated locally available components instead of imported parts, thereby reducing costs and enhancing sustainability for use in LMICs. Consequently, three operational prototypes of the WOCA device are currently available, each with a simplified yet technically functional design shown in figure 1.5.

1.3. Goal of this project

As this graduation project is an extension on an already existing project the scope is determined by A. Knulst. A. Knulst determined that the next step for the WOCA, before implementation in hospital setting, would be to perform a clinical trial in GPH to evaluate the operating mechanism of the WOCA to ensure compatibility with other commercially available VAC devices on its facilitation of wound healing. Therefore, the aim of this graduation project is to prepare the WOCA for a clinical trial at GPH. Details regarding the steps required to achieve this goal are outlined in chapter 2.

2

Approach

This chapter describes the approach for preparing the WOCA for a clinical trial at GPH. This is done by, firstly, making the prototype compliant with the intended design requirements. Secondly, the device is made compliant with the requirements to be used in a clinical trial in Nepal.

2.1. WOCA towards a VAC device suitable for LMICs

The WOCA prototype is developed into a VAC device suitable for LMICs, based on the requirements of E. Raaijmakers. These design requirements are divided into technical and user requirements. The technical requirements require verification, a quality control process to test specifications. The user requirements require validation, a process checking the requirements capture the customer's requirements [4] [18]. Based on the report of E. Raaijmakers this division is made for the design requirements of the WOCA, shown in figure 2.1. Therefore, verification and validation is determined to be necessary for testing the WOCA on its design requirements.

Group	#	Requirement/Wish	Description	User/Technical requirement
Pressure	1.1	Requirement	The device can create and maintain a pressure level of -125 mmHg during one treatment cycle (3-5 days)	Technical
	1.2	Wish	The device has one default pressure level of -125 mmHg and one adjustable pressure level of -80 mmHg	Technical
	1.3	Wish	The device can self-regulate the pressure within 10% of the indicated pressure range	Technical
	1.4	Requirement	The device has a (mechanical) safety stop to ensure that pressure level will never exceed -125 mmHg	Technical
Airflow	2.1	Requirement	The device is able to overcome an air leak ratio of 0-100 mL/hr	Technical
	2.2	Wish	The device is able to overcome an air leak ratio of 100-3000 mL/hr	Technical
Fluid flow	3.1	Requirement	The device is able to extract fluid from a wound with a flow rate ranging from 1-300 mL/day	Technical
Fluid collection	4.1	Requirement	Wound fluids are collected into a sealed canister without spillage	Technical
	4.2	Requirement	The canister is non-leaking, airtight, detachable and can store at least 300 mL of fluids	Technical
	4.3	Requirement	The canister cannot overflow (overflow protection is in place)	Technical
Applicability	5.1	Requirement	The device is compatible with self-made wound dressings	Technical
Portability	7.1	Requirement	Dimensions of the device (including carrying case or frame) should be within 600 x 300 mm and the weight should be < 6 kg	Technical
	7.3	Requirement	The device has a portable and rechargeable power source (battery)	Technical
	7.4	Requirement	The device operates for at least 8 hours on a full battery	Technical
	7.5	Wish	The device is suitable for outdoor use and therefore resistant to UV, splash water, shocks, and scratches	Technical
Noise	8.1	Requirement	The operating sound level does not exceed 35 dB	Technical
Safety	9.1	Requirement	The device should remain stable on the ground without the risk of tipping over	Technical
	9.2	Requirement	The device (or canister) prevents a loss of >300 mL of blood in case of a bleeding	Technical
	9.3	Requirement	The content of the canister and fluid tube should be clearly visible during use (to be able to detect any signs of infection)	Technical
	9.4	Requirement	The device alerts the user in case the pressure level >-30 mmHg (indicating an air leak)	Technical
Cleaning	10.1	Requirement	All external parts of the device are suitable for cleaning with disinfectant	Technical
	10.2	Wish	The canister and connectors are suitable for sterilisation (autoclaving)	Technical
Costs	11.1	Requirement	The selling price of the device is <500 USD	Technical
Reliability	12.1	Wish	The number of components is reduced as much as possible	Technical
Availability	13.1	Wish	The device consists as much as possible out of standard, off-the-shelf components that are widely available	Technical
	13.2	Requirement	Off-the-shelf components are available (online or within 100 km radius) and custom-made parts can be manufactured locally in Nepal and other LMICs	Technical
Lifespan	16.1	Requirement	The device (in package) can withstand transportation on difficult roads	Technical
	16.2	Requirement	The device can withstand rough handling (shocks and small impact)	Technical
	16.3	Requirement	The total lifespan of the device (including small repairs) is at least 3-5 years	Technical

(a) Technical Design Requirements WOCA

Group	#	Req/Wish	Description	User/Technical requirement
Usability	6.1	Requirement	The device is easy to operate by medical staff with minimal training	User
	6.2	Requirement	The device is easy to monitor by patients and caregivers with basic instructions	User
Portability	7.6	Wish	The device can be carried by patients with mobility problems	User
Repairability	14.1	Requirement	The device can be (dis)assembled with local skills and tools	User
	14.2	Requirement	Individual parts can be removed and replaced	User
Maintenance	15.1	Wish	The device is low-maintenance	User

(b) User Design Requirements WOCA

Figure 2.1: Division for the Design Requirements of the WOCA into Technical and User Requirements

2.2. VAC device towards a clinical trial in Nepal

2.2.1. Lack of Medical Device Regulation in Nepal

In LMICs, including Nepal, the regulatory framework for medical devices is often underdeveloped and lacks the same degree of definition as those in high-income countries (HICs) [9]. This is also applicable to clinical trials conducted in Nepal, where specific regulations for the use of medical devices is missing.

2.2.2. ISO Standard as Guideline

Nevertheless, International Standardization Organization (ISO) standards which are internationally recognised guidelines are determined to be able to serve as robust frameworks for ensuring the safety, efficacy, and reliability of medical devices [16]. However, it should be noted that these guidelines are designed for and by HICs and therefore may not be fully applicable to LMICs due to discrepancies in resources and context. [16].

J. van den Boom initiated an analysis to evaluate the applicability of the ISO standard to the Nepalese context. The analysis sought to determine which aspects of the standard is feasible and relevant for the WOCA device. In light of the findings of J. van den Boom, the next steps for this additional safety verification are as follows:

- The analysis initiated by J. van den Boom is reviewed and finalized to ensure that within the ISO standard for VAC devices the ISO criteria applicable to Nepal are correctly identified
- The WOCA device is verified for these applicable ISO criteria to ensure that it meets the international safety and performance requirements where possible.

2.2.3. NRHC

In Nepal, the Nepal Health Research Council (NHRC) is responsible for the regulation of clinical trials. While there are no specific requirements for medical devices in these trials, the NHRC requires a Failure Modes and Effects Analysis (FMEA) risk assessment as part of the approval process for clinical trials involving medical devices. An FMEA risk assessment for the WOCA device is conducted prior to the clinical trial. An FMEA risk assessment identifies and addresses potential risks associated with the use of the device in the clinical setting. This includes an evaluation of potential failure modes, their likelihood, and severity and the mitigation measures required [11].

Following the aforementioned steps, namely using ISO standards as guidelines, and conducting an

FMEA risk assessment, it is determined that a VAC device would be ready for a clinical trial in Nepal as this ensures that the device meets both international safety standards (where applicable), as well as local ethical requirements. Taking these steps would ensure that the WOCA device can be used safely in the clinical trial setting at GPH.

2.3. Report layout

To conclude, the WOCA is prepared for a clinical trial by first ensuring that the WOCA meets the requirements for a VAC device suitable for LMICs. The device is tested for these requirements through verification, tests performed for the technical requirements, and validation, a process performed for the user requirements. Second, the WOCA is made compatible with the requirements for a VAC device to be used in a clinical trial in Nepal. This is done by verification of the applicable ISO standards, and by performing a risk assessment. In order to make the device compatible with the requirements, a redesign is performed on the current WOCA.

Within chapter 3 of this report the verification of the design requirements will be described. Chapter 4 describes the validation of the design requirements. Together these two chapters contain the design requirements testing. Chapter 5 describes the verification of the ISO norms, and chapter 6 describes the risk assessment performed for the WOCA. Together describing the process for preparation for the clinical trial. The redesign needed of the WOCA to be compatible with these requirements is described in chapter 7. Each chapter includes a small introduction, method, result, discussion and conclusion section.
For ease of reading, the process is described as a chronological process, although it is an iterative process. The iterative process of this project is visualized in figure 2.2. The final product of this graduation project is a redesign of the WOCA, which is verified and validated for readiness of a clinical trial at GPH Nepal. Within chapter 8 the readiness of the WOCA will be discussed, and project limitations and recommendations will be provided. The report closes with a conclusion about the readiness for the WOCA to perform a clinical trial described in chapter 9.

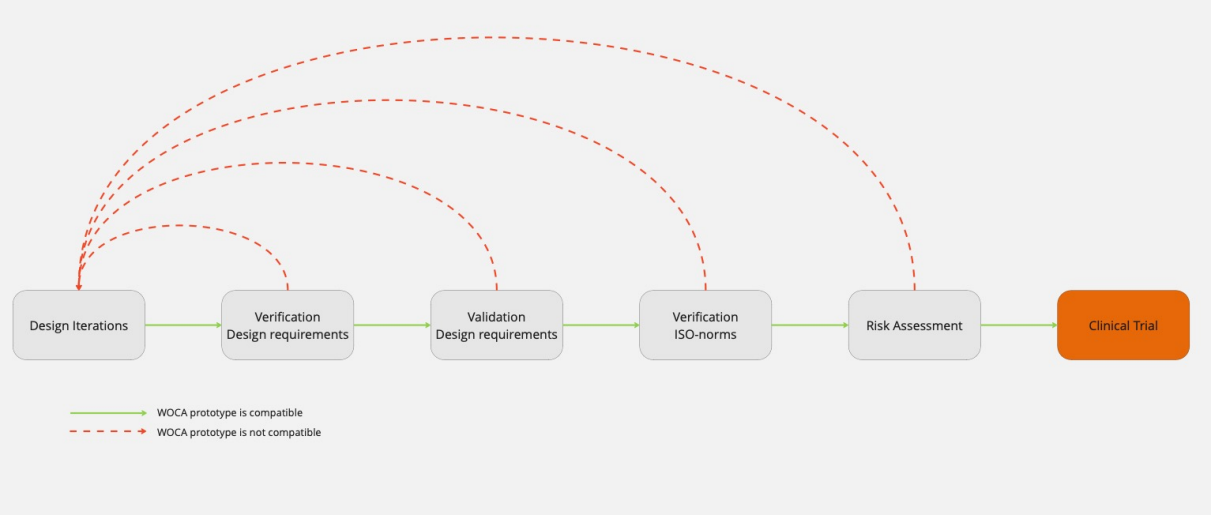


Figure 2.2: Visualization of the iterative process for WOCA prototype development

3

Verification Design Requirements

This chapter outlines the verification of the technical design requirements requiring additional testing. This includes five tests which are briefly described.

3.1. Introduction

The technical requirements are specified in figure 2.1. Only technical requirements that require additional data collection or analysation before the start of this graduation project are included.

3.1.1. Discussed requirements

It is determined that extensive testing is needed for design requirement categories pressure, airflow, portability, noise and lifespan. Containing the following requirements:

Pressure

- 1.1: The device can create and maintain a pressure level of -125 mmHg during one treatment cycle (3-5 days)
- 1.3: The device can self-regulate the pressure within 10% of the indicated pressure range
- 1.4: The device has a (mechanical) safety stop to ensure that pressure will never exceed -125 mmHg

Airflow

- 2.1: The device is able to overcome an air leak ratio of 0-100 mL/hr
- 2.2: The device is able to overcome an air leak ratio of 100-3000 mL/hr

Portability

- 7.4: The device operates for at least 8 hours on a full battery

Noise

- 8.1: The operating sound level does not exceed 35 dB

Lifespan

- 16.1: The device (in package) can withstand transportation on difficult roads

3.1.2. Available materials

The scope of the verification process was limited by the materials and equipment available in the Biomedical Engineering Office at GPH.

3.2. Method

These requirements can be verified by conducting five tests outlined in this section.

3.2.1. Pressure test

1.1

To verify design requirements 1.1 the device's pressure is measured using a FLUKE VT900A Gas Flow Analyser along with the WOCA device and its canister. Additional connecting tubes and components are required. The WOCA's pressure is continuously monitored, initially set at -125 mmHg, and observed for 30 minutes with measurements taken every second.
The test setup is illustrated in figure 3.1.

Figure 3.1: Pressure test set-up

1.3

The method for verification of requirement 1.3 is combined with the method for requirement 1.1. To verificate 1.3 by analysing the data the actual pressure is compared to a range of 10 % of the set pressure.

1.4

By removing the software endstop in the Arduino code the maximum pressure for the device can be measured in case this software is not working properly. This can be done by changing the value of the software endstop (-135 mmHg) into a unreachable value for the motor (-1000 mmHg). After uploading the new Arduino code the same test can be performed as for the verification of requirement 1.1 and 1.3, although 5 minutes for this test is determined enough.

3.2.2. Airflow test

To verify design requirement 2.1 and 2.2, the airflow of the WOCA device is monitored using the FLUKE Analyser. The flow rate is adjusted using a tap to create variations. The Arduino system in the WOCA is connected to a laptop via a cable, and the Arduino software on the laptop displays the pressure. Since the FLUKE analyser cannot measure both flow and pressure simultaneously, the pressure readings is recorded by capturing the laptop screen showing the Arduino software.
The test setup is illustrated in figure 3.2.

3.2.3. Portability test

To verify requirement 7.4, the battery is tested over 8 hours by measuring the pressure level every minute using the FLUKE analyser. This test setup is similar to the one shown in figure 3.1. The measurement frequency is reduced compared to the previous pressure test to accommodate the FLUKE analyser's available storage capacity.

Figure 3.2: Airflow test set-up

3.2.4. Noise level test

To verify requirement 8.1, the device's noise level is analysed using the Decibel X smartphone app. To stimulate real usage conditions, the noise level is measured at a distance of 50 cm from the WOCA device, including its canister. The noise is recorded for 30 seconds when the motor of the device is running.

3.2.5. Lifespan test

To verify requirement 16.1, the WOCA undergoes an 8-hour journey on Nepalese roads in a 4x4 vehicle, travelling on both paved and unpaved surfaces. During transport, the WOCA is packed in cardboard boxes with foam padding, as shown in figure 3.3.

Figure 3.3: Packaging of WOCA for transportation

3.3. Results

3.3.1. Pressure test

1.1

The results of the pressure test are summarised in figure 3.4. All three WOCA pumps are summarized in one figure, using different colours. It can be seen that the pressure fluctuates around the set value

of -125 mmHg.

1.3
Within the same figure 3.4 the pressure is compared to the acceptable 10% pressure range. A maximum limit of -112.5 mmHg and a minimum limit of -137.5 mmHg is indicated.
The actual pressure does not exceed the given limits within the figure.

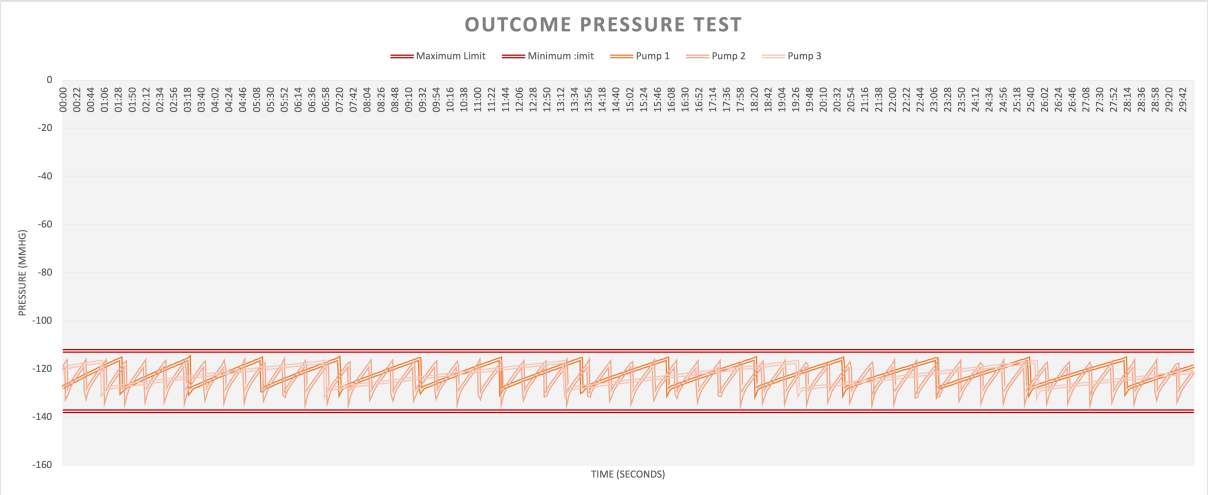


Figure 3.4: Outcome Pressure Test

1.4
The outcome of the maximum test is shown in figure 3.5 showing that the WOCA device is not able to exceed a pressure level of -200 mmHg.

3.3.2. Airflow test
The results of the airflow test are summarised in figure 3.6. According to the graph, pump 1 is able to overcome an airflow of -200 mL/min, pump 2 can handle a maximum airflow of -165 mL/min, and pump 3 is able to overcome an airflow of -202 mL/min. Those measurements are negative, as the measured flow using the FLUKE analyser was in the opposite direction.

3.3.3. Portability test
The pressure recorded during the portability test is displayed in figure 3.7. The graph indicates that the device successfully maintains a pressure of -125 mmHg for the entire duration of 8 hours.

3.3.4. Noise level test
The noise level test results show an average noise level for the device of 51.4 dB, with a minimum of 25.7 dB and a maximum of 81.3 dB.

3.3.5. Lifespan test
After conducting the lifespan test, all three WOCA devices operated correctly and showed no signs of damage.

3.4. Discussion
3.4.1. Pressure test
1.1
As shown in figure 3.4, all three pumps can withstand a pressure of -125 mmHg. However, due to time constraints, pressure measurements were taken for only 30 minutes, while requirement 1.1 specifies

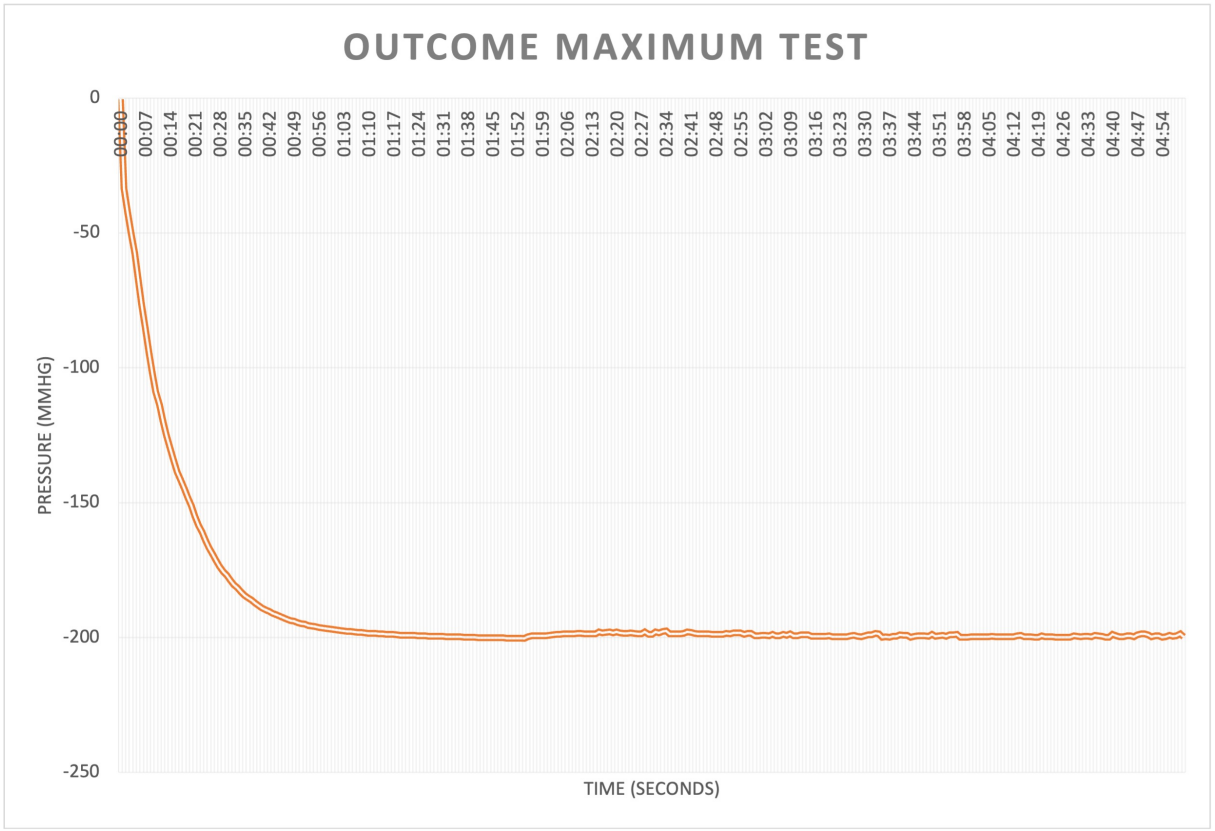


Figure 3.5: Outcome Maximum Test

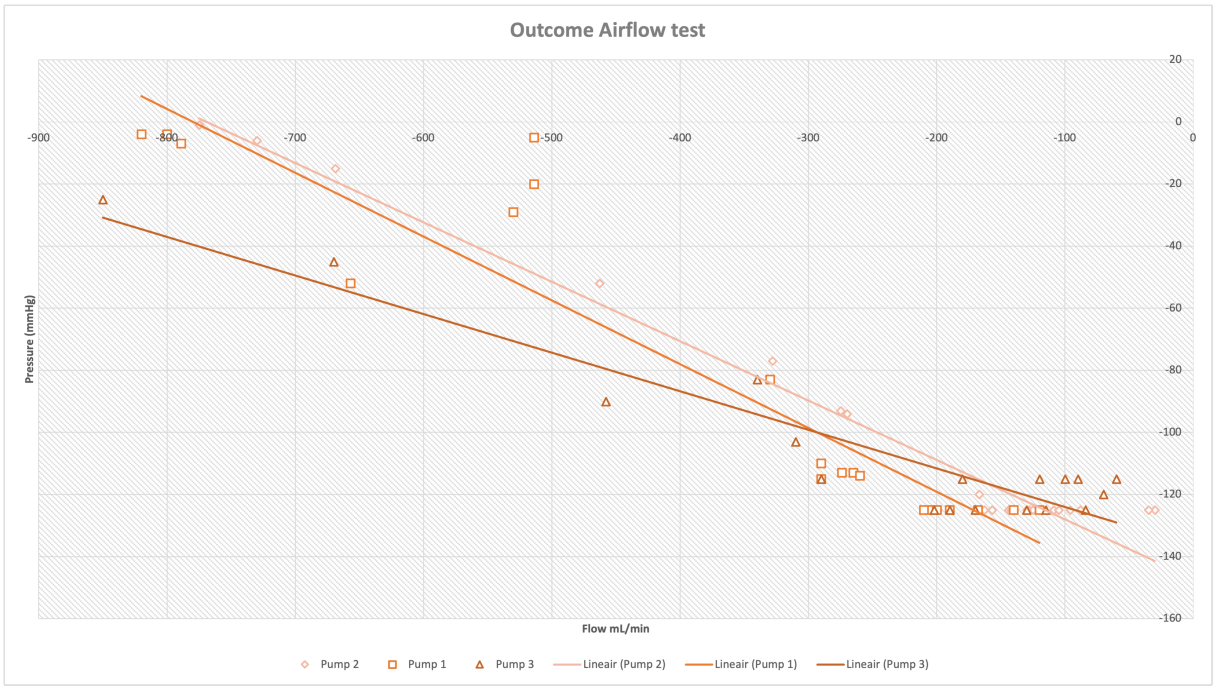


Figure 3.6: Outcome Airflow Test

testing for 3 to 5 days. Before starting the clinical trial, conducting pressure tests with the canister for the full duration of 3 to 5 days is recommended.
Additionally, the portability test indicates that the device can maintain pressure over an extended period,

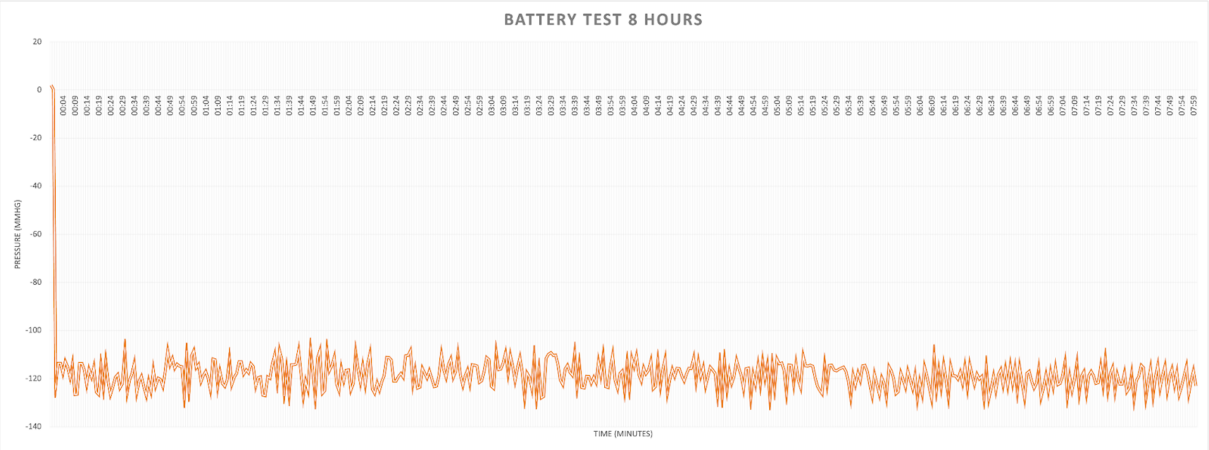


Figure 3.7: Outcome Portability Test

though it showed greater fluctuations. This variability can be attributed to the absence of a canister during testing.

1.3
While all pumps operate within acceptable limits, pump 2 exhibits more fluctuations compared to pump 1 and 3. This behaviour may be attributed to leakage within this pump. It is advisable to establish a maximum allowable leakage for the device, as frequent activation can be uncomfortable for the patient. Nevertheless, the results indicate that the device can respond adequately to this leakage.

3.4.2. 1.4
The maximum test results indicate a mechanical endstop of -200 mmHg, based on the motor's performance. Research shows that VAC therapy is effective up to -175 mmHg, with a maximum of -200 mmHg, confirming that this value poses no danger to the patient [19]. Since the purpose of a mechanical endstop is to prevent dangerous situations, experts on VAC devices recommend a mechanical endstop of -200 mmHg over one at -125 mmHg, as the latter could be overly restrictive and less user-friendly, see Appendix D.

3.4.3. Airflow test
The airflow test results are promising, as the measurements exceed the required airflow levels. However, data collection was challenging due to fluctuations caused by the motor activating to compensate for leakage. It would be easier if the analyser could measure both pressure and airflow simultaneously. The third pump shows a less steep regression line in the graph. This can be attributed to it being the last pump tested, where the focus shifted to identifying the critical point at which the pump could no longer compensate for leakage.
For future research, it is recommended to evaluate various leakage rates, such as -100 L/min, -200 mL/min, -300 mL/min, and -400 mL/min, and documenting the corresponding pressure.

3.4.4. Portability
The portability test was conducted without a canister and lasted only 8 hours. Ideally, this test should be combined with testing requirement 1.1. Additionally, the canister should be connected to the WOCA during the test to better reflect actual performance conditions. It would also be useful to determine how long the device can operate on a full battery.
The portability test was performed with the housing over the device, ad after 8 hours of operation, the temperature was measured, showing no concerning results. The maximum recorded temperature was 37,4 °C in the area of the motor controller, which is designed to isolate heat. Thus, results are not alarming. This test is performed without implementation of a silencer.
The test was conducted on only one of the three WOCA devices. Ideally, all three devices should have been tested. However, since all three use the same battery, it is unlikely that this would yield significant

different results.

3.4.5. Noise level test

Accuracy of testing

The accuracy of the testing is limited due to the inability to find a completely quiet room, resulting in interference from environmental noise which could cause the measurements. By performing background noise measurements this influenced is tried to be limited. Additionally, measurements were made sing a smartphone app; using more precise measurement equipment would enhance accuracy.

Interpretation of Outcomes

The WOCA produces a noise level that exceeds the required limit of 35 dB. The sound is comparable t background music, which is assumed uncomfortable for patients trying to sleep, although not considered dangerous [10].
According to ISO 1000070-4:2021, the maximum A-weighted sound pressure level for low vacuum/low flow thoracic drainage suction equipment is set at 60 dB (A) when measured at 1 meter. This is equivalent to a measurement of 54 dB at a distance of 0.5 meters [1].
While the noise from the WOCA is not harmful, it is considered uncomfortable patients. Therefore, it is recommended that noise reduction measures be implemented before starting the clinical trial. Participants have validated that the noise of the WOCA is an improvement over the AquaVAC (see Appendix D).

Future testing

For future testing, it would be beneficial to set requirements for leakage based on how often the motor activates. This information is considered valuable in relation to the discomfort caused by the noise for the patient.

3.4.6. Lifespan test

16.1

Additionally, testing the device's performance during air transportation would be valuable.

3.5. Conclusion

3.5.1. Pressure test

1.1

As the pressure is not measured for 3 - 5 days, requirement 1.1 is not verified within this graduation project and therefore it is recommended to verify for this requirement before performing the clinical trial.

1.3

Based on the measured data, it can be concluded that the WOCA complies with requirements 1.3, as the graph shows that the pressure holds within the 10 % range.

1.4

Based on the measured data it can be said that the WOCA device is not meeting requirement 1.4, and the device can exceed the limit of -125 mmHg when the software is not working properly.

Although, based on additional research, design requirement 1.4 is deemed undesirable, and the current mechanical endstop of -200 mmHg is considered safe for the patient.

3.5.2. Airflow test

As pump 1 is able to overcome an air leakage of -200 mL/min, pump 2 an air leakage of -165 mL/min, and pump 3 an air leakage of -202 mL/min it could be said that all 3 WOCA devices are able overcome an air leak rate ranging from 100 to 3000 mL/hr. Based on the measured data, it can be concluded that the WOCA meets both requirements 2.1 and 2.2.

3.5.3. Portability test

Based on the measured data from this test, showing that the WOCA is able to maintain a pressure of -125 mmHg for at least 8 hours on a full battery it can be concluded that requirement 7.4 has been met.

3.5.4. Noise level test

Based on the measured noise for the WOCA of on average of 51,4 dB it is concluded that the WOCA is exceeding the operating desired noise level of 35 dB, and therefore is not meeting requirement 8.1.

3.5.5. Lifespan test

Based on the outcome that the WOCA is still operationable after transportation on challenging roads, it is concluded that requirement 16.1 is verified for the WOCA.

The results of the verification tests are summarized in figure 3.8. In this figure, green indicates that a requirement is met, orange indicates that additional verification is needed, and red indicates that a requirement was not met. The findings show that the WOCA has not been verified for all technical requirements.

Before conducting a clinical trial, it is essential to implement noise reduction; however, the implementation of a mechanical endstop at -125 mmHg is not deemed necessary. Furthermore, it is recommended to conduct a pressure test over a period of 3 to 5 days prior to the clinical trial.

Group	#	Requirement/Wish	Description	Verification
Pressure	1.1	Requirement	The device can create and maintain a pressure level of -125 mmHg during one treatment cycle (3-5 days)	
	1.3	Wish	The device can self-regulate the pressure within 10% of the indicated pressure range	
	1.4	Requirement	The device has a (mechanical) safety stop to ensure that pressure level will never exceed -125 mmHg	
Airflow	2.1	Requirement	The device is able to overcome an air leak ratio of 0-100 mL/hr	
	2.2	Wish	The device is able to overcome an air leak ratio of 100-3000 mL/hr	
Portability	7.4	Requirement	The device operates for at least 8 hours on a full battery	
Noise	8.1	Requirement	The operating sound level does not exceed 35 dB	
Lifespan	16.1	Requirement	The device (in package) can withstand transportation on difficult roads	

Figure 3.8: Outcomes tests performed for Design Requirements Verification

4

Validation Design Requirements

Within this chapter the validation process for the design requirements is described. By performing interviews end users are asked whether or not the device is meeting the intended user design requirements.

4.1. Introduction

The user requirements are validated during the validation process, which requires input from experts. Interviews have been identified as the most effective method for this purpose. Participants are recruited from INF hospitals, specifically targeting nurses who work there. Ideally, these participants should have experience with the AquaVAC, and it is essential that they are proficient in English. The availability of staff is taken into consideration during recruitment.

Efforts are also made to address any cultural differences between the participants and the researcher.

4.2. Method

The validation method involves an interview protocol. Design requirements are presented as yes/no questions, and there is an opportunity for participants to provide feedback. Additionally, the interview includes other questions aimed at identifying ways to improve the WOCA. The summaries of the interviews, including the interview protocol, can be found in appendix D.

By knowing that the Nepalian culture is less likely to answer with no to questions, it is highlighted during the interview often that there is no right or wrong and that it helps to give feedback. Also, it is tried to create a comfortable space for the participants so that they feel comfortable, and it is highlighted that the feedback will not be shared with other people working at INF.

The outcome of the validated design requirements is determined by comparing the number of participant who agree with the validation to those who disagree.

4.3. Results

The results of the interview are presented in figure 4.1.

Design requirements 6.1, 6.2, 7.2, 9.3 and 12.1 received validation from all participants. Design requirements 9.1, 14.1, 14.2, 15.1 and 16.2 were validated by most participants, although some responses included 'No Answer' (NA) from those who chose not to respond, or because the question was misunderstood. One participant did not validate design requirements 7.6 an 16.2.

