Design and Development of a Sterilizer and Cleaner Device For Menstrual cups

In order to be awarded the Master's Degree in Electromechanical Engineering option Aeronautics

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Abstract

Menstrual cups are a fast growing reusable alternative to female sanitary protections. However this latter needs a certain maintenance for its use: it must be cleaned 3-4 times a day and sterilized at least two times per cycle. This given, most menstrual cups users are forced to avoid changing it in public places or work-places, resulting on the non respect of the cleaning medical guidelines. In addition, the lack of solution for the maintenance drags the adoption of this economic and ecological solution. In this work, the design and development of a dedicated device for cleaning and sterilizing menstrual cups has been achieved. First the problem has been highlighted and analysed through surveys, interviews and gathered data. A state of art showed that the problem wasn't properly addressed, thereby justifying the urgency of a solution. Several conceptual designs emerged, from which different prototypes for cleaning and sterilizing menstrual cups were created. This R&D phase was carried alongside menstrual cup users using a Design Thinking methodology. A task clarification taking into account technical and non-technical requirements (legal, environmental, business and medical), jointly with in-real-conditions user's tests allowed to objectively choose between the prototyped cleaners and sterilizers. Finally, the chosen ones have been merged into the final 2in1 device, and its functionalities have been further developed and optimized. This device allows women to clean menstrual cups without the dependence on private sinks on toilet cabins, and offers them an integrated solution for the sterilization.

Keywords : Menstrual cups, sterilizer, cleaner, design methodology

Résumé

Les coupes menstruelles constituent une alternative réutilisable aux protections hygiéniques féminines traditionelles et qui connait un essor depuis quelques années. Cependant cette dernière nécessite un certain entretien pour son utilisation : elle doit être nettoyée 3-4 fois par jour et stérilisée au moins deux fois par cycle. Ceci étant, la plupart des utilisatrices de coupes menstruelles sont obligées d'éviter de la changer dans les lieux publics ou sur les lieux de travail, ce qui entraîne le non respect des consignes médicales de nettoyage. De plus, le manque de solution pour la maintenance freine l'adoption de cette solution économique et écologique. Dans ce travail, la conception et le développement d'un dispositif dédié au nettoyage et à la stérilisation des coupes menstruelles ont été réalisés. Tout d'abord, le problème a été mis en évidence et analysé au moyen d'enquêtes, d'entretiens et de collectes de données. Un état de l'art a montré que le problème n'était pas résolu de maniere satisfaisante, justifiant ainsi l'urgence d'une solution. Plusieurs conceptions ont émergé, à partir desquelles différents prototypes de nettoyage et de stérilisation des coupes menstruelles ont été dévéloppés. Cette phase de R&D a été menée en collaboration avec des utilisatrices de coupes menstruelles en suivant une méthodologie *Design Thinking*. Un cahier de charges prenant en compte les exigences techniques et non techniques (légales, environnementales, commerciales et médicales), et des tests d'utilisatrices en conditions réelles, ont permis de choisir objectivement entre les prototypes de nettoyeurs et de stérilisateurs. Enfin, les solutions choisies ont été fusionnées dans un dispositif 2en1, et leurs fonctionnalités ont été encore améliorées et optimisées. Le dispositif obtenu permet aux femmes de nettoyer leurs coupes menstruelles en absence d'évier privatif dans les toilettes, et leur offre également une solution intégrée pour la stérilisation.

Mot-clefs : Coupe menstruelle, stérilisateur, nettoyeur, design thinking

Table des matières

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I would also thank every person that has helped me on this project and has encouraged me to continue with it for the past 2 years. First, my friends that support me from the earlies stages of the project and gave counsel and motivation when I needed the most. I would like to specially thank Lara and Arthur, who joined the adventure and have contributed to the project a lot. I do not forget all the testers, interns and coaches that have taken active part in the project devoting their time to the development of Tulipal.

I am very grateful to my family that have always believed on my capabilities ; and specially to my mother, who encourages me to reach my goals in life and has devoted her time to the reading and correction of the present text.

Let us not forget the Cercle Polytechnique, which occupied my time when my studies did not. This association thought me that with the perfect combination of fun, motivation and dedicated work, even the craziest projects are possible. It has also brought to my life experiences, fun, friends and memories. Finally, I am deeply grateful to all my friends, who have influenced me on the right way and have contributed with their humour, thoughts and personalities to the person I am and the engineer I am about to become.

Foreword

The role of the engineer

The simplest definition of an engineer is that of a person who, by exploiting and applying his scientific knowledge can manage to build and design new products or processes. It is in the soul of an engineer to innovate and thus, he (or she) has a determining role in our society ; just looking at all the objects, machines, processes that surround us and define our societal relationships we may perceive how engineering impact our lives.

The role of the engineer should not stop on producing new inventions, but these ones should have a rationale behind. Since these new inventions are one of the key influences that shapes our society, they should have a goal that contributes to a more balanced and fairer, sustainable and equitable society. We, engineers, are agents of change and ambition and determination that drive us also dictate the impact of our actions. These challenges, that we decide to take part in or in which we decide to work as engineers, may address different societal objectives. Here are two must-have goals of important relevancy that personally guide me as a young and to-become engineer :

1. On one hand, **inequalities**, among which the one of gender becomes an increasingly burning issue.
2. Secondly, climate change, which demands an urgent energetic and **ecological transition** in our society.

Both of them can be tackled from an engineering perspective. Either as the **big responsibility** that we may uptake in facing them and or by considering those issues as a **great opportunity** to have a positive influence in our society.

"Pour ce qui est de l'avenir, il ne s'agit pas de le prévoir, mais de le rendre possible." -Antoine de Saint Exupéry, Citadelle, 1948

Gender inequality

"Nearly half of the world's population menstruate at some point in their life and yet there are secrets, myths and taboos all around the world about this natural process." [13]

Menstruation and menstrual hygiene are to be considered as pivotal issues for gender equality. In fact, menstruation have a huge impact on women's life from a cultural, educational, and socio-economic point of view.

Cultural impact of menstruations.

Today, menstruation is still overlooked in most societies. While in Europe, governments are acting and mentalities start to change, periods are still a big stigma in low-income countries. The taboo surrounding menstruation is present overall : old fashioned devices, misunderstandings, fears, rejections, lack of economic support and very many other elements that have become an important impediment to introduce innovative solutions to solve long lasting problems in women life. Plan International in the UK has carried out one of the largest international surveys on menstruation, for example, showing that 70% of girls in India have never heard of menstruation before their first period. In the UK, this study found that 1 out of 5 girls are harassed about their period while 48% of girls are embarrassed talking about it [13].

Educational impact of menstruations.

One of the most important international issues is access to education for young girls who are menstruating [24]. While in developed countries the access to education is not directly linked to the regular appearance of periods, in low income countries does have an important impact. According to that same survey report, 20% of girls in India drop out of school after having their first period, and 70% of girls in Malawi miss 1 of 3 days of school every month because of their period [13]. In 2015 the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) estimated that at least five hundred million women lacked sufficient resources to manage their periods. With insufficient menstrual solutions, many girls missed a week of school every month or they dropped out for good.

Socio-economic impact of menstruations.

"Period poverty", or the economic difficulty directly linked to menstruation, is a societal issue both for developing countries as well as for developed countries, since it remains highly taboo. The women most frequently affected span from homeless women, asylum seekers, refugees, inmates, and adolescent girls. To overcome this problem, women usually are forced to use their own remedies (using toilet paper, fabric, etc.), with the subsequent lack of hygienic and quality control that may end provoking important health problems. In the worst scenario, they are compelled to exchange unprotected sex to be able to buy the basics to cover their periodic necessities.

Access to safe and hygienic sanitary protections should be a right, as menstrual health is fundamental to the advancement of human rights, education and equality between men and women [31]. Innovating on period-related solutions and looking for ways of improving the actual available solutions all over the world is a way of breaking taboos, contributing to the education and demystification of such a regular hormonal cycle ; and last but not least helping women to live their periods easier, safer and more naturally.

The ecological transition

"Each degree matters, each year matters, and each decision matters : not acting today is adding to the burden of the next generations [...]. Limiting global warming to 1.5° C is not impossible but requires strong and immediate policies." [1]

Humans are responsible of approximately 1°C of temperature rise before pre-industrial era. The Intergovernmental Panel on Climate Change (IPCC) has quantified 4 different scenarios for global warming in the XXI century, the so called RCP (Representative Concentration Pathway) scenarios [14].

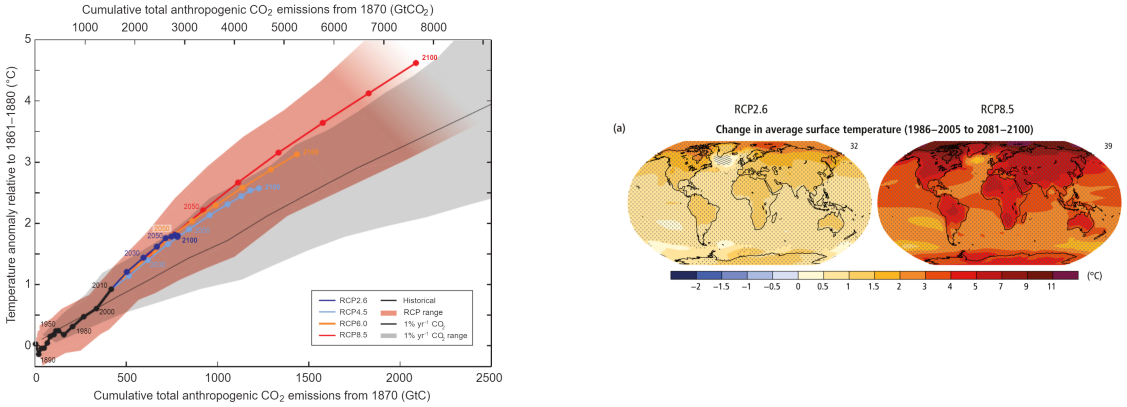


FIGURE 1: RCP scenarios. [14]

Due to the inertia of climate change, the emissions of today contribute to the global warming of tomorrow. In 2016, countries agreed (Paris Agreement, 2016 [21]) to reach the ambitious goal of limiting global warming rise to a level well below 2 °C and continuing efforts to limit it to 1.5 °C (RCP 2.6, Figure 1), in order to prevent dangerous climate impacts (RCP 4.5, RCP 6 and RCP 8.5). Only one year later, the goal seemed to be impossible ; according to nature climate change, *"the likely range of global temperature increase is 2-4.9° C , with median 3.2° C and a 5% (1%) chance that it will be less than 2° C (1.5° C) "* [27].

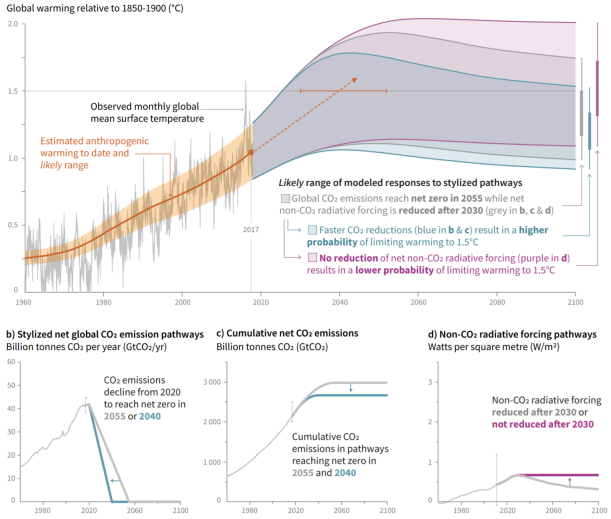


FIGURE 2: Paris agreement's scenarios to achieve the RCP 2.6 goal.

Even if the 2.6 RCP was reached, the risk of rising 1.5 or 2 degrees of global warming is still very high with devastating effects : climate change with the rise of mean temperature with higher probability of drought and precipitation deficits ; global mean sea level rise causing migrations ; impacts on biodiversity and ecosystems ; or climate-related damages on health, livelihoods, foods , water supply or economic growth [35]. And all of those without even imaging the impacts of more dangerous RCP scenarios.

1. Valérie Masson-Delmotte, Co-Chair of Working Group I of the IPCC (8th of october 2018 – french Senate intervention)

Limiting those impacts can be achieved by reducing the CO2 emissions. If the 1.5 °C goal want to be achieved, with or without overshoot, the following graph shows the CO2 emissions evolution to be adopted.

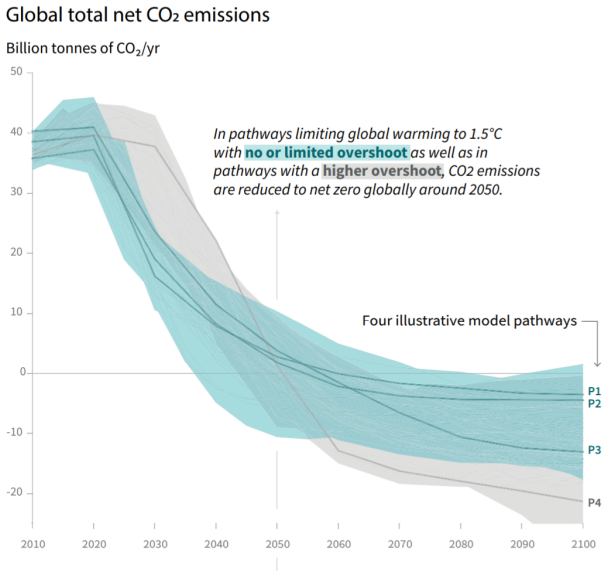


FIGURE 3: The CO2 emissions evolution to be adopted, on a no or limited 1.5°C overshoot scenario..

In order to have a no or limited overshoot (of temperature above 1.5°C) scenario, emissions should stop growing from tomorrow and start decreasing at a rate of 5% per year. If people ask themselves what does 5% emission reduction per year look like or how could it affects our daily life if not done on a controlled way [2], we just need to acknowledge that 2020 global emissions are likely to decrease between 4% and 7%, due to the confinement forced by the COVID-19 pandemic. [16].

"Sustainable development supports, and often enables, the fundamental societal and systems transitions and transformations that help limit global warming to 1.5° C. Such changes facilitate the pursuit of climate-resilient development pathways that achieve ambitious mitigation and adaptation in conjunction with poverty eradication and efforts to reduce inequalities"

The ecological transition [3] should be taken into account in every project to contribute to the greatest challenge of our era : the global warming.

2. One day, sooner than later, we might be forced to reduce emissions if transition remains non-existent for the next decades. Or we can start changing on decreasing on a controlled way such changes can be more predictable.

3. The ecological transition refers to energy transition (energy efficiency, preference for renewable energies), industrial transition (local production of recyclable goods in a circular economy perspective) as well as agri-food transition (replacement of an industrial agriculture by an organic one) [23].

Chapitre 1

Introduction

1.1 Context

At first sight, gender equality and ecological transition, seem to have nothing in common. However, as briefly introduced in the previous section, every product has its own and direct impact. One of the fields where we still find a lot of non-reusable products are the period-related products ; in fact, sanitary applications are the fifth single use plastic device most found in marine litter [7]. When talking about the impact of menstruation in different domains of our society, and combining it with the ecological transition, there's something that immediately comes into the mind of a lot of women : the menstrual cup. Menstrual cups are a reusable sanitary protection that cost in average, 10% of the traditional sanitary protections price, with additionally just only a 1.5% of their climate change impact [1]. A huge difference that needs to be taken into consideration.

1.1.1 The period and female hygienic protections

"Menstruation is an educational and socio-economic issue across the world, not just a monthly biological event".

Half of the world population, i.e. women, have their period over half of their life. Indeed, a woman manages her menstrual blood flow on average 65 days per year, or 2250 days on average during her life which is equivalent to more than six years throughout her life. Following the narrative, this natural process happens to more than 300 million people every day. Globally, this represents 1.9 billion women, that is to say 26% of the population who is in menstruation age. And yet, for some reason, there are still taboos, absence of innovation and lack of access to solutions, what all together refers to as menstrual precarity.

In addition to societal problems involving the period as the ones mentioned above, the classical solutions used by most of women to tackle menstruation are not exempt from problems. First, due to the historic monopole in the production of tampons and cleaning pads, lack of transparency concerning these traditional hygienic protections dominates the market. Indeed, the latter protections contain chemicals such as chlorine for bleach and perfumes used to make the product more attractive, or even pesticides utilized in cotton cultivation. In addition, these protections are intended for single use which strongly collides current mentality and go against the efforts devoted to fighting climate change and its devastating effects [1].

Short history of modern menstrual products innovation

Women have handled menstruation in a variety of creative ways throughout history. Before the modern era (prior to 1800's), rags were put between the legs and washed and dried for reuse. The first commercial articles available came in the 1890's with products like the ones showed in Figure 1.1, ancestors to the nowadays sanitary napkins. [15]

1. The ecological impact of traditional sanitary protections will be discussed latter on this report.

FIGURE 1.1: Belted sanitary pants

FIGURE 1.2: Menstrual cup.

Then, during the First World War, cellulose was noticed to be more effective at absorbing blood compared to cloth bandages and inspired the first cellulose Kotex sanitary napkin (1918), produced as a belted sanitary pad. In the meanwhile, home-made menstrual rags were still in use throughout Europe. In 1933, the first tampon was patented, and later commercialized under the name of "Tampax". Almost one century after, this latter device is still in use worldwide, overall in developed countries where welfare allows women to easily access to it, and only small changes have been introduced since. The first beltless pads came out in 1972, and it is only in the 1980's, when pads started to appear in the market. As of 2000, over 80% of women used tampons, with pads and panty liners close behind in terms of percentage of use.

However, *new* reusable protections have emerged lately and started to be considered by an increasing number of women across the world [2]. One of those devices is the menstrual cup that was created back in the 1930's, and updated later on, with certain improvements introduced with a a patent dated back in 1956, that conforms a cup very similar to the model available today.

1.1.2 Menstrual cup

The menstrual cup, or simply the "cup" (Figure 1.2), is an alternative to traditional hygienic protections. It is a container made of medical silicone or thermoplastic elastomer (TPE) which is inserted into the vagina and intends to collect blood during the menstrual cycle. The cup is reusable (while applying the necessary cleaning measures) and last for five years.

The adoption of the cup requires a familiarization phase that extends over several cycles ; 73% of women want to continue using this hygienic product [26]. According to the Journal of Obstetric and Gynaecology report [33], the reasons why women consider this product as best and most effective method rely majorly on the following aspects : the cup is respectful to the environment ; trustworthy and works well ; economic ; discreet and comfortable ; it requires lower frequency of protection changes ; the non-need for spare protection to be carried with you ; the product life of 5 years ; and the ability to facilitate better knowledge and understanding of your menstrual flow.

The aforementioned aspects link directly to the advantages that the menstrual cup provides as an alternative to disposable periodic protection :

— **Portable** : According to doctors, the menstrual cup (and other internal female sanitary protection, as sponges or tampons) can be kept for a maximum recommended time between 6 and 8 hours. The reason behind it is to prevent menstrual blood from accumulating in the vagina and thus to avoid any possible toxic shock syndrome [22] [2].

— **Better for health** : The menstrual cup is made of medical silicone or thermoplastic elastomer (TPE). Both are neutral materials for the human body used in many prosthesis. The cup is not industrially treated, it does not contain additives, bleaching agents, latex, bisphenol (BPA), phthalates or deodorants. Finally, some of them go through numerous tests and meet various high-level quality standards [3]

— **Ecological** : As it will be lately discussed, every action, process or product has an impact on the environment. The menstrual cup is reusable for up to 10 years term, making it a low environmental impact product [1].

— **Inexpensive** : The menstrual cup costs on average between € 20 and € 30 for a period of 5 years (0.42€ per month). In the other hand a box of tampons (basic package needs for one period) contains 22, at

2. Reusable sanitary protection as menstrual cups, period panties or reusable pants.
3. Standards : ISO 10993-5, ISO 10993-10, ISO 13485 : 2004.

an average price in Belgium of 5 €. It gives a final figure of € 325 for a complete term of 5 years (and 13 periods per year) [31]. The menstrual cup's price is unbeatable and is even much more worth when about the comparison is made in terms of raw production (1-2€/cup).

Indeed, there are other green alternatives to the cup as the reusable napkins, "period panties", reusable applicators used for tampons and finally, the bio alternatives for tampons and sanitary pads. However, the menstrual cup is the most widely used reusable hygiene product. From the above considerations and after listing all its advantages, basically in terms of portability, health impact, ecological footprint and price, then several questions need to be tackled and answered : Why the cup is not used worldwide and stands as the perfect solution ? Why are tampons and classical sanitary protections far more used than cups ? And the answer spots directly to the device maintenance. This reusable solution may have a lot of advantages, but because of its reusable characteristic it needs a certain degree of careful maintenance.

1.2 Problematic

Unlike traditional hygienic protections which are fundamentally intended for unique use, the menstrual cup maintains its integrity for a longer use term for which it requires some level of maintenance. Despite the strengths and advantages of the cup, its maintenance is not always easy and at certain extent may cause demotivation from adopting this reusable solution. As others methods (as it is the case for tampons) the cup must be **inserted and retired** from the vagina. But due to its reusuability main purpose, the cup unlike the others non-reusable devices, needs to be **cleaned** 3 or 4 times a day [4] and ideally **sterilized** at least at the beginning and at the end of the menstruation period. In addition, in some cases, a **psychological barrier** may appear that also stops potential users from adopting it on regular basis.

1.2.1 Identifying the issue

According to the Journal of Obstetrics and Gynaecology [33], the reasons that lead women not to consider the menstrual cup as an optimal solution are (sorted by highest importance) :

1. The fact that the product must be washed between each use, and thus requires some maintenance ;
2. The use of his hand when removing the cup, washing it and replacing it ;
3. A foreign product in her vagina ;
4. The difficulty of inserting the menstrual cup ;
5. Concern about infertility and infections ;
6. The leaks ;
7. The initial expense.

The origin of some of these reluctancies (specifically n°3 and n°5 and n°6) can be tackled by educating about periods and demystifying the use of menstrual cups. In regards to impediment n°4, two surveys have been carried, with almost 1000 answers, in order to better understand the problematics and how important they are. According to this latter, the difficulty of inserting the menstrual cup disappears after the first cycles, once the user has adopted the menstrual cup and becomes familiar with the use procedures. To get further on the analysis of the reasoning, the first two arguments are about the menstrual cup cleaning, a problem that directly links to its maintenance. Unfortunately, the cleaning issue does not disappear with practice or education. But finding a solution to such a main problem as it appears to be, the cleaning procedure, would first solve the two most important hindrances to the menstrual cup adoption, and on the other hand, it will make the daily day of menstrual cup users much easier.

Finally, something that is not perceived straightforward from non-users of the cup, but remains still unsolved for regular users, refers to the sterilization of the device itself. The present report describes how to tackle specifically all those problems from a technical point of view by developing one device that solves both (in one shot) : **the cleaning and the sterilizing of the cup.**

1.2.2 Survey results

Two main surveys (by chronological order) :

4. In order to decrease the probability of the toxic shock syndrome.

1. **Identify the issue and analyze the use of menstrual cup.** *Launched in December 2018 and 459 answers received.* The survey included several questions to better understand the menstrual cup users' profile and behaviour, how they live within the menstrual cup. On the other hand, non menstrual users were asked about the barriers they face regarding menstrual cup adoption.
2. **Running a problems' analysis and developing a business survey.** *Launched in January 2019, with 326 answers received.* In this survey users and non users were asked about the different problems identified on the first survey and the ones highlighted by the Journal of Obstetrics and Gynaecology, and which was the degree of importance they give to these problems and an eventual solution.

Firstly, data from the second survey has been numerated and analyzed to identify the most important menstrual cup problems according to users and non-users.

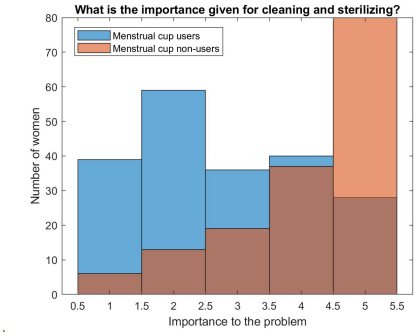


FIGURE 1.3: Importance of cup cleaning and sterilisation.

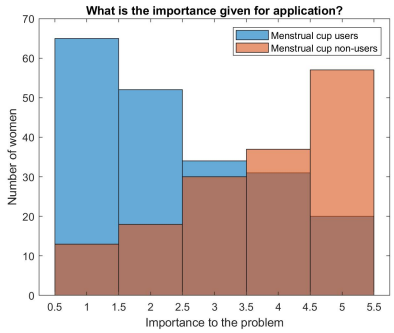


FIGURE 1.4: Importance of cup application.

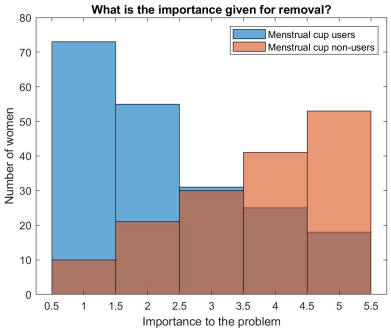


FIGURE 1.5: Importance of cup removal.

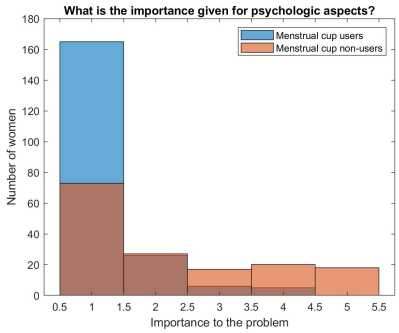


FIGURE 1.6: Importance of psychological aspects.

These 4 figures quantify the four main problems highlighted by the Journal of Obstetrics and Gynaecology as perceived from both, menstrual cup users and non-users. How women would answer to the question : *What is the importance (1 the least and 5 the most) you assign to the problem of ... ?*. The goal is to validate whether the two main problems to solve are the cleaning and the sterilisation of menstrual cups or not.

As expected, the cleaning, sterilisation and manipulation of menstrual cup are strong impediments for menstrual cup adoption. However, once the menstrual cup is adopted, the trend of histograms 2 and 3 (menstrual cup removal and application) has been inverted. This trend has been predicted before and is not a surprise ; in fact, the reluctancy of manipulating the cup remains just during the first cycles. Our main hypothesis has been validated and only the maintenance (cleaning and sterilisation) continues to be a problem also for users.

By analyzing answers from the second survey (within the knowledge base gained after the first survey analysis), the first histogram can be better understood. Why cleaning and sterilisation of menstrual cups problem is not as important as we could have thought ? This issue is strongly related to the frequency of cleaning and sterilisation of menstrual cups. The following figures show how often users clean their cup :

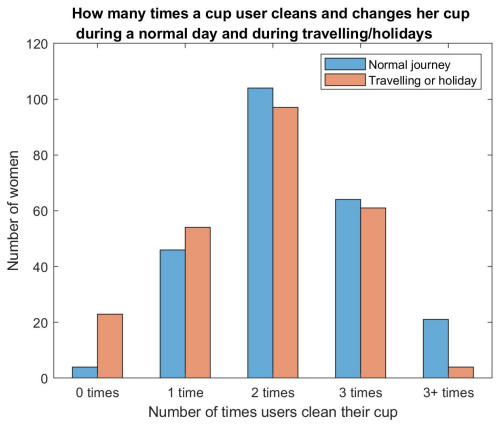


TABLE 1.1: How often users clean their menstrual cups per day.

In fact, the problem is greater than what could be interpreted from the first histogram. Users are not respecting the recommendations from doctors to change cups 3-4 times a day. This situation gets even worse when they are travelling or on holidays mainly due to the difficulty for a majority of them to carry out such a cleaning when they are in public places (at work, at university, on the move, ...) because public toilets often lack private sinks (Only 28.7% of women answered to always have access to a private sink). Therefore, most of the users are constrained (and also self-limited) to change their cup only at home which reduces changes to 2 times a day, while at home in the morning and in the evening. Regarding sterilization, instructions recommend doing so every day. Gynaecologists also advise same. However, the survey let us know that 95% of users do not follow these recommendations.

To sum up, the issues are on the one hand, **cleaning process of the cup during the day** and on the other hand, **sterilization**. The goal is to dedicate a single object to addressed both topics, making it ready to use easily, healthy and as regularly as needed, anytime and anywhere, thus removing the constraint of needing a private sink and making sterilization more regular and efficient.

1.3 First solution : TRIAXES

This problem and the development of a first solution for cleaning and sterilizing the menstrual cup was firstly tackled during the TRIAXES 2018-2019 edition by one of the teams created under its umbrella. The present document stands as a continuation of the technical development carried by that team and the further enhancement of the prototype developed there at. TRIAXES is a course-project where students from four different fields (polytechnic engineering, law, business engineering and industrial design) work jointly to develop a product based on the *Design Thinking* approach by creating a technical and design solution, a business plan and a statement on the legal aspects involved in the development of such a new product.

The team created what later became **Tulipal** (Chapter 7), a menstrual cup startup [5] devoted to the development of complementary menstrual cup's products ; one of which is the object of this Masther Thesis. During the TRIAXES phase, the team chose the topic (menstrual cups), identified the problems (cup cleaning and sterilizing), designed a non-functional prototype based on a poor R&D phase [6], created a business plan (that has been completely changed from its original statement and largely improved [7]) and finally made some primary art search (with no analysis perspective and without following a proper methodology).

Still, there are few though pivotal concepts reused in this Master Thesis from the TRIAXES project which are the previous surveys carried out to identify the problems (The systematic data analysis is new), and the prototype developed that inspired the actual solution presented in this current report. All the other sections and parts were first put into question and then redone, modified and accommodated to a much advanced and comprehensive perspective.

5. Founded by one of the original TRIAXES' members, Lucas Secades and a business engineering student external to the TRIAXES team, Lara Soggiu.
6. Poor because of the time devoted to the R& D and the low questioned prototype.
7. Lara Soggiu (Tulipal co-founderg) made a new business plan as her 2020 Master Thesis.

Chapitre 2

Task clarification

The goal of the task clarification analysis is to study the problems identified, and describe and define functionalities that the product must have integrated in order to solve those problems and satisfy the user needs. As repeatedly mentioned above, the two main issues that the device aims to solve are the sterilization and the cleaning of the menstrual cup. However, this device intends to become a commercial product and therefore it must equally encounter not only the users' expectations but also the business, environmental and legal aspects derived from its production and commercialization. Each of the features the device must embrace are ranked by their priority : **3 corresponds to the highest priority** (most important ones) and **1 to the lowest** (less important ones) and. Because of the impossibility of matching all the requirements, the priority levels will help during the R&D phase to make the right choices between the different options, solutions and/or prototypes. Also, when quantifying was possible, values were given to the features [1]. For example, in Figure 2.1, the 312.5 cm^5 (volume) and the 0.5kg (mass) specifications come from the users : "*The device should not weigth more than a regular 50cl water bottle filled up, and should have more or less the same voulme as a 25cl cup (for drinking)*". This given, a 25% margin was applied to the volume (125% of 25cl being 312.5 cm^3) and the weight of the given example is more or less 0.5kg.

2.1 Assumptions

The following assumptions, that arise from the surveys presented previously, are stated for enabling focusing the efforts on a more precise product, timely and efficiently. These assumptions must always be respected regardless of the priority degree of other features.

1. The device will be sterilized always at home, once per day at most. Therefore, there is no need to develop a sterilizer that would run in continuously.
2. The cleaning must be able to be undertaken in every random place where we could find a toilet, in absence of a public sink. As a non-exhaustive list of possible places we may refer to different locations : someone's house, public place, workplace, hotel, festival, open space meeting, university, ...
3. Both aspects (sterilization and cleaning) must not be solved with two completely different devices, but on the contrary, should leverage on each other and therefore reuse the parts as to create the best 2in1 device possible.

2.2 Technical needs

The technical needs refer directly to solve the basic problem of sterilization and cleaning from an engineering point of view. To do so, the foreseen device which would meet those requirements separately should be able to work together and provide the user the solution to clean and sterilize the device at once. Based on the issues outlined above, the goal is to create a product that allows users to clean their cup easily, healthy and safely, everywhere despite the privacy conditions, even in a public place in the absence of a private sink. In addition, this product must sterilize optimally, efficiently and intuitively while offering a dedicated sole object. Ergonomic constraints must be added for consideration, since the device aims to be portable.

1. Most of the feature further presented are qualitative features and not quantitative

As it will be shown on the chapter 5 (Design & Development), the 2 main functionalities (cleaning and sterilizing) are first developed separately and then both have been merged in order to create the final 2in1 product. Not all the features that the device must integrate presented here were found before the R&D phase. But for the sake of clarity they are presented here regardless of their chronological order. In fact, some of those appeared later on during the tests of the prototypes or during the R&D phase itself.

Ergonomics		
Features	Value	Priority (1 to 3)
Smallest volume	< 312.5 cm3	3
Lightweigth	< 0.5 kg	1
Can be used with both hands	/	2
Easy of use		
Features	Value	Priority (1 to 3)
Few number of mouvements	< 2	1
Intuitive	/	2
Fast	< 1 minute	2
Use wherever	/	3
Cleaning		
Features	Value	Priority (1 to 3)
Remaining blood acceptance	0%	3
Easy to dissasemble to clean inside	/	2
Reusable method	/	3
Design		
Features	Value	Priority (1 to 3)
Attractive design	/	2
Simple	/	2
The form helps the user to use it	/	1
Materials & production		
Features	Value	Priority (1 to 3)
Production can be industrialized	/	
Compatibility		
Features	Value	Priority (1 to 3)
Compatible with all cups stems	/	2
Compatible with all cups sizes	/	2
Compatible with a cup sterilizer	/	3
Safety		
Features	Value	Priority (1 to 3)
Cleaning without finger contact	/	3
Can be a medical device	/	1
Can be ISO certified	/	3

FIGURE 2.1: Design & Technical specifications for the cup cleaner.

Ergonomics		
Features	Value	Priority (1 to 3)
Smallest volume	< 312.5 cm3	3
Must not add a lot of pieces to the device	1 or 2 pieces	2
Easy of use		
Features	Value	Priority (1 to 3)
Only 1 button ON/OFF	1-2 different	1
Intuitive	/	2
Fast	less than 10 minutes	2
Sterilizing		
Features	Value	Priority (1 to 3)
Must use water	/	3
Adapt to external pressure	/	1
Sterilize the cleaner too	/	2
Doesn't damage the cup of the cleaner	/	3
Design		
Features	Value	Priority (1 to 3)
Attractive design	/	2
Simple	/	2
The form helps the user to use it	/	1
Materials & production		
Features	Value	Priority (1 to 3)
Production can be industrialized	/	3
Compatibility		
Features	Value	Priority (1 to 3)
Compatible with all cups stems	/	2
Compatible with all cups sizes	/	2
Compatible with a cup cleaner	/	3
Can sterilize other objects	/	1
Safety		
Features	Value	Priority (1 to 3)
Sterilize as much as other sterilizers	99,99% germs	2
Can be a medical device	/	1
Can be ISO certified	/	3

FIGURE 2.2: Design & Technical specifications for the cup cleaner.

