

Thesis for the Degree
Master of Science



**Development of a Vacuum Extraction System
for Low- and Middle-Income Countries**
Redesign of a state-of-the-art vacuum extractor

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Abstract

Vacuum extraction is a form of assisted vaginal birth where a vacuum cup is attached onto the fetal head by means of suction on which traction force is then exerted to facilitate birth. Vacuum extraction is often regarded as a safer option than the cesarean section and forceps delivery, due to decreased risk of maternal and fetal complications. The increase in popularity of handheld disposable vacuum extractors in low-resource clinical settings demonstrate the need for more ergonomic vacuum extraction solutions geared towards LMICs. In this report an ergonomic and affordable vacuum extraction system is developed by reinventing the pump mechanism of an existing vacuum extractor. Two types of manual pumping mechanisms more suitable with cleaning are explored and tested on their ability to create partial vacuum. One of which is able to reach the required partial vacuum of 0.08 MPa (0.02 MPa pressure) and poses as most promising for implementation. From this, a final prototype is developed and evaluated on usability in a modern clinical setting. The result of the functional validation and usability evaluation show that this pump mechanism can successfully be integrated in a vacuum extraction system to create a more affordable and convenient vacuum extraction system that may make vacuum extraction more accessible in LMICs.

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Introduction

1

Vacuum extraction is a form of assisted vaginal birth, generally performed in case of prolonged second stage of labour or fetal distress, where a vacuum cup is attached to the fetal head by means of suction to which traction force is applied in conjunction with uterine contractions to facilitate birth. When positioned correctly, the traction force applied to the extractor contributes to a more favourable presentation of the fetal head through the cervix.

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1.1 Background

Reports of utilizing suction force for assisted vaginal birth date back to the early 18th century; however, it was Scottish obstetrician Sir James Young Simpson¹ in 1849 who developed the first practical instrument for assisting vaginal birth making use of suction [1]. In alternative to the obstetrical forceps, relying on friction created by the pinching force of the graspers for adhesion, Simpson's device attached to the fetus by creating a partial vacuum between the fetal scalp and the dome shaped end of his device [2] reducing the risk of maternal and neonatal facial injuries [3]. Although Simpson demonstrated the capacity of his device for high traction force [4], it was not until the work of Malmstrom [5] in the 1950's that the use of suction in assisted vaginal birth became a widespread alternative to the obstetrical forceps[6]. Compared to cesarean section, assisted vaginal birth is associated with reduced risk of (postpartum) hemorrhage, infection, wound disruption and injury, venous thromboembolism and death. In addition to shorter recovery time and lower cost [7]. For this reason there has been a push to (re)introduce the use of vacuum extraction, especially in low-resource countries where in various hospital C-section remains the method of choice. [8].

Since the vacuum extractor was first introduced, a wide range of variations in its design have been proposed. The literature review attached to the appendix provides an in-depth analysis of design characteristics of vacuum extractors and its influence on use and outcome. Early versions of vacuum extractors, consisting of a suction cup in combination with a hand operated vacuum pump, have shown to be impractical [1]. By demonstrating the impact of correct application and positioning of the vacuum cup, Bird [9] emphasized the importance of a free hand, making one-hand operated vacuum extraction devices the new standard. Electrically operated vacuum extractors, freeing the obstetrician (or their assistant) of any effort of producing the partial vacuum, presented itself as an ideal solution for modern clinical settings. However, the reinvention of the vacuum extractor as a disposable device in the 90's started replacing electrical vacuum extraction solutions. One of these disposable vacuum extractors, the Kiwi OmniCup (seen in Figure 1.1) has been the subject of numerous clinical studies [10–14] and gained a lot of popularity among obstetricians due to its ease of use [15].

1: Neil Arnott (1829), who had employed the vacuum principle for assisted birth before Simpson, is mentioned in Simpson's work, and may have been the source of inspiration for his invention coined the "air tractor".



Figure 1.1: The Kiwi OmniCup
The pump integrated in the handle allows for the creation of suction through a squeezing motion and simultaneously exertion of traction force.

1.2 Incentive

As maternal and neonatal mortality remain a serious issue in low-resource countries [17, 18] and may partly be prevented with the implementation of vacuum extraction, hospitals benefit from the (re)introduction of vacuum extraction [8]. Because traditional vacuum extraction systems generally used in low-resource settings are often impractical and unwieldy (see Figure 1.2), the Kiwi OmniCup's popularity extends beyond modern clinical settings to low-resource hospitals. While the individual price of the devices is relatively low, its disposable nature creates a high upkeep price and constant demand for restock. As a result of a lack in funds, low-resource settings rely on donated equipment and devices like the Kiwi OmniCup tend to be reused (see Figure 1.3).



Figure 1.2: An example of a traditional vacuum extraction set, advertised on the website of UNICEF[16]. Traditional vacuum extraction solutions used in LMICs often consist of a metal or silicone vacuum cup attached to a modified bicycle pump, with in between a jar for the collection of maternal fluid and tissue. In order to generate the needed suction, the continuous pumping (sometimes up to 20 minutes) of an additional assistant is necessary.

1.3 Problem Statement

Due to the innate design of the Kiwi OmniCup, proper cleaning is difficult and its reliability can not be guaranteed after a single use. Consequently, by reusing the device, unnecessary equipment failure and transmission of infectious diseases is risked. In an attempt to make the Kiwi OmniCup safer and more accessible in low-resource settings, Vacca developed a re-usable version which is further explored in section 2.4.2. Although the reusable version of the Kiwi OmniCup remains successful at achieving assisted birth [19], its tedious assembly eliminates part of the ergonomics the Kiwi OmniCup is so much appraised for.

To effectively make vacuum extraction devices more accessible in low-resource countries, a low cost, easy to use vacuum extractor ought to be developed. By redesigning the Kiwi OmniCup to a reusable device, without sacrificing its ease of use, this project in collaboration with obstetricians Barbara Nolens and Marlieke de Fouw, aims to fulfill the need for a low-cost easy to use vacuum extractor.

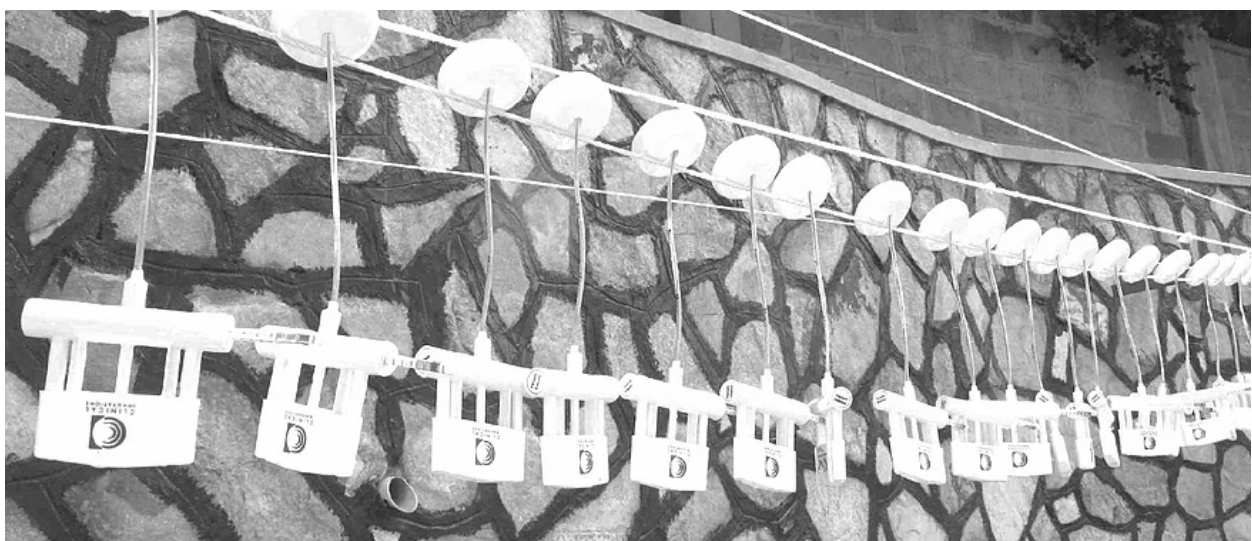


Figure 1.3: Due to a lack of resources, Kiwi OmniCups in a Mulago Hospital (Uganda) are soaked and hung out to dry to be sterilized and used again later. (Courtesy of Mulago Mama [mulagomama.org])

1.4 Scope

This project aspires to develop a working prototype of an affordable vacuum extraction system geared towards reusability. As will become apparent from the analysis in the following chapter, distinctive elements of the vacuum extractor require a different approach to design. Currently, the market presents solutions for reusable vacuum cups and tubing, although not for a reusable handheld vacuum pump. For this reason, the project mainly focuses on the design of a cleanable pumping mechanism and its integration into a reusable vacuum extractor. To ensure a working prototype can be created within the limits of this project, the design will be restricted to only the primary functional aspects of the vacuum extractor as described in section 2.1. Although the design of the vacuum cup may significantly influence the outcome of the vacuum extraction procedure, it can be approached as an independent design challenge and is therefore left outside the scope of this project. For advice with respect to vacuum cup design the literature study attached to the appendix should be consulted.

1.5 Structure

This report follows the structure of a classic *analysis - synthesis - evaluation* approach to the design process as depicted by Yaldiz and Asatekin [20]. To revise the design of the Kiwi OmniCup to allow reuse, cleanability has to be integrated early into the design process. Preparatory to the synthesis, an analysis of the vacuum extractor is performed intended to gain a deeper understanding of the problem and its proposed solutions. Subsequently, a list of device requirements and requirements specific to LMICs is generated. The conceptualization of a solution is decomposed in four distinct design challenges, each of which is broken down into functional parameters. Solutions to each functional parameter are defined and gathered into a morphological chart. From this morphological chart two concepts are generated. Both concepts are validated and evaluated with a prototype on the basis of which a conclusive prototype is created. All three prototypes are subjectively evaluated on usability by the intended user in modern hospital settings. The feedback is used to create a conclusive design. The final chapter provides recommendations for further development of the device.

The following chapter covers the working, structure and variations in design of the vacuum extractor. The first section outlines the basics of the vacuum extractor. Thereafter, an overview and categorization of vacuum extraction devices currently available is provided. The third section breaks down the vacuum extractor into its elementary components based on functionality. The final section of this chapter focuses on the Kiwi OmniCup and its reusable variant.

2.1 Fundamentals

The vacuum extractor, in its essence, is a tool to provide the obstetrician with a comfortable way to apply traction force to the fetus. Applying additional traction force to the fetus allows the obstetrician to move the fetal head in a more favourable position and increase the total expulsion force in order to overcome the resistance of the birth canal and facilitate vaginal birth[21]. Adhesion to the fetus is created by reducing the pressure in an enclosed volume covering a part of the fetal scalp. This pressure difference between the so-called vacuum cup and the atmosphere pushes the cup onto the fetal scalp. Additionally, when a rigid vacuum cup is used, part of the fetal scalp is sucked into the cup as a result of the suction, forming mechanical interlocking between the vacuum cup and the scalp greatly benefiting the cup's adhesion to the scalp [22]. This typical swelling of the fetal scalp, referred to as caput succedaneum or chignon, is often witnessed after vacuum extraction is performed [23].

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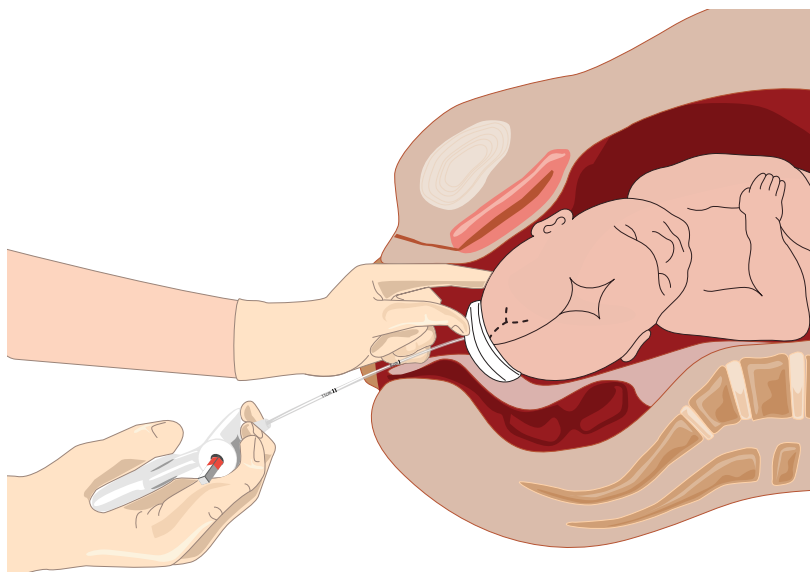


Figure 2.1: Image frame from "5 Step Vacuum Technique instructions" quick reference guide published by Clinical Innovations [24] shows how to properly exert traction force with the Kiwi OmniCup vacuum extractor.

2.2 Available Solutions

As mentioned in section 1.1, different variations of the vacuum extractor exist. Appendix A.1 provides an overview of the different vacuum extractors currently available. In general, three categories of vacuum extractor systems can be distinguished:

Disposable vacuum extractors

Disposable vacuum extractors are single use vacuum extraction systems that eliminate the need for disinfection and sterilization. Additionally, single-use vacuum extraction solutions require no source of electricity, no maintenance and little to no assembly. Although being manually powered, meaning continuous physical effort is required to maintain a stable vacuum, operation of single-use systems is often a lot less laborious than reusable manual vacuum extractors, due to the smaller pump chamber. As a result of the compact form factor and straightforward design (see Figure 2.2), single-use vacuum extractors are generally more easy to use and handle. For this reason the disposable vacuum extractor has gained a lot of popularity. The downside of all this the high price per procedure and constant need for restock. Additionally a high amount of waste is created.



Figure 2.2: An example of a disposable vacuum extractor: The MityOne Vacuum Extraction System equipped with a bell shaped vacuum cup. Alongside the Kiwi OmniCup one of the disposable vacuum extraction systems currently available.[25]

Reusable manual vacuum extractors

Contrary to single-use vacuum extractors, reusable manual vacuum extractors, as the name implies, are designed for reuse. Often through disassembly, the device can be cleaned and sterilized partly or entirely to be used again. Due to its modular nature, most reusable vacuum extractors are compatible with different vacuum cups. Reusable manual vacuum extractors are often simpler than motorized vacuum extractors (see Figure 2.3), require no source of electricity and as a result are generally much cheaper making the reusable manual vacuum extractor an attractive option in low-resource settings. Despite the fact, reusable manual vacuum extractors are generally impractical due to unwieldy design and the necessity for continuous effort.



Figure 2.3: An example of a reusable vacuum extractor: The MityVac Reusable Handheld Vacuum Extraction System. Only the handle, attached to the stem of the cup, is design for exertion of traction. Consequently, two hands are necessary to operate the device or the use is required to switch grip [26]

Motorized vacuum extractors

The motorized vacuum extractor features an electrically operated pump, meaning no physical effort is necessary to maintain the partial vacuum. Subsequently, the stability of the vacuum is independent of the skill and stamina of the operator. Beside the pump, components of the motorized vacuum extractors have to be sterilized before use. Similar to reusable manual vacuum extractors, different vacuum cups are often compatible with motorized vacuum extractors. Maternal tissue and fluid are collected in a liquid trap to prevent debris collecting in the motor. Motorized vacuum extractors are generally bulkier, heavier and harder to move. The main drawbacks are its cost, required access to a power source and periodically need for maintenance and repair.



Figure 2.4: An example of a motorized vacuum extractor: The Medela Vacuum Extraction System. The suction pump can be operated with the foot pedal.[27]

Advantages and disadvantages of device categories

Parameter	Disposable	Reusable manual	Motorized
Affordability	--	+	-
Ergonomics	++	-	+
Maintenance	++	-	--
Cleanability	++*	-	-
Electricity	++	++	--
Assembly	++	--	-

* Disposable vacuum extractors do not require cleaning.