Remarks during validation:

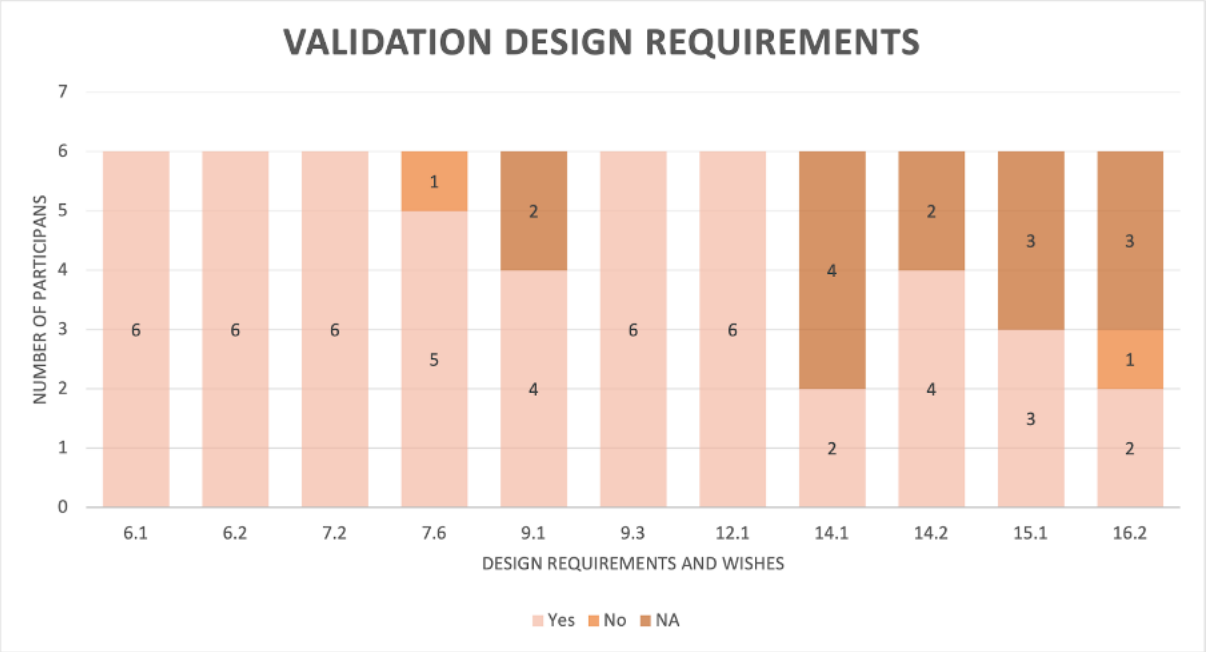


Figure 4.1: Results of validation design requirements (NA = No Answer)

- 7.6: One participant did not validate this requirement because individuals with mobility issues may also lack full finger function, making the device non-portable for them
- 16.2: One participant did not validate this requirement because the device is not water-resistant

4.4. Discussion

4.4.1. Validation process

Although the Nepali culture as taken into account, it was determined that yes/no questions were necessary for validation. Efforts were made to create an open environment during the interviews to minimize cultural influence, although it still was noted that participants were more inclined to answer with 'yes' rather than 'no. This observation was further supported by additional interviews with Western nurses, who were more willing to provide feedback (see Appendix D)/

It was tried to include as many participants as possible, although this was limited due to the availability of the nurses. To address this, some pairs of participants were interviewed together, which introduced potential bias. In the context of Nepali culture, individuals might have given more reliable responses in individual interviews, especially considering the existing hierarchy. However, due to the participants' difficulties with the English language, interviewing two people together helped them better understand the questions.

4.4.2. Recommendations

Additional validation

It was observed that Nepali staff was less comfortable discussing the technical questions related to the device compared to the Western nurses interviewed (see Appendix D). This difference was not accounted for prior to the validation process. into account before performing the validation. Based on this outcome, it is recommended to conduct additional validation with Biomedical engineers from INF hospitals for the more technical questions (design requirements 12.1, 14.1, 15.1, 16.2).

Redesign

For improving portability for individuals who lack full finger function it is recommended to implement a carrying strap for the WOCA

Manual

When writing a manual for the WOCA it is recommended to inform about the device not being water resistance.

4.5. Conclusion

Based on these findings, user requirements 6.1, 6.2, 7.2, 7.6, 9.1, 9.3, 12.1, and 14.2 are validated for the WOCA device in GPH. A summary of the validation results is presented in Figure 4.2.

Based on this outcome it is recommended to, before conducting the clinical trial, validate the user requirements 12.1, 14.1, 15.1, and 16.2 with the biomedical engineers of INF hospitals.

Group	#	Req/Wish	Description	Validation
Usability	6.1	Requirement	The device is easy to operate by medical staff with minimal training	
	6.2	Requirement	The device is easy to monitor by patients and caregivers with basic instructions	
Portability	7.2	Requirement	The canister is firmly attached to the device, while it can be easily removed for emptying	
	7.6	Wish	The device can be carried by patients with mobility problems	
Safety	9.1	Requirement	The device should remain stable on the ground without the risk of tipping over	
	9.3	Requirement	The content of the canister and fluid tube should be clearly visible during use (to be able to detect any signs of infection)	
Reliability	12.1	Wish	The number of components is reduced as much as possible	
Repairability	14.1	Requirement	The device can be (dis)assembled with local skills and tools	
	14.2	Requirement	Individual parts can be removed and replaced	
Maintenance	15.1	Wish	The device is low-maintenance	
Lifespan	16.2	Requirement	The device can withstand rough handling (shocks and small impact)	

Figure 4.2: Outcome Validation

5

Verification applicable ISO norms

5.1. Introduction

5.1.1. Suitable ISO standard

ISO 10079-4:2021 is the standard for medical suction equipment and is the appropriate ISO standard for a VAC device. Although a VAC device can be used in various settings, the applicability of this standard depends on how the WOCA is used.

5.1.2. Suitable ISO norms

A detailed description of the criteria from ISO 10079-4:2021 can be found in the appendix E.

These criteria, based on the work of J. van den Boom, are assessed for their applicability to the VAC device, which functions as a low-vacuum/low-flow system. The relevance of each criterion has been evaluated.

It was observed that some of the requirements from the ISO standard are already considered and integrated into the device's design requirements.

This section discusses the criteria that require additional testing. A summary of the analysed ISO criteria, and the suitable steps taken is attached in Appendix E.

5.2. Method

5.2.1. Criteria 6.2.2.1.

Collection containers shall not implode, crack or permanently deform and shall meet the requirements of Clause 7, as appropriate, after being subjected to a pressure of either 120% of the manufacturer's recommended maximum vacuum level or 95 kPa below atmospheric, whichever is the stronger vacuum level, for 5 minutes.

This criterion is tested by exposing the canister to the maximum pressure for the WOCA for 5 minutes. To do this, the software end stop in the Arduino code is removed. First, connect the laptop to the Arduino board of the WOCA, and use the Arduino software to change the value of -135 in line 126 to -1000. After saving this change to the Arduino board, the WOCA is connected to the FLUKE analyzer to monitor the pressure for 5 minutes with measurements taken every minute. The target pressure is set to -125 mmHg.

5.2.2. Criteria 6.3.3.1.

Collection container exhaust ports It shall not be possible to connect suction tubing to the collection container exhaust ports.

This criterion is further validated during user testing, where the canister lid's one-way principle is assessed for connecting the tubes from the dressing to the canister and from the WOCA to the canister. The goal is to determine whether users understand this feature correctly.

5.2.3. Criteria 7.1.

Suction equipment shall operate, within the manufacturer's specifications, when in its normal operating position and placed on a sloping surface (10 +/-1) degree from the horizontal.

For testing this criteria for the WOCA device there is a focus on the overflow protection mechanism. Whereby the performance of the overflow protection is tested on a inclined surface at 10 degrees from the horizontal.

5.2.4. Criteria 7.2.2.1.

Overfill protection devices shall not activate at least 90% of the indicated maximum capacity of the collection container has been reached.

This criteria is tested by allowing 270 mL of fluid in the canister and determining whether or not the overflow protection is activated.

5.2.5. Criteria 7.2.2.2.

When an overfill protection device is activated, suction shall crease and prevent > 5 ml of fluid from passing downstream of the overfill protection device within 2 minutes.

This is tested by testing the working mechanism of the overflow protection by getting water to the canister. The amount of time can be measured between the moment 500 mL of fluid is gathered in the canister by the WOCA, and the moment the canister stops collecting water. Also, the amount of actual water collected in the canister can be measured after the performed test.

5.3. Results

5.3.1. Criteria: 6.2.2.1.

Canister was not damaged or deformed after reaching -200 mmHg for 5 minutes. Figure 5.1 shows the test set-up for this test.

5.3.2. Criteria 6.3.3.1.

One-way use of the redesigned lid is validated during the interview by all the included participants, see Appendix D.

5.3.3. Criteria 7.1.

Testing of the situation for the overflow protection is shown in figure 5.2, the working mechanism of the overflow protection under this surface of 10 degrees can be found as video in the supplementary documents attached to this report.

5.3.4. Criteria 7.2.2.1

Overfill protection devices shall not activate at least 90% of the indicated maximum capacity of the collection container has been reached

Due to difficulties with achieving functional, and stable overflow protection it turned out not feasible to perform the tests for the overflow protection with this precision during this graduation project.

5.3.5. Criteria 7.2.2.2

When an overfill protection device is activated, suction shall increase and prevent >5ml of fluid from passing downstream of the overfill protection device within 2 min.

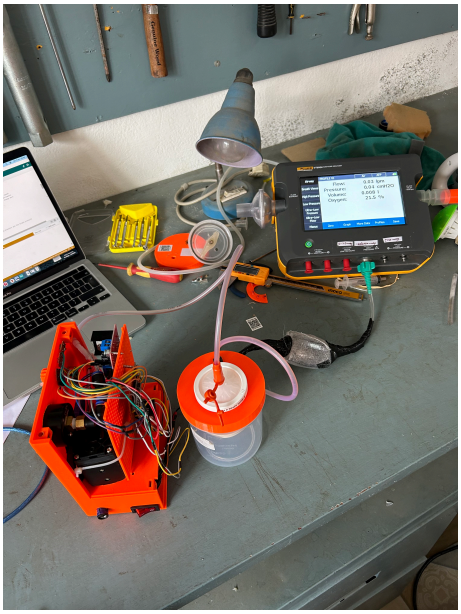


Figure 5.1: Performed maximum test including canister

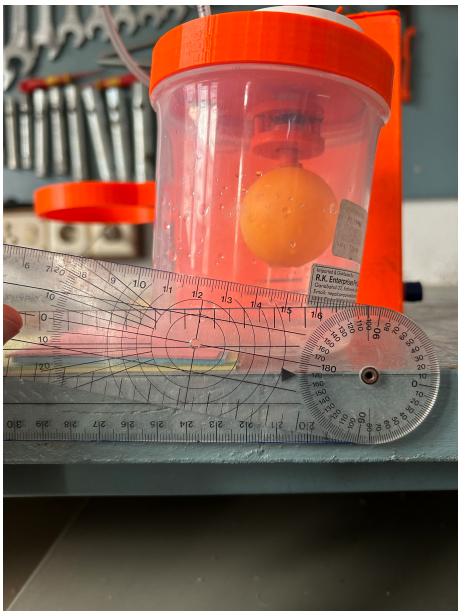


Figure 5.2: Overflowprotection test for ISO-norm criteria 7.1.

Due to difficulties with achieving functional, and stable overflow protection it turned out not feasible to perform the tests for the overflow protection with this precision during this graduation project.

5.4. Discussion

5.4.1. Criteria 6.2.2.1.

This testing is conducted using the current version of the WOCA, which includes a plastic canister. However, as discussed later in this report, a new iteration of the WOCA incorporates a glass canister. It would be beneficial to conduct similar testing with the newly implemented glass canister.

5.4.2. Criteria 6.3.3.1.
Participants validated the one-way use of this lid by trying it themselves. Some recommended implementing colour coding for the tube connections to the lid. However, this would add an extra step to the assembly process and would not be applicable if different tubes are used for the dressing, therefore this feedback is not adapted in the redesigned WOCA. Concerns about damaging the lid and tubes were also considered, but the likelihood of material damage is low, as this was tested during the validation process.

5.4.3. Criteria 7.1.
This testing involves adding water directly to the canister, resulting in a large volume being introduced at once, which is unlikely to occur in a real-world setting where the exudate from a wound would be much less. The rapid influx of water creates a flow that affects the overflow protection, which needs to remain stable during such flow. It has been determined that the overflow protection operates more effectively when there is no flow, allowing for greater stability. The use of the 'fake wound' created for testing could have solved this problem.
Although water is used in the test instead of wound fluid, this primarily affects the floatability of the floater and does not impact the overflow protection mechanism as the density of exudate is higher than that of water. If the floater functions properly with water, it also works with exudate. However, due to the increased protein content, exudate is stickier than water, which may influence the cleaning of the overflow protection [5].

5.4.4. Criteria 7.2.2.1.
Additional testing for this criteria is recommended, as it was not feasible within this graduation project. If the overflow protection activates before 90% of the maximum capacity, it does not endanger the patient but may cause discomfort for the user.

5.4.5. Criteria 7.2.2.2.
The same considerations apply to this criteria as to criteria 7.2.2.1. It is still recommended to test this criteria, as a delay in the operation of the overflow protection is viewed as more dangerous compared to activation of the overflow protection too early. However, the precision of 5 mL is not deemed critical.

5.5. Conclusion
Based on the outcome of the verification of the discussed requirements it can be said that the criteria 6.2.2.1., 6.3.3.1, and 7.1 of the ISO 10079-4:2021 are verified for the WOCA. Before conducting a clinical trial it is recommended based on the ISO-norm analysation to first test for the Criteria 7.2.2.1. and 7.2.2.2. The outcome of this verification is summarized in figure 5.3.

Category	Subcategory	#	Criteria	Verification
Strength		6.2.2.	Collection containers shall not implode, crack or permanently deform and shall meet the requirements of Clause 7, as appropriate, after being subjected to a pressure of either 120% of the manufacturer's recommended maximum vacuum level or 95 kPa below atmospheric, whichever is the stronger vacuum level, for 5 minutes.	
Connections	Collection container exhaust ports	6.3.3.	It shall not be possible to connect suction tubing to the collection container exhaust ports.	
Performance requirements	Operating position	7.1.	Suction equiment shall operate, within the manufscturer's specifications, when in its normal operating position and placed on a sloping surface (10 ±1) ° from the horizontal	
Protection devices	Overfill protection devices	7.2.2.1.	Overfill protection devices shall not activate at least 90% of the indicated maximum capacity of the collection container has been reached	
		7.2.2.2.	When an overfill protection device is activated, suction shall cease and prevent >5 mL of fluid from passing downstream of the overfill protection device within 2 minutes	

Figure 5.3: Outcome ISO criteria verification

6

Risk Assessment

Within this chapter the performed risk assessment for the WOCA device is described. By including students with different background, and expert VAC users the potential hazards and risks for the WOCA are determined, and suitable recommended actions are discussed.

6.1. Introduction

As mentioned in the general introduction of this report, a risk assessment for the WOCA device is conducted in preparation for a clinical trial. This section outlines the steps for a Failure Mode and Effects Analysis (FMEA) risk assessment and explains how these steps are applied specifically to the WOCA.

6.2. Method

The FMEA risk assessment involves both experts in VAC devices and students from various disciplines, including clinical technology, electrical engineering, mechanical engineering, and industrial design. This approach aims to create a comprehensive overview of potential failures from different perspectives.
The FMEA process is organized as follows:

- Identification of the Potential Failure Modes: Participants brainstorm and compile a list of possible failure modes for the WOCA device. This is done by examining each process step and component, and encompasses mechanical, electrical, and clinical failures.
- Assessment of Effects and Severity: For each failure mode, the group discusses its potential effects on device performance and patient safety. Each effect assesses a severity rating, with scores ranging from 1 to 10, based on the potential impact.
- Determination of causes and likelihood: The group analyses the causes of each failure mode and assesses their likelihood of occurrence, which also scores for a number from 1 to 10
- Risk Priority Number (RPN) calculation: An RPN calculates for each failure mode by multiplying the severity, likelihood, and detectability ratings. This helps prioritize the risks that need action.
- Recommendations for Mitigation: Finally, the group develops recommendations for addressing the high-priority risks. Typically, an RPN value of 150 is used as the threshold for determining the necessary actions.

It has been decided to create a single risk assessment that summarizes the views of all participants.

6.3. Results

The full risk assessment can be found in appendix B.
An RPN of 150 indicates the need for action, while the highest score recorded in the Risk Assessment is 70, indicating that no immediate actions are necessary. However recommendations are provided

for any score above 30. These recommendation include staff training and suggestions for improving cleanability documentation and manuals.

Table 6.1 highlights the three risks with the highest RPN scores and their corresponding recommended actions.

Potential risk	RPN	Recommended action
Amount of pressure given during treatment too high due to pressure sensor not calibrated	70	Include in manual to check the pressure sensor when installing the device, and check the pressure sensor every half a year
Overflow protection stops working during treatment, whereby canister becomes overfull	63	Include in manual to check the overflow protection when cleaning the canister
Tubes/canister are not properly cleaned, which could cause infection of patient	54	Give staff training about the importance of cleaning

Table 6.1: Risk Priority Number (RPN) and recommended actions for different risks.

6.4. Discussion

The FMEA risk assessment is conducted with students and experts on VAC devices in the Netherlands, even though the WOCA is intended for use in Nepal. This geographical difference makes it more challenging to identify potential risks specific to the Nepali context. However, during the validation process, efforts were made to address risks that are more likely to arise in Nepal. Including the perspectives of participants from HICs in this FMEA risk assessment provides valuable insights into the potential risks associated with the device, drawing on their technical expertise.

Additionally, it would be beneficial to conduct the FMEA risk assessment with staff from the biomedical office at GPH or other biomedical engineers working in hospital in LMICs. This would help identify potential risks specific to devices used in those settings.

Furthermore, after the device is used or following the clinical trial, it would be valuable to conduct another FMEA risk assessment. This would involve documenting any issues that arose during use and proposing solutions to address them.

6.5. Conclusion

The results of the FMEA risk assessment for the WOCA indicate that no significant risks or hazards have been identified. This assessment can be included with the application to the NHRC.

7

Redesign

This chapter outlines the design iterations made to align the WOCA device with the requirements outlined earlier in the report. It includes two main functional improvements namely the canister implementation and the noise reduction. By analysing the functional requirements multiple design concepts are developed, and the most promising concept is selected using a Harris profile. This chapter details the design process, explains design decisions, and concludes with the final redesign at GPH.

7.1. Introduction

There are two main redesign issues where this graduation project focus on. First, it is necessary to implement the canister to the WOCA for allowing full function of the device. Secondly, the reduction of noise is necessary as highlighted during the validation.

The requirements for both the canister implementation and noise reduction are divided into three categories: relevant initial design requirements, non-functional requirements, and material specifications.

7.1.1. Applicable Functional Design Requirements

Canister implementation

Based on the initial design requirements of E. Raaijmakers the relevant groups within the design requirements for the canister implementation are considered 'fluid collection' and 'applicability'. To enhance readability, these are presented in table 7.1 again.

Group	#	Requirement
Fluid Collection	4.1	Wounds fluids are collected into a sealed canister without spillage
	4.2	The canister is non-leaking, airtight, detachable and can store at least 300 mL of fluids
	4.3	The canister cannot overflow (overflow protection is in place)
Applicability	5.1	The device is compatible with self-made wound dressings

Table 7.1: Initial design requirements applicable for the canister implementation

Although not specified in the design requirements, the report of E. Raaijmakers mentions the necessity of a bacterial filter. This filter prevents bacteria from entering the motor through the canister, making it essential to place the bacterial filter between the motor and the canister.

The relevant initial design requirements can be summarized into the following components for the canister implementation:

- Canister

- Tube from dressing to canister
- Tube from canister to motor
- Overflow protection
- Bacterial filter

Noise reduction

For noise reduction the relevant initial design requirement group is considered 'noise', this design requirement is shown in table 7.2.

Group	#	Requirement
Noise	8.1	The operating sound level does not exceed 35 dB

Table 7.2: Initial design requirements applicable for the noise reduction

7.1.2. Applicable Non-Functional Design Requirements

For the non-functional requirements related to the canister implementation and noise reduction, the initial design requirements from E. Raaijmakers are referenced again. The non-functional requirements to consider include, but are not limited to, **costs, repairability and usability**.

7.1.3. Material Restrictions

Based on the intended goal of the design, the materials used must be available at GPH and comply with the non-functional requirements. For instance, cost and availability are important factors to consider when making design choices and selecting suitable materials.

Canister implementation

Based on the work of predecessors and the staff of GPH, the following material restrictions are set for the canister implementation:

- The canister must be a 500 mL plastic container that is already available at GPH and ordered by J. van den Boom
- The Bacterial filter must be from a Nidek Nuvo Mk5 oxygen concentrator, as specified by the Biomedical Engineering Office at GPH. The filter has an outer diameter of 9 mm and an internal diameter of 6 mm
- The tube connecting the dressing to the canister must be a flexible incubation tube with an internal diameter of 4 mm, as specified by the staff at GPH

Noise reduction

There are no additional material restrictions for the noise reduction.

7.1.4. Design Plan

Canister implementation

The requirements for the canister implementation reveal some interdependencies between components that need to be addressed:

- The placement of the bacterial filter
- The tube from the motor to the canister

Placement of bacterial filter

Certain restrictions apply to the placement of the bacterial filter:

- WOCA output: 4 mm inner diameter
- Bacterial filter: 9 mm outer diameter (on both sides)
- Placement requirement: The filter must be positioned between the canister and the motor

Considerations
The number of components are minimized as much as possible (design requirement 12.1). To enhance the functionality of the bacterial filter, the filter should be attached to a stable component to reduce the risk of falling or being damaged. Therefore, placing the bacterial filter in the middle of the assembly (motor-tube-bacterial filter-tube-canister) is not considered.
Two placement options for the bacterial filter are being evaluated:

- Directly on the WOCA
- Directly on the canister

In both scenarios, a connector between the tube and the bacterial filter is necessary. However, limited space for connecting the filter to the WOCA makes assembly challenging. Additionally, placing the filter on the WOCA makes the design more vulnerable for damage since the filter would extend outside the housing. For these reasons, it has been decided to place the bacterial filter on the canister. This configuration allows for a more secure connection and minimizes the risk of damage to the WOCA.

Tube from motor to canister
Certain restrictions apply to the design of the tube:

- WOCA output: 4 mm inner diameter
- Bacterial filter: 9 mm outer diameter (on both sides)
- Tube requirement: must allow the canister to move freely in and out of the canister holder

Considerations
The selection of the tube is limited to the types available at GPH. Two options are being considered:

- Heating a rigid tube to achieve the desired shape
- Using a flexible tube

Heating a rigid tube to the desired shape restricts the canister's range of motion compared to a flexible tube. Additionally, heating requires extra manufacturing steps. Therefore, a flexible tube is used.
Although there were concerns about the availability of flexible tubes, surgeons confirmed that the incubation tube, which is also used for the dressing, is well available within GPH. This tube meets the necessary requirements and fits with the bacterial filter, eliminating the need for an additional connector between the filter and the tube.

The selected tube and its connection to the bacterial filter are shown in figure 7.1.

Based on these determinations, the following designs and their requirements are developed, with Must Haves designated as MH and Should Haves as SH.
Lid of Canister

- MH-01: The lid of the canister must be airtight
- MH-02: The connection between the lid and the canister must be airtight
- MH-03: The lid must allow for easy connection and disconnection of a tube with an inner diameter of 4 mm and an outer diameter of 6 mm
- MH-04: The lid must accommodate a bacterial filter with an outer diameter of 9 mm

Overflow protection

- MH-01: The overflow protection must activate at 300 mL
- MH-02: The overflow protection must be integrated into a 500 mL plastic canister
- SH-01: The overflow protection should alarm when activated

Canister holder

- MH-01: The canister holder must secure the canister to the WOCA housing
- MH-02: The canister holder must allow for easy attachment and detachment of the canister

Figure 7.1: Placement of bacterial filter and desired tube to motor

- MH-03: The canister holder must hold the canister
- MH-04: The canister holder must provide stability for the canister
- MH-05: The canister holder must allow for visibility of the canister during treatment

Noise reduction

The feedback regarding noise reduction identifies two distinct issues: the sound produced when the device is switched on and the overall noise generated by the device.

Gradual motor control

Based on the work of predecessors, it was determined that using gradual motor control can minimize the sound produced when the motor is switched on. Therefore, by reverting to N. Nicolai's design and using a different type of motor along with gradual motor control in the Arduino code, the noise can be reduced. The specifications of the motor and the Arduino code can be found in Appendix A.

Silencer

To address the overall sound of the device, implementing a silencer has been identified as a suitable solution. A silencer is preferred over a muffler because it allows airflow from the motor, preventing overheating of the device.
It is recommended to place the silencer inside the housing for a more professional appearance and to reduce the risk of damage. The requirements for the silencer are as follows:

- MH-01: The silencer must effectively reduce noise
- MH-02: The silencer must not obstruct airflow or cause of the WOCA motor to overheat

Although pre-made silencers are considered, these do not meet the design requirements for the WOCA primarily due to their high costs. Therefore, designing a custom silencer using 3D printing is seen as the best option.
Based on performed research, three possible approaches to reduce noise are identified

- Using a chamber design
- Incorporating foam
- Extending the length of the silencer

Testing these options and their combinations helps determine the most effective silencer design for the WOCA.

7.2. Method

This section discusses the design considerations that led to the final design of the WOCA at GPH. The design choices are tailored specifically to the capabilities of GPH.

7.2.1. Redesigned lid for canister

Design approach

The primary challenge of this redesign is ensuring that the lid is airtight. The process begins with researching potential airtight materials. Once suitable materials are identified, the overall lid design is created. Following that, the various airtight connections are developed and integrated, including connections between the lid and the canister, the lid and the dressing tube, and the lid and the bacterial filter.

Suitable material

To identify suitable airtight materials, initial performed brainstorm sessions focus on possible airtight solutions, followed by additional research. Promising airtight solutions are summarized in 7.2

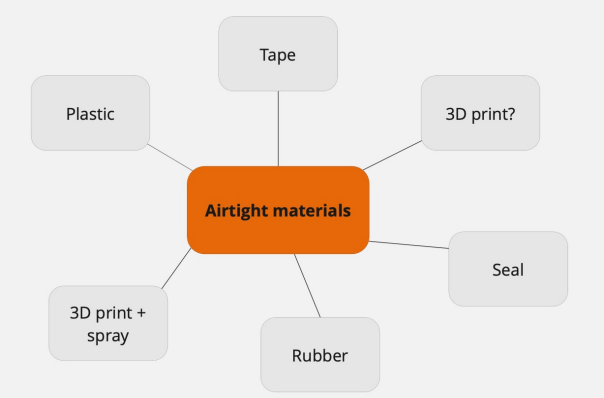


Figure 7.2: Possible Airtight Materials

This sparks interest in exploring airtight 3D printing options. 3D printing is appealing due to its potential to create designs tailored specifically to meet particular needs.

Design of the lid

During the redesign of the lid, two options are considered: a complete redesign of the lid or the attachment of the original plastic lid.
3D printed attachment of the original plastic lid:

- Design challenge: There is a risk for leakage between the attachment and the original lid

Completely 3D printed lid:

- Design challenge: Creating an airtight screw for a 3D printed lid may pose difficulties

Connection between lid and canister

For this connection existing options for creating an airtight seal are explored. The original canister lid already includes a rubber O-ring designed to ensure an airtight connection.

Connection between lid and bacterial filter

The connection between the lid and the bacterial filter must be stable, as the filter is used in between patients and only is replaced when dirty by the Biomedical Office. Therefore, the connection must allow for the (de)attachment of the bacterial filter, but it should not be easily removed.

Connection between lid and dressing tube

Since the dressing tube needs to be easily attached and detached from the lid of the canister, a connection pillar with a 4 mm inside diameter is incorporated in the lid. Both direct integration of this connection piece in the redesigned lid and 3D printing a custom connection pillar are considered. However, due to the challenges associated with 3D printing these shapes, it was decided to purchase this connection piece online. To ensure an airtight connection, suitable airtight materials are explored.

7.2.2. Overflow protection

Design approach

Initially, a brainstorm session explores different overflow protection mechanisms and related applications. From this discussion, three potential concepts for overflow protection are analyzed. Using a Harris profile, the most promising design is selected and refined into the final design.

Brainstorming

During the brainstorming session, existing overflow mechanisms are discussed. The results of this brainstorm are illustrated in 7.3.

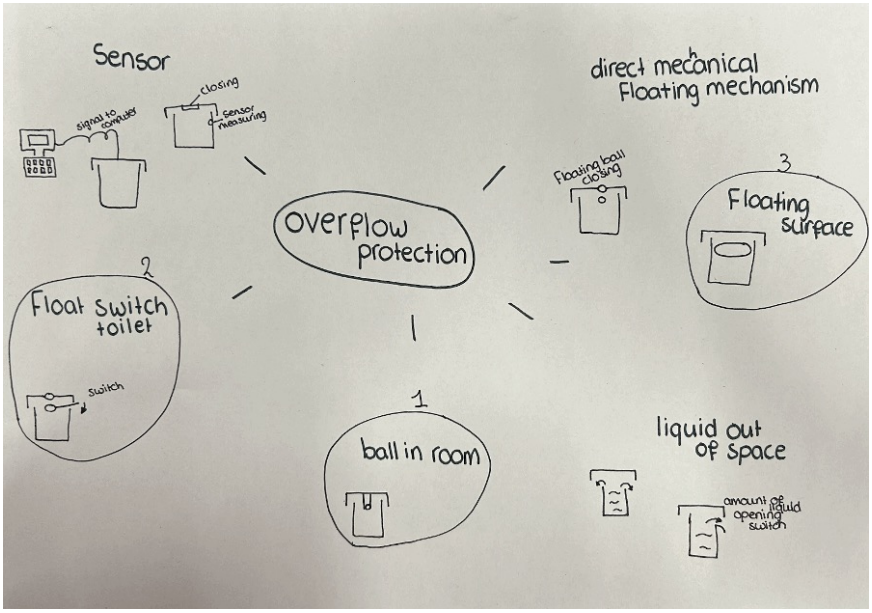


Figure 7.3: Brainstormsession for possible overflow protection mechanisms

3 considered concepts

The brainstorming session yielded three potential options for overflow protection:

- 'Floater in Room': A floater that moves within a chamber and uses its material properties to block airflow when it reaches 300 mL of fluid
- 'Float switch': Similar to mechanisms used in toilets, this concepts involves a float that activates a mechanical switch when the fluid level reaches 300 mL, turning the device on or off
- 'Sensors': A sensor that detects when the fluid level reaches 300 mL and connects to the Arduino to stop the system

A Harris profile is created for the overflow protection, taking into account the non-functional requirements. These non-functional requirements include:

- Reliability: Minimizing the number of components
- Costs: Keeping expenses manageable
- Lifespan: Ensuring the device can withstand rough handling

Function	**Floater in room**	**Float switch**	**Sensors**
Reliability	+	-	++
Costs	++	++	–
Lifespan	+	–	++

Table 7.3: Harris Profile Overflow protection

Most promising concept
Using the Harris profile in table 7.3, the most promising design is identified. 'Costs' is the most critical factor in this evaluation, leading to the conclusion that the 'floater in room' concept is most promising.

Components of concept
Analysing the 'floater in room' concept in relation to the goal of the overflow protection, the individual components and their functions are as follows:

- Floater: Measures the fluid level
- Closing mechanism: Activates the overflow protection
- Stick: Triggers the mechanism at the desired fluid level
- Cage: Guides the movement of the floater

For each component, suitable materials and solutions must be identified. This process takes into account the component's function, the availability of materials at GPH, and the associated costs. The following options are considered for each component.
Floater

- 3D-printed custom floater: This option is cost-effective and allows for a design tailored to fit the canister easily
- Existing floater from suction device at GPH: Utilizing pre-existing and functional materials
- Ping Pong Ball: An inexpensive option that is capable of floating

Closing mechanism

- 3D printed connection: This allows for a custom design, potentially reducing the number of components since the stick could also serve as the closing mechanism
- Rubber: Provides an effective airtight seal
- Plastic: Another option that can create an airtight connection

An airtight connection is necessary, ideally positioned directly at the output of the bacterial filter.

Prototype testing shows that rubber can form an airtight connection with plastic; however, rubber cannot be placed directly on the output of the bacterial filter due to its tapered shape. Using a syringe is explored, as it fits perfectly at the output of the bacterial filter and features a built-in airtight closing mechanism.

For the cage and the stick, existing materials are considered, such as using a straw as a stick. Additionally, 3D printing is an option, allowing for easy redesign and size adjustments to meet specific requirements.

7.2.3. Canister holder
Design Approach
To meet the design requirements for the canister holder, solutions are needed for securing the canister within the holder and for attaching the canister holder to the WOCA housing. Through brainstorming, three potential concepts are identified. The most suitable option is selected using a Harris profile.

Brainstorming

Attachment concepts between the canister and the WOCA housing are explored and shown in figure 7.4.

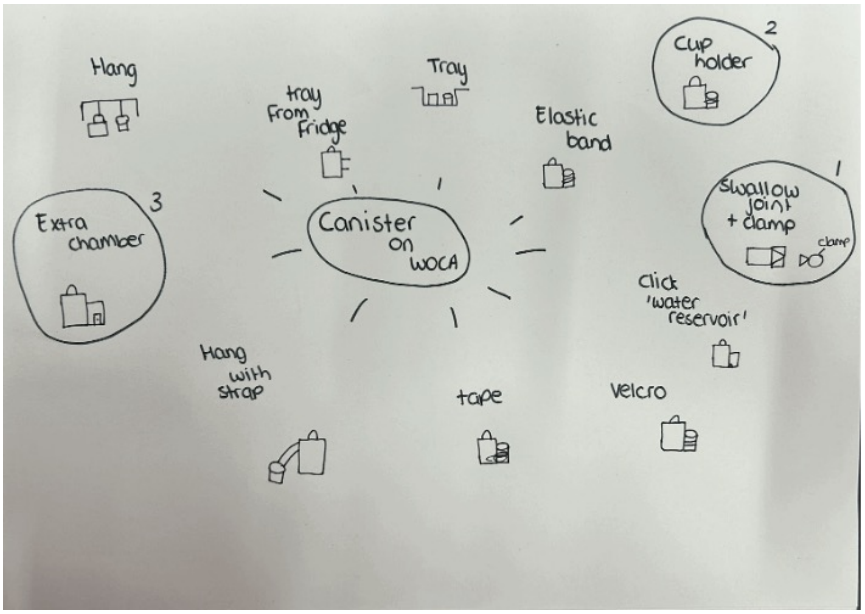


Figure 7.4: Brainstorm Canister on WOCA

Based on this brainstorm, the following concepts are evaluated:

- Hose clamp + swallow joint
- Cup holder + screws
- Extra chamber + glue

Key non-functional requirements for the canister holder design include usability (easy monitoring and operation of the device), cost-effectiveness, and reliability (minimizing the number of components).

