WOCA: A low-cost device for
Negative Pressure Wound Therapy
in low and middle-income countries

APPENDICES

TABLE OF CONTENT

Appendix A: Project brief

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: Raaijmakers
initials: E.R.L. given name: Eileen
student number: 4308778
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): IPD / DfI / SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: Honours Programme Master
specialisation / annotation: Medisign / Tech. in Sustainable Design / Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: J.C. Diehl dept. / section: DfS
** mentor: A. Albayrak dept. / section: AED
2nd mentor: A. Knulst
organisation: GP Hospital & TU Delft (3mE)
city: Pokhara country: Nepal

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

Vacuum Assisted Wound Closure for Low Middle Income Countries

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 14 - 12 - 2020

28 - 05 - 2020 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Vacuum Assisted Closure (VAC)

Vacuum Assisted Closure (VAC) or Negative Pressure Wound Therapy (NPWT) is an alternative method of wound management, often used for difficult or non-healing wounds (Agarwal, Kukrele, & Sharma, 2019). During VAC therapy, the wound is sealed from the environment and a negative pressure of 125 mmHg is applied at the wound bed, using a vacuum dressing connected to a suction pump (see figure 1). The dressing can stay for 2-3 days before it needs to be changed, usually improvement is visible after 5 days. This relatively new technique was first proposed by Argenta and Morykwas in 1997 and has proven its effectiveness in various large studies in the past decades (Argenta & Morykwas, 1997). Positive effects of VAC therapy include stabilization of the wound environment, reduction of wound edema, reduction of bacterial load, improved tissue perfusion and angiogenesis (Agarwal et al., 2019). Wounds treated with VAC often heal faster, need less change of bandages and less revision surgery to clean the wound debridement. In the long term, VAC treatment can be more economical compared to conventional wound dressing (Agarwal et al., 2019). Non-healing or chronic wounds, such as (pressure) ulcers caused by leprosy or amputation can usually be treated well with VAC. In developing countries these types of wounds are common and lead to severe disabilities without adequate treatment. Considering the increased risk of infection and low accessibility to healthcare, there is an urgent need for faster and cheaper wound healing techniques in low-income settings (Yadav, Rawal, & Baxi, 2017).

Green Pastures Hospital (Pokhara, Nepal)

Green Pastures Hospital has been serving people affected by leprosy and disability (often extremely poor) in western Nepal for more than 60 years. This hospital is – together with two smaller hospitals in Surkhet and Banke - ruled by a Cristian NGO called International Nepal Fellowship (INF). GP hospital has 100 beds and a large team of medical professionals, consisting of local and foreign (para)medics. Around 30% of care is delivered for free, half of the hospital budget derives from fundings, mainly overseas (INF Nepal, 2020).

The assignment

The staff of GP Hospital uses a simple aquarium pump that has been adapted to create negative pressure to treat wounds of many patients (see figure 2). Treatment with this 'Turtle VAC' has shown positive results in terms of wound healing but has its limitations, according to the local medical staff. At this moment, GP Hospital has two Turtle VACs that were brought in by a foreign doctor, one is currently broken. Arjan Knulst (biomedical engineer and TU Delft researcher) is founder of this assignment and searches for a better solution.
Other stakeholders include INF Nepal, Suraj (plastic surgeon at GPH), Salome (trains nurses of INF hospitals) Nepalese patients, nurses, other (para)medical staff members, sponsors, Global Initiative and the local government.

Opportunities and limitations

The VAC devices currently on the market are not suitable for the use in LMIC because they are too complex to operate and maintain and rely on consumables that are not locally available. Accordingly, there is a need for an improved VAC system that is durable, reusable, portable, economical, low-power and an interface that is easy-to-use among less-trained populations (Karki et al., 2019). Limitations are related to the low-resource setting and include: Poor availability of (medical) materials and equipment, low financial means, low level of education (patients and staff), issues with hygiene and sterilization, issues related to infrastructure, power supply and connectivity. Due to the COVID-19 pandemic there is no ability to travel to Nepal and all interaction will happen online.

space available for images / figures on next page

introduction (continued): space for images

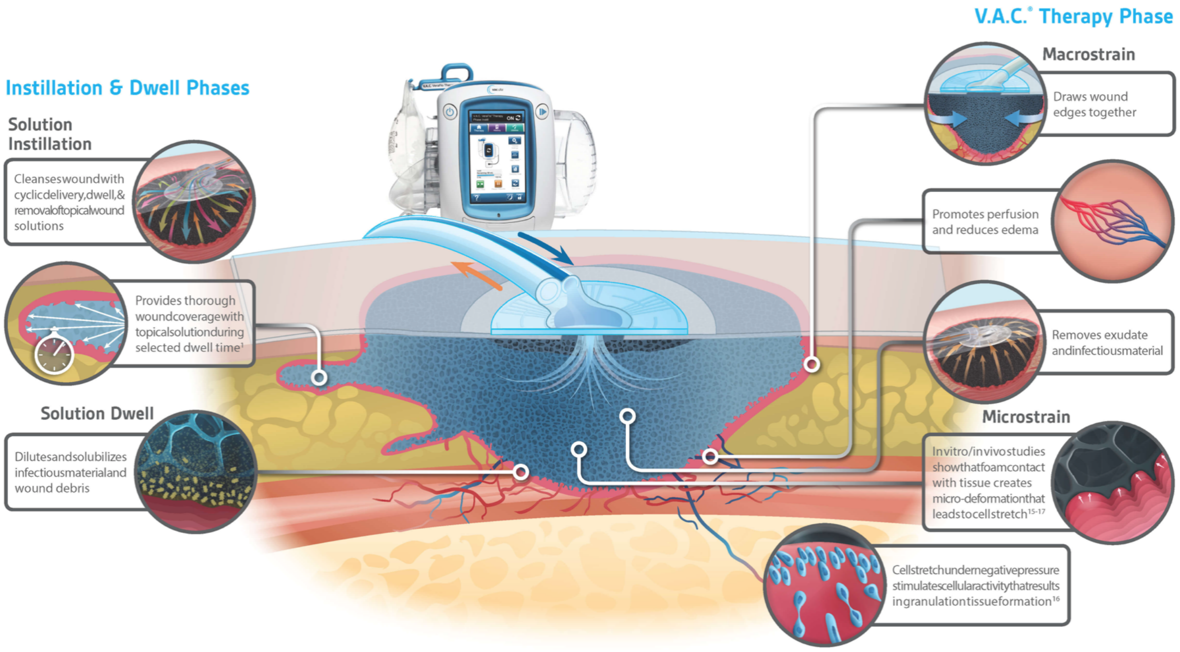


image / figure 1: The principle of Vacuum Assisted Wound Closure explained + a regular (western) VAC device

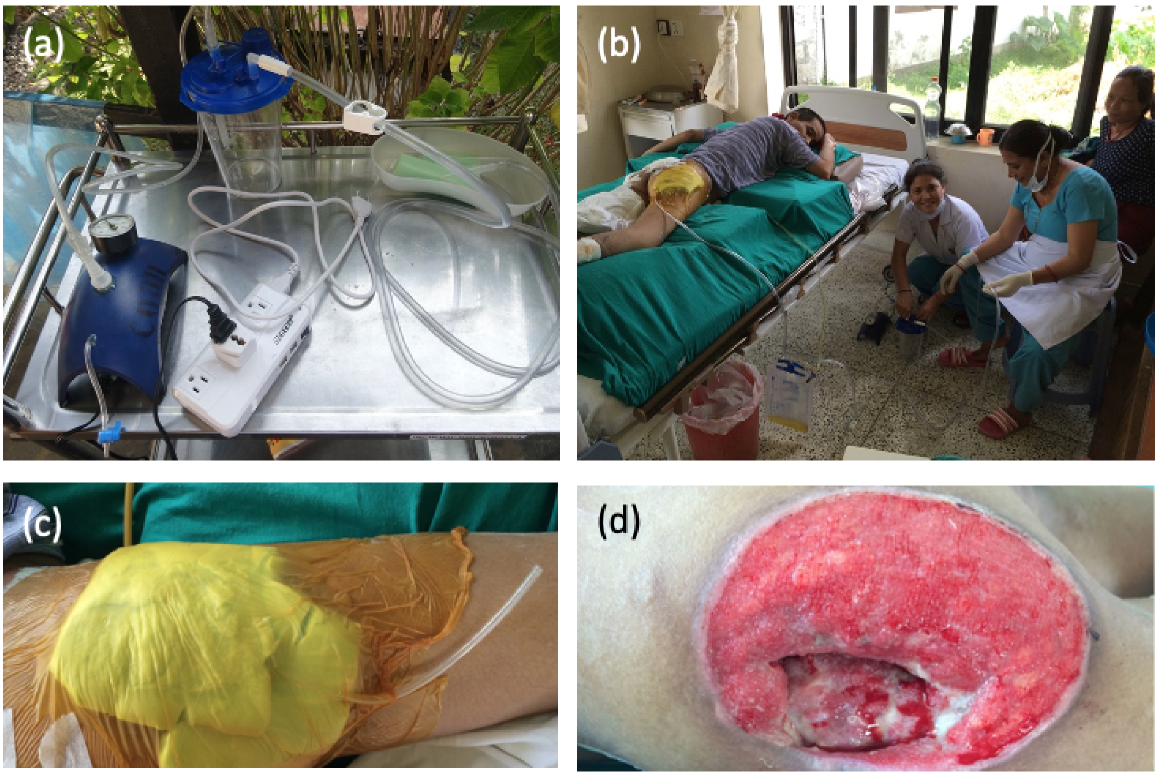


image / figure 2: (a) Turtle VAC system (b) GP hospital patient (c) VAC dressing (d) Result after 5 days of VAC treatment