2.3 Device Structure

Although the market overview in section A.1 presents a wide range of variation in vacuum extractors, every vacuum extraction system consists of the same basic elements. In certain devices elements can be difficult to distinguish from one another, however, the vacuum extractor can roughly be divided in the following five main elements:

Vacuum Cup

The vacuum cup is the interface between the fetal scalp and the vacuum extractor, and responsible for creating adequate adhesion when subjected to a partial vacuum. A general distinction is made between rigid and pliable cups (see Figure 2.5). Typically, pliable vacuum cups are associated with reduced fetal scalp trauma [28] whereas rigid vacuum cups experience a lower overall rate of detachment [29]. Due to the properties of flexible material and the method of manufacturing, pliable cups tend to be larger, have thicker walls and an axial symmetry. Consequently, pliable vacuum cups are only suitable for low occiput anterior and outlet presentation births. Rigid vacuum cups, such as the Malmström cup (see Figure 2.7), may additionally also be suitable for birth in transverse, occipito-posterior and difficult occipito-anterior positions[30].

Vacuum Pump

The vacuum pump provides a way to create suction in order to achieve the desired level of partial vacuum. Vacuum pumps may either be powered electrically or manually [31]. Electrically powered pumps are able to maintain a stable amount of partial vacuum without continuous effort of the user, however, access to a power source is necessary. Manually powered pumps are often smaller and cheaper but require continuous physical effort in order to establish the partial vacuum.

Table 2.1: Overview of advantages and disadvantages of vacuum extraction device categories.



Figure 2.5: Side to side comparison of a pliable and rigid vacuum cup. *Left:* The Silc Cup, a pliable vacuum cup. *Right:* The original Malmström cup, a rigid vacuum cup.



Figure 2.6: The original Malmström cup. An airtight connection between the cup and the pump is ensured by the silicone tubing while the traction chain running through the tubing provides the necessary strength.

Suction Tubing

As creation of partial vacuum directly inside the vacuum cup is not realistic, a channel to direct airflow from the vacuum cup to the vacuum pump is needed. The suction tubing provides an enclosed volume to force flow of air from the vacuum cup to the vacuum pump. In most vacuum extraction systems this is facilitated by a silicone tubing, as is the case with the original Malmström cup and Birds version of the Malmström cup (see Figure 2.6).

Traction Handle

The traction handle serves as a gripping-point for the obstetrician to comfortably exert the necessary amount of traction force in order to facilitate birth. The traction handle can be a plain bar (as seen in Bird's version of the Malmström cup Figure 2.7) or integrated into one of the other elements. The traction handle of the Silc cup (see Figure 2.5 *Left*), for example, is integrated into its one-piece design. Differently, the traction handle of Kiwi's OmniCup (Figure 1.1) simultaneously serves as a part of the hand pump.

Traction connection

The vacuum cup, traction handle and the connection between these elements are subjected to high levels of traction force. The suction tubing, and the way it is connected, are often unable to withstand the traction force that is necessary to facilitate birth. As a result, an additional connection between the vacuum cup and pump is generally present. The original Malmström cup (Figure 2.6), for example, utilizes a chain that is mechanically connected to the vacuum cup and pump. Alternatively suction tubing and traction connection may be integrated in one piece as is done with the Mityvac MityOne (see Figure 2.2).

Optional components

The previously mentioned components are essential to the functioning of the vacuum extractor, however, most vacuum extractors available feature additional functionalities. Nearly every vacuum extractor features a vacuum release button, which allows the obstetrician to nullify the created vacuum. Most vacuum extractors also feature a sensor to provide feedback on the created vacuum. Additionally, some vacuum extractors feature a pressure gauge indicating the amount of traction force exerted.

2.4 The (reusable) Kiwi OmniCup

The Kiwi OmniCup, a proven successful device for convenient vacuum extraction, is taken as starting point of the design. The following section specifically analyzes the design of the Kiwi OmniCup and its reusable version.



Figure 2.7: Bird's version of the Malmström cup. A centrally fixed chain provides attachment for the traction handle. A silicone tube is attached to the eccentrically placed tube connector to guide airflow from the vacuum cup to the vacuum pump.

2.4.1 Overview of the Kiwi OmniCup

The convenience of Kiwi's OmniCup primarily stems from its integrated pump and small form-factor that allow for creation of suction alongside exertion of traction with a single hand[14]. Figure A.13 in appendix A.2 provides an overview of the structure of the kiwi omnicup according the elements listed in section 2.3. The piston, directly attached to the traction handle, features a lubricated O-ring which creates an airtight seal against the pump's cover. Two flexible discs both covering a hole and held in place by a plastic retainer, function as check-valves. By squeezing the piston into the cover the volume inside the pump's chamber is reduced. When the piston is released, springs on either side of the pump retract the piston back increasing the volume of the pump's chamber. Due to the configuration of the valves, a partial vacuum is created. The level of partial vacuum inside the vacuum cup is indicated by a calibrated spring extending a rod from one side of the traction handle according to the pressure present inside. On opposite site of the traction handle a button for the release of vacuum is located. A rigid plastic vacuum cup is attached to the traction handle by a tube, which directs the flow of air. The durability of this connection is guaranteed by a metal cable running from the vacuum cup to the traction handle. Because the cable and tubing are recessed into the cup and connected parallel to the its surface, the low profile of the vacuum cup is conserved, making it suitable for assisting births in all positions of the vertec [10, 30] furthermore adding to the convenience of the device.

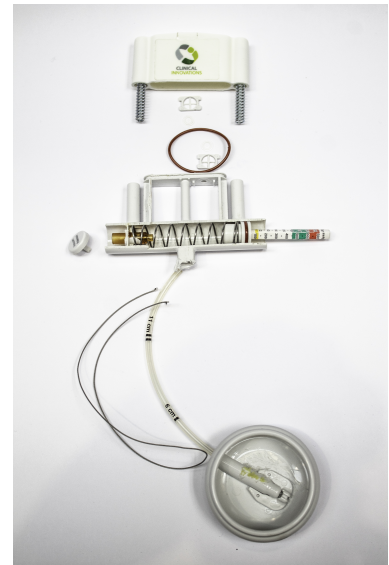


Figure 2.8: Disassembly and section cut of the Kiwi OmniCup.

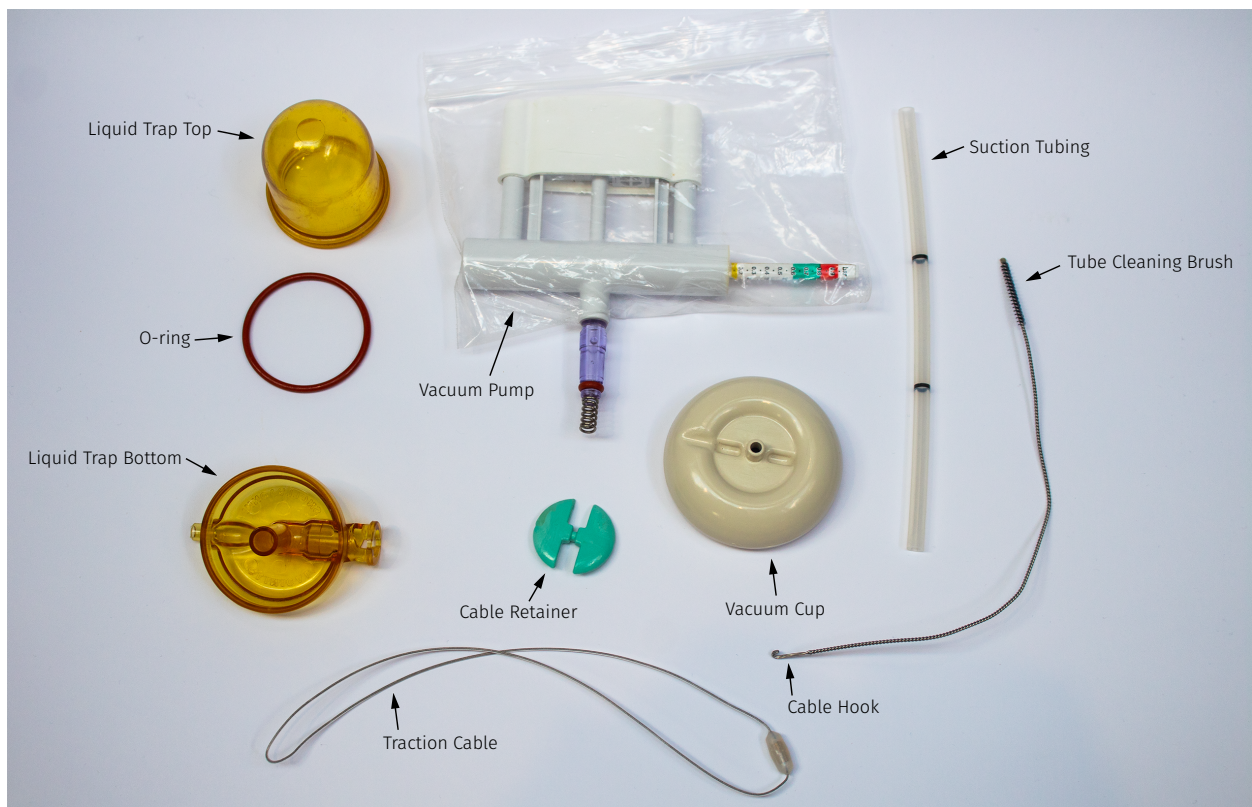


Figure 2.9: Complete disassembly of the reusable Kiwi OmniCup designed by Vacca.

2.4.2 Overview of the Reusable Kiwi OmniCup

The reusable version of the Kiwi OmniCup (Figure 2.10), as mentioned in section 1.3, aims to reduce the cost of use by allowing reuse. The vacuum cup, traction connection and suction tubing can be detached from the device (as seen in figure Figure 2.9) to be cleaned and sterilized. The pump, unchanged from the original Kiwi OmniCup, is not suitable for cleaning, disinfection or sterilization and therefore 'protected' from pathogens by a zip-lock bag. To avoid maternal tissue or fluids from entering the pump, a removable liquid trap to collect debris is mounted to the pump. A silicone tube connects this liquid trap to the cup and a metal cable running through this tube ensures the durability of the connection. To assemble the device, the metal cable has to be run through the liquid trap, the silicone tube and the cup after which the cable is secured by a plastic restrainer. The silicone tube is then slid over the dedicated hole of the vacuum cup and the liquid trap.



Figure 2.10: The reusable Kiwi OmniCup designed by Vacca.

2.4.3 Mathematical Model

To better understand the working of the Kiwi OmniCup, a simplified mathematical model of its pump system can be created based on Boyle's Law. For this calculation the following assumptions are made:

- ▶ Air inside the device is an ideal gas.
- ▶ Air is unable to enter the device and only able to leave the device through the outlet valve.
- ▶ Opening and closing of the valves is assumed to be effortless.
- ▶ No air remains in the piston when it is fully compressed.
- ▶ The spring is not compressed when it is at its maximum height.

The total volume of air relevant for this model is grouped in two segments, divided at the position of the inlet valve.

1. The volume of air demarcated by the piston and the piston-cover (V_{pump}), given by the formula described in 2.1, where A_{piston} is simplified to a rectangle.

$$V_{pump} = A_{piston} \cdot h_{piston} \quad (2.1)$$

Where V_{pump} is the volume of the pump, h_{piston} the distance between the piston and the cover and, A_{piston} , defined by $l_{piston} \cdot w_{piston}$ where l_{piston} and w_{piston} are the length and the width of the piston respectively.

2. The volume of air in the remainder of the device (V_{rest}), given by the formula described in 2.2, where the volume of the tubing and the decrease in volume as a result of the pressure gauge are neglected.

$$V_{rest} = V_{handle} + V_{cup} \quad (2.2)$$

Where V_{handle} is defined as $\pi(\frac{1}{2}d_{handle})^2 \cdot l_{handle}$ with l_{handle} and d_{handle} being the length and diameter of the handle respectively. V_{cup} is approximated with the water displacement method.

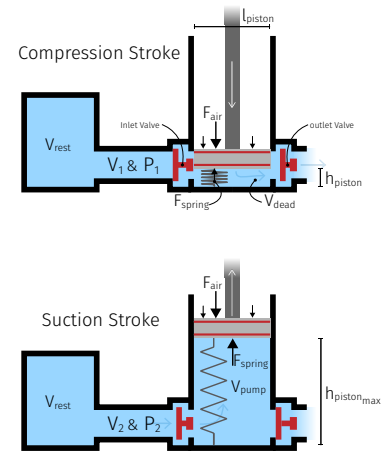


Figure 2.11: Schematic representation of the pump stroke relevant for the calculation of the change in pressure.

The pressure inside the device changes according to the change in volume, as described by Boyle's in equation 2.3, unless the air is able to flow freely through one of the valves.

$$P_1 \cdot V_1 = P_2 \cdot V_2 \quad (2.3)$$

Where P_2 is the new pressure inside the device, P_1 the current pressure inside the device, V_1 defined by the sum of V_{pump} and V_{rest} when h_{piston} is at its minimum and V_2 defined by the sum of V_{pump} and V_{rest} when h_{piston} is at its maximum.

When the piston is squeezed into the pump, h_{piston} decreases and thus V_{pump} decreases. As a result, the pressure inside the pump (P_{pump}) increases, forcing air to escape through the outlet valve equating P_{pump} again to P_{atmos} . When the piston retracts as a result of the springs, h_{piston} increases, causing V_{pump} to increase and, as a result, P_{pump} to decrease. The inlet valve allows air to flow from V_{rest} to V_{pump} , equating the pressure in the pump and the cup. As a result the pressure in V_{rest} (P_{rest}) decreases. After each pump cycle the air pressure decreases and the position of the piston reaches an equilibrium according to the the force of the air pressure (F_{air}) and the force exerted by the spring (F_{spring}), expressed as $F_{air} = F_{spring}$. Where F_{air} and F_{spring} are defined as:

$$F_{spring} = kx = k(h_{piston_{max}} - h_{piston}) \quad (2.4)$$

$$F_{air} = PA = (P_{atmos} - P_2) \cdot A_{piston} \quad (2.5)$$

Therefore:

$$k(h_{piston_{max}} - h_{piston}) = (P_{atmos} - P_2) \cdot A_{piston} \quad (2.6)$$

According to Boyle's law as described in A.1 P_2 can be expressed as:

$$P_2 = \frac{P_1 \cdot V_1}{V_2} = \frac{P_1 \cdot V_{rest}}{V_{rest} + h_{piston} \cdot A_{piston}} \quad (2.7)$$

Replacing P_2 in Equation 2.6 with that what is defined in Equation 2.7 gives:

$$k(h_{piston_{max}} - h_{piston}) = (P_{atmos} - \frac{P_1 \cdot V_{rest}}{V_{rest} + h_{piston} \cdot A_{piston}}) \cdot A_{piston} \quad (2.8)$$

Which can be rewritten as:

$$ah^2 + bh + c = 0 \quad (2.9)$$

Where:

$$\begin{aligned} a &= -k \\ b &= k \cdot h_{piston_{max}} - \frac{k \cdot V_{rest}}{A_{piston}} - P_{atmos} \cdot A_{piston} \\ c &= \left(\frac{k \cdot h_{piston_{max}}}{A_{piston}} + P_1 - P_{atmos} \right) \cdot V_{rest} \end{aligned}$$

Listing 2.1: The following values are used:

$$\begin{aligned} l_{piston} &= 45 \cdot 10^{-3} \text{ m} \\ w_{piston} &= 10 \cdot 10^{-3} \text{ m} \\ h_{piston(max)} &= 0.03 \text{ m} \\ P_{1(start)} &= P_{atmos} = 101325 \text{ Pa} \\ V_{rest} &= V_{cup} + V_{frame} \\ V_{cup} &= 20 \cdot 10^{-6} \text{ m}^3 \\ V_{frame} &= \pi \left(\frac{1}{2} d_{handle} \right)^2 \cdot l_{handle} \\ d_{handle} &= 0.01 \text{ m} \\ l_{handle} &= 0.10 \text{ m} \\ k &= 2 \cdot 2 \cdot 10^3 \text{ N/m (See Appendix A.3.1)} \end{aligned}$$

Solving for h gives the h_{piston} after each subsequent cycle of the pump. Knowing h_{piston} , the pressure at the end of each pump cycle can be calculated. Figure 2.12 visualizes the change in pressure after consecutive pump cycles.