Most promising design

The evaluation of these concepts are summarized in table 7.4.

	Hose clamp + swallow joint	Cup holder + screws	Extra chamber + glue
Usability	+	++	-
Costs	-	+	-
Reliability	-	+	+

Table 7.4: Harris profile canister holder

Due to the need for additional materials, the hose clamp with swallow joint scores lower in terms of cost and, with its multiple components, is also less reliable. The extra chamber concept requires substantial additional 3D printed material, making it less cost-effective compared to the cupholder, and its full enclosure reduces usability. Consequently, the cupholder with screws is determined to be most promising.
This outcome aligns with the brainstorming results from E. Raaijmakers.

7.2.4. Silencer

In line with the silencer's design requirements, three potential silencer designs are tested to measure noise reduction (in dB) and any effect on the motor's temperature (in °C).

Testing protocol

Testing was conducted in a quiet room to ensure accurate noise measurement of the WOCA, maintaining a 50 cm distance to replicate the distance between patient and WOCA during treatment. Measurements are taken using the Decibel X app on a smartphone, only allowing measurements for 30 seconds. Initial baseline measurements ('zero measurements') are recorded for both noise and motor temperature before testing.
The WOCA is set to a target pressure of -125 mmHg and operates for 5 minutes. To capture stable operating noise, continuous noise is measured from the 3rd minute. After 5 minutes, the WOCA is powered off, and the motor temperature is measured. This protocol is followed for each silencer design. Starting with a small silencer the use of foam is determined, with results shown in 7.5. Results shown in table 7.7. After this the determination for a chamber design is decided, for both these silencers foam was used. Outcomes are shown in table 7.5. After this it is determined what size of silencer is desired. Therefore, a long and small silencer are compared, both with the use of a chamber and foam. Outcomes are summarized in table 7.7.

Silencer	Average Noise (dB)	Temperature Increase (°C)
With foam	54.3 dB	+16.1 °C
Without foam	61.3 dB	+15.5 °C
Without silencer	61.7 dB	+11.9 °C

Table 7.5: Measured noise for determining the use of foam

Silencer	Average Noise (dB)	Temperature Increase (°C)
Chamber	55.9 dB	+15.4 °C
No chamber	55.8 dB	+14.8 °C
No silencer	61.7 dB	+14.1 °C

Table 7.6: Measured noise for determining the use of a chamber for the silencer

Silencer	Average Noise (dB)	Temperature Increase (°C)
Long	53.7 dB	+11.9 °C
Small	59.9 dB	+11.4 °C
Without silencer	61.7 dB	+11.9 °C

Table 7.7: Measured noise for determining the use of small or long silencer

The test set up is illustrate in figure 7.5.

For the choice between using no chamber, or a chamber design it is chosen to use a chamber although the difference is very small (0,1 dB). This choice is made based on additional testing for the mean value when the device is turning on. This test is performed after implementing the gradual motor control. Also, looking at the data it could be said that the silencer with only foam is very similar to the outcome of a silencer with long and chamber and foam design. Although, also for this silencer it is shown that the mean dB when starting on for the device is for only foam 58,1 dB and for the use of all 3 components is determined at 51,4 dB.

A silencer design combining foam, a chamber, and an extended length appears to be the most effective in reducing noise without raising the motor's temperature.

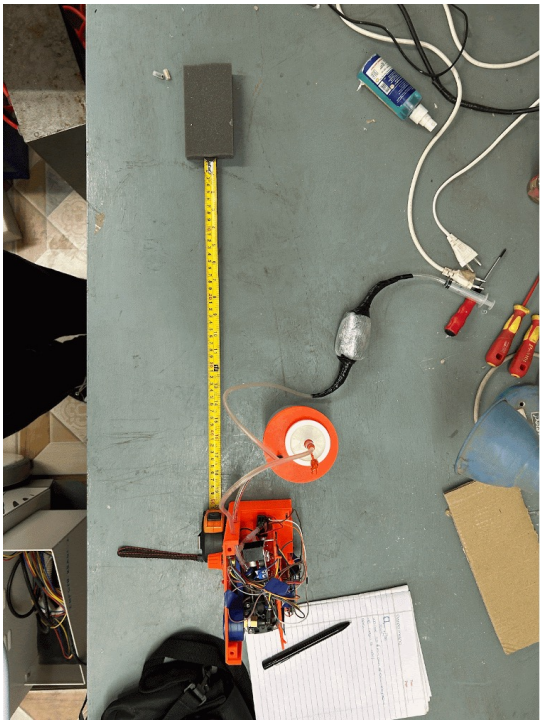
7.3. Results

7.3.1. Redesigned lid for canister

Suitable material

Research and prototyping confirmed the feasibility of producing an airtight 3D printed lid. Specific print settings used to achieve airtight results are documented in Appendix A.

(a) Quiet room to perform testing



(b) Components used in the test set up

Figure 7.5: Test set up for the silencer

Lid Design

A fully 3D printed lid was chosen over alternative methods for a more professional appearance and streamlined manufacturing process.

Connection between lid and canister

To ensure an airtight seal, the O-ring from the original canister lid was integrated into the redesigned lid by creating a recessed groove. This approach leverages existing materials and proven solutions.

Connection between lid and bacterial filter

To simplify manufacturing and reduce the number of components, a single hole was created in the canister lid for the bacterial filter connection. Using a 9 mm silicone tube for this connection was deemed optimal, based on available materials and airtight properties.

Connection between lid and dressing tube

The purchased connector includes a screw, which is incorporated into the lid. When paired with sealing tape, this ensures an airtight connection.

The resulting design is an airtight 3D printed lid featuring an integrated O-ring for the canister seal, a silicone connection to securely attach the bacterial filter, and a tube connection sealed with Teflon tape for added airtightness. Additionally, the screw thread from the original canister lid was recreated using the SolidWorks helix tool. The final lid design is shown in figure 7.6.

7.3.2. Overflow protection

For each component, the selected design choice and its suitability are discussed.

Floater

Due to reproducibility issues, the old floater was unsuitable. Calculations showed that a 3D printed floater would not fit in the canister, and therefore was not an option. Thus, a Ping Pong Ball is selected as the best option.

(a) Redesigned lid of canister top view

(b) Redesigned lid of canister bottom view

Figure 7.6: Redesigned lid of canister

Closing mechanism

Testing shows that the rubber and plastic components of a syringe could form an airtight seal. To enable movement between parts, the outer plastic of a 10 mL syringe is combined with the rubber from a 5 mL syringe. For optimal sealing performance, the rubber is positioned upside down to allow for deformation, enhancing the airtight connection.

Cage

A 3D printed cage is selected for this design because of the ability to precisely shape the form to fit both the syringe and the ping pong ball. The cage is constructed from two separate components, allowing for the Ping Pong Ball to be securely enclosed.

Stick

The stick is also 3D printed to achieve a more professional appearance and streamline manufacturing. The connection between the rubber and the stick is secured with a minimized amount of glue, to allow for movement of the rubber, enhancing the potential for an airtight seal.

This results in an overflow protection system that employs a Ping Pong Ball as a floater, which is glued to a 3D printed stick. This stick ensures that the overflow protection activates at the correct fluid level. At the opposite end, the stick is attached to the rubber of a 10 mL syringe, positioned upside down to create an airtight seal when the fluid level reaches 300 mL, triggering the overflow protection. The airtight connection is made using the plastic casing from a 5 mL syringe, which fits perfectly into the bacterial filter, securing the lid of the canister.

To ensure that the overflow protection remains inactive when the canister is empty but still ready for use, a 3D printed cage is designed to fit snugly around the plastic casing of the syringe when fluid enters the canister. The final design of the overflow protection is illustrated in figure 7.7.

(a) Overflow protection out of cage

(b) Overflow protection in cage

Figure 7.7: Overflow protection

7.3.3. Canister holder

The canister holder features a 3D printed circular design that encircles the canister, facilitating easy portability. It is securely screwed onto the WOCA housing and incorporates a T-shaped connector to provide a stable connection between the canister and the holder. The final design of the canister holder is shown in figure 7.8.

The current version of the canister holder at GPH is glued in place to prevent damage to the housing while the device was undergoing verification and validation. However, using screws would not pose a risk of breaking the housing, as demonstrated in the appendix .... and is preferred due to a more stable connection.

7.3.4. Silencer

A 3D printed silencer is designed that incorporates both foam material and a chamber. This long silencer is sized to fit the available space within the WOCA housing. The final design of the silencer is displayed in figure 7.9. To confirm that the silencer does not obstruct airflow, measurements for the airflow were taken both with and without the silencer, showing no unusual results.

7.4. Discussion

The design process was mainly conducted individually, with guidance from A. Knulst. Ideally, group collaboration would have enhanced creativity in the design. Although some brainstorming sessions included input from others, overall participation was limited.

7.4.1. Noise reduction

In addressing the noise reduction issue, existing ideas were referenced.

Gradual motor control

Given the success of gradual motor control in N. Nicolai's version, it was decided to re-implement this feature. However, the motors ordered from AliExpress in Nepal did not support gradual motor control. Due to the unknown specification of these motors, it is difficult to pinpoint the exact issue. Based on research it could be said that it is most likely that the AliExpress motor does not support Pulse Width Modulation (PWM), the method used by the Arduino to regulate motor speed. Where the motor ordered from the Netherlands did support for PWM.
The open-source publication's material list for the WOCA includes a link to a motor with more reliable specifications; further details can be found in Appendix A.

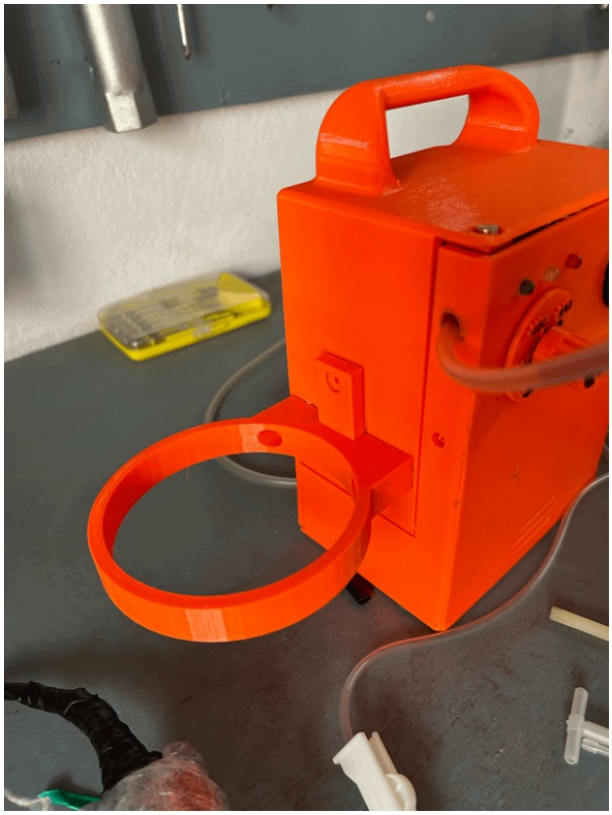


Figure 7.8: Final design of the canister holder

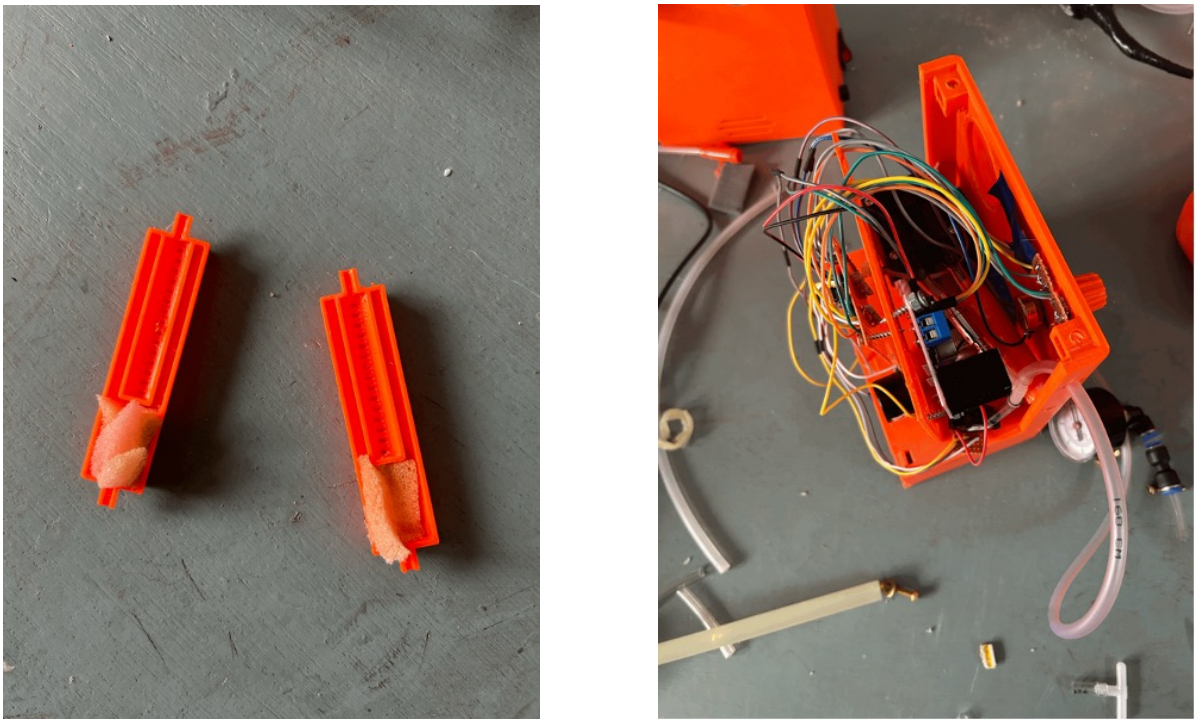
Silencer

Initially, designing a custom silencer for the WOCA was seen as a valuable educational opportunity, despite being time-consuming. This experience helped create a silencer tailored to the WOCA's needs, although it may not perform as well as commercially available options.
The testing process for the silencer's optimal properties could have been more professional. Access to quality measurement equipment and a quiet environment was limited, leading to external noise affecting the results.
Further research is needed to design an effective silencer for the WOCA, potentially by refining the design process or exploring ready-made options. Other combinations of silencer designs, such as a longer silencer with foam, could also be tested.
Temperature comparisons between the device with and without the silencer indicated minimal differences. The absence of increased temperature in later designs was likely due to reduced foam usage. Future measurements should assess the device's temperature over longer periods, such as five days of use. Attempts to measure the motor's temperature were obstructed by the rib gate, which can reach high temperatures but poses no safety risk to users. An additional performed flow test confirmed that the silencer does not block airflow.

7.4.2. Canister implementation

The canister design is based on a plastic container selected for this project. However, a glass canister is preferable due to its allowance for autoclaving. The open-source publication suggests a widely available glass canister and adapts the design to fit its specifications, as detailed in Appendix A.

The redesigned lid, overflow protection, and canister holder are primarily made with 3D printing, a cost-effective and accessible method at GPH. However, exploring designs with alternative materials could enhance the product's versatility.



(a) Inside of the silencer

(b) Silencer integrated in WOCA

Figure 7.9: Final design of the silencer

Redesigned lid

The redesigned lid is made from 3D printed material. While this choice simplifies the design process, it limits the cleanability of the lid. Although the 3D printed material can withstand cleaning with wipes and disinfectants- showing no visible damage- participants in the validation process noted that this is the most common cleaning method used in GPH. However, it's important to note that the material is not suitable for autoclaving.

Overflow protection

While the overflow protection is functional, its complexity and numerous components make it less reliable. The open-source publication simplifies the design by connecting the cage directly to the lid, which reduces the number of components (see Appendix A). However, this design still requires both a 5 mL and a 10 mL syringe, resulting in significant waste. A fresh pair of eyes on this design is highly recommended.
Like the redesigned lid, the cleanability of the overflow protection is also inadequate. In fact, the overflow protection is even more exposed to wound fluid than the lid. The design aims to minimize corners and work with edges, but this goal has not been fully realized. Future redesigns should prioritize improving cleanability.

The ink cartridge from a pen was initially considered for the stick due to its stiffness and small connection point to the rubber. However, it was ultimately rejected because it did not meet the professional manufacturing standards and appearance required for the design at GPH.

Canister holder

The amount of material used in the 3D print could be minimized and optimized for sufficient strength, which has not been done in the current design. Additionally, several alternative designs for the canister holder could be considered that do not require 3D printed materials.

To improve ease of use, the canister is now positioned on the side of the WOCA, making it more accessible when the housing is removed. In E. Raaijmakers' original design, however, the canister

was placed at the back of the WOCA housing.

7.5. Conclusion

7.5.1. Final Redesign

The final redesign of the three WOCA devices at GPH incorporates various components, including gradual motor control, a silencer for noise reduction, overflow protection, a canister holder, and a redesigned lid for the canister implementation. Additionally, a scale plate for measuring pressure has been included. This comprehensive integration of components is illustrated in figure 7.10

Figure 7.10: Final Redesign of the WOCA devices in GPH

8

Discussion

This chapter provides a short discussion of the outcome of this graduation project and includes recommendations and proposed next steps for the project.

8.1. General discussion

The verification and validation of the design requirements for the WOCA, verification of the applicable ISO-criteria and performance of a risk assessment indicate no risks for the users. However, the device is not made compatible with the design requirements for noise (8.1) and pressure (1.4). Based on the performed research within the graduation project design requirement 1.4 was deemed undesirable. Although, the reduction of noise is determined important for patient's comfort before conducting the clinical trial.

Furthermore, additional verification and validation is recommended before the performance of a clinical trial. Additional testing is recommended for the verification of design requirement 1.1, as well as the validation of design requirements 12.1, 14.1, 15.1, and 16.2. Moreover, verification of ISO criteria 7.2.2.1 and 7.2.2.2 is also recommended. These steps are important for ensuring the relevant standards determined with this graduation project for preparing the WOCA for the clinical trial.

When comparing the WOCA to the currently available AquaVAC at GPH, user feedback has validated that the WOCA represents an improvement, including in terms of noise reduction (see Appendix D).

8.2. Next steps

8.2.1. NHREC approval

A draft application for the clinical trial of the WOCA in GPH has been prepared within this graduation, and can be found in appendix C. This clinical trial is aims to evaluate the WOCA's operating mechanism and confirm its compatibility with other commercially available VAC devices in terms of its effectiveness for wound healing.

8.2.2. Open-source-publication

As for the improvement of wound care for LMICs widely there was an opportunity during this graduation project to apply for a open-source-publication for the WOCA design so that the device can be rebuild in other hospitals, focussing on LMICs. The manuscript, handed in for approval is attached in Appendix A.
In addition to this open-source-publication relying on a 3D printer it also is deemed interesting to design a version of the WOCA not relying on the availability of a 3d printer.

8.3. Recommendations

For the development of the WOCA VAC device, creating a manual, including a cleanability document, is recommended. The insights gathered during this graduation project are summarized in drafts of both a manual and a cleanability document. These documents are included in the supplementary materials for this project and will be shared with future students working on the WOCA project.

8.3.1. Redesign

In addition to noise reduction, which is essential for preparing the WOCA for a clinical trial, this section summarizes recommendations for a WOCA redesign based on findings from this graduation project.

Recommended improvements for the current WOCA at GPH

- Integration of a glass canister to allow for autoclaving
- Battery level alarm to allow for timely recharging
- Overflow protection alarm to allow for timely emptying the canister
- Addition of a carrying strap to improve portability

Considerations for a full redesign

- Placing the handle in the centre of the housing for balanced carrying of the device
- Dark blue or grey colouring of the device, based on feedback of users during validation (see appendix D)
- Implementation of a Power Connection Board (PCB) for better cable management

8.4. Limitations

Understanding the context is crucial for the development of this project, especially considering the gap between HICs and LMICs. Conducting the graduation project in Nepal provided some insights into these contextual factors; however, it also highlighted the challenges in bridging this gap. Designing a device for LMICs requires careful consideration of local conditions, resources, and needs, and this project demonstrates that overcoming these challenges will always be complex.

9

Conclusion

This section will conclude by reflecting on the original goal of the graduation project and the outcomes accomplished.

The initial goal of this graduation project was to improve wound care in LMICs by preparing the WOCA device for a clinical trial at GPH. To achieve this goal, the project focused on verifying technical design requirements, validating user design requirements, verifying applicable ISO criteria, and conducting a risk assessment. By the development of a redesign for the WOCA it was aimed to ensure adherence to these standards.

In conclusion, the extensive testing and improvements made to the device have contributed to the WOCA project, by bringing the device closer to its readiness for a clinical trial. However, based on this graduation project it is determined that the OCA device is not successfully made compatible with the allowable noise level. Therefore, a redesign is necessary to reduce noise before starting the clinical trial. Additionally, further testing is recommended to verify design requirement 1.1, validate design requirements 12.1, 14.1, 15.1, and 16.2, and verify ISO criteria 7.2.2.1 and 7.2.2.2.

Although the initial goal of this graduation project has not been fully achieved, significant progress has been made for the WOCA device, and the improvement of wound care within LMICs. Key improvements for the WOCA include the implementation of the canister and efforts to reduce noise. Furthermore, verification and validation of design requirements, along with verification of applicable ISO criteria, have been completed, as well as a comprehensive risk assessment.

Key steps taken during this graduation project to improve wound care in LMICs include the planned open-source publication of the WOCA device, which will make the device accessible to hospitals in these regions, as well as the development of a study protocol for the clinical trial of the WOCA at GPH.

References

[1] Bracefox - Admin. *Hoeveel decibel is schadelijk: dit wil je weten over gehoorschade tijdens festivals*. Aug. 2023. URL: https://www.bracefox.nl/blog/hoeveel-decibel-is-schadelijk-festivals/#:~:text=Als%20je%20bijvoorbeeld%20van%2050,log(afstand1%20%2F%20afstand2)..

[2] Pawan Agarwal, Rajeev Kukrele, and Dhananjaya Sharma. "Vacuum assisted closure (VAC)/negative pressure wound therapy (NPWT) for difficult wounds: A review". In: *Journal of Clinical Orthopaedics and Trauma* 10.5 (Sept. 2019), pp. 845–848. DOI: 10.1016/j.jcot.2019.06.015. URL: https://doi.org/10.1016/j.jcot.2019.06.015.

[3] Hansel Gould B. Cocjin et al. "Wound-Healing Following Negative-Pressure Wound Therapy with Use of a Locally Developed AquaVac System as Compared with the Vacuum-Assisted Closure (VAC) System". In: *Journal of Bone and Joint Surgery* 101.22 (Oct. 2019), pp. 1990–1998. DOI: 10.2106/jbjs.19.00125. URL: https://doi.org/10.2106/jbjs.19.00125.

[4] Systems Engineering Fundamentals. *Validation Verification*. Tech. rep. 2001. URL: https://ocw.tudelft.nl/wp-content/uploads/Validation-verification.pdf.

[5] Richard M. Gore, Geraldine Mogavero Newmark, and Margaret D. Gore. *Ascites and Peritoneal Fluid Collections*. Jan. 2008, pp. 2119–2133. DOI: 10.1016/b978-1-4160-2332-6.50117-2. URL: https://doi.org/10.1016/b978-1-4160-2332-6.50117-2.

[6] S. Guo and L.A. DiPietro. "Factors affecting wound healing". In: *Journal of Dental Research* 89.3 (Feb. 2010), pp. 219–229. DOI: 10.1177/0022034509359125. URL: https://doi.org/10.1177/0022034509359125.

[7] Krister Järbrink et al. "Prevalence and incidence of chronic wounds and related complications: a protocol for a systematic review". In: *Systematic Reviews* 5.1 (Sept. 2016). DOI: 10.1186/s13643-016-0329-y. URL: https://doi.org/10.1186/s13643-016-0329-y.

[8] Arjan J. Knulst et al. "Directions for surgical capacity developments in Nepal: a population□based assessment". In: *Tropical Medicine International Health* 24.9 (Aug. 2019), pp. 1128–1137. DOI: 10.1111/tmi.13292. URL: https://doi.org/10.1111/tmi.13292.

[9] A. Maccaro et al. "On the universality of medical device regulations: the case of Benin". In: *BMC Health Services Research* 22.1 (Aug. 2022). DOI: 10.1186/s12913-022-08396-2. URL: https://doi.org/10.1186/s12913-022-08396-2.

[10] *Nepal*. URL: https://data.who.int/countries/524.

[11] Nhrcadmin. *Home*. URL: https://nhrc.gov.np/.

[12] Noa Nicolai. "WOCA a battery powered wound pump designed for use in low-resource settings". In.

[13] Nethra Palaniswamy and Lokendra Phadera. *Poverty Equity Brief Nepal South Asia April 2024*. Tech. rep. 2024. URL: https://datacatalogfiles.worldbank.org/ddh-published/0064942/DR0092450/Global_POVEQ_NPL.pdf?versionId=2024-04-16T15:19:58.0316650Z#:~:text=The%20national%20poverty%20line%20is,line%20of%2037%2C879%20Nepali%20rupees..

[14] Cleveland Clinic Medical Professional. *Negative pressure wound therapy*. Sept. 2024. URL: https://my.clevelandclinic.org/health/treatments/17313-negative-pressure-wound-therapy.

[15] Eileen Raaijmakers. *Design of a low-cost device for Negative Pressure Wound Therapy in low and middle-income countries*. Aug. 2022.

[16] *Vacuum-Assisted closure of a wound*. Mar. 2024. URL: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/vacuumassisted-closure-of-a-wound.

[17] Matt Watson. *Green Pastures Hospital - International Nepal Fellowship*. Mar. 2023. URL: https://www.inf.org/our-work/green-pastures-hospital/.

[18] Yor-in. *Effectief meten: validatie verificatie*. URL: https://www.yor-in.nl/in-de-praktijk/effectief-meten-validatie-verificatie#:~:text=%E2%80%9CBij%20een%20validatie%20onderzoek%20je,betrekking%20tot%20veiligheid%20en%20kwaliteit.%E2%80%9D.

[19] Vasudev Zaver and Pradeep Kankanalu. *Negative pressure wound therapy*. Sept. 2023. URL: https://www.ncbi.nlm.nih.gov/books/NBK576388/.

A

Manuscript Open-Source-Publication

This appendix includes the manuscript for the open-source-publication of the WOCA. This publication is handed in for review, and still awaiting for approval

HardwareX

A low-cost and portable vacuum pump system for negative pressure wound therapy in LMIC context: WOCA Wound Care Pump

--Manuscript Draft--

Manuscript Number:	OHX-D-24-00163
Article Type:	VSI: Open-source Med-Tech
Section/Category:	Low-cost alternative
Keywords:	Medical Device; Negative Pressure Wound Therapy; Vacuum-Assisted Closure therapy; Wound care; Low-cost; Low-resource setting
Corresponding Author:	Arjan J. Knulst, PhD Delft University of Technology Delft, NETHERLANDS
First Author:	Arjan J. Knulst, PhD, MSc
Order of Authors:	Arjan J. Knulst, PhD, MSc
	Salome Berger, MSc
	Jorijn van den Boom, MSc
	Noa Nicolai, MSc
	Suraj Maharjan, PhD, MD
	Eileen Raaijmakers, MSc
	Chang-Lung Tsai, BSc
	Lisa van de Weerd, BSc
	Jenny Dankelman, PhD, MSc
	Jan-Carel Diehl, PhD, MSc
Manuscript Region of Origin:	NEPAL
Suggested Reviewers:	Peter Culmer, PhD Professor, University of Leeds Passionate about using engineering science to address global healthcare challenges.
	Thomas van de Akker, dr. Professor, Vrije Universiteit Amsterdam interest in Global health issues
	June Madete, PhD senior lecturer, researcher, Kenyatta University biomedical engineer living in the context of inteded use of the device described in the manuscript
	Reinou S. Groen, PhD MD Medical Doctor, Alaska Native Tribal Health Consortium wide experience in global health issues
	Jelle Stekelenburg, PhD MD professor, University of Groningen expert in global surgery
Abstract:	Negative Pressure Wound Therapy (NPWT) is an effective treatment that aids the healing of chronic wounds. However, high treatment cost of commercial systems has limited its use and availability in developing countries. Here, we introduce the Wound

	Care (WOCA) Pump, a portable and affordable vacuum pump system design for use in low-resource settings. It features a simple interface for smooth operation and monitoring. It also allows treatment pressure adjustments from 70 to 125 mmHg that is automatically controlled by the system. A rechargeable battery supplies power throughout a treatment cycle and enables portability of the device. 3D printed custom parts and widely available components are used to guarantee future repair and maintenance of the device. A standard laboratory bottle, which can be cleaned and reused, is used as a canister. The only consumable in the system is the bacterial filter that needs to be periodically replaced. Future modification, such as matching of different dressing sets, would be easily achievable with the design files shared online. Testing results shows minimal air leakage, optimal pressure control, and functional safety mechanisms for the system. Hereby, we hope this detailed documentation could contribute a small step in narrowing existing global healthcare gaps.

Cover Letter

Dear editor,

I hope you are doing well.

I'm pleased to submit our manuscript for consideration of publication in the special issue on Open Source Medical devices. It was our first time of preparing a manuscript of HardwareX, which uses quite a different template compared to regular journals. If this results in any omissions from our side, please do inform us to correct any issue in filling the system.

The Mendeley dataset has been set to Public today (Sunday Sept. 29th), but I was unaware it will take the Mendeley data moderators up to 2 business days to moderate it and make it public. I apologize for that, we waited until last moment to make it not public too early. The data set should be available through the DOI from 1st or 2nd. Until then the DOI URL provided in the portal and manuscript specifications table will not work. As I expect it will take few days for reviewers to access the manuscript the public version should be available in time. The preview can be used instead until the moderation has completed: https://data.mendeley.com/preview/r95wgtmffn?a=6f5ae446-df58-4852-b750-37f800c4787c

We hope the manuscript will be considered for publication in HardwareX special issue, and we are looking forward to a smooth process.

Kind regards

Arjan J. Knulst

Graphical Abstract

WOCA

A low-cost and portable vacuum pump system for negative pressure wound therapy

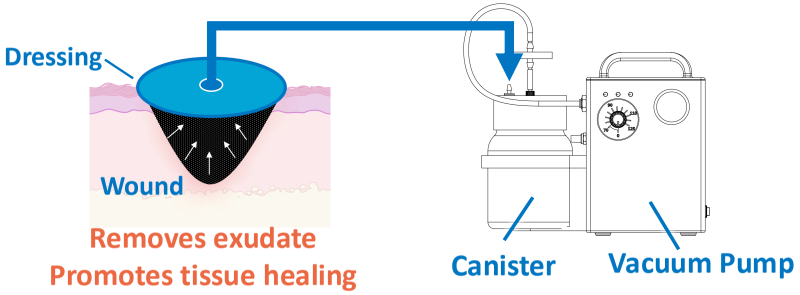
THE CHALLENGE

In developing countries…

- Challenging living conditions
- Chronic wounds (e.g. diabetic foot ulcers & pressure sores)
- Untreated patients tend to develop to disabilities or death

Negative Pressure Wound Therapy…

- Clinically effective treatment
- But **TOO COSTLY** to become widely accessible



OUR DEVICE

Easy
Build, repair and maintain with detailed documentation, 3D printed parts & widely available components

Reusable
Canister that can be easily cleaned and reused

Automatic
Pressure controlled by open-source software

Simple
Interface to adjust negative pressure settings (70 to 125 mmHg) and safe monitoring of treatment

Portable
Rechargeable battery that lasts throughout the treatment

Article title

A low-cost and portable vacuum pump system for negative pressure wound therapy in LMIC context: WOCA Wound Care Pump

Authors

Arjan J. Knulst[a,b,*], Salome Berger[d], Jorijn van den Boom[a], Noa Nicolai[a], Suraj Maharjan[e], Eileen Raaijmakers[c], Chang-Lung Tsai[a], Lisa van de Weerd[a], Jenny Dankelman[a], Jan-Carel Diehl[c]

Affiliations

[a] Department of Biomechanical Engineering, Delft University of Technology, Delft, the Netherlands

[b] Biomedical engineering department, Green Pastures Hospital and Rehabilitation Center, International Nepal Fellowship, Pokhara, Nepal.

[c] Industrial Design Engineering, Delft University of Technology, Delft, the Netherlands.

[d] Shining Hospital Surkhet, International Nepal Fellowship, Birendranagar, Nepal

[e] Reconstructive surgery department, Green Pastures Hospital and Rehabilitation Center, International Nepal Fellowship, Pokhara, Nepal.

Corresponding author's email address and Twitter handle

Correspondence should be addressed to Arjan J. Knulst

Abstract

Negative Pressure Wound Therapy (NPWT) is an effective treatment that aids the healing of chronic wounds. However, high treatment cost of commercial systems has limited its use and availability in developing countries. Here, we introduce the Wound Care (WOCA) Pump, a portable and affordable vacuum pump system design for use in low-resource settings. It features a simple interface for smooth operation and monitoring. It also allows treatment pressure adjustments from 70 to 125 mmHg that is automatically controlled by the system. A rechargeable battery supplies power throughout a treatment cycle and enables portability of the device. 3D printed custom parts and widely available components are used to guarantee future repair and maintenance of the device. A standard laboratory bottle, which can be cleaned and reused, is used as a canister. The only consumable in the system is the bacterial filter that needs to be periodically replaced. Future modification, such as matching of different dressing sets, would be easily achievable with the design files shared online. Testing results shows minimal air leakage, optimal pressure control, and functional safety mechanisms for the system. Hereby, we hope this detailed documentation could contribute a small step in narrowing existing global healthcare gaps.