2.2.1 Cleaning

The cleaning functionality is the one that will let the user clean her menstrual cup in the worst possible scenario when she is in a toilet that lacks a private sink. The idea is that once the user is at the toilet, she will first retire the menstrual cup, then empty it and finally use the cleaning device to clean the blood remaining in the cup without major external needs [2], and be able to reuse the device safely afterwards. According to the results of the surveys, the cleaning is the most important feature for users, and therefore shall guide the device's development. First, by regarding the ergonomics of the device. It aims to be a portable device so it must be the lightest, smallest and most wearable possible. If the device were to be operational for just that one function, i.e. the cleaning, the procedure would then need to be simple, intuitive and be performed fast. The cleaning procedure should then be possibly performed anywhere and as the cup it serves, be a reusable mechanism. Figure 2.1 summarises the features that the cleaner should have in principle. Whenever a value constraint exists, this one is given. Finally, the features are ranked on ascendant priority.

2.2.2 Sterilizing

The second main functionality is sterilization. As stated with the assumptions, the foreseen device is intended to be used at home (or at least at a secured, stable and healthy environment due to the duration of the process). That implies that the cup cannot be sterilized in a public toilet as the cleaner can be. Moreover, the device must meet also the third assumption and needs to be fully compatible with the cleaner. Altogether requirements in terms of Ergonomics, Design, Materials & Production or Compatibility have to be addressed jointly instead of separately for two distinct functions. One advantage of having a 2in1 device is that the cleaner could be sterilized each time the cup does, but we must be sure that neither the cup's nor the cleaner's components are damaged during the sterilization. The timing regarding the sterilization is a bit longer than the one required for just cleaning purposes. The procedure has to be intuitive in its whole and only one button and a screen or LED to be used. Sterilizer's prototypes that add the smaller number of pieces to the cleaner and help the product to be the most efficient and operational 2in1 possible will be prioritized. Finally, the

2. Minor needs could include the use of small tablets, water from the public sink, some toilet paper...

sterilizer should be able to sterilize to minimum the same extent that other sterilizers in the market propose. As before, the functional analysis has been translated onto specifications on Figure 2.2.

2.3 Not technical needs

Other type of requirements may exist but those are of more subjective nature and strongly depend on non-technical considerations. Those might not be crucial to ensure correct performance, but they could indirectly influence the device conceptualization and its development. First, even if a solution is the best one from a technical point of view, it could not be the one that best fits the market constraints or meets the users' satisfaction levels. For example, users could prefer a solution that takes more time to perform a task but that make less noise or its design is prettier ; industrial perspective might not be driven by perceptions but by efficiency and technical rigor but still would need to have those other user-driven elements into account if the product is to be profitable.

We can divide such non-technical user's needs in two categories ; on one hand, we will consider the requirements that are imposed by the development of the project from a point of view other than the technical, i.e. environmental, business and legal. On the other hand, there are the user's wishes that root on the individuals themselves and their own circumstances.

2.3.1 User's willings

Some of the user willings , were already detected from the first surveys. Other have been identified during the several tests and talks with the users during the development phase. However, all are presented here at the same time as they have been compiled together at the beginning of the project. In the Chapter 5, the different type of tests undertaken throughout the project are detailed. The findings are presented here chronologically and in relation to the type of tests that have helped to identify the user's requirements (in the form of feedbacks).

Since they depend on the persona (the users), they do not follow a hard logical pattern but on the contrary, they respond to subjective reasons. This is why some of them could not be predicted, and there are not strong technical arguments that could support them.

User willings		
Features	Value	Priority (1 to 3)
The device mustn't touch the ground when cleaning	/	3
Noise while cleaning	Don't make	2
Not direct contact with other stuffs in the bag	/	2
Small free-detachable pieces	Not exist	1
Colours and design must be striking	/	1

FIGURE 2.3: User willings for the final device.

2.3.2 Business, environmental & Legal aspects

The following features are the result of non-technical requirements necessary that are to be considered in the final menstrual cups products as to fit into the market, and follow a sustainable and resilient approach. As the device is developed in a multi layered perspective combining technical with business and legal perspectives, the device must encounter some requirements to be able to respect a feasible and successful business plan and the intellectual protection rights and subsequent constraints (IPRs).

From the IPR point of view, one the strongest ways of protecting an invention, if not the strongest one, is the patent, which gives the intellectual property to an inventor and enables him to exploit his invention at its sole benefit. However, before being patentable, the device should be free to operate. Both concepts (patentability and freedom to operate) will be explained and discussed on Chapter 6.

Additionally, and as stated on the Foreword, ecological approach is a driving force in this project. Some requirements in this respect will be presented here including the reparability of the device, long life item, low carbon emission, low energy demand...

Finally, the business plan has been developed in parallel to the development and production phases and with the contributions of a busines engineer student. The studies carried during her Master Thesis raised awareness on certain economic restrictions majorly regarding the production price and its external look. Doubtless, the device should give due answer to some market needs.

Law		
Features	Value	Priority (1 to 3)
Free to operate	/	3
New and different design	/	2
Must be patentable	/	2
Business & Marketing		
Features	Value	Priority (1 to 3)
Price	20-30 € production	3
Must be able to be sold in pharmacies	/	1
Must look clean, simple and robust	/	3
Environemental		
Features	Value	Priority (1 to 3)
Easy to repair	/	3
Low carbon emissions	< 10kg of CO2	3
Last long	> 5years	3
Recycled materials	>70% recyclable (in mass)	3

FIGURE 2.4: Technical requirements from a business & legal point of view for the final device.

The previous constraints will be discussed and evaluated on the Environmental, Legal & Business chapter 6.

2.4 Design brief

Commonly, on R&D student projects in university, almost only technical specifications are taken into account. Eventually, very few times, the project will evolve, get funds and end as a spin-off project, then the non technical specifications are taken into account at the end, once the device is already developed, which means changing and challenging again the device. In this project, both (technical and non-technical) are taken into account from the beginning. Developing a device for more than one year that do not correspond to the users (user willings and market), that has already been developed [3] (law) or do not match your own convictions, is a non efficient way of carrying a R&D project.

The device that should be developed is a **2in1 device** that **solve both problems : cleaning and sterilizing of menstrual cups** (within the assumptions frame) ; that has been developed with the **menstrual cup users** and for the menstrual cup users ; having a **simple, ergonomic and minimalist** design ; the most **carbon neutral** possible ; **free to operate** and eventually **patentable** ; and with a production price that would allow the device to be the **value proposition of a profitable business model**.

3. Or at least some features have already been claimed.

Chapitre 3

State of art

The aim of the state-of-the-art study is to conduct a literature and industrial search and gain a comprehensive overview of the existing methods for cleaning objects and sterilizing devices. It will allow to equally analyze the existing devices intended to clean and sterilize menstrual cups. Since no adapted device existed at the earlies stages of this project, the TRIAXES R&D phase was carried without analysing any tier-device. However, some of them have appeared later on either on the market or as new patents, and therefore, have been also subject to analysis despite the period of appearance.

Devices that are currently commercialised are presented in this section while the patents will be discussed later in this report. Since the device intends to become a commercial commodity, it needs to meet business and legal constraints. In that respect, it is crucial to know well the market and find the niche where the new device may be allocated and has a higher (financial) success rate. Detecting and analyzing the different existing mechanisms (in this case, optional cleaning and sterilizing methods) allows to choose the ones that best fit all the device's needs by adapting them to the factual constraints and requirements.

The following sections present the results of the previous mentioned research : the **literature overview** and the **market research** will be both addressed independently for first cleaning and then sterilizing requirements, and therefore results are also clearly differentiated.

During the former TRIAXES project, half of the first part of the *state of art* analysis was already carried out with a resulting literature and industrial overview of the currently existing methods for cleaning objects (sterilizing methods wasn't yet done). Said analysis will not be displayed here, only the results from the literature-related search will as they are the baseline for further review. The second analysis, carried out in relation to industrial existing solutions, could not be done because nothing existed at that time. In the short timeframe of a year, several products and solutions have emerged on either industrial market or patent's databases.

3.1 Products in literature

A prior state-of-art research is always needed for the proper development of a device. Knowing what already exists in the industry in the precise domain of cleaning and sterilizing mechanisms but equally in similar fields, will provide a clear understanding of the methods and mechanisms that could be exploited as a starting point for a sterilizer and cleaner device for specific purposes as it is the case of the cup.

3.1.1 Cleaning mechanisms

The idea behind traditional cleaning methods is to use one material as a base, then apply a tangential force to other material where the dirt is and, by friction, separate the dirt. The subsequent steps will be to absorb, store or dilute the dirt which has been detached.

Brushes :
Most of the clean products use this type of mechanism : from toothbrushes to brooms. The idea is that the dirt will separate from the material when friction is applied by the brushes. An example that can be adapted

to cups are the brushes used for glass cleaning in bars.

Shaker :
Shaking mechanisms use the water both for applying friction and diluting dirt. Those are not the most common cleaning method due to its low efficiency rate. However, it becomes rather useful when the dirt cannot be reached with brushes or sponges. Water jets are far more efficient, but they are not so different from shakers, since they also use water for diluting and applying the tangential force. Among others, washing machines are based on this type of cleaning methods.

Sponge :
The sponges are a very well-known mechanism. Those are softer than the brushes thus provoking less damages to the objects. Moreover, there is not need of water to dilute because they directly absorb dirt. However, this latter specificity makes this mechanism not subject to long-term reuse.

Solvents :
The principle is to dissolve the dirt by attacking the dirt particles with liquid solutions (they might contain some chemicals diluted). Sometimes, they are used alone when none of the precedent described cleaning mechanism can be used like for cleaning the pipes. Still, most of the time they are used coupled to brushes, shakers or sponges ; the most common type of solvents used in the daily life are all sorts of soaps and detergents.

3.1.2 Sterilizing methods

Sterilization refers to any process that destroys all forms of life, such as microorganisms or other biological agents, to avoid health issues ; it is particularly used in food and medical applications [25]. The most used principles are to either kill them by using chemicals, pressure, radiation or heat, or to use filtration to better remove them, without eliminating. Since complete sterility cannot be achieved, the sterility of a product (material, food or device) can be defined only in terms of probability.

For each of the sterilization families, there are different sterilization process. However only the ones that can be applied to the present application and comply with the strongest specifications stated in the previous Chapter are here presented [1].

Heat sterilization :
Heat sterilization is the most effective and widely used method of sterilization that can be achieved through different heating mechanisms as boiling water (100°C), steam (120-140°C) and coupled with pressure or dry air heat (+-250°C), with the ultimate goal of heating the biological agents present in the product surface and killing them by destroying some of their essential cell constituents.

Steam. Among all the methods available for sterilization, the moist heat (saturated steam) is the most common used method. Moist heat destroys microorganisms by the irreversible denaturation of enzymes and structural proteins [34].

Boiling water. Boiling is a very simple method. Heating water to a high temperature, 100°C, kills most of the pathogenic organisms that causes waterborne diseases. This later is the one of the two most used methods since it can be easily done at home.

Hot air. Dry heat sterilization technique requires higher temperatures and longer exposure time than the two previous ones. Dry heat causes most of the damage to living organisms by oxidizing molecules. As for boiling water, this method can be performed at home and requires just an oven.

Radiation sterilization :
Sterilization can be achieved by using ionising or non-ionising radiation. Radiation consists of electromagnetic waves with small wavelength, thus carrying high amounts of energy ; when intercepting a surface those waves exchange energy with the atoms of the latter causing either ionisation (inducing genetic damage and chemical changes in key biological macromolecules) or heating the atoms if energy is not enough to allow ionization taking place. It is a method that is growing in recent years though can only be used with radiation-resistant materials.

1. For example, flaming or toxic gas have not been presented.

Non-ionizing radiation. The most common source of non-ionizing radiation are UV. The energy on UV photons is insufficient to ionize [2] the microorganisms but sufficient to achieve commercially sterile temperature [8]. Heat is enough to destroy the nucleic acids of microorganisms and thus disrupting their DNA.

Ionizing radiation. The principle behind ionizing radiation (through E-beams for example) relies on delivering an accurate and precise dose to a product where the biological composition is well known in order to make its microbial architecture to decompose due to atoms and molecules ionisation, and thus achieve a certain sterility assurance level [11].

Chemical sterilization :
Chemical sterilization consists on using chemical bactericidal agents that attack some (or almost all) vital functions of the microrganism's cell(s). Among chemicals there exist two main families : gases like Ethylene Oxide, Ozone or Nitrogen dioxide ; or liquids like Hydrogen peroxide, Glutaraldehyde or Hypochlorite.

This type of sterilization is used when products cannot be sterilized by one of the previous presented methods : ra :diation or heat. In fact, not all products resist high temperatures or radiation. [3]

Filtration sterilization :
Filtration can only be used with gases or liquids, never with physic products, so it is not relevant in our case. It is commonly used when gases or liquids are sensitive to heat exposure (for example gases that are inflammable). The liquid or gas go through a filter that blocks the microorganisms (the filter holes depend on the size of the microorganism itself that needs to be removed) [12].

At the end, chemical, radiation or filtration appeared to be either too complex or not in compliance with some of the constraints specified before such as volume, price, toxicity, material resistance and others. The classical solutions which are widely used and reliable are saturated steam under pressure, hot air and boiling water. These are the ones that will be analyzed and adapted to the specific requirements of the menstrual-cup-related processes.

3.2 Existing solutions

Users have founded solutions to the cup problems (listed on the previous section) by adapting existing cleaning and sterilizing solutions [3]. At the beginning (just a couple of years ago), these solutions were created by the users themselves, the so called classical solutions. However, since the market for menstrual cup products is growing so rapidly, different dedicated products appear each month, most of them in the field of sterilizers and wash lotions. These products are devices that offer the users optimized and more efficient ways of solving the problems that were traditionally solved by the classical solutions.

3.2.1 Classical solutions

Even if a lot of products have emerged, most of the users are still often using classical methods for sterilizing. As it will be shown later for the cleaning, no well-adapted solution exists nowadays, which justifies the ongoing attachment to the classical methods described below. Important to remark that as presented on Chapter 2, not all users respect the 6-8 hours time frame for cup cleaning, so they do not really clean it outside in public places. The classical solutions are the following.

Boiling :
The classic sterilizing solution is the "the pan" method. It consists on filling a pan with water, waiting until it starts boiling and then introducing the cup on the water for at least 7 minutes. This is what is recommended on the cup's notices.

Cleaning at home :
Cleaning at home is not a problem since users can do it simply, safely and rapidly. They usually clean the cups under the shower with sanitary napkins or other napkins that only use for this purpose.

2. Ionizing radiation consists of electromagnetic waves or atomic particles with the capacity to strike an electron with sufficient force to strip it from its atom thus creating an ion. [28]
3. Technical solutions that weren't created for menstrual cups applications.

Wipes :
The classic wipes used for hands cleaning are also used by cup users for cleaning it when they are in public toilets. Though rapid and convenient when outside home, this solution goes against the principle of ecology-friendly aim of the cup.

Bottle of water :
It is the most adopted solution for cleaning the cup in public places. Users take a bottle of water with them and then use their hands to wash the cup. The toilet is utilized as a sink, and the bottle of water as a tap. Some companies have taken advantage of this situation and propose a small bottle of water as an adapted cleaning device. This is shown in Figure 3.1, but it should be noted that this device is nothing more than a regular bottle.

3.2.2 Dedicated products

The dedicated products are the ones that have been specially designed and developed for the menstrual cups. Most of them are sterilizers.

As said before, the market of menstrual cups evolves very rapidly : In late 2018, a market study did not reveal any cleaner or sterilizer product adapted for the cups and only few patents could be found. A couple of months later, in February 2019, a preliminary study showed that some products had appeared but they were only available in China and their quality was doubtful (Sterilizer I : water boiler and Sterilizer II : microwave sterilizer). A third research was carried out in September 2019, and this time the number of sterilizers, cup-related products and cleaners had increased exponentially (sterilizer III : steamer). The ascendant trend continues, and in 2020, two new sterilizers had appeared (Sterilizer IV : steamer 2.0 and Sterilizer V : UV sterilizer). Although they still are a few actors on the cup market, this trend shows the opportunity that this market offers and how the needs are currently (still partially) solved.

Cleaners

The dedicated cleaners (Figure 3.1) are : wipes, small bottles of water, brushes and washers. The first and last ones being the most sold among the brands.

FIGURE 3.1: Dedicated menstrual cup cleaners. From left to right : bottle of water, wipes, brushes and washers.

Wipes :
The traditional wipes have been adapted by cup brands to the cleaning of the cup. They claim to offer better results than the classical ones. As we can see in Figure 3.1, the wipes are advertised as capable to be used on the go, which includes public places. The following problems have been identified :

Type	Subtype	Description
Non technical	Environemental	It's not ecologic. Users uses the cup mostly because of its ecologic impact. Cleaning it with a not reusable system has the same impact as using tampons.
Technical	Cleaning	Cannot clean inside the small holes of the cup.
Technical	User	Most of users rather prefer not to clean it than clean it this way.

FIGURE 3.2: Wipes cleaner problems.

Bottle of water :
It is advertised as a dedicated object but is nothing more than a blow of marketing of the brand "Gobi" (Figure 3.1). This brand proposes its "mini gourdi" as solution to the detected problem. Still it is nothing else but a simple bottle of water with reduced dimensions. The user may employ this type of bottle rather than others for cleaning the cup within the traditional solution. The following problems have been identified :

Type	Subtype	Description
Technical	Cleaning	Users have to use the toilet as a sink
Technical	Cleaning	May not have enough water
Technical	Cleaning	Must use their fingers but cannot properly wash them
Technical	User	Not user friendly at all (imaging the position of users in order to use the toilet as a sink)
Technical	User	Most of users rather prefer not to clean it than clean it this way.

FIGURE 3.3: Bottle cleaner problems.

Brushes :
This kind of brushes gives answer to a specific cleaning problem : the blood which is inside the small holes allocated in the upper part of the cup is hard to remove. This kind of small brush fits perfectly inside these holes and let the user clean the cup easily. However, the brushes are not recyclable as the cup. An example of those are shown in Figure 3.1. Finally, this solution **is private sink dependent**, so it has not been further analyzed.

Washers :
These wash lotions are specially proposed for cup use. It disinfects the cup though it cannot be considered as a replacement for the sterilization. In addition, users still need to carry a bottle of water with them. This solution is **private sink dependent**, so it hasn't been further analyzed.

3.2.3 Sterilizers

Today, it exists 5 kinds of different sterilizers. Among them, 4 are apparently developed and produced by the same company ; the fifth type is widely commercialised by several brands. The Chinese company that originally developed this kind of sterilizers sold it to different companies that branded same product differently (as it is shown in the figure below).

FIGURE 3.4: Same sterilizer device sold by two different brands.

Currently available sterilizers use either UV technology, water steam or water boiling. The market analysis is summarised in Figure 3.13. It is interesting to remark that users seem to prefer water steam sterilizers rather than UV ones. In addition, the UV sterilizers are also sold as multi paramedical devices sterilizers.

Sterilizer I. Water boiling :
The water boiling sterilizer is only sold at Chinese retailers (Alibaba, Aliexpress...) and Chinese companies via Amazon. It was the first sterilizer on the market announced as fully adapted to menstrual cups (January 2019).

Sterilizer II. Microwave sterilizer :
The microwave sterilizer consists on a container made of plastic material that resists microwave radiations and high temperatures (100°C). Users only have to fill it with water (1), put the cup inside (2), introduce

the whole inside a microwave and heat it during several minutes. The higher the power mode selected, the faster water will start boiling and the faster the sterilization process will take place. There are two types of these sterilizers ; the first one consists of a simple plastic recipient with a hole on the tap which allow steam from water boiling to escape from inside ; the second type consists of a container made of an elastic polymer allowing the container to easily being folded up.

FIGURE 3.5: Microwave sterilizer device.

Even if the first kind of microwave sterilizers exists since several years, this is not still used widely by users. The following table summarises the problems of this kind of sterilizers.

Type	Subtype	Description
Technical	Sterilizing	Since water starts evaporating, the cup will remain with no water by the end of the process, thus the sterilization is not properly done
Non-technical	Users	Dirty approach because water goes out og the device.
Non-technical	Users	User do not like to share devices intended for food consumption with the menstrual cup sterization

FIGURE 3.6: Microwave sterilizers problems.

Sterilizer III. Steamer :
From a technological point of view, it's a very simple device. It consists of a steamer controlled by a time switch that heats a certain amount of water using a PTC heating element. The only user interface elements are a red LED and the switch. As shown in the circuit below, the power source is the grid that feeds both, the LED and the heating element. Then, users can push the switch and it will be down for 3 minutes, with no further control required, neither in terms of pressure, water level, or temperature. In this scenario, the process for users goes as follows : 1. Connect the steamer to the grid ; 2. Open the steamer ; 3. Put water inside ; 4. Put the cup inside ; 5. Press the switch (LED turns on) ; 6. Wait 3 minutes (until LED turns off) ; 7. User can pick up the cup.

FIGURE 3.7: Sterilizer III : steamer.

The different problems have been identified after testing and challenging it by users (Figure 3.9).

Sterilizer IV. Steamer 2.0 :
The second version of the steamer presented before appeared on the market in 2020. It looks like a completely

new device but the principle remains the same, and most of the changes are merely of aesthetic nature.

FIGURE 3.8: Sterilizer IV : steamer 2.0.

However, some of the problems that had been identified on its first version were solved.

Problems of the Steamer (Sterilizer III)			Sterilizer IV: Steamer 2.0	
Type	Subtype	Description	Problems solved?	Comments
Technical	Materials	Environment is too hot after 3 minutes.	Partially solved	Due to a bigger size
Non technical	User experience	User doesn't know if there's a lot of water or not.	Not solved	
Technical	Sterilizing	It could be either (depending on the amount of water put first): water left after the 3 minutes which doesn't look pro or it's been a minute the PTC is heating without water which is bad for materials and lifetime.	Not solved	
Technical	User experience	If the button is pressed and no water is inside, no way of stopping the process. So user have to either wait 3 minutes until it stops or power off the device.	Solved	
Technical	Device	Cup is not fixed inside	Solved	
Technical	Materials	Materials are not very good looking.	Partially solved	Materials look better
Technical	Device	LED looks not very pro.	Partially solved	
Technical	Device	Button doesn't work very well	Solved	
Non technical	Environemental	Comes from China	Not solved	
Non technical	User	USA plug. Not adapted to Europe ones.	Not solved	
Non technical	User	Too big	Not solved	Even bigger

FIGURE 3.9: Steamer 2.0 solved problems.

Sterilizer V. UV sterilizer :
It consists of a small hard plastic box of more or less 12x6x6cm. It uses UV light which has shorter length than visible light and therefore a higher density energy. There are several classifications of UV. In this context, products are using Germicidal UV's to destroy the DNA of bacteria and prevent these from recurring. This technology is well known and used since the middle of the 19th century. According to Pixie Cup, UV destroys 99.9% of bacteria and viruses. Here 5 LEDs are used to diffuse UVs. They are arranged on the upper plane inside the device, one in each corner and one in the middle. LEDs are squares of 3-4mm each side. The sterilization time is 2 minutes.

FIGURE 3.10: Sterilizer V : UV sterilizer.

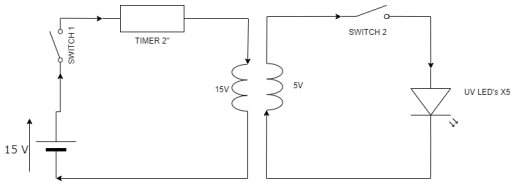


FIGURE 3.11: UV sterilizer circuit.

The user's scenario follows in this case the process : 1. Connect to the current source via a mini USB cable or using 3AAA batteries ; 2. Put the menstrual cup inside ; 3. Close the device ; 4. Push the button ; 5. Wait for 2 minutes ; 6. Open the device ; 7. Remove the menstrual cup.

The system has two switches, one managed by the user which allows to initiate the 2 minutes UV sterilization. The other is managed by the device itself when the user closes it. This second switch ensures user's safety because it makes that LEDs are only powered when the device is closed, thus preventing eyes damaging. The device is powered by 15V and the LEDs run at 5V. In the integrated circuit illustrated in Figure 3.11, some components have been identified like logical gates, plus a timer and a small transformer circuit. Again, technical and non-technical problems have been identified.

Type	Subtype	Description
Technical	Sterilizing	Is it powerful enough?
Technical	Sterilizing	Are all the parts of the cup properly sterilized?
Technical	Sterilizing	Is it powerful enough
Non technical	User experience	Cannot stop the process by pushing the button
Technical	Material	LEDs durability

FIGURE 3.12: UV sterilizer problems.

UV test. By comparing UV sterilizers used for other applications, the UV lights integrated in this device seemed to be not powerful enough. Then, a search for articles and techniques to validate the sterilization power of the device was carried, leading to the conclusion that the current application might not work at all since they might be regular blue LEDs (scam) or simply not powerful enough when compared to certified UVC sterilizers. In addition, the distance between the cup and the LEDs appeared to be too large. The inside of the box does not reflect UV rays, thus only one side of the cup is sterilized (considering that those were indeed UVC LEDs which might not be the case).

3.3 Market Research and Analysis

The following figures summarises which options users have nowadays avaiable to clean and sterilize their menstrual cups and their performances.

Type	Device	Cleaning	Sterilizing	Ease-of-use	Enrgonomic	Sink dependant	Other device dependant
Classical solutions	Cleaning only at home (2x/day)	High	No	High	Yes	Yes	No
	Wipes	Medium	No	Medium	Yes	No	No
	Bottle of water	Medium	No	Low	No	No	No
	Pan boiling	No	Yes	Medium	No	No	Yes
Dedicated solutions	Wipes	Medium	No	High	Yes	No	No
	Bottle of water	Medium	No	Low	No	Yes	No
	Brushes	High	No	Medium	Yes	Yes	No
	Washers	High	No	Medium	Yes	Yes	No
	Sterilizer: water boiling	No	No	High	No	No	No
	Microwave sterilizer	No	Yes	Medium	Yes	No	Yes
	Steamer	No	Yes	High	No	No	No
	Steamer 2.0	No	Yes	High	No	No	No
	UV Sterilizer	No	No	High	Yes	No	No

FIGURE 3.13: Market analysis and comparison.

The market analysis shows that there is not a completely and perfectly adapted solution for the cleaning when being in public spaces, outside the house. In fact, as one can see from Figure 3.13, there's a tradeof that exist between cleaning and sink dependence ; the only product that is easy to use, cleans properly and is not sink dependant are the non-reusable wipes (Figure 3.1), thus from an ecological point of view has almost the same effect as using tampons (Figure 3.14). Finally, the sterilizers are not yet optimized in its performance and design, and its environmental impact [4] could be far reduced.

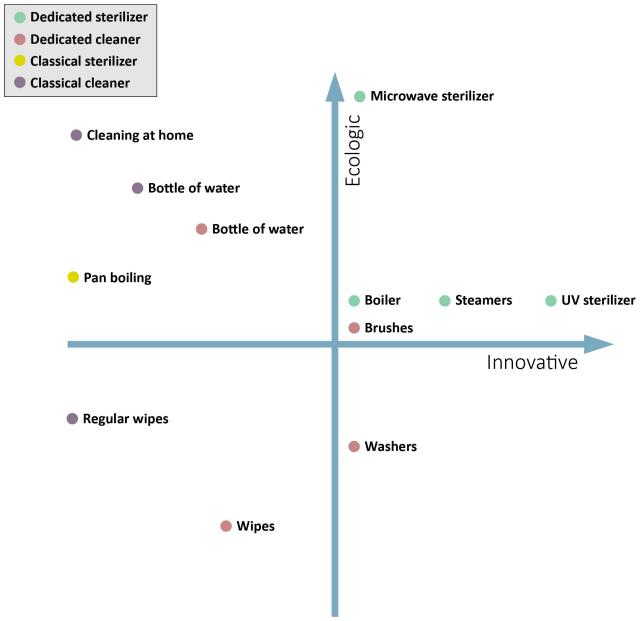


FIGURE 3.14: Ecological vs innovative market analysis.

4. Sterilizers III, IV and V are not ecological because they are bought by European users from an USA shop which delocate the production in China (made in China). In order to purchase the product this has to travel almost 1 time the Earth circumference, and the second greatest source of greenhouse emissions gases is transportation [30].

Chapitre 4

Design & Development

As stated in the Introduction Chapter, this Master Thesis is the continuation of the TRIAXES project developed by Lucas Secades Casino during the academic year 2018-2019. The work developed by the end of the TRIAXES project was a proof of concept, and consisted of a very early still non-functional prototype. The goal of this work is to benefit from previous results achieved with that device and upgrade it.

The approach followed on this Master Thesis is the Design Thinking Methodology. This process is [18] about immersing yourself in the customer experience and gathering the data needed which will allow the innovator to take a step further and be able to analyze the problem from another perspective (Chapter 1). Once the data is produced, it is transformed into insights and specifications, as they are stated in Chapter 2, technical and non-technical needs. Such procedure helps the innovator to agree on design criteria from the preliminary ideas, provides and insight on what is critical to the success of the different solutions (solution suggestions that come from brainstorming). The first step in the process is to brainstorm about different ideas inspired on what already exists (related or not to the domain), as done in Chapter III. Then, once those ideas are transformed into solutions, they have to be built, examined and then tested with rough prototypes that allows pushing forward by developing innovations and preparing them for real-world experiments.

4.1 R&D phase 1 : TRIAXES prototype.

The TRIAXES prototype is a 2in1 non-functional device that was intended to clean menstrual cups by means of an inner brush and to sterilize them by water boiling. It was not functional because it was not properly sealed for cleaning, and the brushes were neither perfectly accommodated nor fit the menstrual cup, so it wasn't possible to clean them. In addition, the sterilization part was not implemented yet, and only developed in laboratory. It was more of a 3D printed idea that an actual prototype.

A non-exhaustive and not well structured list of technical and non-technical needs was created which three main detected constraints are the same as the hypothesis stated at the beginning of the Chapter 2. The device was developed after comparing the different cleaning mechanisms found in literature and adapting one of them to the menstrual cup problem. For the sterilization, the water boiling was directly chosen because of its simplicity, and therefore other mechanism weren't even considered.

4.1.1 Brief R&D summary : conceptual designs

The two main requirements addressed the way to find how a) to clean a small quantity of blood from the menstrual cup without sink access ; b) to sterilize the cup ; and c) to have the two functions integrated within one unique device. Then, the problem was divided into 3 technical sub-problems : the cleaning mode, the sterilizing mode and the 2in1 device.

Cleaning

By analyzing the products in literature (as done in the-state-of-art Section) some prototypes have emerged : sponge, brush (I), brush (II), shaker (I) and shaker (II).

The first category is the *shaker*, with which the idea is to put the cup inside of the product fulfilled with water, and then, by shaking the cup, the blood will be erased and diluted onto the water, thanks to the friction between the wall of the cup and the water itself. From this concept, there exist two ways of creating the shake effect, either it is the cup that moves while the water is fixed (Figure 4.2) ; or the cup is not fixed at all, and both, the water and the cup shake together by outer motion.

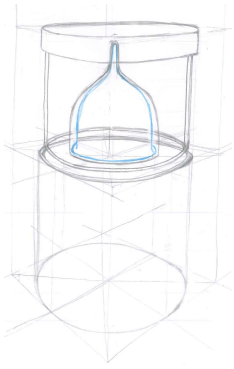


FIGURE 4.1: Shaker concept cleaning method. Menstrual cup highlighted in blue.

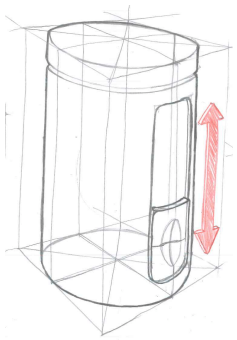


FIGURE 4.2: Zipper system for axial motion.

The two precedent different ways of creating the required motion have been conceptualised : a chaotic motion of the cup inside of the object (shaker I), and a controlled axial motion or the cup (shaker II). The first one is easy to be reproduced, since it does only need shaking the object filled with water which will cause the cup to start moving in different directions. On the other hand, the controlled motion has been designed as described in Figure 4.2. The cup will be placed inside the device surrounded by water, then the user could tight the wire from outside of the object by screwing a component. Once the cup is tied and blocked by the wire, the user could now use a mechanism (close to a zipper) to transform its axial hand external movement into an internal axial movement to make the cup go up and down on the water.

The second concept relies on the use of brushes to clean the cup. Same idea as before, by friction, the brushes will make the blood dilute onto the water. The brushes will embrace the cup's shape. Thanks to the symmetry of the cup, a simple axial rotation of the brushes it is enough to properly reach and clean all the internal surface of the cup.

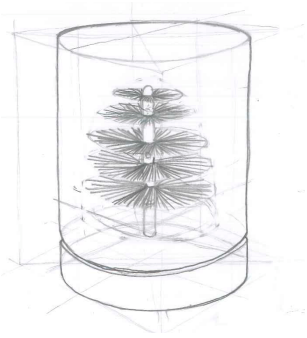


FIGURE 4.3: Brushes concept cleaning method.

In order to accomplish this internal motion two different mechanisms with its positive and negative points have been conceptualised. The first one consists of leaving the upper part within one degree of freedom (axial rotation), as shown in Figure 4.4 so it could rotate easily (brush I). The second one, using cranks and gearings (Figure 4.5) , it is a more complex solution (brush II). The advantage of the latter is that both gearings and the crank could be exploited up to give more power than with the first one.

The third cleaning method is to use **sponges** (Figure 4.6) that could absorb the blood from the cup. These sponges should embrace the shape of the cup (Menstrual cup is highlighted in blue and the sponge in red.

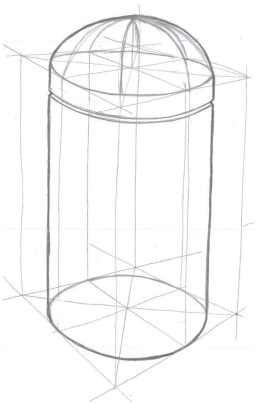


FIGURE 4.4: Rotating top for axial rotation.

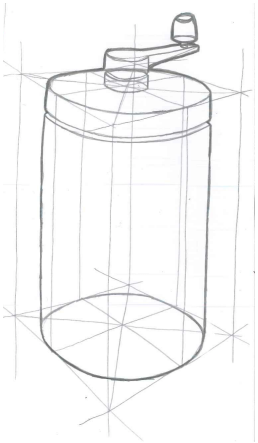


FIGURE 4.5: Crank and gearing mechanism for axial rotation.

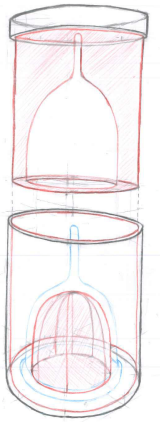


FIGURE 4.6: Sponge concept cleaning method.

By comparing the different conceptualised prototypes, the brush (I) has been chosen to be further developed and prototyped.

Conceptual design	Shaker (I)	Shaker (II)	Brush (I)	Brush (II)	Sponge
Adaptability to sterilisation	HIGH	HIGH	MEDIUM	MEDIUM	LOW
Easy to clean menstrual cups	MEDIUM	MEDIUM	HIGH	HIGH	LOW
Ecologic	HIGH	HIGH	MEDIUM	MEDIUM	LOW
Technical complexity	MEDIUM	HIGH	HIGH	MEDIUM	MEDIUM
Customer preferance	LOW	MEDIUM	HIGH	LOW	MEDIUM

FIGURE 4.7: Trade of conceptual design choice.

The shaker, hasn't been developed on this first phase but has been later prototyped and optimised as will lately be presented.