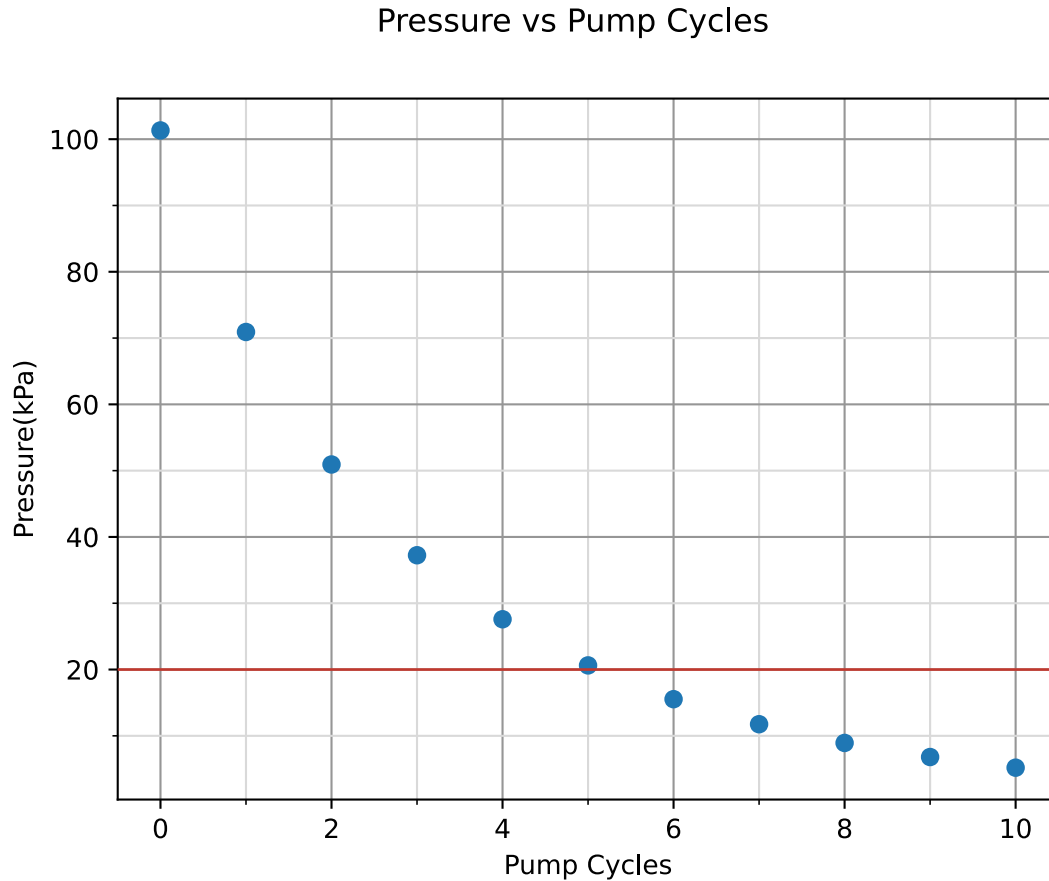


Figure 2.12: Plot of the decrease in pressure with each subsequent stroke of the pump.

The plot shows that about 5 pump cycles are necessary to achieve the desired pressure. This however is without any dead volume which has a significant effect on the pump cycles required (see section 4.1.1).

2.5 Conclusion

The vacuum extractor provides the obstetrician with a comfortable way to apply traction force to the fetus. From the market analyses in section 2.2 can be concluded that no convenient in use (handheld and one hand operated), affordable and reusable vacuum extraction device suitable for low- and middle-income countries is available. A reusable manual vacuum extractor seems the most favorable solution to solve this due to low maintenance and upkeep cost. To achieve this, each component of the vacuum extractor requires its design revised to accommodate cleaning and sterilization.

To make vacuum extraction devices more accessible in low-resource countries, a low cost, easy to use vacuum extractor should be developed. Beside ergonomic and affordability requirements, several other requirements have to be met before the device can be considered a potential successful solution. Park, Kim, and Shin [32] devised a framework for evaluating medical devices. Combined with additional literature, the following chapter aims to define the requirements for a functional, reusable vacuum extractor suitable for low-resource hospital settings.

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3.1 Device Specific Requirements

From the aforementioned goal, three device specific requirements fundamental to the success of this project can be derived: functionality, ergonomics and cleanability.

3.1.1 Functionality

As mentioned in section 2.1, the vacuum extractor is essentially a tool to provide the obstetrician with a comfortable way to exert traction on the fetus. In order to facilitate this, the device first has to be capable of creating the required level of partial vacuum. Secondly, the device may not fail under the exerted traction force¹.

Traction Force

Several studies report measurements of traction force during vacuum extraction. Vacca [13] found that, when the correct technique is employed, 113 N traction force is sufficient to achieve vaginal birth in 79.8% (n=95) of the cases and no more than 132 N is necessary to achieve birth in virtually all cases. Baskett, Fanning, and Young [11] reports similar findings, indicating that for 85.7% (n=480) of the vacuum extractions, less than 111 N traction force was necessary to achieve birth. Saling and Hartung [33] reported significantly higher traction forces, with 29.7% (n=22) of the cases needing more than 194N traction force to achieve birth. Hofmeyr et al. [34] reported a maximum of 193 N traction force (n=18). A recent study by Pettersson et al. [35] showed maximum values of traction force can get as high as 452 N. Unfortunately no preexistence, quantitative standard exist with respect to failure [36]. Measurements of traction force diverge significantly², to remain within safe margins, the highest reported force is assumed. Additionally a safety factor is applied. The load at failure can be calculated with the formula in equation 3.1.

1: While other functions, such as a vacuum release or pressure gauge, may be essential for convenient use, they are ignored as of now since they are not essential to the functioning of the device.

2: See the literature review attached for further information.

Concluding that, the device should be able to survive traction forces of up to 904N.

$$F_{failure} = F_{Design} \cdot SF = 452N \cdot 2 = 904N \quad (3.1)$$

Where $F_{failure}$ is the load at failure, F_{Design} is the estimated maximum load, in this case 452N and SF the Safety Factor in this case 2.

Suction Force

To prevent cup detachment, a sufficient level of partial vacuum inside the vacuum cup is necessary [37]. The required level of vacuum can be approached with the formula $P = \frac{F}{A}$ where P is the required level of vacuum, F the traction force applied and A the area of the cup. However, the adhesion force as a result of the mechanical interlocking is not taken into account. Consequently, the traction capacity of the cup at a certain vacuum in reality is much higher [38]. Required levels of partial vacuum are difficult to calculate accurately due to the complex nature of the cup's adhesion. Furthermore no extensive literature on safe levels of vacuum is present. Recommended levels for vacuum are largely based on trial and error. Kuit [22] summarized seventeen articles published prior to 1997 and concluded that a level of partial vacuum between $7N/cm^2$ (0.07 MPa) and $8N/cm^2$ (0.08 MPa) with a temporary increase up to $9N/cm^2$ (0.09 MPa) is generally accepted. Subsequently, the device should be able to provide a partial vacuum of at least 0.08 MPa.

3.1.2 Ergonomics

Achieving a degree of convenience similar to that of the Kiwi OmniCup is paramount to the success of the device. Fundamental to the ergonomics of the Kiwi OmniCup is its one-handed operability, allowing creation of vacuum as well as exertion of traction force with the same hand. This leaves the other hand free to ensure correct positioning and adhesion of the cup which is essential to a successful vacuum extraction procedure [39]. Moreover, no additional staff to create and maintain the suction is necessary

Grip strength and span

Operation with a single hand means forces that need to be provided may not exceed that which can be comfortably supplied by one hand. Additionally, grip span should not exceed comfortable lengths. Maximum grip force is dependent on the grip span, as measured by Lee et al. [40]. When suction is created through a squeezing motion of the hand, similar to that of the Kiwi OmniCup, grip span and necessary force should be adjusted according to the table shown in 3.1.

	45 mm (N)	50 mm (N)	55 mm (N)	60 mm (N)	65 mm (N)
Overall	427.9	430.8	433.6	414.6	378.0
Small hand	411.2	410.9	404.8	391.2	354.6
Medium hand	438.9	442.4	447.1	411.7	378.1
Large hand	459.3	470.5	495.6	483.3	443.0

Table 3.1: Maximum levels of achievable gripping force. From Lee et al. [40].

Size and Weight

The size and weight of the device should allow the obstetrician to hold the device with a single hand for the entire duration of the procedure (limited to 20-30 minutes [41]). The US Department of Defense in "Human engineering design guidelines" states that for handheld devices, dimensions should be less than 10 x 25 x 13 centimeters and weight should not exceed 2.3 kg [42]. When traction force is exerted with the device, a momentum may be created due to the positioning of the traction cable's attachment point. To limit strain on the wrist, momentum should be minimized by positioning the attachment point in line with the wrist.

3.1.3 Cleanability

Defining requirements for the cleanability of reusable medical instruments in general is a complex task as a multitude of factors play an important role. To ensure the design of an instrument can be properly cleaned in order to be used again, four facets of cleaning have to be covered: Device Design, Device Compatibility, Instruction for Use and the human factor. The process of cleaning itself can be divided in three levels: Point-of-use processing, thorough cleaning and sterilization or disinfection [43] as is further described in Appendix A.4.

Device Design

The importance of thorough cleaning is often overlooked. When soil is left in the device, proper disinfection and sterilization is not possible[44]. The device should be designed such that the removal of all soil is attainable. Appendix A.4.3 provides an overview of strategies to achieve this goal. Appendix A.4.2 provides a list of features that should be avoided or implemented with extra consideration when designing a reusable medical instrument. Because low-resource settings often do not possess over advanced cleaning equipment, the device should be cleanable with basic cleaning tools. Depending on the application either disinfection or sterilization of the device is necessary, as specified by the CDC[45] summarized in Appendix A.4.1. The vacuum cup and tubing will come in contact with mucous membrane and therefore require high-level disinfection. The remaining parts of the device only require low-level disinfection.

Cleaning Compatibility

A wide range of disinfection and sterilization methods exist, however, designing a device that can be sterilized equally well by multiple methods is generally not worthwhile [46]. For this reason it is better to focus on a single method of disinfection/sterilization. Oosting [47] emphasizes the need for context-specific equipment, as instruments can not be used safely without proper sterilization. In low-resource settings, sterilization and high-level disinfection are often performed with crude methods such as using boiling water [48] or harsh chemical[49]. Consequently, material and design appropriate for this method of sterilization have to be designed. In this project, the device will be designed to be sterilized with a glutaraldehyde-based formulation, as used in Mulago National Referral Hospital for vacuum extraction systems.

Instruction For Use (IFU)

Adequate design and use of materials is essential for cleanability, however, a device designed for disinfection or sterilization is only reusable when the cleaning procedure is correctly followed. For this reason, the device should come with a concise step by step guide for cleaning of the equipment in low-resource settings[50].

3.2 LMIC Specific Requirements

Medical instruments specifically designed for low-resource settings require careful consideration of the context of use. While affordability is a primary barrier to the accessibility of medical instruments in developing countries, it is a misconception that it is always the primary barrier [51]. The following section lists three factors additional to affordability that are vital to the success of medical instruments in low-resource settings.

3.2.1 Affordability

Creating more affordable and sustainable devices is a critical step towards making medical instruments more accessible in developing countries [52]. To achieve this, medical devices have to be designed specifically for the world's poorest [53]. Affordability, however, is a relative term and dependent on the benefits of the implementation of the technology. Although dropping, maternal and neonatal morbidity is still a widespread problem, especially in developing countries [54, 55]. Vacuum extraction, as opposed to caesarean delivery, may be implemented to reduce maternal and neonatal risk [8].

The Cost of Vacuum Extractors

UNICEF provides an indicative price of 546.45 USD for a manual reusable vacuum extraction set³ [56], although similar vacuum extraction systems are sold on Indiamart for as low as 16 euro [57]. The difference in price may be attributed to quality and quality control. The Kiwi OmniCup

3: In their supply catalogue accessed on 6th of April 2021

retails for a price of around 40 EUR [58], which is a steep investment per extraction considering that manual reusable vacuum extraction sets can be acquired for less than half that price. More advanced vacuum extraction units however, such as the Mityvac Reusable Handheld Pump, retail for significantly higher prices on Indiamart[59]. To earn a competitive spot in the vacuum extraction market, retail prices of a proposed solution should equal to that of low-price manual reusable vacuum extraction sets.

3.2.2 Spare parts & Consumables

Malkin [60] identified "a lack of spare parts" and "lack of consumables" along with cost to be the main principal, design-related barriers to the accessibility of health care technology in developing countries. Independently of cost, spare parts and consumables are often hard to acquire in low-resource countries due to lacking infrastructure and organization [61]. Equipment eventually needs repair and without the right spare parts, equipment only lasts up until that moment. Malkin [60] specifies numerous issues that may hinder the availability of spare parts: the spare parts are not made anymore, the hospital does not possess the required payment methods to acquire spare parts or the cost of spare parts is simply too high. Medical devices for low-resource settings have to be designed with repair in mind. When maintenance requires spare parts, hospitals benefit when these parts are easily obtainable.

3.2.3 Challenging Environments

Clinical settings in low-resource countries are often deprived of facilities necessary to utilize equipment designed for developed countries. Functioning and proper cleaning often require access to a power source and/or running water, without most modern equipment is rendered useless [62]. When (improvised) facilities allow utilization of medical devices, challenging environments demand for more often repair [47]. Even when spare parts are available, the lack of tools may obstruct proper repair. Designing medical devices for low-resource setting requires taking into account relying on sub-standard facilities for use and maintenance.

3.2.4 Training & Instructions

Perry and Malkin [63], aiming to find the percentage of donated medical devices out of service, reported an average of 38.3% of medical equipment to be non-functioning, with the lack of training being one of the main reasons. Similarly, Peña-Mohr [64] reported 39% of the equipment donated to developing countries to never having worked with lack of training and manuals as one of the main reasons. This goes to show that the lack of proper training and instructions is a real obstacle in third world hospitals and can restrict the use of equipment. Especially considering that most medical equipment is designed for developed countries. Therefore, medical devices should be supplied with instructions and staff should be adequately trained.

3.3 Overview of Requirements

R1. Functional Requirements

R1.1 The device should be able to survive traction force levels of up to 900N applied to the opening of the vacuum cup and the traction handle [35].

R1.2 The device should provide the ability to create suction up to at least 0.08 MPa of partial vacuum (0.02 MPa absolute pressure) [22].

R2. Ergonomical Requirements

R2.1 Creation of the partial vacuum (defined in R1.1) and exertion of adequate traction force (defined in R1.2) should be completely achievable with a single hand.

R2.2 Grip strength required to reach the partial vacuum defined in R1.2 should be no higher than values defined by Lee et al. [40] according to the span of the pump's grip.

R2.3 Span length of the pump's grip should be no larger than the values defined by Lee et al. [40] in accordance with the grip force required to achieve partial vacuum defined in R1.2.

R2.4 Dimensions of the handheld pump should not exceed 10 x 25 x 13 centimeters as defined by the US Department of Defense [42].

R2.5 The total weight of the device should not exceed 2.3 kg as defined by the US Department of Defense [42].

R2.6 Positioning of the traction cable attachment should be in line with the wrist, provide a natural traction movement and stimulate traction in ideal direction.

R3. Cleanability Requirements

R3.1 The device should be designed such that removal of soil on all surfaces is attainable [44].

R3.2 The vacuum cup and suction tubing should be compatible with high-level disinfection available in low-resource settings [48, 49]. For this report glutaraldehyde-based formulation disinfection is assumed as high-level disinfection method [65].

R3.3 The device, apart from the vacuum cup and suction tubing, should be compatible with low-level sterilization available in low-resource settings [48, 49]. (Similar to the vacuum cup and suction tubing glutaraldehyde-based formulation disinfection is assumed as low-level disinfection method[65].)

R3.4 At least 500 cleaning cycles should be passed without impacting the functionality ergonomics or cleanability of the device.