Keywords

Medical Device, Negative Pressure Wound Therapy, Vacuum-Assisted Closure therapy, Wound care, Low-cost, Low-resource setting

Specifications table

Hardware name	WOCA Wound Pump
Subject area	• Biomedical Engineering • Open source and low-cost alternatives to existing devices • Low-resource Contexts
Hardware type	• Medical Device • Negative Pressure Wound Therapy Pump • Vacuum Assisted Wound Closure Pump
Closest commercial analog	3M™ ActiV.A.C.™ Therapy Unit
Open source license	Creative Commons Attribution 4.0 International license
Cost of hardware	Approximately 280 Euros
Source file repository	https://doi.org/10.17632/r95wgtmffn

1 Hardware in context

Wound management remains a serious issue in developing countries or Low- and Middle Income Countries (LMICs). Poor access to healthcare and challenging living conditions tend to contribute to the high prevalence of chronic wounds in these regions [1, 2]. Chronic wounds such as diabetic foot ulcers and pressures sores are everyday occurrence for many people living in LMICs. Without adequate treatment, such wounds may lead to permanent disabilities or even death.

Negative Pressure Wound Therapy (NPWT), also known as Vacuum Assisted Closure (VAC), is a versatile and effective treatment that aids the optimization of healing of chronic wounds. NPWT utilizes a controlled negative pressure to stimulate wound healing by reducing inflammatory exudate and promoting granulation of tissue [3]. It requires a vacuum device that is connected to a sealed vacuum dressing. However, the use of commercial devices, such as the V.A.C Therapy (3M, USA), are too costly for NPWT to become widely accessible in LMICs. A study on NPWT used on Medicare Home Health Patients have shown that average cost per treatment was 899 USD for traditional devices and 1624 USD for disposable (single-use) devices [4].

Under this context, a project to develop a device for suitable use in LMICs was initiated. In Green Pastures Hospital, Nepal, originally a converted aquarium pump AquaVAC (Figure 1) was used. Though effective in terms of wound healing [6], limitations such as poor patient mobility and repairability exist. The aim was therefore formulated as follows: “Develop a low-cost, portable VAC system that uses standard and widely available components and consumables”.

An initial conceptual design of the Wound Care (WOCA) Pump (Figure 2) was made [7]. Based on this concept, a functional prototype was constructed, featuring a 3D printed housing and an Arduino microcontroller [8]. In this document, the latest developments of the WOCA Pump will be presented. A detailed technical documentation of the latest design will be shared, in the hope of narrowing gaps and decreasing barriers to healthcare in LMICs.

Figure 1: Setup of the converted aquarium pump (AquaVAC) used in Green Pastures Hospital.

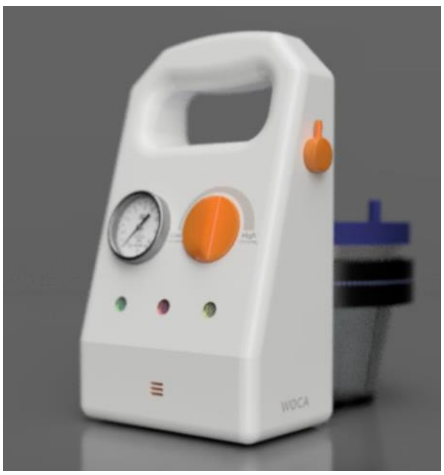


Figure 2: Conceptual design of the WOCA Pump [7].

2 Hardware description

The WOCA Pump (Figure 3) is a medical device designed as an easy-to-use system that can be easily modified and made compatible to different wound closure dressing pads. It includes a vacuum pump and a canister. The vacuum pump is connected to the canister and creates negative pressure required for suction. Dressing pads applied to the wound can be connected to the canister to remove exudate from the patient. A block diagram of how the WOCA pump functions is shown in Figure 4.

The hardware is easy to manufacture and assemble. It relies on commonly available electronic, mechanical and additively manufactured parts. To control the system various hardware components are used. These include a microcontroller (Arduino Nano), DC motor driver (L298N), and a pressure sensor (MPX5050DP). A simple interface that includes a pressure gauge, LEDs and alarm buzzer provides necessary information to the user. Controls include a power switch and control knob for adjusting pressure required for the treatment. Power is provided by a 12V 6800mAh lithium battery that can be recharged through a DC power supply. The use of wire to board connectors eases the (dis)assembly process. The open-source Arduino environment provides an easy platform for further modification of the software. The canister is also designed to be reused and cleanable. Parts can be easily disassembled, cleaned, reassembled, and then reused. The only consumable is the canister filter that needs to be periodically replaced. The following highlights the main concepts in the design:

- **Automatic** pressure control.
- **Portable** design with a battery that lasts at least one treatment cycle (3-5 days).
- **Simple** interface enables smooth operation & monitoring.
- **Easy** to repair and maintain with widely available components.
- **Reusable and cleanable** canister.

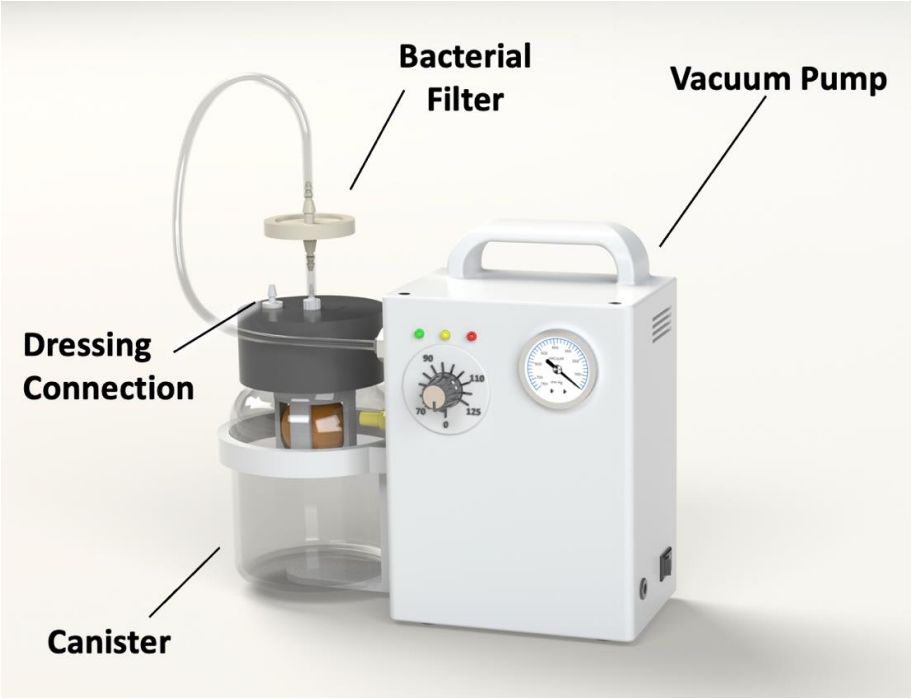


Figure 3: The WOCA Pump consists of a vacuum pump, bacterial filter, and canister.

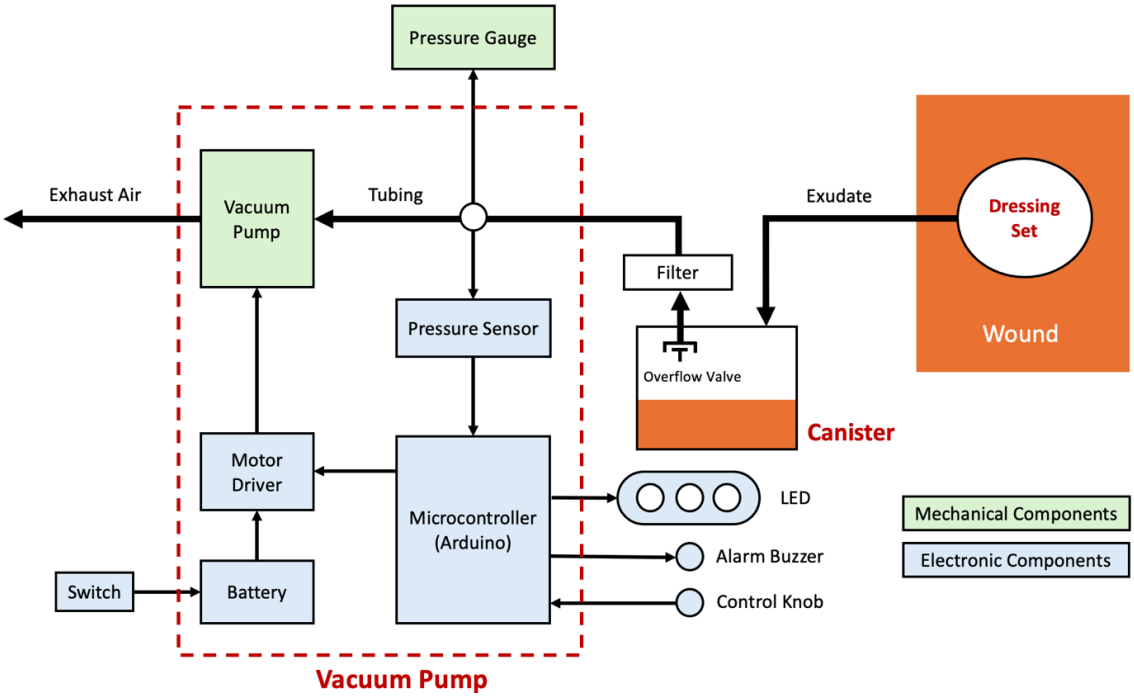


Figure 4: System Block Diagram of WOCA Pump.

3 Design files summary

This section features a list of all the files needed to reproduce the WOCA Pump (Table 1). The bill of materials (Designator: BOM) of the vacuum pump and canister are provided separately in Excel file and pdf format. The assembly (Designator: ASM) and part (Designator: MFG) files are constructed in Solidworks 2024. In case of the need for further modification, a software version of at least 2024 may be needed. The STL files of the parts that needed to be 3D printed are also provided in addition to the Solidworks part file. The software code (Designator: SW) used to control the microcontroller is provided in INO file format that can be opened and modified in Arduino IDE.

Table 1: WOCA Pump design files

Designator	Design file name	File type	Open-source License	Location of the file
BOM01	WOCA Vacuum Pump	.xlsx, pdf	CC 4.0	Specifications Table: Source file repository
BOM02	WOCA Canister	.xlsx, pdf		
ASM01	Vacuum Pump Assembly	.sldasm		
ASM02	Canister Assembly	.sldasm		
MFG01	Front Housing	.stl, .sldprt		
MFG02	Back Housing	.stl, .sldprt		
MFG03	Canister Holder	.stl, .sldprt		
MFG04	Hole Grid	.stl, .sldprt		
MFG05	Canister Lid	.stl, .sldprt		
MFG06	Ball Cage	.stl, .sldprt		
MFG07	Piston	.stl, .sldprt		
MFG08	Pressure Setting Plate	.stl, .sldprt		
SW01	WOCA Arduino Code	.ino		

4 Bill of materials summary

The complete bill of materials is provided online in the design files folder. Additional information such as specifications, manufacturer, model, and links to the sources are listed in detail. The bill of materials is listed separately for the vacuum pump and canister in Table 2 and Table 3. All components and consumables such as filaments and wires required to build one WOCA pump are listed. 3D printed parts are manufactured in the workshop in Delft University of Technology, which has no costs. However, the weight of the parts is calculated to give an estimate of the total filament needed to 3D print the parts. The cost of purchasing the filament were also included.

Table 2: Bill of materials of the WOCA Vacuum Pump.

Designator	Component	Number	Cost per unit- €	Total cost - €	Source of materials	Material type
Manufactured Parts						
MFG01	Housing, Front	1 pcs	N/A	N/A	Delft University of Technology Workshop	PET-G
MFG02	Housing, Back	1 pcs	N/A	N/A		PET-G
MFG03	Canister Holder	1 pcs	N/A	N/A		PET-G
MFG04	Hole Grid	1 pcs	N/A	N/A		PET-G
MFG08	Pressure Setting Plate	1 pcs	N/A	N/A		PET-G
Procured Mechanical Parts						
ME01	Vacuum Pump	1 pcs	17.84	17.84	Mouser NL	Metal

ME02	Pressure Gauge	1 pcs	9.74	9.74	Dominga IT	Metal
ME03	Connector, Bulkhead	1 pcs	3.61	3.61	Distrelec NL	Brass
ME04	Connector, T	2 pcs	3.24	6.48	Distrelec NL	Polymer
ME05	Connector, Elbow Female	1 pcs	2.67	2.67	RS NL	Brass
ME06	Connector, DiffOD	1 pcs	3.09	3.09	Distrelec NL	Polymer
ME07	Connector, Hose	1 pcs	0.68	0.68	Distrelec NL	Brass
ME08	Check Valve	1 pcs	8.90	8.90	Distrelec NL	Polymer
ME09	Silencer	1 pcs	1.81	1.81	Distrelec NL	Brass
ME10	Tubes, OD 6 mm	2 m	0.51	1.02	Distrelec NL	PU
ME11	Tubes, OD 8 mm	1 m	0.72	0.72	Distrelec NL	PU
ME12	Bolt, M4x16mm	2 pcs	0.11	0.22	Distrelec NL	Stainless Steel
ME13	Bolt, M4x10mm	5 pcs	0.08	0.40	Distrelec NL	Stainless Steel
ME14	Bolt, M3x20mm	2 pcs	0.07	0.14	Distrelec NL	Stainless Steel
ME15	Bolt, M3x16mm	8 pcs	0.06	0.48	Distrelec NL	Stainless Steel
ME16	Bolt, M3x6mm	1 pcs	0.06	0.06	Distrelec NL	Stainless Steel
ME17	Nut, M4	7 pcs	0.04	0.28	Distrelec NL	Stainless Steel
ME18	Nut, M3	10 pcs	0.03	0.30	Distrelec NL	Polymer
ME19	Cable Ties	1 pack	3.37	3.37	Distrelec NL	Polymer
ME20	Rubber Feet	4 pcs	0.12	0.48	Distrelec NL	NBR
ME21	Thread Seal Tape	1 roll	1.30	1.30	Distrelec NL	PTFE
ME22	Foam Tape	1 roll	5.49	5.49	Amazon NL	Polymer
ME23	3D Printer Filament	866 g	0.05	47.63	RS NL	PET-G
Procured Electronic Parts						
EE01	Microcontroller	1 pcs	23.16	23.16	Mouser NL	Electronics
EE02	Motor Driver	1 pcs	7.11	7.11	Reichelt	Electronics
EE03	Pressure Sensor	1 pcs	24.00	24.00	Mouser NL	Electronics
EE04	Potentiometer	1 pcs	0.84	0.84	Mouser NL	Electronics
EE05	Control Knob	1 pcs	0.46	0.46	Mouser NL	Polymer
EE06	Resistor, 220ohm	4 pcs	0.09	0.36	Mouser NL	Electronics
EE07	LED Red	1 pcs	0.36	0.36	Mouser NL	Electronics
EE08	LED Green	1 pcs	0.36	0.36	Mouser NL	Electronics
EE09	LED Yellow	1 pcs	0.36	0.36	Mouser NL	Electronics
EE10	Piezo Buzzer	1 pcs	1.34	1.34	RS NL	Electronics
EE11	Lithium Battery	1 pcs	37.15	37.15	LedstripKoning	Electronics
EE12	Prototype Board	1 pcs	5.50	5.50	Mouser NL	Electronics
EE13	DC Power Connector	1 pcs	0.81	0.81	Mouser NL	Electronics
EE14	Rocker Switch	1 pcs	0.95	0.95	Mouser NL	Electronics
EE15	Wire, Jumper	1 pack	3.67	3.67	Mouser NL	Electronics
EE16	Wire, 20 AWG	5 ft	0.68	3.40	Mouser NL	Electronics
EE17	Wire, 20 AWG	5 ft	0.68	3.40	Mouser NL	Electronics
EE18	Pin Terminals	10 pcs	0.21	2.10	Mouser NL	Electronics
EE19	Breakaway Header	1 pcs	1.40	1.40	Mouser NL	Electronics
EE20	Heat Shrink, 2mm	1 pcs	0.33	0.33	Mouser NL	Polyolefin
EE21	Heat Shrink, 5mm	1 pcs	0.52	0.52	Mouser NL	Polyolefin
EE22	DC Adapter, Male	1 pcs	1.77	1.77	Mouser NL	Electronics
EE23	DC Adapter, Female	1 pcs	1.77	1.77	Mouser NL	Electronics
			Total Cost	237.82		

Table 3: Bill of materials of the WOCA Canister.

Designator	Component	Number	Cost per unit- €	Total cost - €	Source of materials	Material type
Manufactured Parts						
MFG05	Canister Lid	1 pcs	N/A	N/A	TU Delft Workshop	PET-G
MFG06	Ball Cage	1 pcs	N/A	N/A		PET-G
MFG07	Piston	1 pcs	N/A	N/A		PET-G
Procured Parts						
ME10	Tubes, OD 6 mm	0.5 m	0.51	0.26	Distrelec NL	PU
ME23	3D Printer Filament	94 g	0.06	5.17	RS NL	PET-G
CS01	500ml Bottle	1 pcs	19.50	19.50	Eurofysica NL	Glass
CS02	Syringe, 10ml	1 pcs	0.56	0.56	24Pharma NL	Polymer
CS03	Syringe, 5ml	1 pcs	0.59	0.59	24Pharma NL	Polymer
CS04	Bacterial Filter	1 pcs	5.31	5.31	AliExpress	Polymer
CS05	Hose Bulkhead Connector	1 pcs	0.89	0.89	AliExpress	Polymer
CS06	Syringe Adapter	1 pcs	0.36	0.36	Amazon NL	Polymer
CS07	Table Tennis Ball	1 pcs	0.41	0.41	Decathlon NL	Polymer
CS08	Silicone Gasket	1 pcs	3.50	3.50	Local Hardware	Silicone
CS09	Quick Glue	1 pcs	4.99	4.99	Amazon NL	Polymer
			Total Cost	41.54		

5 Build instructions

5.1 Vacuum Pump Assembly

5.1.1 Prepare Equipment

The equipment listed in Table 4 are needed during the assembly of the vacuum pump.

Table 4: Equipment needed to build the WOCA vacuum pump

No.	Equipment	Model Used
1	3D Printer	Ultimaker S2+
2	Multimeter	RS PRO IDM 71
3	Wire Stripper	RS PRO 613-044
4	Ferrule Crimp Tool	RS PRO 122-1790
5	Side Cutter	RS PRO 536-420
6	Soldering Station	Weller Digital Rework Station WXR3 (solder & heat gun)
7	Hex Key 2.5 mm	N/A
8	Hex Key 3.0 mm	N/A
9	Screwdriver 2.5 mm	N/A
10	Laptop Computer	Macbook Pro

5.1.2 3D Print Parts

Download STL files provided in the design file folder. Import the STL files to the preferred 3D printer slicing software, e.g.: Cura (Ultimaker, the Netherlands) for slicing. A layer height of 0.2mm, 20% infill density, and a tree support only on build plate is recommended. Save file in Gcode file format and import to the 3D printer to start printing. Wait for 3D print to finish. Remove all support and file the burred edges on the finished parts. A hot air gun can be used optionally to clean up the parts.

PET-G is the preferred choice of material due to its higher shock resistance and chemical stability. Other common materials such as PLA and ABS can also be used depending on availability. Figure 5 shows the 3D printed parts.

Figure 5: 3D printed parts of the WOCA Vacuum Pump.

5.1.3 Solder Wires to Electronic Components

The components that needed to have wires soldered are listed in the Table 5. Cut wires to lengths as specified in the table and strip ends with a wire stripper to solder. Use red AWG 20 wires (EE16) for live connections and black AWG 20 (EE17) for neutral connections. Use the ferrule crimp tool to make the connectors for the pin terminals (EE18). For the jumper wires, there is no need to make the female Dupont connectors. The jumper wires (EE15) should come with both ends already in Dupont typed connectors. Simply cut one end to length and solder the wires to the components. Use heat shrinks to protect the solder (Figure 6A). All components soldered with wires are shown in Figure 6C.

Table 5: List of components needed to have wires soldered.

Designator	Component	Wire Type	Length	Connector Type
ME01	Vacuum Pump	AWG 20 Wire (Red & Black)	20 cm	Pin Terminals
EE03	Pressure Sensor	Jumper Wire	20 cm	Female Dupont
EE04	Potentiometer	Jumper Wire	25 cm	Female Dupont
EE13	DC Power Connector	AWG 20 Wire (Red & Black)	20 cm	Pin Terminals
EE14	Rocker Switch	AWG 20 Wire (Red)	20 cm	Pin Terminals
EE07-09	LED Red, Green, Yellow	Jumper Wire	30 cm	Female Dupont

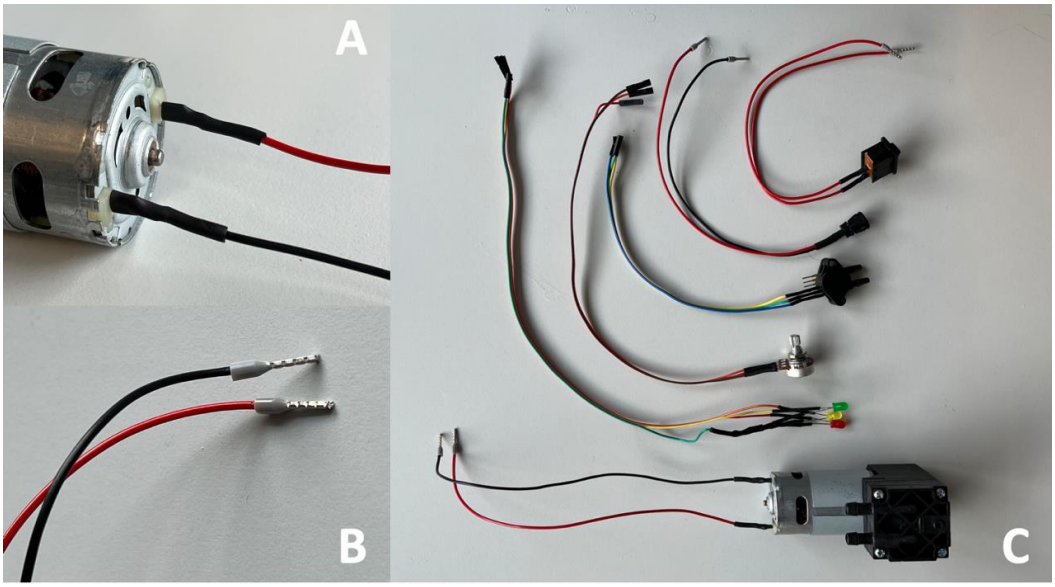


Figure 6: (A) Heat shrinks applied to protect solder. (B) Pin terminals connections.
(C) A display of all components soldered with wires.

5.1.4 Solder Electronic Components to Prototype Board

A schematic of the connections on the Prototype Board (EE12) are shown in Figure 7. The Piezo Buzzer (EE10), Microcontroller (EE01) and Resistors (EE06) are soldered on the board. Cut AWG20 wires (EE16) to make connections on the board. Cut and solder Breakaway Headers (EE19) to make the pin connectors. Check solders with a multimeter.

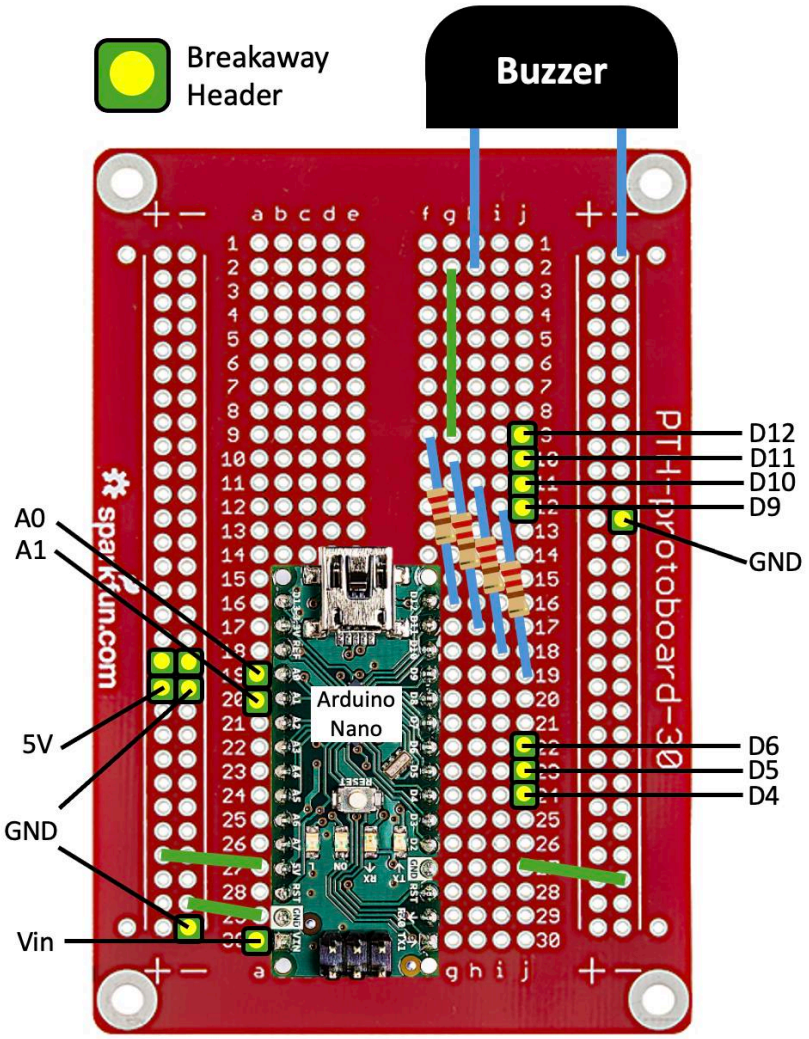


Figure 7: Schematic of the connections on the prototype board.

5.1.5 Assemble Components to Hole Grid

Assemble the soldered Prototype Board (EE12), Motor Driver (EE02), and Pressure Sensor (EE03) to the Hole Grid (MFG04) as shown in Figure 8. Remove jumper pins (ENA, ENB) on the motor driver (Figure 9).

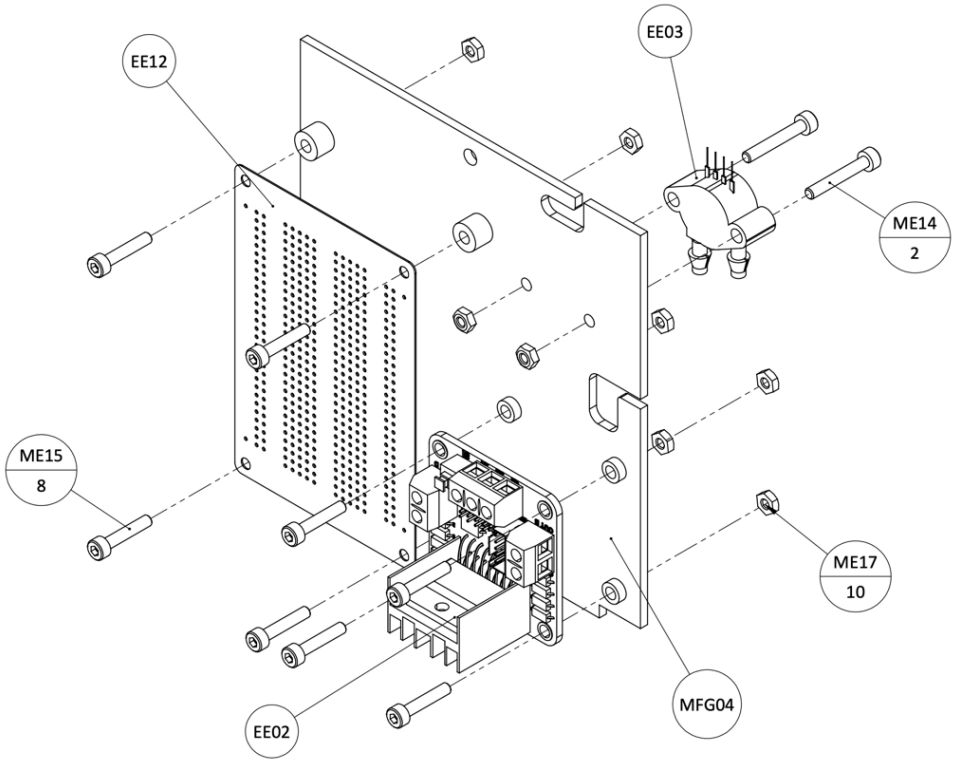


Figure 8: Instructions for assembling components on the Hole Grid.

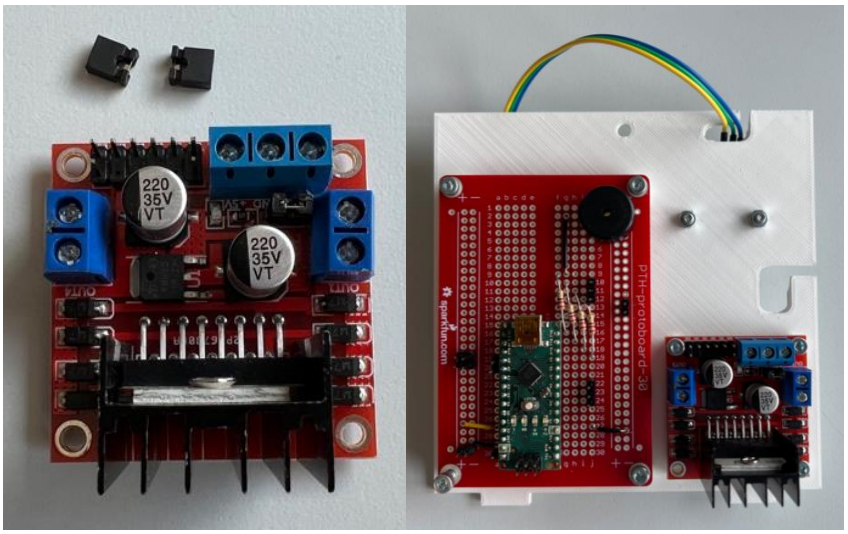


Figure 9: (Left) Motor Driver with jumper pins removed. (Right) Components assembled on the Hole Grid.

5.1.6 Install Pressure Gauge

Install the Pressure Gauge (ME02) to Front Housing (MFG01) as shown in Figure 10. Remove the right screw from the pressure gauge. Insert the pressure gauge into the slot and screw it to the housing with a M3x6mm Bolt (ME16). Apply Thread Seal Tape (ME21) on the thread when assembling the Elbow Female Connector (EE05).

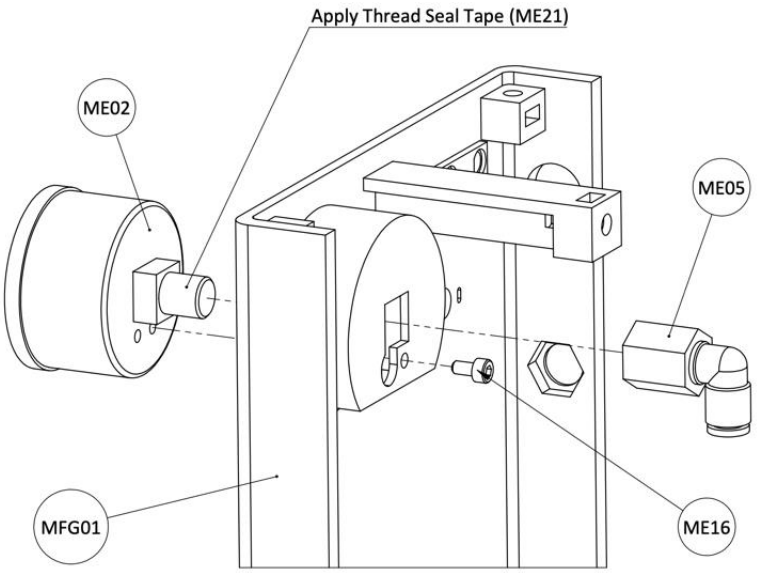


Figure 10: Instructions for installing the Pressure Gauge on the Front Housing.

5.1.7 Assemble Components to Front Housing

Cut strips of Foam Tape and apply to housing for the vacuum pump as shown in Figure 11. Slide the Vacuum Pump (ME01) in and secure with Cable Ties (ME19). Assemble the rest of the components to the housing as shown in Figure 12.

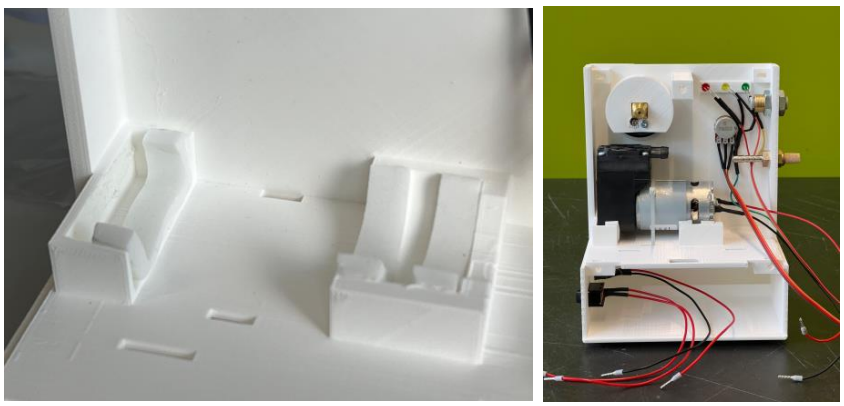


Figure 11: (Left) Foam Tape applied to the housing for the vacuum pump. (Right) Components assembled on the Front Housing.