Sterilisation

Regarding the sterilisation, water boiling has been chosen as the optimal method because using others seemed to be technically challenging for the team within the short TRIAXES time frame. Water must be heated by an outter source, the one that could easily fit on small devices were heating elements. The heating element was intended to be in contact with water and connected to the base through an adapter inspired on the one in modern electric kettles.

However, the device's volume being relatively small, water would be certainly evaporated trough the process and thus exposing the menstrual cup to non water contact. Eventually, there would be no water left by the end of the 10 minutes sterilization process, and that could be a problem since the menstrual cup's upper parts would have not been in contact with the sterilizing medium (boiling water) for several minutes . In order to avoid too much water vaporization, a regulation was developed based on PWM regulation principle. The aim was to set the desired temperature around 100 degrees so when water would start evaporating, the heating element would stop heating as shown on figure 4.8 and oscillated under 100°C.

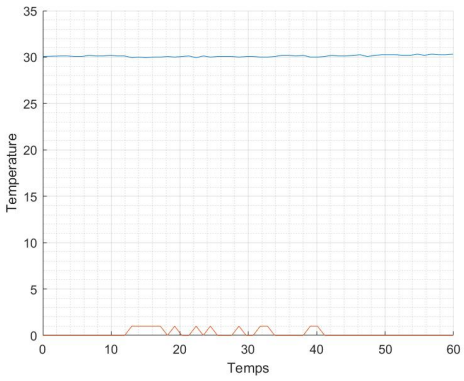


FIGURE 4.8: Example of regulation around 30°C. Water temperature in blue ; red curve the Arduino command on the heating element : ON (1) or OFF (0).

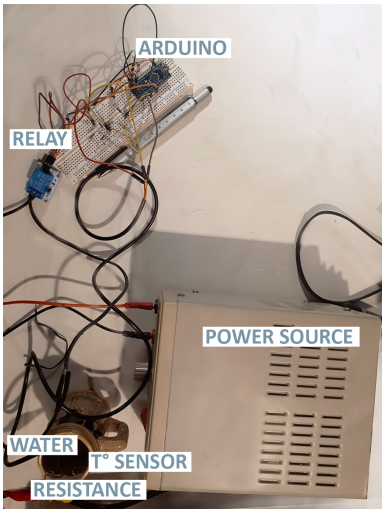


FIGURE 4.9: Triaxes in-lab prototype.

The heating element was connected to the grid and commanded trough a relay that was itself controlled by an arduino (Figure 4.9) which calculated the regulation error using a temperature sensor. This circuit has not been implemented because the impossibility of finding a heating element fitting the dimensions constraints. The regulation and the electric circuit have been validated in a lab-prototype with a too much powerful 2000W resistance.

2in1 device

Finally, the 2in1 device was developed once the two prior main functionalities were conceptualised and agreed upon : cleaning by means of brushes and axial rotation and sterilizing by water boiling. Cleaning was meant to be done around 3-4 times per day during each period, meaning a rough 20 times per period, while sterilizing was meant to be done at least 2 times per period (at its beginning and at its the end). The goal was to have something at home that once coupled to the device could sterilize the menstrual cup with the benefits of sterilizing the whole device at once. Two main parts have emerged, basically the base (located at home) and the body (which was carried to clean the menstrual cup). The way of coupling both, the base for the sterilizing process and the body for the cleaning, was chosen as a multi-folded set of caps.

4.1.2 Prototype description

The prototype developed is the one shown in Figure 4.10. It has two modes, the cleaning and the sterilizing one, both sharing most of the parts for efficiency and resources saving : body, brushes, upper cap, though still having different lower caps. The sterilization mode will also need the base.

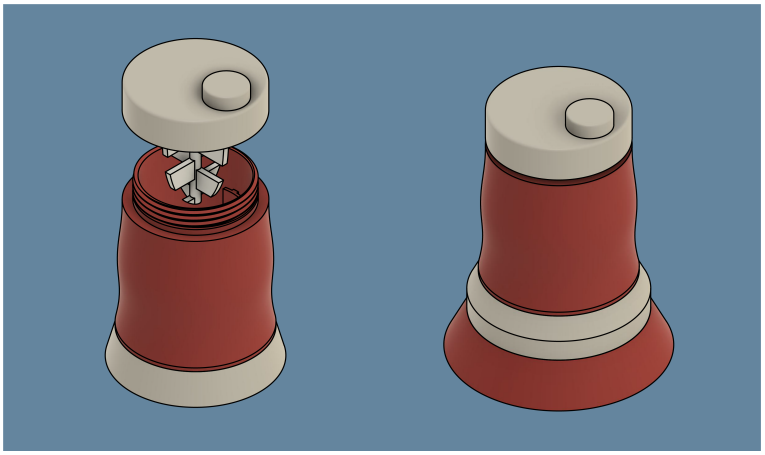


FIGURE 4.10: TRIAXES prototype.

To go from the cleaning mode to the sterilizing mode, users only have to change the lower cap from the cleaning mode (the mechanical cap) with the so-called electric cap as illustrated in Figure 4.11, step 1 and 2. The electric cap has a heating element and adapter (with an electrical connection) allowing it to be plugged into the base. The cleaning and sterilizing scenarios are illustrated below.

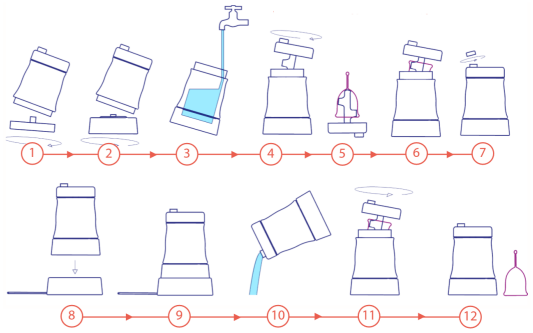


FIGURE 4.11: Sterilizing scenario.

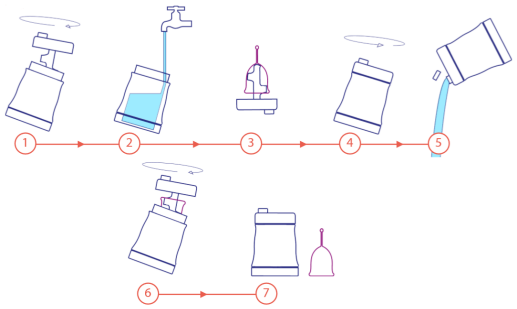


FIGURE 4.12: Cleaning scenario.

The main advantage of this device is the double solution mode : cleaning and sterilizing jointly achieved with same device.

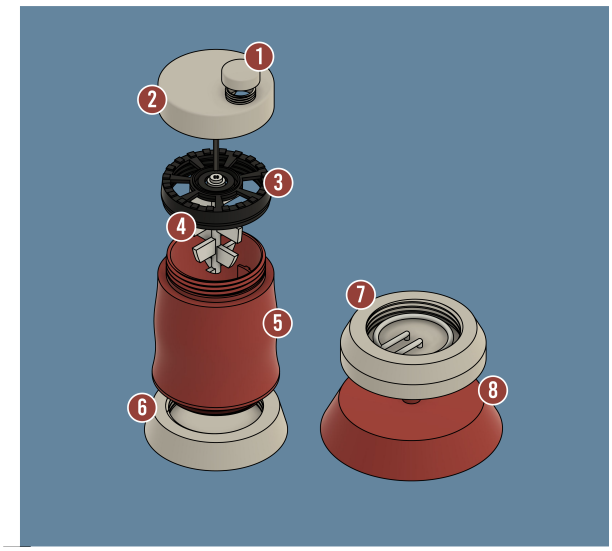


FIGURE 4.13: TRIAXES version.

1. **The on top cap**. This cap has a small opening used to drain water during cleaning mechanical (see usage scenarios). This small opening (in the form of a plug) ensures also depressurization during the sterilization phase.
2. **The upper cap**. The upper cap is used to fill the device with water needed for both sterilization and cleaning modes. It also hermetically closes the device and it contains the inner part of the cap that allows the rotational motion.
3. **The inner cap**. It is the part that facilitates the motion while the device is hermetically closed. It works similarly to safety caps.
4. **The brush**. The cap also has a silicone brush which is used to clean the inside of the cup. It embraces the regular cup size.
5. **The body**. The body acts a water container and used in both modes. While cleaning, it contains the water where the blood will be diluted using the brushes ; and while sterilizing it also contains the water that will be boiled up.
6. **The mechanical lower cap**. It is lighter and smaller than the electric one and has an extrusion which serves to block the stem of the cup (not represented on Figure 4.13).
7. **The electric lower cap**. The second lower cap allows sterilization and is composed of a heating resistor, a temperature sensor, and connectors.

8. **The base**. The base consists of an electrical circuit that powers the heating element and controls the sterilization process by regulating the water temperature. If water temperature is not regulated, water would start to evaporate and no water would be left by the end of the process, thus some parts (upper ones) could be not well sterilized.

4.1.3 Tests & Results

There are three kinds of user [1] tests that have been done : focus group, short-term tests and long-term tests. Running such tests allow to receive feedback on the device, thus helping with R&D iteration. The test carried out were :

— **Short-term** tests are tests done without actually the device on real conditions. Users do not need to be on their periods, they can give their feedback by challenging them and thinking on how to use it. This kind of tests is done very often and allows to iterate faster.

— **Long-term test** are the ones where the device is practically tested on real conditions. They allow to find problems and receive feedback on issues that may not appear during short-term tests.

— **Focus group** applied to an R&D process is a research method where a group of people are questioned about a service or a product with the aim of gathering information to help with the further development of the referred product or service. The goal is to oversee a discussion of 5 to 10 people, chosen as the product's persona [2],where participants discuss and give their opinions about 10-20 questions about the product. Because the group discusses intensively, it provides a richer understanding of the perception of the product, and improvements that could not appear during the classical tests (short and long ones) are enabled to happen.

The TRIAXES version cleaning mode was further developed in order to make the device pseudo-functional and was subject to the aforementioned three kind of tests. However, the sterilization mode could not be carried out due to the impossibility of prototyping a water boiling sterilizer.

Short-term tests
The short-term tests have been done on a very regular basis during the last year. Users that accepted to follow the project development gave their coordinates so they could have been contacted. The different feedbacks are not summarized here but have been very helpful during the development at different stages of the process.

Focus group
Only one focus group was formed, while another one is already scheduled for September 2020. The focus group started in April 2019 with the goal of validating the solution proposed and its conceptual design. A non-functional device was presented but could not be tested yet. The group was composed of a mediator (final year law student) and 8 girls with the following characteristics :

— Menstrual cup users : 6 menstrual cup users and 2 non-users of menstrual cups.

— Profession : 5 university-degree students (engineering (1), economics (1), communication (1) and 3 young workers (management (1), designer (1) and law (1)).

— Age : all between 20 and 25 years old.

The answers and feedback received are summarized in the following table :

1. As opposed to technical tests that are the ones carried during the R&D phase and allows to chose between different prototypes.
2. "Personas are archetypal characters created to represent the different user types within a targeted demographic, attitude or behaviour set that might use a site, brand or product a similar way. Personas are often combined with market segmentation to represent specific customers." [19]

Specification	Type	Description
User	Advantage	Even with all of its actuals disadvantages, users need this kind of device to clean and sterilize
Sterilising	Advantage	Avoid using the pot
User	Advantage	Help to make cup adoption
User	Advantage	The 2in1 combination is perfect and cool. Solve both problems
User	Advantage	Price is not a problem since it's medical
Design	Idea	reattach the top cap to the body ?
Design	Idea	Device should be more discrete
Design	Idea	Why not only 1 lower tap?
User	Idea	How to trust the device from a medical point of view?
User	Idea	Provide a fabric small bag to avoid contact with other items inside the bag?
Non-technical	Drawback	Too many plastic
Design	Drawback	Too many pieces
User	Drawback	The device touchs the ground in the cleaning scenario, and it's not very clean
Design	Drawback	It's big, so not very discrete and not very easy to carry on the bag
Design	Drawback	Colors are too strike
Sterilizing	Drawback	Is the sterilizer powerful enough to boil that amount of water?
User	Drawback	Problem to touch it with your hands

FIGURE 4.14: Focus group feedbacks.

Long-term

Only the mechanical (cleaning) part could be tested on real conditions, because the sterilizing part was not yet developed at that very moment. The aim was to receive feedback coming from the product's persona but with slightly little differences. To that end, five user categories were chosen to test the device :

1. A young woman between 18 and 25 years old strongly active at university ;
2. An active woman who is no longer a student ;
3. A young girl aged between 16 and 18 who is part of Generation Z ;
4. A young woman having to hide her use of the cup (in principle, because modesty, Or personal circumstances such as living in a shared apartment, etc.) ;
5. A very open-minded woman.

The long-term test were part of the Design Thinking innovation approach, allowing iterative prototyping during longer cycles than the short terms and thus continuous improvement. A free test system was proposed to the testers. Firstly, the device was presented during a first interview that was followed by a complete period cycle test from which feedback was collected. If the user wanted to continue using the product, it was possible to keep the prototype and continue giving feedback every 3 months.

For those tests, several documents were created including a confidentiality agreement, a manual explaining the conditions and advice for using the device, and finally, the testing strategy including the different questions asked in the first and second interview. The feedback after one month of use is summarised on the following table :

Specification	Type	Description
User	Advantage	The device meets the values of the menstrual cup: ecological (reusable), economical, innovative, non-gendered, good for health (no products) and practical.
Design	Advantage	One feature does not take precedence over the other: some testers want a cleaning solution and others sterilization.
Design	Advantage	Users trust the product, are not surprised and are not afraid.
Design	Advantage	The device size is suitable for female testers.
Sterilizing	Idea	The testers would like to have the choice in the colors.
Sterilising	Idea	Waxed fabric bag: it would be interesting to receive a fabric bag with the device in order to be able to transport it in complete safety since the latter is waterproof.
User	Drawback	The device is not intuitive, the first time it is difficult to use it.
Design	Drawback	Sealing problem: the appearance of a water leak at the bottom of the device, water on the floor in the toilet when using the device, water in the bag after use because the device does not dry well.
User	Drawback	Non-complete cleaning: there are traces and residues in the bottom of the cup and it does not clean the holes in the cup.
Design	Drawback	Quality: the quality of the device is not convincing.
User	Drawback	Rotation technique: complicated to understand at the start.
User	Drawback	Problem with the stem of the cup.

FIGURE 4.15: Long term feedbacks.

4.2 R&D phase 2 : Multi-prototyping

This phase started from previous results presented on previous steps (focus group and long-term tests). It is difficult to keep a hard chronological order because changes started already after the focus group started (April 2019), but not implemented in the functional prototype that, on its side, has been tested on long-term tests (January 2020). This phase is characterized by the questioning of the cleaning and sterilizing solution of the so-called TRIAXES prototype device, followed by the multi-prototyping of cleaning, sterilizing and 2in1 devices (more than 10 devices have been designed, prototyped and tested). In fact, during the early steps of the first R& D phase, other alternatives could have been explored (prototyped and challenged) and have not, both sterilizing and cleaning solutions.

4.2.1 Preliminary ideas and improvements

Based on the feedbacks received on the TRIAXES version, several ideas appeared after a global project and device brainstorming. The first version developed appeared to be helpful, an interesting solution and was pointing on the right direction of how merging the cleaning and sterilization features ; but was still far from **the** functional and marketable device wished.

Regarding the cleaning function, the drawbacks of the brush cleaner (sealing, inner and outer brushes) were upgraded by an iterative design process. In addition, some conceptual design that initially had not been chosen have been later on prototyped and investigated as the shaker and new conceptual design have been explored, like it is the case of the membrane cleaner. Instead of only prototyping the boiling water solution (which already started to generate problems due to its feasibility), other ones were considered as feasible alternatives, as the steam sterilization, so both methods were prototyped simultaneously. Finally, also the way of merging both functionalities has been challenged, and new conceptual designs of the 2in1 device emerged. In summary, 3 new cleaning prototypes have been developed and tested ; 2 sterilizing in lab-prototypes [3] have been tested ; then for each function, a method has been chosen according to the task clarification, and re-adapted into a 2in1 device.

4.2.2 Cleaning

The three prototypes developed are called : shaker cleaner, membrane cleaner and brush cleaner.

3. In lab-prototypes are prototypes that are not available for user test but only their functions and feasibility are challenged.

Shaker cleaner

The cleaner developed is much easier to produce and has no major innovation principle. Opposite to the 2 shaker conceptual designs presented on the R&D phase 1, the one developed here incorporates a fixed cup inside the bottle so the chaotic motion created by shaking only affects the water.

The first version of this shaker it's a copy of a Korean patent [20], that has been copied and prototyped [4] in order to show users what could be available in the market in the near future months / years so they can compare with the 2in1 device developed through this Master Thesis. This first version is not intended to be sold since it's a copy, but by challenging to users and implementing upgrades and removing its drawbacks, the future versions (if further developed) of the shaker cleaner could have sufficient major changes to be considered as an innovation, thus becoming an invention [5]. However the primarily goal on a R&D project is always to explore all the possibilities.

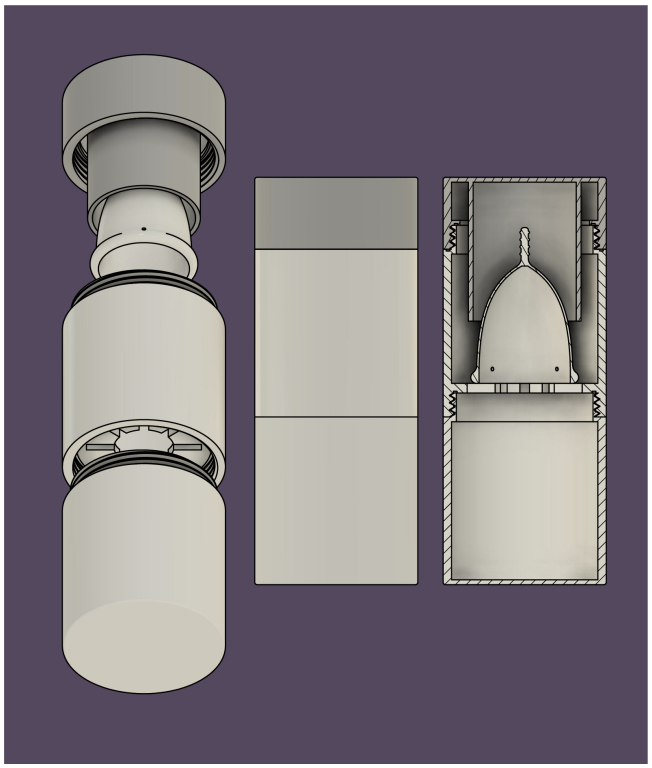


FIGURE 4.16: Korean patent prototype.

The first version (Korean patent, Figure 4.16) has 3 main parts :

— **Upper cap.** It is used to block the motion of the cup inside the device and allow the user to insert the cup inside.

— **Body.** It contains the cup and has a platform that blocks the cup from going onto the lower cap while allowing water passing through.

— **Lower cap.** It closes the device and is used to fill the device with water.

As said before, it has been prototyped and challenged by users (the other 2 cleaners were shown at the same time). The feedback received on this device was unbiased since users did not know it was a Korean patent. Once received, a second improved version was developed. The following table summarises the drawbacks of the first version, the ideas to improve the mechanisms and if the second version of the device has already implemented them all.

4. The first version of the shaker has been 3D modelized by Arthur Vanderbreetstraeten, Biomedical engineering student, as part of his Tulipal intership.

5. This is the patent's tradeof, it protects from being copied and commercialised (free to operate principle), but boost innovation by publishing the plans.

Specification	Type	Description	Ideas to solve	Shaker v2
User	Drawback	The mouvement is not very smooth	Inherent to the shakers or use the first conceptual design of the R&D phase 1	Not implemented yet
Design	Drawback	It's too big	Reduce size and adapat the device to the cup size	Implemented
Design	Drawback	Don't really know if it's well cleaned. Lack of confidence in the design	Optimise the water flow by reducing the number of extrusion and make them smoother. Change the inner corners into spherical geometries. Make the body from a translucid or transparent material, so the user can see when the cup is cleaned.	Implemented
User	Drawback	It's a bit noisy due to the water hitting the walls, so not very discrete	Soundproof by making 3 layers of material instead of one. The central one being made of soundproofing material as acoustic foam or use the first conceptual design of the R&D phase 1 (If it's the cup that moves and the device is filled up with water, there's no noise)	Not implemented yet
Design	Drawback	It's not very aesthtic.	Make it prettier with smoother geometries	Implemented
Sterilising	Drawback	Not easy to shake because of the ergonimc design	Adapt the outter shape so it embrance the hand when closed	Implemented

FIGURE 4.17: Korean shaker patent drawbacks and ideas to implement on further versions.

As already mentioned, a second version has been prototyped following the brainstorming and the ideas to solve the Korean patent drawbacks. The user only needs to fill the lower cap and close the lower part of the device, then go to the private toilet, empty the cup on the toilet and insert it back on the device by the upper part. Finally, users will shake to dilute the blood on the water, and once confirmed no more blood remains on the cup, empty the water on the toilet by opening the lower cap. The cup would not fall since it is blocked thanks to the extrusions.

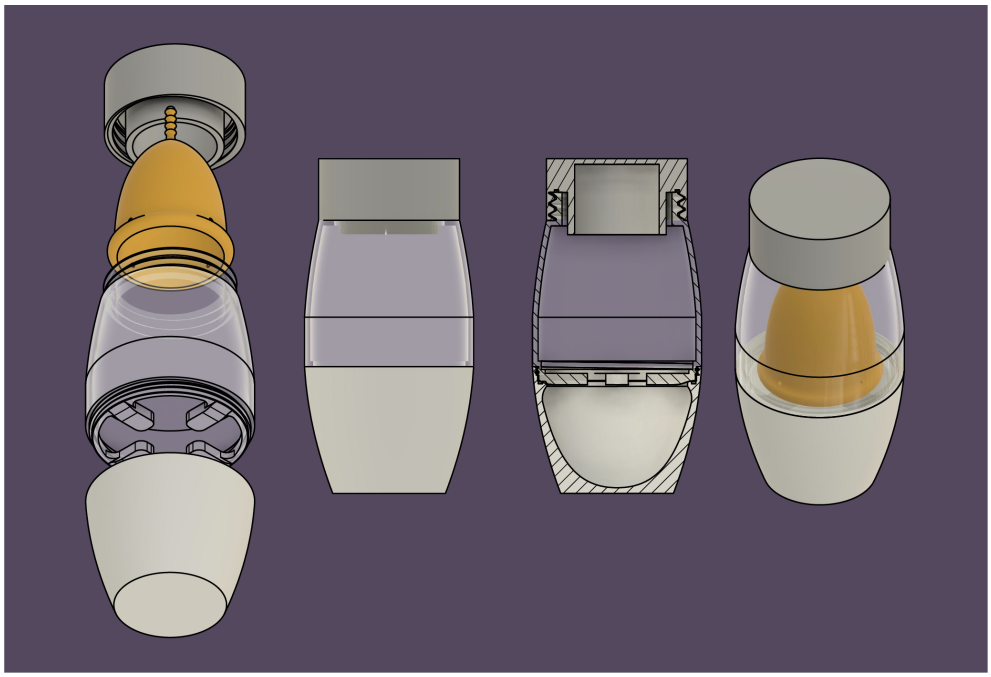


FIGURE 4.18: Seconder version of the shaker cleaner.

A third version would consist on a mix of the first conceptual design of the shaker presented previously (shaker I) which advantages were not that far from the brush cleaner conceptual design, combined with the second version of the upgraded Korean patent.

Membrane cleaner

The conceptual design that will be presented derives, on one hand from the the observation that the easiest and most intuitive way of cleaning the menstrual cup is by using hands (the way they do when a private sink is available) ; and on the other hand, from the constraint of not touching the cup when cleaning in absence of a private sink.

This prototype is made up of a container with a hole in the upper surface where a membrane is placed. The membrane has a hollow bell shape. On the outer side has a smooth surface while the inner surface is made up of a sort of brush.

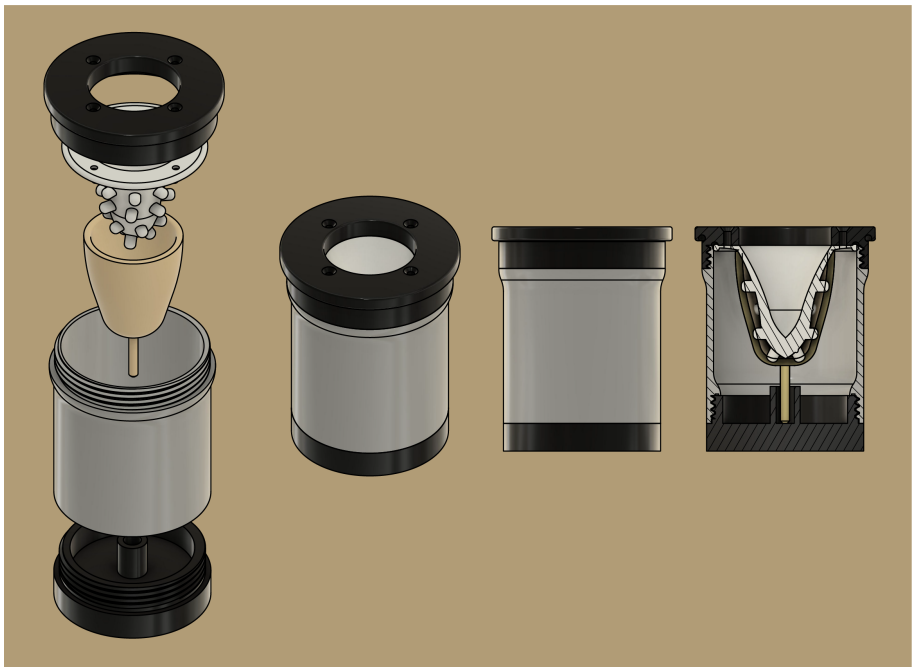


FIGURE 4.19: Membrane cleaner.

An interesting characteristic is that the sealing is not ensured by caoutchouc o-rings but the silicone membrane itself. It has also 2 caps (lower and upper) that are used to place the cup. This is a non-functional prototype, not because of the sealing but because of the user experience : the lower cap did not do anything special and there was no way of emptying the water from inside. Again, users have been challenged with the cleaning mechanism which requires filling the device with water and cleaning the cup by inserting the fingers in the cavity and guiding the silicone (elastic material) to rub the cup walls.

Specification	Type	Description
User	Drawback	The fingers go to deep. The feeling is very awkward.
Design	Drawback	Lower tap has no function
Cleaning	Drawback	The brush is too big. The brush is in contact with the cup so the user cannot transmit the motion with her fingers because it's blocked.
Design	Drawback	There's no way of emptying the device easily.
Design	Drawback	The way the membrane is attached to the inner part of the upper tap does not work (either screzs or glue)
Design	Drawback	It does not have an ergonomic shape.
User	Drawback	It's not very attractive.

FIGURE 4.20: Feedback from the membrane cleaner.

Finally, 2 versions have been conceptualised and prototyped leveraging the first version feedback. On the second version, the brush cavity was made smaller so the feeling was less weird when inserting the fingers. The third version (Figure 4.21) has major changes. The finger motion has been replaced by a joystick hidden under a small flat membrane on top of the cleaner ; the user can transmit motion from a rotating movement on the joystick to the shaft to which a membrane brush is attached.

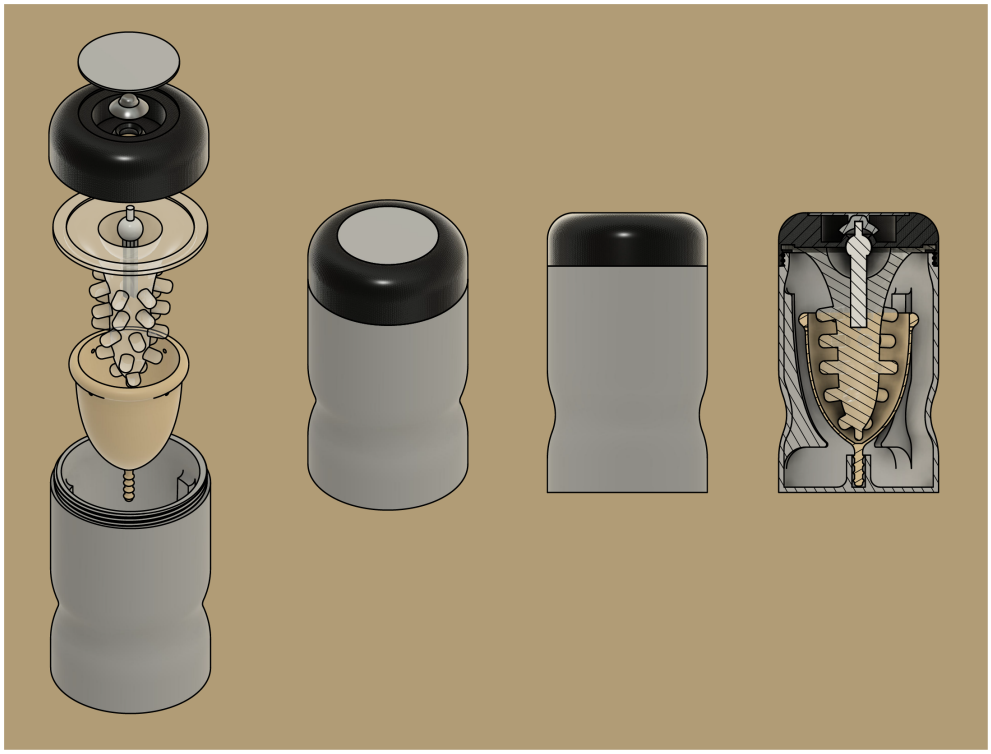


FIGURE 4.21: Membrane cleaner v3.

The following table shows how the drawbacks have been solved. Drawback regarding the cleaner water emtying have not been implemented in the design because what matters is the cleaning mechanism and not how which cap type is chosen.

Specification	Type	Description	Membrane cleaner v2	Membrane cleaner v3
User	Drawback	The fingers go to deep. The feeling is very awkward.	Partiallt solved	Solved
Design	Drawback	Lower tap has no function	Not implemented yet	Not implemented yet
Cleaning	Drawback	The brush is too big. The brush is in contact with the cup so the user cannot transmit the motion with her fingers because it's blocked.	Not solved	Solved
Design	Drawback	There's no way of emptying the device easily.	Not implemented yet	Not implemented yet
Design	Drawback	The way the membrane is attached to the inner part of the upper tap does not work (either screzs or glue)	Not solved	Solved
Design	Drawback	It does not have an ergonomic shape.	Not solved	Solved
User	Drawback	It's not very attractive.	Not solved	Solved

FIGURE 4.22: Membrane cleaners comparison.

Brush cleaner

The conceptual design of the brush cleaner has already been developed during the phase 1. However, it was not functional and brushes had not been chosen as the result of an R&D process.

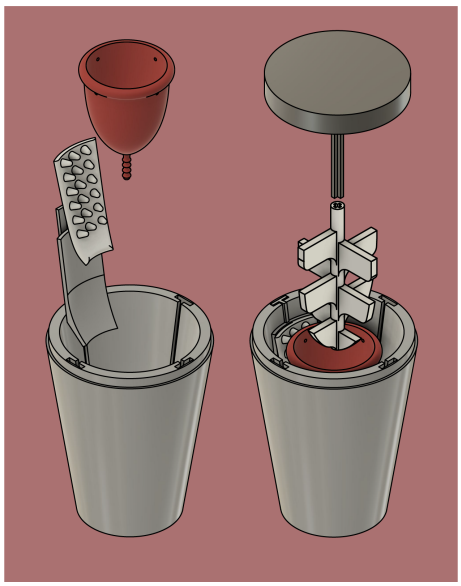


FIGURE 4.23: Brush cleaner principle.

This new version has two types of brushes that will be developed and optimized :

— **Inner brushes.** Inner brushes clean the inner cavity of the menstrual cups. Motion provoked by the user is transmitted to the brush by the shaft.

— **Outer brushes.** Outer brushes serve as a mechanism to block the cup inside the device and avoid the cup from rotating at the same time as the inner brush does. If the cup rotates due to the friction of the inner brush on its walls, it does not matter because the outer brush will also clean the outer walls of the menstrual cup.

Regarding the outer brushes, a parametric study has been carried. The parameters used are : 1) The type of the brush's bristles ;

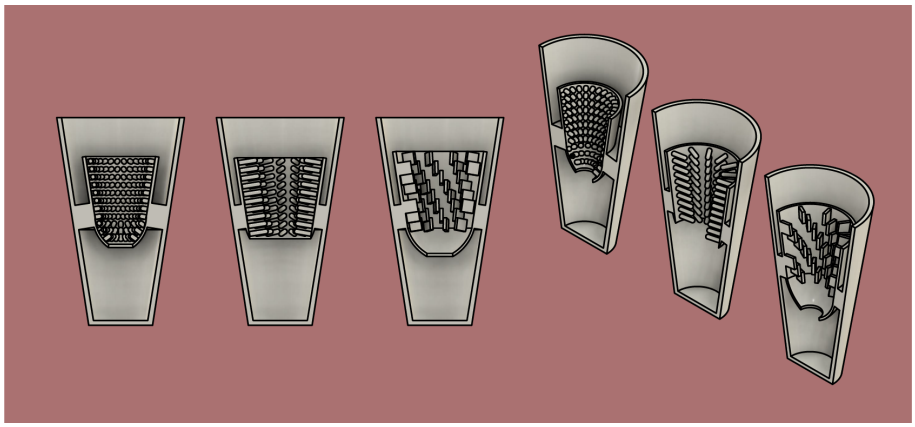


FIGURE 4.24: Type of brushes bristles.

2) The number of individual inner brushes and their size (in degrees covered) ;

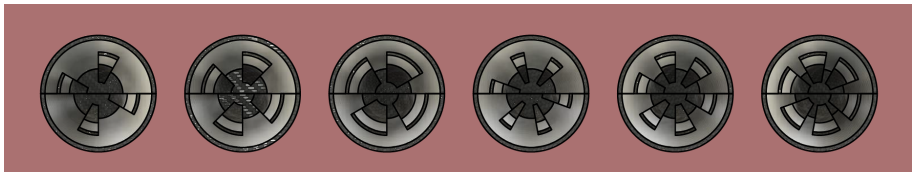


FIGURE 4.25: Inner brushes size and number possibilities.

and 3) The way of fixating the brush to the inner walls of the device.

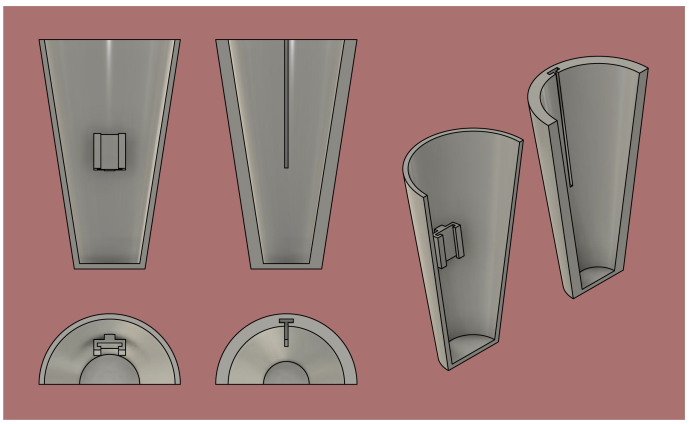


FIGURE 4.26: Brush attach types.