R3.5 The material of the components subjected to high-level sterilization should be bio-compatible.

R4. Affordability Requirements

R4.1 The retail price of the device should be within the range of the Kiwi OmniCup, about 40 euros.

R5. Spare parts & Consumables

R5.1 Potential spare parts necessary for repair of the device should easily be obtainable.

R5.2 The necessity of consumables for the functioning of the device should be avoided as much as possible in the design.

R6. Challenging Environments

R6.1 Designing medical devices for low-resource settings requires taking into account relying on sub-standard facilities for use and maintenance.

R6.2 The device should be repairable with commonly available tools.

R6.3 Cleaning of the device should be attainable with basic cleaning equipment such as brushes and scourers.

R7. Training & Instructions

R7.1 The device should come with a concise step by step guide for cleaning of the equipment in low-resource settings[50].

R7.2 Proper training should be provide through either in person or through digital substitutes.

R7.3 The device should come with a concise step by step guide for use.

**DESIGN OF THE VACUUM EXTRACTOR
FOR LOW- AND MIDDLE-INCOME COUNTRIES**

Conceptualization

4

The following chapter covers the steps taken to achieve a concept of a reusable one-handed vacuum extractor.

Problem breakdown

Section 2.3 demonstrates how vacuum extraction systems can be divided into five distinct elements. While each element is related to the others in a sense that they ought to be compatible, individual elements can be approached as independent design problems. In order to simplify the design process, the device is broken down in different components according to section 2.3. Each component requires it's design revised to meet the requirements listed in section 3. Besides its fastening to the traction connection and suction tubing, the design of the vacuum cup is initially disregarded as this is outside the scope of the project. Components are broken down further in functional parameters (FP) which serve as the starting point for the ideation. The functional parameters together with its solutions are compiled in a morphological chart from which concepts are generated.

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4.1 Vacuum Pump

The use of lubrication and O-rings in the Kiwi OmniCup, which is vital to the working of piston pumps, hinders proper cleaning as debris is easily retained[67, 68]. This is one of the reasons why the Kiwi OmniCup is unsuitable for reuse. Disassembly of the pump (including the O-ring) and reapplication of lubrication after sterilization may pose a solution[69], however leaves the user with significant preparations before use. For this reason, a different pump system is preferred. Robison, Beaty, et al. [66] provides an overview of classifications of commonly used pumping mechanisms (Figure 4.1). Aside from the reciprocating positive displacement pump,¹ the pump mechanisms presented in Figure 4.1 are either unsuitable with manual operation, too large or too complex for convenient cleaning, leaving only the reciprocating positive displacement pump as a potential solution. Three types of reciprocating positive displacements can be differentiated: piston pumps, plunger pumps and diaphragm pumps (see Figure 4.2). The piston pump and similarly the plunger pump are incompatible with this application for the aforementioned reason. As a result, only the diaphragm pump may be a potential solution.

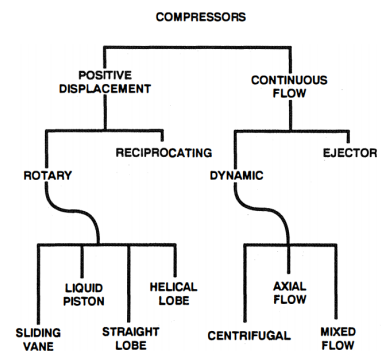


Figure 4.1: Overview of classifications of compressor types. Although Robison, Beaty, et al. [66] describes compressors, compressors and vacuum pumps are in principle comparable [66].

1: A Reciprocating positive displacement pump move fluid through a system by repeatedly enclosing a fixed volume with mechanical back-and-forth movement.

4.1.1 Diaphragm Pump

The diaphragm pump, in contrast to the piston pump, relies on the flexibility of its membrane for change in volume and therefore requires

no O-rings or lubrication which makes it a suitable system for a cleanable pump[70]. The diaphragm pump requires a chamber sealed (FP1.2) by a diaphragm (FP1.1) and two check valves to work (FP1.3 & FP1.4).

FP1.1 Diaphragm Type

The design of the diaphragm is dependent on its hardness and constrained by the maximum allowable size of the dead volume. Materials such as TPE's or silicone may be utilized to create bio-compatible diaphragms. A flexible diaphragm allows for more organic forms of deformation (See Figure 4.3 top), where as a stiffer diaphragm requires its design to be adapted to the desired deformation (See Figure 4.3 bottom). In turn, a stiffer diaphragm is more resilient and therefore might be more suitable to create an airtight connection without the need of an additional mounting system (see FP1.2) or function as a spring to supply counter-force (see FP2.1). The ratio of dead volume² to total volume of the pump's chamber, determines the maximum level of partial vacuum achievable by the membrane pump according to equation 4.1 [71].

$$V_{dead_{max}} = \frac{P_{des}}{P_{atmos}} \cdot V_{pump} \quad (4.1)$$

An ideal system is assumed implying air functions as an ideal gas, no leakage of air from the system, no deformation of the device, effortless valves and the pump returns to its original position after each pump cycle. Where $V_{dead_{max}}$ is the maximum allowable size of the dead volume, P_{des} the level of partial vacuum to be achieved, P_{atmos} the atmospheric pressure and V_{pump} the total volume of the pump's chamber. See appendix A.3.2 for further details.

As shown in section 2.4.3, the volume of the pump's chamber decreases with each subsequent pump cycle due to the force as a result of the decrease in pressure. This decrease of volume affects the maximum allowable size of the dead volume. Taking this into account in Equation 4.1 gives Equation 4.2.

$$V_{dead_{max}} = \frac{P_{des}}{P_{atmos}} \cdot \left((h_{diaphragm_{max}} - \frac{(P_{atmos} - P_{des}) \cdot A_{diaphragm}}{k}) \cdot A_{diaphragm} \right) \quad (4.2)$$

Again, an ideal system is assumed. Where $V_{dead_{max}}$ is the maximum size of the dead volume, P_{des} the level of partial vacuum to be achieved, P_{atmos} the atmospheric pressure and V_{pump} the total volume of the pump's chamber.

Figure 4.4 shows the effect of size of the dead volume on the change in pressure in the Kiwi OmniCup after subsequent pump cycles. See appendix FIXME for the equation

FP1.2 Diaphragm connection to pump

A sealed volume is critical to the functioning of the pumping system, however, for thorough cleaning all surfaces have to be accessible. Disassembly of the pump's chamber is therefore required. A seal between the diaphragm and pump's chamber that ensures an airtight connection

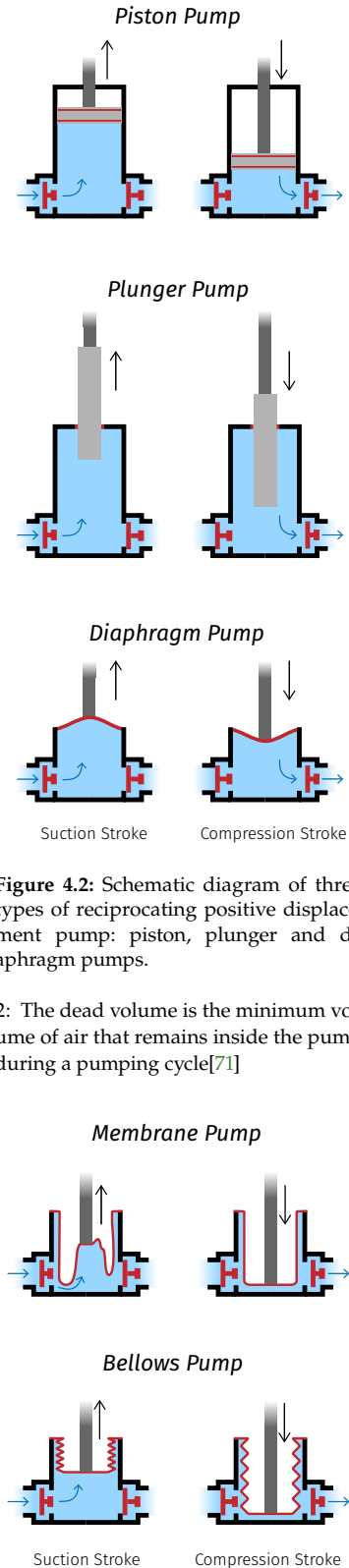


Figure 4.2: Schematic diagram of three types of reciprocating positive displacement pump: piston, plunger and diaphragm pumps.

2: The dead volume is the minimum volume of air that remains inside the pump during a pumping cycle[71]

Figure 4.3: Schematic diagram of a membrane and bellows pump.

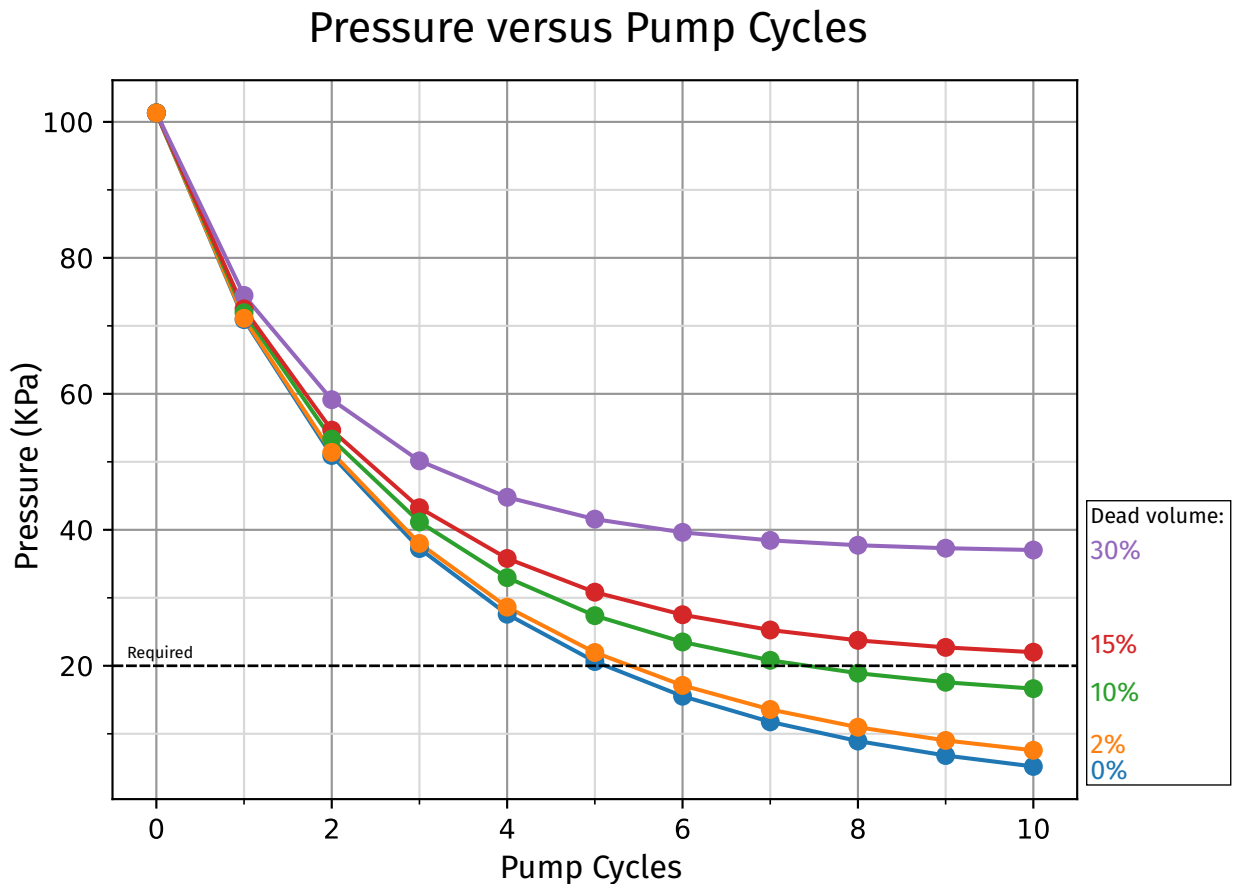


Figure 4.4: Effect of the size of the dead volume on the change in pressure after subsequent pump cycles.

and is simultaneously detachable may solve this problem. **Figure 4.9 R1.2** gives an overview of different mounting systems that can provide such a seal. A careful consideration has to be made between functionality and complexity as increased complexity is generally accompanied by increased cost and decreased cleanability.

FP1.3 & FP1.4 Check Valves

Two check valves, also known as one-way valves or non-return valves, direct the flow of air and ensure the desired change in pressure. Check valves vary greatly in shape, size, complexity and performance for different applications[72]. **Figure 4.9 R1.3 & R1.4** provides an overview of different check valves. Two important parameters of check valves are the cracking (opening) pressure and reseal (closing) pressure. Opening of the valves as early as possible is desirable for this application and therefore valves with low cracking and reseal pressure are favored. The valves inside the pump add an additional layer of complexity. To minimize further disassembly, valves should be optimized for cleanability.

4.2 Traction Handle

The handle should be comfortable to hold, however, in order for creation of suction and exertion of traction to be achievable with the same hand, the actuation of the pump has to be integrated into the traction handle taking into account force, motion and range of operation (FP2.1) & (FP2.2).

4.2.1 Ergonomics

As mentioned in section 3.1.2, essential to the convenience of the handle is the maximum range of movement and the maximum force required to create suction. The force required to increase the volume of the pump's chamber by moving the diaphragm is determined by the area of the diaphragm as shown in Equation 4.3.

$$F = P \cdot A \quad (4.3)$$

Where F is the force on the diaphragm as a result of the pressure, P is the pressure inside the pump and A the area of the diaphragm.

The greater the area of the diaphragm, the higher the amount of force necessary to create suction. Increasing the area of the diaphragm also means the volume of the pump increases. As a result, more air is displaced per stroke of the pump meaning less strokes are necessary to reach the desired vacuum. The same result can be achieved by increasing the height of the pump, however, as a result pumping strokes become greater in distance, and thus a large grip span is necessary.

FP2.1 Counterforce

A pump cycle consist of a motion in two directions: one to decrease the chamber volume and one to increase the volume. Considering that motion opposite to squeezing allows for significantly less force and is generally less comfortable, it is ergonomically beneficial to implement a source of counter force [73]. As a result only one direction of motion has to be supplied by the hand (see Figure 4.5). The counter-force may be supplied by different features, textbfFigure 4.9 R2.1 show an overview of different features that may provide the required counter-force (FP2.1).

FP2.2 Translation of Motion

Opposed to a unidirectional movement in the handle, as seen in the Kiwi OmniCup (Figure 1.1), a rotational movement may be utilized, as seen in the MityOne (Figure 2.2). The direction, distance and required force of the pump can be influenced by using the principle of a lever (FP2.2). Three classes of levers are distinguished, with each an inverted version: a class one lever, having the fulcrum between the effort and the load; a class two lever, having the load between the effort and the fulcrum and a class three lever, having the effort between the fulcrum and the load (see Figure 4.6). Table 4.1 shows the influence of each type of lever on the system. Each lever type is included in the Morphological chart (Figure 4.9 R2.2).

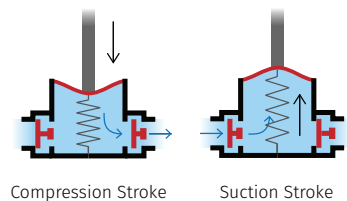


Figure 4.5: Schematic diagram of a diaphragm pump with a spring.

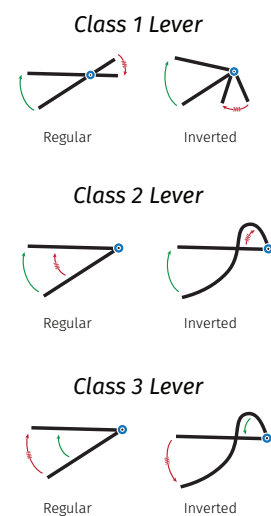


Figure 4.6: Schematic representation of the three classes of lever. Blue indicates the point of the fulcrum, red indicates the load and green indicates the effort.