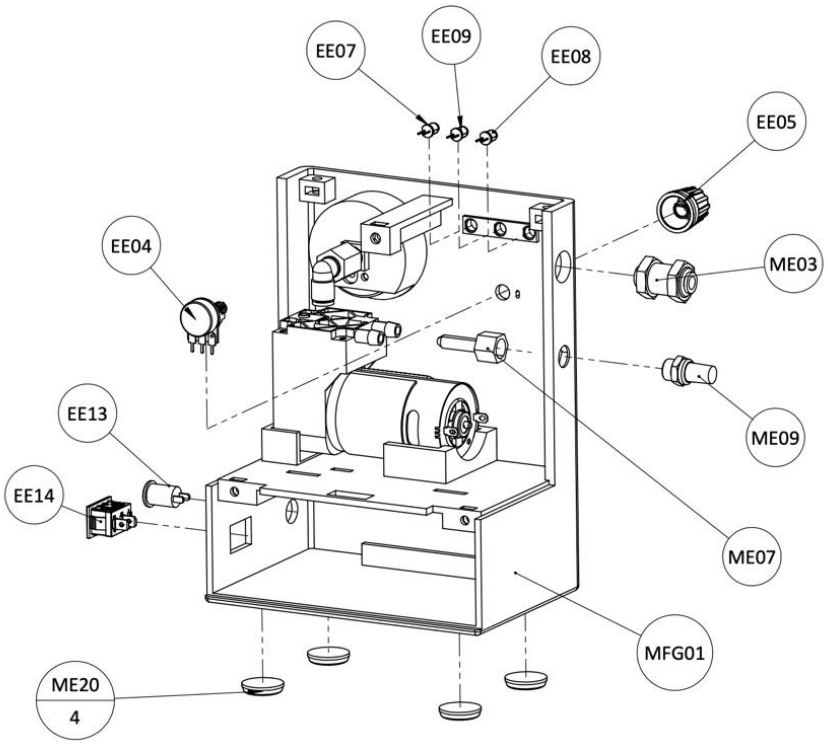


Figure 12: Instructions for assembling components to the Front Housing

5.1.8 Connect Tubing

Connect tubing as shown in Figure 13. OD 8mm Tube (ME11) are used to make connections with the Vacuum Pump (ME01), otherwise OD 6mm Tubes (ME10) are used. Cut the lengths of the tubes as specified in Figure 13. Carefully bend the tubes in a loop to fit into the space inside the Front Housing as shown in Figure 14.

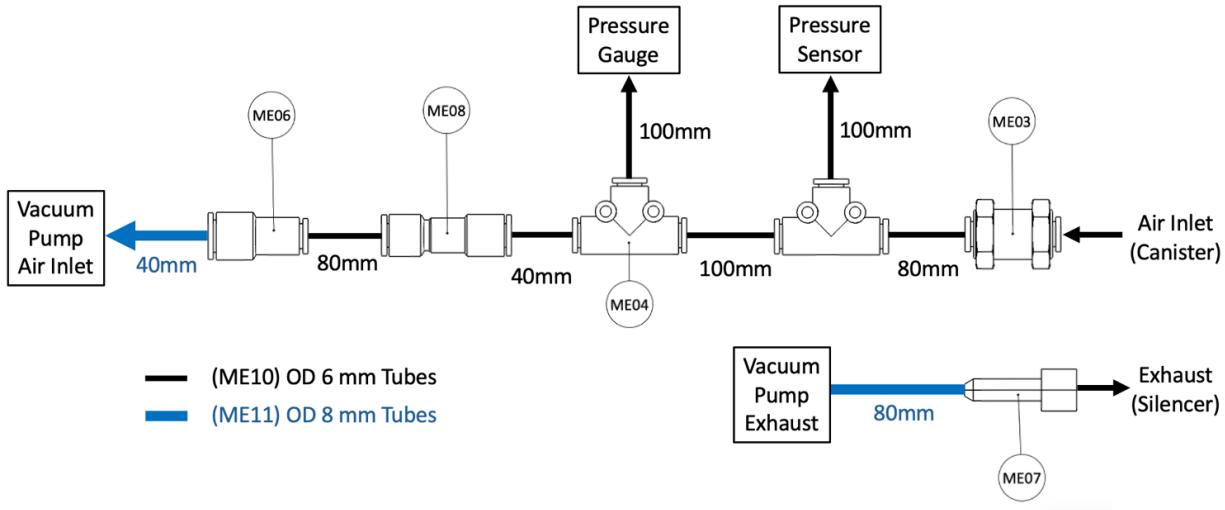


Figure 13: Instructions for connecting the tubing for the WOCA vacuum pump.

Figure 14: Components in the WOCA vacuum pump with all the tubing connected.

5.1.9 Complete the Electrical Circuit Connections

A schematic of the electrical circuit in the WOCA Vacuum Pump is shown in Figure 15. Follow the figure to connect the components to the correct input and output pins on the Prototype Board. Use a jumper wire (EE15) to connect pins (ENA, IN1, IN2) on the Motor Driver to pins (D6, D5, D4) on the Prototype Board.

12V power is supplied from the Lithium Battery to the Motor Driver. The Motor Driver then supplies 5V power to the Microcontroller. There will be a voltage drop between the 5V power supply from the Motor Driver and the Microcontroller. It should be noted that the Pressure Sensor and Potentiometer should be wired to the 5V power supply from the Microcontroller to give correct readings.

The Lithium Battery (EE11), Prototype Board (EE12), and the Motor Driver (EE02) should share a common ground. Make a split wire connection with a crimped pin terminal (EE18) at the common end and a Female Dupont connector and a crimped pin terminal at the split end. The split wire is shown in Figure 16A. The common end is connected to the pin (GND) on the Motor Driver. The terminal pin end of the split wire is connected to the cathode of the battery, while the Dupont end is connected to the pin (GND) on the Prototype Board. Use a Male DC Adapter (EE22) for the charging port and a Female DC Adapter (EE23) for the output port of the Lithium Battery. Complete the power connections by wiring the DC Power Connector (EE13) and the Rocker Switch (EE14) to the Lithium Battery (EE11) and Motor Driver (EE02). A screwdriver will be needed to connect the pin terminals.

Insert the wires of the components to the grooves on the Hole Grid. Insert the power connections from the battery compartment through the hole on the Front Housing. These features protect cables from clipping when closing the housing. The completed connection is shown in Figure 16C.

Turn on the power switch to check if circuit is complete. LED lights of Microcontroller and Motor Driver should light up if the circuit is correctly connected. Use a multimeter to measure voltage to check for connections.

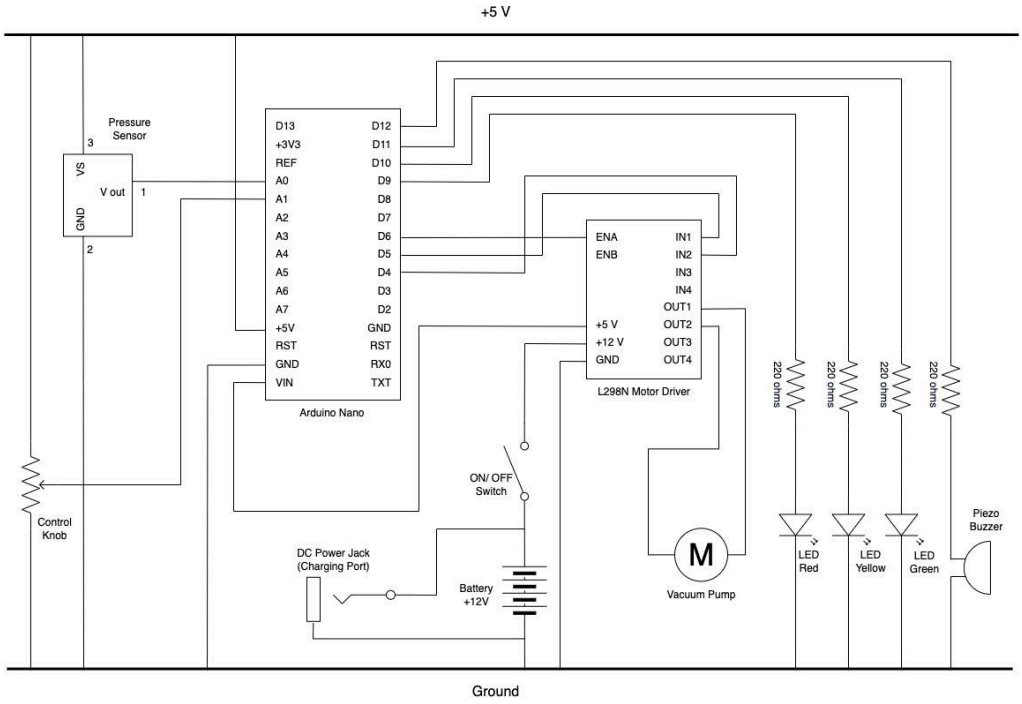


Figure 15: Schematic of the electrical circuit in the WOCA Vacuum Pump.

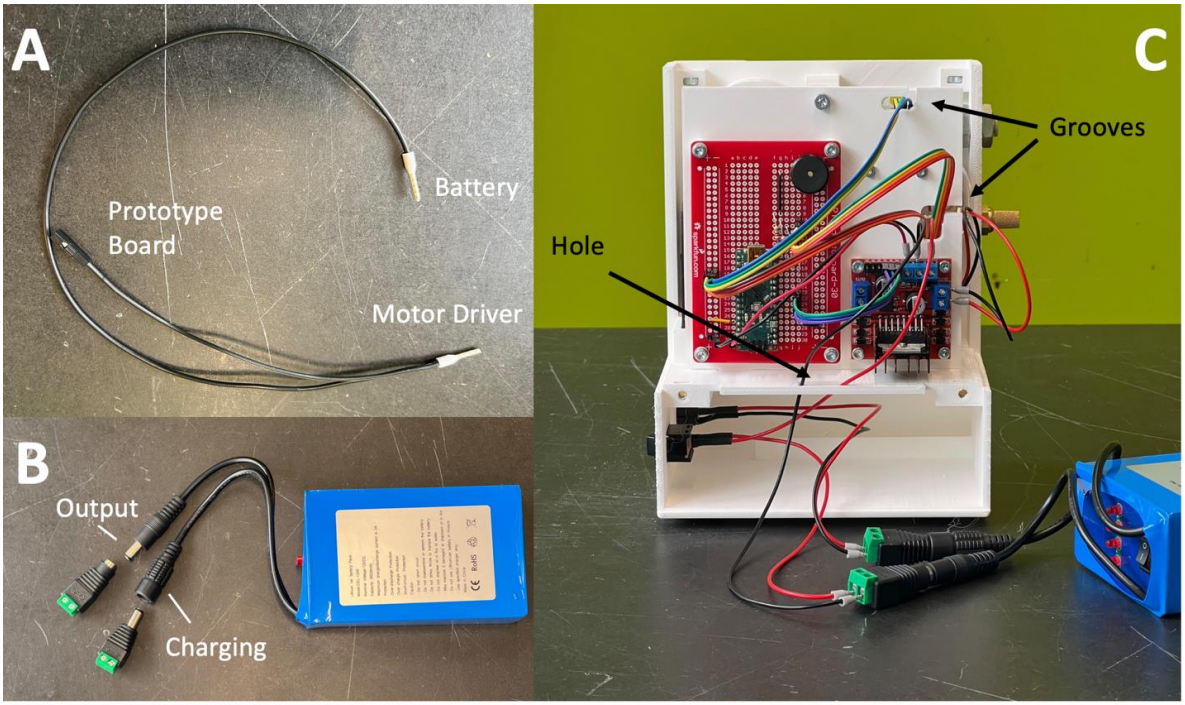


Figure 16: (A) Split wire for the power connections. (B) DC Adapters for the Lithium Battery. (C) Grooves on the Hole Grid and the hole on the Front Housing to protect the wire connections from clipping.

5.1.10 Upload Arduino Software

Download and install the latest Arduino software (IDE) from the official Arduino website (ww.arduino.cc). Install the environment on a computer. Download the INO file, WOCA Arduino Code (SW01), from the design files folder. Connect the computer and microcontroller with a USB wire. Upload the code to the microcontroller. Once the upload is complete, the pressure reading values should be visible on the serial communication window in the Arduino IDE software.

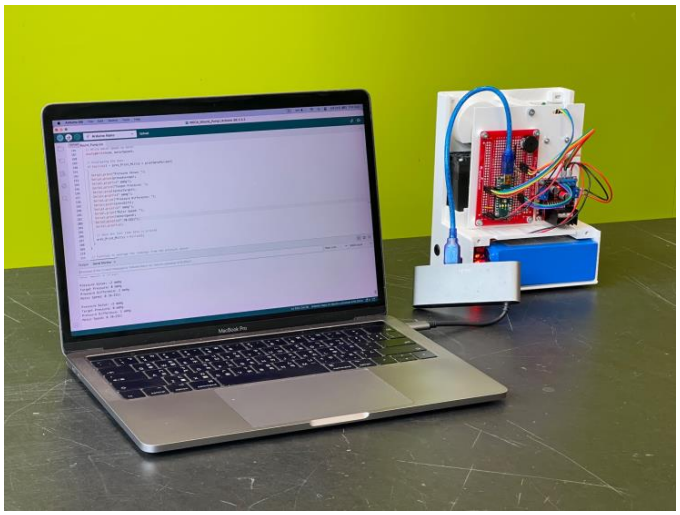


Figure 17: Microcontroller (Arduino Nano) connected to a computer with a USB wire.

5.1.11 Complete the Assembly

Complete the assembly as shown in Figure 18. Assemble Back Housing (MFG02) and the Canister Holder (MFG03). Insert the nuts in the grooves of the Front Housing (MFG01). Screw the bolt on the Hole Grid (MFG04). Close the Back Housing and screw the rest of the bolts. Finally, use quick glue to attach the Pressure Setting Plate (MFG08) to finish the assembly. Turn the control knob counterclockwise to the end. The indicator should align to the pressure setting zero. The completed WOCA Vacuum Pump is shown in Figure 19.

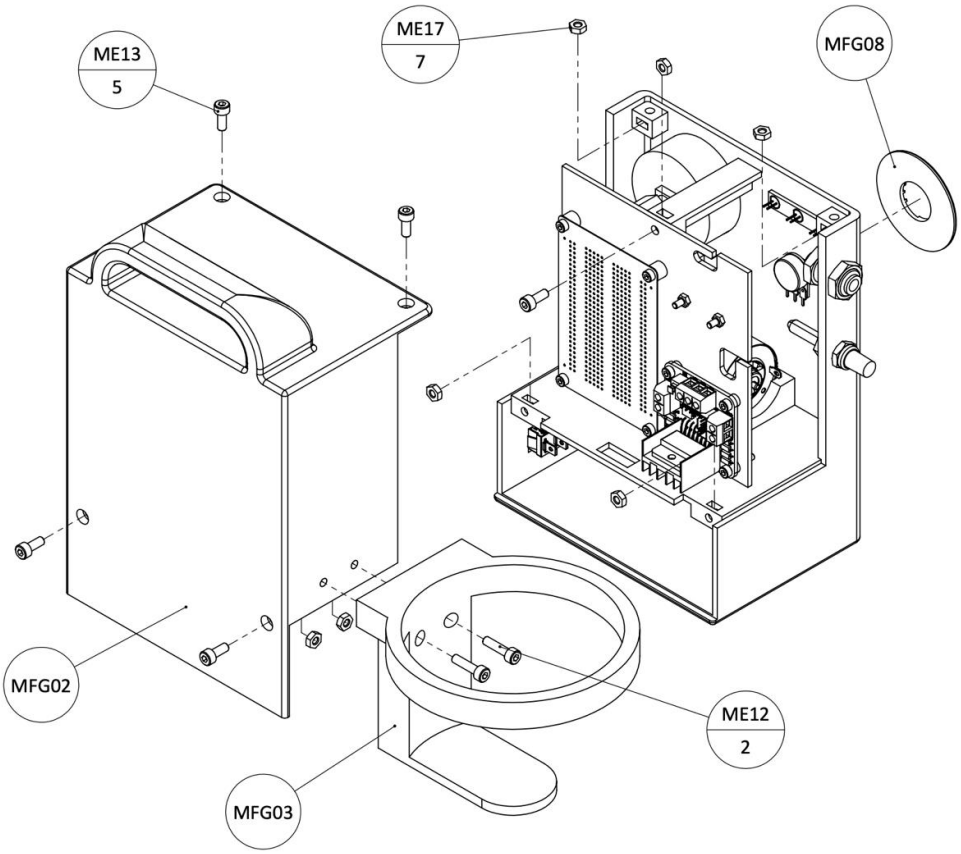


Figure 18: Instructions to assemble Back Housing and Canister Holder.

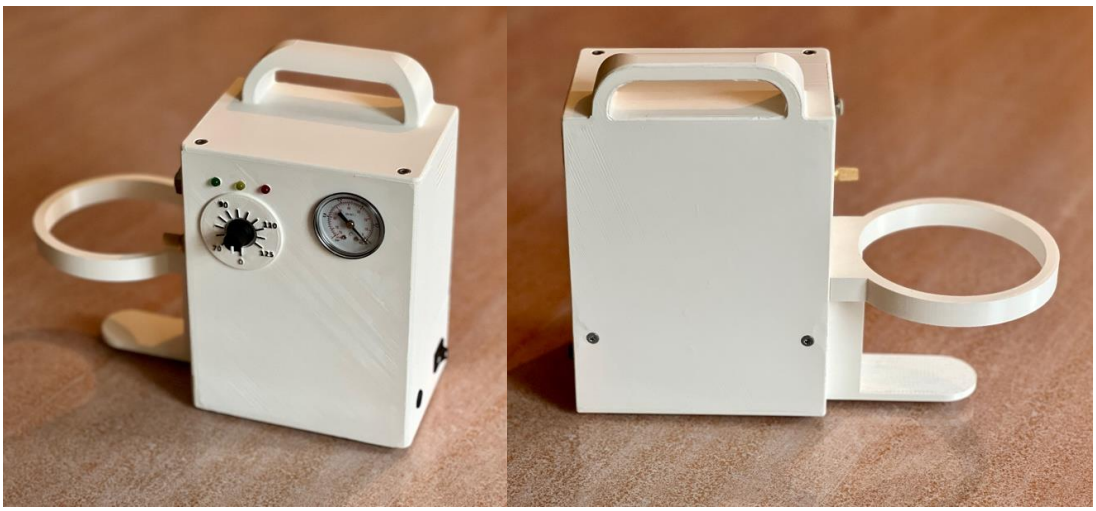


Figure 19: Completed WOCA Vacuum Pump.

5.2 Canister Assembly

5.2.1 Prepare Equipment

The equipment listed in Table are needed during the assembly of the WOCA canister.

Table 6: Equipment needed to build the WOCA canister

No.	Equipment	Model Used
1	3D Printer	Ultimaker S2+
2	Side Cutter	RS PRO 536-420

5.2.2 3D Print Parts

Download STL files provided in the design file folder and 3D print as described in assembly in vacuum pump. Use a finer setting (layer height: 0.16mm) and a higher minimum wall/perimeter line count (wall line count: 4) to print the canister lid (MFG05) to ensure airtight performance. For the ball cage (MFG06) and the piston (MFG07), normal settings can be used.

Figure 20: 3D printed parts of the WOCA Canister.

5.2.3 Assemble Canister Lid

Assemble the canister as shown in the exploded view in Figure 21. The rubber seal is removed from of a 5ml syringe (CS03) and glued with the piston (MFG06) using quick glue (CS09). A 10ml syringe is cut to length (35mm) to serve as a shaft for the piston. A short OD 6mm Tube (ME10) with a length of 16mm is inserted to the opening to the vacuum pump on the canister lid (MFG04). There might be some tolerance on the tube and 3D printed canister lid opening. A tight fit is expected to make the lid airtight. In case of difficulty in inserting the tube, a round file can be used to carefully widen the opening. An in-line bacterial filter is connected to the opening of the vacuum pump with another OD 6mm Tube (ME10). Take note of the direction of the filter. The air inlet of the filter should be facing towards the canister lid and outlet should be connected to the vacuum pump. Figure 22 shows the complete canister before and after the assembly.

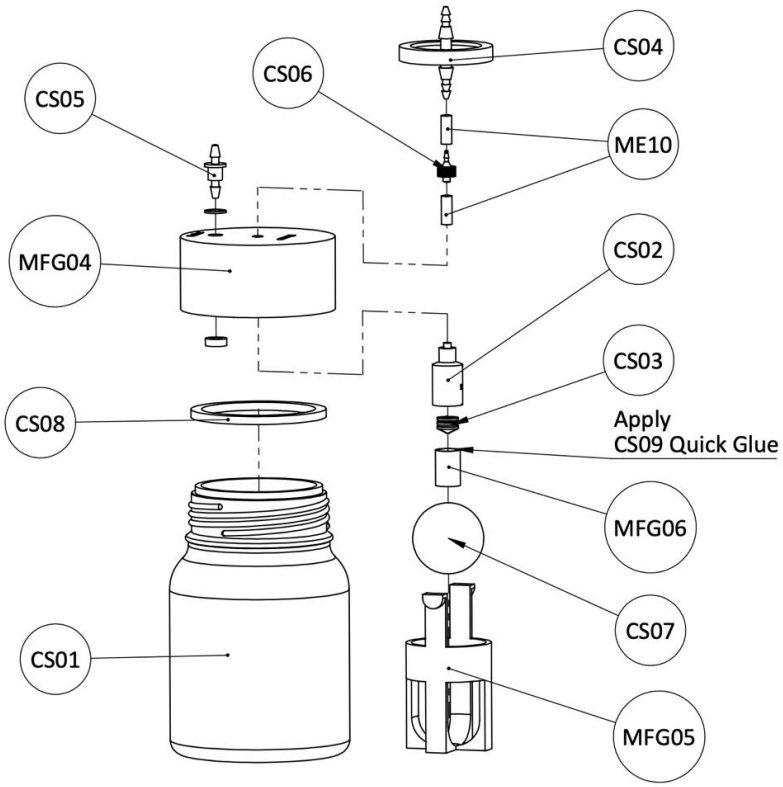


Figure 21: Instructions for assembling the WOCA canister lid.

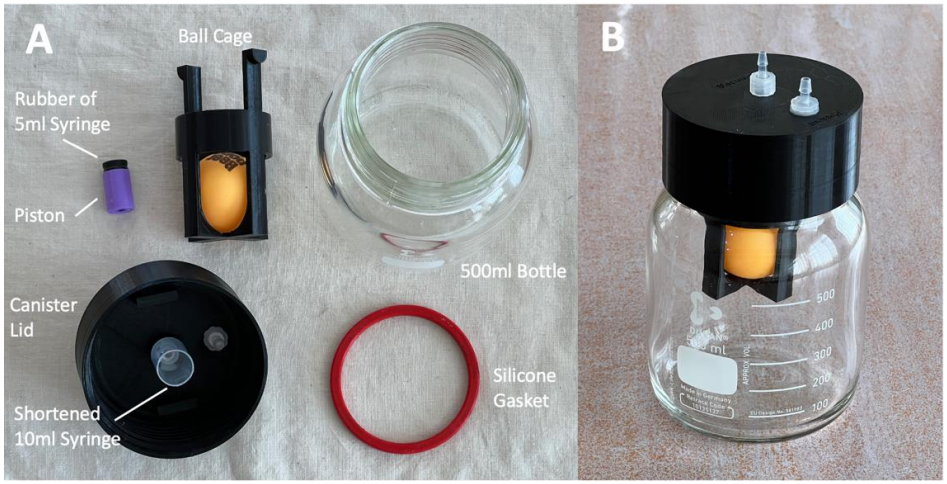


Figure 22: (A) Components of WOCA Canister. (B) WOCA Canister after assembly.

6 Operation instructions

6.1 Description of Operation

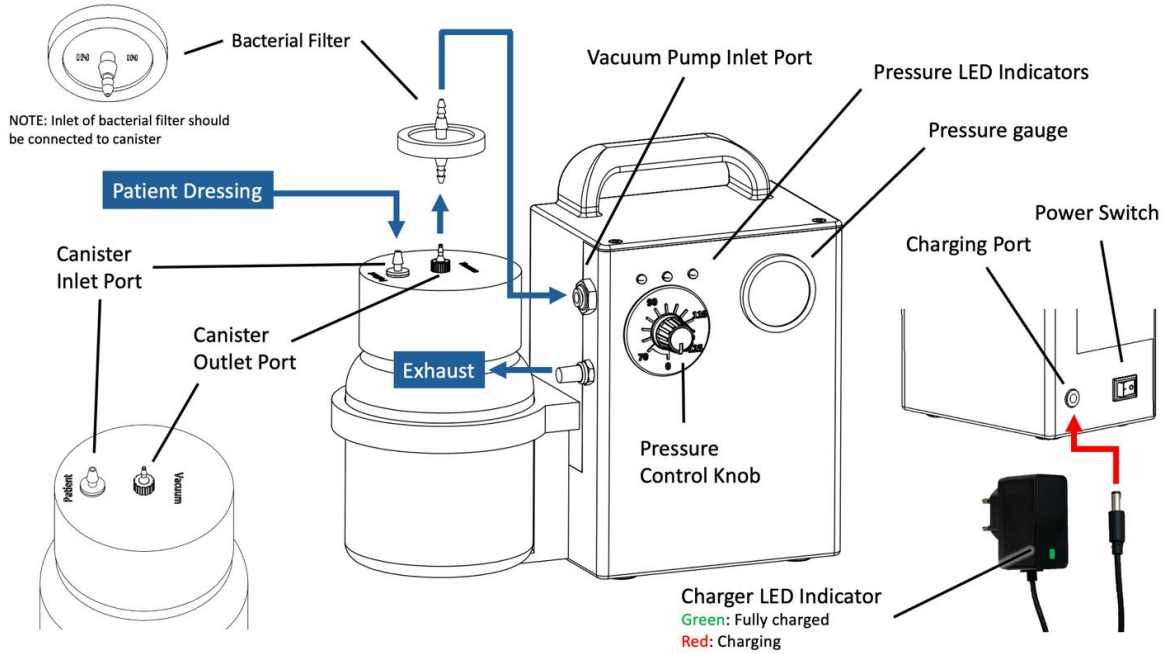


Figure 23: Connections and controls of the WOCA Pump System

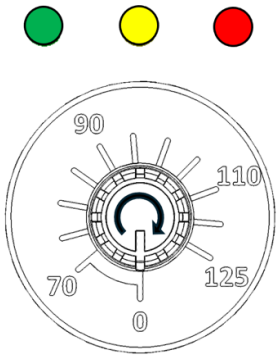
The connections and controls of the WOCA Pump is illustrated in Figure 23. Air and exudate (body fluid) from the patient dressing enters the system via the inlet port of the canister. The body fluids are stored in the canister while air exits via the outlet port of the canister. Air exiting the outlet port of the canister is filtered and enters the inlet port of the vacuum pump. Vacuum pressure is generated by a vacuum motor inside the pump and regulated by the microcontroller. The pressure gauge and pressure sensor sense the vacuum pressure generated and sustained throughout the vacuum pump, canister, and dressing pad. Exhaust air of the vacuum motor passes through a silencer before exiting the vacuum pump.

The power of the device can be turned on and off by a power switch. Pressure settings are adjusted through a control knob from a range of 70 to 125 mmHg. A 12V 6800 mAh rechargeable battery is installed inside to supply power. Power capacity is expected to sustain continuous mobile operation of the system throughout a single treatment (3-5 days). A 12V DC charger can be connected to the charging port to charge the battery. LED indicator on the charger shows red when charging and green when fully charged.

The definitions of the pressure LED indicators and alarms are shown in Figure 24. The LEDs, buzzer alarm, and pressure gauge are used as indicators for the device. When the power is switched on, there will always be two short blink/ beep on all the LEDs and the buzzer. The green LED will be constantly on when the when pressure setting is zero. The pressure knob is turned clockwise and adjusted to a targeted pressure and the vacuum pump will start to operate. The yellow LED will start to blink when pressure is out of range. The pump will continuously operate until the system reaches the desired pressure range (within 10% of targeted pressure). Once pressure reaches the settings, the green LED will start to blink. The vacuum pump will operate intermittently to maintain the pressure in the system. The pressure gauge can be used to verify whether the system is operating in the desired pressure settings.

A safety limit is set to the system to protect the device from damage and patient from harm. The red LED and buzzer alarm will be constantly on when vacuum pressure exceeds 135 mmHg. The motor will also be forced to stop until the vacuum pressure of the system resumes under the safety limit.

There is also an overflow protection valve on the canister. Once the body fluid reaches the maximum capacity that can be stored, it triggers the overflow valve to block the air inlet of the vacuum pump. The alarm of the vacuum pump will set off and the motor will stop operating until the canister is emptied.



LED & Alarms	Device State
All LEDs OFF	Power OFF
Green LED ON	Power ON, Zero pressure
Green LED BLINK	Pressure within 10% target range
Yellow LED BLINK	Pressure out of 10% target range
Red LED & alarm ON	Pressure exceeds safety limit of 135 mmHg

Figure 24: Definition of different LEDs and alarm states in the WOCA Vacuum Pump. Rotate the control knob clockwise to adjust target pressure. Pressure range from 70 to 125 mmHg.

6.2 Flowchart of the Arduino Control Software

The flowchart of how the Arduino software controls the WOCA Pump is shown in Figure 25.

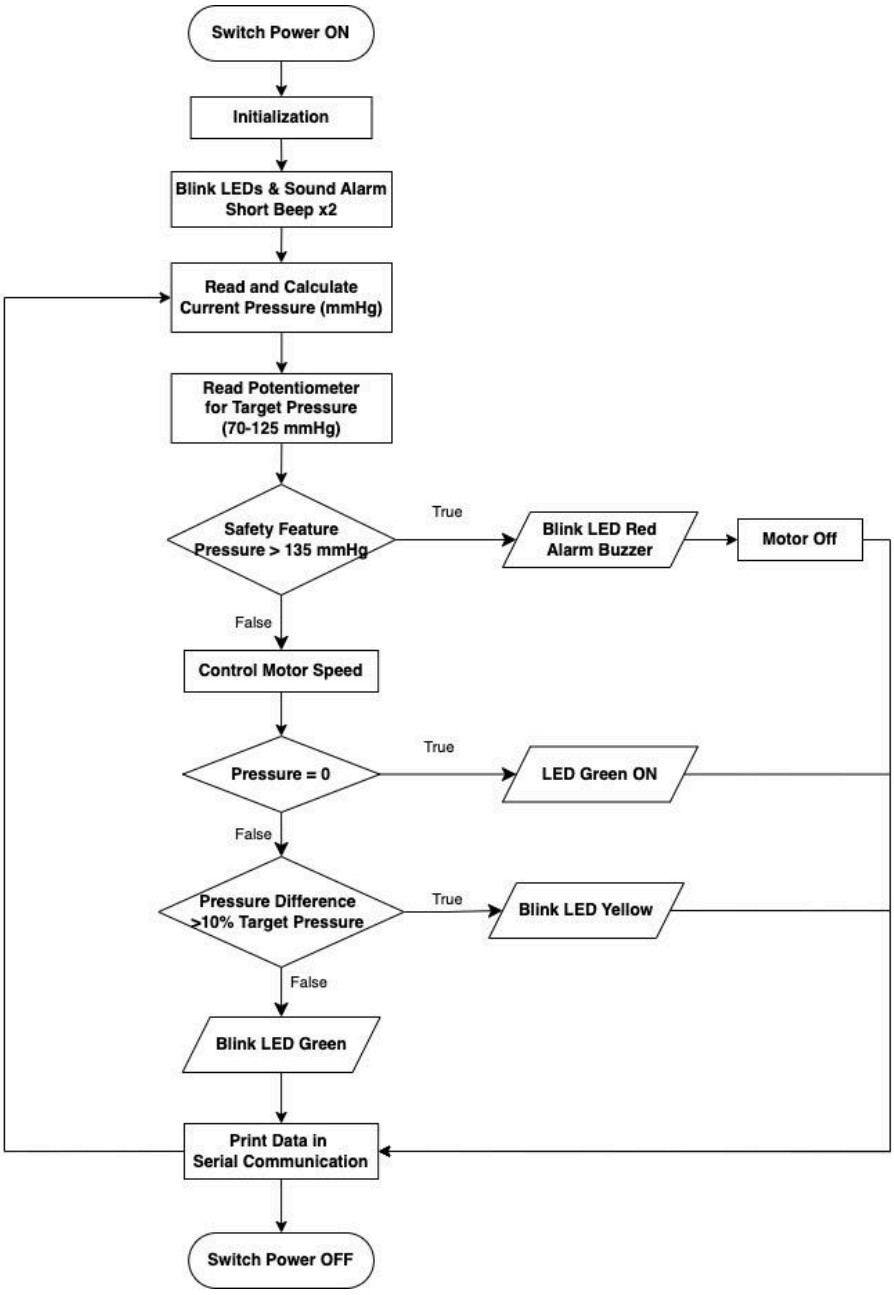


Figure 25: Flowchart of Arduino control software of the WOCA Pump

6.3 Standard Operation Procedure

The standard operation procedure for clinical use are shown in Table 7. Please follow the steps and read the warnings.

Table 7: Standard operation procedure for clinical use

Step	Instruction	Description
1	Charge Battery	It usually needs >8hr to fully charge battery. The indicator on the charger turns red when charging and turns green when fully charged. Currently, the device has no battery level indicator function yet.
2	Connect Vacuum Pump, Canister, and Dressing Pad	Take note of the markings on the canister lid. Connect the inlet port of the vacuum pump to the filter and to the outlet port of the canister (marked with "Vacuum"). Connect dressing pad to the inlet port of the canister (marked with "Patient"). **WARNING:** Do not connect the dressing pad directly to the inlet port of the vacuum pump. This may harm the patient and damage the device. A canister with filter should always be used. **WARNING:** Do not connect reverse connections of the inlet and outlet port of the canister. This may result in the overflow valve to not function and damage the vacuum pump.
3	Turn Power ON	Check if control knob is turned to 0. Turn on the power switch and look at the LEDs and listen to the buzzer. There should be two short blinks and two short beeps once the power is turned on.
4	Check Pressure	Check if the green LED is constantly lighted while the pressure setting is set to zero. Readings on the pressure gauge should also be zero.
5	Adjust Pressure Setting	Turn the control knob clockwise slowly and listen if the motor is operating. The yellow LED should blink constantly while the motor is operating. Once vacuum pressure reaches the adjusted setting, the green LED will start to blink.
6	Treatment	Leave the power of the vacuum pump on during the treatment. The green LED should continue to blink throughout the treatment. The microcontroller will control the vacuum pump to regulate the pressure.
7	Turn Power OFF	Turn the control knob counterclockwise until pressure setting is 0. The yellow LED will constantly blink due to the residual pressure inside the system. The vacuum pump will stop operating and pressure will gradually drop. Turn power switch off.
8	Disconnect Vacuum Pump, Canister, and Dressing Pad	Disconnect the dressing pad from the canister. There will be a sudden drop of readings on the pressure gauge due to the release of pressure. Disconnect the vacuum pump and canister. **WARNING:** Do not disconnect the system while the power is ON.
9	Cleaning	Dispose the exudate stored in the canister properly. Disassemble and clean the canister before use again, according to the hospital's cleaning and disinfection procedures.