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

This project will focus on the design of a VAC system, based on the working principle of a converted aquarium pump.
This design should include:
1. Mobile suction unit to generate continuous pressure of -125 mmHg
2. Integrated reservoir to collect fluids
3. Tube system to apply suction on the wound bed
4. Vacuum dressing to seal airtight.

The design should have only essential functions and be focused on use inside the hospital by local staff with limited knowledge about VAC systems.

Existing products (e.g NANOVA™ Therapy system) are not suitable for this context, because these are too expensive, depend on special consumables and cannot be locally repaired. The Turtle VAC has shown to be an effective low-budget alternative but has its limitations. Therefore, the following issues should be addressed in this project:

> Affordability: The price of regular VAC systems on the market does not suit the hospital budget
> Availability & Repairability: The Turtle VAC was brought in and not locally manufactured. Not all parts are locally available (the pump is not), which makes replacement or repair of the device very difficult
> Embodiment: The Turtle VAC makes too much noise and has long cables, which is uncomfortable for the patient. It also affects the mobility of the patient and the dressing often starts leaking
> Interface: The Turtle VAC is too complicated to use, as the Nepali staff is not used to VAC systems
> Sterilization: The foam needs to be sterilized and dry in the sun for 20 min.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

In this project I am going to use the AquaVAC prototype as a working principle and design a new device (incl. suction unit and dressing) that is able to apply negative pressure with the adequate parameters (1), adapted to be used in the local context (2) and build from components that are locally available or can be 3D printed (3).

Main project goal: Final design validated at TRL 5* build from widely available or locally made components and consumables + implementation strategy. Additionally:
- Try out co-creation with stakeholders in Nepal
- Consider training (or manual) needed to operate/repair the device
- Consider lifespan and end-of-life (disposal vs. sterilization)
Batch size: Very small, 10 pieces for the use in GP hospitals and 2 smaller clinics.

The design approach was inspired by 'Roadmap for design for surgical equipment for safe surgery worldwide' and includes four phases:

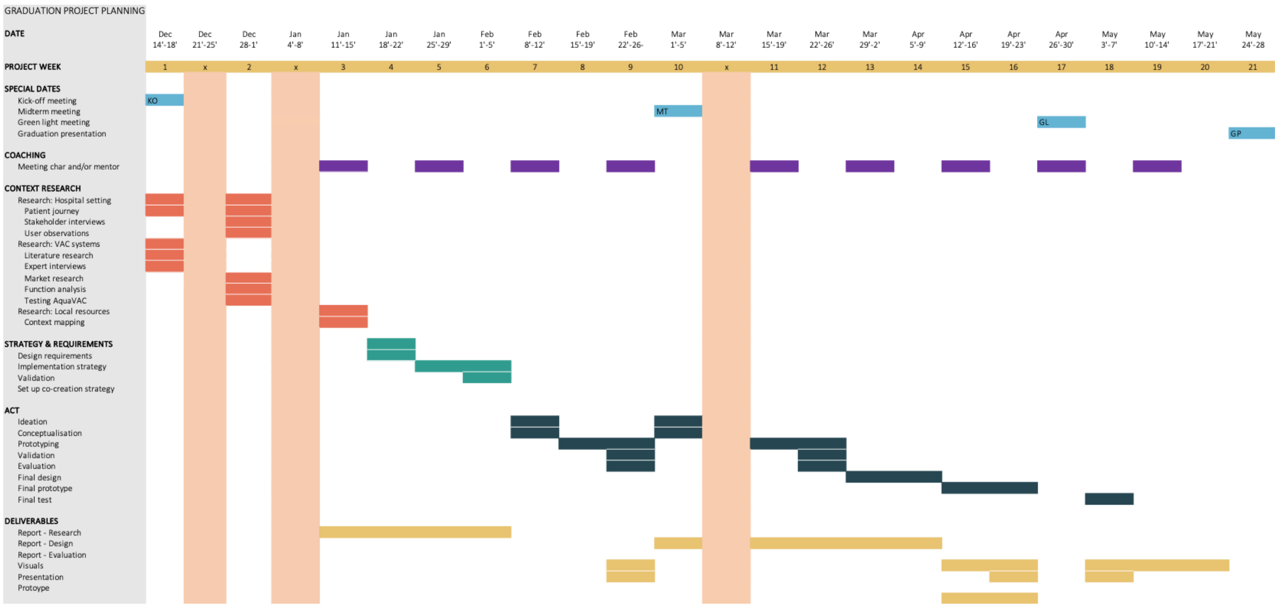
Phase 0: Identify a clear need
Phase 1: Ensure a proper understanding of the context
Phase 2: Determine the implementation strategy and design requirements
Phase 3: Act
Extra: Business case & implementation (*part of annotation, further explained in 'motivation and personal ambition')

*Technology Readiness Level

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 14 - 12 - 2020 28 - 5 - 2020 end date



Phase 1: Ensure a proper understanding of the context (3 weeks)
The research can be divided into three study areas: Hospital setting, VAC systems and Local resources. Each area will be explored, using existing design methods.

Phase 2: Determine the implementation strategy and design requirements (2 weeks)
Results of the previous phase are transformed into easy-to-communicate design requirements and implementation strategy which will be validated with stakeholders in the field.

Phase 3: Act (15 weeks)
Based on all findings, design cycles will take place, following the regular steps: Ideation, conceptualization, prototyping, testing & validation, evaluation. Using the method 'Research through design', aim for short design cycles and multiple iterations based on new findings. Involve stakeholders in the process through (digital) co-creation.

Meetings and coaching
My goal is to meet every two weeks with at least one of my supervisors, these meetings will be planned ahead. The idea is to also have meetings with peers from Global Initiative, probably in the same sequence. With Arjan (client from Nepal) I will try to meet on a less regular basis, approximately every 4 weeks/ before or after a new milestone.

Final deliverables
This will include a thesis report and final presentation, accompanied with a physical prototype and visuals.

Initials & Name E.R.L. Raaijmakers Student number 4308778

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I'm setting up this project because I want to combine the knowledge from my bachelor Clinical Technology and master IPD to contribute to the Sustainable Development Goal of 'Good health and well-being'.

This project includes two annotations:
1. Medisign: Design for the complex medical context, working closely together with healthcare professionals
2. Health Innovation and Entrepreneurship: In an additional chapter of my thesis I will reflect upon the societal/business value of the final solution and describe the next steps needed to commercialize it.

In this project I would like to show that I am able to obtain a clear understanding of a complex medical and intercultural environment and design a low-cost medical device that fits into this context. I will use my previous insights and experiences from projects I did abroad, including the AED project where we designed a centrifuge for low-resource settings. I will use my knowledge about medicine and design when defining and validating design requirements. Lastly, I will use the knowledge (minor) electives about business and entrepreneurship to construct a business model and implementation strategy.