Lever Type	Direction	Force	Range
Class 1 Regular	Equal	Dependent*	Dependent*
Class 1 Inverted	Inverted	Dependent*	Dependent*
Class 2 Regular	Regular	Decreased	Increased
Class 2 Inverted	Inverted	Decreased	Increased
Class 3 Regular	Regular	Increased	Decreased
Class 3 Inverted	Inverted	Increased	Decreased

* Dependent on the load-fulcrum length in relation to the effort-fulcrum length.

4.3 Traction Connection

The device will be subjected to high levels of traction force, as described in section 1, therefore a strong connection between the cup and pump is vital. Consequently, a medium with a high resistance to traction force (FP3.1) that can adequately be attached to the vacuum cup (FP3.2) and vacuum pump (FP3.3) is required.

FP3.1 Traction Cable

Different types of cables may be included to achieve the desired strength of the cup-pump connection. The Kiwi OmniCup, for example, solves the issue of traction force with a nylon coated metal wire rope running through the tubing mechanically connected to the vacuum cup and pump (as seen in figure Figure 2.8). The traction cable ought to be flexible and not obstruct use. Figure 4.9 R3.1 provides different solutions for traction cables.

FP3.2 & FP3.3 Traction Connection

The complexity of selecting a proper traction cable lies in its connection to the rest of the device. To ensure the device can be cleaned and sterilized properly, the traction cable and vacuum cup should be detachable from the device, especially since both cup and and its connection to the vacuum pump require a higher level of disinfection than the rest of the device. Figure 4.9 R3.2 & R3.3 show different type of connections that may pose as a potential solution.

4.4 Suction Tubing

Creation of suction directly inside the vacuum cup is not realistic, as mentioned in section 2.3, therefore, a medium (FP4.1) has to be found that connects to both vacuum cup (FP4.3) and vacuum pump (FP4.2) and guides the flow of air from one to the other.

Table 4.1: Effect of each lever class on the direction, force and range of the concept.



Figure 4.7: Different types of traction cables seen on metal cups. *Left:* The Malmström Cup, *Middle:* The BIRD-Malmström Cup. *Right:* Bird's revised version of the BIRD-Malmström Cup.

FP4.1 Suction Tubing

Air can simply be guided with the use of tubing. However, to avoid the necessity of an additional connection specifically to withstand traction force³ and as a result enhance cleanability, the tubing and its connection to the rigid parts of the vacuum pump and cup should be able to withstand the required levels of traction force as listed in section 1. Unfortunately, flexible tubing and especially its connection to rigid parts is generally not able to endure high levels of traction force. As a result the main deterministic factor for selection of tubing, beside the requirements listed in chapter 3, is its ability to form a connection with the rigid parts of the vacuum pump. Figure 4.9 R4.1 shows different solutions for suction tubing.

FP4.2 & FP4.3 Tubing Connection

Similar to the traction cable, the suction tubing and vacuum cup should be detachable from the device. To achieve this, a detachable connection between the suction tubing and the vacuum pump is required. The advantage of joining a flexible and rigid part is that a detachable airtight connection can be achieved without the need for additional sealant. A disadvantage however is that a strong bond between a flexible and a rigid part is hard to achieve. Figure 4.9 R4.2 & R4.3 show different possibilities for connecting the tubing to the vacuum cup and pump.

4.5 Concept Creation

The aforementioned functional parameters are summarized in the morphological chart seen in Figure 4.9. Different potential solutions to the functional parameters are explored through web-search or derived from existing devices. These sub-solutions are included, on the basis of the design requirements listed in chapter 3, in the corresponding row of the morphological chart.

From each row a solution is selected and combined to create a concept for functional validation. Selection of sub-solution is based on evaluation of functionality, cleanability, affordability and its compatibility with other solutions to form an ergonomically responsible design. Complexity is often a good indicator for cleanability and affordability. For this reason more simple solutions are favored over more complex solutions. As a working prototype will be created in the following chapter, availability and prototypability of the sub-solutions inevitably play a role in selection of solutions.



Figure 4.8: Different types of tubing with the potential to resist high levels of traction force. From top to bottom: Metal wire reinforced PVC tubing[74], Nylon mesh braid reinforced PVC tubing[75], normal PVC tubing[76].

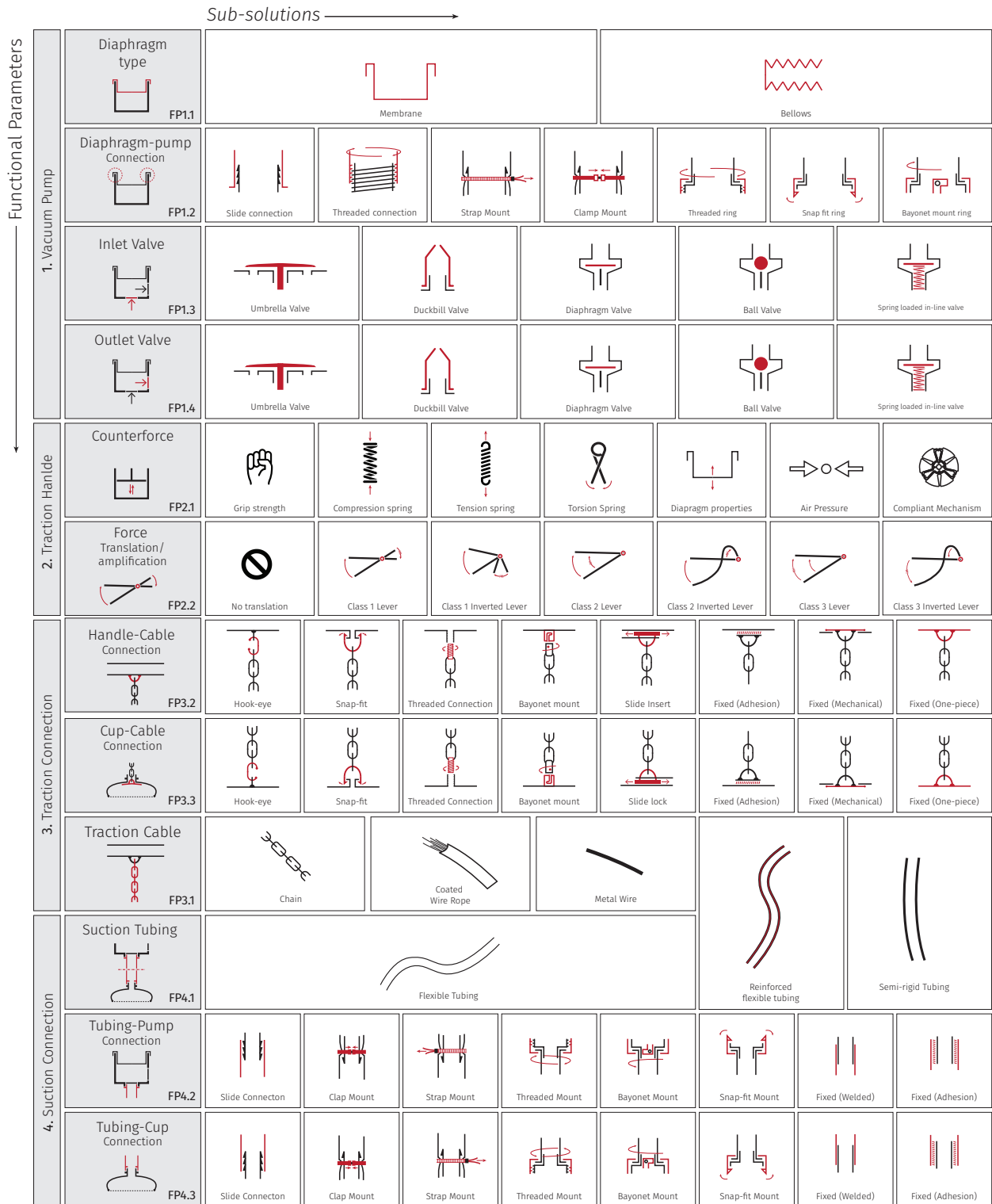


Figure 4.9: The morphological chart. An overview of the functional parameters and the associated sub-solutions are provided in the morphological chart.

4.5.1 Concepts

Two concepts are created: one utilizing a cup-shaped membrane (Figure 4.10) and one utilizing a bellows-shaped diaphragm (Figure 4.11). Both concepts are designed with cleanability in mind. Most surfaces can be accessed and cleaned. The insides of the pump are accessible through disassembly, by removing the diaphragm. The channels and tubing can be cleaned through flushing, as described in Appendix A.4.3, or with the use of a tube brush (as seen in Figure 2.10). The inside of the bellows may be cleaned with a round brush.

Concept A

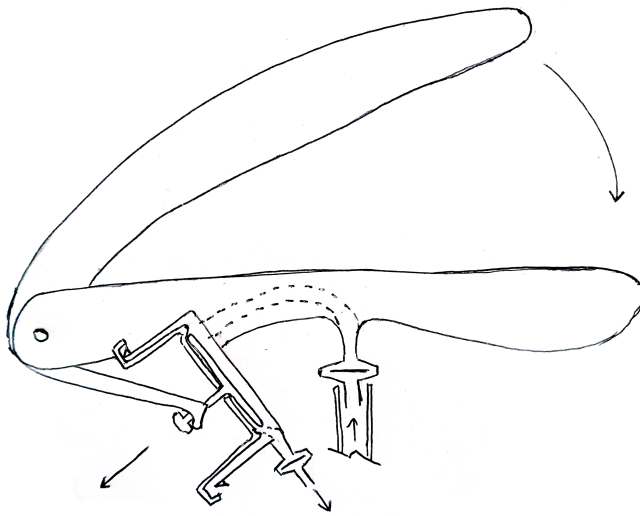


Figure 4.10: *Concept A:* The membrane is attached to the pump by sliding over the edges of the pump's chamber. In- and outlet valve are both diaphragm valves for easy attachment. The counter-force is supplied partly by the air pressure and the diaphragm's material properties. The frame and handle of the pump form a class 1 inverted lever. A reinforced silicone tubing, fixed with adhesion to the cup and pump, functions as both traction cable and suction tubing.

Concept B

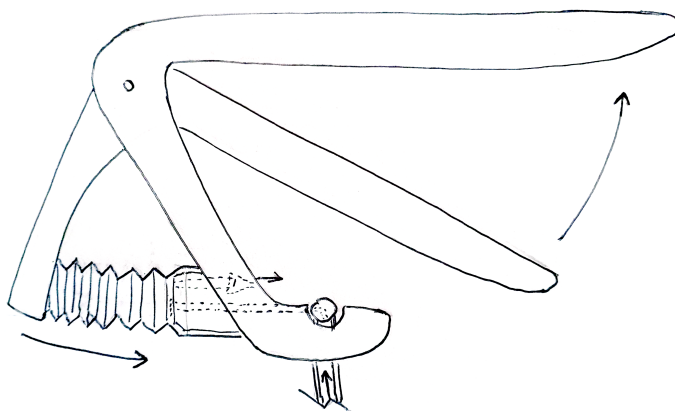


Figure 4.11: *Concept B:* The bellows is attached to the pump, similar to the concept A, by being slid over the pump's frame. An umbrella valve functions as inlet valve, while a duckbill valve functions as outlet valve. The frame and handle function as a class 1 lever. Reinforced silicone tubing is used as traction cable and suction tubing. The vacuum cup is fixed to the tubing, and attaches to the frame with a simplified bayonet mount.

The functional requirements defined in chapter 3 are paramount to the success of the device. The following chapter seeks to validate the performance of the concepts created in chapter 5. Because an early prototype is likely not representative of the structural integrity of the final designs, only the ability to provide adequate suction force will be validated. The capacity of the device to survive high levels of traction force is mainly dependent on device material, thickness of critical features and the method of joining individual components which may be easily adjusted accordingly in later phases of development.

5.1 Validation Method

The aim of this validation is to prove that both membrane and bellows pump described in section 4.1.1 can successfully be integrated in a handheld vacuum extraction device and simultaneously are capable of producing adequate suction by hand. Two proof of concept prototypes are created: prototype A, featuring a membrane (described in section 5.1.1); and prototype B, featuring a bellows (described in section 5.1.2). A manometer, measuring pressure between 0 and -0,1 MPa (0,1 and 0 MPa), is placed at the position where the vacuum cup is usually attached to the suction tubing to measure the created pressure.

5.1.1 Prototype A - membrane pump

The membrane pump, seen in Figure 5.5 and Figure A.15, is designed around a diaphragm taken from an existing membrane pump. The frame, sealed by the membrane, creates a closed volume. A stem equipped with a rigid disc is attached through a hole in the middle of the diaphragm and functions as the point of application for the handle. Both frame and handle of the pump are 3D printed from PLA (see model in Figure 5.1) and connected via a pin. By removing the pin, the handle can be detached from the frame and the diaphragm can be removed in order to clean the insides of the pump. The configuration of the frame and handle can be categorized as a class one inverted lever. By Squeezing the handles together, the volume of the pump's chamber can be expanded. The elasticity of the membrane returns the handle to its original position. Two diaphragm check valves regulate the flow of air through the channels (see Figure 5.2) to create the partial vacuum. The vacuum cup, valves and pump are connected with reinforced silicone tubing fixed to the device.

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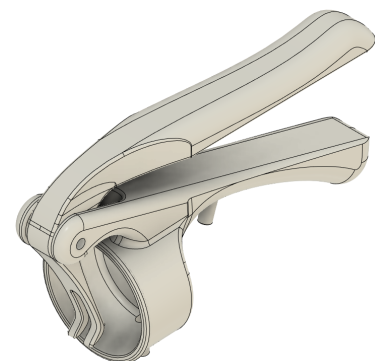


Figure 5.1: Isometric view of the CAD model of the frame and handle of prototype A.

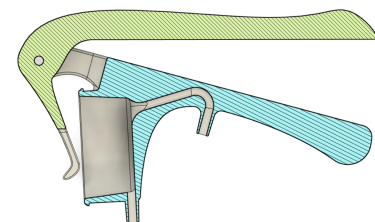


Figure 5.2: Side-view cross-section of the frame and handle of prototype A.

5.1.2 Prototype B - Bellows Pump

The bellows pump, seen in Figure 5.3 and Figure A.16, features a 3D printed bellows made of a thermoplastic elastomer and a 3D printed frame and handle made of PLA. A solid and airtight connection between the bellows and frame is ensured through an o-ringlike extrusion on the inside of the bellows and a notch in the frame of the pump. To reduce the dead volume of the pump, a cylinder protrudes the bellows and fills the dead volume when the bellows is fully compressed. Contrary to the membrane pump prototype, the configuration of the frame and handle of the bellows pump prototype can be categorized as a class one lever. Similar to the membrane pump, the frame and handle of the bellows pump are connected by a pin. Removing the pin allows for detachment of the handle. The bellows can be removed by pulling it from the frame. The flow of air from the cup to the pump is regulated by an umbrella valve, while the flow of air out of the pump is regulated by a duckbill valve. Both valves can be removed from the pump's frame. A reinforced silicone tube fixed to the vacuum cup is attached to the pump with a connection derivative of a bayonet mount.

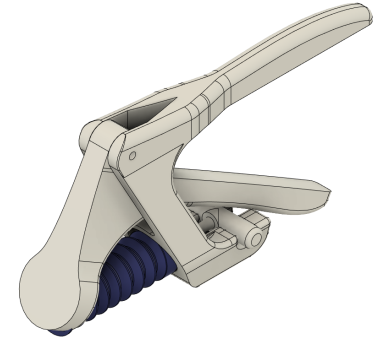


Figure 5.3: Isometric view of the CAD model of the frame and handle of prototype B.

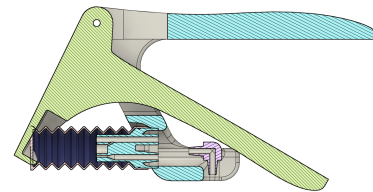


Figure 5.4: Side-view cross-section of the frame, handle and bellows.

5.2 Validation Results

A manometer was attached to the suction tubing, where the vacuum cup otherwise would be placed, and the pump was then operated via the handle to create suction. Prototype A was able to achieve a pressure of up to 0.055 MPa partial vacuum in less than 6 pumps. Prototype B was able to reach a pressure of up to 0.08 MPa partial vacuum also in less than 4 pumps, although the handle did not survive the testing.