On the other hand, the inner brush has also been subject to a parametric study. The parameters used for the inner brush are the type of brush bristles (rounded, flat...), their size (surface and height), the thickness of the brush shaft, the type of silicone, the shaft inner profile and the bristles' density. The following table indicates the parameters of the 3 types of brushes considered in Figure 4.28.

Brush		Bristles			Shaft	
Number	Material	Type	Size	Density	Thickness	Profile
N°1	Silicone Platinium (Sorta Clear 12)	Cylindrical	Medium	Medium	Medium	Cross
N°2	Silicone Platinium (Sorta Clear 12)	Rectagular	Big	Low	Small	Cross
N°3	Silicone Platinium (Dragon skin)	Cylindrical	Medium	High	High	Circle

FIGURE 4.27: Description of the three chosen inner brushes configurations.

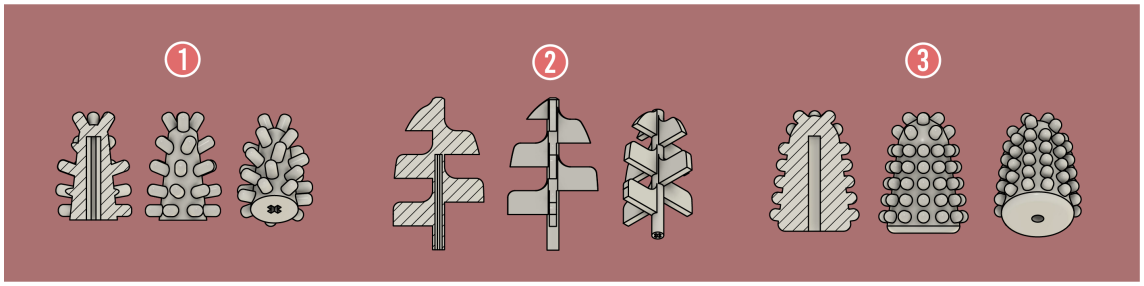


FIGURE 4.28: Different inner brushes configurations.

Different inner and outer brushes have been prototype through silicone moulding. The chosen ones are those illustrated on figure 4.23.

Cleaner choice

At this point, three different functional cleaners have been developed so far. The compliance with the technical and non-technical constraints has been compared for the 3 prototypes. For each of the cleaners a number between 1 and 3 has been given to quantify how the cleaner complies with the specification (compliance number, 3 the best, 1 the worst). Each specification has also a priority number. In order to quantify which cleaner is better, results have been ranked by the sum of the product of each category priority number and the compliance number.

Ergonomics			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Smallest volume	< 312.5 cm3	3	1	3	2	6	2	6
Lightweigth	< 0.5 kg	1	2	2	3	3	3	3
Can be used with both hands	/	2	2	4	2	4	3	6
Easy of use			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Few number of mouvements	< 2	1	2	2	1	1	3	3
Intuitive	/	2	3	6	1	2	1	2
Fast	< 1 minute	2	2	4	3	6	3	6
Use wherever	/	3	1	3	3	9	3	9
Cleaning			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Remaining blood acceptance	0%	3	1	3	3	9	3	9
Easy to dissasemble to clean inside	/	2	3	6	2	4	1	2
Reusable method	/	3	3	9	3	9	3	9
Design			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Attractive design	/	2	3	6	2	4	3	6
Simple	/	2	3	6	1	2	1	2
The form helps the user to use it	/	1	3	3	2	2	2	2
Materials & production			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Production can be industrialized	/	3	3	9	2	6	2	6
Compatibility			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Compatible with all cups stems	/	2	3	6	2	4	2	4
Compatible with all cups sizes	/	2	3	6	2	4	2	4
Compatible with a cup sterilizer	/	3	1	3	1	3	3	9
Safety			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Cleaning without finger contact	/	3	3	9	2	6	1	3
Can be a medical device	/	1	1	1	1	1	1	1
Can be ISO certified	/	3	2	6	3	9	3	9
		Total		**97**		**94**		**101**

FIGURE 4.29: Technical compliance between cleaners.

User willings			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
The device mustn't touch the ground when cleaning	/	3	1	3	2	6	2	6
Noise while cleaning	Don't make	3	1	3	3	9	3	9
Not direct contact with other stuffs in the bag	/	2	2	4	1	2	2	4
Small free-detachable pieces	Not exist	1	3	3	2	2	1	1
Colours and design must be minimalist	/	1	2	2	2	2	2	2
		Total		**15**		**21**		**22**

FIGURE 4.30: User willings compliance between cleaners.

Law			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Free to operate	/	3	1	3	2	6	3	9
New and different design	/	2	1	2	2	4	3	6
Must be patentable	/	2	2	4	3	6	2	4
Business & Marketing			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Price	20-30 € production	3	3	9	2	6	1	3
Must be able to be sold in pharmacies	/	1	2	2	2	2	2	2
Must look clean, simple and robust	/	3	2	6	2	6	2	6
Environemental			Shaker		Membrane		Brush	
Features	Value	Priority (1 to 3)						
Easy to repair	/	3	3	9	2	6	1	3
Low carbon emissions	< 10kg of CO2	3	3	9	3	9	3	9
Last long	> 5years	3	2	6	2	6	2	6
Recycled materials	>70% recyclable (in m	3	2	6	2	6	2	6
		Total		**32**		**35**		**38**

FIGURE 4.31: Non technical compliance between cleaners.

The brush cleaner remains the best option.

4.2.3 Sterilizing

As introduced before, the sterilization was only tested on a in-lab prototype by means of water boiling regulated using a temperature sensor. The principle was validated but the biggest challenge was to try to find a heating element powerful enough. Due to the struggle of finding one heating element meeting the needs and the rise of steam based on the menstrual cup sterilizer, the steam sterilization has been also considered and further investigated. A fast analysis about the feasibility (in terms of volume needed, materials, cost, etc.) has been carried out and its results showed that UV sterilization do not comply with the needs of the device.

Following the phase 1, some ideas of prototype have emerged :

Version name	TRIAXES version	Boiler	PTC self regulated boiler	Steamer	Induction version	UV sterilizer
Sterilization method	Boiling water	Boiling water	Boiling water	Water steam	Water steam or boiling water	UV radiation
Technology	Boil water and keep it at 100°C using a regulation loop and a water Temperature sensor. The heating element is commanded by an Arduino and in contact with water	Boil water as a modern boiler does. Regulate it with a sensor and the heating element is not in contact with the water (aluminum plate in between). Can be a PTC	Boil water and keep it at 100°C using a PTC heating element selfregulated at 100°C or 90°C	Boil a small amount of water during a few minutes and sterilize with the steam created.	Use the induction principle as on the modern kitchens. Hard technology.	Sterilize by non-ionizing radiation created by the UV LEDs
Environement	Between 90-100°C boiling water	Between 90-100°C boiling water	90 or 100°C boiling water	>100°C	Magnetic field and +-100°C	Non-ionizing radiative

FIGURE 4.32: Sterilizing prototype ideas.

The induction version is based on a complex technology, thus the magnetic environment could be not feasible with all electronic dimensions involved, so it has been discarded directly. As explained before, the UV version has also been discarded. The only difference between the TRIAXES version and the boiler one is the presence of an aluminium plate between the water and the heating element. This difference will create changes in final stages of the R&D, but in early stages, both solutions could be prototyped and tested within a single prototype.

The sterilizing prototype has two main parts :

1. **Sterilization technology.** It's the sterilization principle chosen, among the ones found on the state of the art chapter, to be implemented and adapted to the menstrual cup case.
2. **Power supply.** The way the sterilization mechanism (included the electronics needed) will be powered .

They will be presented as developed separately but they have been developed together. The UV sterilizer, steamer and boiler have different power requirements, and vice-versa the power availability (driven by the power supply scheme chosen) will influence which sterilizer can be powered within a given scheme.

In conclusion, 3 different sterilizers prototypes were designed : boiler, PTC [6] self-regulated boiler and steamer. Regarding the last ones, since both use the PTC technology to heat water, they share the same v0 version. In addition, different power supply circuit schemes and options will be evaluated and prototyped, each of them with their advantages and drawbacks.

6. PTC stands for Positive Temperature Coefficient. These are self-regulated heating elements that uses ceramics which resistance increases exponentially over a certain temperature. They self regulate because over the critical temperature, current decreases drastically and stop heating by Joules effect.

PTC self-regulated boiler and steamer v0

The two solutions have been prototyped within the same 3D model because the only thing that changes between them, at this early stage of development, is the PTC heating element. The figure below (4.33) shows this prototype marked in blue the heating element and in red the aluminium plate.

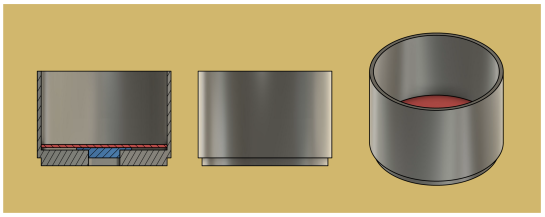


FIGURE 4.33: Bench test for : PTC self-regulated boiler and steamer v0

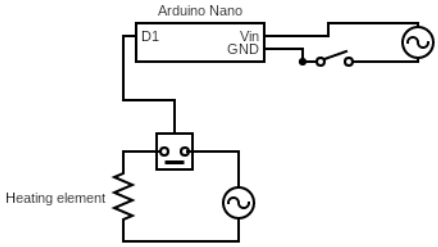


FIGURE 4.34: PTC self-regulated electric circuit scheme.

For the PTC self-regulated boiler, the PTC used is regulated around 100°C and for the steamer around 130°C. The way these prototypes work relies in simply letting current flow through the heating element. The relay (Figure 4.34) is only there to control and switch it off after a delay as to enabling performing different tests.

Boiler v0

The Boiler v0 is illustrated on Figure 4.35, being marked in red the heating element and in blue the waterproof temperature sensor.

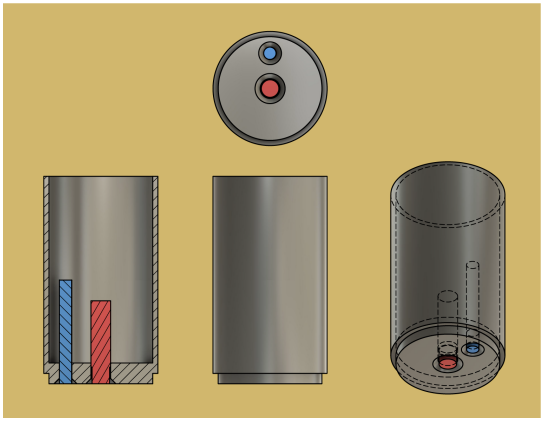


FIGURE 4.35: Boiler v0.

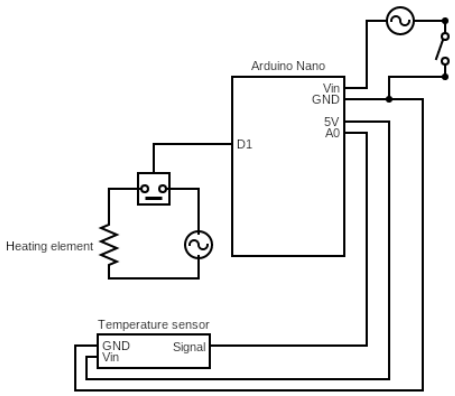


FIGURE 4.36: Boiler v0 electric circuit scheme.

The goal of this prototype is to validate the boiler version and try to identify the problems that will be encountered through further R&D stages. The power and control units are not modelized, but can be seen on the scheme circuit on Figure 4.36. The grid powers the Arduino (through a transformer not shown in the circuit) that can be controlled by a switch. When the Arduino is powered, the regulation code starts. Information about the water temperature is communicated to the Arduino which will control a relay that lets the current pass through the heating element. Once the temperature recorded by the temperature sensor is above 100°C, the Arduino powers off the relay, so the heating element turns off. This kind of regulation control system is a very simple and easy to implement one and it has been inspired on the PWM modulation.

Tests

Some tests have been performed to evaluate the technology's viability at first approach and thus, to support making the right choice of a prototype for further development.

Version	Test	Results
Boiler	Volume of water lost	HIGH
Boiler	Time to raise to 100°C	LOW
Boiler	Homogeneous boiling	No
Boiler	Size of heating element	Medium
Boiler	Regulation control system validated	Yes
PTC boiler	Temperature	80°C
PTC boiler	Size of heating element	Big
PTC boiler	Volume of water lost	Small
PTC boiler	Time to raise to 100°C	HIGH
PTC steamer	Time to boil as a function of volume	MEDIUM
PTC steamer	Size of heating element	Small
PTC steamer	Cup stability due to the presence of steam under it	Good
PTC steamer	T° of the environement (steam)	100°C

FIGURE 4.37: Boiler, PTC boiler and PTC steamer tests.

The steamer performances were much better than the rates obtained from others, which led choosing it among other alternatives.

4.2.4 Steamer v1

A second version (Steamer v1) was developed which main difference is that it has been adapted to the menstrual cup use.

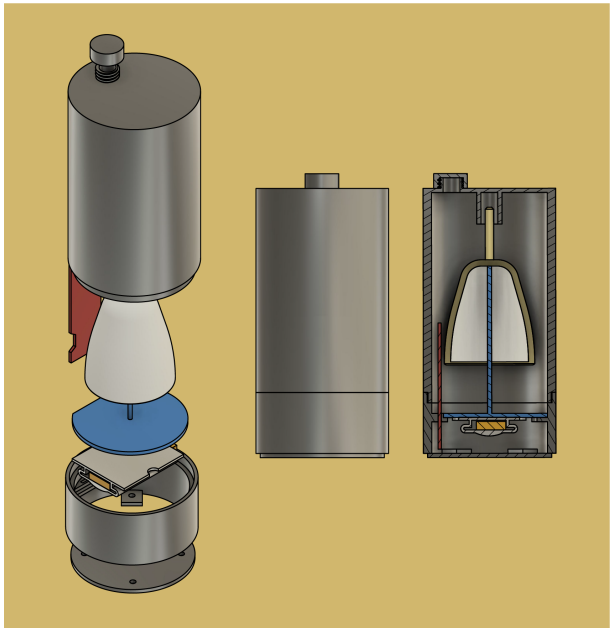


FIGURE 4.38: Steamer v1.

It has two mains parts. The first one is the body which will contain the steam and the cup. The device is closed with one big body-cap and an upper small cap. The upper cap is intended to be automatically opened when the pressure starts raising, but for the sake of simplicity the cap used for this version is a normal one. Since it has been adapted to the menstrual cup, the aluminium plate (in blue) has now a rod to support the cup and the body has also an extrusion which will capture the cup's rod. Additionally, another functionality

has been added : the water level measurements [7] (in red). This will indicate the user how much water needs to be put inside and will tell the heating element when to stop heating. Finally, the bottom part contains the electronic pieces : the heating element (already tested before) and the new water level sensor module. This version is much more adapted to the cup than the ones prototyped before.

Power supply unit

The chosen heating element is the PTC. The ones available are the market need to be powered either at 12V DC or at 220-240V AC. The other elements on the device need different input voltage, Arduino uno can be powered at 5V or either 7-12V ; in the other hand most of the sensors that could be used to develop the device as water-level, temperature or pressure modules need to be powered up at 5V. Having all these different components in the device means that transformers need to be used. A quick search in the market shows that transformers are very expensive compared to other modules, so the power supply unit must be designed wisely.

A lot of companies in different domains start to develop their devices in such a way that can be powered (or charged) using USB (an industry standard that establishes specifications for cables and connectors). This is a great benefit in two ways :

— First, the company do not need to provide their own charger or USB adapter (an expensive item) because we assume that everyone has at least one at their homes. In addition recent multiple plugs and house grids provide incorporate USB adapter.

— Second, it goes on a more sustainable development. All of the manufactures align behind an industrial standard which means that you can use one charger or adapter to a lot of devices, decreasing the number of electronic waste.

Since the 12V PTC versions are not that far from the 5V DC current, an USB charger might be able to power the sterilizer. This would make the device simpler and cheaper. However, the output power from an USB adapter is of about 10W (2A $\times$ 5.3V), therefore a trade of must be done regarding power, costs and simplicity.

Three different schemes design have been developed in order to be tested and compared, then one will be chosen and optimized for the sterilizer.

— **The USB adapter.** The device will be powered with an USB-C adapter, reducing cost and making the device simpler and more minimalist. However, a transformer to rise voltage from 5V to 12V will be needed.

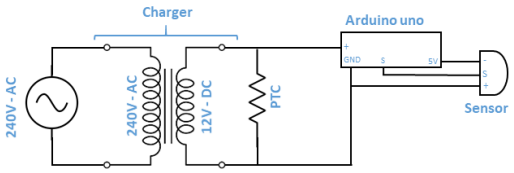


FIGURE 4.39: Charger electric circuit scheme.

— **The charger.** The device will be powered with a 12V pre-manufactured charger. No needs to develop an specific power electronics module. This will make R&D simpler, but more expensive and less pretty, since chargers are standard. This will likely offer more power since the output power of this kind of chargers can be chosen (30-50W).

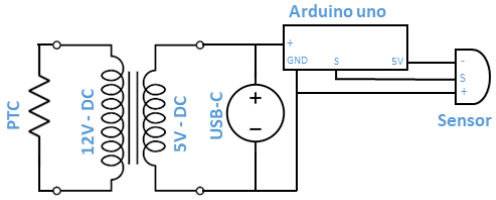


FIGURE 4.40: USB electric circuit scheme.

7. This sensor disappear on further version. The reason (not explicated in this report) is because of the low-tech approach developed within the environmental goals .

— **Direct charging.** The device will be powered direct from the grid, and an inner transformer will allow to power other electronics at lower voltage. In principle a lot of power is available for the PTC.

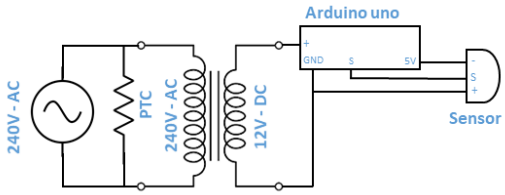


FIGURE 4.41: Direct powering electric circuit scheme.

The table below summarises the different tradeof :

Characteristics	Direct	Charger	USB
PTC voltage	220V	12V	12V
Avaiable power	Very high	20-60W	10-15W
Price	Medium	High	Low
Design	Medium	Bad	Good

FIGURE 4.42: Comparaison between powering solutions.

The type of PTC heating element (220V or 12V), is not a problem because availability and prices are the same. According to Figure 4.42, the charger scheme has been eliminated. The only drawback of the USB scheme is the available power, is it 10-15W enough to sterilize a menstrual cup using heat ?

Using the thermal equation $Q_1 = C_p.\Delta T.m$ where C_p is the specific heat coefficient of water, ΔT is the water's temperature to rise and m the quantity of water to be heated in mass, and $Q_2 = C_l.m$, where is C_l si the latent heat, the energy needed for the sterilization can be computed. By adding Q_1 and Q_2 and dividing by an amount of time the process should take, the power needed to perform it is calculated. The figure below shows the time needed to rise and evaporate a certain amount of water for a given input power.

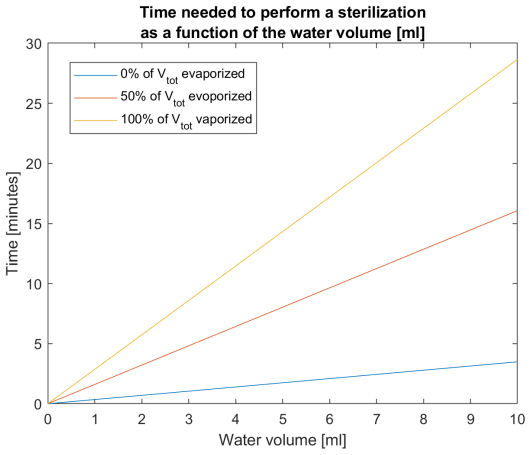
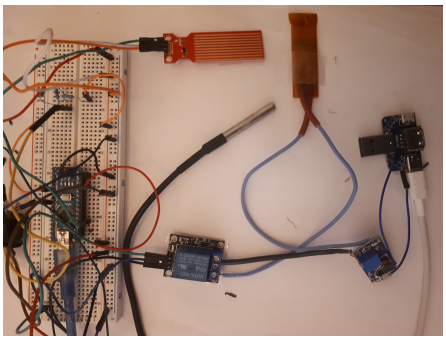


FIGURE 4.43: Water heating and evaporization simulation.

Some assumptions have been done : all the input power available goes to the PTC, C_p is constant along the process, perfect heating (no dissipation)... ; but it gives a first look of how difficult it will be to meet the time requirements for sterilization using an USB charger even with the most optimistic power consumption from the PTC and electronics. If this schemes is going to be selected, some tradeof must be done regarding time required and quantity of water. Without any tests, 5ml of water is assumed to be enough to sterilize (based on Sterilizer III and IV : *Steamer* and *Steamer 2.0* specifications), so 15 minutes for the whole process can be considered.

If sterilizations was meant by boiling water, the USB charger option would haven't been an option. The volume of water needed for this kind of sterilization is 100-200 ml. Since the time needed is proportional to

the mass (or volume) of water, the previous figure should be multiplied by a scale factor of 10-20, giving times of 50-150 minutes which is not acceptable. In addition heat dissipation could no longer be neglected and would probably make it impossible to rise 100 °C. Both schemes have been prototyped in order to evaluate the actual performances of such a circuit in terms of feseability, cost and power supply. Figures below show the actual circuits :



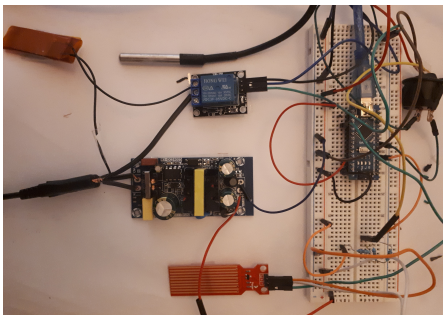


FIGURE 4.44: a) USB circuit b) Direct charging circuit.

The actual performances of the circuits for a 10ml water volume are shown on the figure below. The direct charging solution starts boiling after 6 minutes (362 seconds). The USB one takes too much time and boiling is never reached within desired times (below 15 minutes).

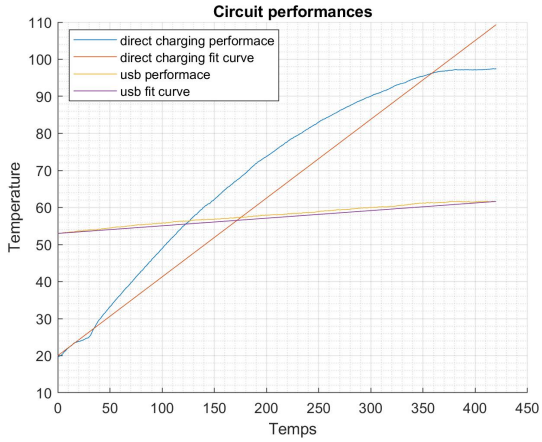


FIGURE 4.45: USB and direct charging performances.

The conclusion is that the power of the USB-C is not enough to make sterilization by means of evaporation feasible. So the Direct charging scheme has been chosen.

4.2.5 2in1 Design

The cleaning will be ensured by a brush cleaner and the sterilization by a steamer. Now that they have been developed separately, a 2in1 device have to be designed for merging both solutions. The TRIAXES 2in1 design could not be entirely reuse because in that conceptual design, the heating came from the lower part and the inner brush was at the upper part. The steamer can not simply replace the boiler because if so, the sterilizer part would only sterilize the outer menstrual cup walls since the cavity is facing upwards, as illustrated in the figure below.

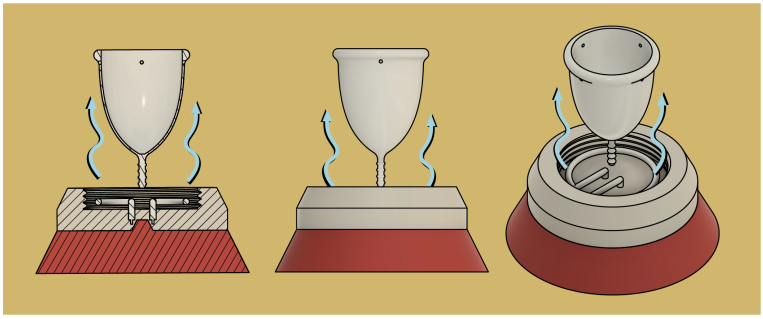


FIGURE 4.46: Representation of steam generation on TRIAXES prototype.

The constraint detected was that the heat source and its container for the water to be evaporated must be on same side than the brush (bottom or top). The following prototype solves the defined problem.

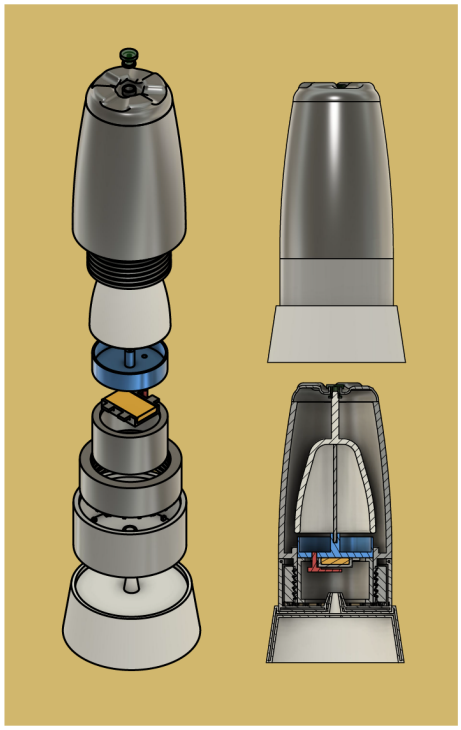


FIGURE 4.47: 2in1 prototype.

4.3 R&D phase 3 : Tulipal prototype.

The Tulipal 2in1 device it's the result of an iterative R& D process where the cleaning, sterilizing and 2in1 solution chosen on previous phase have been further developed, improved and optimized. It consist on a brush cleaner and steamer merged in a 2in1 device making it possible to solve the two problems previously announced in a simple and efficient way. In addition, the device has the advantage of being minimalist and pleasant.

4.3.1 Cleaning

Cleaning is provided by the mechanical part of the device and has the advantage of not requiring access to a private sink in the toilet cabin. The only constraint is that you must have the device with you during your daily moves (from home).

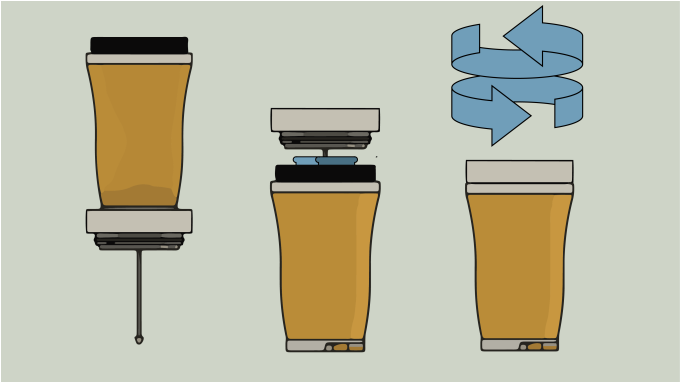


FIGURE 4.48: Device on cleaning mode.

This cleaning is done by diluting the blood of menstruation in a closed chamber filled with water in which the cup is located. To ensure total dilution, brushes rub the walls of the cup to remove the remaining blood as best as possible.

4.3.2 Sterilizing

Sterilization is ensured by the electromechanical part of the device. This solution makes possible to sterilize the menstrual cup and the device itself at the same itime, allowing the cleaner to be also sterilized. This cannot only be done in a private place, like at home.

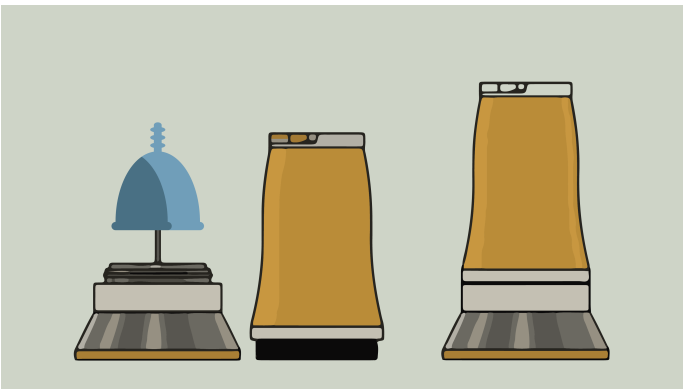


FIGURE 4.49: Device on sterilizing mode.

Sterilization is done via water vapor, generated by means of a resistance which heats a container containing liquid water.

4.3.3 User's scenarios

Since the device has a dual functionality, it therefore has two mechanisms : one for cleaning and the other for sterilization. During prototyping, several assumptions are made beforehand for the proper functioning of the device :

— The have a source of clean water near her private cabin (toilet), as well as at home.

— The user has a bag to dry the cup as the one that most cup's brands gives when a menstrual cup is purchased.

Cleaning

FIGURE 4.50: User's scenario : cleaning mode.

When the user enters the toilet, public or private, she opens the device from above using the upper external plug. If she wishes, she can fit it into the lower part for one-handed use. Then, the user fills the device with ¾ water at a water source (1), puts the cap back on (2) and goes to her private cabin (3). There, she removes (4) and empties (5) her cup in the toilet to place it on the internal brushes of the device (attached to the top cap) (6). Thus, the cup is secure thanks to an absence of play between it and the internal brushes allowing the user to easily close the device by screwing the external cap (7) without risk of dropping the cup. From then on, the user can start the cleaning mechanism. By periodically rotating the top cap, the user will generate an internal movement of the brush which, by friction, will remove the residues of menstrual blood (8) and dilute them in water. Finally, simply unscrew the drain small cap located on the lower part of the device and empty the water into the toilet (8bis). When all the water has been drained, the user can open the device (9) and remove the cup (10). Finally, the cup is dried using the fabric's bag supplied with it when it is purchased (11) and the user can replace the cup (12) and store the device.

Sterilizing

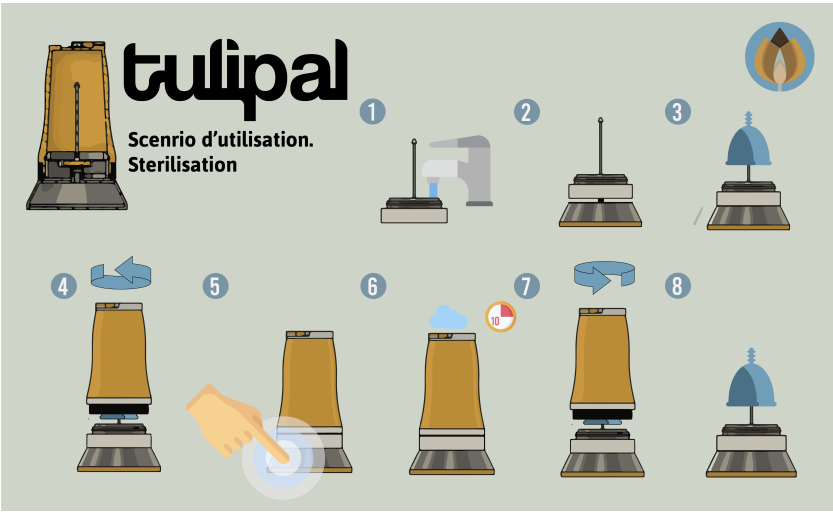


FIGURE 4.51: User's scenario : sterilizing mode

The cup can be sterilized anywhere with a power outlet and a water source. Since the recommended sterilization frequency is lower than that of cleaning, it can be done at home. Thus, during the sterilization mechanism, the user will begin by removing the upper external cap of the device and fill it with water (1) (10-20ml), the cap thus acting here as a water container. Then, the user plugs the cap onto the base through the cable adapter (thereby creating n electrical connection) (2) and deposits the cup on the shaft (3). It is then necessary to screw the body of the device on the cap (4) and start the sterilization by pressing the switch (5). Finally, after ten minutes (6), the cup and the inner part of the device will be sterilized. Finally, the user can unscrew the body of the device (7) and recover the sterilized cup (8).

4.3.4 Technical description

The prototype is made up of three main parts :

1. **The base.** The base remains at home and provides power to the electrical part. It also has all the electronics necessary for control as well as the interface for the user.
2. **The cap.** This cap acts both as a container to heat the water until it evaporates, and also as the system for transmitting the movement of the user's hand to the inner brushes intended for cleaning.
3. **The body.** The body serves as a water container and helps retain heat when heating water during the sterilization.

The figure below shows an exploded view of the Tulipal 2in1 device and all the parts. All the mechanical parts are represented there, others as the outer brushes and the electronics are missing.

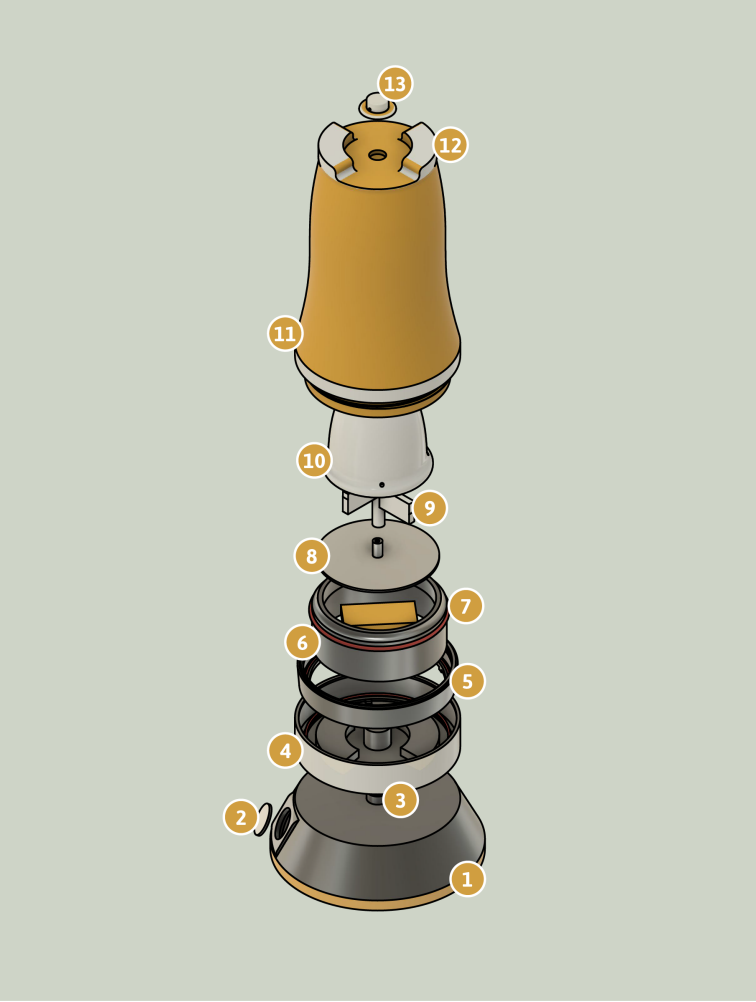


FIGURE 4.52: Device's parts.

Below, each sub-point section describes the element of the number corresponding to Figure 4.52.