Personal learning ambitions
- Work remotely and individually due to COVID-19 restrictions. Get creative with 'field' research, testing and validation methods.
- Project & time management; Being responsible for all communication and planning within this project.
- Develop prototyping & testing skills; Come up with different test setups, transfer insights into design iterations
- Develop 3D modelling and additive manufacturing skills
- Develop render skills; Make clear, representable visuals to use in the final presentation

REFERENCES

[1] Agarwal, P., Kukrele, R., & Sharma, D. (2019). Vacuum assisted closure (VAC)/negative pressure wound therapy (NPWT) for difficult wounds: A review. J Clin Orthop Trauma, 10(5), 845-848. doi:10.1016/j.jcot.2019.06.015
Argenta, L. C., & Morykwas, M. J. (1997). Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg, 38(6), 563-576; discussion 577.
[2] Estillore, K. M., Quevedo, G. L., & Bonifacio, L. R. (2013). Improvised suction apparatus for closure of large soft tissue deficit. Malays Orthop J, 7(2), 29-33. doi:10.5704/moj.1307.002
European Space Agency. (n.d.). Technology Readiness Levels (TRL). Retrieved from https://www.esa.int/Enabling_Support/Space_Engineering_Technology/Shaping_the_Future/Technology_Readiness_Levels_TRL
[3] INF Nepal. (2020). Annual Report 2019-20. Retrieved from https://www.inf.org/wp/wp-content/uploads/2020/11/AR-INFN-2020-web.pdf
[4] Karki, B., Rai, S. M., Nakarmi, K., Laminchhane, A., Maharjan, N., Giri, P., . . . Ludwig, C. A. (2019). Pilot Study to Assess Safety and Usability of the Kyron NPWT System. Plast Reconstr Surg Glob Open, 7(8), e2334. doi:10.1097/gox.0000000000002334
[5] Oosting R.M., Dankelman J., Wauben L.S.G.L., Madete J., & Groen R.S. (2019). Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide. GHTC 2018 - IEEE Global Humanitarian Technology Conference, Proceedings,.

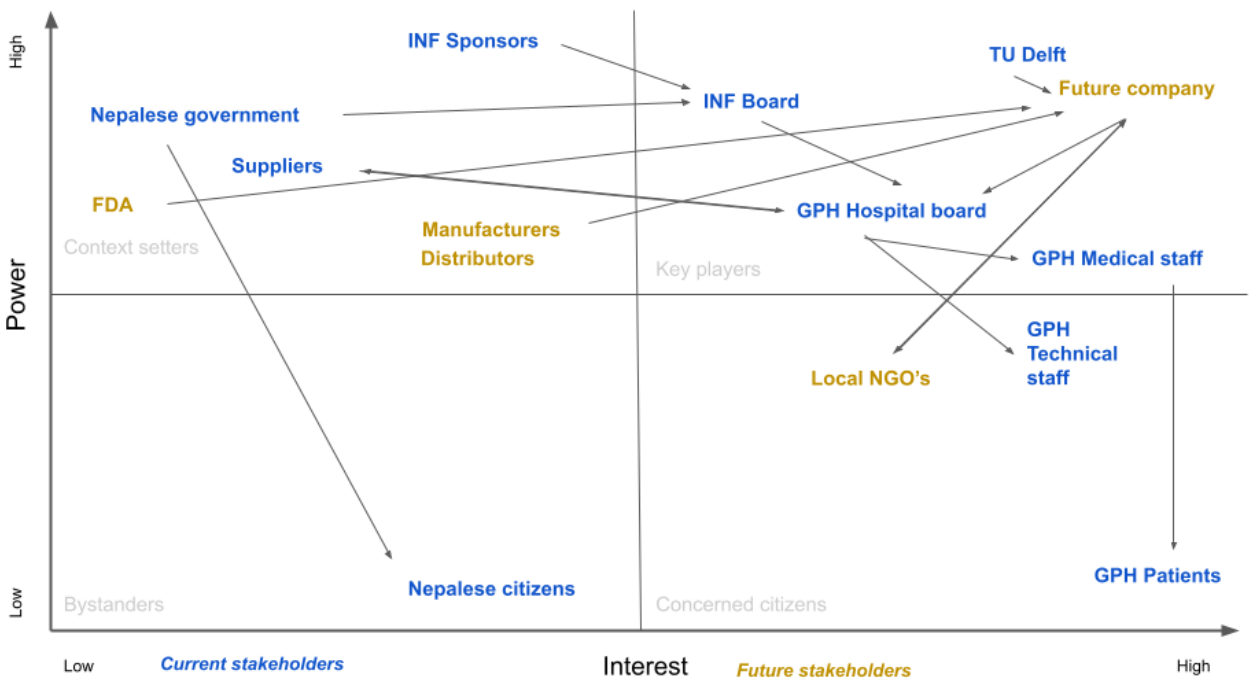
FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

[6] Yadav, S., Rawal, G., & Baxi, M. (2017). Vacuum assisted closure technique: a short review. Pan Afr Med J, 28, 246. doi:10.11604/pamj.2017.28.246.9606

Appendix B: Stakeholder analysis

This image shows an overview of the current and future stakeholders for this project of desining a low-cost NPWT device for low-resource settings



In table 1 the most important stakeholders and their needs, wants and expectations (related to the new product) are listed.

Stakeholder	Description	Need
Patients	Poor, loss of function/mobility, in pain, without work no income, want to resume work to support their family, worry about costs and income, fear for stigma, scared, not familiar with healthcare, uncomfortable in a hospital environment, language barrier, return home, regain freedom and autonomy	Receive care that cures the wounds (especially the pain) as quickly as possible that is affordable (means: almost free) and sufficient to return home and resume work to generate income.
GPH Medical staff	Foreign/Nepalese, drive to help patients in the best possible way, deal with lack of resources, lack of medical supplies, financial means, etc. need to improvise	Provide the best care possible to their patients and use the available resources to help as many patients as possible
GPH Technical staff	Foreign/Nepalese, drive to solve problems with technical solutions, deal with poor equipment (donated, second hand) and limited availability of components and tools needed for repair, need to improvise. Creative use of what is available. Hard to keep a routine.	Solve technical issues around the hospital, ensure hospital equipment is working properly.

Stakeholder	Description	Need
Suppliers	Deal with difficult infrastructure, interest to make profit, power because if there is no supply (of dressings e.g) care cannot be provided	Sale and delivery of medical goods to healthcare facilities in Nepal as a profitable business.
GPH Hospital board	Leading the hospital, reporting to the INF board. Care about hospital organisation, make sure patients receive adequate care, prevent accidents and mistakes. Contact with other parties, suppliers, local government (permits) and other NGO's. Responsible for purchases, care about budget, decide what to buy and when. Care about INF board approval. Hire the medical staff Deal with staff turnover, inconsistency and other crisis	Make responsible decisions regarding the hospital organisation and budget, in line with the hospital policies and approved by the INF Board.
INF board	Care about their mission: helping the poor population, publicity to attract sponsors to maintain their budget. Wish to expand their resources and capacity to help more people (never enough). Hire/elect the hospital board and provide supervision. Writing annual reports.	Lead projects that contribute to the general mission that is helping the poor and underserved people of Nepal, while attracting and maintaining sponsors to fund these projects.
INF sponsors	Mainly overseas, power to withdraw at any time, want to make a difference, acknowledgement/publicity, update on how the money is spent, involved in case of a special project that needs extra funding.	Provide financial means that contribute to the INF mission, good publicity and acknowledgement.
Nepalese government	Give out permits to NGO's, hospitals and forgein doctors > power. Aim to improve the healthcare system, public health still underfunded and underdeveloped. Dealing with large crises, natural disasters, pandemic etc. Corruption	Improved healthcare system for the citizens of Nepal
Nepalese citizens	Main concern is to survive, generate income Lack of believe in government and modern healthcare (due to high costs), prefer to be independent,	Affordable healthy that is easily accessible
TU Delft	Make impact, provide learning experience for students, continuations of projects (spin-offs), awards and prices	Make impact that contributes to the mission 'healthcare for all' while providing learning experiences for TU Delft students
FDA	Certification of medical goods criteria are included in the ISO standards, quality control.	Protect public health by ensuring safety and efficiency of medical equipment on the international market

Table 1: Most important stakeholders in the WOCA wound project

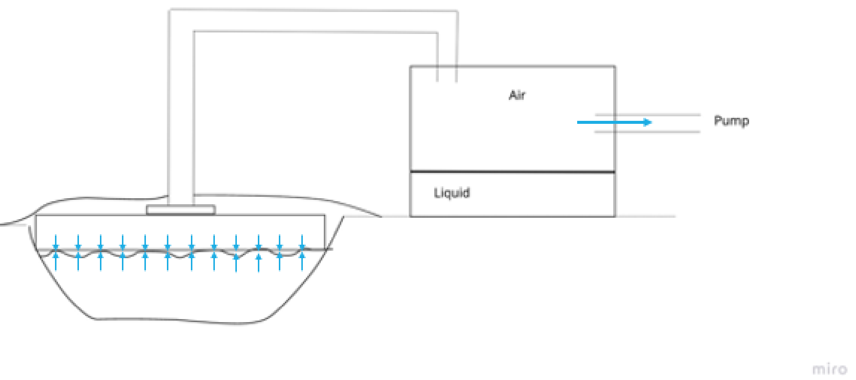
Appendix C: Analysis of a NPWT system

$$P = (Q * dp)\,\eta$$

P = Power [Watt]
Q = flow rate [m3/s]
dp = Pressure difference [Pa]
η = Pump efficiency