Device	Achieved Vacuum (MPa)	Number of pump cycles
Prototype A	-0.055	5*
Prototype B	-0.075	3 [†]
Prototype C	-0.082	3

* Dependent on the speed of pumping, pumping overly fast may reduce required cycles.

[†] Due to the valve air leaks and pressure drops gradually.

Table 5.1: Table showing the achievable vacuum and required amount of pump cycles with each pump prototype whereby the atmospheric pressure is considered 0.

5.2.1 Interpretation

Prototype A was not able to achieve the required partial vacuum. This can most likely be attributed to the seal of the membrane. The seal between the membrane and the pump is not tight enough to prevent air from leaking into the device. As a result the created vacuum in the chamber is compromised. Only prototype B was able to achieve the required partial vacuum although the construction of the device was not strong enough to survive the necessary pumping force. This is most likely due to the material thickness and printing orientation.



Figure 5.5: Photo of prototype A.



Figure 5.6: Photo of prototype B.

5.3 Conclusive Prototype

From the validation, two options to create a working device can be derived: improve the diaphragm's seal of prototype A or change the frame of prototype B to survive the pumping forces. Improving the seal of the membrane most likely requires an additional, further complicating the design and its cleanability. Additionally, prototyping with silicone is difficult as special molding techniques are necessary. For this reason, prototype B is chosen as input for the conclusive prototype.

5.3.1 Prototype C - Bellows Pump Version 2

According to the conclusion of the validation results, a conclusive prototype is made, seen in Figure 5.9 and Figure A.17. While the general shape of the bellows pump prototype presented in section 5.1.2 remains the same, to reduce the force required to operate the device the diameter and thus the area of the bellows is reduced. Additionally, the length of the handle relative to the arm covering the bellows is increased. To provide enough room for the rotational movement of the handle, the traction connection is slightly lower than the position of the bellows. The traditional shaped bayonet mount proved to be unsuitable for high levels of traction force, in the conclusive design the suction tubing is connected with a thicker traction bar that snaps into the frame of the device instead. The frame of the device is made continuous to distribute the forces more equally and guarantee the structural integrity. The frame furthermore restricts the movement of the handle to only the designed direction. Prototype C is validated similar to Prototype A and B. The result of the suction test is included in table 5.1.

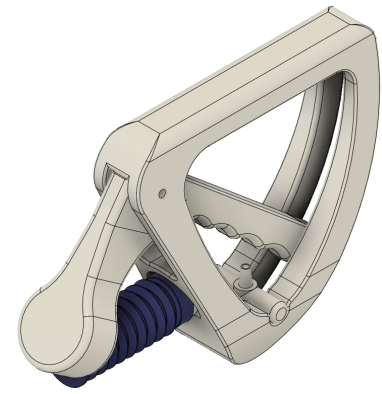


Figure 5.7: Isometric view of the CAD model of the frame and handle of prototype C.

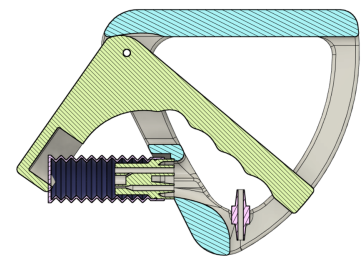


Figure 5.8: Side-view cross-section of the frame and handle of prototype C.

Figure 5.9: Photo of prototype C.

5.4 Optimizable Parameters

The device as designed in section 5.3.1 allows to achieve the desired partial vacuum of 0.8 bar, however, the device is not optimized for ergonomic use. Several parameters can be adjust to make the device more comfortable to use.

5.4.1 Bellows area and length

To reduce the pump cycles necessary to achieve the desired partial vacuum, the volume of the bellows may be increased. Volume of the bellows can be increased by either increasing the length or the area of the bellows, or both. Increasing the length results in longer pump strokes which requires a longer grip span. Increasing the area of the bellows results in a higher force exerted by the partial vacuum. To compensate for this, the spring constant of the bellows may be increased. Consequently, more force is necessary to compress the bellows. The benefit of increasing the length as opposed to the area is that a more lengthy bellows decreases the dead volume ratio while a greater area has no effect on the dead volume ratio.

5.4.2 Handle and arm length

The force required to compress the bellows can be reduced by reducing the ratio of handle to arm length, where the handle length is the distance between the fulcrum and the application point of force on the handle and the arm length is the distance between the fulcrum and the position of the bellows. Increasing the handle length reduces the force required, although a greater grip span is necessary. Similarly, bringing the bellows closer to the fulcrum results in an increased travel arc of the handle and thus a greater grip span is necessary. Considerations have to be made about maximum grip size and strength, and the maximum comfortable pump cycles.

5.4.3 Vacuum Stability

Air inevitably enters the device through the interface of the vacuum cup and the fetal scalp. As a result, the pressure in the device slowly increases and additional pump cycles are necessary to maintain the desired partial vacuum. The volume of air required to mitigate the partial vacuum is dependent on the total volume of air inside the device. A greater total volume requires more air to undo the partial vacuum. Consequently, a greater total volume acts as a buffer and thus creates a more stable vacuum. For this reason may be opted to enlarge the volume of air inside the device to create a more stable vacuum. The downside of this however is that more pump cycles are necessary to achieve the desired partial vacuum.

Usability Evaluation

6

Usability testing is an important tool to identify strengths in a design and opportunities for improvement of a device [77]. Especially in early stages of the design process, feedback from the intended user may obviate costly errors in the long run. While usability testing is only one facet of evaluating medical devices, it is an important one and one that can be executed in the current design phase.

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6.1 Evaluation Method

The main goal of this usability evaluation is to identify design oversights that may lead to errors, gauge the user’s perception of the device and compare the three different prototypes created in chapter 5. The participating obstetricians are presented with the devices and asked about their perception of the device and whether it suits their personal needs for comfortable use.

6.2 Evaluation Results

The evaluation was conducted in two sessions. In total 10 participants were involved. Participants of the first session, taking place in the Leiden University Medical Center, were: Marlieke de Fouw, gynaecologist; Thomas van den Akker, gynaecologist and professor at VU Amsterdam; Maite Timmermans, gynecology and obstetrics resident; Manon Gijtenbeek, gynecology and obstetrics resident; Floor Prein, gynecology and obstetrics resident; Marieke Veenhof, gynaecologist. Participants of the second session, taking place in the Canisius Wilhelmina Hospital, were: Barbara Nolens, gynaecologist; Lotte Hamel, physician assistant gynecology; Annelore Arts, tropical doctor and gynecologist in training; Thanh Mai Bui, tropical doctor in training.

6.2.1 Perception

The small form factor of prototype A was perceived among most participants as elegant, and comfortable to hold. Prototype B, although having a small form factor, was less appreciated and perceived as flimsy. In contrast, prototype C was described as robust and sturdy and perceived as simple and easy in use. The waved shapes of the handle were appreciated and provided the user with cues on how the device should be held. One participant expressed a fear of the Kiwi OmniCup breaking during high levels of traction force, which may be alleviated with a more sturdy design. The plastic version of the pump and vacuum cup and the absence of a metal chain have a less frightening appearance to both



Figure 6.1: Barbara (left) with Lotte (right) testing prototype C on the phantom.

obstetrician and the expecting mother. The simple design also contributes to a tranquil appearance of the instrument.

6.2.2 Use

Prototype C was tested on a phantom consisting of a ball and a model of the birth canal (see Figure 6.1). The ability to operate the device with one hand was emphasised as crucial to success. Additionally, significantly fewer actions were required to assemble the device compared to the reusable Kiwi OmniCup. The squeezing motion of prototype C was described as comfortable, for some even more comfortable than the Kiwi OmniCup. The way the vacuum extractor is held and used differs from person to person. Some preferred holding the handle with the thumb closest to the fulcrum whereas others naturally held the device with the pinkie closest to the fulcrum. Some prefer having the back of the hand facing up when pulling while others prefer having the back of the hand face down. Although, all types of movement required were said to be executable comfortably. One participant indicated that having the tubing attached closer to the fingers, as is the case with the kiwi OmniCup, allows for more control over the direction of traction. However, this opinion was not shared among all participants.

Pulling and Pumping

The handle is located within the frame of the pump. A pump motion is initiated by moving the handle with force of the fingers to the topside of the frame, in the same direction as the traction force. As a result, when exerting traction force the handle is naturally squeezed and the bellows is engaged. Consequently, part of the force to create traction force is

absorbed by the bellows and additional force is required to reach the desired traction force. Because quite the effort is required to exert the necessary traction force, requiring additional traction makes use less comfortable. To solve this, some participants naturally switched their grip to the frame of the vacuum extractor to be able to exert more traction force. When asked whether the need to switch grip made use less comfortable, participant indicated that, beside there being limited space, it had little effect.

Additional Features

The absence of a vacuum release button and a pressure gauge was noticed in both sessions. While a vacuum release button was deemed essential, the opinions about the necessity of a pressure gauge were divided. The pressure gauge was indicated to be mostly used for confirming the required pressure is achieved and to notice when pressure was dropping to timely increase the vacuum. Creating too high vacuum was not seen as a concern. Considering the fact that each additional feature increases price and further complicates cleaning, participants concluded that the device may be better without a pressure gauge. Consistent use of the device may teach the user to rely on other indicators for vacuum level feedback.

Reuse

Even though the device was designed to be sterilized in its entirety, only the part that enters the body requires sterilization. Because some hospitals in third world countries have to deal with numerous consequent vacuum extractions, it may be preferable to provide the device with several



Figure 6.2: Marlieke (left) and Thomas (right) discussing the grip of prototype C.



Figure 6.3: Maite (left) and Manon (right) testing the suction on a phantom of a baby.

vacuum cup and tubing combinations so the part that has to be sterilized can be replaced and the amount of complete devices required is reduced. As a result the vacuum cup and tubing can be replaced and sterilized, while the rest of the device can be disinfected with a cloth. At the end of the day the entire device can be sterilized to prevent build-up of bacteria. Furthermore, it was noticed that small parts tend to get lost quickly, when removed for cleaning. If possible, the umbrella and duckbill valve should be enlarged in size and made of a material with a notable color.

6.3 Implications for Design

According to the results of the evaluation, the following changes can be made to the design to better accommodate the user.

Frame and handle

To allow comfortable exertion of traction force when holding the frame instead of the handle, the design of the frame has to be adjusted. This may be achieved by rounding off the inner part of the frame and possibly adding ridges where the fingers can be positioned. Additionally more space should be created between the handle and the frame to allow for comfortable gripping.

Vacuum release

A vacuum release button may be added to the device. While on top of the frame may be an obvious choice, it should not be accidentally pressed and, in order for the vacuum release to work it should be in contact with the volume of air that is connected to the volume of air inside the cup. In the current design, only two rigid parts come in contact with the enclosed air, the part to where the bellows is connected and the traction bar. Either an additional hollow volume ought to be created or vacuum release should be positioned on one of the aforementioned parts. Alternatively, a different solution may be resorted to.

Pressure Gauge

Whether a pressure gauge should be included should depend on a cost-benefit analysis. A pressure gauge that does not have a significant effect on price and cleanability may be worth implementing.

Check Valves

To prevent the check valves from being lost when they are removed for cleaning, the valves should be increased in size. Ideally, the in- and outlet check valve may be combined into one piece. Additionally, a distinct color may be given to the part to further minimize the chance of it getting lost in cleaning.

Chapter 5 and 6 proof the value of the concept functionally and ergonomically. This chapter provides recommendations for the further development and validation of the device.

7.1 Evaluations of Requirements

Section 3 provides guidelines that help create a successful device geared towards low and middle income countries. Several of these requirements have been evaluated in previous chapters, however, certain aspects of the design remain to be developed and evaluated before the device is ready for clinical trials and ultimately introduced into the market. The following section covers the listed requirements, whether the design complies with the requirement and what should be done in order to evaluate the design with respect to that requirement.

R1 Functional Evaluation

R1.2 has been validated in section 5.2, when significant changes are made to the bellows **R1.2** ought to be evaluated again. To adequately evaluate **R1.1** either a representative prototype or (FEM) model has to be created. For this, material for the frame, bellows, tubing and vacuum cup have to be defined taking into consideration the possibilities for connection between the different elements. Beside maximum level of traction force, durability also has to be evaluated.

R2 Ergonomic Evaluation

Creation of vacuum and exertion of traction can be achieved with a single hand (**R2.1**), as shown in the usability evaluation in section 6.2. Although not objectively measured, grip strength and span required fall within comfortable levels (**R2.2** & **R2.3**). **R2.4** & **R2.5** should be evaluated when a final design is proposed. **R2.6** is validated (see Figure 6.1). Furthermore, the conclusive design has to be subjected to a more representative usability test. Safety, easy of use and efficiency have to be evaluated in the intended setting, low- and middle resource hospital settings.

R3 Cleanability Evaluation

To evaluate whether the device is cleanable (**R3.1**), a validation protocol should be developed. The compatibility of the material with the intended method of cleaning should be verified and cleanability (**R3.5**) should be tested with devices that have been used multiple times to simulate

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reality (**R3.2 & R3.3**). A combination of different types of soils to mimic environments in clinical conditions should be used in accordance with ASTM Standard: F3208 - 17 & WK57707. Worst case dwell time and worst case cleaning time should be assumed (**R3.4**). Also cleaning validation on surgical trays and cross contamination should be studied.

R4 Affordability Evaluation

The sale price of the device has to be estimated and evaluated whether this is affordable for low-resource settings. Also the added benefit of the device has to be weighed against the price relative to what other products offer. In order to create such an estimate, the price of the material and production techniques used have to be known. Additionally, an estimate of the production size is necessary.

R5, R6& R7 LMIC Specific Evaluation

When a final prototype is created, the device should be subjected to thorough testing to find main points of repair (**R5.1**). Durability of the diaphragm and check valves should be evaluated in order to find out when replacement is required (**R5.2**). For repair and maintenance, use in sub-optimal environments should be evaluated (**R6.1, R6.2 & R6.3**). Furthermore instructions for use should be developed and evaluated in the relevant environment (**R7.1 & R7.2**).

7.2 Additional Features

Three additional features were omitted: Pressure gauge, force gauge and vacuum release. Every additional feature complicates the design and therefore the cleaning process. The force gauge was indicated in the evaluation to be not used at all, and is therefore omitted from the final design. The pressure gauge however is occasionally used after the first few pumps to confirm the desired level of vacuum is achieved. The bellows may be designed according to the pressure that is desired to be achieved. The pressure limit of the pump may be perceived as an inherent pressure gauge feature. The absence of the vacuum release was one of the first features that was noticed, a vacuum release should be included in the device.

7.3 Material Selection and production

Design is an iterative process where different facets influence each other. Durability, for example, is partly determined by the material used, however, shape also plays a key role. Similar, producibility is mainly dependent on shape, although the choice of material greatly influences its cost. When selecting a material for production, different aspects of design have to be considered and making trade-offs is inevitable. The following section provides a starting point for the selection of material and production techniques.

7.3.1 Frame & Handle

Metal is an exceptionally suitable material for medical devices that are subjected to high levels of force [78], and therefore when considering the functional requirements, may be the superior material for this application. However, using metal imposes restrictions to form that make it costly to create certain necessary shapes. The saving cost saving aspect of using polymers is attractive, especially when designing for LMIC's [79]. Additionally, injection molding, a production technique suitable for a majority of the commonly used plastics, provides the necessary freedom in form. Consequently, plastic may be a particular suitable option for this application. The world of plastics is huge and to select the perfect material is a study on its own[80]. Considering the requirements dictated in chapter 3, strength, stiffness, chemical resistance and heat resistance are the main determining factors when selecting a material for the frame and handle. Most medical device made of plastic are made out of a commodity thermoplastics. The low cost, excellent performance, and easy processability of commodity thermoplastics such as polyvinyl chloride, makes them notably suitable for medical instruments.