1. The base

The base, so called because the (portable) device rests on itself during the sterilization phase. It contains all the electronics necessary for the user to be able to initiate the sterilization. It also supplies power to the heating element (PTC) inside the portable device. In particular, it contains : an interface system for the user (one button and one LED light) ; a relay ; a cable to connect the base to a socket ; a logic control circuit with a timer. These electronics are not shown in the previous figure.

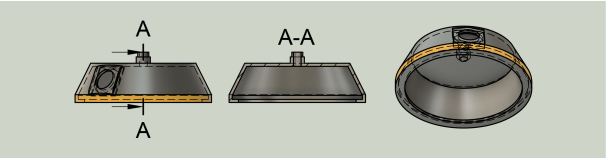


FIGURE 4.53: Device 2in1 base.

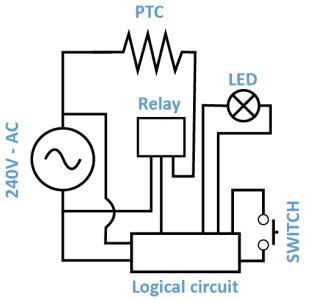


FIGURE 4.54: Device 2in1 base.

In the final circuit (Figure 4.41), the Arduino that was still present on the steamer prototyped on the previous section has been replaced by a logical circuit, thus the transformer is no longer needed. The power supply scheme is still almost the same.

2. User interface

The user interface is the set of parts, mechanisms or electronics that allow the user to interact with the device during sterilization. In Figure 4.52, it is represented by a button. The interface consists of a switch with a translucid surface which is illuminated by an inner white LED. The UX diagram is represented on Figure 4.55, where state 0 the device is *sleeping*, LED is OFF and the PTC is not powered ; and state 1 where the PTC is powered and the LED is blinking. When the sterilizes finishes, the LED is ON for 5 minutes. User can at every moment stop the sterilizing by pushing the switch and change from state 1 towards state 0.

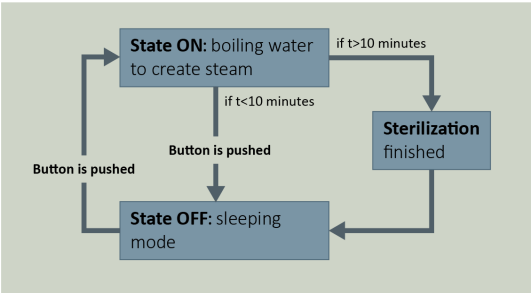


FIGURE 4.55: UX diagram.

3. The cable adapter

The cable adapter is an adapter that has 360 degrees of freedom like the one on electric kettles. This adapter connects the heating element (PTC) with the PSU and user interface electronics inside the base.

4. The outer cap

The outer cap is one of the two pieces that create the safety type inspired cap. It is the one on the outside (Figure 4.58, yellow cut part) and which will transmit the movement. It contains the inner part of the cap and blocks it in its inner wall. In addition, it has the female part of the cable adapter explained before, as well as the internal structure part. Finally it has two notches which will serve the user to be able to attach this piece to the body (second mounting position) and allow the one hand use of the device. The red piece is one of the O-rings that provide the seal.

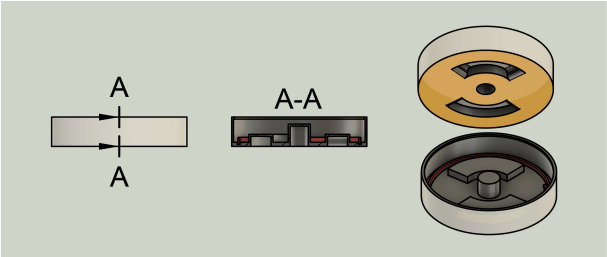


FIGURE 4.56: Device 2in1 outer cap.

5. The inner cap

The inner cap is the inner part of lower cap. It allows the cap to be tightened to the body (and seal) while maintaining a certain degree of freedom so that the outer cap can rotate freely.

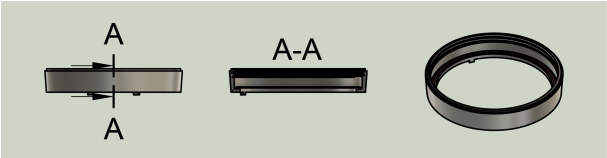


FIGURE 4.57: Device 2in1 inner cap.

It work as follows :

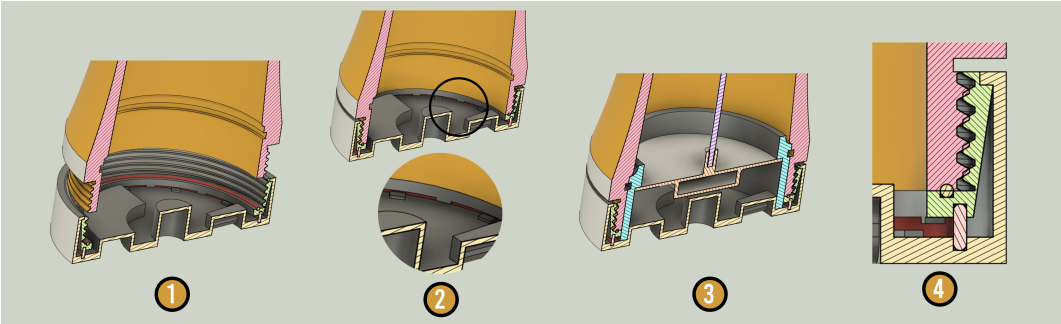


FIGURE 4.58: Lower cap mechanism.

When first screwing the lower cap into the body, the extrusions on the lid of the outer cap will hit the same extrusion on the inner cap's bottom surface, thus making the inner cap screw into the body (1,2). Then once the lower cup is completely screwed into the body, due to friction the inner cap will be tightened to the body (3), allowing the outer cap to rotate freely because of the play between the inner and outer cap(4). Now the device is sealed and the rotating movement from the user is transmitted to the shaft through the outer cap. There's no a completely 360°free movement since there are two extrusions [8] User can rotate the cap of 180 °back and forward, but since the bristles of the brush are disposed every 90°, 180°are enough to ensure that the whole inner surface of the cup is cleaned.

6. The inner structure and PTC heating element

The inner structure is located on the lower cap and isolates the cable connector and the PTC from the rest of the device, allowing the interior to be sealed. On this is deposited the aluminium plate which will be heated by the PTC. When the plate is installed, this creates a small 15ml container on which the user will pour water during the sterilization phase. Again, it has an O-ring for dynamic sealing.

8. For the sake of clarity, the number of extrusions has been multiplied on Figure 4.58 with respect to 4.57.

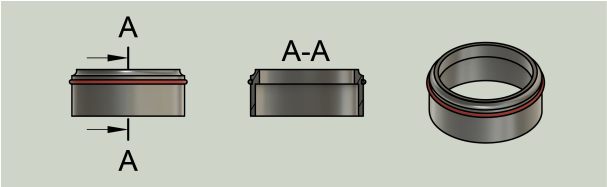


FIGURE 4.59: Device 2in1 inner structure and PTC heating element.

7. The seals

There are two main types of seals :

1. Static sealing : It provides a seal between pieces in the absence of movement.
2. Dynamic sealing : It provides a dynamic seal during the rotational movement. The parts must have a certain play to be able to rotate while isolating the passage of water between the main container and the rest of the device.

The first static seal is located between the aluminium plate and the internal structure in the lower cap ; and on the upper cap. The second one is located at the top of the threads. The dynamic seal is located between the body of the container and the inner structure.

8. The aluminium plate

The aluminum plate has two functions :

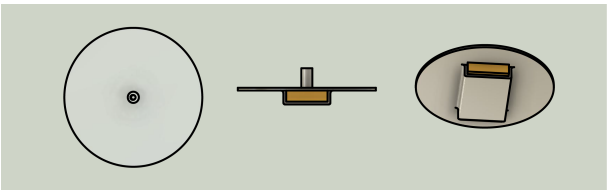


FIGURE 4.60: Device 2in1 aluminium plate.

— High thermal conductivity and heat resistance to increase the speed of heat transfer from resistance to water.

— It has a lower notch on which the PTC resistor is placed as well as an upper notch to which the brushes are attached.

9. The brush

The brush is the mechanism chosen to clean the cup among the three options developed (membrane, brush and shaker cleaner). The brush mechanism consist on an inner brush (Figure 4.61) and an outer set of brushes (Figure 4.62. The inner brush rubs the remaining residues on the cup and dilutes them in water. The outer set of brushes are intended to block the cup inside the device and prevent from rotating when the inner brush do ; these later haven't been implemented yet to the final device.

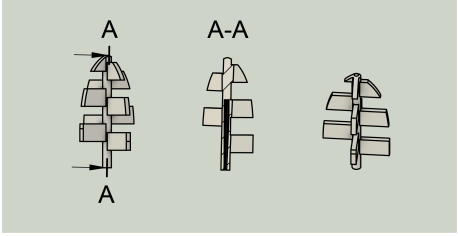


FIGURE 4.61: Device 2in1 brush.

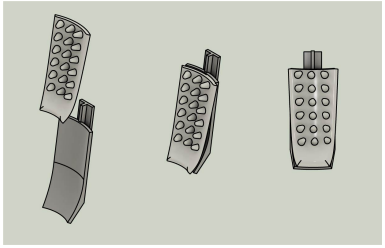


FIGURE 4.62: Device 2in1 outer brush.

The goal being to provide a durable brush over time, both brushes are made of medical silicone, like the cup itself. The filaments of a traditional brush are replaced by small bristles which embrace the shape of the menstrual cup. To increase inner brush's rigidity, there is an inner hole (with a cross profile) where a metal rod is inserted. This shaft will be fixed on one side (bottom) to the aluminium plate described previously, and on the other (top) to the inner brush.

The menstrual cup is marketed in several sizes which take into account different criteria : age, sportsmanship, menstrual flow and finally the number of deliveries. These sizes prevent leakage in menstruating women. The developed brushes are also used to adapt the whole device to the different cup sizes. All the pieces remain the same for S, M or L size except the brushes which are produced on 3 different sizes. To choose the 3 inner brush dimensions, first of all the 3 average S, M and L menstrual cups have been created from data gathered from more than 170 menstrual cup models. The data extracted from each menstrual cup was available online [29] in the form of :

Name	Type	Size	Diameter (mm)	Total length	Body length (mm)	Stem length	Capacity to holes	Capacity full (ml)	Countries	Popularity	Weight
Juju		XL	40	78	58	20	22	27	Australia	MEDIUM	2
Lunette		L	45	72	53	19	25	30	UE	HIGH	3

FIGURE 4.63: Data gathered from each menstrual cup model.

Data has been filtered (Figure 4.64) in order to keep only the ones associated to potential clients : 1) EU and USA users ; 2) not XL (few percent), nor S (teen cups) and 3) menstrual cups with a regular stem (straight one, not rounded).

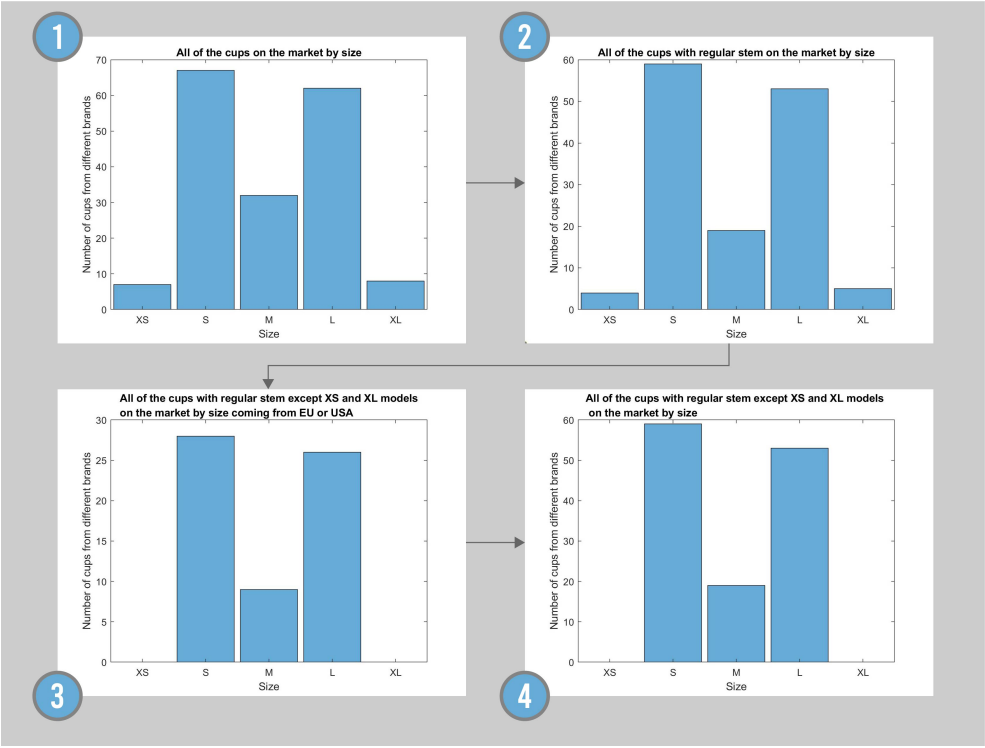


FIGURE 4.64: Filters applied to menstrual cup data.

Then, a weight factor is used to try to give a representation of the number of cups in the market of each brand. For example the Lunette cup has high popularity, so it should influence more the average menstrual cup dimensions than one that has low popularity (HIGH=3 ; MEDIUM=2 ; LOW=1). Once this weight factor attributed, the 6 main characteristic that define the cup are computed as follows (for each category S, M and L) :

$$d = \frac{\sum_{i=1}^{N} k_i * d_i}{\sum_{i=1}^{N} k_i} \tag{4.3.1}$$

where N is the total number of cups on each category after filtering ; d_i is the dimension of i cup model and k_i its popularity weight factor associated. The final average dimensions for each category are :

Category	Diameter (mm)	Total length (mm)	Body length (mm)	Stem length (mm)	Capacity to holes (ml)	Capacity full (ml)
S	41.0556	67.9444	46.4444	21.5	20.0185	25.2037
M	43.2143	68.4286	51	17.4286	24.3571	29.3571
L	45.84	70.72	52.4	18.32	27.04	33.7

FIGURE 4.65: Average S,M and L dimensions..

Finally, three type of inner brushes have been developed in such a way that they embrace each of the different average menstrual cups.

10. The menstrual cup

Below there's a 3D model of a classic cup available on the market. It is this which happens to be the object to be cleaned and sterilized and for which the prototype which is the subject of this report is designed.

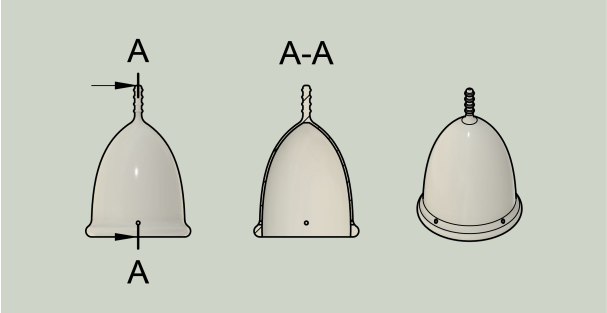


FIGURE 4.66: Classic menstrual cup.

11. The body

The body is the largest part of the device. It has two main functions :

— **Sterilization :** It acts as a barrier to conserve heat inside the device and therefore increases the speed of this phase. In addition, during the sterilization phase, the body will also be sterilized.

— **Cleaning :** The body acts as a container for water.

Other secondary features are exploited through the body :

— It determines the shape and ergonomics of the device. It should be easy to take and handle while having a simple and minimalist design.

— It has the ridged part onto which the external upper plug is screwed, which makes the device completely waterproof.

— It also has the counter shapes of the notches of the external cap which providing the second mounting position for one-handed use.

— It also has a hole in the upper part that connects with the base's cable adapter.

Two important parts are not shown schematically in the figure below : for the first, it is a notch from the upper part which is used to attach and block the rod. The second consists of three external brushes attached to the body wall and arranged from top to bottom.

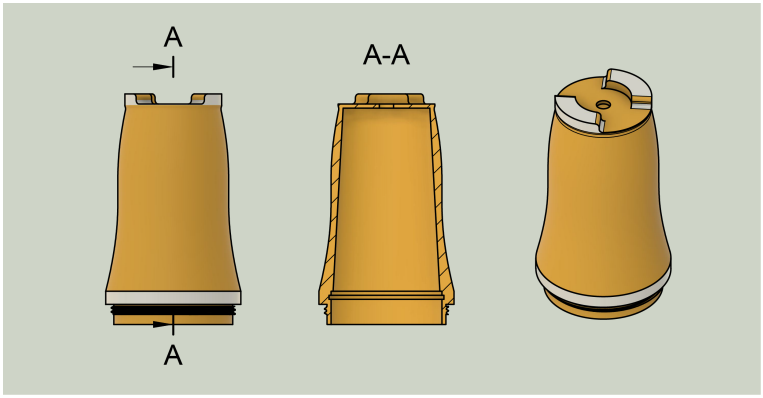


FIGURE 4.67: Device 2in1 body.

12. The second mounting position

The second mounting position is the one that allows the user to use device without needing to deposit it on the ground. In fact, opposed to what is shown on the user scenario for the cleaning mode (step 6), the menstrual cup can be directly inserted inside the device without previously inserting it on the inner brush. This avoids depositing the device on the ground and step 6 would be replaced by (new 6th and 7th steps, the 8th corresponding to the previous 7th) :

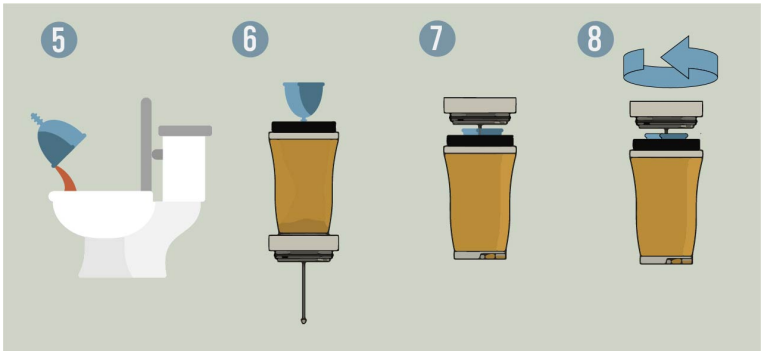


FIGURE 4.68: Second mounting position cleaning scenario.

This system is chosen to able one-handed use of the device during cleaning. This mechanism is schematised by two notches in the lower cap which fit together with the counter-shapes located on the top part of the body, as shown in the image below. The mechanism is not yet fixed and could evolve into a mechanism with clamping (to clip mechanism) or a magnetic (with magnets) system.

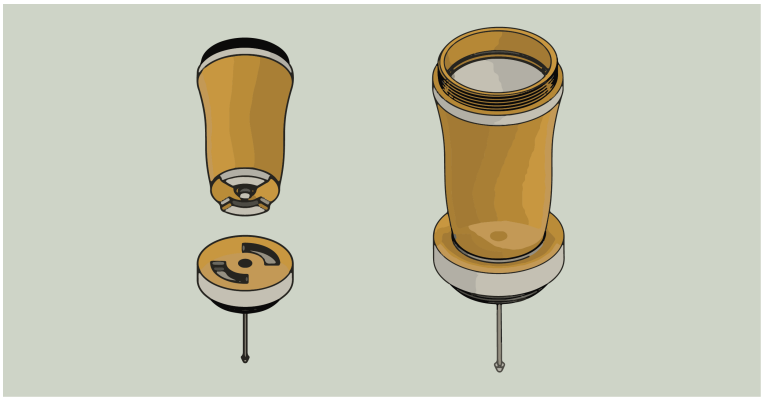


FIGURE 4.69: Device 2in1 cap clip mechanism.

13. The top cap

The top cap is assembled to the body and has different functionalities : during the **sterilization**, it ensures the depressurization of the device ; during the **cleaning**, it's used as a water drain when the cup is cleaned.

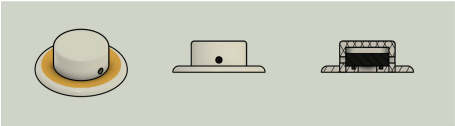


FIGURE 4.70: Device 2in1 top cap.

The type of cap hasn't been chosen yet, however its state of the art and its task clarification study have been made :

Type	Description	Ease-to-open	It opens itself with pressure inside?	Cap integrated to body?
Screw-cap	Cap that screws into a screwed extrusion	LOW	NO	NO
Push-spring cap	Cap that opens and closes with the same mechanism as pens have	HIGH	NO	YES
Hidden cap	An extrusion that hides inside the cap that can easily being opened: *camelbak water bottle* type	HIGH	MAYBE (if well sized)	YES
Sport cap	Cap that is inserted with pressure (sport plastic bottles)	MEDIUM	MAYBE (if well sized)	MAYBE (with a stripe)

FIGURE 4.71: Cap types analysis.

Dimensions and ergonomic

The dimensions of the device (Figure 4.72) have been chosen to make the device the smallest and easiest-to-carry as possible. Device's dimensions have been optimized and are derived from the menstrual cup dimensions. Each millimeter mattered ; several dimensions' configurations have been prototyped and printed in order to find the one that fitted the best the menstrual cup and still allowed to clean and sterilize without any problem.

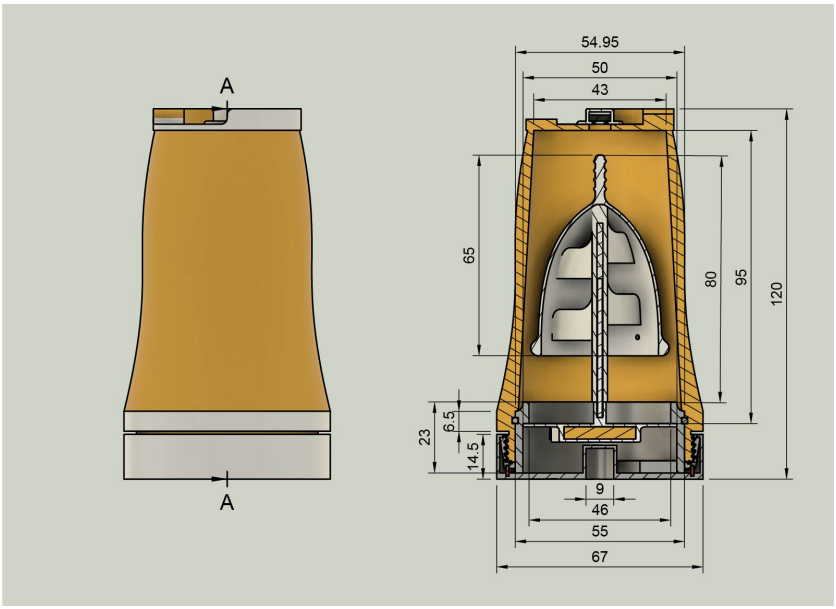


FIGURE 4.72: Tulipal 2in1 device main dimensions (in mm).

The menstrual cup designed here has the diameter dimensions of a M size (43mm), but its length is under the average M sizes (68mm). This is why there are still 10mm between the cup's stem and upper cap (70mm is the average length of L size menstrual cups previously presented).

4.3.5 Tests & Results

The user tests carried on this device :

— **Short-term.** This version has been developed with an iterative process where every 1-2 weeks, feedback from two girls is gathered. One of them is a menstrual cup user and the other is a non-user, but willing to make the pass to the cup.

— **Long-term.** Since the device is not fully functional (see next section : further development), this latter could have not been done yet. Once the minor challenges still present are solved and optimizations are implemented, the device is going to be tested by 5 different girls (as the test done for the TRIAXES version).

— **Focus group** A focus group with 10 different users is already programmed for September 2020.

4.3.6 Further development

The current device is not finished yet, and yet improvements from the focus group and long term feedbacks are to come. But before, the following parts still need to be challenged, finished or further developed :

1. **Outer brushes.** Still to be implemented on the device. The system to attach and remove them has also to be developed. *(on going)*
2. **Outer cap.** After the state of art, the different caps have to be purchased or adapted to the device. (to do)
3. **Dynamic sealing.** Some conceptual designs are currently being designed based on some examples used in the industry : electric tooth-brushes, pistons... *(on going)*
4. **Assembly.** Currently pieces are attached between them using glue. The goal is to avoid glue and use mechanism allowing the user to easy-repair and dismantle the device. *(to do)*
5. **Durability test silicone.** A durability test should be carried on the device in order to test if the brushes last as long as the menstrual cup. *(to do)*
6. **Logical circuit.** The logical circuit presented before is not made yet. In fact the Arduino is still used but is too powerful to this applications. *(to do)*
7. **On-board circuit.** The current circuit has not been miniaturised, neither integrated on a on board circuit. This goes might be a bit difficult and thus inefficient to try to do it by alone. A company has been contacted in order to get a quote regarding the on board circuit prototype. *(on going)*
8. **The second mounting position.** The mechanism allowing the user to do the second mounting position has to be further improved (if clamping) or prototyped if the magnet one is chosen. *(on going)*
9. **The cable adapter.** The state of art has been done and examples of adapter have been purchased and are currently being studied. *(on going)*

To avoid some problems and bottle necks of the project (dynamic sealing, cable adapter...) a new conceptual design based on this device is currently being investigated. The idea behind this new version would be that the user would not carry with her the heating element in the device but this latter would rather be in the base. The device would have a lower aluminium surface, that in contact with the base (also with an aluminium surface) would be heated by the PTC through the base (thermal connection) when the sterilizing is started. This would allow to solve partially the dynamic sealing (which is currently the biggest bottleneck of the device's development) and avoid to implement a cable adapter. In addition this would make the cleaner device (without the base) smaller and lighter since it does not longer contain the PTC and cable adapter. For sure this version could carry with her new challenges, but that's what R& D is about !

Chapitre 5

Legal, Environmental, Medical & Business aspects

Along the technical approach, there are 4 different aspects that have influenced the final prototype are : legal, environmental, medical and business aspects. First of all, because of the current existing patents, changes have been implemented on the device because otherwise the device couldn't be commercialized. As stated on the introduction, environmental is very important for this project. Are menstrual cup as green as we think ? What about the duo menstrual cup and Tulipal 2in1 device ? If compared to the tampons or sanitary pads, which one is better from an environmental point of view ? To quantify the impacts, a LCA (Life Cycle Assesment) [1] of sanitary products has been analyzed and the one of the 2in1 device has been made from scratch. The LCA allowed to identify the most impactful categories of the device's life cycle, thus taking action on materials choice, parts conception or electronics on-boarded. On the other hand, a question that hasn't been addressed yet is the regarding the medical status. Is it a medical device and if does does, is it compliant with the correspondent regulations ? Finally, this Master Thesis has been done simultaneously with a Business Plan Master Thesis (Business Engineering, Solvay), strong constraints were imposed through the whole development from this latter.

5.1 Legal aspects

Doing R&D without having a scope of what's the patent landscape of your current invention could be fatal for this latter. Analyzing what already exist in the market is insufficient, some inventions can be patented or are being patented (the process could last several years), and still not being available to purchase on the market. This is why prior art search is a key on every R&D project. Trough this project, 3 different prior art search have been done, the findings will be presented in the following sections.

The patentability of the invention refers to the possibility of protecting some aspects of the device in order avoid being copied. But before discussing patenteability, another concept is more important : the freedom to operate, which is the ability of a company to commercialise products without legal liabilities to third parties like others patent's holders. Both capacities, patentability and freedom to operate, might be shared or not. A product can be patentable since a patent does not cover all the aspects of a device but cannot be commercialise because it is not free to operate (eg. a device can protect some minor features but cannot be commercialised because its main functionalities are already patented). Vice versa, a product can be free to operate but not patentable (e.g. a device is protected in Korea, but not in Europe, thus you can commercialise it but cannot protect it since novelty is not respected). In order to take into account all these aspects, a legal strategy was set up from the very first prototype.

5.1.1 Current strategy

From the first moment (November 2018), the aim of the project was to patent the invention. No public visuals or elements of the project are available. In addition, every person that has seen the prototypes is

1. "*LCA is the factual analysis of a product's entire life cycle in terms of sustainability. Every part of a product's life cycle [...] can have an impact on the environment in many ways. With LCA, you can evaluate the environmental impacts of your product or service from the very first to the very last or from cradle to grave*" [10].

subject to an NDA that stop him or her from divulging any aspect of the R&D phase. Other protections foreseen are copyright for the device name and the design and model protection, that protects an specific shape of a given object.

For the moment two kinds of actions have been taken :

— **E-Dpo.** E-Dpos are not a legal protection themselves but can be useful lately if some legal issues appear at any moment. It's a proof that at the given time of the e-dpo's deposit, the current invention (object of the e-dpo) already existed. Two e-dpo have been registered, one of the TRIAXES version in June 2019, and the one of the final Tulipal prototype in July 2020.

— **Non disclosure agreement.** NDAs have been given on different occasions for different reasons : tests (users), partnerships (CEOs), R&D (experts) and coachings (entrepreneurs).

5.1.2 Prior art search

For prior art search, there exist different database where patents can be found [2] and are classified. In order to find a patent one can either search through an advance search where some fields should be specified : title (keywords), date (range), countries, inventors ; or searching by classification. Every patent fall into a precise classification where other similar inventions can be founded.

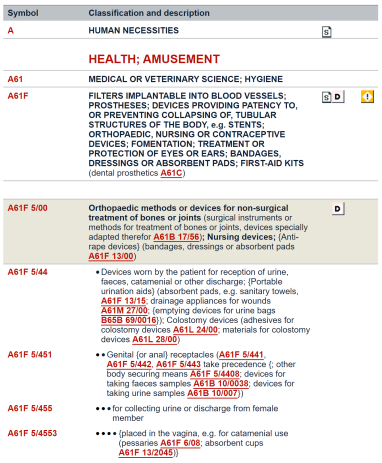


FIGURE 5.1: Classification familly for the menstrual cup related inventions.

The aim of a prior art search is to find all the patents that could influence the freedom to operate or the patentability of an invention. A proper methodology was developed alongside a Belgian patent office consultant [3]. After analysis, a total of 63 patents were judged to be relevant ; separating them in those that can influence the freedom to operate or the patenteability, gives the distribution below. They have also been ranked in HIGH, MEDIUM or LOW similarity with respect to the Tulipal 2in1 device. It's important to say that not all the publications that appeared are granted patents, they are either on examination, granted or refused.

— Patents that could be an issue to freedom to operate (International or European patents) : 19 from which 1 of HIGH similarity and 3 of MEDIUM similarity. The others are not really a problem but they should be cited on an eventual patent.

— Patents that could be an issue to patenteability (The previous ones and others that are not European or International patents) : 63 from which 10 of HIGH similarity and 18 of MEDIUM similarity. Again, LOW ones are not a risk for patenteability.

5.1.3 Patenteability and freedom to operate

All the HIGH and MEDIUM ones have been analyzed, however not all of them are presented on this report. As an example, the analysis of the publication that had the higher risk for the freedom to operate

2. Some examples are : espacenet, wipo or Google Patents
3. Nico Deconinck, Patent searcher at the Belgian Intelelctual Property Office. Qualified Patent Information Professional : reg. 20190032100012.

(thus patenteability too) for the Tulipal 2in1 device, is presented here. In addition this patent has a HIGH similarity and is the most important one (among the 63 patents mentioned before) because it's a 2in1 device that intends to clean and sterilize menstrual cups, other HIGH similarity publications are either cleaners or sterilizers. This publication is called *Container for cleaning and sterilizing menstrual cups* (Figure 5.2) [17].

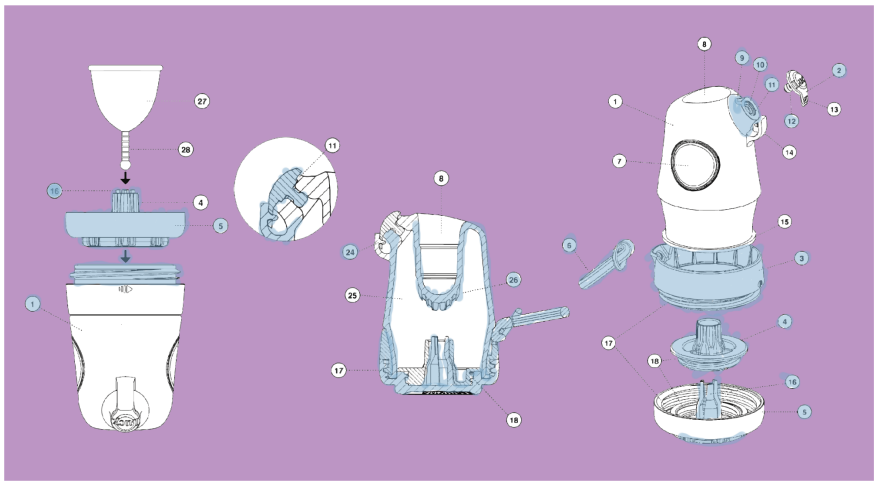


FIGURE 5.2: Publication : Container for cleaning and sterilizing menstrual cups.

The present patent describes a device that cleans menstrual cups by means of a shaker made of elastic material and sterilizes using the microwave (as the sterilizer that already exist in the market presented in the state of art section). This claims' patent analysis has forced to change some of the features of prior prototypes. It also justifies some of the choices that have been made. The changes implemented in the Tulipal 2in1 presented at the end on this section were done in order to gain, at least, **the freedom to operate**.

The table below summarises the analysis of the patent. First of all, since it's a recent publication, it is still in examination, so none of its claims have been granted. The so called search report, is a report done by a patent organism that tells the author which claims should being reformulated because they cannot be claimed. This is a very important information because even if a claim could be a risk to the Tulipal 2in1 device (red YES, on the Tulipal column), if it cannot be claimed, then it's not a problem and can still be present in the device. The claims that may be a risk are those that are not mentioned on the search report (thus they might be granted) and are in conflict with some of the Tulipal 2in1 device's features. There are three and are highlighted in orange. After analysis it can be concluded that what the inventor try to patent is not the 2in1 device but some minor features.

Name		CONTAINER FOR CLEANING AND STERILIZING MENSTRUAL CUPS				
Publication date		26-03-20				
Countries		WO				
Legal status		Examination				
Freedom to operate		Could be a risk				
Patenteability		Could be a risk				
N° claim	**State of art**	**Claim**	**Figure**	**Search report**	**Tulipal**	**Comment**
1	Container for cleaning and sterilizing menstrual cups (microwaves resistant)	Lower cap that closes the container with an extrusion that block the cup stem and maintains firmly the cup.	5, 16	YES	YES	
2	Claim 1	The second mounting position		NO	NO	This position is not used (cup projected outwardly)
3	Claim 2	Container made of elastic material		YES	YES	
4	Claims 1-2	Elastic material is silicone, polymer or copolymer		YES	NO	
5	Claims 1-4	Holding is in the form of projections to retain the cup	16	YES	YES	
6	Claims 1-5	Central ring that enables to attch the elastic container to the lid	3	NO	NO	None of the devices developed needed such a ring
7	Claims 1-6	Clamp around the holding	4	NO	NO	Holding mean is done differently
8	Claims 1-7	The inner brush is bell-shaped and in contact withe the menstrual cup	26,27	NO	YES	Blocks one type of brush
9	Claims 1-8	Discharging means for liquid inside and allow steam to be expelled		YES	YES	
10	Claim 9	The type of cap (bottle neck)	9,10,12	NO	YES	Blocks one type of cap
11	Claim 10	A recess that mades easier to open the cap	21	NO	NO	
12	Claim 10	A stripe that attachs the cap to the container	14,24	NO	NO	
13	Claim 1-12	Lid has a protruding portion at the outside that ables the second mounting position.	20	NO	YES	Here is not the position that is blocked but the mechanism. So, this type of mechanism is blocked
14	Claim 1-14	Bumps to release air when in the second mounting position	22	NO	NO	Air release is not needed
15	Claim 1-15	Flexible string	6	NO	NO	Not used

FIGURE 5.3: Claims analysis.