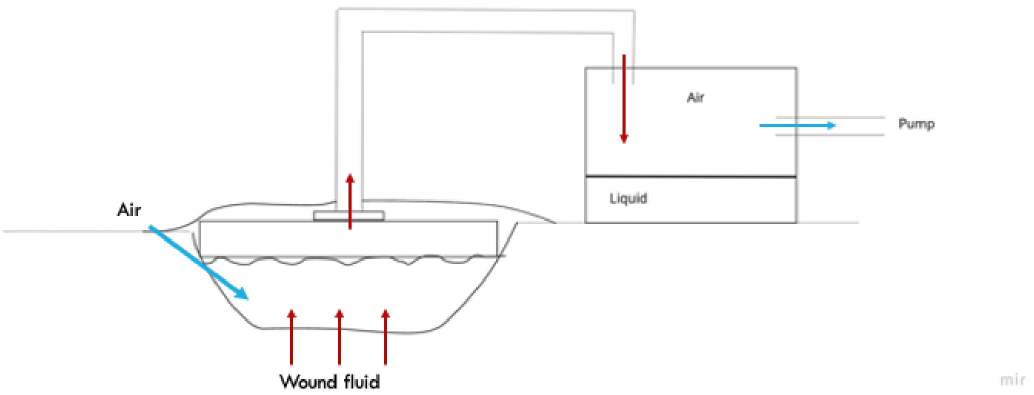
$$V1 * P1 = P2 * V2$$

V = Volume [m3]Q
P = Pressure [Pa]



$$Q = Qwound + Qair$$

(NOTE: Viscious frcition is not included)



Fixed	Variable	Unknown
V_system [m3] *V_canister [m3]* *P_atmosphere [Pa]* *P_max_pump [Pa]* *Q_max_pump [L/min]* *Power_pump [Watt]* *N_pump [%]* *V_tubes [m3]* *D_tubes [mm]* *L_tubes [mm]*	*A_wound [m2]* *V_dressing [m3]* *P_system [mmHg] / [Pa]* *Q_pump [L/min] / [% of max]* *Q_fluids [L/min]* *Q_valve [L/min]*	*Q_wound[L/min] / [mL/day]* *Q_airleak [L/min]*

System parameters

Power

Q = Flow rate [m^3/s] → 100 mL/day
dp = Pressure [Pa]
P = Power [Watt]
η = Pump efficiency → 25%

- Most of the pump power is expended in leakage, along with frictional losses, which value depends on system design.

> $Q := Qwound + Qair$

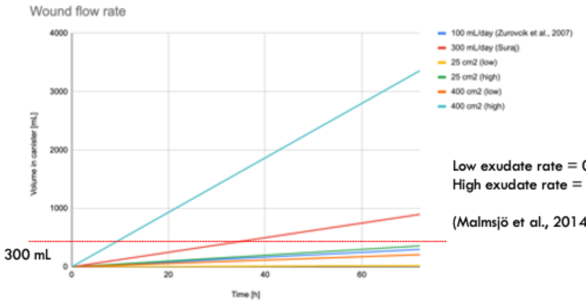
$$\frac{1}{864000000} \quad (4.1)$$

> $PowerVAC := \frac{Q \cdot dp}{\eta};$

$$7.72 \times 10^{-5} \quad (4.2)$$

- Qwound is very small > only 0.001 mL per sec.
- Without leakage the power needed to create pressure is only 77 micro watt
- Qair is assumed >> Qwound

WOUND FLOW RATE ?



Low exudate rate = 0.3 mL/cm2/24 h
High exudate rate = 2.8 mL/cm2/24 h

(Malmsjö et al., 2014)

AIR LEAKAGE?

Air leakage over time

Ideal Gas Law: Psystem * Vsystem = n * R * T
Air leak 60 mL
Ignore Wound flow rate
Canister of 300 mL

> $R := 8.314; T := 300;$ [K]

$$R := 8.314 \quad T := 300 \quad [K] \quad (7.3.1)$$

> $Vsystem := 300 \cdot 10^{-6}$ [m3]

$$Vsystem := \frac{3}{10000} \quad [m3] \quad (7.3.2)$$

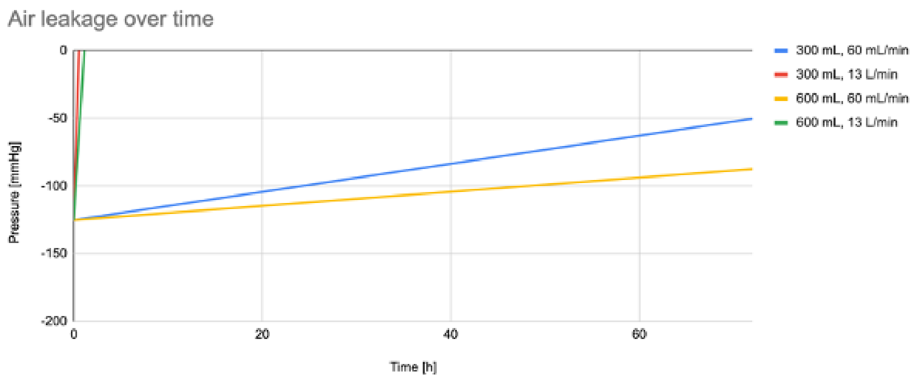
> $VolumeFlow := \frac{MoleFlow \cdot R \cdot T}{dp};$

$$VolumeFlow := 0.1496647215\ MoleFlow \quad (7.3.3)$$

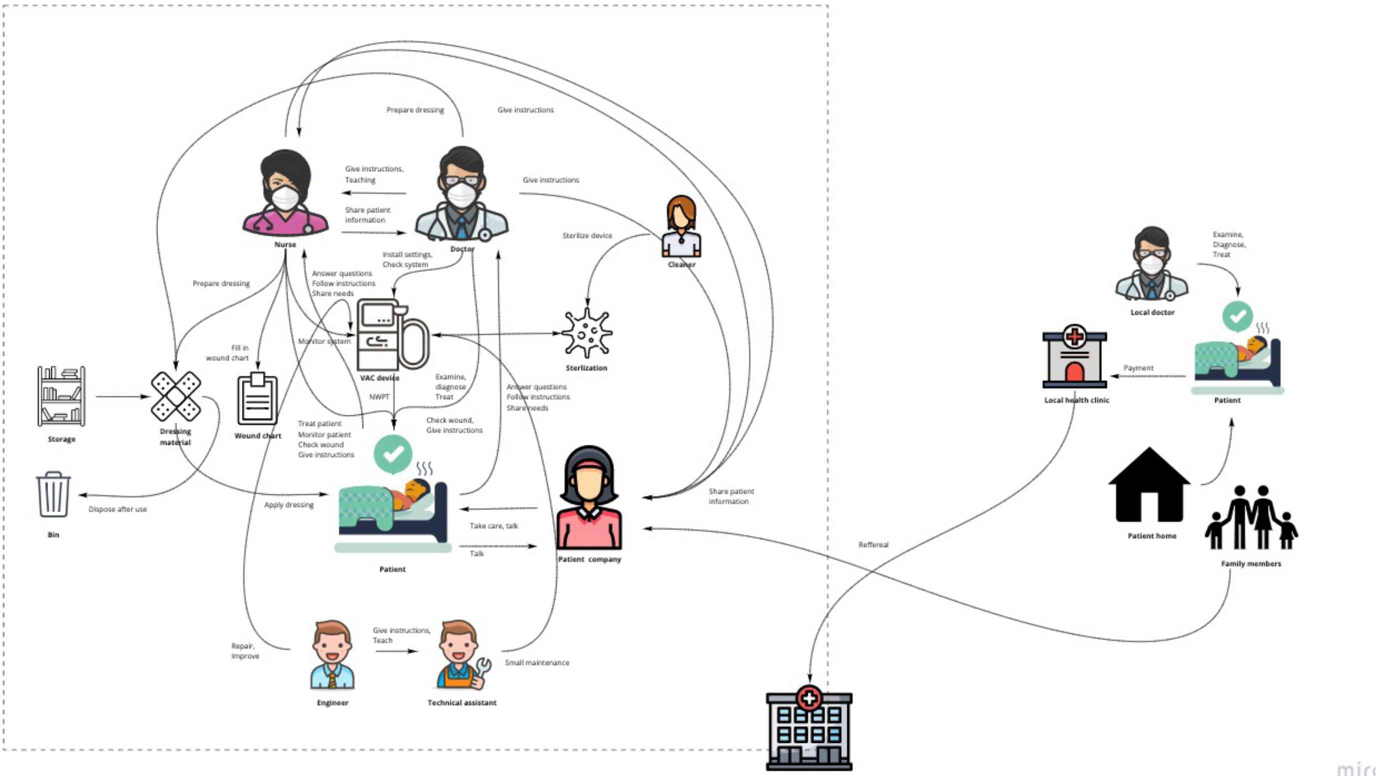
> $VolumeFlow := \frac{(60) \cdot 10^{-6}}{60 \cdot 60 \cdot 24};$ [m3/s]