7.3.2 Bellows

For the bellows to function properly, it has to be made out of a semi-flexible material. While silicone is a flexible material often used in clinical devices, it lacks the hardness to resist the force resulting from low levels of partial vacuum. Thermoplastic elastomers (TPE) are suitable for clinical use and offer great variability in hardness[81]. Thermoplastic polyurethanes and thermoplastic copolyester provide good resistance to disinfectants and have favorable flexibility and elasticity properties. Even though the shape of the bellows as presented in section 5.3.1 is rather simple, the configuration of coves makes injection molding difficult. To ensure proper mold release, blow-molding¹ may present itself as a solution. Achieving accurate wall thickness is more difficult than with injection molding although minor variation in dimensions is not detrimental to the functioning of the device[82].

1: Image of blow molding technique

7.3.3 Check Valves

Two type of check valves are included in the design: the umbrella and duckbill check valve. The allowance of deformation of both valve's material ensure proper functioning as well as attachment to the pump. Umbrella and duckbill valves are commonly found in aquarium equipment and therefore widely available at little cost. Section 6.2 concluded that in the cleaning process small pieces are at risk of getting lost. For this reason, combining both valves in one piece may reduce this risk. Even though the design permits combination of both umbrella and duckbill valve into one piece, creating an additional custom part significantly increases the price of the device. This has to be taken into consideration when making a choice.

7.3.4 Traction & Suction Connection

Different types of plastics may provide a suitable solution for tubing with adequate resistance to traction force. The success or failure of the system, however, is dependent on the toughness of the connection between the tubing and vacuum cup, and the tubing and traction bar. Fixing the vacuum cup and traction bar to the tubing may be the ideal solution. Properly joining rigid and flexible materials however is complicated, and interfaces where debris can get stuck between should be avoided. Fusing two types of plastic, a rigid plastic for the vacuum cup and traction bar and a more flexible plastic for the tubing, together through co-injection molding may solve this problem[83].

7.4 Conclusive Design

Figure 7.1 provides a render of how a suggested final concept may look considering the recommendations given in this chapter. Figure 7.2 shows a cad model of the assembled version and Figure 7.3 presents an exploded view.

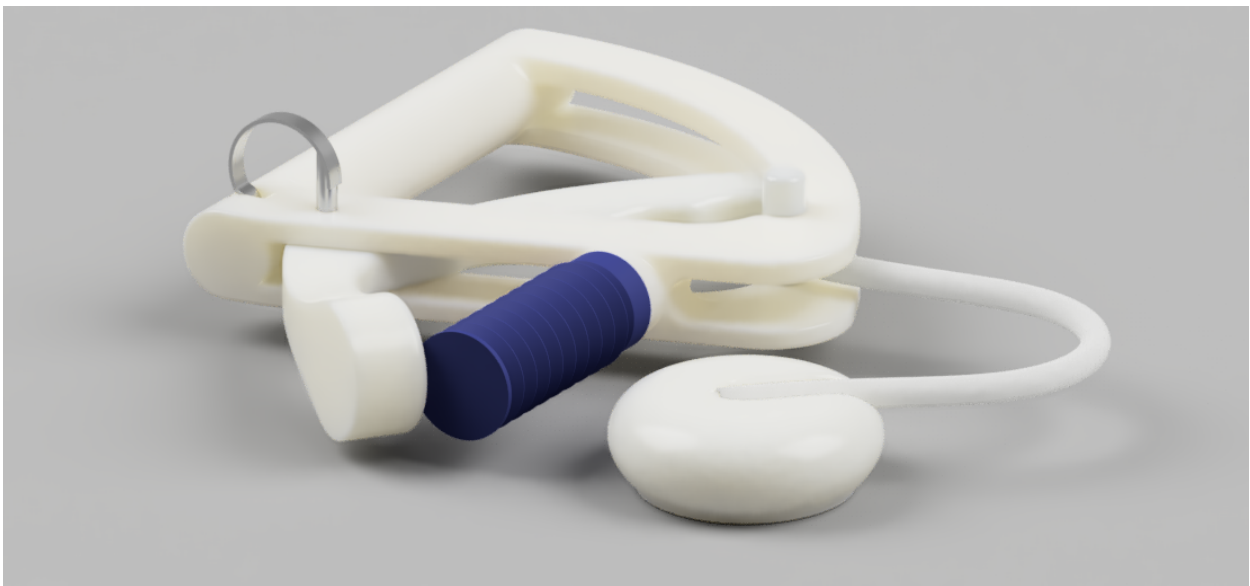


Figure 7.1: Render of a suggested final concept.



Figure 7.2: 3D model of the suggested final concept.

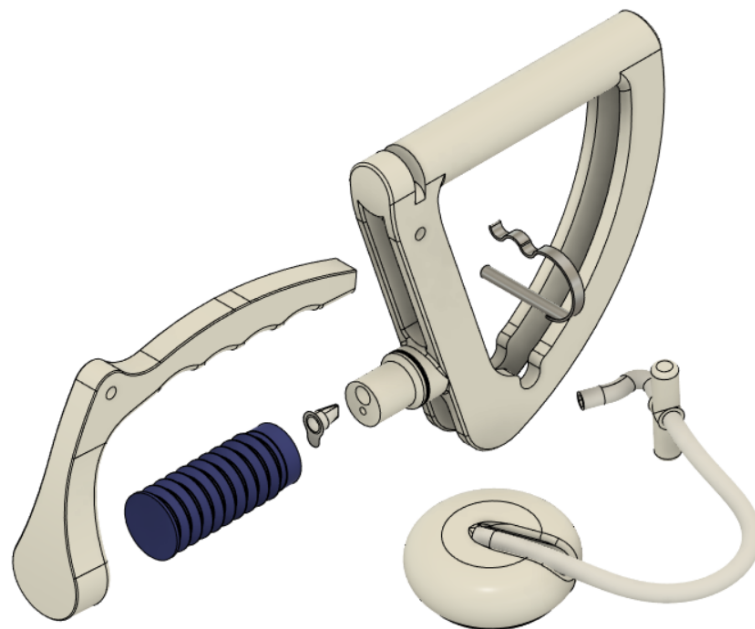


Figure 7.3: Exploded view of the suggested final concept.

8.1 Results

To make vacuum extraction devices more accessible in low-resource settings, a reusable redesign of a popular disposable vacuum extractor, the Kiwi OmniCup, is made to increase its affordability. Two types of manual pumping mechanisms more suitable for cleaning according to Scott and Hitchins [67] and Spiegelberg [84], are explored and tested on their ability to create partial vacuum. The validation shows a small sized bellows pump to be able to reach the required partial vacuum of 0.08 MPa. The functional validation indicated the integration of a bellows pump to be a promising solution for a more affordable reusable vacuum extractor. Corresponding with research by Hayman, Gilby, and Arulkumaran [14] and Sláma and Soltés [85], the usability evaluation showed the integration of the hand-pump to be a convenient solution for the creation of suction.

8.2 Implication

This report provides a new approach to pump design for a handheld fetal vacuum extractor that is more compatible with cleaning methods. The described design may be included in a new generation of vacuum extraction systems in order to reduce the cost of vacuum extraction without diminishing ergonomic convenience provided by disposable vacuum extraction systems. Consequently, vacuum extraction may be more accessible in low-resource hospital settings opening the doors to the more widespread use of vacuum extraction.

8.3 Limitations

Selection of solutions to the functional parameters found in Figure 4.9 for the creation of the concepts was partly determined by the availability of resources. The impact of Corona Virus pandemic and consequential governmental measures taken made timely access to prototyping necessities more difficult, with as a result occasionally less optimal solutions had to be resorted to. Nonetheless, the results have shown to be functionally applicable for use in vacuum extraction systems.

8.4 Further Research

Different combinations of sub-solutions may be generated to create different concepts. Furthermore, concepts should be optimized on the

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parameters defined in section 5.4. Chapter 7 provides an overall list of steps that should be taken to improve the device. Additionally, before clinical trials can be initiated, optimal materials and production methods should be determined.

Howitt et al. [53] states that medical solutions aimed at low-resource countries also have the potential to be disruptive technologies in modern clinical settings. With the potential to reducing waste, a reusable vacuum extractor may be a more sustainable solution to vacuum extraction than disposable devices currently available.

8.5 Conclusion

To make vacuum extraction devices more accessible in low-resource countries, a low cost, easy to use vacuum extractor is required. A bellows pump can be successfully integrated in a vacuum extraction system to create a functional and more cleanable device. The device can pose a more favorable solution to vacuum extraction in low- and middle-income countries due to greater affordability and less reliance on infrastructure than disposable vacuum extraction systems and a higher level of convenience than traditional systems. As a result of implementation of such a device, vacuum extraction may become more accessible in LMICs.

APPENDIX

A

Appendix

A.1 Market Overview

The following section provides a list of some of the commonly used vacuum extraction systems available on today's market.

A.1.1 Single-use vacuum extractors



Brand: Kiwi®
Model: OmniCup™
Manufacturer: Clinical Innovations
Estimated Price: €40
Description: All-in-one, single hand operated, disposable plastic vacuum extractor with integrated pressure gauge and flexible stem.

Figure A.1: Kiwi® OmniCup™ [24]



Brand: Kiwi®
Model: ProCup™
Manufacturer: Clinical Innovations
Estimated Price: €40
Description: All-in-one, single hand operated, disposable plastic vacuum extractor with integrated pressure gauge and rigid stem.

Figure A.2: Kiwi® ProCup™ [24]



Brand: MityOne
Model: 10068 MitySoftBell Cup
Manufacturer: Cooper Surgical
Estimated Price: €45 per 12
Description: All-in-one, single hand operated, disposable plastic vacuum extractor with integrated manometer and rigid stem. Also available with a Malmström shaped cup.

Figure A.3: MityOne MitySoftBell [25]

A.1.2 Reusable manual vacuum extractors



Brand: Mityvac
Model: Reusable Handheld Pump
Manufacturer: Cooper Surgical
Estimated Price: €180
Description: Hand operated vacuum pump with a manometer and detachable tubing. One-piece vacuum cup and traction handle design.

Figure A.4: Mityvac Reusable Handheld Pump[26]



Brand: Utah Medical
Model: Manual blue vacuum pump
Manufacturer: Utah Medical Products Inc.
Estimated Price: €60
Description: Hand operated vacuum pump with a manometer and detachable tubing. Suitable for different types of vacuum cups.

Figure A.5: Utah Medical vacuum extractor [86]



Brand: MedGyn
Model: HVP-100
Manufacturer: MedGyn Products Inc.
Estimated Price: N/A
Description: Hand operated vacuum pump with manometer and detachable tubing, similar to the Mityvac Reusable Handheld Pump. Suitable for different types of vacuum cups.

Figure A.6: MedGyn HVP-100 [87]



Brand: Sun Surgical
Model: Vacuum Extractor
Manufacturer: Sun Surgical
Estimated Price: €35
Description: Hand operated bicycle style vacuum pump with liquid trap and manometer. Compatible with Bird and Malmström cups.

Figure A.7: Sun Surgical vacuum extractor[88]



Brand: MEI
Model: Vacuum Extractor
Manufacturer: Medical Equipment India
Estimated Price: €75
Description: Hand operated bicycle style vacuum pump with liquid trap and manometer. Compatible with Bird and Malmström cups.

Figure A.8: MEI vacuum extractor[89]

A.1.3 Motorized vacuum extractors



Brand: ATMOS

Model: S 351 NATAL

Manufacturer: ATMOS MedizinTechnik GmbH & Co. KG

Estimated Price: €2500

Description: Fully automated low noise electrical vacuum extractor equipped with a liquid trap and foot pedal for mid procedure operation. Compatible with different types of vacuum cups.

Figure A.9: ATMOS S 351 NATAL [90]



Brand: MedGyn

Model: Portable Vacuum Pump

Manufacturer: MedGyn Products Inc.

Estimated Price: €2300

Description: Electrical vacuum extractor equipped with vacuum control, manometer and battery for up to 2 hours of portable use. Compatible with different types of vacuum cups.

Figure A.10: MedGyn Portable Vacuum Pump[91]



Brand: Medela

Model: Medela VAD system

Manufacturer: Medela

Estimated Price: €2700

Description: Electrical vacuum extractor equipped with vacuum control, manometer and foot pedal for mid procedure operation. Compatible with different types of vacuum cups.

Figure A.11: Medela VAD system [27]



Brand: ARDO

Model: Senator

Manufacturer: ARDO Medical

Estimated Price: €2.000

Description: Multi-purpose electrical vacuum extractor equipped with detachable liquid trap, vacuum control and manometer. Compatible with different types of vacuum cups.

Figure A.12: ARDO Senator [92]

A.2 Kiwi OmniCup Device Components

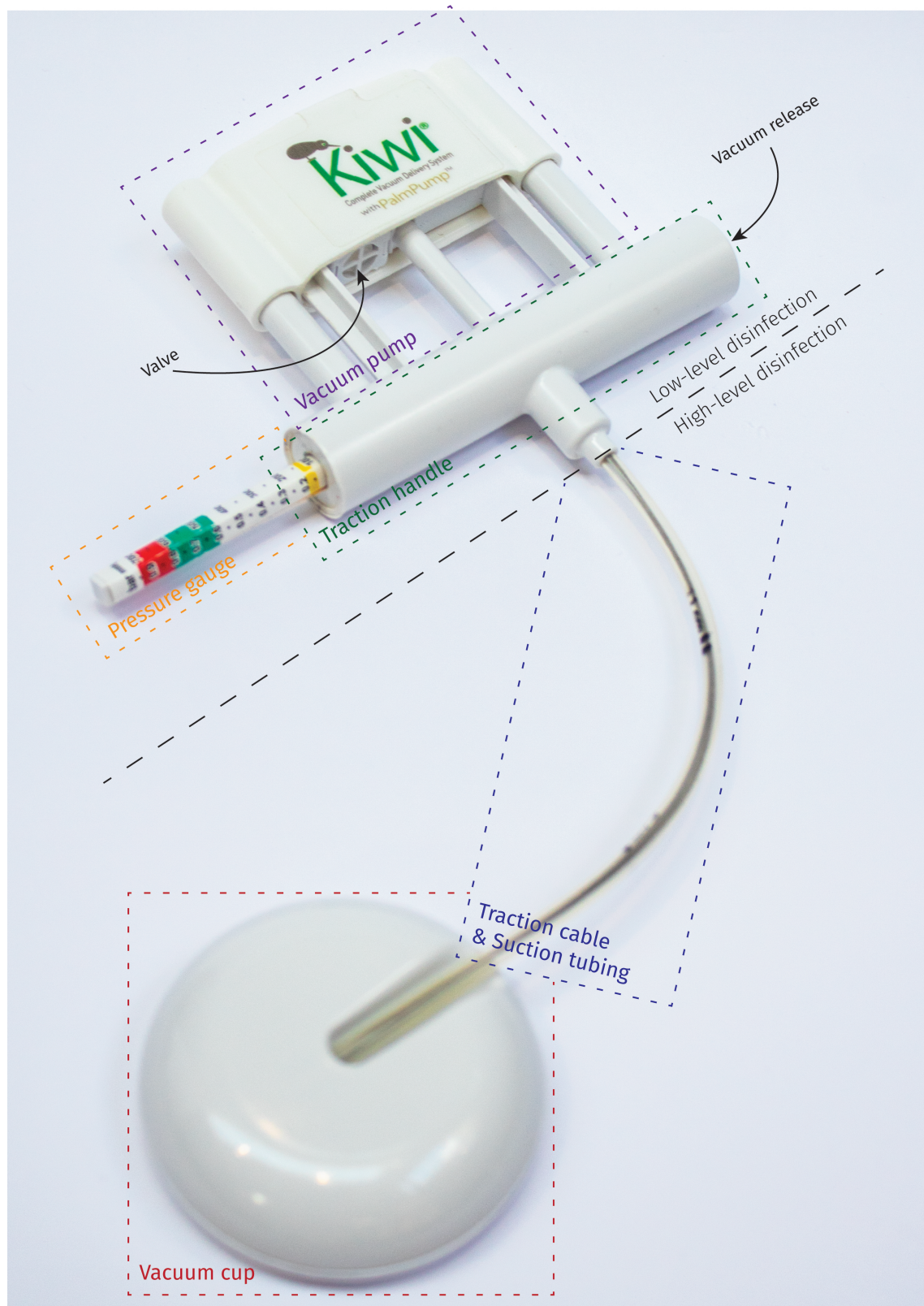


Figure A.13: Different elements of the Kiwi OmniCup.