The 3 claims previously mentioned explain why the following choices have been made :

1. **Inner brush. (claim 8)** The bell shaped inner brushes cannot being exploited for the brush prototype. In addition the first version (or even second and third) of the membrane cleaner could be subject to a conflict in terms of freedom to operate because of the similar bell shaped brushes they have.
2. **Outer cap. (claim 10)** The small outer cap should not use the same mechanism as the one claimed by the inventor. For example a screw cap could be used.
3. **Second mounting position (Claim 13)** (blocking the bottom cap in the top side). The patent claim the second mounting position for holding the cup (as the one in Figure 5.2, on the left), which is not used in the Tulipal prototype ; however the way the cap is blocked on the body could be similar as the one-hand mechanism developed for the Tulipal 2in1 device. Thus the mounting mechanism should be different, for example by a clip mechanism or using magnets.

By making these choices (an other not presented here derived from other patents' similar analysis), the **device became free to operate**, since none of claims are violated. Thereby, the device can be commercialised without any legal issue. Finally, regarding the intellectual property protection, the device **should be able to be patented**, however which parts can be claimed by the patent are still not known and will be the result of a new legal analysis. What is taken for sure is that the claims that have not been granted to cleaners and sterilizers (i.e container device for cleaning and sterilizing menstrual cups) won't be granted for the Tulipal 2in1 device ; however, others that do not appear in any cleaner patent as the brush system (inner and outer brushes), the cleaning mechanism made of the set of caps or the 2in1 solution (how the cleaner and sterilizer are merged), **might be patentable** and will depend on the different national patent office's appreciation.

5.2 Environmental

Environmental aspects have been chosen to be a major constraint in this project so the prototype has been developed following some resilient and eco-design rules that have direct effect on its environmental impact. This latter has been chosen as the climate change impact and is measurable using the equivalent kg CO2 emissions unit.

5.2.1 Menstrual cup's environmental impact

Studies has shown the difference impact on climate change of different hygienic protections (Figure 5.4) [1]. For each of them, difference contributors (raw materials, transportation, manufacturing, disposal...) have been analysed and taken into account [4]. They highlight the advantages of the menstrual cup against traditional sanitary protections : *"The impact of reusable menstrual cup used for one year was less than the 1.5% the environmental impact of the alternative products and approximately only 10% of the cost. Thereby clearly demonstrating the overall value of reusable option in a class highly used and important consumer products".*

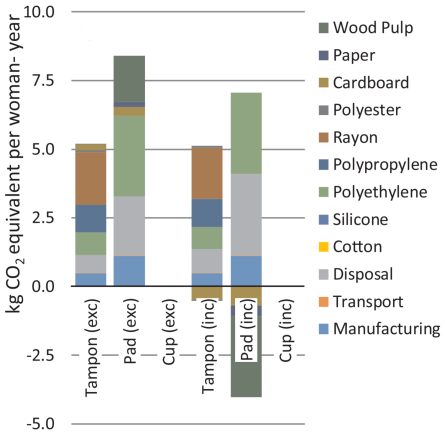


FIGURE 5.4: Details of contributors to climate change for menstrual cups, tampons and sanitary pads. [1]

4. The difference between inc and exc is that exc analysis do not take into account the effect (negative) of biogenic carbon. This latter takes into account the sequestration of carbon from the atmosphere into biological resources that are lately transformed into raw materials : wood, paper, cardboard...

However, these studies [1] do not take into account the sterilizing and 3-4 [5] times a day cleaning of menstrual cups. Since a solution should be addressed to these problems, the latter analysis should include the life cycle assessment of complementary solutions (as the 2in1 Tulipal device) in order to properly compared different period solutions. Thereby, a similar LCA has been addressed to measure the impact of the use of menstrual cup alongside a cleaning and sterilizing device during one year. The goal is to determine if the menstrual cup remains a better ecological option than regular tampons and sanitary pads when used with complementary devices ; and where efforts (from an ecological point of view) should be done on the device life cycle in order to have smaller environmental impact.

5.2.2 Life cycle assessment : Tulipal device

The evaluate the goal previously announce, a LCA assessment has been performed on the 2in1 device, and then added to the results of the menstrual cup LCA presented before. A LCA analysis is characterized by 4 main steps :

Goal & scope definition

A first order LCA analysis of the 2in1 Tulipal device will be done providing a general overview of the environmental impacts of this latter. From all impact categories, only the most impactful one will be studied : climate change (in eq kg CO2 emissions). In order to be able to compare both results (sanitary protections LCA and device LCA), the same functional unit should be used, so the analysis was based on one year of coverage for one woman for one year. The device will be reusable for at least 5 years, thus only one fifth of the device is needed to provide the coverage.

Inventory analysis

The inventory analysis characterizes the process flow of a product's life cycle in term of inputs and outputs, figure 5.5 summarises it. There are three main systems taken into account : device production, device use, and device disposal. For the first ones, the materials needed as inputs for the manufacture process are divided in plastic, metal and electronics (already manufactured). Inputs for use are only the resources needed to perform sterilization (water and energy) and cleaning (water). Finally the device disposal input is the device itself.

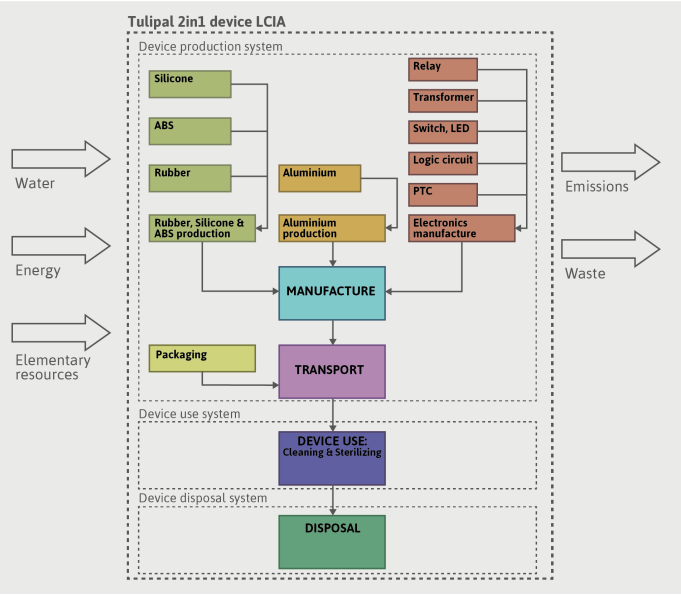


FIGURE 5.5: Scoping diagram for LCA of Tulipal 2in1 device.

However, due to its complexity not all the electronics could have been added. It could have been possible to find all the components of the logical circuit, relay and transformer ; however it's out of this analysis scope since the goal is to give an overall overview. In order to take into account these electronics, a micro controller carbon footprint has been manually added to the analysis [32].

5. They assume that they have to be cleaned every 12h, when in reality is every 6-8 hours

Impact assessment

The impact of the different contributors to climate change of the device are summarized on the figure below for the different systems. The most impactful part are the plastic production and the electronics.

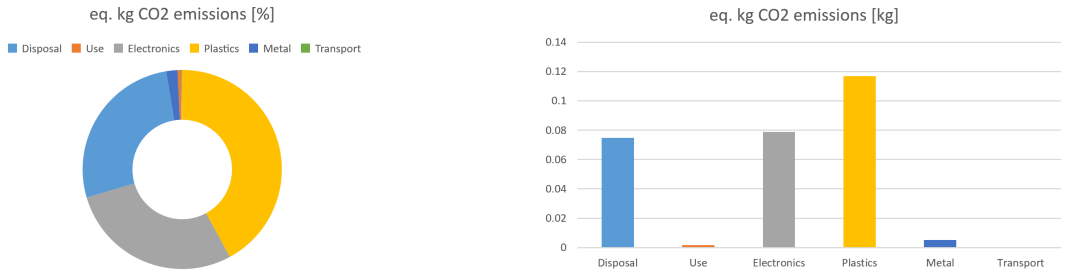


FIGURE 5.6: contributors to climate change of the device.

Interpretation

If the device's impact on climate change (0.4 kg CO2) is added to the menstrual cup one, both remain far below the impacts of tampons or sanitary pads coverage for one woman for one year. The 2in1 device do not add that much of the CO2 emissions, making it a perfect solution that shares the ecology aspect alongside the menstrual cup. In addition, the impact do not stop there, the device can have a negative eq kg CO2 emission because as previously announced in the Introduction chapter, this kind of solution will make women start using menstrual cup since the two major problems are solved. A quick exercise can show the potential of this impact. Assuming that (data from ref cup) :

1. The percentage of women using tampons and sanitary pads on USA is similar to Europe. thus, 42% use tampons and 62% use sanitary pads (percentages include women who said they used both). Assume that the ones that use both, use them at the same time (tampon + sanitary pad). [4]
2. Assume that in Europe, 8% of women use menstrual cups [26] [2].
3. From the women that are no-users of menstrual cups, 1/3 had already thought about start using menstrual cups. (Strong assumption).
4. From the women that already thought about using menstrual cups, 40% of them would use them if cleaning and sterilizing problems were solved.

On the table below, TAM refers to the menstruated women in Belgium ; SAM refers to the women using each of the sanitary protections ; and SOM refers to the women that would buy the tulipal device : 24% of menstrual cup users ; 40% of 1/3 of tampons and sanitary pads users.

	TAM	SAM	SOM	Without Tulipal (eq kg CO2)	WitTulipal (eq kg CO2)	Deficit (eq kg CO2)
Menstrual cup users	3210224	256818	64204	10324.0836	113202.806	102878.7226
Tampons users	3210224	1447519.19	193002.558	7382347.846	6483108.4	-899239.4485
Sanitary pads users	3210224	2006390	267518.667	15449203	13507228.8	-1941974.18
					Total	-2738334.906

FIGURE 5.7: Tulipal possible impact on CO2 emissions.

Emissions would rise a little bit due to the menstrual cup users start using the Tulipal device, but would drastically decrease (-2661 eq. tonnes CO2) due to the women starting using menstrual cups thanks to the Tulipal 2in1 device. The previous exercise, even if it's based on strong assumptions, **shows the potential positive effect that the Tulipal 2in1 device would have on global warming**. This impact would come primarily from traditional sanitary protection users shifting to a reusable and almost neutral CO2 emissions solution as the menstrual cup.

5.3 Medical

Medical devices in Europe are classified as : Class I, Class IIa, Class IIb and Class III. Class III being the one holding the highest risk for the patients. If a device falls into one of the classes, then the manufacturer is

obliged to comply with the Medical Device Directives (MDD) [6], with some explicit essential requirements [7].

5.3.1 Medical device analysis

If medical device is class I, then the manufacturer can self-certificate the product ; if the class is higher, then it needs a notified body to analyse and verify that it complies with the requirement of the given class. The verifying protocol can take up to 2 years.

It's then really important if the developed device falls into one of the classes and which one. First of all, on the MDR [6] definition (Article 2), it says that *"The following products shall also be deemed to be medical devices : [...] products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point."* where the Article 1(4) refers to *"[...] medical devices, accessories for medical devices, and products listed in Annex XVI to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as "devices"."*

The only way the device falls into the definition of medical device is that the cup is itself a medical device or is either listed on the Annex XVI. The Annex XVI is the following :

ANNEX XVI

LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

FIGURE 5.8: Annex XVI. MDR 2017/745.

Menstrual cups do not fall under none of the previous products. Menstrual cups are neither medical devices in Europe, which means that are considered to be an everyday object of consumption [5]. However, this is not the case in the USA, where menstrual cups are Class II medical device under the FDA regulations [9]. If the device was intended to be sold in the USA, another analysis should be done regarding the FDA regulations to evaluate if the 2in1 device falls into any category of medical device and if it does, make the device compliant . Since menstrual cups are neither a medical device or on Annex XVI, this means the device is not considered a medical device. The further development and production of the device should be done as if the device was a medical device, because regulations can change by new laws and policies whenever.

5.4 Business

Since the device is intended to be commercialised, it should meet some business requirements. These requirements result on the Master Thesis : *Business Plan - Tulipal* [31], which based all of its business model on the 2in1 device [8] here developed as its value proposition. Some of the requirements were already integrated through the whole R& D project, others had still to be validated and implemented :

1. **Can be sold on pharmacies.**This was a weak requirement and has not completely been taken into account, however talks have been hold with pharmacy owners and the device could be sold at theirs. Since selling in pharmacies is a complex process, the online sale has been preferred.
2. **Must look clean, simple and robust.** One of the drawbacks on the TRIAXES version was not being robust enough (a lot of play, look cheap, a lot of different pieces, water leaks...). This latter implies

6. After April 2021, a new regulation is going to be applied, the Medical Device Regulation (MDR 2017/745)
7. "The CE marking applied to a medical device guarantees that the essential requirements are met and thus that the performance, safety and benefits of the medical device have been considered proven for the circumstances of use intended by the manufacturer."
8. However, due to delays and minor details, the business plan was developed around the TRIAXES version, and not the Tulipal 2in1 device. But the business plan remains the same.

that testers stop using the device very early, and tests were used to gather feedback from a business perspective too. The short -term test have shown the appreciation from users to the present device.

3. **Price (20-30€).** The price constraint imposed in order the 2in1 device to fit in the business model has been respected (Figure 5.9).

2in1 device	Production											Post production	
Part/component or process	ABS parts	PTC heating element	Button and LED	Logic circuit	Transformer (if needed)	Connector	Power grid wire	Magnets	Silicone	Aluminium parts	O-rings	Assembly	Logistics
Price per unit	5€	4€	1€	1€	3€	1€	1€	-	2 €	1 €	1 €	2 €	1 €
Total	23€												

FIGURE 5.9: Price analysis of Tulipal 2in1 device.

The **Tulipal 2in1 device responds perfectly** to the demand that wasn't fulfilled by the current menstrual cup's complementary devices intended for cleaning or sterilizing. The solution market analysis carried on during the state of art (Figures 3.13 and 3.14) has been completed with the developed device. The following figure illustrates how the new menstrual cup sterilizing and/or cleaning solutions landscape would look like :

Type	Device	Cleaning	Sterilizing	Ease-of-use	Ergonomic	Sink dependant	Other device dependant	Ecologic
Classical solutions	Cleaning only at home (2x/day)	High	No	High	Yes	Yes	No	Yes
	Wipes	Medium	No	Medium	Yes	No	No	Medium
	Bottle of water	Medium	No	Low	No	No	No	Yes
	Pan boiling	No	Yes	Medium	No	No	Yes	Yes
Dedicated solutions	Wipes	Medium	No	High	Yes	No	No	No
	Bottle of water	Medium	No	Low	No	Yes	No	Yes
	Brushes	High	No	Medium	Yes	Yes	No	Yes
	Washers	High	No	Medium	Yes	Yes	No	No
	Sterilizer: boiler	No	No	High	No	No	No	No
	Microwave sterilizer	No	Yes	Medium	Yes	No	Yes	Yes
	Steamer	No	Yes	High	No	No	No	No
	Steamer 2.0	No	Yes	High	No	No	No	No
	UV Sterilizer	No	No	High	Yes	No	No	No
	Tulipal 2in1 device	**High**	**Yes**	**High**	**Yes**	**No**	**No**	**Yes**

FIGURE 5.10: Market vs 2in1 Tulipal device, analysis and comparison.

Chapitre 6

Conclusion

This report summarises the whole work accomplished during the past 19 months, from February 2019 (since the end of the TRIAXES course) until August 2020. The inherited work from TRIAXES (prototype idea, surveys and problematic), the time devoted, the personal and professional implication, a prototyping grant and the access to different kind of resources (coaches, experts, FabLab, BEAMS Lab...) made possible to investigate a lot of different aspects and go very deep into the R& D. The final device is no longer a fast prototyped version like the TRIAXES version was, but a solid and well developed device almost ready to take the next step. The Tulipal 2in1 device solves the sink dependence for menstrual cup cleaning and offers at the same time an integrated sterilizer.

However, the aim of this project goes beyond solving the menstrual cup problems. It's about using the solution developed to contribute to make a societal shift. A shift towards a more sustainable and resilient society. A shift towards gender equality. On one side, innovating, talking and developing business about menstrual cups creates awareness about the subject, breaking pre-existant taboos and demystifying periods. On the other side, even if the hygienic protections are not the most impactful industry contributor to global warming, every product or service should be questioned in terms of its environmental impact, and hygienic protections are not an exemption. Adapting and reinventing the traditional products and the way they're consumed is what the ecological transition is about. For the moment, this transition is perceived as an option among most of business models, but soon or late it won't be anymore. The later the sustainable and resilient approaches are taken into account, the less flexible we'll be to implement them. This project is nothing more than a tiny brick among millions of others willing to contribute to a more equal society and fighting against the biggest challenge of our era : global warming.

Through the 19 months (or even 23 if counted from the TRIAXES start), there's been a rise of new patents and available solutions related to menstrual cups. This latter is not a bad sign for the project, it shows the potential and the need for a good solution. As announced, I am aware that the device is not far from been accomplished and some challenges are yet to be solved ; but once the fully functional device is ready and the feedbacks from the long-term tests are implemented, a new R& D phase will begin : pre-industrialisation. This phase will be characterized on adapting the functional solution to an industrial process (production, logistics, assembly...), and by numerous user tests to further optimize minor details.

The place allocated to the non technical part was small compared to the others, however, the work done on these areas has gone far beyond of what's been presented. This report and its associated work (design and develop of a cleaner and sterilizer device) are only one part of a bigger and more ambitious project : **Tulipal**. Tulipal is the result of several months of work on different areas : marketing, business, design, legal, administrative and technical aspects, with the ultimate goal of creating a business around the developed device. The better all the previous aspects are built together, the better the market will respond to the arrival of this new product, and the bigger the impact on the previous mentioned societal objectives will be.

In conclusion this work has allowed to develop one of the two keys in order the Tulipal project to succeed : the 2in1 device that solves the repeatedly problems for users and non users. The other important key, the business plan, is already developed [31]. The destination might be still a bit far away but the journey looks to be exciting.

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Chapitre 7

Appendix

A Prototypes description

The following figure shows a comparison between the different main prototypes developed sizes.

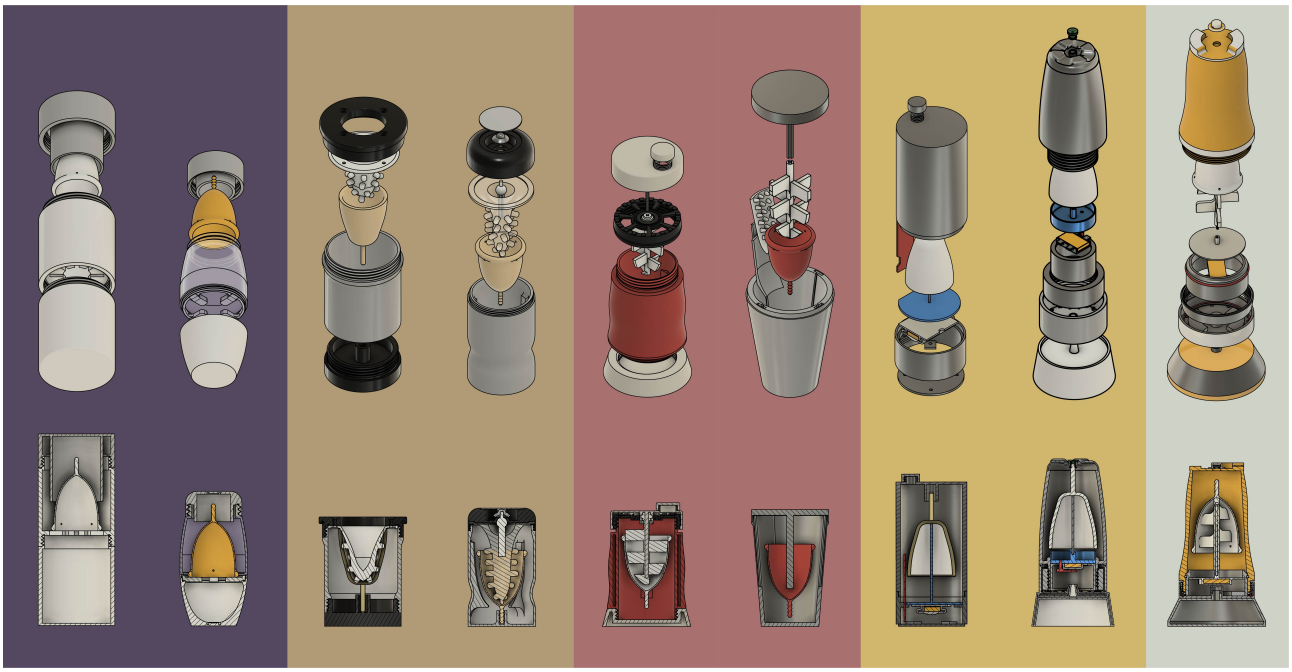

FIGURE 7.1: Family prototype.

Tulipal 2in1 device

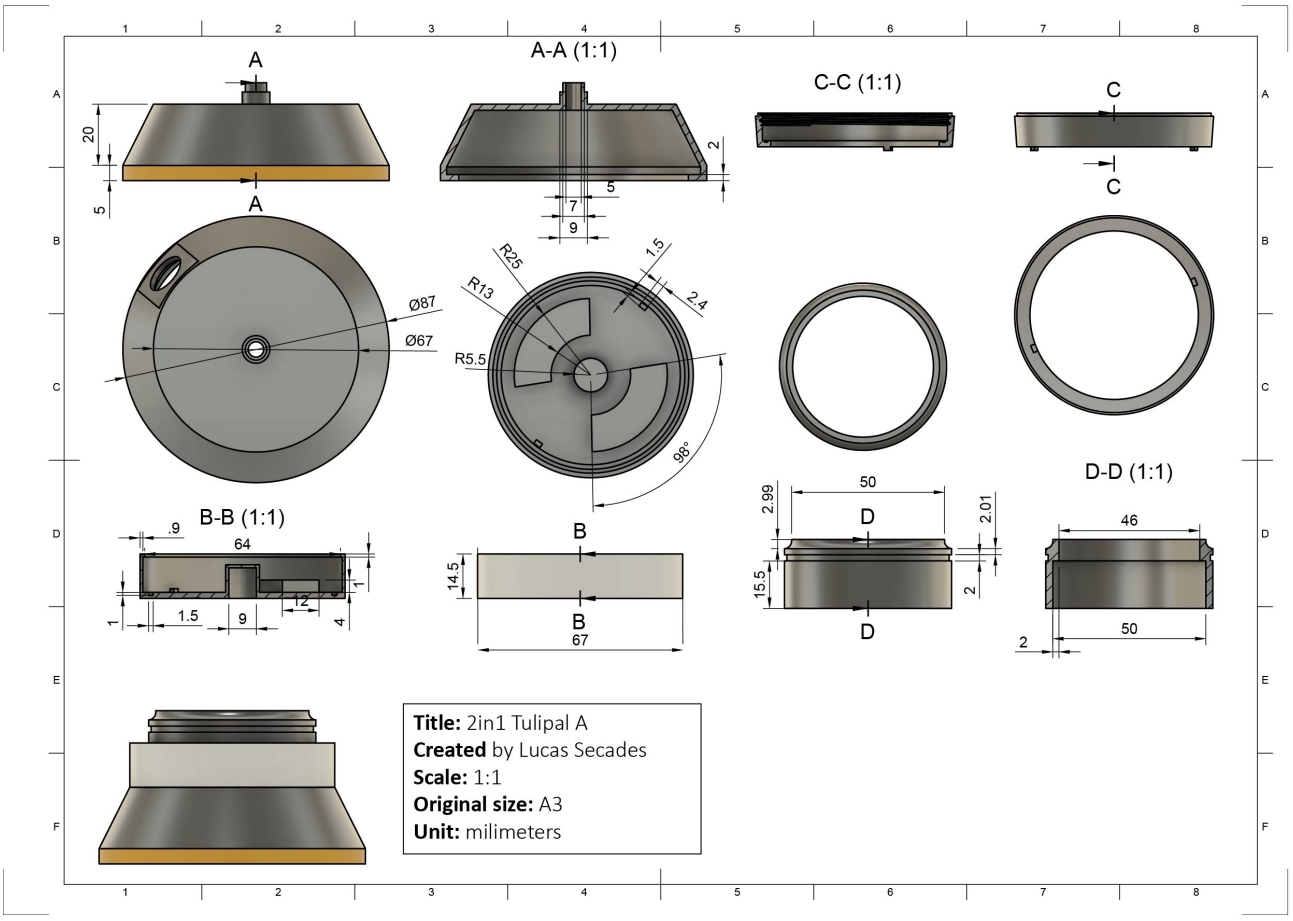

FIGURE 7.2: Tulipal 2in1 device plan A.

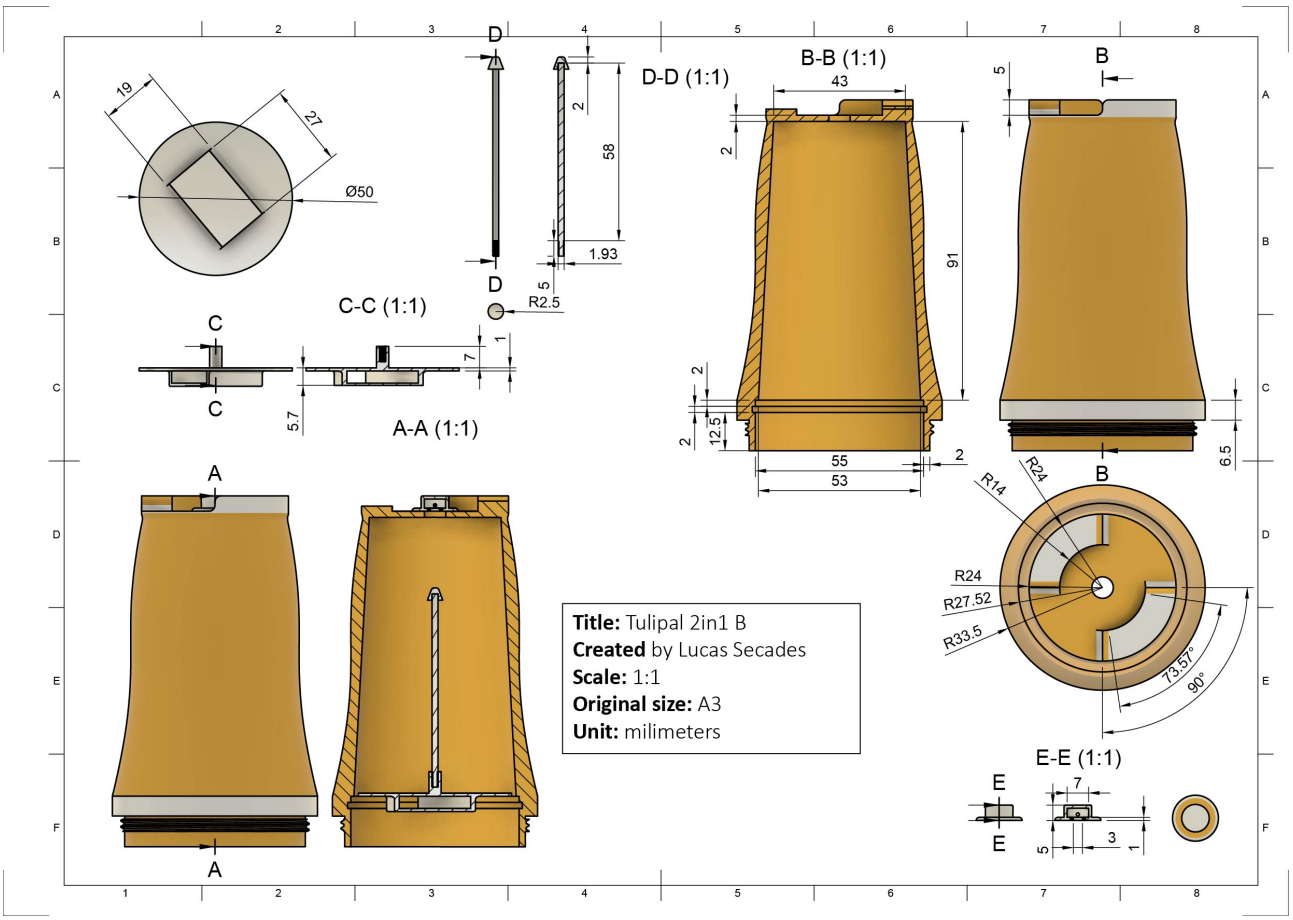

FIGURE 7.3: Tulipal 2in1 device plan B.

Shaker cleaner

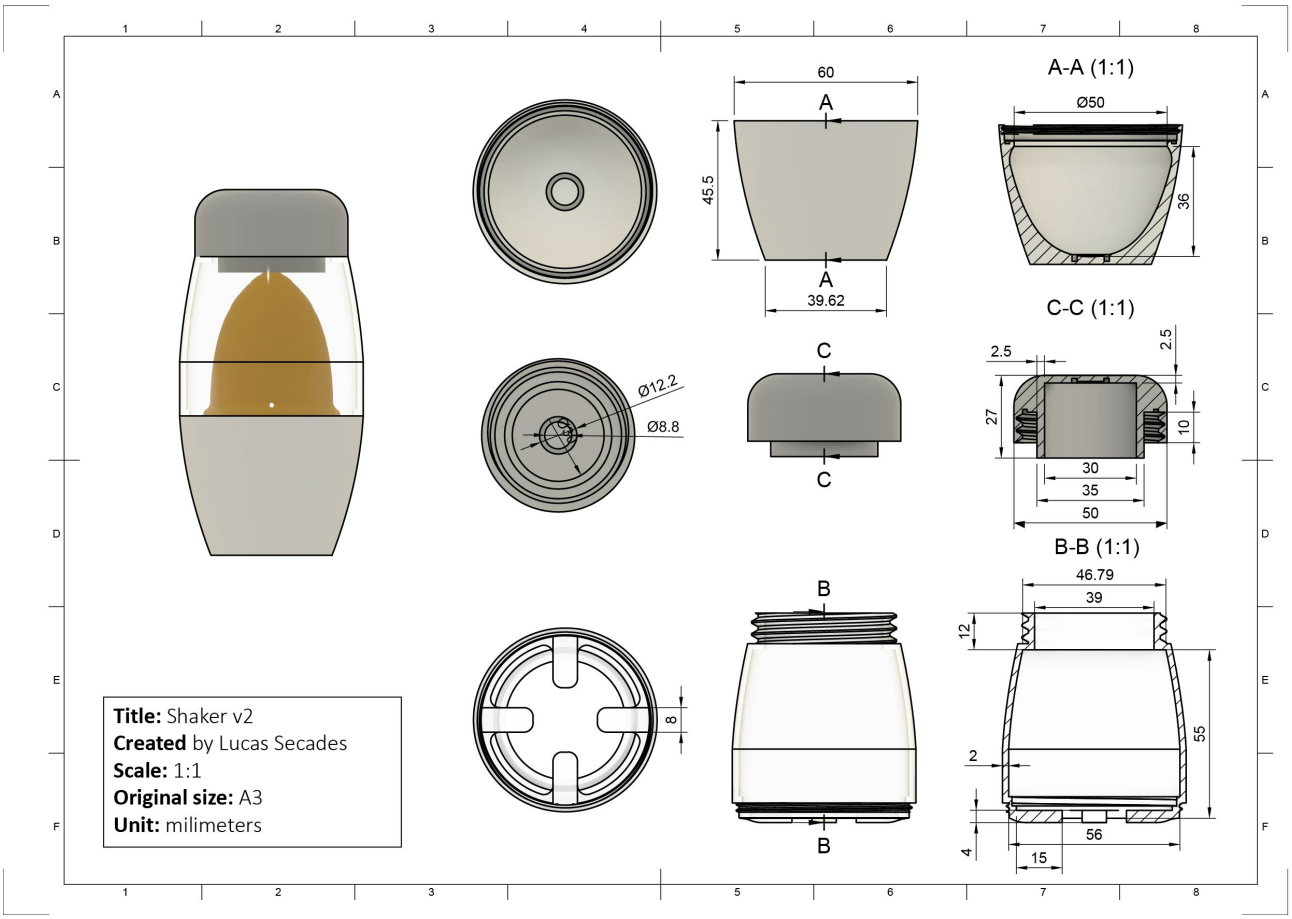

FIGURE 7.4: Shaker v2 plan.

Membrane cleaner

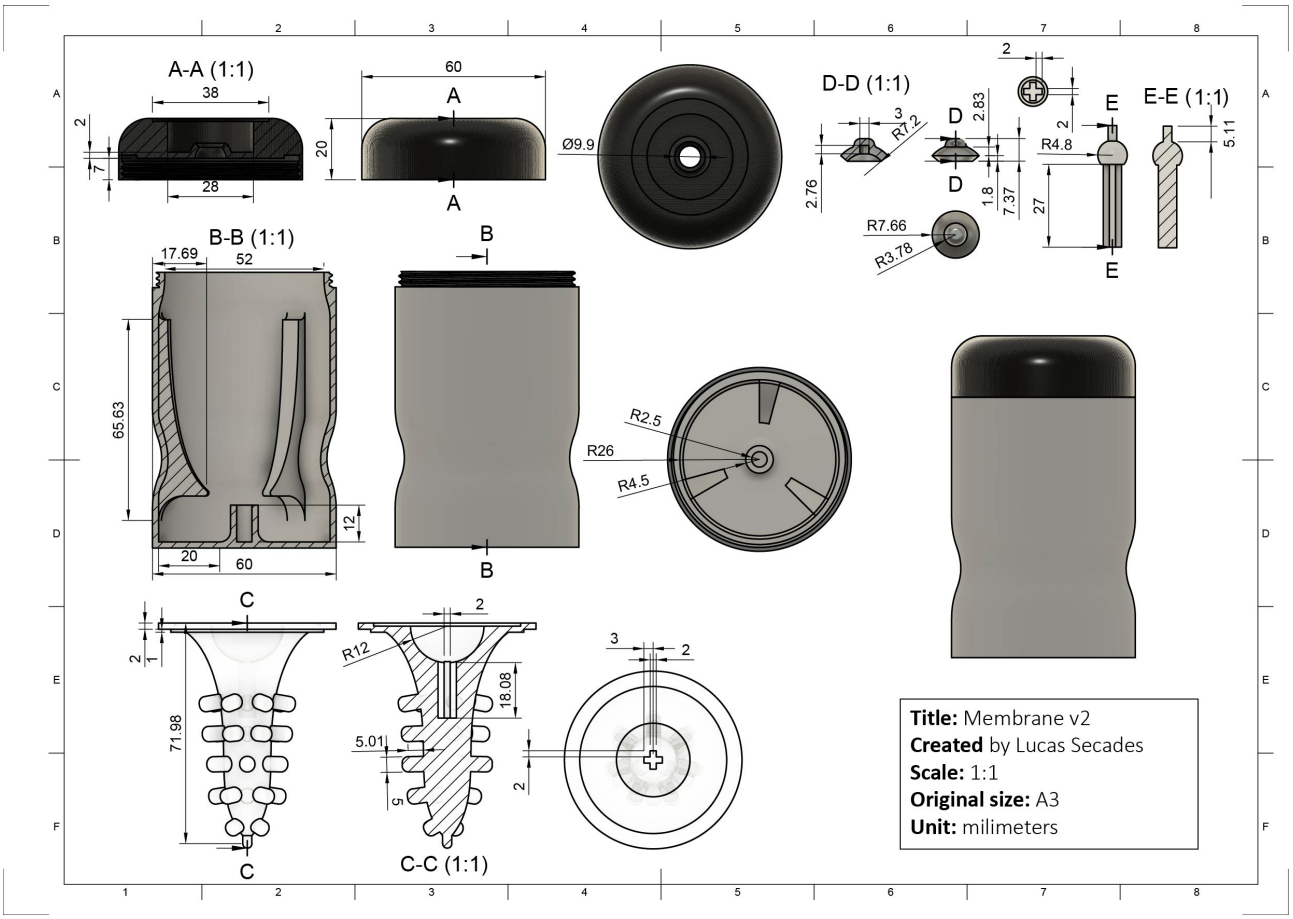

FIGURE 7.5: Membrane cleaner v2.