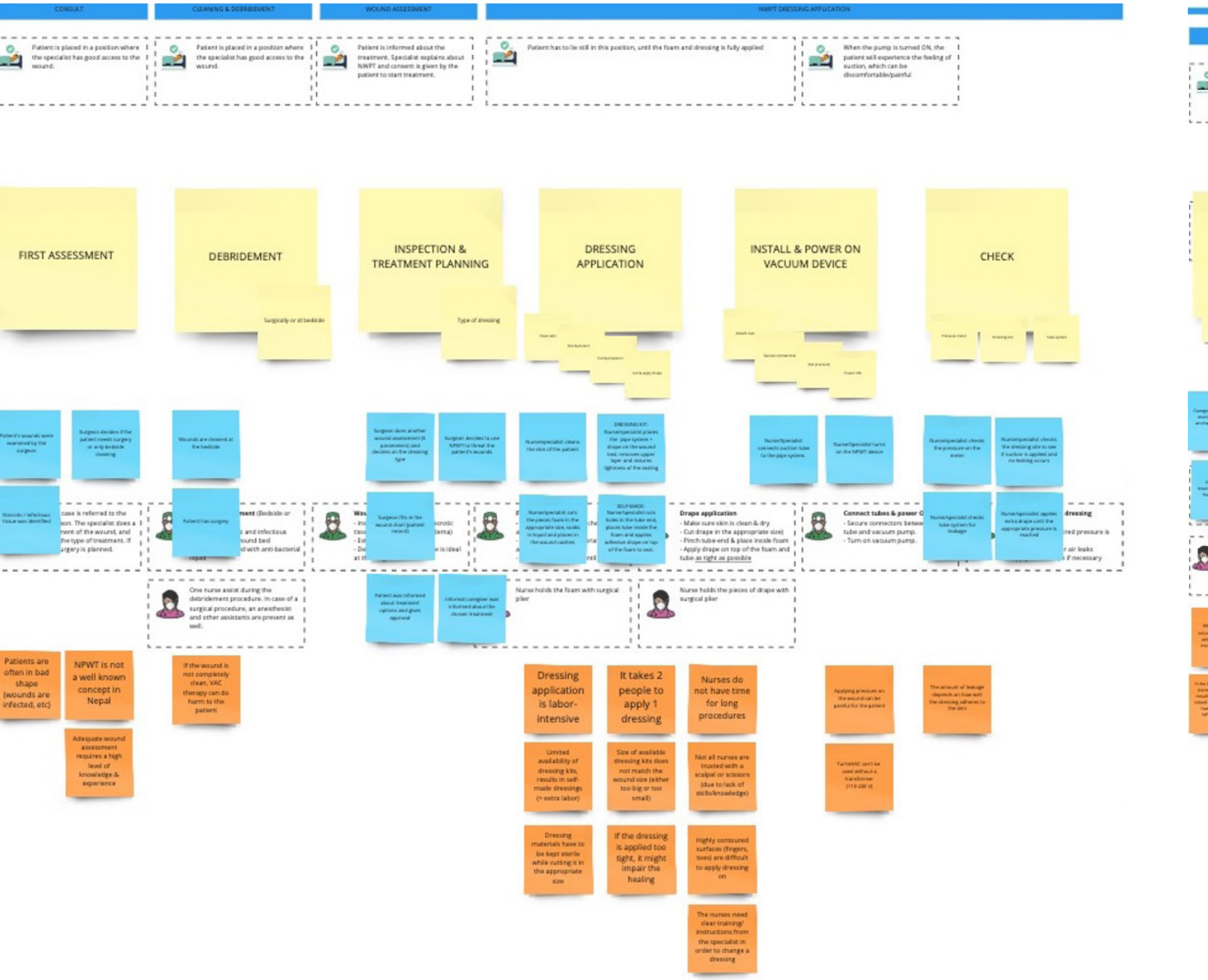
$$VolumeFlow := \frac{1}{1440000000} \quad \left[\frac{m3}{s}\right] \quad (7.3.4)$$

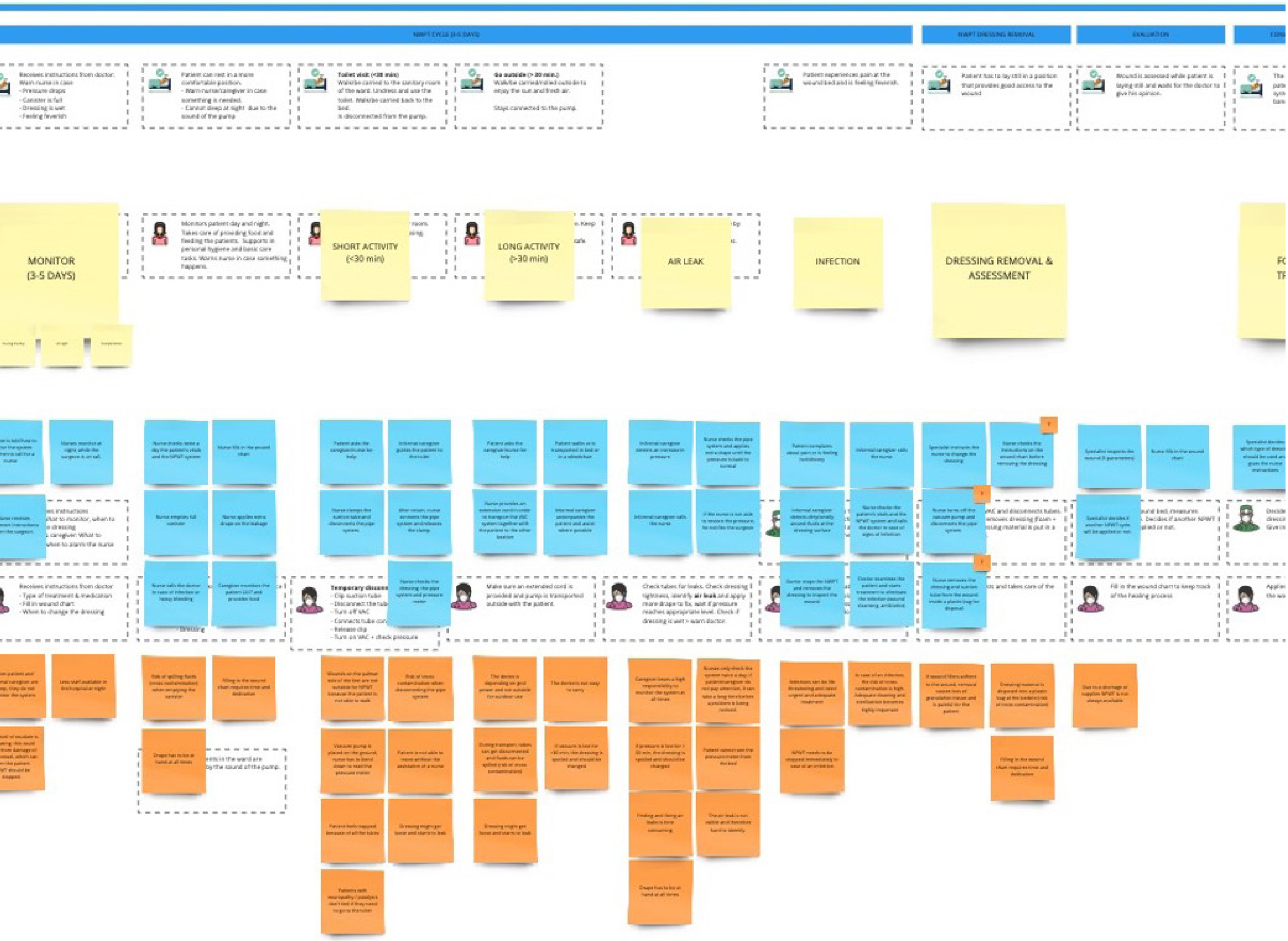
AIR LEAKAGE?