A.3 Physics of the Kiwi OmniCup

A.3.1 Determination of Spring constant

Due to limited test equipment, the spring constant is determined by stretching of the spring. Hereby, the spring constant for compression and extension are assumed to be the same. The length of the spring is measured under load with increments of 0.5kg starting with 0kg. The average stretch is 2.4 mm per 0.5 kg.

$$\begin{aligned} 0.5kg &= 4.9N \\ \frac{4.9}{2.4} &= 2.0N/mm \\ K &= 2.0N/mm \end{aligned}$$

Weight (kg)	Absolute spring size (mm)	Spring stretch (mm)	Cumulative spring stretch (mm)
0	48.5	0	0
0.5	50.7	2.2	2.2
1.0	53.2	2.5	4.7
1.5	55.3	2.1	6.9
2.0	57.9	2.6	6.9
2.5	60.3	2.4	11.9
Average	-	2.4	-

Table A.1: Measurements of spring stretch.

A.3.2 Derivation of Equation 4.1 in section 4.1.1

Considering only the pump, the resulting pressure follows from Boyle's law according to equation A.1. Where P_1 and V_1 are the pressure and volume of air respectively inside the pump when the piston is fully decompressed. P_2 and V_2 are the pressure and volume of air respectively inside the pump when the piston is fully retracted.

$$P_1 \cdot V_1 = P_2 \cdot V_2 \quad (\text{A.1})$$

When P_{rest} is 0, only one cycle of the pump is required to achieve the maximum level of partial vacuum, as no air can enter the device through the valves. Each subsequent stroke of the pump therefore changes nothing in the resulting pressure inside the pump. The resulting pressure can be calculated by rewriting equation A.1 as equation A.2. When P_{rest} is greater than 0, air can flow to the pump but only in that direction, meaning pressure can only be increased. Consequently, P_2 is the maximum level of

partial vacuum regardless of the size of P_{rest} . Although, the larger P_{rest} , the longer it takes to achieve the maximum level of partial vacuum.

$$\frac{P_1 \cdot V_1}{V_2} = P_2 \quad (A.2)$$

The parameters in A.2 can be replaced to create the formula as described in section 4.1.1. P_1 is equal to the atmospheric pressure due to the way the valves are configured and is therefore replaced with P_{atmos} . V_1 is the volume of the pump when the piston is fully decompressed, and thus indicates the dead volume V_{dead} . V_2 is the volume of the pump when the piston is fully retracted, and thus the total volume of the pump V_{total} . P_2 represents the maximum level of partial vacuum, however, as a certain level of partial vacuum is required, this can be rewritten as the desired pressure ($P_{desired}$).

$$\frac{P_{atmos} \cdot V_{dead_{max}}}{V_{total}} = P_{desired} \quad (A.3)$$

Rewriting equation A.3 to isolate V_{dead} gives equation A.4, the formula for maximum dead volume.

$$\frac{P_{desired} \cdot V_{total}}{P_{atmos}} = V_{dead} \quad (A.4)$$

Example Calculation

With a desired partial vacuum of $0.08MPa$ ($0.02MPa$ pressure) and a pump volume similar to that of the kiwi omniscup ($0.045 \cdot 0.010 \cdot 0.03 = 0.0000135m^3$), the calculation is as shown in equation A.5.

$$V_{dead_{max}} = \frac{0.02}{0.101325} \cdot 1.35 \cdot 10^{-5} = 0.0266 \cdot 10^{-5} \quad (A.5)$$

Of the total pump volume of $1.35 \cdot 10^{-5}m^3$ only $0.266 \cdot 10^{-5}m^3$ may be dead volume which is about 20% of the pump's total volume.

A.3.3 Derivation of Equation 4.2 in section 4.1.1

The formula for the maximum allowable dead volume is given in equation 4.1 and provided below.

$$V_{dead_{max}} = \frac{P_{des}}{P_{atmos}} \cdot V_{pump} \quad (A.6)$$

V_{pump} can be calculated with $h_{diaphragm}$ and $A_{diaphragm}$ according to equation A.7 where $h_{diaphragm}$ is the height of the diaphragm and $A_{diaphragm}$ the area of the diaphragm.

$$V_{pump} = h_{diaphragm} \cdot A_{diaphragm} \quad (A.7)$$

$h_{diaphragm}$ is calculated according to equation A.8 where $h_{diaphragm_{max}}$ is the maximum height of the diaphragm and u the compression of the diaphragm.

$$h_{diaphragm} = h_{diaphragm_{max}} - u \quad (A.8)$$

u is determined by Hooke's law according to equation A.9 where $f_{diaphragm}$ is the force on the diaphragm as a result of the vacuum and k the spring constant of the diaphragm.

$$u = \frac{f_{diaphragm}}{k} \quad (A.9)$$

$f_{diaphragm}$ follows from equation A.10.

$$f_{diaphragm} = (P_{atmos} - P_{des}) \cdot A_{diaphragm} \quad (A.10)$$

Combining equation A.7, A.8, A.9 and A.10 into equation A.6 gives equation A.11.

$$V_{dead_{max}} = \frac{P_{des}}{P_{atmos}} \cdot \left(h_{diaphragm_{max}} - \frac{(P_{atmos} - P_{des}) \cdot A_{diaphragm}}{k} \right) \cdot A_{diaphragm} \quad (A.11)$$

Example Calculation

Again, with a desired partial vacuum of 0.08 MPa (0.02 MPa pressure) and a pump volume similar to that of the kiwi omnipump ($h_{diaphragm_{max}} = 0.03$ m, $A_{diaphragm} = 0.045 \cdot 0.010 = 0.00045$ m²), the calculation for the maximum allowable dead volume is as shown in equation A.12.

$$V_{dead_{max}} = \frac{0.02}{0.101325} \cdot \left(0.03 - \frac{(0.101325 - 0.02) \cdot 0.00045}{4 \cdot 10^3} \right) \cdot 0.00045 = 0.185125 \cdot 10^{-5} \quad (A.12)$$

Of the total pump volume of $1.35 \cdot 10^{-5}$ m³ only $0.185 \cdot 10^{-5}$ m³ may be dead volume when the retraction of the diaphragm as a result of the partial vacuum is taken into consideration which is about 14% of the pump's total volume.

A.3.4 Calculation used to plot Figure 4.4

According to Boyle's law given in equation 2.3, the following can be stated about the volume and pressure of the device when the piston is compressed and expanded:

$$V_{dead} \cdot P_{atmos} + V_{rest} \cdot P_{old} = (V_{dead} + V_{piston} + V_{rest}) \cdot P_{new} \quad (A.13)$$

Where V_{Dead} is the volume of air in the dead space, P_{atmos} the atmospheric pressure, V_{rest} the volume of air in the remained of the device, P_{old} the pressure in the device at the start of a pump stroke, V_{piston} the volume of air in the pump minus that of the dead space and P_{new} the pressure inside the device at the end of a pump stroke.

Where V_{pump} can be written as:

$$V_{piston} = h \cdot A_{piston} \tag{A.14}$$

Combining equation A.13 and equation A.14 with equation 2.6 (Where $P_2 = P_{new}$) gives:

$$(h_{piston_{max}} - h) \cdot k = \left(P_{atmos} - \frac{V_{dead} \cdot P_{atmos} + V_{rest} \cdot P_{old}}{V_{dead} + V_{rest} + A_{piston} \cdot h} \right) \cdot A_{piston} \tag{A.15}$$

Rewriting this equation gives:

$$-kh^2 + \left(k \cdot h_{piston_{max}} - \frac{k \cdot (V_{rest} + V_{dead})}{A_{piston}} - p_{atm} \cdot A_{piston} \right) \cdot h + \frac{k \cdot h_{piston_{max}} \cdot (V_{rest} + V_{dead})}{A_{piston}} + V_{rest} \cdot (p_{old} - p_{atm}) = 0$$

Again solving the quadratic equation for h, with the parameters below, yields the height h to which the piston returns after decompression. Inserting that value into equation A.13 combined with A.14 gives the pressure in the system after expansion. Setting this new pressure as P_{old} allows for calculation of the next iteration.

$$a = -k$$

$$b = k \cdot h_{max} - \frac{k \cdot (V_{rest} + V_{dead})}{A_{piston}} - p_{atm} \cdot A_{piston}$$

$$c = \frac{k \cdot h_{max} \cdot (V_{rest} + V_{dead})}{A_{piston}} + V_{rest} \cdot (p_{start} - p_{atm})$$

A.4 Design for Cleanability

A.4.1 Reusable device lifecycle

Figure A.14 provides an overview of the use cycle of reusable and disposable medical instruments. The path followed is dependent on the required level of disinfection and sterilization.

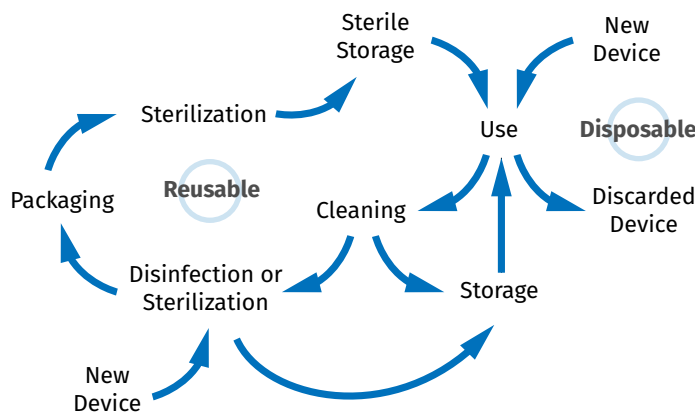


Figure A.14: Overview of the use cycle of reusable and disposable medical instruments.

Cleaning

Regardless of the type of disinfection or sterilization used, the ability to thoroughly clean the device is paramount to proper disinfection and sterilization. To achieve this, shapes and mechanisms that complicate cleaning should be minimized or avoided. Small angles, tiny features, crevices and areas that are overall hard to reach are difficult to clean. The FDA and ASTM international both provide a list of design features that should be minimized or avoided to guarantee cleanability. A combination of both lists is found in Appendix A.4.2.

Sterilization & Disinfection

To determine the level of sterilization necessary, the part of the body the device comes in contact with has to be considered. The CDC makes a distinction between four levels of cleaning. Low, intermediate, high and critical. Devices that only come in contact with intact skin, labeled noncritical items, require less exhaustive cleaning than semi-critical items that will come in contact with mucous membrane or non-intact skin. Critical items require the most thorough methods of cleaning as they will enter tissue or vascular system or blood will flow through them. See the list below.

Sterilization

- ▶ Critical items (will enter tissue or vascular system or blood will flow through them)

Disinfection

- ▶ High-level (semicritical items; [except dental] will come in contact with mucous membrane or nonintact skin)
- ▶ Intermediate-level (some semicritical items¹ and noncritical items)
- ▶ Low-level (noncritical items; will come in contact with intact skin)

Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) [45]

Vacuum extraction systems generally fall in two categories of disinfection and sterilization; non critical, the parts that remain outside the patient, and semicritical, the part that enters the vaginal cavity of the patient (see Figure A.13). The vacuum cup, suction tubing, traction cable and the attachments between these parts come in contact with mucous membrane and therefore require high level sterilization. The pump system and traction handle remain outside the body and therefore only require low-level sterilization.

Sterilization & Disinfection in LMICs

Sterilization processes used in low-resource settings are often much simpler than those used in modern hospitals. In mulago, devices are disinfected using a solution sold under the brand name Cidex, which consists of the chemical Glutaraldehyde [65]. Devices are first cleaned by hand, then soaked in Glutaraldehyde after which they are left to

dry. These simple ways of cleaning have to be taken into account when designing a medical instrument for low-resource settings.

A.4.2 List of features to avoid

According to ASTM[84] and the FDA[67].

- | | |
|--|---|
| <ul style="list-style-type: none"> - Inaccessible cracks and crevices - Long, narrow interior channels - Serrated edges - Hinges - Coils - Acute angles - Junctions between insulating sheaths - Blind ends - Threaded areas - Sleeves | <ul style="list-style-type: none"> - Valves that regulate the flow of fluid (stopcocks) - Mixed Materials - Fine features - Braided cables - Pliable materials such as silicone - Rubber (O-ring) - Textured surfaces - Springs |
|--|---|

A.4.3 Design strategies for cleaning

For some complicated designs the use of elements listed in section A.4.2 is unavoidable. To make a device that can be used in a clinical environment the following section provides an overview of four design strategies that help to ensure the device's cleanability based on the theory of Golde [93]. These four design strategies are: **reprocessing**, **disassembly**, **Flushing** and **Encapsulation**.

Reprocessing

Reprocessing covers the reuse of the device and is divided into three categories: reusable, reposable and disposable. Choosing for a disposable instrument, as is the case with the Kiwi OmniCup, prevents the need of taking cleaning, disinfection and sterilization into account when designing and guarantees a sterile device if packaging and production happens properly. Additionally, wear, tear and life cycles of the device are much less of concern. However all these benefits carry a downside, the much higher cost of use. Reusable devices are cheaper in use, although require a cleanable design. A combination of reusable and disposable, reposable, also lies within the realm of possibilities. A device may be partly reusable, meaning certain components need to be replaced every use. Parts of the device that are complex to clean may be disposed of while easier to clean components can be used again.

Disassembly

Reusable devices that inevitably have space that are hard to reach may be designed in such a way that these parts can be accessed by disassembling the device. This allows for more freedom in shape although designing for disassembly adds another layer of complexity to the device. Additionally, after sterilization and disinfection the device may not be handled again

until it is in the operating room. Assembly takes time and in some cases special tools which may prolong the procedure.

Flushing

Instead of choosing for disassembly, a design may incorporate flushing. By guiding a cleaning solution under pressure through the device hard to reach areas may be cleaned. Flushing requires far less effort to incorporate into the design compared to disassembly. Although creating sufficient flow that ensures cleaning of all spaces is a complex task. Additionally, verifying whether the internal components have been cleaned adequately is difficult.

Encapsulation

Areas that remain particularly difficult to clean may be encapsulated. The encapsulation prevents pathogens from settling in hard to reach areas and leaves only an easy to clean smooth surface. For a successful encapsulation a proper seal between the device and the cover is required. If the seal breaks, the cleanability of the device is compromised. A proper seal is hard to design making encapsulation a risky strategy.

A.5 Prototypes - disassembled

A.5.1 Prototype A - disassembled



Figure A.15: Disassembled view of prototype A

A.5.2 Prototype B - disassembled

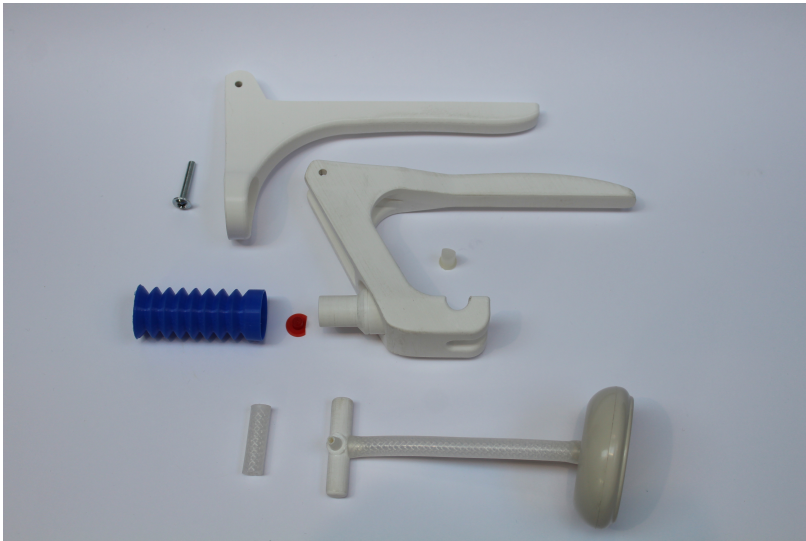


Figure A.16: Disassembled view of prototype B

A.5.3 Prototype C - disassembled



Figure A.17: Disassembled view of prototype C

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