A.1 Dimensions optimization

Each of the parts from each prototype have been presented without explaining their development. Each of them are the result of a small R&D iteration. For the sake of clarity only two examples are going to be explained in order to give an overall view of this kind of design iteration. The first example is a parametric study on the dimensions to achieve a perfect play between the inner and outer cap from the 2in1 Tulipal device ; the second example concerns the shaft and joystick development from the membrane cleaner v2.

Lower cap. 2in1 Tulipal device.

- **Goal :** Achieve perfect play allowing to have a smooth feeling when rotating but not too much play so that the inner cap does not move.
- **Methodology :** Vary some of the dimensions and print different parts. Check the feeling and choose the best one.

The following figure shows the different dimensions that influence the play between the two parts.

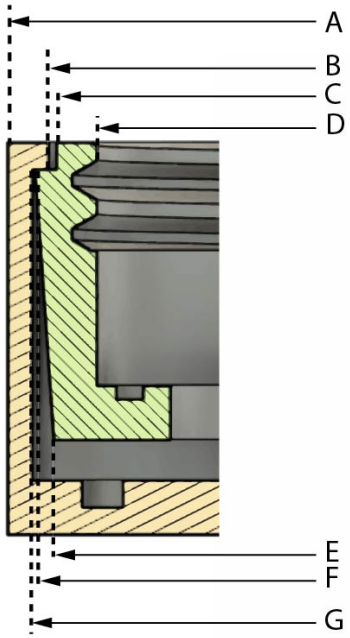

FIGURE 7.6: Cap different parametric dimensions.

6 iterations were needed in order to find a good combination, Figure 7.6 shows the different prototype's dimensions. Between the first three and the last three, an overall optimization was made to minimize the cap volume.

	Radius (length in mm)					
Dimension	v1.1	v1.2	v1.3	v2.1	v2.2	v2.3
A	37	37	37	33.5	33.5	33.5
B	35.2	35.2	35.2	31.5	31.8	32
C	35	35.1	35.15	31.5	31.7	31.9
D	32	32	32	30	30	30
E	34.5	34.58	34.68	31	31	31
F	35.5	35.9	35.95	32.5	32.5	32.5
G	36	36	36	32.5	32.6	32.6

FIGURE 7.7: Inner and outer cap prototype.

Joystick. Cleaner membrane v2.

In this case, the iteration did not concerned the dimensions but the design of an specific part, the joystick mechanism. Even if they look pretty close, they have major conceptual differences.

— **Goal :** Achieve smooth motion with low friction joystick based mechanism.

— **Methodology :** R&D fast iteration process.

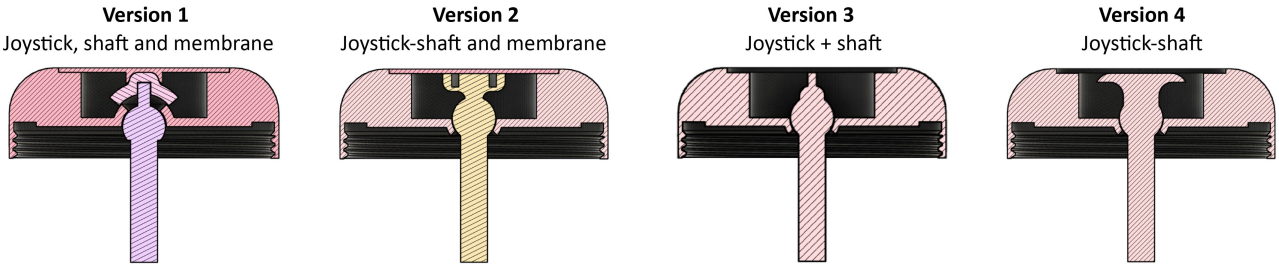

FIGURE 7.8: Joystick iteration.

The iteration of the conceptual designs and prototypes went as follows :

1. **First version.** It had a separate joystick and shaft that were assembled to allow motion transmission. In addition a membrane was added on the top intended to hide the mechanism.
   Problems : There were too much friction between the joystick part and the cap.
2. **Second version.** The friction was much lower between the shaft and the cap than between the cap and the joystick. Thus the mechanism was inverted and the friction was much lower. This latter also allowed to merge the shaft and the joystick. In addition, place was created for inserting a magnet.
   Problems : Still to much friction due to the outer membrane not being flexible enough.
3. **Third version.** This version has the membrane removed and the joystick top part was transformed into a rod that serves as a true-joystick controller adapter.
   Problems : It worked fine but it was too big and fragile.
4. **Fourth version.** The joystick was implemented on the part itself and the rod became thicker to increase resistance.

A.2 3D pieces printed

A total of 181 parts have been 3D printed trough the whole R&D process :

— **Materials.** Among them, 85% have been printed in generic PLA, 10% in ABS and 5% in other materials like : PETG, PC or transparent PLA.

— **3D printers.** Most of them have been printed using the Prusa MK3S (98%) with or without enclosure. Several Prusa printers were available at the BEAMS (2 Prusa MK3S) and at the FabLab of the ULB (7 Prusa MK3S and 1 Prusa Mini). The other 2% of the parts were printed on an Ultimaker 2+ and the EDEN 260V (SLS printer).

— **Devices.** The distribution of the different parts printed regarding the device they were printed for is the following :

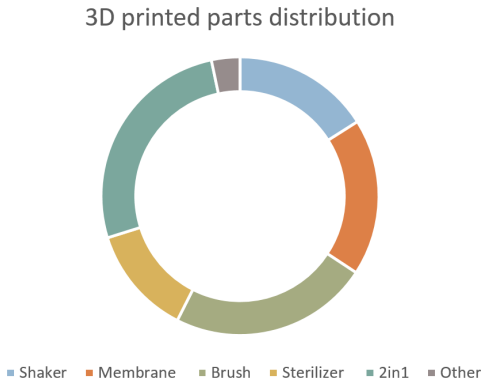

FIGURE 7.9: 3D printed parts distribution.

B Material choice

In this section we are going to discuss the different materials used for each part of the prototype :

1. **Body parts.** These are the main parts of all of the prototypes and include : bodies, caps, shafts, structures...
2. **Brushes.** For the cleaners two of them need brushes : inner, outer and membrane brushes.
3. **Other.** They include minor parts where material choice was not that important.

Body parts

Regarding the material different constraints exist with different level of awareness. First of all the material have its technical constraints, and then the business related ones. Those are the following :

Material Body		
Description	Type	Value
Material	Production	Avaiability and 3D printer performances
Flexibility	Technical	E > 2000 Mpa
Working temperature	Technical	90-150°C
Cost	User	<70€/kg (3D printing)
Wet environement resistance	Technical	<1% water absorption
Recyclability	Business	-
Density	User	< 5g/cm3

FIGURE 7.10: Body parts' material needs.

In order to evaluate the working temperatures of a material, we must relate somehow some thermal properties to mechanical behaviour. Opposite to what we could think, the melting point does not give us directly the temperature working range. Before reaching the melting point, two other caracteristic temperatures are reached : the heat deflection temperature (Th) and the glass transition temperature (Tg). Those are the easiest way to identify the temperature working range of a material and how it withstand heat.The heat deflection temperature is the temperature at which the material will start to deform under a specified load (given in the specifications sheets of a material, in the table below the load taken is 1.8MPa). In a practical sense, it is a guideline for how hot the material can get before it becomes too weak to be usable. In the other hand, the glass transition temperature (Tg) is the point where the material begins to loose the ability to hold it's shape. Which means that below the glass transition temperature, the material will be rigid and brittle. If you bend it slightly, it will return to it's original shape. Above the glass transition temperature, the material will become progressively more soft and rubbery. If you bend it the deformation will be permanent. Since the highest temperatures are reached through the sterilization process where no load is applied to the device (other than it's own gravity and the inner pressure), the property that will dictate the usability of the material during the sterilization process is the glass transition temperature.

Regarding the flexibility, it's important that the material do not bend easily because keeping the inside seal is an important characteristic the device should maintain in both uses : mechanical cleaning and sterilisation. The young modulus(E) gives us an information of how the material resists to deformation.

The material cost is important. The material chosen should remain affordable because on one hand it intends to be industrialised, and in the other hand the prototyping process must not be very expensive. Materials on the form of filaments are more expensive that on the raw form. For example polycarbonate can be found around 3€/kg on the raw form, which is much lower than its 80€/kg for 3D printing.

The wet environment on which our device will be used and stored is a wet environment. Users will mostly leave it on the bathroom. In addition, the cleaning needs water to be performed and the sterilisation steam. The material should have low water absortion (Wa) value.

Since the device will be carried the whole day on the user bag, we must look after the weigh, so density must be also checked.

Most of the 3D printers are not adapted to print all the 3D materials (metals, plastics...). Even inside

a group, for example 3D plastic materials, the printer should be able to heat up to certain temperatures to be able to print within a specific material. The temperature is called extrusion printer temperature (Tp).

Finally, recyclable can be an important aspect to take into account.

The following analysis will be focused on plastic materials because metals such aluminium are very hard to prototype. The 2 different ways have their own drawbacks :

1. 3D printing : 3D metal printers are very expensive to use.
2. Machining : Need strong technical skills.

Metal can be an option since in the industrialisation process is affordable and in addition it matches well most of the needs (cf. table above). For this first phase of prototypying, we are going to focus on using plastic materials. The following have been studied :

Material	Th(°C) 1.8Mpa	Tg (°C)	Tp (°C)	E (MPa)	Cost (€/kg)	Wa (%) 24h	Rec.	Rho (g/cm3)
Polyether ether ketone (PEEK)	156	143	450	4100	600	0,45	?	1,3
Polyetherimide (Ultem/PEI)	195	215	380	3500	280	0,19	?	1,27
Polycarbonate (PC)	140	155	290	2410	80	0,35	?	1,20
Polyamide (Nylon)	80	52	255	5000	33	1-5	?	1,13
Polyamide glass reinforced (Nylon 6.6 20%)	220	66,3	260	5400	64	1-5	?	1,3
Polycarbonate-ABS	100	120	280	1900	80	0.7	?	1.13
Polypropylene PP reinforced 30%	120	-20 ?	250	6500	128	0.1	?	1.2
Acrylonitrile Butadiene Styrene (ABS)	98	105	230	2030	25	0.6	?	1.07
Polyethylene Terephthalate (PET)	70	76	240	/	/	/	?	/
Polysulfone	174	190	330	2500	150	0.2	?	1.25
Polylactic acid (PLA)	56	60-65	205	3500	25	2.2	?	1.24

FIGURE 7.11: Body parts' material market comparison.

The materials chosen are BAS and PLA since they are much more affordable and easier to print. ABS tests showed that it resist on the sterilizer heating environment ; and PLA allowed fast printing processes.

B.1 Brushes

There are different types of polymers that can be used. Menstrual cups are either in TPE or in Silicone (Platinium) for medical devices purposes. Using the same material as the menstrual cups prevents erosion and ensures longevity. Regarding the different TPE and silicone available, the choice was mainly driven by the ease of prototyping associated to the material. This latter depends strongly on the molding prototype technique chosen and the mix ratio [1](for silicone).

Material	Mixed viscosity	Pot life	Cure time	Mix ratio	Hardness	Avaiable without purchasing
TPE	Not easy to prototype					No
Ecoflex 00-50	8000 cps	18 min	3 hrs	1A:1B	00-50 (under A class)	Yes
Dragon Skin 10 very fast	23000 cps	4 min	30 mins	1A:1B	10A	Yes
Sorta Clear 12	6000 cps	40 min	12 hrs	1A:1B	12A	Yes
Sorta Clear 40	35000 cps	60 min	16 hrs	100A:10B	40A	No

FIGURE 7.12: Brushes materials comparison.

1. Silicone are made by mixing two different liquids, A and B. The silicone mix composition is determined by the quantity of A and B, defined in terms of mix ratio by volume or by mass.

Prototyping inner and outer brushes had different needs. On one hand, moulds for inner brushes were too complex, so low viscosity and high pot life were needed in order to let all the mix flow inside the mould. In the other hand, this constraint was non-existent for outter brushes moulds, thus a fast silicone was preferable to accelerate the parametric study (a lot of brushes were prototyped). Finally, since menstrual cups have a hardness of 40 A, silicone with high hardness were preferable. The Sorta Clear 12 for inner brushes, and the Dragon skin 10 very fast, for the outer brushes, were chosen for the prototyping phase.

B.2 Other

— **Sealings** are made of o-rings because they are available on different sizes and profiles, thus it was easier to prototype.

— Aluminium has been chosen as the material for the sterilizer's **metal plate**. This latter is light-weight, resistant to corrosion, recyclable and easy to prototype using CNC machinery.

C Fabrication & production process

In order to create the functional prototypes from the 3D models on chapter 4. First only the first production phase on Figure 7.1 has been used because the prototype volume (in number of units) was not enough to need to enter on higher phases. However all the others were investigated and analyzed.

For the R&D phase, different fabrication, production processes and methodologies of the prototypes have been used :

1. **3D printing.** For each prototype or component a different 3D printing approach has been followed. Depending on the urgency, quality or material chosen to print, different techniques and printers have been used.
2. **Silicone moulding.** Since a lot of brushes (inner and outer) have been prototyped, the silicone moulding has been an important part of the R&D. Depending on the type of brush, different techniques have been used.
3. **Aluminium machining.** Here the aluminium machining through a CNC machine was used.
4. **Static sealing.** In order to properly test the prototypes, static sealing had to be understood and implemented in the different parts.

C.1 Production phases

There exist different ways of prototype's production : injection moulding or 3D printing. In each of them there are different methods like FDM, SLA or SLS 3D printers, which have different advantages and drawbacks. Again in injection moulding there exist : aluminium, steel or resin moulding. For all of these methods, there's a trade-of to make between materials used, money invested, price per unit, time production, quality and quantity.

Phase	Quantity	Technology	Material	Price set up process	Price per unit	Price per unit (all included)	Time	Quality
Prototyping	0-10 units	3D printing. FDM printing	PLA	Free. 3D printer available	6 €	6 €	1 day / unit / 3D printer	LOW
Proof of business	10-50 units	3D printing. FDM printing	Filament materials	Free. But need to invest in post processing process.	8 €	8 €	2 days / unit / 3D printer	MEDIUM
	50-200 units	3D printing. SLA/SLS printing.	Resins or filamnet maerials	2-5k€ for SLS 3D printer	14 €	25 €	2-3 days / unit / 3D printer	HIGH
Proof of business	100-500 units	Silicone mould.	Different type of ressins	Silicone mould fabrication: 500-1k€	15 €	17.50 €	4 weeks: 1 week for the BE, 2 weeks production and 1 week delivering	HIGH
Industrialisation	>10-20k€	Steel mould.	Plastics	Bureau d'etudes et industrie: 10-15k€. Creation de moules: 30-40k€/par moule	4 €	4€ (for an avergae 100k units)	5 months: Devis (1 week), study of 3D model (1 week), re-modelling of the 3D model to adapt it to the industrialisation phase (1 month), Find industry and partnership (1 month) Mould iteration (2 months) Finishing, production and delivery (1 month)	VERY HIGH

FIGURE 7.13: Phase production methods.

1. **Prototyping.** During this phase what is important is to fast iterate and produce at low price. High quantities or high quality are not mandatory. Thus 3D printing FDM [2] technology works pretty well.
2. **Proof of business.** For this phase higher quality is required because users are going to use the devices and more units are needed, thus higher production volume. There exist two options. The first one is to keep using the FDM printing technology but with different materials that allow post-processing thus giving smoothest definition (higher visual quality) or use multi material 3D printers that allow to have soluble supports to print more complex parts. The second one is to print with SLS or SLA [3] printers that allow a much higher quality but price would be much higher.
3. **First sales.** For this phase much bigger quantities are needed but still lower than 1k units. Cheap injection method like resin moulding is used. This latter use SLS and SLA printers to create high quality parts which are used to create the silicon moulds. Then different materials can be poured on it to create high quality parts.
4. **Industrialisation.** This phase demands industrial quantities, thus the only solution and widely used is the plastic injection on steel or aluminium moulds. These moulds last longer and are created by machining processes.

2. FDM stands for fused deposition modelling, and is an additive manufacturing technique where layers of melted plastic are deposited to create prototypes.

3. SLS stands for Selective laser sintering and SLA for stereolithography. They use laser (SLS) and photochemical (SLA) as power to create a solid structure by binding points in space defined by a 3D model.

C.2 3D printing

In this section the different techniques for 3D printing are presented. First of all, the way different pieces were prototyped was the following :

1. **Sketch.** The part is conceptualised and dimensions are sketched on paper.
2. **3D model.** A 3D model is created using a CAD software. In this case the one used is *Fusion 360*.
3. **Easy-print** The part is printed using a PRUSA MK3S printer or a Ultimaker 2 and with PLA (easiest to use 3D filament). This allows to fast-prototyping since no post processing is needed (in contrast to the EDEN 260 V printer) and PLA do not need high performance printers.
4. **More complex-print if needed.** If the part works as expected and no bugs are detected, then the part is printed using ABS (if temperature resistance is needed) or VeroClear (using the EDEN 260V printer if precision is needed).

The PLA parts were printed using a Prusa MK3S. It's a very easy-to-use 3D printer and a lot of different tutorials are available which allows fast learning and debugging. The drawback of this printer is that it needs weekely maintenance because some errors appear on this 3D printer during the project. The most common ones being successfully repaired/solved are :

— Wrong calibration. Do a re-calibration.

— First layer calibration error. Manual and visual calibration. Playing with the sensor heigth and the bed.

— Fan error. It has been replaced.

— Hotend is blocked. Heat it to let all the blocked filament flow, or dismantle it.

The ABS parts were also printed using a Prusa MK3S, but this latter has been upgraded and a close enclosure has been built. ABS demands higher performances from the 3D printer (hotend T°260°C and bed T°110°C) compared to PLA (hotend T°210°C and bed T°60°C). For avoiding common errors on ABS printing the enclosure is needed because otherwise the environment is not hot enough and delamination and wrapping might appeared. The enclosure has been successfully built and the ABS parts were printed perfectly. Final result :

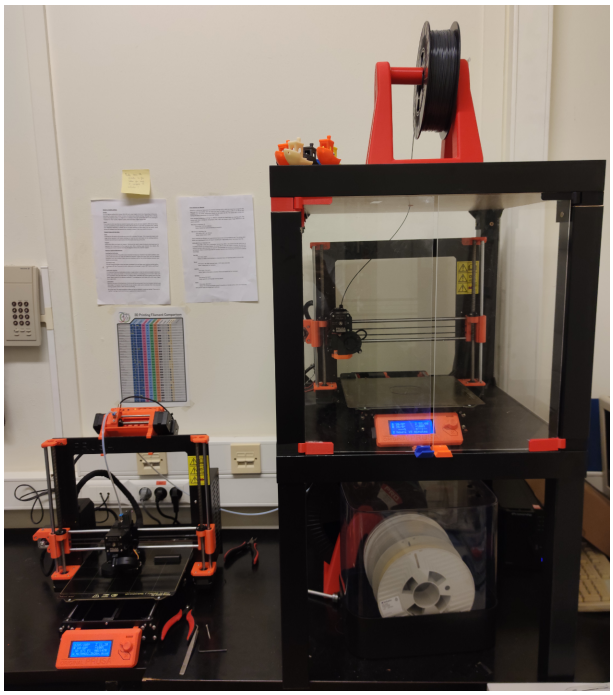

FIGURE 7.14: 3D printing setup : 1 PRUSA MK3S multi-material (left) and 1 PRUSA MK3S with an enclosure (right).

C.3 Silicone moulding

The silicone moulding is a technique that consist on creating a 3D mould (PLA works fine and is precise enough) and then pouring the silicone solution inside. If the mould has been properly designed then the poured silicone would take the place counter-shape of the mould.

Inner brushes

The mould parts should have different characteristics :

1. A container on the top side, where the the silicone liquid is poured.
2. A channel trough which the silicone will enter the mould.
3. Small pipe(s) through which the air inside can scape. This (these) pipe(s) should start from the bottom of the mould. Depending on the geometry or the complexity, one or several will be needed. The height of these pipes should be higher that the part to be moulded, so when hydrostatic equilibrium reached, the silicone will stop at the right place.
4. Place to screws, so that the different parts of the mould can be fixed together.
5. If one part is too complex to be printed with the Prusa MK3S, then divided it in different parts. Also different parts are needed to take out the brush when it's solidified.

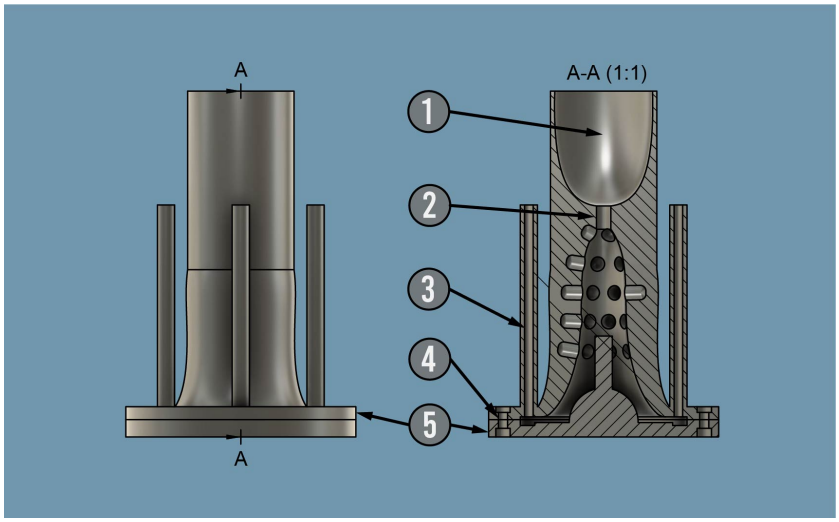

FIGURE 7.15: Different characteristics of a inner brush mould.

Process for the 3D model creation :

1. Create the part that one want to be the result of the moulding process, in this case the brush.
2. Create the mould by subtracting to a solid cube or cylinder the previous part.
3. Divide it in the number of pieces needed, to allow being printed.
4. Add the upper container and air pipes.

Once the mould parts are printed, the process for moulding is :

1. Assemble the different printed components to create the mould.
2. Compute the original part volume, and add a 25% safe margin (air pipes) to calculate the silicone volume's needed.
3. Mix the silicone following the manufacturer instructions and pour it.
4. Shake the mould to make the silicone better flowing.
5. Wait until the cure time is reached, open the mould, cut the silicone from the air pipes and the upper channel.

Here are two different examples, for the membrane brush one (2 pieces needed and pouring from the bottom of the brush) and for the brush cleaner inner brush (3 pieces needed and pouring from the top of the brush).

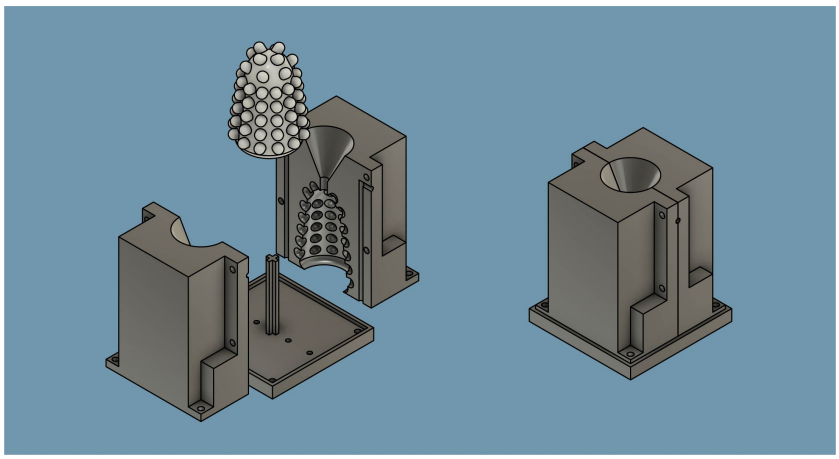

FIGURE 7.16: Brush cleaner inner brush mould.

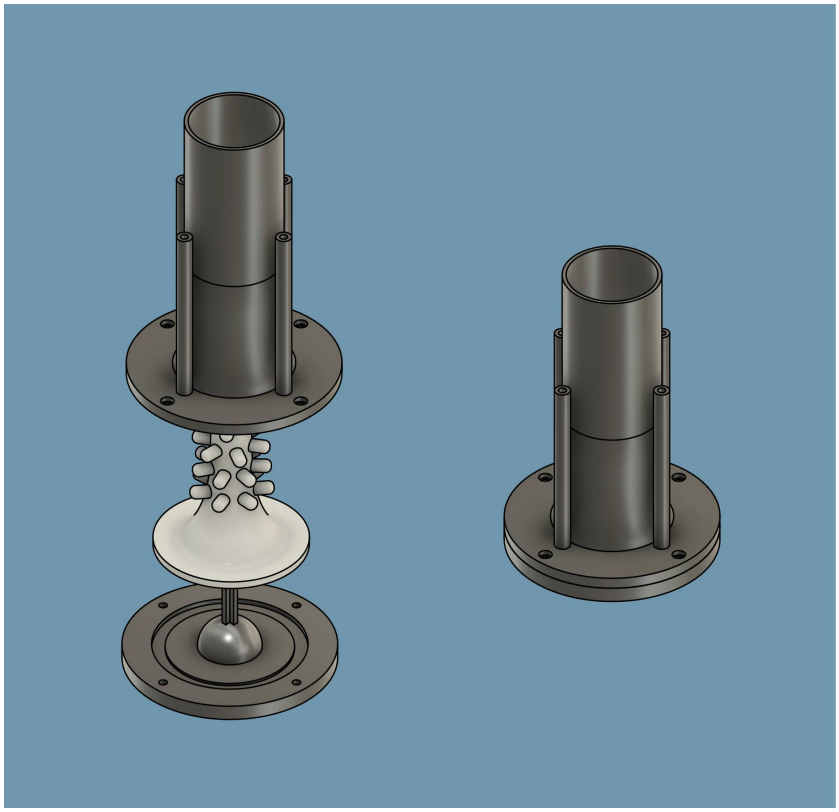

FIGURE 7.17: Membrane brush mould.

Outer brushes

The outer brushes are prototyped differently. Since the curvature radius is very high, the brushes can be approximate to being flat, thus the geometry is very simple : a flat plate with different kind of extrusions. Thereby, moulds can be directly prototyped as :

— A flat surface with intrusions.

— Each of the intrusions have a small air pipe to allow air from escaping

The process for moulding is :

1. Put the printed part in height. Either using small legs or an interchangeable printed part (Figure 7.18).
2. Mix the silicone following the manufacturer instructions and pour it.
3. Wait until the cure time is reached, and take the surface out.
4. Cut the moulded bed within the outer brush shape.

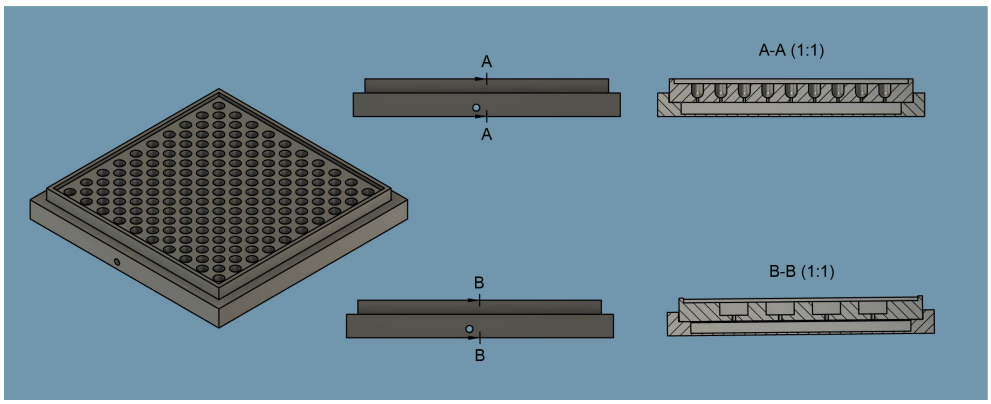

FIGURE 7.18: Brush cleaner outer brush mould. Two different patterns.

C.4 Aluminium machining

The CNC machining was used to prototype the sterilizer base and other components. For the sake of simplicity only one example will be presented here.

CNC machining has 3 main steps :

1. **CAD.** Computer-aided design which is the same as 3D modelling.
2. **CAM.** Computer-aided manufacturing which consist on creating the manufacturing process with a dedicated software using the CAD model.
3. **CNC machine calibration and preparation.** Once the .nc code from the CAM is created, the CNC must be prepared, calibrated and the metal raw piece, which is going to be manufactured, installed.

CAD

As said before, this step is the same as the one for 3D modelling. The same software can be used, and the final piece that one wants to manufacture must be modelized. In this case it's a 60mm diameter aluminium plate of 2mm high, with 4 3mm holes.

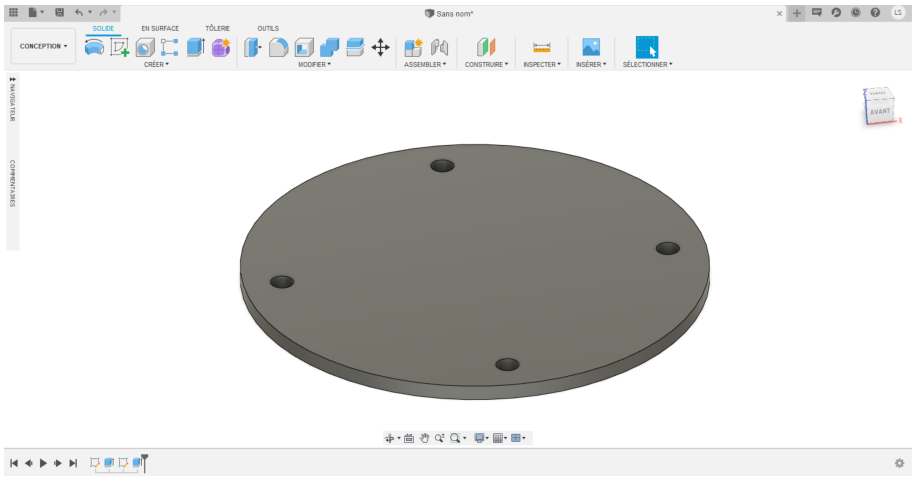

FIGURE 7.19: CAD step.

CAM

From the previous 3D part, a CAM is going to be created. First of all, the different manufacturing operations must be identified. Since it's a very simple part, only two are needed : drilling and outline milling. The right tool must be selected on the CAM software, in this case it's a 8mm flat aluminium fuse. These are the CAM steps :

1. Create the block from which the part will be manufactured. In this case a 60x60mm aluminium plate. The bigger this part, the more waste will be.

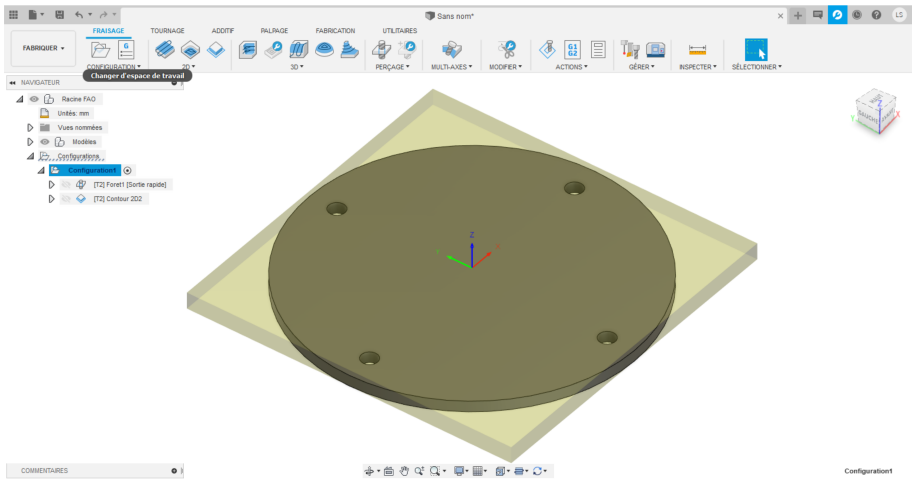

FIGURE 7.20: CAM first step : original part.

2. For the drilling, the holes are chosen and the operation will automatically be created.

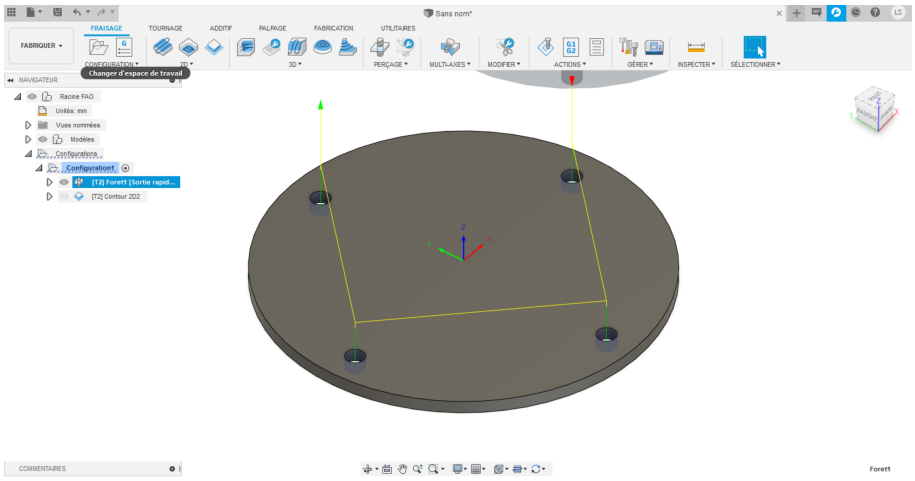

FIGURE 7.21: CAM second step : drilling.

3. For the outline milling, the bottom outline from the cylinder is chosen. One can either choose to do it on one pass or multiple passes. Multiple passes are preferred even if it takes more time to avoid damaging the mechanism and the fuse.