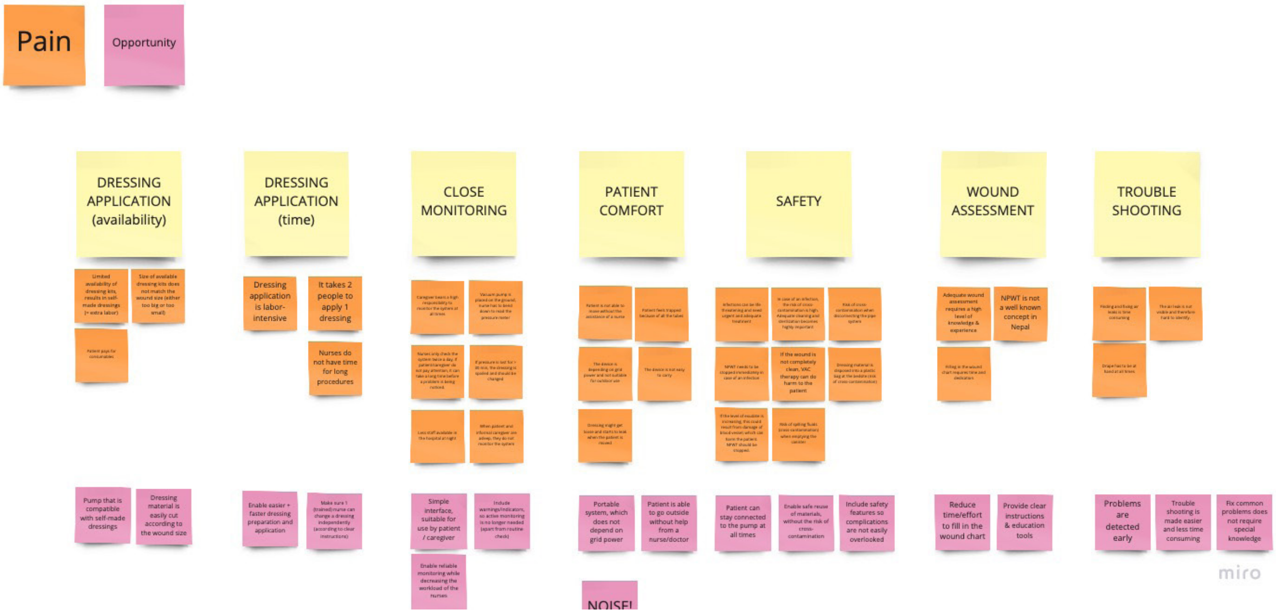
Appendix D: Patient Journey Analysis




CONSULT
CLEANING & DEBRIDEMENT
WOUND ASSESSMENT
NWPT DRESSING APPLICATION
Patient is placed in a position where the specialist has good access to the wound.
Patient is placed in a position where the specialist has good access to the wound.
Patient is informed about the treatment. Specialist explains about NWPT and consent is given by the patient to start treatment.
Patient has to lie still in this position, until the foam and dressing is fully applied
When the pump is turned ON, the patient will experience the feeling of suction, which can be discomfortable/painful
FIRST ASSESSMENT
DEBRIDEMENT
Surgically or at bedside
INSPECTION & TREATMENT PLANNING
Type of dressing
DRESSING APPLICATION
INSTALL & POWER ON VACUUM DEVICE
CHECK
Drape application
- Make sure skin is clean & dry
- Cut drape in the appropriate size)
- Pinch tube-end & place inside foam
- Apply drape on top of the foam and tube as tight as possible
Connect tubes & power ON
- Secure connectors between tube and vacuum pump.
- Turn on vacuum pump.
One nurse assist during the debridement procedure. In case of a surgical procedure, an anesthesist and other assistants are present as well.
Nurse holds the foam with surgical plier
Nurse holds the pieces of drape with surgical plier
Patients are often in bad shape (wounds are infected, etc)
NPWT is not a well known concept in Nepal
Adequate wound assessment requires a high level of knowledge & experience
If the wound is not completely clean, VAC therapy can do harm to the patient
Dressing application is labor-intensive
It takes 2 people to apply 1 dressing
Nurses do not have time for long procedures
Limited availability of dressing kits, results in self-made dressings (= extra labor)
Size of available dressing kits does not match the wound size (either too big or too small)
Not all nurses are trusted with a scalpel or scissors (due to lack of skills/knowledge)
Dressing materials have to be kept sterile while cutting it in the appropriate size
If the dressing is applied too tight, it might impair the healing
Highly contoured surfaces (fingers, toes) are difficult to apply dressing on
The nurses need clear training/ instructions from the specialist in order to change a dressing


MONITOR (3-5 DAYS)
SHORT ACTIVITY (<30 min)
LONG ACTIVITY (>30 min)
AIR LEAK
INFECTION
DRESSING REMOVAL & ASSESSMENT

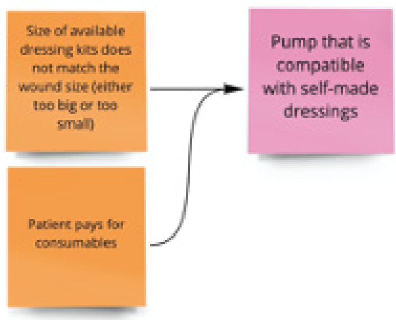
3.6.3 PAINS AND OPPORTUNITIES



During the analysis of the patient journey, several causes for pain are indicated. Pain should be mitigated and there are several opportunities to do so. In the upcoming paragraph the main pain causes that should be mitigated with this design are discussed and possible design solutions are proposed.

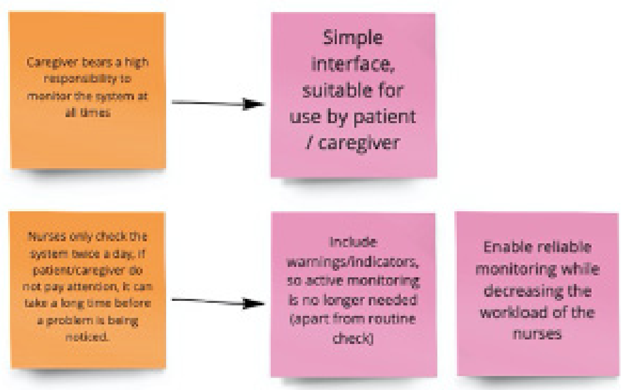
DRESSING AVAILABILITY

The application of the dressing is a difficult process. Often the right size of the dressing kit is not available and the costs should be minimal. Therefore, self-made dressings are common in Nepal. The design goal of this research is not to improve the dressing kits, but to design a pump. From this can be concluded that the pump has to be compatible with self-made dressings.



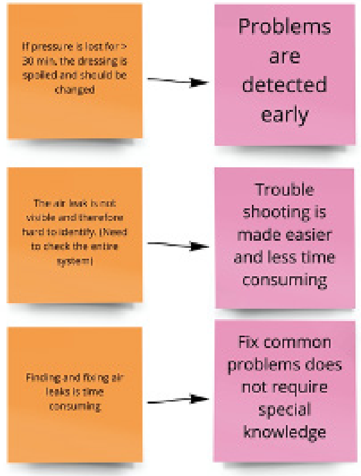
MONITORING

In Nepal the caregiver bears a high responsibility to the monitoring of the patient. This in non-medical staff. The medical staff at the hospital do not have the time to constantly monitor the patient with a complex wound. As a result, a person without medical background should be able to monitor the system and detect and solve common problems. Therefore, a simple interface with warning indicators is a design requirement for the pump.



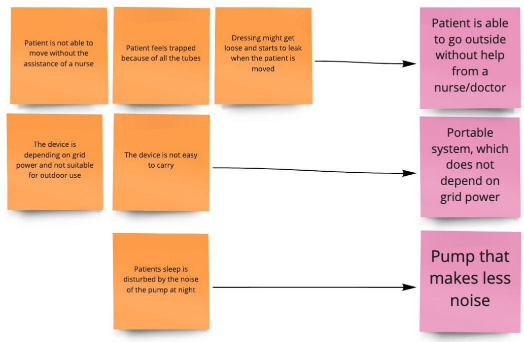
TROUBLE SHOOTING

Air leaks is a common accident during the applicating of the NPWT. When this happens, pressure drops. If the pressure is lost for more than 30 minutes, the dressing should be replaced. Hence, the pump design should detect and notice when this happens. Moreover, the pump should be straightforward and possible to use for someone without special knowledge. If a common problem occur with the pump, detecting and fixing those problems should be easy to do.