7 Validation and characterization

7.1 Leakage Test

A leakage test is performed to verify whether leaks in the system (vacuum pump and canister) is acceptable. The pressure difference between measurements in 0 minutes and 3 minutes should be less than 10 mmHg.

7.1.1 Equipment

Table 8: Equipment used to perform the WOCA Pump leakage test.

No.	Equipment	Model used
1	Timer	Iphone timer function
2	Handheld Digital Manometer	Greisinger GMH 3100

7.1.2 Test Instructions

Table 9: Instructions for the WOCA Pump leakage test.

Steps	Instruction	Description
1	Connect Vacuum Pump to Canister	Connect the inlet port of the vacuum pump to the bacterial filter and outlet port of the canister (marked with “Vacuum”).
2	Connect Handheld Digital Manometer	Use a PU Tube(OD 6mm, ID 4mm) and connect the handheld digital manometer to the inlet port of the canister (marked with “Patient”).
3	Turn Power ON	Check if control knob is turned to 0. Turn on the power switch.
4	Adjust Pressure	Turn the control knob clockwise to adjust pressure settings to 125 mmHg.
5	Wait for Pressure to Increase	The pressure is expected to gradually increase while the yellow LED continue to blink. When pressure reaches 125 mmHg, the green LED will start to blink.
6	Turn Power OFF	Wait for around 3 minutes for pressure to stabilize and then turn the power switch off.
7	Record Pressure Measurements	Start timer and record pressure measurements from the handheld digital manometer (0 min, 1 min, 2 min, 3 min, 5 min).

7.1.3 Test Results

Test results of the leakage test are shown in Table 10. With a pressure setting of 125 mmHg, measured pressure within the system from 0 to 3 minutes dropped from 123 mmHg to 117 mmHg. A 6 mmHg drop of pressure shows minimal leakage for the system and is considered acceptable.

Table 11: Results for the WOCA Pump leakage test.

Pressure Setting	Handheld Digital Manometer Measurement				
	0 minute	1 minute	2 minute	3 minute	5 minute
125 mmHg	123	122	120	117	112

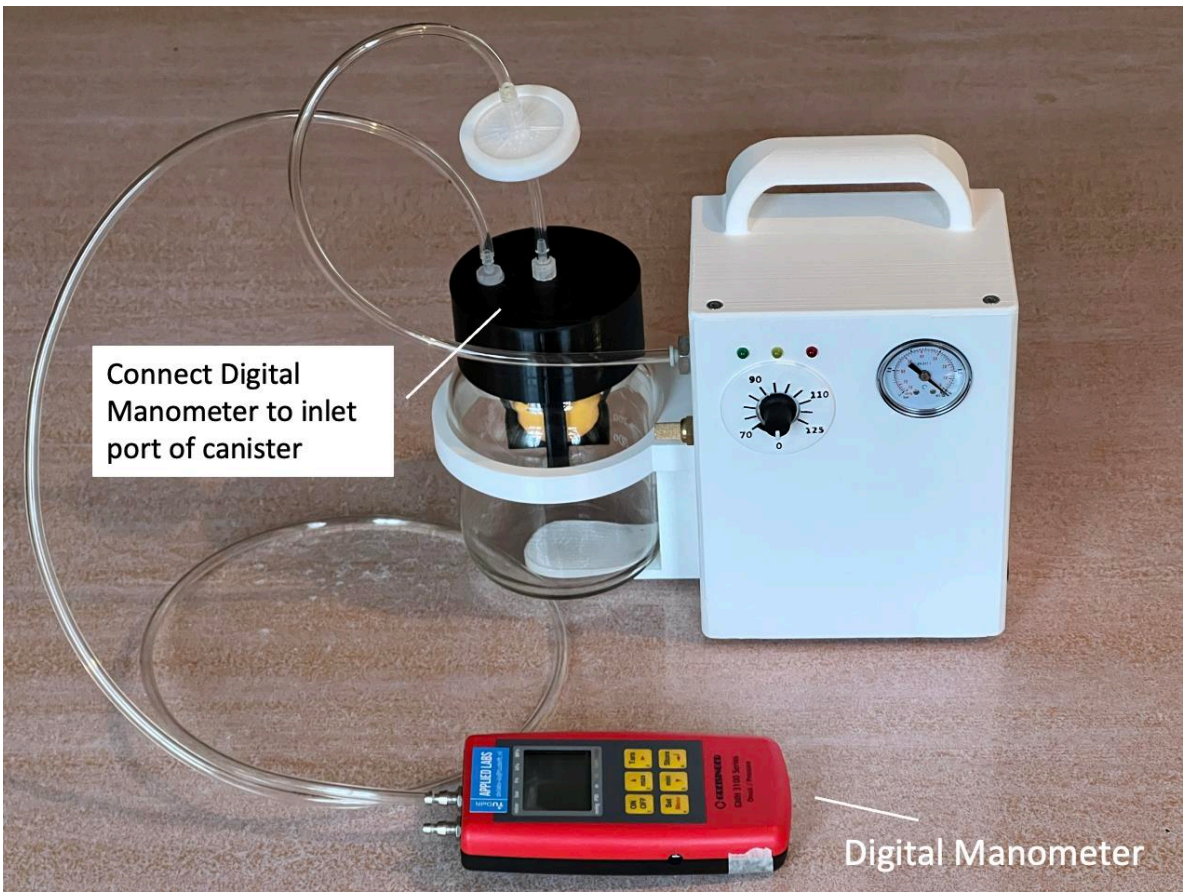


Figure 26: Setup for leakage test of the WOCA Pump

7.2 Pressure Control Test

A pressure control test is performed to verify how well pressure is controlled. The vacuum pump is connected to the canister and adjusted to different pressure settings. Readings from the digital manometer, pressure gauge, and the pressure sensor should all be within 10% range of pressure settings.

7.2.1 Equipment

Table 12: Equipment used to perform the WOCA Pump pressure control test.

No.	Equipment	Model used
1	Timer	Iphone timer function
2	Handheld Digital Manometer	Greisinger GMH 3100
3	Laptop Computer	Macbook Pro

7.2.2 Test Instructions

Table 13: Instructions for the WOCA Pump pressure control test.

Steps	Instruction	Description
1	Connect Computer	Remove Back Housing. Use a usb cable to connect the Arduino microcontroller to the computer. Open the serial monitor in Arduino IDE to read sensor values.
2	Connect Vacuum Pump to Canister	Connect the inlet port of the vacuum pump to the filter (outlet port) of the canister.
3	Connect Handheld Digital Manometer	Use a PU Tube (OD 6mm, ID 4mm) to connect the handheld digital manometer to the suction inlet of the canister.
4	Turn Power ON	Check if control knob is turned to 0. Turn on the power switch.
5	Adjust Pressure	Turn the control knob clockwise to adjust pressure settings to 70, 90, 110, and 125 mmHg.
6	Wait for Pressure to Increase	The pressure is expected to gradually increase while the yellow LED continue to blink. When pressure reaches 125 mmHg, the green LED will start to blink.
7	Record Pressure Measurements	Start timer and record pressure measurements from the handheld digital manometer and the pressure gauge at 0, 3, 5, and 10 minutes.
8	Turn Power OFF	Turn the control knob counterclockwise to 0 and turn off the power switch. Disconnect the digital manometer.

7.2.3 Test Results

Test results for the pressure control tests are shown in Table 14 and Figure 27. These results show that the pressure control is stable within the 5-minute testing time frame. Small spikes are visible In the values recorded from the sensor, showing that the motor is turned on to compensate the loosing pressure due to air leakage.

Table 14: Recorded pressure values from the digital manometer and pressure gauge in the WOCA Pump pressure control test.

Pressure Setting (mmHg)	Measurement Device	Pressure Measurement in Different Time		
		0 minute	3 minute	5 minute
70	Digital Manometer	71	71	72
	Pressure Gauge	70	70	70
90	Digital Manometer	92	90	91
	Pressure Gauge	88	88	88
110	Digital Manometer	111	110	111
	Pressure Gauge	110	110	110
125	Digital Manometer	125	124	123
	Pressure Gauge	123	120	120

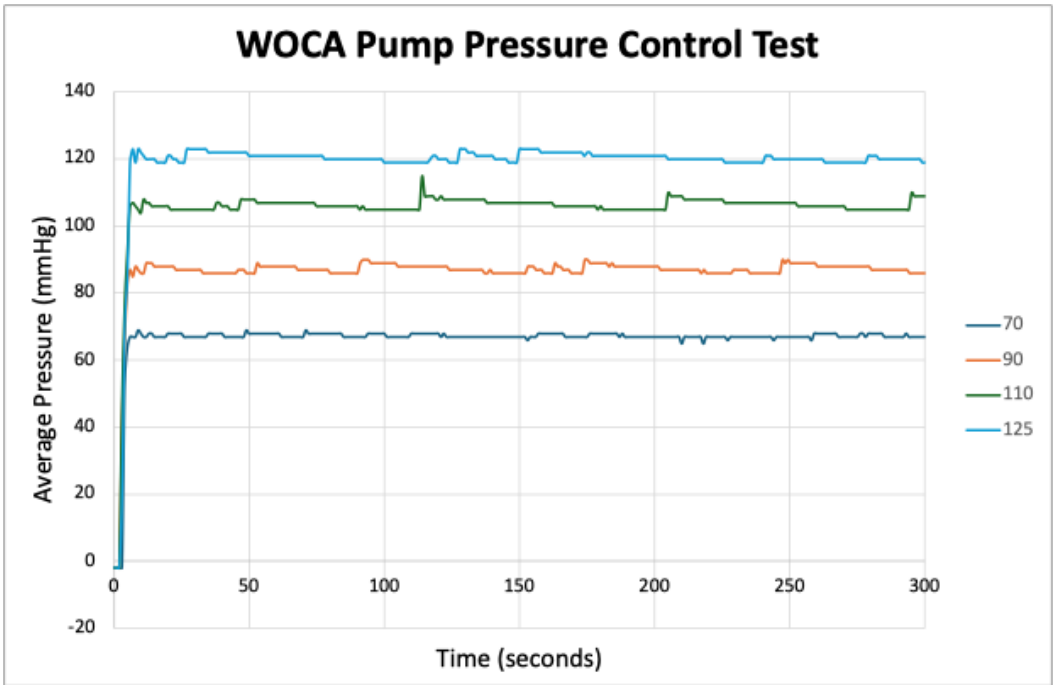


Figure 27: Recorded pressure values from the sensor in the WOCA Pump pressure control test.

7.3 Safety Alarm Test

A safety alarm test is performed to verify whether the safety mechanisms of the device are functioning. For this test, no extra equipment is needed. The canister is disconnected from the vacuum pump. A sudden blockage of the air inlet of the vacuum pump will cause a sudden increase of pressure within the system. This should light the red LED, sound the buzzer alarm, and stop the motor. The test is repeat the three times for repeatability.

7.3.1 Test Instructions

Table 15: Instructions for the WOCA Pump safety alarm test.

Steps	Instruction	Description
1	Disconnect Canister	Disconnect tubing between vacuum pump and canister.
2	Turn Power ON	Check if control knob is turned to 0. Turn on the power switch.
3	Set Pressure to 125 mmHg	Turn the control knob clockwise to adjust pressure setting to 125 mmHg. The vacuum pump will operate continuously.
4	Block Vacuum Pump Air Inlet	Use a finger or a tube cap to block the tube from the vacuum pump. The pressure is expected to rise sharply and set off the safety alarm.
5	Release Pressure and Turn Power Off	Turn the control knob to 0. Release the finger from the tube to release the pressure. Turn off the power of the device after testing.

7.4 Overflow Valve Test

An overflow valve test is performed to verify whether the device will stop when the canister is full. Only an additional water container that is at least 500 ml is needed to perform this test. When the canister is full, the overflow valve will block the air passage to the vacuum pump. The sudden spike in pressure will trigger the safety alarm and stop the motor. The test is repeated three times for repeatability. When overflow valve is not functioning water will pass the valve and travel to the pump quickly. Make sure to shut down the pump immediately to prevent fluid from entering the device.

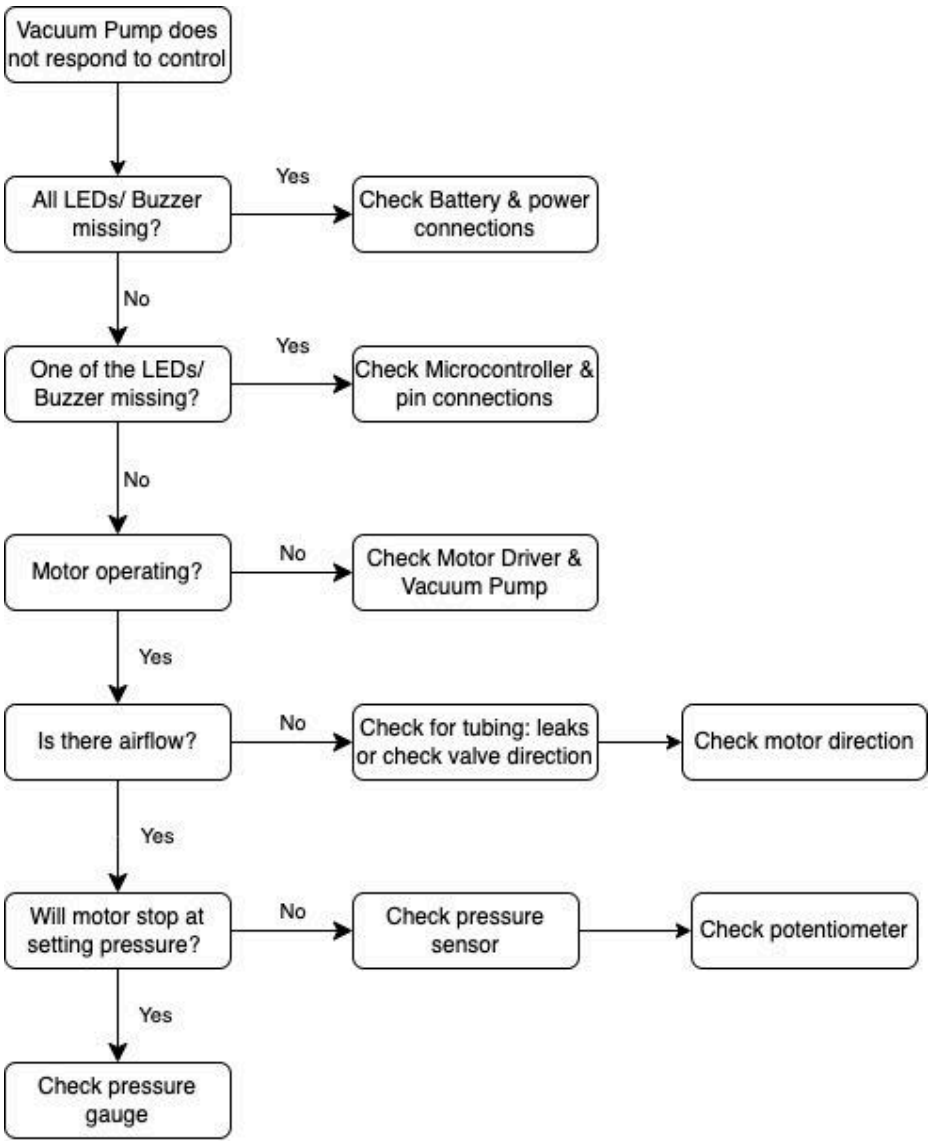
7.4.1 Test Instructions

Steps	Instruction	Description
1	Fill Container	Fill water container with water.
2	Connect Vacuum Pump to Canister	Connect the inlet port of the vacuum pump to the filter (outlet port) of the canister.
3	Put Suction Tube in Water Container	Use a PU Tube (OD 6mm, ID 4mm) to connect the suction inlet of the canister. Emerge the opening of the tube in the water.
4	Turn Power ON	Check if control knob is turned to 0. Turn on the power switch.
5	Set Pressure to 125 mmHg	Turn the control knob clockwise to adjust pressure setting to 125 mmHg.
6	Wait for Canister to Fill	Water from the container will start filling the canister. Once maximum capacity of the canister is reached, the overflow valve should be triggered.
7	Turn Power OFF and Empty Canister	Turn control knob to 0 and turn power off. Remove the tube from the water. Open the lid of the canister and empty the water.

7.5 General Troubleshooting

Before reviewing the troubleshooting chart, the following steps may be useful to isolate any malfunctions:

1. Make sure the battery is fully charged.
2. Make sure the filter and tubes are clean.
3. Make sure the canister is empty.
4. Make sure there are no leaks by checking the fittings and connectors. Reapply thread seal if there is leakage on the threads. Make a clean cut on the PU tubes or replace the tubes and reconnect to the push-in fittings.



8 Ethics statements

No animal or human subjects were used in this study.

9 CRediT author statement

Arjan Knulst: Writing- review & editing, Conceptualization, Methodology, Funding acquisition, Resources, Project administration, Conceptualization, Supervision.

Salome Berger: Conceptualization, Validation.

Jorijn van den Boom: Investigation, Methodology, Software.

Noa Nicolai: Investigation, Methodology, Software.

Suraj Maharjan: Conceptualization, Validation.

Eileen Raaijmakers: Conceptualization, Methodology, Investigation, Data curation, Visualization.

Chang-Lung Tsai: Writing – Original draft, Data Curation, Software, Visualization.

Lisa van de Weerd: Conceptualization, Methodology, Investigation, Data curation, Validation.

Jenny Dankelman: Writing- review & editing, Conceptualization, Funding acquisition, Supervision.

Jan-Carel Diehl: Writing- review & editing, Conceptualization, Funding acquisition, Supervision.

10 Acknowledgments

Funding for building and testing various prototypes and covering travel costs of students to Nepal was granted by the Delft Global Initiative.

Funding for a clinical validation study using a small series of 3 WOCA devices was granted by Sunita project. Sunita project is a UK Aid fund matched project being implemented in Nepal by International Nepal Fellowship (INF) and EMMS International.

Funding for documenting and preparing for Open Hardware publication was granted by Delft Open Hardware Fund.

Funding:
Sunita is a UK Aid fund matched project being implemented in Nepal by International Nepal Fellowship (INF) and EMMS International.

11 References

1. Järbrink, K., et al., *Prevalence and incidence of chronic wounds and related complications: a protocol for a systematic review.* Syst Rev, 2016. **5**(1): p. 152.
2. Mazuz, R., *Wound Care in the Developing World - Gaps, Opportunities, and Realities.* Current Dermatology Reports, 2019. **8**(4): p. 199-207.
3. Zaver, V. and P. Kankanalu. *Negative Pressure Wound Therapy*. 2023 [cited 2024 September 11]; Available from: https://www.ncbi.nlm.nih.gov/books/NBK576388/.
4. Fout, B. and M. Plotzke, *Comparing Traditional and Disposable Negative-Pressure Wound Therapy Use by Medicare Home Health Patients.* Advances in Skin & Wound Care, 2022. **35**(1).
5. Clinic, C. *Negative Pressure Wound Therapy*. 2024 July 19 [cited 2024 September 11]; Available from: https://my.clevelandclinic.org/health/treatments/17313-negative-pressure-wound-therapy.
6. Cocjin, H.G.B., et al., *Wound-Healing Following Negative-Pressure Wound Therapy with Use of a Locally Developed AquaVac System as Compared with the Vacuum-Assisted Closure (VAC) System.* JBJS, 2019. **101**(22).
7. Raaijmakers, E., *Design of a low-cost device for Negative Pressure Wound Therapy in low and middle-income countries*, in *Industrial Design Engineering*. 2022, Delft University of Technology.
8. Nicolai, N., *WOCA A battery powered wound pump designed for use in low-resource settings*, in *Technical innovations in Medicine Congres*. 2023: Utrecht, Netherlands.

Design Files

Click here to download Design Files http://doi.org/10.17632/r95wgtmffn

B

Appendix Risk Assessment

This appendix contains the outcome of the performed risk assessment.

Failure Mode and Effect Analysis - FMEA

INTERNATIONAL NEPAL FELLOWSHIP

Part or Process Name		Facilities Affected		Prepared By	Lisa van de Weerd
Program		FMEA Start Date		Last Updated	
Core Team	2 user-experts from Erasmus MC, 1 master student Electrical Engin	Revision Level		FMEA Number	

Process Step, Operation, Function or Requirements	Potential Failure Mode	Potential Effect(s) of Failure	S	Class	Potential Cause(s) of Failure	O	Current Controls/ Evaluation Method	D	S x O	RPN	Recommended Action (s)	Assigned To	Due Date	Action Results					
														Action Taken & Effective Date	O	D	Diff	PCT %	RPN
Connect lid to canister	Incorrect connection between lid and canister	Leakage during treatment	3		Turning cap incorrect on canister	6	Alarming system	1	18	18									
	Wrong connection of tubes on the lid of canister	Overflowprotection not working	9		Wrong placement of tubes on canister	2	One-way fit for tubes	1	18	18									
Connection between tube from patient to canister and the canister	Leakage in the connection between the tube and canister, but tube stays connected to canister	Leakage during treatment	3		Connection of tubes correctly made	5	Alarming system	1	15	15									
	Unrecognized leakage during treatment for long period	Overheating of motor	5		Motor trying to overcome leakge for too long	2	Alarming system, noise of motor	1	10	10									
	Tube comes loose from canister during treatment	Wound fluid of patient is leaking on the ground	3		Connection of tubes incorrectly made	5	Alarming system	1	15	15	Include in manual: If this happens everything sould be cleaned, and tube including dressing should be replaced. Also staff should be trained.								
Connection between tube from canister to motor and canister	Leakage in the connection between the tube and canister, but tube stays connected to canister	Leakage during treatment	3		Connection of tubes made incorrectly	5	Alarming system	1	15	15									
	Tube comes loose from canister during treatment	Leakage during treatment	3		Connection of tubes made incorrectly	2	Alarming system	1	6	6									
Canister placement	Canister falls over	Overflowprotection not working; canister overfull with fluid of patient	5		Canister knocked out of canister holder	1		7	5	35	Include in manual to make it protocol to put canister in holder, and tell patient that canister belongs in holder. Also staff should be trained.								
		Overflowprotection not working; fluid from patient in device	5		Canister knocked out of canister holder	1		7	5	35	Include in manual to make it protocol to put canister in holder, and tell patient that canister belongs in holder. Also staff should be trained.								
Wound of patient is bleeding	Blood of patient in canister	300 mL of blood collected from patient	7		Wound of patient is bleeding during treatment.	3	Tubes and canister seethrough, so that blood is recognisable	2	21	42	Include in manual to make caregivers, patient and nurses aware of this risks and the importance of monitoring this during treatment								
			5		Pressure sensor not calibrated well	2		7	10	70	Include in manual to check pressure sensor when installing device + check every half a year								

Failure Mode and Effect Analysis - FMEA

INTERNATIONAL NEPAL FELLOWSHIP

Part or Process Name		Facilities Affected		Prepared By	Lisa van de Weerd
Program		FMEA Start Date		Last Updated	
Core Team	2 user-experts from Erasmus MC, 1 master student Electrical Engin	Revision Level		FMEA Number	

Process Step, Operation, Function or Requirements	Potential Failure Mode	Potential Effect(s) of Failure	S	Class	Potential Cause(s) of Failure	O	Current Controls/ Evaluation Method	D	S x O	RPN	Recommended Action (s)	Assigned To	Due Date	Action Results: Action Taken & Effective Date	Action Results: O	Action Results: D	Action Results: Diff	Action Results: PCT %	Action Results: RPN
Set pressure	Offset in pressure	Given amount of pressure during treatment too high	5		Pressure wrongly set by staff	3	Visual feedback	3	15	45	Include in manual to check the pressure when cleaning the device, train staff on the importance of setting the correct pressure								
			5		Patient/staff accidently bumps into pressure knob	3	Visual feedback	2	15	30									
		Given amount of pressure during treatment too low	2		Pressure sensor not calibrated well	2		7	4	28									
			2		Pressure wrongly set by staff	3	Visual feedback	3	6	18									
			2		Patient/staff accidently bumps into pressure knob	4	Visual feedback	2	8	16									
On/off switching device	Device accidently switched on	Device switched on besides treatment, unneccesairy	1		Patient/staff accidently bumps into pressure knob	3	Sound	1	3	3									
	Device accidently switched off during treatment	Treatment less effective. When dressing attached to wound and treatment is stoped for a longer period, changes for bacterial grow are higher.	5		Patient/staff accidently bumps into pressure knob	3	No sound anymore	3	15	45	Include in manual that after 2 hours of device being off, dressing including tube should be changed								
Battery	Forgot to charge the battery	Treatment can't start	2		Battery empty	3	Device not starting	1	6	6	Battery percentage tracking								
		Device stops during treatment	5		Battery empty	3	No sound anymore	3	15	45	Include in manual that after 2 hours of device being off, dressing including tube should be changed								
Water on device	Water in housing	Water close to power supply	9		Water in housing	1	Battery in seperate space within housing + battery has overurrent protection	1	9	9									
Cleaning of device	Filter not changed when being dirty/full	Dirt getting into motor of device	5		Staff doesn't see the filter needs change	3	Visual feedback	1	15	15									
	Tubes/canister not properly cleaned between patients	Infection patient	9		Not properly cleaned	3	Protocol	2	27	54	Give staff training about importance of cleaning								
Components:																			
Cable breaks	Cable breaks during treatment	Device/treatment stops	3		During use of device cable has too much slack/breaks	3	Housing	1	9	9									
Motor	Stops working during treatment	Device/treatment stops	3		Motor breaks down	2	No sound anymore	3	6	18									
Motorcontroller	Stops working during treatment	Device/treatment stops	3		Motorcontroller breaks down	2	No sound anymore	3	6	18									
Arduino	Stops working during treatment	Device/treatment stops	3		Arduino breaks down	2	No sound anymore	3	6	18									

Failure Mode and Effect Analysis - FMEA

INTERNATIONAL NEPAL FELLOWSHIP

Part or Process Name		Facilities Affected		Prepared By	Lisa van de Weerd
Program		FMEA Start Date		Last Updated	
Core Team	2 user-experts from Erasmus MC, 1 master student Electrical Engin	Revision Level		FMEA Number	

Process Step, Operation, Function or Requirements	Potential Failure Mode	Potential Effect(s) of Failure	S	Class	Potential Cause(s) of Failure	O	Current Controls/ Evaluation Method	D	S x O	RPN	Recommended Action (s)	Assigned To	Due Date	Action Results					
														Action Taken & Effective Date	O	D	Diff	PCT %	RPN
Battery	Stops working during treatment	Device/treatment stops	3		Battery breaks down	2	No sound anymore	3	6	18									
Overflowprotection	Stops working during treatment	Canister becomes overf	3		Overflowprotection bre	3		7	9	63	Include in manual to check overflow protection when cleaning the canister, train staff for this								
LED lights	Stops working during treatment	No lights in alarming sys	2		Lights break down	2	Visual feedback	5	4	20									
Silencer	Stops working during treatment	Sound not silenced anyr	2		Silencer stops working	1	More sound	3	2	6									

C

NHRC proposal: Clinical Trial for the WOCA Vacuum-Assisted Closure (VAC) Device

This appendix includes a copy of the document for the NHRC proposal for the Clinical Trial of the WOCA VAC device. Note that the proposal is designed by author, but is reviewed and improved by supervisor A. Knulst and collaborator of the clinical trial S. Maharjan. This current version is still a draft.

RESEARCH PROTOCOL

TITLE OF RESEARCH:
Clinical Trial for the WOCA Vacuum-Assisted Closure (VAC) device

PRINCIPAL INVESTIGATOR:
(dr. S. Maharjan, Green Pastures Hospital)

STUDY SITE:
(INF Green Pastures Hospital Pokhara)

COLLABORATORS:
(dr. ir. A.J. Knulst, Biomedical Engineering, Green Pastures Hospital)

(dr. A. Shrestha, Palliative Care Department, Green Pastures Hospital)

STUDY PROTOCOL

1. SUMMARY OF PROPOSAL

(Provide a summary of the proposal)
The objective of this Clinical Trial is to evaluate the performance of the WOCA device as a Vacuum-Assisted Closure device.
The efficacy of the WOCA is evaluated based on the following criteria: infection rate, healing time, wound size reduction, complication rate, exudate levels, Visual Analogue Scale (VAS) pain score, and costs of treatment.

A review of the literature will be conducted to analyse the performance of other VAC devices that have been used in similar clinical trials, both low cost VAC devices as commercial VAC devices. The results of this evaluation will then be compared to the performance of the WOCA.

A total of 15 patients deemed suitable for VAC therapy will be included in the study. The selected patients will be treated with VAC therapy in Green Pastures by using the WOCA. A strict protocol will be employed to ensure the accurate measurement of all relevant parameters throughout the treatment. The inclusion criteria for participants will be as follows:
Inclusion criteria for participants would be:

- The wounds to be treated with VAC therapy must be suitable for this procedure

The research period will last for four months, from October 2024 to February 2025, with two months of documentation from February 2025 to March 2025.

If the WOCA is comparable or superior to other used VAC devices in terms of infection rate, healing time, wound size reduction, complication rate, exudate levels, VAS pain scores, patient experience, staff experience, and the average costs, it would be beneficial to utilise the WOCA in LMIC.

2. INTRODUCTION

2.1 Background

Vacuum Assisted Closure therapy (VAC) is a method commonly used for large wounds, such as pressure sores. Currently, International Nepal Fellowship (INF) hospitals utilise the Turtle VAC as a VAC device, however, the staff have expressed concerns regarding the usability of this device.
Therefore, a team of students, under the supervision of Arjan Knulst designed and built a new VAC device, the Wound Care (WOCA) device, constructed from locally available components in Nepal.
The device is currently operational and has been validated by the nursing staff of INF hospitals as being user-friendly. The final step before implementing the device in a clinical setting would be to validate its performance.

To ascertain whether the WOCA VAC device is a good device to use for VAC therapy within the hospital, its performance will be compared to that of both low cost VAC devices as well as commercial VAC devices documented in literature.

2.2 Rationale / Justification

The results of the interviews conducted during the WOCA development indicate that the nurses of INF Hospitals would prefer to utilise the WOCA as a VAC device within the hospital setting. Furthermore, the nurses believe that utilising the WOCA within the hospital setting would be a more comfortable option for patients. The WOCA has undergone rigorous testing and risk evaluation, and has been proven to be a safe and effective device for use in a hospital setting.

Nevertheless, prior to utilising the device within the hospital setting, it would be prudent to conduct trials in a controlled environment with a limited number of patients. In order to ascertain that the device functions comparably to other VAC devices, and therefore can be used as a VAC treatment, it is necessary to conduct further tests. If the device functions as anticipated, it may be employed in all INF hospitals.

2.3 General Objective

The objective of this study is to evaluate the effectiveness and patient and staff experience of the WOCA device as a viable VAC system for the treatment of chronic wounds.

2.4 Specific Objective(s)

1. To assess the infection rate of the WOCA compared to low cost, and commercial VAC devices.
2. Evaluate the healing time for the WOCA compared to low cost, and commercial VAC devices.
3. Measure the wound size reduction for the WOCA compared to low cost, and commercial VAC devices.
4. Document the complication rate for the WOCA compared to low cost, and commercial VAC devices.
5. Monitor the exudate levels for the WOCA compared to low cost, and commercial VAC devices.
6. Evaluate the Visual Analogue Scale (VAS) pain score for the WOCA compared to low cost, and commercial VAC devices.
7. Evaluate the patient and user experience for the WOCA VAC device.

2.5 Research Hypothesis

We expect a Null Hypotheses (N0):
using the WOCA as VAC therapy will have no negative effect on the infection rate, healing time, wound size reduction, complication rate, exudate levels, Visual Analogue Scale (VAS) pain score, patient experience, and staff experience compared to low cost VAC devices and commercial VAC devices.

3. METHODS

3.1 Research Design

A total of 15 patients deemed suitable for VAC therapy will be included in the study. The aforementioned patients may undergo VAC therapy in Green Pastures Hospital Pokhara. A strict protocol will be employed to ascertain the parameters throughout the course of treatment. Treatment will follow regular procedures for VAC treatment, including dressing preparations.

Inclusion criteria:

- The wounds must be suitable for VAC therapy.

Exclusion criteria:

- Lack of documentation
- People with uncontrolled diabetes or bleeding disorders.
- Patients with infectious diseases, because of changes for transfer of infections
- Pregnant women

Research Protocol

- Patient inclusion by PI
- Taking informed consent by PI
- Wound preparation, VAC application, and wound assessment using the wound assessment form, by a surgeon, all according to usual care.
- Wound assessment after 4 days by a surgeon, followed by reapplication of VAC or termination of the VAC treatment. Repetition of this assessment and reapplication until termination. Reason for termination can be successful treatment, or clinical conditions to terminate the VAC treatment. All according to usual care.
- Regular inspection of dressing and device by nurses. Any deviating findings to be reported to PI. All according to usual care.
- After termination of treatment, the patient experience with the WOCA will be assessed using a feedback form.
- At the end of the study, the clinical staff user experience with the WOCA will be assessed using a feedback form.

3.2 Justification of Research Design

The WOCA was built as an improvement for the Turtle VAC, currently used in INF hospitals. Up until now tests were done, taking into account the relevant ISO-norms (International Design and Performance Standards), which showed that the WOCA would be safe to use. Furthermore, design validation is done with nurses from INF hospitals, who saw benefits of using the WOCA. A good next step would be to see whether or not the WOCA is comparable in clinical performance to other VAC devices during VAC therapy. If the WOCA is comparable in clinical performance with other VAC devices, it would be a good device to use in INF hospitals.

3.3 Study Site and its Justification

Green Pastures Hospital Pokhara, this hospital is chosen because of the patients with chronic wounds visiting the hospital. Also there is technical support for the WOCA. Therefore, it is a good location to recruit participants.

3.2 Study Population

Recommended study population for this type of study:
Determining the WOCA clinical validation as a pilot study, the recommended size for the study is 12 participants. This number of participants is based on the research of Julious, 2005.

Available participants for the study:
The available number of participants is estimated at 15 patients, receiving VAC therapy can be received at Green Pastures Hospital.