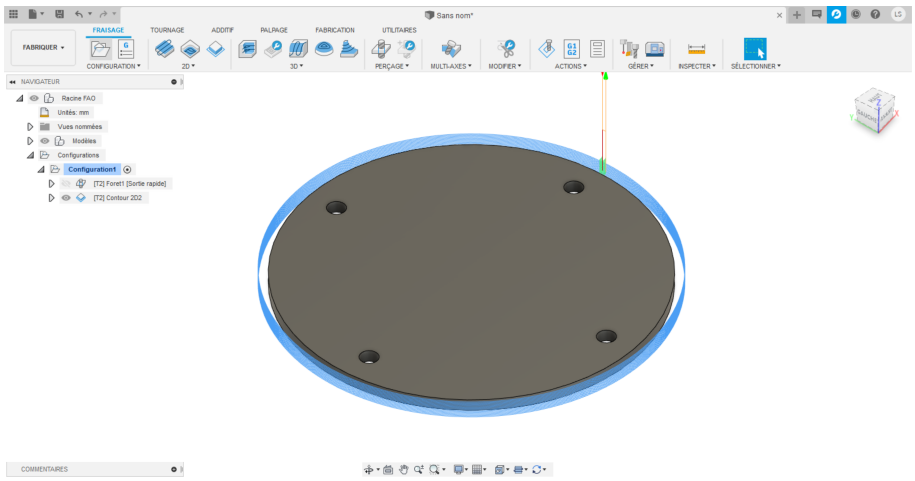

FIGURE 7.22: CAM third step : outline milling.

CAM

Once the .nc file is exported for the CNC machine (RS-274D driver), the CNC must be prepared.

1. First, the part should be attached to the CNC plate and the CNC should be calibrated as its orgine coincides with the origine of the CAM file.
2. Now the .nc file can be run. The following figures shows a simulation using the CAM software of what the CNC will do :

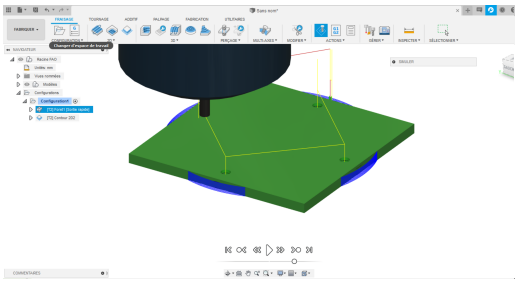

FIGURE 7.23: Holes drilling.

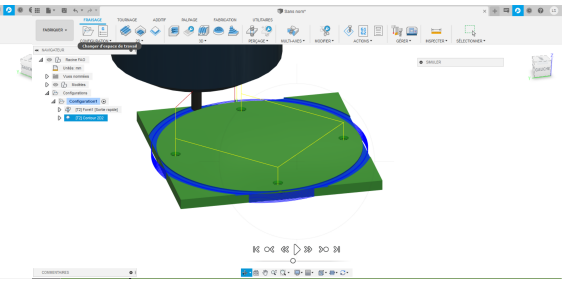

FIGURE 7.24: Outline milling.

The part, once manufactured, will look as in Figure 7.25. Only the corners are wasted.

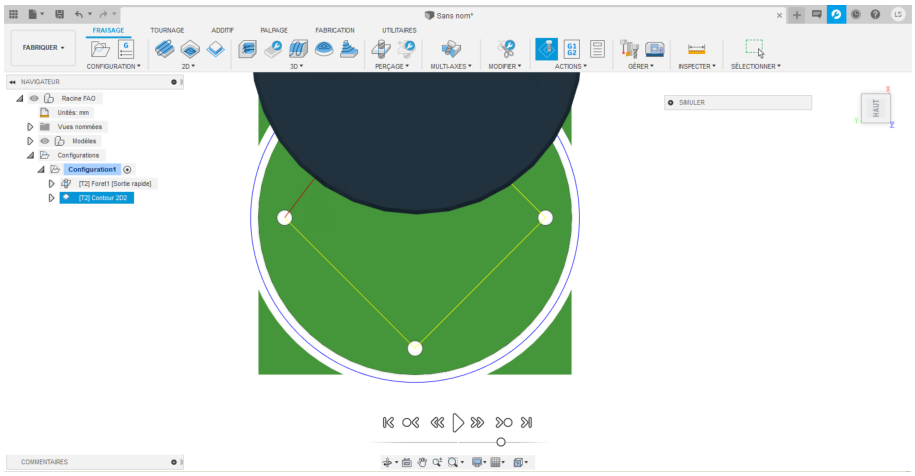

FIGURE 7.25: Finished part.

D Prototype codes

D.1 Arduino

This arduino code is the one used for the first kind of sterilizers **boiler v0**.

— **Input :**It gets the water temperature on the boiler. *PIN 2*

— **Output :** It creates a regulation around 95°C by controlling the heating element trough a relay. *PIN 5*

```
#include <OneWire.h>
#include <DallasTemperature.h>

#define ONE_WIRE_BUS 2

OneWire oneWire(ONE_WIRE_BUS);

DallasTemperature sensors(&oneWire);

 float Celcius=0;
 float Fahrenheit=0;
 float temp;
 float power;
 int timing=0;
void setup(void)
{
 pinMode(5, OUTPUT);
  Serial.begin(9600);
  sensors.begin();
  digitalWrite(5, HIGH);
}

void loop(void)
{
  sensors.requestTemperatures();
   delay(1000);
   timing+=1;
  temp=sensors.getTempCByIndex(0);
  if (temp>95){
    digitalWrite(5, LOW);
    power=0;
  }
  else{
    digitalWrite(5, HIGH);
    power=1;
  }
  Celcius=temp;
  Fahrenheit=sensors.toFahrenheit(Celcius);
  Serial.print(Celcius);
  Serial.print(" ");
  Serial.println(timing);


}
```

FIGURE 7.26: Arduino boiler code.

This arduino code is the one used for the last version on the 2in1 Tulipal device. It's the code needed to create the user interface described on the UX diagram of Figure 4.55.

```
int inPin = 6;   // choose the input pin (for a pushbutton)
int resPin = 10; // pin for the heating resistor
int val = 0;
int compteur = 0;
int button = 0;
boolean push = false;

void setup(void) {
  Serial.begin(9600);
  pinMode(inPin, INPUT);
  pinMode(resPin, OUTPUT);
}

void loop(void){
  val = digitalRead(inPin);
  if (val == HIGH) {          // check if the input is HIGH (button released)
    delay(100);
    if (button==0){
      digitalWrite(resPin, true);
      button = 1;
    }
    else if (button==1){
      digitalWrite(resPin, false);
      button = 0;
    }
  compteur = 0;
  }
  delay(100);
}
```

FIGURE 7.27: Arduino code of the Tulipal 2in1 device.

E Problem analysis

E.1 Data analysis

Menstrual cup

This matlab code refers to the data processing of menstrual cups dimensions.

— **Input :** A database of 180 different menstrual cups. For each of them, popularity, provenance, size and dimensions were given.

— **Output :** The average dimensions for 3 menstrual cups' sizes (S,M,L) based on provenance and popularity.

```
clc;
clear all;
close all;

%%
%Data from:https://menstrualcupreviews.net/comparison/
%Data to complete: https://putacupinit.com/metricchart/
opts = detectImportOptions('database_cup.xlsx');
preview('database_cup.xlsx',opts);
D = readmatrix('database_cup.xlsx','Range','D:I');
E = readmatrix('database_cup.xlsx','Range','J:K','OutputType','char');
A = readmatrix('database_cup.xlsx','Range','A:C','OutputType','char');

%D for dimensions where for the columns:
% 1) Diameter ; 2) Total length ; 3) Body length ; 4) Stem length ;
% 5)Capacity to holes ; 6) Total capacity

%E for: 1) Provenance 2) Popularity

%A for: 1) Brand ; 2) Type ; 3) Size

data_formats = '%C%C%C%f%f%f%f%f%f%C%C%f';
C = readtable('database_cup.csv','Format',data_formats);
figure()
h1 = histogram(C.Size,{'XS','S','M','L','XL'});
title('All of the cups on the market by size');
xlabel('Size');
ylabel('Number of cups from different brands');

%% Cups avec tige normale
figure()
k1=0;
for k = 1:length(C.Type)
    if (C.Type(k-k1) =='x')==1
        C(k-k1,:)=[];
        k1=k1+1;
    end

end

h = histogram(C.Size,{'XS','S','M','L','XL'});
title('All of the cups with regular stem on the market by size');
xlabel('Size');
ylabel('Number of cups from different brands');
%% On retire les XL et XS (extremites)
figure()
k1=0;
for k = 1:length(C.Size)
    if (C.Size(k-k1) =='XS' || C.Size(k-k1)=='XL')==1
```

```
50          C(k-k1,:)=[];
51          k1=k1+1;
52      end
53
54  end
55  h = histogram(C.Size,{'XS','S','M','L','XL'});
56  title('All of the cups with regular stem except XS and XL models \newline on
        the market by size');
57  xlabel('Size');
58  ylabel('Number of cups from different brands');
59
60  %% On garde juste les cups venant d'EU et US
61  figure()
62  k1=0;
63  for k = 1:length(C.Countries)
64      if (C.Countries(k-k1) =='US' || C.Countries(k-k1)=='EU')==0
65          C(k-k1,:)=[];
66          k1=k1+1;
67      end
68
69  end
70  h = histogram(C.Size,{'XS','S','M','L','XL'});
71  title(' All of the cups with regular stem except XS and XL models \newline on
        the market by size coming from EU or USA');
72  xlabel('Size');
73  ylabel('Number of cups from different brands');
74
75  %%
76
77  for k = 1:length(C.Popularity)
78      if (C.Popularity(k) =='HIGH')==1
79          C.Weight(k)=C.Weight(k)*3;
80      elseif (C.Popularity(k) =='MEDIUM')==1
81          C.Weight(k)=C.Weight(k)*2;
82      end
83
84  end
85  C.Weight;
86
87  D_t=[0 0 0; 0 0 0; 0 0 0; 0 0 0; 0 0 0];
88  D_nt=[0 0 0]
89  D_average=[0 0 0; 0 0 0; 0 0 0; 0 0 0; 0 0 0];
90  for k = 1:length(C.Diameter)
91      if (C.Size(k) =='S')==1
92      a=1;
93      D_nt(a)=D_nt(a)+C.Weight(k);
94
95      %Diameter
96      D_t(1,a)=D_t(1,a)+(C.Diameter(k)*C.Weight(k));
97
98      %Body_length
99      D_t(2,a)=D_t(2,a)+(C.Body_length(k)*C.Weight(k));
100
101     %Stem_length
102     D_t(3,a)=D_t(3,a)+(C.Stem_length(k)*C.Weight(k));
103
104     %Capacity_holes
105     D_t(4,a)=D_t(4,a)+(C.Capacity_holes(k)*C.Weight(k));
106
107     %Capacity_full
108     D_t(5,a)=D_t(5,a)+(C.Capacity_full(k)*C.Weight(k));
```

```
109
110         elseif (C.Size(k) =='M')==1
111         a=2;
112         D_nt(a)=D_nt(a)+C.Weight(k);
113
114         %Diameter
115         D_t(1,a)=D_t(1,a)+(C.Diameter(k)*C.Weight(k));
116
117         %Body_length
118         D_t(2,a)=D_t(2,a)+(C.Body_length(k)*C.Weight(k));
119
120         %Stem_length
121         D_t(3,a)=D_t(3,a)+(C.Stem_length(k)*C.Weight(k));
122
123         %Capacity_holes
124         D_t(4,a)=D_t(4,a)+(C.Capacity_holes(k)*C.Weight(k));
125
126         %Capacity_full
127         D_t(5,a)=D_t(5,a)+(C.Capacity_full(k)*C.Weight(k));
128
129         elseif (C.Size(k) =='L')==1
130         a=3;
131         D_nt(a)=D_nt(a)+C.Weight(k);
132
133         %Diameter
134         D_t(1,a)=D_t(1,a)+(C.Diameter(k)*C.Weight(k));
135
136         %Body_length
137         D_t(2,a)=D_t(2,a)+(C.Body_length(k)*C.Weight(k));
138
139         %Stem_length
140         D_t(3,a)=D_t(3,a)+(C.Stem_length(k)*C.Weight(k));
141
142         %Capacity_holes
143         D_t(4,a)=D_t(4,a)+(C.Capacity_holes(k)*C.Weight(k));
144
145         %Capacity_full
146         D_t(5,a)=D_t(5,a)+(C.Capacity_full(k)*C.Weight(k));
147
148         end
149     end
150     for i=1:5
151         for j=1:3
152             D_average(i,j)=D_t(i,j)/D_nt(j);
153         end
154     end
```

[frame=single]

Survey

The following matlab survey codes discretize the data from the surveys and create the histograms.

— **Input :** Data, driscretized or not, from the different surveys.

— **Output :** Histograms illustrating the importance of different answers.

First survey data analysis :

```
clc;
clear all;
close all;

figure();
x1=[1 2 3 4 5 6 7 8 9 10];
y1=[0;1;0;1;4;12;21;45;60;97];
S=bar(x1,y1,1);
xlabel('Satisfaction degree')
ylabel('Number of women')
title('Degree of satisfaction')
S(1).FaceColor = '#66AAD7';
figure();
x2= categorical({'0 times','1 time','2 times','3 times','3+ times'});
x2 = reordercats(x2,{'0 times','1 time','2 times','3 times','3+ times'});

y2_normal=[4 46 104 64 21];
y2_spec=[23 54 97 61 4];
y2=[y2_normal ; y2_spec];
S=bar(x2,y2,1);


legend('Normal journey','Travelling or holiday')
xlabel('Number of times users clean their cup')
ylabel('Number of women')
title('How many times a cup user cleans and changes her cup \newline during a
    normal day and during travelling/holidays')
S(1).FaceColor = '#66AAD7';
S(2).FaceColor = '#E89875';

figure();
x3= categorical({'No, they are private','No they are public','Yes, sometimes',
    'Yes, always'});
x3 = reordercats(x3,{'No, they are private','No they are public','Yes,
    sometimes','Yes, always'});

y3=[3 162 131 161];
S3=bar(x3,y3,1);
S3(1).FaceColor = '#66AAD7';

ylabel('Number of women')
title('Do women have aces to privates sinks during their daily life?')
```

[frame=single]

Second survey data analysis :

```
clc;
clear all;
close all;

opts = detectImportOptions('Importance_problemes_cup_responses.xlsx');
preview('Importance_problemes_cup_responses.xlsx',opts);
A = readmatrix('Importance_problemes_cup_responses.xlsx','Range','H:K');
A_user= A(1:202,:);
A_non_user= A(202:356,:);
%1Quelle est l'importance que vous donnez au probleme du nettoyage journalier?

%2Quelle est l'importance que vous donnez au probleme d'application de la Cup?

%3Quelle est l'importance que vous donnez au probleme du retrait de la Cup?

%4Quelle est l'importance que vous donnez aux aspects psychologiques (la vue
    du sang, la manipulation avec ses mains,...)?
l_A_u=length(A_user(:,1));
l_A_Nu=length(A_non_user(:,1));

% for i = 1:l_A_u
%     fprintf('Number at position %d = %6.2f\n', k1, numlist{k1})
% end
p=4;
h1 = histogram(A_user(:,p));
hold on
h2 = histogram(A_non_user(:,p));
legend([h1 h2],'Menstrual cup users','Menstrual cup non-users')
xlabel('Importance to the problem')
ylabel('Number of women')
title('What is the importance given for psychologic aspects?')
```

[frame=single]

E.2 Tests

Focus group

The focus group carried on may 2019 was organised as :

— **Moderator.** A girl (one of the team members) moderated the debate and asked the questions. She helped to summarized the global opinion and manage the different speaking times between the focus group's participants.

— **Technical expert.** A technical expert (one of the team members) was there to explain the mechanisms and how the device worked from a technical point of view. He also answered questions when needed but didn't participate a lot after all.

— **People taking notes.** Two persons were in charged of taking notes and synthesizing the information during the focus group.

— **Participants.** All of them were girls between 18 and 30 years old, both menstrual cup users and not-users.

The questions asked were the following :

1. Does the device follow the reusable principle of the cup ?
2. What do you think of the product ? What do you like ?
3. Does the product answer the problem (s) you encounter when using the cup ?
4. If you are not using the Cup, does the product meet the constraint (s) that have kept you from using it. What personally do you find unsatisfactory about the product ?
5. What do you think needs improvement ?
6. Which feature do you prefer ? Cleaner> Sterilizer ? Or the opposite ?
7. Would you assume this kind of product ? In the sense that you will hide it at all costs or possibly see it as an accessory ?
8. Would you be afraid to order it on the internet ? What if there would be a pharmacy for this product : would you go there ?
9. If a cup would be offered with the purchase of the product, would you buy it or would you prefer to keep your own ?
10. We create a partnership with an brand A and you have a menstrual cup brand B, would be it a problem ?
11. How do you see the design of such a product, regarding shape and colors ? Would you like to be able to customize it ?
12. Under what conditions would you trust this product (to use it) ?
13. What price would you pay for this product ?

Long-term tests

Regarding the long-term test, first 4 kind of users have been contacted. For each of them, the TRIAXES device cleaner was provided with a document explaining how to use it. The document is the following :

tulipal

DOCUMENT TEST DISPOSITIF

Bonjour chère ambassadrice,
Tulipal vous remercie de faire partie du projet!
Objectifs : Les objectifs de ce test est que tu nous aides avec tous tes feedbacks (bons et mauvais!). On sait que notre dispositif est loin d'être parfait, c'est donc pour cela qu'on a besoin de ton aide!

Document: Ce document a pour but de te donner des indications sur l'utilisation du dispositif mais n'hésite pas à l'utiliser de la manière qui te conviens le mieux!

CONDITIONS ET CONSEILS D'UTILISATION

1. Le dispositif est destiné au nettoyage "mécanique" de la cup, et assure celui-ci en dehors du domicile, et au domicile.

2. Le dispositif ne prend pas en charge la stérilisation de la cup, et doit donc être nettoyé au savon (savon adapté) si l'intérieur est sale.

3. Le dispositif fourni est réalisé en impression 3D, et est donc plus fragile. Pour une utilisation optimale il est recommandé de veiller à ne pas le détériorer et de le manipuler délicatement (notamment lors de la phase de nettoyage du dispositif).

4. Étant limité par la technologie de production (impression 3D), le système peut émettre quelques fuites (notamment lors de la phase de vidange du dispositif).

5. Il est recommandé de ne pas transporter le dispositif rempli d'eau dans votre sac, ni de laisser de l'eau dedans lorsqu'il n'est pas utilisé.

6. Les brosses en silicone sont détachables, cependant afin de ne pas impacter le nettoyage il est recommandé de ne pas les extraires de leur position. Il peut arriver que celles-ci se décrochent (auquel cas vous pouvez nous contacter afin que nous regardions le problème).

7. Si des pièces viennent à casser merci de prendre contact avec nous afin que nous remplacions celles-ci le plus rapidement possible.

8. Il est recommandé de tenir une note comportant les remarques, que vous avez relevées afin d'être le plus exhaustif possible dans le feedback.

NOTES

9. Le sac en tissu peut avoir différentes fonctionalitées, à vous de vous trouver la votre (secher la cup, isoler le dispositif à l'interieur du sac...).

UTILISATION DU DISPOSITIF / SCENARIO

Le dessin ci-dessous ne corresponde pas exactement au nombre des points cités ci-après. Il s'agit uniquement d'une aide visuel.

1. Vous munir du dispositif lors de vos déplacements journaliers (sac à mains, sac de cours), en veillant à ne pas mettre de poids dessus.
2. Lors de votre passage au WC ouvrez le dispositif par le haut (bouchon externe) remplissez le dispositif au ¾ d'eau à l'évier.
3. Replacer sans visser le bouchon externe sur le dispositif.
4. Dirigez vous dans la cabine privative.
5. Posez le dispositif au sol ou sur le réservoir du WC. (si celui-ci le permet).
6. Retirez le bouchon externe.
7. Retirer et vider votre cup dans les toilettes.
8. Placez la cup sur les brosses internes.
9. Refermez le dispositif et visser le bouchon externe.
10. Le bouchon externe permet une fois fermé de générer un mouvement interne des brosses par rotation.
11. Effectuez une dizaine de rotations (le mouvement peut etre de va et vient).
12. Dévissez le bouchon d'évacuation et vidanger le dispositif.(Attention des fuites sont à anticiper lors de cette action!).
13. Une fois vidangé, revissez le bouchon d'évacuation.
14. Ouvrir le dispositif pour récupérer votre cup.
15. Posez le dispositif au sol ou sur le reservoir du WC.
16. Replacez votre cup.
17. Refermez le dispositif
18. Rangez le dispositif dans votre sac.

tulipal

FIGURE 7.28: TRIAXES cleaner test document.

This given, two interviews were handled with each of the users. One at the very beginning (before the test) and a second one after 1 month, in order to identify possible upgrades based on drawbacks.

First interview (before test).

- Privatate information : Last name ; First name ; E-mail ; Date of Birth and Occupation.
- Character : [4]
- Preferred channels : Social networks ? ; TV ? Radio ? ; Newspapers ? ; Mail ? or Brands and influencers ?
- Questions :
  1. Does this device meet the values you encounter when using the cup ? What are they ? Which do you think is the most important ?
  2. Do you think this product will solve all the problems you encounter when using the Cup ?
  3. What functionality is most important to you when using the device ? Sterilization or cleaning ?
  4. Do you trust this product ?
  5. What price would you be prepared to give for this device ?

Second interview (after test). First questions :

1. What was your first reaction upon seeing the device ?
2. How do you find the aesthetic of the device ?
   - a. Does the shape of the device seem best suited to you ? No

4. from https ://www.16personalities.com/fr/test-de-personnalite

- b. Getting started ? Very difficult
- c. Material ?
- d. size ? Our product is big enough for a small bag
- e. Do you see another design ?
- f. Color ?
- g. Would you like to be able to customize it ?

3. Is the device instinctive enough when used for the first time ?
4. How would you rate the quality of the product (scale from 1 (very low quality) to 5 (very good quality))
5. Do you think this product is innovative (on a scale of 1 to 5) ?
6. When you think of this product, do you think it is a product that you need (on a scale of 1 to 5) ?

Cleaning :

1. Is it easily transportable in a handbag ? Did you have to use a larger bag ?
2. Is the device discreet enough when you carry it ?
3. Is it easy to use it outside of my home ?
4. Should the device be supplied with specific packaging ? With a fabric bag ?
5. Is the device intuitive enough and easy to use when cleaning ?
6. Are you free from the following blockage : having to leave a public toilet to wash the cup in the common sink ?
7. In your opinion, does the device respond to the problem of cleaning the cup in public places ?
8. Does this product answer all the problems you encounter when using the Cup ?
9. What price would you be prepared to give for this device ? Has this price changed since the last time ?
10. What do you think needs improvement ?
    - a. Size ?
    - b. Rotation technique ?
    - c. Intuitiveness ?
    - d. Fluidity ?
    - e. Aspect ?
    - f. Clarity ?
    - g. Noise / Silence ?
11. Where would you like to buy this device ?
12. Do you trust this product ?
13. Have you noticed any functional malfunctions while using the device ?
14. With the explanations of use given during the first interview, did you notice one (or more) lack (s) (remarks that the device did not support) during its use ? If so, can you list them ?
15. Do you still trust this product ?
16. If this product were on the market today, would you buy it (on a scale of 1 to 5) ?
17. If this product were on the market today, what price would you be willing to pay ?
18. On a scale of 1 to 10, would you recommend it to those around you ?
19. Is it a problem for you to talk to other cup users you know around you ?
20. Overall, what did you like the most about this product ?
21. What would you like to improve ?
22. Do you have any other comments / suggestions / thoughts for us ?
23. Do you have any brand or logo ideas ?

F Legal aspects

F.1 Patent search methodology

The goal of a patent search is to identify the different patents or publications that can be a problem with the developed invention in terms of patenteability and freedom to operate. The following methodlogy is the one used for the previous presented work on chapter 5.

1. Identify interesting classifications from similar patents to our device. In our case A6171/4553.
2. Search on these classifications and filter them by designed countries. Used EP (European) or WO (Worldwide) patents. Gives an insight of the patents that could be a problem in order to be free to operate.
3. Identify from those, the ones that are similar to our device. For example, a lot were menstrual cups (with different functionalities like smart cups) fall into the same classification. Find devices complementary to the menstrual cup (sterilize, clean, store, apply, remove...).
4. Search on the prior classifications (other than EP OR WO) interesting patents similar to our device. For example a lot of KR (Korea) ones. Gives an insight of patents that could be a problem for patenteability.
5. Create an excel with different categories for the patents. In this case those are : Name, Brief description, Application number, Inventor, Applicant, Date, Designated countries, Legal status.
6. Once the excel is done, search all the cited or citing patents related to the ones on the excel file and add it to the excel. Citing are the patents that authors have mentioned, and cited are other patents that have cited that patent.
7. Check the cited and citing documents of the new added patents to see if they are somehow related to our device, if they do, then add them.
8. Once the excel is completed done with the citing and cited iteration, sort the patents by LOW, MIDDLE and HIGH similarity. For example low are related patents as menstrual cups, MEDIUM are devices related to the cup as containers or applicators ; and finally HIGH are sterilizers, cleaners or 2in1 devices for the menstrual cup.
9. For the MEDIUM and HIGH similarity ones, analyze the claims and learn how they work from a technical point of view.

After analysis, a total of 63 patents were judged to be relevant. The figure below shows the 12 first publications from the 63 relevant ones :

Priorité	Name	Description	Application number - I	Publication date	Inventor	Applicant	Designed countries	Patent legal state	Status: cited/citing	Status: claims	Status: fonctionement
LOW	PORTABLE AND FUNCTIONAL VAGINAL WASHING APPARATUS	Disclosed is an apparatus with convenient portability that may clean women, prevent inflammation in a vagina from being occurred, and improve a massage effect. A portable functional apparatus for cleaning a vagina, includes a body having a donut shape;	EP2769746	27-08-14	SHIN MI CHONG [KR]; SHIN IN SUNG [KR]	SHIN MI CHONG [KR]; SHIN IN SUNG [KR]	EP	The application is deemed to be withdrawn	Fait	Pas fait	
LOW	SMART MENSTRUAL CUP	An embodiment of the present invention provides a smart menstrual cup comprising: a menstrual cup, a measuring unit for measuring menstrual blood received in the storage unit; and a control unit for generating a signal on the basis of measurement information from the measuring unit or processing information obtained on the basis of the measurement information.	WO2017010800	19-01-17	HWANG RYONG [KR]	LOON LAB [KR]	WO	Examination is in progress	Fait	Pas fait	
LOW	DEVICE AND METHOD FOR MONITORING FEMININE HYGIENE	A device and method for the monitoring of feminine hygiene. More specifically, sensor information is obtained from a wearable device worn inside the vagina of a user.	WO2017015767	02-02-17	MURISON BRUCE DONALD [CA]; FERRARI FRANK JOSEPH [CA]; SCHEURING ADAM [NO]; GULDAHL ANDERS [NO]	STANDARD INNOVATION CORP [CA]	WO	The application is deemed to be withdrawn	Fait	Pas fait	
LOW	FOLDABLE MENSTRUATION CUP	Disclosed is a foldable menstruation cup, comprising an outer cup body, a flow guiding pipe and a foldable portion.	WO2017031813	02-03-17	LIN YECHENG [CN]	GUANGZHOU TIANYUAN SILICONE MACHINE TECH CO LTD [CN]	WO	The application is deemed to be withdrawn	Fait	Pas fait	
LOW	MENSTRUATION DEVICE	Menstruation device for collecting body fluids in the vagina, the device comprising a disk shaped body having a first end face and an opposite second end face, wherein the first end face is provided with cup shaped recess that is centered with respect to a circumference of the disk shaped body, and the device is made from a resilient absorbent material.	WO2017192040	09-11-17	MAN CORA MEE-LING [NL]; WILLEMS FERDINANDUS MARIA JACOBUS CHRISTINA [NL]	WILLEMS WINKELS B V [NL]	WO	The application is deemed to be withdrawn	Fait	Pas fait	
LOW	CONTAINER FOR MENSTRUAL COLLECTION AND EMPTYING THEREOF	A container for menstrual collection and emptying thereof, in the shape of a cup or of a flat cup, with a drainage tube 3 composed of at least one very flexible thin-walled portion , and a wall portion of greater thickness.	EP3603589	05-02-20	LLOVERAS MACIÀ JOAQUIM [ES]; ISERTE JENÉ MONTSERRAT [ES]	UNIV CATALUNYA POLITECNICA [ES]	EP	Request for examination was made	Fait	Pas fait	
LOW	APPLICATOR DEVICE FOR A MENSTRUAL CUP	The invention comprises two cylindrical parts (2, 3) which are able to be coupled to each other with an axial sliding movement to insert the menstrual cup.	EP3485854	22-05-19	GARRIGA I RODÓ JOAN [ES]	ECAREYOU INNOVATION S L [EP]	EP	Request for examination was made	Fait	Pas fait	
LOW	GROOVED MENSTRUAL CUP, PRODUCTION METHOD THEREOF, AND ASSOCIATED DISINFECTION METHOD AND KIT	Cup + desinfection device.	EP3658085	03-06-20	LE COURT CLARISSE [FR]	CLARIPHARM [FR]	EP	Request for examination was made	Pas trouvé citing documents: ni onglet ni original doc.	Pas fait	
HIGH	CONTAINER FOR CLEANING AND STERILIZING MENSTRUAL CUPS	The present invention relates to a container for cleaning and sterilizing a menstrual.	WO2020060424	26-03-20	LEQUAY PAUL [FR]; SLOWIK IGA [PL]	SHE IS LUCID SPOLKA Z OGRANICZONA ODPOWIEDZIALNOSCIA [PL]	WO	The international publication has been made	Fait	Fait	Fait
MEDIUM	Portable physiological cup storage device	The invention discloses a portable physiological cup storage device, which comprises a top cover, a supporting plate for placing physiological cups and a base, wherein the top cover and the supportingplate are connected in insertion mode, and the supporting plate is also connected with the base in insertion mode.	CN108464883	31-08-18	DING LIPING; LI ZHONGHAO	DING LIPING; LI ZHONGHAO	CN	ENTRY INTO FORCE OF REQUEST FOR SUBSTANTIVE EXAMINATION	Pas trouvé citing ni cited: traudire la bibliographie?	Fait	Pas fait
HIGH	A MENSTRUAL CUP STERILIZER	The present invention relates to a menstrual cup sterilizer, which comprises: a case main body; a UV LED lamp; a power supply unit; and a control unit. According to the menstrual cup sterilizer of the present invention, the sterilizer is formed of small portable menstrual cup which can perform sterilization, and thus can be carried easily when going out.	KR101981235	23-05-19	LEE SUNG HYUN [KR]	LEE SUNG HYUN [KR]	KR	DECISION TO GRANT OR REGISTRATION OF PATENT RIGHT	Pas trouvé citing documents: ni onglet ni original doc.	Fait	Pas fait

FIGURE 7.29: Example of the excel publications sheet.

F.2 NDAs

The following document refers to the french version of an NDA intended for testers.

Le présent accord de confidentialité est conclu entre d'une part ..... (NOM), domicilié.e .....(ADRESSE). Ci-après désigné.e « la TESTEUSE ».
Et d'autre part,
Mr Lucas Secades Casino, domicilié à Boulevard Brandt Whitlock 80, 1200, Bruxelles
ci-après désigné « PORTEUR DU PROJET ».

Objet de l'accord de confidentialité
Dans le cadre des recherches et développements du produit industriel proposé par Tulipal composé d'un système de nettoyage portable ainsi qu'un procédé de stérilisation de la coupe menstruelle, dans le but de sa commercialisation future, le PORTEUR DU PROJET, a divulgué à la TESTEUSE des informations confidentielles afin d'obtenir des informations relatives à l'avis et l'utilisation du dispositif de la part de la TESTEUSE. Les differents prototypes du dispositif sont développés par Tulipal, représentée par le PORTEUR DU PROJET. Pour ce faire, le PORTEUR DU PROJET a présenté et expliqué à la TESTEUSE le fonctionnement technique du prototype de l'invention faisant l'objet de cet accord de confidentialité, ainsi que des informations relatives au plan stratégique et commerciale de Tulipal.

Informations confidentielles
Les Informations divulguées par le PORTEUR DU PROJET, pourraient inclure, sans que cette liste soit énumérée de manière exhaustive : toutes données, de quelque nature que ce soit, notamment des données techniques, scientifiques, financières, commerciales, y compris des plans, des prototypes, dessins, représentations graphiques, savoir-faire, peu importe leur forme ou la manière dont ces informations sont divulguées, que ce soit oralement, par écrit ou via tout support, y compris via tout support électronique.
Ces informations sont ci-après dénommées « INFORMATIONS CONFIDENTIELLES ».

La TESTEUSE convient de réserver une totale confidentialité, en tout temps et tous lieux, du contenu de tous les échanges (INFORMATIONS CONFIDENTIELLES), qu'elles ont débutés, qu'elles débutent ce jour ou pourraient poursuivre en vue d'une phase de test d'un des prototypes développés par Tulipal et dont ceci serait testé par la TESTEUSE. La TESTEUSE s'engage à ce que cette confidentialité reste totale et restera en vigueur durant au minimum 2 ans.

La TESTEUSE s'engage concrètement à :

a. Ne pas divulguer des INFORMATIONS CONFIDENTIELLES et ;
b. Ne faire aucune copie d'INFORMATIONS CONFIDENTIELLES et ;
c. Ne jamais utiliser d'INFORMATIONS CONFIDENTIELLES dans un but commercial ou dans tout autre but que l'objectif du présent accord.

Le PORTEUR DE PROJET souhaite, en effet, protéger l'ensemble de ses droits de propriété intellectuelle et son knowhow, de même que leurs valeurs et intérêts à l'égard des INFORMATIONS CONFIDENTIELLES .

La TESTEUSE reconnaît que la divulgation, en violation du présent accord, de la confidentialité constitue pour le PORTEUR DE PROJET et Tulipal un préjudice grave et difficilement réparable. Par conséquent la TESTEUSE pourrait se voir réclamer par le PORTEUR DE PROJET un montant forfaitaire de dommages et intérêts fixés à un minimum de 5000 euros.
Le présent accord est soumis au droit belge .

Fait à ..... (LIEU), le ..... (DATE). Signatures :

FIGURE 7.30: Tester's NDA.

G Tulipal

Tulipal is the name of a start-up which is currently being created, and which value proposition is the 2in1 device (cleaner and sterilizer) developed through this Master Thesis.

As explained before, the present idea was born during the TRIAXES project chich took place from September 2018 to February 2019. Once the academic project ended, in view of the potential of the project and the innovative nature of the invented product, TRIAXES' professors, as well as the many users of the cup, encouraged the team to continue with it. During almost 6 months (until September 2019) the project progressed slowly. After that, the team changed, and a new student joined the team. The student, Lara, decided to make her Master Thesis on the subject ; and jointly with this one, it allowed the team to devote more time to the project. After one year of hard work, the project was ready to go one step further.

Nowadays, Tulipal is a reality. It's a medtech startup where 4 people work on full-time (1 co-founder and 3 interns). The team is young and multidisciplinary, and yet is ready to welcome new people on marketing & communication and business development. The startup is supervised and counselled by several professionals and coaches. From a technical point of view, the device is developed at the BEAMS (ULB) ; and on the entrepreneurial side, the start-up integrates the LifeTech cluster, and Start.LAB (ULB student incubator). The R&D process and business plan were faster developed thanks to a 5000€ grant received from the *Fondation pour les Generations Futures*, and 2 intern scholarships funded by *B-Scholarship*.