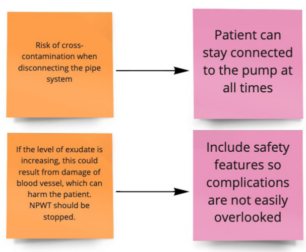
PORTABILITY

The NWPT cycle is as least 3-5 days and with repeated cycles probably much longer. During the time in the hospital, the patient need to go to the toilet and other short activities but also should be able to do longer activities, such as a walk or going outside with a visitor. Currently NWPT system is not easy to carry or suitable for outdoor use. If a portable NWPT system could be designed, the patient comfort would increase tremendously.



SAFETY

During the therapy, several issues might occur, such as an air leak, a bleeding or an infection. If these issues are not solved adquately, these can lead to complications and serious damage to the patient. Therefore, it is important to integrate features issues into the design, to warn the medical staff in case of such an event.



Appendix D: List of requirements

-

Group	#	Req/Wish	Description
Pressure	1.1	Req	The device can create and maintain a pressure level of -125 mmHg during one treatment cycle (3-5 days).
	1.2	Wish	The device has one default pressure level of -125 mmHg and one adjustable pressure level of 80 mmHg
	1.3	Wish	The device can self-regulate the pressure within 10% of the indicated pressure range
	1.4	Req	The device has a (mechanical) safety stop to ensure the pressure level will never exceed -200 mmHg
Air flow	2.1	Req	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
Fluid flow	3.1	Req	The device is able to extract fluids from a wound with a flow rate ranging from 1-300 mL/day
Fluid collection	4.1	Req	Wound fluids are collected into a sealed canister without spillage
	4.2	Req	The canister is non-leaking, airtight, detachable and can store at least 300 mL of fluids.
	4.3	Req	The canister cannot overflow (overflow protection is in place)
Applicability	5.1	Req	The device is compatible with self-made wound dressings
Usability	6.1	Req	The device is easy to operate by medical traff with minimal training
	6.2	Req	The device is easy to monitor by patients and caregivers with basic instructions
Portability	7.1	Req	Dimensions of the device (including carrying case or frame) should be within 600 x 300 mm and the weight should be < 6 kg
	7.2	Req	The canister is firmly attached to the device, while it can

			be easily removed for emptying
	7.3	Req	The device has a portable and rechargeable power source (battery)
	7.4	Req	The device operates for at least 8 hours on a full battery
	7.5	Wish	The device is suitable for outdoor use and therefore resistant to UV, splash water, shocks, and scratches.
	7.6	Wish	The device can be carried by patients with mobility problems
Noise	8.1	Req	The operating sound level does not exceed 35 dB.
Safety	9.1	Req	The device should remain stable on the ground without the risk of tipping over
	9.2	Req	The device (or canister) prevents a loss of > 300 mL of blood in case of a bleeding
	9.3	Req	The content of the canister and fluid tube should be clearly visible during use (to be able to detect any signs of infection)
	9.4	Req	The device alerts the user in case the pressure level is > above -70 mmHg (indicating an air leak)
Cleaning	10.1	Req	All external parts of the device are suitable for cleaning with disinfectant.
	10.2	Wish	The canister and connectors are suitable for sterilisation (autoclaving)
Costs	11.1	Req	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
	13.2	Req	Off-the-shelf components are available (online or within 100km radius) and custom-made parts can be manufactured locally in Nepal and other LMICs.
Repairability	14.1	Req	The device can be (dis)assembled with local skills and tools
	14.2	Req	Individual parts can be removed and replaced
Maintenance	15.1	Wish	The device is low-maintenance
Lifespan	16.1	Req	The device (in package) can withstand transportation on difficult roads

Appendix I: Weighted criteria

I. Weighted Criteria

Criteria were selected from the 'List of requirements'.

roup	#	Wish/Req	Description	Weight
sability	7.1	Req	The device should be easy to operate by medical traff with minimal training	8
	7.2	Req	The device should be easy to monitor by patients and caregivers with minimal instructions	8
rtability	8.3	Req	The canister should be firmly attached to the device (also when lifting/carrying)	9
	8.4	Wish	The device (with canister) should be easy to carry	5
	8.5	Wish	The device should enable carrying by patients with disabilities or other mobility problems (using crutches, wheelchairs etc)	3
	8.7	Wish	The device should be suitable for outdoor use and therefore resistant to UV, splash water, shocks, and scratches.	3
eaning	10.3	Wish	The device should be easy and fast to clean	5
fety	11.2	Req	The content of the canister and fluid tube should be clearly visible during use (to be able to detect any signs of infection)	8
	11.4	Req	The device should provide stability to the canister	9
osts	12.2	Wish	The production price of the device should not exceed 300 USD	3
vailability	13.1	Wish	The device should be made, as much as possible, from standard off-the-shelf components that are widely available	8
	13.2	Req	The device should be compatible with standard medical suction canisters, and allow variation in canister shape and size within the given boundaries	9
	13.2	Wish	Custom-made components should be suitable for local manufacturing in LMIC	5
aintenance id repair	14.1	Req	The device should be easy to (dis)assemble with local skills and tools	4
	14.2	Wish	Internal parts should be easy to remove and replace	4
fespan	15.1	Req	The device should be able to withstand rough handling (shocks and small impact)	8
	15.2	Wish	The lifespan of the device should be 3-5 years, including small repairs.	4
OTAL				103

Appendix J: Weighted criteria scores of concepts

Concept 1-4 are scored on weighted criteria that are presented on the previous page.

Table 1 includes the weighted scores and argumentation of concept 1 (VacuRamp) and concept 2 (ModiVac):

Score concept 1	Argumentation	Weighted score	Score concept 2	Argumentation	Weighted score
9	Simple design, clear indication where the canister should be placed, air inlet clearly visible, large interface, easy to lift or move when e.g examining the patient	72	8	Clear indcation where the canister should be placed. Small interface, but one-button operation. Can be placed in different locations, depending on the needs of the patient	64
8	Interface under an angle, visible from above (while patient is in bed) or from the side. Canister is clearly visible, as well as the pressure level indicator	64	7	Small and compact design, interface can be hard to interpret. No indicator for pressure level	56
3	There is little contact surface between housing and canister, velcro slips easily on the surface of the canister (lack of grip). When lifting, the canister is tilted to one side, tends to fall out of the housing	27	6	The canister is enclosed and clamped. Limited surface contact between canister and canister holder. Hard material, is possible to slip.	54
4	Due to unequal distribution of weight, the device is leaning to one side when lifting, which does not feel comfortable	24	7	Design is small and light. Shape (squared) is not ideal for carying.	42
6	Straps can be adjusted, so the device can be carryed in different placed (on the hip, around the shoulder, attached to a wheelchair). The unequal weight distribution and angluar design can complicate carrying for patients	18	9	Due to the modular design, elements can be removed or added, according to the individual needs of the patient	27
8	Due to the simplicity of the shape, risks of damage are limited. The housing fully covers the internal components, water cannot enter. The housing can be easily made from scratch-proof and UV-restistant sheet material	24	6	Snap fit connections might fill with dust and dirt	18
8	Uniformal shape is easy to wipe, no ridges or parts that are hard to reach. Corners might be a bit difficult (rounding might be preferred)	40	4	Snap fit connections and ridges are difficult to clean	20
10	Canister is almost entirely exposed, as well as the tubes. Device can be placed on the bed/nightstand/windowsill	80	9	Canister is fully exposed and in sight	72
4	Limited enclosure of the canister, little contact surface between the canister and the housing (round shape + flat surface). Canister has the freedom to move	36	4	No equal distribution of weight, the device is small and light so it has no weight to counter the weight of the fluids insight the canister	36
9	Housing can be made from cheap (sheet) material, as well as the handle. Very affordable design	27	5	Snap fits may require more complex housing shape, which contributes to extra costs	15
9	Sheet material is widely available (although custom made), as well as velcro, the handle and carrying straps	63	5	Canister holder and housing are both custom-made	35
4	Smaller canisters are hard to fit, because they have a lot of space to move inside the housing and therefore need more secure tighning	32	6	Clamping enables mulitple sizes and shapes of canisters to fit. Because the design is small, smaller canister are convenient. Due to modularity, different canister holders can be attached (also suitable for larger canisters)	48
10	Sheet material is easy to process, this can be done locally	50	6	Material of the canister holder should be durable and restistant to bending, which can be difficult to find	30
10	Housing can be delivered as a kit, using basic screws and bolts to assemble	40	6	Small and compact design requires smaller screws and fastenings	24
8	Left components contains all internal parts in one place, everything is easy to reach.Velcro can be easily removed. Only the handle is hard to replace	32	6	Small and compact design provides less freedom for part positioning , to make parts easy to reach	24
7	Due to the geometric shape the housing protects the internal components. No special shock-absorbing features. The handle sticks out and might be prone to bending/breaking	56	5	The canister holder is sticking out and might break during a fall	40
5	The handle might be prone to damage and cannot be replaced	10	8	The internal components are well protected inside the housing, canister holder and straps can be easily replaced to extend the lifespan	16
		695			**621**