Extra:
Cocjin et al. (2019) included 36 participants in their research to compare the AquaVAC with a commercial VAC device (VAC ATS; KCI). 19 participants received VAC therapy using AquaVAC, and 17 participants received the VAC ATS system.

Literature:
Poweranalyse-Wikistatistiek.(z.d.). https://wikistatistiek.amc.nl/index.php/Poweranalyse#Waarom_doe_ik_een_poweranalyse_of_steekproefgrootteberekening

Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics*, *4*(4), 287–291. https://doi.org/10.1002/pst.185

Cocjin, H. G. B., Jingco, J. K. P., Tumaneng, F. D. C., & Coruña, J. M. R. (2019). Wound-Healing Following Negative-Pressure Wound Therapy with Use of a Locally Developed AquaVac System as Compared with the Vacuum-Assisted Closure (VAC) System. *Journal Of Bone And Joint Surgery*, *101*(22), 1990–1998. https://doi.org/10.2106/jbjs.19.00125

3.4 Data Collection

The documentation of parameters is shown in additional wound assessment form, see Appendix A. This data will be collected at time of first application of a VAC dressing, and on subsequent VAC dressing changes every 4 days, or when clinical reasons for early VAC dressing changes occur. Wound preparation and VAC dressing installation will be done by a surgeon. Data will be collected by a surgeon.

Regular dressing and device checks will be done by nurses, and noted on a log sheet.

PI will evaluate the patient experience with treatment of the WOCA VAC after ending treatment using the patient experience feedback form, Appendix C.

PI will evaluate the clinical staff experience with using the WOCA VAC after ending the study, using the clinical staff experience form, Appendix D.

3 WOCA VAC devices are available on site for this study.

3.5 Regarding Clinical Trials

(For clinical trials, please include the trial treatment, detailed explanation of the trial procedures including all invasive procedures, alternative procedure(s) or treatment(s) that

may be available, the risks, discomforts, and inconveniences associated with the study, provisions for management of any adverse reactions, provisions of insurance coverage for any permanent disability or death. Include details of the contact person if adverse effects occur.)
to do
details of procedure. Including dressing preparation, wound preparation and vac application. Explain this is common practise, only difference is the device. Alternative is exiting aquavac/turtlevac.

4. DATA MANAGEMENT, ANALYSIS AND FINDINGS

4.1 Data Management and Analysis

The researcher will have a hard copy of the wound assessment form for the research. They will write down the measurements of the parameters. They will store these measurements in the patient file, and a copy will be stored in the research file storage.

The patient experience form and clinical staff will be available as hardcopy. The filled forms will be collected in the research file storage.

Wound assessment forms, patient experience forms and clinical staff experience forms will be digitalised, and made anonymous, and therefore stored in an online, secured (hard) drive. So that the rest of the research team, who need the information for analysing the data, have access to the data as well.

Data will be analysed by the research team (PI and collaborators).

4.2 Supervision and Monitoring

Instruction for nurses how to document the parameters. They will receive a comprehensive list of instructions on how to document the parameters.
Furthermore, the research team will provide supervision, and an additional student from the TU Delft will assist during the research period. The data will be gathered and analysed following the conclusion of the research period, with the results documented in a research paper.
The Principal Investigator is responsible for the flow of the research. He will make sure that everything is well documented, and monitored according to this document. This also includes training the staff in how and what to document according to the research.

4.3 Potential Biases

The study will be subject to selection bias, as the participants will be only from 1 hospital: Green Pastures Hospital. Therefore, the participation sample is not representative for all the people using VAC therapy. Also good to mention is that the hospital is located in Nepal, therefore the majority of the participants will be Nepali, which also is not representable for other countries.

4.4 Limitations of Study

One limitation of the research is the number of participants. Additionally, the participants selected may not be representative of the population. Furthermore, it would be preferable to include additional countries beyond Nepal.

4.5 Expected Outcome of Research Results

Publication as a research paper, and conference presentation.

4.6 Plans for Utilisation of Research Findings

The research findings will be documented and shared as a research paper. The WOCA design will be made publically available for anyone to build and use.

5. ETHICAL CONSIDERATIONS

5.1 Participant Involvement

A total of 15 patients will be included in the research study after they have been selected from among those receiving VAC therapy at Green Pastures Hospital Pokhara.
The participants will undergo the standard VAC therapy, with the exception that the device will be the WOCA VAC device.

5.2 Vulnerable Participants

The study will only include participants who are suitable for VAC therapy, which will be patients with acute as well as chronic wounds. Most of the participants will also be patients with disability and/or leprosy affected.

5.3 Expected Risks and Benefits for Participants

The expected risks for the participants will be the risks known for using VAC therapy. For example bleeding of a wound, and therefore the loss of blood because of the VAC therapy. Furthermore, the chance for getting an infected wound because of the closure of the wound using VAC therapy. Besides, there is a chance for adverse events.
Those risks are risks which come with using VAC therapy, and as our participants already decide on taking VAC therapy this is not an extra risk because of the research. Also, patients are monitored on these adverse events, as part of usual care.

The WOCA is a prototype, and therefore it could be that the device breaks down and is not working for unexpected reasons. In this case we have more devices as backup, or even revert to the traditional TurleVAC, to minimze a negative effect on the treatment.
The WOCA is properly tested for reliability and for detecting any alarming situations. The WOCA includes a software safety stop that switches off the vacuum pump if the vacuum level would exceed -150mmHg. In case some serious software error would occur that prevents the WOCA to switch off when excess vacuum levels occur, the maximum achievable vacuum level is only -200mmHG. These levels of vacuum are not desired, but also not dangerous for the patients. With this in mind, everything is done to guarantee the safety of the WOCA. For further explanation about the safety of the WOCA see also the attached Failure Mode and Effect Analysis (FMEA) risk assessment.

5.4 Informed Consent Process

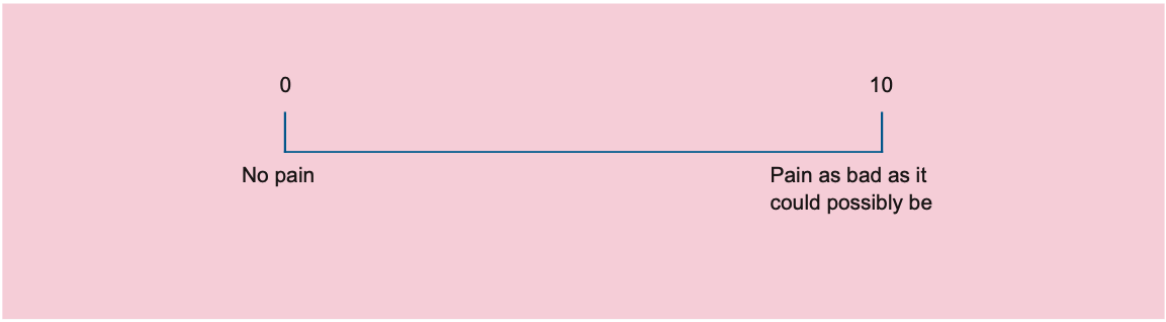
All the participants of the research will be asked to give consent to participate in the research. Once they are selected to start VAC therapy they will be asked whether or not they want to participate in the research.

A written informed consent will be provided to each participant. Should they wish to participate, they are required to sign the informed consent document. The informed consents will be securely stored. The participant will be provided with an informed consent document in both English and Nepali, and will be asked to confirm that they have a full understanding of the study design, the potential risks and benefits associated with their participation in the research. The responsibility for gathering informed consents and ensuring that participants have a comprehensive understanding of the potential risks and benefits associated with the research project rests with the principal investigator.
5.6 Compensation for Injuries
No compensation.
5.7 Sensitivity to Nepali Culture and Social Values
Not applicable.
5.5 Costs and Compensation to Participants, where applicable
Not applicable.
5.6 Privacy and Data Confidentiality
All data will be stored in a locked filing cabinet that only the PI can access. *All digital data will be stored on an encrypted local harddrive and on an encrypted external harddrive.* *All data will be anonymised, with only the PI having the key between patient file and the anonymous data.* *The analysed data will be used for presentations and publications in international conferences and journals.*

Appendix A: Wound Care Assessment Protocol

	Progression in time			
Date of assessment **Wound Characteristics**				
How does the patient experience pain during treatment? (using VAS scoring card, number from 0 to 10, 0 is no pain, 10 is maximum pain)				
Picture of the Wound with a Scale				
Location (drawing diagram on back side and put number.)				
For ulcers: Stage (I, II, III, IV, X) See back for more explanation				
Wound size (cm) (define length and height)				
Wound bed: draw the wound and indicate the location of different tissues within wound bed. The patient's head is 12 o'clock Code: N = necrotic F = fibrine G = granulation E = epithelial				
Exudate levels (Amount in mL)				
Smell (none, little, moderate, large)				
Infected (yes/no)				
Quality (serous, bloody, brown, green, pus)				
Undermining (cm) (indicate on wound bed drawing)				

Wound margins: (irritation free, epithelialization, red, white swelling)				
Surrounding skin: (swelling, oedema, red, painful, eczematous(allergy), white, brown, haematoma)				
Topical wound treatment: cleansing				
Dressing				
Covering				
Special instructions				
Contributing Factor Management: Pressure & shear relief measure				
Nutritional Care				
Skin care				
Time needed for patient				
Remarks				
Signature				



Appendix B: INFORMED CONSENT FORM

Information Sheet

1. Introduction

Namaste!! My name is _____ , I am a _____(post) and work for International Nepal Fellowship Nepal. I have come here to conduct a clinical Trial for the WOCA Vacuum-Assisted Closure (VAC) Device. Ethical clearance was sought from Nepal Health Research Council, Ramshah Path, Kathmandu prior to its implementation.

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to understand the information provided in this sheet. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. This study is conducted among patients with chronic wounds that could benefit from Vacuum Assisted Closure (VAC) therapy treatment. This is a proven treatment method around the world.

You are invited because your wound could benefit from VAC therapy.

This study is carried out to find out if our locally made VAC device (called WOCA) has comparable clinical results as high-end VAC devices that are currently not available in Nepal. The device was developed in collaboration with Delft University of Technology and INF Green Pastures Hospital. The WOCA was thoroughly tested on functionality, safety and reliability. We are also studying the perception of the WOCA by the patient and the clinical staff in the hospital.

3. What procedures will be followed in this study

If you take part in this study, you will be asked to undergo application of a special wound dressing designed for VAC therapy, and be connected to the WOCA VAC device. The surgeon will evaluate your wound, clean and prepare it for VAC therapy, and place the VAC dressing. While the VAC therapy is ongoing the medical team will regularly check the dressing and the device. After 4 days of VAC therapy the dressing will be removed for assessment of the wound. If longer treatment is required a new dressing will be applied for another 4 days. If the treatment was successful the procedure will end. After completing treatment you will be asked to fill an evaluation form about the WOCA device.

Your participation in the study will last until the treatment will be terminated.

If you agree to take part in this study, the following will happen to you:

- The researcher will welcome you and check your personal information.
- The researcher will evaluate your wound and decide if it can be treated by VAC therapy.
- You will be admitted to the ward.
- In the operating room the wound will be assessed, cleaned and prepared.
- A VAC dressing will be placed on the wound.
- The VAC device will be connected to the VAC dressing and switched on.

- When everything is fine you will be admitted to the ward.
- Regularly nurses will check the VAC dressing and device.
- Every 4 days the researcher will remove the dressing to assess the wound in the procedure room.
- After assessment the researcher will decide to apply a new dressing for another 4 days, or to end the treatment when healing is sufficient.
- After ending the treatment you will fill a form to rate your experience with the VAC device.

4. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to be admitted to the hospital and undergo all the procedures that are outlined above.

5. What Is Not Standard Care or is Experimental in This Study

The study is being conducted because the WOCA device is not yet proven to be a standard *VAC device* in participants with *chronic wounds*. The VAC treatment itself is proven and standard in many hospitals around the world. Only the device to provide the vacuum required for treatment is not yet standard. We hope that your participation will help us to determine whether *the WOCA VAC device* is equal or superior to existing commercial VAC devices that are not available in Nepal.

6. Possible Risks and Side Effects

(Insert Intervention or Procedure) may have the following side effects or risks *(Explain reasonably foreseeable risks or inconveniences here; it may be best to list them in detail)*.

Allergic reactions can occur with any drug. Common symptoms may include: rash, itching etc.

Rarely, a severe and possibly life-threatening allergic reaction can occur. Symptoms of a severe reaction include: swelling of the face, difficulty breathing, or a sudden drop in blood pressure that may cause dizziness. If you have any of these symptoms, call your doctor at once.

(Intervention or investigation) is still being tested; therefore, you may experience other side effects that have not yet been reported. However, you will be kept informed of any significant new findings that may relate to your willingness to continue to take part in this study.

If you experience any new symptoms, you should contact your doctor or the Principal Investigator as soon as possible.

Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs.

In addition, as you cannot (take any other medication) to treat your *(insert condition here)* while you are (receiving the study medicine), there is a possibility your condition may worsen. If this occurs, your doctor will *(explain rescue/crossover/alternative therapy)*.

7. Possible Benefits from Participating in the Study

If you participate in this trial you may reasonably expect to benefit from the trial of the WOCA VAC device in the following way: *Improved healing of a chronic wound, while keeping mobility during VAC treatment.*

8. Alternatives to Participation

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be VAC therapy using our current VAC device that has limited performance, or receiving standard dressing wound care.

The benefits of our current VAC device are:

Well-known device that staff is familiar with.

and the risks are:

Very limited mobility while receiving VAC therapy as our standard VAC needs mains/city line power.

Tripping risk as there are many wires, parts and pieces and tubes around the bed.

The benefits of standard dressing wound care are:

No device, only dressings.

and the risks are:

Slower healing

Daily dressing change

9. Costs & Payments if Participating in the Study

There will be no payment/reimbursement for the participation in the study.

10. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, or the Investigator of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow

instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

11. Compensation for Injury

If you follow the directions of the doctors in charge of this study and you are physically injured due to the trial substance or procedure given under the plan for this study, the INF Green Pastures Hospital will / will not pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by the INF Green Pastures Hospital.

12. Confidentiality of Study and Medical Records

Information collected for this study will be kept confidential. Data collected are the property of *INF Green Pastures Hospital.* In the event of any publication regarding this study, your identity will remain confidential.

13. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the Principal Investigator, *Dr Suraj Maharjan.*

In case of any injuries during the course of this study, you may contact the Principal Investigator, *Dr Suraj Maharjan.*

Appendix C: Patient experience with the WOCA

For our research we are curious what your experience as a patient is with the WOCA device. We list some questions that can be answered. We value your honest opinion and feedback.

Patient ID:	**Scoring chart. Put a X-mark somewhere between leftmost and rightmost option.**				
Was the noise of the device disturbing you during the day?	No disturbance at all		Neutral		A lot of disturbance
Explanation/comments:					
Was the noise of the device bothering you during the night?	No disturbance at all		Neutral		A lot of disturbance
Explanation/comments:					
Was it easy to monitor the status of the device?	Very easy		Neutral		Very difficult
Explanation/comments:					
Was it possible to move around the hospital while connected to the device	Very easy		Neutral		Very difficult
Explanation/comments:					
Was it possible to use the bathroom while connected to the device?	Very easy		Neutral		Very difficult
Explanation/comments:					
Did you experience any problems with the device while receiving treatment?	No problems at all		Neutral		Many problems
Explanation/comments:					
Did you feel safe while receiving treatment with the device?	Very safe		Neutral		Very unsafe
Explanation/comments:					

Was it clear what to do when the device was giving an audible alarm?	Very clear		Neutral		Very unclear
Explanation/comments:					

Appendix D: Clinical staff experience with the WOCA

Staff ID:					
Position:					
How many WOCA VAC treatments did you attend in total?					
How was your experience with the WOCA during these VAC treatments?					
	Scoring chart. Put a X-mark somewhere between leftmost and rightmost option.				
Was the WOCA easy to connect to a patient?	Very easy to connect		Neutral		Very difficult to connect
Explanation/comments:					
Was it easy to get tubing and canister free of air leaks?	Very easy		Neutral		Very difficult
Explanation/comments:					
Was the WOCA easy to use?	Very easy to use		Neutral		Very difficult to use
Explanation/comments:					
Did you feel the patient was safe while connected to the WOCA?	Very safe		Neutral		Very unsafe
Explanation/comments:					
Was it easy to empty the canister and place it back?	Very easy		Neutral		Very difficult
Explanation/comments:					
Were status LEDs useful (green, yellow, red LED; solid, blinking LED)?	Very useful		Neutral		Very not useful
Explanation/comments:					

Was the audible alarm useful?	Very useful		Neutral		Very not useful
Explanation/comments:					
Was it clear when the device was having a problem that needed to be addressed?	Very clear		Neutral		Very unclear
Explanation/comments:					
Was it clear what to do when the device was giving an audible alarm?	Very clear		Neutral		Very unclear
Explanation/comments:					

D

Appendix Validation Summaries

This appendix contains summaries of the interviews conducted, following the full interview protocol. The first section includes the summaries for the participants included in the validation, while the second section covers the summaries of additional participants who were excluded from validation. Full interview transcriptions are available in the supplementary documents.

D.1. Summaries Participants

D.1.1. Summary Validation Participant 1

Years of experience:
Experience with western VAC systems (years).
0 years of experience with working in a hospital in Nepal, also experience with turtleVAC.

Points for attention:

- The number ons the scale plate for setting the desired pressure does not exactly match the amount of pressure scale plate needs adjustment
- If the pressure gauge is causing a lot of leakage I would remove it, but you have to ask other nurses as well.
- ifferent canister for children (smaller)

Performance of WOCA

(6) Usability

Show the device and don't tell how to use it. Let them tell you how they think it should be used.

Do they have feedback/any thoughts? How do they think it works, what are the buttons for?

Participant: Looks clear. Scale plate for setting pressure needs adjustment: number on scale plate for pressure should match amount of pressure

Explain how the device is used

Do you think the device is easy to operate by medical staff with minimal training (6.1)
Participant: Yes
Do you think the device is easy to monitor by patients and caregivers with basic instructions (6.2)
Participant: Yes
How would you use the lid? Do you think it is a 'one-way use'. (extra)
Participant: Yes

(7)Portability

Do you think the canister is firmly attached to the device, while it can be easily removed for emptying? (7.2)
Participant: Yes
Do you think the device can be carried by patients with mobility problems? (user/expert) (7.6)
Participant: People with full finger function can, but with it would be challenging
Do you have other ideas for portability of the device?
Participant: Carrying straps would be a good idea, handle in the middle would make carrying easier.

(9) Safety

Do you think the device will remain stable on the ground without the risk of tipping over? (9.1)
Participant: Yes
Do you think the content of the canister and fluid tube are visible during use (to be able to detect any signs of infection)? (9.3)
Participant: Yes

What kind of situation needs an alarm?
Participant: Constant leaking, running out of battery

(10) Cleaning
How is the cleaning of such devices done in your hospital?
Participant: Device itself clean with spirit, floater and container sterilization if possible, we would do it with pyrex/virex 10 minutes in and cleaning by hand first and then putting in solution. Using hot water, then it is kind of sterile, not totally though. Wouldn't put it in the autoclave.
Do you think all external parts of the device are suitable for cleaning with disinfectant? (10.1)
Do you think the canister and connectors are suitable for sterilization (autoclaving)? (10.2)

(12) Reliability
Do you think the number of components is reduced as much as possible? (12.1)
Participant: Yes

(13) Availability
How would you change the tubes and filters?
Do you think that is easy?
Participant: Yes
Do you think it is is needed to have a detachable tube from the pump to the canister
Participant: It would be good to change the tube when the filter needs to be changed as well, so make it not detachable. So that the biomedical department can then change the tube and filter at once.
Should the canister be on the ground because of hard handling?

(14) Repairability
Do you think the device can be (dis)assembled with local skills and tools? (14.1)
Do you think the individual parts can be removed and replaced? (14.2)

(15) Maintenance
Do you think the device is low-maintenance? (15.1)
Participant: Yes

(16) Lifespan
In what sort of use cases do you think you would use the device? (inside the hospital, for people to take it home?)
- Where would you use the device? Are there other requirements for that as well?

Participant: Would only use it for inpatients (toilet and sit outside)

Do you think the device can withstand rough handling (shocks and small impact) (16.2)
- What sort of handling would you think can happen to the device?

Performance of the WOCA
Questions to rate on scale of 1-5
1. Noise

Do you think the noise would disturb the patient/medical staff? (1 no disturbance, 5 a lot of disturbance)

Participant: 5, after implementing silencer 2

2. Easy to use

Do you think the device is easy to use for a nurse? (5 very easy to use)

Participant: 4

- *No tubes in the way*

Participant: 4

- *No change for accidentally knocking over the canister?*

Participant: 3 or 4

- *No change for accidentally breaking the device?*
- *Do you think the canister is easy to replace?*

Participant: 4

- *Do you think the amount of fluid is easy to see?*

Participant: 5

- *Do you think the tubes are easy to connect/deasamble?*

Participant: 4

- *Do you think the amount of pressure is easy to set?*

Participant: 5 (if scale is in right place)

- *Do you think the device is simple to use?*

Participant: 4 or 5

Do you think the device is easy to use for a patient?

Participant: 3 or 4

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

Participant: 4

Do you think the device is easy to use for a caregiver?

Participant: yes it's easy to use

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

3. Alarming system

Do you think the safety alarm for overflow is adequate?

Participant: there is not really an alarm, would be nice to have. No alarm, but overflow protection itself 4

Do you think the safety alarm for not accurate pressure is adequate?

Participant: 4

Do you think the safety stop for -200 mmHg is adequate?

Participant: I would set it to -150 mmHg

4. Portable

Do you think the device is portable for the patient?

Participant: 3

Do you think the device can be used outside?

Participant: 4

5. Design

Do you think the device looks nice?

Participant: 3

Do you think the device looks professional?
Participant: 4
Do you think the WOCA is simple to use?
Participant: 5
Do you think the WOCA has components which can be deleted?
Participant: maybe pressure gauge, but I like it

6. Replacement
   Do you think the device is easy to repair when broken?
   Participant: inside 1, only outside 4
   Do you think the components are easy to assemble/disassemble?
   Participant: 4

Second, comparison with AquaVAC
The WOCA was made to improve, compared to the AquaVAC on the following points. Can you tell, based on your experience, whether or not this is reached? Please also with some comments.

Turtle VAC compared to WOCA
Participant: Benefits WOCA: easier to handle, clear where tubes should go, portable (battery, detachable for patient), and more control over the suction. Noise of turtle and WOCA were similar, where the turtle gave a continuous noise which is experienced as less comfortable.

WOCA compared to western system
Benefits WOCA: simple, more easy to use. Western system everything single use, think it is a good idea to clean and reuse things.

Last questions:
Does the WOCA meet your requirements/expectations for a VAC system in your hospital/context? Why yes/no?
Would you use the WOCA in your hospital? And would you prefer the WOCA over the AquaVAC?

Participant: Yes

D.1.2. Summary Validation Participant 2

Years of experience:
No experience with turtleVAC only VAC system whereby actively generating pressure is needed, 15 years of experience in hospital in Nepal

Points for attention:
Colour (orange) is too bright, prefer grey/green/white. Pressure gauge preferred if not leaking too much. Scale for setting pressure should be placed correctly.

Performance of WOCA:

(6) Usability

Show the device and don't tell how to use it. Let them tell you how they think it should be used.

Do they have feedback/any thoughts? How do they think it works, what are the buttons for?

Explain how the device is used

Do you think the device is easy to operate by medical staff with minimal training (6.1)
Participant: Yes
Do you think the device is easy to monitor by patients and caregivers with basic instructions (6.2)
Participant: Yes
How would you use the lid? Do you think it is a 'one-way use'. (extra)
Participant: Yes

(7)Portability

Do you think the canister is firmly attached to the device, while it can be easily removed for emptying? (7.2)
Participant: Yes
Do you think the device can be carried by patients with mobility problems? (user/expert) (7.6)
Participant: Yes, it is a little bit heavy but it's fine
Do you have other ideas for portability of the device?
Participant: Possibility to hang it on a wheelchair

(9) Safety

Do you think the device will remain stable on the ground without the risk of tipping over? (9.1)
Participant: Yes
Do you think the content of the canister and fluid tube are visible during use (to be able to detect any signs of infection)? (9.3)
Participant: Yes
What kind of situation needs an alarm?
Telling how the alarm works, do you think that is a good system? What would you improve?
Participant: alarm when something is wrong with the device, when the canister is full. Also sound for the pressure alarm.

(10) Cleaning

How is the cleaning of such devices done in your hospital?

Participant: cannister, and all components sterilization because within patients. Steralization with lysol (or Midas could be possible) solution overnight and use the autoclave next morning.
Do you think all external parts of the device are suitable for cleaning with disinfectant? (10.1)
Do you think the canister and connectors are suitable for sterilization (autoclaving)? (10.2)

(12) Reliability
Do you think the number of components is reduced as much as possible? (12.1)
Participant: Yes

(13) Availability
How would you change the tubes and filters?
Participant: Reuse canisters within patients if you can clean it.
Do you think that is easy?
Participant: Yes, with training.
Do you think it is needed to have a detachable tube from the pump to the canister?
Participant: No, I would only replace it if it is broken.
Should the canister be on the ground because of hard handling?
Canister was already on ground in this design

(14) Repairability
Do you think the device can be (dis)assembled with local skills and tools? (14.1)
Participant: Yes
Do you think the individual parts can be removed and replaced? (14.2)
Participant: Yes

(15) Maintenance
Do you think the device is low-maintenance? (15.1)

In what sort of use cases do you think you would use the device? (inside the hospital, for people to take it home?)
- Where would you use the device? Are there other requirements for that as well?

Participant: only in hospital

Do you think the device can withstand rough handling (shocks and small impact) (16.2)
- What sort of handling would you think can happen to the device?

Participant: it should be handled with care

How would you make the device more robust? (to expand the lifespan of the device)
- total lifespan of the device (including small repairs) is at least 3-5 years (16.3)

<u>Performance of the WOCA</u>
<u>Questions to rate on scale of 1-5</u>
1. Noise
   Do you think the noise would disturb the patient/medical staff? (1 no disturbance, 5 a lot of disturbance)
   Participant: 3
2. Easy to use

Do you think the device is easy to use for a nurse?
- *No tubes in the way*

Participant: 5
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

Participant: 3
- *Do you think the canister is easy to replace?*

Participant: 5
- *Do you think the amount of fluid is easy to see?*

Participant: 5
- *Do you think the tubes are easy to connect/deasamble?*

Participant: 5
- *Do you think the amount of pressure is easy to set?*
- *Do you think the device is simple to use?*

Participant: 5

Do you think the device is easy to use for a patient?
- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

Do you think the device is easy to use for a caregiver?
- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

3. Alarming system

   Do you think the safety alarm for overflow is adequate?

   Participant: Yes, sound would be nice as well

   Do you think the safety alarm for not accurate pressure is adequate?

   Participant: 3

   Do you think the safety stop for -200 mmHg is adequate?
4. Portable

   Do you think the device is portable for the patient?

   Do you think the device can be used outside?

   Participant: 5
5. Design

   Do you think the device looks nice?

   Participant: 5

   Do you think the device looks professional?

   Participant: 5

   Do you think the WOCA is simple to use?

   Participant: 5

   Do you think the WOCA has components which can be deleted?
6. Replacement

   Do you think the device is easy to repair when broken?

   Participant: 3

   Do you think the components are easy to assemble/disassemble?

Last questions:

Does the WOCA meet your requirements/expectations for a VAC system in your hospital/context? Why yes/no?

Participant: Yes

D.1.3. Summary Validation Participant 3+4

Years of experience:
Used turtle VAC for the last year, both participants have some experience with this. Participant 1 has 16 years of experience with working in the hospital in Nepal, participant 2 has 6 years of experience working in the hospital in Nepal.

Points of attention:

- Lack of material for making the dressing, would be nice if all types of tubes fit with the device
- Concerns about the availability for the material needed for the VAC system (dressing and foam)
- Carrying device by using an iron trolly is preferred, this would make a lot of extra noise

(6) Usability

Give the device and don't tell how to use it. Let them tell you how they think it should be used.

Do they have feedback/any thoughts? How do they think it works, what are the buttons for?

Explain how the device is used

Do you think the device is easy to operate by medical staff with minimal training (6.1)

Participants: Yes

Do you think the device is easy to monitor by patients and caregivers with basic instructions (6.2)

Participants: Yes

How would you use the lid? Do you think it is a 'one-way use'. (extra)

Participants: Yes

(7)Portability

Do you think the canister is firmly attached to the device, while it can be easily removed for emptying? (7.2)

Participants: Yes

Do you think the device can be carried by patients with mobility problems? (user/expert) (7.6)

Participants: Something extra needed (trolly) for people in a wheelchair.

Do you have other ideas for portability of the device?

Participants: Using a trolly to carry the device, would make a lot of noise when putting it on an iron trolly.

It could be an option to use a carrying strip → what would you think of that idea?

(9) Safety

Do you think the device will remain stable on the ground without the risk of tipping over? (9.1)

Do you think the content of the canister and fluid tube are visible during use (to be able to detect any signs of infection)? (9.3)

Participants: Yes

What kind of situation needs an alarm?

Participants: Vacuum not working properly, battery

Telling how the alarm works, do you think that is a good system? What would you improve?
Participants: Yes works good

(10) Cleaning
How is the cleaning of such devices done in your hospital?
Participants: Based on cleaning TurtleVAC; canister with detergent and soap, when shortage of tubing it will be cleaned with.a spray from operation theatre. Same tubes would be used within patients. Canister TurtleVAC is made from glass, would be sun/airdried. The outside would be wiped, and cleaned with detergent (lid of canister).
Do you think all external parts of the device are suitable for cleaning with disinfectant? (10.1)
Participants: Not sure, should test that
Do you think the canister and connectors are suitable for sterilization (autoclaving)? (10.2)
Participants: Also need to test the autoclaving.

(12) Reliability
Do you think the number of components is reduced as much as possible? (12.1)
Participants: Yes

(13) Availability
How would you change the tubes and filters?
Do you think that is easy?
Do you think it is is needed to have a detachable tube from the pump to the canister
*Participants: *Interpreted as both options possible**

(14) Repairability
Do you think the device can be (dis)assembled with local skills and tools? (14.1)
Do you think the individual parts can be removed and replaced? (14.2)
Participants: Yes

(15) Maintenance
Do you think the device is low-maintenance? (15.1)

In what sort of use cases do you think you would use the device? (inside the hospital, for people to take it home?)
- Where would you use the device? Are there other requirements for that as well?

Participants: In the hospital, and take into the community with instruction for family members.

Do you think the device can withstand rough handling (shocks and small impact) (16.2)
- What sort of handling would you think can happen to the device?

Participants: Yes, but addition of a small trolly would be better

How would you make the device more robust? (to expand the lifespan of the device)
- total lifespan of the device (including small repairs) is at least 3-5 years (16.3)

What do you think of the color?
Participants: Color is good.
What do you think of removing the gauge?
Participants: Don't remove it, changing the numbers would be nice.

Performance of the WOCA

Questions to rate on scale of 1-5

1. Noise

   Do you think the noise would disturb the patient/medical staff? (1 no disturbance, 5 a lot of disturbance)

Participants: 2

2. Easy to use

   Do you think the device is easy to use for a nurse?

Participants: 1

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*

Participants: 1

- *No change for accidentally breaking the device?*
- *Do you think the canister is easy to replace?*
- *Do you think the amount of fluid is easy to see?*

Participants: 1

- *Do you think the tubes are easy to connect/deasamble?*

Participants: 1

- *Do you think the amount of pressure is easy to set?*

Participants: 1

- *Do you think the device is simple to use?*

Participants: 1

Do you think the device is easy to use for a patient?

Participants: 2

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

Do you think the device is easy to use for a caregiver?

Participants: 2

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

3. Alarming system

   Do you think the safety alarm for overflow is adequate?

Participants: 2

Do you think the safety alarm for not accurate pressure is adequate?

Participants: 2, extra sound would be nice.

Do you think the safety stop for -200 mmHg is adequate?

Participants: That's good.

4. Portable

   Do you think the device is portable for the patient?

Participants: 1

Do you think the device can be used outside?

Participants: 1

5. Design

   Do you think the device looks nice?

Participants: 1

Do you think the device looks professional?

Participants: 2

Do you think the WOCA is simple to use?

Do you think the WOCA has components which can be deleted?

(asked whether the WOCA has the minimum amount of components)

Participants: 1

6. Replacement

Do you think the device is easy to repair when broken?

Participants: Yes, we would send it to biomedical office

Do you think the components are easy to assemble/disassemble?

Second, comparison with AquaVAC

The WOCA was made to improve, compared to the AquaVAC on the following points. Can you tell, based on your experience, whether or not this is reached? Please also with some comments.

Participants: WOCA can easily remove the canister, and tubes, alarming system, tubes are visible.

Last questions:

Does the WOCA meet your requirements/expectations for a VAC system in your hospital/context? Why yes/no?

Would you use the WOCA in your hospital? And would you prefer the WOCA over the AquaVAC?

Participants: Yes, if we have availability for the necessary materials (dressing and foam).

D.1.4. Summary Validation Participant 5+6

During this interview I gave the device without gauge, to see whether or not they like it with or without.
A Nepali Biomedical Engineer colleague was there as well during the interview. Who sometimes helped with translating, and helping with understanding for both me and the participants.

Years of experience: 33 Nepali context Participant 2, new one participant 1
Experience turtle VAC few times used (2 times a year or so)
Experience with TurtleVAC, a lot of years experience in healthcare Nepalese context.

Points for attention:

- *Canister is too small*
- *Bigger tubes needed*
- *Use a hook to carry the device, also on the wheelchair*
- *Detachable tube from motor to canister so that you can easily put on again when patient accidentally loses it*

(6) Usability
Give the device and don't tell how to use it. Let them tell you how they think it should be used.
Do they have feedback/any thoughts? How do they think it works, what are the buttons for?

Explain how the device is used
Do you think the device is easy to operate by medical staff with minimal training (6.1)
Yes, with some training
Do you think the device is easy to monitor by patients and caregivers with basic instructions (6.2)
Yes, with some training
How would you use the lid? Do you think it is a 'one-way use'. (extra)
Yes

(7)Portability
Do you think the canister is firmly attached to the device, while it can be easily removed for emptying? (7.2)
Yes
Do you think the device can be carried by patients with mobility problems? (user/expert) (7.6)
Yes
Do you have other ideas for portability of the device?
It could be an option to use a carrying strip → what would you think of that idea?
Carry the device on a trolly, using a clamp or big tubes to make it more portable for the patient.

(9) Safety
Do you think the device will remain stable on the ground without the risk of tipping over? (9.1)
Yes, but should be handled with care.

Do you think the content of the canister and fluid tube are visible during use (to be able to detect any signs of infection)? (9.3)
Yes.
What kind of situation needs an alarm?
Telling how the alarm works, do you think that is a good system? What would you improve?
Good, alarm when canister is full, when there is an infection.
Extra question: would you prefer an alarm for low battery?
Yes

(10) Cleaning
How is the cleaning of such devices done in your hospital?
Participant: tubes with running water, and then use Sablon or Spiridon. Canister can be cleaned as well like that. Small tubes are harder to clean.
Do you think all external parts of the device are suitable for cleaning with disinfectant? (10.1)
Do you think the canister and connectors are suitable for sterilization (autoclaving)? (10.2)

(12) Reliability
Do you think the number of components is reduced as much as possible? (12.1)
Participant: Yes

(13) Availability
How would you change the tubes and filters?
Do you think that is easy?
Do you think it is is needed to have a detachable tube from the pump to the canister
Participants: Yes, because it can become loose because of handling of patients and visitors.
Should the canister be on the ground because of hard handling?

(14) Repairability
Do you think the device can be (dis)assembled with local skills and tools? (14.1)
Participant: Would give the device to the biomedical office when having technical difficulties.
Do you think the individual parts can be removed and replaced? (14.2)

(15) Maintenance
Do you think the device is low-maintenance? (15.1)
Participant: Yes

(16) Lifespan
Other: Can the device withstand transportation on difficult roads? (see on way to Surkhet) (16.1)

In what sort of use cases do you think you would use the device? (inside the hospital, for people to take it home?)

- Where would you use the device? Are there other requirements for that as well?

Participants: only use the device in the hospital

Do you think the device can withstand rough handling (shocks and small impact) (16.2)

- What sort of handling would you think can happen to the device?

How would you make the device more robust? (to expand the lifespan of the device)

- total lifespan of the device (including small repairs) is at least 3-5 years (16.3)

What do you think of the color?
What do you think of removing the gauge?
Participants: we like the gauge, but same scale would be more clear (there was some misunderstanding).

Performance of the WOCA

Questions to rate on scale of 1-5
Other way around (1 really bad, 5 really good)

1. Noise
   Do you think the noise would disturb the patient/medical staff? (1 no disturbance, 5 a lot of disturbance)
   Participants: 4
2. Easy to use
   Do you think the device is easy to use for a nurse?
   Participants: 5
   - *No tubes in the way*
   - *No change for accidentally knocking over the canister?*
   - *No change for accidentally breaking the device?*
   - *Do you think the canister is easy to replace?*
   - *Do you think the amount of fluid is easy to see?*
   - *Do you think the tubes are easy to connect/deasamble?*
   - *Do you think the amount of pressure is easy to set?*
   - *Do you think the device is simple to use?*

   Do you think the device is easy to use for a patient?
   Participants: cannot say now.
   - *No tubes in the way*
   - *No change for accidentally knocking over the canister?*
   - *No change for accidentally breaking the device?*

   Do you think the device is easy to use for a caregiver?
   - *No tubes in the way*
   - *No change for accidentally knocking over the canister?*
   - *No change for accidentally breaking the device?*
3. Alarming system (1 not too good, 5 very good)
   Do you think the safety alarm for overflow is adequate?
   Participants: 4, alarm you need
   Do you think the safety alarm for not accurate pressure is adequate?
   Participants: 5
   Do you think the safety stop for -200 mmHg is adequate?
4. Portable
   Do you think the device is portable for the patient?
   Participants: 5
   Do you think the device can be used outside?
   Participants: 5
5. Design
   Do you think the device looks nice?

Participants: 5, better a light color, blue or green.
Do you think the device looks professional?
Participants: 3
Do you think the WOCA is simple to use?
Participants: 5
Do you think the WOCA has components which can be deleted?

6. Replacement
   Do you think the device is easy to repair when broken?
   Participants: could not understand, but would bring to biomedical when something breaks as I understood correctly.
   Do you think the components are easy to assemble/disassemble?
   Participants: 5

Second, comparison with AquaVAC
The WOCA was made to improve, compared to the AquaVAC on the following points. Can you tell, based on your experience, whether or not this is reached? Please also with some comments.

Participants: Prefer the WOCA, because it needs no electricity, less space, less converters, and it is light. But, a bigger canister would be nice.

Last questions:
Does the WOCA meet your requirements/expectations for a VAC system in your hospital/context? Why yes/no?

Would you use the WOCA in your hospital? And would you prefer the WOCA over the AquaVAC?

D.2. Summaries Additional Participants

D.2.1. Summary Additional Participant 1

Years of experience:
38 years experience in western context with wound care, and palliative care. Has seen people using VAC systems, not applied dressing or used machines his/herself.
Experience of one month working in a Nepalian context, never used the TurtleVAC.

Points for attention
- Warning on the device to not take it near water.
- Alarm should be louder, so that it is still alarming, now it can become white noise.

Performance of WOCA:
(6) Usability
Give the device and don't tell how to use it. Let them tell you how they think it should be used.
Do they have feedback/any thoughts? How do they think it works, what are the buttons for?

Explain how the device is used
Do you think the device is easy to operate by medical staff with minimal training (6.1)
Participant: Yes
Do you think the device is easy to monitor by patients and caregivers with basic instructions (6.2)
Participant: Yes
How would you use the lid? Do you think it is a 'one-way use'. (extra)
Participant: Yes one-way use, color indication might be nice.

(7)Portability
Do you think the canister is firmly attached to the device, while it can be easily removed for emptying? (7.2)
Participant: Yes
Do you think the device can be carried by patients with mobility problems? (user/expert) (7.6)
Participant: Depending on the mobility issue, when in need for a stick it is not possible.
Do you have other ideas for portability of the device?
Participant: Bag or rucksack.
It could be an option to use a carrying strip → what would you think of that idea?

(9) Safety
Do you think the device will remain stable on the ground without the risk of tipping over? (9.1)
Participant: Yes
Do you think the content of the canister and fluid tube are visible during use (to be able to detect any signs of infection)? (9.3)
Participant: Yes
What kind of situation needs an alarm?
Participant: Sound would be nice as well, next to the light. Alarm when the canister is full, the battery is running out. Alarm so that people don't go near water with the device.
Telling how the alarm works, do you think that is a good system? What would you improve?
Participant: alarm for pressure is good.

(10) Cleaning

How is the cleaning of such devices done in your hospital?

Participant: Outside would be cleaned with antiseptic wipes, in Nepal other wipes with probably chlorhexidine water solution. We would change all the tubes, they wouldn't do that here so they will clean it with chlorhexidine or antiseptic type of liquid. Overflowprotection needs redesign to make it easier to clean, would put that in the autoclave, and soap and water.

Do you think all external parts of the device are suitable for cleaning with disinfectant? (10.1)

Do you think the canister and connectors are suitable for sterilization (autoclaving)? (10.2)

(12) Reliability

Do you think the number of components is reduced as much as possible? (12.1)

Participant: Yes

(13) Availability

How would you change the tubes and filters?

Do you think that is easy?

Participant: Yes with a little bit of training.

Do you think it is is needed to have a detachable tube from the pump to the canister

Participant: Would prefer to change the tube within patients, as well as the filter, so yes.

Should the canister be on the ground because of hard handling?

Participant: Yes, keep it close to each other.

(14) Repairability

Do you think the device can be (dis)assembled with local skills and tools? (14.1)

Participant: Yes

Do you think the individual parts can be removed and replaced? (14.2)

Participant: Yes

(15) Maintenance

Do you think the device is low-maintenance? (15.1)

Participant: Yes

In what sort of use cases do you think you would use the device? (inside the hospital, for people to take it home?)

- Where would you use the device? Are there other requirements for that as well?

Participant: In the hospital, bathroom, could use it at home probably when the community staff can look after the dressing.

Do you think the device can withstand rough handling (shocks and small impact) (16.2)

- What sort of handling would you think can happen to the device?

Participant: can break because of rough handling, or people would open the box out of curiosity.

How would you make the device more robust? (to expand the lifespan of the device)

Participant: I think the device looks robust

What do you think of the color?

Participant: I think the color is good, bright color gives lower change for tipping over.
What do you think of removing the gauge?
Participant: I like the gauge, extra indicator to see when something is wrong but depending on how much leaking it is causing.

Performance of the WOCA
Questions to rate on scale of 1-5

1. Noise
   Do you think the noise would disturb the patient/medical staff? (1 no disturbance, 5 a lot of disturbance)

Participant: 4

2. Easy to use
   Do you think the device is easy to use for a nurse?

Participant: 1

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*
- *Do you think the canister is easy to replace?*
- *Do you think the amount of fluid is easy to see?*
- *Do you think the tubes are easy to connect/deasamble?*
- *Do you think the amount of pressure is easy to set?*
- *Do you think the device is simple to use?*

Do you think the device is easy to use for a patient?

Participant: 2

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

Do you think the device is easy to use for a caregiver?

Participant: 2

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

3. Alarming system
   Do you think the safety alarm for overflow is adequate?

Participant: 5, it is not an alarm

Do you think the safety alarm for not accurate pressure is adequate?

Participant: 3

Do you think the safety stop for -200 mmHg is adequate?

4. Portable
   Do you think the device is portable for the patient?

Participant: 2

Do you think the device can be used outside?

Participant: 2

5. Design
   Do you think the device looks nice?

Participant: 1

Do you think the device looks professional?

Participant: 2

Do you think the WOCA is simple to use?

Participant: 2

Do you think the WOCA has components which can be deleted?

Participant: 1

6. Replacement

Do you think the device is easy to repair when broken?

Participant: 2

Do you think the components are easy to assemble/disassemble?

Participant: 2

Second, comparison with Western VAC systems

How do you see the WOCA compared to Western used VAC systems?

Participant: I feel like I have not enough expertise to answer that.

Last questions:

Does the WOCA meet your requirements/expectations for a VAC system in your hospital/context? Why yes/no?

Participant: Yes, I would use the WOCA.

D.2.2. Summary Additional Participant 2

Years of experience:
Worked in Western context with VAC devices, did volunteering in India and just arrived in Nepal. Not a lot of experience with working in healthcare within Nepal or India. Never worked with the TurtleVAC.

Points for attention:
- *Protocol for safely emptying the canister.*
- *Replaceable battery would be nice*

(6) Usability
Give the device and don't tell how to use it. Let them tell you how they think it should be used.
Do they have feedback/any thoughts? How do they think it works, what are the buttons for?

Explain how the device is used
Do you think the device is easy to operate by medical staff with minimal training (6.1)
Participant: Yes
Do you think the device is easy to monitor by patients and caregivers with basic instructions (6.2)
Participant: Yes
How would you use the lid? Do you think it is a 'one-way use'. (extra)
Participant: Yes, color coding would be nice.

(7)Portability
Do you think the canister is firmly attached to the device, while it can be easily removed for emptying? (7.2)
Participant: Easy to knock canister out of holder
Do you think the device can be carried by patients with mobility problems? (user/expert) (7.6)
Participant: Yes, when attaching a strap.
Do you have other ideas for portability of the device?
Participant: Make something to hang it on a wheelchair or walker.
It could be an option to use a carrying strip → what would you think of that idea?

(9) Safety
Do you think the device will remain stable on the ground without the risk of tipping over? (9.1)
Participant: Can tip over.
Do you think the content of the canister and fluid tube are visible during use (to be able to detect any signs of infection)? (9.3)
Participant: Yes
What kind of situation needs an alarm?
Participant: Running out of battery, incorrect amount of pressure, disconnect of suction, bacteria filter full.
Telling how the alarm works, do you think that is a good system? What would you improve?
Participant: Blinking lights and sound.

(10) Cleaning

How is the cleaning of such devices done in your hospital?

Participant: Nepal hospital: Outside with wipes and disinfectant. Autoclave the canister. Wipe the tube from the motor, and filter both soak it with disinfection solution and, autoclave it. In Western context would replace everything after 1 time use.

Do you think all external parts of the device are suitable for cleaning with disinfectant? (10.1)

Do you think the canister and connectors are suitable for sterilization (autoclaving)? (10.2)

(12) Reliability

Do you think the number of components is reduced as much as possible? (12.1)

Participant: Would be nice if parts of overflowprotection could be reduced.

(13) Availability

How would you change the tubes and filters?

Do you think that is easy?

Participant: Yes

Do you think it is is needed to have a detachable tube from the pump to the canister

Participant: Would prefer it myself, but don't think it would be used in Nepalese context for cleaning. Don't think it is necessary.

Should the canister be on the ground because of hard handling?

Participant: Yes

(14) Repairability

Do you think the device can be (dis)assembled with local skills and tools? (14.1)

Participant: Yes

Do you think the individual parts can be removed and replaced? (14.2)

Participant: I don't have enough knowledge to answer.

(15) Maintenance

Do you think the device is low-maintenance? (15.1)

Participant: Yes, when having a replaceable battery

In what sort of use cases do you think you would use the device? (inside the hospital, for people to take it home?)

- Where would you use the device? Are there other requirements for that as well?

Do you think the device can withstand rough handling (shocks and small impact) (16.2)

- What sort of handling would you think can happen to the device?

What do you think of the color?

Participant: Maybe more subtle, grey or blue.

What do you think of removing the gauge?

Participant: I don't like that they have different measurements, so I would remove it.

<u>Performance of the WOCA</u>

<u>Questions to rate on scale of 1-5</u>

1. Noise

Do you think the noise would disturb the patient/medical staff? (1 no disturbance, 5 a lot of disturbance)

Participant: 3

2. Easy to use

Participant: 4.5 - 5

Do you think the device is easy to use for a nurse?

- *No tubes in the way*

Participant: 4

- *No change for accidentally knocking over the canister?*

Participant: 1

- *No change for accidentally breaking the device?*

Participant: 3 - 4: Change for breaking device is low, but you could disconnect the tubings.

- *Do you think the canister is easy to replace?*

Participant: 5

- *Do you think the amount of fluid is easy to see?*

Participant: 5

- *Do you think the tubes are easy to connect/deasamble?*

Participant: 5

- *Do you think the amount of pressure is easy to set?*

Participant: 5

- *Do you think the device is simple to use?*

Do you think the device is easy to use for patients and caregivers?

Participant: 4

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

Do you think the device is easy to use for a caregiver?

- *No tubes in the way*
- *No change for accidentally knocking over the canister?*
- *No change for accidentally breaking the device?*

3. Alarming system

Do you think the safety alarm for overflow is adequate?

Participant: No, a sound would be nice as well. 1

Do you think the safety alarm for not accurate pressure is adequate?

Participant: 2

Do you think the safety stop for -200 mmHg is adequate?

4. Portable

Do you think the device is portable for the patient?

Participant: 4

Do you think the device can be used outside?

Participant: 4

5. Design

Do you think the device looks nice?

Participant: 4

Do you think the device looks professional?

Participant: just change the color

Do you think the WOCA is simple to use?

Participant: can't answer that

Do you think the WOCA has components which can be deleted?

6. Replacement

   Do you think the device is easy to repair when broken?

Participant: 5

Do you think the components are easy to assemble/disassemble?

Last questions:
Does the WOCA meet your requirements/expectations for a VAC system in your hospital/context? Why yes/no?

Would you use the WOCA in your hospital?
Participant: If I would be able to buy good materials for the dressing, and depending on the costs.

E

Appendix ISO norm verification

This document supplements the work of J. van den Boom. It provides a brief analysis of the ISO criteria and explains their compliance with the WOCA.

	Applicability	Relevance	Action	Complies?	Notes
6 Design Requirements					
6.1 General					
6.1.1 Suction equipment classified as medical electrical equipment, as defined in 3.63 of IEC 60601-1:2005+AMD1:2012 +AMD2:2020 shall meet the relevant requirements of IEC 60601-1.	Maybe	High		Includes technical file	
6.1.2 Suction equipment intended to be dismantled by the user (e.g. for cleaning) shall be designed to facilitate correct assembly or marked to indicate correct reassembly	Yes	High		Includes technical file	
6.1.3 Suction equipment shall meet the requirements of Clause 7, as appropriate, after dismantling and reassembly in accordance with the manufacturer's instructions.	Yes	High		Includes technical file	
6.1.4 Suction equipment shall be designed to be operated by one person, unaided.	Yes	Middle		Yes	Designed for operation of 1 nurse
6.1.5 Means shall be provided to prevent foam passing from the collection container into the vaccum source	Yes	Middle		Yes	Bacterial philter
6.2 Collection containers					
6.2.1 Capacity					
Collection containers shall clearly show the level of contents and have a usable volume of ≥ 500 ml	Yes	Middle		Yes	Visible on canister
6.2.2 Strength					
Collection containers shall not implode, crack or permanently deform and shall meet the requirements of Clause 7, as appropriate, after being subjected to a pressure of either 120 % of the manufacturer's recommended maximum vacuum level or 95 kPa below atmospheric, whichever is the stronger vacuum level, for 5 min.	Maybe	Middle		Yes	Canister not damaged after maximum test
Reusable collection containers shall be tested after 30 cycles of cleanig and disinfection or sterilization as recommended by the manufacturer (See 9.4g)	Yes	Middle		No	Plastic container is probably not suitable for this, therefore better to implement the glass canister
6.3 Connections					
6.3.1 Tubing connectors					
Connectors for suction tubing and intermediate tubing shall be designed to facilitate correct assembly when all parts are mated and have an inside diameter equal to or larger than the inside diameter of the largest suction tubing or intermediate tubing size specified by the manufacturer (see 9.4 n)	Yes	High		Yes	Tubings and connection pieces are well aligned, no blockages or restrictions
6.3.2 Collection container inlet ports					
Collection container inlet ports shall not be compatible with any of the conical connectors specified in ISO 5356-1 or any of the smallbore connectors specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6, ISO 80369-7	Yes	Middle		Yes	There is not detachble tube from WOCA to canister, so the tubes won't be compatible
Collection container inlet ports shall have an inside diameter ≥ 6 mm	Yes	Low		Yes	
6.3.3 Collection container exhaust ports					
It shall not be possible to connect suction tubing to the collection container exhaust ports.	Yes	High		Yes	One-way fit for the canister lid
6.4 Suction tubing and intermediate tubing					
6.4.1 suction tubing and intermediate tubing shall have:					
an inside diamter ≥ 6mm	No	Low		No	Connections can be made with dressing tubes of >6 mm diameter, tubes used in WOCA device do not have this diameter. In the Netherlands it is tested with a tube towards dressing of 6 mm diameter.
a degree of collapse ≤ 0.5 throughout its entire length	No	Middle		No	Tubes are chosen not to be changed
6.4.2 Suction tubing shall have					
a length of ≥ 1.3 m	Yes	Middle		Yes	Tubes of every length can be connected to the device
6.4.3					
Suction tubing and connectors, in their ready-to-use state after any preparation for use recommended by the manufacturer, shall be evaluated for biological safety according to ISO 10993-1.	Yes	Middle		Includes technical file	
6.4.4					
Suction tubing and intermediate tubing shall be made of materials suitable for their intended use and the environmental conditions that they can be subjected to during transport, storage or when in use (see 8.4).	Yes	Middle		Includes technical file	
6.4.5					
Suction tubing shall be manufactured to reduce, to a minimum, the risks posed by substances leaching from the materials	Yes	Middle		Includes technical file	
~~*6.4.6*~~					
Manufacturers of suction tubing intended for the treatment of children or pregnant or nursing women and made of materials that incorporate phthalates, which are classified as carcinogenic, mutagenic or toxic to reproduction, shall provide a specific justification for the use of these substances in their risk management file. [See also 9.3 h) for additional marking and instructions for use requirements].					
6.5 Vacuum level indicators					
6.5.1					
Suction equipment with an operator-adjustable vacuum regulator shall indicate the vacuum level at the inlet side of the vacuum regulator (see Figure C.1).	Yes	High		Yes	Includes an gauge
6.5.2					
The full scale of analogue vacuum level indicators shall be ≤ 200 % of the maximum vacuum level specified by the manufacturer (see 9.3 l).	Yes	Low		Yes	Gauge shows 200% of maximum vacuum level
6.5.3					
Analog displays shall have graduations ≥ 2 mm apart with each graduation representing ≤ 5 % of the full-scale value.	Yes	Low		Yes	Gauge complies
~~*6.5.4*~~					
Digital displays shall indicate the vacuum level at intervals ≤ 5 % of the full-scale value.					
6.5.5					
Movement of rotary analogue vacuum level indicators should be anti-clockwise for an increase in vacuum level.	Yes	High		Yes	Gauge complies
~~*6.5.6*~~					

Vacuum level indicators on suction equipment intended for thoracic drainage shall be accurate to within ± 5 % of the full-scale value in the middle three-fifths of the operating range.					
6.5.7					
Vacuum level indicators, except as specified in 6.5.6, shall be accurate to within +- 5% of the fullscale value	Yes	Middle		Unknown	Gauge is not measured for it's accuracy. As the added value gauge was under discussion there was no priority in testing its performance.
6.5.8					
Vacuum level indicators, on low vaccum suction equipment, shall be fitted between the vaccum source and the collection container	Yes	Middle		Yes	Complies
6.6 Environmental conditions for transport and storage					
6.6.1					
The manufacturer shall specify, in the instructions for use, the environmental conditions that the suction equipment can withstand whilst in its protective transport packaging without affecting its performance when operated at ambient conditions [see 9.4 jj).	Yes	Middle		No	Should be included in detailed manual
6.6.2					
If the instructions for use state a more restricted range of environmental conditions of transport and storage than those specified in 6.6.3, they shall be justified in the risk management file.	No				
6.6.3 Unless otherwise indicated in the instructions for use, suction equipment, suction tubing and intermediate tubing shall withstand, whilst in their protective transport packaging, the following environmental conditions.					
Temperatures from – 40 °C to + 70 °C	Yes	Middle		Unknown	Testing in such situation is not considered feasible within project
Relative humidity from 15 % to 90 % non-condensing	Yes	Middle		Unknown	Testing in such situation is not considered feasible within project
Atmospheric pressures from 620 hPa to 1060 hPa.	Yes	Middle		Unknown	Testing in such situation is not considered feasible within project
7 Performance requirements					
7.1 Operating position					
Suction equipment shall operate, within the manufacturer's specifications, when in its normal operating position and placed on a sloping surface (10 ± 1)° from the horizontal.	Yes	Middle		Yes	Device (including overflow protection) is tested at a sloping surface
7.2 Protection devices					
7.2.1 Contamination protection					
Means shall be provided to prevent contamination of the vacuum source (e.g. a microbial filter).	Yes	Middle		Yes	Bacterial filter
7.2.2 Overfill protection devices					
7.2.2.1 Overfill protection devices shall not activate at least 90% of the indicated maximum capacity of the collection container has been reached	Yes	Middle		Yes	Tested in additional overflow tests
7.2.2.2 When an overfill protection device is activated, suction shall cease and prevent >5ml of fluid from passing downstream of the overfill protection device within 2 min.	Yes	Middle		Yes	Tested in additonal overflow tests
7.2.3 Pressure protection					
7.2.3.1 Negative pressure protection					
If a means to limit the maximum vacuum level is fitted the vacuum shall not exceed the maximum vacuum level by more than 10 %.	Yes	High		Yes	Tested with the verification of the design requirements for pressure regulation within 10%
~~*7.2.3.2 Positive pressure protection*~~					
Thoracic drainage suction equipment shall not develop a positive pressure of more than 1 kPa at the patient inlet with a free air flow of 10 l/min.					
7.2.3.3 Protection against reverse flow					
Means shall be provided which prevents fluid flowing back to the patient due to the pressure differential between the equipment and the patient	Yes	High		Yes	By putting the canister in the canister holder fluid will not flow back to patient, can be added to manual to put canister on the ground when patient lies in bed. This will be recommended to add to the manual instructions.
7.3 Noise					
The maximum A-weighted sound pressure level (steady or peak value) shall;					
for low vacuum/low flow and thoracic drainage suction equipment be <60 dB (A)	Yes	Low		Yes	Tested in noise test
for all other suction equipment, be <70 dB (A)	No	Low			
7.4 Air leakage					
Leakage into the collection container assembly shall:					
for general use suction equipemtn, be <1 kPa pressure drop	Yes	High		Yes	Tested in flow/pressure test
for thoracic drainage suction equipment, be <4 ml/min flow					
7.5 Vacuum levels and free air flows					
Suction equipment shall develop the vacuum level and free air flow within the time limits given in Table 1, for the equipment's stated category, at the maximum indicated vacuum level setting.	Yes	Middle			
7.6 Accuracy					
7.6.1					
The accuracy of the cycling frequency of intermittent vacuum equipment shall be within ± 10 % of the specified fixed frequency ([see 9.3 pj) or the mid-range setting, if adjustable.	Yes			Yes	Tested in pressure test
7.6.2					
The accuracy of the vacuum levels shall be within ± 10 % of the set or fixed vacuum level at zero flow.	Yes			Yes	Tested in pressure test
~~***7.7 Pharyngeal suction equipment***~~					
Suction equipment intended for pharyngeal suction shall evacuate ≥ 200 ml of simulated vomitus in not more than 10 s.					
8 Additional/alternative requirements for suction equipment, suction tubing and intermediate tubing designed for field use or transport use					
8.1 Physical requirements					
8.1.1					
Suction equipment intended for field use or transport use, including any carrying case or frame, shall pass through a (600 × 300) mm opening.	Yes	High		Yes	Complies
8.1.2					

Suction equipment intended for field use or transport use, complete with its carrying case or frame and accessories, shall not exceed a mass of 6 kg	Yes	High		Yes	Complies
8.2 Strength					
8.2.1					
Suction equipment intended for field use or transport use shall meet the requirements of Clause 7 after being dropped from a height of 1 m onto a concrete floor in the worst-case orientation.	Yes	Low		No	Chosen not to be tested
8.2.2					
If the suction equipment is designed to be operated outside of its carrying case, it shall comply with 8.2.1 without its carrying case	No				
8.3 Stability					
Foot-operated suction equipment intended for field use or transport use shall meet the requirements given in Clause 7 as appropriate when placed on a surface 20° ± 2 ° from the horizontal	No				
8.4 Environmental conditions during operation					
8.4.1					
The manufacturer shall specify in the instructions for use the environmental conditions under which the suction equipment, suction tubing and intermediate tubing can operate within its specifications (see 9.4 i)).	Yes				Should be included in manual
8.4.2					
If the instructions for use state a more restricted range of environmental operating conditions than those specified in 8.4.3, they shall be justifed in the risk management file	Yes				Should be included in documentation
8.4.3					
Unless otherwise indicated in the instructions for use, the suction equipment, suction tubing and intermediate tubing shall operate within its specifications whilst being subjected to the following environmental conditions:					
a temperature range of (0 to + 40) °C;	Yes	High		Yes	Environment in which all tests are performed
a relative humidity range of (15 to 90) %, non-condensing, but not requiring a water vapour partial pressure > 50 hPa	Yes	High		Yes	Environment in which all tests are performed
an atmospheric pressure range of 620 hPa to 1 060 hPa.	Yes	High		Yes	Environment in which all tests are performed
8.5 Collection container capacity					
collection containers for field use or transport use shall:					
have a usable volume ≥ 300 ml if provided with an overfill protection device that stops the flow or	Yes	High		Yes	Canister of 500 mL with overflowprotection at 300 mL
have a usable volume ≥ 200 ml if designed to continue operating when the collection container is full.	No				
9 Information supplied by the manufacturer					
9.1 General					
9.1.1					
Information supplied by the manufacturer shall comply with ISO 20417.	Yes				Should be included in documentation/manual
9.1.2					
Information needed to identify the manufacturer and to use the suction equipment safely shall be set out on the suction equipment itself, or if not applicable, on the case or on the packaging or in the instructions for use or be made available on the manufacturer's website	Yes				Should be included in documentation/manual
9.1.3					
Labels shall be provided in a human readable format and may be supplemented by machine-readable information, such as radio frequency identification (RFID) or bar codes.	Yes				Should be included in documentation/manual
9.1.4					
Instructions for use may be provided to the user in a non-paper format (e.g. electronic format).	Yes				Should be included in documentation/manual
9.1.5					
Markings shall be durable and legible following exposure to typical substances the marking will contact during its intended use and remain legible for the intended duration of use.	Yes				Should be included in documentation/manual
Check conformance by exposing the appropriate marking areas of the product to the applicable substances listed for a cumulative duration of time equivalent to the expected exposure duration in use:	Yes				Should be included in documentation/manual
drugs or chemicals which will contact the product in use and are listed in the instruction for use (IFU);	Yes				Should be included in documentation/manual
artificial saliva					
artificial mucus					
if applicable, artificial skin oil					
any other substances identified through the risk management process.					
9.2 Symbols					
Where appropriate information shall take the form of symbols complying with ISO 7000 and EN 15986	Yes				Should be included in documentation/manual
9.3 Marking					
The following information shall be marked either on the suction equipment, the case or the appropriate part:					
a) the name or trade name and address of the manufacturer and, in addition, the name and address of the authorized representative;	Yes				Should be included in documentation/manual
b) details necessary for the user to identify the device and the contents of the packaging;	Yes				Should be included in documentation/manual
c) the word "sterile," if applicable, or the appropriate symbol;					Not applicable/feasible in nepalian context, but can be taken into account by developing extensive cleanibility protocol
d) the batch code preceded by the word "LOT" or serial number or the appropriate symbol;					
e) an indication of the date by which the device or parts thereof can be used in safety, expressed as the year and month;					Not applicable/feasible in nepalian context, but can be taken into account by developing extensive cleanibility protocol
f) if applicable, an indication that the suction equipment or parts thereof are for single use or the appropriate symbol. The manufacturer's indication of single use shall be consistent;					Not applicable/feasible in nepalian context, but can be taken into account by developing extensive cleanibility protocol

g) if applicable, a warning to the effect that the suction equipment contains components made from natural rubber latex or the appropriate symbol (see also 5.1);					Has no priority in Nepalian context
h) if applicable, a warning to the effect that the suction tubing contains phthalates or the appropriate symbol (see 6.4.6);					Has no priority in Nepalian context
i) accessible exhaust ports marked with the word "exhaust" or the appropriate symbol;	No				One way fit of lid is used
j) inlet ports marked with the word "inlet" or the appropriate symbol;	No				One way fit of lid is used
k) the usable volume of the collection container, expressed in millilitres and graduations at 50 ml to 250 ml intervals;	Yes	Low		Yes	Is within design of the canister
l) the maximum vacuum level for which the equipment is designed expressed as the occluded (no-flow) value in kPa;					Pressure scale to set pressure does not exceed -125 mmHg
m) the direction of adjustment to increase the vacuum level;					Marked by use of numbers
n) the performance category (e.g. "high vacuum/high flow", "medium vacuum", "low vacuum/high flow", "low vacuum/low flow", "intermittent vacuum", "pharyngeal suction" or "thoracic drainage" as appropriate), or, alternatively the range of vacuum levels and free air flows. This marking shall be visible from the normal operating position;					Could be a nice addition
o) the mode e.g. (continuous or intermittent vacuum) on suction equipment that can provide both modes;	No				
p) the cycling frequency (if fixed) or range (if adjustable) for intermittent vacuum equipment.	No				
9.4 Instructions for use					
Manufacturers shall provide instructions for use and include the following information:					Could be taken into account when designing executive manual
a) the name or trade name and address of the manufacturer and, in addition, the name and address of the authorized representative;					
b) the intended purpose of the device, if not obvious;					
c) a warning that the suction equipment should only be used by persons who have received adequate instructions in its use;					
d) instructions on how to make the suction equipment operational in all intended modes of operation and any limitations on the use of the equipment;					
e) the function test(s) to be performed by the user prior to use;					
f) guidance on performance as either: 1) the performance category (e.g. medical suction, high vacuum, high flow), or 2) the vacuum levels and free air flows obstainable.					
g) the recommended methods for cleaning and disinfection or sterilization of all reusable parts and an estimated life in terms of use cycles, if applicable (see 5.2);					
h) instructions for the dismantling and reassembly of components if applicable (see 6.1.2) including an illustration of the component parts in their correct relationship;					
i) instructions on the test procedure to be carried out after dismantling and reassembly of the equipment;					
j) the environmental conditions that the suction equipment can withstand during transport and storage whilst in its protective transport packaging;					
k) if the suction equipment is intended for field use or transport use, the environmental conditions under which it can be stored or transported between uses (i.e. when out of its protective transport packaging);					
l) if the suction equipment is intended for field use or transport use, the environmental conditions under which it can be operated within its performance specifications;					
m) any special storage and/or operating conditions;					
n) size and type of suction tubing and connection to the collection container including any maximum length, if applicable;					
o) disclosure if the suction tubing contains phthalates which are carcinogenic, mutagenic or toxic to reproduction (see 6.4.5 and 6.4.6);					
p) useable volume of the collection container;					
q) details of the operation of any overfill protection device fitted to the collection container assembly and the usable capacity of the collection container in all the recommended inclined planes of operation;					
r) if applicable, a statement to the effect that suction ceases when the overfill protection device operates and the method of correcting this situation;					
s) method of emptying the collection container and operation after overflow has occurred;					
t) a statement advising removal and servicing of the suction equipment if liquids or solids have been drawn into the vacuum pump;					
u) the method of controlling frothing in the collection container, if applicable;					
v) instructions for operating the vacuum regulator, if supplied, and for setting the required vacuum level;					
w) the recommended vacuum source for the vacuum regulator;					
x) disclosure of any components containing natural rubber latex;					
y) fault-finding and correction procedures;					
z) recommendations for maintenance including a recommendation for frequency of approved or factory service;					
aa) a list of parts, including part numbers, that can be replaced by the user;					
bb) whether or not the suction equipment is suitable for use in an MRI environment;					
cc) any warnings and/or precautions to take					
dd) the date of publication or revision of the instructions for use or the version number.					