Table 1 includes the weighted scores and argumentation of concept 3 (WoundBag) and concept 4 (SuctionPillar):

Score concept 3	Argumentation	Weighted score	Score concept 4	Argumentation	Weighted score
9	Large interface, indicator for pressure level. It's clear where the canister should be placed	72	6	Limited interface, when on the ground it can be hard to reach for the medical staff	48
8	Large interface, sufficient space for alarms/indicated on the top. When placed on the ground interface is still visible.	64	5	No clear interface / indication where the user should look. Canister is clearly visible	40
8	Canister is fully enclosed, and safely stored inside the bag. If the compartment is firm and strecheable enough, the canister should be held in place	72	7	When placed on the ground, the canister is kept in place. The soft material around the canister provides support in every direction. When lifted, the canister might lean to one side or fall out of the holder	63
8	Bag enables comfortable carrying, around the hip or as a shoulder bag. However, device is large and bulky, so it can shake/bumb	48	5	Due to cilindric shape the device is difficult to carry. Limited possibilities to attach a carrying strap, so a seperate bag or frame might be needed to carry the device. It is an advantage that the weight is centred and the design is symetric	30
7	The adjustable strap enables carrying in multiple ways. Due to the soft bag it is comfortable to put on the lap. The relatively large size and weight could be a difficulty for patients that are not very strong	21	3	Difficult to put on the lap. Might shake when someone walks on crutches	9
8	Just like a bag, the device can be carried outside. The bag provides protection to the internal components. It would be better if the bag could be closed, when going outside (although canister and interface wouldn't be visible)	24	4	Dust and dirst could collect inside the cylinder	12
3	The bag is made of fabric, which can get dirty easily, especially when placed on the ground. It might be really hard to clean/sterilize	15	5	Cleaning can be difficult do the the ridges and the soft material inside the bottom part.Bacteria can get inside, when not througouhly cleaned	25
4	Canister is enclosed, and mostly covered so it can be hard to see	32	9	Canister is placed in the centre and clearly visible at all times	72
9	The canister is placed inside the bag, which keeps it stable.	81	8	Because the weight is centred and the canister is placed on top, the holder provides stability to the canister. However, due to the height there is a risk of falling over (remove rubber feet, or increase diameter	72
4	The bag should be made fo cleanable fabric, which adds costs	12	4	Housing is quite complex, which can increase production costs	12
8	All components are widely avaiable, assuming the bag can be produced from locally available fabrics	56	7	All components are widely avaialble	49
4	The amount of strecht within the bag is limited, if all canisters would fit, it might be difficult to keep the smaller ones stable and visible	32	9	The shape allows different heights and diameters of the canister, the point of gravity will stay in the middle	72
7	It should be possible to make the bag in a local sewing workshop	35	6	Round shape can be more difficult to produce	30
8	The bag can be made using a sewing pattern. The box-shaped housing can be easily assembled. Also, bigger screws can be hidden in de bottom part of the device (covered by fabric)	32	7	Placement of the components is likely to be more difficult due to the round shape of the housing. Parts can be reached from below or above	28
8	Components can be taken out of the bag. The internal parts can be removed from the box	32	7	All parts are easy to replace, except for the housing	28
8	When safely stored in the bag, the device is protected against shocks and impact	64	7	Round shape can help to absorb shocks, as well as the rubber feet. The housing has parts that are exposed or sticking out, and therefore prone to damage	56
8	The protection of the bag can increase the lifespan of the product	16	6	The shape of the housing has an abnormal shape, some parts are exposed, which makes the design less robuust	12
		708			**658**

Appendix K: Bill of Materials

	Part name	Qnt	Specifications	Production	Material	Estimated price	Weight	Shipping from	Link
1	Vacuum pump	1	*Topsflo, TM30B-A* Mini diaphragm air pump Brush DC 4.4 Watt 4.5L/min Max vacuum: 60 kPa Hose ID 4 mm Ideal lifetime = 15000 hrs	Off-the-shelf	Pump head: Nylon Membrane: EPDM Valve: EPDM	$40.00	150g	China	https://www.alibaba.com/ shorturl.at/noz27 http://www.topsflo.com/ shorturl.at/EKPR4
2	Pressure sensor	1	*CFSENSOR, XGZP6899D040KPD* Pressure range: 0-40 kPa Resolution: 23 bit 5V DC Accuracy ± 2.5% 0.02w	Off-the-shelf	PPS	$4.50	5g	China	https://dutch.alibaba.com/ shorturl.at/CHMT0
3	MOSFET driver	1	0-24V Top Mosfet Button IRF520 3.3V, 5V Output: 0-24V	Off-the-shelf	-	$0.35	8g	Chinca	https://nl.aliexpress.com shorturl.at/nrtZ7
4	Microcontroller	1	Arduino Nano V3.0 ATmega328P 5V, 1.2 Watt MicroB USB	Off-the-shelf	-	$2.24	5g	China	https://nl.aliexpress.com/ shorturl.at/mrLRV
5	Potentiometer	1	0.03W	Off-the-shelf	Metal, Plastic	$0.05	4g	China	https://nl.aliexpress.com/ shorturl.at/fjLQ2
6	Battery pack + charger	1	Rechargeable battery pack incl. charger 12.6V 9900 mAh	Off-the-shelf	Lith-ion	$8.87	300g	China	https://nl.aliexpress.com/ shorturl.at/kqwXZ
7	Switch	1	15mmx10mm	Off-the-shelf	Plastic	$0.182	5g	China	https://nl.aliexpress.com/ shorturl.at/W4689
8	LED	9	CHANZON, 0805 Smd Led Diode 2.0-3.2V, 20mA	Off-the-shelf	-	$0.02	1g	China	https://nl.aliexpress.com/ shorturl.at/imqsE
9	Speaker	1	Bunui, Buzzer BR 0.5Watt 20mm	Off-the-shelf	Metal	$0.60	5g	Chica	https://nl.aliexpress.com/i shorturl.at/DMTUZ
10	Manometer	1	*NGS, YZ402-01-1* Vacuum pressure gauge 0- -30 inHg PT ⅛ (thread)	Off-the-shelf	Metal, plastic	$3.30	60g	China	https://nl.aliexpress.com/ shorturl.at/BJMWZ
11	Vacuum relief		Spring SL - 1/4	Off-the-shelf	Messing	$1.02	20g	China	https://nl.aliexpress.com/

	valve		0 ~ 0.9Mpa		(Copper)				shorturl.at/jqrv5
12	Connector L	2	6mm Push-in connector, L-shape, two inlets	Off-the-shelf	Plastic	$0.35	5g	China	https://nl.aliexpress.com/ shorturl.at/fijU7
13	Connector T	3	6mm Push-in connector, T-shape, 3 inlets	Off-the-shelf	Plastic	$0.42	5g	China	https://nl.aliexpress.com/ shorturl.at/fijU7
13	Internal tube	1	6x4 mm Length: 30 cm	Cutted	PU	$0.31 ($0.93 /m)	10g	China	https://nl.aliexpress.com/ shorturl.at/glnrX
14	Housing front		174 cm3	3D printed	PETG				
15	Housing back		141 cm3	3D printed	PETG				
16	Dressing tube connector		8.5 cm3	3D printed	PETG				
17	Turning knob		9.7 cm3	3D printed	PETG				
18	Canister holder bottom		Volume = 0.18	3D printed	PETG				
19	Canister holder top			3D printed	PETG				
20	Canister holder ring			3D printed	PETG				

-

Appendix L: Calculation of costs

Off-the-shelf components

#	Part name	Estimated price ($US)
	Vacuum pump	40
	Pressure sensor	4.5
	MOSFET driver	0.35
	Arduino Nano	2.24
	Potentiometer	0.05
	Battery pack (incl. charger)	8.87
	Switch	0.182
	LED	0.02
	Speaker	0.6
	Manometer	3.3
	Vacuum relief valve	1.02
	Internal tube	0.31
	Connector L	0.7
	Connector T	1.26
	PCB	2
	TOTAL	**65.402**

3D-printed parts

Part name	Mass (g)	Costs of filament (USD/kg)	Printing time (h)	Costs of energy in Nepal (USD/kWh)	Print's energy consumption (kWh)	Costs of material (USD)	Costs of energy (USD)	Total costs (USD)
Housing front	212	29.3	44	0.065	8.8	6.2116	0.572	6.7836